List Of Approved Devices

Sr No.	License Number	Details
1		1.License Holder Name: GETINGE MEDICAL INDIA PVT. LTD ,203-204, B-WING,FULCRUM,SAHAR ROAD ,MUMBAI SUBURBAN MAHARASHTRA ,400099 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COLLAGEN COATED WOVEN AND KNITTED VASCULAR PROSTHESIS AND PATCHES (INTERGARD,HEMACAROTID,HEMAPATCH,HEMAGARD AND HEMAGARD CAROTID)-IT IS INDICATED FOR SURGICAL REPAIR , BYPASS,OR REPLACEMENT OF ARTERIES IN THE TREATMENT OF ANEURYSMAL AND OCCLUSIVE DISEASE OF THE ABVDOMINAL AORTA VISCERAL ARTERIES AND PERIPHERAL ARTERIES .DUE TO LOW POROSITY THESES PRODUCTS ARE RECOMMRNDED FOR USE IN PATIENT REQUIRING HEPARINIZATION PRIOR OR DURING SURGERY., ANTIMICROBIAL COLLAGEN COATED WOVEN AND KNITTED VASCULAR PROD\STHESIS AND PATCHES(INTERGARD SYNERGY)-IT IS INDICATED FOR SURGICAL REPAIR,BYPASS OR REPLACEMENT OF ARTERIES IN THE TREATMENT OF ANEURYSMAL AND OCCLUSIVE DISEASE OF THE VISCERAL AND PERIPHERAL,ARTERIES. VASCULAR PATCH ANGIOPLASTRY INCLUDING THE REPAIR OF THE CAROTID ARTERY DUE TO LOW POROSITY THESES PRODUCTS ARE RECOMMENDED FOR USE IN PATIENTS REQUITRING HEPARINIZATION PRIOR OR DURING SURGERY. ,ANTIMICROBIAL COLLAGEN COATED WOVEN AND KNITTED VASCULAR PROSTHESIS AND PATCHES (INTERGARD SILVER,HEMAPATCH SILVER)-IT IS INDICATED FOR SURGICAL REPAIR,BYPASS,OR REPLACEMENT OF ARTERIES IN THE TREATMENT OF ANEURYSMAL AND OCCLUSIVE DISEASE OF THE ABDOMINAL AORTA VISCERAL ARTERIES AND PERIPHERAL ARTERIES. DUE TO LOW POROSITY THESES PRODUCTS ARE RECOMMENDED FOR USE IN PATIENTS REQUIRING HEPARINIZATION PRIOR OR DURING SURGERY,COLLAGEN COATED AND HEPARIN BONDED KNITTED VASCULAR PROSTHESIS AND PATCHES (INTERGARD HEPARIN,HEMACAROTID HEPARIN)-IT IS INDICATED FOR SURGICAL REPAIR,BYPASS OR REPLACEMENT OF ARTERIES IN THE TREATMENT OF ANEURYSMAL AND OCCLUSIVE DISEASES OF THE VISCERAL AND PERIPHERAL,ARTERIES .VASCULAR PATCH ANGIOPLASTY INCLUDING THE REPAIR OF THE CAROTID ARTERY DUE TO LOW POROSITY THESE PRODUCTS ARE RECOMMENDED FOR USE IN PATIENTS REQUIRING HEPARINIZATION PRIOR OR DURING SURGERY.

2	02/SCof2018	1.License Holder Name: GPC MEDICAL LIMITED 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:NASAL OXYGEN CATHETER-IT IS USED FOR EFFICIENT ADMINISTRATION OF OXYGEN FOR GREATER COMFORT OF PATIENT,YANKAUR SUCTION SET-IT IS USED FOR REMOVAL OF SECRETION AND BLOOD PUS DURING SURGICAL PROCEDURE,EXTENSION LINE(GPC EXTENSION LINE)-IT IS USED TO EXTEND THE INFUSION LINE,REDON DRAIN CATHETER-IT IS AN EFFECTIVE DEVICE FOR CLOSE WOUND DRAINAGE UNDER NEGATIVE PRESSURE WITH THE OPTION TO USE ONE CATHETER OR TWO CATHETERS SIMULTANEOUSLY,PRESSURE MONITORING LINE (GPC PRESSURE MONITORING LINE)-IT IS USED FOR HIGH PRESSURE MONITORING AND CONNECTION BETWEEN SYRINGE AND INFUSION PUMP.,SUCTION CATHETER(GPC SUCTION CATHETER)-IT IS USED FOR REMOVAL OF SECRETION FROM MOUTH, TRACHEA, AND BRONCHIAL TUBE.,INFANT FEEDING TUBE(GPC INFANT FEEDING TUBE)-IT IS USED FOR NEONATES AND PAEDIATRIC NUTRITIONAL FEEDING,EXTENSION LINE-IT IS USED TO EXTEND THE INFUSION LINE,IV FLOW REGULATOR (GPC IV FLOW REGULATOR)-IT IS USED TO DELIVER ACCURATE VOLUME OF IV FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM.,IV INFUSION SET(GPC IV INFUSION SET)-THE INFUSION SETS ARE USED ONLY FOR GRAVITY FEED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER OR CANNULA. ,NASAL OXYGEN CATHETER (GPC NASAL OXYGEN CATHETER)-IT IS USED FOR EFFICIENT ADMINISTRATION OF OXYGEN FOR GREATER COMFORT OF PATIENT, THORACIC TROCAR CATHETER-IT IS USED FOR RAPID NON OPERATIONAL PLEURAL AND CHEST DRAINAGE,YANKAUR SUCTION SET(GPC YANKAUR SUCTION SET)-IT IS USED FOR REMOVAL OF SECRETION AND BLOOD PUS DURING SURGICAL PROCEDURE, CHEST/THORACIC DRAINAGE CATHETER(GPC CHEST/THORACIC DRAINAGE CATHETER)-IT IS USED FOR POST OPERATIVE DRAINAGE AFTER CARDIO THORACIC SURGERY,OXYGEN CATHETER(GPC OXYGEN CATHETER)-IT IS USED FOR DIRECT ADMINISTRATION OF OXYGEN THROUGH THE NASO PHARYNX,REDON DRAIN CATHETER (GPC REDON DRAIN CATHETER)-IT IS AN EFFECTIVE DEVICE FOR CLOSE WOUND DRAINAGE UNDER NEGATIVE PRESSURE WITH THE OPTION TO USE ONE CATHETER OR TWO CATHETERS SIMULTANEOUSLY,CLOSE WOUND SUCTION SET-IT IS USED FOR REMOVAL OF SECRETION AND BLOOD PUS DURING SURGICAL PROCEDURES,NELATON CATHETER-IT IS USED FOR BLADDER CATHETERISATION THROUGH URETHRA,RYLE'S TUBE / NASOGASTRIC TUBE(GPC RYLE'S TUBE / NASOGASTRIC TUBE)-IT IS USED FOR NUTRITIONAL FEEDING PURPOSE OR ASPIRATION OF

	INTESTINAL SECRETION,TRACHEOSTOMY TUBE(GPC TRACHEOSTOMY TUBE)-IT IS USED TO MAINTAIN PATIENT AIRWAY THROUGH TRACHEOSTOMY TO MECHANICALLY VENTILATED PATIENT.,SUCTION CATHETER-IT IS USED FOR REMOVAL OF SECRETION FROM MOUTH, TRACHEA, AND BRONCHIAL TUBE.,MUCUS EXTRACTOR(GPC MUCUS EXTRACTOR)-IT IS USED FOR ASPIRATION OF SECRETION FROM OROPHARYNX IN NEWLY BORN BABIES, PRESSURE MONITORING LINE-IT IS USED FOR HIGH PRESSURE MONITORING AND CONNECTION BETWEEN SYRINGE AND INFUSION PUMP.,TRACHEOSTOMY TUBE-IT IS USED TO MAINTAIN PATIENT AIRWAY THROUGH TRACHEOSTOMY TO MECHANICALLY VENTILATED PATIENT.,IV CANNULA(GPC IV CANNULA)-THE PRODUCT IS USED TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM AND FOR WITHDRAWAL OF BLOOD.,FEMALE CATHETER(GPC FEMALE CATHETER)-IT IS USED FOR SHORT TERM BLADDER CATHETERISATION THROUGH URETHRA IN FEMALES, KEHR'S T TUBE(GPC KEHR'S T TUBE)-IT IS USED FOR SHORT TERM POST-OPERATIVE DRAINAGE OF COMMON BILE DUCT,URETHRAL CATHETER(GPC URETHRAL CATHETER)-IT IS USED FOR URINE DRAINAGE,UMBILICAL CATHETER(GPC UMBILICAL CATHETER)-IT IS USED TO ACCESS THE UMBILICAL VESSEL OF PRE-MATURED INFANTS OR NEWLY BORN BABIES,SAFETY IV CANNULA-SAFETY IV CANNULA IS USED TO PROVIDE ACCESS IN TO THE PERIPHERAL VASCULAR SYSTEM FOR THE ADMINISTRATION OF FLUIDS AND DRUGS AND FOR WITHDRAWAL OF BLOOD. SAFETY IV CANNULA IS USED TO DELIVER IV FLUIDS AND MEDICINES IN TO CIRCULATING SYSTEM. THE PRODUCT HAS INTEGRATED PASSIVE SAFETY FEATURES TO COVER THE NEEDLE AFTER USE TO PREVENT THE ACCIDENTAL NEEDLE PRICK INJURIES.,CHEST/THORACIC DRAINAGE CATHETER-IT IS USED FOR POST OPERATIVE DRAINAGE AFTER CARDIO THORACIC SURGERY,FEMALE CATHETER-IT IS USED FOR SHORT TERM BLADDER CATHETERISATION THROUGH URETHRA IN FEMALES,CLOSE WOUND SUCTION SET(GPC CLOSE WOUND SUCTION SET)-IT IS USED FOR REMOVAL OF SECRETION AND BLOOD PUS DURING SURGICAL PROCEDURES,OXYGEN CATHETER-IT IS USED FOR DIRECT ADMINISTRATION OF OXYGEN THROUGH THE NASO PHARYNX,3 WAY STOP COCK-IT IS USED FOR PRESSURE INFUSION AND BLOOD PRESSURE MONITORING,3 WAY STOP COCK(GPC 3 WAY STOP COCK)-IT IS USED FOR PRESSURE INFUSION AND BLOOD PRESSURE MONITORING,IV INFUSION SET-THE INFUSION SETS ARE USED ONLY FOR GRAVITY FEED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER OR CANNULA.,SAFETY IV CANNULA(GPC SAFETY IV CANNULA)-SAFETY IV CANNULA IS USED TO PROVIDE

	ACCESS IN TO THE PERIPHERAL VASCULAR SYSTEM FOR THE ADMINISTRATION OF FLUIDS AND DRUGS AND FOR WITHDRAWAL OF BLOOD. SAFETY IV CANNULA IS USED TO DELIVER IV FLUIDS AND MEDICINES IN TO CIRCULATING SYSTEM. THE PRODUCT HAS INTEGRATED PASSIVE SAFETY FEATURES TO COVER THE NEEDLE AFTER USE TO PREVENT THE ACCIDENTAL NEEDLE PRICK INJURIES., MALE EXTERNAL CATHETER(GPC MALE EXTERNAL CATHETER)-IT IS USED FOR URINE INCONTINENCE IN MALE PATIENT,FOLEY BALLOON CATHETER-IT IS A URINARY TRACT CATHETER USED FOR SHORT TERM URINE DRAINAGE,RECTAL CATHETER-IT IS USED FOR INTRODUCTION OF ENEMA SOLUTION INTO RECTUM,STOMACH TUBE (GPC STOMACH TUBE)-IT IS USED FOR GASTRO INTESTINAL DRAINAGE,IV CANNULA-THE PRODUCT IS USED TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM AND FOR WITHDRAWAL OF BLOOD.,INFANT FEEDING TUBE-IT IS USED FOR NEONATES AND PAEDIATRIC NUTRITIONAL FEEDING, FOLEY BALLOON CATHETER(GPC FOLEY BALLOON CATHETER)-IT IS A URINARY TRACT CATHETER USED FOR SHORT TERM URINE DRAINAGE,THORACIC TROCAR CATHETER(GPC THORACIC TROCAR CATHETER)-IT IS USED FOR RAPID NON OPERATIONAL PLEURAL AND CHEST DRAINAGE,IV FLOW REGULATOR-IT IS USED TO DELIVER ACCURATE VOLUME OF IV FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM.,URETHRAL CATHETER-IT IS USED FOR URINE DRAINAGE,NELATON CATHETER(GPC NELATON CATHETER)-IT IS USED FOR BLADDER CATHETERISATION THROUGH URETHRA, ENDOTRACHEAL TUBE(GPC ENDOTRACHEAL TUBE)-IT IS USED TO PROVIDE A DIRECT AND UNIMPEDED AIRWAY FOR GASES TO PASS TO AND FROM THE LUNGS.,STOMACH TUBE-IT IS USED FOR GASTRO INTESTINAL DRAINAGE,LEVIN'S TUBE-IT IS USED FOR GASTRO INTESTINAL DRAINAGE,RECTAL CATHETER(GPC RECTAL CATHETER)-IT IS USED FOR INTRODUCTION OF ENEMA SOLUTION INTO RECTUM, LEVIN'S TUBE(GPC LEVIN'S TUBE)-IT IS USED FOR GASTRO INTESTINAL DRAINAGE,RYLE'S TUBE / NASOGASTRIC TUBE-IT IS USED FOR NUTRITIONAL FEEDING PURPOSE OR ASPIRATION OF INTESTINAL SECRETION,MUCUS EXTRACTOR-IT IS USED FOR ASPIRATION OF SECRETION FROM OROPHARYNX IN NEWLY BORN BABIES,MALE EXTERNAL CATHETERS-IT IS USED FOR URINE INCONTINENCE IN MALE PATIENT,KEHR'S T TUBE-IT IS USED FOR SHORT TERM POST-OPERATIVE DRAINAGE OF COMMON BILE DUCT, UMBILICAL CATHETER-IT IS USED TO ACCESS THE UMBILICAL VESSEL OF PRE-MATURED INFANTS OR NEWLY BORN BABIES, ENDOTRACHEAL TUBE-IT IS USED TO PROVIDE A DIRECT AND UNIMPEDED AIRWAY FOR GASES TO PASS TO AND FROM THE LUNGS.

3	03-13-0966	1.License Holder Name: TTK HEALTHCARE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:NATURAL RUBBER LATEX MALE CONDOMS(ULINZI - FOR EXPORT)-TO AVOID UN WANTED PREGNANCY AND PREVENTION OF TRANSMISSION OF SEXUALLY TRANSMITTED INFECTIONS (STI)
4	0499	1.License Holder Name: QUALPRO DIAGNOSTICS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:25-OH VITAMIN D ELISA-THE PRODUCT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM AND IS BASED ON THE ENZYME LINKED IMMUNOSORBENT ASSAY ALSO KNOWN AS ELISA

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5	0623	1.License Holder Name: CORAL CLINICAL SYSTEMS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:ENZYMATIC ASSAY FOR THE DETECTION OF MAPLE SYRUP URINE DISEASE (MSUD) IN NEW BORN DRIED BLOOD SPOTS(BORNSAFE MSUD)-BORNSAFE NEONATAL MSUD SCREEENING ASSAY IS AN ENZYMATIC COLORIMETRIC METHOD FOR THE QUANTITATIVE DETECTION OF MAPLE SYRUP URINE DISEASE IN NEW BORN USING BLOOD SPOT SAMPLES DRIED ON WHATMAN S&S 903 FILTER COLLECTION PAPER. THIS TEST IS INTENDED AS A SCREENING METHOD FOR MEASURING THE L-BRANCHED-CHAIN AMINO ACID (BCAA) CONCENTRATIONS IN NEWBORN SPOT SPECIMENS.,ENZYMATIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF G6PD DEFICIENCY IN NEW BORN DRIED BLOOD SPOTS(BORNSAFE G6PD)-BORNSAFE G6PD IS INTENDED FOR THE QUANTITATIVE DETERMINATION OD GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD) DEFICIENCY IN NEONATES USING BLOOD SPOT SAMPLES DRIED ON WHATMAN S&S FILTER COLLECTION PAPER,ENZYMATIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF PHENYLALANINE LEVELS IN NEW BORN DRIED BLOOD SPOTS(BORNSAFE PKU)-NEONATAL PKU SCREENING ASSAY IS AN ENZYMATIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF PHENYLALANINE CONCENTRATIONS IN NEONATES USING BLOOD SPOT SAMPLES DRIED ON WHATMAN S& S 903 FILTER PAPER., ENZYMATIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF BIOTINIDASE DEFICIENCY IN NEW BORN DRIED BLOOD SPOTS (BORNSAFE BIOTINIDASE)-BORNSAFE NEONATAL BIOTINIDASE SCREENING ASSAY IS AN ENZYMATIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF BIOTINIDASE ACTIVITY IN NEONATES USING BLOOD SPOT SAMPLES DRIED ON WHATMAN S&S 903 FILTER COLLECTION PAPER. THIS KIT IS PARTICULARLY SUITABLE FOR USE IN A NEONATAL SCREENING PROGRAM AS AN AID IN IDENTIFYING BIOTINIDASE DEFICIENCY IN NEWBORNS. THE KIT SHOULD NOT BE USED FOR CONFIRMATORY TESTING OR TO MONITOR THERAPY
6	13/28/17	1.License Holder Name: DYNAMIC TECHNO MEDICALS PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:SURGICAL SUTURE (DYNALON)-USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.

7	132/UA/SC/P-2007	1.License Holder Name: LOTUS SURGICAL PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:SYNTHETIC ABSORBABLE MONOFILAMENT POLY(P-DIOXANONE) UNI-DIRECTIONAL WITH END LOOP & BI-DIRECTIONAL BARBED SUTURE(BARB-E)-BARB-E SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION IN MICROSURGERY AND IN OPHTHALMIC SURGERY. THIS TYPE OF SUTURES IS PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT IS REQUIRED.,SYNTHETIC ABSORBABLE POLY(GLYCOLIDE-CO-L-LACTIDE)/ (POLYGLACTIN 910), CALCIUM STEARATE & ANTIBACTERIAL TRICLOSAN SUTURE(SOLUS 910 AM+)-SOLUS 910 AM+ ANTIBACTERIAL SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, EXCEPT FOR OPHTHALMIC, CARDIOVASCULAR AND NEUROLOGICAL TISSUES.
8	1648	1.License Holder Name: OSSEOUS SURGICALS 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:TIBIA NAIL(- - -)-TO JOINT THE BROKEN BONES

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9	19/RR/AP/2006/MD/R	1.License Holder Name: RELISYS MEDICAL DEVICES LIMITED 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:POST DILATATION CATHETER-1.1. BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. 1.2. BALLOON DILATATION OF A CORONARY ARTERY OCCLUSION, FOR THE PURPOSE OF RESTORING CORONARY FLOW IN PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION. 1.3. BALLOON DILATATION OF A STENT AFTER IMPLANTATION. ,PRE DILATATION CATHETER -PRE-DILATATION CATHETER IS A MINIMALLY INVASIVE PROCEDURE TO OPEN UP BLOCKED CORONARY ARTERIES, ALLOWING BLOOD TO CIRCULATE UNOBSTRUCTED TO THE HEART MUSCLE.,SIROLIMUS ELUTING CORONARY STENT SYSTEM-THE RELISYS SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES. SIROLIMUS ELUTING CORONARY STENT SYSTEM IS ALSO INDICATED FOR TREATMENT OF ABRUPT OF THREATENED CLOSURE IN PATIENTS WITH FAILED INTERVENTIONAL THERAPY. THE DRUG COATING IS INTENDED TO INHIBIT RESTENOSIS. ,EVEROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM -THE RELISYS EVEROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES. EVEROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM IS ALSO INDICATED FOR TREATMENT OF ABRUPT OF THREATENED CLOSURE IN PATIENTS WITH FAILED INTERVENTIONAL THERAPY. THE DRUG COATING IS INTENDED TO INHIBIT RESTENOSIS. ,COBALT CHROMIUM CORONARY BARE METAL STENT-COMMERCIALIZED AS A COMPONENT FOR STENT SYSTEM,COBALT CHROMIUM CORONARY STENT DELIVERY SYSTEM-THE RELISYS COBALT CHROMIUM CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES.

10	25-AMD/23/2012	1.License Holder Name: GAJANAN SURGICAL INDUSTRIES 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:ABSORBABLE GELATIN SPONGE USP(NA)-INTENDED FOR THE CONTROL OF SURFACE BLEEDING FROM VASCULAR ACCESS SITES AND PERCUTANEOUS CATHETERS OR TUBES.
11	25-PD/44	1.License Holder Name: LAXMI INDUSTRIES 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:ELASTIC ADHESIVE BANDAGE-SURGICAL DRESSINGS,ROLLED GAUZE-SURGICAL DRESSINGS,PLASTER OF PARIS BANDAGE-SURGICAL DRESSINGS, COTTON CREPE BANDAGE(FLEXICREPE)-SURGICAL DRESSINGS,X-RAY DETECTABLE ABSORBENT COTTON GAUZE-SURGICAL DRESSINGS,BANDAGE CLOTH-SURGICAL DRESSING,PLASTER OF PARIS BANDAGE(LAX-O-PLAST)-SURGICAL DRESSING,ROLLED BANDAGE-SURGICAL DRESSING,ABSORBENT GAUZE-SURGICAL DRESSING,ABSORBENT COTTON GAUZE-SURGICAL DRESSING, ADHESIVE TAPE-SURGICAL DRESSING,X-RAY DETECTABLE ABDOMINAL PACK-SURGICAL DRESSINGS,ABSORBENT LINT-SURGICAL DRESSINGS,COTTON CREPE BANDAGE-SURGICAL DRESSINGS,ROLLED BANDAGE FOR PLASTER OF PARIS-SURGICAL DRESSINGS
12	28-KD/159	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT. LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:ETHYLENE OXIDE STERILISATION OF CLASS A & B PRODUCTS-ETHYLENE OXIDE STERILISATION OF PRODUCTS FALLING UNDER CLASS A AND B. INTENDED USE OF THE PRODUCTS WOULD BE AS DECIDED BY THE MEDICAL DEVICE MANUFACTURER.
13	42/CT/AP/2012/S/R	1.License Holder Name: HEALTHIUM MEDTECH PRIVATE LIMITED 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:STERILE POLYPROPYLENE MESH(TRULENE MESH)-TRULENE MESH USED FOR THE REPAIR OF HERNIA,STERILE BONEWAX(TRUWAX)-BONE WAX USED FOR CONTROL OF BLEEDING FROM BONE SURFACE

14	627-B(H)	1.License Holder Name: POLY MEDICURE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:VIAL ACCESS SPIKE (VIAL ADAPTER)(KD-SPIKE)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL.
15	637-B(H)	1.License Holder Name: HARSORIA HEALTHCARE PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER KIT SINGLE LUMEN(GENERIC,CADON, SEMILLAS)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTION,BLOOD SAMPLING CENTRAL VENOUS PRESSURE MONITORING AND INJECTION CONTRAST MEDIA.,CENTRAL VENOUS CATHETER KIT TRIPLE LUMEN(GENERIC,CADON, SEMILLAS)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTION,BLOOD SAMPLING CENTRAL VENOUS PRESSURE MONITORING AND INJECTION CONTRAST MEDIA.,CENTRAL VENOUS CATHETER KIT DOUBLE LUMEN(GENERIC,CADON, SEMILLAS)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTION,BLOOD SAMPLING CENTRAL VENOUS PRESSURE MONITORING AND INJECTION CONTRAST MEDIA.
16	667-B(H)	1.License Holder Name: DEGANIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:STERILE THREE WAY NELATON IRRIGATION CATHETER BLUE TIP FOR SINGLE USE ONLY (BIOMETRIX)-DRAINAGE OF URINE,STERILE NELATON IRRIGATION CATHETER FOR SINGLE USE ONLY(UROVISION)-DRAINAGE OF URINE, STERILE NELATON IRRIGATION CATHETER FOR SINGLE USE ONLY. (DOVER COVIDIEN USA)-DRAINAGE OF URINE,STERILE DOVER COUNCILL TWO WAY NELATON IRRIGATION CATHETER FOR SINGLE USE ONLY(DOVER COVIDIEN)-DRAINAGE OF URINE,STERILE THREE WAY NELATON IRRIGATION CATHETER BLUE LINE FOR SINGLE USE ONLY(AQUARIUS)-DRAINAGE OF URINE,STERILE DOVER TWO L. WAY BLUE LINE NELATON IRRIGATION CATHETER FOR SINGLE USE ONLY (DOVER COVIDIEN)-DRAINAGE OF URINE,STERILE THREE WAY NELATON IRRIGATION CATHETER WHITE LINE FOR SINGLE USE ONLY (RUSCH TELEFLEX)-DRAINAGE OF URINE,STERILE THREE WAY NELATON IRRIGATION CATHETER WHITE LINE FOR SINGLE USE ONLY. (ROCAMED)-DRAINAGE OF URINE,STERILE THREE WAY NELATON IRRIGATION CATHETER BLUE LINE FOR SINGLE USE ONLY.-DRAINAGE OF URINE

17	675-B(H)	1.License Holder Name: HARSORIA HEALTHCARE PVT LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:EXTENSION TUBE/LINE /SET(EKOMED)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUID/MEDICATIONS IN MEDICAL APPLICATION ,THREE WAY STOP COCK (EKOMED)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,I.V.CANNULA (VIGGOFLON/EKOCAN/EKOCAN PLUS /EKOCAN SAFE)-THE IV CANNULA IS A PASSIVE DEVICES TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND /OR BLOOD COMPONENTS ,OR TO FACILITATE THE PLACEMENT OF VASCULAR

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18	695-B(H)	1.License Holder Name: AUXEINMEDICAL PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATE-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURE IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREW TO PROPERLY ALIGN THE FRACTURED BONE.,BONE PLATE-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURE IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREW TO PROPERLY ALIGN THE FRACTURED BONE.,PINS, WIRES AND STAPLES-PINS,WIRES AND STAPLES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS, WIRES AND STAPLES SUPPORT TO FIX THE BONE PLATES.,BONE PLATE-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURE IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREW TO PROPERLY ALIGN THE FRACTURED BONE.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,BONE PLATE-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURE IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREW TO PROPERLY ALIGN THE FRACTURED BONE.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,BONE PLATE-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURE IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREW TO PROPERLY ALIGN THE FRACTURED BONE.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,PINS, WIRES AND STAPLES-PINS,WIRES AND STAPLES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS, WIRES AND STAPLES SUPPORT TO FIX THE BONE PLATES.,PINS, WIRES AND STAPLES-PINS,WIRES AND STAPLES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS, WIRES AND STAPLES SUPPORT TO FIX THE BONE PLATES.,PINS, WIRES AND STAPLES-PINS,WIRES AND STAPLES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS, WIRES AND STAPLES SUPPORT TO FIX THE BONE PLATES.,PINS, WIRES AND STAPLES-PINS,WIRES AND STAPLES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS, WIRES AND STAPLES SUPPORT TO FIX THE BONE PLATES.,BONE SCREW-BONE SCREWS ARE USED DURING THE

	SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR ALONG WITH BONE PLATES OR INTERLOCKING NAILS.,BONE NAIL IMPLANT-BONE NAIL IMPLANTS ARE COMMONLY USED TO FIX THE LONG BONE FRACTURES.,BONE NAIL IMPLANT-BONE NAIL IMPLANTS ARE COMMONLY USED TO FIX THE LONG BONE FRACTURES.,PINS, WIRES AND STAPLES-PINS,WIRES AND STAPLES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS, WIRES AND STAPLES SUPPORT TO FIX THE BONE PLATES.,BONE SCREWS-BONE SCREWS ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR ALONG WITH BONE PLATES OR INTERLOCKING NAILS., PINS, WIRES AND STAPLES-PINS,WIRES AND STAPLES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS, WIRES AND STAPLES SUPPORT TO FIX THE BONE PLATES.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,ENDOPROSTHESIS-ENDOPROSTHESIS ARE SPECIALLY USED IN FEMUR NECK FRACTURE. WHEN FEMUR BONE HEAD IS DAMAGED OR FRACTURED., ENDOPROSTHESIS-ENDOPROSTHESIS ARE SPECIALLY USED IN FEMUR NECK FRACTURE. WHEN FEMUR BONE HEAD IS DAMAGED OR FRACTURED.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,PINS, WIRES AND STAPLES-PINS,WIRES AND STAPLES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS, WIRES AND STAPLES SUPPORT TO FIX THE BONE PLATES.,PINS, WIRES AND STAPLES-PINS,WIRES AND STAPLES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS, WIRES AND STAPLES SUPPORT TO FIX THE BONE PLATES.,ENDOPROSTHESIS-ENDOPROSTHESIS ARE SPECIALLY USED IN FEMUR NECK FRACTURE. WHEN FEMUR BONE HEAD IS DAMAGED OR FRACTURED.,ENDOPROSTHESIS-ENDOPROSTHESIS ARE SPECIALLY USED IN FEMUR NECK FRACTURE. WHEN FEMUR BONE HEAD IS DAMAGED OR FRACTURED.,BONE PLATE-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURE IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREW TO PROPERLY ALIGN THE FRACTURED

	BONE.,ENDOPROSTHESIS-ENDOPROSTHESIS ARE SPECIALLY USED IN FEMUR NECK FRACTURE. WHEN FEMUR BONE HEAD IS DAMAGED OR FRACTURED.,BONE SCREWS-BONE SCREWS ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR ALONG WITH BONE PLATES OR INTERLOCKING NAILS., BONE NAIL IMPLANT-BONE NAIL IMPLANTS ARE COMMONLY USED TO FIX THE LONG BONE FRACTURES,BONE NAIL IMPLANT-:BONE NAIL IMPLANTS ARE COMMONLY USED TO FIX THE LONG BONE FRACTURES.,BONE SCREW-BONE SCREWS ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR ALONG WITH BONE PLATES OR INTERLOCKING NAILS.,PINS, WIRES AND STAPLES-PINS,WIRES AND STAPLES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS, WIRES AND STAPLES SUPPORT TO FIX THE BONE PLATES.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.

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19	6/UA/2018	1.License Holder Name: PENTA LATEX LLP 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:MALE LATEX CONDOM (MANFORCE CONDOMS WITH BENZOCAINE, MANFORCE CONDOMS MANGO FLAVOUR WITH BENZOCAINE, MANFORCE STAYLONG CONDOMS WITH BENZOCAINE, MANFORCE STAYLONG CONDOMS MANGO FLAVOUR WITH BENZOCAINE, MANFORCE STAYLONG CONDOMS ORANGE FLAVOUR WITH BENZOCAINE, MANFORCE STAYLONG CONDOMS PINEAPPLE FLAVOUR WITH BENZOCAINE, MANFORCE STAYLONG CONDOM PAN FLAVOUR WITH BENZOCAINE, MANFORCE CONDOMS TOFFEE FLAVOUR WITH BENZOCAINE, MANFORCE STAMINA CONDOM ORANGE FLAVOUR WITH BENZOCAINE, MANFORCE STAMINA PINEAPPLE FLAVOUR WITH BENZOCAINE, MANFORCE STAYLONG SUNNY EDITION BELA FLAVOUR WITH BENZOCAINE, MANFORCE CONDOM ORANGE FLAVOUR WITH BENZOCAINE, MANFORCE CONDOM PINEAPPLE FLAVOUR WITH BENZOCAINE.)-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM(ROYAL NATURAL CONDOMS, ROYAL CHOCOLATE FLAVOUR CONDOMS, ROYAL STRAWBERRY FLAVOUR CONDOMS, ROYAL COFFEE FLAVOUR CONDOMS, ROYAL BLACK GRAPES FLAVOUR CONDOMS.)-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES.,MALE LATEX CONDOM(MANFORCE CONDOMS, MANFORCE CONDOMS BUBBLEGUM FLAVOUR, MANFORCE CONDOMS COFFEE FLAVOUR, MANFORCE CONDOMS MANGO FLAVOUR, MANFORCE CONDOMS ALOE VERA FLAVOUR, MANFORCE CONDOMS BANANA FLAVOUR , MANFORCE CONDOMS STRAWBERRY FLAVOUR, MANFORCE CONDOMS CHOCOLATE FLAVOUR, MANFORCE CONDOMS JASMINE FLAVOUR, MANFORCE CONDOMS PAN FLAVOUR, MANFORCE CONDOMS VANILLA FLAVOUR, MANFORCE CONDOMS BLACK GRAPES FLAVOUR, MANFORCE CONDOMS BUTTERSCOTCH FLAVOUR, MANFORCE CONDOM MIX FRUIT FLAVOUR, MANFORCE CONDOMS GREEN APPLE FLAVOUR, MANFORCE CONDOMS ROSE FLAVOUR, MANFORCE GAME CONDOMS EXOTIC FLAVOUR, MANFORCE CONDOMS ORANGE FLAVOUR, MANFORCE CONDOMS PINEAPPLE FLAVOUR , SUPER MANFORCE CONDOMS LITCHI FLAVOUR, MANFORCE CONDOMS GUAVA FLAVOUR , MANFORCE ULTRATHIN CONDOMS MELON FLAVOUR, MANFORCE CONDOMS SUNNY EDITION BELA FLAVOUR, MANFORCE CONDOMS HAZELNUT FLAVOUR, MANFORCE CONDOM TOFFEE FLAVOUR, MANFORCE CONDOMS MINT FLAVOUR, MANFORCE XXL CONDOMS MUSK FLAVOUR, MANFORCE

	CONDOM BELGIAN CHOCOLATE, MANFORCE WILD CONDOMS , MANFORCE WILD CONDOMS COMBO PACK, MANFORCE CONDOMS COCKTAIL , MANFORCE SUNNY LEONE LIMITED EDITION, MANFORCE INTENSE CONDOMS)-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES.,MALE LATEX CONDOM(MANFORCE CONDOMS, MANFORCE CONDOMS BUBBLEGUM FLAVOUR, MANFORCE CONDOMS COFFEE FLAVOUR, MANFORCE CONDOMS MANGO FLAVOUR, MANFORCE CONDOMS ALOE VERA FLAVOUR, MANFORCE CONDOMS BANANA FLAVOUR , MANFORCE CONDOMS STRAWBERRY FLAVOUR, MANFORCE CONDOMS CHOCOLATE FLAVOUR, MANFORCE CONDOMS JASMINE FLAVOUR, MANFORCE CONDOMS PAN FLAVOUR, MANFORCE CONDOMS VANILLA FLAVOUR, MANFORCE CONDOMS BLACK GRAPES FLAVOUR, MANFORCE CONDOMS BUTTERSCOTCH FLAVOUR, MANFORCE CONDOM MIX FRUIT FLAVOUR, MANFORCE CONDOMS GREEN APPLE FLAVOUR, MANFORCE CONDOMS ROSE FLAVOUR, MANFORCE GAME CONDOMS EXOTIC FLAVOUR, MANFORCE CONDOMS ORANGE FLAVOUR, MANFORCE CONDOMS PINEAPPLE FLAVOUR , SUPER MANFORCE CONDOMS LITCHI FLAVOUR, MANFORCE CONDOMS GUAVA FLAVOUR , MANFORCE ULTRATHIN CONDOMS MELON FLAVOUR, MANFORCE CONDOMS SUNNY EDITION BELA FLAVOUR, MANFORCE CONDOMS HAZELNUT FLAVOUR, MANFORCE CONDOM TOFFEE FLAVOUR, MANFORCE CONDOMS MINT FLAVOUR, MANFORCE XXL CONDOMS MUSK FLAVOUR, MANFORCE CONDOM BELGIAN CHOCOLATE, MANFORCE WILD CONDOMS , MANFORCE WILD CONDOMS COMBO PACK, MANFORCE CONDOMS COCKTAIL, MANFORCE SUNNY LEONE LIMITED EDITION, MANFORCE INTENSE CONDOMS)-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES.,MALE LATEX CONDOM (CONTROL NATURE ADAPTA , CONTROL NATURE)-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES.

20	776-B(H)	1.License Holder Name: SD BIOSENSOR HEALTHCARE PVT. LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ULTRA DENGUE IGM CAPTURE ELISA(NA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE DETECTION OF ANTI-DENGUE IGM IN HUMAN SERUM OR PLASMA.,STANDARD GLUCONAVII GDH BLOOD GLUCOSE TEST STRIP (NA)-IT IS USED FOR QUANTITATIVE DETERMINATION OF GLUCOSE IN BLOOD.,ULTRA CHIKUNGUNYA IGM ELISA(NA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE DETECTION OF CHIKUNGUNYA IGM IN HUMAN SERUM OR PLASMA.,ULTRA TSUTSUGAMUSHI IGM/IGG (NA)-ONE STEP RAPID TEST KIT FOR THE DETECTION OF IGM/IGG ANTIBODIES TO O.TSUTSUGAMUSHI IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,STANDARD CODE FREE PLUS BLOOD GLUCOSE TEST STRIP(NA)-IT IS DESIGNED FOR SELF-TESTING BLOOD GLUCOSE USING FRESH CAPILLARY WHOLE BLOOD FROM FINGER PRICK, PALM, FOREARM OR UPPER ARM.,ULTRA DENGUE IGG CAPTURE ELISA(NA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE DETECTION OF ANTI-DENGUE IGG IN HUMAN SERUM OR PLASMA.,SD CHECK GOLD BLOOD GLUCOSE TEST STRIP(NA)-IT IS DESIGNED FOR SELF-TESTING BLOOD GLUCOSE USING FRESH CAPILLARY WHOLE BLOOD FROM FINGER PRICK.,STANDARD MENTOR BLOOD GLUCOSE TEST STRIP (NA)-IT IS USED FOR QUANTITATIVE DETERMINATION OF GLUCOSE IN BLOOD.

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21	783-B(H)	1.License Holder Name: SCEPTRE MEDICAL DEVICES PVT LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:DISPOSABLE PERFUSION SET / 3 WAY STOP COCK(REIN, JETFLOW, JETLITE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAW OF FLUID AND PRESSURE MONITORING.,DISPOSABLE PERFUSION SETS /MEASURED VOLUME IV SET / IV SET(REIN , JETFLOW, JETLITE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,CATHETERS / MULTIPLE LUMEN CATHETER(REIN CATH , REIN , JETFLOW , JETLITE)-INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTION OR DRUGS,CATHERS / SINGLE NEEDLE/ LUMEN CATHETER(REIN CATH , REIN , JETFLOW, JETLITE)-THE SINGLE-NEEDLE DIALYSIS , IN WHICH CASE ONLY ONE CANNULA OR A SINGLE-LUMEN CATHETER IS USED TO ACCESS THE BLOOD,CATHETERS / GUIDING CATHETER / GUIDEWIRE WITH ADVANCER(REIN CATH , JETFLOW, JETLITE)-THE GUIDE CATHETER PROVIDES SUPPORT FOR DEVICE ADVANCEMENT., CATHETERS INTRAMUSCULAR PRESSURE MONITORING CATHETER / PRESSURE MONITORING LINE(REIN , JETFLOW, JETLITE)-A MODIFIED FIBRE OPTIC TRANSDUCER -TIPPED CATHETER SYYTEM FOR MEASURING INTRAMUSCULAR PRESSURE DURING EXERCISE WAS DETERMINED,DISPOSABLE HYPODERMIC NEEDLE / TRANSDUCER PROTECTOR AS AN ACCESSORIES FOR BLOOD TUBING SET / HEMODIALYSIS CANNULA(REIN, JETFLOW, JETLITE)-A THIN NEEDLE IS INSERTED INTO AN AREA OF ABNORMAL-APPEARING TISSUE OR BODY FLUID. AS WITH OTHER TYPE OF BIOPSIES , THE SAMPLE COLLECTED DURING FINE NEEDLE ASPIRATION CAN HELP MAKE A DIAGNOSIS OR RULE OUT CONDITION SUCH AS CANCER.,BLOOD TUBING SET(OXYFLOW)-ALLOWING THE ARTERIAL BLOOD TO FLOW TO THE DIALYZER AND THE DIALYZED BLOOD TO RETURN FROM THE DIALYZER TO THE CIRCULATION THROUGH THE CANNULA IN THE VEIN,BLOOD TUBING SET(REIN,JETFLOW, JETLITE)-ALLOWING THE ARTERIAL BLOOD TO FLOW TO THE DIALYZER AND THE DIALYZED BLOOD TO RETURN FROM THE DIALYZER TO THE CIRCULATION THROUGH THE CANNULA IN THE VEIN,CATHETERS / PERITONEAL DIALYSIS CATHETER(REIN CATH, REIN , JETFLOW, JETLITE)-THAT ALLOWS DILAYSIS FLUIDS TO ENTER THE ABDOMINAL CAVITY , DWELL INSIDE FOR A WHILE, AND THEN DRAIN BACK OUT AGAIN, DISPOSABLE HYPODERMIC NEEDLE /BONE MARROW NEEDLE / BIOPSY NEEDLE(REIN, JETFLOW,JETLITE)-NEEDLE INSERTED IN BONE MARROW TO COLLECT SAMPLE,IV CANNULA / TRANSDUCER

		PROTECTOR AS AN ACCESSORIES FOR BLOOD TUBING SET / HEMODIALYSIS CANNULA(REIN, JETFLOW, JETLITE)-ALLOWING THE ARTERIAL BLOOD TO FLOW TO THE DIALYZER AND THE DIALYZED BLOOD TO RETURN FROM THE DIALYZER TO THE CIRCULATION THROUGH THE CANNULA IN THE VEIN,A.V FISTULA NEEDLE(REIN, JETFLOW, JETLITE)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLE WHEN THE DIALYSIS IS CARRIED OUT, DISPOSABLE HYPODERMIC SYRINGE(REIN,JETFLOW,JETLITE)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,A,V FISTULA NEEDLE(OXYFLOW)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLE WHEN THE DIALYSIS IS CARRIED OUT ,DISPOSABLE PERFUSION SETS / D 3 WAY STOP COCK WITH EXTENSION SETS(REIN, JETFLOW, JETLITE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAW OF FLUID AND PRESSURE MONITORING.,CATHETERS / DOUBLE & TRIPLE LUMEN(REIN CATH, REIN, JETFLOW, JETLITE)-CATHETER USE FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FORM THE PATIENT,DISPOSABLE PERFUSION SET / SHARP INJURY BLOOD ADMINISTRATION SETS / B.T SET(REIN, JETFLOW, JETLITE)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN
22	786-B(H)	1.License Holder Name: NEWTECH MEDICAL DEVICES 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:DRUG ELUTING STENT (INSISTENT, KORONAR)-DRUG ELUTING STENT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS INCLUDING THOSE WITH DIABETES MELITUS.

23	AD/067	1.License Holder Name: LIFELINE MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:INTRAOCULAR LENS (STRIDENT)-IT IS INTENDED TO BE PLACED IN THE POSTERIOR CHAMBER OF THE EYE REPLACING THE CATARACTOUS NATURAL HUMAN LENS ,INTRAOCULAR LENS(STRIDENT)-IT IS INTENDED TO BE PLACED IN THE POSTERIOR CHAMBER OF THE EYE REPLACING CATARACTOUS NATURAL HUMAN LENS ,INTRAOCULAR LENS (SPIRANT)-IT IS INTENDED TO BE PLACED IN THE POSTERIOR CHAMBER OF THE EYE REPLACING THE CATARACTOUS NATURAL HUMAN LENS,INTRAOCULAR LENS(SPIRANT)-IT IS INTENDED TO BE PLACED IN THE POSTERIOR CHAMBER OF THE EYE REPLACING CATARACTOUS NATURAL HUMAN LENS
24	DD/296	1.License Holder Name: PREGNA INTERNATIONAL LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:COPPER T CU 380A (MFRIYAA T CU 380A)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY

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25	G/25/2247	1.License Holder Name: VECTOR BIOTEK PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:LYSE(VECTOR LYSE-30)-LYSE FOR MINDRAY BC-30 3 PART DIFFERENTIAL BLOOD CELL COUNTER,DILUENT(VECTOR DILUENT 30)-DILUENT FOR MINDRAY BC-30 3 PART DIFFERENTIAL BLOOD CELL COUNTER,CLEANER (CLEANER-ERM)-CLEANER FOR ERMA 3 PART DIFFERENTIAL BLOOD CELL COUNTER,PROBE CLEANER(VEC PROBE CLEANER)-PROBE CLEANER FOR MINDRAY 3 PART DIFFERENTIAL BLOOD CELL COUNTER,CLEANER(CLEANER-DIA)-CLEANER FOR DIATRON 3 PART DIFFERENTIAL BLOOD CELL COUNTER,CLEANER(BONAVERA COUNT EZ)-CLEANER FOR BONAVERA COUNT 3 PART DIFFERENTIAL BLOOD CELL COUNTER,RINSE(BONAVERA COUNT RINSE)-RINSE FOR BONAVERA COUNT 3 PART DIFFERENTIAL BLOOD CELL COUNTER, LYSE(BONAVERA COUNT LYSE)-LYSE FOR BONAVERA COUNT 3 PART DIFFERENTIAL BLOOD CELL COUNTER,DILUENT(BONAVERA COUNT DILUENT)-DILUENT FOR BONAVERA COUNT 3 PART DIFFERENTIAL BLOOD CELL COUNTER,DILUENT(DILUENT-DIA)-DILUENT FOR DIATRON 3 PART DIFFERENTIAL BLOOD CELL COUNTER,STRONG CLEANER(STRONG CLEANER-NK)-CLEANER FOR NIHON KOHDEN 3 PART DIFFERENTIAL BLOOD CELL COUNTER, CLEANER(CLEANAC-NK)-CLEANER FOR NIHON KOHDEN 3 PART DIFFERENTIAL BLOOD CELL COUNTER,LYSE(VECTOR LYSE 10E)-LYSE FOR MINDRAY BC-10E 3 PART DIFFERENTIAL BLOOD CELL COUNTER, LYSE(LYSE-MED)-LYSE FOR MEDONIC 3 PART DIFFERENTIAL BLOOD CELL COUNTER,DILUENT(DILUENT-MED)-DILUENT FOR MEDONIC 3 PART DIFFERENTIAL BLOOD CELL COUNTER,LYSE(LYSE-DIA)-LYSE FOR DIATRON 3 3 PART DIFFERENTIAL BLOOD CELL COUNTER,LYSE (LYSE-SWL)-LYSE FOR SWELAB 3 PART DIFFERENTIAL BLOOD CELL COUNTER,DILUENT(DILUENT-SWL)-DILUENT FOR SWELAB 3 PART DIFFERENTIAL BLOOD CELL COUNTER,CLEANER(EZ-MR)-PROBE CLEANER FOR MINDRAY 3 PART DIFFERENTIAL BLOOD CELL COUNTER,PROBE CLEANER(PROBE CLEANER -MR)-PROBE CLEANER FOR MINDRAY 3 PART DIFFERENTIAL BLOOD CELL COUNTER, CLEANER(VECTOR PROBE CLEANER 10E)-PROBE CLEANERFOR MINDRAY BC-10E 3 PART DIFFERENTIAL BLOOD CELL COUNTER, DILUENT(VECTOR DILUENT 10E)-DILUENT FOR MINDRAY 10E 3 PART DIFFERENTIAL BLOOD CELL COUNTER,CLEANER(VECTOR PROBE CLEANER 30)-PROBE CLEANERFOR MINDRAY BC-30 3 PART DIFFERENTIAL BLOOD CELL COUNTER,CLEANER(CELL CLEANER-SY)-CLEANER FOR SYSMEX 3 PART DIFFERENTIAL BLOOD CELL COUNTER

26	G/28/1298	1.License Holder Name: BIO-TECH VISION CARE PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:HYDROPHILIC ACRYLIC FOLDABLE PHAKIC TORIC INTRAOCULAR LENS (EYECRYL PHAKIC TORIC)-EYECRYL PHAKIC TORIC IOLS ARE INDICATED IN PHAKIC ADULTS FOR THE CORRECTION OR REDUCTION OF MODERATE TO HIGH MYOPIA WITH CO-EXISTING ASTIGMATISM.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

27	G/28/1379	1.License Holder Name: VERITAS BIOVENTIONS PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ENDOSSEOUS DENTAL IMPLANT(WANECORE, WANECORE XP)-DENTAL IMPLANT IS INDICATED FOR SURGICAL PLACEMENT IN THE UPPER OR LOWER JAW ARCHES, TO PROVIDE A ROOT FORM MEANS FOR SINGLE OF MULTIPLE UNITS' PROSTHETIC APPLIANCE ATTACHMENTS TO RESTORE PATIENT'S CHEWING FUNCTION. IMPLANT CAN PLACED WITH CONVENTIONAL TWO STAGES SURGICAL PROCESS WITH AN OPTION FOR TRANSMUCOSAL HEALING OR THEY CAN PLACED IN SINGLE STAGE SURGICAL PROCESS FOR IMMEDIATE LOADING., EVEROLIMUS ELUTING CORONARY STENT SYSTEM(EVADER, EVERNIC, EVERNIA, EVERTON)-THE CORONARY STENT IS INDICATED FOR ELECTIVE IMPLANTATION AND FOR TREATMENT OF ACUTE OR THREATENED CLOSURE FOLLOWING INTERVENTION IN THE CORONARY VASCULATURE, INCLUDING SAPHENOUS VEIN GRAFTS & IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. THE ISSUES OF REPEATED RESTENOSIS ARE ALWAYS BIG PROBLEM IN METALLIC STENT AND TO OVERCOME THIS ISSUE DRUG ELUTING STENTS (DES) ARE USE FOR ANGIOPLASTY. THE EVEROLIMUS ELUTING CORONARY STENT SYSTEM (DRUG ELUTING STENT) IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO CORONARY ARTERY LESIONS WITH A REFERENCE VESSEL. DIAMETER RANGING FROM 2.25 MM TO 4.0 MM AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. EVEROLIMUS DRUG INHIBITS GROWTH FACTOR AND CYTOKINE STIMULATED CELL PROLIFERATION AND PREVENTS VASCULAR HYPERPLASIA IN ALLOGRAFT AND ANGIOPLASTY MODELS. ALSO EVEROLIMUS MODULATES INFLAMMATORY CELL FUNCTION AND BLOCKS SMOOTH MUSCLE CELL PROLIFERATION. BY NOT KILLING CELLS, IT PREVENTS VESSEL DAMAGE AND ALLOWS RAPID AND COMPLETE RE-ENDOTHELIZATION WITHIN 30 DAYS. EVEROLIMUS THEREBY MINIMIZES THE POTENTIAL FOR THROMBOSIS.,ENDOSSEOUS DENTAL PROSTHETICS(WANECORE PROSTHETICS)-GINGIVA FORMER CONTOURING THE GINGIVA AFTER UNCOVER OF IMPLANT, USE WITH TRANSGINGIVAL HEALING. TRANSFER COMPONENTS ARE USED TO TRANSFER OF IMPLANT POSITION TO THE LABORATORY.,ENDOSSEOUS DENTAL PROSTHETICS(WANECORE PROSTHETICS)-ABUTMENTS GIVE WIDE RANGE OF OPTIONS DURING THE SINGLE, MULTIPLE OR FULL MOUTH RESTORATION OF DENTAL IMPLANT AFTER OSSEOINTEGRATION.

28	G/28/1385	1.License Holder Name: SAHAJANAND MEDICAL TECHNOLOGIES PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:PERIPHERICS - PACLITAXEL DRUG COATED PTA BALLOON(PERIPHERICS)-THE PERIPHERICS PACLITAXEL DRUG COATED PTA BALLOON CATHETER IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY, AFTER APPROPRIATE VESSEL PREPARATION, OF DE NOVO OR RESTENOTIC LESIONS UP TO 200MM IN LENGTH IN NATIVE INFRAPOPLITEAL ARTERIES AND POPLITEAL ARTERIES (SUPERFICIAL FEMORAL) WITH REFERENCE VESSEL DIAMETERS OF 2-12MM.
29	G/28/1395	1.License Holder Name: NANO THERAPEUTICS PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:NON-COMPLIANT PTCA DILATATION CATHETER(MARVELA NC PTCA DILATATION CATHETER)-MARVELA NC PTCA DILATATION CATHETER IS INDICATED FOR: • BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. • BALLOON DILATATION OF A STENT AFTER IMPLANTATION (BALLOON MODELS 1.25MM 5.00MM)., SEMI-COMPLIANT PTCA DILATATION CATHETER(MARVELA SC PTCA DILATATION CATHETER)-MARVELA SC PTCA DILATATION CATHETER IS INDICATED FOR: • BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. • BALLOON DILATATION OF A STENT AFTER IMPLANTATION (BALLOON MODELS 1.25MM 5.00MM).

30	G/28/1396	1.License Holder Name: ENVISION SCIENTIFIC PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:SIROLIMUS COATED BALLOON CATHETER(DEVOIR, VANQUISHER)-SIROLIMUS COATED BALLOON CATHETER IS INTENDED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. SIROLIMUS COATED BALLOON CATHETER IS THEREFORE INDICATED TO DILATE THE DISEASED SEGMENT(S) AND DELIVER DRUG IN A CORONARY ARTERY OR A GRAFT, TO IMPROVE MYOCARDIAL PERFUSION WITH LESION LENGTHS RANGING FROM 10.00 TO 40.00 MM AND DIAMETERS RANGING FROM 1.50 MM TO 4.00 MM.,SIROLIMUS ELUTING BIODEGRADABLE POLYMER STENT SYSTEM (ABRAX COCR)-• ABRAX COCR IS INDICATED FOR TREATMENT OF PATIENTS WITH STENOSIS IN CORONARY ARTERIES AND FOR IMPROVING AND MAINTAINING THE CORONARY LUMINAL DIAMETER IN PATIENTS INCLUDING THOSE WITH SYMPTOMATIC ISCHEMIC DISEASE, STABLE ANGINA, AND UNSTABLE ANGINA DUE TO LESIONS OF LENGTH 40 MM IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER FROM 2.25MM TO 4.00MM. • AN ELECTIVE IMPLANTATION AND IN THE TREATMENT OF ACUTE OR THREATENED CLOSURE ASSOCIATED WITH A CORONARY INTERVENTION AND IN PATIENTS UNDERGOING PRIMARY PCI (PERCUTANEOUS CORONARY INTERVENTION) IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION. ALSO, IT IS INDICATED IN PATIENTS WITH DIABETES MELLITUS AND LESIONS IN CORONARY ARTERIES WITH DIFFUSE PROLIFERATIVE DISEASE. ,SIROLIMUS COATED BALLOON CATHETER (MAGICTOUCH - SCB)-SIROLIMUS COATED BALLOON CATHETER IS INTENDED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. SIROLIMUS COATED BALLOON CATHETER IS THEREFORE INDICATED TO DILATE THE DISEASED SEGMENT(S) AND DELIVER DRUG IN A CORONARY ARTERY OR A GRAFT, TO IMPROVE MYOCARDIAL PERFUSION WITH BALLOON LENGTHS RANGING FROM 10.00 TO 40.00 MM AND DIAMETERS RANGING FROM 1.50 MM TO 4.00 MM TO TREAT LESION LENGTH FROM 8.00 MM TO 38.00 MM. THE DEVICE IS INTENDED FOR USE IN FOLLOWING CONDITIONS: PATIENTS WITH IN STENT RESTENOSIS OF PREVIOUS STENT IMPLANTATION. PATIENTS WITH DISEASE IN SMALL VESSELS WHERE DRUG ELUTING STENT IMPLANTATION IS EITHER NOT FEASIBLE OR INVOLVING HIGHER RISK OF RESTENOSIS. PATIENTS WITH BIFURCATION LESIONS, WHERE SIDE BRANCH STENT TREATMENT INCREASES RISKS OF DISSECTION,

	RESTENOSIS AND A BALLOON CATHETER TREATMENT IS MORE ADVISED.,SIROLIMUS ELUTING CORONARY STENT SYSTEM (ABLUMINUS DES+, FUTURE, FUSION, ABLUMINUS - DM AND ABLUMINUS - AMI)-• SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR TREATMENT OF PATIENTS WITH STENOSIS IN CORONARY ARTERIES AND FOR IMPROVING AND MAINTAINING THE CORONARY LUMINAL DIAMETER IN PATIENTS INCLUDING THOSE WITH SYMPTOMATIC ISCHEMIC DISEASE, STABLE ANGINA, AND UNSTABLE ANGINA DUE TO LESIONS OF LENGTH 40 MM IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER FROM 2.25MM TO 5.00MM. • AN ELECTIVE IMPLANTATION AND IN THE TREATMENT OF ACUTE OR THREATENED CLOSURE ASSOCIATED WITH A CORONARY INTERVENTION AND IN PATIENTS UNDERGOING PRIMARY PCI (PERCUTANEOUS CORONARY INTERVENTION) IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION. ALSO, IT IS INDICATED IN PATIENTS WITH DIABETES MELLITUS AND LESIONS IN CORONARY ARTERIES WITH DIFFUSE PROLIFERATIVE DISEASE. ,SIROLIMUS COATED PTA BALLOON CATHETER(MAGIC TOUCH PTA)-• SIROLIMUS COATED PTA 0.014" OTW BALLOON CATHETER IS INTENDED TO USE IN DILATATION OF STENOSIS IN THE ILIAC, FEMORAL, ILIOFEMORAL, POPLITEAL, INFROPOPLITEAL AND RENAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. • SIROLIMUS COATED PTA 0.018" OTW CATHETER IS INTENDED FOR USE IN DILATATION OF PERIPHERAL ARTERIES, SUCH AS THE ILIAC, FEMORAL, ILIO FEMORAL, POPLITEAL, INFRA POPLITEAL AND RENAL ARTERIES. • SIROLIMUS COATED PTA 0.035" OTW CATHETER IS INTENDED FOR DILATATION OF LESIONS IN THE FEMORAL, ILIAC, POPLITEAL, INFRAPOPLITEAL AND RENAL ARTERIES. • SIROLIMUS COATED PTA 0.014" RX DILATATION CATHETER IS INTENDED FOR DILATATION OF LESIONS IN THE ILIAC, FEMORAL, POPLITEAL, INFRAPOPLITEAL, RENAL AND CAROTID ARTERIES.,SIROLIMUS BASED NANO CARRIER ELUTING STENT SYSTEM(ABLUMINUS NP)-THE SIROLIMUS BASED NANO CARRIER ELUTING STENT SYSTEM IS INTENDED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. RECOGNIZED USE OF INTRACORONARY STENTS CURRENTLY INCLUDES BUT IS NOT LIMITED TO THE TREATMENT OF DE NOVO OR RESTENOTIC LESIONS IN NATIVE CORONARY ARTERIES AND IN DE NOVO LESIONS OF SAPHENOUS VEIN GRAFTS. THE SIROLIMUS BASED NANO CARRIER ELUTING STENT SYSTEM IS AVAILABLE FOR INTRACORONARY IMPLANTATION FOR INNER VESSEL DIAMETERS OF 2.25 TO 4.00 MM.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

31	G/28/1431	1.License Holder Name: ORTHOTECH 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:MODULAR SHOULDER REPLACEMENT SYSTEM - HINGE(ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY),MODULAR SHOULDER REPLACEMENT SYSTEM - HINGE(ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY),MODULAR SHOULDER REPLACEMENT SYSTEM -ROD(ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) ,MODULAR SHOULDER REPLACEMENT SYSTEM -ROD(ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY),MODULAR SHOULDER REPLACEMENT SYSTEM - HINGE(ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) ,MODULAR SHOULDER REPLACEMENT SYSTEM - CUP(ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY), MODULAR SHOULDER REPLACEMENT SYSTEM - CUP(ECO, ORTHOSIS) -CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) ,MODULAR SHOULDER REPLACEMENT SYSTEM - HINGE(ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) ,MODULAR SHOULDER REPLACEMENT SYSTEM - CUP(ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) , MODULAR SHOULDER REPLACEMENT SYSTEM - CUP(ECO, ORTHOSIS) -CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) ,MODULAR SHOULDER REPLACEMENT SYSTEM - CUP(ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) ,MODULAR SHOULDER REPLACEMENT SYSTEM - CUP(ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) , MODULAR SHOULDER REPLACEMENT SYSTEM - CUP(ECO, ORTHOSIS) -CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) ,HA COATED SHOULDER REPLACEMENT SYSTEM (ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY),MODULAR SHOULDER REPLACEMENT SYSTEM - CUP(ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) , SHOULDER REPLACEMENT SYSTEM (ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) ,SHOULDER REPLACEMENT SYSTEM (ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY),HA COATED SHOULDER REPLACEMENT SYSTEM

	(ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY),SHOULDER REPLACEMENT SYSTEM (ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) ,HA COATED SHOULDER REPLACEMENT SYSTEM(ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY),HA COATED ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) ,HA COATED ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) ,HA COATED SHOULDER REPLACEMENT SYSTEM (ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY),SHOULDER REPLACEMENT SYSTEM (ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) ,TOTAL HIP MODULAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT , ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-CEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) , HA COATED ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) ,TOTAL HIP MODULAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,HA COATED ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) , BIPOLAR HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,MODULAR TOTAL HIP STEM(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,TOTAL HIP MODULAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,TOTAL HIP MODULAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,TOTAL HIP MODULAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,MONOBLOCK TOTAL HIP STEM(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,UNCEMENTED POROUS COATED CUP (SHELL) (ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,UNCEMENTED POROUS COATED CUP (SHELL)(ECO, ORTHOSIS) -INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,RING LOCK MODULAR BIPOLAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,BIPOLAR HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,BIPOLAR HIP PROSTHESIS - STEM WITH HEAD (ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,BIPOLAR HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS)

	-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,MODULAR BIPOLAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,TOTAL HIP MODULAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,MODULAR BIPOLAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,MODULAR STEM(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,BIPOLAR HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,MODULAR TOTAL HIP STEM (ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,MODULAR TOTAL HIP STEM(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,HA COATED BONE CAGE(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,MODULAR BIPOLAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT, MODULAR STEM(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,BONE CAGE(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,ACETABULAR CUP(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,ACETABULAR CUP(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT , ACETABULAR CUP(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,ACETABULAR CUP(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT , UNCEMENTED MODULAR STEM (POROUS COATED)(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT , UNCEMENTED MODULAR STEM (POROUS COATED)(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,MONOBLOCK TOTAL HIP STEM(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,UNCEMENTED MODULAR STEM (HA COATED) (ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,MODULAR STEM(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,MODULAR TOTAL HIP STEM (ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,BONE CAGE(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,HA COATED BONE CAGE(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. , THOMPSON HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,THOMPSON HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,MODULAR STEM(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT , MONOBLOCK TOTAL HIP STEM(ECO, ORTHOSIS)-INTENDED TO BE

	IMPLANTED TO REPLACE A HIP JOINT ,MONOBLOCK TOTAL HIP STEM (ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,THOMPSON HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT, REVISION HIP STEM(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-CEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) ,UNCEMENTED MODULAR STEM (POROUS COATED)(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,REVISION HIP STEM(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,THOMPSON HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-CEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) ,HA COATED ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) ,HA COATED ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) ,HA COATED ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) ,UNCEMENTED HA COATED CUP (SHELL)(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-CEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) ,HA COATED ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) ,BONE WIRE(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,BONE PLATES(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,BONE WIRE(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,BONE PLATES(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,HA COATED BONE HOOK(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,HA COATED BONE HOOK (ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-CEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) ,HA COATED BONE PLATES(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE.,UNCEMENTED MODULAR STEM (POROUS COATED)(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE

	A HIP JOINT ,HA COATED BONE PLATES(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,BONE NAIL(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-CEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) ,MODULAR SHOULDER REPLACEMENT SYSTEM -ROD HA COATED(ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY),ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-CEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) ,MODULAR SHOULDER REPLACEMENT SYSTEM -ROD HA COATED(ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY),TOTAL HIP MODULAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,BONE HOOK(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,TOTAL HIP MODULAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,BONE NAIL(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,RING LOCK MODULAR BIPOLAR HEAD (ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,HA COATED BONE ROD(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,RING LOCK MODULAR BIPOLAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,BONE ROD (ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,RING LOCK MODULAR BIPOLAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,BONE SCREW(ECO, ORTHOSIS)-INTENDED FOR IMPLANTATION INTO PREPARED BONE DURING ORTHOPAEDIC SURGERY WHEN THE SURGEON DETERMINES THE NEED FOR ADDITIONAL FIXATION: BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE. , UNCEMENTED HA COATED CUP (SHELL)(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,HA COATED BONE SCREW(ECO, ORTHOSIS)-INTENDED FOR IMPLANTATION INTO PREPARED BONE DURING ORTHOPAEDIC SURGERY WHEN THE SURGEON DETERMINES THE NEED FOR ADDITIONAL FIXATION: BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE. ,UNCEMENTED HA COATED CUP (SHELL) (ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,MODULAR SHOULDER REPLACEMENT SYSTEM -ROD(ECO,

	ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) ,UNCEMENTED HA COATED CUP (SHELL)(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,MODULAR SHOULDER REPLACEMENT SYSTEM -ROD (ECO, ORTHOSIS)-CEMENTED FIXATION DURING SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) ,UNCEMENTED HA COATED CUP (LINER) (ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,BONE SCREW(ECO, ORTHOSIS)-INTENDED FOR IMPLANTATION INTO PREPARED BONE DURING ORTHOPAEDIC SURGERY WHEN THE SURGEON DETERMINES THE NEED FOR ADDITIONAL FIXATION: BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE., UNCEMENTED POROUS COATED CUP (SHELL)(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,AUSTIN MOORE HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,REVISION HIP STEM(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,AUSTIN MOORE HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT, RING LOCK MODULAR BIPOLAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,HA COATED BONE SCREW (ECO, ORTHOSIS)-INTENDED FOR IMPLANTATION INTO PREPARED BONE DURING ORTHOPAEDIC SURGERY WHEN THE SURGEON DETERMINES THE NEED FOR ADDITIONAL FIXATION: BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE. ,RING LOCK MODULAR BIPOLAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT , BONE HOOK(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,UNCEMENTED POROUS COATED CUP (SHELL)(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,HA COATED BONE ROD(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,MODULAR BIPOLAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT, BONE ROD(ECO, ORTHOSIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGE BONE. ,REVISION HIP STEM(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,BIPOLAR HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT, UNCEMENTED MODULAR STEM (HA COATED)(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,BIPOLAR HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS)-INTENDED TO BE

	IMPLANTED TO REPLACE A HIP JOINT,UNCEMENTED MODULAR STEM (HA COATED)(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,AUSTIN MOORE HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,UNCEMENTED MODULAR STEM (HA COATED)(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT , AUSTIN MOORE HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS) -INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,RING LOCK MODULAR BIPOLAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT ,BIPOLAR HIP PROSTHESIS - STEM WITH HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,UNCEMENTED HA COATED CUP (LINER) (ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT , MODULAR SHOULDER REPLACEMENT SYSTEM -ROD HA COATED (ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) ,ELBOW REPLACEMENT SYSTEM (ECO, ORTHOSIS)-CEMENTED FIXATION FOR ELBOW REPLACEMENT (IMPLANT FOR HUMAN BODY) ,MODULAR SHOULDER REPLACEMENT SYSTEM -ROD HA COATED(ECO, ORTHOSIS)-UNCEMENTED FIXATION FOR SHOULDER REPLACEMENT (IMPLANT FOR HUMAN BODY) ,RING LOCK MODULAR BIPOLAR HEAD(ECO, ORTHOSIS)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

32	G/28/1470	1.License Holder Name: OMEX MEDICAL TECHNOLOGY 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE UMBILICAL CATHETER-UMBILICAL CATHETER IS USED FOR ARTERIAL BLOOD SAMPLING, ARTERIAL PRESSURE MEASUREMENT, BLOOD PH AND BLOOD GAS ANALYSIS, FLUIDS AND DRUGS ADMINISTRATION., STERILE DISPOSABLE INFANT FEEDING TUBE-INFANT FEEDING TUBE IS USED TO PROVIDE NUTRITION TO PEOPLE WHO CANNOT OBTAIN NUTRITION BY MOUTH.,STERILE DISPOSABLE CLOSE WOUND SUCTION SET-THE CLOSED-WOUND SUCTION UNIT IS USED TO DRAIN SURGICAL WOUNDS OF SEROSANGUINEOUS FLUID TO PREVENT INFECTIONS, HEMATOMAS, OR OTHER MATERIALS FROM ACCUMULATING AND INTERFERING WITH WOUND HEALING.,STERILE DISPOSABLE INFUSION SET WITH AIR VENT-INFUSION SET IS USED FOR THE SHORT-TERM INFUSION OF INTRAVENOUS FLUIDS.,STERILE DISPOSABLE RYLE'S TUBE-RYLE'S TUBE IS USED TO REMOVE THE CONTENTS OF THE STOMACH, INCLUDING AIR, TO DECOMPRESS THE STOMACH, OR TO REMOVE SMALL SOLID OBJECTS AND FLUID, SUCH AS POISON, FROM THE STOMACH.,STERILE DISPOSABLE YANKEUR SUCTION SET-YANKAUER SUCTION SET IS USED TO SUCTION OROPHARYNGEAL SECRETIONS IN ORDER TO PREVENT ASPIRATION., STERILE DISPOSABLE INFUSION SET WITHOUT AIRVENT-INFUSION SET IS USED FOR THE SHORT-TERM INFUSION OF INTRAVENOUS FLUIDS.,STERILE DISPOSABLE 3 WAY STOPCOCK WITH/WITHOUT EXTENSION LINE-3 WAY STOPCOCKS ARE USED TO REDUCE TO LINES DOWN TO ONE, FOR DRUGS/DRUG INFUSION PURPOSES AND FOR THE ATTACHMENT OF EXTENSION LINES.,STERILE DISPOSABLE CHEST DRAINAGE CATHETER-CHEST DRAINAGE CATHETER IS USED WHEN A PATIENT HAS A PNEUMOTHORAX OR HEMOTHORAX., STERILE DISPOSABLE SUCTION CATHETER-SUCTION CATHETER IS USED FOR REMOVAL OF SECRETION FROM MOUTH OROPHARYNX TRACHEA AND BRONCHIAL TUBES.,STERILE DISPOSABLE URINE COLLECTION BAG-URINE COLLECTION BAG IS USED TO COLLECT THE URINE.,STERILE DISPOSABLE MALE EXTERNAL CATHETER-MALE EXTERNAL CATHETER IS USED FOR COLLECTING URINE IN MEN WHO HAVE NO URINARY RETENTION OR URINARY OBSTRUCTION.,STERILE DISPOSABLE NASAL OXYGEN CATHETER-NASAL OXYGEN CATHETER IS USED FOR EASY AND EFFICIENT ADMINISTRATION OF OXYGEN VIA NASOPHARYNGEAL ROUTE.,STERILE DISPOSABLE URETHRAL/NELTON CATHETER-URETHRAL/ NELTON CATHETER IS USED FOR SHORT TERM URINARY DRAINAGE.,STERILE DISPOSABLE FOLEY BALLOON CATHETER-IT IS USED TO ASSIST PEOPLE WHO CANNOT URINATE ON THEIR OWN.,STERILE DISPOSABLE IV FLOW REGULATOR SET WITH/WITHOUT AIR VENT-IV FLOW REGULATOR SET

	ARE USED TO DELIVER FLUIDS INTO A PATIENT'S BODY IN A CONTROLLED MANNER.,STERILE DISPOSABLE KARMAN TYPE CANNULA-KARMAN TYPE CANNULA IS USED FOR ABORTION & GYNECOLOGY USE,STERILE DISPOSABLE MICRO-DRIP INFUSION SET WITH/ WITHOUT AIR VENT-MICRO-DRIP INFUSION SET IS USED FOR THE SHORT-TERM INFUSION OF INTRAVENOUS FLUIDS.,STERILE DISPOSABLE STOMACH TUBE-STOMACH TUBE IS USED FOR LONG-TERM ENTERAL NUTRITION.,STERILE DISPOSABLE ABDOMINAL DRAINAGE KIT-ABDOMINAL DRAINAGE KIT IS MOST SUITABLE FOR POST OPERATIVE DRAINAGE SURGERY.,STERILE DISPOSABLE UMBILICAL CORD CLAMP-UMBILICAL CORD CLAMP IS USED IN NEW BORN BABIES TO STOP THE FLOW OF BLOOD AT THE TIME OF BIRTH, STERILE DISPOSABLE BLOOD ADMINISTRATION SET-BLOOD ADMINISTRATION SET IS USED TO DELIVER BLOOD INTO A PATIENT'S BODY IN A CONTROLLED MANNER.,STERILE DISPOSABLE RECTAL CATHETER-RECTAL CATHETER IS USED TO RELIEVE ABDOMINAL DISTENTION AND ASSIST THE PATIENT TO PASS FLATUS.,STERILE DISPOSABLE GIBBON'S CATHETER-GIBBON'S CATHETER IS USED FOR LONG TERM URINARY DRAINAGE.,STERILE DISPOSABLE ENDOTRACHEAL TUBE-ENDOTRACHEAL TUBE IS USED IN GENERAL ANESTHESIA,STERILE DISPOSABLE INTRAVENOUS CANNULA-IV CANNULA IS DESIGNED TO PROVIDE RAPID VENOUS ACCESS WITH GREATER PATIENT COMFORT DURING INFUSION.,STERILE DISPOSABLE MEASURED VOLUME SET-MEASURED VOLUME SET IS USED TO DELIVER A FIXED VOLUME OF IV FLUID AT A FIXED RATE, USUALLY WITH ADDED MEDICATION.,STERILE DISPOSABLE LEVIN'S TUBE-LEVIN'S TUBE IS USED TO REMOVE THE CONTENTS OF THE STOMACH, INCLUDING AIR, TO DECOMPRESS THE STOMACH, OR TO REMOVE SMALL SOLID OBJECTS AND FLUID, SUCH AS POISON, FROM THE STOMACH.,STERILE DISPOSABLE SCALP VEIN SET-SCALP VEIN SET IS USED TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,STERILE DISPOSABLE INFANT MUCUS EXTRACTOR-INFANT MUCUS EXTRACTOR IS CONVENIENT TO EXTRACT MUCUS SPECIMEN FOR MICROBIOLOGICAL EXAMINATION.

33	G/28/1645	1.License Holder Name: PERFECT MEDICARE PRODUCTS 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:HIP REPLACEMENT SYSTEM (MODULAR) HEAD(PERFECT)-HIP REPLACEMENT SYSTEM AND ARE INTENDED FOR USE IN: PARTIAL HIP ARTHROPLASTY & ARE INTENDED FOR CEMENTED OR UNCEMENTED USE. PARTIAL HIP ARTHROPLASTY IS RELIABLE AND EFFECTIVE TREATMENT OPTION FOR HIP FRACTURES AND DISEASED FEMORAL HEADS AND/OR NECKS. THE BIPOLAR SHELL ARTICULATES AGAINST THE HOST ACETABULAR ARTICULAR CARTILAGE, PRESERVING ACETABULAR BONE STOCK FOR FUTURE CONSIDERATIONS. TOTAL HIP ARTHROPLASTY & ARE INTENDED FOR CEMENTED AND/OR UNCEMENTED USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUNDBONE TO SEAT AND SUPPORT THE COMPONENTS.,HIP REPLACEMENT SYSTEM (MODULAR) HEAD(PERFECT)-HIP REPLACEMENT SYSTEM AND ARE INTENDED FOR USE IN: PARTIAL HIP ARTHROPLASTY & ARE INTENDED FOR CEMENTED OR UNCEMENTED USE. PARTIAL HIP ARTHROPLASTY IS RELIABLE AND EFFECTIVE TREATMENT OPTION FOR HIP FRACTURES AND DISEASED FEMORAL HEADS AND/OR NECKS. THE BIPOLAR SHELL ARTICULATES AGAINST THE HOST ACETABULAR ARTICULAR CARTILAGE, PRESERVING ACETABULAR BONE STOCK FOR FUTURE CONSIDERATIONS. TOTAL HIP ARTHROPLASTY & ARE INTENDED FOR CEMENTED AND/OR UNCEMENTED USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUNDBONE TO SEAT AND SUPPORT THE COMPONENTS.,REVISION STEM (PERFECT)-INTENDED FOR USE IN HIP ARTHROPLASTY,HIP REPLACEMENT SYSTEM (BIPOLAR) CUP(PERFECT)-HIP REPLACEMENT SYSTEM AND ARE INTENDED FOR USE IN: PARTIAL HIP ARTHROPLASTY & ARE INTENDED FOR CEMENTED OR UNCEMENTED USE. PARTIAL HIP ARTHROPLASTY IS RELIABLE AND EFFECTIVE TREATMENT OPTION FOR HIP FRACTURES AND DISEASED FEMORAL HEADS AND/OR NECKS. THE BIPOLAR SHELL ARTICULATES AGAINST THE HOST ACETABULAR ARTICULAR CARTILAGE, PRESERVING ACETABULAR BONE STOCK FOR FUTURE CONSIDERATIONS. TOTAL HIP ARTHROPLASTY & ARE INTENDED FOR CEMENTED AND/OR UNCEMENTED USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY

	REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUNDBONE TO SEAT AND SUPPORT THE COMPONENTS.,HIP REPLACEMENT SYSTEM (MODULAR) CUP(PERFECT)-HIP REPLACEMENT SYSTEM AND ARE INTENDED FOR USE IN: PARTIAL HIP ARTHROPLASTY & ARE INTENDED FOR CEMENTED OR UNCEMENTED USE. PARTIAL HIP ARTHROPLASTY IS RELIABLE AND EFFECTIVE TREATMENT OPTION FOR HIP FRACTURES AND DISEASED FEMORAL HEADS AND/OR NECKS. THE BIPOLAR SHELL ARTICULATES AGAINST THE HOST ACETABULAR ARTICULAR CARTILAGE, PRESERVING ACETABULAR BONE STOCK FOR FUTURE CONSIDERATIONS. TOTAL HIP ARTHROPLASTY & ARE INTENDED FOR CEMENTED AND/OR UNCEMENTED USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUNDBONE TO SEAT AND SUPPORT THE COMPONENTS.,KNEE REPLACEMENT SYSTEM FEMORAL COMPONENT(PERFECT)-THE SYSTEM FOR KNEE ARTHROPLASTY CONSTRAINED IS INTENDED TO REPLACE THE ARTICULAR SURFACE OF THE DISTAL FEMUR, PROXIMAL TIBIA AND PATELLAR SURFACE DURING THE SURGICAL PROCEDURE OF TOTAL KNEE JOINT REPLACEMENT, PERFORMED IN CIRCUMSTANCES WHERE THIS JOINT, IN SKELETALLY MATURE INDIVIDUALS, ARE IMPAIRED AS A RESULT OF PATHOLOGIES SUCH AS NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (OSTEOARTHROSIS), TRAUMATIC ARTHRITIS, ANKYLOSIS OF NON-INFECTIOUS ORIGIN AND KNEE ARTHRODESIS. THE PRODUCT IS INDICATED FOR THE REPLACEMENT OF THE NATURAL JOINT IN PRIMARY KNEE ARTHROPLASTY PROCEDURES IN PATIENTS WHO, ACCORDING TO THE CLINICAL EVALUATION, REQUIRE MEDIAL-LATERAL, ANTERIOR-POSTERIOR AND VARUS / VALGUS TOTALLY RESTRICTED STABILIZATION DUE TO INADEQUATE FUNCTION OF LIGAMENTS NEEDING (FEMORAL AND TIBIAL) WEDGES AND/OR EXTENSIONS, DUE TO POOR QUALITY OR ABSENCE OF BONE STOCK. IT IS ALSO INDICATED FOR THE PARTIAL OR TOTAL REPLACEMENT OF COMPONENTS IN REVISION PROCEDURES OF KNEE ARTHROPLASTY. ,KNEE REPLACEMENT SYSTEM ADAPTER(PERFECT)-THE SYSTEM FOR KNEE ARTHROPLASTY CONSTRAINED IS INTENDED TO REPLACE THE ARTICULAR SURFACE OF THE DISTAL FEMUR, PROXIMAL TIBIA AND PATELLAR SURFACE DURING THE SURGICAL PROCEDURE OF TOTAL KNEE JOINT REPLACEMENT, PERFORMED IN CIRCUMSTANCES WHERE THIS JOINT, IN SKELETALLY MATURE INDIVIDUALS, ARE IMPAIRED AS A RESULT OF PATHOLOGIES SUCH AS NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (OSTEOARTHROSIS), TRAUMATIC

	ARTHRITIS, ANKYLOSIS OF NON-INFECTIOUS ORIGIN AND KNEE ARTHRODESIS. THE PRODUCT IS INDICATED FOR THE REPLACEMENT OF THE NATURAL JOINT IN PRIMARY KNEE ARTHROPLASTY PROCEDURES IN PATIENTS WHO, ACCORDING TO THE CLINICAL EVALUATION, REQUIRE MEDIAL-LATERAL, ANTERIOR-POSTERIOR AND VARUS / VALGUS TOTALLY RESTRICTED STABILIZATION DUE TO INADEQUATE FUNCTION OF LIGAMENTS NEEDING (FEMORAL AND TIBIAL) WEDGES AND/OR EXTENSIONS, DUE TO POOR QUALITY OR ABSENCE OF BONE STOCK. IT IS ALSO INDICATED FOR THE PARTIAL OR TOTAL REPLACEMENT OF COMPONENTS IN REVISION PROCEDURES OF KNEE ARTHROPLASTY. ,KNEE REPLACEMENT SYSTEM ALL POLY TIBIA COMPONENT(PERFECT)-THE SYSTEM FOR KNEE ARTHROPLASTY CONSTRAINED IS INTENDED TO REPLACE THE ARTICULAR SURFACE OF THE DISTAL FEMUR, PROXIMAL TIBIA AND PATELLAR SURFACE DURING THE SURGICAL PROCEDURE OF TOTAL KNEE JOINT REPLACEMENT, PERFORMED IN CIRCUMSTANCES WHERE THIS JOINT, IN SKELETALLY MATURE INDIVIDUALS, ARE IMPAIRED AS A RESULT OF PATHOLOGIES SUCH AS NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (OSTEOARTHROSIS), TRAUMATIC ARTHRITIS, ANKYLOSIS OF NON-INFECTIOUS ORIGIN AND KNEE ARTHRODESIS. THE PRODUCT IS INDICATED FOR THE REPLACEMENT OF THE NATURAL JOINT IN PRIMARY KNEE ARTHROPLASTY PROCEDURES IN PATIENTS WHO, ACCORDING TO THE CLINICAL EVALUATION, REQUIRE MEDIAL-LATERAL, ANTERIOR-POSTERIOR AND VARUS / VALGUS TOTALLY RESTRICTED STABILIZATION DUE TO INADEQUATE FUNCTION OF LIGAMENTS NEEDING (FEMORAL AND TIBIAL) WEDGES AND/OR EXTENSIONS, DUE TO POOR QUALITY OR ABSENCE OF BONE STOCK. IT IS ALSO INDICATED FOR THE PARTIAL OR TOTAL REPLACEMENT OF COMPONENTS IN REVISION PROCEDURES OF KNEE ARTHROPLASTY. ,KNEE REPLACEMENT SYSTEM ALL POLY TIBIA COMPONENT(PERFECT)-THE SYSTEM FOR KNEE ARTHROPLASTY CONSTRAINED IS INTENDED TO REPLACE THE ARTICULAR SURFACE OF THE DISTAL FEMUR, PROXIMAL TIBIA AND PATELLAR SURFACE DURING THE SURGICAL PROCEDURE OF TOTAL KNEE JOINT REPLACEMENT, PERFORMED IN CIRCUMSTANCES WHERE THIS JOINT, IN SKELETALLY MATURE INDIVIDUALS, ARE IMPAIRED AS A RESULT OF PATHOLOGIES SUCH AS NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (OSTEOARTHROSIS), TRAUMATIC ARTHRITIS, ANKYLOSIS OF NON-INFECTIOUS ORIGIN AND KNEE ARTHRODESIS. THE PRODUCT IS INDICATED FOR THE REPLACEMENT OF THE NATURAL JOINT IN PRIMARY KNEE ARTHROPLASTY PROCEDURES IN PATIENTS WHO, ACCORDING TO THE CLINICAL EVALUATION, REQUIRE MEDIAL-LATERAL, ANTERIOR-POSTERIOR AND VARUS / VALGUS TOTALLY RESTRICTED STABILIZATION DUE TO

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	SYSTEM ULNAR COMPONENT(PERFECT)-PERFECT ELBOW REPLACEMENT SYSTEM IS INTENDED FOR USE IN PRIMARY AND REVISION ELBOW ARTHROPLASTY & ALSO INTENDED FOR CEMENTED AND/OR UNCEMENTED USE. THE GOAL OF THE ELBOW ARTHROPLASTY IS RESTORE FUNCTIONAL MECHANICS OF ELBOW, PAIN RELIEF, TO RESTORE OF MOTION AND STABILITY OF ELBOW., KNEE REPLACEMENT SYSTEM FEMORAL COMPONENT(PERFECT)-THE SYSTEM FOR KNEE ARTHROPLASTY CONSTRAINED IS INTENDED TO REPLACE THE ARTICULAR SURFACE OF THE DISTAL FEMUR, PROXIMAL TIBIA AND PATELLAR SURFACE DURING THE SURGICAL PROCEDURE OF TOTAL KNEE JOINT REPLACEMENT, PERFORMED IN CIRCUMSTANCES WHERE THIS JOINT, IN SKELETALLY MATURE INDIVIDUALS, ARE IMPAIRED AS A RESULT OF PATHOLOGIES SUCH AS NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (OSTEOARTHROSIS), TRAUMATIC ARTHRITIS, ANKYLOSIS OF NON-INFECTIOUS ORIGIN AND KNEE ARTHRODESIS. THE PRODUCT IS INDICATED FOR THE REPLACEMENT OF THE NATURAL JOINT IN PRIMARY KNEE ARTHROPLASTY PROCEDURES IN PATIENTS WHO, ACCORDING TO THE CLINICAL EVALUATION, REQUIRE MEDIAL-LATERAL, ANTERIOR-POSTERIOR AND VARUS / VALGUS TOTALLY RESTRICTED STABILIZATION DUE TO INADEQUATE FUNCTION OF LIGAMENTS NEEDING (FEMORAL AND TIBIAL) WEDGES AND/OR EXTENSIONS, DUE TO POOR QUALITY OR ABSENCE OF BONE STOCK. IT IS ALSO INDICATED FOR THE PARTIAL OR TOTAL REPLACEMENT OF COMPONENTS IN REVISION PROCEDURES OF KNEE ARTHROPLASTY. ,KNEE REPLACEMENT SYSTEM INSERT POLY (PERFECT)-THE SYSTEM FOR KNEE ARTHROPLASTY CONSTRAINED IS INTENDED TO REPLACE THE ARTICULAR SURFACE OF THE DISTAL FEMUR, PROXIMAL TIBIA AND PATELLAR SURFACE DURING THE SURGICAL PROCEDURE OF TOTAL KNEE JOINT REPLACEMENT, PERFORMED IN CIRCUMSTANCES WHERE THIS JOINT, IN SKELETALLY MATURE INDIVIDUALS, ARE IMPAIRED AS A RESULT OF PATHOLOGIES SUCH AS NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (OSTEOARTHROSIS), TRAUMATIC ARTHRITIS, ANKYLOSIS OF NON-INFECTIOUS ORIGIN AND KNEE ARTHRODESIS. THE PRODUCT IS INDICATED FOR THE REPLACEMENT OF THE NATURAL JOINT IN PRIMARY KNEE ARTHROPLASTY PROCEDURES IN PATIENTS WHO, ACCORDING TO THE CLINICAL EVALUATION, REQUIRE MEDIAL-LATERAL, ANTERIOR-POSTERIOR AND VARUS / VALGUS TOTALLY RESTRICTED STABILIZATION DUE TO INADEQUATE FUNCTION OF LIGAMENTS NEEDING (FEMORAL AND TIBIAL) WEDGES AND/OR EXTENSIONS, DUE TO POOR QUALITY OR ABSENCE OF BONE STOCK. IT IS ALSO INDICATED FOR THE PARTIAL OR TOTAL REPLACEMENT OF COMPONENTS IN REVISION PROCEDURES OF KNEE

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CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

34	IMP/IVD/2018/000001	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ATELLICA CH MICROALBUMIN_2 CALIBRATOR (ALB_2 CAL) (ATELLICA CH MICROALBUMIN_2 CALIBRATOR (ALB_2 CAL))-THE ATELLICA® CH MICROALBUMIN_2 CALIBRATOR (ALB_2 CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ALB_2 ASSAY USING THE ATELLICA® CH ANALYZER.,ADVIA® CHEMISTRY MYOGLOBIN (MYO) REAGENTS(ADVIA® CHEMISTRY MYOGLOBIN (MYO) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF MYOGLOBIN IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. MEASUREMENT OF MYOGLOBIN AIDS IN THE RAPID DIAGNOSIS OF HEART OR RENAL DISEASE.,ATELLICA CH GLUCOSE HEXOKINASE_3 (GLUH_3) (ATELLICA CH GLUCOSE HEXOKINASE_3 (GLUH_3))-THE ATELLICA® CH GLUCOSE HEXOKINASE_3 (GLUH_3) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM, CEREBROSPINAL FLUID (CSF), PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA, SODIUM FLUORIDE/POTASSIUM OXALATE), AND URINE USING THE ATELLICA® CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CARBOHYDRATE METABOLISM DISORDERS INCLUDING DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, IDIOPATHIC HYPOGLYCEMIA, AND INSULIN OVERDOSE,ADVIA® CHEMISTRY PYRIDOXAL-5'-PHOSPHATE CONCENTRATED (P5P_C) REAGENT(ADVIA® CHEMISTRY PYRIDOXAL-5'-PHOSPHATE CONCENTRATED (P5P_C) REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED MAINLY IN THE DIAGNOSIS AND TREATMENT OF LIVER DISEASE AND TO MONITOR THE COURSE OF TREATMENT FOR HEPATITIS AND ACTIVE POST-NECROTIC CIRRHOSIS.,ATELLICA CH FRUC CAL(ATELLICA CH FRUC CAL)-THE ATELLICA® CH FRUCTOSAMINE CALIBRATOR (FRUC CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FRUC ASSAY USING THE ATELLICA® CH ANALYZER.,ADVIA® CHEMISTRY FRUCTOSAMINE (FRUC) REAGENTS (ADVIA® CHEMISTRY FRUCTOSAMINE (FRUC) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF GLYCATED PROTEIN (FRUCTOSAMINE) IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. , ATELLICA CH HDL/LDL CAL(ATELLICA CH HDL/LDL CAL)-THE ATELLICA™ CH HDL/LDL CHOLESTEROL CALIBRATOR (HDL/LDL CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE DHDL AND DLDL ASSAYS USING THE ATELLICA™ CH ANALYZER.,ADVIA®

	CHEMISTRY THERAPEUTIC DRUG MONITORING (TDM)CALIBRATORS (ADVIA® CHEMISTRY THERAPEUTIC DRUG MONITORING (TDM) CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA® CHEMISTRY SYSTEMS FOR THE THERAPEUTIC DRUG METHODS.,ATELLICA CH CRP_2 CAL(ATELLICA CH CRP_2 CAL)-THE ATELLICA® CH CREACTIVE PROTEIN_2 CALIBRATORS (CRP_2 CAL) ARE FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE CRP_2 ASSAY USING THE ATELLICA® CH ANALYZER.,ADVIA® CHEMISTRY URIC ACID (UA) REAGENTS(ADVIA® CHEMISTRY URIC ACID (UA) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF RENAL FAILURE, GOUT, AND ECLAMPSIA.,ATELLICA CH GAMMAGLUTAMYL TRANSFERASE (GGT)(ATELLICA CH GAMMAGLUTAMYL TRANSFERASE (GGT))-THE ATELLICA™ CH GAMMAGLUTAMYL TRANSFERASE (GGT) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF GAMMA-GLUTAMYL TRANSFERASE IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF HEPATOBILIARY DISEASE AND IN THE EVALUATION OF PATIENTS WITH ALCOHOLISM.,ATELLICA CH HIGH SENSITIVITY CREACTIVE PROTEIN (HSCRP)(ATELLICA CH HIGH SENSITIVITY CREACTIVE PROTEIN (HSCRP))-THE ATELLICA™ CH HIGH SENSITIVITY C-REACTIVE PROTEIN (HSCRP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF CREACTIVE PROTEIN (CRP) IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA) USING THE ATELLICA™ CH ANALYZER. IN ACUTE PHASE RESPONSE, INCREASED LEVELS OF A NUMBER OF PLASMA PROTEINS, INCLUDING CRP, ARE OBSERVED. MEASUREMENT OF CRP IS USEFUL FOR THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY, INFLAMMATORY DISORDERS, AND ASSOCIATED DISEASES. HIGH SENSITIVITY CRP (HSCRP) MEASUREMENTS MAY BE USED AS AN INDEPENDENT RISK MARKER FOR THE IDENTIFICATION OF INDIVIDUALS AT RISK FOR FUTURE CARDIOVASCULAR DISEASE. MEASUREMENT OF HSCRP, WHEN USED IN CONJUNCTION WITH TRADITIONAL CLINICAL LABORATORY EVALUATION OF ACUTE CORONARY SYNDROMES, MAY BE USEFUL AS AN INDEPENDENT MARKER OF PROGNOSIS FOR RECURRENT EVENTS IN PATIENTS WITH STABLE CORONARY DISEASE OR ACUTE CORONARY SYNDROMES.,ATELLICA CH FRUCTOSAMINE (FRUC)(ATELLICA CH FRUCTOSAMINE (FRUC))-THE ATELLICA® CH FRUCTOSAMINE (FRUC) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN

	THE QUANTITATIVE MEASUREMENT OF GLYCATED PROTEIN (FRUCTOSAMINE) IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA) USING THE ATELLICA® CH ANALYZER. MEASUREMENT OF FRUCTOSAMINE IS REPRESENTATIVE OF BLOOD GLUCOSE LEVELS OVER THE PRECEDING 2–3 WEEKS, AND IS USEFUL FOR MONITORING DIABETIC PATIENTS.,ADVIA® CHEMISTRY UREA NITROGEN (UN) REAGENT(ADVIA® CHEMISTRY UREA NITROGEN (UN) REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF UREA NITROGEN (AN END PRODUCT OF NITROGEN METABOLISM) IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF KIDNEY DISEASE, URINARY TRACT OBSTRUCTION, AND ACUTE OR CHRONIC RENAL FAILURE.,ATELLICA CH LDL CHOLESTEROL DIRECT (DLDL)(ATELLICA CH LDL CHOLESTEROL DIRECT (DLDL))-THE ATELLICA™ CH LDL CHOLESTEROL DIRECT (DLDL) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE RISK ASSESSMENT OF CORONARY ARTERY DISEASE,ADVIA® CHEMISTRY URIC ACID CONCENTRATED (UA_C) REAGENTS(ADVIA® CHEMISTRY URIC ACID CONCENTRATED (UA_C) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF RENAL FAILURE, GOUT, AND ECLAMPSIA., ATELLICA CH DIRECT HDL CHOLESTEROL (DHDL)(ATELLICA CH DIRECT HDL CHOLESTEROL (DHDL))-THE ATELLICA™ CH DIRECT HDL CHOLESTEROL (DHDL) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIPID DISORDERS (SUCH AS DIABETES MELLITUS), ARTHEROSCLEROSIS AND VARIOUS OTHER LIVER AND RENAL DISEASES, AND FOR THE ASSESSMENT FOR THE RISK OF DEVELOPING CARDIOVASCULAR DISEASE.,ATELLICA CH URINE TOTAL PROTEIN CALIBRATOR (UPRO CAL)(ATELLICA CH URINE TOTAL PROTEIN CALIBRATOR (UPRO CAL))-THE ATELLICA® CH URINE TOTAL PROTEIN CALIBRATOR (UPRO CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE UPRO ASSAY USING THE ATELLICA® CH ANALYZER.,ATELLICA CH C-REACTIVE PROTEIN_2 (CRP_2)(ATELLICA CH C-REACTIVE PROTEIN_2 (CRP_2))-THE ATELLICA™ CH C-REACTIVE PROTEIN_2 (CRP_2) ASSAY IS FOR IN

	VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF C-REACTIVE PROTEIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE EVALUATION OF INFECTION, TISSUE INJURY, INFLAMMATORY DISORDERS, AND ASSOCIATED DISEASES. INCREASES IN C-REACTIVE PROTEIN VALUES ARE NON-SPECIFIC FOR MANY DISEASE PROCESSES AND SHOULD NOT BE INTERPRETED WITHOUT A COMPLETE CLINICAL EVALUATION,ADVIA® CHEMISTRY UREA NITROGEN CONCENTRATED (UN_C) REAGENTS(ADVIA® CHEMISTRY UREA NITROGEN CONCENTRATED (UN_C) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF UREA NITROGEN (AN END PRODUCT OF NITROGEN METABOLISM) IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF KIDNEY DISEASE, URINARY TRACT OBSTRUCTION, AND ACUTE OR CHRONIC RENAL FAILURE.,ATELLICA CH CREATININE_2 (CREA_2)(ATELLICA CH CREATININE_2 (CREA_2))-THE ATELLICA® CH CREATININE_2 (CREA_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE USING THE ATELLICA® CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASES, AND IN MONITORING RENAL DIALYSIS.,ADVIA CHEMISTRY PYRIDOXAL-5'-PHOSPHATE (P5P) REAGENT(ADVIA CHEMISTRY PYRIDOXAL-5'-PHOSPHATE (P5P) REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED MAINLY IN THE DIAGNOSIS AND TREATMENT OF LIVER DISEASE AND TO MONITOR THE COURSE OF TREATMENT FOR HEPATITIS AND ACTIVE POST-NECROTIC CIRRHOSIS.,ATELLICA CH CHOLESTEROL_2 (CHOL_2)(ATELLICA CH CHOLESTEROL_2 (CHOL_2))-THE ATELLICA™ CH CHOLESTEROL_2 (CHOL_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF DISORDERS INVOLVING EXCESS CHOLESTEROL IN THE BLOOD AND IN LIPID AND LIPOPROTEIN METABOLISM DISORDERS, ADVIA® CHEMISTRY IRON_2 (IRON_2) REAGENTS(ADVIA® CHEMISTRY IRON_2 (IRON_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) ON ADVIA®

	CHEMISTRY XPT SYSTEMS. MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF IRON DEFICIENCY ANEMIAS AND HEMOCHROMATOSIS.,ATELLICA CH 2-MICROGLOBULIN (B2M) (ATELLICA CH 2-MICROGLOBULIN (B2M))-THE ATELLICA™ CH 2-MICROGLOBULIN (B2M) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF 2-MICROGLOBULIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA) USING THE ATELLICA™ CH ANALYZER. THE B2M ASSAY AIDS IN THE DIAGNOSIS OF ACTIVE RHEUMATOID ARTHRITIS AND KIDNEY DISEASE.,ATELLICA CH APOLIPOPROTEIN A1 (APO A1)(ATELLICA CH APOLIPOPROTEIN A1 (APO A1))-THE ATELLICA™ CH APOLIPOPROTEIN A1 (APO A1) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A1 IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED TO AID IN THE ASSESSMENT OF RISK FOR ARTERIOSCLEROSIS AND CORONARY ARTERY DISEASE.,ATELLICA CH ASPARTATE AMINOTRANSFERASE (AST)(ATELLICA CH ASPARTATE AMINOTRANSFERASE (AST))-THE ATELLICA™ CH ASPARTATE AMINOTRANSFERASE (AST) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) ON THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED TO AID IN THE DIAGNOSIS AND TREATMENT OF CERTAIN TYPES OF LIVER AND HEART DISEASE, ATELLICA CH ALPHA-1-ACID GLYCOPROTEIN (AAG)(ATELLICA CH ALPHA-1-ACID GLYCOPROTEIN (AAG))-THE ATELLICA™ CH ALPHA-1-ACID GLYCOPROTEIN (AAG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALPHA-1-ACID GLYCOPROTEIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA) USING THE ATELLICA™ CH ANALYZER. MEASUREMENTS OF ALPHA-1-ACID GLYCOPROTEIN (OROSOMUCOID) MAY AID IN THE DIAGNOSIS OF COLLAGEN (CONNECTIVE TISSUE) DISORDERS, TUBERCULOSIS, INFECTION, EXTENSIVE MALIGNANCY, AND DIABETES.,ATELLICA CH APOLIPOPROTEIN A1 & B CALIBRATOR (APO A1 &(ATELLICA CH APOLIPOPROTEIN A1 & B CALIBRATOR (APO A1 &)-THE ATELLICA™ CH APOLIPOPROTEIN A1 & B CALIBRATOR (APO A1 & B CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE APO A1 AND APO B ASSAYS ON THE ATELLICA™ CH ANALYZER., ATELLICA CH COMPLEMENT C3 (C3)(ATELLICA CH COMPLEMENT C3 (C3))-THE ATELLICA™ CH COMPLEMENT C3 (C3) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF COMPLEMENT C3 IN HUMAN SERUM USING THE ATELLICA™ CH ANALYZER. MEASUREMENT OF COMPLEMENT C3 LEVELS IS

	IMPORTANT IN THE DETERMINATION OF INHERITED OR ACQUIRED DEFICIENCIES AS WELL AS THE DIAGNOSIS OF INFLAMMATORY AND NECROTIC DISORDERS.,ATELLICA CH ALKALINE PHOSPHATASE, CONCENTRATED (ALP_2C)(ATELLICA CH ALKALINE PHOSPHATASE, CONCENTRATED (ALP_2C))-THE ATELLICA™ CH ALKALINE PHOSPHATASE, CONCENTRATED (ALP_2C) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. MEASUREMENTS OF ALKALINE PHOSPHATASE OR ITS ISOENZYMES ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIVER, BONE, PARATHYROID, AND INTESTINAL DISEASES.,ATELLICA CH CALCIUM (CA)(ATELLICA CH CALCIUM (CA))-THE ATELLICA™ CH CALCIUM (CA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PARATHYROID DISEASE, A VARIETY OF BONE DISEASES, CHRONIC RENAL FAILURE, AND TETANY.,ATELLICA CH ALPHA-1-ANTITRYPSIN (AAT)(ATELLICA CH ALPHA-1-ANTITRYPSIN (AAT))-THE ATELLICA™ CH ALPHA-1-ANTITRYPSIN (AAT) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALPHA-1-ANTITRYPSIN LEVELS IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. MEASUREMENTS OF ALPHA-1-ANTITRYPSIN LEVELS ARE USED IN THE DIAGNOSIS OF JUVENILE AND ADULT CIRRHOSIS OF THE LIVER. IN ADDITION, ALPHA-1-ANTITRYPSIN DEFICIENCY HAS BEEN ASSOCIATED WITH PULMONARY EMPHYSEMA.,ATELLICA CH TDM CALIBRATORS (TDM CAL)(ATELLICA CH TDM CALIBRATORS (TDM CAL))-THE ATELLICA® CH TDM CALIBRATORS (TDM CAL) ARE FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE DGN ASSAY USING THE ATELLICA® CH ANALYZER.,ATELLICA CH UREA NITROGEN (UN_C)(ATELLICA CH UREA NITROGEN (UN_C))-THE ATELLICA™ CH UREA NITROGEN (UN_C) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF UREA NITROGEN (AN END PRODUCT OF NITROGEN METABOLISM) IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF KIDNEY DISEASE, URINARY TRACT OBSTRUCTION, AND ACUTE OR CHRONIC RENAL FAILURE,ATELLICA CH COMPLEMENT C4 (C4)(ATELLICA CH COMPLEMENT C4 (C4))-THE ATELLICA™ CH COMPLEMENT C4 (C4) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF COMPLEMENT C4 IN HUMAN SERUM USING THE ATELLICA™ CH

	ANALYZER. MEASUREMENT OF COMPLEMENT C4 LEVELS IS IMPORTANT IN THE DETERMINATION OF INHERITED OR ACQUIRED DEFICIENCIES AS WELL AS THE DIAGNOSIS OF INFLAMMATORY AND NECROTIC DISORDERS.,ATELLICA CH URIC ACID (UA)(ATELLICA CH URIC ACID (UA))-THE ATELLICA™ CH URIC ACID (UA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF RENAL FAILURE, GOUT, AND ECLAMPSIA,ATELLICA CH IMMUNOGLOBULIN A_2 (IGA_2) (ATELLICA CH IMMUNOGLOBULIN A_2 (IGA_2))-THE ATELLICA™ CH IMMUNOGLOBULIN A_2 (IGA_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED TO AID IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S INABILITY TO RESIST INFECTIOUS AGENTS.,ATELLICA CH TRIGLYCERIDES (CONCENTRATED) (TRIG)(ATELLICA CH TRIGLYCERIDES (CONCENTRATED) (TRIG))-THE ATELLICA™ CH TRIGLYCERIDES (CONCENTRATED) (TRIG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA) USING THE ATELLICA™ CH ANALYZER. MEASUREMENTS OF TRIGLYCERIDES ARE USED IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH DIABETES MELLITUS, NEPHROSIS, LIVER OBSTRUCTION, OTHER DISEASES INVOLVING LIPID METABOLISM, OR VARIOUS ENDOCRINE DISORDERS.,ATELLICA CH LACTATE DEHYDROGENASE LP (LDLP)(ATELLICA CH LACTATE DEHYDROGENASE LP (LDLP))-THE ATELLICA™ CH LACTATE DEHYDROGENASE LP (LDLP) IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE ACTIVITY IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED MAINLY IN THE DIAGNOSIS AND TREATMENT OF MYOCARDIAL AND PULMONARY INFARCTION.,ATELLICA CH TRANSFERRIN (TRF) (ATELLICA CH TRANSFERRIN (TRF))-THE ATELLICA® CH TRANSFERRIN (TRF) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TRANSFERRIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA) USING THE ATELLICA® CH ANALYZER. SUCH MEASUREMENTS ARE USED TO AID IN THE DIAGNOSIS OF MALNUTRITION, CHRONIC INFECTION, ACUTE HEPATITIS, POLYCYTHEMIA, PERNICIOUS ANEMIA, AND RED BLOOD CELL DISORDERS, SUCH AS IRON DEFICIENCY ANEMIA.,ADVIA® CHEMISTRY TOTAL BILIRUBIN_2 (TBIL_2) REAGENTS(ADVIA®

	CHEMISTRY TOTAL BILIRUBIN_2 (TBIL_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN SERUM AND PLASMA OF ADULTS AND NEONATES ON THE ADVIA® CHEMISTRY XPT SYSTEMS. MEASUREMENT OF TOTAL BILIRUBIN, AN ORGANIC COMPOUND FORMED DURING THE NORMAL AND ABNORMAL DESTRUCTION OF RED BLOOD CELLS, IS USED IN THE DIAGNOSIS AND TREATMENT OF LIVER, HEMOLYTIC HEMATOLOGICAL, AND METABOLIC DISORDERS, INCLUDING HEPATITIS AND GALLBLADDER BLOCK. A TOTAL BILIRUBIN MEASUREMENT IN NEWBORN INFANTS IS INTENDED TO AID IN INDICATING THE RISK OF BILIRUBIN ENCEPHALOPATHY (KERNICTERUS),ATELLICA CH TOTAL PROTEIN II (TP)(ATELLICA CH TOTAL PROTEIN II (TP))-THE ATELLICA™ CH TOTAL PROTEIN II (TP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF A VARIETY OF DISEASES INVOLVING THE LIVER, KIDNEY, OR BONE MARROW, AS WELL AS OTHER METABOLIC AND NUTRITIONAL DISORDERS.,ATELLICA CH CYSTATIN C_2 CALIBRATOR (CYSC_2 CAL) (ATELLICA CH CYSTATIN C_2 CALIBRATOR (CYSC_2 CAL))-THE ATELLICA® CH CYSTATIN C_2 CALIBRATORS (CYSC_2 CAL) ARE FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF THE ATELLICA® CH CYSTATIN C_2 (CYSC_2) ASSAY ON THE ATELLICA® CH ANALYZER.,ATELLICA CH MICROALBUMIN_2 (ALB_2)(ATELLICA CH MICROALBUMIN_2 (ALB_2))-THE ATELLICA® CH MICROALBUMIN_2 (ALB_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN URINE USING THE ATELLICA® CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF MICROALBUMINURIA AND ARE HELPFUL FOR THE DETECTION AND TREATMENT OF PATIENTS AT RISK FROM RENAL DISEASE.,ADVIA® CHEMISTRY PREALBUMIN (PREALB) REAGENTS(ADVIA® CHEMISTRY PREALBUMIN (PREALB) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF PREALBUMIN (TRANSTHYRETIN) IN HUMAN SERUM ON ADVIA® CHEMISTRY XPT SYSTEMS. PREALBUMIN IS THE PREFERRED MARKER OF VISCERAL PROTEIN STATUS.,ATELLICA CH AMYLASE (AMYLAS)(ATELLICA CH AMYLASE (AMYLAS))-THE ATELLICA™ CH AMYLASE (AMYLAS) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF AMYLASE ACTIVITY IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED PRIMARILY IN THE DIAGNOSIS AND MONITORING OF ACUTE PANCREATITIS

	(INFLAMMATION OF THE PANCREAS).,ADVIA® CHEMISTRY DIGOXIN (DIG) REAGENTS(ADVIA® CHEMISTRY DIGOXIN (DIG) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF DIGOXIN, A CARDIOVASCULAR DRUG, IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS.,ATELLICA CH ALANINE AMINOTRANSFERASE P5P (ALTPLC)(ATELLICA CH ALANINE AMINOTRANSFERASE P5P (ALTPLC))-THE ATELLICA™ CH ALANINE AMINOTRANSFERASE P5P (ALTPLC) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) ON THE ATELLICA™ CH ANALYZER. THIS ASSAY IS USED TO AID IN THE DIAGNOSIS AND TREATMENT OF CERTAIN TYPES OF LIVER DISEASE.,ATELLICA CH IMMUNOGLOBULIN M_2 (IGM_2)(ATELLICA CH IMMUNOGLOBULIN M_2 (IGM_2))-THE ATELLICA™ CH IMMUNOGLOBULIN M_2 (IGM_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION IN IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN AND POTASSIUM EDTA) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED TO AID IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S INABILITY TO RESIST INFECTIOUS AGENTS.,ATELLICA CH ALBUMIN (ALB)(ATELLICA CH ALBUMIN (ALB))-THE ATELLICA™ CH ALBUMIN (ALB) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CHRONIC INFLAMMATORY DISEASES, COLLAGEN DISEASES, AND LIVER AND KIDNEY DISORDERS,ATELLICA® CH WRCRP (WRCRP)(ATELLICA® CH WRCRP (WRCRP))-THE ATELLICA® CH WIDE RANGE C-REACTIVE PROTEIN (WRCRP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF C-REACTIVE PROTEIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA® CH ANALYZER. MEASUREMENT OF C-REACTIVE PROTEIN AIDS IN EVALUATION OF THE AMOUNT OF INJURY TO BODY TISSUES., ATELLICA CH SPECIAL CHEMISTRY CALIBRATOR (SPCL CHEM CAL) (ATELLICA CH SPECIAL CHEMISTRY CALIBRATOR (SPCL CHEM CAL))-THE ATELLICA® CH SPECIAL CHEMISTRY CALIBRATOR (SPCL CHEM CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE LAC AND TIBC ASSAYS USING THE ATELLICA® CH ANALYZER,ATELLICA® CH WRCRP CAL (WRCRP CAL)(ATELLICA® CH WRCRP CAL (WRCRP CAL))-THE ATELLICA® CH WIDE RANGE C-REACTIVE PROTEIN CALIBRATORS (WRCRP CAL) ARE FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE WRCRP ASSAY USING THE ATELLICA® CH

	ANALYZER., ATELLICA CH ALANINE AMINOTRANSFERASE (ALT) (ATELLICA CH ALANINE AMINOTRANSFERASE (ALT))-THE ATELLICA™ CH ALANINE AMINOTRANSFERASE (ALT) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. THIS ASSAY IS USED TO AID IN THE DIAGNOSIS AND TREATMENT OF CERTAIN TYPES OF LIVER AND HEART DISEASE,ATELLICA® CH CALCIUM_2 (CA_2)(ATELLICA® CH CALCIUM_2 (CA_2))-THE ATELLICA® CH CALCIUM_2 (CA_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE ON THE ATELLICA® CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PARATHYROID DISEASE, A VARIETY OF BONE DISEASES, CHRONIC RENAL FAILURE, AND TETANY.,ATELLICA CH HAPTOGLOBIN (HAPT)(ATELLICA CH HAPTOGLOBIN (HAPT))-THE ATELLICA® CH HAPTOGLOBIN (HAPT) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF HAPTOGLOBIN IN HUMAN SERUM USING THE ATELLICA® CH ANALYZER. SUCH MEASUREMENTS ARE USED AS AN AID IN THE DIAGNOSIS OF HEMOLYTIC DISORDERS.,ADVIA® CHEMISTRY DIRECT BILIRUBIN_2 (DBIL_2) REAGENTS(ADVIA® CHEMISTRY DIRECT BILIRUBIN_2 (DBIL_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USEFUL IN THE SCREENING OF LIVER FUNCTION DISORDERS OR IN THE DIAGNOSIS OF JAUNDICE.,ATELLICA CH ASPARTATE AMINOTRANSFERASE P5P (ASTPLC)(ATELLICA CH ASPARTATE AMINOTRANSFERASE P5P (ASTPLC))-THE ATELLICA™ CH ASPARTATE AMINOTRANSFERASE P5P (ASTPLC) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) ON THE ATELLICA™ CH ANALYZER. THIS ASSAY IS USED TO AID IN THE DIAGNOSIS AND TREATMENT OF CERTAIN TYPES OF LIVER AND HEART DISEASE.,ATELLICA CH CYSTATIN C_2 (CYSC_2)(ATELLICA CH CYSTATIN C_2 (CYSC_2))-THE ATELLICA® CH CYSTATIN C_2 (CYSC_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA) USING THE ATELLICA® CH ANALYZER. MEASUREMENT OF CYSTATIN C AIDS IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASE, ATELLICA CH GLUCOSE OXIDASE (GLUO)(ATELLICA CH GLUCOSE OXIDASE (GLUO))-THE ATELLICA™ CH GLUCOSE OXIDASE (GLUO) ASSAY IS

	FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM, CEREBROSPINAL FLUID (CSF), PLASMA (LITHIUM HEPARIN), AND URINE USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CARBOHYDRATE METABOLISM DISORDERS INCLUDING DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, IDIOPATHIC HYPOGLYCEMIA, AND INSULIN OVERDOSE,ATELLICA CH CREATINE KINASE (CK_L)(ATELLICA CH CREATINE KINASE (CK_L))-THE ATELLICA™ CH CREATINE KINASE (CK_L) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CREATINE KINASE ACTIVITY IN HUMAN PLASMA (LITHIUM HEPARIN) OR SERUM ON THE ATELLICA™ CH ANALYZER. THE ASSAY CAN BE USED TO AID IN THE DIAGNOSIS AND TREATMENT OF MYOCARDIAL INFARCTION AND MUSCLE DISEASES, SUCH AS DUCHENNE PROGRESSIVE MUSCULAR DYSTROPHY.,ADVIA® CHEMISTRY LACTATE DEHYDROGENASE PL (LDPL) REAGENTS(ADVIA® CHEMISTRY LACTATE DEHYDROGENASE PL (LDPL) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE ACTIVITY IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS.. SUCH MEASUREMENTS ARE USED MAINLY IN THE DIAGNOSIS AND TREATMENT OF MYOCARDIAL AND PULMONARY INFARCTION.,ADVIA® CHEMISTRY MYOGLOBULIN CALIBRATOR (MYO CAL)(ADVIA® CHEMISTRY MYOGLOBULIN CALIBRATOR (MYO CAL))-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA® CHEMISTRY SYSTEMS FOR THE ADVIA CHEMISTRY MYOGLOBIN (MYO) ASSAY.,ADVIA® CHEMISTRY HS CRP CAL CARDIO PHASE HS CRP(ADVIA® CHEMISTRY HS CRP CAL CARDIO PHASE HS CRP)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA® CHEMISTRY SYSTEMS FOR THE CARDIOPHASE® HSCRP METHOD, ADVIA® CHEMISTRY HAPTOGLOBIN (HAPT) REAGENTS(ADVIA® CHEMISTRY HAPTOGLOBIN (HAPT) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF HAPTOGLOBIN IN HUMAN SERUM ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED AS AN AID IN THE DIAGNOSIS OF HEMOLYTIC DISORDERS.,ADVIA® CHEMISTRY TRIGLYCERIDES_2 (TRIG_2) REAGENT(ADVIA® CHEMISTRY TRIGLYCERIDES_2 (TRIG_2) REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS., ATELLICA CH APOLIPOPROTEIN B (APO B)(ATELLICA CH APOLIPOPROTEIN B (APO B))-THE ATELLICA™ CH APOLIPOPROTEIN B (APO B) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN B IN HUMAN

	SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED TO AID IN THE ASSESSMENT OF RISK FOR ARTERIOSCLEROSIS AND CORONARY ARTERY DISEASE.,ADVIA® CHEMISTRY WIDE RANGE CREACTIVE PROTEIN (WRCRP) REAGENTS(ADVIA® CHEMISTRY WIDE RANGE CREACTIVE PROTEIN (WRCRP) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF THE CONCENTRATION OF CREACTIVE PROTEIN IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEM.,ATELLICA CH PREALBUMIN (PREALB)(ATELLICA CH PREALBUMIN (PREALB))-THE ATELLICA™ CH PREALBUMIN (PREALB) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF PREALBUMIN (TRANSTHYRETIN) IN HUMAN SERUM USING THE ATELLICA™ CH ANALYZER. PREALBUMIN IS THE PREFERRED MARKER OF VISCERAL PROTEIN STATUS. SUCH MEASUREMENTS MAY AID IN THE ASSESSMENT OF THE NUTRITIONAL STATUS OF THE PATIENT.,ADVIA® CHEMISTRY ALT ALANINE AMINOTRANSFERASE REAGENTS(ADVIA® CHEMISTRY ALT ALANINE AMINOTRANSFERASE REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS., ADVIA® CHEMISTRY FRUCTOSAMINE CALIBRATOR (FRUC CAL) (ADVIA® CHEMISTRY FRUCTOSAMINE CALIBRATOR (FRUC CAL))-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF THE ADVIA® CHEMISTRY FRUCTOSAMINE (FRUC) ASSAY ON ADVIA CHEMISTRY SYSTEMS.,ADVIA CHEMISTRY MICROALBUMIN_2 CALIBRATOR(ADVIA CHEMISTRY MICROALBUMIN_2 CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA® CHEMISTRY SYSTEMS FOR THE MICROALBUMIN_2 METHOD.,ATELLICA CH IMMUNOGLOBULIN G_2 (IGG_2)(ATELLICA CH IMMUNOGLOBULIN G_2 (IGG_2))-THE ATELLICA™ CH IMMUNOGLOBULIN G_2 (IGG_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED TO AID IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S INABILITY TO RESIST INFECTIOUS AGENTS.,ADVIA® CHEMISTRY LDL CHOLESTEROL DIRECT (DLDL) REAGENTS(ADVIA® CHEMISTRY DIRECT LDL CHOLESTEROL (DLDL) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE RISK ASSESSMENT OF CORONARY ARTERY DISEASE.,ATELLICA CH LIPOPROTEIN(A) (LP(A))(ATELLICA CH LIPOPROTEIN(A) (LP(A)))-THE

	ATELLICA™ CH LIPOPROTEIN(A) (LP(A)) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF LIPOPROTEIN(A) IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. MEASUREMENT OF LIPOPROTEIN(A) MAY AID IN THE DIAGNOSIS OF DISORDERS OF LIPID (FAT) METABOLISM AND ASSESSING PERSONS AT RISK FOR CARDIOVASCULAR DISEASES WHEN USED IN CONJUNCTION WITH CLINICAL EVALUATION AND OTHER LIPOPROTEIN TESTS.,ADVIA® CHEMISTRY TRIGLYCERIDES_2 CONCENTRATED (TRIG_C) REAGENTS (ADVIA® CHEMISTRY TRIGLYCERIDES_2 CONCENTRATED (TRIG_C) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS.,ATELLICA CH ANTI-STREPTOLYSIN-O_2 (ASO_2)(ATELLICA CH ANTI-STREPTOLYSIN-O_2 (ASO_2))-THE ATELLICA™ CH ANTI-STREPTOLYSIN-O_2 (ASO_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ANTI-STREPTOLYSIN-O (ASO) IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA) USING THE ATELLICA™ CH ANALYZER. THIS CAN ASSIST THE CLINICIAN TO ESTABLISH THE DEGREE OF INFECTION DUE TO GROUP A HEMOLYTIC STREPTOCOCCI. INCREASED ASO LEVELS ARE ALSO ASSOCIATED WITH RHEUMATIC FEVER AND GLOMERULONEPHRITIS.,ADVIA® CHEMISTRY LACTATE REAGENTS(ADVIA® CHEMISTRY LACTATE REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF LACTATE IN HUMAN PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN ASSESSING CIRCULATORY FUNCTION AND OXYGEN STATUS. INCREASED CONCENTRATION OF LACTATE IN THE BLOOD IS AN INDICATOR OF ANAEROBIC METABOLISM, DECREASED BLOOD FLOW TO THE TISSUES, AND INSUFFICIENT OXYGEN DELIVERY. IN CASES OF SEVERE OXYGEN DEPRIVATION, LACTIC ACIDOSIS MAY OCCUR; THEREFORE, LACTATE MAY BE USED AS AN INDICATOR OF SEVERITY OF CIRCULATORY FAILURE.,ATELLICA CH CHOLINESTERASE (CHE) (ATELLICA CH CHOLINESTERASE (CHE))-THE ATELLICA™ CH CHOLINESTERASE (CHE) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CHOLINESTERASE ENZYME ACTIVITY IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF ORGANOPHOSPHORUS POISONING AND OF CERTAIN LIVER DISEASES, SUCH AS CIRRHOSIS AND ACUTE AND CHRONIC HEPATITIS.,ADVIA® CHEMISTRY AAG 1 –ACID GLYCOPROTIEN REAGENTS(ADVIA® CHEMISTRY AAG 1 –ACID GLYCOPROTIEN REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF 1-ACID GLYCOPROTEIN IN

	HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS., ADVIA® CHEMISTRY FERRITIN (FRT) REAGENTS(ADVIA® CHEMISTRY FERRITIN (FRT) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF FERRITIN IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. ,ADVIA® CHEMISTRY LIPOPROTEIN (A) CALIBRATOR(ADVIA® CHEMISTRY LIPOPROTEIN (A) CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA® CHEMISTRY SYSTEMS FOR THE ADVIA CHEMISTRY LIPOPROTEIN(A) (LPA) ASSAY.,ADVIA CHEMISTRY ALKALINE PHOSPHATASE (ALPDEA) REAGENT(ADVIA CHEMISTRY ALKALINE PHOSPHATASE (ALPDEA) REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY SYSTEMS. SUCH MEASUREMENTS ARE USED MAINLY IN THE DIAGNOSIS AND TREATMENT OF HEPATOBILIARY AND BONE DISEASE.,ADVIA® CHEMISTRY MAGNESIUM (MG) REAGENTS(ADVIA® CHEMISTRY MAGNESIUM (MG) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM, PLASMA, AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS.,ATELLICA CH AMYLASE_2 (AMY_2) (ATELLICA CH AMYLASE_2 (AMY_2))-THE ATELLICA® CH AMYLASE_2 (AMY_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF AMYLASE ACTIVITY IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE USING THE ATELLICA® CH ANALYZER. SUCH MEASUREMENTS ARE USED PRIMARILY IN THE DIAGNOSIS AND MONITORING OF ACUTE PANCREATITIS (INFLAMMATION OF THE PANCREAS). , ADVIA® CHEMISTRY CALCIUM_2 CONCENTRATED (CA_2C) REAGENT(ADVIA CHEMISTRY CA_2C CALICUM _2 REAGENTS , CONCENTRATED)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), OR URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PARATHYROID DISEASE, A VARIETY OF BONE DISEASES, CHRONIC RENAL FAILURE, AND TETANY..,ATELLICA CH PANCREATIC AMYLASE_2 (PAMY_2) (ATELLICA CH PANCREATIC AMYLASE_2 (PAMY_2))-THE ATELLICA® CH PANCREATIC AMYLASE_2 (PAMY_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF PANCREATIC AMYLASE IN HUMAN SERUM AND URINE USING THE ATELLICA® CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PANCREATIC DISORDERS.,ADVIA® CHEMISTRY TOTAL PROTEIN II (TP II) REAGENTS(ADVIA® CHEMISTRY TOTAL PROTEIN II (TP II) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN

	HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF A VARIETY OF DISEASES INVOLVING THE LIVER, KIDNEY, OR BONE MARROW, AS WELL AS OTHER METABOLIC AND NUTRITIONAL DISORDERS.,ADVIA® CHEMISTRY CREATINE KINASE (CK_L) REAGENTS (ADVIA® CHEMISTRY CREATINE KINASE (CK_L) REAGENTS)-THE ADVIA® CHEMISTRY CREATINE KINASE (CK_L) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CREATINE KINASE ACTIVITY IN HUMAN PLASMA (LITHIUM HEPARIN) OR SERUM ON ADVIA CHEMISTRY SYSTEMS. THE ASSAY CAN BE USED TO AID IN THE DIAGNOSIS AND TREATMENT OF MYOCARDIAL INFARCTION AND MUSCLE DISEASES, SUCH AS DUCHENNE PROGRESSIVE MUSCULAR DYSTROPHY.,ADVIA® CHEMISTRY TOTAL PROTEIN REAGENTS, CONCENTRATED(ADVIA® CHEMISTRY TOTAL PROTEIN REAGENTS, CONCENTRATED)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS,ATELLICA CH LACTATE_2 (LAC_2) (ATELLICA CH LACTATE_2 (LAC_2))-THE ATELLICA® CH LACTATE_2 (LAC_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LACTATE IN HUMAN PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA AND SODIUM FLUORIDE) AND CEREBROSPINAL FLUID (CSF) USING THE ATELLICA CH ANALYZER., ADVIA® CHEMISTRY PANCREATIC AMYLASE (PAMY) REAGENTS (ADVIA® CHEMISTRY PANCREATIC AMYLASE (PAMY) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF PANCREATIC AMYLASE IN HUMAN SERUM ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT PANCREATIC DISORDER,ADVIA® CHEMISTRY LIPASE (LIP) REAGENTS(ADVIA® CHEMISTRY LIPASE (LIP) REAGENTS)-THIS IN VITRO DIAGNOSTIC METHOD MEASURES THE CONCENTRATION OF LIPASE IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS.,ADVIA® CHEMISTRY RHEUMATOID FACTOR (RF) REAGENTS(ADVIA® CHEMISTRY RHEUMATOID FACTOR (RF) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF RHEUMATOID FACTOR IN HUMAN SERUM ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS.,ADVIA® CHEMISTRY MAGNESIUM REAGENTS ,(MG_C) CONCENTRATED(ADVIA® CHEMISTRY MAGNESIUM REAGENTS , (MG_C) CONCENTRATED)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM, PLASMA, AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS,ADVIA® CHEMISTRY CARDIOPHASE™ HIGH SENSITIVITY CREACTIVE PROTEIN

	(HSCRP) REAGENTS(ADVIA® CHEMISTRY CARDIOPHASE™ HIGH SENSITIVITY CREACTIVE PROTEIN (HSCRP) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF CREACTIVE PROTEIN (CRP) IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN OR POTASSIUM EDTA) ON ADVIA® CHEMISTRY XPT SYSTEMS., ADVIA® CHEMISTRY ALANINE AMINOTRANSFERASE CONCENTRATED (ALT_C) REAGENTS(ADVIA® CHEMISTRY ALANINE AMINOTRANSFERASE CONCENTRATED (ALT_C) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. ,ADVIA® CHEMISTRY CYSTATIN –C (CYSC CAL)(ADVIA® CHEMISTRY CYSTATIN –C (CYSC CAL))-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF CYSTATIN-C (CYSC) METHOD ON ADVIA® CHEMISTRY.,ADVIA® CHEMISTRY TRANFERRIN REAGENTS(ADVIA® CHEMISTRY TRANFERRIN REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF TRANSFERRIN IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS.,ADVIA® CHEMISTRY MICROALBUMIN _2 (ALB_2) REAGENTS(ADVIA® CHEMISTRY MICROALBUMIN _2 (ALB_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF MICROALBUMIN IN HUMAN URINE ON ADVIA® CHEMISTRY XPT SYSTEMS.,ADVIA® CHEMISTRY WIDE RANGE C- REACTIVE PROTEIN CALIBRATOR (WR CRP CAL)(ADVIA® CHEMISTRY WIDE RANGE C-REACTIVE PROTEIN CALIBRATOR (WR CRP CAL))-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA® CHEMISTRY SYSTEMS FOR THE WIDE RANGE C-REACTIVE PROTEIN (WRCRP) METHOD., ADVIA® CHEMISTRY LACTATE DEHYDROGENASE LP (LDLP) REAGENTS(ADVIA® CHEMISTRY LACTATE DEHYDROGENASE LP (LDLP) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE ACTIVITY IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS.,ADVIA® CHEMISTRY CYSTATIN C (CYSC) REAGENT (ADVIA® CHEMISTRY CYSTATIN C (CYSC) REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA) ON ADVIA® CHEMISTRY XPT SYSTEMS. MEASUREMENT OF CYSTATIN C AIDS IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASE.,ADVIA® CHEMISTRY CHOLINESTERASE (CHE) REAGENTS(ADVIA® CHEMISTRY CHOLINESTERASE (CHE) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CHOLINESTERASE ENZYME ACTIVITY IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) ON ADVIA® CHEMISTRY XPT SYSTEMS. ,ADVIA®

	CHEMISTRY B2M CAL 2-MICROGLOBULIN CALIBRATOR(ADVIA® CHEMISTRY B2M CAL 2-MICROGLOBULIN CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA® CHEMISTRY SYSTEMS FOR THE ADVIA CHEMISTRY ß2-MICROGLOBULIN METHOD.,ADVIA® CHEMISTRY ASPARTATE AMINOTRANSFERASE (AST) REAGENTS(ADVIA® CHEMISTRY ASPARTATE AMINOTRANSFERASE (AST) REAGENTS)-OR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS.,ADVIA® CHEMISTRY LIPOPROTEIN(A) (LPA) REAGENTS(ADVIA® CHEMISTRY LIPOPROTEIN(A) (LPA) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF LIPOPROTEIN(A) IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS.,ADVIA® CHEMISTRY 2MICROGLOBULIN (B2M) REAGENTS(ADVIA® CHEMISTRY 2MICROGLOBULIN (B2M) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF 2MICROGLOBULIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA) ON ADVIA® CHEMISTRY XPT SYSTEMS., ADVIA CHEMISTRY AAT ALPHA-1-ANTITRYPSIN REAGENTS(ADVIA CHEMISTRY AAT ALPHA-1-ANTITRYPSIN REAGENTS)-THIS IN VITRO DIAGNOSTIC ASSAY IS INTENDED TO QUANTITATIVELY MEASURE ALPHA1ANTITRYPSIN LEVELS IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. , ADVIA® CHEMISTRY ASPARTATE AMINOTRANSFERASE CONCEN- TRATED (AST_C) REAGENTS(ADVIA® CHEMISTRY ASPARTATE AMINOTRANSFERASE CONCEN- TRATED (AST_C) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS.,ATELLICA CH LIQUID SPECIFIC PROTEIN CALIBRATORS (LSP CAL)(ATELLICA CH LIQUID SPECIFIC PROTEIN CALIBRATORS (LSP CAL))-THE ATELLICA® CH LIQUID SPECIFIC PROTEIN CALIBRATORS (LSP CAL) ARE FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE AAG, AAT, ASO_2, C3, C4, HAPT, IGA_2, IGG_2, IGM_2, PREALB, RF AND TRF ASSAYS USING THE ATELLICA® CH ANALYZER,ATELLICA CH HSCRP CAL (ATELLICA CH HSCRP CAL)-THE ATELLICA® CH HIGH SENSITIVITY CREACTIVE PROTEIN CALIBRATOR (HSCRP CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE HSCRP ASSAY USING THE ATELLICA® CH ANALYZER.,ATELLICA CH LP(A) CAL(ATELLICA CH LP(A) CAL)-THE ATELLICA™ CH LIPOPROTEIN(A) CALIBRATOR (LP(A) CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE LP(A) ASSAY USING THE ATELLICA™ CH ANALYZER.,ADVIA CHEMISTRY COMPLEMENT C4 REAGENTS (ADVIA CHEMISTRY COMPLEMENT C4 REAGENTS)-FOR IN

	VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF COMPLEMENT C4 IN HUMAN SERUM ON ADVIA® CHEMISTRY XPT SYSTEMS. MEASUREMENT OF COMPLEMENT C4 LEVELS IS IMPORTANT IN THE DETERMINATION OF INHERITED OR ACQUIRED DEFICIENCIES AS WELL AS THE DIAGNOSIS OF INFLAMMATORY AND NECROTIC DISORDERS. ,ADVIA CHEMISTRY COMPLEMENT C3 REAGENTS(ADVIA CHEMISTRY COMPLEMENT C3 REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF COMPLEMENT C3 IN HUMAN SERUM ON ADVIA® CHEMISTRY XPT SYSTEMS. MEASUREMENT OF COMPLEMENT C3 LEVELS IS IMPORTANT IN THE DETERMINATION OF INHERITED OR ACQUIRED DEFICIENCIES AS WELL AS THE DIAGNOSIS OF INFLAMMATORY AND NECROTIC DISORDERS.,ADVIA CHEMISTRY CHOLESTEROL_2 (CHOL_2) REAGENT(ADVIA CHEMISTRY CHOLESTEROL_2 (CHOL_2) REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF DISORDERS INVOLVING EXCESS CHOLESTEROL IN THE BLOOD AND IN LIPID AND LIPOPROTEIN METABOLISM DISORDERS. ,ADVIA CHEMISTRY CHOLESTEROL CONCENTRATE (CHOL_C) REAGENT (ADVIA CHEMISTRY CHOLESTEROL CONCENTRATE (CHOL_C) REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF DISORDERS INVOLVING EXCESS CHOLESTEROL IN THE BLOOD AND IN LIPID AND LIPOPROTEIN METABOLISM DISORDERS. ,ADVIA® CHEMISTRY CREACTIVE PROTEIN_2 (CRP_2) REAGENTS(ADVIA® CHEMISTRY CREACTIVE PROTEIN_2 (CRP_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF THE CONCENTRATION OF CREACTIVE PROTEIN IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE EVALUATION OF INFECTION, TISSUE INJURY, INFLAMMATORY DISORDERS, AND ASSOCIATED DISEASES. INCREASES IN CREACTIVE PROTEIN (CRP) VALUES ARE NON-SPECIFIC FOR MANY DISEASE PROCESSES AND SHOULD NOT BE INTERPRETED WITHOUT A COMPLETE CLINICAL EVALUATION. ,ADVIA® CHEMISTRY CREATININE_2 (CREA/ CREA_2) REAGENTS(ADVIA® CHEMISTRY CREATININE_2 (CREA/ CREA_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASES,

	AND IN MONITORING RENAL DIALYSIS. , ADVIA® CHEMISTRY CREATININE CONCENTRATED (CRE_2C) REAGENTS(ADVIA® CHEMISTRY CREATININE CONCENTRATED (CRE_2C) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASES, AND IN MONITORING RENAL DIALYSIS. ,ADVIA CHEMISTRY CREATINE KINASE (CKNAC) REAGENTS (ADVIA CHEMISTRY CREATINE KINASE (CKNAC) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CREATINE KINASE ACTIVITY IN HUMAN SERUM AND PLASMA ON THE ADVIA CHEMISTRY SYSTEMS. SUCH MEASUREMENTS ARE USED MAINLY IN THE DIAGNOSIS AND TREATMENT OF MYOCARDIAL INFARCTION AND MUSCLE DISEASES SUCH AS DUCHENNE PROGRESSIVE MUSCULAR DYSTROPHY. , ADVIA® CHEMISTRY DIRECT HDL CHOLESTEROL (DHDL) REAGENTS(ADVIA® CHEMISTRY DIRECT HDL CHOLESTEROL (DHDL) REAGENTS) -FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE RISK ASSESSMENT OF CORONARY ARTERY DISEASE. ,ADVIA® CHEMISTRY IMMUNOGLOBULIN M_2 (IGM_2) REAGENTS(ADVIA® CHEMISTRY IMMUNOGLOBULIN M_2 (IGM_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN AND POTASSIUM EDTA) ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED TO AID IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S INABILITY TO RESIST INFECTIOUS AGENTS. ,ADVIA® CHEMISTRY INORGANIC PHOSPHORUS (IP) REAGENTS(ADVIA® CHEMISTRY INORGANIC PHOSPHORUS (IP) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE DETERMINATION OF INORGANIC PHOSPHORUS IN HUMAN SERUM, PLASMA, AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF KIDNEY DISEASES, PARATHYROID GLAND DISORDERS, AND VITAMIN D IMBALANCE., ADVIA® CHEMISTRY CALCIUM_2 (CA_2) REAGENT(ADVIA® CHEMISTRY CALCIUM_2 (CA_2) REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA, OR URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PARATHYROID DISEASE, A VARIETY OF BONE DISEASES, CHRONIC RENAL FAILURE, AND TETANY.,ADVIA® CHEMISTRY INORGANIC PHOSPHORUS CONCENTRATED (IP_C)

	REAGENTS(ADVIA® CHEMISTRY INORGANIC PHOSPHORUS CONCENTRATED (IP_C) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE DETERMINATION OF INORGANIC PHOSPHORUS IN HUMAN SERUM, PLASMA, AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF KIDNEY DISEASES, PARATHYROID GLAND DISORDERS, AND VITAMIN D IMBALANCE.,ADVIA® CHEMISTRY CALCIUM CONCENTRATED (CA_C) REAGENTS(ADVIA® CHEMISTRY CALCIUM CONCENTRATED (CA_C) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), OR URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PARATHYROID DISEASE, A VARIETY OF BONE DISEASES, CHRONIC RENAL FAILURE, AND TETANY,ADVIA CHEMISTRY APO A1/B CALIBRATOR(ADVIA CHEMISTRY APO A1/B CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA® CHEMISTRY SYSTEMS FOR THE APOLIPOPROTEIN A-1 (APO A-1) AND APOLIPOPROTEIN B (APO B) METHODS. ,ADVIA® CHEMISTRY APOLIPOPROTEIN B (APO B) REAGENTS(ADVIA® CHEMISTRY APOLIPOPROTEIN B (APO B) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN B IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED TO AID IN THE ASSESSMENT OF RISK FOR ARTERIOSCLEROSIS AND CORONARY ARTERY DISEASE,ADVIA CHEMISTRY LIQUID SPECIFIC PROTEIN CALIBRATORS (ADVIA CHEMISTRY LIQUID SPECIFIC PROTEIN CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA® CHEMISTRY SYSTEMS FOR THE 1-ACID-GLYCOPROTEIN (AAG), ALPHA-1-ANTITRYPSIN (AAT), ANTI-STREPTOLYSIN-O_2 (ASO_2), COMPLEMENT C3 (C3), COMPLEMENT C4 (C4), FERRITIN (FRT), HAPTOGLOBIN (HAPT), IMMUNOGLOBULIN A_2 (IGA_2), IMMUNOGLOBULIN G_2 (IGG_2), IMMUNOGLOBULIN M_2 (IGM_2), PREALBUMIN (PREALB), RHEUMATOID FACTOR (RF), AND TRANSFERRIN (TRF) METHODS. ,ADVIA® CHEMISTRY ANTISTREPTOLYSINO_2 (ASO_2) REAGENTS(ADVIA® CHEMISTRY ANTISTREPTOLYSINO_2 (ASO_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF ANTISTREPTOLYSINO (ASO) ANTIBODIES IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. THIS CAN ASSIST THE CLINICIAN TO ESTABLISH THE DEGREE OF INFECTION DUE TO GROUP A HEMOLYTIC STREPTOCOCCI. INCREASED ASO LEVELS ARE ALSO ASSOCIATED WITH RHEUMATIC FEVER AND POST STREPTOCOCCAL GLOMERULONEPHRITIS.,ADVIA® CHEMISTRY

	CALCIUM (CA) REAGENTS(ADVIA® CHEMISTRY CALCIUM (CA) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), OR URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PARATHYROID DISEASE, A VARIETY OF BONE DISEASES, CHRONIC RENAL FAILURE, AND TETANY. , ADVIA® CHEMISTRY APOLIPOPROTEIN A1 (APO A1) REAGENTS(ADVIA® CHEMISTRY APOLIPOPROTEIN A1 (APO A1) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A1 IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED TO AID IN THE ASSESSMENT OF RISK FOR ARTERIOSCLEROSIS AND CORONARY ARTERY DISEASE,ADVIA® CHEMISTRY AMYLASE (AMYLAS) REAGENTS(ADVIA® CHEMISTRY AMYLASE (AMYLAS) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF AMYLASE ACTIVITY IN HUMAN SERUM, PLASMA, AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED PRIMARILY IN THE DIAGNOSIS AND MONITORING OF ACUTE PANCREATITIS (INFLAMMATION OF THE PANCREAS).,ADVIA CHEMISTRY AMMONIA (AMM) REAGENTS(ADVIA CHEMISTRY AMMONIA (AMM) REAGENTS)-THIS IN VITRO DIAGNOSTIC METHOD IS INTENDED TO QUANTITATIVELY MEASURE THE CONCENTRATION OF AMMONIA IN HUMAN PLASMA (LITHIUM HEPARIN OR POTASSIUM EDTA) ON ADVIA® CHEMISTRY XPT SYSTEMS.,ADVIA CHEMISTRY ALBUMIN CONCENTRATED (ALB_C) REAGENT(ADVIA CHEMISTRY ALBUMIN CONCENTRATED (ALB_C) REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF ALBUMIN IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN) ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CHRONIC INFLAMMATORY DISEASES, COLLAGEN DISEASES, AND LIVER AND KIDNEY DISORDERS. ,ADVIA CHEMISTRY URINE TOTAL PROTEIN CALIBRATOR (UPRO-CAL)(ADVIA CHEMISTRY URINE TOTAL PROTEIN CALIBRATOR (UPRO-CAL))-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA® CHEMISTRY SYSTEMS FOR THE URINE TOTAL PROTEIN METHOD. ,ADVIA CHEMISTRY ALKALINE PHOSPHATASE_2 CONCENTRATED REAGENTS (ALP_2C)(ADVIA CHEMISTRY ALKALINE PHOSPHATASE_2 CONCENTRATED REAGENTS (ALP_2C))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. MEASUREMENTS OF ALKALINE PHOSPHATASE OR ITS ISOENZYMES ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIVER, BONE, PARATHYROID, AND

	INTESTINAL DISEASES.,ADVIA CHEMISTRY GLUCOSE HEXOKINASE_3 REAGENTS(ADVIA CHEMISTRY GLUCOSE HEXOKINASE_3 REAGENTS) -FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM, CEREBROSPINAL FLUID (CSF), PLASMA AND URINE ON THE ADVIA CHEMISTRY SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CARBOHYDRATE METABOLISM DISORDERS INCLUDING DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, IDIOPATHIC HYPOGLYCEMIA, AND INSULIN OVERDOSE. ,ADVIA CHEMISTRY ALBUMIN REAGENTS (ALB)(ADVIA CHEMISTRY ALBUMIN REAGENTS (ALB))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) ON THE ADVIA CHEMISTRY SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CHRONIC INFLAMMATORY DISEASES, COLLAGEN DISEASES, AND LIVER AND KIDNEY DISORDERS. ,ADVIA CHEMISTRY GLUCOSE OXIDASE REAGENTS(ADVIA CHEMISTRY GLUCOSE OXIDASE REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM, CEREBROSPINAL FLUID (CSF), PLASMA, AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CARBOHYDRATE ETABOLISM DISORDERS INCLUDING DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, IDIOPATHIC HYPOGLYCEMIA, AND INSULIN OVERDOSE. ,ADVIA® CHEMISTRY IMMUNOGLOBULIN A_2 (IGA_2) REAGENTS(ADVIA® CHEMISTRY IMMUNOGLOBULIN A_2 (IGA_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED TO AID IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S INABILITY TO RESIST INFECTIOUS AGENTS. ,ADVIA® CHEMISTRY IMMUNOGLOBULIN G_2 (IGG_2) REAGENT(ADVIA® CHEMISTRY IMMUNOGLOBULIN G_2 (IGG_2) REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED TO AID IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S INABILITY TO RESIST INFECTIOUS AGENTS. ,ADVIA CHEMISTRY SPECIAL CHEMISTRY CALIBRATOR(ADVIA CHEMISTRY SPECIAL CHEMISTRY CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA® CHEMISTRY SYSTEMS FOR THE ACID PHOSPHATASE (TOTAL AND NON-PROSTATIC), LACTATE, LIPASE, AND TOTAL IRON-BINDING CAPACITY (TIBC) METHODS., ADVIA® CHEMISTRY GAMMA-

	GLUTAMYL TRANSFERASE (GGT) REAGENT(ADVIA® CHEMISTRY GAMMA-GLUTAMYL TRANSFERASE (GGT) REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF GAMMA-GLUTAMYL TRANSFERASE IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF HEPATOBILIARY DISEASE AND IN THE EVALUATION OF PATIENTS WITH ALCOHOLISM. , ADVIA CHEMISTRY HDL/LDL CHOLESTEROL CALIBRATOR (ADVIA CHEMISTRY HDL/LDL CHOLESTEROL CALIBRATOR)-THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA® CHEMISTRY SYSTEMS FOR THE DIRECT HDL CHOLESTEROL, HDL II AND DIRECT LDL CHOLESTEROL METHODS. ,ADVIA CHEMISTRY C-REACTIVE PROTEIN _2 CALIBRATOR (ADVIA CHEMISTRY C-REACTIVE PROTEIN _2 CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA® CHEMISTRY SYSTEMS FOR THE C-REACTIVE PROTEIN_2 (CRP_2) METHOD. ,ATELLICA CH LACTATE (LAC) (ATELLICA CH LACTATE (LAC))-THE ATELLICA™ CH LACTATE (LAC) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LACTATE IN HUMAN PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA AND SODIUM FLUORIDE) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN ASSESSING CIRCULATORY FUNCTION AND OXYGEN STATUS. INCREASED CONCENTRATION OF LACTATE IN THE BLOOD IS AN INDICATOR OF ANAEROBIC METABOLISM, DECREASED BLOOD FLOW TO THE TISSUES, AND INSUFFICIENT OXYGEN DELIVERY. IN CASES OF SEVERE OXYGEN DEPRIVATION, LACTIC ACIDOSIS MAY OCCUR; THEREFORE, LACTATE MAY BE USED AS AN INDICATOR OF SEVERITY OF CIRCULATORY FAILURE, ATELLICA CH MAGNESIUM (MG)(ATELLICA CH MAGNESIUM (MG))-THE ATELLICA™ CH MAGNESIUM (MG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE USING THE ATELLICA™ CH ANALYZER. MAGNESIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF HYPOMAGNESEMIA (ABNORMALLY LOW LEVELS OF MAGNESIUM) AND HYPERMAGNESEMIA (ABNORMALLY HIGH LEVELS OF MAGNESIUM), ATELLICA CH RHEUMATOID FACTOR (RF) (ATELLICA CH RHEUMATOID FACTOR (RF))-THE ATELLICA™ CH RHEUMATOID FACTOR (RF) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR IN HUMAN SERUM USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS. RHEUMATOID FACTORS ARE AUTO-ANTIBODIES DIRECTED AGAINST THE FC PORTION OF IGG. THE MAJORITY OF RHEUMATOID FACTORS ARE IGM, BUT MAY BE IGG OR

	IGA. CONDITIONS GIVING RISE TO SUCH FACTORS INCLUDE RHEUMATIC CONDITIONS AND CHRONIC INFLAMMATORY PROCESSES,ATELLICA CH LIPASE (LIP)(ATELLICA CH LIPASE (LIP))-THE ATELLICA™ CH LIPASE (LIP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LIPASE IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. LIPASE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF DISEASES OF THE PANCREAS, SUCH AS ACUTE PANCREATITIS AND OBSTRUCTION OF THE PANCREATIC DUCT, ATELLICA CH 2MICROGLOBULIN CALIBRATOR (B2M CAL) (ATELLICA CH 2MICROGLOBULIN CALIBRATOR (B2M CAL))-THE ATELLICA® CH 2MICROGLOBULIN CALIBRATOR (B2M CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE B2M ASSAY USING THE ATELLICA® CH ANALYZER., ATELLICA CH INORGANIC PHOSPHORUS (IP)(ATELLICA CH INORGANIC PHOSPHORUS (IP))-THE ATELLICA™ CH INORGANIC PHOSPHORUS (IP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHOROUS IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF KIDNEY DISEASES, PARATHYROID GLAND DISORDERS, AND VITAMIN D IMBALANCE,ATELLICA CH PANCREATIC AMYLASE (PAMY) (ATELLICA CH PANCREATIC AMYLASE (PAMY))-THE ATELLICA™ CH PANCREATIC AMYLASE (PAMY) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF PANCREATIC AMYLASE IN HUMAN SERUM USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PANCREATIC DISORDERS,ATELLICA CH IRON_2 (IRON_2)(ATELLICA CH IRON_2 (IRON_2))-THE ATELLICA™ CH IRON_2 (IRON_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF IRON DEFICIENCY ANEMIAS AND HEMOCHROMATOSIS

35	IMP/IVD/2018/000002	1.License Holder Name: SAIFY TRADERS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SMART CARE BLOOD GLUCOSE STRIP(SMART CARE BLOOD GLUCOSE STRIP)-BLOOD GLUCOSE TESTING,BLOOD GLUCOSE MONITORING SYSTEM(SMART CARE)-THIS SYSTEM IS INTENDED FOR USE OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) BY PEOPLE WITH DIABETES AT HOME AND BY HEALTH CARE PROFESSIONALS IN CLINICAL SETTINGS AS AN AID TO MONITORING THE EFFECTIVENESS OF DIABETES CONTROL. IT IS INTENDED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE (SUGAR) IN FRESH WHOLE BLOOD SAMPLES (FROM THE FINGER, PALM, FOREARM, UPPER ARM, CALF AND THIGH). IT SHOULD NOT BE USED FOR THE DIAGNOSIS OF DIABETES, OR TESTING ON NEWBORNS

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

36	IMP/IVD/2018/000003	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARCHITECT ANTI-HBC IGM CONTROLS-VERIFICATION OF THE CALIBRATION OF ARCHITECT ISYSTEM WHEN USED FOR QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC IGM) IN HUMAN SERUM AND PLASMA.,ALINITY I EBV VCA IGM CALIBRATOR(ALINITY I EBV VCA IGM CALIBRATOR)-THE ALINITY I EBV VCA IGM CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA.,ARCHITECT ANTI-HBC II CONTROLS-USED FOR ESTIMATION OF TEST PRECISIÓN AND THE DETECTION OF ARCHITECT ISYSTEM WHEN USED FOR QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM AND PLASMA.,ALINITY I CHAGAS REAGENT KIT(ALINITY I CHAGAS REAGENT KIT)-THE ALINITY I CHAGAS ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TRYPANOSOMA CRUZI (T. CRUZI) IN HUMAN SERUM AND PLASMA, INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING) ON THE ALINITY I ANALYZER.,ARCHITECT ANTI-HBC II CALIBRATORS-USED FOR THE CALIBRATION OF ARCHITECT ISYSTEM WHEN USED FOR QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM AND PLASMA.,ARCHITECT EBV VCA IGG CALIBRATOR(ARCHITECT EBV VCA IGG CALIBRATOR)-THE ARCHITECT EBV VCA IGG CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA.,ARCHITECT ANTI-HBC II REAGENT KIT-INTENDED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM AND PLASMA, INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING)., ALINITY I EBV VCA IGG REAGENT KIT(ALINITY I EBV VCA IGG REAGENT KIT)-THE ALINITY I EBV VCA IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT ANTI-HBE CALIBRATORS-USED FOR THE CALIBRATION OF ARCHITECT ISYSTEM WHEN USED FOR QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B E ANTIGEN (ANTI-HBE) IN HUMAN SERUM AND PLASMA, ARCHITECT EBV VCA IGM CONTROLS(ARCHITECT EBV VCA IGM

	CONTROLS)-THE ARCHITECT EBV VCA IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA.,ARCHITECT HBE AG CONTROLS-USED FOR VERIFICATION OF ACCURACY AND PRECISIÓN OF THE ARCHITECT ISYSTEM WHEN USED FOR QUALITATIVE DETECTION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA., ALINITY I EBV VCA IGG CALIBRATOR(ALINITY I EBV VCA IGG CALIBRATOR)-THE ALINITY I EBV VCA IGG CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA.,ALINITY I HBE AG QUANTITATIVE CONTROLS-USED FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA.,ARCHITECT CHAGAS CALIBRATORS(ARCHITECT CHAGAS CALIBRATORS)-THE ARCHITECT CHAGAS CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TRYPANOSOMA CRUZI (T. CRUZI) IN HUMAN SERUM AND PLASMA.,ARCHITECT HBE AG REAGENT KIT-INTENDED FOR QUALITATIVE DETECTION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA AN AS AID IN DIAGNOSIS AND MONITORING OF HEPATITIS B VIRAL INFECTION.,ALINITY I EBV EBNA-1 IGG CALIBRATOR(ALINITY I EBV EBNA-1 IGG CALIBRATOR)-THE ALINITY I EBV EBNA-1 IGG CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR NUCLEAR ANTIGEN-1 (EBNA-1) IN HUMAN SERUM AND PLASMA.,ARCHITECT ANTI-HCV CONTROLS-USED FOR THE VERIFICATION OF CALIBRATION OF ARCHITECT I SYSTEM WHEN USED FOR QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM AND PLASMA.,ALINITY I HAVAB IGM CONTROLS(ALINITY I HAVAB IGM CONTROLS)-THE ALINITY I HAVAB IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS A VIRUS (IGM ANTI-HAV) IN HUMAN SERUM AND PLASMA., ARCHITECT ANTI-HCV CALIBRATOR-USED FOR THE CALIBRATION OF ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM

	AND PLASMA.,ALINITY I TOXO IGG CALIBRATOR(ALINITY I TOXO IGG CALIBRATOR)-THE ALINITY I TOXO IGG CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ARCHITECT ANTI-HCV REAGENT KIT-INTENDED FOR QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM AND PLASMA . ,ALINITY I HAVAB IGG CALIBRATOR(ALINITY I HAVAB IGG CALIBRATOR)-THE ALINITY I HAVAB IGG CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODY TO HEPATITIS A VIRUS (IGG ANTI-HAV) IN HUMAN SERUM AND PLASMA.,ARCHITECT HIV AG-AB COMBO CONTROLS-INTENDED FOR THE ESTIMATION OF TEST PRECISION AND DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR SIMULTANEOUS QUALITATIVE DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND/OR TYPE 2 (HIV-1/HIV-2) IN HUMAN SERUM OR PLASMA.,ALINITY I EBV EBNA-1 IGG REAGENT KIT(ALINITY I EBV EBNA-1 IGG REAGENT KIT)-THE ALINITY I EBV EBNA-1 IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR NUCLEAR ANTIGEN-1 (EBNA-1) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT HIV AG-AB COMBO CALIBRATOR-USED FOR CALIBRATION OF ARCHITECT I SYSTEM WHEN USED FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND/OR TYPE 2 (HIV-1/HIV-2) IN HUMAN SERUM OR PLASMA.,ARCHITECT EBV EBNA-1 IGG CALIBRATOR(ARCHITECT EBV EBNA-1 IGG CALIBRATOR)-THE ARCHITECT EBV EBNA-1 IGG CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR NUCLEAR ANTIGEN-1 (EBNA-1) IN HUMAN SERUM AND PLASMA., ARCHITECT HIV AG-AB COMBO REAGENT KIT-INTENDED FOR SIMULTANEOUS QUALITATIVE DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND/OR TYPE 2 (HIV-1/HIV-2) IN HUMAN SERUM OR PLASMA INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING)., ARCHITECT PEPSINOGEN I CONTROLS(ARCHITECT PEPSINOGEN I CONTROLS)-THE ARCHITECT PEPSINOGEN I CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN I IN HUMAN SERUM AND PLASMA.,ALINITY I ANTI-HBC

	IGM CALIBRATORS-INTENDED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC IGM) IN HUMAN SERUM AND PLASMA.,ARCHITECT HAVAB-IGG CONTROLS (ARCHITECT HAVAB-IGG CONTROLS)-THE ARCHITECT HAVAB-IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODY TO HEPATITIS A VIRUS (IGG ANTI-HAV) IN HUMAN SERUM AND PLASMA.,ALINITY I ANTI-HBE REAGENT KIT-INTENDED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B E ANTIGEN (ANTI-HBE) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT ICARBAMAZEPINE REAGENT KIT (ARCHITECT ICARBAMAZEPINE REAGENT KIT)-THE ARCHITECT I CARBAMAZEPINE ASSAY IS AN IN VITRO CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE MEASUREMENT OF CARBAMAZEPINE, AN ANTICONVULSANT DRUG, IN HUMAN SERUM OR PLASMA ON THE ARCHITECT I SYSTEM WITH STAT PROTOCOL CAPABILITY.,ALINITY I ANTI-HBE CONTROLS-USED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B E ANTIGEN (ANTI-HBE) IN HUMAN SERUM AND PLASMA.,ARCHITECT CHAGAS REAGENT KIT(ARCHITECT CHAGAS REAGENT KIT)-THE ARCHITECT CHAGAS ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TRYPANOSOMA CRUZI (T. CRUZI) IN HUMAN SERUM AND PLASMA INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING)., ALINITY I HBE AG QUANTITATIVE CALIBRATORS-USED FOR THE CALIBRATION OF THE ALINITY I ANALYZER AND ARE TO BE USED ONLY WITH THE ALINITY I HBEAG REAGENT KIT.,ARCHITECT IGENTAMICIN REAGENT KIT(ARCHITECT IGENTAMICIN REAGENT KIT)-THE ARCHITECT IGENTAMICIN ASSAY IS AN IN VITRO CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF GENTAMICIN, AN ANTIBIOTIC DRUG, IN HUMAN SERUM OR PLASMA ON THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY.,ARCHITECT HBE AG CALIBRATORS-USED FOR THE CALIBRATION OF ARCHITECT ISYSTEM WHEN USED FOR QUALITATIVE DETECTION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA.,ARCHITECT HAVAB-IGG REAGENT KIT(ARCHITECT HAVAB-IGG REAGENT KIT)-THE ARCHITECT HAVAB-IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF IGG ANTIBODY TO HEPATITIS A VIRUS (IGG ANTI-HAV)

	IN HUMAN SERUM AND PLASMA. THE ARCHITECT HAVAB-IGG ASSAY IS INDICATED AS AN AID IN THE DIAGNOSIS OF HEPATITIS A VIRAL INFECTION OR DETECTION OF IGG ANTI-HAV.,ALINITY I ANTI-HBE CALIBRATORS-USED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B E ANTIGEN (ANTI-HBE) IN HUMAN SERUM AND PLASMA.,HPV CONTROL KIT(ABBOTT REALTIME HIGH RISK HPV CONTROL KIT)-THE ABBOTT REALTIME HIGH RISK HPV CONTROLS ARE USED TO ESTABLISH RUN VALIDITY OF THE ABBOTT REALTIME HIGH RISK HPV ASSAY WHEN USED FOR THE DETECTION OF HIGH RISK HUMAN PAPILLOMAVIRUS (HPV) DNA IN CLINICAL SPECIMENS., ALINITY I ANTI-HBC IGM-INTENDED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC IGM) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,HPV AMPLIFICATION REAGENT KIT(ABBOTT REALTIME HIGH RISK HPV AMPLIFICATION REAGENT KIT)-THE ABBOTT REALTIME HIGH RISK HPV IS A QUALITATIVE IN VITRO TEST FOR THE DETECTION OF DNA FROM 14 HIGH RISK HUMAN PAPILLOMAVIRUS (HPV) GENOTYPES 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, AND 68 IN CLINICAL SPECIMENS.,ALINITY I ANTI-HBC IGM CONTROLS-USED FOR THE VERIFICATION OF THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC IGM) IN HUMAN SERUM AND PLASMA.,ARCHITECT CHAGAS CONTROLS(ARCHITECT CHAGAS CONTROLS)-THE ARCHITECT CHAGAS CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TRYPANOSOMA CRUZI (T. CRUZI) IN HUMAN SERUM AND PLASMA., ALINITY I ANTI-HBC II CONTROLS-USED FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM AND PLASMA.,ARCHITECT EBV VCA IGM CALIBRATOR(ARCHITECT EBV VCA IGM CALIBRATOR)-THE ARCHITECT EBV VCA IGM CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA., ALINITY I ANTI-HBC II CALIBRATORS-USED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM AND PLASMA.,ARCHITECT EBV VCA IGG REAGENT KIT(ARCHITECT EBV VCA IGG REAGENT KIT)-THE

	ARCHITECT EBV VCA IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA. THE ASSAY IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF INFECTIOUS MONONUCLEOSIS (IM) AND AN AID IN DETERMINING THE STAGE OF EBV INFECTION.,ALINITY I ANTI-HBC II REAGENT KIT-INTENDED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM AND PLASMA, INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEARTBEATING) ON THE ALINITY I ANALYZER.,ARCHITECT PEPSINOGEN II CALIBRATORS(ARCHITECT PEPSINOGEN II CALIBRATORS)-THE ARCHITECT PEPSINOGEN II CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN II IN HUMAN SERUM AND PLASMA.,ALINITY I HBE AG CONTROLS-USED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA., ARCHITECT EBV EBNA-1 IGG REAGENT KIT(ARCHITECT EBV EBNA-1 IGG)-THE ARCHITECT EBV EBNA-1 IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR NUCLEAR ANTIGEN-1 (EBNA-1) IN HUMAN SERUM AND PLASMA. THE ASSAY IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF INFECTIOUS MONONUCLEOSIS (IM) AND AN AID IN DETERMINING THE STAGE OF EBV INFECTION.,ALINITY I HBE AG CALIBRATORS-USED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA.,ALINITY I RHTLV-I/II REAGENT KIT (ALINITY I RHTLV-I/II REAGENT KIT)-THE ALINITY I RHTLV-I/II ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HTLV-I AND HTLV-II IN HUMAN SERUM AND PLASMA INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING) ON THE ALINITY I ANALYZER. THE ALINITY I RHTLV-I/II ASSAY IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF HTLV-I AND HTLV-II INFECTION AND AS A SCREENING TEST TO PREVENT TRANSMISSION OF HTLV-I AND HTLV-II TO RECIPIENTS OF BLOOD, BLOOD COMPONENTS, CELLS, TISSUE AND ORGANS.,ALINITY I HBE AG REAGENT KIT-INTENDED FOR THE QUALITATIVE DETECTION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER AND IS TO BE USED AS AN AID IN THE DIAGNOSIS AND MONITORING OF HEPATITIS B VIRAL INFECTION.,

	ALINITY I RHTLV-I/II CONTROLS(ALINITY I RHTLV-I/II CONTROLS)-THE ALINITY I RHTLV-I/II CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HTLV-I AND HTLV-II IN HUMAN SERUM AND PLASMA.,ALINITY I HIV AG-AB COMBO CONTROLS-INTENDED FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND/OR TYPE 2 (HIV-1/HIV-2) IN HUMAN SERUM OR PLASMA.,ARCHITECT EBV EBNA-1 IGG CONTROLS(ARCHITECT EBV EBNA-1 IGG CONTROLS)-THE ARCHITECT EBV EBNA-1 IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR NUCLEAR ANTIGEN-1 (EBNA-1) IN HUMAN SERUM AND PLASMA., ARCHITECT ANTI-HBE CONTROLS-USED FOR VERIFICATION OF ACCURACY AND PRECISIÓN OF THE ARCHITECT ISYSTEM WHEN USED FOR QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B E ANTIGEN (ANTI-HBE) IN HUMAN SERUM AND PLASMA.,ARCHITECT EBV VCA IGM REAGENT KIT(ARCHITECT EBV VCA IGM REAGENT KIT)-THE ARCHITECT EBV VCA IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA. THE ASSAY IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF INFECTIOUS MONONUCLEOSIS (IM) AND AN AID IN DETERMINING THE STAGE OF EBV INFECTION.,ARCHITECT ANTI-HBE REAGENT KIT-INTENDED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B E ANTIGEN (ANTI-HBE) IN HUMAN SERUM AND PLASMA AS AN AID IN DIAGNOSIS AND MONITORING OF HEPATITIS B VIRAL INFECTION.,ALINITY I EBV VCA IGM CONTROLS(ALINITY I EBV VCA IGM CONTROLS)-THE ALINITY I EBV VCA IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA.,ARCHITECT ANTI-HBC IGM REAGENT KIT-INTENDED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC IGM) IN HUMAN SERUM AND PLASMA.,ALINITY I CHAGAS CONTROLS(ALINITY I CHAGAS CONTROLS)-THE ALINITY I CHAGAS CONTROLS ARE FOR THE

	ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TRYPANOSOMA CRUZI (T. CRUZI) IN HUMAN SERUM AND PLASMA., ALINITY I ANTI-HCV CALIBRATOR-USED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM AND PLASMA.,ALINITY I EBV EBNA-1 IGG CONTROLS (ALINITY I EBV EBNA-1 IGG CONTROLS)-THE ALINITY I EBV EBNA-1 IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR NUCLEAR ANTIGEN-1 (EBNA-1) IN HUMAN SERUM AND PLASMA.,ARCHITECT ANTI-HBC IGM CALIBRATORS-INTENDED FOR THE CALIBRATION OF ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC IGM) IN HUMAN SERUM AND PLASMA.,ALINITY I PEPSINOGEN I CONTROLS(ALINITY I PEPSINOGEN I CONTROLS)-THE ALINITY I PEPSINOGEN I CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN I IN HUMAN SERUM AND PLASMA.,ALINITY I HIV AG-AB COMBO CALIBRATOR-USED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND/OR TYPE 2 (HIV-1/HIV-2) IN HUMAN SERUM OR PLASMA.,ALINITY I EBV VCA IGG CONTROLS (ALINITY I EBV VCA IGG CONTROLS)-THE ALINITY I EBV VCA IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA.,ALINITY I ANTI-HCV CONTROLS-USED FOR THE VERIFICATION OF THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM AND PLASMA.,ALINITY I PEPSINOGEN II REAGENT KIT (ALINITY I PEPSINOGEN II REAGENT KIT)-THE ALINITY I PEPSINOGEN II (PG II) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN II IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER. ,ALINITY I ANTI-HCV REAGENT KIT-INTENDED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO

	HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM AND PLASMA, INCLUDING SPECIMENS COLLECTED POST MORTEM (NON-HEART BEATING) ON THE ALINITY I ANALYZER..,ALINITY I EBV VCA IGM REAGENT KIT(ALINITY I EBV VCA IGM REAGENT KIT)-THE ALINITY I EBV VCA IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ALINITY I HIV AG-AB COMBO REAGENT KIT-USED FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND/OR TYPE 2 (HIV-1/HIV-2) IN HUMAN SERUM OR PLASMA INCLUDING SPECIMENS COLLECTED POST MORTEM (NONHEART-BEATING) ON THE ALINITY I ANALYZER.,ALINITY I PEPSINOGEN I CALIBRATORS(ALINITY I PEPSINOGEN I CALIBRATORS)-THE ALINITY I PEPSINOGEN I CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN I IN HUMAN SERUM AND PLASMA. , ALINITY I PEPSINOGEN II CONTROLS(ALINITY I PEPSINOGEN II CONTROLS)-THE ALINITY I PEPSINOGEN II CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN II IN HUMAN SERUM AND PLASMA.,ALINITY I PEPSINOGEN II CALIBRATORS(ALINITY I PEPSINOGEN II CALIBRATORS)-THE ALINITY I PEPSINOGEN II CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN II IN HUMAN SERUM AND PLASMA.,ALINITY I PEPSINOGEN I REAGENT KIT(ALINITY I PEPSINOGEN I REAGENT KIT)-THE ALINITY I PEPSINOGEN I (PG I) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN I IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER. ,ALINITY I TOXO IGM CALIBRATOR (ALINITY I TOXO IGM CALIBRATOR)-THE ALINITY I TOXO IGM CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ARCHITECT HAVAB-IGM CALIBRATOR(ARCHITECT HAVAB-IGM CALIBRATOR)-THE ARCHITECT HAVAB-IGM CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS A VIRUS (IGM ANTI-HAV) IN HUMAN SERUM AND PLASMA.,ALINITY I TOXO IGG REAGENT KIT(ALINITY I TOXO IGG REAGENT KIT)-THE ALINITY I TOXO IGG ASSAY IS A

	CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT RHTLV-I/II CONTROLS(ARCHITECT RHTLV-I/II CONTROLS)-THE ARCHITECT RHTLV-I/II CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HTLV-I AND HTLV-II IN HUMAN SERUM AND PLASMA.,ALINITY I CHAGAS CALIBRATOR(ALINITY I CHAGAS CALIBRATOR)-THE ALINITY I CHAGAS CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TRYPANOSOMA CRUZI (T. CRUZI) IN HUMAN SERUM AND PLASMA.,ARCHITECT TOXO IGM CALIBRATOR (ARCHITECT TOXO IGM CALIBRATOR)-THE ARCHITECT TOXO IGM CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA., ARCHITECT TOXO IGG AVIDITY CALIBRATOR & CONTROLS(ARCHITECT TOXO IGG AVIDITY CALIBRATOR & CONTROLS)-THE ARCHITECT TOXO IGG AVIDITY CALIBRATOR IS INTENDED FOR THE CREATION OF AN ACTIVE CALIBRATION FOR THE ASSAYS OF THE ARCHITECT TOXO IGG AVIDITY REAGENT KIT. AN ACTIVE CALIBRATION IS REQUIRED BY THE ARCHITECT ISYSTEM, HOWEVER THE CALIBRATION IS NOT USED TO PRODUCE TOXO IGG AVIDITY RESULTS.,ALINITY I TOXO IGG AVIDITY CONTROLS (ALINITY I TOXO IGG AVIDITY CONTROLS)-THE ALINITY I TOXO IGG AVIDITY CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER.,ALINITY I TOXO IGG AVIDITY REAGENT KIT(ALINITY I TOXO IGG AVIDITY REAGENT KIT)-THE ALINITY I TOXO IGG AVIDITY ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE DETERMINATION OF THE AVIDITY OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ALINITY I TOXO IGM REAGENT KIT(ALINITY I TOXO IGM REAGENT KIT)-THE ALINITY I TOXO IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ALINITY I SYPHILIS TP CONTROLS (ALINITY I SYPHILIS TP CONTROLS)-THE ALINITY I SYPHILIS TP CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO

	TREPONEMA PALLIDUM (TP) IN HUMAN SERUM AND PLASMA. , ARCHITECT SYPHILIS TP CONTROLS(ARCHITECT SYPHILIS TP CONTROLS)-THE ARCHITECT SYPHILIS TP CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM AND PLASMA., ALINITY I SYPHILIS TP CALIBRATOR (ALINITY I SYPHILIS TP CALIBRATOR)-THE ALINITY I SYPHILIS TP CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM AND PLASMA. ,ALINITY I RHTLV-I/II CALIBRATOR(ALINITY I RHTLV-I/II CALIBRATOR)-THE ALINITY I RHTLV-I/II CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HTLV-I AND HTLV-II IN HUMAN SERUM AND PLASMA., ARCHITECT TOXO IGG AVIDITY REAGENT KIT(ARCHITECT TOXO IGG AVIDITY)-THE ARCHITECT TOXO IGG AVIDITY ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE DETERMINATION OF THE AVIDITY OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ARCHITECT PEPSINOGEN I REAGENT KIT(ARCHITECT PEPSINOGEN I)-THE ARCHITECT PEPSINOGEN I (PG I) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN I IN HUMAN SERUM AND PLASMA., ARCHITECT HBEAG QUANTITATIVE CALIBRATORS(ARCHITECT HBEAG QUANTITATIVE CALIBRATORS)-TTHE ARCHITECT HBEAG QUANTITATIVE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM AND ARE TO BE USED ONLY WITH THE ARCHITECT HBEAG REAGENT KIT. THE ARCHITECT HBEAG ASSAY IN COMBINATION WITH THE ARCHITECT HBEAG QUANTITATIVE CALIBRATORS IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA AND IS TO BE USED AS AN AID IN MONITORING OF PATIENTS WITH HEPATITIS B VIRAL INFECTION.,ALINITY I TOXO IGM CONTROLS (ALINITY I TOXO IGM CONTROLS)-THE ALINITY I TOXO IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA. ,ARCHITECT TOXO IGG CALIBRATORS (ARCHITECT TOXO IGG CALIBRATORS)-ARCHITECT TOXO IGG CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE

	QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ARCHITECT TOXO IGM CONTROLS (ARCHITECT TOXO IGM CONTROLS)-THE ARCHITECT TOXO IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA. , ARCHITECT TOXO IGG CONTROLS(ARCHITECT TOXO IGG CONTROLS)-THE ARCHITECT TOXO IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ARCHITECT SYPHILIS TP CALIBRATOR (ARCHITECT SYPHILIS TP CALIBRATOR)-THE ARCHITECT SYPHILIS TP CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM AND PLASMA., ARCHITECT HBEAG QUANTITATIVE CONTROLS (ARCHITECT HBEAG QUANTITATIVE CONTROLS)-THE ARCHITECT HBEAG QUANTITATIVE CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA.,ALINITY I HAVAB IGG REAGENT KIT(ALINITY I HAVAB IGG REAGENT KIT)-THE ALINITY I HAVAB IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODY TO HEPATITIS A VIRUS (IGG ANTI-HAV) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER. THE ALINITY I HAVAB IGG ASSAY IS TO BE USED AS AN AID IN THE DIAGNOSIS OF HEPATITIS A VIRAL INFECTION OR DETECTION OF IGG ANTI-HAV.,ALINITY I SYPHILIS TP REAGENT KIT (ALINITY I SYPHILIS TP REAGENT KIT)-THE ALINITY I SYPHILIS TP ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM AND PLASMA, INCLUDING SPECIMENS COLLECTED POSTMORTEM (NON-HEART-BEATING) ON THE ALINITY I ANALYZER. THE ALINITY I SYPHILIS TP ASSAY IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF SYPHILIS INFECTION AND AS A SCREENING TEST TO PREVENT TRANSMISSION OF TREPONEMA PALLIDUM TO RECIPIENTS OF BLOOD, BLOOD COMPONENTS, CELLS, TISSUE AND ORGANS, ARCHITECT SYPHILIS TP REAGENT KIT(ARCHITECT SYPHILIS TP)-THE ARCHITECT SYPHILIS TP ASSAY IS A CHEMILUMINESCENT

	MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM AND PLASMA, INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING). THE ARCHITECT SYPHILIS TP ASSAY IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF SYPHILIS INFECTION AND AS A SCREENING TEST TO PREVENT TRANSMISSION OF TREPONEMA PALLIDUM TO RECIPIENTS OF BLOOD, BLOOD COMPONENTS, CELLS, TISSUE AND ORGANS, ARCHITECT HAVAB-IGM CONTROLS(ARCHITECT HAVAB-IGM CONTROLS)-THE ARCHITECT HAVAB-IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS A VIRUS (IGM ANTI-HAV) IN HUMAN SERUM AND PLASMA., ARCHITECT RHTLV-I/II CALIBRATOR(ARCHITECT RHTLV-I/II CALIBRATOR)-THE ARCHITECT RHTLV-I/II CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HTLV-I AND HTLV-II IN HUMAN SERUM AND PLASMA.,ARCHITECT PEPSINOGEN II CONTROLS (ARCHITECT PEPSINOGEN II CONTROLS)-THE ARCHITECT PEPSINOGEN II CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN II IN HUMAN SERUM AND PLASMA.,ARCHITECT TOXO IGM REAGENT KIT(ARCHITECT TOXO IGM)-THE ARCHITECT TOXO IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA,ALINITY I HAVAB IGM CALIBRATOR(ALINITY I HAVAB IGM CALIBRATOR)-THE ALINITY I HAVAB IGM CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS A VIRUS (IGM ANTI-HAV) IN HUMAN SERUM AND PLASMA.,ARCHITECT EBV VCA IGG CONTROLS(ARCHITECT EBV VCA IGG CONTROLS)-THE ARCHITECT EBV VCA IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA.,ARCHITECT TOXO IGG REAGENT KIT(ARCHITECT TOXO IGG REAGENT KIT)-THE ARCHITECT TOXO IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ARCHITECT

	RHTLV-I/II REAGENT KIT(ARCHITECT RHTLV-I/II)-THE ARCHITECT RHTLV-I/II ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HTLV-I AND HTLV-II IN HUMAN SERUM AND PLASMA INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING). THE ARCHITECT RHTLV-I/II ASSAY IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF HTLV-I AND HTLV-II INFECTION AND AS A SCREENING TEST TO PREVENT TRANSMISSION OF HTLV-I AND HTLV-II TO RECIPIENTS OF BLOOD, BLOOD COMPONENTS, CELLS, TISSUE AND ORGANS.,ARCHITECT PEPSINOGEN II REAGENT KIT(ARCHITECT PEPSINOGEN II REAGENT KIT)-THE ARCHITECT PEPSINOGEN II (PG II) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN II IN HUMAN SERUM AND PLASMA.,ARCHITECT PEPSINOGEN I CALIBRATORS (ARCHITECT PEPSINOGEN I CALIBRATORS)-THE ARCHITECT PEPSINOGEN I CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN I IN HUMAN SERUM AND PLASMA., ALINITY I HAVAB IGM REAGENT KIT(ALINITY I HAVAB IGM REAGENT KIT)-THE ALINITY I HAVAB IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS A VIRUS (IGM ANTI-HAV) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER. THE ALINITY I HAVAB IGM ASSAY IS TO BE USED AS AN AID IN THE DIAGNOSIS OF ACUTE OR RECENT HEPATITIS A VIRAL INFECTION., ALINITY I HAVAB IGG CONTROLS(ALINITY I HAVAB IGG CONTROLS)-THE ALINITY I HAVAB IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODY TO HEPATITIS A VIRUS (IGG ANTI-HAV) IN HUMAN SERUM AND PLASMA.,ALINITY I TOXO IGG CONTROLS(ALINITY I TOXO IGG CONTROLS)-THE ALINITY I TOXO IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ARCHITECT ICARBAMAZEPINE CALIBRATORS(ARCHITECT ICARBAMAZEPINE CALIBRATORS)-THE ARCHITECT ICARBAMAZEPINE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF CARBAMAZEPINE, AN ANTICONVULSANT DRUG, IN HUMAN SERUM OR PLASMA.,ARCHITECT HAVAB-IGG CALIBRATOR(ARCHITECT

	HAVAB-IGG CALIBRATOR)-THE ARCHITECT HAVAB-IGG CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODY TO HEPATITIS A VIRUS (IGG ANTI-HAV) IN HUMAN SERUM AND PLASMA.,ARCHITECT IGENTAMICIN CALIBRATOR KIT(ARCHITECT IGENTAMICIN CALIBRATOR KIT)-THE ARCHITECT IGENTAMICIN CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF GENTAMICIN, AN ANTIBIOTIC DRUG, IN HUMAN SERUM OR PLASMA,ARCHITECT HAVAB-IGM REAGENT KIT (ARCHITECT HAVAB-IGM)-THE ARCHITECT HAVAB-IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS A VIRUS (IGM ANTI-HAV) IN HUMAN SERUM AND PLASMA. THE ARCHITECT HAVAB-IGM ASSAY IS INDICATED FOR USE AS AN AID IN THE DIAGNOSIS OF ACUTE OR RECENT HEPATITIS A VIRAL INFECTION.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

37	IMP/IVD/2018/000005	1.License Holder Name: OMEGA DX (ASIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TESTOSTERONE ELISA (PATHOZYME® TESTOSTERONE)-PATHOZYME® TESTOSTERONE IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE IN HUMAN SERUM, CARBON ANTIGEN(IMMUTREP® CABON ANTIGEN)-IMMUTREP® CABON ANTIGEN KIT IS IN-VITRO DIAGNOSTIC KIT USE FOR NON-TREPONEMAL FLOCCULATION TEST FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF REAGIN ANTIBODIES IN SERUM OR PLASMA.,CRP TURBIDIMETRY KIT(AVITEX® TURBO CRP)-AVITEX® TURBO CRP IS A TURBIDIMETRY KIT FOR MEASUREMENT OF C-REACTIVE PROTEIN (CRP) ANTIBODIES IN HUMAN SERUM OR PLASMA,VISITECT CD4(VISITECT CD4 RAPID TEST)-THE VISTECT CD4 RAPID TEST IS A SEMI-QUANTITATIVE ASSAY FOR THE ESTIMATION OF CD4 PROTEIN ON THE SURFACE OF CD4+ T CELLS IN HUMAN WHOLE BOOD TO INDICATE WHETHER THE LEVEL IS ABOVE OR BELOW 350 CELLS/UL WITHIN PRE-DIAGNOSED HIV PATIENTS, VISITECT® CD4 ADVANCED DISEASE(VISITECT® CD4 ADVANCED DISEASE)-VISITECT® CD4 ADVANCED DISEASE IS A SEMI-QUANTITATIVE ASSAY FOR THE ESTIMATION OF CD4 PROTEIN ON THE SURFACE OF CD4+ T CELLS IN HUMAN WHOLE BLOOD TO INDICATE WHETHER THE LEVEL IS ABOVE OR BELOW 200 CELLS/L WITHIN PRE-DIAGNOSED HIV PATIENTS,FEBRILE ANTIGEN KIT (MICROPATH® PROTEUS OX19)-MICROPATH® PROTEUS OX19 IS AN IN-VITRO DIAGNOSTIC KIT USED FOR DETECTION OF ANTIBODIES TO VARIOUS BACTERIAL PATHOGENS BY THE SLIDE OR TUBE AGGLUTINATION METHOD,FEBRILE ANTIGEN KIT(MICROPATH® OD)-MICROPATH® SAL O-D IS AN IN-VITRO DIAGNOSTIC KIT USED FOR DETECTION OF ANTIBODIES TO VARIOUS BACTERIAL PATHOGENS BY THE SLIDE OR TUBE AGGLUTINATION METHOD,ASO TURBIDIMETRY KIT(AVITEX® TURBO ASO)-AVITEX® TURBO ASO IS A TURBIDIMETRY KIT FOR MEASUREMENT OF ANTI-STREPTOLYSIN-O (ASO) ANTIBODIES IN HUMAN SERUM OR PLASMA,OVARIAN CANCER ANTIGEN AG 125 ELISA(PATHOZYME® OVARIAN CANCER ANTIGEN AG 125 ELISA)-PATHOZYME® OVARIAN CANCER ANTIGEN AG 125 ELISA IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF OVARIAN CANCER ANTIGEN 125 IN HUMAN SERUM.,STREPTROCOCCAL GROUPING REAGENT (LANCE FIELD TEST) (AVIPATH® STREP)-AVIPATH® STREP IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE IDENTIFICATION OF LABORATORY ISOLATES OF LANCEFIELD'S GROUPS A, B, C, D, F AND G STREPTOCOCCI.,LH (LUTEINIZING HORMONE) ELISA(PATHOZYME® LH)-PATHOZYME® LH IS AN IN-VITRO DIAGNOSTIC KIT IS USED FOR THE QUANTITATIVE

	DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM, FREE T4 (THYROXINE) ELISA(PATHOZYME® FREE T4)-PATHOZYME® FREE T4 IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF FREETHYROXINE (FT4) IN HUMAN SERUM. FOR PROFESSIONAL USE ONLY ,HETERPPHILE ANTIBODY TEST(AVITEX® IM)-AVITEX® IM IS AN IN-VITRO DIAGNOSTIC KIT USED FOR DETECTION AND SEMI-QUANTITATIVE MEASUREMENT OF THE HETEROPHILE ANTIBODY ASSOCIATED WITH INFECTIOUS MONONUCLEOSIS (IM) ,RF TURBIDIMETRY KIT(AVITEX® TURBO RF)-AVITEX® TURBO RF IS A TURBIDIMETRY KIT FOR MEASUREMENT OF RHEUMATOID FACTOR (RF) IN HUMAN SERUM OR PLASMA,HCG (HUMAN CHORIONIC GONADOTROPIN) ELISA (PATHOZYME® HCG)-PATHOZYME® HCG IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN HUMAN SERUM,TOTAL T3 (TRIIODOTHYRONINE) ELISA(PATHOZYME® T3)-PATHOZYME® T3 IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) IN HUMAN SERUM , FERRITIN ELISA(PATHOZYME® FERRITIN ELISA)-PATHOZYME® FERRITIN ELISA IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM,SLE TEST(AVITEX® SLE)-AVITEX® SLE IS AN IN-VITRO DIAGNOSTIC KIT USED FOR PRESUMPTIVE DETECTION OF THE SYSTEMIC LUPUSERYTHE-MATOSUS (SLE) IN HUMAN SERUM BY THEDETECTION AND QUANTITATION OF ANTIBODIES IN SERUM TODEOX-YRIBONUCLEOPROTEIN (DNP).,TSH (THYROID STIMULATING HORMONE) ELISA(PATHOZYME® TSH)-PATHOZYME® TSH IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM ,OESTRADIOL ELISA(PATHOZYME® OESTRADIOL)-PATHOZYME® OESTRADIOL IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL OESTRADIOL (E2) IN HUMAN SERUM OR PLASMA. ,FEBRILE ANTIGEN KIT (MICROPATH® PROTEUS OX2)-MICROPATH® PROTEUS OX2 IS AN IN-VITRO DIAGNOSTIC KIT USED FOR DETECTION OF ANTIBODIES TO VARIOUS BACTERIAL PATHOGENS BY THE SLIDE OR TUBE AGGLUTINATION METHOD,SYPHILIS AB ELISA TEST(PATHOZYME® SYPHILIS COMPETIRION)-PATHOZYME® SYPHILIS COMPETIRION IS A COMPETITIVE ENZYME IMMUNOASSAY (EIA) FOR THE DETECTION OF TOTAL ANTIBODIES T TREPONEMA PALLIDUM IN HUMAN SERA.,FSH (FOLLICLE STIMULATING HORMONE) ELISA(PATHOZYME® FSH)-PATHOZYME® FSH IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN SERUM.,MICROALBUMIN TURBIDIMETRY

	KIT(AVITEX® TURBO MICROALBUMIN)-AVITEX® TURBO MICROALBUMIN IS A TURBIDIMETRY KIT FOR MEASUREMENT OF MICROALBUMIN IN HUMAN URINE,FEBRILE ANTIGEN KIT (MICROPATH® PROTEUS OXK)-MICROPATH® PROTEUS OXK IS AN IN-VITRO DIAGNOSTIC KIT USED FOR DETECTION OF ANTIBODIES TO VARIOUS BACTERIAL PATHOGENS BY THE SLIDE OR TUBE AGGLUTINATION METHOD,RHEUMATOID FACTOR TEST(AVITEX® RF)-AVITEX® RF IS AN IN-VITRO DIAGNOSTIC KIT USED FOR DETECTION OF RHEUMATOID FACTOR (RF) IN HUMAN SERUM. RF IS FOUND IN SERA OF PATIENTS WITH RHEUMATOID ARTHRITIS AND IS BELIEVED TO BE IGM ANTIBODIES DIRECTED AGAINST THE PATIENTS OWN IMMUNOGLOBULIN G.,CEA (CARCINOEMBRYONIC AG) ELISA (PATHOZYME® CEA (CARCINOEMBRYONIC AG) ELISA)-PATHOZYME® CEA (CARCINOEMBRYONIC AG) ELISA IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA)IN HUMAN SERUM.,ROTAVIRUS ANTIGEN TEST(VIROTECT® ROTA)-VIROTECT® ROTA IS AN IN-VITRO DIAGNOSTIC KIT USED FOR DETECTION OF ROTAVIRUS IN FAECAL SAMPLES.,VISITECT® CD4 ADVANCED DISEASE(VISITECT® CD4 ADVANCED DISEASE)-VISITECT® CD4 ADVANCED DISEASE IS A SEMI-QUANTITATIVE ASSAY FOR THE ESTIMATION OF CD4 PROTEIN ON THE SURFACE OF CD4+ T CELLS IN HUMAN WHOLE BLOOD TO INDICATE WHETHER THE LEVEL IS ABOVE OR BELOW 200 CELLS/L WITHIN PRE-DIAGNOSED HIV PATIENTS,ULTRA SENSITIVE TSH ELISA (PATHOZYME® ULTRASENSITIVE TSH)-PATHOZYME® ULTRASENSITIVE TSH IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM WITH A SENSITIVITY OF 0.05 UIU/ML ,FEBRILE ANTIGEN KIT(MICROPATH® BRUCELLA MELITENSIS)-MICROPATH® BRUCELLA MELITENSIS IS AN IN-VITRO DIAGNOSTIC KIT USED FOR DETECTION OF ANTIBODIES TO VARIOUS BACTERIAL PATHOGENS BY THE SLIDE OR TUBE AGGLUTINATION METHOD,ASO TEST(AVITEX® ASO)-AVITEX® ASO IS AN IN-VITRO DIAGNOSTIC KIT USED FOR DETECTION OF ANTI-STREPTOLYSIN-O (ASO) ANTIBODIES IN HUMAN SERUM.,FEBRILE ANTIGEN KIT (MICROPATH® BRUCELLA ABORTUS)-MICROPATH® BRUCELLA ABORTUS IS AN IN-VITRO DIAGNOSTIC KIT USED FOR DETECTION OF ANTIBODIES TO VARIOUS BACTERIAL PATHOGENS BY THE SLIDE OR TUBE AGGLUTINATION METHOD,CRP TEST(AVITEX® CRP)-AVITEX® CRP IS AN IN-VITRO DIAGNOSTIC KIT USED FOR DETECTION OF C-REACTIVE PROTEIN IN HUMAN SERUM.,TREPONEMA PALLIDUM HEMAGGLUTINATION TEST(IMMUTREP® TPHA)-IMMUTREP® TPHA IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE DETECTION OF ANTIBODIES TO TREPONEMA PALLIDUM IN SERUM OR CSF,AFP

		(ALPHAFETOPROTEIN) ELISA(PATHOZYME®AFP (ALPHAFETOPROTEIN) ELISA)-PATHOZYME®AFP (ALPHAFETOPROTEIN) ELISA IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF ALPHA-FETOPROTEIN (AFP) IN HUMAN SERUM,PROLACTIN ELISA(PATHOZYME® PROLACTIN)-PATHOZYME® PROLACTIN IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM. ,FEBRILE ANTIGEN KIT(MICROPATH® HD)-MICROPATH® SAL H-D IS AN IN-VITRO DIAGNOSTIC KIT USED FOR DETECTION OF ANTIBODIES TO VARIOUS BACTERIAL PATHOGENS BY THE SLIDE OR TUBE AGGLUTINATION METHOD,PROGESTERONE ELISA(PATHOZYME® PROGESTERONE)-PATHOZYME® PROGESTERONE IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE THE QUANTITATIVE DETERMINATION OF TOTAL PROGESTERONE IN HUMAN SERUM ,TOTAL T4 (THYROXINE) ELISA(PATHOZYME® T4)-PATHOZYME® T4 IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM. FOR PROFESSIONAL USE ONLY ,FREET3 (TRIIODOTHYRONINE) ELISA(PATHOZYME® FREE T3)-PATHOZYME® FREE T3 IS AN IN-VITRO DIAGNOSTIC KIT USED FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM,RPR REAGENT(IMMUTREP® RPR)-IMMUTREP® RPR IS IN-VITRO DIAGNOSTIC KIT USE FOR NON-TREPONEMAL FLOCCULATION TEST FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF REAGIN ANTIBODIES IN SERUM OR PLASMA.
38	IMP/IVD/2018/000006	1.License Holder Name: ARKRAY HEALTHCARE PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLUCOSE TEST STRIPS (TRUSTCHECK GLUCO)-THE USE OF TEST STRIPS IS TO MEASURE GLUCOSE (BETA-D-GLUCOSE) IN FRESH CAPILLARY WHOLE BLOOD FORM FINGERTIP.

39	IMP/IVD/2018/000007	1.License Holder Name: BIOMERIEUX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NUCLISENS EASYMAG EXTRACTION BUFFER 3(NUCLISENS)-ENABLE THE AUTOMATED EXTRACTION (PURIFICATION AND CONCENTRATION) OF TOTAL NUCLEIC ACIDS (RNA/DNA) FROM HOMOGENEOUS HUMAN BIOLOGICAL FLUID SAMPLES.,ARGENE(HHV6 R-GENE)-THE HHV6 R-GENE KIT USING THE REAL TIME PCR TECHNOLOGY AFTER EXTRATCTION OF THE VIRAL DNA, ENABLES TO DETECT AND/OR QUANTIFY THE GENOME OF HHV-6 IN WHOLE BLOOD, BLOOD PLASMA, CEREBROSPINAL FLUID AND BRONCHOALVEOLAR LIQUID SAMPLES,NUCLISENS EASYMAG EXTRACTION BUFFER 1(NUCLISENS)-ENABLE THE AUTOMATED EXTRACTION (PURIFICATION AND CONCENTRATION) OF TOTAL NUCLEIC ACIDS (RNA/DNA) FROM HOMOGENEOUS HUMAN BIOLOGICAL FLUID SAMPLES.,NUCLISENS EASYMAG EXTRACTION BUFFER 1(NUCLISENS)-ENABLE THE AUTOMATED EXTRACTION (PURIFICATION AND CONCENTRATION) OF TOTAL NUCLEIC ACIDS (RNA/DNA) FROM HOMOGENEOUS HUMAN BIOLOGICAL FLUID SAMPLES.,NUCLISENS EASYMAG EXTRACTION BUFFER 2(NUCLISENS)-ENABLE THE AUTOMATED EXTRACTION (PURIFICATION AND CONCENTRATION) OF TOTAL NUCLEIC ACIDS (RNA/DNA) FROM HOMOGENEOUS HUMAN BIOLOGICAL FLUID SAMPLES.,NUCLISENS EASY Q HIV-1 V2.0(NUCLISENS EASY Q HIV-1 V2.0)-NUCLISENS EASY Q HIV-1 V2.0 IS A NUCLEIC ACID AMPLIFICATION ASSAY FOR THE QUANTITATIVE DETERMINATION OF HIV-1 RNA IN HUMAN EDTA PLASMA AND EDTA WHOLE BLOOD., NUCLISENS EASYMAG LYSIS BUFFER(NUCLISENS)-ENABLE THE AUTOMATED EXTRACTION (PURIFICATION AND CONCENTRATION) OF TOTAL NUCLEIC ACIDS (RNA/DNA) FROM HOMOGENEOUS HUMAN BIOLOGICAL FLUID SAMPLES.,NUCLISENS LYSIS BUFFER(NUCLISENS) -INTENDED TO BE USED FOR THE RELEASE OF TOTAL NUCLEIC ACID FROM BIOLOGICAL SPECIMENS,NUCLISENS EASYMAG MAGNETIC SILICA(NUCLISENS)-ENABLE THE AUTOMATED EXTRACTION (PURIFICATION AND CONCENTRATION) OF TOTAL NUCLEIC ACIDS (RNA/DNA) FROM HOMOGENEOUS HUMAN BIOLOGICAL FLUID SAMPLES.,CMV R-GENE-REAL TIME DETECTION AND QUANTIFICATION KIT(CMV R-GENE-REAL TIME DETECTION AND QUANTIFICATION KIT)-THE CMV R-GENE KIT, USING THE REAL TIME PCR TECHNOLOGY AFTER EXTRACTION OF THE VIRAL DNA, ENABLES TO DETECT AND/OR MEASURE OF THE GENOME OF CMV IN WHOLE, BLOOD, PLASMA, SERUM, CSF, BAL, AMNIOTIC FLUID AND URINE SAMPLES,EBV R-GENE REAL TIME DETECTION AND QUANTIFICATION KIT(EBV R-GENE REAL TIME DETECTION AND QUANTIFICATION KIT)-THE EBV R-GENE KIT IS USED TO DETECT AND/OR MEASURE THE EBV

		VIRAL LOAD IN WHOLE BLOOD AND VARIOUS OTHER SAMPLES. THE VIRAL LOAD REPRESENTS THE NUMBER OF VIRIONS AND/OR THE NUMBER OF EBV-INFECTED B LYMPHOCYTES IN THE REPLICATION PHASE. THIS KIT CANNOT BE USED FOR SCREENING DONORS.,BK VIRUS R-GENE REAL TIME DETECTION AND QUANTIFICATION KIT(BK VIRUS R-GENE REAL TIME DETECTION AND QUANTIFICATION KIT)-BK VIRUS R-GENE DETECTS AND/OR QUANTIFIES THE VIRAL LOAD OF BK VIRUS IN WHOLE BLOOD, PLASMA AND URINE SAMPLES. THE VIRAL LOAD IS MEASURED USING A QUANTIFICATION STANDARD PROVIDED IN THE KIT. THE TECHNIQUE USED IS REAL-TIME PCR AFTER VIRAL DNA EXTRACTION.
40	IMP/IVD/2018/000010	1.License Holder Name: MINDRAY MEDICAL INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLUCOSE (GLU) KIT (GOD-POD METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF GLU CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS.,BC-3D(MINDRAY)-BC-3D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED & SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS. PLEASE REFER TO THE , GLUCOSE (GLU) KIT (HK METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF GLU CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS.,B-30 CONTROL(MINDRAY) -B30 CONTROL IS A HEMATOLOGY REFERENCE CONTROL USED TO MONITOR THE PERFORMANCE OF BC SERIES OF HEMATOLOGY ANALYZER. THE MEAN VALUES AND EXPECTED RANGE OF THE PARAMETER ARE DISPLAYED IN QUALITY CONTROL GRAPHS WITH UPPER AND LOWER CONTROL LIMITS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

41	IMP/IVD/2018/000011	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ATELLICA CH BENZODIAZEPINES (BNZ)(ATELLICA CH BENZODIAZEPINES (BNZ))-THE ATELLICA™ CH BENZODIAZEPINE (BNZ) ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 200 NG/ML OR 300 NG/ML CUTOFF. THE BNZ ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMIQUANTITATIVE ANALYSES OF BENZODIAZEPINES IN HUMAN URINE USING THE ATELLICA™ CH ANALYZER. THE BNZ ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/ MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ATELLICA CH AMPHETAMINES (AMP)(ATELLICA CH AMPHETAMINES (AMP))-THE ATELLICA™ CH AMPHETAMINES (AMP) ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 300 NG/ML, 500 NG/ML (SAMHSA INITIAL TEST CUTOFF LEVEL), OR 1000 NG/ML CUTOFF. THE AMP ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMIQUANTITATIVE ANALYSES OF AMPHETAMINES IN HUMAN URINE USING THE ATELLICA™ CH ANALYZER.THE AMP ASSAY PROVIDES ONLY A PRELIMINARY TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ADVIA® CHEMISTRY AMPHETAMINES_ 2 REAGENTS (ADVIA® CHEMISTRY AMPHETAMINES_ 2 REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF AMPHETAMINES IN HUMAN URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. THE ADVIA CHEMISTRY AMPHETAMINES_2 (AMPH_2) ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE ANALYTICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY

	METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED, ATELLICA CH LITHIUM_2 (LITH_2)(ATELLICA CH LITHIUM_2 (LITH_2))-THE ATELLICA® CH LITHIUM_2 (LITH_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LITHIUM IN HUMAN SERUM AND PLASMA (SODIUM HEPARIN OR POTASSIUM EDTA) USING THE ATELLICA® CH ANALYZER. SUCH MEASUREMENTS ARE USED AS AN AID IN THE MONITORING OF LITHIUM THERAPY.,ATELLICA CH AMMONIA (AMM) (ATELLICA CH AMMONIA (AMM))-THE ATELLICA™ CH AMMONIA (AMM) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA) USING THE ATELLICA™ CH ANALYZER. AMMONIA MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF SEVERE LIVER DISORDERS SUCH AS CIRRHOSIS, HEPATITIS, AND REYE'S SYNDROME,ADVIA CHEMISTRY LITHIUM_2 (LITH_2)(ADVIA CHEMISTRY LITHIUM_2 (LITH_2))-THE ADVIA® CHEMISTRY LITHIUM_2 (LITH_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LITHIUM IN HUMAN SERUM AND PLASMA (SODIUM HEPARIN OR POTASSIUM EDTA) USING THE ADVIA® CHEMISTRY SYSTEMS. SUCH MEASUREMENTS ARE USED AS AN AID IN THE MONITORING OF LITHIUM THERAPY.,ADVIA® CHEMISTRY DRUG CALIBRATOR I(ADVIA® CHEMISTRY DRUG CALIBRATOR I)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE ANALYSIS OF PHENOBARBITAL_2 (PHNB_2), PHENYTOIN_2 (PHYN_2), AND THEOPHYLLINE_2 (THEO_2) METHODS ON THE ADVIA CHEMISTRY SYSTEMS.,ATELLICA CH URINARY/CEREBROSPINAL FLUID PROTEIN CALIBRATOR (UCFP CAL) (ATELLICA CH URINARY/CEREBROSPINAL FLUID PROTEIN CALIBRATOR (UCFP CAL))-THE ATELLICA® CH URINARY/CEREBROSPINAL FLUID PROTEIN CALIBRATOR (UCFP CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE UCFP ASSAY USING THE ATELLICA® CH ANALYZER.,ATELLICA CH CANNABINOIDS THC (THC)(ATELLICA CH CANNABINOIDS THC (THC))-THE ATELLICA™ CH CANNABINOIDS THC (THC) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMIQUANTITATIVE DETERMINATION OF CANNABINOIDS IN HUMAN URINE USING THE ATELLICA™ CH ANALYZER. THE THC ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY

	METHOD. 1 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ADVIA® CHEMISTRY A1C_E PRETREATMENT SOLUTION (A1C_E PRE)(ADVIA® CHEMISTRY A1C_E PRETREATMENT SOLUTION (A1C_E PRE))-FOR USE WITH THE ADVIA® CHEMISTRY ENZYMATIC HEMOGLOBIN A1C (A1C_E) ASSAY.,ATELLICA CH CARBAMAZEPINE (CARB)(ATELLICA CH CARBAMAZEPINE (CARB))-THE ATELLICA™ CH CARBAMAZEPINE (CARB) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CARBAMAZEPINE, AN ANTI-CONVULSANT DRUG, IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. CARB TEST RESULTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF CARBAMAZEPINE OVERDOSE AND IN MONITORING LEVELS OF CARBAMAZEPINE TO ENSURE APPROPRIATE THERAPY,ADVIA® CHEMISTRY URINARY/CEREBROSPIN AL FLUID PROTEIN (UCFP)(ADVIA® CHEMISTRY URINARY/CEREBROSPIN AL FLUID PROTEIN (UCFP))-THE UCFP METHOD USED ON THE ADVIA® CHEMISTRY SYSTEM IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN URINE AND CEREBROSPINAL FLUID.,ATELLICA CH CARBON DIOXIDE, CONCENTRATED (CO2_C)(ATELLICA CH CARBON DIOXIDE, CONCENTRATED (CO2_C))-THE ATELLICA™ CH CARBON DIOXIDE, CONCENTRATED (CO2_C) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CARBON DIOXIDE IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF NUMEROUS POTENTIALLY SERIOUS DISORDERS ASSOCIATED WITH CHANGES IN BODY ACID- BASE BALANCE., ATELLICA CH ENZYMATIC HEMOGLOBIN A1C_E CALIBRATOR (A1C_E CAL)(ATELLICA CH ENZYMATIC HEMOGLOBIN A1C_E CALIBRATOR (A1C_E CAL))-THE ATELLICA® CH ENZYMATIC HEMOGLOBIN A1C CALIBRATOR (A1C_E CAL) IS FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF THE ATELLICA® CH ENZYMATIC HEMOGLOBIN A1C ASSAY ON THE ATELLICA® CH ANALYZER.,ATELLICA CH ENZYMATIC CREATININE_2 (ECRE_2)(ATELLICA CH ENZYMATIC CREATININE_2 (ECRE_2))-THE ATELLICA® CH ENZYMATIC CREATININE_2 (ECRE_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA), AND URINE USING THE ATELLICA® CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASES, AND IN MONITORING RENAL DIALYSIS,ATELLICA CH ENZYMATIC

	HEMOGLOBIN A1C (A1C_E)(ATELLICA CH ENZYMATIC HEMOGLOBIN A1C (A1C_E))-THE ATELLICA® CH ENZYMATIC HEMOGLOBIN A1C (A1C_E) ASSAY IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF MMOL/MOL HBA1C (IFCC) AND % HBA1C (DCCT/NGSP) IN HUMAN ANTICOAGULATED VENOUS WHOLE BLOOD AND HEMOLYSATE FOR USE ON THE ATELLICA® CH ANALYZER. MEASUREMENT OF HEMOGLOBIN A1C IS USED AS AN AID IN THE DIAGNOSIS AND MONITORING OF LONG-TERM BLOOD GLUCOSE CONTROL IN PATIENTS WITH DIABETES MELLITUS, AND AS AN AID IN THE IDENTIFICATION OF PATIENTS AT RISK FOR DEVELOPING DIABETES MELLITUS.,ATELLICA CH COCAINE METABOLITE (COC)(ATELLICA CH COCAINE METABOLITE (COC))-THE ATELLICA™ CH COCAINE METABOLITE (COC) ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 150 NG/ML (SAMHSA INITIAL TEST CUTOFF LEVEL) OR 300 NG/ML CUTOFF. THE COC ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMIQUANTITATIVE ANALYSES OF BENZOYLECGONINE (COCAINE METABOLITE) IN HUMAN URINE USING THE ATELLICA™ CH ANALYZER. THE COC ASSAY PROVIDESONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY /MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ADVIA® CHEMISTRY ENZYMATIC HEMOGLOBIN A1C (A1C_E) ASSAY(ADVIA® CHEMISTRY ENZYMATIC HEMOGLOBIN A1C (A1C_E) ASSAY)-THE ADVIA® CHEMISTRY ENZYMATIC HEMOGLOBIN A1C (A1C_E) ASSAY IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF MMOL/MOL HBA1C (IFCC) AND % HBA1C (DCCT/NGSP) IN HUMAN ANTICOAGULATED VENOUS WHOLE BLOOD AND HEMOLYSATE FOR USE ON THE ADVIA CHEMISTRY SYSTEMS. MEASUREMENT OF HEMOGLOBIN A1C IS USED AS AN AID IN THE DIAGNOSIS AND MONITORING OF LONG-TERM BLOOD GLUCOSE CONTROL IN PATIENTS WITH DIABETES MELLITUS, AND AS AN AID IN THE IDENTIFICATION OF PATIENTS AT RISK FOR DEVELOPING DIABETES MELLITUS.,ATELLICA CH DIRECT BILIRUBIN 2 (DBIL_2) (ATELLICA CH DIRECT BILIRUBIN 2 (DBIL_2))-THE ATELLICA™ CH DIRECT BILIRUBIN 2 (DBIL_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USEFUL IN

	THE SCREENING OF LIVER FUNCTION DISORDERS OR IN THE DIAGNOSIS OF JAUNDICE,ADVIA® CHEMISTRY ENZYMATIC HEMOGLOBIN A1C CALIBRATOR (A1C_E CAL)(ADVIA® CHEMISTRY ENZYMATIC HEMOGLOBIN A1C CALIBRATOR (A1C_E CAL))-THE ADVIA® CHEMISTRY ENZYMATIC HEMOGLOBIN A1C (A1C_E) CALIBRATOR IS FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF THE ADVIA CHEMISTRY ENZYMATIC HEMOGLOBIN A1C ASSAY ON THE ADVIA CHEMISTRY SYSTEMS.,ATELLICA CH ALBUMIN BCP (ALBP)(ATELLICA CH ALBUMIN BCP (ALBP))-THE ATELLICA™ CH ALBUMIN BCP (ALBP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF ALBUMIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA) USING THE ATELLICA™ CH ANALYZER. ALBUMIN MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF NUMEROUS DISEASES PRIMARILY INVOLVING THE LIVER OR KIDNEYS,ATELLICA CH URINARY/CEREBROSPINAL FLUID PROTEIN (UCFP)(ATELLICA CH URINARY/CEREBROSPINAL FLUID PROTEIN (UCFP))-THE ATELLICA® CH URINARY/CEREBROSPINAL FLUID PROTEIN (UCFP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN URINE AND CEREBROSPINAL FLUID USING THE ATELLICA CH ANALYZER.,ATELLICA CH BARBITURATES (BRB)(ATELLICA CH BARBITURATES (BRB))-THE ATELLICA™ CH BARBITURATES (BRB) ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 200 NG/ML OR 300 NG/ML CUTOFF. THE BRB ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMIQUANTITATIVE ANALYSES OF BARBITURATES IN HUMAN URINE USING THE ATELLICA™ CH ANALYZER. THE BRB ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/ MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ADVIA® CHEMISTRY URINARY/CEREBROSPIN AL FLUID PROTEIN CALIBRATOR (UCFP CAL)(ADVIA® CHEMISTRY URINARY/CEREBROSPIN AL FLUID PROTEIN CALIBRATOR (UCFP CAL))-THE URINARY/CEREBROSPINAL FLUID PROTEIN CALIBRATOR IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE URINARY/CEREBROSPINAL FLUID PROTEIN (UCFP) METHOD ON THE ADVIA® CHEMISTRY SYSTEM.,ATELLICA CH OPIATES (OP)(ATELLICA CH OPIATES (OP))-THE ATELLICA™ CH OPIATES (OP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMIQUANTITATIVE

	ANALYSES OF OPIATES IN HUMAN URINE USING THE ATELLICA™ CH ANALYZER.1 THE OP ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.2 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ATELLICA CH A1C_3 CALIBRATOR (A1C_3 CAL)(ATELLICA CH A1C_3 CALIBRATOR (A1C_3 CAL))-THE ATELLICA™ CH A1C_3 CALIBRATOR (A1C_3 CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE A1C_3 ASSAY USING THE ATELLICA™ CH ANALYZER.,ATELLICA CH PHENYTOIN (PHNY)(ATELLICA CH PHENYTOIN (PHNY))-THE ATELLICA™ CH PHENYTOIN (PHNY) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF PHENYTOIN (DILANTIN, DIPHENYLHYDANTOIN), AN ANTI-EPILEPTIC DRUG, IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. PHNY TEST RESULTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PHENYTOIN OVERDOSE AND IN MONITORING LEVELS OF PHENYTOIN TO ENSURE APPROPRIATE THERAPY.,ATELLICA CH TOBRAMYCIN (TOB)(ATELLICA CH TOBRAMYCIN (TOB))-THE ATELLICA™ CH TOBRAMYCIN (TOB) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF TOBRAMYCIN, AN AMINOGLYCOSIDE ANTIBIOTIC, IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. TOB TEST RESULTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF TOBRAMYCIN OVERDOSE AND IN MONITORING LEVELS OF TOBRAMYCIN TO ENSURE APPROPRIATE THERAPY. ,ATELLICA CH PROPOXYPHENE (PPX)(ATELLICA CH PROPOXYPHENE (PPX))-THE ATELLICA™ CH PROPOXYPHENE (PPX) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMIQUANTITATIVE ANALYSES OF PROPOXYPHENE IN HUMAN URINE USING THE ATELLICA™ CH ANALYZER. THE PPX ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/ MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.1 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS

	ARE USED.,ATELLICA CH ALKALINE PHOSPHATASE_2 CALIBRATOR (ALP_2 CAL)(ATELLICA CH ALKALINE PHOSPHATASE_2 CALIBRATOR (ALP_2 CAL))-THE ATELLICA™ CH ALKALINE PHOSPHATASE_2 CALIBRATOR (ALP_2 CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ALP_2C ASSAY USING THE ATELLICA™ CH ANALYZER.,ATELLICA CH DIGOXIN (DGN)(ATELLICA CH DIGOXIN (DGN))-THE ATELLICA™ CH DIGOXIN (DGN) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF DIGOXIN, A CARDIOVASCULAR DRUG, IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF DIGOXIN OVERDOSE AND IN MONITORING LEVELS OF DIGOXIN TO ENSURE APPROPRIATE THERAPY.,ATELLICA CH CHEM III CALIBRATOR (CHEM III CAL)(ATELLICA CH CHEM III CALIBRATOR (CHEM III CAL))-THE ATELLICA® CH CHEM III CALIBRATOR (CHEM III CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE AMM ASSAY USING THE ATELLICA® CH ANALYZER.,ATELLICA CH PHENCYCLIDINE (PCP)(ATELLICA CH PHENCYCLIDINE (PCP))-THE ATELLICA™ CH PHENCYCLIDINE (PCP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMIQUANTITATIVE ANALYSES OF PHENCYCLIDINE IN HUMAN URINE USING THE ATELLICA™ CH ANALYZER, USING A CUTOFF OF 25 NG/ML. THE PCP ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. THE SEMI-QUANTITATIVE MODE IS FOR PURPOSES OF ENABLING LABORATORIES TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC-MS) OR LIQUID CHROMATOGRAPHY/TANDEM MASS SPECTROMETRY (LC-MS/MS) OR PERMITTING LABORATORIES TO ESTABLISH QUALITY CONTROL PROCEDURES. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ATELLICA CH PHENOBARBITAL (PHNB)(ATELLICA CH PHENOBARBITAL (PHNB))-THE ATELLICA™ CH PHENOBARTIBAL (PHNB) ASSAY IS FOR IN VITRO DIAGNOSTIC USE FOR THE QUANTITATIVE MEASUREMENT OF PHENOBARBITAL, AN ANTI-EPILEPTIC DRUG AND SEDATIVE-HYPNOTIC DRUG, IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) ON THE ATELLICA™ CH ANALYZER. PHNB TEST RESULTS ARE USED IN MONITORING LEVELS OF PHENOBARBITAL TO ENSURE APPROPRIATE THERAPY AND IN THE

	DIAGNOSIS AND TREATMENT OF PHENOBARBITAL OVERDOSE., ATELLICA CH THEOPHYLLINE (THEO)(ATELLICA CH THEOPHYLLINE (THEO))-THE ATELLICA® CH THEOPHYLLINE (THEO) ASSAY IS FOR IN VITRO DIAGNOSTIC USE FOR THE QUANTITATIVE DETERMINATION OF THEOPHYLLINE IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) ON THE ATELLICA® CH ANALYZER.,ATELLICA CH ENZ 3 CALIBRATOR (ENZ 3 CAL)(ATELLICA CH ENZ 3 CALIBRATOR (ENZ 3 CAL))-THE ATELLICA® CH ENZ 3 CALIBRATOR (ENZ 3 CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE CK_L ASSAY USING THE ATELLICA® CH ANALYZER.,ATELLICA CH ECSTASY (XTC)(ATELLICA CH ECSTASY (XTC))-THE ATELLICA™ CH ECSTASY (XTC) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMIQUANTITATIVE ANALYSES OF METHYLENEDIOXYMETHAMPHETAMINE (MDMA) AND CLOSELY RELATED DRUGS IN HUMAN URINE USING THE ATELLICA™ CH ANALYZER. THE XTC ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.1 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED,ATELLICA CH METHADONE (MDN)(ATELLICA CH METHADONE (MDN))-THE ATELLICA™ CH METHADONE (MDN) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMIQUANTITATIVE DETERMINATION OF METHADONE IN HUMAN URINE USING THE ATELLICA™ CH ANALYZER. THE MDN ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ATELLICA CH ACETAMINOPHEN (ACET)(ATELLICA CH ACETAMINOPHEN (ACET))-THE ATELLICA™ CH ACETAMINOPHEN (ACET) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ACETAMINOPHEN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DETECTION OF ACUTE

	OVERDOSE.,ATELLICA CH LITHIUM (LI)(ATELLICA CH LITHIUM (LI))-THE ATELLICA™ CH LITHIUM (LI) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LITHIUM IN HUMAN SERUM AND PLASMA (SODIUM HEPARIN OR EDTA) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED AS AN AID IN THE MONITORING OF LITHIUM THERAPY.,ATELLICA CH ENZ 1 CALIBRATOR (ENZ 1 CAL)(ATELLICA CH ENZ 1 CALIBRATOR (ENZ 1 CAL))-THE ATELLICA® CH ENZ 1 CALIBRATOR (ENZ 1 CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE CHE, GGT, LDLP, AND LIP ASSAYS USING THE ATELLICA® CH ANALYZER.,ATELLICA CH ENZ 2 CALIBRATOR (ENZ 2 CAL)(ATELLICA CH ENZ 2 CALIBRATOR (ENZ 2 CAL))-THE ATELLICA® CH ENZ 2 CALIBRATOR (ENZ 2 CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ALT, ALTPLC, AST, AND ASTPLC ASSAYS USING THE ATELLICA® CH ANALYZER.,ADVIA® CHEMISTRY CARBAMAZEPINE_2 (CARB_2) REAGENTS(ADVIA® CHEMISTRY CARBAMAZEPINE_2 (CARB_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE ANALYSIS OF CARBAMAZEPINE IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS,ATELLICA CH A-LYTE® INTEGRATED MULTISENSOR (IMT NA K CL)(ATELLICA CH A-LYTE® INTEGRATED MULTISENSOR (IMT NA K CL))-THE A-LYTE® INTEGRATED MULTISENSOR (IMT NA K CL) IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM AND CHLORIDE (NA, K, CL) IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN) AND URINE USING THE ATELLICA® CH ANALYZER. MEASUREMENTS OF SODIUM OBTAINED BY THIS DEVICE ARE USED IN THE DIAGNOSIS AND TREATMENT OF ALDOSTERONISM (EXCESSIVE SECRETION OF THE HORMONE ALDOSTERONE), DIABETES INSIPIDUS (CHRONIC EXCRETION OF LARGE AMOUNTS OF DILUTE URINE, ACCOMPANIED BY EXTREME THIRST), ADRENAL HYPERTENSION, ADDISON'S DISEASE (CAUSED BY DESTRUCTION OF THE ADRENAL GLANDS), DEHYDRATION, INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION, OR OTHER DISEASES INVOLVING ELECTROLYTE IMBALANCE. MEASUREMENTS OF POTASSIUM OBTAINED BY THIS DEVICE ARE USED TO MONITOR ELECTROLYTE BALANCE IN THE DIAGNOSIS AND TREATMENT OF DISEASE CONDITIONS CHARACTERIZED BY LOW OR HIGH BLOOD POTASSIUM LEVELS. CHLORIDE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF ELECTROLYTE AND METABOLIC DISORDERS SUCH AS CYSTIC FIBROSIS AND DIABETIC ACIDOSIS.,ATELLICA CH DRUG CAL (DRUG CAL)(ATELLICA CH DRUG CAL (DRUG CAL))-THE ATELLICA® CH DRUG CAL (DRUG CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE PHNB, PHNY AND THEO ASSAYS USING THE ATELLICA® CH ANALYZER.,ATELLICA CH VALPROIC ACID (VPA)

	(ATELLICA CH VALPROIC ACID (VPA))-THE ATELLICA™ CH VALPROIC ACID (VPA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE FOR THE QUANTITATIVE MEASUREMENT OF VALPROIC ACID IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. VPA TEST RESULTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF VALPROIC ACID OVERDOSE AND IN MONITORING LEVELS OF VALPROIC ACID TO ENSURE APPROPRIATE THERAPY.,ATELLICA CH VANCOMYCIN (VANC)(ATELLICA CH VANCOMYCIN (VANC))-THE ATELLICA™ CH VANCOMYCIN (VANC) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF VANCOMYCIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. VANC TEST RESULTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF VANCOMYCIN OVERDOSE AND IN MONITORING LEVELS OF VANCOMYCIN TO ENSURE APPROPRIATE THERAPY.,ATELLICA CH A-LYTE® IMT STANDARD B + SALT BRIDGE (IMT STANDARD B + SALT BRIDGE)(ATELLICA CH A-LYTE® IMT STANDARD B + SALT BRIDGE (IMT STANDARD B + SALT BRIDGE))-THE ALYTE™ IMT STANDARD B + SALT BRIDGE IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING NA, K, AND CL ASSAYS USING THE ATELLICA™ CH ANALYZER.,ATELLICA CH A-LYTE® IMT DILUENT (IMT DILUENT)(ATELLICA CH A-LYTE® IMT DILUENT (IMT DILUENT))-THE ALYTE™ IMT DILUENT IS FOR IN VITRO DIAGNOSTIC USE IN DILUTING IMT SAMPLES USING THE ATELLICA™ CH ANALYZER.,ATELLICA CH A-LYTE® IMT STANDARD A (IMT STANDARD A)(ATELLICA CH A-LYTE® IMT STANDARD A (IMT STANDARD A))-THE ALYTE™ IMT STANDARD A IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING NA, K, AND CL ASSAYS USING THE ATELLICA™ CH ANALYZER.,ATELLICA CH SALICYLATE (SAL)(ATELLICA CH SALICYLATE (SAL))-THE ATELLICA™ CH SALICYLATE (SAL) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF SALICYLATE IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS OF SALICYLATE TOXICITY AND OVERDOSE.,ADVIA® CHEMISTRY ENZYME 2 CALIBRATOR (ENZ 2 CAL)(ADVIA® CHEMISTRY ENZYME 2 CALIBRATOR (ENZ 2 CAL))-ADVIA® CHEMISTRY ENZYME 2 CALIBRATOR IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ALANINE AMINOTRANSFERASE (ALT); ALANINE AMINOTRANSFERASE, CONCENTRATED REAGENTS (ALT_C); ALANINE AMINOTRANSFERASE (P5P) (ALTP5P); ALANINE AMINOTRANSFERASE (P5P), CONCENTRATED REAGENTS (ALTP_C); ASPARTATE AMINOTRANSFERASE (AST); ASPARTATE AMINOTRANSFERASE, CONCENTRATED REAGENTS (AST_C); ASPARTATE AMINOTRANSFERASE (P5P) (ASTP5P); AND ASPARTATE

	AMINOTRANSFERASE (P5P), CONCENTRATED REAGENTS (ASTP_C) ASSAYS ON THE ADVIA CHEMISTRY SYSTEMS,ADVIA® CHEMISTRY ENZYME 3 CALIBRATOR (ADVIA® CHEMISTRY ENZYME 3 CALIBRATOR)-ADVIA® CHEMISTRY ENZYME 3 CALIBRATOR IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF THE ADVIA CHEMISTRY CREATINE KINASE (CK_L) ASSAY ON THE ADVIA CHEMISTRY SYSTEMS.,ADVIA® CHEMISTRY PROPOXYPHENE_2 (PPX_2) REAGENTS(ADVIA® CHEMISTRY PROPOXYPHENE_2 (PPX_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMIQUANTITATIVE ANALYSIS OF PROPOXYPHENE IN HUMAN URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. THE ADVIA CHEMISTRY PROPOXYPHENE_2 (PPX_2) ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED,ATELLICA CH TOTAL BILIRUBIN_2 (TBIL_2)(ATELLICA CH TOTAL BILIRUBIN_2 (TBIL_2))-THE ATELLICA™ CH TOTAL BILIRUBIN_2 (TBIL_2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF HEMOLYTIC, BILIARY, AND LIVER DISORDERS, INCLUDING HEPATITIS AND CIRRHOSIS,ADVIA® CHEMISTRY VALPROIC ACID_2 (VPA_2) REAGENTS(ADVIA® CHEMISTRY VALPROIC ACID_2 (VPA_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE ANALYSIS OF VALPROIC ACID IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS, ATELLICA® IM ACID / BASE(ATELLICA® IM ACID / BASE)-THE ATELLICA® IM ACID / BASE IS FOR IN VITRO DIAGNOSTIC USE WITH THE ATELLICA™ IM ANALYZER. ATELLICA® IM ACID / BASE IS A SYSTEM FLUID USED TO INITIATE THE CHEMILUMINESCENT REACTION. IT IS USED WITH ALL ATELLICA IM ASSAYS.,ATELLICA® IM CLEANER(ATELLICA® IM CLEANER)-THE ATELLICA® IM CLEANER IS FOR IN VITRO DIAGNOSTIC USE WITH THE ATELLICA™ IM ANALYZER. WHEN DILUTED, ATELLICA® IM CLEANER IS A SYSTEM FLUID USED TO PERFORM AUTOMATED CLEANING ACTIVITIES.,ADVIA® CHEMISTRY GENTAMICIN_2 (GENT_2) REAGENTS(ADVIA® CHEMISTRY GENTAMICIN_2 (GENT_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE

	IN THE QUANTITATIVE ANALYSIS OF GENTAMICIN IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS,ADVIA® CHEMISTRY BENZODIAZEPINE _2 REAGENTS(ADVIA® CHEMISTRY BENZODIAZEPINE _2 REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF BENZODIAZEPINES IN HUMAN URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. THE ADVIA CHEMISTRY BENZODIAZEPINE_2 (BENZ_2) ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ADVIA® CHEMISTRY COCAINE METABOLITE_2 (COCA_2) REAGENTS(ADVIA® CHEMISTRY COCAINE METABOLITE_2 (COCA_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF BENZOYLECGONINE (COCAINE METABOLITE) IN HUMAN URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. THE ADVIA CHEMISTRY COCAINE METABOLITE_2 (COCA_2) ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED,ATELLICA CH HEMOGLOBIN A1C_3 (A1C_3)(ATELLICA CH HEMOGLOBIN A1C_3 (A1C_3))-THE ATELLICA™ CH HEMOGLOBIN A1C_3 (A1C_3) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C, A DIABETES MARKER, IN HUMAN WHOLE BLOOD USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED FOR MONITORING THE LONG-TERM CARE OF PERSONS WITH DIABETES. THE HBA1C AND TOTAL HEMOGLOBIN (THB) VALUES GENERATED AS PART OF THE ATELLICA™ CH ANALYZER PERCENT (%) A1C_3 ASSAY ARE INTENDED FOR USE IN THE CALCULATION OF THE HBA1C/TOTAL HEMOGLOBIN RATIO, AND MUST NOT BE USED INDIVIDUALLY FOR DIAGNOSTIC PURPOSES., ATELLICA® CH OXYCODONE (OXY)(ATELLICA® CH OXYCODONE (OXY))-THE ATELLICA® CH OXYCODONE (OXY) ASSAY IS A

	HOMOGENOUS ENZYME IMMUNOASSAY WITH 100 NG/ML AND 300 NG/ML CUTOFFS. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF OXYCODONE IN HUMAN URINE USING THE ATELLICA® CH ANALYZER. THE SEMIQUANTITATIVE MODE IS FOR THE PURPOSES OF ENABLING LABORATORIES TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS LIQUID CHROMATOGRAPHY/MASS SPECTROMETRY (LC/MS) OR PERMITTING LABORATORIES TO ESTABLISH QUALITY CONTROL PROCEDURES. THE ATELLICA® CH OXYCODONE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD(S) MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL TEST RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) AND LC/MS ARE THE PREFERRED CONFIRMATORY METHODS.1,2 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ADVIA® CHEMISTRY BARBITURATE_2 REAGENTS(ADVIA® CHEMISTRY BARBITURATE_2 REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF BARBITURATES IN HUMAN URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. THE ADVIA CHEMISTRY BARBITURATE_2 (BARB_2) ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ADVIA® CHEMISTRY CANNABINOID_2 REAGENTS(ADVIA® CHEMISTRY CANNABINOID_2 REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF CANNABINOIDS IN HUMAN URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. THE ADVIA CHEMISTRY CANNABINOID_2 (THC_2) ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. 1 GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. 2 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL

	CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ADVIA® CHEMISTRY PHENCYCLIDINE_2 (PCP_2) REAGENTS(ADVIA® CHEMISTRY PHENCYCLIDINE_2 (PCP_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF PHENCYCLIDINE (PCP) IN HUMAN URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. THE ADVIA CHEMISTRY PHENCYCLIDINE_2 (PCP_2) ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ADVIA CHEMISTRY HEMOGLOBIN A1C_3 REAGENTS(ADVIA CHEMISTRY HEMOGLOBIN A1C_3 REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C, A DIABETES MARKER, IN WHOLE BLOOD ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED FOR MONITORING THE LONG-TERM CARE OF PERSONS WITH DIABETES. THE A1C_3 AND TOTAL HEMOGLOBIN (THB_3) VALUES GENERATED AS PART OF THE ADVIA CHEMISTRY HBA1C% AND HBA1CR ASSAYS ARE INTENDED FOR USE IN THE CALCULATION OF THE HBA1C/TOTAL HEMOGLOBIN RATIO, AND MUST NOT BE USED INDIVIDUALLY FOR DIAGNOSTIC PURPOSES. ,ADVIA® CHEMISTRY ECSTASY (XTC) REAGENTS(ADVIA® CHEMISTRY ECSTASY (XTC) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF METHYLENEDIOXYMETHAMPHETAMINE (MDMA) AND CLOSELY RELATED DRUGS IN HUMAN URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. THE ADVIA CHEMISTRY ECSTASY (XTC) ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. 1 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ATELLICA® IM WASH(ATELLICA® IM WASH)-THE ATELLICA® IM WASH IS FOR IN VITRO DIAGNOSTIC USE WITH THE

	ATELLICA™ IM ANALYZER. ATELLICA® IM WASH IS USED TO RINSE CUVETTES DURING REACTION STEPS.,ADVIA® CHEMISTRY TOBRAMYCIN_2 (TOB_2) REAGENTS(ADVIA® CHEMISTRY TOBRAMYCIN_2 (TOB_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE ANALYSIS OF TOBRAMYCIN IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS,ATELLICA CH ALBUMIN BCP CALIBRATOR (ALBP CAL)(ATELLICA CH ALBUMIN BCP CALIBRATOR (ALBP CAL))-THE ATELLICA ® CH ALBUMIN BCP CALIBRATOR (ALBP CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA CH ALBP ASSAY USING THE ATELLICA ® CH ANALYZER.,ATELLICA® CH NACETYLPROCAINAMIDE (NAPA) (ATELLICA® CH NACETYLPROCAINAMIDE (NAPA))-THE ATELLICA® CH NACETYLPROCAINAMIDE (NAPA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE FOR THE QUANTITATIVE DETERMINATION OF NACETYLPROCAINAMIDE IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN, SODIUM HEPARIN, POTASSIUM EDTA) ON THE ATELLICA® CH ANALYZER. NACETYLPROCAINAMIDE MEASUREMENTS MAY BE USED IN THERAPEUTIC DRUG MONITORING TO MAINTAIN ADEQUATE PROCAINAMIDE THERAPY.,ADVIA® CHEMISTRY METHADONE_2 (MDN_2) REAGENTS(ADVIA® CHEMISTRY METHADONE_2 (MDN_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF METHADONE IN HUMAN URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. THE ADVIA CHEMISTRY METHADONE_2 (MDN_2) ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED,ATELLICA CH TOTAL IRON BINDING CAPACITY (TIBC) (ATELLICA CH TOTAL IRON BINDING CAPACITY (TIBC))-THE ATELLICA™ CH TOTAL IRON BINDING CAPACITY (TIBC) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF TOTAL IRON BINDING CAPACITY IN HUMAN SERUM ON THE ATELLICA™ CH ANALYZER. MEASUREMENT OF TOTAL IRON BINDING CAPACITY IS USED IN THE DIAGNOSIS AND TREATMENT OF ANEMIA, ADVIA® CHEMISTRY THEOPHYLLINE_2 (THEO_2) REAGENTS(ADVIA® CHEMISTRY THEOPHYLLINE_2 (THEO_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE THE QUANTITATIVE ANALYSIS OF THEOPHYLLINE IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS.,ATELLICA CH ETHYL ALCOHOL (ETOH)

	(ATELLICA CH ETHYL ALCOHOL (ETOH))-THE ATELLICA™ CH ETHYL ALCOHOL (ETOH) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ETHYL ALCOHOL (ETHANOL) IN HUMAN URINE, SERUM, AND PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA, SODIUM FLUORIDE/POTASSIUM OXALATE) USING THE ATELLICA™ CH ANALYZER. ETHYL ALCOHOL TEST RESULTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF ALCOHOL INTOXICATION AND POISONING,ADVIA® CHEMISTRY OPIATE_2 (OP_2) REAGENTS(ADVIA® CHEMISTRY OPIATE_2 (OP_2) REAGENTS) -FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF OPIATES IN HUMAN URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. THE ADVIA CHEMISTRY OPIATE_2 (OP_2) ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. 1 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ATELLICA® CH PROCAINAMIDE (PROC)(ATELLICA® CH PROCAINAMIDE (PROC))-THE ATELLICA® CH PROCAINAMIDE (PROC) ASSAY IS FOR IN VITRO DIAGNOSTIC USE FOR THE QUANTITATIVE DETERMINATION OF PROCAINAMIDE IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN, SODIUM HEPARIN, POTASSIUM EDTA) ON THE ATELLICA® CH ANALYZER. PROCAINAMIDE MEASUREMENTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF PROCAINAMIDE OVERDOSE, AND IN THERAPEUTIC DRUG MONITORING.,ADVIA® CHEMISTRY PHENOBARBITAL_2 (PHNB_2) REAGENTS(ADVIA® CHEMISTRY PHENOBARBITAL_2 (PHNB_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE ANALYSIS OF PHENOBARBITAL IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS,ADVIA CHEMISTRY A1C_3 CALIBRATOR(ADVIA CHEMISTRY A1C_3 CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF A1C_3 (A1C_3 AND A1C_3M) AND TOTAL HEMOGLOBIN_3 (THB_3 AND THB_3M) METHODS ON ADVIA® CHEMISTRY SYSTEMS, ATELLICA® CH LIDOCAINE (LIDO)(ATELLICA® CH LIDOCAINE (LIDO))-THE ATELLICA® CH LIDOCAINE (LIDO) ASSAY IS FOR IN VITRO DIAGNOSTIC USE FOR THE QUANTITATIVE DETERMINATION OF LIDOCAINE IN HUMAN SERUM OR PLASMA (SODIUM HEPARIN, POTASSIUM EDTA) ON THE ATELLICA® CH ANALYZER. LIDOCAINE MEASUREMENTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF LIDOCAINE OVERDOSE, AND IN THERAPEUTIC DRUG

	MONITORING.,ADVIA® CHEMISTRY ALBUMIN BCP REAGENT(ADVIA® CHEMISTRY ALBUMIN BCP REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF ALBUMIN IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. ALBUMIN MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF NUMEROUS DISEASES PRIMARILY INVOLVING THE LIVER OR KIDNEYS ,ATELLICA CH METHADONE METABOLITE (EDDP) (METMTB)(ATELLICA CH METHADONE METABOLITE (EDDP) (METMTB))-THE ATELLICA™ CH METHADONE METABOLITE (EDDP) (METMTB) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF METHADONE METABOLITE IN HUMAN URINE USING THE ATELLICA™ CH ANALYZER. THE METMTB ASSAY PROVIDES ONLY A PRELIMINARY TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/ MASS SPECTROSCOPY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED,ADVIA CHEMISTRY ENZYME 1 CALIBRATOR (ADVIA CHEMISTRY ENZYME 1 CALIBRATOR)-ADVIA® CHEMISTRY ENZYME 1 CALIBRATOR IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF GAMMA-GLUTAMYL TRANSFERASE (GGT), LACTATE DEHYDROGENASE P-L (LDPL), LACTATE DEHYDROGENASE L-P (LDLP), CHOLINESTERASE (CHE), AND LIPASE (LIP) ASSAYS ON THE ADVIA CHEMISTRY SYSTEMS. , ADVIA CHEMISTRY ALKALINE PHOSPHATASE_2 (ALP_2) CALIBRATOR(ADVIA CHEMISTRY ALKALINE PHOSPHATASE_2 (ALP_2) CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA® CHEMISTRY SYSTEMS FOR THE ADVIA CHEMISTRY ALKALINE PHOSPHATASE_2 CONCENTRATED (ALP_2C) ASSAY ,ADVIA® CHEMISTRY ETHANOL_2 (ETOH_2) REAGENTS (ADVIA® CHEMISTRY ETHANOL_2 (ETOH_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE ANALYSIS OF ETHYL ALCOHOL (ETHANOL) IN HUMAN URINE, SERUM, OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS.,ATELLICA CH GENTAMICIN (GENT)(ATELLICA CH GENTAMICIN (GENT))-THE ATELLICA™ CH GENTAMICIN (GENT) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF GENTAMICIN, AN AMINOGLYCOSIDE ANTIBIOTIC, IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ CH ANALYZER. GENT TEST RESULTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF GENTAMICIN OVERDOSE AND IN MONITORING LEVELS OF GENTAMICIN TO ENSURE APPROPRIATE THERAPY,ADVIA® CHEMISTRY ALBUMIN BCP CALIBRATOR(ADVIA® CHEMISTRY

	ALBUMIN BCP CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF THE ADVIA® CHEMISTRY ALBUMIN BCP (ALBP) ASSAY ON ADVIA CHEMISTRY SYSTEMS. ,ADVIA® CHEMISTRY VANCOMYCIN_2 (VANC_2) REAGENTS(ADVIA® CHEMISTRY VANCOMYCIN_2 (VANC_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE ANALYSIS OF VANCOMYCIN IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS, ATELLICA® CH TACROLIMUS (TACR)(ATELLICA® CH TACROLIMUS (TACR))-THE ATELLICA® CH TACROLIMUS (TACR) ASSAY IS FOR IN VITRO DIAGNOSTIC USE FOR THE QUANTITATIVE ANALYSIS OF TACROLIMUS AND METABOLITE IN HUMAN WHOLE BLOOD USING THE ATELLICA® CH ANALYZER AS AN AID IN THE MANAGEMENT OF TACROLIMUS THERAPY IN LIVER AND KIDNEY TRANSPLANT PATIENTS.,ATELLICA CH TOTAL PROTEIN_2 (URINE) (UPRO) (ATELLICA CH TOTAL PROTEIN_2 (URINE) (UPRO))-THE ATELLICA™ CH TOTAL PROTEIN_2 (URINE) (UPRO) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN URINE AND CEREBROSPINAL FLUID (CSF) USING THE ATELLICA™ CH ANALYZER. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PROTEINURIA, AS WELL AS CONDITIONS LEADING TO THE BREAKDOWN OF THE BLOOD-CENTRAL NERVOUS SYSTEM BARRIER,ADVIA® CHEMISTRY PHENYTOIN_2 (PHNY_2) REAGENTS(ADVIA® CHEMISTRY PHENYTOIN_2 (PHNY_2) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE ANALYSIS OF PHENYTOIN IN HUMAN SERUM OR PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS.,ATELLICA® CH MYCOPHENOLIC ACID (MPA)(ATELLICA® CH MYCOPHENOLIC ACID (MPA))-THE ATELLICA® CH MYCOPHENOLIC ACID (MPA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE ANALYSIS OF MYCOPHENOLIC ACID IN HUMAN PLASMA (LITHIUM HEPARIN, POTASSIUM EDTA) AS AN AID IN THE MANAGEMENT OF MYCOPHENOLATE MOFETIL THERAPY IN TRANSPLANT PATIENTS USING THE ATELLICA® CH ANALYZER.

42	IMP/IVD/2018/000015	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTICOLOR ANTIBODIES REAGENTS(1. BD MULTITEST 6-COLOR TBNK REAGENT ; 2. BD MULTITEST 6-COLOR TBNK REAGENT WITH BD TRUCOUNT TUBES)-BD MULTITEST™ 6-COLOR TBNK REAGENT WITH OR WITHOUT TRUCOUNT TUBE IS INTENDED FOR USE WITH BD FACSLYRIC™, BD FACSCANTO™ II, AND BD FACSCANTO™ FLOW CYTOMETERS TO DETERMINE THE PERCENTAGES AND ABSOLUTE COUNTS OF THE FOLLOWING MATURE HUMAN LYMPHOCYTE SUBSETS IN PERIPHERAL WHOLE BLOOD FOR IMMUNOPHENOTYPING: • T LYMPHOCYTES (CD3+) • B LYMPHOCYTES (CD19+) • NATURAL KILLER (NK) LYMPHOCYTES (CD3–CD16+ AND/OR CD56+) •HELPER/INDUCER T LYMPHOCYTES (CD3+CD4+) •SUPPRESSOR/CYTOTOXIC T LYMPHOCYTES (CD3+CD8+),HUMAN LEUKOCYTE ANTIGEN (HLA) TYPING IVDS(BD™ HLA-B27 KIT)-THE BD™ HLA-B27 SYSTEM IS A QUALITATIVE TWO-COLOR DIRECT IMMUNOFLUORESCENCE METHOD FOR THE RAPID DETECTION OF HLA-B27 ANTIGEN EXPRESSION IN ERYTHROCYTE-LYSED WHOLE BLOOD (LWB) USING THE BD FACSCANTO FAMILY OF FLOW CYTOMETERS, OR THE BD FACSCALIBUR, BD FACSORT, OR BD FACSCAN FLOW CYTOMETER.,MULTICOLOR ANTIBODIES REAGENT (BD TRITEST CD3/CD16+CD56/CD45)-BD TRITEST CD3/CD16+CD56/CD45 (CAT#340300) IS A THREE-COLOR DIRECT IMMUNOFLUORESCENCE REAGENT FOR USE WITH A SUITABLY EQUIPPED FLOW CYTOMETER TO IDENTIFY AND DETERMINE THE PERCENTAGES AND ABSOLUTE COUNTS OF MATURE HUMAN T LYMPHOCYTES (CD3+) AND NATURAL KILLER (NK) (CD3–CD16+CD56+) LYMPHOCYTE SUBSETS IN ERYTHROCYTE-LYSED WHOLE BLOOD. WHEN USED WITH TRUCOUNT™ TUBES, ABSOLUTE COUNTS OF THESE POPULATIONS CAN BE ENUMERATED FROM A SINGLE TUBE. BD TRITEST REAGENT AND TRUCOUNT TUBES CAN BE USED WITH THE FACS LOADER. REAGENT CAN BE USED WITH OR WITHOUT AN ISOTYPE CONTROL.,REAGENT FOR INSTRUMENT/ANALYSER IVD'S(BD FACSPRESTO CARTRIDGE KIT)-FOR USE ONLY WITH THE BD FACSPRESTO™ NEAR-PATIENT CD4 COUNTER. THE BD FACSPRESTO NEAR-PATIENT CD4 COUNTER IS AN AUTOMATED SYSTEM FOR IN VITRO DIAGNOSTIC USE IN PERFORMING THE DIRECT ENUMERATION OF CD4 ABSOLUTE COUNT, CD4 PERCENTAGE OF LYMPHOCYTES, AND HEMOGLOBIN CONCENTRATION IN HUMAN WHOLE BLOOD,MULTICOLOR ANTIBODIES REAGENTS(BD TRITEST CD4/CD8/CD3)-BD TRITEST CD4/CD8/CD3 (340298) A THREECOLOR DIRECT IMMUNOFLUORESCENCE REAGENT USED WITH BD TRUCOUNT™

	ABSOLUTE COUNT TUBES FOR IDENTIFYING AND DETERMINING ABSOLUTE COUNTS IN CELLS/L OF MATURE HUMAN T LYMPHOCYTES (CD3+), HELPER/INDUCER (CD3+CD4+) T LYMPHOCYTES, AND SUPPRESSOR/CYTOTOXIC (CD3+CD8+) T LYMPHOCYTES IN ERYTHROCYTELYSED WHOLE BLOOD.,GENERAL LABORATORY REAGENT AND CONSUMABLES IVDS(BD FACS 7-COLOR SETUP BEADS)-BD FACS 7 –COLOR SETUP BEADS ARE FOR IN VITRO DIAGNOSTIC USE ON A BD FACSCANTO FLOW CYTOMETER WITH BD FACSCANTO SOFTWARE. THE BEADS ARE USED TO ADJUST DETECTOR VOLTAGES, TO SET FLUORESCENCE COMPENSATION, AND TO MONITOR DAILY INSTRUMENT PERFORMANCE. FOR USE ONLY WITH BD FACS 7-COLOR SETUP BEADS LOT IDS:85537, 85538, 85539, 85540, 85541,85542, 85543, 85544, 85545, 85546,85547, 85548, 85549, 85550, 85551,85552, 85553, 85554, 85555, 85556,85557, 85558, 85559, 85560, 85561,85562, 85563, 85564, 85565, 85566,85567, 85568, 85569, 85570, 85571,MULTICOLOR ANTIBODY REAGENT(BD FACS COUNT CD4 REAGENT KIT)-BD FACS COUNT CD4 REAGENT KIT (CAT#339010) IS USED TO ENUMERATE THE ABSOLUTE COUNTS OF CD4 T LYMPHOCYTES AND DETERMINE THE PERCENTAGE OF LYMPHOCYTES THAT ARE CD4 T LYMPHOCYTES IN UNLYSED WHOLE BLOOD (CD4 COUNTS AND CD4 PERCENTAGES). THE REAGENTS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE ON A BD FACSCOUNT™ INSTRUMENT.,GENERAL LABORATABLES IVDSORY REAGENT AND CONSUM(BD CALIBRITE 3 COLOR KIT)-BD CALIBRITE™ BEADS ARE DESIGNED FOR USE FACSCOMP™ OR AUTOCOMP™ SOFTWARE AND THE FACS FAMILY OF FLOW CYTOMETERS, BEADS ARE USED TO ADJUST INSTRUMENT SETTINGS, SET FLUORESCENCE COMPENSATION, AND CHECK INSTRUMENT SENSITIVITY.,GENERAL LABORATORY REAGENT AND CONSUMABLE IVD(BD™ FC BEADS 2-COLOR KIT)-THE BD™ FC BEADS 2-COLOR KIT IS USED TO ESTABLISH FLUORESCENCE COMPENSATION FOR A BD FLOW CYTOMETER.,CD CELL MARKER (CLUSTER OF DIFFERENTIATION) IVDS(BD ONE FLOW PCST)-THE BD ONEFLOW™ PCST (PLASMA CELL SCREENING TUBE) IS INTENDED FOR FLOW-CYTOMETRIC IMMUNOPHENOTYPING OF NORMAL POLYCLONAL AND ABERRANT PLASMA CELL POPULATIONS IN BONE MARROW AS AN AID IN THE DIAGNOSIS OF HEMATOLOGICAL DISORDERS. THE BD ONEFLOW PCST TUBE IS DESIGNED FOR USE WITH A SUITABLY EQUIPPED BD FLOW CYTOMETER AND SOFTWARE DESIGNATED FOR IN VITRO DIAGNOSTIC USE. THE IFU OF THE PRODUCT IS UPDATED TO SUPPORT THE LAUNCH OF THE PRODUCT ON BD FACSLYRIC INSTRUMENT.,MULTICOLOR ANTIBODIES REAGENTS(BD TRITEST CD3/CD4/CD45)-BD TRITEST CD3/CD4/CD45 (CAT#340383) IS A THREE COLOR DIRECT IMMUNOFLUORESCENCE REAGENT FOR USE

	WITH A SUITABLY EQUIPPED FLOW CYTOMETER TO IDENTIFY AND DETERMINE THE PERCENTAGES AND ABSOLUTE COUNTS OF MATURE HUMAN T LYMPHOCYTES (CD3+) AND HELPER/INDUCER(CD3+CD4+) T LYMPHOCYTE SUBSETS IN ERYTHROCYTE-LYSED WHOLE BLOOD. WHEN USED WITH BD TRUCOUNT™ TUBES, ABSOLUTE COUNTS OF THESE POPULATIONS CAN BE ENUMERATED FROM A SINGLE TUBE. THIS BD TRITEST REAGENT AND BD TRUCOUNT TUBES CAN BE USED WITH THE BD FACS™ LOADER. THE REAGENT CAN BE USED WITH OR WITHOUT AN ISOTYPE CONTROL. ,GENERAL LABORATORY REAGENT AND CONSUMABLES IVDS(BD ONEFLOW™ SETUP BEADS)-BD ONEFLOW™ SETUP BEADS ARE INTENDED TO SET VOLTAGES APPROPRIATE FOR THE BD MULTICOLOR TUBE ASSAY WHEN USED WITH A SUITABLY EQUIPPED BD™ FLOW CYTOMETER AND SOFTWARE DESIGNATED FOR IN VITRO DIAGNOSTIC USE.,MULTICOLOR ANTIBODIES REAGENTS(BD MULTITEST CD3/CD8/CD45/CD4)-BD MULTITEST CD3/CD8/CD45/CD4 (340499) IS USED FOR DETERMINING PERCENTAGES AND ABSOLUTE COUNTS OF HUMAN HELPER/INDUCER AND SUPPRESSOR/CYTOTOXIC T LYMPHOCYTES IN ERYTHROCYTE-LYSED WHOLE BLOOD. ,GENERAL LABORATORY REAGENT AND CONSUMABLES IVDS(BD CALIBRITE APC BEADS)-BD CALIBRITE™ BEADS ARE DESIGNED FOR USE FACSCOMP™ OR AUTOCOMP™ SOFTWARE AND THE FACS FAMILY OF FLOW CYTOMETERS, BEADS ARE USED TO ADJUST INSTRUMENT SETTINGS, SET FLUORESCENCE COMPENSATION, AND CHECK INSTRUMENT SENSITIVITY,MULTICOLOR ANTIBODY REAGENT(BD FACSCOUNT REAGENT KIT)-BD FACSCOUNT REAGENT KIT (CAT#340167) IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN ENUMERATING THE ABSOLUTE COUNTS OF CD4, CD8, AND CD3 T LYMPHOCYTES IN UNLYSED WHOLE BLOOD, USING THE BD FACSCOUNT™ INSTRUMENT.,GENERAL LABORATORY REAGENT AND CONSUMABLES IVDS(BD CALIBRITE BEADS)-BD CALIBRITE™ BEADS ARE DESIGNED FOR USE FACSCOMP™ OR AUTOCOMP™ SOFTWARE AND THE FACS FAMILY OF FLOW CYTOMETERS, BEADS ARE USED TO ADJUST INSTRUMENT SETTINGS, SET FLUORESCENCE COMPENSATION, AND CHECK INSTRUMENT SENSITIVITY.,TRUCOUNT TUBES(BD TRUCOUNT TUBES)-BD TRUCOUNT™ TUBES ARE USED FOR DETERMINING ABSOLUTE COUNTS OF LEUCOCYTES IN BLOOD, REAGENT FOR INSTRUMENT/ANALYSER IVD'S(BD FACSPRESTO CARTRIDGE)-FOR USE ONLY WITH THE BD FACSPRESTO™ NEAR-PATIENT CD4 COUNTER. THE BD FACSPRESTO NEAR-PATIENT CD4 COUNTER IS AN AUTOMATED SYSTEM FOR IN VITRO DIAGNOSTIC USE IN PERFORMING THE DIRECT ENUMERATION OF CD4 ABSOLUTE COUNT, CD4 PERCENTAGE OF LYMPHOCYTES, AND HEMOGLOBIN CONCENTRATION IN HUMAN WHOLE BLOOD,MULTICOLOR

	ANTIBODIES REAGENT(BD MULTITEST 6-COLOR TBNK REAGENT WITH BD TRUCOUNT TUBES)-YOUR SUBMITTED PROPOSED CHANGE IN PRODUCT INSERT IS NOTED BY THIS OFFICE.,GENERAL LABORATORY REAGENT AND CONSUMABLES IVDS(BD™ FC BEADS 8 COLOR BEADS)-BD™ FC BEADS 8-COLOR KIT FOR BD ONEFLOW™ ASSAYS (BD FC BEADS) ARE INTENDED TO ALLOW SOFTWARE TO DETERMINE SPILLOVER VALUES (SOVS) FOR FLUORESCENCE COMPENSATION. BD FC BEADS ARE DESIGNED FOR USE WITH A SUITABLY EQUIPPED BD™ FLOW CYTOMETER AND SOFTWARE DESIGNATED FOR IN VITRO DIAGNOSTIC USE.,MULTICOLOR ANTIBODIES REAGENTS(BD FACSCOUNT CONTROL KIT)-BD FACSCOUNT CONTROL KIT (CAT#340166) IS NTENDED FOR IN VITRO DIAGNOSTIC USE IN SETTING UP THE BD FACSCOUNT™ INSTRUMENT AND FOR CHECKING LINEARITY,GENERAL LABORATORY REAGENT AND CONSUMABLES IVDS(BD FC BEADS 5 COLOR KIT)-THE BD™ FC BEADS 5-COLOR KIT (BD FC BEADS) IS USED TO ESTABLISH FLUORESCENCE COMPENSATION FOR A BD FLOW CYTOMETER., MULTICOLOR ANTIBODIES REAGENT(BD TRITEST CD3 FITC/CD4 PE/CD45 PERCP REAGENT 50 TESTS)-BD TRITEST CD3 FITC/CD4 PE/CD45 PERCP REAGENT 50 TESTS IS USED TO IDENTIFY AND DETERMINE THE PERCENTAGES AND ABSOLUTE COUNTS OF MATURE HUMAN T LYMPHOCYTES (CD3+) AND HELPER/INDUCER (CD3+CD4+) TLYMPHOCYTE SUBSETS IN ERYTHROCYTE-LYSED WHOLE BLOOD.,GENERAL LABORATORY REAGENT AND CONSUMABLES IVDS(BD FC BEADS 7 COLOR KIT)-THE BD™ FC BEADS 7-COLOR KIT (BD FC BEADS) IS USED TO ESTABLISH FLUORESCENCE COMPENSATION FOR A BD FLOW CYTOMETER.,MULTICOLOR ANTIBODIES REAGENT(BD MULTITEST CD3 FITC/CD8 PE/CD45 PERCP/CD4 APC REAGENT 50 TESTS)-YOUR SUBMITTED PROPOSED CHANGE IN PRODUCT INSERT IS NOTED BY THIS OFFICE.,GENERAL LABORATORY REAGENT AND CONSUMABLES IVDS(BD™ CS&T BEADS)-BD™ CS&T BEADS ARE USED ON A BD FLOWCYTOMETER TO PROVIDE A STANDARDIZED METHOD TO PERFORM QUALITY CONTROL OF THE INSTRUMENT'S OPTICS, ELECTRONICS, AND FLUIDICS, AND FOR ADJUSTING FLUORESCENCE COMPENSATION. ON SOME BD INSTRUMENTS, BD CS&T BEADS ARE ALSO USED FOR ADJUSTING DETECTOR VOLTAGES,MULTICOLOR ANTIBODIES REAGENT(BD TRITEST CD4 FITC/CD8 PE/CD3 PERCP REAGENT 50 TESTS)-BD TRITEST CD4 FITC/CD8 PE/CD3 PERCP REAGENT 50 TESTS USED TO IDENTIFY AND DETERMINE THE ABSOLUTE COUNTS OF MATURE HUMAN T LYMPHOCYTES (CD3+), HELPER/INDUCER (CD3+CD4+) T LYMPHOCYTES, AND SUPPRESSOR/CYTOTOXIC (CD3+CD8+) T LYMPHOCYTES IN ERYTHROCYTELYSED WHOLE BLOOD.,CD CELL MARKER (CLUSTER OF DIFFERENTIATION) IVDS(BD

	ONE FLOW PCD)-THE BD ONEFLOW™ PCD (PLASMA CELL DISORDERS) TUBE, WHEN RUN IN PARALLEL WITH THE BD ONEFLOW™ PCST (PLASMA CELL SCREENING TUBE), IS INTENDED FOR FLOW-CYTOMETRIC IMMUNOPHENOTYPING OF NORMAL AND ABERRANT PLASMA CELLS IN BONE MARROW AS AN AID IN THE DIAGNOSIS OF MULTIPLE MYELOMA AND OTHER PLASMA CELL DISORDERS. THE BD ONEFLOW PCD TUBE IS DESIGNED FOR USE WITH A SUITABLY EQUIPPED BD FLOW CYTOMETER AND SOFTWARE DESIGNATED FOR IN VITRO DIAGNOSTIC USE. THE IFU OF THE PRODUCT IS UPDATED TO SUPPORT THE LAUNCH OF THE PRODUCT ON BD FACSLYRIC INSTRUMENT.,MULTICOLOR ANTIBODIES REAGENTS(BD MULTITEST CD3 FITC/CD16 + CD56 PE/CD45 PERCP/CD19 APC REAGENT 50 TESTS)-YOUR SUBMITTED PROPOSED CHANGE FOR UPDATE PRODUCT INSERT IS NOTED BY THIS OFFICE.,CD CELL MARKER (CLUSTER OF DIFFERENTIATION) IVDS(BD ONEFLOW™ LST)-THE BD ONEFLOW™ LST (LYMPHOID SCREENING TUBE) IS INTENDED FOR FLOW-CYTOMETRIC IMMUNOPHENOTYPING OF NORMAL AND ABERRANT MATURE LYMPHOCYTE POPULATIONS OF B, T, AND NK LINEAGES IN PERIPHERAL BLOOD, BONE MARROW, AND LYMPH NODES, AS AN AID IN THE DIAGNOSIS OF HEMATOLOGICAL DISORDERS. THE BD ONEFLOW LST IS DESIGNED FOR USE WITH A SUITABLY EQUIPPED BD FLOW CYTOMETER AND SOFTWARE DESIGNATED FOR IN VITRO DIAGNOSTIC USE. THE IFU OF THE PRODUCT IS UPDATED TO SUPPORT THE LAUNCH OF THE PRODUCT ON BD FACSLYRIC INSTRUMENT.,MULTICOLOR ANTIBODIES REAGENTS(BD MULTITEST CD3/CD16+56/CD45/CD19)-BD MULTITEST CD3/CD16+56/CD45/CD19 (CAT#340500) IS USED FOR DETERMINING PERCENTAGES AND ABSOLUTE COUNTS OF HUMAN T, NATURAL KILLER, AND B LYMPHOCYTES IN ERYTHROCYTE- LYSED WHOLE BLOOD. ,MULTICOLOR REAGENT(BD STEM CELL ENUMERATION KIT (50 TESTS))-THE BD™ STEM CELL ENUMERATION (SCE) KIT PROVIDES SIMULTANEOUS ENUMERATION OF VIABLE DUAL-POSITIVE CD45+/CD34+ HEMATOPOIETIC STEM CELL POPULATIONS IN CD34+ ABSOLUTE COUNTS (CELLS/L) AS WELL AS THE PERCENTAGE OF THE TOTAL VIABLE LEUCOCYTE COUNT THAT IS CD34+ (%CD34),MULTICOLOR ANTIBODY REAGENT(BD LEUCOCOUNT™ KIT)-THE BD LEUCOCOUNT™ KIT (CAT#340523) IS DESIGNED FOR COUNTING RESIDUAL WHITE BLOOD CELLS (RWBCS) IN LEUCOREDUCED BLOOD PRODUCTS.,MULTICOLOR ANTIBODY REAGENT(BD LEUCOCOUNT™ KIT)-THE BD LEUCOCOUNT™ KIT CONSISTS OF BD LEUCOCOUNT™ REAGENT (PROPIDIUM IODIDE FLUORESCENT DYE) AND BD TRUCOUNT™ TUBES AND IS INTENDED FOR USE WITH THE BD FACSCALIBUR™, BD FACSORT™, BD FACSCAN™, AND BD FACSVIA™ FLOW CYTOMETER SYSTEMS, OR FOR

	A FLOW CYTOMETER EQUIPPED WITH A 488-NM ARGON ION LASER ABLE TO THRESHOLD ON FL2, FOR ENUMERATING RESIDUAL WHITE BLOOD CELLS (RWBCS) IN LEUCOREDUCED BLOOD PRODUCTS., MULTICOLOR ANTIBODIES REAGENT(BD MULTITEST 6-COLOR TBNK REAGENT)-YOUR SUBMITTED PROPOSED CHANGE IN PRODUCT INSERT IS NOTED BY THIS OFFICE.,MULTICOLOR ANTIBODIES REAGENT(BD TRITEST CD3 FITC/CD4 PE/CD45 PERCP REAGENT 50 TESTS + TRUCOUNT TUBES)-BD TRITEST CD3 FITC/CD4 PE/CD45 PERCP REAGENT 50 TESTS + TRUCOUNT TUBES IS USED TO IDENTIFY AND DETERMINE THE PERCENTAGES AND ABSOLUTE COUNTS OF MATURE HUMAN T LYMPHOCYTES (CD3+) AND HELPER/INDUCER (CD3+CD4+) T-LYMPHOCYTE SUBSETS IN ERYTHROCYTE-LYSED WHOLE BLOOD.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

43	IMP/IVD/2018/000016	1.License Holder Name: BIO-RAD LABORATORIES (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IH-QC 5(IH-QC 5)-IH-QC TUBES ARE INTENDED TO CONTROL THE ID-SYSTEM MANUALLY AND/OR WITH INSTRUMENTS FOR THE DETERMINATION OF THE ABO SYSTEM, RH (RH) SYSTEM, KELL (KEL) SYSTEM, AND/OR FURTHER IMMUNOHEMATOLOGY TESTS AS LISTED IN TABLE .(IH-QC MODULAR SYSTEM),COOMBS-SERUM IGG(COOMBS-SERUM IGG)-USED FOR THE DETECTION OF CELL BOUND BLOOD GROUP LGG ANTIBODIES,IH-QC 1 (IH-QC 1)-IH-QC TUBES ARE INTENDED TO CONTROL THE ID-SYSTEM MANUALLY AND/OR WITH INSTRUMENTS FOR THE DETERMINATION OF THE ABO SYSTEM, RH (RH) SYSTEM, KELL (KEL) SYSTEM, AND/OR FURTHER IMMUNOHEMATOLOGY TESTS AS LISTED IN TABLE .(IH-QC MODULAR SYSTEM),ANTI-IGM(ANTI-IGM)-USED FOR THE DETECTION OF THE IGM LOADING ON HUMAN RED BLOOD CELLS,IH-QC 3(IH-QC 3) -IH-QC TUBES ARE INTENDED TO CONTROL THE ID-SYSTEM MANUALLY AND/OR WITH INSTRUMENTS FOR THE DETERMINATION OF THE ABO SYSTEM, RH (RH) SYSTEM, KELL (KEL) SYSTEM, AND/OR FURTHER IMMUNOHEMATOLOGY TESTS AS LISTED IN TABLE .(IH-QC MODULAR SYSTEM),ANTI-IGG(ANTI-IGG)-USED FOR THE DETECTION OF THE IGG LOADING ON HUMAN RED BLOOD CELLS,IH-QC 4(IH-QC 4) -IH-QC TUBES ARE INTENDED TO CONTROL THE ID-SYSTEM MANUALLY AND/OR WITH INSTRUMENTS FOR THE DETERMINATION OF THE ABO SYSTEM, RH (RH) SYSTEM, KELL (KEL) SYSTEM, AND/OR FURTHER IMMUNOHEMATOLOGY TESTS AS LISTED IN TABLE .(IH-QC MODULAR SYSTEM),DIACLON COOMBS-SERUM GREEN(DIACLON COOMBS-SERUM GREEN)-USED FOR THE DETECTION OF CELL BOUND BLOOD GROUP LGG ANTIBODIES AND/ OR COMPONENT OF COMPLEMENT,IH-QC 8(IH-QC 8)-IH-QC TUBES ARE INTENDED TO CONTROL THE ID-SYSTEM MANUALLY AND/OR WITH INSTRUMENTS FOR THE DETERMINATION OF THE ABO SYSTEM, RH (RH) SYSTEM, KELL (KEL) SYSTEM, AND/OR FURTHER IMMUNOHEMATOLOGY TESTS AS LISTED IN TABLE .(IH-QC MODULAR SYSTEM),DIACLON COOMBS-SERUM UNCOLORED(DIACLON COOMBS-SERUM UNCOLORED)-USED FOR THE DETECTION OF CELL BOUND BLOOD GROUP LGG ANTIBODIES AND/ OR COMPONENT OF COMPLEMENT,IH-QC 7(IH-QC 7)-IH-QC TUBES ARE INTENDED TO CONTROL THE ID-SYSTEM MANUALLY AND/OR WITH INSTRUMENTS FOR THE DETERMINATION OF THE ABO SYSTEM, RH (RH) SYSTEM, KELL (KEL) SYSTEM, AND/OR FURTHER IMMUNOHEMATOLOGY TESTS AS LISTED IN TABLE .(IH-QC MODULAR SYSTEM),DIACLON COMPLETE CROSSMATCH(DIACLON COMPLETE CROSSMATCH)-THE ID-CARD "DIACLON COMPLETE CROSSMATCH " IS CONFIGURED TO MEET THE ABOVE

	REQUIREMENTS IN ONE EASY STEP. • ABO-CONFIRMATION OF BOTH DONOR AND RECIPIENT. • MAJOR COMPATIBILITY IN ANTI-HUMAN GLOBULIN (AHG) AND ENZYME TEST. • AUTOCONTROL (AHG TEST). , IH-QC 6(IH-QC 6)-IH-QC TUBES ARE INTENDED TO CONTROL THE ID-SYSTEM MANUALLY AND/OR WITH INSTRUMENTS FOR THE DETERMINATION OF THE ABO SYSTEM, RH (RH) SYSTEM, KELL (KEL) SYSTEM, AND/OR FURTHER IMMUNOHEMATOLOGY TESTS AS LISTED IN TABLE .(IH-QC MODULAR SYSTEM),DC-SCREENING II(DC-SCREENING II)-THE CONFIGURATION OF THE ID-CARD "DC-SCREENING II" ALLOWS DIFFERENTIATION BETWEEN LGG AND C3D COATING OF RED CELLS DURING INVESTIGATION OF A POSITIVE DAT WITH POLYSPECIFIC AHG, IN ONE EASY STEP. ,IH-QC 2(IH-QC 2)-IH-QC TUBES ARE INTENDED TO CONTROL THE ID-SYSTEM MANUALLY AND/OR WITH INSTRUMENTS FOR THE DETERMINATION OF THE ABO SYSTEM, RH (RH) SYSTEM, KELL (KEL) SYSTEM, AND/OR FURTHER IMMUNOHEMATOLOGY TESTS AS LISTED IN TABLE .(IH-QC MODULAR SYSTEM),DAT LGG1/GG3(DAT LGG1/GG3)-DETERMINATION OF IGG SUBCLASSES,NACL, ENZYME TEST AND COLD AGGLUTININS(NACL, ENZYME TEST AND COLD AGGLUTININS)-ID-CARD USED FOR DETECTION OF SALINE AND ENZYME REACTIVE ANTIBODIES (FOR REVERSE GROUPING, ANTIBODY SCREENING AND IDENTIFICATION, COMPATIBILITY TESTS),ANTI-C4(ANTI-C4)-USED FOR THE DETECTION OF C4 COMPLEMENT ON HUMAN RED BLOOD CELLS, ANTI-C3(ANTI-C3)-USED FOR THE DETECTION OF C3 COMPLEMENT ON HUMAN RED BLOOD CELLS,ANTI-IGA(ANTI-IGA)-USED FOR THE DETECTION OF THE IGA LOADING ON HUMAN RED BLOOD CELLS, DIACLON ANTI- C3D(DIACLON ANTI- C3D)-USED FOR THE DETECTION OF C3D COMPLEMENT ON HUMAN RED BLOOD CELLS,ID-DILUENT 2 (ID-DILUENT 2)-"ID-DILUENT 2" IS A MODIFIED LOW IONIC STRENGTH SOLUTION MADE FOR THE ID-SYSTEM, FOR PREPARING 5% RED CELL SUSPENSIONS FOR BLOOD GROUPING AS WELL AS 0.8% RED CELL SUSPENSIONS FOR CROSSMATCHING, AUTOCONTROL, DIRECT ANTI-HUMAN GLOBULIN TEST, BLOOD GROUPING OF NEWBORNS AND TEST CELLS PREPARED IN THE LABORATORY ,ID-DILUENT 1(ID-DILUENT 1)-ID-DILUENT 1" IS A MODIFIED BROMELIN SOLUTION IN WHICH THE ENZYME ACTIVITY IS STABILISED FOR A LONG PERIOD. SPECIALLY PREPARED FOR THE ID-SYSTEM. "ID-DILUENT 1" IS USED FOR PREPARING SUSPENSIONS OF RED CELLS FOR BLOOD GROUPING AND AS AN ADDITIVE FOR ENZYME TESTS WITH UNTREATED RED CELLS FOR ANTIBODY DETECTION AND CROSSMATCHING. ,DIACIDEL(DIACIDEL)-THIS REAGENT IS FOR THE ACID ELUTION OF SEROLOGICAL ANTIBODIES,ID-PAGIA HEPARIN/PF4 ANTIBODY TEST KIT(ID-PAGIA HEPARIN/PF4 ANTIBODY TEST KIT)-USED FOR THE DETECTION OF ANTIBODIES

	AGAINST THE HEPARIN/PLATELET FACTOR 4 COMPLEX .,WASH SOLUTION A(WASH SOLUTION A)-USED TO PREVENT THE BACTERIAL OR OTHER CONTAMINATION OF THE PIPETTING SYSTEM OF AN INSTRUMENT AND TO ELIMINATE THE RISK OF ANY CROSS-CONTAMINATION,ID-DIACELL ABO/I-II-III(ID-DIACELL ABO/I-II-III)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM AGAINST A1 , A2, B AND ANTIBODY SCREENING IN PATIENTS WITH 3 CELLS,ALBUMIN 22%(ALBUMIN 22%)-USED AS AN ENHANCER FOR INCOMPLETE ANTIBODIES.,DIACELL ABO A2(DIACELL ABO A2)-USED FOR THE DETECTION OF SERUM ANTIBODIES AGAINST A2,ANTI-D REFERENCE REAGENT(ANTI-D REFERENCE REAGENT)-USED TO ASSIST IN THE DAILY QUALITY MONITORING OF ROUTINE ANTIBODY DETECTION PROCEDURES,ID-DIASCREEN I- II-III-IV(ID-DIASCREEN I-II-III-IV)-THIS TEST CELLS ARE FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM FOR ANTIBODY SCREENING.,ID-DIASCREEN I-II-III-IV-VP- VIP(ID-DIASCREEN I-II-III-IV-VP- VIP)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM FOR ANTIBODY SCREENING,ID-DIACELL ABO/ I-II(ID-DIACELL ABO/ I-II)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM AGAINST A 1, A2, B AND H AND ANTIBODY SCREENING IN PATIENTS WITH 2 CELLS,ID-PNH TEST(ID-PNH TEST)-USED TO DETECT THE PRESENCE OF OAF AND MIRL PROTEINS ON RED BLOOD CELLS AND IDENTIFY ABNORMALLY RED CELL POPULATION OF THE MARCHIAFAVA- MICHELI SYNDROME (PNH) ,WASH SOLUTION B (WASH SOLUTION B)-USED TO PREVENT THE BACTERIAL OR OTHER CONTAMINATION OF THE PIPETTING SYSTEM OF AN INSTRUMENT AND TO ELIMINATE THE RISK OF ANY CROSS- CONTAMINATION, DIAMED CELL FREEZE(DIAMED CELL FREEZE)-SPECIAL BUFFER FOR EASY FREEZING OF RED CELLS, ALLOWING THE PRESERVATION OF INTERESTING ANTIGEN CONFIGURATIONS SO THAT THE LABORATORY HAS RARE RED CELLS AVAILABLE AT ANY TIME., DIAMED CELL THAW(DIAMED CELL THAW)-SPECIAL BUFFER FOR EASY THAWING OF RED CELLS, ALLOWING THE PRESERVATION OF INTERESTING ANTIGEN CONFIGURATIONS SO THAT THE LABORATORY HAS RARE RED CELLS AVAILABLE AT ANY TIME.,ID-CELLWASH-P(ID-CELLWASH-P)-LIQUID REAGENT USED FOR THE WASH OF PAPANIZED RED BLOOD CELLS,ID-CELLSTAB(ID-CELLSTAB)-"ID-CELLSTAB" IS A SPECIALLY FORMULATED GLYCINE BUFFERED SALINE WHICH STABILISES RED CELLS AT 0.8% CONCENTRATION FOR USE IN THE ID- SYSTEM FOR 4 WEEKS AFTER PREPARATION .,DIACLON RHESUS CONTROL(DIACLON RHESUS CONTROL)-USED AS A NEGATIVE CONTROL FOR THE WHOLE MONOCLONAL RHESUS REAGENTS FROM THE DIACLON RANGE AND IS DESIGNED TO DETECT A POSSIBLE NONSPECIFIC AGGLUTINATION

	DUE TO REACTION MEDIUM,ID-DIA(DIEGO) POSITIVE(ID-DIA(DIEGO) POSITIVE)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM AGAINST DIA ,DIACELL I + II(DIACELL I + II)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES FOR ANTIBODY SCREENING,ALBUMIN 6%(ALBUMIN 6%)-USED TO ASSIST IN THE DAILY QUALITY MONITORING OF ROUTINE ANTIBODY DETECTION PROCEDURES,ID-DIACELL ABO A1 , A2 , B(ID-DIACELL ABO A1 , A2 , B)-USED FOR THE DETECTION OF SERUM ANTIBODIES AGAINST A 1, A2, B,COOMBS ANTI- LGG(COOMBS ANTI- LGG)-THE ID-CARD "COOMBS ANTI-LGG" ALLOWS THE TESTING OF 6 SAMPLES, FOR DIRECT AND INDIRECT ANTIGLOBULIN TEST (DAT/IAT), ANTIBODY SCREENING, ANTIBODY IDENTIFICATION AND CROSSMATCH.,LISS/COOMBS + ENZYME TEST(LISS/COOMBS + ENZYME TEST)-USED FOR THE ANTIBODY SCREENING USING IN CONJUCTION TEST CELL REAGENTS FOR THE INDIRECT AGGLUTINATION TEST IAT AND PAPANIZED TEST CELL REAGENTS,DAT IGG- DILUTION(DAT IGG- DILUTION)-THE ID-CARD "DAT LGG-DILUTION" PROVIDES AN INDICATION OF THE CLINICAL IMPORTANCE OF THE DAT POSITIVE RESULT.,ID-PNH TEST REAGENTS(ID-PNH TEST REAGENTS)-USED TO DETECT THE PRESENCE OF OAF AND MIRL PROTEINS ON RED BLOOD CELLS AND IDENTIFY ABNORMALLY RED CELL POPULATION OF THE MARCHIAFAVA- MICHELI SYNDROME (PNH) ,LISS/COOMBS (LISS/COOMBS)-THE ID-CARD "LISS/COOMBS" IS SUITABLE FOR THE DAT, FOR THE COMPATIBILITY TEST, FOR ANTIBODY SCREENING AND IDENTIFICATION WITH "ID-DIACELL" AND "ID-DIAPANEL",REVERSE GROUPING WITH ANTIBODY SCREENING(REVERSE GROUPING WITH ANTIBODY SCREENING)-THE CARD IS USED WITH THE TEST CELL REAGENTS FOR THE REVERSE GROUPING AND ANTIBODY SCREENING TESTS,DC-SCREENING I(DC-SCREENING I)-THE CONFIGURATION OF THE ID-CARD "DC SCREENING I" IS STRUCTURED TO PROVIDE CLINICALLY IMPORTANT ANSWERS. IT CONSISTS OF ANTI-LGG, - LGA, -LGM, -C3C AND -C3D. IT ALLOWS THIS IMPORTANT INVESTIGATION TO BE PERFORMED IN ONE EASY STEP.

44	IMP/IVD/2018/000018	1.License Holder Name: M/S AVANTOR PERFORMANCE MATERIALS INDIA LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SC-CAL PLUS HEMATOLOGY CALIBRATOR(SC-CAL PLUS HEMATOLOGY CALIBRATOR)-SC CAL PLUS IS DESIGNED FOR USE IN THE CALIBRATION OF HEMATOLOGY ANALYZER,MULTI SERA CALIBRATOR(MULTI SERA CALIBRATOR)-MULTI SERA CALIBRATOR IS USED FOR CALIBRATION OF QUANTITATIVE DETERMINATION OF ROUTINE CHEMISTRY ANALYSTES ON MINDRAY BS MEASUREMENT SYSTEM,M-50 LBA LYSE(M-50 LBA LYSE)-M-50 LBA LYSE APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLOGY ANALYZER. IT IS USED TO LYSE RED BLOOD CELLS AND COUNT WBC'S AND BASOPHILS.,ALPHA, HYDROXYBUTYRATEDEHYDOGENASE KIT (ALPHA, HYDROXYBUTYRATEDEHYDOGENASE KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF A HBDH ACTIVITY IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,M-50 D DILUENT(M-50 D DILUENT)-M-50 D DILUENTS APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLOGY ANALYZER. IT IS USED TO PROVIDE A STABLE ENVIRONMENT FOR COUNTING AND SIZING BLOOD CELLS,LIPOPROTEIN (A) CONTROL N&P(LIPOPROTEIN (A) CONTROL N&P)-LIPOPROTEIN (A) N & P IS USED IN LIPID ANALYTE QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY,BILIRUBIN TOTAL KIT(BILIRUBIN TOTAL KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BIL-T CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS.,LIPOPROTEIN (A) KIT(LIPOPROTEIN (A) KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LP(A) CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS.,M-30 CFL LYSE(M-30 CFL LYSE)-FOR USE ON MINDRAY THREE PART DIFFERENTIAL HEMATOLOGY ANALYZER FOR USE AS A CYANIDE FREE LYTIC REAGENT FOR QUANTITATIVELY DETERMINING HEMOGLOBIN AND FOR COUNTING AND SIZING LEUKOCYTES,V-28 CFL LYSE(V-28 CFL LYSE)-A CYANIDE FREE LYSE REAGENT, INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN AND LEUKOCYTE COUNTING AND SIZING,M-50 LEO (I) LYSE(M-50 LEO (I) LYSE)-M-50 LEO (I) LYSE APPLIES TO 5 PART DIFFERNTIAL AUTO HEMATOLOGY ANALYSE_R. IT IS USED TO LYSE RED BLOOD CELLS AND 4 DIFFERENTIATES WBC'S,M-58 LBA LYSE(M-58 LBA LYSE)-M-58 L8A LYSE APPLIES TO MINDRAY BC-5600 , 8C-5800 AUTO HEMATOLOGY ANALYZER. IT BREAKS DOWN RED BLOOD CELL MEMBRANE AND 2 DIFFERENTIATES W8C'S TO BASOPHILS AND OTHER W8C'S,MULTI CONTROL SERA N(MULTI CONTROL SERA N)-MULTI CONTROL SERA N

	IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION ON MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY, CREATINE KINASE KIT(CREATINE KINASE KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE (CK) ACTIVITY IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS.,V-28 R RINSE(V-28 R RINSE)-AN AZIDE FREE FILTERED SOLUTION FOR USE IN CLEANING HEMATOLOGY ANALYZER,V-28 D DILUENT(V-28 D DILUENT)-ANAZIDE FREE FILTERED ISOTONIC SOLUTION FOR USE IN BLOOD CELL COUNTING AND SIZING,M-30 D DILUENT(M-30 D DILUENT)-IT IS USE ON MINDRAY THREE PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS USE AS AZIDE FREE, FILTERED ISOTONIC SOLUTION FOR COUNTING AND SIZING OF BLOOD CELLS, PHOSPHORUS KIT(PHOSPHORUS KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF P CONCENTRATION IN SERUM,, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS.,ASPARTATE AMINOTRANSFERASE KIT(ASPARTATE AMINOTRANSFERASE KIT)-AST REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF AST ACTIVITY IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS., BC- 5D(BC- 5D)-BC - 50 IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS,M-30 R RINSE(M-30 R RINSE)-IT IS USE ON MINDRAY THREE PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS USE AS AZIDE FREE, FILTERED ISOTONIC SOLUTION FOR CLEANING HEMATOLOGY ANALYSER,CREATININE KIT (CREATININE KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATININE CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS.,TOTAL CHOLESTEROL KIT (TOTAL CHOLESTEROL KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TC CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,TOTAL BILE ACIDS KIT(TOTAL BILE ACIDS KIT)-IN VITRO TEST .FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILE ACID CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,M-50 CLEANSER(M-50 CLEANSER)-M-50 CLEANSER APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLGY ANALYZER. IT IS AN ISOTONIC , CLEANING SOLUTION USE TO CLEAN THE ANALYSER,CALCIUM KIT(CALCIUM KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CA CONCENTRATION IN SERUM,PLASMA OR URINE ON PHOTOMETRIC SYSTEM,V-28 P PROBE CLEANSER(V-28 P PROBE CLEANSER)-INTENDED FOR CLEANING THE HEMATOLOGY ANALYZER PERIODICALLY,COMPLEMENT C4 KIT(COMPLEMENT C4 KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF C4 CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,C-REACTIVE

	PROTEIN KIT(C-REACTIVE PROTEIN KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CRP CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,V- 28E-Z CLEANSER(V- 28E-Z CLEANSER) -INTENDED FOR CLEANING THE HEMATOLOGY ANALYZER PERIODICALLY,M-58 D DILUENT(M-58 D DILUENT)-M-58 D DILUENTS APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT PROVIDE A STABLE ENVIRONMENT FOR COUNTING AND SIZINQ BLOOD CELLS.,M-50 LH LYSE(M-50 LH LYSE)-M-50 LH LYSE APPLIES TO 5 PART DIFFERNTIAL AUTO HEMATOLOGY ANALYSER. IT IS USED TO LYSE RED BLOOD CELLS AND DETERMINE THE HGB,LACTATE DEHYDROGENASE KIT(LACTATE DEHYDROGENASE KIT)-LDH REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,B30 CONTROL(B30 CONTROL)-B30 CONTROL IS A HEMATOLOGY REFERENCE CONTROL USED TO MONITOR THE PERFORMANCE OF BC SERIES OF HEMATOLOGY ANALYZER. THE MEAN VALUES AND EXPECTED RANGE OF THE PARAMETER ARE DISPLAYED IN QUALITY CONTROL GRAPHS WITH UPPER AND LOWER CONTROL LIMITS. CLINICAL LABORATORIES USE STABLIZED BLOOD CELL SUSPENSION TO MONITOR CORRESPONDING PARAMETER. DAILY USE OF THIS WHOLE BLOOD CONTROL PROVIDES CONTROL DATA FOR CONFRIMING THE PRECISION AND ACCURACY OF INSTRUMENT, COMPLEMENT C3 KIT(COMPLEMENT C3 KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF C3 CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS.,ALKALINE PHOSPHATASE KIT (ALKALINE PHOSPHATASE KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALP ACTIVITY IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS.,LDL- CHOLESTEROL KIT(LDL-CHOLESTEROL KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LDL-CHOLESTEROL (LDL-C) CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS.,ANTI BODIES AGAINST STREPTOLYSIN O (ASO) KIT(ANTI BODIES AGAINST STREPTOLYSIN O (ASO) KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ASO CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS.,IMMUNOGLOBULIN M KIT (IMMUNOGLOBULIN M KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGM CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM.,M-58 LH LYSE(M-58 LH LYSE)-M-58 LH LYSE APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT BREAKS DOWN RED BLOOD CELL MEMBRANE AND CONVERTS HEMOGLOBIN TO A HEMOGLOBIN COMPLEX TO DETERMINE THE HG8.,UREA KIT(UREA KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF UREA CONCENTRATION IN

	SERUM, PLASMA AND URINE ON PHOTOMETRIC SYSTEMS.,PROBE CLEANSER(PROBE CLEANSER)-PROBE CLEANSER APPLIES TO MINDRAY BC-5600 , 8C-5800 AUTO HEMATOLOQV ANALYZER. IT IS USED TO CLEAN THE ANALYZER REQULARLY,M-58 LEO (I) LYSE(M-58 LEO (I) LYSE)-M-58 LEO (I) LYSE APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT BREAKS DOWN RED BLOOD CELL MEMBRANE AND COOPERATES WITH THE M-58 LEO (II) LYSE TO 4 DIFFERENTIATE W8C'S .,TRIGLYCERIDES KIT(TRIGLYCERIDES KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TG CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,M-52 PROBE CLEANSER(M-52 PROBE CLEANSER)-PROBE CLEANSER APPLIES TO MINDRAY BC-5150AUTO HEMATOLOGY ANALYZER. IT IS USED TO CLEAN THE ANALYZER REGULARLY,PRE ALBUMIN CALIBRATOR(PRE ALBUMIN CALIBRATOR)-PRE ALBUMIN CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF SPECIFIC PROTEINS ON MINDRAY BS MEASUREMENT SYSTEM,TOTAL PROTEIN KIT(TOTAL PROTEIN KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TP CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS.,M-52 D DILUENT(M-52 D DILUENT)-M-52 D DILUENT PROIVDE STABLE SOLUTION ENVIRONMENT FOR BLOOD CELLS, DILUTE BLOOD SAMPLE, GENERATES SHEATH FLUID AND PROVIDE CONDUCTANCE IN BLOOD CELL ANALYSIS PROCESS,LIPIDS CALIBRATOR(LIPIDS CALIBRATOR)-LIPIDS CALIBRATOR IS USED FOR CALIBRATION OF QUANTITATIVE DETERMINATION OF LIPIDS ANALYTES ON MINDRAY BS MEASUREMENT SYSTEM.,HDL-CHOLESTEROL KIT(HDL-CHOLESTEROL KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF HDL-CHOLESTEROL (HDL-C) CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS, HEMOGLOBIN A1C (HBA1C) KIT(HEMOGLOBIN A1C (HBA1C) KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF HBA1C CONCENTRATION IN HUMAN WHOLE BLOOD ON PHOTOMETRIC SYSTEMS,M-50 P PROBE CLEANSER(M-50 P PROBE CLEANSER)-M-50 P PROBE CLEANSER APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLOGY ANALYZER. IT IS USED TO CLEAN THE ANALYZER REGULARLY,M-58 LEO (II)LYSE(M-58 LEO (II)LYSE)-M-58 LEO (II) LYSE APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT COOPERATES WITH THE M-58 LEO (I) LYSE TO 4 DIFFERENTIATE W8C'S,LIPASE (LIP)KIT(LIPASE (LIP)KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LIP CONCENTRATION IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,IMMUNOGLOBULIN A KIT(IMMUNOGLOBULIN A KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGA CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,IRON (FE) KIT

	(IRON (FE) KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM AND HEPARIN PLASMA ON PHOTOMETRIC SYSTEM,URIC ACID KIT(URIC ACID KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF UA CONCENTRATION IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS.,LIPOPROTEIN (A) CALIBRATOR(LIPOPROTEIN (A) CALIBRATOR)-LIPOPORTEIN (A) CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF LIPID ANALYTE ON MIND RAY BS MEASUREMENT SYSTEM,CARBO DIOXIDE (CO2) KIT (CARBO DIOXIDE (CO2) KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF C02 CONCENTRATION IN SERUM AND HEPARIN PLASMA ON PHOTOMETRIC SYSTEM,M-50 LEO (II) LYSE(M-50 LEO (II) LYSE)-M-50 LEO (II) LYSE APPLIES TO 5 PART DIFFERNTIAL AUTO HEMATOLOGY ANALYSER. IT IS USED TO LYSE RED BLOOD CELLS AND 4 DIFFERENTIATES WBC'S,BILIRUBIN DIRECT KIT(BILIRUBIN DIRECT KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BIL-D CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS,MULTI CONTROL SERA P(MULTI CONTROL SERA P)-MULTI CONTROL SERA P IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION ON MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY,APOLIPOPROTEIN B KIT(APOLIPOPROTEIN B KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF APOB CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM, IMMUNOGLOBULIN G KIT(IMMUNOGLOBULIN G KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGG CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,CK-MB CALIBRATOR(CK-MB CALIBRATOR)-CK-MB CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF CARDIAC ANALYTE ON MINDRAY BS MEASUREMENT SYSTEM,RHEUMATOID FACTOR (RF) KIT (RHEUMATOID FACTOR (RF) KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF RF CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS.,PRE ALBUMIN KIT(PRE ALBUMIN KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF PA CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS.,SPECIFIC PROTEIN CALIBRATOR(SPECIFIC PROTEIN CALIBRATOR)-SPECIFIC PROTEINS CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF SPECIFIC PROTEINS ON MINDRAY BS MEASUREMENT SYSTEM,ALPHA-AMYLASE KIT(ALPHA-AMYLASE KIT)-ALPHA AMY REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF A AMYLASE ACTIVITY IN SERUM. PLASMA OR URINE ON PHOTOMETRIC SYSTEM,CHOLINESTERASE (CHE) KIT(CHOLINESTERASE (CHE) KIT)-CHE REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CHE ACTIVITY IN SERUM OR

	PLASMA ON PHOTOMETRIC SYSTEM,GAMMA GLUTAMYLTRANSFERASE KIT(GAMMA GLUTAMYLTRANSFERASE KIT) -GGT REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF GAMMA-GLUTAMYLTRANSFERASE ACTIVITY IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,MAGNESIUM KIT(MAGNESIUM KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF MG CONCENTRATION IN SERUM, PLASMA AND URINE ON PHOTOMETRIC SYSTEMS.,CREATINE KINASE - MB KIT(CREATINE KINASE - MB KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE MB ACTIVITY IN SERUM ON PHOTOMETRIC SYSTEM,M-52 LH LYSE(M-52 LH LYSE)-M-52 LH LYSE FUTHER PROCESS THE BLOOD CELL THAT HAVE BEEN PROCESSED BY M-52 DIFF LYSE. IT TURNS HEMOGLOBIN INTO METHEMOGLOBIN, WHICH THEN MEASURED BY THE COLORIMETRIC METHOD. IT IS ALSO PROCESSES W8C'S TO INTENSIFY THE DIFFERENCE BETWEEN BASOPHILES AND OTHER W8C SUB POPULATIONS AND IN CORPORATE CYTOMETRY TO REALIZE BASOPHIL ANALYSIS,ALANINE AMINOTRANSFERASE KIT(ALANINE AMINOTRANSFERASE KIT)-ALT REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE ACTIVITY IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS., APOLIPOPROTEIN A1 KIT(APOLIPOPROTEIN A1 KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF APOA1 CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,ALBUMIN KIT (ALBUMIN KIT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALB CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS.,M-52 DIFF LYSE(M-52 DIFF LYSE)-M-52 DIFF LYSE DISSOLVES RBCS IN THE BLOOD CELL ANALYSIS PROCESS. IT PROCESSES W8CS TO INTENSIFY THE DIFFERENCE OF THE WBC SUB POPULATIONS AND IN CORPORATE LASER SCATTER AND FLOW CYTOMETRY TO REALIZE DIFF CHANNEL WBC ANALYSIS, CD-80 DETERGENT(CD-80 DETERGENT)-CLEAN SAMPLE AND REAGENT PROBES, MIXERS AND CUVETTES OF THE CHEMISTRY ANALYZER

45	IMP/IVD/2018/000019	1.License Holder Name: AAMX BIOMEDICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LUMI - D-DILUENT (SWELAB)-USED IN VITRO DIAGNOSTICS,ALFA DILUENT(SWELAB)-USED IN IN-VITRO DIAGNOSTICS,EASY CLEANER(BOULE)-USED IN VITRO DIAGNOSTICS,ALFA LYSE WITH RFID(SWELAB)-USED IN IN-VITRO DIAGNOSTICS,LUMI - L1 LYSE (SWELAB)-USED IN VITRO DIAGNOSTICS ,ALFA LYSE(SWELAB)-USED IN IN-VITRO DIAGNOSTICS, LUMI- L2 LYSE (SWELAB)-USED IN VITRO DIAGNOSTICS ,ALFA DILUENT WITH RFID(SWELAB)-USED IN IN-VITRO DIAGNOSTICS, CLEANING KIT(BOULE)-USED IN IN-VITRO DIAGNOSTICS
46	IMP/IVD/2018/000020	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROL DIFF NORMAL (BOULE)-FOR IN-VITRO DIAGNOSTIC USE,CONTROL DIFF LOW(BOULE) -FOR IN-VITRO DIAGNOSTIC USE,CAL(BOULE)-FOR IN-VITRO DIAGNOSTIC USE,CONTROL DIFF HIGH(BOULE)-FOR IN-VITRO DIAGNOSTIC USE,CONTROL DIFF TRI-LEVEL(BOULE)-FOR IN-VITRO DIAGNOSTIC USE
47	IMP/IVD/2018/000021	1.License Holder Name: LAB X 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EASY CLEANER (BOULE)-USED IN VITRO DIAGNOSTICS ,M SERIES DILUENT WITH RFID (MEDONIC)-USED IN INVITRO DIAGNOSTICS,M51- L1 LYSE (MEDONIC)-USED IN VITRO DIAGNOSTICS ,ALFA DILUENT WITH RFID(SWELAB)-USED IN INVITRO DIAGNOSTICS,M51- D-DILUENT(MEDONIC)-USED IN VITRO DIAGNOSTICS ,CLEANING KIT(BOULE)-USED IN INVITRO DIAGNOSTICS,M51- L2 LYSE (MEDONIC)-USED IN VITRO DIAGNOSTICS ,ALFA DILUENT(SWELAB)-USED IN INVITRO DIAGNOSTICS,M SERIES DILUENT(MEDONIC)-USED IN INVITRO DIAGNOSTICS,ALFA LYSE (SWELAB)-USED IN INVITRO DIAGNOSTICS,M SERIES LYSE WITH RFID (MEDONIC)-USED IN INVITRO DIAGNOSTICS,M SERIES LYSE(MEDONIC) -USED IN INVITRO DIAGNOSTICS,ALFA LYSE WITH RFID(SWELAB)-USED IN INVITRO DIAGNOSTICS

48	IMP/IVD/2018/000022	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVIA CHEMISTRY TOXICOLOGY CALIBRATOR 2(ADVIA CHEMISTRY TOXICOLOGY CALIBRATOR 2)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMI-QUANTITATIVE CALIBRATION OF ADVIA CHEMISTRY SYSTEMS FOR THE SERUM BARBITURATE (SBRB), SERUM BENZODIAZEPINE (SBNZ) AND TRICYCLIC ANTIDEPRESSANT (TCA) LIKE METHODS,ATELLICA CH DRUG CAL II (DRUG II CAL)(ATELLICA CH DRUG CAL II (DRUG II CAL))-THE ATELLICA ® CH DRUG CAL II (DRUG II CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE CARB, GENT, TOB, VANC AND VPA ASSAYS USING THE ATELLICA ® CH ANALYZER.,ADVIA CHEMISTRY MULTI-DRUG URINE CONTROLS (ADVIA CHEMISTRY MULTI-DRUG URINE CONTROLS)-FOR IN VITRO DIAGNOSTIC USE IN THE PERFORMANCE MONITORING OF ADVIA CHEMISTRY SYSTEMS FOR THE AMPHETAMINE (AMPHET), BARBITURATE (BARB), BENZODIAZEPINE (BENZO), COCAINE METABOLITE (COCAIN), METHADONE (METHA), METHADONE METABOLITE (METMTB), OPIATE ETC,ATELLICA CH MULTI-DRUG URINE CONTROLS (MULTIDRUG QC)(ATELLICA CH MULTI-DRUG URINE CONTROLS (MULTIDRUG QC))-THE ATELLICA™ CH MULTI-DRUG URINE CONTROLS (MULTIDRUG QC) ARE FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE METMTB ASSAY USING THE ATELLICA™ CH ANALYZER.,ADVIA CHEMISTRY TOX AMMONIA CALIBRATOR(ADVIA CHEMISTRY TOX AMMONIA CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ETHANOL, AMMONIA, ACETAMINOPHEN, AND SALICYLATE ASSAYS ON THE ADVIA® CHEMISTRY SYSTEMS,ATELLICA CH TOXICOLOGY CALIBRATOR (TOX CAL)(ATELLICA CH TOXICOLOGY CALIBRATOR (TOX CAL))-THE ATELLICA ® CH TOXICOLOGY CALIBRATOR (TOX CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ACET, ETOH AND SAL ASSAYS USING THE ATELLICA ® CH ANALYZER., ADVIA CHEMISTRY METHADONE METABOLITE 1000NG/ML CALIBRATOR(ADVIA CHEMISTRY METHADONE METABOLITE 1000NG/ML CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA CHEMISTRY SYSTEMS FOR THE METHADONE METABOLITE (METMTB) METHOD.,ATELLICA CH METHADONE METABOLITE 1000 NG/ML URINE CALIBRATOR (METMTB CAL) (ATELLICA CH METHADONE METABOLITE 1000 NG/ML URINE CALIBRATOR (METMTB CAL))-THE ATELLICA® CH METHADONE METABOLITE 1000 NG/ML URINE CALIBRATOR (METMTB CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE METMTB ASSAY USING THE ATELLICA® CH ANALYZER.,ADVIA CHEMISTRY SERUM BENZODIAZEPINES REAGENT(ADVIA CHEMISTRY SERUM

	BENZODIAZEPINES REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF BENZODIAZEPINES IN HUMAN SERUM OR PLASMA ON THE ADVIA CHEMISTRY SYSTEMS.,ADVIA CHEMISTRY METHADONE METABOLITE REAGENT(ADVIA CHEMISTRY METHADONE METABOLITE REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF METHADONE METABOLITE IN HUMAN URINE ON THE ADVIA CHEMISTRY SYSTEMS.,ADVIA CHEMISTRY SERUM BARBITURATES REAGENT(ADVIA CHEMISTRY SERUM BARBITURATES REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF BARBITURATES IN HUMAN SERUM OR PLASMA ON THE ADVIA CHEMISTRY SYSTEMS.,ADVIA CHEMISTRY DRUG CALIBRATOR II(ADVIA CHEMISTRY DRUG CALIBRATOR II)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF CARBAMAZEPINE_2 (CARB_2), GENTAMICIN_2 (GENT_2), TOBRAMYCIN_2 (TOB_2), VALPROIC ACID_2 (VPA_2), AND VANCOMYCIN_2 (VANC_2) METHODS ON THE ADVIA CHEMISTRY SYSTEMS.,ADVIA CHEMISTRY NEGATIVE DRUG URINE CALIBRATOR (ADVIA CHEMISTRY NEGATIVE DRUG URINE CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA CHEMISTRY SYSTEMS FOR THE AMPHETAMINE (AMPHET), BARBITURATE (BARB), BENZODIAZEPINE (BENZO, COCAINE METABOLITE (COCAIN), METHADONE (METHA), OPIATE 2000 NG/ML (OP2000), PHENCYCLIDINE (PCP) AND PROPOXYPHENE (PROPOX) METHODS, ADVIA CHEMISTRY TOXICOLOGY NEGATIVE CALIBRATOR(ADVIA CHEMISTRY TOXICOLOGY NEGATIVE CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMI-QUANTITATIVE CALIBRATION OF ADVIA CHEMISTRY SYSTEMS FOR THE SERUM BARBITURATE (SBRB), SERUM BENZODIAZEPINE (SBNZ) AND TRICYCLIC ANTIDEPRESSANT (TCA) LIKE METHODS.,ADVIA CHEMISTRY TRICYCLICS ANTI-DEPRESSANTS REAGENT(ADVIA CHEMISTRY TRICYCLICS ANTI-DEPRESSANTS REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF TRICYCLIC ANTIDEPRESSANTS IN HUMAN SERUM, PLASMA, OR URINE ON THE ADVIA CHEMISTRY SYSTEMS.,ADVIA CHEMISTRY TOXICOLOGY CALIBRATOR 1(ADVIA CHEMISTRY TOXICOLOGY CALIBRATOR 1)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMI-QUANTITATIVE CALIBRATION OF ADVIA CHEMISTRY SYSTEMS FOR THE SERUM BARBITURATE (SBRB), SERUM BENZODIAZEPINE (SBNZ) AND TRICYCLIC ANTIDEPRESSANT (TCA) LIKE METHODS.,ADVIA CHEMISTRY TOXICOLOGY CONTROLS (ADVIA CHEMISTRY TOXICOLOGY CONTROLS)-FOR IN VITRO DIAGNOSTIC USE IN MONITORING ASSAY CONDITIONS IN MEASUREMENT OF BARBITURATE AND BENZODIAZEPINE IN HUMAN

		SERUM AND PLASMA AND TRICYCLIC ANTIDEPRESSANT (TCA) DRUGS IN HUMAN SERUM, PLASMA AND URINE ON THE ADVIA CHEMISTRY SYSTEMS,ADVIA CHEMISTRY TOXICOLOGY CALIBRATOR 4(ADVIA CHEMISTRY TOXICOLOGY CALIBRATOR 4)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMI-QUANTITATIVE CALIBRATION OF ADVIA CHEMISTRY SYSTEMS FOR THE SERUM BARBITURATE (SBRB), SERUM BENZODIAZEPINE (SBNZ) AND TRICYCLIC ANTIDEPRESSANT (TCA) LIKE METHODS.,ADVIA CHEMISTRY TOXICOLOGY CALIBRATOR 3(ADVIA CHEMISTRY TOXICOLOGY CALIBRATOR 3)-FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE OR SEMI-QUANTITATIVE CALIBRATION OF ADVIA CHEMISTRY SYSTEMS FOR THE SERUM BARBITURATE (SBRB), SERUM BENZODIAZEPINE (SBNZ), AND TRICYCLIC ANTIDEPRESSANT (TCA) LIKE METHODS
49	IMP/IVD/2018/000023	1.License Holder Name: M/S. R.K.AGENCY 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SWELAB ALFA REAGENT(SWELAB ALFA DILUENT)- THE BOULE SWELAB ALFA DILUENT REAGENT IS INTENDED TO USED WITH THE SWELAB ALFA HEMATOLOGY ANALYZER SYSTEMS.,SWELAB ALFA REAGENT(SWELAB ALFA DILUENT WITH RFID)- THE BOULE SWELAB ALFA DILUENT WITH REFID REAGENT IS INTENDED TO USED FOR SWELAB ALFA HEMATOLOGY ANALYZER SYSTEMS WITH NEW VERSION., SWELAB ALFA REAGENT(SWELAB ALFA LYSE WITH RFID)- THE BOULE SWELAB ALFA LYSE WITH RFID REAGENT IS INTENDED TO USE WITH THE SWELAB ALFA HEMATOLOGY ANALYZER SYSTEM WITH THE NEW VERSION.,SWELAB ALFA REAGENT(SWELAB ALFA LYSE)- THE BOULE SWELAB ALFA LYSE REAGENT IS INTENDED TO USED WITH THE SWELAB ALFA HEMATOLOGY ANALYZER SYSTEMS., HEMATOLOGY CLEANING KIT(BOULE CLEANING KIT)- BOULE CLEANING KIT IS INTENDED FOR USE WITH THE SWELAB, SWELAB ALFA SERIES HEMATOLOGY SYSTEMS.
50	IMP/IVD/2018/000024	1.License Holder Name: LAB X 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROL DIFF HIGH (BOULE)-USED IN IN VITRO DIAGNOSTICS,CONTROL DIFF TRI LEVEL (BOULE)-USED IN IN VITRO DIAGNOSTICS,CONTROL DIFF NORMAL (BOULE)-USED IN IN VITRO DIAGNOSTICS,CONTROL DIFF LOW (BOULE)-USED IN IN VITRO DIAGNOSTICS,CALIBRATOR(BOULE)-USED IN IN VITRO DIAGNOSTICS

51	IMP/IVD/2018/000025	1.License Holder Name: AAMX BIOMEDICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROL DIFF HIGH (BOULE)-FOR IN-VITRO DIAGNOSTIC USE,CONTROL DIFF LOW(BOULE) -FOR IN-VITRO DIAGNOSTIC USE,CONTROL DIFF NORMAL(BOULE)-FOR IN-VITRO DIAGNOSTIC USE,CONTROL DIFF TRILEVEL(BOULE)-FOR IN-VITRO DIAGNOSTIC USE,CALIBRATOR(BOULE)-FOR IN-VITRO DIAGNOSTIC USE
52	IMP/IVD/2018/000026	1.License Holder Name: M/S.TRANSASIA BIO-MEDICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRI-LEVEL QUALITY CONTROL KIT(TRI-LEVEL QUALITY CONTROL KIT)-USED TO ESTABLISH THE PERFORMANCE OF ELECTROLYTE ANALYZERS USING CONTROLS.,BI-LEVEL QC KIT(BI-LEVEL QC KIT)-USED TO MONITOR THE PERFORMANCE OF THE EASYLYTE ANALYZERS.

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53	IMP/IVD/2018/000029	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOGLOBIN A1C CONTROLS-INTENDED FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE HEMOGLOBIN A1C ASSAY ON THE ARCHITECT C8000 AND C4000 SYSTEMS.,ALINITY C ALANINE AMINOTRANSFERASE REAGENT KIT (ALINITY C ALANINE AMINOTRANSFERASE REAGENT KIT)-THE ALINITY C ALANINE AMINOTRANSFERASE ASSAY IS USED FOR THE QUANTITATION OF ALANINE AMINOTRANSFERASE IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,HEMOGLOBIN A1C CALIBRATOR-INTENDED FOR USE IN THE CALIBRATION OF THE HEMOGLOBIN A1C ASSAY ON THE ARCHITECT C8000 AND C4000 SYSTEMS.,ALINITY C-SERIES DETERGENT B(ALINITY C-SERIES DETERGENT B)-THE ALINITY C-SERIES DETERGENT B IS AN ONBOARD SOLUTION USED WITH SELECTED DIAGNOSTIC PROCEDURES AND IN CONJUNCTION WITH THE SMARTWASH FEATURE TO REDUCE CARRYOVER BETWEEN SPECIFIC ASSAY COMBINATIONS., HEMOGLOBIN A1C REAGENT-USED IN CLINICAL LABORATORIES FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF PERCENT HEMOGLOBIN A1C (NGSP) OR HBA1C FRACTION MMOL/MOL (IFCC) IN HUMAN WHOLE BLOOD AND HEMOLYSATE ON THE ARCHITECT C8000 AND C4000 SYSTEMS,ALINITY C AMYLASE REAGENT KIT (ALINITY C AMYLASE REAGENT KIT)-THE ALINITY C AMYLASE ASSAY IS USED FOR THE QUANTITATION OF AMYLASE IN HUMAN SERUM, PLASMA, OR URINE ON THE ALINITY C ANALYZER.,ALINITY C HEMOGLOBIN A1C CONTROLS-USED FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY C HEMOGLOBIN A1C ASSAY ON THE ALINITY C ANALYSER.,ALINITY C ICT URINE CALIBRATOR KIT(ALINITY C ICT URINE CALIBRATOR KIT)-FOR USE IN THE CALIBRATION OF THE URINE SODIUM, POTASSIUM, AND CHLORIDE ASSAYS.,ALINITY C HEMOGLOBIN A1C CALIBRATORS-INTENDED FOR CALIBRATION OF THE ALINITY C HEMOGLOBIN A1C ASSAY ON ALINITY C ANALYZER., ALINITY C ULTRA HDL REAGENT KIT(ALINITY C ULTRA HDL REAGENT KIT)-THE ALINITY C ULTRA HDL ASSAY IS USED FOR THE QUANTITATION OF HIGH DENSITY LIPOPROTEIN (HDL) CHOLESTEROL IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER., ALINITY C HEMOGLOBIN A1C REAGENT KIT-INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF PERCENT HEMOGLOBIN A1C (NGSP) OR HBA1C FRACTION MMOL/MOL (IFCC) IN HUMAN WHOLE BLOOD AND HEMOLYSATE ON THE ALINITY C ANALYZER.., ALINITY C TOTAL BILIRUBIN REAGENT KIT(ALINITY C TOTAL BILIRUBIN REAGENT KIT)-THE ALINITY C TOTAL BILIRUBIN ASSAY IS

	USED FOR THE QUANTITATION OF TOTAL BILIRUBIN IN HUMAN SERUM OR PLASMA OF ADULTS AND NEONATES ON THE ALINITY C ANALYZER.,ALINITY C GLUCOSE REAGENT KIT-INTENDED FOR THE QUANTITATION OF GLUCOSE IN HUMAN SERUM, PLASMA, URINE, OR CEREBROSPINAL FLUID (CSF).,ALINITY C DIRECT BILIRUBIN REAGENT KIT(ALINITY C DIRECT BILIRUBIN REAGENT KIT)-THE ALINITY C DIRECT BILIRUBIN ASSAY IS USED FOR THE QUANTITATIVE ANALYSIS OF DIRECT BILIRUBIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,DIRECT BILIRUBIN(DIRECT BILIRUBIN)-THE DIRECT BILIRUBIN ASSAY IS USED FOR THE QUANTITATIVE ANALYSIS OF DIRECT BILIRUBIN IN HUMAN SERUM OR PLASMA. ,ALINITY C-SERIES DETERGENT A(ALINITY C-SERIES DETERGENT A)-THE ALINITY C-SERIES DETERGENT A IS AN ONBOARD SOLUTION USED IN DAILY MAINTENANCE, SELECTED DIAGNOSTIC PROCEDURES, AND IN CONJUNCTION WITH THE SMARTWASH FEATURE TO REDUCE CARRYOVER BETWEEN SPECIFIC ASSAY COMBINATIONS. ,ICT URINE CALIBRATOR (ICT URINE CALIBRATOR)-FOR USE IN THE CALIBRATION OF THE URINE SODIUM, POTASSIUM, AND CHLORIDE ASSAYS. ,ALINITY C CARBON DIOXIDE REAGENT KIT(ALINITY C CARBON DIOXIDE REAGENT KIT)-THE ALINITY C CARBON DIOXIDE ASSAY IS USED FOR THE QUANTITATION OF CARBON DIOXIDE IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ULTRA HDL(ULTRA HDL)-THE ULTRA HDL (UHDL) ASSAY IS USED FOR THE QUANTITATION OF HIGH-DENSITY LIPOPROTEIN (HDL) CHOLESTEROL IN HUMAN SERUM OR PLASMA. ,ALINITY C-SERIES MAINTENANCE SOLUTIONS(ALINITY C-SERIES MAINTENANCE SOLUTIONS)-THE ALINITY C-SERIES MAINTENANCE SOLUTIONS ARE ONBOARD SOLUTIONS USED TO PERFORM THE AUTOMATED DAILY MAINTENANCE PROCEDURE AND SELECTED DIAGNOSTIC PROCEDURES ON THE ALINITY C ANALYZER.,GLUCOSE(GLUCOSE)-THE GLUCOSE ASSAY IS USED FOR THE QUANTITATION OF GLUCOSE IN HUMAN SERUM, PLASMA, URINE, OR CEREBROSPINAL FLUID (CSF)., ALINITY C TOTAL BILIRUBIN REAGENT KIT(ALINITY C TOTAL BILIRUBIN REAGENT KIT)-THE ALINITY C TOTAL BILIRUBIN ASSAY IS USED FOR THE QUANTITATION OF TOTAL BILIRUBIN IN HUMAN SERUM OR PLASMA OF ADULTS AND NEONATES ON THE ALINITY C ANALYZER.,CARBON DIOXIDE (CARBON DIOXIDE)-THE CARBON DIOXIDE ASSAY IS USED FOR THE QUANTITATION OF CARBON DIOXIDE IN HUMAN SERUM OR PLASMA.,AMYLASE(AMYLASE)-THE AMYLASE ASSAY IS USED FOR THE QUANTITATION OF AMYLASE IN HUMAN SERUM, PLASMA, OR URINE.,ALANINE AMINOTRANSFERASE (ALANINE AMINOTRANSFERASE)-THE ALANINE AMINOTRANSFERASE (ALT) ASSAY IS USED FOR THE QUANTITATION OF ALANINE AMINOTRANSFERASE IN HUMAN SERUM OR PLASMA.

54	IMP/IVD/2018/000030	1.License Holder Name: PAMMVI EXPORT PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTI DRUG OF ABUSE URINE TEST (PANEL)(INSTANT-VIEW MULTI DRUG OF ABUSE URINE TEST (PANEL))-INTENDED TO BE USED IN VITRO FOR THE EXAMINATION OF URINE SPECIMEN SOLELY FOR THE PURPOSE OF SCREENING POTENTIAL ABUSE OF ONE OR MORE DRUGS.,TROPONIN I RAPID TEST- WHOLE BLOOD/ SERUM(INSTANT-VIEW TROPONIN I WHOLE BLOOD/SERUM TEST (CASSETTE))-FOR THE RAPID QUALITATIVE DETECTION OF CARDIAC TROPONIN I (CTNI) IN HUMAN WHOLE BLOOD OR SERUM,PCP SINGLE PANEL (CASSETTE)(INSTANT-VIEW PHENCYCLIDINE (PCP) CASSETTE TEST)-INTENDED TO PROVIDE QUALITATIVE SCREENING RESULTS FOR PHENCYCLIDINE (PCP) IN HUMAN URINE,THC SINGLE PANEL (CASSETTE)(INSTANT-VIEW MARIJUANA (THC) URINE CASSETTE TEST)-INTENDED TO BE USED TO DETECT 11-NOR-9-THC-9-CARBOXYLIC ACID (THC), A MAJOR METABOLITE OF MARIJUANA, IN HUMAN URINE

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55	IMP/IVD/2018/000031	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVIA CENTAUR TOTAL HCG (THCG) (ADVIA CENTAUR TOTAL HCG (THCG))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN SERUM USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THE RESULTS OBTAINED FROM HCG SPECIMENS ARE USED AS AN AID IN THE ASSESSMENT OF PREGNANCY STATUS. THIS ASSAY DETECTS THE INTACT HCG MOLECULE AND FREE BETA-SUBUNITS OF THE HCG MOLECULE., ADVIA CENTAUR CALIBRATOR A(CAL A)(ADVIA CENTAUR CALIBRATOR A(CAL A))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FOLLOWING ASSAYS USING ADVIA CENTAUR® OR ACS:180® SYSTEMS: FT3 T3 T4 TUP FT4 THEO2 ,ATELLICA IM ANTIHEPATITIS B CORE TOTAL (HBCT)(ATELLICA IM ANTIHEPATITIS B CORE TOTAL (HBCT))-THE ATELLICA™ IM ANTI-HEPATITIS B CORE TOTAL (HBCT) ASSAY IS FOR IN VITRO-DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF TOTAL ANTIBODIES TO THE CORE ANTIGEN OF THE HEPATITIS B VIRUS (HBV) IN HUMAN SERUM AND PLASMA (EDTA) USING THE ATELLICA™ IM ANALYZER. THIS ASSAY CAN BE USED AS AN AID IN THE DIAGNOSIS OF INDIVIDUALS WITH ACUTE OR CHRONIC HEPATITIS B VIRUS (HBV) INFECTION AND IN THE DETERMINATION OF THE CLINICAL STATUS OF HBV-INFECTED INDIVIDUALS IN CONJUNCTION WITH OTHER HBV SEROLOGICAL MARKERS FOR THE LABORATORY DIAGNOSIS OF HBV DISEASE ASSOCIATED WITH HBV INFECTION. THIS ASSAY CAN ALSO BE USED AS AN AID IN THE DIFFERENTIAL DIAGNOSIS IN INDIVIDUALS DISPLAYING SIGNS AND SYMPTOMS OF HEPATITIS IN WHOM ETIOLOGY IS UNKNOWN. , ADVIA CENTAUR HA (HA)(ADVIA CENTAUR HA (HA))-THE ADVIA CENTAUR HYALURONIC ACID (HA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF HYALURONIC ACID IN HUMAN SERUM USING THE ADVIA CENTAUR SYSTEMS. THE HA ASSAY IS A COMPONENT OF THE ELF TEST WHICH IS INDICATED, IN CONJUNCTION WITH OTHER LABORATORY FINDINGS AND CLINICAL ASSESSMENTS, AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF THE SEVERITY OF LIVER FIBROSIS IN PATIENTS WITH SIGNS AND SYMPTOMS OF CHRONIC LIVER DISEASE. THIS TEST IS NOT INTENDED FOR USE ON ANY OTHER SYSTEM. ,ADVIA CENTAUR HER- 2/NEU CALIBRATOR (H2N CAL) (ADVIA CENTAUR HER- 2/NEU CALIBRATOR (H2N CAL))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING ADVIA CENTAUR OR ACS: 180 HER-2/NEU ASSAYS , ADVIA CENTAUR ELF QUALITY CONTROL (ELF QC)(ADVIA CENTAUR ELF QUALITY CONTROL (ELF QC))-FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND

	ACCURACY OF THE ELF TEST AND OF THE HA, PIIINP, AND TIMP- 1 ASSAYS ON THE ADVIA CENTAUR SYSTEMS. ,ADVIA CENTAUR BRAHMS PROCALCITONIN (PCT) (ADVIA CENTAUR BRAHMS PROCALCITONIN (PCT))-THE ADVIA CENTAUR® BRAHMS PROCALCITONIN (PCT) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, AND SODIUM HEPARIN) USING THE ADVIA CENTAUR CP SYSTEM. THE ADVIA CENTAUR BRAHMS PCT ASSAY IS INTENDED FOR USE, IN CONJUNCTION WITH OTHER LABORATORY FINDINGS AND CLINICAL ASSESSMENTS, AS AN AID IN: THE RISK ASSESSMENT OF CRITICALLY ILL PATIENTS ON THEIR FIRST DAY OF INTENSIVE CARE UNIT (ICU) ADMISSION FOR PROGRESSION TO SEVERE SEPSIS AND SEPTIC SHOCK. • ASSESSING THE CUMULATIVE 28-DAY RISK OF ALL-CAUSE MORTALITY FOR PATIENTS DIAGNOSED WITH SEVERE SEPSIS OR SEPTIC SHOCK IN THE ICU OR WHEN OBTAINED IN THE EMERGENCY DEPARTMENT OR OTHER MEDICAL WARDS PRIOR TO ICU ADMISSION, USING PERCENT CHANGE IN PCT LEVEL OVER TIME. • DECISION-MAKING ON ANTIBIOTIC THERAPY FOR PATIENTS WITH SUSPECTED OR CONFIRMED LOWER RESPIRATORY TRACT INFECTIONS (LRTI) – DEFINED AS COMMUNITY-ACQUIRED PNEUMONIA (CAP), ACUTE BRONCHITIS, AND ACUTE EXACERBATION OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (AECOPD) – IN AN INPATIENT SETTING OR AN EMERGENCY DEPARTMENT. • DECISION-MAKING ON ANTIBIOTIC DISCONTINUATION FOR PATIENTS WITH SUSPECTED OR CONFIRMED SEPSIS. ,FT3 MASTER CURVE MATERIAL (FT3 MCM)(FT3 MASTER CURVE MATERIAL (FT3 MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR SYSTEMS FT3 ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM. ,ADVIA CENTAUR HCV QUALITY CONTROL (HCV QC) (ADVIA CENTAUR HCV QUALITY CONTROL (HCV QC))-FOR MONITORING THE PERFORMANCE OF THE HCV ASSAY ON THE ADVIA CENTAUR® SYSTEMS. THE PERFORMANCE OF THE HCV QUALITY CONTROL MATERIAL HAS NOT BEEN ESTABLISHED WITH ANY OTHER ANTI-HCV ASSAY ,ADVIA CENTAUR HBCT QUALITY CONTROL MATERIAL (HBCT QC)(ADVIA CENTAUR HBCT QUALITY CONTROL MATERIAL (HBCT QC))-FOR MONITORING THE PERFORMANCE OF THE HBC TOTAL ASSAY ON THE ADVIA CENTAUR SYSTEMS. THE PERFORMANCE OF THE HBC TOTAL QUALITY CONTROL MATERIAL HAS NOT BEEN ESTABLISHED WITH ANY OTHER ANTI-HBC TOTAL ASSAYS. ,ADVIA CENTAUR ENHANCED ESTRADIOL (EE2) (ADVIA CENTAUR ENHANCED ESTRADIOL (EE2))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN

	HUMAN SERUM AND PLASMA (HEPARINIZED AND EDTA) USING THE ADVIA CENTAUR, ADVIA CENTAUR XP AND ADVIA CENTAUR CP SYSTEMS., ADVIA CENTAUR HIV AG/AB COMBO (CHIV)(ADVIA CENTAUR HIV AG/AB COMBO (CHIV))-THE ADVIA CENTAUR HIV AG/AB COMBO (CHIV) ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUSES TYPE 1 (INCLUDING GROUP “O”) AND TYPE 2, IN SERUM AND PLASMA (POTASSIUM-EDTA) TO AID IN THE DIAGNOSIS OF HIV INFECTION, USING THE ADVIA CENTAUR, ADVIA CENTAUR XP AND ADVIA CENTAUR CP SYSTEMS. ,ADVIA CENTAUR CYCLOSPORINE CALIBRATOR (CSA CAL) (ADVIA CENTAUR CYCLOSPORINE CALIBRATOR (CSA CAL))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR® SYSTEMS CYCLOSPORINE ASSAY. ,ADVIA CENTAUR GENTAMICIN CALIBRATOR (GENT CAL) (ADVIA CENTAUR GENTAMICIN CALIBRATOR (GENT CAL))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR® OR ACS:180 GENTAMICIN ASSAYS. ,ADVIA CENTAUR CA19-9 MASTER CURVE MATERIAL (CA19-9 MCM)(ADVIA CENTAUR CA19-9 MASTER CURVE MATERIAL (CA19-9 MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR SYSTEM CA 19-9TM ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ADVIA CENTAUR HBC IGM QUALITY CONTROL (AHBCM QC) (ADVIA CENTAUR HBC IGM QUALITY CONTROL (AHBCM QC))-ADVIA CENTAUR® SYSTEMS. THE PERFORMANCE OF THE HBC IGM QUALITY CONTROL MATERIAL HAS NOT BEEN ESTABLISHED WITH ANY OTHER ANTI-HBC IGM ASSAYS.,ADVIA CENTAUR CKMB DILUENT (ADVIA CENTAUR CKMB DILUENT)- THE ADVIA CENTAUR CKMB DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY. ,ADVIA CENTAUR HBC TOTAL ASSAY (HBCT) (ADVIA CENTAUR HBC TOTAL ASSAY (HBCT))-THE ADVIA CENTAUR CP HBC TOTAL ASSAY IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE DETERMINATION OF TOTAL ANTIBODIES TO THE CORE ANTIGEN OF THE HEPATITIS B VIRUS (HBC TOTAL) IN HUMAN SERUM OR EDTA PLASMA USING THE ADVIA CENTAUR CP SYSTEM. THIS ASSAY CAN BE USED AS AN AID IN THE DIAGNOSIS OF INDIVIDUALS WITH ACUTE OR CHRONIC HEPATITIS B VIRUS (HBV) INFECTION AND IN THE DETERMINATION OF THE CLINICAL STATUS OF HBV INFECTED INDIVIDUALS IN CONJUNCTION WITH OTHER HBV SEROLOGICAL MARKERS FOR THE LABORATORY DIAGNOSIS OF HBV DISEASE ASSOCIATED WITH HBV INFECTION. THIS ASSAY CAN ALSO BE USED AS AN AID IN THE DIFFERENTIAL DIAGNOSIS IN INDIVIDUALS

	DISPLAYING SIGNS AND SYMPTOMS OF HEPATITIS IN WHOM ETIOLOGY IS UNKNOWN. ,ADVIA CENTAUR CARCINOEMBRY ONIC ANTIGEN DILUENT (CEA DIL)(ADVIA CENTAUR CARCINOEMBRY ONIC ANTIGEN DILUENT (CEA DIL))-THE ADVIA CENTAUR CEA DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY.,ADVIA CENTAUR CALIBRATOR U (CAL U)(ADVIA CENTAUR CALIBRATOR U (CAL U))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FOLLOWING ASSAYS USING ADVIA CENTAUR OR ACS:180 SYSTEMS. ,ADVIA CENTAUR FOLATE DILUENT (ADVIA CENTAUR FOLATE DILUENT)-THE ADVIA CENTAUR FOL DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY. , ADVIA CENTAUR CALIBRATOR B (CAL B)(ADVIA CENTAUR CALIBRATOR B (CAL B))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FOLLOWING ASSAYS USING ADVIA CENTAUR SYSTEMS. ,CENTAUR THYROXINE DILUENT (T4 DIL) (CENTAUR THYROXINE DILUENT (T4 DIL))-THE ADVIA CENTAUR T4 DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY. ,ADVIA CENTAUR HBC IGM (AHBCM) (ADVIA CENTAUR HBC IGM (AHBCM))-THE ADVIA CENTAUR® HBC IGM (AHBCM) ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGM RESPONSE TO THE CORE ANTIGEN OF THE HEPATITIS B VIRUS (HBC IGM) IN HUMAN SERUM OR PLASMA (EDTA, LITHIUM OR SODIUM HEPARINIZED) USING THE ADVIA CENTAUR, ADVIA CENTAUR XP AND ADVIA CENTAUR CP SYSTEMS. THIS ASSAY IS USED IN COMBINATION WITH OTHER HEPATITIS B VIRUS (HBV) MARKER ASSAYS TO DEFINE THE CLINICAL STATUS OF KNOWN HBV INFECTED PATIENTS OR IT CAN BE COMBINED WITH OTHER HBV, HAV (HEPATITIS A VIRUS), AND HCV (HEPATITIS C VIRUS) ASSAYS FOR THE DIAGNOSIS OF PATIENTS PRESENTING SYMPTOMS OF ACUTE VIRAL HEPATITIS. ,ADVIA CENTAUR HER- 2/NEU MASTER CURVE MATERIAL (H2N MCM)(ADVIA CENTAUR HER- 2/NEU MASTER CURVE MATERIAL (H2N MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® HER-2/NEU ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM., CHIV QUALITY CONTROL KIT (CHIV QC)(CHIV QUALITY CONTROL KIT (CHIV QC))-THE ADVIA CENTAUR HIV AG/AB COMBO (CHIV) ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUSES TYPE 1 (INCLUDING GROUP “O”) AND TYPE 2, IN SERUM AND PLASMA (POTASSIUM-EDTA) TO AID IN THE DIAGNOSIS OF HIV INFECTION, USING THE ADVIA CENTAUR, ADVIA CENTAUR XP AND ADVIA CENTAUR CP SYSTEMS. ,ADVIA

	CENTAUR TRIIODOTHYRONIN E (T3) (ADVIA CENTAUR TRIIODOTHYRONIN E (T3))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) IN SERUM USING THE ADVIA CENTAUR CP, ADVIA CENTAUR, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. MEASUREMENTS OF TRIIODOTHYRONINE ARE USED IN THE DIAGNOSIS AND TREATMENT OF THYROID DISEASE. ,ADVIA CENTAUR MULTI-DILUENT 7 (MULTI DIL 7)(ADVIA CENTAUR MULTI-DILUENT 7 (MULTI DIL 7))-ADVIA CENTAUR MULTI-DILUENT 7 IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE RESPECTIVE ASSAY. , ADVIA CENTAUR ENHANCED ESTRADIOL MASTER CURVE MATERIAL (ADVIA CENTAUR ENHANCED ESTRADIOL MASTER CURVE MATERIAL) -THE ADVIA CENTAUR ENHANCED ESTRADIOL (EE2) MASTER CURVE MATERIALS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR ENHANCED ESTRADIOL ASSAY.,ADVIA CENTAUR EHIV QUALITY CONTROL MATERIAL (EHIV QC)(ADVIA CENTAUR EHIV QUALITY CONTROL MATERIAL (EHIV QC))-THE ADVIA CENTAUR HIV 1/O/2 ENHANCED (EHIV) ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO THE HUMAN IMMUNODEFICIENCY VIRUS TYPE 1, INCLUDING SUBTYPE O, AND/OR TYPE 2 IN SERUM OR PLASMA (EDTA, LITHIUM OR SODIUM HEPARINIZED) USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS.,ADVIA CENTAUR PHENYTOIN (PHTN) (ADVIA CENTAUR PHENYTOIN (PHTN))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF PHENYTOIN IN SERUM OR PLASMA USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. , LH2 MASTER CUREVE MATERIAL (LH MCM)(LH2 MASTER CUREVE MATERIAL (LH MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR LH ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM. ,ADVIA CENTAUR HCV (AHCV) (ADVIA CENTAUR HCV (AHCV))-THE ADVIA CENTAUR® HCV (AHCV) ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) ANTIBODIES TO HEPATITIS C VIRUS (HCV) IN HUMAN SERUM OR PLASMA (EDTA, LITHIUM OR SODIUM HEPARINIZED) USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS. THE ASSAY MAY BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL AND CLINICAL INFORMATION TO AID IN THE DIAGNOSIS OF INDIVIDUALS WITH SYMPTOMS OF HEPATITIS AND IN INDIVIDUALS AT RISK FOR HEPATITIS C INFECTION. ,ADVIA CENTAUR MYOGLOBIN MASTER

	CURVE MATERIAL (MYO MCM)(ADVIA CENTAUR MYOGLOBIN MASTER CURVE MATERIAL (MYO MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR MYOGLOBIN ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM. ,ADVIA CENTAUR HER- 2/NEU 1, 2 QUALITY CONTROL (H2N QC) (ADVIA CENTAUR HER- 2/NEU 1, 2 QUALITY CONTROL (H2N QC))-FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND THE ACCURACY OF THE ADVIA CENTAUR® HER-2/NEU ASSAY. , ADVIA CENTAUR FT3 (FT3)(ADVIA CENTAUR FT3 (FT3))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN SERUM USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS. MEASUREMENTS OF FREE TRIIODOTHYRONINE ARE USED IN THE DIAGNOSIS AND TREATMENT OF THYROID DISEASE. ,ADVIA CENTAUR FOLATE (ADVIA CENTAUR FOLATE)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF FOLATE IN SERUM OR RED BLOOD CELLS USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS. ,FOLLICLE STIMULATION HORMONE MASTER CURVE MATERIAL (FSH MCM)(FOLLICLE STIMULATION HORMONE MASTER CURVE MATERIAL (FSH MCM))-THE ADVIA CENTAUR FOLLICLE STIMULATING HORMONE (FSH) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR FSH ASSAY. ,ADVIA CENTAUR FOLATE ASCORBIC (LYOPHILIZED) ASCORBIC ACID DILUENT (ADVIA CENTAUR FOLATE ASCORBIC (LYOPHILIZED) ASCORBIC ACID DILUENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF FOLATE IN SERUM OR RED BLOOD CELLS USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT, AND ADVIA CENTAUR CP SYSTEMS. ,ADVIA CENTAUR (FSH)(ADVIA CENTAUR (FSH))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF FOLLICLE-STIMULATING HORMONE (FSH) IN SERUM USING THE ADVIA CENTAUR SYSTEMS.,ADVIA CENTAUR CA19-9 READYPACK (CA19-9)(ADVIA CENTAUR CA19-9 READYPACK (CA19-9))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE, SERIAL DETERMINATION OF CA 19-9 IN HUMAN SERUM AND TO AID IN THE MANAGEMENT OF PATIENTS WITH GI CARCINOMA USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THE TEST IS INTENDED FOR USE AS AN AID IN MONITORING PATIENTS PREVIOUSLY TREATED FOR GI CANCER. SERIAL TESTING FOR CA 19-9 IN THE SERUM OF PATIENTS WHO ARE CLINICALLY FREE OF DISEASE SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL METHODS USED FOR THE

	EARLY DETECTION OF CANCER RECURRENCE. THE TEST IS ALSO INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF GI CANCER PATIENTS WITH METASTATIC DISEASE BY MONITORING THE PROGRESSION OR REGRESSION OF DISEASE IN RESPONSE TO TREATMENT. THE ADVIA CENTAUR CA 19-9 ASSAY IS NOT INTENDED FOR USE ON ANY OTHER SYSTEM.,ADVIA CENTAUR FERRITIN (FER) (ADVIA CENTAUR FERRITIN (FER))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF FERRITIN IN SERUM OR PLASMA USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS TO AID IN THE DIAGNOSIS OF IRON DEFICIENCY ANEMIA AND IRON OVERLOAD, ADVIA CENTAUR EE2 DILUENT(ADVIA CENTAUR EE2 DILUENT)-THE ADVIA CENTAUR EE2 DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY.,ADVIA CENTAUR MULTI-DILUENT 4 (MULTI-DIL 4) (ADVIA CENTAUR MULTI-DILUENT 4 (MULTI-DIL 4))-ADVIA CENTAUR MULTI-DILUENT 4 IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE RESPECTIVE ASSAY,ADVIA CENTAUR PHENOBARBITAL CALIBRATOR (PHNB CAL)(ADVIA CENTAUR PHENOBARBITAL CALIBRATOR (PHNB CAL))-FOR IN VITRO DIAGNOSTIC USE CALIBRATING THE ADVIA CENTAUR® OR ACS:180® PHENOBARBITAL ASSAYS.,ADVIA CENTAUR DIG MASTER CURVE MATERIAL (DIG MCM) (ADVIA CENTAUR DIG MASTER CURVE MATERIAL (DIG MCM))-THE ADVIA CENTAUR® DIGOXIN (DIG) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR DIGOXIN ASSAY., ATELLICA IM HEPATITIS B SURFACE ANTIGEN II (HBSII)(ATELLICA IM HEPATITIS B SURFACE ANTIGEN II (HBSII))-THE ATELLICA™ IM HEPATITIS B SURFACE ANTIGEN II (HBSII) ASSAY IS FOR IN VITRO-DIAGNOSTIC USE IN THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, SODIUM HEPARIN, AND SODIUM CITRATE) USING THE ATELLICA™ IM ANALYZER. THE ASSAY MAY BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL AND CLINICAL INFORMATION TO DIAGNOSE INDIVIDUALS WITH ACUTE OR CHRONIC HEPATITIS B INFECTION. THE ASSAY MAY ALSO BE USED TO SCREEN FOR HEPATITIS B INFECTION IN PREGNANT WOMEN TO IDENTIFY NEONATES WHO ARE AT RISK OF ACQUIRING HEPATITIS B DURING THE PERINATAL PERIOD. , ADVIA CENTAUR LH(LH)(ADVIA CENTAUR LH(LH))- FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN SERUM USING THE ADVIA CENTAUR, ADVIA CENTAUR XP AND ADVIA CP SYSTEMS. , ADVIA CENTAUR THYROXINE MASTER CURVE MATERIAL (T4 MCM) (ADVIA CENTAUR THYROXINE MASTER CURVE MATERIAL (T4 MCM))-

	THE ADVIA CENTAUR THYROXINE (T4) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR T4 ASSAY.,ADVIA CENTAUR FER MASTER CURVE MATERIAL (FER MCM)(ADVIA CENTAUR FER MASTER CURVE MATERIAL (FER MCM))-THE ADVIA CENTAUR® FERRITIN (FER) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR FER ASSAY. , ADVIA CENTAUR PHENOBARBITAL (PHNB)(ADVIA CENTAUR PHENOBARBITAL (PHNB))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF PHENOBARBITAL IN SERUM OR PLASMA USING THE ADVIA CENTAUR®, ADVIA CENTAUR CP, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS.,ADVIA CENTAUR CORTISOL URINE RECONSTITUTION BUFFER (COR RECON)(ADVIA CENTAUR CORTISOL URINE RECONSTITUTION BUFFER (COR RECON))-THE URINE RECONSTITUTION BUFFER IS USED TO RECONSTITUTE URINE SAMPLES THAT HAVE BEEN EXTRACTED AS DESCRIBED IN URINARY CORTISOL EXTRACTION PROCEDURE. EXTRACTED URINARY CORTISOL LEVELS ARE DETERMINED ON RECONSTITUTED URINE SAMPLES USING THE ADVIA CENTAUR SYSTEMS.,ADVIA CENTAUR CA19-9 DILUENT (CA19- 9 DIL)(ADVIA CENTAUR CA19-9 DILUENT (CA19- 9 DIL))-THE ADVIA CENTAUR CA 19-9 DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY.,ADVIA CENTAUR CORTISOL (COR)(ADVIA CENTAUR CORTISOL (COR))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CORTISOL IN SERUM OR URINE USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS. MEASUREMENTS OF CORTISOL ARE USED IN THE DIAGNOSIS AND TREATMENT OF DISORDERS OF THE ADRENAL GLAND.,ATELLICA IM CA 125II (ATELLICA IM CA 125II)-THE ATELLICA™ IM CA 125II™ (CA 125II™) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE, SERIAL DETERMINATION OF CA 125 IN HUMAN SERUM AND TO AID IN THE MANAGEMENT OF PATIENTS WITH OVARIAN CARCINOMA USING THE ATELLICA™ IM ANALYZER. THE TEST IS INTENDED FOR USE AS AN AID IN MONITORING PATIENTS PREVIOUSLY TREATED FOR OVARIAN CANCER. SERIAL TESTING FOR CA 125 IN THE SERUM OF PATIENTS WHO ARE CLINICALLY FREE OF DISEASE SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL METHODS USED FOR THE EARLY DETECTION OF CANCER RECURRENCE. THE TEST IS ALSO INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF OVARIAN CANCER PATIENTS WITH METASTATIC DISEASE BY MONITORING THE PROGRESSION OR REGRESSION OF DISEASE IN RESPONSE TO TREATMENT. IT IS RECOMMENDED THAT THE ATELLICA IM CA 125II

	ASSAY BE USED UNDER THE ORDER OF A PHYSICIAN TRAINED AND EXPERIENCED IN THE MANAGEMENT OF GYNECOLOGICAL CANCERS. THIS ASSAY IS NOT INTENDED FOR SCREENING OR DIAGNOSIS OF OVARIAN CANCER OR FOR USE ON ANY OTHER SYSTEM.,ADVIA CENTAUR MYOGLOBIN (MYO)(ADVIA CENTAUR MYOGLOBIN (MYO))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN SERUM OR PLASMA AND AS AN AID IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS.,ATELLICA IM FREE PROSTATESPECIFIC ANTIGEN (FPSA)(ATELLICA IM FREE PROSTATESPECIFIC ANTIGEN (FPSA))-THE ATELLICA™ IM FREE PROSTATESPECIFIC ANTIGEN (FPSA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF FREE PROSTATESPECIFIC ANTIGEN IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. THE ATELLICA IM FPSA ASSAY IS INTENDED TO BE USED IN CONJUNCTION WITH THE ATELLICA IM PSA ASSAY IN MEN AGED 50 YEARS OR OLDER WITH TOTAL PSA VALUES BETWEEN 4 AND 10 NG/ML AND A DIGITAL RECTAL EXAM (DRE) NONSUSPICIOUS FOR CANCER TO DETERMINE THE PERCENT FREE PSA VALUE. THE PERCENT FREE PSA VALUE CAN BE USED AS AN AID IN DISCRIMINATING BETWEEN PROSTATE CANCER AND BENIGN PROSTATIC DISEASE. PROSTATE BIOPSY IS REQUIRED FOR THE DIAGNOSIS OF PROSTATE CANCER.,CA 125 II MASTER CURVE MATERIAL (CA 125 LL MCM) (CA 125 II MASTER CURVE MATERIAL (CA 125 LL MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR CA 125II ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ADVIA CENTAUR CARCINOEMBRY ONIC ANTIGEN MASTER CURVE MATERIAL (CEA MCM)(ADVIA CENTAUR CARCINOEMBRY ONIC ANTIGEN MASTER CURVE MATERIAL (CEA MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® CEA ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM,CA 125 LL CALIBRATOR (CA 125 LL CAL)(CA 125 LL CALIBRATOR (CA 125 LL CAL))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR SYSTEMS CA 125II ASSAY. ,ADVIA CENTAUR TOTAL HCG DILUENT (THCG DIL)(ADVIA CENTAUR TOTAL HCG DILUENT (THCG DIL))-THE ADVIA CENTAUR THCG DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY.,ADVIA CENTAUR CA 125 II (CA 125II) (ADVIA CENTAUR CA 125 II (CA 125II))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE, SERIAL DETERMINATION OF CA 125 IN HUMAN SERUM AND TO AID IN THE

	MANAGEMENT OF PATIENTS WITH OVARIAN CARCINOMA USING THE ADVIA CENTAUR, ADVIA CENTAUR XP AND ADVIA CENTAUR CP SYSTEMS. THE TEST IS INTENDED FOR USE AS AN AID IN MONITORING PATIENTS PREVIOUSLY TREATED FOR OVARIAN CANCER. SERIAL TESTING FOR CA 125 IN THE SERUM OF PATIENTS WHO ARE CLINICALLY FREE OF DISEASE SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL METHODS USED FOR THE EARLY DETECTION OF CANCER RECURRENCE. THE TEST IS ALSO INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF OVARIAN CANCER PATIENTS WITH METASTATIC DISEASE BY MONITORING THE PROGRESSION OR REGRESSION OF DISEASE IN RESPONSE TO TREATMENT. IT IS RECOMMENDED THAT THE ADVIA CENTAUR CA 125II ASSAY BE USED UNDER THE ORDER OF A PHYSICIAN TRAINED AND EXPERIENCED IN THE MANAGEMENT OF GYNECOLOGICAL CANCERS. THIS ASSAY IS NOT INTENDED FOR SCREENING OR DIAGNOSIS OF OVARIAN CANCER OR FOR USE ON ANY OTHER SYSTEM. ,ATELLICA IM PROSTATESPECIFIC ANTIGEN (PSA)(ATELLICA IM PROSTATESPECIFIC ANTIGEN (PSA))-THE ATELLICA™ IM PROSTATESPECIFIC ANTIGEN (PSA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF PROSTATESPECIFIC ANTIGEN IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. THIS ASSAY IS INDICATED FOR THE MEASUREMENT OF SERUM PSA, IN CONJUNCTION WITH A DIGITAL RECTAL EXAM (DRE), AS AN AID IN THE DETECTION OF PROSTATE CANCER IN MEN AGED 50 YEARS AND OLDER. THIS ASSAY IS FURTHER INDICATED AS AN AID IN THE MANAGEMENT (MONITORING) OF PATIENTS WITH PROSTATE CANCER,ADVIA CENTAUR CORTISOL MASTER CURVE MATERIAL (COR MCM) (ADVIA CENTAUR CORTISOL MASTER CURVE MATERIAL (COR MCM))-THE ADVIA CENTAUR® CORTISOL (COR) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR CORTISOL ASSAY. ,ATELLICA IM CA 19-9 (CA 19-9)(ATELLICA IM CA 19-9 (CA 19-9))-THE ATELLICA™ IM CA 199™ (CA 199) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE, SERIAL DETERMINATION OF CA 199 IN HUMAN SERUM AND TO AID IN THE MANAGEMENT OF PATIENTS WITH GASTROINTESTINAL (GI) CARCINOMA USING THE ATELLICA™ IM ANALYZER. THE TEST IS INTENDED FOR USE AS AN AID IN MONITORING PATIENTS PREVIOUSLY TREATED FOR GI CANCER. SERIAL TESTING FOR CA 199 IN THE SERUM OF PATIENTS WHO ARE CLINICALLY FREE OF DISEASE SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL METHODS USED FOR THE EARLY DETECTION OF CANCER RECURRENCE. THE TEST IS ALSO INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF GI CANCER PATIENTS WITH METASTATIC DISEASE BY MONITORING

	THE PROGRESSION OR REGRESSION OF DISEASE IN RESPONSE TO TREATMENT. THE ATELLICA IM CA 199 ASSAY IS NOT INTENDED FOR USE ON ANY OTHER SYSTEM.,ADVIA CENTAUR DIGOXIN (DIG) (ADVIA CENTAUR DIGOXIN (DIG))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF DIGOXIN IN SERUM USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS. ,ATELLICA IM ALPHA FETOPROTEIN (AFP)(ATELLICA IM ALPHA FETOPROTEIN (AFP))-THE ATELLICA™ IM ALPHA FETOPROTEIN (AFP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALPHA-FETOPROTEIN USING THE ATELLICA™ IM ANALYZER FOR: • HUMAN SERUM AND AMNIOTIC FLUID FROM SPECIMENS OBTAINED AT 15–20 WEEKS GESTATION, AS AN AID IN DETECTING OPEN NEURAL TUBE DEFECTS (NTDS) WHEN USED IN CONJUNCTION WITH ULTRASONOGRAPHY AND AMNIOGRAPHY TESTING; • HUMAN SERUM, AS AN AID IN MANAGING NON-SEMINOMATOUS TESTICULAR CANCER WHEN USED IN CONJUNCTION WITH PHYSICAL EXAMINATION, HISTOLOGY/PATHOLOGY, AND OTHER CLINICAL EVALUATION PROCEDURES., ADVIA CENTAUR (ELF CAL)(ADVIA CENTAUR (ELF CAL))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE HA, PIIINP, AND TIMP-1 ASSAYS ON THE ADVIA CENTAUR SYSTEMS. , ATELLICA IM CA 15-3 (CA 15-3)(ATELLICA IM CA 15-3 (CA 15-3))-THE ATELLICA™ IM CA 153® (CA 153) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE SERIAL DETERMINATION OF CANCER ANTIGEN CA 153 IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. WHEN USED IN CONJUNCTION WITH OTHER CLINICAL AND DIAGNOSTIC PROCEDURES, SERIAL TESTING WITH THE ATELLICA IM CA 153 ASSAY IS USEFUL FOR MONITORING THE COURSE OF DISEASE AND THERAPY IN METASTATIC BREAST CANCER PATIENTS, AND FOR DETECTION OF RECURRENCE IN PREVIOUSLY TREATED STAGE II, WITH GREATER THAN TWO POSITIVE LYMPH NODES, OR STAGE III BREAST CANCER PATIENTS. THIS ASSAY IS NOT INTENDED FOR USE ON ANY OTHER SYSTEM.,ADVIA CENTAUR HIV 1/O/2 ENHANCED (EHIV)(ADVIA CENTAUR HIV 1/O/2 ENHANCED (EHIV))-THE ADVIA CENTAUR HIV 1/O/2 ENHANCED (EHIV) ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO THE HUMAN IMMUNODEFICIENCY VIRUS TYPE 1, INCLUDING SUBTYPE O, AND/OR TYPE 2 IN SERUM OR PLASMA (EDTA, LITHIUM OR SODIUM HEPARINIZED) USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS. ,ADVIA CENTAUR TIMP-1(ADVIA CENTAUR TIMP-1)-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR THEOPHYLLINE 2 ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS

	UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ADVIA CENTAUR FT4 MASTER CURVE MATERIAL (FT4 MCM)(ADVIA CENTAUR FT4 MASTER CURVE MATERIAL (FT4 MCM))-THE ADVIA CENTAUR® FREE THYROXINE (FT4) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR FT4 ASSAY. ,ADVIA CENTAUR CALIBRATOR 27 (ADVIA CENTAUR CALIBRATOR 27)-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR SYSTEMS THEOPHYLLINE 2 ASSAY ,ADVIA CENTAUR FT4 (FT4)(ADVIA CENTAUR FT4 (FT4))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN SERUM OR PLASMA (HEPARINIZED OR EDTA), USING THE ADVIA CENTAUR, ADVIA CENTAUR XP AND ADVIA CENTAUR CP SYSTEMS. MEASUREMENTS OF FREE THYROXINE ARE USED IN THE DIAGNOSIS AND TREATMENT OF THYROID DISEASE. , ATELLICA IM ANTI-HEPATITIS B SURFACE ANTIGEN 2 (AHBS2) (ATELLICA IM ANTI-HEPATITIS B SURFACE ANTIGEN 2 (AHBS2))-THE ATELLICA™ IM ANTI-HEPATITIS B SURFACE ANTIGEN 2 (AHBS2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF TOTAL ANTIBODIES TO HEPATITIS B SURFACE ANTIGEN IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER. THE ASSAY RESULTS MAY BE USED AS AN AID IN THE DETERMINATION OF SUSCEPTIBILITY TO HEPATITIS B VIRUS (HBV) INFECTION IN INDIVIDUALS PRIOR TO OR FOLLOWING HBV VACCINATION OR WHERE VACCINATION STATUS IS UNKNOWN. ASSAY RESULTS MAY BE USED WITH OTHER HBV SEROLOGICAL MARKERS FOR THE LABORATORY DIAGNOSIS OF HBV DISEASE ASSOCIATED WITH HBV INFECTION. A REACTIVE ASSAY RESULT WILL ALLOW A DIFFERENTIAL DIAGNOSIS IN INDIVIDUALS DISPLAYING SIGNS AND SYMPTOMS OF HEPATITIS IN WHOM ETIOLOGY IS UNKNOWN.,ADVIA CENTAUR GENTAMICIN (GENT)(ADVIA CENTAUR GENTAMICIN (GENT)) -FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF GENTAMICIN IN SERUM OR PLASMA USING THE ADVIA CENTAUR, ADVIA CENTAUR XP AND ADVIA CENTAUR CP SYSTEMS.,ADVIA CENTAUR CALIBRATOR 30(ADVIA CENTAUR CALIBRATOR 30)- FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FOLLOWING ASSAY(S) USING ADVIA CENTAUR, ADVIA CENTAUR XP, AND ADVIA CENTAUR CP SYSTEMS: ENHANCED ESTRADIOL (EE2)., VERSANT® SAMPLE PREPARATION 1.0 REAGENTS,BOX 2(VERSANT® SAMPLE PREPARATION 1.0 REAGENTS,BOX 2)-THE VERSANT® SAMPLE PREPARATION 1.0 REAGENTS KIT IS INTENDED TO BE USED, ALONG WITH THE VERSANT KPCR MOLECULAR SYSTEM SAMPLE PREPARATION MODULE (SP MODULE), FOR THE ISOLATION AND

	PURIFICATION OF NUCLEIC ACIDS FOR IN VITRO DIAGNOSTIC APPLICATIONS. THE PRODUCT IS INTENDED FOR USE BY LABORATORY PROFESSIONALS TRAINED IN MOLECULAR BIOLOGY TECHNIQUES. END USERS ARE RESPONSIBLE FOR VALIDATING LABORATORY DEVELOPED METHODS USED IN CONJUNCTION WITH THESE REAGENTS. RESULTS GENERATED USING THE SAMPLE PREPARATION PROCEDURE IN CONJUNCTION WITH ANY DIAGNOSTIC ASSAY SHOULD BE INTERPRETED WITH REGARD TO OTHER CLINICAL OR LABORATORY FINDINGS. FOR IN VITRO DIAGNOSTIC USE. , ADVIA CENTAUR HAV TOTAL (AHAVT) (ADVIA CENTAUR HAV TOTAL (AHAVT))-THE ADVIA CENTAUR HAV TOTAL (HAVT) ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF TOTAL ANTIBODIES TO HEPATITIS A VIRUS (ANTI-HAV) IN HUMAN NEONATAL, PEDIATRIC, AND ADULT SERUM OR PLASMA (POTASSIUM EDTA, LITHIUM OR SODIUM HEPARINIZED) USING THE ADVIA CENTAUR CP, ADVIA CENTAUR, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THIS ANTI-HAV ASSAY IS INDICATED AS AN AID IN THE DIAGNOSIS OF PREVIOUS OR ONGOING HEPATITIS A VIRAL INFECTION OR IN THE IDENTIFICATION OF HAV-SUSCEPTIBLE INDIVIDUALS FOR VACCINATION. ,ATELLICA IM VITAMIN D TOTAL (VITD)(ATELLICA IM VITAMIN D TOTAL (VITD))-THE ATELLICA™ IM VITAMIN D TOTAL (VITD) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL 25(OH)VITAMIN D IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, AND SODIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER. THE ATELLICA IM VITD ASSAY IS INTENDED AS AN AID IN THE DETERMINATION OF VITAMIN D SUFFICIENCY.,ADVIA CENTAUR PROLACTIN (PRL)(ADVIA CENTAUR PROLACTIN (PRL))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF PROLACTIN IN SERUM USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. ,ATELLICA IM VITAMIN B12 (VB12)(ATELLICA IM VITAMIN B12 (VB12))-THE ATELLICA™ IM VITAMIN B12 (VB12) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF VITAMIN B 12 IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER.,ADVIA CENTAUR PIIINP (ADVIA CENTAUR PIIINP)-THE ADVIA CENTAUR AMINO-TERMINAL PROPEPTIDE OF TYPE III PROCOLLAGEN (PIIINP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF AMINO-TERMINAL PROPEPTIDE OF TYPE III PROCOLLAGEN IN HUMAN SERUM USING THE ADVIA CENTAUR SYSTEMS. THE ADVIA CENTAUR PIIINP ASSAY IS A COMPONENT OF THE ADVIA CENTAUR ELF TEST WHICH IS INDICATED, IN CONJUNCTION WITH OTHER LABORATORY FINDINGS AND CLINICAL ASSESSMENTS, AS AN AID IN

	THE DIAGNOSIS AND ASSESSMENT OF THE SEVERITY OF LIVER FIBROSIS IN PATIENTS WITH SIGNS AND SYMPTOMS OF CHRONIC LIVER DISEASE. ,ATELLICA IM FOLATE (FOL)(ATELLICA IM FOLATE (FOL))-THE ATELLICA™ IM FOLATE (FOL) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN SERUM AND RED BLOOD CELLS USING THE ATELLICA™ IM ANALYZER., ADVIA CENTAUR RUBELLA M (RUB M) (ADVIA CENTAUR RUBELLA M (RUB M))-FOR IN VITRO DIAGNOSTIC USE FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO THE RUBELLA VIRUS IN SERUM OR PLASMA USING THE ADVIA CENTAUR CP, ADVIA CENTAUR, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS., ATELLICA IM CREATINE KINASE MB (CKMB)(ATELLICA IM CREATINE KINASE MB (CKMB))-THE ATELLICA™ IM CREATINE KINASE MB (CKMB) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CKMB IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM ANTI-HEPATITIS B E ANTIGEN (AHBE)(ATELLICA IM ANTI-HEPATITIS B E ANTIGEN (AHBE))-THE ATELLICA™ IM ANTI-HEPATITIS B E ANTIGEN (AHBE) ASSAY IS FOR IN VITRO-DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF ANTIBODY RESPONSE TO THE E ANTIGEN OF THE HEPATITIS B VIRUS (HBV) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, AND SODIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER. USE THIS ASSAY IN COMBINATION WITH OTHER HBV MARKER ASSAYS TO DEFINE THE CLINICAL STATUS OF KNOWN HBV-INFECTED PATIENTS.,ATELLICA IM BTYPE NATRIURETIC PEPTIDE (BNP)(ATELLICA IM BTYPE NATRIURETIC PEPTIDE (BNP))-THE ATELLICA™ IM BTYPE NATRIURETIC PEPTIDE (BNP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF BTYPE NATRIURETIC PEPTIDE IN HUMAN PLASMA (EDTA) USING THE ATELLICA™ IM ANALYZER. THIS ASSAY IS INDICATED FOR THE MEASUREMENT OF PLASMA BNP AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF THE SEVERITY OF HEART FAILURE. IN PATIENTS WITH ACUTE CORONARY SYNDROMES (ACS), THIS TEST, IN CONJUNCTION WITH OTHER KNOWN RISK FACTORS, CAN ALSO BE USED TO PREDICT SURVIVAL AS WELL AS TO PREDICT THE LIKELIHOOD OF FUTURE HEART FAILURE. THIS ASSAY IS NOT INTENDED FOR USE ON ANY OTHER SYSTEM.,ATELLICA IM HEPATITIS B E ANTIGEN (HBEAG)(ATELLICA IM HEPATITIS B E ANTIGEN (HBEAG))-THE ATELLICA™ IM HEPATITIS B E ANTIGEN (HBEAG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF THE HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, AND SODIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER. THIS ASSAY IS USED IN COMBINATION WITH OTHER HEPATITIS B VIRUS

	(HBV) MARKER ASSAYS TO DEFINE THE CLINICAL STATUS OF KNOWN HBV INFECTED PATIENTS. USE THIS ASSAY AS AN AID IN DIAGNOSIS OF INDIVIDUALS WITH ACUTE AND CHRONIC HEPATITIS B INFECTION. ,ATELLICA IM ANTI-THYROGLOBULIN (ATG)(ATELLICA IM ANTI-THYROGLOBULIN (ATG))-THE ATELLICA™ IM ANTI-THYROGLOBULIN (ATG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF AUTOANTIBODIES AGAINST THYROGLOBULIN IN HUMAN SERUM AND PLASMA (EDTA) USING THE ATELLICA™ IM ANALYZER. THIS ASSAY IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF HASHIMOTO'S AND GRAVES' DISEASES, WHICH ARE AUTOIMMUNE DISEASES AFFECTING THE THYROID GLAND.,ATELLICA IM HEPATITIS B CORE ANTIGEN (AHBCM)(ATELLICA IM HEPATITIS B CORE ANTIGEN (AHBCM))-THE ATELLICA™ IM HEPATITIS B CORE ANTIGEN (AHBCM) ASSAY IS FOR IN VITRO-DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF IGM RESPONSE TO THE CORE ANTIGEN OF THE HEPATITIS B VIRUS (HBC IGM) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, AND SODIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER. THIS ASSAY IS USED IN COMBINATION WITH OTHER HEPATITIS B VIRUS (HBV) MARKER ASSAYS TO DEFINE THE CLINICAL STATUS OF KNOWN HBV-INFECTED PATIENTS OR IT CAN BE COMBINED WITH OTHER HBV, HAV (HEPATITIS A VIRUS), AND HCV (HEPATITIS C VIRUS) ASSAYS FOR THE DIAGNOSIS OF PATIENTS PRESENTING SYMPTOMS OF ACUTE VIRAL HEPATITIS. ,ATELLICA IM B-TYPE NATRIURETIC PEPTIDE MASTER CURVE MATERIAL (BNP MCM)(ATELLICA IM B-TYPE NATRIURETIC PEPTIDE MASTER CURVE MATERIAL (BNP MCM))-THE ATELLICA™ IM B-TYPE NATRIURETIC PEPTIDE MASTER CURVE MATERIAL (BNP MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM BNP ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM., ATELLICA IM CARCINOEMBRYONIC ANTIGEN (CEA)(ATELLICA IM CARCINOEMBRYONIC ANTIGEN (CEA))-THE ATELLICA™ IM CARCINOEMBRYONIC ANTIGEN (CEA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN IN HUMAN SERUM TO AID IN THE MANAGEMENT OF CANCER PATIENTS IN WHOM CHANGING CONCENTRATIONS OF CEA ARE OBSERVED USING THE ATELLICA™ IM ANALYZER,ATELLICA IM VITAMIN D TOTAL MASTER CURVE MATERIAL (VITD MCM)(ATELLICA IM VITAMIN D TOTAL MASTER CURVE MATERIAL (VITD MCM))-THE ATELLICA™ IM VITAMIN D TOTAL MASTER CURVE MATERIAL (VITD MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM VITD ASSAY. , ADVIA CENTAUR® HER-

	2/NEU ASSAY (H2N)(ADVIA CENTAUR® HER-2/NEU ASSAY (H2N))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE HER-2/NEU PROTEIN IN HUMAN SERUM USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. HER-2/NEU VALUES OBTAINED MAY BE USED IN THE FOLLOW-UP AND MONITORING OF PATIENTS WITH METASTATIC BREAST CANCER WHOSE INITIAL SERUM HER-2/NEU LEVEL IS GREATER THAN 15 NG/ML. HER-2/NEU VALUES SHOULD BE USED IN CONJUNCTION WITH INFORMATION AVAILABLE FROM CLINICAL AND OTHER DIAGNOSTIC PROCEDURES IN THE MANAGEMENT OF BREAST CANCER. THE CLINICAL UTILITY OF THE MEASUREMENT OF HER-2/NEU IN SERUM AS A PROGNOSTIC INDICATOR FOR EARLY RECURRENCE AND IN THE MANAGEMENT OF PATIENTS ON IMMUNOTHERAPY HAS NOT BEEN FULLY ESTABLISHED. THIS TEST SHOULD BE USED BY OR UNDER THE ORDER OF A PHYSICIAN. THIS ASSAY IS NOT INTENDED FOR USE ON ANY OTHER SYSTEM.,ATELLICA IM B-TYPE NATRIURETIC PEPTIDE CALIBRATOR (BNP CAL)(ATELLICA IM B-TYPE NATRIURETIC PEPTIDE CALIBRATOR (BNP CAL))-THE ATELLICA™ IM BTYPE NATRIURETIC PEPTIDE CALIBRATOR (BNP CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM BNP ASSAY USING THE ATELLICA™ IM ANALYZER,ADVIA CENTAUR HBSAG II(ADVIA CENTAUR HBSAG II)-THE ADVIA CENTAUR® HBSAGII (HBSII) ASSAY IS AN IN VITRO IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM-HEPARIN, SODIUM-HEPARIN, OR SODIUM-CITRATE) USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THE ASSAY MAY BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL AND CLINICAL INFORMATION TO DIAGNOSE INDIVIDUALS WITH ACUTE OR CHRONIC HEPATITIS B INFECTION. THE ASSAY MAY ALSO BE USED TO SCREEN FOR HEPATITIS B INFECTION IN PREGNANT WOMEN TO IDENTIFY NEONATES WHO ARE AT RISK OF ACQUIRING HEPATITIS B DURING THE PERINATAL PERIOD.,ATELLICA IM B- TYPE NATRIURETIC PEPTIDE QUALITY CONTROL (BNP QC)(ATELLICA IM B- TYPE NATRIURETIC PEPTIDE QUALITY CONTROL (BNP QC))-THE ATELLICA™ IM BTYPE NATRIURETIC PEPTIDE QUALITY CONTROL (BNP QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND THE ACCURACY OF THE ATELLICA IM BNP ASSAY USING THE ATELLICA™ IM ANALYZE,ADVIA CENTAUR TOTAL HCG MASTER CURVE MATERIAL (THCG MCM) (ADVIA CENTAUR TOTAL HCG MASTER CURVE MATERIAL (THCG MCM))-THE ADVIA CENTAUR® TOTAL HCG (THCG) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND

	REPORTABLE RANGE OF THE ADVIA CENTAUR THCG ASSAY., ATELLICA IM CREATINE KINASE MB DILUENT (CKMB DIL)(ATELLICA IM CREATINE KINASE MB DILUENT (CKMB DIL))-ATELLICA IM CREATINE KINASE MB DILUENT (CKMB DIL) USED AS DILUENT,ADVIA CENTAUR FOLATE MASTER CURVE MATERIAL (MCM) (ADVIA CENTAUR FOLATE MASTER CURVE MATERIAL (MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® SYSTEM FOLATE ASSAYS. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ATELLICA IM CREATINE KINASE MB CALIBRATOR (CKMB CAL)(ATELLICA IM CREATINE KINASE MB CALIBRATOR (CKMB CAL))-THE ATELLICA™ IM CREATINE KINASE MB CALIBRATOR (CKMB CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM CKMB ASSAY USING THE ATELLICA™ IM ANALYZER., ADVIA CENTAUR FOLATE DTT/RELEASIN G AGENT (ADVIA CENTAUR FOLATE DTT/RELEASIN G AGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF FOLATE IN SERUM OR RED BLOOD CELLS USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT, AND ADVIA CENTAUR CP SYSTEMS. ,ATELLICA IM CREATINE KINASE MB MASTER CURVE MATERIAL (CKMB MCM) (ATELLICA IM CREATINE KINASE MB MASTER CURVE MATERIAL (CKMB MCM))-THE ATELLICA™ IM CREATINE KINASE MB MASTER CURVE MATERIAL (CKMB MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM CKMB ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM, ADVIA CENTAUR RUBELLA M QUALITY CONTROL MATERIAL (RUB M QC) (ADVIA CENTAUR RUBELLA M QUALITY CONTROL MATERIAL (RUB M QC))-FOR MONITORING THE PERFORMANCE OF THE ADVIA CENTAUR RUBELLA M ASSAY ON THE ADVIA CENTAUR SYSTEMS. THE PERFORMANCE OF THE ADVIA CENTAUR RUBELLA M QUALITY CONTROL MATERIAL HAS NOT BEEN ESTABLISHED WITH ANY OTHER RUBELLA IGM ASSAYS. ,ATELLICA IM VITAMIN D TOTAL DILUENT (VITD DIL)(ATELLICA IM VITAMIN D TOTAL DILUENT (VITD DIL))-ATELLICA IM VITAMIN D TOTAL DILUENT (VITD DIL) INTENDED TO BE USED FOR DIULTION OF ASSAY.,ADVIA CENTAUR RUBELLA G (RUB G) (ADVIA CENTAUR RUBELLA G (RUB G))- FOR IN VITRO DIAGNOSTIC USE FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTIBODIES TO THE RUBELLA VIRUS IN SERUM OR PLASMA USING THE ADVIA CENTAUR CP, ADVIA CENTAUR, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. ,ATELLICA IM VITAMIN D TOTAL QUALITY CONTROL (VITD QC)(ATELLICA IM VITAMIN D TOTAL QUALITY CONTROL (VITD QC))-THE ATELLICA™ IM VITAMIN D TOTAL QUALITY CONTROL (VITD QC) IS FOR IN VITRO DIAGNOSTIC USE IN

	MONITORING THE PRECISION AND THE ACCURACY OF THE ATELLICA IM VITD ASSAY USING THE ATELLICA™ IM ANALYZER.,ADVIA CENTAUR TRIIODOTHYRONIN E DILUENT (T3 DIL) (ADVIA CENTAUR TRIIODOTHYRONIN E DILUENT (T3 DIL))-THE ADVIA CENTAUR T3 DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY. ,ATELLICA IM VB12 MASTER CURVE MATERIAL (VB12 MCM)(ATELLICA IM VB12 MASTER CURVE MATERIAL (VB12 MCM))-THE ATELLICA™ IM VITAMIN B12 MASTER CURVE MATERIAL (VB12 MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA IM VB12 ASSAY.,ADVIA CENTAUR THYROXINE (T4) (ADVIA CENTAUR THYROXINE (T4))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN SERUM USING THE ADVIA CENTAUR CP, ADVIA CENTAUR, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. MEASUREMENTS OF THYROXINE ARE USED IN THE DIAGNOSIS AND TREATMENT OF THYROID DISEASE. ,ATELLICA IM VB12 DILUENT(ATELLICA IM VB12 DILUENT)-ATELLICA IM VITAMIN B12 DILUENT (VB12 DIL) IS INTENDED TO BE USED FOR DILUTION OF ASSAYS,ADVIA CENTAUR AHBS2 MASTER CURVE MATERIAL(ADVIA CENTAUR AHBS2 MCM)-ADVIA CENTAUR AHBS2 MCM THE ADVIA CENTAUR® ANTI-HBS2 (AHBS2) MASTER CURVE MATERIAL (MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR AHBS2 ASSAY.,ATELLICA IM T3/T4/ VB12 ANC (ATELLICA IM T3/T4/ VB12 ANC)-ATELLICA IM T3/T4/ VB12 ANC , ADVIA CENTAUR ANTI HBS-2 QUALITY CONTROL MATERIAL(ADVIA CENTAUR ANTI HBS-2 QUALITY CONTROL MATERIAL)-THE ADVIA CENTAUR® ANTI-HBS2 QUALITY CONTROL IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ADVIA CENTAUR ANTI-HBS2 ASSAY USING THE ADVIA CENTAUR® SYSTEMS.,ATELLICA IM VB12 DTT / REL(ATELLICA IM VB12 DTT / REL) -ATELLICA IM VB12 DTT / REL USED AS RELEASING AGENT,ADVIA CENTAUR ANTI-HBS2(ADVIA CENTAUR ANTI-HBS2)-THE ADVIA CENTAUR® ANTI-HBS2 (AHBS2) ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF TOTAL ANTIBODIES TO HEPATITIS B SURFACE ANTIGEN IN HUMAN SERUM OR PLASMA (EDTA OR HEPARINIZED) USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS. THE ASSAY RESULTS MAY BE USED AS AN AID IN THE DETERMINATION OF SUSCEPTIBILITY TO HEPATITIS B VIRUS (HBV) INFECTION IN INDIVIDUALS PRIOR TO OR FOLLOWING HBV VACCINATION OR WHERE VACCINATION STATUS IS UNKNOWN. ASSAY RESULTS MAY BE USED WITH OTHER HBV SEROLOGICAL MARKERS FOR THE LABORATORY DIAGNOSIS OF HBV

	DISEASE ASSOCIATED WITH HBV INFECTION. A REACTIVE ASSAY RESULT WILL ALLOW A DIFFERENTIAL DIAGNOSIS IN INDIVIDUALS DISPLAYING SIGNS AND SYMPTOMS OF HEPATITIS IN WHOM ETIOLOGY IS UNKNOWN.,ATELLICA IM CALIBRATOR C(ATELLICA IM CALIBRATOR C)-THE ATELLICA™ IM CALIBRATOR C (CAL C) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FOLLOWING ATELLICA IM ASSAYS USING THE ATELLICA™ IM ANALYZER: VB12 AND FER., ADVIA CENTAUR CPSA (CPSA) (ADVIA CENTAUR CPSA (CPSA))-THIS IN VITRO DIAGNOSTIC ASSAY IS INTENDED TO QUANTITATIVELY MEASURE COMPLEXED PROSTATE SPECIFIC ANTIGEN (CPSA) IN HUMAN SERUM USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT, ADVIA CENTAUR CP SYSTEMS. THIS ASSAY IS INDICATED FOR THE MEASUREMENT OF THE SERUM COMPLEXED PSA IN CONJUNCTION WITH THE DIGITAL RECTAL EXAM (DRE) AS AN AID IN THE DETECTION OF PROSTATE CANCER IN MEN AGED 50 YEARS OR OLDER. BIOPSY OF THE PROSTATE IS REQUIRED FOR THE DIAGNOSIS OF PROSTATE CANCER. THIS ASSAY IS FURTHER INDICATED AS AN AID IN THE MANAGEMENT(MONITORING) OF PROSTATE CANCER PATIENTS,ATELLICA IM FOLATE DTT/RELEASING AGENT (FOL DTT / REL)(ATELLICA IM FOLATE DTT/RELEASING AGENT (FOL DTT / REL))-ATELLICA IM FOL DTT/REL USED AS RELEASING AGENT.,ADVIA CENTAUR SYPHILIS (SYPH)(ADVIA CENTAUR SYPHILIS (SYPH))-THE ADVIA CENTAUR SYPHILIS (SYPH) ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO TREPONEMA PALLADIUM IN HUMAN SERUM OR PLASMA(EDTA,LITHIUM OR SODIUM HEPARINIZED,CITRATE USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT, ADVIA CENTAUR CP SYSTEMS AS AN AID IN THE DIAGNOSIS OF SYPHILIS.,ATELLICA IM RBC FOLATE ASCORBIC ACID/ ASCORBIC ACID DILUENT (RBC FOL)(ATELLICA IM RBC FOLATE ASCORBIC ACID/ ASCORBIC ACID DILUENT (RBC FOL))-ATELLICA IM RBC FOLATE ASCORBIC ACID/ ASCORBIC ACID DILUENT (RBC FOL) USED AS DILUENT.,ATELLICA IM ANDROSTENEDIONE MASTER CURVE MATERIAL (ANDRO MCM)(ATELLICA IM ANDROSTENEDIONE MASTER CURVE MATERIAL (ANDRO MCM))-THE ATELLICA® IM ANDROSTENEDIONE MASTER CURVE MATERIAL (ANDRO MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA® IM ANDRO ASSAY.,ATELLICA IM FOLATE MASTER CURVE MATERIAL (FOL MCM)(ATELLICA IM FOLATE MASTER CURVE MATERIAL (FOL MCM))-THE ATELLICA™ IM FOLATE MASTER CURVE MATERIAL (FOL MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM FOL ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-

	POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM, ATELLICA IM ANDROSTENEDIONE (ANDRO)(ATELLICA IM ANDROSTENEDIONE (ANDRO))-THE ATELLICA IM® ANDROSTENEDIONE (ANDRO) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF ANDROSTENEDIONE IN HUMAN SERUM AND PLASMA (DIPOTASSIUM EDTA AND LITHIUM HEPARIN) USING THE ATELLICA IM ANALYZER. ANDROSTENEDIONE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF INDIVIDUALS WITH EXCESSIVE LEVELS OF ANDROGEN (MALE SEX HORMONE) PRODUCTION.,ATELLICA IM ANCILLARY PROBE WASH 1 (APW1)(ATELLICA IM ANCILLARY PROBE WASH 1 (APW1))-ATELLICA IM APW1 USED AS AN ANCILLARY REAGENT PACK,ADVIA CENTAUR® ANDROSTENEDIONE MASTER CURVE MATERIAL (ANDRO MCM)(ADVIA CENTAUR® ANDROSTENEDIONE MASTER CURVE MATERIAL (ANDRO MCM))-THE ADVIA CENTAUR® ANDROSTENEDIONE MASTER CURVE MATERIAL (ANDRO MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR ANDRO ASSAY.,ATELLICA IM FOLATE DILUENT (FOL DIL)(ATELLICA IM FOLATE DILUENT (FOL DIL))-ATELLICA IM FOLATE DILUENT (FOL DIL) INTENDED TO BE USED FOR DILUTION OF ASSAY., ADVIA CENTAUR® ANDROSTENEDIONE (ANDRO)(ADVIA CENTAUR® ANDROSTENEDIONE (ANDRO))-THE ADVIA CENTAUR® ANDROSTENEDIONE (ANDRO) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF ANDROSTENEDIONE IN HUMAN SERUM AND PLASMA (DIPOTASSIUM EDTA AND LITHIUM HEPARIN) USING THE ADVIA CENTAUR CP SYSTEM. ANDROSTENEDIONE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF INDIVIDUALS WITH EXCESSIVE LEVELS OF ANDROGEN (MALE SEX HORMONE) PRODUCTION., ATELLICA IM CALIBRATOR 1 (CAL 1)(ATELLICA IM CALIBRATOR 1 (CAL 1))-THE ATELLICA™ IM CALIBRATOR 1 (CAL 1) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM ATG ASSAY USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM HEPATITIS C (AHCV) (ATELLICA IM HEPATITIS C (AHCV))-THE ATELLICA™ IM HEPATITIS C (AHCV) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) ANTIBODIES TO HEPATITIS C VIRUS (HCV) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, AND SODIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER. THE ASSAY MAY BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL AND CLINICAL INFORMATION TO AID IN THE DIAGNOSIS OF INDIVIDUALS WITH SYMPTOMS OF HEPATITIS AND IN INDIVIDUALS AT RISK FOR HEPATITIS C INFECTION. ,ATELLICA IM ANTI-THYROGLOBULIN QUALITY CONTROL (ATG QC)(ATELLICA IM ANTI-THYROGLOBULIN

	QUALITY CONTROL (ATG QC))-THE ATELLICA™ IM ANTITHYROGLOBULIN QUALITY CONTROL (ATG QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND THE ACCURACY OF THE ATELLICA IM ATG ASSAY USING THE ATELLICA™ IM ANALYZER.,ADVIA CENTAUR THEOPHYLLINE 2 (THEO 2) (ADVIA CENTAUR THEOPHYLLINE 2 (THEO 2))-THEOPHYLLINE (1,3-DIMETHYLXANTHINE) IS A POTENT BRONCHODILATOR AND RESPIRATORY STIMULANT THAT IS OFTEN USED PROPHYLACTICALLY TO CONTROL THE SYMPTOMS OF CHRONIC ASTHMA. THEOPHYLLINE ALSO IS USED TO TREAT ACUTE ASTHMATIC EPISODES, NEONATAL APNEA, CHEYNE-STOKES RESPIRATION, AND ACUTE PULMONARY EDEMA. THEOPHYLLINE HAS A NARROW THERAPEUTIC RANGE IN SERUM FROM 10 TO 20 G/ML (55.5 TO 111 MOL/L). TOXICITY MAY OCCUR WHEN SERUM THEOPHYLLINE LEVELS EXCEED 20 G/ML (111 MOL/L). TOXIC SIDE EFFECTS RANGE FROM HEADACHE AND SLIGHT NAUSEA TO CENTRAL NERVOUS SYSTEM DAMAGE OR DEATH. IN ADDITION, SERUM THEOPHYLLINE LEVELS BELOW 10 G/ML (55.5 MOL/L) MAY BE INEFFECTIVE IN TREATING CHRONIC ASTHMA. ,ATELLICA IM ANTI-THYROGLOBULIN MASTER CURVE MATERIAL (ATG MCM)(ATELLICA IM ANTI-THYROGLOBULIN MASTER CURVE MATERIAL (ATG MCM))-THE ATELLIC IM ANTI-THYROGLOBULIN MASTER CURVE MATERIAL (ATG MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM ATG ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ATELLICA IM MULTI-DILUENT 15(ATELLICA IM MULTI-DILUENT 15)-ATELLICA IM MULTI-DILUENT 15 IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE RESPECTIVE ASSAY.,ATELLICA IM ANTI-THYROGLOBULIN DILUENT (ATG DIL)(ATELLICA IM ANTI-THYROGLOBULIN DILUENT (ATG DIL))-ATELLICA IM ANTI-THYROGLOBULIN DILUENT (ATG DIL) IS USED FOR DILUTION OF ASSAY.,ATELLICA IM BRAHMS PROCALCITONIN MASTER CURVE MATERIAL (PCT MCM)(ATELLICA IM BRAHMS PROCALCITONIN MASTER CURVE MATERIAL (PCT MCM))-THE ATELLICA® IM BRAHMS PROCALCITONIN MASTER CURVE MATERIAL (PCT MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA® IM BRAHMS PCT ASSAY., VERSANT® SAMPLE PREPARATION 1.2 REAGENTS,BOX 1(VERSANT® SAMPLE PREPARATION 1.2 REAGENTS,BOX 1)-THE VERSANT SAMPLE PREPARATION 1.2 REAGENTS CAN BE USED MANUALLY OR WITH THE VERSANT KPCR MOLECULAR SYSTEM SAMPLE PREPARATION MODULE, FOR THE ISOLATION AND PURIFICATION OF DNA FROM HUMAN BLOOD SAMPLES FOR IN VITRO DIAGNOSTIC APPLICATIONS.

	THE PRODUCT IS INTENDED FOR USE BY LABORATORY PROFESSIONALS TRAINED IN MOLECULAR BIOLOGY TECHNIQUES. END USERS ARE RESPONSIBLE FOR VALIDATING LABORATORY DEVELOPED METHODS USED IN CONJUNCTION WITH THESE REAGENTS. RESULTS GENERATED USING THE SAMPLE PREPARATION PROCEDURE IN CONJUNCTION WITH ANY DIAGNOSTIC ASSAY SHOULD BE INTERPRETED WITH REGARD TO OTHER CLINICAL OR LABORATORY FINDINGS. FOR IN VITRO DIAGNOSTIC USE.,ATELLICA IM SYPHILIS (SYPH)(ATELLICA IM SYPHILIS (SYPH))-THE ATELLICA™ IM SYPHILIS (SYPH) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF ANTIBODIES TO TREPONEMA PALLIDUM IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, SODIUM HEPARIN, AND CITRATE) USING THE ATELLICA™ IM ANALYZER AS AN AID IN THE DIAGNOSIS OF SYPHILIS. ,VERSANT® SAMPLE PREPARATION 1.2 REAGENTS,BOX 2(VERSANT® SAMPLE PREPARATION 1.2 REAGENTS,BOX 2)-THE VERSANT SAMPLE PREPARATION 1.2 REAGENTS CAN BE USED MANUALLY OR WITH THE VERSANT KPCR MOLECULAR SYSTEM SAMPLE PREPARATION MODULE, FOR THE ISOLATION AND PURIFICATION OF DNA FROM HUMAN BLOOD SAMPLES FOR IN VITRO DIAGNOSTIC APPLICATIONS. THE PRODUCT IS INTENDED FOR USE BY LABORATORY PROFESSIONALS TRAINED IN MOLECULAR BIOLOGY TECHNIQUES. END USERS ARE RESPONSIBLE FOR VALIDATING LABORATORY DEVELOPED METHODS USED IN CONJUNCTION WITH THESE REAGENTS. RESULTS GENERATED USING THE SAMPLE PREPARATION PROCEDURE IN CONJUNCTION WITH ANY DIAGNOSTIC ASSAY SHOULD BE INTERPRETED WITH REGARD TO OTHER CLINICAL OR LABORATORY FINDINGS. FOR IN VITRO DIAGNOSTIC USE.,ADVIA CENTAUR BRAHMS PCT QUALITY CONTROL MATERIAL(ADVIA CENTAUR BRAHMS PCT QUALITY CONTROL MATERIAL)-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING ADVIA CENTAUR® SYSTEMS CKMB ASSAYS,VERSANT® SAMPLE PREPARATION 1.0 REAGENTS,BOX 1 (VERSANT® SAMPLE PREPARATION 1.0 REAGENTS,BOX 1)-THE VERSANT® SAMPLE PREPARATION 1.0 REAGENTS KIT IS INTENDED TO BE USED, ALONG WITH THE VERSANT KPCR MOLECULAR SYSTEM SAMPLE PREPARATION MODULE (SP MODULE), FOR THE ISOLATION AND PURIFICATION OF NUCLEIC ACIDS FOR IN VITRO DIAGNOSTIC APPLICATIONS. THE PRODUCT IS INTENDED FOR USE BY LABORATORY PROFESSIONALS TRAINED IN MOLECULAR BIOLOGY TECHNIQUES. END USERS ARE RESPONSIBLE FOR VALIDATING LABORATORY DEVELOPED METHODS USED IN CONJUNCTION WITH THESE REAGENTS. RESULTS GENERATED USING THE SAMPLE PREPARATION PROCEDURE IN CONJUNCTION WITH ANY DIAGNOSTIC ASSAY SHOULD BE INTERPRETED WITH REGARD TO OTHER CLINICAL

	OR LABORATORY FINDINGS. FOR IN VITRO DIAGNOSTIC USE. , ADVIA CENTAUR CKMB CALIBRATOR (ADVIA CENTAUR CKMB CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING ADVIA CENTAUR® SYSTEMS CKMB ASSAYS ,ADVIA CENTAUR HEPATITIS B E ANTIGEN (HBEAG) (ADVIA CENTAUR HEPATITIS B E ANTIGEN (HBEAG))-THE ADVIA CENTAUR® HBEAG ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF THE HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA USING THE ADVIA CENTAUR CP SYSTEM. THIS ASSAY IS USED IN COMBINATION WITH OTHER HEPATITIS B VIRUS (HBV) MARKER ASSAYS TO DEFINE THE CLINICAL STATUS OF KNOWN HBV INFECTED PATIENTS. USE THIS ASSAY AS AN AID IN DIAGNOSIS OF INDIVIDUALS WITH ACUTE AND CHRONIC HEPATITIS B INFECTION. ,ADVIA CENTAUR ACID/BASE REAGENTS(ADVIA CENTAUR ACID/BASE REAGENTS)-ADVIA CENTAUR ACID/BASE REAGENTS ARE A SYSTEM FLUID USED TO INITIATE THE CHEMILUMINESCENT REACTION. THEY ARE USED WITH ALL ADVIA CENTAUR ASSAYS.,ADVIA CENTAUR HAV IGM QUALITY CONTROL (AHAVM QC) (ADVIA CENTAUR HAV IGM QUALITY CONTROL (AHAVM QC))-FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE HAV IGM ASSAY ON THE ADVIA CENTAUR SYSTEMS. THE PERFORMANCE OF THE HAV IGM QUALITY CONTROL MATERIAL HAS NOT BEEN ESTABLISHED WITH ANY OTHER ANTI-HAV IGM ASSAYS ,ADVIA CENTAUR PROLACTIN MASTER CURVE MATERIAL (PRL MCM)(ADVIA CENTAUR PROLACTIN MASTER CURVE MATERIAL (PRL MCM))-THE ADVIA CENTAUR® PROLACTIN (PRL) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR PRL ASSAY.,ADVIA CENTAUR HAV IGM (AHAVM)(ADVIA CENTAUR HAV IGM (AHAVM))-THE ADVIA CENTAUR HAV IGM (AHAVM) ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGM RESPONSE TO THE HEPATITIS A VIRUS (HAV) IN HUMAN SERUM OR PLASMA (EDTA, LITHIUM OR SODIUM HEPARINIZED) USING THE ADVIA CENTAUR AND ADVIA CENTAUR XP SYSTEMS. THIS ASSAY IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF ACUTE OR RECENT INFECTION(USUALLY 6 MONTHS OR LESS) WITH HEPATITIS A VIRUS. , ADVIA CENTAUR PHENYTOIN CALIBRATOR (PHTN CAL) (ADVIA CENTAUR PHENYTOIN CALIBRATOR (PHTN CAL)) - FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR® OR ACS:180® PHENYTOIN ASSAYS. ,ADVIA CENTAUR HEPATITIS B SURFACE ANTIGEN II CONFIRMATORY (ADVIA CENTAUR HEPATITIS B SURFACE ANTIGEN II CONFIRMATORY)-THE ADVIA CENTAUR® HBSAG CONFIRMATORY (CONF) ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUALITATIVE CONFIRMATION

	OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OR PLASMA (EDTA, LITHIUM OR SODIUM HEPARIN, CITRATE) USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THE ASSAY IS INTENDED TO BE USED TO CONFIRM THE PRESENCE OF HBSAG IN SAMPLES THAT ARE REPEATEDLY REACTIVE USING THE ADVIA CENTAUR HBSAG ASSAY. , ADVIA CENTAUR HAV TOTAL QUALITY CONTROL (AHAVT QC) (ADVIA CENTAUR HAV TOTAL QUALITY CONTROL (AHAVT QC))-FOR MONITORING THE PERFORMANCE OF THE HAV TOTAL ASSAY ON ADVIA CENTAUR® SYSTEMS. THE PERFORMANCE OF THE HAV TOTAL QUALITY CONTROL MATERIAL HAS NOT BEEN ESTABLISHED WITH ANY OTHER ANTI-HAV TOTAL ASSAY. ,ADVIA CENTAUR PROBE WASH 3 (ADVIA CENTAUR PROBE WASH 3)-ADVIA CENTAUR PROBE WASH 3 IS FOR THE CLEANING OF PRIMARY REAGENT PROBES BETWEEN VARIOUS APPLICATIONS ,ADVIA CENTAUR CARCINOEMBRY ONIC ANTIGEN (CEA)(ADVIA CENTAUR CARCINOEMBRY ONIC ANTIGEN (CEA))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN CEA) IN SERUM TO AID IN THE MANAGEMENT OF CANCER PATIENTS IN WHOM CHANGING CONCENTRATIONS OF CEA ARE OBSERVED USING THE ADVIA CENTAUR AND ADVIA CENTAUR XP SYSTEMS.,ADVIA CENTAUR HBSAG CONFIRMATORY QUALITY CONTROL(ADVIA CENTAUR HBSAG CONFIRMATORY QUALITY CONTROL)-FOR MONITORING THE PERFORMANCE OF THE ADVIA CENTAUR® HBSAG, HBSAGII, AND HBSAG CONFIRMATORY ASSAYS ON THE ADVIA CENTAUR SYSTEMS. THE PERFORMANCE OF THE ADVIA CENTAUR HBSAG QUALITY CONTROL MATERIAL HAS NOT BEEN ESTABLISHED WITH ANY OTHER HBSAG OR HBSAG CONFIRMATORY ASSAYS. ,ADVIA CENTAUR RUBELLA G QUALITY CONTROL MATERIAL (RUBG QC) (ADVIA CENTAUR RUBELLA G QUALITY CONTROL MATERIAL (RUBG QC))-FOR MONITORING THE PERFORMANCE OF THE ADVIA CENTAUR RUBELLA G ASSAY ON THE ADVIA CENTAUR SYSTEMS. THE PERFORMANCE OF THE ADVIA CENTAUR RUBELLA G QUALITY CONTROL MATERIAL HAS NOT BEEN ESTABLISHED WITH ANY OTHER RUBELLA IGG ASSAYS. ,ADVIA CENTAUR MCM INTACT PARATHYROID HORMONE MASTER CURVE MATERIAL (IPTH MCM)(ADVIA CENTAUR MCM INTACT PARATHYROID HORMONE MASTER CURVE MATERIAL (IPTH MCM))-THE ADVIA CENTAUR® INTACT PARATHYROID HORMONE (PTH) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR INTACT PARATHYROID HORMONE (PTH) ASSAY.,ATELLICA IM HIV AG/AB COMBO (CHIV) (ATELLICA IM HIV AG/AB COMBO (CHIV))-THE ATELLICA™ IM HIV AG/AB COMBO (CHIV) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN

	THE SIMULTANEOUS QUALITATIVE DETECTION OF HUMAN MMUNODEFICIENCY VIRUS P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUSES TYPE 1 (INCLUDING GROUP “O”) AND TYPE 2 IN HUMAN SERUM AND PLASMA (EDTA), TO AID IN THE DIAGNOSIS OF HIV INFECTION, USING THE ATELLICA™ IM ANALYZER. 11. PRODUCT DESCRIPTION: THE ATELLICA™ IM HIV AG/AB COMBO (CHIV) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE SIMULTANEOUS QUALITATIVE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUSES TYPE 1 (INCLUDING GROUP “O”) AND TYPE 2 IN HUMAN SERUM AND PLASMA (EDTA), TO AID IN THE DIAGNOSIS OF HIV INFECTION, USING THE ATELLICA™ IM ANALYZER , ADVIA CENTAUR HBEAG QUALITY CONTROL MATERIAL (HBEAG QC) (ADVIA CENTAUR HBEAG QUALITY CONTROL MATERIAL (HBEAG QC))- FOR MONITORING THE PERFORMANCE OF THE HBEAG ASSAY ON THE ADVIA CENTAUR® SYSTEMS. THE PERFORMANCE OF THE HBEAG QUALITY CONTROL MATERIAL HAS NOT BEEN ESTABLISHED WITH ANY OTHER HBEAG ASSAY. ,ADVIA CENTAUR PHENYTOIN MASTER CURVE MATERIAL (PHTN MCM)(ADVIA CENTAUR PHENYTOIN MASTER CURVE MATERIAL (PHTN MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® PHENYTOIN ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ADVIA CENTAUR QC INTACT PARATHYROID HORMONE (IPTH) QUALITY CONTROL(ADVIA CENTAUR QC INTACT PARATHYROID HORMONE (IPTH) QUALITY CONTROL)-THE ADVIA CENTAUR® INTACT PARATHYROID HORMONE (PTH) QUALITY CONTROL IS FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND ACCURACY OF THE ADVIA CENTAUR INTACT PARATHYROID HORMONE (PTH) ASSAY.,ADVIA CENTAUR TRIIODOTHYRONIN E MASTER CURVE MATERIAL (T3 MCM) (ADVIA CENTAUR TRIIODOTHYRONIN E MASTER CURVE MATERIAL (T3 MCM)) -THE ADVIA CENTAUR TRIIODOTHYRONINE (T3) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR T3 ASSAY.,ADVIA CENTAUR INTACT PARATHYROID HORMONE (IPTH) (ADVIA CENTAUR INTACT PARATHYROID HORMONE (IPTH))-THE ADVIA CENTAUR® INTACT PARATHYROID HORMONE (PTH) REAGENT IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (PTH) IN HUMAN SERUM AND PLASMA USING THE ADVIA CENTAUR XP AND ADVIA CENTAUR XPT SYSTEMS. THIS ASSAY IS INTENDED TO BE USED TO AID IN THE DIFFERENTIAL DIAGNOSIS OF HYPERPARATHYROIDISM, HYPOPARATHYROIDISM, OR DISORDERS

	OF CALCIUM METABOLISM. THIS ASSAY CAN BE USED INTRA-OPERATIVELY,ATELLICA® IM SARS-COV-2 IGG QUALITY CONTROL (COV2G QC)(ATELLICA® IM SARS-COV-2 IGG QUALITY CONTROL (COV2G QC))-THE ATELLICA® IM SARS-COV-2 IGG QUALITY CONTROL (COV2G QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND ACCURACY OF THE ATELLICA® IM SARS-COV-2 IGG (COV2G) ASSAY USING THE ATELLICA® IM ANALYZER.,ADVIA CENTAUR MULTI- DILUENT 13(ADVIA CENTAUR MULTI- DILUENT 13)-ADVIA CENTAUR MULTI-DILUENT 13 IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE RESPECTIVE ASSAY. ,ADVIA CENTAUR ANCILLARY PROBE WASH 2 (ADVIA CENTAUR ANCILLARY PROBE WASH 2)-ADVIA CENTAUR ANCILLARY PROBE WASH 2 IS FOR THE CLEANING OF PRIMARY REAGENT PROBES BETWEEN VARIOUS APPLICATIONS.,ADVIA CENTAUR VB12 DILUENT (ADVIA CENTAUR VB12 DILUENT)-THE ADVIA CENTAUR VB12 DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY. ,ADVIA CENTAUR SARS-COV-2 TOTAL QUALITY CONTROL (COV2T QC) (ADVIA CENTAUR SARS-COV-2 TOTAL QUALITY CONTROL (COV2T QC))-THE ADVIA CENTAUR® SARS-COV-2 TOTAL QUALITY CONTROL (COV2T QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND ACCURACY OF THE ADVIA CENTAUR COV2T ASSAY USING THE ADVIA CENTAUR® SYSTEMS.,ADVIA CENTAUR CALIBRATOR C (VB12, FERRITIN) (ADVIA CENTAUR CALIBRATOR C (VB12, FERRITIN))- FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FOLLOWING ASSAYS USING ADVIA CENTAUR® SYSTEMS: VB12, FERRITIN ,ADVIA CENTAUR ANCILLARY PROBE WASH 3(ADVIA CENTAUR ANCILLARY PROBE WASH 3)-ADVIA CENTAUR ANCILLARY PROBE WASH 3 IS FOR THE CLEANING OF PRIMARY REAGENT PROBES BETWEEN VARIOUS APPLICATIONS.,ADVIA CENTAUR T3/T4/VB12 ANCILLARY REAGENT(ADVIA CENTAUR T3/T4/VB12 ANCILLARY REAGENT)-FOR USE AS AN ANCILLARY REAGENT WITH THE ADVIA CENTAUR T3, T4 AND VB12 ASSAYS USING THE ADVIA CENTAUR ANALYZER ,ATELLICA IM SARS-COV-2 TOTAL (COV2T) (ATELLICA IM SARS-COV-2 TOTAL (COV2T))-THE ATELLICA® IM SARS-COV-2 TOTAL (COV2T) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVEAND QUANTITATIVE DETECTION OF TOTAL ANTIBODIES (IGG AND IGM), INCLUDING NEUTRALIZING ANTIBODIES, TO SARS-COV-2 IN HUMAN SERUM AND PLASMA (EDTA AND LITHIUM HEPARIN) OBTAINED BYVENIPUNCTURE OR CAPILLARY PUNCTURE USING THE ATELLICA® IM ANALYZER.THIS ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF PATIENTS WITH SUSPECTED SARS-COV-2INFECTION AND AS AN AID IN IDENTIFYING PATIENTS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS-COV-2, INDICATING RECENT

	OR PRIOR INFECTION. A POSITIVE TEST RESULT MAY INDICATE VACCINE-DERIVEDANTIBODIES TO SARS-COV-2 IN VACCINATED INDIVIDUALS.,ADVIA CENTAUR VB12 DTT/RELEASING AGENT(ADVIA CENTAUR VB12 DTT/RELEASING AGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN SERUM OR PLASMA USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT, AND ADVIA CENTAUR CP SYSTEMS TO AID IN THE DIAGNOSIS OF IRON DEFICIENCY ANEMIA AND IRON OVERLOAD., ATELLICA IM CMV IGG QUALITY CONTROL (CMV IGG QC)(ATELLICA IM CMV IGG QUALITY CONTROL (CMV IGG QC))-THE ATELLICA® IM CMV IGG QUALITY CONTROL (CMV IGG QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM CMV IGG ASSAY USING THE ATELLICA® IM ANALYZER.,ADVIA CENTAUR VB12 MASTER CURVE MATERIAL (VB12 MCM) (ADVIA CENTAUR VB12 MASTER CURVE MATERIAL (VB12 MCM))-THE ADVIA CENTAUR® VITAMIN B12 (VB12) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR VB12 ASSAY. , ATELLICA IM NT-PROBNP (PBNP)(ATELLICA IM NT-PROBNP (PBNP))-THE ATELLICA® IM NTPROBNP (PBNP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF NTERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NTPROBNP) IN HUMAN SERUM AND PLASMA (DIPOTASSIUM EDTA AND LITHIUM HEPARIN) USING THE ATELLICA® IM ANALYZER. IN INDIVIDUALS SUSPECTED OF HAVING CONGESTIVE HEART FAILURE (CHF), MEASUREMENTS OF NTPROBNP ARE USED AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF SEVERITY., ADVIA CENTAUR VB12 (ADVIA CENTAUR VB12)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN SERUM OR PLASMA USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. ,ATELLICA IM CMV IGG (CMV IGG) (ATELLICA IM CMV IGG (CMV IGG))-THE ATELLICA® IM CMV IGG (CMV IGG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS (CMV) IN HUMAN PEDIATRIC AND ADULT SERUM AND PLASMA (DIPOTASSIUM EDTA AND LITHIUM HEPARIN) USING THE ATELLICA® IM ANALYZER. THE ASSAY IS USED TO DETERMINE CMV IGG SEROLOGICAL STATUS AND AS AN AID IN THE DIAGNOSIS OF CMV INFECTION.,ADVIA CENTAUR MULTI- DILUENT 10(ADVIA CENTAUR MULTI- DILUENT 10)-ADVIA CENTAUR MULTI-DILUENT 10 IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE RESPECTIVE ASSAY.,ADVIA CENTAUR® SARS-COV-2 IGG (COV2G) (ADVIA CENTAUR® SARS-COV-2 IGG (COV2G))-THE ADVIA CENTAUR® SARS-COV-2 IGG (COV2G) ASSAY IS FOR IN VITRO

	DIAGNOSTIC USE IN THE QUALITATIVE AND SEMI-QUANTITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA (EDTA AND LITHIUM HEPARIN) USING THE ADVIA CENTAUR® SYSTEMS.THIS ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF PATIENTS WITH SUSPECTED SARS-COV-2 INFECTION AND AS AN AID IN IDENTIFYING PATIENTS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS-COV-2, INDICATING RECENT OR PRIOR INFECTION.,ADVIA CENTAUR PROGESTERONE (PRGE) (ADVIA CENTAUR PROGESTERONE (PRGE))-THE ATELLICA™ IM PROGESTERONE (PRGE) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER.,ADVIA CENTAUR SARS-COV2 TOTAL (COV2T)(ADVIA CENTAUR SARS-COV2 TOTAL (COV2T))-THE ADVIA CENTAUR SARS-COV-2 TOTAL (COV2T) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETECTION OF TOTAL ANTIBODIES (INCLUDING IGG AND IGM) TO SARS-COV-2 IN HUMAN SERUM AND PLASMA (EDTA AND LITHIUM HEPARIN) USING THE ADVIA CENTAUR SYSTEMS. THIS ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF PATIENTS WITH SUSPECTED SARS-COV-2 INFECTION AND AS AN AID IN IDENTIFYING PATIENTS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARSCOV-2, INDICATING RECENT OR PRIOR INFECTION.,ADVIA CENTAUR HBSAG QUALITY CONTROL (ADVIA CENTAUR HBSAG QUALITY CONTROL)-FOR MONITORING THE PERFORMANCE OF THE ADVIA CENTAUR® HBSAG, HBSAGII, AND HBSAG CONFIRMATORY ASSAYS ON THE ADVIA CENTAUR SYSTEMS. THE PERFORMANCE OF THE ADVIA CENTAUR HBSAG QUALITY CONTROL MATERIAL HAS NOT BEEN ESTABLISHED WITH ANY OTHER HBSAG OR HBSAG CONFIRMATORY ASSAYS. ,ADVIA CENTAUR® SARS-COV-2 IGG QUALITY CONTROL (COV2G QC)(ADVIA CENTAUR® SARS-COV-2 IGG QUALITY CONTROL (COV2G QC))-THE ADVIA CENTAUR® SARS-COV-2 IGG QUALITY CONTROL (COV2G QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND ACCURACY OF THE ADVIA CENTAUR® SARS-COV-2 IGG(COV2G) ASSAY USING THE ADVIA CENTAUR® SYSTEMS. ,ADVIA CENTAUR MULTI- DILUENT 2(ADVIA CENTAUR MULTI- DILUENT 2)-ADVIA CENTAUR MULTI-DILUENT 2 IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE RESPECTIVE ASSAY., ATELLICA IM SARS-COV-2 TOTAL QUALITY CONTROL (COV2T QC) (ATELLICA IM SARS-COV-2 TOTAL QUALITY CONTROL (COV2T QC))-THE ATELLICA® IM SARS-COV-2 TOTAL QUALITY CONTROL (COV2T QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND ACCURACY OF THE ATELLICA IM COV2T ASSAY USING THE ATELLICA® IM ANALYZER., ADVIA CENTAUR PSA MASTER CURVE MATERIAL (PSA MCM) (ADVIA CENTAUR PSA MASTER CURVE

	MATERIAL (PSA MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® PSA ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM. , ATELLICA IM NT-PROBNP MASTER CURVE MATERIAL (PBNP MCM)(ATELLICA IM NT-PROBNP MASTER CURVE MATERIAL (PBNP MCM))-THE ATELLICA™ IM NT-PROBNP (PBNP) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM PBNP ASSAY. ,ADVIA CENTAUR CALIBRATOR Q (CAL Q)(ADVIA CENTAUR CALIBRATOR Q (CAL Q))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING ADVIA CENTAUR® OR ACS:180® PSA ASSAYS , ATELLICA® IM SARS-COV-2 IGG (COV2G)(ATELLICA® IM SARS-COV-2 IGG (COV2G))-THE ATELLICA® IM SARS-COV-2 IGG (COV2G) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMI-QUANTITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA (EDTA AND LITHIUM HEPARIN) USING THE ATELLICA® IM ANALYZER. THIS ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF PATIENTS WITH SUSPECTED SARS-COV-2 INFECTION AND AS AN AID IN IDENTIFYING PATIENTS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS- COV-2, INDICATING RECENT OR PRIOR INFECTION. ,ADVIA CENTAUR PROSTATE- SPECIFIC ANTIGEN (PSA) (ADVIA CENTAUR PROSTATE- SPECIFIC ANTIGEN (PSA))-THIS IN VITRO DIAGNOSTIC ASSAY IS INTENDED TO QUANTITATIVELY MEASURE PROSTATE-SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM USING THE ADVIA CENTAUR CP SYSTEM. THIS ASSAY IS INDICATED FOR THE MEASUREMENT OF SERUM PSA IN CONJUNCTION WITH DIGITAL RECTAL EXAM (DRE) AS AN AID IN THE DETECTION OF PROSTATE CANCER IN MEN AGED 50 YEARS AND OLDER. THIS ASSAY IS FURTHER INDICATED AS AN AID IN THE MANAGEMENT (MONITORING) OF PATIENTS WITH PROSTATE CANCER. ,ADVIA CENTAUR SARS-COV2 ANTIGEN (COV2AG)(ADVIA CENTAUR SARS-COV2 ANTIGEN (COV2AG))-THE ADVIA CENTAUR® SARS-COV-2 ANTIGEN (COV2AG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID ANTIGEN IN NASOPHARYNGEAL (NP) SWAB AND ANTERIOR NASAL (AN) SWAB SPECIMENS FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER WITHIN THE FIRST 7 DAYS OF SYMPTOM ONSET, OR FROM ASYMPTOMATIC INDIVIDUALS, USING THE ADVIA CENTAUR® XP AND ADVIA CENTAUR® XPT SYSTEMS. THIS ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF PATIENTS WITH SUSPECTED SARS-COV-2 INFECTION.,ADVIA CENTAUR HEPATITIS B SURFACE ANTIGEN II (ADVIA CENTAUR HEPATITIS B SURFACE ANTIGEN II)-THE ADVIA

	CENTAUR® HBSAGII (HBSII) ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM-HEPARIN, SODIUM-HEPARIN, OR SODIUM-CITRATE) USING THE ADVIA CENTAUR CP SYSTEM. THE ASSAY MAY BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL AND CLINICAL INFORMATION TO DIAGNOSE INDIVIDUALS WITH ACUTE OR CHRONIC HEPATITIS B INFECTION. THE ASSAY MAY ALSO BE USED TO SCREEN FOR HEPATITIS B INFECTION IN PREGNANT WOMEN TO IDENTIFY NEONATES WHO ARE AT RISK OF ACQUIRING HEPATITIS B DURING THE PERINATAL PERIOD. ,ATELLICA® IM SARS-COV-2 IGG (SCOVG) (ATELLICA® IM SARS-COV-2 IGG (SCOVG))-THE ATELLICA® IM SARS-COV-2 IGG (SCOVG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND QUANTITATIVE DETECTION OF IGG ANTIBODIES, INCLUDING NEUTRALIZING ANTIBODIES, TO SARS-COV-2 IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) OBTAINED BY VENIPUNCTURE OR CAPILLARY PUNCTURE USING THE ATELLICA® IM ANALYZER. THIS ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF PATIENTS WITH SUSPECTED SARS-COV-2 INFECTION AND AS AN AID IN IDENTIFYING PATIENTS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS-COV-2, INDICATING RECENT OR PRIOR INFECTION.,ADVIA CENTAUR PRGE CALIBRATOR E (CAL E) (ADVIA CENTAUR PRGE CALIBRATOR E (CAL E))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FOLLOWING ASSAYS USING ADVIA CENTAUR® SYSTEMS: CORTISOL PROGESTERONE TESTOSTERONE., ATELLICA IM SARS-COV-2 ANTIGEN CALIBRATOR (COV2AG CAL) (ATELLICA IM SARS-COV-2 ANTIGEN CALIBRATOR (COV2AG CAL))-THE ATELLICA® IM SARS-COV-2 ANTIGEN CALIBRATOR (COV2AG CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM COV2AG ASSAY USING AN ATELLICA® IMMUNOASSAY ANALYZER.,ADVIA CENTAUR PRGE MCM (ADVIA CENTAUR PRGE MCM)-THE ADVIA CENTAUR® PROGESTERONE (PRGE) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR PROGESTERONE ASSAY. ,ADVIA CENTAUR SARS-COV-2 ANTIGEN QUALITY CONTROL (COV2AG QC)(ADVIA CENTAUR SARS-COV-2 ANTIGEN QUALITY CONTROL (COV2AG QC))-THE ADVIA CENTAUR® SARS-COV-2 ANTIGEN QUALITY CONTROL (COV2AG QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND ACCURACY OF THE ADVIA CENTAUR COV2AG ASSAY USING THE ADVIA CENTAUR® SYSTEMS.,VERSANT® TISSUE PREPARATION REAGENTS KIT (BOX 3)(VERSANT® TISSUE PREPARATION REAGENTS KIT (BOX 3))-THE VERSANT® TISSUE PREPARATION REAGENTS ARE INTENDED FOR THE EXTRACTION OF NUCLEIC ACIDS (DNA AND RNA)

	FROM FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) TISSUE SECTIONS AND FRESH FROZEN (FF) TISSUES. THE PRODUCT IS INTENDED FOR USE BY LABORATORY PROFESSIONALS TRAINED IN MOLECULAR BIOLOGY TECHNIQUES. THE VERSANT TISSUE PREPARATION REAGENTS ARE DESIGNED FOR USE EITHER MANUALLY OR ON A TISSUE PREPARATION SYSTEM (TPS) CONSISTING OF A HAMILTON MICROLAB STARLET IVD INSTRUMENT MODIFIED TO PROCESS TISSUE SAMPLES USING A PROPRIETARY SIEMENS HEALTHCARE DIAGNOSTICS PROTOCOL. END USERS ARE RESPONSIBLE FOR VALIDATING LABORATORY-DEVELOPED METHODS USED IN CONJUNCTION WITH THESE REAGENTS AND FOR IMPLEMENTING APPROPRIATE QUALITY-CONTROL MEASURES. RESULTS GENERATED USING THE SAMPLE PREPARATION PROCEDURE IN CONJUNCTION WITH ANY DIAGNOSTIC ASSAY SHOULD BE INTERPRETED WITH REGARD TO OTHER CLINICAL OR LABORATORY FINDINGS. FOR IN VITRO DIAGNOSTIC USE.,ATELLICA IM SARS-COV-2 ANTIGEN QUALITY CONTROL (COV2AG QC) (ATELLICA IM SARS-COV-2 ANTIGEN QUALITY CONTROL (COV2AG QC))-THE ATELLICA® IM SARS-COV-2 ANTIGEN QUALITY CONTROL (COV2AG QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND ACCURACY OF THE ATELLICA IM COV2AG ASSAY USING AN ATELLICA® IMMUNOASSAY ANALYZER.,VERSANT® TISSUE PREPARATION REAGENTS KIT (BOX 2)(VERSANT® TISSUE PREPARATION REAGENTS KIT (BOX 2))-THE VERSANT® TISSUE PREPARATION REAGENTS ARE INTENDED FOR THE EXTRACTION OF NUCLEIC ACIDS (DNA AND RNA) FROM FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) TISSUE SECTIONS AND FRESH FROZEN (FF) TISSUES. THE PRODUCT IS INTENDED FOR USE BY LABORATORY PROFESSIONALS TRAINED IN MOLECULAR BIOLOGY TECHNIQUES. THE VERSANT TISSUE PREPARATION REAGENTS ARE DESIGNED FOR USE EITHER MANUALLY OR ON A TISSUE PREPARATION SYSTEM (TPS) CONSISTING OF A HAMILTON MICROLAB STARLET IVD INSTRUMENT MODIFIED TO PROCESS TISSUE SAMPLES USING A PROPRIETARY SIEMENS HEALTHCARE DIAGNOSTICS PROTOCOL. END USERS ARE RESPONSIBLE FOR VALIDATING LABORATORY-DEVELOPED METHODS USED IN CONJUNCTION WITH THESE REAGENTS AND FOR IMPLEMENTING APPROPRIATE QUALITY-CONTROL MEASURES. RESULTS GENERATED USING THE SAMPLE PREPARATION PROCEDURE IN CONJUNCTION WITH ANY DIAGNOSTIC ASSAY SHOULD BE INTERPRETED WITH REGARD TO OTHER CLINICAL OR LABORATORY FINDINGS. FOR IN VITRO DIAGNOSTIC USE.,COV2AG SAMPLE LYSIS REAGENT(COV2AG SAMPLE LYSIS REAGENT)-COV2AG SAMPLE LYSIS REAGENT IS FOR INACTIVATION OF NASAL SWAB SPECIMENS PRIOR TO PROCESSING SAMPLES WITH THE ADVIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

	CENTAUR COV2AG AND ATELLICA IM COV2AG ASSAYS., VERSANT® HBV DNA 1.0 ASSAY (KPCR) BOX 2(VERSANT® HBV DNA 1.0 ASSAY (KPCR) BOX 2)-THE VERSANT® HBV DNA 1.0 ASSAY (KPCR) IS AN IN VITRO NUCLEIC ACID AMPLIFICATION ASSAY FOR THE DIRECT QUANTITATION OF HUMAN HEPATITIS B VIRUS (HBV) DNA IN PLASMA OR SERUM OF HBV-INFECTED INDIVIDUALS OVER THE RANGE OF 13 IU/ML TO 7X108 IU/ML USING THE VERSANT KPCR MOLECULAR SYSTEM. THE ASSAY IS INTENDED TO BE USED IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS OF DISEASE STATUS TO AID IN THE MANAGEMENT OF HBV-INFECTED INDIVIDUALS UNDERGOING ANTIVIRAL THERAPY. THE VERSANT HBV DNA 1.0 ASSAY (KPCR) IS NOT INTENDED FOR USE AS A BLOOD DONOR SCREENING ASSAY FOR HBV OR AS A DIAGNOSTIC ASSAY TO CONFIRM THE PRESENCE OF HBV INFECTION. THIS ASSAY IS INTENDED FOR USE WITH THE VERSANT KPCR MOLECULAR SYSTEM. FOR IN VITRO DIAGNOSTIC USE.,ATELLICA® IM SARS-COV-2 IGG MASTER CURVE MATERIAL (SCOVG MCM)(ATELLICA® IM SARS-COV-2 IGG MASTER CURVE MATERIAL (SCOVG MCM))-THE ATELLICA® IM SARS-COV-2 IGG MASTER CURVE MATERIAL (SCOVG MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND MEASURING INTERVAL OF THE ATELLICA® IM SARS-COV-2 IGG (SCOVG) ASSAY.,VERSANT® HBV DNA 1.0 ASSAY (KPCR) BOX 1 (VERSANT® HBV DNA 1.0 ASSAY (KPCR) BOX 1)-THE VERSANT® HBV DNA 1.0 ASSAY (KPCR) IS AN IN VITRO NUCLEIC ACID AMPLIFICATION ASSAY FOR THE DIRECT QUANTITATION OF HUMAN HEPATITIS B VIRUS (HBV) DNA IN PLASMA OR SERUM OF HBV-INFECTED INDIVIDUALS OVER THE RANGE OF 13 IU/ML TO 7X108 IU/ML USING THE VERSANT KPCR MOLECULAR SYSTEM. THE ASSAY IS INTENDED TO BE USED IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS OF DISEASE STATUS TO AID IN THE MANAGEMENT OF HBV-INFECTED INDIVIDUALS UNDERGOING ANTIVIRAL THERAPY. THE VERSANT HBV DNA 1.0 ASSAY (KPCR) IS NOT INTENDED FOR USE AS A BLOOD DONOR SCREENING ASSAY FOR HBV OR AS A DIAGNOSTIC ASSAY TO CONFIRM THE PRESENCE OF HBV INFECTION. THIS ASSAY IS INTENDED FOR USE WITH THE VERSANT KPCR MOLECULAR SYSTEM. FOR IN VITRO DIAGNOSTIC USE.,ATELLICA IM SARS-COV-2 ANTIGEN (COV2AG)(ATELLICA IM SARS-COV-2 ANTIGEN (COV2AG))-THE ATELLICA® IM SARS-COV-2 ANTIGEN (COV2AG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID ANTIGEN IN NASOPHARYNGEAL (NP) SWAB AND ANTERIOR NASAL (AN) SWAB SPECIMENS FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER WITHIN THE FIRST 7 DAYS OF

	SYMPTOM ONSET, OR FROM ASYMPTOMATIC INDIVIDUALS, USING AN ATELLICA® IMMUNOASSAY ANALYZER. THIS ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF PATIENTS WITH SUSPECTED SARS-COV-2 INFECTION.,VERSANT® HIV-1 RNA 1.5 ASSAY (KPCR) BOX 1 (VERSANT® HIV-1 RNA 1.5 ASSAY (KPCR) BOX 1)-THE VERSANT® HIV-1 RNA 1.5 ASSAY (KPCR) IS AN IN VITRO NUCLEIC ACID AMPLIFICATION ASSAY FOR THE QUANTITATION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) RNA IN PLASMA FROM HIV-1 INFECTED INDIVIDUALS, OVER THE RANGE OF 37 TO 11,000,000 COPIES/ML, USING THE VERSANT KPCR MOLECULAR SYSTEM. THE ASSAY IS INTENDED TO BE USED IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS OF DISEASE STATUS, AS AN AID IN THE MANAGEMENT OF INDIVIDUALS INFECTED WITH HIV-1. MONITORING HIV-1 RNA SERIAL RESULTS FROM THE ASSAY CAN BE USED TO ASSESS THE PROGNOSIS OF DISEASE PROGRESSION, AND AS AN AID IN ASSESSING VIRAL RESPONSE TO ANTIRETROVIRAL TREATMENT MEASURED BY CHANGES IN PLASMA HIV-1 RNA LEVELS. THE VERSANT HIV-1 RNA 1.5 ASSAY (KPCR) IS NOT INTENDED FOR USE AS A DONOR SCREENING ASSAY FOR HIV-1 OR AS A DIAGNOSTIC ASSAY TO CONFIRM THE PRESENCE OF HIV-1 INFECTION. FOR IN VITRO DIAGNOSTIC USE.,ADVIA CENTAUR SARS-COV-2 ANTIGEN CALIBRATOR (COV2AG CAL)(ADVIA CENTAUR SARS-COV-2 ANTIGEN CALIBRATOR (COV2AG CAL))-THE ADVIA CENTAUR® SARS-COV-2 ANTIGEN CALIBRATOR (COV2AG CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR COV2AG ASSAY USING THE ADVIA CENTAUR® SYSTEMS.,VERSANT® HCV RNA 1.0 ASSAY (KPCR) BOX 2(VERSANT® HCV RNA 1.0 ASSAY (KPCR) BOX 2)-THE VERSANT® HCV RNA 1.0 ASSAY (KPCR) IS AN IN VITRO NUCLEIC ACID AMPLIFICATION ASSAY FOR THE QUANTITATION OF HEPATITIS C VIRUS (HCV) RNA IN SERUM AND PLASMA OF HCV-INFECTED INDIVIDUALS OVER THE RANGE OF 15 TO 1 X 108 IU/ML USING THE VERSANT KPCR MOLECULAR SYSTEM. THE ASSAY IS INTENDED TO BE USED IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS OF DISEASE STATUS TO AID IN THE MANAGEMENT OF HCV-INFECTED INDIVIDUALS UNDERGOING ANTIVIRAL THERAPY. THE VERSANT HCV RNA 1.0 ASSAY (KPCR) IS NOT INTENDED FOR USE AS A DONOR SCREENING ASSAY FOR HCV OR AS A DIAGNOSTIC ASSAY TO CONFIRM THE PRESENCE OF HCV INFECTION. THIS ASSAY IS INTENDED FOR USE WITH THE VERSANT KPCR MOLECULAR SYSTEM. FOR IN VITRO DIAGNOSTIC USE., ADVIA CENTAUR SARS-COV2 IGG (SCOVG)(ADVIA CENTAUR SARS-COV2 IGG (SCOVG))-THE ADVIA CENTAUR® SARS-COV-2 IGG (SCOVG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND QUANTITATIVE

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	DETECTION OF IGG ANTIBODIES, INCLUDING NEUTRALIZING ANTIBODIES, TO SARS-COV-2 IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) OBTAINED BY VENIPUNCTURE OR CAPILLARY PUNCTURE USING THE ADVIA CENTAUR® SYSTEM. THIS ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF PATIENTS WITH SUSPECTED SARS-COV-2 INFECTION AND AS AN AID IN IDENTIFYING PATIENTS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS-COV-2, INDICATING RECENT OR PRIOR INFECTION.,VERSANT® HCV RNA 1.0 ASSAY (KPCR) BOX 1(VERSANT® HCV RNA 1.0 ASSAY (KPCR) BOX 1)-THE VERSANT® HCV RNA 1.0 ASSAY (KPCR) IS AN IN VITRO NUCLEIC ACID AMPLIFICATION ASSAY FOR THE QUANTITATION OF HEPATITIS C VIRUS (HCV) RNA IN SERUM AND PLASMA OF HCV-INFECTED INDIVIDUALS OVER THE RANGE OF 15 TO 1 X 108 IU/ML USING THE VERSANT KPCR MOLECULAR SYSTEM. THE ASSAY IS INTENDED TO BE USED IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS OF DISEASE STATUS TO AID IN THE MANAGEMENT OF HCV-INFECTED INDIVIDUALS UNDERGOING ANTIVIRAL THERAPY. THE VERSANT HCV RNA 1.0 ASSAY (KPCR) IS NOT INTENDED FOR USE AS A DONOR SCREENING ASSAY FOR HCV OR AS A DIAGNOSTIC ASSAY TO CONFIRM THE PRESENCE OF HCV INFECTION. THIS ASSAY IS INTENDED FOR USE WITH THE VERSANT KPCR MOLECULAR SYSTEM. FOR IN VITRO DIAGNOSTIC USE., ATELLICA® IM SARS-COV-2 IGG QUALITY CONTROL (SCOVG QC) (ATELLICA® IM SARS-COV-2 IGG QUALITY CONTROL (SCOVG QC))-THE ATELLICA® IM SARS-COV-2 IGG QUALITY CONTROL (SCOVG QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND ACCURACY OF THE ATELLICA® IM SARS-COV-2 IGG (SCOVG) ASSAY USING THE ATELLICA® IM ANALYZER.,VERSANT® HIV-1 RNA 1.5 ASSAY (KPCR) , BOX 2(VERSANT® HIV-1 RNA 1.5 ASSAY (KPCR) , BOX 2)-THE VERSANT® HIV-1 RNA 1.5 ASSAY (KPCR) IS AN IN VITRO NUCLEIC ACID AMPLIFICATION ASSAY FOR THE QUANTITATION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) RNA IN PLASMA FROM HIV-1 INFECTED INDIVIDUALS, OVER THE RANGE OF 37 TO 11,000,000 COPIES/ML, USING THE VERSANT KPCR MOLECULAR SYSTEM. THE ASSAY IS INTENDED TO BE USED IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS OF DISEASE STATUS, AS AN AID IN THE MANAGEMENT OF INDIVIDUALS INFECTED WITH HIV-1. MONITORING HIV-1 RNA SERIAL RESULTS FROM THE ASSAY CAN BE USED TO ASSESS THE PROGNOSIS OF DISEASE PROGRESSION, AND AS AN AID IN ASSESSING VIRAL RESPONSE TO ANTIRETROVIRAL TREATMENT MEASURED BY CHANGES IN PLASMA HIV-1 RNA LEVELS. THE VERSANT HIV-1 RNA 1.5 ASSAY (KPCR) IS NOT INTENDED FOR USE AS A DONOR SCREENING ASSAY FOR HIV-1 OR AS A DIAGNOSTIC ASSAY

	TO CONFIRM THE PRESENCE OF HIV-1 INFECTION. FOR IN VITRO DIAGNOSTIC USE., ADVIA CENTAUR SARS-COV-2 IGG QUALITY CONTROL (SCOVG QC)(ADVIA CENTAUR SARS-COV-2 IGG QUALITY CONTROL (SCOVG QC))-THE ADVIA CENTAUR® SARS-COV-2 IGG QUALITY CONTROL (SCOVG QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND ACCURACY OF THE ADVIA CENTAUR® SARS-COV-2 IGG (SCOVG) ASSAY USING THE ADVIA CENTAUR® SYSTEMS.,VERSANT® TISSUE PREPARATION REAGENTS KIT (BOX 1)(VERSANT® TISSUE PREPARATION REAGENTS KIT (BOX 1)) -THE VERSANT® TISSUE PREPARATION REAGENTS ARE INTENDED FOR THE EXTRACTION OF NUCLEIC ACIDS (DNA AND RNA) FROM FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) TISSUE SECTIONS AND FRESH FROZEN (FF) TISSUES. THE PRODUCT IS INTENDED FOR USE BY LABORATORY PROFESSIONALS TRAINED IN MOLECULAR BIOLOGY TECHNIQUES. THE VERSANT TISSUE PREPARATION REAGENTS ARE DESIGNED FOR USE EITHER MANUALLY OR ON A TISSUE PREPARATION SYSTEM (TPS) CONSISTING OF A HAMILTON MICROLAB STARLET IVD INSTRUMENT MODIFIED TO PROCESS TISSUE SAMPLES USING A PROPRIETARY SIEMENS HEALTHCARE DIAGNOSTICS PROTOCOL. END USERS ARE RESPONSIBLE FOR VALIDATING LABORATORY-DEVELOPED METHODS USED IN CONJUNCTION WITH THESE REAGENTS AND FOR IMPLEMENTING APPROPRIATE QUALITY-CONTROL MEASURES. RESULTS GENERATED USING THE SAMPLE PREPARATION PROCEDURE IN CONJUNCTION WITH ANY DIAGNOSTIC ASSAY SHOULD BE INTERPRETED WITH REGARD TO OTHER CLINICAL OR LABORATORY FINDINGS. FOR IN VITRO DIAGNOSTIC USE.,ADVIA CENTAUR SARS-COV-2 IGG MASTER CURVE MATERIAL (SCOVG MCM)(ADVIA CENTAUR SARS-COV-2 IGG MASTER CURVE MATERIAL (SCOVG MCM))-THE ADVIA CENTAUR® SARS-COV-2 IGG MASTER CURVE MATERIAL (SCOVG MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND MEASURING INTERVAL OF THE ADVIA CENTAUR SARS-COV-2 IGG (SCOVG) ASSAY.,ADVIA CENTAUR HIGH-SENSITIVITY TROPONIN I (TNIH)(ADVIA CENTAUR HIGH-SENSITIVITY TROPONIN I (TNIH))-THE ADVIA CENTAUR® HIGH-SENSITIVITY TROPONIN I (TNIH) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF CARDIAC TROPONIN I IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN) USING THE ADVIA CENTAUR XP AND ADVIA CENTAUR XPT SYSTEMS. THE ASSAY CAN BE USED TO AID IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI). , ATELLICA IM ENHANCED LIVER FIBROSIS QUALITY CONTROL (ELF QC)(ATELLICA IM ENHANCED LIVER FIBROSIS QUALITY CONTROL (ELF QC))-THE ATELLICA™ IM ENHANCED LIVER FIBROSIS QUALITY CONTROL (ELF™ QC) IS FOR IN VITRO DIAGNOSTIC USE IN

	MONITORING THE PRECISION AND THE ACCURACY OF THE ATELLICA IM ELF TEST AND THE ATELLICA IM HA, PIIINP, AND TIMP1 ASSAYS USING THE ATELLICA™ IM ANALYZER ,ADVIA CENTAUR PROBE WASH 4(ADVIA CENTAUR PROBE WASH 4)-THE ADVIA CENTAUR PROBE WASH 4 IS USED TO CLEAN PRIMARY REAGENT PROBES IN ORDER TO MITIGATE REAGENT CARRYOVER,ADVIA CENTAUR VANCOMYCIN MASTER CURVE MATERIAL (VANC MCM)(ADVIA CENTAUR VANCOMYCIN MASTER CURVE MATERIAL (VANC MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® VANCOMYCIN ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ADVIA CENTAUR NT-PROBNP MASTER CURVE MATERIAL (PBNP MCM)(ADVIA CENTAUR NT-PROBNP MASTER CURVE MATERIAL (PBNP MCM))-THE ADVIA CENTAUR® NT-PROBNP (PBNP) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR PBNP ASSAY, ATELLICA IM TSH3UL MCM (TSH3-UL MCM)(ATELLICA IM TSH3UL MCM (TSH3-UL MCM))-THE ATELLICA™ IM THYROID STIMULATING HORMONE 3-ULTRA MASTER CURVE MATERIAL (TSH3-UL MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM TSH3-UL ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM ,ADVIA CENTAUR HIGH-SENSITIVITY TROPONIN I MASTER CURVE MATERIAL (TNIH MCM)(ADVIA CENTAUR HIGH-SENSITIVITY TROPONIN I MASTER CURVE MATERIAL (TNIH MCM))-THE ADVIA CENTAUR® HIGH-SENSITIVITY TROPONIN I (TNIH) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR HIGH-SENSITIVITY TROPONIN I (TNIH) ASSAY.,ADVIA CENTAUR MULTI-DILUENT 7(ADVIA CENTAUR MULTI-DILUENT 7)-ADVIA CENTAUR MULTI-DILUENT 7 IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE RESPECTIVE ASSAY., ADVIA CENTAUR NT- PROBNP (PBNP)(ADVIA CENTAUR NT- PROBNP (PBNP))-THE ADVIA CENTAUR® NT-PROBNP (PBNP) ASSAY IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE MEASUREMENT OF N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM AND PLASMA ON THE ADVIA CENTAUR CP, ADVIA CENTAUR XP AND ADVIA CENTAUR XPT SYSTEMS. IN INDIVIDUALS SUSPECTED OF HAVING CONGESTIVE HEART FAILURE (CHF) MEASUREMENTS OF NT-PROBNP ARE USED AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF SEVERITY. ,ADVIA CENTAUR CARBAMAZEPIN E MASTER CURVE MATERIAL (CARB MCM) (ADVIA CENTAUR CARBAMAZEPIN E MASTER CURVE MATERIAL (CARB MCM)

	)-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® CARBAMAZEPINE ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO- POINT CALIBRATION HAS BEEN PERFORMED ON TH.E SYSTEM. ,ATELLICA IM RUBELLA IGM (RUB M) (ATELLICA IM RUBELLA IGM (RUB M))-THE ATELLICA™ IM RUBELLA IGM (RUB M) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO THE RUBELLA VIRUS IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER., ATELLICA IM DHEASO4 MASTER CURVE MATERIAL (DHEAS MCM) (ATELLICA IM DHEASO4 MASTER CURVE MATERIAL (DHEAS MCM))-THE ATELLICA™ IM DHEA-SO4 MASTER CURVE MATERIAL (DHEAS MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM DHEAS ASSAY,ATELLICA IM TOXOPLASMA IGM (TOXO M)(ATELLICA IM TOXOPLASMA IGM (TOXO M))-THE ATELLICA™ IM TOXOPLASMA IGM (TOXO M) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER. THE ATELLICA IM TOXO M ASSAY IS USED TO MEASURE IGM ANTIBODY AGAINST T. GONDII, WHICH IS PRESUMPTIVE OF ACUTE, RECENT, OR REACTIVATED TOXOPLASMA INFECTION. ANY MEASUREMENT OF IGM ANTIBODY TO T. GONDII MUST BE PERFORMED IN CONJUNCTION WITH THE DETERMINATION OF IGG ANTIBODY TO T. GONDII. THIS ASSAY IS NOT INTENDED FOR USE IN SCREENING BLOOD, PLASMA, OR TISSUE DONORS.,ATELLICA IM FERRITIN (FER)(ATELLICA IM FERRITIN (FER))-THE ATELLICA™ IM FERRITIN (FER) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER. THIS ASSAY CAN BE USED AS AN AID IN THE DIAGNOSIS OF IRON DEFICIENCY ANEMIA AND IRON OVERLOAD,ATELLICA IM RUBELLA IGG (RUB G) (ATELLICA IM RUBELLA IGG (RUB G))-THE ATELLICA™ IM RUBELLA IGG (RUB G) ASSAY IS AN IGG-ANTIBODY CAPTURE MICROPARTICLE DIRECT CHEMILUMINESCENT IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTIBODIES TO THE RUBELLA VIRUS IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER. THIS ASSAY IS USED AS AN AID IN THE ASSESSMENT OF IMMUNE STATUS TO RUBELLA IN INDIVIDUALS INCLUDING WOMEN OF CHILD-BEARING AGE. ,ATELLICA IM TOTAL IGE (TIGE)(ATELLICA IM TOTAL IGE (TIGE))-THE ATELLICA™ IM TOTAL IGE (TIGE) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL IGE IN HUMAN SERUM USING THE

	ATELLICA™ IM ANALYZER, ATELLICA IM HEPATITIS C (AHCV) (ATELLICA IM HEPATITIS C (AHCV))-THE ATELLICA™ IM HEPATITIS C (AHCV) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) ANTIBODIES TO HEPATITIS C VIRUS (HCV) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, AND SODIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER. THE ASSAY MAY BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL AND CLINICAL INFORMATION TO AID IN THE DIAGNOSIS OF INDIVIDUALS WITH SYMPTOMS OF HEPATITIS AND IN INDIVIDUALS AT RISK FOR HEPATITIS C INFECTION.,ATELLICA IM THYROID STIMULATING HORMONE 3-ULTRA (TSH3UL)(ATELLICA IM THYROID STIMULATING HORMONE 3-ULTRA (TSH3UL))-THE ATELLICA™ IM THYROID STIMULATING HORMONE 3ULTRA (TSH3UL) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH, THYROTROPIN) IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER. MEASUREMENTS OF THYROID STIMULATING HORMONE PRODUCED BY THE ANTERIOR PITUITARY ARE USED IN THE DIAGNOSIS OF THYROID OR PITUITARY DISORDERS.,ATELLICA IM ALPHA FETOPROTEIN MASTER CURVE MATERIAL (AFP MCM) (ATELLICA IM ALPHA FETOPROTEIN MASTER CURVE MATERIAL (AFP MCM))-THE ATELLICA™ IM ALPHA FETOPROTEIN MASTER CURVE MATERIAL (AFP MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM AFP ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM, ATELLICA IM DIGOXIN MASTER CURVE MATERIAL (DIG MCM) (ATELLICA IM DIGOXIN MASTER CURVE MATERIAL (DIG MCM))-THE ATELLICA™ IM DIGOXIN MASTER CURVE MATERIAL (DIG MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM DIG ASSAY., ATELLICA IM CA 15-3 (CA 15-3)(ATELLICA IM CA 15-3 (CA 15-3))-THE ATELLICA™ IM CA 153® (CA 153) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE SERIAL DETERMINATION OF CANCER ANTIGEN CA 153 IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. WHEN USED IN CONJUNCTION WITH OTHER CLINICAL AND DIAGNOSTIC PROCEDURES, SERIAL TESTING WITH THE ATELLICA IM CA 153 ASSAY IS USEFUL FOR MONITORING THE COURSE OF DISEASE AND THERAPY IN METASTATIC BREAST CANCER PATIENTS, AND FOR DETECTION OF RECURRENCE IN PREVIOUSLY TREATED STAGE II, WITH GREATER THAN TWO POSITIVE LYMPH NODES, OR STAGE III BREAST CANCER PATIENTS. THIS ASSAY IS NOT INTENDED FOR USE ON ANY OTHER SYSTEM.,ATELLICA IM DHEASO4

	(DHEAS)(ATELLICA IM DHEASO4 (DHEAS))-THE ATELLICA™ IM DHEASSO4 (DHEAS) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE (DHEAS) IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM MULTIDILUENT 2 (MULTI DIL 2)(ATELLICA IM MULTIDILUENT 2 (MULTI DIL 2))-NA,ATELLICA IM INTACT PARATHYROID HORMONE (PTH)(ATELLICA IM INTACT PARATHYROID HORMONE (PTH))-THE ATELLICA™ IM INTACT PARATHYROID HORMONE (PTH) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE IN HUMAN SERUM AND PLASMA USING THE ATELLICA™ IM ANALYZER. THIS ASSAY IS INTENDED TO BE USED TO AID IN THE DIFFERENTIAL DIAGNOSIS OF HYPERPARATHYROIDISM OR HYPOPARATHYROIDISM. THIS ASSAY CAN BE USED INTRA-OPERATIVELY., ATELLICA IM FREE PROSTATE-SPECIFIC ANTIGEN CALIBRATOR (FPSA CAL)(ATELLICA IM FREE PROSTATE-SPECIFIC ANTIGEN CALIBRATOR (FPSA CAL))-THE ATELLICA™ IM FREE PROSTATE-SPECIFIC ANTIGEN CALIBRATOR (FPSA CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM FPSA ASSAY USING THE ATELLICA™ IM ANALYZER., ATELLICA IM SEX HORMONE BINDING GLOBULIN (SHBG)(ATELLICA IM SEX HORMONE BINDING GLOBULIN (SHBG))-THE ATELLICA™ IM SEX HORMONE BINDING GLOBULIN (SHBG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF SEX-HORMONE-BINDING GLOBULIN (SHBG) IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER, ATELLICA IM CARCINOEMBRYONIC MASTER CURVE MATERIAL (CEA MCM) (ATELLICA IM CARCINOEMBRYONIC MASTER CURVE MATERIAL (CEA MCM))-THE ATELLICA™ IM CARCINOEMBRYONIC MASTER CURVE MATERIAL (CEA MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM CEA ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM, ATELLICA IM DIGITOXIN (DGTN)(ATELLICA IM DIGITOXIN (DGTN))-THE ATELLICA™ IM DIGITOXIN (DGTN) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF DIGITOXIN IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER., ATELLICA IM CAL D (ATELLICA IM CAL D)-NA,ATELLICA IM ANTI-THYROID PEROXIDASE (ATPO)(ATELLICA IM ANTI-THYROID PEROXIDASE (ATPO))-THE ATELLICA™ IM ANTI-THYROID PEROXIDASE (ATPO) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF AUTOANTIBODIES AGAINST THYROID PEROXIDASE IN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER.,

	ATELLICA IM TOXOPLASMA IGM QUALITY CONTROL (TOXO M QC)(ATELLICA IM TOXOPLASMA IGM QUALITY CONTROL (TOXO M QC))-THE ATELLICA™ IM TOXOPLASMA IGM QUALITY CONTROL (TOXO M QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM TOXO M ASSAY USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM PROGESTERONE (PRGE) (ATELLICA IM PROGESTERONE (PRGE))-THE ATELLICA™ IM PROGESTERONE (PRGE) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM TOXOPLASMA IGG QUALITY CONTROL (TOXO G QC)(ATELLICA IM TOXOPLASMA IGG QUALITY CONTROL (TOXO G QC))-THE ATELLICA™ IM TOXOPLASMA IGG QUALITY CONTROL (TOXO G QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM TOXO G ASSAY USING THE ATELLICA™ IM ANALYZER, ATELLICA IM HOMOCYSTEINE (HCY)(ATELLICA IM HOMOCYSTEINE (HCY))-THE ATELLICA™ IM HOMOCYSTEINE (HCY) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL HOMOCYSTEINE IN HUMAN SERUM AND PLASMA (EDTA AND LITHIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER. THIS DIAGNOSTIC TEST IS DESIGNED TO QUANTITATIVELY MEASURE HOMOCYSTEINE IN SERUM OR PLASMA. SUCH MEASUREMENT CAN AID IN THE DIAGNOSIS AND TREATMENT OF PATIENTS SUSPECTED OF HAVING HOMOCYSTEINURIA OR HYPERHOMOCYSTEINEMIA., ATELLICA IM SYPHILIS QUALITY CONTROL (SYPH QC)(ATELLICA IM SYPHILIS QUALITY CONTROL (SYPH QC))-THE ATELLICA™ IM SYPHILIS QUALITY CONTROL (SYPH QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM SYPH ASSAY USING THE ATELLICA™ IM ANALYZER, ATELLICA IM CORTISOL (COR)(ATELLICA IM CORTISOL (COR))-THE ATELLICA™ IM CORTISOL MASTER CURVE MATERIAL (COR MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM COR ASSAY.,ATELLICA IM RUBELLA IGM QUALITY CONTROL (RUB M QC) (ATELLICA IM RUBELLA IGM QUALITY CONTROL (RUB M QC))-THE ATELLICA™ IM RUBELLA IGM QUALITY CONTROL (RUB M QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM RUB M ASSAY USING THE ATELLICA™ IM ANALYZER.,VANCOMYCIN CALIBRATOR (VANC CAL)(VANCOMYCIN CALIBRATOR (VANC CAL))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR® SYSTEMS VANCOMYCIN ASSAYS.,ATELLICA IM PROSTATE-SPECIFIC ANTIGEN MASTER CURVE MATERIAL (PSA MCM)(ATELLICA IM PROSTATE-SPECIFIC ANTIGEN MASTER CURVE MATERIAL (PSA MCM))-THE ATELLICA™ IM

	PROSTATE-SPECIFIC ANTIGEN MASTER CURVE MATERIAL (PSA MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM PSA ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ADVIA CENTAUR TOXOPLASMA M (TOXO M) QUALITY CONTROL MATERIAL(ADVIA CENTAUR TOXOPLASMA M (TOXO M) QUALITY CONTROL MATERIAL)-FOR MONITORING THE PERFORMANCE OF THE ADVIA CENTAUR TOXOPLASMA M ASSAY ON THE ADVIA CENTAUR SYSTEMS. THE PERFORMANCE OF THE ADVIA CENTAUR TOXOPLASMA M QUALITY CONTROL MATERIAL HAS NOT BEEN ESTABLISHED WITH ANY OTHER TOXOPLASMA IGM ASSAYS.,ATELLICA IM CALIBRATOR Q (CAL Q)(ATELLICA IM CALIBRATOR Q (CAL Q))-THE ATELLICA™ IM CALIBRATOR Q (CAL Q) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM PSA ASSAY USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM PTH QC (PTH QC)(ATELLICA IM PTH QC (PTH QC))-THE ATELLICA™ IM INTACT PARATHYROID HORMONE QUALITY CONTROL (PTH QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND THE ACCURACY OF THE ATELLICA IM PTH ASSAY USING THE ATELLICA™ IM ANALYZER. , ATELLICA IM HEPATITIS B SURFACE ANTIGEN II CONFIRMATORY (HBSII CONF)(ATELLICA IM HEPATITIS B SURFACE ANTIGEN II CONFIRMATORY (HBSII CONF))-THE ATELLICA™ IM HEPATITIS B SURFACE ANTIGEN II CONFIRMATORY (HBSII CONF) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OR PLASMA (EDTA, LITHIUM OR SODIUM HEPARIN, CITRATE) USING THE ATELLICA™ IM ANALYZER. THE ASSAY IS INTENDED TO BE USED TO CONFIRM THE PRESENCE OF HBSAG IN SAMPLES THAT ARE REPEATEDLY REACTIVE USING THE ATELLICA IM ANALYZER., ATELLICA IM TOTAL THYROXINE MASTER CURVE MATERIAL (T4 MCM)(ATELLICA IM TOTAL THYROXINE MASTER CURVE MATERIAL (T4 MCM))-THE ATELLICA™ IM TOTAL THYROXINE MASTER CURVE MATERIAL (T4 MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM T4 ASSAY,ATELLICA IM HEPATITIS B SURFACE ANTIGEN II QUALITY CONTROL (HBSII QC)(ATELLICA IM HEPATITIS B SURFACE ANTIGEN II QUALITY CONTROL (HBSII QC))-THE ATELLICA™ IM HEPATITIS B SURFACE ANTIGEN II QUALITY CONTROL (HBSII QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM HBSII AND HBSII CONF ASSAYS USING THE ATELLICA™ IM ANALYZER.,ADVIA CENTAUR MULTI-DILUENT 1 (MULTI- DIL 1)(ADVIA CENTAUR MULTI-DILUENT 1 (MULTI-DIL 1))-THIS PRODUCT IS A KIT THATCONTAINS DILUENT IN

	ANCILLARY PACKS (2-PACK; 6-PACK) OR IN BOTTLES (50 ML BOTTLE). SEE INSTRUCTIONS FOR USE FOR ADDITIONAL DETAILS., ATELLICA IM HEPATITIS B E ANTIGEN QUALITY CONTROL (HBEAG QC) (ATELLICA IM HEPATITIS B E ANTIGEN QUALITY CONTROL (HBEAG QC))-THE ATELLICA™ IM HEPATITIS B E ANTIGEN QUALITY CONTROL (HBEAG QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM HBEAG ASSAY USING THE ATELLICA™ IM ANALYZER.,ADVIA CENTAUR BR MASTER CURVE MATERIAL (BR MCM) (ADVIA CENTAUR BR MASTER CURVE MATERIAL (BR MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® SYSTEMS BR ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM,ATELLICA IM HEPATITIS A IGM (AHAVM) (ATELLICA IM HEPATITIS A IGM (AHAVM))-THE ATELLICA™ IM HEPATITIS A IGM (AHAVM) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF IGM RESPONSE TO THE HEPATITIS A VIRUS (HAV) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, AND SODIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER. THIS ASSAY IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF ACUTE OR RECENT INFECTION (USUALLY 6 MONTHS OR LESS) WITH HEPATITIS A VIRUS,ATELLICA IM BRAHMS PROCALCITONIN (PCT)(ATELLICA IM BRAHMS PROCALCITONIN (PCT))-THE ATELLICA™ IM BRAHMS PROCALCITONIN (PCT) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF PROCALCITONIN IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, AND SODIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER. THE ATELLICA IM BRAHMS PCT ASSAY IS INDICATED, IN CONJUNCTION WITH OTHER LABORATORY FINDINGS AND CLINICAL ASSESSMENTS, AS AN AID IN THE RISK ASSESSMENT OF CRITICALLY ILL PATIENTS ON THEIR FIRST DAY OF INTENSIVE CARE UNIT (ICU) ADMISSION FOR PROGRESSION TO SEVERE SEPSIS AND SEPTIC SHOCK.,ATELLICA IM ANTI-HEPATITIS B CORE TOTAL QUALITY CONTROL (HBCT QC)(ATELLICA IM ANTI-HEPATITIS B CORE TOTAL QUALITY CONTROL (HBCT QC))-THE ATELLICA™ IM ANTI-HEPATITIS B CORE TOTAL QUALITY CONTROL (HBCT QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM HBCT ASSAY USING THE ATELLICA™ IM ANALYZER.,ADVIA CENTAUR VITAMIN D TOTAL (VITD) DILUENT(ADVIA CENTAUR VITAMIN D TOTAL (VITD) DILUENT)-THE ADVIA CENTAUR VITAMIN D TOTAL DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY., ATELLICA IM HER-2/NEU MASTER CURVE MATERIAL (H2N MCM) (ATELLICA IM HER-2/NEU MASTER CURVE MATERIAL (H2N MCM))-THE ATELLICA™ IM HER-2/NEU MASTER CURVE MATERIAL (H2N

	MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM H2N ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ADVIA CENTAUR BR (BR)(ADVIA CENTAUR BR (BR))-THE ADVIA CENTAUR® BR ASSAY IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE SERIAL DETERMINATION OF CANCER ANTIGEN CA 27.29 IN HUMAN SERUM USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR C(:> SYSTEMS. THE TEST IS INTENDED FOR USE AS AN AID IN-MONITORING PATIENTS PREVIOUSLY TREATED FOR STAGE II OR STAGE ILL BREAST CANCER. SERIAL TESTING FOR CA 27.29 IN THE SERUM OF PATIENTS WHO ARE CLINICALLY REE OF DISEASE SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL METHODS USED FOR THE EARLY DETECTION OF CANCER RECURRENCE. THE TEST IS ALSO INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF BREAST CANCER PATIENTS WITH METASTATIC DISEASE BY MONITORING THE PROGRESSION OR REGRESSION OF DISEASE IN RESPONSE TO TREATMENT.,ATELLICA IM HER2/NEU QUALITY CONTROL (H2N QC)(ATELLICA IM HER2/NEU QUALITY CONTROL (H2N QC))-THE ATELLICA™ IM HER2/NEU QUALITY CONTROL (H2N QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND THE ACCURACY OF THE ATELLICA IM H2N ASSAY USING THE ATELLICA™ IM ANALYZER.,ADVIA CENTAUR ANTI-TG {ATG) (ADVIA CENTAUR ANTI-TG {ATG))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF AUTOANTIBODIES AGAINST THYROGLOBULIN IN SERUM OR EDTA PLASMA USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS. THIS ASSAY IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF HASHIMOTO'S AND GRAVES' DISEASES WHICH ARE AUTOIMMUNE DISEASES AFFECTING THE THYROID GLAND. ,ATELLICA IM HER2/NEU CALIBRATOR (H2N CAL)(ATELLICA IM HER2/NEU CALIBRATOR (H2N CAL))-THE ATELLICA™ IM HER2/NEU CALIBRATOR (H2N CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM H2N ASSAY USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM BR 27.29 (BR)(ATELLICA IM BR 27.29 (BR))-THE ATELLICA™ IM BR 27.29 (BR) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE SERIAL DETERMINATION OF CANCER ANTIGEN CA 27.29 IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. THE TEST IS INTENDED FOR USE AS AN AID IN MONITORING PATIENTS PREVIOUSLY TREATED FOR STAGE II OR STAGE III BREAST CANCER. SERIAL TESTING FOR CA 27.29 IN THE SERUM OF PATIENTS WHO ARE CLINICALLY FREE OF DISEASE SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL METHODS

	USED FOR THE EARLY DETECTION OF CANCER RECURRENCE. THE TEST IS ALSO INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF BREAST CANCER PATIENTS WITH METASTATIC DISEASE BY MONITORING THE PROGRESSION OR REGRESSION OF DISEASE IN RESPONSE TO TREATMENT., ATELLICA IM HIV 1/O/2 ENHANCED QUALITY CONTROL (EHIV QC)(ATELLICA IM HIV 1/O/2 ENHANCED QUALITY CONTROL (EHIV QC))-THE ATELLICA™ IM HIV 1/O/2 ENHANCED QUALITY CONTROL (EHIV QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM EHIV ASSAY USING THE ATELLICA™ IM ANALYZER., ATELLICA IM TOTAL IGE DILUENT (TIGE DIL)(ATELLICA IM TOTAL IGE DILUENT (TIGE DIL))-ATELLICA IM TOTAL IGE DILUENT (TIGE DIL) USED AS DILUENT.,ATELLICA IM HIV 1/O/2 ENHANCED (EHIV) (ATELLICA IM HIV 1/O/2 ENHANCED (EHIV))-THE ATELLICA™ IM HIV 1/O/2 ENHANCED (EHIV) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1, INCLUDING SUBTYPE O, AND/OR TYPE 2 IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, AND SODIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER., ATELLICA IM ANTI-THYROID PEROXIDASE MASTER CURVE MATERIAL (ATPO MCM)(ATELLICA IM ANTI-THYROID PEROXIDASE MASTER CURVE MATERIAL (ATPO MCM))-THE ATELLICA™ IM ANTI-THYROID PEROXIDASE MASTER CURVE MATERIAL (ATPO MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM ATPO ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM,ATELLICA IM CPSA PRE(ATELLICA IM CPSA PRE)-NA ,ATELLICA IM TOTAL TRIIODOTHYRONINE DILUENT (T3 DIL)(ATELLICA IM TOTAL TRIIODOTHYRONINE DILUENT (T3 DIL))-ATELLICA IM TOTAL TRIIODOTHYRONINE DILUENT (T3 DIL) USED AS A DILUENT., ATELLICA IM CALIBRATOR Y (CAL Y)(ATELLICA IM CALIBRATOR Y (CAL Y))-THE ATELLICA™ IM CALIBRATOR Y (CAL Y) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM CPSA ASSAY USING THE ATELLICA™ IM ANALYZER.,ATELLICA ANTI-THYROID PEROXIDASE DILUENT (ATPO DIL)(ATELLICA ANTI-THYROID PEROXIDASE DILUENT (ATPO DIL))-ATELLICA ANTI-THYROID PEROXIDASE DILUENT (ATPO DIL) USED AS DILUENT.,ATELLICA IM HIV AG/AB COMBO QUALITY CONTROL (CHIV QC)(ATELLICA IM HIV AG/AB COMBO QUALITY CONTROL (CHIV QC))-THE ATELLICA™ IM HIV AG/AB COMBO QUALITY CONTROL (CHIV QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM CHIV ASSAY USING THE ATELLICA™ IM ANALYZER., ATELLICA IM HCY DILUENT (HCY DIL)(ATELLICA IM HCY DILUENT (HCY DIL))-ATELLICA IM HCY DILUENT (HCY DIL) USED AS DILUENT.

	ATELLICA IM CA 125II MASTER CURVE MATERIAL (CA 125II MCM) (ATELLICA IM CA 125II MASTER CURVE MATERIAL (CA 125II MCM))-THE ATELLICA™ IM CA 125II™ MASTER CURVE MATERIAL (CA 125II™ MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM CA 125II™ ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM,ATELLICA IM TOTAL HUMAN CHORIONIC GONADOTROPIN (THCG)(ATELLICA IM TOTAL HUMAN CHORIONIC GONADOTROPIN (THCG))-THE ATELLICA™ IM TOTAL HCG (THCG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. THE RESULTS OBTAINED FROM HCG SPECIMENS ARE USED AS AN AID IN THE ASSESSMENT OF PREGNANCY STATUS. THIS ASSAY DETECTS THE INTACT HCG MOLECULE AND FREE BETA-SUBUNITS OF THE HCG MOLECULE.,ATELLICA IM CA 125II CALIBRATOR (CA 125II CAL)(ATELLICA IM CA 125II CALIBRATOR (CA 125II CAL))-THE ATELLICA™ IM CA 125II™ CALIBRATOR (CA 125II™ CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM CA 125II ASSAY USING THE ATELLICA™ IM ANALYZER., ADVIA CENTAUR MULTI-DILUENT 12 (MULTI-DIL 12) (ADVIA CENTAUR MULTI-DILUENT 12 (MULTI-DIL 12))-ADVIA CENTAUR MULTI-DILUENT 12 IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE RESPECTIVE ASSAY. , ATELLICA IM CA 19-9 MASTER CURVE MATERIAL (CA 19-9 MCM)(ATELLICA IM CA 19-9 MASTER CURVE MATERIAL (CA 19-9 MCM))-THE ATELLICA™ IM CA 19-9™ MASTER CURVE MATERIAL (CA 19-9™ MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM CA 19-9™ ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM. ,ATELLICA IM FER MCM(ATELLICA IM FER MCM)-THE ATELLICA™ IM FERRITIN MASTER CURVE MATERIAL (FER MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM FER ASSAY. ,ATELLICA IM CA 19-9 DIL(ATELLICA IM CA 19-9 DIL)-NA, ATELLICA IM HOMOCYSTEINE CALIBRATOR (HCY CAL)(ATELLICA IM HOMOCYSTEINE CALIBRATOR (HCY CAL))-THE ATELLICA™ IM HOMOCYSTEINE CALIBRATOR (HCY CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM HCY ASSAY USING THE ATELLICA™ IM ANALYZER,ATELLICA IM CA 15-3 MASTER CURVE MATERIAL (CA 15-3 MCM) (ATELLICA IM CA 15-3 MASTER CURVE MATERIAL (CA 15-3 MCM))-THE ATELLICA™ IM CA 15-3® MASTER CURVE MATERIAL (CA 15-3® MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM CA 15-3®

	ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM,ATELLICA IM PROLACTIN (PRL) (ATELLICA IM PROLACTIN (PRL))-THE ATELLICA™ IM PROLACTIN (PRL) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM CA 15-3 CALIBRATOR (CA 15-3 CAL)(ATELLICA IM CA 15-3 CALIBRATOR (CA 15-3 CAL))-THE ATELLICA™ IM CA 153® CALIBRATOR (CA 153® CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM CA 153 ASSAY USING THE ATELLICA™ IM ANALYZER,ATELLICA IM ENHANCED ESTRADIOL (EE2)(ATELLICA IM ENHANCED ESTRADIOL (EE2))-THE ATELLICA™ IM ENHANCED ESTRADIOL (EE2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER., ATELLICA IM BR 27.29 MASTER CURVE MATERIAL (BR MCM) (ATELLICA IM BR 27.29 MASTER CURVE MATERIAL (BR MCM))-THE ATELLICA™ IM BR 27.29 MASTER CURVE MATERIAL (BR MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM BR ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM., ATELLICA IM SEX HORMONE BINDING GLOBULIN MASTER CURVE MATERIAL (SHBG MCM)(ATELLICA IM SEX HORMONE BINDING GLOBULIN MASTER CURVE MATERIAL (SHBG MCM))-THE ATELLICA™ IM SEX HORMONE BINDING GLOBULIN MASTER CURVE MATERIAL (SHBG MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM SHBG ASSAY,ATELLICA IM BR 27.29 CALIBRATOR (BR CAL)(ATELLICA IM BR 27.29 CALIBRATOR (BR CAL)) -THE ATELLICA™ IM BR 27.29 CALIBRATOR (BR CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM BR ASSAY USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM CALIBRATOR 80 (CAL 80)(ATELLICA IM CALIBRATOR 80 (CAL 80))- THE ATELLICA™ IM CALIBRATOR 80 (CAL 80) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM TIGE ASSAY USING THE ATELLICA™ IM ANALYZER,ATELLICA IM BR PRETREATMENT REAGENT (BR PRE) (ATELLICA IM BR PRETREATMENT REAGENT (BR PRE))-NA ,ATELLICA IM SEX HORMONE BINDING GLOBULIN CALIBRATOR (SHBG CAL) (ATELLICA IM SEX HORMONE BINDING GLOBULIN CALIBRATOR (SHBG CAL))-THE ATELLICA™ IM SEX HORMONE BINDING GLOBULIN CALIBRATOR (SHBG CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM SHBG ASSAY USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM HEPATITIS C QUALITY CONTROL (AHCV

	QC)(ATELLICA IM HEPATITIS C QUALITY CONTROL (AHCV QC))-THE ATELLICA™ IM HEPATITIS C QUALITY CONTROL (AHCV QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM AHCV ASSAY USING THE ATELLICA™ IM ANALYZER., ATELLICA IM TOTAL IGE MASTER CURVE MATERIAL (TIGE)(ATELLICA IM TOTAL IGE MASTER CURVE MATERIAL (TIGE))-THE ATELLICA™ IM TOTAL IGE MASTER CURVE MATERIAL (TIGE MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM TIGE ASSAY ,ATELLICA IM ANTI-HEPATITIS B SURFACE ANTIGEN MASTER CURVE MATERIAL (AHBS2 MCM) (ATELLICA IM ANTI-HEPATITIS B SURFACE ANTIGEN MASTER CURVE MATERIAL (AHBS2 MCM))-THE ATELLICA™ IM ANTI-HEPATITIS B SURFACE ANTIGEN 2 MASTER CURVE MATERIAL (AHBS2 MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM AHBS2 ASSAY.,ATELLICA IM BRAHMS PROCALCITONIN QUALITY CONTROL (PCT QC)(ATELLICA IM BRAHMS PROCALCITONIN QUALITY CONTROL (PCT QC))-THE ATELLICA™ IM BRAHMS PROCALCITONIN QUALITY CONTROL (PCT QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND THE ACCURACY OF THE ATELLICA IM PCT ASSAY USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM ANTI-HEPATITIS B SURFACE ANTIGEN 2 QUALITY CONTROL (AHBS2 QC)(ATELLICA IM ANTI-HEPATITIS B SURFACE ANTIGEN 2 QUALITY CONTROL (AHBS2 QC))-THE ATELLICA™ IM ANTIHEPATITIS B SURFACE ANTIGEN 2 QUALITY CONTROL (AHBS2 QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM AHBS2 ASSAY USING THE ATELLICA™ IM ANALYZER., ATELLICA IM TESTOSTERONE II MASTER CURVE MATERIAL (TSTII MCM)(ATELLICA IM TESTOSTERONE II MASTER CURVE MATERIAL (TSTII MCM))-THE ATELLICA™ IM TESTOSTERONE II MASTER CURVE MATERIAL (TSTII MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM TSTII ASSAY.,ATELLICA IM ANTI-HEPATITIS B E ANTIGEN QUALITY CONTROL (AHBE QC)(ATELLICA IM ANTI-HEPATITIS B E ANTIGEN QUALITY CONTROL (AHBE QC))-THE ATELLICA™ IM ANTI-HEPATITIS B E ANTIGEN QUALITY CONTROL (AHBE QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM AHBE ASSAY USING THE ATELLICA™ IM ANALYZER,ATELLICA IM HOMOCYSTEINE MASTER CURVE MATERIAL (HCY MCM)(ATELLICA IM HOMOCYSTEINE MASTER CURVE MATERIAL (HCY MCM))-THE ATELLICA™ IM HOMOCYSTEINE MASTER CURVE MATERIAL (HCY MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM HCY ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES

	AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ATELLICA IM HEPATITIS A TOTAL QUALITY CONTROL (HAVT QC)(ATELLICA IM HEPATITIS A TOTAL QUALITY CONTROL (HAVT QC))-THE ATELLICA™ IM HEPATITIS A TOTAL QUALITY CONTROL (HAVT QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM HAVT ASSAY USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM PROGESTERONE MASTER CURVE MATERIAL (PRGE MCM)(ATELLICA IM PROGESTERONE MASTER CURVE MATERIAL (PRGE MCM))-THE ATELLICA™ IM PROGESTERONE MASTER CURVE MATERIAL (PRGE MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM PRGE ASSAY,ATELLICA IM HEPATITIS A TOTAL (AHAVT) (ATELLICA IM HEPATITIS A TOTAL (AHAVT))-THE ATELLICA™ IM HEPATITIS A TOTAL (AHAVT) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL ANTIBODIES TO HEPATITIS A VIRUS (ANTI-HAV) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, AND SODIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER. AN ASSAY FOR ANTI-HAV IS INDICATED AS AN AID IN THE DIAGNOSIS OF PREVIOUS OR ONGOING HEPATITIS A VIRAL INFECTION, OR FOR THE DETECTION OF ANTI-HAV AFTER VACCINATION.,ATELLICA IM ATELLICA IM CORTISOL MASTER CURVE MATERIAL (COR MCM)(ATELLICA IM ATELLICA IM CORTISOL MASTER CURVE MATERIAL (COR MCM))-THE ATELLICA™ IM CORTISOL MASTER CURVE MATERIAL (COR MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM COR ASSAY., ATELLICA IM MULTIDILUENT 2 (ATELLICA IM MULTIDILUENT 2)-NA,ATELLICA IM PROLACTIN MASTER CURVE MATERIAL (PRL MCM)(ATELLICA IM PROLACTIN MASTER CURVE MATERIAL (PRL MCM))-THE ATELLICA™ IM PROLACTIN MASTER CURVE MATERIAL (PRL MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM PRL ASSAY,ATELLICA IM CALIBRATOR D (CAL D)(ATELLICA IM CALIBRATOR D (CAL D))-THE ATELLICA™ IM CALIBRATOR D (CAL D) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FOLLOWING ATELLICA IM ASSAYS USING THE ATELLICA™ IM ANALYZER: AFP AND CEA.,ATELLICA IM CALIBRATOR Z (CAL Z)(ATELLICA IM CALIBRATOR Z (CAL Z))-THE ATELLICA™ IM CALIBRATOR Z (CAL Z) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM DGTN ASSAY USING THE ATELLICA™ IM ANALYZER. ,ATELLICA IM HEPATITIS A IGM QUALITY CONTROL (AHAVM QC)(ATELLICA IM HEPATITIS A IGM QUALITY CONTROL (AHAVM QC))-THE ATELLICA™ IM HEPATITIS A IGM QUALITY CONTROL (AHAVM QC) IS FOR IN VITRO DIAGNOSTIC USE IN

	MONITORING THE PERFORMANCE OF THE ATELLICA IM AHAVM ASSAY USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM ANTI-THYROID PEROXIDASE QUALITY CONTROL (ATPO QC)(ATELLICA IM ANTI-THYROID PEROXIDASE QUALITY CONTROL (ATPO QC))-THE ATELLICA™ IM ANTITHYROID PEROXIDASE QUALITY CONTROL (ATPO QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND THE ACCURACY OF THE ATELLICA IM ATPO ASSAY USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM CA 19-9 (CA 19-9) (ATELLICA IM CA 19-9 (CA 19-9))-THE ATELLICA™ IM CA 199™ (CA 199) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE, SERIAL DETERMINATION OF CA 199 IN HUMAN SERUM AND TO AID IN THE MANAGEMENT OF PATIENTS WITH GASTROINTESTINAL (GI) CARCINOMA USING THE ATELLICA™ IM ANALYZER. THE TEST IS INTENDED FOR USE AS AN AID IN MONITORING PATIENTS PREVIOUSLY TREATED FOR GI CANCER. SERIAL TESTING FOR CA 199 IN THE SERUM OF PATIENTS WHO ARE CLINICALLY FREE OF DISEASE SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL METHODS USED FOR THE EARLY DETECTION OF CANCER RECURRENCE. THE TEST IS ALSO INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF GI CANCER PATIENTS WITH METASTATIC DISEASE BY MONITORING THE PROGRESSION OR REGRESSION OF DISEASE IN RESPONSE TO TREATMENT. THE ATELLICA IM CA 199 ASSAY IS NOT INTENDED FOR USE ON ANY OTHER SYSTEM.,THE ATELLICA™ IM TOTAL HCG MASTER CURVE MATERIAL (THCG MCM)(THE ATELLICA™ IM TOTAL HCG MASTER CURVE MATERIAL (THCG MCM))-THE ATELLICA™ IM TOTAL HCG MASTER CURVE MATERIAL (THCG MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM THCG ASSAY.,ATELLICA IM CA 125II(ATELLICA IM CA 125II)-THE ATELLICA™ IM CA 125II™ (CA 125II™) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE, SERIAL DETERMINATION OF CA 125 IN HUMAN SERUM AND TO AID IN THE MANAGEMENT OF PATIENTS WITH OVARIAN CARCINOMA USING THE ATELLICA™ IM ANALYZER. THE TEST IS INTENDED FOR USE AS AN AID IN MONITORING PATIENTS PREVIOUSLY TREATED FOR OVARIAN CANCER. SERIAL TESTING FOR CA 125 IN THE SERUM OF PATIENTS WHO ARE CLINICALLY FREE OF DISEASE SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL METHODS USED FOR THE EARLY DETECTION OF CANCER RECURRENCE. THE TEST IS ALSO INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF OVARIAN CANCER PATIENTS WITH METASTATIC DISEASE BY MONITORING THE PROGRESSION OR REGRESSION OF DISEASE IN RESPONSE TO TREATMENT. IT IS RECOMMENDED THAT THE ATELLICA IM CA 125II ASSAY BE USED UNDER THE ORDER OF A PHYSICIAN TRAINED AND EXPERIENCED IN

	THE MANAGEMENT OF GYNECOLOGICAL CANCERS. THIS ASSAY IS NOT INTENDED FOR SCREENING OR DIAGNOSIS OF OVARIAN CANCER OR FOR USE ON ANY OTHER SYSTEM.,ATELLICA IM MULTIDILUENT 3 (ATELLICA IM MULTIDILUENT 3)-ATELLICA IM MULTIDILUENT 3 USED AS DILUENT.,ATELLICA IM RUBELLA IGG (RUB G) (ATELLICA IM RUBELLA IGG (RUB G))-THE ATELLICA™ IM RUBELLA IGG (RUB G) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTIBODIES TO THE RUBELLA VIRUS IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM TOTAL HUMAN CHORIONIC GONADOTROPIN DILUENT (THCG DIL)(ATELLICA IM TOTAL HUMAN CHORIONIC GONADOTROPIN DILUENT (THCG DIL))-ATELLICA IM TOTAL HUMAN CHORIONIC GONADOTROPIN DILUENT USED AS DILUENT.,ATELLICA IM HEPATITIS B SURFACE ANTIGEN II (HBSII)(ATELLICA IM HEPATITIS B SURFACE ANTIGEN II (HBSII))-THE ATELLICA™ IM HEPATITIS B SURFACE ANTIGEN II (HBSII) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, SODIUM HEPARIN, AND SODIUM CITRATE) USING THE ATELLICA™ IM ANALYZER. THE ASSAY MAY BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL AND CLINICAL INFORMATION TO DIAGNOSE INDIVIDUALS WITH ACUTE OR CHRONIC HEPATITIS B INFECTION. THE ASSAY MAY ALSO BE USED TO SCREEN FOR HEPATITIS B INFECTION IN PREGNANT WOMEN TO IDENTIFY NEONATES WHO ARE AT RISK OF ACQUIRING HEPATITIS B DURING THE PERINATAL PERIOD.,ATELLICA IM CORTISOL URINE RECONSTITUTION BUFFER(ATELLICA IM CORTISOL URINE RECONSTITUTION BUFFER)-THE ATELLICA™ IM CORTISOL URINE RECONSTITUTION BUFFER IS FOR IN VITRO DIAGNOSTIC USE TO RECONSTITUTE URINE SAMPLES THAT HAVE BEEN EXTRACTED AS DESCRIBED IN URINARY CORTISOL EXTRACTION PROCEDURE. EXTRACTED URINARY CORTISOL LEVELS ARE DETERMINED ON RECONSTITUTED URINE SAMPLES USING THE ATELLICA™ IM ANALYZER,ATELLICA IM COMPLEXED PROSTATESPECIFIC ANTIGEN QUALITY CONTROL (CPSA QC)(ATELLICA IM COMPLEXED PROSTATESPECIFIC ANTIGEN QUALITY CONTROL (CPSA QC))-THE ATELLICA™ IM COMPLEXED PROSTATESPECIFIC ANTIGEN QUALITY CONTROL (CPSA QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND THE ACCURACY OF THE ATELLICA IM CPSA ASSAY USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM CALIBRATOR O (CAL O)| ATELLICA IM CALIBRATOR O (CAL O) (ATELLICA IM CALIBRATOR O (CAL O)| ATELLICA IM CALIBRATOR O (CAL O))-THE ATELLICA™ IM CALIBRATOR O (CAL O) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM ATPO ASSAY

	USING THE ATELLICA™ IM ANALYZER, ATELLICA IM COMPLEXED PROSTATE-SPECIFIC ANTIGEN MASTER CURVE MATERIAL (CPSA MCM)(ATELLICA IM COMPLEXED PROSTATE-SPECIFIC ANTIGEN MASTER CURVE MATERIAL (CPSA MCM))-THE ATELLICA™ IM COMPLEXED PROSTATE-SPECIFIC ANTIGEN MASTER CURVE MATERIAL (CPSA MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM CPSA ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ADVIA CENTAUR CA 15-3 (CA 15-3)(ADVIA CENTAUR CA 15-3 (CA 15-3))-THE ADVIA CENTAUR® CA 15- 3 ASSAY IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE SERIAL DETERMINATION OF CANCER ANTIGEN CA 15-3 IN HUMAN SERUM USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CP SYSTEMS. WHEN USED IN CONJUNCTION WITH OTHER CLINICAL AND DIAGNOSTIC PROCEDURES, SERIAL TESTING WITH THE ADVIA CENTAUR CA 15-3 ASSAY IS USEFUL FOR MONITORING THE COURSE OF DISEASE AND THERAPY IN METASTATIC BREAST CANCER PATIENTS, AND FOR DETECTION OF RECURRENCE IN PREVIOUSLY TREATED STAGE 11, WITH GREATER THAN TWO POSITIVE LYMPH NODES, OR STAGE ILL BREAST CANCER PATIENTS. THIS ASSAY IS NOT INTENDED FOR USE ON ANY OTHER SYSTEM., ATELLICA IM HIV AG/AB COMBO (CHIV) (ATELLICA IM HIV AG/AB COMBO (CHIV))-THE ATELLICA™ IM HIV AG/AB COMBO (CHIV) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE SIMULTANEOUS QUALITATIVE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUSES TYPE 1 (INCLUDING GROUP “O”) AND TYPE 2 IN HUMAN SERUM AND PLASMA (EDTA), TO AID IN THE DIAGNOSIS OF HIV INFECTION, USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM PTH MCM (PTH MCM) (ATELLICA IM PTH MCM (PTH MCM))-THE ATELLICA™ IM INTACT PARATHYROID HORMONE MASTER CURVE MATERIAL (PTH MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM PTH ASSAY,ATELLICA IM SYPHILIS (SYPH)(ATELLICA IM SYPHILIS (SYPH)) -THE ATELLICA™ IM SYPHILIS (SYPH) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF ANTIBODIES TO TREPONEMA PALLIDUM IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, SODIUM HEPARIN, AND CITRATE) USING THE ATELLICA™ IM ANALYZER AS AN AID IN THE DIAGNOSIS OF SYPHILIS.,ATELLICA IM TOTAL THYROXINE DILUENT (T4 DIL)| ATELLICA IM TOTAL THYROXINE DILUENT (T4 DIL)(ATELLICA IM TOTAL THYROXINE DILUENT (T4 DIL)| ATELLICA IM TOTAL THYROXINE DILUENT (T4 DIL))-ATELLICA IM TOTAL THYROXINE

	DILUENT (T4 DIL)| ATELLICA IM TOTAL THYROXINE DILUENT (T4 DIL) USED AS DILUENT.,ATELLICA IM HEPATITIS B E ANTIGEN (HBEAG) (ATELLICA IM HEPATITIS B E ANTIGEN (HBEAG))-THE ATELLICA™ IM HEPATITIS B E ANTIGEN (HBEAG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF THE HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, AND SODIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER. THIS ASSAY IS USED IN COMBINATION WITH OTHER HEPATITIS B VIRUS (HBV) MARKER ASSAYS TO DEFINE THE CLINICAL STATUS OF KNOWN HBVINFECTED PATIENTS. USE THIS ASSAY AS AN AID IN DIAGNOSIS OF INDIVIDUALS WITH ACUTE AND CHRONIC HEPATITIS B INFECTION,ATELLICA IM TOTAL TRIIODOTHYRONINE (T3)(ATELLICA IM TOTAL TRIIODOTHYRONINE (T3))-THE ATELLICA™ IM TOTAL TRIIODOTHYRONINE (T3) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. MEASUREMENTS OF TRIIODOTHYRONINE ARE USED IN THE DIAGNOSIS AND TREATMENT OF THYROID DISEASE.,ATELLICA IM FREE PROSTATESPECIFIC ANTIGEN (FPSA)(ATELLICA IM FREE PROSTATESPECIFIC ANTIGEN (FPSA))-THE ATELLICA™ IM FREE PROSTATESPECIFIC ANTIGEN (FPSA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF FREE PROSTATESPECIFIC ANTIGEN IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. THE ATELLICA IM FPSA ASSAY IS INTENDED TO BE USED IN CONJUNCTION WITH THE ATELLICA IM PSA ASSAY IN MEN AGED 50 YEARS OR OLDER WITH TOTAL PSA VALUES BETWEEN 4 AND 10 NG/ML AND A DIGITAL RECTAL EXAM (DRE) NONSUSPICIOUS FOR CANCER TO DETERMINE THE PERCENT FREE PSA VALUE. THE PERCENT FREE PSA VALUE CAN BE USED AS AN AID IN DISCRIMINATING BETWEEN PROSTATE CANCER AND BENIGN PROSTATIC DISEASE. PROSTATE BIOPSY IS REQUIRED FOR THE DIAGNOSIS OF PROSTATE CANCER.,ATELLICA IM T3/T4/VB12 ANC (ATELLICA IM T3/T4/VB12 ANC)-ATELLICA IM T3/T4/VB12 ANC USED AS ANCILLARY REAGENT.,ATELLICA IM CARCINOEMBRYONIC ANTIGEN (CEA)(ATELLICA IM CARCINOEMBRYONIC ANTIGEN (CEA))-THE ATELLICA™ IM CARCINOEMBRYONIC ANTIGEN (CEA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN IN HUMAN SERUM TO AID IN THE MANAGEMENT OF CANCER PATIENTS IN WHOM CHANGING CONCENTRATIONS OF CEA ARE OBSERVED USING THE ATELLICA™ IM ANALYZER,ATELLICA IM LUTEINIZING HORMONE MASTER CURVE MATERIAL (LH MCM)(ATELLICA IM LUTEINIZING HORMONE MASTER CURVE MATERIAL (LH MCM))-THE ATELLICA™ IM

	LUTEINIZING HORMONE MASTER CURVE MATERIAL (LH MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM LH ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM. ,ATELLICA IM ANTI-HEPATITIS B E ANTIGEN (AHBE)(ATELLICA IM ANTI-HEPATITIS B E ANTIGEN (AHBE))-THE ATELLICA™ IM ANTI-HEPATITIS B E ANTIGEN (AHBE) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF ANTIBODY RESPONSE TO THE E ANTIGEN OF THE HEPATITIS B VIRUS (HBV) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, AND SODIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER. USE THIS ASSAY IN COMBINATION WITH OTHER HBV MARKER ASSAYS TO DEFINE THE CLINICAL STATUS OF KNOWN HBV-INFECTED PATIENTS.,ATELLICA IM CALIBRATOR 30 (CAL 30) (ATELLICA IM CALIBRATOR 30 (CAL 30))-THE ATELLICA™ IM CALIBRATOR 30 (CAL 30) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM EE2 ASSAY USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM TOXOPLASMA IGG (TOXO G) (ATELLICA IM TOXOPLASMA IGG (TOXO G))-THE ATELLICA™ IM TOXOPLASMA IGG (TOXO G) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER. THE MEASUREMENT OF TOXOPLASMA IGG MAY BE USED TO AID IN THE ASSESSMENT OF A PATIENT'S IMMUNOLOGICAL RESPONSE FROM INDIVIDUALS INCLUDING WOMEN OF CHILDBEARING AGE. THIS ASSAY MAY BE UTILIZED WITH A TOXOPLASMA IGM RESULT TO DETERMINE RECENT SEROLOGICAL RESPONSE TO TOXOPLASMA GONDII. THIS ASSAY IS NOT INTENDED FOR USE IN SCREENING BLOOD, PLASMA, OR TISSUE DONORS.,ATELLICA IM ENHANCED ESTRADIOL MASTER CURVE MATERIAL (EE2 MCM)(ATELLICA IM ENHANCED ESTRADIOL MASTER CURVE MATERIAL (EE2 MCM))-THE ATELLICA™ IM ENHANCED ESTRADIOL MASTER CURVE MATERIAL (EE2 MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM EE2 ASSAY. ,ATELLICA IM TOXOPLASMA IGM (TOXO M)(ATELLICA IM TOXOPLASMA IGM (TOXO M))-THE ATELLICA™ IM TOXOPLASMA IGM (TOXO M) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER. THE ATELLICA IM TOXO M ASSAY IS USED TO MEASURE IGM ANTIBODY AGAINST T. GONDII, WHICH IS PRESUMPTIVE OF ACUTE, RECENT, OR REACTIVATED TOXOPLASMA INFECTION. ANY MEASUREMENT OF IGM ANTIBODY TO T. GONDII MUST BE

	PERFORMED IN CONJUNCTION WITH THE DETERMINATION OF IGG ANTIBODY TO T. GONDII. THIS ASSAY IS NOT INTENDED FOR USE IN SCREENING BLOOD, PLASMA, OR TISSUE DONORS.,ATELLICA IM ENHANCED ESTRADIOL DILUENT (EE2 DIL)(ATELLICA IM ENHANCED ESTRADIOL DILUENT (EE2 DIL))-ATELLICA IM ENHANCED ESTRADIOL DILUENT (EE2 DIL) USED AS A DILUENT.,ATELLICA IM PROSTATESPECIFIC ANTIGEN (PSA)(ATELLICA IM PROSTATESPECIFIC ANTIGEN (PSA))-THE ATELLICA™ IM PROSTATESPECIFIC ANTIGEN (PSA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF PROSTATESPECIFIC ANTIGEN IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. THIS ASSAY IS INDICATED FOR THE MEASUREMENT OF SERUM PSA, IN CONJUNCTION WITH A DIGITAL RECTAL EXAM (DRE), AS AN AID IN THE DETECTION OF PROSTATE CANCER IN MEN AGED 50 YEARS AND OLDER. THIS ASSAY IS FURTHER INDICATED AS AN AID IN THE MANAGEMENT (MONITORING) OF PATIENTS WITH PROSTATE CANCER,ATELLICA IM TESTOSTERONE II (TSTII)(ATELLICA IM TESTOSTERONE II (TSTII))-THE ATELLICA™ IM TESTOSTERONE II (TSTII) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE (BOUND AND UNBOUND) IN HUMAN SERUM AND PLASMA USING THE ATELLICA™ IM ANALYZER. MEASUREMENTS OF TESTOSTERONE ARE USED IN THE DIAGNOSIS AND TREATMENT OF DISORDERS INVOLVING THE MALE SEX HORMONES (ANDROGENS), INCLUDING PRIMARY AND SECONDARY HYPOGONADISM, DELAYED OR PRECOCIOUS PUBERTY, IMPOTENCE IN MALES AND, IN FEMALES, HIRSUTISM (EXCESSIVE HAIR) AND VIRILIZATION (MASCULINIZATION) DUE TO TUMORS, POLYCYSTIC OVARIES, AND ADRENOGENITAL SYNDROMES., ATELLICA IM RUBELLA IGM (RUB M)(ATELLICA IM RUBELLA IGM (RUB M))-THE ATELLICA™ IM RUBELLA IGM (RUB M) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO THE RUBELLA VIRUS IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER., ATELLICA IM TOTAL THYROXINE (T4)(ATELLICA IM TOTAL THYROXINE (T4))-THE ATELLICA™ IM TOTAL THYROXINE (T4) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. MEASUREMENTS OF THYROXINE ARE USED IN THE DIAGNOSIS AND TREATMENT OF THYROID DISEASE., ATELLICA IM CARCINOEMBRYONIC ANTIGEN (CEA DIL)(ATELLICA IM CARCINOEMBRYONIC ANTIGEN (CEA DIL))-THE ATELLICA™ IM CARCINOEMBRYONIC ANTIGEN (CEA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN IN HUMAN SERUM TO AID IN THE

	MANAGEMENT OF CANCER PATIENTS IN WHOM CHANGING CONCENTRATIONS OF CEA ARE OBSERVED USING THE ATELLICA™ IM ANALYZER.,ADVIA CENTAUR CYCLOSPORINE (CSA)(ADVIA CENTAUR CYCLOSPORINE (CSA))-THE ADVIA CENTAUR® CYCLOSPORINE (CSA) ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAV FOR THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE IN HUMAN WHOLE BLOOD USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CP SYSTEMS. THIS ASSAY IS INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF CYCLOSPORINE THERAPY IN KIDNEY, HEART, AND LIVER TRANSPLANT PATIENTS. ,ATELLICA IM ANTIHEPATITIS B CORE TOTAL (HBCT) (ATELLICA IM ANTIHEPATITIS B CORE TOTAL (HBCT)) -THE ATELLICA™ IM ANTI-HEPATITIS B CORE TOTAL (HBCT) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF TOTAL ANTIBODIES TO THE CORE ANTIGEN OF THE HEPATITIS B VIRUS (HBV) IN HUMAN SERUM AND PLASMA (EDTA) USING THE ATELLICA™ IM ANALYZER. THIS ASSAY CAN BE USED AS AN AID IN THE DIAGNOSIS OF INDIVIDUALS WITH ACUTE OR CHRONIC HEPATITIS B VIRUS (HBV) INFECTION AND IN THE DETERMINATION OF THE CLINICAL STATUS OF HBV-INFECTED INDIVIDUALS IN CONJUNCTION WITH OTHER HBV SEROLOGICAL MARKERS FOR THE LABORATORY DIAGNOSIS OF HBV DISEASE ASSOCIATED WITH HBV INFECTION. THIS ASSAY CAN ALSO BE USED AS AN AID IN THE DIFFERENTIAL DIAGNOSIS IN INDIVIDUALS DISPLAYING SIGNS AND SYMPTOMS OF HEPATITIS IN WHOM ETIOLOGY IS UNKNOWN.,ATELLICA IM LUTEINIZING HORMONE (LH) (ATELLICA IM LUTEINIZING HORMONE (LH))-THE ATELLICA™ IM LUTEINIZING HORMONE (LH) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM HER2/NEU (H2N)(ATELLICA IM HER2/NEU (H2N))-THE ATELLICA™ IM HER2/NEU (H2N) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE HER2/NEU PROTEIN IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. HER2/NEU VALUES OBTAINED MAY BE USED IN THE FOLLOW-UP AND MONITORING OF PATIENTS WITH METASTATIC BREAST CANCER WHOSE INITIAL SERUM HER2/NEU LEVEL IS > 15 NG/ML. HER2/NEU VALUES SHOULD BE USED IN CONJUNCTION WITH INFORMATION AVAILABLE FROM CLINICAL AND OTHER DIAGNOSTIC PROCEDURES IN THE MANAGEMENT OF BREAST CANCER. THE CLINICAL UTILITY OF THE MEASUREMENT OF HER2/NEU IN SERUM AS A PROGNOSTIC INDICATOR FOR EARLY RECURRENCE AND IN THE MANAGEMENT OF PATIENTS ON IMMUNOTHERAPY HAS NOT BEEN FULLY ESTABLISHED. THIS TEST

	SHOULD BE USED BY OR UNDER THE ORDER OF A PHYSICIAN. THIS ASSAY IS NOT INTENDED FOR USE ON ANY OTHER SYSTEM.,ADVIA CENTAUR VITAMIN D TOTAL MASTER CURVE MATERIAL (VITD MCM) (ADVIA CENTAUR VITAMIN D TOTAL MASTER CURVE MATERIAL (VITD MCM))-THE ADVIA CENTAUR® VITAMIN D (VITD) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR VITD ASSAY.,ATELLICA IM HEPATITIS B CORE ANTIGEN (AHBCM) (ATELLICA IM HEPATITIS B CORE ANTIGEN (AHBCM))-THE ATELLICA™ IM HEPATITIS B CORE ANTIGEN (AHBCM) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF IGM RESPONSE TO THE CORE ANTIGEN OF THE HEPATITIS B VIRUS (HBC IGM) IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN, AND SODIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER. THIS ASSAY IS USED IN COMBINATION WITH OTHER HEPATITIS B VIRUS (HBV) MARKER ASSAYS TO DEFINE THE CLINICAL STATUS OF KNOWN HBV-INFECTED PATIENTS OR IT CAN BE COMBINED WITH OTHER HBV, HAV (HEPATITIS A VIRUS), AND HCV (HEPATITIS C VIRUS) ASSAYS FOR THE DIAGNOSIS OF PATIENTS PRESENTING SYMPTOMS OF ACUTE VIRAL HEPATITIS.,ATELLICA IM MULTI- DILUENT 10(ATELLICA IM MULTI- DILUENT 10)-NA,ATELLICA IM TOXOPLASMA IGG (TOXO G) (ATELLICA IM TOXOPLASMA IGG (TOXO G))-THE ATELLICA™ IM TOXOPLASMA IGG (TOXO G) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER. THE MEASUREMENT OF TOXOPLASMA IGG MAY BE USED TO AID IN THE ASSESSMENT OF A PATIENT'S IMMUNOLOGICAL RESPONSE FROM INDIVIDUALS INCLUDING WOMEN OF CHILDBEARING AGE. THIS ASSAY MAY BE UTILIZED WITH A TOXOPLASMA IGM RESULT TO DETERMINE RECENT SEROLOGICAL RESPONSE TO TOXOPLASMA GONDII. THIS ASSAY IS NOT INTENDED FOR USE IN SCREENING BLOOD, PLASMA, OR TISSUE DONORS.,ATELLICA IM FREE TRIIODOTHYRONINE MASTER CURVE MATERIAL (FT3 MCM)(ATELLICA IM FREE TRIIODOTHYRONINE MASTER CURVE MATERIAL (FT3 MCM))-THE ATELLICA™ IM FREE TRIIODOTHYRONINE MASTER CURVE MATERIAL (FT3 MCM) IS FOR INVITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM FT3 ASSAY.THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM, ATELLICA IM COMPLEXED PROSTATESPECIFIC ANTIGEN (CPSA) (ATELLICA IM COMPLEXED PROSTATESPECIFIC ANTIGEN (CPSA))-THE ATELLICA™ IM COMPLEXED PROSTATESPECIFIC ANTIGEN (CPSA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE

	QUANTITATIVE MEASUREMENT OF COMPLEXED PROSTATESPECIFIC ANTIGEN (CPSA) IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER.THIS ASSAY IS INDICATED FOR THE MEASUREMENT OF SERUMCOMPLEXED PSA IN CONJUNCTION WITH DIGITAL RECTAL EXAM (DRE) AS AN AID IN THE DETECTION OF PROSTATE CANCER IN MEN AGED 50 YEARS OR OLDER. BIOPSY OF THE PROSTATE IS REQUIRED FOR THE DIAGNOSIS OF PROSTATE CANCER. THIS ASSAY IS FURTHER INDICATED AS AN AID IN THE MANAGEMENT (MONITORING) OF PROSTATE CANCER PATIENTS.,ATELLICA IM ANCILLARY PROBE WASH 3(ATELLICA IM ANCILLARY PROBE WASH 3)-NA,ATELLICA IM ANTI-HEPATITIS B SURFACE ANTIGEN 2 (AHBS2) (ATELLICA IM ANTI-HEPATITIS B SURFACE ANTIGEN 2 (AHBS2))-THE ATELLICA™ IM ANTI-HEPATITIS B SURFACE ANTIGEN 2 (AHBS2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF TOTAL ANTIBODIES TO HEPATITIS B SURFACE ANTIGEN IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER. THE ASSAY RESULTS MAY BE USED AS AN AID IN THE DETERMINATION OF SUSCEPTIBILITY TO HEPATITIS B VIRUS (HBV) INFECTION IN INDIVIDUALS PRIOR TO OR FOLLOWING HBV VACCINATION OR WHERE VACCINATION STATUS IS UNKNOWN. ASSAY RESULTS MAY BE USED WITH OTHER HBV SEROLOGICAL MARKERS FOR THE LABORATORY DIAGNOSIS OF HBV DISEASE ASSOCIATED WITH HBV INFECTION. A REACTIVE ASSAY RESULT WILL ALLOW A DIFFERENTIAL DIAGNOSIS IN INDIVIDUALS DISPLAYING SIGNS AND SYMPTOMS OF HEPATITIS IN WHOM ETIOLOGY IS UNKNOWN., ATELLICA IM FOLLICLE STIMULATING HORMONE (FSH)(ATELLICA IM FOLLICLE STIMULATING HORMONE (FSH))-THE ATELLICA™ IM FOLLICLE STIMULATING HORMONE (FSH) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF FOLLICLE-STIMULATING HORMONE (FSH) IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER., ATELLICA IM BR 27.29 (BR) (ATELLICA IM BR 27.29 (BR))-THE ATELLICA™ IM BR 27.29 (BR) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE SERIAL DETERMINATION OF CANCER ANTIGEN CA 27.29 IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. THE TEST IS INTENDED FOR USE AS AN AID IN MONITORING PATIENTS PREVIOUSLY TREATED FOR STAGE II OR STAGE III BREAST CANCER. SERIAL TESTING FOR CA 27.29 IN THE SERUM OF PATIENTS WHO ARE CLINICALLY FREE OF DISEASE SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL METHODS USED FOR THE EARLY DETECTION OF CANCER RECURRENCE. THE TEST IS ALSO INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF BREAST CANCER PATIENTS WITH METASTATIC DISEASE BY MONITORING THE PROGRESSION OR REGRESSION OF

	DISEASE IN RESPONSE TO TREATMENT.,ATELLICA IM MYOGLOBIN MASTER CURVE MATERIAL (MYO MCM)(ATELLICA IM MYOGLOBIN MASTER CURVE MATERIAL (MYO MCM))-THE ATELLICA™ IM MYOGLOBIN MASTER CURVE MATERIAL (MYO MCM) IS FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ATELLICA™ IM MYO ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM,ATELLICA IM ALPHA FETOPROTEIN (AFP) (ATELLICA IM ALPHA FETOPROTEIN (AFP))-THE ATELLICA™ IM ALPHA FETOPROTEIN (AFP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALPHA-FETOPROTEIN USING THE ATELLICA™ IM ANALYZER FOR: • HUMAN SERUM AND AMNIOTIC FLUID FROM SPECIMENS OBTAINED AT 15–20 WEEKS GESTATION, AS AN AID IN DETECTING OPEN NEURAL TUBE DEFECTS (NTDS) WHEN USED IN CONJUNCTION WITH ULTRASONOGRAPHY AND AMNIOGRAPHY TESTING; • HUMAN SERUM, AS AN AID IN MANAGING NON-SEMINOMATOUS TESTICULAR CANCER WHEN USED IN CONJUNCTION WITH PHYSICAL EXAMINATION, HISTOLOGY/PATHOLOGY, AND OTHER CLINICAL EVALUATION PROCEDURES.,ATELLICA IM TROPONIN I ULTRA MASTER CURVE MATERIAL (TNI MCM)(ATELLICA IM TROPONIN I ULTRA MASTER CURVE MATERIAL (TNI MCM))-THE ATELLICA™ IM TROPONIN I ULTRA MASTER CURVE MATERIAL (TNI-ULTRA® MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM TNI-ULTRA ASSAY , ATELLICA IM HEPATITIS B CORE ANTIGEN QUALITY CONTROL (AHBCM QC)(ATELLICA IM HEPATITIS B CORE ANTIGEN QUALITY CONTROL (AHBCM QC))-THE ATELLICA™ IM HEPATITIS B CORE ANTIGEN QUALITY CONTROL (AHBCM QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM AHBCM ASSAY USING THE ATELLICA™ IM ANALYZER., ATELLICA IM TROPONIN I ULTRA (TNI-ULTRA)(ATELLICA IM TROPONIN I ULTRA (TNI-ULTRA))-THE ATELLICA™ IM TROPONIN I ULTRA (TNIULTRA®) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN) USING THE ATELLICA™ IM ANALYZER. CARDIAC TROPONIN I DETERMINATIONS AID IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION AND IN THE RISK STRATIFICATION OF PATIENTS WITH NON-ST SEGMENT ELEVATION ACUTE CORONARY SYNDROMES WITH RESPECT TO RELATIVE RISK OF MORTALITY, MYOCARDIAL INFARCTION (MI) OR INCREASED PROBABILITY OF ISCHEMIC EVENTS REQUIRING URGENT REVASCULARIZATION PROCEDURES.,ATELLICA IM RUBELLA IGG QUALITY CONTROL (RUB G QC) (ATELLICA IM RUBELLA IGG QUALITY

	CONTROL (RUB G QC))-THE ATELLICA™ IM RUBELLA IGG QUALITY CONTROL (RUB G QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM RUB G ASSAY USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM MULTIDILUENT 13 (ATELLICA IM MULTIDILUENT 13)-NA,ATELLICA IM TISSUE INHIBITOR OF MATRIX METALLOPROTEINASE 1 (TIMP-1)(ATELLICA IM TISSUE INHIBITOR OF MATRIX METALLOPROTEINASE 1 (TIMP-1))-THE ATELLICA™ IM TISSUE INHIBITOR OF MATRIX METALLOPROTEINASE 1 (TIMP1) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF TIMP1 IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. THE TIMP1 ASSAY IS A COMPONENT OF THE ATELLICA IM ELF™ TEST WHICH IS INDICATED, IN CONJUNCTION WITH OTHER LABORATORY FINDINGS AND CLINICAL ASSESSMENTS, AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF THE SEVERITY OF LIVER FIBROSIS IN PATIENTS WITH SIGNS AND SYMPTOMS OF CHRONIC LIVER DISEASE. THIS TEST IS NOT INTENDED FOR USE ON ANY OTHER SYSTEM.,ATELLICA IM CALIBRATOR B (CAL B)(ATELLICA IM CALIBRATOR B (CAL B))-THE ATELLICA™ IMCALIBRATOR B (CAL B) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FOLLOWING ATELLICA IM ASSAYSUSING THE ATELLICA™ IM ANALYZER: DIG, FSH, LH, PRL, AND THCG,ATELLICA IM CALIBRATOR A (CAL A)(ATELLICA IM CALIBRATOR A (CAL A))-THE ATELLICA™ IM CALIBRATOR A (CAL A) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FOLLOWING ATELLICA IM ASSAYSUSING THE ATELLICA™ IM ANALYZER: FT3, T3, T4, TUP, AND FT4.,ATELLICA IM THYROID UPTAKE (TUP)(ATELLICA IM THYROID UPTAKE (TUP))-THE ATELLICA™ IM THYROID UPTAKE (TUP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE ASSESSMENT OF UNSATURATED THYROID BINDING PROTEINS IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER.,ATELLICA IM FOLLICE STIMULATING HORMONE MASTER CURVE MATERIAL (FT3 MCM)(ATELLICA IM FOLLICE STIMULATING HORMONE MASTER CURVE MATERIAL (FT3 MCM))-THE ATELLICA™ IM FOLLICLE STIMULATING HORMONE MASTER CURVE MATERIAL (FSH MCM) IS FOR IN VITRO DIAGNOSTIC USE INTHE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM FSH ASSAY,ATELLICA IM FREE THYROXINE MASTER CURVE MATERIAL (FT4 MCM)(ATELLICA IM FREE THYROXINE MASTER CURVE MATERIAL (FT4 MCM))-THE ATELLICA™ IM FREE THYROXINE MASTER CURVEMATERIAL (FT4 MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM FT4 ASSAY,ATELLICA IM MULTI-DILUENT 11(ATELLICA IM MULTI-DILUENT 11)-NA,ATELLICA IM MULTI-DILUENT 1(ATELLICA IM MULTI-DILUENT 1)-IT IS INTENDED TO BE USED FOR DILUTION, ATELLICA IM ENHANCED LIVER FIBROSIS CALIBRATOR (ELF CAL)

	(ATELLICA IM ENHANCED LIVER FIBROSIS CALIBRATOR (ELF CAL))-THE ATELLICA™ IM ENHANCED LIVER FIBROSIS CALIBRATOR (ELF™ CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FOLLOWING ATELLICA IM ASSAYS USING THE ATELLICA™IM ANALYZER: HA, PIIINP, AND TIMP1,ADVIA CENTAUR (CKMB)(ADVIA CENTAUR (CKMB))-FOR IN VITRO DIAGNOSTIC USE IN 12 NON- THE QUANTITATIVE DETERMINATION MONTHS STERILE OF CK-MB IN SERUM OR HEPARINIZED PLASMA USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CP SYSTEMS, ADVIA CENTAUR ANTI-T G MASTER CURVE MATERIAL (ATG MCM) (ADVIA CENTAUR ANTI-T G MASTER CURVE MATERIAL (ATG MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® ANTI-TG ASSAY ON THE ADVIA CENTAUR SYSTEMS. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM. ,ADVIA CENTAUR CYCLOSPORINE PRETREATMENT (CSA PRE) (ADVIA CENTAUR CYCLOSPORINE PRETREATMENT (CSA PRE))-THE ADVIA CENTAUR CYCLOSPORINE PRETREATMENT REAGENT IS FOR THE MANUAL PRETREATMENT OF PATIENT SAMPLES TO LYSE THE CELLS AND SOLUBILIZE THE CYCLOSPORINE. ,ADVIA CENTAUR ANTI-TPO (ATPO)(ADVIA CENTAUR ANTI-TPO (ATPO))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF AUTOANTIBODIES AGAINST THYROID PEROXIDASE IN SERUM OR PLASMA USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS.,ADVIA CENTAUR CALIBRATOR G (CAL G)(ADVIA CENTAUR CALIBRATOR G (CAL G))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING ADVIA CENTAUR® SYSTEMS BR ASSAYS. ,ADVIA CENTAUR CALIBRATOR 1 (CAL 1) (ADVIA CENTAUR CALIBRATOR 1 (CAL 1))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR® ANTI-TG ASSAY ON THE ADVIA CENTAUR SYSTEMS.,ADVIA CENTAURCSA MASTER CURVE MATERIAL(ADVIA CENTAURCSA MASTER CURVE MATERIAL)-FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR® CYCLOSPORINE (CSA) ASSAY. ,ADVIA CENTAUR QUALITY CONTROL ANTI-TG 1,2 ATG QC)(ADVIA CENTAUR QUALITY CONTROL ANTI-TG 1,2 ATG QC))-FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND THE ACCURACY OF THE ADVIA CENTAUR® ANTI-TG ASSAY ON THE ADVIA CENTAUR SYSTEMS. ,ADVIA CENTAUR IGE DILUENT(ADVIA CENTAUR IGE DILUENT)-THE ADVIA CENTAUR IGE DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ADVIA CENTAUR TIGE ASSAY.,ADVIA CENTAUR ANTI-HBE (AHBE) (ADVIA CENTAUR ANTI-HBE (AHBE))-THE ADVIA CENTAUR ANTI-HBE (AHBE) ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE

	QUALITATIVE DETERMINATION OF ANTIBODY RESPONSE TO THE E ANTIGEN OF THE HEPATITIS B VIRUS (HBV) IN HUMAN SERUM AND PLASMA USING THE ADVIA CENTAUR AND ADVIA CENTAUR XP SYSTEMS. USE THIS ASSAY IN COMBINATION WITH OTHER HEPATITIS B VIRUS (HBV) MARKER ASSAYS TO DEFINE THE CLINICAL STATUS OF KNOWN HBV INFECTED PATIENTS.,ATELLICA IM FREE THYROXINE (FT4)(ATELLICA IM FREE THYROXINE (FT4))-THE ATELLICA™ IM FREE THYROXINE (FT4) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF FREE THYROXINE IN HUMAN SERUM AND PLASMA (EDTA AND HEPARIN), USING THE ATELLICA™ IM ANALYZER. MEASUREMENTS OF FREE THYROXINE ARE USED IN THE DIAGNOSIS AND TREATMENT OF THYROID DISEASE.,ADVIA CENTAUR CA 15-3 MASTER CURVE MATERIAL (CA 15-3 MCM)(ADVIA CENTAUR CA 15-3 MASTER CURVE MATERIAL (CA 15-3 MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® CA 15-3® ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM. ,ADVIA CENTAUR BNP CALIBRATOR (BNP CAL) (ADVIA CENTAUR BNP CALIBRATOR (BNP CAL))-REFER TO THE CALIBRATOR ASSIGNED VALUE CARD FOR THE ASSIGNED VALUE OF EACH CALIBRATOR. THE ASSIGNED VALUES ARE TRACEABLE TO INTERNAL STANDARDS MANUFACTURED USING SYNTHETIC HUMAN BNP (AMINO ACID 77- 108). ,ATELLICA IM DIGOXIN (DIG)(ATELLICA IM DIGOXIN (DIG))-THE ATELLICA™ IM DIGOXIN (DIG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF DIGOXIN IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER., ATELLICA IM TOTAL TRIIODOTHYRONINE MASTER CURVE MATERIAL (T3 MCM)(ATELLICA IM TOTAL TRIIODOTHYRONINE MASTER CURVE MATERIAL (T3 MCM))-THE ATELLICA™ IM TOTAL TRIIODOTHYRONINE MASTER CURVE MATERIAL (T3 MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM T3 ASSAY ,ATELLICA IM MULTIDILUENT 5(ATELLICA IM MULTIDILUENT 5)-ATELLICA IM MULTIDILUENT 5 USED AS DILUENT., ATELLICA IM CALIBRATOR E (CAL E) (ATELLICA IM CALIBRATOR E (CAL E))-THE ATELLICA™ IM CALIBRATOR E (CAL E) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FOLLOWING ATELLICA IM ASSAYS USING THE ATELLICA™ IM ANALYZER: COR AND PRGE. ,ADVIA CENTAUR TOXOPLASMA G (TOXO G)(ADVIA CENTAUR TOXOPLASMA G (TOXO G))-THE ADVIA CENTAUR® TOXOPLASMA G (TOXO G) ASSAY IS AN IGG ANTIBODY CAPTURE MICROPARTICLE DIRECT CHEMILUMINOMETRIC IN VITRO DIAGNOSTIC IMMUNOASSAY INTENDED FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN SERUM OR PLASMA

	(EDTA, HEPARIN) USING THE ADVIA CENTAUR, ADVIA CENTAUR CP, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THE MEASUREMENT OF TOXOPLASMA IGG MAY BE USED TO AID IN THE ASSESSMENT OF A PATIENT'S IMMUNOLOGICAL RESPONSE FROM INDIVIDUALS INCLUDING WOMEN OF CHILDBEARING AGE. THIS ASSAY MAY BE UTILIZED WITH A TOXOPLASMA IGM RESULT TO DETERMINE RECENT SEROLOGICAL RESPONSE TO TOXOPLASMA GONDII. THIS ASSAY IS NOT INTENDED FOR USE IN SCREENING BLOOD, PLASMA, OR TISSUE DONORS. ,ADVIA CENTAUR CKMB II MASTER CURVE MATERIAL (CKMB MCM) (ADVIA CENTAUR CKMB II MASTER CURVE MATERIAL (CKMB MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® CKMB ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ADVIA CENTAUR VALPROIC ACID MASTER CURVE MATERIAL (VALP MCM)(ADVIA CENTAUR VALPROIC ACID MASTER CURVE MATERIAL (VALP MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® VALPROIC ACID ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ADVIA CENTAUR CALIBRATOR 28(ADVIA CENTAUR CALIBRATOR 28)-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING ADVIA CENTAUR SYSTEMS VALPROIC ACID ASSAYS.,ADVIA CENTAUR CARBAMAZEPIN E (CARB) (ADVIA CENTAUR CARBAMAZEPIN E (CARB))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CARBAMAZEPINE IN SERUM OR PLASMA USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CP SYSTEMS. ,ADVIA CENTAUR VITAMIN D TOTAL (VITD) (ADVIA CENTAUR VITAMIN D TOTAL (VITD))-THE ADVIA CENTAUR® VITAMIN D TOTAL (VITD) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL 25(OH)VITAMIN D IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM-HEPARIN, SODIUM-HEPARIN) USING THE ADVIA CENTAUR, ADVIA CENTAUR CP, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THE ADVIA CENTAUR VITD ASSAY IS INTENDED AS AN AID IN THE DETERMINATION OF VITAMIN D SUFFICIENCY.,ADVIA CENTAUR TUP (ADVIA CENTAUR TUP)-FOR IN VITRO DIAGNOSTIC USE IN THE ASSESSMENT OF UNSATURATED THYROID BINDING PROTEINS IN SERUM USING THE ADVIA CENTAUR®, ADVIA CENTAUR CP, AND ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS.,ADVIA CENTAUR CA 15-3 CALIBRATOR (CA 15-3 CAL) (ADVIA CENTAUR CA 15-3 CALIBRATOR (CA 15-3 CAL))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR® CA 15-3® ASSAY. ,ADVIA CENTAUR CPSA MASTER CURVE MATERIAL (CPSA MCM)(ADVIA

	CENTAUR CPSA MASTER CURVE MATERIAL (CPSA MCM))-FOR.IN VITRO DIAGNOSTIC USE FOR 9 EVALUATING THE ADVIA CENTAUR® SYSTEM CPSA ASSAYS. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO- POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM. ,ADVIA CENTAUR ALPHA-FETOPROTEIN MASTER CURVE MATERIAL (AFP MCM)(ADVIA CENTAUR ALPHA- FETOPROTEIN MASTER CURVE MATERIAL (AFP MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® AFP ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM. ,ADVIA CENTAUR SHBG MASTER CURVE MATERIAL (SHBG MCM)(ADVIA CENTAUR SHBG MASTER CURVE MATERIAL (SHBG MCM))-THE ADVIA CENTAUR® SHBG MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR SHBG ASSAY.,ADVIA CENTAUR TSH3-UL MASTER CURVE MATERIAL (TSH3-UL MCM)(ADVIA CENTAUR TSH3-UL MASTER CURVE MATERIAL (TSH3-UL MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® TSH3-UL ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ADVIA CENTAUR CALIBRATOR D (CAL D)(ADVIA CENTAUR CALIBRATOR D (CAL D))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FOLLOWING ASSAYS USING ADVIA CENTAUR® OR ACS:180® SYSTEMS: AFP CEA.,ADVIA CENTAUR FREE PSA (FPSA) (ADVIA CENTAUR FREE PSA (FPSA))-THE ADVIA CENTAUR® FREE PSA (FPSA) ASSAY IS FOR IN VITRO QUANTITATIVE MEASUREMENT OF FREE PROSTATE-SPECIFIC ANTIGEN IN HUMAN SERUM USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THE ADVIA CENTAUR F PSA ASSAY IS INTENDED TO BE USED IN CONJUNCTION WITH THE ADVIA CENTAUR PSA ASSAY IN MEN AGED 50 YEARS OR OLDER WITH TOTAL PSA VALUES BETWEEN 4 AND 10 NG/ML AND DIGITAL RECTAL EXAM (DRE) NON-SUSPICIOUS FOR CANCER TO DETERMINE THE PERCENT FREE PSA VALUE. THE PERCENT FREE PSA VALUE CAN BE USED AS AN AID IN DISCRIMINATING BETWEEN PROSTATE CANCER AND BENIGN PROSTATIC DISEASE. PROSTATE BIOPSY IS REQUIRED FOR THE DIAQNOSIS OF PROSTATE CANCER. ,ADVIA CENTAUR AFP (AFP) (ADVIA CENTAUR AFP (AFP))-FOR IN VITRO DIAGNOSTIC USE IN HE QUANTITATIVE DETERMINATION MONTHS OF ALPHA-FETOPROTEIN (AFP) IN THE FOLLOWING: • HUMAN SERUM AND IN AMNIOTIC FLUID FROM SPECIMENS OBTAINED AT 15 TO 20 WEEKS GESTATION, AS AN AID IN DETECTING OPEN NEURAL TUBE DEFECTS (NTDS) WHEN USED IN CONJUNCTION WITH ULTRASONOGRAPHY AND AMNIOGRAPHY

	TESTING HUMAN SERUM, AS AN AID IN MANAGING NON-SEMINOMATOUS TESTICULAR CANCER WHEN USED IN CONJUNCTION WITH PHYSICAL EXAMINATION, HISTOLOGY/PATHOLOGY, AND OTHER CLINICAL EVALUATION PROCEDURES, USING THE ADVIA CENTAUR, ADVIA CENTAUR XP AND ADVIA CENTAUR CP SYSTEMS. , ADVIA CENTAUR VALPROIC ACID (VALP)(ADVIA CENTAUR VALPROIC ACID (VALP))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF VALPROIC ACID IN SERUM OR PLASMA USING THE ADVIA CENTAUR®, ADVIA CENTAUR CP, AND ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS.,ATELLICA IM HYALURONIC ACID (HA)(ATELLICA IM HYALURONIC ACID (HA))-THE ATELLICA™ IM HYALURONIC ACID (HA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF HYALURONIC ACID IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. THE ATELLICA IM HA ASSAY IS A COMPONENT OF THE ELF™ TEST WHICH IS INDICATED, IN CONJUNCTION WITH OTHER LABORATORY FINDINGS AND CLINICAL ASSESSMENTS, AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF THE SEVERITY OF LIVER FIBROSIS IN PATIENTS WITH SIGNS AND SYMPTOMS OF CHRONIC LIVER DISEASE. THIS TEST IS NOT INTENDED FOR USE ON ANY OTHER SYSTEM.,ATELLICA IM MULTI-DILUENT 12 (ATELLICA IM MULTI-DILUENT 12)-IT IS INTENDED TO BE USED FOR DILUTION ,ADVIA CENTAUR TNI-ULTRA(ADVIA CENTAUR TNI-ULTRA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN SERUM, HEPARINIZED OR EDTA PLASMA USING THE ADVIA CENTAUR CP, ADVIA CENTAUR, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. CARDIAC TROPONIN I DETERMINATIONS AID IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION AND IN THE RISK STRATIFICATION OF PATIENTS WITH NON-ST SEGMENT ELEVATION ACUTE CORONARY SYNDROMES WITH RESPECT TO RELATIVE RISK OF MORTALITY, MYOCARDIAL INFARCTION (MI) OR INCREASED PROBABILITY OF ISCHEMIC EVENTS REQUIRING URGENT REVASCULARIZATION PROCEDURES,ATELLICA IM CYCLOSPORINE PRE(ATELLICA IM CYCLOSPORINE PRE)-NA,ATELLICA IM CYCLOSPORINE CALIBRATOR (CSA CAL)(ATELLICA IM CYCLOSPORINE CALIBRATOR (CSA CAL))-THE ATELLICA™ IM CYCLOSPORINE CALIBRATOR (CSA CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM CSA ASSAY USING THE ATELLICA™ IM ANALYZER,ADVIA CENTAUR MULTI-DILUENT 15(ADVIA CENTAUR MULTI-DILUENT 15)-THE ADVIA CENTAUR MULTI-DILUENT 15 IS FOR USE IN CONJUNCTION WITH THE ADVIA CENTAUR BNP AND TSH3-UL REAGENTS. ADVIA CENTAUR MULTI-DILUENT 15 IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE RESPECTIVE ASSAYS.,ATELLICA

	IM PW3(ATELLICA IM PW3)-NA,ATELLICA IM CYCLOSPORINE MASTER CURVE MATERIAL (CSA MCM)(ATELLICA IM CYCLOSPORINE MASTER CURVE MATERIAL (CSA MCM))-THE ATELLICA™ IM CYCLOSPORINE MASTER CURVE MATERIAL (CSA MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THEATELLICA™ IM CSA ASSAY,ATELLICA IM MYOGLOBIN (MYO)(ATELLICA IM MYOGLOBIN (MYO))-THE ATELLICA™ IM MYOGLOBIN (MYO) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM AND PLASMA (HEPARIN) AND AS AN AID IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION USING THE ATELLICA™ IM ANALYZER., ATELLICA IM NTERMINAL PROPEPTIDE OF TYPE III PROCOLLAGEN (PIIINP)(ATELLICA IM NTERMINAL PROPEPTIDE OF TYPE III PROCOLLAGEN (PIIINP))-THE ATELLICA™ IM NTERMINAL PROPEPTIDE OF TYPE III PROCOLLAGEN (PIIINP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF AMINO-TERMINAL PROPEPTIDE OF TYPE III PROCOLLAGEN IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. THE ATELLICA IM PIIINP ASSAY IS A COMPONENT OF THE ATELLICA IM ELF™ TEST WHICH IS INDICATED, IN CONJUNCTION WITH OTHER LABORATORY FINDINGS AND CLINICAL ASSESSMENTS, AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF THE SEVERITY OF LIVER FIBROSIS IN PATIENTS WITH SIGNS AND SYMPTOMS OF CHRONIC LIVER DISEASE. THIS TEST IS NOT INTENDED FOR USE ON ANY OTHER SYSTEM.,ATELLICA IM HIGH SENSITIVITY TROPONIN I (TNIH) (ATELLICA IM HIGH SENSITIVITY TROPONIN I (TNIH))-THE ATELLICA™ IM HIGH SENSITIVITY TROPONIN I (TNIH) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF CARDIAC TROPONIN I IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN) USING THE ATELLICA™ IM ANALYZER. THE ASSAY CAN BE USED TO AID IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI),ADVIA CENTAUR HCY (HCY)(ADVIA CENTAUR HCY (HCY))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL HOMOCYSTEINE (HCY) IN SERUM OR PLASMA USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS. THIS DIAGNOSTIC TEST IS DESIGNED TO QUANTITATIVELY MEASURE HCY IN SERUM OR PLASMA. SUCH MEASUREMENT CAN AID IN THE DIAGNOSIS AND TREATMENT OF PATIENTS SUSPECTED OF HAVING HOMOCVSTEINURIA OR HYPERHOMOCYSTEINEMIA. HETEROPHILIC ANTIBODIES IN HUMAN SERUM CAN REACT WITH REAGENT IMMUNOGLOBULINS, INTERFERING WITH IN VITRO IMMUNOASSAYS. PATIENTS ROUTINELY EXPOSED TO ANIMALS OR TO ANIMAL SERUM PRODUCTS CAN BE PRONE TO THIS INTERFERENCE AND ANOMALOUS VALUES MAY BE

	OBSERVED. ADDITIONAL INFORMATION MAY BE REQUIRED FOR DIAGNOSIS. ,ADVIA CENTAUR ANTI-HBE QUALITY CONTROL MATERIAL(ADVIA CENTAUR ANTI-HBE QUALITY CONTROL MATERIAL)-FOR MONITORING THE PERFORMANCE OF THE HBEAG ASSAY ON THE ADVIA CENTAUR® SYSTEMS. THE PERFORMANCE OF THE HBEAG QUALITY CONTROL MATERIAL HAS NOT BEEN ESTABLISHED WTH ANY OTHER HBEAG ASSAY.,ADVIA CENTAUR CPSA PRETREATMENT REAGENT (CPSA PRE)(ADVIA CENTAUR CPSA PRETREATMENT REAGENT (CPSA PRE))-THIS IN VITRO DIAGNOSTIC ASSAY IS INTENDED TO QUANTITATIVELY MEASURE COMPLEXED PROSTATE SPECIFIC ANTIGEN (CPSA) IN HUMAN SERUM USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT, AND ADVIA CENTAUR CP SYSTEMS. THIS ASSAY IS INDICATED FOR THE MEASUREMENT OF SERUM COMPLEXED PSA IN CONJUNCTION WITH DIGITAL RECTAL EXAM (DRE) AS AN AID IN THE DETECTION OF PROSTATE CANCER IN MEN AGED 50 YEARS OR OLDER. BIOPSY OF THE PROSTATE IS REQUIRED FOR THE DIAGNOSIS OF PROSTATE CANCER. THIS ASSAY IS FURTHER INDICATED AS AN AID IN THE MANAGEMENT (MONITORING) OF PROSTATE CANCER PATIENTS. , ADVIA CENTAUR DHEA-S04 (DHEAS)(ADVIA CENTAUR DHEA-S04 (DHEAS))-THE ADVIA CENTAUR® DHEAS ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE, QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE (DHEAS) IN HUMAN SERUM AND PLASMA USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS.,ADVIA CENTAUR SYPHILIS QUALITY CONTROL (SYPH QC) (ADVIA CENTAUR SYPHILIS QUALITY CONTROL (SYPH QC))-FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PERFORMANCE OF THE SYPHILIS (SYPH) ASSAY ON THE ADVIA CENTAUR® SYSTEMS. THE PERFORMANCE OF THE SYPH QUALITY CONTROL MATERIAL HAS NOT BEEN ESTABLISHED WITH ANY OTHER SYPHILIS ASSAY. ,ADVIA CENTAUR MULTI-DILUENT 3 (MULTI-DIL 3)(ADVIA CENTAUR MULTI-DILUENT 3 (MULTI-DIL 3))-ADVIA CENTAUR MULTI-DILUENT 3 IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE RESPECTIVE ASSAY.,ADVIA CENTAUR DHEAS MASTER CURVE MATERIAL (DHEAS MCM)(ADVIA CENTAUR DHEAS MASTER CURVE MATERIAL (DHEAS MCM))-FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE IN THE ADVIA CENTAUR® DEHYDROEPIANDROSTERONE SULFATE (DHEAS) ASSAYS. ,ADVIA CENTAUR CALIBRATOR Z (CAL Z) (ADVIA CENTAUR CALIBRATOR Z (CAL Z))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE FOLLOWING ASSAYS USING ADVIA CENTAUR® SYSTEMS: CARBAMAZEPINE DIGITOXIN TOBRAMYCIN ,ADVIA CENTAUR DIGITOXIN (DGTN) (ADVIA CENTAUR DIGITOXIN (DGTN))-

	FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF DIGITOXIN IN SERUM OR PLASMA USING THE ADVIA CENTAUR AND ADVIA CENTAUR XP AND ADVIA CENTAUR CP SYSTEMS. THE ADVIA CENTAUR DIGITOXIN (DGTN) ASSAY WAS COMPARED WITH THE ACS:180® DIGITOXIN ASSAY. FOR 289 SAMPLES IN THE RANGE OF 2.74 TO 41.90 NG/ML (3.58 TO 54.76 NMOL/L), THE RELATIONSHIP BETWEEN THE ADVIA CENTAUR DGTN ASSAY AND THE ACS:180 DIGITOXIN ASSAY IS DESCRIBED BY THE EQUATION: ADVIA CENTAUR DGTN = 0.98 (ACS:180 DIGITOXIN) + 0.26 NG/ML CORRELATION COEFFICIENT (R) = 0.98 ,ADVIA CENTAUR ADVIA CENTAUR TESTOSTERONE II TESTOSTERONE II (TSTII)(ADVIA CENTAUR ADVIA CENTAUR TESTOSTERONE II TESTOSTERONE II (TSTII))-THE ADVIA CENTAUR® TESTOSTERONE II (TSTII) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE (BOUND AND UNBOUND) IN HUMAN SERUM AND PLASMA USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS. MEASUREMENTS OF TESTOSTERONE ARE USED IN THE DIAGNOSIS AND TREATMENT OF DISORDERS INVOLVING THE MALE SEX HORMONES (ANDROGENS),INCLUDING PRIMARY AND SECONDARY HYPOGONADISM, DELAYED OR PRECOCIOUS PUBERTY, IMPOTENCE IN MALES AND, IN FEMALES, HIRSUTISM (EXCESSIVE HAIR) AND VIRILIZATION (MASCULINIZATION) DUE TO TUMORS, POLYCYSTIC OVARIES, AND ADRENOGENITAL SYNDROMES. ,ADVIA CENTAUR HCY DILUENT (HCY OIL) (ADVIA CENTAUR HCY DILUENT (HCY OIL))-THE ADVIA CENTAUR HCY DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY. ,ADVIA CENTAUR ,MULTI-DILUENT 5 (MULTI-DIL 5)(ADVIA CENTAUR , MULTI-DILUENT 5 (MULTI-DIL 5))-ADVIA CENTAUR MULTI-DILUENT 5 IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE RESPECTIVE ASSAY.,ADVIA CENTAUR SHBG (SHBG) (ADVIA CENTAUR SHBG (SHBG))-THE ADVIA CENTAUR® SHBG ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF SEX HORMONE-BINDING GLOBULIN (SHBG) IN HUMAN SERUM AND PLASMA USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS. FOR PROFESSIONAL USE. THE ADVIA CENTAUR SHBG ASSAY IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF ANDROGEN DISORDERS. ,ADVIA CENTAUR TESTOSTERONE II MASTER CURVE MATERIAL (TSTII MGM) (ADVIA CENTAUR TESTOSTERONE II MASTER CURVE MATERIAL (TSTII MGM))-THE ADVIA CENTAUR® TESTOSTERONE II (TSTII) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR TESTOSTERONE II

	(TSTII) ASSAY.,ADVIA CENTAUR HCY CALIBRATOR (HCY CAL) (ADVIA CENTAUR HCY CALIBRATOR (HCY CAL))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING ADVIA CENTAUR® SYSTEMS HCY ASSAYS. , ADVIA CENTAUR FPSA CALIBRATOR (FPSA CAL)(ADVIA CENTAUR FPSA CALIBRATOR (FPSA CAL))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING ADVIA CENTAUR® SYSTEMS FPSA ASSAYS. ,ADVIA CENTAUR TOTAL IGE (TIGE)(ADVIA CENTAUR TOTAL IGE (TIGE))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL IGE IN SERUM USING THE ADVIA CENTAUR®, ADVIA CENTAUR CP, AND ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS.,ADVIA CENTAUR ATPO MASTER CURVE MATERIAL (ATPO MCM)(ADVIA CENTAUR ATPO MASTER CURVE MATERIAL (ATPO MCM))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING ADVIA CENTAUR® OR ACS:180® ATPO ASSAYS,ADVIA CENTAUR CALIBRATOR Y (CAL Y)(ADVIA CENTAUR CALIBRATOR Y (CAL Y))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING ADVIA CENTAUR® OR ACS:180® CPSA ASSAYS. ,ADVIA CENTAUR TSH(ADVIA CENTAUR TSH)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH, THYROTROPIN) IN SERUM USING THE ADVIA CENTAUR®, ADVIA CENTAUR CP, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS.,ADVIA CENTAUR MULTI-DILUENT 11(ADVIA CENTAUR MULTI-DILUENT 11)-THE ADVIA CENTAUR MULTI-DILUENT 11 IS FOR USE IN CONJUNCTION WITH THE ADVIA CENTAUR AHBS, AHBS2, IPTH, AND TNI-ULTRA REAGENTS. ADVIA CENTAUR MULTI-DILUENT 11 IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE RESPECTIVE ASSAY.,ADVIA CENTAUR TSH MASTER CURVE MATERIAL (TSH MCM)(ADVIA CENTAUR TSH MASTER CURVE MATERIAL (TSH MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR TSH ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM. ,ADVIA CENTAUR CALIBRATOR 80(ADVIA CENTAUR CALIBRATOR 80)-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR® TOTAL IGE (TIGE) QUANTITATIVE ASSAY ON THE ADVIA CENTAUR SYSTEMS.,ADVIA CENTAUR VITAMIN D TOTAL (VITD) QUALITY CONTROL MATERIAL(ADVIA CENTAUR VITAMIN D TOTAL (VITD) QUALITY CONTROL MATERIAL)-FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND ACCURACY OF THE ADVIA CENTAUR VITAMIN D TOTAL (VITD) ASSAY ON THE ADVIA CENTAUR SYSTEMS., ADVIA CENTAUR TN-I ULTRA MASTER CURVE MATERIAL (TN-I ULTRA MCM)(ADVIA CENTAUR TN-I ULTRA MASTER CURVE MATERIAL (TN-I ULTRA MCM))-THE ADVIA CENTAUR® TNI-ULTRA® MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF

	CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR TNI-ULTRA ASSAY.,ADVIA CENTAUR ANCILLARY PROBE WASH 1 (ADVIA CENTAUR ANCILLARY PROBE WASH 1)-ADVIA CENTAUR ANCILLARY PROBE WASH 1 IS FOR THE CLEANINQ OF ORIMARV REAOENT PROBES BETWEEN VARIOUS APPLICATIONS. ,ADVIA CENTAUR TSH3-ULTRA (TSH3-UL)(ADVIA CENTAUR TSH3-ULTRA (TSH3-UL))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH, THYROTROPIN) IN SERUM, HEPARINIZED PLASMA, AND EDTA PLASMA USING THE ADVIA CENTAUR®, ADVIA CENTAUR CP, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. MEASUREMENTS OF THYROID STIMULATING HORMONE PRODUCED BY THE ANTERIOR PITUITARY ARE USED IN THE DIAGNOSIS OF THYROID OR PITUITARY DISORDERS.,ADVIA CENTAUR SHBG CALIBRATOR (SHBG CAL) (ADVIA CENTAUR SHBG CALIBRATOR (SHBG CAL))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR® SHBG ASSAY ON THE ADVIA CENTAUR SYSTEMS. ,ADVIA CENTAUR CPSA QUALITY CONTROL 1,2,3 (CPSA QC) (ADVIA CENTAUR CPSA QUALITY CONTROL 1,2,3 (CPSA QC))-FOR IN VITRO DIAGNOSTIC USE TO 9 MONITOR THE PRECISION AND THE MONTHS ACCURACY OF THE ADVIA CENTAUR® OR ACS:180® CPSA ASSAYS. ,ADVIA CENTAUR ATG DILUENT (ATG OIL)(ADVIA CENTAUR ATG DILUENT (ATG OIL))-FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND THE ACCURACY OF THE ADVIA CENTAUR ANTI-TG ASSAY ON THE ADVIA CENTAUR SYSTEMS.,ADVIA CENTAUR BR PRETREATMENT ANCILLARY REAGENT (BR PRE)(ADVIA CENTAUR BR PRETREATMENT ANCILLARY REAGENT (BR PRE))-THE ADVIA CENTAUR BR ASSAY IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE SERIAL DETERMINATION OF CANCER ANTIGEN CA 27.29 IN HUMAN SERUM USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, ADVIA CENTAUR XPT, AND ADVIA CENTAUR CP SYSTEMS. THE TEST IS INTENDED FOR USE AS AN AID IN MONITORING PATIENTS PREVIOUSLY TREATED FOR STAGE II OR STAGE ILL BREAST CANCER. SERIAL TESTING FOR CA 27.29 IN THE SERUM OF PATIENTS WHO ARE CLINICALLY FREE OF DISEASE SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL METHODS USED FOR THE EARLY DETECTION OF CANCER RECURRENCE. THE TEST IS ALSO INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF BREAST CANCER PATIENTS WITH METASTATIC DISEASE BY MONITORING THE PROGRESSION OR REGRESSION OF DISEASE IN RESPONSE TO TREATMENT. ,ATELLICA IM FREE TRIIODOTHYRONINE (FT3)(ATELLICA IM FREE TRIIODOTHYRONINE (FT3))-THE ATELLICA™ IM FREE TRIIODOTHYRONINE (FT3) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN

	SERUM USING THE ATELLICA™ IM ANALYZER. MEASUREMENTS OF FREE TRIIODOTHYRONINE ARE USED IN THE DIAGNOSIS AND TREATMENT OF THYROID DISEASE.,ADVIA CENTAUR BNP (BNP) (ADVIA CENTAUR BNP (BNP))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF B-TYPE NATRIURETIC PEPTIDE (BNP) IN HUMAN PLASMA USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, ADVIA CENTAUR XPT AND ADVIA CENTAUR CP SYSTEMS. THIS ASSAY IS INDICATED FOR THE MEASUREMENT OF PLASMA BNP AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF THE SEVERITY OF HEART FAILURE. IN PATIENTS WITH ACUTE CORONARY SYNDROMES (ACS), THIS TEST, IN CONJUNCTION WITH OTHER KNOWN RISK FACTORS, CAN ALSO BE USED TO PREDICT SURVIVAL AS WELL AS TO PREDICT THE LIKELIHOOD OF FUTURE HEART FAILURE. THIS ASSAY IS NOT INTENDED FOR USE ON ANY OTHER SYSTEM. ,ATELLICA IM CALIBRATOR U (CAL U)(ATELLICA IM CALIBRATOR U (CAL U))-THE ATELLICA™IM CALIBRATOR U (CAL U) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM MYO ASSAY USING THE ATELLICA™ IM ANALYZER.,ADVIA CENTAUR HCY MASTER CURVE MATERIAL (HCY MCM)(ADVIA CENTAUR HCY MASTER CURVE MATERIAL (HCY MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® HCYASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM.,ATELLICA IM HIGH SENSITIVITY TROPONIN I MASTER CURVE MATERIAL (TNIH MCM)(ATELLICA IM HIGH SENSITIVITY TROPONIN I MASTER CURVE MATERIAL (TNIH MCM))-THE ATELLICA™ IM HIGH-SENSITIVITY TROPONIN I(TNIH) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM HIGH-SENSITIVITY TROPONIN I (TNIH) ASSAY,ATELLICA IM CYCLOSPORINE (CSA) (ATELLICA IM CYCLOSPORINE (CSA))-THE ATELLICA™ IM CYCLOSPORINE (CSA) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE IN HUMAN WHOLE BLOOD (EDTA) USING THE ATELLICA™ IM ANALYZER. THIS ASSAY IS INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF CYCLOSPORINE THERAPY IN KIDNEY, HEART, AND LIVER TRANSPLANT PATIENTS.,ADVIA CENTAUR BNP QUALITY CONTROL 1,2,3 (BNP QC) (ADVIA CENTAUR BNP QUALITY CONTROL 1,2,3 (BNP QC))-FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND THE ACCURACY OF THE ADVIA CENTAUR® OR ACS:180® BNP ASSAYS. ,ADVIA CENTAUR CALIBRATOR O (CAL 0)(ADVIA CENTAUR CALIBRATOR O (CAL 0))-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR® ANTI-TPO ASSAY ON THE ADVIA CENTAUR SYSTEMS.,ADVIA CENTAUR ANTI-TPO DILUENT

	(ATPO OIL) (ADVIA CENTAUR ANTI-TPO DILUENT (ATPO OIL))-THE ADVIA CENTAUR ATPO DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY. ,ADVIA CENTAUR QUALITY CONTROL ANTI- TPO (ATPO)(ADVIA CENTAUR QUALITY CONTROL ANTI- TPO (ATPO))-FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND THE ACCURACY OF THE ADVIA CENTAUR® ANTI-TPO ASSAY ON THE ADVIA CENTAUR SYSTEMS., ADVIA CENTAUR BNP MASTER CURVE MATERIAL (BNP MCM) (ADVIA CENTAUR BNP MASTER CURVE MATERIAL (BNP MCM))-FOR IN VITRO DIAGNOSTIC USE FOR EVALUATING THE ADVIA CENTAUR® BNP ASSAY. THIS MATERIAL IS INTENDED TO BE RUN SINGLY AS UNKNOWN SAMPLES AFTER A TWO-POINT CALIBRATION HAS BEEN PERFORMED ON THE SYSTEM. ,ADVIA CENTAUR VANCOMYCIN (VANC)(ADVIA CENTAUR VANCOMYCIN (VANC))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF VANCOMYCIN IN SERUM OR PLASMA USING THE ADVIA CENTAUR®, ADVIA CENTAUR CP, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS.,ADVIA CENTAUR TOXOPLASMA M (TOXO M)(ADVIA CENTAUR TOXOPLASMA M (TOXO M))-THE ADVIA CENTAUR® TOXOPLASMA M (TOXO M) ASSAY IS AN IGM ANTIBODY CAPTURE MICROPARTICLE DIRECT CHEMILUMINOMETRIC IN VITRO DIAGNOSTIC IMMUNOASSAY INTENDED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN SERUM OR PLASMA (EDTA, HEPARIN) USING THE ADVIA CENTAUR, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THE ADVIA CENTAUR TOXO M ASSAY IS USED TO MEASURE IGM ANTIBODY AGAINST T. GONDII WHICH IS PRESUMPTIVE OF AN ACUTE, RECENT, OR REACTIVATED TOXOPLASMA INFECTION. ANY MEASUREMENT OF IGM ANTIBODY TO T. GONDII MUST BE PERFORMED IN CONJUNCTION WITH THE DETERMINATION OF IGG ANTIBODY TO T. GONDII. THIS ASSAY IS NOT INTENDED FOR USE IN SCREENING BLOOD, PLASMA, OR TISSUE DONORS. ,ADVIA CENTAUR IGE MASTER CURVE MATERIAL (IGE MCM)(ADVIA CENTAUR IGE MASTER CURVE MATERIAL (IGE MCM))-THE ADVIA CENTAUR® IGE MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR TOTAL IGE (TIGE) ASSAY.,ADVIA CENTAUR TOXOPLASMA G (TOXO G) QUALITY CONTROL MATERIAL(ADVIA CENTAUR TOXOPLASMA G (TOXO G) QUALITY CONTROL MATERIAL)-FOR MONITORING THE PERFORMANCE OF THE ADVIA CENTAUR TOXOPLASMA G ASSAY ON THE ADVIA CENTAUR SYSTEMS. THE PERFORMANCE OF THE ADVIA CENTAUR TOXOPLASMA G QUALITY CONTROL MATERIAL HAS NOT BEEN ESTABLISHED WITH ANY OTHER TOXOPLASMA IGG ASSAYS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

56	IMP/IVD/2018/000032	1.License Holder Name: BIO-RAD LABORATORIES (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MUELLER HINTON (MUELLER HINTON)-MUELLER-HINTON AGAR IS A STANDARDIZED SOLID MEDIUM RECOMMENDED FOR ANTIMICROBIAL SUSCEPTIBILITY TESTING BY THE AGAR DIFFUSION OR AGAR DILUTION METHOD.,NOVOBIOCINE(NOVOBIOCINE)-DIFFERENTIATION OF COAGULASE-NEGATIVE STAPHYLOCOCCI,LIQUID ANTI-RABIES NUCLEOCAPSID CONJUGATE(LIQUID ANTI-RABIES NUCLEOCAPSID CONJUGATE)-WITH THE RABIES-SPECIFIC LABELLED POLYCLONAL ANTIBODIES CONTAINED IN THE PRODUCT WHICH ARE TARGETED AGAINST THE RIBO-NUCLEOPROTEIN COMPLEX OF THE RABIES VIRUS, ALL CURRENTLY KNOWN LYSSAVIRUSGENOTYPES CAN BE DETECTED WITH THE DIRECT IMMUNOFLUORESCENCETEST (IFT) IRRESPECTIVE OF THE ANIMAL SPECIES TESTED. POLYCLONAL ANTIBODIES, WHICH ARE PRODUCED BY THE MEANS OF THE PASTEUR STRAIN (PV) ARE KNOWN FOR THEIR GOOD SPECIFICITY. THE SENSITIVITY OF THE ANTI-RABIES NUCLOECAPSID CONJUGATE MAY BE REDUCED WHEN TESTING LYSSAVIRUS GENOTYPE 3 (MOKOLA VIRUS), 5 (EUROPEAN BAT LYSSAVIRUS, EBLV-1) AND 6 (EBLV-2) STRAINS. IN THIS CASE THE SAMPLES SHOULD BE EXAMINED MORE CAREFULLY. IN ALL CASES AN APPROPRIATE WORKING DILUTION SHOULD BE TESTED IN ADVANCE, KETOCONAZOLE 50 G(KETOCONAZOLE 50 G)-STUDY OF THE SUSCEPTIBILITY OF FUNGI TO ANTIFUNGAL AGENTS,C.L.E.D.(C.L.E.D.)-THIS PRODUCT IS A CYSTINE LACTOSE ELECTROLYTE DEFICIENT AGAR FOR THE ISOLATION AND DIFFERENTIATION OF MICROORGANISMS ISOLATED FROM URINE,BACITRACIN (BACITRACIN)-PRESOMPTIVE IDENTIFICATION OF GROUP A BÊTA-HAEMOLYTIC STREPTOCOCCI.,MUELLER HINTON(MUELLER HINTON)-MUELLER-HINTON AGAR IS A STANDARDIZED SOLID MEDIUM RECOMMENDED FOR ANTIMICROBIAL SUSCEPTIBILITY TESTING BY THE AGAR DIFFUSION OR AGAR DILUTION METHOD.,MONOLISA™ TOTAL ANTI-HAV PLUS(MONOLISA™ TOTAL ANTI-HAV PLUS)-KIT FOR DETECTION AND QUANTIFICATION OF TOTAL ANTIBODIES TO HAV IN SERUM/PLASMA BY ENZYME IMMUNOASSAY,CANDISELECT™ (CANDISELECT™)-SELECTIVE CHROMOGENIC CULTURE MEDIUM FOR THE ISOLATION OF YEASTS, DIRECT IDENTIFICATION OF CANDIDA ALBICANS, AND PRESUMPTIVE IDENTIFICATION OF C. TROPICALIS, C. GLABRATA AND C. KRUSEI,FLUCONAZOLE 25 G(FLUCONAZOLE 25 G)-STUDY OF THE SUSCEPTIBILITY OF CANDIDA SPECIES TO TRIAZOLE ANTIFUNGAL AGENTS (FLUCONAZOLE, VORICONAZOLE) STREPBSELECT(STREPBSELECT)-SELECTIVE ISOLATION MEDIUM FOR

	STREPTOCOCCUS AGALACTIAE SCREENING,PIPERACILLIN 30 G (PIPERACILLIN 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., MRSASELECT™II(MRSASELECT™II)-SELECTIVE AND DIFFERENTIAL CHROMOGENIC CULTURE MEDIUM FOR THE ISOLATION AND DIRECT IDENTIFICATION OF METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS (MRSA),PLATELIA™ DENGUE NS1 AG(PLATELIA™ DENGUE NS1 AG)-QUALITATIVE OR SEMI-QUANTITATIVE DETECTION OF DENGUE VIRUS NS1 ANTIGEN IN HUMAN SERUM OR PLASMA BY ENZYME IMMUNOASSAY,PLATELIA SARS-COV-2 TOTAL AB(PLATELIA SARS-COV-2 TOTAL AB)-THE PLATELIA SARS-COV-2 TOTAL AB ASSAY IS A SEMI-QUANTITATIVE IN VITRO DIAGNOSTIC TEST, IN A ONE-STEP ANTIGEN CAPTURE FORMAT, FOR THE DETECTION OF IGM/IGA/IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN, ACD OR CITRATE) SPECIMENS. THIS ASSAY IS AN AID FOR THE DIAGNOSIS OF PATIENTS WITH SYMPTOMS SUGGESTIVE OF INFECTION CAUSED BY SARS-COV- 2. IN CONJUNCTION WITH CLINICAL PRESENTATION AND TESTING WITH OTHER METHODS (RT-PCR, CT-SCAN, SPECIFIC DETECTION FOR ANTI-SARS-COV-2 IGM/IGA/IGG ANTIBODIES), PLATELIA SARS-COV-2 TOTAL AB CAN BE USED TO HELP DIAGNOSE COVID-19 DISEASE. THIS ASSAY CAN ALSO BE USED AS A SCREENING TOOL FOR DETECTING THE PRESENCE OF ANTI-SARS-COV-2 TOTAL ANTIBODIES IN ORDER TO DETERMINE INDIVIDUALS' IMMUNE STATUS REGARDING EXPOSURE TO SARS-COV-2. PLATELIA SARS-COV-2 TOTAL AB CAN BE USED MANUALLY OR ON AUTOMATED SYSTEMS. IN THE US, THIS KIT IS FOR EMERGENCY USE ONLY AND FOR PRESCRIPTION USE ONLY. IT SHOULD NOT BE USED FOR SCREENING OF DONATED BLOOD. RESULTS FROM THE PLATELIA SARS-COV-2 TOTAL AB ASSAY SHOULD NOT BE USED AS THE SOLE BASIS FOR DIAGNOSIS OR FOR INFORMING INFECTION STATUS. SPECIMENS SHOULD BE COLLECTED IN CLIA CERTIFIED LABORATORIES AND/OR BY HEALTHCARE WORKERS AT THE POINT-OF-CARE. TESTING FACILITIES WITHIN THE UNITED STATES AND ITS TERRITORIES ARE REQUIRED TO REPORT ALL POSITIVE RESULTS TO THE APPROPRIATE PUBLIC HEALTH AUTHORITIES. PACK SIZE: 96, 480,MONOLISA™ HAV IGM PLUS(MONOLISA™ HAV IGM PLUS)-KIT FOR DETECTION OF ANTI-HAV IGM IN SERUM/PLASMA BY ENZYME IMMUNOASSAY , SASELECT™(SASELECT™)-SELECTIVE AGAR MEDIUM FOR THE ISOLATION AND DIRECT IDENTIFICATION OF STAPHYLOCOCCUS AUREUS,PASTOREX™ STREP A(PASTOREX™ STREP A)-PASTOREX™ STREP ASSAY IS A RAPID AGGLUTINATION TEST FOR GROUPING

	STREPTOCOCCI ACCORDING TO LANCEFIELD CLASSIFICATION. THE TEST INVOLVES USE OF LATEX SUSPENSIONS SPECIFIC FOR GROUPS A, B, C, D, F, AND G. IDENTIFICATION OF GROUP-SPECIFIC ANTIGENS BY HOMOLOGOUS ANTISERA REQUIRES A PRIOR ENZYMATIC EXTRACTION.,LYOPHILIZED ADSORBED ANTI RABIES NUCLEOCAPSID CONJUGATE(LYOPHILIZED ADSORBED ANTI RABIES NUCLEOCAPSID CONJUGATE)-WITH THE RABIES-SPECIFIC LABELLED POLYCLONAL ANTIBODIES CONTAINED IN THE PRODUCT WHICH ARE TARGETED AGAINST THE RIBO-NUCLEOPROTEIN COMPLEX OF THE RABIES VIRUS, ALL CURRENTLY KNOWN LYSSAVIRUSGENOTYPES CAN BE DETECTED WITH THE DIRECT IMMUNOFLUORESCENCETEST (IFT) IRRESPECTIVE OF THE ANIMAL SPECIES TESTED. POLYCLONAL ANTIBODIES, WHICH ARE PRODUCED BY THE MEANS OF THE PASTEUR STRAIN (PV) ARE KNOWN FOR THEIR GOOD SPECIFICITY. THE SENSITIVITY OF THE ANTI-RABIES NUCLOECAPSID CONJUGATE MAY BE REDUCED WHEN TESTING LYSSAVIRUS GENOTYPE 3 (MOKOLA VIRUS), 5 (EUROPEAN BAT LYSSAVIRUS, EBLV-1) AND 6 (EBLV-2) STRAINS. IN THIS CASE THE SAMPLES SHOULD BE EXAMINED MORE CAREFULLY. IN ALL CASES AN APPROPRIATE WORKING DILUTION SHOULD BE TESTED IN ADVANCE., AMPHOTERICIN B 100 G(AMPHOTERICIN B 100 G)-STUDY OF THE SUSCEPTIBILITY OF FUNGI TO ANTIFUNGAL AGENTS,PLATELIA™ RABIES II KIT(PLATELIA™ RABIES II KIT)-THE PLATELIA™ RABIES II KIT IS AN IN VITRO DIAGNOSTIC ELISA TEST ALLOWING DETECTION AND TITRATION OF IGG ANTI RABIES VIRUS GLYCOPROTEIN IN ANIMAL (DOGS, CATS AND FOXES) SERUM.,VORICONAZOLE 1 G (VORICONAZOLE 1 G)-STUDY OF THE SUSCEPTIBILITY OF CANDIDA SPECIES TO TRIAZOLE ANTIFUNGAL AGENTS (FLUCONAZOLE, VORICONAZOLE),ACCESS HCV AB PLUS QC(ACCESS HCV AB PLUS QC)-THE ACCESS HCV AB PLUS QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS HCV AB PLUS ASSAY , CEFOTETAN 30 G(CEFOTETAN 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., ACCESS HCV AB PLUS CALIBRATORS(ACCESS HCV AB PLUS CALIBRATORS)-THE ACCESS HCV AB PLUS CALIBRATORS ARE INTENDED FOR USE WITH THE ACCESS HCV AB PLUS ASSAY FOR THE DETECTION OF ANTI-HCV ANTIBODIES IN HUMAN SERUM AND PLASMA, USING THE ACCESS IMMUNOASSAY SYSTEMS,DORIPENEM 10 G(DORIPENEM 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,

	ACCESS HCV AB PLUS(ACCESS HCV AB PLUS)-THE ACCESS HCV AB PLUS ASSAY IS AN IMMUNOENZYMATIC METHOD FOR THE DETECTION OF ANTIBODIES TO THE HEPATITIS C VIRUS IN HUMAN SERUM OR PLASMA, USING THE ACCESS IMMUNOASSAY SYSTEMS, OFLOXACIN 5 G(OFLOXACIN 5 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., ACCESS HIV COMBO Q.C(ACCESS HIV COMBO Q.C)-THE ACCESS HIV COMBO QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS HIV COMBO ASSAY.,CIPROFLOXACIN 5 G (CIPROFLOXACIN 5 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., ACCESS HIV COMBO CALIBRATORS(ACCESS HIV COMBO CALIBRATORS)-THE ACCESS HIV COMBO CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS HIV COMBO ASSAY FOR THE QUALITATIVE DETECTION OF HIV-1 ANTIGEN AND HIV-1/HIV-1-O/HIV-2 ANTIBODIES IN HUMAN SERUM AND PLASMA (LI HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS.,ERYTHROMYCIN 15 G (ERYTHROMYCIN 15 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., ACCESS HIV COMBO (ACCESS HIV COMBO)-THE ACCESS HIV COMBO ASSAY IS A PARAMAGNETIC-PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HIV-1 P24 ANTIGEN AND ANTIBODIES TO HIV-1 (GROUPS M AND O) AND HIV-2 IN HUMAN SERUM AND PLASMA (LI HEPARIN), USING THE ACCESS IMMUNOASSAY SYSTEMS,NALIDIXIC ACID 30 G(NALIDIXIC ACID 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,PLATELIA RABIES II KIT(PLATELIA RABIES II KIT)-THE PLATELIA RABIES II KIT IS AN IN VITRO DIAGNOSTIC ELISA TEST ALLOWING DETECTION AND TITRATION OF IGG ANTI RABIES VIRUS GLYCOPROTEIN IN HUMAN SERUM AND PLASMA.,CEFEPIME 30 G + CLAVULANIC ACID 10 G(CEFEPIME 30 G + CLAVULANIC ACID 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., GEENIUS™ HCV SUPPLEMENTAL CONTROLS(GEENIUS™ HCV

	SUPPLEMENTAL CONTROLS)-THE GEENIUS™ HCV SUPPLEMENTAL CONTROLS ARE INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE GEENIUS™ HCV SUPPLEMENTAL ASSAY (92501).,C.L.E.D.(C.L.E.D.)-CYSTINE LACTOSE ELECTROLYTE DEFICIENT AGAR FOR THE ISOLATION AND DIFFERENTIATION OF MICROORGANISMS ISOLATED FROM URINE,ACCESS® HCV AB V3 CALIBRATORS(ACCESS® HCV AB V3 CALIBRATORS)-THE ACCESS HCV AB V3 CALIBRATORS KIT IS FOR THE CALIBRATION OF THE ACCESS IMMUNOASSAY SYSTEMS WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HCV IN HUMAN SERUM AND PLASMA.,RPR(RPR)-KITS FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETECTION OF NON TREPONEMAL SYPHILIS-ASSOCIATED, REAGIN, ANTIBODIES IN HUMAN SERUM OR PLASMA BY MACROSCOPIC AGGLUTINATION ON DISPOSABLE TEST CARDS, ACCESS® HCV AB V3(ACCESS® HCV AB V3)-THE ACCESS HCV AB V3 IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO THE HEPATITIS C VIRUS IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN, K2-EDTA, K3-EDTA, CITRATE, CPDA-1 OR ACD), USING THE ACCESS IMMUNOASSAY SYSTEMS. THE ACCESS HCV AB V3 IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF HCV INFECTION AND AS A SCREENING TEST FOR BLOOD AND PLASMA DONORS. THE ASSAY IS NOT INTENDED FOR THE TESTING OR SCREENING OF POOLED SPECIMENS.,IMIPENEM 10 G(IMIPENEM 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,ACCESS®HCV AB V3 QC (ACCESS®HCV AB V3 QC)-THE ACCESS HCV AB V3 QC IS INTENDED FOR MONITORING THE SYSTEM PERFORMANCE OF THE ACCESS HCV AB V3.,PASTOREX™ STREP EXTRACTION ENZYME(PASTOREX™ STREP EXTRACTION ENZYME)-PASTOREX™ STREP ASSAY IS A RAPID AGGLUTINATION TEST FOR GROUPING STREPTOCOCCI ACCORDING TO LANCEFIELD CLASSIFICATION. THE TEST INVOLVES USE OF LATEX SUSPENSIONS SPECIFIC FOR GROUPS A, B, C, D, F, AND G. IDENTIFICATION OF GROUP-SPECIFIC ANTIGENS BY HOMOLOGOUS ANTISERA REQUIRES A PRIOR ENZYMATIC EXTRACTION., GENSCREEN™ ULTRA HIV AG-AB(GENSCREEN™ ULTRA HIV AG-AB)-SCREENING KIT FOR THE DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HIV-1 AND HIV-2 IN HUMAN SERUM/PLASMA BY ENZYME IMMUNOASSAY,IMIPENEM10G+EDTA (IMIPENEM10G+EDTA)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND

	SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., MONOLISA™ ANTI-HCV PLUS VERSION 3(MONOLISA™ ANTI-HCV PLUS VERSION 3)-SCREENING KIT FOR ANTI-HCV ANTIBODIES (HEPATITIS C VIRUS) IN HUMAN PLASMA OR SERUM USING AN ENZYME IMMUNO-ASSAY TECHNIQUE.,AMPICILLIN +SULBACTAM 10 / 10 G(AMPICILLIN +SULBACTAM 10 / 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., SABOURAUD CHLORAMPHENICOL GENTAMICIN AGAR(SABOURAUD CHLORAMPHENICOL GENTAMICIN AGAR)-SABOURAUD CHLORAMPHENICOL GENTAMICIN AGAR IS RECOMMENDED FOR THE ISOLATION OF ALL SPECIES OF YEASTS AND FILAMENTOUS FUNGI FROM BIOLOGICAL SPECIMENS PRESENTING MIXED FUNGAL AND BACTERIAL FLORA.,PEFLOXACIN 5G(PEFLOXACIN 5G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,GEENIUS™ HCV SUPPLEMENTAL ASSAY(GEENIUS™ HCV SUPPLEMENTAL ASSAY)-GEENIUS™ HCV SUPPLEMENTAL ASSAY IS A QUALITATIVE SINGLE-USE IMMUNOCHROMATOGRAPHIC TEST FOR THE CONFIRMATION OF THE PRESENCE OF ANTIBODIES ASSOCIATED WITH INFECTION CAUSED BY THE HEPATITIS C VIRUS (HCV) IN HUMAN VENOUS WHOLE BLOOD, SERUM OR PLASMA SPECIMENS FROM BLOOD DONORS OR HOSPITALIZED PATIENTS. GEENIUS™ HCV SUPPLEMENTAL ASSAY IS INTENDED FOR USE AS AN ADDITIONAL TEST TO CONFIRM THE PRESENCE OF ANTIBODIES TO HCV FOR SPECIMENS FOUND TO BE REACTIVE BY SCREENING PROCEDURES. THE RESULTS OF THE GEENIUS™ HCV SUPPLEMENTAL ASSAY ARE READ AND INTERPRETED ONLY BY THE GEENIUS™ SYSTEM WITH DEDICATED SOFTWARE.,PASTOREX™ STREP B(PASTOREX™ STREP B) -PASTOREX™ STREP ASSAY IS A RAPID AGGLUTINATION TEST FOR GROUPING STREPTOCOCCI ACCORDING TO LANCEFIELD CLASSIFICATION. THE TEST INVOLVES USE OF LATEX SUSPENSIONS SPECIFIC FOR GROUPS A, B, C, D, F, AND G. IDENTIFICATION OF GROUP-SPECIFIC ANTIGENS BY HOMOLOGOUS ANTISERA REQUIRES A PRIOR ENZYMATIC EXTRACTION,MONOLISA™ HBS AG ULTRA CONFIRMATORY(MONOLISA™ HBS AG ULTRA CONFIRMATORY)-TEST FOR THE CONFIRMATION OF HBS AG IN HUMAN SERUM OR PLASMA, NORFLOXACIN 10 G(NORFLOXACIN 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., KOVACS(KOVACS)-KOVACS REAGENT IS INTENDED FOR THE

	DEMONSTRATION OF INDOLE PRODUCTION BY BACTERIA POSSESSING A TRYPTOPHANASE (GRAM (-) BACTERIA, ESPECIALLY ENTEROBACTERIACEAE).,DOXYCYCLINE 30 G(DOXYCYCLINE 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,NEW LAV BLOT I(NEW LAV BLOT I)-THE NEW LAV-BLOT I KIT IS INTENDED TO THE DETECTION OF HUMAN ANTI-HIV-1 ANTIBODIES IN SERUM OR PLASMA BY IMMUNOBLOTTING IN ORDER TO CONFIRM A POSITIVE ANTI-HIV-1 RESPONSE AND SPECIFY ITS ANTIGENIC SPECIFICITY WITHIN THE SCOPE OF AIDS DIAGNOSIS,CEFOPERAZONE (75G) + SULBACTAM (30 G) (CEFOPERAZONE (75G) + SULBACTAM (30 G))-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,MAC CONKEY + CRYSTAL VIOLET(MAC CONKEY + CRYSTAL VIOLET)-MAC CONKEY + CRYSTAL VIOLET MEDIUM IS USED TO ISOLATE AND ENUMERATE ENTEROBACTERIACEAE. IT IS PARTICULARLY ADAPTED FOR THE ISOLATION OF SALMONELLA, SHIGELLA AND ENTEROPATHOGENIC ESCHERICHIA COLI., QUINUPRISTIN DALFOPRISTIN 15G(QUINUPRISTIN DALFOPRISTIN 15G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,NEW LAV BLOT II(NEW LAV BLOT II)-THE NEW LAV-BLOT II KIT IS INTENDED TO THE DETECTION OF HUMAN ANTI-HIV-2 ANTIBODIES IN SERUM OR PLASMA BY IMMUNOBLOTTING IN ORDER TO CONFIRM A POSITIVE ANTI-HIV-2 RESPONSE AND SPECIFY ITS ANTIGENIC SPECIFICITY WITHIN THE SCOPE OF AIDS DIAGNOSIS.,OLEANDOMYCIN 15 G(OLEANDOMYCIN 15 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,DECISCAN™ HCV PLUS(DECISCAN™ HCV PLUS)-IMMUNOBLOT FOR THE DETECTION OF ANTI-HCV ANTIBODIES IN HUMAN SERUM OR PLASMA ,NITROXOLIN 20 G (NITROXOLIN 20 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., GEENIUS™ HIV 1/2 CONFIRMATORY ASSAY(GEENIUS™ HIV 1/2 CONFIRMATORY ASSAY)-A QUALITATIVE ASSAY FOR THE CONFIRMATION AND DIFFERNTIATION OF INDIVIDUAL ANTIBODIES

	TO HIV -1 AND HIV-2 IN WHOLE BLOOD, SERUM, OR PLASMA SPECIMENS,PRISTINAMYCIN 15 G(PRISTINAMYCIN 15 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,MONOLISA™ HBS AG ULTRA(MONOLISA™ HBS AG ULTRA)-KIT FOR THE DETECTION OF THE SURFACE ANTIGEN OF THE HEPATITIS B VIRUS IN THE HUMAN SERUM OR PLASMA BY ENZYME IMMUNOASSAY TECHNIQUE,PIPERACILLIN 75 G + TAZOBACTAM 10 G(PIPERACILLIN 75 G + TAZOBACTAM 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,BLOOD AGAR BASE(BLOOD AGAR BASE)-BLOOD AGAR BASE IS A MEDIUM ENABLING THE ISOLATION OF FASTIDIOUS BACTERIA AND DEMONSTRATION OF THEIR HAEMOLYTIC CHARACTERISTICS, WITHOUT INTERFERING WITH THE FORMATION OF PIGMENTS,PLATELIA™ ASPERGILLUS IGG(PLATELIA™ ASPERGILLUS IGG)-DETECTION OF IGG ANTI-ASPERGILLUS ANTIBODIES IN HUMAN SERUM OR PLASMA USING AN IMMUNOENZYMATIC METHOD, SABOURAUD CHLORAMPHENICOL AGAR(SABOURAUD CHLORAMPHENICOL AGAR)-SABOURAUD CHLORAMPHENICOL AGAR IS RECOMMENDED FOR THE SELECTIVE ISOLATION OF YEASTS AND FILAMENTOUS FUNGI (DERMATOPHYTES AND OTHER FUNGI) FROM BIOLOGICAL SPECIMENS PRESENTING MIXED FUNGAL AND BACTERIAL FLORA.,ERTAPENEM 10 G(ERTAPENEM 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,MONOLISA™ ANTI-HBC PLUS(MONOLISA™ ANTI-HBC PLUS) -DETECTION KIT FOR ANTIBIOTICS TO NUCLEOCAPSID ANTIGEN (CORE) OF THE HEPATITIS B VIRUS INHUMAN SERUM OR PLASMA BY ENZYME,NORFLOXACIN 5G(NORFLOXACIN 5G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFTOLOZANE + TAZOBACTAM 30/10 G(CEFTOLOZANE + TAZOBACTAM 30/10 G)-ANTIBIOTIC DISKS ARE USED TO PERFORM A SEMI-QUANTITATIVE ANTIMICROBIAL SUSCEPTIBILITY TESTING USING DISK DIFFUSION METHOD.,PASTOREX™ MENINGITIS S. PNEUMONIAE(PASTOREX™ MENINGITIS S. PNEUMONIAE)-EIA FOR DETECTION OF STREPTOCOCCUS PNEUMONIAE IN CEREBROSPINAL FLUID (CSF), SERUM, AND URINE SPECIMENS,BRAIN-HEART(BRAIN-HEART)-BRAIN-HEART BROTH IS AN ENRICHED MEDIUM SUITABLE

	FOR THE GROWTH OF A WIDE VARIETY OF MICRO-ORGANISMS, REGARDLESS OF THEIR RESPIRATORY MODE (AEROBIC OR ANAEROBIC). THIS MEDIUM CAN BE USED FOR: • THE GROWTH OF ANAEROBIC BACTERIA • BLOOD CULTURES • THE GROWTH OF FASTIDIOUS BACTERIA SUCH AS STREPTOCOCCI (INCLUDING S. PNEUMONIAE), NEISSERIA MENINGITIDIS, ETC. AFTER ADDING 2% AGAR, THIS MEDIUM CAN ALSO BE USED FOR THE ISOLATION AND SUBCULTURE OF ACTINOMYCES (A. ISRAELII AND A. BOVIS).,PASTOREX™ MENINGITIS CONTROL(PASTOREX™ MENINGITIS CONTROL)-REAGENTS FOR CONTROL TESTS OF PASTOREX MENINGITIS KIT,CHOCOLATE + PVS(CHOCOLATE + PVS)-CHOCOLATE AGAR ENRICHED WITH THE POLYVITAMIN SUPPLEMENT (PVS) (CHOCOLATE + PVS) IS DESIGNED FOR THE ISOLATION OF FASTIDIOUS BACTERIA SUCH AS NEISSERIA (GONOCOCCUS AND MENINGOCOCCUS) AND HAEMOPHILUS.,STREPTOMYCIN 10 G (STREPTOMYCIN 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,T.C.B.S.(T.C.B.S.)-T.C.B.S. (THIOSULPHATE BILE CITRATE SALT SUCROSE) AGAR IS RECOMMENDED FOR THE GROWTH OF V. CHOLERAE, V. PARAHAEMOLYTICUS AND V. ALGINOLYTICUS.,PASTOREX™ STAPH-PLUS(PASTOREX™ STAPH-PLUS)-PASTOREX™ STAPH-PLUS IS A RAPID AGGLUTINATION TEST FOR THE SIMULTANEOUS DETECTION OF THE FIBRINOGEN AFFINITY (CLUMPING FACTOR), PROTEIN A, AND CAPSULAR POLYSACCHARIDES OF STAPHYLOCOCCUS AUREUS., MONOLISA™ ANTI-HBS PLUS(MONOLISA™ ANTI-HBS PLUS)-ENZYME IMMUNOASSAY(EIA) FOR THE DETECTION NAD LEVEL DETERMINATIO OF ANTIBODY TO HEPATITIS B SURFACE ANTIGEN (ANTI-HBS) IN HUMAN SERUM OF PLASMA.,PLATELIA™ ASPERGILLUS AG (PLATELIA™ ASPERGILLUS AG)-DETECTION OF ASPERGILLUS GALACTOMANNAN ANTIGEN IN SERUM AND BRONCHOALVEOLAR LAVAGE (BAL) FLUID,MONOLISA™ HCV AG-AB ULTRA V2 (MONOLISA™ HCV AG-AB ULTRA V2)-COMBINED SCREENING KIT FOR ANTI-HCV ANTIBODIES AND THE VIRAL ANTIGEN OF THE HEPATITIS C VIRUS IN SERUM OR HUMAN PLASMA USING AN ENZYME IMMUNOASSAY TECHNIQUES.,PASTOREX™ MENINGITIS N. MENINGITIDIS C(PASTOREX™ MENINGITIS N. MENINGITIDIS C)-EIA FOR DETECTION OF ESCHERICHIA COLI GROUP C IN CEREBROSPINAL FLUID (CSF), SERUM, AND URINE SPECIMENS,PASTOREX™ STAPH-PLUS(PASTOREX™ STAPH-PLUS)-PASTOREX™ STAPH-PLUS IS A RAPID AGGLUTINATION TEST FOR THE SIMULTANEOUS DETECTION OF THE FIBRINOGEN AFFINITY (CLUMPING FACTOR), PROTEIN A, AND CAPSULAR POLYSACCHARIDES OF STAPHYLOCOCCUS AUREUS,

	PASTOREX™ STREP(PASTOREX™ STREP)-PASTOREX™ STREP ASSAY IS A RAPID AGGLUTINATION TEST FOR GROUPING STREPTOCOCCI ACCORDING TO LANCEFIELD CLASSIFICATION. THE TEST INVOLVES USE OF LATEX SUSPENSIONS SPECIFIC FOR GROUPS A, B, C, D, F, AND G. IDENTIFICATION OF GROUP-SPECIFIC ANTIGENS BY HOMOLOGOUS ANTISERA REQUIRES A PRIOR ENZYMATIC EXTRACTION,TPHA(TPHA) -TPHA KITS ARE INTENDED FOR USE FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETECTION OF ANTIBODIES TO TREPONEMA PALLIDUM IN HUMAN SERUM AND PLASMA. THE PRODUCT MAY BE USED FOR THE SCREENING OF BLOOD DONORS, AND TO AID IN THE DIAGNOSIS OF PATIENTS WHERE SYPHILIS INFECTION IS SUSPECTED.,PLATELIA™ CANDIDA AG PLUS(PLATELIA™ CANDIDA AG PLUS)-DETECTION OF THE MANNAN ANTIGEN OF CANDIDA IN HUMAN SERUM OR PLASMA BY IMMUNOENZYMATIC ASSAY, PLATELIA™CANDIDA AB PLUS(PLATELIA™CANDIDA AB PLUS)-DETECTION OF ANTI-MANNAN CANDIDA ANTIBODIES IN HUMAN SERUM OR PLASMA BY IMMUNOENZYMATIC ASSAY,PASTOREX™ MENINGITIS N.MENINGITIDIS B/E.COLI K1(PASTOREX™ MENINGITIS N. MENINGITIDIS B/E.COLI K1)-EIA FOR DETECTION OF NEISSERIA MENINGITIDIS GROUP B AND ESCHERICHIA COLI STRAIN K1 IN CEREBROSPINAL FLUID (CSF), SERUM, AND URINE SPECIMENS, PASTOREX™ MENINGITIS H. INFLUENZAE B(PASTOREX™ MENINGITIS H. INFLUENZAE B)-EIA FOR DETECTION OF HAEMOPHILUS INFLUENZAE TYPE B IN CEREBROSPINAL FLUID (CSF), SERUM, AND URINE SPECIMENS,PASTOREX™ STREP D(PASTOREX™ STREP D)-PASTOREX™ STREP ASSAY IS A RAPID AGGLUTINATION TEST FOR GROUPING STREPTOCOCCI ACCORDING TO LANCEFIELD CLASSIFICATION. THE TEST INVOLVES USE OF LATEX SUSPENSIONS SPECIFIC FOR GROUPS A, B, C, D, F, AND G. IDENTIFICATION OF GROUP-SPECIFIC ANTIGENS BY HOMOLOGOUS ANTISERA REQUIRES A PRIOR ENZYMATIC EXTRACTION.,PASTOREX™ CRYPTO PLUS (PASTOREX™ CRYPTO PLUS)-DETECTION OF SOLUBLE CRYPTOCOCCUS NEOFORMANS ANTIGENS IN BIOLOGICAL FLUIDS (SERUM, C.S.F., B.A.L.,URINE),FUNGITEST™(FUNGITEST™)-DETERMINATION OF THE SENSITIVITY OF YEAST TO ANTIFUNGAL AGENTS,TETRACYCLINE 30 G(TETRACYCLINE 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,AMPICILLIN 10 G(AMPICILLIN 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,TICARCILLIN 75 G + CLAVULANIC ACID 10 G

	(TICARCILLIN 75 G + CLAVULANIC ACID 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,TOBRAMYCIN 30 G(TOBRAMYCIN 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,TOBRAMYCIN 10 G(TOBRAMYCIN 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,SYPHILIS TOTAL AB(SYPHILIS TOTAL AB)-THE SYPHILIS TOTAL AB IS A SEMI-QUANTITATIVE ENZYME IMMUNOASSAY KIT FOR THE DETECTION OF TOTAL ANTIBODIES (IGG, IGM AND IGA) TO TREPONEMA PALLIDUM IN HUMAN SERUM OR PLASMA. IT'S INDICATED FOR THE SCREENING OF BLOOD DONORS, AND AS AN AID IN THE DIAGNOSIS OF PATIENTS WHERE SYPHILIS INFECTION IS SUSPECTED IN CONJUNCTION WITH CLINICAL SIGNS AND SYMPTOMS.,PASTOREX™ MENINGITIS(PASTOREX™ MENINGITIS)-COMPLETE KIT FOR DETECTION OF N. MENINGITIDIS A, B; E. COLI K1, C, Y/W 135; HAEMOPHILUS INFLUENZAE TYPE B; S. PNEUMONIAE; AND GROUP B STREPTOCOCCI,PASTOREX™ MENINGITIS STREPTOCOCCUS B(PASTOREX™ MENINGITIS STREPTOCOCCUS B)-EIA FOR DETECTION OF GROUP B STREPTOCOCCI IN CEREBROSPINAL FLUID (CSF), SERUM, AND URINE SPECIMENS,CEFOTAXIME 30 G + CLAVULANIC ACID 10 G(CEFOTAXIME 30 G + CLAVULANIC ACID 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,COLISTIN 50 G(COLISTIN 50 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD, GEENIUS HIV 1/2 CONFIRMATORY CONTROLS(GEENIUS HIV 1/2 CONFIRMATORY CONTROLS)-THE GEENIUS HIV 1/2 CONFIRMATORY CONTROLS ARE INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE GEENIUS HIV 1/2 CONFIRMATORY ASSAY, PASTOREX™ MENINGITIS N. MENINGITIDIS A(PASTOREX™ MENINGITIS N. MENINGITIDIS A)-EIA FOR DETECTION OF NEISSERIA MENINGITIDIS GROUP A IN CEREBROSPINAL FLUID (CSF), SERUM, AND URINE SPECIMENS,CEFPIROME 30 G(CEFPIROME 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING

	BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,LEVOFLOXACIN 5 G(LEVOFLOXACIN 5 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFPROZIL 30 G(CEFPROZIL 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFTAZIDIME 10 G(CEFTAZIDIME 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFTIBUTEN 30 G(CEFTIBUTEN 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFOPERAZONE 75 G(CEFOPERAZONE 75 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,AMPICILLIN 2 G(AMPICILLIN 2 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFACLOR 30 G(CEFACLOR 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,PIPERACILLIN + TAZOBACTAM 30/6 G(PIPERACILLIN + TAZOBACTAM 30/6 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., STREPTOMYCIN 300 G(STREPTOMYCIN 300 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,POLYMIXIN 300 IU (50 G)(POLYMIXIN 300 IU (50 G))-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,MINOCYCLINE 30 G(MINOCYCLINE 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN

	VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,GENTAMICIN 10 G(GENTAMICIN 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,COLISTIN 10 G(COLISTIN 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., MEROPENEM 10G +EDTA(MEROPENEM 10G +EDTA)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD,NETILMICIN 10 G(NETILMICIN 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,FOSFOMYCIN 200 G(FOSFOMYCIN 200 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,PENICILLIN 1 IU(PENICILLIN 1 IU)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., VANCOMYCIN 5 G(VANCOMYCIN 5 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD, SULPHONAMIDES 300 G(SULPHONAMIDES 300 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,LINEZOLID 10 G(LINEZOLID 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,AMOXICILLIN + CLAVULANIC ACID 2/1 G(AMOXICILLIN + CLAVULANIC ACID 2/1 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., CEFIXIME 5 G(CEFIXIME 5 G)-THESE DISKS ARE USED TO SEMI

	QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., MUPIROCIN 200 G(MUPIROCIN 200 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., KANAMYCIN 30 G(KANAMYCIN 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD, GENTAMICIN 10 UI/15 G(GENTAMICIN 10 UI/15 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,PENICILLIN 6 G (10 IU)(PENICILLIN 6 G (10 IU))-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,NETILMICIN 30 G(NETILMICIN 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,PIPERACILLIN + TAZOBACTAM 100/10 G(PIPERACILLIN + TAZOBACTAM 100/10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., CEFPODOXIME 10 G(CEFPODOXIME 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., MOXIFLOXACIN 5 G(MOXIFLOXACIN 5 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., OXACILLIN 1G(OXACILLIN 1G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., CLARITHROMYCIN 15 G(CLARITHROMYCIN 15 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION

	METHOD.,PIPERACILLIN 100 G(PIPERACILLIN 100 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,MEROPENEM 10 G(MEROPENEM 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,TEMOCILLINE 30 G(TEMOCILLINE 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CARBENICILLIN 100 G(CARBENICILLIN 100 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFTAZIDIME 30 G(CEFTAZIDIME 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFUROXIME 30 G(CEFUROXIME 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFOPERAZONE 30G(CEFOPERAZONE 30G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFOTAXIME 30 G(CEFOTAXIME 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,AMOXICILLIN 25G(AMOXICILLIN 25G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFALEXIN 30 G(CEFALEXIN 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,AMOXICILLIN + CLAVULANIC ACID 20 / 10 G(AMOXICILLIN + CLAVULANIC ACID 20 / 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND

	SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., AMIKACIN 30 G(AMIKACIN 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., CEFTAZIDIME 30 G + CLAVULANIC ACID 10 G(CEFTAZIDIME 30 G + CLAVULANIC ACID 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., CEFEPIME 30 G(CEFEPIME 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., MECILLINAM 10 G(MECILLINAM 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., TEICOPLANIN 30 G(TEICOPLANIN 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., CEPHALOTHIN 30 G(CEPHALOTHIN 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., VANCOMYCIN 30 G(VANCOMYCIN 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., METRONIDAZOLE 4 G(METRONIDAZOLE 4 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,TRIMETHOPRIM 1,25 G + SULFAMETHOXAZOLE 23,75 G (TRIMETHOPRIM 1,25 G + SULFAMETHOXAZOLE 23,75 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,OXACILLIN 5 G(OXACILLIN 5 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., CEFAMANDOLE 30 G(CEFAMANDOLE 30 G)-THESE DISKS ARE

	USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFOXITIN 30 G(CEFOXITIN 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CLINDAMYCIN 2 G(CLINDAMYCIN 2 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CHLORAMPHENICOL 30 G(CHLORAMPHENICOL 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,URISELECT™ 4(URISELECT™ 4)-NON SELECTIVE CHROMOGENIC MEDIUM FOR THE DIRECT ISOLATION, DIFFERENTIATION AND ENUMERATION OF URINARY TRACT PATHOGENS,TRIMETHOPRIM 5 G(TRIMETHOPRIM 5 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,SPARFLOXACIN 5 G(SPARFLOXACIN 5 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD,TELITHROMYCIN 15 G(TELITHROMYCIN 15 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,NITROFURANTOIN 300 G(NITROFURANTOIN 300 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,FOSFOMYCIN 50 G(FOSFOMYCIN 50 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,AZITHROMYCIN 15 G(AZITHROMYCIN 15 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFAZOLIN 30 G(CEFAZOLIN 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO

	SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,MUELLER-HINTON(MUELLER-HINTON)-ISOLATION MEDIUM FOR ANTIMICROBIAL SUSCEPTIBILITY TESTING,AZTREONAM 30 G (AZTREONAM 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., CEFTAROLINE 5G(CEFTAROLINE 5G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., URISELECT™ 4(URISELECT™ 4)-NON SELECTIVE CHROMOGENIC MEDIUM FOR THE DIRECT ISOLATION, DIFFERENTIATION AND ENUMERATION OF URINARY TRACT PATHOGENS,CEFOTAXIME 5 G (CEFOTAXIME 5 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., LACTA™ TEST(LACTA™ TEST)-RAPID DETECTION OF RESISTANCE TO THIRD GENERATION CEPHALOSPORINS FOR ENTEROBACTERIACEAE,OPTOCHIN(OPTOCHIN)-PRESOMPTIVE IDENTIFICATION OF PNEUMOCOCCI.,TIGECYCLINE 15 G (TIGECYCLINE 15 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., LINEZOLID 30 G(LINEZOLID 30 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., GENTAMICIN 120 G(GENTAMICIN 120 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., FUSIDIC ACID 10 G(FUSIDIC ACID 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD., BACITRACIN 10 IU (130 G)(BACITRACIN 10 IU (130 G))-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFTRIAXONE 30 G(CEFTRIAXONE 30 G)-THESE DISKS

		ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CEFIXIME 10 G(CEFIXIME 10 G)-THESE DISKS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.
57	IMP/IVD/2018/000033	1.License Holder Name: MICROGENE DIAGNOSTIC SYSTEMS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE METER (ACCUSURE FORA)-THE ACCUSURE FORA BLOOD GLUCOSE METER IS USED WITH ACCUSURE FORA BLOOD GLUCOSE TEST STRIPS TO QUANTITATIVELY MEASURE GLUCOSE IN WHOLE BLOOD,BLOOD GLUCOSE TEST STRIPS(ACCUSURE SIMPLE)-ACCUSURE SIMPLE BLOOD GLUCOSE TEST STRIP IS INTENDED TO MONITOR THE BLOOD GLUCOSE LEVEL IN HUMAN BLOOD,BLOOD GLUCOSE METER (ACCUSURE PRO)-THE ACCUSURE PRO BLOOD GLUCOSE METER IS USED WITH ACCUSURE PRO BLOOD GLUCOSE TEST STRIPS TO QUANTITATIVELY MEASURE GLUCOSE IN WHOLE BLOOD,BLOOD GLUCOSE TEST STRIPS(ACCUSURE PRO)-ACCUSURE PRO BLOOD GLUCOSE TEST STRIPS IS USED ALONG WITH BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO MONITOR BLOOD GLUCOSE IN WHOLE BLOOD,BLOOD GLUCOSE METER(ACCUSURE SIMPLE)-THE ACCUSURE SIMPLE BLOOD GLUCOSE METER IS USED WITH ACCUSURE SIMPLE BLOOD GLUCOSE TEST STRIPS TO QUANTITATIVELY MEASURE GLUCOSE IN WHOLE BLOOD

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58	IMP/IVD/2018/000034	1.License Holder Name: APEX DIAGNOSTICS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HCG ONE STEP PREGNANCY STRIP TEST (COLLOIDAL GOLD) STRIP-CASSETTE-MIDSTREAM(OEM)-A HUMAN CHORIONIC GONADOTROPIN (HCG) TESTS REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE PRELIMINARY SELF-TESTING OF HCG IN URINE/BODY FLUIDS, CHIKUNGUNYA IGM RAPID TEST(CASSETTE)-THE CHIKUNGUNYA IGM RAPID TEST CASSETTE IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTI-CHIKUNGUNYA VIRUS (CHIK) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH CHIK.,TYPHOID IGG/IGM RAPID TEST(CASSETTE)-THE TYPHOID IGG/IGM RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF ANTI-SALMONELLA TYPHI (S. TYPHI) IGG AND IGM IN HUMAN SERUM AND PLASMA . IT IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH S. TYPHI. ANY REACTIVE SPECIMEN WITH THE TYPHOID IGG/IGM RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S).,DENGUE NS1-DENGUE IGG/IGM COMBO RAPID TEST(COMBO CASSETTE)-THE DENGUE NS1+IGM/IGG COMBO RAPID TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF DENGUE VIRUS NS1 ANTIGEN AND IGM/IGG ANTIBODIES TO DENGUE VIRUS IN WHOLE BLOOD, SERUM OR PLASMA TO AID IN THE DIAGNOSIS OF DENGUE VIRAL INFECTION.,CARDIAC TROPONIN I DIAGNOSTIC KIT (COLLOIDAL GOLD)(CASSETTE)-THE CTNI RAPID TEST (WHOLE BLOOD/SERUM/PLASMA) IS A RAPID VISUAL IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF CARDIAC TROPONIN I IN HUMAN WHOLE BLOOD, SERUM, OR PLASMA SPECIMENS. THIS KIT IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (MI).,MALARIA P.F./PAN AG RAPID TEST (CASSETTE)-(MALARIA ANTIGEN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF MALARIA ANTIGEN FOR ALL SPECIES IN BLOOD/BODY FLUIDS),FSH ONE STEP MENOPAUSE TEST(STRIP-CASSETTE-MIDSTREAM)-THE FSH MENOPAUSE RAPID TEST (CASSETTE) IS A RAPID LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF FOLLICLE-STIMULATING HORMONE (FSH) LEVEL IN URINE TO EVALUATE THE ONSET OF MENOPAUSE IN WOMEN.,REAGENT STRIP FOR URINALYSIS (1-14 PARAMETERS)-URS URINALYSIS REAGENT STRIPS ARE A COMBINATION FROM 1-14 PARAMETERS (ASCORBIC ACID/ BILIRUBIN /BLOOD CELLS/GLUCOSE/ KETONE /LEUKOCYTE

	PEROXIDASE/SPECIFIC GRAVITY/UROBILINOGEN/NITRITE / PH /PROTEIN / /CALCIUM/MICRO-ALBUMIN/CREATININE & OTHER URINARY ANALYTES TEST REAGENTS /STRIPS/KITS, ARE MEDICAL DEVICES INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE URINALYSIS AND FOR IN VITRO DIAGNOSTICS USE. ,LH ONE STEP OVULATION TEST (COLLOIDAL GOLD)(STRIP-CASSETTE-MIDSTREAM) -THE LH ONE STEP OVULATION TEST (URINE) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF LUTEINIZING HORMONE (LH) IN URINE TO AID IN THE DETECTION OF OVULATION.,HCG ONE STEP PREGNANCY STRIP TEST (COLLOIDAL GOLD)(STRIP-CASSETTE-MIDSTREAM)-A HUMAN CHORIONIC GONADOTROPIN (HCG) TESTS REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE PRELIMINARY SELF-TESTING OF HCG IN URINE/BODY FLUIDS,DENGUE NS1 RAPID TEST(CASSETTE) -THE DENGUE NS1 ANTIGEN RAPID TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF DENGUE VIRUS NS1 ANTIGEN IN WHOLE BLOOD, SERUM OR PLASMA TO AID IN THE DIAGNOSIS OF DENGUE VIRAL INFECTION. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.

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59	IMP/IVD/2018/000036	1.License Holder Name: CEPHEID INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:XPERT XPRESS FLU/RSV (XPERT XPRESS FLU/RSV)-THE CEPHEID XPERT® XPRESS FLU/RSV ASSAY, PERFORMED ON THE GENEXPERT® INSTRUMENT SYSTEMS, IS AN AUTOMATED, MULTIPLEX REAL-TIME, REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION (RT-PCR) ASSAY INTENDED FOR THE IN VITRO QUALITATIVE DETECTION AND DIFFERENTIATION OF INFLUENZA A, INFLUENZA B, AND RESPIRATORY SYNCYTIAL VIRUS (RSV) VIRAL RNA. THE XPERT XPRESS FLU/RSV ASSAY USES NASOPHARYNGEAL (NP) SWAB AND NASAL SWAB (NS) SPECIMENS COLLECTED FROM PATIENTS WITH SIGNS AND SYMPTOMS OF RESPIRATORY INFECTION. THE XPERT XPRESS FLU/RSV ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF INFLUENZA AND RESPIRATORY SYNCYTIAL VIRUS INFECTIONS IN CONJUNCTION WITH CLINICAL AND EPIDEMIOLOGICAL RISK FACTORS. NEGATIVE RESULTS DO NOT PRECLUDE INFLUENZA VIRUS OR RSV INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER PATIENT MANAGEMENT DECISIONS. PERFORMANCE CHARACTERISTICS FOR INFLUENZA A WERE ESTABLISHED DURING THE 2015-2016 INFLUENZA SEASON FOR NP SWAB SPECIMENS AND THE 2016-2017 INFLUENZA SEASON FOR NS SPECIMENS. WHEN OTHER NOVEL INFLUENZA A VIRUSES ARE EMERGING, PERFORMANCE CHARACTERISTICS MAY VARY. IF INFECTION WITH A NOVEL INFLUENZA A VIRUS IS SUSPECTED BASED ON CURRENT CLINICAL AND EPIDEMIOLOGICAL SCREENING CRITERIA RECOMMENDED BY PUBLIC HEALTH AUTHORITIES, SPECIMENS SHOULD BE COLLECTED WITH APPROPRIATE INFECTION CONTROL PRECAUTIONS FOR NOVEL VIRULENT INFLUENZA VIRUSES AND SENT TO STATE OR LOCAL HEALTH DEPARTMENTS FOR TESTING. VIRAL CULTURE SHOULD NOT BE ATTEMPTED IN THESE CASES UNLESS A BSL 3+ FACILITY IS AVAILABLE TO RECEIVE AND CULTURE SPECIMENS.,XPERT MRSA ASSAY(XPERT MRSA)-THE CEPHEID XPERT MRSA ASSAY PERFORMED IN THE GENEXPERT® DX SYSTEM (XPERT MRSA) IS A QUALITATIVE IN VITRO DIAGNOSTIC TEST DESIGNED FOR RAPID DETECTION OF METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) FROM NASAL SWABS IN PATIENTS AT RISK FOR NASAL COLONIZATION. THE TEST UTILIZES AUTOMATED REAL-TIME POLYMERASE CHAIN REACTION (PCR) TO DETECT MRSA DNA. THE XPERT MRSA ASSAY IS INTENDED TO AID IN THE PREVENTION AND CONTROL OF MRSA INFECTIONS IN HEALTHCARE SETTINGS. THE XPERT MRSA ASSAY IS NOT INTENDED TO DIAGNOSE MRSA NOR TO GUIDE OR MONITOR TREATMENT FOR MRSA INFECTIONS. CONCOMITANT CULTURES ARE NECESSARY ONLY TO RECOVER

	ORGANISMS FOR EPIDEMIOLOGICAL TYPING OR FOR FURTHER SUSCEPTIBILITY TESTING.,XPERT BCR-ABL ULTRA(XPERT BCR-ABL ULTRA)-THE XPERT BCR-ABL ULTRA, PERFORMED ON THE CEPHEID GENEXPERT® INSTRUMENT SYSTEMS, IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETECTION OF THE BCR-ABL1 CHROMOSOMAL TRANSLOCATION MRNA TRANSCRIPTS (TYPES E13A2/B2A2 OR E14A2/B3A2) AND THE ABL1 ENDOGENOUS CONTROL MRNA TRANSCRIPT IN PERIPHERAL BLOOD SPECIMENS FROM PATIENTS PREVIOUSLY DIAGNOSED WITH CHRONIC MYELOGENOUS LEUKEMIA (CML). THE TEST UTILIZES AUTOMATED, QUANTITATIVE, REAL-TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (QPCR). XPERT BCR-ABL ULTRA WILL NOT REPORT THE SPECIFIC TYPE OF BCR-ABL1 MRNA TRANSCRIPT PRESENT. THE XPERT BCR-ABL ULTRA IS INDICATED AS AID IN THE MONITORING OF BCR-ABL1 MRNA TRANSCRIPT LEVELS IN PATIENTS DIAGNOSED WITH CML. SERIAL TESTING FOR BCR-ABL1 MRNA TRANSCRIPT LEVELS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL MEASURES OF DISEASE STATUS, RISK FACTORS, AND PROFESSIONAL GUIDELINES TO GUIDE PATIENT MANAGEMENT.,XPERT CARBA-R (XPERT CARBA-R)-THE XPERT CARBA-R ASSAY, PERFORMED ON THE GENEXPERT® INSTRUMENT SYSTEMS, IS A QUALITATIVE IN VITRO DIAGNOSTIC TEST DESIGNED FOR THE DETECTION AND DIFFERENTIATION OF THE BLAKPC, BLANDM, BLAVIM, BLAOXA-48, AND BLAIMP GENE SEQUENCES ASSOCIATED WITH CARBAPENEM-NON-SUSCEPTIBILITY. THE TEST UTILIZES AUTOMATED REAL-TIME POLYMERASE CHAIN REACTION (PCR). THE XPERT CARBA-R ASSAY IS INTENDED AS AN AID TO INFECTION CONTROL IN THE DETECTION OF CARBAPENEM-NON-SUSCEPTIBLE BACTERIA THAT COLONIZE PATIENTS IN HEALTHCARE SETTINGS. A NEGATIVE XPERT CARBA-R ASSAY RESULT DOES NOT PRECLUDE THE PRESENCE OF OTHER RESISTANCE MECHANISMS. THE XPERT CARBA-R ASSAY IS FOR USE WITH THE FOLLOWING SAMPLE TYPES: PURE COLONIES THE ASSAY IS PERFORMED ON CARBAPENEM-NON-SUSCEPTIBLE PURE COLONIES OF ENTEROBACTERIACEAE, ACINETOBACTER BAUMANNII, OR PSEUDOMONAS AERUGINOSA, WHEN GROWN ON BLOOD AGAR OR MACCONKEY AGAR. FOR TESTING PURE COLONIES, THE XPERT CARBA-R ASSAY SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY TESTS INCLUDING PHENOTYPIC ANTIMICROBIAL SUSCEPTIBILITY TESTING. THE IDENTIFICATION OF A BLAIMP, BLANDM, OR BLAVIM METALLO-BETA-LACTAMASE GENE (I.E., THE GENES THAT ENCODE THE IMP, NDM, AND VIM METALLO-BETA-LACTAMASES, RESPECTIVELY) MAY BE USED AS AN AID TO CLINICIANS IN DETERMINING APPROPRIATE THERAPEUTIC STRATEGIES FOR PATIENTS WITH KNOWN OR SUSPECTED

	CARBAPENEM-NON- SUSCEPTIBLE BACTERIAL INFECTIONS. RECTAL AND PERIRECTAL SWAB SPECIMENS THE ASSAY IS PERFORMED ON RECTAL AND PERIRECTAL SWAB SPECIMENS FROM PATIENTS AT RISK FOR INTESTINAL COLONIZATION WITH CARBAPENEM-NON-SUSCEPTIBLE BACTERIA. CONCOMITANT CULTURES ARE NECESSARY TO RECOVER ORGANISMS FOR EPIDEMIOLOGICAL TYPING, ANTIMICROBIAL SUSCEPTIBILITY TESTING, AND FOR FURTHER CONFIRMATORY BACTERIAL IDENTIFICATION. THE XPERT CARBA-R ASSAY, WHEN PERFORMED ON RECTAL AND PERIRECTAL SWAB SPECIMENS, IS NOT INTENDED TO GUIDE OR MONITOR TREATMENT FOR CARBAPENEM-NON-SUSCEPTIBLE BACTERIAL INFECTIONS OR TO DETERMINE INFECTION FROM CARBAPENEM-NON-SUSCEPTIBLE BACTERIA.,XPERT FACTOR II & FACTOR V(XPERT FACTOR II & FACTOR V)-THE XPERT FACTOR II & FACTOR V ASSAY IS A QUALITATIVE IN VITRO DIAGNOSTIC GENOTYPING TEST FOR THE DETECTION OF FACTOR II AND FACTOR V ALLELES FROM SODIUM CITRATE OR EDTA ANTICOAGULATED WHOLE BLOOD. THE TEST IS PERFORMED ON THE CEPHEID GENEXPERT® DX SYSTEM SOFTWARE VERSION 4.0 OR HIGHER. THIS TEST IS INTENDED TO PROVIDE RESULTS FOR FACTOR II (G20210A) AND FACTOR V LEIDEN (G1691A) MUTATIONS AS AN AID IN THE DIAGNOSIS IN INDIVIDUALS WITH SUSPECTED THROMBOPHILIA.,XPERT XPRESS SARS-COV-2(XPERT XPRESS SARS-COV-2)-THE XPERT XPRESS SARS-COV-2 TEST IS A RAPID, REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN UPPER RESPIRATORY SPECIMENS (SUCH AS NASOPHARYNGEAL, OROPHARYNGEAL, NASAL, OR MID-TURBINATE SWAB AND/OR NASAL WASH/ ASPIRATE) COLLECTED FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. TESTING OF NASOPHARYNGEAL, OROPHARYNGEAL, NASAL, OR MID-TURBINATE SWAB AND NASAL WASH/ASPIRATE SPECIMENS USING THE XPERT XPRESS SARS-COV-2 TEST RUN ON THE GENEXPERT DX AND GENEXPERT INFINITY SYSTEMS IS LIMITED TO LABORATORIES CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C. § 263A, TO PERFORM HIGH AND MODERATE COMPLEXITY TESTS. TESTING OF NASOPHARYNGEAL, NASAL, OR MID-TURBINATE SWAB SPECIMENS USING THE XPERT XPRESS SARS-COV-2 TEST RUN ON THE GENEXPERT XPRESS SYSTEM (TABLET AND HUB CONFIGURATIONS) IS AUTHORIZED TO BE DISTRIBUTED AND USED IN PATIENT CARE SETTINGS OUTSIDE OF THE CLINICAL LABORATORY ENVIRONMENT. RESULTS ARE FOR THE DETECTION OF SARS-COV-2 RNA. THE SARS-COV-2 RNA IS GENERALLY DETECTABLE IN UPPER RESPIRATORY SPECIMENS DURING THE ACUTE PHASE OF INFECTION. POSITIVE

	RESULTS ARE INDICATIVE OF ACTIVE INFECTION WITH SARS-COV-2; CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. LABORATORIES WITHIN THE UNITED STATES AND ITS TERRITORIES ARE REQUIRED TO REPORT ALL POSITIVE RESULTS TO THE APPROPRIATE PUBLIC HEALTH AUTHORITIES. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER PATIENT MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. TESTING WITH THE XPERT XPRESS SARS-COV-2 TEST IS INTENDED FOR USE BY TRAINED OPERATORS WHO ARE PROFICIENT IN PERFORMING TESTS USING EITHER GENEXPERT DX, GENEXPERT INFINITY AND/OR GENEXPERT XPRESS SYSTEMS. THE XPERT XPRESS SARS-COV-2 TEST IS ONLY FOR USE UNDER THE FOOD AND DRUG ADMINISTRATION'S EMERGENCY USE AUTHORIZATION.,XPERT BCR-ABL ULTRA(XPERT BCR-ABL ULTRA)- THE XPERT BCR-ABL ULTRA TEST IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATION OF BCR-ABL1 AND ABL1 MRNA TRANSCRIPTS IN PERIPHERAL BLOOD SPECIMENS OF DIAGNOSED T (9;22) POSITIVE CHRONIC MYELOID LEUKEMIA (CML) PATIENTS EXPRESSING BCR-ABLL FUSION TRANSCRIPTS TYPE E13A2 AND/OR E14A2. THE TEST UTILIZES AUTOMATED, QUANTITATIVE, REAL-TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-QPCR). THE XPERT BCR-ABL ULTRA TEST IS INTENDED TO MEASURE BCR-ABL1 TO ABL1 PERCENT RATIOS ON THE INTERNATIONAL SCALE (IS), AND ALSO EXPRESSED AS A LOG MOLECULAR REDUCTION (MR VALUE) FROM A BASELINE OF 100% (IS), IN T(9;22) POSITIVE CML PATIENTS DURING MONITORING OF TREATMENT WITH TYROSINE KINASE INHIBITORS (TKIS). THE TEST DOES NOT DIFFERENTIATE BETWEEN E13A2/B2A2 OR E14A2/B3A2 FUSION TRANSCRIPTS AND DOES NOT MONITOR OTHER RARE FUSION TRANSCRIPTS RESULTING FROM T(9;22). THIS TEST IS NOT INTENDED FOR THE DIAGNOSIS OF CML. THE XPERT BCR-ABL ULTRA TEST IS INTENDED FOR USE ONLY ON THE CEPHEID GENEXPERT® DX SYSTEM AND THE GENEXPERT INFINITY SYSTEM.

60	IMP/IVD/2018/000037	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROSCAN POS MIC E 37 (MICROSCAN POS MIC E 37)-FOR USE WITH MICROSCAN DRIED GRAM POSITIVE MIC/COMBO AND DRIED GRAM POSITIVE BREAKPOINT COMBO AND DRIED GRAM POSITIVE ID TYPE 2 OR 3 PANELS. MICROSCAN POS PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF RAPIDLY GROWING AEROBIC AND FACULTATIVE GRAM POSITIVE COCCI, SOME FASTIDIOUS AEROBIC GRAM POSITIVE COCCI AND LISTERIA MONOCYTOGENES. REFER TO LIMITATIONS OF PROCEDURE SECTION FOR USE WITH FASTIDIOUS STREPTOCOCCI,MICROSCAN HNID PANEL(MICROSCAN HNID PANEL)-THE HNID SYSTEM IS DESIGNED FOR RAPID IDENTIFICATION OF AND DETECTION OF -LACTAMASE PRODUCTION IN NEISSERIA SPECIES, HAEMOPHILUS SPECIES, BRANHAMELLA CATARRHALIS AND GARDNERELLA VAGINALIS. BIOTYPING OF HAEMOPHILUS INFLUENZAE AND HAEMOPHILUS PARAINFLUENZAE MAY ALSO BE PERFORMED.,MICROSCAN POS MIC STA 35(MICROSCAN POS MIC STA 35)-FOR USE WITH MICROSCAN DRIED GRAM POSITIVE MIC/COMBO AND DRIED GRAM POSITIVE BREAKPOINT COMBO AND DRIED GRAM POSITIVE ID TYPE 2 OR 3 PANELS. MICROSCAN POS PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF RAPIDLY GROWING AEROBIC AND FACULTATIVE GRAM POSITIVE COCCI, SOME FASTIDIOUS AEROBIC GRAM POSITIVE COCCI AND LISTERIA MONOCYTOGENES. REFER TO LIMITATIONS OF PROCEDURE SECTION FOR USE WITH FASTIDIOUS STREPTOCOCCI.,MICROSCAN RAPID ANAEROBE ID PANEL(MICROSCAN RAPID ANAEROBE ID PANEL)-THE MICROSCAN RAPID ANAEROBE IDENTIFICATION PANEL IS DESIGNED FOR RAPID IDENTIFICATION OF ANAEROBIC BACTERIA ISOLATED FROM HUMAN CLINICAL SPECIMENS.,MICROSCAN NEGATIVE MIC EN 47(MICROSCAN NEGATIVE MIC EN 47)-FOR USE WITH MICROSCAN DRIED GRAM NEGATIVE MIC/COMBO PANELS AND DRIED GRAM NEGATIVE BREAKPOINT COMBO PANELS. MICROSCAN PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF AEROBIC AND FACULTATIVELY ANAEROBIC GRAMNEGATIVE BACILLI.,MICROSCAN RAPID NEG ID PANEL TYPE 3-MICROSCAN RAPID PANELS ARE DESIGNED FOR USE IN DETERMINING IDENTIFICATION TO THE SPECIES LEVEL OF RAPIDLY GROWING AEROBIC AND FACULTATIVELY ANAEROBIC GRAM-NEGATIVE BACILLI (ENTEROBACTERIACEAE, GLUCOSE NON-FERMENTERS, AND

	NON-ENTEROBACTERIACEAE GLUCOSE FERMENTERS).,MICROSCAN RAPID NEG ID PANEL TYPE 4-MICROSCAN RAPID PANELS ARE DESIGNED FOR USE IN DETERMINING IDENTIFICATION TO THE SPECIES LEVEL OF RAPIDLY GROWING AEROBIC AND FACULTATIVELY ANAEROBIC GRAM-NEGATIVE BACILLI (ENTEROBACTERIACEAE, GLUCOSE NON-FERMENTERS, AND NON-ENTEROBACTERIACEAE GLUCOSE FERMENTERS).,MICROSCAN MINERAL OIL-FOR OIL OVERLAYS ON MICROSCAN PANELS, MICROSCAN NEG ID PANEL TYPE 2-MICROSCAN PANELS ARE DESIGNED FOR USE IN DETERMINING IDENTIFICATION TO THE SPECIES LEVEL OF AEROBIC AND FACULTATIVELY ANAEROBIC GRAM-NEGATIVE BACILLI.,MICROSCAN RAPID INDOLE REAGENT-F-FOR RAPID NEG ID INDOLE TEST,MICROSCAN 0.8% SULFLANILIC ACID-FOR NITRATE TEST,MICROSCAN NEG COMBO PANEL TYPE 72-MICROSCAN PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF AEROBIC AND FACULTATIVELY ANAEROBIC GRAM-NEGATIVE BACILLI.,MICROSCAN RAPID NEG ID PANEL TYPE 4-MICROSCAN RAPID PANELS ARE DESIGNED FOR USE IN DETERMINING IDENTIFICATION TO THE SPECIES LEVEL OF RAPIDLY GROWING AEROBIC AND FACULTATIVELY ANAEROBIC GRAM-NEGATIVE BACILLI (ENTEROBACTERIACEAE, GLUCOSE NON-FERMENTERS, AND NON-ENTEROBACTERIACEAE GLUCOSE FERMENTERS).,MICROSCAN NEG MIC PANEL TYPE 44-MICROSCAN PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF AEROBIC AND FACULTATIVELY ANAEROBIC GRAM-NEGATIVE BACILLI.,MICROSCAN PEPTIDASE-FOR USE WITH MICROSCAN PANELS,MICROSCAN NEG NON ENTERO COMBO PANEL TYPE 71-MICROSCAN PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF AEROBIC AND FACULTATIVELY ANAEROBIC GRAM-NEGATIVE BACILLI.,MICROSCAN POS COMBO PANEL TYPE 41-MICROSCAN POS PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF RAPIDLY GROWING AEROBIC AND FACULTATIVE GRAM POSITIVE COCCI, SOME FASTIDIOUS AEROBIC GRAM POSITIVE COCCI AND LISTERIA MONOCYTOGENES.,MICROSCAN MICROSTREP PLUS PANEL TYPE 6-MICROSCAN MICROSTREP PLUS PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY OF AEROBIC NON-ENTEROCOCCAL STREPTOCOCCI (INCLUDING STREPTOCOCCUS PNEUMONIAE) AND HAEMOPHILUS SPP., MICROSCAN MICROSTREP PLUS PANEL TYPE 1-MICROSTREP PLUS

	PANELS ARE DESIGNED FOR USE IN DETERMINING QUANTITATIVE AND/OR QUALITATIVE ANTIMICROBIAL AGENT SUSCEPTIBILITY OF COLONIES GROWN ON SOLID MEDIA OF AEROBIC STREPTOCOCCI, INCLUDING STREPTOCOCCUS PNEUMONIAE.,MICROSCAN ALPHA NAPTHOL-FOR VP TEST ON MICROSCAN PANEL,MICROSCAN KOVAC' S REAGENT-FOR INDOLE TEST,MICROSCAN NEG URINE COMBO PANEL TYPE 55-FOR THE DETERMINATION OF ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF RAPIDLY GROWING AEROBIC AND FACULTATIVE GRAM-NEGATIVE BACTERIA.,MICROSCAN PEPTIDASE-FOR USE WITH MICROSCAN PANELS,MICROSCAN MINERAL OIL-FOR OIL OVERLAYS ON MICROSCAN PANELS,MICROSCAN HNID INDOLE REAGENT-FOR HNID INDOLE TEST,MICROSCAN 0.5% N,N-DIMETHYLALPHANAPTHYLAMINE-FOR NITRATE TEST ON MICROSCAN PANEL,MICROSCAN HNID INOCULUM BROTH-FOR USE WITH HNID PANELS,MICROSCAN 10% FERRIC CHLORIDE-FOR TDA TEST,MICROSCAN 0.4% SALINE WITH PLURONIC-FOR USE WITH MICROSCAN PANELS,MICROSCAN POS ID PANEL TYPE 3-FOR THE DETERMINATION OF IDENTIFICATION TO THE SPECIES LEVEL OF RAPIDLY GROWING AEROBIC AND FACULTATIVE GRAM-POSITIVE COCCI, SOME FASTIDIOUS AEROBIC COCCI AND LISTERIA MONOCYTOGENES.,MICROSCAN 3ML INOCULUM WATER-FOR USE WITH MICROSCAN PANELS,MICROSCAN YEAST TURBIDITY STANDARD-FOR RAPID YEAST ID PANEL,MICROSCAN EHRLICH'S REAGENT-FOR RAPID ANAEROBE ID INDOLE TEST,MICROSCAN 3ML INOCULUM SALINE-FOR USE WITH MICROSCAN PANELS,MICROSCAN POS MIC PANEL TYPE 33-MICROSCAN POS PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF RAPIDLY GROWING AEROBIC AND FACULTATIVE GRAM POSITIVE COCCI, SOME FASTIDIOUS AEROBIC GRAM POSITIVE COCCI AND LISTERIA MONOCYTOGENES.,MICROSCAN 40% POTASSIUM HYDROXIDE-FOR VP TEST,MICROSCAN RAPID YEAST ID PANEL-THE RAPID YEAST IDENTIFICATION PANEL IS DESIGNED FOR RAPID IDENTIFICATION OF YEAST AND YEAST-LIKE SPECIES ISOLATED FROM CLINICAL SPECIMENS.,MICROSCAN NEGATIVE MIC NF 50(MICROSCAN NEGATIVE MIC NF 50)-FOR USE WITH MICROSCAN DRIED GRAM NEGATIVE MIC/COMBO PANELS AND DRIED GRAM NEGATIVE BREAKPOINT COMBO PANELS. MICROSCAN PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF AEROBIC AND FACULTATIVELY ANAEROBIC GRAMNEGATIVE BACILLI.,MICROSCAN NEG BREAKPOINT COMBO 50(MICROSCAN NEG BREAKPOINT COMBO 50)-FOR USE WITH MICROSCAN DRIED GRAM NEGATIVE MIC/COMBO

	PANELS AND DRIED GRAM NEGATIVE BREAKPOINT COMBO PANELS. MICROSCAN PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF AEROBIC AND FACULTATIVELY ANAEROBIC GRAMNEGATIVE BACILLI.,MICROSCAN XYLENE REAGENT-FOR RAPID ANAEROBE ID INDOLE TEST,MICROSCAN NEG BREAKPOINT COMBO PANEL TYPE 46(MICROSCAN NEG BREAKPOINT COMBO PANEL TYPE 46)-FOR USE WITH MICROSCAN DRIED GRAM NEGATIVE MIC/COMBO PANELS AND DRIED GRAM NEGATIVE BREAKPOINT COMBO PANELS. MICROSCAN PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF AEROBIC AND FACULTATIVELY ANAEROBIC GRAM NEGATIVE BACILLI.,MICROSCAN 0.05N SODIUM HYDROXIDE-FOR RAPID YEAST ID NITROPHENYL TESTS,MICROSCAN 0.05N SODIUM HYDROXIDE REAGENT-FOR RAPID YEAST ID NITROPHENYL TESTS,MICROSCAN NEG BREAKPOINT COMBO PANEL TYPE 48-MICROSCAN PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF AEROBIC AND FACULTATIVELY ANAEROBIC GRAM-NEGATIVE BACILLI.,MICROSCAN NEG BREAKPOINT COMBO PANEL TYPE 42-MICROSCAN PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF AEROBIC AND FACULTATIVELY ANAEROBIC GRAM-NEGATIVE BACILLI.,MICROSCAN POS COMBO PANEL TYPE 39-MICROSCAN POS PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF RAPIDLY GROWING AEROBIC AND FACULTATIVE GRAM POSITIVE COCCI, SOME FASTIDIOUS AEROBIC GRAM POSITIVE COCCI AND LISTERIA MONOCYTOGENES.,MICROSCAN POS BREAKPOINT COMBO PANEL TYPE 29-MICROSCAN POS PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF RAPIDLY GROWING AEROBIC AND FACULTATIVE GRAM POSITIVE COCCI, SOME FASTIDIOUS AEROBIC GRAM POSITIVE COCCI AND LISTERIA MONOCYTOGENES.,MICROSCAN INOCULUM WATER WITH PLURONIC-FOR USE WITH MICROSCAN PANELS,MICROSCAN NEG MIC PANEL TYPE 37-MICROSCAN PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY AND/OR IDENTIFICATION TO THE SPECIES LEVEL OF AEROBIC AND FACULTATIVELY ANAEROBIC GRAM-NEGATIVE BACILLI.

61	IMP/IVD/2018/000038	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BNZ2(BNZ2)-ONLINE DAT BENZODIAZEPINES II (BNZ2) IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE DETECTION OF BENZODIAZEPINES IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS AT A CUTOFF CONCENTRATION OF 200 NG/ML. BENZODIAZEPINES II PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GCMS) OR LIQUID CHROMATOGRAPHY COUPLED WITH TANDEM MASS SPECTROMETRY (LCMS/MS) IS THE PREFERRED CONFIRMATORY METHOD.1,2 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ELECSYS VITAMIN D TOTAL II(ELECSYS VITAMIN D TOTAL II)-THIS ASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25HYDROXYVITAMIN D IN HUMAN SERUM AND PLASMA. THIS ASSAY IS TO BE USED AS AN AID IN THE ASSESSMENT OF VITAMIN D SUFFICIENCY.,ADPTEST(ADPTEST)-ASSAY FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PLATELET FUNCTION FOLLOWING STIMULATION OF THE PLATELET ADENOSINE DIPHOSPHATE (ADP) RECEPTORS. THE REAGENT IS INTENDED FOR USE IN PLATELET AGGREGATION TESTING WITH WHOLE BLOOD SAMPLES.,ELECSYS FOLATE III(ELECSYS FOLATE III)-BINDING ASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN SERUM AND PLASMA.,TRAPTEST(TRAPTEST)-ASSAY FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PLATELET FUNCTION TRIGGERED BY TRAP6. THE REAGENT IS INTENDED FOR USE IN PLATELET FUNCTION TESTING WITH WHOLE BLOOD.,PRECICONTROL SCC(PRECICONTROL SCC)-PRECICONTROL SCC IS USED FOR QUALITY CONTROL OF THE ELECSYS SCC IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,COBAS® PLASMA SEPARATION CARD (COBAS® PLASMA SEPARATION CARD)-THE COBAS® PLASMA SEPARATION CARD IS INTENDED FOR THE COLLECTION AND STABILIZATION OF DRIED PLASMA FROM WHOLE BLOOD SPECIMENS, FOR SUBSEQUENT IN VITRO DIAGNOSTIC EXAMINATION.,ELECSYS PTH STAT(ELECSYS PTH STAT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE IN HUMAN SERUM AND PLASMA FOR THE DIFFERENTIAL DIAGNOSIS OF HYPERCALCEMIA AND HYPOCALCEMIA. THIS ASSAY CAN BE USED INTRAOPERATIVELY.,PROSTAGLANDIN E1 REAGENT (PROSTAGLANDIN E1 REAGENT)-REAGENT FOR THE QUANTITATIVE

	IN VITRO DETERMINATION OF PLATELET FUNCTION TRIGGERED BY ADENOSINE DIPHOSPHATE AND PROSTAGLANDIN E1 REAGENT (IN CONJUNCTION WITH REAGENT ADPTEST). THE REAGENT IS INTENDED FOR USE IN PLATELET FUNCTION TESTING WITH WHOLE BLOOD SAMPLES.,ELECSYS FOLATE III(ELECSYS FOLATE III)-THIS ASSAY IS USED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FOLATE IN ERYTHROCYTES (RED BLOOD CELLS, RBC).,LIQUID CONTROL SET (LIQUID CONTROL SET)-FOR USE AS A QUALITY CONTROL CONTROL FOR IMPEDANCE AGGREGOMETRY BASED ON THE ANALYSIS OF AN ARTIFICIAL LIQUID CONTROL MATERIAL.,ELECSYS CORTISOL II (ELECSYS CORTISOL II)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM, PLASMA AND SALIVA. THE DETERMINATION OF CORTISOL IS USED FOR THE RECOGNITION AND TREATMENT OF FUNCTIONAL DISORDERS OF THE ADRENAL GLAND.,NACI/CACL2 SOLUTION (NACI/CACL2 SOLUTION)-FOR USE AS A SAMPLE DILUENT IN PLATELET AGGREGATION FUNCTION TESTING WITH THE MULTIPLATE ANALYZER UNDER REDUCED CALCIUM CONCENTRATIONS ASSOCIATED WITH THE USE OF CITRATED BLOOD SAMPLES. ,FOLATE III CALSET(FOLATE III CALSET)-FOLATE III CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS FOLATE III ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ELECSYS ANDROSTENEDIONE-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ANDROSTENEDIONE IN HUMAN SERUM AND PLASMA. THE DETERMINATION OF ANDROSTENEDIONE IS USED AS AN AID IN DIAGNOSIS AND DIFFERENTIAL DIAGNOSIS OF ANDROGENS RELATED ENDOCRINE FUNCTION IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON COBAS E IMMUNOASSAY ANALYZERS.,CYCLOSPORINE CALSET(CYCLOSPORINE CALSET)-CYCLOSPORINE CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS CYCLOSPORINE ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS ., GPIIB/IIIA ANTAGONIST REAGENT(GPIIB/IIIA ANTAGONIST REAGENT) -THE REAGENT IS INTENDED FOR USE AS QUALITY CONTROL IN PLATELET FUNCTION TESTING WITH WHOLE BLOOD SAMPLES.,ANTI-TPO CALSET(ANTI-TPO CALSET)-ANTITPO CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS ANTITPO ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,SAMPLE CLEANER 2(SAMPLE CLEANER 2)-WASH SOLUTION FOR SAMPLE PROBES ON ROCHE/HITACHI COBAS C SYSTEMS.,FT3 III CALSET(FT3 III CALSET)-FT3 III CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS FT3 III ASSAY.,ASPITEST(ASPITEST)-ASSAY FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PLATELET

	FUNCTION TRIGGERED BY ARACHIDONIC ACID. THE REAGENT IS INTENDED FOR USE IN PLATELET FUNCTION TESTING WITH WHOLE BLOOD SAMPLES.,CALSET FOLATE(CALSET FOLATE)-CALSET FOLATE IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS FOLATE ASSAY,BNZII(BNZII)-BENZODIAZEPINES II (BNZII) IS AN IN VITRO DIAGNOSTIC TEST FOR THE SEMIQUANTITATIVE AND QUALITATIVE DETECTION OF BENZODIAZEPINES IN HUMAN URINE AT CUTOFF CONCENTRATIONS OF 100 NG/ML, 200 NG/ML, AND 300 NG/ML WHEN CALIBRATED WITH NORDIAZEPAM ON COBAS INTEGRA SYSTEMS. SEMIQUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. SEMIQUANTITATIVE ASSAYS ARE INTENDED TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) OR LIQUID CHROMATOGRAPHY COUPLED WITH TANDEM MASS SPECTROMETRY (LC/MS/MS). BENZODIAZEPINES II PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GC/MS OR LC/MS/MS IS THE PREFERRED CONFIRMATORY METHOD. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,HGH CALSET(HGH CALSET)-HGH CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS HGH ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ASTP2(ASTP2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE (AST) WITH PYRIDOXAL PHOSPHATE ACTIVATION IN HUMAN SERUM AND PLASMA ON COBAS C SYSTEMS.,ELECSYS FT3 III(ELECSYS FT3 III)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE IN HUMAN SERUM AND PLASMA., PRECICONTROL MATERNAL CARE-PRECICONTROL MATERNAL CARE IS USED FOR QUALITY CONTROL OF SPECIFIED ELECSYS IMMUNOASSAYS ON COBAS E IMMUNOASSAY ANALYZERS.,VITAMIN B12 II CALSET(VITAMIN B12 II CALSET)-VITAMIN B12 II CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ROCHE CARDIAC IQC (ROCHE CARDIAC IQC)-THE ROCHE CARDIAC IQC TEST SERVES AS A PERFORMANCE CHECK FOR THE OPTICAL SYSTEM OF THE COBAS INSTRUMENT FROM ROCHE DIAGNOSTICS., PRECICONTROL ACTIVE B12(PRECICONTROL ACTIVE B12)-PRECICONTROL ACTIVE B12 IS USED FOR QUALITY CONTROL OF THE ELECSYS ACTIVE B12 IMMUNOASSAY ON THE ELECSYS AND COBAS E

	IMMUNOASSAY ANALYZERS.,BM-LACTATE(BM-LACTATE)-TEST STRIPS FOR THE IN VITRO QUANTITATIVE DETERMINATION OF LACTATE IN FRESH OR HEPARINISED FRESH CAPILLARY BLOOD WITH ACCUTREND PLUS, ACCUTREND LACTATE OR ACCUSPORT METERS., ELECSYS VITAMIN B12 II(ELECSYS VITAMIN B12 II)-BINDING ASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM AND PLASMA.,ACCUTREND CONTROL CH1 (ACCUTREND CONTROL CH1)-FOR PERFORMANCE CHECKS OF THE ACCUTREND GCT OR ACCUTREND PLUS METER USING ACCUTREND CHOLESTEROL TEST STRIPS.,ELECSYS ANTI-HBS II(ELECSYS ANTI-HBS II)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HUMAN ANTIBODIES TO THE HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA., ACCUTREND CHOLESTEROL(ACCUTREND CHOLESTEROL)-TEST STRIP FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN FRESH OR HEPARINISED FRESH CAPILLARY BLOOD. USE ONLY WITH THE FOLLOWING METERS: ACCUTREND GC, ACCUTREND GCT OR ACCUTREND PLUS.,ACCELERATOR-I(ACCELERATOR-I)-SPECIAL DILUENT FOR IGA,ACCUTREND TRIGLYCERIDES(ACCUTREND TRIGLYCERIDES)-TEST STRIP FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN FRESH OR HEPARINISED FRESH CAPILLARY OR HEPARINISED/EDTA VENOUS BLOOD.,FPCAL (FPCAL)-CHECK THE PHOTOMETER PRECISION ON INTEGRA ANALYZER,ACCUTREND CONTROL TG 1(ACCUTREND CONTROL TG 1)-FOR PERFORMANCE CHECKS OF THE ACCUTREND GCT OR ACCUTREND PLUS METER USING ACCUTREND TRIGLYCERIDES TEST STRIPS. SUITABLE FOR SELFTESTING.,DILUENT UNIVERSAL(DILUENT UNIVERSAL)-DILUENT UNIVERSAL IS USED AS A SAMPLE DILUENT IN CONJUNCTION WITH ELECSYS ASSAY REAGENTS,ALTP2(ALTP2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE (ALT) WITH PYRIDOXAL PHOSPHATE ACTIVATION IN HUMAN SERUM AND PLASMA ON COBAS C SYSTEMS., PRECICONTROL TUMOR MARKER(PRECICONTROL TUMOR MARKER)-PRECICONTROL TUMOR MARKER IS USED FOR QUALITY CONTROL OF ELECSYS IMMUNOASSAYS ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,BM-CONTROL-LACTATE(BM-CONTROL-LACTATE)-FOR PERFORMANCE CHECKS OF THE ACCUSPORT, ACCUTREND LACTATE OR ACCUTREND PLUS METER WITH BMLACTATE TEST STRIPS.,HCG STAT CALSET(HCG STAT CALSET)-HCG STAT CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS HCG STAT ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS ,PRECICONTROL ANTI-HAV II (PRECICONTROL ANTI-HAV II)-PRECICONTROL ANTIHAV II IS USED FOR QUALITY CONTROL OF THE ELECSYS ANTIHAV II

	IMMUNOASSAY,C.F.A.S. PROTEINS(C.F.A.S. PROTEINS)-C.F.A.S. (CALIBRATOR FOR AUTOMATED SYSTEMS) PROTEINS IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS.,ELECSYS ANTI-HAV II(ELECSYS ANTI-HAV II)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETECTION OF TOTAL ANTIBODIES (IGG AND IGM) TO HEPATITIS A VIRUS (HAV) IN HUMAN PEDIATRIC (AGES 2 THROUGH 21 YEARS) AND ADULT SERUM AND PLASMA.,ELECSYS CA 72-4(ELECSYS CA 72-4)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CA 724 IN HUMAN SERUM AND PLASMA. THE ASSAY IN PARTICULAR SERVES AS AN AID IN THE THERAPEUTIC MONITORING OF CARCINOMAS OF THE STOMACH AND OVARIES. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZER., ELECSYS ANTI-SARS-COV-2(ELECSYS ANTI-SARS-COV-2)-ELECSYS ANTISARSCOV2 IS AN IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETECTION OF ANTIBODIES (INCLUDING IGG) TO SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARSCOV2) IN HUMAN SERUM AND PLASMA. THE TEST IS INTENDED AS AN AID IN THE DETERMINATION OF THE IMMUNE REACTION TO SARSCOV2. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON COBAS E IMMUNOASSAY ANALYZERS.,PRECICONTROL ISD(PRECICONTROL ISD)-PRECICONTROL ISD IS USED FOR QUALITY CONTROL OF SPECIFIED ELECSYS IMMUNOASSAYS ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,COMBUR 10 TEST M(COMBUR 10 TEST M)-THE COMBUR10 TEST M ARE TEST STRIPS FOR THE IN VITRO QUALITATIVE OR SEMIQUANTITATIVE DETERMINATION OF PH, LEUKOCYTES, NITRITE, PROTEIN, GLUCOSE, KETONES, UROBILINOGEN, BILIRUBIN, ERYTHROCYTES AND SPECIFIC GRAVITY IN URINE WITH THE COBAS U 411 URINE ANALYZER. THESE MEASUREMENTS ARE USEFUL IN THE EVALUATION OF RENAL, URINARY, HEPATIC AND METABOLIC DISORDERS,ELECSYS IGE II (ELECSYS IGE II)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E IN HUMAN SERUM AND PLASMA.,PRECI CONTROL ANTI-SARS-COV-2(PRECI CONTROL ANTI-SARS-COV-2)-PRECICONTROL ANTISARSCOV2 IS USED FOR QUALITY CONTROL OF THE ELECSYS ANTISARSCOV2 IMMUNOASSAY ON THE COBAS E IMMUNOASSAY ANALYZERS., ELECSYS N-MID OSTEOCALCIN(ELECSYS N-MID OSTEOCALCIN)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF NMID OSTEOCALCIN IN HUMAN SERUM AND PLASMA. THE DETERMINATION IS USED FOR THE CONTROL OF ANTIRESORPTIVES THERAPEUTIC EFFICIENCY, E.G. FOR PATIENTS WITH OSTEOPOROSIS

	OR HYPERCALCEMIA.,CALSET ANDROSTENEDIONE -CALSET ANDROSTENEDIONE IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS ANDROSTENEDIONE ASSAY ON COBAS E IMMUNOASSAY ANALYZERS.,IGE CALSET (IGE CALSET)-IGE CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS IGE II ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,C.F.A.S. DAT QUALITATIVE PLUS CLINICAL(C.F.A.S. DAT QUALITATIVE PLUS CLINICAL)-THE C.F.A.S. DAT QUALITATIVE PLUS CLINICAL CALIBRATOR IS DESIGNED FOR THE QUALITATIVE CALIBRATION OF THE ROCHE ASSAYS FOR DRUGS OF ABUSE IN HUMAN URINE ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS AS LISTED ABOVE IN SYSTEM INFORMATION.,EVEROLIMUS CALSET(EVEROLIMUS CALSET)-EVEROLIMUS CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS EVEROLIMUS ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ELECSYS TOXO IGM(ELECSYS TOXO IGM)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ISD SAMPLE PRETREATMENT(ISD SAMPLE PRETREATMENT)-ISD SAMPLE PRETREATMENT IS AN IN VITRO DIAGNOSTIC REAGENT INTENDED FOR THE EXTRACTION OF SPECIFIC ANALYTES FROM SPECIMENS. IT IS USED TOGETHER WITH SPECIFIED IMMUNOASSAYS ON ELECSYS AND COBAS E ANALYZERS., ALP2S(ALP2S)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM AND PLASMA ON THE COBAS C SYSTEM.,HIL TEST(HIL TEST)-IN VITRO TEST FOR THE SEMIQUANTITATIVE DETERMINATION OF THE LIPEMIA INDEX, HEMOLYSIS INDEX AND ICTERUS INDEX IN CITRATED PLASMA ON COBAS T SYSTEMS.,ELECSYS HSV-2 IGG(ELECSYS HSV-2 IGG)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES TO HSV2 IN HUMAN SERUM AND PLASMA. THE TEST IS INTENDED FOR USE AS AN AID IN THE ASSESSMENT OF IMMUNE STATUS AND AS AN AID IN THE DIAGNOSIS OF HSV INFECTION. ,ELECSYS IGF-1(ELECSYS IGF-1)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF INSULINLIKE GROWTH FACTOR1 (IGF1) IN HUMAN SERUM AND PLASMA. THE IGF1 DETERMINATION IS INTENDED TO BE USED AS AN AID IN THE ASSESSMENT OF GROWTH DISORDERS IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS.,PRECICONTROL RUBELLA IGM(PRECICONTROL RUBELLA IGM)-PRECICONTROL RUBELLA IGM IS USED FOR QUALITY CONTROL OF THE ELECSYS RUBELLA IGM IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ELECSYS VITAMIN D TOTAL II(ELECSYS VITAMIN D TOTAL II)-THIS ASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25HYDROXYVITAMIN D

	IN HUMAN SERUM AND PLASMA. THIS ASSAY IS TO BE USED AS AN AID IN THE ASSESSMENT OF VITAMIN D SUFFICIENCY.,CAL PLASMA (CAL PLASMA)-CAL PLASMA IS USED FOR CALIBRATION OF SPECIFIED COAGULATION ASSAYS ON INDICATED COBAS T COAGULATION ANALYZERS.,ELECSYS ANTI-CCP(ELECSYS ANTI-CCP) -IMMUNOASSAY FOR THE IN VITRO SEMI-QUANTITATIVE DETERMINATION OF HUMAN IGG AUTOANTIBODIES TO CYCLIC CITRULLINATED PEPTIDES IN HUMAN SERUM THE RESULTS OF THE ASSAY ARE INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS IN COMBINATION WITH OTHER CLINICAL AND LABORATORY FINDINGS.,ELECSYS HSV-1 IGG(ELECSYS HSV-1 IGG)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES TO HSV1 IN HUMAN SERUM AND PLASMA. THE TEST IS INTENDED FOR USE AS AN AID IN THE ASSESSMENT OF IMMUNE STATUS AND AS AN AID IN THE DIAGNOSIS OF HSV INFECTION. ,CORTISOL II CALSET(CORTISOL II CALSET)-CORTISOL II CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS CORTISOL II ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,PHNY(PHNY)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF PHENYTOIN IN SERUM OR HEPARINIZED PLASMA ON COBAS INTEGRA SYSTEMS.,PRECICONTROL ANTI-CCP(PRECICONTROL ANTI-CCP)-PRECICONTROL ANTICCP IS USED FOR QUALITY CONTROL OF THE ELECSYS ANTICCP IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,LDLC3(LDLC3)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LDL-CHOLESTEROL IN HUMAN SERUM AND PLASMA.,PRECICONTROL CORTISOL SALIVA (PRECICONTROL CORTISOL SALIVA)-PRECICONTROL CORTISOL SALIVA IS USED FOR QUALITY CONTROL OF THE ELECSYS CORTISOL II IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,VANC(VANC)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF VANCOMYCIN IN SERUM OR HEPARINIZED PLASMA ON COBAS INTEGRA SYSTEMS.,ELECSYS ANTI-TPO(ELECSYS ANTI-TPO)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ANTIBODIES TO THYROID PEROXIDASE IN HUMAN SERUM AND PLASMA. THE ANTITPO DETERMINATION IS USED AS AN AID IN THE DIAGNOSIS OF AUTOIMMUNE THYROID DISEASES.,GENT(GENT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF GENTAMICIN IN SERUM OR PLASMA ON COBAS INTEGRA SYSTEMS.,ELECSYS ANTI-TSHR (ELECSYS ANTI-TSHR)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF AUTOANTIBODIES TO TSH RECEPTOR IN HUMAN SERUM USING A HUMAN THYROID STIMULATING MONOCLONAL ANTIBODY. THE ANTITSH RECEPTOR

	DETERMINATION IS USED AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF GRAVES' DISEASE.,FREE VALPROIC ACID CALIBRATORS(FREE VALPROIC ACID CALIBRATORS)-COBAS FP FREE VALPROIC ACID CALIBRATORS ARE FOR USE IN THE CALIBRATION OF ROCHE METHODS FOR THE QUANTITATIVE DETERMINATION OF FREE VALPROIC ACID IN HUMAN SERUM AND PLASMA ON ROCHE CLINICAL CHEMISTRY ANALYZERS.,ELECSYS HGH(ELECSYS HGH)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HUMAN GROWTH HORMONE (HGH; FORMS WITH MOLECULAR MASSES OF 20 KDA AND 22 KDA) IN HUMAN SERUM AND PLASMA., CARB4(CARB4)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CARBAMAZEPINE IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS SYPHILIS(ELECSYS SYPHILIS)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF TOTAL ANTIBODIES TO TREPONEMA PALLIDUM IN HUMAN SERUM AND PLASMA. THE TEST IS INTENDED AS AN AID IN THE DIAGNOSIS OF SYPHILIS INFECTION. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE COBAS E IMMUNOASSAY ANALYZER.,DER FIB CON (DER FIB CON)-DERIVED FIBRINOGEN CONTROL IS USED FOR QUALITY CONTROL OF ROCHE PROTHROMBIN TIME DERIVED FIBRINOGEN ASSAY ON INDICATED COBAS T ANALYZERS., PRECICONTROL GROWTH(PRECICONTROL GROWTH)-PRECICONTROL GROWTH IS USED FOR QUALITY CONTROL OF SPECIFIED IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,DIGITOXIN CALSET(DIGITOXIN CALSET)-DIGITOXIN CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS DIGITOXIN ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,CALSET IGF-1(CALSET IGF-1)-CALSET IGF1 IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS IGF1 ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ELECSYS CHAGAS(ELECSYS CHAGAS)-IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO TRYPANOSOMA CRUZI (T. CRUZI, THE CAUSATIVE AGENT OF THE CHAGAS DISEASE) IN HUMAN SERUM AND PLASMA.,ELECSYS HCG+BETA(ELECSYS HCG+BETA)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THE SUM OF HUMAN CHORIONIC GONADOTROPIN (HCG) PLUS THE HCG BETASUBUNIT IN HUMAN SERUM AND PLASMA. THIS ASSAY IS INTENDED FOR USE AS AN AID IN: EARLY DETECTION AND MONITORING OF PREGNANCY. THE TEST IS ALSO INTENDED FOR THE USE AS ONE COMPONENT IN COMBINATION WITH OTHER PARAMETERS TO EVALUATE THE RISK OF TRISOMY 21 (DOWN SYNDROME). FURTHER TESTING IS REQUIRED FOR DIAGNOSIS OF CHROMOSOMAL ABERRATIONS. ONCOLOGY, TO

	SERVE THE MANAGEMENT OF PATIENTS WITH TROPHOBLASTIC DISEASES. THIS ASSAY IS USEFUL IN THE DETECTION AND MONITORING OF HCGPRODUCING TUMOR CELLS OF EITHER OVARIAN, PLACENTAL OR TESTICULAR ORIGIN. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZER., TOBR(TOBR)-IN VITRO DIAGNOSTIC REAGENT SYSTEM FOR THE QUANTITATIVE DETERMINATION OF TOBRAMYCIN IN SERUM OR HEPARINIZED PLASMA ON COBAS INTEGRA SYSTEMS.,CALSET PROBNP II(CALSET PROBNP II)-CALSET PROBNP II IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS PROBNP II ASSAY ON THE COBAS E 801 IMMUNOASSAY ANALYZER.,ELECSYS TOXO IGG (ELECSYS TOXO IGG)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ACTH CALSET (ACTH CALSET)-ACTH CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS ACTH ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,COAGUCHEK APTT TEST(COAGUCHEK APTT TEST)-THE COAGUCHEK APTT TEST IS AN IN-VITRO ASSAY FOR THE DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME1 (APTT) USING THE COAGUCHEK PRO II METER. THE TEST CAN BE USED WITH EITHER CAPILLARY, VENOUS, OR ARTERIAL FRESH WHOLE BLOOD.,ELECSYS PRO BNP II(ELECSYS PRO BNP II)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF NTERMINAL PRO BTYPE NATRIURETIC PEPTIDE IN HUMAN SERUM AND PLASMA. THIS ASSAY IS INDICATED AS AN AID IN THE DIAGNOSIS OF INDIVIDUALS SUSPECTED OF HAVING CONGESTIVE HEART FAILURE AND DETECTION OF MILD FORMS OF CARDIAC DYSFUNCTION. THE TEST ALSO AIDS IN THE ASSESSMENT OF HEART FAILURE SEVERITY IN PATIENTS DIAGNOSED WITH CONGESTIVE HEART FAILURE. THIS ASSAY IS FURTHER INDICATED FOR THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROME AND CONGESTIVE HEART FAILURE, AND IT CAN ALSO BE USED FOR MONITORING THE TREATMENT IN PATIENTS WITH LEFT VENTRICULAR DYSFUNCTION. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS., ALTLP(ALTLP)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE (ALT) WITH PYRIDOXAL PHOSPHATE ACTIVATION IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,CA 15-3 II CALSET (CA 15-3 II CALSET)-CA 153 II CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS CA 153 II ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,LIDO(LIDO)-IN VITRO

	DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF LIDOCAINE IN SERUM OR HEPARINIZED PLASMA ON COBAS INTEGRA SYSTEMS,T3 CALSET(T3 CALSET)-T3 CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS T3 ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,DILUENT UNIVERSAL 2(DILUENT UNIVERSAL 2)-DILUENT UNIVERSAL 2 IS USED AS A SAMPLE DILUENT IN CONJUNCTION WITH ELECSYS ASSAY REAGENTS.,TESTOSTERONE II CALSET II(TESTOSTERONE II CALSET II) -TESTOSTERONE II CALSET II IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS TESTOSTERONE II ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,GGT-2(GGT-2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF GAMMAGLUTAMYLTRANSFERASE (GGT) IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS PROLACTIN II(ELECSYS PROLACTIN II)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,DIBU(DIBU)-IN VITRO REAGENT FOR THE DETERMINATION OF THE DIBUCAINE NUMBER TO BE USED IN CONJUNCTION WITH THE IN VITRO TEST CHOLINESTERASE GEN.2, ON ROCHE/HITACHI COBAS C SYSTEMS.,PROLACTIN II CALSET(PROLACTIN II CALSET)-PROLACTIN II CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS PROLACTIN II ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS,A1MG2(A1MG2)-IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ALPHA 1MICROGLOBULIN IN HUMAN URINE ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS TESTOSTERONE II(ELECSYS TESTOSTERONE II)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,D-DI2 CON(D-DI2 CON)-DDIMER GEN. 2 CONTROL I/II IS USED FOR QUALITY CONTROL OF THE DDIMER GEN. 2 ASSAY ON INDICATED COBAS T ANALYZERS.,ELECSYS MYOGLOBIN(ELECSYS MYOGLOBIN)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS., A1CD2(A1CD2)-THE HEMOLYZING REAGENT IS USED AS DILUENT FOR THE TINAQUANT HEMOGLOBIN A1C GEN.3 ASSAY ON COBAS C SYSTEMS.,ELECSYS TACROLIMUS(ELECSYS TACROLIMUS)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION

	OF TACROLIMUS IN HUMAN WHOLE BLOOD. THE ASSAY IS USED AS AN AID IN THE MANAGEMENT OF HEART, LIVER AND KIDNEY TRANSPLANT PATIENTS RECEIVING TACROLIMUS THERAPY. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS., PRECICHROM I/II(PRECICHROM I/II)-PRECICHROM I/II IS USED FOR THE QUALITY CONTROL OF PHOTOMETRIC COAGULATION ASSAYS., CALSET MYOGLOBIN(CALSET MYOGLOBIN)-CALSET MYOGLOBIN IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS MYOGLOBIN ASSAY ON THE COBAS E 801 IMMUNOASSAY ANALYZER.,GENT2 (GENT2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF GENTAMICIN IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,MYOGLOBIN CALSET(MYOGLOBIN CALSET)-MYOGLOBIN CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS MYOGLOBIN ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,AST(AST)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE (AST) IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,PRECICONTROL LUNG CANCER(PRECICONTROL LUNG CANCER)-PRECICONTROL LUNG CANCER IS USED FOR QUALITY CONTROL OF THE ELECSYS SCC, PROGRP, CYFRA 211 AND NSE IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS,PRECISET DAT PLUS II(PRECISET DAT PLUS II)-THE PRECISET DAT PLUS II CALIBRATORS ARE DESIGNED FOR THE CALIBRATION OF THE ROCHE ASSAYS FOR DRUGS OF ABUSE IN HUMAN URINE ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS., PRECICONTROL HBEAG(PRECICONTROL HBEAG)-PRECICONTROL HBEAG IS USED FOR QUALITY CONTROL OF THE ELECSYS HBEAG IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,PRECIBIL(PRECIBIL)-PRECIBIL IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION IN THE RANGE UP TO 20 MG BILIRUBIN/DL (342 MOL/L) FOR THE QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS., DILUENT PROGESTERONE/ ESTRADIOL(DILUENT PROGESTERONE/ ESTRADIOL)-DILUENT ESTRADIOL/PROGESTERONE IS USED AS A SAMPLE DILUENT IN CONJUNCTION WITH THE ELECSYS ESTRADIOL II, ELECSYS PROGESTERONE II AND ELECSYS PROGESTERONE III ASSAY. ,PRECICONTROL HBA1C PATH(PRECICONTROL HBA1C PATH)-PRECICONTROL HBA1C PATH IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS.,BASIC WASH(BASIC WASH)-BASIC WASH IS USED AS ALKALINE WASH SOLUTION FOR REACTION CELLS ON THE ROCHE/HITACHI COBAS C ANALYZERS., THC 2(THC 2)-CANNABINOIDS II (THC2) IS AN IN VITRO DIAGNOSTIC

	TEST FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETECTION OF CANNABINOIDS IN HUMAN URINE ON ROCHE/HITACHI COBAS C SYSTEMS AT CUTOFF CONCENTRATIONS OF 20 NG/ML, 50 NG/ML AND 100 NG/ML. SEMIQUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. SEMIQUANTITATIVE ASSAYS ARE INTENDED TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GCMS). CANNABINOIDS II PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GCMS IS THE PREFERRED CONFIRMATORY METHOD.1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,PRECLEAN II M(PRECLEAN II M)-WASH SOLUTION FOR THE REMOVAL OF SUBSTANCES WHICH POTENTIALLY INTERFERE WITH THE DETECTION OF SIGNALS.,UIBC(UIBC)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF THE UNSATURATED IRON-BINDING CAPACITY IN HUMAN SERUM AND PLASMA.,PROCELL II M(PROCELL II M)-SYSTEM SOLUTION FOR GENERATING ELECTROCHEMICAL SIGNALS IN COBAS E IMMUNOASSAY ANALYZERS. ,ALP2L(ALP2L)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM AND PLASMA ON THE COBAS C SYSTEM., PRECICONTROL MULTIMARKER(PRECICONTROL MULTIMARKER)-PRECICONTROL MULTIMARKER IS USED FOR QUALITY CONTROL OF SPECIFIED IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. ,PRECICONTROL HBA1C NORM (PRECICONTROL HBA1C NORM)-PRECICONTROL HBA1C NORM IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS.,PRECICONTROL HBSAG II(PRECICONTROL HBSAG II)-PRECICONTROL HBSAG II IS USED FOR QUALITY CONTROL OF THE ELECSYS HBSAG II AND ELECSYS HBSAG II QUANT IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,PT OWREN(PT OWREN)-IN VITRO ASSAY FOR THE DETERMINATION OF THE OWRENS PROTHROMBIN TIME IN CITRATED PLASMA ON THE INDICATED COBAS T ANALYZERS. THE OWRENS PROTHROMBIN TIME IS INTENDED AS AN AID IN THE MANAGEMENT OF VITAMIN K ANTAGONIST THERAPY.,PRECICONTROL ANTI-HBC II(PRECICONTROL ANTI-HBC II)-PRECICONTROL ANTIHBC II IS USED FOR QUALITY CONTROL OF THE ELECSYS ANTIHBC II IMMUNOASSAY ON THE

	ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,APOBT(APOBT) -IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN B IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS TOTAL PSA(ELECSYS TOTAL PSA)-THIS ASSAY, A QUANTITATIVE IN VITRO DIAGNOSTIC TEST FOR TOTAL (FREE + COMPLEXED) PROSTATESPECIFIC ANTIGEN (TPSA) IN HUMAN SERUM AND PLASMA, IS INDICATED FOR THE MEASUREMENT OF TOTAL PSA IN CONJUNCTION WITH DIGITAL RECTAL EXAMINATION (DRE) AS AN AID IN THE DETECTION OF PROSTATE CANCER IN MEN AGED 50 YEARS OR OLDER. PROSTATE BIOPSY IS REQUIRED FOR DIAGNOSIS OF PROSTATE CANCER. THE TEST IS FURTHER INDICATED FOR SERIAL MEASUREMENT OF TPSA TO AID IN THE MANAGEMENT OF CANCER PATIENTS. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZER., PHOS2(PHOS2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF PHOSPHORUS IN HUMAN SERUM, PLASMA AND URINE.,PROGRP CALSET(PROGRP CALSET)-PROGRP CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS PROGRP ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,MYO2 (MYO2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS. ,ELECSYS HIV AG(ELECSYS HIV AG)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF THE P24 ANTIGEN OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV 1, GROUPS M AND O) IN HUMAN SERUM AND PLASMA AND IN CELL CULTURE SUPERNATES.,PRECIPATH FRUCTOSAMINE(PRECIPATH FRUCTOSAMINE)-PRECINORM FRUCTOSAMINE AND PRECIPATH FRUCTOSAMINE ARE FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS.,PRECICONTROL HIV GEN II (PRECICONTROL HIV GEN II)-PRECICONTROL HIV GEN II IS USED FOR QUALITY CONTROL OF THE ELECSYS HIV COMBI PT, ELECSYS HIV DUO AND ELECSYS HIV AG IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,PRECISET LP(A) GEN.2 (PRECISET LP(A) GEN.2)-PRECISET LP(A) GEN.2 IS INTENDED FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE VALUE SHEETS.,FREE PSA CALSET(FREE PSA CALSET)-FREE PSA CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS FREE PSA ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS, PRECICONTROL LP(A) GEN.2(PRECICONTROL LP(A) GEN.2)-PRECICONTROL LP(A) GEN.2 IS INTENDED FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE

	QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS., ELECSYS T4(ELECSYS T4)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THYROXINE IN HUMAN SERUM AND PLASMA.,ISE REFERENCE ELECTROLYTE(ISE REFERENCE ELECTROLYTE)-THE ISE ANALYTICAL UNIT OF THE ROCHE/HITACHI COBAS C SYSTEMS IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM AND CHLORIDE IN SERUM, PLASMA OR URINE USING ION SELECTIVE ELECTRODES.,ANTITG CALSET(ANTITG CALSET)-ANTITG CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS ANTITG ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ALBP(ALBP)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,FOLATE RBC (FOLATE RBC)-THIS ASSAY IS USED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FOLATE IN ERYTHROCYTES (RED BLOOD CELLS, RBC).,AMYL2(AMYL2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF AMYLASE IN HUMAN SERUM, PLASMA AND URINE ON ROCHE/HITACHI COBAS C SYSTEMS.,CALSET IGFBP3(CALSET IGFBP3)-CALSET IGFBP3 IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS IGFBP3 ASSAY ON THE COBAS E IMMUNOASSAY ANALYZERS.,IGG-2(IGG-2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGG IN HUMAN SERUM, PLASMA, CEREBROSPINAL FLUID AND URINE ON ROCHE/HITACHI COBAS C SYSTEMS.,PRECICONTROL EVEROLIMUS (PRECICONTROL EVEROLIMUS)-PRECICONTROL EVEROLIMUS IS USED FOR QUALITY CONTROL OF THE ELECSYS EVEROLIMUS IMMUNOASSAY.,TRIGL(TRIGL)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA.,CROSSLAPS CALSET(CROSSLAPS CALSET) -CROSSLAPS CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS CROSSLAPS/SERUM ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,C.F.A.S. LIPIDS (C.F.A.S. LIPIDS)-C.F.A.S. (CALIBRATOR FOR AUTOMATED SYSTEMS) LIPIDS IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE VALUE SHEETS.,ELECSYS EVEROLIMUS(ELECSYS EVEROLIMUS)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF EVEROLIMUS IN HUMAN WHOLE BLOOD. THE ASSAY IS USED AS AN AID IN THE MANAGEMENT OF KIDNEY, LIVER AND HEART TRANSPLANT PATIENTS RECEIVING EVEROLIMUS THERAPY.,INSTC(INSTC)-TEST FOR ACCURACY AND PRECISION OF SAMPLE AND REAGENT PIPETTING WITH DYE SOLUTION AND SALINE SOLUTION ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS FREE PSA(ELECSYS FREE PSA)-IMMUNOASSAY FOR THE IN VITRO

	QUANTITATIVE DETERMINATION OF FREE PROSTATESPECIFIC ANTIGEN IN HUMAN SERUM AND PLASMA. THIS ASSAY IS INDICATED FOR MEASUREMENT OF FPSA IN CONJUNCTION WITH THE ELECSYS TOTAL PSA ASSAY TO DEVELOP A RATIO (% FPSA) OF FPSA TO TPSA. THIS RATIO IS USEFUL WHEN USED IN CONJUNCTION WITH THE ELECSYS TOTAL PSA TEST AS AN AID IN DISTINGUISHING PROSTATE CANCER FROM BENIGN PROSTATIC CONDITIONS IN MEN AGE 50 YEARS OR OLDER WHO HAVE A DIGITAL RECTAL EXAMINATION (DRE) THAT IS NOT SUSPICIOUS FOR PROSTATE CANCER AND AN ELECSYS TOTAL PSA VALUE IN THE RANGE 4 NG/ML TO 10 NG/ML. PROSTATE BIOPSY IS REQUIRED FOR THE DIAGNOSIS OF PROSTATE CANCER. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZER.,ELECSYS CMV IGG(ELECSYS CMV IGG)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA. RESULTS WITH THIS ASSAY ARE USED TO INDICATE PAST OR RECENT INFECTION WITH CMV. ,PRECLEAN M(PRECLEAN M)-WASH SOLUTION FOR THE REMOVAL OF SUBSTANCES WHICH POTENTIALLY INTERFERE WITH THE DETECTION OF SIGNALS.,PRECICONTROL CMV IGM(PRECICONTROL CMV IGM)-PRECICONTROL CMV IGM IS USED FOR QUALITY CONTROL OF THE ELECSYS CMV IGM IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. ,ELECSYS AMH(ELECSYS AMH)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ANTIMÜLLERIAN HORMONE (AMH) IN HUMAN SERUM AND PLASMA. THE DETERMINATION OF AMH IS USED FOR THE ASSESSMENT OF THE OVARIAN RESERVE AND THE PREDICTION OF RESPONSE TO CONTROLLED OVARIAN STIMULATION (COS) IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS. ,GLUC2(GLUC2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM, PLASMA AND URINE ON THE COBAS C SYSTEM.,ELECSYS ANTI-HBC IGM(ELECSYS ANTI-HBC IGM)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF IGM ANTIBODIES TO THE HEPATITIS B CORE ANTIGEN IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE COBAS E IMMUNOASSAY ANALYZER.,ROCHE CARDIAC CONTROL D-DIMER(ROCHE CARDIAC CONTROL D-DIMER)-THE ROCHE CARDIAC CONTROL D DIMER QUALITY CONTROLS ARE USED WITH THE ROCHE CARDIAC D DIMER TEST FOR QUALITY CONTROL TESTING ON THE COBAS INSTRUMENT FROM ROCHE DIAGNOSTICS.,PRECICONTROL VITAMIN D TOTAL II(PRECICONTROL VITAMIN D TOTAL II)-PRECICONTROL VITAMIN D TOTAL II IS USED FOR QUALITY CONTROL OF THE ELECSYS VITAMIN D TOTAL II ASSAY,

	PRECICONTROL HCC(PRECICONTROL HCC)-PRECICONTROL HCC IS USED FOR QUALITY CONTROL OF THE ELECSYS PIVKAII IMMUNOASSAY ON THE COBAS E IMMUNOASSAY ANALYZERS., PRECICONTROL VARIA(PRECICONTROL VARIA)-PRECICONTROL VARIA IS USED FOR QUALITY CONTROL OF SPECIFIED ELECSYS IMMUNOASSAYS ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. ,LI(LI)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LITHIUM IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,CALSET ACTIVE B12(CALSET ACTIVE B12)-CALSET ACTIVE B12 IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS ACTIVE B12 ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,THE-2(THE-2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF THEOPHYLLINE IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS., ELECSYS CYCLOSPORINE(ELECSYS CYCLOSPORINE)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CYCLOSPORINE IN HUMAN WHOLE BLOOD. THE ASSAY IS USED AS AN AID IN THE MANAGEMENT OF HEART, LIVER, KIDNEY, LUNG AND BONE MARROW TRANSPLANT PATIENTS RECEIVING CYCLOSPORINE THERAPY.,BNZ2(BNZ2)-BENZODIAZEPINES II (BNZ2) IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETECTION OF BENZODIAZEPINES IN HUMAN URINE ON ROCHE/HITACHI COBAS C SYSTEMS AT CUTOFF CONCENTRATIONS OF 100 NG/ML, 200 NG/ML, AND 300 NG/ML. SEMI-QUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. BENZODIAZEPINES II PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC MS) OR LIQUID CHROMATOGRAPHY COUPLED WITH TANDEM MASS SPECTROMETRY (LC MS/MS) IS THE PREFERRED CONFIRMATORY METHOD.1,2 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ELECSYS ACTIVE B12(ELECSYS ACTIVE B12)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ACTIVE VITAMIN B12 (HOLOTRANSCOBALAMIN) IN HUMAN SERUM. THE ASSAY IS USED AS AN AID IN THE DIAGNOSIS AND TREATMENT OF VITAMIN B12 DEFICIENCY.,A1CD(A1CD)-THE HEMOLYZING REAGENT IS USED AS DILUENT FOR THE TINAQUANT HEMOGLOBIN A1CDX GEN.3 ASSAY ON THE COBAS C SYSTEM., HCG+BETA CALSET(HCG+BETA CALSET)-HCG+BETA CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS HCG+BETA ASSAY

	ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,BENZ (BENZ)-BENZODIAZEPINES (BENZ) IS AN IN VITRO DIAGNOSTIC TEST FOR THE SEMI-QUANTITATIVE DETECTION OF BENZODIAZEPINES IN HUMAN URINE AT A CUTOFF CONCENTRATION OF 100 NG/ML AND THE QUALITATIVE DETECTION OF BENZODIAZEPINES IN HUMAN URINE AT CUTOFF CONCENTRATIONS OF 100 NG/ML, 200 NG/ML, AND 300 NG/ML ON COBAS INTEGRA SYSTEMS. SEMI-QUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. SEMI-QUANTITATIVE ASSAYS ARE INTENDED TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS). BENZODIAZEPINES PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GC/MS IS THE PREFERRED CONFIRMATORY METHOD.1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED., CA 19-9 CALSET(CA 19-9 CALSET)-CA 199 CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS CA 199 ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS,GLUC3(GLUC3)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM, PLASMA, URINE AND CSF ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS HIV COMBI PT (ELECSYS HIV COMBI PT)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF HIV1 P24 ANTIGEN AND ANTIBODIES TO HIV1, INCLUDING GROUP O, AND HIV2 IN HUMAN SERUM AND PLASMA,TT(TT)-IN VITRO ASSAY FOR THE DETERMINATION OF THROMBIN TIME (TT) IN HUMAN CITRATED PLASMA ON THE INDICATED COBAS T ANALYZERS.,ELECSYS HBSAG II QUANT II(ELECSYS HBSAG II QUANT II)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN CONFIRMED HBSAG POSITIVE HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE COBAS E IMMUNOASSAY ANALYZER.,ALTPM(ALTPM)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE (ALT) WITH PYRIDOXAL PHOSPHATE ACTIVATION IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,CALSET PTH STAT (CALSET PTH STAT)-CALSET PTH STAT IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS PTH STAT ASSAY FOR INTACT PTH (PARATHYROID HORMONE) ON THE ELECSYS AND COBAS E

	IMMUNOASSAY ANALYZERS.,C.F.A.S. HBA1C(C.F.A.S. HBA1C)-C.F.A.S. (CALIBRATOR FOR AUTOMATED SYSTEMS) HBA1C IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE ENCLOSED VALUE SHEETS.,ESTRADIOL III CALSET(ESTRADIOL III CALSET)-ESTRADIOL III CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS ESTRADIOL III ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. ,OPI2(OPI2)-OPIATES II (OPI2) IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETECTION OF MORPHINE AND ITS METABOLITES IN HUMAN URINE ON ROCHE/HITACHI COBAS C SYSTEMS AT CUTOFF CONCENTRATIONS OF 300 NG/ML AND 2000 NG/ML. SEMIQUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. SEMIQUANTITATIVE ASSAYS ARE INTENDED TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GCMS). OPIATES II PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GCMS IS THE PREFERRED CONFIRMATORY METHOD. 1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ELECSYS CYFRA 21-1(ELECSYS CYFRA 21-1)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FRAGMENTS OF CYTOKERATIN 19 IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZER., NACL DILUENT 9%(NACL DILUENT 9%)-NACL DILUENT 9% IS USED AS A SAMPLE DILUENT IN CONJUNCTION WITH ASSAY REAGENTS ON COBAS C SYSTEM.,ELECSYS AMH PLUS(ELECSYS AMH PLUS)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ANTIMÜLLERIAN HORMONE (AMH) IN HUMAN SERUM AND PLASMA. THE DETERMINATION OF AMH IS USED FOR THE ASSESSMENT OF THE OVARIAN RESERVE AND THE PREDICTION OF RESPONSE TO CONTROLLED OVARIAN STIMULATION (COS) IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS. IN ADDITION, THE DETERMINATION OF AMH (IN PMOL/L) IN COMBINATION WITH BODY WEIGHT IS USED FOR THE ESTABLISHMENT OF THE INDIVIDUAL DAILY DOSE OF THE HUMAN RECOMBINANT FOLLICLE-STIMULATING HORMONE (RFSH) FOLLITROPIN DELTA OF FERRING (IN ACCORDANCE WITH THE

	CURRENT PRESCRIBING INFORMATION OF THE FERRING FOLLITROPIN DELTA) IN CONTROLLED OVARIAN STIMULATION FOR THE DEVELOPMENT OF MULTIPLE FOLLICLES IN WOMEN UNDERGOING AN ASSISTED REPRODUCTIVE TECHNOLOGY PROGRAM. ,ELECSYS RUBELLA IGM(ELECSYS RUBELLA IGM)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF IGM ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA.,ELECSYS ANTI-TG(ELECSYS ANTI-TG)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ANTIBODIES TO THYROGLOBULIN IN HUMAN SERUM AND PLASMA. THE ANTITG DETERMINATION IS USED AS AN AID IN THE DETECTION OF AUTOIMMUNE THYROID DISEASES.,KAPP2(KAPP2)-IMMUNOTURBIDIMETRIC IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF BOUND AND FREE IMMUNOGLOBULINS OF THE KAPPA LIGHT CHAIN TYPE IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,PRECICONTROL AMH PLUS (PRECICONTROL AMH PLUS)-PRECICONTROL AMH PLUS IS A LYOPHILIZED CONTROL SERUM BASED ON AN EQUINE SERUM MATRIX WITH ADDED BOVINE AMH (MALE FETAL BOVINE SERUM) IN TWO CONCENTRATION RANGES. ,ELECSYS RUBELLA IGG(ELECSYS RUBELLA IGG)-THIS ASSAY IS FOR THE IN VITRO QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND HEPARIN, EDTA AND CITRATE PLASMA. THIS ASSAY MAY BE USED AS AN AID IN THE ASSESSMENT OF IMMUNE STATUS TO RUBELLA IN INDIVIDUALS INCLUDING WOMEN OF CHILDBEARING AGE. ,ELECSYS ANTI-HBC II(ELECSYS ANTI-HBC II)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF IGG AND IGM ANTIBODIES TO THE HEPATITIS B CORE ANTIGEN IN HUMAN SERUM AND PLASMA,IGM-2(IGM-2)-N VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGM IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS ESTRADIOL III (ELECSYS ESTRADIOL III)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM AND PLASMA. ,PRECICONTROL ANTI-HAV IGM(PRECICONTROL ANTI-HAV IGM)-PRECICONTROL ANTI HAV IGM IS USED FOR QUALITY CONTROL OF THE ELECSYS ANTI HAV IGM IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,AMH CALSET (AMH CALSET)-AMH CALSET CONTAINS TWO AMH CONCENTRATION LEVELS IN A LYOPHILIZED EQUINE SERUM MATRIX. AMH CAL1 CONTAINS ONLY ENDOGENOUS EQUINE AMH, WHILE AMH CAL2 CONTAINS ADDED BOVINE AMH (MALE FETAL BOVINE SERUM) IN AN EQUINE SERUM MATRIX. ,PRECINORM PUC(PRECINORM PUC)-PRECINORM PUC (PROTEINS IN URINE/CSF) IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE

	QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS., ELECSYS PLGF(ELECSYS PLGF)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PLACENTAL GROWTH FACTOR (PLGF) IN HUMAN SERUM.THE PLGF ASSAY IS USED IN COMBINATION WITH THE ELECSYS SFLT1 ASSAY TO DETERMINE THE SFLT1/PLGF RATIO. THE SFLT1/PLGF RATIO IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF PREECLAMPSIA IN CONJUNCTION WITH OTHER DIAGNOSTIC AND CLINICAL INFORMATION. IN ADDITION THE SFLT1/PLGF RATIO IS INTENDED FOR USE AS AN AID IN SHORT-TERM PREDICTION OF PREECLAMPSIA (RULE-OUT AND RULE-IN) IN PREGNANT WOMEN WITH SUSPICION OF PREECLAMPSIA IN CONJUNCTION WITH OTHER DIAGNOSTIC AND CLINICAL INFORMATION. THIS ASSAY IS INTENDED FOR THE USE AS ONE COMPONENT, IN COMBINATION WITH OTHER PARAMETERS, TO EVALUATE THE RISK OF EARLY-ONSET PREECLAMPSIA DURING THE FIRST TRIMESTER OF PREGNANCY.,TRSF2(TRSF2)-IN VITRO TEST FOR THE QUANTITATIVE IMMUNOLOGICAL DETERMINATION OF HUMAN TRANSFERRIN IN SERUM AND PLASMA.,DILUENT UNIVERSAL (DILUENT UNIVERSAL)-DILUENT UNIVERSAL IS USED AS A SAMPLE DILUENT IN CONJUNCTION WITH ELECSYS ASSAY REAGENTS.,ALBT2 (ALBT2)-IN VITRO TEST FOR THE QUANTITATIVE IMMUNOLOGICAL DETERMINATION OF ALBUMIN IN HUMAN URINE ON THE COBAS C SYSTEM.,FERRITIN CALSET(FERRITIN CALSET)-FERRITIN CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS FERRITIN ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS, ROCHE CARDIAC D-DIMER(ROCHE CARDIAC D-DIMER)-QUANTITATIVE IMMUNOLOGICAL TEST FOR THE DETECTION OF D DIMER IN HEPARINIZED VENOUS BLOOD FOR USE WITH THE COBAS INSTRUMENT. THE ROCHE CARDIAC D DIMER TEST SERVES AS AN AID WHEN DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLISM IS SUSPECTED. A NEGATIVE D DIMER RESULT IS AN INDICATION THAT THESE DISEASES CAN BE RULED OUT WITH HIGH PROBABILITY, ELECSYS FERRITIN(ELECSYS FERRITIN)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE COBAS E IMMUNOASSAY ANALYZER.,FERR2(FERR2)-IN VITRO TEST FOR THE QUANTITATIVE IMMUNOLOGICAL DETERMINATION OF HUMAN FERRITIN IN SERUM AND PLASMA ON COBAS INTEGRA SYSTEMS., PRECICONTROL SYPHILIS(PRECICONTROL SYPHILIS)-PRECICONTROL SYPHILIS IS USED FOR QUALITY CONTROL OF THE ELECSYS SYPHILIS IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,NACL (DILUENT NACL 9%)(NACL (DILUENT NACL 9%))-DILUENT NACL 9 % IS USED AS A SAMPLE

	DILUENT IN CONJUNCTION WITH ASSAY REAGENTS ON COBAS C SYSTEMS.,DILUENT NSE(DILUENT NSE)-DILUENT NSE IS USED AS A SAMPLE DILUENT IN CONJUNCTION WITH THE ELECSYS NSE ASSAY., ROCHE CARDIAC CONTROL PROBNP(ROCHE CARDIAC CONTROL PROBNP)-ROCHE CARDIAC CONTROL PROBNP IS USED FOR QUALITY CONTROL OF THE ROCHE CARDIAC PROBNP+ TEST ON THE COBAS INSTRUMENT.,NSE CALSET(NSE CALSET)-NSE CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS NSE ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ROCHE CARDIAC PROBNP+(ROCHE CARDIAC PROBNP+)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF NT PROBNP IN HEPARINISED VENOUS BLOOD FOR USE WITH THE COBAS INSTRUMENT. THE ROCHE CARDIAC PROBNP+ TEST SERVES AS AN AID IN THE DIAGNOSIS OF PATIENTS WITH SUSPECTED HEART FAILURE, IN THE MONITORING OF PATIENTS WITH COMPENSATED LEFT VENTRICULAR DYSFUNCTION AND IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES.,ELECSYS NSE(ELECSYS NSE)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF NEURON-SPECIFIC ENOLASE (NSE) IN HUMAN SERUM. NSE MEASUREMENTS ARE UTILIZED IN MONITORING THERAPY AND PROGRESS IN PATIENTS WITH TUMOR DISEASES, PARTICULARLY SMALL CELL LUNG CANCER AND NEUROBLASTOMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE COBAS E IMMUNOASSAY ANALYZER.,PRECICONTROL TOXO IGM (PRECICONTROL TOXO IGM)-PRECICONTROL TOXO IGM IS USED FOR QUALITY CONTROL OF THE ELECSYS TOXO IGM IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS,DILUENT HEPATITIS A(DILUENT HEPATITIS A)-DILUENT HEPATITIS A IS USED AS A SAMPLE DILUENT IN CONJUNCTION WITH THE ELECSYS ANTIHAV ASSAY.,SERUM BARBITURATES CALIBRATORS(SERUM BARBITURATES CALIBRATORS)-ABUSCREEN ONLINE SERUM BARBITURATES CALIBRATORS ARE FOR USE IN THE CALIBRATION OF THE ROCHE METHODS FOR THE QUANTITATIVE DETERMINATION OF SERUM BARBITURATES IN HUMAN SERUM, PLASMA AND URINE ON CLINICAL CHEMISTRY ANALYZERS.,PRECICONTROL ANTI-HAV (PRECICONTROL ANTI-HAV)-PRECICONTROL ANTIHAV IS USED FOR QUALITY CONTROL OF THE ELECSYS ANTIHAV IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,IL-6 CALSET(IL-6 CALSET)-IL 6 CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS IL 6 ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ELECSYS ANTI-HAV(ELECSYS ANTI-HAV)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TOTAL ANTIBODIES TO THE HEPATITIS A VIRUS

	IN HUMAN SERUM. THE ANTIHAV ASSAY IS USED AS AN AID TO DETECT A PAST OR EXISTING HEPATITIS A INFECTION, AND TO OBSERVE THE IMMUNE RESPONSE AFTER HAV VACCINATION. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE COBAS E IMMUNOASSAY ANALYZER.,ELECSYS IL-6 (ELECSYS IL-6)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF INTERLEUKIN 6 (IL 6) IN SERUM AND PLASMA. THIS ASSAY CAN BE USED TO AID IN THE MANAGEMENT OF CRITICALLY ILL PATIENTS AS EARLY INDICATOR FOR ACUTE INFLAMMATION.,ELECSYS ACTH(ELECSYS ACTH)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ADRENOCORTICOTROPIC HORMONE (ACTH) IN HUMAN EDTA PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,CARB(CARB)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF CARBAMAZEPINE IN SERUM OR HEPARINIZED PLASMA ON COBAS INTEGRA SYSTEMS., INSULIN CALSET(INSULIN CALSET)-INSULIN CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS INSULIN ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,CON 1(CON 1)-CON 1 IS USED FOR QUALITY CONTROL OF SPECIFIED COAGULATION ASSAYS ON INDICATED COBAS T COAGULATION ANALYZERS., ELECSYS INSULIN(ELECSYS INSULIN)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HUMAN INSULIN IN HUMAN SERUM AND PLASMA. THE DETERMINATION OF INSULIN IS UTILIZED IN THE DIAGNOSIS AND THERAPY OF VARIOUS DISORDERS OF CARBOHYDRATE METABOLISM, INCLUDING DIABETES MELLITUS AND HYPOGLYCEMIA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,TOTAL MPA CALIBRATORS (TOTAL MPA CALIBRATORS)-THE ROCHE TOTAL MPA CALIBRATORS ARE DESIGNED FOR THE CALIBRATION OF THE ROCHE TOTAL MPA ASSAY FOR THE QUANTITATIVE DETERMINATION OF MYCOPHENOLIC ACID IN HUMAN SERUM AND PLASMA ON ROCHE AUTOMATED CLINICAL CHEMISTRY ANALYZERS.,TG II CALSET(TG II CALSET)-TG II CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS TG II ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ELECSYS IL-6(ELECSYS IL-6)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF INTERLEUKIN 6 (IL 6) IN SERUM AND PLASMA. THIS ASSAY CAN BE USED TO AID IN THE MANAGEMENT OF CRITICALLY ILL PATIENTS AS EARLY INDICATOR FOR ACUTE INFLAMMATION.,ELECSYS TG II(ELECSYS TG II)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THYROGLOBULIN IN HUMAN SERUM AND PLASMA.

	DETERMINATION OF TG IS USED AS AN AID IN MONITORING AFTER THYROID ABLATION. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,PRECICONTROL TOXO IGG (PRECICONTROL TOXO IGG)-PRECICONTROL TOXO IGG IS USED FOR QUALITY CONTROL OF THE ELECSYS TOXO IGG AND TOXO IGG AVIDITY IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,PRO BNP II CALSET(PRO BNP II CALSET) -PROBNP II CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS PROBNP II ASSAY ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,PRECICONTROL CLINCHEM MULTI 1 (PRECICONTROL CLINCHEM MULTI 1)-PRECICONTROL CLINCHEM MULTI 1 IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS.,ELECSYS T3(ELECSYS T3)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS., ELECSYS TOXO IGG AVIDITY(ELECSYS TOXO IGG AVIDITY)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF THE AVIDITY OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA. ,TACROLIMUS CALSET(TACROLIMUS CALSET)-TACROLIMUS CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS TACROLIMUS ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,PRECINORM FRUCTOSAMINE (PRECINORM FRUCTOSAMINE)-PRECINORM FRUCTOSAMINE AND PRECIPATH FRUCTOSAMINE ARE FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS.,AFP CALSET II(AFP CALSET II)-AFP CALSET II IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS AFP ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ELECSYS ANTI-HAV IGM(ELECSYS ANTI-HAV IGM)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETECTION OF IGM ANTIBODIES TO HEPATITIS A VIRUS (ANTI HAV IGM) IN HUMAN SERUM AND PLASMA (POTASSIUM EDTA, LITHIUM OR SODIUM HEPARIN, SODIUM CITRATE). THE ASSAY IS INTENDED FOR USE AS AN AID IN THE LABORATORY DIAGNOSIS OF AN ACUTE OR RECENTLY ACQUIRED HEPATITIS A VIRUS INFECTION,ELECSYS CEA (ELECSYS CEA)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN IN HUMAN SERUM AND PLASMA. THIS ASSAY IS FURTHER INDICATED FOR SERIAL MEASUREMENT OF CEA TO AID IN THE MANAGEMENT OF CANCER PATIENTS. THE ELECTROCHEMILUMINESCENCE

	IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZER.,PRECISET TDM I (PRECISET TDM I)-PRECISET TDM I IS FOR USE IN THE CALIBRATION OF THE ROCHE ASSAYS FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN, CARBAMAZEPINE, GENTAMICIN, PHENYTOIN, PHENOBARBITAL, PRIMIDONE, THEOPHYLLINE, TOBRAMYCIN, VALPROIC ACID AND VANCOMYCIN IN HUMAN SERUM AND PLASMA ON ROCHE CLINICAL CHEMISTRY ANALYZERS. THE DILUENT IS NEGATIVE HUMAN SERUM AND MAY BE USED FOR DILUTION OF HIGH SAMPLES OR AS A BLANK SAMPLE. ,ELECSYS AFP(ELECSYS AFP)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF 1FETOPROTEIN IN HUMAN SERUM AND PLASMA. THIS ASSAY IS INTENDED FOR THE USE AS: AN AID IN THE DIAGNOSIS OF HEPATOCELLULAR CARCINOMA (HCC) AN AID IN THE MANAGEMENT OF PATIENTS WITH NONSEMINOMATOUS GERM CELL TUMORS. ONE COMPONENT IN COMBINATION WITH OTHER PARAMETERS TO EVALUATE THE RISK OF TRISOMY 21 (DOWN SYNDROME). FURTHER TESTING IS REQUIRED FOR DIAGNOSIS OF CHROMOSOMAL ABERRATIONS. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE COBAS E 801 IMMUNOASSAY ANALYZER., PRECICONTROL HSV(PRECICONTROL HSV)-PRECICONTROL HSV IS USED FOR QUALITY CONTROL OF THE ELECSYS HSV1 IGG AND ELECSYS HSV2 IGG IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,CLEAN CELL M(CLEAN CELL M)-SYSTEM SOLUTION FOR CLEANING THE DETECTION UNIT OF ELECSYS OR COBAS E IMMUNOASSAY ANALYZERS.,AMIKM(AMIKM)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF AMIKACIN IN SERUM OR HEPARINIZED PLASMA ON COBAS INTEGRA SYSTEMS,ISE CLEANING SOLUTION/ELECSYS SYSCLEAN(ISE CLEANING SOLUTION/ELECSYS SYSCLEAN)-FOR THE CLEANING OF ISE UNITS ON ROCHE/HITACHI ANALYZERS. FOR THE CLEANING OF ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,CALSET PIVKA-II(CALSET PIVKA-II)-CALSET PIVKAII IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS PIVKAII ASSAY ON THE COBAS E IMMUNOASSAY ANALYZERS. ,PROBEWASH M(PROBEWASH M)-CLEANING SOLUTION FOR RINSING THE MODULAR ANALYTICS E170, COBAS E 601 AND COBAS E 602 ANALYZERS DURING OPERATION WHEN CHANGING REAGENTS. ,ELECSYS PIVKA-II(ELECSYS® PIVKA-II) -IMMUNOASSAY FOR THE QUANTITATIVE MEASUREMENT OF PROTEIN INDUCED BY VITAMIN K ABSENCE OR ANTAGONIST-II (PIVKAII) IN HUMAN SERUM AND PLASMA. THE ASSAY IS USED AS AN AID IN THE DIAGNOSIS OF HEPATOCELLULAR CARCINOMA (HCC).THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON COBAS E IMMUNOASSAY ANALYZERS. ,PROCELL M

	(PROCELL M)-SYSTEM SOLUTION FOR GENERATING ELECTROCHEMICAL SIGNALS IN MODULAR ANALYTICS E170, COBAS E 601 AND COBAS E 602 IMMUNOASSAY ANALYZERS. PROCELL M IS USED IN CONJUNCTION WITH ELECSYS ASSAY REAGENTS., PRECICONTROL TOXO IGG AVIDITY(PRECICONTROL TOXO IGG AVIDITY)-PRECICONTROL TOXO IGG AVIDITY IS USED FOR QUALITY CONTROL OF THE ELECSYS TOXO IGG AVIDITY IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. , CLEANCELL(CLEANCELL)-SYSTEM SOLUTION FOR CLEANING THE DETECTION UNIT OF ELECSYS 2010 AND COBAS E 411 IMMUNOASSAY ANALYZERS. CLEANCELL IS USED IN CONJUNCTION WITH ELECSYS ASSAY REAGENTS.,C-F-A-S- CYSTATIN C(C-F-A-S- CYSTATIN C)-C.F.A. S. (CALIBRATOR FOR AUTOMATED SYSTEMS) CYSTATIN C IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE VALUE SHEETS.,PROCELL(PROCELL)-SYSTEM SOLUTION FOR GENERATING ELECTROCHEMICAL SIGNALS IN ELECSYS 2010 AND COBAS E 411 IMMUNOASSAY ANALYZERS. PROCELL IS USED IN CONJUNCTION WITH ELECSYS ASSAY REAGENTS.,MG(MG)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM, PLASMA AND URINE ON THE COBAS C 111 SYSTEM.,PRECICONTROL UNIVERSAL(PRECICONTROL UNIVERSAL)-PRECICONTROL UNIVERSAL IS USED FOR QUALITY CONTROL OF ELECSYS IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,LSD(LSD)-LYSERGIC ACID DIETHYLAMIDE (LSD) ASSAY IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE DETECTION OF LSD AND ITS METABOLITES IN HUMAN URINE.,DILUENT MULTIASSAY(DILUENT MULTIASSAY)-DILUENT MULTIASSAY IS USED AS A SAMPLE DILUENT IN CONJUNCTION WITH ELECSYS ASSAY REAGENTS.,LSD CALIBRATION/CONTROL PACK(LSD CALIBRATION/CONTROL PACK)-THE ABUSCREEN ONLINE LSD CALIBRATION/CONTROL PACK IS DESIGNED FOR CALIBRATION AND QUALITY CONTROL OF THE ROCHE ASSAYS FOR LSD (LYSERGIC ACID DIETHYLAMIDE) IN HUMAN URINE,PTH (1-84) CALSET(PTH (1-84) CALSET)-PTH (184) CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS PTH (184) ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,PRECICONTROL; CMV IGG (PRECICONTROL; CMV IGG)-PRECICONTROL CMV IGG IS USED FOR QUALITY CONTROL OF THE ELECSYS CMV IGG IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. ,ELECSYS T-UPTAKE(ELECSYS T-UPTAKE)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THYROXINEBINDING CAPACITY (TBC OR T4UPTAKE) IN HUMAN SERUM AND PLASMA.,CALSET ANTI-TSHR(CALSET ANTI-TSHR)-CALSET ANTITSHR IS USED FOR

	CALIBRATING THE QUANTITATIVE ELECSYS ANTITSHR ASSAY ON THE COBAS E IMMUNOASSAY ANALYZERS.,ELECSYS SYSWASH (ELECSYS SYSWASH)-USED AS AN ADDITIVE TO THE DISTILLED WATER CONTAINER FOR THE ELECSYS 2010 AND COBAS E 411 ANALYZERS.,FE STANDARD(FE STANDARD)-FE STANDARD (IRON STANDARD) IS FOR USE IN THE CALIBRATION OF QUANTITATIVE UNSATURATED IRON BINDING CAPACITY (UIBC) ASSAYS., CALIBRATOR BETA 2-MICROGLOBULIN(CALIBRATOR BETA 2-MICROGLOBULIN)-THE CALIBRATOR BETA 2MICROGLOBULIN IS INTENDED FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE VALUE SHEETS.,CSAII(CSAII)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE A IN HUMAN WHOLE BLOOD AS AN AID IN THE MANAGEMENT OF CYCLOSPORINE THERAPY IN TRANSPLANT PATIENTS.,B2MG(B2MG)-IMMUNOTURBIDIMETRIC ASSAY FOR THE QUANTITATIVE IN VITRO DETERMINATION OF BETA 2MICROGLOBULIN (B2MG) IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,SBARB (SBARB)-SERUM BARBITURATES (SBARB) IS AN IN VITRO DIAGNOSTIC TEST FOR THE DETECTION OF BARBITURATES AND THEIR METABOLITES IN HUMAN SERUM, HEPARINIZED PLASMA, OR URINE ON COBAS INTEGRA SYSTEMS. THIS REAGENT SYSTEM IS INTENDED FOR USE IN TOXICOLOGICAL SCREENINGS WHERE THE ANALYTICAL RESULT IS USED IN THE MANAGEMENT OF BARBITURATE USE OR OVERDOSE. SERUM BARBITURATES PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,UF HEP CON(UF HEP CON)-UNFRACTIONATED HEPARIN LOW AND HIGH CONTROLS ARE USED FOR QUALITY CONTROL OF THE ANTIXA CHROMOGENIC ASSAY ON INDICATED COBAS T ANALYZERS.,CA2(CA2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA, AND URINE ON THE COBAS C SYSTEM.,ANTI-XA(ANTI-XA)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ANTI-XA ACTIVITY OF UNFRACTIONATED (UFH) AND LOW MOLECULAR WEIGHT (LMWH) HEPARINS IN CITRATED PLASMA ON THE INDICATED COBAS T ANALYZERS. THE ASSAY IS INTENDED AS AN AID IN THE MANAGEMENT OF ANTI-XA HEPARIN THERAPY.,COAGUCHEK PT CONTROLS(COAGUCHEK PT CONTROLS)-COAGUCHEK PT CONTROLS

	ARE USED FOR SYSTEM CHECKS AND QUALITY CONTROL TESTING OF PROTHROMBIN TIME WITH THE COAGUCHEK PRO II METER AND COAGUCHEK PT TEST STRIPS.,LMW HEP CON(LMW HEP CON)-LOW MOLECULAR WEIGHT HEPARIN LOW AND HIGH CONTROLS ARE USED FOR QUALITY CONTROL OF THE ANTIXA CHROMOGENIC ASSAY ON INDICATED COBAS T ANALYZERS.,ISE STANDARD LOW(ISE STANDARD LOW)-ISE STANDARD LOW IS FOR USE IN THE CALIBRATION OF ION SELECTIVE ELECTRODES ON ROCHE/HITACHI ANALYZERS AND COBAS C ANALYZERS.,HEP CAL SET(HEP CAL SET)-LMWH AND UFH CALIBRATOR SET IS USED FOR CALIBRATION OF THE ANTIXA CHROMOGENIC ASSAY ON INDICATED COBAS T ANALYZERS.,STFR CONTROL SET(STFR CONTROL SET)-STFR CONTROL SET IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHOD AS SPECIFIED IN THE VALUE SHEETS.,BLANK CAL(BLANK CAL)-BLANK CAL IS USED FOR CALIBRATION OF ROCHE COAGULATION ASSAYS ON INDICATED COBAS T ANALYZERS.,PRECISET STFR(PRECISET STFR)-PRECISET STFR IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE VALUE SHEETS.,CYFRA 21-1 CALSET(CYFRA 21-1 CALSET)-CYFRA 211 CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS CYFRA 211 ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS,CK-MB CALSET(CK-MB CALSET)-CK MB CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS CK MB ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ELECSYS PTH(ELECSYS PTH)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE IN HUMAN SERUM AND PLASMA FOR THE DIFFERENTIAL DIAGNOSIS OF HYPERCALCEMIA AND HYPOCALCEMIA. THIS ASSAY CAN BE USED INTRAOPERATIVELY.,ISE SOLUTION 3(ISE SOLUTION 3)-THE INTEGRA ISE SOLUTION 3 IS AN IN VITRO DIAGNOSTIC CALIBRATOR INTENDED FOR THE CALIBRATION OF THE COBAS INTEGRA ISE MODULE FOR THE DETERMINATION OF SODIUM, POTASSIUM, CHLORIDE AND LITHIUM.,NMID OSTEOCALCIN CALSET(NMID OSTEOCALCIN CALSET)-NMID OSTEOCALCIN CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS NMID OSTEOCALCIN ASSAY.,ISE SOLUTION 2(ISE SOLUTION 2)-THE ISE MODULE OF THE COBAS INTEGRA SYSTEMS IS INTENDED FOR USE IN THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM, CHLORIDE, AND LITHIUM CONCENTRATIONS IN UNDILUTED SERUM AND PLASMA USING ION-SELECTIVE ELECTRODES.,PRECICONTROL PROGRP(PRECICONTROL PROGRP)-PRECICONTROL PROGRP IS USED FOR QUALITY CONTROL OF THE ELECSYS PROGRP IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ISE

	SOLUTION 1(ISE SOLUTION 1)-THE ISE MODULE OF THE COBAS INTEGRA SYSTEMS IS INTENDED FOR USE IN THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM, CHLORIDE, AND LITHIUM CONCENTRATIONS IN UNDILUTED SERUM AND PLASMA USING ION-SELECTIVE ELECTRODES.,ELECSYS HIV DUO(ELECSYS HIV DUO)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF HIV1 P24 ANTIGEN AND ANTIBODIES TO HIV1, INCLUDING GROUP O, AND HIV2 IN HUMAN SERUM AND PLASMA. THE SUBRESULTS (HIV AG AND ANTIHIV) ARE INTENDED AS AN AID IN THE SELECTION OF THE CONFIRMATION ALGORITHM FOR REACTIVE SAMPLES.,APTT MEDS(APTT MEDS)-IN VITRO ASSAY FOR THE DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME IN CITRATED PLASMA ON INDICATED COBAS T ANALYZERS.,CONTROL SET BETA 2-MICROGLOBULIN(CONTROL SET BETA 2-MICROGLOBULIN)-CONTROL SET BETA 2MICROGLOBULIN IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHOD AS SPECIFIED IN THE VALUE SHEETS.,ELECSYS TROPONIN T HS STAT(ELECSYS TROPONIN T HS STAT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN T IN HUMAN SERUM AND PLASMA. THIS ASSAY CAN BE USED AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF ACUTE CORONARY SYNDROME TO IDENTIFY NECROSIS, E.G. ACUTE MYOCARDIAL INFARCTION,ELECSYS HCG STAT(ELECSYS HCG STAT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN IN HUMAN SERUM AND PLASMA. THIS ASSAY IS INTENDED FOR USE ESPECIALLY IN THE DIAGNOSIS AND MONITORING OF PREGNANCY. ,ELECSYS TROPONIN I(ELECSYS TROPONIN I)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I IN HUMAN SERUM AND PLASMA. THIS ASSAY IS INTENDED TO AID IN THE DIAGNOSIS AND TREATMENT OF MYOCARDIAL INFARCTION AND CARDIAC MUSCLE DAMAGE. ,ELECSYS PTH (1-84)(ELECSYS PTH (1-84))-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF BIOINTACT PARATHYROID HORMONE, PTH (184) IN HUMAN SERUM AND PLASMA FOR THE DIFFERENTIAL DIAGNOSIS OF HYPERCALCEMIA AND HYPOCALCEMIA. THIS ASSAY CAN BE USED INTRAOPERATIVELY., CALSET TROPONIN I(CALSET TROPONIN I)-CALSET TROPONIN I IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS TROPONIN I ASSAY ON THE COBAS E IMMUNOASSAY ANALYZER.,CLEAN(CLEAN)-WASH SOLUTION FOR EXTRA WASH CYCLES FOR SAMPLE/REAGENT PROBES,CALSET TROPONIN T HS(CALSET TROPONIN T HS)-CALSET TROPONIN T HS IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS TROPONIN T HS ASSAY ON THE COBAS E IMMUNOASSAY ANALYZER.,ALTP(ALTP)-IN VITRO TEST FOR THE QUANTITATIVE

	DETERMINATION OF ALANINE AMINOTRANSFERASE(ALT) WITH PYRIDOXAL PHOSPHATE ACTIVATION IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,TROPONIN T HS STAT CALSET(TROPONIN T HS STAT CALSET)-TROPONIN T HS STAT CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS TROPONIN T HS STAT ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,TUPTAKE CALSET(TUPTAKE CALSET)-TUPTAKE CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS TUPTAKE ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,TROPONIN T CALSET(TROPONIN T CALSET)-TROPONIN T CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS TROPONIN T ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS,ELECSYS TOTAL P1NP (ELECSYS TOTAL P1NP)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TOTAL P1NP IN HUMAN SERUM AND PLASMA. THIS ASSAY IS INTENDED FOR USE IN MONITORING THERAPY FOLLOWING THE DIAGNOSISOF OSTEOPOROSIS IN POST-MENOPAUSAL WOMEN AND IN PATIENTS DIAGNOSEDWITH PAGET'S DISEASE OF THE BONE.,CRPHS(CRPHS)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF C REACTIVE PROTEIN (CRP) IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS. MEASUREMENT OF CRP IS OF USE FOR THE DETECTION AND EVALUATION OF INFLAMMATORY DISORDERS AND ASSOCIATED DISEASES, INFECTION AND TISSUE INJURY.,ELECSYS ANTI- HBE (ELECSYS ANTI- HBE)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF HUMAN ANTIBODIES TO THE HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY "ECLIA" IS INTENDED FOR USE ON THE COBAS E IMMUNOASSAY ANALYZER., FERR4(FERR4)-IN VITRO TEST FOR THE QUANTITATIVE IMMUNOLOGICAL DETERMINATION OF HUMAN FERRITIN IN SERUM AND PLASMA ON COBAS INTEGRA SYSTEMS.,TOTAL P1NP CALSET (TOTAL P1NP CALSET)-TOTAL P1NP CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS TOTAL P1NP ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,DIG(DIG)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN IN SERUM OR HEPARINIZED PLASMA ON COBAS INTEGRA SYSTEMS.,B2MG(B2MG)-IMMUNOTURBIDIMETRIC ASSAY FOR THE QUANTITATIVE IN VITRO DETERMINATION OF BETA 2MICROGLOBULIN (B2MG) IN HUMAN URINE ON ROCHE/HITACHI COBAS C SYSTEMS.,QUIN(QUIN)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF QUINIDINE IN SERUM OR HEPARINIZED PLASMA ON COBAS INTEGRA SYSTEMS,ELECSYS SCC (ELECSYS SCC)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE

	DETERMINATION OF SQUAMOUS CELL CARCINOMA (SCC) ANTIGEN IN HUMAN SERUM AND PLASMA. THE ASSAY IS USED AS AN AID IN THE MANAGEMENT OF PATIENTS WITH SQUAMOUS CELL CARCINOMA. THE RESULTS MUST BE INTERPRETED IN CONJUNCTION WITH OTHER METHODS IN ACCORDANCE WITH STANDARD CLINICAL MANAGEMENT GUIDELINES. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZER.,CALSET GDF 15(CALSET GDF 15) -CALSET GDF 15 IS A LYOPHILIZED EQUINE SERUM MATRIX WITH ADDED RECOMBINANT GDF 15 IN TWO CONCENTRATION RANGES., FREE BETA HCG CALSET(FREE BETA HCG CALSET)-FREE BETA HCG CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS FREE BETA HCG ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,IGM (IMMUNOGLOBULIN M)(IGM (IMMUNOGLOBULIN M))-IN VITRO TEST FOR THE QUANTITATIVE IMMUNOLOGICAL DETERMINATION OF HUMAN IMMUNOGLOBULIN M IN SERUM AND PLASMA ON COBAS INTEGRA SYSTEMS. IN ADDITION TO THE STANDARD APPLICATION (TEST IGM, TEST ID 0077), THE SENSITIVE APPLICATION (TEST IGMP, TEST ID 0177) IS DESIGNED FOR THE QUANTITATIVE DETERMINATION OF LOW IGM CONCENTRATIONS IN E.G. PEDIATRIC SAMPLES.,ELECSYS HE4(ELECSYS HE4)-IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HE4 IN HUMAN SERUM AND PLASMA. THE ASSAY IS USED AS AN AID IN MONITORING RECURRENCE OR PROGRESSIVE DISEASE IN PATIENTS WITH EPITHELIAL OVARIAN CANCER. SERIAL TESTING FOR PATIENT HE4 VALUES SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL FINDINGS USED FOR MONITORING OVARIAN CANCER. IT IS FURTHER INTENDED TO BE USED IN CONJUNCTION WITH THE ELECSYS CA 125 II ASSAY AS AN AID IN ESTIMATING THE RISK OF EPITHELIAL OVARIAN CANCER IN PREMENOPAUSAL AND POSTMENOPAUSAL WOMEN PRESENTING WITH PELVIC MASS. THE RESULTS MUST BE INTERPRETED IN CONJUNCTION WITH OTHER METHODS IN ACCORDANCE WITH STANDARD CLINICAL MANAGEMENT GUIDELINES. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,IGA-C(IGA-C)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGA SPECIFICALLY IN HUMAN CEREBROSPINAL FLUID AND CORRESPONDING HUMAN SERUM / PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS FREE BETA HCG(ELECSYS FREE BETA HCG)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FREE BETA HCG (FREE BETASUBUNIT OF HUMAN CHORIONIC GONADOTROPIN) IN HUMAN SERUM. THIS ASSAY IS INTENDED FOR THE USE AS ONE COMPONENT IN COMBINATION WITH OTHER PARAMETERS TO EVALUATE THE RISK

	OF TRISOMY 21 (DOWN SYNDROME) DURING THE FIRST TRIMESTER OF PREGNANCY. FURTHER TESTING IS REQUIRED FOR DIAGNOSIS OF CHROMOSOMAL ABERRATIONS. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZER.,CHOL2(CHOL2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,CC 25MM(CC 25MM)-CALCIUM CHLORIDE 25 MM IS USED FOR IN VITRO COAGULATION ASSAYS ON INDICATED COBAS T ANALYZERS.,ALT (ALT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE (ALT) IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS., ELECSYS ANTI HCV II (ELECSYS ANTI HCV II)-THE ELECSYS ANTIHCV II ASSAY IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HEPATITIS C VIRUS (HCV) IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE COBAS E IMMUNOASSAY ANALYZER,CO2-L(CO2-L)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BICARBONATE (HCO3 -) IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS HIV AG CONFIRMATORY TEST(ELECSYS HIV AG CONFIRMATORY TEST)-IMMUNOASSAY FOR IN VITRO CONFIRMATION OF THE PRESENCE OF HIVP24 ANTIGEN IN HUMAN SERUM AND PLASMA SAMPLES REPEATEDLY REACTIVE OR BORDERLINE WHEN TESTED WITH THE ELECSYS HIV AG ASSAY.,IGGT (IMMUNOGLOBULIN G TURBIDIMETRIC)(IGGT (IMMUNOGLOBULIN G TURBIDIMETRIC))-IN VITRO TEST FOR THE QUANTITATIVE IMMUNOLOGICAL DETERMINATION OF HUMAN IMMUNOGLOBULIN G IN SERUM, PLASMA AND CEREBROSPINAL FLUID ON COBAS INTEGRA SYSTEMS., PRECICONTROL HIV; HIV-2+GRPO(PRECICONTROL HIV; HIV-2+GRPO) -PRECICONTROL HIV; HIV2+GRPO IS USED FOR QUALITY CONTROL OF THE ELECSYS HIV COMBI PT AND ELECSYS HIV DUO IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,LDHI2(LDHI2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE IN HUMAN SERUM AND PLASMA. ,ASTP(ASTP)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE(AST) WITH PYRIDOXAL PHOSPHATE ACTIVATION IN HUMAN SERUM AND PLASMA ONROCHE/HITACHI COBAS C SYSTEMS.,HDLC4(HDLC4)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF THE HDLCHOLESTEROL CONCENTRATION IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS IGFBP-3 (ELECSYS IGFBP-3)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF INSULINLIKE GROWTH FACTOR

	BINDING PROTEIN3 (IGFBP3) IN HUMAN SERUM AND PLASMA. THE IGFBP3 DETERMINATION IS INTENDED TO BE USED AS AN AID IN THE ASSESSMENT OF GROWTH DISORDERS IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS.,ELECSYS CK-MB (ELECSYS CK-MB)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THE MB ISOENZYME OF CREATINE KINASE IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE COBAS E IMMUNOASSAY ANALYZER. ,ACID WASH(ACID WASH)-ACID WASH IS USED AS ACID WASH SOLUTION FOR REACTION CELLS ON THE ROCHE/HITACHI COBAS C ANALYZERS.,HAPT2(HAPT2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF HAPTOGLOBIN IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS DHEA-S(ELECSYS DHEA-S)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE (DHEAS) IN HUMAN SERUM AND PLASMA.,ROCHE CARDIAC POC TROPONIN T CONTROL(ROCHE CARDIAC POC TROPONIN T CONTROL)-THE ROCHE CARDIAC POC TROPONIN T CONTROL IS USED FOR QUALITY CONTROL OF THE ROCHE CARDIAC POC TROPONIN T TEST ON THE COBAS INSTRUMENT,VITAMIN D TOTAL II CALSET(VITAMIN D TOTAL II CALSET)-VITAMIN D TOTAL II CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS ASSAY REAGENTS.,MYOGLOBIN STAT CALSET(MYOGLOBIN STAT CALSET)-MYOGLOBIN STAT CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS MYOGLOBIN STAT ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,CALSET II PTH(CALSET II PTH)-CALSET II PTH IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS PTH ASSAY FOR INTACT PTH (PARATHYROID HORMONE) ON THE COBAS E IMMUNOASSAY ANALYZERS.,SMS(SMS)-WASH SOLUTION FOR REAGENT PROBES AND REACTION CELLS ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS SFLT-1(ELECSYS SFLT-1)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF SOLUBLE FMSLIKE TYROSINE KINASE1 (SFLT1) IN HUMAN SERUM. THE SFLT1 ASSAY IS USED IN COMBINATION WITH THE ELECSYS PLGF ASSAY TO DETERMINE THE SFLT1/PLGF RATIO. THE SFLT1/PLGF RATIO IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF PREECLAMPSIA IN CONJUNCTION WITH OTHER DIAGNOSTIC AND CLINICAL INFORMATION. IN ADDITION THE SFLT1/PLGF RATIO IS INTENDED FOR USE AS AN AID IN SHORT-TERM PREDICTION OF PREECLAMPSIA (RULE-OUT AND RULE-IN) IN PREGNANT WOMEN WITH SUSPICION OF PREECLAMPSIA IN CONJUNCTION WITH OTHER DIAGNOSTIC AND CLINICAL INFORMATION. ,SCCS(SCCS)-WASH SOLUTION FOR REACTION CELLS ON ROCHE/HITACHI COBAS C SYSTEMS.,DHEA-S

	CALSET(DHEA-S CALSET)-DHEAS CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS DHEAS ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,NAOHD (NAOHD)-WASH SOLUTION FOR REAGENT PROBES AND REACTION CELLS ON ROCHE/HITACHI COBAS C SYSTEMS.,CALSET PTH(CALSET PTH)-CALSET PTH IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS PTH ASSAY FOR INTACT PTH (PARATHYROID HORMONE) ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ECO-D (ECO-D)-ECOTERGENT IS AN ADDITIVE TO THE REACTION BATH TO REDUCE SURFACE TENSION ON COBAS C SYSTEMS.,ELECSYS PROGESTERONE III(ELECSYS PROGESTERONE III)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM AND PLASMA. ,TP2(TP2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM AND PLASMA.,SFLT-1 CALSET(SFLT-1 CALSET)-SFLT1 CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS SFLT1 ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. ,RF-II(RF-II)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS (RFII) IN HUMAN SERUM AND PLASMA.,ELECSYS FSH(ELECSYS FSH)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FOLLICLESTIMULATING HORMONE IN HUMAN SERUM AND PLASMA.,LIPC(LIPC)-ENZYMATIC IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LIPASE IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS LH (ELECSYS LH)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE IN HUMAN SERUM AND PLASMA. ,ELECSYS MYOGLOBIN STAT(ELECSYS MYOGLOBIN STAT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. ,PROGESTERONE III CALSET(PROGESTERONE III CALSET)-PROGESTERONE III CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS PROGESTERONE III ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. ,PRECISET RF(PRECISET RF)-PRECISET RF IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS.,DILUENT MULTIASSAY(DILUENT MULTIASSAY)-DILUENT MULTIASSAY IS USED AS A SAMPLE DILUENT IN CONJUNCTION WITH ELECSYS ASSAY REAGENTS.,D-DI2 CAL SET(D-DI2 CAL SET)-DDIMER GEN.2 CALIBRATOR SET IS FOR USE IN THE CALIBRATION OF QUANTITATIVE DDIMER ROCHE METHODS ON THE INDICATED COBAS T ANALYZERS.,CA 125 II CALSET(CA 125 II CALSET) -CA 125 II CALSET II IS USED FOR CALIBRATING THE QUANTITATIVE

	ELECSYS CA 125 II ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,GLOBAL CAL(GLOBAL CAL)-GLOBAL CALIBRATOR IS USED FOR CALIBRATION OF ROCHE COAGULATION ASSAYS ON INDICATED COBAS T ANALYZERS.,SERUM PROTEINS T-STANDARD(SERUM PROTEINS T-STANDARD)-C.F.A.S. (CALIBRATOR FOR AUTOMATED SYSTEMS) PROTEINS IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE VALUE SHEETS.,CRP 4(CRP 4)-IMMUNOTURBIDIMETRIC ASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CRP IN HUMAN SERUM AND PLASMA ON COBAS C SYSTEMS,ELECSYS TSH(ELECSYS TSH)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THYROTROPIN IN HUMAN SERUM AND PLASMA.,ROCHE CARDIAC POC TROPONIN T 2-LEVEL CONTROL(ROCHE CARDIAC POC TROPONIN T 2-LEVEL CONTROL)-THE ROCHE CARDIAC POC TROPONIN T 2 LEVEL CONTROL IS USED FOR QUALITY CONTROL OF THE ROCHE CARDIAC POC TROPONIN T TEST ON THE COBAS INSTRUMENT,ELECSYS SIROLIMUS(ELECSYS SIROLIMUS)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF SIROLIMUS IN HUMAN WHOLE BLOOD. THE ASSAY IS USED AS AN AID IN THE MANAGEMENT OF KIDNEY TRANSPLANT PATIENTS RECEIVING SIROLIMUS THERAPY.,PHNO2(PHNO2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF PHENOBARBITAL IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,SHBG CALSET (SHBG CALSET)-SHBG CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS SHBG ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. ,ANTITHROMBIN(ANTITHROMBIN)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ANTITHROMBIN III ACTIVITY IN HUMAN PLASMA ON INDICATED COBAS T ANALYZERS.,LH CALSET II(LH CALSET II)-LH CALSET II IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS LH ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. , COAGUCHEK APTT CONTROLS(COAGUCHEK APTT CONTROLS)-COAGUCHEK APTT CONTROLS ARE USED FOR SYSTEM CHECKS AND QUALITY CONTROL TESTING OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) WITH THE COAGUCHEK PRO II METER AND COAGUCHEK APTT TEST STRIPS.,SIROLIMUS CALSET(SIROLIMUS CALSET)-SIROLIMUS CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS SIROLIMUS ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,FREE PHENYTOIN CONTROLS (FREE PHENYTOIN CONTROLS)-COBAS FP FREE PHENYTOIN CONTROLS ARE ASSAYED QUALITY CONTROL SAMPLES INTENDED FOR USE ON COBAS CHEMISTRY SYSTEMS WITH COBAS REAGENTS AND CALIBRATORS FOR THE QUANTITATIVE DETERMINATION OF

	FREE PHENYTOIN IN SERUM AND PLASMA.,FSH CALSET II(FSH CALSET II)-FSH CALSET II IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS FSH ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,FREE VALPROIC ACID CONTROLS(FREE VALPROIC ACID CONTROLS)-COBAS FP FREE VALPROIC ACID CONTROLS ARE ASSAYED QUALITY CONTROL SAMPLES INTENDED FOR USE ON COBAS CHEMISTRY SYSTEMS WITH COBAS REAGENTS AND CALIBRATORS FOR THE QUANTITATIVE DETERMINATION OF FREE VALPROIC ACID IN HUMAN SERUM AND PLASMA, PRECICONTROL AMH(PRECICONTROL AMH)-PRECICONTROL AMH IS A LYOPHILIZED CONTROL SERUM BASED ON AN EQUINE SERUM MATRIX WITH ADDED BOVINE AMH (MALE FETAL BOVINE SERUM) IN TWO CONCENTRATION RANGES. THE CONTROLS ARE USED FOR MONITORING THE ACCURACY AND PRECISION OF THE ELECSYS AMH IMMUNOASSAY.,APTT LUPUS(APTT LUPUS)-IN VITRO ASSAY, WITH INCREASED LUPUS SENSITIVITY, FOR THE DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) IN CITRATED PLASMA ON THE INDICATED COBAS T ANALYZERS. THE APTT IS USED TO EVALUATE THE INTRINSIC COAGULATION PATHWAY.,ELECSYS PROGRP(ELECSYS PROGRP)-IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGRP IN HUMAN PLASMA AND SERUM. THE ASSAY IS USED TO AID IN THE DIFFERENTIAL DIAGNOSIS IN LUNG CANCER1 AND IN THE MANAGEMENT OF PATIENTS WITH SMALL CELL LUNG CANCER IN CONJUNCTION WITH OTHER CLINICAL METHODS THE RESULTS MUST BE INTERPRETED IN CONJUNCTION WITH OTHER METHODS IN ACCORDANCE WITH STANDARD CLINICAL MANAGEMENT GUIDELINES. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZER.,NAPA2(NAPA2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF NACETYLPROCAINAMIDE IN HUMAN SERUM OR PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,PLGF CALSET(PLGF CALSET)-PLGF CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS PLGF ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. ,TROP T SENSITIVE(TROP T SENSITIVE)-QUALITATIVE IMMUNOLOGICAL TEST FOR THE SPECIFIC DETECTION OF CARDIAC TROPONIN T IN HEPARINISED OR EDTA VENOUS BLOOD., CEA CALSET(CEA CALSET)-CEA CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS CEA ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ASTPM(ASTPM)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE (AST) WITH PYRIDOXAL PHOSPHATE ACTIVATION IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS,ELECSYS CALCITONIN(ELECSYS CALCITONIN)-

	IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CALCITONIN (THYROCALCITONIN) IN SERUM AND PLASMA. THE CALCITONIN DETERMINATION IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS AND TREATMENT OF DISEASES INVOLVING THE THYROID AND PARATHYROID GLANDS, INCLUDING CARCINOMA AND HYPERPARATHYROIDISM IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,PHNY2(PHNY2)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF PHENYTOIN IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEM.,T4 CALSET(T4 CALSET)-T4 CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS T4 ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ISE DEPROTEINIZER(ISE DEPROTEINIZER)-ISE DEPROTEINIZER IS A CLEANING SOLUTION INTENDED FOR USE WITH THE COBAS INTEGRA AND COBAS C ISE MODULES FOR CLEANING THE ION-SELECTIVE ELECTRODES.,CALSET AMH PLUS(CALSET AMH PLUS)-CALSET AMH PLUS CONTAINS TWO AMH CONCENTRATION LEVELS IN A LYOPHILIZED EQUINE SERUM MATRIX. AMH PLUS CAL1 CONTAINS ONLY ENDOGENOUS EQUINE AMH, WHILE AMH PLUS CAL2 CONTAINS ADDED BOVINE AMH (MALE FETAL BOVINE SERUM) IN AN EQUINE SERUM MATRIX. ,MG2(MG2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM, PLASMA AND URINE ON ROCHE/HITACHI COBAS C SYSTEMS.,PRECICONTROL HE4 (PRECICONTROL HE4)-PRECICONTROL HE4 IS USED FOR QUALITY CONTROL OF THE ELECSYS HE4 IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,APTT HIGHS(APTT HIGHS) -IN VITRO ASSAY FOR THE DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME IN CITRATED PLASMA ON INDICATED COBAS T ANALYZERS.,PRECICONTROL HBSAGII QUANT II(PRECICONTROL HBSAGII QUANT II)-PRECICONTROL HBSAG II QUANT II IS USED FOR QUALITY CONTROL OF THE ELECSYS HBSAG II QUANT II IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,PREA(PREA)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF PREALBUMIN IN HUMAN SERUM AND PLASMA.,ELECSYS S100(ELECSYS S100)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF S100 (S100 A1B AND S100 BB) IN HUMAN SERUM. THIS ASSAY CAN BE USED TO AID IN THE MANAGEMENT OF PATIENTS SUFFERING FROM MALIGNANT MELANOMA (ELECSYS S100 ASSAY IS NOT SUITABLE FOR THE DIAGNOSIS OF MALIGNANT MELANOMA) TO AID IN THE MANAGEMENT OF PATIENTS AFTER POTENTIAL BRAIN INJURY IN CONJUNCTION WITH CLINICAL INFORMATION AND IMAGING

	TECHNIQUES THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZER.,TRIGB(TRIGB)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES WITH GLYCEROL BLANKING IN HUMAN SERUM AND PLASMA.,PRECICONTROL ANTI HCV (PRECICONTROL ANTI HCV)-PRECICONTROL ANTIHCV IS USED FOR QUALITY CONTROL OF THE ANTIHCV AND ANTIHCV II IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,RF CONTROL SET (RF CONTROL SET)-RF CONTROL SET IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHOD AS SPECIFIED IN THE VALUE SHEETS.,HE4 CALSET(HE4 CALSET)-HE4 CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS HE4 ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS,TPUC3(TPUC3)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF PROTEIN IN HUMAN URINE AND CEREBROSPINAL FLUID.,ELECSYS HBSAG II (ELECSYS HBSAG II)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE COBAS E IMMUNOASSAY ANALYZER.,PRECIMAT GLYCEROL(PRECIMAT GLYCEROL)-PRECIMAT GLYCEROL IS FOR USE IN THE CALIBRATION OF SPECIFIED QUANTITATIVE ROCHE TRIGLYCERIDE ASSAYS., PRECICONTROL ANTI- HBE(PRECICONTROL ANTI- HBE)-PRECICONTROL ANTIHBE IS USED FOR QUALITY CONTROL OF THE ELECSYS ANTIHBE IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS,LACT2(LACT2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LACTATE IN HUMAN PLASMA AND CSF ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS HBEAG (ELECSYS HBEAG)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE COBAS E IMMUNOASSAY ANALYZER.,LIPC(LIPC)-ENZYMATIC IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LIPASE IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS., ELECSYS HBSAG CONFIRMATORY TEST(ELECSYS HBSAG CONFIRMATORY TEST)-IMMUNOASSAY FOR IN VITRO CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN IN HUMAN SERUM AND PLASMA SAMPLES REPEATEDLY REACTIVE WHEN TESTED WITH THE ELECSYS HBSAG II ASSAY,LPA2(LPA2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN (A) IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,DILUENT UNIVERSAL(DILUENT UNIVERSAL)-DILUENT

	UNIVERSAL IS USED AS A SAMPLE DILUENT IN CONJUNCTION WITH ELECSYS ASSAY REAGENTS.,UREAL(UREAL)-N VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF UREA/UREA NITROGEN IN HUMAN SERUM, PLASMA AND URINE.,PRECICONTROL MATERNAL CARE(PRECICONTROL MATERNAL CARE)-PRECICONTROL MATERNAL CARE IS USED FOR QUALITY CONTROL OF THE ELECSYS FREE HCG AND PAPPA IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,TRSF2(TRSF2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TRANSFERRIN IN HUMAN URINE., SCC CALSET(SCC CALSET)-SCC CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS SCC ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,IRON2(IRON2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS PAPP-A(ELECSYS PAPP-A)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PREGNANCY ASSOCIATED PLASMA PROTEIN A IN HUMAN SERUM. THIS ASSAY IS INTENDED FOR THE USE AS ONE COMPONENT IN COMBINATION WITH OTHER PARAMETERS TO EVALUATE THE RISK OF TRISOMY 21 (DOWN SYNDROME) DURING THE FIRST TRIMESTER OF PREGNANCY. FURTHER TESTING IS REQUIRED FOR DIAGNOSIS OF CHROMOSOMAL ABERRATIONS. ,UA2(UA2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA AND URINE.,PAPP-A CALSET(PAPP-A CALSET)-PAPP A CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS PAPP-A ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ALP2 (ALP2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,PRECICONTROL THYROAB (PRECICONTROL THYROAB)-PRECICONTROL THYROAB IS USED FOR QUALITY CONTROL OF THE ELECSYS ANTITSHR, ANTITPO AND ANTITG IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,HBDH2(HBDH2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF HYDROXYBUTYRATE DEHYDROGENASE (HBDH) IN SERUM AND PLASMA.,FOLATE RBC CALSET(FOLATE RBC CALSET)-FOLATE RBC CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS FOLATE RBC ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS., HEMOLYZING REAGENT GEN. 2(HEMOLYZING REAGENT GEN. 2)-THE HEMOLYZING REAGENT IS USED AS DILUENT FOR THE TINAQUANT HEMOGLOBIN A1C ASSAYS ON COBAS INTEGRA SYSTEMS, PRECICONTROL ANTI-HBC IGM(PRECICONTROL ANTI-HBC IGM)-PRECICONTROL ANTIHBC IGM IS USED FOR QUALITY CONTROL OF THE ELECSYS ANTIHBC IGM IMMUNOASSAY ON THE ELECSYS AND

	COBAS E IMMUNOASSAY ANALYZERS.,PRECIMAT FRUCTOSAMINE (PRECIMAT FRUCTOSAMINE)-PRECIMAT FRUCTOSAMINE IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS., PRECICONTROL THYRO SENSITIVE(PRECICONTROL THYRO SENSITIVE)-PRECICONTROL THYRO SENSITIVE IS USED FOR QUALITY CONTROL OF THE ELECSYS TSH AND ELECSYS TG II IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,CELL WASH SOLUTION I/NAOH-D(CELL WASH SOLUTION I/NAOH-D)-CELL WASH SOLUTION I / NAOHD IS USED AS ALKALINE WASH SOLUTION FOR REACTION CELLS ON ROCHE/HITACHI SYSTEMS.,ELECSYS TG II CONFIRMATORY TEST(ELECSYS TG II CONFIRMATORY TEST)-TG II CONFIRMATORY TEST IS INTENDED FOR USE IN COMBINATION WITH THE ELECSYS TG II DETERMINATION TO ASSESS POTENTIAL INTERFERENCE EFFECTS AND AS AN AID TO CONFIRM THE RESPECTIVE TG RESULTS.,CHECK SOLUTION SAMPLE(CHECK SOLUTION SAMPLE)-TEST FOR ACCURACY AND PRECISION OF SAMPLE AND REAGENT PIPETTING WITH DYE SOLUTION AND SALINE SOLUTION ON ROCHE/HITACHI COBAS C SYSTEMS.,CALSET FT4 III (CALSET FT4 III)-CALSET FT4 III IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS FT4 III ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,NH3L(NH3L)-ENZYMATIC IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN PLASMA.,ELECSYS SHBG(ELECSYS SHBG)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF SEX HORMONEBINDING GLOBULIN IN HUMAN SERUM AND PLASMA., NH3L2(NH3L2)-ENZYMATIC IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN PLASMA.,TSH CALSET(TSH CALSET)-TSH CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS TSH ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,SERUM BENZODIAZEPINES CALIBRATORS(SERUM BENZODIAZEPINES CALIBRATORS)-ABUSCREEN ONLINE SERUM BENZODIAZEPINES CALIBRATORS ARE FOR USE IN THE CALIBRATION OF ROCHE METHODS FOR THE QUANTITATIVE DETERMINATION OF SERUM BENZODIAZEPINES IN HUMAN SERUM, PLASMA AND URINE ON ROCHE CLINICAL CHEMISTRY ANALYZERS., ELECSYS C-PEPTIDE(ELECSYS C-PEPTIDE)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CPEPTIDE IN HUMAN SERUM, PLASMA AND URINE. THE ASSAY IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS AND TREATMENT OFPATIENTS WITH ABNORMAL INSULIN SECRETION. ,SBENZ(SBENZ)-SERUM BENZODIAZEPINES (SBENZ) IS AN IN VITRO DIAGNOSTIC TEST FOR THE DETECTION OF BENZODIAZEPINES AND THEIR METABOLITES IN HUMAN SERUM, HEPARINIZED PLASMA, OR URINE ON COBAS INTEGRA SYSTEMS. THIS REAGENT SYSTEM IS INTENDED FOR USE IN

	TOXICOLOGICAL SCREENINGS WHERE THE ANALYTICAL RESULT IS USED IN THE MANAGEMENT OF BENZODIAZEPINE USE OR OVERDOSE. SERUM BENZODIAZEPINES PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED. ,FOLATE RBC HEMOLYZING REAGENT(FOLATE RBC HEMOLYZING REAGENT)-FOLATE RBC HEMOLYZING REAGENT IS INTENDED TO BE USED IN CONJUNCTION WITH THE ELECSYS FOLATE RBC ASSAY FOR THE DETERMINATION OF FOLATE IN ERYTHROCYTES.,AMY-P(AMY-P)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF PANCREATIC AMYLASE IN HUMAN SERUM, PLASMA AND URINE ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS -CROSSLAPS/SERUM(ELECSYS -CROSSLAPS/SERUM)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF DEGRADATION PRODUCTS OF TYPE I COLLAGEN IN HUMAN SERUM AND PLASMA AS AN AID IN ASSESSING BONE RESORPTION. THE TEST MAY BE USED AS AN AID IN MONITORING ANTIRESORPTIVE THERAPIES IN OSTEOPOROTIC PATIENTS. ,ROCHE CARDIAC CK-MB(ROCHE CARDIAC CK-MB)-QUANTITATIVE IMMUNOLOGICAL TEST FOR THE DETECTION OF THE MB CREATINE KINASE ISOENZYME IN HEPARINISED VENOUS BLOOD FOR USE WITH THE COBAS SYSTEM.,PRECICONTROL HIV (PRECICONTROL HIV)-PRECICONTROL HIV IS USED FOR QUALITY CONTROL OF THE ELECSYS HIV COMBI PT AND ELECSYS HIV AG IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,ROCHE CARDIAC CONTROL CK-MB(ROCHE CARDIAC CONTROL CK-MB)-THE ROCHE CARDIAC CONTROL CK MB QUALITY CONTROL IS USED FOR QUALITY CONTROL FOR THE ROCHE CARDIAC CK MB ASSAY, USING THE COBAS ANALYZER BY ROCHE DIAGNOSTICS.,CA 72-4 CALSET(CA 72-4 CALSET)-CA 724 CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS CA 724 ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS., APOAT(APOAT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A 1 IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,ELECSYS FT4 III (ELECSYS FT4 III)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FREE THYROXINE IN HUMAN SERUM AND PLASMA.,ALTL(ALTL)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE (ALT) IN HUMAN

	SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS., ELECSYS CA 19-9(ELECSYS CA 19-9)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CA 199, IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,PRIM(PRIM)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF PRIMIDONE IN SERUM OR HEPARINIZED PLASMA ON COBAS INTEGRA SYSTEMS., CALCITONIN CALSET(CALCITONIN CALSET)-CALCITONIN CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS CALCITONIN ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS., PROC2(PROC2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF PROCAINAMIDE IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,C-PEPTIDE CALSET(C-PEPTIDE CALSET)-CPEPTIDE CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS CPEPTIDE ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. ,APTT(APTT)-IN VITRO ASSAY, WITH REDUCED LUPUS SENSITIVITY, FOR THE DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) IN CITRATED PLASMA ON THE INDICATED COBAS T ANALYZERS. THE APTT IS USED TO EVALUATE THE INTRINSIC COAGULATION PATHWAY.,TOTAL PSA CALSET II(TOTAL PSA CALSET II)-TOTAL PSA CALSET II IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS TOTAL PSA ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,DDIMER GEN.2 CALIBRATOR(DDIMER GEN.2 CALIBRATOR)-DDIMER GEN.2 CALIBRATOR IS USED FOR CALIBRATION OF THE ROCHE TINAQUANT DDIMER GEN.2 ASSAY ON THE INDICATED COBAS T COAGULATION ANALYZERS.,ELECSYS CA 125 II(ELECSYS CA 125 II)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF OC 125 REACTIVE DETERMINANTS IN HUMAN SERUM, LIHEPARIN, K2EDTA AND K3EDTA, AS WELL AS LIHEPARIN PLASMA TUBES CONTAINING SEPARATING GEL ON COBAS E ANALYZERS. THESE DETERMINANTS ARE ASSOCIATED WITH A HIGH MOLECULAR WEIGHT GLYCOPROTEIN IN SERUM AND PLASMA OF WOMEN WITH PRIMARY EPITHELIAL INVASIVE OVARIAN CANCER (EXCLUDING THOSE WITH CANCER OF LOW MALIGNANT POTENTIAL). THIS IMMUNOASSAY IS INDICATED FOR USE AS AN AID IN THE DETECTION OF RESIDUAL OR RECURRENT OVARIAN CARCINOMA. THIS IMMUNOASSAY IS FURTHER INDICATED FOR USE IN MONITORING PATIENTS FOR DISEASE PROGRESS OR RESPONSE TO THERAPY. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON COBAS E IMMUNOASSAY ANALYZERS.,COC2(COC2)-COCAINE II (COC2) IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETECTION OF BENZOYLECGONINE, THE

	PRIMARY METABOLITE OF COCAINE, IN HUMAN URINE ON ROCHE/HITACHI COBAS C SYSTEMS AT CUTOFF CONCENTRATIONS OF 150 AND 300 NG/ML. SEMIQUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. SEMIQUANTITATIVE ASSAYS ARE INTENDED TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GCMS). COCAINE II PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GCMS IS THE PREFERRED CONFIRMATORY METHOD.1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,S100 CALSET(S100 CALSET)-S100 CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS S100 ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS., ELECSYS CMV IGM(ELECSYS CMV IGM)-IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETERMINATION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA. RESULTS OBTAINED WITH THIS ASSAY ARE USED AS AN AID IN THE DIAGNOSIS OF RECENT CMV INFECTIONS. ,ELECSYS CA 15-3 II(ELECSYS CA 15-3 II)-IMMUNOLOGICAL IN VITRO ASSAY FOR QUANTITATIVE DETERMINATION OF CA 153 IN HUMAN SERUM AND PLASMA TO AID IN THE MANAGEMENT OF BREAST CANCER PATIENTS. IN CONJUNCTION WITH OTHER CLINICAL AND DIAGNOSTIC PROCEDURES, SERIAL TESTING WITH THIS ASSAY IS AN AID IN THE EARLY DETECTION OF RECURRENCE IN PREVIOUSLY TREATED STAGE II AND III BREAST CANCER PATIENTS FOR MONITORING RESPONSE TO THERAPY IN METASTATIC BREAST CANCER PATIENTS THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZER.,SAMPLE CLEANER 1(SAMPLE CLEANER 1)-WASH SOLUTION FOR SAMPLE PROBES ON ROCHE/HITACHI COBAS C SYSTEMS.,PRECICONTROL ANTI-HBS(PRECICONTROL ANTI-HBS)-PRECICONTROL ANTI HBS IS USED FOR QUALITY CONTROL OF THE ELECSYS ANTI HBS AND ELECSYS ANTI HBS II IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,VALP (VALP)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF VALPROIC ACID IN SERUM OR HEPARINIZED PLASMA ON COBAS INTEGRA SYSTEMS,KAOLIN SUSPENSION(KAOLIN SUSPENSION)-KAOLIN SUSPENSION IS USED FOR FIBRINOGEN TESTING ON INDICATED COBAS T ANALYZERS.,TINA-QUANT D-DIMER

	GEN.2(TINA-QUANT D-DIMER GEN.2)-IN VITRO ASSAY FOR THE QUANTITATIVE IMMUNOLOGICAL DETERMINATION OF FIBRIN DEGRADATION PRODUCTS (DDIMER AND XOLIGOMERS) IN HUMAN CITRATED PLASMA ON THE INDICATED COBAS T ANALYZERS. IN CONJUNCTION WITH A NON-HIGH CLINICAL PROBABILITY ASSESSMENT, A NORMAL DDIMER RESULT (LESS THAN 0.5 MICROGRAM FEUA)/ML) IS INTENDED AS AN AID IN THE EXCLUSION OF DEEP VEIN THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE). A) FIBRINOGEN EQUIVALENT UNIT,CON P+(CON P+)-CON P+ IS USED FOR QUALITY CONTROL OF SPECIFIED COAGULATION ASSAYS ON INDICATED COBAS T COAGULATION ANALYZERS.,CKMB(CKMB)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF THE CATALYTIC ACTIVITY OF CREATINE KINASE MB SUBUNIT (CK MB) IN HUMAN SERUM AND PLASMA ON ROCHE/ HITACHI COBAS C SYSTEMS.,OWREN'S VERONAL BUFFER(OWREN'S VERONAL BUFFER)-OWREN'S VERONAL BUFFER IS USED FOR FIBRINOGEN TESTING ON INDICATED COBAS T ANALYZERS.,CK(CK)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE (CK) IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,CLEANSOL(CLEANSOL)-CLEANSOL IS USED TO CLEAN THE PIPETTING NEEDLE AS PART OF THE MAINTENANCE PROCEDURE ON INDICATED COBAS T ANALYZERS.,PT REC(PT REC)-IN VITRO ASSAY FOR THE DETERMINATION OF PROTHROMBIN TIME AND DERIVED FIBRINOGEN IN CITRATED PLASMA ON THE INDICATED COBAS T ANALYZERS. THE PROTHROMBIN TIME IS USED FOR EVALUATION OF THE EXTRINSIC COAGULATION PATHWAY AND AS AN AID IN THE MANAGEMENT OF VITAMIN K ANTAGONIST THERAPY. THE DERIVED FIBRINOGEN RESULT IS INTENDED AS AN AID IN THE EXCLUSION OF FIBRINOGEN DEFICIENCY.,DAY CLEAN(DAY CLEAN)-CLEANING SOLUTION FOR IN VITRO COAGULATION ASSAYS ON INDICATED COBAS T ANALYZERS.,CONTROL SET DAT II(CONTROL SET DAT II)-THE CONTROL SET DAT II IS FOR USE AS AN ASSAYED CONTROL IN THE ROCHE TEST SYSTEM FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF DRUGS OF ABUSE IN HUMAN URINE ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS AS LISTED ABOVE IN SYSTEM INFORMATION.,IMIDAZOLE BUFFER(IMIDAZOLE BUFFER)-IMIDAZOLE BUFFER IS USED FOR IN VITRO COAGULATION ASSAYS ON INDICATED COBAS T ANALYZERS.,APTT SCREEN(APTT SCREEN)-IN VITRO ASSAY FOR THE DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) IN CITRATED PLASMA ON THE INDICATED COBAS T ANALYZERS. THE APTT IS USED TO EVALUATE THE INTRINSIC COAGULATION PATHWAY.,PRECICONTROL HBSAG AUTO CONFIRM-PRECICONTROL HBSAG AUTO CONFIRM IS USED FOR QUALITY CONTROL OF THE ELECSYS HBSAG II AUTO

	CONFIRM IMMUNOASSAY ON THE COBAS E IMMUNOASSAY ANALYZER.,D-DIMER GEN.2 CONTROL I/II(D-DIMER GEN.2 CONTROL I/II)-D-DIMER GEN.2 CONTROL I/II IS USED FOR QUALITY CONTROL OF THE ROCHE TINAQUANT DDIMER GEN.2 ASSAY ON INDICATED COBAS T COAGULATION ANALYZERS.,PRECICONTROL ANTIP53 (PRECICONTROL ANTIP53)-PRECICONTROL ANTI-P53 IS USED FOR QUALITY CONTROL OF THE ELECSYS ANTI-P53 IMMUNOASSAY ON COBAS E IMMUNOASSAY ANALYZERS.,C-F-A-S- CK-MB(C-F-A-S- CK-MB)-C.F.A.S. (CALIBRATOR FOR AUTOMATED SYSTEMS) CK MB IS FOR USE IN THE CALIBRATION OF ROCHE METHODS FOR THE QUANTITATIVE DETERMINATION OF CK MB ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE VALUE SHEETS.,SARS-COV-2 EXTRACTION SOLUTION C(SARS-COV-2 EXTRACTION SOLUTION C)-SARS-COV-2 EXTRACTION SOLUTION C IS INTENDED FOR THE VIRUS LOAD REDUCTION OF SAMPLES ELUTED IN TRANSPORT MEDIA TO BE USED WITH THE ELECSYS SARS-COV-2 ANTIGEN ASSAY.,CRPL3(CRPL3)-IMMUNOTURBIDIMETRIC ASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CRP IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS., ELECSYS ANTIP53(ELECSYS ANTIP53)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ANTIP53 AUTOANTIBODIES IN HUMAN SERUM AND PLASMA. THE ASSAY IS USED TO AID IN THE DIAGNOSIS OF ESOPHAGEAL CANCER, COLORECTAL CANCER AND BREAST CANCER IN CONJUNCTION WITH OTHER TESTS. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON COBAS E IMMUNOASSAY ANALYZERS.,PRECICONTROL TROPONIN(PRECICONTROL TROPONIN) -PRECICONTROL TROPONIN IS USED FOR QUALITY CONTROL OF THE ELECSYS TROPONIN T HS, ELECSYS TROPONIN T HS STAT, ELECSYS TROPONIN I AND ELECSYS TROPONIN I STAT IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,SARS-COV-2 EXTRACTION SOLUTION(SARS-COV-2 EXTRACTION SOLUTION)-SARSCOV2 EXTRACTION SOLUTION IS INTENDED FOR THE ELUTION, VIRUS LOAD REDUCTION AND TRANSPORTATION OF SAMPLES TO BE USED WITH THE ELECSYS SARSCOV2 ANTIGEN ASSAY,BILD2(BILD2) -IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN CONCENTRATION IN HUMAN SERUM AND PLASMA ON COBAS C SYSTEMS.,ELECSYS ANTI-SARS-COV-2 S(ELECSYS ANTI-SARS-COV-2 S)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ANTIBODIES (INCLUDING IGG) TO THE SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARSCOV2) SPIKE (S) PROTEIN RECEPTOR BINDING DOMAIN (RBD) IN HUMAN SERUM AND PLASMA. THE TEST IS INTENDED AS AN AID TO ASSESS THE ADAPTIVE HUMORAL IMMUNE RESPONSE TO THE SARSCOV2 S

	PROTEIN. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON COBAS E IMMUNOASSAY ANALYZERS.,FIBRINOGEN(FIBRINOGEN)-IN VITRO ASSAY FOR THE DETERMINATION OF FIBRINOGEN CONCENTRATION (CLAUSS METHOD) IN CITRATED PLASMA ON INDICATED COBAS T ANALYZERS.,CALSET ANTI-SARS-COV-2 S(CALSET ANTI-SARS-COV-2 S)-CALSET ANTISARSCOV2 S IS USED FOR CALIBRATING THE ELECSYS ANTISARSCOV2 S ASSAY ON COBAS E IMMUNOASSAY ANALYZERS. ,VANC3(VANC3)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF VANCOMYCIN IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,PRECICONTROL ANTI-SARS-COV-2 S(PRECICONTROL ANTI-SARS-COV-2 S)-PRECICONTROL ANTISARSCOV2 S IS USED FOR QUALITY CONTROL OF THE ELECSYS ANTISARSCOV2 S IMMUNOASSAY ON COBAS E IMMUNOASSAY ANALYZERS,COMBUR 10 TEST UX(COMBUR 10 TEST UX)-THE COMBUR10 TEST UX ARE TEST STRIPS FOR THE IN VITRO QUALITATIVE OR SEMI-QUANTITATIVE DETERMINATION OF PH, LEUKOCYTES, NITRITE, PROTEIN, GLUCOSE, KETONES, UROBILINOGEN, BILIRUBIN, ERYTHROCYTES AND SPECIFIC GRAVITY IN URINE WITH THE URISYS 1100 URINE ANALYZER AND BY VISUAL READING. THESE MEASUREMENTS ARE USEFUL IN THE EVALUATION OF RENAL, URINARY, HEPATIC AND METABOLIC DISORDERS. COMBUR10 TEST UX ARE TEST STRIPS FOR SINGLE USE ONLY. COMBUR10 TEST UX ARE SCREENING TESTS AND CAN AID IN THE DIAGNOSIS OF PATHOLOGICAL CONDITIONS,ELECSYS HBSAG II AUTO CONFIRM-IMMUNOASSAY FOR IN VITRO CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN IN HUMAN SERUM AND PLASMA SAMPLES REPEATEDLY REACTIVE WHEN TESTED WITH THE ELECSYS HBSAG II ASSAY. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON THE COBAS E IMMUNOASSAY ANALYZER.,PRECISET TDM II(PRECISET TDM II)-THE PRECISET TDM II CALIBRATORS ARE DESIGNED FOR THE CALIBRATION OF THE ROCHE ASSAYS FOR THE QUANTITATIVE DETERMINATION OF AMIKACIN, LIDOCAINE, NACETYLPROCAINAMIDE, PROCAINAMIDE AND QUINIDINE IN HUMAN SERUM AND PLASMA ON ROCHE CLINICAL CHEMISTRY ANALYZERS.,PRECICONTROL SARS-COV-2 ANTIGEN(PRECICONTROL SARS-COV-2 ANTIGEN)-PRECICONTROL SARS COV 2 ANTIGEN IS USED FOR QUALITY CONTROL OF THE ELECSYS SARS COV 2 ANTIGEN IMMUNOASSAY ON COBAS E IMMUNOASSAY ANALYZERS.,CONTROL SET DAT CLINICAL(CONTROL SET DAT CLINICAL)-THE CONTROL SET DAT CLINICAL IS FOR USE AS AN ASSAYED CONTROL IN THE ROCHE TEST SYSTEM FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF DRUGS OF ABUSE IN HUMAN URINE ON

	AUTOMATED CLINICAL CHEMISTRY ANALYZERS AS LISTED ABOVE IN SYSTEM INFORMATION.,ELECSYS SARS-COV-2 ANTIGEN(ELECSYS SARS-COV-2 ANTIGEN)-ELECSYS SARS COV 2 ANTIGEN IS AN IMMUNOASSAY FOR THE IN VITRO QUALITATIVE DETECTION OF THE NUCLEOCAPSID ANTIGEN OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS COV 2) IN NASOPHARYNGEAL AND OROPHARYNGEAL SWAB SAMPLES FROM PATIENTS WITH SIGNS AND SYMPTOMS SUGGESTIVE OF COVID 19, OR KNOWN OR SUSPECTED EXPOSURE TO SARS COV 2. THE TEST IS INTENDED AS AN AID IN THE DIAGNOSIS OF SARS COV 2 INFECTION. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON COBAS E IMMUNOASSAY ANALYZERS.,ROCHE CARDIAC POC TROPONIN T(ROCHE CARDIAC POC TROPONIN T)-QUANTITATIVE IMMUNOLOGICAL TEST FOR THE DETECTION OF CARDIAC TROPONIN T IN HEPARINIZED VENOUS BLOOD FOR USE WITH THE COBAS INSTRUMENT. THE TEST IS INTENDED AS AN EARLY AID IN DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION AND IDENTIFICATION OF PATIENTS WITH AN ELEVATED MORTALITY RISK,CALSET ANTIP53 (CALSET ANTIP53)-CALSET ANTI-P53 IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS ANTI-P53 ASSAY ON COBAS E IMMUNOASSAY ANALYZERS.,TINA-QUANT D-DIMER GEN.2(TINA-QUANT D-DIMER GEN.2)-IN VITRO TEST FOR THE QUANTITATIVE IMMUNOLOGICAL DETERMINATION OF FIBRIN DEGRADATION PRODUCTS (DDIMER AND XOLIGOMERS) IN CITRATED PLASMA ON INDICATED COBAS T ANALYZERS. IN CONJUNCTION WITH A NONHIGH CLINICAL PROBABILITY ASSESSMENT, A NORMAL DDIMER RESULT (LESS THAN 0.5 MICROGRAM FEU/ML) IS INTENDED AS AN AID IN THE EXCLUSION OF DEEP VEIN THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE).,ELECSYS DIGOXIN(ELECSYS DIGOXIN)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF DIGOXIN IN HUMAN SERUM AND PLASMA. MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF DIGOXIN OVERDOSE AND IN MONITORING LEVELS OF DIGOXIN TO ENSURE PROPER THERAPY.,ELECSYS TROPONIN T HS(ELECSYS TROPONIN T HS)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN T IN HUMAN SERUM AND PLASMA. THIS ASSAY CAN BE USED AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF ACUTE CORONARY SYNDROME TO IDENTIFY NECROSIS, E.G. ACUTE MYOCARDIAL INFARCTION.,CRP T-CONTROL N(CRP T-CONTROL N)-CRP T CONTROL N IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS.,IGA (IMMUNOGLOBULIN A)(IGA (IMMUNOGLOBULIN A))-IN VITRO TEST FOR THE QUANTITATIVE IMMUNOLOGICAL DETERMINATION OF HUMAN IMMUNOGLOBULIN A

	IN SERUM AND PLASMA ON COBAS INTEGRA SYSTEMS. IN ADDITION TO THE STANDARD APPLICATION (TEST IGA, TEST ID 0075), THE SENSITIVE APPLICATION (TEST IGAP, TEST ID 0175) IS DESIGNED FOR THE QUANTITATIVE DETERMINATION OF LOW IGA CONCENTRATIONS IN E.G. PEDIATRIC SAMPLES.,TROPONIN T HS CALSET(TROPONIN T HS CALSET)-TROPONIN T HS CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS TROPONIN T HS ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,CRPLX(CRPLX)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF C REACTIVE PROTEIN IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,AMPII(AMPII)-AMPHETAMINES II (AMPII) IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETECTION OF AMPHETAMINES AND METHAMPHETAMINES IN HUMAN URINE ON COBAS INTEGRA SYSTEMS AT CUTOFF CONCENTRATIONS OF 300 NG/ML, 500 NG/ML AND 1000 NG/ML WHEN CALIBRATED WITH D METHAMPHETAMINE. SEMI-QUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. SEMI-QUANTITATIVE ASSAYS ARE INTENDED TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS). AMPHETAMINES II PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GC/MS IS THE PREFERRED CONFIRMATORY METHOD.1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED., BARB(BARB)-BARBITURATES (BARB) IS AN IN VITRO DIAGNOSTIC TEST FOR THE SEMI-QUANTITATIVE AND QUALITATIVE DETECTION OF BARBITURATES IN HUMAN URINE AT A CUTOFF CONCENTRATION OF 200 NG/ML ON COBAS INTEGRA SYSTEMS. SEMI-QUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. SEMI-QUANTITATIVE ASSAYS ARE INTENDED TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY GC/MS).BARBITURATES PLUS PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A-MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GC MS IS THE PREFERRED CONFIRMATORY METHOD.1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG

	OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ACET2(ACET2)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF ACETAMINOPHEN OVERDOSE IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,PHNO(PHNO)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF PHENOBARBITAL IN SERUM OR HEPARINIZED PLASMA ON COBAS INTEGRA SYSTEMS.,CONTROL SET DAT I(CONTROL SET DAT I)-THE CONTROL SET DAT I IS FOR USE AS AN ASSAYED CONTROL IN THE ROCHE TEST SYSTEM FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF DRUGS OF ABUSE IN HUMAN URINE ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS AS LISTED ABOVE IN SYSTEM INFORMATION.,ACETA (ACETA)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TOXIC LEVELS OF ACETAMINOPHEN IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,CON 2(CON 2)-CONTROL 2 IS USED FOR QUALITY CONTROL OF ROCHE COAGULATION ASSAYS ON INDICATED COBAS T ANALYZERS.,PT SCREEN(PT SCREEN)-IN VITRO ASSAY FOR THE DETERMINATION OF PROTHROMBIN TIME IN CITRATED PLASMA ON INDICATED COBAS T ANALYZER.,AT(AT)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTITHROMBIN ACTIVITY IN CITRATED PLASMA ON THE INDICATED COBAS T ANALYZERS. THE ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF ANTITHROMBIN DEFICIENCY.,A1CX3(A1CX3)-THE TINA-QUANT HEMOGLOBIN A1CDX GEN.3 ASSAY IS INTENDED FOR USE AS AN AID IN DIAGNOSIS OF DIABETES AND AS AN AID IN IDENTIFYING PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. IT IS AN IN VITRO DIAGNOSTICS REAGENT SYSTEM INTENDED FOR QUANTITATIVE DETERMINATION OF MMOL/MOL HEMOGLOBIN A1C (IFCC) AND % HEMOGLOBIN A1C (DCCT/NGSP) IN HEMOLYSATE OR WHOLE BLOOD ON THE ROCHE/HITACHI COBAS C 513 CLINICAL CHEMISTRY ANALYZER. HBA1C DETERMINATIONS ARE USEFUL FOR MONITORING OF LONG-TERM BLOOD GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS.,PRECISET DAT PLUS I (PRECISET DAT PLUS I)-THE PRECISET DAT PLUS I CALIBRATORS ARE DESIGNED FOR THE CALIBRATION OF THE ROCHE ASSAYS FOR DRUGS OF ABUSE IN HUMAN URINE ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS,SALI(SALI)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TOXIC LEVELS OF SALICYLATE IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS., PRECIMAT CHROMOGEN(PRECIMAT CHROMOGEN)-PRECIMAT CHROMOGEN IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE ENCLOSED VALUE SHEET,ELECSYS CMV IGG AVIDITY(ELECSYS CMV IGG AVIDITY)-IMMUNOASSAY FOR THE IN

	VITRO QUALITATIVE DETERMINATION OF THE AVIDITY OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA. ,IGA-2(IGA-2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGA IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,TDM CONTROL SET(TDM CONTROL SET)-THE TDM CONTROL SET IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHOD AS SPECIFIED IN THE VALUE SHEETS.,PT CAL SET(PT CAL SET)-PT CAL SET IS USED FOR CALIBRATION OF THE SPECIFIED PT ASSAYS ON INDICATED COBAS T ANALYZERS IN UNITS % OF NORMAL AND INR. IN ADDITION THE PT CAL SET CAN BE USED TO DETERMINE THE LOCAL ISI.,ISE CALIBRATOR INDIRECT / URINE (ISE CALIBRATOR INDIRECT / URINE)-FOR USE IN THE CALIBRATION OF ION SELECTIVE ELECTRODES ON THE COBAS C SYSTEM WITHIN EACH ISE MEASURING CYCLE.,FRA(FRA)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF GLYCATED PROTEINS (FRUCTOSAMINE) IN HUMAN SERUM AND PLASMA.,ISE INTERNAL STANDARD GEN.2(ISE INTERNAL STANDARD GEN.2)-THE ISE MODULE OF THE ROCHE/HITACHI SYSTEMS IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM AND CHLORIDE IN SERUM, PLASMA OR URINE USING ION SELECTIVE ELECTRODES.,ISE CALIBRATOR DIRECT(ISE CALIBRATOR DIRECT)-THE ISE CALIBRATOR DIRECT IS AN IN VITRO DIAGNOSTIC CALIBRATOR INTENDED FOR THE CALIBRATION OF THE COBAS INTEGRA ISE MODULE FOR THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM, CHLORIDE AND LITHIUM.,A1C-3(A1C-3)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF MMOL/MOL HEMOGLOBIN (IFCC) AND % HEMOGLOBIN A1C (DCCT/NGSP) IN WHOLE BLOOD OR HEMOLYSATE ON ROCHE/HITACHI COBAS C SYSTEMS. HBA1C DETERMINATIONS ARE USEFUL MONITORING OF LONG-TERM BLOOD GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. MOREOVER, THIS TEST IS TO BE USED AS AN AID IN DIAGNOSIS OF DIABETES AND IDENTIFYING PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES.,ISE CALIBRATION KIT (ISE CALIBRATION KIT)-FOR USE IN THE CALIBRATION OF ION SELECTIVE ELECTRODES ON THE COBAS C SYSTEM.,ASO(ASO)-IN VITRO TEST FOR THE QUANTITATIVE IMMUNOLOGICAL DETERMINATION OF HUMAN ANTISTREPTOLYSIN O IN SERUM ON COBAS INTEGRA SYSTEMS.,C.F.A.S. PAC(C.F.A.S. PAC)-C.F.A.S. (CALIBRATOR FOR AUTOMATED SYSTEMS) PAC (PREALBUMIN-ASLOCERULOPLASMIN) IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE VALUE SHEETS.,AT(AT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF HUMAN

	ANTITHROMBIN ACTIVITY IN PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,LAMB2(LAMB2)-IMMUNOTURBIDIMETRIC IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF BOUND AND FREE IMMUNOGLOBULINS OF THE LAMBDA LIGHT CHAIN TYPE IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,CON P (CON P)-CON P IS USED FOR QUALITY CONTROL OF SPECIFIED COAGULATION ASSAYS ON INDICATED COBAS T COAGULATION ANALYZERS.,CON 4(CON 4)-CON 4 IS USED FOR QUALITY CONTROL OF SPECIFIED COAGULATION ASSAYS ON INDICATED COBAS T COAGULATION ANALYZERS.,CON N(CON N)-CON N IS USED FOR QUALITY CONTROL OF SPECIFIED COAGULATION ASSAYS ON INDICATED COBAS T COAGULATION ANALYZERS.,ALBT2(ALBT2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN URINE, SERUM, PLASMA AND CSF (ALBUMIN CSF/SERUM RATIO) ON ROCHE/HITACHI COBAS C SYSTEMS.,ASLOT(ASLOT)-IN VITRO TEST FOR THE QUANTITATIVE IMMUNOLOGICAL DETERMINATION OF ANTISTREPTOLYSIN O IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,AAT2(AAT2)-IN VITRO TEST FOR THE QUANTITATIVE IMMUNOLOGICAL DETERMINATION OF HUMAN ALPHA 1ANTITRYPSIN IN HUMAN SERUM AND PLASMA ON COBAS INTEGRA SYSTEMS.,PYP (PYRIDOXAL PHOSPHATE)(PYP (PYRIDOXAL PHOSPHATE))-FOR THE MODIFICATION OF ALANINE AMINOTRANSFERASE/GLUTAMIC PYRUVIC TRANSAMINASE (ALT/GPT) OR ASPARTATE AMINOTRANSFERASE/GLUTAMIC OXALOACETIC TRANSAMINASE (AST/GOT) REAGENTS TOINCLUDE PYRIDOXAL 5 PHOSPHATE. , ELECSYS BRAHMS PCT(ELECSYS BRAHMS PCT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PCT (PROCALCITONIN) IN HUMAN SERUM AND PLASMA. THE ELECSYS BRAHMS PCT ASSAY CAN BE USED TO AID IN THE EARLY DETECTION OF CLINICALLY RELEVANT BACTERIAL INFECTIONS. THE ELECSYS BRAHMS PCT ASSAY IS INDICATED AS AN AID TO BE USED IN CONJUNCTION WITH CLINICAL EVALUATION FOR: THE EARLY DETECTION OF CLINICALLY RELEVANT BACTERIAL INFECTIONS, THE ASSESSMENT OF THE DEGREE OF SEVERITY AND THE PROGNOSIS OF THE OUTCOME OF SYSTEMIC BACTERIAL INFECTION, SEPSIS, AND SEPTIC SHOCK, IDENTIFYING PATIENTS THAT BENEFIT FROM ANTIBIOTIC TREATMENT, MONITORING OF ANTIBIOTIC THERAPY, ASSESSING THE SUCCESS OF ANTIBIOTIC THERAPY IN PATIENTS WITH SUSPECTED OR CONFIRMED BACTERIAL INFECTION. ,ASTL (ASTL)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE (AST) IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS,APTT LOWS(APTT LOWS)-IN VITRO ASSAY FOR THE DETERMINATION OF ACTIVATED

	PARTIAL THROMBOPLASTIN TIME IN CITRATED PLASMA ON INDICATED COBAS T ANALYZERS.,C.F.A.S (CALIBRATOR FOR AUTOMATED SYSTEMS)(C.F.A.S (CALIBRATOR FOR AUTOMATED SYSTEMS))-CALIBRATOR FOR AUTOMATED SYSTEMS (C.F.A.S.) IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE VALUE SHEETS.,THROMBIN TIME(THROMBIN TIME)-IN VITRO ASSAY FOR THE DETERMINATION OF THROMBIN TIME IN CITRATED HUMAN PLASMA ON INDICATED COBAS T ANALYZERS.,PRECICONTROL RUBELLA IGG(PRECICONTROL RUBELLA IGG)-PRECICONTROL RUBELLA IGG IS USED FOR QUALITY CONTROL OF THE ELECSYS RUBELLA IGG IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS,COAGUCHEK XS PT CONTROLS (COAGUCHEK XS PT CONTROLS)-COAGUCHEK XS PT CONTROLS ARE USED FOR SYSTEM CHECKS AND QUALITY CONTROL TESTING OF PROTHROMBIN TIME) WITH THE COAGUCHEK XS PLUS OR COAGUCHEK XS PRO METER AND COAGUCHEK XS PT TEST STRIPS., AMIK2(AMIK2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF AMIKACIN IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS,THEO2(THEO2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF THEOPHYLLINE IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,CHECK (CHECK)-REAGENT PIPETTING CHECK.,PPX(PPX)-PROPOXYPHENE PLUS (PPX) IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETECTION OF PROPOXYPHENE AND ITS METABOLITES IN HUMAN URINE ON ROCHE/HITACHI COBAS C SYSTEMS AT A CUTOFF CONCENTRATION OF 300 NG/ML. SEMIQUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. MEASUREMENTS OBTAINED BY THIS DEVICE ARE USED IN THE DIAGNOSIS OF PROPOXYPHENE USE OR ABUSE AND DO NOT MEASURE A LEVEL OF TOXICITY. SEMIQUANTITATIVE ASSAYS ARE INTENDED TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GCMS). PROPOXYPHENE PLUS PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GCMS IS THE PREFERRED CONFIRMATORY METHOD.1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,SDR II(SDR II)-THE COBAS FP SAMPLE DILUTION REAGENT II IS AN AQUEOUS SOLUTION INTENDED FOR USE AS A

	GENERIC DILUENT FOR ALL COBAS TDM ASSAYS PERFORMED ON COBAS INTEGRA CHEMISTRY SYSTEMS,PRECICONTROL CARDIAC II (PRECICONTROL CARDIAC II)-PRECICONTROL CARDIAC II IS USED FOR QUALITY CONTROL OF SPECIFIED IMMUNOASSAYS ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,BENZ(BENZ)-BENZODIAZEPINES PLUS (BENZ) IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETECTION OF BENZODIAZEPINES IN HUMAN URINE ON ROCHE/HITACHI COBAS C SYSTEMS AT CUTOFF CONCENTRATIONS OF 100 NG/ML, 200 NG/ML, AND 300 NG/ML. SEMI-QUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. SEMI-QUANTITATIVE ASSAYS ARE INTENDED TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS).BENZODIAZEPINES PLUS PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GC/MS IS THE PREFERRED CONFIRMATORY METHOD.1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,C3C-2(C3C-2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT C3C IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,OPI (OPI)-OPIATES 300/2000 (OPI) IS AN IN VITRO DIAGNOSTIC TEST FOR THE SEMIQUANTITATIVE AND QUALITATIVE DETECTION OF MORPHINE AND ITS METABOLITES IN HUMAN URINE AT CUTOFF CONCENTRATIONS OF 300 NG/ML AND 2000 NG/ML ON COBAS INTEGRA SYSTEMS. SEMIQUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. SEMIQUANTITATIVE ASSAYS ARE INTENDED TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS). OPIATES 300/2000 PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GC/MS IS THE PREFERRED CONFIRMATORY METHOD.1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,BILT3(BILT3)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN SERUM AND

	PLASMA OF ADULTS AND NEONATES ON ROCHE/HITACHI COBAS C SYSTEMS,TOBR2(TOBR2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TOBRAMYCIN IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS,PRECIPATH PUC(PRECIPATH PUC)-PRECIPATH PUC (PROTEINS IN URINE/CSF) IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS., ISE REFERENCE SOLUTION(ISE REFERENCE SOLUTION)-TO ESTABLISH A STABLE ION REFERENCE POTENTIAL DURING THE ISE MEASURING CYCLE ON THE COBAS C SYSTEM.,ALB2(ALB2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM AND PLASMA ON THE COBAS C SYSTEM.,C4-2(C4-2)-IMMUNOTURBIDIMETRIC ASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HUMAN C4 IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,COMBUR 10 TEST(COMBUR 10 TEST)-TEST STRIPS FOR THE SEMIQUANTITATIVE DETERMINATION OF SPECIFIC GRAVITY (SG), PH, LEUCOCYTES (LEU), NITRITE (NIT), PROTEIN (PRO), GLUCOSE (GLU), KETONES (KET), UROBILINOGEN (UBG), BILIRUBIN (BIL) AND BLOOD (ERY/HB) IN URINE FOR EVALUATION BY VISUAL READING. ,MTQL(MTQL)-METHAQUALONE (MTQL) IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETECTION OF METHAQUALONE AND ITS METABOLITES IN HUMAN URINE ON ROCHE/HITACHI COBAS C SYSTEMS AT A CUTOFF CONCENTRATION OF 300 NG/ML. SEMIQUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. SEMIQUANTITATIVE ASSAYS ARE INTENDED TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GCMS). METHAQUALONE PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GCMS IS THE PREFERRED CONFIRMATORY METHOD.1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,MPA(MPA)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TOTAL MYCOPHENOLIC ACID IN SERUM OR PLASMA AS AN AID IN THE MANAGEMENT OF MYCOPHENOLIC ACID THERAPY IN RENAL AND CARDIAC TRANSPLANT PATIENTS ON ROCHE/HITACHI COBAS C SYSTEMS.,AMMONIA/ETHANOL/CO2 CONTROL NORMAL (AMMONIA/ETHANOL/CO2 CONTROL NORMAL)-AMMONIA/ETHANOL/CO2 CONTROL NORMAL IS FOR USE IN

	QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS., FREE PHENYTOIN CALIBRATORS(FREE PHENYTOIN CALIBRATORS)-COBAS FP FREE PHENYTOIN CALIBRATORS ARE FOR USE IN THE CALIBRATION OF ROCHE METHODS FOR THE QUANTITATIVE DETERMINATION OF FREE PHENYTOIN IN HUMAN SERUM AND PLASMA ON ROCHE CLINICAL CHEMISTRY ANALYZERS.,C-F-A-S-MYOGLOBIN(C-F-A-S- MYOGLOBIN)-C.F.A.S. (CALIBRATOR FOR AUTOMATED SYSTEMS) MYOGLOBIN IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE VALUE SHEETS.,ISE STANDARD HIGH(ISE STANDARD HIGH)-ISE STANDARD HIGH IS FOR USE IN THE CALIBRATION OF ION SELECTIVE ELECTRODES ON ROCHE/HITACHI ANALYZERS AND COBAS C ANALYZERS.,CONTROL SET DAT III(CONTROL SET DAT III)-THE CONTROL SET DAT III IS FOR USE AS AN ASSAYED CONTROL IN THE ROCHE TEST SYSTEM FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF DRUGS OF ABUSE IN HUMAN URINE ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS AS LISTED ABOVE IN SYSTEM INFORMATION,CALSET CK-MB(CALSET CK-MB)-CALSET CK MB IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS CK MB ASSAY ON THE COBAS E IMMUNOASSAY ANALYZER., DIGOXIN CALSET(DIGOXIN CALSET)-DIGOXIN CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS DIGOXIN ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,THEO(THEO)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF THEOPHYLLINE IN SERUM OR HEPARINIZED PLASMA ON COBAS INTEGRA SYSTEMS.,ELECSYS DIGITOXIN(ELECSYS DIGITOXIN)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF DIGITOXIN IN HUMAN SERUM AND PLASMA. THE MEASUREMENT IS USED FOR IDENTIFYING AND TREATING DIGITOXIN INTOXICATION AND MONITORING DIGITOXIN LEVELS TO SUPPORT A THERAPY. ,STFR (STFR)-IN VITRO TEST FOR THE QUANTITATIVE IMMUNOLOGICAL DETERMINATION OF SOLUBLE TRANSFERRIN RECEPTOR IN HUMAN SERUM AND PLASMA ON COBAS INTEGRA SYSTEMS. , AMMONIA/ETHANOL/CO2 CALIBRATOR(AMMONIA/ETHANOL/CO2 CALIBRATOR)-AMMONIA/ETHANOL/CO 2 CALIBRATOR IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE VALUE SHEETS.,MYOGLOBIN CONTROL SET(MYOGLOBIN CONTROL SET)-MYOGLOBIN CONTROL SET IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS.,SI2(SI2)-IN VITRO TEST FOR THE SEMI-QUANTITATIVE DETERMINATION OF THE LIPEMIA

	INDEX, HEMOLYSIS INDEX AND ICTERUS INDEX IN HUMAN SERUM AND PLASMA ON COBAS C SYSTEMS.,ELECSYS CK-MB STAT(ELECSYS CK-MB STAT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THE MB ISOENZYME OF CREATINE KINASE IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. ,COAGUCHEK XS PT TEST PST (COAGUCHEK XS PT TEST PST)-THE COAGUCHEK XS PT TEST PST IS AN IN-VITRO ASSAY FOR THE DETERMINATION OF PROTHROMBIN TIME (PT) USING THE COAGUCHEK INRANGE / COAGUCHEK XS METER. THE TEST USES FRESH CAPILLARY WHOLE BLOOD AND IS INTENDED FOR PATIENT SELF-TESTING ONLY.,CONTROL TEST M (CONTROL TEST M)-THE CONTROL TEST M CALIBRATION STRIP IS USED TO PERFORM THE CALIBRATION OF THE COBAS AND URISYS REFLECTANCE PHOTOMETERS AND TO CHECK THE ANALYZERS PERFORMANCE,QUIN2(QUIN2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF QUINIDINE IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,CYSC2(CYSC2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,PROC(PROC)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF PROCAINAMIDE IN SERUM OR HEPARINIZED PLASMA ON COBAS INTEGRA SYSTEMS.,CREJ2(CREJ2) -IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE ON ROCHE/HITACHI COBAS C SYSTEMS.,START (ANTIGEN EXCESS REAGENT)(START (ANTIGEN EXCESS REAGENT))-IN VITRO REAGENT FOR THE DETECTION OF ANTIGEN EXCESS IN URINE AND CSF SAMPLES TO BE USED IN CONJUNCTION WITH THE IN VITRO TEST TINAQUANT ALBUMIN GEN.2, CAT.NO.05167043 190,ON ROCHE/HITACHI COBAS C SYSTEMS.,PRECICONTROL CHAGAS (PRECICONTROL CHAGAS)-PRECICONTROL CHAGAS IS USED FOR QUALITY CONTROL OF THE ELECSYS CHAGAS IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,TOTAL MPA CONTROLS(TOTAL MPA CONTROLS)-THE ROCHE TOTAL MPA CONTROLS ARE FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHOD AS SPECIFIED IN THE VALUE SHEETS.,CELL WASH SOLUTION II / ACID WASH(CELL WASH SOLUTION II / ACID WASH)-CELL WASH SOLUTION II / ACID WASH IS USED AS ACID WASH SOLUTION FOR REACTION CELLS ON ROCHE/HITACHI SYSTEMS.,COAGUCHEK XS PT TEST (COAGUCHEK XS PT TEST)-TEST STRIPS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PROTHROMBIN TIME) IN CAPILLARY BLOOD OR FROM NON-ANTICOAGULATED VENOUS BLOOD USING

	COAGUCHEK XS/XS PLUS/XS PRO METERS.,CK-MB STAT CALSET(CK-MB STAT CALSET)-CK MB STAT CALSET IS USED FOR CALIBRATING THE QUANTITATIVE ELECSYS CK MB STAT ASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS.,CLEAN(CLEAN)-WASH SOLUTION FOR EXTRA WASH CYCLES FOR THE REAGENT/SAMPLE PROBE ON THE COBAS C 111 ANALYZER.,GLDH3(GLDH3)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF GLUTAMATE DEHYDROGENASE (GLDH) IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,C.F.A.S. IGA/IGM CSF(C.F.A.S. IGA/IGM CSF)-C.F.A.S. (CALIBRATOR FOR AUTOMATED SYSTEMS) IGA/IGM CSF IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE VALUE SHEETS.,COBAS U PACK(COBAS U PACK)-THE COBAS U PACK IS A CASSETTE WITH TESTSTRIPS FOR THE IN VITRO QUALITATIVE OR SEMI QUANTITATIVE DETERMINATION OF PH, LEUKOCYTES , NITRITE, PROTEIN, GLUCOSE, KETONES, UROBILINOGEN, BILIRUBIN, COLOR AND ERYTHROCYTES IN URINE WITH THE COBAS URINE ANALYZER.,COMBUR 10 TEST M(COMBUR 10 TEST M)-TEN PATCH TEST STRIP FOR THE SEMI QUANTITATIVE DETERMINATION OF SPECIFIC GRAVITY, PH, LEUKOCYTES, NITRITE, PROTEIN, GLUCOSE, KETONE BODIES, UROBILINOGEN, BILIRUBIN AND BLOOD IN URINE,ASTLP(ASTLP)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE (AST) WITH PYRIDOXAL PHOSPHATE ACTIVATION IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS,AMPS2(AMPS2)-AMPHETAMINES II (AMPS2) IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETECTION OF AMPHETAMINES AND METHAMPHETAMINES IN HUMAN URINE ON ROCHE/HITACHI COBAS C SYSTEMS AT CUTOFF CONCENTRATIONS OF 300 NG/ML, 500 NG/ML, AND 1000 NG/ML WHEN CALIBRATED WITH D METHAMPHETAMINE. SEMI-QUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. SEMI-QUANTITATIVE ASSAYS ARE INTENDED TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC MS). AMPHETAMINES II PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GC MS IS THE PREFERRED CONFIRMATORY METHOD.1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE

	RESULTS ARE USED.,PRECICONTROL CMV IGG AVIDITY (PRECICONTROL CMV IGG AVIDITY)-PRECICONTROL CMV IGG AVIDITY IS USED FOR QUALITY CONTROL OF THE ELECSYS CMV IGG AVIDITY IMMUNOASSAY ON THE ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. ,D DIMER GEN.2 CALIBRATOR SET(D DIMER GEN.2 CALIBRATOR SET)-DDIMER GEN.2 CALIBRATOR SET IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE ENCLOSED VALUE SHEETS.,CERU(CERU)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CERULOPLASMIN IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,IGM-C (IGM-C)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGM SPECIFICALLY IN HUMAN CEREBROSPINAL FLUID AND CORRESPONDING HUMAN SERUM / PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,CYSTATIN C CONTROL SET, GEN-2(CYSTATIN C CONTROL SET, GEN-2)-CYSTATIN C CONTROL SET IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHODS.,ISE DILUENT GEN.2(ISE DILUENT GEN. 2)-THE ISE MODULE OF THE ROCHE/HITACHI COBAS C SYSTEMS IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM, AND CHLORIDE IN SERUM, PLASMA OR URINE USING ION-SELECTIVE ELECTRODES.,D-DI2(D-DI2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF FIBRIN DEGRADATION PRODUCTS INCLUDING DDIMER AND XOLIGOMERS IN HUMAN PLASMA ON ROCHE AUTOMATED CLINICAL CHEMISTRY ANALYZERS., D DIMER GEN.2 CONTROL I/II(D DIMER GEN.2 CONTROL I/II)-DDIMER GEN.2 CONTROL I/II IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHODS AS SPECIFIED IN THE ENCLOSED VALUE SHEETS.,CHE2 (CHE2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CHOLINESTERASE IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,ISE ETCHER(ISE ETCHER)-THE ISE ETCHER IS A CLEANING SOLUTION INTENDED FOR USE WITH THE COBAS INTEGRA AND COBAS C 111 ISE MODULES FOR CLEANING THE ION-SELECTIVE SODIUM ELECTRODE.,ELECSYS GDF-15(ELECSYS GDF-15)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF GROWTH DIFFERENTIATION FACTOR 15 (GDF 15) IN HUMAN SERUM AND PLASMA. THE ELECSYS GDF 15 ASSAY IS INTENDED AS AN AID IN RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROME (ACS) OR CHRONIC HEART FAILURE (CHF). ,CHE(CHE)-FOR THE QUANTITATIVE DETERMINATION OF CHOLINESTERASE IN SERUM, PLASMA AND WHOLE BLOOD MANUALLY AND ON ROCHE AUTOMATED CLINICAL CHEMISTRY ANALYZERS.,C.F.A.S. PUC(C.F.A.S. PUC)-C.F.A.S. (CALIBRATOR FOR

	AUTOMATED SYSTEMS) PUC (PROTEINS IN URINE/CSF) IS FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE VALUE SHEETS.,AAGP2(AAGP2)-IN VITRO TEST FOR THE QUANTITATIVE IMMUNOLOGICAL DETERMINATION OF HUMAN ALPHA 1ACID GLYCOPROTEIN IN HUMAN SERUM AND PLASMA ON COBAS INTEGRA SYSTEMS.,AMMONIA/ETHANOL/CO2 CONTROL ABNORMAL (AMMONIA/ETHANOL/CO2 CONTROL ABNORMAL)-AMMONIA/ETHANOL/CO2 CONTROL ABNORMAL IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS., PRECICONTROL CLINCHEM MULTI 2(PRECICONTROL CLINCHEM MULTI 2)-PRECICONTROL CLINCHEM MULTI 2 IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS., COAGUCHEK PT TEST(COAGUCHEK PT TEST)-THE COAGUCHEK PT TEST IS AN IN-VITRO ASSAY FOR THE DETERMINATION OF PROTHROMBIN TIME (PT) USING THE COAGUCHEK PRO II METER. THE TEST CAN BE USED WITH EITHER CAPILLARY, VENOUS, OR ARTERIAL FRESH WHOLE BLOOD,HCYS(HCYS)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TOTAL LHOMOCYSTEINE IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS. THE ASSAY CAN ASSIST IN THE DIAGNOSIS OF PATIENTS SUSPECTED OF HAVING HYPERHOMOCYSTEINEMIA OR HOMOCYSTINURIA.,ACP2(ACP2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ACID PHOSPHATASE IN HUMAN SERUM ON ROCHE/HITACHI COBAS C SYSTEMS.,MICRAL-TEST (MICRAL-TEST)-30 TEST STRIPS FOR THE IMMUNOLOGICAL, SEMI-QUANTITATIVE IN VITRO DETERMINATION OF URINARY ALBUMIN OR EVALUATION BY VISUAL READING.,PCP(PCP)-PHENCYCLIDINE PLUS (PCP) IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETECTION OF PHENCYCLIDINE AND ITS METABOLITES IN HUMAN URINE ON ROCHE/HITACHI COBAS C SYSTEMS AT A CUTOFF CONCENTRATION OF 25 NG/ML. SEMIQUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. SEMIQUANTITATIVE ASSAYS ARE INTENDED TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GCMS). PHENCYCLIDINE PLUS PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GCMS IS THE PREFERRED CONFIRMATORY METHOD.1

	CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,VALP2(VALP2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF VALPROIC ACID IN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,COBAS U CALIBRATION STRIP(COBAS U CALIBRATION STRIP)-THE CALIBRATION STRIP IS USED TO PERFORM THE CALIBRATION OF THE COBAS U URINE ANALYZER,HEMOLYZING REAGENT(HEMOLYZING REAGENT)-THE HEMOLYZING REAGENT IS USED AS A DILUENT FOR THE TINE-QUANT A1C-3 GEN.2,C.F.A.S. DAT QUALITATIVE PLUS(C.F.A.S. DAT QUALITATIVE PLUS)-THE C.F.A.S. DAT QUALITATIVE PLUS CALIBRATOR IS DESIGNED FOR THE QUALITATIVE CALIBRATION OF THE ROCHE ASSAYS FOR DRUGS OF ABUSE IN HUMAN URINE ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS.,CLEANER(CLEANER)-CLEANER IS A WASH SOLUTION FOR SAMPLE AND REAGENT PROBES AND TUBING.,CREP2(CREP2)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE ON ROCHE/HITACHI COBAS C SYSTEMS.,MDN2(MDN2)-METHADONE II (MDN2) IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETECTION OF METHADONE IN HUMAN URINE ON ROCHE/HITACHI COBAS C SYSTEMS AT A CUTOFF CONCENTRATION OF 300 NG/ML. SEMIQUANTITATIVE TEST RESULTS MAY BE OBTAINED THAT PERMIT LABORATORIES TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM. SEMIQUANTITATIVE ASSAYS ARE INTENDED TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GCMS). METHADONE II PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GCMS IS THE PREFERRED CONFIRMATORY METHOD.1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,ETOH2(ETOH2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ETHANOL IN HUMAN SERUM, PLASMA AND URINE ON ROCHE/HITACHI COBAS C SYSTEMS.

62	IMP/IVD/2018/000040	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 IGG/IGM RAPID TEST-FOR QUALITATIVE DETECTION OF ANTIBODIES TO 2019-NCOV IN WHOLE BLOOD/SERUM/ PLASMA,CARDIAC TROPONIN I RAPID TEST CASSETTE-DETECTION OF CARDIAC TROPONIN I (CTNI) IN WHOLE BLOOD, SERUM OR PLASMA,TYPHOID TEST CASSETTE-DETECTION OF ANTIBODIES (IGG AND IGM) TO SALMONELLA TYPHI (S. TYPHI) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA,SYPHILIS RAPID TEST CASSETTE/STRIP-DETECTION OF TP ANTIBODIES (IGG AND IGM) IN WHOLE BLOOD, SERUM OR PLASMA,HCG PREGNANCY RAPID TEST CASSETTE/ STRIP/ MIDSTREAM-DETECTION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN URINE TO AID IN THE EARLY DETECTION OF PREGNANCY

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

63	IMP/IVD/2018/000042	1.License Holder Name: SANDOR MEDICAIDS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROL LEVELS 1-3(I-STAT)-AQUEOUS ASSAYED CONTROL FLUIDS ARE AVAILABLE FOR VERIFYING THE INTEGRITY OF NEWLY RECEIVED CARTRIDGES. I-STAT CONTROL LEVEL 1, 2 AND 3 ARE FORMULATED AT THREE CLINICALLY RELEVANT LEVELS WITH KNOWN PH AND WITH KNOWN CONCENTRATIONS OF: A. SODIUM B. POTASSIUM C. PCO2 D. PO2 E. CHLORIDE F. IONIZED CALCIUM G. GLUCOSE H. LACTATE I. BUN J. UREA K. CREATININE,TRICONTROLS CONTROL LEVELS 1 -3(I-STAT)-AQUEOUS-BASED CONTROL FLUIDS ARE AVAILABLE FOR VERIFYING THE INTEGRITY OF NEWLY RECEIVED CARTRIDGES. I-STAT TRICONTROLS LEVEL 1, 2 AND 3 ARE FORMULATED AT THREE CLINICALLY RELEVANT LEVELS WITH DEFINED PH AND HEMATOCRIT VALUES AND WITH KNOWN CONCENTRATIONS OF: SODIUM PCO2 GLUCOSE POTASSIUM PO2 LACTATE CHLORIDE TCO2 BUN/UREA IONIZED CALCIUM CREATININE,TRICONTROLS CALIBRATION VERIFICATION SET LEVELS 1-5(I-STAT)-CALIBRATION VERIFICATION IS A PROCEDURE INTENDED TO VERIFY THE ACCURACY OF RESULTS OVER THE ENTIRE MEASUREMENT RANGE OF A TEST. THE PERFORMANCE OF THIS PROCEDURE AT DEFINED INTERVALS MAY BE REQUIRED BY REGULATORY ACCREDITATION BODIES. WHILE THE CALIBRATION VERIFICATION SET CONTAINS FIVE LEVELS, VERIFICATION OF THE MEASUREMENT RANGE COULD BE ACCOMPLISHED USING THE LOWEST, HIGHEST AND MID LEVELS., CALIBRATION VERIFICATION SET LEVELS 1-5(I-STAT)-THIS MATERIAL IS INTENDED FOR USE TO MONITOR THE MEASUREMENTS OF: A. PH AND PCO2 AND PO2 IN BLOOD GAS ANALYZERS, B. NA, K, CL AND CA++IN ELECTROLYTE ANALYZERS, AND; C. GLUCOSE, LACTATE, BUN AND CREATININE IN ANALYZERS WHICH MEASURE THESE METABOLITES. THE CALIBRATION IS PROVIDED AT FIVE CLINICALLY SIGNIFICANT LEVELS TO MAKE POSSIBLE VERIFICATION OF INSTRUMENT PERFORMANCE AT DIFFERENT POINTS FOR EACH ANALYTE.,CHEM8+ CALIBRATION VERIFICATION LEVEL 1B(I-STAT)-THIS MATERIAL IS INTENDED FOR USE TO VERIFY THE CALIBRATION OF THE I-STAT CHEM8+ TCO2 AT THE LOW END OF THE REPORTABLE RANGE.

64	IMP/IVD/2018/000043	1.License Holder Name: SANDOR MEDICAIDS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CK-MB LEVELS 1-3(I-STAT)-I-STAT CK-MB CONTROL LEVELS 1, 2, AND 3 ARE INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL WHICH CAN BE USED TO VERIFY THE INTEGRITY OF NEWLY RECEIVED I-STAT CK-MB CARTRIDGES.,TOTAL B-HCG CONTROL CALIBRATION VERIFICATION KIT(I-STAT)-I-STAT TOTAL -HCG CALIBRATION VERIFICATION MATERIALS ARE USED TO VERIFY THE CALIBRATION OF THE I-STAT TOTAL -HCG TEST THROUGHOUT THE REPORTABLE RANGE.,TOTAL B-HCG CONTROL LEVELS 1-3(I-STAT)-I-STAT TOTAL -HCGCONTROLS LEVELS 1, 2, AND 3 ARE USED TO MONITOR PERFORMANCE OF THE I-STAT TOTAL -HCG TEST.,CTNI CALIBRATION VERIFICATION SET(I-STAT)-I-STAT CTNI CALIBRATION VERIFICATION SETS ARE INTENDED FOR USE AS AN ASSAYED PLASMA MATERIAL TO VERIFY THE GREATER PORTION OF THE REPORTABLE RANGE FOR I-STAT CTNI CARTRIDGES,ACT CONTROL LEVELS 1-2(I-STAT)-I-STAT ACT CONTROL LEVEL 1 AND 2 ARE INTENDED FOR USE TO VERIFY THE INTEGRITY OF NEWLY RECEIVED I-STAT ACT CARTRIDGES. THE CONTROLS PRODUCE CLOTTING TIMES EXPECTED FOR MODERATE AND HIGH LEVEL HEPARINIZATION TO INDICATE THAT THE CARTRIDGES ARE FUNCTIONING PROPERLY.,PT CONTROL LEVELS 1-2(I-STAT)-I-STAT PT CONTROL LEVEL 1 (NORMAL) AND LEVEL 2 (ABNORMAL)ARE USED TO VERIFY THE INTEGRITY OF NEWLY RECEIVED PT/INR CARTRIDGES.,BNP CONTROL LEVELS 1-3(I-STAT)-I-STAT BNP CONTROL LEVELS 1, 2, AND 3 ARE INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL WHICH CAN BE USED TO VERIFY THE INTEGRITY OF NEWLY RECEIVED I-STAT BNP CARTRIDGES.,BNP CALIBRATION VERIFICATION SET (I-STAT)-THE I-STAT BNP CALIBRATION VERIFICATION SETS ARE INTENDED FOR USE AS AN ASSAYED PLASMA MATERIAL TO VERIFY THE GREATER PORTION OF THE REPORTABLE RANGE FOR I-STAT BNP CARTRIDGES.,CTNI CONTROL LEVELS 1-3(I-STAT)-I-STAT CTNI CONTROL LEVELS 1, 2, AND 3 ARE INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL WHICH CAN BE USED TO VERIFY THE INTEGRITY OF NEWLY RECEIVED I-STAT CTNI CARTRIDGES.,CK-MB CALIBRATION VERIFICATION SET(I-STAT)-I-STAT CK-MB CALIBRATION VERIFICATION SETS ARE INTENDED FOR USE AS AN ASSAYED PLASMA MATERIAL TO VERIFY THE GREATER PORTION OF THE REPORTABLE RANGE FOR I-STAT CKMB CARTRIDGES.

65	IMP/IVD/2018/000045	1.License Holder Name: SANDOR MEDICAIDS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BNP CARTRIDGE(I-STAT)-THE I-STAT BNP TEST IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF B-TYPE NATRIURETIC PEPTIDE (BNP) IN WHOLE BLOOD OR PLASMA SAMPLES USING EDTA AS THE ANTICOAGULANT. BNP MEASUREMENTS CAN BE USED AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF THE SEVERITY OF CONGESTIVE HEART FAILURE.,CREA CARTRIDGE(I-STAT)-THE TEST FOR CREATININE, AS PART OF THE I-STAT SYSTEM, IS FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN WHOLE BLOOD ON THE I-STAT HANDHELD. CREATININE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASES, IN MONITORING RENAL DIALYSIS, AND AS A CALCULATION BASIS FOR MEASURING OTHER URINE ANALYTES. ,EG6+ CARTRIDGE(I-STAT)-THE TEST FOR PCO2, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF CARBON DIOXIDE PARTIAL PRESSURE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PCO2MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES. BICARBONATE IS USED IN THE DIAGNOSIS AND TREATMENT OF NUMEROUS POTENTIALLY SERIOUS DISORDERS ASSOCIATED WITH CHANGES IN BODY ACID-BASE BALANCE. THE TEST FOR PH, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PH IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PH MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES. THE TEST FOR HEMATOCRIT, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PACKED RED BLOOD CELL VOLUME FRACTION IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. HEMATOCRIT MEASUREMENTS CAN AID IN THE DETERMINATION AND MONITORING OF NORMAL OR ABNORMAL TOTAL RED CELL VOLUME STATUS INCLUDING, BUT NOT LIMITED TO, CONDITIONS SUCH AS ANEMIA, ERYTHROCYTOSIS, AND BLOOD LOSS RELATED TO TRAUMA AND SURGERY. THE TEST FOR PO2, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF OXYGEN PARTIAL PRESSURE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PO2 MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES. THE TEST FOR SODIUM, AS PART OF THE I-STAT

	SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. SODIUM MEASUREMENTS ARE USED FOR MONITORING ELECTROLYTE IMBALANCES. THE TEST FOR POTASSIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF POTASSIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. POTASSIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS AND MONITORING OF DISEASES AND CLINICAL CONDITIONS THAT MANIFEST HIGH AND LOW POTASSIUM LEVELS.,CK-MB CARTRIDGE(I-STAT)-THE I-STAT CK-MB TEST IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF CREATINE KINASE MB MASS IN WHOLE BLOOD OR PLASMA SAMPLES. CK-MB MEASUREMENTS CAN BE USED AS AN AID IN THE DIAGNOSIS AND TREATMENT OF MYOCARDIAL INFARCTION (MI).,G3+ CARTRIDGE(I-STAT)-THE TEST FOR PCO2, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF CARBON DIOXIDE PARTIAL PRESSURE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PCO2 MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES. BICARBONATE IS USED IN THE DIAGNOSIS AND TREATMENT OF NUMEROUS POTENTIALLY SERIOUS DISORDERS ASSOCIATED WITH CHANGES IN BODY ACID-BASE BALANCE. THE TEST FOR PH, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PH IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PH MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES. THE TEST FOR PO2, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF OXYGEN PARTIAL PRESSURE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PO2 MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES.,EC8+ CARTRIDGE(I-STAT)-THE TEST FOR PCO2, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF CARBON DIOXIDE PARTIAL PRESSURE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PCO2 MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES. BICARBONATE IS USED IN THE DIAGNOSIS AND TREATMENT OF NUMEROUS POTENTIALLY SERIOUS DISORDERS ASSOCIATED WITH CHANGES IN BODY ACID-BASE BALANCE. THE TEST FOR PH, AS PART OF THE I-

	STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PH IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PH MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES. THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. SODIUM MEASUREMENTS ARE USED FOR MONITORING ELECTROLYTE IMBALANCES. THE TEST FOR POTASSIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF POTASSIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. POTASSIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS AND MONITORING OF DISEASES AND CLINICAL CONDITIONS THAT MANIFEST HIGH AND LOW POTASSIUM LEVELS. THE TEST FOR CHLORIDE, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF CHLORIDE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. CHLORIDE MEASUREMENTS ARE PRIMARILY USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF ELECTROLYTE AND METABOLIC DISORDERS INCLUDING, BUT NOT LIMITED TO, CYSTIC FIBROSIS, DIABETIC ACIDOSIS, AND HYDRATION DISORDERS. THE TEST FOR GLUCOSE AS PART OF THE I-STAT SYSTEM IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF GLUCOSE IN ARTERIAL, VENOUS OR CAPILLARY WHOLE BLOOD. GLUCOSE MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF CARBOHYDRATE METABOLISM DISORDERS INCLUDING, BUT NOT LIMITED TO, DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, IDIOPATHIC HYPOGLYCEMIA, AND PANCREATIC ISLET CELL CARCINOMA. THE TEST FOR BLOOD UREA NITROGEN (BUN/UREA), AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF BUN/UREA IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. BLOOD UREA NITROGEN MEASUREMENTS ARE USED FOR THE DIAGNOSIS, MONITORING, AND TREATMENT OF CERTAIN RENAL AND METABOLIC DISEASES. THE TEST FOR HEMATOCRIT, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PACKED RED BLOOD CELL VOLUME FRACTION IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. HEMATOCRIT MEASUREMENTS CAN AID IN THE DETERMINATION AND MONITORING OF NORMAL OR ABNORMAL TOTAL RED CELL VOLUME STATUS INCLUDING, BUT NOT LIMITED TO, CONDITIONS SUCH AS ANEMIA, ERYTHROCYTOSIS, AND BLOOD LOSS RELATED TO TRAUMA AND SURGERY.,E3+ CARTRIDGE (I-STAT)-THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM IN

	ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. SODIUM MEASUREMENTS ARE USED FOR MONITORING ELECTROLYTE IMBALANCES. THE TEST FOR POTASSIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF POTASSIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. POTASSIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS AND MONITORING OF DISEASES AND CLINICAL CONDITIONS THAT MANIFEST HIGH AND LOW POTASSIUM LEVELS. THE TEST FOR HEMATOCRIT, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PACKED RED BLOOD CELL VOLUME FRACTION IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. HEMATOCRIT MEASUREMENTS CAN AID IN THE DETERMINATION AND MONITORING OF NORMAL OR ABNORMAL TOTAL RED CELL VOLUME STATUS INCLUDING, BUT NOT LIMITED TO, CONDITIONS SUCH AS ANEMIA, ERYTHROCYTOSIS, AND BLOOD LOSS RELATED TO TRAUMA AND SURGERY. ,6+ CARTRIDGE(I-STAT)-THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. SODIUM MEASUREMENTS ARE USED FOR MONITORING ELECTROLYTE IMBALANCES. THE TEST FOR POTASSIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF POTASSIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. POTASSIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS AND MONITORING OF DISEASES AND CLINICAL CONDITIONS THAT MANIFEST HIGH AND LOW POTASSIUM LEVELS. THE TEST FOR HEMATOCRIT, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PACKED RED BLOOD CELL VOLUME FRACTION IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. HEMATOCRIT MEASUREMENTS CAN AID IN THE DETERMINATION AND MONITORING OF NORMAL OR ABNORMAL TOTAL RED CELL VOLUME STATUS INCLUDING, BUT NOT LIMITED TO, CONDITIONS SUCH AS ANEMIA, ERYTHROCYTOSIS, AND BLOOD LOSS RELATED TO TRAUMA AND SURGERY. THE TEST FOR GLUCOSE AS PART OF THE I-STAT SYSTEM IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF GLUCOSE IN ARTERIAL, VENOUS OR CAPILLARY WHOLE BLOOD. GLUCOSE MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF CARBOHYDRATE METABOLISM DISORDERS INCLUDING, BUT NOT LIMITED TO, DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, IDIOPATHIC HYPOGLYCEMIA, AND PANCREATIC ISLET CELL CARCINOMA. THE TEST FOR CHLORIDE, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF CHLORIDE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. CHLORIDE MEASUREMENTS ARE

	PRIMARILY USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF ELECTROLYTE AND METABOLIC DISORDERS INCLUDING, BUT NOT LIMITED TO, CYSTIC FIBROSIS, DIABETIC ACIDOSIS, AND HYDRATION DISORDERS. THE TEST FOR BLOOD UREA NITROGEN (BUN/UREA), AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF BUN/UREA IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. BLOOD UREA NITROGEN MEASUREMENTS ARE USED FOR THE DIAGNOSIS, MONITORING, AND TREATMENT OF CERTAIN RENAL AND METABOLIC DISEASES. , CHEM8+ CARTRIDGE(I-STAT)-THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. SODIUM MEASUREMENTS ARE USED FOR MONITORING ELECTROLYTE IMBALANCES. THE TEST FOR POTASSIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF POTASSIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. POTASSIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS AND MONITORING OF DISEASES AND CLINICAL CONDITIONS THAT MANIFEST HIGH AND LOW POTASSIUM LEVELS. THE TEST FOR HEMATOCRIT, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PACKED RED BLOOD CELL VOLUME FRACTION IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. HEMATOCRIT MEASUREMENTS CAN AID IN THE DETERMINATION AND MONITORING OF NORMAL OR ABNORMAL TOTAL RED CELL VOLUME STATUS INCLUDING, BUT NOT LIMITED TO, CONDITIONS SUCH AS ANEMIA, ERYTHROCYTOSIS, AND BLOOD LOSS RELATED TO TRAUMA AND SURGERY. THE TEST FOR GLUCOSE AS PART OF THE I-STAT SYSTEM IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF GLUCOSE IN ARTERIAL, VENOUS OR CAPILLARY WHOLE BLOOD. GLUCOSE MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF CARBOHYDRATE METABOLISM DISORDERS INCLUDING, BUT NOT LIMITED TO, DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, IDIOPATHIC HYPOGLYCEMIA, AND PANCREATIC ISLET CELL CARCINOMA. THE TEST FOR CHLORIDE, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF CHLORIDE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. CHLORIDE MEASUREMENTS ARE PRIMARILY USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF ELECTROLYTE AND METABOLIC DISORDERS INCLUDING, BUT NOT LIMITED TO, CYSTIC FIBROSIS, DIABETIC ACIDOSIS, AND HYDRATION DISORDERS. THE TEST FOR BLOOD UREA NITROGEN (BUN/UREA), AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF BUN/UREA IN ARTERIAL, VENOUS, OR

	CAPILLARY WHOLE BLOOD. BLOOD UREA NITROGEN MEASUREMENTS ARE USED FOR THE DIAGNOSIS, MONITORING, AND TREATMENT OF CERTAIN RENAL AND METABOLIC DISEASES. THE TEST FOR TCO2, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF TOTAL CARBON DIOXIDE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. CARBON DIOXIDE IS USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF NUMEROUS POTENTIALLY SERIOUS DISORDERS ASSOCIATED WITH CHANGES IN BODY ACID-BASE BALANCE. THE TEST FOR IONIZED CALCIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF IONIZED CALCIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. IONIZED CALCIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF CONDITIONS INCLUDING, BUT NOT LIMITED TO, PARATHYROID DISEASE, A VARIETY OF BONE DISEASES, CHRONIC RENAL DISEASE, TETANY, AND DISTURBANCES RELATED TO SURGICAL AND INTENSIVE CARE. THE TEST FOR CREATININE, AS PART OF THE I-STAT SYSTEM, IS FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN WHOLE BLOOD ON THE I-STAT HANDHELD. CREATININE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASES, IN MONITORING RENAL DIALYSIS, AND AS A CALCULATION BASIS FOR MEASURING OTHER URINE ANALYTES. ,EC4+CARTRIDGE(I-STAT)-THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. SODIUM MEASUREMENTS ARE USED FOR MONITORING ELECTROLYTE IMBALANCES. THE TEST FOR POTASSIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF POTASSIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. POTASSIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS AND MONITORING OF DISEASES AND CLINICAL CONDITIONS THAT MANIFEST HIGH AND LOW POTASSIUM LEVELS. THE TEST FOR HEMATOCRIT, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PACKED RED BLOOD CELL VOLUME FRACTION IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. HEMATOCRIT MEASUREMENTS CAN AID IN THE DETERMINATION AND MONITORING OF NORMAL OR ABNORMAL TOTAL RED CELL VOLUME STATUS INCLUDING, BUT NOT LIMITED TO, CONDITIONS SUCH AS ANEMIA, ERYTHROCYTOSIS, AND BLOOD LOSS RELATED TO TRAUMA AND SURGERY. THE TEST FOR GLUCOSE AS PART OF THE I-STAT SYSTEM IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF GLUCOSE IN ARTERIAL, VENOUS OR CAPILLARY WHOLE BLOOD. GLUCOSE MEASUREMENTS ARE USED IN THE DIAGNOSIS,

	MONITORING, AND TREATMENT OF CARBOHYDRATE METABOLISM DISORDERS INCLUDING, BUT NOT LIMITED TO, DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, IDIOPATHIC HYPOGLYCEMIA, AND PANCREATIC ISLET CELL CARCINOMA. ,CG8+ CARTRIDGE(I-STAT)- THE TEST FOR PH, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PH IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PH MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES. THE TEST FOR PO2, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF OXYGEN PARTIAL PRESSURE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PO2 MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES. THE TEST FOR PCO2, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF CARBON DIOXIDE PARTIAL PRESSURE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PCO2 MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES. BICARBONATE IS USED IN THE DIAGNOSIS AND TREATMENT OF NUMEROUS POTENTIALLY SERIOUS DISORDERS ASSOCIATED WITH CHANGES IN BODY ACID-BASE BALANCE. THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. SODIUM MEASUREMENTS ARE USED FOR MONITORING ELECTROLYTE IMBALANCES. THE TEST FOR POTASSIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF POTASSIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. POTASSIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS AND MONITORING OF DISEASES AND CLINICAL CONDITIONS THAT MANIFEST HIGH AND LOW POTASSIUM LEVELS. THE TEST FOR IONIZED CALCIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF IONIZED CALCIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. IONIZED CALCIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF CONDITIONS INCLUDING, BUT NOT LIMITED TO, PARATHYROID DISEASE, A VARIETY OF BONE DISEASES, CHRONIC RENAL DISEASE, TETANY, AND DISTURBANCES RELATED TO SURGICAL AND INTENSIVE CARE. THE TEST FOR GLUCOSE AS PART OF THE I-STAT SYSTEM IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF GLUCOSE IN ARTERIAL, VENOUS OR CAPILLARY WHOLE BLOOD.

	GLUCOSE MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF CARBOHYDRATE METABOLISM DISORDERS INCLUDING, BUT NOT LIMITED TO, DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, IDIOPATHIC HYPOGLYCEMIA, AND PANCREATIC ISLET CELL CARCINOMA. THE TEST FOR HEMATOCRIT, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PACKED RED BLOOD CELL VOLUME FRACTION IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. HEMATOCRIT MEASUREMENTS CAN AID IN THE DETERMINATION AND MONITORING OF NORMAL OR ABNORMAL TOTAL RED CELL VOLUME STATUS INCLUDING, BUT NOT LIMITED TO, CONDITIONS SUCH AS ANEMIA, ERYTHROCYTOSIS, AND BLOOD LOSS RELATED TO TRAUMA AND SURGERY.,CTNL CARTRIDGE(I-STAT)-THE I-STAT CARDIAC TROPONIN I (CTNI) TEST IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF CARDIAC TROPONIN I (CTNI) IN WHOLE BLOOD OR PLASMA. MEASUREMENTS OF CARDIAC TROPONIN I ARE USED IN THE DIAGNOSIS AND TREATMENT OF MYOCARDIAL INFARCTION AND AS AN AID IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES WITH RESPECT TO THEIR RELATIVE RISK OF MORTALITY.,TOTAL B-HCG CARTRIDGE(I-STAT)-THE I-STAT TOTAL BETA-HUMAN CHORIONIC GONADOTROPIN (-HCG) ASSAY IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE AND QUALITATIVE DETERMINATION OF BETA-HUMAN CHORIONIC GONADOTROPIN IN WHOLE BLOOD OR PLASMA SAMPLES. -HCG CAN BE USED FOR THE DETECTION OF EARLY PREGNANCY,KAOLIN ACT CARTRIDGE(I-STAT)-I-STAT KAOLIN ACTIVATED CLOTTING TIME (KAOLIN ACT) TEST IS AN IN VITRO DIAGNOSTIC TEST THAT USES FRESH, WHOLE BLOOD TO MONITOR HIGH DOSE HEPARIN ANTICOAGULATION FREQUENTLY ASSOCIATED WITH CARDIOVASCULAR SURGERY.,G CARTRIDGE(I-STAT)-THE TEST FOR GLUCOSE AS PART OF THE I-STAT SYSTEM IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF GLUCOSE IN ARTERIAL, VENOUS OR CAPILLARY WHOLE BLOOD. GLUCOSE MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF CARBOHYDRATE METABOLISM DISORDERS INCLUDING, BUT NOT LIMITED TO, DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, IDIOPATHIC HYPOGLYCEMIA, AND PANCREATIC ISLET CELL CARCINOMA.,EG7+ CARTRIDGE(I-STAT)-THE TEST FOR PCO2, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF CARBON DIOXIDE PARTIAL PRESSURE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PCO2 MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES. BICARBONATE IS

	USED IN THE DIAGNOSIS AND TREATMENT OF NUMEROUS POTENTIALLY SERIOUS DISORDERS ASSOCIATED WITH CHANGES IN BODY ACID-BASE BALANCE. THE TEST FOR PH, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PH IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PH MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES. THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. SODIUM MEASUREMENTS ARE USED FOR MONITORING ELECTROLYTE IMBALANCES. THE TEST FOR POTASSIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF POTASSIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. POTASSIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS AND MONITORING OF DISEASES AND CLINICAL CONDITIONS THAT MANIFEST HIGH AND LOW POTASSIUM LEVELS. THE TEST FOR IONIZED CALCIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF IONIZED CALCIUM IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. IONIZED CALCIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF CONDITIONS INCLUDING, BUT NOT LIMITED TO, PARATHYROID DISEASE, A VARIETY OF BONE DISEASES, CHRONIC RENAL DISEASE, TETANY, AND DISTURBANCES RELATED TO SURGICAL AND INTENSIVE CARE. THE TEST FOR HEMATOCRIT, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PACKED RED BLOOD CELL VOLUME FRACTION IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. HEMATOCRIT MEASUREMENTS CAN AID IN THE DETERMINATION AND MONITORING OF NORMAL OR ABNORMAL TOTAL RED CELL VOLUME STATUS INCLUDING, BUT NOT LIMITED TO, CONDITIONS SUCH AS ANEMIA, ERYTHROCYTOSIS, AND BLOOD LOSS RELATED TO TRAUMA AND SURGERY. THE TEST FOR PO2, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF OXYGEN PARTIAL PRESSURE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PO2 MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES.,CG4+ CARTRIDGE(I-STAT)-THE TEST FOR PCO2, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF CARBON DIOXIDE PARTIAL PRESSURE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PCO2 MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND

	TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES. BICARBONATE IS USED IN THE DIAGNOSIS AND TREATMENT OF NUMEROUS POTENTIALLY SERIOUS DISORDERS ASSOCIATED WITH CHANGES IN BODY ACID-BASE BALANCE. THE TEST FOR PH, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PH IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PH MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES. THE TEST FOR LACTATE, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF LACTATE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. THE I-STAT LACTATE TEST IS USEFUL FOR (1) THE DIAGNOSIS AND TREATMENT OF LACTIC ACIDOSIS IN CONJUNCTION WITH MEASUREMENTS OF BLOOD ACID/BASE STATUS, (2) MONITORING TISSUE HYPOXIA AND STRENUOUS PHYSICAL EXERTION, AND (3) DIAGNOSIS OF HYPERLACTATEMIA. THE TEST FOR PO2, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF OXYGEN PARTIAL PRESSURE IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD. PO2 MEASUREMENTS ARE USED IN THE DIAGNOSIS, MONITORING, AND TREATMENT OF RESPIRATORY DISTURBANCES AND METABOLIC AND RESPIRATORY-BASED ACID-BASE DISTURBANCES.,CELITE ACT CARTRIDGE(I-STAT)-THE I-STAT CELITE ACTIVATED CLOTTING TIME (CELITEACT) TEST IS AN IN VITRO DIAGNOSTIC TEST THAT USES FRESH, WHOLE BLOOD, AND IS USEFUL FOR MONITORING PATIENTS RECEIVING HEPARIN FOR TREATMENT OF PULMONARY EMBOLISM OR VENOUS THROMBOSIS, AND FOR MONITORING ANTICOAGULATION THERAPY IN PATIENTS UNDERGOING MEDICAL PROCEDURES SUCH AS CATHETERIZATION, CARDIAC SURGERY, SURGERY, ORGAN TRANSPLANT, AND DIALYSIS.,PT/INR CARTRIDGE(I-STAT)-I-STAT PT, A PROTHROMBIN TIME TEST IS USEFUL FOR MONITORING PATIENTS RECEIVING ORAL ANTICOAGULATION THERAPY SUCH AS COUMADIN OR WARFARIN.

66	IMP/IVD/2018/000046	1.License Holder Name: HORIBA INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABX ERYTROL(ABX ERYTROL)-ABX ERYTROL IS A TRI-LEVEL CONTROL INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR USE IN MONITORING THE ACCURACY AND PRECISION OF HORIBA MEDICAL HEMATOLOGY BLOOD CELL COUNTERS FOR ERYTHROBLAST (NRBC) PARAMETER., BFTROL(HORIBA MEDICAL)-"BFTROL IS A CONTROL INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR USE IN MONITORING THE ACCURACY AND PRECISION OF HORIBA MEDICAL HEMATOLOGY BLOOD CELL COUNTERS FOR LEUCOCYTES (WBC) AND ERYTHROCYTES (RBC) IN BODY FLUIDS. REFER TO THE BFTROL ASSAY VALUE DATA SHEET FOR SPECIFIC INSTRUMENT MODELS.", ABX MINOCAL(ABX MINOCAL)-ABX MINOCAL IS A MULTIPARAMETER BLOOD CALIBRATOR INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR USE IN CALIBRATION OF HEMATOLOGY BLOOD CELL COUNTERS.,ABX DIFFTROL(ABX DIFFTROL)-ABX DIFFTROL IS A TRI-LEVEL MULTIPARAMETER CONTROL INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR USE IN MONITORING THE ACCURACY AND PRECISION OF HORIBA MEDICAL HEMATOLOGY BLOOD CELL COUNTERS.,ABX MINOTROL(ABX MINOTROL CRP)-ABX MINOTROL CRP IS A TRI-LEVEL MULTIPARAMETER CONTROL INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR USE IN MONITORING THE ACCURACY AND PRECISION OF HORIBA MEDICAL HEMATOLOGY BLOOD CELL COUNTERS WITH CRP PARAMETER MEASUREMENT.,ABX MINOTROL(ABX MINOTROL RETIC)-"ABX MINOTROL RETIC IS A TRI-LEVEL CONTROL INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR USE IN MONITORING THE ACCURACY AND PRECISION OF HORIBA MEDICAL HEMATOLOGY BLOOD CELL COUNTERS FOR RETICULOCYTE (RET) PARAMETER.,ABX MINOTROL(ABX MINOTROL 16)-ABX MINOTROL 16 IS A TRI-LEVEL MULTIPARAMETER CONTROL INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR USE IN MONITORING THE ACCURACY AND PRECISION OF HEMATOLOGY BLOOD CELL COUNTERS.

67	IMP/IVD/2018/000047	1.License Holder Name: ARKRAY HEALTHCARE PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTIPLE ELECTROLYTE IVD, ION-SELECTIVE ELECTRODE (ISE)(SPOTCHEM E-PLATE)-FOR USE WITH SPOTCHEM SE/ SPOTCHEM EL ANALYZER. FOR IN VITRO DIAGNOSTIC USE,GLYCATED HEMOGLOBIN (HBA1C) IVD, KIT, LIQUID CHROMATOGRAPHY(ELUENT 80 CV)-THIS PRODUCT IS INTENDED FOR THE DETERMINATION OF HEMOGLOBIN A1 C IN HUMAN WHOLE BLOOD,GLYCATED HEMOGLOBIN (HBA1C) IVD, CALIBRATOR (CALIBRATOR LITE)-CALIBRATION OF ADAMS A1C LITE SERIES, LACTATE ELECTRODE(LACTATE PRO2 TEST STRIP)-LACTATE PRO2 TEST STRIP ARE SUITABLE FOR SELF- TESTING OF LACTATE LEVELIN WHOLE BLOOD. FOR IN VITRO DIAGNOSTIC USE ONLY.,GLYCATED HEMOGLOBIN (HBA1C) IVD, KIT, LIQUID CHROMATOGRAPHY (HEMOLYSIS WASHING SOLUTION LITE H)-THIS PRODUCT IS INTENDED FOR THE DETERMINATION OF HEMOGLOBIN A1C IN HUMAN WHOLE BLOOD ,GLYCATED HEMOGLOBIN (HBA1C) IVD, KIT, LIQUID CHROMATOGRAPHY(HEMOLYSIS WASHING SOLUTION 80H)-THIS PRODUCT IS INTENDETD FOR THE DETERMINATION OF HEMOGLOBIN A1C IN HUMAN WHOLE BLOOD,GLYCATED HEMOGLOBIN (HBA1C) IVD, KIT, LIQUID CHROMATOGRAPHY(ELUENT 80CT)-THIS PRODUCT IS INTENDED FOR THE DETERMINATION OF HEMOGLOBIN A2 , FETAL HEMOGLOBIN AND HEMOGLOBIN A1C IN HUMAN WHOLE BLOOD , GLYCATED HEMOGLOBIN (HBA1C)IVD, KIT, LIQUID CHROMATOGRAPHY(ELUENT 80B)-THESE PRODUCT ARE INTENDED FOR THE DETERMINATION OF HEMOGLOBIN NA1C IN HUMAN WHOLE BLOOD,GLYCATED HEMOGLOBIN (HBA1C)IVD, KIT, LIQUID CHROMATOGRAPHY(ELUENT 80A)-THESE PRODUCT ARE INTENDED FOR THE DETERMINATION OF HEMOGLOBIN NA1C IN HUMAN WHOLE BLOOD,GLYCATED HEMOGLOBIN (HBA1C)IVD, CONTROL(CONTROL DILUTION SET 80)-THE PRODUCT IS INTENDED FOR THE DETERMINATION OF HEMOGLOBIN A1C IN HUMAN WHOLE BLOOD , GLYCATED HEMOGLOBIN (HBA1C) ANALYZER IVD(COLUMN UNIT 80)-COLUMN UNIT 80 IS INTENDED FOR THE DETERMINATION OF HEMOGLOBIN IN HUMAN WHOLE BLOOD,GLYCATED HEMOGLOBIN (HBA1C) ANALYZER IVD(COLUMN UNIT 80T)-COLUMN UNIT 80T IS INTENDED FOR THE DERTERMINATION OF HEMOGLOBIN A1C IN HUMAN WHOLE BLOOD FOR USE WITH ADAMS FOR IN VITRO DIAGNOSTIC USE ONLY,GLYCATED HEMOGLOBIN (HBA1C) IVD, CALIBRATOR(CALIBRATOR 80)-CALIBRATION OF ADAMS A1C SERIES.,MULTIPLE URINE ANALYTE IVD, CONTROL(AUTION STICKS 10 PA)-FOR THE DETERMINATION OF GLUCOSE, PROTEIN, BILIRUBIN, UROBILINOGEN, CREATININE,PH, SPECIFIC GRAVITY, BLOOD, KETONES, NITRITE AND LEUKOCYTES IN URINE,AMMONIA IVD, KIT,

	SPECTROPHOTOMETRY(AMMONIA TEST KIT II)-THE AMMONIA TEST KIT II IS A REAGENT KIT USED WITH THE AMMONIA CHECKER II OR POCKET CHEM BA, TO MEASURE BLOOD AMMONOIA LEVEL BASED ON THE MICRO DIFFUSION METHOD.,MULTIPLE URINE ANALYTE IVD, CONTROL(AUTION SCREEN MICROALBUMIN/CREATININE)-THIS PRODUCT IS FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE DETERMINATION OF ALBUMIN AND CREATININE IN URINE.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

68	IMP/IVD/2018/000048	1.License Holder Name: MEDICAL BUREAU 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMATOLOGY CLEANER (EUROCOUNT CLEANER)-CLEANER CLEANING REAGENT IS A STABILIZED AND MICROFILTERED DETERGENT SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON HEMATOLOGY ANALYZERS ,HEMATOLOGY REAGENT - LYSE(CT LYSE DIFF)-LYSE-DIFF LYSING REAGENT IS A STABILIZED AND MICRO-FILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE THREE-PART DIFFERENTIATION (LYM, MID, GRAN) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON HEMATOLOGY ANALYZERS., HEMATOLOGY REAGENT- CLEANER(CT CLEANER)-CLEANER CLEANING REAGENT IS A STABILIZED AND MICROFILTERED DETERGENT SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON HEMATOLOGY ANALYZERS ,HEMATOLOGY REAGENT- DILUENT(EUROCOUNT DILUENT)-DIATRO•DIL-DIFF DILUENT IS A BUFFERED, STABILIZED AND MICRO-FILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN (HGB) CONCENTRATION ON HEMATOLOGY ANALYZERS,HEMATOLOGY REAGENT- DILUENT(CT DILUENT DIFF)-DIATRO•DIL-DIFF DILUENT IS A BUFFERED, STABILIZED AND MICRO-FILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN (HGB) CONCENTRATION ON HEMATOLOGY ANALYZERS,HEMATOLOGY REAGENT LYSE(EUROCOUNT LYSE)-LYSE-DIFF LYSING REAGENT IS A STABILIZED AND MICRO-FILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE THREE-PART DIFFERENTIATION (LYM, MID, GRAN) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON HEMATOLOGY ANALYZERS

69	IMP/IVD/2018/000050	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACT5 DIFF, CTL PLUS-COULTER AC•T 5DIFF CONTROL PLUS IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF THE COULTER AC•T 5DIFF HEMATOLOGY ANALYZERS IN CONJUNCTION WITH COULTER AC•T 5DIFF REAGENT SYSTEM. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE. THE ASSIGNED VALUES AND EXPECTED RANGES ON THE TABLE OF EXPECTED RESULTS CAN BE USED TO MONITOR INSTRUMENT PERFORMANCE. THIS PRODUCT CAN ALSO BE USED TO ESTABLISH YOUR OWN LABORATORY MEAN.,ACT5 DIFF CAL-AC•T 5DIFF CAL CALIBRATOR IS INTENDED FOR THE DETERMINATION OF CALIBRATION FACTORS FOR COULTER AC•T 5DIFF SERIES HEMATOLOGY ANALYZERS IN CONJUNCTION WITH AC•T 5DIFF REAGENT SYSTEM ONLY. REFER TO OPERATOR'S MANUAL OR ON-LINE HELP SYSTEM.
70	IMP/IVD/2018/000051	1.License Holder Name: TRUWORTH HEALTH TECHNOLOGIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOSMART GOLD HEMOGLOBIN TEST STRIP(HEMOSMART GOLD)-FOR THE QUANTITATIVE MEASUREMENT OF HEMOGLOBIN IN WHOLE BLOOD USING THE HEMOSMART GOLD HEMOGLOBIN METER IN THE RANGE OF 4 G/DL TO 24 G/DL.,UASURE BLOOD URIC ACID TEST STRIP (UASURE)-UASURE BLOOD URIC ACID TEST STRIPS ARE DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF URIC ACID IN WHOLE BLOOD FOR THE UASURE BLOOD URIC ACID METER, INTENDED FOR SELF-TESTING BY INDIVIDUALS AND BY HEALTHCARE PROFESSIONALS.,GLUCOSURE LIGHT BLOOD GLUCOSE TEST STRIP (GLUCOSURE LIGHT)-THE GLUCOSURE LIGHT BLOOD GLUCOSE TEST STRIPS ARE TO BE USED WITH THE GLUCOSURE LIGHT BLOOD GLUCOSE METER TO QUANTITATIVELY MEASURE GLUCOSE IN CAPILLARY WHOLE BLOOD TAKEN FROM FINGERTIPS, PALM, OR FOREARM. THE GLUCOSURE LIGHT BLOOD GLUCOSE MONITORING SYSTEM IS PLASMA-CALIBRATED FOR EASY COMPARISON TO LAB RESULTS. IT IS INTENDED FOR SELF-TESTING BY PERSONS WITH DIABETES AND BY HEALTH CARE PROFESSIONALS. IT IS NOT INDICATED FOR THE DIAGNOSIS OR SCREENING OF DIABETES OR FOR NEONATAL USE.

71	IMP/IVD/2018/000052	1.License Holder Name: CEVA POLCHEM PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NDV F KIT(NEWCASTLE DISEASE VIRUS ANTIBODY KIT)-TO MEASURE AMOUNT OF ANTIBODIES TO NDV F IN CHICKEN SERUM SAMPLES,CASTV GP B KIT (CHICKEN ASTROVIRUS GROUP B ANTIBODY TEST KIT)-TO MEASURE THE AMOUNT OF ANTIBODIES TO CASTV IN THE SERUM OF CHICKENS, MS(MYCOPLASMA SYNOVIAE ANTIBODY TEST KIT)-TO TEST ANTIBODY TITRE AGAINST MS IN CHICKEN SERUM,FADV GP 1(FOWL ADENOVIRUS GROUP 1 ANTIBODY TEST KIT)-TO MEASURE THE AMOUNT OF ANTIBODY TO FADV IN THE SERUM OF CHICKENS,MG-MS (MYCOPLASMA GALLISEPTICUM-SYNOVIAE ANTIBODY TEST KIT)-TO TEST ANTIBODIES AGAINST MG AND MS IN CHICKEN SERUM,REO (AVIAN REOVIRUS ANTIBODY TEST KIT)-TO MEASURE THE AMOUNT OF ANTIBODY TO REO IN THE SERUM OF CHICKENS,SALMONELLA ENTERITIDIS (SALM GP D)(SALMONELLA GROUP D ANTIBODY TEST KIT)-TO TEST ANTIBODIES AGAINST SALMONELLA GROUP D IN CHICKEN SERUM,ALV(AG) LLAG P27(AVIAN LEUKOSIS VIRUS (P27) TEST KIT)-TO MEASURE THE AMOUNT OF ALV ANTIGEN IN VARIOUS SAMPLES TAKEN FROM CHICKENS,ILT(INFECTIOUS LARYNGOTRACHEITIS ANTIBODY TEST KIT)-TO TEST ANTIBODIES AGAINST ILT IN CHICKEN SERUM,REV(RETICULOENDOTHELIOSIS VIRUS ANTIBODY TEST KIT)-TO MEASURE THE AMOUNT OF ANTIBODY TO REV IN THE SERUM OF CHICKENS,AE(AVIAN ENCEPHALOMYELITIS ANTIBODY TEST KIT)-TO DETECT ANTIBODY LEVELS AGAINST AE IN CHICKEN SERUM,EDS(EGG DROP SYNDROME VIRUS ANTIBODY TEST KIT)-TO TEST ANTIBODIES AGAINST EDS IN CHICKEN SERUM,MG(MYCOPLASMA GALLISEPTICUM ANTIBODY TEST KIT)-TO TEST ANTIBODIES AGAINST MG IN CHICKEN SERUM,CHICKEN SALMONELLA ANTIBODY TEST KIT (LPS B AND D COMBINED) /SALMONELLA ENTERITIDIS/ TYPHIMURIUM (SALM GPB/D) (SALMONELLA GROUP B&D ANTIBODY TEST KIT)-TO TEST ANTIBODIES AGAINST SAL GRP B AND GRP D IN CHICKEN SERUM,CAV (CHICKEN ANEMIA VIRUS ANTIBODY TEST KIT)-FOR TESTING ANTIBODY TITRE AGAINST CAV FROM CHICKEN SERUM,NDV (NEWCASTLE DISEASE VIRUS ANTIBODY TEST KIT)-TO TEST ANTIBODIES AGAINST NDV IN CHICKEN SERUM,IBD(INFECTIOUS BURSAL DISEASE VIRUS ANTIBODY TEST KIT)-TO TEST ANTIBODIES AGAINST IBD IN CHICKEN SERUM,CHICKEN SALMONELLA TYPHIMURIUM ANTIBODY TEST KIT (LPS GROUP B)(SALMONELLA GROUP B ANTIBODY TEST KIT)-TO TEST ANTIBODIES AGAINST SALMONELLA TYPHIMURIUM (SAL GRP B) IN CHICKEN SERUM,IBV (INFECTIOUS BRONCHITIS VIRUS ANTIBODY TEST KIT)-TO TEST ANTIBODIES AGAINST IBV IN CHICKEN SERUM

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72	IMP/IVD/2018/000053	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:UREA NITROGEN (BUN) STAT-SYSTEM REAGENT FOR THE QUANTITATIVE DETERMINATION OF UREA NITROGEN IN HUMAN SERUM ON BECKMAN COULTER AU ANALYZERS. OSR6641 FOR USE ON THE AU5800, AU2700 AND AU5400 SYSTEMS ONLY.,CREATININE(CREATININE)-KINETIC COLOUR TEST (JAFFÉ METHOD) FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE ON BECKMAN COULTER AU ANALYSERS.,DIRECT BILIRUBIN-SYSTEM REAGENT FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYZERS. OSR6611 FOR USE ON THE AU5800, AU2700 AND AU5400 SYSTEMS ONLY.,CALCIUM OCPC (CALCIUM OCPC)-PHOTOMETRIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF TOTAL CALCIUM IN HUMAN SERUM, PLASMA AND URINE ON BECKMAN COULTER AU ANALYSERS.,SYSTEM MONITORING SOLUTION-THE SYSTEM MONITORING SOLUTION IS A GENERAL PURPOSE REAGENT INTENDED TO BE USED WITH THE BECKMAN COULTER AU ANALYZERS FOR THE DETECTION OF ABNORMAL REACTION MONITORS.,IGA(IGA)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,APO A1 AND B CALIBRATOR-THE APO A1 & B CALIBRATOR IS A LIQUID HUMAN SERUM MATRIX CALIBRATOR INTENDED TO BE USED WITH THE APO A1 AND APO B REAGENTS (OSR6142 & OSR6143 RESPECTIVELY) FOR THE QUANTITATIVE DETERMINATION OF APO A1 & APO B ON BECKMAN COULTER ANALYZERS.,IGG(IGG)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN SERUM, PLASMA AND CEREBROSPINAL FLUID ON BECKMAN COULTER AU ANALYSERS.,IMMAGE IMMUNOCHEMISTRY SYSTEMS DIL 2 DILUENT 2(IMMAGE IMMUNOCHEMISTRY SYSTEMS DIL 2 DILUENT 2)-DILUENT 2 IS INTENDED FOR USED WITH THE IMMAGE IMMUNOCHEMISTRY SYSTEMS AND REAGENTS FOR THE QUANTITATIVE DETERMINATIONS OF COMPONENTS IN BIOLOGICAL FLUIDS.,UREA/UREA NITROGEN (UREA/UREA NITROGEN)-KINETIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM, PLASMA AND URINE ON BECKMAN COULTER ANALYSERS,TOTAL PROTEIN REAGENT (TOTAL PROTEIN REAGENT)-TPM REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 800 SYSTEM AND SYNCHRON SYSTEMS PROTEIN CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM, PLASMA OR CEREBROSPINAL FLUID

	(CSF).,IRON(IRON)-PHOTOMETRIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM AND PLASMA ON AU BECKMAN COULTER ANALYSERS.,IMMAGE IMMUNOCHEMISTRY SYSTEMS DIL 1 DILUENT 1(IMMAGE IMMUNOCHEMISTRY SYSTEMS DIL 1 DILUENT 1)-DILUENT 1 IS INTENDED FOR USE WITH THE IMMAGE IMMUNOCHEMISTRY SYSTEMS AND REAGENTS FOR THE QUANTITATIVE DETERMINATIONS OF COMPONENTS IN BIOLOGICAL FLUIDS.,UREA STAT /UREA NITROGEN STAT(UREA STAT /UREA NITROGEN STAT)-KINETIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM, PLASMA AND URINE ON BECKMAN COULTER ANALYSERS.,UREA NITROGEN (BUN) REAGENT (UREA NITROGEN (BUN) REAGENT)-BUNM OR UREAM REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 800 SYSTEM AND SYNCHRON SYSTEMS AQUA CAL 1, 2 AND 3, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF UREA NITROGEN OR UREA CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE. THE SYSTEM CAN BE CONFIGURED TO REPORT RESULTS AS EITHER UREA NITROGEN IN DEFAULT UNITS OF MG/DL OR UREA IN DEFAULT UNITS OF MMOL/L.,TRIGLYCERIDE (TRIGLYCERIDE)-ENZYMATIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDE IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,IMMAGE IMMUNOCHEMISTRY SYSTEMS BUF 2 BUFFER 2(IMMAGE IMMUNOCHEMISTRY SYSTEMS BUF 2 BUFFER 2)-BUFFER 2 IS INTENDED FOR USE WITH THE IMMAGE IMMUNOCHEMISTRY SYSTEMS AND REAGENTS FOR THE QUANTITATIVE DETERMINATIONS OF COMPONENTS IN BIOLOGICAL FLUIDS.,UIBC(UIBC)-PHOTOMETRIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF UNSATURATED IRON BINDING CAPACITY (UIBC) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,TRIGLYCERIDE-SYSTEM REAGENT FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDE CONCENTRATIONS IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYZERS. OSR66118 FOR USE ON THE AU5800, AU2700 AND AU5400 SYSTEMS ONLY.,CK (NAC)(CK (NAC))-KINETIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE, EC 2.7.3.2 (CK), IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,ALBUMIN-SYSTEM REAGENT FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM ON BECKMAN COULTER CLINICAL CHEMISTRY AU ANALYZERS. OSR6602 FOR USE ON THE AU5800, AU2700 AND AU5400 SYSTEMS ONLY.,DIRECT BILIRUBIN (DIRECT BILIRUBIN)-PHOTOMETRIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,UREA NITROGEN-

	SYSTEM REAGENT FOR THE QUANTITATIVE DETERMINATION OF UREA NITROGEN IN HUMAN SERUM AND URINE ON BECKMAN COULTER AU ANALYZERS. OSR6634 FOR USE ON THE AU5800, AU2700 AND AU5400 SYSTEMS ONLY.,TOTAL PROTEIN(TOTAL PROTEIN)-PHOTOMETRIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,CHOLESTEROL-SYSTEM REAGENT FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL CONCENTRATIONS IN HUMAN SERUM ON BECKMAN COULTER AU ANALYZERS. OSR6616 FOR USE ON THE AU5800, AU2700 & AU5400 SYSTEMS ONLY.,ALP(ALP)-KINETIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE, EC 3.1.3.1 (ALP), IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,TOTAL PROTEIN-SYSTEM REAGENT FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM ON BECKMAN COULTER AU ANALYZERS. OSR6632 FOR USE ON THE AU5800, AU2700 AND AU5400 SYSTEMS ONLY.,CK-MB(CK-MB)-ENZYMATIC IMMUNO-INHIBITION TEST FOR THE QUANTITATIVE DETERMINATION OF THE CREATINE KINASE-MB ISOENZYME (CK-MB) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,ALP-SYSTEM REAGENT FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYZERS. OSR6604 FOR USE ON THE AU5800, AU2700 AND AU5400 SYSTEMS ONLY.,MAGNESIUM(MAGNESIUM)-PHOTOMETRIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM, PLASMA AND URINE ON BECKMAN COULTER ANALYSERS.,CALCIUM (ARSENAZO)-SYSTEM REAGENT FOR THE QUANTITATIVE DETERMINATION OF CALCIUM CONCENTRATIONS IN HUMAN SERUM, PLASMA AND URINE ON BECKMAN COULTER AU ANALYZERS. OSR66117 FOR USE ON THE AU5800, AU2700 AND AU5400 SYSTEMS ONLY,CHOLESTEROL (CHOLESTEROL)-ENZYMATIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,URIC ACID-SYSTEM REAGENT FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM, HEPARINIZED PLASMA AND URINE ON BECKMAN COULTER AU ANALYZERS. OSR6698 FOR USE ON THE AU5800, AU2700 AND AU5400 SYSTEMS ONLY.,C3(C3)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF C3 (COMPLEMENT 3) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,CREATININE-SYSTEM REAGENT FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM AND URINE ON BECKMAN COULTER AU ANALYZERS. OSR6678 FOR

	USE ON THE AU5800, AU2700 AND AU5400 SYSTEMS ONLY,URIC ACID (URIC ACID)-ENZYMATIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA AND URINE ON BECKMAN COULTER ANALYSERS.,TOTAL BILIRUBIN-SYSTEM REAGENT FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYZERS. OSR6612 FOR USE ON THE AU5800, AU2700 AND AU5400 SYSTEMS ONLY,IGM(IGM)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,GLUCOSE (GLUCOSE)-QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM , PLASMA,URINE, HEAEMOLYSATE AND CEREBROSPINAL FLUID ON BECKMAN COULTER AU ANALYSERS.,CERULOPLASMIN (CERULOPLASMIN)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF CERULOPLASMIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,HMX PAK REAGENT KIT-FOR USE ON COULTER HMX HEMATOLOGY ANALYZERS TO LYSE ERYTHROCYTES AND PRESERVE LEUKOCYTES. USE WITH ONLY ISOTON III OR ISOTON 4 DILUENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS.,ALBUMIN(ALBUMIN)-PHOTOMETRIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS,LYSE S III DIFF LYTIC REAGENT-FOR USE AS AN ERYTHROCYTE LYTIC AGENT FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN AND FOR LEUKOCYTE COUNTING AND SIZING ON COULTER HMX, LH 500, LH 750, AND LH 780 HEMATOLOGY ANALYZERS. USE WITH ONLY ISOTON III OR LH SERIES DILUENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE.,INORGANIC PHOSPHOROUS (INORGANIC PHOSPHOROUS)-PHOTOMETRIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHOROUS IN HUMAN SERUM, PLASMA AND URINE ON BECKMAN COULTER ANALYSERS.,DXH CELL LYSE-ERYTHROCYTE LYTIC AGENT FOR QUANTITATIVE DETERMINATION OF HEMOGLOBIN, ENUMERATION OF NRBC, AND COUNTING AND SIZING LEUKOCYTES ON UNICEL DXH COULTER CELLULAR ANALYSIS SYSTEMS. USE ONLY WITH COULTER DXH DILUENT.,URINARY/CSF PROTEIN (URINARY/CSF PROTEIN)-PHOTOMETRIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN URINE AND CEREBROSPINAL FLUID (CSF) ON BECKMAN COULTER ANALYSERS., LYSE S 4 LYTIC REAGENT-FOR USE AS AN ERYTHROCYTE LYTIC AGENT FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN AND FOR LEUKOCYTE COUNTING AND SIZING ON COULTER HMX, LH

	500*, LH 750†, AND LH 780 HEMATOLOGY ANALYZERS. USE ONLY WITH ISOTON 4 DILUENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE. *USE ONLY IF SOFTWARE VERSION IS 2A OR HIGHER. † USE ONLY IF SOFTWARE VERSION IS 2B OR HIGHER.,TOTAL BILIRUBIN(TOTAL BILIRUBIN)-PHOTOMETRIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,TRANSFERRIN (TRANSFERRIN)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF TRANSFERRIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,LIH(LIH)-PHOTOMETRIC TEST FOR THE SEMI-QUANTITATIVE ASSESSMENT OF LIPAEMIA/TURBIDITY, ICTERUS AND HAEMOLYSIS (LIH) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,C4(C4) -IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF C4 (COMPLEMENT 4) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,CRP(CRP)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,CALCIUM ARSENAZO(CALCIUM ARSENAZO)-PHOTOMETRIC COLOR TEST FOR QUANTITATIVE DETERMINATION OF TOTAL CALCIUM IN HUMAN SERUM AND PLASMA AND URINE ON AU BECKAMAN COULTER ANALYZERS ,APO A1(APO A1)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF APO A1 (APOLIPOPROTEIN A1) IN HUMAN SERUM ON BECKMAN COULTER ANALYSERS.,APO B(APO B)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF APO B (APOLIPOPROTEIN B) IN HUMAN SERUM ON BECKMAN COULTER ANALYSERS.,IMMUNOCHEMISTRY SYSTEM LPA CAL LIPOPROTEIN(A) CALIBRATOR(IMMUNOCHEMISTRY SYSTEM LPA CAL LIPOPROTEIN(A) CALIBRATOR)-LPA CAL (LIPOPROTEIN(A) CALIBRATOR), WHEN USED IN CONJUNCTION WITH LIPOPROTEIN(A) REAGENTS, IS INTENDED FOR USE ON IMMAGE SYSTEM FOR THE CALIBRATION OF THESE REAGENTS.,GLUCOSE REAGENT (GLUCOSE OXIDASE)(GLUCOSE REAGENT (GLUCOSE OXIDASE))-GLUCM REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS AQUA CAL 1 AND 2, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE CONCENTRATION IN HUMAN SERUM, PLASMA, URINE OR CEREBROSPINAL FLUID (CSF).,IMMAGE IMMUNOCHEMISTRY SYSTEMS BUF 1 BUFFER 1(IMMAGE IMMUNOCHEMISTRY SYSTEMS BUF 1 BUFFER 1)-BUFFER 1 IS INTENDED FOR USE WITH THE IMMAGE IMMUNOCHEMISTRY SYSTEMS AND REAGENTS FOR THE QUANTITATIVE DETERMINATIONS OF COMPONENTS IN BIOLOGICAL

	FLUIDS.,AST(AST)-KINETIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE, EC 2.6.1.1 (AST), IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,WASH SOLUTION(WASH SOLUTION)-CLEANING CONCENTRATE.,ALT(ALT)-KINETIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE, EC 2.6.1.2 (ALT), IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

73	IMP/IVD/2018/000054	1.License Holder Name: MINDRAY MEDICAL INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:M-30D DILUENT (MINDRAY)-IT IS USE ON MINDRAY THREE PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS USE AS AZIDE FREE, FILTERED ISOTONIC SOLUTION FOR COUNTING AND SIZING OF BLOOD CELLS, CORTISOL CALIBRATORS(MINDRAY)-MINDRAY CORTISOL CALIBRATORS (CORTISOL CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE CORTISOL ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,MULTI CONTROL SERA N(MINDRAY)-MULTI CONTROL SERA N IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION ON MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY,ELUENT B(MINDRAY)-THIS PRODUCT APPLIES TO MINDRAY H50/H50P AUTOMATED GLYCOHEMOGLOBIN ANALYZER. THE PRODUCT PARTICIPATES IN THE MEASUREMENT OF HBA1C IN BLOOD SAMPLES,MR URINE STANDARD(MINDRAY)-MR URINE STANDARD IS INTENDED FOR USE AS CALIBRATOR FOR IN VITRO TESTING FOR THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM, AND CHLORIDE CONCENTRATION IN URINE SAMPLE ON ION-SELECTIVE ELECTRODE ON ISE MODULES ON BS SERIES AUTOMATIC CHEMISTRY ANALYZERS. BEFORE CARRYING OUT CLINICAL PRACTICE, PARAMETERS OF THE CHEMISTRY ANALYZER NEED TO BE CALIBRATED AS INSTRUCTED IN INSTRUMENT MANUAL.,CREATINE KINASE MB (CLIA)(MINDRAY)-THE CL-SERIES CREATINE KINASE MB ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY(CLIA) FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE MB (CK-MB) IN HUMAN SERUM OR PLASMA,MR URINE QUALITY CONTROL(MINDRAY) -MR URINE QUALITY CONTROL IS AN ELECTROLYTE REFERENCE URINE CONTROL USED TO MONITOR THE URINE MODE PERFORMANCE OF ION-SELECTIVE ELECTRODE ON ISE MODULES ON AUTOMATIC CHEMISTRY ANALYZERS. DAILY USE OF THIS URINE CONTROL PROVIDES QUALITY CONTROL DATA FOR CONFIRMING THE PRECISION AND ACCURACY OF URINE SAMPLE TESTS.,TOTAL TRIIODOTHYRONINE (CLIA)(MINDRAY)-THE CL-SERIES T3 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE (T3) IN HUMAN SERUM.,M-30CFL LYSE(MINDRAY)-FOR USE ON MINDRAY THREE PART DIFFERENTIAL HEMATOLOGY ANALYZER FOR USE AS A CYANIDE FREE LYTIC REAGENT FOR QUANTITATIVELY DETERMINING HEMOGLOBIN AND FOR COUNTING AND SIZING LEUKOCYTES, VITAMIN B12 (CLIA)(MINDRAY)-THE CL-SERIES VITAMIN B12 (VB12) ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE

	QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM OR PLASMA.,MAGNESIUMMG KITXYLIDYL BLUE METHOD)(MINDRAY) -IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF MG CONCENTRATION IN SERUM, PLASMA AND URINE ON PHOTOMETRIC SYSTEM,FREE T4 CALIBRATORS(MINDRAY)-MINDRAY FREE T4 CALIBRATORS (FT4 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE FREE THYROXINE (FT4) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,MR BUFFER SOLUTION(MINDRAY)-MR BUFFER SOLUTION APPLIES TO MINDRAY BS SERIES AUTO CHEMISTRY A NALYZERS. IT IS USED TO DILUTE SAMPLES BEFORE THEY ARE DISPOSED TO THE ELECTRODES FLOWCELL. U SE THE MR BUFFER SOLUTION AS INSTRUCTED BY THE OPERATOR'S MANUAL OF T HE ANALYZER.,THYROID FUNCTION MULTI CONTROL (L)(MINDRAY)-MINDRAY THYROID FUNCTION MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF THYROID FUNCTION ANALYTES.,M-68LN LYSE(MINDRAY)-THE M-68LN LYSE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF NRBC-RELATED PARAMETERS TOGETHER WITH M-68FN DYE., SYSTEM DETECTION SOLUTION(MINDRAY)-FOR USE WITH THE CL-SERIES ANALYZER IN SYSTEM MAINTENANCE.,MR SERUM STANDARD (MINDRAY)-R SERUM STANDARD IS INTENDED FOR USE AS CALIBRATOR FOR IN VITRO TESTING FOR THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM, AND CHLORIDE CONCENTRATION IN SERUM AND PLASMA SAMPLE ON ION-SELECTIVE ELECTRODE ON ISE MODULES ON BS SERIES AUTOMATIC CHEMISTRY ANALYZERS). BEFORE CARRYING OUT CLINICAL PRACTICE, PARAMETERS OF THE CHEMISTRY ANALYZER NEED TO BE CALIBRATED AS INSTRUCTED IN INSTRUMENT MANUAL., HYALURONIC ACID (CLIA)(MINDRAY)-THE CL-SERIES HA ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF HYALURONIC ACID (HA) IN HUMAN SERUM.,M-68FD DYE(MINDRAY)-THE M-68FD DYE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN WBC DIFFERENTIATION IN THE DIFF CHANNEL TOGETHER WITH M-68LD LYSE,FERRITIN (CLIA)(MINDRAY)-THE CL-SERIES FERR ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FERRITIN (FERR) IN HUMAN SERUM OR PLASMA,M-68FN DYE(MINDRAY)-THE M-68FN DYE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF NRBC-

	RELATED PARAMETERS TOGETHER WITH M-68LN LYSE.,IMMUNOASSAY MULTI CONTROL (L)(MINDRAY)-MINDRAY IMMUNOASSAY MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF IMMUNOASSAY MULTI ANALYTES.,M-68LB LYSE (MINDRAY)-THE M-68LB LYSE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN WBC COUNTING AND MEASUREMENT OF BASOPHIL-RELATED PARAMETERS.,PCT CONTROL (H)(MINDRAY)-USED IN IN VITRO DIAGNOSTICS (FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF PCT).,M-68FR DYE(MINDRAY)-THE M-68FR DYE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF RET-RELATED PARAMETERS TOGETHER WITH M-68DR DILUENT.,MYOGLOBIN (CLIA) (MINDRAY)-THE CL-SERIES MYOGLOBIN ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN (MYO) IN HUMAN SERUM OR PLASMA.,M-68LH LYSE(MINDRAY)-THE M-68LH LYSE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT IS FORMULATED TO MEASURE THE HEMOGLOBIN-RELATED PARAMETERS,TSH CALIBRATORS(MINDRAY)-MINDRAY TSH CALIBRATORS (TSH CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE THYROID-STIMULATING HORMONE (TSH) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,M-68LD LYSE(MINDRAY)-THE M-68LD LYSE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN WBC DIFFERENTIATION IN THE DIFF CHANNEL TOGETHER WITH M-68FD DYE.,ELUENT A(MINDRAY)-THIS PRODUCT APPLIES TO MINDRAY H50/H50P AUTOMATED GLYCOHEMOGLOBIN ANALYZER. THE PRODUCT PARTICIPATES IN THE MEASUREMENT OF HBA1C IN BLOOD SAMPLES,M-58LEO(II) LYSE(MINDRAY)-M-58 LEO (II) LYSE APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT COOPERATES WITH THE M-58 LEO (I) LYSE TO 4 DIFFERENTIATE W8C'S,LIVER FIBROSIS MULTI CONTROL (H)(MINDRAY)-MINDRAY LIVER FIBROSIS MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF LIVER

	FIBROSIS ANALYTES.,M-58LEO(I)LYSE(MINDRAY)-M-58 LEO (I) LYSE APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT BREAKS DOWN RED BLOOD CELL MEMBRANE AND COOPERATES WITH THE M-58 LEO (II) LYSE TO 4 DIFFERENTIATE W8C'S .,TOTAL HUMAN CHORIONIC GONADOTROPIN (CLIA) (MINDRAY)-THE CL-SERIES TOTAL HCG ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL HUMAN CHORIONIC GONADOTROPIN (TOTAL HCG) IN HUMAN SERUM.,M-58LH LYSE(MINDRAY)-M-58 LH LYSE APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT BREAKS DOWN RED BLOOD CELL MEMBRANE AND CONVERTS HEMOGLOBIN TO A HEMOGLOBIN COMPLEX TO DETERMINE THE HG8.,TESTOSTERONE CALIBRATORS(MINDRAY)-MINDRAY TESTOSTERONE CALIBRATORS (TESTO CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE TESTOSTERONE (TESTO) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER. ,M-53 LH LYSE(MINDRAY)-M-53LH LYSE BREAKS DOWN RED BLOOD CELL MEMBRANE AND CONVERTS HEMOGLOBIN TO A HEMOGLOBIN COMPLEX TO DETERMINE THE HGB. IT 2-DIFFERENTIATES WBCS TO BASO AND OTHER WBCS, AND DETERMINES WBCS AMOUNT.,THYROID FUNCTION MULTI CONTROL (H)(MINDRAY)-MINDRAY THYROID FUNCTION MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF THYROID FUNCTION ANALYTES.,M-53P CLEANSER(MINDRAY)-M-53P PROBE CLEANSER APPLIES TO MINDRAY BC-5300, BC-5380 BC-5100, BC-5180, ULTIMA 5 AUTO HEMATOLOGY ANALYZER. IT IS USED TO CLEAN THE ANALYZER REGULARLY. USE THE M-53P PROBE CLEANER AS INSTRUCTED BY THE OPERATOR'S MANUAL OF THE ANALYZER.,MYO CALIBRATORS(MINDRAY)-MINDRAY MYOGLOBIN CALIBRATORS (MYO CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVEMYOGLOBIN (MYO) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,M-53 LEO (II) LYSE (MINDRAY)-M-53LEO(II) LYSE COOPERATES WITH THE M-53LEO(I) LYSE TO 4-DIFFERENTIATE WBCS.,REPRODUCTIVE MULTI CONTROL (H)(MINDRAY)-MINDRAY REPRODUCTIVE MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF REPRODUCTIVE HORMONE ANALYTES.,M-53D DILUENT(MINDRAY)-M-53D DILUENT PROVIDES A STABLE ENVIRONMENT FOR COUNTING

	AND SIZING BLOOD CELLS.,FOLLICLE STIMULATING HORMONE (CLIA)(MINDRAY)-THE CL-SERIES FSH ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN SERUM OR PLASMA.,M-58D DILUENT(MINDRAY)-M-58 D DILUENTS APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT PROVIDE A STABLE ENVIRONMENT FOR COUNTING AND SIZINQ BLOOD CELLS.,IMMUNOASSAY MULTI CONTROL (H)(MINDRAY)-MINDRAY IMMUNOASSAY MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF IMMUNOASSAY MULTI ANALYTES., M-58LBA LYSE(MINDRAY)-M-58 L8A LYSE APPLIES TO MINDRAY BC-5600 , 8C-5800 AUTO HEMATOLOGY ANALYZER. IT BREAKS DOWN RED BLOOD CELL MEMBRANE AND 2 DIFFERENTIATES W8C'S TO BASOPHILS AND OTHER W8C'S,HEMOLYSIS SOLUTION(MINDRAY)-THIS PRODUCT APPLIES TO MINDRAY H50/H50P AUTOMATED GLYCOHEMOGLOBIN ANALYZER. USED FOR PRE-TREATMENT OF BLOOD SAMPLES BEFORE HBA1C ANALYSIS.,REAGENT MODULE (CALA,CALB,WASTE)(MINDRAY)-FOR USE WITH THE ISE MODULE DAILY RINSE CLEANING DILUENT,ESTRADIOL (CLIA)(MINDRAY)-THE CL-SERIES E2 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL (E2) IN HUMAN SERUM.,M-68DR DILUENT(MINDRAY)-THE M-68DR DILUENT APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF RET-RELATED PARAMETERS TOGETHER WITH M-68FR DYE.,TOTAL THYROXINE (CLIA)(MINDRAY)-THE CL-SERIES T4 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE (T4) LEVELS IN HUMAN SERUM OR PLASMA.,M-50LBA LYSE(MINDRAY)-M-50 LBA LYSE APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLOGY ANALYZER. IT IS USED TO LYSE RED BLOOD CELLS AND COUNT WBC'S AND BASOPHILS.,PROLACTIN(CLIA)(MINDRAY)-THE CL-SERIES PRL ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN HUMAN SERUM OR PLASMA.,M-50P PROBE CLEANSER(MINDRAY)-M-50 P PROBE CLEANSER APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLOGY ANALYZER. IT IS USED TO CLEAN THE ANALYZER REGULARLY,RED BLOOD CELL FOLATE RELEASING REAGENT(MINDRAY)-RED BLOOD CELL FOLATE RELEASING REAGENT IS USED FOR THE PRETREATMENT OF WHOLE BLOOD SAMPLES TO RELEASE FOLATES IN ERYTHROCYTES (RED BLOOD

	CELLS, RBC), IN ORDER TO TEST THE FOLATE CONCENTRATION IN ERYTHROCYTES USING THE FOLATE (CLIA) REAGENT KIT.,M-52D DILUENT(MINDRAY)-M-52 D DILUENT PROVIDE STABLE SOLUTION ENVIRONMENT FOR BLOOD CELLS, DILUTE BLOOD SAMPLE, GENERATES SHEATH FLUID AND PROVIDE CONDUCTANCE IN BLOOD CELL ANALYSIS PROCESS,SAMPLE DILUENT(MINDRAY)-MINDRAY SAMPLE DILUENT IS INTENDED FOR DILUTION OF SAMPLES IN WHICH ANALYTE CONCENTRATION HAS EXCEEDED THE MEASURING RANGE OF RESPECTIVE CHEMILUMINESCENT IMMUNOASSAY REAGENTS., MULTI CONTROL SERA P(MINDRAY)-MULTI CONTROL SERA P IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION ON MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY, INSULIN (CLIA)(MINDRAY)-THE CL-SERIES INSULIN ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM OR PLASMA.,M-52DIFF LYSE(MINDRAY)-M-52 DIFF LYSE DISSOLVES RBCS IN THE BLOOD CELL ANALYSIS PROCESS. IT PROCESSES W8CS TO INTENSIFY THE DIFFERENCE OF THE WBC SUB POPULATIONS AND IN CORPORATE LASER SCATTER AND FLOW CYTOMETRY TO REALIZE DIFF CHANNEL WBC ANALYSIS,REPRODUCTIVE MULTI CONTROL (L)(MINDRAY)-MINDRAY REPRODUCTIVE MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF REPRODUCTIVE HORMONE ANALYTES.,M-52LH LYSE(MINDRAY)-M-52 LH LYSE FUTHER PROCESS THE BLOOD CELL THAT HAVE BEEN PROCESSED BY M-52 DIFF LYSE. IT TURNS HEMOGLOBIN INTO METHEMOGLOBIN, WHICH THEN MEASURED BY THE COLORIMETRIC METHOD. IT IS ALSO PROCESSES W8C'S TO INTENSIFY THE DIFFERENCE BETWEEN BASOPHILES AND OTHER W8C SUB POPULATIONS AND IN CORPORATE CYTOMETRY TO REALIZE BASOPHIL ANALYSIS,LIVER FIBROSIS MULTI CONTROL (L)(MINDRAY)-MINDRAY LIVER FIBROSIS MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF LIVER FIBROSIS ANALYTES.,M-53 CLEANSER (1L X 4)(MINDRAY)-AN-AZIDE FREE FILTERED SOLUTION FOR USE IN CLEANING HEMATOLOGY ANALYZER,THYROID-STIMULATING HORMONE (CLIA)(MINDRAY)-THE CL-SERIES TSH ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN HUMAN SERUM.,SPECIFIC

	PROTEINS CALIBRATOR(MINDRAY)-SPECIFIC PROTEINS CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF SPECIFIC PROTEINS ON MINDRAY BS MEASUREMENT SYSTEM, ESTRIOL CALIBRATORS(MINDRAY)-MINDRAY ESTRIOL CALIBRATORS (E3 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE ESTRIOL (E3) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,M-53 LEO (I) LYSE(MINDRAY)-M-53LEO(I) LYSE BREAKS DOWN RED BLOOD CELL MEMBRANE AND COOPERATES WITH THE M-53LEO(II) LYSE TO 4-DIFFERENTIATE WBCS.,SYSTEM WASH SOLUTION(MINDRAY)-SYSTEM WASH SOLUTION IS USED TO PRIME THE SUBSTRATE DISPENSING TUBE IN ORDER TO CLEAN THE TUBES.,M-68DS DILUENT(MINDRAY)-THE M-68DS DILUENT APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF PARAMETERS RELATED TO RBC, PLT, WBC, RET AND NRBC. M-68DS DILUENT ALSO APPLIES TO SC-120 AUTO SLIDE MAKER & STAINER AND CRP-M100 SPECIFIC PROTEIN ANALYZER MANUFACTURED BY MINDRAY. IT PARTICIPATES IN THE CLEANING OF RELATED COMPONENTS OF THE AUTO SLIDE MAKER & STAINER AND SPECIFIC PROTEIN ANALYZER.,FERRITIN CALIBRATORS (MINDRAY)-MINDRAY FERRITIN CALIBRATORS (FERR CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE FERRITIN (FERR) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,PHOSPHORUS(P) KIT (PHOSPHOMOLYBDATE METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF P CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,FOLATE (CLIA)(MINDRAY)-THE CL-SERIES FOLATE ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN SERUM, PLASMA OR RED BLOOD CELLS.,M-50 LEO (I) LYSE(MINDRAY)-M-50 LEO (I) LYSE APPLIES TO 5 PART DIFFERNTIAL AUTO HEMATOLOGY ANALYSE_R. IT IS USED TO LYSE RED BLOOD CELLS AND 4 DIFFERENTIATES WBC'S,ANTIBODY TO THYROGLOBULIN (CLIA) (MINDRAY)-THE CL-SERIES ANTI-TG ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO THYROGLOBULIN (ANTI-TG) IN HUMAN SERUM OR PLASMA.,M-50 LEO (II) LYSE(MINDRAY)-M-50 LEO (II) LYSE APPLIES TO 5 PART DIFFERNTIAL AUTO HEMATOLOGY ANALYSER. IT IS USED TO LYSE RED BLOOD CELLS AND 4 DIFFERENTIATES WBC'S,25-OH-VITAMIN D TOTAL (CLIA)(MINDRAY)-THE CL-SERIES VD-T ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF 25-OH-VITAMIN D TOTAL IN HUMAN SERUM OR PLASMA. VITAMIN D IS A NECESSARY FAT-SOLUBLE STEROID HORMONE PRECURSOR THAT IS INFLUENCED BY KINDS OF FACTOR.

	SUCH AS SUNLIGHT, DIETARY, AGE, FAT, RACE, AND SO ON.,M-50 LH LYSE(MINDRAY)-M-50 LH LYSE APPLIES TO 5 PART DIFFERNTIAL AUTO HEMATOLOGY ANALYSER. IT IS USED TO LYSE RED BLOOD CELLS AND DETERMINE THE HGB,SUBSTRATE SOLUTION(MINDRAY)-MINDRAY SUBSTRATE SOLUTION IS INTENDED FOR USE WITH THE MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND SPECIFIC MINDRAY IMMUNOASSAY REAGENTS.,M-50 CLEANSER(MINDRAY)-M-50 CLEANSER APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLGY ANALYZER. IT IS AN ISOTONIC , CLEANING SOLUTION USE TO CLEAN THE ANALYSER,PARATHYROID HORMONE (CLIA)(MINDRAY)-THE CL-SERIES PTH ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PTH IN HUMAN SERUM OR PLASMA.,M-18R RINSE (MINDRAY)-FOR USE ON MINDRAY BC-1800/BC-2800/BC-2600 HEMATOLOGY ANALYZER. FOR USE AS AN AZIDE-FREE, FILTERED ISOTONIC SOLUTION FOR COUNTING AND SIZING BLOOD CELLS. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,WASH BUFFER (MINDRAY)-MINDRAY WASH BUFFER IS INTENDED FOR USE WITH THE CL-SERIES IMMUNOASSAY SYSTEMS AND SPECIFIC CL-SERIES IMMUNOASSAY REAGENTS. ,PRE ALBUMIN CALIBRATOR(MINDRAY)-PRE ALBUMIN CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF SPECIFIC PROTEINS ON MINDRAY BS MEASUREMENT SYSTEM,PTH CALIBRATORS(MINDRAY)-MINDRAY PTH CALIBRATORS (PTH CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE PTH ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,M-30R RINSE (MINDRAY)-IT IS USE ON MINDRAY THREE PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS USE AS AZIDE FREE, FILTERED ISOTONIC SOLUTION FOR CLEANING HEMATOLOGY ANALYSER, HEMOGLOBIN A1C CONTROL(MINDRAY)-QUALITY CONTROL OVER THE TEST ON HBA1C IN WHOLE BLOOD TO MONITOR AND ASSESS THE ACCURACY OF THE TEST RESULT,M-50D DILUENT(MINDRAY)-M-50 D DILUENTS APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLOGY ANALYZER. IT IS USED TO PROVIDE A STABLE ENVIRONMENT FOR COUNTING AND SIZING BLOOD CELLS,TOTAL HCG CALIBRATORS(MINDRAY)-MINDRAY TOTAL HCG CALIBRATORS (HCG CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE TOTAL HUMAN CHORIONIC GONADOTROPHIN (TOTAL HCG) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,KIT,CLEANING SOLUTION, ISE(MINDRAY)-INTENDED FOR CLEANING THE CHEMISTRY ANALYZER,THYROGLOBULIN (CLIA)(MINDRAY)-THE CL-SERIES TG ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) IN HUMAN

	SERUM OR PLASMA.,TOTAL BILE ACIDSTBAKITENZYMATIC CYCLING ASSAY)(MINDRAY)-IN VITRO TEST .FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILE ACID CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,FOLATE CALIBRATORS (MINDRAY)-MINDRAY FOLATE CALIBRATORS (FOLATE CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE FOLATE ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,M30P PROBE CL(MINDRAY)-FOR USE ON MINDRAY BC-3000PLUS/BC-3000CT/BC-3200 HEMATOLOGY ANALYZER. FOR USE AS AN AZIDE-FREE, FILTERED ISOTONIC SOLUTION FOR COUNTING AND SIZING BLOOD CELLS. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,CORTISOL (CLIA)(MINDRAY)-THE CL-SERIES CORTISOL ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM, PLASMA OR URINE.,NA/K CHECK SOLUTION(INTERNATIONAL)(MINDRAY)-MR NA/K CHECK SOLUTION IS A KIND OF MAINTENANCES SOLUTIONS USED TO MONITOR THE SODIUM/POTASSIUM ION-SELECTIVE PERFORMANCE OF ION-SELECTIVE ELECTRODE INSTALLED IN ISE MODULES ON AUTOMATIC CHEMISTRY ANALYZERS.,FREE T3 CALIBRATORS(MINDRAY)-MINDRAY FREE T3 CALIBRATORS (FT3 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE FREE TRIIODOTHYRONINE (FT3) ASSAY ON MINDRAY CL-SERIESCHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,URIC ACID(UA) KIT(URICASE-PEROXIDASE METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF UA CONCENTRATION IN SERUM, PLASMA AND URINE ON PHOTOMETRIC SYSTEM,ACTH CALIBRATORS (MINDRAY)-MINDRAY ACTH CALIBRATORS (ACTH CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE ADRENOCORTICOTROPIC HORMONE (ACTH) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,TOTAL PROTEIN(TP)KIT (BIURET METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TP CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,METABOLIC MULTI CONTROL (H)(MINDRAY)-MINDRAY METABOLIC MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF PTH, CT, 25-OH-VITAMIN D TOTAL, VB12, FOLATE, FERRITIN ANALYTES.,V-52LH LYSE(EN/90ML×4)(MINDRAY)-V-52LH LYSE APPLIES TO BC-5000VET VETERINARY AUTO HEMATOLOGY ANALYZER MANUFACTURED BY MINDRAY, IT DISSOLVES RBCS, REALIZES WBC COUNTING, BASOPHIL DIFFERENTIAL AND HEMOGLOBIN

	MEASUREMENT.,INSULIN CALIBRATORS(MINDRAY)-MINDRAY INSULIN CALIBRATORS (INSULIN CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE INSULIN ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,TOTAL BILIRUBIN (T-BIL) KIT(DSA METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BIL - T CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,PROLACTIN CALIBRATORS(MINDRAY)-MINDRAY PROLACTIN CALIBRATORS (PRL CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE PROLACTIN (PRL) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,V-52DIFF LYSE(EN/300ML×4)(MINDRAY) -V-52DIFF APPLIES TO BC-5000VET VETERINARY AUTO HEMATOLOGY ANALYZER MANUFACTURED BY MINDRAY, IT DISSOLVES RBCS AND DIFFERENTIATES WBCS.,FREE THYROXINE (CLIA)(MINDRAY)-THE CL-SERIES FT4 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM OR PLASMA.,M-18P PROBE CLEANSER(MINDRAY)-FOR USE ON MINDRAY BC-1800/BC-2800/BC-2600 HEMATOLOGY ANALYZER. FOR USE AS A CLEANING REAGENT FOR HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,ANTI-THYROID ANTIBODIES CONTROL (L)(MINDRAY)-MINDRAY ANTI-THYROID ANTIBODIES CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF ANTI-THYROID ANTIBODIES ANALYTES.,IMMUNOGLOBULIN G(IGG) KIT(IMMUNOTURBIDIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGG CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,VITAMIN B12 CALIBRATORS(MINDRAY)-MINDRAY VITAMIN B12 CALIBRATORS (VB12 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE VB12 ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,BC-5D ((HIGH/NORMAL/LOW)*2/EN3ML*6)(MINDRAY)-BC - 50 IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS, TESTOSTERONE (CLIA)(MINDRAY)-THE CL-SERIES TESTO ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE (TESTO) IN HUMAN SERUM AND PLASMA. ,IMMUNOGLOBULIN A(IGA) KIT(IMMUNOTURBIDIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGA CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,ADRENOCORTICOTROPIC HORMONE (CLIA)

	(MINDRAY)-THE CL-SERIES ACTH ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ADRENOCORTICOTROPIC HORMONE (ACTH) IN HUMAN EDTA PLASMA.,IRON(FE)KIT(COLORIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM AND HEPARIN PLASMA ON PHOTOMETRIC SYSTEM,ANTI-THYROID ANTIBODIES CONTROL (H)(MINDRAY)-MINDRAY ANTI-THYROID ANTIBODIES CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF ANTI-THYROID ANTIBODIES ANALYTES.,IGM KIT (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGM CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM., PROGESTERONE (CLIA)(MINDRAY)-THE CL-SERIES PROG ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE (PROG) IN HUMAN SERUM.,ISE-URINE DILUENT(MINDRAY)-ISE URINE DILUENT IS INTENDED FOR USE AS DILUENT FOR URINE BEFORE TEST ON ISE MODULES ON MINDRAY BS SERIES CHEMISTRY ANALYZERS.,25-OH-VITAMIN D TOTAL CALIBRATORS(MINDRAY)-MINDRAY 25-OH-VITAMIN D TOTAL CALIBRATORS (VD-T CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE 25-OH-VITAMIN D TOTAL ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER., HEMOGLOBIN A1C(HBA1C)KIT(ENZYMATIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF HBA1C CONCENTRATION IN HUMAN WHOLE BLOOD ON PHOTOMETRIC SYSTEMS.,PROCALCITONIN (CLIA)(MINDRAY)-THECL-SERIESPROCALCITONIN ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONINPCT IN HUMAN SERUM OR PLASMA.,HBA1C CONTROL P(MINDRAY)-HBA1C CONTROL P IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,ANTIBODY TO THYROID PEROXIDASE (CLIA)(MINDRAY)-THE CL-SERIES ANTI-TPO ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTI-TPO IN HUMAN SERUM OR PLASMA.,B55 CONTROL(MINDRAY)-B55 HEMATOLOGY CONTROL IS A HEMATOLOGY REFERENCE CONTROL USED TO MONITOR THE PERFORMANCE OF BC SERIES HEMATOLOGY ANALYZERS. THE REFERENCE VALUES AND EXPECTED RANGES OF PARAMETERS ARE DISPLAYED IN THE QUALITY CONTROL GRAPHS WITH UPPER AND LOWER CONTROL LIMITS. CLINICAL LABORATORIES USE STABILIZED,

	SIMULATED BLOOD CELL SUSPENSION TO MONITOR CORRESPONDING PARAMETERS. DAILY USE OF THIS WHOLE BLOOD CONTROL PROVIDES QUALITY CONTROL DATA FOR CONFIRMING THE PRECISION AND ACCURACY OF INSTRUMENT.,LH CALIBRATORS (MINDRAY)-MINDRAY LH CALIBRATORS (LH CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE LUTEINIZING HORMONE (LH) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,V-28R RINSE(MINDRAY)-AN AZIDE-FREE FILTERED ISOTONIC SOLUTION FOR USE IN BLOOD CELL COUNTING AND SIZING. USE AS DIRECTED IN INSTRUMENT OPERATION MANUAL.,CK-MB CALIBRATORS(MINDRAY)-MINDRAY CK-MB CALIBRATORS (CK-MB CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE CREATINE KINASE MB (CK-MB) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,V-28CFL LYSE (MINDRAY)-A CYANIDE FREE LYSE REAGENT, INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN AND LEUKOCYTE COUNTING AND SIZING,LUTEINIZING HORMONE (CLIA)(MINDRAY)-THE CL-SERIES LH ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM OR PLASMA.,M-58 CLEANSER (MINDRAY)-PROBE CLEANSER APPLIES TO MINDRAY BC-5600, BC-5800, BC-3300, BC-3600 AUTO HEMATOLOGY ANALYZER. IT IS USED TO CLEAN THE ANALYZER REGULARLY. USE THE PROBE CLEANER AS INSTRUCTED BY THE OPERATOR'S MANUAL OF THE ANALYZER., DEHYDROEPIANDROSTERONE SULFATE (CLIA)(MINDRAY)-THE CL-SERIES DHEA-S ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) IN HUMAN SERUM OR PLASMA.,MULTI SERA CALIBRATOR(MINDRAY)-MULTI SERA CALIBRATOR IS USED FOR CALIBRATION OF QUANTITATIVE DETERMINATION OF ROUTINE CHEMISTRY ANALYSTES ON MINDRAY BS MEASUREMENT SYSTEM,ESTRADIOL CALIBRATORS(MINDRAY)-MINDRAY ESTRADIOL CALIBRATORS (E2 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE ESTRADIOL (E2) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,ALT KIT(MINDRAY)-ALT REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE ACTIVITY IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEM.,C-PEPTIDE (CLIA) (MINDRAY)-THE CL-SERIES C-PEPTIDE ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OFC-PEPTIDE (C-PEPTIDE) IN HUMAN SERUM, PLASMA OR URINE.,AST KIT(MINDRAY)-AST REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OR PLASMA ON PHOTOMETRIC SYSTEM IN SERUM AST ACTIVITY,FSH CALIBRATORS(MINDRAY)-

	MINDRAY FSH CALIBRATORS (FSH CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE FOLLICLE STIMULATING HORMONE (FSH) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,ALP KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALP ACTIVITY IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,PCT CALIBRATORS (MINDRAY)-USED IN IN VITRO DIAGNOSTICS(TO CALIBRATE THE QUANTITATIVE PROCALCITONIN (PCT) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER).,GGT KIT (MINDRAY)-GGT REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF GAMMA-GLUTAMYLTRANSFERASE ACTIVITY IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,ESTRIOL (CLIA)(MINDRAY)-THE CL-SERIES E3 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ESTRIOL (E3) IN HUMAN SERUM. ,LDH KIT(MINDRAY)-LDH REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,DHEA-S CALIBRATORS(MINDRAY)-MINDRAY DHEA-S CALIBRATORS (DHEA-S CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVEDEHYDROEPIANDROSTERONE SULFATE (DHEA-S) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,HBDH KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF A HBDH ACTIVITY IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,TOTAL T3 CALIBRATORS (MINDRAY)-MINDRAY TOTAL T3 CALIBRATORS (T3 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE TOTAL TRIIODOTHYRONINE (T3) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,UREA KIT (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF UREA CONCENTRATION IN SERUM, PLASMA AND URINE ON PHOTOMETRIC SYSTEM,TOTAL T4 CALIBRATORS(MINDRAY)-MINDRAY TOTAL T4 CALIBRATORS (T4 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE TOTAL THYROXINE (T4) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,T-BIL KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BIL - T CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,PCT CONTROL (L) (MINDRAY)-USED IN IN VITRO DIAGNOSTICS (FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF PCT).,D-BIL KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BIL-D CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,COLLAGEN TYPE IV

	(CLIA)(MINDRAY)-THE CL-SERIES C IV ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF COLLAGEN TYPE IV (C IV) IN HUMAN SERUM., CREA KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATININE CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,METABOLIC MULTI CONTROL (L)(MINDRAY)-MINDRAY METABOLIC MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF PTH, CT, 25-OH-VITAMIN D TOTAL, VB12, FOLATE, FERRITIN ANALYTES.,CK KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATININE CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,LAMININ (CLIA)(MINDRAY)-THE CL-SERIES LAMININ ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF LAMININLN IN HUMAN SERUM., CK-MB KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE-MB (CK-MB) ACTIVITY IN SERUM ON PHOTOMETRIC SYSTEMS.,C-PEPTIDE CALIBRATORS (MINDRAY)-MINDRAY C-PEPTIDE CALIBRATORS (C-PEPTIDE CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVEC-PEPTIDE ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,HDL KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BIL-D CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,ANTI-TG CALIBRATORS(MINDRAY)-MINDRAY ANTI-TG CALIBRATORS (ANTI-TG CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE ANTIBODY TO THYROGLOBULIN (ANTI-TG) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,LDL KIT (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LDLCHOLESTEROL CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,HEMOGLOBIN A 1C CALIBRATOR(MINDRAY)-TEST AND CALIBRATE HBA1C IN WHOLE BLOOD TO GUARANTEE THAT THE TEST RESULT IS ACCURATE,APOA1 KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF APOA1 CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,THYROGLOBULIN CALIBRATORS (MINDRAY)-MINDRAY THYROGLOBULIN CALIBRATORS (TG CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE THYROGLOBULIN (TG) ASSAY ON MINDRAY CL-SERIESCHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,APOB KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF APOB CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,PROGESTERONE CALIBRATORS (MINDRAY)-MINDRAY PROGESTERONE CALIBRATORS (PROG CAL)

	ARE INTENDED TO CALIBRATE THE QUANTITATIVE PROGESTERONE (PROG) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER. ,C4 KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF C4 CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,FREE TRIIODOTHYRONINE (CLIA) (MINDRAY)-THE CL-SERIES FT3 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM.,CRP KIT (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CRP CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,ACTH CONTROL (H)(MINDRAY)-MINDRAY ACTH CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF ACTH ANALYTE.,V-52D DILUENT (EN/20L×1)(MINDRAY)-V-52D DILUENT APPLIES TO BC-5000VET VETERINARY AUTO HEMATOLOGY ANALYZER MANUFACTURED BY MINDRAY, IT IS USED IN SAMPLE DILUTION, BLOOD CELL COUNTING, VOLUME MEASUREMENT AND HEMOGLOBIN MEASUREMENT.,ACTH CONTROL (L)(MINDRAY)-MINDRAY ACTH CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF ACTH ANALYTE.,V-28D DILUENT (MINDRAY)-AN AZIDE-FREE FILTERED ISOTONIC SOLUTION FOR USE IN BLOOD CELL COUNTING AND SIZING. USE AS DIRECTED IN INSTRUMENT OPERATION MANUAL.,ANTI-TPO CALIBRATORS (MINDRAY)-MINDRAY ANTI-TPO CALIBRATORS (ANTI-TPO CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE ANTIBODIES TO THYROID PEROXIDASE (ANTI-TPO) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,V-28E E-Z CLEAN (MINDRAY)-INTENDED FOR CLEANING THE HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATION MANUAL.,V28P PROBE CL(MINDRAY)-INTENDED FOR CLEANING THE HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATION MANUAL.,-AMYLASE(-AMY) KIT (IFCC METHOD)(MINDRAY)-A AMY REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF A AMYLASE ACTIVITY IN SERUM. PLASMA OR URINE ON PHOTOMETRIC SYSTEM,TRIGLYCERIDES(TG) KIT (GPO-POD METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TG CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,SC-CAL PLUS CALIBRATOR (MINDRAY)-SC CAL PLUS IS DESIGNED FOR USE IN THE CALIBRATION OF HEMATOLOGY ANALYZER,TOTAL CHOLESTEROL(TC) KIT(CHOD-

	POD METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TC CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,S30 CALIBRATOR(MINDRAY)-S30 CALIBRATOR IS INTENDED FOR USE AS CALIBRATOR FOR WBC, RBC, HGB, MCV AND PLT PARAMETERS ON HEMATOLOGY ANALYZERS. BEFORE CARRYING OUT CLINICAL PRACTICE, PARAMETERS OF THE HEMATOLOGY ANALYZER NEED TO BE CALIBRATED AS INSTRUCTED IN INSTRUMENT MANUAL.,M-18E E-Z CLEANSER(MINDRAY)-FOR USE ON MINDRAY BC-1800/BC-2800/BC-2600 HEMATOLOGY ANALYZER. FOR USE AS A CLEANING REAGENT FOR CLEANING HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,M-18D DILUENT(MINDRAY)-FOR USE ON MINDRAY BC-1800/BC-2800/BC-2600 HEMATOLOGY ANALYZER. FOR USE AS AN AZIDE-FREE, FILTERED ISOTONIC SOLUTION FOR COUNTING AND SIZING BLOOD CELLS. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,M-18CFL LYSE(MINDRAY)-FOR USE ON MINDRAY BC-1800/BC-2800/BC-2600 HEMATOLOGY ANALYZER. FOR USE AS A CYANIDE-FREE LYTIC REAGENT FOR QUANTITATIVELY DETERMINING HEMOGLOBIN AND FOR COUNTING AND SIZING LEUKOCYTES. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,LIPOPROTEIN(A) CONTROL N&P(MINDRAY)-LIPOPROTEIN (A) N & P IS USED IN LIPID ANALYTE QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY, LIPOPROTEIN(A) CALIBRATOR(MINDRAY)-LIPOPORTEIN (A) CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF LIPID ANALYTE ON MIND RAY BS MEASUREMENT SYSTEM,LIPIDS CALIBRATOR(MINDRAY)-LIPID CALIBRATOR IS USED FOR CALIBRATION OF QUANTITATIVE DETERMINATION OF LIPID ANALYTES ON MINDRAY BS MEASUREMENT SYSTEM,LIPASE(LIP)KIT (ENZYMATIC COLORIMETRIC ASSAY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LIP CONCENTRATION IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEM, HBA1C CONTROL N(MINDRAY)-HBA1C CONTROL N IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,BC-6D(MINDRAY)-BC-6D IS IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.,ANTIBODIES AGAINST STREPTOLYSIN O(ASO)KIT (PARTICLE-ENHANCED IMMUNOTURBIDIMETRIC ASSAY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ASO CONCENTRATION

	IN SERUM ON PHOTOMETRIC SYSTEM,ALBUMIN(ALB) KIT (BCG METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALB CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM.,DIRECT BILIRUBIN(D-BIL) KIT(DSA METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF D-BIL CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,FRUCTOSAMINE(FUN)KIT(COLORIMETRIC ASSAY)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF FRUCTOSAMINE CONCENTRATION IN SERUM, HEPARIN PLASMA ON PHOTOMETRIC SYSTEMS.,CREATININE KIT (MODIFIED JAFFE METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATININE CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,LPA KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LP(A) CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS., COMPLEMENT C3 KIT (IMMUNOTURBIDIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF C3 CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,PA (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF PA CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS., DETERGENT(INDIRECT)(INTERNATIONAL)(MINDRAY)-MR DETERGENT SOLUTION APPLIES TO MINDRAY BS SERIES AUTO CHEMISTRY ANALYZERS. IT IS USED TO CLEAN THE ELECTRODES FLOW CELL AS WELL AS THE PIPELINE OF THE ISE MODULE.,PROBE CLEANSER (M-68/EN)(MINDRAY)-PROBE CLEANSER APPLIES TO MINDRAY BC-20, BC-21, BC-10, BC-11, BC-6800, BC-6600, BC-5000, BC-5150, BC-5390 CRP, BC-5180 CRP, BC-30S, BC-31S, BC-20S, BC-21S, BC-5120, BC-5130, BC-5310 CRP, BC-5100 CRP, BC-5140, BC-30, BC-31, BC-6000, BC-6000PLUS, BC-6100, BC-6100PLUS, BC-6200, BC-6600PLUS, BC-6700PLUS, BC-6800PLUS AUTO HEMATOLOGY ANALYZER, BC-5000VET VETERINARY AUTO HEMATOLOGY ANALYZER, SC-120 AUTO SLIDE MAKER & STAINER AND CRP-M100 SPECIFIC PROTEIN ANALYZER. IT IS USED TO CLEAN THE INSTRUMENT REGULARLY., CALCIUM(CA) KIT(ARSENAZO III METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CA CONCENTRATION IN SERUM,PLASMA OR URINE ON PHOTOMETRIC SYSTEM, CHOLINESTERASE(CHE)KIT(BUTYRYLTHIOCHOLINE METHOD) (MINDRAY)-CHE REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CHE ACTIVITY IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEM,CK-MB CALIBRATOR(MINDRAY)-CK-MB CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF CARDIAC ANALYTE ON MINDRAY BS MEASUREMENT SYSTEM,CARBON DIOXIDE(CO2)KIT(ENZYMATIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE

		DETERMINATION OF C02 CONCENTRATION IN SERUM AND HEPARIN PLASMA ON PHOTOMETRIC SYSTEM,CD80 DETERGENT(MINDRAY)-CLEAN SAMPLE AND REAGENT PROBES, MIXERS AND CUVETTES OF THE CHEMISTRY ANALYZER MANUFACTURED BY MINDRAY., REAGENT,M-30E E-Z CLEANSER(MINDRAY)-FOR USE ON MINDRAY BC-3000/BC-3000PLUS/BC-3000CT/ BC-3200 HEMATOLOGY ANALYZER. FOR USE AS A CLEANING REAGENT FOR CLEANING HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,RHEUMATOID FACTOR(RF)KIT (PARTICLE-ENHANCED IMMUNOTURBIDIMETRIC ASSAY METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF RF CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,BC-RET(MINDRAY)-BC-RET IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.
74	IMP/IVD/2018/000055	1.License Holder Name: ASPEN DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EASYTOUCH BLOOD URIC ACID TEST STRIPS (NON-STERILE)(EASYTOUCH)-INTENDED FOR THE PRELIMINARY SELF TESTING OF URIC ACID LEVELS IN BLOOD

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75	IMP/IVD/2018/000056	1.License Holder Name: DEEP MEDITECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FIBRINOGEN DEGRADATION PRODUCT (FDP) DETECTION KIT (NEPHELOMETRY) (GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF FDP, COMPLEMENT C4 (C4) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF C4,2-MICROGLOBULIN (2-MG) DETECTION KIT (NEPHELOMETRY)(GENRUI) -FOR IN VITRO QUANTITATIVE DETERMINATION OF 2-MG, PEPSINOGEN I (PGI) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF PGI,LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 (LP-PLA2) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF LP-PLA2,GLYCATED HEMOGLOBIN (HBA1C) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF HBA1C,ANTI-STREPTOLYSIN O DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF ASO,C-REACTIVE PROTEIN DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF CRP,COMPLEMENTC3 (C3) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF C3,IMMUNOGLOBULIN A (IGA) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF IGA,IMMUNOGLOBULIN M (IGM) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF IGM,RHEUMATOID FACTOR DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF RF,CYSTATIN C DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF CYS-C,HUMAN MICRO-ALBUMINURIA DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF MALB,D-DIMER DETECTION KIT(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF D-DIMER,RETINOL BINDING PROTEIN (RBP) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF RBP,HIGH SENSITIVE C-REACTIVE PROTEIN DETECTION KIT (NEPHELOMETRY) (GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF HS-CRP, NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN (NGAL) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF NGAL,SERUM AMYLOID PROTEIN A (SAA) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF SAA,ANTI-CYCLIC CITRULLINATED PEPTIDE ANTIBODY DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE

		DETERMINATION OF CCP,IMMUNOGLOBULIN G (IGG) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF IGG,PEPSINOGEN II (PGII) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF PGII
76	IMP/IVD/2018/000057	1.License Holder Name: IDEXX LABORATORIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ROTA-CORONA-K99 AG TEST(IDEXX ROTA-CORONA-K99 AG TEST)-SERODIAGNOSIS ROTAVIRUS/CORONAVIRUS INFECTION BY ELISA,BRUCELLOSIS SERUM AB TEST(IDEXX BRUCELLOSIS SERUM AB TEST)-SERODIAGNOSIS OF BRUCELLOSIS BY ELISA,PARATUBERCULOSIS SCREENING AB TEST(IDEXX PARATUBERCULOSIS SCREENING AB TEST)-SERODIAGNOSIS OF PARATUBERCULOSIS BY ELISA, PARATUBERCULOSIS SCREENING AB TEST(IDEXX PARATUBERCULOSIS SCREENING AB TEST)-SERODIAGNOSIS OF PARATUBERCULOSIS BY ELISA,PARATUBERCULOSIS VERIFICATION AB TEST(IDEXX PARATUBERCULOSIS VERIFICATION AB TEST)-SERODIAGNOSIS OF PARATUBERCULOSIS BY ELISA,FASCIOLOSIS VERIFICATION TEST(IDEXX FASCIOLOSIS VERIFICATION TEST)-SERODIAGNOSIS OF FASCIOLOSIS BY ELISA,BLUETONGUE COMPETITION AB TEST(IDEXX BLUETONGUE COMPETITION AB TEST)-SERODIAGNOSIS OF BLUETONGUE BY ELISA,CCPP AB TEST(IDEXX CCPP AB TEST)-SERODIAGNOSIS OF CCPP BY ELISA,BRUCELLOSIS OVINE/CAPRINE AB TEST(IDEXX BRUCELLOSIS OVINE/CAPRINE AB TEST)-SERODIAGNOSIS OF BRUCELLOSIS BY ELISA,BRUCELLOSIS MILK AB TEST(IDEXX BRUCELLOSIS MILK AB TEST)-SERODIAGNOSIS OF BRUCELLOSIS BY ELISA,ROSE BENGALE AG TEST(POURQUIER* ROSE BENGALE AG TEST)-SERODIAGNOSIS OF BRUCELLOSIS BY AGGLUTINATION,ROSE BENGALE AG TEST(POURQUIER* ROSE BENGALE AG TEST)-SERODIAGNOSIS OF BRUCELLOSIS BY AGGLUTINATION

77	IMP/IVD/2018/000059	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LYSE FOR HEMATOLOGY ANALYZERS-TO LYSE THE CELLS FOR FURTHER TESTING USING HEMATOLOGY ANALYZER, SUCH AS COMPLETE BLOOD COUNT (CBC).,DYE FOR HEMATOLOGY ANALYZERS-USED AS CONSUMABLE IN HEMATOLOGY ANALYZER FOR ESTIMATION OF VARIOUS HEMATOLOGY PARAMETERS, SUCH AS COMPLETE BLOOD COUNT (CBC).,URINE ANALYSIS WITH SHEATH LIQUID-USED TO WRAP SAMPLE TO FORM A SHEATH FLOW TO CONDUCT URINE PHYSICAL COMPONENT COUNTING ON FUS SEDIMENT ANALYZERS,DILUENT FOR HEMATOLOGY ANALYZERS-TO DILUTE BLOOD FOR FURTHER TESTING USING HEMATOLOGY ANALYZER, SUCH AS COMPLETE BLOOD COUNT (CBC).,CLEANER-USED FOR CLEANING VARIOUS PARTS OF HEMATOLOGY ANALYZER LIKE PROBE, NEEDLES, BATH, TUBING ETC.

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78	IMP/IVD/2018/000060	1.License Holder Name: M/S.TRANSASIA BIO-MEDICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URO-DIP 2VGK(URO-DIP 2VGK)-RAPID SEMI-QUANTITATIVE URINE DETERMINATION OF GLUCOSE AND KETONES.,REAGENT FOR ACETOINTEST(REAGENT FOR ACETOINTEST)-"A SUPPLEMENTARY COLOUR FORMING REAGENT FOR THE TEST FOR THE FORMATION OF ACETOIN, IS INCLUDED IN SOME OF THE MICROBILOGY DIAGNOSTIC KITS. " ,URO-DIP 2VPG (URO-DIP 2VPG)-RAPID SEMI-QUANTITATIVE URINE DETERMINATION OF PROTEIN AND GLUCOSE.,REAGENT FOR INDOLTEST(REAGENT FOR INDOLTEST)-"A SUPPLEMENTARY COLOUR FORMING REAGENT FOR THE TEST FOR INDOL PRODUCTION, USED FOR THE SET OF TESTS OF DIAGNOSTIC MICROBIOLOGY KITS." ,ERBA H360 LYSE(ERBA H360 LYSE)-ERBA H360 LYSE IS USED TO DISSOLVE RED BLOOD CELLS FOR COUNTING HEMOGLOBIN AND WHITE BLOOD CELLS ON HEMATOLOGY ANALYSERS H360.,ENTEROTEST 24 N(ENTEROTEST 24 N)-THE KIT IS DESIGNED FOR THE ROUTINE IDENTIFICATION OF CLINICALLY IMPORTANT SPECIES OF FAMILY ENTEROBACTERIACEAE WITHOUT THE USE OF REAGENTS. ,ERBA H560 LYSE2(ERBA H560 LYSE2)-ERBA H560 LYSE2 IS USED FOR DIFFERENTIATION OF WHITE BLOOD CELLS ON HEMATOLOGY ANALYSERS H560. ,REAGENT FOR PHENYLALANINETEST(REAGENT FOR PHENYLALANINETEST)-A SUPPLEMENTARY REAGENT FOR MICROBILOGY DIAGNOSTIC KITS CONTAINING TEST FOR THE DETECTION OF PHENYLALANINE DEAMINASE AND SERVES FOR COLOUR EXPRESSION OF THIS TEST. , ERBA H560 DIL(ERBA H560 DIL)-ERBA H560 DIL IS USED TO DILUTED BLOOD AND PROVIDE A STABLE ENVIRONMENT FOR COUNTING AND SIZING BLOOD CELLS ON HEMATOLOGY ANALYSERS H560. , SUSPENSION MEDIUM MIC(SUSPENSION MEDIUM MIC)-SUPPLEMENTARY PREPARATION FOR MIC KITS (MIC G-I, G-II, URINE, NEFERM, STAPHY), WHICH ARE DESIGNED FOR ANTIBIOTIC SUSCEPTIBILITY TESTING. ,ERBA H560 LYSE1(ERBA H560 LYSE1)-ERBA H560 LYSE1 IS USED TO DISSOLVE RED BLOOD CELLS FOR COUNTING HEMOGLOBIN AND WHITE BLOOD CELLS ON HEMATOLOGY ANALYSERS H560. ,ENTEROTEST 24 (ENTEROTEST 24)-"THE KIT IS INTENDED FOR THE ROUTINE IDENTIFICATION OF IMPORTANT SPECIES OF FAMILY ENTEROBACTERIACEAE WITHIN 24 HOURS. " ,ERBA H360 DIL(ERBA H360 DIL)-ERBA H360 DIL IS USED TO DILUTED BLOOD AND PROVIDE A STABLE ENVIRONMENT FOR COUNTING AND SIZING BLOOD CELLS ON HEMATOLOGY ANALYSERS H360.,ENTERO-SCREEN(ENTERO-SCREEN)-"THE KIT IS INTENDED FOR THE IDENTIFICATION OF ENTEROBACTERIA BY MEANS OF EIGHT BIOCHEMICAL TESTS: GLUCOSE (ANAEROBIC), ACETOIN, PHENYLALANINE, INDOL, SUCROSE,UREASE, LYSINE, ORNITHIN." ,

	NEFERMTEST 24 N(NEFERMTEST 24 N)-THE KIT IS DESIGNED FOR THE ROUTINE IDENTIFICATION OF GRAM NEGATIVE NON-FERMENTING BACTERIA AND FAMILIES VIBRIONACEAE, AEROMONADACEAE AND PLEIOMONAS SHIGELLOIDES PRESENT MAINLY IN CLINICAL MATERIAL USING 24 BIOCHEMICAL TESTS. ,MIC COLISTIN(MIC COLISTIN)-THE KIT IS DESIGNED TO TEST SUSCEPTIBILITY OF GRAM-NEGATIVE BACTERIA TO COLISTIN ON THE BASIS OF MIC DETERMINATION.

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79	IMP/IVD/2018/000061	1.License Holder Name: SD BIOSENSOR HEALTHCARE PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:UNCUT SHEET OF STANDARD Q HIV/SYPHILIS COMBO(NA)-IT IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES SPECIFIC TO HIV-1 INCLUDING SUBTYPE O, HIV-2 AND SYPHILIS (TREPONEMA PALLIDUM) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,UNCUT-SHEET OF STANDARD Q HBSAG (BULK)(NA)-IT IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) PRESENT IN SERUM, PLASMA OR WHOLE BLOOD., DIAGNOSTIC BUFFER SOLUTION (COMPONENT OF COVID-19 AG KIT) (NA)-IT ALLOWS A BETTER MIGRATION OF THE LATEX MICROSPHERE LEADING TO A BETTER AND A MORE HOMOGENOUS SIGNAL. ,UNCUT-SHEET OF STANDARD Q HCV AB (BULK)(NA)-IT IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES TO HCV PRESENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,UNCUT SHEET OF STANDARD Q COVID-19 IGG(NA)-STANDARD Q COVID-19 IGM/IGG DUO TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES TO COVID-19 PRESENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD,UNCUT-SHEET OF STANDARD Q HIV 1/2 AB 3-LINE (BULK)(NA)-IT IS A RAPID, QUALITATIVE IMMUNOASSAY TO DETECT CIRCULATING ANTIBODIES AGAINST HIV IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,UNCUT SHEET OF STANDARD Q COVID -19 AG(NA)-STANDARD Q COVID-19 AG TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIGENS TO COVID-19 PRESENT IN HUMAN NASOPHARYNX AND OROPHARYNX,UNCUT SHEET OF STANDARD Q COVID-19 IGM(NA)-STANDARD Q COVID-19 IGM/IGG DUO TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES TO COVID-19 PRESENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD, UNCUT-SHEET OF STANDARD Q DENGUE NS1 AG (BULK)(NA)-IT IS AN IMMUNE CHROMATOGRAPHIC ASSAY FOR THE DETECTION OF DENGUE NS1 ANTIGENS IN HUMAN SERUM, PLASMA OR WHOLE BLOOD SAMPLES.,UNCUT –SHEET OF STANDARD Q DENGUE IGM/IGG (BULK)(NA)-IT IS AN IMMUNE CHROMATOGRAPHIC ASSAY FOR THE DETECTION OF IGM/IGG ANTIBODIES AGAINST DENGUE VIRUS IN HUMAN SERUM, PLASMA OR WHOLE BLOOD SAMPLES.,UNCUT SHEET OF STANDARD Q COVID-19 IGM/IGG COMBO (BULK)(NA)-T IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES TO COVID-19 PRESENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,UNCUT-SHEET OF

	STANDARD Q MALARIA P.F/PAN AG (BULK)(NA)-IT IS AN IMMUNE CHROMATOGRAPHIC ASSAY FOR THE DIFFERENTIAL DETECTION BETWEEN PLASMODIUM FALCIPARUM HISTIDINE RICH PROTEIN –II (HRP-II) AND PLASMODIUM SPECIES (PLASMODIUM FALCIPARUM, P. VIVAX, P. OVALE AND P. MALARIAE) LACTATE DEHYDROGENASE (PLDH) IN HUMAN WHOLE BLOOD.,UNCUT-SHEET OF STANDARD Q MALARIA P.F/P.V AG (BULK)(NA)-IT IS A RAPID AND MEMBRANE BASED IMMUNE CHROMATOGRAPHY FOR THE QUALITATIVE DETECTION OF PLASMODIUM FALCIPARUM SPECIFIC HISTIDINE RICH PROTEIN –II (HRP-II) AND PLASMODIUM VIVAX SPECIFIC PLDH (PLASMODIUM LACTATE DEHYDROGENASE) IN HUMAN WHOLE BLOOD SPECIMEN.

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80	IMP/IVD/2018/000062	1.License Holder Name: HORIBA INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:YUMIZEN G DDI 2 (YUMIZEN G DDI 2)-YUMIZEN G DDI 2 IS A DIAGNOSTIC TEST USED FOR QUANTITATIVE DETERMINATION OF DDIMER IN PLASMA ON YUMIZEN G LINE.,YUMIZEN G PT RECO 10(YUMIZEN G PT RECO 10)-YUMIZEN G PT RECO 10 IS A RECOMBINANT HUMAN THROMBOPLASTIN REAGENT -PRODUCED BY GENETIC TECHNOLOGY IN ESCHERICHIA COLI WITH OWN SOLVENT USED FOR DETERMINATION OF PROTHROMBIN TIME (PT). ,CTRL DDI I & II(CTRL DDI I & II)-THE DDIMER TWO LEVELS CONTROLS ARE INTENDED TO CONTROL MEASUREMENTS OF YUMIZEN G DDI 2 TEST.,YUMIZEN G APTT LIQ 2(YUMIZEN G APTT LIQ 2)-YUMIZEN G APTT LIQ 2 IS A LIQUID, READY TO USE, RABBIT BRAIN PHOSPHOLIPID REAGENT USED FOR DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT).,YUMIZEN G AT(YUMIZEN G AT)-YUMIZEN G AT IS A CHROMOGENIC ASSAY USED FOR THE QUANTITATIVE DETERMINATION OF ANTITHROMBIN (AT) ACTIVITY IN HUMAN CITRATED PLASMA.,YUMIZEN G APTT 4(YUMIZEN G APTT 4)-YUMIZEN G APTT 4 IS A RABBIT BRAIN PHOSPHOLIPID REAGENT USED FOR DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) ,YUMIZEN G CLEANER(YUMIZEN G CLEANER)-YUMIZEN G CLEANER WASHING SOLUTION IS TO BE USED FOR DAILY MAINTENANCE AND CLEANING OF YUMIZEN G800 AND YUMIZEN G1500 / G1550 COAGULATION ANALYZER.,YUMIZEN G PT LIQ 4(YUMIZEN G PT LIQ 4)-YUMIZEN G PT LIQ 4 IS A LIQUID, READY TO USE, RABBIT BRAIN THROMBOPLASTIN REAGENT USED FOR DETERMINATION OF PROTHROMBIN TIME (PT).,YUMIZEN G CLEAN SYS(YUMIZEN G CLEAN SYS)-YUMIZEN G CLEAN WASHING SOLUTION SYS IS TO BE USED FOR DAILY MAINTENANCE AND CLEANING OF AUTOMATED HORIBA MEDICAL COAGULATION ANALYSERS., YUMIZEN G FIB 2(YUMIZEN G FIB 2)-YUMIZEN G FIB 2 IS A FIBRINOGEN REAGENT USED FOR QUANTITATIVE DETERMINATION OF FIBRINOGEN LEVELS IN PLASMA. ,YUMIZEN G CAL(YUMIZEN G CAL)-YUMIZEN G CAL CALIBRATOR PLASMA IS INTENDED TO CALIBRATE OF THE FOLLOWING COAGULATION TESTS: • ANTITHROMBIN (AT). • FIBRINOGEN (FIB) • PROTHROMBIN TIME (PT) ,YUMIZEN G CACI2 4 (YUMIZEN G CACI2 4)-YUMIZEN G CACI2 4 IS INTENDED FOR HAEMOSTASIS SCREENING TESTS SUCH AS ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT). ,YUMIZEN G SORB(YUMIZEN G SORB)-YUMIZEN G SORB WASHING SOLUTION IS TO BE USED FOR DAILY MAINTENANCE AND CLEANING OF YUMIZEN G800/ G1500/ G1550 HEMOSTASIS ANALYZERS.,YUMIZEN G IMIDAZOL(YUMIZEN G IMIDAZOL)-YUMIZEN G IMIDAZOL IS INTENDED FOR DILUTION OF

	SAMPLES AND CONTROLS FOR FIBRINOGEN ASSAYS (FIB). ,YUMIZEN G APTT LIQ 4(YUMIZEN G APTT LIQ 4)-YUMIZEN G APTT LIQ 4 IS A LIQUID, READY TO USE, RABBIT BRAIN PHOSPHOLIPID REAGENT USED FOR DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT).,YUMIZEN G CTRL I & II(YUMIZEN G CTRL I & II)-"YUMIZEN G CTRL I & II TWO LEVELS CONTROL PLASMAS ARE INTENDED TO CONTROL OF THE FOLLOWING COAGULATION TESTS: · PROTHROMBIN TIME (PT), · ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), · FIBRINOGEN (FIB), · THROMBIN TIME (TT) ONLY FOR CONTROL I, · ANTITHROMBIN III (ATIII)." ,YUMIZEN G FIB 5(YUMIZEN G FIB 5)-YUMIZEN G FIB 5 IS A FIBRINOGEN REAGENT USED FOR QUANTITATIVE DETERMINATION OF FIBRINOGEN LEVELS IN PLASMA.,YUMIZEN G INR KIT(YUMIZEN G INR KIT)-THE YUMIZEN G INR KIT IS A RECOMBINANT HUMAN THROMBOPLASTIN REAGENT PRODUCED BY GENETIC TECHNOLOGY IN ESCHERICHIA COLI WITH SOLVENT AND CONTROLS USED EXCLUSIVELY FOR DETERMINATION OF INTERNATIONAL NORMALIZED RATIO (INR) DIMENSION OF PROTHROMBIN TIME (PT) ON YUMIZEN G100 INR DEVICE. ,YUMIZEN G TT(YUMIZEN G TT)-YUMIZEN G TT IS A FREEZE-DRIED REAGENT USED FOR DETERMINATION OF THROMBIN TIME (TT). ,YUMIZEN G PT 5 (YUMIZEN G PT 5)-YUMIZEN G PT 5 IS A RABBIT BRAIN THROMBOPLASTIN REAGENT WITH OWN SOLVENT USED FOR DETERMINATION OF PROTHROMBIN TIME (PT).

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81	IMP/IVD/2018/000306	1.License Holder Name: BIOMERIEUX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIDAS SARS-COV-2 IGM (VIDAS SARS-COV-2 IGM)-FOR THE DETECTION OF IMMUNOGLOBULIN M (IGM) SPECIFIC FOR SARS-COV-2 IN HUMAN SERUM OR PLASMA, VIDAS PROLACTIN(VIDAS PROLACTIN)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS, FOR THE ENZYME IMMUNOASSAY DETERMINATION OF HUMAN PROLACTIN IN HUMAN SERUM OR PLASMA,VIDAS SARS-COV-2 IGG (VIDAS SARS-COV-2 IGG)-FOR THE DETECTION OF IMMUNOGLOBULIN G (IGG) SPECIFIC FOR SARS-COV-2 IN HUMAN SERUM OR PLASMA,VIDAS TOTAL IGE(VIDAS TOTAL IGE)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS, FOR THE IMMUNOENZYMATIC DETERMINATION OF TOTAL HUMAN IGE IN HUMAN SERUM OR PLASMA ,VIDAS HBC IGM II(VIDAS HBC IGM II)-FOR THE DETERMINATION OF ANTI-HEPATITIS B VIRUS CORE ANTIGEN IGM (ANTI-HBC IGM) IN HUMAN SERUM OR PLASMA.,VIDAS FERRITIN (VIDAS FERRITIN)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS FOR THE DETERMINATION OF HUMAN FERRITIN IN HUMAN SERUM OR PLASMA ,VIDAS ANTI-HCV(VIDAS ANTI-HCV)-FOR THE DETECTION OF IGG ANTIBODIES TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM OR PLASMA (HEPARIN),VIDAS PROGESTERONE(VIDAS PROGESTERONE)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS FOR THE QUANTITATIVE MEASUREMENT OF PROGESTERONE IN HUMAN SERUM OR PLASMA,VIDAS ANTI-HBC TOTAL II(VIDAS ANTI-HBC TOTAL II)-FOR THE DETECTION OF TOTAL ANTIBODIES AGAINST THE HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM OR PLASMA,VIDAS FSH(VIDAS FSH)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS FOR THE DETERMINATION OF HUMAN FOLLICLE STIMULATING HORMONE IN HUMAN SERUM OR PLASMA,VIDAS HIV DUO ULTRA(VIDAS HIV DUO ULTRA)-FOR THE COMBINED DETECTION OF ANTI-HIV-1 (GROUPS M AND O) AND ANTI-HIV-2 TOTAL IMMUNOGLOBULINS AND HIV-1-P24 ANTIGEN IN HUMAN SERUM OR PLASMA,VIDAS LH(VIDAS LH)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS FOR THE DETERMINATION OF HUMAN LUTEINIZING HORMONE IN HUMAN SERUM OR PLASMA,VIDAS PTH (1-84)(VIDAS PTH (1-84))-USED FOR THE QUANTITATIVE MEASUREMENT OF THE BIOLOGICALLY ACTIE PARATHYROID HORMONE PTH (1-84) IN HUMAN SERUM OR PLASMA,VIDAS HCG(VIDAS HCG)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS, FOR THE QUANTITATIVE MEASUREMENT OF HUMAN CHORIONIC GONADOTROPIN IN HUMAN SERUM OR PLASMA,VIDAS VWF(VIDAS VWF)-FOR THE QUANTITATIVE MEASUREMENT OF VON WILLEBRAND FACTOR IN HUMAN PLASMA , VIDAS EBV VCA IGM (VIDAS EBV VCA IGM)-VIDAS EBV VCA IGM IS AN AUTOMATED TEST FOR USE ON THE VIDAS FAMILY INSTRUMENTS,

	FOR THE QUALITATIVE DETECTION OF ANTI-VCA IGM IN HUMAN SERUM ,VIDAS HBE/ANTI-HBE(VIDAS HBE/ANTI-HBE)-FOR THE DETECTION OF THE HEPATITIS B E-ANTIGEN (HBE AG) OR ANTIBODIES (ANTI-HBE) IN HUMAN SERUM OR PLASMA,VIDAS EBV VCA/EA IGG(VIDAS EBV VCA/EA IGG)-VIDAS EBV VCA/EA IGG IS AN AUTOMATED TEST FOR USE ON THE VIDAS FAMILY INSTRUMENTS, FOR THE QUALITATIVE DETECTION OF ANTI-VCA AND ANTI-EA IGG IN HUMAN SERUM,VIDAS CA 19-9(VIDAS CA 19-9)-FOR THE MEASUREMENT OF 1116-NS-19-9 REACTIVE ANTIGENIC DETERMINANTS IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN OR EDTA) ,VIDAS EBV EBNA IGG(VIDAS EBV EBNA IGG)-VIDAS EBV EBNA IGG IS AN AUTOMATED TEST FOR USE ON THE VIDAS FAMILY INSTRUMENTS, FOR THE QUALITATIVE DETECTION OF ANTI-EBNA IGG IN HUMAN SERUM ,VIDAS B2 MICROGLOBULIN(VIDAS B2 MICROGLOBULIN)-FOR THE QUANTITATIVE MEASUREMENT OF B2 MICROGLOBULIN IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN OR EDTA) AND IN URINE ,VIDAS T4(VIDAS T4)-FOR USE ON THE INSTRUMENTS OF THE VIDAS FAMILY FOR THE DETERMINATION OF TOTAL THYROXINE (T4) IN HUMAN SERUM AND PLASMA,VIDAS HIGH SENSITIVE TROPONIN I(VIDAS HIGH SENSITIVE TROPONIN I)-FOR THE DETERMINATION OF HUMAN CARDIAC TROPONIN I IN HUMAN SERUM OR PLASMA.,VIDAS MEASLES IGG(VIDAS MEASLES IGG)-FOR USE ON THE INSTRUMENTS OF THE VIDAS FAMILY, FOR THE DETECTION OF IGG ANTIBODIES TO MEASLES (RUBEOLA) VIRUS IN HUMAN SERUM, VIDAS DIGOXIN(VIDAS DIGOXIN)-FOR THE IMMUNOENZYMATIC DETERMINATION OF DIGOXIN IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN OR EDTA). IT IS INTENDED FOR USE IN MONITORING TREATMENT TO ENSURE APPROPRIATE THERAPY. , VIDAS® 25 OH VITAMIN D TOTAL (VITD)(VIDAS® 25 OH VITAMIN D TOTAL (VITD))-FOR USE ON THE INSTRUMENTS OF THE VIDAS FAMILY FOR THE DETERMINATION OF 25-HYDROXYVITAMIN D TOTAL IN HUMAN SERUM OR PLASMA,VIDAS ANTI HBS TOTAL II (AHBS)(VIDAS ANTI HBS TOTAL II (AHBS))-IMMUNOENZYMATIC DETECTION OF ANTIBODIES TO HEPATITIS B SURFACE ANTIGEN (ANTI-HBS) IN HUMAN SERUM OR PLASMA,VIDAS CK-MB(VIDAS CK-MB)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS FOR THE QUANTITATIVE MEASUREMENT OF THE MB ISOENZYME OF HUMAN CREATINE KINASE IN HUMAN SERUM OR PLASMA ,VIDAS B.R.A.H.M.S PCT(VIDAS B.R.A.H. M.S PCT)-FOR THE DETERMINATION OF HUMAN PROCALCITONIN IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN).,VIDAS LYME IGG (LYG)(VIDAS LYME IGG (LYG))-FOR USE ON THE VIDAS FAMILY OF INSTRUMENTS, FOR THE DETECTION OF IGG ANTIBODIES TO BORRELIA BURGDORFERI SENSU LATO (SL) IN HUMAN SERUM OR PLASMA,VIDAS TPSA(VIDAS TPSA)-FOR THE QUANTITATIVE

	MEASUREMENT OF PROSTATE SPECIFIC ANTIGEN (PSA) LEVELS IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN OR EDTA) ,VIDAS® AMH (AMH)(VIDAS® AMH (AMH))-FOR USE ON THE VIDAS FAMILY OF INSTRUMENTS FOR THE QUANTITATIVE MEASUREMENT OF TOTAL 17 -ESTRADIOL IN HUMAN SERUM OR PLASMA,VIDAS PROTEIN C (VIDAS PROTEIN C)-FOR THE QUANTITATIVE MEASUREMENT OF PROTEIN C IN HUMAN PLASMA ,VIDAS T3(VIDAS T3)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS FOR THE QUANTITATIVE MEASUREMENT OF TOTAL TRIIODOTHYRONINE (T3) IN HUMAN ,VIDAS TOXO IGG AVIDITY(VIDAS TOXO IGG AVIDITY)-FOR THE DETERMINATION OF ANTI-TOXOPLASMA IGG AVIDITY IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN, SODIUM CITRATE, EDTA) , VIDAS TSH(VIDAS TSH)-FOR THE IMMUNOENZYMATIC DETERMINATION OF THYROID-STIMULATING HORMONE IN HUMAN SERUM OR PLASMA.,VIDAS CA 125 II(VIDAS CA 125 II)-FOR THE MEASUREMENT OF OC 125 ANTIGENIC DETERMINANTS IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN OR EDTA),VIDAS FT3(VIDAS FT3)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS, FOR THE QUANTITATIVE MEASUREMENT OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM OR PLASMA,VIDAS AFP(VIDAS AFP)-FOR THE QUANTITATIVE MEASUREMENT OF HUMAN ALPHA FETO-PROTEIN IN SERUM, PLASMA (LITHIUM HEPARIN OR EDTA),VIDAS FT4(VIDAS FT4) -FOR USE ON THE INSTRUMENTS OF THE VIDAS® FAMILY, FOR THE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM OR PLASMA ,VIDAS TOXO IGG II(VIDAS TOXO IGG II)-FOR THE QUANTITATIVE MEASUREMENT OF ANTI-TOXOPLASMA IGG IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN OR EDTA) .,VIDAS TESTOSTERONE II (TES2)(VIDAS TESTOSTERONE II (TES2))-FOR USE ON THE INSTRUMENTS OF THE VIDAS FAMILY FOR THE QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE IN HUMAN SERUM OR PLASMA,VIDAS CMV IGG(VIDAS CMV IGG)-FOR THE QUANTITATIVE MEASUREMENT, OF ANTI-CYTOMEGALOVIRUS IGG (CMVG) IN HUMAN SERUM, ,VIDAS H.PYLORI IGG(VIDAS H.PYLORI IGG)-FOR USE ON THE INSTRUMENTS OF THE VIDAS FAMILY, FOR THE DETECTION OF ANTI-HELICOBACTER PYLORI IGG ANTIBODIES IN HUMAN SERUM OR PLASMA,VIDAS CMV IGM(VIDAS CMV IGM)-FOR THE DETECTION OF ANTI-CYTOMEGALOVIRUS IGM (CMVM) IN HUMAN SERUM, ,VIDAS LYME IGM (LYM)(VIDAS LYME IGM (LYM))-FOR USE ON THE VIDAS FAMILY OF INSTRUMENTS, FOR THE DETECTION OF IGM ANTIBODIES TO BORRELIA BURGDORFERI SENSU LATO (SL) IN HUMAN SERUM OR PLASMA,VIDAS RUB IGM(VIDAS RUB IGM)-FOR THE DETECTION OF ANTI-RUBELLA IGM (RBM) IN HUMAN SERUM , VIDAS ANTI-HEV IGG (HEVG)(VIDAS ANTI-HEV IGG (HEVG))-FOR USE ON THE VIDAS® FAMILY OF INSTRUMENTS FOR THE DETECTION OF

	IGG ANTIBODY TO HEPATITIS E VIRUS IN HUMAN SERUM AND PLASMA,VIDAS CEA(VIDAS CEA)-FOR THE QUANTITATIVE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN (CEA) IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN) ,VIDAS HAV IGM(VIDAS HAV IGM)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS FOR THE DETECTION OF IGM DIRECTED AGAINST THE HEPATITIS A VIRUS (HAV) AFTER IMMUNOCAPTURE, IN HUMAN SERUM OR PLASMA, VIDAS FPSA(VIDAS FPSA)-FOR THE QUANTITATIVE MEASUREMENT OF THE FREE FRACTION OF PROSTATE SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN OR EDTA) ,VIDAS ANTI-HAV TOTAL(VIDAS ANTI-HAV TOTAL)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS FOR THE QUANTITATIVE MEASUREMENT OF TOTAL IMMUNOGLOBULINS DIRECTED AGAINST THE HEPATITIS A VIRUS (HAV) IN HUMAN SERUM OR PLASMA,VIDAS RUB IGG II(VIDAS RUB IGG II)-FOR THE QUANTITATIVE MEASUREMENT OF IMMUNOGLOBULINS G (IGG) DIRECTED AGAINST THE RUBELLA VIRUS IN HUMAN SERUM OR PLASMA (HEPARIN OR EDTA) .,VIDAS MUMPS IGG(VIDAS MUMPS IGG)-FOR USE ON THE INSTRUMENTS OF THE VIDAS FAMILY, FOR THE DETECTION OF IGG ANTIBODIES TO MUMPS VIRUS IN HUMAN SERUM ,VIDAS NT-PROBNP2 (VIDAS NT-PROBNP2)-FOR THE DETERMINATION OF N TERMINAL FRAGMENT OF BRAIN-TYPE NATRIURETIC PEPTIDE IN HUMAN SERUM OR PLASMA (LITHIUM AND SODIUM HEPARIN). THE VIDAS NT-PROBNP2 (PBN2) TEST IS USED AS AN AID IN THE DIAGNOSIS OF SUSPECTED HEART FAILURE., VIDAS ANTI-HEV IGM (HEVM)(VIDAS ANTI-HEV IGM (HEVM))-FOR USE ON THE VIDAS® FAMILY OF INSTRUMENTS FOR THE DETECTION OF IGM ANTIBODY TO HEPATITIS E VIRUS IN HUMAN SERUM AND PLASMA,VIDAS TOXO IGM(VIDAS TOXO IGM)-FOR THE DETECTION OF ANTI-TOXOPLASMA IGM IN SERUM ,VIDAS VARICELLA ZOSTER IGG (VIDAS VARICELLA ZOSTER IGG)-FOR USE ON THE INSTRUMENTS OF THE VIDAS FAMILY, FOR THE DETECTION OF IGG ANTIBODIES TO VARICELLA ZOSTER VIRUS IN HUMAN SERUM ,VIDAS C. DIFFICILE TOXIN A & B(VIDAS C. DIFFICILE TOXIN A & B)-FOR THE QUALITATIVE DETECTION OF CLOSTRIDIUM DIFFICILE TOXIN A AND TOXIN B IN STOOL SPECIMENS.,QUALITY CONTROL VIDAS (QCV)(QUALITY CONTROL VIDAS (QCV))-FOR USE ON THE VIDAS® SYSTEM TO DETECT ABNORMAL OPERATION OF THE VIDAS AND MINI VIDAS INSTRUMENT PIPETTE MECHANISMS AND OPTICAL SYSTEMS.,VIDAS D-DIMER EXCLUSION II(VIDAS D-DIMER EXCLUSION II)-FOR THE IMMUNOENZYMATIC DETERMINATION OF FIBRIN DEGRADATION PRODUCTS (FBDP) IN HUMAN PLASMA (SODIUM CITRATE). ,VIDAS ANTI-TG(VIDAS ANTI-TG)-FOR USE ON THE INSTRUMENTS OF THE VIDAS FAMILY FOR THE DETECTION OF THE IGG CLASS OF THYROGLOBULIN AUTOANTIBODIES (ANTI-TG) IN HUMAN SERUM OR

	PLASMA ,VIDAS C. DIFFICILE GDH(VIDAS C. DIFFICILE GDH)-DETECT THE C. DIFFICILE ANTIGEN, GLUTAMATE DEHYDROGENASE, AS A SCREEN FOR THE PRESENCE OF C. DIFFICILE IN FECAL SPECIMENS FROM PERSON SUSPECTED OF HAVING C.DIFFICILE INFECTION.,VIDAS ANTI-TPO (VIDAS ANTI-TPO)-FOR USE ON THE INSTRUMENTS OF THE VIDAS FAMILY FOR THE DETECTION OF THE IGG CLASS OF THYROID PEROXIDASE AUTOANTIBODIES (ANTI-TPO) IN HUMAN SERUM OR PLASMA ,VIDAS CMV IGG AVIDITY II(VIDAS CMV IGG AVIDITY II)-FOR THE DETERMINATION OF ANTI-CMV IGG AVIDITY IN HUMAN SERUM. THIS TEST IS AN AID IN DIAGNOSING CMV INFECTIONS.,VIDAS MYOGLOBIN(VIDAS MYOGLOBIN)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS FOR THE DETERMINATION OF HUMAN MYOGLOBIN IN SERUM OR PLASMA ,VIDAS CA 15-3(VIDAS CA 15-3)-FOR THE QUANTITATIVE MEASUREMENT OF CA 15-3 LEVELS IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN OR EDTA) ,VIDAS TSH3(VIDAS TSH3)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS, FOR THE THIRD GENERATION IMMUNOASSAY OF HUMAN THYROTROPIN HORMONE IN HUMAN SERUM OR PLASMA,VIDAS HBS AG ULTRA(VIDAS HBS AG ULTRA)-FOR THE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBS AG) IN HUMAN SERUM OR PLASMA,VIDAS ESTRADIOL II(VIDAS ESTRADIOL II)-FOR USE ON THE VIDAS FAMILY OF INSTRUMENTS FOR THE QUANTITATIVE MEASUREMENT OF TOTAL 17 -ESTRADIOL IN HUMAN SERUM OR PLASMA ,VIDAS ANTI-DENGUE IGM(VIDAS ANTI-DENGUE IGM)-VIDAS® ANTI-DENGUE IGM (DENM) IS A QUALITATIVE ASSAY FOR USE ON THE VIDAS® FAMILY OF INSTRUMENTS, FORTHE DETECTION OF IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM .,VIDAS CORTISOL S (VIDAS CORTISOL S)-FOR USE ON THE VIDAS FAMILY INSTRUMENTS, FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM, PLASMA OR URINE ,VIDAS TB IGRA (VIDAS TB IGRA)-THE VIDAS® TB-IGRA (TBRA) ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF INDIVIDUALS INFECTED WITH MYCOBACTERIUM TUBERCULOSIS (LATENT INFECTION OR ACTIVE DISEASE).,VIDAS DENGUE NS1 AG(VIDAS DENGUE NS1 AG)-VIDAS® DENGUE NS1 AG (DEAG) IS A QUALITATIVE ASSAY FOR USE ON THE VIDAS® FAMILY OF INSTRUMENTS, FOR THE DETECTION OF THE DENGUE NS1 ANTIGEN IN HUMAN SERUM .,ID COLOR CATALASE(ID COLOR CATALASE)-DETECTION OF CATALASE,VIDAS NEPHROCHECK (VIDAS NEPHROCHECK)-VIDAS® NEPHROCHECK® IS AN AUTOMATED TEST FOR USE ON THE VIDAS® 3 INSTRUMENT FOR THE QUANTITATIVE DETERMINATION OF TIMP2 (TISSUE INHIBITOR OF METALLOPROTEINASE2) AND IGFBP7 (INSULIN-LIKE GROWTH FACTORBINDING PROTEIN 7) PROTEINS IN HUMAN URINE ,VIDAS ANTI DENGUE IGG(VIDAS ANTI DENGUE IGG)-VIDAS® ANTI-DENGUE IGG (DENG) IS A QUALITATIVE ASSAY FOR USE ON THE VIDAS®

		FAMILY OF INSTRUMENTS, FOR THE DETECTION OF IGG ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM
82	IMP/IVD/2018/000307	1.License Holder Name: UNIQUE DIAGNOSTICS & SCIENTIFIC 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:M SERIES DILUENT (MEDONIC)-THE BOULE MEDONIC M SERIES DILUENT & LYSE REAGENTS ARE INTENDED FOR USE WITH THE MEDONIC M-SERIES HEMATOLOGY ANALYZER SYSTEMS IN IN-VITRO DIAGNOSTICS.,M SERIES LYSE(MEDONIC)-THE BOULE MEDONIC M SERIES DILUENT & LYSE REAGENTS ARE INTENDED FOR USE WITH THE MEDONIC M-SERIES HEMATOLOGY ANALYZER SYSTEMS IN IN-VITRO DIAGNOSTICS.,M SERIES LYSE WITH RFID(MEDONIC)-THE BOULE MEDONIC M SERIES DILUENT & LYSE REAGENTS ARE INTENDED FOR USE WITH THE MEDONIC M-SERIES HEMATOLOGY ANALYZER SYSTEMS IN IN-VITRO DIAGNOSTICS.,CLEANING KIT(BOULE)-THE BOULE CLEANING KIT IS INTENDED FOR USE WITH THE MEDONIC M-SERIES HEMATOLOGY SYSTEMS IN IN-VITRO DIAGNOSTICS.,M SERIES DILUENT WITH RFID(MEDONIC)-THE BOULE MEDONIC M SERIES DILUENT & LYSE REAGENTS ARE INTENDED FOR USE WITH THE MEDONIC M-SERIES HEMATOLOGY ANALYZER SYSTEMS IN IN-VITRO DIAGNOSTICS.
83	IMP/IVD/2018/000308	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:THE ALERE NMP22® BLADDERCHEK® TEST(THE ALERE NMP22® BLADDERCHEK® TEST)-THE ALERE NMP22® BLADDERCHEK® TEST IS AN IN VITRO IMMUNOASSAY INTENDED FOR THE QUALITATIVE DETECTION OF THE NUCLEAR MITOTIC APPARATUS PROTEIN (NUMA), WHICH IS AN ABUNDANT COMPONENT OF THE NUCLEAR MATRIX PROTEINS, IN URINE OF PERSONS WITH RISK FACTORS OR SYMPTOMS OF BLADDER CANCER OR WITH A HISTORY OF BLADDER CANCER

84	IMP/IVD/2018/000308	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALERE™ FILARIASIS TEST STRIP(ALERE™ FILARIASIS TEST STRIP)-THE ALERE™ FILARIASIS TEST STRIP IS AN IN VITRO IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF WUCHERERIA BANCROFTI ANTIGEN IN HUMAN CAPILLARY WHOLE BLOOD SAMPLES COLLECTED BY FINGERSTICK.,BINAXNOW® MALARIA(BINAXNOW® MALARIA)-THE BINAXNOW® MALARIA TEST IS AN IN VITRO IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF PLASMODIUM ANTIGENS CIRCULATING IN HUMAN VENOUS AND CAPILLARY EDTA WHOLE BLOOD OF INDIVIDUALS WITH SIGNS AND SYMPTOMS OF MALARIAL INFECTION.,BINAXNOW® G6PD (BINAXNOW® G6PD)-THE BINAXNOW® G6PD (GLUCOSE-6-PHOSPHATE DEHYDROGENASE) TEST IS AN IN VITRO ENZYME CHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF G6PD ENZYME ACTIVITY IN HUMAN VENOUS WHOLE BLOOD, COLLECTED IN HEPARIN OR ETHYLENEDIAMINETETRAACETIC ACID (EDTA).,ALERE™ BINAXNOW® STREPTOCOCCUS PNEUMONIAE ANTIGEN CARD(ALERE™ BINAXNOW® STREPTOCOCCUS PNEUMONIAE ANTIGEN CARD)-THE ALERE BINAXNOW® STREPTOCOCCUS PNEUMONIAE ANTIGEN CARD IS AN IN VITRO RAPID IMMUNOCHROMATOGRAPHIC (ICT) ASSAY FOR THE DETECTION OF STREPTOCOCCUS PNEUMONIAE (S. PNEUMONIAE) ANTIGEN IN THE URINE OF PATIENTS WITH PNEUMONIA AND IN THE CEREBRAL SPINAL FLUID (CSF) OF PATIENTS WITH MENINGITIS.,THE ALERE BINAXNOW LEGIONELLA URINARY ANTIGEN CARD(THE ALERE BINAXNOW® LEGIONELLA URINARY ANTIGEN CARD)-THE ALERE BINAXNOW® LEGIONELLA URINARY ANTIGEN CARD (ALERE BINAXNOW® LEGIONELLA) IS AN IN VITRO RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF LEGIONELLA PNEUMOPHILA SEROGROUP 1 ANTIGEN (L. PNEUMOPHILA SEROGROUP 1 ANTIGEN) IN URINE SPECIMENS FROM PATIENTS WITH SYMPTOMS OF PNEUMONIA.

85	IMP/IVD/2018/000309	1.License Holder Name: M/S.TRANSASIA BIO-MEDICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DAILY CLEANER KIT (DAILY CLEANER KIT)-USED IN THE CLEANING PROCESS OF THE ANALYZERS BY REMOVING PROTEIN BUILDUP ON THE ELECTRODES AND THE ANALYZERS FLOW PATH.,INTERNAL FILLING SOLUTION (INTERNAL FILLING SOLUTION)-USED IN THE ANALYSIS OF PATIENT SAMPLES AND CALIBRATIONS. SOLUTION IS PLACED IN THE REFERENCE ELECTRODE EXTERNAL RESERVOIR.,RED TEST DYE SOLUTION(RED TEST DYE SOLUTION)-USED TO TROUBLESHOOT THE EASYLYTE ANALYZERS.,URINE STANDARD SOLUTION(URINE STANDARD SOLUTION)-USED TO MONITOR THE PERFORMANCE OF THE EASYLYTE ANALYZERS WHEN OPERATING IN THE “URINE” MODE.,EEL RED TEST DYE SOLUTION(EEL RED TEST DYE SOLUTION)-USED FOR TROUBLESHOOTING FLUID FLOW ISSUES ON THE EASYELECTROLYTE ANALYZERS.,DAILY RINSE/CLEANING SOLUTION KIT(DAILY RINSE/CLEANING SOLUTION KIT)-USED TO REMOVE PROTEIN DEPOSITS FROM THE FLUID AND SENSOR PATHS ON THE EASYLYTE CA/PH ANALYZERS.,RED TEST DYE SOLUTION(RED TEST DYE SOLUTION)-USED TO TROUBLESHOOT THE EASYBLOODGAS AND EASYSTAT ANALYZERS.

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86	IMP/IVD/2018/000314	1.License Holder Name: OMEGA DX (ASIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOODPRINT® MICROARRAY 200+ FOOD IGG KIT(FOODPRINT® MICROARRAY 200+ FOOD IGG 16PT)-THE FOODPRINT® MICROARRAY 200+ FOOD IGG KIT IS A RAPID COLORIMETRIC MICROARRAY-BASED ELISA FOR THE MEASUREMENT OF IGG ANTIBODIES TO 215 FOODS IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.,FOOD DETECTIVE® INDIAN SUBCONTINENT PROFESSIONAL(FOOD DETECTIVE® INDIAN SUBCONTINENT PROFESSIONAL)-IN VITRO QUALITATIVE MEASUREMENT OF IGG IN HUMAN BLOOD SPECIFIC TO FOOD FOOD ANTIGENS. IT IS AN AID IN HIGHLIGHTING POSSIBLE FOOD INTOLERANCE,FOODPRINT® MICROARRAY 200+ FOOD IGG KIT (FOODPRINT® MICROARRAY 200+ FOOD IGG 4PT)-THE FOODPRINT® MICROARRAY 200+ FOOD IGG KIT IS A RAPID COLORIMETRIC MICROARRAY-BASED ELISA FOR THE MEASUREMENT OF IGG ANTIBODIES TO 215 FOODS IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.,FOODPRINT® MICROARRAY 200+ FOOD IGG KIT (FOODPRINT® MICROARRAY 200+ FOOD IGG 64PT)-THE FOODPRINT® MICROARRAY 200+ FOOD IGG KIT IS A RAPID COLORIMETRIC MICROARRAY-BASED ELISA FOR THE MEASUREMENT OF IGG ANTIBODIES TO 215 FOODS IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.

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87	IMP/IVD/2018/000317	1.License Holder Name: M/S.TRANSASIA BIO-MEDICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NA/K/LI EEL REAGENT MODULE(NA/K/LI EEL REAGENT MODULE)-USED TO CALIBRATE THE NA, K AND LI SENSORS. REAGENT MODULE CONTAINS AN ELECTRONIC CHIP WITH ENCODED INFORMATION THAT IS AUTOMATICALLY READ BY THE ANALYZER. CONTAINS BUFFERED CALIBRANTS AS WELL AS A WASTE CONTAINER TO COLLECT WASTE., EEL URINE DILUENT(EEL URINE DILUENT)-USED TO DILUTE URINE SAMPLES PRIOR TO ANALYSIS,URINE DILUENT(URINE DILUENT)-USED TO DILUTE URINE SAMPLES PRIOR TO ANALYSIS ON EASYLYTE ANALYZERS.,ISE MODULE NA/K/CL/LI REAGENT PACK – LOW VOLUME, NO WASTE(ISE MODULE NA/K/CL/LI REAGENT PACK – LOW VOLUME, NO WASTE)-THE PACK IS INTENDED FOR USE TO CALIBRATE THE NA, K, CL, AND LI SENSORS. IT CONTAINS BUFFERED CALIBRANTS AND A WASTE CONTAINER TO COLLECT WASTE., NA/K/CA/PH SOLUTION PACK(EASYLYTE NA/K/CA/PH SOLUTION PACK)-USED TO CALIBRATE THE NA, K, CA AND PH SENSORS. SOLUTION PACK CONTAINS AN ELECTRONIC CHIP WITH ENCODED INFORMATION THAT IS AUTOMATICALLY READ BY THE ANALYZER. CONTAINS BUFFERED CALIBRANTS AS WELL AS A WASTE CONTAINER TO COLLECT WASTE.,WASH SOLUTION(WASH SOLUTION) -USED TO REACTIVATE THE NA SENSOR ON THE EASYLYTE ANALYZERS.,URINE DILUENT(ISE URINE DILUENT)-THE ISE MODULE URINE DILUENT IS USED TO DILUTE URINE SAMPLES PRIOR TO ANALYSIS.,NA/K/LI SOLUTIONS PACK(EASYLYTE NA/K/LI SOLUTIONS PACK)-USED TO CALIBRATE THE NA, K AND LI SENSORS. SOLUTION PACK CONTAINS AN ELECTRONIC CHIP WITH ENCODED INFORMATION THAT IS AUTOMATICALLY READ BY THE ANALYZER. CONTAINS BUFFERED CALIBRANTS AS WELL AS A WASTE CONTAINER TO COLLECT WASTE.,NA/K/CL/CA/LI SOLUTION PACK (EASYLYTE NA/K/CL/CA/LI SOLUTION PACK)-USED TO CALIBRATE THE NA, K, CL, CA AND LI SENSORS. SOLUTION PACK CONTAINS AN ELECTRONIC CHIP WITH ENCODED INFORMATION THAT IS AUTOMATICALLY READ BY THE ANALYZER. CONTAINS BUFFERED CALIBRANTS AS WELL AS A WASTE CONTAINER TO COLLECT WASTE., NA/K/CL/LI SOLUTION PACK(EASYLYTE NA/K/CL/LI SOLUTION PACK)-USED TO CALIBRATE THE NA, K, CL AND LI SENSORS. SOLUTION PACK CONTAINS AN ELECTRONIC CHIP WITH ENCODED INFORMATION THAT IS AUTOMATICALLY READ BY THE ANALYZER. CONTAINS BUFFERED CALIBRANTS AS WELL AS A WASTE CONTAINER TO COLLECT WASTE.,NA/K/CL SOLUTION PACK (EASYLYTE NA/K/CL SOLUTION PACK)-USED TO CALIBRATE THE NA, K AND CL SENSORS. SOLUTION PACK CONTAINS AN ELECTRONIC

	CHIP WITH ENCODED INFORMATION THAT IS AUTOMATICALLY READ BY THE ANALYZER. CONTAINS BUFFERED CALIBRANTS AS WELL AS A WASTE CONTAINER TO COLLECT WASTE.,DAILY CLEANER KIT(ISE DAILY CLEANER KIT)-USED TO REMOVE THE PROTEIN DEPOSITS FROM THE FLUID AND SENSOR PATH ON THE ISE MODULE.,NA/K/CL EEL REAGENT MODULE(NA/K/CL EEL REAGENT MODULE)-USED TO CALIBRATE THE NA, K AND CL SENSORS. REAGENT MODULE CONTAINS AN ELECTRONIC CHIP WITH ENCODED INFORMATION THAT IS AUTOMATICALLY READ BY THE ANALYZER. CONTAINS BUFFERED CALIBRANTS AS WELL AS A WASTE CONTAINER TO COLLECT WASTE.,NA/K SOLUTION PACK(EASYLYTE NA/K SOLUTION PACK)-USED TO CALIBRATE THE NA AND K SENSORS. SOLUTION PACK CONTAINS AN ELECTRONIC CHIP WITH ENCODED INFORMATION THAT IS AUTOMATICALLY READ BY THE ANALYZER. CONTAINS BUFFERED CALIBRANTS AS WELL AS A WASTE CONTAINER TO COLLECT WASTE.,ISE MODULE NA/K/CL/LI REAGENT PACK – NO WASTE(ISE MODULE NA/K/CL/LI REAGENT PACK – NO WASTE)-THE PACK IS INTENDED FOR USE TO CALIBRATE THE NA, K, CL, AND LI SENSORS. IT CONTAINS BUFFERED CALIBRANTS AND A WASTE CONTAINER TO COLLECT WASTE.,ISE MODULE NA/K/CL/LI REAGENT PACK(ISE MODULE NA/K/CL/LI REAGENT PACK)-THE PACK IS INTENDED FOR USE TO CALIBRATE THE NA, K, CL, AND LI SENSORS. IT CONTAINS BUFFERED CALIBRANTS AND A WASTE CONTAINER TO COLLECT WASTE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

88	IMP/IVD/2018/000318	1.License Holder Name: PERKINELMER HEALTH SCIENCES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DELFIA® XPRESS PLGF 1-2-3(DELFIA® XPRESS PLGF 1- 2-3)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF PLACENTAL GROWTH FACTOR (PLGF) IN MATERNAL SERUM USING THE 6000 DELFIA® XPRESS CLINICAL RANDOM ACCESS SCREENING PLATFORM. THE KIT IS USED AS AN AID IN SCREENING PREGNANT WOMEN FOR PRE-ECLAMPSIA IN ALL TRIMESTERS OF PREGNANCY AND FOR SCREENING FOR RISK OF DOWN'S SYNDROME IN THE FIRST TRIMESTER OF PREGNANCY., AUTODELFIA® NEONATAL IRT KIT(AUTODELFIA® NEONATAL IRT KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN IMMUNOREACTIVE TRYPSIN(OGEN) (IRT) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CYSTIC FIBROSIS USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM.,DELFIA® NEONATAL 17- OH PROGESTERONE KIT(DELFIA® NEONATAL 17- OH PROGESTERONE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN 17-OH-PROGESTERONE IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL ADRENAL HYPERPLASIA (CAH).,DELFIA® NEONATAL IRT KIT(DELFIA® NEONATAL IRT KIT)-THIS KITS IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN IMMUNOREACTIVE TRYPSIN (OGEN) (IRT) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CYSTIC FIBROSIS, NEOBASE™ NON-DERIVATIZED MSMS KIT(NEOBASE™ NON-DERIVATIZED MSMS KIT)-THIS TANDEM MASS SPECTROMETRY (MSMS) REAGENT KIT IS INTENDED FOR THE MEASUREMENT AND EVALUATION OF AMINO ACIDS, SUCCINYLACETONE, FREE CARNITINE, AND ACYLCARNITINE CONCENTRATIONS FROM NEWBORN HEEL PRICK BLOOD SAMPLES DRIED ON FILTER PAPER. QUANTITATIVE ANALYSIS OF THESE ANALYTES (TABLE 1) AND THEIR RELATIONSHIP WITH EACH OTHER IS INTENDED TO PROVIDE ANALYTE CONCENTRATION PROFILES THAT MAY AID IN SCREENING NEWBORNS FOR METABOLIC DISORDERS,CHEMAGIC™ DNA CS200 KIT(CHEMAGIC™ DNA CS200 KIT)-THE CHEMAGIC™ DNA CS200 KIT IS INTENDED FOR THE EXTRACTION AND PURIFICATION OF DNA FROM HUMAN WHOLE BLOOD OR PLASMA FOR ANALYSIS BY IN VITRO DIAGNOSTIC TEST SYSTEMS. THE PRODUCT IS INTENDED FOR PROFESSIONAL USERS SUCH AS TECHNICIANS AND PHYSICIANS TRAINED IN MOLECULAR BIOLOGY TECHNIQUES. ,NEOBASE™ SUCCINYLACETONE ASSAY SOLUTION(NEOBASE™ SUCCINYLACETONE ASSAY SOLUTION)-THE NEOBASE™ SUCCINYLACETONE ASSAY SOLUTION IS INTENDED FOR IN VITRO

	DIAGNOSTIC USE WITH THE NEOBASE NONDERIVATIZED MSMS KIT (3040-0010/3040-001U) AND THE NEOBASE NONDERIVATIZED ASSAY SOLUTIONS (3041-0020).,NEONATAL G6PD KIT(NEONATAL G6PD KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD) CONCENTRATIONS IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR G6PD DEFICIENCY. , NEONATAL BIOTINIDASE KIT(NEONATAL BIOTINIDASE KIT)-THIS KIT IS INTENDED FOR THE SEMI-QUANTITATIVE DETERMINATION OF BIOTINIDASE ACTIVITY IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR BIOTINIDASE DEFICIENCY,AUTODELFIA® PAPPA KIT(AUTODELFIA® PAPPA KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN PAPP-A (PREGNANCY ASSOCIATED PLASMA A) IN MATERNAL SERUM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM,PLGF CONTROLS(PLGF CONTROLS)-PLGF CONTROL IS A LYOPHILIZED HUMAN CONTROL SERUM. IT IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR PRECISION OF LABORATORY MEASUREMENT PROCEDURES FOR THE DELFIA®PLGF ASSAYS. TWO LEVELS OF CONTROLS ARE AVAILABLE TO ALLOW PERFORMANCE MONITORING WITHIN THE CLINICAL RANGE. THE VALUE ASSIGNMENT HAS BEEN ESTABLISHED IN ACCORDANCE WITH THE ESSENTIAL REQUIREMENTS – ANNEX 1 – OF THE IVD DIRECTIVE 98/79/EC. THIS PRODUCT IS NOT INTENDED TO BE USED AS A CALIBRATOR,AUTODELFIA®HAFP/FREE HCGß DUAL KIT(AUTODELFIA®HAFP/FREE HCGß DUAL KIT)-THIS KIT IS INTENDED FOR THE SIMULTANEOUS QUANTITATIVE DETERMINATION OF HUMAN ALPHAFETOPROTEIN (HAFP) AND THE FREE SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN (FREE HCG) IN MATERNAL SERUM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: IN THE FIRST TRIMESTER OF PREGNANCY: HAFP / FREE HCG + PAPP-A HAFP / FREE HCG + PAPP-A + NT (NUCHAL TRANSLUCENCY) IN THE SECOND TRIMESTER OF PREGNANCY: HAFP / FREE HCG HAFP / FREE HCG + UE3 , DELFIA® XPRESS UE3 KIT(DELFIA® XPRESS UE3 KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN UNCONJUGATED ESTRIOL (UE3) IN MATERNAL SERUM USING THE 6000 DELFIA® XPRESS CLINICAL RANDOM ACCESS SCREENING PLATFORM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW IN SECOND TRIMESTER SCREENING: HAFP + FREE HCGß + UE3 FREE HCGß + UE3,DELFIA® FREE HCGß KIT(DELFIA® FREE HCGß KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE FREE ß SUBUNIT OF

	HUMAN CHORIONIC GONADOTROPIN (FREE HCGß) IN MATERNAL SERUM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: IN THE FIRST TRIMESTER OF PREGNANCY: FREE HCGß + PAPP-A FREE HCGß + PAPP-A + NT (NUCHAL TRANSLUCENCY) IN THE SECOND TRIMESTER OF PREGNANCY: FREE HCGß + HAFP FREE HCGß + HAFP + UE3 ,DELFIA® XPRESS PAPP-A KIT(DELFIA® XPRESS PAPP-A KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF PAPP-A (PREGNANCY ASSOCIATED PLASMA PROTEIN A) IN MATERNAL SERUM USING THE 6000 DELFIA® XPRESS CLINICAL RANDOM ACCESS SCREENING PLATFORM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW IN THE FIRST TRIMESTER SCREENING: PAPP-A + FREE HCGß PAPP-A + FREE HCGß + NT (NUCHAL TRANSLUCENCY).,DELFIA®HAFP/FREE HCGß DUAL KIT (DELFIA®HAFP/FREE HCGß DUAL KIT)-THIS KIT IS INTENDED FOR THE SIMULTANEOUS QUANTITATIVE DETERMINATION OF HUMAN ALPHAFETOPROTEIN (HAFP) AND THE FREE SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN (FREE HCG) IN MATERNAL SERUM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: IN THE FIRST TRIMESTER OF PREGNANCY: HAFP / FREE HCG + PAPP-A HAFP / FREE HCG + PAPP-A + NT (NUCHAL TRANSLUCENCY) IN THE SECOND TRIMESTER OF PREGNANCY: HAFP / FREE HCG HAFP / FREE HCG + UE3 ,PRENATAL BOBS™ (PRENATAL BOBS™)-THIS BACS-ON-BEADS™ ASSAY IS INTENDED FOR THE DETECTION OF GAINS AND LOSSES OF DNA IN CHROMOSOMAL REGIONS ASSOCIATED WITH 9 MICRODELETION SYNDROMES AND CHROMOSOMES 13, 18, 21, X, AND Y IN HUMAN DNA USING THE LUMINEX® 100/200™ INSTRUMENT SYSTEM . THE PRENATAL BOBS™ KIT CAN BE USED AS AN AID IN DIAGNOSIS OF ANEUPLOIDIES OF CHROMOSOMES 13, 18, 21, X AND Y, AND OF COPY NUMBER ABNORMALITIES IN THE MICRODELETION SYNDROME REGIONS COVERED BY THE PRODUCT,NEONATAL PHENYLALANINE KIT(NEONATAL PHENYLALANINE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF PHENYLALANINE IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR ELEVATED LEVELS OF PHENYLALANINE IN THE BLOOD. ,DELFIA® XPRESS HAFP KIT(DELFIA® XPRESS HAFP KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN ALPHA-FETOPROTEIN (HAFP) IN MATERNAL SERUM (DURING THE FIRST AND SECOND TRIMESTERS OF PREGNANCY) AND AMNIOTIC FLUID (DURING THE SECOND TRIMESTER OF PREGNANCY) USING THE 6000 DELFIA® XPRESS CLINICAL RANDOM ACCESS SCREENING PLATFORM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: IN THE FIRST TRIMESTER OF

	PREGNANCY: HAFP (IN SERUM ONLY) + FREE HCG + PAPP-A HAFP (IN SERUM ONLY) + FREE HCG + PAPP-A + NT (NUCHAL TRANSLUCENCY) IN THE SECOND TRIMESTER OF PREGNANCY: HAFP (IN SERUM ONLY) + FREE HCG HAFP (IN SERUM ONLY) + FREE HCG + UE3,AUTODELFIA® NEONATAL HTSH KIT(AUTODELFIA® NEONATAL HTSH KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID STIMULATING HORMONE (HTSH) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL (NEONATAL) HYPOTHYROIDISM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM. ,DELFIA® XPRESS FREE HCGß KIT(DELFIA® XPRESS FREE HCGß KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE FREE ß SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN (FREE HCGß) IN MATERNAL SERUM USING THE 6000 DELFIA® XPRESS CLINICAL RANDOM ACCESS SCREENING PLATFORM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: IN THE FIRST TRIMESTER OF PREGNANCY: FREE HCGß + PAPP-A FREE HCGß + PAPP-A + NT (NUCHAL TRANSLUCENCY) IN THE SECOND TRIMESTER OF PREGNANCY: FREE HCGß + HAFP FREE HCGß + HAFP + UE3,DELFIA® PAPP-A KIT(DELFIA® PAPP-A KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF PAPP-A (PREGNANCY ASSOCIATED PLASMA PROTEIN A) IN MATERNAL SERUM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: PAPP-A + FREE HCGß PAPP-A + FREE HCGß + NT (NUCHAL TRANSLUCENCY) ,NEOBASE™ NON-DERIVATIZED ASSAY SOLUTIONS (NEOBASE™ NON-DERIVATIZED ASSAY SOLUTIONS)-INTENDED FOR IN VITRO DIAGNOSTIC USE WITH THE NEOBASE NON-DERIVATIZED MSMS KIT AND NEOBASE SUCCINYLACETONE ASSAY SOLUTION, DELFIA® NEONATAL HTSH KIT(DELFIA® NEONATAL HTSH KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID STIMULATING HORMONE (HTSH) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL (NEONATAL) HYPOTHYROIDISM. , DELFIA® WASH CONCENTRATE(DELFIA® WASH CONCENTRATE)-THE DELFIA® WASH CONCENTRATE IS INTENDED FOR IN VITRO USE WITH THE DELFIA XPRESS CLINICAL SCREENING RANDOM ACCESS PLATFORM OR WITH THE DELFIA PLATEWASH., AUTODELFIA®NEONATAL 17-OH-PROGESTERONE KIT (AUTODELFIA®NEONATAL 17-OH-PROGESTERONE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN 17 -OH-PROGESTERONE IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL ADRENAL HYPERPLASIA (CAH) USING THE 1235 AUTODELFIA® AUTOMATIC

	IMMUNOASSAY SYSTEM. ,DELFIA® DILUENT I(DELFIA® DILUENT I)-THE DELFIA® DILUENT I IS INTENDED TO BE USED WITH AUTODELFIA® AND DELFIA KITS FOR SAMPLE DILUTION. THE USE OF DILUENT I IN SAMPLE DILUTION OR OTHER PURPOSES IS DESCRIBED IN THE KIT INSERTS.,AUTODELFIA® FREE HCGß KIT(AUTODELFIA® FREE HCGß KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE FREE ß SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN (FREE HCGß) IN MATERNAL SERUM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM.,NEONATAL TOTAL GALACTOSE KIT(NEONATAL TOTAL GALACTOSE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL GALACTOSE (GALACTOSE AND GALACTOSE-1-PHOSPHATE) CONCENTRATIONS IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR GALACTOSEMIA. ,NEOLSD MSMS KIT(NEOLSD MSMS KIT)-THE NEOLSD™ MSMS KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF THE ACTIVITY OF THE ENZYMES ACID--GLUCOCEREBROSIDASE (ABG), ACID-SPHINGOMYELINASE (ASM), ACID--GLUCOSIDASE (GAA), -GALACTOCEREBROSIDASE (GALC), -GALACTOSIDASE A (GLA) AND -L-IDURONIDASE (IDUA) IN DRIED BLOOD SPOTS (DBS) FROM NEWBORN BABIES. THE ANALYSIS OF THE ENZYMATIC ACTIVITY IS INTENDED AS AN AID IN SCREENING NEWBORNS FOR THE FOLLOWING LYSOSOMAL STORAGE DISORDERS (LSD) RESPECTIVELY; GAUCHER DISEASE, NIEMANN-PICK A/B DISEASE, POMPE DISEASE, KRABBE DISEASE, FABRY DISEASE, AND MPS I DISEASE. ,DELFIA® ENHANCEMENT SOLUTION(DELFIA® ENHANCEMENT SOLUTION)-THE ENHANCEMENT SOLUTION IS INTENDED FOR IN VITRO USE IN THE QUANTITATIVE DETERMINATION OF EUROPIUM (EU3+) AND SAMARIUM (SM3+) IN DISSOCIATION-ENHANCED TIME-RESOLVED FLUOROIMMUNOASSAYS.,CHS™ MSMS STEROIDS KIT(CHS™ MSMS STEROIDS KIT)-THIS IN VITRO DIAGNOSTIC HIGH PERFORMANCE LIQUID CHROMATOGRAPHY TANDEM MASS SPECTROMETRY (HPLC-MSMS) REAGENT KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF 10 STEROIDS IN HUMAN SERUM SAMPLES. DETERMINATION OF CONCENTRATION PROFILES OF THESE ANALYTES MAY AID IN THE CLINICAL RECOGNITION, DIAGNOSIS AND TREATMENT OF DISEASES AFFECTING THE ADRENAL GLANDS, OVARIES, TESTES, AND PLACENTA. , AUTODELFIA®INHIBIN A KIT(AUTODELFIA®INHIBIN A KIT)-THE KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF DIMERIC HUMAN INHIBIN A IN MATERNAL SERUM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM. THE KIT IS INTENDED FOR SCREENING FOR RISK OF DOWN'S SYNDROME (TRISOMY 21) IN THE SECOND TRIMESTER OF PREGNANCY AND USED

	TOGETHER WITH RISK CALCULATION SOFTWARE, E.G. LIFECYCLE™ FOR PRENATAL SCREENING. THE KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: INHIBIN A + FREE HCG / HCG + HAFP + UE3 INHIBIN A + FREE HCG / HCG + HAFP. ,JB-2 STAINING SYSTEM(JB-2 STAINING SYSTEM)-THE JB-2 STAINING SYSTEM IS DESIGNED TO STAIN HEMOGLOBIN ON RESOLVE HEMOGLOBIN ELECTROPHORESIS GELS (FR-9120, FR-9400, FR-9360).,RESOLVE® HEMOGLOBIN KIT(RESOLVE® HEMOGLOBIN KIT)-THE RESOLVE SYSTEMS HEMOGLOBIN KIT IS DESIGNED TO SEPARATE WHOLE BLOOD, CORD BLOOD OR DRIED BLOOD SPOT SPECIMEN FOR DETECTION OF NORMAL AND VARIANT HEMOGLOBIN BY ISOELECTRONIC FOCUSING. THE KIT IS DESIGNED TO BE RUN ON A FLAT-BED ELECTROFOCUSING UNIT. THE ASSAY IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF NEONATAL AND ADULT HEMOGLOBINOPATHIES,DELFIA® DILUENT 3(DELFIA® DILUENT 3)-THE DELFIA® DILUENT 3 IS INTENDED TO BE USED WITH AUTODELFIA® AND DELFIA KITS FOR SAMPLE DILUTION, FRAGILEASE™ FRAGILE X PCR KIT(FRAGILEASE™ FRAGILE X PCR KIT) -THE FRAGILEASE KIT IS INTENDED TO AMPLIFY AND DETECT THE CYTOSINE-GUANINE-GUANINE (CGG) TRINUCLEOTIDE REPEAT SEQUENCE IN THE 5'-UNTRANSLATED REGION OF THE FRAGILE X MENTAL RETARDATION-1 (FMR-1) GENE. THE TEST CONSISTS OF A DNA AMPLIFICATION STEP, FOLLOWED BY FRAGMENT SIZING ON A MICROFLUIDIC CAPILLARY ELECTROPHORESIS INSTRUMENT AND SUBSEQUENT DETECTION OF THE NUMBER OF CGG REPEATS TO AID THE DIAGNOSIS OF FRAGILE X SYNDROME AND FRAGILE X ASSOCIATED DISORDERS E.G. TREMOR AND ATAXIA SYNDROME (FX-TAS) AND PRIMARY OVARIAN INSUFFICIENCY (FX-POI).,GSP® NEONATAL HTSH KIT(GSP® NEONATAL HTSH KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID STIMULATING HORMONE (HTSH) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL (NEONATAL) HYPOTHYROIDISM USING THE GSP® INSTRUMENT.,DELFIA® WASH CONCENTRATE(DELFIA® WASH CONCENTRATE)-THE WASH CONCENTRATE IS INTENDED FOR IN VITRO USE WITH THE DELFIA® PLATEWASH OR THE AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM AFTER DILUTION WITH DEIONIZED WATER.,GSP® NEONATAL G6PD KIT(GSP® NEONATAL G6PD KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD) ACTIVITY IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR G6PD DEFICIENCY USING THE GSP® INSTRUMENT,DELFIA® DILUENT II(DELFIA® DILUENT II)-THE DELFIA® DILUENT II IS INTENDED TO BE USED WITH AUTODELFIA®

	AND DELFIA KITS FOR SAMPLE DILUTION. THE USE OF DILUENT II IN SAMPLE DILUTION OR OTHER PURPOSES IS DESCRIBED IN THE KIT INSERTS.,GSP® NEONATAL PHENYLALANINE KIT(GSP® NEONATAL PHENYLALANINE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF PHENYLALANINE CONCENTRATIONS IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR PHENYLKETONURIA BY USING THE GSP® INSTRUMENT.,DELFIA® INDUCER(DELFIA® INDUCER)-THE DELFIA INDUCER IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF EUROPIUM (EU3+) IN DISSOCIATION-ENHANCED TIME-RESOLVED FLUORO-IMMUNOASSAYS WHEN USING THE GSP INSTRUMENT,GSP® NEONATAL IRT KIT(GSP® NEONATAL IRT KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN IMMUNOREACTIVE TRYPSIN(OGEN) (IRT) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CYSTIC FIBROSIS USING THE GSP® INSTRUMENT.,NEOBASE™ 2 SUCCINYLACETONE ASSAY SOLUTION(NEOBASE™ 2 SUCCINYLACETONE ASSAY SOLUTION)-THE NEOBASE™ 2 SUCCINYLACETONE ASSAY SOLUTION IS INTENDED FOR IN VITRO DIAGNOSTIC USE WITH THE NEOBASE™ 2 NON-DERIVATIZED MSMS KIT (3044-0010, 3044-001U) AND THE NEOBASE™ 2 NON-DERIVATIZED ASSAY SOLUTIONS (3045-0010) TO EXTRACT SUCCINYLACETONE FROM BLOOD SAMPLES DRIED ON FILTER PAPER. MEASUREMENT OF ARGININOSUCCINIC ACID REQUIRES USE OF NEOBASE 2 SUCCINYLACETONE ASSAY SOLUTION.,DELFIA® INDUCER(DELFIA® INDUCER)-THE DELFIA® INDUCER IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF EUROPIUM (EU3+) IN DISSOCIATION-ENHANCED TIME-RESOLVED FLUOROIMMUNOASSAYS WHEN USING THE GSP® INSTRUMENT,NEOBASE™ 2 NON-DERIVATIZED ASSAY SOLUTIONS (NEOBASE™ 2 NON-DERIVATIZED ASSAY SOLUTIONS)-THE NEOBASE™ 2 NON-DERIVATIZED ASSAY SOLUTIONS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE WITH THE NEOBASE™ 2 NON-DERIVATIZED MSMS KIT (3044-0010, 3044-001U) TO EXTRACT TARGET ANALYTES FROM BLOOD SAMPLES DRIED ON FILTER PAPER AND TO CARRY TARGET ANALYTES TO THE MSMS SYSTEM.,GSP® NEONATAL THYROXINE (T4) KIT(GSP® NEONATAL THYROXINE (T4) KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROXINE (T4) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL (NEONATAL) HYPOTHYROIDISM USING THE GSP® INSTRUMENT, DELFIA® / AUTODELFIA® PAPP-A/ FREE HCGß DUAL DBS KIT (DELFIA® / AUTODELFIA® PAPP-A/ FREE HCGß DUAL DBS KIT)-THIS

	KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN PAPP-A (PREGNANCY ASSOCIATED PLASMA PROTEIN A) AND FREE ß SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN (FREE HCGß) IN MATERNAL BLOOD DRIED ON FILTER PAPER USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM OR THE MODULAR DELFIA® SYSTEM. ,DELFIA® NEONATAL THYROXINE (T4) KIT(DELFIA® NEONATAL THYROXINE (T4) KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROXINE (T4) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL (NEONATAL) HYPOTHYROIDISM.,NEOBASE™ 2 NON-DERIVATIZED MSMS KIT (NEOBASE™ 2 NON-DERIVATIZED MSMS KIT)-THE NEOBASE™ 2 NON-DERIVATIZED MSMS KIT IS INTENDED FOR THE MEASUREMENT AND EVALUATION OF AMINO ACID, SUCCINYLACETONE, FREE CARNITINE, ACYLCARNITINE, NUCLEOSIDE AND LYSOPHOSPHOLIPID CONCENTRATIONS (TABLE 1) WITH A TANDEM MASS SPECTROMETER FROM NEWBORN HEEL PRICK BLOOD SPECIMENS DRIED ON FILTER PAPER. QUANTITATIVE ANALYSIS OF THESE ANALYTES AND THEIR RELATIONSHIP WITH EACH OTHER IS INTENDED TO PROVIDE ANALYTE CONCENTRATION PROFILES THAT MAY AID IN SCREENING NEWBORNS FOR METABOLIC DISORDERS.,NEONATAL GALT KIT (NEONATAL GALT KIT)-THIS KIT IS INTENDED FOR THE (SEMI-QUANTITATIVE) DETERMINATION OF GALACTOSE-1-PHOSPHATE URIDYL TRANSFERASE (GALT) CONCENTRATIONS IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CLASSICAL GALACTOSEMIA CAUSED BY GALT DEFICIENCY.,RESOLVE®HB ELUTION SOLUTION(RESOLVE®HB ELUTION SOLUTION)-THE RESOLVE HB ELUTION SOLUTION IS INTENDED FOR IN VITRO USE WITH THE RESOLVE HEMOGLOBIN KITS 9FR-9120, FR-9400, FR-9360) FOR ISOELECTRIC FOCUSING),CHS™ MSMS STEROIDS TOOL BOX(CHS™ MSMS STEROIDS TOOL BOX)-THE CHS™ MSMS STEROIDS TOOL BOX IS INTENDED FOR IN VITRO DIAGNOSTIC USE WITH THE CHS MSMS STEROIDS KIT (3070-0020)., DELFIA®/AUTODELFIA®PLGF 1-2-3(DELFIA®/AUTODELFIA®PLGF 1-2-3)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF PLACENTAL GROWTH FACTOR (PLGF) IN MATERNAL SERUM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM OR THE MODULAR DELFIA® SYSTEM. THE KIT IS USED AS AN AID IN SCREENING PREGNANT WOMEN FOR PRE-ECLAMPSIA IN ALL TRIMESTERS OF PREGNANCY AND FOR SCREENING FOR RISK OF DOWN'S SYNDROME IN THE FIRST TRIMESTER OF PREGNANCY. , AUTODELFIA® NEONATAL THYROXINE (T4) KIT(AUTODELFIA® NEONATAL THYROXINE (T4) KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROXINE (T4) IN

	BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL (NEONATAL) HYPOTHYROIDISM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM.,DELFIA / AUTODELFIA UNCONJUGATED ESTRIOL (UE3) KIT(DELFIA / AUTODELFIA UNCONJUGATED ESTRIOL (UE3) KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF UNCONJUGATED ESTRIOL (UE3) IN MATERNAL SERUM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM OR THE MODULAR DELFIA® SYSTEM. THIS KIT IS INTENDED FOR SCREENING FOR DOWN'S SYNDROME (TRISOMY 21) IN THE SECOND TRIMESTER OF PREGNANCY. THIS KIT IS INTENDED FOR USE IN E.G. ONE OF THE COMBINATIONS DESCRIBED BELOW: UE3 + HAFP + FREE HCG/HCG UE3 + HAFP + FREE HCG/HCG + INHIBIN A, DELFIA® WASH CONCENTRATE(DELFIA® WASH CONCENTRATE)-WASH CONCENTRATE IS INTENDED FOR IN VITRO DIAGNOSTIC USE. WASH CONCENTRATE CAN BE USED WITH THE DELFIA® PLATEWASH AFTER DILUTION WITH DEIONIZED WATER. IT CAN ALSO BE USED WITH OTHER DELFIA INSTRUMENTS.,SARS-COV-2 RT-QPCR REAGENT KIT(SARS-COV-2 RT-QPCR REAGENT KIT)-THE KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF SARS-COV-2 (SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2) NUCLEIC ACIDS IN RNA EXTRACTED FROM THE HUMAN OROPHARYNGEAL SWAB, NASOPHARYNGEAL SWAB, AND SALIVA AS AN AID IN DIAGNOSING PATIENTS SUSPECTED OF COVID-19 (CORONAVIRUS DISEASE) BY THEIR HEALTHCARE PROVIDER .,GSP® NEONATAL TOTAL GALACTOSE KIT(GSP® NEONATAL TOTAL GALACTOSE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL GALACTOSE (GALACTOSE AND GALACTOSE-1- PHOSPHATE) CONCENTRATIONS IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR GALACTOSEMIA USING THE GSP® INSTRUMENT,GSP®/DELFIA® ANTI-SARS-COV-2 IGG KIT (GSP®/DELFIA® ANTI-SARS-COV-2 IGG KIT)-THE GSP®/DELFIA® ANTI-SARS-COV-2 IGG KIT IS AN IMMUNOASSAY TO BE USED FOR QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA AND/OR HUMAN BLOOD SPECIMENS DRIED ON FILTER PAPER.,GSP® NEONATAL BIOTINIDASE KIT(GSP® NEONATAL BIOTINIDASE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF HUMAN BIOTINIDASE ACTIVITY IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR BIOTINIDASE DEFICIENCY USING THE GSP® INSTRUMENT,GSP® WASH CONCENTRATE(GSP® WASH CONCENTRATE)-WASH CONCENTRATE IS INTENDED FOR IN VITRO DIAGNOSTIC USE ESPECIALLY WITH THE GSP INSTRUMENT. IT CAN ALSO BE USED WITH DELFIA® AND AUTODELFIA® INSTRUMENTS.,

	GSP® NEONATAL GALT KIT(GSP® NEONATAL GALT KIT)-THIS KIT IS INTENDED FOR THE SEMI-QUANTITATIVE DETERMINATION OF GALACTOSE-1-PHOSPHATE URIDYL TRANSFERASE (GALT) ACTIVITY IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CLASSICAL GALACTOSEMIA CAUSED BY GALT DEFICIENCY USING THE GSP® INSTRUMENT. ,GSP® NEONATAL 17- OHPROGESTERONE KIT(GSP® NEONATAL 17-OHPROGESTERONE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN 17-OH-PROGESTERONE IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL ADRENAL HYPERPLASIA (CAH) USING THE GSP® INSTRUMENT

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

89	IMP/IVD/2018/000319	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVIA CHEMISTRY CAL CO2 CALIBRATOR/DILUENT(ADVIA CHEMISTRY CAL CO2 CALIBRATOR/DILUENT)-THE CO2 CALIBRATOR/DILUENT IS INTENDED FOR IN VITRO DIAGNOSTIC USE TO CALIBRATE THE ENZYMATIC DETERMINATION OF CO2 ON VARIOUS SIEMENS HEALTHCARE DIAGNOSTICS INSTRUMENTS. TO CALIBRATE ADVIA IMS® SYSTEMS, THIS PRODUCT IS USED IN CONJUNCTION WITH SIEMENS CHEMISTRY CALIBRATOR (PROD. NO. T03-1291-62). TO CALIBRATE ADVIA® CHEMISTRY SYSTEMS, THIS PRODUCT IS USED AS A STAND-ALONE PRODUCT. THE RECONSTITUTED STABILITY AND SSVS ARE NOT AFFECTED WHEN THIS PRODUCT IS USED IN PLACE OF DISTILLED WATER TO RECONSTITUTE SIEMENS CHEMISTRY CALIBRATOR. ,CLINITEK NOVUS® CALIBRATION KIT (CAL 1- 4 KIT) (CLINITEK NOVUS® CALIBRATION KIT (CAL 1- 4 KIT))-CLINITEK NOVUS® CALIBRATION KIT IS INTENDED TO BE USED WITH THE CLINITEK NOVUS URINALYSIS CASSETTE TO CALIBRATE THE CLINITEK NOVUS AUTOMATED URINE CHEMISTRY ANALYZER. ,ADVIA ® CHEMISTRY (LITH) LITHIUM REAGENTS(ADVIA ® CHEMISTRY (LITH) LITHIUM REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LITHIUM IN HUMAN SERUM AND PLASMA ON ADVIA CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED AS AN AID IN THE MONITORING OF LITHIUM THERAPY. ,CLINITEK NOVUS® RINSE ADDITIVE(CLINITEK NOVUS® RINSE ADDITIVE)-THE CLINITEK NOVUS® RINSE ADDITIVE IS DILUTED FOR USE AS THE RINSE SOLUTION IN THE CLINITEK NOVUS AUTOMATED URINE CHEMISTRY SYSTEM.,ADVIA ® CHEMISTRY CALIBRATOR(ADVIA ® CHEMISTRY CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF CHEMISTRY ASSAYS ON ADVIA® CHEMISTRY SYSTEMS.,ADVIA 120/2120/2120I DEFOAMER (ADVIA 120/2120/2120I DEFOAMER)-FOR IN VITRO DIAGNOSTIC USE AS A DEFOAMING REAGENT ON THE ADVIA® 120/2120/2120I HEMATOLOGY SYSTEMS. ,ADVIA CHEMISTRY (TIBC) TIBC REAGENTS (ADVIA CHEMISTRY (TIBC) TIBC REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE MEASUREMENT OF TOTAL IRON BINDING CAPACITY IN HUMAN SERUM ON ADVIA® CHEMISTRY XPT SYSTEMS. MEASUREMENT OF TOTAL IRON BINDING CAPACITY IS USED IN THE DIAGNOSIS AND TREATMENT OF ANEMIA. ,ADVIA 120/2120/2120I EZ WASH (ADVIA 120/2120/2120I EZ WASH)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF RED BLOOD CELLS, WHITE BLOOD CELLS, AND PLATELETS IN BLOOD ON ADVIA® 120/2120/2120I HEMATOLOGY SYSTEMS, WHICH ARE QUANTITATIVE, AUTOMATED HEMATOLOGY ANALYZERS THAT PROVIDE

	INFORMATION FOR IN VITRO DIAGNOSTIC USE IN CLINICAL LABORATORIES. THE EZ WASH IS USED AS A CLEANSING AGENT ON THE ADVIA® 120/2120/2120I SYSTEMS. ,ADVIA CHEMISTRY (HBA1C/DENAT) HEMOGLOBIN DENATURANT REAGENT(ADVIA CHEMISTRY (HBA1C/DENAT) HEMOGLOBIN DENATURANT REAGENT)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C, A DIABETESMARKER, IN WHOLE BLOOD ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED FOR MONITORING THE LONG-TERM CARE OF PERSONS WITH DIABETES. THE A1C_3M AND TOTAL HEMOGLOBIN (THB_3M) VALUES GENERATED AS PART OF THE ADVIA CHEMISTRY HBA1C% AND HBA1CR ASSAYS ARE INTENDED FOR USE IN THE CALCULATION OF THE HBA1C/TOTAL HEMOGLOBIN RATIO, AND MUST NOT BE USED INDIVIDUALLY FOR DIAGNOSTIC PURPOSES. , CLINITEK ATLAS® RINSE ADDITIVE(CLINITEK ATLAS® RINSE ADDITIVE)-THE CLINITEK ATLAS® RINSE ADDITIVE IS DILUTED FOR USE AS THE RINSE SOLUTION IN THE CLINITEK ATLAS AUTOMATED URINE CHEMISTRY SYSTEM.,ADVIA CHEMISTRY (UPRO_2) TOTAL PROTEIN_2 (URINE) REAGENTS (ADVIA CHEMISTRY (UPRO_2) TOTAL PROTEIN_2 (URINE) REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN URINE AND CEREBROSPINAL FLUID (CSF) ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PROTEINURIA, AS WELL AS CONDITIONS LEADING TO THE BREAKDOWN OF THE BLOOD-CNS BARRIER. ,CLINITEK ATLAS® CALIBRATION KIT(CLINITEK ATLAS® CALIBRATION KIT)-THE CLINITEK ATLAS® CALIBRATION KIT CONTAINS FOUR DIFFERENT CALIBRATION SOLUTIONS (CALIBRATORS #1, #2, #3, AND #4). THE CALIBRATORS ARE USED WITH THE CLINITEK ATLAS REAGENT PAKS TO CALIBRATE THE CLINITEK ATLAS AUTOMATED URINE CHEMISTRY ANALYZER. CALIBRATION ENABLES THE USER TO OBTAIN READINGS IN A URINE SPECIMEN FOR: COLOR, CLARITY, GLUCOSE, BILIRUBIN, KETONE (ACETOACETIC ACID), SPECIFIC GRAVITY, OCCULT BLOOD, PH, PROTEIN, UROBILINOGEN, NITRITE, LEUKOCYTES, AND CREATININE.,ATELLICA CH CO2 CALIBRATOR/DILUENT (CO2 CAL) (ATELLICA CH CO2 CALIBRATOR/DILUENT (CO2 CAL))-THE ATELLICA® CH CO2 CALIBRATOR/DILUENT (CO2 CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE CO2_C ASSAY USING THE ATELLICA® CH ANALYZER.,CLINITEK ATLAS® CALIBRATOR #4 (CLINITEK ATLAS® CALIBRATOR #4)-THE CLINITEK ATLAS® CALIBRATION KIT CONTAINS FOUR DIFFERENT CALIBRATION SOLUTIONS (CALIBRATORS #1, #2, #3, AND #4). THE CALIBRATORS ARE USED WITH THE CLINITEK ATLAS REAGENT PAKS TO CALIBRATE THE CLINITEK ATLAS AUTOMATED URINE CHEMISTRY ANALYZER.

	CALIBRATION ENABLES THE USER TO OBTAIN READINGS IN A URINE SPECIMEN FOR: COLOR, CLARITY, GLUCOSE, BILIRUBIN, KETONE (ACETOACETIC ACID), SPECIFIC GRAVITY, OCCULT BLOOD, PH, PROTEIN, UROBILINOGEN, NITRITE, LEUKOCYTES, AND CREATININE.,ATELLICA CH CHEMISTRY CALIBRATOR (CHEM CAL)(ATELLICA CH CHEMISTRY CALIBRATOR (CHEM CAL))-THE ATELLICA® CH CHEMISTRY CALIBRATOR (CHEM CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE CHEMISTRY ASSAYS: ALB, CA, CHOL_2, CREA_2, DBIL_2, ECRE_2, GLUH_3, GLUO, IRON_2, LI, MG, IP, TBIL_2, TP, TRIG, UA, AND UN_C USING THE ATELLICA® CH ANALYZER.,DCA MICROALBUMIN/CREATININE LOW AND HIGH CONTROL KIT(DCA MICROALBUMIN/CREATININE LOW AND HIGH CONTROL KIT)-THE DCA MICRO ALBUMIN/CREATININE LOW AND HIGH CONTROLS ARE INTENDED FOR USE AS CONTROLS FOR THE QUALITY CONTROL PURPOSES IN DCA SYSTEMS MICRO ALBUMIN/CREATININE ASSAY.,ADVIA 120/2120/2120I OPTIPOINT(ADVIA 120/2120/2120I OPTIPOINT)-ADVIA OPTIPOINT IS USED TO ADJUST THE GAINS OF ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS.,ADVIA CENTAUR WASH 1(ADVIA CENTAUR WASH 1)-ADVIA CENTAUR WASH 1 IS A SYSTEM FLUID USED FOR WASHING CUVETTES BETWEEN REACTION STEPS. FOR SOME ASSAYS, IT IS USED FOR PARTICLE RESUSPENSION.,ADVIA 120/2120/2120I CN-FREE CBC TIMEPAC (ADVIA 120/2120/2120I CN-FREE CBC TIMEPAC)-THE ADVIA 120/2120/2120I HEMATOLOGY SYSTEM COMPLETE BLOOD COUNT (CBC) METHOD IS INTENDED TO QUANTITATIVELY MEASURE THE FOLLOWING HEMATOLOGICAL PARAMETERS: WBC, RBC, HGB, CELLULAR HBG, HCT, MCV, MCH, MCHC, CHCM, CH, RDW, HDW, PLT AND MPV.,ADVIA 120/2120/2120I SHEATH RINSE 20L AND 10L(ADVIA 120/2120/2120I SHEATH RINSE 20L AND 10L)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF RED BLOOD CELLS, WHITE BLOOD CELLS, AND PLATELETS IN BLOOD ON ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS,ADVIA 120/2120/2120I CBC TIMEPAC(ADVIA 120/2120/2120I CBC TIMEPAC)-THE ADVIA 120/2120/2120I HEMATOLOGY SYSTEM COMPLETE BLOOD COUNT (CBC) METHOD IS INTENDED TO QUANTITATIVELY MEASURE THE FOLLOWING HEMATOLOGICAL PARAMETERS: WBC, RBC, HGB, CELLULAR HBG, HCT, MCV, MCH, MCHC, CHCM, CH, RDW, HDW, PLT AND MPV.,ADVIA 120/2120/2120I AUTORETIC(ADVIA 120/2120/2120I AUTORETIC)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF RETICULOCYTES IN BLOOD ON ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS.,ADVIA 120/2120/2120I PEROX SHEATH(ADVIA 120/2120/2120I PEROX SHEATH)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF WHITE BLOOD CELLS AND SUBPOPULATIONS IN

	BLOOD ON ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS.,ADVIA 120/2120/2120I DIFF TIMEPAC(ADVIA 120/2120/2120I DIFF TIMEPAC) -FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF WHITE BLOOD CELLS AND SUBPOPULATIONS IN BLOOD ON ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS., ATELLICA CH ALYTE™ IMT DILUTION CHECK (IMT DILUTION CHECK) (ATELLICA CH ALYTE™ IMT DILUTION CHECK (IMT DILUTION CHECK)) -THE ALYTE™ IMT DILUTION CHECK IS FOR IN VITRO DIAGNOSTIC USE TO MONITOR AND ADJUST THE DILUTION RATIO FOR THE IMT NA K CL ASSAYS ON THE ATELLICA™ CH ANALYZER.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

90	IMP/IVD/2018/000334	1.License Holder Name: SD BIOSENSOR HEALTHCARE PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STANDARD F IFOB FIA CONTROL(NA)-IT IS INTENDED FOR QUALITY CONTROL OF THE STANDARD F IFOB. THE CONTROL SOLUTION HELPS TO ENSURE THAT THE SYSTEM IS WORKING CORRECTLY.,STANDARD E TB FERON TUBES 100(NA)-TB FERON TUBES IS INTENDED TO COLLECT BLOOD SPECIMEN FOR USE WITH STANDARD E TB FERON ELISA KIT., STANDARD F TSUTSUGAMUSHI IGM/IGG (NA)-IT IS A FLUORESCENT IMMUNOASSAY FOR THE DETECTION OF IGM/IGG ANTIBODIES AGAINST ORIENTIA TSUTSUGAMUSHI IN HUMAN SERUM, PLASMA OR WHOLE BLOOD SAMPLES.,STANDARD E TB FERON TUBES 200(NA)-TB FERON TUBES IS INTENDED TO COLLECT BLOOD SPECIMEN FOR USE WITH STANDARD E TB FERON ELISA KIT.,STANDARD F CK-MB CONTROL(NA)-IT IS INTENDED FOR QUALITY CONTROL OF THE STANDARD F CK-MB. THE CONTROL SOLUTION HELPS TO ENSURE THAT THE SYSTEM IS WORKING CORRECTLY,STANDARD E TB FERON TUBES 300(NA)-TB FERON TUBES IS INTENDED TO COLLECT BLOOD SPECIMEN FOR USE WITH STANDARD E TB FERON ELISA KIT, STANDARD COVID-19 AG CONTROL(NA)-IT IS INTENDED FOR USE AS AN EXTERNAL QUALITY CONTROL MATERIAL TO MONITOR THE PERFORMANCE OF STANDARD Q COVID-19 AG TEST AND STANDARD F COVID-19 AG FIA. ,STANDARD F DENGUE IGM/IGG FIA(NA)-IT IS A FLUORESCENCE IMMUNOASSAY FOR THE DETECTION OF IGM/IGG ANTIBODIES AGAINST DENGUE VIRUS IN HUMAN SERUM, PLASMA OR WHOLE BLOOD SAMPLES.,STANDARD E TB FERON ELISA(NA)-IT IS AN IN VITRO DIAGNOSTIC TEST USE TO DETECTION OF INTERFERON – (IFN-) BY ENZYME LINKED IMMUNOSORBENT ASSAY IS USED TO IDENTIFY IN VITRO RESPONSES TO THOSE REC. TB AG THAT ARE ASSOCIATED WITH MYCOBACTERIUM TUBERCULOSIS INFECTION. , STANDARD F CK-MB FIA(NA)-IT IS A FLUORESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL CREATINE KINASE ISOENZYME –MB (CK –MB) LEVELS IN HUMAN SERUM, PLASMA AND WHOLE BLOOD. ,STANDARD Q COVID-19 IGM/IGG COMBO(NA)-STANDARD Q COVID-19 IGM/IGG COMBO TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES TO SARS-COV-2 PRESENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD,STANDARD GLUCONAVII GDH BLOOD GLUCOSE TEST STRIP(NA)-IT IS DESIGNED FOR SELF TESTING BLOOD GLUCOSE USING FRESH CAPILLARY WHOLE BLOOD FROM FINGER PRICK, PALM, FOREARM OR UPPER ARM OR FRESH VENOUS BLOOD.,STANDARD COVID-19 IGM/IGG CONTROL(NA)-IT IS INTENDED FOR USE AS AN EXTERNAL QUALITY CONTROL MATERIAL TO MONITOR THE PERFORMANCE OF STANDARD Q COVID-19 IGM/IGG

	COMBO, STANDARD Q COVID-19 IGM/IGG DUO AND STANDARD F COVID-19 IGM/IGG DUO FIA,STANDARD F PCT FIA (SERUM)(NA)-IT IS USE TO MEASURES THE PCT IN THE SERUM FROM THE HUMAN., STANDARD F IFOB FIA(NA)-IT IS A FECAL IMMUNOCHEMICAL TEST (FIT) FOR DETECTION AND QUANTIFICATION OF HEMOGLOBIN (HB) IN FECAL SPECIMEN.,MULTICARE U-ALBUMIN TEST KIT(NA)-IT IS USED TO MEASURE THE ALBUMIN IN THE URINE FROM THE HUMAN., STANDARD F NT-PRO BNP FIA(NA)-IT IS AN IN VITRO DIAGNOSTIC USE TO MEASURE THE N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE (NT-PRO BNP) IN SERUM, PLASMA AND WHOLE BLOOD., STANDARD GLUCOSE CONTROL SOLUTION(NA)-STANDARD GLUCOSE CONTROL SOLUTION IS FOR USE WITH THE BLOOD GLUCOSE MONITORING SYSTEM TO CHECK THAT THE METER AND TEST STRIPS ARE WORKING TOGETHER FOR SELF-TESTING.,DIAGNOSTIC BUFFER SOLUTION (COMPONENT OF COVID-19 KIT)(NA)-IT ALLOWS A BETTER MIGRATION OF THE LATEX MICROSPHERE LEADING TO A BETTER AND A MORE HOMOGENOUS SIGNAL. ,SDB U-ALBUMIN CONTROL(NA) -IT IS USED TO CHECK THE PERFORMANCE OF MULTICARE SYSTEM FOR U-ALBUMIN TESTING. ,UNCUT SHEET OF STANDARD Q COVID-19 IGM/IGG COMBO (BULK)(NA)-IT IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES TO COVID-19 PRESENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,STANDARD CODE FREE PLUS BLOOD GLUCOSE TEST STRIP(NA)-STANDARD CODE FREE PLUS BLOOD GLUCOSE TEST STRIP IS DESIGNED FOR SELF-TESTING BLOOD GLUCOSE USING FRESH CAPILLARY WHOLE BLOOD FROM FINGER PRICK, PALM, FOREARM OR UPPER ARM.,UNCUT SHEET OF STANDARD Q COVID -19 AG (BULK)(NA)-STANDARD Q COVID-19 AG TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIGENS TO COVID-19 PRESENT IN HUMAN NASOPHARYNX AND OROPHARYNX,SD CODEFREE BLOOD GLUCOSE TEST STRIP(NA)-SD CODEFREE BLOOD GLUCOSE TEST STRIP IS DESIGNED FOR SELF TESTING BLOOD GLUCOSE USING FRESH CAPILLARY WHOLE BLOOD FROM FINGER PRICK, PALM, FOREARM OR UPPER ARM. ,STANDARD Q COVID-19 IGM/IGG DUO(NA)-STANDARD Q COVID-19 IGM/IGG DUO TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES TO COVID-19 PRESENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD,SD CHECK GOLD BLOOD GLUCOSE TEST STRIP(NA)-SD CHECK GOLD BLOOD GLUCOSE TEST STRIP IS DESIGNED FOR SELF TESTING BLOOD GLUCOSE USING FRESH CAPILLARY WHOLE BLOOD FROM FINGER PRICK.,SDB LIPID CONTROL SOLUTION(NA)-SDB LIPID CONTROL SOLUTION IS INTENDED FOR CHECKING THE PERFORMANCE AS SYSTEM BETWEEN LIPIDOCARE ANALYZER AND

	LIPIDOCARE LIPID TEST STRIP.,STANDARD F HBA1C (NA)-IT IS USED FOR QUANTITATIVE MEASUREMENT OF HBA1C IN HUMAN CAPILLARY OR VENOUS WHOLE BLOOD.,STANDARD LIPIDOCARE LIPID TEST STRIPS-LIPID PROFILE(NA)-STANDARD LIPIDOCARE LIPID TEST STRIPS-LIPID PROFILE IS USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL, HIGH-DENSITY LIPOPROTEIN (HDL) CHOLESTEROL AND TRIGLYCERIDES IN THE BLOOD ,STANDARD F PCT CONTROL(NA)-IT IS DESIGNED TO MONITOR THE PERFORMANCE OF STANDARD F PCT FIA AND STANDARD F ANALYZERS,STANDARD F PCT -02 CONTROL(NA)-IT IS INTENDED FOR QUALITY CONTROL OF THE STANDARD F PCT. THE CONTROL SOLUTION HELPS TO ENSURE THAT THE SYSTEM IS WORKING CORRECTLY.,STANDARD F S. PNEUMONIAE AG FIA(NA)-IT IS USED FOR THE QUALITATIVE DETECTION OF S. PNEUMONIAE CPS AG PRESENT IN URINE SAMPLES FROM PATIENTS WITH RESPIRATORY SYMPTOMS.,STANDARD LIPIDOCARE LIPID TEST STRIPS - TG(NA)-STANDARD LIPIDOCARE LIPID TEST STRIPS - TRIGLYCERIDES IS USED FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN THE BLOOD. ,STANDARD F CRP(NA)-IT IS USE TO MEASURES THE CRP IN THE HUMAN SERUM, PLASMA AND WHOLE BLOOD SAMPLE.,STANDARD F H.PYLORI AG FIA(NA)-IT IS A QUALITATIVE IMMUNOASSAY TO DETECT H. PYLORI AG IN THE HUMAN FECAL SPECIMEN. ,STANDARD F HSCRP(NA)-IT IS AN IN VITRO DIAGNOSTIC USE TO MEASURES THE CRP IN THE HUMAN SERUM, PLASMA AND WHOLE BLOOD SAMPLE.,STANDARD Q FILARISIS AG TEST(NA)-IT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF WUCHERERIA BANCROFTI ANTIGENS IN HUMAN SERUM, PLASMA OR WHOLE BLOOD SAMPLES.,MULTICARE CRP TEST KIT(NA)-IT IS USED TO MEASURE THE C-REACTIVE PROTEIN (CRP) IN THE HUMAN BLOOD SAMPLE.,STANDARD A1CCARE TEST KIT (NA)-STANDARD A1CCARE TEST SYSTEM IS AN IN VITRO DIAGNOSTIC SYSTEM FOR A QUANTITATIVE MEASUREMENT OF GLYCATED HEMOGLOBIN (HBA1C) IN HUMAN CAPILLARY OR VENOUS WHOLE BLOOD. ,STANDARD F PCT FIA(NA)-IT IS USE TO MEASURES THE PCT IN THE WHOLE BLOOD, SERUM AND PLASMA FROM THE HUMAN., STANDARD LIPIDOCARE LIPID TEST STRIPS - TC(NA)-STANDARD LIPIDOCARE LIPID TEST STRIPS – TOTAL CHOLESTEROL IS USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL IN THE BLOOD. ,MULTICARE HBA1C TEST KIT(NA)-IT IS USED TO MEASURE THE GLYCATED HEMOGLOBIN (HBA1C) IN THE HUMAN BLOOD.,STANDARD M SPIN-X VIRAL RNA EXTRACTION KIT(NA)-IT IS AN IN VITRO DIAGNOSTIC KIT DESIGNED FOR THE EXTRACTION OF VIRAL RNA FROM VARIOUS HUMAN SAMPLES,STANDARD M NCOV REAL TIME DETECTION KIT(NA)-STANDARD M NCOV REAL-TIME

	DETECTION KIT IS USED FOR IDENTIFICATION AND DETECTION OF NOVEL CORONAVIRUS (2019-NCOV) OR 1 AB (RDRP) GENE AND E GENE IN HUMAN NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, AND SPUTUM SPECIMENS USING REVERSE TRANSCRIPTION (RT) REAL-TIME PCR,STANDARD F LYME IGM/IGG FIA(NA)-IT IS A FLUORESCENT IMMUNOASSAY FOR THE DETECTION OF IGM/IGG ANTIBODIES AGAINST BORRELIA BURGDORFERI IN HUMAN SERUM, PLASMA OR WHOLE BLOOD SAMPLES.,STANDARD GLUCONAVII CONTROL SOLUTION(NA)-IT IS INTENDED FOR QUALITY CONTROL OF THE STANDARD GLUCONAVII GDH AND STANDARD GLUCONAVII NFC BLOOD GLUCOSE MONITORING SYSTEM. THE CONTROL SOLUTION HELPS TO ENSURE THAT THE SYSTEM IS WORKING CORRECTLY. , STANDARD F VITAMIN D FIA(NA)-STANDARD F VITAMIN D FIA IS AN IN VITRO DIAGNOSTIC FOR THE QUANTITATIVE MEASUREMENT OF TOTAL 25-HYDROXY VITAMIN D (25-OH VITAMIN D) IN HUMAN SERUM.,STANDARD DENGUE NS1 AG FIA CONTROL(NA)-IT IS USED TO MEASURE THE PERFORMANCE OF STANDARD F DENGUE NS1 AGTEST .,STANDARD F STREP A AG FIA(NA)-IT IS THE FLUORESCENCE IMMUNOASSAY TO DETECT GROUP A STREPTOCOCCAL (STREP A) ANTIGEN PRESENT IN THROAT,MULTICARE LIPID PROFILE TEST KIT (NA)-IT IS USE TO MEASURE TOTAL CHOLESTEROL ,HIGH –DENSITY LIPOPROTEIN (HDL) CHOLESTEROL AND TRIGLYCERIDES IN THE HUMAN BLOOD SAMPLE AND CALCULATE ESTIMATED VALUES FOR LOW-DENSITY LIPOPROTEIN (LDL) CHOLESTEROL, LDL/HDL RATIO AND NON-HDL CHOLESTEROL. ,UNCUT SHEET OF BLOOD GLUCOSE TEST STRIP (BULK)(NA)-IT IS DESIGNED FOR SELF-TESTING BLOOD GLUCOSE USING FRESH CAPILLARY WHOLE BLOOD FROM FINGER PRICK, PALM, FOREARM OR UPPER ARM.,STANDARD G6PD TEST(NA)-IT IS USED FOR THE QUANTITATIVE MEASUREMENT OF TOTAL-HEMOGLOBIN CONCENTRATION AND G6PD ENZYMATIC ACTIVITY IN HUMAN FRESH WHOLE BLOOD SPECIMEN.,STANDARD F TSH FIA CONTROL(NA)-IT IS AN IN VITRO DIAGNOSTIC USE TO MEASURES THE TSH IN HUMAN SERUM. THE QUANTITY MEASUREMENT OF THE TSH IS USEFUL IN THE DIAGNOSIS OF HYPOTHYROIDISM OR HYPERTHYROIDISM. THIS TEST IS ONLY FOR A PROFESSIONAL USE AND INITIAL SCREENING TEST.,SDB HBA1C CONTROL(NA)-IT IS USED TO CHECK THE PERFORMANCE OF STANDARD F SYSTEM FOR HBA1C TESTING. ,STANDARD F LH FIA(NA)-IT IS AN FLUORESCENT IMMUNOASSAY TO MEASURE LH LEVEL IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD. THE QUANTITATIVE MEASUREMENT OF THE LH HELPS EVALUATE FERTILITY ISSUES, FUNCTION OF REPRODUCTIVE ORGANS (OVARIES OR TESTICLES), TO DETECT THE OVULATION; TO EVALUATE PITUITARY FUNCTION, OR TO EVALUATE EARLY OR DELAYED SEXUAL MATURATION (PUBERTY) IN CHILDREN.,

	STANDARD Q COVID -19 AG(NA)-STANDARD COVID-19 AG TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIGENS TO COVID-19 PRESENT IN HUMAN NASOPHARYNX AND OROPHARYNX ,STANDARD F TSH FIA(NA)-IT IS AN IN VITRO DIAGNOSTIC USE TO MEASURES THE TSH IN HUMAN SERUM. THE QUANTITY MEASUREMENT OF THE TSH IS USEFUL IN THE DIAGNOSIS OF HYPOTHYROIDISM OR HYPERTHYROIDISM. THIS TEST IS ONLY FOR A PROFESSIONAL USE AND INITIAL SCREENING TEST , STANDARD F TNI FIA(NA)-IT IS A FLUORESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL TROPONIN I (CTNI) LEVELS IN HUMAN SERUM, PLASMA AND WHOLE BLOOD.,STANDARD F D-DIMER FIA(NA)-STANDARD F D-DIMER FIA IS AN IN VITRO DIAGNOSTIC USE TO MEASURE THE D-DIMER IN PLASMA AND WHOLE BLOOD SAMPLE. THE QUANTITATIVE MEASUREMENT OF THE D-DIMER USEFUL IN THE DIAGNOSIS OF EVALUATION OF CIRCULATING DERIVATIVES OF CROSSLINKED FIBRIN DEGRADATION PRODUCT., STANDARD F BETA-HCG CONTROL(NA)-IT IS USED TO MONITOR THE PERFROMANCE OF STANDARD F BETA-HCG FIA AND STANDARD F ANALYZER.,STANDARD F LH FIA CONTROL(NA)-IT IS AN FLUORESCENT IMMUNOASSAY TO MEASURE LH LEVEL IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD. THE QUANTITATIVE MEASUREMENT OF THE LH HELPS EVALUATE FERTILITY ISSUES, FUNCTION OF REPRODUCTIVE ORGANS (OVARIES OR TESTICLES), TO DETECT THE OVULATION; TO EVALUATE PITUITARY FUNCTION, OR TO EVALUATE EARLY OR DELAYED SEXUAL MATURATION (PUBERTY) IN CHILDREN.,STANDARD F TSH-II FIA(NA)-IT IS AN IN VITRO DIAGNOSTIC USE TO MEASURES THE TSH IN HUMAN SERUM AND WHOLE BLOOD.,STANDARD F RSV AG FIA(NA)-STANDARD F RSV AG FIA IS THE FLUORESCENCE IMMUNOASSAY TO DETECT RSV ANTIGEN PRESENT IN NASOPHARYNGEAL SWAB OR NASOPHARYNGEAL ASPIRATE/WASH SPECIMENS FROM PATIENTS WITH SYMPTOMS OF A VIRAL RESPIRATORY INFECTION,STANDARD F U-ALBUMIN(NA)-IT IS USE TO MEASURES THE ALBUMIN IN THE URINE FROM THE HUMAN., STANDARD G6PD CONTROL(NA)-IT IS INTENDED FOR USE AS A QUALITY CONTROL MATERIAL TO CHECK THE PERFORMANCE OF STANDARD G6PD SYSTEM.,STANDARD F FT4 (NA)-IT IS AN QUANTITATIVE DIAGNOSIS TO BE USED AS AN AID IN THE ASSESSMENT OF THYROID STATUS.,STANDARD F D-DIMER FIA CONTROL(NA)-STANDARD F D-DIMER FIA CONTROL IS AN IN VITRO DIAGNOSTIC USE TO MEASURE THE D-DIMER IN PLASMA AND WHOLE BLOOD SAMPLE. THE QUANTITATIVE MEASUREMENT OF THE D-DIMER USEFUL IN THE DIAGNOSIS OF EVALUATION OF CIRCULATING DERIVATIVES OF CROSSLINKED FIBRIN DEGRADATION PRODUCT., STANDARD F T4 (NA)-IT IS AN QUANTITATIVE DIAGNOSIS TO BE USED

	AS AN AID IN THE ASSESSMENT OF THYROID STATUS,STANDARD F CHIKUNGUNYA IGM/IGG FIA(NA)-IT IS A FLUORESCENCE IMMUNOASSAY FOR THE DETECTION OF IGM/IGG ANTIBODIES AGAINST CHIKUNGUNYA VIRUS IN HUMAN SERUM, PLASMA, OR WHOLE BLOOD SAMPLES.,STANDARD F COVID-19 AG FIA(NA)-STANDARD F COVID-19 AG FIA IS THE FLUORESCENT IMMUNOASSAY TO DETECT COVID-19 INFECTION IN HUMAN NASOPHARYNGEAL SWAB SPECIMEN, IDENTIFYING EXISTENCE OF COVID-19 VIRAL NUCLEOPROTEIN ANTIGENS ,STANDARD Q LEPTOSPIRA IGM/IGG(NA) -IT IS AN IMMUNO CHROMATOGRAPHIC ASSAY FOR THE DETECTION OF IGM/IGG ANTIBODIES AGAINST LEPTOSPIRA BACTERIA IN HUMAN SERUM, PLASMA, OR WHOLE BLOOD SAMPLES.,STANDARD MENTOR BLOOD GLUCOSE TEST STRIPS(NA)-IT IS DESIGNED FOR SELF TESTING BLOOD GLUCOSE USING FRESH CAPILLARY WHOLE BLOOD FROM FINGER PRICK, PALM, FOREARM OR UPPER ARM.,STANDARD F DENGUE NS1 AG FIA(NA)-IT IS A FLUORESCENCE IMMUNOASSAY FOR THE DETECTION OF DENGUE NS1 ANTIGENS IN HUMAN SERUM, PLASMA, OR WHOLE BLOOD SAMPLES.,STANDARD DENGUE IGM/IGG FIA CONTROL(NA)-IT IS USED TO MEASURE THE PERFORMANCE OF STANDARD F DENGUE IGM/IGG TEST .,SDB CRP CONTROL(NA)-IT IS INTENDED FOR USE AS A QUALITY CONTROL MATERIAL TO CHECK THE PERFORMANCE OF MULTICARE SYSTEM CRP TESTING., STANDARD F BETA-HCG(NA)-IT IS A FLUORESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL BETA-HCG LEVELS IN HUMAN SERUM, PLASMA AND WHOLE BLOOD.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

91	IMP/IVD/2018/000335	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HCV ELISA KIT(NANBASE C-96 3.0)-FOR IN-VITRO QUALITATIVE DETECTION AND SCREENING ASSAY OF ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM OR PLASMA.,ANTI-HBSAG ELISA KIT(ANTISURASE B-96 TMB)-FOR IN VITRO QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B SURFACE ANTIGEN (ANTI-HBS) IN HUMAN SERUM OR PLASMA.,HIV 1/2 ELISA KIT(HIVASE 1+2)-FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND/OR TYPE 2 (ANTI-HIV 1/2) IN HUMAN SERUM OR PLASMA.,ANTI-HCV ELISA KIT(NANBASE C-96 V4.0)-FOR IN-VITRO QUALITATIVE DETECTION AND SCREENING ASSAY OF ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM OR PLASMA.,ANTI-HBC ELISA KIT(ANTICORASE B-96 TMB)-FOR IN VITRO QUALITATIVE DETECTION OF TOTAL ANTIBODY TO HEPATITIS B VIRUS CORE ANTIGEN (ANTI-HBC TOTAL) IN HUMAN SERUM OR PLASMA,ANTI-HBE/HBE AG ELISA KIT(EASE BN-96)-FOR IN VITRO QUALITATIVE TESTING OF HBEAG AND ANTI-HBE IN HUMAN SERUM OR PLASMA.,ANTI-HBC IGM ELISA KIT(ANTICORASE MB-96)-FOR IN VITRO QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS B VIRUS CORE ANTIGEN (ANTI-HBC IGM) IN HUMAN SERUM OR PLASMA,HBSAG ELISA KIT(SURASE B-96 TMB)-FOR IN-VITRO QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OR PLASMA.
92	IMP/IVD/2018/000336	1.License Holder Name: M/S.TRANSASIA BIO-MEDICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ESR CONTROL(ESR CONTROL)-HEMATOLOGICAL CONTROL OF THE DETERMINATION OF THE ERYTHROCYTE SEDIMENTATION RATE (ESR),VACU-TEC CUVETTE-L(VACU-TEC CUVETTE-L)-VACUUM TUBES FOR BLOOD DRAWING, WITHOUT OUTERTUBES, CONTAINING SODIUM CITRATE SOLUTION FOR DIRECT DETERMINATION OF THE ESR USING DIESSE ORIGINAL LINE INSTRUMENTS. COMPLETE WITH IDENTIFICATION LABEL. SAMPLE VOLUME: 1 ML.,LATEX CUVETTES FOR VES-MATIC (LATEX CUVETTES FOR VES-MATIC)-PERIODICAL CALIBRATION OF VES-MATIC 20, VES-MATIC 30 AND VES-MATIC EASY OPTICAL SENSOR. FOR TECHNICAL SERVICE ONLY,ESR CONTROL CUBE(ESR CONTROL CUBE)-HEMATOLOGICAL CONTROL OF THE DETERMINATION OF THE ERYTHROCYTE SEDIMENTATION RATE (ESR)

93	IMP/IVD/2018/000337	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:M SERIES DILUENT WITH RFID(MEDONIC)-USED IN IN VITRO DIAGNOSTICS,ALFA LYSE (SWELAB)-USED IN IN VITRO DIAGNOSTICS,M SERIES DILUENT (MEDONIC)-USED IN IN VITRO DIAGNOSTICS,ALFA LYSE WITH RFID (SWELAB)-USED IN IN VITRO DIAGNOSTICS,ALFA DILUENT WITH RFID (SWELAB)-USED IN IN VITRO DIAGNOSTICS,M SERIES LYSE(MEDONIC) -USED IN IN VITRO DIAGNOSTICS,M SERIES LYSE WITH RFID (MEDONIC)-USED IN IN VITRO DIAGNOSTICS,ALFA DILUENT(SWELAB)-USED IN IN VITRO DIAGNOSTICS,CLEANING KIT(BOULE)-USED IN IN VITRO DIAGNOSTICS
94	IMP/IVD/2018/000338	1.License Holder Name: SAS ENTERPRISES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:M51- D-DILUENT (MEDONIC)-USED IN VITRO DIAGNOSTICS ,CLEANING KIT(BOULE)-USED FOR IN VITRO DIAGNOSTICS,M51- L2 LYSE (MEDONIC)-USED IN VITRO DIAGNOSTICS ,M SERIES DILUENT(MEDONIC)-USED FOR IN VITRO DIAGNOSTICS,M51- L1 LYSE (MEDONIC)-USED IN VITRO DIAGNOSTICS ,M SERIES DILUENT WITH RFID(MEDONIC)-USED FOR IN VITRO DIAGNOSTICS,EASY CLEANER(BOULE)-USED IN VITRO DIAGNOSTICS,M SERIES LYSE WITH RFID(MEDONIC)-USED FOR IN VITRO DIAGNOSTICS,M SERIES LYSE(MEDONIC)-USED FOR IN VITRO DIAGNOSTICS
95	IMP/IVD/2018/000339	1.License Holder Name: KANNU IMPEX (INDIA) PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLUCO LAB AUTO-CODING TEST STRIPS-THE GLUCOSE TEST STRIP IS USED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE LEVEL IN WHOLE BLOOD.,CLOVER A1C TEST CARTRIDGE-IT IS USED FOR MEASURING THE PERCENT CONCENTRATION OF HEMOGLOBIN A1C,HEALTH PRO TEST STRIPS-THE GLUCOSE TEST STRIPS ARE USED TO MEASURE THE LEVEL OF GLUCOSE IN HUMAN BLOOD USING FRESH CAPILLARY WHOLE BLOOD SAMPLES.,GLUNEOLITE TEST STRIP-THE TEST STRIPS ARE USED TO MEASURE THE LEVEL OF GLUCOSE IN HUMAN BLOOD USING FRESH WHOLE BLOOD SAMPLE FROM CAPILLARY OR VENOUS BLOOD.,ELEMENT TEST STRIP-THE GLUCOSE TEST STRIP IS USED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE LEVEL IN WHOLE BLOOD

96	IMP/IVD/2018/000340	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARCHITECT CYCLOSPORINE CALIBRATORS(ARCHITECT CYCLOSPORINE CALIBRATORS)-THE ARCHITECT CYCLOSPORINE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE IN HUMAN WHOLE BLOOD.,ALINITY I AFP CONTROLS-USED FOR THE ESTIMATION OF TEST PRECISION AND DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF ALPHAFETOPROTEIN (AFP) IN HUMAN SERUM, PLASMA, AND AMNIOTIC FLUID.,ALINITY I CYCLOSPORINE REAGENT KIT(ALINITY I CYCLOSPORINE REAGENT KIT)-THE ALINITY I CYCLOSPORINE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE IN HUMAN WHOLE BLOOD ON THE ALINITY I SYSTEM.,ALINITY I FREE PSA REAGENT KIT -INTENDED FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM, ALINITY I CYCLOSPORINE CALIBRATORS(ALINITY I CYCLOSPORINE CALIBRATORS)-THE ALINITY I CYCLOSPORINE CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE IN HUMAN WHOLE BLOOD.,ALINITY I CEA CALIBRATORS-USED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) IN HUMAN SERUM AND PLASMA,ARCHITECT CYCLOSPORINE REAGENT KIT(ARCHITECT CYCLOSPORINE REAGENT KIT)-THE ARCHITECT CYCLOSPORINE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE IN HUMAN WHOLE BLOOD ON THE ARCHITECT I SYSTEM.,ALINITY I FREE PSA CALIBRATORS-USED ARE FOR THE CALIBRATION OF ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM,ALINITY I STAT CK-MB REAGENT KIT(ALINITY I STAT CK-MB REAGENT KIT)-THE ALINITY I STAT CK-MB ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF THE MB ISOENZYME OF CREATINE KINASE (CK-MB) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ALINITY I CEA CONTROLS-INTENDED FOR THE ESTIMATION OF TEST PRECISION AND DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER (REAGENTS, CALIBRATORS AND INSTRUMENT), WHEN USED FOR THE

	QUANTITATIVE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN (CEA) IN HUMAN SERUM OR PLASMA,ALINITY I STAT MYOGLOBIN REAGENT KIT(ALINITY I STAT MYOGLOBIN REAGENT KIT)-THE ALINITY I STAT MYOGLOBIN ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ALINITY I FREE PSA CONTROLS-INTENDED FOR VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM,ARCHITECT HBSAG CALIBRATORS (ARCHITECT HBSAG CALIBRATORS)-THE ARCHITECT HBSAG CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA.,ALINITY I BRAHMS PCT REAGENT KIT(ALINITY I BRAHMS PCT REAGENT KIT)-THE ALINITY I BRAHMS PCT ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER., ALINITY I RUBELLA IGM CONTROLS(ALINITY I RUBELLA IGM CONTROLS)-THE ALINITY I RUBELLA IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA.,ALINITY I AFP CALIBRATORS-USED FOR THE CALIBRATION OF ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF ALPHA-FETOPROTEIN (AFP) IN HUMAN SERUM, PLASMA AND AMNIOTIC FLUID.,ALINITY H-SERIES PHOSPHATE BUFFER REAGENT(ALINITY H-SERIES PHOSPHATE BUFFER REAGENT)-ALINITY H-SERIES PHOSPHATE BUFFER MAINTAINS OPTIMAL PH FOR STAINING THAT CONTRIBUTES TO THE RELIABILITY OF THE STAIN QUALITY. PROMOTES THE APPROPRIATE CONDITIONS FOR THE INTERACTION OF THE DYES AND COLOR PRODUCTION. PROVIDES RINSING SOLUTION FOR THE STAINED SLIDES AND THE ASPIRATION PROBE. RINSING THE ASPIRATION AND PIERCE PROBES BETWEEN SAMPLES. , ALINITY I CEA REAGENT KIT-USED FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER,ALINITY I-SERIES CONCENTRATED WASH BUFFER(ALINITY I-SERIES CONCENTRATED WASH BUFFER)-ALINITY I-SERIES CONCENTRATED WASH BUFFER (LIST NUMBER 06P1368) IS USED AS A CLEANING SOLUTION TO WASH SAMPLE AND REAGENT PIPETTOR ASSEMBLIES AND TO WASH ZONES

	DURING ASSAY PROCESSING. ,ALINITY I AFP REAGENT KIT-INTENDED FOR THE QUANTITATIVE DETERMINATION OF ALPHA-FETOPROTEIN (AFP) ON THE ALINITY I ANALYZER IN: 1. HUMAN SERUM OR PLASMA TO AID IN MONITORING DISEASE PROGRESSION DURING THE COURSE OF DISEASE AND TREATMENT OF PATIENTS WITH NONSEMINOMATOUS TESTICULAR CANCER. 2. HUMAN SERUM, PLASMA, AND AMNIOTIC FLUID AT 15 TO 21 WEEKS GESTATION TO AID IN THE DETECTION OF FETAL OPEN NEURAL TUBE DEFECTS (NTD).,SARS-COV-2 IGG CALIBRATOR KIT(SARS-COV-2 IGG CALIBRATOR KIT)-THE SARS-COV-2 IGG CALIBRATOR KIT IS FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA.,ALINITY I HBSAG CONFIRMATORY V.1 REAGENT KIT(ALINITY I HBSAG CONFIRMATORY V.1 REAGENT KIT)-THE ALINITY I HBSAG CONFIRMATORY V.1 ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA BY MEANS OF SPECIFIC ANTIBODY NEUTRALIZATION ON THE ALINITY I ANALYZER.,SARS-COV-2 IGG CONTROL KIT(SARS-COV-2 IGG CONTROL KIT)-THE SARS-COV-2 IGG CONTROL KIT IS FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA.,ALINITY I HBSAG CONFIRMATORY V.1 CONTROLS(ALINITY I HBSAG CONFIRMATORY V.1 CONTROLS)-THE ALINITY I HBSAG CONFIRMATORY V.1 CONTROLS ARE FOR THE VERIFICATION OF CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA BY MEANS OF SPECIFIC ANTIBODY NEUTRALIZATION.,SARS-COV-2 IGM REAGENT KIT(SARS-COV-2 IGM REAGENT KIT)-THE SARS-COV-2 IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA ON THE ARCHITECT I SYSTEM.,ALINITY I HBSAG CONFIRMATORY V.1 CALIBRATORS(ALINITY I HBSAG CONFIRMATORY V.1 CALIBRATORS)-THE ALINITY I HBSAG CONFIRMATORY V.1 CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA BY MEANS OF SPECIFIC ANTIBODY NEUTRALIZATION.,ARCHITECT PROBE CONDITIONING SOLUTION(ARCHITECT PROBE CONDITIONING SOLUTION)-THE ARCHITECT PROBE CONDITIONING SOLUTION IS

	USED AS PART OF THE DAILY MAINTENANCE PROCEDURE. THE SAMPLE PIPETTOR PROBE IS CONDITIONED WITH THIS SOLUTION AFTER CLEANING WITH SODIUM HYPOCHLORITE TO PREVENT NON-SPECIFIC BINDING OF ANALYTES IN THE PROBE.,ARCHITECT HBSAG REAGENT KIT-INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA .,ARCHITECT CMV IGG CALIBRATORS(ARCHITECT CMV IGG CALIBRATORS)-THE ARCHITECT CMV IGG CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION AND SEMI-QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA.,ALINITY I TOTAL PSA CONTROLS(NIL)-USED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROSTATE SPECIFIC ANTIGEN (BOTH FREE PSA AND PSA COMPLEXED TO ALPHA-1-ANTICHYMOTRYPSIN) IN HUMAN SERUM.,ARCHITECT CONCENTRATE WASH BUFFER(ARCHITECT CONCENTRATE WASH BUFFER)-CONCENTRATED WASH BUFFER IS A SOLUTION CONTAINING PHOSPHATE SALINE. WASH BUFFER IS USED THROUGHOUT ASSAY PROCESSING AND IS PUMPED TO THE SAMPLE AND REAGENT PIPETTING ASSEMBLIES AND THE TWO WASH ZONES.,ALINITY I TOTAL PSA CALIBRATORS(NIL)-USED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROSTATE SPECIFIC ANTIGEN (BOTH FREE PSA AND PSA COMPLEXED TO ALPHA-1-ANTICHYMOTRYPSIN) IN HUMAN SERUM.,ALINITY I CMV IGG AVIDITY CONTROLS(ALINITY I CMV IGG AVIDITY CONTROLS)-THE ALINITY I CMV IGG AVIDITY CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER.,ALINITY I TOTAL PSA REAGENT KIT(NIL)-USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL PSA (BOTH FREE PSA AND PSA COMPLEXED TO ALPHA-1-ANTICHYMOTRYPSIN) IN HUMAN SERUM ON THE ALINITY I ANALYZER,ARCHITECT RUBELLA IGG CALIBRATORS(ARCHITECT RUBELLA IGG CALIBRATORS)-THE ARCHITECT RUBELLA IGG CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION AND QUALITATIVE DETECTION OF IGG ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA TO AID IN THE DETERMINATION OF IMMUNE STATUS TO RUBELLA.,ALINITY I ANTI-TPO REAGENT KIT (ALINITY I ANTI-TPO REAGENT KIT)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS OF THYROID PEROXIDASE AUTOANTIBODIES (ANTI-TPO).,ALINITY I-SERIES PROBE CONDITIONING SOLUTION(ALINITY I-SERIES PROBE CONDITIONING

	SOLUTION)-THE ALINITY I-SERIES PROBE CONDITIONING SOLUTION IS USED AS PART OF MAINTENANCE PROCEDURES. AFTER THE SAMPLE PIPETTOR PROBE IS CLEANED, THIS SOLUTION IS USED TO CONDITION THE PROBE TO PREVENT THE NONSPECIFIC BINDING OF ANALYTES IN THE PROBE.,ALINITY I ANTI-TG REAGENT KIT-INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS OF THYROGLOBULIN AUTOANTIBODIES (ANTI-TG) IN HUMAN SERUM AND PLASMA,ALINITY I CORTISOL REAGENT KIT(ALINITY I CORTISOL REAGENT KIT)-THE ALINITY I CORTISOL ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM, PLASMA OR URINE ON THE ALINITY I ANALYZER. THE ALINITY I CORTISOL ASSAY IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS AND TREATMENT OF ADRENAL DISORDERS., ARCHITECT HBSAG MANUAL DILUENT-USED FOR MANUALLY DILUTING SPECIMENS FOR TESTING USING THE ARCHITECT HBSAG CONFIRMATORY V.1 REAGENT KIT.,ARCHITECT TRIGGER SOLUTION (ARCHITECT TRIGGER SOLUTION)-THE FUNCTION OF TRIGGER SOLUTION IS TO PRODUCE THE CHEMILUMINESCENT REACTION THAT PROVIDES THE FINAL READ.,ARCHITECT HBSAG CALIBRATORS-USED FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA.,ALINITY PRE-TRIGGER SOLUTION(ALINITY PRE-TRIGGER SOLUTION)-ALINITY PRE-TRIGGER SOLUTION – USED TO PREPARE THE ACRIDINIUM DYE FOR THE ADDITION OF TRIGGER SOLUTION BY SEPARATING THE ACRIDINIUM DYE FROM THE CONJUGATE THAT IS BOUND TO THE MICROPARTICLE COMPLEX.,ARCHITECT HBSAG CONTROLS-USED FOR THE VERIFICATION OF THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA.,SARS-COV-2 IGG CONTROL KIT(SARS-COV-2 IGG CONTROL KIT)-THE SARS-COV-2 IGG CONTROL KIT IS FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA.,ARCHITECT HBSAG QUALITATIVE II CONTROLS-USED ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION AND FOR THE CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA.,SARS-COV-2 IGG CALIBRATOR KIT(SARS-COV-2 IGG CALIBRATOR KIT)-THE SARS-COV-2 IGG CALIBRATOR KIT IS FOR THE CALIBRATION OF THE

	ALINITY I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA., ARCHITECT ANTI-HBS REAGENT KIT-USED FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO HEPATITIS B SURFACE ANTIGEN (ANTI-HBS) IN HUMAN SERUM AND PLASMA.,SARS-COV-2 IGG REAGENT KIT(SARS-COV-2 IGG REAGENT KIT)-THE SARS-COV-2 IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA ON THE ALINITY I SYSTEM.,ARCHITECT HBSAG QUALITATIVE II CONFIRMATORY REAGENT KIT-INTENDED FOR THE CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING),SARS-COV-2 IGM CONTROL KIT(SARS-COV-2 IGM CONTROL KIT)-THE SARS-COV-2 IGM CONTROL KIT IS FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA.,ARCHITECT HBSAG QUALITATIVE II CONFIRMATORY MANUAL DILUENT-USED FOR MANUALLY DILUTING SPECIMENS FOR TESTING ON THE ARCHITECT ISYSTEM USING THE ARCHITECT I HBSAG QUALITATIVE II CONFIRMATORY REAGENT KIT.,ARCHITECT AFP REAGENT KIT (ARCHITECT AFP REAGENT KIT)-THE ARCHITECT AFP ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF ALPHA-FETOPROTEIN (AFP) IN: 1. HUMAN SERUM OR PLASMA TO AID IN MONITORING DISEASE PROGRESSION DURING THE COURSE OF DISEASE AND TREATMENT OF PATIENTS WITH NONSEMINOMATOUS TESTICULAR CANCER. 2. HUMAN SERUM, PLASMA AND AMNIOTIC FLUID AT 15 TO 21 WEEKS GESTATION TO AID IN THE DETECTION OF FETAL OPEN NEURAL TUBE DEFECTS (NTD). TEST RESULTS WHEN USED IN CONJUNCTION WITH ULTRASONOGRAPHY OR AMNIOGRAPHY ARE A SAFE AND EFFECTIVE AID IN THE DETECTION OF FETAL OPEN NTD.,ARCHITECT ANTI-HBS CALIBRATORS-INTENDED FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO HEPATITIS B SURFACE ANTIGEN (ANTI-HBS) IN HUMAN SERUM AND PLASMA.,ARCHITECT PRE-TRIGGER SOLUTION (ARCHITECT PRE-TRIGGER SOLUTION)-THE FUNCTION OF THE PRE-TRIGGER SOLUTION IS TO SPLIT THE ACRIDINIUM DYE OFF THE CONJUGATE BOUND TO THE MICROPARTICLE COMPLEX. THIS PROCESS PREPARES THE ACRIDINIUM DYE FOR THE ADDITION OF THE TRIGGER SOLUTION.,ALINITY I HBSAG MANUAL DILUENT-INTENDED TO BE USED WITH THE ALINITY I HBSAG REAGENT KIT OR

	THE ALINITY I HBSAG CONFIRMATORY V.1 REAGENT KIT.,SARS-COV-2 IGM CALIBRATOR KIT(SARS-COV-2 IGM CALIBRATOR KIT)-THE SARS-COV-2 IGM CALIBRATOR KIT IS FOR THE CALIBRATION OF THE ALINITY I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA., ALINITY I HBSAG QUALITATIVE II REAGENT KIT-INTENDED FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING) ON THE ALINITY I ANALYZER.,ARCHITECT RUBELLA IGG REAGENT KIT(ARCHITECT RUBELLA IGG REAGENT KIT)-ARCHITECT RUBELLA IGG IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION AND QUALITATIVE DETECTION OF IGG ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA ON THE ARCHITECT ISYSTEM.,ALINITY I HBSAG QUALITATIVE II CONTROLS-USED ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION AND FOR THE CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA USING THE ALINITY I HBSAG QUALITATIVE II AND HBSAG QUALITATIVE II CONFIRMATORY REAGENT KITS.,ALINITY H-SERIES HGB REAGENT(ALINITY H-SERIES HGB REAGENT)-ALINITY H-SERIES HGB REAGENT ACTS AS A LYSING AGENT IN THE HEMOGLOBIN DILUTION BY DESTROYING RED BLOOD CELL MEMBRANES FOR ALINITY HQ ANALYZER. ,ALINITY I HBSAG CALIBRATORS-USED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA.,ARCHITECT RUBELLA IGG CONTROLS(ARCHITECT RUBELLA IGG CONTROLS)-THE ARCHITECT RUBELLA IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM (REAGENTS, CALIBRATORS AND INSTRUMENT) WHEN USED FOR THE QUANTITATIVE DETERMINATION AND QUALITATIVE DETECTION OF IGG ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA TO AID IN THE DETERMINATION OF IMMUNE STATUS TO RUBELLA., ARCHITECT HBSAG QUALITATIVE II CALIBRATORS-USED FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR QUALITATIVE DETECTION AND CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA .,ARCHITECT RUBELLA IGM REAGENT KIT(ARCHITECT RUBELLA IGM REAGENT KIT)-THE ARCHITECT RUBELLA IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR

	THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA.,ALINITY I HBSAG QUALITATIVE II CALIBRATORS-USED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR QUALITATIVE DETECTION AND CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA USING THE ALINITY I HBSAG QUALITATIVE II AND HBSAG QUALITATIVE II CONFIRMATORY REAGENT KITS.,ARCHITECT CMV IGG AVIDITY REAGENT KIT(ARCHITECT CMV IGG AVIDITY REAGENT KIT)-THE ARCHITECT CMV IGG AVIDITY ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE DETERMINATION OF THE AVIDITY OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA.,ARCHITECT HBSAG QUALITATIVE II REAGENT KIT-INTENDED FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING).,ALINITY H-SERIES RECTIC REAGENT(ALINITY H-SERIES RECTIC REAGENT)-ALINITY H-SERIES RECTIC REAGENT STAINS NUCLEIC ACIDS IN CELLS IN THE RETIC DILUTION FOR ALINITY HQ ANALYZER. ,ALINITY I ANTI-HBS SPECIMEN DILUENT-USED FOR MANUALLY DILUTING SPECIMENS FOR TESTING ON THE ALINITY I ANALYZER USING THE ALINITY I ANTIHBS REAGENT KIT.,ARCHITECT CMV IGG AVIDITY CALIBRATOR & CONTROL(ARCHITECT CMV IGG AVIDITY CALIBRATOR & CONTROL)-THE ARCHITECT CMV IGG AVIDITY CALIBRATOR IS INTENDED FOR THE CREATION OF AN ACTIVE CALIBRATION FOR THE ASSAYS OF THE ARCHITECT CMV IGG AVIDITY REAGENT KIT. AN ACTIVE CALIBRATION IS REQUIRED BY THE ARCHITECT I SYSTEM, HOWEVER THE CALIBRATION IS NOT USED TO PRODUCE CMV IGG AVIDITY RESULTS. THE ARCHITECT CMV IGG AVIDITY CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM.,ALINITY I ANTI-HBS CONTROLS-USED FOR THE ESTIMATION OF TEST PRECISIÓN AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER (REAGENTS, CALIBRATORS AND INSTRUMENT), WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF ANTIBODY TO HEPATITIS B SURFACE ANTIGEN (ANTI-HBS) IN HUMAN SERUM OR PLASMA., ARCHITECT MULTI-ASSAY MANUAL DILUENT(ARCHITECT MULTI-ASSAY MANUAL DILUENT)-THE ARCHITECT MULTI-ASSAY MANUAL DILUENT CONTAINS PHOSPHATE BUFFERED SALINE.IT IS USED TO DILUTE ELEVATED SAMPLES PRIOR TO TESTING PER THE ASSAY PRODUCT INSERT.,ALINITY I ANTI-HBS CALIBRATORS-INTENDED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO HEPATITIS B

	SURFACE ANTIGEN (ANTI-HBS) IN HUMAN SERUM AND PLASMA., ARCHITECT CEA CALIBRATORS(ARCHITECT CEA CALIBRATORS)-THE ARCHITECT CEA CALIBRATORS ARE FOR CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) IN HUMAN SERUM AND PLASMA.,ALINITY I ANTI-HBS REAGENT KIT-USED FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO HEPATITIS B SURFACE ANTIGEN (ANTI-HBS) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT CMV IGM CONTROLS (ARCHITECT CMV IGM CONTROLS)-THE ARCHITECT CMV IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM (REAGENTS, CALIBRATORS AND INSTRUMENT) WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA.,ALINITY I HBSAG QUALITATIVE II CONFIRMATORY MANUAL DILUENT-USED FOR MANUALLY DILUTING SPECIMENS FOR TESTING ON THE ALINITY I ANALYZER USING THE ALINITY I HBSAG QUALITATIVE II CONFIRMATORY REAGENT KIT.,ARCHITECT HBSAG CONFIRMATORY V.1 REAGENT KIT(ARCHITECT HBSAG CONFIRMATORY V.1 REAGENT KIT)-THE ARCHITECT HBSAG CONFIRMATORY V.1 ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA BY MEANS OF SPECIFIC ANTIBODY NEUTRALIZATION.,ALINITY I HBSAG QUALITATIVE II CONFIRMATORY REAGENT KIT-INTENDED FOR THE CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING) BY MEANS OF SPECIFIC ANTIBODY NEUTRALIZATION ON THE ALINITY I ANALYZER.,ALINITY I RUBELLA IGG CALIBRATORS(ALINITY I RUBELLA IGG CALIBRATORS)-THE ALINITY I RUBELLA IGG CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED QUANTITATIVE DETERMINATION AND QUALITATIVE DETECTION OF IGG ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA TO AID IN THE DETERMINATION OF IMMUNE STATUS TO RUBELLA.,ARCHITECT ANTI-HBS SPECIMEN DILUENT-USED FOR MANUALLY DILUTING SPECIMENS FOR TESTING ON THE ARCHITECT I SYSTEM USING THE ARCHITECT ANTI-HBS REAGENT KIT.,ARCHITECT TOTAL PSA CALIBRATORS(ARCHITECT TOTAL PSA CALIBRATORS)-THE ARCHITECT TOTAL PSA CALIBRATORS ARE FOR CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROSTATE SPECIFIC ANTIGEN (BOTH FREE PSA AND PSA

	COMPLEXED TO ALPHA-1-ANTICHYMOTRYPSIN) IN HUMAN SERUM.,ARCHITECT HBSAG NEXT CONFIRMATORY MANUAL DILUENT (ARCHITECT HBSAG NEXT CONFIRMATORY MANUAL DILUENT)-THE HBSAG NEXT CONFIRMATORY MANUAL DILUENT IS USED FOR MANUALLY DILUTING SPECIMENS FOR TESTING ON THE ARCHITECT ISYSTEM.,ARCHITECT TOTAL PSA REAGENT KIT(ARCHITECT TOTAL PSA REAGENT KIT)-THE ARCHITECT TOTAL PSA ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL PSA (BOTH FREE PSA AND PSA COMPLEXED TO ALPHA-1- ANTICHYMOTRYPSIN) IN HUMAN SERUM: 1. AS AN AID IN THE DETECTION OF PROSTATE CANCER WHEN USED IN CONJUNCTION WITH DIGITAL RECTAL EXAM (DRE) IN MEN 50 YEARS OR OLDER. PROSTATIC BIOPSY IS REQUIRED FOR DIAGNO$IS OF CANCER. 2. AS AN ADJUNCTIVE TEST TO AID IN THE MANAGEMENT OF PROSTATE CANCER PATIENTS.,ARCHITECT HBSAG NEXT QUALITATIVE CALIBRATORS(ARCHITECT HBSAG NEXT QUALITATIVE CALIBRATORS)-THE HBSAG NEXT QUALITATIVE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR QUALITATIVE DETECTION AND CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA.,ARCHITECT FREE PSA CALIBRATORS(ARCHITECT FREE PSA CALIBRATORS)-THE ARCHITECT FREE PSA CALIBRATORS ARE FOR CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM.,ARCHITECT HBSAG NEXT CONFIRMATORY REAGENT KIT(ARCHITECT HBSAG NEXT CONFIRMATORY REAGENT KIT)-THE HBSAG NEXT CONFIRMATORY ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA INCLUDING SPECIMENS COLLECTED POST MORTEM (NONHEART- BEATING) BY MEANS OF SPECIFIC ANTIBODY NEUTRALIZATION ON THE ARCHITECT ISYSTEM., ARCHITECT CEA REAGENT KIT(ARCHITECT CEA REAGENT KIT)-THE ARCHITECT CEA ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) IN HUMAN SERUM AND PLASMA.,ARCHITECT HBSAG NEXT QUALITATIVE REAGENT KIT (ARCHITECT HBSAG NEXT QUALITATIVE REAGENT KIT)-THE HBSAG NEXT QUALITATIVE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA INCLUDING SPECIMENS COLLECTED POST MORTEM (NON-HEART-BEATING) ON THE ARCHITECT ISYSTEM.,

	ARCHITECT CMV IGG REAGENT KIT(ARCHITECT CMV IGG REAGENT KIT)-THE ARCHITECT CMV IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION AND SEMIQUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA.,ARCHITECT HBSAG NEXT QUALITATIVE CONTROLS (ARCHITECT HBSAG NEXT QUALITATIVE CONTROLS)-THE HBSAG NEXT QUALITATIVE CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION AND FOR THE CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA.,ARCHITECT RUBELLA IGM CONTROLS (ARCHITECT RUBELLA IGM CONTROLS)-THE ARCHITECT RUBELLA IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA.,ALINITY I HBSAG REAGENT KIT-INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT AFP CONTROLS(ARCHITECT AFP CONTROLS) -THE ARCHITECT AFP CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF ALPHAFETOPROTEIN (AFP) IN HUMAN SERUM, PLASMA AND AMNIOTIC FLUID.,ALINITY I HBSAG CONTROLS-USED FOR THE VERIFICATION OF THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA.,ARCHITECT CMV IGG CONTROLS (ARCHITECT CMV IGG CONTROLS)-THE ARCHITECT CMV IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION AND SEMI-QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA.,ARCHITECT ANTI-HBS CONTROLS-USED FOR THE ESTIMATION OF TEST PRECISIÓN AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF ANTIBODY TO HEPATITIS B SURFACE ANTIGEN (ANTI-HBS) IN HUMAN SERUM OR PLASMA., ARCHITECT CEA CONTROLS(ARCHITECT CEA CONTROLS)-THE ARCHITECT CEA CONTROLS ARE FOR THE ESTIMATION OF TEST

	PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM (REAGENTS, CALIBRATORS AND INSTRUMENT), WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN (CEA) IN HUMAN SERUM OR PLASMA.,SARS-COV-2 IGG II QUANT CALIBRATOR KIT(SARS-COV-2 IGG II QUANT CALIBRATOR KIT)-THE SARS-COV-2 IGG II QUANT CALIBRATOR KIT IS FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA., ALINITY I T-UPTAKE REAGENT KIT(ALINITY I T-UPTAKE REAGENT KIT) -THE ALINITY I T-UPTAKE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF THE TOTAL BINDING CAPACITY OF HUMAN SERUM OR PLASMA FOR THE THYROID HORMONE, THYROXINE (T4), ON THE ALINITY I ANALYZER. THE ALINITY I T-UPTAKE ASSAY IS TO BE USED IN CONJUNCTION WITH TOTAL T4 TO YIELD A CALCULATED FREE THYROXINE INDEX (FTI), AS AN AID IN THE ASSESSMENT OF THYROID FUNCTION STATUS.,SARS-COV-2 IGG II QUANT CALIBRATOR KIT(SARS-COV-2 IGG II QUANT CALIBRATOR KIT)-THE SARS-COV-2 IGG II QUANT CALIBRATOR KIT IS FOR THE CALIBRATION OF THE ALINITY I SYSTEM WHEN USED FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA., ALINITY TRIGGER SOLUTION(ALINITY TRIGGER SOLUTION)-ALINITY TRIGGER SOLUTION USED TO PRODUCE THE CHEMILUMINESCENT REACTION THAT PROVIDES THE FINAL READ.,SARS-COV-2 IGG II QUANT CONTROL KIT(SARS-COV-2 IGG II QUANT CONTROL KIT)-THE SARS-COV-2 IGG II QUANT CONTROL KIT IS FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA., ARCHITECT HBSAG CONFIRMATORY V.1 CONTROLS(ARCHITECT HBSAG CONFIRMATORY V.1 CONTROLS)-THE ARCHITECT HBSAG CONFIRMATORY V.1 CONTROLS ARE FOR THE VERIFICATION OF CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA BY MEANS OF SPECIFIC ANTIBODY NEUTRALIZATION.,SARS-COV-2 IGG II QUANT CONTROL KIT(SARS-COV-2 IGG II QUANT CONTROL KIT)-THE SARS-COV-2 IGG II QUANT CONTROL KIT IS FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I SYSTEM WHEN USED FOR THE

	QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA., ARCHITECT HBSAG CONFIRMATORY V.1 CALIBRATORS(ARCHITECT HBSAG CONFIRMATORY V.1 CALIBRATORS)-THE ARCHITECT HBSAG CONFIRMATORY V.1 CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA BY MEANS OF SPECIFIC ANTIBODY NEUTRALIZATION.,SARS-COV-2 IGG II QUANT REAGENT KIT(SARS-COV-2 IGG II QUANT REAGENT KIT)-THE SARS-COV-2 IGG II QUANT ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA ON THE ARCHITECT I SYSTEM. THE SARS-COV-2 IGG II QUANT ASSAY IS TO BE USED AS AN AID IN THE DIAGNOSIS OF SARS-COV-2 INFECTION IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY TESTS. THE ASSAY IS ALSO TO BE USED AS AN AID IN EVALUATING IMMUNE STATUS OF INFECTED INDIVIDUALS AND TO MONITOR ANTIBODY RESPONSE IN INDIVIDUALS THAT HAVE RECEIVED THE COVID-19 VACCINE, BY QUANTITATIVELY MEASURING IGG ANTIBODIES AGAINST THE SPIKE RECEPTOR-BINDING DOMAIN (RBD) OF SARS-COV-2. RESULTS FROM THE SARS-COV-2 IGG II QUANT ASSAY SHOULD NOT BE USED AS THE SOLE BASIS FOR DIAGNOSIS OF SARS-COV-2 INFECTION.,ALINITY I CMV IGG CALIBRATORS(ALINITY I CMV IGG CALIBRATORS)-THE ALINITY I CMV IGG CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION AND SEMIQUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA.,SARS-COV-2 IGG II QUANT REAGENT KIT(SARS-COV-2 IGG II QUANT REAGENT KIT)-THE SARS-COV-2 IGG II QUANT ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA ON THE ARCHITECT I SYSTEM. THE SARS-COV-2 IGG II QUANT ASSAY IS TO BE USED AS AN AID IN THE DIAGNOSIS OF SARS-COV-2 INFECTION IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY TESTS. THE ASSAY IS ALSO TO BE USED AS AN AID IN EVALUATING IMMUNE STATUS OF INFECTED INDIVIDUALS AND TO MONITOR ANTIBODY RESPONSE IN INDIVIDUALS THAT HAVE RECEIVED THE COVID-19 VACCINE, BY QUANTITATIVELY MEASURING IGG ANTIBODIES AGAINST THE SPIKE RECEPTOR-BINDING DOMAIN (RBD) OF SARS-COV-2. RESULTS FROM THE SARS-COV-2 IGG II QUANT ASSAY SHOULD NOT BE USED AS THE SOLE BASIS FOR DIAGNOSIS OF SARS-

	COV-2 INFECTION.,ARCHITECT FREE PSA REAGENT KIT(ARCHITECT FREE PSA REAGENT KIT)-THE ARCHITECT FREE PSA ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM.,ARCHITECT CMV IGM CALIBRATOR (ARCHITECT CMV IGM CALIBRATOR)-THE ARCHITECT CMV IGM CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM (REAGENTS, CALIBRATORS AND INSTRUMENT) WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA.,ALINITY I CMV IGM REAGENT KIT(ALINITY I CMV IGM REAGENT KIT)-THE ALINITY I CMV IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ALINITY S CONCENTRATED WASH BUFFER(ALINITY S CONCENTRATED WASH BUFFER)-THE ALINITY S CONCENTRATED WASH BUFFER IS PUMPED TO SAMPLE AND REAGENT PIPETTOR ASSEMBLIES AND WASH ZONES DURING ASSAY PROCESSING TO DISCARD UNBOUND ANALYTE FROM THE REACTION MIXTURE IN REACTION VESSELS ON THE ALINITY S SYSTEM.,SARS-COV-2 IGM CONTROL KIT(SARS-COV-2 IGM CONTROL KIT)-THE SARS-COV-2 IGM CONTROL KIT IS FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA.,SARS-COV-2 IGG REAGENT KIT(SARS-COV-2 IGG REAGENT KIT)-THE SARS-COV-2 IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA ON THE ARCHITECT I SYSTEM., ARCHITECT RUBELLA IGM CALIBRATOR(ARCHITECT RUBELLA IGM CALIBRATOR)-THE ARCHITECT RUBELLA IGM CALIBRATOR 1 IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA.,ALINITY I RUBELLA IGM REAGENT KIT (ALINITY I RUBELLA IGM REAGENT KIT)-THE ALINITY I RUBELLA IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ALINITY I RUBELLA IGG CONTROLS(ALINITY I RUBELLA IGG CONTROLS)-THE ALINITY I RUBELLA IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER (REAGENTS, CALIBRATORS AND INSTRUMENT) WHEN USED FOR THE

	QUANTITATIVE DETERMINATION AND QUALITATIVE DETECTION OF IGG ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA TO AID IN THE DETERMINATION OF IMMUNE STATUS TO RUBELLA., ALINITY I RUBELLA IGM CALIBRATORS(ALINITY I RUBELLA IGM CALIBRATORS)-THE ALINITY I RUBELLA IGM CALIBRATORS 1 IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA.,ALINITY H-SERIES WBC REAGENT (ALINITY H-SERIES WBC REAGENT)-ALINITY H-SERIES WBC REAGENT ACTS AS DILUENT FLUID FOR THE WBC MEASUREMENT AND LYSIS RED BLOOD CELLS FOR ALINITY HQ ANALYZER.,ARCHITECT FREE PSA CONTROLS(ARCHITECT FREE PSA CONTROLS)-THE ARCHITECT FREE PSA CONTROLS ARE FOR VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM.,ARCHITECT CMV IGM REAGENT KIT (ARCHITECT CMV IGM REAGENT KIT)-THE ARCHITECT CMV IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA.,SARS-COV-2 IGM CALIBRATOR KIT(SARS-COV-2 IGM CALIBRATOR KIT)-THE SARS-COV-2 IGM CALIBRATOR KIT IS FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA.,ALINITY I MULTI-ASSAY MANUAL DILUENT(ALINITY I MULTI-ASSAY MANUAL DILUENT)-THE ALINITY I MULTI-ASSAY MANUAL DILUENT IS USED FOR THE MANUAL DILUTION OF SPECIMENS ACROSS MULTIPLE ALINITY I ASSAYS. THE ASSAYS THAT UTILIZE MULTI-ASSAY MANUAL DILUENT FOR SAMPLE DILUTION ARE IDENTIFIED IN THE RESPECTIVE REAGENT PACKAGE INSERTS., ALINITY I CMV IGG CONTROLS(ALINITY I CMV IGG CONTROLS)-THE ALINITY I CMV IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION AND SEMIQUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA.,ALINITY I CMV IGG REAGENT KIT(ALINITY I CMV IGG REAGENT KIT)-THE ALINITY I CMV IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION AND SEMIQUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER., ARCHITECT AFP CALIBRATORS(ARCHITECT AFP CALIBRATORS)-THE ARCHITECT AFP CALIBRATORS ARE FOR THE CALIBRATION OF THE

	ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF ALPHA-FETOPROTEIN (AFP) IN HUMAN SERUM, PLASMA AND AMNIOTIC FLUID.,ALINITY I RUBELLA IGG REAGENT KIT (ALINITY I RUBELLA IGG REAGENT KIT)-THE ALINITY I RUBELLA IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION AND QUALITATIVE DETECTION OF IGG ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER. THE ALINITY I RUBELLA IGG ASSAY IS TO BE USED AS AN AID IN THE DETERMINATION OF IMMUNE STATUS TO RUBELLA.,SARS-COV-2 IGM REAGENT KIT(SARS-COV-2 IGM REAGENT KIT)-THE SARS-COV-2 IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA ON THE ALINITY I SYSTEM.,ALINITY I CMV IGM CALIBRATOR(ALINITY I CMV IGM CALIBRATOR)-THE ALINITY I CMV IGM CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER (REAGENTS, CALIBRATOR AND INSTRUMENT) WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA.,ALINITY I CMV IGM CONTROLS(ALINITY I CMV IGM CONTROLS)-THE ALINITY I CMV IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER (REAGENTS, CALIBRATORS AND INSTRUMENT) WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA.,ALINITY I CMV IGG AVIDITY REAGENT KIT(ALINITY I CMV IGG AVIDITY REAGENT KIT)-THE ALINITY I CMV IGG AVIDITY ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE DETERMINATION OF THE AVIDITY OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT TOTAL PSA CONTROLS(ARCHITECT TOTAL PSA CONTROLS)-THE ARCHITECT TOTAL PSA CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROSTATE SPECIFIC ANTIGEN (BOTH FREE PSA AND PSA COMPLEXED TO ALPHA-1-ANTICHYMOTRYPSIN) IN HUMAN SERUM.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

97	IMP/IVD/2019/000001	1.License Holder Name: IRIS HEALTHCARE TECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:APO A1/A2/B CALIBRATOR HIGH(DIALAB)-LYOPHILIZED HUMAN BASED CALIBRATOR FOR USE IN CALIBRATION OF IMMUNOTURBIDIMETRIC ASSAYS.,HOMOCYSTIENE CALIBRATOR SET, 5 LEVEL(DIALAB)-LIQUID STANDARD REAGENT USED FOR CALIBRATION OF HOMOCYSTIENE, CLINICAL BIOCHEMISTRY.,LDH-L, IFCC(DIALAB)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF LDH-L IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,DIACON -N(DIALAB) -CONTROLS USED FOR QUANTITATIVE DETERMINATION OF VARIOUS ANALYTES OF CLINICAL BIOCHEMISTRY,CK-NAC, OPT. DGKC / IFCC (DIALAB)-USED FOR ESTIMATION OF CK-NAC IN HUMAN SERUM OR PLASMA., ADENOSINE DEAMINASE (ADA)(DIALAB)-USED FOR QUANTITATIVE ESTIMATION OF ADENOSINE DEAMINASE (ADA) IN HUMAN SERUM, PLASMA, PLEURAL FLUID AND CEREBROSPINAL FLUID, CLINICAL BIOCHEMISTRY,APO B 5+1(DIALAB)-USED FOR QUANTITATIVE IN VITRO DETERMINATION OF APO B (APOLIPOPROTEIN B) IN HUMAN SERUM BY TURBIDIMETRIC ASSAY., APOLIPOPROTEIN A1 (5+1)(DIALAB)-IMMUNO-TURBIDIMETRY, COPPER, 3,5-DIBROMO-PAESA(DIALAB)-USED FOR ESTIMATION OF COPPER IN HUMAN SERUM OR PLASMA.,PROTEIN CALIBRATOR HIGH (DIALAB)-AQUEOUS CALIBRATOR FOR QUANTITATIVE IN VITRO DETERMINATION OF IMMUNOTURBIDIMETRIC ASSAYS.,LIPASE, ENZYMATIC, COLORIMETRIC(DIALAB)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF LIPASE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS, CHOLESTEROL STANDARD(DIALAB)-USED AS A STANDARD FOR ASSAYS OF CHOLESTEROL, CLINICAL BIOCHEMISTRY,UIBC, FERENE(DIALAB)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF UIBC IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,DIACAL CK-MB(DIALAB)-LYOPHILIZED CALIBRATION SERUM FOR CALIBRATION OF THE TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATINE KINASE MB IN HUMAN SERUM OR PLASMA.,COPPER STANDARD(DIALAB)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF COPPER IN SERUM OR PLASMA.,LDL CHOLESTEROL CALIBRATOR(DIALAB)-LYOPHILIZED CALIBRATION SERUM FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN HUMAN SERUM OR PLASMA ,ALPHA-AMYLASE, CNP-G3(DIALAB)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF -AMYLASE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,LPA CALIBRATOR HIGH(DIALAB)-AQUEOUS

	CALIBRATOR USED FOR CALIBRATION OF TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPOPROTEIN A IN HUMAN SERUM , ZINC, 5-BR-PAPS(DIALAB)-USED FOR ESTIMATION OF ZINC IN HUMAN SERUM, PLASMA OR URINE.,HDL CHOLESTEROL CALIBRATOR (DIALAB)-LYOPHILIZED CALIBRATION SERUM FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) IN HUMAN SERUM OR PLASMA ,PHOSPHORUS INORGANIC, MOLYBDATE(DIALAB)-USED REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF PHOSPHORUS IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS.,ALKALINE PHOSPHATASE, MOD. IFCC (DIALAB)-USED FOR QUANTITATIVE ESTIMATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR PLASMA,ZINC STANDARD (DIALAB)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ZINC IN SERUM, PLASMA OR URINE, COMPLEMENT C4 (5+1)(DIALAB)-USED FOR QUANTITATIVE ESTIMATION OF COMPLEMENT C4 IN HUMAN SERUM.,GLUCOSE HEXOKINASE(DIALAB)-USED FOR ESTIMATION OF GLUCOSE IN HUMAN SERUM OR PLASMA OR URINE,MAGNESIUM XYLIDYL BLUE (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF MAGNESIUM IN HUMAN SERUM, PLASMA, CEREBROSPINAL FLUID OR URINE ON PHOTOMETRIC SYSTEMS, GLUCOSE GOD-POD(DIALAB)-USED FOR ESTIMATION OF GLUCOSE IN HUMAN SERUM OR PLASMA,IRON FERENE(DIALAB)-DIAGNOSTIC REAGENT FOR THE QUANTITATIVE IN VITRO DETERMINATION OF IRON IN HUMAN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS, CRP CALLIBRATORS(DIALAB)-USED FOR ESTIMATION OF CRP IN HUMAN SERUM ,CALCIUM STANDARD(DIALAB)-USED FOR QUANTITATIVE ESTIMATION OF CALCIUM IN HUMAN SERUM, PLASMA OR URINE.,CRP(DIALAB)-USED FOR ESTIMATION OF CRP IN HUMAN SERUM ,CHOLESTEROL HDL DIRECT(DIALAB)-USED FOR QUANTITATIVE ESTIMATION OF CHOLESTEROL HDL IN HUMAN SERUM OR PLASMA.,MICROALBUMIN CALLIBRATOR(DIALAB)-CALIBRATION USED FOR QUANTITIATIVE DETERMIANTION OF MICROALBUMIN, ADA CALIBRATOR(DIALAB)-LYOPHILIZED CALIBRATION SERUM USED AS A CALIBRATOR IN ASSAYS FOR ADA, CLINICAL BIOCHEMISTRY,MICROALBUMIN(DIALAB)-USED FOR ESTIMATION OF MICROALBUMIN IN HUMAN URINE, HOMOCYSTEINE ENZYMATIC CYCLING(DIALAB)-USED FOR QUANTITATIVE ESTIMATION OF HOMOCYSTEINE IN HUMAN SERUM OR PLASMA, CLINICAL BIOCHEMISTRY,HBA1C CONTROL(DIALAB)-CONTROL LYSATE USED FOR QUANTITIATIVE DETERMIANTION OF HBA1C, AMMONIA ENZYMATIC, UV (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF AMMONIA IN HUMAN

	PLASMA ON PHOTOMETRIC SYSTEMS.,HBA1C CALLIBRATOR(DIALAB) -CALIBRATION LYSATE USED FOR QUANTITIATIVE DETERMIANTION OF HBA1C,AMMONIA STANDARD (DIALAB)-FOR THE USE IN TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF AMMONIA IN HUMAN PLASMA ON PHOTOMETRIC SYSTEMS,H BA1C(DIALAB)-USED FOR ESTIMATION OF HBA1C IN HUMAN BLOOD,AMMONIA CONTROL SET 2 LEVELS (DIALAB)-FOR THE USE IN TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF AMMONIA IN HUMAN PLASMA ON PHOTOMETRIC SYSTEMS,DIACAL AUTO(DIALAB)-CALIBRATION SERUM USED FOR QUANTITIATIVE DETERMIANTION OF VARIOUS ANALYTES,CERULOPLASMIN 5+1(DIALAB)-USED FOR QUANTITATIVE ESTIMATION OF CERULOPLASMIN IN HUMAN SERUM, BILLIRUBIN AUTO TOTAL(DIALAB)-USED FOR ESTIMATION OF TOTAL BILIRUBIN IN HUMAN SERUM OR PLASMA,CREATINE KINASE-MB (CK-MB)(DIALAB)-USED FOR QUANTITATIVE ESTIMATION OF CREATININE KINASE (CK-MB) IN HUMAN SERUM OR PLASMA,GAMMA -GT(DIALAB)-USED FOR ESTIMATION OF GGT IN HUMAN SERUM OR PLASMA, COMPLEMENT C3 (5+1)(DIALAB)-USED FOR QUANTITATIVE ESTIMATION OF COMPLEMENT C3 IN HUMAN SERUM.,CREATININE (DIALAB)-USED FOR ESTIMATION OF CREATININE IN HUMAN SERUM OR PLASMA OR URINE,CALCIUM, ARSENAZO(DIALAB)-USED FOR QUANTITATIVE ESTIMATION OF CALCIUM IN HUMAN SERUM, PLASMA OR URINE.,PROTEIN TOTAL(DIALAB)-USED FOR ESTIMATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA,CHOLESTEROL LDL DIRECT(DIALAB)-USED FOR QUANTITATIVE ESTIMATION OF CHOLESTEROL LDL IN HUMAN SERUM OR PLASMA.,GPT / ALT (DIALAB)-USED FOR ESTIMATION OF GPT/ALT IN HUMAN SERUM OR PLASMA,LIPOPROTEIN A(DIALAB)-USED FOR QUANTITATIVE ESTIMATION OF LIPOPROTEIN A IN HUMAN SERUM,GOT-AST(DIALAB) -USED FOR ESTIMATION OF GOT/AST IN HUMAN SERUM OR PLASMA, CREATININE STANDARD(DIALAB)-AQUEOUS STANDARD USED FOR CALIBRATION OF CREATININE, CLINICAL BIOCHEMISTRY,UREA UV-AUTO(DIALAB)-USED FOR ESTIMATION OF UREA IN HUMAN SERUM OR PLASMA OR URINE,HOMOCYSTEINE.CONTROLS SET, 4 LEVELS (DIALAB)-CONTROLS USED FOR QUANTITATIVE DETERMINATION OF HOMOCYSTEINE,URIC ACID TBHBA(DIALAB)-USED FOR ESTIMATION OF URIC ACID IN HUMAN SERUM OR PLASMA OR URINE,HEMOLYSIS REAGENT(DIALAB)-USED FOR PREPARATION OF HUMAN BLOOD SAMPLES USED IN HBA1C DIRECT ASSAY,TRIGLYCERIDES(DIALAB)-USED FOR ESTIMATION OF TRIGLYCERIDE IN HUMAN SERUM OR PLASMA,GLUCOSE STANDARD(DIALAB)-AQUEOUS STANDARD USED FOR CALIBRATION OF GLUCOSE, CLINICAL BIOCHEMISTRY, CHOLESTEROL(DIALAB)-USED FOR ESTIMATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA,TRIPLE CONTROL (ASO, CRP, RF)

	(DIALAB)-CONTROLS USED FOR QUANTITATIVE DETERMINATION OF ASO, CRP & RF,ALBUMIN DETECTION KIT(DIALAB)-USED FOR ESTIMATION OF ALBUMIN IN HUMAN SERUM OR PLASMA,DIACON-P (DIALAB)-LIQUID CONTROL FOR ANALYSIS IN CLINICAL BIOCHEMISTRY,MICROALBUMIN CONTROL(DIALAB)-CONTROLS USED FOR QUANTITIATIVE DETERMIANTION OF MICROALBUMIN, ASO CALIBRATOR HIGH(DIALAB)-USED AS STANDARD CALLIBRATOR IN IMMUNOTURBIDIMETRIC ASSAYS FOR ANTI-STREPTOLYSIN O (ASO), PROTEIN CONTROL(DIALAB)-CONTROLS USED FOR QUANTITIATIVE DETERMIANTION OF CRP,ASO 5+1(DIALAB)-USED FOR QUANTITATIVE ESTIMATION OF ASO (ANTI-STREPTOLYSIN O) IN HUMAN SERUM, LATEX IMMUNO-TURBIDIMETRY,RF 5+1(DIALAB)-USED FOR QUANTITATIVE ESTIMATION OF RF(RHEUMATOID FACTOR) IN HUMAN SERUM BY IMMUNOTURBIDIMETRY, CARBON DIOXIDE (CO2, BICARBONATE) PEP-C (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE (CO2) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,RF CALIBRATOR HIGH (DIALAB)-FOR USE AS A CALIBRATOR IN IMMUNOTURBIDIMETRIC ASSAYS FOR RF,BILIRUBIN AUTO DIRECT DCA(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,CO2 STANDARD(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE (CO2) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,CO2 CONTROL(DIALAB)-FOR QUALITY CONTROL OF THE QUANTITATIVE IN VITRO DETERMINATION OF CARBON DIOXIDE (CO2, BICARBONATE) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS., PROTEIN TOTAL STANDARD (DIALAB)-AQUEOUS STANDARD USED FOR CALIBRATION OF PROTEIN TOTAL, ADA CONTROL SET, 2 LEVELS(DIALAB)-LYOPHILIZED CONTROL SERUM USED AS A CONTROL IN ASSAYS FOR ADA,UREA STANDARD (DIALAB)-AQUEOUS STANDARD USED FOR CALIBRATION OF UREA, ALBUMIN STANDARD(DIALAB)-AQUEOUS STANDARD USED FOR CALIBRATION OF ALBUMIN

98	IMP/IVD/2019/000002	1.License Holder Name: NANZ MED SCIENCE PHARMA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HCG ONE STEP PREGNANCY STRIP TEST (COLLOIDAL GOLD)-THE HCG ONE STEP PREGNANCY TEST STRIP, DEVICE AND MID STREAM (URINE) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HUMAN CHORIONIC GONADOTROPIN IN URINE TO AID IN THE EARLY DETECTION OF PREGNANCY.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

99	IMP/IVD/2019/000003	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DXFLEX DAILY QC FLUOROSPHERES(DXFLEX DAILY QC FLUOROSPHERES)-DXFLEX DAILY QC FLUOROSPHERES IS A SUSPENSION OF FLUORESCENT MICROSPHERES, INTENDED FOR DAILY VERIFICATION OF THE DXFLEX FLOW CYTOMETER'S OPTICAL ALIGNMENT AND FLUIDICS SYSTEM., INFINITY AMMONIA REAGENT(INFINITY AMMONIA REAGENT)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF AMMONIA (NH3) CONCENTRATIONS IN HUMAN PLASMA FOR USE ON THE BECKMAN COULTER A CHEMISTRY ANALYZERS.,FLOW-COUNT FLUOROSPHERES(FLOW-COUNT FLUOROSPHERES)-- FLOW-COUNT FLUOROSPHERES IS A FLUORESCENT MICROSPHERE REAGENT FOR DIRECT DETERMINATION OF LYMPHOCYTES, AND LYMPHOCYTE SUBSET CELL POPULATION PERCENTAGES AND ABSOLUTE COUNTS IN BIOLOGICAL SPECIMENS USING CYTOMICS FC 500, NAVIOS AND NAVIOS EX FLOW CYTOMETRY SYSTEMS AS WELL AS CD34+ CELL POPULATION PERCENTAGES AND ABSOLUTE COUNTS IN BIOLOGICAL SPECIMENS USING CYTOMICS FC 500 FLOW CYTOMETRY SYSTEMS.,COULTER 5C CELL CONTROL-5C CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUALS OR ONLINE HELP SYSTEM. THE ASSIGNED VALUES AND EXPECTED RANGES ON THE TABLE OF EXPECTED RESULTS CAN BE USED TO MONITOR INSTRUMENT PERFORMANCE. THIS PRODUCT CAN ALSO BE USED TO ESTABLISH YOUR OWN LABORATORY MEAN.,CYTO-STAT/COULTER CLONE MY4-FITC-CYTO-STAT/COULTER CLONE MY4-FITC IS A FLUORESCENT MURINE MONOCLONAL ANTIBODY REAGENT USED TO IDENTIFY AND ENUMERATE THE PERCENTAGE OF MY4+ MONOCYTES IN WHOLE BLOOD BY FLOW CYTOMETRY., COULTER LIN-C LINEARITY CONTROL-COULTER LIN-C LINEARITY CONTROLS ARE INTENDED TO VERIFY THE REPORTABLE RANGE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUAL OR ONLINE HELP SYSTEM.,FLOW-CHECK FLUOROSPHERES(FLOW-CHECK FLUOROSPHERES)-FLOW-CHECK FLUOROSPHERES ARE AN ASSAYED SUSPENSION OF FLUOROSPHERES (FLUORESCENT MICROSPHERES) USED FOR DAILY VERIFICATION OF A FLOW CYTOMETER'S OPTICAL ALIGNMENT AND FLUIDICS SYSTEM.,COULTER 4C-ES CELL CONTROL-4C-ES CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL

	MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS AND WITH THE SPECIFIC COULTER REAGENTS.,FLOW-SET FLUOROSPHERES(FLOW-SET FLUOROSPHERES)-- FLOW-SET FLUOROSPHERES ARE A SUSPENSION OF FLUOROSPHERES (FLUORESCENT MICROSPHERES) USED AS AN AID IN OPTIMIZING A FLOW CYTOMETER FOR QUANTITATIVE ANALYSIS OF HUMAN LEUKOCYTES,COULTER 5C CELL CONTROL-5C CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUALS OR ONLINE HELP SYSTEM. THE ASSIGNED VALUES AND EXPECTED RANGES ON THE TABLE OF EXPECTED RESULTS CAN BE USED TO MONITOR INSTRUMENT PERFORMANCE. THIS PRODUCT CAN ALSO BE USED TO ESTABLISH YOUR OWN LABORATORY MEAN.,QUICKCOMP 4 KIT(QUICKCOMP 4 KIT)-THE QUICKCOMP 4 KIT CONSISTS OF FOUR SINGLE-COLOR FLUORESCENT REAGENTS COMPRISED OF ONE MONOCLONAL ANTIBODY EACH. EACH ANTIBODY IS LABELED WITH ONE OF FOUR FLUOROCHROMES: FITC, PE, ECD OR PC5. THE QUICKCOMP 4 KIT AND THE QUICKCOMP 2 KIT MAY BE USED WITH THE CYTO-COMP CELL KIT TO ADJUST COLOR COMPENSATION SETTINGS ON A FLOW CYTOMETER EQUIPPED WITH AUTOSETUP SOFTWARE, PRIOR TO MULTI-COLOR ANALYSIS WITH FITC, PE, ECD AND/OR PC5 CONJUGATED MONOCLONAL ANTIBODY REAGENTS.,IO TEST CD3-PC7(IO TEST CD3-PC7)-IOTEST CD3-PC7 IS A FLUORESCENT MURINE MONOCLONAL ANTIBODY REAGENT USED TO IDENTIFY AND ENUMERATE THE PERCENTAGE OF CD3+ T LYMPHOCYTES IN HUMAN WHOLE BLOOD BY FLOW CYTOMETRY., QUICKCOMP2 KIT(QUICKCOMP2 KIT)-THE QUICKCOMP 2 KIT CONSISTS OF TWO SINGLE-COLOR FLUORESCENT REAGENTS COMPRISED OF ONE MONOCLONAL ANTIBODY EACH. EACH ANTIBODY IS LABELED WITH EITHER FITC OR PE. THE QUICKCOMP 4 KIT AND THE QUICKCOMP 2 KIT MAY BE USED WITH THE CYTO-COMP CELL KIT TO ADJUST COLOR COMPENSATION SETTINGS ON A FLOW CYTOMETER EQUIPPED WITH AUTOSETUP SOFTWARE, PRIOR TO MULTI-COLOR ANALYSIS WITH FITC, PE, ECD AND/OR PC5 CONJUGATED MONOCLONAL ANTIBODY REAGENTS.,COULTER 4C-ES CELL CONTROL-4C-ES CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS AND WITH THE SPECIFIC COULTER REAGENTS., CYTO-COMP CELL KIT(CYTO-COMP CELL KIT)-THE CYTO-COMP CELL KIT CONSISTS OF A LYOPHILIZED PREPARATION OF HUMAN

	LYMPHOCYTES AND A BUFFER TO RECONSTITUTE THE CELLS. THE CYTO-COMP CELL KIT IS USED WITH THE CYTO-COMP REAGENT KIT TO ADJUST COLOR COMPENSATION SETTINGS ON A FLOW CYTOMETER PRIOR TO MULTICOLOR ANALYSIS WITH FITC, RD1, ECD, AND/OR PC5 CONJUGATED MONOCLONAL ANTIBODY REAGENTS, COULTER 5C CELL CONTROL-5C CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUALS OR ONLINE HELP SYSTEM. THE ASSIGNED VALUES AND EXPECTED RANGES ON THE TABLE OF EXPECTED RESULTS CAN BE USED TO MONITOR INSTRUMENT PERFORMANCE. THIS PRODUCT CAN ALSO BE USED TO ESTABLISH YOUR OWN LABORATORY MEAN.,IMMUNOPREP REAGENT SYSTEM WHOLE BLOOD LYSING REAGENTS(IMMUNOPREP REAGENT SYSTEM WHOLE BLOOD LYSING REAGENTS)-THE IMMUNOPREP REAGENT SYSTEM IS COMPRISED OF GENERAL PURPOSE LABORATORY REAGENTS USED TO PREPARE LEUKOCYTES FROM WHOLE BLOOD FOR IMMUNOFLUORESCENCE MEASUREMENTS ON OPTICAL FLOW CYTOMETERS. THE IMMUNOPREP REAGENT SYSTEM (PN 7546946) IS INTENDED FOR USE ON THE COULTER Q-PREP WORKSTATION; THE IMMUNOPREP REAGENT SYSTEM (PN 7546999) IS INTENDED FOR USE ON THE COULTER MULTI-Q-PREP WORKSTATION, THE COULTER TQ-PREP WORKSTATION, AND THE FP 1000,COULTER BODY FLUID CONTROL(COULTER BODY FLUID CONTROL)-BODY FLUID CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE AND VERIFY THE MEASURING RANGE OF THE BODY FLUID CYCLE OF UNICEL DXH COULTER CELLULAR ANALYSIS SYSTEMS LISTED IN THE TABLE OF EXPECTED RESULTS, IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO THE SYSTEM HELP OR INSTRUCTIONS FOR USE.,IMMUNO-TROL LOW CELLS(IMMUNO-TROL LOW CELLS)-IMMUNO-TROL LOW CELLS IS AN ASSAYED, LYSABLE WHOLE BLOOD QUALITY CONTROL PRODUCT FOR IMMUNOPHENOTYPING ANALYSIS USING MONOCLONAL ANTIBODY REAGENTS AND FLOW CYTOMETRY. IT PROVIDES A POSITIVE CELL CONTROL THAT IS PROCESSED IN THE SAME MANNER AS A WHOLE BLOOD SAMPLE. THIS ALLOWS VERIFICATION OF REAGENT PERFORMANCE AND THE METHODS USED FOR STAINING TARGETED CELLS, LYSING ERYTHROCYTES, AND ANALYZING SAMPLES WITH FLOW CYTOMETRY.,COULTER 6C CELL CONTROL(COULTER 6C CELL CONTROL)-6C CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF UNICEL DXH COULTER CELLULAR ANALYSIS SYSTEMS LISTED IN THE TABLE OF

	EXPECTED RESULTS, IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. THE ASSIGNED VALUES AND EXPECTED RANGES ON THE TABLE OF EXPECTED RESULTS CAN BE USED TO MONITOR INSTRUMENT PERFORMANCE. THIS PRODUCT CAN ALSO BE USED TO ESTABLISH YOUR OWN LABORATORY MEAN.,IMMUNO-TROL CELLS (IMMUNO-TROL CELLS)-IMMUNO-TROL CELLS IS AN ASSAYED, LYSABLE WHOLE BLOOD QUALITY CONTROL PRODUCT FOR IMMUNOPHENOTYPING ANALYSIS USING MONOCLONAL ANTIBODY REAGENTS AND FLOW CYTOMETRY. IT PROVIDES A POSITIVE CELL CONTROL THAT IS PROCESSED IN THE SAME MANNER AS A WHOLE BLOOD SAMPLE. THIS ALLOWS VERIFICATION OF REAGENT PERFORMANCE AND THE METHODS USED FOR STAINING TARGETED CELLS, LYSING ERYTHROCYTES, AND ANALYZING SAMPLES WITH FLOW CYTOMETRY.,COULTER LIN-X LINEARITY CONTROL(COULTER LIN-X LINEARITY CONTROL)-COULTER LIN-X LINEARITY CONTROLS ARE INTENDED TO ASSESS CALIBRATION AND VERIFY THE REPORTABLE RANGE OF UNICEL DXH COULTER CELLULAR ANALYSIS SYSTEMS LISTED IN THE TABLE OF EXPECTED RESULTS, IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO THE INSTRUCTIONS FOR USE OR SYSTEM HELP,IOTEST MSIGG1-PC7 (IOTEST MSIGG1-PC7)-IOTEST MSIGG1 ISOTYPIC CONTROL REAGENT IS LABELED WITH A SINGLE FLUOROCHROME, PC7. THIS PRODUCT IS INTENDED TO BE USED AS A QUALITY CONTROL REAGENT TO MONITOR THE LEVELS OF NONSPECIFIC ANTIBODY BINDING IN CELL SURFACE STAINING PROCEDURES WHICH USE IOTEST MONOCLONAL ANTIBODY REAGENTS OF THE MOUSE IGG1 SUBCLASS, CONJUGATED TO PC7. IOTEST MSIGG1-PC7 IS INTENDED "FOR IN VITRO DIAGNOSTIC USE" WHEN USED WITH IOTEST MONOCLONAL ANTIBODY REAGENTS LABELED "FOR IN VITRO DIAGNOSTIC USE." ,COULTER RETIC-X CELL CONTROL(COULTER RETIC-X CELL CONTROL)-RETIC-X CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF UNICEL DXH COULTER CELLULAR ANALYSIS SYSTEMS LISTED IN THE TABLE OF EXPECTED RESULTS, IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. THE ASSIGNED VALUES AND EXPECTED RANGES ON THE TABLE OF EXPECTED RESULTS CAN BE USED TO MONITOR INSTRUMENT PERFORMANCE. THIS PRODUCT CAN ALSO BE USED TO ESTABLISH YOUR OWN LABORATORY MEAN,CYTO-STAT TRICHROME CD45-FITC/CD19-RD1/ CD3-PC5(CYTO-STAT TRICHROME CD45-FITC/CD19-RD1/ CD3-PC5)-CYTO-STAT TRICHROME CD45-FITC/CD19-RD1/ CD3-PC5 MONOCLONAL ANTIBODY REAGENT IS A THREE-COLOR FLUORESCENT REAGENT COMPRISED OF THREE MURINE MONOCLONAL ANTIBODIES. EACH ANTIBODY IS LABELED WITH A DIFFERENT COLOR FLUOROCHROME. THE REAGENT ALLOWS

	SIMULTANEOUS IDENTIFICATION AND ENUMERATION OF TOTAL CD3+ (T), AND CD19+ (B) LYMPHOCYTES IN WHOLE BLOOD BY FLOW CYTOMETRY.1-3 AN ISOTYPIC CONTROL, CYTO-STAT TRICHROME CD45-FITC/MSIGG1-RD1/MSIGG1-PC5, IS USED TO MONITOR NONSPECIFIC STAINING.,COULTER RETIC PREP REAGENT KIT-FOR USE IN THE PREPARATION OF WHOLE-BLOOD SAMPLES FOR RETICULOCYTE ENUMERATION ON COULTER HMX AND LH 500 HEMATOLOGY ANALYZERS. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE.,IOTEST CD4-PC7 (IOTEST CD4-PC7)-IOTEST CD4 IS A FLUORESCENT MURINE MONOCLONAL ANTIBODY REAGENT USED TO IDENTIFY AND ENUMERATE THE PERCENTAGE OF CD4+ (INDUCER) LYMPHOCYTES IN WHOLE BLOOD BY FLOW CYTOMETRY.,COULTER 5C CELL CONTROL-5C CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUALS OR ONLINE HELP SYSTEM. THE ASSIGNED VALUES AND EXPECTED RANGES ON THE TABLE OF EXPECTED RESULTS CAN BE USED TO MONITOR INSTRUMENT PERFORMANCE. THIS PRODUCT CAN ALSO BE USED TO ESTABLISH YOUR OWN LABORATORY MEAN.,IMMUNO-BRITE STANDARDS KIT (IMMUNO-BRITE STANDARDS KIT)-INTENDED FOR USE AS A FLOW CYTOMETRY QUALITY CONTROL REAGENT FOR DETERMINING INSTRUMENT LINEARITY AND FOR STANDARDIZATION OF FLUORESCENCE INTENSITY.,COULTER RETIC-C CELL CONTROL-RETIC-C CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUALS OR ONLINE HELP SYSTEM., CYTO-STAT/ COULTER CLONE MSIGG1-RD1/ MSIGG2A-FITC(CYTO-STAT/ COULTER CLONE MSIGG1-RD1/ MSIGG2A-FITC)-CYTO-STAT/COULTER CLONE MSIGG1-RD1/ MSIGG2A-FITC ISOTYPIC CONTROL REAGENT IS COMPRISED OF TWO MURINE MONOCLONAL ANTIBODIES, EACH LABELED WITH A DIFFERENT FLUOROCHROME. THIS PRODUCT IS INTENDED FOR USE AS A QUALITY CONTROL REAGENT TO MONITOR THE LEVELS OF NONSPECIFIC ANTIBODY BINDING IN CELL SURFACE STAINING PROCEDURES WHICH USE CYTO-STAT/COULTER CLONE MONOCLONAL ANTIBODY REAGENTS COMPRISED OF THE MOUSE IGG2A AND IGG1 SUBCLASSES CONJUGATED TO FITC OR RD1, RESPECTIVELY. CYTO-STAT/COULTER CLONE MSIGG1-RD1/ MSIGG2A-FITC IS INTENDED "FOR IN VITRO DIAGNOSTIC USE" WHEN USED WITH CYTO-STAT/COULTER CLONE

	MONOCLONAL ANTIBODY REAGENTS LABELED "FOR IN VITRO DIAGNOSTIC USE,COULTER 5C CELL CONTROL-5C CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUALS OR ONLINE HELP SYSTEM. THE ASSIGNED VALUES AND EXPECTED RANGES ON THE TABLE OF EXPECTED RESULTS CAN BE USED TO MONITOR INSTRUMENT PERFORMANCE. THIS PRODUCT CAN ALSO BE USED TO ESTABLISH YOUR OWN LABORATORY MEAN,COULTER CYTO-TROL CONTROL CELLS KIT(COULTER CYTO-TROL CONTROL CELLS KIT)-THE COULTER CYTO-TROL CONTROL CELLS KIT IS USED TO ASSESS THE ACTIVITY OF MONOCLONAL ANTIBODIES BY FLOW CYTOMETRY.,COULTER S-CAL CALIBRATOR-S-CAL CALIBRATOR IS INTENDED FOR THE DETERMINATION OF CALIBRATION FACTORS FOR COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUAL OR ONLINE HELP SYSTEM.,CLENZ SOLUTION(CLENZ SOLUTION)-CLENZ SOLUTION IS A CLEANING AGENT INTENDED FOR USE ON SYNCHRON SYSTEMS, COULTER S-CAL CALIBRATOR-S-CAL CALIBRATOR IS INTENDED FOR THE DETERMINATION OF CALIBRATION FACTORS FOR COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUAL OR ONLINE HELP SYSTEM.,CYTO-STAT TETRACHROME CD45-FITC/CD56-RD1/ CD19-ECD/CD3-PC5 (CYTO-STAT TETRACHROME CD45-FITC/CD56-RD1/ CD19-ECD/CD3-PC5)-CYTO-STAT TETRACHROME CD45-FITC/CD4-RD1/ CD8-ECD/CD3-PC5 AND CYTO-STAT TETRACHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 MONOCLONAL ANTIBODY REAGENTS ARE FOR USE ON THE CYTOMICS FC 500, NAVIOS, AND NAVIOS EX FLOW CYTOMETERS. THE REAGENTS ARE ALSO USED WITH THE TETRACXP SYSTEM FOR FC 500 FLOW CYTOMETRY SYSTEM, NAVIOS TETRA SOFTWARE FOR THE NAVIOS SYSTEM, AND NAVIOS EX TETRA SOFTWARE FOR THE NAVIOS EX SYSTEM. USED ALONE OR IN COMBINATION WITH THE AUTOMATED SYSTEMS, THE REAGENTS ARE INTENDED "FOR IN VITRO DIAGNOSTIC USE" AND ALLOW SIMULTANEOUS IDENTIFICATION AND ENUMERATION OF TOTAL CD3+, TOTAL CD4+, TOTAL CD8+, DUAL CD3+CD4+, DUAL CD3+CD8+ AND/OR TOTAL CD3+, CD19+ AND CD3-CD56+ LYMPHOCYTE PERCENTAGES AND ABSOLUTE COUNTS IN WHOLE BLOOD BY FLOW CYTOMETRY. THE SYSTEMS ALSO PROVIDE THE CD4/CD8 RATIO WHEN USING CD45-FITC/CD4-RD1/ CD8-ECD/CD3-PC5. THESE REAGENTS ARE INDICATED FOR USE IN THE IMMUNOLOGIC

	ASSESSMENT OF PATIENTS HAVING OR SUSPECTED OF HAVING IMMUNE DEFICIENCY.,COULTER RETIC-C CELL CONTROL-RETIC-C CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUALS OR ONLINE HELP SYSTEM.,CYTO-STAT TETRACHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5(CYTO-STAT TETRACHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5)-CYTO-STAT TETRACHROME CD45-FITC/CD4-RD1/ CD8-ECD/CD3-PC5 AND CYTO-STAT TETRACHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 MONOCLONAL ANTIBODY REAGENTS ARE FOR USE ON THE CYTOMICS FC 500, NAVIOS, AND NAVIOS EX FLOW CYTOMETERS. THE REAGENTS ARE ALSO USED WITH THE TETRACXP SYSTEM FOR FC 500 FLOW CYTOMETRY SYSTEM, NAVIOS TETRA SOFTWARE FOR THE NAVIOS SYSTEM, AND NAVIOS EX TETRA SOFTWARE FOR THE NAVIOS EX SYSTEM. USED ALONE OR IN COMBINATION WITH THE AUTOMATED SYSTEMS, THE REAGENTS ARE INTENDED "FOR IN VITRO DIAGNOSTIC USE" AND ALLOW SIMULTANEOUS IDENTIFICATION AND ENUMERATION OF TOTAL CD3+, TOTAL CD4+, TOTAL CD8+, DUAL CD3+CD4+, DUAL CD3+CD8+ AND/OR TOTAL CD3+, CD19+ AND CD3-CD56+ LYMPHOCYTE PERCENTAGES AND ABSOLUTE COUNTS IN WHOLE BLOOD BY FLOW CYTOMETRY. THE SYSTEMS ALSO PROVIDE THE CD4/CD8 RATIO WHEN USING CD45-FITC/CD4-RD1/ CD8-ECD/CD3-PC5. THESE REAGENTS ARE INDICATED FOR USE IN THE IMMUNOLOGIC ASSESSMENT OF PATIENTS HAVING OR SUSPECTED OF HAVING IMMUNE DEFICIENCY., COULTER LIN-C LINEARITY CONTROL-COULTER LIN-C LINEARITY CONTROLS ARE INTENDED TO VERIFY THE REPORTABLE RANGE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUAL OR ONLINE HELP SYSTEM,CYTO-STAT TRICHROME CD8-FITC/CD4-RD1/ CD3-PC5 (CYTO-STAT TRICHROME CD8-FITC/CD4-RD1/ CD3-PC5)-CYTO-STAT TRICHROME CD8-FITC/CD4-RD1/CD3-PC5 MONOCLONAL ANTIBODY REAGENT IS A THREE-COLOR FLUORESCENT REAGENT COMPRISED OF THREE MURINE MONOCLONAL ANTIBODIES. EACH ANTIBODY IS LABELED WITH A DIFFERENT COLOR FLUOROCHROME. THE REAGENT ALLOWS SIMULTANEOUS IDENTIFICATION AND ENUMERATION OF TOTAL CD3+, TOTAL CD4+, TOTAL CD8+, DUAL CD3+/CD4+ AND DUAL CD3+/CD8+ LYMPHOCYTES IN WHOLE BLOOD BY FLOW CYTOMETRY.1-3 CYTO-STAT/COULTER CLONE MO2-RD1/KC56-FITC IS USED TO IDENTIFY THE LOCATION OF A LYMPHOCYTE GATE AND TO PROVIDE A MEASUREMENT OF NONLYMPHOCYTE

	CONTAMINATION WITHIN THE GATE. AN ISOTYPIC CONTROL, CYTO-STAT TRICHROME MSIGG1-FITC/MSIGG1-RD1/MSIGG1-PC5, IS USED TO MONITOR NONSPECIFIC STAINING.,COULTER S-CAL CALIBRATOR-S-CAL CALIBRATOR IS INTENDED FOR THE DETERMINATION OF CALIBRATION FACTORS FOR UNICEL DXH COULTER CELLULAR ANALYSIS SYSTEMS LISTED IN THE TABLE OF EXPECTED RESULTS, IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO THE INSTRUCTIONS FOR USE OR SYSTEM HELP.,IO TEST CD8-ECD(CYTO-STAT/COULTER CLONE CD8-ECD)-CYTO-STAT/COULTER CLONE CD8-ECD (CD8) IS A FLUORESCENT MURINE MONOCLONAL ANTIBODY REAGENT USED TO IDENTIFY AND ENUMERATE THE PERCENTAGE OF CD8+ (SUPPRESSOR/CYTOTOXIC) LYMPHOCYTES IN WHOLE BLOOD BY FLOW CYTOMETRY.,COULTER 5C CELL CONTROL-5C CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUALS OR ONLINE HELP SYSTEM. THE ASSIGNED VALUES AND EXPECTED RANGES ON THE TABLE OF EXPECTED RESULTS CAN BE USED TO MONITOR INSTRUMENT PERFORMANCE. THIS PRODUCT CAN ALSO BE USED TO ESTABLISH YOUR OWN LABORATORY MEAN.,WHOLE BLOOD LYSING REAGENTS-WHOLE BLOOD LYSING REAGENTS ARE USED TO PREPARE LEUKOCYTES FROM WHOLE BLOOD FOR IMMUNOFLUORESCENCE MEASUREMENTS ON OPTICAL FLOW CYTOMETERS OR FLUORESCENCE MICROSCOPES. THE WHOLE BLOOD LYSING REAGENTS ARE REAGENTS USED TO PREPARE LEUKOCYTES FROM WHOLE BLOOD FOR DIRECT AND/OR INDIRECT IMMUNOFLUORESCENCE CELL SURFACE STAINING WITH COULTER CLONE AND CYTO-STAT/ COULTER CLONE MONOCLONAL ANTIBODIES.,COULTER 5C CELL CONTROL-5C CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUALS OR ONLINE HELP SYSTEM. THE ASSIGNED VALUES AND EXPECTED RANGES ON THE TABLE OF EXPECTED RESULTS CAN BE USED TO MONITOR INSTRUMENT PERFORMANCE. THIS PRODUCT CAN ALSO BE USED TO ESTABLISH YOUR OWN LABORATORY MEAN.,IO TEST CD8-PC7(CYTO-STAT/COULTER CLONE CD8-PC7)-IOTEST CD8-PC71 IS A FLUORESCENT MURINE MONOCLONAL ANTIBODY REAGENT USED TO IDENTIFY AND ENUMERATE THE PERCENTAGE OF CD8+ (SUPPRESSOR/CYTOTOXIC) LYMPHOCYTES IN WHOLE BLOOD BY FLOW CYTOMETRY.,COULTER RETIC C-CELL CONTROL-RETIC-C CELL

	CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUALS OR ONLINE HELP SYSTEM.,IOTEST CD3-PC7 (IOTEST CD3-PC7)-IOTEST CD3-PC7 IS A FLUORESCENT MURINE MONOCLONAL ANTIBODY REAGENT USED TO IDENTIFY AND ENUMERATE THE PERCENTAGE OF CD3+ T LYMPHOCYTES IN HUMAN WHOLE BLOOD BY FLOW CYTOMETRY.,COULTER LATRON CONTROL 2-COULTER LATRON CONTROL AND LATRON PRIMER ARE FOR USE ON THE COULTER HMX, LH 500, LH 750 AND LH 780 HEMATOLOGY ANALYZERS. COULTER LATRON CONTROL IS INTENDED FOR USE IN MONITORING THE VOLUME, CONDUCTIVITY AND LIGHT SCATTER PARAMETERS. IT SHOULD BE USED IMMEDIATELY FOLLOWING COULTER LATRON PRIMER, WHICH IS FOR USE IN PREPARING THE SAMPLE LINE.,CYTO-STAT/COULTER CLONE T11-FITC-CYTO-STAT/COULTER CLONE T11-RD1 OR T11-FITC IS A FLUORESCENT MURINE MONOCLONAL ANTIBODY REAGENT USED TO IDENTIFY AND ENUMERATE THE PERCENTAGE OF CD2+ (T11+) T LYMPHOCYTES IN WHOLE BLOOD BY FLOW CYTOMETRY,COULTER LATRON PRIMER 1-COULTER LATRON CONTROL AND LATRON PRIMER ARE FOR USE ON THE COULTER HMX, LH 500, LH 750 AND LH 780 HEMATOLOGY ANALYZERS. COULTER LATRON CONTROL IS INTENDED FOR USE IN MONITORING THE VOLUME, CONDUCTIVITY AND LIGHT SCATTER PARAMETERS. IT SHOULD BE USED IMMEDIATELY FOLLOWING COULTER LATRON PRIMER, WHICH IS FOR USE IN PREPARING THE SAMPLE LINE.,FLOWCARE PLG CD4 REAGENT-THE FLOWCARE PLG CD4 REAGENT IS FOR USE ON THE COULTER EPICS XL/XL-MCL OR EQUIVALENT FLOW CYTOMETER. THE REAGENT KIT COMBINES TWO FLUORESCENTLABELED MONOCLONAL ANTIBODIES IN A SINGLE REAGENT FORMULATION. IT IS INTENDED “FOR IN VITRO DIAGNOSTIC USE” FOR THE ENUMERATION OF CD4 ABSOLUTE CELL COUNT AND CD4 LYMPHOCYTE PERCENTAGE IN COMBINATION WITH A WHITE BLOOD CELL (WBC) COUNT FROM A HEMATOLOGY INSTRUMENT AS A DUAL PLATFORM MEASUREMENT, OR INDEPENDENTLY WHEN USED IN COMBINATION WITH FLOW-COUNT FLUOROSPHERES AS A SINGLE PLATFORM MEASUREMENT.,COULTER 4C-ES CELL CONTROL-4C-ES CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS AND WITH THE SPECIFIC COULTER REAGENTS,COULTER LATRON CP-X (COULTER LATRON CP-X)-COULTER LATRON CP-X CONTROL IS INTENDED FOR USE ON UNICEL DXH COULTER CELLULAR ANALYSIS SYSTEMS THAT USE VCSN TECHNOLOGY, IN CONJUNCTION WITH

	SPECIFIC COULTER REAGENTS. IT IS USED TO MONITOR THE VOLUME, CONDUCTIVITY AND LIGHT SCATTER PARAMETER MEASUREMENTS., COULTER 6C PLUS CELL CONTROL-6C PLUS CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF UNICEL DXH COULTER CELLULAR ANALYSIS SYSTEMS LISTED IN THE TABLE OF EXPECTED RESULTS, IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. THE ASSIGNED VALUES AND EXPECTED RANGES ON THE TABLE OF EXPECTED RESULTS CAN BE USED TO MONITOR INSTRUMENT PERFORMANCE. THIS PRODUCT CAN ALSO BE USED TO ESTABLISH YOUR OWN LABORATORY MEAN.,CYTO-STAT/COULTER CLONE B1-RD1-CYTO-STAT/COULTER CLONE B1-RD1 OR B1-FITC IS USED TO ENUMERATE THE PERCENT OF B1 LYMPHOCYTES IN WHOLE BLOOD BY FLOW CYTOMETRY.,COULTER 4C-ES CELL CONTROL-4C-ES CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS AND WITH THE SPECIFIC COULTER REAGENTS.,COULTER 4C-ES CELL CONTROL-4C-ES CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS AND WITH THE SPECIFIC COULTER REAGENTS.,COULTER 5C CELL CONTROL-5C CELL CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR THE PERFORMANCE OF COULTER HEMATOLOGY ANALYZERS LISTED IN THE TABLE OF EXPECTED RESULTS IN CONJUNCTION WITH SPECIFIC COULTER REAGENTS. REFER TO YOUR PRODUCT MANUALS OR ONLINE HELP SYSTEM. THE ASSIGNED VALUES AND EXPECTED RANGES ON THE TABLE OF EXPECTED RESULTS CAN BE USED TO MONITOR INSTRUMENT PERFORMANCE. THIS PRODUCT CAN ALSO BE USED TO ESTABLISH YOUR OWN LABORATORY MEAN.

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100	IMP/IVD/2019/000007	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIGH RANGE ACTIVATED CLOTTING TIME CARTRIDGE(MEDTRONIC HIGH RANGE ACTIVATED CLOTTING TIME CARTRIDGE)- THE HR-ACT IS INTENDED FOR USE IN DETERMINING THE ACTIVATED CLOTTING TIME OF WHOLE BLOOD. FOR IN VITRO DIAGNOSTIC USE. INTENDED TO MONITOR THE EFFECTS OF HEPARINIZATION IN CARDIOVASCULAR AND CATH LAB. (>=1.0 UNIT OF HEPARIN PER ML). MEDTRONIC ACTIVATED CLOTTING TIME CARTRIDGES ARE DESIGNED SPECIFICALLY FOR USE IN THE ACT PLUS INSTRUMENT. FOR OPERATING INSTRUCTIONS, CONSULT THE ACT PLUS INSTRUMENT OPERATOR'S MANUAL.

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101	IMP/IVD/2019/000012	1.License Holder Name: ASRITHA DIATECH INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IRON FERROZINE (BULK)(IRON FERROZINE (BULK))-REAGENTS FOR MEASUREMENT OF IRON, CREATININE (BULK)(CREATININE (BULK))-REAGENTS FOR MEASUREMENT OF CREATININE,FERRITIN – TURBIDIMETRIC (BULK)(FERRITIN – TURBIDIMETRIC (BULK))-REAGENTS FOR MEASUREMENT OF FERRITIN,CRP TURBIDIMETRIC (BULK)(CRP TURBIDIMETRIC (BULK))-REAGENTS FOR MEASUREMENT OF C-REACTIVE PROTEIN, ASLO TURBIDIMETRIC (BULK)(ASLO TURBIDIMETRIC (BULK))-REAGENTS FOR MEASUREMENT OF ANTI-STREPTOLYSINE O,URIC ACID (BULK)(URIC ACID (BULK))-REAGENTS FOR MEASUREMENT OF URIC ACID,UREA/BUN (BULK)(UREA/BUN (BULK))-REAGENTS FOR MEASUREMENT OF UREA,TRIGLYCERIDES (BULK)(TRIGLYCERIDES (BULK))-REAGENTS FOR MEASUREMENT OF TRIGLYCERIDES,TIBC (BULK)(TIBC (BULK))-REAGENTS FOR MEASUREMENT OF TOTAL IRON BILDING CAPACITY,MAGNESIUM (BULK)(MAGNESIUM (BULK))-REAGENTS FOR MEASUREMENT OF MAGNESIUM,LDH (BULK)(LDH (BULK))-REAGENTS FOR MEASUREMENT OF LDH,CHOLESTEROL MR (BULK)(CHOLESTEROL MR (BULK))-REAGENTS FOR MEASUREMENT OF CHOLESTEROL,ALKALINE PHOSPHATASE BR(BULK)(ALKALINE PHOSPHATASE BR(BULK))-REAGENTS FOR MEASUREMENT OF ALKALINE PHOSPHATASE,RF TURBIDIMETRIC (BULK)(RF TURBIDIMETRIC (BULK))-REAGENTS FOR MEASUREMENT OF RHEUMATOID FACTORS,BILLIRUBIN TOTAL AND DIRECT WITH CALIBRATOR (BULK)(BILLIRUBIN TOTAL AND DIRECT WITH CALIBRATOR (BULK))-REAGENTS FOR MEASUREMENT OF BILIRRUBIN TOTAL AND DIRECT,AST/GOT BR OPT. (BULK)(AST/GOT BR OPT. (BULK))-REAGENTS FOR MEASUREMENT OF AST/GOT, MICROALBUMIN TURBIDIMETRIC (BULK)(MICROALBUMIN TURBIDIMETRIC (BULK))-REAGENTS FOR MEASUREMENT OF MICROALBUMIN,CALCIUM ARSENAZO III COLOR (BULK)(CALCIUM ARSENAZO III COLOR (BULK))-REAGENTS FOR MEASUREMENT OF CALCIUM,GGT BR (BULK)(GGT BR (BULK))-REAGENTS FOR MEASUREMENT OF GGT,ALT/GPT BR OPT (BULK)(ALT/GPT BR OPT (BULK))-REAGENTS FOR MEASUREMENT OF ALT/GPT

102	IMP/IVD/2019/000017	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALINITY I ANTI-TG CALIBRATORS(ALINITY I ANTI-TG CALIBRATORS)-USED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THE IGG CLASS OF THYROGLOBULIN AUTOANTIBODIES (ANTI-TG) IN HUMAN SERUM AND PLASMA.,ALINITY I T-UPTAKE CALIBRATORS(ALINITY I T-UPTAKE CALIBRATORS)-THE ALINITY I T-UPTAKE CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THE TOTAL BINDING CAPACITY OF HUMAN SERUM OR PLASMA FOR THYROID HORMONE THYROXINE (T4).,ALINITY I ANTI-TPO CALIBRATORS(ALINITY I ANTI-TPO CALIBRATORS)-USED CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THE IGG CLASS OF THYROID PEROXIDASE AUTOANTIBODIES (ANTI-TPO) IN HUMAN SERUM AND PLASMA.,ALINITY I T-UPTAKE CONTROLS(ALINITY I T-UPTAKE CONTROLS)-THE ALINITY I T-UPTAKE CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THE TOTAL BINDING CAPACITY OF HUMAN SERUM OR PLASMA FOR THYROID HORMONE THYROXINE (T4).,ALINITY I BRAHMS PCT CONTROLS(ALINITY I BRAHMS PCT CONTROLS)-THE ALINITY I BRAHMS PCT CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN SERUM AND PLASMA.,ALINITY I STAT CK-MB CALIBRATORS(ALINITY I STAT CK-MB CALIBRATORS)-THE ALINITY I STAT CK-MB CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CKMB IN HUMAN SERUM AND PLASMA.,ALINITY I B·R·A·H·M·S PCT CALIBRATORS(ALINITY I B·R·A·H·M·S PCT CALIBRATORS)-THE ALINITY I B·R·A·H·M·S PCT CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN SERUM AND PLASMA.,ALINITY I STAT MYOGLOBIN CALIBRATORS(ALINITY I STAT MYOGLOBIN CALIBRATORS)-THE ALINITY I STAT MYOGLOBIN CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM AND PLASMA.,ALINITY I ANTI-TPO CONTROLS(ALINITY I ANTI-TPO CONTROLS)-USED FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF

	THE ALINITY I ANALYZER (REAGENTS, CALIBRATORS AND INSTRUMENT) WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THE IGG CLASS OF THYROID PEROXIDASE AUTOANTIBODIES (ANTI-TPO) IN HUMAN SERUM AND PLASMA.,ALINITY I CORTISOL CALIBRATORS(ALINITY I CORTISOL CALIBRATORS)-THE ALINITY I CORTISOL CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM, PLASMA OR URINE.,ALINITY I ANTI-TG CONTROLS(ALINITY I ANTI-TG CONTROLS)-USED FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER (REAGENTS, CALIBRATORS AND INSTRUMENT) WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THE IGG CLASS OF THYROGLOBULIN AUTOANTIBODIES (ANTI-TG) IN HUMAN SERUM AND PLASMA.

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103	IMP/IVD/2019/000019	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: ADVIA CENTAUR IRI DILUENT (ADVIA CENTAUR IRI DILUENT)-THE ADVIA CENTAUR LRL DILUENT IS FOR USE IN CONJUNCTION WITH THE ADVIA CENTAUR LRL REAGENTS. THE ADVIA CENTAUR LRL DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY. , ATELLICA IM CPEPTIDE CALIBRATOR (CPS CAL)(ATELLICA IM CPEPTIDE CALIBRATOR (CPS CAL))-THE ATELLICA™ IM CPEPTIDE CALIBRATOR (CPS CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM CPS ASSAY USING THE ATELLICA™ IM ANALYZER.,ADVIA CENTAUR CPS MASTER CURVE MATERIAL (ADVIA CENTAUR CPS MASTER CURVE MATERIAL)-THE ADVIA CENTAUR® C-PEPTIDE (CPS) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR C-PEPTIDE ASSAY. , ATELLICA IM C-PEPTIDE MASTER CURVE MATERIAL (CPS MCM) (ATELLICA IM C-PEPTIDE MASTER CURVE MATERIAL (CPS MCM))-THE ATELLICA™ IM C-PEPTIDE MASTER CURVE MATERIAL (CPS MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM CPS ASSAY.,ADVIA CENTAUR INSULIN (IRI) (ADVIA CENTAUR INSULIN (IRI))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF INSULIN IN SERUM USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THIS ASSAY CAN BE USED TO AID IN THE DIAGNOSIS AND TREATMENT OF DIABETES MELLITUS AND HYPOGLYCEMIA. , ATELLICA IM INSULIN CALIBRATOR (IRI CAL)(ATELLICA IM INSULIN CALIBRATOR (IRI CAL))-THE ATELLICA™ IM INSULIN CALIBRATOR (IRI CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM IRI ASSAY USING THE ATELLICA™ IM ANALYZER, ADVIA CENTAUR IRI CALIBRATOR (ADVIA CENTAUR IRI CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR® SYSTEMS INSULIN ASSAYS. , ATELLICA IM DILUENT (IRI DIL) (ATELLICA IM DILUENT (IRI DIL))-THE ATELLICA IM INSULIN (IRI DIL) IS USED FOR DILUTION IN THE QUANTITATIVE DETERMINATION OF INSULIN IN THE HUMAN SERUM.,ADVIA CENTAUR IRI MASTER CURVE MATERIAL(ADVIA CENTAUR IRI MASTER CURVE MATERIAL)-THE ADVIA CENTAUR® INSULIN (IRI) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR INSULIN ASSAY. , ATELLICA IM INSULIN MASTER CURVE MATERIAL (IRI MCM)(ATELLICA IM INSULIN MASTER CURVE MATERIAL (IRI MCM))-THE ATELLICA™ IM INSULIN MASTER CURVE MATERIAL (IRI MCM) IS FOR IN VITRO

	DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA™ IM IRI ASSAY. , ADVIA CENTAUR CPS CALIBRATOR (ADVIA CENTAUR CPS CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR® SYSTEMS C-PEPTIDE ASSAYS.,ATELLICA IM CPEPTIDE (CPS)(ATELLICA IM CPEPTIDE (CPS))-THE ATELLICA™ IM CPEPTIDE (CPS) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CPEPTIDE IN HUMAN SERUM AND URINE USING THE ATELLICA™ IM ANALYZER. THIS ASSAY CAN BE USED TO AID IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH ABNORMAL INSULIN SECRETION INCLUDING DIABETES MELLITUS,ADVIA CENTAUR C-PEPTIDE (CPS) (ADVIA CENTAUR C-PEPTIDE (CPS))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN SERUM OR URINE USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THIS ASSAY CAN BE USED TO AID IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH ABNORMAL INSULIN SECRETION INCLUDING DIABETES MELLITUS.,ATELLICA IM INSULIN (IRI)(ATELLICA IM INSULIN (IRI))-THE ATELLICA™ IM INSULIN (IRI) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM USING THE ATELLICA™ IM ANALYZER. THIS ASSAY CAN BE USED TO AID IN THE DIAGNOSIS AND TREATMENT OF DIABETES MELLITUS AND HYPOGLYCEMIA

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	LIAISON® RUBELLA IGG II CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® RUBELLA IGG II CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON®, LIAISON® XL AND LIAISON® XS. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVES IN THE RELEVANT AREA SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.. LIAISON® XS ANALYZER.THE CERTIFICATE OF ANALYSIS BAR CODES GIVES IN THE RELEVANT AREA SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XS ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® CONTROL EA IGG(LIAISON® CONTROL EA IGG)-THE LIAISON® EA IGG CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® EA IGG CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® CONTROL ANTI-HBC(LIAISON® CONTROL ANTI-HBC)-THE LIAISON® ANTI-HBC CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® ANTI-HBC CONTROLS HAVE NOT

	BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. ,LIAISON® T4(LIAISON® T4)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE (T4) IN HUMAN SERUM AND HUMAN PLASMA. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY., LIAISON® XL MUREX CONTROL HBSAG QUANT(LIAISON® XL MUREX CONTROL HBSAG QUANT)-THE LIAISON® XL MUREX HBSAG QUANT CONTROLS (NEGATIVE AND POSITIVE) ARE INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE AND RELIABILITY OF THE LIAISON® XL MUREX HBSAG QUANT ASSAY. THE PERFORMANCE CHARACTERISTICS OF LIAISON® XL MUREX HBSAG QUANT CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® XL. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® FT3(LIAISON® FT3)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM AND PLASMA. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY., LIAISON® XL MUREX HBSAG QUANT(LIAISON® XL MUREX HBSAG QUANT)-THE LIAISON® XL MUREX HBSAG QUANT ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA SAMPLES INCLUDED SPECIMENS COLLECTED POST-MORTEM (NON-HEART BEATING). THE ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF HBV INFECTION IN INDIVIDUALS WITH OR WITHOUT SYMPTOMS OF HEPATITIS AND IN THE MONITORING OF TREATMENT AND DISEASE STATUS. IT IS ALSO INTENDED AS A SCREENING TEST FOR BLOOD AND HEMOCOMPONENTS DONORS AS WELL AS FOR ORGAN, TISSUE AND CELLS POST-MORTEM DONORS. THE TEST HAS TO BE PERFORMED

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	ON THE LIAISON® XL ANALYZER ONLY,LIAISON® CONTROL CARDIOLIPIN IGM(LIAISON® CONTROL CARDIOLIPIN IGM)-THE LIAISON® CARDIOLIPIN IGM CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENT IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CARDIOLIPIN IGM CONTROLS HAVE NOT BEEN ESTABLISHED IN CONNECTION WITH ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS. WARNING: THE LIAISON® CARDIOLIPIN IGM CONTROLS ARE PREDILUTED AND THEREFORE MUST NOT BE USED TO CHECK ADEQUACY OF DILUTION PROCEDURE.,HBSAG CONFIRMATORY TEST(HBSAG CONFIRMATORY TEST)-THE HBSAG CONFIRMATORY TEST IS AN IN VITRO NEUTRALIZATION ASSAY FOR CONFIRMATION OF THE PRESENCE OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA SAMPLES FOUND REPEATEDLY REACTIVE FOR HBSAG BY LIAISON® XL MUREX HBSAG QUANT ([REF] 310250) OR LIAISON® HBSAG ([REF] 310100).,LIAISON® MUMPS IGG(LIAISON® MUMPS IGG)-THE LIAISON® MUMPS IGG ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE SEMI-QUANTITATIVE DETERMINATION OF SPECIFIC IGG ANTIBODIES TO MUMPS VIRUS IN HUMAN SERUM OR PLASMA SAMPLES. IT IS INTENDED TO BE USED AS AN AID IN THE DETERMINATION OF SEROLOGICAL STATUS TO MUMPS VIRUS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® XL MUREX CONTROL HIV AB/AG (LIAISON® XL MUREX CONTROL HIV AB/AG)-THE LIAISON® XL MUREX HIV AB / AG CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® XL MUREX HIV AB / AG CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® XL. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® CONTROL TOXO IGG II(LIAISON® CONTROL TOXO IGG II)-THE LIAISON® TOXO IGG II CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® TOXO IGG II CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS

	GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL,LIAISON® SARS-COV-2 IGM(LIAISON® SARS-COV-2 IGM)-THE LIAISON® SARS-COV-2 IGM USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF SPECIFIC IGM ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM OR PLASMA SAMPLES. THE ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF COVID-19 AND TO SUPPORT THE STUDY OF THE IMMUNE STATUS OF PATIENTS WHO MAY HAVE BEEN EXPOSED TO AND INFECTED BY SARS-COV-2. RESULTS FROM THE LIAISON® SARS-COV-2 IGM TEST SHOULD NOT BE USED AS THE SOLE BASIS TO DIAGNOSE OR EXCLUDE SARS-COV-2 INFECTION OR TO INFORM OF AN INFECTION STATUS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® XL ANALYZER ONLY.,LIAISON® AFP(LIAISON® AFP)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF ALPHA-FETOPROTEIN (AFP) IN HUMAN SERUM AS WELL AS IN EDTA AND HEPARINISED HUMAN PLASMA OR AMNIOTIC FLUID FOR PREGNANCY MONITORING AND DURING THE FOLLOW-UP OF TUMOUR PATIENTS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® ANTI-HBC(LIAISON® ANTI-HBC)-THE LIAISON® ANTI-HBC ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF TOTAL ANTIBODIES TO HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CMV IGG II(LIAISON® CMV IGG II)-THE LIAISON® CMV IGG II ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGG ANTIBODIES TO HCMV IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® XL MUREX CONTROL HIV AB/AG HT(LIAISON® XL MUREX CONTROL HIV AB/AG HT)-THE LIAISON® XL MUREX HIV AB / AG HT CONTROLS (NEGATIVE AND POSITIVE FOR ANTI-HIV-1 ANTIBODIES AND FOR HIV P24 ANTIGEN) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® XL MUREX HIV AB / AG HT CONTROLS HAVE NOT BEEN ESTABLISHED

	FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® CONTROL RUBELLA IGG(LIAISON® CONTROL RUBELLA IGG)-THE LIAISON® RUBELLA IGG CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® RUBELLA IGG CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL®. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® XL MUREX HCV AB(LIAISON® XL MUREX HCV AB)-THE LIAISON® XL MUREX HCV AB ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF SPECIFIC ANTIBODIES TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® XL ANALYZERS ONLY.,LIAISON® XL CONTROL TOXO IGG AVIDITY (LIAISON® XL CONTROL TOXO IGG AVIDITY)-THE LIAISON® XL TOXO IGG AVIDITY CONTROLS ([REF] 310796) ARE TO BE USED IN LIAISON® CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® XL TOXO IGG AVIDITY CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF

	THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® XL MUREX CONTROL HCV AB (LIAISON® XL MUREX CONTROL HCV AB)-THE LIAISON® XL MUREX HCV AB CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® XL MUREX HCV AB CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® XL. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® MEASLES IGM (LIAISON® MEASLES IGM)-THE LIAISON ® MEASLES IGM ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF SPECIFIC IGM ANTIBODIES TO MEASLES VIRUS IN HUMAN SERUM OR PLASMA SAMPLES. IT IS INTENDED TO BE USED AS AN AID IN THE DETERMINATION OF SEROLOGICAL STATUS TO MEASLES VIRUS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® XL MUREX HBSAG QUANT SPECIMEN DILUENT(LIAISON® XL MUREX HBSAG QUANT SPECIMEN DILUENT)-LIAISON® XL MUREX HBSAG QUANT SPECIMEN DILUENT ([REF] 310252) IS TO BE USED TO DILUTE SPECIMENS CONTAINING HBSAG CONCENTRATIONS ABOVE THE ASSAY RANGE (ABOVE 150 IU/ML) OF LIAISON® XL MUREX HBSAG QUANT ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE DILUENT HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® XL.,LIAISON® CA 15-3®(LIAISON® CA 15-3®)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE CA 15-3® ANTIGEN IN HUMAN SERUM AS WELL AS EDTA AND HEPARINISED PLASMA DURING THE FOLLOW-UP OF PATIENTS WITH BREAST CARCINOMA. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® XL MUREX HIV AB/AG(LIAISON® XL MUREX HIV AB/AG)-THE LIAISON® XL MUREX HIV AB / AG ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE COMBINED QUALITATIVE DETERMINATION OF P24 ANTIGEN OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) AND SPECIFIC ANTIBODIES TO BOTH HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (GROUP M AND GROUP O) AND/OR HUMAN IMMUNODEFICIENCY VIRUS TYPE 2 (HIV-2) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® XL ANALYZERS

	ONLY,LIAISON® 2-MICROGLOBULIN(LIAISON® 2-MICROGLOBULIN)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF 2-MICROGLOBULIN (B2M) IN HUMAN SERUM AS WELL AS EDTA, CITRATED, AND HEPARINISED HUMAN PLASMA. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY. URINE THE USE OF URINE SAMPLES IS ALSO POSSIBLE. FOR THIS PURPOSE “B2MU” HAS TO BE SELECTED IN THE SAMPLE LOADING DIALOGUE (INSTEAD OF “B2MS”). NEVER START “B2MU” WITH SERUM OR PLASMA SAMPLES! THE SELECTION OF “B2MU” INCREASES AUTOMATICALLY THE SAMPLE VOLUME PIPETTED TO 100 L. THE CALIBRATOR VOLUMES AND OTHER CHARACTERISTICS OF THE REACTION REMAIN UNAFFECTED, THE CONCENTRATIONS ARE STILL EXPRESSED AS MG/L. INTEGRAL CALIBRATION IS ALWAYS PERFORMED BY THE “B2MS” PROCEDURE; ADAPTATION OF RESULT OUTPUT FOR “B2MU” OCCURS AUTOMATICALLY, IF SELECTED. SPONTANEOUS URINE WHICH HAS BEEN ADJUSTED TO PH 6-8 WITH 0.5 M NAOH SOLUTION IMMEDIATELY AFTER COLLECTION SHOULD BE USED FOR THE DETERMINATION WITHIN 24 HOURS; FOR LONGER STORAGE THE SPECIMENS SHOULD BE FROZEN AT -20 °C. A PRELIMINARY UPPER REFERENCE RANGE FOR 2-MICROGLOBULIN IN URINE OBTAINED BY THIS METHOD HAS BEEN ESTIMATED TO 0.3 MG/L ON A BASIS OF 127 APPARENTLY NORMAL PROBANDS (FEMALE AND MALE). EACH LABORATORY SHOULD ESTABLISH ITS OWN REFERENCE RANGE.,LIAISON® XL MUREX HIV AB/AG HT(LIAISON® XL MUREX HIV AB/AG HT)-THE LIAISON® XL MUREX HIV AB / AG HT ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE COMBINED QUALITATIVE DETERMINATION OF P24 ANTIGEN OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) AND SPECIFIC ANTIBODIES TO BOTH HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (GROUP M AND GROUP O) AND/OR HUMAN IMMUNODEFICIENCY VIRUS TYPE 2 (HIV-2) IN HUMAN SERUM OR PLASMA SAMPLES. THE LIAISON® XL MUREX HIV AB / AG HT ASSAY IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF HIV-1/HIV-2 INFECTION AND AS A SCREENING TEST FOR DONATED BLOOD AND PLASMA. THE TEST HAS TO BE PERFORMED ON THE LIAISON® XL ANALYZER ONLY.,LIAISON® CONTROL VCA IGG(LIAISON® CONTROL VCA IGG)-THE LIAISON® VCA IGG CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® VCA IGG CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS,

	WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® RUBELLA IGG II(LIAISON® RUBELLA IGG II)-THE LIAISON® RUBELLA IGG II ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION AND QUALITATIVE DETECTION OF SPECIFIC IGG ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY (LIAISON®, LIAISON® XL, LIAISON® XS),LIAISON® CONTROL INSULIN(LIAISON® CONTROL INSULIN)-THE LIAISON® INSULIN CONTROLS (LEVEL 1 AND LEVEL 2) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® INSULIN CONTROLS HAVE NOT BEEN ESTABLISHED IN CONNECTION WITH ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® CONTROL SARS-COV-2 S1/S2 IGG(LIAISON® CONTROL SARS-COV-2 S1/S2 IGG)-THE LIAISON® SARS-COV-2 S1/S2 IGG CONTROLS (NEGATIVE AND POSITIVE) ARE INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE AND RELIABILITY OF T HE LIAISON® SARS-COV-2 S1/S2 IGG ASSAY. THE PERFORMANCE CHARACTERISTICS OF LIAISON® SARS-COV-2 S1/S2 IGG CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY ASSAYS OR INSTRUMENT PLATFORMS OTHER THAN LIAISON® XL. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® CONTROL CARDIOLIPIN IGG

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	(LIAISON® CONTROL CARDIOLIPIN IGG)-THE LIAISON® CARDIOLIPIN IGG CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENT IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CARDIOLIPIN IGG CONTROLS HAVE NOT BEEN ESTABLISHED IN CONNECTION WITH ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS. WARNING: THE LIAISON® CARDIOLIPIN IGG CONTROLS ARE PREDILUTED AND THEREFORE MUST NOT BE USED TO CHECK ADEQUACY OF DILUTION PROCEDURE.,LIAISON® SARS-COV-2 S1/S2 IGG(LIAISON® SARS-COV-2 S1/S2 IGG)-THE LIAISON® SARS-COV-2 S1/S2 IGG USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF ANTI-S1 AND ANTI-S2 SPECIFIC IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM OR PLASMA SAMPLES. THE ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF COVID-19 AND TO SUPPORT THE STUDY OF THE IMMUNE STATUS OF INFECTED PATIENT BY PROVIDING AN INDICATION OF THE PRESENCE OF NEUTRALIZING IGG ANTIBODIES AGAINST SARS-COV-2. RESULTS FROM THE LIAISON® SARS-COV-2 S1/S2 IGG TEST SHOULD NOT BE USED AS THE SOLE BASIS TO DIAGNOSE OR EXCLUDE SARS-COV2 INFECTION OR TO INFORM ABOUT INFECTION STATUS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® XL ANALYZER ONLY., LIAISON® ANTI-TG(LIAISON® ANTI-TG)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF AUTOANTIBODIES AGAINST THYROGLOBULIN (TG) IN HUMAN SERUM AS WELL AS IN EDTA AND HEPARINISED HUMAN PLASMA. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® ANA SCREEN (LIAISON® ANA SCREEN)-THE LIAISON® ANA SCREEN ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE COLLECTIVE QUALITATIVE DETERMINATION OF AUTOANTIBODIES DIRECTED AGAINST THE FOLLOWING ANTIGENS: DOUBLE-STRANDED DNA (DSDNA), RNP/SM (70 KDA), SS-A (RO) (RICH IN 60 KDA), SS-B (LA), SCL-70, JO-1, CENTROMERE (CENP-B) AND MITOCHONDRIA IN HUMAN SERUM OR PLASMA, ALONG WITH DETECTION OF SERA POSITIVE FOR HEP-2 IMMUNOFLUORESCENCE ANTIBODY TEST. THIS TEST IS INTENDED AS AN AID IN THE DIAGNOSIS OF CONNECTIVE TISSUE DISEASES (CTD), SUCH AS SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), MIXED CONNECTIVE TISSUE DISEASE (MCTD), SJÖGREN'S SYNDROME (SS), SYSTEMIC SCLEROSIS (SSC), IDIOPATIC POLYMYOSITIS (PM), DERMATOMYOSITIS (DM) AND CREST SYNDROME (CALCINOSIS, RAYNAUD PHENOMENON, ESOPHAGEAL DYSMOTILITY, SCLERODACTYLY, AND TELANGIECTASIA). THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER.,LIAISON® ANTI-TPO(LIAISON® ANTI-TPO)-IN VITRO ASSAY FOR THE

	QUANTITATIVE DETERMINATION OF AUTOANTIBODIES AGAINST THYROID PEROXIDASE (TPO) IN HUMAN SERUM AS WELL AS IN EDTA, CITRATED AND HEPARINISED HUMAN PLASMA. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY,LIAISON® CLEANING KIT(LIAISON® CLEANING KIT)-THE LIAISON® CLEANING KIT IS USEFUL TO IMPROVE ROUTINE MAINTENANCE OF THE LIAISON® SYSTEM. IT INTERVENES TO CLEAN THE PIPETTOR AND THE WASHER NEEDLES, CONTRIBUTING TO GUARANTEE COMPLETE SERVICEABILITY OF THE STARTER REAGENT PUMPS. THE KIT CAN ONLY BE USED WITH LIAISON® INSTRUMENTS, WITH SOFTWARE VERSION 1.943 OR HIGHER. THE LIAISON® CLEANING KIT CONSISTS OF TWO SEPARATE COMPONENTS: 1. LIAISON® CLEAN TOOL. 2. LIAISON® PUMP TOOL. THE KIT IS SUFFICIENT FOR 10 WEEKLY MAINTENANCE SESSIONS WITH CLEAN TOOL AND TWO MONTHLY MAINTENANCE SESSIONS WITH PUMP TOOL. MAINTENANCE WITH LIAISON® CLEANING KIT DOES NOT REPLACE ROUTINE MAINTENANCE OF THE LIAISON® SYSTEM.,LIAISON® RUBELLA IGG II (LIAISON® RUBELLA IGG II)-THE LIAISON® RUBELLA IGG II ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION & QUALITATIVE DETECTION OF SPECIFIC IGG ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY. (LIAISON®, LIAISON® XL, LIAISON® XS),LIAISON® CONTROL ANA SCREEN (LIAISON® CONTROL ANA SCREEN)-THE LIAISON® CONTROL ANA SCREEN CONTROLS (310301) ARE TO BE USED IN LIAISON® CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS.,LIAISON® RUBELLA IGG(LIAISON® RUBELLA IGG)-THE LIAISON® RUBELLA IGG ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGG ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CONTROL HGH(LIAISON® CONTROL HGH)-THE LIAISON® HGH CONTROLS (LEVEL 1 AND LEVEL 2) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® HGH CONTROLS HAVE NOT BEEN ESTABLISHED IN CONNECTION WITH ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF

	CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL,LIAISON® CA 19-9TM(LIAISON® CA 19-9TM)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE CA 19-9™ ANTIGEN IN HUMAN SERUM AS WELL AS EDTA OR CITRATED HUMAN PLASMA DURING THE FOLLOW-UP OF PATIENTS WITH GASTROINTESTINAL TUMOURS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® TOXO IGM(LIAISON® TOXO IGM)-THE LIAISON® TOXO IGM ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY., LIAISON® HGH(LIAISON® HGH)-THE LIAISON ® HGH ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HUMAN GROWTH HORMONE IN HUMAN SERUM SPECIMENS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CONTROL EBV IGM(LIAISON® CONTROL EBV IGM)-THE LIAISON® EBV IGM CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® EBV IGM CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® TG(LIAISON® TG)-IN VITRO ASSAY FOR THE DETERMINATION OF HUMAN THYROGLOBULIN (HTG) IN HUMAN SERUM AS WELL AS HEPARINISED AND CITRATED HUMAN PLASMA. THE TEST HAS TO BE

	PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CARDIOLIPIN IGG(LIAISON® CARDIOLIPIN IGG)-THE LIAISON® CARDIOLIPIN IGG ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE IN VITRO SEMI-QUANTITATIVE DETERMINATION OF AUTOANTIBODIES OF IGG CLASS DIRECTED AGAINST CARDIOLIPIN IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER., LIAISON® CONTROL TOXO IGM(LIAISON® CONTROL TOXO IGM)-THE LIAISON® TOXO IGM CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENT IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® TOXO IGM CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT DIFFERENT FROM LIAISON® AND LIAISON® XL. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® TTG IGA (LIAISON® TTG IGA)-THE LIAISON® TTG IGA ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF AUTOANTIBODIES OF IGA CLASS DIRECTED AGAINST TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM OR PLASMA.THE PRESENCE OF IGA AUTOANTIBODIES TO TISSUE TRANSGLUTAMINASE, IN CONJUNCTION WITH OTHER LABORATORY TESTS AND CLINICAL FINDINGS MAY AID IN THE DIAGNOSIS AND MONITORING OF COELIAC DISEASE (GLUTEN-SENSITIVE ENTEROPATHY).THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® FGF 23(LIAISON® FGF 23)-LIAISON® FGF 23 ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF INTACT FGF23 POLYPEPTIDE IN HUMAN PLASMA EDTA SPECIMENS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® PROLACTIN XT(LIAISON® PROLACTIN XT)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM AND PLASMA. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® RUBELLA IGM(LIAISON® RUBELLA IGM)-THE LIAISON® RUBELLA IGM ASSAY USES CHEMILUMINESCENCE

	IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGM ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CMV IGM II(LIAISON® CMV IGM II)-THE LIAISON® CMV IGM II ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE SEMI-QUANTITATIVE DETERMINATION OF SPECIFIC IGM ANTIBODIES TO HCMV IN HUMAN SERUM OR PLASMA SAMPLES.THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CONTROL CMV IGG II(LIAISON® CONTROL CMV IGG II)-THE LIAISON® CMV IGG II CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CMV IGG II CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL®. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL,LIAISON® CONTROL CMV IGM II(LIAISON® CONTROL CMV IGM II)-THE LIAISON® CMV IGM II CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CMV IGM II CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL,LIAISON® CONTROL RUBELLA IGM(LIAISON® CONTROL RUBELLA IGM)-THE

	LIAISON® RUBELLA IGM CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® RUBELLA IGM CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL®.,LIAISON® CONTROL MEASLES IGM(LIAISON® CONTROL MEASLES IGM)-THE LIAISON® MEASLES IGM CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® MEASLES IGM CONTROLS HAVE NOT BEEN ESTABLISHED IN CONNECTION WITH ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® INSULIN(LIAISON® INSULIN)-THE LIAISON® INSULIN ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM OR EDTA-PLASMA SPECIMENS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CONTROL MEASLES IGG(LIAISON® CONTROL MEASLES IGG)-THE LIAISON® MEASLES IGG CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® MEASLES IGG CONTROLS HAVE NOT BEEN ESTABLISHED IN CONNECTION WITH ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL

	VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® MUMPS IGM(LIAISON® MUMPS IGM) -THE LIAISON® MUMPS IGM ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF SPECIFIC IGM ANTIBODIES TO MUMPS VIRUS IN HUMAN SERUM OR PLASMA SAMPLES. IT IS INTENDED TO BE USED AS AN AID IN THE DETERMINATION OF SEROLOGICAL STATUS TO MUMPS VIRUS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® EBNA IGG(LIAISON® EBNA IGG)-THE LIAISON® EBNA IGG ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGG ANTIBODIES TO EPSTEIN-BARR VIRUS NUCLEAR ANTIGEN (EBNA) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CONTROL EBNA IGG(LIAISON® CONTROL EBNA IGG)-THE LIAISON® EBNA IGG CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® EBNA IGG CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL®. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® CONTROL DHEA-S(LIAISON® CONTROL DHEA-S)-THE LIAISON® DHEA-S CONTROLS (LEVEL 1 AND LEVEL 2) ARE TO BE USED IN LIAISON® CHEMILUMINESCENT IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® DHEA-S CONTROLS HAVE NOT BEEN ESTABLISHED IN CONNECTION WITH ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION

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	ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® T3(LIAISON® T3)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE (T3) IN HUMAN SERUM AS WELL AS IN HEPARINISED AND EDTA PLASMA. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® TOXO IGG II (LIAISON® TOXO IGG II)-THE LIAISON® TOXO IGG ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM OR PLASMA SAMPLES FOR SCREENING OF PREGNANT WOMEN. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® TSH (LIAISON® TSH)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN HUMAN SERUM AND PLASMA. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® EA IGG(LIAISON® EA IGG)-THE LIAISON® EA IGG ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGG ANTIBODIES TO EPSTEIN-BARR VIRUS EARLY ANTIGEN-DIFFUSE [EA(D)] IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CONTROL VZV IGM (LIAISON® CONTROL VZV IGM)-THE LIAISON® VZV IGM CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® VZV IGM CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® CMV IGG AVIDITY II(LIAISON® CMV IGG AVIDITY II)-THE LIAISON® CMV IGG AVIDITY II ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE DETERMINATION OF ANTIGEN-BINDING

	AVIDITY OF IGG ANTIBODIES TO HCMV IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® HAV IGM(LIAISON® HAV IGM)-THE LIAISON® HAV IGM ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF IGM IMMUNOGLOBULIN TO HEPATITIS A VIRUS (IGM ANTI-HAV) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY., LIAISON® ANTI-HAV(LIAISON® ANTI-HAV)-THE LIAISON® ANTI-HAV ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF TOTAL ANTIBODIES TO HEPATITIS A VIRUS (ANTI-HAV) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® FSH(LIAISON® FSH)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE-STIMULATING HORMONE (FSH; FOLLITROPIN) IN HUMAN SERUM AS WELL AS CITRATED PLASMA FOR THE FERTILITY DIAGNOSTICS OF BOTH SEXES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® VZV IGM(LIAISON® VZV IGM)-THE LIAISON® VZV IGM ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF SPECIFIC IGM ANTIBODIES TO VARICELLA-ZOSTER VIRUS (VZV) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY., LIAISON® DSDNA(LIAISON® DSDNA)-THE LIAISON® DSDNA ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF AUTOANTIBODIES OF IGG CLASS DIRECTED AGAINST DOUBLE-STRANDED DNA (DSDNA) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER.,LIAISON® BORRELIA IGM QUANT(LIAISON® BORRELIA IGM QUANT)-THE LIAISON® BORRELIA IGM QUANT ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGM ANTIBODIES TO BORRELIA BURGDORFERI SENSU LATO (INCLUDING STRAINS BORRELIA BURGDORFERI SENSU STRICTU, BORRELIA GARINII, BORRELIA AFZELII) IN HUMAN SERUM, PLASMA OR CEREBROSPINAL FLUID (CSF) SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CONTROL HSV-1/2 IGG(LIAISON® CONTROL HSV-1/2 IGG)-THE LIAISON® HSV-1/2 IGG CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® HSV-1/2 IGG CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS

	OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® CONTROL CMV IGG AVIDITY II(LIAISON® CONTROL CMV IGG AVIDITY II)-THE LIAISON® CMV IGG AVIDITY II CONTROLS (LOW AND HIGH) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CMV IGG AVIDITY II CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® VCA IGG(LIAISON® VCA IGG)-THE LIAISON® VCA IGG ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGG ANTIBODIES TO EPSTEIN-BARR VIRAL CAPSID ANTIGENS (VCA) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILYLIAISON® CONTROL VCA IGG,LIAISON® XL TOXO IGG AVIDITY(LIAISON® XL TOXO IGG AVIDITY)-THE LIAISON® XL TOXO IGG AVIDITY ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE DETERMINATION OF ANTIGEN-BINDING AVIDITY OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® C-PEPTID(LIAISON® C-PEPTID)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM, HEPARINISED OR CITRATED PLASMA, AND URINE. THE TEST HAS TO BE PERFORMED ON THE

	LIAISON® ANALYZER FAMILY.,LIAISON® FERRITIN(LIAISON® FERRITIN)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® IGF-I (LIAISON® IGF-I)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF IGF-I (INSULIN-LIKE GROWTH FACTOR I) IN HUMAN SERUM. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CA 125 IITM(LIAISON® CA 125 IITM)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF CA 125 ANTIGEN IN HUMAN SERUM AS WELL AS IN EDTA OR HEPARINISED HUMAN PLASMA DURING THE FOLLOW-UP OF PATIENTS WITH PRIMARY INVASIVE OVARIAN CARCINOMA. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® BRAHMS PCT II GEN(LIAISON® BRAHMS PCT II GEN)-LIAISON ® BRAHMS PCT® II GEN ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PROCALCITONIN IN HUMAN SERUM AND PLASMA SPECIMENS. THE ASSAY IS INTENDED FOR USE, IN CONJUNCTION WITH OTHER LABORATORY FINDINGS AND CLINICAL ASSESSMENTS, TO AID IN THE RISK ANALYSIS OF CRITICALLY ILL PATIENTS FOR PROGRESSION OF RELEVANT BACTERIAL INFECTIONS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CEA(LIAISON® CEA)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) IN HUMAN SERUM AS WELL AS IN EDTA OR HEPARINISED HUMAN PLASMA DURING THE FOLLOW-UP OF CANCER PATIENTS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CONTROL MUMPS IGM (LIAISON® CONTROL MUMPS IGM)-THE LIAISON® MUMPS IGM CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® MUMPS IGM CONTROLS HAVE NOT BEEN ESTABLISHED IN CONNECTION WITH ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER

	OPERATOR'S MANUAL.,LIAISON® DIRECT RENIN(LIAISON® DIRECT RENIN)-THE LIAISON® DIRECT RENIN ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF RENIN IN HUMAN EDTA-PLASMA SPECIMENS. RENIN MEASUREMENT IS OF HELP IN THE DIAGNOSIS AND TREATMENT OF A NUMBER OF HYPERTENSION TYPES IN HUMANS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CORTISOL(LIAISON® CORTISOL)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM, PLASMA (AND URINE). THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® HSV-1/2 IGG(LIAISON® HSV-1/2 IGG)-THE LIAISON® HSV-1/2 IGG ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF SPECIFIC IGG ANTIBODIES TO HERPES SIMPLEX VIRUS TYPES 1 AND/OR 2 (HSV-1 AND/OR HSV-2) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CONTROL BORRELIA IGM QUANT / BORRELIA IGM II(LIAISON® CONTROL BORRELIA IGM QUANT / BORRELIA IGM II)-THE LIAISON® BORRELIA IGM QUANT / BORRELIA IGM II AND BORRELIA IGM LIQUOR CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® BORRELIA IGM CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. WARNING: THE LIAISON® BORRELIA IGM QUANT / BORRELIA IGM II SERUM CONTROLS ARE PREDILUTED AND THEREFORE MUST NOT BE USED TO CHECK ADEQUACY OF DILUTION PROCEDURE.,LIAISON®ACTH(LIAISON®ACTH)-THE LIAISON® ACTH ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ADRENOCORTICOTROPIC HORMONE IN HUMAN EDTA-PLASMA SPECIMENS (STORED FROZEN). THE DETERMINATION OF ACTH IN

	CONJUNCTION WITH OTHER LABORATORY TESTS AND CLINICAL FINDINGS CAN HELP IN INVESTIGATING ADRENAL DYSFUNCTION IN HUMANS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CONTROL BRAHMS PCT II GEN (LIAISON® CONTROL BRAHMS PCT II GEN)-THE LIAISON® BRAHMS PCT® II GEN CONTROLS (LEVEL 1 AND LEVEL 2) HAVE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® BRAHMS PCT® II GEN CONTROLS HAVE NOT BEEN ESTABLISHED IN CONNECTION WITH ANY OTHER ASSAY OR INSTRUMENT PLATFORM. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® XL CLEANING TOOL(LIAISON® XL CLEANING TOOL)-THE LIAISON® XL CLEANING TOOL IS USEFUL TO IMPROVE ROUTINE MAINTENANCE OF THE LIAISON® XL ANALYZER FAMILY. IT INTERVENES TO CLEAN THE WASHER NEEDLES AND TUBES, ACCORDING TO THE INDICATIONS PROVIDED IN THE USER DOCUMENTATION OR IN THE KIT SPECIFIC PACKAGE INSERT. THE KIT CAN ONLY BE USED WITH LIAISON® XL ANALYZER FAMILY. THE KIT IS SUFFICIENT FOR 20 MAINTENANCE SESSIONS. MAINTENANCE WITH LIAISON® XL CLEANING TOOL DOES NOT REPLACE ROUTINE MAINTENANCE OF THE LIAISON® XL ANALYZER FAMILY.,LIAISON® BORRELIA IGM II(LIAISON® BORRELIA IGM II)-THE LIAISON ® BORRELIA IGM II ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF SPECIFIC IGM ANTIBODIES TO BORRELIA BURGDORFERI SENSU LATO (INCLUDING STRAINS BORRELIA BURGDORFERI SENSU STRICTU, BORRELIA GARINII, BORRELIA AFZELII) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY., LIAISON® CONTROL VZV IGG(LIAISON® CONTROL VZV IGG)-THE LIAISON® VZV IGG CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® VZV IGG CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR

	INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL®. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® CONTROL HSV-1/2 IGM(LIAISON® CONTROL HSV-1/2 IGM)-THE LIAISON® HSV-1/2 IGM CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® HSV-1/2 IGM CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® VZV IGG(LIAISON® VZV IGG)-THE LIAISON® VZV IGG ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGG ANTIBODIES TO VARICELLA-ZOSTER VIRUS (VZV) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® EBV IGM(LIAISON® EBV IGM)-THE LIAISON® EBV IGM ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGM ANTIBODIES TO EPSTEIN-BARR VIRAL CAPSID ANTIGENS (VCA) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® DHEAS(LIAISON® DHEAS)-THE LIAISON® DHEA-S ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULPHATE IN HUMAN SERUM OR PLASMA SPECIMENS. THE TEST HAS TO BE

	PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CONTROL DSDNA(LIAISON® CONTROL DSDNA)-THE LIAISON® CONTROL DSDNA CONTROLS (310311) ARE TO BE USED IN LIAISON® CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS.,LIAISON® XL HCG(LIAISON® XL HCG)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG AND HCG) IN HUMAN SERUM. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY..,LIAISON® CONTROL ANTI-HAV(LIAISON® CONTROL ANTI-HAV)-THE LIAISON® ANTI-HAV CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® ANTI-HAV CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL®. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® HSV-2 IGG(LIAISON® HSV-2 IGG)-THE LIAISON® HSV-2 IGG ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF SPECIFIC IGG ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE 2 (HSV-2) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® BORRELIA IGG(LIAISON® BORRELIA IGG)-THE LIAISON ® BORRELIA IGG ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGG ANTIBODIES TO BORRELIA BURGDORFERI SENSU LATO (INCLUDING STRAINS BORRELIA BURGDORFERI SENSU STRICTU, BORRELIA GARINII, BORRELIA AFZELII) IN HUMAN SERUM, PLASMA OR CEREBROSPINAL FLUID (CSF) SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® CARDIOLIPIN IGM (LIAISON® CARDIOLIPIN IGM)-THE LIAISON® CARDIOLIPIN IGM ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA)

	TECHNOLOGY FOR THE IN VITRO SEMIQUANTITATIVE DETERMINATION OF AUTOANTIBODIES OF IGM CLASS DIRECTED AGAINST CARDIOLIPIN IN HUMAN SERUM OR PLASMA SAMPLES.THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER., LIAISON® CONTROL DIRECT RENIN(LIAISON® CONTROL DIRECT RENIN)-THE LIAISON® DIRECT RENIN CONTROLS (LEVEL 1 AND LEVEL 2) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® DIRECT RENIN CONTROLS HAVE NOT BEEN ESTABLISHED IN CONNECTION WITH ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® LH(LIAISON® LH)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINISING HORMONE (LH; LUTROPIN) IN HUMAN SERUM AS WELL AS EDTA PLASMA FOR FERTILITY DIAGNOSTICS OF BOTH SEXES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® HSV-1/2 IGM(LIAISON® HSV-1/2 IGM)-THE LIAISON® HSV-1/2 IGM ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF SPECIFIC IGM ANTIBODIES TO HERPES SIMPLEX VIRUS TYPES 1 AND/OR 2 (HSV-1 AND/OR HSV-2) IN HUMAN SERUM OR PLASMA SAMPLES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® MEASLES IGG(LIAISON® MEASLES IGG)-THE LIAISON® MEASLES IGG ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE SEMI-QUANTITATIVE DETERMINATION OF SPECIFIC IGG ANTIBODIES TO MEASLES VIRUS IN HUMAN SERUM OR PLASMA SAMPLES. IT IS INTENDED TO BE USED AS AN AID IN THE DETERMINATION OF SEROLOGICAL STATUS TO MEASLES VIRUS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY., LIAISON® CONTROL MUMPS IGG(LIAISON® CONTROL MUMPS IGG)-THE LIAISON® MUMPS IGG CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON®

	MUMPS IGG CONTROLS HAVE NOT BEEN ESTABLISHED IN CONNECTION WITH ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® CONTROL HSV-2 IGG(LIAISON® CONTROL HSV-2 IGG)-THE LIAISON® HSV-2 IGG CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® HSV-2 IGG CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL®. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® CONTROL BORRELIA IGG(LIAISON® CONTROL BORRELIA IGG)-THE LIAISON ® BORRELIA IGG AND BORRELIA IGG LIQUOR CONTROLS (NEGATIVE AND POSITIVE) ARE TO BE USED IN LIAISON ® CHEMILUMINESCENCE IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® BORRELIA IGG CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-

	HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

105	IMP/IVD/2019/000021	1.License Holder Name: DIASORIN HEALTHCARE INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIAISON® VITAMIN B12 CONTROL SET(LIAISON® VITAMIN B12 CONTROL SET)-THE DIASORIN LIAISON® VITAMIN B12 CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE OF THE LIAISON® VITAMIN B12 ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® VITAMIN B12 CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® XL., LIAISON® CALPROTECTIN CONTROL SET(LIAISON® CALPROTECTIN CONTROL SET)-THE DIASORIN LIAISON® CALPROTECTIN CONTROLSET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE OF THE LIAISON® CALPROTECTIN ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® CALPROTECTIN CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® AND LIAISON® XL.,LIAISON® FOLATE CONTROL SET(LIAISON® FOLATE CONTROL SET)-THE DIASORIN LIAISON® FOLATE CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE OF THE LIAISON® FOLATE ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® FOLATE CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® XL. , LIAISON® C. DIFFICILE GDH CONTROL SET(LIAISON® C. DIFFICILE GDH CONTROL SET)-THE DIASORIN LIAISON® C. DIFFICILE GDH CONTROLSETIS INTENDEDFORUSEAS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE ACCURACY AND PRECISION OF THE DIASORIN LIAISON® C. DIFFICILE GDH ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® C. DIFFICILE GDH CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® AND LIAISON® XL.,LIAISON® ELASTASE-1 CONTROL SET(LIAISON® ELASTASE-1 CONTROL SET)-THE DIASORIN LIAISON® ELASTASE-1 CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE OF THE LIAISON® ELASTASE-1 ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® ELASTASE-1 CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® XL.,LIAISON® C. DIFFICILE TOXINS A&B(LIAISON® C. DIFFICILE TOXINS A&B)-THE DIASORIN LIAISON® C. DIFFICILE TOXINS A&B ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) INTENDED FOR THE

	QUALITATIVE DETERMINATION OF CLOSTRIDIUM DIFFICILE TOXINS A AND B IN HUMAN FECES ON THE LIAISON® ANALYZER FAMILY. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST THE CLINICIAN IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS.,LIAISON® ELASTASE-1(LIAISON® ELASTASE-1)-THE DIASORIN LIAISON® ELASTASE-1 ASSAY IS AN IN VITRO DIAGNOSTIC CHEMILUMINESCENT IMMUNOASSAY (CLIA) INTENDED FOR THE QUANTITATIVE DETERMINATION OF FECAL PANCREATIC ELASTASE IN HUMAN STOOL SPECIMENS FROM ADULTS AND CHILDREN. THE TEST IS AN AID FOR DIAGNOSIS OF EXOCRINE PANCREATIC INSUFFICIENCY. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST THE CLINICIAN IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS. THE ASSAY MUST BE PERFORMED ON THE LIAISON® XL ANALYZER. ,LIAISON® THYMIDINE KINASE SPECIMEN DILUENT(LIAISON® THYMIDINE KINASE SPECIMEN DILUENT)-THE LIAISON® THYMIDINE KINASE SPECIMEN DILUENT IS INTENDED FOR USE WITH THE LIAISON® THYMIDINE KINASE ASSAY FOR DILUTING SPECIMENS WITH HIGH LEVELS OF THYMIDINE KINASE > 100 U/L. THE LIAISON® THYMIDINE KINASE SPECIMEN DILUENT SET IS DESIGNED FOR USE WITH THE LIAISON® THYMIDINE KINASE (REF 310960) AND THE LIAISON® ANALYZER FAMILY.,LIAISON® Q.S.E.T. BUFFER(LIAISON® Q.S.E.T. BUFFER)-THE DIASORIN LIAISON® Q.S.E.T. BUFFER (QUANTITATIVE STOOL EXTRACTION AND TEST) IS INTENDED FOR USE IN THE PREPARATION OF HUMAN STOOL SPECIMENS FOR TESTING IN DESIGNATED DIASORIN STOOL ASSAYS.,LIAISON® C. DIFFICILE GDH (LIAISON® C. DIFFICILE GDH)-THE DIASORIN LIAISON® C. DIFFICILE GDH ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) INTENDED FOR USE AS A SCREENING ASSAY TO DETECT CLOSTRIDIUM DIFFICILE ANTIGEN, GLUTAMATE DEHYDROGENASE, IN HUMAN FECES FROM PERSONS SUSPECTED OF HAVING C. DIFFICILE DISEASE. THIS ASSAY DOES NOT DISTINGUISH TOXIGENIC FROM NONTOXIGENIC STRAINS OF C. DIFFICILE. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST THE CLINICIAN IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS. TESTING MUST BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® VITAMIN B12(LIAISON® VITAMIN B12)-THE DIASORIN LIAISON® VITAMIN B12 ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM, SST SERUM AND LITHIUM HEPARIN PLASMA. MEASUREMENTS OBTAINED BY THIS DEVICE ARE USED IN THE DIAGNOSIS AND TREATMENT OF ANEMIA'S OF GASTROINTESTINAL MALABSORPTION.

	ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL OR LABORATORY DATA TO ASSIST THE CLINICIAN IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS. THE ASSAY MUST BE PERFORMED ON THE LIAISON® XL ANALYZER. ,LIAISON® CALCITONIN LL GEN(LIAISON® CALCITONIN LL GEN)-THE DIASORIN LIAISON® CALCITONIN LL-GEN ASSAY IS A ONE-STEP SANDWICH CHEMILUMINESCENCE IMMUNOASSAY (CLIA) INTENDED FOR THE QUANTITATIVE DETERMINATION OF CALCITONIN IN HUMAN SERUM. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST IN THE DIAGNOSIS AND MANAGEMENT OF CONDITIONS INVOLVING AN EXCESS OR DEFICIENCY OF CALCITONIN. THE TEST HAS TO BE PERFORMED ON THE LLALSON® ANALYZER FAMILY,LIAISON® FOLATE(LIAISON® FOLATE)-THE DIASORIN LIAISON® FOLATE ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF FOLIC ACID IN HUMAN SERUM, SST SERUM AND LITHIUM HEPARIN PLASMA. FOLIC ACID MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF ANEMIAS. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL OR LABORATORY DATA TO ASSIST THE CLINICIAN IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS. THE ASSAY MUST BE PERFORMED ON THE LIAISON® XL ANALYSER, LIAISON® H. PYLORI SA CONTROL SET(LIAISON® H. PYLORI SA CONTROL SET)-THE DIASORIN LIAISON® H. PYLORISA CONTROLSET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE ACCURACY AND PRECISION OF THE DIASORIN LIAISON® H. PYLORI SA ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® H. PYLORI SA CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® AND LIAISON® XL., LIAISON® MERIDIAN H. PYLORI SA(LIAISON® MERIDIAN H. PYLORI SA)-THE DIASORIN LIAISON® MERIDIAN H. PYLORI SA ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY INTENDED FOR THE QUALITATIVE DETERMINATION OF HELICOBACTER PYLORI (H. PYLORI) ANTIGEN IN HUMAN STOOL. THE TEST IS AN AID IN THE DIAGNOSIS OF PATIENTS SUSPECTED OF H. PYLORI INFECTION AND TO MEASURE POST THERAPY RESPONSE FROM PATIENTS. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST THE CLINICIAN IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.*,LIAISON® C. DIFFICILE TOXINS A&B CONTROL SET(LIAISON® C. DIFFICILE TOXINS A&B CONTROL SET)-THE DIASORIN LIAISON® C. DIFFICILE TOXINS A&B CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY

	CONTROL SAMPLES TO MONITOR THE ACCURACY AND PRECISION OF THE DIASORIN LIAISON® C. DIFFICILE TOXINS A&B ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® C. DIFFICILE TOXINS A&B CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® AND LIAISON® XL.,LIAISON® MERIDIAN H. PYLORI SA CONTROL SET(LIAISON® MERIDIAN H. PYLORI SA CONTROL SET)-THE DIASORIN LIAISON® MERIDIAN H. PYLORI SA CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE OF THE LIAISON® MERIDIAN H. PYLORI SA ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® MERIDIAN H. PYLORI SA CONTROL SET HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® , LIAISON® XL, AND LIAISON® XS. LIAISON® ANALYZER THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XS ANALYZER THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XS ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® H. PYLORI LGG(LIAISON® H. PYLORI LGG)-THE DIASORIN LIAISON® H. PYLORI LGG ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF LGG ANTIBODIES TO HELICOBACTER PYLORI IN HUMAN SERUM FROM SYMPTOMATIC ADULTS AS AN AID IN THE DIAGNOSIS OF HELICOBACTER PYLORI INFECTION. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL OR LABORATORY DATA TO ASSIST THE CLINICIAN IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® ANDROSTENEDIONE CONTROL SET(LIAISON® ANDROSTENEDIONE CONTROL SET)-THE DIASORIN LIAISON® ANDROSTENEDIONE CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE OF THE LIAISON® ANDROSTENEDIONE ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON®

	ANDROSTENEDIONE CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® AND LIAISON® XL.,LIAISON® BAP OSTASE® SPECIMEN DILUENT(LIAISON® BAP OSTASE® SPECIMEN DILUENT)-THE BAP OSTASE® SPECIMEN DILUENT IS INTENDED FOR USE WITH THE LIAISON® BAP OSTASE® ASSAY FOR DILUTING SPECIMENS WITH HIGH LEVELS OF BAP > 120 GLL. THE LIAISON® BAP OSTASE® SPECIMEN DILUENT SET IS DESIGNED FOR USE WITH THE LIAISON@ BAP OSTASE® (T REF I 310970)AND THE LIAISON® ANALYZER FAMILY.,LIAISON® ANDROSTENEDIONE(LIAISON® ANDROSTENEDIONE)-THE DIASORIN LIAISON® ANDROSTENEDIONE ASSAY IS AN IN VITRO DIAGNOSTIC CHEMILUMINESCENT IMMUNOASSAY (CLIA) INTENDED FOR THE QUANTITATIVE DETERMINATION OF 4-ANDROSTENEDIONE IN HUMAN SERUM AND EDTA PLASMA. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST THE CLINICIAN IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS. THE ASSAY MUST BE PERFORMED ON THE LIAISON® ANALYZER FAMILY*.,LIAISON® H. PYLORI LGG CONTROL SET (LIAISON® H. PYLORI LGG CONTROL SET)-THE DIASORIN LIAISON® H. PYLORI LGG CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE OF THE LIAISON® H. PYLORI LGG ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON@ H. PYLORI LGG CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® AND LIAISON® XL.,LIAISON® WASH/SYSTEM LIQUID(LIAISON® WASH/SYSTEM LIQUID)-LIAISON® WASH/SYSTEM LIQUID IS REQUIRED ON THE LIAISON® AND LIAISON® XL ANALYZERS TO WASH THE MAGNETIC PARTICLES USED IN LIAISON® IMMUNOASSAYS. THE LIAISON® WASH/SYSTEM LIQUID IS ALSO REQUIRED FOR RINSING THE PIPETTING NEEDLES AND TUBING SYSTEM OF THE LIAISON® ANALYZER. USE ONLY THE DIASORIN APPROVED 10 L CONTAINERS PROVIDED WITH THE LIAISON® AND LIAISON® XL ANALYZERS.,LIAISON® SAMPLE DILUENT A(LIAISON® SAMPLE DILUENT A)-THE LIAISON® SAMPLE DILUENT A IS INTENDED FOR STOOL SPECIMEN PREPARATION WHEN MENTIONED IN THE RESPECTIVE DIASORIN STOOL ASSAY. STOOL PROCESSING REQUIRES THE USE OF THE DIASORIN LIAISON® STOOL EXTRACTION DEVICES WHICH ARE PROVIDED IN THE RESPECTIVE ASSAYS. THE INFORMATION GIVEN IN THE INSTRUCTIONS FOR USE OF THESE ASSAYS MUST BE STRICTLY FOLLOWED.,LIAISON® HSV-1 CONTROL SET(LIAISON® HSV-1 CONTROL SET)-THE LIAISON® CONTROL HSV-1 IGG ([____REF____] 310831) ARE TO BE USED TO PROVIDE DAILY

	QUALITY CONTROL OF THE LIAISON® HSV 1 TYPE SPECIFIC IGG CHEMILUMINESCENT IMMUNOASSAY (CLIA). THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL., LIAISON® BAP OSTASE® CONTROL SET(LIAISON® BAP OSTASE® CONTROL SET)-THE DIASORIN LIAISON® BAP OSTASE® CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE ACCURACY AND PRECISION OF THE DIASORIN LIAISON® BAP OSTASE® ASSAY. THE PERFORMANCE CHARACTERISTICS OF LIAISON@ CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL., LIAISON® HSV-1(LIAISON® HSV-1)-THE DIASORIN LIAISON® HSV-1 TYPE SPECIFIC IGG ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) TO BE USED WITH THE LIAISON® ANALYZER FOR THE QUALITATIVE DETERMINATION OF SPECIFIC IGG ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE 1 (HSV-1) IN HUMAN SERUM. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY., LIAISON® CALCITONIN LL GEN SPECIMEN DILUENT(LIAISON® CALCITONIN LL GEN SPECIMEN DILUENT)-THE DIASORIN LIAISON® CALCITONIN LL-GEN SPECIMEN DILUENT IS INTENDED FOR USE WITH THE DIASORIN LIAISON® CALCITONIN LL-GEN ASSAY FOR DILUTING SPECIMENS WITH HIGH LEVELS OF CALCITONIN > 2000 PG/ML., LIAISON® N-TACT PTH GEN II SPECIMEN DILUENT(LIAISON® N-TACT PTH GEN II SPECIMEN DILUENT)-THE LIAISON® N-TACT® PTH GEN II SPECIMEN DILUENT IS INTENDED FOR DILUTING PATIENT SPECIMENS WITH HIGH LEVELS OF PTH > 1900 PG/ML WITH THE LIAISON® N-TACT® PTH GEN II ASSAY.,LIAISON® CALPROTECTIN(LIAISON® CALPROTECTIN)-THE DIASORIN LIAISON® CALPROTECTIN ASSAY IS AN IN VITRO DIAGNOSTIC CHEMILUMINESCENT IMMUNOASSAY (CLIA) INTENDED FOR THE QUANTITATIVE MEASUREMENT, IN HUMAN STOOL, OF FECAL CALPROTECTIN, A NEUTROPHILIC PROTEIN THAT IS A MARKEROF MUCOSAL INFLAMMATION. THE LIAISON® CALPROTECTIN ASSAY CAN BE USED AS AN AID IN THE DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (LBD), SPECIFICALLY CROHN'S DISEASE AND ULCERATIVE COLITIS, AND AS AN AID IN DIFFERENTIATION OF IBD FROM IRRITABLE BOWEL SYNDROME (LBS). TEST RESULTS ARE TO BE USED IN CONJUNCTION WITH INFORMATION OBTAINED FROM THE PATIENTS' CLINICAL EVALUATION AND OTHER DIAGNOSTIC PROCEDURES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® N-TACT PTH GEN II CONTROL SET(LIAISON® N-TACT PTH GEN II CONTROL SET)-THE DIASORIN LIAISON® N-TACT® PTH GEN II

	CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE ACCURACY AND PRECISION OF THE DIASORIN LIAISON® N-TACT® PTH GEN II ASSAY. THE PERFORMANCE CHARACTERISTICS OF LIAISON® N-TACT® PTH GEN II CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® AND LIAISON® XL.,LIAISON® CALCITONIN LL GEN CONTROL SET(LIAISON® CALCITONIN LL GEN CONTROL SET)-THE DIASORIN LIAISON® CALCITONIN LL-GEN CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE DIASORIN LIAISON® CALCITONIN LL-GEN ASSAY. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CALCITONIN LL-GEN CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.,LIAISON® N-TACT PTH GEN II(LIAISON® N-TACT PTH GEN II)-THE LIAISON® N-TACT® PTH GEN II IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY (CLIA) INTENDED FOR THE QUANTITATIVE DETERMINATION OF INTACT HUMAN PARATHYROID HORMONE IN SERUM, EDTA AND LITHIUM HEPARIN PLASMA SAMPLES. MEASUREMENTS OF PARATHYROID HORMONE LEVELS ARE USED IN THE DIFFERENTIAL DIAGNOSIS OF HYPERCALCEMIA AND HYPOCALCEMIA RESULTING FROM DISORDERS OF CALCIUM METABOLISM. THE TEST IS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® SHBG(LIAISON® SHBG)-THE DIASORIN LIAISON® SHBG ASSAY IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY (CLIA) INTENDED FOR THE QUANTITATIVE DETERMINATION OF SEX HORMONE-BINDING GLOBULIN IN SERUM AND PLASMA. THE LIAISON® SHBG ASSAY IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF ANDROGEN DISORDERS. THE ASSAY IS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® PROGESTERONE II GEN CONTROL SET(LIAISON® PROGESTERONE II GEN CONTROL SET)-THE DIASORIN LIAISON® PROGESTERONE II GEN CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE OF THE DIASORIN LIAISON® PROGESTERONE II GEN ASSAY ON THE LIAISON® ANALYZER FAMILY. THE PERFORMANCE CHARACTERISTICS OF LIAISON® PROGESTERONE II GEN CONTROL SET HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.,LIAISON® BAP OSTASE®(LIAISON® BAP OSTASE®)-: THE DIASORIN LIAISON@ BAP OSTASE® ASSAY IS A ONE STEP DELAYED ADDITION SANDWICH CHEMILUMINESCENCE IMMUNOASSAY (CLIA) INTENDED FOR THE QUANTITATIVE DETERMINATION OF BONE ALKALINE PHOSPHATASE (BAP) IN

	HUMAN SERUM. THIS DEVICE IS INTENDED TO BE USED AS AN AID IN THE MANAGEMENT OF OSTEOPOROSIS AND PAGET'S DISEASE. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY*.,LIAISON® PROGESTERONE II GEN(LIAISON® PROGESTERONE II GEN)-THE LIAISON® PROGESTERONE II GEN ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® THYMIDINE KINASE CONTROL SET (LIAISON® THYMIDINE KINASE CONTROL SET)-THE DIASORIN LIAISON® THYMIDINE KINASE CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE ACCURACY AND PRECISION OF THE DIASORIN LIAISON® THYMIDINE KINASE ASSAY. THE PEFFORMANCE CHARACTERISTICS OF LIAISON® CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.,LIAISON® ESTRADIOL II GEN CONTROL SET(LIAISON® ESTRADIOL II GEN CONTROL SET)-THE DIASORIN LIAISON® ESTRADIOL II GEN CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE ACCURACY AND PRECISION OF THE DIASORIN LIAISON® ESTRADIOL II GEN ASSAY. THE PERFORMANCE CHARACTERISTICS OF LIAISON® ESTRADIOL II GEN CONTROL SET HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.,LIAISON® H. PYLORI SA(LIAISON® H. PYLORI SA)-THE DIASORIN LIAISON® H. PYLORI SA IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) INTENDED FOR THE QUALITATIVE DETERMINATION OF H. PYLORI STOOL ANTIGEN IN HUMAN FECES ON THE LIAISON® ANALYZER FAMILY. THE TEST IS AN AID IN THE DIAGNOSIS OF H. PYLORI INFECTION AND TO MONITOR RESPONSE DURING AND POST-THERAPY IN PATIENTS. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST THE CLINICIAN IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS.,LIAISON® ESTRADIOL II GEN(LIAISON® ESTRADIOL II GEN)-THE DIASORIN LIAISON® ESTRADIOL II GEN ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) INTENDED FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST IN THE DIAGNOSIS AND MANAGEMENT OF CONDITIONS INVOLVING AN EXCESS OR DEFICIENCY OF ESTRADIOL. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® THYMIDINE KINASE(LIAISON® THYMIDINE KINASE)-THE DIASORIN LIAISON® THYMIDINE KINASE IS A QUANTITATIVE IMMUNOASSAY

	FOR THE IN VITRO DETERMINATION OF THYMIDINE KINASE (TK) ACTIVITY IN HUMAN SERUM OR EDTA PLASMA. DETERMINATION OF SERUM THYMIDINE KINASE ACTIVITY IS USEFUL FOR PROGNOSIS AND MONITORING OF PATIENTS WITH HEMATOLOGICAL MALIGNANCIES.ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST IN THE DIAGNOSIS AND MANAGEMENT OF CONDITIONS INVOLVING HEMATOLOGIC MALIGNANCIES. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY. THIS ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE.,LIAISON® 25 OH VITAMIN D TOTAL SPECIMEN DILUENT(LIAISON® 25 OH VITAMIN D TOTAL SPECIMEN DILUENT)-THE LIAISON® 25 OH VITAMIN D TOTAL SPECIMEN DILUENT MAY BE USED TO DILUTE SPECIMENS WITH VALUES GREATER THAN 150 NG/ML BY THE LIAISON® 25 OH VITAMIN D TOTAL KIT,LIAISON® OSTEOCALCIN CONTROL SET(LIAISON® OSTEOCALCIN CONTROL SET)-THE DIASORIN LIAISON® OSTEOCALCIN CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE ACCURACY AND PRECISION OF THE DIASORIN LIAISON® OSTEOCALCIN ASSAY. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON®AND LIAISON® XL, LIAISON® 25-OH VITAMIN D TOTAL CONTROL SET(LIAISON® 25-OH VITAMIN D TOTAL CONTROL SET)-THE DIASORIN LIAISON® 25 OH VITAMIN D TOTAL CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE OF THE DIASORIN LIAISON® 25 OH VITAMIN D TOTAL ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® 25 OH VITAMIN D TOTAL CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® AND LIAISON® XL.,LIAISON® OSTEOCALCIN(LIAISON® OSTEOCALCIN)-THE DIASORIN LIAISON® OSTEOCALCIN ASSAY IS A CHEMILUMINESCENCE IMMUNOASSAY (CLIA) INTENDED FOR THE QUANTITATIVE DETERMINATION OF OSTEOCALCIN IN HUMAN SERUM. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST IN THE DIAGNOSIS OF POSTMENOPAUSAL OSTEOPOROSIS AND IN THE MANAGEMENT OF CONDITIONS INVOLVING AN EXCESS OR DEFICIENCY OF OSTEOCALCIN. THIS ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® 25-OH VITAMIN D TOTAL ASSAY(LIAISON® 25-OH VITAMIN D TOTAL ASSAY)-THE LIAISON® 25 OH VITAMIN D TOTAL ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE

	DETERMINATION OF 25-HYDROXYVITAMIN D AND OTHER HYDROXYLATED VITAMIN D METABOLITES IN HUMAN SERUM, EDTA-PLASMA OR LITHIUM HEPARIN PLASMA TO BE USED IN THE ASSESSMENT OF VITAMIN D SUFFICIENCY USING THE LIAISON® ANALYZER FAMILY*. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL OR LABORATORY DATA TO ASSIST THE CLINICIAN IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS IN AN ADULT POPULATION.,LIAISON® SHBG CONTROL SET(LIAISON® SHBG CONTROL SET)-THE DIASORIN LIAISON® SHBG CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE OF THE LIAISON® SHBG ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® SHBG CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® AND LIAISON® XL.,LIAISON® TESTOSTERONE CONTROL SET(LIAISON® TESTOSTERONE CONTROL SET)-THE DIASORIN LIAISON® TESTOSTERONE CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE ACCURACY AND PRECISION OF THE DIASORIN LIAISON® TESTOSTERONE IMMUNOASSAY. THE PERFORMANCE CHARACTERISTICS OF LIAISON® TESTOSTERONE CONTROL SET HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.,LIAISON® OSTEOCALCIN SPECIMEN DILUENT (LIAISON® OSTEOCALCIN SPECIMEN DILUENT)-THE LIAISON® OSTEOCALCIN SPECIMEN DILUENT IS INTENDED FOR USE WITH THE LIAISON® OSTEOCALCIN ASSAY FOR DILUTING SPECIMENS WITH HIGH LEVELS OF OSTEOCALCIN > 300 NG/ML. THE LIAISON@ OSTEOCALCIN SPECIMEN DILUENT SET IS DESIGNED FOR USE WITH THE LIAISON® OSTEOCALCIN (REF 310950) AND THE LIAISON® ANALYZER FAMILY.,LIAISON® TESTOSTERONE(LIAISON® TESTOSTERONE)-THE LIAISON® TESTOSTERONE IS A DIRECT, COMPETITIVE, CHEMILUMINESCENCE IMMUNOASSAY (CLIA) INTENDED FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM AND EDTA PLASMA ON THE LIAISON® ANALYZER. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE. MEASUREMENT OF TESTOSTERONE IS USED IN THE DIAGNOSIS AND TREATMENT OF DISORDERS INVOLVING THE MALE SEX HORMONES (ANDROGENS), INCLUDING PRIMARY AND SECONDARY HYPOGONADISM, DELAYED OR PRECOCIOUS PUBERTY, IMPOTENCE IN MALES AND, IN FEMALES HIRSUTISM (EXCESSIVE HAIR) AND VIRILIZATION (MASCULINIZATION) DUE TO TUMORS, POLYCYSTIC OVARIES, AND ADRENOGENITAL SYNDROMES.THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY*.,

	LIAISON® ROTAVIRUS CONTROL SET(LIAISON® ROTAVIRUS CONTROL SET)-THE DIASORIN LIAISON® ROTAVIRUS CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE ACCURACY AND PRECISION OF THE DIASORIN LIAISON® ROTAVIRUS ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® ROTAVIRUS CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON®, LIAISON® XL AND LIAISON® XS. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XS ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XS ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® ALDO NEUTRALIZATION BUFFER(LIAISON® ALDO NEUTRALIZATION BUFFER)-THE DIASORIN LIAISON® ALDO NEUTRALIZATION BUFFER IS INTENDED TO NEUTRALIZE URINE SAMPLES AFTER ACID HYDROLYSIS AND BEFORE URINE SAMPLES ARE TESTED ON THE LIAISON® ALDOSTERONE ASSAY.,LIAISON® SARS-COV-2 TRIMERICS IGG(LIAISON® SARS-COV-2 TRIMERICS IGG)-THE LIAISON® SARS-COV-2 TRIMERICS IGG ASSAY USES CHEMILUMINESCENCE IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF ANTI-TRIMERIC SPIKE PROTEIN SPECIFIC IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM OR PLASMA SAMPLES. THE ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF COVID-19 AND TO SUPPORT THE STUDY OF THE IMMUNE STATUS OF INFECTED PATIENTS AND TO ASSESS IGG RESPONSE AGAINST SARS-COV-2 IN VACCINE RECIPIENTS, BY PROVIDING AN INDICATION OF THE PRESENCE OF NEUTRALIZING IGG ANTIBODIES AGAINST SARS-COV-2. RESULTS FROM THE LIAISON® SARS-COV-2 TRIMERICS IGG ASSAY SHOULD NOT BE USED AS THE SOLE BASIS TO DIAGNOSE OR EXCLUDE SARS-COV-2 INFECTION OR TO INFORM ABOUT INFECTION STATUS. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY*.,LIAISON® ALDOSTERONE CONTROL SET (LIAISON® ALDOSTERONE CONTROL SET)-THE DIASORIN LIAISON®

	ALDOSTERONE CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE ACCURACY OF THE DIASORIN LIAISON® ALDOSTERONE ASSAY. THE PERFORMANCE CHARACTERISTICS OF LIAISON® ALDOSTERONE CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL., LIAISON® ADENOVIRUS(LIAISON® ADENOVIRUS)-THE DIASORIN LIAISON® ADENOVIRUS ASSAY IS AN IN VITRO DIAGNOSTIC CHEMILUMINESCENT IMMUNOASSAY (CLIA) INTENDED FOR THE QUALITATIVE DETERMINATION OF ADENOVIRUS ANTIGEN IN HUMAN STOOL SPECIMENS. THIS TEST IS USED PRIMARILY AS AN AID FOR THE DIAGNOSIS OF ACUTE VIRAL GASTROENTERITIS. TEST RESULTS ARE TO BE USED IN CONJUNCTION WITH INFORMATION OBTAINED FROM THE PATIENT'S CLINICAL EVALUATION AND OTHER DIAGNOSTIC PROCEDURES. THE ASSAY MUST BE PERFORMED ON THE LIAISON® ANALYZER FAMILY*.,LIAISON® ALDOSTERONE (LIAISON® ALDOSTERONE)-THE LIAISON® ALDOSTERONE ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY AND IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ALDOSTERONE IN HUMAN SERUM, EDTA PLASMA AND TREATED URINE SAMPLES. ALDOSTERONE MEASUREMENTS ARE INTENDED FOR USE IN THE DIAGNOSIS AND TREATMENT OF PRIMARY ALDOSTERONISM (A DISORDER CAUSED BY EXCESSIVE SECRETION OF ALDOSTERONE BY THE ADRENAL GLAND), HYPERTENSION CAUSED BY PRIMARY ALDOSTERONISM, SELECTIVE HYPOALDOSTERONISM, EDEMATOUS STATES AND OTHER CONDITIONS OF ELECTROLYTE IMBALANCE. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON® EHEC TOXINS CONTROL SET(LIAISON® EHEC TOXINS CONTROL SET)-THE DIASORIN LIAISON® EHEC TOXINS CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE ACCURACY AND PRECISION OF THE DIASORIN LIAISON® EHEC TOXINS ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® EHEC TOXINS CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® AND LIAISON® XL. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL

	VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® XL 1,25 DIHYDROXYVITAMIN D SPECIMEN DILUENT(LIAISON® XL 1,25 DIHYDROXYVITAMIN D SPECIMEN DILUENT)-THE DIASORIN LIAISON® XL 1,25 DIHYDROXYVITAMIN D DILUENT IS INTENDED FOR DILUTING PATIENT SPECIMENS WITH HIGH LEVELS OF 1,25 (OH)2 D >200 PG/ML WITH THE LIAISON® XL 1,25 DIHYDROXYVITAMIN D ASSAY.,LIAISON® 25 OH VITAMIN D TOTAL ASSAY 200(LIAISON® 25 OH VITAMIN D TOTAL ASSAY 200)-THE LIAISON® 25 OH VITAMIN D TOTAL ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUANTITATIVE DETERMINATION OF 25-HYDROXYVITAMIN D AND OTHER HYDROXYLATED VITAMIN D METABOLITES IN HUMAN SERUM, EDTA-PLASMA OR LITHIUM HEPARIN PLASMA TO BE USED IN THE ASSESSMENT OF VITAMIN D SUFFICIENCY USING THE LIAISON® ANALYZER FAMILY*. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL OR LABORATORY DATA TO ASSIST THE CLINICIAN IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS IN AN ADULT POPULATION.,LIAISON® XL 1,25 DIHYDROXYVITAMIN D CONTROLS(LIAISON® XL 1,25 DIHYDROXYVITAMIN D CONTROLS)-THE DIASORIN LIAISON® XL 1,25 DIHYDROXYVITAMIN D CONTROLS ARE INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE OF THE DIASORIN LIAISON® XL 1,25 DIHYDROXYVITAMIN D ASSAY. THE PERFORMANCE CHARACTERISTICS OF LIAISON® LIAISON® XL 1,25 DIHYDROXYVITAMIN D CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® XL.,LIAISON® CAMPYLOBACTER AG(LIAISON® CAMPYLOBACTER AG)-THE DIASORIN LIAISON® CAMPYLOBACTER AG ASSAY USES CHEMILUMINESCENT IMMUNOASSAY (CLIA) TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF CAMPYLOBACTER ANTIGENS IN HUMAN STOOL SPECIMENS. THE TEST MAY BE USED AS AN AID IN THE DIAGNOSIS OF ACUTE BACTERIAL GASTROENTERITIS. THE ASSAY MUST BE PERFORMED ON THE LIAISON® ANALYZER FAMILY*.,LIAISON® XL 1,25 DIHYDROXYVITAMIN D(LIAISON® XL 1,25 DIHYDROXYVITAMIN D)-THE DIASORIN LIAISON® XL 1,25 DIHYDROXYVITAMIN D IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY (CLIA) INTENDED FOR THE QUANTITATIVE DETERMINATION OF 1,25 DIHYDROXYVITAMIN D (1,25(OH)2D) IN SERUM, EDTA AND LITHIUM HEPARIN PLASMA. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST THE CLINICIAN IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS IN ADULT POPULATIONS. THE TEST IS TO BE PERFORMED ON THE LIAISON® XL

	ANALYZER.,LIAISON® EHEC TOXINS(LIAISON® EHEC TOXINS)-THE DIASORIN LIAISON® EHEC TOXINS ASSAY IS AN IN VITRO DIAGNOSTIC CHEMILUMINESCENT IMMUNOASSAY (CLIA) INTENDED FOR THE QUALITATIVE DETECTION OF SHIGA TOXINS 1 AND 2 IN STOOL SPECIMENS, BROTH CULTURES, AND FROM INDIVIDUAL COLONIES OR COLONY SWEEPS OF AGAR PLATES. THE LIAISON® EHEC TOXINS ASSAY IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF ENTEROHEMORRHAGIC E. COLI (EHEC) INFECTIONS. TEST RESULTS ARE TO BE USED IN CONJUNCTION WITH INFORMATION OBTAINED FROM THE PATIENTS' CLINICAL EVALUATION AND OTHER DIAGNOSTIC PROCEDURES. THE ASSAY MUST BE PERFORMED ON THE LIAISON® ANALYZER FAMILY*., LIAISON® SARS-COV-2 TRIMERICS IGG CONTROL SET(LIAISON® SARS-COV-2 TRIMERICS IGG CONTROL SET)-THE DIASORIN LIAISON® SARS-COV-2 TRIMERICS IGG CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE OF THE LIAISON® SARS-COV-2 TRIMERICS IGG ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® SARS-COV-2 TRIMERICS IGG CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON® XL AND LIAISON® XS. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XS ANALYZER THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XS ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® CAMPYLOBACTER AG CONTROL SET(LIAISON® CAMPYLOBACTER AG CONTROL SET)-THE DIASORIN LIAISON® CAMPYLOBACTER AG CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE OF THE LIAISON® CAMPYLOBACTER AG ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® CAMPYLOBACTER AG CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON®, LIAISON® XL AND LIAISON® XS. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S

	MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XS ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XS ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.,LIAISON® TRIMERICS IGG DILUENT ACCESSORY(LIAISON® TRIMERICS IGG DILUENT ACCESSORY)-THE DIASORIN LIAISON® TRIMERICS IGG DILUENT ACCESSORY IS INTENDED FOR DILUTING SPECIMENS WITH HIGH LEVELS OF ANTI-TRIMERIC SPIKE PROTEIN SPECIFIC IGG ANTIBODIES TO SARS-COV-2 ABOVE THE ASSAY MEASURING RANGE > 2080 BAU/ML FOR USE WITH THE LIAISON® SARS-COV-2 TRIMERICS IGG ASSAY (REF 311510).,LIAISON® ROTAVIRUS(LIAISON® ROTAVIRUS)-THE DIASORIN LIAISON® ROTAVIRUS ASSAY IS AN IN VITRO DIAGNOSTIC CHEMILUMINESCENT IMMUNOASSAY (CLIA) INTENDED FOR THE QUALITATIVE DETERMINATION OF ROTAVIRUS ANTIGEN IN HUMAN STOOL SPECIMENS. THIS TEST IS USED PRIMARILY AS AN AID FOR THE DIAGNOSIS OF ACUTE VIRAL GASTROENTERITIS. TEST RESULTS ARE TO BE USED IN CONJUNCTION WITH INFORMATION OBTAINED FROM THE PATIENTS' CLINICAL EVALUATION AND OTHER DIAGNOSTIC PROCEDURES. THE ASSAY MUST BE PERFORMED ON THE LIAISON® ANALYZER FAMILY*.,LIAISON® ADENOVIRUS CONTROL SET(LIAISON® ADENOVIRUS CONTROL SET)-THE DIASORIN LIAISON® ADENOVIRUS CONTROL SET IS INTENDED FOR USE AS ASSAYED QUALITY CONTROL SAMPLES TO MONITOR THE PERFORMANCE OF THE DIASORIN LIAISON® ADENOVIRUS ASSAY. THE PERFORMANCE CHARACTERISTICS OF THE LIAISON® ADENOVIRUS CONTROLS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAY OR INSTRUMENT PLATFORMS DIFFERENT FROM THE LIAISON®, LIAISON® XL AND LIAISON® XS. LIAISON® ANALYZER. THE CERTIFICATE OF ANALYSIS GIVES SPECIFIC INFORMATION ON THE LOT OF CONTROLS, WHICH SHOULD BE MANUALLY ENTERED IN THE ANALYZER SOFTWARE PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL. LIAISON® XL ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XL ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER

		OPERATOR'S MANUAL. LIAISON® XS ANALYZER. THE CERTIFICATE OF ANALYSIS BAR CODES GIVE SPECIFIC INFORMATION ON THE LOT OF CONTROLS AND SHOULD BE READ BY THE HAND-HELD BAR CODE SCANNER OF THE LIAISON® XS ANALYZER PRIOR TO LOADING THE CONTROL VIALS ON BOARD. FOR DETAILS, REFER TO THE ANALYZER OPERATOR'S MANUAL.
106	IMP/IVD/2019/000023	1.License Holder Name: MICROGENE DIAGNOSTIC SYSTEMS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(ACCUSURE GOLD)-ACCUSURE GOLD BLOOD GLUCOSE TEST STRIPS IS USED ALONG WITH BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO MONITOR BLOOD GLUCOSE IN WHOLE BLOOD, BLOOD GLUCOSE METER(ACCUSURE GOLD BLOOD GLUCOSE METER) -THE ACCUSURE GOLD BLOOD GLUCOSE METER IS USED WITH THE ACCUSURE GOLD BLOOD GLUCOSE TEST STRIP TO QUANTITATIVELY MEASURE GLUCOSE IN WHOLE BLOOD.
107	IMP/IVD/2019/000024	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BUFFERED SOLUTION FOR GENERAL LAB USE(BD FACS LYSING SOLUTION)-BD FACS™ LYSING SOLUTION IS INTENDED FOR LYSING RED BLOOD CELLS FOLLOWING DIRECT IMMUNOFLUORESCENCE STAINING OF HUMAN PERIPHERAL BLOOD CELLS WITH MONOCLONAL ANTIBODIES PRIOR TO FLOW CYTOMETRIC ANALYSIS.,BUFFERED SOLUTION FOR GENERAL LAB USE(BD STABILIZING FIXATIVE)-BD™ STABILIZING FIXATIVE (3X CONCENTRATE) IS INTENDED FOR PRESERVING IMMUNOFLUORESCENCE STAINING OF HUMAN PERIPHERAL BLOOD CELLS WITH MONOCLONAL ANTIBODIES PRIOR TO FLOW CYTOMETRIC ANALYSIS.,BUFFERED SOLUTION FOR GENERAL LAB USE(BD STABILIZING FIXATIVE (3X CONCENTRATE))-BD™ STABILIZING FIXATIVE IS INTENDED FOR PRESERVING IMMUNOFLUORESCENCE STAINING OF HUMAN PERIPHERAL BLOOD CELLS PRIOR TO FLOW CYTOMETRIC ANALYSIS
108	IMP/IVD/2019/000025	1.License Holder Name: ARKRAY HEALTHCARE PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TEST STRIP(POCKETCHEM HEMOG)-THE POCKET CHEMTM HEMO G TEST STRIP IS DESIGNED FOR QUANTITATIVE HEMOGLOBIN DETERMINATION FROM WHOLE BLOOD

109	IMP/IVD/2019/000026	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMATOLOGY CALIBRATOR/CONTROL IVDS(BD™ MULTI-CHECK CONTROL)-BD™ MULTI-CHECK CONTROL IS INTENDED AS A COMPLETE PROCESS CONTROL FOR IMMUNOPHENOTYPING BY FLOW CYTOMETRY. IT IS A CONTROL FOR ANTIBODY STAINING, RED BLOOD CELL (RBC) LYSIS, INSTRUMENT SETUP AND PERFORMANCE, AND DATA ANALYSIS ON BD FACSLYRIC™, BD FACSCANTO™ II, BD FACSCANTO™, AND BD FACSCALIBUR™ FLOW CYTOMETERS. THE BD MULTI-CHECK CONTROL IS ALSO INTENDED AS A CD4 AND %CD4 PROCESS CONTROL FOR ANTIBODY STAINING, INSTRUMENT PERFORMANCE, AND DATA ANALYSIS ON THE BD FACSPRESTO™ SYSTEM, AN IMAGING CYTOMETER.,HAEMATOLOGY CALIBRATOR/CONTROL IVDS (BD STEM CELL CONTROL KIT)-THE BD™ STEM CELL CONTROL IS INTENDED AS A COMPLETE, TWO-LEVEL, PROCESS CONTROL FOR IMMUNOPHENOTYPING AND ENUMERATION OF LEUCOCYTES BY FLOW CYTOMETRY. IT IS A CONTROL FOR ANTIBODY STAINING, RED BLOOD CELL (RBC) LYSIS, INSTRUMENT SETUP AND PERFORMANCE, AND DATA ANALYSIS.,HEMATOLOGY CALIBRATOR/CONTROL IVDS (BD™ MULTI-CHECK CD4 LOW CONTROL)-BD™ MULTI-CHECK CD4 LOW CONTROL IS INTENDED AS A COMPLETE PROCESS CONTROL FOR IMMUNOPHENOTYPING BY FLOW CYTOMETRY. IT IS A CONTROL FOR ANTIBODY STAINING, RED BLOOD CELL (RBC) LYSIS, INSTRUMENT SETUP AND PERFORMANCE, AND DATA ANALYSIS ON BD FACSLYRIC™, BD FACSCANTO™ II, BD FACSCANTO™, AND BD FACSCALIBUR™ FLOW CYTOMETERS. THE BD MULTI-CHECK CD4 LOW CONTROL IS ALSO INTENDED TO BE A CD4 AND %CD4 PROCESS CONTROL FOR ANTIBODY STAINING, INSTRUMENT PERFORMANCE, AND DATA ANALYSIS ON THE BD FACSPRESTO™ SYSTEM, AN IMAGING CYTOMETER.,HAEMATOLOGY CALIBRATOR/CONTROL IVDS (BD RETIC COUNT CONTROL KIT)-THE BD RETIC-COUNT™ CONTROL IS A TRILEVEL,ASSAYED HEMATOLOGY CONTROL DESIGNED TO DOCUMENT AND MONITOR VALUES OBTAINED FROM MANUAL AND AUTOMATED RETICULOCYTE COUNTING METHODS.,HAEMATOLOGY CALIBRATOR/ CONTROL IVDS(BD LEUCOCOUNT CONTROL RBC)-THE BD LEUCOCOUNT™ RBC CONTROL KIT CONSISTS OF RED BLOOD CELL (RBC) LOW AND RBC HIGH PROCESS CONTROLS INTENDED FOR USE WITH THE BD LEUCOCOUNT™ KIT TO MONITOR THE PROCESS FOR ENUMERATION OF RESIDUAL LEUCOCYTES IN LEUCOREDUCED RBC PRODUCTS, INCLUDING DILUTION, STAINING,INSTRUMENT SETUP, AND WHITE BLOOD CELL (WBC) ENUMERATION. FOR IN VITRO DIAGNOSTIC USE.,HAEMATOLOGY CALIBRATOR/CONTROL IVDS(BD MULTI-CHECK CD4 LOW CONTROL)-THE BD™ MULTI-CHECK CD4 LOW

	CONTROL IS INTENDED AS A COMPLETE PROCESS CONTROL FOR IMMUNOPHENOTYPING BY FLOW CYTOMETRY. IT IS A CONTROL FOR ANTIBODY STAINING, RED BLOOD CELL (RBC) LYSIS, INSTRUMENT SETUP AND PERFORMANCE, AND DATA ANALYSIS.,HAEMATOLOGY CALIBRATOR/ CONTROL IVDS(BD LEUCOCOUNT COMBO CONTROL KIT, (PLT CONTROL AND RBC CONTROL, 25 TESTS EACH))-THE BD LEUCOCOUNT™ RBC CONTROL KIT CONSISTS OF RED BLOOD CELL (RBC) LOW AND RBC HIGH PROCESS CONTROLS INTENDED FOR USE WITH THE BD LEUCOCOUNT™ KIT TO MONITOR THE PROCESS FOR ENUMERATION OF RESIDUAL LEUCOCYTES IN LEUCOREDUCED RBC PRODUCTS, INCLUDING DILUTION, STAINING, INSTRUMENT SETUP, AND WHITE BLOOD CELL (WBC) ENUMERATION. FOR IN VITRO DIAGNOSTIC USE. AND THE BD LEUCOCOUNT™ PLT CONTROL KIT CONSISTS OF PLATELET (PLT) LOW AND PLT HIGH PROCESS CONTROLS INTENDED FOR USE WITH THE BD LEUCOCOUNT™ KIT TO MONITOR THE PROCESS FOR ENUMERATION OF RESIDUAL LEUCOCYTES IN LEUCOREDUCED PLATELET PRODUCTS, INCLUDING DILUTION, STAINING,INSTRUMENT SETUP, AND WHITE BLOOD CELL (WBC) ENUMERATION. FOR IN VITRO DIAGNOSTIC USE., HAEMATOLOGY CALIBRATOR/CONTROL IVDS(BD MULTI-CHECK CONTROL)-THE BD™ MULTI-CHECK CONTROL IS INTENDED AS A COMPLETE PROCESS CONTROL FOR IMMUNOPHENOTYPING BY FLOW CYTOMETRY. IT IS A CONTROL FOR ANTIBODY STAINING, RED BLOOD CELL (RBC) LYSIS, INSTRUMENT SETUP AND PERFORMANCE, AND DATA ANALYSIS,HAEMATOLOGY CALIBRATOR/ CONTROL IVDS(BD LEUCOCOUNT™ PLT CONTROL. HIGH PLT)-THE BD LEUCOCOUNT™ PLT CONTROL KIT CONSISTS OF PLATELET (PLT) LOW AND PLT HIGH PROCESS CONTROLS INTENDED FOR USE WITH THE BD LEUCOCOUNT™ KIT TO MONITOR THE PROCESS FOR ENUMERATION OF RESIDUAL LEUCOCYTES IN LEUCOREDUCED PLATELET PRODUCTS, INCLUDING DILUTION, STAINING, INSTRUMENT SETUP, AND WHITE BLOOD CELL (WBC) ENUMERATION. FOR IN VITRO DIAGNOSTIC USE.,HAEMATOLOGY CALIBRATOR/CONTROL IVDS(BD LEUCOCOUNT PLT CONTROL KIT (25 TESTS))-THE BD LEUCOCOUNT™ PLT CONTROL IS USED TO MONITOR METHODS FOR ENUMERATION OF RESIDUAL LEUCOCYTES IN LEUCOREDUCED PLATELET PRODUCTS, INCLUDING THE DILUTION AND STAINING PROCESS, METHOD SETUP, AND WBC ENUMERATION,HAEMATOLOGY CALIBRATOR/CONTROL IVDS(BD LEUCOCOUNT RBC CONTROL KIT (25 TESTS))-THE BD LEUCOCOUNT™ RBC CONTROL IS USED TO MONITOR METHODS FOR ENUMERATION OF RESIDUAL LEUCOCYTES IN LEUCOREDUCED RBC PRODUCTS, INCLUDING THE DILUTION AND STAINING PROCESS, METHOD SETUP, AND WBC ENUMERATION., HAEMATOLOGY CALIBRATOR/CONTROL IVDS(BD LEUCOCOUNT

	COMBO CONTROL KIT (25 TESTS))-THE BD LEUCOCOUNT™ RBC CONTROL IS USED TO MONITOR METHODS FOR ENUMERATION OF RESIDUAL LEUCOCYTES IN LEUCOREDUCED RBC PRODUCTS, INCLUDING THE DILUTION AND STAINING PROCESS, METHOD SETUP, AND WBC ENUMERATION.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

110	IMP/IVD/2019/000027	1.License Holder Name: POCT SERVICES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URIC ACID MONO SL (ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,ACID SOLUTION(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,SYSTEM SOLUTION(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,SYSTEM CLEANING SOLUTION(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,URIC ACID SL(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,TOTAL PROTEIN PLUS(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,PHOSPHORUS(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,MICROPROTEIN PLUS STANDARD 100MG/DL (ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,MICROPROTEIN PLUS (ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,MAGNESIUM XYLIDYL (ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,UREA UV SL(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,TRIGLYCERIDES MONO SL NEW (ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,TRIGLYCERIDES SL (ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,LDHL SL(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,LIPASE SL(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,ISE CONTROL II(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,ISE CONTROL I(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,ISE REFERENCE SOLUTION(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,ISE DILUENT(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,ISE CLEANER/CONDITIONER(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,ISE CALIBRATORS(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,IRON FERENE(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,HBA1C(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,GAMMA-GT PLUS SL(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,ELITROL II (ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,ELITROL I(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,ELICAL 2(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,CREATININE PAP SL(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,CREATININE JAFFE(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,CK NAC SL(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,CK-MB CONTROL(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,CK-MB SL(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,CHOLESTEROL LDL SL 2G(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,CHOLESTEROL HDL 2G CALIBRATOR(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE, CHOLESTEROL SL(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE, CHOLESTEROL HDL SL 2G(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE, CHLORIDE(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,CALCIUM ARSENAZO(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,CHOLESTEROL LDL 2G CALIBRATOR(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE, BILIRUBIN TOTAL & DIRECT 4+1(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,BILIRUBIN TOTAL 4+1(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE, BILIRUBIN DIRECT 4+1(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE, AST/GOT 4+1 SL(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,AMYLASE

		SL(ELITECH)-FOR IN-VITRO DIAGNOSTICS USE,ALT/GPT 4+1 SL (ELITECH)-FOR IN-VITRO DIAGNOSTIC USE ONLY,HBA1C CALIBRATOR SET(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,HBA1C CONTROL L+H (ELITECH)-FOR IN-VITRO DIAGNOSTIC USE,ALP (DEA) SL(ELITECH)-FOR IN-VITRO DIAGNOSTICS USE,ALBUMIN(ELITECH)-FOR IN-VITRO DIAGNOSTIC USE
111	IMP/IVD/2019/000029	1.License Holder Name: M/S.ROCHE DIABETES CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROL SOLUTION (ACCU-CHEK GUIDE CONTROLS)-THE CONTROL SOLUTION IS INTENDED FOR PERFORMING CONTROL TESTS ON ACCU-CHEK GUIDE BLOOD GLUCOSE METERS AND ACCU-CHEK GUIDE TEST STRIPS. TESTING CONTROL SOLUTIONS WITH KNOWN GLUCOSE LEVELS ESTABLISHES THAT THE OPERATOR AND THE SYSTEM ARE PERFORMING ACCEPTABLY. CONTROL RESULTS MUST BE WITHIN THE DEFINED ACCEPTABLE RANGES BEFORE VALID PATIENT TESTING IS ALLOWED.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

112	IMP/IVD/2019/000031	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALINITY I HE4 REAGENT KIT(ALINITY I HE4 REAGENT KIT)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF HE4 ANTIGEN IN HUMAN SERUM ON THE ALINITY I ANALYZER.THE ALINITY I HE4 ASSAY IS TO BE USED AS AN AID IN MONITORING RECURRENCE OR PROGRESSIVE DISEASE IN PATIENTS WITH EPITHELIAL OVARIAN CANCER. ,ARCHITECT CA 125 II CONTROLS (ARCHITECT CA 125 II CONTROLS)-THE ARCHITECT CA 125 II CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF OC125 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA.,ALINITY I CA 15-3 REAGENT KIT (ALINITY I CA 15-3 REAGENT KIT)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF DF3 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER. THE ALINITY I CA 15-3 ASSAY IS TO BE USED AS AN AID IN THE MANAGEMENT OF STAGE II AND III IN BREAST CANCER PATIENTS.,ARCHITECT BNP CONTROLS (ARCHITECT BNP CONTROLS)-THE ARCHITECT BNP CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM (REAGENTS, CALIBRATORS AND INSTRUMENT), WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN B-TYPE NATRIURETIC PEPTIDE (BNP) IN HUMAN EDTA PLASMA.,ALINITY I CA 125 LL REAGENT KIT(ALINITY I CA 125 LL REAGENT KIT)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF OC 125 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.THE ALINITY I CA 125 II ASSAY IS TO BE USED AS AN AID IN MONITORING RESPONSE TO THERAPY FOR PATIENTS WITH EPITHELIAL OVARIAN CANCER,ARCHITECT CA 19-9 XR REAGENT KIT(ARCHITECT CA 19-9 XR REAGENT KIT)-THE ARCHITECT CA 19-9XR ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF 1116-NS-19-9 REACTIVE DETERMINANTS IN HUMAN SERUM OR PLASMA ON THE ARCHITECT ISYSTEM.,ALINITY I CA 19-9XR REAGENT KIT(ALINITY I CA 19-9XR REAGENT KIT)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF 1116-NS-19-9 REACTIVE DETERMINANTS IN HUMAN SERUM OR PLASMA ON THE ALINITY I ANALYZER. THE ALINITY I CA 19-9XR ASSAY IS TO BE USED AS AN AID IN THE MANAGEMENT OF PANCREATIC CANCER PATIENTS IN CONJUNCTION WITH OTHER CLINICAL METHODS.,NSE CALIBRATORS(NSE CALIBRATORS)-THE NSE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF NEURONSPECIFIC ENOLASE (NSE) IN HUMAN SERUM.,ALINITY I HE4

	CONTROLS(ALINITY I HE4 CONTROLS)-INTENDED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HE4 ANTIGEN IN HUMAN SERUM,ARCHITECT GALECTIN-3 REAGENT KIT(ARCHITECT GALECTIN-3 REAGENT KIT)-THE ARCHITECT GALECTIN-3 ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF GALECTIN-3 IN HUMAN SERUM AND EDTA PLASMA.,ALINITY I HE4 CALIBRATORS(ALINITY I HE4 CALIBRATORS)-INTENDED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HE4 ANTIGEN IN HUMAN SERUM., NSE CONTROLS(NSE CONTROLS)-THE NSE CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF NEURON-SPECIFIC ENOLASE (NSE) IN HUMAN SERUM.,ALINITY I CA 15-3 CONTROLS(ALINITY I CA 15-3 CONTROLS)-INTENDED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF DF3 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA.,ARCHITECT METHOTREXATE EXTENDED RANGE CONTROLS(ARCHITECT METHOTREXATE EXTENDED RANGE CONTROLS)-THE ARCHITECT METHOTREXATE EXTENDED RANGE CONTROLS ARE USED TO PROVIDE ASSURANCE OF ACCURACY WHEN PERFORMING MANUAL SAMPLE DILUTIONS., ALINITY I CA 15-3 CALIBRATORS(ALINITY I CA 15-3 CALIBRATORS)-INTENDED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF DF3 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA.,ARCHITECT METHOTREXATE REAGENT KIT(ARCHITECT METHOTREXATE REAGENT KIT)-THE ARCHITECT METHOTREXATE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF METHOTREXATE IN HUMAN SERUM AND PLASMA ON THE ARCHITECT ISYSTEM.,ALINITY I CA 125 II CONTROLS(ALINITY I CA 125 II CONTROLS)-INTENDED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF OC 125 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA., ARCHITECT HE4 CALIBRATORS(ARCHITECT HE4 CALIBRATORS)-THE ARCHITECT HE4 CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HE4 ANTIGEN IN HUMAN SERUM.,ALINITY I CA 125 II CALIBRATORS(ALINITY I CA 125 II CALIBRATORS)-INTENDED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF OC 125 DEFINED ANTIGEN IN

	HUMAN SERUM AND PLASMA.,ALINITY I GALECTIN-3 CALIBRATORS (ALINITY I GALECTIN-3 CALIBRATORS)-THE ALINITY I GALECTIN-3 CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF GALECTIN-3 IN HUMAN SERUM AND EDTA PLASMA.,ALINITY I CA 19-9XR CONTROLS(ALINITY I CA 19-9XR CONTROLS)-INTENDED FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER (REAGENTS, CALIBRATORS AND INSTRUMENT), WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF 1116-NS-19-9 REACTIVE DETERMINANTS IN HUMAN SERUM OR PLASMA.,ARCHITECT METHOTREXATE CALIBRATORS(ARCHITECT METHOTREXATE CALIBRATORS)-THE ARCHITECT METHOTREXATE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF METHOTREXATE IN HUMAN SERUM AND PLASMA.,ALINITY I CA 19-9XR CALIBRATORS (ALINITY I CA 19-9XR CALIBRATORS)-INTENDED ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF 1116-NS-19-9 REACTIVE DETERMINANTS IN HUMAN SERUM OR PLASMA.,ARCHITECT CA 15-3 CALIBRATORS(ARCHITECT CA 15-3 CALIBRATORS)-THE ARCHITECT CA 15-3 CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF DF3 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA.,ALINITY I METHOTREXATE CALIBRATORS(ALINITY I METHOTREXATE CALIBRATORS)-THE ALINITY I METHOTREXATE CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF METHOTREXATE IN HUMAN SERUM AND PLASMA.,ARCHITECT GALECTIN-3 CALIBRATORS(ARCHITECT GALECTIN-3 CALIBRATORS)-THE ARCHITECT GALECTIN-3 CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF GALECTIN-3 IN HUMAN SERUM AND EDTA PLASMA.,ARCHITECT CYFRA 21-1 CALIBRATORS (ARCHITECT CYFRA 21-1 CALIBRATORS)-THE ARCHITECT CYFRA 21-1 CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN CYTOKERATIN 19 FRAGMENTS IN HUMAN SERUM AND PLASMA. ,ARCHITECT METHOTREXATE CONTROLS(ARCHITECT METHOTREXATE CONTROLS)-THE ARCHITECT METHOTREXATE LOW, MEDIUM, AND HIGH CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF METHOTREXATE IN HUMAN

	SERUM AND PLASMA.,ALINITY I CYFRA 21-1 REAGENT KIT(ALINITY I CYFRA 21-1 REAGENT KIT)-THE ALINITY I CYFRA 21-1 ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN CYTOKERATIN 19 FRAGMENTS IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ALINITY I GALECTIN-3 CONTROLS(ALINITY I GALECTIN-3 CONTROLS)-THE ALINITY I GALECTIN-3 CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF GALECTIN-3 IN HUMAN SERUM AND EDTA PLASMA.,ALINITY I METHOTREXATE REAGENT KIT(ALINITY I METHOTREXATE REAGENT KIT)-THE ALINITY I METHOTREXATE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF METHOTREXATE IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT BNP CALIBRATORS(ARCHITECT BNP CALIBRATORS)-THE ARCHITECT BNP ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF HUMAN B-TYPE NATRIURETIC PEPTIDE (BNP) IN HUMAN EDTA PLASMA ON THE ARCHITECT ISYSTEM.,ARCHITECT CYFRA 21-1 CONTROLS(ARCHITECT CYFRA 21-1 CONTROLS)-THE ARCHITECT CYFRA 21-1 CONTROLS ARE USED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN CYTOKERATIN 19 FRAGMENTS IN HUMAN SERUM AND PLASMA.,ARCHITECT GALECTIN-3 CONTROLS (ARCHITECT GALECTIN-3 CONTROLS)-THE ARCHITECT GALECTIN-3 CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF GALECTIN-3 IN HUMAN SERUM AND EDTA PLASMA.,ALINITY I BNP CONTROLS(ALINITY I BNP CONTROLS)-THE ALINITY I BNP CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN B-TYPE NATRIURETIC PEPTIDE (BNP) IN HUMAN EDTA PLASMA., ARCHITECT CA 19-9 XR CALIBRATORS(ARCHITECT CA 19-9 XR CALIBRATORS)-THE ARCHITECT CA 19-9XR CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF 1116-NS-19-9 REACTIVE DETERMINANTS IN HUMAN SERUM OR PLASMA.,ALINITY I METHOTREXATE CONTROLS(ALINITY I METHOTREXATE CONTROLS)-THE ALINITY I METHOTREXATE LOW, MEDIUM, AND HIGH CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I

	ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF METHOTREXATE IN HUMAN SERUM AND PLASMA.,NSE REAGENT KIT (NSE REAGENT KIT)-THE NSE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF NEURON-SPECIFIC ENOLASE (NSE) IN HUMAN SERUM ON THE ARCHITECT I SYSTEM.,ALINITY I BNP REAGENT KIT(ALINITY I BNP REAGENT KIT)-THE ALINITY I BNP ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN B-TYPE NATRIURETIC PEPTIDE (BNP) IN HUMAN EDTA PLASMA ON THE ALINITY I ANALYZER. THE ALINITY I BNP ASSAY IS TO BE USED AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF SEVERITY OF HEART FAILURE.,ARCHITECT CA 15-3 CONTROLS (ARCHITECT CA 15-3 CONTROLS)-THE ARCHITECT CA 15-3 CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF DF3 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA.,ARCHITECT THYROGLOBULIN CONTROLS(ARCHITECT THYROGLOBULIN CONTROLS)-THE ARCHITECT THYROGLOBULIN CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) IN HUMAN SERUM AND PLASMA.,ARCHITECT CA 125 II REAGENT KIT(ARCHITECT CA 125 II REAGENT KIT)-THE ARCHITECT CA 125 II ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF OC 125 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA ON THE ARCHITECT ISYSTEM.,ALINITY I CYFRA 21-1 CALIBRATORS(ALINITY I CYFRA 21-1 CALIBRATORS)-THE ALINITY I CYFRA 21-1 CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN CYTOKERATIN 19 FRAGMENTS IN HUMAN SERUM AND PLASMA.,ARCHITECT BNP REAGENT KIT (ARCHITECT BNP REAGENT KIT)-THE ARCHITECT BNP CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN B-TYPE NATRIURETIC PEPTIDE (BNP) IN HUMAN EDTA PLASMA.,ARCHITECT THYROGLOBULIN(ARCHITECT THYROGLOBULIN)-THE ARCHITECT THYROGLOBULIN ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN IN HUMAN SERUM AND PLASMA ON THE ARCHITECT ISYSTEM.,ARCHITECT CA 125 II CALIBRATORS(ARCHITECT CA 125 II CALIBRATORS)-THE ARCHITECT CA 125 II CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED

	FOR THE QUANTITATIVE DETERMINATION OF OC 125 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA.,ARCHITECT THYROGLOBULIN CALIBRATORS(ARCHITECT THYROGLOBULIN CALIBRATORS)-THE ARCHITECT THYROGLOBULIN CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) IN HUMAN SERUM AND PLASMA.,ARCHITECT HE4 REAGENT KIT (ARCHITECT HE4 REAGENT KIT)-THE ARCHITECT HE4 ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF HE4 ANTIGEN IN HUMAN SERUM.,ALINITY I BNP CALIBRATORS(ALINITY I BNP CALIBRATORS)-THE ALINITY I BNP CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN B-TYPE NATRIURETIC PEPTIDE (BNP) IN HUMAN EDTA PLASMA.,ARCHITECT HE4 CONTROLS(ARCHITECT HE4 CONTROLS)-THE ARCHITECT HE4 CONTROLS ARE USED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HE4 ANTIGEN IN HUMAN SERUM.,ALINITY I METHOTREXATE EXTENDED RANGE CONTROLS(ALINITY I METHOTREXATE EXTENDED RANGE CONTROLS)-THE ALINITY I METHOTREXATE EXTENDED RANGE CONTROLS ARE USED TO PROVIDE ASSURANCE OF ACCURACY WHEN PERFORMING MANUAL SAMPLE DILUTIONS.,ARCHITECT CA 19-9 XR CONTROLS(ARCHITECT CA 19-9 XR CONTROLS)-THE ARCHITECT CA 19-9XR CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM (REAGENTS, CALIBRATORS AND INSTRUMENT), WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF 1116-NS-19-9 REACTIVE DETERMINANTS IN HUMAN SERUM OR PLASMA.,ALINITY I CYFRA 21-1 CONTROLS(ALINITY I CYFRA 21-1 CONTROLS)-THE ALINITY I CYFRA 21-1 CONTROLS ARE USED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN CYTOKERATIN 19 FRAGMENTS IN HUMAN SERUM AND PLASMA.,ARCHITECT CA 15-3 REAGENT KIT(ARCHITECT CA 15-3 REAGENT KIT)-THE ARCHITECT CA 15-3 ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF DF3 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA ON THE ARCHITECT ISYSTEM. ,ARCHITECT CYFRA 21-1(ARCHITECT CYFRA 21-1)-THE ARCHITECT CYFRA 21-1 ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF HUMAN CYTOKERATIN 19 FRAGMENTS IN HUMAN SERUM AND PLASMA.,ALINITY I GALECTIN-3 REAGENT KIT

	(ALINITY I GALECTIN-3 REAGENT KIT)-THE ALINITY I GALECTIN-3 ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF GALECTIN-3 IN HUMAN SERUM AND EDTA PLASMA ON THE ALINITY I ANALYZER.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

113	IMP/IVD/2019/000032	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASPARTATE AMINOTRANSFERASE REAGENT (AST- 2 X 100)(ASPARTATE AMINOTRANSFERASE REAGENT (AST- 2 X 100))-AST- REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS ENZYME VALIDATOR SET, IS INTENDED FOR QUANTITATIVE DETERMINATION OF PYRIDOXAL-5'-PHOSPHATE ASPARTATE AMINOTRANSFERASE CONCENTRATION IN HUMAN SERUM OR PLASMA. USE OF THIS PRODUCT, IN CONJUNCTION WITH THE SYNCHRON SYSTEMS ENZYME VALIDATOR SET, WILL RESULT IN ASSAY VALUES WHICH ARE COMPATIBLE WITH THE METHODS RECOMMENDED BY THE INTERNATIONAL FEDERATION OF CLINICAL CHEMISTRY (IFCC).1,MICROALBUMIN REAGENT (MA 2 X 100) (MICROALBUMIN REAGENT (MA 2 X 100))-MA REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS MA CALIBRATOR, IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALBUMIN CONCENTRATION IN HUMAN URINE.,ASPARTATE AMINOTRANSFERASE REAGENT (AST- 2 X 300)(ASPARTATE AMINOTRANSFERASE REAGENT (AST- 2 X 300))-AST- REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS ENZYME VALIDATOR SET, IS INTENDED FOR QUANTITATIVE DETERMINATION OF PYRIDOXAL-5'-PHOSPHATE ASPARTATE AMINOTRANSFERASE CONCENTRATION IN HUMAN SERUM OR PLASMA. USE OF THIS PRODUCT, IN CONJUNCTION WITH THE SYNCHRON SYSTEMS ENZYME VALIDATOR SET, WILL RESULT IN ASSAY VALUES WHICH ARE COMPATIBLE WITH THE METHODS RECOMMENDED BY THE INTERNATIONAL FEDERATION OF CLINICAL CHEMISTRY (IFCC).1, ICHEM 10SG URINE CHEMISTRY STRIPS (ICHEM 10SG URINE CHEMISTRY STRIPS)-THE ICHEM100 URINE CHEMISTRY ANALYZER (ICHEM100) IS A SEMI-AUTOMATED BENCHTOP URINE CHEMISTRY ANALYZER INTENDED FOR THE IN VITRO MEASUREMENT OF THE FOLLOWING ANALYTES: GLUCOSE, PROTEIN, BILIRUBIN, UROBILINOGEN, PH, SPECIFIC GRAVITY, BLOOD, KETONES, NITRITE, LEUKOCYTE ESTERASE, ASCORBIC ACID, AND COLOR. THE ICHEM100 IS INTENDED FOR USE ONLY WITH ICHEM 10 SG URINE CHEMISTRY STRIPS AND IS INTENDED FOR USE EXCLUSIVELY BY HEALTHCARE PROFESSIONALS. THESE MEASUREMENTS ARE USEFUL IN THE EVALUATION OF RENAL, URINARY, AND METABOLIC DISORDERS., SYNCHRON SYSTEMS DRUG CALIBRATOR 2(SYNCHRON SYSTEMS DRUG CALIBRATOR 2)-THE SYNCHRON SYSTEMS DRUG CALIBRATOR 2, USED IN CONJUNCTION WITH SYNCHRON DIGOXIN AND

	ACETAMINOPHEN REAGENTS (P/N 650182 AND 472169), IS INTENDED FOR USE ON THE SYNCHRON SYSTEMS FOR THE CALIBRATION OF DIGOXIN AND ACETAMINOPHEN.,LACTATE DEHYDROGENASE REAGENT (LD 2 X 300)(LACTATE DEHYDROGENASE REAGENT (LD 2 X 300))-LD REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON ENZYME VALIDATOR SET, IS INTENDED FOR QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE CONCENTRATION IN HUMAN SERUM OR PLASMA. USE OF THIS PRODUCT, IN CONJUNCTION WITH THE SYNCHRON ENZYME VALIDATOR SET, WILL RESULT IN ASSAY VALUES WHICH ARE COMPATIBLE WITH THE METHODS RECOMMENDED BY THE INTERNATIONAL FEDERATION OF CLINICAL CHEMISTRY (IFCC), SYNCHRON SYSTEMS NO FOAM(SYNCHRON SYSTEMS NO FOAM)-IT IS FOR USE ON UNICEL DXC SYSTEMS TO IMPEDE FOAMING ,UNICEL DXC SYNCHRON SYSTEMS HDL CALIBRATOR(UNICEL DXC SYNCHRON SYSTEMS HDL CALIBRATOR)-FOR USE IN THE CALIBRATION OF HDL REAGENT ON UNICEL DXC SYNCHRON SYSTEMS.,IMMAGE IMMUNOCHEMISTRY SYSTEMS AMG ALPHA-2-MACROGLOBULIN REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS AMG ALPHA-2-MACROGLOBULIN REAGENT)-AMG REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 2, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ALPHA2-MACROGLOBULIN (AMG) IN HUMAN SERUM BY RATE NEPHELOMETRY.,IMMAGE IMMUNOCHEMISTRY SYSTEMS BUF 4 BUFFER 4(IMMAGE IMMUNOCHEMISTRY SYSTEMS BUF 4 BUFFER 4)-BUFFER 4 IS INTENDED FOR USE WITH THE IMMAGE IMMUNOCHEMISTRY SYSTEMS AND REAGENTS FOR THE QUANTITATIVE DETERMINATIONS OF COMPONENTS IN BIOLOGICAL FLUIDS.,SYNCHRON SYSTEMS AMMONIA/ALCOHOL CONTROL LEVEL 2(SYNCHRON SYSTEMS AMMONIA/ALCOHOL CONTROL LEVEL 2)-AMMONIA/ALCOHOL LIQUID-CONTROL IS DESIGNED FOR MONITORING THE RELIABILITY AND OVERALL PERFORMANCE OF BECKMAN COULTER AMMONIA AND ALCOHOL TEST SYSTEMS IN THE CLINICAL LABORATORY USING BECKMAN COULTER SYNCHRON ANALYZERS.,IMMAGE IMMUNOCHEMISTRY SYSTEMS AAT ALPHA-1-ANTITRYPSIN REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS AAT ALPHA-1- ANTITRYPSIN REAGENT)-AAT REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 2, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ALPHA 1-ANTITRYPSIN (AAT) IN HUMAN SERUM BY RATE NEPHELOMETRY.,VIGIL SEROLOGY CONTROL LEVEL 1(VIGIL SEROLOGY CONTROL LEVEL 1)-VIGIL SEROLOGY STABILIZED LIQUID-CONTROL IS DESIGNED FOR MONITORING THE OVERALL PERFORMANCE OF ANTI-STREPTOLYSIN O, RHEUMATOID FACTOR,

	AND C-REACTIVE PROTEIN TEST SYSTEMS IN THE CLINICAL LABORATORY. THE USE OF FOUR LEVELS OF CONTROL ENABLES THE LABORATORIAN TO MONITOR CHANGES IN CALIBRATION ALONG WITH ANALYTICAL ERROR AND IMPRECISION. VIGIL SEROLOGY IS NOT INTENDED FOR USE AS A STANDARD.,IMMAGE IMMUNOCHEMISTRY SYSTEMS TRF TRANSFERRIN REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS TRF TRANSFERRIN REAGENT)-TRF REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 1, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TRANSFERRIN (TRF) IN HUMAN SERUM BY RATE NEPHELOMETRY,IMMAGE IMMUNOCHEMISTRY SYSTEMS TRU URINE TRANSFERRIN REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS TRU URINE TRANSFERRIN REAGENT)-TRU REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND URINE PROTEIN CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF URINE TRANSFERRIN (TRU) IN HUMAN URINE BY RATE NEPHELOMETRY.,IMMAGE IMMUNOCHEMISTRY SYSTEMS ALB ALBUMIN REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS ALB ALBUMIN REAGENT)-ALB REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 3, IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALBUMIN (ALB) IN HUMAN SERUM OR CEREBROSPINAL FLUID (CSF) BY RATE NEPHELOMETRY.,VIGIL PROTEIN CONTROL LEVEL 3(VIGIL PROTEIN CONTROL LEVEL 3)-VIGIL PROTEIN STABILIZED LIQUID-CONTROLS ARE DESIGNED FOR MONITORING THE RELIABILITY AND OVERALL PERFORMANCE OF SPECIFIC PROTEIN TEST SYSTEMS IN THE CLINICAL LABORATORY. THE USE OF THREE LEVELS OF CONTROL ENABLES THE LABORATORIAN TO MONITOR CHANGES IN CALIBRATION ALONG WITH ANALYTICAL ERROR AND IMPRECISION.,IMMAGE IMMUNOCHEMISTRY SYSTEMS FER FERRITIN REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS FER FERRITIN REAGENT)-FER REAGENT, WHEN USED IN CONJUNCTION WITH THE IMMAGE IMMUNOCHEMISTRY SYSTEMS AND FERRITIN CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN (FER) IN HUMAN SERUM BY TURBIDIMETRIC IMMUNOASSAY, SYNCHRON SYSTEMS 200 NG/ML THC URINE CALIBRATOR (SYNCHRON SYSTEMS 200 NG/ML THC URINE CALIBRATOR)-THE BECKMAN COULTER 20, 50, 100, AND 200 NG/ML THC URINE CALIBRATORS, IN CONJUNCTION WITH SYNCHRON REAGENTS, ARE INTENDED FOR USE ON SYNCHRON SYSTEMS FOR THE CALIBRATION OF CANNABINOID 20 NG/ML (PART NO. 445824), CANNABINOID 50 NG (PART NO. 445820) AND CANNABINOID 100 NG (PART NO. 445990) ENZYME IMMUNOASSAYS. 20 AND 50 NG/ML CALIBRATORS

	ARE TO BE USED ONLY FOR CANNABINOID 20 NG CALIBRATION; 50 AND 100 NG/ML CALIBRATORS ARE TO BE USED ONLY FOR CANNABINOID 50 NG CALIBRATION; AND THE 100 AND 200 NG/ML CALIBRATORS ARE TO BE USED ONLY FOR CANNABINOID 100 NG CALIBRATION.,IMMAGE IMMUNOCHEMISTRY SYSTEMS IGE TOTAL IMMUNOGLOBULIN E REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS IGE TOTAL IMMUNOGLOBULIN E REAGENT)-IGE REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND IGE CALIBRATOR, IS INTENDED FOR QUANTITATIVE DETERMINATION OF TOTAL IMMUNOGLOBULIN E (IGE) CONCENTRATION IN HUMAN SERUM OR PLASMA BY RATE TURBIDIMETRY,VIGIL LIPID CONTROL LEVEL 3(VIGIL LIPID CONTROL LEVEL 3)-VIGIL LIPID CONTROL STABILIZED LIQUID-CONTROL SERUMS ARE INTENDED FOR MONITORING THE RELIABILITY OF MANUAL AND AUTOMATED IN VITRO DIAGNOSTIC ASSAYS OF LIPID ANALYTES. THE VALUES FOR THIS CONTROL HAVE BEEN ESTABLISHED USING BECKMAN COULTER REAGENTS ON BECKMAN COULTER CLINICAL ANALYZERS, AND ARE SPECIFIC FOR THOSE SYSTEMS. THE USE OF THREE OR MORE LEVELS OF CONTROL ENABLES THE LABORATORIAN TO MONITOR CHANGES IN CALIBRATION LINEARITY ALONG WITH ANALYTICAL ERROR AND IMPRECISION.,IMMAGE IMMUNOCHEMISTRY SYSTEMS APB APOLIPOPROTEIN B REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS APB APOLIPOPROTEIN B REAGENT)-APB REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND APO CAL (APOLIPOPROTEIN CALIBRATOR), IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN B (APB) IN HUMAN SERUM BY RATE NEPHELOMETRY.,VIGIL LIPID CONTROL LEVEL 1(VIGIL LIPID CONTROL LEVEL 1)-VIGIL LIPID CONTROL STABILIZED LIQUID-CONTROL SERUMS ARE INTENDED FOR MONITORING THE RELIABILITY OF MANUAL AND AUTOMATED IN VITRO DIAGNOSTIC ASSAYS OF LIPID ANALYTES. THE VALUES FOR THIS CONTROL HAVE BEEN ESTABLISHED USING BECKMAN COULTER REAGENTS ON BECKMAN COULTER CLINICAL ANALYZERS, AND ARE SPECIFIC FOR THOSE SYSTEMS. THE USE OF THREE OR MORE LEVELS OF CONTROL ENABLES THE LABORATORIAN TO MONITOR CHANGES IN CALIBRATION LINEARITY ALONG WITH ANALYTICAL ERROR AND IMPRECISION.,CREATININE REAGENT (CR-S 2 X 300)(CREATININE REAGENT (CR-S 2 X 300))-CR-S REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS AQUA CAL 1 AND 2, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF CREATININE CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE.,SYNCHRON SYSTEMS DRUG CALIBRATOR 3 PLUS(SYNCHRON SYSTEMS DRUG CALIBRATOR 3

	PLUS)-THE SYNCHRON SYSTEMS DRUG CALIBRATOR 3 PLUS, USED IN CONJUNCTION WITH SYNCHRON GENTAMICIN REAGENT (P/N 469137) AND TOBRAMYCIN REAGENT (P/N 467983) IS INTENDED FOR USE ON THE SYNCHRON SYSTEMS FOR THE CALIBRATION OF GENTAMICIN AND TOBRAMYCIN.,SYNCHRON SYSTEMS ENZYME VALIDATOR SET LEVELS 1 & 2(SYNCHRON SYSTEMS ENZYME VALIDATOR SET LEVELS 1 & 2)-THE SYNCHRON ENZYME VALIDATOR SET, IN CONJUNCTION WITH SPECIFIED ENZYME ASSAYS ON SYNCHRON SYSTEMS, IS INTENDED TO PROVIDE POINTS OF REFERENCE IN THE MEASUREMENT OF SELECTED HUMAN ENZYMES. USE OF THIS PRODUCT WILL RESULT IN ASSAY VALUES WHICH ARE COMPATIBLE WITH THOSE FROM METHODS RECOMMENDED BY THE INTERNATIONAL FEDERATION OF CLINICAL CHEMISTRY (IFCC) AND THE GERMAN SOCIETY FOR CLINICAL CHEMISTRY (DEUTSCHE GESELLSCHAFT FÜR KLINISCHE CHEMIE, DGKCH). LIPASE VALUES ARE SPECIFIC FOR THE LIP REAGENT ON SYNCHRON SYSTEMS, IMMAGE IMMUNOCHEMISTRY SYSTEMS DNB ANTIDEOXYRIBONUCLEASE-B REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS DNB ANTIDEOXYRIBONUCLEASE-B REAGENT)-DNB REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND DNASE B CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ANTIBODIES TO DEOXYRIBONUCLEASE B (DNB) IN HUMAN SERUM BY RATE NEPHELOMETRY.,SYNCHRON CONTROL MULTILEVEL COMPREHENSIVE CHEMISTRY CONTROL SERUM(SYNCHRON CONTROL MULTILEVEL COMPREHENSIVE CHEMISTRY CONTROL SERUM)-SYNCHRON CONTROLS ARE MADE FROM STABILIZED HUMAN SERUM AND ARE DESIGNED TO MONITOR THE PERFORMANCE OF SYNCHRON SYSTEMS IN THE CLINICAL LABORATORY. SYNCHRON CONTROL LEVELS 1, 2, AND 3 BEAR A QUANTITATIVE RELATIONSHIP TO ONE ANOTHER; LEVEL 2 IS MANUFACTURED BY COMBINING EQUAL QUANTITIES OF LEVELS 1 AND 3. THE USE OF THREE LEVELS ENABLES THE LABORATORIAN TO MONITOR CHANGES IN CALIBRATION AND LINEARITY ALONG WITH ANALYTICAL ERROR AND IMPRECISION.,SYNCHRON SYSTEMS 50 NG/ML THC URINE CALIBRATOR(SYNCHRON SYSTEMS 50 NG/ML THC URINE CALIBRATOR)-THE BECKMAN COULTER 20, 50, 100, AND 200 NG/ML THC URINE CALIBRATORS, IN CONJUNCTION WITH SYNCHRON REAGENTS, ARE INTENDED FOR USE ON SYNCHRON SYSTEMS FOR THE CALIBRATION OF CANNABINOID 20 NG/ML (PART NO. 445824), CANNABINOID 50 NG (PART NO. 445820) AND CANNABINOID 100 NG (PART NO. 445990) ENZYME IMMUNOASSAYS. 20 AND 50 NG/ML CALIBRATORS ARE TO BE USED ONLY FOR CANNABINOID 20 NG CALIBRATION; 50 AND 100 NG/ML CALIBRATORS ARE TO BE USED

	ONLY FOR CANNABINOID 50 NG CALIBRATION; AND THE 100 AND 200 NG/ML CALIBRATORS ARE TO BE USED ONLY FOR CANNABINOID 100 NG CALIBRATION..,ASPARTATE AMINOTRANSFERASE REAGENT (AST 2 X 400)(ASPARTATE AMINOTRANSFERASE REAGENT (AST 2 X 400))-AST REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S), IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM OR PLASMA.,SYNCHRON SYSTEMS VANCOMYCIN CALIBRATOR(SYNCHRON SYSTEMS VANCOMYCIN CALIBRATOR)-THE SYNCHRON SYSTEMS VANCOMYCIN CALIBRATOR, USED IN CONJUNCTION WITH SYNCHRON VANCOMYCIN REAGENT, IS INTENDED FOR USE ON THE SYNCHRON SYSTEMS FOR THE CALIBRATION OF VANCOMYCIN.,IMMAGE IMMUNOCHEMISTRY SYSTEMS IGA IMMUNOGLOBULIN A REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS IGA IMMUNOGLOBULIN A REAGENT)-IGA REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 1, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN SERUM BY RATE NEPHELOMETRY.,SYNCHRON SYSTEMS AMMONIA/ALCOHOL CONTROL LEVEL 3(SYNCHRON SYSTEMS AMMONIA/ALCOHOL CONTROL LEVEL 3)-AMMONIA/ALCOHOL LIQUID-CONTROL IS DESIGNED FOR MONITORING THE RELIABILITY AND OVERALL PERFORMANCE OF BECKMAN COULTER AMMONIA AND ALCOHOL TEST SYSTEMS IN THE CLINICAL LABORATORY USING BECKMAN COULTER SYNCHRON ANALYZERS.,DIRECT BILIRUBIN REAGENT (DBLL 2 X 300)(DIRECT BILIRUBIN REAGENT (DBLL 2 X 300))-DBIL REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS BILIRUBIN CALIBRATOR, IS INTENDED FOR QUANTITATIVE DETERMINATION OF DIRECT (CONJUGATED) BILIRUBIN CONCENTRATION IN HUMAN SERUM OR PLASMA.,IMMUNOGLOBULIN G REAGENT (IG-G 2 X 150) (IMMUNOGLOBULIN G REAGENT (IG-G 2 X 150))-IG-G REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS CAL 1, IS INTENDED FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G CONCENTRATION IN HUMAN SERUM OR PLASMA., CREATINE KINASE REAGENT (CK 2 X 200)(CREATINE KINASE REAGENT (CK 2 X 200))-CK REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S), IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE ACTIVITY IN HUMAN SERUM OR PLASMA.,IMMUNOGLOBULIN M REAGENT (IG-M 2 X 150)(IMMUNOGLOBULIN M REAGENT (IG-M 2 X 150))-IG-M REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS CAL 1, IS INTENDED FOR QUANTITATIVE DETERMINATION OF

	IMMUNOGLOBULIN M CONCENTRATION IN HUMAN SERUM OR PLASMA.,DIRECT BILIRUBIN REAGENT (DBIL 2 X 200)(DIRECT BILIRUBIN REAGENT (DBIL 2 X 200))-DBIL REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS BILIRUBIN CALIBRATOR, IS INTENDED FOR QUANTITATIVE DETERMINATION OF DIRECT (CONJUGATED) BILIRUBIN CONCENTRATION IN HUMAN SERUM OR PLASMA.,VIGIL SEROLOGY CONTROL LEVEL 3(VIGIL SEROLOGY CONTROL LEVEL 3)-VIGIL SEROLOGY STABILIZED LIQUID-CONTROL IS DESIGNED FOR MONITORING THE OVERALL PERFORMANCE OF ANTI-STREPTOLYSIN O, RHEUMATOID FACTOR, AND C-REACTIVE PROTEIN TEST SYSTEMS IN THE CLINICAL LABORATORY. THE USE OF FOUR LEVELS OF CONTROL ENABLES THE LABORATORIAN TO MONITOR CHANGES IN CALIBRATION ALONG WITH ANALYTICAL ERROR AND IMPRECISION. VIGIL SEROLOGY IS NOT INTENDED FOR USE AS A STANDARD.,BUN REAGENT (BUN 2 X 300)(BUN REAGENT (BUN 2 X 300))-BUN REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS MULTI CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF UREA NITROGEN CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE,-GLUTAMYL TRANSFERASE REAGENT (GGT 2 X 200)(-GLUTAMYL TRANSFERASE REAGENT (GGT 2 X 200))-GGT REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS ENZYME VALIDATOR SET, IS INTENDED FOR QUANTITATIVE DETERMINATION OF -GLUTAMYL TRANSFERASE CONCENTRATION IN HUMAN SERUM OR PLASMA. USE OF THIS PRODUCT, IN CONJUNCTION WITH THE SYNCHRON SYSTEMS ENZYME VALIDATOR SET, WILL RESULT IN ASSAY VALUES WHICH ARE COMPATIBLE WITH THE METHODS RECOMMENDED BY THE INTERNATIONAL FEDERATION OF CLINICAL CHEMISTRY (IFCC),TOTAL PROTEIN REAGENT (TP 2 X 300)(TOTAL PROTEIN REAGENT (TP 2 X 300))-TP REAGEENT, WHEN USED IN CONJUCTION WITH INICEL DXC 600/800 SYSTEMS(S) AND SYNCHRON SYSTEMS MULTI CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN CONCENTRATION IN HUMAN SERUM OR PLASMA, AMMONIA REAGENT (AMM 2 X 25)(AMMONIA REAGENT (AMM 2 X 25)) -AMM REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS AMMONIA CALIBRATORS, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF AMMONIA CONCENTRATION IN HUMAN PLASMA., TOTAL BILIRUBIN REAGENT (TBIL 2 X 400)(TOTAL BILIRUBIN REAGENT (TBIL 2 X 400))-TBIL REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS BILIRUBIN CALIBRATOR, IS INTENDED FOR

	QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN CONCENTRATION IN HUMAN SERUM OR PLASMA,IMMAGE IMMUNOCHEMISTRY SYSTEMS A1M ALPHA-1-MICROGLOBULIN REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS A1M ALPHA-1-MICROGLOBULIN REAGENT)-A1M REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND URINE PROTEIN CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ALPHA-1-MICROGLOBULIN (A1M) IN HUMAN URINE BY RATE NEPHELOMETRY.,DIRECT LDL CHOLESTEROL REAGENT (LDLD 2 X 100)(DIRECT LDL CHOLESTEROL REAGENT (LDLD 2 X 100))-LDLD REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS LDLD CALIBRATOR, IS INTENDED FOR THE DIRECT QUANTITATIVE DETERMINATION OF LOW-DENSITY LIPOPROTEIN CHOLESTEROL IN HUMAN SERUM OR PLASMA,SYNCHRON ALKALINE PHOSPHATASE REAGENT (ALP 2 X 400)(SYNCHRON ALKALINE PHOSPHATASE REAGENT (ALP 2 X 400))-ALP (IFCC-DGKCH) REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON ENZYME VALIDATOR SET, IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE CONCENTRATION IN HUMAN SERUM OR PLASMA. USE OF THIS PRODUCT, IN CONJUNCTION WITH THE SYNCHRON ENZYME VALIDATOR SET, WILL RESULT IN ASSAY VALUES WHICH ARE COMPATIBLE WITH THE METHODS RECOMMENDED BY THE INTERNATIONAL FEDERATION OF CLINICAL CHEMISTRY (IFCC).1,C-REACTIVE PROTEIN REAGENT (C-RP 2 X 200)(C-REACTIVE PROTEIN REAGENT (C-RP 2 X 200))-C-RP REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS CAL 5 PLUS, IS INTENDED FOR QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN CONCENTRATION IN HUMAN SERUM OR PLASMA,PREALBUMIN REAGENT (PAB 2 X 100) (PREALBUMIN REAGENT (PAB 2 X 100))-PAB REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS PAB CALIBRATOR, IS INTENDED FOR QUANTITATIVE DETERMINATION OF PREALBUMIN CONCENTRATION IN HUMAN SERUM OR PLASMA.,CHOLESTEROL REAGENT (CHOL 2 X 300)(CHOLESTEROL REAGENT (CHOL 2 X 300))-CHOL REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS MULTI CALIBRATOR, IS INTENDED FOR QUANTITATIVE DETERMINATION OF CHOLESTEROL CONCENTRATION IN HUMAN SERUM OR PLASMA,IMMAGE IMMUNOCHEMISTRY SYSTEMS CCRP HIGH SENSITIVITY CARDIAC CRP REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS CCRP HIGH SENSITIVITY CARDIAC CRP REAGENT)-HIGH SENSITIVITY CARDIAC C-REACTIVE PROTEIN (CCRP)

	REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE 800 IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 5 PLUS, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM OR PLASMA BY RATE TURBIDIMETRY., PHOSPHORUS REAGENT (PHS 2 X300)(PHOSPHORUS REAGENT (PHS 2 X300))-PHS REAGENT, IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS MULTI CALIBRATOR. IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHORUS CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE,VIGIL SEROLOGY CONTROL LEVEL C(VIGIL SEROLOGY CONTROL LEVEL C)-VIGIL SEROLOGY STABILIZED LIQUID-CONTROL IS DESIGNED FOR MONITORING THE OVERALL PERFORMANCE OF ANTI-STREPTOLYSIN O, RHEUMATOID FACTOR, AND C-REACTIVE PROTEIN TEST SYSTEMS IN THE CLINICAL LABORATORY. THE USE OF FOUR LEVELS OF CONTROL ENABLES THE LABORATORIAN TO MONITOR CHANGES IN CALIBRATION ALONG WITH ANALYTICAL ERROR AND IMPRECISION. VIGIL SEROLOGY IS NOT INTENDED FOR USE AS A STANDARD.,IMMAGE IMMUNOCHEMISTRY SYSTEMS ANTI-STREPTOLYSIN O REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS ANTI-STREPTOLYSIN O REAGENT)-ASO REAGENT, WHEN USED IN CONJUCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 5 PLUS, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ANTIBODIES TO STREPTOLYSIN O (ASO) IN HUMAN SERUM OR PLASMA BY RATE NEPHELOMETRY.,SYNCHRON SYSTEMS AMMONIA/ALCOHOL CONTROL LEVEL 1(SYNCHRON SYSTEMS AMMONIA/ALCOHOL CONTROL LEVEL 1)-AMMONIA/ALCOHOL LIQUID-CONTROL IS DESIGNED FOR MONITORING THE RELIABILITY AND OVERALL PERFORMANCE OF BECKMAN COULTER AMMONIA AND ALCOHOL TEST SYSTEMS IN THE CLINICAL LABORATORY USING BECKMAN COULTER SYNCHRON ANALYZERS.,IMMAGE IMMUNOCHEMISTRY SYSTEM BUFFER 3(IMMAGE IMMUNOCHEMISTRY SYSTEM BUFFER 3)-BUFFER 3 IS INTENDED FOR USED WITH THE IMMAGE IMMUNOCHEMISTRY SYSTEMS AND REAGENT FOR THE QUANTITATIVE DETERMINATIONS OF THE COMPONENTS IN BIOLOGICAL FLUIDS.,SYNCHRON SYSTEMS CO2 ALKALINE BUFFER (ALK BUF)(SYNCHRON SYSTEMS CO2 ALKALINE BUFFER (ALK BUF))-ISE ELECTROLYTE BUFFER REAGENT AND ISE ELECTROLYTE REFERENCE REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS AQUA CAL 1 AND 2, ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF CALCIUM CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE., IMMAGE IMMUNOCHEMISTRY SYSTEMS COMPLEMENT C4 REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS COMPLEMENT C4 REAGENT)

	-C4 REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATORS 1, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT C4 IN HUMAN SERUM BY RATE NEPHELOMETRY,SYNCHRON SYSTEMS 100 NG/ML THC URINE CALIBRATOR(SYNCHRON SYSTEMS 100 NG/ML THC URINE CALIBRATOR)-THE BECKMAN COULTER 20, 50, 100, AND 200 NG/ML THC URINE CALIBRATORS, IN CONJUNCTION WITH SYNCHRON REAGENTS, ARE INTENDED FOR USE ON SYNCHRON SYSTEMS FOR THE CALIBRATION OF CANNABINOID 20 NG/ML (PART NO. 445824), CANNABINOID 50 NG (PART NO. 445820) AND CANNABINOID 100 NG (PART NO. 445990) ENZYME IMMUNOASSAYS. 20 AND 50 NG/ML CALIBRATORS ARE TO BE USED ONLY FOR CANNABINOID 20 NG CALIBRATION; 50 AND 100 NG/ML CALIBRATORS ARE TO BE USED ONLY FOR CANNABINOID 50 NG CALIBRATION; AND THE 100 AND 200 NG/ML CALIBRATORS ARE TO BE USED ONLY FOR CANNABINOID 100 NG CALIBRATION.,IMMAGE IMMUNOCHEMISTRY SYSTEMS CRP C-REACTIVE PROTEIN REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS CRP C-REACTIVE PROTEIN REAGENT)-CRP REAGENT, WHEN USED IN CONJUCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 5 PLUS, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM OR PLASMA BY RATE NEPHELOMETRY,-GLUTAMYL TRANSFERASE REAGENT (GGT 2 X400)(-GLUTAMYL TRANSFERASE REAGENT (GGT 2 X400))-GGT REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS ENZYME VALIDATOR SET, IS INTENDED FOR QUANTITATIVE DETERMINATION OF -GLUTAMYL TRANSFERASE CONCENTRATION IN HUMAN SERUM OR PLASMA. USE OF THIS PRODUCT, IN CONJUNCTION WITH THE SYNCHRON SYSTEMS ENZYME VALIDATOR SET, WILL RESULT IN ASSAY VALUES WHICH ARE COMPATIBLE WITH THE METHODS RECOMMENDED BY THE INTERNATIONAL FEDERATION OF CLINICAL CHEMISTRY (IFCC).1, IMMAGE IMMUNOCHEMISTRY SYSTEMS HPT HAPTOGLOBIN REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS HPT HAPTOGLOBIN REAGENT)-HPT REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 1, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HAPTOGLOBIN (HPT) IN HUMAN SERUM BY RATE NEPHELOMETRY, HAPTOGLOBIN REAGENT (HPT 2 X 100)(HAPTOGLOBIN REAGENT (HPT 2 X 100))-HPT REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS CAL 1, IS INTENDED FOR QUANTITATIVE DETERMINATION OF HAPTOGLOBIN CONCENTRATION IN HUMAN SERUM OR PLASMA BY TURBIDIMETRY., IMMAGE IMMUNOCHEMISTRY SYSTEMS APA APOLIPOPROTEIN A1

	REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS APA APOLIPOPROTEIN A1 REAGENT)-APA REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND APO CAL (APOLIPOPROTEIN CALIBRATOR), IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A-1 (APA) IN HUMAN SERUM BY RATE NEPHELOMETRY,SYNCHRON SYSTEMS ANTIFOAM (SYNCHRON SYSTEMS ANTIFOAM)-IT IS FOR USE ON UNICEL DXC SYSTEMS TO IMPEDE ANTIFOAMING,IMMAGE IMMUNOCHEMISTRY SYSTEMS CER CERULOPLASMIN REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS CER CERULOPLASMIN REAGENT)-CER REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 2, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF CERULOPLASMIN (CER) IN HUMAN SERUM BY RATE NEPHELOMETRY., TOTAL IRON BINDING CAPACITY REAGENT (IBCT 2 X 100)(TOTAL IRON BINDING CAPACITY REAGENT (IBCT 2 X 100))-IBCT REAGENT, WHEN USED IN CONJUNCTION WITH DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS FE/IBCT CALIBRATOR KIT, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL IRON BINDING CAPACITY IN HUMAN SERUM OR HEPARINIZED (SODIUM) PLASMA., SYNCHRON SYSTEMS TOTAL IRON BINDING CAPACITY (IBCT) COLUMN KIT(SYNCHRON SYSTEMS TOTAL IRON BINDING CAPACITY (IBCT) COLUMN KIT)-IBCT REAGENT, WHEN USED IN CONJUNCTION WITH DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS FE/IBCT CALIBRATOR KIT, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL IRON BINDING CAPACITY IN HUMAN SERUM OR HEPARINIZED (SODIUM) PLASMA.,ANTISTREPTOLYSIN-O REAGENT (ASO- 2 X 100)(ANTISTREPTOLYSIN-O REAGENT (ASO- 2 X 100))-ASO- REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS CAL 5 PLUS, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ANTIBODIES TO STREPTOLYSIN-O CONCENTRATIONS IN HUMAN SERUM OR PLASMA.,URIC ACID REAGENT (URIC 2 X 300)(URIC ACID REAGENT (URIC 2 X 300))-URIC REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS MULTI CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF URIC ACID CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE.,APOLIPOPROTEIN B REAGENT (APOB 2 X 100) (APOLIPOPROTEIN B REAGENT (APOB 2 X 100))-APOB REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS APO CALIBRATOR, IS INTENDED FOR QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN B CONCENTRATION IN HUMAN SERUM OR PLASMA.,SYNCHRON SYSTEMS MA CALIBRATOR (SYNCHRON SYSTEMS MA CALIBRATOR)-

	MA CALIBRATORS WHEN USED IN CONJUNCTION WITH DXC SYSTEMS MA REAGENT IS INTENDED FOR USE ON THE UNICEL DXC SYNCHRON SYSTEMS FOR THE CALIBRATORS OF MICROALBUMIN.,ISE ELECTROLYTE BUFFER (ELEC BUF)(ISE ELECTROLYTE BUFFER (ELEC BUF))-ISE ELECTROLYTE BUFFER REAGENT, ISE ELECTROLYTE REFERENCE REAGENT, CO2 ALKALINE BUFFER AND CO2 ACID REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS AQUA CAL 1 AND 3, ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF CARBON DIOXIDE IN HUMAN SERUM OR PLASMA.,C4 REAGENT (C4 2 X 100)(C4 REAGENT (C4 2 X 100))-C4 REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS CAL 1, IS INTENDED FOR QUANTITATIVE DETERMINATION OF COMPLEMENT C4 CONCENTRATION IN HUMAN SERUM OR PLASMA BY TURBIDIMETRY.,SYNCHRON SYSTEMS ETOH CALIBRATOR (SYNCHRON SYSTEMS ETOH CALIBRATOR)-THE ETOH CALIBRATOR, IN CONJUNCTION WITH SYNCHRON REAGENT, IS INTENDED FOR USE ON SYNCHRON SYSTEMS FOR THE CALIBRATION OF ALCOHOL ENZYMATIC ASSAY.,TRANSFERRIN REAGENT (TRFN 2 X 150) (TRANSFERRIN REAGENT (TRFN 2 X 150))-TRFN REAGENT WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEMS AND SYNCHRON SYSTEMS CAL 1 IS INTENDED FOR QUANTITATIVE DETERMINATION OF TRANSFERRIN CONCENTRATION IN HUMAN SERUM OR PLASMA.,SYNCHRON SYSTEMS 20 NG/ML THC URINE CALIBRATOR(SYNCHRON SYSTEMS 20 NG/ML THC URINE CALIBRATOR)-THE BECKMAN COULTER 20, 50, 100, AND 200 NG/ML THC URINE CALIBRATORS, IN CONJUNCTION WITH SYNCHRON REAGENTS, ARE INTENDED FOR USE ON SYNCHRON SYSTEMS FOR THE CALIBRATION OF CANNABINOID 20 NG/ML (PART NO. 445824), CANNABINOID 50 NG (PART NO. 445820) AND CANNABINOID 100 NG (PART NO. 445990) ENZYME IMMUNOASSAYS. 20 AND 50 NG/ML CALIBRATORS ARE TO BE USED ONLY FOR CANNABINOID 20 NG CALIBRATION; 50 AND 100 NG/ML CALIBRATORS ARE TO BE USED ONLY FOR CANNABINOID 50 NG CALIBRATION; AND THE 100 AND 200 NG/ML CALIBRATORS ARE TO BE USED ONLY FOR CANNABINOID 100 NG CALIBRATION.,C3 REAGENT (C3 2 X 100)(C3 REAGENT (C3 2 X 100))-C3 REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS CAL 1, IS INTENDED FOR QUANTITATIVE DETERMINATION OF COMPLEMENT C3 CONCENTRATION IN HUMAN SERUM OR PLASMA BY RATE TURBIDIMETRY.,SYNCHRON C-REACTIVE PROTEIN REAGENT (CRP 2 X 200)(SYNCHRON C-REACTIVE PROTEIN REAGENT (CRP 2 X 200))-CRP REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS CAL 5 PLUS, IS INTENDED FOR

	QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN CONCENTRATION IN HUMAN SERUM OR PLASMA.,IMMAGE IMMUNOCHEMISTRY SYSTEMS IGMLC LOW CONCENTRATION IMMUNOGLOBULIN M REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS IGMLC LOW CONCENTRATION IMMUNOGLOBULIN M REAGENT)-IGMLC REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CEREBROSPINAL FLUID PROTEIN CALIBRATOR, IS INTENDED FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M IN HUMAN SERUM OR CEREBROSPINAL FLUID (CSF) BY RATE NEPHELOMETRY.,ISE ELECTROLYTE REFERENCE (ELEC REF)(ISE ELECTROLYTE REFERENCE (ELEC REF))-ISE ELECTROLYTE BUFFER REAGENT, ISE ELECTROLYTE REFERENCE REAGENT, CO2 ALKALINE BUFFER AND CO2 ACID REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS AQUA CAL 1 AND 3, ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF CARBON DIOXIDE IN HUMAN SERUM OR PLASMA.,VALPROIC ACID REAGENT (VPA 2 X 100)(VALPROIC ACID REAGENT (VPA 2 X 100))-VPA REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS DRUG CALIBRATOR 1 SET, IS INTENDED FOR QUANTITATIVE DETERMINATION OF VALPROIC ACID CONCENTRATION IN HUMAN SERUM OR PLASMA.,VIGIL PROTEIN CONTROL LEVEL 1(VIGIL PROTEIN CONTROL LEVEL 1)-VIGIL PROTEIN STABILIZED LIQUID-CONTROLS ARE DESIGNED FOR MONITORING THE RELIABILITY AND OVERALL PERFORMANCE OF SPECIFIC PROTEIN TEST SYSTEMS IN THE CLINICAL LABORATORY. THE USE OF THREE LEVELS OF CONTROL ENABLES THE LABORATORIAN TO MONITOR CHANGES IN CALIBRATION ALONG WITH ANALYTICAL ERROR AND IMPRECISION.,IMMAGE IMMUNOCHEMISTRY SYSTEMS IGG IMMUNOGLOBULIN G REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS IGG IMMUNOGLOBULIN G REAGENT)-IGG REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 1, IS INTENDED FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN SERUM OR CEREBROSPINAL FLUID (CSF) BY RATE NEPHELOMETRY.,SYNCHRON SYSTEMS CO2 ACID REAGENT (CO2 ACID)(SYNCHRON SYSTEMS CO2 ACID REAGENT (CO2 ACID))-ISE ELECTROLYTE BUFFER REAGENT, ISE ELECTROLYTE REFERENCE REAGENT, CO2 ALKALINE BUFFER AND CO2 ACID REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS AQUA CAL 1 AND 3, ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF CARBON DIOXIDE IN HUMAN SERUM OR PLASMA.,IMMAGE IMMUNOCHEMISTRY SYSTEMS IGU URINE IMMUNOGLOBULIN G REAGENT (IMMAGE

	IMMUNOCHEMISTRY SYSTEMS IGU URINE IMMUNOGLOBULIN G REAGENT)-IGU REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND URINE PROTEIN CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF URINE IMMUNOGLOBULIN G (IGU) IN HUMAN URINE BY RATE NEPHELOMETRY.,AMYLASE REAGENT (AMY7 2 X 200)(AMYLASE REAGENT (AMY7 2 X 200))-AMY7 REAGENT, IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL AMYLASE ACTIVITY IN HUMAN SERUM, PLASMA OR URINE.,SYNCHRON SYSTEMS CAL 5 PLUS CALIBRATOR 5 PLUS(SYNCHRON SYSTEMS CAL 5 PLUS CALIBRATOR 5 PLUS)-THE SYNCHRON SYSTEMS CAL 5 PLUS, USED IN CONJUNCTION WITH SYNCHRON REAGENTS, IS INTENDED FOR USE IN THE CALIBRATION OF ASO-, CRP AND CRPH ON UNICEL DXC SYSTEMS.,IMMAGE IMMUNOCHEMISTRY SYSTEMS CSF-CAL CEREBROSPINAL FLUID PROTEIN CALIBRATOR(IMMAGE IMMUNOCHEMISTRY SYSTEMS CSF-CAL CEREBROSPINAL FLUID PROTEIN CALIBRATOR)-CSF CAL (CEREBROSPINAL FLUID PROTEIN CALIBRATOR), WHEN USED IN CONJUNCTION WITH BECKMAN COULTER LOW CONCENTRATION IMMUNOGLOBULIN A (IGALC) AND LOW CONCENTRATION IMMUNOGLOBULIN M (IGMLC) REAGENTS IS INTENDED FOR USE ON IMMAGE FOR THE CALIBRATION OF THESE REAGENTS.,SYNCHRON SYSTEMS SYNCHRON MULTI CALIBRATOR (SYNCHRON SYSTEMS SYNCHRON MULTI CALIBRATOR)-THE SYNCHRON MULTI CALIBRATOR, USED IN CONJUNCTION WITH SYNCHRON REAGENTS, IS INTENDED FOR USE ON SYNCHRON SYSTEMS FOR THE CALIBRATION OF ALBUMIN, BLOOD UREA NITROGEN (UREA), CALCIUM, CHOLESTEROL, GLUCOSE, INORGANIC PHOSPHORUS, LACTATE, MAGNESIUM, TOTAL PROTEIN, TRIGLYCERIDES, AND URIC ACID.,SYNCHRON SYSTEMS 75 NG/ML THC URINE CONTROL(SYNCHRON SYSTEMS 75 NG/ML THC URINE CONTROL)-THE BECKMAN COULTER 10, 20, 40, 75, AND 125 NG/ML THC URINE CONTROLS, IN CONJUNCTION WITH SYNCHRON REAGENTS, ARE INTENDED FOR USE ON SYNCHRON SYSTEMS FOR MONITORING THE QUALITY CONTROL FOR CANNABINOID IN THE CLINICAL LABORATORY. THE 10 AND 40 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 20 NG REAGENT, THE 20 AND 75 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 50 NG REAGENT AND THE 75 AND 125 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 100 NG REAGENT., SYNCHRON SYSTEMS CAL 1 CALIBRATOR 1(SYNCHRON SYSTEMS CAL 1 CALIBRATOR 1)-THE BECKMAN COULTER DXC CALIBRATOR 1 (CAL 1), USED IN CONJUNCTION WITH DXC REAGENTS, IS INTENDED FOR

	THE CALIBRATION OF IMMUNOPROTEIN TESTS ON UNICEL DXC SYNCHRON SYSTEMS.,CARTRIDGE CHEMISTRY WASH SOLUTION (CCWA 2 X 300)(CARTRIDGE CHEMISTRY WASH SOLUTION (CCWA 2 X 300))-SYNCHRON SYSTEM(S) CARTRIDGE CHEMISTRY WASH SOLUTION IS INTENDED FOR USE WITH THE UNICEL DXC 600/800 SYSTEM(S) FOR CLEANING AND MAINTAINING THE CARTRIDGE CHEMISTRY SUB SYSTEM.,SYNCHRON SYSTEMS BILIRUBIN CALIBRATOR(SYNCHRON SYSTEMS BILIRUBIN CALIBRATOR)-THE BILIRUBIN CALIBRATOR, IN CONJUNCTION WITH SYNCHRON TOTAL BILIRUBIN REAGENT (P/N 442745 OR 476861) OR SYNCHRON DIRECT BILIRUBIN REAGENT (P/N 439715 OR 476856), IS INTENDED FOR USE ON SYNCHRON SYSTEMS FOR THE CALIBRATION OF TOTAL BILIRUBIN OR DIRECT BILIRUBIN.,HBDIL DXC(HBDIL DXC)-HBDIL REAGENT, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C CONCENTRATION IN HUMAN WHOLE BLOOD. THE A1C3 AND HB3 VALUES GENERATED AS PART OF THE HBA1C3 ASSAY ARE INTENDED FOR USE IN THE CALCULATION OF THE A1C3/HB3 RATIO AND MUST NOT BE USED INDIVIDUALLY,SYNCHRON SYSTEMS SYNCHRON PROTEIN CALIBRATOR LEVELS 1 AND 2(SYNCHRON SYSTEMS SYNCHRON PROTEIN CALIBRATOR LEVELS 1 AND 2)-SYNCHRON SYSTEMS PROTEIN CALIBRATORS 1 AND 2 ARE STABILIZED LIQUID CALIBRATORS DESIGNED FOR USE WITH SYNCHRON SYSTEMS FOR THE CALIBRATION OF TOTAL PROTEIN AND ALBUMIN.,ULTIMATE -D BILIRUBIN CONTROL LEVEL 2(ULTIMATE -D BILIRUBIN CONTROL LEVEL 2)-ULTIMATE-D BILIRUBIN LIQUID CONTROLS ARE STABILIZED AND DESIGNED FOR USE IN THE QUALITY CONTROL OF TOTAL AND DIRECT-ACTING (CONJUGATED) BILIRUBIN DETERMINATIONS BY MANUAL AND AUTOMATED ANALYTICAL SYSTEMS. MULTIPLE LEVELS ARE AVAILABLE SEPARATELY TO PROVIDE CONTROL ACROSS THE RANGE OF LINEARITY OR AT SPECIFIC LEVELS.,SAMPLE DILUENT 1 DIL 1(SAMPLE DILUENT 1 DIL 1)-SYNCHRON SYSTEM(S) SAMPLE DILUENT 1 IS INTENDED FOR USE WITH THE UNICEL DXC 600/800 SYSTEM(S) AND REAGENTS FOR ONBOARD SAMPLE DILUTION IN THE QUANTITATIVE DETERMINATIONS OF COMPONENTS IN BIOLOGICAL FLUIDS., GLUCOSE REAGENT (GLUH 2 X 300)(GLUCOSE REAGENT (GLUH 2 X 300))-UNICEL DXC SYNCHRON SYSTEMS GLUCOSE REAGENT (GLUH), WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYNCHRON SYSTEM(S) AND SYNCHRON SYSTEMS AQUA CAL 1 AND 3, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE CONCENTRATION IN HUMAN SERUM, PLASMA, URINE OR CEREBROSPINAL FLUID (CSF).,IMMUNOCHEMISTRY SYSTEMS CAL 2 CALIBRATOR 2(IMMUNOCHEMISTRY SYSTEMS CAL 2 CALIBRATOR 2)-CAL 2 (CALIBRATOR 2), WHEN USED IN CONJUNCTION WITH

	BECKMAN COULTER ALPHA1-ANTITRYPSIN (AAT), CERULOPLASMIN (CER), PROPERDIN FACTOR B (PFB), ALPHA2-MACROGLOBULIN (AMG), AND ANTITHROMBIN III (AT3) REAGENTS, IS INTENDED FOR USE ON IMMAGE SYSTEMS FOR THE CALIBRATION OF THESE REAGENTS.,HEMOGLOBIN A1C REAGENT (HBA1C3 250)(HEMOGLOBIN A1C REAGENT (HBA1C3 250))-THE UNICEL DXC SYNCHRON SYSTEMS HEMOGLOBIN A1C3 (HBA1C3) REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYNCHRON SYSTEMS, UNICEL DXC SYNCHRON SYSTEMS HBA1C3 CALIBRATORS AND HBDIL REAGENT, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C CONCENTRATION IN HUMAN WHOLE BLOOD. THE A1C3 AND HB3 VALUES GENERATED AS PART OF THE HBA1C3 ASSAY ARE INTENDED FOR USE IN THE CALCULATION OF THE A1C3/HB3 RATIO AND MUST NOT BE USED INDIVIDUALLY.,IMMAGE IMMUNOCHEMISTRY SYSTEMS RHEUMATOID FACTOR REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS RHEUMATOID FACTOR REAGENT)-RF REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATORS 5 PLUS IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR(RF)IN HUMAN SERUM AND PLASMA BY RATE NEPHELOMETRY ,SYNCHRON SYSTEMS PHOSPHORUS REAGENT (SYNCHRON SYSTEMS PHOSPHORUS REAGENT)-PHOSM REAGENT, IN CONJUNCTION WITH UNICEL DXC 800 SYSTEM AND THE SYNCHRON SYSTEMS AQUA CAL 1 AND 2, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHORUS CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE.,IMMAGE IMMUNOCHEMISTRY SYSTEM LAMBDA LIGHT CHAIN REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEM LAMBDA LIGHT CHAIN REAGENT)-LAM REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 1, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF LAMBDA LIGHT CHAIN(LAM) IN HUMAN SERUM BY RATE NEPHELOMETRY,IMMAGE IMMUNOCHEMISTRY SYSTEMS LPAX LIPOPROTEIN (A) REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS LPAX LIPOPROTEIN (A) REAGENT)-LPAX REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND LIPOPROTEIN(A) CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN(A) (LPAX) IN HUMAN SERUM OR PLASMA BY RATE NEPHELOMETRY.1,2,SYNCHRON SYSTENS AQUA CAL 1(SYNCHRON SYSTENS AQUA CAL 1)-THE BECKMAN COULTER AQUA CAL 1,2 AND 3 ARE INTENDED FOR USE ON UNICEL DXC SYSTEM FOR THE CALIBRATOR OF SODIUM, POTASSIUM, CHLORIDE, UREA NITROGEN, UREA, GLUCOSE CREATININE, CALCIUM, CARBON DIOXIDE, AND PHOSPHORUS,HEMOGLOBIN A1C REAGENT (HBA1C- 400)

	(HEMOGLOBIN A1C REAGENT (HBA1C- 400))-THE HEMOGLOBIN A1C-REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYNCHRON SYSTEMS, UNICEL DXC SYNCHRON SYSTEMS HBA1C-CALIBRATORS AND SYNCHRON AND AU SYSTEMS HEMOLYZING REAGENT, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C CONCENTRATION IN HUMAN WHOLE BLOOD., IMMAGE IMMUNOCHEMISTRY SYSTEMS HIGH SENSITIVITY C-REACTIVE PROTEIN REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS HIGH SENSITIVITY C-REACTIVE PROTEIN REAGENT)-CRPH REAGENT, WHEN USED IN CONJUCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 5 PLUS, IS INTENDED FOR QUANTITATIVE DETERMINATION OF HIGH SENSTIVITY C-REACTIVE PROTEIN (CRPH) CONCENTRATION IN HUMAN SERUM OR PLASMA BY RATE TURBIDIMETRY,LACTATE REAGENT (LACT 2 X 50)(LACTATE REAGENT (LACT 2 X 50))-LACT REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS MULTI CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF LACTATE CONCENTRATION IN HUMAN PLASMA AND CEREBROSPINAL FLUID (CSF).,IMMAGE IMMUNOCHEMISTRY SYSTEM COMPLEMENT C3 REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEM COMPLEMENT C3 REAGENT)-C3 REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATORS 1, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT C3 IN HUMAN SERUM BY RATE NEPHELOMETRY,VIGIL LIPID CONTROL LEVEL 4(VIGIL LIPID CONTROL LEVEL 4)-VIGIL LIPID CONTROL STABILIZED LIQUID-CONTROL SERUMS ARE INTENDED FOR MONITORING THE RELIABILITY OF MANUAL AND AUTOMATED IN VITRO DIAGNOSTIC ASSAYS OF LIPID ANALYTES. THE VALUES FOR THIS CONTROL HAVE BEEN ESTABLISHED USING BECKMAN COULTER REAGENTS ON BECKMAN COULTER CLINICAL ANALYZERS, AND ARE SPECIFIC FOR THOSE SYSTEMS. THE USE OF THREE OR MORE LEVELS OF CONTROL ENABLES THE LABORATORIAN TO MONITOR CHANGES IN CALIBRATION LINEARITY ALONG WITH ANALYTICAL ERROR AND IMPRECISION.,SYNCHRON SYSTEMS AQUA CAL 3(SYNCHRON SYSTEMS AQUA CAL 3)-THE BECKMAN COULTER AQUA CAL 1,2 AND 3 ARE INTENDED FOR USE ON UNICEL DXC SYSTEM FOR THE CALIBRATOR OF SODIUM, POTASSIUM, CHLORIDE, UREA NITROGEN, UREA, GLUCOSE CREATININE, CALCIUM, CARBON DIOXIDE, AND PHOSPHORUS,SYNCHRON SYSTEMS 125 NG/ML THC URINE CONTROL (SYNCHRON SYSTEMS 125 NG/ML THC URINE CONTROL)-THE BECKMAN COULTER 10, 20, 40, 75, AND 125 NG/ML THC URINE CONTROLS, IN CONJUNCTION WITH SYNCHRON REAGENTS, ARE INTENDED FOR USE ON SYNCHRON SYSTEMS FOR MONITORING THE

	QUALITY CONTROL FOR CANNABINOID IN THE CLINICAL LABORATORY. THE 10 AND 40 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 20 NG REAGENT, THE 20 AND 75 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 50 NG REAGENT AND THE 75 AND 125 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 100 NG REAGENT.,VCHEM 10SG URINE CHEMISTRY STRIPS (VCHEM 10SG URINE CHEMISTRY STRIPS)-VCHEM URINE CHEMISTRY STRIPS ARE INTENDED FOR IN VITRO MEASUREMENT OF THE FOLLOWING ANALYTES IN URINE: GLUCOSE, PROTEIN, BILIRUBIN, UROBILINOGEN, PH, SPECIFIC GRAVITY, BLOOD, KETONES, NITRITE, LEUKOCYTES, AND ASCORBIC ACID. VCHEM URINE CHEMISTRY STRIPS ARE INTENDED FOR VISUAL USE ONLY. SYNCHRON SYSTEMS 10 NG/ML THC URINE CONTROL(SYNCHRON SYSTEMS 10 NG/ML THC URINE CONTROL)-THE BECKMAN COULTER 10, 20, 40, 75, AND 125 NG/ML THC URINE CONTROLS, IN CONJUNCTION WITH SYNCHRON REAGENTS, ARE INTENDED FOR USE ON SYNCHRON SYSTEMS FOR MONITORING THE QUALITY CONTROL FOR CANNABINOID IN THE CLINICAL LABORATORY. THE 10 AND 40 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 20 NG REAGENT, THE 20 AND 75 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 50 NG REAGENT AND THE 75 AND 125 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 100 NG REAGENT.,SYNCHRON SYSTEMS AQUA CAL 2 (SYNCHRON SYSTEMS AQUA CAL 2)-THE BECKMAN COULTER AQUA CAL 1,2 AND 3 ARE INTENDED FOR USE ON UNICEL DXC SYSTEM FOR THE CALIBRATOR OF SODIUM, POTASSIUM, CHLORIDE, UREA NITROGEN, UREA, GLUCOSE CREATININE, CALCIUM, CARBON DIOXIDE, AND PHOSPHORUS,ULTIMATE -D BILIRUBIN CONTROL LEVEL 4(ULTIMATE -D BILIRUBIN CONTROL LEVEL 4)-ULTIMATE-D BILIRUBIN LIQUID CONTROLS ARE STABILIZED AND DESIGNED FOR USE IN THE QUALITY CONTROL OF TOTAL AND DIRECT-ACTING (CONJUGATED) BILIRUBIN DETERMINATIONS BY MANUAL AND AUTOMATED ANALYTICAL SYSTEMS. MULTIPLE LEVELS ARE AVAILABLE SEPARATELY TO PROVIDE CONTROL ACROSS THE RANGE OF LINEARITY OR AT SPECIFIC LEVELS.,IRON REAGENT (FE 2 X 200)(IRON REAGENT (FE 2 X 200))-FE REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS FE/IBCT CALIBRATOR KIT, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM OR HEPARINIZED PLASMA.,CALIBRATOR 5 PLUS (CAL 5 PLUS) (CALIBRATOR 5 PLUS (CAL 5 PLUS))-CAL 5 PLUS (CALIBRATOR 5 PLUS), WHEN USED IN CONJUNCTION WITH BECKMAN COULTER

	REAGENTS, IS INTENDED FOR USE ON THE IMMAGE IMMUNOCHEMISTRY SYSTEM FOR THE CALIBRATION OF ANTI-STREPTOLYSIN O (ASO), C-REACTIVE PROTEIN (CRP AND CRPH), AND RHEUMATOID FACTOR (RF).,LIPASE REAGENT (LIP 2 X 60)(LIPASE REAGENT (LIP 2 X 60))-LIP REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS ENZYME VALIDATOR SET, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF LIPSAE ACTIVITY IN HUMAN SERUM OR PLASMA IN RANDOM ACCESS MODE.,IMMAGE IMMUNOCHEMISTRY SYSTEMS AAG ALPHA-1-ACID GLYCOPROTEIN REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS AAG ALPHA-1-ACID GLYCOPROTEIN REAGENT)-AAG REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 1, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ALPHA1-ACID GLYCOPROTEIN (AAG) IN HUMAN SERUM BY RATE NEPHELOMETRY.,ALANINE AMINOTRANSFERASE REAGENT (ALT 2 X 400)(ALANINE AMINOTRANSFERASE REAGENT (ALT 2 X 400))-ALT REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S), IS INTENDED FOR THE QUANTITATIVE DETERMINATION AF ALANINE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM OR PLASMA,IMMAGE IMMUNOCHEMISTRY SYSTEMS KAP KAPPA LIGHT CHAIN REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS KAP KAPPA LIGHT CHAIN REAGENT)-KAP REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 1, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF KAPPA LIGHT CHAIN (KAP) (FREE AND BOUND) IN HUMAN SERUM AND URINE BY RATE NEPHELOMETRY,SYNCHRON AND AU SYSTEMS HEMOLYZING REAGENT(SYNCHRON AND AU SYSTEMS HEMOLYZING REAGENT)-THE HEMOGLOBIN A1C-REAGENT WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYNCHRON SYSTEMS UNICEL DXC SYNCHRON SYSTEM HBA1C-CALIBRATORS AND SYNCHRON AND AU SYSTEMS HEMOLYZING REAGENT, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C CONCENTRATION IN HUMAN WHOLE BLOOD. , SYNCHRON SYSTEMS WASH CONCENTRATE II(SYNCHRON SYSTEMS WASH CONCENTRATE II)-NOT APPLICABLE,CREATININE REAGENT (CREM)(CREATININE REAGENT (CREM))-CREM REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 800 SYSTEM AND SYNCHRON SYSTEMS AQUA CAL 1 AND 2, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF CREATININE CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE,SYNCHRON SYSTEMS DRUG CALIBRATOR 1(SYNCHRON SYSTEMS DRUG CALIBRATOR 1)-THE BECKMAN COULTER SYNCHRON SYSTEMS DRUG CALIBRATOR 1, WHEN USED IN CONJUNCTION WITH SYNCHRON REAGENTS, IS INTENDED FOR USE

	ON THE SYNCHRON SYSTEMS FOR THE CALIBRATION OF CARBAMAZEPINE, PHENOBARBITAL, PHENYTOIN, THEOPHYLLINE, AND VALPROIC ACID.,HDL CHOLESTEROL REAGENT (HDL CHOLESTEROL REAGENT HDL 2 X 200)-FOR USE ON UNICEL DXC SYNCHRON SYSTEMS FOR THE QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN SERUM OR PLASMA.,IMMAGE IMMUNOCHEMISTRY SYSTEMS FER CAL FERRITIN CALIBRATOR (IMMAGE IMMUNOCHEMISTRY SYSTEMS FER CAL FERRITIN CALIBRATOR)-BECKMAN COULTER FERRITIN CALIBRATOR, WHEN USED IN CONJUNCTION WITH FERRITIN (P/N 447160) REAGENT, IS INTENDED FOR USE ON THE IMMAGE IMMUNOCHEMISTRY SYSTEMS, FOR THE CALIBRATION OF FERRITIN.,MAGNESIUM REAGENT (MG 2 X 100)(MAGNESIUM REAGENT (MG 2 X 100))-MG REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS MULTI CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE.,SYNCHRON SYSTEMS DAT DRUG FREE URINE CONTROL(SYNCHRON SYSTEMS DAT DRUG FREE URINE CONTROL)-THE BECKMAN COULTER DAT DRUG FREE URINE CONTROL, IN CONJUNCTION WITH SYNCHRON REAGENTS, IS INTENDED FOR USE ON SYNCHRON SYSTEMS FOR MONITORING THE QUALITY CONTROL FOR AMPHETAMINES, BARBITURATES, BENZODIAZEPINE, COCAINE METABOLITE, METHADONE, METHAQUALONE, OPIATES, PHENCYCLIDINE, PROPOXYPHENE, AND CANNABINOID.,MICROPROTEIN REAGENT (M-TP 2 X 50) (MICROPROTEIN REAGENT (M-TP 2 X 50))-M-TP RAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS MICROPROTEIN CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL MICROPROTEIN IN HUMAN URINE AND CEREBRESPINAL FLUID (CSF),SYNCHRON SYSTEMS PAB CALIBRATOR(SYNCHRON SYSTEMS PAB CALIBRATOR) -PAB CALIBRATOR, WHEN USED IN CONJUNCTION WITH DXC PAB REAGENT (P/N 475106), IS INTENDED FOR USE ON THE UNICEL DXC SYNCHRON SYSTEMS FOR THE CALIBRATION OF PREALBUMIN., ALANINE AMINOTRANFERASE REAGENT (ALT 2 X 200)(ALANINE AMINOTRANFERASE REAGENT (ALT 2 X 200))-ALT REAGENT, WHEN USED IN CONJUCTION WITH UNICEL DXC 600/800 SYSTEMS(S), IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM OR PLASMA, SYNCHRON ALKALINE PHOSPHATASE REAGENT (ALP 2 X 200)(SYNCHRON ALKALINE PHOSPHATASE REAGENT (ALP 2 X 200))-ALP (IFCC-DGKCH) REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON ENZYME VALIDATOR SET, IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALKALINE

	PHOSPHATASE CONCENTRATION IN HUMAN SERUM OR PLASMA. USE OF THIS PRODUCT, IN CONJUNCTION WITH THE SYNCHRON ENZYME VALIDATOR SET, WILL RESULT IN ASSAY VALUES WHICH ARE COMPATIBLE WITH THE METHODS RECOMMENDED BY THE INTERNATIONAL FEDERATION OF CLINICAL CHEMISTRY (IFCC)., ALBUMIN REAGENT (ALB 2 X 300)-ALB REAGENT, WHEN USED IN CONJUCTION WITH UNICEL DXC 600/800 SYSTEMS(S) AND SYNCHRON SYSTEMS MULTI CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN CONCENTRATION IN HUMAN SERUM OR PLASMA,SYNCHRON SYSTEMS DAT NEGATIVE URINE CALIBRATOR(SYNCHRON SYSTEMS DAT NEGATIVE URINE CALIBRATOR)-THE BECKMAN COULTER DAT NEGATIVE URINE CALIBRATOR, IN CONJUNCTION WITH SYNCHRON REAGENTS, IS INTENDED FOR USE ON SYNCHRON SYSTEMS FOR THE CALIBRATION OF AMPHETAMINES, BARBITURATES, BENZODIAZEPINE, CANNABINOID 20 NG, CANNABINOID 50 NG, CANNABINOID 100 NG, COCAINE METABOLITE, METHADONE, METHAQUALONE, OPIATE, PHENCYCLIDINE AND PROPOXYPHENE ENZYME IMMUNOASSAYS., SYNCHRON SYSTEMS FE/IBCT CALIBRATORS KIT (SYNCHRON SYSTEMS FE/IBCT CALIBRATORS KIT)-THE FE/IBCT CALIBRATOR KIT IN CONJUNCTION WITH SYNCHRON SYSTEMS IRON REAGENT OR SYNCHRON SYSTEMS IBCT IS INTENDED FOR THE CALIBRATION OF IRON OR TOTAL IRON BINDING CAPACITY ,ULTIMATE -D BILIRUBIN CONTROL LEVEL 1(ULTIMATE -D BILIRUBIN CONTROL LEVEL 1)-ULTIMATE-D BILIRUBIN LIQUID CONTROLS ARE STABILIZED AND DESIGNED FOR USE IN THE QUALITY CONTROL OF TOTAL AND DIRECT-ACTING (CONJUGATED) BILIRUBIN DETERMINATIONS BY MANUAL AND AUTOMATED ANALYTICAL SYSTEMS. MULTIPLE LEVELS ARE AVAILABLE SEPARATELY TO PROVIDE CONTROL ACROSS THE RANGE OF LINEARITY OR AT SPECIFIC LEVELS., APOLIPOPROTEIN A REAGENT (APOA 2 X 100) (APOLIPOPROTEIN A REAGENT (APOA 2 X 100))-APOA REAGENT WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEMS AND SYNCHRON SYSTEMS APO CALIBRATOR IS INTENDED FOR QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A-1 CONCENTRATION IN HUMAN SERUM AND PLASMA.,VIGIL SEROLOGY CONTROL LEVEL 2(VIGIL SEROLOGY CONTROL LEVEL 2)-VIGIL SEROLOGY STABILIZED LIQUID-CONTROL IS DESIGNED FOR MONITORING THE OVERALL PERFORMANCE OF ANTI-STREPTOLYSIN O, RHEUMATOID FACTOR, AND C-REACTIVE PROTEIN TEST SYSTEMS IN THE CLINICAL LABORATORY. THE USE OF FOUR LEVELS OF CONTROL ENABLES THE LABORATORIAN TO MONITOR CHANGES IN CALIBRATION ALONG WITH ANALYTICAL ERROR AND IMPRECISION. VIGIL SEROLOGY IS NOT INTENDED FOR USE AS A STANDARD.,

	ASPARTATE AMINOTRANSFERASE REAGENT (AST 2 X 200)(ASPARTATE AMINOTRANSFERASE REAGENT (AST 2 X 200))-AST REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S), IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM OR PLASMA.,ENZYMATIC CREATININE REAGENT (CR-E 2 X 200) (ENZYMATIC CREATININE REAGENT (CR-E 2 X 200))-CR-E REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC SYSTEM(S) AND SYNCHRON SYSTEMS AQUA CAL 1 AND 2, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF CREATININE (CR-E) CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE.,SYNCHRON SYSTEM ALBUMIN REAGENT (SYNCHRON SYSTEM ALBUMIN REAGENT)-ALBM REAGENT WHEN USED IN CONJUNCTION WITH UNICEL DXC 800 SYSTEMS AND SYNCHRON SYSTEMS PROTEIN CALIBRATORS IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALBUMIN CONCENTRATION IN HUMAN SERUM AND PLASMA. , ULTIMATE -D BILIRUBIN CONTROL LEVEL 3(ULTIMATE -D BILIRUBIN CONTROL LEVEL 3)-ULTIMATE-D BILIRUBIN LIQUID CONTROLS ARE STABILIZED AND DESIGNED FOR USE IN THE QUALITY CONTROL OF TOTAL AND DIRECT-ACTING (CONJUGATED) BILIRUBIN DETERMINATIONS BY MANUAL AND AUTOMATED ANALYTICAL SYSTEMS. MULTIPLE LEVELS ARE AVAILABLE SEPARATELY TO PROVIDE CONTROL ACROSS THE RANGE OF LINEARITY OR AT SPECIFIC LEVELS.,TOTAL BILIRUBIN REAGENT (TBIL 2 X 200)(TOTAL BILIRUBIN REAGENT (TBIL 2 X 200))-TBIL REAGENT, WHEN USED IN CONJUCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS BILIRUBIN CALIBRATOR, IS INTENDED FOR QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN CONCENTRATION IN HUMAN SERUM OR PLASMA,IMMUNOCHEMISTRY SYSTEMS CAL 3 CALIBRATOR 3 (IMMUNOCHEMISTRY SYSTEMS CAL 3 CALIBRATOR 3)-CAL 3 (CALIBRATOR 3), WHEN USED IN CONJUNCTION WITH BECKMAN COULTER ALBUMIN (ALB) AND PREALBUMIN (PAB) REAGENTS, IS INTENDED FOR USE ON IMMAGE SYSTEMS FOR THE CALIBRATION OF THESE REAGENTS., CARBAMAZEPINE REAGENT (CAR 2 X 100)(CARBAMAZEPINE REAGENT (CAR 2 X 100))-CAR REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS DRUG CALIBRATOR 1 SET, IS INTENDED FOR QUANTITATIVE DETERMINATION OF CARBAMAZEPINE CONCENTRATION IN HUMAN SERUM OR PLASMA.,VIGIL PROTEIN CONTROL LEVEL 2(VIGIL PROTEIN CONTROL LEVEL 2)-VIGIL PROTEIN STABILIZED LIQUID-CONTROLS ARE DESIGNED FOR MONITORING THE RELIABILITY AND OVERALL PERFORMANCE OF SPECIFIC PROTEIN TEST SYSTEMS IN THE CLINICAL LABORATORY.

	THE USE OF THREE LEVELS OF CONTROL ENABLES THE LABORATORIAN TO MONITOR CHANGES IN CALIBRATION ALONG WITH ANALYTICAL ERROR AND IMPRECISION.,UREA REAGENT (UREA REAGENT (UREA 2 X 300))-.UREA REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS MULTI CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF UREA CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE,SYNCHRON SYSTEMS 20 NG/ML THC URINE CONTROL(SYNCHRON SYSTEMS 20 NG/ML THC URINE CONTROL)-THE BECKMAN COULTER 10, 20, 40, 75, AND 125 NG/ML THC URINE CONTROLS, IN CONJUNCTION WITH SYNCHRON REAGENTS, ARE INTENDED FOR USE ON SYNCHRON SYSTEMS FOR MONITORING THE QUALITY CONTROL FOR CANNABINOID IN THE CLINICAL LABORATORY. THE 10 AND 40 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 20 NG REAGENT, THE 20 AND 75 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 50 NG REAGENT AND THE 75 AND 125 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 100 NG REAGENT.,CREATINE KINASE REAGENT (CK 2 X 400)(CREATINE KINASE REAGENT (CK 2 X 400))-CK REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S), IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE ACTIVITY IN HUMAN SERUM OR PLASMA.,SYNCHRON SYSTEMS 40 NG/ML THC URINE CONTROL (SYNCHRON SYSTEMS 40 NG/ML THC URINE CONTROL)-THE BECKMAN COULTER 10, 20, 40, 75, AND 125 NG/ML THC URINE CONTROLS, IN CONJUNCTION WITH SYNCHRON REAGENTS, ARE INTENDED FOR USE ON SYNCHRON SYSTEMS FOR MONITORING THE QUALITY CONTROL FOR CANNABINOID IN THE CLINICAL LABORATORY. THE 10 AND 40 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 20 NG REAGENT, THE 20 AND 75 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 50 NG REAGENT AND THE 75 AND 125 NG/ML CONTROLS ARE TO BE USED ONLY IN CONJUNCTION WITH THE CANNABINOID 100 NG REAGENT.,IMMUNOCHEMISTRY SYSTEMS LEVEL 2 URINE PROTEIN CONTROL(IMMUNOCHEMISTRY SYSTEMS LEVEL 2 URINE PROTEIN CONTROL)-URINE PROTEIN CONTROL LEVEL 2 INTENDED FOR USE WITH BECKMAN COULTER CLINICAL SYSTEMS IN CONJUNCTION WITH ALPHA-1 MICROGLOBULIN , MICRO ALBUMIN, URINE TRANSFERRIN AND IMMUNOGLOBULIN G KITS IN THE QUALITY CONTROL IN URINARY ALPHA -1 MICROGLOBULIN ALBUMIN TRANFERRIN AND IMMUNOGLOBULIN G DETERMINATION.,PANCREATIC AMYLASE REAGENT (PAM 2 X 60)(PANCREATIC AMYLASE REAGENT (PAM 2 X

	60))-PAM REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S), IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF PANCREAS-SPECIFIC AMYLASE ACTIVITY IN HUMAN SERUM, PLASMA, OR URINE.,LACTATE DEHYDROGENASE REAGENT (LACTATE DEHYDROGENASE REAGENT (LD-P 2 X 200))-FOR USE ON SYNCHRON SYSTEMS FOR THE QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE (PYRUVATE TO LACTATE) IN SERUM OR PLASMA.,IMMUNOGLOBULIN A REAGENT (IG-A 2 X 150)(IMMUNOGLOBULIN A REAGENT (IG-A 2 X 150))-IG-A REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS CAL 1, IS INTENDED FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A CONCENTRATION IN HUMAN SERUM OR PLASMA.,IMMAGE IMMUNOCHEMISTRY SYSTEMS PAB PREALBUMIN REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS PAB PREALBUMIN REAGENT)-PAB REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 3, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF PREALBUMIN (PAB) IN HUMAN SERUM BY RATE NEPHELOMETRY.,IMMAGE IMMUNOCHEMISTRY SYSTEMS PFB PROPERDIN FACTOR B REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS PFB PROPERDIN FACTOR B REAGENT)-PFB REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 2, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF PROPERDIN FACTOR B (PFB) IN HUMAN SERUM BY RATE NEPHELOMETRY., SALICYLATE REAGENT (SALY 2 X 45) KIT(SALICYLATE REAGENT (SALY 2 X 45) KIT)-SALY REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS SALICYLATE CALIBRATOR, IS INTENDED FOR QUANTITATIVE DETERMINATION OF SALICYLATE CONCENTRATION IN HUMAN SERUM OR PLASMA.,APO CAL APOLIPOPROTEIN CALIBRATOR(APO CAL APOLIPOPROTEIN CALIBRATOR)-APO CAL (APOLIPOPROTEIN CALIBRATOR), WHEN USED IN CONJUNCTION WITH BECKMAN COULTER APOLIPOPROTEIN A-1 AND B REAGENTS, IS INTENDED FOR USE ON IMMAGE SYSTEMS FOR THE CALIBRATION OF THESE REAGENTS.,IMMUNOCHEMISTRY SYSTEMS CAL 1 CALIBRATOR 1 (IMMUNOCHEMISTRY SYSTEMS CAL 1 CALIBRATOR 1)-CAL 1 (CALIBRATOR 1), WHEN USED IN CONJUNCTION WITH BECKMAN COULTER ALPHA1-ACID GLYCOPROTEIN (AAG), COMPLEMENT C3 (C3), COMPLEMENT C4 (C4), HAPTOGLOBIN (HPT), IMMUNOGLOBULIN A (IGA), IMMUNOGLOBULIN G (IGG), IMMUNOGLOBULIN M (IGM), KAPPA LIGHT CHAIN (KAP), LAMBDA LIGHT CHAIN (LAM), AND TRANSFERRIN (TRF) REAGENTS, IS INTENDED FOR USE ON IMMAGE SYSTEMS FOR THE CALIBRATION OF THESE REAGENTS.,

	IMMUNOCHEMISTRY SYSTEMS UCAL URINE PROTEIN CALIBRATOR (IMMUNOCHEMISTRY SYSTEMS UCAL URINE PROTEIN CALIBRATOR)-UCAL (URINE PROTEIN CALIBRATOR), WHEN USED IN CONJUNCTION WITH BECKMAN COULTER MICROALBUMIN (MA), URINE TRANSFERRIN (TRU), ALPHA-1- MICROGLOBULIN (A1M) AND URINE IMMUNOGLOBULIN G (IGU) REAGENTS, IS INTENDED FOR USE ON IMMAGE FOR THE CALIBRATION OF THESE REAGENTS.,IMMAGE IMMUNOCHEMISTRY SYSTEMS MA MICROALBUMIN REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS MA MICROALBUMIN REAGENT)-MA REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND URINE PROTEIN CALIBRATOR, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF MICRO QUANTITIES OF ALBUMIN (MA) IN HUMAN URINE BY RATE NEPHELOMETRY.,VIGIL LIPID CONTROL LEVEL 2(VIGIL LIPID CONTROL LEVEL 2)-VIGIL LIPID CONTROL STABILIZED LIQUID-CONTROL SERUMS ARE INTENDED FOR MONITORING THE RELIABILITY OF MANUAL AND AUTOMATED IN VITRO DIAGNOSTIC ASSAYS OF LIPID ANALYTES. THE VALUES FOR THIS CONTROL HAVE BEEN ESTABLISHED USING BECKMAN COULTER REAGENTS ON BECKMAN COULTER CLINICAL ANALYZERS, AND ARE SPECIFIC FOR THOSE SYSTEMS. THE USE OF THREE OR MORE LEVELS OF CONTROL ENABLES THE LABORATORIAN TO MONITOR CHANGES IN CALIBRATION LINEARITY ALONG WITH ANALYTICAL ERROR AND IMPRECISION.,SYNCHRON SYSTEMS MICROPROTEIN CALIBRATOR (SYNCHRON SYSTEMS MICROPROTEIN CALIBRATOR)-THE MICROPROTEIN CALIBRATOR, USED IN CON-JUNCTION WITH SYNCHRON REAGENTS, IS INTENDED FOR USE ON SYNCHRON SYSTEMS FOR THE CALIBRATION OF MICROPROTEIN REAGENT., TOTAL IRON BINDING CAPACITY REAGENT (IBCT 2 X 100)(TOTAL IRON BINDING CAPACITY REAGENT (IBCT 2 X 100))-IBCT REAGENT, WHEN USED IN CONJUNCTION WITH DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS FE/IBCT CALIBRATOR KIT, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL IRON BINDING CAPACITY IN HUMAN SERUM OR HEPARINIZED (SODIUM) PLASMA., HIGH SENSITIVITY CARDIAC C-REACTIVE PROTEIN REAGENT (CRPH 2 X 200)(HIGH SENSITIVITY CARDIAC C-REACTIVE PROTEIN REAGENT (CRPH 2 X 200))-HIGH SENSITIVITY CARDIAC C-REACTIVE PROTEIN (CRPH) REAGENT WHEN USED IN CONJUNCTION WITH THE UNICEL DXC 600/800 SYSTEMS AND SYNCHRON SYSTEMS CAL 5 PLUS IS INTENDED FOR THE QUANTITATIVE DETERMINATION OD C-REACTIVE PROTEIN IN HUMAN PLASMA AND SERUM ,IMMAGE LMMUNOCHEMISTRY SYSTEMS AT3 ANTITHROMBIN III REAGENT (IMMAGE LMMUNOCHEMISTRY SYSTEMS AT3 ANTITHROMBIN III REAGENT)-AT3 REAGENT, WHEN USED IN CONJUNCTION WITH

	IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 2, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ANTITHROMBIN III (AT3) IN HUMAN PLASMA BY RATE NEPHELOMETRY. ONLY ANTITHROMBIN III CONCENTRATION IS MEASURED, NOT ITS ACTIVITY.,TRIGLYCERIDES REAGENT (TG 2 X 300)(TRIGLYCERIDES REAGENT (TG 2 X 300))-TG REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON SYSTEMS MULTI CALIBRATOR, IS INTENDED FOR QUANTITATIVE DETERMINATION OF TOTAL TRIGLYCERIDES CONCENTRATION IN HUMAN SERUM OR PLASMA. ,SYNCHRON SYSTEMS APO CALIBRATOR(SYNCHRON SYSTEMS APO CALIBRATOR)-APO CAL (APOLIPOPROTEIN CALIBRATOR), WHEN USED IN CONJUNCTION WITH BECKMAN COULTER APOLIPOPROTEIN A-1 AND B REAGENTS, IS INTENDED FOR USE ON UNICEL DXC SYSTEMS FOR THE CALIBRATION OF THESE REAGENTS.,IMMAGE IMMUNOCHEMISTRY SYSTEMS IGM IMMUNOGLOBULIN M REAGENT (IMMAGE IMMUNOCHEMISTRY SYSTEMS IGM IMMUNOGLOBULIN M REAGENT)-IGM REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CALIBRATOR 1, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM BY RATE NEPHELOMETRY.,IMMUNOCHEMISTRY SYSTEMS LEVEL 1 URINE PROTEIN CONTROL(IMMUNOCHEMISTRY SYSTEMS LEVEL 1 URINE PROTEIN CONTROL)-URINE PROTEIN CONTROL LEVEL 1 IS INTENDED FOR USE WITH BECKMAN COULTER CLINICAL SYSTEMS IN CONJUNCTION WITH THE ALPHA 1 MICROGLOBULIN, MICRO ALBUMIN URINE TRANSFERRIN AND IMMUNOGLOBULIN G KITS, IN THE QUALITY CONTROL OF URINARY ALPHA 1 MICROGLOBULIN, MICRO ALBUMIN URINE TRANSFERRIN AND IMMUNOGLOBULIN G DETERMINATION.,IMMAGE IMMUNOCHEMISTRY SYSTEMS IGALC LOW CONCENTRATION IMMUNOGLOBULIN A REAGENT(IMMAGE IMMUNOCHEMISTRY SYSTEMS IGALC LOW CONCENTRATION IMMUNOGLOBULIN A REAGENT)-IGALC REAGENT, WHEN USED IN CONJUNCTION WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND CEREBROSPINAL FLUID PROTEIN CALIBRATOR, IS INTENDED FOR QUANTITATIVE DETERMINATION OF LOW CONCENTRATION IMMUNOGLOBULIN A (IGALC) IN HUMAN SERUM OR CEREBROSPINAL FLUID (CSF) BY RATE NEPHELOMETRY., LACTATE DEHYDROGENASE REAGENT (LD 2 X 200)(LACTATE DEHYDROGENASE REAGENT (LD 2 X 200))-LD REAGENT, WHEN USED IN CONJUNCTION WITH UNICEL DXC 600/800 SYSTEM(S) AND SYNCHRON ENZYME VALIDATOR SET, IS INTENDED FOR QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE CONCENTRATION IN HUMAN SERUM OR PLASMA. USE OF THIS PRODUCT, IN CONJUNCTION WITH THE SYNCHRON

	ENZYME VALIDATOR SET, WILL RESULT IN ASSAY VALUES WHICH ARE COMPATIBLE WITH THE METHODS RECOMMENDED BY THE INTERNATIONAL FEDERATION OF CLINICAL CHEMISTRY (IFCC)

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

114	IMP/IVD/2019/000035	1.License Holder Name: BIOMERIEUX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VITEK 2 AST-N407(VITEK 2 AST-N407)-THE VITEK 2 GRAM NEGATIVE SUSCEPTIBILITY CARD IS INTENDED FOR USE WITH THE VITEK 2 SYSTEMS IN CLINICAL LABORATORIES AS AN IN VITRO TEST TO DETERMINE THE SUSCEPTIBILITY OF CLINICALLY SIGNIFICANT AEROBIC GRAM NEGATIVE BACILLI TO ANTIMICROBIAL AGENTS WHEN USED AS INSTRUCTED.,VITEK 2 AST-GN 96(VITEK 2 AST-GN 96)-FOR VETERINARY USE ONLY. THE VITEK® 2 GRAM NEGATIVE SUSCEPTIBILITY CARD IS INTENDED FOR USE WITH THE VITEK 2 SYSTEMS TO DETERMINE THE SUSCEPTIBILITY OF CLINICALLY SIGNIFICANT AEROBIC GRAM-NEGATIVE BACILLI TO ANTIMICROBIAL AGENTS ,VITEK 2 AST-N406(VITEK 2 AST-N406)-THE VITEK 2 GRAM NEGATIVE SUSCEPTIBILITY CARD IS INTENDED FOR USE WITH THE VITEK 2 SYSTEMS IN CLINICAL LABORATORIES AS AN IN VITRO TEST TO DETERMINE THE SUSCEPTIBILITY OF CLINICALLY SIGNIFICANT AEROBIC GRAM NEGATIVE BACILLI TO ANTIMICROBIAL AGENTS WHEN USED AS INSTRUCTED.,VITEK 2 104 WELL CARD(VITEK 2 OPUS AST-N01F)-IT IS INTENDED TO BE USED TO DETERMINE THE SUSCEPTIBILITY OF CLINICALLY SIGNIFICANT AEROBIC GRAM-NEGATIVE BACILLI TO ANTIMICROBIAL AGENTS.,VITEK 2 AST-N405 (VITEK 2 AST-N405)-THE VITEK 2 GRAM NEGATIVE SUSCEPTIBILITY CARD IS INTENDED FOR USE WITH THE VITEK 2 SYSTEMS IN CLINICAL LABORATORIES AS AN IN VITRO TEST TO DETERMINE THE SUSCEPTIBILITY OF CLINICALLY SIGNIFICANT AEROBIC GRAM NEGATIVE BACILLI TO ANTIMICROBIAL AGENTS WHEN USED AS INSTRUCTED.,VITEK 2 AST-N363(VITEK 2 AST-N363)-INTENDED FOR USE WITH THE VITEK 2 SYSTEMS IN CLINICAL LABORATORIES AS AN IN VITRO TEST TO DETERMINE THE SUSCEPTIBILITY OF CLINICALLY SIGNIFICANT AEROBIC GRAM NEGATIVE BACILLI TO ANTIMICROBIAL AGENTS.,VITEK 2 AST-ST03(VITEK 2 AST-ST03)-INTENDED FOR USE WITH THE VITEK 2 SYSTEMS IN CLINICAL LABORATORIES AS AN INVITRO TEST TO DETERMINE THE SUSCEPTIBILITY OF S. PNEUMONIAE, BETA-HEMOLYTIC STREPTOCOCCUS, AND VIRIDANS STREPTOCOCCUS TO ANTIMICROBIAL AGENTS,VITEK 2 AST-YS08 (VITEK 2 AST-YS08)-INTENDED FOR USE WITH THE VITEK 2 SYSTEMS IN CLINICAL LABORATORIES AS AN IN VITRO TEST TO DETERMINE THE SUSCEPTIBILITY OF CLINICALLY SIGNIFICANT YEASTS TO ANTIFUNGAL AGENTS.,VITEK 2 AST-N281(VITEK 2 AST-N281)-INTENDED FOR USE WITH THE VITEK 2 SYSTEMS IN CLINICAL LABORATORIES AS AN IN VITRO TEST TO DETERMINE THE SUSCEPTIBILITY OF CLINICALLY SIGNIFICANT AEROBIC GRAM NEGATIVE BACILLI TO ANTIMICROBIAL AGENTS .,VITEK 2 AST-N364

	(VITEK 2 AST-N364)-INTENDED FOR USE WITH THE VITEK 2 SYSTEMS IN CLINICAL LABORATORIES AS AN IN VITRO TEST TO DETERMINE THE SUSCEPTIBILITY OF CLINICALLY SIGNIFICANT AEROBIC GRAM NEGATIVE BACILLI TO ANTIMICROBIAL AGENTS,VITEK 2 AST-GP 79 (VITEK 2 AST-GP 79)-FOR VETERINARY USE ONLY. THE VITEK® 2 GRAM POSITIVE SUSCEPTIBILITY CARD IS INTENDED FOR USE WITH THE VITEK 2 SYSTEMS TO DETERMINE THE SUSCEPTIBILITY OF STAPHYLOCOCCUS SPP., ENTEROCOCCUS SPP., AND S. AGALACTIAE TO ANTIMICROBIAL AGENTS . ,VITEK 2 ANC(VITEK 2 ANC)-INTENDED FOR USE WITH THE VITEK 2 SYSTEMS FOR THE AUTOMATED IDENTIFICATION OF MOST CLINICALLY SIGNIFICANT ANAEROBIC ORGANISMS AND CORYNEBACTERIUM SPECIES.,VITEK 2 NH(VITEK 2 NH)-INTENDED FOR USE WITH THE VITEK 2 SYSTEMS FOR THE AUTOMATED IDENTIFICATION OF MOST CLINICALLY SIGNIFICANT FASTIDIOUS ORGANISMS.,VITEK 2 AST-P628(VITEK 2 AST-P628)-INTENDED FOR USE WITH THE VITEK 2 SYSTEMS IN CLINICAL LABORATORIES AS AN IN VITRO TEST TO DETERMINE THE SUSCEPTIBILITY OF STAPHYLOCOCCUS SPP., ENTEROCOCCUS SPP., AND S.AGALACTIAE TO ANTIMICROBIAL AGENTS.,VITEK 2 AST-GN69 (VITEK 2 AST-GN69)-INTENDED FOR USE WITH THE VITEK 2 SYSTEMS IN CLINICAL LABORATORIES AS AN IN VITRO TEST TO DETERMINE THE SUSCEPTIBILITY OF CLINICALLY SIGNIFICANT AEROBIC GRAM NEGATIVE BACILLI TO ANTIMICROBIAL AGENTS .,VITEK 2 AST N280 (VITEK 2 AST N280)-INTENDED FOR USE WITH THE VITEK 2 SYSTEMS IN CLINICAL LABORATORIES AS AN IN VITRO TEST TO DETERMINE THE SUSCEPTIBILITY OF CLINICALLY SIGNIFICANT AEROBIC GRAM NEGATIVE BACILLI TO ANTIMICROBIAL AGENTS,VITEK 2 YST(VITEK 2 YST)-INTENDED FOR USE WITH VITEK 2 SYSTEMS FOR THE AUTOMATED IDENTIFICATION OF MOST CLINICALLY SIGNIFICANT YEASTS AND YEAST-LIKE ORGANISMS.,VITEK 2 GP(VITEK 2 GP)-INTENDED FOR USE WITH VITEK 2 SYSTEMS FOR THE AUTOMATED IDENTIFICATION OF MOST SIGNIFICANT GRAM-POSITIVE ORGANISMS.,VITEK 2 AST-N235(VITEK 2 AST-N235)-INTENDED FOR USE WITH THE VITEK 2 SYSTEMS IN CLINICAL LABORATORIES AS AN IN VITRO TEST TO DETERMINE THE SUSCEPTIBILITY OF CLINICALLY SIGNIFICANT AEROBIC GRAM NEGATIVE BACILLI TO ANTIMICROBIAL AGENTS ,VITEK 2 GN(VITEK 2 GN)-INTENDED FOR USE WITH THE VITEK 2 SYSTEMS FOR THE AUTOMATED IDENTIFICATION OF MOST CLINICALLY SIGNIFICANT FERMENTING AND NON-FERMENTING GRAM NEGATIVE BACILLI

115	IMP/IVD/2019/000036	1.License Holder Name: POCT SERVICES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLUCOSE PAP SL (ELITECH)-IT IS INTENDED FOR THE QUANTITATIVE IN-VITRO DIAGNOSTIC DETERMINATION OF GLUCOSE LEVEL IN HUMAN SERUM & PLASMA.
116	IMP/IVD/2019/000037	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLUCOSE PAP SL (ELITECH)-IT IS INTENDED FOR THE QUANTITATIVE IN-VITRO DIAGNOSTIC DETERMINATION OF GLUCOSE LEVEL IN HUMAN SERUM & PLASMA.

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117	IMP/IVD/2019/000038	1.License Holder Name: POCT SERVICES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASO-TURBI(LABKIT)-QUANITATIVE DETERMINATION OF ASO IN HUMAN SAMPLES,LDLC-D (LABKIT)-QUANTITATIVE DETERMINATION OF CHOLESTEROL LDL IN HUMAN SAMPLES.,HDLC-D(LABKIT)-QUANTITATIVE DETERMINATION OF CHOLESTEROL HDL IN HUMAN SAMPLES,MICROALBUMIN TURBI (LABKIT)-SERUM CONTROL FOR B2 MICROALBUMIN TURBIDIMETRY ASSAY,APO-CAL(LABKIT)-SERUM CALIBRATOR FOR APO A1/B TURBIDIMETRY ASSAY,COMPLEMENT C4(LABKIT)-QUANTITATIVE DETERMINATION OF COMPLEMENT C4 IN HUMAN SAMPLES, COMPLEMENT C3(LABKIT)-QUANTITATIVE DETERMINATION OF COMPLEMENT C3 IN HUMAN SAMPLES,APO B(LABKIT)-QUANTITATIVE DETERMINATION OF HUMAN APOLIPOPROTEIN B (APO B),APO A1(LABKIT)-QUANTITATIVE DETERMINATION OF HUMAN APOLIPOPROTEIN A1 (APO A1),FERRITIN(LABKIT)-SERUM CONTROL FOR FERRITIN TURBIDIMETRY ASSAY,ASO/CRP/RF-CTROL H(LABKIT) -SERUM CONTROL MULTICOMPONENT FOR ASO, CRP, RF TURBIDIMETRY ASSYS WITH VALUES IN PATHOLOGICAL RANGE,CRP TURBI(LABKIT)-QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SAMPLES,RF TURBI(LABKIT)-QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR IN HUMAN SAMPLES,RF LATEX KIT(LABKIT)-QUALITATIVE DETERMINATION OF RHEUMATOID FACTOR IN HUMAN SAMPLES,CRP LATEX KIT(LABKIT)-QUALITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SAMPLES.,ASO LATEX KIT(LABKIT)-QUALITATIVE DETERMINATION OF ASO IN HUMAN SAMPLES,LABTROL H PATHOLOGICAL(LABKIT)-LABTROL PATHOLOGICAL IS MULTIPARAMETRIC CONTROL SERA INTENDED FOR ACCURACY CONTROL OF LABKIT CLINICAL CHEMISTRY REAGENTS. THE CONCENTRATIONS AND ACTIVITIES ARE IN THE PATHOLOGICAL RANGE(BOVINE SOURCE),CHE CHOLINESTERASE (LABKIT)-QUANTITATIVE DETERMINATION OF THE CHOLINESTERASE ACTIVITY IN HUMAN SAMPLES,AMYLASE-LQ(LABKIT)-QUANTITATIVE DETERMINATION OF THE ALPHA-AMYLASE ACTIVITY IN HUMAN SAMPLES.,ACP ACID PHOSPHATASE(LABKIT)-QUANTITATIVE DETERMINATION OF ACID PHOSPHATASE (ACP) ACTIVITY IN HUMAN SAMPLES.,LABTROL H CAL(LABKIT)-LABTROL H IS A MULTIPARAMETRIC CALIBRATOR INTENDED FOR THE CALIBRATION OF LABKIT REAGENTS(BOVINE SOURCE),TIBC(LABKIT)-QUANTITAVIE DETERMINATION OF IRON TIBC IN HUMAN SAMPLES,PROTEIN U & CSF (LABKIT)-QUANTITATIVE DETERMINATION OF TOTAL URINARY & CSF PROTEIN IN HUMAN SAMPLES,LIPASE-LQ(LABKIT)-QUANTITATIVE DETERMINATION OF THE LIPASE ACTIVITY IN HUMAN SAMPLES, LABTROL H NORMAL(LABKIT)-LABTROL NORMAL IS

	MULTIPARAMETRIC CONTROL SERA INTENDED FOR ACCURACY CONTROL OF LABKIT CLINICAL CHEMISTRY REAGENTS. THE CONCENTRATIONS AND ACTIVITIES ARE IN THE NORMAL RANGE OR AT THE NORMAL THRESHOLD (BOVINE SOURCE)

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118	IMP/IVD/2019/000039	1.License Holder Name: M/S AVANTOR PERFORMANCE MATERIALS INDIA LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HBA1C RAPID QUANTITATIVE TEST(FINECARE)-USED QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C IN HUMAN BLOOD. THE TEST IS USED AS AN AID TO MONITOR LONG-TERM GLYCEMIC STATUS IN PATIENTS WITH DIABETES MELLITUS.,CTNI-NT PROBNP(CTNI-NTPROBNP RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF CTN I AND NT-PROBNP IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION AND SUSPECTED CONGESTIVE HEART FAILURE. ,T4 RAPID QUANTITATIVE TEST (FINECARE)-QUANTITATIVE DETERMINATION OF THYROXINE (TOTAL T4) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID TO THE ASSESSMENT OF THYROID FUNCTION.,-HCG(-HCG RAPID QUANTITATIVE TEST)-"QUANTITATIVE DETERMINATION OF -HCG IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF EARLY DETECTION OF PREGNANCY.",T3 RAPID QUANTITATIVE TEST (FINECARE)-QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (TOTAL T3) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID TO THE ASSESSMENT OF THYROID FUNCTION.,H-FABP(H-FABP RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF H-FABP IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION. ,TSH RAPID QUANTITATIVE TEST (FINECARE)-QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID TO ASSIST IN THE ASSESSMENT OF PITUITARY GLAND AND THYROID FUNCTION.,CK-MB /MYO/CTN I(CK-MB/MYO/CTN I RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF CTNI, CK-MB AND MYO IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION. ,VITAMIN D RAPID QUANTITATIVE TEST(FINECARE)-QUANTITATIVE DETERMINATION OF TOTAL 25(OH) D2/D3 LEVEL IN HUMAN SERUM/PLASMA. THE TEST IS USED AS AN AID IN MANAGEMENT AND MONITORING OF REGULATING THE CONCENTRATION OF CALCIUM AND PHOSPHATE IN THE BLOODSTREAM AND PROMOTING THE HEALTH GROWTH AND REMODELING OF BONE.,TROPONIN I (TROPONIN I RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF CTN I IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS

	OF ACUTE MYOCARDIAL INFARCTION (AMI). ,NAGL RAPID QUANTITATIVE TEST(FINECARE)-QUANTITATIVE DETERMINATION OF NEUTROPHIL GELATINASE ASSOCIATED LIPOCALIN (NAGL) CONCENTRATION IN HUMAN URINE. THE TEST IS USED AS AN AID FOR THE DIAGNOSIS OF KIDNEY INJURIES.,PCT(PCT RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF PCT IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO DIAGNOSIS SEVERE, BACTERIAL INFECTION AND SEPSIS. ,BNP RAPID QUANTITATIVE TEST(FINECARE)-INTENDED FOR QUANTITATIVE DETERMINATION OF BRAIN NATRIURETIC PEPTIDES (BNP) IN HUMAN WHOLE BLOOD OR PLASMA.,CRP(CRP RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF CRP IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS USED AS AN AID TO PREDICT FUTURE CARDIOVASCULAR DISEASES (CVD) AS WELLAS TO SEE INFECTION AND INFLAMMATION. ,PROGESTERONE RAPID QUANTITATIVE TEST(FINECARE)-INTENDED FOR QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM, WHOLE BLOOD OR PLASMA. ,D-DIMER(D-DIMER RAPID QUANTITATIVE TEST)-"QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN WHOLE BLOOD AND PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF THROMBOSIS AND THROMBOTIC DISEASES." ,FSH RAPID QUANTITATIVE TEST(FINECARE)-INTENDED FOR QUANTITATIVE MEASUREMENT OF FOLLICLE-STIMULATING HORMONE (FSH) IN HUMAN WHOLE BLOOD OR PLASMA. ,MYO(MYO RAPID QUANTITATIVE TEST)-"QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI). " ,LH RAPID QUANTITATIVE TEST (FINECARE)-INTENDED FOR QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN WHOLE BLOOD OR PLASMA. , NT-PROBNP(NT-PROBNP RAPID QUANTITATIVE TEST)-"QUANTITATIVE DETERMINATION OF NT-PROBNP IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS USED AS AN AID FOR THE DIAGNOSIS OF SUSPECTED CONGESTIVE HEART FAILURE. " ,CK-MB (CK-MB RAPID QUANTITATIVE TEST)-"QUANTITATIVE DETERMINATION OF CK-MB IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI). " ,ONE STEP D-DIMER (ONE STEP D-DIMER RAPID QUANTITATIVE TEST)-"QUANTITATIVE ANALYSIS OF CROSS-LINKED FIBRIN DEGRADATION PRODUCTS CONTAINING D-DIMER IN HUMAN WHOLE BLOOD OR PLASMA. THE TEST IS USED AS AN AID IN DETECTING THE PRESENCE AND ASSESSING THE DEGREE OF INTRAVASCULAR COAGULATION OR THROMBOEMBOLIC EVENTS INCLUDING PULMONARY EMBOLISM. " ,

	ONE STEP PCT(ONE STEP PCT RAPID QUANTITATIVE TEST)-"QUANTITATIVE MEASUREMENT OF PROCALCITONIN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS USED AS AN AID TO DIAGNOSE AND CONTROL THE TREATMENT OF SEVERE, BACTERIAL INFECTION AND SEPSIS." ,ONE STEP MAU(ONE STEP MAU RAPID QUANTITATIVE TEST)-"QUANTITATIVE DETERMINATION OF MAU IN HUMAN URINE. THIS TEST IS USED AS AN AID TO DIAGNOSIS OF KIDNEY DAMAGE." ,CRP-PCT(CRP-PCT RAPID QUANTITATIVE TEST)-"QUANTITATIVE DETERMINATION OF CRP AND PCT IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO SEE INFECTION AND INFLAMMATION AND USED TO AID IN THE EARLY DETECTION OF CLINICALLY RELEVANT BACTERIAL INFECTIONS."

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119	IMP/IVD/2019/000040	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCESS SENSITIVE ESTRADIOL-THE ACCESS SENSITIVE ESTRADIOL ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS VITAMIN B12-THE ACCESS VITAMIN B12 ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS.,COULTER LH SERIES PAK REAGENT KIT (COULTER LH SERIES PAK REAGENT KIT)-FOR USE ON COULTER HMX, LH 500, LH 750, AND LH 780 HEMATOLOGY ANALYZERS TO LYSE ERYTHROCYTES AND PRESERVE LEUKOCYTES. USE WITH ONLY LH SERIES OR ISOTON 4 DILUENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE.,ACCESS PROLACTIN-THE ACCESS PROLACTIN ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS,PREALBUMIN(PREALBUMIN)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF PREALBUMIN IN HUMAN SERUM ON BECKMAN COULTER AU ANALYSERS.,ACCESS INTACT PTH-THE ACCESS INTACT PTH ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (PARATHYRIN, PTH) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,-1 ACIDGLYCOPROTEIN(-1 ACIDGLYCOPROTEIN)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF -1 ACIDGLYCOPROTEIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,ACCESS MYOGLOBIN-THE ACCESS MYOGLOBIN ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ASO(ASO)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF ASO (ANTI-STREPTOLYSIN O) ANTIBODIES IN HUMAN SERUM ON BECKMAN COULTER ANALYSERS.,ACCESS HYBRITECH PSA-THE ACCESS HYBRITECH PSA ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROSTATE SPECIFIC ANTIGEN (PSA) LEVELS IN HUMAN SERUM USING THE ACCESS

	IMMUNOASSAY SYSTEMS.,SERUM PROTEIN MULTI-CALIBRATOR 1 (SERUM PROTEIN MULTI-CALIBRATOR 1)-THE SERUM PROTEIN MULTI-CALIBRATOR IS INTENDED TO BE USED WITH THE IMMUNOTURBIDIMETRIC REAGENTS LISTED IN THE IFU FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G, IMMUNOGLOBULIN A, IMMUNOGLOBULIN M, COMPLEMENT 3, COMPLEMENT 4, TRANSFERRIN, C-REACTIVE PROTEIN, ANTI-STREPTOLYSIN O AND FERRITIN ON BECKMAN COULTER ANALYSERS. THE MATERIAL IS PREPARED FROM HUMAN SERUM WITH THE CONSTITUENT VALUES ADJUSTED WHERE NECESSARY BY THE ADDITION OF ANALYTICAL GRADE CHEMICALS AND APPROPRIATE SERUM PROTEINS.,ACCESS HYBRITECH FREE PSA-THE ACCESS HYBRITECH FREE PSA ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (FREE PSA) IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS FOLATE(ACCESS FOLATE)-THE ACCESS FOLATE ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLIC ACID LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) OR RED BLOOD CELLS USING THE ACCESS IMMUNOASSAY SYSTEMS. FOLATE LEVELS IN SERUM AND PLASMA (HEPARIN) OR RED BLOOD CELLS ARE USED TO ASSESS FOLATE STATUS. THE SERUM FOLATE LEVELS IS AN INDICATOR OF RECENT FOLATE INTAKE. A LOW RBC FOLATE VALUE CAN INDICATE A PROLONGED FOLATE DEFICIENCY.,ACCESS HFSH CALIBRATORS-THE ACCESS HFSH CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS HFSH ASSAY FOR THE QUANTITATIVE DETERMINATION OF FSH LEVELS IN HUMAN SERUM USING THE ACCESS IMUNOASSAY SYSTEMS.",HBA1C (HEMOGLOBIN A1C)(HBA1C (HEMOGLOBIN A1C))-THE HBA1C (HEMOGLOBIN A1C) REAGENT, WHEN USED IN CONJUNCTION WITH BECKMAN COULTER SYSTEMS, HBA1C CALIBRATORS, AND SYNCHRON AND AU HEMOLYZING REAGENT, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C CONCENTRATION IN HUMAN WHOLE BLOOD. THE ABSOLUTE HBA1C AND TOTAL HEMOGLOBIN (THB) VALUES GENERATED AS PART OF THE HBA1C ASSAY ARE INTENDED FOR USE IN THE CALCULATION OF THE HBA1C/TOTAL HEMOGLOBIN RATIO, AND MUST NOT BE USED INDIVIDUALLY FOR DIAGNOSTIC PURPOSES.,ACCESS HFSH-THE ACCESS HFSH ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE (FSH) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,HBA1C ADVANCED(HBA1C

	ADVANCED)-THE HBA1C (HEMOGLOBIN A1C) ADVANCED ASSAY ON THE BECKMAN COULTER DXC 700 AU CHEMISTRY ANALYZER, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF MMOL/MOL HBA1C (IFCC) OR %HBA1C (DCCT/NGSP) CONCENTRATION IN HUMAN VENOUS WHOLE BLOOD. THE DETERMINATION OF HBA1C IS USED AS AN AID IN THE DIAGNOSIS OF DIABETES MELLITUS, FOR THE MONITORING OF LONG-TERM BLOOD GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS AND IDENTIFYING PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES MELLITUS. FOR IN VITRO DIAGNOSTIC USE ONLY.,ACCESS FREE T4-THE ACCESS FREE T4 ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS.,PYRIDOXAL PHOSPHATE LIQUID(PYRIDOXAL PHOSPHATE LIQUID)-PYRIDOXAL PHOSPHATE LIQUID (CAT. NO. 60106) IS SUPPLIED FOR PYRIDOXAL PHOSPHATE ACTIVATION IN RELEVANT ASSAYS.,ACCESS FREE T3-THE ACCESS FREE T3 ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS., HAPTOGLOBIN(HAPTOGLOBIN)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF HAPTOGLOBIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,ACCESS FERRITIN CALIBRATORS-THE ACCESS FERRITIN CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS FERRITIN ASSAY FOR THE QUANTITATIVE DETERMINATION OF FERRITIN LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS.,LACTATE(LACTATE)-ENZYMATIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF L-LACTATE IN HUMAN PLASMA AND CEREBROSPINAL FLUID (CSF) ON BECKMAN COULTER ANALYSERS.,ACCESS FERRITIN-THE ACCESS FERRITIN ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FERRITIN LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS.,RF LATEX(RF LATEX)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF RF (RHEUMATOID FACTOR) ANTIBODIES IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,ACCESS ESTRADIOL-THE ACCESS ESTRADIOL ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS,D-DIMER(D-DIMER)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF

	D-DIMER IN HUMAN PLASMA ON BECKMAN COULTER AU ANALYSERS.,ACCESS CK-MB-THE ACCESS CK-MB ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CK-MB LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS., D-DIMER CONTROL(D-DIMER CONTROL)-THE D-DIMER CONTROL IS A LYOPHILISED CONTROL IN A HUMAN SERUM MATRIX INTENDED TO BE USED TO MONITOR THE ANALYTICAL PERFORMANCE OF THE D-DIMER OSR60135 ON BECKMAN COULTER ANALYSERS.,ACCESS SARS-COV-2 IGG(ACCESS SARS-COV-2 IGG)-THE ACCESS SARS-COV-2 IGG ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY INTENDED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM, SERUM SEPARATOR TUBES AND PLASMA (LITHIUM HEPARIN, DIPOTASSIUM EDTA, TRIPOTASSIUM EDTA, AND SODIUM CITRATE). THE ACCESS SARS-COV-2 IGG ASSAY IS INTENDED FOR USE AS AN AID IN IDENTIFYING INDIVIDUALS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS-COV-2, INDICATING RECENT OR PRIOR INFECTION. AT THIS TIME, IT IS UNKNOWN FOR HOW LONG ANTIBODIES PERSIST FOLLOWING INFECTION AND IF THE PRESENCE OF ANTIBODIES CONFERS PROTECTIVE IMMUNITY. TESTING IS LIMITED TO LABORATORIES CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C. §263A, THAT MEET REQUIREMENTS TO PERFORM MODERATE OR HIGH COMPLEXITY TESTS. RESULTS ARE FOR THE DETECTION OF SARS-COV-2 ANTIBODIES. IGG ANTIBODIES TO SARS-COV-2 ARE GENERALLY DETECTABLE IN BLOOD SEVERAL DAYS AFTER INITIAL INFECTION, ALTHOUGH THE DURATION OF TIME ANTIBODIES ARE PRESENT POST-INFECTION IS NOT WELL CHARACTERIZED. INDIVIDUALS MAY HAVE DETECTABLE VIRUS PRESENT FOR SEVERAL WEEKS FOLLOWING SEROCONVERSION. LABORATORIES WITHIN THE UNITED STATES AND ITS TERRITORIES ARE REQUIRED TO REPORT ALL POSITIVE RESULTS TO THE APPROPRIATE PUBLIC HEALTH AUTHORITIES. THE SENSITIVITY OF THE ACCESS SARS-COV-2 IGG ASSAY AFTER INFECTION IS UNKNOWN. NEGATIVE RESULTS DO NOT PRECLUDE ACUTE SARS-COV-2 INFECTION. IF ACUTE INFECTION IS SUSPECTED, DIRECT TESTING FOR SARS-COV-2 IS NECESSARY. FALSE POSITIVE RESULTS FOR THE ACCESS SARS-COV-2 IGG ASSAY MAY OCCUR DUE TO CROSS-REACTIVITY FROM PRE-EXISTING ANTIBODIES OR OTHER POSSIBLE CAUSES. THE ACCESS SARS-COV-2 IGG ASSAY IS ONLY FOR USE UNDER THE FOOD AND DRUG ADMINISTRATION'S EMERGENCY USE AUTHORIZATION., CHOLINESTERASE(CHOLINESTERASE)-KINETIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF CHOLINESTERASE, EC 3.1.1.8

	(CHE) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,ß-2 MICROGLOBULIN(ß-2 MICROGLOBULIN)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF BETA-2 MICROGLOBULIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,PREALBUMIN CALIBRATOR (PREALBUMIN CALIBRATOR)-THE PREALBUMIN CALIBRATOR IS A LIQUID HUMAN SERUM BASED MATRIX CALIBRATOR INTENDED TO BE USED WITH THE PREALBUMIN REAGENT OSR6175 FOR THE QUANTITATIVE DETERMINATION OF PREALBUMIN ON BECKMAN COULTER ANALYSERS.,ACCESS SARS-COV-2 IGM(ACCESS SARS-COV-2 IGM)-THE ACCESS SARSCOV2 IGM IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY INTENDED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO SARSCOV2 IN HUMAN SERUM, SERUM SEPARATOR TUBES AND PLASMA (LITHIUM HEPARIN, DIPOTASSIUM EDTA, TRIPOTASSIUM EDTA, SODIUM CITRATE). THE ACCESS SARSCOV2 IGM IS INTENDED FOR USE AS AN AID IN IDENTIFYING INDIVIDUALS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARSCOV2, INDICATING RECENT OR PRIOR INFECTION. AT THIS TIME, IT IS UNKNOWN FOR HOW LONG ANTIBODIES PERSIST FOLLOWING INFECTION AND IF THE PRESENCE OF ANTIBODIES CONFERS PROTECTIVE IMMUNITY. THE ACCESS SARS-COV-2 IGM SHOULD NOT BE USED TO DIAGNOSE ACUTE SARS-COV-2 INFECTION. TESTING IS LIMITED TO LABORATORIES CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C. §263A, THAT MEET REQUIREMENTS TO PERFORM MODERATE OR HIGH COMPLEXITY TESTS. RESULTS ARE FOR THE DETECTION OF SARS-COV-2 ANTIBODIES. IGM ANTIBODIES TO SARS-COV-2 ARE GENERALLY DETECTABLE IN BLOOD SEVERAL DAYS AFTER INITIAL INFECTION, ALTHOUGH THE DURATION OF TIME ANTIBODIES ARE PRESENT POST-INFECTION IS NOT WELL CHARACTERIZED. INDIVIDUALS MAY HAVE DETECTABLE VIRUS PRESENT FOR SEVERAL WEEKS FOLLOWING SEROCONVERSION. LABORATORIES WITHIN THE UNITED STATES AND ITS TERRITORIES ARE REQUIRED TO REPORT ALL RESULTS TO THE APPROPRIATE PUBLIC HEALTH AUTHORITIES. THE SENSITIVITY OF THE ACCESS SARS-COV-2 IGM ASSAY EARLY AFTER INFECTION IS UNKNOWN. NEGATIVE RESULTS DO NOT PRECLUDE ACUTE SARS-COV-2 INFECTION. IF ACUTE INFECTION IS SUSPECTED, DIRECT TESTING FOR SARS-COV-2 IS NECESSARY. FALSE POSITIVE RESULTS FOR THE ACCESS SARSCOV2 IGM ASSAY MAY OCCUR DUE TO CROSS REACTIVITY FROM PREEXISTING ANTIBODIES OR OTHER POSSIBLE CAUSES. DUE TO THE RISK OF FALSE POSITIVE RESULTS, CONFIRMATION OF POSITIVE RESULTS SHOULD BE CONSIDERED USING A SECOND DIFFERENT ASSAY. SAMPLES SHOULD ONLY BE

	TESTED FROM INDIVIDUALS THAT ARE 8 DAYS TO 30 DAYS POST SYMPTOM ONSET. SARS-COV-2 ANTIBODY NEGATIVE SAMPLES COLLECTED 8 DAYS OR MORE POST SYMPTOM ONSET SHOULD BE REFLEXED TO A TEST THAT DETECTS AND REPORTS SARS-COV-2 IGG. THE ACCESS SARS-COV-2 IGM ASSAY IS ONLY FOR USE UNDER THE FOOD AND DRUG ADMINISTRATION'S EMERGENCY USE AUTHORIZATION.,SERUM PROTEIN MULTI-CALIBRATOR 2(SERUM PROTEIN MULTI-CALIBRATOR 2)-THE SERUM PROTEIN MULTI-CALIBRATOR 2 IS INTENDED TO BE USED WITH THE BECKMAN COULTER IMMUNO-TURBIDIMETRIC REAGENTS LISTED IN THE IFU FOR THE QUANTITATIVE DETERMINATION OF -1 ACIDGLYCOPROTEIN, -1 ANTITRYPSIN, -2 MICROGLOBULIN, CERULOPLASMIN AND HAPTOGLOBIN ON BECKMAN COULTER ANALYSERS. THE MATERIAL IS PREPARED FROM HUMAN SERUM WITH THE CONSTITUENT VALUES ADJUSTED WHERE NECESSARY BY THE ADDITION OF ANALYTICAL GRADE CHEMICALS AND APPROPRIATE SERUM PROTEINS.,ALPHA-AMYLASE(ALPHA-AMYLASE)-KINETIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF -AMYLASE, [1,4--D-GLUCAN 4-GLUCANOHYDROLASE, EC 3.2.1.1], IN HUMAN SERUM, PLASMA AND URINE ON BECKMAN COULTER ANALYSERS.,CRP LATEX CALIBRATOR HIGHLY SENSITIVE SET(CRP LATEX CALIBRATOR HIGHLY SENSITIVE SET)-THE CRP CALIBRATOR (LATEX) IS A LIQUID HUMAN SERUM BASED MATRIX CALIBRATOR INTENDED TO BE USED WITH THE HIGHLY SENSITIVE APPLICATION OF THE CRP LATEX REAGENT OSR6X99 FOR THE QUANTITATIVE DETERMINATION OF CRP ON BECKMAN COULTER AU ANALYSERS.,FERRITIN(FERRITIN)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,ACCESS TOTAL BHCG (5TH IS)(ACCESS TOTAL BHCG (5TH IS))-THE ACCESS TOTAL BHCG (5TH IS) ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL BHCG LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS. THIS ASSAY IS INTENDED FOR USE AS AN AID IN THE EARLY DETECTION OF PREGNANCY. THE CONCENTRATION OF BHCG DETERMINED BY THIS KIT CAN ALSO BE USED IN CONJUNCTION WITH AFP, UNCONJUGATED ESTRIOL, AND INHIBIN A CONCENTRATIONS IN DOWN SYNDROME (TRISOMY 21) RISK ASSESSMENT. SUCH AN APPROACH HAS BEEN VERIFIED ON THE BASIS OF MULTIVARIATE GAUSSIAN DISTRIBUTION ANALYSIS.,ACCESS HLH(ACCESS HLH)-THE ACCESS HLH ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) LEVELS IN HUMAN

	SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS., CRP LATEX(CRP LATEX)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS. THE NORMAL APPLICATION IS TO BE USED FOR THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY, INFLAMMATORY DISORDERS AND ASSOCIATED DISEASES. THE HIGHLY SENSITIVE APPLICATION IS NOT A GENERAL SCREENING TEST FOR INFECTION/INFLAMMATION.,ACCESS TPO ANTIBODY (ACCESS TPO ANTIBODY)-THE ACCESS TPO ANTIBODY ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROPEROXIDASE ANTIBODY (TPOAB) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,RF LATEX CALIBRATOR (RF LATEX CALIBRATOR)-THE RF LATEX CALIBRATOR IS A LIQUID HUMAN SERUM BASED MATRIX CALIBRATOR INTENDED TO BE USED WITH THE RF LATEX REAGENT OSR61105 FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR ON BECKMAN COULTER ANALYSERS.,P-5-P(P-5-P)-OSR60180 FOR USE WITH 3-PART-REAGENT ENABLED SYSTEMS ONLY FOR RELEVANT ASSAYS.,LIPASE (LIPASE)-KINETIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF LIPASE IN HUMAN SERUM AND PLASMA ON AU BECKMAN COULTER ANALYSERS.,CRP LATEX CALIBRATOR NORMAL (N) SET(CRP LATEX CALIBRATOR NORMAL (N) SET)-THE CRP CALIBRATOR (LATEX) IS A LIQUID HUMAN SERUM BASED MATRIX CALIBRATOR INTENDED TO BE USED WITH THE NORMAL APPLICATION OF THE CRP (LATEX) REAGENT OSR6X99 FOR THE QUANTITATIVE DETERMINATION OF CRP ON BECKMAN COULTER AU ANALYSERS.,D-DIMER CALIBRATOR(D-DIMER CALIBRATOR)-THE D-DIMER CALIBRATOR IS A LYOPHILISED CALIBRATOR IN A HUMAN SERUM MATRIX INTENDED TO BE USED WITH THE D-DIMER OSR60135 FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA ON BECKMAN COULTER ANALYSERS.,LDL CHOLESTEROL CALIBRATOR(LDL CHOLESTEROL CALIBRATOR)-THE LDL CHOLESTEROL CALIBRATOR IS A LYOPHILIZED HUMAN SERUM. IT IS DESIGNED TO PROVIDE SUITABLE CALIBRATION LEVELS FOR BECKMAN COULTER AU ANALYZERS EMPLOYING THE QUANTITATIVE LDL CHOLESTEROL REAGENT.

120	IMP/IVD/2019/000042	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IQ CALIBRATOR PACK(IQ CALIBRATOR PACK)-IQ CALIBRATOR IS INTENDED FOR IN VITRO DIAGNOSTIC USE WITH IQ 200 SERIES ANALYZERS,URINE/CSF ALBUMIN-THE URINE /CSF ALBUMIN REAGENT IS INTENDED TO BE USED FOR THE QUANTITATION OF ALBUMIN CONCENTRATION IN HUMAN URINE AND CEREBROSPINAL FLUID (CSF) ON THE BECKMAN COULTER AU CLINICAL CHEMISTRY SYSTEMS AS AN AID IN THE DIAGNOSIS OF KIDNEY DISEASES.,IRIS SYSTEM CLEANSER PACK(IRIS SYSTEM CLEANSER PACK)-IRIS SYSTEM CLEANSER IS INTENDED FOR IN VITRO DIAGNOSTIC USE WITH IQ 200 SERIES ANALYZERS AND IRIS DIAGNOSTIC INSTRUMENTS. ,URINE/CSF ALBUMIN CALIBRATOR-THE URINE/CSF ALBUMIN CALIBRATOR IS INTENDED TO BE USED TO CALIBRATE THE URINE/CSF ALBUMIN REAGENT ON THE BECKMAN COULTER AU CLINICAL CHEMISTRY SYSTEMS.,IQ BODY FLUIDS LYSING REAGENT (IQ BODY FLUIDS LYSING REAGENT)-IQ BODY FLUIDS LYSING REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC USE WITH IQ 200 SERIES ANALYZER,IQ PRECISION KIT(IQ PRECISION KIT)-FOR THE VERIFICATION OF THE IQ200 ANALYZER AT THE TIME OF INSTALLATION OR DURING ROUTINE SERVICE VISITS. FOR IN VITRO DIAGNOSTIC USE WITH IQ200 SERIES ANALYZERS.,IRIS DILUENT PACK (IRIS DILUENT PACK)-IRIS DILUENT IS INTENDED FOR IN VITRO DIAGNOSTIC USE WITH IQ 200 SERIES ANALYZERS AND IRIS INSTRUMENTS,IQ CONTROL/FOCUS SET(IQ CONTROL/FOCUS SET)-IQ CONTROL/FOCUS SET IS INTENDED FOR IN VITRO DIAGNOSTIC USE WITH IQ 200 SERIES ANALYZERS.,IRISPEC CA/CB CONTROLS(IRISPEC CA/CB CONTROLS)-IRISPEC CA/CB IS AN ASSAYED QC MATERIAL FOR MONITORING OF URINE CHEMISTRY ANALYTES AND DEVICES LISTED IN THIS INSTRUCTION FOR USE. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHEM VELOCITY WASH SOLUTION(ICHEM VELOCITY WASH SOLUTION)-THE ICHEMVELOCITY WASH SOLUTION IS A BUFFER SOLUTION FOR ROUTINE RINSE OF ICHEMVELOCITY URINE CHEMISTRY SYSTEM. THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC USE WITH THE ICHEMVELOCITY. ,ICHEM VELOCITY CALCHECK KIT(ICHEM VELOCITY CALCHECK KIT)-THE ICHEMVELOCITY CALCHEK REAGENTS ARE A SET OF BUFFER-BASED SOLUTIONS INTENDED FOR THE IN VITRO MONITORING OF SPECIFIC GRAVITY, COLOR, AND CLARITY. THE ICHEMVELOCITY CALCHEK REAGENTS ARE MANUFACTURED FOR USE ONLY WITH THE ICHEMVELOCITY URINE CHEMISTRY SYSTEM AND ARE INTENDED FOR USE EXCLUSIVELY BY HEALTHCARE PROFESSIONALS. FOR IN VITRO DIAGNOSTIC USE WITH THE ICHEM VELOCITY SYSTEM ,IRISPEC CA/CB/CC CONTROL(IRISPEC CA/CB/CC CONTROL)-IRISPEC

		CA/CB/CC IS AN ASSAYED QC MATERIAL FOR MONITORING OF URINE CHEMISTRY ANALYTES AND DEVICES AS LISTED IN THIS INSTRUCTION FOR USE. FOR IN VITRO DIAGNOSTIC USE ONLY
121	IMP/IVD/2019/000045	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROL SERUM 2-THE CONTROL SERUM 2 IS A LYOPHILISED HUMAN SERUM CONTROL INTENDED TO BE USED IN CONJUNCTION WITH THE CONTROL SERUM 1 ODC0003 TO MONITOR THE ANALYTICAL PERFORMANCE OF THE BECKMAN COULTER SYSTEM REAGENTS LISTED IN THE ENCLOSED TABLE ON BECKMAN COULTER ANALYSERS.,SYSTEM CALIBRATOR (SYSTEM CALIBRATOR)-THE SYSTEM CALIBRATOR IS A CALIBRATION SERUM INTENDED TO BE USED WITH BECKMAN COULTER SYSTEM REAGENTS ON BECKMAN COULTER AU ANALYSERS,CONTROL SERUM 1-THE CONTROL SERUM 1 IS A LYOPHILISED HUMAN SERUM CONTROL INTENDED TO BE USED IN CONJUNCTION WITH THE CONTROL SERUM 2 ODC0004 TO MONITOR THE ANALYTICAL PERFORMANCE OF THE BECKMAN COULTER SYSTEM REAGENTS LISTED IN THE ENCLOSED TABLE ON BECKMAN COULTER ANALYSERS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

122	IMP/IVD/2019/000047	1.License Holder Name: IDEXX LABORATORIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SNAP®FELINEPROBNP (IDEXX SNAP®FELINEPROBNP)-IN VITRO TEST FOR THE MEASUREMENT OF CIRCULATING NTPROBNP IN FELINE SERUM AND EDTA PLASMA.,PM AB TEST(IDEXX PM AB TEST)-SERODIAGNOSIS OF PM BY ELISA,CATALYST® WHOLE BLOOD SEPARATORS(IDEXX CATALYST® WHOLE BLOOD SEPARATORS)-USED WITH THE CATALYST DX* CHEMISTRY ANALYZER ON-BOARD CENTRIFUGE TO SEPARATE LITHIUM HEPARINIZED WHOLE BLOOD.,IBV AB TEST (IDEXX IBV AB TEST)-SERODIAGNOSIS OF IBV BY ELISA,SNAP® LEPTO (), 5 (IDEXX SNAP® LEPTO (), 5)-IN VITRO DIAGNOSTIC FOR THE DETECTION OFANTI-LEPTOSPIRA ANTIBODIES IN CANINE SERUM, ALV-J AB TEST(IDEXX ALV-J AB TEST)-SERODIAGNOSIS OF ALV -J BY ELISA,SNAP® CPL®(IDEXX SNAP® CPL®)-FOR THE DETERMINATION OF PANCREAS-SPECIFIC LIPASE LEVELS IN CANINE SERUM,IBD AB TEST(IDEXX IBD AB TEST)-SERODIAGNOSIS OF IBD BY ELISA,SNAP® COMBO PLUS (FELV/FIV)(IDEXX SNAP® COMBO PLUS (FELV/FIV))-DETECTION OF FELINE LEUKEMIA VIRUS (FELV) ANTIGEN AND ANTIBODIES TO FELINE IMMUNODEFICIENCY VIRUS (FIV) IN FELINE SERUM, PLASMA OR WHOLE BLOOD,MG AB TEST(IDEXX MG AB TEST)-SERODIAGNOSIS OF MG BY ELISA,SNAP® FELV AG(IDEXX SNAP® FELV AG)-DETECTION OF FELINE LEUKEMIA VIRUS (FELV) ANTIGEN IN FELINE SERUM, PLASMA OR WHOLE BLOOD.,REO AB TEST(IDEXX REO AB TEST)-SERODIAGNOSIS OF REO BY ELISA.,SNAP® 4DX® PLUS (IDEXX SNAP® 4DX® PLUS)-IN VITRO DIAGNOSTIC FOR THE DETECTION OF DIROFILARIAIMMITIS ANTIGEN, ANTIBODYTO ANAPLASMAPHAGOCYTOPHILUM, ANTIBODY TO ANAPLASMAPLATYS, ANTIBODY TO BORRELIA BURGDORFERI, ANTIBODY TO EHRLICHIACANIS AND ANTIBODY TO EHRLICHIAEWINGII IN CANINE SERUM, PLASMA OR WHOLE BLOOD, ALV AG TEST(IDEXX ALV AG TEST)-SERODIAGNOSIS OF ALV BY ELISA,SNAP® GIARDIA(IDEXX SNAP® GIARDIA)-FOR THE DETECTION OF GIARDIA ANTIGEN IN CANINE AND FELINE FECES.,CAV AB TEST (IDEXX CAV AB TEST)-SERODIAGNOSIS OF CAV BY ELISA, PROCYTEDX®, STAIN PACK(IDEXX PROCYTEDX®, STAIN PACK)-CONTAINS BOTH RETICULOCYTE ANDLEUKOCYTE STAIN POUCHES THAT ARE SPECIALLY FORMULATED FOR USE IN THE PROCYTEDX* HEMATOLOGY ANALYZER.,NDV AB TEST(IDEXX NDV AB TEST)-SERODIAGNOSIS OF NDV BY ELISA,CATALYST SDMA & TT4 KIT(IDEXX CATALYST SDMA & TT4 KIT)-USED WITH THE IDEXX CATALYST DX™ CHEMISTRY ANALYZER FOR THE DETECTION OF SDMA (SYMMETRIC DIMETHYLARGININE) AND TOTAL T4 (THYROXIN) IN CANINE & FELINE

	(DOMESTIC) IN SERUM OR PLASMA.,IBD-XR AB TEST(IDEXX IBD-XR AB TEST)-SERODIAGNOSIS OF IBD BY ELISA,VETSTAT® CALIBRATION GAS(IDEXX VETSTAT® CALIBRATION GAS)-GAS USED FOR THE CALIBRATION OF THE IDEXX VETSTAT ANALYZER.,SE AB X2(IDEXX SE AB X2)-SERODIAGNOSIS OF SALMONELLA ENTERITIDIS BY ELISA, CATALYST TEST SDMA(IDEXX CATALYST TEST SDMA)-USED WITH THE IDEXX CATALYST DX™ CHEMISTRY ANALYZER FOR THE DETECTION OF SDMA (SYMMETRIC DIMETHYLARGININE),REV AB TEST (IDEXX REV AB TEST)-SERODIAGNOSIS OF REO BY ELISA.,SNAP® HEARTWORM(IDEXX SNAP® HEARTWORM)-SEMIQUANTITATIVE DETECTION OF DIROFILARIAIMMITIS (D. IMMITIS) ANTIGEN IN CANINE AND FELINE WHOLE BLOOD, SERUM OR PLASMA.,MG/MS AB TEST (IDEXX MG/MS AB TEST)-SERODIAGNOSIS OF MG & MS BY ELISA, CATALYST® TOTAL T4 TEST (12)(IDEXX CATALYST® TOTAL T4 TEST (12))-FOR THE QUANTITATIVE MEASUREMENT OF TOTAL T4 (THYROXINE) IN CANINE AND FELINE (DOMESTIC) SERUM OR PLASMA.,MS AB TEST(IDEXX MS AB TEST)-SERODIAGNOSIS OF MS BY ELISA,PROCYTEDX QUALITY CONTROL SET(IDEXX PROCYTEDX QUALITY CONTROL SET)-STABILIZED WHOLE BLOOD MATRIX DESIGNED FOR STATISTICAL PROCESS CONTROL OF THE IDEXX PROCYTEDX* HEMATOLOGY ANALYZER.,NEOSPORA X2 AB TEST (IDEXX NEOSPORA X2 AB TEST)-SERODIAGNOSIS OF NEOSPORA BY ELISA,SNAP® LEPTO (), 10 (IDEXX SNAP® LEPTO (), 10)-IN VITRO DIAGNOSTIC FOR THE DETECTION OFANTI-LEPTOSPIRA ANTIBODIES IN CANINE SERUM,ALV AB TEST(IDEXX ALV AB TEST)-SERODIAGNOSIS OF ALV BY ELISA, SNAP® CORTISOL(IDEXX SNAP® CORTISOL)-QUANTITATIVE MEASUREMENT OF CORTISOL IN DOG SERUM.,AE AB TEST(IDEXX AE AB TEST)-SERODIAGNOSIS OF AE BY ELISA,PETCHEK® FIV AB(IDEXX PETCHEK® FIV AB)-DESIGNED TO SCREEN FOR AND CONFIRM THE PRESENCE OF FELINE IMMUNODEFICIENCY VIRUS (FIV) IN FELINE SERUM OR PLASMA.,BOVINE HAEMATOLOGY SAMPLE PREPARATION KIT(IDEXX BOVINE HAEMATOLOGY SAMPLE PREPARATION KIT)-PROVIDES THE MATERIALS FOR THE COLLECTION AND PREPARATION OF BOVINE BLOOD FOR ANALYSIS ON THE IDEXX VETAUTOREAD. ,SNAP® LEISHMANIA(IDEXX SNAP® LEISHMANIA)-IN VITRO DETECTION OF LEISHMANIADONOVANI OR LEISHMANIAINFANTUM (L. DONOVANI OR L. INFANTUM) ANTIBODIES IN CANINE WHOLE BLOOD, SERUM, OR PLASMA.,SNAP® CPL®(IDEXX SNAP® CPL®)-FOR THE DETERMINATION OF PANCREAS-SPECIFIC LIPASE LEVELS IN CANINE SERUM,SNAP® COMBO PLUS (FELV/FIV) (IDEXX SNAP® COMBO PLUS (FELV/FIV))-DETECTION OF FELINE LEUKEMIA VIRUS (FELV) ANTIGEN AND ANTIBODIES TO FELINE IMMUNODEFICIENCY VIRUS (FIV) IN FELINE SERUM, PLASMA OR

	WHOLE BLOOD,SNAP® FPL®(IDEXX SNAP® FPL®)-IN VITRO TEST FOR THE DETERMINATION OF PANCREAS-SPECIFIC LIPASE LEVELS IN FELINE SERUM,COAGDX™ CARTRIDGE WHOLE BLOOD APTT APTTWB (IDEXX COAGDX™ CARTRIDGE WHOLE BLOOD APTT APTTWB)-INTENDED FOR IN VITRO USE IN PERFORMING AQUANTITATIVE, ONE-STAGE ACTIVATED PARTIALTHROMBOPLASTIN TIME (APTT), COAGDX™ CARTRIDGE CITRATED BLOOD PT PTC(IDEXX COAGDX™ CARTRIDGE CITRATED BLOOD PT PTC)-INTENDED FOR IN VITRO USE IN PERFORMING AQUANTITATIVE, ONE-STAGE PROTHROMBIN TIME, COAGDX™ CARTRIDGE CITRATED BLOOD APTTC(IDEXX COAGDX™ CARTRIDGE CITRATED BLOOD APTTC)-TEST INTENDED FOR IN VITRO USE IN PERFORMINGA QUANTITATIVE, ONE-STAGE ACTIVATED PARTIALTHROMBOPLASTIN TIME (APTT),PROCYTEDX®, REAGENT KIT(IDEXX PROCYTEDX®, REAGENT KIT)-SET OF REAGENTS FOR HEMATOLOGY ANALYSIS WITH THE PROCYTEDX ANALYZER.,SNAP® FPL®(IDEXX SNAP® FPL®)-IN VITRO TEST FOR THE DETERMINATION OF PANCREAS-SPECIFIC LIPASE LEVELS IN FELINE SERUM,SNAP® BILE ACIDS(IDEXX SNAP® BILE ACIDS)-QUANTITATIVE MEASUREMENT OF BILE ACIDS IN CANINE OR FELINE SERUM.,SNAP® 4DX® PLUS(IDEXX SNAP® 4DX® PLUS)-IN VITRO DIAGNOSTIC FOR THE DETECTION OF DIROFILARIAIMMITIS ANTIGEN, ANTIBODYTO ANAPLASMAPHAGOCYTOPHILUM, ANTIBODY TO ANAPLASMAPLATYS, ANTIBODY TO BORRELIA BURGDORFERI, ANTIBODY TO EHRLICHIACANIS AND ANTIBODY TO EHRLICHIAEWINGII IN CANINE SERUM, PLASMA OR WHOLE BLOOD, PROCYTEDX® KIT(IDEXX PROCYTEDX® KIT)-DESIGNED FOR STATISTICAL PROCESS CONTROL OF THE IDEXX PROCYTEDX* HEMATOLOGY ANALYZER,COAGDX™ CARTRIDGE WHOLE BLOOD PT PTWB(IDEXX COAGDX™ CARTRIDGE WHOLE BLOOD PT PTWB)-INTENDEDFOR IN VITRO USE IN PERFORMING A QUANTITATIVE,ONE-STAGE PROTHROMBIN TIME,SNAP® TOTAL TT4(IDEXX SNAP® TOTAL TT4)-FOR THE QUANTITATIVE MEASUREMENT OF TOTAL T4 (THYROXINE) IN CANINE, FELINE (DOMESTIC) AND EQUINE SERUM OR PLASMA.,SNAP® TOTAL TT4(IDEXX SNAP® TOTAL TT4)-FOR THE QUANTITATIVE MEASUREMENT OF TOTAL T4 (THYROXINE) IN CANINE, FELINE (DOMESTIC) AND EQUINE SERUM OR PLASMA., SNAP® HEARTWORM(IDEXX SNAP® HEARTWORM)-SEMIQUANTITATIVE DETECTION OF DIROFILARIAIMMITIS (D. IMMITIS) ANTIGEN IN CANINE AND FELINE WHOLE BLOOD, SERUM OR PLASMA., SNAP® FOAL IGG KIT(IDEXX SNAP® FOAL IGG KIT)-SEMI-QUANTITATIVE DETECTION OF IMMUNOGLOBULIN G (IGG) IN EQUINE SERUM,PLASMA OR WHOLE BLOOD,SNAP® FELV AG(IDEXX SNAP® FELV AG)-DETECTION OF FELINE LEUKEMIA VIRUS (FELV) ANTIGEN IN FELINE SERUM, PLASMA OR WHOLE BLOOD.,SNAP® GIARDIA(IDEXX

	SNAP® GIARDIA)-FOR THE DETECTION OF GIARDIA ANTIGEN IN CANINE AND FELINE FECES.,HEARTWORM PETCHEK® 2 PLATE KIT (IDEXX HEARTWORM PETCHEK® 2 PLATE KIT)-DETECTION OF DIROFILARIAIMMITIS (D. IMMITIS) ANTIGEN INCANINE OR FELINE SERUM OR PLASMA.,SNAP® HEARTWORM(IDEXX SNAP® HEARTWORM)-SEMIQUANTITATIVE DETECTION OF DIROFILARIAIMMITIS (D. IMMITIS) ANTIGEN IN CANINE AND FELINE WHOLE BLOOD, SERUM OR PLASMA.,SNAP®FELINEPROBNP(IDEXX SNAP®FELINEPROBNP)-IN VITRO TEST FOR THE MEASUREMENT OF CIRCULATING NTPROBNP IN FELINE SERUM AND EDTA PLASMA., VETTUBES(IDEXX VETTUBES)-HEMATOCRIT TUBES TO BE USED WITH THE VETAUTOREAD ANALYZER.,CATALYST® FRUCTOSAMINE(IDEXX CATALYST® FRUCTOSAMINE)-QUANTITATIVELY MEASURES FRUCTOSAMINE CONCENTRATION IN ANIMAL SERUM. ,UPCPREP, IDEXX URINE P:C RATIO(IDEXX UPCPREP, IDEXX URINE P:C RATIO)-PROVIDES THE COMPONENTS NEEDED TO PREPARE A URINE SAMPLE TO BE RUN ON THE VETTEST OR CATALYSTDX ANALYZERS.,SNAP® 4DX® PLUS(IDEXX SNAP® 4DX® PLUS)-IN VITRO DIAGNOSTIC FOR THE DETECTION OF DIROFILARIAIMMITIS ANTIGEN, ANTIBODYTO ANAPLASMAPHAGOCYTOPHILUM, ANTIBODY TO ANAPLASMAPLATYS, ANTIBODY TO BORRELIA BURGDORFERI, ANTIBODY TO EHRLICHIACANIS AND ANTIBODY TO EHRLICHIAEWINGII IN CANINE SERUM, PLASMA OR WHOLE BLOOD, CATALYST® CRP TEST (6)(IDEXX CATALYST® CRP TEST (6))-QUANTITATIVELY MEASURES CANINE C-REACTIVE PROTEIN CONCENTRATION IN ANIMAL SERUM OR PLASMA.,SNAP® COMBO PLUS (FELV/FIV)(IDEXX SNAP® COMBO PLUS (FELV/FIV))-DETECTION OF FELINE LEUKEMIA VIRUS (FELV) ANTIGEN AND ANTIBODIES TO FELINE IMMUNODEFICIENCY VIRUS (FIV) IN FELINE SERUM, PLASMA OR WHOLE BLOOD,SNAP® PARVO(IDEXX SNAP® PARVO)-FOR THE DETECTION OF CANINE PARVOVIRUS (CPV) ANTIGEN IN CANINE FECES.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

123	IMP/IVD/2019/000049	1.License Holder Name: DIASYS DIAGNOSTIC INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROL BLOOD MULTILEVEL(R5H CONT DIFF HIGH)-R5H CONT DIFF IS A 3-LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS., CONTROL BLOOD MULTILEVEL(R5H CONT DIFF NORMAL)-R5H CONT DIFF IS A 3-LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS.,CONTROL BLOOD MULTILEVEL(R5H CONT DIFF LOW)-R5H CONT DIFF IS A 3-LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS,CONTROL BLOOD MULTILEVEL(R3H CONT DIFF HIGH)-R3H CONT DIFF IS A 3-LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS., WHOLE BLOOD CALIBRATORS(R5H CALIBRATOR)-R5H CALIBRATOR IS DESIGNED FOR USE IN THE CALIBRATION OF DIASYS HEMATOLOGY ANALYZERS.,CONTROL BLOOD MULTILEVEL(R3H CONT DIFF NORMAL)-R3H CONT DIFF IS A 3-LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS.,CONTROL BLOOD MULTILEVEL(R3H CONT DIFF LOW)-R3H CONT DIFF IS A 3-LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS., WHOLE BLOOD CALIBRATORS(R3H CALIBRATOR)-R3H CALIBRATOR IS DESIGNED FOR USE IN THE CALIBRATION OF DIASYS HEMATOLOGY ANALYZERS.

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124	IMP/IVD/2019/000051	1.License Holder Name: ANAND BROTHERS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INHIBIN A ELISA KIT (IMMUNOTECH S.R.O)-THE INHIBIN A (ELISA) KIT IS INTENDED TO DETECT DIMERIC INHIBIN A IN HUMAN SERUM OR PLASMA,INHIBIN B GEN II ELISA KIT(INHIBIN B GEN II ELISA KIT)-THE INHIBIN B GEN II (ELISA) KIT IS INTENDED TO DETECT INHIBIN B IN HUMAN SERUM AND LITHIUM HEPARIN PLASMA,AMH GEN II CALIBRATOR & CONTROL (IMMUNOTECH S.R.O)-THE ANTI-MULLERIAN HOEMONE (AMH) GEN II CALIBRATORS ARE INTENDED TO CALIBRATE THE AMH GEN II ELISA ASSAY,INHIBIN B GEN II CALIBRATOR & CONTROL(INHIBIN B GEN II CALIBRATOR & CONTROL)-THE CALIBRATORS ARE INTENDED TO CALIBRATE THE INHIBIN B GEN II ELISA ASSAY FOR THE MEASUREMENT OF INHIBIN B GEN II IN HUMAN SERUM AND LITHIUM HEPARIN PLASMA,AMH GEN II KIT(IMMUNOTECH S.R.O)-THE KIT IS INTENDED TO DETECT ANTI-MULLERIAN HORMONE (AMH) GEN II IN HUMAN SERUM AND LITHIUM HEPARIN PKASMA
125	IMP/IVD/2019/000051	1.License Holder Name: ANAND BROTHER'S 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:25-OH VITAMIN D TOTAL ELISA KIT(25-OH VITAMIN D TOTAL ELISA KIT)-IMMUNO ENZYMETRIC ASSAY FOR THE IN VITRO DETERMINATION OF 25-HYDROXYVITAMIN D2 AND D3 IN HUMAN SERUM.

126	IMP/IVD/2019/000053	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCESS SARS-COV-2 IGG CALIBRATOR(ACCESS SARS-COV-2 IGG CALIBRATOR)-THE ACCESS SARS-COV-2 IGG CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS SARS-COV-2 IGG ASSAY FOR THE IN VITRO QUALITATIVE DETECTION OF SARS-COV-2 IGG ANTIBODIES IN HUMAN SERUM, SERUM SEPARATOR TUBES AND PLASMA (LITHIUM HEPARIN, DIPOTASSIUM EDTA, TRIPOTASSIUM EDTA, AND SODIUM CITRATE) FOR USE ON THE ACCESS FAMILY OF IMMUNOASSAY SYSTEMS ONLY.,ACCESS SARS-COV-2 IGG II CALIBRATORS(ACCESS SARS-COV-2 IGG II CALIBRATORS)-THE ACCESS SARS-COV-2 IGG II CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS SARS-COV-2 IGG II ASSAY FOR THE IN VITRO SEMI-QUANTITATIVE AND QUALITATIVE DETECTION OF SARS-COV-2 IGG ANTIBODIES IN HUMAN PLASMA (LITHIUM HEPARIN, DIPOTASSIUM EDTA, TRIPOTASSIUM EDTA, AND SODIUM CITRATE) FOR USE ON THE ACCESS IMMUNOASSAY SYSTEMS ONLY.,ACCESS SARS-COV-2 IGG (ACCESS SARS-COV-2 IGG)-THE ACCESS SARS-COV-2 IGG ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY INTENDED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM, SERUM SEPARATOR TUBES AND PLASMA (LITHIUM HEPARIN, DIPOTASSIUM EDTA, TRIPOTASSIUM EDTA, AND SODIUM CITRATE). THE ACCESS SARS-COV-2 IGG ASSAY IS INTENDED FOR USE AS AN AID IN IDENTIFYING INDIVIDUALS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS-COV-2, INDICATING RECENT OR PRIOR INFECTION. AT THIS TIME, IT IS UNKNOWN FOR HOW LONG ANTIBODIES PERSIST FOLLOWING INFECTION AND IF THE PRESENCE OF ANTIBODIES CONFERS PROTECTIVE IMMUNITY. TESTING IS LIMITED TO LABORATORIES CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C. §263A, THAT MEET REQUIREMENTS TO PERFORM MODERATE OR HIGH COMPLEXITY TESTS. RESULTS ARE FOR THE DETECTION OF SARS-COV-2 ANTIBODIES. IGG ANTIBODIES TO SARS-COV-2 ARE GENERALLY DETECTABLE IN BLOOD SEVERAL DAYS AFTER INITIAL INFECTION, ALTHOUGH THE DURATION OF TIME ANTIBODIES ARE PRESENT POST-INFECTION IS NOT WELL CHARACTERIZED. INDIVIDUALS MAY HAVE DETECTABLE VIRUS PRESENT FOR SEVERAL WEEKS FOLLOWING SEROCONVERSION. LABORATORIES WITHIN THE UNITED STATES AND ITS TERRITORIES ARE REQUIRED TO REPORT ALL POSITIVE RESULTS TO THE APPROPRIATE PUBLIC HEALTH AUTHORITIES. THE SENSITIVITY OF THE ACCESS SARS-COV-2 IGG ASSAY AFTER INFECTION IS UNKNOWN. NEGATIVE RESULTS DO NOT PRECLUDE ACUTE SARS-

	COV-2 INFECTION. IF ACUTE INFECTION IS SUSPECTED, DIRECT TESTING FOR SARS-COV-2 IS NECESSARY. FALSE POSITIVE RESULTS FOR THE ACCESS SARS-COV-2 IGG ASSAY MAY OCCUR DUE TO CROSS-REACTIVITY FROM PRE-EXISTING ANTIBODIES OR OTHER POSSIBLE CAUSES. THE ACCESS SARS-COV-2 IGG ASSAY IS ONLY FOR USE UNDER THE FOOD AND DRUG ADMINISTRATION'S EMERGENCY USE AUTHORIZATION.,ACCESS DIGOXIN CALIBRATORS (ACCESS DIGOXIN CALIBRATORS)-THE ACCESS DIGOXIN CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS DIGOXIN ASSAY FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS., ACCESS SARS-COV-2 IGG QC(ACCESS SARS-COV-2 IGG QC)-THE ACCESS SARS-COV-2 IGG QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS SARS-COV-2 IGG ASSAY. THE ACCESS SARS-COV-2 IGG QC IS FOR USE ON THE ACCESS FAMILY OF IMMUNOASSAY SYSTEMS ONLY.,ACCESS SARS-COV-2 IGG II QC (ACCESS SARS-COV-2 IGG II QC)-THE ACCESS SARS-COV-2 IGG II QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS SARS-COV-2 IGG II ASSAY USING THE ACCESS IMMUNOASSAY SYSTEMS ONLY.,ACCESS SARS-COV-2 IGM CALIBRATOR(ACCESS SARS-COV-2 IGM CALIBRATOR)-THE ACCESS SARS-COV-2 IGM CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS SARS-COV-2 IGM ASSAY FOR THE IN VITRO QUALITATIVE DETECTION OF SARS-COV-2 IGM ANTIBODIES IN HUMAN SERUM, SERUM SEPARATOR TUBES AND PLASMA (LITHIUM HEPARIN, DIPOTASSIUM EDTA, TRIPOTASSIUM EDTA, SODIUM CITRATE) FOR USE ON THE ACCESS FAMILY OF IMMUNOASSAY SYSTEMS ONLY., ACCESS INTACT PTH(ACCESS INTACT PTH)-THE ACCESS INTACT PTH ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (PARATHYRIN, PTH) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS. IT IS INDICATED TO AID IN THE DIFFERENTIAL DIAGNOSIS OF HYPERPARATHYROIDISM, HYPOPARATHYROIDISM, OR HYPERCALCEMIA OF MALIGNANCY AND CAN BE USED INTRAOPERATIVELY. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL DATA TO ASSIST THE CLINICIAN IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS.,ACCESS SARS-COV-2 IGM QC(ACCESS SARS-COV-2 IGM QC)-THE ACCESS SARS-COV-2 IGM QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS SARS-COV-2 IGM ASSAY. THE ACCESS SARS-COV-2 IGM QC IS FOR USE ON THE ACCESS FAMILY OF IMMUNOASSAY SYSTEMS ONLY.,ACCESS SARS-COV-2 IGG II REAGENT KIT (ACCESS SARS-COV-2 IGG II REAGENT KIT)-THE

	ACCESS SARS-COV-2 IGG II ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY INTENDED FOR THE SEMI-QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN PLASMA (LITHIUM HEPARIN, DIPOTASSIUM EDTA, TRIPOTASSIUM EDTA, AND SODIUM CITRATE). THE ACCESS SARS-COV-2 IGG II ASSAY IS INTENDED FOR USE AS AN AID IN IDENTIFYING INDIVIDUALS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS-COV-2, INDICATING RECENT OR PRIOR INFECTION. AT THIS TIME, IT IS UNKNOWN FOR HOW LONG ANTIBODIES PERSIST FOLLOWING INFECTION AND IF THE PRESENCE OF ANTIBODIES CONFERS PROTECTIVE IMMUNITY. THE ACCESS SARS-COV-2 IGG II SHOULD NOT BE USED TO DIAGNOSE OR EXCLUDE ACUTE SARS-COV-2 INFECTION. TESTING IS LIMITED TO LABORATORIES CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C. §263A, THAT MEET REQUIREMENTS TO PERFORM MODERATE OR HIGH COMPLEXITY TESTS. RESULTS ARE FOR THE DETECTION OF SARS-COV-2 ANTIBODIES. IGG ANTIBODIES TO SARS-COV-2 ARE GENERALLY DETECTABLE IN BLOOD SEVERAL DAYS AFTER INITIAL INFECTION, ALTHOUGH THE DURATION OF TIME ANTIBODIES ARE PRESENT POST-INFECTION IS NOT WELL CHARACTERIZED. INDIVIDUALS MAY HAVE DETECTABLE VIRUS PRESENT FOR SEVERAL WEEKS FOLLOWING SEROCONVERSION. LABORATORIES WITHIN THE UNITED STATES AND ITS TERRITORIES ARE REQUIRED TO REPORT ALL RESULTS TO THE APPROPRIATE PUBLIC HEALTH AUTHORITIES. THE SENSITIVITY OF THE ACCESS SARS-COV-2 IGG II ASSAY EARLY AFTER INFECTION IS UNKNOWN. NEGATIVE RESULTS DO NOT PRECLUDE ACUTE SARS-COV-2 INFECTION. IF ACUTE INFECTION IS SUSPECTED, DIRECT TESTING FOR SARS-COV-2 IS NECESSARY. FALSE POSITIVE RESULTS FOR THE ACCESS SARS-COV-2 IGG II ASSAY MAY OCCUR DUE TO CROSS-REACTIVITY FROM PRE-EXISTING ANTIBODIES OR OTHER POSSIBLE CAUSES. THE ACCESS SARS-COV-2 IGG II ASSAY IS ONLY FOR USE UNDER THE FOOD AND DRUG ADMINISTRATION'S EMERGENCY USE AUTHORIZATION.,ACCESS CORTISOL CALIBRATORS-THE ACCESS CORTISOL CALIBRATOR S0 IS INTENDED FOR USE WITH THE ACCESS CORTISOL ASSAY TO DILUTE PATIENT SAMPLES CONTAINING ANALYTE CONCENTRATIONS GREATER THAN THE ANALYTE SPECIFIC S5 CALIBRATOR.",ACCESS SAMPLE DILUENT A(ACCESS SAMPLE DILUENT A)-THE ACCESS SAMPLE DILUENT A IS INTENDED FOR USE WITH ACCESS ASSAYS TO DILUTE PATIENT SAMPLES CONTAINING ANALYTE CONCENTRATIONS GREATER THAN THE ANALYTE SPECIFIC S5 CALIBRATOR,ACCESS CORTISOL-THE ACCESS CORTISOL ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE

	QUANTITATIVE DETERMINATION OF CORTISOL LEVELS IN HUMAN SERUM, PLASMA (HEPARIN, EDTA) AND URINE USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS HLH CALIBRATORS(ACCESS HLH CALIBRATORS)-THE ACCESS HLH CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS HLH ASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS., ACCESS CK-MB CALIBRATORS-THE ACCESS CK-MB CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS CK-MB ASSAY FOR THE QUANTITATIVE DETERMINATION OF CK-MB LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS,UNICEL DXI WASH BUFFER II(UNICEL DXI WASH BUFFER II)-ACCESS WASH BUFFER II IS INTENDED FOR USE WITH THE ACCESS IMMUNOASSAY SYSTEMS AND SPECIFIC ACCESS IMMUNOASSAY REAGENTS.,ACCESS CK-MB CALIBRATORS-THE ACCESS CK-MB CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS CK-MB ASSAY FOR THE QUANTITATIVE DETERMINATION OF CK-MB LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.",ACCESS PROGESTERONE DE CALIBRATORS(ACCESS PROGESTERONE DE CALIBRATORS)-THE ACCESS PROGESTERONE DE CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS PROGESTERONE ASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS., ACCESS CK-MB-THE ACCESS CK-MB ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CK-MB LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS 25(OH) VITAMIN D TOTAL CALIBRATORS FOR USE ON THE ACCESS 2 IMMUNOASSAY SYSTEM(ACCESS 25(OH) VITAMIN D TOTAL CALIBRATORS FOR USE ON THE ACCESS 2 IMMUNOASSAY SYSTEM)-THE ACCESS 25(OH) VITAMIN D TOTAL CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS 25(OH) VITAMIN D TOTAL ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25-HYDROXYVITAMIN D [25(OH)D] LEVELS IN HUMAN SERUM AND PLASMA USING THE UNICEL DXI 800 IMMUNOASSAY SYSTEMS. RESULTS ARE TO BE USED AS AN AID IN THE ASSESSMENT OF VITAMIN D SUFFICIENCY. † UNICEL DXI 600, UNICEL DXI 800, UNICEL DXC 880I, UNICEL DXC 860I, UNICEL DXC 680I, AND UNICEL DXC 660I, ACCESS BR MONITOR CALIBRATORS-THE ACCESS BR MONITOR CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS BR MONITOR ASSAY FOR THE QUANTITATIVE DETERMINATION QUANTITATIVE DETERMINATION OF CA 15-3 ANTIGEN LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN)USING THE ACCESS IMMUNOASSAY SYSTEMS,CONTRAD 70(CONTRAD 70)-FOR USE WITH

	ACCESS IMMUNOASSAY SYSTEMS,ACCESS BR MONITOR-THE ACCESS BR MONITOR ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CA 15-3 ANTIGEN LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS, ACCESS 25(OH) VITAMIN D TOTAL FOR USE ON THE UNICEL DXI IMMUNOASSAY SYSTEM(ACCESS 25(OH) VITAMIN D TOTAL FOR USE ON THE UNICEL DXI IMMUNOASSAY SYSTEM)-THE ACCESS 25(OH) VITAMIN D TOTAL ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25-HYDROXYVITAMIN D [25(OH) VITAMIN D] LEVELS IN HUMAN SERUM AND PLASMA USING THE UNICEL DXI IMMUNOASSAY SYSTEMS. RESULTS ARE TO BE USED AS AN AID IN THE ASSESSMENT OF VITAMIN D SUFFICIENCY. † UNICEL DXI 600, UNICEL DXI 800, UNICEL DXC 880I, UNICEL DXC 860I, UNICEL DXC 680I, AND UNICEL DXC 660I,ACCESS AFP SAMPLE DILUENT-THE ACCESS AFP SAMPLE DILUENT IS INTENDED FOR USE WITH THE ACCESS AFP ASSAY TO DILUTE PATIENT SAMPLES CONTAINING AFP CONCENTRATIONS GREATER THAN THE S6 CALIBRATOR.,ACCESS IL-6 QC(ACCESS IL-6 QC)-THE ACCESS IL-6 QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS IL-6 ASSAY., ACCESS AFP CALIBRATORS-THE ACCESS AFP CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS AFP ASSAY FOR THE QUANTITATIVE DETERMINATION OF AFP LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS SHBG(ACCESS SHBG)-THE ACCESS SHBG ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF SEX HORMONE BINDING GLOBULIN LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS AFP-THE ACCESS AFP REAGENT KIT IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALPHA-FETOPROTEIN (AFP) LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS TPO ANTIBODY CALIBRATORS(ACCESS TPO ANTIBODY CALIBRATORS)-THE ACCESS TPO ANTIBODY CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS TPO ANTIBODY ASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROPEROXIDASE ANTIBODY (TPOAB) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS VITAMIN B12 CALIBRATORS-THE ACCESS VITAMIN B12 CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS VITAMIN B12 ASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS HLH(ACCESS HLH)-THE ACCESS

	HLH ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS VITAMIN B12-THE ACCESS VITAMIN B12 ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS., ACCESS FREE T3 CALIBRATORS(ACCESS FREE T3 CALIBRATORS)-THE ACCESS FREE T3 CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS FREE T3 ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEM$, ACCESS UNCONJUGATED ESTRIOL CALIBRATORS-THE ACCESS UNCONJUGATED ESTRIOL ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF UNCONJUGATED ESTRIOL LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS 25(OH) VITAMIN D TOTAL CALIBRATORS FOR USE ON THE UNICEL DXI IMMUNOASSAY SYSTEM(ACCESS 25(OH) VITAMIN D TOTAL CALIBRATORS FOR USE ON THE UNICEL DXI IMMUNOASSAY SYSTEM) -THE ACCESS 25(OH) VITAMIN D TOTAL CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS 25(OH) VITAMIN D TOTAL ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25-HYDROXYVITAMIN D [25(OH)D] LEVELS IN HUMAN SERUM AND PLASMA USING THE UNICEL DXI 800 IMMUNOASSAY SYSTEMS. RESULTS ARE TO BE USED AS AN AID IN THE ASSESSMENT OF VITAMIN D SUFFICIENCY. † UNICEL DXI 600, UNICEL DXI 800, UNICEL DXC 880I, UNICEL DXC 860I, UNICEL DXC 680I, AND UNICEL DXC 660I, ACCESS ULTRASENSITIVE INSULIN CALIBRATORS-THE ACCESS ULTRASENSITIVE INSULIN CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS ULTRASENSITIVE INSULIN ASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN LEVELS IN HUMAN SERUM AND PLASMA (EDTA) USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS TOTAL BHCG (5 IS)(ACCESS TOTAL BHCG (5 IS))-THE ACCESS TOTAL HCG (5TH IS) ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL HCG LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEM$. THIS ASSAY IS INTENDED FOR USE AS AN AID IN THE EARLY DETECTION OF PREGNANCY. THE CONCENTRATION OF HCG DETERMINED BY THIS KIT CAN ALSO BE USED IN CONJUNCTION WITH AFP, UNCONJUGATED ESTRIOL, AND INHIBIN A CONCENTRATIONS IN DOWN SYNDROME (TRISOMY 21) RISK ASSESSMENT. SUCH AN

	APPROACH HAS BEEN VERIED ON THE BASIS OF MULTIVARIATE GAUSSIAN DISTRIBUTION ANALYSIS,ACCESS ULTRASENSITIVE INSULIN-THE ACCESS ULTRASENSITIVE INSULIN ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN LEVELS IN HUMAN SERUM AND PLASMA (EDTA) USING THE ACCESS IMMUNOASSAY SYSTEMS.",ACCESS TOTAL BHCG (5 IS) CALIBRATORS(ACCESS TOTAL BHCG (5 IS) CALIBRATORS)-THE ACCESS TOTAL HCG (5TH IS) CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS TOTAL HCG (5TH IS) ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL HCG LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS ULTRASENSITIVE HGH CALIBRATORS-THE ACCESS ULTRASENSITIVE HGH CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS ULTRASENSITIVE HGH ASSAY FOR THE QUANTITATIVE DETERMINATION OF HGH LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.",ACCESS RED BLOOD CELL FOLATE LYSING AGENT (ACCESS RED BLOOD CELL FOLATE LYSING AGENT)-FOR THE PREPARATION OF RED BLOOD CELL HEMOLYSATES IN THE ACCESS FOLATE ASSAY.,ACCESS ULTRASENSITIVE HGH-THE ACCESS ULTRASENSITIVE HGH ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HGH LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS STFR QC2 AND QC3(ACCESS STFR QC2 AND QC3)-THE ACCESS STFR QC2 AND QC3 IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS STFR ASSAY.,ACCESS TOTAL T4 CALIBRATORS-THE ACCESS TOTAL T4 CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS TOTAL T4 ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYOXINE (T4) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS TPO ANTIBODY (ACCESS TPO ANTIBODY)-THE ACCESS TPO ANTIBODY CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS TPO ANTIBODY ASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROPEROXIDASE ANTIBODY (TPOAB) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS TOTAL T4-THE ACCESS TOTAL T4 ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE (T4) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.", ACCESS WASH BUFFER II(ACCESS WASH BUFFER II)-ACCESS WASH BUFFER II IS INTENDED FOR USE WITH THE ACCESS IMMUNOASSAY SYSTEMS AND SPECIFIC ACCESS IMMUNOASSAY REAGENTS.,ACCESS TOTAL T3 CALIBRATORS-THE ACCESS TOTAL T3 CALIBRATORS ARE

	INTENDED TO CALIBRATE THE ACCESS TOTAL T3 ASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS IL-6(ACCESS IL-6)-THE ACCESS IL-6 ASSAY IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF IL-6 LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN). THIS ASSAY IS USED TO ASSIST IN IDENTIFYING SEVERE INFLAMMATORY RESPONSE IN PATIENTS WITH CONFIRMED COVID-19 ILLNESS TO AID IN DETERMINING THE RISK OF INTUBATION WITH MECHANICAL VENTILATION, IN CONJUNCTION WITH CLINICAL FINDINGS AND THE RESULTS OF OTHER LABORATORY TESTING. THE ASSAY MAY ALSO BE USED TO AID IN THE STUDY OF INFLAMMATORY DISEASE. THE ACCESS IL-6 ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY AND IS INTENDED FOR USE ON ACCESS IMMUNOASSAY ANALYZERS. ,ACCESS TOTAL T3-THE ACCESS TOTAL T3 ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS IL-6 CALIBRATORS(ACCESS IL-6 CALIBRATORS)-THE ACCESS IL-6 CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS IL-6 ASSAY FOR THE QUANTITATIVE DETERMINATION OF IL-6 LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS THYROID UPTAKE CALIBRATOR-THE ACCESS THYROID UPTAKE CALIBRATOR IS INTENDED TO CALIBRATE THE ACCESS THYROID UPTAKE ASSAY FOR THE ASSESSMENT OF THE THYROXINE BINDING CAPACITY OF UNSATURATED PROTEINS IN SERUM AND PLASMA, USING THE ACCESS IMMUNOASSAY SYSTEMS.,UNICEL DXL ACCESS IMMUNOASSAY SYSTEMS WASH BUFFER II (UNICEL DXL ACCESS IMMUNOASSAY SYSTEMS WASH BUFFER II)-THE UNICEL DXI ACCESS IMMUNOASSAY SYSTEMS WASH BUFFER II DILUENT PACK IS INTENDED FOR USE WITH THE UNICEL DXI IMMUNOASSAY SYSTEMS., ACCESS THYROGLOBULIN CALIBRATORS-THE ACCESS THYROGLOBULIN CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS THYROGLOBULIN ASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS HYBRITECH P2PSA(ACCESS HYBRITECH P2PSA)-ACCESS HYBRITECH P2PSA IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT ASSAY USED IN COMBINATION WITH THE ACCESS HYBRITECH PSA AND FREE PSA ASSAYS TO CALCULATE THE BECKMAN COULTER PHI, A MULTIVARIATE INDEX, INTENDED TO AID THE DETERMINATION OF THE RISK OF PROSTATE CANCER USING HUMAN SERUM ON THE

	ACCESS IMMUNOASSAY SYSTEMS. BECKMAN COULTER PHI IS USED AS AN AID IN DISTINGUISHING PROSTATE CANCER FROM BENIGN PROSTATIC CONDITIONS IN MEN AGED 50 YEARS AND OLDER WITH TOTAL PSA 2.0 TO 10.0 NG/ML, WITH DIGITAL RECTAL EXAMINATION FINDINGS THAT ARE NOT SUSPICIOUS FOR CANCER. PROSTATIC BIOPSY IS REQUIRED FOR DIAGNOSIS OF CANCER, ACCESS THYROGLOBULIN ANTIBODY II CALIBRATORS-THE ACCESS THYROGLOBULIN ANTIBODY II CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS THYROGLOBULIN ANTIBODY II ASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN ANTIBODY LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS HYBRITECH P2PSA QC(ACCESS HYBRITECH P2PSA QC)-THE ACCESS HYBRITECH P2PSA QC ARE TRI-LEVEL CONTROLS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF IMMUNOENZYMATIC PROCEDURES FOR THE QUANTITATIVE MEASUREMENT OF [-2]PROPSA ISOFORM OF PROSTATE SPECIFIC ANTIGEN (PSA) USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS TESTOSTERONE-THE ACCESS TESTOSTERONE ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS., CITRANOX(CITRANOX)-FOR USE WITH ACCESS IMMUNOASSAY SYSTEMS,ACCESS THYROGLOBULIN-THE ACCESS THYROGLOBULIN ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS 25(OH) VITAMIN D TOTAL FOR USE ON THE ACCESS 2 IMMUNOASSAY SYSTEM(ACCESS 25(OH) VITAMIN D TOTAL FOR USE ON THE ACCESS 2 IMMUNOASSAY SYSTEM)-THE ACCESS 25(OH) VITAMIN D TOTAL ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25-HYDROXYVITAMIN D [25(OH) VITAMIN D] LEVELS IN HUMAN SERUM AND PLASMA USING THE UNICEL DXI IMMUNOASSAY SYSTEMS. RESULTS ARE TO BE USED AS AN AID IN THE ASSESSMENT OF VITAMIN D SUFFICIENCY. † UNICEL DXI 600, UNICEL DXI 800, UNICEL DXC 880I, UNICEL DXC 860I, UNICEL DXC 680I, AND UNICEL DXC 660I, ACCESS THYROGLOBULIN ANTIBODY II-THE ACCESS THYROGLOBULIN ANTIBODY II (TGAB) ASSAY IS A PARAMAGNETIC PARTICLE,CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN ANTIBODY LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS HYBRITECH P2PSA CALIBRATORS

	(ACCESS HYBRITECH P2PSA CALIBRATORS)-THE ACCESS HYBRITECH P2PSA CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS HYBRITECH P2PSA ASSAY TO AID THE DETERMINATION OF THE RISK OF PROSTATE CANCER USING HUMAN SERUM ON THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS SUBSTRATE-ACCESS SUBSTRATE IS INTENDED FOR USE WITH THE ACCESS IMMUNOASSAY SYSTEMS AND SPECIFIC ACCESS IMMUNOASSAY REAGENTS,ACCESS DIGOXIN(ACCESS DIGOXIN)-THE ACCESS DIGOXIN ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS MYOGLOBIN CALIBRATORS-THE ACCESS MYOGLOBIN CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS MYOGLOBIN ASSAY FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS FOLATE(ACCESS FOLATE)-THE ACCESS FOLATE ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLIC ACID LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) OR RED BLOOD CELLS USING THE ACCESS IMMUNOASSAY SYSTEMS. FOLATE LEVELS IN SERUM AND PLASMA (HEPARIN) OR RED BLOOD CELLS ARE USED TO ASSESS FOLATE STATUS. THE SERUM FOLATE LEVELS IS AN INDICATOR OF RECENT FOLATE INTAKE. A LOW RBC FOLATE VALUE CAN INDICATE A PROLONGED FOLATE DEFICIENCY.,ACCESS TESTOSTERONE CALIBRATORS-THE ACCESS TESTOSTERONE CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS TESTOSTERONE ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS UNCONJUGATED ESTRIOL(ACCESS UNCONJUGATED ESTRIOL)-THE ACCESS UNCONJUGATED ESTRIOL ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF UNCONJUGATED ESTRIOL LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS MYOGLOBIN-THE ACCESS MYOGLOBIN ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS FOLATE CALIBRATORS(ACCESS FOLATE CALIBRATORS)-THE ACCESS FOLATE CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS FOLATE ASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLIC ACID LEVELS IN HUMAN SERUM, PLASMA (HEPARIN) AND RED BLOOD CELLS USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS INTRINSIC FACTOR ANTIBODY QC-

	THE ACCESS INTRINSIC FACTOR AB QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS INTRINSIC FACTOR AB ASSAY,ACCESS SYSTEM CHECK SOLUTION(ACCESS SYSTEM CHECK SOLUTION)-FOR USE WITH THE ACCESS IMMUNOASSAY SYSTEMS IN THE WEEKLY MAINTENANCE SYSTEM CHECK PROCEDURE.,ACCESS INTRINSIC FACTOR ANTIBODY-THE ACCESS INTRINSIC FACTOR AB ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE DETECTION OF INTRINSIC FACTOR ANTIBODY IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS THYROID UPTAKE(ACCESS THYROID UPTAKE)-THE ACCESS THYROID UPTAKE ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE ASSESSMENT OF THE THYROXINE-BINDING CAPACITY OF UNSATURATED PROTEINS IN SERUM AND PLASMA, USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS INTRINSIC FACTOR ANITBODY CALIBRATORS-THE ACCESS INTRINSIC FACTOR AB CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS INTRINSIC FACTOR AB ASSAY FOR THE DETECTION OF INTRINSIC FACTOR ANTIBODY IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS INHIBIN A QC-THE ACCESS INHIBIN A QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS INHIBIN A ASSAY.,ACCESS INHIBIN A CALIBRATORS-THE ACCESS INHIBIN A CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS INHIBIN A ASSAY FOR THE QUANTITATIVE DETERMINATION OF DIMERIC INHIBIN A LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN AND EDTA) AS AN AID IN THE DIAGNOSIS AND MONITORING OF VARIOUS HORMONAL REPRODUCTIVE DISORDERS USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS HYPERSENSITIVE HTSH CALIBRATORS-THE ACCESS HYPERSENSITIVE HTSH CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS HYPERSENSITIVE HTSH ASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID-STIMULATING HORMONE (THYROTROPIN, HTSH) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS. THIS ASSAY IS CAPABLE OF PROVIDING 3RD GENERATION (HYPERSENSITIVE HTSH) AND/OR 2ND GENERATION (FAST HTSH) RESULTS,ACCESS INHIBIN A-THE ACCESS INHIBIN A ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DIMERIC INHIBIN A IN HUMAN SERUM AND PLASMA (HEPARIN AND EDTA) AS AN AID IN THE DIAGNOSIS AND MONITORING OF VARIOUS HORMONAL REPRODUCTIVE DISORDERS USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS HYPERSENSITIVE HTSH-SAMPLES CONTAINING TOTAL PROSTATE SPECIFIC ANTIGEN (PSA) CONCENTRATIONS GREATER THAN THE $5

	CALIBRATOR.,ACCESS HYBRITECH PSA SAMPLE DILUENT-THE ACCESS HYBRITECH PSA SAMPLE DILUENT IS INTENDED FOR USE WITH THE ACCESS HYBRITECH PSA ASSAY TO DILUTE PATIENT, ACCESS HYBRITECH PSA CALIBRATORS-THE ACCESS HYBRITECH PSA CALIBRATORS ARE INTENDED FOR MONITORING SYSTEM PERFORMANCE OF IMMUNOENZYMATIC PROCEDURES FOR THE QUANTITATIVE MEASUREMENT OF TOTAL PROSTATE SPECIFIC ANTIGEN (PSA) USING THE ACCESS IMMUNOASSAY SYSTEMS., ACCESS HYBRITECH PSA QC-THE ACCESS HYBRITECH PSA QC ARE TRI-LEVEL CONTROLS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF IMMUNOENZYMATIC PROCEDURES FOR THE QUANTITATIVE MEASUREMENT OF TOTAL PROSTATE SPECIFIC ANTIGEN (PSA) USING THE ACCESS IMMUNOASSAY SYSTEMS., ACCESS HYBRITECH PSA-THE ACCESS HYBRITECH PSA ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROSTATE SPECIFIC ANTIGEN (PSA) LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS HYBRITECH FREE PSA QC-THE ACCESS HYBRITECH FREE PSA QC ARE BI-LEVEL CONTROLS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF IMMUNOENZYMATIC PROCEDURES FOR THE QUANTITATIVE MEASUREMENT OF FREE PROSTATE SPECIFIC ANTIGEN (FREE PSA) USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS HYBRITECH FREE PSA-THE ACCESS HYBRITECH FREE PSA ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (FREE PSA) IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS HYBRITECH FREE PSA CALIBRATORS-THE ACCESS HYBRITECH FREE PSA CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS HYBRITECH FREE PSA ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (FPSA) LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS HLH CALIBRATORS-THE ACCESS HLH ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS., ACCESS HFSH CALIBRATORS-THE ACCESS HFSH CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS HFSH ASSAY FOR THE QUANTITATIVE DETERMINATION OF FSH LEVELS IN HUMAN SERUM USING THE ACCESS IMUNOASSAY SYSTEMS,ACCESS HFSH-THE ACCESS HFSH ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE (FSH)

	LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS GI MONITOR CALIBRATORS-THE ACCESS GI MONITOR CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS GI MONITOR ASSAY FOR THE QUANTITATIVE DETERMINATION OF CA 19-9 ANTIGEN IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.",ACCESS GI MONITOR-THE ACCESS GI MONITOR ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF CA 19-9 ANTIGEN IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.",ACCESS FREE T4 CALIBRATORS-THE ACCESS FREE T4 CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS FREE T4 ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE THYOXINE LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS FREE T4-THE ACCESS FREE T4 ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS FREE T3-THE ACCESS FREE T3 ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS FERRITIN CALIBRATORS-THE ACCESS FERRITIN CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS FERRITIN ASSAY FOR THE QUANTITATIVE DETERMINATION OF FERRITIN LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS FERRITIN-THE ACCESS FERRITIN ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FERRITIN LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS ESTRADIOL CALIBRATORS-THE ACCESS ESTRADIOL CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS ESTRADIOL ASSAY FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS ESTRADIOL-THE ACCESS ESTRADIOL ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS EPO CALIBRATORS-THE ACCESS EPO CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS EPO ASSAY FOR THE QUANTITATIVE DETERMINATION OF EPO LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY

	SYSTEMS.,ACCESS EPO-THE ACCESS EPO ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ERYTHROPOIETIN LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS DIGOXIN CALIBRATORS-THE ACCESS DIGOXIN CALIBRATOR S0 IS INTENDED FOR USE WITH THE ACCESS DIGOXIN ASSAY TO DILUTE PATIENT SAMPLES CONTAINING ANALYTE CONCENTRATIONS GREATER THAN THE ANALYTE SPECIFIC S5 CALIBRATOR,ACCESS DHEA-S CALIBRATORS-THE ACCESS DHEA-S CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS DHEA-S ASSAY FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS DHEA-S-INTENDED USE: THE ACCESS DHEA-S ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,IGM(IGM) -IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,ACCESS STFR-THE ACCESS STFR ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF SOLUBLE TRANSFERRIN RECEPTOR (STFR) LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS SAMPLE DILUENT A-THE ACCESS SAMPLE DILUENT A IS INTENDED FOR USE WITH ACCESS ASSAYS TO DILUTE PATIENT SAMPLES CONTAINING ANALYTE CONCENTRATIONS GREATER THAN THE ANALYTE SPECIFIC S5 CALIBRATOR,ACCESS PROLACTIN CALIBRATORS-THE ACCESS PROLACTIN CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS PROLACTIN ASSAY FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS PROLACTIN-THE ACCESS PROLACTIN ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS PROGESTERONE CALIBRATORS-THE ACCESS PROGESTERONE CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS PROGESTERONE ASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS., ACCESS PROGESTERONE-THE ACCESS PROGESTERONE ASSAY IS A

	PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS., ACCESS OV MONITOR CALIBRATORS-THE ACCESS OV MONITOR CALIBRATORS ARE INTENDED TO CALIBRATE THE OV MONITOR ASSAY FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN (CA125) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS OV MONITOR-THE ACCESS OV MONITOR ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CA 125 ANTIGEN LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS OSTASE QC-THE ACCESS OSTASE QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS OSTASE ASSAY,ACCESS OSTASE CALIBRATORS-THE ACCESS OSTASE CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS OSTASE ASSAY FOR THE QUANTITATIVE DETERMINATION OF BONE ALKALINE PHOSPHATASE (BAP) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS OSTASE-THE ACCESS OSTASE ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR USE WITH THE ACCESS IMMUNOASSAY SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF BONE ALKALINE PHOSPHATASE (BAP), AN INDICATOR OF OSTEOBLASTIC ACTIVITY, IN HUMAN SERUM AND PLASMA.,ACCESS STFR QC (LEVEL 1)-THE ACCESS STFR QC1 IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS STFR ASSAY.,ACCESS STFR CALIBRATORS-THE ACCESS STFR CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS STFR ASSAY FOR THE QUANTITATIVE DETERMINATION OF SOLUBLE TRANSFERRIN RECEPTOR LEVELS IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS."

127	IMP/IVD/2019/000054	1.License Holder Name: M/S.TRANSASIA BIO-MEDICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OPTISOL-XL 750 (OPTISOL-XL 750)-OPTI-SOL XL 750 IS A CONCENTRATED SOLUTION FOR A CLEANING OF FULLY AUTOMATED URINE ANALYSER LAURA XL. ,UREA(UREA 275)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF UREA IN HUMAN SERUM, PLASMA AND URINE.,DEKAPHAN LAURA(DEKAPHAN LAURA)-DEKAPHAN LAURA ARE INTENDED FOR OBJECTIVE SEMI-QUANTITATIVE ANALYSIS BY URINE READERS. THE STRIPS ARE MADE WITH ZONES. THE ZONES AT CONTACT WITH INDIVIDUAL URINE COMPONENTS, CHANGE THEIR COLOURING, INTENSITY AND SHADE OF WHICH IS PROPORTIONATE TO CONCENTRATION OF THE DETERMINED SUBSTANCE. THE RESULTANT COLOURING IS ASSESSED OBJECTIVELY BY THE URINE READERS LAURA,MICROALBUMIN(MAL 10)-"DIAGNOSTIC REAGENT FOR IN VITRO QUANTITATIVE DETERMINATION OF MICROALBUMIN (MAL) IN HUMAN URINE BY TURBIDIMETRIC IMMUNOASSAY. ", MICROALBUPHAN LAURA(MICROALBUPHAN LAURA)-MICROALBUPHAN LAURA ARE INTENDED FOR OBJECTIVE SEMI-QUANTITATIVE ANALYSIS BY URINE READERS. THE STRIPS ARE MADE WITH TWO ZONES. THE ZONES AT CONTACT WITH INDIVIDUAL URINE COMPONENTS, CHANGE THEIR COLOURING, INTENSITY AND SHADE OF WHICH IS PROPORTIONATE TO CONCENTRATION OF THE DETERMINED SUBSTANCE. THE RESULTANT COLOURING IS ASSESSED OBJECTIVELY BY THE URINE READERS LAURA, CHOLESTEROL(CHOL 440)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GGT IN HUMAN SERUM AND PLASMA.,TETRAPHAN SG LAURA(TETRAPHAN SG LAURA)-TETRAPHAN SG LAURA ARE INTENDED FOR OBJECTIVE SEMI-QUANTITATIVE ANALYSIS BY URINE READERS. THE STRIPS ARE MADE WITH FOUR ZONES. THE ZONES AT CONTACT WITH INDIVIDUAL URINE COMPONENTS, CHANGE THEIR COLOURING, INTENSITY AND SHADE OF WHICH IS PROPORTIONATE TO CONCENTRATION OF THE DETERMINED SUBSTANCE. THE RESULTANT COLOURING IS ASSESSED OBJECTIVELY BY THE URINE READERS LAURA ,ERBA NORM(ERBA NORM)-CONTROL SERUM (ASSAYED) IS INTENDED FOR MONITORING THE ACCURACY AND PRECISION OF COMMONLY USED CLINICAL CHEMISTRY ASSAYS IN NORMAL RANGE.,URINORM (URINORM)-"URINORM CONTROL URINES ARE A LIQUID SYNTHETIC MATERIAL WITH CONCENTRATIONS WITHIN THE NORMAL (URINORM N) AND PATHOLOGICAL (URINORM P) RANGES. URINORM CONTROL URINES ARE DESIGNED FOR VERIFICATION AND CONFIRMATION OF PRECISION AND ACCURACY OF PHAN (URO-DIP 10E) DIAGNOSTIC STRIPS AS WELL AS LAURA, LAURA SMART, URO-DIPCHECK 240E,

	URO-DIPCHECK 400E, LAURA M URINE ANALYSERS (FOR THE VISUAL AND OBJECTIVE EVALUATION). ",AST/GOT 330(AST/GOT 330)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF AST/GOT (ASPARTATE,OPTISOL-XL 1500 (OPTISOL-XL 1500)-OPTI-SOL XL 1500 IS A CONCENTRATED SOLUTION FOR A CLEANING OF FULLY AUTOMATED URINE ANALYSER LAURA XL.,CREATINE KINASE(CK 110)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATINE KINASE IN HUMAN SERUM AND PLASMA.,DEKAPHAN AUTO (DEKAPHAN AUTO)-DEKAPHAN AUTO ARE INTENDED FOR OBJECTIVE ANALYSIS BY AUTOMATED URINE ANALYSER LAURA XL. THE STRIPS ARE MADE WITH TEN ZONES. THE ZONES AT CONTACT WITH INDIVIDUAL URINE COMPONENTS, CHANGE THEIR COLOURING, INTENSITY AND SHADE OF WHICH IS PROPORTIONATE TO CONCENTRATION OF THE DETERMINED SUBSTANCE. THE RESULTANT COLOURING IS ASSESSED OBJECTIVELY BY THE URINE ANALYSER LAURA XL,LIPOPROTEIN (A)(LP (A))-IN VITRO QUANTITATIVE DETERMINATION OF LIPOPROTEIN (A) IN HUMAN SERUM BY IMMUNOTURBIDIMETRY.,ERBA H3 CON N (ERBA H3 CON N)-ERBA H3 CON IS A CONTROL (NORMAL LEVEL) DESIGNED TO MONITOR ACCURACY AND PRECISION OF AUTOMATED H360 HEMATOLOGY ANALYZERS. ,ERBA PATH(ERBA PATH)-CONTROL SERUM (ASSAYED) IS INTENDED FOR MONITORING THE ACCURACY AND PRECISION OF COMMONLY USED CLINICAL CHEMISTRY ASSAYS IN PATHOLOGICAL RANGE.,ERBA H3 CON H (ERBA H3 CON H)-ERBA H3 CON IS A CONTROL (HIGH LEVEL) DESIGNED TO MONITOR ACCURACY AND PRECISION OF AUTOMATED H360 HEMATOLOGY ANALYZERS. , GAMMAGLUTAMYLTRANSFERASE(GGT 110)-DIAGNOSTIC REAGENT FOR IN VITRO QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN B IN HUMAN SERUM,ERBA H3 CON L(ERBA H3 CON L)-ERBA H3 CON IS A CONTROL (LOW LEVEL) DESIGNED TO MONITOR ACCURACY AND PRECISION OF AUTOMATED H360 HEMATOLOGY ANALYZERS. ,IRON (FE 125)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IRON IN SERUM AND PLASMA. PHOTOMETRIC TEST USING CHROMOGEN FERROZINE.,HDL DIRECT(HDL 160)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM.,URIC ACID (SINGLE REAGENT)(UA 440)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA AND URINE.,URIC ACID(UA 275)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA AND URINE.,XL MULTICAL(XL MULTICAL)-LYOPHILIZED CALIBRATOR BASED ON HUMAN SERUM. THE CONCEN-TRATIONS AND ACTIVITIES ARE SUITABLE FOR

	CALIBRATION OF CLINICAL CHEMISTRY,MICROALBUMIN(MAL 5)-DIAGNOSTIC REAGENT FOR IN VITRO QUANTITATIVE DETERMINATION OF MICROALBUMIN (MAL),MAL CONTROL(MAL CON) -ACCURACY CONTROL FOR QUANTITATIVE IMMUNOCHEMICAL DETERMINATION OF MICROALBUMIN IN URINE BY,UIBC(UIBC 125)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IRON IN SERUM AND PLASMA. PHOTOMETRIC TEST USING CHROMOGEN FERROZINE.,LACTATEDEHYDROGENASE-P (LDH 110)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM.,ERBA XL AUTOWASH AC/AL(XL AUTOWASH AC/AL)-ERBA XL AUTOWASH AC/AL IS A SOLUTION USED WITH ERBA XL AUTO ANALYZERS.,LDL DIRECT(LDL C 80)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LDL CHOLESTEROL IN HUMAN SERUM AND PLASMA.,HDL DIRECT(HDL C 160)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM.,LDL DIRECT(LDL 80)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LDL CHOLESTEROL IN HUMAN SERUM AND PLASMA.,APOLIPOPROTEIN A1 (APO A1)-DIAGNOSTIC REAGENT FOR IN VITRO QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A1 IN HUMAN SERUM BY TURBIDIMETRIC IMMUNOASSAY.,XL CALIBRANT B(XL CAL B)-CALIBRANT B IS A BUFFERED SALINE REAGENT USED FOR 2 POINT CALIBRATION OF SODIUM, POTASSIUM AND CHLORIDE ELECTROLYTES IN,XL CALIBRANT A(XL CAL A)-CALIBRANT A IS A BUFFERED SALINE REAGENT USED FOR ONE POINT CALIBRATION OF SODIUM, POTASSIUM AND CHLORIDE ELECTROLYTES IN THE ISE MODULE OF THE XL CLINICAL CHEMISTRY AUTO-ANALYZER., ALKALINE PHOSPHATASE(ALP 110)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ALP IN HUMAN, APOLIPOPROTEIN B(APO B)-DIAGNOSTIC REAGENT FOR IN VITRO QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN B IN HUMAN SERUM,MAGNESIUM(MG 88)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF MAGNESIUM IN HUMAN, BILIRUBIN DIRECT 330(BIL D 330)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF BILIRUBIN DIRECT IN HUMAN SERUM AND PLASMA.,CALCIUM(CA 120)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA OR URINE.

128	IMP/IVD/2019/000055	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:UIBC, FERENE(UIBC, FERENE)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF UNSATURATED IRON BINDING CAPACITY IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. ,DIACON N (DIACON N)-LYOPHILIZED CONTROL SERUM FOR THE USE IN TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES IN HUMAN SAMPLES ON PHOTOMETRIC SYSTEMS. , DIACAL AUTO (DIACAL AUTO)-LYOPHILIZED CALIBRATION SERUM FOR THE USE IN TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES IN HUMAN SAMPLES ON PHOTOMETRIC SYSTEMS.

129	IMP/IVD/2019/000056	1.License Holder Name: M/S. CPC DIAGNOSTICS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FCAL TURBO KIT (BUHLMANN (KK-CAL))-THE BÜHLMANN FCAL® TURBO IS AN AUTOMATED IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF CALPROTECTIN IN HUMAN STOOL SPECIMENS INTENDED AS AN AID IN THE ASSESSMENT OF INTESTINAL MUCOSAL INFLAMMATION. THE ASSAY RESULTS CAN BE USED AS AN AID TO DIAGNOSIS IN DISTINGUISHING ORGANIC, INFLAMMATORY DISEASE OF THE GASTROINTESTINAL TRACT (INFLAMMATORY BOWEL DISEASE, IBD, E.G. CROHN'S DISEASE OR ULCERATIVE COLITIS, UC) FROM FUNCTIONAL DISEASE (IRRITABLE BOWEL SYNDROME, IBS), IN PATIENTS WITH CHRONIC ABDOMINAL PAIN, ABOVE THE AGE OF FOUR, AND AS AN AID TO IBD DISEASE MONITORING.,FCAL ELISA CALPROTECTIN(BÜHLMANN (EK-CAL, EK-CAL2, EK-CAL2-WEX))-THE BÜHLMANN FCAL® ELISA IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF CALPROTECTIN IN HUMAN STOOL SPECIMENS INTENDED AS AN AID TO THE ASSESSMENT OF INTESTINAL MUCOSAL INFLAMMATION. THE ASSAY RESULTS CAN BE USED AS AN AID TO DIAGNOSIS IN DISTINGUISHING ORGANIC, INFLAMMATORY DISEASE OF THE GASTROINTESTINAL TRACT (INFLAMMATORY BOWEL DISEASE, IBD, E.G. CROHN'S DISEASE OR ULCERATIVE COLITIS, UC) FROM FUNCTIONAL DISEASE (IRRITABLE BOWEL SYNDROME, IBS), IN PATIENTS WITH CHRONIC ABDOMINAL PAIN, ABOVE THE AGE OF FOUR, AND AS AN AID TO IBD DISEASE MONITORING.,GANGLIOCOMBI LIGHT ELISA KIT(BUHLMANN (EK-GCL-S))-BÜHLMANN GANGLIOCOMBITM LIGHT ELISA, IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO DETECT ANTIBODIES AGAINST DEFINED RELEVANT NEURAL ANTIGENS GM1, GD1B AND GQ1B (IGG AND IGM) IN SERUM SAMPLES FROM PATIENTS WITH SUSPECTED PERIPHERAL NEUROPATHIES WITH AN UNKNOWN ETIOLOGY. IT ALLOWS QUANTITATIVE CLASSIFICATION OF RESULTS INTO TITRE CATEGORIES AND SERVES AS AN AID TO DIAGNOSIS OF NEUROPATHIES,GANGLIOCOMBI MAG ELISA KIT(BUHLMANN (EK-GCM))-BÜHLMANN GANGLIOCOMBITM MAG ELISA, IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO DETECT AUTO-ANTIBODIES AGAINST DEFINED RELEVANT NEURAL ANTIGENS/EPITOPES IN SERUM SAMPLES FROM PATIENTS WITH SUSPECTED PERIPHERAL NEUROPATHIES WITH AN UNKNOWN ETIOLOGY. IT ALLOWS QUANTITATIVE CLASSIFICATION OF RESULTS INTO TITRE CATEGORIES AND SERVES AS AN AID TO DIAGNOSIS OF NEUROPATHIES,ACE KINETIC(BUHLMANN ACE KINETIC (KK-ACK, KK-ACK2, KK-ACK4, KK-ACKX))-THE BUHLMANN ACE KINETIC TEST IS INTENDED FOR THE DIRECT AND QUANTITATIVE IN VITRO

		DIAGNOSTIC DETERMINATION OF ANGIOTENSIN CONVERTING ENZYME (ACE) ACTIVITY IN SERUM BY AN ENZYMATIC ASSAY.
130	IMP/IVD/2019/000056	1.License Holder Name: M/S. CPC DIAGNOSTICS PVT, LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACE KINETIC(BUHLMANN ACE KINETIC (KK-ACK, KK-ACK2, KK-ACK4, KK-ACKX))-THE BUHLMANN ACE KINETIC TEST IS INTENDED FOR THE DIRECT AND QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ANGIOTENSIN CONVERTING ENZYME (ACE) ACTIVITY IN SERUM BY AN ENZYMATIC ASSAY.
131	IMP/IVD/2019/000062	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MSWAB™ COLLECTION, PRESERVATION AND TRANSPORT SYSTEM(MSWAB™ COLLECTION, PRESERVATION AND TRANSPORT SYSTEM)-MSWAB™ IS A COLLECTION, TRANSPORT AND PRESERVATION SYSTEM INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING GRAM POSITIVE AEROBIC AND FACULTATIVE ANAEROBIC BACTERIA, HSV 1 AND HSV 2 FROM THE COLLECTION SITE TO THE TESTING LABORATORY. IN THE LABORATORY, MSWAB™ SPECIMENS ARE PROCESSED USING STANDARD CLINICAL LABORATORY OPERATING PROCEDURES FOR CULTURE

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

132	IMP/IVD/2019/000063	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARCHITECT HCV AG CONTROLS(ARCHITECT HCV AG CONTROLS)-THE ARCHITECT HCV AG CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CORE ANTIGEN TO HEPATITIS C VIRUS IN HUMAN SERUM AND PLASMA.,ALINITY I INSULIN CALIBRATORS-USED FOR THE CALIBRATION OF ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN INSULIN IN HUMAN SERUM AND PLASMA.,ARCHITECT INSULIN REAGENT KIT(ARCHITECT INSULIN REAGENT KIT)-THE ARCHITECT INSULIN ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF HUMAN INSULIN IN HUMAN SERUM OR PLASMA. ,ARCHITECT SCC REAGENT KIT(ARCHITECT SCC REAGENT KIT)-THE ARCHITECT SCC ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF SQUAMOUS CELL CARCINOMA ANTIGEN (SCC AG) IN HUMAN SERUM AND PLASMA.,ALINITY I SCC CALIBRATORS(ALINITY I SCC CALIBRATORS)-THE ALINITY I SCC CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF SQUAMOUS CELL CARCINOMA ANTIGEN (SCC AG) IN HUMAN SERUM AND PLASMA.,ARCHITECT SCC CONTROLS (ARCHITECT SCC CONTROLS)-ARCHITECT SCC CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF SQUAMOUS CELL CARCINOMA ANTIGEN (SCC AG) IN HUMAN SERUM AND PLASMA.,ALINITY I SCC CONTROLS (ALINITY I SCC CONTROLS)-THE ALINITY I SCC CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF SQUAMOUS CELL CARCINOMA ANTIGEN (SCC AG) IN HUMAN SERUM AND PLASMA.,ARCHITECT PROGRP CONTROLS (ARCHITECT PROGRP CONTROLS)-USED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PRO-GASTRIN-RELEASING PEPTIDE (PROGRP) IN HUMAN SERUM AND PLASMA., ALINITY I PROGRP CALIBRATORS(ALINITY I PROGRP CALIBRATORS)-THE ALINITY I PROGRP CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PRO-GASTRINRELEASING PEPTIDE (PROGRP) IN HUMAN SERUM AND PLASMA.,ARCHITECT SCC CALIBRATORS (ARCHITECT SCC CALIBRATORS)-ARCHITECT SCC CALIBRATORS ARE

	FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF SQUAMOUS CELL CARCINOMA ANTIGEN (SCC AG) IN HUMAN SERUM AND PLASMA., ALINITY I PROGRP CONTROLS(ALINITY I PROGRP CONTROLS)-THE ALINITY I PROGRP CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PRO-GASTRIN-RELEASING PEPTIDE (PROGRP) IN HUMAN SERUM AND PLASMA., ARCHITECT PROGRP REAGENT KIT(ARCHITECT PROGRP REAGENT KIT)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF PROGRP IN HUMAN SERUM AND PLASMA ON THE ARCHITECT I SYSTEM. THE ARCHITECT PROGRP ASSAY IS TO BE USED TO AID IN THE DIFFERENTIAL DIAGNOSIS OF LUNG CANCER IN CONJUNCTION WITH OTHER CLINICAL METHODS.,ALINITY I PROGRP REAGENT KIT (ALINITY I PROGRP REAGENT KIT)-THE ALINITY I PROGRP ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF PROGRP IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT PROGRP CALIBRATORS(ARCHITECT PROGRP CALIBRATORS)-USED FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PRO-GASTRIN-RELEASING PEPTIDE (PROGRP) IN HUMAN SERUM AND PLASMA. , ARCHITECT HCV AG REAGENT KIT(ARCHITECT HCV AG REAGENT KIT)-THE ARCHITECT HCV AG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS C VIRUS CORE ANTIGEN IN HUMAN SERUM AND PLASMA.,ALINITY I INSULIN REAGENT KIT-INTENDED FOR QUANTITATIVE DETERMINATION OF HUMAN INSULIN IN HUMAN SERUM OR PLASMA ON THE ALINITY I ANALYZER.,ALINITY I SCC REAGENT KIT(ALINITY I SCC REAGENT KIT)-THE ALINITY I SCC ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF SQUAMOUS CELL CARCINOMA ANTIGEN (SCC AG) IN HUMAN SERUM AND PLASMA TO BE USED AS AN AID IN THE MANAGEMENT OF PATIENTS WITH SQUAMOUS CELL CARCINOMA ON THE ALINITY I ANALYZER.,ALINITY I INSULIN CONTROLS-INTENDED FOR THE VERIFICATION OF ACCURACY AND PRECISION OF ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN INSULIN IN HUMAN SERUM AND PLASMA.,ALINITY I PIVKA-II CALIBRATORS(ALINITY I PIVKA-II CALIBRATORS)-THE ALINITY I PIVKA-II CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PIVKA-II IN HUMAN SERUM AND PLASMA.,ALINITY I PIVKA-II CONTROLS(ALINITY I PIVKA-II CONTROLS)-THE ALINITY I PIVKA-II CONTROLS ARE FOR THE

	VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PIVKA-II IN HUMAN SERUM AND PLASMA.,ALINITY I PIVKA-II REAGENT KIT(ALINITY I PIVKA-II REAGENT KIT)-THE ALINITY I PIVKA-II (PROTEIN INDUCED BY VITAMIN K ABSENCE OR ANTAGONIST-II) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF PIVKA-II IN HUMAN SERUM OR PLASMA ON THE ALINITY I ANALYZER., ARCHITECT INSULIN CALIBRATORS(ARCHITECT INSULIN CALIBRATORS)-THE ARCHITECT INSULIN CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN INSULIN IN HUMAN SERUM AND PLASMA.,ARCHITECT HCV AG CALIBRATORS(ARCHITECT HCV AG CALIBRATORS)-THE ARCHITECT HCV AG CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CORE ANTIGEN TO HEPATITIS C VIRUS IN HUMAN SERUM AND PLASMA.,ARCHITECT PIVKA-II REAGENT KIT(ARCHITECT PIVKA-II)-THE ARCHITECT PIVKA-II (PROTEIN INDUCED BY VITAMIN K ABSENCE OR ANTAGONIST-II) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF PIVKA-II IN HUMAN SERUM OR PLASMA. THE ARCHITECT PIVKA-II ASSAY IS INDICATED FOR USE AS AN AID FOR DIAGNOSIS OF HCC (HEPATO-CELLULAR CARCINOMA), MONITORING OF HIGH RISK PATIENTS (HEPATITIS C VIRUS INFECTIONS, HEPATITIS/CIRRHOSIS, HEPATITIS B VIRUS INFECTIONS) FOR DEVELOPMENT OF HCC, AND IN MANAGEMENT OF HCC.,ARCHITECT PIVKA-II CALIBRATORS (ARCHITECT PIVKA-II CALIBRATORS)-THE ARCHITECT PIVKA-II CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PIVKA-II IN HUMAN SERUM AND PLASMA.,ARCHITECT PIVKA-II CONTROLS(ARCHITECT PIVKA-II CONTROLS)-THE ARCHITECT PIVKA-II CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PIVKA-II IN HUMAN SERUM AND PLASMA.,ARCHITECT INSULIN CONTROLS (ARCHITECT INSULIN CONTROLS)-THE ARCHITECT INSULIN CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN INSULIN IN HUMAN SERUM AND PLASMA.

133	IMP/IVD/2019/000064	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NT PRO BNP(EXDIA)-FOR IN VITRO DIAGNOSTICS USE,PCT(EXDIA)-FOR IN VITRO DIAGNOSTICS USE,TROPONIN I(EXDIA)-FOR IN VITRO DIAGNOSTICS USE,IFOB (EXDIA)-FOR IN VITRO DIAGNOSTICS USE,D DIMER(EXDIA)-FOR IN VITRO DIAGNOSTICS USE,BETA-HCG(EXDIA)-FOR IN VITRO DIAGNOSTICS USE,EXDIA 3 IN 1 (TROPONIN I / CK-MB / MYOGLOBIN) (EXDIA)-FOR IN VITRO DIAGNOSTICS USE
134	IMP/IVD/2019/000065	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD BBL™ MYCOPREPKITS (BD BBL™ MYCOPREP KITS)-THE BD BBL™ MYCOPREP™ KITS ARE USED FOR THE DIGESTION AND DECONTAMINATION OF CLINICAL SPECIMENS SUSPECTED TO CONTAIN MYCOBACTERIA, ESPECIALLY MYCOBACTERIUM TUBERCULOSIS.
135	IMP/IVD/2019/000066	1.License Holder Name: QIAGEN INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGENE HC2 HIGH-RISK HPV DNA TEST-USED FOR THE QUALITATIVE DETECTION OF HUMAN PAPILLOMA VIRUS (HPV) TYPES 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 AND 68 IN CERVICAL SPECIMENS.,AMNISURE ROM TEST-THE IN VITRO DETECTION OF AMNIOTIC FLUID IN VAGINAL DISCHARGE OF PREGNANT WOMEN.,DIGENE HC2 HPV DNA TEST (HIGH-RISK AND LOW-RISK)-USED FOR THE QUALITATIVE DETECTION OF HUMAN PAPILLOMA VIRUS (HPV) TYPES 6, 11, 16, 18, 31, 33, 35, 39, 42, 43, 44, 45, 51, 52, 56, 58, 59 AND 68 AND ANALYSIS OF HPV DNA LOW AND HIGH RISK GROUPS IN CERVICAL SPECIMENS: HPV TYPES 6/11/42/43/44 AND 16/18/31/33/35/39/45/51/52/56/58/59/68.

136	IMP/IVD/2019/000067	1.License Holder Name: BIOMERIEUX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FILMARRAY PNEUMONIA PANEL PLUS(FILMARRAY PNEUMONIA PANEL PLUS)-THE FILMARRAY® PNEUMONIA PANEL PLUS IS A MULTIPLEXED NUCLEIC ACID TEST INTENDED FOR USE WITH FILMARRAY®, FILMARRAY® 2.0, OR FILMARRAY® TORCH SYSTEMS FOR THE SIMULTANEOUS DETECTION AND IDENTIFICATION OF MULTIPLE RESPIRATORY VIRAL AND BACTERIAL NUCLEIC ACIDS, AS WELL AS SELECT ANTIMICROBIAL RESISTANCE GENES, IN SPUTUM-LIKE SPECIMENS (INDUCED OR EXPECTORATED SPUTUM, OR ENDOTRACHEAL ASPIRATES) OR BRONCHOALVEOLAR LAVAGE (BAL)-LIKE SPECIMENS (BAL OR MINI-BAL) OBTAINED FROM INDIVIDUALS SUSPECTED OF LOWER RESPIRATORY TRACT INFECTION.,FILMARRAY GASTROINTESTINAL (GI) PANEL (FILMARRAY GASTROINTESTINAL (GI) PANEL)-THE FILMARRAY GI PANEL IS CAPABLE OF THE SIMULTANEOUS DETECTION AND IDENTIFICATION OF NUCLEIC ACIDS FROM MULTIPLE BACTERIA, VIRUSES, AND PARASITES DIRECTLY FROM STOOL SAMPLES IN CARY BLAIR TRANSPORT MEDIA OBTAINED FROM INDIVIDUALS WITH SIGNS AND/OR SYMPTOMS OF GASTROINTESTINAL INFECTION.,FILMARRAY PNEUMONIA PANEL (FILMARRAY PNEUMONIA PANEL)-THE FILMARRAY® PNEUMONIA PANEL IS A MULTIPLEXED NUCLEIC ACID TEST INTENDED FOR USE WITH FILMARRAY®, FILMARRAY® 2.0, OR FILMARRAY® TORCH SYSTEMS FOR THE SIMULTANEOUS DETECTION AND IDENTIFICATION OF MULTIPLE RESPIRATORY VIRAL AND BACTERIAL NUCLEIC ACIDS, AS WELL AS SELECT ANTIMICROBIAL RESISTANCE GENES, IN SPUTUM-LIKE SPECIMENS (INDUCED OR EXPECTORATED SPUTUM, OR ENDOTRACHEAL ASPIRATES) OR BRONCHOALVEOLAR LAVAGE (BAL)-LIKE SPECIMENS (BAL OR MINI-BAL) OBTAINED FROM INDIVIDUALS SUSPECTED OF LOWER RESPIRATORY TRACT INFECTION.,FILMARRAY MENINGITIS/ENCEPHALITIS (ME) PANEL (FILMARRAY MENINGITIS/ENCEPHALITIS (ME) PANEL)-THE FILMARRAY ME PANEL IS CAPABLE OF SIMULTANEOUS DETECTION AND IDENTIFICATION OF MULTIPLE BACTERIAL, VIRAL, AND YEAST NUCLEIC ACIDS DIRECTLY FROM CEREBROSPINAL FLUID SPECIMENS OBTAINED VIA LUMBAR PUNCTURE FROM INDIVIDUALS WITH SIGNS AND/OR SYMPTOMS OF MENINGITIS AND/OR ENCEPHALITIS.,BIOFIRE BCID2 PANEL(BIOFIRE BCID2 PANEL)-FOR THE SIMULTANEOUS QUALITATIVE DETECTION AND IDENTIFICATION OF MULTIPLE BACTERIAL AND YEAST NUCLEIC ACIDS AND SELECT GENETIC DETERMINANTS ASSOCIATED WITH ANTIMICROBIAL RESISTANCE., FILMARRAY RESPIRATORY PANEL 2 PLUS (RP2 PLUS)(FILMARRAY RESPIRATORY PANEL 2 PLUS (RP2 PLUS))-FOR THE SIMULTANEOUS

	QUALITATIVE DETECTION AND IDENTIFICATION OF MULTIPLE RESPIRATORY VIRAL AND BACTERIAL NUCLEIC ACIDS IN NASOPHARYNGEAL SWABS (NPS) OBTAINED FROM INDIVIDUALS SUSPECTED OF RESPIRATORY TRACT INFECTIONS.,BIOFIRE RESPIRATORY PANEL 2.1 (BIOFIRE RESPIRATORY PANEL 2.1)-INTENDED FOR THE SIMULTANEOUS QUALITATIVE DETECTION AND DIFFERENTIATION OF NUCLEIC ACIDS FROM MULTIPLE VIRAL AND BACTERIAL RESPIRATORY ORGANISMS, INCLUDING NUCLEIC ACID FROM SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2), IN NASOPHARYNGEAL SWABS (NPS),FILMARRAY BLOOD CULTURE IDENTIFICATION (BCID) PANEL(FILMARRAY BLOOD CULTURE IDENTIFICATION (BCID) PANEL)-THE FILMARRAY BCID PANEL IS CAPABLE OF SIMULTANEOUS DETECTION AND IDENTIFICATION OF MULTIPLE BACTERIAL AND YEAST NUCLEIC ACIDS AND SELECT GENETIC DETERMINANTS OF ANTIMICROBIAL RESISTANCE.

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137	IMP/IVD/2019/000071	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CINTEC® HISTOLOGY KIT (CINTEC® HISTOLOGY KIT)-THE CINTEC® HISTOLOGY KIT IS AN IMMUNOHISTOCHEMISTRY ASSAY FOR THE QUALITATIVE DETECTION OF THE P16INK4A ANTIGEN ON TISSUE SECTIONS PREPARED FROM FORMALIN-FIXED, PARAFFIN-EMBEDDED CERVICAL BIOPSIES. IT IS INDICATED TO BE USED IN CONJUNCTION WITH H&E-STAINED SLIDES PREPARED FROM THE SAME CERVICAL TISSUE SPECIMEN AS AN AID TO INCREASE DIAGNOSTIC ACCURACY AND INTER-OBSERVER AGREEMENT IN THE DIAGNOSIS OF HIGH-GRADE CERVICAL INTRAEPITHELIAL NEOPLASIA AND CERVICAL CARCINOMA.,CINTEC® PLUS KIT(CINTEC® PLUS KIT)-THE CINTEC® PLUS KIT IS AN IMMUNOCYTOCHEMISTRY ASSAY FOR THE SIMULTANEOUS QUAL-ITATIVE DETECTION OF THE P16INK4A AND KI-67 PROTEINS IN CERVICAL CYTOLOGY PREPARATIONS. IT IS INTENDED TO BE USED AS AN AID IN THE IDENTIFICATION OF WOMEN WITH HIGH-GRADE CERVICAL INTRAEPITHELIAL LESIONS IN A SCREENING POPULATION, AND IN THE SUB-GROUPS OF PATIENTS WITH A PAP CYTOLOGY RESULT OF ASC-US (ATYPICAL SQUAMOUS CELLS OF UNDE-TERMINED SIGNIFICANCE) OR LSIL (LOW GRADE SQUAMOUS INTRAEPITHELIAL LESION), OR IN PATIENTS WITH POSITIVE HIGH-RISK HPV TEST RESULTS. THE KIT IS INTENDED TO BE USED IN MEDICAL CYTOLOGY LABORATORIES. INTERPRETATION OF THE TEST RESULTS MAY ONLY BE MADE BY A CERTIFIED PROFESSIONAL IN CONJUNCTION WITH THE PATIENT´S CLINICAL HISTORY AND ADDITIONAL DIAGNOSTIC TESTS THAT HAVE BEEN PERFORMED., CINTEC® WASH BUFFER (10X)(CINTEC® WASH BUFFER (10X))-USED FOR THE WASHING DURING STAINING PROCEDURES OF TISSUE SECTIONS PREPARED FROM FORMALIN-FIXED, PARAFFIN-EMBEDDED CERVICAL BIOPSIES.

138	IMP/IVD/2019/000072	1.License Holder Name: ADT INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 KIT (GENEPROOF SARS-COV-2 PCR KIT)-THE PCR KIT IS INTENDED FOR DETECTION OF SARS-COV-2 USING REVERSE TRANSCRIPTION REAL-TIME POLYMERASE CHAIN REACTION (PCR) METHOD. IT DETECTS SPECIFIC SEQUENCES OF THE VIRUS GENOME (RDRP GENE, E GENE AND N GENE) IN A SINGLE REACTION. THE MECHANISM OF MULTIPLEX TARGETING ENSURES HIGH SENSITIVITY OF SARS-COV-2 DETECTION. THE PRESENCE OF RDRP/E IS INDICATED BY THE INCREASED FLUORESCENCE IN FAM CHANNEL WHILE THE INCREASED FLUORESCENCE IN CY5 CHANNEL CONFIRMS THE PRESENCE OF N GENE.,HEPATITIS B VIRUS (HBV) PCR KIT (GENEPROOF HEPATITIS B VIRUS (HBV) PCR KIT)-THIS KIT IS DESIGNED FOR HEPATITIS B VIRUS (HBV) DETECTION BY THE REAL-TIME PCR.,COVID-19 KIT(GENEPROOF SARS-COV-2 SCREENING PCR KIT)-THE PCR KIT IS INTENDED FOR DETECTION OF SARS-COV-2, BY THE REVERSE TRANSCRIPTION REAL-TIME POLYMERASE CHAIN REACTION (PCR) METHOD. THE SARS-COV-2 DETECTION CONSISTS IN AMPLIFICATION OF SPECIFIC REGION IN RDRP GENE, E GENE AND N GENE.,HEPATITIS C VIRUS (HCV) PCR KIT(GENEPROOF HEPATITIS C VIRUS (HCV) PCR KIT)-THIS KIT IS DESIGNED FOR HEPATITIS C VIRUS (HCV) DETECTION BY THE REAL TIME PCR.,CYTOMEGALO VIRUS (CMV) PCR KIT(GENEPROOF CYTOMEGALO VIRUS (CMV) PCR KIT)-THIS KIT IS DESIGNED FOR CYTOMEGALOVIRUS DETECTION BY THE REAL TIME PCR.

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139	IMP/IVD/2019/000074	1.License Holder Name: INKARP INSTRUMENTS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASO(ICHROMA™)-ICHROMA™ ASO IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF ANTI STREPTOLYSIN O (ASO) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF SCARLET FEVER, RHEUMATIC FEVER AND POST INFECTIOUS GLOMERULONEPHRITIS ALONG WITH SEVERAL OTHER CONDITIONS.,TEST FOR CYSTATIN C(ICHROMA™ CYSTATIN C)-ICHROMA™ CYSTATIN C IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF RENAL DISEASE. FOR IN VITRO DIAGNOSTIC USE ONLY.,H. PYLORI SA(ICHROMA™)-ICHROMA™ H. PYLORI SA (H. PYLORI STOOL ANTIGEN) IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE DETERMINATION OF H. PYLORI ANTIGEN IN HUMAN FECES. IT IS USEFUL AS AN AID IN THE DIAGNOSIS OF H. PYLORI INFECTION AND TO DEMONSTRATE LOSS OF H. PYLORI ANTIGEN FOLLOWING TREATMENT.,TEST FOR MICROALBUMINURIA (ICHROMA™ MICROALBUMIN)-ICHROMA™ MICROALBUMIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF MICROALBUMIN IN HUMAN URINE. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF KIDNEY DAMAGE FROM DIABETES.,CALPROTECTIN(ICHROMA™)-ICHROMA™ CALPROTECTIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR QUANTITATIVE DETERMINATION OF CALPROTECTIN (MRP8/14; S100A8/S100A9) IN HUMAN FECES. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THE REFLEX GASTROINTESTINAL INFLAMMATION CAUSED BY SEVERAL PATHOLOGIES (INFLAMMATORY BOWEL DISEASE, COLORECTAL CANCER AND SOME ENTEROPATHIES).,TEST FOR HBA1C(ICHROMA™ HBA1C)-ICHROMA™ HBA1C IN CONJUNCTION WITH THE ICHROMA™ READER IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF HBA1C (HEMOGLOBIN A1C) IN HUMAN WHOLE BLOOD. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THE LONG-TERM GLYCEMIC STATUS IN PATIENTS WITH DIABETES MELLITUS.,CORTISOL(ICHROMA™)-ICHROMA™ CORTISOL IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF CONCENTRATION OF CORTISOL., TEST FOR HUMAN IGG AUTOANTIBODIES TO CYCLIC CITRULLINATED PEPTIDES(ICHROMA™ ANTI-CCP)-ICHROMA™ ANTI-CCP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE OR

	SEMI-QUANTITATIVE DETERMINATION OF HUMAN IGG AUTOANTIBODIES TO CYCLIC CITRULLINATED PEPTIDES (CCP) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA) IN COMBINATION WITH OTHER CLINICAL AND LABORATORY FINDINGS., RF IGM (ICHROMA™)- ICHROMA™ RF IGM IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF RF IGM IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF RHEUMATOID ARTHRITIS.,TEST FOR PROLACTIN(ICHROMA™ PRL)-ICHROMA™ PRL IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN(PRL) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF HYPOTHALAMIC-PITUITARY DISORDERS.,PROGESTERONE (ICHROMA™)-ICHROMA™ PROGESTERONE IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THE CAUSE OF INFERTILITY, TRACK OVULATION, DIAGNOSE AN ECTOPIC OR FAILING PREGNANCY, MONITOR THE HEALTH OF A PREGNANCY.,ATEST FOR CREATINE KINASE ISOENZYME-MB(ICHROMA™ CK-MB)-ICHROMA™ CK-MB IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE ISOENZYME-MB (CK-MB) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAC INFARCTION (AMI) AND ACUTE CORONARY SYNDROME (ACS). FOR IN VITRO DIAGNOSTIC USE ONLY.,TN I PLUS(ICHROMA™)-ICHROMA™ TN I PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN-I (TN-I) IN HUMAN WHOLE BLOOD/ SERUM/PLASMA ITIS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION(AMI),TEST FOR TESTOSTERONE(ICHROMA™ TESTOSTERONE)-ICHROMA™ TESTOSTERONE IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ANDROGEN LEVEL.,VITAMIN D (ICHROMA™)-ICHROMA™ VITAMIN D IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25(OH)D2/D3 LEVEL IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF REGULATING THE CONCENTRATION OF CALCIUM AND PHOSPHATE IN THE BLOODSTREAM AND PROMOTING THE HEALTHY GROWTH AND REMODELING OF BONE.,TEST FOR HIGH SENSITIVE C-REACTIVE PROTEIN(ICHROMA™ HSCRP)-ICHROMA™ HSCRP IS A

	FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CRP IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF RISK OF CARDIOVASCULAR DISEASES.,ANTI-CCP PLUS (CHROMA™)-ICHROMA™ ANTI-CCP PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE OR SEMI-QUANTITATIVE DETERMINATION OF HUMAN IGG AUTO ANTIBODIES TO CYCLIC CITRULLINATED PEPTIDES (CCP) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA) IN COMBINATION WITH OTHER CLINICAL AND LABORATORY FINDINGS.,TEST FOR FOLLICLE STIMULATING HORMONE(ICHROMA™ FSH)-ICHROMA™ FSH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE(FSH) IN HUMAN SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF CONCENTRATION OF FSH.,T3(ICHROMA™)-ICHROMA™ T3 IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (TOTAL T3) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF THYROID DISORDERS., TEST FOR CRP(ICHROMA™ CRP)-ICHROMA™ CRP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CRP IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF AUTOIMMUNE DISEASES AND INFECTIOUS PROCESSES, SUCH AS RHEUMATOID ARTHRITIS.,TOTAL IGE(ICHROMA™)-ICHROMA™ TOTAL IGE IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL IGE IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN DIAGNOSIS AND MANAGEMENT OF ALLERGIC DISEASE.,TEST FOR D-DIMER(ICHROMA™ D-DIMER)-ICHROMA™ D-DIMER IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN WHOLE BLOOD / PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF POST THERAPEUTIC EVALUATION OF THROMBOEMBOLIC DISEASE PATIENTS.,CARDIAC TRIPLE(ICHROMA™)-ICHROMA™ CARDIAC TRIPLE IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONINI (TNI), CREATINE KINASE (CKMB) AND MYOGLOBIN IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION (AMI) AND ACUTE CORONARY SYNDROME (ACS).,TEST FOR CARDIAC TROPONIN-I(ICHROMA™ TN-I)-ICHROMA™ TN-I IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF

	CARDIAC TROPONIN-I (TN-I) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION (AMI).,NT-PROBNP(ICHROMA™)-ICHROMA™ NT-PROBNP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF NT-PROBNP IN HUMAN WHOLE BLOOD/ SERUM/PLASMA. IT IS USEFUL AS AN AID IN THE DIAGNOSIS OF PERSONS SUSPECTED OF HAVING CONGESTIVE HEART FAILURE.,TEST FOR PROCALCITONIN(ICHROMA™ PCT)-ICHROMA™ PCT IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF BACTERIAL INFECTION AND SEPSIS,AMH(ICHROMA™)-ICHROMA™ AMH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF AMH (ANTI-MÜLLERIAN HORMONE) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF PREMATURE OVARIAN INSUFFICIENCY, MENOPAUSE AND OVARIAN RESERVE.,TEST FOR FERRITIN(ICHROMA™ FERRITIN)-ICHROMA™ FERRITIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN QUANTIFIES HUMAN FERRITIN,IL-6(ICHROMA™)-ICHROMA™ IL-6 IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETECTION OF IL-6 IN HUMAN WHOLE BLOOD /SERUM/PLASMA. IT IS HELPFUL AS AN AID IN MANAGEMENT AND MONITORING OF INFLAMMATORY DISEASE., TEST FOR MYOGLOBIN(ICHROMA™ MYOGLOBIN)-ICHROMA™ MYOGLOBIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION (AMI)., COVID-19 AB(ICHROMA)-ICHROMA™ COVID-19 AB IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE DETERMINATION OF IGG/IGM ANTIBODIES AGAINST 'NOVEL CORONAVIRUS' IN HUMAN WHOLE BLOOD /SERUM/ PLASMA. IT IS HELPFUL AS AN AID IN THE SCREENING OF EARLY MILD, ASYMPTOMATIC OR ACUTE PATIENTS FOR IDENTIFICATION OF 'NOVEL CORONAVIRUS (EG, SARS-COV-2)' INFECTION WITH HIGH SENSITIVITY.,TEST FOR PROCALCITONIN(ICHROMA™ PCT PLUS)-ICHROMA™ PCT PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF BACTERIAL INFECTION AND SEPSIS.,TEST FOR LUTEINIZING HORMONE(ICHROMA™ LH)-ICHROMA™ LH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE

	QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF EVALUATING FERTILITY ISSUES, FUNCTION OF REPRODUCTIVE ORGANS (OVARIES OR TESTICLES), OR DETECTION OF THE OVULATION.,TEST FOR T4 (ICHROMA™ T4)-ICHROMA™ T4 IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THYROID DISORDER. FOR IN VITRO DIAGNOSTIC USE ONLY.,TEST FOR THYROID STIMULATING HORMONE (ICHROMA™ TSH)-ICHROMA™ TSH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TSH IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF MEASUREMENT IN THE ASSESSMENT OF THYROID FUNCTION. FOR IN VITRO DIAGNOSTIC USE ONLY.,TEST FOR TOTAL BETA HUMAN CHORIONIC GONADOTROPIN (ICHROMA™ -HCG)-ICHROMA™ -HCG IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL BETA HUMAN CHORIONIC GONADOTROPIN (TOTAL -HCG) LEVEL IN HUMAN WHOLE BLOOD OR SERUM OR PLASMA.

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140	IMP/IVD/2019/000078	1.License Holder Name: TOSOH INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:G8 -THALASSEMIA ELUTION BUFFER KIT(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN F & A2 IN BLOOD SPECIMENS, GX ELUTION BUFFER NO.1 (S)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN BLOOD SPECIMENS ,GX ASSAY KIT(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN BLOOD SPECIMENS,G11 VARIANT ELUTION BUFFER NO.2 (S)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN BLOOD SPECIMENS,G11 VARIANT ELUTION BUFFER NO.3 (S)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN BLOOD SPECIMENS, HEMOGLOBIN A1C CONTROL SET(TOSOH)-FOR THE QUALITY CONTROL OF THE TOSOH AUTOMATED GLYCOHEMOGLOBIN ANALYZERS, STANDARD ANALYSIS MODE AND VARIANT ANALYSIS MODE,G11 F&A2 CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AUTOMATED GLYCOHEMOGLOBIN ANALYZER HLC-723G11 -THALASSEMIA ANALYSIS MODE,G11 -THALASSEMIA ELUTION BUFFER NO.1 (S)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN F & A2 IN BLOOD SPECIMENS,G8 VARIANT ELUTION BUFFER HSI NO.3 (S) (TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN BLOOD SPECIMENS.,G8 -THALASSEMIA DILUTING SOLUTION (S)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN F & A2 IN BLOOD SPECIMENS,G11 VARIANT ELUTION BUFFER NO.1 (S) (TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN BLOOD SPECIMENS,GX ELUTION BUFFER NO.3 (S)(TOSOH) -FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN BLOOD SPECIMENS,GX ELUTION BUFFER NO.2 (S)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN BLOOD SPECIMENS, HSI HEMOLYSIS & WASH SOLUTION (L)(TOSOH)-DESIGNED FOR USE WITH HLC-723 SERIES OF ANALYZER FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) & HEMOGLOBIN F & A2 IN BLOOD SPECIMENS,TSKGEL GX(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN BLOOD SPECIMENS,G8 HEMOGLOBIN F&A2 CALIBRATOR (TOSOH)-FOR THE CALIBRATION OF THE TOSOH AUTOMATED GLYCOHEMOGLOBIN ANALYZER HLC-723G8 -THALASSEMIA ANALYSIS MODE, HEMOGLOBIN A1C CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AUTOMATED GLYCOHEMOGLOBIN ANALYZERS ,G11 -

	THALASSEMIA ELUTION BUFFER NO.2 (S)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN F & A2 IN BLOOD SPECIMENS,G8 HEMOGLOBIN F&A2 CONTROL SET (TOSOH)-FOR THE QUALITY CONTROL OF THE TOSOH AUTOMATED GLYCOHEMOGLOBIN ANALYZER HLC-723G8 -THALASSEMIA ANALYSIS MODE,G8 VARIANT ELUTION BUFFER HSI NO.1 (S) (TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN BLOOD SPECIMENS.,TSKGEL G11 -THAL.(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN F & A2 IN BLOOD SPECIMENS,G8 VARIANT ELUTION BUFFER HSI NO.2 (S) (TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN BLOOD SPECIMENS,TSKGEL G11 VARIANT(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN BLOOD SPECIMENS,G11 F&A2 CONTROL SET (TOSOH)-FOR THE QUALITY CONTROL OF THE TOSOH AUTOMATED GLYCOHEMOGLOBIN ANALYZER HLC-723G11 -THALASSEMIA ANALYSIS MODE. ,HSI HEMOLYSIS & WASH SOLUTION (LL)(TOSOH)-DESIGNED FOR USE WITH HLC-723 SERIES OF ANALYZER FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) & HEMOGLOBIN F & A2 IN BLOOD SPECIMENS,G11 -THALASSEMIA ELUTION BUFFER NO.3 (S) (TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN F & A2 IN BLOOD SPECIMENS,TSKGEL G8 -THAL. HSI (TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN F & A2 IN BLOOD SPECIMENS,TSKGEL G8 VARIANT HSI (TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN BLOOD SPECIMENS.

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141	IMP/IVD/2019/000079	1.License Holder Name: VIVACHEK LIFECARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(VIVACHEK FAD BLOOD GLUCOSE TEST STRIP)-FOR DIAGNOSIS OF BLOOD GLUCOSE LEVEL IN HUMAN.,BLOOD GLUCOSE METER(VIVACHEK ECO)-THE VIVACHEK ECO BLOOD GLUCOSE METER IS DESIGNED TO QUANTITATIVELY MEASURE THE GLUCOSE CONCENTRATION IN FRESH CAPILLARY WHOLE BLOOD.,BLOOD GLUCOSE TEST STRIPS (VIVACHEK ECO BLOOD GLUCOSE TEST STRIPS)-FOR DIAGNOSIS OF BLOOD GLUCOSE LEVEL IN HUMAN., BLOOD GLUCOSE METER(VIVACHEK FAD)-THE VIVACHEK FAD BLOOD GLUCOSE METER IS DESIGNED TO QUANTITATIVELY MEASURE THE GLUCOSE CONCENTRATION IN FRESH WHOLE BLOOD.,BLOOD GLUCOSE TEST STRIPS (VIVACHEK INO BLOOD GLUCOSE TEST STRIPS)-FOR DIAGNOSIS OF BLOOD GLUCOSE LEVEL IN HUMAN., BLOOD GLUCOSE METER(VIVACHEK INO)-VIVACHEK LNO BLOOD GLUCOSE METER IS DESIGNED TO QUANTITATIVELY MEASURE THE GLUCOSE CONCENTRATION IN FRESH CAPILLARY WHOLE BLOOD., BLOOD GLUCOSE METER(VIVACHEK ECO PLUS)-THE VIVACHEK ECO PLUS BLOOD GLUCOSE METER IS DESIGNED TO QUANTITATIVELY MEASURE THE GLUCOSE CONCENTRATION IN FRESH CAPILLARY WHOLE BLOOD.

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142	IMP/IVD/2019/000080	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTI-C RARE ANTISERA (ANTI-C (ANTI-RH4) (MONOCLONAL) BIOCLONE®)-QUALITATIVE TEST WITH MONOCLONAL ANTIBODIES FOR RECOGNITION OF THE C¯ (RH4) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,ANTI-N RARE ANTISERA(ANTI-N (ANTI- MNS2))-QUALITATIVE TEST FOR RECOGNITION OF THE N (MNS2) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,ANTI-HUMAN GLOBULIN ANTI-LGG (RABBIT) (GREEN) ORTHO BIOVUE SYSTEM (IGG CASSETTE)(ANTI-HUMAN GLOBULIN ANTI-LGG (RABBIT) (GREEN) ORTHO® BIOVUE SYSTEM (IGG CASSETTE))-QUALITATIVE PROCEDURE FOR THE DETECTION OF IGG BOUND TO RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE ,ANTI-HUMAN GLOBULIN ANTI-LGG, -C3D; POLYSPECIFIC (RABBIT AND MURINE MONOCLONAL) (GREEN) ORTHO BIOVUE SYSTEM (POLY CASSETTE)(ANTI-HUMAN GLOBULIN ANTI-LGG, -C3D; POLYSPECIFIC (RABBIT AND MURINE MONOCLONAL) (GREEN) ORTHO BIOVUE® SYSTEM (POLY CASSETTE))-QUALITATIVE PROCEDURE FOR THE DETECTION OF IGG OR COMPLEMENT BOUND TO RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE ,ANTI-A BLOOD GROUPING REAGENT(BLOOD GROUPING REAGENT ANTI-A (ANTI-ABO1) (MURINE MONOCLONAL BLEND) BIOCLONE®)-QUALITATIVE TEST WITH BLENDED MONOCLONAL ANTIBODIES FOR RECOGNITION OF THE A (ABO1) ANTIGEN AND ITS SUBGROUPS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,ANTI-A1 LECTIN(ANTI-A1 LECTIN (ANTI-ABO4))-QUALITATIVE TEST FOR THE FURTHER CHARACTERIZATION OF SAMPLES ALREADY CLASSIFIED AS GROUP A (ABO1) OR GROUP AB (ABO3) FOR IN VITRO DIAGNOSTIC USE ,ANTI-C RARE ANTISERA (ANTI-C (ANTI- RH2) (MONOCLONAL) BIOCLONE®)-QUALITATIVE TEST WITH MONOCLONAL ANTIBODIES FOR RECOGNITION OF THE C (RH2) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,0.8% BIOVUE SCREEN(0.8% BIOVUE® SCREEN)-FOR USE WITH THE ORTHO BIOVUE® SYSTEM TO DETECT OR IDENTIFY UNEXPECTED BLOOD GROUP ANTIBODIES BY ENZYME AND NON-ENZYME METHODS FOR IN VITRO DIAGNOSTIC USE ,AFFIRMAGEN (AFFIRMAGEN®)-FOR CONFIRMATION OF ABO FORWARD (RED CELL) GROUPING IN THE ORTHO® BIOVUE SYSTEM FOR IN VITRO DIAGNOSTIC USE ,ANTI-C3B, -C3D BIOCLONE(ANTI-C3B, -C3D BIOCLONE®)-QUALITATIVE TEST FOR THE DETECTION OF A COMPONENT OF COMPLEMENT BOUND TO RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE ,ANTI-JKB RARE ANTISERA(ANTI-JKB (ANTI-JK2)(MONOCLONAL) BIOCLONE®)-QUALITATIVE TEST WITH

	MONOCLONAL ANTIBODIES FOR RECOGNITION OF THE JKB (JK2) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,ANTI-B BLOOD GROUPING REAGENT(BLOOD GROUPING REAGENT ANTI-B (ANTI-ABO2) (MURINE MONOCLONAL BLEND) BIOCLONE®)-QUALITATIVE TEST WITH BLENDED MONOCLONAL ANTIBODIES FOR RECOGNITION OF THE B (ABO2) ANTIGEN ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE, AFFIRMAGEN(AFFIRMAGEN®)-TO CONFIRM THE ABO FORWARD (RED CELL) GROUP. FOR IN VITRO DIAGNOSTIC USE ,BOVINE ALBUMIN POLYMERIZED(BOVINE ALBUMIN POLYMERIZED)-FOR QUALITATIVE USE IN ANTIBODY DETECTION, IDENTIFICATION, TITRATION AND COMPATIBILITY TESTING FOR IN VITRO DIAGNOSTIC USE ,NEUTRAL ORTHO BIOVUE SYSTEM (NEUTRAL CASSETTE)(NEUTRAL ORTHO BIOVUE® SYSTEM (NEUTRAL CASSETTE))-PRINCIPALLY FOR USE IN ANTIBODY DETECTION USING ENZYME PROCEDURES FOR IN VITRO DIAGNOSTIC USE ,ANTI-C3D BIOCLONE(ANTI-C3D BIOCLONE®)-QUALITATIVE TEST FOR THE DETECTION OF A COMPONENT OF COMPLEMENT BOUND TO RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE ,AFFIRMAGEN 4(AFFIRMAGEN® 4)-FOR CONFIRMATION OF ABO FORWARD (RED CELL) GROUPING IN THE ORTHO® BIOVUE SYSTEM FOR IN VITRO DIAGNOSTIC USE ,ELISA HCV TEST KIT(ORTHO® HCV 3.0 ELISA TEST SYSTEM WITH ENHANCED SAVE)-ORTHO® HCV 3.0 ELISA TEST SYSTEM WITH ENHANCED SAVE IS A QUALITATIVE, ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE DETECTION OF ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE,ANTI-IGG, -C3D; POLYSPECIFIC BIOCLONE (CLEAR)(ANTI-IGG, -C3D; POLYSPECIFIC BIOCLONE® (CLEAR))-QUALITATIVE TEST FOR THE DETECTION OF IGG OR COMPLEMENT BOUND TO RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,SURGISCREEN(SURGISCREEN®)-QUALITATIVE TEST TO DETECT UNEXPECTED BLOOD GROUP ANTIBODIES FOR IN VITRO DIAGNOSTIC USE ,ANTI-S RARE ANTISERA (ANTI-S (ANTI- MNS3))-QUALITATIVE TEST FOR RECOGNITION OF THE S (MNS3) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,SELECTOGEN(SELECTOGEN®)-QUALITATIVE TEST TO DETECT UNEXPECTED BLOOD GROUP ANTIBODIES FOR IN VITRO DIAGNOSTIC USE ,ANTI-LEB RARE ANTISERA(ANTI-LEB(ANTI-LE2) BIOCLONE® 2.0)-QUALITATIVE TEST WITH MONOCLONAL ANTIBODIES FOR RECOGNITION OF THE LEB (LE2) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,ANTI-FYA RARE ANTISERA(ANTI-FYA (ANTI- FY1))-QUALITATIVE TEST FOR RECOGNITION OF THE FYA (FY1) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,ANTI-JKA RARE ANTISERA (ANTI-JKA (ANTI-JK1)(MONOCLONAL) BIOCLONE®)-QUALITATIVE

	TEST WITH MONOCLONAL ANTIBODIES FOR RECOGNITION OF THE JKA (JK1) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,ORTHO RH-HR CONTROL(ORTHO® RH-HR CONTROL)-CONTROL REAGENT FOR ANTI-D (RH1) FOR SLIDE AND MODIFIED TUBE TESTS FOR IN VITRO DIAGNOSTIC USE ,0.8% ORTHO RED CELL DILUENT(0.8% ORTHO® RED CELL DILUENT)-TO BE USED IN THE ORTHO BIOVUE® SYSTEM FOR THE PREPARATION OF 0.8% RED CELL SUSPENSIONS FOR IN VITRO DIAGNOSTIC USE ,ANTI-LEA RARE ANTISERA(ANTI-LEA(ANTI-LE1) BIOCLONE® 2.0)-QUALITATIVE TEST WITH MONOCLONAL ANTIBODIES FOR RECOGNITION OF THE LEA (LE1) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,ANTI-FYB RARE ANTISERA(ANTI-FYB (ANTI-FY2))-QUALITATIVE TEST FOR RECOGNITION OF THE FYB (FY2) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE, ORTHO ANTIBODY ENHANCEMENT SOLUTION(ORTHO® ANTIBODY ENHANCEMENT SOLUTION)-LOW IONIC STRENGTH SOLUTION (LISS) FOR USE IN ANTIBODY DETECTION, IDENTIFICATION AND COMPATIBILITY TESTING. FOR IN VITRO DIAGNOSTIC USE,BOVINE ALBUMIN 22%(BOVINE ALBUMIN 22%)-FOR QUALITATIVE USE IN ANTIBODY DETECTION, IDENTIFICATION, TITRATION AND COMPATIBILITY TESTING FOR IN VITRO DIAGNOSTIC USE , AFFIRMAGEN 4(AFFIRMAGEN® 4)-TO CONFIRM THE ABO FORWARD (RED CELL) GROUP FOR IN VITRO DIAGNOSTIC USE ,0.8% SURGISCREEN(0.8% SURGISCREEN®)-FOR USE WITH THE ORTHO BIOVUE® SYSTEM TO DETECT OR IDENTIFY UNEXPECTED BLOOD GROUP ANTIBODIES FOR IN VITRO DIAGNOSTIC USE ,ANTI-IGG, -C3D; POLYSPECIFIC BIOCLONE (GREEN)(ANTI-IGG, -C3D; POLYSPECIFIC BIOCLONE® (GREEN))-QUALITATIVE TEST FOR THE DETECTION OF IGG OR COMPLEMENT BOUND TO RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE ,ANTI-IGG(ANTI-IGG)-QUALITATIVE TEST FOR THE DETECTION OF IGG BOUND TO RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE ,0.8% RESOLVE PANEL A(0.8% RESOLVE® PANEL A)-FOR USE WITH THE ORTHO BIOVUE® SYSTEM TO DETECT OR IDENTIFY UNEXPECTED BLOOD GROUP ANTIBODIES FOR IN VITRO DIAGNOSTIC USE,RESOLVE PANEL C(RESOLVE® PANEL C UNTREATED - RESOLVE® PANEL C FICIN TREATED)-QUALITATIVE TEST FOR THE IDENTIFICATION OF UNEXPECTED BLOOD GROUP ANTIBODIES; MAY BE USED IN PARALLEL WITH RESOLVE PANEL C FICIN TREATED. FOR IN VITRO DIAGNOSTIC USE,RESOLVE PANEL B (RESOLVE® PANEL B)-QUALITATIVE TEST TO DETECT AND/OR IDENTIFY UNEXPECTED BLOOD GROUP ANTIBODIES FOR IN VITRO DIAGNOSTIC USE,RESOLVE PANEL A(RESOLVE® PANEL A)-QUALITATIVE TEST TO DETECT AND/OR IDENTIFY UNEXPECTED BLOOD GROUP ANTIBODIES FOR IN VITRO DIAGNOSTIC USE,

	BLOODGROUPINGREAGENTSANTI-D(ANTI-RH1)(MONOCLONAL)ANTI-C(ANTI-RH2)(MONOCLONAL)ANTI-E(ANTI-RH3)(MONOCLONAL)ANTI-C(ANTI-RH4)(MONOCLONAL)ANTI-E(ANTI-RH5)(MONOCLONAL) CONTROLORTHOBIOVUESYSTEM(RH/HRCASSETTE)(BLOOD GROUPING REAGENTS ANTI-D (ANTI-RH1) (MONOCLONAL) ANTI-C (ANTI-RH2) (MONOCLONAL) ANTI-E (ANTI-RH3) (MONOCLONAL) ANTI-C– (ANTI-RH4) (MONOCLONAL) ANTI-E (ANTI-RH5) (MONOCLONAL) CONTROL ORTHO BIOVUE® SYSTEM (RH/HR CASSETTE))-QUALITATIVE TEST FOR RECOGNITION OF THE D (RH1), C (RH2), E (RH3), C¯ (RH4) AND E (RH5) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,BLOOD GROUPING REAGENTS ANTI-C (ANTI-RH2) (MONOCLONAL) ANTI-E(ANTI-RH3) (MONOCLONAL)ANTI-C(ANTI-RH4)(MONOCLONAL)ANTI-E(ANTI-RH5) (MONOCLONAL)ANTI-K(ANTI-K1)(MONOCLONAL)ORTHO BIOVUE SYSTEM(RH/KCASSETTE)(BLOOD GROUPING REAGENTS ANTI-C (ANTI-RH2) (MONOCLONAL) ANTI-E (ANTI-RH3) (MONOCLONAL) ANTI-C– (ANTI-RH4) (MONOCLONAL) ANTI-E (ANTI-RH5) (MONOCLONAL) ANTI-K (ANTI-K1) (MONOCLONAL) CONTROL ORTHO BIOVUE® SYSTEM (RH/K CASSETTE))-QUALITATIVE TEST FOR RECOGNITION OF THE C (RH2), E (RH3), C– (RH4), E (RH5) AND K (K1) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,BLOOD GROUPING REAGENTS ANTI-A (MONOCLONAL) ANTI-B (MONOCLONAL) ANTI-A,B ANTI-D (ANTI-D RH1)(MONOCLONAL) CONTROL ANTI-HUMAN GLOBULIN ANTI-IGG (RABBIT) (GREEN) ORTHO BIOVUE SYSTEM (NEWBORN CASSETTE)(BLOOD GROUPING REAGENTS ANTI-A (ANTI-ABO1) (MONOCLONAL) ANTI-B (ANTI-ABO2) (MONOCLONAL) ANTI-A,B (ANTI-ABO3) (MONOCLONAL) ANTI-D (ANTI-RH1) (MONOCLONAL) CONTROL ANTI-HUMAN GLOBULIN ANTI-IGG (RABBIT) (GREEN) ORTHO BIOVUE® SYSTEM (NEWBORN CASSETTE))-QUALITATIVE TEST FOR RECOGNITION OF THE A (ABO1), B (ABO2) AND D (RH1) ANTIGENS ON HUMAN RED BLOOD CELLS AND FOR THE DETECTION OF CELL-BOUND IGG ANTIBODY IN NEWBORNS FOR IN VITRO DIAGNOSTIC USE,BLOOD GROUPING REAGENTS ANTI-A (MONOCLONAL) ANTI-B (MONOCLONAL) ANTI-A,B (MONOCLONAL) ANTI-D ANTI-DRH1)(MONOCLONAL)ANTI-D (ANTI-D RH1) (MONOCLONAL)CONTROL ORTHO BIOVUE SYSTEM(ABO-DD GROUPING CASSETTES)(BLOOD GROUPING REAGENTS ANTI-A (ANTI-ABO1) (MONOCLONAL) ANTI-B (ANTI-ABO2) (MONOCLONAL) ANTI-A, B (ANTI-ABO3) (MONOCLONAL) ANTI-D (ANTI-RH1) (MONOCLONAL) ANTI-D (ANTI-RH1) (MONOCLONAL) CONTROL ORTHO BIOVUE® SYSTEM (ABO-DD GROUPING CASSETTE))-QUALITATIVE TEST FOR RECOGNITION OF THE A (ABO1), B (ABO2), AND D (RH1) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,BLOOD GROUPING REAGENTS ANTI-A (MONOCLONAL) ANTI-B

	(MONOCLONAL) ANTI-D (ANTI-D RH1)(MONOCLONAL) ORTHO BIOVUE® SYSTEM (ABD CONFIRMATION CASSETTE)(BLOOD GROUPING REAGENTS ANTI-A (ANTI-ABO1) (MONOCLONAL) ANTI-B (ANTI-ABO2) (MONOCLONAL) ANTI-D (ANTI-RH1) (MONOCLONAL) ORTHO BIOVUE® SYSTEM (ABD CONFIRMATION CASSETTE))-QUALITATIVE TEST FOR CONFIRMATION OF THE A (ABO1), B (ABO2) AND D (RH1) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,REAGENT RED BLOOD CELLS 0.8% AFFIRMAGEN 4 (REAGENT RED BLOOD CELLS 0.8% AFFIRMAGEN® 4)-FOR USE WITH ORTHO BIOVUE® SYSTEM TO CONFIRM THE ABO FORWARD (RED CELL) GROUP FOR IN VITRO DIAGNOSTIC USE,REAGENT RED BLOOD CELLS 0.8% AFFIRMAGEN 3(REAGENT RED BLOOD CELLS 0.8% AFFIRMAGEN® 3)-FOR USE WITH ORTHO BIOVUE® SYSTEM TO CONFIRM THE ABO FORWARD (RED CELL) GROUP FOR IN VITRO DIAGNOSTIC USE,ORTHO COOMBS CONTROL(ORTHO® COOMBS CONTROL)-QUALITATIVE TEST TO CONFIRM THE VALIDITY OF NEGATIVE ANTIGLOBULIN TESTS FOR IN VITRO DIAGNOSTIC USE , REAGENT RED BLOOD CELLS 0.8% AFFIRMAGEN(REAGENT RED BLOOD CELLS 0.8% AFFIRMAGEN®)-FOR USE WITH ORTHO BIOVUE® SYSTEM TO CONFIRM THE ABO FORWARD (RED CELL) GROUP FOR IN VITRO DIAGNOSTIC USE,0.8% RESOLVE PANEL C SYSTEM(0.8% RESOLVE® PANEL C SYSTEM)-FOR USE WITH THE ORTHO BIOVUE® SYSTEM TO DETECT OR IDENTIFY UNEXPECTED BLOOD GROUP ANTIBODIES BY ENZYME AND NON-ENZYME METHODS FOR IN VITRO DIAGNOSTIC USE ,SELECTOGEN(SELECTOGEN®)-QUALITATIVE TEST TO DETECT AND/OR IDENTIFY UNEXPECTED BLOOD GROUP ANTIBODIES FOR IN VITRO DIAGNOSTIC USE ,0.8% RESOLVE PANEL B (0.8% RESOLVE® PANEL B)-FOR USE WITH THE ORTHO BIOVUE® SYSTEM TO DETECT OR IDENTIFY UNEXPECTED BLOOD GROUP ANTIBODIES FOR IN VITRO DIAGNOSTIC USE,BLOOD GROUPING REAGENT, ANTI-D (RH-1)(ANTI-D (ANTI-RH-1) BIOCLONE®)-QUALITATIVE TEST WITH MONOCLONAL-POLYCLONAL ANTIBODIES FOR RECOGNITION OF THE D (RH1) ANTIGEN ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,0.8% SELECTOGEN(0.8% SELECTOGEN®)-FOR USE WITH THE ORTHO BIOVUE® SYSTEM TO DETECT OR IDENTIFY UNEXPECTED BLOOD GROUP ANTIBODIES FOR IN VITRO DIAGNOSTIC USE,ANTI-HUMAN GLOBULIN ANTI-LGG (RABBIT) ANTI-HUMAN GLOBULIN ANTI-C3B, -C3D CONTROL ORTHO BIOVUE SYSTEM (DAT/IDAT CASSETTES)(ANTI-HUMAN GLOBULIN ANTI-LGG (RABBIT) ANTI-HUMAN GLOBULIN ANTI-C3B, -C3D (MONOCLONAL) CONTROL ORTHO BIOVUE® SYSTEM (DAT/IDAT CASSETTES))-QUALITATIVE PROCEDURE FOR THE DETECTION OF IGG OR COMPLEMENT BOUND TO RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE ,ANTI-HUMAN GLOBULIN ANTI-LGG, -C3D;

	POLYSPECIFIC (RABBIT AND MURINE MONOCLONAL) (GREEN) NEUTRAL SOLUTION ORTHO BIOVUE SYSTEM (POLY/NEUTRAL CASSETTE)(ANTI-HUMAN GLOBULIN ANTI-LGG, -C3D; POLYSPECIFIC (RABBIT AND MURINE MONOCLONAL) (GREEN) NEUTRAL SOLUTION ORTHO BIOVUE® SYSTEM (POLY/NEUTRAL CASSETTE))-QUALITATIVE PROCEDURE FOR THE DETECTION OF UNEXPECTED BLOOD GROUP ANTIBODIES BY ENZYME AND NON-ENZYME PROCEDURES FOR IN VITRO DIAGNOSTIC USE ,ANTI-S RARE ANTISERA(ANTI-S (ANTI- MNS4))-QUALITATIVE TEST FOR RECOGNITION OF THE S^{-} (MNS4) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,BLOOD GROUPING REAGENTS ANTI-A (MONOCLONAL) ANTI-B (MONOCLONAL) ANTI-D (ANTI-D RH1) (MONOCLONAL) CONTROL REVERSE DILUENT ORTHO BIOVUE SYSTEM (ABO-RH REVERSE GROUPING CASSETTE)(BLOOD GROUPING REAGENTS ANTI-A (ANTI-ABO1) (MONOCLONAL) ANTI-B (ANTI-ABO2) (MONOCLONAL) ANTI-D (ANTI-RH1)(MONOCLONAL) CONTROL REVERSE DILUENT ORTHO BIOVUE® SYSTEM (ABO-RH REVERSE GROUPING CASSETTE))-QUALITATIVE TEST FOR DETERMINATION OF THE ABO BLOOD GROUP AND D (RH1) ANTIGENS ON HUMAN RED BLOOD CELLS AND FOR DETERMINATION OF EXPECTED BLOOD GROUP ANTIBODIES FOR IN VITRO DIAGNOSTIC USE,REVERSE DILUENT ORTHO BIOVUE SYSTEM (REVERSE DILUENT CASSETTE)(REVERSE DILUENT ORTHO BIOVUE® SYSTEM (REVERSE DILUENT CASSETTE))-PRINCIPALLY FOR USE IN THE DETERMINATION OF EXPECTED ABO BLOOD GROUP ANTIBODIES AND ANTIBODY SCREEN PROCEDURES FOR DIRECT AGGLUTINATION FOR IN VITRO DIAGNOSTIC USE ,SURGISCREEN(SURGISCREEN®)-QUALITATIVE TEST TO DETECT AND/OR IDENTIFY UNEXPECTED BLOOD GROUP ANTIBODIES FOR IN VITRO DIAGNOSTIC USE ,ANTI-E RARE ANTISERA (ANTI-E (ANTI-RH3) (MONOCLONAL) BIOCLONE®)-QUALITATIVE TEST WITH MONOCLONAL ANTIBODIES FOR RECOGNITION OF THE E (RH3) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,ANTI-D BLOOD GROUPING REAGENT(ANTI-D (ANTI-RH1))-QUALITATIVE TEST FOR RECOGNITION OF THE D (RH1) ANTIGEN ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,ANTI-K RARE ANTISERA(ANTI-CELLANO (ANTI-KEL2))-QUALITATIVE TEST FOR RECOGNITION OF THE K^{-} (KEL2) ANTIGEN ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,ORTHO A2 CELLS (ORTHO® A2 CELLS)-FOR CONFIRMATION OF THE PRESENCE OF ANTI-A AND IDENTIFICATION OF ANTI-A1 FOR IN VITRO DIAGNOSTIC USE ,ANTI-A,B BLOOD GROUPING REAGENT(BLOOD GROUPING REAGENT ANTI-A,B (ANTI-ABO3) (MURINE MONOCLONAL BLEND) BIOCLONE®)-QUALITATIVE TEST WITH BLENDED MONOCLONAL ANTIBODIES FOR RECOGNITION OF THE A (ABO1) ANTIGEN AND ITS

	SUBGROUPS AND/OR THE B (ABO2) ANTIGEN ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE,ANTI-M RARE ANTISERA(ANTI-M (ANTI- MNS1))-QUALITATIVE TEST FOR RECOGNITION OF THE M (MNS1) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE

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143	IMP/IVD/2019/000082	1.License Holder Name: CEPHEID INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:XPERT MTB/XDR(XPERT MTB/XDR)-THE XPERT MTB/XDR ASSAY, PERFORMED ON THE GENEXPERT INSTRUMENT SYSTEMS, IS A NESTED REAL-TIME POLYMERASE CHAIN REACTION (PCR) IN VITRO DIAGNOSTIC TEST FOR THE DETECTION OF EXTENSIVELY DRUG RESISTANT (XDR) MYCOBACTERIUM TUBERCULOSIS (MTB) COMPLEX DNA IN UNPROCESSED SPUTUM SAMPLES OR CONCENTRATED SEDIMENTS PREPARED FROM SPUTUM. IN SPECIMENS WHERE MTB IS DETECTED, THE XPERT MTB/XDR ASSAY CAN ALSO DETECT ISONIAZID (INH) RESISTANCE ASSOCIATED MUTATIONS IN THE KATG AND FABG1 GENES, OXYRAHPC INTERGENIC REGION AND INHA PROMOTER; ETHIONAMIDE (ETH) RESISTANCE ASSOCIATED WITH INHA PROMOTER MUTATIONS ONLY; FLUOROQUINOLONE (FLQ) RESISTANCE ASSOCIATED MUTATIONS IN THE GYRA AND GYRB QUINOLONE RESISTANCE DETERMINING REGIONS (QRDR); AND SECOND LINE INJECTABLE DRUG (SLID) ASSOCIATED MUTATIONS IN THE RRS GENE AND THE EIS PROMOTER REGION. THE XPERT MTB/XDR ASSAY IS INTENDED FOR USE AS A REFLEX TEST FOR A SPECIMEN (UNPROCESSED SPUTUM OR CONCENTRATED SPUTUM SEDIMENTS) THAT IS DETERMINED TO BE MTB POSITIVE. THIS TEST IS INTENDED AS AN AID IN THE DIAGNOSIS OF XDR TUBERCULOSIS (TB) WHEN USED IN CONJUNCTION WITH CLINICAL AND OTHER LABORATORY FINDINGS..,XPERT MTB/RIF ULTRA(XPERT MTB/RIF ULTRA)-THE XPERT MTB/RIF ULTRA ASSAY, PERFORMED ON THE GENEXPERT INSTRUMENT SYSTEMS, IS A SEMI-QUANTITATIVE, NESTED REAL-TIME POLYMERASE CHAIN REACTION (PCR) IN VITRO DIAGNOSTIC TEST FOR THE DETECTION OF MYCOBACTERIUM TUBERCULOSIS (MTB) COMPLEX DNA IN UNPROCESSED SPUTUM SAMPLES OR CONCENTRATED SEDIMENTS PREPARED FROM INDUCED OR EXPECTORATED SPUTUM. IN SPECIMENS WHERE MYCOBACTERIUM TUBERCULOSIS COMPLEX IS DETECTED, THE XPERT MTB/RIF ULTRA ASSAY CAN ALSO DETECT RIFAMPIN-RESISTANCE ASSOCIATED MUTATIONS OF THE RPOB GENE. THE XPERT MTB/RIF ULTRA ASSAY IS INTENDED FOR USE WITH SPECIMENS FROM PATIENTS FOR WHOM THERE IS CLINICAL SUSPICION OF TUBERCULOSIS (TB) AND WHO HAVE RECEIVED NO ANTITUBERCULOSIS THERAPY, OR LESS THAN 3 DAYS OF THERAPY IN THE LAST 6 MONTHS. THIS TEST IS INTENDED AS AN AID IN THE DIAGNOSIS OF PULMONARY TUBERCULOSIS WHEN USED IN CONJUNCTION WITH CLINICAL AND OTHER LABORATORY FINDINGS., XPERT SA NASAL COMPLETE(XPERT SA NASAL COMPLETE)-THE CEPHEID XPERT SA NASAL COMPLETE ASSAY PERFORMED IN THE

	GENEXPERT® DX SYSTEM IS A QUALITATIVE IN VITRO DIAGNOSTIC TEST DESIGNED FOR RAPID AND SIMULTANEOUS DETECTION OF STAPHYLOCOCCUS AUREUS (SA) AND METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) FROM NASAL SWABS IN PATIENTS AT RISK FOR NASAL COLONIZATION, INCLUDING PRE-SURGICAL PATIENTS. THE TEST UTILIZES AUTOMATED REAL-TIME POLYMERASE CHAIN REACTION (PCR) TO DETECT MRSA/SA DNA. THE XPERT SA NASAL COMPLETE ASSAY IS INTENDED TO AID IN THE PREVENTION AND CONTROL OF MRSA/SA INFECTIONS IN HEALTHCARE SETTINGS. THE XPERT SA NASAL COMPLETE ASSAY IS NOT INTENDED TO GUIDE OR MONITOR TREATMENT FOR MRSA/SA INFECTIONS. CONCOMITANT CULTURES ARE NECESSARY ONLY TO RECOVER ORGANISMS FOR EPIDEMIOLOGICAL TYPING OR FOR FURTHER SUSCEPTIBILITY TESTING.,XPERT MTB/RIF(XPERT MTB/RIF) -THE XPERT MTB/RIF ASSAY FOR USE WITH THE CEPHEID GENEXPERT® SYSTEM IS A SEMI-QUANTITATIVE, NESTED REAL-TIME PCR IN-VITRO DIAGNOSTIC TEST FOR THE DETECTION OF: • MYCOBACTERIUM TUBERCULOSIS COMPLEX DNA IN SPUTUM SAMPLES OR CONCENTRATED SEDIMENTS PREPARED FROM INDUCED OR EXPECTORATED SPUTA THAT ARE EITHER ACID-FAST BACILLI (AFB) SMEAR POSITIVE OR NEGATIVE • RIFAMPIN-RESISTANCE ASSOCIATED MUTATIONS OF THE RPOB GENE IN SAMPLES FROM PATIENTS AT RISK FOR RIFAMPIN RESISTANCE THE XPERT MTB/RIF ASSAY IS INTENDED FOR USE WITH SPECIMENS FROM UNTREATED PATIENTS FOR WHOM THERE IS CLINICAL SUSPICION OF TUBERCULOSIS (TB). USE OF THE XPERT MTB/RIF ASSAY FOR THE DETECTION OF M. TUBERCULOSIS (MTB) OR DETERMINATION OF RIFAMPIN SUSCEPTIBILITY HAS NOT BEEN VALIDATED FOR PATIENTS WHO ARE RECEIVING TREATMENT FOR TUBERCULOSIS.,XPERT CT/NG (XPERT CT/NG)-THE XPERT CT/NG ASSAY, PERFORMED ON THE GENEXPERT® INSTRUMENT SYSTEMS, IS A QUALITATIVE IN VITRO REAL-TIME PCR TEST FOR THE AUTOMATED DETECTION AND DIFFERENTIATION OF GENOMIC DNA FROM CHLAMYDIA TRACHOMATIS (CT) AND/OR NEISSERIA GONORRHOEAE (NG) TO AID IN THE DIAGNOSIS OF CHLAMYDIAL AND GONORRHEAL UROGENITAL DISEASE. THE ASSAY MAY BE USED TO TEST THE FOLLOWING SPECIMENS FROM ASYMPTOMATIC AND SYMPTOMATIC INDIVIDUALS: FEMALE AND MALE URINE, ENDOCERVICAL SWAB, AND PATIENT-COLLECTED VAGINAL SWAB (COLLECTED IN A CLINICAL SETTING).

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144	IMP/IVD/2019/000083	1.License Holder Name: IDEXX LABORATORIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CANINE ANGIOSTRONGYLUS VASORUM ANTIGEN TEST KIT(IDEXX ANGIO DETECT)-IN VITRO DIAGNOSTIC FOR THE DETECTION OF ANGIOSTRONGYLUSVASORUM ANTIGEN IN CANINE SERUM OR PLASMA.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

145	IMP/IVD/2019/000084	1.License Holder Name: BIOMERIEUX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EBV R-GENE REAL TIME DETECTION AND QUANTIFICATION KIT(EBV R-GENE REAL TIME DETECTION AND QUANTIFICATION KIT)-THE EBV R-GENE KIT IS USED TO DETECT AND/OR MEASURE THE EBV VIRAL LOAD IN WHOLE BLOOD AND VARIOUS OTHER SAMPLES. THE VIRAL LOAD REPRESENTS THE NUMBER OF VIRIONS AND/OR THE NUMBER OF EBV-INFECTED B LYMPHOCYTES IN THE REPLICATION PHASE. THIS KIT CANNOT BE USED FOR SCREENING DONORS.,SARS-COV-2 RESPI R-GENE(SARS-COV-2 RESPI R-GENE)-THE SARSCOV2 RESPI RGENE® KIT ALLOWS A QUALITATIVE DETECTION AND DIFFERENTIATION OF SARSCOV2, INFLUENZA A (IA), INFLUENZA B (IB), RESPIRATORY SYNCYTIAL VIRUS (RSV) AND HUMAN METAPNEUMOVIRUS (HMPV) USING THE REAL TIME PCR TECHNOLOGY AFTER EXTRACTION OF THE VIRAL RNA IN NASOPHARYNGEAL SWABS. A CELLULAR CONTROL (CC) INCLUDED IN THE KIT EVALUATES THE QUALITY OF SAMPLE COLLECTION BY VALIDATING THE PRESENCE OF CELLS.,ADENOVIRUS R-GENE QUANTIFICATION & DETECTION KIT(ADENOVIRUS R-GENE QUANTIFICATION & DETECTION KIT)-THE ADENOVIRUS R-GENE® KIT ENABLES THE DETECTION AND/OR QUANTIFICATION OF THE GENOME OF ALL ADENOVIRUS SEROTYPES IN WHOLE BLOOD, PLASMA, CSF, BIOPSIES, STOOL, BRONCHOALVEOLAR LAVAGE FLUID (BAL), NASAL ASPIRATES, SWAB SAMPLES AND OCULAR SAMPLES., SARS-COV-2 R-GENE(SARS-COV-2 R-GENE)-FOR THE DETECTION OF NCOV-2019, OR COVID-19 OR SARS-COV-2,RSV/HMPV R-GENE (RSV/HMPV R-GENE)-RSV/HMPV R-GENE® ALLOWS A RAPID DETECTION OF RSV AND HMPV VIRUSES USING THE 5'NUCLEASE TECHNIQUE.,BORDETELLA PARAPERTUSSIS R-GENE(BORDETELLA PARAPERTUSSIS R-GENE)-THE BORDETELLA PARAPERTUSSIS R-GENE® KIT ENABLES RAPID DETECTION OF BORDETELLA PARAPERTUSSIS USING 5' NUCLEASE TECHNIQUE, A REAL TIME ANALYSIS TECHNOLOGY.,HCOV/HPIV R-GENE(HCOV/HPIV R-GENE)-HCOV/HPIV R-GENE® ALLOWS A RAPID DETECTION OF HUMAN CORONAVIRUS AND HUMAN PARAINFLUENZA VIRUS USING THE 5' NUCLEASE TECHNIQUE, A REAL TIME PCR ANALYSIS TECHNOLOGY., ENTEROVIRUS R-GENE REAL TIME-PCR DETECTION KIT (ENTEROVIRUS R-GENE REAL TIME-PCR DETECTION KIT)-THE ENTEROVIRUS R-GENE KIT RAPIDLY DETECTS THE ENTEROVIRUS GENOME USING THE REAL-TIME PCR TECHNIQUE ON CSF, RESPIRATORY SAMPLES (THROAT SWABS AND NASOPHARYNGEAL SECRETIONS), STOOL AND CELL CULTURES.,RHINO&EV/CC R-GENE (RHINO&EV/CC R-GENE)-RHINO&EV/CC R-GENE® ALLOWS A RAPID

	DETECTION OF ENTEROVIRUS AND RHINOVIRUS USING THE 5' NUCLEASE TECHNIQUE, A REAL TIME ANALYSIS TECHNOLOGY., PARVOVIRUS B19 R-GENE REAL-TIME DETECTION AND QUANTIFICATION KIT(PARVOVIRUS B19 R-GENE REAL-TIME DETECTION AND QUANTIFICATION KIT)-PARVOVIRUS B19 R-GENE® KIT IS USED TO DETECT AND/OR QUANTIFY THE GENOME OF PARVOVIRUS B19 GENOTYPES IN WHOLE BLOOD, BLOOD PLASMA, SERUM, WHOLE BONE MARROW AND MEDULLARY PLASMA, PARECHOVIRUS R-GENE(PARECHOVIRUS R-GENE)-THE PARECHOVIRUS R-GENE® KIT ENABLES THE RAPID AND QUALITATIVE DETECTION OF THE HUMAN PARECHOVIRUS (HPEV) IN SAMPLES OF CEREBROSPINAL FLUID (CSF) (HPEV) USING 5' NUCLEASE REAL-TIME ASSAY TECHNOLOGY.,LEGIO/PNEUMO CC R-GENE(LEGIO/PNEUMO CC R-GENE)-THE LEGIO PNEUMO/CC R-GENE® KIT ALLOWS THE QUALITATIVE DETECTION OF LEGIONELLA PNEUMOPHILA SEROGROUPS 1 TO 15 IN RESPIRATORY SAMPLES (BAL, SPUTUM, TRACHEOBRONCHIAL ASPIRATE FLUID),INFLUENZA A (M) GROUP & H1N1 2009 R-GENE(INFLUENZA A (M) GROUP & H1N1 2009 R-GENE)-THE KIT INFLUENZA A(M) GROUP & H1N1 2009 R-GENE ALLOWS RAPID DETECTION OF THE SEASONAL INFLUENZA A VIRUSES AND INFLUENZA A VIRUSES AND INFLUENZA A/H1N1 2009., BORDETELLA R-GENE REAL-TIME PCR KIT(BORDETELLA R-GENE REAL-TIME PCR KIT)-THE BORDETELLA R-GENE® KIT ENABLES RAPID DETECTION OF BORDETELLA BACTERIA CONTAINING IS481 SEQUENCE VIA PCR ON RESPIRATORY TISSUE SAMPLES (NASOPHARYNGEAL ASPIRATIONS OR EXPECTORATIONS), INFLUENZA A/B R-GENE(INFLUENZA A/B R-GENE)-INFLUENZA A/B R-GENE ALLOWS A RAPID DETECTION OF VIRUSES INFLUENZA A AND B USING THE 5' NUCLEASE TECHNIQUE A REAL TIME ANALYSIS TECHNOLOGY.,BK VIRUS R-GENE REAL TIME DETECTION AND QUANTIFICATION KIT(BK VIRUS R-GENE REAL TIME DETECTION AND QUANTIFICATION KIT)-BK VIRUS R-GENE DETECTS AND/OR QUANTIFIES THE VIRAL LOAD OF BK VIRUS IN WHOLE BLOOD, PLASMA AND URINE SAMPLES. THE VIRAL LOAD IS MEASURED USING A QUANTIFICATION STANDARD PROVIDED IN THE KIT. THE TECHNIQUE USED IS REAL-TIME PCR AFTER VIRAL DNA EXTRACTION., CHLA/MYCO PNEUMO R-GENE(CHLA/MYCO PNEUMO R-GENE)-CHLA/MYCO PNEUMO R-GENE® ALLOWS FOR THE RAPID DETECTION OF CHLAMYDIA PNEUMONIAE AND MYCOPLASMA PNEUMONIAE VIA THE 5'NUCLEASE TECHNIQUE, A REAL TIME ANALYSIS TECHNOLOGY., CMV R-GENE-REAL TIME DETECTION AND QUANTIFICATION KIT(CMV R-GENE-REAL TIME DETECTION AND QUANTIFICATION KIT)-THE CMV R-GENE KIT, USING THE REAL TIME PCR TECHNOLOGY AFTER EXTRACTION OF THE VIRAL DNA, ENABLES TO DETECT AND/OR

		MEASURE OF THE GENOME OF CMV IN WHOLE, BLOOD, PLASMA, SERUM, CSF, BAL, AMNIOTIC FLUID AND URINE SAMPLES,ADV/HBOV R-GENE(ADV/HBOV R-GENE)-ADV/HBOV R-GENE® ALLOWS FOR THE RAPID DETECTION OF ALL SPECIES OF ADENOVIRUS (A,B,C,D,E,F,G) AND PARTICULARLY SEROTYPES FROM 1 TO 52, AS WELL AS THE 4 SPECIES OF BOCAVIRUS VIA THE 5' NUCLEASE TECHNIQUE, A REAL TIME PCR ANALYSIS TECHNOLOGY.,CELL CONTROL R-GENE(CELL CONTROL R-GENE)-CELL CONTROL R-GENE® MAKES IT POSSIBLE TO VALIDATE THE RESULTS OBTAINED AFTER REAL TIME PCR AMPLIFICATION BY VERIFYING THE PRESENCE OF CELLS IN THE EXTRACTED SAMPLE.
146	IMP/IVD/2019/000085	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD MGIT TBC IDENTIFICATION TEST (TBC ID)(BD MGIT TBC IDENTIFICATION TEST (TBC ID))-THE BD MGIT™ TBC IDENTIFICATION TEST (TBC ID) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF MYCOBACTERIUM TUBERCULOSIS COMPLEX (MTBC) ANTIGEN FROM AFB SMEAR-POSITIVE BD MGIT TUBES. THE DEVICE WILL DETECT THE FOLLOWING SPECIES OF THE MTBC: M. TUBERCULOSIS, M. BOVIS, M. AFRICANUM, AND M. MICROTI.

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147	IMP/IVD/2019/000086	1.License Holder Name: M/S. CPC DIAGNOSTICS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 IGG(IFLASH) -THE IFLASH-SARS-COV-2 IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR QUALITATIVE DETERMINATION OF IGG ANTIBODY TO SARS-COV-2 IN HUMAN SERUM OR PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER. THE IFLASH-SARS-COV-2 IGG AIDS IN THE DIAGNOSIS OF SARS-COV-2 INFECTION AND THE DETERMINATION OF IMMUNITY.,IFLASH – LAMININ KIT(IFLASH)-"THE IFLASH-LAMININ ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF LAMININ IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH – FT3 KIT(IFLASH)-"THE IFLASH-FT3 ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH – 25-OH VITAMIN D KIT(IFLASH)-"THE IFLASH-25OH VITAMIN D ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF 25OH VITAMIN D IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH – T3 KIT(IFLASH)-"THE IFLASH-T3 ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE (T3) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH – FT4 KIT(IFLASH)-"THE IFLASH-FT4 ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH – INSULIN KIT(IFLASH)-"THE IFLASH-INSULIN ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH – TRIGGER SOLUTION(1×)(IFLASH)-FOR USE IN THE IFLASH IMMUNOASSAY ANALYZER TO PROVIDE THE ALKALINE ENVIRONMENT. ,IFLASH – WASH BUFFER(1×)(IFLASH)-FOR USE IN THE IFLASH IMMUNOASSAY ANALYZER TO CLEAN THE PIPELINE SYSTEM., IFLASH – WASH BUFFER(10×(IFLASH)-FOR USE IN THE IFLASH IMMUNOASSAY ANALYZER TO CLEAN THE PIPELINE SYSTEM.,IFLASH – ANTI-CCP KIT(IFLASH)-"THE IFLASH-ANTI-CCP ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO

	CYCLIC CITRULLINATED PEPTIDE IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH – COL IV KIT (IFLASH)-"THE IFLASH-COI ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF COI IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH – HA KIT(IFLASH)-"THE IFLASH-HA ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF HA IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH – FERRITIN KIT(IFLASH)-"THE IFLASH-FERRITIN ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FERRITIN SPECIFIC ANTIGEN IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH – CORTISOL KIT(IFLASH)-"THE IFLASH-CORTISOL ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH – C-PEPTIDE KIT(IFLASH)-"THE IFLASH-C-PEPTIDE ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM, PLASMA AND URINE USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH – TSH KIT(IFLASH)-"THE IFLASH-TSH ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE TSH IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH – ADIPONECTIN KIT(IFLASH)-"THE IFLASH-ADIPONECTIN ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ADIPONECTIN IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH – FOLATE KIT(IFLASH)-THE IFLASH-FOLATE ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN SERUM, PLASMA AND ERYTHROCYTE USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH – PRE TRIGGER SOLUTION 1×)(IFLASH)-FOR USE IN THE IFLASH IMMUNOASSAY ANALYZER TO REACT WITH ACRIDINIUM ESTER FOR CHEMILUMINISCENCE ,IFLASH – PIIIPN-P KIT(IFLASH)-"THE IFLASH-PPN-P ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PPN-P IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",SARS-COV-2 IGM(IFLASH)-THE IFLASH-SARS-COV-2 IGM ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT

	IMMUNOASSAY (CLIA) FOR QUALITATIVE DETERMINATION OF IGM ANTIBODY TO SARS-COV-2 IN HUMAN SERUM OR PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER. THE IFLASH-SARA-COV-2 IGM AIDS IN THE DIAGNOSIS OF SARS-COV-2 INFECTION AND THE DETERMINATION OF IMMUNITY.,IFLASH – VITAMIN B12 KIT(IFLASH)- THE IFLASH-VITAMIN B12 ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH – PCT KIT (IFLASH)-"THE IFLASH–PCT ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PCT IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER"

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148	IMP/IVD/2019/000089	1.License Holder Name: DIASORIN HEALTHCARE INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIAISON® CONTROL FPSA (LIAISON® CONTROL FPSA)-THE LIAISON® FPSA CONTROLS (LOW AND HIGH) ARE TO BE USED IN LIAISON® FPSA CHEMILUMINESCENT IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROL FPSA HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.,LIAISON LIGHT CHECK 12(LIAISON LIGHT CHECK 12)-LIGHT CHECK REAGENT REQUIRED TO CHECK THE VALIDITY OF STARTER REAGENTS STARTER 1 AND 2 AS WELL AS THE FUNCTIONING OF THE MEASUREMENT AND PIPETTING UNITS. A LIGHT CHECK HAS TO BE CARRIED OUT ON THE LIAISON® ANALYZER EITHER ONCE DAILY PRIOR TO STARTING THE FIRST MEASUREMENT SERIES OR EACH TIME A NEW LOT OF STARTER REAGENTS IS USED. THIS CONTROL PROGRAMME CONCOMITANTLY CHECKS THE PROPER FUNCTIONING OF THE INSTRUMENT AND OF THE STARTER REAGENTS TO AVOID DATA LOSS DUE TO INSTRUMENT DEFECTS OR INADVERTENTLY PLACED OR EXPIRED STARTER REAGENTS., LIAISON® FPSA(LIAISON® FPSA)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE HUMAN PROSTATE-SPECIFIC ANTIGEN (FPSA) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARINISED). THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON ENDOCRINOLOGY DILUENT(LIAISON ENDOCRINOLOGY DILUENT)-LIAISON® ENDOCRINOLOGY DILUENT IS EXCLUSIVELY INTENDED WITH LIAISON® ASSAYS FOR THE DILUTION OF SERUM/PLASMA SAMPLES WITH HIGH CONCENTRATIONS ABOVE THE MEASURING RANGE OR RE-DISSOLUTION OF EXTRACTION RESIDUES FROM URINE SAMPLES, WHEN THE USE OF THE DILUENT IS EXPRESSIVELY MENTIONED IN THE INSTRUCTION FOR USE OF THE RESPECTIVE LIAISON® ASSAY KIT. THE INFORMATION GIVEN IN THE INSTRUCTIONS FOR USE OF THE RESPECTIVE KITS MUST BE STRICTLY OBSERVED!,LIAISON® PSA(LIAISON® PSA)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN PROSTATE-SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM AND PLASMA (HEPARINISED, EDTA) DURING THE FOLLOW-UP OF PATIENTS WITH CARCINOMA OF THE PROSTATE. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY,LIAISON CONTROL TG(LIAISON CONTROL TG)-THE LIAISON® TG CONTROLS (LOW AND HIGH) ARE TO BE USED IN LIAISON® CHEMILUMINESCENT IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROL TG HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT

	PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL, LIAISON® CONTROL PSA(LIAISON® CONTROL PSA)-THE LIAISON® PSA CONTROLS (LOW AND HIGH) ARE TO BE USED IN LIAISON® CHEMILUMINESCENT IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROL PSA HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.,LIAISON CONTROL ACTH(LIAISON CONTROL ACTH)-THE LIAISON® ACTH CONTROLS (LOW AND HIGH) ARE TO BE USED IN LIAISON® ACTH CHEMILUMINESCENT IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROL ACTH HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL,LIAISON TTG IGA CONTROL(LIAISON TTG IGA CONTROL)-THE LIAISON® CONTROL TTG IGA CONTROLS ([REF] 310321) ARE TO BE USED IN LIAISON® CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROL TTG IGA HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.,LIAISON CONTROL THYROID 3(LIAISON CONTROL THYROID 3)-PRECISION OR ACCURACY CONTROL FOR IN-LABORATORY QUALITY ASSURANCE OF TEST RESULTS PERFORMED WITH LIAISON® THYROID ASSAYS (FT3, FT4, T3, T4 AND TSH) ON THE LIAISON® ANALYZER FAMILY. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROL THYROID 1, 2, 3 HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.,LIAISON CONTROL THYROID 2(LIAISON CONTROL THYROID 2)-PRECISION OR ACCURACY CONTROL FOR IN-LABORATORY QUALITY ASSURANCE OF TEST RESULTS PERFORMED WITH LIAISON® THYROID ASSAYS (FT3, FT4, T3, T4 AND TSH) ON THE LIAISON® ANALYZER FAMILY. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROL THYROID 1, 2, 3 HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.,LIAISON CONTROL THYROID 1(LIAISON CONTROL THYROID 1)-PRECISION OR ACCURACY CONTROL FOR IN-LABORATORY QUALITY ASSURANCE OF TEST RESULTS PERFORMED WITH LIAISON® THYROID ASSAYS (FT3, FT4, T3, T4 AND TSH) ON THE LIAISON® ANALYZER FAMILY. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROL THYROID 1, 2, 3 HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON®

	AND LIAISON® XL.,LIAISON XL STARTER KIT(LIAISON XL STARTER KIT)-STARTER KIT REAGENTS PRODUCE THE CHEMILUMINESCENCE SIGNAL THAT ALLOWS THE PHOTOMULTIPLIER OF LIAISON® ANALYZER FAMILY TO DETECT AN IMMUNOLOGICAL REACTION. LIAISON® STARTER KIT ([REF] 319102) IS INTENDED TO BE USED ON LIAISON® ANALYZER, WHILE LIAISON® XL STARTER KIT ([REF] 319200) IS INTENDED TO BE USED ON LIAISON® AND LIAISON® XL ANALYZERS.,LIAISON STARTER KIT(LIAISON STARTER KIT)-STARTER KIT REAGENTS PRODUCE THE CHEMILUMINESCENCE SIGNAL THAT ALLOWS THE PHOTOMULTIPLIER OF LIAISON® ANALYZER FAMILY TO DETECT AN IMMUNOLOGICAL REACTION. LIAISON® STARTER KIT ([REF] 319102) IS INTENDED TO BE USED ON LIAISON® ANALYZER, WHILE LIAISON® XL STARTER KIT ([REF] 319200) IS INTENDED TO BE USED ON LIAISON® AND LIAISON® XL ANALYZERS.,LIAISON MULTI CONTROL TUMOR MARKER(LIAISON MULTI CONTROL TUMOR MARKER)-THE LIAISON® MULTI-CONTROL TUMOUR MARKERS (AFP, CA 125 IITM, CA 15-3®, CA 19-9TM, CEA, FERRITIN, HCG AND ß2-MICROGLOBULIN) ARE TO BE USED IN LIAISON® CHEMILUMINESCENT IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® MULTI-CONTROL TUMOUR MARKERS HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.,LIAISON CONTROL ANTI-TPO (LIAISON CONTROL ANTI-TPO)-THE LIAISON® ANTI-TPO CONTROLS (LOW AND HIGH) ARE TO BE USED IN LIAISON® ANTI-TPO CHEMILUMINESCENT IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROL ANTI-TPO HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.,LIAISON CONTROL ANTI-TG(LIAISON CONTROL ANTI-TG)-THE LIAISON® ANTI-TG CONTROLS (LOW AND HIGH) ARE TO BE USED IN LIAISON® CHEMILUMINESCENT IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROL ANTI-TG HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL,LIAISON IGF-1 CONTROL(LIAISON IGF-1 CONTROL)-THE LIAISON® IGF-I CONTROLS (LOW AND HIGH) ARE TO BE USED IN LIAISON® CHEMILUMINESCENT IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® IGF-I CONTROL HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.

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149	IMP/IVD/2019/000091	1.License Holder Name: MPRS BIOLOGICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LH(HUBI LH)-HUBI LH IS AN IN-VITRO DIAGNOSTIC TEST BASED ON IMMUNOCHROMATOGRAPHY. THE TEST IS REQUIRED TO BE APPLIED TO HUBI QUAN PRO FOR QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN BLOOD SPECIMENS.,D-DIMER (HUBI D-DIMER)-HUBI D-DIMER IS A RAPID, POINT OF CARE TEST BASED ON THE IMMUNOCHROMATOGRAPHIC ASSAY TO BE USED WITH THE HUBI-QUAN PRO ANALYZER FOR THE QUANTITATIVE DETERMINATION OF CROSS-LINKED FIBRIN DEGRADATION PRODUCTS (D-DIMERS) IN CITRATE OR EDTA ANTICOAGULATED WHOLE BLOOD OR PLASMA SPECIMENS.,PCT(HUBI PCT)-HUBI PCT IS ONE STEP IN-VITRO DIAGNOSTIC TEST BASED ON IMMUNOCHROMATOGRAPHY. IT MUST BE USED WITH HUBI QUAN PRO AND DESIGNED FOR QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN SERUM OR PLASMA OR WHOLE BLOOD.,HCG(HUBI-HCG)-HUBI HCG IS A QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN HUMAN WHOLE BLOOD OR PLASMA.,BNP(HUBI-BNP)-HUBI-BNP IS A RAPID, POINT OF CARE TEST BASED ON IMMUNOCHROMATOGRAPHY ASSAY TO BE USED WITH THE HUBI QUAN PRO FOR THE QUANTITATIVE MEASUREMENT OF B-TYPE OR BRAIN NATRIURETIC PEPTIDE (BNP) IN EDTA ANTICOAGULATED WHOLE BLOOD OR PLASMA SPECIMENS.,BNP/TNI/CK-MB(HUBI CARDIAC 3-IN-1(B) (BNP/TNI/CK-MB))-HUBI CARDIAC 3-IN-1(B) IS A QUANTITATIVE DETERMINATION OF CK-MB (CREATINE KINASE-MUSCLE/BRAIN), BNP (BRAIN NATRIURETIC PEPTIDE) AND CARDIAC TROPONIN I IN HUMAN WHOLE BLOOD OR PLASMA.,TSH(HUBI TSH)-HUBI TSH IS ONE STEP IN VITRO DIAGNOSTIC TEST BASED ON IMMUNOCHROMATOGRAPHY. IT MUST BE USED WITH HUBI QUAN PRO AND DESIGNED FOR QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM OR PLASMA OR WHOLE BLOOD.,FSH(HUBI FSH)-HUBI FSH IS AN IN-VITRO DIAGNOSTIC TEST BASED ON IMMUNOCHROMATOGRAPHY. TE TEST IS REQUIRED TO BE APPLIED TO HUBI QUAN PRO, AN ANALYZER DESIGNED FOR QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN BLOOD SPECIMENS.,TROPONIN I(HUBI-TROPONIN I)-HUBI-TROPONIN I IS ONE STEP IN-VITRO DIAGNOSTIC TEST BASED ON IMMUNOCHROMATOGRAPHY. IT MUST BE USED WITH HUBI QUAN PRO AND DESIGNED FOR QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I IN HUMAN WHOLE BLOOD OR PLASMA.

150	IMP/IVD/2019/000092	1.License Holder Name: IDEXX LABORATORIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CSFV AG SERUM PLUS TEST(IDEXX CSFV AG SERUM PLUS TEST)-SERODIAGNOSIS OF CSFV BY ELISA,MILK PREGNANCY TEST(IDEXX MILK PREGNANCY TEST)-BOVINE PREGNANCY DIAGNOSIS BY ELISA,BOVINE PREGNANCY TEST (IDEXX BOVINE PREGNANCY TEST)-BOVINE PREGNANCY DIAGNOSIS BY ELISA,RAPID VISUAL PREGNANCY TEST(IDEXX RAPID VISUAL PREGNANCY TEST)-BOVINE PREGNANCY DIAGNOSIS BY ELISA, TOXOTEST AB TEST(IDEXX TOXOTEST AB TEST)-SERODIAGNOSIS OF TOXOPLASMOSIS BY ELISA,Q FEVER AB TEST(IDEXX Q FEVER AB TEST)-SERODIAGNOSIS OF Q FEVER BY ELISA,NEOSPORA AB TEST (IDEXX NEOSPORA AB TEST)-SERODIAGNOSIS OF NEOSPORA BY ELISA,CHLAMYDIOSIS TOTAL AB TEST(IDEXX CHLAMYDIOSIS TOTAL AB TEST)-SERODIAGNOSIS OF CHLAMYDIOSIS BY ELISA, BRUCELLOSIS SERUM X2 AB TEST(IDEXX BRUCELLOSIS SERUM X2 AB TEST)-SERODIAGNOSIS OF BRUCELLOSIS BY ELISA,BRUCELLA OVIS AB TEST(IDEXX BRUCELLA OVIS AB TEST)-SERODIAGNOSIS OF BRUCELLA OVIS BY ELISA,BRUCELLOSIS MILK X2 AB TEST(IDEXX BRUCELLOSIS MILK X2 AB TEST)-SERODIAGNOSIS OF BRUCELLOSIS BY ELISA,CAEV/MVV TOTAL AB TEST(IDEXX CAEV/MVV TOTAL AB TEST)-SERODIAGNOSIS OF CAEV/ MVV AB BY ELISA,APV AB TEST (IDEXX APV AB TEST)-SERODIAGNOSIS OF APV BY ELISA,ORT AB TEST(IDEXX ORT AB TEST)-SERODIAGNOSIS OF ORT BY ELISA,SWINE SALMONELLA AB TEST(IDEXX SWINE SALMONELLA AB TEST)-SERODIAGNOSIS OF SWINE SALMONELLOSIS BY ELISA,CSFV AB TEST (IDEXX CSFV AB TEST)-SERODIAGNOSIS OF CSFV BY ELISA

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151	IMP/IVD/2019/000093	1.License Holder Name: ANAND BROTHERS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREMIER® ROTACLONE® (PREMIER® ROTACLONE®)-PREMIER® ROTACLONE® IS AN ENZYME IMMUNOASSAY (EIA) INTENDED FOR THE DETECTION OF ROTAVIRUS ANTIGEN IN HUMAN FECAL SPECIMENS,PREMIER® CAMPY (PREMIER® CAMPY)-PREMIER CAMPY ENZME IMMUNOASSAY (EIA) IS AN IN VITRO QUALITATIVE PROCEDURE FOR THE DETECTION OF SPECIFIC CAMPYLOBACTER ANTIGENS IN STOOL.,PREMIER® CRYPTOCOCCAL ANTIGEN(PREMIER® CRYPTOCOCCAL ANTIGEN)-PREMIER® CRYPTOCOCCAL ANTIGEN ENZYME (EIA) IS A SCREENING OR A SEMI-QUANTITATIVE TEST SYSTEM FOR THE DETECTION OF CAPSULAR POLYSACCHARIDE ANTIGENS OF CRYPTOCOCCUS NEOFORMANS IN SERUM AND CEREBROSPINAL FLUID (CSF)., MERIFLUOR® (CRYPTOSPORIDIUM/GIARDIA(MERIFLUOR® (CRYPTOSPORIDIUM/GIARDIA)-MERIFLUOR (CRYPTOSPORIDIUM/GIARDIA) (MERIFLUOR C/G) IS AN IN VITRO DIRECT IMMUNOFLUORESCENT DETECTION PROCEDURE FOR THE SIMULTANEOUS DETECTION OF CRYPTOSPORIDIUM OOCYSTS AND GIARDIO CYSTS IN FECAL MATERIAL.,MERIFLUOR® PNEUMOCYSTIS (MERIFLUOR® PNEUMOCYSTIS)-MERIFLUOR® PNEUMOCYSTIS IS AN IN VITRO PROCEDURE FOR THE DETECTION OF PNEUMOCYSTIS CARINII CYSTS AND TROPHOZOITES IN DIRECT SMEARS OF RESPIRATORY TRACT SPECIMENS,TRU LEGIONELLA®(TRU LEGIONELLA®)-THE TRU LEGIONELLA ASSAY IS AN IN VITRO, RAPID, LATERAL-FLOW IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF LEGIONELLA PNEUMOPHILA SEROGROUP 1 ANTIGEN IN HUMAN URINE SPECIMENS.,CRYPTOCOCCAL LATEX AGGLUTINATION (CRYPTOCOCCAL LATEX AGGLUTINATION)-THE CRYTOCOCCAL ANTIGEN LATEX AGGLUTINATION SYSTEMS (CALS)TM IS A QUALITATIVE AND SEMI QUANTITATIVE TEST SYSTEM FOR THE DETECTION OF CAPSULAR POLYSACCHARIDE ANTIGEN OF CRYPTOCOCCUS NEOFORMANS IN SERUM AND CEREBROSPINAL FLUID (CSF).,PREMIER® PLATINUM HPSA PLUS(PREMIER® PLATINUM HPSA PLUS)-PREMIER® PLATINUM HPSA PLUS ENZYME IMMUNOASSAY (EIA) IS AN IN VITRO QUALITATIVE PROCEDURE FOR THE DETECTION OF HELICOBACTER PYLORI ANTIGENS IN HUMAN STOOL. THE RESULTS ARE INTENDED TO AID IN THE DIAGNOSIS OF H. PYLORI INFECTION AND TO MONITOR RESPONSE DURING AND POST-THERAPY IN PATIENTS. ACCEPTED MEDICAL PRACTICE RECOMMENDS THAT TESTING BY ANY CURRENT METHOD, TO CONFIRM ERADICATION BE DONE AT LEAST FOUR WEEKS FOLLOWING COMPLETION OF THERAPY,PREMIER® TOXIN A&B (PREMIER® TOXIN A&B)-PREMIER® TOXIN A&B IS A QUALITATIVE

		ENZYME IMMUNOASSAY FOR THE DETECTION OF CLOSTRIDIUM DIFFICILE TOXIN A AND TOXIN B IN STOOL FROM PATIENTS WITH ANTIBIOTIC ASSOCIATED DIARRHEA. PREMIER TOXINS A&B IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF C. DIFFICILE ASSOCIATED DISEASE (CDAD)
152	IMP/IVD/2019/000094	1.License Holder Name: M/S. R.K.AGENCY 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BOULE HEMATOLOGY CONTROL (NORMAL)(BOULE CONTROL - DIFF NORMAL)-BOULE HEMATOLOGY CONTROL IS INTENDED TO BE USED TO MONITOR THE PERFORMANCE OF MULTI- PARAMETER HEMATOLOGY ANALYZERS., BOULE HEMATOLOGY CONTROL (LOW)(BOULE CONTROL-DIFF LOW) -BOULE HEMATOLOGY CONTROL IS INTENDED TO BE USED TO MONITOR THE PERFORMANCE OF MULTI- PARAMETER HEMATOLOGY ANALYZERS., BOULE HEMATOLOGY CONTROL (HIGH)(BOULE CONTROL - DIFF HIGH)-BOULE HEMATOLOGY CONTROL IS INTENDED TO BE USED TO MONITOR THE PERFORMANCE OF MULTI= PARAMETER HEMATOLOGY ANALYZERS.,BOULE HEMATOLOGY CONTROL (TRI LEVEL)(BOULE CONTROL DIFF TRI LEVEL)- BOULD HEMATOLOGY CONTROL IS INTENDED TO BE USED TO MONITOR THE PERFORMANCE OF MULTI- PARAMETER HEMATOLOGY ANALYZERS., BOULE HEMATOLOGY CALIBRATOR(BOULE CALIBRATOR)- HEMATOLOGY CALIBRATOR IS INTENDED TO CALIBRATION OF MULTI- PARAMETER HEMATOLOGY ANALYZERS.

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153	IMP/IVD/2019/000096	1.License Holder Name: IMMUCOR INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CAPTURE ASSAYS (IMMUCOR)-CAPTURE-R READY-ID IS INTENDED FOR USE IN THE IDENTIFICATION OF UNEXPECTED IGG ANTIBODIES TO RED BLOOD CELLS BY MANUAL, SEMI-AUTOMATED AND AUTOMATED METHODS. , CAPTURE-R POSITIVE CONTROL SERUM (WEAK); CAPTURE-R NEGATIVE CONTROL SERUM(IMMUCOR)-IMMUCOR CAPTURE-R POSITIVE CONTROL SERUM (WEAK) AND CAPTURE-R NEGATIVE CONTROL SERUM ARE RUN CONTROLS TO BE USED IN CAPTURE-R SOLID PHASE ASSAYS, INCLUDING CAPTURE-R SELECT, CAPTURE-R READY-SCREEN AND CAPTURE-R READY ID. ,RARE BLOOD GROUPING SERA(IMMUCOR REFERENCELLS-4)-REFERENCELLS (POOLED CELLS) ARE INTENDED FOR USE IN TUBE AND MICROPLATE ABO SERUM GROUPING TESTS.,CMT PLATES(IMMUCOR)-CMT PLATES ARE INTENDED TO BE USED IN HEMAGGLUTINATION ASSAY ON IMMUCOR AUTOMATED INSTRUCTIONS,RARE BLOOD GROUP SERA(IMMUCOR ANTI-K MONO (GAMMACLONE))-GAMMA-CLONE ANTI-K (MONOCLONAL) IS INTENDED FOR THE DETECTION OF THE K (KELL KEL1) ANTIGEN ON RED BLOOD CELLS BY TUBE TEST.,PANOSCREEN I, II AND III(IMMUCOR)-PANOSCREEN IS INTENDED FOR USE IN THE DETECTION OF UNEXPECTED RED BLOOD CELL BLOOD GROUP ANTIBODIES.,ANTI B(IMMUCOR)-IMMUCOR IMMUCOR ANTI-A SERIES 1 (MURINE MONOCLONAL), ANTI-B SERIES 1 (MURINE MONOCLONAL), ANTI-B SERIES 3 (MURINE MONOCLONAL) AND ANTI-A,B SERIES 1 (MURINE MONOCLONAL BLEND) ARE INTENDED FOR USE IN SLIDE, TUBE AND MICROPLATE TESTS.,ANTI-C3D, C3D (MURINE MONOCLONAL) GAMMA CLONE(IMMUCOR)-GAMMA CLONE ANTI-HUMAN GLOBULIN, ANTI- C3B-C3D (MURINE MONOCLONAL) IS INTENDED FOR USE IN DIRECT ANTIGLOBULIN TESTS WHERE THE DETECTION OF C3 (AS C3B OR C3D) IS REQUIRED.,RARE BLOOD GROUPING SERA(IMMUCOR DAT POSITIVE CONTROL CELL)-IMMUCOR'S DAT POSITIVE CONTROL CELL IS DESIGNED TO BE USED ONLY WITH THE IMMUCOR AUTOMATED INSTRUMENTS. DAT POSITIVE CONTROL CELLS ARE IGG-COATED RED BLOOD CELLS USED AS A CONTROL TO CONFIRM THE VALIDITY OF THE DAT ASSAY AND OTHER ASSAYS UTILIZING THE DIRECT ANTIGLOBULIN TEST ON IMMUCOR AUTOMATED INSTRUMENTS.,SPECIMEN DILUENT (IMMUCOR)-SPECIMEN DILUENT IS A READY FOR USE ISOTONIC SOLUTION USED FOR DILUTING RED BLOOD CELLS FROM BLOOD SAMPLES FOR TESTING ON IMMUCOR AUTOMATED INSTRUMENTS.,RARE BLOOD GROUPING SERA(IMMUCOR PANOCELL 16)-PANOCELL IS INTENDED FOR USE IN THE IDENTIFICATION OF UNEXPECTED RED CELL BLOOD GROUP ANTIBODIES.,ANTI-C (MONOCLONAL) SERIES 1

	// ANTI-C/ ANTI-E/ ANTI-E (MONOCLONAL) GAMMA CLONE (IMMUCOR)-IMMUCOR MONOCLONAL BLOOD GROUPING REAGENTS ANTI-C, ANTI-E, ANTI-C, ANTI-E ARE INTENDED FOR THE DETECTION OF C, E, C AND E ANTIGENS IN SLIDE, TUBE AND MICROPLATE TESTS., ANTI A(IMMUCOR)-IMMUCOR ANTI-A SERIES 1 (MURINE MONOCLONAL), ANTI-B SERIES 1 (MURINE MONOCLONAL), ANTI-B SERIES 3 (MURINE MONOCLONAL) AND ANTI-A,B SERIES 1 (MURINE MONOCLONAL BLEND) ARE INTENDED FOR USE IN SLIDE, TUBE AND MICROPLATETESTS.,ANTI IGG, C3D (POLYSPECIFIC) (MURINE MONOCLONAL) GAMMA-CLONE(IMMUCOR)-FOR USE IN DIRECT OR INDIRECT ANTIGLOBULIN TESTS WHERE THE DETECTION OF IGG OR C3(ASC3B OR C3D) IS REQUIRED.,ANTI A,B(IMMUCOR)-IMMUCOR ANTI-A SERIES 1 (MURINE MONOCLONAL), ANTI-B SERIES 1 (MURINE MONOCLONAL), ANTI-B SERIES 3 (MURINE MONOCLONAL) AND ANTI-A,B SERIES 1 (MURINE MONOCLONAL BLEND) ARE INTENDED FOR USE IN SLIDE, TUBE AND MICROPLATE TESTS.,CORQC EXTEND STANDARD, CORQC EXTEND COMPLETE(IMMUCOR)-CORQC EXTEND IS INTENDED TO USE IN MANUAL TEST TUBE AND AUTOMATED (E.G. GALILEO) ASSAYS FOR QUALITY CONTROL OF ROUTINE RH AND KELL BLOOD GROUPING REAGENTS.,RARE BLOOD GROUP SERA(IMMUCOR ANTI-LEA (MURINE MONOCLONAL) GAMMA-CLONE)-GAMMA-CLONE ANTI-LEA (MURINE MONOCLONAL) INTENDED FOR THE DETECTION OF THE LEA (LE1) ANTIGENS ON RED BLOOD CELLS BY THE TUBE TEST METHOD.,MONOCLONAL CONTROL(IMMUCOR)-MONOCLONAL CONTROL IS INTENDED TO BE USED AS A CONTROL FOR IMMUCOR LOW PROTEIN BLOOD GROUPING REAGENTS AND GAMMA-CLONE BLOOD GROUPING REAGENTS USED IN SLIDE, TUBE AND MICROPLATE TEST.,CAPTURE ASSAYS(IMMUCOR CAPTURE R READY SCREEN (4))-CAPTURE-R® READY-SCREEN (4) ARE INTENDED FOR USE IN THE DETECTION OF UNEXPECTED IGG ANTIBODIES TO RED BLOOD CELLS BY MANUAL, SEMI-AUTOMATED OR AUTOMATED SOLID PHASE RED BLOOD CELL ADHERENCE METHODS.,ANTI-IGG (MURINE MONOCLONAL) GAMMA-CLONE(IMMUCOR)-GAMMA-CLONE ANTI-HUMAN GLOBULIN ANTI-IGG (MURINE MONOCLONAL) GREEN OR INTENDED FOR USE IN DIRECT OR INDIRECT ANTIGLOBULIN TESTS WHERE THE DETECTION OF IGG IS REQUIRED.,CAPTURE ASSAYS (IMMUCOR)- THE CAPTURE-R® SELECT SOLID PHASE SYSTEM PROVIDES MODIFIED MICROWELLS FOR THE IMMOBILIZATION OF HUMAN ERYTHROCYTES FOR USE IN SOLID PHASE ASSAYS FOR THE DETECTION OF IGG RED BLOOD CELL ANTIBODIES TO CORRESPONDING RED BLOOD CELL ANTIGENS (E.G., ANTIBODY SCREENING, SELECTED RED BLOOD CELL PANELS, CROSSMATCHING, OR ANTIGEN PHENOTYPING).,ANTI FYB(IMMUCOR)-IMMUCOR ANTI FYB BLOOD GROUPING REAGENTS ARE INTENDED FOR THE

	DETECTION OF FYB ON THE RED BLOOD CELLS BY THE INDIRECT ANTI-GLOBULIN TEST.,CAPTURE ASSAYS(IMMUCOR CAPTURE R READY SCREEN (3))-CAPTURE-R® READY-SCREEN (3) ARE INTENDED FOR USE IN THE DETECTION OF UNEXPECTED IGG ANTIBODIES TO RED BLOOD CELLS BY MANUAL, SEMI-AUTOMATED OR AUTOMATED SOLID PHASE RED BLOOD CELL ADHERENCE METHODS.,ANTI A1 LECTIN(IMMUCOR)-IMMUCOR A1 LECTIN IS USED TO DIFFERENTIATE A1 RED BLOOD CELLS FROM THOSE OF OTHER A SUBGROUPS IN SALINE SLIDE OR TUBE TESTS.,CAPTURE ASSAYS (IMMUCOR)-ANTI-IGG-COATED INDICATOR RED CELLS FOR USE IN CAPTURE-R READY-SCREEN®, CAPTURE-R READY-ID® OR CAPTURE-R® SELECT SOLID PHASE ASSAYS FOR THE DETECTION OF IGG ANTIBODIES TO RED BLOOD CELLS.,CAPTURE-P POSITIVE CONTROL SERUM (WEAK); CAPTURE-P NEGATIVE CONTROL SERUM (IMMUCOR)-IMMUCOR CAPTURE-P POSITIVE CONTROL SERUM (WEAK) AND CAPTURE-P NEGATIVE CONTROL SERUM ARE RUN CONTROLS TO BE USED IN CAPTURE-P AND CAPTURE-P AND CAPTURE –P READY SCREEN SOLID PHASE ASSAYS,CAPTURE ASSAYS(IMMUCOR CAPTURE P SERUM)-FOR USE IN THE DETECTION OF ANTIBODIES TO PLATELETS.,RARE BLOOD GROUPING SERA (IMMUCOR ANTI-LEB (MURINE MONOCLONAL) GAMMA-CLONE)-GAMMA-CLONE ANTI-LEB (MURINE MONOCLONAL) ARE INTENDED FOR THE DETECTION OF THE LEB (LE2) ANTIGENS ON RED BLOOD CELLS BY THE TUBE TEST METHOD.,CAPTURE ASSAYS(IMMUCOR CAPTURE R READY SCREEN (POOLED CELLS))-CAPTURE-R® READY-SCREEN POOLED CELLS ARE INTENDED FOR USE IN THE DETECTION OF UNEXPECTED IGG ANTIBODIES TO RED BLOOD CELLS BY MANUAL, SEMI-AUTOMATED OR AUTOMATED SOLID PHASE RED BLOOD CELL ADHERENCE METHODS.,RARE BLOOD GROUPING SERA(IMMUCOR ANTI-JKA (MONOCLONAL) GAMMA-CLONE)-GAMMA-CLONE ANTI-JKA (MONOCLONAL) BLOOD GROUPING REAGENTS ARE INTENDED FOR THE DETECTION OF THE JKA (JK1) ANTIGEN ON RED BLOOD CELLS BY TUBE TEST.,RARE BLOOD GROUPING SERA(IMMUCOR REFERENCELLS- 2)-REFERENCELLS ARE INTENDED FOR USE IN TUBE AND MICROPLATE ABO SERUM GROUPING TESTS.,CAPTURE ASSAYS (IMMUCOR CAPTURE- P)-FOR USE IN THE DETECTION OF ANTIBODIES TO PLATELETS.,RARE BLOOD GROUPING SERA(IMMUCOR ANTI-JKB (MONOCLONAL) GAMMA-CLONE)-GAMMA-CLONE ANTI-JKB (MONOCLONAL) BLOOD GROUPING REAGENT ARE INTENDED FOR THE DETECTION OF THE JKB (JK2) ANTIGENS, ON RED BLOOD CELLS BY TUBE TEST.,RARE BLOOD GROUPING SERA(IMMUCOR PANOCELL (FICIN-TREATED))-FICIN-TREATED PANOCELL REAGENT RED BLOOD CELLS ARE INTENDED FOR USE IN THE IDENTIFICATION OF UNEXPECTED RED BLOOD CELL BLOOD GROUP ANTIBODIES.,

	CAPTURE ASSAYS(IMMUCOR CAPTURE LISS)-CAPTURE LISS IS INTENDED FOR USE AS A LOW IONIC STRENGTH POTENTIATOR AND SAMPLE ADDITION INDICATOR IN CAPTURE SOLID PHASE TESTS FOR THE DETECTION OF ANTIBODIES (CAPTURE-R® SELECT, CAPTURE-R® READY-SCREEN®, CAPTURE-R READY-ID®, CAPTURE-R READY-ID EXTEND, CAPTURE-P®, CAPTURE-P READY-SCREEN® AND CAPTURE-CMV®).,RARE BLOOD GROUPING SERA(IMMUCOR PANOCELL 20)-PANOCELL IS INTENDED FOR USE IN THE IDENTIFICATION OF UNEXPECTED RED CELL BLOOD GROUP ANTIBODIES.,RARE BLOOD GROUPING SERA(IMMUCOR ANTI-S (MONOCLONAL) GAMMA-CLONE)-GAMMA-CLONE ANTI-S (MONOCLONAL) BLOOD GROUPING REAGENTS ARE INTENDED FOR THE DETECTION OF THE S (MNS3) ANTIGEN ON RED BLOOD CELLS BY TUBE TEST.,RARE BLOOD GROUPING SERA(IMMUCOR ANTI-K)-IMMUCOR ANTI-K¯ BLOOD GROUPING REAGENT IS INTENDED FOR THE DETECTION OF THE K (KEL2) ANTIGEN ON RED BLOOD CELLS BY THE INDIRECT ANTIGLOBULIN TEST.,RARE BLOOD GROUP SERA (IMMUCOR ANTI-N (MURINE MONOCLONAL) GAMMA-CLONE)-GAMMA-CLONE ANTI-M (MURINE MONOCLONAL) AND ANTI-N (MURINE MONOCLONAL) ARE INTENDED FOR THE DETECTION OF THE M (MNS1) AND N (MNS2) ANTIGENS, RESPECTIVELY, ON RED BLOOD CELLS BY TUBE TEST.,RARE BLOOD GROUPING SERA(IMMUCOR W.A. R.M. (WARM AUTOANTIBODY REMOVAL MEDIUM))-W.A.R.M. IS USED FOR THE REMOVAL OF WARM-REACTIVE AUTOANTIBODY FROM RED BLOOD CELLS TO FACILITATE RESOLUTION OF SEROLOGICAL COMPLEXITIES.,RARE BLOOD GROUP SERA(IMMUCOR ANTI-M (MURINE MONOCLONAL) GAMMA-CLONE)-GAMMA-CLONE ANTI-M (MURINE MONOCLONAL) AND ANTI-N (MURINE MONOCLONAL) ARE INTENDED FOR THE DETECTION OF THE M (MNS1) AND N (MNS2) ANTIGENS, RESPECTIVELY, ON RED BLOOD CELLS BY TUBE TEST., RARE BLOOD GROUPING SERA(IMMUCOR ANTI-FYA (MONOCLONAL) GAMMA-CLONE)-GAMMA-CLONE ANTI-FYA (MONOCLONAL) BLOOD GROUPING REAGENT IS INTENDED FOR THE DETECTION OF THE FYA (FY1) ANTIGEN ON RED BLOOD CELLS BY THE INDIRECT ANTIGLOBULIN TEST.,RARE BLOOD GROUPING SERA(IMMUCOR ANTI –H LECTIN)-ANTI-H LECTIN (ULEX EUROPÆUS) IS INTENDED FOR USE IN THE DETECTION OF H (H1) ANTIGEN ON RED BLOOD CELLS AND IN SALIVIA BY TUBE TEST.,ANTI D(IMMUCOR)-IMMUCOR ANTI-D SERIES 5 (MONOCLONAL BLEND) IS INTENDED FOR USE IN SLIDE, TUBE AND MICROPLATE TESTS.,CAPTURE ASSAYS(IMMUCOR CAPTURE P READY SCREEN)-FOR USE IN THE DETECTION OF ANTIBODIES TO PLATELETS.,RARE BLOOD GROUPING SERA(IMMUCOR GAMMA ELU-KIT II)-GAMMA ELU-KIT II IS INTENDED FOR USE IN THE RAPID ACID ELUTION OF ANTIBODIES FROM INTACT RED BLOOD CELLS.

154	IMP/IVD/2019/000097	1.License Holder Name: QIAGEN INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PAXGENE BLOOD RNA KIT (50) CE-KIT FOR PURIFICATION OF INTRACELLULAR RNA FROM WHOLE BLOOD.

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155	IMP/IVD/2019/000098	1.License Holder Name: SYSMEX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:UX CLEAN-C(UX CLEAN-C) -FOR IN VITRO DIAGNOSTIC USE ONLY UX CLEAN-C IS A CONCENTRATED WASHING SOLUTION TO CLEAN THE CHM ANALYSIS SECTION OF THE SYSMEX FULLY AUTOMATED INTEGRATED ANALYZER (UX-2000). DO NOT USE UX-CLEAN-C FOR CLEANING THE FCM ANALYSIS SECTION. NEVER USE THE FCM ASPIRATION NOZZLE TO ASPIRATION UX CLEAN-C, OTHERWISE THE INSTRUENT MAY MALFUNCTION.,MEDITAPE II 9U(MEDITAPE II 9U)-"MEDITAPE II 9U IS A URINALYSIS TEST STRIP WITH REAGENT PADS FOR THE DETERMINATION OF GLUCOSE, PROTEIN, BILIRUBIN, UROBILINOGEN, PH, BLOOD, KETONES, NITRITE AND LEUKOCYTES. MEDITAPE II 9U IS FOR USE THE SYSMEX FULLY AUTOMATED INTEGRATED URINE ANALYZER (UX-2000) ONLY. EACH TEST STRIP INCLUDES A CALIBRATION PAD THAT CORRECTS FOR INTERFERENCE FROM THE NATURAL COLOR OF URINE AUTOMATICALLY",MEDITAPE II 7U (MEDITAPE II 7U)-MEDITAPE II 7U IS A URINALYSIS TEST STRIP WITH REAGENT PADS FOR THE DETERMINATION OF GLUCOSE, PROTEIN, BILIRUBIN, UROBILINOGEN, PH, BLOOD, KETONES. MEDITAPE II 7U IS FOR USE THE SYSMEX FULLY AUTOMATED INTEGRATED URINE ANALYZER (UX-2000) ONLY. EACH TEST STRIP INCLUDES A CALIBRATION PAD THAT CORRECTS FOR INTERFERENCE FROM THE NATURAL COLOR OF URINE AUTOMATICALLY,MEDITAPE II 10U (MEDITAPE II 10U)-"MEDITAPE II 10U IS A URINALYSIS TEST STRIP WITH REAGENT PADS FOR THE DETERMINATION OF GLUCOSE, PROTEIN, BILIRUBIN, UROBILINOGEN, CREATININE, PH, BLOOD, KETONES, NITRITE AND LEUKOCYTES. MEDITAPE II 10U IS FOR USE THE SYSMEX FULLY AUTOMATED INTEGRATED URINE ANALYZER (UX-2000) ONLY. EACH TEST STRIP INCLUDES A CALIBRATION PAD THAT CORRECTS FOR INTERFERENCE FROM THE NATURAL COLOR OF URINE AUTOMATICALLY",MEDITAPE II 10K(MEDITAPE II 10K)-"MEDITAPE II 10K IS A URINALYSIS TEST STRIP WITH REAGENT PADS FOR THE DETERMINATION OF GLUCOSE, PROTEIN, ALBUMIN, BILIRUBIN, CREATININE, PH, BLOOD, KETONES, NITRITE AND LEUKOCYTES. MEDITAPE II 10K IS FOR USE THE SYSMEX FULLY AUTOMATED INTEGRATED URINE ANALYZER (UX-2000) ONLY. EACH TEST STRIP INCLUDES A CALIBRATION PAD THAT CORRECTS FOR INTERFERENCE FROM THE NATURAL COLOR OF URINE AUTOMATICALLY"

156	IMP/IVD/2019/000104	1.License Holder Name: MHS PHARMACEUTICALS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIP(GLUCORITE)-BLOOD GLUCOSE STRIP GS260 IS USED BY INDIVIDUALS WITH DIABETES. IT'S FOR CHECKING ON GLUCOSE LEVELS IN CAPILLARY WHOLE BLOOD (CB) FROM FINGER TIP, PALM AND FOREARM. IT'S AN AID IN MANAGEMENT OF DIABETES AT HOME AND CLINICAL SITES,BLOOD GLUCOSE TEST STRIP(RIGHTEST)-BLOOD GLUCOSE STRIP GS260 IS USED BY INDIVIDUALS WITH DIABETES. IT'S FOR CHECKING ON GLUCOSE LEVELS IN CAPILLARY WHOLE BLOOD (CB) FROM FINGER TIP, PALM AND FOREARM. IT'S AN AID IN MANAGEMENT OF DIABETES AT HOME AND CLINICAL SITES
157	IMP/IVD/2019/000105	1.License Holder Name: IDEXX LABORATORIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IDEXX UA STRIPS (100) (IDEXX)-USE VISUALLY OR ON THE IDEXX VETLAB* UA™ ANALYZER FOR THE TESTING OF CAT, DOG OR HORSE URINE.,VETLAB UA CALIBRATION STRIPS(IDEXX)-USED TO CALIBRATE THE IDEXX VETLAB* UA™ ANALYZER AND TO CHECK ITS PERFORMANCE.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

158	IMP/IVD/2019/000106	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ISE BUFFER(ISE BUFFER)-REAGENT USED IN CONJUGATION WITH THE ISE MODULE OF BECKMAN COULTER AU ANALYZERS FOR THE QUANTITATIVE (INDIRECT) DETERMINATION OF SODIUM (NA+) POTASSIUM (K+) AND CHLORIDE (CL-) CONCENTRATE IONS IN HUMAN SERUM PLASMA AND URINE,ITA CONTROL SERUM LEVEL 1(ITA CONTROL SERUM LEVEL 1)-THE ITA CONTROL SERUM IS A LIQUID HUMAN SERUM CONTROL INTENDED TO BE USED IN-CONJUNCTION WITH ITA CONTROL SERA ODC0015 AND ODC0016 TO MONITOR THE ANALYTICAL PERFORMANCE OF THE BECKMAN COULTER SYSTEM REAGENTS LISTED BELOW ON BECKMAN COULTER ANALYSERS. ALPHA-1 ACIDGLYCOPROTEIN, FERRITIN, ALPHA-1 ANTITRYPSIN, HAPTOGLOBIN, ANTI-STREPTOLYSIN O, IMMUNOGLOBULIN A, BETA-2 MICROGLOBULIN, IMMUNOGLOBULIN G, CERULOPLASMIN, IMMUNOGLOBULIN M, COMPLEMENT 3, PREALBUMIN, COMPLEMENT 4, RHEUMATOID FACTOR, C-REACTIVE PROTEIN, TRANSFERRIN.,ISE REFERENCE(ISE REFERENCE)-REAGENT USED IN CONJUGATION WITH THE ISE MODULE OF BECKMAN COULTER AU ANALYZERS FOR THE QUANTITATIVE (INDIRECT) DETERMINATION OF SODIUM (NA+) POTASSIUM (K+) AND CHLORIDE (CL-) CONCENTRATE IONS IN HUMAN SERUM PLASMA AND URINE,HDL/LDL CHOLESTEROL CONTROL SERUM(HDL/LDL CHOLESTEROL CONTROL SERUM)-THE HDL/LDL-CHOLESTEROL CONTROL SERUM IS A LYOPHILISED HUMAN SERUM CONTROL DESIGNED TO MONITOR THE ANALYTICAL PERFORMANCE OF THE HDL AND LDL CHOLESTEROL REAGENTS, OSR6187 AND OSR6183 RESPECTIVELY, ON BECKMAN COULTER ANALYSERS.,ISE INTERNAL REFERENCE(ISE INTERNAL REFERENCE)-REAGENT USED IN CONJUGATION WITH THE ISE MODULE OF BECKMAN COULTER AU ANALYZERS FOR THE QUANTITATIVE (INDIRECT) DETERMINATION OF SODIUM (NA+) POTASSIUM (K+) AND CHLORIDE (CL-) CONCENTRATE IONS IN HUMAN SERUM PLASMA AND URINE,URINE/CSF ALBUMIN CALIBRATOR(URINE/CSF ALBUMIN CALIBRATOR)-THE URINE/CSF ALBUMIN CALIBRATOR IS INTENDED TO BE USED TO CALIBRATE THE URINE/CSF ALBUMIN REAGENT ON THE BECKMAN COULTER AU CLINICAL CHEMISTRY SYSTEMS.,ISE LOW/HIGH URINE STANDARD(ISE LOW/HIGH URINE STANDARD)-REAGENT USED IN CONJUGATION WITH THE ISE MODULE OF BECKMAN COULTER AU ANALYZERS FOR THE QUANTITATIVE (INDIRECT) DETERMINATION OF SODIUM (NA+) POTASSIUM (K+) AND CHLORIDE (CL-) CONCENTRATE IONS IN HUMAN SERUM PLASMA AND URINE,LDL CHOLESTEROL CALIBRATOR(LDL CHOLESTEROL CALIBRATOR)-THE LDL-CHOLESTEROL CALIBRATOR IS A

	LYOPHILISED HUMAN SERUM CALIBRATOR INTENDED TO BE USED WITH THE LDL-CHOLESTEROL REAGENT OSR6183/OSR6283 FOR THE QUANTITATIVE DETERMINATION OF LDL-CHOLESTEROL ON BECKMAN COULTER ANALYSERS.,ISE NA+/K+ SELECTIVITY CHECK (ISE NA+/K+ SELECTIVITY CHECK)-REAGENT USED IN CONJUGATION WITH THE ISE MODULE OF BECKMAN COULTER AU ANALYZERS FOR THE QUANTITATIVE (INDIRECT) DETERMINATION OF SODIUM (NA+) POTASSIUM (K+) AND CHLORIDE (CL-) CONCENTRATE IONS IN HUMAN SERUM PLASMA AND URINE ,URINE/CSF ALBUMIN (URINE/CSF ALBUMIN)-THE URINE/CSF ALBUMIN REAGENT IS INTENDED TO BE USED FOR THE QUANTITATION OF ALBUMIN CONCENTRATION IN HUMAN URINE AND CEREBROSPINAL FLUID (CSF) ON THE BECKMAN COULTER AU CLINICAL CHEMISTRY SYSTEMS AS AN AID IN THE DIAGNOSIS OF KIDNEY DISEASES., CLEANING SOLUTION (CLEANING SOLUTION)-IT IS USED FOR CLEANING CONCENTRATE ,DIGOXIN(DIGOXIN)-IMMUNO-INHIBITION TEST FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN IN HUMAN SERUM ON BECKMAN COULTER ANALYSERS.,ISE HIGH SERUM STANDARD(ISE HIGH SERUM STANDARD)-REAGENT USED IN CONJUGATION WITH THE ISE MODULE OF BECKMAN COULTER AU ANALYZERS FOR THE QUANTITATIVE (INDIRECT) DETERMINATION OF SODIUM (NA+) POTASSIUM (K+) AND CHLORIDE (CL-) CONCENTRATE IONS IN HUMAN SERUM PLASMA AND URINE,CREATININE (ENZYMATIC)(CREATININE (ENZYMATIC))-ENZYMATIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE ON BECKMAN COULTER AU ANALYSERS.,ISE MID STANDARD(ISE MID STANDARD)-REAGENT USED IN CONJUGATION WITH THE ISE MODULE OF BECKMAN COULTER AU ANALYZERS FOR THE QUANTITATIVE (INDIRECT) DETERMINATION OF SODIUM (NA+) POTASSIUM (K+) AND CHLORIDE (CL-) CONCENTRATE IONS IN HUMAN SERUM PLASMA AND URINE, EDDP(EDDP)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND SEMI-QUANTITATIVE ASSAY OF EDDP (2-ETHYLIDINE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE) IN HUMAN URINE ON BECKMAN COULTER AU ANALYSERS.,BICARBONATE (BICARBONATE)-SYSTEM REAGENT FOR THE QUANTITATIVE DETERMINATION OF BICARBONATE IN HUMAN SERUM AND PLASMA ON BERCKMAN COULTER ANALYSERS ,DIGITOXIN(DIGITOXIN)-IMMUNO-INHIBITION TEST FOR THE QUANTITATIVE DETERMINATION OF DIGITOXIN IN HUMAN SERUM ON BECKMAN COULTER ANALYSERS.,ALPHA AMYLASE (ALPHA AMYLASE)-QUANTITATIVE DETERMINATION OF ALPHA AMYLASE [1,4-ALPHA-D-GLUCAN 4-GLUCANOHYDROLASE EC 3.2.1.1] IN HUMAN SERUM AND URINE AND PLASMA ON BECKMAN COULTER ANALYSERS ,GENTAMYCIN

	(GENTAMYCIN)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GENTAMYCIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,BICARBONATE CALIBRATOR(BICARBONATE CALIBRATOR)- INTENDED TO BE USED WITH THE BICARBONATE REAGENT OSR6190/OSR6290 FOR THE QUANTITATIVE DETERMINATION OF BICARBONATE ON BECKMAN COULTER ANAYSERS ,CK-MB CALIBRATOR(CK-MB CALIBRATOR)-THE CK-MB CALIBRATOR IS A LYOPHILISED HUMAN SERUM CALIBRATOR DESIGNED FOR CALIBRATION OF THE CK-MB REAGENT OSR61155 ON BECKMAN COULTER ANALYSERS.,LDH (LDH)-KINETIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE, EC 1.1.1.27 (LDH) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS ,CRP (LATEX) CONTROL SERUM(CRP (LATEX) CONTROL SERUM)-THE CRP (LATEX) CONTROL SERUM IS A LIQUID HUMAN SERUM CONTROL DESIGNED TO MONITOR THE ANALYTICAL PERFORMANCE OF THE SENSITIVE AND HIGHLY SENSITIVE APPLICATIONS OF THE CRP LATEX REAGENT OSR6X99 ON BECKMAN COULTER ANALYSERS.,ISE LOW SERUM STANDARD (ISE LOW SERUM STANDARD)-REAGENT USED IN CONJUGATION WITH THE ISE MODULE OF BECKMAN COULTER AU ANALYZERS FOR THE QUANTITATIVE (INDIRECT) DETERMINATION OF SODIUM (NA+) POTASSIUM (K+) AND CHLORIDE (CL-) CONCENTRATE IONS IN HUMAN SERUM PLASMA AND URINE,DIGOXIN CALIBRATOR(DIGOXIN CALIBRATOR)-THE DIGOXIN CALIBRATOR IS A LIQUID HUMAN SERUM BASED MATRIX CALIBRATOR INTENDED TO BE USED WITH THE DIGOXIN REAGENT OSR6404 FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN ON BECKMAN COULTER ANALYSERS.,GGT (GGT)-QUANTITATIVE DETERMINATION OF GAMMA-GLUMAMYLTRANSFERASE, EC 2.3.2.2(GGT) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS. OSR6620 FOR USE ON THE AU5800, AU2700 AND AU5400 SYSTEMS ONLY.,ICHEM VELOCITY URINE CHEMISTRY STRIPS(ICHEM VELOCITY URINE CHEMISTRY STRIPS)-THE ICHEMVELOCITY STRIPS ARE MANUFACTURED FOR USE ONLY WITH THE ICHEMVELOCITY URINE CHEMISTRY SYSTEM AND ARE INTENDED FOR USE EXCLUSIVELY BY HEALTHCARE PROFESSIONALS. THESE QUALITATIVE OR SEMI-QUANTITATIVE MEASUREMENTS CAN BE USED ALONG WITH OTHER DIAGNOSTIC TOOLS IN THE EVALUATION OF RENAL, URINARY, AND METABOLIC DISORDERS.,HBDH(HBDH)-USED FOR THE QUANTITATIVE DETERMINATION OF 2-HYDROXYGENASE EC 2.2.4.3 (HBDH) IN HUMAN SERUM PLASMA ON BECKMAN COULTER AU ANALYSERS., CONTROL SERUM 1(CONTROL SERUM 1)-THE CONTROL SERUM 1 IS A LYOPHILISED HUMAN SERUM CONTROL INTENDED TO BE USED IN-CONJUNCTION WITH THE CONTROL SERUM 2 ODC0004 TO MONITOR

	THE ANALYTICAL PERFORMANCE OF THE BECKMAN COULTER SYSTEM REAGENTS ON BECKMAN COULTER ANALYSERS.,CLEANING SOLUTION-CLEANING CONCENTRATE,LDL CHOLESTEROL(LDL CHOLESTEROL)-ENZYMATIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF LDL-CHOLESTEROL IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,MYOGLOBIN CALIBRATOR(MYOGLOBIN CALIBRATOR)-THE MYOGLOBIN CALIBRATOR IS A BUFFER BASED MATRIX CONTAINING HUMAN MYOGLOBIN INTENDED TO BE USED WITH THE MYOGLOBIN REAGENT OSR6168 FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN ON BECKMAN COULTER ANALYSERS.,ITA CONTROL SERUM LEVEL 2 (ITA CONTROL SERUM LEVEL 2)-THE ITA CONTROL SERUM IS A LIQUID HUMAN SERUM CONTROL INTENDED TO BE USED IN-CONJUNCTION WITH ITA CONTROL SERA ODC0014 AND ODC0016 TO MONITOR THE ANALYTICAL PERFORMANCE OF THE BECKMAN COULTER SYSTEM REAGENTS LISTED BELOW ON BECKMAN COULTER ANALYSERS. ALPHA-1 ACIDGLYCOPROTEIN, FERRITIN, ALPHA-1 ANTITRYPSIN, HAPTOGLOBIN, ANTI-STREPTOLYSIN O, IMMUNOGLOBULIN A, BETA-2 MICROGLOBULIN, IMMUNOGLOBULIN G, CERULOPLASMIN, IMMUNOGLOBULIN M, COMPLEMENT 3, PREALBUMIN, COMPLEMENT 4, RHEUMATOID FACTOR, C-REACTIVE PROTEIN, TRANSFERRIN.,MYOGLOBIN(MYOGLOBIN)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM ON BECKMAN COULTER ANALYSERS., HDL- CHOLESTEROL(HDL- CHOLESTEROL)-ENZYMATIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF HDL-CHOLESTEROL IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS. OSR6687 FOR USE ON THE AU5800, AU2700 AND AU5400 SYSTEMS ONLY.,CK-MB CONTROL SERUM LEVEL 2(CK-MB CONTROL SERUM LEVEL 2)-THE CK-MB CONTROL SERUM LEVEL 2 IS A LYOPHILISED HUMAN SERUM CONTROL DESIGNED TO MONITOR THE ACCURACY AND PRECISION OF THE CK-MB REAGENT OSR61155 ON BECKMAN COULTER ANALYSERS.,HDL-CHOLESTEROL CALIBRATOR(HDL-CHOLESTEROL CALIBRATOR)-THE HDL-CHOLESTEROL CALIBRATOR IS A LYOPHILISED HUMAN SERUM CALIBRATOR INTENDED TO BE USED WITH THE HDL-CHOLESTEROL REAGENT OSR6187/OSR6287/OSR6687 FOR THE QUANTITATIVE DETERMINATION OF HDL-CHOLESTEROL ON BECKMAN COULTER ANALYSERS.,SYSTEM CALIBRATOR(SYSTEM CALIBRATOR)-THE SYSTEM CALIBRATOR IS A CALIBRATION SERUM INTENDED TO BE USED WITH BECKMAN COULTER SYSTEM REAGENTS ON BECKMAN COULTER AU ANALYSERS.,CK-MB CONTROL SERUM LEVEL 1(CK-MB CONTROL SERUM LEVEL 1)-THE CK-MB CONTROL SERUM LEVEL 1 IS A LYOPHILISED HUMAN SERUM CONTROL DESIGNED TO MONITOR THE

	ACCURACY AND PRECISION OF THE CK-MB REAGENT OSR61155 ON BECKMAN COULTER ANALYSERS.,ITA CONTROL SERUM LEVEL 3(ITA CONTROL SERUM LEVEL 3)-THE ITA CONTROL SERUM IS A LIQUID HUMAN SERUM CONTROL INTENDED TO BE USED IN-CONJUNCTION WITH ITA CONTROL SERA ODC0014 AND ODC0015 TO MONITOR THE ANALYTICAL PERFORMANCE OF THE BECKMAN COULTER SYSTEM REAGENTS LISTED BELOW ON BECKMAN COULTER ANALYSERS. ALPHA-1 ACIDGLYCOPROTEIN, FERRITIN, ALPHA-1 ANTITRYPSIN, HAPTOGLOBIN, ANTI-STREPTOLYSIN O, IMMUNOGLOBULIN A, BETA-2 MICROGLOBULIN, IMMUNOGLOBULIN G, CERULOPLASMIN, IMMUNOGLOBULIN M, COMPLEMENT 3, PREALBUMIN, COMPLEMENT 4, RHEUMATOID FACTOR, C-REACTIVE PROTEIN, TRANSFERRIN., URINE CALIBRATOR(URINE CALIBRATOR)-THE URINE CALIBRATOR IS A LIQUID HUMAN URINE CALIBRATOR INTENDED TO BE USED WITH THE BECKMAN COULTER SYSTEM REAGENTS LISTED BELOW ON BECKMAN COULTER ANALYSERS. -AMYLASE OSR6X06/OSR6X82, CALCIUM OSR6X13/OSR6X117, GLUCOSE OSR6X21, INORGANIC PHOSPHOROUS OSR6X22, UREA OSR6X34/OSR6X41, URIC ACID OSR6X98, CREATININE OSR6X78/OSR6X204, MAGNESIUM OSR6X89., DAU SPECIALITY CONTROL(DAU SPECIALITY CONTROL)-THE DAU SPECIALITY CONTROL IS A HUMAN URINE BASED LIQUID CONTROL DESIGNED TO MONITOR THE ANALYTICAL PERFORMANCE OF THE DAU REAGENTS LISTED BELOW ON BECKMAN COULTER ANALYSERS. AMPHETAMINES/ECSTASY OSR6323, BARBITURATES OSR6315, BENZODIAZEPINES OSR6316, COCAINE OSR6317, EDDP OSR6318, OPIATES OSR6320.,DAU MULTI-DRUG CONTROL(DAU MULTI-DRUG CONTROL)-THE DAU MULTI-DRUG CONTROL IS A HUMAN URINE BASED LIQUID CONTROL DESIGNED TO MONITOR THE ANALYTICAL PERFORMANCE OF THE DAU REAGENTS LISTED BELOW ON BECKMAN COULTER ANALYSERS. AMPHETAMINES/ECSTASY OSR6323, BARBITURATES OSR6315, BENZODIAZEPINES OSR6316, COCAINE OSR6317, EDDP OSR6318, METHADONE OSR6319, *OPIATE 2K MICROGENICS CATALOGUE NO. 1815296/100099/100090, *PCP MICROGENICS CATALOGUE NO. 1815784/100173/100172, *PROPOXPHENE MICROGENICS CATALOGUE NO. 1661523/100171/100170. *THE TESTS LISTED ARE FOR USE WITH MICROGENICS LABELLED REAGENTS ONLY.,DIGITOXIN CALIBRATOR (DIGITOXIN CALIBRATOR)-THE DIGITOXIN CALIBRATOR IS A LIQUID HUMAN SERUM BASED MATRIX CALIBRATOR INTENDED TO BE USED WITH THE DIGITOXIN REAGENT OSR6403 FOR THE QUANTITATIVE DETERMINATION OF DIGITOXIN ON BECKMAN COULTER ANALYSERS., LDH(LDH)-KINETIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE, EC 1.1.1.27 (LDH) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU

		ANALYZERS.,CONTROL SERUM 2(CONTROL SERUM 2)-THE CONTROL SERUM 2 IS A LYOPHILISED HUMAN SERUM CONTROL INTENDED TO BE USED IN-CONJUNCTION WITH THE CONTROL SERUM 1 ODC0003 TO MONITOR THE ANALYTICAL PERFORMANCE OF THE BECKMAN COULTER SYSTEM REAGENTS ON BECKMAN COULTER ANALYSERS.
159	IMP/IVD/2019/000107	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIMENSION CLINICAL CHEMISTRY SYSTEM CHEM II CALIBRATOR(DIMENSION CLINICAL CHEMISTRY SYSTEM CHEM II CALIBRATOR)-CHEM II CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT TO BE USED TO CALIBRATE THE DIMENSION CLINICAL CHEMISTRY SYSTEM FOR THE MAGNESIUM (MG), PHOSPHORUS (PHOS) AND TRIGLYCERIDE (TGL) METHODS., DIMENSION CLINICAL CHEMISTRY SYSTEM IRON CALIBRATOR (DIMENSION CLINICAL CHEMISTRY SYSTEM IRON CALIBRATOR)-THE IRON CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED TO CALIBRATE THE IRON METHOD FOR DIMENSION CLINICAL CHEMISTRY SYSTEM.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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160	IMP/IVD/2019/000108	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIMENSION® CLINICAL CHEMISTRY SYSTEM DRUG CALIBRATOR II(DIMENSION® CLINICAL CHEMISTRY SYSTEM DRUG CALIBRATOR II)-DRUG CALIBRATOR II IS AN IN-VITRO DIAGNOSTIC PRODUCT INTENDED FOR THE CALIBRATION OF THE FOLLOWING METHODS PACKAGED IN FLEX REAGENT CARTRIDGES: ACETAMINOPHEN (ACTM), CARBAMAZEPINE (CRBM), DIGITOXIN (DGTX), GENTAMICIN (GENT), LIDOCAINE (LIDO), N-ACETYLPROCAINAMIDE (NAPA), PROCAINAMIDE (PROC), TOBRAMYCIN (TPBR), VALPROIC ACID (VALP), VANCOMYCIN (VANC). , DIMENSION® CLINICAL CHEMISTRY SYSTEM DOA-POSITIVE CONTROL(DIMENSION® CLINICAL CHEMISTRY SYSTEM DOA-POSITIVE CONTROL)-THE DRUGS OF ABUSE POSITIVE CONTROL IS AN IN-VITRO DIAGNOSTIC PRODUCT INTENDED AS A QUALITY CONTROL PRODUCT FOR THE FOLLOWING METHODS PACKAGED IN FLEX REAGENT CARTRIDGES: AMPHETAMINE (AMPH), METHADONE (METH), BARBITURATES (BARB), OPIATES (OPI), BENZODIAZEPINES (BENZ), PHENCYCLIDINE (PCP), COCAINE METABOLITE (COC), AND CANNABINOIDS (THC).,DIMENSION® CLINICAL CHEMISTRY SYSTEM DOA-NEGATIVE CONTROL(DIMENSION® CLINICAL CHEMISTRY SYSTEM DOA-NEGATIVE CONTROL)-THE DRUGS OF ABUSE NEGATIVE CONTROL IS AN IN-VITRO DIAGNOSTIC PRODUCT INTENDED AS A QUALITY CONTROL PRODUCT FOR THE FOLLOWING METHODS PACKAGED IN FLEX REAGENT CARTRIDGES: AMPHETAMINE (AMPH), METHADONE (METH), BARBITURATES (BARB), OPIATES (OPI), BENZODIAZEPINES (BENZ), PHENCYCLIDINE (PCP), COCAINE METABOLITE (COC), AND CANNABINOIDS (THC).

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

161	IMP/IVD/2019/000109	1.License Holder Name: SYSMEX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:UFII CONTROL(UFII CONTROL)-UFII CONTROL CONTAINS CONTROL PARTICLES FOR USE IN QUALITY CONTROL MODE OF THE SYSMEX FULLY AUTOMATED URINE PARTICLE ANALYZER (UF-1000I AND UF-500I) AND FULLY AUTOMATED INTEGRATED URINE ANALYZER (UX-2000)., CALIBRATOR(CA CAL S)-THE PRODUCT IS APPLIED TO CALIBRATE THE SENSITIVITY OF LEDS USED FOR BLOOD COAGULATION ANALYZER. ,UF-CONTROL(UF-CONTROL)-FOR IN-VITRO DIAGNOSTIC USE ONLY. UF-CONTROL CONTAINS CONTROL PARTICLES FOR USE IN QUALITY CONTROL MEASUREMENT PROCEDURE OF THE SYSMEX FULLY AUTOMATED URINE PARTICLE ANALYZER. THE QUALITY CONTROL PARAMETERS INCLUDE: RBC (/L), WBC (/L), EC (/L), CAST (/L), BACT (/L), COND. (MS/CM). NOTE: COND. (MS/CM) IS NOT REPORTABLE PARAMETER.,MEDITAPE CHECK 2(MEDITAPE CHECK 2)-MEDITAPE CHECK 2 IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PRECISION AND ACCURACY OF THE SYSMEX FULLY AUTOMATED INTEGRATED URINE ANALYZER (UX-2000). ,MEDITAPE CHECK 1 (MEDITAPE CHECK 1)-MEDITAPE CHECK 1 IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PRECISION AND ACCURACY OF THE SYSMEX FULLY AUTOMATED INTEGRATED URINE ANALYZER (UX-2000). ,UFII CALIBRATOR(UFII CALIBRATOR)-UFII CALIBRATOR IS A CALIBRATION MATERIAL DEVELOPED TO ADJUST THE SENSITIVITY OF THE SYSMEX FULLY AUTOMATED URINE PARTICLE ANALYZER (UF-1000I AND UF-500I) AND FULLY AUTOMATED INTEGRATED URINE ANALYZER (UX-2000). UF CALIBRATOR IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY. UF CALIBRATOR IS ONLY TO BE USED BY TRAINED FIELD SERVICE PERSONNEL. ,UF-CALIBRATOR(UF-CALIBRATOR)-UF-CALIBRATOR IS A CALIBRATION MATERIAL DEVELOPED TO ADJUST THE SENSITIVITY OF THE SYSMEX FULLY AUTOMATED URINE PARTICLE ANALYZER. UF-CALIBRATOR IS ONLY TO BE USED BY TRAINED FIELD SERVICE PERSONNEL. THE CALIBRATION PARAMETERS INCLUDE: WBC (/L), COND. (MS/CM). NOTE: COND. (MS/CM) IS NOT REPORTABLE PARAMETER

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

162	IMP/IVD/2019/000111	1.License Holder Name: M/S. BEACON DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASO LATEX-TO BE USED FOR QUALITATIVE DETERMINATION OF ASO IN SERUM/PLASMA,CRP LATEX-TO BE USED FOR QUALITATIVE DETERMINATION OF CRP IN SERUM/PLASMA,CRP TURBILATEX WITH CALIBRATOR-TO BE USED FOR QUANTITATIVE DETERMINATION OF CRP IN SERUM/PLASMA,RF TURBILATEX KIT WITH CALIBRATOR-TO BE USED FOR QUANTITATIVE DETERMINATION OF RF IN SERUM/PLASMA. ,HBA1C KIT WITH CALIBRATOR-TO BE USED FOR QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C IN HUMAN BLOOD.,RF/ASO/CRP POSITIVE CONTROL-TO BE USED FOR QUANTITATIVE DETERMINATION OF ASO, CRP, RF IN SERUM.,CRP ULTRA TURBILATEX WITH CALIBRATOR-TO BE USED FOR QUANTITATIVE DETERMINATION OF LOW LEVEL OF CRP IN SERUM.,MICROALBUMIN TURBILATEX KIT WITH CALIBRATOR-TO BE USED FOR QUANTITATIVE DETERMINATION OF MICROALBUMIN IN URINE.,ASO TURBILATEX KIT WITH CALIBRATOR-TO BE USED FOR QUANTITATIVE DETERMINATION OF ASO IN SERUM/PLASMA,RF LATEX-TO BE USED FOR QUALITATIVE DETERMINATION OF RF IN SERUM/PLASMA
163	IMP/IVD/2019/000112	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIMENSION® CLINICAL CHEMISTRY SYSTEM PURIFIED WATER DILUENT(DIMENSION® CLINICAL CHEMISTRY SYSTEM PURIFIED WATER DILUENT)-FOR USE WITH SIEMENS DIMENSION CLINICAL CHEMISTRY SYSTEM AS SYSTEM WATER AND AS A DILUENT.,DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE SAMPLE PROBE CLEANER(DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE SAMPLE PROBE CLEANER)-FOR USE ON THE DIMENSION SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE.,DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE CHEMISTRY WASH(DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE CHEMISTRY WASH)-FOR USE ON THE DIMENSION SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE.

164	IMP/IVD/2019/000113	1.License Holder Name: DIASORIN HEALTHCARE INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIAISON PSA CONTROL (LIAISON PSA CONTROL)-THE LIAISON® PSA CONTROLS (LOW AND HIGH) ARE TO BE USED IN LIAISON® CHEMILUMINESCENT IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROL PSA HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.,LIAISON FPSA(LIAISON FPSA)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE HUMAN PROSTATE-SPECIFIC ANTIGEN (FPSA) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARINISED). THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON PSA(LIAISON PSA)-IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN PROSTATE-SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM AND PLASMA (HEPARINISED, EDTA) DURING THE FOLLOW-UP OF PATIENTS WITH CARCINOMA OF THE PROSTATE. THE TEST HAS TO BE PERFORMED ON THE LIAISON® ANALYZER FAMILY.,LIAISON FPSA CONTROL (LIAISON FPSA CONTROL)-THE LIAISON® FPSA CONTROLS (LOW AND HIGH) ARE TO BE USED IN LIAISON® FPSA CHEMILUMINESCENT IMMUNOASSAYS (CLIA) AS A MEANS OF CHECKING RELIABILITY OF ASSAY RUNS. THE PERFORMANCE CHARACTERISTICS OF LIAISON® CONTROL FPSA HAVE NOT BEEN ESTABLISHED FOR ANY OTHER ASSAYS OR INSTRUMENT PLATFORMS DIFFERENT FROM LIAISON® AND LIAISON® XL.
165	IMP/IVD/2019/000114	1.License Holder Name: MICROGENE DIAGNOSTIC SYSTEMS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE METER (ACCUSURE SOUL)-THE ACCUSURE SOUL BLOOD GLUCOSE METER IS USED WITH THE ACCUSURE SOUL BLOOD GLUCOSE TEST STRIPS TO QUANTITATIVELY MEASURE GLUCOSE IN WHOLE BLOOD.,BLOOD GLUCOSE TEST STRIP(ACCUSURE SOUL)-ACCUSURE SOUL BLOOD GLUCOSE TEST STRIPS IS USED ALONG WITH BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO MONITOR BLOOD GLUCOSE IN HUMAN BLOOD ,BLOOD GLUCOSE TEST STRIPS(ACCUSURE FORA BLOOD GLUCOSE TEST STRIPS)-ACCUSURE FORA BLOOD GLUCOSE TEST STRIPS IS USED ALONG WITH BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO MONITOR BLOOD GLUCOSE IN WHOLE BLOOD

166	IMP/IVD/2019/000117	1.License Holder Name: BIOCELL MEDICARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HBA1C CONTROL HIGH (ISE)-FOR EVALUATION OF RESULTS VIS A VIS WITH HBA1C KIT., SYSTEMIC SOLUTION(ISE)-FOR CLEANING AND MAINTENANCE OF THE EQUIPMENT.,HBA1C CALIBRATOR(ISE)-TO BE USED IN CONJUNCTION WITH HBA1C KIT FOR CALIBRATION.,SYSTEM CLEANER(ISE)-FOR CLEANING AND MAINTENANCE OF THE EQUIPMENT.,HBA1C KIT(ISE)-FOR EVALUATION OF GLYCEATED HEMOGLOBIN IN PATIENT SAMPLES.,RINSE SOLUTION (CVT)(ISE)-FOR CLEANING AND MAINTENANCE OF THE EQUIPMENT.,HBA1C CONTROL LOW(ISE)-FOR EVALUATION OF RESULTS VIS A VIS WITH HBA1C KIT
167	IMP/IVD/2019/000118	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTI-KELL RARE ANTISERA(ANTI-KELL (KEL1) MONOCLONAL IGM (HUMAN) BIOCLONE®)-QUALITATIVE TEST WITH MONOCLONAL ANTIBODY FOR RECOGNITION OF THE KELL ANTIGEN ON HUMAN RED BLOOD CELLS. FOR IN VITRO DIAGNOSTIC USE.,ANTI-E RARE ANTISERA (ANTI-E (RH5) MONOCLONAL IGM BLEND (HUMAN) BIOCLONE®)-QUALITATIVE TEST WITH MONOCLONAL ANTIBODIES FOR RECOGNITION OF THE E (RH5) ANTIGEN ON HUMAN RED BLOOD CELLS. FOR IN VITRO DIAGNOSTIC USE.,ORTHO BLISS(ORTHO® BLISS)-LOW IONIC STRENGTH SOLUTION (LISS) FOR USE WITH THE ORTHO BIOVUE® SYSTEM. FOR IN VITRO DIAGNOSTIC USE

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168	IMP/IVD/2019/000119	1.License Holder Name: M/S.TRANSASIA BIO-MEDICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ERBA THROMBIN TIME (ERBA THROMBIN TIME)-INTENDED FOR THE DETERMINATION OF THE THROMBIN TIME.,ERBA PROTIME(ERBA PROTIME)-INTENDED FOR THE DETERMINATION OF THE PROTHROMBIN TIME (PT).,ERBA LA1 SCREEN (ERBA LA1 SCREEN)-INTENDED FOR THE QUALITATIVE DETERMINATION OF LA (LUPUS ANTICOAGULANTS) IN HUMAN PLASMA.,ERBA FACTOR X DEFICIENT PLASMA(ERBA FACTOR X DEFICIENT PLASMA)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE FACTOR X IN PATIENTS SUSPECTED OF HAVING A CONGENITAL OR ACQUIRED DEFICIENCY OF THIS COAGULATION PROTEIN.,ERBA CONTROL P(ERBA CONTROL P)-"PATHOLOGICAL HAEMOSTASIS ROUTINE CONTROL ",ERBA FACTOR IX DEFICIENT PLASMA(ERBA FACTOR IX DEFICIENT PLASMA)-"INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE FACTOR IX IN PATIENTS SUSPECTED OF HAVING A CONGENITAL OR ACQUIRED DEFICIENCY OF THIS COAGULATION PROTEIN. ",ERBA FACTOR VIII DEFICIENT PLASMA(ERBA FACTOR VIII DEFICIENT PLASMA)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE FACTOR VIII IN PATIENTS SUSPECTED OF HAVING A CONGENITAL OR ACQUIRED DEFICIENCY OF THIS COAGULATION PROTEIN.,ERBA FACTOR XI DEFICIENT PLASMA(ERBA FACTOR XI DEFICIENT PLASMA) -"INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE FACTOR XI IN PATIENTS SUSPECTED OF HAVING A CONGENITAL OR ACQUIRED DEFICIENCY OF THIS COAGULATION PROTEIN. ",ERBA STANDARD PLASMA(ERBA STANDARD PLASMA)-HAEMOSTASIS CALIBRATION PLASMA.,ERBA THROMBIN REAGENT(ERBA THROMBIN REAGENT)-INTENDED FOR USE IN THE QUANTITATIVE DETERMINATION OF FIBRINOGEN IN HUMAN PLASMA.,ERBA PT-INR MULTICAL(ERBA PT-INR MULTICAL)-"A SET OF CITRATED PLASMA INTENDED FOR ESTABLISHING CALIBRATION CURVES REQUIRED IN TESTING FOR PROTHROMBIN TIME (PT) AND FOR AIDING IN THE VERIFICATION OF THE ISI VALUE OF THE ERBA PROTIME USED. ", ERBA FACTOR XII DEFICIENT PLASMA(ERBA FACTOR XII DEFICIENT PLASMA)-"INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE FACTOR XII IN PATIENTS SUSPECTED OF HAVING A CONGENITAL OR ACQUIRED DEFICIENCY OF THIS COAGULATION PROTEIN. ",ERBA OWRENS VERONAL BUFFER(ERBA OWRENS VERONAL BUFFER)-UNIVERSAL BUFFER USED IN QUANTITATIVE COAGULATION STUDIES ON HUMAN PLASMA.,ERBA PROTEIN S CLOTTING(ERBA PROTEIN S CLOTTING)-INTENDED FOR THE DETERMINATION OF FUNCTIONAL PROTEIN S LEVELS IN HUMAN PLASMA BY CLOTTING,ERBA PROTIME LS(ERBA PROTIME LS)-"A LIQUID READY TO USE RABBIT BRAIN

	THROMBOPLASTIN INTENDED FOR THE DETERMINATION OF THE PROTHROMBIN TIME (PT). ",ERBA CONTROL N(ERBA CONTROL N)-NORMAL HAEMOSTASIS ROUTINE CONTROL,ERBA CONTROL N PLUS (ERBA CONTROL N PLUS)-"NORMAL HAEMOSTASIS CONTROL (SPECIAL ASSAYS) ",ERBA CALCIUM CHLORIDE(ERBA CALCIUM CHLORIDE)-"ERBA CALCIUM CHLORIDE – 0.025 M CACL2 IS INTENDED FOR USE WITH ERBA ACTIME REAGENT FOR THE DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) OR FOR THE ASSAYS OF INTRINSIC PATHWAY FACTORS. ",ERBA CONTROL P PLUS(ERBA CONTROL P PLUS)-"ABNORMAL HAEMOSTASIS CONTROL (SPECIAL ASSAYS) ",ERBA LA CONTROL HIGH(ERBA LA CONTROL HIGH)-CONTROL FOR THE DETERMINATION OF LUPUS ANTICOAGULANTS (LA).,ERBA DDIMER CALIBRATOR(ERBA DDIMER CALIBRATOR)-"ERBA DDIMER CALIBRATOR MAY BE USED TO ESTABLISH CALIBRATION CURVE IN THE QUANTITATIVE DETERMINATION OF D-DIMER. ",ERBA CHROM ANTITHROMBIN III (ERBA CHROM ANTITHROMBIN III)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF ANTITHROMBIN III (AT-III) ACTIVITY IN HUMAN CITRATED PLASMA BY CHROMOGENIC ASSAY., ERBA CHROM PROTEIN C(ERBA CHROM PROTEIN C)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF PROTEIN C IN HUMAN PLASMA USING A CHROMOGENIC ASSAY METHOD.,ERBA LA2 CONFIRM(ERBA LA2 CONFIRM)-INTENDED FOR THE QUALITATIVE DETERMINATION OF LA (LUPUS ANTICOAGULANTS) IN HUMAN PLASMA.,ERBA FACTOR VII DEFICIENT PLASMA(ERBA FACTOR VII DEFICIENT PLASMA)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE FACTOR VII IN PATIENTS SUSPECTED OF HAVING A CONGENITAL OR ACQUIRED DEFICIENCY OF THIS COAGULATION PROTEIN.,ERBA FACTOR V DEFICIENT PLASMA(ERBA FACTOR V DEFICIENT PLASMA)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE FACTOR V IN PATIENTS SUSPECTED OF HAVING A CONGENITAL OR ACQUIRED DEFICIENCY OF THIS COAGULATION PROTEIN.,ERBA FACTOR II DEFICIENT PLASMA(ERBA FACTOR II DEFICIENT PLASMA)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE FACTOR II IN PATIENTS SUSPECTED OF HAVING A CONGENITAL OR ACQUIRED DEFICIENCY OF THIS COAGULATION PROTEIN.,ERBA DDIMER R(ERBA DDIMER R)-ERBA DDIMER R IS AN IMMUNOTURBIDIMETRIC ASSAY USED FOR THE QUANTITATIVE DETERMINATION OF THE FIBRIN DEGRADATION PRODUCTS THAT CONTAIN D-DIMER IN HUMAN PLASMA.,ERBA DDIMER CONTROL N+P(ERBA DDIMER CONTROL N+P)-ERBA DDIMER CONTROL N + P MAY BE USED AS A LOW AND A HIGH CONTROLS RESPECTIVELY, FOR THE D-DIMER TESTS.,ERBA ACTIME(ERBA ACTIME)-"INTENDED FOR THE DETERMINATION OF THE ACTIVATED

	PARTIAL THROMBOPLASTIN TIME (APTT), AND RELATED COAGULATION USING PHOSPHOLIPID EXTRACT AND A NEAR-COLLODIAL PARTICLE ACTIVATOR. "

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169	IMP/IVD/2019/000121	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABIA HEV IGG(ABIA HEV IGG)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO HEPATITIS E VIRUS (HEV) IN HUMAN SERUM OR PLASMA ,ABIA TESTOSTERONE(ABIA TESTOSTERONE)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE CONCENTRATION IN HUMAN SERUM ,ABIA FT4(ABIA FT4)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) CONCENTRATION IN HUMAN SERUM ,ABIA PROGESTERONE(ABIA PROGESTERONE)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE CONCENTRATION IN HUMAN SERUM ,ABIA HEV IGM(ABIA HEV IGM)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO HEPATITIS E VIRUS (HEV) IN HUMAN SERUM OR PLASMA. ,ABIA TSH(ABIA TSH)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE IN HUMAN SERUM. ,ABIA TG AB(ABIA TG AB) -IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETECTION OF ANTI-THYROGLOBULIN (TG) CONCENTRATION IN HUMAN SERUM ,ABIA HCG(ABIA HCG)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETERMINATION OF INTACT HUMAN CHORIONIC GONADOTROPIN (HCG) CONCENTRATION IN HUMAN SERUM ,ABIA FSH(ABIA FSH)-"IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE (FSH) CONCENTRATION IN HUMAN SERUM " ,ABIA IGE TOTAL(ABIA IGE TOTAL)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL IMMUNOGLOBULIN E (IGE) CONCENTRATION IN HUMAN SERUM ,ABIA LH(ABIA LH)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) CONCENTRATION IN HUMAN SERUM ,ABIA T3 TOTAL(ABIA T3 TOTAL)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE CONCENTRATION IN HUMAN SERUM. ,ABIA FT3(ABIA FT3)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE CONCENTRATION IN HUMAN SERUM. ,ABIA T4 TOTAL(ABIA T4 TOTAL)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE (T4) CONCENTRATION IN HUMAN SERUM,ABIA TPO AB(ABIA TPO AB)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE

		DETERMINATION OF ANTI-THYROID PEROXIDASE CONCENTRATION IN HUMAN SERUM ,ABIA PRL(ABIA PRL)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) CONCENTRATION IN HUMAN SERUM ,ABIA CORTISOL(ABIA CORTISOL)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETERMINATION OF CORTISOL CONCENTRATION IN HUMAN SERUM ,ABIA TG(ABIA TG)-IN-VITRO-DIAGNOSTIC TEST KIT INTENDED FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) CONCENTRATION IN HUMAN SERUM
170	IMP/IVD/2019/000122	1.License Holder Name: SYSMEX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:UC-CONTROL(UC-CONTROL)-FOR IN-VITRO DIAGNOSTICS USE ONLY UC-CONTROL IS USED FOR QUALITY CONTROLLING THE SYSMEX URINE CHEMISTRY ANALYZER (UC-3500 AND UC-1000)
171	IMP/IVD/2019/000124	1.License Holder Name: NECTAR BIO PHARMA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE MONITORING SYSTEM(DR TRUST)-SYSTEM IS INTENDED FOR USE OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) BY PEOPLE WITH DIABETES AT HOME AND HEALTH CARE PROFESSIONAL IN CLINICAL SETTING AS AN AID TO MONITORING THE EFFECTIVENESS OF DIABETES CONTROL. IT IS INTENDED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE (SUGAR) IN FRESH WHOLE BLOOD SAMPLE (FROM THE FINGER,PALM,FOREARM AND UPPER ARM.,BLOOD GLUCOSE TEST STRIP(DR. TRUST BLOOD GLUCOSE TEST STRIPS)-BLOOD GLUCOSE TESTING

172	IMP/IVD/2019/000125	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ITA CONTROL SERUM 3-THE ITA CONTROL SERUM IS A LIQUID HUMAN SERUM CONTROL INTENDED TO BE USED IN-CONJUNCTION WITH ITA CONTROL SERA ODC0014 AND ODC0015 TO MONITOR THE ANALYTICAL PERFORMANCE OF THE BECKMAN COULTER SYSTEM REAGENTS,ITA CONTROL SERUM 2-THE ITA CONTROL SERUM IS A LIQUID HUMAN SERUM CONTROL INTENDED TO BE USED IN-CONJUNCTION WITH ITA CONTROL SERA ODC0014 AND ODC0016 TO MONITOR THE ANALYTICAL PERFORMANCE OF THE BECKMAN COULTER SYSTEM REAGENTS,ITA CONTROL SERUM 1-THE ITA CONTROL SERUM IS A LIQUID HUMAN SERUM CONTROL INTENDED TO BE USED IN-CONJUNCTION WITH ITA CONTROL SERA ODC0015 AND ODC0016 TO MONITOR THE ANALYTICAL PERFORMANCE OF THE BECKMAN COULTER SYSTEM REAGENTS.,CRP (LATEX) CONTROL SERUM-THE CRP (LATEX) CONTROL SERUM IS A LIQUID HUMAN SERUM CONTROL DESIGNED TO MONITOR THE ANALYTICAL PERFORMANCE OF THE SENSITIVE AND HIGHLY SENSITIVE APPLICATIONS OF THE CRP LATEX REAGENT OSR6199 ON BECKMAN COULTER ANALYSERS.

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173	IMP/IVD/2019/000126	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BENCHMARK SPECIAL STAINS WASH II(BENCHMARK SPECIAL STAINS WASH II)-THE BENCHMARK SPECIAL STAINS WASH II IS INTENDED FOR LABORATORY USE TO PRODUCE OPTIMIZED STAINING RESULTS FOR USE WITH THE SPECIAL STAINS REAGENTS AND STAINING KITS. WHEN DILUTED AND PREPARED ACCORDING TO INSTRUCTIONS, THIS SOLUTION PROVIDES A STABLE AQUEOUS ENVIRONMENT FOR QUALITATIVE HISTOLOGICAL STAIN IN SECTIONS OF FORMALIN-FIXED, PARAFFINEMBEDDED (FFPE) TISSUE STAINED ON A BENCHMARK SPECIAL STAINS INSTRUMENT. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. ,ANTI- ACTIN, MUSCLE (HUC 1-1) PRIMARY ANTIBODY(ANTI- ACTIN, MUSCLE (HUC 1-1) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) ANTI-ACTIN, MUSCLE (HUC 1-1) MAY BE USED TO AID IN THE IDENTIFICATION OF CELLS OF NORMAL AND ABNORMAL MYOCYTIC LINEAGE AS AN AID IN DIAGNOSIS OF ANAPLASTIC TUMORS. ANTI-ACTIN, MUSCLE (HUC 1-1) SPECIFICALLY BINDS TO ANTIGENS LOCATED IN THE CYTOPLASM OF MYOCYTIC CELLS. THIS ANTIBODY IS INTENDED FOR LABORATORY USE TO QUALITATIVELY IDENTIFY BY LIGHT MICROSCOPY MUSCLE ACTIN IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIEN'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY., BENCHMARK SPECIAL STAINS LIQUID COVERSLIP(BENCHMARK SPECIAL STAINS LIQUID COVERSLIP)-BENCHMARK SPECIAL STAINS LIQUID COVERSLIP IS A PREDILUTED COVERSLIP SOLUTION INTENDED FOR LABORATORY USE AS A BARRIER BETWEEN THE AQUEOUS REAGENTS AND THE AIR. THIS BARRIER PREVENTS EVAPORATION, THEREBY PROVIDING A STABLE AQUEOUS ENVIRONMENT FOR SPECIAL STAINS REACTIONS ON A BENCHMARK SPECIAL STAINS INSTRUMENT. BENCHMARK SPECIAL STAINS LIQUID COVERSLIP IS ALSO USED TO SOLUBILIZE PARAFFIN DURING THE DEPARAFFINIZATION PROCESS FOR SLIDES CONTAINING FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) TISSUES WHEN USING THE AFB STAINING PROCEDURE ON A BENCHMARK SPECIAL STAINS INSTRUMENT. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC USE.,PATHWAY ANTI-C-KIT (9.7) PRIMARY ANTIBODY(PATHWAY

	ANTI-C-KIT (9.7) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' PATHWAY ANTI-C-KIT (9.7) PRIMARY ANTIBODY IS INTENDED FOR LABORATORY USE, VIA LIGHT MICROSCOPY, FOR THE QUALITATIVE DETECTION OF KIT PROTEIN IN FORMALIN FIXED, PARAFFIN-EMBEDDED GASTROINTESTINAL STROMAL TUMORS (GISTS) USING EITHER AN AUTOMATED IMMUNOHISTOCHEMISTRY STAINING SYSTEM OR A MANUAL ASSAY. IT IS INDICATED AS AN AID IN THE DIAGNOSIS OF GIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY, TUMOR MORPHOLOGY, AND OTHER DIAGNOSTIC TESTS EVALUATED BY A QUALIFIED PATHOLOGIST. IT MAY BE USED AFTER THE DIAGNOSIS OF GIST AS AN AID IN THE SELECTION OF GIST PATIENTS WHO MAY QUALIFY FOR IMATINIB MESYLATE (GLEEVEC®/GLIVEC®) THERAPY. PATHWAY ANTI-C- KIT (9.7) PRIMARY ANTIBODY IS OPTIMIZED FOR USE ON VENTANA AUTOMATED SLIDE STAINER AND FOR MANUAL APPLICATION IN COMBINATION WITH VENTANA MEDICAL SYSTEMS' IVIEW™ DAB DETECTION KIT AND ACCESSORIES. THE CIINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. NOTE: THE TEST IS NOT INTENDED AS THE SOLE BASIS FOR MAKING THE DIAGNOSIS OF GIST AND IS NOT INTENDED AS THE SOLE BASIS FOR SELECTING GLEEVEC/GLIVEC THERAPY. THE PROPORTION OF C-KIT NEGATIVE GIST PATIENTS WHO CAN RESPOND TO GLEEVEC/GLIVEC HAS NOT BEEN ESTABLISHED. A NEGATIVE RESULT WOULD NOT NECESSARILY EXCLUDE THE DIAGNOSIS OF GIST, NOR SHOULD IT PRECLUDE TREATMENT WITH GLEEVEC/GLIVEC (14, 34, 39). ALL OF THE SUBJECTS IN THE NOVARTIS GLEEVEC/GLIVEC CLINICAL TRIALS WERE SELECTED USING AN INVESTIGATIONAL IMMUNOCYTOCHEMICAL ANTIBODY (ICA). NONE OF THE SUBJECTS IN THOSE TRIALS WERE SELECTED USING THE VENTANA PATHWAY ANTI-C-KIT(9.7) PRIMARY ANTIBODY. THE VENTANA PATHWAY ANTI-C-KIT (9.7) PRIMARY ANTIBODY WAS COMPARED TO THE ICA ON INDEPENDENT SETS OF SAMPLES AND FOUND TO PROVIDE ACCEPTABLY CONCORDANT RESULTS.,BENCHMARK SPECIAL STAINS DEPARAFFINIZATION SOLUTION (10X)(BENCHMARK SPECIAL STAINS DEPARAFFINIZATION SOLUTION (10X))-BENCHMARK SPECIAL STAINS DEPARAFFINIZATION SOLUTION (10X) IS INTENDED FOR LABORATORY USE TO SOLUBILIZE PARAFFIN DURING THE DEPARAFFINIZATION PROCESS FOR SLIDES CONTAINING FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) TISSUES DURING SPECIAL

	STAINS PROCEDURES ON A BENCHMARK SPECIAL STAINS INSTRUMENT. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,ANTI-CYTOKERATIN 5/6 (D5/16B4) MOUSE MONOCLONAL PRIMARY ANTIBODY(ANTI-CYTOKERATIN 5/6 (D5/16B4) MOUSE MONOCLONAL PRIMARY ANTIBODY)-ANTI-CYTOKERATIN 5/6 (D5/16B4) MOUSE MONOCLONAL PRIMARY ANTIBODY (ANTI-CYTOKERATIN 5/6 (D5/16B4)) DETECTS CYTOKERATINS 5 AND 6. CYTOKERATIN 5 IS EXPRESSED IN VARIOUS EPITHELIA AND MESOTHELIAL CELLS, WHILE CYTOKERATIN 6 IS EXPRESSED BY PROLIFERATING SQUAMOUS EPITHELIUM. THIS ANTIBODY EXHIBITS A CYTOPLASMIC STAINING PATTERN AND MAY BE USED TO AID IN THE IDENTIFICATION OF SQUAMOUS CELL CARCINOMA AND IN DISTINGUISHING MALIGNANT MESOTHELIOMA FROM LUNG ADENOCARCINOMAS. THE DETECTION OF CYTOKERATIN 5 IN MYOEPITHELIAL CELLS WITH THIS ANTIBODY MAY ALSO BE USED TO AID IN THE DETERMINATION OF BREAST AND PROSTATE MALIGNANCIES. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,RABBIT ANTI-DNP ANTIBODY(RABBIT ANTI-DNP ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) RABBIT ANTI-DNP ANTIBODY IS INTENDED FOR USE WITH THE ISH DETECTION KITS TO DETECT DINITROPHENYL (DNP) LABELED PROBES THAT HAVE HYBRIDIZED TO TARGETS IN SAMPLES OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUES STAINED USING A VENTANA AUTOMATED SLIDE STAINER AND VISUALIZED BY LIGHT MICROSCOPY. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS., VENTANA HE 600 HEMATOXYLIN(VENTANA HE 600 HEMATOXYLIN)-VENTANA HE 600 SOLUTIONS ARE INTENDED FOR USE AS A QUALITATIVE HISTOLOGIC STAIN TO DEMONSTRATE NUCLEAR AND CYTOPLASMIC STAINING OF FIXED TISSUE COMPONENTS IN PARAFFIN EMBEDDED TISSUE. VENTANA HE 600 HEMATOXYLIN IS A PROGRESSIVE STAIN USED FOR NUCLEAR STAINING. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS

	INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,PROTEASE 1 (PROTEASE 1)-THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) PROTEASE 1 IS AN ENDOPEPTIDASE (ALKALINE PROTEASE) OF THE SERINE PROTEASE FAMILY AND CLEAVES ANTIGENS (PROTEINS) IN THE TISSUE SECTION, ALLOWING PRIMARY ANTIBODIES TO RECOGNIZE AND BIND EPITOPE(S). THE REAGENT IS INTENDED FOR ENZYMATIC DIGESTION OF SECTIONS OF ROUTINE FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE ON VENTANA AUTOMATED SLIDE STAINERS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,VENTANA HE 600 WASH (VENTANA HE 600 WASH)-VENTANA HE 600 SOLUTIONS ARE INTENDED FOR USE AS A QUALITATIVE HISTOLOGIC STAIN TO DEMONSTRATE NUCLEAR AND CYTOPLASMIC STAINING OF FIXED TISSUE COMPONENTS IN PARAFFIN EMBEDDED TISSUE. VENTANA HE 600 WASH REAGENT IS USED AS A RINSE SOLUTION ON THE VENTANA HE 600 SYSTEM.THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA ANTI-CYCLIN D1 (SP4-R) RABBIT MONOCLONAL PRIMARY ANTIBODY(VENTANA ANTI-CYCLIN D1 (SP4-R) RABBIT MONOCLONAL PRIMARY ANTIBODY)-" VENTANA ANTI-CYCLIN D1 (SP4-R) RABBIT MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI- CYCLIN D1 (SP4-R)) IS DIRECTED AGAINST THE CYCLIN D1 MOLECULE, A KEY CELL CYCLE REGULATOR, EXPRESSED PRIMARILY DURING THE G1 PHASE OF THE CELL CYCLE. THIS ANTIBODY EXHIBITS A NUCLEAR STAINING PATTERN, AND MAY BE USED TO AID IN THE IDENTIFICATION OF MANTLE CELL LYMPHOMA, AND BREAST CARCINOMA. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE." ,VENTANA HE 600 COVERSLIP ACTIVATOR (VENTANA HE 600 COVERSLIP ACTIVATOR)-VENTANA HE 600 SOLUTIONS ARE INTENDED FOR USE AS A QUALITATIVE HISTOLOGIC STAIN TO DEMONSTRATE NUCLEAR AND CYTOPLASMIC STAINING OF FIXED TISSUE COMPONENTS IN PARAFFIN EMBEDDED TISSUE.

	VENTANA HE 600 COVERSLIP ACTIVATOR IS A LIMONENE SOLUTION THAT ACTIVATES THE GLUE LAYER ON THE COVERSLIP ALLOWING IT TO ADHERE TO THE UNDERLYING SLIDE AND TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,HEMATOXYLIN (HEMATOXYLIN)-THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC USE. VENTANA MEDICAL SYSTEMS HEMATOXYLIN COUNTERSTAIN REAGENT IS A IS MODIFIED GILL'S HEMATOXYLIN AND IS INTENDED FOR STAINING CELLULAR NUCLEI ON SLIDES CONTAINING CELLS FROM FROZEN TISSUE, FORMALIN FIXED AND PARAFFIN EMBEDDED TISSUE, OR CYTOLOGIC PREPARATIONS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS., VENTANA HE 600 EOSIN(VENTANA HE 600 EOSIN)-VENTANA HE 600 SOLUTIONS ARE INTENDED FOR USE AS A QUALITATIVE HISTOLOGIC STAIN TO DEMONSTRATE NUCLEAR AND CYTOPLASMIC STAINING OF FIXED TISSUE COMPONENTS IN PARAFFIN EMBEDDED TISSUE. IN THE VENTANA HE 600 SYSTEM, VENTANA HE 600 EOSIN PROVIDES A COUNTERSTAIN FOR THE HEMATOXYLIN STAINED CELLULAR NUCLEI AND ALSO ALLOWS THE NON-NUCLEAR TISSUE COMPONENTS TO BE CLEARLY DIFFERENTIATED FROM EACH OTHER. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,FITC ANTI- ALBUMIN PRIMARY ANTIBODY(FITC ANTI- ALBUMIN PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) SYSTEMS FITC ANTI-ALBUMIN PRIMARY ANTIBODY IS A GOAT DERIVED POLYCLONAL ANTIBODY LABELED WITH FLUORESCEIN AND SPECIFICALLY DIRECTED AGAINST HUMAN ALBUMIN. THIS REAGENT SHOULD BE USED IN CONJUNCTION WITH A PANEL OF ANTIBODIES TO AID IN THE IDENTIFICATION OF HUMAN ALBUMIN IN TARGET TISSUE (E.G., IN THE DIAGNOSIS OF RENAL OR DERMAL PATHOLOGIES). FITC ANTI-ALBUMIN IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN SECTIONS OF FROZEN TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER

	CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY., VENTANA HE 600 CLEANING SOLUTION(VENTANA HE 600 CLEANING SOLUTION)-VENTANA HE 600 SOLUTIONS ARE INTENDED FOR USE AS A QUALITATIVE HISTOLOGIC STAIN TO DEMONSTRATE NUCLEAR AND CYTOPLASMIC STAINING OF FIXED TISSUE COMPONENTS IN PARAFFIN EMBEDDED TISSUE. VENTANA HE 600 CLEANING SOLUTION IS AN ONBOARD CLEANING SOLUTION DESIGNED TO QUICKLY AND EFFICIENTLY DISSOLVE HEMATOXYLIN PRECIPITATE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,HPV FAMILY 6 SYSTEM CONTROL SLIDES (B)(HPV FAMILY 6 SYSTEM CONTROL SLIDES (B))-THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) HPV FAMILY 6 SYSTEM CONTROL SLIDES (B) CONTAIN 10 SLIDES FOR USE ON THE BENCHMARK SERIES AUTOMATED SLIDE STAINERS. EACH SLIDE CONTAINS ONE FORMALIN FIXED, PARAFFIN EMBEDDED CONDYLOMA TISSUE SECTION. SLIDES ARE DESIGNED TO ALLOW THE USER TO CHECK THE INSTRUMENT'S IN SITU HYBRIDIZATION (ISH) STAINING FUNCTION. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. ,ANTI-BCL-2 (SP66) RABBIT MONOCLONAL PRIMARY ANTIBODY(ANTI-BCL-2 (SP66) RABBIT MONOCLONAL PRIMARY ANTIBODY)-ANTI-BCL-2 (SP66) RABBIT MONOCLONAL PRIMARY ANTIBODY IS DIRECTED AGAINST HUMAN BCL-2 EXPRESSED BY B-CELLS OF THE MANTLE ZONE AND INTERFOLLICULAR T CELLS. THIS ANTIBODY EXHIBITS A CYTOPLASMIC STAINING PATTERN AND MAY BE USED TO AID IN THE IDENTIFICATION OF FOLLICULAR LYMPHOMAS AND DIFFUSE LARGE CELL LYMPHOMAS. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE., CONFIRM ANTI-ALK1 (ALK01) PRIMARY ANTIBODY(CONFIRM ANTI-ALK1 (ALK01) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI-ALK1 (ALK01) PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY DIRECTED AGAINST P80 PROTEIN PRESENT IN HUMAN TISSUE. THIS ANTIBODY IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN SECTIONS OF

	FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY.,ANTIBODY DILUENT(ANTIBODY DILUENT)-THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) ANTIBODY DILUENT IS A BUFFERED, PROTEINACEOUS SOLUTION USED TO DILUTE RABBIT AND MOUSE ANTIBODIES FOR USE ON VENTANA AUTOMATED SLIDE STAINERS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.,FITC ANTI-IGM PRIMARY ANTIBODY(FITC ANTI-IGM PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) SYSTEMS FITC ANTI-IGM (IMMUNOGLOBULIN M) PRIMARY ANTIBODY IS A GOAT DERIVED POLYCLONAL ANTIBODY LABELED WITH FLUORESCEIN AND SPECIFICALLY DIRECTED AGAINST HUMAN IGM. THIS REAGENT SHOULD BE USED IN CONJUNCTION WITH A PANEL OF ANTIBODIES TO AID IN THE IDENTIFICATION OF IMMUNOGLOBULIN M IN IGM TARGET TISSUE (E.G., IN THE DIAGNOSIS OF RENAL OR DERMAL PATHOLOGIES). FITC ANTI-IGM IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN SECTIONS OF FROZEN TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY.,ANTI-C-MYC (Y69) RABBIT MONOCLONAL PRIMARY ANTIBODY(ANTI-C-MYC (Y69) RABBIT MONOCLONAL PRIMARY ANTIBODY)-ANTI-C-MYC (Y69) RABBIT MONOCLONAL PRIMARY ANTIBODY (ANTI-C-MYC (Y69)) IS DIRECTED AGAINST THE TRANSCRIPTION FACTOR C-MYC, AN IMPORTANT FACTOR IN CELL CYCLE REGULATION. THE ANTI-C- MYC (Y69) ANTIBODY EXHIBITS A NUCLEAR STAINING PATTERN AND MAY BE USED TO AID IN THE CHARACTERIZATION OF LYMPHOMA. THIS ANTIBODY IS INTENDED

	FOR QUALITATIVE STAINING OF SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,MELANOMA TRIPLE COCKTAIL (HMB45+A103+T311) PRIMARY ANTIBODY(MELANOMA TRIPLE COCKTAIL (HMB45+A103+T311) PRIMARY ANTIBODY)-MELANOMA TRIPLE COCKTAIL (HMB45+A103+T311) PRIMARY ANTIBODY USE-MELANOMA TRIPLE COCKTAIL (HMB45+AL03+T31I) IS AN ANTIBODY COCKTAIL OF ANTI- MELANOSOME (HMB45), ANTI-MART-1/MELAN A (AL03), AND ANTI- TYROSINASE (T31L) MOUSE MONOCLONAL ANTIBODIES. THIS ANTIBODY COCKTAIL DEMONSTRATES CYTOPLASMIC STAINING AND MAY BE USED TO AID IN THE IDENTIFICATION OF MELANOMA. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OFFONNALIN;.FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE,BLUING REAGENT(BLUING REAGENT)- THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC USE. VENTANA MEDICAL SYSTEMS' BLUING REAGENT IS AN AQUEOUS SOLUTION OF BUFFERED LITHIUM CARBONATE. THIS REAGENT IS INTENDED FOR USE ON VENTANA AUTOMATED SLIDE STAINERS AND FOR BLUING HEMATOXYLIN STAINED SECTIONS ON GLASS SLIDES. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.,CONFIRM ANTI-DESMIN (DE-R-11) PRIMARY ANTIBODY(CONFIRM ANTI-DESMIN (DE-R-11) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-DESMIN (DE-R-11) PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY (IGG1, LIGHT CHAIN KAPPA) DIRECTED AGAINST DESMIN. THIS ANTIBODY IS INTENDED FOR USE TO QUALITATIVELY IDENTIFY DESMIN IN MYOCYTIC CELLS BY LIGHT MICROSCOPY IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. CONFIRM ANTI-DESMIN (DE-R-11) MAY BE USED TO AID IN THE IDENTIFICATION OF CELLS OF NORMAL AND ABNORMAL MYOCYTIC LINEAGE AS AN AID IN DIAGNOSIS OF

	ANAPLASTIC TUMORS. CONFIRM ANTI-DESMIN (DE-R-11) SPECIFICALLY BINDS TO ANTIGENS LOCATED IN THE CYTOPLASM OF MYOCYTIC CELLS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY., ANTI-CD43 (L60) MOUSE MONOCLONAL PRIMARY ANTIBODY(ANTI-CD43 (L60) MOUSE MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) ANTI-CD43 (L60) MOUSE MONOCLONAL PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY DIRECTED AGAINST AN EPITOPE PRESENT ON HUMAN MONOCYTES, GRANULOCYTES AND LYMPHOCYTES. THIS REAGENT MAY BE USED TO AID IN THE IDENTIFICATION OF CELLS OF LYMPHOID AND MYELOMONOCYTIC LINEAGE. ANTI-CD43 (L60) IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS., CONFIRM ANTI-KI-67 (30-9) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-KI-67 (30-9) RABBIT MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-KI-67 (30-9) PRIMARY ANTIBODY IS A RABBIT MONOCLONAL ANTIBODY (IGG) DIRECTED AGAINST C-TERMINAL PORTION OF KI-67 ANTIGEN. STAINING FOR KI-67 CAN BE USED TO AID IN ASSESSING THE PROLIFERATIVE ACTIVITY OF NORMAL AND NEOPLASTIC TISSUE. THIS ANTIBODY IS INTENDED FOR USE TO IDENTIFY STAINED PROLIFERATING CELLS BY LIGHT MICROSCOPY IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,ANTI-CD7 (SP94) RABBIT MONOCLONAL PRIMARY ANTIBODY(ANTI-CD7 (SP94) RABBIT MONOCLONAL PRIMARY ANTIBODY)-ANTI-CD7 (SP94) RABBIT MONOCLONAL PRIMARY ANTIBODY (ANTI-CD7 (SP94)) IS

	DIRECTED AGAINST THE 40KD TRANSMEMBRANE GLYCOPROTEIN, CD7 WHICH IS PRESENT IN THYMOCYTES AND MATURE T CELLS. ANTI-CD7 (SP94) MAY BE USED TO AID IN THE IDENTIFICATION OF T CELL LYMPHOMAS. THIS ANTIBODY IS INTENDED FOR QUALITATIVE STAINING OF SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE., CONFIRM ANTI-CD45RO (UCHL-1) PRIMARY ANTIBODY (CONFIRM ANTI-CD45RO (UCHL-1) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-CD45RO (UCHL-1) PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY (IGG2A) DIRECTED AGAINST CD45RO. THIS ANTIBODY IS INTENDED FOR USE TO QUALITATIVELY IDENTIFY CD45RO BY LIGHT MICROSCOPY IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY.,ALU POSITIVE CONTROL PROBE(ALU POSITIVE CONTROL PROBE)-VENTANA MEDICAL SYSTEMS, INC.'S (VENTANA) ALU POSITIVE CONTROL PROBE IS A COCKTAIL OF OLIGONUCLEOTIDE PROBES LABELED WITH FLUORESCEIN THAT IS TO BE USED AS A POSITIVE CONTROL TO DETERMINE THE PRESERVATION OF DNA DURING SPECIMEN COLLECTION, PROCESSING, FIXATION AND HANDLING. ALU POSITIVE CONTROL PROBE IS TO BE USED IN CONJUNCTION WITH ISH IVIEWBLUE DETECTION KIT, AND OTHER ACCESSORY REAGENTS TO STAIN TISSUE SECTIONS THAT ARE FIXED IN NEUTRAL BUFFERED FORMALIN AND PARAFFIN EMBEDDED, OR CYTOLOGICAL SPECIMENS ON THE BENCHMARK, BENCHMARK XT, AND BENCHMARK ULTRA AUTOMATED SLIDE STAINERS. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. POSITIVE RESULTS AID IN THE CLASSIFICATION OF NORMAL AND ABNORMAL SPECIMENS, AND SERVE AS AN ADJUNCT TO CONVENTIONAL HISTOPATHOLOGY OR CYTOPATHOLOGY TESTS. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,CONFIRM ANTI-ESTROGEN RECEPTOR (ER)

	(SP1) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-ESTROGEN RECEPTOR (ER) (SP1) RABBIT MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. CONFIRM ANTI-ESTROGEN RECEPTOR (ER) (SP1) RABBIT MONOCLONAL PRIMARY ANTIBODY IS INTENDED FOR LABORATORY USE FOR THE QUALITATIVE DETECTION OF ESTROGEN RECEPTOR (ER) ANTIGEN IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED BREAST TISSUE ON A VENTANA AUTOMATED SLIDE STAINER WITH VENTANA DETECTION KITS AND ANCILLARY REAGENTS. CONFIRM ANTI-ER (SP1) IS DIRECTED AGAINST AN EPITOPE PRESENT ON HUMAN ER ALPHA PROTEIN LOCATED IN THE NUCLEUS OF ER POSITIVE NORMAL AND NEOPLASTIC CELLS. CONFIRM ANTI-ER (SP1) IS INDICATED AS AN AID IN THE MANAGEMENT, PROGNOSIS, AND PREDICTION OF HORMONE THERAPY FOR BREAST CARCINOMA. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. PRESCRIPTION USE ONLY.,ANTI-ERG (EPR3864) RABBIT MONOCLONAL PRIMARY ANTIBODY(ANTI-ERG (EPR3864) RABBIT MONOCLONAL PRIMARY ANTIBODY)-ANTI-ERG (EPR3864) RABBIT MONOCLONAL PRIMARY ANTIBODY (ANTI-ERG (EPR3864)) IS DIRECTED AGAINST THE C-TERMINUS OF THE ETS TRANSCRIPTION REGULATOR, ERG, AND IS CAPABLE OF DETECTING BOTH WILDTYPE ERG, AND TRUNCATED ERG RESULTING FROM ERG GENE REARRANGEMENT. THIS ANTIBODY EXHIBITS A NUCLEAR STAINING PATTERN AND MAY BE USED TO AID IN THE IDENTIFICATION OF PROSTATE ADENOCARCINOMAS THROUGH THE DETECTION OF TRUNCATED ERG. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,CONFIRM ANTI- TYROSINASE (T311) MOUSE MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI- TYROSINASE (T311) MOUSE MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC USE. VENTANA MEDICAL SYSTEMS CONFIRM ANTI-TYROSINASE (T311) MOUSE MONOCLONAL PRIMARY ANTIBODY IS DESIGNED TO QUALITATIVELY DETECT THE PRESENCE OF TYROSINASE EXPRESSING CELLS VIA LIGHT MICROSCOPY IN FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. POSITIVE RESULTS AID IN THE CLASSIFICATION OF MELANOMA. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE

	COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,ANTI-CYTOKERATIN (CAM 5.2) MOUSE MONOCLONAL PRIMARY ANTIBODY (ANTI-CYTOKERATIN (CAM 5.2) MOUSE MONOCLONAL PRIMARY ANTIBODY)-ANTI-CYTOKERATIN (CAM 5.2) MOUSE MONOCLONAL PRIMARY ANTIBODY (ANTI- CYTOKERATIN (CAM 5.2)) IS DIRECTED AGAINST CYTOKERATIN 7 AND CYTOKERATIN 8 PRESENT ON SECRETORY EPITHELIA BUT NOT ON STRATIFIED SQUAMOUS EPITHELIA. THIS ANTIBODY MAY BE USED TO AID IN THE IDENTIFICATION OF TUMORS OF EPITHELIAL ORIGIN SUCH AS COLORECTAL, PANCREATIC, AND NON-SMALL CELL LUNG CANCER AND IN DISTINGUISHING CARCINOMAS FROM OTHER MALIGNANT TUMORS OF NON-EPITHELIAL ORIGIN. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,CONFIRM ANTI-S100 (4C4.9) PRIMARY ANTIBODY(CONFIRM ANTI-S100 (4C4.9) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-S100 (4C4.9) PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY (IGG2A) DIRECTED AGAINST S100 PROTEIN. THE ANTIBODY IS INTENDED FOR USE TO QUALITATIVELY IDENTIFY S100 PROTEIN BY LIGHT MICROSCOPY IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY.,ANTI-CD22 (SP104) RABBIT MONOCLONAL PRIMARY ANTIBODY(ANTI-CD22 (SP104) RABBIT MONOCLONAL PRIMARY ANTIBODY)-ANTI-CD22 (SP104) RABBIT MONOCLONAL PRIMARY ANTIBODY (ANTI- CD22 (SP104)) IS DIRECTED AGAINST THE TYPE 1 INTEGRAL MEMBRANE GLYCOPROTEIN, CD22. ANTI-CD22 (SP104) EXHIBITS A CELL MEMBRANOUS AND/OR CYTOPLASMIC STAINING PATTERN AND MAY BE USED TO AID IN THE IDENTIFICATION OF B-CELL LYMPHOMAS. THIS ANTIBODY IS INTENDED FOR QUALITATIVE STAINING OF SECTIONS OF FORMALIN-FIXED, PARAFFIN- EMBEDDED TISSUE. THIS PRODUCT SHOULD BE

	INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,CONFIRM ANTI-VIMENTIN (V9) PRIMARY ANTIBODY(CONFIRM ANTI-VIMENTIN (V9) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-VIMENTIN (V9) PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY (IGG1) DIRECTED AGAINST VIMENTIN. THIS ANTIBODY IS INTENDED FOR USE TO QUALITATIVELY IDENTIFY VIMENTIN BY LIGHT MICROSCOPY IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY.,ANTI-CHROMOGRANIN A (LK2H10) PRIMARY ANTIBODY(ANTI-CHROMOGRANIN A (LK2H10) PRIMARY ANTIBODY)-ANTI-CHROMOGRANIN A (LK2H10) PRIMARY ANTIBODY IS DIRECTED AGAINST THE CHROMOGRANIN A PROTEIN FOUND IN THE SECRETORY GRANULES OF MOST NEUROENDOCRINE CELLS. THIS ANTIBODY EXHIBITS A CYTOPLASMIC STAINING PATTERN AND MAY BE USED TO AID IN THE IDENTIFICATION OF TUMORS OF NEUROENDOCRINE ORIGIN. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,FITC ANTI-FIBRINOGEN PRIMARY ANTIBODY(FITC ANTI-FIBRINOGEN PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) FITC ANTI-FIBRINOGEN PRIMARY ANTIBODY IS A GOAT DERIVED POLYCLONAL ANTIBODY LABELED WITH FLUORESCEIN AND SPECIFICALLY DIRECTED AGAINST HUMAN FIBRINOGEN. THIS REAGENT SHOULD BE USED IN CONJUNCTION WITH A PANEL OF ANTIBODIES TO AID IN THE IDENTIFICATION OF FIBRINOGEN IN TARGET TISSUE (E.G., IN THE DIAGNOSIS OF RENAL OR DERMAL PATHOLOGIES). FITC ANTI-FIBRINOGEN IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN SECTIONS OF FROZEN TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND

	EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY.,ANTI-CD44 (SP37) RABBIT MONOCLONAL PRIMARY ANTIBODY(ANTI-CD44 (SP37) RABBIT MONOCLONAL PRIMARY ANTIBODY)-ANTI-CD44 (SP37) RABBIT MONOCLONAL PRIMARY ANTIBODY IS DIRECTED AGAINST THE CD44 PROTEIN. CD44 IS A TYPE I TRANSMEMBRANE RECEPTOR PROTEIN EXPRESSED IN SEVERAL CELL TYPES INCLUDING T AND B LYMPHOCYTES, MONOCYTES, GRANULOCYTES, ERYTHROCYTES, FIBROBLASTS, EPITHELIAL, AND MAST CELLS. THIS ANTIBODY EXHIBITS A MEMBRANEOUS STAINING PATTERN AND MAY BE USED TO DETECT THE CD44 STANDARD AND VARIANT PROTEINS IN A VARIETY OF NEOPLASTIC TISSUES, INCLUDING SQUAMOUS CELL AND UROTHELIAL CARCINOMA. THE ANTIBODY IS INTENDED·FOR QUALITATIVE STAINING OF SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,FITC ANTI-C3 PRIMARY ANTIBODY(FITC ANTI-C3 PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) FITC ANTI-C3 (COMPLEMENT 3) PRIMARY ANTIBODY IS A GOAT DERIVED POLYCLONAL ANTIBODY LABELED WITH FLUORESCEIN AND SPECIFICALLY DIRECTED AGAINST HUMAN C3. THIS REAGENT SHOULD BE USED IN CONJUNCTION WITH A PANEL OF ANTIBODIES TO AID IN THE IDENTIFICATION OF COMPLEMENT 3 IN C3 TARGET TISSUE (E.G., IN THE DIAGNOSIS OF RENAL OR DERMAL PATHOLOGIES). FITC ANTI-C3 IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN SECTIONS OF FROZEN TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,ALU POSITIVE CONTROL PROBE II(ALU POSITIVE CONTROL PROBE II)-THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) ALU POSITIVE CONTROL PROBE II IS A COCKTAIL OF OLIGONUCLEOTIDE PROBES LABELED WITH DNP THAT IS TO BE USED AS A POSITIVE CONTROL TO DETERMINE THE PRESERVATION OF DNA DURING SPECIMEN COLLECTION, PROCESSING, FIXATION, AND HANDLING. ALU POSITIVE

	CONTROL PROBE II IS TO BE USED IN CONJUNCTION WITH ISH IVIEW™ BLUE PLUS DETECTION KIT, AND OTHER ACCESSORY REAGENTS TO STAIN NEUTRAL BUFFERED FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE SPECIMENS ON THE BENCHMARK® SERIES AUTOMATED SLIDE STAINERS. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. POSITIVE RESULTS AID IN THE CLASSIFICATION OF NONNAL AND ABNORMAL SPECIMENS, AND SERVE AS AN ADJUNCT TO CONVENTIONAL HISTOPATHOLOGY TESTS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY.,CONFIRM ANTI- PROGESTERONE RECEPTOR (PR) (1E2) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI- PROGESTERONE RECEPTOR (PR) (1E2) RABBIT MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. CONFIRM ANTI-PROGESTERONE RECEPTOR (PR) (1E2) RABBIT MONOCLONAL (IGG) IS INTENDED FOR LABORATORY USE FOR THE QUALITATIVE DETECTION OF PROGESTERONE RECEPTOR (PR) ANTIGEN IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER WITH VENTANA DETECTION KITS AND ANCILLARY REAGENTS. CONFIRM ANTI-PR (1E2) IS DIRECTED AGAINST AN EPITOPE PRESENT ON HUMAN PROGESTERONE RECEPTOR PROTEIN LOCATED IN THE NUCLEUS OF PR POSITIVE NORMAL AND NEOPLASTIC CELLS. CONFIRM ANTI-PR (1E2) IS INDICATED AS AN AID IN THE MANAGEMENT, PROGNOSIS, AND PREDICTION OF THERAPY OUTCOME OF BREAST CARCINOMA. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. PRESCRIPTION USE ONLY.,CONFIRM ANTI-CD15 (MMA) MOUSE MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-CD15 (MMA) MOUSE MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGRIOSTIC USE. VENTANA MEDICAL SYSTEMS' CONFIRM ANTI-CD15 (MMA) MOUSE MONOCLONAL PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY (IGM, KAPPA) DIRECTED AGAINST A CARBOHYDRATE EPITOPE PRESENT ON MOST GRANULOCYTIC CELLS. THIS ANTIBODY IS INTENDED FOR USE TO QUALITATIVELY IDENTIFY CD15 BY LIGHT MICROSCOPY IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE STAINED ON THE VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING,

	MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS., CONFIRM ANTI-P53 (DO7) PRIMARY ANTIBODY(CONFIRM ANTI-P53 (DO7) PRIMARY ANTIBODY)-VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-P53 (DO-7) PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY (IGG1, KAPPA) DIRECTED AGAINST HUMAN P53. THE ANTIBODY IS INTENDED FOR LABORATORY USE TO QUALITATIVELY IDENTIFY BY LIGHT MICROSCOPY WILD TYPE AND MUTANT P53 IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS., CONFIRM ANTI-CD45, LCA (RP2/18) PRIMARY ANTIBODY(CONFIRM ANTI-CD45, LCA (RP2/18) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI-CD45, LCA (RP2/18) PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY (LGG1) DIRECTED AGAINST CD45. CONFIRM ANTI-CD45, LCA (RP2/18) MAY BE USED IN IMMUNOCYTOCHEMICAL METHODS TO AID IN THE IDENTIFICATION OF NORMAL AND ABNORMAL CELLS OF LEUKOCYTIC LINEAGE AND AS AN AID IN THE DIAGNOSIS OF ANAPLASTIC TUMORS. CONFIRM ANTI- CD45, LCA (RP2/18) SPECIFICALLY BINDS TO ANTIGENS LOCATED ON THE MEMBRANE OF LEUKOCYTES. STAINING IS MOST CONSISTENT FOR LYMPHOCYTIC CELLS WITH LESS CONSISTENT REACTION IN OTHER LEUKOCYTES (MACROPHAGES/ HISTIOCYTES/MYELOID CELLS). THE EPITOPE RECOGNIZED BY THE ANTIBODY IS LCA-RB. CONFIRM ANTI-CD45, LCA (RP2/18) IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN LEUKOCYTES IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING OF CELL COMPONENTS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY., CONFIRM ANTI-CD68 (KP-1) PRIMARY ANTIBODY(CONFIRM ANTI-CD68 (KP-1) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR

	IN VITRO DIAGNOSTIC USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-CD68 (KP-1) PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY, CLASS IGG1 KAPPA. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. CONFIRM ANTI-CD68 REACTS WITH A 110 KD INTRACELLULAR GLYCOPROTEIN ASSOCIATED WITH THE CELL MEMBRANE OF MACROPHAGES AND SOME MYELOID ELEMENTS. UNEXPECTED ANTIGEN EXPRESSION OR LOSS OF EXPRESSION MAY OCCUR, ESPECIALLY IN NEOPLASMS. OCCASIONALLY STROMAL ELEMENTS SURROUNDING HEAVILY STAINED TISSUE OR CELLS WILL SHOW IMMUNOREACTIVITY. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,CONFIRM ANTI-CD23 (SP23) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-CD23 (SP23) RABBIT MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI- CD23 (SP23) RABBIT MONOCLONAL PRIMARY ANTIBODY IS DESIGNED TO QUALITATIVELY DETECT THE PRESENCE OF CD23 EXPRESSING CELLS VIA LIGHT MICROSCOPY IN FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE. POSITIVE STAINING MAY BE USEFUL IN CLASSIFYING SMALL LYMPHOCYTIC LYMPHOMA/LEUKEMIA FROM OTHER SMALL B-CELL LYMPHOMAS INCLUDING MANTLE CELL AND MARGINAL ZONE LYMPHOMA. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS,CONFIRM ANTI-EGFR (5B7) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-EGFR (5B7) RABBIT MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI-EGFR (5B7) RABBIT MONOCLONAL ANTIBODY IS A PRIMARY ANTIBODY DESIGNED TO QUALITATIVELY DETECT THE PRESENCE OF THE INTERNAL DOMAIN OF EGFR VIA LIGHT MICROSCOPY IN FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE FOLLOWING STAINING ON A VENTANA AUTOMATED SLIDE STAINER. THIS ANTIBODY IS DIRECTED AGAINST THE INTERNAL DOMAIN OF THE HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR (ALSO CALLED EGFR, ERBBL OR HER 1).

	THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENTS CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,CONFIRM ANTI-CD8 (SP57) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-CD8 (SP57) RABBIT MONOCLONAL PRIMARY ANTIBODY)-VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI-CD8 (SP57) RABBIT MONOCLONAL PRIMARY ANTIBODY (CONFIRM ANTI-CD8 (SP57)) IS INTENDED FOR THE QUALITATIVE DETECTION OF CD8 IN SECTIONS OF NORMAL AND NEOPLASTIC HUMAN TISSUES. THE CD8 GLYCOPROTEIN IS PRESENT ON CYTOTOXIC/SUPPRESSOR T LYMPHOCYTES THAT RECOGNIZE ANTIGEN IN THE CONTEXT OF MHC CLASS 1 MOLECULES. CD8 POSITIVE STAINING RESULTS MAY AID IN IDENTIFYING T-CELL LYMPHOMAS AND IN IDENTIFYING THE T CYTOTOXIC/SUPPRESSOR CELL SUBSET OF T LYMPHOCYTES IN NORMAL TISSUES. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA PD-L1 (SP142) IHC ASSAY(VENTANA PD-L1 (SP142) IHC ASSAY)-VENTANA PD-LI (SP142) ASSAY IS A QUALITATIVE IMMUNOHISTOCHEMICAL ASSAY USING RABBIT MONOCLONAL ANTI-PD-LL CLONE SP142 INTENDED FOR USE IN THE ASSESSMENT OF THE PD-LL PROTEIN IN FONNALIN- FIXED, PARAFFIN-EMBEDDED (FFPE) UROTHELIAL CARCINOMA TISSUE STAINED WITH OPTIVIEW DAB IHC DETECTION KIT AND OPTIVIEW AMPLIFICATION KIT ON A VENTANA BENCHMARK ULTRA INSTRUMENT. PD-LL STATUS IS DETERMINED BY THE PROPORTION OF TUMOR AREA OCCUPIED BY PD-LL EXPRESSING TUMOR-INFILTRATING IMMUNE CELLS (PER CENT IC) OF ANY INTENSITY. PD-LL EXPRESSION IN GREATER THAN OR EQUAL TO 5 PER CENT IC DETERMINED BY VENTANA PD-LI (SP142) ASSAY IN UROTHELIAL CARCINOMA TISSUE IS ASSOCIATED WITH INCREASED OBJECTIVE RESPONSE RATE (ORR) IN A NON-RANDOMIZED STUDY OFTECENTRIQ (ATEZOLIZUMAB). THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA ANTI-CD10 (SP67) RABBIT MONOCLONAL PRIMARY ANTIBODY(VENTANA ANTI-CD10 (SP67) RABBIT MONOCLONAL PRIMARY ANTIBODY)-VENTANA ANTI-CD10 (SP67) RABBIT MONOCLONAL PRIMARY ANTIBODY IS DIRECTED AGAINST THE CD10 MOLECULE, OR COMMON ACUTE LYMPHOBLASTIC LEUKEMIA ANTIGEN (CALLA), EXPRESSED ON THE

	SURFACE OF EARLY LYMPHOID CELLS, AND ON VARIOUS NONLYMPHOID TISSUES INCLUDING BREAST MYOEPITHELIAL CELLS, BILE CANALICULI, FIBROBLASTS, KIDNEY TUBULAR BRUSH BORDERS AND SMALL INTESTINE EPITHELIUM. THIS ANTIBODY EXHIBITS A CELL MEMBRANOUS AND/OR CYTOPLASMIC STAINING PATTERN AND MAY BE USED TO AID IN THE IDENTIFICATION OF BURKITT'S LYMPHOMA AND FOLLICULAR GERM CELL LYMPHOMA, AND IN THE CLASSIFICATION OF SOME CARCINOMAS SUCH AS RENAL CELL CARCINOMA. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFONNATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,RABBIT MONOCLONAL NEGATIVE CONTROL IG(RABBIT MONOCLONAL NEGATIVE CONTROL IG)-"RABBIT MONOCLONAL NEGATIVE CONTROL IG IS INTENDED FOR LABORATORY USE AS A CONTROL FOR NONSPECIFIC BINDING OF RABBIT IMMUNOGLOBULIN IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE WHEN STAINED ON VENTANA BENCHMARK IHC/ISH PLATFORMS (BENCHMARK GX, BENCHMARK XT, AND BENCHMARK ULTRA). THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE." ,ANTI-P53 (BP53-11) PRIMARY ANTIBODY(ANTI-P53 (BP53-11) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) ANTI-P53 PRIMARY ANTIBODY (BP53-11) IS A MOUSE MONOCLONAL ANTIBODY DIRECTED AGAINST BOTH THE MUTANT AND WILD TYPE OF THE P53 NUCLEAR PHOSPHOPROTEIN. VERY RARE NORMAL CELLS EXPRESS P53, BUT ALTERATIONS IN THE P53 SUPPRESSOR GENE RESULT IN AN OVERPRODUCTION OF THIS PROTEIN IN MALIGNANCIES. THIS REAGENT MAY BE USED TO AID IN THE IDENTIFICATION OF ABNORMALLY PROLIFERATING CELLS IN NEOPLASTIC CELL POPULATIONS. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY.,HEMATOXYLIN II(HEMATOXYLIN II)-THIS

	REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC USE. VENTANA MEDICAL SYSTEMS HEMATOXYLIN II COUNTERSTAIN REAGENT IS A MODIFIED MAYER'S HEMATOXYLIN AND IS INTENDED FOR STAINING CELLULAR NUCLEI ON SLIDES CONTAINING CELLS FROM FROZEN TISSUE, FORMALIN FIXED AND PARAFFIN EMBEDDED TISSUE, OR CYTOLOGIC PREPARATIONS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,CONFIRM ANTI-BCL-2 (124) MOUSE MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-BCL-2 (124) MOUSE MONOCLONAL PRIMARY ANTIBODY)-VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI-BCL-2 (124) MOUSE MONOCLONAL PRIMARY ANTIBODY (CONFIRM ANTI-BCL-2 (124)) IS DIRECTED AGAINST HUMAN BCL-2 EXPRESSED BY B CELLS OF THE MANTLE ZONE AND INTERFOLLICULAR T CELLS. THIS ANTIBODY EXHIBITS A CYTOPLASMIC STAINING PATTERN AND MAY BE USED TO AID IN THE IDENTIFICATION OF FOLLICULAR LYMPHOMAS AND DIFFUSE LARGE CELL LYMPHOMAS, AND TO DIFFERENTIATE FOLLICULAR LYMPHOMAS FROM REACTIVE LYMPH NODES. CONFIRM ANTI-BCL-2 (124) IS DESIGNED TO QUALITATIVELY DETECT THE PRESENCE OF CELLS EXPRESSING BCL-2 PROTEIN VIA LIGHT MICROSCOPY IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE., CONFIRM ANTI-THYROID TRANSCRIPTION FACTOR-1 (8G7G3/1) MOUSE MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-THYROID TRANSCRIPTION FACTOR-1 (8G7G3/1) MOUSE MONOCLONAL PRIMARY ANTIBODY)-CONFIRM ANTI-THYROID TRANSCRIPTION FACTOR-I (8G7G3/1) MOUSE MONOCLONAL PRIMARY ANTIBODY (CONFIRM ANTI-THYROID TRANSCRIPTION FACTOR-I (8G7G3/1)) IS DESIGNED TO QUALITATIVELY DETECT THE PRESENCE OF THYROID TRANSCRIPTION FACTOR-I (TTF-1) EXPRESSING CELLS. TTF-1 POSITIVE STAINING RESULTS MAY AID IN THE CLASSIFICATION OF NEOPLASMS OF THE LUNG AND THYROID. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING OF SECTIONS OF FORMALIN-FIXED, PARAFFINEMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGI1OSTIC (IVD) USE.,CONFIRM ANTI-CD34 (QBEND/10) PRIMARY

	ANTIBODY(CONFIRM ANTI-CD34 (QBEND/10) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI-CD34 (QBEND/10) PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY (IGG1) DIRECTED AGAINST HUMAN CD34. THIS ANTIBODY IS INTENDED FOR USE TO QUALITATIVELY IDENTIFY CD34 BY LIGHT MICROSCOPY IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE STAINED ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,ENDOGENOUS BIOTIN BLOCKING KIT (ENDOGENOUS BIOTIN BLOCKING KIT)-THIS KIT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) ENDOGENOUS BIOTIN BLOCKING KIT MAY BE USED TO AID IN THE REDUCTION OF NON SPECIFIC STAINING CAUSED BY ENDOGENOUS BIOTIN PRESENT IN CELLS AND TISSUES STAINED ON VENTANA AUTOMATED SLIDE STAINERS. BLOCKER A SPECIFICALLY BINDS TO ENDOGENOUS BIOTIN PRESENT IN THE TISSUE; BLOCKER B SATURATES THE REMAINING BINDING SITES OF THE EGG WHITE AVIDIN IN BLOCKER A, THUS REDUCING THE NON-SPECIFIC STAINING. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT’S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,CONFIRM ANTI-CD56 (123C3) MOUSE MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-CD56 (123C3) MOUSE MONOCLONAL PRIMARY ANTIBODY)-VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI-CD56 (123C3) MOUSE MONOCLONAL PRIMARY ANTIBODY (CONFIRM ANTI- CD56 (123C3)) IS DIRECTED AGAINST THE CD56 MOLECULE OR NEURAL CELL ADHESION MOLECULE EXPRESSED BY MOST NEUROECTODERMALLY DERIVED CELL LINES, TISSUES AND NEOPLASMS. IT IS ALSO EXPRESSED ON SOME MESODERMALLY DERIVED TUMORS, ON NATURAL KILLER CELLS, AND NK CELL LYMPHOMAS. THIS ANTIBODY EXHIBITS A MEMBRANE/CYTOPLASMIC STAINING PATTERN AND MAY BE USED TO AID IN THE IDENTIFICATION OF SMALL CELL CARCINOMAS, NEUROBLASTOMA, AND RHABDOMYOSARCOMA. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN

	CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA BASAL CELL COCKTAIL (34E12+P63)(VENTANA BASAL CELL COCKTAIL (34E12+P63))-"VENTANA BASAL CELL COCKTAIL (34EL2+P63) IS AN ANTIBODY COCKTAIL OF ANTI-P63 (4A4) AND ANTI-KERATIN (34E12). ANTI-P63 (4A4) REACTS WITH THE P63 MOLECULE IN THE NUCLEI OF HUMAN PROSTATIC BASAL CELLS AND UROTHELIAL TISSUES. ANTI- KERATIN (34EI2) REACTS WITH CYTOKERATINS 1, 5, 10 AND 14, AND STAINS THE CYTOPLASM OF HUMAN PROSTATIC BASAL CELLS. THIS ANTIBODY COCKTAIL MAY BE USED TO AID IN THE DIFFERENTIATION OF BENIGN AND MALIGNANT PROSTATIC LESIONS. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN- EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE." , CONFIRM ANTI-CD20 (L26) PRIMARY ANTIBODY(CONFIRM ANTI-CD20 (L26) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI-CD20 (L26) PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY (IGG2A, KAPPA) DIRECTED AGAINST AN EPITOPE PRESENT ON HUMAN B LYMPHOCYTES. THIS ANTIBODY IS INTENDED FOR USE TO QUALITATIVELY IDENTIFY CELLS OF B LYMPHOCYTIC LINEAGE BY LIGHT MICROSCOPY IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS., NEUVISION BLOCKING REAGENT(NEUVISION BLOCKING REAGENT)-THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS, INC. (VENTANA) NEUVISION BLOCKING REAGENT IS A PROTEIN BLOCKING SOLUTION SUITABLE FOR USE WITH THE NEUVISION NUCLEAR STAIN KIT. IT IS INTENDED TO BE USED IN THE PREPARATION OF SAMPLES FOR INTERPRETATION BY IMAGE ANALYSIS. THIS REAGENT MAY BE USED TO AID IN THE REDUCTION OF NON-SPECIFIC STAINING ON SOME TISSUES STAINED ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND

	EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS., CONFIRM ANTI-CD3 (2GV6) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-CD3 (2GV6) RABBIT MONOCLONAL PRIMARY ANTIBODY)-CONFIRM ANTI-CD3 (2GV6) RABBIT MONOCLONAL PRIMARY ANTIBODY (CONFIRM ANTI-CD3 (2GV6) ANTIBODY) IS A RABBIT MONOCLONAL ANTIBODY (IGG) DIRECTED AGAINST THE NONGLYCOSYLATED EPSILON CHAIN OF THE HUMAN CD3 MOLECULE. CONFIRM ANTI-CD3 (2GV6) ANTIBODY IS INTENDED FOR USE TO QUALITATIVELY IDENTIFY T CELLS BY LIGHT MICROSCOPY IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE ON A VENTANA BENCHMARK IHC/ISH SERIES OF AUTOMATED INSTRUMENTS. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,PROTEASE 3(PROTEASE 3)-VENTANA MEDICAL SYSTEMS (VENTANA) PROTEASE 3 IS AN ENDOPEPTIDASE (ALKALINE PROTEASE) OF THE SERINE PROTEASE FAMILY AND CLEAVES ANTIGENS (PROTEINS) IN THE TISSUE SECTION, ALLOWING PRIMARY ANTIBODIES TO RECOGNIZE AND BIND EPITOPE(S). THE REAGENT IS INTENDED FOR ENZYMATIC DIGESTION OF SECTIONS OF ROUTINE FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE ON VENTANA AUTOMATED SLIDE STAINERS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS., VENTANA ANTI-MLH1 (M1) MOUSE MONOCLONAL PRIMARY ANTIBODY(VENTANA ANTI-MLH1 (M1) MOUSE MONOCLONAL PRIMARY ANTIBODY)-VENTANA ANTI-MLH1 (M1) MOUSE MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-MLH1 (M1) ANTIBODY) IS INTENDED FOR THE QUALITATIVE DETECTION OF MLH1 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. VENTANA ANTI-MLH1 (M1) ANTIBODY IS READY TO USE ON BENCHMARK ULTRA, XT AND GX INSTRUMENTS WITH THE OPTIVIEW DAB IHC DETECTION KIT AND ANCILLARY REAGENTS. VENTANA ANTI-MLH1 (M1) ANTIBODY IS PART OF THE VENTANA MMR IHC PANEL WHICH INCLUDES VENTANA ANTI-PMS2 (A16-4) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-MSH2 (G219-1129) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-MSH6 (SP93) RABBIT MONOCLONAL PRIMARY ANTIBODY AND

	VENTANA ANTI-BRAF V600E (VE1) MOUSE MONOCLONAL PRIMARY ANTIBODY. THE VENTANA MMR IHC PANEL IS INDICATED FOR THE DETECTION OF MISMATCH REPAIR PROTEIN DEFICIENCY AS A TEST FOR THE IDENTIFICATION OF INDIVIDUALS AT RISK FOR LYNCH SYNDROME IN PATIENTS DIAGNOSED WITH COLORECTAL CANCER (CRC), AND, WITH BRAF V600E STATUS, AS AN AID TO DIFFERENTIATE BETWEEN SPORADIC AND PROBABLE LYNCH SYNDROME CRC IN THE ABSENCE OF MLH1 PROTEIN EXPRESSION. THESE PRODUCTS SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS.,CONFIRM ANTI-TOPOISOMERASE II (JS5B4) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-TOPOISOMERASE II (JS5B4) RABBIT MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEM$' CONFIRM ANTI-TOPOISOMERASE ILALPHA (JS5B4) RABBIT MONOCLON;:TL PRIMARY ANTIBODY IS DESIGNED TO QUALITATIVELY DETECT THE PRESENCE OFTOPOISOMERASE ILALPHA EXPRESSING CELLS VIA LIGHT MICROSCOPY IN FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE FOLLOWING STAINING ON A VENTANA BENCHMARK XT INSTRUMENT. DURING THE CELL CYCLE, TOPOISOMERASE ILALPHA IS EXPRESSED IN THE GL, S, G2, AND M PHASE BUT IS ABSENT IN THE GO (QUIESCENT) PHASE.I ASSESSMENT OF THE PROPORTION OF POSITIVE STAINING CELLS FOR TOPOISOMERASE ILALPHA MAY AID IN EVALUATION OF THE PROLIFERATIVE ACTIVITY OF NORMAL AND/OR NEOPLASTIC TISSUE. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENTS CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,VENTANA ANTI-MSH2 (G219-1129) MOUSE MONOCLONAL PRIMARY ANTIBODY(VENTANA ANTI-MSH2 (G219-1129) MOUSE MONOCLONAL PRIMARY ANTIBODY)-VENTANA ANTI-MSH2 (G219-1129) MOUSE MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-MSH2 (G219-1129) ANTIBODY) IS INTENDED FOR THE QUALITATIVE DETECTION OF MSH2 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. VENTANA ANTI-MSH2 (G219-1129) ANTIBODY IS READY TO USE ON BENCHMARK ULTRA, XT AND GX INSTRUMENTS WITH THE OPTIVIEW DAB IHC DETECTION KIT AND ANCILLARY REAGENTS. VENTANA ANTI-MSH2 (G219-1129) ANTIBODY IS PART OF THE VENTANA MMR IHC PANEL WHICH INCLUDES VENTANA ANTI-MLH1 (M1) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-PMS2 (A16-4) MOUSE MONOCLONAL

	PRIMARY ANTIBODY, VENTANA ANTI-MSH6 (SP93) RABBIT MONOCLONAL PRIMARY ANTIBODY AND VENTANA ANTI-BRAF V600E (VE1) MOUSE MONOCLONAL PRIMARY ANTIBODY. THE VENTANA MMR IHC PANEL IS INDICATED FOR THE DETECTION OF MISMATCH REPAIR PROTEIN DEFICIENCY AS A TEST FOR THE IDENTIFICATION OF INDIVIDUALS AT RISK FOR LYNCH SYNDROME IN PATIENTS DIAGNOSED WITH COLORECTAL CANCER (CRC), AND, WITH BRAF V600E STATUS, AS AN AID TO DIFFERENTIATE BETWEEN SPORADIC AND PROBABLE LYNCH SYNDROME CRC IN THE ABSENCE OF MLH1 PROTEIN EXPRESSION. THESE PRODUCTS SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,"VENTANA ANTI-P120 CATENIN (98) MOUSE MONOCLONAL PRIMARY ANTIBODY "("VENTANA ANTI-P120 CATENIN (98) MOUSE MONOCLONAL PRIMARY ANTIBODY ")-VENTANA ANTI-P120 CATENIN (98) MOUSE MONOCLONAL PRIMARY ANTIBODY IS DIRECTED AGAINST HUMAN JUXTAMEMBRANE PROTEIN P120 EXPRESSED AS A PART OF THE CELL-CELL ADHESION COMPLEX IN EPITHELIAL TISSUES. CYTOPLASMIC ACCUMULATION OF P120 IS ASSOCIATED WITH LOBULAR BREAST CARCINOMA WHEREAS DUCTAL NEOPLASMS RETAIN MEMBRANOUS LOCALIZATION. THIS ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN- EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. ,VENTANA ANTI-MSH6 (SP93) RABBIT MONOCLONAL PRIMARY ANTIBODY(VENTANA ANTI-MSH6 (SP93) RABBIT MONOCLONAL PRIMARY ANTIBODY)-VENTANA ANTI-MSH6 (SP93) RABBIT MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-MSH6 (SP93) ANTIBODY) IS INTENDED FOR THE QUALITATIVE DETECTION OF MSH6 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. VENTANA- ANTI-MSH6 (SP93) ANTIBODY IS READY TO USE ON BENCHMARK ULTRA, XT AND GX INSTRUMENTS WITH THE OPTIVIEW DAB IHC DETECTION KIT AND ANCILLARY REAGENTS. VENTANA ANTI-MSH6 (SP93) ANTIBODY IS PART OF THE VENTANA MMR IHC PANEL WHICH INCLUDES VENTANA ANTI-MLH1 (M1) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-PMS2 (A16-4) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-MSH2 (G219-1129) MOUSE MONOCLONAL PRIMARY ANTIBODY AND VENTANA ANTI-BRAF V600E (VE1) MOUSE MONOCLONAL PRIMARY ANTIBODY. THE VENTANA MMR IHC PANEL IS INDICATED FOR THE DETECTION OF MISMATCH REPAIR PROTEIN

	DEFICIENCY AS A TEST FOR THE IDENTIFICATION OF INDIVIDUALS AT RISK FOR LYNCH SYNDROME IN PATIENTS DIAGNOSED WITH COLORECTAL CANCER (CRC), AND, WITH BRAF V600E STATUS, AS AN AID TO DIFFERENTIATE BETWEEN SPORADIC AND PROBABLE LYNCH SYNDROME CRC IN THE ABSENCE OF MLH1 PROTEIN EXPRESSION. THESE PRODUCTS SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,PROTEASE 2 (PROTEASE 2)-THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) PROTEASE 2 IS AN ENDOPEPTIDASE (ALKALINE PROTEASE) OF THE SERINE PROTEASE FAMILY AND CLEAVES ANTIGENS (PROTEINS) IN THE TISSUE SECTION, ALLOWING PRIMARY ANTIBODIES TO RECOGNIZE AND BIND EPITOPE(S). THE REAGENT IS INTENDED FOR ENZYMATIC DIGESTION OF SECTIONS OF ROUTINE FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE ON VENTANA AUTOMATED SLIDE STAINERS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,VENTANA ANTI-BRAF V600E (VE1) MOUSE MONOCLONAL PRIMARY ANTIBODY(VENTANA ANTI-BRAF V600E (VE1) MOUSE MONOCLONAL PRIMARY ANTIBODY)-VENTANA ANTI-BRAF V600E (VE1) MOUSE MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-BRAF V600E (VE1) ANTIBODY) IS INTENDED FOR THE QUALITATIVE DETECTION OF BRAF V600E PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. VENTANA ANTI-BRAF V600E (VE1) ANTIBODY IS READY TO USE ON BENCHMARK ULTRA, XT AND GX INSTRUMENTS WITH THE OPTIVIEW DAB IHC DETECTION KIT AND ANCILLARY REAGENTS. VENTANA ANTI-BRAF V600E (VE1) ANTIBODY IS PART OF THE VENTANA MMR IHC PANEL WHICH INCLUDES VENTANA ANTI-MLH1 (M1) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-PMS2 (A16-4) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-MSH2 (G219-1129) MOUSE MONOCLONAL PRIMARY ANTIBODY AND VENTANA ANTI-MSH6 (SP93) RABBIT MONOCLONAL PRIMARY ANTIBODY. THE VENTANA MMR IHC PANEL IS INDICATED FOR THE DETECTION OF MISMATCH REPAIR PROTEIN DEFICIENCY AS A TEST FOR THE IDENTIFICATION OF INDIVIDUALS AT RISK FOR LYNCH SYNDROME IN PATIENTS DIAGNOSED WITH COLORECTAL CANCER (CRC), AND, WITH BRAF V600E STATUS, AS AN AID TO DIFFERENTIATE BETWEEN SPORADIC AND PROBABLE LYNCH SYNDROME CRC IN THE

	ABSENCE OF MLH1 PROTEIN EXPRESSION. THESE PRODUCTS SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,ANTI-GLYPICAN 3 (GC33) MOUSE MONOCLONAL PRIMARY ANTIBODY(ANTI-GLYPICAN 3 (GC33) MOUSE MONOCLONAL PRIMARY ANTIBODY)-ANTI-GLYPICAN 3 (GC33) MOUSE MONOCLONAL PRIMARY ANTIBODY (ANTI- GLYPICAN 3 (GC33)) IS DIRECTED AGAINST THE HEPARAN SULFATEPROTEOGLYCAN, GLYPICAN 3. THIS ANTIBODY MAY BE USEDTO AID IN THE DIFFERENTIATION OF HEPATOCELLULAR CARCINOMA FROM NORMAL LIVER OR BENIGN LESIONS. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN.EMBEDDED TISSUE.THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA ANTI-PMS2 (A16-4) MOUSE MONOCLONAL PRIMARY ANTIBODY(VENTANA ANTI-PMS2 (A16-4) MOUSE MONOCLONAL PRIMARY ANTIBODY)-VENTANA ANTI-PMS2 (A16-4) MOUSE MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-PMS2 (A16-4) ANTIBODY) IS INTENDED FOR THE QUALITATIVE DETECTION OF PMS2 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. VENTANA ANTI-PMS2 (A16-4) ANTIBODY IS READY TO USE ON BENCHMARK ULTRA, XT AND GX INSTRUMENTS WITH THE OPTIVIEW DAB IHC DETECTION KIT, OPTIVIEW AMPLIFICATION KIT AND ANCILLARY REAGENTS. VENTANA ANTI-PMS2 (A16-4) ANTIBODY IS PART OF THE VENTANA MMR IHC PANEL WHICH INCLUDES VENTANA ANTI-MLH1 (M1) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-MSH2 (G219-1129) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-MSH6 (SP93) RABBIT MONOCLONAL PRIMARY ANTIBODY AND VENTANA ANTI-BRAF V600E (VE1) MOUSE MONOCLONAL PRIMARY ANTIBODY. THE VENTANA MMR IHC PANEL IS INDICATED FOR THE DETECTION OF MISMATCH REPAIR PROTEIN DEFICIENCY AS A TEST FOR THE IDENTIFICATION OF INDIVIDUALS AT RISK FOR LYNCH SYNDROME IN PATIENTS DIAGNOSED WITH COLORECTAL CANCER (CRC), AND, WITH BRAF V600E STATUS, AS AN AID TO DIFFERENTIATE BETWEEN SPORADIC AND PROBABLE LYNCH SYNDROME CRC IN THE ABSENCE OF MLH1 PROTEIN EXPRESSION. THESE PRODUCTS SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,CELL CONDITIONING SOLUTION (CC1)

	(CELL CONDITIONING SOLUTION (CC1))-THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC USE. VENTANA® MEDICAL SYSTEMS' (VENTANA) CELL CONDITIONING SOLUTION (CC1) IS A PRE DILUTED SOLUTION USED AS A PRETREATMENT STEP IN THE PROCESSING OF TISSUE SAMPLES FOR IMMUNOHISTOCHEMISTRY (IHC) REACTIONS CARRIED OUT ON VENTANA BENCHMARK® AND BENCHMARK XT AUTOMATED SLIDE STAINERS.,ANTI-PAN KERATIN (AE1/AE3/PCK26) PRIMARY ANTIBODY(ANTI-PAN KERATIN (AE1/AE3/PCK26) PRIMARY ANTIBODY)-ANTI-PAN KERATIN (AE1/AE3/PCK26) PRIMARY ANTIBODY (ANTI-PAN KERATIN (AE1/AE3/PCK26) IS A COCKTAIL OF ANTIBODIES DIRECTED AGAINST KERATINS PRESENT IN SIMPLE AND COMPLEX EPITHELIAL CELLS. THIS PRODUCT EXHIBITS A CYTOPLASMIC STAINING PATTERN AND MAY BE USED TO AID IN THE IDENTIFICATION OF NORMAL AND ABNORMAL EPITHELIAL CELLS, AND AS AN AID IN DETERMINING TUMOR LINEAGE. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,HYBREADY SOLUTION(HYBREADY SOLUTION) -VENTANA MEDICAL SYSTEMS (VENTANA) HYBREADY SOLUTION IS A FORMAMIDE-BASED BUFFER INTENDED FOR USE WITH IN SITU HYBRIDIZATION BASED ASSAYS ON VENTANA BENCHMARK SERIES INSTRUMENTS. THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC USE. ,AMPLIFICATION KIT (AMPLIFICATION KIT)-VENTANAMEDICAL SYSTEMS, INC.'S (VENTANA) AMPLIFICATION KIT MAY BE USED IN CONJUNCTION WITH VENTANA DETECTION KITS TO INCREASE THE SIGNAL INTENSITY OF WEAK STAINING MOUSE AND RABBIT PRIMARY ANTIBODIES. THE KIT IS TO BE-USED FOR QUALITATIVE STAINING OF FORMALIN-FIXED, PARAFFIN- EMBEDDED TISSUE, FROZEN TISSUE OR CYTOLOGICAL PREPARATIONS ON VENTANA AUTOMATED SIDE STAINERS WITH VENTANA PRIMARY ANTIBODIES, DETECTION KITS AND ANCILLARY REAGENTS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,HER2 3-IN-1 XENOGRAFT CONTROL SLIDES(HER2 3-IN-1 XENOGRAFT CONTROL SLIDES)-THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) HER2 3-IN-L XENOGRAFT CONTROL SLIDES ARE INTENDED TO BE

	USED AS ASSAYED, SEMI-QUANTITATIVE QUALITY CONTROL MATERIAL IN CONJUNCTION WITH THE INFORM HER2 DNA PROBE AND INFORM CHROMOSOME 17 PROBE FOR USE IN MONITORING PERFORMANCE OF THE PROBES FOR IN SITU HYBRIDIZATION (ISH). LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. THREE DIFFERENT HUMAN CARCINOMA CELL LINES, EACH WITH A DIFFERENT HER2 GENE STATUS THAT REPRESENTS THE DYNAMIC RANGE, ARE GENERATED AS TUMORS (XENOGRAFTS) IN SCID MICE. THE THREE XENOGRAFTS ARE PARAFFIN EMBEDDED, SECTIONED AND PLACED ON CHARGED SLIDES. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. ,ANTI-CD30 (BER-H2) MOUSE MONOCLONAL PRIMARY ANTIBODY(ANTI-CD30 (BER-H2) MOUSE MONOCLONAL PRIMARY ANTIBODY)-THE ANTI-CD30 (BER-H2) MOUSE MONOCLONAL PRIMARY ANTIBODY (ANTI-CD30 (BER-H2)) IS INTENDED FOR LABORATORY USE IN THE DETECTION OF THE CD30 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE STAINED WITH BENCHMARK IHC/ISH INSTRUMENTS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY HISTOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,PATHWAY HER-2 4 IN 1 CONTROL SLIDES (PATHWAY HER-2 4 IN 1 CONTROL SLIDES)-THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) PATHWAY HER-2 4 IN 1 CONTROL SLIDES CONSIST OF FORMALIN FIXED, PARAFFIN EMBEDDED, CULTURED HUMAN BREAST CELL LINES AND ARE INTENDED TO BE USED AS ASSAYED, SEMI-QUANTITATIVE QUALITY CONTROL MATERIAL, IN CONJUNCTION WITH VENTANA PATHWAY HER2 (4B5) PRIMARY ANTIBODY, FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNOHISTOCHEMICAL ANTI-C-ERBB- 2/HER-2 STAINING PROCESS ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION USE ONLY. ,ANTI-THYROID TRANSCRIPTION FACTOR-

	1 (SP141) RABBIT MONOCLONAL PRIMARY ANTIBODY(ANTI-THYROID TRANSCRIPTION FACTOR-1 (SP141) RABBIT MONOCLONAL PRIMARY ANTIBODY)-ANTI-THYROID TRANSCRIPTION FACTOR-1 (SP141) RABBIT MONOCLONAL PRIMARY ANTIBODY (ANTI- TTF-1 (SP141)) IS DIRECTED AGAINST THE THYROID TRANSCRIPTION FACTOR-1 (TTF-1) PROTEIN. THIS ANTIBODY EXHIBITS A NUCLEAR STAINING PATTERN AND MAY BE USED TO AID IN THE CLASSIFICATION OF NEOPLASMS OF THE LUNG AND THYROID. THIS ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN- EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFONNATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,REACTION BUFFER CONCENTRATE (10X) (REACTION BUFFER CONCENTRATE (10X))-THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA® MEDICAL SYSTEMS' (VENTANA) REACTION BUFFER CONCENTRATE (10X) IS A TRIS BASED BUFFER SOLUTION (PH 7.6 ± 0.2) USED TO RINSE SLIDES BETWEEN STAINING STEPS AND PROVIDE A STABLE AQUEOUS ENVIRONMENT FOR THE IMMUNOHISTOCHEMISTRY (IHC) OR IN SITU HYBRIDIZATION (ISH) REACTIONS CARRIED OUT ON BENCHMARK® AND BENCHMARK XT AUTOMATED SLIDE STAINING SYSTEMS.,ULTRA CELL CONDITIONING SOLUTION (ULTRA CC2)(ULTRA CELL CONDITIONING SOLUTION (ULTRA CC2))-ULTRA CELL CONDITIONING SOLUTION (ULTRA CC2) FROM VENTANA MEDICAL SYSTEMS, INC. (VENTANA) IS A PREDILUTED SOLUTION USED AS A PRETREATMENT STEP IN THE PROCESSING OF TISSUE SAMPLES DURING IMMUNOHISTOCHEMISTRY (IHC) AND IN SITU HYBRIDIZATION (ISH) ON THE VENTANA BENCHMARK ULTRA INSTRUMENT. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA PD-L1 (SP263) RABBIT MONOCLONAL PRIMARY ANTIBODY(VENTANA PD-L1 (SP263) RABBIT MONOCLONAL PRIMARY ANTIBODY)-VENTANA -PD-LI (SP263) RABBIT MONOCLONAL PRIMARY ANTIBODY IS INTENDED FOR LABORATORY USE IN THE DETECTION OF THE PD-LL PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. IT IS INTENDED TO BE STAINED WITH THE VENTANA BENCHMARK SERIES OF IMMUNOHISTOCHEMICAL AUTOMATED SLIDE STAINERS. IT IS INDICATED AS AN AID IN THE ASSESSMENT OF PD-LL EXPRESSION IN NON-SMALL CELL LUNG CANCER (NSCLC) AND OTHER TUMOR TYPES. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,CELL CONDITIONING SOLUTION (CC2)(CELL CONDITIONING SOLUTION

	(CC2))-CELL CONDITIONING SOLUTION (CC2) FROM VENTANA MEDICAL SYSTEMS, INC. (VENTANA) IS A PREDILUTED SOLUTION USED AS A PRETREATMENT STEP IN THE PROCESSING OF TISSUE SAMPLES DURING IMMUNOHISTOCHEMISTRY (IHC) AND IN SITU HYBRIDIZATION (ISH) ON VENTANA BENCHMARK, BENCHMARK GX, AND BENCHMARK XT INSTRUMENTS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,10X SSC(10X SSC)-THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC USE. VENTANA MEDICAL SYSTEMS' (VENTANA®) 10X SSC, SODIUM CHLORIDE SODIUM CITRATE BUFFER SOLUTION IS USED FOR STRINGENCY WASHES AND TO RINSE SLIDES BETWEEN STAINING STEPS AND PROVIDE A STABLE AQUEOUS ENVIRONMENT FOR THE IN SITU HYBRIDIZATION REACTIONS CARRIED OUT ON A VENTANA AUTOMATED SLIDE STAINER.,LIQUID COVERSLIP (LOW TEMPERATURE)(LIQUID COVERSLIP (LOW TEMPERATURE))-VENTANA MEDICAL SYSTEMS' (VENTANA) LIQUID COVERSLIP (LOW TEMPERATURE) SOLUTION IS A PREDILUTED SOLUTION USED AS A BARRIER BETWEEN THE AQUEOUS REAGENTS AND THE AIR. THIS PREVENTS EVAPORATION, THEREBY PROVIDING A STABLE AQUEOUS ENVIRONMENT FOR IMMUNOHISTOCHEMISTRY AND SPECIAL STAINS REACTIONS CARRIED OUT ON VENTANA AUTOMATED SLIDE STAINERS. THIS PRODUCT IS DESIGNED FOR USE ON THE ES, NEXES IHC OR NEXES SPECIAL STAINS AUTOMATED SLIDE STAINERS. THIS REAGENT IS NOT TO BE USED ON THE VENTANA BENCHMARK OR BENCHMARK XT AUTOMATED SLIDE STAINERS. THE COVERSLIP SOLUTION THAT IS CURRENTLY BEING USED ON THE BENCHMARK OR BENCHMARK XT AUTOMATED SLIDE STAINERS MUST NOT BE USED AS A SUBSTITUTE FOR THIS PRODUCT.,EZ PREP CONCENTRATE (10X)(EZ PREP CONCENTRATE (10X))-VENTANA MEDICAL SYSTEMS' (VENTANA) EZ PREP CONCENTRATE (10X) SOLUTION (EZ PREP) IS USED FOR PARAFFIN REMOVAL FROM TISSUE SAMPLES DURING IMMUNOHISTOCHEMISTRY AND IN SITU HYBRIDIZATION REACTIONS, AND TO DILUTE 2X SSC DURING STRINGENCY WASHES DURING IN SITU HYBRIDIZATION REACTIONS CARRIED OUT ON VENTANA AUTOMATED SLIDE STAINERS. THIS PRODUCT IS DESIGNED FOR USE ON BENCHMARK SERIES AUTOMATED SLIDE STAINERS. THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,ULTRA CELL CONDITIONING SOLUTION (ULTRA CC1)(ULTRA CELL CONDITIONING SOLUTION (ULTRA CC1))-ULTRA CELL CONDITIONING SOLUTION (ULTRA CC1) FROM VENTANA MEDICAL SYSTEMS, INC. (VENTANA) IS A PRE DILUTED SOLUTION USED AS A PRETREATMENT STEP IN THE PROCESSING OF TISSUE SAMPLES FOR IMMUNOHISTOCHEMISTRY (IHC) REACTIONS CARRIED OUT ON THE VENTANA BENCHMARK ULTRA INSTRUMENT. THIS PRODUCT IS

	INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,CONFIRM ANTI-TOTAL CMET (SP44) RABBIT MONOCLONAL PRIMARY ANTIBODY (CONFIRM ANTI-TOTAL CMET (SP44) RABBIT MONOCLONAL PRIMARY ANTIBODY)-VENTANA MEDICAL SYSTEMS1 (VENTANA) CONFIRM ANTI-TOTAL C-MET (SP44) RABBIT MONOCLONAL PRIMARY ANTIBODY IS DIRECTED AGAINST A MEMBRANOUS AND/OR CYTOPLASMIC EPITOPE PRESENT IN HUMAN NORMAL EPITHELIAL OR TUMOR CELLS. THIS ANTIBODY MAY BE USED TO AID IN THE IDENTIFICATION OF NORMAL AND NEOPLASTIC C-MET EXPRESSING CELLS. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY HISTOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENTS CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,ULTRA LCS (PREDILUTE)(ULTRA LCS (PREDILUTE))-ULTRA LCS (PREDILUTE) FROM VENTANA MEDICAL SYSTEMS, INC. (VENTANA), ALSO KNOWN AS ULTRA LCS OR ULTRA LIQUID COVERSLIP (HIGH TEMPERATURE), IS A PREDILUTED COVERSLIP SOLUTION USED AS A BARRIER BETWEEN THE AQUEOUS REAGENTS AND THE AIR. THIS BARRIER PREVENTS EVAPORATION, THEREBY PROVIDING A STABLE AQUEOUS ENVIRONMENT FOR THE IMMUNOHISTO-CHEMISTRY OR IN SITU HYBRIDIZATION REACTIONS CARRIED OUT ON THE VENTANA BENCHMARK ULTRA INSTRUMENT. THIS PRODUCT IS DESIGNED FOR USE ON THE VENTANA BENCHMARK ULTRA INSTRUMENT. THIS REAGENT IS NOT TO BE USED ON THE VENTANA NEXES IHC, NEXES SPECIAL STAINS OR ES AUTOMATED SLIDE STAINERS. ,ANTI-EPITHELIAL RELATED ANTIGEN (MOC-31) MOUSE MONOCLONAL PRIMARY ANTIBODY(ANTI-EPITHELIAL RELATED ANTIGEN (MOC-31) MOUSE MONOCLONAL PRIMARY ANTIBODY)-ANTI-EPITHELIAL RELATED ANTIGEN (MOC-31) MOUSE MONOCLONAL PRIMARY ANTIBODY (ANTI-EPITHELIAL RELATED ANTIGEN (MOC31)) IS DIRECTED AGAINST THE 40KD EPITHELIAL CELL ADHESION MOLECULE, EPITHELIAL RELATED ANTIGEN. EPITHELIAL RELATED ANTIGEN IS EXPRESSED IN MOST NORMAL EPITHELIAL CELLS IN TISSUES INCLUDING LUNG, BREAST, PANCREAS, AND COLON. THIS ANTIBODY EXHIBITS A MEMBRANOUS AND/OR CYTOPLASMIC STAINING PATTERN IN NEOPLASTIC AND NORMAL TISSUE. ANTI-EPITHELIAL RELATED ANTIGEN (MOC-31) MOUSE MONOCLONAL PRIMARY ANTIBODY MAY BE USED AS AN AID IN THE DIFFERENTIATION OF LUNG ADENOCARCINOMA AND MESOTHELIOMA. THE ANTIBODY IS INTENDED FOR QUALITATIVE

	STAINING OF SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE., CONFIRM ANTI-CD4 (SP35) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-CD4 (SP35) RABBIT MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI-CD4 (SP35) RABBIT MONOCLONAL PRIMARY ANTIBODY IS INTENDED FOR THE QUALITATIVE DETECTION OF CD4 IN SECTIONS OF FORMALIN- FIXED, PARAFFIN-EMBEDDED NORMAL AND NEOPLASTIC HUMAN TISSUES. CD4 IS PRESENT ON HELPER-INDUCER T LYMPHOCYTES THAT RECOGNIZE ANTIGEN IN THE CONTEXT OF MHC CLASS 2 MOLECULES. CD4 POSITIVE STAINING RESULTS MAY AID IN IDENTIFYING T-CELL LYMPHOMAS AND IN IDENTIFYING THE T HELPER-INDUCER CELL SUBSET OF T LYMPHOCYTES IN NORMAL TISSUES. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,CINTEC P16 HISTOLOGY(CINTEC P16 HISTOLOGY)-CINTEC PL6 HISTOLOGY IS AN IMMUNOHISTOCHEMISTRY ASSAY FOR THE QUALITATIVE DETECTION OF THE PL6INK4A PROTEIN ON FORMALIN-FIXED, PARAFFINEMBEDDED TISSUE SECTIONS PREPARED FROM CERVICAL BIOPSIES. IT IS INDICATED TO BE USED IN CONJUNCTION WITH H&ESTAINED SLIDES PREPARED FROM THE SAME CERVICAL TISSUE SPECIMEN AS AN AID TO INCREASE DIAGNOSTIC ACCURACY AND INTER-OBSERVER AGREEMENT IN THE DIAGNOSIS OF HIGH-GRADE CERVICAL INTRAEPITHELIAL NEOPLASIA. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,CONFIRM ANTI-CALRETININ (SP65) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-CALRETININ (SP65) RABBIT MONOCLONAL PRIMARY ANTIBODY)-VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI-CALRETININ (SP65) RABBIT MONOCLONAL PRIMARY ANTIBODY (CONFIRM ANTI-CALRETININ (SP65)) IS DIRECTED AGAINST THE CALCIUM BINDING PROTEIN, CALRETININ, EXPRESSED BY NORMAL AND REACTIVE MESOTHELIUM, ECCRINE GLANDS OF SKIN, SERTOLI CELLS OF THE TESTIS, OVARIAN STROMAL CELLS AND ADRENAL CORTICAL CELLS.

	THIS ANTIBODY EXHIBITS A NUCLEAR AND CYTOPLASMIC STAINING PATTERN AND MAY BE USED TO AID IN THE IDENTIFICATION OF MESOTHELIOMA, AND IN DISTINGUISHING MESOTHELIOMA FROM ADENOCARCINOMA. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFONNATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE., VENTANA ANTI-P63 (4A4) MOUSE MONOCLONAL PRIMARY ANTIBODY(VENTANA ANTI-P63 (4A4) MOUSE MONOCLONAL PRIMARY ANTIBODY)-VENTANA ANTI-P63 (4A4) MOUSE MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-P63 (4A4)) IS DIRECTED AGAINST THE P63 PROTEIN. THIS ANTIBODY EXHIBITS A NUCLEAR STAINING PATTERN AND MAY BE USED TO AID IN THE DIFFERENTIATION OF BENIGN AND MALIGNANT PROSTATIC OR BREAST LESIONS, AND IN THE DIFFERENTIATION OF LUNG SQUAMOUS CELL CARCINOMA AND LUNG ADENOCARCINOMA. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (ND) USE.,ANTI-CYTOKERATIN 10 (SP99) RABBIT MONOCLONAL PRIMARY ANTIBODY(ANTI-CYTOKERATIN 10 (SP99) RABBIT MONOCLONAL PRIMARY ANTIBODY) -ANTI-CYTOKERATIN 10 (SP99) RABBIT MONOCLONAL PRIMARY ANTIBODY (ANTI- CYTOKERATIN 10 (SP99)) IS DIRECTED AGAINST THE 56.5KD MEMBER OF THE TYPE 1 CYTOKERATIN FAMILY, CYTOKERATIN 10. CYTOKERATIN 10 IS EXPRESSED IN KERATINIZING STRATIFIED EPITHELIA, BUT IS ABSENT FROM THE BASAL LAYER, IN VARIOUS ORGANS INCLUDING THE SKIN. ANTI- CYTOKERATIN 10 (SP99) EXHIBITS A CYTOPLASMIC STAINING PATTERN AND MAY BE USED TO AID IN THE IDENTIFICATION OF WELL DIFFERENTIATED SQUAMOUS CARCINOMAS OF THE CERVIX AND ANUS. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING OF SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,CONFIRM ANTI-S100 (POLYCLONAL) PRIMARY ANTIBODY(CONFIRM ANTI-S100 (POLYCLONAL) PRIMARY ANTIBODY)-VENTANA MEDICAL SYSTEMS, INC. (VENTANA) CONFIRM ANTI-S100 (POLYCLONAL) PRIMARY

	ANTIBODY (CONFIRM ANTI-S100 (POLYCLONAL)) CONTAINS RABBIT ANTISERUM DIRECTED AGAINST AN EPITOPE FOUND ON S100 PROTEIN AND MAY BE USED TO AID IN THE IDENTIFICATION OF CELLS OF NORMAL AND ABNORMAL NEURONAL AND NEUROENDOCRINE LINEAGE AND AS AN AID IN THE DIAGNOSIS OF ANAPLASTIC TUMORS. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTION OF FORMALIN- FIXED, PARAFFIN-EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA HE 600 DIFFERENTIATING SOLUTION(VENTANA HE 600 DIFFERENTIATING SOLUTION)-VENTANA HE 600 SOLUTIONS ARE INTENDED FOR USE AS A QUALITATIVE HISTOLOGIC STAIN TO DEMONSTRATE NUCLEAR AND CYTOPLASMIC STAINING OF FIXED TISSUE COMPONENTS IN PARAFFIN EMBEDDED TISSUE. VENTANA HE 600 DIFFERENTIATING SOLUTION IS A WEAK ACID SOLUTION THAT REMOVES NON-SPECIFIC STAINING OF THE HEMATOXYLIN FROM THE TISSUE AND THE GLASS SLIDE SURFACE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,CONFIRM ANTI-CYTOKERATIN 7 (SP52) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-CYTOKERATIN 7 (SP52) RABBIT MONOCLONAL PRIMARY ANTIBODY)-VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI- CYTOKERATIN 7 (SP52) RABBIT MONOCLONAL PRIMARY ANTIBODY (CONFIRM ANTI-CYTOKERATIN 7 (SP52)) IS DIRECTED AGAINST A TYPE II CYTOKERATIN PROTEIN EXPRESSED BY MOST DUCTAL, GLANDULAR AND TRANSITIONAL EPITHELIA. CYTOKERATIN 7 EXHIBITS A CYTOPLASMIC LOCALIZATION. THIS ANTIBODY MAY BE USED TO AID IN THE IDENTIFICATION OF NORMAL AND NEOPLASTIC CELLS OF OVARY, LUNG AND BREAST EPITHELIAL ORIGIN WHICH EXPRESS CYTOKERATIN 7, AND THOSE OF COLONIC AND PROSTATE EPITHELIAL LINEAGE WHICH LACK CYTOKERATIN 7 PRODUCTION. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA HE 600 ORGANIC SOLUTION(VENTANA HE 600 ORGANIC SOLUTION)-VENTANA HE 600 SOLUTIONS ARE INTENDED FOR USE AS A

	QUALITATIVE HISTOLOGIC STAIN TO DEMONSTRATE NUCLEAR AND CYTOPLASMIC STAINING OF FIXED TISSUE COMPONENTS IN PARAFFIN EMBEDDED TISSUE. VENTANA HE 600 ORGANIC SOLUTION IS USED TO DEPARAFFINIZE TISSUE PRIOR TO STAINING. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,SPECIAL STAINS (10X) WASH(SPECIAL STAINS (10X) WASH)-VENTANA MEDICAL SYSTEMS' (VENTANA) SPECIAL STAINS (10X) WASH IS USED IN CONJUNCTION WITH VENTANA SPECIAL STAINS REAGENT KITS. WHEN DILUTED ACCORDING TO INSTRUCTIONS, SPECIAL STAINS (10X) WASH IS AN OPTIMIZED SOLUTION USED FOR ALL VENTANA SPECIAL STAINS REAGENT KITS. THIS REAGENT PROVIDES A STABLE AQUEOUS ENVIRONMENT FOR SPECIAL HISTOLOGICAL STAINING REACTIONS PERFORMED ON THE NEXES SPECIAL STAINS AUTOMATED SLIDE STAINER. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA HE 600 BLUING(VENTANA HE 600 BLUING)-VENTANA HE 600 SOLUTIONS ARE INTENDED FOR USE AS A QUALITATIVE HISTOLOGIC STAIN TO DEMONSTRATE NUCLEAR AND CYTOPLASMIC STAINING OF FIXED TISSUE COMPONENTS IN PARAFFIN EMBEDDED TISSUE. VENTANA HE 600 BLUING IS USED IN CONJUNCTION WITH VENTANA HE 600 HEMATOXYLIN DURING TISSUE STAINING AND WHEN APPLIED TO TISSUE SECTIONS WILL CHANGE THE HUE OF HEMATOXYLIN FROM PURPLE TO BLUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,FITC ANTI-LAMBDA PRIMARY ANTIBODY(FITC ANTI-LAMBDA PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA® MEDICAL SYSTEMS' (VENTANA) SYSTEMS FITC ANTI-LAMBDA PRIMARY ANTIBODY IS A BURRO DERIVED POLYCLONAL ANTIBODY LABELED WITH FLUORESCEIN AND SPECIFICALLY DIRECTED AGAINST HUMAN LAMBDA LIGHT CHAINS. THIS REAGENT SHOULD BE USED IN CONJUNCTION WITH A PANEL OF ANTIBODIES TO AID IN THE IDENTIFICATION OF LAMBDA LIGHT CHAINS IN TARGET TISSUE (E.G., IN THE DIAGNOSIS OF RENAL OR DERMAL PATHOLOGIES). FITC ANTI-LAMBDA IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN SECTIONS OF FROZEN TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER

	CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY., VENTANA HE 600 TRANSFER FLUID(VENTANA HE 600 TRANSFER FLUID)-VENTANA HE 600 SOLUTIONS ARE INTENDED FOR USE AS A QUALITATIVE HISTOLOGIC STAIN TO DEMONSTRATE NUCLEAR AND CYTOPLASMIC STAINING OF FIXED TISSUE COMPONENTS IN PARAFFIN EMBEDDED TISSUE. VENTANA HE 600 TRANSFER FLUID SOLUBILIZES AND REMOVES AQUEOUS REAGENTS FROM THE TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,FITC ANTI-KAPPA PRIMARY ANTIBODY(FITC ANTI-KAPPA PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA® MEDICAL SYSTEMS' (VENTANA) SYSTEMS FITC ANTI-KAPPA PRIMARY ANTIBODY IS A GOAT DERIVED POLYCLONAL ANTIBODY LABELED WITH FLUORESCEIN AND SPECIFICALLY DIRECTED AGAINST HUMAN KAPPA IMMUNOGLOBULIN LIGHT CHAINS. THIS REAGENT SHOULD BE USED IN CONJUNCTION WITH A PANEL OF ANTIBODIES TO AID IN THE IDENTIFICATION OF KAPPA IN TARGET TISSUE (E.G., IN THE DIAGNOSIS OF RENAL OR DERMAL PATHOLOGIES). FITC ANTI-KAPPA IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN SECTIONS OF FROZEN TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY.,CONFIRM ANTI-CD5 (SP19) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-CD5 (SP19) RABBIT MONOCLONAL PRIMARY ANTIBODY)-VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI-CD5 (SP19) RABBIT MONOCLONAL PRIMARY ANTIBODY IS DIRECTED AGAINST HUMAN CD5 EXPRESSED ON THE PLASMA MEMBRANE OF VIRTUALLY ALL HUMAN T CELLS AND THE B1A SUBSET OF HUMAN B CELLS FOUND IN THE FOLLICULAR MANTLE ZONES, BONE MARROW AND PERIPHERAL BLOOD. STAINING CD5 IS COMMONLY USED AS PART OF SEVERAL IHC PANELS TO DETERMINE T CELL AND B CELL SUBCLASSIFICATIONS. CD5 MAY BE USED TO AID IN THE IDENTIFICATION OF T CELL LYMPHOMAS, AND CERTAIN B CELL LYMPHOMAS, INCLUDING MANTLE CELL LYMPHOMA. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN

	FIXED, PARAFFIN EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,CONFIRM ANTI-LAMBDA RABBIT POLYCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-LAMBDA RABBIT POLYCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-LAMBDA RABBIT POLYCLONAL PRIMARY ANTIBODY IS DIRECTED AGAINST LAMBDA IMMUNOGLOBULIN LIGHT CHAINS. STAINING FOR LAMBDA LIGHT CHAINS CAN BE USED TO AID IN THE IDENTIFICATION OF CELLS OF NORMAL AND ABNORMAL B CELL LINEAGE THIS ANTIBODY IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN B CELLS AND PLASMA CELLS EXPRESSING LAMBDA LIGHT CHAIN IMMUNOGLOBULINS IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. CONFIRM ANTI-LAMBDA RABBIT POLYCLONAL SPECIFICALLY BINDS TO ANTIGENS LOCATED IN THE CELL MEMBRANE AND CYTOPLASMIC REGIONS OF NORMAL B CELLS AND PLASMA CELLS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION USE ONLY., LCS (PREDILUTE)(LCS (PREDILUTE))-VENTANA MEDICAL SYSTEMS' (VENTANA) LCS (PREDILUTE), ALSO KNOWN AS LCS OR LIQUID COVERSLIP (HIGH TEMPERATURE) IS A PREDILUTED COVERSLIP SOLUTION USED AS A BARRIER BETWEEN THE AQUEOUS REAGENTS AND THE AIR. THIS BARRIER PREVENTS EVAPORATION, THEREBY PROVIDING A STABLE AQUEOUS ENVIRONMENT FOR THE IMMUNOHISTOCHEMISTRY OR IN SITU HYBRIDIZATION REACTIONS CARRIED OUT ON VENTANA AUTOMATED SLIDE STAINER. THIS PRODUCT IS DESIGNED FOR USE ON THE BENCHMARK AND BENCHMARK XT AUTOMATED SLIDE STAINERS. THIS REAGENT IS NOT TO BE USED ON THE VENTANA NEXES IHC, NEXES SPECIAL STAINS OR ES AUTOMATED SLIDE STAINERS. THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC USE.,VENTANA SILVER ISH DNP DETECTION KIT(VENTANA SILVER ISH DNP DETECTION KIT)-THE VENT ANA SILVER ISH DNP DETECTION KIT IS AN INDIRECT SYSTEM FOR DETECTING DNPLABELED TARGETS. THE KIT IS INTENDED TO IDENTIFY TARGETS BY SILVER IN SITU HYBRIDIZATION (ISH) M SECTIONS OF FONNALIN-FIXED, PARAFFIN-EMBEDDED TISSUE THAT ARE STAINED ON BENCHMARK IHC/ISH INSTRUMENTS. THIS

	PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED READER IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA RED ISH DIG DETECTION KIT(VENTANA RED ISH DIG DETECTION KIT)-THE VENTANA RED ISH DIG DETECTION KIT IS AN INDIRECT SYSTEM FOR DETECTING DIG-LABELED TARGETS. THE KIT IS INTENDED TO IDENTIFY TARGETS BY CHROMOGENIC RED IN SITU HYBRIDIZATION (ISH) IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE THAT ARE STAINED ON BENCHMARK IHC/ISH INSTRUMENTS. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED READER IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,ANTI-CEA (TF-3H8-1) PRIMARY ANTIBODY(ANTI-CEA (TF-3H8-1) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC USE. VENTANA MEDICAL SYSTEMS' (VENTANA) CEA (TF 3H8-L) PRIMARY ANTIBODY MAY BE USED TO AID IN THE IDENTIFICATION OF CELLS OF NORMAL AND ABNORMAL EPITHELIAL LINEAGE AS AN AID IN DIAGNOSIS OF ANAPLASTIC TUMORS. CEA (TF 3H8-L) PRIMARY ANTIBODY SPECIFICALLY BINDS TO ANTIGENS LOCATED IN THE PLASMA MEMBRANE AND CYTOPLASMIC REGIONS OF NORMAL SIMPLE EPITHELIAL CELLS. CEA (TF 3H8-1) IS A MOUSE MONOCLONAL ANTIBODY (IGG1) DIRECTED AGAINST CARCINOEMBRYONIC ANTIGEN (CEA). THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.,CONFIRM ANTI-KERATIN (34E12) MOUSE MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-KERATIN (34E12) MOUSE MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC USE. VENTANA MEDICAL SYSTEMS1 CONFIRM ANTI-KERATIN (34BE12) MOUSE MONOCLONAL PRIMARY ANTIBODY RECOGNIZES CYTOKERATINS 1, 5, 10, AND 14 AND IS USED AS AN AID IN THE IDENTIFICATION OF BASAL CELLS IN PROSTATE, AND MYOEPITHELIAL CELLS IN BREAST, VIA LIGHT MICROSCOPY IN FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE FOLLOWING STAINING ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE

	BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENTS CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS,RNA POSITIVE CONTROL PROBE(RNA POSITIVE CONTROL PROBE)-"VENTANA MEDICAL SYSTEMS, LNC.'S (VENTANA) RNA POSITIVE CONTROL PROBE IS AN OLIGONUCLEOTIDE PROBE COCKTAIL LABELED WITH FLUORESCEIN THAT IS TO BE USED AS A POSITIVE CONTROL TO DETERMINE THE PRESERVATION OF MRNA DURING SPECIMEN COLLECTION, PROCESSING AND HANDLING. RNA POSITIVE CONTROL PROBE IS TO BE USED IN CONJUNCTION WITH ISH IVIEWBLUE DETECTION KIT, AND OTHER ACCESSORY REAGENTS TO STAIN TISSUE SECTIONS THAT ARE FIXED IN NEUTRAL BUFFERED FORMALIN AND PARAFFIN EMBEDDED ON THE BENCHMARK, BENCHMARK XT, OR BENCHMARK ULTRA AUTOMATED SLIDE STAINERS. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. POSITIVE RESULTS AID IN THE CLASSIFICATION OF NORMAL AND ABNORMAL SPECIMENS, AND SERVE AS AN ADJUNCT TO CONVENTIONAL HISTOPATHOLOGY OR CYTOPATHOLOGY TESTS. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE." , CONFIRM ANTI-PROSTATE SPECIFIC ANTIGEN (PSA) RABBIT POLYCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-PROSTATE SPECIFIC ANTIGEN (PSA) RABBIT POLYCLONAL PRIMARY ANTIBODY) -THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI-PROSTATE SPECIFIC ANTIGEN (PSA)PRIMARY ANTIBODY IS A RABBIT POLYCLONAL ANTIBODY (LG) DIRECTED AGAINST BOTH FREE AND BOUND HUMAN PROSTATE SPECIFIC ANTIGEN (PSA). THIS ANTIBODY IS INTENDED FOR USE TO QUALITATIVELY IDENTIFY PSA BY LIGHT MICROSCOPY IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE FOLLOWING STAINING ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENTS CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,VENTANA BASAL CELL COCKTAIL (34ßE12+P63)(VENTANA BASAL CELL COCKTAIL (34ßE12+P63))-VENTANA BASAL CELL COCKTAIL (34BE12+P63) IS AN ANTIBODY COCKTAIL OF ANTI-P63 (4A4) AND ANTI-KERATIN (34BE12). ANTI-P63 (4A4) REACTS WITH THE P63 MOLECULE IN THE NUCLEI OF HUMAN PROSTATIC BASAL CELLS AND UROTHELIAL TISSUES. ANTI- KERATIN (34BE12) REACTS WITH CYTOKERATINS I, 5,

	10 AND 14, AND STAINS THE CYTOPLASM OF HUMAN PROSTATIC BASAL CELLS. THIS ANTIBODY COCKTAIL MAY BE USED TO AID IN THE DIFFERENTIATION OF BENIGN AND MALIGNANT PROSTATIC LESIONS. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN- EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE., CONFIRM ANTI-ESTROGEN RECEPTOR (ER) (SP1) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-ESTROGEN RECEPTOR (ER) (SP1) RABBIT MONOCLONAL PRIMARY ANTIBODY)- THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. CONFIRM ANTI-ESTROGEN RECEPTOR (ER) (SPI) RABBIT MONOCLONAL PRIMARY ANTIBODY IS INTENDED FOR LABORATORY USE FOR THE QUALITATIVE DETECTION OF ESTROGEN RECEPTOR (ER) ANTIGEN IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED BREAST TISSUE ON A VENTANA AUTOMATED SLIDE STAINER WITH VENTANA DETECTION KITS AND ANCILLARY REAGENTS. CONFIRM ANTI-ER (SPI) IS DIRECTED AGAINST AN EPITOPE PRESENT ON HUMAN ER ALPHA PROTEIN LOCATED IN THE NUCLEUS OF ER POSITIVE NORMAL AND NEOPLASTIC CELLS. CONFIRM ANTI-ER (SPI) IS INDICATED AS AN AID IN THE MANAGEMENT, PROGNOSIS, AND PREDICTION OF HORMONE THERAPY FOR BREAST CARCINOMA. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFONNATION, AND PROPER CONTROLS. PRESCRIPTION USE ONLY.,CONFIRM ANTI-CYTOKERATIN (AE1) PRIMARY ANTIBODY(CONFIRM ANTI-CYTOKERATIN (AE1) PRIMARY ANTIBODY)-"THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-CYTOKERATIN (AEL) IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN CYTOKERATIN IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. CONFIRM ANTI- CYTOKERATIN (AE1) MAY BE USED TO AID IN THE IDENTIFICATION OF CELLS OF NORMAL AND ABNORMAL EPITHELIAL LINEAGE AS AN AID IN DIAGNOSIS OF ANAPLASTIC TUMORS. CONFIRM ANTI-CYTOKERATIN (AE1) SPECIFICALLY BINDS TO ANTIGENS LOCATED IN THE CYTOPLASMIC REGIONS OF NORMAL EPITHELIAL CELLS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED

	PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY." , CONFIRM ANTI-CYTOKERATIN 20 (SP33) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-CYTOKERATIN 20 (SP33) RABBIT MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI- CYTOKERATIN 20 (SP33) RABBIT MONOCLONAL PRIMARY ANTIBODY IS DIRECTED AGAINST A TYPE I CYTOKERATIN PROTEIN OF MATURE ENTEROCYTES AND GOBLET CELLS OF THE GASTRIC AND INTESTINAL MUCOSA. THIS ANTIBODY PRODUCES A CYTOPLASMIC STAINING PATTERN, AND MAY BE USED TO AID IN THE IDENTIFICATION OF NONNAL CYTOKERATIN 20 EXPRESSING CELLS AND NEOPLASTIC CELLS OF COLONIC EPITHELIAL LINEAGE. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY HISTOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,CONFIRM ANTI-MITF (C5/D5) MOUSE MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-MITF (C5/D5) MOUSE MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-MITF (C5/D5) MOUSE MONOCLONAL PRIMARY ANTIBODY IS A MOUSE MONOCLONAL COCKTAIL. THIS ANTIBODY COCKTAIL REAGENT DETECTS MICROPHTHALMIA TRANSCRIPTION FACTOR (MITF) PROTEINS 52-56KD OF MITF EXPRESSING CELLS IN NORMAL AND NEOPLASTIC TISSUES. THIS ANTIBODY IS USED IN THE IDENTIFICATION OF MELANOTIC LESIONS SUCH AS MALIGNANT MELANOMA AND MELANOTIC NEUROFIBROMA. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE. THE CLINICAL INTERPRETATION OF ANY STAINING OR ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENTS CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,ANTI-CYTOKERATIN 17 (SP95) RABBIT MONOCLONAL PRIMARY ANTIBODY (ANTI-CYTOKERATIN 17 (SP95) RABBIT MONOCLONAL PRIMARY ANTIBODY)-ANTI-CYTOKERATIN 17 (SP95) RABBIT MONOCLONAL PRIMARY ANTIBODY (ANTI- CYTOKERATIN 17 (SP95)) IS DIRECTED AGAINST CYTOKERNTIN 17 EXPRESSED IN BASAL CELLS OF COMPLEX

	EPITHELIA, GLANDULAR EPITHELIUM WITH MYOEPITHELIAL COMPONENT, AND TRANSITIONAL AND PSEUDOSTRATIFIED EPITHELIA. THIS ANTIBODY MAY BE USED TO AID IN THE IDENTIFICATION OF SQUAMOUS CELL CARCINOMAS IN VARIOUS TISSUES INCLUDING THE CERVIX, LUNG, AND ORAL CAVITY. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,CONFIRM ANTI-EPIDERMAL GROWTH FACTOR RECEPTOR (3C6) PRIMARY ANTIBODY (CONFIRM ANTI-EPIDERMAL GROWTH FACTOR RECEPTOR (3C6) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) (3C6) PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY (IGG1) DIRECTED AGAINST THE EXTRACELLULAR DOMAIN OF HUMAN EGFR PROTEIN OF 170KD. THE ANTIBODY ALSO RECOGNIZES THE TYPE III VARIANT OF 145KD. THIS ANTIBODY IS INTENDED FOR LABORATORY USE, VIA LIGHT MICROSCOPY, FOR THE QUALITATIVE DETECTION OF EGFR IN FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY.,HPV 3 IN 1 SYSTEM CONTROL SLIDES(HPV 3 IN 1 SYSTEM CONTROL SLIDES)-"THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS, INC.S (VENTANA) HPV 3 IN 1 SYSTEM CONTROL SLIDES CONTAINS 10 SLIDES FOR USE ON BENCHMARK SERIES AUTOMATED SLIDE STAINERS. EACH SLIDE CONTAINS THREE FORMALIN- FIXED, PARAFFIN-EMBEDDED ARTIFICIAL TUMORS GENERATED USING CHARACTERIZED HUMAN CELL LINES. SLIDES ARE DESIGNED TO ALLOW THE USER TO CHECK THE INSTRUMENT'S IN SITU HYBRIDIZATION (ISH) STAINING PERFORMANCE. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION." ,CONFIRM ANTI-IGF-1R (G11) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-IGF-1R(G11) RABBIT MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI-LGF-IR (GI I) PRIMARY ANTIBODY IS A RABBIT MONOCLONAL ANTIBODY DIRECTED AGAINST

	IGF-LR. THIS ANTIBODY IS INTENDED FOR USE TO QUALITATIVELY IDENTIFY IGF-LR POSITIVE CELLS BY LIGHT MICROSCOPY IN SECTIONS OF FONNALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST,OPTIVIEW DAB IHC DETECTION KIT (OPTIVIEW DAB IHC DETECTION KIT)-OPTIVIEW DAB IHC DETECTION KIT (OPTIVIEW) IS AN INDIRECT, BIOTIN-FREE SYSTEM FOR DETECTING MOUSE IGG, MOUSE IGM AND RABBIT PRIMARY ANTIBODIES. THE KIT IS INTENDED TO IDENTIFY TARGETS BY IMMUNOHISTOCHEMISTRY (IHC) IN SECTIONS OF FORMALIN- FIXED, PARAFFIN-EMBEDDED AND FROZEN TISSUE THAT ARE STAINED ON THE VENTANA AUTOMATED SLIDE STAINERS AND VISUALIZED BY LIGHT MICROSCOPY. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION. RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. ,ISH IVIEW BLUE PLUS DETECTION KIT(ISH IVIEW BLUE PLUS DETECTION KIT)-VENTANA MEDICAL SYSTEMS, INC.S (VENTANA) ISH IVIEWBLUE PLUS DETECTION KIT CONSISTS OF A PRIMARY RABBIT ANTI-DNP ANTIBODY FOLLOWED BY AN INDIRECT BIOTIN STREPTAVIDIN SYSTEM FOR DETECTING VENTANA DNP LABELED PROBES AND ANTIBODIES. THIS KIT IS INTENDED FOR STAINING SECTIONS OF ROUTINELY FIXED (NEUTRAL BUFFERED FORMALIN), PARAFFIN EMBEDDED TISSUE ON THE BENCHMARK SERIES AUTOMATED SLIDE STAINERS. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING INTENSITY. POSITIVE RESULTS AID IN THE CLASSIFICATION OF NORMAL AND ABNORMAL CELLS AND TISSUES AND SERVE AS AN ADJUNCT TO CONVENTIONAL HISTOPATHOLOGY TESTS. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. , CONFIRM ANTI-SYNAPTOPHYSIN (SP11) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-SYNAPTOPHYSIN (SP11) RABBIT MONOCLONAL PRIMARY ANTIBODY)-"THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI- SYNAPTOPHYSIN (SP11) RABBIT MONOCLONAL PRIMARY ANTIBODY IS DESIGNED TO QUALITATIVELY

	DETECT THE PRESENCE OF SYNAPTOPHYSIN EXPRESSING CELLS VIA LIGHT MICROSCOPY IN FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE. POSITIVE STAINING RESULTS MAY AID IN THE CLASSIFICATION OF NEUROENDOCRINE TUMORS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS." ,ISH PROTEASE 1(ISH PROTEASE 1)-THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) ISH PROTEASE 1 IS INTENDED FOR ENZYMATIC DIGESTION OF TISSUE SECTIONS THAT HAVE BEEN FORMALIN- FIXED AND PARAFFIN-EMBEDDED OR OF WHOLE CELL PREPARATIONS WHERE PERMEABILIZATION OF MULTIPLE MEMBRANES BECOMES A CRITICAL STEP IN THE IN SITU HYBRIDIZATION (ISH) PROCESS. IT IS USED IN THE ISH PROCESS TO REMOVE PROTEIN THAT SURROUNDS THE TARGET DNA OR RNA SEQUENCES OF INTEREST. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.,VENTANA ISH IVIEW BLUE DETECTION KIT(VENTANA ISH IVIEW BLUE DETECTION KIT)- "VENTANA MEDICAL SYSTEMS, LNC.S (VENTANA) ISH IVIEWBLUE DETECTION KIT CONSISTS OF A PRIMARY MOUSE ANTI-FLUORESCEIN ANTIBODY THAT, WHEN FOLLOWED BY AN INDIRECT BIOTIN STREPTAVIDIN SYSTEM, ALLOWS THE DETECTION OF FLUORESCEIN-LABELED PROBES. THE KIT IS INTENDED TO BE USED AS A DETECTION SYSTEM FOR A VARIETY OF VENTANA ISH PROBES TO STAIN SECTIONS THAT ARE FIXED IN NEUTRAL BUFFERED FORMALIN, PARAFFIN EMBEDDED TISSUE, OR CYTOLOGICAL PREPARATIONS ON THE BENCHMARK, BENCHMARK XT, OR BENCHMARK ULTRA AUTOMATED SLIDE STAINERS. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. POSITIVE RESULTS AID IN THE CLASSIFICATION OF NORMAL AND ABNORMAL SPECIMENS, AND SERVE AS AN ADJUNCT TO CONVENTIONAL HISTOPATHOLOGY OR CYTOPATHOLOGY TESTS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL

	HISTORY AND OTHER DIAGNOSTIC TESTS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE." ,CONFIRM ANTI-KERATIN (AE3) PRIMARY ANTIBODY(CONFIRM ANTI-KERATIN (AE3) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC USE. VENTANA MEDICAL SYSTEMS' (VENTANA) CONFIRM ANTI-KERATIN (AE3) IS A MOUSE MONOCLONAL ANTIBODY (IGGI, KAPPA) DIRECTED AGAINST BASIC CYTOKERATINS OFH 65-67, 64, 59, 56, AND 52 KD. UNEXPECTED ANTIGEN EXPRESSION OR LOSS OF EXPRESSION MAY OCCUR, ESPECIALLY IN NEOPLASMS. OCCASIONALLY STROMAL ELEMENTS SURROUNDING HEAVILY STAINED TISSUE OR CELLS WILL SHOW IRNMUNOREACTIVITY. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENTS CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.,ISH PROTEASE 3(ISH PROTEASE 3)-VENTANA MEDICAL SYSTEMS (VENTANA) ISH PROTEASE 3 IS AN ENDOPEPTIDASE OF THE SERINE PROTEASE FAMILY, WHICH IS NONSPECIFIC AND CLEAVES ALL PEPTIDE BONDS. ISH PROTEASE 3 IS A LOW ACTIVITY ENZYME FORMULATION RELATIVE TO THE STRONGER ISH PROTEASE 2. ISH PROTEASE 3 IS USED IN THE IN SITU HYBRIDIZATION PROCESS TO REMOVE PROTEIN THAT SURROUNDS THE TARGET DNA OR RNA SEQUENCES OF INTEREST. THE INCUBATION TIME AND TEMPERATURE HAVE BEEN CAREFULLY OPTIMIZED BY PROBE TYPE ON THE BENCHMARK OR BENCHMARK XT AUTOMATED SLIDE STAINER TO PREVENT DISRUPTION OF TISSUE OR CELLULAR INTEGRITY. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. POSITIVE RESULTS AID IN THE CLASSIFICATION OF NORMAL AND ABNORMAL SPECIMENS, AND SERVE AS AN ADJUNCT TO CONVENTIONAL HISTOPATHOLOGY OR CYTOPATHOLOGY TESTS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. ,EBER POSITIVE SPECIMEN SLIDES(EBER POSITIVE SPECIMEN SLIDES)-VENTANA MEDICAL SYSTEMS (VENTANA) EBER (EPSTEIN-BARR VIRUS ENCODED RNA) POSITIVE SPECIMEN SLIDES CONTAIN 10 SLIDES FOR USE ON THE BENCHMARK OR BENCHMARK XT AUTOMATED SLIDE STAINER. EACH SLIDE CONTAINS TWO CELL PELLETS, ONE NEGATIVE

	AND ONE POSITIVE, FIXED IN 10 PER CENT NEUTRAL BUFFERED FORMALIN (NBF). SLIDES ARE DESIGNED TO ALLOW THE USER TO CHECK THE INSTRUMENT'S IN SITU HYBRIDIZATION (ISH) STAINING FUNCTION AND TO CONFIRM APPROPRIATE STAINING RESULTS BY THE VENTANA INFORM EBER PROBE. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. ,CONFIRM ANTI-CD99 (O13) MOUSE MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-CD99 (O13) MOUSE MONOCLONAL PRIMARY ANTIBODY)-"VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-CD99 (O13) MOUSE MONOCLONAL PRIMARY ANTIBODY (CONFIRM ANTI-CD99 (O13)) IS DIRECTED AGAINST HUMAN CD99 EXPRESSED ON T LYMPHOCYTES, CORTICAL THYMOCYTES, GRANULOSA CELLS OF THE OVARY, PANCREATIC ISLET CELLS, CNS EPENDYMAL CELLS AND SERTOLI'S CELLS. CD99 SHOWS A PLASMA MEMBRANE LOCATION. THIS ANTIBODY MAY BE USED AS PART OF A PANEL TO AID IN THE IDENTIFICATION OF EWING'S SARCOMA AND RELATED PERIPHERAL NEUROECTODERMAL TUMORS. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE." ,PATHWAY ANTI-HER-2/NEU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY(PATHWAY ANTI-HER-2/NEU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC USE. VENTANA MEDICAL SYSTEMS, INC.'S (VENTANA) PATHWAY ANTI-HER-2/NEU (4B5) RABBIT MONOCLONAL PRIMARY ANTIBODY (PATHWAY HER2 (4B5)) IS A RABBIT MONOCLONAL ANTIBODY INTENDED FOR LABORATORY USE FOR THE SEMI-QUANTITATIVE DETECTION OF HER2 ANTIGEN IN SECTIONS OF FORMALIN-FIXED, PARAFFIN- EMBEDDED NORMAL AND NEOPLASTIC TISSUE ON A VENTANA AUTOMATED IMMUNOHISTOCHEMISTRY SLIDE STAINING DEVICE. IT IS INDICATED AS AN AID IN THE ASSESSMENT OF BREAST CANCER PATIENTS FOR WHOM HERCEPTIN TREATTNENT IS CONSIDERED. NOTE: ALL OF THE PATIENTS IN THE HERCEPTIN CLINICAL TRIALS WERE SELECTED USING A CLINICAL TRIAL ASSAY. NONE OF THE PATIENTS IN THOSE TRIALS WERE SELECTED USING PATHWAY ANTI-HER- 2/NEU (4B5). PATHWAYANTI-HER-2/NEU (4B5) WAS COMPARED TO PATHWAY HER-2 (CLONE CBI I) PRIMARY ANTIBODY ON AN INDEPENDENT SAMPLE SET AND FOUND TO PROVIDE ACCEPTABLY CONCORDANT RESULTS. THE ACTUAL CORRELATION OF PATHWAY ANTI-HER-2/NEU (4B5) TO CLINICAL OUTCOME HAS NOT BEEN ESTABLISHED. THE VIAS IMAGE ANALYSIS SYSTEM IS AN ADJUNCTIVE OPTIONAL

	COMPUTER-ASSISTED IMAGE ANALYSIS SYSTEM FUNCTIONALLY CONNECTED TO AN INTERACTIVE MICROSCOPE. IT IS INTENDED FOR USE AS AN AID TO THE PATHOLOGIST IN THE DETECTION, CLASSIFICATION AND COUNTING OF CELLS OF INTEREST BASED ON MARKER INTENSITY, SIZE AND SHAPE USING APPROPRIATE CONTROLS TO ASSURE THE VALIDITY OF THE VIAS SCORES. PRESCRIPTION USE ONLY.,ISH BLOCK(ISH BLOCK)-VENTANA MEDICAL SYSTEM'S (VENTANA) ISH BLOCK IS USED TO DECREASE NON-SPECIFIC HYBRIDIZATION OF NICK-LABELED PROBES DURING IN SITU HYBRIDIZATION STAINING PROCESS. ISH BLOCK REAGENT IS TO BE USED IN CONJUNCTION WITH VENTANA ISH PROBES, AND OTHER ACCESSORY REAGENTS TO STAIN SLIDES ON THE BENCHMARK SERIES AUTOMATED SLIDE STAINERS. THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. ,VENTANA ANTI-HELICOBACTER PYLORI (SP48) RABBIT MONOCLONAL PRIMARY ANTIBODY(VENTANA ANTI-HELICOBACTER PYLORI (SP48) RABBIT MONOCLONAL PRIMARY ANTIBODY)-" VENTANA ANTI-HELICOBACTER PYLORI (SP48) RABBIT MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-H. PYLORI (SP48)) IS DESIGNED TO QUALITATIVELY DETECT THE PRESENCE OF HELICOBACTER PYLORI IN FORMALIN- FIXED, PARAFFIN-EMBEDDED GASTRIC BIOPSY TISSUE VIA LIGHT MICROSCOPY. IMMUNOHISTOCHEMICAL STAINING WITH THIS ANTIBODY PRODUCT MAY AID IN THE DIAGNOSIS OF HELICOBACTER PYLORI INFECTION. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE." ,CONFIRM ANTI-P53 (DO-7) PRIMARY ANTIBODY(CONFIRM ANTI-P53 (DO-7) PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-P53 (DO-7) PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY (IGGL, KAPPA) DIRECTED AGAINST HUMAN P53. THE ANTIBODY IS INTENDED FOR LABORATORY USE TO QUALITATIVELY IDENTIFY BY LIGHT MICROSCOPY WILD TYPE AND MUTANT P53 IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.,ANTI-MUC1 (H23) MOUSE MONOCLONAL

	PRIMARY ANTIBODY(ANTI-MUC1 (H23) MOUSE MONOCLONAL PRIMARY ANTIBODY)-ANTI-MUCI (H23) MOUSE MONOCLONAL PRIMARY ANTIBODY IS DIRECTED AGAINST THE MEMBRANE BOUND, GLYCOSYLATED PHOSPHOPROTEIN MUCL. THIS ANTIBODY MAY BE USED TO AID IN THE IDENTIFICATION OF NORMAL AND NEOPLASTIC MUC1 EXPRESSING CELLS. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OFFONNALIN-FIXED, PARAFFINEMBEDDED HUMAN TISSUE. MUCL IS OVEREXPRESSED IN BREAST CARCINOMA AND NON SMALL CELL LUNG CARCINOMA. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFONNATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,ULTRAVIEW UNIVERSAL ALKALINE PHOSPHATASE RED DETECTION KIT (ULTRAVIEW UNIVERSAL ALKALINE PHOSPHATASE RED DETECTION KIT)-THE VENTANA ULTRAVIEW UNIVERSAL ALKALINE PHOSPHATASE RED DETECTION KIT (ULTRAVIEW AP RED DETECTION KIT) IS AN INDIRECT BIOTIN-FREE SYSTEM FOR DETECTING MOUSE IGG, MOUSE IGM AND RABBIT PRIMARY ANTIBODIES USING LIGHT MICROSCOPY. THE KIT IS INTENDED FOR LABORATORY USE TO IDENTIFY TARGETS BY IMMUNOHISTOCHEMISTRY (IHC) IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE THAT ARE STAINED ON VENTANA BENCHMARK IHC/ISH INSTRUMENTS. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,ULTRAVIEW UNIVERSAL DAB DETECTION KIT(ULTRAVIEW UNIVERSAL DAB DETECTION KIT)-VENTANA MEDICAL SYSTEMS (VENTANA) ULTRAVIEW UNIVERSAL DAB DETECTION KIT IS AN INDIRECT, BIOTIN-FREE SYSTEM FOR DETECTING MOUSE IGG, MOUSE IGM AND RABBIT PRIMARY ANTIBODIES. THE KIT IS INTENDED TO IDENTIFY TARGETS BY IMMUNOHISTOCHEMISTRY (IHC) IN SECTIONS OF FORMALINFIXED, PARAFFIN-EMBEDDED AND FROZEN TISSUE THAT ARE STAINED ON THE BENCHMARK, BENCHMARK XT, AND BENCHMARK ULTRA INSTRUMENTS. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,ULTRAVIEW SISH DETECTION KIT(ULTRAVIEW SISH DETECTION KIT)-THIS DETECTION KIT IS INTENDED FOR IN VITRO DIAGNOSTIC USE. VENTANA MEDICAL SYSTEMS (VENTANA) ULTRAVIEW SISH DETECTION KIT IS AN INDIRECT, BIOTINFREE SYSTEM FOR DETECTING RABBIT PRIMARY ANTIBODIES. THE KIT IS

	INTENDED TO IDENTIFY TARGETS BY IN SITU HYBRIDIZATION (ISH) IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE THAT ARE STAINED ON THE BENCHMARK SERIES AUTOMATED SLIDE STAINERS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENTS CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. ,CONFIRM ANTI-PAX5 (SP34) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-PAX5 (SP34) RABBIT MONOCLONAL PRIMARY ANTIBODY)-"VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-PAX5 (SP34) RABBIT MONOCLONAL PRIMARY ANTIBODY IS DIRECTED AGAINST A NUCLEAR EPITOPE PRESENT IN HUMAN B LYMPHOCYTES. THIS ANTIBODY MAY BE USED TO AID IN THE IDENTIFICATION OF NORMAL AND NEOPLASTIC CELLS OF B-LYMPHOCYTIC LINEAGE. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, SHALL BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE." ,LAMBDA POSITIVE SPECIMEN SLIDES (LAMBDA POSITIVE SPECIMEN SLIDES)-VENTANA MEDICAL SYSTEMS (VENTANA) LAMBDA POSITIVE SPECIMEN SLIDES CONTAIN 10 SLIDES FOR USE ON THE BENCHMARK OR BENCHMARKXT AUTOMATED SLIDE STAINER. EACH SLIDE CONTAINS ONE PARAFFIN EMBEDDED, 10 PER CENT NEUTRAL BUFFERED FORMALIN (NBF) FIXED TISSUE SECTION OF NORMAL HUMAN TONSIL. SLIDES ARE DESIGNED TO ALLOW THE USER TO CHECK THE INSTRUMENT'S IN SITU HYBRIDIZATION (ISH) STAINING FUNCTION AND TO CONFIRM DETECTION OF LAMBDA LIGHT CHAIN MRNA IN PLASMA CELLS. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. ,ANTI-CD30 (BER-H2) MOUSE MONOCLONAL PRIMARY ANTIBODY(ANTI-CD30 (BER-H2) MOUSE MONOCLONAL PRIMARY ANTIBODY)-THE ANTI-CD30 (BER-H2) MOUSE MONOCLONAL PRIMARY ANTIBODY (ANTI-CD30 (BER-H2)) IS INTENDED FOR LABORATORY USE IN THE DETECTION OF THE CD30 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE STAINED WITH A VENTANA BENCHMARK SERIES IMMUNOHISTOCHEMICAL (IHC) AUTOMATED SLIDE STAINER. CD30 POSITIVE STAINING RESULTS MAY AID IN THE IDENTIFICATION OF CLASSICAL HODGKIN LYMPHOMA AND ANAPLASTIC LARGE CELL

	LYMPHOMA. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,RED COUNTERSTAIN II(RED COUNTERSTAIN II)-THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) RED COUNTERSTAIN II IS INTENDED TO AID MICROSCOPIC BRIGHT FIELD OBSERVATION FOR VENTANA DNP LABELED PROBES. RED COUNTERSTAIN II IS FOR USE WITH FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON THE BENCHMARK SERIES AUTOMATED SLIDE STAINERS. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. POSITIVE RESULTS AID IN THE CLASSIFICATION OF NORMAL AND ABNORMAL SPECIMENS, AND SERVE AS AN ADJUNCT TO CONVENTIONAL HISTOPATHOLOGY TESTS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY. ,ULTRAVIEW SILVER WASH II(ULTRAVIEW SILVER WASH II)- THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC USE. VENTANA MEDICAL SYSTEMS (VENTANA) ULTRAVIEW SILVER WASH II SOLUTION IS USED TO RINSE SLIDES BETWEEN STAINING STEPS AND PROVIDE A STABLE AQUEOUS ENVIRONMENT FOR THE IN SITU HYBRIDIZATION CHROMOGEN REACTION CARRIED OUT ON A VENTANA AUTOMATED SLIDE STAINER WHEN USING THE ULTRAVIEW SISH DETECTION KIT. ,ISH PROTEASE 2(ISH PROTEASE 2)-THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) ISH PROTEASE 2 IS AN ENDOPEPTIDASE OF THE SERINE PROTEASE FAMILY, WHICH IS NONSPECIFIC AND CLEAVES ALL PEPTIDE BONDS. ISH PROTEASE 2 IS A MEDIUM ACTIVITY ENZYME FORMULATION RELATIVE TO THE STRONGER ISH PROTEASE 1 AND THE WEAKER ISH PROTEASE 3. ISH PROTEASE 2 IS USED IN THE IN SITU HYBRIDIZATION PROCESS TO REMOVE PROTEIN THAT SURROUNDS THE TARGET DNA OR RNA SEQUENCES OF INTEREST. THE INCUBATION TIME AND TEMPERATURE HAVE BEEN CAREFULLY OPTIMIZED BY PROBE TYPE ON THE BENCHMARK OR BENCHMARK XT AUTOMATED SLIDE STAINER TO PREVENT DISRUPTION OF TISSUE OR CELLULAR INTEGRITY. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. POSITIVE RESULTS AID IN THE CLASSIFICATION OF NORMAL AND ABNORMAL SPECIMENS, AND SERVE AS AN ADJUNCT TO CONVENTIONAL HISTOPATHOLOGY OR

	CYTOPATHOLOGY TESTS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,KAPPA POSITIVE SPECIMEN SLIDES(KAPPA POSITIVE SPECIMEN SLIDES)-VENTANA MEDICAL SYSTEMS (VENTANA) KAPPA POSITIVE SPECIMEN SLIDES CONTAIN 10 SLIDES FOR USE ON THE BENCHMARK OR BENCHMARK XT AUTOMATED SLIDE STAINER. EACH SLIDE CONTAINS ONE PARAFFIN EMBEDDED, 10 PER CENT NEUTRAL BUFFERED FORMALIN (NBF) FIXED TISSUE SECTION OF NORMAL HUMAN TONSIL. SLIDES ARE DESIGNED TO ALLOW THE USER TO CHECK THE INSTRUMENTS IN SITU HYBRIDIZATION (ISH) STAINING FUNCTION AND TO CONFIRM DETECTION OF KAPPA IMMUNOGLOBULIN LIGHT CHAIN MESSENGER RNA (MRNA) IN PLASMA CELLS. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION.,ANTI-P40 (BC28) MOUSE MONOCLONAL PRIMARY ANTIBODY(ANTI-P40 (BC28) MOUSE MONOCLONAL PRIMARY ANTIBODY)-ANTI-P40 (BC28) MOUSE MONOCLONAL PRIMARY ANTIBODY [ANTI-P40 (BC28)] IS INTENDED FOR LABORATORY USE IN THE DETECTION OF THE P40 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,OPTIVIEW AMPLIFICATION KIT (250)(OPTIVIEW AMPLIFICATION KIT (250))-"OPTIVIEW AMPLIFICATION KIT MAY BE USED IN CONJUNCTION WITH THE OPTIVIEW DAB ME DETECTION KIT (OPTIVIEW DETECTION KIT) TO INCREASE THE STAINING INTENSITY OF MOUSE AND RABBIT PRIMARY ANTIBODIES. THE KIT IS TO BE USED FOR QUALITATIVE STAINING OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE, FROZEN TISSUE, OR CYTOLOGICAL PREPARATIONS ON VENTANA BENCHMARK ADVANCED STAINING AUTOMATED SLIDE STAINERS WITH VENTANA PRIMARY ANTIBODIES AND ANCILLARY REAGENTS. VISUALIZED BY LIGHT MICROSCOPY. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE." ,HPV FAMILY 16 SYSTEM CONTROL SLIDES (C)(HPV FAMILY 16 SYSTEM CONTROL SLIDES (C))-THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC

	(IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) HPV FAMILY 16 SYSTEM CONTROL SLIDES (C) CONTAIN 10 SLIDES FOR USE ON THE BENCHMARK SERIES AUTOMATED SLIDE STAINER. EACH SLIDE CONTAINS TWO LIQUID BASED CELL LINE PREPS, PREPARED USING PRESERVCYT SOLUTION, A METHANOL BASED, BUFFERED PRESERVATIVE SOLUTION. SLIDES ARE DESIGNED TO ALLOW THE USER TO CHECK THE INSTRUMENT'S IN SITU HYBRIDIZATION (ISH) STAINING FUNCTION. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. ,CONFIRM ANTI-CD79A (SP18) RABBIT MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-CD79A (SP18) RABBIT MONOCLONAL PRIMARY ANTIBODY)-VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI- CD79A (SP18) RABBIT MONOCLONAL PRIMARY ANTIBODY IS INTENDED FOR THE DETECTION OF CD79A IN NORMAL AND NEOPLASTIC HUMAN TISSUES. ANTI- CD79A IS DIRECTED AGAINST A PROTEIN EXPRESSED ON THE SURFACE OF B LYMPHOCYTES AT ALL STAGES OF MATURATION, FROM B LYMPHOCYTE PRECURSORS THROUGH PLASMA CELLS. EXPRESSION OF CD79A MAY AID IN THE IDENTIFICATION OF B CELL LINEAGE IN MALIGNANT LYMPHOMAS. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. ,VENTANA ANTI-E-CADHERIN (36) MOUSE MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-E-CADHERIN (36) MOUSE MONOCLONAL PRIMARY ANTIBODY)-VENTANA ANTI-E-CADHERIN (36) MOUSE MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-E- CADHERIN (36)) IS DIRECTED AGAINST THE CYTOPLASMIC DOMAIN OF THE HUMAN TRANSMEMBRANE PROTEIN E- CADHERIN EXPRESSED AS A PART OF THE CELL-CELL ADHESION COMPLEX IN EPITHELIAL TISSUES. REDUCTION OR LOSS OF EXPRESSION IS ASSOCIATED WITH INVASIVE CARCINOMA AND POSSIBLY METASTASIS IN A VARIETY OF CARCINOMAS. THIS ANTIBODY MAY BE USED TO AID IN THE DIFFERENTIATION OF IN-SITU AND/OR INVASIVE LOBULAR CARCINOMA FROM IN SITU AND/OR INVASIVE DUCTAL CARCINOMA OF THE BREAST. THIS ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. TEST RESULTS SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS., OPTIVIEW AMPLIFICATION KIT(OPTIVIEW AMPLIFICATION KIT)-OPTIVIEW AMPLIFICATION KIT MAY BE USED IN CONJUNCTION WITH

	THE OPTIVIEW DAB ICH DETECTION KIT (OPTIVIEW DETECTION KIT) TO INCREASE THE STAINING INTENSITY OF MOUSE AND RABBIT PRIMARY ANTIBODIES. THE KIT IS TO BE USED FOR QUALITATIVE STAINING OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE, FROZEN TISSUE, OR CYTOLOGICAL PREPARATIONS ON VENTANA BENCHMARK ADVANCED STAINING AUTOMATED SLIDE STAINERS WITH VENTANA PRIMARY ANTIBODIES AND ANCILLARY REAGENTS VISUALIZED BY LIGHT MICROSCOPY. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. ,CONFIRM ANTI-LMO2 (1A9-1) MOUSE MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-LMO2 (1A9-1) MOUSE MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-LMO2 (1A9-1) MOUSE MONOCLONAL PRIMARY ANTIBODY IS DESIGNED TO QUALITATIVELY DETECT THE PRESENCE OF LMO2 EXPRESSING CELLS VIA LIGHT MICROSCOPY IN FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE. POSITIVE STAINING RESULTS MAY AID IN THE CLASSIFICATION OF B-CELL LYMPHOMAS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,FITC ANTI- IGA PRIMARY ANTIBODY(FITC ANTI- IGA PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE VENTANA MEDICAL SYSTEMS (VENTANA) SYSTEMS FITC ANTI-IGA (IMMUNOGLOBULIN A) PRIMARY ANTIBODY IS A GOAT DERIVED POLYCLONAL ANTIBODY LABELED WITH FLUORESCEIN AND SPECIFICALLY DIRECTED AGAINST HUMAN IGA. THIS REAGENT SHOULD BE USED IN CONJUNCTION WITH A PANEL OF ANTIBODIES TO AID IN THE IDENTIFICATION OF IMMUNOGLOBULIN A IN IGA TARGET TISSUE (E.G., IN THE DIAGNOSIS OF RENAL OR DERMAL PATHOLOGIES). FITC ANTI-IGA IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN SECTIONS OF FROZEN TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE

	PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY.,CONFIRM ANTI-KAPPA RABBIT POLYCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-KAPPA RABBIT POLYCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-KAPPA RABBIT POLYCLONAL PRIMARY ANTIBODY IS DIRECTED AGAINST KAPPA IMMUNOGLOBULIN LIGHT CHAINS. STAINING FOR KAPPA LIGHT CHAINS CAN BE USED TO AID IN THE IDENTIFICATION OF CELLS OF NORMAL AND ABNORMAL B CELL LINEAGE. THIS ANTIBODY IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN B CELLS AND PLASMA CELLS EXPRESSING KAPPA LIGHT CHAIN IMMUNOGLOBULINS IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. CONFIRM ANTI-KAPPA RABBIT POLYCLONAL SPECIFICALLY BINDS TO ANTIGENS LOCATED IN THE CELL MEMBRANE AND CYTOPLASMIC REGIONS OF NORMAL B CELLS AND PLASMA CELLS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION USE ONLY., FITC ANTI-C1Q PRIMARY ANTIBODY(FITC ANTI-C1Q PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) SYSTEMS FITC ANTI-C1Q (COMPLEMENT 1Q) PRIMARY ANTIBODY IS A GOAT DERIVED POLYCLONAL ANTIBODY LABELED WITH FLUORESCEIN AND SPECIFICALLY DIRECTED AGAINST HUMAN C1Q. THIS REAGENT SHOULD BE USED IN CONJUNCTION WITH A PANEL OF ANTIBODIES TO AID IN THE IDENTIFICATION OF COMPLEMENT 1Q IN C1Q TARGET TISSUE (E.G., IN THE DIAGNOSIS OF RENAL OR DERMAL PATHOLOGIES). FITC ANTI-C1Q IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN SECTIONS OF FROZEN TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY.,CONFIRM ANTI-EMA (E29) MOUSE MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-EMA (E29) MOUSE MONOCLONAL PRIMARY ANTIBODY)-VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-EMA (E29) MOUSE MONOCLONAL PRIMARY ANTIBODY (CONFIRM ANTI-EMA (E29)) IS

	DIRECTED AGAINST EPITHELIAL MEMBRANE ANTIGEN EXPRESSED ON THE APICAL SURFACE OF GLANDULAR EPITHELIA. THIS GLYCOPROTEIN IS PRIMARILY MEMBRANE LOCALIZED ON NORMAL AND TUMOR TISSUE, ALTHOUGH IT MAY EXHIBIT A CYTOPLASMIC LOCALIZATION IN LESS DIFFERENTIATED CARCINOMAS. THIS ANTIBODY MAY BE USED TO AID IN THE IDENTIFICATION OF EPITHELIAL MEMBRANE ANTIGEN IN ADENOCARCINOMAS DERIVED FROM SECRETORY EPITHELIA, MALIGNANT MESOTHELIOMA, RENAL CELL CARCINOMAS AND MENINGIOMAS. THE ANTIBODY IS INTENDED FOR QUALITATIVE STAINING IN SECTIONS OF FORMALIN-FIXED, PARAFFIN- EMBEDDED TISSUE. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. ,CONFIRM ANTI-MELANOSOME (HMB45) MOUSE MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-MELANOSOME (HMB45) MOUSE MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC USE. VENTANA MEDICAL SYSTEMS (VENTANA) CONFIRM ANTI-MELANOSOME (HMB45) IS A MOUSE MONOCLONAL ANTIBODY (IGG1, KAPPA) DIRECTED AGAINST AN ONCOFETAL ANTIGEN PRESENT WITHIN IMMATURE MELANOSOMES IN THE CYTOPLASM OF ACTIVATED AND NEOPLASTIC MELANOCYTES. CONFIRM ANTI-MELANOSOME (HMB45) IS INTENDED FOR LABORATORY USE TO QUALITATIVELY DETECT, VIA LIGHT MICROSCOPY, CELLS CONTAINING IMMATURE MELANOSOMES IN SECTIONS OF FORMAL IN FIXED, PARAFFIN EMBEDDED TISSUE FOLLOWING STAINING ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS., CONFIRM ANTI-MART-1/MELAN A (A103) MOUSE MONOCLONAL PRIMARY ANTIBODY(CONFIRM ANTI-MART-1/MELAN A (A103) MOUSE MONOCLONAL PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEM$, INC.'S (VENTANA) CONFIRM ANTI-MART-1/MELAN A (A103) MOUSE MONOCLONAL PRIMARY ANTIBODY IS A MOUSE MONOCLONAL ANTIBODY (IGG1) DIRECTED AGAINST MELAN A. THIS ANTIBODY IS DESIGNED TO QUALITATIVELY DETECT THE PRESENCE OF MELAN A BY LIGHT MICROSCOPY IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. POSITIVE STAINING MAY AID IN THE CLASSIFICATION OF MELANOMA. THE CLINICAL INTERPRETATION OF

	ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS.,FITC ANTI- IGG PRIMARY ANTIBODY(FITC ANTI- IGG PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) SYSTEMS FITC ANTI-IGG (IMMUNOGLOBULIN G) PRIMARY ANTIBODY IS A GOAT DERIVED POLYCLONAL ANTIBODY LABELED WITH FLUORESCEIN AND SPECIFICALLY DIRECTED AGAINST HUMAN IGG. THIS REAGENT SHOULD BE USED IN CONJUNCTION WITH A PANEL OF ANTIBODIES TO AID IN THE IDENTIFICATION OF IMMUNOGLOBULIN G IN IGG TARGET TISSUE (E.G., IN THE DIAGNOSIS OF RENAL OR DERMAL PATHOLOGIES). FITC ANTI-IGG IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN SECTIONS OF FROZEN TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY.,FITC ANTI-C4 PRIMARY ANTIBODY(FITC ANTI-C4 PRIMARY ANTIBODY)-THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS (VENTANA) SYSTEMS FITC ANTI-C4 (COMPLEMENT 4) PRIMARY ANTIBODY IS A SHEEP DERIVED POLYCLONAL ANTIBODY LABELED WITH FLUORESCEIN AND SPECIFICALLY DIRECTED AGAINST HUMAN C4. THIS REAGENT SHOULD BE USED IN CONJUNCTION WITH A PANEL OF ANTIBODIES TO AID IN THE IDENTIFICATION OF COMPLEMENT 4 IN C4 TARGET TISSUE (E.G., IN THE DIAGNOSIS OF RENAL OR DERMAL PATHOLOGIES). FITC ANTI-C4 IS INTENDED FOR LABORATORY USE TO QUALITATIVELY STAIN SECTIONS OF FROZEN TISSUE ON A VENTANA AUTOMATED SLIDE STAINER. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. PRESCRIPTION ONLY.

174	IMP/IVD/2019/000127	1.License Holder Name: A & A ENTERPRISES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOOD PANEL FOR DETECTION OF FOOD ALLERGIES(PROTIA ALLERGY-Q 64)-FOR DIAGNOSIS OF FOOD ALLERGENS IN HUMAN SERUM,IVD STRIPS FOR DETECTION OF IGG-F IN WHOLE BLOOD OR SERUM(IMMUNECHECK IGG-F)-TOTAL IGG MEASUREMENT,ALLERGY DETECTION PANEL FOR FOOD AND INHALED ALLERGENS(PROTIA ALLERGY-Q 96M)-FOR DETECTION OF ALLERGENS IN HUMAN SERUM COMING FROM FOOD AND INHALED ALLERGENS., ATOPY PANEL FOR DETECTION OF SKIN ALLERGIES(PROTIA ALLERGY-Q)-DIAGNOSIS OF ALLERGIES OF SKIN, IVD STRIPS FOR DETECTION OF IGG IN WHOLE BLOOD AND SERUM (IMMUNE CHECK IGG)-FOR DETECTION OF TOTAL IGG IN HUMAN WHOLE BLOOD AND SERUM, INHALENT PANEL FOR DETECTION OF INHALED ALLERGENS(PROTIA ALLERGY-Q 64)-FOR DIAGNOSIS OF ALLERGY GENERATED THROUGH INHALATION
175	IMP/IVD/2019/000129	1.License Holder Name: SYSMEX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLEANING SOLUTION (CLEANING SOLUTION)-FOR IN VITRO DIAGNOSTIC USE ONLY. CLEANING SOLUTION IS INTENDED TO CLEAN THE SAMPLE PATHWAY OF FLOW CYTOMETERS. IT IS A BUFFERED DETERGENT SOLUTION FOR FLOW SYSTEMS.,DECONTAMINATION SOLUTION (DECONTAMINATION SOLUTION)-FOR IN VITRO DIAGNOSTIC USE ONLY. DECOMTAMINATION SOLUTION IS INTENDED TO REDUCE PROTEIN IN SAMPLE PATHWAY OF FLOW CYTOMETERS AND PROVIDE BUFFER CAPACITY,COUNT CHECK BEADS GREEN(COUNT CHECK BEADS GREEN)-COUNT CHECK BEADS GREEN ARE QC PARTICLES FOR ABSOLUTE COUNTING QUALITY CONTROL ON FLOW CYTOMETERS WITH TRUE VOLUMETRIC ABSOLUTE COUNTING FEATURE. FOR LASERS WITH 532 NM EMISSION. FOR DAILY QUALITY CONTROL.,HYPOCHLORITE SOLUTION(HYPOCHLORITE SOLUTION)-FOR IN VITRO DIAGNOSTIC USE ONLY. HYPOCHLORITE SOLUTION IS INTENDED TO REDUCE PROTEIN IN SAMPLE PATHWAY OF FLOW CYTOMETERS.

176	IMP/IVD/2019/000130	1.License Holder Name: RENNEX MEDICAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLUCOMETER (ROMOCHECK PLUS)-ROMO CHECK PLUS BLOOD GLUCOSE METER WORKS WITH ROMO CHECK PLUS BLOOD GLUCOSE TEST STRIPS TO MEASURE THE GLUCOSE CONCENTRATION IN WHOLE BLOOD., GLUCOSE TEST STRIPS (ROMOCHECK PLUS)-FOR TESTING BLOOD GLUCOSE
177	IMP/IVD/2019/000131	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COULTER TRUCOLOR WRIGHT-GIEMSA STAIN BUFFER-FOR USE ON COULTER SLIDESTAINERS WHICH DELIVER A VARIETY OF SOLUTIONS TO BUFFER WHOLE BLOOD FILMS PREPARED ON GLASS MICROSCOPE SLIDES.,COLUTER TRUCOLOR MAY-GRUNWALD STAIN-FOR USE ON COULTER SLIDESTAINERS WHICH DELIVER A VARIETY OF SOLUTIONS TO STAIN WHOLE BLOOD FILMS PREPARED ON GLASS MICROSCOPE SLIDES.,COULTER TRUCOLOR WRIGHT STAIN BUFFER-FOR USE ON COULTER SLIDESTAINERS WHICH DELIVER A VARIETY OF SOLUTIONS TO BUFFER WHOLE BLOOD FILMS PREPARED ON GLASS MICROSCOPE SLIDES.,COULTER TRUCOLOR WRIGHT STAIN-FOR USE ON COULTER SLIDESTAINERS WHICH DELIVER A VARIETY OF SOLUTIONS TO STAIN WHOLE BLOOD FILMS PREPARED ON GLASS MICROSCOPE SLIDES.,COULTER TRUCOLOR WRIGHT-GIEMSA STAIN-FOR USE ON COULTER SLIDESTAINERS WHICH DELIVER A VARIETY OF SOLUTIONS TO STAIN WHOLE BLOOD FILMS PREPARED ON GLASS MICROSCOPES SLIDES.,COULTER TRUCOLOR GIEMSA STAIN-FOR USE ON COULTER SLIDESTAINERS WHICH DELIVER A VARIETY OF SOLUTIONS TO STAIN WHOLE BLOOD FILMS PREPARED ON GLASS MICROSCOPE SLIDES

178	IMP/IVD/2019/000132	1.License Holder Name: M/S.TRANSASIA BIO-MEDICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EC CARTRIDGE M(EC CARTRIDGE M)-EC CARTRIDGE IS AN IVD KIT INTENDED FOR CALIBRATION AND QUANTIFICATION OF SODIUM (NA+), POTASSIUM (K+), IONIZED CALCIUM (ICA2+) AND CHLORIDES (CI-) ON THE EC 90 ANALYZER,ELITE H CLEAN(ELITE H CLEAN)-ELITE H CLEAN IS SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYSERS CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND DEPOSITS ON ELITE HEMATOLOGY ANALYSERS. ,MICROALBUMIN-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF MICROALBUMIN IN URINE.,ELITE H580 LYSE3 (ELITE H580 LYSE3)-ELITE H580 LYSE3 IS USED FOR DIFFERENTIATION OF WHITE BLOOD CELLS ON HEMATOLOGY ANALYSERS ELITE 580. ,EC URINE DILUENT(EC URINE DILUENT)-URINE DILUENT IS A BUFFERED REAGENT USED TO DILUTE URINE SAMPLES FOR THE QUANTIFICATION OF SODIUM (NA+), POTASSIUM (K+) AND CHLORIDES (CL-) ON AN EC 90 ANALYZER,ELITE H580 DIL (ELITE H580 DIL)-ELITE H580 DIL IS USED TO DILUTED BLOOD AND PROVIDE A STABLE ENVIRONMENT FOR COUNTING AND SIZING BLOOD CELLS ON HEMATOLOGY ANALYSERS ELITE 580. ,EC CARTRIDGE S(EC CARTRIDGE S)-EC CARTRIDGE IS AN IVD KIT INTENDED FOR CALIBRATION AND QUANTIFICATION OF SODIUM (NA+), POTASSIUM (K+), IONIZED CALCIUM (ICA2+) AND CHLORIDES (CI-) ON THE EC 90 ANALYZER,ELITE H580 LYSE2(ELITE H580 LYSE2) -ELITE H580 LYSE2 IS USED FOR DIFFERENTIATION OF WHITE BLOOD CELLS ON HEMATOLOGY ANALYSERS ELITE 580. ,EC CARTRIDGE L (EC CARTRIDGE L)-EC CARTRIDGE IS AN IVD KIT INTENDED FOR CALIBRATION AND QUANTIFICATION OF SODIUM (NA+), POTASSIUM (K+), IONIZED CALCIUM (ICA2+) AND CHLORIDES (CI-) ON THE EC 90 ANALYZER,ELITE H580 LYSE1(ELITE H580 LYSE1)-ELITE H580 LYSE1 IS USED TO DISSOLVE RED BLOOD CELLS FOR COUNTING HEMOGLOBIN AND WHITE BLOOD CELLS ON HEMATOLOGY ANALYSERS ELITE 580. ,MAL CONTROL-ACCURACY CONTROL FOR QUANTITATIVE IMMUNOCHEMICAL DETERMINATION OF MICROALBUMIN IN URINE BY TURBIDIMETRY AND NEPHELOMETRY , ELITE H5 CON H(ELITE H5 CON H)-ELITE H5 CON IS A CONTROL (HIGH LEVEL) DESIGNED TO MONITOR ACCURACY AND PRECISION OF AUTOMATED HEMATOLOGY ANALYZERS. ,FERRITIN CONTROL LOW (FERRITIN CONTROL LOW)-ACCURACY CONTROL (LOW LEVEL) FOR THE DETERMINATION OF FERRITIN IN SERUM BY IMMUNOTURBIDIMETRY. ,FERRITIN(FERRITIN)-QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA BY

	TURBIDIMETRIC IMMUNOASSAY. ,FERRITIN CONTROL HIGH(FERRITIN CONTROL HIGH)-ACCURACY CONTROL (HIGH LEVEL) FOR THE DETERMINATION OF FERRITIN IN SERUM BY IMMUNOTURBIDIMETRY. , ELITE H5 CON N(ELITE H5 CON N)-ELITE H5 CON IS A CONTROL (NORMAL LEVEL) DESIGNED TO MONITOR ACCURACY AND PRECISION OF AUTOMATED HEMATOLOGY ANALYZERS. ,FERRITIN (FERRITIN)-QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA BY TURBIDIMETRIC IMMUNOASSAY. ,FERRITIN CALIBRATOR(FERRITIN CALIBRATOR)-CALIBRATOR FOR IMMUNOTURBIDIMETRIC DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA. ,FERRITIN CALIBRATOR(FERRITIN CALIBRATOR)-CALIBRATOR FOR IMMUNOTURBIDIMETRIC DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA. ,ELITE H CAL (ELITE H CAL)-ELITE H CAL IS DESIGNED FOR USE IN THE CALIBRATION OF HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. , APOLIPOPROTEIN CALIBRATOR SET(APOLIPOPROTEIN CALIBRATOR SET)-"SET OF CALIBRATORS FOR IMMUNOTURBIDIMETRIC DETERMINATION OF APOLIPOPROTEINS A1 AND B IN HUMAN SERUM AND PLASMA (5 × 0,5 ML). " ,FERRITIN CONTROL LOW(FERRITIN CONTROL LOW)-ACCURACY CONTROL (LOW LEVEL) FOR THE DETERMINATION OF FERRITIN IN SERUM BY IMMUNOTURBIDIMETRY. , APOLIPOPROTEIN B(APOLIPOPROTEIN B)-REAGENT KIT FOR IMMUNOTURBIDIMETRIC DETERMINATION OF APOLIPOPROTEIN B (APO B) IN HUMAN SERUM AND PLASMA. ,FERRITIN CONTROL HIGH (FERRITIN CONTROL HIGH)-ACCURACY CONTROL (HIGH LEVEL) FOR THE DETERMINATION OF FERRITIN IN SERUM BY IMMUNOTURBIDIMETRY. ,APOLIPOPROTEIN A1(APOLIPOPROTEIN A1)-"REAGENT KIT FOR IMMUNOTURBIDIMETRIC DETERMINATION OF APOLIPOPROTEIN A1 (APO A1) IN HUMAN SERUM AND PLASMA. " , ELITE H5 CON L(ELITE H5 CON L)-ELITE H5 CON IS A CONTROL (LOW LEVEL) DESIGNED TO MONITOR ACCURACY AND PRECISION OF AUTOMATED HEMATOLOGY ANALYZERS.

179	IMP/IVD/2019/000134	1.License Holder Name: M/S AVANTOR PERFORMANCE MATERIALS INDIA LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HBA1C CALIBRATOR-HBA1C CALIBRATOR IS INTENDED FOR THE PERCENT DETERMINATION OF HBA1C IN HUMAN BLOOD USING HIGH PERFORMANCE LIQUID CHROMATOGRAPHY(HPLC) ,HBA1C REAGENT KIT(IEC)-APPLICABLE TO MEASURE THE CONTENT OF HBA1C IN THE WHOLE BLOOD OF HUMAN BODY,HBA1C REAGENT KIT(HPLC)-APPLICABLE TO QUANTITATIVE EXAMINATION THE CONTENT OF HBA1C IN THE WHOLE BLOOD OF HUMAN BODY WITH LIFOTRONIC H SERIES HEMOGLOBIN ANALYZER.IT ADOPTS HIGH PERFORMANCE LIQUID CHROMATOGRAPHY(HPLC) METHOD TO MEASURE THE LEVEL OF HBA1AB,HBA1C,HBAO.AND THE ANALYZER CALCULATES THE REST ITEMS. ,HBA1C CONTROL MATERIAL-HBA1C CONTROL MATERIAL IS INTENDED FOR THE SYSTEM QUALITY CONTROL FOR ACCURACY AND REPETABILITY

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

180	IMP/IVD/2019/000135	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HTLV I/II CONTROLS-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE FOR USE IN MONITORING THE PERFORMANCE OF THE AUTOMATED SUITABLE VITROS SYSTEMS WHEN USED WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HTLV I/II TEST FOR THE DETERMINATION OF ANTIBODIES TO HTLV I AND/OR II.,ABO-RH/REVERSE GROUPING CASSETTE(BLOOD GROUPING REAGENTS ANTI-A (ANTI-ABO1) (MONOCLONAL) ANTI-B (ANTI-ABO2) (MONOCLONAL) ANTI-D (ANTI-RH1) (MONOCLONAL) CONTROL REVERSE DILUENT ORTHO BIOVUE® SYSTEM (ABO-RH/REVERSE GROUPING CASSETTE))-QUALITATIVE TEST FOR DETERMINATION OF THE ABO BLOOD GROUP AND D (RH1) ANTIGENS ON HUMAN RED BLOOD CELLS AND FOR DETERMINATION OF EXPECTED BLOOD GROUP ANTIBODIES FOR IN VITRO DIAGNOSTIC USE ,VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG CALIBRATOR-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG REAGENT PACK WHEN USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG CALIBRATOR IS A CHEMILUMINESCENT IMMUNOASSAY TEST INTENDED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM USING VITROS IMMUNODIAGNOSTIC AND INTEGRATED SYSTEMS.,HIV COMBO CALIBRATOR(VITROS IMMUNODIAGNOSTIC PRODUCTS HIV COMBO CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPES 1, INCLUDING GROUP M AND O, AND/OR 2 (ANTI-HIV-1 AND ANTI-HIV-2) AND HIV P24 ANTIGEN IN HUMAN SERUM AND PLASMA (HEPARIN AND EDTA) IN ADULTS, PREGNANT WOMEN, ADOLESCENTS AND CHILDREN. ,VITROS IMMUNODIAGNOSTIC PRODUCTS ANTISARS-COV-2 IGG CONTROLS-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR USE IN MONITORING THE PERFORMANCE OF THE VITROS IMMUNODIAGNOSTIC AND INTEGRATED SYSTEMS WHEN USED FOR THE DETERMINATION OF IGG ANTIBODIES TO SARS-COV-2.,HBE CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS HBE CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM WHEN USED FOR THE

	DETECTION OF HBEAG AND ANTI-HBE.,VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HTLV I/II CALIBRATOR-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR USE IN THE CALIBRATION OF THE AUTOMATED SUITABLE VITROS SYSTEMS FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO HTLV I AND/OR II IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA AND CITRATE).,ANTI-HBE ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBE REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HEPATITIS B E ANTIGEN (ANTI-HBE) IN HUMAN SERUM USING THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM. , VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HTLV I/II REAGENT PACK-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR THE IN VITRO QUALITATIVE DETECTION OF ANTIBODIES TO HUMAN T-CELL LYMPHOTROPIC VIRUS TYPES I AND/OR II, (HTLV-I AND HTLV-II) IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA AND CITRATE) IN ADULTS, PREGNANT WOMEN, ADOLESCENTS AND CHILDREN, USING THE AUTOMATED SUITABLE VITROS SYSTEMS. , ANTI-HBC CALIBRATOR(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI- HBC) IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN OR CITRATE). ,VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG REAGENT PACK-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG REAGENT PACK WHEN USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG CALIBRATOR IS A CHEMILUMINESCENT IMMUNOASSAY TEST INTENDED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM USING VITROS IMMUNODIAGNOSTIC AND INTEGRATED SYSTEMS.,ANTI-HBC CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM WHEN USED FOR THE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC). ,VITROS IMMUNODIAGNOSTIC PRODUCTS B•R•A•H•M•S PCT CALIBRATORS-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE SUITABLE VITROS SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF PROCALCITONIN (PCT) IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN AND EDTA).,ANTI-HBC ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC REAGENT PACK)-FOR IN

	VITRO DIAGNOSTIC USE ONLY. FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM OR PLASMA (EDTA, HEPARIN OR CITRATE) USING THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM,BLOOD GROUPING REAGENTS ANTI-A (MONOCLONAL) ANTI-B (MONOCLONAL) ANTI-A,B (MONOCLONAL)ANTI-D ANTI-RH1) (MONOCLONAL)ANTI-D (ANTI-RH1)(MONOCLONAL)CONTROL ORTHO BIOVUE SYSTEM(ABO-DD GROUPING CASSETTES)(BLOOD GROUPING REAGENTS ANTI-A (ANTI-ABO1) (MONOCLONAL) ANTI-B (ANTI-ABO2) (MONOCLONAL) ANTI-A,B (ANTI-ABO3) (MONOCLONAL) ANTI-D (ANTI-RH1) (MONOCLONAL) ANTI-D (ANTI-RH1) (MONOCLONAL) CONTROL ORTHO BIOVUE® SYSTEM (ABO-DD GROUPING CASSETTE)) -QUALITATIVE TEST FOR RECOGNITION OF THE A (ABO1), B (ABO2) AND D (RH1) ANTIGENS ON HUMAN RED BLOOD CELLS. FOR IN VITRO DIAGNOSTIC USE,ANTI-HBC IGM CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC IGM CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM WHEN USED FOR THE DETECTION OF ANTIHBC IGM.,HS TROPONIN I CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS HS TROPONIN I CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF CARDIAC TROPONIN I IN HUMAN SERUM AND PLASMA (HEPARIN). ,ANTI-HBC IGM CALIBRATOR(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC IGM CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM FOR THE QUALITATIVE DETERMINATION OF IGM ANTIBODY TO HEPATITIS B VIRUS CORE ANTIGEN (HBC) IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN OR CITRATE). ,VITROS IMMUNODIAGNOSTIC PRODUCTS NT-PROBNP II CALIBRATORS (VITROS IMMUNODIAGNOSTIC PRODUCTS NT-PROBNP II CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE SUITABLE VITROS SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF N-TERMINAL PRO BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN).,HBSAG ES CONFIRMATORY ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS HBSAG ES CONFIRMATORY KIT)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUALITATIVE CONFIRMATION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA (HEPARIN) SPECIMENS FOUND TO BE REPEATEDLY REACTIVE USING VITROS IMMUNODIAGNOSTIC PRODUCTS HBSAG ES ASSAY WITH IMMUNODIAGNOSTIC SYSTEMS,

	AND INTEGRATED SYSTEM. ,VITROS IMMUNODIAGNOSTIC PRODUCTS NT-PROBNP II REAGENT PACK(VITROS IMMUNODIAGNOSTIC PRODUCTS NT-PROBNP II REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF N-TERMINAL PRO BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE SUITABLE VITROS SYSTEMS TO AID IN THE DIAGNOSIS OF HEART FAILURE AND FOR THE RISK STRATIFICATION OF ACUTE CORONARY SYNDROME AND HEART FAILURE. THE TEST IS FURTHER INDICATED AS AN AID IN THE ASSESSMENT OF INCREASED RISK OF CARDIOVASCULAR EVENTS AND MORTALITY IN PATIENTS WHO HAVE STABLE CORONARY ARTERY DISEASE. THE TEST CAN ALSO BE USED IN THE ASSESSMENT OF HEART FAILURE SEVERITY IN PATIENTS DIAGNOSED WITH HEART FAILURE.,HBSAG CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS HBSAG CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF IMMUNODIAGNOSTIC SYSTEM AND INTEGRATED SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN OR CITRATE). ,HS TROPONIN I LOW CONTROL(VITROS IMMUNODIAGNOSTIC PRODUCTS HS TROPONIN I LOW CONTROL)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE MEASUREMENT OF CARDIAC TROPONIN I IN HUMAN SERUM AND PLASMA (HEPARIN).,HBSAG ES CALIBRATOR(VITROS IMMUNODIAGNOSTIC PRODUCTS HBSAG ES CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND INTEGRATED SYSTEM FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA (HEPARIN). ,VITROS IMMUNODIAGNOSTIC PRODUCTS B•R•A•H•M•S PCT CONTROLS-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE SUITABLE VITROS SYSTEMS WHEN USED FOR THE MEASUREMENT OF PROCALCITONIN (PCT).,SYPHILIS TPA ASSAY (VITROS IMMUNODIAGNOSTIC PRODUCTS SYPHILIS TPA REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUALITATIVE DETERMINATION OF TOTAL (IGG AND IGM) ANTIBODIES TO TREPONEMA PALLIDUM (TP) SPECIFIC ANTIGENS IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA AND CITRATE) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. , VITROS IMMUNODIAGNOSTIC PRODUCTS NT-PROBNP II CONTROLS (VITROS IMMUNODIAGNOSTIC PRODUCTS NT-PROBNP II CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE

	PERFORMANCE OF THE SUITABLE VITROS SYSTEMS WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF N-TERMINAL PRO BRAIN NATRIURETIC PEPTIDE (NT-PROBNP).,NEPHROCHECK TEST ASSAY (VITROS IMMUNODIAGNOSTIC PRODUCTS NEPHROCHECK TEST REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. THE VITROS IMMUNODIAGNOSTIC PRODUCTS NEPHROCHECK TEST REAGENT PACK IS INTENDED FOR THE IN VITRO QUANTITATIVE DIRECT MEASUREMENT OF TIMP-2 (TISSUE INHIBITOR OF METALLOPROTEINASE 2) AND IGFBP-7 (INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN 7) IN HUMAN URINE, USING THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEMS TO BE USED IN CONJUNCTION WITH CLINICAL EVALUATION AS AN AID IN THE RISK ASSESSMENT OF ACUTE KIDNEY INJURY IN THE CRITICALLY ILL. ,VITROS IMMUNODIAGNOSTIC PRODUCTS B•R•A•H•M•S PCT REAGENT PACK-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF PROCALCITONIN (PCT) IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN AND EDTA) USING THE SUITABLE VITROS SYSTEMS. THE VITROS B•R•A•H•M•S PCT TEST IS INDICATED AS AN AID TO BE USED IN CONJUNCTION WITH CLINICAL EVALUATION FOR: • THE EARLY DETECTION AND DIFFERENTIAL DIAGNOSIS OF CLINICALLY RELEVANT BACTERIAL INFECTIONS, • THE ASSESSMENT OF THE DEGREE OF SEVERITY AND THE PROGNOSIS OF THE OUTCOME OF SYSTEMIC BACTERIAL INFECTION, SEPSIS, SEVERE SEPSIS AND SEPTIC SHOCK, • IDENTIFYING PATIENTS THAT BENEFIT FROM ANTIBIOTIC TREATMENT, • MONITORING OF ANTIBIOTIC THERAPY WITHIN THE MEASURING RANGE, • THE ASSESSMENT OF SUCCESSFUL ANTIBIOTIC THERAPY IN PATIENTS WITH SUSPECTED OR CONFIRMED BACTERIAL INFECTION.,NEPHROCHECK TEST CALIBRATOR(VITROS IMMUNODIAGNOSTIC PRODUCTS NEPHROCHECK TEST CALIBRATOR) -FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEMS WITH THE VITROS NEPHROCHECK TEST (NCHEK) IN HUMAN URINE. ,HS TROPONIN I ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS HS TROPONIN I REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF CARDIAC TROPONIN I (CTNI) IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,FOLATE ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS FOLATE REAGENT PACK 1/2)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF FOLATE IN HUMAN SERUM AND PLASMA (HEPARIN) AND WHOLE BLOOD (RED CELL FOLATE) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS, TO

	AID IN THE DIFFERENTIAL DIAGNOSIS OF ANEMIA. ,VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN REAGENT PACK-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. THE VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN TEST IS A CHEMILUMINESCENT IMMUNOASSAY INTENDED FOR THE QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID ANTIGENS IN NASOPHARYNGEAL (NP) AND NASAL SPECIMENS FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 WITHIN SEVEN DAYS OF THE ONSET OF SYMPTOMS, OR MID-TURBINATE SPECIMENS COLLECTED FROM ASYMPTOMATIC INDIVIDUALS, USING THE VITROS IMMUNODIAGNOSTIC SYSTEM AND THE VITROS INTEGRATED SYSTEMS,FREE THYROID CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS FREE THYROID CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE MEASUREMENT OF TSH, FREE T3 AND FREE T4. , VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG 2 CALIBRATOR-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR USE IN THE CALIBRATION OF THE VITROS IMMUNODIAGNOSTIC SYSTEMS AND INTEGRATED SYSTEMS FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETECTION OF IGG ANTIBODY TO SARS-COV-2 IN HUMAN SERUM.,REVERSE DILUENT CASSETTE (REVERSE DILUENT ORTHO BIOVUE® SYSTEM (REVERSE DILUENT CASSETTE))-PRINCIPALLY FOR USE IN THE DETERMINATION OF EXPECTED ABO BLOOD GROUP ANTIBODIES AND ANTIBODY SCREEN PROCEDURES FOR DIRECT AGGLUTINATION FOR IN VITRO DIAGNOSTIC USE ,VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG 2 REAGENT PACK-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG 2 REAGENT PACK WHEN USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG 2 CALIBRATOR IS A CHEMILUMINESCENT IMMUNOASSAY TEST INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM USING THE VITROS IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS.,NEUTRAL CASSETTE(NEUTRAL ORTHO BIOVUE® SYSTEM (NEUTRAL CASSETTE))-PRINCIPALLY FOR USE IN ANTIBODY DETECTION USING ENZYME PROCEDURES FOR IN VITRO DIAGNOSTIC USE,VITROS IMMUNODIAGNOSTIC PRODUCTS TSH3 CALIBRATORS-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR USE IN THE CALIBRATION OF THE AUTOMATED SUITABLE VITROS IMMUNODIAGNOSTIC SYSTEMS AND THE VITROS INTEGRATED SYSTEMS FOR THE QUANTITATIVE

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO AT THE CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

	MEASUREMENT OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM AND PLASMA (EDTA AND LITHIUM HEPARIN)., NEPHROCHECK TEST CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS NEPHROCHECK TEST CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEMS WITH THE VITROS NEPHROCHECK TEST (NCHEK). ,VITROS IMMUNODIAGNOSTIC PRODUCTS ANTISARS-COV-2 IGG QUANTITATIVE CONTROLS-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR USE IN MONITORING THE PERFORMANCE OF THE VITROS IMMUNODIAGNOSTIC SYSTEMS AND THE VITROS INTEGRATED SYSTEMS WHEN USED WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG QUANTITATIVE REAGENT PACK USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI- SARS-COV-2 IGG QUANTITATIVE CALIBRATOR FOR THE DETERMINATION OF IGG ANTIBODIES TO SARS-COV-2.,POLY/NEUTRAL CASSETTES(ANTI-HUMAN GLOBULIN ANTI-IGG, -C3D; POLYSPECIFIC (RABBIT AND MURINE MONOCLONAL) (GREEN) NEUTRAL SOLUTION ORTHO BIOVUE® SYSTEM (POLY/NEUTRAL CASSETTE))- QUALITATIVE PROCEDURE FOR THE DETECTION OF UNEXPECTED BLOOD GROUP ANTIBODIES BY ENZYME AND NON-ENZYME PROCEDURES FOR IN VITRO DIAGNOSTIC USE ,VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG QUANTITATIVE REAGENT PACK-FOR IN VITRO DIAGNOSTIC USE ONLY. THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG QUANTITATIVE REAGENT PACK WHEN USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG QUANTITATIVE CALIBRATORS IS A CHEMILUMINESCENT IMMUNOASSAY TEST INTENDED FOR THE QUALITATIVE AND QUANTITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA (DIPOTASSIUM EDTA, TRIPOTASSIUM EDTA AND LITHIUM HEPARIN).,FERRITIN CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS FERRITIN CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF FERRITIN IN HUMAN SERUM AND PLASMA (HEPARIN). ,VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN REAGENT PACK-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. THE VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN REAGENT PACK, WHEN USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN CALIBRATOR, IS A CHEMILUMINESCENT IMMUNOASSAY INTENDED FOR THE QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID

	PROTEIN ANTIGENS IN NASOPHARYNGEAL (NP) AND ANTERIOR NASAL SWAB SPECIMENS COLLECTED IN CDC'S FORMULATION OF VTM, WHO'S FORMULATION OF VTM, COPAN UNIVERSAL TRANSPORT MEDIA (UTM)®, HARDY R99 VTM, FLEXTRANS™ TRANSPORT MEDIA, SALINE OR PHOSPHATE BUFFERED SALINE (PBS) FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER WITHIN SEVEN DAYS OF THE ONSET OF SYMPTOMS USING THE VITROS IMMUNODIAGNOSTIC SYSTEM AND THE VITROS INTEGRATED SYSTEMS,B12/FOLATE REAGENT PACK 3(VITROS IMMUNODIAGNOSTIC PRODUCTS B12/FOLATE REAGENT PACK 3)-FOR USE IN CONJUNCTION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS VITAMIN B12 AND FOLATE REAGENT PACKS 1 AND 2 USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,VITROS IMMUNODIAGNOSTIC PRODUCTS TSH3 REAGENT PACK-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR THE QUANTITATIVE MEASUREMENT OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM AND PLASMA (EDTA AND LITHIUM HEPARIN) USING THE AUTOMATED SUITABLE VITROS IMMUNODIAGNOSTIC SYSTEMS AND THE VITROS INTEGRATED SYSTEMS.,INSULIN ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS INSULIN REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF INSULIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. , VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 TOTAL CONTROLS-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR USE IN MONITORING THE PERFORMANCE OF THE VITROS IMMUNODIAGNOSTIC SYSTEMS AND THE VITROS INTEGRATED SYSTEMS WHEN USED FOR THE DETERMINATION OF ANTIBODIES TO SARS-COV-2.,POLY CASSETTES(ANTI-HUMAN GLOBULIN ANTI-IGG, -C3D; POLYSPECIFIC (RABBIT AND MURINE MONOCLONAL) (GREEN) ORTHO BIOVUE® SYSTEM (POLY CASSETTE))-QUALITATIVE PROCEDURE FOR THE DETECTION OF IGG OR COMPLEMENT BOUND TO RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE ,VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG QUANTITATIVE CALIBRATOR-FOR IN VITRO DIAGNOSTIC USE ONLY. THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG QUANTITATIVE REAGENT PACK WHEN USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG QUANTITATIVE CALIBRATORS IS A CHEMILUMINESCENT IMMUNOASSAY TEST INTENDED FOR THE QUALITATIVE AND QUANTITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA (DIPOTASSIUM EDTA, TRIPOTASSIUM EDTA AND LITHIUM HEPARIN),UNIVERSAL

	WASH REAGENT(VITROS IMMUNODIAGNOSTIC PRODUCTS UNIVERSAL WASH REAGENT)-FOR USE WITH THE LMMUNODIAGNOSTIC SYSTEM AND INTEGRATED SYSTEM.,SIGNAL REAGENT(VITROS IMMUNODIAGNOSTIC PRODUCTS SIGNAL REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY FOR THE GENERATION OF THE LUMINESCENCE SIGNAL ON THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS ,NTX CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS NTX CALIBRATORS)- FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF CROSS-LINKED N-TELOPEPTIDES OF TYPE 1 COLLAGEN (NTX) IN HUMAN URINE. ,IGG CASSETTES(ANTI-HUMAN GLOBULIN ANTI-IGG (RABBIT) (GREEN) ORTHO BIOVUE® SYSTEM (IGG CASSETTE))-QUALITATIVE PROCEDURE FOR THE DETECTION OF IGG BOUND TO RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE ,TOTAL T4 CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS TOTAL T4 CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF TOTAL THYROXINE (T4) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN).,TOTAL T4 ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS TOTAL T4 REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF TOTAL THYROXINE (T4) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS TO AID IN THE DIFFERENTIAL DIAGNOSIS OF THYROID DISEASE.,TOTAL T3 ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS TOTAL T3 REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF TOTAL TRIIODOTHYRONINE (T3) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS, TO AID IN THE DIFFERENTIAL DIAGNOSIS OF THYROID DISEASE. ,RH/K CASSETTE(BLOOD GROUPING REAGENTS ANTI-C (ANTI-RH2) (MONOCLONAL) ANTI-E (ANTI-RH3) (MONOCLONAL) ANTI-C– (ANTI-RH4) (MONOCLONAL) ANTI-E (ANTI-RH5) (MONOCLONAL) ANTI-K (ANTI-K1) (MONOCLONAL) CONTROL ORTHO BIOVUE® SYSTEM (RH/K CASSETTE))-QUALITATIVE TEST FOR RECOGNITION OF THE C (RH2), E (RH3), C– (RH4), E (RH5) AND K (K1) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE ,FREE T4 ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS FREE T4 REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF FREE THYROXINE (FT4) IN HUMAN SERUM USING THE IMMUNODIAGNOSTIC SYSTEMS

	AND THE INTEGRATED SYSTEMS, TO AID IN THE DIFFERENTIAL DIAGNOSIS OF THYROID DISEASE. ,TOTAL T3 CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS TOTAL T3 CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF TOTAL TRIIODOTHYRONINE (T3) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). ,FREE T4 CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS FREE T4 CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF FREE THYROXINE (FT4) IN HUMAN SERUM. ,ABD CONFIRMATION CASSETTE(BLOOD GROUPING REAGENTS ANTI-A (ANTI-ABO1) (MONOCLONAL) ANTI-B (ANTI-ABO2) (MONOCLONAL) ANTI-D (ANTI-RH1) (MONOCLONAL) ORTHO BIOVUE® SYSTEM (ABD CONFIRMATION CASSETTE))-QUALITATIVE TEST FOR CONFIRMATION OF THE A (ABO1), B (ABO2) AND D (RH1) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE ,HIV COMBO ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS HIV COMBO REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPES 1, INCLUDING GROUP M AND O, AND/OR 2 (ANTI-HIV-1 AND ANTI-HIV-2) AND HIV P24 ANTIGEN IN HUMAN SERUM AND PLASMA (HEPARIN AND EDTA) IN ADULTS, PREGNANT WOMEN, ADOLESCENTS AND CHILDREN, USING THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM. THE RESULTS OF THE VITROS HIV COMBO TEST, IN CONJUNCTION WITH OTHER SEROLOGICAL EVIDENCE AND CLINICAL INFORMATION, MAY BE USED AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HIV-1 AND/OR HIV-2 IN PERSONS AT HIGH AND LOW RISK FOR HIV INFECTION AND AS A SCREENING TEST FOR THE DETECTION OF HIV-1 AND/OR HIV-2 IN BLOOD DONORS. ,T3 UPTAKE CALIBRATORS (VITROS IMMUNODIAGNOSTIC PRODUCTS T3 UPTAKE CALIBRATORS) - FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE ASSESSMENT OF THYROID HORMONE BINDING CAPACITY IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). ,MAINTENANCE PACK(VITROS IMMUNODIAGNOSTIC PRODUCTS MAINTENANCE PACK)-FOR USE IN THE DECONTAMINATION OF THE LMMUNODIAGNOSTIC SYSTEM AND INTEGRATED SYSTEM , AS DETAILED IN THE LMMUNODIAGNOSTIC SYSTEM AND INTEGRATED SYSTEM MAINTENANCE AND DIAGNOSTIC GUIDE,T3 UPTAKE ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS T3 UPTAKE REAGENT PACK)- FOR IN VITRO DIAGNOSTIC USE ONLY.

	FOR THE QUANTITATIVE ASSESSMENT OF THYROID HORMONE BINDING CAPACITY IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS TO AID IN THE DIFFERENTIAL DIAGNOSIS OF THYROID DISEASE. ,ESTRADIOL ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS ESTRADIOL REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF ESTRADIOL IN HUMAN SERUM AND PLASMA (HEPARIN OR EDTA) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. , FREE T3 CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS FREE T3 CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). ,LH ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS LH REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS ,FREE T3 ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS FREE T3 REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS TO AID IN THE DIFFERENTIAL DIAGNOSIS OF THYROID DISEASE. , PROGESTERONE ASSAY (VITROS IMMUNODIAGNOSTIC PRODUCTS PROGESTERONE REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF PROGESTERONE IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,TOTAL -HCG II CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS TOTAL -HCG II CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF HUMAN CHORIONIC GONADOTROPIN (HCG) AND ITS -SUBUNIT IN HUMAN SERUM AND PLASMA (HEPARIN AND EDTA). ,ESTRADIOL CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS ESTRADIOL CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF ESTRADIOL IN HUMAN SERUM AND PLASMA (HEPARIN OR EDTA). , TOTAL -HCG II ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS TOTAL -HCG II REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE

	ONLY. FOR THE QUANTITATIVE MEASUREMENT OF HUMAN CHORIONIC GONADOTROPIN (HCG) AND ITS -SUBUNIT IN HUMAN SERUM AND PLASMA (HEPARIN AND EDTA) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. , TESTOSTERONE CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS TESTOSTERONE CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE MEASUREMENT OF TESTOSTERONE IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). ,TESTOSTERONE CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS TESTOSTERONE CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF TESTOSTERONE IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). ,B12 ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS VITAMIN B12 REAGENT PACK 1/ 2)- FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF VITAMIN B12 IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS, TO AID IN THE DIFFERENTIAL DIAGNOSIS OF ANEMIA. , TESTOSTERONE ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS TESTOSTERONE REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF TESTOSTERONE IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. , PROLACTIN ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS PROLACTIN REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF PROLACTIN IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,CEA ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS CEA REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN (CEA) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,AFP CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS AFP CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF ALPHA-FETOPROTEIN (AFP) IN HUMAN SERUM, PLASMA (EDTA OR HEPARIN) AND AMNIOTIC FLUID. ,CEA CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS CEA CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE

	IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF CEA IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). ,SYSTEM CLEANING SOLUTION(VITROS IMMUNODIAGNOSTIC PRODUCTS SYSTEM CLEANING SOLUTION)-FOR USE IN THE DECONTAMINATION OF THE LMMUNODIAGNOSTIC SYSTEM AND INTEGRATED SYSTEM , AS DETAILED IN THE LMMUNODIAGNOSTIC SYSTEM AND INTEGRATED SYSTEM MAINTENANCE AND DIAGNOSTIC GUIDE,LH CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS LH CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). ,TOTAL PSA II ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS TOTAL PSA II REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF TOTAL (FREE AND COMPLEXED) PROSTATE-SPECIFIC ANTIGEN (TPSA) IN HUMAN SERUM AND PLASMA (HEPARIN AND EDTA) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,AFP ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS AFP REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF ALPHA-FETOPROTEIN (AFP) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS IN (I) MATERNAL SERUM, PLASMA (EDTA OR HEPARIN) AND AMNIOTIC FLUID, TO AID IN THE DETECTION OF OPEN NEURAL TUBE DEFECTS IN THE SECOND TRIMESTER OF PREGNANCY AND (II) HUMAN SERUM AND PLASMA (EDTA OR HEPARIN), TO AID IN THE MANAGEMENT OF PATIENTS WITH NON-SEMINOMATOUS TESTICULAR CANCER OR PRIMARY HEPATOCELLULAR CARCINOMA.,PROGESTERONE CALIBRATORS (VITROS IMMUNODIAGNOSTIC PRODUCTS PROGESTERONE CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF PROGESTERONE IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN).,PROLACTIN CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS PROLACTIN CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF PROLACTIN IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). ,CA 125 II CALIBRATORS (VITROS IMMUNODIAGNOSTIC PRODUCTS CA 125 II™ CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF OC 125

	DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). ,CA 125 II ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS CA 125 II™ REAGENT PACK)- FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF OC 125 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,CA 19-9 ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS CA 19-9™ REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF 1116-NS-19-9 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN), USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. , FREE PSA ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS FREE PSA REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF FREE PROSTATE-SPECIFIC ANTIGEN (FPSA) IN HUMAN SERUM AND PLASMA (HEPARIN AND EDTA) TO BE USED IN CONJUNCTION WITH THE VITROS TOTAL PSA II ASSAY TO DERIVE A RATIO OF FREE PSA TO TOTAL PSA (%FPSA) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,CA 15-3 ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS CA 15-3™ REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF DF3 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN), USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,CA 15-3 CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS CA 15-3™ CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF DF3 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) ,TOTAL PSA II CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS TOTAL PSA II CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF TPSA IN HUMAN SERUM AND PLASMA (HEPARIN AND EDTA). ,FREE PSA CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS FREE PSA CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF FPSA IN HUMAN SERUM AND PLASMA (HEPARIN AND EDTA). ,ANTI-HBS ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBS REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF ANTIBODY TO HEPATITIS B SURFACE ANTIGEN (ANTI-HBS) IN HUMAN SERUM AND PLASMA (HEPARIN OR CITRATE) FOLLOWING HEPATITIS B VIRUS (HBV) VACCINATION OR INFECTION

	USING THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM.,ANTI-HAV IGM CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HAV IGM CONTROLS)- FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE DETECTION OF ANTI-HAV IGM. ,RED CELL FOLATE PACK(VITROS IMMUNODIAGNOSTIC PRODUCTS RED CELL FOLATE PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR WHOLE BLOOD SAMPLE PREPARATION, TO ALLOW THE QUANTITATIVE MEASUREMENT OF RED CELL FOLATE USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,FSH CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS FSH CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). ,ANTI-HAV IGM CALIBRATOR(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HAV IGM CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUALITATIVE DETERMINATION OF IGM ANTIBODY TO HEPATITIS A VIRAL ANTIGEN (HAV) IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN OR CITRATE). ,ANTI-HAV TOTAL ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HAV TOTAL REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HUMAN HEPATITIS A VIRUS (ANTI-HAV) IN HUMAN SERUM OR PLASMA (EDTA, HEPARIN OR CITRATE) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,ANTI-HAV IGM ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HAV IGM REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUALITATIVE DETERMINATION OF IGM ANTIBODY TO HEPATITIS A VIRUS (HAV) IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN OR CITRATE) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,FSH ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS FSH REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF FOLLICLE STIMULATING HORMONE (FSH) CONCENTRATION IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,ANTI-HAV TOTAL CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HAV TOTAL CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE DETECTION OF

	ANTIBODIES TO HEPATITIS A VIRUS (ANTI-HAV). ,ANTI-HAV TOTAL CALIBRATOR(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HAV TOTAL CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HEPATITIS A VIRUS (ANTI-HAV) IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN OR CITRATE) ,CA 19-9 CALIBRATORS (VITROS IMMUNODIAGNOSTIC PRODUCTS CA 19-9™ CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF 1116-NS199 DEFINED ANTIGEN IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). ,TOXOPLASMA IGG ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS TOXOPLASMA IGG REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE AND QUALITATIVE MEASUREMENT OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA OR SODIUM CITRATE), USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS, TO AID IN THE DIAGNOSIS OF TOXOPLASMA GONDII INFECTION. ,RUBELLA IGM CALIBRATOR(VITROS IMMUNODIAGNOSTIC PRODUCTS RUBELLA IGM CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUALITATIVE DETECTION OF RUBELLA IGM IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA OR SODIUM CITRATE). ,RUBELLA IGM ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS RUBELLA IGM REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA OR SODIUM CITRATE), USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS TO AID IN THE DIAGNOSIS OF ACUTE OR RECENT RUBELLA INFECTION. ,TOXOPLASMA IGG CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS TOXOPLASMA IGG CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE AND QUALITATIVE MEASUREMENT OF TOXOPLASMA IGG IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA OR SODIUM CITRATE). ,RUBELLA IGG CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS RUBELLA IGG CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF RUBELLA IGG IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA OR SODIUM CITRATE). , TOXOPLASMA IGM ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

	TOXOPLASMA IGM REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA OR SODIUM CITRATE) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS TO AID IN THE DIAGNOSIS OF ACUTE OR RECENT TOXOPLASMA GONDII INFECTION. ,CMV IGM CALIBRATOR(VITROS IMMUNODIAGNOSTIC PRODUCTS CMV IGM CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUALITATIVE DETECTION OF CYTOMEGALOVIRUS (CMV) IGM IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA OR SODIUM CITRATE). ,CMV IGM ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS CMV IGM REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS (CMV) IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA OR SODIUM CITRATE) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS TO AID IN THE DIAGNOSIS OF ACUTE OR RECENT CMV INFECTION. ,CMV IGG CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS CMV IGG CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE SEMI-QUANTITATIVE DETERMINATION OF CYTOMEGALOVIRUS (CMV) IGG IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA OR SODIUM CITRATE). , RUBELLA IGG ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS RUBELLA IGG REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA OR SODIUM CITRATE) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS TO AID IN THE DETERMINATION OF IMMUNE STATUS TO RUBELLA. ,CMV IGG ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS CMV IGG REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS (CMV) IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA OR SODIUM CITRATE) TO AID IN THE DIAGNOSIS OF CMV INFECTION, USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,CK-MB CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS CK-MB CALIBRATORS)- FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF CK-MB IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). , DAT/IDAT CASSETTE(ANTI-HUMAN GLOBULIN ANTI-IGG (RABBIT) ANTI-HUMAN GLOBULIN ANTI-C3B, -C3D (MONOCLONAL) CONTROL

	ORTHO BIOVUE® SYSTEM (DAT/IDAT CASSETTE))-QUALITATIVE PROCEDURE FOR THE DETECTION OF IGG OR COMPLEMENT BOUND TO RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE ,MYOGLOBIN ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS MYOGLOBIN REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF MYOGLOBIN IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS, TO AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION. ,NT-PROBNP ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS NT-PROBNP REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF N-TERMINAL PRO BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS TO AID IN THE DIAGNOSIS OF CONGESTIVE HEART FAILURE AND FOR THE RISK STRATIFICATION OF ACUTE CORONARY SYNDROME AND CONGESTIVE HEART FAILURE. ,METABOLISM CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS METABOLISM CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE MEASUREMENT OF CORTISOL IN HUMAN SERUM, PLASMA (HEPARIN OR EDTA) OR URINE. ,INTACT PTH ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS INTACT PTH REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF INTACT PARATHYROID HORMONE (IPTH) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,CK-MB ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS CK-MB REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF CK-MB IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,HIGH SAMPLE DILUENT B (VITROS IMMUNODIAGNOSTIC PRODUCTS HIGH SAMPLE DILUENT B)-FOR SAMPLE DILUTION, TO ALLOW THE ASSAY OF SAMPLES WITH VALUES GREATER THAN THE CALIBRATION RANGE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE MEASUREMENT OF TOTAL -HCG, CK-MB, FERRITIN, CORTISOL, CEA, CA 15-3™, CA 125 II™, CA19-9™, PSA, ANTI-HBS, TROPONIN I, MYOGLOBIN, ANTI-HAV TOTAL, RUBELLA IGG, TOXOPLASMA IGG*, NT-PROBNP, CMV IGG*, ANTI-HBC, INSULIN AND C-PEPTIDE. ,NTX CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS NTX CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE

	IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE MEASUREMENT OF NTX. ,TROPONIN I ES ASSAY (VITROS IMMUNODIAGNOSTIC PRODUCTS TROPONIN I ES REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF CARDIAC TROPONIN I (CTNI) IN HUMAN SERUM AND PLASMA (HEPARIN AND EDTA) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS TO AID IN THE ASSESSMENT OF MYOCARDIAL DAMAGE AND RISK STRATIFICATION. ,VITROS XT TRIG-CHOL SLIDES(VITROS XT CHEMISTRY PRODUCTS TRIG-CHOL SLIDES)-FOR IN-VITRO DIAGNOSTIC USE ONLY. THE TRIG TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS TRIG-CHOL SLIDES QUANTITATIVELY MEASURE TRIGLYCERIDE (TRIG) CONCENTRATION IN SERUM AND PLASMA USING APPLICABLE VITROS SYSTEMS. TRIGLYCERIDE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH DIABETES MELLITUS, NEPHROSIS, LIVER OBSTRUCTION, OTHER DISEASES INVOLVING LIPID METABOLISM, OR VARIOUS ENDOCRINE DISORDERS. THE CHOL TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS TRIG-CHOL SLIDES QUANTITATIVELY MEASURE CHOLESTEROL (CHOL) CONCENTRATION IN SERUM AND PLASMA USING APPLICABLE VITROS SYSTEMS. LIPOPROTEIN MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIPID DISORDERS (SUCH AS DIABETES MELLITUS), ATHEROSCLEROSIS, AND VARIOUS LIVER AND RENAL DISEASES., CORTISOL CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS CORTISOL CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF CORTISOL IN HUMAN SERUM, PLASMA (HEPARIN OR EDTA) OR URINE. ,FOLATE CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS FOLATE CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF FOLATE IN HUMAN SERUM, PLASMA (HEPARIN) AND WHOLE BLOOD. ,B12 CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS VITAMIN B12 CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF VITAMIN B12 IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). ,NT-PROBNP CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS NT-PROBNP CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF

	N-TERMINAL PRO BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). ,MYOGLOBIN CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS MYOGLOBIN CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF MYOGLOBIN IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). , TROPONIN I ES CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS TROPONIN I ES CALIBRATORS)- FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF CARDIAC TROPONIN I (CTNI) IN HUMAN SERUM AND PLASMA (HEPARIN AND EDTA). ,TOXOPLASMA IGM CALIBRATOR(VITROS IMMUNODIAGNOSTIC PRODUCTS TOXOPLASMA IGM CALIBRATOR)- FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUALITATIVE DETECTION OF TOXOPLASMA IGM IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA OR SODIUM CITRATE). ,RE CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS RE CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE MEASUREMENT OF SELECTED ANALYTES. ,C-PEPTIDE ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS C-PEPTIDE REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF C-PEPTIDE IN HUMAN SERUM AND PLASMA (EDTA AND LITHIUM HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,HIGH SAMPLE DILUENT A(VITROS IMMUNODIAGNOSTIC PRODUCTS HIGH SAMPLE DILUENT A)-FOR SAMPLE DILUTION, TO ALLOW THE ASSAY OF SAMPLES WITH VALUES GREATER THAN THE CALIBRATION RANGE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE MEASUREMENT OF TSH, AFP, PROLACTIN, ESTRADIOL, PROGESTERONE AND NTX. ,INSULIN CALIBRATOR (VITROS IMMUNODIAGNOSTIC PRODUCTS INSULIN CALIBRATOR)- FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF INSULIN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN). ,ABO-RH GROUPING CASSETTE(BLOOD GROUPING REAGENTS ANTI-A (ANTI-ABO1) (MONOCLONAL) ANTI-B (ANTI-ABO2) (MONOCLONAL) ANTI-A, B (ANTI-ABO3) (MONOCLONAL) ANTI-D (ANTI-RH1) (MONOCLONAL) ANTI-CDE (ANTI-RH1,2,3) (MONOCLONAL) CONTROL ORTHO BIOVUE®

	SYSTEM (ABO-RH GROUPING CASSETTE))-QUALITATIVE TEST FOR RECOGNITION OF THE A (ABO1), B (ABO2), D (RH1), C (RH2) AND E (RH3) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE ,C-PEPTIDE CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS C-PEPTIDE CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF C-PEPTIDE IN HUMAN SERUM AND PLASMA (EDTA AND LITHIUM HEPARIN). ,SYPHILIS TPA CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS SYPHILIS TPA CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE DETERMINATION OF ANTIBODIES TO TREPONEMA PALLIDUM (TP) SPECIFIC ANTIGENS. ,SYPHILIS TPA CALIBRATOR(VITROS IMMUNODIAGNOSTIC PRODUCTS SYPHILIS TPA CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA AND CITRATE). ,INTACT PTH CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS INTACT PTH CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE MEASUREMENT OF INTACT PARATHYROID HORMONE (IPTH).,25-OH VITAMIN D CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS 25-OH VITAMIN D CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF TOTAL 25-OH VITAMIN D IN HUMAN SERUM. ,INTACT PTH CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS INTACT PTH CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF INTACT PARATHYROID HORMONE (IPTH) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN). ,FERRITIN ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS FERRITIN REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF FERRITIN IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. , ANEMIA CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS ANEMIA CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE

	INTEGRATED SYSTEMS WHEN USED FOR THE MEASUREMENT OF THE ANALYTES (FERRITIN AND VITAMIN B12) ,HIGH SAMPLE DILUENT B ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS HIGH SAMPLE DILUENT B REAGENT PACK)-FOR SAMPLE DILUTION, TO ALLOW THE ASSAY OF SAMPLES WITH VALUES GREATER THAN THE CALIBRATION RANGE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE MEASUREMENT OF SELECTED ANALYTES.,HIGH SAMPLE DILUENT A ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS HIGH SAMPLE DILUENT A REAGENT PACK)-FOR SAMPLE DILUTION, TO ALLOW THE ASSAY OF SAMPLES WITH VALUES GREATER THAN THE CALIBRATION RANGE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE MEASUREMENT OF SELECTED ANALYTES, VITROS XT TBIL-ALKP SLIDES(VITROS XT CHEMISTRY PRODUCTS TBIL-ALKP SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. THE TBIL TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS TBIL-ALKP SLIDES QUANTITATIVELY MEASURE TOTAL BILIRUBIN (TBIL) CONCENTRATION IN SERUM AND PLASMA USING APPLICABLE VITROS SYSTEMS. MEASUREMENTS OF THE LEVELS OF BILIRUBIN, AN ORGANIC COMPOUND FORMED DURING THE NORMAL AND ABNORMAL DESTRUCTION OF RED BLOOD CELLS, ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIVER, HEMOLYTIC HEMATOLOGICAL AND METABOLIC DISORDERS, INCLUDING HEPATITIS AND GA LL BLADDER BLOCK. THE ALKP TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS TBIL-ALKP SLIDES QUANTITATIVELY MEASURE ALKALINE PHOSPHATASE (ALKP) ACTIVITY IN SERUM AND PLASMA USING APPLICABLE VITROS SYSTEMS. MEASUREMENTS OF ALKA LINE PHOSPHATASE OR ITS ISOENZYMES ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIVER, BONE, PARATHYROID, AND INTESTINAL DISEASES.,CORTISOL ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS CORTISOL REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF CORTISOL IN HUMAN SERUM, PLASMA (HEPARIN OR EDTA) OR URINE USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. , VITROS XT GLU-CA SLIDES(VITROSXT CHEMISTRY PRODUCTS GLU-CA SLIDES)-FOR IN-VITRO DIAGNOSTIC USE ONLY. THE GLU TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS GLU-CA SLID ES QUANTITATIVELY MEASURES GLU COSE {GLU) CONCENTRATION IN SERUM, PLASMA, URINE, AND CEREBROSPINAL FLUID {CSF) USING APP LICABLE VITROS SYSTEMS. GLUCOSE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CARBOHYDRATE METABOLISM DISORDERS INCLUDING DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, IDIOPATHIC HYPOGLYCEMIA, AND OF

	PANCREATIC ISLET CELL CARCINOMA. THE CA TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS GLU-CA SLIDES QUANTITATIVELY MEASURES· CALCIUM (CA) CONCENTRATION IN SERUM, PLASMA, AND URINE USING APPLICABLE VITROS SYSTEMS. CALCIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PARATHYROID DISEASE, A VARIETY OF BONE DISEASES, CHRONIC RENA L DISEASE AND TETANY (INTERMITTENT MUSCULAR CONTRACTIONS OR SPASMS).,TOTAL THYROID CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS TOTAL THYROID CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS WHEN USED FOR THE MEASUREMENT OF TSH, TOTAL T3 AND TOTAL T4 AND FOR THE ASSESSMENT OF THYROID HORMONE BINDING CAPACITY. ,25-OH VITAMIN D ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS 25-OH VITAMIN D REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF TOTAL 25-OH VITAMIN D IN HUMAN SERUM USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,HBEAG CALIBRATOR(VITROS IMMUNODIAGNOSTIC PRODUCTS HBEAG CALIBRATOR)- FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM FOR THE QUALITATIVE DETECTION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM ,HBEAG ASSAY (VITROS IMMUNODIAGNOSTIC PRODUCTS HBEAG REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUALITATIVE DETECTION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM USING THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM. ,ANTI-HBE CALIBRATOR(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBE CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B E ANTIGEN (ANTI-HBE) IN HUMAN SERUM ,ANTI-HBC IGM ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC IGM REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUALITATIVE DETERMINATION OF IGM ANTIBODY TO HEPATITIS B VIRUS CORE ANTIGEN (HBC) IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN OR CITRATE) USING THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM. THIS DEVICE IS FOR USE AS AN AID IN THE DIAGNOSIS OF ACUTE OR RECENT HEPATITIS B INFECTION (USUALLY SIX MONTHS OR LESS) , ANTI-HBS CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBS CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM WHEN USED FOR THE

	MEASUREMENT OF ANTI-HBS.,ANTI-HBS CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBS CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ANTI-HBS IN HUMAN SERUM AND PLASMA (HEPARIN OR CITRATE).,ANTI-HCV CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HCV CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF THE IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM WHEN USED FOR THE DETECTION OF ANTIBODIES TO HEPATITIS C VIRUS (ANTI-HCV). ,ANTI-HIV 1 + 2 CONTROLS(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HIV 1 + 2 CONTROLS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN MONITORING THE PERFORMANCE OF IMMUNODIAGNOSTIC SYSTEM AND INTEGRATED SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPES 1 AND/OR 2 (ANTI-HIV 1 AND ANTI-HIV 2) IN HUMAN SERUM AND PLASMA (HEPARIN OR CITRATE). ,ANTI-HIV 1 + 2 CALIBRATOR (VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HIV 1 + 2 CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE ONLY FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEM AND INTEGRATED SYSTEM FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPES 1 AND/OR 2 (ANTI-HIV 1 AND ANTI-HIV 2) IN HUMAN SERUM AND PLASMA (HEPARIN OR CITRATE). ,ANTI-HIV 1 + 2 ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HIV 1 + 2 REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPES 1 AND/OR 2 (ANTI-HIV 1 AND ANTI-HIV 2) IN HUMAN SERUM AND PLASMA (HEPARIN OR CITRATE) USING IMMUNODIAGNOSTIC SYSTEM AND INTEGRATED SYSTEM ,HBSAG ES ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS HBSAG ES REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM AND PLASMA (HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND INTEGRATED SYSTEM. ,ANTI-HCV CALIBRATOR(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HCV CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN OR CITRATE). ,ANTI-HCV ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HCV REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO

	HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN OR CITRATE), USING IMMUNODIAGNOSTIC SYSTEM AND THE INTEGRATED SYSTEM,NTX ASSAY(VITROS IMMUNODIAGNOSTIC PRODUCTS NTX REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY FOR THE QUANTITATIVE MEASUREMENT OF CROSS-LINKED N-TELOPEPTIDES OF TYPE 1 COLLAGEN (NTX) IN HUMAN URINE AS AN INDICATOR OF HUMAN BONE RESORPTION USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS. ,TSH CALIBRATORS(VITROS IMMUNODIAGNOSTIC PRODUCTS TSH CALIBRATORS)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR USE IN THE CALIBRATION OF THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN).,TSH ASSAY (VITROS IMMUNODIAGNOSTIC PRODUCTS TSH REAGENT PACK)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR THE QUANTITATIVE MEASUREMENT OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM AND PLASMA (EDTA OR HEPARIN) USING THE IMMUNODIAGNOSTIC SYSTEMS AND THE INTEGRATED SYSTEMS TO AID IN THE DIFFERENTIAL DIAGNOSIS OF THYROID DISEASE., NEWBORN CASSETTE(BLOOD GROUPING REAGENTS ANTI-A (ANTI-ABO1) (MONOCLONAL) ANTI-B (ANTI-ABO2) (MONOCLONAL) ANTI-A, B (ANTI-ABO3) (MONOCLONAL) ANTI-D (ANTI-RH1) (MONOCLONAL) CONTROL ANTI-HUMAN GLOBULIN ANTI-IGG (RABBIT) (GREEN) ORTHO BIOVUE® SYSTEM (NEWBORN CASSETTE))-QUALITATIVE TEST FOR RECOGNITION OF THE A (ABO1), B (ABO2) AND D (RH1) ANTIGENS ON HUMAN RED BLOOD CELLS AND FOR THE DETECTION OF CELL-BOUND IGG ANTIBODY IN NEWBORNS FOR IN VITRO DIAGNOSTIC USE ,ADK CASSETTE(BLOOD GROUPING REAGENTS ANTI-A (ANTI-ABO1) (MONOCLONAL) ANTI-B (ANTI-ABO2) (MONOCLONAL) ANTI-D (ANTI-RH1) (MONOCLONAL) ANTI-D (ANTI-RH1) (MONOCLONAL) ANTI-K (ANTI-K1) (MONOCLONAL) CONTROL ORTHO BIOVUE® SYSTEM (ADK CASSETTE))- QUALITATIVE TEST FOR RECOGNITION OF THE A (ABO1), B (ABO2), D (RH1) AND K (K1) ANTIGENS ON HUMAN RED BLOOD CELLS FOR IN VITRO DIAGNOSTIC USE

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	B12 (HOLOTRANSCOBALAMIN) CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HOLOTRANSCOBALAMIN IN HUMAN SERUM.,ALINITY I 2ND GENERATION TESTOSTERONE REAGENT KIT(ALINITY I 2ND GENERATION TESTOSTERONE REAGENT KIT)-THE ALINITY I 2ND GENERATION TESTOSTERONE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER. THE ALINITY I 2ND GENERATION TESTOSTERONE ASSAY IS TO BE USED FOR THE MEASUREMENT OF TESTOSTERONE IN THE DIAGNOSIS AND TREATMENT OF DISORDERS INVOLVING THE MALE SEX HORMONES (ANDROGENS), INCLUDING PRIMARY AND SECONDARY HYPOGONADISM, DELAYED OR PRECOCIOUS PUBERTY, IMPOTENCE IN MALES AND, IN FEMALES, HIRSUTISM (EXCESSIVE HAIR) AND VIRILIZATION (MASCULINIZATION) DUE TO TUMORS, POLYCYSTIC OVARIES, AND ADRENOGENITAL SYNDROMES.,ARCHITECT HOMOCYSTEINE CALIBRATORS(ARCHITECT HOMOCYSTEINE CALIBRATORS)-THE ARCHITECT HOMOCYSTEINE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL L-HOMOCYSTEINE IN HUMAN SERUM OR PLASMA.,ARCHITECT ANTI-CCP CONTROLS (ARCHITECT ANTI-CCP CONTROLS)-THE ARCHITECT ANTI-CCP CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM (REAGENTS, CALIBRATORS AND INSTRUMENT) WHEN USED FOR THE SEMI-QUANTITATIVE DETERMINATION OF THE IGG CLASS OF AUTOANTIBODIES SPECIFIC TO CYCLIC CITRULLINATED PEPTIDE (CCP) IN HUMAN SERUM OR PLASMA., ALINITY I HOMOCYSTEINE CONTROLS(ALINITY I HOMOCYSTEINE CONTROLS)-THE ALINITY I HOMOCYSTEINE CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I (REAGENTS, CALIBRATORS AND INSTRUMENT), WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL L-HOMOCYSTEINE IN HUMAN SERUM OR PLASMA.,ALINITY I 2ND GENERATION TESTOSTERONE CALIBRATORS(ALINITY I 2ND GENERATION TESTOSTERONE CALIBRATORS)-THE ALINITY I 2ND GENERATION TESTOSTERONE CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM AND PLASMA.,ARCHITECT ACTIVE-B12 (HOLOTRANSCOBALAMIN) REAGENT KIT(ARCHITECT ACTIVE-B12 (HOLOTRANSCOBALAMIN))-THE ARCHITECT ACTIVE-B12 (HOLOTRANSCOBALAMIN) ASSAY IS A

	CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF HOLOTRANSCOBALAMIN IN HUMAN SERUM ON THE ARCHITECT ISYSTEM. ACTIVE-B12 (HOLOTRANSCOBALAMIN) IS USED AS AN AID IN THE DIAGNOSIS AND TREATMENT OF VITAMIN B12 DEFICIENCY.,ARCHITECT 2ND GENERATION TESTOSTERONE REAGENT KIT(ARCHITECT 2ND GENERATION TESTOSTERONE REAGENT KIT)-THE ARCHITECT 2ND GENERATION TESTOSTERONE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM AND PLASMA. MEASUREMENTS OF TESTOSTERONE ARE USED IN THE DIAGNOSIS AND TREATMENT OF DISORDERS INVOLVING THE MALE SEX HORMONES (ANDROGENS), INCLUDING PRIMARY AND SECONDARY HYPOGONADISM, DELAYED OR PRECOCIOUS PUBERTY, IMPOTENCE IN MALES AND, IN FEMALES, HIRSUTISM (EXCESSIVE HAIR) AND VIRILIZATION (MASCULINIZATION) DUE TO TUMORS, POLYCYSTIC OVARIES, AND ADRENOGENITAL SYNDROMES.,ALINITY I 2ND GENERATION TESTOSTERONE CONTROLS(ALINITY I 2ND GENERATION TESTOSTERONE CONTROLS)-THE ALINITY I 2ND GENERATION TESTOSTERONE CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM AND PLASMA.,ARCHITECT 2ND GENERATION TESTOSTERONE CALIBRATORS(ARCHITECT 2ND GENERATION TESTOSTERONE CALIBRATORS)-THE ARCHITECT 2ND GENERATION TESTOSTERONE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM AND PLASMA.,ARCHITECT 2ND GENERATION TESTOSTERONE CONTROLS(ARCHITECT 2ND GENERATION TESTOSTERONE CONTROLS)-THE ARCHITECT 2ND GENERATION TESTOSTERONE CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM AND PLASMA.,ARCHITECT ANTI-CCP REAGENT KIT (ARCHITECT ANTI-CCP)-THE ARCHITECT ANTI-CCP ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE SEMI-QUANTITATIVE DETERMINATION OF THE IGG CLASS OF AUTOANTIBODIES SPECIFIC TO CYCLIC CITRULLINATED PEPTIDE (CCP) IN HUMAN SERUM OR PLASMA ON THE ARCHITECT ISYSTEM. DETECTION OF ANTI-CCP ANTIBODIES IS USED AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA) AND SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL INFORMATION. AUTOANTIBODY LEVELS REPRESENT ONE PARAMETER IN A

	MULTICRITERION DIAGNOSTIC PROCESS, ENCOMPASSING BOTH CLINICAL AND LABORATORY-BASED ASSESSMENTS.,ALINITY I HOMOCYSTEINE REAGENT KIT(ALINITY I HOMOCYSTEINE REAGENT KIT)-THE ALINITY I HOMOCYSTEINE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL L-HOMOCYSTEINE IN HUMAN SERUM OR PLASMA ON THE ALINITY I ANALYZER.,ALINITY I ANTI-CCP CALIBRATORS(ALINITY I ANTI-CCP CALIBRATORS)-THE ALINITY I ANTI-CCP CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE SEMI-QUANTITATIVE DETERMINATION OF THE IGG CLASS OF AUTOANTIBODIES SPECIFIC TO CYCLIC CITRULLINATED PEPTIDE (CCP) IN HUMAN SERUM OR PLASMA.,ALINITY I ANTI-CCP CONTROLS(ALINITY I ANTI-CCP CONTROLS)-THE ALINITY I ANTI-CCP CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER (REAGENTS, CALIBRATORS AND INSTRUMENT) WHEN USED FOR THE SEMI-QUANTITATIVE DETERMINATION OF THE IGG CLASS OF AUTOANTIBODIES SPECIFIC TO CYCLIC CITRULLINATED PEPTIDE (CCP) IN HUMAN SERUM OR PLASMA.,ALINITY I HOMOCYSTEINE CALIBRATORS(ALINITY I HOMOCYSTEINE CALIBRATORS)-THE ALINITY I HOMOCYSTEINE CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL L-HOMOCYSTEINE IN HUMAN SERUM OR PLASMA.,ALINITY I ANTI-CCP REAGENT KIT(ALINITY I ANTI-CCP REAGENT KIT)-THE ALINITY I ANTI-CCP ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE SEMI-QUANTITATIVE DETERMINATION OF THE IGG CLASS OF AUTOANTIBODIES SPECIFIC TO CYCLIC CITRULLINATED PEPTIDE (CCP) IN HUMAN SERUM OR PLASMA ON THE ALINITY I ANALYZER., ARCHITECT HOMOCYSTEINE REAGENT KIT(ARCHITECT HOMOCYSTEINE)-THE ARCHITECT HOMOCYSTEINE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL L-HOMOCYSTEINE IN HUMAN SERUM OR PLASMA ON THE ARCHITECT ISYSTEM. HOMOCYSTEINE VALUES CAN ASSIST IN THE DIAGNOSIS AND TREATMENT OF PATIENTS SUSPECTED OF HAVING HYPERHOMOCYSTEINEMIA AND HOMOCYSTINURIA.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO

182	IMP/IVD/2019/000138	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EMIT II PLUS OXYCODONE POSITIVE CONTROL 300(EMIT II PLUS OXYCODONE POSITIVE CONTROL 300)-THE EMIT® II PLUS OXYCODONE POSITIVE AND NEGATIVE CUTOFF CONTROLS ARE FOR USE WITH THE EMIT® II PLUS OXYCODONE ASSAY.,EMIT 2000 CARBAMAZEPINE CALIBRATORS (EMIT 2000 CARBAMAZEPINE CALIBRATORS)-THE EMIT® 2000 CARBAMAZEPINE CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT ® 2000 CARBAMAZEPINE ASSAY,EMIT® II PLUS SPECIALTY MULTI DRUG CALIBRATOR/CONTROL LEVEL 3(EMIT® II PLUS SPECIALTY MULTI DRUG CALIBRATOR/CONTROL LEVEL 3)-THE EMIT® II PLUS SPECIALTY MULTI DRUG CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS OXYCODONE ASSAY. THESE PRODUCTS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED ON THE OXYCODONE ASSAY CUTOFF,EMIT II PLUS 6-AM/ECSTASY CALIBRATOR/CONTROL LEVEL 1(EMIT II PLUS 6-AM/ECSTASY CALIBRATOR/CONTROL LEVEL 1)-WHEN USED AS CALIBRATORS, THE MATERIALS ARE FOR THE CALIBRATION OF THE EMIT® II PLUS 6-ACETYLMORPHINE AND EMIT® II PLUS ECSTASY ASSAYS. WHEN USED AS CONTROLS, THE MATERIALS MAY BE USED AS QUALITY CONTROL MATERIALS BASED ON THE SPECIFIC EMIT® II PLUS 6-ACETYLMORPHINE AND EMIT® II PLUS ECSTASY ASSAY CUTOFFS,DIMENSION® VISTA/DIMENSION® EXL SARS-COV-2 IGG CALIBRATOR (COV2G CAL/ CV2G CAL)(IMENSION® VISTA/DIMENSION® EXL SARS-COV-2 IGG CALIBRATOR (COV2G CAL/ CV2G CAL))-THE SARS-COV-2 IGG CALIBRATOR (COV2G CAL/CV2G CAL) IS AN IN VITRO DIAGNOSTIC PRODUCT FOR CALIBRATION OF THE SARS-COV-2 IGG ANTIBODY ASSAY (COV2G/CV2G) ON THE DIMENSION VISTA® SYSTEM AND THE DIMENSION® EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE.,EMIT® II PLUS SPECIALTY DRUG CALIBRATOR/CONTROL LEVEL 4(EMIT® II PLUS SPECIALTY DRUG CALIBRATOR/CONTROL LEVEL 4)-THE EMIT® II PLUS SPECIALTY DRUG CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS BUPRENORPHINE ASSAY. THESE PRODUCTS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED ON THE BUPRENORPHINE ASSAY CUTOFF.,DIMENSION® VISTA/DIMENSION® EXL SARSCOV2 IGG QUALITY CONTROL (COV2G QC/CV2G QC) (DIMENSION® VISTA/DIMENSION® EXL SARSCOV2 IGG QUALITY CONTROL (COV2G QC/CV2G QC))-THE SARSCOV2 IGG QUALITY CONTROL (COV2G QC/CV2G QC) MATERIAL IS AN IN VITRO DIAGNOSTIC PRODUCT TO MONITOR THE ACCURACY OF THE SARSCOV2 IGG ANTIBODY ASSAY (COV2G/CV2G) ON THE

	DIMENSION VISTA® SYSTEM AND THE DIMENSION® EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE.,EMIT CALIBRATOR/CONTROL LEVEL 2(EMIT CALIBRATOR/CONTROL LEVEL 2)-EMIL CALIBRATOR/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT II PLUS AMPHETAMINES, BARBITURATE, CANNABINOIDS, BENZODIAZEPINE, COCAINE METABOLITE, ECSTASY, METHADONE, METHAQUALONE, MONOCLONAL AMPHETAMINE/METHAMPHETAMINE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE ASSAYS,DIMENSION® EXL™ SARSCOV2 IGG (CV2G) ASSAY(DIMENSION® EXL™ SARSCOV2 IGG (CV2G) ASSAY)-THE DIMENSION® EXL™ SARSCOV2 IGG (CV2G) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMI-QUANTITATIVE DETECTION OF IGG ANTIBODIES TO SARSCOV2 IN HUMAN SERUM AND PLASMA (DIPOTASSIUM EDTA AND LITHIUM HEPARIN) USING THE DIMENSION® EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE. THIS ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF PATIENTS WITH SUSPECTED SARSCOV2 INFECTION AND AS AN AID IN IDENTIFYING PATIENTS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARSCOV2, INDICATING RECENT OR PRIOR INFECTION.,EMIT CALIBRATOR/CONTROL LEVEL 5(EMIT CALIBRATOR/CONTROL LEVEL 5)-EMIL CALIBRATOR/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT II PLUS AMPHETAMINES, BARBITURATE, CANNABINOIDS, BENZODIAZEPINE, COCAINE METABOLITE, ECSTASY, METHADONE, METHAQUALONE, MONOCLONAL AMPHETAMINE/METHAMPHETAMINE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE ASSAYS,EMIT II PLUS OXYCODONE POSITIVE CONTROL 100(EMIT II PLUS OXYCODONE POSITIVE CONTROL 100)-THE EMIT® II PLUS OXYCODONE NEGATIVE AND POSITIVE CUTOFF CONTROLS ARE FOR USE WITH THE EMIT® II PLUS OXYCODONE ASSAY.,EMIT CALIBRATOR/CONTROL LEVEL 4 (EMIT CALIBRATOR/CONTROL LEVEL 4)-EMIL CALIBRATOR/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT II PLUS AMPHETAMINES, BARBITURATE, CANNABINOIDS, BENZODIAZEPINE, COCAINE METABOLITE, ECSTASY, METHADONE, METHAQUALONE, MONOCLONAL AMPHETAMINE/METHAMPHETAMINE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE ASSAYS,EMIT® II PLUS SPECIALTY MULTI DRUG CALIBRATOR/CONTROL LEVEL 4(EMIT® II PLUS SPECIALTY MULTI DRUG CALIBRATOR/CONTROL LEVEL 4)-THE EMIT® II PLUS SPECIALTY MULTI DRUG CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS OXYCODONE ASSAY. THESE PRODUCTS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED ON THE OXYCODONE ASSAY CUTOFF,EMIT CALIBRATOR/CONTROL LEVEL 3(EMIT CALIBRATOR/CONTROL

	LEVEL 3)-EMIL CALIBRATOR/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT II PLUS AMPHETAMINES, BARBITURATE, CANNABINOIDS, BENZODIAZEPINE, COCAINE METABOLITE, ECSTASY, METHADONE, METHAQUALONE, MONOCLONAL AMPHETAMINE/METHAMPHETAMINE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE ASSAYS,EMIT® II PLUS SPECIALTY MULTI DRUG CALIBRATOR/CONTROL LEVEL 1(EMIT® II PLUS SPECIALTY MULTI DRUG CALIBRATOR/CONTROL LEVEL 1)-THE EMIT® II PLUS SPECIALTY MULTI DRUG CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS OXYCODONE ASSAY. THESE PRODUCTS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED ON THE OXYCODONE ASSAY CUTOFF.,EMIT II PLUS SPECIALTY DRUG CONTROL POSITIVE(EMIT II PLUS SPECIALTY DRUG CONTROL POSITIVE)-THE EMIT® II PLUS SPECIALTY DRUG CONTROL NEGATIVE AND CONTROL POSITIVE ARE FOR USE WITH THE EMIT® II PLUS BUPRENORPHINE ASSAY,EMIT II PLUS OXYCODONE NEGATIVE CONTROL 300(EMIT II PLUS OXYCODONE NEGATIVE CONTROL 300)-THE EMIT® II PLUS OXYCODONE POSITIVE AND NEGATIVE CUTOFF CONTROLS ARE FOR USE WITH THE EMIT® II PLUS OXYCODONE ASSAY.,EMIT II PLUS SPECIALTY DRUG CONTROL NEGATIVE(EMIT II PLUS SPECIALTY DRUG CONTROL NEGATIVE)-THE EMIT® II PLUS SPECIALTY DRUG CONTROL NEGATIVE AND CONTROL POSITIVE ARE FOR USE WITH THE EMIT® II PLUS BUPRENORPHINE ASSAY.,EMIT® II PLUS SPECIALTY MULTI DRUG CALIBRATOR/CONTROL LEVEL 2 (EMIT® II PLUS SPECIALTY MULTI DRUG CALIBRATOR/CONTROL LEVEL 2)-THE EMIT® II PLUS SPECIALTY MULTI DRUG CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS OXYCODONE ASSAY. THESE PRODUCTS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED ON THE OXYCODONE ASSAY CUTOFF.,EMIT® II PLUS SPECIALTY DRUG CALIBRATOR/CONTROL LEVEL 1(EMIT® II PLUS SPECIALTY DRUG CALIBRATOR/CONTROL LEVEL 1)-THE EMIT® II PLUS SPECIALTY DRUG CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS BUPRENORPHINE ASSAY. THESE PRODUCTS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED ON THE BUPRENORPHINE ASSAY CUTOFF.,EMIT II PLUS OXYCODONE NEGATIVE CONTROL 100(EMIT II PLUS OXYCODONE NEGATIVE CONTROL 100)-THE EMIT® II PLUS OXYCODONE POSITIVE AND NEGATIVE CUTOFF CONTROLS ARE FOR USE WITH THE EMIT® II PLUS OXYCODONE ASSAY.,DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX REAGENT CARTRIDGE FERR (CAL) CALIBRATOR(DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX REAGENT CARTRIDGE FERR (CAL) CALIBRATOR)-THE FERRITIN

	CALIBRATOR IS AN IN-VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED TO CALIBRATE THE FERRITIN METHOD FOR THE DIMENSION CLINICAL CHEMISTRY SYSTEMS WITH THE HETEROGENEOUS IMMUNOASSAY METHOD.,EMIT® II PLUS OXYCODONE ASSAY(EMIT® II PLUS OXYCODONE ASSAY)-THE EMIT® II PLUS OXYCODONE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH 100 NG/ML AND 300 NG/ML CUTOFFS. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF OXYCODONE IN HUMAN URINE. THE EMIT® II PLUS OXYCODONE ASSAY IS DESIGNED FOR USE WITH A NUMBER OF CLINICAL CHEMISTRY ANALYZERS. THE SEMIQUANTITATIVE MODE IS FOR THE PURPOSES OF ENABLING LABORATORIES TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS LIQUID CHROMATOGRAPHY/ MASS SPECTROMETRY (LC/MS) OR PERMITTING LABORATORIES TO ESTABLISH QUALITY CONTROL PROCEDURES. THE EMIT® II PLUS OXYCODONE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD(S) MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL TEST RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) AND LC/MS ARE THE PREFERRED CONFIRMATORY METHODS.1,2 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,EMIT® LSD 2.5 NG/ML CALIBRATOR(EMIT® LSD 2.5 NG/ML CALIBRATOR)-THE EMIT® LSD CALIBRATORS ARE FOR USE ONLY WITH THE EMIT® II LSD ASSAY.,DIMENSION EXL INTEGRATED CHEMISTRY SYSTEM LOCI MODULE LOCI TNIH CAL(DIMENSION EXL INTEGRATED CHEMISTRY SYSTEM LOCI MODULE LOCI TNIH CAL)-THE LOCI HIGH SENSITIVITY TROPONIN 1 CALIBRATOR (LOCI TNIH CAL) IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE CALIBRATION OF THE CARDIAC HIGH SENSITIVITY TROPONIN 1 (TNIH) ASSAY ON THE DIMENSION EXL INTEGRATED CHEMISTRY SYSTEM WITH LOCI MODULE.,EMIT 2000 PHENOBARBITAL CALIBRATORS(EMIT 2000 PHENOBARBITAL CALIBRATORS)-FOR CALIBRATING EMIT 2000 PHENOBARBITAL ASSAYS,DIMENSION EXL INTEGRATED CHEMISTRY SYSTEM LOCI MODULE FLEX REAGENT CARTRIDGE TNIH(DIMENSION EXL INTEGRATED CHEMISTRY SYSTEM LOCI MODULE FLEX REAGENT CARTRIDGE TNIH)-THE HIGH SENSITIVITY TROPONIN 1 (TNIH) ASSAY IS USED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF CARDIAC TROPONIN 1 IN HUMAN SERUM OR PLASMA USING THE DIMENSION EXL INTEGRATED CHEMISTRY SYSTEM WITH LOCI MODULE. THE ASSAY CAN BE USED TO AID IN THE

	DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI).,DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE PHOS (DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE PHOS)-THE PHOS METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF INORGANIC PHOSPHORUS IN SERUM, PLASMA AND URINE ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM. MEASUREMENTS OF PHOSPHORUS (INORGANIC) ARE USED IN THE DIAGNOSIS AND TREATMENT OF BONE, PARATHYROID AND RENAL DISEASE. , DIMENSION® HEMOGLOBIN A1C KIT (DIMENSION® HEMOGLOBIN A1C KIT)-THE DIMENSION® HEMOGLOBIN A1C ASSAY IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF %HBA1C (DCCT/NGSP)AND MMOL/MOL HBA1C (IFCC) IN HUMAN ANTICOAGULATED VENOUS WHOLE BLOOD FOR USE ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM. MEASUREMENT OF HEMOGLOBIN A1C IS USED AS AN AID IN DIAGNOSIS AND MONITORING OF LONG-TERM BLOOD GLUCOSE CONTROL IN PATIENTS WITH DIABETES MELLITUS AND AS AN AID IN THE IDENTIFICATION OF PATIENTS AT RISK FOR DEVELOPING DIABETES MELLITUS. ,EMIT 2000 GENTAMICIN PLUS CALIBRATORS(EMIT 2000 GENTAMICIN PLUS CALIBRATORS)-FOR CALIBRATING EMIT 2000 GENTAMICIN PLUS ASSAY,DIMENSION VISTA/DIMENSION EXL SARSCOV2 TOTAL ANTIBODY QUALITY CONTROL (COV2T/CV2T POS/NEG)(DIMENSION VISTA/DIMENSION EXL SARSCOV2 TOTAL ANTIBODY QUALITY CONTROL (COV2T/CV2T POS/NEG))-THE SARS-COV-2 TOTAL ANTIBODY QUALITY CONTROL (COV2T/CV2T POS/NEG) MATERIAL IS AN IN VITRO DIAGNOSTIC PRODUCT TO MONITOR THE ACCURACY OF THE SARS-COV-2 TOTAL ANTIBODY ASSAY (COV2T/CV2T) ON THE DIMENSION VISTA® SYSTEM AND THE DIMENSION® EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE.,DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE CTNI (CAL) CALIBRATOR (DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE CTNI (CAL) CALIBRATOR)-THE CTNI CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED TO CALIBRATE THE CARDIAC TROPONIN I METHODS FOR THE DIMENSION CLINICAL CHEMISTRY SYSTEMS WITH THE HETEROGENEOUS IMMUNOASSAY MODULE.,DIMENSION VISTA/DIMENSION EXL SARS-COV-2 TOTAL ANTIBODY CALIBRATOR (COV2T CAL/CV2T CAL)(DIMENSION VISTA/DIMENSION EXL SARS-COV-2 TOTAL ANTIBODY CALIBRATOR (COV2T CAL/CV2T CAL))-THE SARS-COV-2 TOTAL ANTIBODY CALIBRATOR (COV2T CAL/CV2T CAL) IS AN IN VITRO DIAGNOSTIC PRODUCT FOR CALIBRATION OF THE SARS-COV-2 TOTAL ANTIBODY ASSAY (COV2T/CV2T) ON THE

	DIMENSION VISTA® SYSTEM AND THE DIMENSION® EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE.,EMIT II PLUS 6-AM/ECSTASY CALIBRATOR/CONTROL LEVEL 4(EMIT II PLUS 6-AM/ECSTASY CALIBRATOR/CONTROL LEVEL 4)-WHEN USED AS CALIBRATORS, THE MATERIALS ARE FOR THE CALIBRATION OF THE EMIT® II PLUS 6-ACETYLMORPHINE AND EMIT® II PLUS ECSTASY ASSAYS. WHEN USED AS CONTROLS, THE MATERIALS MAY BE USED AS QUALITY CONTROL MATERIALS BASED ON THE SPECIFIC EMIT® II PLUS 6-ACETYLMORPHINE AND EMIT® II PLUS ECSTASY ASSAY CUTOFFS,DIMENSION® EXL™ SARS-COV-2 TOTAL ANTIBODY ASSAY (CV2T)(DIMENSION® EXL™ SARS-COV-2 TOTAL ANTIBODY ASSAY (CV2T))-THE DIMENSION® EXL™ SARSCOV2 TOTAL ANTIBODY ASSAY (CV2T) IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETECTION OF TOTAL ANTIBODIES (INCLUDING IGG AND IGM) TO SARSCOV2 VIRUS IN HUMAN SERUM AND PLASMA (EDTA, LITHIUM HEPARIN) USING THE DIMENSION® EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE.,DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE REAGENT CARTRIDGE FERR (DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE REAGENT CARTRIDGE FERR)-THE FERR METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE FERRITIN IN HUMAN SERUM AND HEPARINIZED PLASMA. MEASUREMENTS OF FERRITIN AID IN THE DIAGNOSIS OF DISEASES AFFECTING IRON METABOLISM, SUCH AS HEMOCHROMATOSIS AND IRON DEFICIENCY ANEMIA. ,DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENOUS IMMUNOASSAY MODULE FLEX® REAGENT CATRIDGE MYO(DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENOUS IMMUNOASSAY MODULE FLEX® REAGENT CATRIDGE MYO)-THE MYOGLOBIN CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TOBE USED TO CALIBRATE THE MYOGLOBIN (MYO) METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM WITH THE HETEROGENOUS IMMUNOASSAY MODULE,EMIT 2000 PROCAINAMIDE CALIBRATORS (EMIT 2000 PROCAINAMIDE CALIBRATORS)-FOR CALIBRATING EMIT 2000 PHENYTOIN ASSAY,DIMENSION® HETEROGENOUS IMMUNOASSAY MODULE MYO CALIBRATOR(DIMENSION® HETEROGENOUS IMMUNOASSAY MODULE MYO CALIBRATOR)-THE MYO METHOD FOR DIMENSION® CLINICAL CHEMISTRY SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE MYOGLOBIN IN HUMAN SERUM AND HEPARINIZED PLASMA. MYOGLOBIN MEASUREMENTS CAN BE USED AS AN AID IN

	DIAGNOSING MYOCARDIAL INFARCTION,DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE CSAE(DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE CSAE)-THE CSAE METHOD IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE CYCLOSPORINE A (CSA) IN HUMAN WHOLE BLOOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM. MEASUREMENTS OF CSA ARE USED AS AN AID IN THE MANAGEMENT OF HEART, LIVER AND KIDNEY TRANSPLANT PATIENTS. ,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE CRP (DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE CRP)-THE CRP METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM AND HEPARINIZED PLASMA., DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE TOBR(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE TOBR)-THE TOBR METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO MEASURE TOBRAMYCIN, AN AMINOGLYCOSIDE ANTIBIOTIC IN HUMAN SERUM OR PLASMA. TOBR TEST RESULTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF TOBRAMYCIN OVERDOSE AND IN MONITORING LEVELS OF TOBRAMYCIN TO ENSURE APPROPRIATE THERAPY,DIMENSION® EXLTM INTEGRATED CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE AMPH(DIMENSION® EXLTM INTEGRATED CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE AMPH)-THE AMPH METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM PROVIDES REAGENTS FOR AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF AMPHETAMINES IN HUMAN URINE USING A CUTOFF OF EITHER 300, 500 OR 1000 NG/ML. MEASUREMENTS OBTAINED WITH THE AMPH METHOD ARE USED IN THE DIAGNOSIS AND TREATMENT OF AMPHETAMINES USE OR OVERDOSE.,DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX REAGENT CARTRIDGE CTNI(DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX REAGENT CARTRIDGE CTNI)-THE CTNI METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE CARDIAC TROPONIN-I LEVELS IN HUMAN SERUM AND HEPARINIZED PLASMA TO AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION AND IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES WITH RESPECT TO THEIR RELATIVE RISK OF MORTALITY. ,

	DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE TU(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE TU)-THE TU METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO MEASURE THE RELATIVE LEVEL OF UNSATURATED THYROXINE BINDING GLOBULIN (UTBG) IN HUMAN SERUM AND PLASMA,DIMENSION CLINICAL CHEMISTRY SYSTEM CSAE (CAL) CALIBRATOR(DIMENSION CLINICAL CHEMISTRY SYSTEM CSAE (CAL) CALIBRATOR)-THE CSAE CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED TO CALIBRATE THE CYCLOSPORINE, EXTENDED RANGE METHODS FOR THE DIMENSION CLINICAL CHEMISTRY SYSTEMS ON THE SYVA, EMIT 2000 CYCLOSPORINE SPECIFIC ASSAY,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE CHK(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE CHK)-FOR CHECKING PROPER FUNCTIONING OF THE FLUID METERING AND PHOTOMETRIC MEASURING SYSTEM ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM. IT IS RUN DAILY AS PART OF THE SYSTEM CHECK ROUTINE.,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE CRP(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE CRP)-THE CRP METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM AND HEPARINIZED PLASMA.,DIMENSION® EXLTM INTEGRATED CHEMISTRY SYSTEM LOCI MODULE LOCI ANEMIA CAL(DIMENSION® EXLTM INTEGRATED CHEMISTRY SYSTEM LOCI MODULE LOCI ANEMIA CAL)-THE LOCI ANEMIA CAL IS AN IN-VITRO DIAGNOSTIC PRODUCT FOR THE CALIBRATION OF THE LOCI FOLATE (FOLA) AND LOCI VITAMIN B12 (VB12) ON THE DIMENSION EXL CLINICAL CHEMISTRY SYSTEMS WITH LOCI MODULE,DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE IBCT(DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE IBCT)-THE IBCT METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE TOTAL IRON BINDING CAPACITY IN HUMAN SERUM. , DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE PCHE(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE PCHE)-THE PCHE METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF PSEUDOCHOLINESTERASE ACTIVITY IN HUMAN SERUM AND HEPARINIZED PLASMA. PCHE MEASUREMENTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF CHOLINESTERASE

	INHIBITION DISORDERS,DIMENSION® CRP CALIBRATOR (DIMENSION® CRP CALIBRATOR)-THE DIMENSION C-REACTIVE PROTIEN CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT TO BE USED TO CALIBRATE THE DIMENSION CLINICAL CHEMISTRY STSTEM FOR THE C-REACTIVE PROTIEN (CRP METHOD).,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE UCFP (DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE UCFP)-THE UCFP METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN URINE AND CEREBROSPINAL FLUID,DIMENSION CLINICAL CHEMISTRY SYSTEM PALB CAL(DIMENSION CLINICAL CHEMISTRY SYSTEM PALB CAL)-THE PREALBUMIN CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED FOR THE CALIBRATOR OF THE PREALBUMIN METHOD ON THE DIMENSION CLINICAL CHEMISTRY SYSTEMS,DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE PBNP CALIBRATOR (DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE PBNP CALIBRATOR)-THE PBNP CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED TO CALIBRATE THE N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (PBNP CAT NO.RF423 AND LPBN CAT NO.RF523) METHODS FOR THE DIMENSION CLINICAL CHEMISTRY SYSTEMS WITH THE HETEROGENEOUS IMMUNOASSAY MODULE,DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENOUS IMMUNOASSAY MODULE FLEX REAGENT CARTRIDGE LMMB(DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENOUS IMMUNOASSAY MODULE FLEX REAGENT CARTRIDGE LMMB)-THE LMMB METHOD FOR DIMENSION® CLINICAL CHEMISTRY SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE THE MB ISOENZYME OF CREATINE KINASE (EC 2.7.3.2) IN HUMAN SERUM AND PLASMA FOR CONFIRMATION OF ACUTE MYOCARDIAL INFARCTION.,DIMENSION® EXLTM INTEGRATED CHEMISTRY SYSTEM LOCI MODULE FLEX REAGENT CARTRIDGE VB12(DIMENSION® EXLTM INTEGRATED CHEMISTRY SYSTEM LOCI MODULE FLEX REAGENT CARTRIDGE VB12) -THE VB12 METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF VITAMIN B12 (B12) IN HUMAN SERUM AND PLASMA ON THE DIMENSION® EXL™ WITH LM INTEGRATED CHEMISTRY SYSTEM. MEASUREMENTS OF VITAMIN B12 MAY BE USED IN THE DIAGNOSIS OF VITAMIN B12 DEFICIENCY.,EMIT® LSD CONTROL LEVEL 2(EMIT® LSD CONTROL LEVEL 2)-THE EMIT® LSD CONTROLS ARE INTENDED FOR USE IN VERIFYING THE CORRECT FUNCTIONING AND TO CONFIRM CALIBRATION OF THE EMIT® II LSD

	ASSAY,DIMENSION® EXLTM INTEGRATED CHEMISTRY SYSTEM LOCI MODULE FLEX REAGENT CARTRIDGE FOLA(DIMENSION® EXLTM INTEGRATED CHEMISTRY SYSTEM LOCI MODULE FLEX REAGENT CARTRIDGE FOLA)-THE FOLA METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF FOLATE IN HUMAN SERUM AND PLASMA ON THE DIMENSION® EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE. MEASUREMENTS OF FOLATE MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF FOLATE DEFICIENCY,DIMENSION VISTA SYSTEM DIMENSION EXL SYSTEM (MULTI 2 DIL) MULTI 2 SAMPLE DILUENT(DIMENSION VISTA SYSTEM DIMENSION EXL SYSTEM (MULTI 2 DIL) MULTI 2 SAMPLE DILUENT)-MULTI 2 SAMPLE DILUENT IS AN INVITRO DIAGNOSTIC PRODUCT USED TO DILUTE SAMPLES THAT EXCEED THE MEASURING RANGE OF SPECIFIC ASSAYS ON DIMENSIONS VISTA AND EXL INTEGRATED CHEMISTRY SYSTEMS WITH LOCI MODULE,DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX REAGENT CARTRIDGE PBNP(DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX REAGENT CARTRIDGE PBNP)-THE PBNP ASSAY USED ON THE DIMENSION CLINICAL CHEMISTRY SYSTEMS WITH THE HETEROGENEOUS IMMUNOASSAY MODULE IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM OR PLASMA,DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE MG(DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE MG)-THE MG METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM, HEPARINIZED PLASMA AND URINE,DIMENSION® HETEROGENOUS IMMUNOASSAY MODULE HCG CALIBRATOR(DIMENSION® HETEROGENOUS IMMUNOASSAY MODULE HCG CALIBRATOR)-THE HUMAN GONADOTROPIN CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED TO CALIBRATE THE HUMAN CHRONIC GONADOTROPIN METHODS FOR THE DIMENSION CLINICAL SYSTEM WITH THE HETEROGENOUS IMMUNOASSAY MODULE,DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT ALB(DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT ALB)-THE ALB METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM AND PLASMA , DIMENSION® EXLTM INTEGRATED CHEMISTRY SYSTEM LOCI MODULE FLEX REAGENT CARTRIDGE VITD(DIMENSION® EXLTM INTEGRATED CHEMISTRY SYSTEM LOCI MODULE FLEX REAGENT CARTRIDGE VITD)

	-THE LOCI VITAMIN D TOTAL ASSAY IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF TOTAL 25(OH)VITAMIN D IN HUMAN SERUM AND PLASMA ON THE DIMENSION® EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE. MEASUREMENTS OF VITAMIN D ARE USED IN THE ASSESSMENT OF VITAMIN D SUFFICIENCY.,DIMENSION CLINICAL CHEMISTRY SYSTEM CKI/MBI CAL(DIMENSION CLINICAL CHEMISTRY SYSTEM CKI/MBI CAL)-THE CKI/MBI CAL IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE CALIBRATOR OF THE CREATINE KINASE (CKI) AND CREATINE KINASE MB (MBI) METHODS ON THE DIMENSION CLINICAL CHEMISTRY SYSTEM,DIMENSION® CLINICAL CHEMISTRY SYSTEM TU CALIBRATOR(DIMENSION® CLINICAL CHEMISTRY SYSTEM TU CALIBRATOR)-THE THYRONINE UPTAKE CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT TO BE USED TO CALIBRATE THE DIMENSION CLINICAL CHEMISTRY SYSTEMS FOR THE THYRONINE UPTAKE (TU) METHOD,DIMENSION CLINICAL CHEMISTRY SYSTEM IBCT CALIBRATOR (DIMENSION CLINICAL CHEMISTRY SYSTEM IBCT CALIBRATOR)-THE IBCT CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT TO BE USED TO CALIBRATE THE TOTAL BINDING CAPACITY (IBCT) METHOD FOR THE DIMENSION CLINICAL CHEMISTRY SYSTEM , DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE T4(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE T4)-THE T4 METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE IN HUMAN SERUM AND PLASMA,EMIT TOX SALICYLIC ACID CALIBRATORS(EMIT TOX SALICYLIC ACID CALIBRATORS)-FOR CALIBRATION OF THE EMIT TOX SALICYLIC ACID ASSAY,DIMENSION® CLINICAL CHEMISTRY SYSTEM SIRO CAL(DIMENSION® CLINICAL CHEMISTRY SYSTEM SIRO CAL)-THE SIROLIMUS CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE CALIBRATION OF SIROLIMUS (SIRO) ON THE DIMENSION CLINICAL CHEMISTRY SYSTEMS,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE ETOH(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE ETOH)-THE ETOH METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF ETHYL ALCOHOL (ETHANOL) IN HUMAN SERUM, PLASMA, AND URINE ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM. ETHYL ALCOHOL TEST RESULTS MAY BE USED IN THE DIAGNOSIS AND MONITORING OF ETHYL ALCOHOL INTOXICATION AND POISONING. DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE RCRP(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE RCRP)-THE C-REACTIVE PROTEIN EXTENDED RANGE (RCRP) METHOD USED ON THE DIMENSION® CLINICAL

	CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF CRP IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN). MEASUREMENT OF C-REACTIVE PROTEIN IS USEFUL FOR THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY, INFLAMMATORY DISORDERS AND ASSOCIATED DISEASES. SUMMARY: C-REACTIVE PROTEIN IS ONE OF THE “ACUTE PHASE” PROTEINS, THE SERUM OR PLASMA LEVELS OF WHICH RISE DURING A GENERAL, UNSPECIFIC RESPONSE TO INFECTIONS AND NON-INFECTIOUS INFLAMMATORY PROCESSES SUCH AS RHEUMATOID ARTHRITIS, CARDIOVASCULAR DISEASE AND PERIPHERAL VASCULAR DISEASE. CRP IS SYNTHESIZED IN THE LIVER AND IS NORMALLY PRESENT AS A TRACE CONSTITUENT OF SERUM OR PLASMA. IN VARIOUS DISEASE STATES RESULTING IN TISSUE INJURY, INFECTION OR INFLAMMATION, CRP VALUES MAY RISE ABOVE NORMAL AFTER AN ACUTE EVENT.1 SINCE ELEVATED CRP VALUES ARE ALWAYS ASSOCIATED WITH PATHOLOGICAL CHANGES, THE CRP ASSAY PROVIDES USEFUL INFORMATION FOR THE DIAGNOSIS, THERAPY AND MONITORING OF INFLAMMATORY PROCESSES AND ASSOCIATED DISEASES.1,2 INCREASES IN CRP VALUES ARE NON-SPECIFIC AND SHOULD NOT BE INTERPRETED WITHOUT A COMPLETE CLINICAL HISTORY. WHEN USING CRP TO ASSESS RISK OF CARDIOVASCULAR AND PERIPHERAL VASCULAR DISEASE, MEASUREMENTS SHOULD BE COMPARED TO PREVIOUS VALUES. MEASUREMENT OF CRP BY HIGH SENSITIVITY ASSAYS MAY ADD TO THE PREDICTIVE VALUE OF OTHER MARKERS USED TO ASSESS THE RISK OF CARDIOVASCULAR AND PERIPHERAL VASCULAR DISEASE.,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE DGTX(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE DGTX)-THE DGTX METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO MEASURE DIGITOXIN, A CARDIOVASCULAR DRUG, IN HUMAN SERUM AND PLASMA. DGTX TEST RESULTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF DIGITOXIN OVERDOSE AND IN MONITORING LEVELS OF DIGITOXIN TO ENSURE APPROPRIATE THERAPY,DIMENSION® RCRP CALIBRATOR (DIMENSION® RCRP CALIBRATOR)-THE DIMENSION REVISED C-REACTIVE PROTEIN CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT TO BE USED TO CALIBRATE THE DIMENSION CLINICAL CHEMISTRY SYSTEM FOR THE C-REACTIVE PROTEIN EXTENDED RANGE (RCRP) METHOD.,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE ACTM(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE ACTM)-THE ACTM METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO MEASURE

	ACETAMINOPHEN, AN ANALGESIC AND ANTIPYRETIC, IN HUMAN SERUM AND PLASMA. ACTM TEST RESULTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF ACETAMINOPHEN OVERDOSE., DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE SAL(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE SAL)-THE SAL METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO MEASURE SALICYLATES, A CLASS OF ANALGESIC, ANTIPYRETIC AND ANTI-INFLAMMATORY DRUGS (INCLUDING ASPIRIN) IN HUMAN SERUM. SALICYLATE TEST RESULTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF SALICYLATE OVERDOSE AND FOR MONITORING SALICYLATE LEVELS DURING THERAPY.,DIMENSION® EXLTM LOCI® MODULE LOCI TNI CAL (DIMENSION® EXLTM LOCI® MODULE LOCI TNI CAL)-THE LOCI TNI CAL IS AN IN VITRO DIAGNOSTIC PRODUCT FOR CALIBRATION OF THE CARDIC TROPONIN(TNI) METHOD ON THE DIMENSION® EXL TM INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE., DIMENSION® PCHE VERIFIER(DIMENSION® PCHE VERIFIER)-THE DIMENSION PSEUDOCHOLINESTERASE VERIFIER IS AN IN VITRO DIAGNOSTIC PRODUCT TO BE USED TO VERIFY THE DIMENSION® CLINICAL CHEMISTRY SYSTEM FOR THE PSEUDOCHOLINESTE(PCHE) METHOD,DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX ® REAGENT CARTRIDGE THY CAL(DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX ® REAGENT CARTRIDGE THY CAL)-THE THYROID CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE CALIBRATION OF THE FREE THYROXINE (FT4) AND THYROID STIMULATING HORMONE (TSH) METHODS ON THE DIMENSION CLINICAL CHEMISTRY SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE,DIMENSION® SAL CALIBRATOR(DIMENSION® SAL CALIBRATOR)-THE SALICYLATE IS AN IN VITRO DIAGNOSTIC PRODUCT TO BE USED TO CALIBRATE THE DIMENSION CLINICAL CHEMISTRY SYSTEM FOR THE SALICYLATE (SAL) METHOD,DIMENSION CLINICAL CHEMISTRY FLEX REAGENT CARTRIDGE AMY (DIMENSION CLINICAL CHEMISTRY FLEX REAGENT CARTRIDGE AMY)-THE AMY METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF AMYLASE ACTIVITY IN HUMAN SERUM, PLASMA AND URINE ,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE SIRO (DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE SIRO)-THE SIRO METHOD IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE SIROLIMUS IN HUMAN WHOLE BLOOD ON THE DIMENSION CLINICAL CHEMISTRY

	SYSTEMS,DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE LDI(DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE LDI)-THE LACTATE DEHYDROGENASE (LDI) METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF TOTAL LACTATE DEHYDROGENASE IN HUMAN SERUM AND PLASMA ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM. ,DIMENSION® MPAT CALIBRATOR(DIMENSION® MPAT CALIBRATOR)-THE MPAT CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE MYCOPHENOLIC ACID (MPAT) METHOD ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM.,DIMENSION CLINICAL CHEMISTRY SYSTEM CSA CAL(DIMENSION CLINICAL CHEMISTRY SYSTEM CSA CAL)-THE CSA CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED TO CALIBRATE THE CYCLOSPORINE (CSA) METHOD FOR THE DIMENSION CLINICAL CHEMISTRY SYSTEMS., DIMENSION® CLINICAL CHEMISTRY SYSTEM T4 CALIBRATOR (DIMENSION® CLINICAL CHEMISTRY SYSTEM T4 CALIBRATOR)-THE DIMENSION THYROXINE CALIBRATOR IS AN IN-VITRO DIAGNOSTIC PRODUCT TO BE USED TO CALIBRATE THE DIMENSION CLINICAL CHEMISTRY SYSTEMS FOR THE THYROXINE (T4) METHOD.,DIMENSION ® EXL™ INTEGRATED CHEMISTRY SYSTEM LOCI ® MODULE FLEX ® REAGENT CARTRIDGE FT3(DIMENSION ® EXL™ INTEGRATED CHEMISTRY SYSTEM LOCI ® MODULE FLEX ® REAGENT CARTRIDGE FT3)-THE FT3 METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF FREE TRIIODOTHYRONINE IN HUMAN SERUM AND PLASMA ON THE DIMENSION® EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE. MEASUREMENTS OF FREE TRIIODOTHYRONINE ARE USED IN THE DIAGNOSIS AND MONITORING OF THYROID DISEASE,DIMENSION® CLINICAL CHEMISTRY SYSTEM UCFP CALIBRATOR(DIMENSION® CLINICAL CHEMISTRY SYSTEM UCFP CALIBRATOR)-THE URINARY/CEREBROSPINAL FLUID PROTEIN CALIBRATOR IS IN VITRO DIAGNOSTIC PRODUCT TO CALIBRATE THE DIMENSION CLINICAL CHEMISTRY SYSTEMS FOR THE URINARY/CEREBROSPINAL FLUID PROTEIN METHOD.,DIMENSION ® EXL™ INTEGRATED CHEMISTRY SYSTEM LOCI ® MODULE LOCI THYR CAL(DIMENSION ® EXL™ INTEGRATED CHEMISTRY SYSTEM LOCI ® MODULE LOCI THYR CAL)-THE LOCI THYR CAL IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE CALIBRATION OF THE LOCI FREE TRIIODOTHYRONINE (FT3), LOCI FREE THYROXINE (FT4L) AND LOCI THYROID STIMULATING HARMONE (TSHL) METHODS ON THE DIMENSION® EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE,DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX REAGENT CARTRIDGE LPBN(DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE

	FLEX REAGENT CARTRIDGE LPBN)-THE LPBN ASSAY USED ON THE DIMENSION CLINICAL CHEMISTRY SYSTEMS WITH THE HETEROGENEOUS IMMUNOASSAY MODULE IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM OR PLASMA.,DIMENSION CLINICAL CHEMISTRY SYSTEM CHEM III CALIBRATOR (DIMENSION CLINICAL CHEMISTRY SYSTEM CHEM III CALIBRATOR)-THE CHEM III CALIBRATOR AS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE CALIBRATOR OF AMMONIA (AMM),CARBON DIOXIDE (ECO2) AND ETHYL ALCOHOL (ETCH) ASSAYS ON THE DIMENSION CLINICAL CHEMISTRY SYSTEM , DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENOUS IMMUNOASSAY MODULE FLEX® REAGENT CATRIDGE LHCG (DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENOUS IMMUNOASSAY MODULE FLEX® REAGENT CATRIDGE LHCG)-THE LHCG METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE IS INTENDED TO QUANTITATIVELY MEASURE INTACT HUMAN CHORIONIC GONADOTROPIN IN HUMAN SERUM AND PLASMA FOR THE EARLY DETECTION OF PREGNANCY.,DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE TAC(DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE TAC)-THE TAC METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF TACROLIMUS IN HUMAN WHOLE BLOOD ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM. MEASUREMENTS OF TACROLIMUS ARE USED AS AN AID IN THE MANAGEMENT OF TACROLIMUS THERAPY IN RENAL AND HEPATIC TRANSPLANT PATIENTS.,DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENOUS IMMUNOASSAY MODULE FLEX® REAGENT CATRIDGE HCG(DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENOUS IMMUNOASSAY MODULE FLEX® REAGENT CATRIDGE HCG)-THE HCG METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE IS INTENDED TO QUANTITATIVELY MEASURE INTACT HUMAN CHORIONIC GONADOTROPIN IN HUMAN SERUM AND PLASMA FOR THE EARLY DETECTION OF PREGNANCY.,DIMENSION CLINICAL CHEMISTRY SYSTEM CSA FLEX REAGENT CARTRIDGE CSA (DIMENSION CLINICAL CHEMISTRY SYSTEM CSA FLEX REAGENT CARTRIDGE CSA)-THE CSA METHOD IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE CYCLOSPORINE A (CSA) IN HUMAN WHOLE BLOOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM. MEASUREMENTS OF CSA ARE USED AS AN AID IN THE MANAGEMENT OF HEART, LIVER AND KIDNEY TRANSPLANT PATIENTS ,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX®

	REAGENT CATRIDGE MPAT(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX® REAGENT CATRIDGE MPAT)-THE MPAT METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF MYCOPHENOLIC ACID (MPA) IN HUMAN EDTA PLASMA ON THE DIMENSIONR CLINICAL CHEMISTRY SYSTEM. MEASUREMENTS OF MPA ARE USED AS AN AID IN THE MANAGEMENT OF MYCOPHENOLIC ACID THERAPY IN RENAL, HEPATIC AND CARDIAC TRANSPLANT PATIENTS.,DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE ECO2(DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE ECO2)-THE ECO2 METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE TOTAL CARBON DIOXIDE IN HUMAN SERUM OR HEPARINIZED PLASMA ,DIMENSION® EXLTM INTEGRATED CHEMISTRY SYSTEM LOCI MODULE LOCI VITD CAL(DIMENSION® EXLTM INTEGRATED CHEMISTRY SYSTEM LOCI MODULE LOCI VITD CAL)-THE VITD CAL IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE CALIBRATION OF THE TOTAL VITAMIN D (VITD) METHOD ON THE DIMENSION EXL INTEGRATED CHEMISTRY SYSTEM WITH LOCI MODULE,DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE PALB(DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE PALB)-THE PALB METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF PREALBUMIN IN HUMAN SERUM AND PLASMA. PREALBUMIN LEVELS ARE USEFUL IN THE MONITORING OF NUTRITIONAL STATUS AND/OR NUTRITIONAL SUPPORT ,SYVA ® EMIT ® 2000 PHENOBARBITAL ASSAY(SYVA ® EMIT ® 2000 PHENOBARBITAL ASSAY)-THE EMIT® 2000 PHENOBARBITAL ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF PHENOBARBITAL IN HUMAN SERUM OR PLASMA. EMIT® 2000 ASSAYS ARE DESIGNED FOR USE WITH MOST CHEMISTRY ANALYZERS,DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE LA(DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE LA)-THE LA METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN ENZYMATIC IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE MEASUREMENT OF LACTIC ACID IN HUMAN PLASMA AND CEREBROSPINAL FLUID (CSF). LACTIC ACID TEST RESULTS MAY BE USED AS AN AID IN THE DIAGNOSIS AND TREATMENT OF LACTIC ACIDOSIS. ,SYVA ® EMIT® 2000 CARBAMAZEPINE ASSAY(SYVA ® EMIT® 2000 CARBAMAZEPINE ASSAY)-THE EMIT® 2000 CARBAMAZEPINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE

	QUANTITATIVE ANALYSIS OF CARBAMAZEPINE IN HUMAN SERUM OR PLASMA. EMIT® 2000 ASSAYS ARE DESIGNED FOR USE WITH MOST CHEMISTRY ANALYZERS.,DIMENSION CLINICAL CHEMISTRY SYSTEM CKI(DIMENSION CLINICAL CHEMISTRY SYSTEM CKI)-THE CKI METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF CREATINE KINASE IN HUMAN SERUM AND PLASMA ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM. , SYVA® EMIT ® TOX™ SERUM BARBITURATE ASSAY(SYVA® EMIT ® TOX™ SERUM BARBITURATE ASSAY)-THE EMIT® TOX™ SERUM BARBITURATE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSIS OF SPECIFIC BARBITURATES IN HUMAN SERUM OR PLASMA.,DIMENSION EXL™ INTEGRATED CHEMISTRY SYSTEM LOCI MODULE FLEX REAGENT CARTRIDGE FT4L (DIMENSION EXL™ INTEGRATED CHEMISTRY SYSTEM LOCI MODULE FLEX REAGENT CARTRIDGE FT4L)-THE FT4L METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF FREE THYROXINE IN HUMAN SERUM AND PLASMA ON THE DIMENSION® EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE. MEASUREMENTS OF FREE THYROXINE ARE USED IN THE DIAGNOSIS AND MONITORING OF THYROID DISEASE. ,SYVA® EMIT ® II PLUS ECSTASY(SYVA® EMIT ® II PLUS ECSTASY)-THE EMIT® II PLUS ECSTASY ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 300 NG/ML OR 500 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN LABORATORIES FOR THE QUALITATIVE AND/OR SEMIQUANTITATIVE ANALYSES OF ETHYLENEDIOXYMETHAMPHETAMINE (MDMA) AND CLOSELY RELATED DRUGS IN HUMAN URINE.,DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX REAGENT CARTRIDGE FT4(DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX REAGENT CARTRIDGE FT4)-THE FT4 METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE FREE THYROXINE (FT4) IN HUMAN SERUM AND HEPARINIZED PLASMA. ,SYVA® EMIT ® II PLUS COCAINE METABOLITE ASSAY(SYVA® EMIT ® II PLUS COCAINE METABOLITE ASSAY)-THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND EMIQUANTITATIVE ANALYSES OF BENZOYLECGONINE (COCAINE METABOLITE) IN HUMAN URINE.,EMIT TOX ACETAMINOPHEN CALIBRATORS(EMIT TOX ACETAMINOPHEN CALIBRATORS)-FOR CALIBRATION OF THE EMIT TOX ACETAMINOPHEN ASSAY,SYVA ® EMIT ® 2000 PHENYTOIN ASSAY(SYVA ® EMIT ® 2000 PHENYTOIN ASSAY)-THE EMIT® 2000 PHENYTOIN ASSAY IS A HOMOGENEOUS

	ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF PHENYTOIN IN HUMAN SERUM OR PLASMA. EMIT® 2000 ASSAYS ARE DESIGNED FOR USE WITH MOST CHEMISTRY ANALYZERS., EMIT® ETHYL ALCOHOL 100 MG/DL CALIBRATOR(EMIT® ETHYL ALCOHOL 100 MG/DL CALIBRATOR)-THE EMIT® ETHYL ALCOHOL CALIBRATORS AND CONTROLS ARE FOR USE WITH THE EMIT® ETHYL ALCOHOL ASSAYS.,SYVA ® EMIT ® 2000 N-ACETYLPROCAINAMIDE ASSAY(SYVA ® EMIT ® 2000 N-ACETYLPROCAINAMIDE ASSAY)-THE EMIT® 2000 N-ACETYLPROCAINAMIDE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF N-ACETYLPROCAINAMIDE IN HUMAN SERUM OR PLASMA. EMIT® 2000 ASSAYS ARE DESIGNED FOR USE WITH MOST CHEMISTRY ANALYZERS (SEE SECTION 6, PROCEDURE, INSTRUMENTS)., DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE SAMPLE DILUENT(DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE SAMPLE DILUENT)-THE SAMPLE DILUENTS IS AN IN VITRO DIAGNOSTIC PRODUCT FOR USE ON THE DIMENSION SYSTEMS WITH HETEROGENEOUS IMMUNOASSAY MODULE. SAMPLE DILUENT IS USED TO DILUTE ELEVATED SAMPLES FOR ANALYSIS. CONSULT FLEX REAGENT CATRIDGE INSTRUCTION FOR USE FOR MANUAL DILUTION PROCEDURE.,SYVA ® EMIT® 2000 DIGOXIN ASSAY(SYVA ® EMIT® 2000 DIGOXIN ASSAY)-THE EMIT® 2000 DIGOXIN ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF DIGOXIN IN HUMAN SERUM OR PLASMA. EMIT® 2000 ASSAYS ARE DESIGNED FOR USE WITH A VARIETY OF CHEMISTRY ANALYZERS.,DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX ® REAGENT CARTRIDGE TSH(DIMENSION CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX ® REAGENT CARTRIDGE TSH)-THE TSH METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE HUMAN THYROID STIMULATING HORMONE (TSH, THYROTROPIN) IN HUMAN SERUM AND PLASMA. , SYVA® EMIT® TOX™ SERUM CALIBRATORS(SYVA® EMIT® TOX™ SERUM CALIBRATORS)-THE EMIT® TOX™ SERUM CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT® TOX™ SERUM BARBITURATE AND BENZODIAZEPINE ASSAYS AS A REFERENCE FOR THE SEMIQUANTITATIVE ANALYSIS OF BARBITURATES AND BENZODIAZEPINES IN HUMAN SERUM.,EMIT® II PLUS SPECIALTY DRUG CALIBRATOR/CONTROL LEVEL 2(EMIT® II PLUS SPECIALTY DRUG CALIBRATOR/CONTROL LEVEL 2)-THE EMIT® II PLUS

	SPECIALTY DRUG CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS BUPRENORPHINE ASSAY. THESE PRODUCTS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED ON THE BUPRENORPHINE ASSAY CUTOFF.,SYVA® EMIT ® TOX™ SERUM TRICYCLIC ANTIDEPRESSANTS CALIBRATOR/CONTROLS(SYVA® EMIT ® TOX™ SERUM TRICYCLIC ANTIDEPRESSANTS CALIBRATOR/CONTROLS)-THE EMIT® TOX™ SERUM TRICYCLIC ANTIDEPRESSANTS CALIBRATOR/CONTROLS ARE INTENDED FOR USE WITH THE EMIT® TOX™ SERUM TRICYCLIC ANTIDEPRESSANTS ASSAY FOR THE QUALITATIVE ANALYSIS OF SPECIFIC TRICYCLIC ANTIDEPRESSANTS IN HUMAN SERUM OR PLASMA.,EMIT 2000 MYCOPHENOLIC ACID (MPA) CALIBRATOR(EMIT 2000 MYCOPHENOLIC ACID (MPA) CALIBRATOR)-THE EMIT® 2000 MYCOPHENOLIC ACID CALIBRATORS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE AS A REFERENCE IN MEASURING MYCOPHENOLIC ACID IN PLASMA USING THE EMIT® 2000 MYCOPHENOLIC ACID ASSAY. ,SYVA® EMIT® TOX™ SERUM BENZODIAZEPINE ASSAY (SYVA® EMIT® TOX™ SERUM BENZODIAZEPINE ASSAY)-THE EMIT® TOX™ SERUM BENZODIAZEPINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSIS OF SPECIFIC BENZODIAZEPINES IN HUMAN SERUM OR PLASMA.,EMIT ETHYL ALCOHOL HIGH CONTROL (EMIT ETHYL ALCOHOL HIGH CONTROL)-THE EMIT® ETHYL ALCOHOL CALIBRATORS AND CONTROLS ARE FOR USE WITH THE EMIT® ETHYL ALCOHOL ASSAYS.,SYVA® EMIT ® PRIMIDONE ASSAY(SYVA® EMIT ® PRIMIDONE ASSAY)-THE EMIT® PRIMIDONE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF PRIMIDONE IN HUMAN SERUM OR PLASMA.,DIMENSION® ACP VERIFIER(DIMENSION® ACP VERIFIER)-THE DIMENSION ACID PHOSPHATASE VERIFIER IS AN IN VITRO DIAGNOSTIC PRODUCT TO BE USED TO VERIFY THE DIMENSION CLINICAL CHEMISTRY SYSTEM FOR THE ACID PHOSPHATASE (ACP) METHOD.,SYVA® EMIT ® TOX™ SERUM TRICYCLIC ANTIDEPRESSANTS ASSAY(SYVA® EMIT ® TOX™ SERUM TRICYCLIC ANTIDEPRESSANTS ASSAY)-THE EMIT® TOX™ SERUM TRICYCLIC ANTIDEPRESSANTS ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUALITATIVE ANALYSIS OF SPECIFIC TRICYCLIC ANTIDEPRESSANTS IN HUMAN SERUM OR PLASMA.,EMIT® LSD 0 NG/ML CALIBRATOR(EMIT® LSD 0 NG/ML CALIBRATOR)-THE EMIT® LSD CALIBRATORS ARE FOR USE ONLY WITH THE EMIT® II LSD ASSAY.,SYVA® EMIT ® II PLUS BARBITURATE ASSAY(SYVA® EMIT ® II PLUS BARBITURATE ASSAY)-THE EMIT® II PLUS BARBITURATE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 200 NG/ML OR 300 NG/ML CUTOFF. THE

	ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF BARBITURATES IN HUMAN URINE. EMIT® II PLUS ASSAYS ARE DESIGNED FOR USE WITH A NUMBER OF CHEMISTRY ANALYZERS. THE EMIT® II PLUS BARBITURATE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.1 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE LI (DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE LI)-THE LI METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE LITHIUM IN HUMAN SERUM AND PLASMA (SODIUM HEPARIN). MEASUREMENTS OF LITHIUM ARE USED TO ASSURE THAT THE PROPER DRUG DOSAGE IS ADMINISTERED IN THE TREATMENT OF PATIENTS WITH MENTAL DISTURBANCES, SUCH AS MANIC-DEPRESSIVE ILLNESS (BIPOLAR DISORDER). ,SYVA® EMIT ® II PLUS BENZODIAZEPINE ASSAY(SYVA® EMIT ® II PLUS BENZODIAZEPINE ASSAY)-THE EMIT® II PLUS BENZODIAZEPINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 200 NG/ML OR 300 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF BENZODIAZEPINES IN HUMAN URINE. EMIT® II PLUS ASSAYS ARE DESIGNED FOR USE WITH A NUMBER OF CHEMISTRY ANALYZERS. THE EMIT® II PLUS BENZODIAZEPINE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.1 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE VALP(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE VALP)-THE VALP METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE MEASUREMENT OF VALPROIC ACID IN HUMAN SERUM OR PLASMA,

	SYVA® EMIT ® II PLUS AMPHETAMINES ASSAY(SYVA® EMIT ® II PLUS AMPHETAMINES ASSAY)-THE EMIT® II PLUS AMPHETAMINES ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 300 NG/ML, 500 NG/ML (SAMHSA INITIAL TEST CUTOFF LEVEL) OR 1000 NG/ML CUTOFF.1 THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF AMPHETAMINES IN HUMAN URINE. EMIT® II PLUS ASSAYS ARE DESIGNED FOR USE WITH A NUMBER OF CHEMISTRY ANALYZERS. THE EMIT® II PLUS AMPHETAMINES ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 300 NG/ML, 500 NG/ML (SAMHSA INITIAL TEST CUTOFF LEVEL) OR 1000 NG/ML CUTOFF.1 THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF AMPHETAMINES IN HUMAN URINE. EMIT® II PLUS ASSAYS ARE DESIGNED FOR USE WITH A NUMBER OF CHEMISTRY ANALYZERS.,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE PROC(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE PROC)-THE PROC METHOD IS USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF PROCAINAMIDE IN HUMAN SERUM OR PLASMA. PROCAINAMIDE MEASUREMENTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF PROCAINAMIDE OVERDOSE, AND IN THERAPEUTIC DRUG MONITORING,SYVA® EMIT ® II PLUS METHADONE ASSAY(SYVA® EMIT ® II PLUS METHADONE ASSAY)-THE EMIT® II PLUS METHADONE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 150 NG/ML OR 300 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF METHADONE IN HUMAN URINE. EMIT® II PLUS ASSAYS ARE DESIGNED FOR USE WITH A NUMBER OF CHEMISTRY ANALYZERS., DIMENSION VISTA SYSTEM DIMENSION EXL SYSTEM CTNI SDIL (DIMENSION VISTA SYSTEM DIMENSION EXL SYSTEM CTNI SDIL)-THE CTNI SAMPLE DILUENT IS AN IN-VITRO DIAGNOSTIC PRODUCT FOR THE DILUTION OF SAMPLES WITH ELEVATED CARDIAC TROPONIN I RESULTS PROCESSED ON THE DIMENSION VISTA SYSTEM AND DIMENSION EXL INTEGRATED CHEMISTRY SYSTEM WITH THE LOCI MODULE,SYVA® EMIT ® TOX™ SALICYLIC ACID ASSAY(SYVA® EMIT ® TOX™ SALICYLIC ACID ASSAY)-THE EMIT® TOX™ SALICYLIC ACID ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF SALICYLIC ACID IN HUMAN SERUM OR PLASMA.,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE LIDO(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE LIDO)-THE LIDO METHOD IS USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM FOR THE QUANTITATIVE DETERMINATION OF LIDOCAINE IN HUMAN SERUM OR

	PLASMA. LIDOCAINE MEASUREMENTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF LIDOCAINE OVERDOSE, AND IN THERAPEUTIC DRUG MONITORING.,SYVA® EMIT ® TOX™ ACETAMINOPHEN ASSAY(SYVA® EMIT ® TOX™ ACETAMINOPHEN ASSAY)-THE EMIT® TOX™ ACETAMINOPHEN ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE ANALYSIS OF ACETAMINOPHEN IN HUMAN SERUM OR PLASMA.,DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE C3 (DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE C3)-THE C3 METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE COMPLEMENT C3 (C3) IN HUMAN SERUM AS AN AID IN THE DIAGNOSIS OF IMMUNOLOGIC DISORDERS ASSOCIATED WITH COMPLEMENT C3 PROTEIN.,SYVA ® EMIT® 2000 VANCOMYCIN ASSAY(SYVA ® EMIT® 2000 VANCOMYCIN ASSAY)-THE EMIT® 2000 VANCOMYCIN ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF VANCOMYCIN IN HUMAN SERUM OR PLASMA. MEASUREMENTS OBTAINED BY THIS ASSAY ARE USED IN THE DIAGNOSIS AND TREATMENT OF VANCOMYCIN OVERDOSE AND IN MONITORING THE LEVEL OF VANCOMYCIN TO ENSURE APPROPRIATE THERAPY, DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE METH(DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE METH)-THE URINE METHADONE SCREEN FLEX® REAGENT CARTRIDGE USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM PROVIDES REAGENTS FOR AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF METHADONE IN HUMAN URINE. MEASUREMENTS OBTAINED WITH THE METH METHOD ARE USED TO DETECT METHADONE USE OR OVERDOSE, AND TO DETERMINE COMPLIANCE WITH METHADONE MAINTENANCE TREATMENT.,SYVA® EMIT ® II PLUS METHAQUALONE ASSAY(SYVA® EMIT ® II PLUS METHAQUALONE ASSAY)-THE EMIT® II PLUS METHAQUALONE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 300 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF METHAQUALONE IN HUMAN URINE.,DIMENSION CLINICAL CHEMISTRY SYSTEM TAC CALIBRATOR(DIMENSION CLINICAL CHEMISTRY SYSTEM TAC CALIBRATOR)-THE TAC CAL IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE CALIBRATION OF THE TACROMILUS (TAC) METHOD ON THE DIMENSION CLINICAL CHEMISTRY SYSTEM,SYVA ® EMIT ® 2000 THEOPHYLLINE ASSAY(SYVA ® EMIT ® 2000 THEOPHYLLINE ASSAY)-THE EMIT® 2000 THEOPHYLLINE ASSAY IS

	A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF THEOPHYLLINE IN HUMAN SERUM OR PLASMA. EMIT® 2000 ASSAYS ARE DESIGNED FOR USE WITH MOST CHEMISTRY ANALYZERS,DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENOUS IMMUNOASSAY MODULE T/F PSA CALIBRATOR(DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENOUS IMMUNOASSAY MODULE T/F PSA CALIBRATOR)-THE T/F PSA CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED TO CALIBRATE THE TOTAL(TPSA) AND FREE (FPSA) PROSTATE SPECIFIC ANTIGEN METHODS FOR THE DIMENSION CLINICAL CHEMISTRY SYSTEMS WITH THE HETEROGENEOUS IMMUNOASSAY MODULE,SYVA ® EMIT ® 2000 TOBRAMYCIN ASSAY (SYVA ® EMIT ® 2000 TOBRAMYCIN ASSAY)-THE EMIT ® 2000 TOBRAMYCIN ASSAY IS A HOMOGENOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF TOBRAMYCIN IN HUMAN SERUM OR PLASMA. EMIT ® 2000 TOBRAMYCIN ASSAY IS DESIGNED FOR USE ON A VARIETY OF CHEMISTRY ANALYSERS.,DIMENSION CLINICAL CHEMISTRY SYSTEM ENZ 1 CAL(DIMENSION CLINICAL CHEMISTRY SYSTEM ENZ 1 CAL)-FOR THE CALIBRATION OF LDI METHOD ON THE DIMENSION CLINICAL CHEMISTRY SYSTEM.,SYVA ® EMIT ® 2000 VALPROIC ACID ASSAY (SYVA ® EMIT ® 2000 VALPROIC ACID ASSAY)-THE EMIT® 2000 VALPROIC ACID ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE ANALYSIS OF VALPROIC ACID IN HUMAN SERUM OR PLASMA., DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE OPI(DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE OPI)-THE OPI FLEX® REAGENT CARTRIDGE USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM PROVIDES REAGENTS FOR AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF OPIATES IN HUMAN URINE USING A CUTOFF LEVEL OF 300 OR 2000 NG/ML. MEASUREMENTS OBTAINED WITH THE OPI METHOD ARE USED IN THE DIAGNOSIS AND TREATMENT OF OPIATES USE OR OVERDOSE.,SYVA® EMIT ® II PLUS PHENCYCLIDINE ASSAY(SYVA® EMIT ® II PLUS PHENCYCLIDINE ASSAY)-THE EMIT® II PLUS PHENCYCLIDINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 25 NG/ML CUTOFF (SAMHSA INITIAL TEST CUTOFF LEVEL).1 THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF PHENCYCLIDINE IN HUMAN URINE.,DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE TRNF(DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE TRNF)-THE TRNF METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN

	IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE TRANSFERRIN (TRNF) IN HUMAN SERUM AND HEPARINIZED PLASMA. ,SYVA ® EMIT ® 2000 TACROLIMUS ASSAY (SYVA ® EMIT ® 2000 TACROLIMUS ASSAY)-THE EMIT® 2000 TACROLIMUS ASSAY IS FOR IN VITRO QUANTITATIVE ANALYSIS OF TACROLIMUS AND METABOLITE IN HUMAN WHOLE BLOOD AS AN AID IN THE MANAGEMENT OF TACROLIMUS THERAPY IN LIVER AND KIDNEY TRANSPLANT PATIENTS.,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE ACP(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE ACP)-THE ACP METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF ACID PHOSPHATASE ACTIVITY OF PROSTATIC ORIGIN IN HUMAN SERUM AND PLASMA,SYVA® EMIT ® II PLUS OPIATE ASSAY(SYVA® EMIT ® II PLUS OPIATE ASSAY)-THE EMIT® II PLUS OPIATE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 300 NG/ML OR 2000 NG/ML CUTOFF (SAMHSA INITIAL TEST CUTOFF LEVEL).1 THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF OPIATES IN HUMAN URINE.,DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE IRON(DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE IRON)-THE IRON METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE IRON IN HUMAN SERUM AND PLASMA. IRON MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF DISEASES SUCH AS IRON DEFICIENCY ANEMIA AND OTHER DISORDERS OF IRON METABOLISM., SYVA ® EMIT ® 2000 CYCLOSPORINE SPECIFIC ASSAY(SYVA ® EMIT ® 2000 CYCLOSPORINE SPECIFIC ASSAY)-THE EMIT® 2000 CYCLOSPORINE SPECIFIC ASSAY IS FOR IN VITRO QUANTITATIVE ANALYSIS OF CYCLOSPORINE (CSA) IN HUMAN WHOLE BLOOD AS AN AID IN THE MANAGEMENT OF CYCLOSPORINE THERAPY IN KIDNEY, HEART AND LIVER TRANSPLANT PATIENTS.,DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE EXTC(DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE EXTC) -THE EXTC FLEX® REAGENT CARTRIDGE USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM PROVIDES REAGENTS FOR AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF METHYLENEDIOXYMETHAMPHETAMINE (MDMA) AND CLOSELY RELATED DRUGS IN HUMAN URINE USING A CUTOFF OF EITHER 300 OR 500 NG/ML. MEASUREMENTS OBTAINED WITH THE EXTC METHOD ARE USED IN THE DIAGNOSIS AND TREATMENT OF ECSTASY USE OR OVERDOSE.,SYVA ® EMIT ® 2000 QUINIDINE ASSAY(SYVA ® EMIT ®

	2000 QUINIDINE ASSAY)-THE EMIT® 2000 QUINIDINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF QUINIDINE IN HUMAN SERUM OR PLASMA. EMIT® 2000 ASSAYS ARE DESIGNED FOR USE WITH MOST CHEMISTRY ANALYZERS.,DIMENSION ® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX ® REAGENT CARTRIDGE MMB(DIMENSION ® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX ® REAGENT CARTRIDGE MMB)-THE MMB METHOD FOR DIMENSION® CLINICAL CHEMISTRY SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE THE MB ISOENZYME OF CREATINE KINASE (EC 2.7.3.2) IN HUMAN SERUM AND PLASMA FOR CONFIRMATION OF ACUTE MYOCARDIAL INFARCTION. ,SYVA® EMIT ® II PLUS PROPOXYPHENE ASSAY(SYVA® EMIT ® II PLUS PROPOXYPHENE ASSAY)-THE EMIT® II PLUS PROPOXYPHENE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 300 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF PROPOXYPHENE IN HUMAN URINE.,DIMENSION ® EXL™ INTEGRATED CHEMISTRY SYSTEM LOCI ® MODULE FLEX ® REAGENT CARTRIDGE LNTP(DIMENSION ® EXL™ INTEGRATED CHEMISTRY SYSTEM LOCI ® MODULE FLEX ® REAGENT CARTRIDGE LNTP)-THE LNTP METHOD IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE MEASUREMENT OF N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM AND PLASMA ON THE DIMENSION® EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE. IN INDIVIDUALS SUSPECTED OF HAVING CONGESTIVE HEART FAILURE (CHF), MEASUREMENTS OF NT-PROBNP ARE USED AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF SEVERITY. THE TEST IS FURTHER INDICATED FOR THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROME AND HEART FAILURE. ,SYVA ® EMIT® 2000 GENTAMICIN PLUS ASSAY(SYVA ® EMIT® 2000 GENTAMICIN PLUS ASSAY)-THE EMIT® 2000 GENTAMICIN PLUS ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF GENTAMICIN IN HUMAN SERUM OR PLASMA. EMIT® 2000 ASSAYS ARE DESIGNED FOR USE WITH MOST CHEMISTRY ANALYZERS, DIMENSION ® EXL™ INTEGRATED CHEMISTRY SYSTEM LOCI ® MODULE LOCI NTP CAL(DIMENSION ® EXL™ INTEGRATED CHEMISTRY SYSTEM LOCI ® MODULE LOCI NTP CAL)-THE NTP METHOD IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE MEASUREMENT OF N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM AND PLASMA ON THE DIMENSION EXL INTEGRATED CHEMISTRY SYSTEMS WITH LOCI MODULE,SYVA® EMIT ® II PLUS

	CANNABINOID ASSAY(SYVA® EMIT ® II PLUS CANNABINOID ASSAY)-THE EMIT® II PLUS CANNABINOID ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 20 NG/ML, 50 NG/ML (SAMHSA INITIAL TEST CUTOFF LEVEL),1 OR 100 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF CANNABINOIDS IN HUMAN URINE. EMIT® II PLUS ASSAYS ARE DESIGNED FOR USE WITH A NUMBER OF CHEMISTRY ANALYZERS.,DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE C4(DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE C4)-THE C4 METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE COMPLEMENT C4 (C4) IN HUMAN SERUM AS AN AID IN THE DIAGNOSIS OF IMMUNOLOGIC DISORDERS ASSOCIATED WITH COMPLEMENT C4 PROTEIN,SYVA® EMIT ® METHOTREXATE ASSAY (SYVA® EMIT ® METHOTREXATE ASSAY)-THE EMIT® METHOTREXATE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF METHOTREXATE IN HUMAN SERUM OR PLASMA.,DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE PCP (DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE PCP)-THE URINE PHENCYCLIDINE SCREEN FLEX® REAGENT CARTRIDGE USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM PROVIDES REAGENTS FOR AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF PHENCYCLIDINE IN HUMAN URINE. MEASUREMENTS OBTAINED WITH THE PCP METHOD ARE USED IN THE DIAGNOSIS AND TREATMENT OF PHENCYCLIDINE USE OR OVERDOSE.,SYVA ® EMIT ® 2000 PROCAINAMIDE ASSAY(SYVA ® EMIT ® 2000 PROCAINAMIDE ASSAY)-THE EMIT® 2000 PROCAINAMIDE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF PROCAINAMIDE IN HUMAN SERUM OR PLASMA. EMIT® 2000 ASSAYS ARE DESIGNED FOR USE WITH MOST CHEMISTRY ANALYZERS, DIMENSION ® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX ® REAGENT CARTRIDGE BARB (DIMENSION ® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE FLEX ® REAGENT CARTRIDGE BARB)-THE BARB METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM PROVIDES REAGENTS FOR AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF BARBITURATES IN HUMAN URINE. MEASUREMENTS OBTAINED WITH THE BARB METHOD ARE USED IN THE DIAGNOSIS AND TREATMENT OF BARBITURATES USE OR

	OVERDOSE.,DIMENSION® TRIGLYCERIDES FLEX® REAGENT CARTRIDGE(DIMENSION® TRIGLYCERIDES FLEX® REAGENT CARTRIDGE)-THE TGL METHOD USED ON THE DIMENSIONR CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA. MEASUREMENTS OBTAINED ARE USED IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH DIABETES MELLITUS, NEPHROSIS, LIVER OBSTRUCTION, OTHER DISEASES INVOLVING LIPID METABOLISM, OR VARIOUS ENDOCRINE DISORDERS ,DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE BENZ(DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE BENZ)-THE URINE BENZODIAZEPINES SCREEN FLEX® REAGENT CARTRIDGE USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM PROVIDES REAGENTS FOR AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF BENZODIAZEPINES IN HUMAN URINE. MEASUREMENTS OBTAINED WITH THE BENZ METHOD ARE USED IN THE DIAGNOSIS AND TREATMENT OF BENZODIAZEPINES USE OR OVERDOSE.,DIMESION® TOTAL PROTEIN/ALBUMIN CALIBRATOR(DIMESION® TOTAL PROTEIN/ALBUMIN CALIBRATOR)-THE TOTAL PROTEIN/ALBUMIN CALIBRATOR IS. IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USCD TO CALIBRATE THE DIMENSION® CLINICAL CHEMISTRY SYSTEM FOR THE TOTAL PROTEIN (TP) AND ALBUMIN (ALB) METHODS,DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE COC(DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE COC)-THE COC FLEX® REAGENT CARTRIDGE USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM PROVIDES REAGENTS FOR AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF BENZOYLECGONINE (COCAINE METABOLITE) IN HUMAN URINE USING A CUTOFF OF 150 OR 300 NG/ML. MEASUREMENTS OBTAINED WITH THE COC METHOD ARE USED IN THE DIAGNOSIS AND TREATMENT OF COCAINE USE OR OVERDOSE,DIMENSION® TOTAL PROTEIN FLEX® REAGENT CARTRIDGE(DIMENSION® TOTAL PROTEIN FLEX® REAGENT CARTRIDGE)-THE TP METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM AND HEPARINIZED PLASMA. MEASUREMENTS OF TOTAL PROTEIN ARE USED IN THE DIAGNOSIS AND TREATMENT OF A VARIETY OF DISEASES INVOLVING THE LIVER, KIDNEY OR BONE MARROW AS WELL AS METABOLIC OR NUTRITIONAL DISORDERS , DIMENSION ® HETEROGENEOUS IMMUNOASSAY MODULE IMT PROBE

	CLEANER(DIMENSION ® HETEROGENEOUS IMMUNOASSAY MODULE IMT PROBE CLEANER)-FOR USE ON THE DIMENSION CLINICAL CHEMISTRY SYSTEM WITH HETEROGENEOUS IMMUNOASSAY MODULE.,DIMENSION® UREA NITROGEN FLEX® REAGENT CARTRIDGE(DIMENSION® UREA NITROGEN FLEX® REAGENT CARTRIDGE)-THE BUN METHOD USED ON THE DIMENSIONR CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF UREA NITROGEN IN HUMAN SERUM, PLASMA AND URINE ,DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE THC(DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE THC)-THE THC FLEX® REAGENT CARTRIDGE USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM PROVIDES REAGENTS FOR AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF CANNABINOIDS IN HUMAN URINE. MEASUREMENTS OBTAINED WITH THE THC METHOD ARE USED IN THE DIAGNOSIS AND TREATMENT OF CANNABINOIDS USE OR OVERDOSE.,DIMENSION® TOTAL BILIRUBIN FLEX® REAGENT CARTRIDGE(DIMENSION® TOTAL BILIRUBIN FLEX® REAGENT CARTRIDGE)-THE TBI METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE TOTAL BILIRUBIN IN HUMAN SERUM AND PLASMA. MEASUREMENTS OF TOTAL BILIRUBIN ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIVER, HEMOLYTIC, HEMATOLOGICAL, AND METABOLIC DISORDERS, INCLUDING HEPATITIS AND GALLBLADDER DISEASE ,DIMENSION ® EXL™ INTEGRATED CHEMISTRY SYSTEM LOCI ® MODULE FLEX ® REAGENT CARTRIDGE NTP(DIMENSION ® EXL™ INTEGRATED CHEMISTRY SYSTEM LOCI ® MODULE FLEX ® REAGENT CARTRIDGE NTP)-THE NTP METHOD IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE MEASUREMENT OF N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM AND PLASMA ON THE DIMENSION® EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE. IN INDIVIDUALS SUSPECTED OF HAVING CONGESTIVE HEART FAILURE (CHF), MEASUREMENTS OF NT-PROBNP ARE USED AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF SEVERITY. THE TEST IS FURTHER INDICATED FOR THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROME AND HEART FAILURE ,DIMENSION® DIRECT BILIRUBIN FLEX® REAGENT CARTRIDGE(DIMENSION® DIRECT BILIRUBIN FLEX® REAGENT CARTRIDGE)-THE DBI METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE DIRECT (CONJUGATED) BILIRUBIN IN HUMAN SERUM AND PLASMA. MEASUREMENTS OF

	DIRECT BILIRUBIN ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIVER, HEMOLYTIC, HEMATOLOGICAL, AND METABOLIC DISORDERS, INCLUDING HEPATITIS AND GALL BLADDER DISEASE ,DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE VANC (DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE VANC)-THE VANC METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO MEASURE VANCOMYCIN, A GLYCOPEPTIDE ANTIBIOTIC IN HUMAN SERUM OR PLASMA. VANC TEST RESULTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF VANCOMYCIN OVERDOSE AND IN MONITORING LEVELS OF VANCOMYCIN TO ENSURE APPROPRIATE THERAPY.,DIMENSION® BILIRUBIN CALIBRATOR(DIMENSION® BILIRUBIN CALIBRATOR)-THE DIMENSION TBI/DBI CALIBRATOR IS AN VITRO DIAGNOSTIC PRODUCT TO THE CALIBRATION OF THE DIRECT BILIRUBIN (DBI) AND TOTAL BILIRUBIN (TBI) METHODSON THE DIMENSION CILINICAL CHEMISTRY SYSTEM.,QUIKLYTE® INTEGRATED MULTISENSORY DILUTION CHECK(QUIKLYTE® INTEGRATED MULTISENSORY DILUTION CHECK)-USED TO MONITOR AND ADJUST FOR THE DILUTION RATIO ON DIMENSION CLINICAL CHEMISTRY SYSTEM WITH THE QUICKLYKE MODULE. ,DIMENSION® ALKALINE PHOSPHATASE FLEX® REAGENT CARTRIDGE(DIMENSION® ALKALINE PHOSPHATASE FLEX® REAGENT CARTRIDGE)-THE ALPI METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF ALKALINE PHOSPHATASE IN HUMAN SERUM AND PLASMA ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM., DIMENSION ® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE REAGENT PROBE CLEANER(DIMENSION ® CLINICAL CHEMISTRY SYSTEM HETEROGENEOUS IMMUNOASSAY MODULE REAGENT PROBE CLEANER)-FOR USE THE DIMENSION CLINICAL CHEMISTRY SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE.,DIMENSION® ALKALINE PHOSPHATASE CALIBRATOR(DIMENSION® ALKALINE PHOSPHATASE CALIBRATOR)-ALPI CALIBRATOR IS AN IN-VITRO DIAGNOSTICS PRODUCT FOR CALIBRATION OF ALKALINE PHOSPHATSE METHOD ON THE DIMENSIONS CLINICAL CHEMISTRY SYSTEM,DIMENSION ® EXL™ INTEGRATED CHEMISTRY SYSTEM LOCI ® MODULE FLEX ® REAGENT CARTRIDGE TSHL(DIMENSION ® EXL™ INTEGRATED CHEMISTRY SYSTEM LOCI ® MODULE FLEX ® REAGENT CARTRIDGE TSHL)-THE TSHL METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF THYROID STIMULATING HORMONE (TSH, THYROTROPIN) IN HUMAN SERUM AND PLASMA ON THE DIMENSION® EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCI® MODULE. MEASUREMENTS OF TSH ARE USED IN THE DIAGNOSIS AND MONITORING OF THYROID DISEASE ,DIMENSION® CARDIOPHASE®

	HIGH SENSTIVITY C-REACTIVE PROTIEN CALIBRATOR (DIMENSION® CARDIOPHASE® HIGH SENSTIVITY C-REACTIVE PROTIEN CALIBRATOR)-THE DIMENSION CCRP CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED TO CALIBRATE THE DIMENSION-CARDIO PHASE® HIGH SENSITIVITY C-REACTIVE PROTEIN (CAT NO. RF434) METHODS FOR THE DIMENSION CLINICAL CHEMISTRY SYSTEMS WITH THE HETEROGENEOUS IMMUNOASSAY MODULE.,EMIT® 2000 MYCOPHENOLIC ACID (MPA) CONTROL(EMIT® 2000 MYCOPHENOLIC ACID (MPA) CONTROL)-THE EMIT® 2000 MYCOPHENOLIC ACID CONTROLS ARE INTENDED FOR USE WITH THE EMIT® 2000 MYCOPHENOLIC ACID ASSAY.,DIMENSION® ASPARTATE AMINOTRANSFERASE FLEX® REAGENT CARTRIDGE(DIMENSION® ASPARTATE AMINOTRANSFERASE FLEX® REAGENT CARTRIDGE)-THE AST METHOD USED ON THE DIMENSION CLINICAL CHEMISTRY SYSTEMS IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM OR PLASMA, DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE MBI(DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE MBI)-THE CREATINE KINASE MB (MBI) METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF CREATINE KINASE MB ISOENZYME ACTIVITY IN HUMAN SERUM AND PLASMA ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM.,DIMENSION® GLUCOSE FLEX® REAGENT CARTRIDGE(DIMENSION® GLUCOSE FLEX® REAGENT CARTRIDGE)-THE GLUC METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM, PLASMA, URINE, AND CEREBROSPINAL FLUID. ,DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE IGM (DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE IGM)-THE IGM METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM AND PLASMA.,DIMENSION® MICROALBUMIN FLEX® REAGENT CARTRIDGE(DIMENSION® MICROALBUMIN FLEX® REAGENT CARTRIDGE)-THE MALB METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE ALBUMIN IN HUMAN URINE ,DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE IGG(DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE IGG)-THE IGG METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE

	IMMUNOGLOBULIN G (IGG) IN HUMAN SERUM AND PLASMA. , DIMENSION® HEMOGLOBIN A1C KIT (DIMENSION® HEMOGLOBIN A1C KIT)-THE HB1C ASSAY ON THE DIMENSIONR CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN ANTICOAGULATED WHOLE BLOOD. MEASUREMENTS OF HEMOGLOBIN A1C ARE EFFECTIVE IN MONITORING LONG-TERM GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS , DIMENSION CLINICAL CHEMISTRY SYSTEM SALT BRIDGE SOLUTION (DIMENSION CLINICAL CHEMISTRY SYSTEM SALT BRIDGE SOLUTION)-USED IN THE REFERENCE ELECTRODE FOR THE MEASUREMENT OF NA+ / K+ / CL- ON THE DIMENSION CLINICAL CHEMISTRY SYSTEM., DIMENSION CHEMISTRY I CALIBRATOR(DIMENSION CHEMISTRY I CALIBRATOR)-THE DIMENSION-CHEMISTRY I CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT TO BE USED TO CALIBRATE DIMENSION CLINICAL CHEMISTRY SYSTEMS FOR THE CALCIUM (CA), CREATININE (CREA/CREA2), ENZYMATIC CREATININE (E2CR), GLUCOSE (GLU/GLUC), LACTIC ACID (LA), BLOOD UREA NITROGEN (BUN) AND URIC ACID (URCA) METHODS ,DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE IGA(DIMENSION ® CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE IGA)-THE IGA METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE IMMUNOGLOBULIN A (IGA) IN HUMAN SERUM AND PLASMA,DIMENSION® ENZYMATIC CREATININE FLEX® REAGENT CARTRIDGE(DIMENSION® ENZYMATIC CREATININE FLEX® REAGENT CARTRIDGE)-THE EZCR METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF CREATININE IN HUMAN SERUM, PLASMA, AND URINE ON THE DIMENSIONR CLINICAL CHEMISTRY SYSTEM. CREATININE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASES, IN MONITORING RENAL DIALYSIS, AND AS A CALCULATION BASIS FOR OTHER URINE ANALYTES ,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE CRBM(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE CRBM)-THE CRBM METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO MEASURE CARBAMAZEPINE, AN ANTI-CONVULSANT DRUG, IN HUMAN SERUM OR PLASMA. CRBM TEST RESULTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF CARBAMAZEPINE OVERDOSE AND IN MONITORING LEVELS OF CARBAMAZEPINE TO ENSURE APPROPRIATE THERAPY.,DIMENSION® AUTOMATED LDL FLEX® REAGENT CARTRIDGE(DIMENSION® AUTOMATED LDL FLEX® REAGENT CARTRIDGE)-THE ALDL METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO

	DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF LOW-DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN HUMAN SERUM AND PLASMA. LDL-C MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIPID DISORDERS SUCH AS DIABETES MELLITUS, ATHEROSCLEROSIS, AND VARIOUS LIVER AND RENAL DISEASES ,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE PTN(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE PTN)-THE PTN METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO MEASURE PHENYTOIN (DILANTIN, DIPHENYLHYDANTOIN), AN ANTI-EPILEPTIC DRUG, IN HUMAN SERUM AND PLASMA. PTN TEST RESULTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PHENYTOIN OVERDOSE AND IN MONITORING LEVELS OF PHENYTOIN TO ENSURE APPROPRIATE THERAPY. PHENYTOIN IS WIDELY USED AND EFFECTIVE FOR ALL TYPES OF SEIZURE DISORDERS EXCEPT ABSENCE SEIZURES.1 IT IS OF VALUE IN THE TREATMENT OF ELEMENTARY PARTIAL (FOCAL) OR COMPLEX PARTIAL EPILEPSY (PSYCHOMOTOR, TEMPORAL LOBE) SEIZURES, BUT INEFFECTIVE IN PETIT MAL EPILEPSY.2 OCCASIONALLY, IT IS USED IN THE TREATMENT OF CARDIAC ARRHYTHMIAS.1 BECAUSE OF CONSIDERABLE INTER-INDIVIDUAL VARIATION AND THE LIMITED CAPACITY FOR THE LIVER TO METABOLIZE PHENYTOIN, BLOOD CONCENTRATIONS SHOULD BE MONITORED TO OBTAIN MAXIMAL ANTI-SEIZURE EFFECT. ONCE METABOLISM IS SATURATED, SMALL DOSAGE CHANGES MAY RESULT IN DISPROPORTIONATE CHANGES IN BLOOD CONCENTRATION AND CAN CAUSE WIDE VARIATIONS IN DOSAGE REQUIREMENTS AMONG PATIENTS.,DIMENSION® AUTOMATED HDL CHOLESTEROL FLEX® REAGENT CARTRIDGE (DIMENSION® AUTOMATED HDL CHOLESTEROL FLEX® REAGENT CARTRIDGE)-THE AHDL METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF HIGH-DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) IN HUMAN SERUM AND PLASMA ON THE DIMENSIONR CLINICAL CHEMISTRY SYSTEM. MEASUREMENTS OF HDL-C ARE USED AS AN AID IN THE DIAGNOSIS OF LIPID DISORDERS (SUCH AS DIABETES MELLITUS), VARIOUS LIVER AND RENAL DISEASES AND IN THE ASSESSMENT OF RISK FOR ATHEROSCLEROSIS AND CARDIOVASCULAR DISEASE ,DIMENSION® HETEROGENOUS IMMUNOASSAY MODULE MMB CALIBRATOR (DIMENSION® HETEROGENOUS IMMUNOASSAY MODULE MMB CALIBRATOR)-THE MASS CREATINE KINASE MB LSOENZYME CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED TO CALILBRATE THE CREATINE KINASE MB LSOENZYME (MMB CAT. NO. RF 420 AND LMMB CAT. NO. RF520) METHOD FOR THE DIMENSION® CITNLCAL CHEMISTRY SYSTEM WITH THE

	HETEROGENEOUS IMMUNOASSAY MODULE .,STRATUS CS ACUTE CARE CCRP TESTPAK(STRATUS CS ACUTE CARE CCRP TESTPAK)-THE STRATUS® CS ACUTE CARE™ CARDIOPHASE® HIGH SENSITIVITY CRP METHOD (HSCRP) IS AN IN VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN LITHIUM AND SODIUM HEPARIN PLASMA. THIS METHOD IS FOR USE BY TRAINED HEALTH CARE PROFESSIONALS IN THE CLINICAL LABORATORY AND POINT OF CARE (POC) SETTINGS.,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE NAPA (DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE NAPA)-THE NAPA METHOD IS USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM FOR THE QUANTITATIVE DETERMINATION OF N-ACETYLPROCAINAMIDE IN HUMAN SERUM OR PLASMA. N-ACETYLPROCAINAMIDE MEASUREMENTS MAY BE USED IN THERAPEUTIC DRUG MONITORING TO MAINTAIN ADEQUATE PROCAINAMIDE THERAPY.,STRATUS CS ACUTE CARE HCG TESTPAK (STRATUS CS ACUTE CARE HCG TESTPAK)-THE STRATUS® CS ACUTE CARE™ BETA HUMAN CHORIONIC GONADOTROPIN METHOD (HCG) IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF THE TOTAL BETA SUBUNIT, VIS, BOTH THE INTACT HCG DIMER AND THE FREE SUBUNIT, OF THE HUMAN CHORIONIC GONADOTROPIN HORMONE IN HEPARINIZED PLASMA. HCG IS USED FOR THE EARLY DETECTION OF PREGNANCY. THIS METHOD IS FOR USE BY TRAINED HEALTH CARE PROFESSIONALS IN THE CLINICAL LABORATORY AND POINT OF CARE (POC) SETTINGS.,DIMENSION® DRUG CALIBRATOR(DIMENSION® DRUG CALIBRATOR)-THE DRUG CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT TO BE USED TO CALIBRATE HE DIGITOXIN (DGNA) ,LITHIUM(LI) ,PHENORBITOL (PHNO), PHENYTOIN(PIN), AND THEOPHYLLINE (THEO) METHODS ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM.,STRATUS CS ACUTE CARE HCG CALPAK(STRATUS CS ACUTE CARE HCG CALPAK)-THE STATUS® CS ACUTE CARE™ BETA HUMAN CHORIONIC GONADOTROPIN CALPAK CALIBRATOR (HCG CALPAK), CATALOG NO. CBHCG-C, IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED FOR CALIBRATION OF THE STRATUS CS ACUTE CARE HCG METHOD.,EMIT CALIBRATOR/CONTROL LEVEL I(EMIT CALIBRATOR/CONTROL LEVEL I)-EMIT CALIBRATOR/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT II PLUS AMPHETAMINES, BARBITURATE, CANNABINOIDS, BENZODIAZEPINE, COCAINE METABOLITE, ECSTASY, METHADONE, METHAQUALONE, MONOCLONAL AMPHETAMINE/METHAMPHETAMINE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE ASSAYS,STRATUS CS ACUTE CARE HCG DILPAK(STRATUS CS ACUTE CARE HCG DILPAK)-THE STRATUS® CS ACUTE CARE™ BETA HUMAN CHORIONIC

	GONADOTROPIN DILUTION PAK (HCG DILPAK), CATALOG NO. CBHCG-D, IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED IN CONJUNCTION WITH THE ACUTE CARE HCG TESTPAK, CATALOG NO. CBHCG, ON THE STRATUS CS ANALYZER FOR THE MEASUREMENT OF SAMPLES WITH ELEVATED HCG LEVELS.,EMIT® LSD 1.5 NG/ML CALIBRATOR(EMIT® LSD 1.5 NG/ML CALIBRATOR)-THE EMIT® LSD CALIBRATORS ARE FOR USE ONLY WITH THE EMIT® II LSD ASSAY.,STRATUS CS ACUTE CARE CARDIOPHASE HIGH SENSITIVITY C-REACTIVE PROTEIN CALPAK(STRATUS CS ACUTE CARE CARDIOPHASE HIGH SENSITIVITY C-REACTIVE PROTEIN CALPAK)-THE STRATUS® CS ACUTE CARE™ CARDIOPHASE® HIGH SENSITIVITY C-REACTIVE PROTEIN CALIBRATOR (CCRP CALPAK), CATALOG NO. CCCRP-C, IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED FOR CALIBRATION OF THE CCRP METHOD ON THE STRATUS CS ANALYZER.,DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENOUS IMMUNOASSAY MODULE FLEX REAGENT CARTRIDGE LTNI(DIMENSION® CLINICAL CHEMISTRY SYSTEM HETEROGENOUS IMMUNOASSAY MODULE FLEX REAGENT CARTRIDGE LTNI)-THE LTNI METHOD FOR THE DIMENSION® CLINICAL CHEMISTRY SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE CARDIAC TROPONIN-I LEVELS IN HUMAN SERUM AND HEPARINIZED PLASMA TO AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION AND IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES WITH RESPECT TO THEIR RELATIVE RISK OF MORTALITY.,STRATUS CS ACUTE CARE MYO DILPAK(STRATUS CS ACUTE CARE MYO DILPAK)-THE STRATUS® CS ACUTE CARE™ MYOGLOBIN DILUTION PAK (MYO DILPAK), CATALOG NO. CMYO-D, IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED IN CONJUNCTION WITH THE ACUTE CARE™ MYO TESTPAK, CATALOG NO. CMYO, FOR THE MEASUREMENT OF SAMPLES WITH ELEVATED LEVELS OF MYOGLOBIN.,EMIT® LSD 0.5 NG/ML CALIBRATOR(EMIT® LSD 0.5 NG/ML CALIBRATOR)-THE EMIT® LSD CALIBRATORS ARE FOR USE ONLY WITH THE EMIT® II LSD ASSAY., STRATUS CS ACUTE CARE MYOGLOBIN CALPAK(STRATUS CS ACUTE CARE MYOGLOBIN CALPAK)-THE STRATUS® CS ACUTE CARE™ MYOGLOBIN CALIBRATOR (MYO CALPAK), IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED FOR THE CALIBRATION OF THE STRATUS CS ACUTE CARE MYO METHOD., DIMENSION CLINICAL CHEMISTRY SYSTEM SPECIAL PROTEIN (CAL) CALIBRATOR(DIMENSION CLINICAL CHEMISTRY SYSTEM SPECIAL PROTEIN (CAL) CALIBRATOR)-THE SPECIAL PROTEIN CALIBRATOR IS USED TO CALIBRATE THE IGA, IGG, IGM,C3,C4, AND TRNF METHODS FOR THE DIMENSION CLINICAL CHEMISTRY SYSTEMS.,STRATUS CS

	ACUTE CARE PBNP DILPAK(STRATUS CS ACUTE CARE PBNP DILPAK)-THE STRATUS® CS ACUTE CARE™ NT-PROBNP DILUTION PAK (PBNP DILPAK), CATALOG NO. CPBNP-D, IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED IN CONJUNCTION WITH THE ACUTE CARE™ PBNP TESTPAK ON THE STRATUS® CS ANALYZER FOR THE MEASUREMENT OF SAMPLES WITH ELEVATED LEVELS OF NT-PROBNP.,DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE AMM(DIMENSION CLINICAL CHEMISTRY SYSTEM FLEX ® REAGENT CARTRIDGE AMM)-THE AMM METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF AMMONIA IN HUMAN PLASMA ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM. AMMONIA MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF SEVERE LIVER DISORDERS SUCH AS CIRRHOSIS, HEPATITIS AND REYE'S SYNDROME,STRATUS CS ACUTE CARE PBNP TESTPAK (STRATUS CS ACUTE CARE PBNP TESTPAK)-THE STRATUS® CS ACUTE CARE™ NT-PROBNP METHOD (PBNP) IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HEPARINIZED PLASMA. IN INDIVIDUALS SUSPECTED OF HAVING CONGESTIVE HEART FAILURE (CHF), MEASUREMENTS OF NT-PROBNP ARE USED AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF SEVERITY. THE TEST IS FURTHER INDICATED FOR THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROME AND HEART FAILURE. THIS METHOD IS FOR USE BY TRAINED HEALTH CARE PROFESSIONALS IN THE CLINICAL LABORATORY AND POINT OF CARE (POC) SETTINGS.,DIMENSION® EXL INTEGRATED CHEMISTRY SYSTEM LOCI® MODULE FLEX® REAGENT CATRIDGE TNI (DIMENSION® EXL INTEGRATED CHEMISTRY SYSTEM LOCI® MODULE FLEX® REAGENT CATRIDGE TNI)-THE TNI METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF CARDIAC TROPONIN I IN HUMAN SERUM AND PLASMA ON THE DIMENSIONR EXL™ INTEGRATED CHEMISTRY SYSTEM WITH LOCIR MODULE. MEASUREMENTS OF CARDIAC TROPONIN I ARE USED TO AID IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI) AND IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES WITH RESPECT TO THEIR RELATIVE RISK OF MORTALITY.,STRATUS CS ACUTE CARE CTNI TESTPAK(STRATUS CS ACUTE CARE CTNI TESTPAK)-THE STRATUS® CS ACUTE CARE™ TROPONIN I METHOD (CTNI) IS AN IN VITRO DIAGNOSTIC TEST FOR THE MEASUREMENT OF CARDIAC TROPONIN I IN HEPARINIZED PLASMA. CARDIAC TROPONIN I MEASUREMENTS CAN BE USED AS AN AID IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI). CARDIAC TROPONIN I CAN ALSO BE USED AS AN AID IN THE RISK

	STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES (ACS) WITH RESPECT TO THEIR RELATIVE RISK OF MORTALITY. THIS METHOD IS FOR USE BY TRAINED HEALTH CARE PROFESSIONALS IN THE CLINICAL LABORATORY AND POINT OF CARE (POC) SETTINGS.,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE PHNO(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE PHNO)-THE PHNO METHOD USED ON DIMENSION® CLINICAL CHEMISTRY SYSTEMS IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO MEASURE PHENOBARBITAL, AN ANTI-EPILEPTIC DRUG AND SEDATIVE-HYPNOTIC DRUG IN HUMAN SERUM AND PLASMA. PHNO TEST RESULTS ARE USED IN MONITORING LEVELS OF PHENOBARBITAL TO ENSURE APPROPRIATE THERAPY AND IN THE DIAGNOSIS AND TREATMENT OF PHENOBARBITAL OVERDOSE. PHENOBARBITAL IS PARTICULARLY USEFUL IN GRAND MAL AND FOCAL SEIZURES AND IN SEIZURES DUE TO WITHDRAWAL OF ALCOHOL OR BARBITURATES. PETIT MAL AND PSYCHOMOTOR SEIZURES DO NOT RESPOND TO THIS DRUG AND MAY BE WORSENED.1 BECAUSE OF CONSIDERABLE INTER-INDIVIDUAL VARIATION AND THE LIMITED CAPACITY FOR THE LIVER TO METABOLIZE PHENOBARBITAL, BLOOD CONCENTRATIONS SHOULD BE MONITORED TO OBTAIN MAXIMAL ANTI-SEIZURE EFFECT. ONCE METABOLISM IS SATURATED, SMALL DOSAGE CHANGES MAY RESULT IN DISPROPORTIONATE CHANGES IN BLOOD CONCENTRATION AND CAN CAUSE WIDE VARIATIONS IN DOSAGE REQUIREMENTS AMONG PATIENTS.,STRATUS CS ACUTE CARE CTNI CALPAK(STRATUS CS ACUTE CARE CTNI CALPAK)-THE STRATUS® CS ACUTE CARE™ TROPONIN I CALIBRATOR (CTNI CALPAK), CATALOG NO. CCTNI-CR, IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED FOR THE CALIBRATION OF THE STRATUS CS ACUTE CARE CTNI METHOD.,EMIT® LSD CONTROL LEVEL 1(EMIT® LSD CONTROL LEVEL 1)-THE EMIT® LSD CONTROLS ARE INTENDED FOR USE IN VERIFYING THE CORRECT FUNCTIONING AND TO CONFIRM CALIBRATION OF THE EMIT® II LSD ASSAY.,STRATUS CS ACUTE CARE CTNI DILPAK(STRATUS CS ACUTE CARE CTNI DILPAK)-THE STRATUS® CS ACUTE CARE™ CARDIAC TROPONIN I DILUTION PAK (CTNI DILPAK), CATALOG NO. CCTNI-D, IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED IN CONJUNCTION WITH THE ACUTE CARE CTNI TESTPAK, CATALOG NO. CCTNI, ON THE STRATUS CS ANALYZER FOR THE MEASUREMENT OF SAMPLES WITH ELEVATED LEVELS OF CARDIAC TROPONIN I..,SYVA ® EMIT® CAFFEINE CONTROL(SYVA ® EMIT® CAFFEINE CONTROL)-THE EMIT® CAFFEINE CONTROL IS INTENDED FOR USE IN VALIDATING INSTRUMENT AND EMIT ® CAFFEINE ASSAY PERFORMANCE,STRATUS CS ACUTE CARE PBNP CALPAK(STRATUS CS ACUTE CARE PBNP CALPAK)-THE

	STRATUS® CS ACUTE CARE™ NT-PROBNP CALIBRATOR (PBNP CALPAK), CATALOG NO. CPBNPM-C, IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED FOR CALIBRATION OF THE STRATUS® CS ACUTE CARE™ PBNP METHOD.,SYVA ® EMIT® II PLUS ETHYL ALCOHOL ASSAY(SYVA ® EMIT® II PLUS ETHYL ALCOHOL ASSAY)-THE EMIT® II PLUS ETHYL ALCOHOL ASSAY IS INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF ETHYL ALCOHOL (ETHANOL) IN HUMAN URINE, SERUM, OR PLASMA. THE EMIT® II PLUS ETHYL ALCOHOL ASSAY IS DESIGNED FOR USE WITH MOST CLINICAL CHEMISTRY ANALYZERS,STRATUS CS ACUTE CARE MYO TESTPAK(STRATUS CS ACUTE CARE MYO TESTPAK)-THE STRATUS® CS ACUTE CARE™ MYOGLOBIN (MYO) METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF MYOGLOBIN IN HEPARINIZED PLASMA. MYOGLOBIN MEASUREMENTS CAN BE USED AS AN AID IN DIAGNOSING MYOCARDIAL INFARCTION. THIS METHOD IS FOR USE BY TRAINED HEALTH CARE PROFESSIONALS IN THE CLINICAL LABORATORY AND POINT OF CARE (POC) SETTINGS.,SYVA ® EMIT® CAFFEINE ASSAY(SYVA ® EMIT® CAFFEINE ASSAY)-THE EMIT® CAFFEINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF CAFFEINE LEVELS IN HUMAN SERUM IN SUBJECTS UNDERGOING THERAPY WITH CAFFEINE, ESPECIALLY IN CASES OF NEONATAL APNEA.,STRATUS CS ACUTE CARE CKMB TESTPAK(STRATUS CS ACUTE CARE CKMB TESTPAK)-THE STRATUS® CS ACUTE CARE™ CKMB METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE MEASUREMENT OF THE MB ISOENZYME OF CREATINE KINASE (ATP: CREATINE N-PHOSPHOSTRANSFERASE, E. C. NO. 2.7.3.2) IN HEPARINIZED PLASMA. CKMB MEASUREMENTS CAN BE USED AS AN AID IN DIAGNOSING ACUTE MYOCARDIAL INFARCTION.1 THIS METHOD IS FOR USE BY TRAINED HEALTH CARE PROFESSIONALS IN THE CLINICAL LABORATORY AND POINT OF CARE (POC) SETTINGS.,SYVA ® EMIT® DISOPYRAMIDE ASSAY(SYVA ® EMIT® DISOPYRAMIDE ASSAY)-THE EMIT® DISOPYRAMIDE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF DISOPYRAMIDE IN HUMAN SERUM OR PLASMA.,STRATUS CS ACUTE CARE CKMB DILPAK(STRATUS CS ACUTE CARE CKMB DILPAK)-THE STRATUS® CS ACUTE CARE™ CKMB DILUTION PAK (CKMB DILPAK), CATALOG NO. CCKMB-D, IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED IN CONJUNCTION WITH THE ACUTE CARE™ CKMB TESTPAK, CATALOG NO. CCKMB, ON THE STRATUS® CS ANALYZER FOR THE MEASUREMENT OF SAMPLES WITH ELEVATED LEVELS OF CKMB,SYVA ® EMIT® CALIBRATOR/CONTROL LEVEL 0(SYVA ® EMIT® CALIBRATOR/CONTROL LEVEL 0)-THE EMIT®

	CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS AMPHETAMINES, BARBITURATE, BENZODIAZEPINE, CANNABINOID, COCAINE METABOLITE, ECSTASY, METHADONE, METHAQUALONE, MONOCLONAL AMPHETAMINE/METHAMPHETAMINE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE ASSAYS. THESE STANDARDS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED UPON SPECIFIED ASSAY CUTOFF LEVELS FOR THE EMIT® II PLUS DRUGS-OF-ABUSE ASSAYS., STRATUS CS ACUTE CARE CKMB CALPAK(STRATUS CS ACUTE CARE CKMB CALPAK)-THE STRATUS® CS ACUTE CARE™ CKMB CALIBRATOR (CKMB CALPAK), CATALOG NO. CCKMB-C, IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED FOR THE CALIBRATION OF THE STRATUS CS ACUTE CARE CKMB METHOD., SYVA ® EMIT® AMIKACIN ASSAY(SYVA ® EMIT® AMIKACIN ASSAY)-THE EMIT® AMIKACIN ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF AMIKACIN IN HUMAN SERUM OR PLASMA,STRATUS CS ACUTE CARE DDMR TESTPAK(STRATUS CS ACUTE CARE DDMR TESTPAK)-THE STRATUS® CS ACUTE CARE™ D-DIMER ASSAY (DDMR) IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF CROSS-LINKED FIBRIN DEGRADATION PRODUCTS (D-DIMER) IN HUMAN CITRATED OR HEPARINIZED PLASMA ON THE STRATUS CS ANALYZER. THE STRATUS CS ACUTE CARE DDMR ASSAY IS INTENDED FOR USE IN CONJUNCTION WITH A NON-HIGH CLINICAL PRETEST PROBABILITY (PTP) ASSESSMENT MODEL TO EXCLUDE PULMONARY EMBOLISM (PE) DISEASE AND AS AN AID IN THE DIAGNOSIS OF VENOUS THROMBOEMBOLISM VTE) [DEEP VEIN THROMBOSIS (DVT) OR PULMONARY EMBOLISM (PE)]. THIS ASSAY IS FOR USE BY TRAINED HEALTH CARE PROFESSIONALS IN THE CLINICAL LABORATORY AND POINT OF CARE (POC) SETTINGS..,SYVA ® EMIT® LIDOCAINE ASSAY(SYVA ® EMIT® LIDOCAINE ASSAY)-THE EMIT® LIDOCAINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF LIDOCAINE IN HUMAN SERUM OR PLASMA.,ACUTE CARE D-DIMER CALPAK(ACUTE CARE D-DIMER CALPAK)-THE STRATUS® CS ACUTE CARE™ D-DIMER CALIBRATOR (DDMR CALPAK), CATALOG NO. CDDMR-C, IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED FOR THE CALIBRATION OF THE STRATUS® CS ACUTE CARE™ D-DIMER (DDMR) METHOD.,SYVA ® EMIT® ETHOSUXIMIDE ASSAY(SYVA ® EMIT® ETHOSUXIMIDE ASSAY)-THE EMIT® ETHOSUXIMIDE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF ETHOSUXIMIDE IN HUMAN SERUM OR PLASMA.,STRATUS CS ACUTE CARE DDMR DILPAK(STRATUS CS ACUTE CARE DDMR DILPAK)-THE STRATUS® CS ACUTE CARE™ D-

	DIMER DILUTION PAK (DDMR DILPAK), CATALOG NO. CDDMR-D, IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED IN CONJUNCTION WITH THE ACUTE CARE™ DDMR TESTPAK FOR THE MEASUREMENT OF SAMPLES WITH ELEVATED LEVELS OF D-DIMER., SYVA ® EMIT® 2000 SIRO/ TACRO PRETREATMENT REAGENT(SYVA ® EMIT® 2000 SIRO/ TACRO PRETREATMENT REAGENT)-THE EMIT® 2000 SIRO/TACRO SAMPLE PRETREATMENT REAGENT IS AN ACCESSORY REAGENT FOR USE WITH THE EMIT® 2000 SIROLIMUS ASSAY AND/OR THE EMIT® 2000 TACROLIMUS ASSAY.,DIMENSION AHDL CALIBRATOR (DIMENSION AHDL CALIBRATOR)-TO CALIBRATE THE AUTOMATED HDL METHOD FOR THE DIMENSION CLINICAL CHEMISTRY SYSTEMS ,SYVA ® EMIT® 2000 MYCOPHENOLIC ACID ASSAY(SYVA ® EMIT® 2000 MYCOPHENOLIC ACID ASSAY)-THE EMIT® 2000 MYCOPHENOLIC ACID ASSAY IS FOR IN VITRO QUANTITATIVE ANALYSIS OF MYCOPHENOLIC ACID IN HUMAN PLASMA AS AN AID IN THE MANAGEMENT OF MYCOPHENOLATE MOFETIL THERAPY IN TRANSPLANT PATIENTS,DIMENSION ALDL CALIBRATOR(DIMENSION ALDL CALIBRATOR)-THE ALDI CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED TO CALIBRATE THE AUTOMATED LDL (ALDL) METHODS FOR THE DIMENSION CLINICAL CHEMISTRY SYSTEMS. ,SYVA ® EMIT® ANTIEPILEPTIC DRUG CALIBRATOR SET(SYVA ® EMIT® ANTIEPILEPTIC DRUG CALIBRATOR SET)-THE EMIT® ANTIEPILEPTIC DRUG CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT® ANTIEPILEPTIC DRUG ASSAYS AS A REFERENCE IN MEASURING ETHOSUXIMIDE AND PRIMIDONE CONCENTRATIONS IN HUMAN SERUM OR PLASMA.,DIMENSION® CREATININE FLEX® REAGENT CARTRIDGE(DIMENSION® CREATININE FLEX® REAGENT CARTRIDGE) -THE CRE2 METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF CREATININE IN HUMAN SERUM, PLASMA, AND URINE ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM. CREATININE MEASURING OTHER MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CERTAIN RENAL DISEASE, IN MONITORING RENAL DIALYSIS, AND AS A CALCULATION BASIS FOR URINE ANALYTES ,SYVA ® EMIT® II LSD ASSAY (30ML/15ML)(SYVA ® EMIT® II LSD ASSAY (30ML/15ML))-THE EMIT® II LSD ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 0.5 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF LYSERGIC ACID DIETHYLAMIDE (LSD) IN HUMAN URINE,DIMENSION® CARDIOPHASE® HIGH SENSITIVITY CRP FLEX® REAGENT CARTRIDGE (DIMENSION® CARDIOPHASE® HIGH SENSITIVITY CRP FLEX® REAGENT CARTRIDGE)-THE DIMENSIONR CARDIOPHASER HIGH SENSITIVITY C-REACTIVE PROTEIN (CCRP) METHOD FOR THE

	DIMENSIONR CLINICAL CHEMISTRY SYSTEM WITH THE HETEROGENEOUS IMMUNOASSAY MODULE IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO QUANTITATIVELY MEASURE C-REACTIVE PROTEIN LEVELS IN HUMAN SERUM AND HEPARINIZED PLASMA ,SYVA ® EMIT® II PLUS 6-ACETYLMORPHINE ASSAY(SYVA ® EMIT® II PLUS 6-ACETYLMORPHINE ASSAY)-THE EMIT® II PLUS 6-ACETYLMORPHINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 10 NG/ML CUTOFF.1 THE ASSAY IS INTENDED FOR USE IN LABORATORIES FOR THE QUALITATIVE AND/OR SEMIQUANTITATIVE ANALYSES OF 6-ACETYLMORPHINE (6-AM), A HEROIN METABOLITE, IN HUMAN URINE. EMIT® II PLUS ASSAYS ARE DESIGNED FOR USE WITH A NUMBER OF CHEMISTRY ANALYZERS. SEMIQUANTITATIVE TEST RESULTS MAY BE USED TO ASSESS ASSAY PERFORMANCE AS PART OF A QUALITY CONTROL PROGRAM AND TO ESTIMATE A DILUTION OF THE SPECIMEN FOR CONFIRMATION BY GC/MS.,DIMESION® CHOLESTEROL CALIBRATOR(DIMESION® CHOLESTEROL CALIBRATOR)-THE DIMENSION® CHOLESTEROL CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT TO BE USED TO CALIBRATE TH DIMENSION® CLINICAL CHEMISTRY SYSTEM FOR THE CHOLESTEROL (CHOL) METHOD. ,SYVA ® EMIT® II PLUS BUPRENORPHINE ASSAY(SYVA ® EMIT® II PLUS BUPRENORPHINE ASSAY)-THE EMIT® II PLUS BUPRENORPHINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 5 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN LABORATORIES FOR THE QUALITATIVE AND/OR SEMIQUANTITATIVE ANALYSES OF BUPRENORPHINE IN HUMAN URINE. EMIT® II PLUS ASSAYS ARE DESIGNED FOR USE WITH A NUMBER OF CHEMISTRY ANALYZERS. THE SEMIQUANTITATIVE MODE IS FOR THE PURPOSE OF ENABLING LABORATORIES TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS LIQUID CHROMATOGRAPHY/ MASS SPECTROMETRY (LC/MS) OR PERMITTING LABORATORIES TO ESTABLISH QUALITY CONTROL PROCEDURES,DIMENSION® MICROALBUMIN CALIBRATOR (DIMENSION® MICROALBUMIN CALIBRATOR)-THE MALB CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE CALIBRATION OF THE MICRO ALBUMIN METHOD ON THE DIMENSION CLINICAL CHEMISTRY SYSTEMS ,EMIT® 2000 N-ACETYLPROCAINAMIDE CALIBRATORS(EMIT® 2000 N-ACETYLPROCAINAMIDE CALIBRATORS)-THE EMIT® 2000 N-ACETYLPROCAINAMIDE CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT® 2000 N-ACETYLPROCAINAMIDE ASSAY.,DIMENSION® URIC ACID FLEX® REAGENT CARTRIDGE (DIMENSION® URIC ACID FLEX® REAGENT CARTRIDGE)-THE URCA METHOD USED ON THE DIMENSION CLINICAL CHEMISTRY SYSTEMS IS AN IN VITRO

	DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA AND URINE,DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE THEO(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE THEO)-THE THEO METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF THEOPHYLLINE IN HUMAN SERUM AND PLASMA, DIMENSION® ENZYME VERIFIER(DIMENSION® ENZYME VERIFIER)-ENZYME VERIFIER IS A DIAGNOSTIC PRODUCT FOR THE VERIFICATION OF ALKALINE PHOSPHATASE (ALP), AMYLASE (AMY), G-GLUTAMYL TRANSFERASE (GGT), ASPARTATE AMINOTRANSFERASE (AST), ALANINE AMINOTRANSFERASE (ALT) METHODS ON THE DIMENSION CLINICAL CHEMISTRY SYSTEMS., DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE DGNA(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE DGNA)-THE DGNA METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO MEASURE DIGOXIN, A CARDIOVASCULAR DRUG, IN HUMAN SERUM AND PLASMA. DGNA TEST RESULTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF DIGOXIN OVERDOSE AND IN MONITORING LEVELS OF DIGOXIN TO ENSURE APPROPRIATE THERAPY,DIMENSION® ENZYME DILUENT (DIMENSION® ENZYME DILUENT)-ENZYME DILUENT IS A BOVINE ALBUMIN BASE IN VITRO DIAGNOSTIC PRODUCT. IT IS INTENDED TO BE USED AS A DILUENT FOR PATIENT SERA WITH ELEVATED ENZYME ACTIVITY WHICH IS ASSAYED ON THE DIMENSION CLINICAL CHEMISTRY SYSTEMS.,EMIT 2000 QUINIDINE CALIBRATORS(EMIT 2000 QUINIDINE CALIBRATORS)-FOR CALIBRATING EMIT 2000 QUINIDINE ASSAY,DIMENSION® ALANINE AMINOTRANSFERASE FLEX® REAGENT CARTRIDGE(DIMENSION® ALANINE AMINOTRANSFERASE FLEX® REAGENT CARTRIDGE)-THE ALANINE AMINOTRANSFERASE (ALTI) METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF ALANINE AMINOTRANSFERASE ACTIVITY IN HUMAN SERUM OR PLASMA ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM. MEASUREMENTS OF ALANINE AMINOTRANSFERASE ARE USED IN THE DIAGNOSIS AND TREATMENT OF CERTAIN LIVER DISEASES AND HEART DISEASES , EMIT 2000 THEOPHYLLINE CALIBRATORS(EMIT 2000 THEOPHYLLINE CALIBRATORS)-FOR CALIBRATING EMIT 2000 THEOPHYLLINE ASSAY,DIMENSION® Y-GLUTAMYL TRANSFERASE FLEX® REAGENT CARTRIDGE(DIMENSION® Y-GLUTAMYL TRANSFERASE FLEX® REAGENT CARTRIDGE)-THE GGT METHOD USED ON THE DIMENSION CLINICAL CHEMISTRY SYSTEMS IS AN IN

	VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF -GLUTAMYL TRANSFERASE ACTIVITY IN HUMAN SERUM AND PLASMA.,EMIT 2000 VALPROIC ACID CALIBRATORS(EMIT 2000 VALPROIC ACID CALIBRATORS)-FOR CALIBRATING EMIT 2000 VALPROIC ACID ASSAY,DIMENSION® CHOLESTEROL FLEX® REAGENT CARTRIDGE(DIMENSION® CHOLESTEROL FLEX® REAGENT CARTRIDGE)-THE CHOL METHOD USED ON THE DIMENSIONR CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL IN HUMAN SERUM AND PLASMA ,EMIT 2000 VANCOMYCIN CALIBRATORS(EMIT 2000 VANCOMYCIN CALIBRATORS)-FOR CALIBRATING EMIT 2000 VANCOMYCIN ASSAY,DIMENSION® ENZYME II CALIBRATOR (DIMENSION® ENZYME II CALIBRATOR)-THE ENZYME II CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE CALIBRATION OF ALANINC AMINOTRANSFERASE (ALTI), ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM,EMIT 2000 TACROLIMUS CALIBRATORS(EMIT 2000 TACROLIMUS CALIBRATORS)-THE EMIT® 2000 TACROLIMUS CALIBRATORS ARE INTENDED FOR USE AS A REFERENCE IN MEASURING TACROLIMUS IN HUMAN WHOLE BLOOD USING THE EMIT® 2000 TACROLIMUS ASSAY.,DIMENSION® CALCIUM FLEX® REAGENT CARTRIDGE(DIMENSION® CALCIUM FLEX® REAGENT CARTRIDGE)-THE CA METHOD USED ON THE DIMENSION CLINICAL CHEMISTRY SYSTEMS IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA AND URINE.,EMIT 2000 DIGOXIN CALIBRATORS(EMIT 2000 DIGOXIN CALIBRATORS)-FOR CALIBRATING EMIT 2000 DIGOXIN ASSAY,DIMENSION® LIPASE CALIBRATOR(DIMENSION® LIPASE CALIBRATOR)-THE LIPL CALIBRATOR IS AN IN VITRO DIAGNOSTIC PRODUCT TO BE USED TO CALIBRATE LIPASE (LIPL) METHOD FOR THE DIMENSION CLINICAL CHEMISTRY SYSTEMS. THIS PRODUCT WAS DESIGNED TO MEET THE NEEDS OF USERS TO ASSURE ACCURATE RESULTS OVER THE ASSAY RANGE OF THE METHOD.,EMIT II PLUS 6-AM/ECSTASY CALIBRATOR/CONTROL LEVEL 3(EMIT II PLUS 6-AM/ECSTASY CALIBRATOR/CONTROL LEVEL 3)-WHEN USED AS CALIBRATORS, THE MATERIALS ARE FOR THE CALIBRATION OF THE EMIT® II PLUS 6-ACETYLMORPHINE AND EMIT® II PLUS ECSTASY ASSAYS. WHEN USED AS CONTROLS, THE MATERIALS MAY BE USED AS QUALITY CONTROL MATERIALS BASED ON THE SPECIFIC EMIT® II PLUS 6-ACETYLMORPHINE AND EMIT® II PLUS ECSTASY ASSAY CUTOFFS, DIMENSION® LIPASE FLEX® REAGENT CARTRIDGE(DIMENSION® LIPASE FLEX® REAGENT CARTRIDGE)-THE LIPL METHOD IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF

	LIPASE IN HUMAN SERUM AND PLASMA ON THE DIMENSION CLINICAL CHEMISTRY SYSTEMS,EMIT 2000 SIROLIMUS CALIBRATOR(EMIT 2000 SIROLIMUS CALIBRATOR)-THE EMIT® 2000 SIROLIMUS CALIBRATORS ARE INTENDED FOR USE IN THE CALIBRATION OF THE EMIT® 2000 SIROLIMUS ASSAY. ,EMIT CYCLOSPORINE SAMPLE PRETREATMENT REAGENT(EMIT CYCLOSPORINE SAMPLE PRETREATMENT REAGENT)-THE EMIT® CYCLOSPORINE SAMPLE PRETREATMENT REAGENT (CSPR) IS FOR IN VITRO DIAGNOSTIC USE AS AN ALTERNATIVE TO METHANOLIC EXTRACTION OF SAMPLES FOR USE WITH THE EMIT® 2000 CYCLOSPORINE SPECIFIC ASSAY , DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE GENT(DIMENSION® CLINICAL CHEMISTRY SYSTEM FLEX REAGENT CARTRIDGE GENT)-THE GENT METHOD USED ON THE DIMENSION® CLINICAL CHEMISTRY SYSTEM IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO MEASURE GENTAMICIN, AN AMINOGLYCOSIDE ANTIBIOTIC IN HUMAN SERUM OR PLASMA. GENT TEST RESULTS MAY BE USED IN THE DIAGNOSIS AND TREATMENT OF GENTAMICIN OVERDOSE AND IN MONITORING LEVELS OF GENTAMICIN TO ENSURE APPROPRIATE THERAPY.,EMIT 2000 CYCLOSPORINE SPECIFIC NEGATIVE CAL(EMIT 2000 CYCLOSPORINE SPECIFIC NEGATIVE CAL)-THE EMIT® 2000 CYCLOSPORINE SPECIFIC CALIBRATORS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE AS A REFERENCE IN MEASURING CYCLOSPORINE (CSA) IN HUMAN WHOLE BLOOD.,EMIT 2000 PHENYTOIN CALIBRATORS(EMIT 2000 PHENYTOIN CALIBRATORS)-FOR CALIBRATING EMIT 2000 PHENYTOIN ASSAY,THE EMIT® 2000 TOBRAMYCIN CALIBRATORS (THE EMIT® 2000 TOBRAMYCIN CALIBRATORS)-THE EMIT® 2000 TOBRAMYCIN CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT ® 2000 TOBRAMYCIN ASSAY.,EMIT ETHYL ALCOHOL NEGATIVE CALIBRATOR(EMIT ETHYL ALCOHOL NEGATIVE CALIBRATOR)-THE EMIT® ETHYL ALCOHOL CALIBRATORS AND CONTROLS ARE FOR USE WITH THE EMIT® ETHYL ALCOHOL ASSAYS,EMIT 2000 CYCLOSPORINE SPECIFIC CALIBRATOR(EMIT 2000 CYCLOSPORINE SPECIFIC CALIBRATOR)-THE EMIT® 2000 CYCLOSPORINE SPECIFIC CALIBRATORS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE AS A REFERENCE IN MEASURING CYCLOSPORINE (CSA) IN HUMAN WHOLE BLOOD.,EMIT II PLUS 6-AM/ECSTASY CALIBRATOR/CONTROL LEVEL 2(EMIT II PLUS 6-AM/ECSTASY CALIBRATOR/CONTROL LEVEL 2)-WHEN USED AS CALIBRATORS, THE MATERIALS ARE FOR THE CALIBRATION OF THE EMIT® II PLUS 6-ACETYLMORPHINE AND EMIT® II PLUS ECSTASY ASSAYS. WHEN USED AS CONTROLS, THE MATERIALS MAY BE USED AS QUALITY CONTROL MATERIALS BASED ON THE SPECIFIC EMIT® II PLUS 6-ACETYLMORPHINE AND EMIT® II PLUS ECSTASY ASSAY CUTOFFS,EMIT® II PLUS SPECIALTY DRUG

		CALIBRATOR/CONTROL LEVEL 3(EMIT® II PLUS SPECIALTY DRUG CALIBRATOR/CONTROL LEVEL 3)-THE EMIT® II PLUS SPECIALTY DRUG CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS BUPRENORPHINE ASSAY. THESE PRODUCTS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED ON THE BUPRENORPHINE ASSAY CUTOFF,EMIT ETHYL ALCOHOL LOW CONTROL(EMIT ETHYL ALCOHOL LOW CONTROL)-THE EMIT® ETHYL ALCOHOL CALIBRATORS AND CONTROLS ARE FOR USE WITH THE EMIT® ETHYL ALCOHOL ASSAYS.,EMIT 2000 SIROLIMUS ASSAY KITS (EMIT 2000 SIROLIMUS ASSAY KITS)-THE EMIT® 2000 SIROLIMUS ASSAY IS FOR THE IN VITRO QUANTITATIVE ANALYSIS OF SIROLIMUS IN HUMAN WHOLE BLOOD AS AN AID IN THE MANAGEMENT OF SIROLIMUS THERAPY IN KIDNEY TRANSPLANT PATIENTS
183	IMP/IVD/2019/000139	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIPASE(LIPASE)-KINETIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF LIPASE IN HUMAN SERUM AND PLASMA ON AU BECKMAN COULTER ANALYSERS.,LDL-CHOLESTEROL CALIBRATOR -THE LDL CHOLESTEROL CALIBRATOR IS A LYOPHILIZED HUMAN SERUM. IT IS DESIGNED TO PROVIDE SUITABLE CALIBRATION LEVELS FOR BECKMAN COULTER AU ANALYZERS EMPLOYING THE QUANTITATIVE LDL CHOLESTEROL REAGENT.
184	IMP/IVD/2019/000140	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVIA 360/560 CALIBRATOR(ADVIA 360/560 CALIBRATOR)-ADVIA® 360/560 CALIBRATOR IS DESIGNED FOR USE IN THE CALIBRATION OF ADVIA 360 AND ADVIA 560 HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.,ADVIA 360 HEMATOLOGY CONTROLS(ADVIA 360 HEMATOLOGY CONTROLS)-ADVIA® 360 CONTROL IS A CONTROL DESIGNED TO MONITOR VALUES ON THE ADVIA 360 HEMATOLOGY ANALYZERS. ,ADVIA 560 CONTROL(ADVIA 560 CONTROL)-ADVIA® 560 CONTROL IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON ADVIA 560 HEMATOLOGY ANALYZERS.

185	IMP/IVD/2019/000141	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVIA CHEMISTRY (CO2_C) CO2 REAGENTS CONCENTRATED(ADVIA CHEMISTRY (CO2_C) CO2 REAGENTS CONCENTRATED)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CARBON DIOXIDE IN HUMAN SERUM AND PLASMA ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF NUMEROUS POTENTIALLY SERIOUS DISORDERS ASSOCIATED WITH CHANGES IN BODY ACID-BASE BALANCE.,ADVIA CHEMISTRY (CO2_L) CARBON DIOXIDE LIQUID REAGENTS(ADVIA CHEMISTRY (CO2_L) CARBON DIOXIDE LIQUID REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CARBON DIOXIDE IN HUMAN SERUM AND PLASMA ON ADVIA CHEMISTRY SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF NUMEROUS POTENTIALLY SERIOUS DISORDERS ASSOCIATED WITH CHANGES IN BODY ACID-BASE BALANCE.,ADVIA CHEMISTRY (ACET) ACETAMINOPHEN REAGENTS(ADVIA CHEMISTRY (ACET) ACETAMINOPHEN REAGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ACETAMINOPHEN IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DETECTION OF ACETAMINOPHEN OVERDOSE.,ADVIA CHEMISTRY (SAL) SALICYLATE REGENTS(ADVIA CHEMISTRY (SAL) SALICYLATE REGENTS)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF SALICYLATE IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN) ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS OF SALICYLATE TOXICITY AND OVERDOSE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

186	IMP/IVD/2019/000144	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVIA® CHEMISTRY XPT PROBE WASH 0 (ADVIA® CHEMISTRY XPT PROBE WASH 0)-FOR IN VITRO DIAGNOSTIC USE AS A CLEANING AGENT ON ADVIA® XPT SYSTEMS.,ADVIA® CHEMISTRY CHLORIDE ELECTRODE(ADVIA® CHEMISTRY CHLORIDE ELECTRODE)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CHLORIDE IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE FOR THEIR INFERENTIAL VALUE AND ARE HELPFUL IN DIAGNOSING DISORDERS OF ACID-BASE AND WATER BALANCE. IT IS ESPECIALLY IMPORTANT TO MEASURE CHLORIDE DURING THE CORRECTION OF HYPOKALEMIC ALKALOSIS AND ALSO DURING SEVERE, PROLONGED VOMITING, WHICH CAN LOWER THE SERUM CHLORIDE LEVEL. ,ADVIA® CHEMISTRY XPT CUVETTE DETERGENT (ADVIA® CHEMISTRY XPT CUVETTE DETERGENT)-FOR IN VITRO DIAGNOSTIC USE AS A CLEANING AGENT ON ADVIA® XPT SYSTEMS.,ADVIA® CHEMISTRY REAGENT PROBE WASH 1(ADVIA® CHEMISTRY REAGENT PROBE WASH 1)-FOR INVITRO USE AS A CLEANING AGENT ON ADVIA CHEMISTRY SYSTEMS.,ADVIA® CHEMISTRY XPT ISE BUFFER 2 (ADVIA® CHEMISTRY XPT ISE BUFFER 2)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CERTAIN ELECTROLYTES IN HUMAN SERUM, PLASMA, AND URINE ON ADVIA® XPT SYSTEMS.,ADVIA® CHEMISTRY ISE URINE STANDARD SET (ADVIA® CHEMISTRY ISE URINE STANDARD SET)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM, AND CHLORIDE IN HUMAN SERUM AND PLASMA ON ADVIA CHEMISTRY SYSTEMS.,ADVIA® CHEMISTRY ISE SERUM STANDARD SET(ADVIA® CHEMISTRY ISE SERUM STANDARD SET)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM, AND CHLORIDE IN HUMAN SERUM AND PLASMA ON ADVIA CHEMISTRY SYSTEMS. POTENTIAL CANCER HAZARD.,ADVIA® CHEMISTRY SODIUM ELECTRODE(ADVIA® CHEMISTRY SODIUM ELECTRODE)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF SODIUM IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF GROSS CHANGES IN WATER AND SALT BALANCE,ALDOSTERONISM, DIABETES INSIPIDUS, ADRENAL HYPERTENSION, ADDISON'SDISEASE,DEHYDRATION,INAPPROPRIATE ANTIDIURETIC HORMONE SECRETION, DIABETIC ACIDOSIS, SEVERE DIARRHEA, OR OTHER DISEASES INVOLVING ELECTROLYTE IMBALANCE.,ADVIA® CHEMISTRY POTASSIUM ELECTRODE(ADVIA®

	CHEMISTRY POTASSIUM ELECTRODE)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF POTASSIUM IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN), AND URINE ON THE ADVIA CHEMISTRY SYSTEMS. SUCH MEASUREMENTS ARE USED TO MONITOR ELECTROLYTE BALANCE IN THE DIAGNOSIS AND TREATMENT OF PRIMARY ALDOSTERONISM, METABOLIC ALKALOSIS, DIARRHEA, SEVERE VOMITING, DIURETIC ADMINISTRATION, DIABETIC KETOACIDOSIS, AND OTHER DISEASES. ,ADVIA® CHEMISTRY CUVETTE CONDITIONER(ADVIA® CHEMISTRY CUVETTE CONDITIONER)-FOR INVITRO DIAGNOSTIC USE AS A CUVETTE CONDITIONER AGENT ON ADVIA CHEMISTRY SYSTEMS.,ADVIA® CHEMISTRY ISE DETERGENT SOLUTION(ADVIA® CHEMISTRY ISE DETERGENT SOLUTION)-FOR INVITRO DIAGNOSTIC USED AS QUANTITATIVE DETERMINATION OF CERTAIN ELECTROLYTES IN HUMAN SERUM, PLASMA AND URINE ON ADVIA CHEMISTRY SYSTEMS.,ADVIA® CHEMISTRY ISE BUFFER(ADVIA® CHEMISTRY ISE BUFFER)-FOR INVITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CERTAIN ELECTROLYTES IN HUMAN SERUM, PLASMA AND URINE ON ADVIA CHEMISTRY SYSTEMS. POTENTIAL CANCER HAZARD. ,ADVIA® CHEMISTRY REAGENT PROBE WASH 2 (ADVIA® CHEMISTRY REAGENT PROBE WASH 2)-FOR INVITRO USE AS A CLEANING AGENT ON ADVIA CHEMISTRY SYSTEMS.,ADVIA® CHEMISTRY REAGENT PROBE WASH 3(ADVIA® CHEMISTRY REAGENT PROBE WASH 3)-FOR INVITRO USE AS A CLEANING AGENT ON ADVIA CHEMISTRY SYSTEMS.,ADVIA® CHEMISTRY CUVETTE WASH SOLUTION(ADVIA® CHEMISTRY CUVETTE WASH SOLUTION)-FOR INVITRO DIAGNOSTIC USE AS A CLEANING AGENT ON ADVIA CHEMISTRY SYSTEMS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

187	IMP/IVD/2019/000145	1.License Holder Name: SIRUS BIOCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:WEST NILE IGM ELISA (WEST NILE DETECT IGM CAPTURE ELISA)-THE WEST NILE DETECTTM IGM CAPTURE ELISA IS DESIGNED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO WEST NILE RECOMBINANT ANTIGENS (WNRA) IN HUMAN SERUM.,SMART DETECT SARS-COV-2 RRT-PCR KIT(SMART DETECTTM SARS-COV-2 RRT-PCR KIT)-SMART DETECTTM SARS-COV-2 RRT-PCR KIT IS A REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SEVERE ACUTE RESPIRATORY SYNDROME-RELATED CORONAVIRUS 2 (SARS-COV-2) IN HUMAN NASOPHARYNGEAL SWAB, ANTERIOR NASAL SWAB AND MID-TURBINATE NASAL SWAB SPECIMENS,LEISHMANIA (KALA AZAR)RAPID TEST(KALAZAR DETECT RAPID TEST)-THE KALAZAR DETECT™ TEST FOR VISCERAL LEISHMANIASIS (VL) IS A RAPID IMMUNOCHROMATOGRAPHIC STRIP ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO MEMBERS OF L. DONOVANI IN HUMAN SERUM TO AID IN THE PRESUMPTIVE DIAGNOSIS OF VL.,SCOV-2 IGM ELISA KIT(SCOV-2 DETECTTM IGM ELISA)-THE SCOV-2 DETECT™ IGM ELISA IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM, DENGUE IGM ELISA(DENV DETECT IGM CAPTURE ELISA)-THE DENV DETECT IGM CAPTURE ELISA IS FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO DENV RECOMBINANT ANTIGENS (DENRA) IN SERUM FOR THE PRESUMPTIVE CLINICAL LABORATORY DIAGNOSIS OF DENGUE VIRUS INFECTION.,SCRUB TYPHUS IGG ELISA(SCRUB TYPHUS DETECT IGG ELISA)-THE SCRUB TYPHUS DETECT™ IGG ELISA TEST FOR EXPOSURE TO ORIENTIA TSUTSUGAMUSHI (OT; FORMERLY RICKETTSIA) IS AN ELISA ASSAY SYSTEM FOR THE DETECTION OF IGG ANTIBODIES IN HUMAN SERUM TO OT-DERIVED RECOMBINANT ANTIGEN.,DENGUE NS1 ELISA(DENV DETECT NS1 ELISA)-THE DENV DETECT NS1 ELISA IS FOR THE EARLY DETECTION OF DENGUE VIRUS (DENV) NS1 ANTIGEN IN HUMAN SERUM.,JE IGM ELISA(JE DETECT IGM ANTIBODY CAPTURE ELISA (MAC-ELISA))-THE JE DETECT IGM ELISA (JE DETECT™ IGM ANTIBODY CAPTURE ELISA (MAC-ELISA)) TEST FOR EXPOSURE TO JAPANESE ENCEPHALITIS VIRUS (JEV) IS AN ELISA ASSAY SYSTEM FOR THE DETECTION OF IGM ANTIBODIES IN HUMAN SERUM TO JEVDERIVED RECOMBINANT ANTIGEN,SCRUB TYPHUS IGM ELISA(SCRUB TYPHUS DETECT IGM ELISA)-THE SCRUB TYPHUS DETECT IGM ELISA TEST FOR EXPOSURE TO ORIENTIA TSUTSUGAMUSHI (OT; FORMERLY RICKETTSIA) IS AN ELISA ASSAY SYSTEM FOR THE DETECTION OF IGM ANTIBODIES IN HUMAN SERUM TO OT-DERIVED RECOMBINANT ANTIGEN.

188	IMP/IVD/2019/000147	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROSCAN RENOK DISPOSABLE R-INOCULATOR SETS-THE AUXILIARY MEDICAL DEVICE IS USED IN CONJUNCTION WITH MICROSCAN RENOK TO SIMULTANEOUSLY REHYDRATE AND INOCULATE MICROSCAN 96 WELL PANELS FOR USE ON MICROSCAN WALKAWAY AND AUTOSCAN-4 MICROBIOLOGY ANALYZERS.,MICROSCAN RENOK DISPOSABLE D-INOCULATOR SETS-THE AUXILIARY MEDICAL DEVICE IS USED IN CONJUNCTION WITH MICROSCAN RENOK TO SIMULTANEOUSLY REHYDRATE AND INOCULATE MICROSCAN 96 WELL PANELS FOR USE ON MICROSCAN WALKAWAY AND AUTOSCAN-4 MICROBIOLOGY ANALYZERS.
189	IMP/IVD/2019/000150	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVIA 360 CLEANER (ADVIA 360 CLEANER)-DETERGENT SOLUTION FOR THE REMOVAL OF CELLULAR DEBRIS ON BLOOD CELL COUNTERS.,ADVIA 560 5P DIFF (ADVIA 560 5P DIFF)-REAGENT FOR DIFFERENTIATION OF LEUCOCYTE SUBPOPULATIONS.,ADVIA 360 LYSE 3P DIFF(ADVIA 360 LYSE 3P DIFF)-REAGENT FOR DIFFERENTIATION OF LEUCOCYTE SUBPOPULATIONS.,ADVIA 360/560 HYPOCLEAN (ADVIA 360/560 HYPOCLEAN)-CLEANING AND BLEACHING SOLUTION FOR BLOOD CELL COUNTERS.,ADVIA 360/560 HYPOCLEAN CC(ADVIA 360/560 HYPOCLEAN CC)-CLEANING AND BLEACHING CONCENTRATE FOR BLOOD CELL COUNTERS.,ADVIA 360/560 DIL(ADVIA 360/560 DIL)-BUFFERED ISOTONIC SOLUTION FOR BLOOD CELL COUNTING.,ADVIA 560 LYSE(ADVIA 560 LYSE)-REAGENT FOR DIFFERENTIATION OF LEUCOCYTE SUBPOPULATIONS.

190	IMP/IVD/2019/000152	1.License Holder Name: KHC HEALTHCARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HUMAN HAPTOGLOBIN KIT FOR USE ON SPAPLUS(HUMAN HAPTOGLOBIN KIT FOR USE ON SPAPLUS)-THIS KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF HUMAN HAPTOGLOBIN IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA, USING THE BINDING SITE SPAPLUS TURBIDIMETRIC ANALSYER. MEASUREMENT OF HAPTOGLOBIN AIDS IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND BODY'S LACK ABILITY TO RESIST INFECTIOUS AGENT. THE TEST RESULT ARE TO BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDING.,OPTILITE® BETA-2 MICROGLOBULIN URINE CONTROL PACK(OPTILITE® BETA-2 MICROGLOBULIN URINE CONTROL PACK)-"THE OPTILITE® BETA-2 MICROGLOBULIN URINE CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® BETA-2 MICROGLOBULIN URINE KIT (LK043.L.OPT AND LK043.L.OPT.A)." ,SPAPLUS WEEKLY WASH PROTOCOL AND BOTTLES(SPAPLUS WEEKLY WASH PROTOCOL AND BOTTLES)-THIS PRODUCT IS INTENDED FOR USE AS A CUVETTE WASH PROCEDURE AS PART OF THE WEEKLYMAINTENANCE REQUIREMENTS ON THE SPAPLUS ANALYSER. ,OPTILITE® FREELITE® LAMBDA FREE CONTROL PACK (OPTILITE® FREELITE® LAMBDA FREE CONTROL PACK)-"THE OPTILITE® FREELITE® LAMBDA FREE CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® FREELITE® LAMBDA FREE KIT (LK018.OPT AND LK018.OPT.A)." ,OPTILITE® CAERULOPLASMIN KIT (OPTILITE® CAERULOPLASMIN KIT)-"THE OPTILITE CAERULOPLASMIN KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF CAERULOPLASMIN IN SERUM AND LITHIUM HEPARIN PLASMA USING THE BINDING SITE OPTILITE ANALYSER TO AID THE DIAGNOSIS OF COPPER METABOLISM DISORDERS. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. " ,OPTILITE® FREELITE® KAPPA FREE CONTROL PACK(OPTILITE® FREELITE® KAPPA FREE CONTROL PACK)-"THE OPTILITE® FREELITE® KAPPA FREE CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® FREELITE® KAPPA FREE KIT (LK016.OPT AND LK016.OPT.A)." ,HUMAN IGG LIQUID REAGENT KIT FOR USE ON THE SPAPLUS(HUMAN IGG LIQUID REAGENT KIT FOR USE ON THE SPAPLUS)-THESE KITS ARE INTENDED FOR THE QUANTIFYING HUMAN IGG AND IGG SUB CLASSES 1,2,3 AND 4 IN SERUM USING THE SPAPLUS ANALYSER. MEASUREMENT OF THESE IMMUNOGLOBULINS IS AN AID IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND BODY'S LACK OF ABILITY TO RESIST INFECTIOUS AGENTS IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS , OPTILITE® IGM CSF CONTROL PACK(OPTILITE® IGM CSF CONTROL

	PACK)-"THE OPTILITE® IGM CSF CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® IGM CSF KIT (LK012.L.OPT)" ,TOTAL HAEMOLYTIC COMPLEMENT(TOTAL HAEMOLYTIC COMPLEMENT)-THIS KIT IS INTENDED FOR MEASURING HUMAN HAEMOLYTIC COMPLETED ACTIVITY BY THR CLASSICAL PATHWAY IN HUMAN SERUM, AS AN AID IN DIAGNOSTIC OF IMMUNOLOGICAL DISORDER ESPECIALLY THOSE ASSOCIATED WITH COMPLEMENT COMPONENT DEFICIENCIES. ,OPTILITE® IGA CSF CONTROL PACK(OPTILITE® IGA CSF CONTROL PACK)-"THE OPTILITE® IGA CSF CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® IGA CSF KIT (LK010.L.OPT).",OPTILITE® CYSTATIN C KIT(OPTILITE® CYSTATIN C KIT)-THE OPTILITE CYSTATIN C KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF CYSTATIN C IN SERUM, LITHIUM HEPARIN PLASMA AND EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. CYSTATIN C MEASUREMENTS IN SERUM AND PLASMA ARE USED AS AN AID IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASES. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS.,OPTILITE® IGM CONTROL PACK(OPTILITE® IGM CONTROL PACK)-"THE OPTILITE® IGM CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® IGM KIT (NK012.OPT AND NK012.OPT.A)." ,HUMAN C4 KIT FOR USE ON SPAPLUS (HUMAN C4 KIT FOR USE ON SPAPLUS)-THIS KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF HUMAN C4 IN SERUM USING THE BINDING SITE SPAPLUS TURBIDIMETRIC ANALYSER. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS., OPTILITE® IGA CONTROL PACK(OPTILITE® IGA CONTROL PACK)-"THE OPTILITE® IGA CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® IGA KIT (NK010.OPT AND NK010.OPT.A)." ,OPTILITE IGE REAGENT (OPTILITE IGE REAGENT)-THE OPTILITE IMMUNOGLOBULIN E IGE REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF IGE IN HUMAN SERUM OR PLASMA (LI-HEP AND EDTA) USING THE BINDING SITE OPTILITE ANALYSER. MEASUREMENT CAN BE USED AS AN AID IN THE DIAGNOSIS OF DISEASE RELATED TO ELEVATED LEVELS OF IGE. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS ,OPTILITE® LOW LEVEL IGG CONTROL PACK (OPTILITE® LOW LEVEL IGG CONTROL PACK)-"THE OPTILITE® LOW LEVEL IGG CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® LOW LEVEL IGG KIT (NK004.LL.OPT) AND OPTILITE® IGG CSF KIT (NK004.L.OPT.A)." ,OPTILITE® CH50 REAGENT(OPTILITE® CH50 REAGENT)-"THE OPTILITE CH50 REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TOTAL CLASSICAL COMPLEMENT ACTIVITY (CH50) IN HUMAN SERUM AND EDTA

	PLASMA USING THE BINDING SITE OPTILITE ANALYSER TO AID IN THE DIAGNOSIS OF IMMUNOLOGICAL DISORDERS, ESPECIALLY THOSE ASSOCIATED WITH DEFICIENCIES OF COMPLEMENT COMPONENTS. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. " ,OPTILITE® IGG CONTROL PACK(OPTILITE® IGG CONTROL PACK)-"THE OPTILITE® IGG CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® IGG KIT (NK004.OPT AND NK004.OPT.A)" ,OPTILITE® FREELITE MX™ KAPPA FREE KIT(OPTILITE® FREELITE MX™ KAPPA FREE KIT)-THE OPTILITE FREELITE MX KAPPA FREE KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF KAPPA FREE LIGHT CHAINS IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA, URINE AND CSF USING THE BINDING SITE OPTILITE ANALYSER. MEASUREMENT OF FREE LIGHT CHAINS AIDS IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, LYMPHOCYTIC NEOPLASMS, WALDENSTRÖM'S MACROGLOBULINAEMIA, AL AMYLOIDOSIS, LIGHT CHAIN DEPOSITION DISEASE AND CONNECTIVE TISSUE DISEASES SUCH AS SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. ,OPTILITE® BETA-2 MICROGLOBULIN CONTROL PACK(OPTILITE® BETA-2 MICROGLOBULIN CONTROL PACK)-"THE OPTILITE® BETA-2 MICROGLOBULIN CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® BETA-2 MICROGLOBULIN KIT (LK043.OPT AND LK043. OPT.A)" ,OPTILITE® IGG4 KIT(OPTILITE® IGG4 KIT)-THE OPTILITE IGG4 KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF IGG4 IN SERUM, LITHIUM HEPARIN AND EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. MEASUREMENT OF THIS IMMUNOGLOBULIN IS AN AID IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S LACK OF ABILITY TO RESIST INFECTIOUS AGENTS. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. ,OPTILITE IGM CSF KIT(OPTILITE IGM CSF KIT)-"THE OPTILITE IGM CSF KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF IGM IN CEREBROSPINAL FLUID (CSF) AND PAIRED CSF AND SERUM SAMPLES USING THE OPTILITE ANALYSER. MEASUREMENT OF THIS IMMUNOGLOBULIN AIDS IN THE ASSESSMENT OF THE BODY'S LACK OF ABILITY TO RESIST INFECTIOUS DISEASE IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS." ,OPTILITE® IGA1 KIT(OPTILITE® IGA1 KIT)-THE OPTILITE IGA SUBCLASS 1 (IGA1) KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF IGA1 IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. MEASUREMENT OF THIS IMMUNOGLOBULIN AIDS IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S

	LACK OF ABILITY TO RESIST INFECTIOUS AGENTS. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. ,OPTILITE IGA CSF KIT(OPTILITE IGA CSF KIT)-"THE OPTILITE IGA CSF KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF IGA IN CEREBROSPINAL FLUID (CSF) AND PAIRED CSF AND SERUM SAMPLES USING THE OPTILITE ANALYSER. MEASUREMENT OF THIS IMMUNOGLOBULIN AIDS IN THE ASSESSMENT OF THE BODY'S LACK OF ABILITY TO RESIST INFECTIOUS DISEASE IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS." ,OPTILITE® IGA2 KIT(OPTILITE® IGA2 KIT)-"THE OPTILITE IGA SUBCLASS 2 (IGA2) KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF IGA2 IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. MEASUREMENT OF THIS IMMUNOGLOBULIN AIDS IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S LACK OF ABILITY TO RESIST INFECTIOUS AGENTS. THE TEST RESULT IS TO BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS. " ,OPTILITE IGM KIT(OPTILITE IGM KIT)-"THE OPTILITE IGM KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF IGM IN HUMAN SERUM, LITHIUM HEPARIN OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. MEASUREMENT OF IGM AIDS IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S LACK OF ABILITY TO RESIST INFECTIOUS AGENTS. THE TEST RESULTS ARE TO BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS." ,OPTILITE® IGG3 KIT(OPTILITE® IGG3 KIT)-THE OPTILITE IGG3 KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF IGG3 IN SERUM, LITHIUM HEPARIN AND EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. MEASUREMENT OF THIS IMMUNOGLOBULIN IS AN AID IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S LACK OF ABILITY TO RESIST INFECTIOUS AGENTS. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. ,OPTILITE IGA KIT(OPTILITE IGA KIT)-THE OPTILITE IGA KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF IGA IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. MEASUREMENT OF IGA AIDS IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S LACK OF ABILITY TO RESIST INFECTIOUS AGENTS. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS ,OPTILITE® IGG2 KIT(OPTILITE® IGG2 KIT)-THE OPTILITE IGG2 KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF IGG2 IN SERUM, LITHIUM HEPARIN AND EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER.

	MEASUREMENT OF THIS IMMUNOGLOBULIN IS AN AID IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S LACK OF ABILITY TO RESIST INFECTIOUS AGENTS. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. ,OPTILITE IGG KIT(OPTILITE IGG KIT)-"THE OPTILITE IGG KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF IGG IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. MEASUREMENT OF THIS IMMUNOGLOBULIN IS AN AID IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S LACK OF ABILITY TO RESIST INFECTIOUS AGENTS. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS." ,OPTILITE® CAERULOPLASMIN CONTROL PACK (OPTILITE® CAERULOPLASMIN CONTROL PACK)-"THE OPTILITE® CAERULOPLASMIN CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® CAERULOPLASMIN KIT (NK045.OPT AND NK045.OPT. A). " ,OPTILITE® BETA-2 MICROGLOBULIN URINE KIT(OPTILITE® BETA-2 MICROGLOBULIN URINE KIT)-"THE OPTILITE BETA-2 MICROGLOBULIN (2M) URINE KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF BETA-2 MICROGLOBULIN IN URINE USING THE BINDING SITE OPTILITE ANALYSER TO AID IN THE DIAGNOSIS OF ACTIVE RHEUMATOID ARTHRITIS AND KIDNEY DISEASE. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS." ,OPTILITE® CH50 CONTROLS(OPTILITE® CH50 CONTROLS)-"THE OPTILITE CH50 CONTROLS ARE INTENDED FOR USE ON THE OPTILITE ANALYSER IN CONJUNCTION WITH THE BINDING SITE OPTILITE CH50 REAGENT (PRODUCT CODE NK095.OPT) FOR THE DETERMINATION OFTOTAL COMPLEMENT ACTIVITY. " ,OPTILITE® BETA-2 MICROGLOBULIN KIT (OPTILITE® BETA-2 MICROGLOBULIN KIT)-"THE OPTILITE BETA-2 MICROGLOBULIN (2M) KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF 2M IN SERUM, LITHIUM HEPARIN, OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER, TO AID IN THE DIAGNOSIS OF ACTIVE RHEUMATOID ARTHRITIS AND KIDNEY DISEASE. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS." ,OPTILITE® C3C KIT (OPTILITE® C3C KIT)-"THE OPTILITE C3C KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF C3C IN SERUM, LITHIUM HEPARIN AND EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. " ,OPTILITE® FREELITE® LAMBDA FREE KIT(OPTILITE® FREELITE® LAMBDA FREE KIT)-"THE OPTILITE FREELITE LAMBDA FREE KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF LAMBDA FREE

	LIGHT CHAINS IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. MEASUREMENT OF FREE LIGHT CHAINS AIDS IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, LYMPHOCYTIC NEOPLASMS, WALDENSTRÖM'S MACROGLOBULINAEMIA, AL AMYLOIDOSIS, LIGHT CHAIN DEPOSITION DISEASE AND CONNECTIVE TISSUE DISEASES SUCH AS SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS." ,HUMAN IGA LIQUID REAGENT KIT FOR USE ON SPAPLUS (HUMAN IGA LIQUID REAGENT KIT FOR USE ON SPAPLUS)-THIS KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF HUMAN IGA IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA, USING THE BINDING SITE SPAPLUS TURBIDIMETRIC ANALSYER MEASUREMENT OF IGA AIDS INTHE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND BODY'S LACK ABILITY TO RESIST INFECTIOUS AGENT. THE TEST RESULT ARE TO BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDING. ,OPTILITE® FREELITE® KAPPA FREE KIT (OPTILITE® FREELITE® KAPPA FREE KIT)-"THE OPTILITE FREELITE KAPPA FREE KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF KAPPA FREE LIGHT CHAINS IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. MEASUREMENT OF FREE LIGHT CHAINS AIDS IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, LYMPHOCYTIC NEOPLASMS, WALDENSTRÖM'S MACROGLOBULINAEMIA, AL AMYLOIDOSIS, LIGHT CHAIN DEPOSITION DISEASE AND CONNECTIVE TISSUE DISEASES SUCH AS SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS." ,OPTILITE IGE CALIBRATOR (OPTILITE IGE CALIBRATOR)-THE OPTILITE IGE CALIBRATOR IS INTENDED FOR THE CALIBRATION OF THE OPTILITE IGE REAGENTS ON THE OPTILITE ANALYSER. ,OPTILITE SAMPLE DILUENT 2(OPTILITE SAMPLE DILUENT 2)-OPTILITE SAMPLE DILUENT 2 IS INTENDED FOR USE AS AN ACCESSORY PACK WITH OPTILITE REAGENTS.,SPAPLUS SAMPLE DILUENT PACK(SPAPLUS SAMPLE DILUENT PACK)-THIS PRODUCT IS FOR USE AS AN ACCESSORY PACK WITH SPAPLUS REAGENTS. IT CONTAINS SUFFICIENT SPAPLUS SAMPLE DILUENT FOR APPROXIMATELY 1200 TESTS DEPENDING ON THE SPECIFICITY OF REAGENT KIT BEING USED. ,OPTILITE LOW LEVEL IGG KIT(OPTILITE LOW LEVEL IGG KIT)-OPTILITE LOW LEVEL IGG KIT IS INTENDED FOR THE QUANTITATIVE IN-VITRO MEASUREMENT OF IGG IN URINE, CEREBROSPINAL FLUID AND PAIRED CSF AND SERUM SAMPLES USING THE OPTILITE ANALYSER. MEASUREMENT OF THIS IMMUNOLOGICAL AIDS IN THE ASSESSMENT OF THE BODY'S LACK OF ABILITY TO RESIST INFECTIOUS DISEASES IN CONJUNCTION FINDING

	WITH OTHER LABORATORY AND CLINICAL FINDINGS.,OPTILITE® IGG1 KIT(OPTILITE® IGG1 KIT)-THE OPTILITE IGG1 KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF IGG1 IN SERUM, LITHIUM HEPARIN AND EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. MEASUREMENT OF THIS IMMUNOGLOBULIN IS AN AID IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S LACK OF ABILITY TO RESIST INFECTIOUS AGENTS. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. ,OPTILITE C-REACTIVE PROTEIN CALIBRATOR(OPTILITE C-REACTIVE PROTEIN CALIBRATOR) -OPTILITE C-REACTIVE PROTEIN CALIBRATOR IS INTENDED FOR THE CALIBRATION OF THE OPTILITE C-REACTIVE PROTEIN REAGENT ON THE OPTILITE ANALYSER.,HUMAN BETA-2 MICROGLOBULIN KIT FOR USE ON THE SPAPLUS(HUMAN BETA-2 MICROGLOBULIN KIT FOR USE ON THE SPAPLUS)-THIS KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF BETA-2 MICROGLOBULIN IN HUMAN SERUM AND URINE USING SPAPLUS ANALYSER, TO AID THE DIAGNOSIS OF ACTIVE RHEUMATOID ARTHRITIS AND KIDNEY DISEASE. THE TEST RESULT IS TO BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS.,OPTILITE LIPOPROTEIN REAGENT(OPTILITE LIPOPROTEIN REAGENT)-OPTILITE LIPOPROTEIN REAGENT IS INTENDED FOR THE QUANTITATIVE IN-VITRO MEASUREMENT OF LP IN SERUM AND PLASMA USING THE BINDING SITE OPTILITE ANALYSER TO AID IN THE ASSESSMENT OF LIPID DISORDER AND RISK OF ATHEROSCLEROTIC CARDIOVASCULAR DISEASE. THIS TEST SHOULD BE USED IN CONJUNCTION FINDING WITH OTHER LABORATORY AND CLINICAL FINDINGS. ,HUMAN C3C KIT FOR USE ON SPAPLUS(HUMAN C3C KIT FOR USE ON SPAPLUS)-THIS KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF HUMAN C3C IN SERUM USING THE BINDING SITE SPAPLUS TURBIDIMETRIC ANALYSER. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS,, OPTILITE SPECIAL WASH 1(OPTILITE SPECIAL WASH 1)-OPTILITE SPECIAL WASH 1 IS INTENDED FOR USE AS AN ACCESSORY PACK WITH OPTILITE REAGENTS.,OPTILITE IGE CONTROL (OPTILITE IGE CONTROL)-OPTILITE IGE CONTROL ARE INTENDED FOR THE USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE OPTILITE IGE REAGENT. ,OPTILITE TRANSFERRIN KIT(OPTILITE TRANSFERRIN KIT)-OPTILITE TRANSFERRIN KIT IS INTENDED FOR QUANTITATIVE IN-VITRO MEASUREMENT OF TRANSFERRIN IN SERUM LITHIUM HEPARIN OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. THE MEASUREMENT OF THE TRANSFERRIN LEVELS AIDS IN THE DIAGNOSIS OF MALNUTRITION, ACUTE INFLAMMATION INFECTION AND IRON DEFICIENCY ANAEMIA. THIS

	TEST SHOULD BE USED IN CONJUNCTION FINDING WITH OTHER LABORATORY AND CLINICAL FINDINGS.,FREELITE® HUMAN KAPPA FREE KIT FOR USE ON THE SIEMENS BN PROSPEC®(FREELITE® HUMAN KAPPA FREE KIT FOR USE ON THE SIEMENS BN PROSPEC®)-THIS KIT IS INTENDED FOR THE QUANTITATION OF KAPPA FREE LIGHT CHAINS IN SERUM AND URINE ON THE BN PROSPEC. MEASUREMENT OF FREE LIGHT CHAINS AIDS IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, LYMPHOCYTIC NEOPLASMS, WALDENSTRÖM'S MACROGLOBULINEMIA, AL AMYLOIDOSIS, LIGHT CHAIN DEPOSITION DISEASE AND CONNECTIVE TISSUE DISEASES SUCH AS SYSTEMIC LUPUS ERYTHEMATOSUS IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. ,OPTILITE C-REACTIVE PROTEIN REAGENT(OPTILITE C-REACTIVE PROTEIN REAGENT)-THE OPTILITE C-REACTIVE PROTEIN REAGENT FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF C-REACTIVE PROTEIN CRP CONCENTRATION IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. THIS TEST SHOULD BE USED IN CONJUNCTION FINDING WITH OTHER LABORATORY AND CLINICAL FINDINGS.,VACCZYME VZV GLYCOPROTEIN IGG LOW LEVEL ENZYME IMMUNOASSAY KIT (VACCZYME VZV GLYCOPROTEIN IGG LOW LEVEL ENZYME IMMUNOASSAY KIT)-THIS ASSAY IS DESIGNED FOR THE IN VITRO MEASUREMENT OF SPECIFIC IGG ANTIBODIES AGAINST VARICELLA ZOSTER VIRUS PRESENT IN HUMAN SERUM, AS AN AID IN THE DETERMINATION OF THE PREVIOUS INFECTION AND RESPONSE VACCINATION. ,OPTILITE ANTI-STREPTOLYSIN O KIT(OPTILITE ANTI-STREPTOLYSIN O KIT)-OPTILITE ANTI-STREPTOLYSIN O KIT IS INTENDED FOR THE QUANTITATIVE IN-VITRO MEASUREMENT OF ANTI-STREPTOLYSIN O IN SERUM USING THE BINDING SITE OPTILITE ANALYSER. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. ,HUMAN C1 INACTIVATOR BINDARID RADIAL IMMUNODIFFUSION KIT(HUMAN C1 INACTIVATOR BINDARID RADIAL IMMUNODIFFUSION KIT)-THIS KIT IS INTENDED FOR MEASURING HUMAN C1 INACTIVATOR (C1 ESTERASE INHIBITOR) IN SERUM AS AN AID IN THE DIAGNOSIS AN TREATMENT OF ANGIODEMA.,OPTILITE C-REACTIVE PROTEIN CONTROLS (OPTILITE C-REACTIVE PROTEIN CONTROLS)-THE OPTILITE C-REACTIVE PROTEIN CONTROLS ARE INTENDED FOR THE USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE OPTILITE C- REACTIVE PROTEIN REAGENT. ,HUMAN IGM KIT FOR USE ON SPAPLUS (HUMAN IGM KIT FOR USE ON SPAPLUS)-THIS KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF HUMAN IGM IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA, USING THE BINDING SITE SPAPLUS TURBIDIMETRIC ANALSYER.

	MEASUREMENT OF IGM AIDS IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND BODY'S LACK ABILITY TO RESIST INFECTIOUS AGENT. THE TEST RESULT ARE TO BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDING., OPTILITE SAMPLE DILUENT 1 (OPTILITE SAMPLE DILUENT 1)-OPTILITE SAMPLE DILUENT 1 IS INTENDED FOR USE AS AN ACCESSORY PACK WITH OPTILITE REAGENTS.,OPTILITE® IGG1 CONTROL PACK(OPTILITE® IGG1 CONTROL PACK)-THE OPTILITE® IGG1 CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® IGG1 KIT (NK006.OPT AND NK006.OPT.A). ,OPTILITE LIPOPROTEIN CALIBRATOR(OPTILITE LIPOPROTEIN CALIBRATOR)-OPTILITE LIPOPROTEIN CALIBRATOR IS INTENDED FOR THE CALIBRATION OF THE OPTILITE LP REAGENT ON THE OPLILITE ANALYSER,SPAPLUS SAMPLE DILUENT 2 PACK(SPAPLUS SAMPLE DILUENT 2 PACK)-THIS PRODUCT IS FOR USE AS AN ACCESSORY PACK WITH SPAPLUS REAGENTS. IT CONTAINS SUFFICIENT SPAPLUS SAMPLE DILUENT 2 FOR APPROXIMATELY 600 TESTS DEPENDING ON THE SPECIFICITY OF REAGENT KIT BEING USED. ,OPTILITE SAMPLE DILUENT 3 (OPTILITE SAMPLE DILUENT 3)-OPTILITE SAMPLE DILUENT 3 IS INTENDED FOR USE AS AN ACCESSORY PACK WITH OPTILITE REAGENTS.,OPTILITE® LOW LEVEL ALBUMIN KIT(OPTILITE® LOW LEVEL ALBUMIN KIT)-"THE OPTILITE LOW LEVEL ALBUMIN KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF ALBUMIN IN CSF, URINE AND SERUM USING THE BINDING SITE OPTILITE ANALYSER TO AID IN THE DIAGNOSIS OF KIDNEY AND INTESTINAL DISEASES. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. " ,OPTILITE HIGH SENSITIVE C-REACTIVE PROTEIN(OPTILITE HIGH SENSITIVE C-REACTIVE PROTEIN)-OPTILITE HIGH SENSITIVE C-REACTIVE PROTEIN KIT IS INTENDED FOR THE QUANTITATIVE IN-VITRO MEASUREMENT OF C-REACTIVE PROTEIN (CRP) IN SERUM LITHIUM HEPARIN OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. THIS TEST SHOULD BE USED IN CONJUNCTION FINDING WITH OTHER LABORATORY AND CLINICAL FINDINGS. , OPTILITE® ALBUMIN KIT(OPTILITE® ALBUMIN KIT)-THE OPTILITE ALBUMIN KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF ALBUMIN IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER TO AID THE DIAGNOSIS OF KIDNEY AND INTESTINAL DISEASES. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. ,OPTILITE RHEUMATOID FACTOR KIT(OPTILITE RHEUMATOID FACTOR KIT)-OPTILITE RHEUMATOID FACTOR KIT IS INTENDED FOR THE QUANTITATIVE IN-VITRO MEASUREMENT OF RHEUMATOID FACTORS IN SERUM USING THE BINDING SITE OPTILITE

	ANALYSER. MEASUREMENT OF RHEUMATOID FACTORY MAY AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS. THIS TEST SHOULD BE USED IN THE CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDING ,OPTILITE® IGA1 CONTROL PACK(OPTILITE® IGA1 CONTROL PACK)-THE OPTILITE® IGA1 CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® IGA1 KIT (NK087.OPT AND NK087 OPT.A). ,OPTILITE LIPOPROTEIN CONTROLS(OPTILITE LIPOPROTEIN CONTROLS)-THE OPTILITE LIPOPROTEIN CONTROLS ARE INTENDED FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE OPTILITE LP REAGENT ,OPTILITE® FREELITE MX™ LAMBDA FREE KIT(OPTILITE® FREELITE MX™ LAMBDA FREE KIT)-"THE OPTILITE FREELITE MX LAMBDA FREE KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF LAMBDA FREE LIGHT CHAINS IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA, URINE AND CSF USING THE BINDING SITE OPTILITE ANALYSER. MEASUREMENT OF FREE LIGHT CHAINS AIDS IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, LYMPHOCYTIC NEOPLASMS, WALDENSTRÖM'S MACROGLOBULINAEMIA, AL AMYLOIDOSIS, LIGHT CHAIN DEPOSITION DISEASE AND CONNECTIVE TISSUE DISEASES SUCH AS SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. " ,OPTILITE® IGG3 CONTROL PACK(OPTILITE® IGG3 CONTROL PACK)-THE OPTILITE® IGG3 CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® IGG3 KIT (LK008.OPT AND LK008.OPT.A). ,OPTILITE® IGG4 CONTROL PACK(OPTILITE® IGG4 CONTROL PACK)-THE OPTILITE® IGG4 CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® IGG4 KIT (LK009.OPT AND LK009.OPT.A). ,OPTILITE® HAPTOGLOBIN CONTROL PACK(OPTILITE® HAPTOGLOBIN CONTROL PACK)-THE OPTILITE HAPTOGLOBIN CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE HAPTOGLOBIN KIT (NK058.OPT AND NK058.OPT.A). ,FREELITE® HUMAN LAMBDA FREE KIT FOR USE ON THE SPAPLUS(FREELITE® HUMAN LAMBDA FREE KIT FOR USE ON THE SPAPLUS)-THIS KIT IS INTENDED FOR THE QUANTITATION OF LAMBDA FREE LIGHT CHAINS IN SERUM AND URINE ON BINDING SITE SPAPLUS. MEASUREMENT OF FREE LIGHT CHAINS IN SERUM AIDS IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, LYMPHOCYTIC NEOPLASMS, WALDENSTRÖM'S MACROGLOBULINAEMIA, AL AMYLOIDOSIS, LIGHT CHAIN DEPOSITION DISEASE AND CONNECTIVE TISSUE DISEASES SUCH AS SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. MEASUREMENT OF FREE LIGHT CHAINS IN URINE AIDS IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, LYMPHOCYTIC NEOPLASMS, WALDENSTRÖM'S MACROGLOBULINAEMIA, AL AMYLOIDOSIS AND

	LIGHT CHAIN DEPOSITION DISEASE IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. ,FREELITE® HUMAN KAPPA FREE KIT FOR USE ON THE SPAPLUS(FREELITE® HUMAN KAPPA FREE KIT FOR USE ON THE SPAPLUS)-"THIS KIT IS INTENDED FOR THE QUANTITATION OF KAPPA FREE LIGHT CHAINS IN SERUM AND URINE ON BINDING SITE SPAPLUS. MEASUREMENT OF FREE LIGHT CHAINS IN SERUM AIDS IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, LYMPHOCYTIC NEOPLASMS, WALDENSTRÖM'S MACROGLOBULINAEMIA, AL AMYLOIDOSIS, LIGHT CHAIN DEPOSITION DISEASE AND CONNECTIVE TISSUE DISEASES SUCH AS SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. MEASUREMENT OF FREE LIGHT CHAINS IN URINE AIDS IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, LYMPHOCYTIC NEOPLASMS, WALDENSTRÖM'S MACROGLOBULINAEMIA, AL AMYLOIDOSIS AND LIGHT CHAIN DEPOSITION DISEASE IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS." ,OPTILITE® C3C CONTROL PACK(OPTILITE® C3C CONTROL PACK)-THE OPTILITE® C3C CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® C3C KIT (NK023.OPT AND NK023.OPT.A). ,OPTILITE® PREALBUMIN KIT (OPTILITE® PREALBUMIN KIT)-THE OPTILITE PREALBUMIN KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF PREALBUMIN IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER TO AID THE ASSESSMENT OF NUTRITIONAL STATUS. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. , OPTILITE® HAPTOGLOBIN KIT(OPTILITE® HAPTOGLOBIN KIT)-THE OPTILITE HAPTOGLOBIN KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF HAPTOGLOBIN IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER TO AID THE DIAGNOSIS OF HAEMOLYTIC DISEASES RELATED TO THE FORMATION OF HAEMOGLOBIN-HAPTOGLOBIN COMPLEXES. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. ,FREELITE® HUMAN LAMBDA FREE KIT FOR USE ON THE SIEMENS BN PROSPEC® (FREELITE® HUMAN LAMBDA FREE KIT FOR USE ON THE SIEMENS BN PROSPEC®)-THIS KIT IS INTENDED FOR THE QUANTITATION OF LAMBDA FREE LIGHT CHAINS IN SERUM AND URINE ON THE BN PROSPEC. MEASUREMENT OF FREE LIGHT CHAINS AIDS IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, LYMPHOCYTIC NEOPLASMS, WALDENSTRÖM'S MACROGLOBULINEMIA, AL AMYLOIDOSIS, LIGHT CHAIN DEPOSITION DISEASE AND CONNECTIVE TISSUE DISEASES SUCH AS SYSTEMIC LUPUS ERYTHEMATOSUS IN CONJUNCTION WITH OTHER

	LABORATORY AND CLINICAL FINDINGS. ,OPTILITE® C4 KIT (OPTILITE® C4 KIT)-THE OPTILITE C4 KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF C4 IN SERUM, LITHIUM HEPARIN OR EDTA PLASMA USING THE BINDING SITE OPTILITE ANALYSER. THIS TEST SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. ,OPTILITE® CH50 CALIBRATOR(OPTILITE® CH50 CALIBRATOR)-"THE OPTILITE CH50 CALIBRATOR IS INTENDED FOR USE ON THE OPTILITE ANALYSER IN CONJUNCTION WITH THE BINDING SITE OPTILITE CH50 REAGENT (PRODUCT CODE: NK095.OPT) FOR THE DETERMINATION OF TOTAL COMPLEMENT ACTIVITY. " ,OPTILITE® C4 CONTROL PACK(OPTILITE® C4 CONTROL PACK)-THE OPTILITE® C4 CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® C4 KIT (NK025.OPT AND NK025. OPT.A). ,OPTILITE® IGG2 CONTROL PACK(OPTILITE® IGG2 CONTROL PACK)-THE OPTILITE® IGG2 CONTROL PACK IS INTENDED TO BE USED WITH THE OPTILITE® IGG2 KIT (NK007.OPT AND NK007.OPT.A) , FREELITE® HUMAN KAPPA FREE KIT FOR USE ON THE ROCHE COBAS® C SYSTEMS(FREELITE® HUMAN KAPPA FREE KIT FOR USE ON THE ROCHE COBAS® C SYSTEMS)-THIS KIT IS INTENDED FOR THE QUANTITATION OF KAPPA FREE LIGHT CHAINS IN SERUM ON THE C501 MODULE OF THE ROCHE COBAS C6000 SERIES AND THE C502 MODULE OF THE ROCHE COBAS C8000 SERIES. MEASUREMENT OF FREE LIGHT CHAINS AIDS IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, LYMPHOCYTIC NEOPLASMS, WALDENSTRÖM'S MACROGLOBULINEMIA, AL AMYLOIDOSIS, LIGHT CHAIN DEPOSITION DISEASE AND CONNECTIVE TISSUE DISEASES SUCH AS SYSTEMIC LUPUS ERYTHEMATOSUS IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. ,FREELITE® HUMAN LAMBDA FREE KIT FOR USE ON THE ROCHE COBAS® C SYSTEMS(FREELITE® HUMAN LAMBDA FREE KIT FOR USE ON THE ROCHE COBAS® C SYSTEMS)-"THIS KIT IS INTENDED FOR THE QUANTITATION OF LAMBDA FREE LIGHT CHAINS IN SERUM ON THE C501 MODULE OF THE ROCHE COBAS C6000 SERIES AND THE C502 MODULE OF THE ROCHE COBAS C8000 SERIES. MEASUREMENT OF FREE LIGHT CHAINS AIDS IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, LYMPHOCYTIC NEOPLASMS, WALDENSTRÖM'S MACROGLOBULINEMIA, AL AMYLOIDOSIS, LIGHT CHAIN DEPOSITION DISEASE AND CONNECTIVE TISSUE DISEASES SUCH AS SYSTEMIC LUPUS ERYTHEMATOSUS IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS."

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191	IMP/IVD/2019/000155	1.License Holder Name: MICROGENE DIAGNOSTIC SYSTEMS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CARESTART MALARIA PLDH (PAN)(CARESTART)-CARESTART MALARIA PLDH (PAN) IS A RAPID TEST IS INTENDED FOR THE DETECTION OF MALARIA ANTIGEN IN HUMAN BLOOD FOR ALL THE FOUR SPECIES OF MALARIA , CARESTART MALARIA HRP2/PLDH (PF/PV) COMBO (CARESTART)-CARESTART MALARIA HRP2/PLDH (PF/PV) IS A RAPID TEST IS INTENDED FOR THE DETECTION OF MALARIA ANTIGEN IN HUMAN BLOOD FOR PF/PV ,SURETEST MALARIA TEST KIT (SURETEST)-SURETEST MALARIA TEST KIT IS A RAPID TEST IS INTENDED FOR QUANTITATIVE DETERMINATION OF MALARIA HISTIDINE-RICH PROTEIN -2 (HRP2) AND LACTATE DEHYDROGENASE IN HUMAN BLOOD AS AN AID IN THE DIAGNOSIS OF MALARIA INFECTION

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192	IMP/IVD/2019/000157	1.License Holder Name: SYSMEX INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:UFII PACK-BAC(UFII PACK-BAC)-FOR IN VITRO DIAGNOSTIC USE ONLY UF II PACK-BAC IS A DILUENT TO ANALYZE BACTERIA IN URINE FOR DETERMINATION OF THE BACTERIAL COUNT WITH THE SYSMEX FULLY AUTOMATED URINE PARTICLE ANALYZERS UF-1000I AND UF-500I.,POCH-PACK L (II)(POCH-PACK L(II))-SYSMEX POCH PACK L (II) IS A REAGENT THAT LYSES RBC FOR ACCURATE WBC COUNT DETERMINATION, WBC TRIMODAL SIZE DISTRIBUTION ANALYSIS AND HEMOGLOBIN LEVEL MEASUREMENT. THE REAGENT IS COLORLESS TRANSPARENT AND CONTAINS NO CYANIDE OR AZIDE COMPOUND. IT IS INTENDED FOR USE IN CONJUNCTION WITH SELECTED SYSMEX POCH-100I AUTOMATED HEMATOLOGY ANALYZER.,UFII SHEATH(UFII SHEATH)-THE UFII SHEATH IS THE SHEATH FLUID USED IN ORDER TO ANALYZE THE DILUTED AND STAINED SAMPLES BY FLOW CYTOMETRY METHOD.,STROMATOLYSER-4DS(STROMATOLYSER-4DS)-STROMATOLYSER-4DS IS TO BE USED TO STAIN THE LEUKOCYTES IN DILUTED AND LYSED BLOOD SAMPLES FOR DETERMINATION OF 4-PART DIFFERENTIAL COUNT, OR 5-PART DIFFERENTIAL COUNT AND WBC COUNT WITH SYSMEX AUTOMATED HEMATOLOGY ANALYZERS (ON XS SERIES ONLY),UXII PACK-SED(UXII PACK-SED)-UXII PACK-SED DILUTES THE ASPIRATED MATERIAL SO THAT ERYTHROCYTES, LEUKOCYTES, EPITHELIAL CELLS, AND CASTS CAN BE MEASURED BY FLOW CYTOMETRY METHOD,UFII PACK-SED(UFII PACK-SED)-UFII PACK-SED DILUTES THE ASPIRATED SAMPLE SO THAT ERYTHROCYTES, LEUKOCYTES, EPITHELIAL CELLS, AND CASTS CAN BE MEASURES BY FLOW CYTOMETRY METHOD.,UXII SHEATH(UXII SHEATH)-THE UXII SHEATH IS THE SHEATH FLUID USED IN ORDER TO ANALYZE THE DILUTED AND STAINED MATERIALS BY FLOW CYTOMETRY METHOD.,SULFOLYSER(SULFOLYSER)-SULFOLYSER IS A REAGENT FOR THE AUTOMATED DETERMINATION OF HEMOGLOBIN CONCENTRATION OF BLOOD WITH SYSMEX AUTOMATED HEMATOLOGY ANALYZERS,POCH-PACK D(II)(POCH-PACK D(II))-DILUENT SYSMEX POCH- PACK D(II) FOR THE POCH-100I AUTOMATED HEMATOLOGY ANALYZER,CELLPACK DCL(CELLPACK DCL)-FOR IN VITRO DIAGNOSTIC USE ONLY CELLPACK DCL IS A REAGENT FOR MEASURING THE NUMBERS AND SIZES OF RBC AND PLATELETS BY THE HYDRODYNAMICALLY FOCUSSED DC DETECTION METHOD. WITH THE ADDITION OF THE SPECIFIED LYSE REAGENT FOR HEMOGLOBIN CONCENTRATION DETERMINATION, IT CAN ALSO BE USED TO ANALYZE HEMOGLOBIN CONCENTRATION. ALSO IT CAN BE USED AS A SHEATH FLUID FOR FCM DETECTOR. THIS REAGENT IS TO BE USED BY CONNECTING TO AN AUTOMATIC HEMATOLOGY ANALYZER

	SPECIFIED BY SYSMEX.,CELLPACK DFL(CELLPACK DFL)-FOR IN VITRO DIAGNOSTIC USE ONLY CELLPACK DFL IS A REAGENT USED IN COMBINATION WITH FLUOROCELL RET. AFTER DILUTING THE BLOOD WITH CELLPACK DFL, FLUOROCELL RET IS USED TO LABEL BLOOD CELL COMPONENTS AND THEREBY ANALYZE RED BLOOD CELL COUNT, RETICULOCYTE COUNT, RETICULOCYTE RATE, PLATELET COUNT, LOW FLUORESCENCE INTENSITY RATE, MIDDLE FLUORESCENCE INTENSITY RATE, HIGH FLUORESCENCE INTENSITY RATE, AND IMMATURE RETICULOCYTE FRACTION COUNT. THIS REAGENT IS TO BE USED BY CONNECTING TO AN AUTOMATED HEMATOLOGY ANALYZER SPECIFIED BY SYSMEX. ,UXII PACK-BAC (UXII PACK-BAC)-FOR IN VITRO DIAGNOSTIC USE ONLY UX PACK - BAC IS A DILUENT TO ANALYZE BACTERIA IN URINE FOR DETERMINATION OF THE BACTERIAL COUNT WITH THE SYSMEX FULLY AUTOMATED INTEGRATED URINE ANALYZER UX-2000. , STROMATOLYSER-WH(STROMATOLYSER-WH)-STROMATOLYSER WH IS A REAGENT THAT LYSES RBC FOR ACCURATE WBC COUNT DETERMINATION WBC TRIMODAL SIZE DISTRIBUTION ANALYSIS AND HEMOGLOBIN LEVEL MEASUREMENT. THE REAGENT IS COLORLESS TRANSPARENT AND CONTAINS NO CYANIDE OR AZIDE COMPOUND. IT IS INTENDED FOR USE IN CONJUNCTION WITH SELECTED SYSMEX AUTOMATED HEMATOLOGY ANALYZER.,STROMATOLYSER-4DL (STROMATOLYSER-4DL)-THE STROMATOLYSER-4DL IS A REAGENT THAT LYSES RBC FOR DETERMINATION OF 4-PART DIFFERENTIAL COUNT, OR 5-PART DIFFERENTIAL COUNT AND WBC COUNT WITH SYSMEX AUTOMATED HEMATOLOGY ANALYZERS (ON XS-SERIES ONLY),UF-CELLSHEATH(UF-CELLSHEATH)-FOR IN VITRO DIAGNOSTIC USE ONLY UF-CELLSHEATH IS A SHEATH FLUID FOR SYSMEX FULLY AUTOMATED URINE PARTICLE ANALYZERS. THIS REAGENT IS USED IN COMBINATION WITH OTHER REAGENTS TO OBTAIN A COUNT OF THE TARGET SUBSTANCE BY MEANS OF THE FLOW CYTOMETRY METHOD. ,CELLPACK(CELLPACK)-CELLPACK IS A DILUENT USED TO DILUTE ASPIRATED ANALYSIS SAMPLES IN ORDER TO MEASURE AN RBC COUNT, WBC COUNT, HEMOGLOBIN CONCENTRATION AND PLATELET COUNT.

193	IMP/IVD/2019/000157	1.License Holder Name: SYSMEX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LYSERCELL WNR (LYSERCELL WNR)-FOR IN VITRO DIAGNOSTIC USE ONLY. LYSERCELL WNR IS A REAGENT PRODUCT TO BE COMBINED AND USED WITH FLUOROCELL WNR. BY HEMOLYZING RED BLOOD CELLS WITH LYSERCELL WNR AND BY DIFFERENTIATING WHITE BLOOD CELLS (NON-BASOPHIL), BASOPHILS, AND NUCLEATED RED BLOOD CELLS WITH LYSERCELL WNR AND FLUOROCELL WNR, THE WHITE BLOOD CELL COUNT, BASOPHIL COUNT, BASOPHIL COUNT, BASOPHIL PERCENTAGE, NUCLEATED RED BLOOD CELL COUNT, AND NUCLEATED RED BLOOD CELL PERCENTAGE ARE ANALYZED. THIS REAGENT IS TO BE USED BY CONNECTING TO AN AUTOMATIC HEMATOLOGY ANALYZER SPECIFIED BY SYSMEX,LYSERCELL WDF (LYSERCELL WDF)-FOR IN VITRO DIAGNOSTIC USE ONLY. LYSERCELL WDF IS A REAGENT USED IN COMBINATION WITH FLUOROCELL WDF. BY HEMOLYZING RED BLOOD CELLS WITH LYSERCELL WDF AND DYEING THE WHITE BLOOD CELL COMPONENTS WITH FLUOROCELL WDF, THE COUNTS AND PERCENTAGES OF NEUTROPHILS, LYMPHOCYTES, MONOCYTES, EOSINOPHILS AND BASOPHILS ARE ANALYZED. THIS REAGENT IS TO BE USED BY CONNECTING TO AN AUTOMATED HEMATOLOGY ANALYZER SPECIFIED BY SYSMEX
194	IMP/IVD/2019/000158	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:UNIVERSAL WASH REAGENT(VITROS IMMUNODIAGNOSTIC PRODUCTS UNIVERSAL WASH REAGENT)-FOR USE WITH THE LMMUNODIAGNOSTIC SYSTEM AND INTEGRATED SYSTEM.

195	IMP/IVD/2019/000159	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVIA AUTOSLIDE MAY-GRUNWALD STAIN(ADVIA AUTOSLIDE MAY-GRUNWALD STAIN)-THE MAY-GRÜNWALD GIEMSA METHOD IS FOR IN VITRO DIAGNOSTIC USE IN THE DIFFERENTIAL STAINING OF BLOOD, BONE MARROW AND BODY FLUID SMEARS ON THE ADVIA® AUTOSLIDE SLIDE MAKER STAINER. STAINED SMEARS ARE EVALUATED TO IDENTIFY AND QUANTIFY CELLS IN WHOLE BLOOD AND OTHER SPECIMENS TO AID CLINICIANS IN THE ASSESSMENT OF VARIOUS CLINICAL CONDITIONS. ,ADVIA AUTOSLIDE GIEMSA STAIN(ADVIA AUTOSLIDE GIEMSA STAIN)-THE MAY-GRÜNWALD GIEMSA METHOD IS FOR IN VITRO DIAGNOSTIC USE IN THE DIFFERENTIAL STAINING OF BLOOD, BONE MARROW AND BODY FLUID SMEARS ON THE ADVIA® AUTOSLIDE SLIDE MAKER STAINER. STAINED SMEARS ARE EVALUATED TO IDENTIFY AND QUANTIFY CELLS IN WHOLE BLOOD AND OTHER SPECIMENS TO AID CLINICIANS IN THE ASSESSMENT OF VARIOUS CLINICAL CONDITIONS. ,ADVIA AUTOSLIDE MAY-GRUNWALD GIEMSA BUFFER(ADVIA AUTOSLIDE MAY-GRUNWALD GIEMSA BUFFER)-THE MAY-GRÜNWALD GIEMSA METHOD IS FOR IN VITRO DIAGNOSTIC USE IN THE DIFFERENTIAL STAINING OF BLOOD, BONE MARROW AND BODY FLUID SMEARS ON THE ADVIA® AUTOSLIDE SLIDE MAKER STAINER. STAINED SMEARS ARE EVALUATED TO IDENTIFY AND QUANTIFY CELLS IN WHOLE BLOOD AND OTHER SPECIMENS TO AID CLINICIANS IN THE ASSESSMENT OF VARIOUS CLINICAL CONDITIONS.

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196	IMP/IVD/2019/000161	1.License Holder Name: BIOGENY DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DS-I(NO.2) STANDARD A STANDARD B)(GENRUI)-IT IS USED WITH ELECTROLYTE ANALYZERS BY PROFESSIONALS, FOR THE DETECTION OF POTASSIUM (K+), SODIUM (NA+), CHLORIDE (CL-), CALCIUM (CA2+), LITHIUM (LI+), PH (PH VALUE) IN HUMAN SERUM.,RHEUMATOID FACTOR DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) CONTENT IN HUMAN SERUM OR PLASMA.,C-REACTIVE PROTEIN DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) CONTENT IN HUMAN SERUM OR WHOLE BLOOD.,ANTI-CYCLIC CITRULLINATED PEPTIDE ANTIBODY DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF ANTI-CYCLIC CITRULLINATED PEPTIDE ANTIBODY (CCP) CONTENT IN HUMAN BLOOD SERUM., GLYCATED HEMOGLOBIN (HBA1C) DETECTION KIT (NEPHELOMETRY) (GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF THE PERCENTAGE CONTENT OF GLYCATED HEMOGLOBIN IN HUMAN BLOOD.,HUMAN MICRO-ALBUMINURIA DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF MICRO-ALBUMINURIA (MALB) IN HUMAN URINE., ANTI-STREPTOLYSIN O DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF ANTI-STREPTOLYSIN O (ASO) CONTENT IN HUMAN SERUM OR PLASMA., HIGH SENSITIVE C-REACTIVE PROTEIN DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF HIGH SENSITIVE C-REACTIVE PROTEIN (HS-CRP) CONTENT IN HUMAN SERUM OR WHOLE BLOOD.

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197	IMP/IVD/2019/000162	1.License Holder Name: SYSMEX INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROLS(XN CHECK L3) -XN CHECK IS INTENDED TO BE USED AS A CONTROL FOR COMPLETE BLOOD CELL COUNT (CBC), WHITE BLOOD CELL DIFFERENTIAL, RETICULOCYTE, NUCLEATED RED BLOOD CELL (NRBC) AND MI-RBC PARAMETERS ON SYSMEX XN SERIES, XN-L SERIES, XN-31 INSTRUMENTS.,CONTROLS(XN CHECK L2)-XN CHECK IS INTENDED TO BE USED AS A CONTROL FOR COMPLETE BLOOD CELL COUNT (CBC), WHITE BLOOD CELL DIFFERENTIAL, RETICULOCYTE, NUCLEATED RED BLOOD CELL (NRBC) AND MI-RBC PARAMETERS ON SYSMEX XN SERIES, XN-L SERIES, XN-31 INSTRUMENTS.,CONTROLS(XN CHECK L1) -XN CHECK IS INTENDED TO BE USED AS A CONTROL FOR COMPLETE BLOOD CELL COUNT (CBC), WHITE BLOOD CELL DIFFERENTIAL, RETICULOCYTE, NUCLEATED RED BLOOD CELL (NRBC) AND MI-RBC PARAMETERS ON SYSMEX XN SERIES, XN-L SERIES, XN-31 INSTRUMENTS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

198	IMP/IVD/2019/000162	1.License Holder Name: SYSMEX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROLS(XN CHECK L1) -XN CHECK IS INTENDED TO BE USED AS A CONTROL FOR COMPLETE BLOOD CELL COUNT (CBC), WHITE BLOOD CELL DIERENTIAL, RETICULOCYTE, AND NUCLEATED RED BLOOD CELL (NRBC) PARAMETERS ON SYSMEX X SERIES INSTRUMENTS.,CONTROLS(WRP CHECK EX)-WRP CHECK EX IS USED FOR VERIFICATION OF THE REPORTABLE RANGE ON SYSMEX XN SERIES HEMATOLOGY ANALYZERS,CONTROLS(E-CHECK (XE) L2)-E-CHECK(XE) IS INTENDED TO BE USED AS A CONTROL FOR COMPLETE BLOOD CELL COUNT (CBC), WHITE BLOOD CELL DIFFERENTIAL, RETICULOCYTE AND NUCLEATED RED BLOOD CELL (NRBC) PARAMETERS ON SYSMEX X-SERIES INSTRUMENTS.,CONTROLS(EIGHTCHECK-3WP-N)-EIGHTCHECK-3WP-N, ARE HEMATOLOGY CONTROL MATERIALS PRIMARILY FOR INTRALABORATORY QUALITY CONTROL OF AUTOMATED, SEMIAUTOMATED AND MANUAL PROCEDURES THAT MEASURE COMPONENTS OF BLOOD. ADDITIONALLY, EIGHTCHECK-3WP-N, CAN BE USED IN EXTERNAL QUALITY ASSESSMENT. DO NOT USE EIGHTCHECK-3WP-N, TO CALIBRATE THE INSTRUMENT!, CONTROLS(EIGHTCHECK-3WP-L)- EIGHTCHECK-3WP-L, ARE HEMATOLOGY CONTROL MATERIALS PRIMARILY FOR INTRALABORATORY QUALITY CONTROL OF AUTOMATED, SEMIAUTOMATED AND MANUAL PROCEDURES THAT MEASURE COMPONENTS OF BLOOD. ADDITIONALLY, EIGHTCHECK-3WP-L, CAN BE USED IN EXTERNAL QUALITY ASSESSMENT. DO NOT USE EIGHTCHECK-3WP-L, TO CALIBRATE THE INSTRUMENT!,CONTROLS (XN CHECK L3)- XN CHECK IS INTENDED TO BE USED AS A CONTROL FOR COMPLETE BLOOD CELL COUNT (CBC), WHITE BLOOD CELL DIERENTIAL, RETICULOCYTE, AND NUCLEATED RED BLOOD CELL (NRBC) PARAMETERS ON SYSMEX X SERIES INSTRUMENTS, CALIBRATOR(XN CAL)-XN CAL IS A CALIBRATOR FOR SYSMEX X SERIES. IT IS DESIGNED FOR THE CALIBRATION AND CALIBRATION VERIFICATION OF WBC, RBC, HGB, HCT, PLT AND RET,CONTROLS (EIGHTCHECK-3WP-H)- EIGHTCHECK-3WP-H, ARE HEMATOLOGY CONTROL MATERIALS PRIMARILY FOR INTRALABORATORY QUALITY CONTROL OF AUTOMATED, SEMIAUTOMATED AND MANUAL PROCEDURES THAT MEASURE COMPONENTS OF BLOOD. ADDITIONALLY, EIGHTCHECK-3WP-H, CAN BE USED IN EXTERNAL QUALITY ASSESSMENT. DO NOT USE EIGHTCHECK-3WP-H, TO CALIBRATE THE INSTRUMENT!,CALIBRATOR(XN CAL PF)-XN CAL PF IS A CALIBRATOR FOR SYSMEX X SERIES. IT IS DESIGNED FOR THE CALIBRATION AND CALIBRATION VERIFICATION OF PLT-F., CONTROLS(EIGHTCHECK-3WP-L)-EIGHTCHECK-3WP-L, ARE

	HEMATOLOGY CONTROL MATERIALS PRIMARILY FOR INTRALABORATORY QUALITY CONTROL OF AUTOMATED, SEMIAUTOMATED AND MANUAL PROCEDURES THAT MEASURE COMPONENTS OF BLOOD. ADDITIONALLY, EIGHTCHECK-3WP-L, CAN BE USED IN EXTERNAL QUALITY ASSESSMENT. DO NOT USE EIGHTCHECK-3WP-L, TO CALIBRATE THE INSTRUMENT!,CONTROLS(E-CHECK (XS) L3)-E-CHECK(XS) IS A HEMATOLOGY CONTROL MATERIAL PRIMARILY FOR INTRALABORATORY QUALITY CONTROL OF AUTOMATED, SEMIAUTOMATED AND MANUAL PROCEDURES THAT MEASURE COMPONENTS OF THE BLOOD. ADDITIONALLY, E-CHECK (XS) CAN BE USED IN EXTERNAL QUALITY ASSESSMENT. DO NOT USE E-CHECK(XS) TO CALIBRATE THE INSTRUMENT,CONTROLS (EIGHTCHECK-3WP-N)-EIGHTCHECK-3WP-N, ARE HEMATOLOGY CONTROL MATERIALS PRIMARILY FOR INTRALABORATORY QUALITY CONTROL OF AUTOMATED, SEMIAUTOMATED AND MANUAL PROCEDURES THAT MEASURE COMPONENTS OF BLOOD. ADDITIONALLY, EIGHTCHECK-3WP-N, CAN BE USED IN EXTERNAL QUALITY ASSESSMENT. DO NOT USE EIGHTCHECK-3WP-N, TO CALIBRATE THE INSTRUMENT!,CONTROLS(XN CHECK L2)-XN CHECK IS INTENDED TO BE USED AS A CONTROL FOR COMPLETE BLOOD CELL COUNT (CBC), WHITE BLOOD CELL DIERENTIAL, RETICULOCYTE, AND NUCLEATED RED BLOOD CELL (NRBC) PARAMETERS ON SYSMEX X SERIES INSTRUMENTS.,CONTROLS(XN CHECK BF)-XN CHECK BF IS INTENDED TO BE USED AS A CONTROL FOR TOTAL NUCLEAR CELL (TNC), WHITE BLOOD CELL, RED BLOOD CELL AND WHITE BLOOD CELL DIFFERENTIAL PARAMETERS ON SYSMEX X SERIES INSTRUMENTS.,CONTROLS(E-CHECK (XE) L1)-E-CHECK(XE) IS INTENDED TO BE USED AS A CONTROL FOR COMPLETE BLOOD CELL COUNT (CBC), WHITE BLOOD CELL DIFFERENTIAL, RETICULOCYTE AND NUCLEATED RED BLOOD CELL (NRBC) PARAMETERS ON SYSMEX X-SERIES INSTRUMENTS.,CONTROLS(XN-L CHECK L1)-XN-L CHECK IS INTENDED TO BE USED AS A CONTROL FOR COMPLETE BLOOD CELL COUNT (CBC), WHITE BLOOD CELL DIFFERENTIAL AND RETICULOCYTE PARAMETERS ON SYSMEX XN-L SERIES INSTRUMENTS.,CONTROLS(E-CHECK (XS) L2)-E-CHECK(XS) IS A HEMATOLOGY CONTROL MATERIAL PRIMARILY FOR INTRALABORATORY QUALITY CONTROL OF AUTOMATED, SEMIAUTOMATED AND MANUAL PROCEDURES THAT MEASURE COMPONENTS OF THE BLOOD. ADDITIONALLY, E-CHECK(XS) CAN BE USED IN EXTERNAL QUALITY ASSESSMENT. DO NOT USE E-CHECK (XS) TO CALIBRATE THE INSTRUMENT,CALIBRATOR(SCS-1000)-THE SCS-1000 IS A CALIBRATOR FOR SYSMEX HAEMATOLOGY ANALYSERS. IT IS DESIGNED FOR THE CALIBRATION AND CALIBRATION VERIFICATION OF WBC, RBC, HGB, HCT/MCV AND PLT,

	CONTROLS(XN-L CHECK L2)- XN-L CHECK IS INTENDED TO BE USED AS A CONTROL FOR COMPLETE BLOOD CELL COUNT (CBC), WHITE BLOOD CELL DIFFERENTIAL AND RETICULOCYTE PARAMETERS ON SYSMEX XN-L SERIES INSTRUMENTS,CONTROLS(XN-L CHECK L3)- XN-L CHECK IS INTENDED TO BE USED AS A CONTROL FOR COMPLETE BLOOD CELL COUNT (CBC), WHITE BLOOD CELL DIFFERENTIAL AND RETICULOCYTE PARAMETERS ON SYSMEX XN-L SERIES INSTRUMENTS,CONTROLS(E-CHECK (XE) L3)-E-CHECK(XE) IS INTENDED TO BE USED AS A CONTROL FOR COMPLETE BLOOD CELL COUNT (CBC), WHITE BLOOD CELL DIFFERENTIAL, RETICULOCYTE AND NUCLEATED RED BLOOD CELL (NRBC) PARAMETERS ON SYSMEX X-SERIES INSTRUMENTS.,CONTROLS(WRP CHECK)-WRP CHECK IS USED FOR VERIFICATION OF THE REPORTABLE RANGE ON SYSMEX XE, XT, XS, XP, KX-21N AND POCH-100I HEMATOLOGY ANALYZERS, CONTROLS(EIGHTCHECK-3WP-H)-EIGHTCHECK-3WP-H, ARE HEMATOLOGY CONTROL MATERIALS PRIMARILY FOR INTRALABORATORY QUALITY CONTROL OF AUTOMATED, SEMIAUTOMATED AND MANUAL PROCEDURES THAT MEASURE COMPONENTS OF BLOOD. ADDITIONALLY, EIGHTCHECK-3WP-H, CAN BE USED IN EXTERNAL QUALITY ASSESSMENT. DO NOT USE EIGHTCHECK-3WP-H, TO CALIBRATE THE INSTRUMENT!,CONTROLS (E-CHECK (XS) L1)-E-CHECK(XS) IS A HEMATOLOGY CONTROL MATERIAL PRIMARILY FOR INTRALABORATORY QUALITY CONTROL OF AUTOMATED, SEMIAUTOMATED AND MANUAL PROCEDURES THAT MEASURE COMPONENTS OF THE BLOOD. ADDITIONALLY, E-CHECK (XS) CAN BE USED IN EXTERNAL QUALITY ASSESSMENT. DO NOT USE E-CHECK(XS) TO CALIBRATE THE INSTRUMENT

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

199	IMP/IVD/2019/000163	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MPA CONTROL(MPA CONTROL)-MORE DIAGNOSTICS MYCOPHENOLIC ACID CONTROL IS INTENDED TO BE USED AS AN ASSAYED CONTROL PRODUCT IN MONITORING ACCURACY AND PRECISION FOR QUANTITATIVE METHODS THAT MEASURE MYCOPHENOLIC ACID.,RAP/TAC/CSA CONTROL(RAP/TAC/CSA CONTROL)-MORE DIAGNOSTICS RAP/TAC/CSA CONTROL IS INTENDED TO BE USED AS A WHOLE BLOOD PRECISION CONTROL PRODUCT FOR THE MEASUREMENT OF RAPAMYCIN,TACROMILUS AND CYCLOSPORINE.,CYCLOSPORINE C2 CONTROL(CYCLOSPORINE C2 CONTROL)-MORE DIAGNOSTICS CYCLOSPORINE C2 CONTROLS ARE ASSAYED QUALITY CONTROL MATERIALS FOR MONITORING AND EVALUATING PRECISION AND ACCURACY OF QUANTITATIVE CYCLOSPORINE MEASUREMENTS IN WHOLE BLOOD.
200	IMP/IVD/2019/000164	1.License Holder Name: MICROGENE DIAGNOSTIC SYSTEMS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENGUE NS1 ELISA(DENV DETECT NS1 ELISA)-DENV DETECT NS1 ELISA IS INTENDED FOR THE DETECTION OF DENGUE NS1 ANTIGEN OF DENGUE VIRUS IN HUMAN SERUM.
201	IMP/IVD/2019/000165	1.License Holder Name: RTS LIFECARE INDIA PRIVATE LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URINE REAGENT STRIPS, URINE (VAGINAL BACTERIAL) PH 0-14 TEST STRIP(SAMPOORNA)-TO TEST PH FROM 0-14,URINE REAGENT STRIPS,3 PARAMETER, NITRITE, LEUKOCYTES PH (AAROGYAM)-TO TEST LEU, NIT, PH,URINE REAGENT STRIPS,URINE (VAGINAL BACTERIAL) PH 4.5-9.0 TEST STRIP(SAKHI)-TO TEST PH 4.5-9.0,URINE REAGENT STRIPS 14 PARAMETERS TEST STRIP(SANKET)-TO TEST 14 PARAMETERS IN URINE,URINE REAGENT STRIPS,URINE (SALIVA) PH 0-14 TEST STRIP(JEEVAN CHETNA)-TO TEST PH 0-14 TEST STRIP

202	IMP/IVD/2019/000166	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMMULITE 2000/IMMULITE 2500 PROBE WASH MODULE(IMMULITE 2000/IMMULITE 2500 PROBE WASH MODULE)-FOR USE IN THE ROUTINE OPERATION OF IMMULITE 2000 AND IMMULITE 2500 ANALYZERS, AS DESCRIBED IN THE OPERATOR'S MANUAL.,IMMULITE PROBE CLEANING KIT(IMMULITE PROBE CLEANING KIT)-FOR USE IN DAILY MAINTENANCE OF THE IMMULITE AND IMMULITE 1000 SYSTEMS- TO MINIMIZE REAGENT CARRY OVER BY REDUCING PROTEIN AND LIPID BUILD UP IN THE PROBE.,IMMULITE 2000/IMMULITE 2500 PROBE CLEANING KIT(IMMULITE 2000/IMMULITE 2500 PROBE CLEANING KIT)-FOR USE IN DAILY MAINTENANCE OF THE IMMULITE 2000 AND IMMULITE 2500 ANALYZERS TO MINIMIZE THE REAGENT CARRYOVER BY REDUCING PROTEIN AND LIPID BUILDUP IN THE PROBES.,IMMULITE PROBE WASH MODULE(IMMULITE PROBE WASH MODULE)-FOR USE IN THE ROUTINE OPERATION OF IMMULITE AND IMMULITE 1000 ANALYZERS, AS DESCRIBED IN THE OPERATOR'S MANUAL.,N ANTISERUM TO HUMAN PLASMINOGEN(N ANTISERUM TO HUMAN PLASMINOGEN)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF COAGULATION FACTORS (FIBRINOGEN, ANTITHROMBIN III AND PLASMINOGEN) IN HUMAN PLASMA AND C1 INHIBITOR (C1INACTIVATOR, C1ESTERASE INHIBITOR) IN HUMAN PLASMA AND SERUM USING THE BN II AND BN PROSPEC SYSTEM.,N ANTISERUM TO HUMAN APOLIPOPROTEIN B(N ANTISERUM TO HUMAN APOLIPOPROTEIN B)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A-I (APO A-I) AND APOLIPOPROTEIN B (APO B) IN HUMAN SERUM AND HEPARINIZED PLASMA BY MEANS OF IMMUNONEPHELOMETRY ON THE BN II AND BN PROSPEC SYSTEM.,N ANTISERUM TO HUMAN C1 INHIBITOR(N ANTISERUM TO HUMAN C1 INHIBITOR)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF COAGULATION FACTORS (FIBRINOGEN, ANTITHROMBIN III AND PLASMINOGEN) IN HUMAN PLASMA AND C1 INHIBITOR (C1INACTIVATOR, C1ESTERASE INHIBITOR) IN HUMAN PLASMA AND SERUM USING THE BN II AND BN PROSPEC SYSTEM,N ANTISERUM TO HUMAN-A2-MACROGLOBULIN(N ANTISERUM TO HUMAN-A2-MACROGLOBULIN)-IN-VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF 2-MACROGLOBULIN IN HUMAN SERUM AND HEPARINIZED PLASMA AS WELL AS URINE BY MEANS OF IMMUNONEPHELOMETRY ON THE BN SYSTEMS. MEASUREMENTS OF 2-MACROGLOBULIN AID IN THE DIAGNOSIS OF BLOOD CLOTTING OR BLOOD LYSIS DISORDERS.,N ANTISERUM TO HUMAN-IG/L-CHAIN,

	L TYPE(N ANTISERUM TO HUMAN-IG/L-CHAIN, L TYPE)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF BOUND AND FREE AND TYPES OF HUMAN IMMUNOGLOBULIN LIGHT CHAINS IN HUMAN SERUM AND URINE BY MEANS OF IMMUNONEPHELOMETRY ON THE BN SYSTEMS.,N LATEX IGM(N LATEX IGM)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF IGM IN HUMAN CEREBROSPINAL FLUID (CSF) BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHILOMETRY USING THE BN II AND BN PROSPEC® SYSTEM.,N LATEX BTP(N LATEX BTP)-IN-VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF BETA-TRACE PROTEIN (BTP) IN HUMAN SERUM, HEPARINIZED AND EDTA-PLASMA, URINE, CSF AND NASAL AND/OR EAR SECRETIONS CONTAINING CSF USING THE BN SYSTEMS,N LATEX ADNASE B(N LATEX ADNASE B)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF ANTI-STREPTOCOCCAL DNASE B (AD-NASE B) IN HUMAN SERUM BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY USING THE BN II AND BN PROSPEC SYSTEM.,N ANTISERUM TO HUMAN TRANSFERRIN(N ANTISERUM TO HUMAN TRANSFERRIN)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF TRANSFERRIN AND HAPTOGLOBIN IN HUMAN SERUM, HEPARINIZED AND EDTA PLASMA, AS WELL AS OF TRANSFERRIN IN HUMAN URINE BY MEANS OF IMMUNONEPHELOMETRY ON THE BN II AND BN PROSPEC SYSTEM,N LATEX FERRITIN(N LATEX FERRITIN)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM OR HEPARINIZED PLASMA BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY USING THE BN II AND BN PROSPEC SYSTEM.,N ANTISERUM TO HUMAN ALBUMIN(N ANTISERUM TO HUMAN ALBUMIN)-IN-VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM, HEPARINIZED AND EDTA PLASMA, AS WELL AS IN HUMAN URINE AND CEREBROSPINAL FLUID (CSF) BY MEANS OF IMMUNONEPHELOMETRY ON THE BN II AND BN PROSPEC SYSTEM,N ANTISERUM TO HUMAN CERULOPLASMIN(N ANTISERUM TO HUMAN CERULOPLASMIN)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF CERULOPLASMIN AND HEMOPEXIN IN HUMAN SERUM AND HEPARINIZED PLASMA BY MEANS OF IMMUNONEPHELOMETRY ON THE BN II AND BN PROSPEC SYSTEM.,N LATEX ASL(N LATEX ASL)-QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN O (ASL) IN HUMAN SERUM, HEPARINIZED PLASMA AND EDTA-PLASMA ON THE BN II AND BN PROSPEC SYSTEMS. MEASUREMENTS OF ANTISTREPTOLYSIN O AID IN THE DIAGNOSIS OF DISEASE CAUSED BY BACTERIA BELONGING TO THE

	GENUS STREPTOCOCCUS AND PROVIDES EPIDEMIOLOGICAL INFORMATION ON THESE DISEASES. PATHOGENIC STREPTOCOCCI ARE ASSOCIATED WITH INFECTIONS, SUCH AS IMPETIGO, URINARY TRACT INFECTIONS, RHEUMATIC FEVER, AND KIDNEY DISEASE.,N RHEUMATOLOGY STANDARD SL(N RHEUMATOLOGY STANDARD SL)-ESTABLISHMENT OF REFERENCE CURVES FOR THE IMMUNONEPHELOMETRIC DETERMINATION OF RHEUMATOID FACTORS (RF) ANTI-STREPTOLYSIN O (ASL) C-REACTIVE PROTEIN (CRP) USING THE BN II AND BN PROSPEC SYSTEM. ,N ANTISERUM TO HUMAN IGG(N ANTISERUM TO HUMAN IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULINS (IGG, IGA AND IGM) IN HUMAN SERUM, HEPARINIZED AND EDTA PLASMA AS WELL AS OF IGG IN HUMAN URINE AND CEREBROSPINAL FLUID (CSF) BY MEANS OF IMMUNONEPHELOMETRY ON THE BN SYSTEMS,N ANTISERUM TO HUMAN IGM(N ANTISERUM TO HUMAN IGM)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULINS (IGG, IGA AND IGM) IN HUMAN SERUM, HEPARINIZED AND EDTA PLASMA AS WELL AS OF IGG IN HUMAN URINE AND CEREBROSPINAL FLUID (CSF) BY MEANS OF IMMUNONEPHELOMETRY ON THE BN SYSTEMS.,N LATEX LP(A) REAGENT(N LATEX LP(A) REAGENT)-IN-VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN(A) [LP (A)] IN HUMAN SERUM AND HEPARINIZED PLASMA BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY USING THE BN II AND BN PROSPEC SYSTEM. MEASUREMENT OF LP(A) AIDS IN THE IDENTIFICATION OF INDIVIDUALS AT RISK FROM CARDIOVASCULAR DISEASE IN SPECIFIC POPULATIONS WHEN USED IN CONJUNCTION WITH CLINICAL EVALUATION,N ANTISERUM TO HUMAN C3C(N ANTISERUM TO HUMAN C3C)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT FACTORS (C3/C3C AND C4/C4C) IN HUMAN SERUM OR HEPARINIZED OR EDTA PLASMA BY MEANS OF IMMUNONEPHELOMETRY ON THE BN II AND BN PROSPEC SYSTEM AS AN AID IN THE DIAGNOSIS OF IMMUNOLOGIC DISORDERS ASSOCIATED WITH COMPLEMENT C3 OR C4 PROTEIN.,N ANTISERUM TO HUMAN FIBRINOGEN(N ANTISERUM TO HUMAN FIBRINOGEN)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF COAGULATION FACTORS (FIBRINOGEN, ANTITHROMBIN III AND PLASMINOGEN) IN HUMAN PLASMA AND C1 INHIBITOR (C1INACTIVATOR, C1ESTERASE INHIBITOR) IN HUMAN PLASMA AND SERUM USING THE BN II AND BN PROSPEC SYSTEM,N LATEX IGE MONO(N LATEX IGE MONO)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF IGE IN HUMAN SERUM, EDTA AND HEPARINIZED PLASMA BY MEANS

	OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY USING THE BN II AND BN PROSPEC SYSTEM.,N ANTISERUM TO HUMAN IGA(N ANTISERUM TO HUMAN IGA)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULINS (IGG, IGA AND IGM) IN HUMAN SERUM, HEPARINIZED AND EDTA PLASMA AS WELL AS OF IGG IN HUMAN URINE AND CEREBROSPINAL FLUID (CSF) BY MEANS OF IMMUNONEPHELOMETRY ON THE BN SYSTEMS.,N ANTISERUM TO HUMAN C4(N ANTISERUM TO HUMAN C4)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT FACTORS (C3/C3C AND C4/C4C) IN HUMAN SERUM OR HEPARINIZED OR EDTA PLASMA BY MEANS OF IMMUNONEPHELOMETRY ON THE BN II AND BN PROSPEC SYSTEM AS AN AID IN THE DIAGNOSIS OF IMMUNOLOGIC DISORDERS ASSOCIATED WITH COMPLEMENT C3 OR C4 PROTEIN.,N LATEX SAA(N LATEX SAA)-IN VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF SERUM AMYLOID A (SAA) IN HUMAN SERUM AND HEPARINIZED PLASMA BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY USING THE BN II OR BN PROSPEC SYSTEM.,N LATEX CYSTATIN C(N LATEX CYSTATIN C)-N LATEX CYSTATIN C IS AN IN VITRO DIAGNOSTICS KIT CONTAINING REAGENTS FOR THE QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM AND HEPARINIZED PLASMA BY MEANS OF PARTICLEENHANCED IMMUNONEPHELOMETRY USING THE BN SYSTEMS. CYSTATIN C MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASES. ,N ANTISERUM TO HUMAN HAPTOGLOBIN(N ANTISERUM TO HUMAN HAPTOGLOBIN)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF TRANSFERRIN AND HAPTOGLOBIN IN HUMAN SERUM, HEPARINIZED AND EDTA PLASMA, AS WELL AS OF TRANSFERRIN IN HUMAN URINE BY MEANS OF IMMUNONEPHELOMETRY ON THE BN II AND BN PROSPEC SYSTEM,N ANTISERUM TO HUMAN 1-ANTITRYPSIN(N ANTISERUM TO HUMAN 1-ANTITRYPSIN)-IN-VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF 1-ANTITRYPSIN (1-PROTEINASE INHIBITOR) IN HUMAN SERUM, HEPARINIZED AND EDTA PLASMA BY MEANS OF IMMUNONEPHELOMETRY ON THE BN II AND BN PROSPEC SYSTEM, ANTI STREPTOCOCCUS DNASE B(ANTI STREPTOCOCCUS DNASE B)-IN-VITRO DIAGNOSTIC FOR THE SEMI-QUANTITATIVE DETERMINATION OF ANTI-STREPTOCOCCUS DESOXYRIBONUCLEASE B (ADNASE B) IN HUMAN SERUM THROUGH THE INHIBITION OF ENZYMATIC DNA CLEAVAGE,N ANTISERUM TO HUMAN ANTITHROMBIN III(N ANTISERUM TO HUMAN ANTITHROMBIN III)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF COAGULATION FACTORS (FIBRINOGEN,

	ANTITHROMBIN III AND PLASMINOGEN) IN HUMAN PLASMA AND C1 INHIBITOR (C1INACTIVATOR, C1ESTERASE INHIBITOR) IN HUMAN PLASMA AND SERUM USING THE BN II AND BN PROSPEC SYSTEM. IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF BOUND AND FREE AND TYPES OF HUMAN IMMUNOGLOBULIN LIGHT CHAINS IN HUMAN SERUM AND URINE BY MEANS OF IMMUNONEPHELOMETRY ON THE BN SYSTEMS.,N LATEX IGA(N LATEX IGA)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF IGA IN HUMAN CEREBROSPINAL FLUID (CSF) AND IN PAIRED CSF AND SERUM SAMPLES BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY USING THE BN II AND BN PROSPEC SYSTEM. THE DETERMINATION OF IGA AIDS IN THE EVALUATION OF THE PATIENT'S IMMUNE SYSTEM,N ANTISERUM TO HUMAN-IG/L-CHAIN, K TYPE(N ANTISERUM TO HUMAN-IG/L-CHAIN, K TYPE)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF COAGULATION FACTORS (FIBRINOGEN, ANTITHROMBIN III AND PLASMINOGEN) IN HUMAN PLASMA AND C1 INHIBITOR (C1INACTIVATOR, C1ESTERASE INHIBITOR) IN HUMAN PLASMA AND SERUM USING THE BN II AND BN PROSPEC SYSTEM. IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF BOUND AND FREE AND TYPES OF HUMAN IMMUNOGLOBULIN LIGHT CHAINS IN HUMAN SERUM AND URINE BY MEANS OF IMMUNONEPHELOMETRY ON THE BN SYSTEMS.,N LATEX CDT KIT(N LATEX CDT KIT)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF CARBOHYDRATE-DEFICIENT TRANSFERRIN (CDT) IN HUMAN SERUM BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY USING THE BN II AND BN PROSPEC SYSTEM FOR THE IDENTIFICATION OF CHRONIC ELEVATED ALCOHOL CONSUMPTION.,N ANTISERUM TO HUMAN PREALBUMIN(N ANTISERUM TO HUMAN PREALBUMIN)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF PREALBUMIN (TRANSTHYRETIN) AND RETINOL-BINDING PROTEIN (RBP) IN HUMAN SERUM AND HEPARINIZED PLASMA BY MEANS OF IMMUNONEPHELOMETRY ON THE BN II AND BN PROSPEC SYSTEM.,N ANTISERUM TO HUMAN 1-ACID GLYCOPROTEIN(N ANTISERUM TO HUMAN 1-ACID GLYCOPROTEIN)-IN-VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF 1-ACID GLYCOPROTEIN IN HUMAN SERUM AND HEPARINIZED PLASMA BY MEANS OF IMMUNONEPHELOMETRY ON THE BN II AND BN PROSPEC SYSTEM.,N SAMPLE DILUENT(N SAMPLE DILUENT)-SOLUTION FOR PREPARING SAMPLE DILUTIONS FOR IMMUNOCHEMICAL DETERMINATIONS WITH THE BN SYSTEMS. THE SOLUTION IS USED WITH THE FOLLOWING TEST: N LATEX BTP (REF 10709757).,N ANTISERUM TO HUMAN HEMOPEXIN(N ANTISERUM TO HUMAN

	HEMOPEXIN)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF CERULOPLASMIN AND HEMOPEXIN IN HUMAN SERUM AND HEPARINIZED PLASMA BY MEANS OF IMMUNONEPHELOMETRY ON THE BN II AND BN PROSPEC SYSTEM ,N/T PROTEIN CONTROL SL/H(N/T PROTEIN CONTROL SL/H) -THE N/T PROTEIN CONTROLS SL/L, M AND H ARE FOR USE AS ASSAYED ACCURACY CONTROLS AND PRECISION CONTROLS IN THE DETERMINATION OF THE FOLLOWING HUMAN SERUM PROTEINS BY IMMUNONEPHELOMETRY WITH THE BN II AND BN PROSPEC SYSTEM AND BY RADIAL IMMUNODIFFUSION (RID) WITH PARTIGEN PLATES. , PROTEIN STANDARD SERUM LC(PROTEIN STANDARD SERUM LC)-N PROTEIN CONTROLS LC1/LC2 ARE ASSAYED INTRALABORATORY QUALITY CONTROLS FOR ASSESSMENT OF PRECISION AND ANALYTICAL BIAS FOR IMMUNOCHEMICAL DETERMINATIONS OF THE PROTEINS IGG IN URINE AND CSF, IGA IN CSF, IGM IN CSF, TRANSFERRIN IN URINE, ALBUMIN IN URINE AND CSF, 2MACROGLOBULIN IN URINE, IMMUNOGLOBULIN LIGHT CHAINS (TYPES KAPPA AND LAMBDA) IN URINE, 1MICROGLOBULIN IN URINE AND -TRACE PROTEIN USING THE BN SYSTEMS. FOR THE PREPARATION OF REFERENCE CURVES FOR THE IMMUNOCHEMICAL DETERMINATION OF 1ANTITRYPSIN (1-PROTEINASE INHIBITOR) IN RADIAL IMMUNODIFFUSION (RID) WITH LC-PARTIGEN PLATES.,N LP (A) STANDARD SY(N LP (A) STANDARD SY)-ESTABLISHMENT OF REFERENCE CURVES FOR THE IMMUNONEPHELOMETRIC DETERMINATION OF HUMAN LIPOPROTEIN(A) [LP(A)] IN SERUM AND PLASMA WITH THE BN II AND BN PROSPEC SYSTEM.,N ANTISERUM TO APOLIPOPROTEIN E(N ANTISERUM TO APOLIPOPROTEIN E)-IN VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A-II (APO A-II)AND APOLIPOPROTEIN E (APO E) IN HUMAN SERUM WITH THE BN SYSTEMS. ,ANTISERUM TO HUMAN C5 (ANTISERUM TO HUMAN C5)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUALITATIVE DETECTION OF C1Q, C3 ACTIVATOR, C5 AND IGD IN HUMAN SERUM, HEPARINIZED AND EDTA-PLASMA BY MEANS OF IMMUNOCHEMICAL GEL PRECIPITATION. ,N PROTEIN CONTROL LC1(N PROTEIN CONTROL LC1)-N PROTEIN CONTROLS LC1/LC2 ARE ASSAYED INTRALABORATORY QUALITY CONTROLS FOR ASSESSMENT OF PRECISION AND ANALYTICAL BIAS FOR IMMUNOCHEMICAL DETERMINATIONS OF THE PROTEINS IGG IN URINE AND CSF, IGA IN CSF, IGM IN CSF, TRANSFERRIN IN URINE, ALBUMIN IN URINE AND CSF, 2MACROGLOBULIN IN URINE, IMMUNOGLOBULIN LIGHT CHAINS (TYPES KAPPA AND LAMBDA) IN URINE, 1MICROGLOBULIN IN URINE AND -TRACE PROTEIN USING THE BN SYSTEMS. ,ANTISERUM TO HUMAN C3 ACTIVATOR (ANTISERUM TO HUMAN C3 ACTIVATOR)-IN-VITRO DIAGNOSTIC

	REAGENTS FOR THE QUALITATIVE DETECTION OF C1Q, C3 ACTIVATOR, C5 AND IGD IN HUMAN SERUM, HEPARINIZED AND EDTA-PLASMA BY MEANS OF IMMUNOCHEMICAL GEL PRECIPITATION. ,N SUPPLEMENTARY REAGENT/ PRECIPITATION(N SUPPLEMENTARY REAGENT/ PRECIPITATION)-SUPPLEMENTARY REAGENT FOR THE QUANTITATIVE IMMUNOCHEMICAL DETERMINATION OF ANTITHROMBIN III, APOLIPOPROTEIN A-I, APOLIPOPROTEIN B, C1-INHIBITOR, FIBRINOGEN, IGA, IGM, IGG2, IGG4, PLASMINOGEN, PREALBUMIN AND RBP WITH THE CORRESPONDING N ANTISERA OR ASL WITH N LATEX ASL, CRP WITH CARDIOPHASE HSCRP AS WELL AS IGG3 WITH N LATEX IGG3 AND IGG4 WITH N LATEX IGG4 ON THE BN II AND BN PROSPEC SYSTEM. ,N APOLIPOPROTEIN STANDARD SERUM (N APOLIPOPROTEIN STANDARD SERUM)-ESTABLISHMENT OF REFERENCE CURVES FOR THE QUANTITATIVE IMMUNONEPHELOMETRIC DETERMINATION OF APOLIPOPROTEIN A-I APOLIPOPROTEIN A-II APOLIPOPROTEIN B APOLIPOPROTEIN E USING THE BN II AND BN PROSPEC SYSTEM. ,N LP (A) CONTROL SY(N LP (A) CONTROL SY)-THE N LP(A) CONTROL SY IS AN ASSAYED CONTROL FOR ACCURACY AND PRECISION OF THE IMMUNONEPHELOMETRIC DETERMINATION OF HUMAN LIPOPROTEIN (A) [LP(A)] IN SERUM OR PLASMA WITH THE BN II AND BN PROSPEC SYSTEM. ,N/T PROTEIN CONTROL SL/L(N/T PROTEIN CONTROL SL/L) -THE N/T PROTEIN CONTROLS SL/L, M AND H ARE FOR USE AS ASSAYED ACCURACY CONTROLS AND PRECISION CONTROLS IN THE DETERMINATION OF THE FOLLOWING HUMAN SERUM PROTEINS BY IMMUNONEPHELOMETRY WITH THE BN II AND BN PROSPEC SYSTEM AND BY RADIAL IMMUNODIFFUSION (RID) WITH PARTIGEN PLATES. , N/T PROTEIN CONTROL SL/M(N/T PROTEIN CONTROL SL/M)-THE N/T PROTEIN CONTROLS SL/L, M AND H ARE FOR USE AS ASSAYED ACCURACY CONTROLS AND PRECISION CONTROLS IN THE DETERMINATION OF THE FOLLOWING HUMAN SERUM PROTEINS BY IMMUNONEPHELOMETRY WITH THE BN II AND BN PROSPEC SYSTEM AND BY RADIAL IMMUNODIFFUSION (RID) WITH PARTIGEN PLATES. ,N LATEX MYOGLOBIN(N LATEX MYOGLOBIN)-IN VITRO DIAGNOSTIC REAGENTS FOR QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM OR HEPARINIZED AND EDTA PLASMA BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY USING THE BN SYSTEMS. ,ANTISERUM TO HUMAN IGD/-CHAIN(ANTISERUM TO HUMAN IGD/-CHAIN)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUALITATIVE DETECTION OF C1Q, C3 ACTIVATOR, C5 AND IGD IN HUMAN SERUM, HEPARINIZED AND EDTA-PLASMA BY MEANS OF IMMUNOCHEMICAL GEL PRECIPITATION. ,N AS IGG2(N AS IGG2)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF IGG SUBCLASSES 1 AND 2 IN HUMAN SERUM,

	HEPARINIZED AND EDTA PLASMA USING THE BN II AND BN PROSPEC SYSTEM.,ANTI-STREPTOCOCCAL HYALURONIDASE(ANTI-STREPTOCOCCAL HYALURONIDASE)-IN-VITRO DIAGNOSTIC FOR THE SEMI-QUANTITATIVE DETERMINATION OF ANTI-STREPTOCOCCAL HYALURONIDASE IN HUMAN SERUM THROUGH THE INHIBITION OF THE ENZYMATIC CLEAVAGE OF HYALURONIC ACID ,N DILUENT(N DILUENT)-N DILUENT IS A SOLUTION FOR PREPARING DILUTIONS FOR IMMUNOCHEMICAL DETERMINATIONS WITH THE BN II AND BN PROSPEC SYSTEM.,N/T RHEUMATOLOGY CONTROL SL/1(N/T RHEUMATOLOGY CONTROL SL/1)-N/T RHEUMATOLOGY CONTROLS ARE LOW OR HIGH LEVEL ASSAYED CONTROLS FOR USE AS ACCURACY AND PRECISION CONTROLS IN THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS (RF), ANTISTREPTOLYSIN O (ASL) AND C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM AND PLASMA USING THE BN II AND BN PROSPEC SYSTEM. ,N LATEX FLC KAPPA(N LATEX FLC KAPPA)-ATELLICA NEPH 630 SYSTEM / BN SYSTEMS: IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF FREE LIGHT CHAINS (FLC), TYPE KAPPA OR TYPE LAMBDA, RESPECTIVELY IN HUMAN SERUM, HEPARINIZED PLASMA AND EDTA PLASMA BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY USING THE BN SYSTEMS OR ATELLICA NEPH 630 SYSTEM. FLC MEASUREMENTS ARE USED AS AN AID IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, WALDENSTRÖM'S MACROGLOBULINEMIA, AMYLOIDOSIS, LIGHT CHAIN DEPOSITION DISEASE AND LYMPHOCYTIC NEOPLASM. ATELLICA CH ANALYZER: IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF FREE LIGHT CHAINS (FLC), TYPE KAPPA OR TYPE LAMBDA, RESPECTIVELY IN HUMAN SERUM AND EDTA PLASMA BY MEANS OF PARTICLEENHANCED TURBIDIMETRY USING THE ATELLICA CH ANALYZER. FLC MEASUREMENTS ARE USED AS AN AID IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, WALDENSTRÖM'S MACROGLOBULINEMIA, AMYLOIDOSIS, LIGHT CHAIN DEPOSITION DISEASE AND LYMPHOCYTIC NEOPLASM.,N PROTEIN STANDARD UY (N PROTEIN STANDARD UY)-N PROTEIN STANDARD UY IS USED FOR PREPARING REFERENCE CURVES FOR THE IMMUNOCHEMICAL DETERMINATION OF 1-MICROGLOBULIN, CYSTATIN C AND -TRACE PROTEIN USING THE BN SYSTEMS. ,N ANTISERUM TO HUMAN FIBRONECTIN(N ANTISERUM TO HUMAN FIBRONECTIN)-IN-VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF FIBRONECTIN IN HUMAN PLASMA BY MEANS OF IMMUNONEPHELOMETRY ON THE BN SYSTEMS ,N LATEX FLC LAMBDA(N LATEX FLC LAMBDA)-ATELLICA NEPH 630 SYSTEM / BN SYSTEMS: IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF FREE LIGHT CHAINS

	(FLC), TYPE KAPPA OR TYPE LAMBDA, RESPECTIVELY IN HUMAN SERUM, HEPARINIZED PLASMA AND EDTA PLASMA BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY USING THE BN SYSTEMS OR ATELLICA NEPH 630 SYSTEM. FLC MEASUREMENTS ARE USED AS AN AID IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, WALDENSTRÖM'S MACROGLOBULINEMIA, AMYLOIDOSIS, LIGHT CHAIN DEPOSITION DISEASE AND LYMPHOCYTIC NEOPLASM. ATELLICA CH ANALYZER: IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF FREE LIGHT CHAINS (FLC), TYPE KAPPA OR TYPE LAMBDA, RESPECTIVELY IN HUMAN SERUM AND EDTA PLASMA BY MEANS OF PARTICLEENHANCED TURBIDIMETRY USING THE ATELLICA CH ANALYZER. FLC MEASUREMENTS ARE USED AS AN AID IN THE DIAGNOSIS AND MONITORING OF MULTIPLE MYELOMA, WALDENSTRÖM'S MACROGLOBULINEMIA, AMYLOIDOSIS, LIGHT CHAIN DEPOSITION DISEASE AND LYMPHOCYTIC NEOPLASM.,N FLC STANDARD SL(N FLC STANDARD SL)-ESTABLISHMENT OF REFERENCE CURVES FOR THE DETERMINATION OF FREE LIGHT CHAINS (FLC), TYPE KAPPA AND TYPE LAMBDA ON THE BN SYSTEM BN PROSPEC SYSTEM, ATELLICA NEPH 630 SYSTEM AND ATELLICA CH ANALYZER. ,N FLC SUPPLEMENTARY REAGENT(N FLC SUPPLEMENTARY REAGENT)-SUPPLEMENTARY REAGENT FOR THE IMMUNONEPHELOMETRIC DETERMINATION OF FREE LIGHT CHAINS (FLC), TYPE KAPPA AND TYPE LAMBDA ON BN SYSTEMS. SUPPLEMENTARY REAGENT FOR THE TURBIDIMETRIC DETERMINATION OF FREE LIGHT CHAINS (FLC), TYPE KAPPA AND TYPE LAMBDA ON ATELLICA CH ANALYZER. A MIXTURE OF BOTH SUPPLEMENTARY REAGENTS IS USED TO SUPPRESS INTERFERENCE BY RHEUMATOID FACTORS AND HUMAN ANTI-MOUSE ANTIBODIES (HAMA). ,N PROTEIN CONTROL LC2(N PROTEIN CONTROL LC2)-N PROTEIN CONTROLS LC1/LC2 ARE ASSAYED INTRALABORATORY QUALITY CONTROLS FOR ASSESSMENT OF PRECISION AND ANALYTICAL BIAS FOR IMMUNOCHEMICAL DETERMINATIONS OF THE PROTEINS IGG IN URINE AND CSF, IGA IN CSF, IGM IN CSF, TRANSFERRIN IN URINE, ALBUMIN IN URINE AND CSF, 2MACROGLOBULIN IN URINE, IMMUNOGLOBULIN LIGHT CHAINS (TYPES KAPPA AND LAMBDA) IN URINE, 1MICROGLOBULIN IN URINE AND -TRACE PROTEIN USING THE BN SYSTEMS. FOR THE PREPARATION OF REFERENCE CURVES FOR THE IMMUNOCHEMICAL DETERMINATION OF 1ANTITRYPSIN (1-PROTEINASE INHIBITOR) IN RADIAL IMMUNODIFFUSION (RID) WITH LC-PARTIGEN PLATES. ,BN II ADDITIVE(BN II ADDITIVE)-WASHING SOLUTION (CONCENTRATE) FOR CLEANING BN II SYSTEM CUVETTES.,N ANTISERUM TO HUMAN APOLIPOPROTEIN A-I(N ANTISERUM TO HUMAN APOLIPOPROTEIN A-I)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE

	DETERMINATION OF APOLIPOPROTEIN A-I (APO A-I) AND APOLIPOPROTEIN B (APO B) IN HUMAN SERUM AND HEPARINIZED PLASMA BY MEANS OF IMMUNONEPHELOMETRY ON THE BN II AND BN PROSPEC SYSTEM,N LATEX STFR(N LATEX STFR)-IN-VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF SOLUBLE TRANSFERRIN RECEPTOR (STFR) IN HUMAN SERUM OR HEPARINIZED PLASMA ON THE BN II AND BN PROSPEC SYSTEM,N LATEX ß2-MICROGLOBULIN(N LATEX ß2-MICROGLOBULIN)-IN-VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF 2-MICROGLOBULIN IN HUMAN SERUM, HEPARINIZED AND EDTA PLASMA, AS WELL AS IN URINE BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY USING THE BN II AND BN PROSPEC SYSTEM, N FLC CONTROL SL 2(N FLC CONTROL SL 2)-THE N FLC CONTROLS SL1 AND SL2 ARE FOR USE AS ASSAYED ACCURACY CONTROLS AND PRECISION CONTROLS IN THE DETERMINATION OF FREE LIGHT CHAINS (FLC), TYPE KAPPA AND TYPE LAMBDA BY IMMUNONEPHELOMETRY WITH THE BN SYSTEMS AND ATELLICA NEPH 630 SYSTEM AND BY TURBIDIMITRY ON THE ATELLICA CH ANALYZER.,N AS IGG1(N AS IGG1)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF IGG SUBCLASSES 1 AND 2 IN HUMAN SERUM, HEPARINIZED AND EDTA PLASMA USING THE BN II AND BN PROSPEC SYSTEM.,N ANTISERUM TO HUMAN –(RBP)(N ANTISERUM TO HUMAN –(RBP))-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF PREALBUMIN (TRANSTHYRETIN) AND RETINOL-BINDING PROTEIN (RBP) IN HUMAN SERUM AND HEPARINIZED PLASMA BY MEANS OF IMMUNONEPHELOMETRY ON THE BN II AND BN PROSPEC SYSTEM.,N APOLIPOPROTEIN A-II(N APOLIPOPROTEIN A-II)-IN VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A-II (APO A-II) AND APOLIPOPROTEIN E (APO E) IN HUMAN SERUM WITH THE BN SYSTEMS,N 1-MICROGLOBULIN(N 1-MICROGLOBULIN)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF 1-MICROGLOBULIN IN HUMAN URINE USING THE BN II AND BN PROSPEC SYSTEM,ANTISERUM TO HUMAN C1Q(ANTISERUM TO HUMAN C1Q)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUALITATIVE DETECTION OF C1Q, C3 ACTIVATOR, C5 AND IGD IN HUMAN SERUM, HEPARINIZED AND EDTA-PLASMA BY MEANS OF IMMUNOCHEMICAL GEL PRECIPITATION. ,N PROTEIN STANDARD PY(N PROTEIN STANDARD PY)-ESTABLISHMENT OF REFERENCE CURVES FOR THE IMMUNOCHEMICAL DETERMINATION OF FIBRINOGEN, ANTITHROMBIN III, PLASMINOGEN, FIBRONECTIN AND C1INHIBITOR USING THE ATELLICA COAG 360 SYSTEM AS WELL AS THE BN II AND BN PROSPEC SYSTEMS. ,N LATEX IGM (N LATEX IGM)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE

	QUANTITATIVE DETERMINATION OF IGM IN HUMAN CEREBROSPINAL FLUID (CSF) BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY USING THE BN II AND BN PROSPEC SYSTEM.,N LATEX IGG3(N LATEX IGG3)-IN-VITRO DIAGNOSTIC FOR THE QUANTITATIVE DETERMINATION OF IGG SUBCLASSES 3 AND 4 (IGG3 AND IGG4) IN HUMAN SERUM AND PLASMA BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY WITH THE BN II AND BN PROSPEC SYSTEM.,N/T PROTEIN CONTROL LC(N/T PROTEIN CONTROL LC)-N/T PROTEIN CONTROL LC IS ASSAYED INTRALABORATORY QUALITY CONTROL FOR ASSESSMENT OF PRECISION AND ANALYTICAL BIAS IN IMMUNONEPHELOMETRIC DETERMINATION OF IGG IN URINE, AND CSF, IGA IN CSF, TRANSFERRIN IN URINE, ALBUMIN IN URINE AND CSF, 2- MACRO-GLOBULIN IN URINEIG/L -CHAINS (K-TYPE AND -TYPE) IN URINE , 1-MICROGLOBULIN IN URINE AND -TRACE PROTEIN USING THE BN II AND BN PROSPEC SYSTEM,CARDIOPHASE HSCRP(CARDIOPHASE HSCRP)-CARDIOPHASE HSCRP IS AN IN-VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM, AND HEPARIN AND EDTA PLASMA BY MEANS OF PARTICLE ENHANCED IMMUNONEPHELOMETRY USING THE BN II AND BN PROSPEC SYSTEM. IN ACUTE PHASE RESPONSE, INCREASED LEVELS OF A NO OF PLASMA PROTEINS, INCLUDING C-REACTIVE PROTEIN, IS OBSERVED. MEASUREMENT OF CRP IS USEFUL FOR DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY, INFLAMMATORY DISORDERS AND ASSOCIATED DISEASES. HIGH SENSITIVITY CRP (HSCRP) MEASUREMENT MAY BE USED AS AN INDEPENDENT RISK MARKER FOR THE IDENTIFICATION OF INDIVIDUALS AT RISK FOR FUTURE CARDIOVASCULAR DISEASE. MEASUREMENT OF HSCRP, WHEN USED IN CONJUCTION WITH TRADITIONAL CLINICAL LABORATORY EVALUATION AF ACUTE CORONARY SYNDROMES, MAY BE USEFUL AS AN INDEPENDENT MARKER OS PROGNOSIS FOR RECURRENT EVENTS, IN PATIENTS WITH SLAB CORONARY DISEASE OR ACUTE CORONARY SYNDROMES.,APOLIPOPROTEIN CONTROL SERUM CHD (APOLIPOPROTEIN CONTROL SERUM CHD)-APOLIPOPROTEIN CONTROL SERUM CHD IS AN ASSAYED CONTROL USED FOR ACCURACY AND PRECISION IN THE QUANTITATIVE IMMUNOCHEMICAL DETERMINATION OF APOLIPOPROTEIN A-I, A-II, B AND E AS WELL AS CREACTIVE PROTEIN (CRP) USING THE BN II AND BN PROSPEC SYSTEM. ,N PROTEIN STANDARD SL(N PROTEIN STANDARD SL)-ESTABLISHMENT OF REFERENCE CURVES FOR THE DETERMINATION OF IGG, IGG 1, IGG 2, IGG 3, IGG 4, IGA, IGM, IGE, C3C, C4, TRANSFERRIN, ALBUMIN, 1-ANTITRYPSIN (1-PROTEINASE INHIBITOR), 2 MACROGLOBULIN, HAPTOGLOBIN, 1-ACID

	GLYCOPROTEIN, PREALBUMIN (TRANSTHYRETIN), HEMOPEXIN, CERULOPLASMIN, RETINOL-BINDING PROTEIN (RBP), IG/L-CHAIN, -TYPE, IG/L-CHAIN, -TYPE, SOLUBLE TRANSFERRIN RECEPTOR (STFR), FERRITIN, 2-MICROGLOBULIN, HOMOCYSTEINE ON THE BN II AND BN PROSPEC SYSTEM. ,N SUPPLEMENTARY REAGENT L(N SUPPLEMENTARY REAGENT L)-SUPPLEMENTARY REAGENT FOR THE IMMUNONEPHELOMETRIC DETERMINATION OF IMMUNOGLOBULIN E (IGE), 2-MICROGLOBULIN (2M), CARBOHYDRATE-DEFICIENT TRANSFERRIN (CDT) AND SOLUBLE TRANSFERRIN RECEPTOR (STFR) USING N LATEX IGE MONO, N LATEX 2-MICROGLOBULIN, N LATEX CDT KIT AND N LATEX STFR ON THE BN II AND BN PROSPEC SYSTEM. A MIXTURE OF BOTH SUPPLEMENTARY REAGENTS IS USED TO SUPPRESS INTERFERENCE BY RHEUMATOID FACTORS AND HUMAN ANTI-MOUSE ANTIBODIES (HAMA). ,N REACTION BUFFER(N REACTION BUFFER)-N REACTION BUFFER IS A REACTION MEDIUM FOR IMMUNCHEMICAL DETERMINATIONS WITH THE BN II AND BN PROSPEC SYSTEM.,N FLC CONTROL SL 1(N FLC CONTROL SL 1)-THE N FLC CONTROLS SL1 AND SL2 ARE FOR USE AS ASSAYED ACCURACY CONTROLS AND PRECISION CONTROLS IN THE DETERMINATION OF FREE LIGHT CHAINS (FLC), TYPE KAPPA AND TYPE LAMBDA BY IMMUNONEPHELOMETRY WITH THE BN SYSTEMS AND ATELLICA NEPH 630 SYSTEM AND BY TURBIDIMITRY ON THE ATELLICA CH ANALYZER. ,N/T RHEUMATOLOGY CONTROL SL/2(N/T RHEUMATOLOGY CONTROL SL/2)-N/T RHEUMATOLOGY CONTROLS ARE LOW OR HIGH LEVEL ASSAYED CONTROLS FOR USE AS ACCURACY AND PRECISION CONTROLS IN THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS (RF), ANTISTREPTOLYSIN O (ASL) AND C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM AND PLASMA USING THE BN II AND BN PROSPEC SYSTEM. ,N LATEX RF KIT(N LATEX RF KIT)-QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS (RF) IN HUMAN SERUM, LITHIUM HEPARIN AND EDTA PLASMA ON THE BN II AND BN PROSPEC SYSTEM AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS., CLEANER SCS(CLEANER SCS)-CLEANER SCS IS USED AS A CLEANING SOLUTION FOR THE BN II / BN PROSPEC SYSTEMS AND THE BCS / BCS XP SYSTEMS.,N LATEX IGG4(N LATEX IGG4)-IN-VITRO DIAGNOSTIC FOR THE QUANTITATIVE DETERMINATION OF IGG SUBCLASSES 3 AND 4 (IGG3 AND IGG4) IN HUMAN SERUM AND PLASMA BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY WITH THE BN II AND BN PROSPEC SYSTEM., N/T PROTEIN CONTROL PY(N/T PROTEIN CONTROL PY)-N/T PROTEIN CONTROL PY IS USED FOR CONTROL OF ACCURACY AND PRECISION IN THE IMMUNOCHEMICAL DETERMINATION OF FIBRINOGEN, ANTITHROMBIN III, PLASMINOGEN, FIBRONECTIN AND C1INHIBITOR

	USING THE ATELLICA COAG 360 SYSTEM, BN II SYSTEM, BN PROSPEC SYSTEM AND BY RADIAL IMMUNODIFFUSION (RID) USING PARTIGEN PLATES.

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203	IMP/IVD/2019/000167	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 (LP-PLA2) DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF LP-PLA2,ANTI-CYCLIC CITRULLINATED PEPTIDE ANTIBODY DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF CCP,CYSTATIN C DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF CYS-C,PEPSINOGEN I (PGI) DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF PGI,IMMUNOGLOBULIN A (IGA) DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF IGA,RHEUMATOID FACTOR DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF RF,2-MICROGLOBULIN (2-MG) DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF 2-MG, FIBRINOGEN DEGRADATION PRODUCT (FDP) DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF FDP,COMPLEMENTC3 (C3) DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF C3,D-DIMER DETECTION KIT-FOR IN VITRO QUANTITATIVE DETERMINATION OF D-DIMER, GLYCATED HEMOGLOBIN (HBA1C) DETECTION KIT (NEPHELOMETRY-FOR IN VITRO QUANTITATIVE DETERMINATION OF HBA1C ,C-REACTIVE PROTEIN DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF CRP,NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN (NGAL) DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF NGAL,HUMAN MICRO-ALBUMINURIA DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF MALB,IMMUNOGLOBULIN M (IGM) DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF IGM,ANTI-STREPTOLYSIN O DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF ASO ,PEPSINOGEN II (PGII) DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF PGII,IMMUNOGLOBULIN G (IGG) DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF IGG,COMPLEMENT C4 (C4) DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF C4,RETINOL BINDING PROTEIN (RBP) DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF RBP,SERUM AMYLOID PROTEIN A (SAA) DETECTION KIT (NEPHELOMETRY)-FOR IN VITRO QUANTITATIVE DETERMINATION OF SAA

204	IMP/IVD/2019/000168	1.License Holder Name: MICROGENE DIAGNOSTIC SYSTEMS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AP 10 BLOOD GLUCOSE METER(ACCUSURE)-AP-10 BLOOD GLUCOSE METER IS USED WITH THE AP-10 BLOOD GLUCOSE TEST STRIPS TO QUANTITATIVELY MEASURE GLUCOSE IN WHOLE BLOOD.,BLOOD GLUCOSE TEST STRIP (AP-10 BLOOD GLUCOSE TEST STRIPS (ACCUSURE SENSOR))-BLOOD GLUCOSE TEST STRIPS IS USED ALONG WITH BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO MONITOR BLOOD GLUCOSE IN WHOLE BLOOD.

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205	IMP/IVD/2019/000170	1.License Holder Name: M/S AVANTOR PERFORMANCE MATERIALS INDIA LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAGLUMI ESTRADIOL (CLIA)(MAGLUMI ESTRADIOL(CLIA))-THE KIT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM.,C IV (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TYPE COLLAGEN (C) IN HUMAN SERUM., MAGLUMI FREE -HCG (CLIA)(MAGLUMI FREE -HCG (CLIA))-THE KIT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF FREE -CHAINS OF HUMAN CHORIONIC GONADOTROPIN FREE -HCG IN HUMAN SERUM.,T3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) IN HUMAN SERUM., MAGLUMI EBV VCA IGG (CLIA)(MAGLUMI EBV VCA IGG (CLIA))-THE KIT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF EBV VCA IGG IN HUMAN SERUM. ,ALBUMIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN URINE., MAGLUMI CALCITONIN (CLIA)(MAGLUMI CALCITONIN (CLIA))-THE KIT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CALCITONIN (CT) IN HUMAN SERUM.,FT3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM.,MAGLUMI 25-OH VITAMIN D (CLIA)(MAGLUMI 25-OH VITAMIN D (CLIA))-THE KIT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM. ,FT4 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM., MAGLUMI HCG/BETA-HCG(CLIA)(MAGLUMI HCG/BETA-HCG(CLIA))-THE KIT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (-SUBUNIT) HCG/-HCG IN HUMAN SERUM.,PRG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE (PRG) IN HUMAN SERUM.,MAGLUMI TG (CLIA)(MAGLUMI TG (CLIA))-THE KIT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) IN HUMAN SERUM. ,INTACT PTH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (INTACT PTH) IN HUMAN SERUM.,MAGLUMI FERRITIN (CLIA)(MAGLUMI FERRITIN (CLIA))-THE KIT HAS BEEN

	DESIGNED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM. ,IGE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) IN HUMAN SERUM., MAGLUMI EBV NA IGG (CLIA)(MAGLUMI EBV NA IGG (CLIA))-THE KIT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF EBV NA IGG IN HUMAN SERUM. ,IGM (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM.,MAGLUMI AMH (CLIA)(MAGLUMI AMH (CLIA))-THE KIT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF ANTI-MULLERIAN HORMONE (AMH) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER ,PAPP-A (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PREGNANCY-ASSOCIATED PLASMA PROTEIN A (PAPP-A) IN HUMAN SERUM.,MAGLUMI OSTEOCALCIN(CLIA)(MAGLUMI OSTEOCALCIN(CLIA))-THE KIT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF OSTEOCALCIN (BGP) IN HUMAN SERUM.,NT-PROBNP (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF N-TERMINAL PROHORMONE B-TYPE NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM.,MAGLUMI EBV VCA IGA (CLIA)(MAGLUMI EBV VCA IGA (CLIA))-THE KIT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF EBV VCA IGA IN HUMAN SERUM. , IGA (URINE SERUM ANALYSIS) (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN URINE.,MAGLUMI TESTOSTERONE (CLIA)(MAGLUMI TESTOSTERONE (CLIA))-THE KIT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM. ,TRAB (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TSH RECEPTOR ANTIBODIES (TRAB) IN HUMAN SERUM.,LH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM., C-PEPTIDE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM AND PLASMA., INSULIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM.,ALDOSTERONE

	(CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALDOSTERONE (ALD) IN HUMAN SERUM, PLASMA AND TREATED URINE.,CK-MB (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MB ISOENZYME OF CREATINE KINASE (CK-MB) IN HUMAN SERUM.,FA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLIC ACID (FA) IN HUMAN SERUM.,T4 (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM.,REV T3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF REVERSE TRIIODOTHYRONINE (REVT3) IN HUMAN SERUM.,GAD 65 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GLUTAMIC ACID DECARBOXYLASE ANTIBODY (GAD65) IN HUMAN SERUM.,CORTISOL (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM OR URINE,PROINSULIN (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROINSULIN IN HUMAN SERUM.,FREE ESTRIOL (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE ESTRIOL IN HUMAN SERUM.,FK 506 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FK 506 IN HUMAN WHOLE BLOOD.,IGF-I (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN-LIKE GROWTH FACTOR- (IGF-) IN HUMAN SERUM.,D-DIMER (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA.,VITAMIN B12 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM., PRL (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PRL IN HUMAN SERUM.,TGA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN AUTOANTIBODY (TGA) IN HUMAN SERUM.,TROPONIN I (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE

	QUANTITATIVE DETERMINATION OF TROPONIN I IN HUMAN SERUM., CRP (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM.,A II (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANGIOTENSIN (A) IN HUMAN PLASMA.,HA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HYALURONIC ACID (HA) IN HUMAN SERUM.,FREE TESTOSTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE IN HUMAN SERUM.,FSH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM.,PG I (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN (PG) IN HUMAN SERUM., CHOLYLGLYCINE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CHOLYLGLYCINE (CG) IN HUMAN SERUM.,PG I (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN (PG) IN HUMAN SERUM.,MYOGLOBIN (CLIA)(MAGLUMI) -THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM.,IAA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN AUTOANTIBODIES (IAA) IN HUMAN SERUM.,ACTH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ADRENOCORTICOTROPIC HORMONE (ACTH) IN HUMAN PLASMA.,TMA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID MICROSOMAL AUTOANTIBODY (TMA) IN HUMAN SERUM.,LAMININ (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LAMININ (LN) IN HUMAN SERUM.,ANTI-TPO (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-TPO IN HUMAN SERUM.,GH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GROWTH HORMONE (GH).,DHEA-S (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF

	DEHYDROEPIANDROSTERONE (DHEA-S) IN HUMAN SERUM.,CSA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE A (CSA) IN HUMAN WHOLE BLOOD.,IGG (URINE ANALYSIS) (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN URINE., TSH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN HUMAN SERUM.,DIGOXIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN IN HUMAN SERUM.,PCT (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PCT IN HUMAN SERUM, PLASMA AND WHOLE BLOOD.,AI (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANGIOTENSIN (A) IN HUMAN PLASMA.,PIIIP N-P (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF COLLAGEN TYPE N-PEPTIDE (PP N-P) IN HUMAN SERUM.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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206	IMP/IVD/2019/000174	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD TOTALYS™ MULTIPROCESSOR INSTALLATION KIT(BD TOTALYS™ MULTIPROCESSOR INSTALLATION KIT)-THE BD TOTALYS™ MULTIPROCESSOR INSTALLATION KIT IS INTENDED TO BE USED BY BD INSTALLATION PERSONNEL ONLY IN THE INSTALLATION OF BD TOTALYS™ MULTIPROCESSOR. IT IS LABELED "TO BE INSTALLED BY AUTHORIZED SERVICE PERSONNEL",BD NON-GYN STAIN KIT(BD NON-GYN STAIN KIT)-THE BD NON-GYN STAIN KIT CONTAINS: BD HEMATOXYLIN STAIN 0.5 AND BD EA/OG COMBO STAIN. THE KIT IS USED IN THE STAINING PROCEDURE FOR THE PREPARATION OF NON-GYNAECOLOGICAL SAMPLES.,BD TOTALYS™ MULTIPROCESSOR CONSUMABLES KIT(BD TOTALYS™ MULTIPROCESSOR CONSUMABLES KIT)-THE BD TOTALYS MULTIPROCESSOR IS USED IN CONJUNCTION WITH THE BD TOTALYS ™ SLIDEPREP TO PREPARE THE BD SURE PATH™ LIQUID-BASED PAP TEST, WHICH IS INTENDED AS A REPLACEMENT FOR THE CONVENTIONAL GYNECOLOGIC PAP SMEAR. THE BD SUREPATH TEST IS INTENDED FOR USE IN THE SCREENING AND DETECTION OF CERVICAL CANCER, PRE-CANCEROUS CERVICAL LESIONS, ATYPICAL CELLS, AND ALL OTHER CYTOLOGIC CATEGORIES AS DEFINED BY THE BETHESDA SYSTEM FOR REPORTING CERVICAL/VAGINAL CYTOLOGIC DIAGNOSES. THE BD TOTALYS™ MULTIPROCESSOR AUTOMATES THE PREPARATION OF AN ENRICHED CELL PELLET FROM A CERVICAL CYTOLOGY SPECIMEN COLLECTED IN A BD SUREPATH ™ COLLECTION VIAL. THE CELL PELLET PRODUCED BY THE BD TOTALYS™ MULTIPROCESSOR IS TRANSFERRED TO THE BD TOTALYS™ SLIDEPREP FOR FURTHER PROCESSING TO PREPARE A BD SUREPATH™ SLIDE. THE BD TOTALYS™ MULTIPROCESSOR CAN BE PROGRAMMED TO PERFORM THE OPTIONAL WITHDRAWAL OF A 0.5 ML ALIQUOT FROM THE BDSUREPATH COLLECTION VIAL, PRIOR TO THE CELL ENRICHMENT PROCESS FOR ANCILLARY TESTING INDICATED FOR USE WITH THE BD TOTALYS MULTIPROCESSOR,BD SUREPATH DIRECT TO SLIDE KIT (BD SUREPATH DIRECT TO SLIDE KIT)-THE BD SUREPATH™ DIRECT TO SLIDE KIT METHOD PRODUCES A LIQUID BASED CYTOLOGY (LBC) SLIDE APPROPRIATE FOR USE IN THE MORPHOLOGICAL EVALUATION OF CERVICAL SAMPLES.,BD TOTALYS SLIDEPREP INSTALL KIT(BD TOTALYS SLIDEPREP INSTALL KIT)-THE BD TOTALYS™ SLIDEPREP INSTALL KIT IS INTENDED TO BE USED BY BD INSTALLATION PERSONNEL IN THE INSTALLATION OF BD TOTALYS™ SLIDEPREP. IT IS LABELED "TO BE INSTALLED BY AUTHORIZED SERVICE PERSONNEL.,BD PREPMATE CONSUMABLES KIT(BD PREPMATE CONSUMABLES KIT)-BD PREPMATE™ CONSUMABLES KIT CONTAINS

	BD DENSITY REAGENT, BD CENTRIFUGE TUBES, BD SYRINGING PIPETTES AND BD ASPIRATOR TIPS. IT IS INTENDED FOR USE WITH THE BO PREPMATE™ AUTOMATED ACCESSORY.,BD TOTALYS SLIDEPREP CONSUMABLES KIT(BD TOTALYS SLIDEPREP CONSUMABLES KIT)-THE BD TOTALYS SLIDEPREP IS AN AUTOMATED LIQUID-BASED THIN LAYER CELL PREPARATION SYSTEM WHICH PRODUCES BD SUREPATH™ LIQUID-BASED PAP TEST SLIDES INTENDED AS REPLACEMENTS FOR CONVENTIONAL GYNECOLOGIC PAP SMEARS. BD SUREPATH LIQUID-BASED PAP TEST SLIDES (FORMERLY AUTOCYTE® PREP SLIDES) ARE INTENDED FOR USE IN THE SCREENING AND DETECTION OF CERVICAL CANCER, PRE-CANCEROUS LESIONS, ATYPICAL CELLS AND ALL OTHER CYTOLOGIC CATEGORIES AS DEFINED BY THE BETHESDA SYSTEM FOR REPORTING CERVICAL/VAGINAL CYTOLOGIC DIAGNOSES,BD CYTORICH RED PRESERVATIVE(BD CYTORICH RED PRESERVATIVE)-BD CYTORICH RED PRESERVATIVE IS INTENDED TO PRESERVE CELLS AND SMALL TISSUE FRAGMENTS IN SUSPENSION. IT IS ALSO USED TO PREPARE CELLS AND SMALL TISSUE FRAGMENTS FOR CYTOLOGICAL AND HISTOLOGICAL EXAMINATION. IT LYSES RED BLOOD CELLS AND SOLUBILIZES PROTEINS. THE PRESERVED SAMPLES ARE COMPATIBLE WITH IMMUNE-HISTOCHEMICAL STAINING AND RESULTS ARE SIMILAR TO THOSE ACHIEVED WITH NEUTRAL BUFFERED FORMALIN.,BD TOTALYS SLIDEPREP NON-GYN TEST KIT (BD TOTALYS SLIDEPREP NON-GYN TEST KIT)-BD TOTALYS™ SLIDEPREP PERFORMS PRE-PROCESSING OF NON-GYN SAMPLES ACCORDING TO A LABORATORY'S APPROVED STANDARD OPERATING PROCEDURES AND/OR BD PROVIDED PROTOCOLS. NON-GYN SAMPLE PROCESSING ON THE BD TOTALYS™ SLIDEPREP BEGINS ONCE A CELL PELLET HAS BEEN PREPARED FOR EACH SAMPLE,BD SUREPATHTM PRESERVATIVE FLUID(BD SUREPATHTM PRESERVATIVE FLUID)-BD SUREPATHTM PRESERVATIVE FLUID IS AN ALCOHOL-BASED PRESERVATIVE FLUID INTENDED FOR THE COLLECTION, PREPARATION AND EXAMINATION OF SPECIMENS FROM A HUMAN BODY FOR DIAGNOSTIC PURPOSES.,BD PREPSTAIN NON-GYN TEST KIT(BD PREPSTAIN NON-GYN TEST KIT)-IT IS AN ALCOHOL-BASED PRESERVATIVE FLUID INTENDED FOR PRESERVATION OF CYTOLOGY CELLS IN SUSPENSION AND THEIR SUBSEQUENT PREPARATION FOR CYTOLOGICAL EVALUATION.,BD CYTOLOGY STAIN KIT(BD CYTOLOGY STAIN KIT)-BD CYTOLOGY STAIN KIT CONTAINS BD HEMATOXYLIN STAIN 0.75 AND BD EA/OG COMBO STAIN. THE CYTOLOGY STAIN KIT IS USED IN THE PAPANICOLAOU STAINING PROCEDURE FOR THE PREPARATION OF SUREPATH PAP TEST SLIDES.,BD DENSITY REAGENT(BD DENSITY REAGENT)-BD DENSITY REAGENT IS A POLYSACCHARIDE SOLUTION

	USED IN THE SUREPATH® CELL ENRICHMENT PROCESS. AN ENRICHMENT STEP, CONSISTING OF CENTRIFUGAL SEDIMENTATION THROUGH DENSITY REAGENT, PARTIALLY REMOVES NON-DIAGNOSTIC DEBRIS AND EXCESS INFLAMMATORY CELLS FROM THE SUREPATH SAMPLE.,BD PREPSTAIN INSTALL KIT(BD PREPSTAIN INSTALL KIT)-BD PREPSTAIN™ INSTALL KIT CONTAINS: BD ALCOHOL BLEND RINSE, BD SUREPATH™ PRESERVATIVE FLUID, BD CYTOLOGY STAIN KIT, BD SETTLING CHAMBERS, BD SUREPATH™ PRECOAT SLIDES, BD PREPSTAIN TRANSFER TIPS, NALGENE BOTTLES AND CAPS, TRIS BUFFERED SALINE PACKS, AND AN INSTALL DOCUMENT PACK. THIS KIT IS INTENDED TO BE USED BY AUTHORIZED SERVICE PERSONNEL DURING INSTALLATION OF BD PREPSTAIN™ SLIDE PROCESSOR.,BD PREPSTAIN™ CONSUMABLES KIT(BD PREPSTAIN™ CONSUMABLES KIT)-BD PREPSTAIN™ CONSUMABLES KIT CONTAINS BD SUREPATH PRECOAT SLIDES, BD TRANSFER TIPS AND BD SETTLING CHAMBERS. BD PREPSTAIN™ CONSUMABLES KIT IS FOR USE WITH THE BD PREPSTAIN™ SYSTEM.,BD PREPMATE INSTALL KIT (BD PREPMATE INSTALL KIT)-BD PREPMATE INSTALL KIT CONTAINS BD DENSITY REAGENT, BD 4ML DISPENSER, DISPENSER TUBINGS, BD CENTRIFUGE TUBES, BD SYRINGING PIPETTES EMPTY VIALS AND CAPS. THIS KIT IS INTENDED TO BE USED BY AUTHORIZED PERSONNEL DURING INSTALLATION OF PREPMATE AUTOMATED ACCESSORY.,BD ALCOHOL BLEND RINSE(BD ALCOHOL BLEND RINSE) -BD ALCOHOL BLEND RINSE IS A REAGENT USED AS AN ALCOHOL WASH DURING THE PREPARATION OF SUREPATH® PAP TEST SLIDES., BD SUREPATH COLLECTION VIAL KIT 500(BD SUREPATH COLLECTION VIAL KIT 500)-BD SUREPATH™ COLLECTION VIAL KIT 500 IS DESIGNED FOR USE WITH BD PREPSTAIN AND BD TOTALYS SYSTEMS FOR THE PROCESSING OF BD SUREPATH LIQUID-BASED PAP TESTS.,BD SUREPATH PRECOAT SLIDES(BD SUREPATH PRECOAT SLIDES)-BD SUREPATH PRECOAT SLIDES ARE COATED TO CREATE A POSITIVE CHARGE ON THE SLIDE SURFACE. THIS POSITIVE CHARGE ENABLES ADHESION OF THE NEGATIVELY CHARGED DIAGNOSTIC CYTOLOGICAL MATERIAL TO THE SLIDE THROUGHOUT THE SLIDE PREPARATION PROCESS.

207	IMP/IVD/2019/000175	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD BACTEC MICRO MGIT CALIBRATION VIAL(BD BACTEC MICRO MGIT CALIBRATION VIAL)-THE BACTEC MICROMGIT DEVICE IS HAND-HELD, BATTERY–OPERATED IN VITRO DIAGNOSTIC INSTRUMENT DESIGNED AND OPTIMIZED TO USE WITH THE BBL 4 ML TUBES FOR THE RAPID DETECTION OF MYCOBACTERIA FROM CLINICAL SPECIMENS (EXCEPT BLOOD AND URINE).,BD BBL CRYSTALSPEC CALIBRATION TUBES(BD BBL CRYSTALSPEC CALIBRATION TUBES)-THE CRYSTALSPEC™ NEPHELOMETER IS A BATTERY-POWERED, PORTABLE DEVICE DESIGNED TO MEASURE THE TURBIDITY OF MICROBIAL SUSPENSIONS EQUIVALENT TO MCFARLAND STANDARDS 0.5 THROUGH 4.0. THE INSTRUMENT CAN BE USED FOR ANY LABORATORY PROCEDURE THAT REQUIRES INOCULUM DENSITY ADJUSTMENTS WITHIN THIS RANGE.,BD PHOENIX EMERGE AST INDICATOR SOLUTION(BD PHOENIX EMERGE AST INDICATOR SOLUTION)-THE BD PHOENIX™ AUTOMATED MICROBIOLOGY SYSTEM IS INTENDED FOR THE RAPID IDENTIFICATION (ID) AND ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) OF CLINICALLY SIGNIFICANT BACTERIA. THE BD PHOENIX SYSTEM PROVIDES RAPID RESULTS FOR MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-POSITIVE BACTERIA AS WELL AS MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-NEGATIVE BACTERIA OF HUMAN ORIGIN. THE BD PHOENIX SYSTEM IS ALSO INTENDED FOR THE RAPID IDENTIFICATION OF YEAST AND YEAST-LIKE ORGANISMS.,BD PHOENIX AST-S INDICATOR SOLUTION(BD PHOENIX AST-S INDICATOR SOLUTION)-THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM IS INTENDED FOR RAPID IDENTIFICATION (ID) AND ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) OF CLINICALLY SIGNIFICANT BACTERIA. THE PHOENIX SYSTEM PROVIDES RAPID RESULTS FOR MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM POSITIVE BACTERIA AS WELL AS MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM NEGATIVE BACTERIA OF HUMAN ORIGIN. THE PHOENIX SYSTEM IS ALSO INTENDED FOR RAPID IDENTIFICATION OF YEAST AND YEAST LIKE ORGANISMS.,BD PHOENIX™ NMIC-411(BD PHOENIX™ NMIC-411)-THE BD PHOENIX™ NMIC PANEL IS USED FOR THE SUSCEPTIBILITY TESTING OF MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-NEGATIVE BACTERIA OF HUMAN ORIGIN WITH SELECTED ANTIMICROBIAL AGENTS (FOR A COMPLETE LISTING OF TAXA, REFER TO THE BD PHOENIX SYSTEM USER'S MANUAL). THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.,BD PHOENIX™ PMIC-84(BD PHOENIX™ PMIC-84)-THE BD PHOENIX™

	PMIC PANEL IS USED FOR THE SUSCEPTIBILITY TESTING OF MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-POSITIVE BACTERIA OF HUMAN ORIGIN WITH SELECTED ANTIMICROBIAL AGENTS (FOR A COMPLETE LISTING OF TAXA, REFER TO THE BD PHOENIX SYSTEM USER'S MANUAL). THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.,BD PHOENIX™ UNMIC/ID-416(BD PHOENIX™ UNMIC/ID-416)-THE BD PHOENIX™ UNMIC/ID PANEL IS USED FOR THE RAPID IDENTIFICATION AND SUSCEPTIBILITY TESTING OF MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-NEGATIVE BACTERIA OF HUMAN ORIGIN WITH SELECTED ANTIMICROBIAL AGENTS. THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.,BD PHOENIX™ YEAST ID(BD PHOENIX™ YEAST ID)-THE BD PHOENIX™ AUTOMATED MICROBIOLOGY SYSTEM IS INTENDED FOR THE IN VITRO RAPID IDENTIFICATION (ID) OF YEAST AND YEAST-LIKE ORGANISMS (FOR A COMPLETE LISTING OF TAXA, REFER TO THE BD PHOENIX SYSTEM USER'S MANUAL). THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.,PHOENIX™ UNMIC-416(PHOENIX™ UNMIC-416)-THE BD PHOENIX™ UNMIC PANEL IS USED FOR THE SUSCEPTIBILITY TESTING OF MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-NEGATIVE BACTERIA OF HUMAN ORIGIN WITH SELECTED ANTIMICROBIAL AGENTS. THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.,PHOENIX AST INDICATOR SOLUTION(PHOENIX AST INDICATOR SOLUTION)-THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM IS INTENDED FOR RAPID IDENTIFICATION (ID) AND ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) OF CLINICALLY SIGNIFICANT BACTERIA. THE PHOENIX SYSTEM PROVIDES RAPID RESULTS FOR MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM POSITIVE BACTERIA AS WELL AS MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM NEGATIVE BACTERIA OF HUMAN ORIGIN. THE PHOENIX SYSTEM IS ALSO INTENDED FOR RAPID IDENTIFICATION OF YEAST AND YEAST LIKE ORGANISMS.,BD PHOENIX™ PMIC/ID-70(BD PHOENIX™ PMIC/ID-70)-THE BD PHOENIX™ PMIC/ID PANEL IS USED FOR THE RAPID IDENTIFICATION AND SUSCEPTIBILITY TESTING OF MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-POSITIVE BACTERIA OF HUMAN ORIGIN WITH SELECTED ANTIMICROBIAL AGENTS (FOR A COMPLETE LISTING OF TAXA, REFER TO THE BD PHOENIX SYSTEM USER'S MANUAL). THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.,BD PHOENIX SMIC/ID-9(BD PHOENIX SMIC/ID-9)-THE BD PHOENIX™ SMIC/ID PANEL IS USED FOR THE RAPID IDENTIFICATION AND SUSCEPTIBILITY TESTING OF MOST STREPTOCOCCUS SPECIES OF

	HUMAN ORIGIN WITH SELECTED ANTIMICROBIAL AGENTS (FOR A COMPLETE LISTING OF TAXA, REFER TO THE BD PHOENIX SYSTEM USER'S MANUAL). THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.,BD PHOENIX GRAM NEGATIVE COMBO PANEL (NMIC / ID – 55)(BD PHOENIX GRAM NEGATIVE COMBO PANEL (NMIC / ID – 55))-THE BD PHOENIX™ NMIC/ID PANEL IS USED FOR THE RAPID IDENTIFICATION AND SUSCEPTIBILITY TESTING OF MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-NEGATIVE BACTERIA OF HUMAN ORIGIN WITH SELECTED ANTIMICROBIAL AGENTS (FOR A COMPLETE LISTING OF TAXA, REFER TO THE BD PHOENIX SYSTEM USER'S MANUAL). THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.,BD PHOENIX NID(BD PHOENIX NID)-THE BD PHOENIX™ NID PANEL IS USED FOR THE RAPID IDENTIFICATION OF MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-NEGATIVE BACTERIA OF HUMAN ORIGIN (FOR A COMPLETE LISTING OF TAXA, REFER TO THE BD PHOENIX SYSTEM USER'S MANUAL). THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.,BD PHOENIX™ PMIC/ID-55 (GRAM POSITIVE COMBO PANEL)(BD PHOENIX™ PMIC/ID-55 (GRAM POSITIVE COMBO PANEL))-THE BD PHOENIX™ PMIC/ID PANEL IS USED FOR THE RAPID IDENTIFICATION AND SUSCEPTIBILITY TESTING OF MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-POSITIVE BACTERIA OF HUMAN ORIGIN WITH SELECTED ANTIMICROBIAL AGENTS (FOR A COMPLETE LISTING OF TAXA, REFER TO THE BD PHOENIX SYSTEM USER'S MANUAL). THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.,BD PHOENIX PID(BD PHOENIX PID)-THE BD PHOENIX™ PID PANEL IS USED FOR THE RAPID IDENTIFICATION OF MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-POSITIVE BACTERIA OF HUMAN ORIGIN (FOR A COMPLETE LISTING OF TAXA, REFER TO THE BD PHOENIX SYSTEM USER'S MANUAL). THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.,PANEL PHOENIX NMIC/ID-421(PANEL PHOENIX NMIC/ID-421)-THE BD PHOENIX™ NMIC/ID PANEL IS USED FOR THE RAPID IDENTIFICATION AND SUSCEPTIBILITY TESTING OF MOST AEROBIC AND FACULTATIVELY ANAEROBIC GRAM-NEGATIVE BACTERIA OF HUMAN ORIGIN WITH SELECTED ANTIMICROBIAL AGENTS (FOR A COMPLETE LISTING OF TAXA, REFER TO THE BD PHOENIX SYSTEM USER'S MANUAL). THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT,PANEL PHOENIX NMIC 500 (PANEL PHOENIX NMIC 500)-THE BD PHOENIX™ NMIC PANEL IS USED FOR THE SUSCEPTIBILITY TESTING OF MOST AEROBIC AND

		FACULTATIVELY ANAEROBIC GRAM-NEGATIVE BACTERIA OF HUMAN ORIGIN WITH SELECTED ANTIMICROBIAL AGENTS (FOR A COMPLETE LISTING OF TAXA, REFER TO THE BD PHOENIX SYSTEM USER'S MANUAL). THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.,BD PHOENIX™ NMIC-404(BD PHOENIX™ NMIC-404)-THE BD PHOENIX™ NMIC PANEL IS USED FOR THE SUSCEPTIBILITY TESTING OF MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-NEGATIVE BACTERIA OF HUMAN ORIGIN WITH SELECTED ANTIMICROBIAL AGENTS (FOR A COMPLETE LISTING OF TAXA, REFER TO THE BD PHOENIX SYSTEM USER'S MANUAL). THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.,BD PHOENIX SMIC/ID-2 (STREP ID COMBO PANEL)(BD PHOENIX SMIC/ID-2 (STREP ID COMBO PANEL))-THE BD PHOENIX™ SMIC/ID PANEL IS USED FOR THE RAPID IDENTIFICATION AND SUSCEPTIBILITY TESTING OF MOST STREPTOCOCCUS SPECIES OF HUMAN ORIGIN WITH SELECTED ANTIMICROBIAL AGENTS (FOR A COMPLETE LISTING OF TAXA, REFER TO THE BD PHOENIX SYSTEM USER'S MANUAL). THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.,BD PHOENIX™ PMIC-95 (GRAM POSITIVE EMERGE PANEL)(BD PHOENIX™ PMIC-95 (GRAM POSITIVE EMERGE PANEL))-THE BD PHOENIX™ PMIC PANEL IS USED FOR THE SUSCEPTIBILITY TESTING OF MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-POSITIVE BACTERIA OF HUMAN ORIGIN WITH SELECTED ANTIMICROBIAL AGENTS (FOR A COMPLETE LISTING OF TAXA, REFER TO THE BD PHOENIX SYSTEM USER'S MANUAL). THIS PANEL IS ONLY FOR USE WITH THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM INSTRUMENT.
208	IMP/IVD/2019/000176	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVIA CHEMISTRY (ECRE_2) CREATININE_2 REAGENTS (ENZYMATIC)(ADVIA CHEMISTRY (ECRE_2) CREATININE_2 REAGENTS (ENZYMATIC))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA (LITHIUM HEPARIN AND POTASSIUM EDTA), AND URINE ON ADVIA® CHEMISTRY XPT SYSTEMS. SUCH MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASES, AND INMONITORING RENAL DIALYSIS

209	IMP/IVD/2019/000177	1.License Holder Name: INKARP INSTRUMENTS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MG REAGENT KIT (MAGNESIUM REAGENT KIT)-USED TO TEST MAGNESIUM LEVELS IN PATIENT SAMPLES,CREA-U REAGENT KIT(URINE CREATININE REAGENT KIT)-USED TO TEST URINE CREATININE IN PATIENT URINE SAMPLES,BUN REAGENT KIT(BLOOD UREA NITROGEN REAGENT KIT)-USED TO TEST BUN LEVELS IN PATIENT SAMPLES,RED TEST DYE SOLUTION(EASYELECTROLYTE RED TEST DYE SOLUTION)-USED TO TROUBLESHOOT THE ANALYZER,TRI-LEVEL QC KIT(TRI-LEVEL QUALITY CONTROL KIT)-USED TO TEST THE PERFORMANCE OF THE ANALYZER,DAILY CLEANING SOLUTION KIT(DAILY CLEANING SOLUTION KIT)-USED TO CLEAN THE ANALYZER AFTER SAMPLE ANALYSIS,BI-LEVEL QC KIT(BI-LEVEL QUALITY CONTROL KIT)-USED TO TEST THE PERFORMANCE OF THE ANALYZER,NA/K/CL REAGENT MODULE(EASYELECTROLYTE REAGENT MODULE, NA/K/CL)-USED IN THE CALIBRATION AND SAMPLE ANALYSIS OF THE EASYELECTROLYTE ANALYZER,NA/K/LI REAGENT MODULE (EASYELECTROLYTE REAGENT MODULE, NA/K/LI)-USED IN THE CALIBRATION AND SAMPLE ANALYSIS OF THE EASYELECTROLYTE ANALYZER,BLOOD GAS/ELECTROLYTE LEVEL 1 QC KIT(EASYQC LEVEL 1 BLOOD GAS AND ELECTROLYTE QUALITY CONTROL KIT)-USED TO TEST THE PERFORMANCE OF THE ANALYZER,ALB REAGENT KIT(ALBUMIN REAGENT KIT)-USED TO TEST ALBUMIN LEVELS IN PATIENT SAMPLES,BI-LEVEL HCT QC KIT(BI-LEVEL HCT QUALITY CONTROL KIT)-USED TO TEST THE PERFORMANCE OF HCT ON THE EASYSTAT ANALYZER,ES REAGENT MODULE(EASYSTAT REAGENT MODULE)-USED IN THE CALIBRATION AND SAMPLE ANALYSIS OF EASYSTAT ANALYZER,ALP REAGENT KIT(ALKALINE PHOSPHATASE REAGENT KIT)-USED TO TEST ALKALINE PHSOPHATASE LEVELS IN PATIENT SAMPLES,RED TEST DYE SOLUTION(EASYBLOODGAS RED TEST DYE SOLUTION)-USED TO TROUBLESHOOT THE ANALYZER,EBD REAGENT MODULE(EASYBLOODGAS REAGENT MODULE)-USED IN THE CALIBRATION AND SAMPLE ANALYSIS OF THE EASYBLOODGAS ANALYZER,BLOOD GAS/ELECTROLYTE LEVEL 3 QC KIT(EASYQC LEVEL 3 BLOOD GAS AND ELECTROLYTE QUALITY CONTROL KIT)-USED TO TEST THE PERFORMANCE OF THE ANALYZER,ALT REAGENT KIT(ALANINE AMINOTRANSFERASE REAGENT KIT)-USED TO TEST ALANINE AMINOTRANSFERASE LEVELS IN PATIENT SAMPLES,BLOOD GAS/ELECTROLYTE LEVEL 2 QC KIT(EASYQC LEVEL 2 BLOOD GAS AND ELECTROLYTE QUALITY CONTROL KIT)-USED TO TEST THE PERFORMANCE OF THE ANALYZER,CA REAGENT KIT(CALCIUM REAGENT KIT)-USED TO TEST CALCIUM LEVELS IN PATIENT SAMPLES, GLU-T REAGENT KIT(GLUCOSE TRINDER REAGENT KIT)-USED TO

	TEST GLUCOSE LEVELS IN PATIENT SAMPLES,AST REAGENT KIT (ASPARTATE AMIONTRANSFERASE REAGENT KIT)-USED TO TEST ASPARTATE AMINOTRANSFERASE LEVELS IN PATIENT SAMPLES,AMY REAGENT KIT(AMYLASE REAGENT KIT)-USED TO TEST AMYLASE LEVELS IN PATIENT SAMPLES,CHOL REAGENT KIT(CHOLESTEROL REAGENT KIT)-USED TO TEST CHOLESTEROL LEVELS IN PATIENT SAMPLES,URINE DILUENT(EASYELECTROLYTE URINE DILUENT)-USED TO DILUTE URINE SAMPLES PRIOR TO ANALYSIS,CK REAGENT KIT (CREATINE KINASE REAGENT KIT)-USED TO TEST CREATINE KINASE LEVELS IN PATIENT SAMPLES,CO2 REAGENT KIT(CARBON DIOXIDE REAGENT KIT)-USED TO TEST CO2 LEVELS IN PATIENT SAMPLES,DBIL REAGENT KIT(DIRECT BILIRUBIN REAGENT KIT)-USED TO TEST BILIRUBIN LEVELS IN PATIENT SAMPLES,FE REAGENT KIT(IRON REAGENT KIT)-USED TO TEST IRON LEVELS IN PATIENT SAMPLES, GLU-H REAGENT KIT(GLUCOSE HEXOKINASE REAGENT KIT)-USED TO TEST GLUCOSE LEVELS IN PATIENT SAMPLES,TP REAGENT KIT (TOTAL PROTEIN REAGENT KIT)-USED TO TEST TOTAL PROTEIN LEVELS IN PATIENT SAMPLES,LDH REAGENT KIT(LACTATE DEHYDROGENASE REAGENT KIT)-USED TO TEST LDH LEVELS IN PATIENT SAMPLES,CREA REAGENT KIT(CREATININE REAGENT KIT)-USED TO TEST CREATININE LEVELS IN PATIENT SAMPLES,TBIL REAGENT KIT(TOTAL BILIRUBIN REAGENT KIT)-USED TO TEST BILIRUBIN LEVELS IN PATIENT SAMPLES,UALB CALIBRATOR KIT (CHEMISTRY UALB CALIBRATOR KIT)-USED TO CALIBRATE THE MICROALBUMIN CHEMISTRY ON THE EASYRA ANALYZER,PHOS REAGENT KIT(PHOSPHORUS REAGENT KIT)-USED TO TEST PHOSPHORUS LEVELS IN PATIENT SAMPLES,URIC REAGENT KIT(URIC ACID REAGENT KIT)-USED TO TEST URIC ACID LEVELS IN PATIENT SAMPLES,NA/K/CL/LI REAGENT PACK(ISE 4 CHANNEL REAGENT PACK - NO WASTE)-USED IN THE CALIBRATION AND SAMPLE ANALYSIS OF THE ISE ELECTRODES,CKMB REAGENT KIT(CREATINE KINASE-MB REAGENT KIT)-USED TO MEASURE THE LEVEL OF CKMB IN A PATIENT SAMPLE,TRIG REAGENT KIT(TRIGLYCERIDES REAGENT KIT)-USED TO TEST TRIGLYCERIDES LEVELS IN PATIENT SAMPLES, TIBC CALIBRATOR KIT(TOTAL IRON BINDING CAPACITY CALIBRATOR KIT)-USED TO CALIBRATE THE TIBC CHEMISTRY ON THE EASYRA ANALYZER,LIP REAGENT KIT(LIPASE REAGENT KIT)-USED TO MEASURE THE LEVEL OF LIPASE IN A PATIENT SAMPLE,TIBC REAGENT KIT(TOTAL IRON BINDING CAPACITY REAGENT KIT)-USED TO MEASURE THE LEVEL OF TIBC IN A PATIENT SAMPLE,WASH 1 CHEMISTRY KIT(WASH 1 CHEMISTRY KIT)-USED TO CLEAN THE PROBE ON THE EASYRA ANALYZER,GGT REAGENT KIT(GAMMA-GLUTAMYL TRANSFERASE REAGENT KIT)-USED TO TEST GGT LEVELS IN PATIENT SAMPLES,HDL REAGENT KIT(HDL CHOLESTEROL REAGENT KIT)-USED

	TO TEST HDL CHOLESTEROL LEVELS IN PATIENT SAMPLES, CHEMISTRY CALIBRATOR KIT(EASYCAL CHEMISTRY CALIBRATOR KIT)-USED TO CALIBRATE THE CHEMISTRIES ON THE EASYRA ANALYZER,LDL REAGENT KIT(LDL CHOLESTEROL REAGENT KIT)-USED TO TEST LDL CHOLESTEROL LEVELS IN PATIENT SAMPLES, URINE CREATININE CALIBRATOR KIT(EASYCAL URINE CREATININE CALIBRATOR KIT)-USED TO CALIBRATE THE URINE CREATININE CHEMISTRY ON THE EASYRA ANALYZER,EASYQC QC KIT - LEVEL B (EASYQC QUALITY CONTROL KIT - LEVEL B)-USED TO TEST THE ACCURACY AND PRECISION OF THE EASYRA CHEMISTRIES,HDL CALIBRATOR KIT(EASYCAL HDL CHEMISTRY CALIBRATOR KIT)-USED TO CALIBRATE THE HDL CHEMISTRY ON THE EASYRA ANALYZER, UALB REAGENT KIT(MICROALBUMIN REAGENT KIT)-USED TO TEST MICROALBUMIN LEVELS IN PATIENT URINE SAMPLES,HBA1C QC KIT - LEVEL 2(HBA1C QUALITY CONTROL KIT - LEVEL 2)-USED TO TEST THE ACCURACY AND PRECISION OF THE HBA1C CHEMISTRY,HBA1C MULTI-CAL SET(EASYCAL HBA1C MULTI-CAL SET)-USED TO CALIBRATE THE HBA1C CHEMISTRY ON THE EASYRA ANALYZER, HBA1C QC KIT - LEVEL 1(HBA1C QUALITY CONTROL KIT - LEVEL 1)-USED TO TEST THE ACCURACY AND PRECISION OF THE HBA1C CHEMISTRY,CLEANER KIT - CHEMISTRY(EASYRA CLEANER KIT - CHEMISTRY)-USED TO CLEAN THE ANALYZER AFTER SAMPLE ANALYSIS,CLEANER KIT - CHEMISTRY AND ISE(EASYRA CLEANER KIT - CHEMISTRY AND ISE)-USED TO CLEAN THE ANALYZER AFTER SAMPLE ANALYSIS,HBA1C HEMOLYZING SOLUTION(HBA1C HEMOLYZING SOLUTION)-USED TO HEMOLYZE HBA1C PATIENT SAMPLES PRIOR TO ANALYSIS,CO2 CALIBRATOR KIT(EASYCAL CO2 CALIBRATOR KIT)-USED TO CALIBRATE THE CO2 CHEMISTRY ON THE EASYRA ANALYZER,SURFACTANT KIT(EASYRA SURFACTANT KIT)-USED AS AN ADDITIVE TO DIH2O TO BE USED WITH THE EASYRA DILUENT,LDL CALIBRATOR KIT(EASYCAL LDL CALIBRATOR KIT)-USED TO CALIBRATE THE LDL CHEMISTRY ON THE EASYRA ANALYZER,HBA1C REAGENT KIT(HBA1C REAGENT KIT)-USED TO TEST HBA1C LEVELS IN PATIENT WHOLE BLOOD SAMPLES,EASYQC QC KIT - LEVEL A(EASYQC QUALITY CONTROL KIT - LEVEL A)-USED TO TEST THE ACCURACY AND PRECISION OF THE EASYRA CHEMISTRIES, PRECISION DYE KIT(EASYRA PRECISION DYE KIT)-USED TO TEST THE PRECISION AND ACCURACY OF THE ANALYZER

210	IMP/IVD/2019/000178	1.License Holder Name: M/S MP BIOMEDICALS INDIA PVT.LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ONE STEP TRAMADOL URINE TEST(NA)-ONE STEP TRAMADOL URINE TEST IS A RAPID ONE STEP TEST FOR THE QUALITATIVE DETECTION OF TRAMADOL AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT OFF LEVEL.,MET URINE TEST(ONE STEP METHAMPHETAMINE URINE TEST)-QUALITATIVE DETECTION OF METHAMPHETAMINE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,ONE STEP MULTI-DRUG URINE TEST PANEL(NA)-ONE STEP MULTI-DRUG URINE TEST PANEL IS CONSISTED OF INDIVIDUAL ONE -STEP IMMUNOASSAYS. THE TEST IS A LATERAL FLOW, ONE-STEP IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC DRUGS AND THEIR METABOLITES IN HUMAN URINE,MDMA URINE TEST(ONE STEP METHYLENEDIOXYMETHAMPHETAMINE URINE TEST) -QUALITATIVE DETECTION OF METHYLENEDIOXYMETHAMPHETAMINE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,ONE STEP MULTI-DRUG URINE TEST (+ADULTERATION AND ALCOHOL) T-CUP(NA)-ONE STEP MULTI-DRUG URINE TEST T-CUP (+ADULTERATION AND ALCOHOL) IS A RAPID ONE STEP TEST FOR THE QUALITATIVE DETECTION OF DRUG OF ABUSE AND THEIR PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT OFF LEVEL ADDITIONAL A SEMI QUANTITATIVE ADULTERATION CONTROL AND THE QUALITATIVE DETECTION OF ALCOHOL.,PCP URINE TEST (ONE STEP PHENCYCLIDINE URINE TEST)-QUALITATIVE DETECTION OF PHENCYCLIDINE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,ONE STEP MULTI-DRUG URINE TEST PANEL(NA)-ONE STEP MULTI-DRUG URINE TEST PANEL IS CONSISTED OF INDIVIDUAL ONE -STEP IMMUNOASSAYS. THE TEST IS A LATERAL FLOW, ONE-STEP IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC DRUGS AND THEIR METABOLITES IN HUMAN URINE,AMP URINE TEST(ONE STEP AMPHETAMINE URINE TEST)-QUALITATIVE DETECTION OF AMPHETAMINE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,ONE STEP MULTI-DRUG URINE TEST (+ADULTERATION AND ALCOHOL) T-CUP(NA)-ONE STEP MULTI-DRUG URINE TEST T-CUP (+ADULTERATION AND ALCOHOL) IS A RAPID ONE STEP TEST FOR THE QUALITATIVE DETECTION OF DRUG OF ABUSE AND THEIR PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT OFF LEVEL ADDITIONAL A SEMI QUANTITATIVE ADULTERATION CONTROL AND THE QUALITATIVE DETECTION OF ALCOHOL.,THC URINE TEST (ONE STEP MARIJUANA URINE TEST)-QUALITATIVE DETECTION OF MARIJUANA AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT

	SPECIFIED CUT-OFF LEVEL.,ONE STEP MULTI-DRUG URINE TEST PANEL(NA)-ONE STEP MULTI-DRUG URINE TEST PANEL IS CONSISTED OF INDIVIDUAL ONE -STEP IMMUNOASSAYS. THE TEST IS A LATERAL FLOW, ONE-STEP IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC DRUGS AND THEIR METABOLITES IN HUMAN URINE,COC URINE TEST(ONE STEP COCAINE URINE TEST)-QUALITATIVE DETECTION OF COCAINE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,ONE STEP MULTI-DRUG URINE TEST (+ADULTERATION AND ALCOHOL) PANEL(NA)-ONE STEP MULTI-DRUG URINE TEST PANEL (+ADULTERATION AND ALCOHOL) IS A RAPID ONE STEP TEST FOR THE QUALITATIVE DETECTION OF DRUG OF ABUSE AND THEIR PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT OFF LEVEL ADDITIONAL A SEMI QUANTITATIVE ADULTERATION CONTROL AND THE QUALITATIVE DETECTION OF ALCOHOL.,BAR URINE TEST(ONE STEP BARBITURATES URINE TEST)-QUALITATIVE DETECTION OF BARBITURATES AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,MTD URINE TEST(ONE STEP METHADONE URINE TEST)-QUALITATIVE DETECTION OF METHADONE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,OXY URINE TEST(ONE STEP OXYCODONE URINE TEST)-QUALITATIVE DETECTION OF OXYCODONE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,TCA URINE TEST(ONE STEP TRICYCLIC ANTIDEPRESSANTS URINE TEST)-QUALITATIVE DETECTION OF TRICYCLIC ANTIDEPRESSANT AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,OPI URINE TEST (2000 NG/ML)(ONE STEP OPIATE URINE TEST)-QUALITATIVE DETECTION OF OPIATE URINE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,OPI URINE TEST (300 NG/ML)(ONE STEP OPIATE URINE TEST)-QUALITATIVE DETECTION OF OPIATE URINE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,MOP URINE TEST(ONE STEP MORPHINE URINE TEST)-QUALITATIVE DETECTION OF MORPHINE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,BUP URINE TEST(ONE STEP BUPRENORPHINE URINE TEST)-QUALITATIVE DETECTION OF BUPRENORPHINE. AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,BZO URINE TEST(ONE STEP BENZODIAZEPINES URINE TEST)-QUALITATIVE DETECTION OF BENZODIAZEPINES AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,COT URINE TEST(ONE STEP COTININE(COT) URINE TEST)-QUALITATIVE DETECTION OF COTININE WHICH IS THE PRINCIPAL METABOLITES NICOTINE, IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,PPX URINE TEST(ONE STEP PROPOXYPHENE URINE TEST)-QUALITATIVE

		DETECTION OF PROPOXYPHENE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,KET URINE TEST (ONE STEP KETAMINE URINE TEST)-QUALITATIVE DETECTION OF KETAMINE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.
211	IMP/IVD/2019/000179	1.License Holder Name: M/S AVANTOR PERFORMANCE MATERIALS INDIA LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:T4 ELISA (BULK)-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUANTITATIVE DETERMINATION OF T4 (THYROXINE) IN HUMAN SERUM.,FT4 ELISA (BULK)-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUANTITATIVE DETERMINATION OF FT4 (FREE THYROXINE) IN HUMAN SERUM,FT3 ELISA (BULK)-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUANTITATIVE DETERMINATION OF FT3 (FREE TRIIODOTHYRONINE) IN HUMAN SERUM.,TSH ELISA (BULK)-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUANTITATIVE DETERMINATION OF TSH (THYROID STIMULATING HORMONE) IN HUMAN SERUM.,T3 ELISA (BULK)-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUANTITATIVE DETERMINATION OF T3 (TRIIODOTHYRONINE) IN HUMAN SERUM.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

212	IMP/IVD/2019/000181	1.License Holder Name: IDEXX LABORATORIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VETSTAT STANDARD REFERENCE CASSETTE L1(IDEXX)-CALIBRATION PLASTIC CARTRIDGE FOR THE VETSTAT ANALYZER,IDEXX CATALYST LYTE 4 CLIP(IDEXX)-USED WITH THE IDEXX CATALYST DXTM CHEMISTRY ANALYZER TO DETECT A VARIETY OF ANALYTES IN ANIMAL SERUM OR PLASMA 3 ANALYTES.,VETSTAT GLUCOSE CASSETTE (5)(IDEXX)-USED FOR THE MEASURE OF DIFFERENT PARAMETERS IN BLOOD SAMPLE USING THE VETSTAT ANALYZER ,VETSTAT IONIZED CALCIUM CASSETTE (5)(IDEXX)-USED FOR THE MEASURE OF DIFFERENT PARAMETERS IN BLOOD SAMPLE USING THE VETSTAT ANALYZER,VETSTAT ELECTROLYTES 8 PLUS CASSETTE (5)(IDEXX)-USED FOR THE MEASURE OF DIFFERENT PARAMETERS IN BLOOD SAMPLE USING THE VETSTAT ANALYZER.,VETSTATRESP/BLOOD GASSES CASSETTE (5)(IDEXX)-USED FOR THE MEASURE OF DIFFERENT PARAMETERS IN BLOOD SAMPLE USING THE VETSTAT ANALYZER, VETSTATHAEMOGLOBIN CALIBRATION CASSETTE(IDEXX)-FOR THE MEASURE OF DIFFERENT PARAMETERS IN BLOOD SAMPLE USING THE VETSTAT ANALYZER,VETSTAT OPTI-CHECK(IDEXX)-USED TO MONITOR THE MEASUREMENT OF PH, PCO2, PO2, SODIUM, POTASSIUM, CHLORIDE, IONIZED CALCIUM, TOTAL HEMOGLOBIN CONTENT AND OXYGEN SATURATION IN THE IDEXX VETSTAT® ELECTROLYTE AND BLOOD GAS ANALYZER.,VETSTAT STANDARD REFERENCE CASSETTE L3(IDEXX)-CALIBRATION PLASTIC CARTRIDGE FOR THE VETSTAT ANALYZER

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

213	IMP/IVD/2019/000183	1.License Holder Name: BIO-RAD LABORATORIES (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VARIANT™NBS SICKLE CELL PROGRAM ELUTION BUFFER 1(VARIANT™NBS SICKLE CELL PROGRAM ELUTION BUFFER 1)-THE BIO-RAD VARIANT™NBS SICKLE CELL PROGRAM IS INTENDED AS A QUANTITATIVE SCREEN FOR THE PRESENCE OF HEMOGLOBIN F, A, S, D, C AND E IN ELUATES OF NEONATAL BLOOD COLLECTED ON FILTER PAPER BY HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD VARIANT™NBS SICKLE CELL PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY.,AUTOIMMUNE EIA ANTI-SS-A/RO TEST (AUTOIMMUNE EIA ANTI-SS-A/RO TEST)-THE BIO-RAD AUTOIMMUNE EIA ANTI-SS-A/RO TEST IS AN ENZYME IMMUNOASSAY (EIA) INTENDED FOR THE DETECTION AND SEMI-QUANTITATIVE MEASUREMENT OF ANTIBODIES AGAINST THE SS-A/RO ANTIGEN IN HUMAN SERUM AND PLASMA AS AN AID IN THE DIAGNOSIS OF CERTAIN RHEUMATIC AUTOIMMUNE DISEASES. FOR IN VITRO DIAGNOSTIC USE,WHOLE BLOOD PRIMER(WHOLE BLOOD PRIMER)-THE VARANT II TURBO HB1AC KIT- 2.0 IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH- PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON VARIANT II TURBO HEMOGLOBIN TESTING SYSTEM AND VARIANT II TURBO LINK HEMOGLOBIN TESTING SYSTEM,AUTOIMMUNE EIA ANTI-DSDNA TEST(AUTOIMMUNE EIA ANTI-DSDNA TEST)-THE BIO-RAD AUTOIMMUNE EIA ANTI-DSDNA TEST IS A QUANTITATIVE ENZYME IMMUNOASSAY (EIA) INTENDED TO SCREEN FOR THE PRESENCE OF DSDNA ANTIBODIES IN HUMAN SERUM AS AN AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). FOR IN VITRO DIAGNOSTIC USE.,D-10™ WASH/DILUENT SOLUTION(D-10™ WASH/DILUENT SOLUTION)-THE D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH- PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE D-10 HEMOGLOBIN TESTING SYSTEM. HEMOGLOBIN A1C MEASUREMENTS ARE USED AS AN AID IN DIAGNOSIS OF DIABETES MELLITUS, AS AN AID TO IDENTIFY PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES MELLITUS AND FOR THE MONITORING OF LONG-TERM BLOOD GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE D-10™ HEMOGLOBIN A1C PROGRAM IS FOR PROFESSIONAL IN VITRO DIAGNOSTICS USE ONLY.,AUTOIMMUNE EIA ANTI-JO-1 TEST (AUTOIMMUNE EIA ANTI-JO-1 TEST)-THE BIO-RAD AUTOIMMUNE EIA

	ANTI-JO-1 TEST IS AN ENZYME IMMUNOASSAY (EIA) INTENDED FOR THE DETECTION AND SEMIQUANTITATIVE MEASUREMENT OF ANTIBODIES AGAINST THE JO-1 ANTIGEN IN HUMAN SERUM AND PLASMA AS AN AID IN THE DIAGNOSIS OF POLYMYOSITIS AND DERMATOMYOSITIS. FOR IN VITRO DIAGNOSTIC USE.,VARIANT™NBS SICKLE CELL PROGRAM ELUTION BUFFER 2(VARIANT™NBS SICKLE CELL PROGRAM ELUTION BUFFER 2)-THE BIO-RAD VARIANT™NBS SICKLE CELL PROGRAM IS INTENDED AS A QUANTITATIVE SCREEN FOR THE PRESENCE OF HEMOGLOBIN F, A, S, D, C AND E IN ELUATES OF NEONATAL BLOOD COLLECTED ON FILTER PAPER BY HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD VARIANT™NBS SICKLE CELL PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY.,AUTOIMMUNE EIA ANA SCREENING TEST (AUTOIMMUNE EIA ANA SCREENING TEST)-THE BIO-RAD AUTOIMMUNE EIA ANA SCREENING TEST IS A QUALITATIVE ENZYME IMMUNOASSAY (EIA) INTENDED TO SCREEN FOR THE PRESENCE OF ANTINUCLEAR ANTIBODIES (ANAS) IN HUMAN SERUM AS AN AID IN THE DIAGNOSIS OF CERTAIN SYSTEMIC RHEUMATIC DISEASES. THIS ASSAY COLLECTIVELY DETECTS, IN ONE WELL, TOTAL ANAS AGAINST DOUBLE STRANDED DNA (DSDNA, NDNA), HISTONES, SS-A/RO, SS-B/LA, SM, SM/RNP, SCL-70, JO-1, AND CENTROMERIC ANTIGENS, ALONG WITH SERA POSITIVE FOR IMMUNOFL UORESCENT (IFA) HEP-2 ANAS. FOR IN VITRO DIAGNOSTIC USE.,D-10™ HEMOGLOBIN A1C PROGRAM CALIBRATOR/DILUENT SET(D-10™ HEMOGLOBIN A1C PROGRAM CALIBRATOR/DILUENT SET)-THE D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE D-10 HEMOGLOBIN TESTING SYSTEM. HEMOGLOBIN A1C MEASUREMENTS ARE USED AS AN AID IN DIAGNOSIS OF DIABETES MELLITUS, AS AN AID TO IDENTIFY PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES MELLITUS AND FOR THE MONITORING OF LONG-TERM BLOOD GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE D-10™ HEMOGLOBIN A1C PROGRAM IS FOR PROFESSIONAL IN VITRO DIAGNOSTICS USE ONLY.,AUTOIMMUNE EIA ANA 6 PROFILE TEST(AUTOIMMUNE EIA ANA 6 PROFILE TEST)-THE BIO-RAD AUTOIMMUNE EIA ANA-6 PROFI LE TEST IS INTENDED FOR THE DETECTION AND SEMI-QUANTITATIVE MEASUREMENT OF ANTIBODIES AGAINST THE FOLLOWING ANA ANTIGENS IN HUMAN SERUM: SS-A/RO, SS-B/LA, SM, SMRNP, SCL-70, AND JO-1. FOR IN VITRO DIAGNOSTIC USE,D-10™ HEMOGLOBIN A1C PROGRAM CALIBRATOR/DILUENT SET(D-10™ HEMOGLOBIN A1C PROGRAM CALIBRATOR/DILUENT SET)-THE D-10™ HEMOGLOBIN A1C PROGRAM

	IS INTENDED FOR THE PERCENT (QUANTITATIVE) DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE D-10™ HEMOGLOBIN TESTING SYSTEM. THE BIO-RAD D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE.,AUTOIMMUNE EIA ANTI-SS-B/LA TEST(AUTOIMMUNE EIA ANTI-SS-B/LA TEST)-THE BIO-RAD AUTOIMMUNE EIA ANTI-SS-B/LA TEST IS AN ENZYME IMMUNOASSAY (EIA) INTENDED FOR THE DETECTION AND SEMI-QUANTITATIVE MEASUREMENT OF ANTIBODIES AGAINST THE SS-B/LA ANTIGEN IN HUMAN SERUM AND PLASMA AS AN AID IN THE DIAGNOSIS OF CERTAIN RHEUMATIC DISEASES. FOR IN VITRO DIAGNOSTIC USE.,D-10™ WASH/DILUENT SOLUTION(D-10™ WASH/DILUENT SOLUTION)-THE D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE PERCENT (QUANTITATIVE) DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE D-10™ HEMOGLOBIN TESTING SYSTEM. THE BIO-RAD D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE.,AUTOIMMUNE EIA ANA SCREENING TEST(AUTOIMMUNE EIA ANA SCREENING TEST)-THE BIO-RAD AUTOIMMUNE EIA ANA SCREENING TEST IS A QUALITATIVE ENZYME IMMUNOASSAY (EIA) INTENDED TO SCREEN FOR THE PRESENCE OF ANTINUCLEAR ANTIBODIES (ANA$) IN HUMAN SERUM AS AN AID IN THE DIAGNOSIS OF CERTAIN SYSTEMIC RHEUMATIC DISEASES. THIS ASSAY COLLECTIVELY DETECTS, IN ONE WELL, TOTAL ANAS AGAINST DOUBLE STRANDED DNA (DSDNA, NDNA), HISTONES, SS-A/RO, SS-B/LA, SM, SM/RNP, SCL-70, JO-1, AND CENTROMERIC ANTIGENS, ALONG WITH SERA POSITIVE FOR IMMUNOFL UORESCENT (IFA) HEP-2 ANAS.FOR IN VITRO DIAGNOSTIC USE.,WASH/DILUENT SOLUTION SET (WASH/DILUENT SOLUTION SET)-THE VARIANT™ II TURBO HBA1C KIT- 2.0 IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION- EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON VARIANT™ II TURBO HEMOGLOBIN TESTING SYSTEM AND VARIANT™ II TURBO LINK HEMOGLOBIN TESTING SYSTEM. THIS TEST IS TO BE USED AS AN AID IN DIAGNOSIS OF DIABETES AND AS AND AID IN IDENTIFYING PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. MEASUREMENTS OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG-TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE VARIANT™ II TURBO HBA1C KIT -2.0 IS INTENDED FOR PROFESSIONAL USE ONLY. THE HEMOGLOBIN CAPILLARY

	COLLECTION SYSTEM (HCCS) IS INTENDED FOR THE COLLECTION OF HUMAN WHOLE BLOOD FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C USING BIO-RAD HPLC METHODS.,VARIANT II HEMOGLOBIN A1C PROGRAM REORDER PACK(VARIANT II HEMOGLOBIN A1C PROGRAM REORDER PACK)-THE BIO-RAD VARIANT II HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C IN HUMAN WHOLE BLOOD USING ION EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) THE BIO-RAD VARIANT II HEMOGLOBIN A1C PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY,D-10™ HEMOGLOBIN A1C PROGRAM ANALYTICAL CARTRIDGE(D-10™ HEMOGLOBIN A1C PROGRAM ANALYTICAL CARTRIDGE)-THE D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE D-10 HEMOGLOBIN TESTING SYSTEM. HEMOGLOBIN A1C MEASUREMENTS ARE USED AS AN AID IN DIAGNOSIS OF DIABETES MELLITUS, AS AN AID TO IDENTIFY PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES MELLITUS AND FOR THE MONITORING OF LONG-TERM BLOOD GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE D-10™ HEMOGLOBIN A1C PROGRAM IS FOR PROFESSIONAL IN VITRO DIAGNOSTICS USE ONLY.,D 10 HEMOGLOBIN A1C PROGRAM(D 10 HEMOGLOBIN A1C PROGRAM)-THE D 10 HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE D 10 HEMOGLOBIN TESTING SYSTEM. HEMOGLOBIN A1C MEASUREMENTS ARE USED AS AN AID IN THE DIAGNOSIS OF DIABETES MELLITUS AND AS AN AID IN IDENTIFYING PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES MELLITUS AND MONITORING LONG TERM GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE D 10 HEMOGLOBIN A1C PROGRAM IS INTENDED FOR PROFESSIONAL & IN VITRO DIAGNOSTIC USE ONLY,D-10™ DUAL PROGRAM HBA2/F/A1C CALIBRATOR/DILUENT SET(D-10™ DUAL PROGRAM HBA2/F/A1C CALIBRATOR/DILUENT SET)-SHORT PROGRAM: THE BIO-RAD D-10™ DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C IN WHOLE BLOOD USING ION-EXCHANGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). EXTENDED PROGRAM: THE BIO-RAD D-10™ DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBINS A2, F AND A1C AND FOR THE DETECTION OF ABNORMAL HEMOGLOBIN IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH-

	PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD D-10 DUAL PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE.,D 10 HEMOGLOBIN A1C PROGRAM REORDER PACK(D 10 HEMOGLOBIN A1C PROGRAM REORDER PACK)-THE D-10 HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP%) IN HUMAN WHOLE BLOOD ION EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE D 10 HEMOGLOBIN TESTING SYSTEM,VARIANT™ II ß-THALASSEMIA SHORT PROGRAM WASH/DILUENT SOLUTION(VARIANT™ II ß-THALASSEMIA SHORT PROGRAM WASH/DILUENT SOLUTION)-THE VARIANT™ II -THALASSEMIA SHORT PROGRAM IS INTENDED FOR SEPARATION AND AREA PERCENT DETERMINATIONS OF HEMOGLOBIN A2 AND F , AND AS AID IN THE IDENTIFICATION OF ABNORMAL HEMOGLOBIN'S IN WHOLE BLOOD USING USING ION-EXCHNGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE VARIANT™ II -THALASSEMIA SHORT PROGRAM IS INTENDED FOR USE ONLY WITH THE BIO-RAD VARIANT™ II HEMOGLOBIN TESTING SYSTEM. FOR IN VITRO DIAGNOSTIC USE.,D- 100 HBA1C CALIBRATOR PACK(D- 100 HBA1C CALIBRATOR PACK)-THE D 100 HBA1C TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP%) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON D 100 HEMOGLOBIN TESTING SYSTEM. HEMOGLOBIN A1C MEASUREMENTS ARE USED AS AN AID IN DIAGNOSIS OF DIABETES MELLITUS, AS AN AID TO IDENTIFY PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. MEASUREMENT OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG TERM GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE D 100 HBA1C TEST IS INTENDED FOR PROFESSIONAL USE ONLY. CALIBRATORS: THE D 100 HBA1C CALIBRATOR PACK IS FOR THE CALIBRATION OF D 100 HEMOGLOBIN TESTING SYSTEM USED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD,VARIANT™ II TURBO HBA1C KIT - 2.0 ELUTION BUFFER B(VARIANT™ II TURBO HBA1C KIT - 2.0 ELUTION BUFFER B)-THE VARIANT™ II TURBO HBA1C KIT- 2.0 IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/ MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH- PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON VARIANT™ II TURBO HEMOGLOBIN TESTING SYSTEM AND VARIANT™ II TURBO LINK HEMOGLOBIN TESTING SYSTEM. MEASUREMENT OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG-TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE BIO-RAD VARIANT™ II TURBO HBA1C KIT - 2.0 IS

	INTENDED FOR PROFESSIONAL USE ONLY.,D- 100 HBA1C ANALYTICAL CARTRIDGE/A1C CALIBRATOR PACK(D- 100 HBA1C ANALYTICAL CARTRIDGE/A1C CALIBRATOR PACK)-THE D 100 HBA1C TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP%) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON D 100 HEMOGLOBIN TESTING SYSTEM. HEMOGLOBIN A1C MEASUREMENTS ARE USED AS AN AID IN DIAGNOSIS OF DIABETES MELLITUS, AS AN AID TO IDENTIFY PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. MEASUREMENT OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG TERM GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE D 100 HBA1C TEST IS INTENDED FOR PROFESSIONAL USE ONLY. CALIBRATORS: THE D 100 HBA1C CALIBRATOR PACK IS FOR THE CALIBRATION OF D 100 HEMOGLOBIN TESTING SYSTEM USED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD,VARIANT™ II TURBO HBA1C KIT - 2.0 ANALYTICAL CARTRIDGE(VARIANT™ II TURBO HBA1C KIT - 2.0 ANALYTICAL CARTRIDGE)-THE VARIANT™ II TURBO HBA1C KIT- 2.0 IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/ MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH- PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON VARIANT™ II TURBO HEMOGLOBIN TESTING SYSTEM AND VARIANT™ II TURBO LINK HEMOGLOBIN TESTING SYSTEM. MEASUREMENT OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG-TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE BIO-RAD VARIANT™ II TURBO HBA1C KIT - 2.0 IS INTENDED FOR PROFESSIONAL USE ONLY.,VARIANT II TURBO HBA1C KIT 2.0(VARIANT II TURBO HBA1C KIT 2.0)-THE VARIANT II TURBO HBA1C KIT-2.0 IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE VARIANT II TURBO HEMOGLOBIN TESTING SYSTEM AND VARIANT II TURBO LINK HEMOGLOBIN TESTING SYSTEM. THIS TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF DIABETES AND AS AN AID IN IDENTIFYING PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. MEASUREMENT OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE VARIANT II TURBO HBA1C KIT-2.0 IS INTENDED FOR PROFESSIONAL USE ONLY. THE HEMOGLOBIN CAPILLARY COLLECTION SYSTEM (HCCS) IS INTENDED FOR THE COLLECTION OF HUMAN WHOLE BLOOD FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C USING BIO-RAD HPLC

	METHODS,VARIANT™ II TURBO HBA1C KIT - 2.0 CALIBRATOR/DILUENT SET(VARIANT™ II TURBO HBA1C KIT - 2.0 CALIBRATOR/DILUENT SET)-THE VARIANT™ II TURBO HBA1C KIT- 2.0 IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/ MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH- PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON VARIANT™ II TURBO HEMOGLOBIN TESTING SYSTEM AND VARIANT™ II TURBO LINK HEMOGLOBIN TESTING SYSTEM. MEASUREMENT OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG-TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE BIO-RAD VARIANT™ II TURBO HBA1C KIT - 2.0 IS INTENDED FOR PROFESSIONAL USE ONLY.,VARIANT II TURBO HBA1C KIT 2.0(VARIANT II TURBO HBA1C KIT 2.0)-THE VARIANT II TURBO HBA1C KIT- 2.0 IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL AND NGSP%) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE VARIANT II TURBO HEMOGLOBIN TESTING SYSTEM AND VARIANT II TURBO LINK HEMOGLOBIN TESTING SYSTEM.,D-10™ WASH/DILUENT SOLUTION(D-10™ WASH/DILUENT SOLUTION)-SHORT PROGRAM: THE BIO-RAD D-10™ DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C IN WHOLE BLOOD USING ION-EXCHANGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). EXTENDED PROGRAM: THE BIO-RAD D-10™ DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBINS A2, F AND A1C AND FOR THE DETECTION OF ABNORMAL HEMOGLOBIN IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD D-10 DUAL PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE.,D 10 DUAL PROGRAM A1C REORDER PACK (D 10 DUAL PROGRAM A1C REORDER PACK)-SHORT PROGRAM: THE BIO-RAD DUAL PROGRAM IS INTENDED FOR THE PERCENTAGE DETERMINATION OF HEMOGLOBIN A1C IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) EXTENDED PROGRAM: THE BIO-RAD D 10 DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBINS A2, F AND A1C AND FOR THE DETECTION OF ABNORMAL HEMOGLOBINS IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC), VARIANT™ II HEMOGLOBIN A1C PROGRAM WASH/DILUENT SOLUTION (VARIANT™ II HEMOGLOBIN A1C PROGRAM WASH/DILUENT SOLUTION)-THE BIO-RAD VARIANT™ II HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH -

	PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD VARIANT™ II HEMOGLOBIN A1C PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY.,D-100 SAMPLE DILUENT(D-100 SAMPLE DILUENT)-THE D 100 HBA1C TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP%) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON D 100 HEMOGLOBIN TESTING SYSTEM. HEMOGLOBIN A1C MEASUREMENTS ARE USED AS AN AID IN DIAGNOSIS OF DIABETES MELLITUS, AS AN AID TO IDENTIFY PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. MEASUREMENT OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG TERM GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE D 100 HBA1C TEST IS INTENDED FOR PROFESSIONAL USE ONLY. CALIBRATORS: THE D 100 HBA1C CALIBRATOR PACK IS FOR THE CALIBRATION OF D 100 HEMOGLOBIN TESTING SYSTEM USED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD,VARIANT™ II TURBO HBA1C KIT - 2.0 ELUTION BUFFER B (VARIANT™ II TURBO HBA1C KIT - 2.0 ELUTION BUFFER B)-THE VARIANT™ II TURBO HBA1C KIT- 2.0 IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON VARIANT™ II TURBO HEMOGLOBIN TESTING SYSTEM AND VARIANT™ II TURBO LINK HEMOGLOBIN TESTING SYSTEM. THIS TEST IS TO BE USED AS AN AID IN DIAGNOSIS OF DIABETES AND AS AND AID IN IDENTIFYING PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. MEASUREMENTS OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG-TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE VARIANT™ II TURBO HBA1C KIT -2.0 IS INTENDED FOR PROFESSIONAL USE ONLY. THE HEMOGLOBIN CAPILLARY COLLECTION SYSTEM (HCCS) IS INTENDED FOR THE COLLECTION OF HUMAN WHOLE BLOOD FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C USING BIO-RAD HPLC METHODS.,VARIANT II THALASSEMIA SHORT PROGRAM REORDER PACK(VARIANT II THALASSEMIA SHORT PROGRAM REORDER PACK)-THE VARIANT II THALASSEMIA SHORT PROGRAM IS INTENDED FOR THE SEPARATION AND AREA PERCENT DETERMINATION OF HEMOGLOBIN A2 AND F AND AS AID IN THE IDENTIFICATION OF ABNORMAL HEMOGLOBINS IN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) THE VARIANT II THALASSEMIA SHORT PROGRAM IS INTENDED FOR USE ONLY WITH THE BIO-RAD VARIANT II HEMOGLOBIN TESTING SYSTEM. FOR IN VITRO DIAGNOSTIC USE

	VARIANT™NBS SICKLE CELL PROGRAM ANALYTICAL CARTRIDGE (VARIANT™NBS SICKLE CELL PROGRAM ANALYTICAL CARTRIDGE)-THE BIO-RAD VARIANT™NBS SICKLE CELL PROGRAM IS INTENDED AS A QUANTITATIVE SCREEN FOR THE PRESENCE OF HEMOGLOBIN F, A, S, D, C AND E IN ELUATES OF NEONATAL BLOOD COLLECTED ON FILTER PAPER BY HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD VARIANT™NBS SICKLE CELL PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY.,D-100 HBA1C ELUTION BUFFER B(D-100 HBA1C ELUTION BUFFER B)-THE D 100 HBA1C TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP%) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON D 100 HEMOGLOBIN TESTING SYSTEM. HEMOGLOBIN A1C MEASUREMENTS ARE USED AS AN AID IN DIAGNOSIS OF DIABETES MELLITUS, AS AN AID TO IDENTIFY PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. MEASUREMENT OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG TERM GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE D 100 HBA1C TEST IS INTENDED FOR PROFESSIONAL USE ONLY. CALIBRATORS: THE D 100 HBA1C CALIBRATOR PACK IS FOR THE CALIBRATION OF D 100 HEMOGLOBIN TESTING SYSTEM USED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD ,VARIANT™NBS SICKLE CELL PROGRAM RETENTION TIME MARKER SET(VARIANT™NBS SICKLE CELL PROGRAM RETENTION TIME MARKER SET)-THE BIO-RAD VARIANT™NBS SICKLE CELL PROGRAM IS INTENDED AS A QUANTITATIVE SCREEN FOR THE PRESENCE OF HEMOGLOBIN F, A, S, D, C AND E IN ELUATES OF NEONATAL BLOOD COLLECTED ON FILTER PAPER BY HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD VARIANT™NBS SICKLE CELL PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY.,VARIANT NBS SICKLE CELL PROGRAM(VARIANT NBS SICKLE CELL PROGRAM)-THE BIO-RAD VARIANT NBS SICKLE CELL PROGRAM IS INTENDED AS A QUANTITATIVE SCREEN FOR THE PRESENCE OF HEMOGLOBIN F,A,S,D, C AND E IN ELUTES OF NEONATAL BLOOD COLLECTED ON FILTER PAPER BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC), VARIANT™ II TURBO HBA1C KIT - 2.0 ELUTION BUFFER A(VARIANT™ II TURBO HBA1C KIT - 2.0 ELUTION BUFFER A)-THE VARIANT™ II TURBO HBA1C KIT- 2.0 IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION- EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON VARIANT™ II TURBO HEMOGLOBIN TESTING SYSTEM AND VARIANT™ II TURBO LINK HEMOGLOBIN TESTING SYSTEM. THIS TEST IS TO BE USED AS AN

	AID IN DIAGNOSIS OF DIABETES AND AS AND AID IN IDENTIFYING PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. MEASUREMENTS OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG-TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE VARIANT™ II TURBO HBA1C KIT -2.0 IS INTENDED FOR PROFESSIONAL USE ONLY. THE HEMOGLOBIN CAPILLARY COLLECTION SYSTEM (HCCS) IS INTENDED FOR THE COLLECTION OF HUMAN WHOLE BLOOD FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C USING BIO-RAD HPLC METHODS.,D-100 HBA1C ELUTION BUFFER A(D-100 HBA1C ELUTION BUFFER A)-THE D 100 HBA1C TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP%) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON D 100 HEMOGLOBIN TESTING SYSTEM. HEMOGLOBIN A1C MEASUREMENTS ARE USED AS AN AID IN DIAGNOSIS OF DIABETES MELLITUS, AS AN AID TO IDENTIFY PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. MEASUREMENT OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG TERM GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE D 100 HBA1C TEST IS INTENDED FOR PROFESSIONAL USE ONLY. CALIBRATORS: THE D 100 HBA1C CALIBRATOR PACK IS FOR THE CALIBRATION OF D 100 HEMOGLOBIN TESTING SYSTEM USED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD ,VARIANT™ II -THALASSEMIA SHORT PROGRAM HEMOGLOBIN A2/F CALIBRATOR/DILUENT SET (VARIANT™ II -THALASSEMIA SHORT PROGRAM HEMOGLOBIN A2/F CALIBRATOR/DILUENT SET)-THE VARIANT™ II -THALASSEMIA SHORT PROGRAM IS INTENDED FOR SEPARATION AND AREA PERCENT DETERMINATIONS OF HEMOGLOBIN A2 AND F , AND AS AID IN THE IDENTIFICATION OF ABNORMAL HEMOGLOBIN'S IN WHOLE BLOOD USING USING ION-EXCHNGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE VARIANT™ II -THALASSEMIA SHORT PROGRAM IS INTENDED FOR USE ONLY WITH THE BIO-RAD VARIANT™ II HEMOGLOBIN TESTING SYSTEM. FOR IN VITRO DIAGNOSTIC USE.,D 100 PREFILTERS(D 100 PREFILTERS)-THE D 100 HBA1C TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP%) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON D 100 HEMOGLOBIN TESTING SYSTEM. HEMOGLOBIN A1C MEASUREMENTS ARE USED AS AN AID IN DIAGNOSIS OF DIABETES MELLITUS, AS AN AID TO IDENTIFY PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. MEASUREMENT OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG TERM GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES

	MELLITUS. THE D 100 HBA1C TEST IS INTENDED FOR PROFESSIONAL USE ONLY. CALIBRATORS: THE D 100 HBA1C CALIBRATOR PACK IS FOR THE CALIBRATION OF D 100 HEMOGLOBIN TESTING SYSTEM USED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD ,D-10™ DUAL PROGRAM ELUTION BUFFER 2(D-10™ DUAL PROGRAM ELUTION BUFFER 2)-SHORT PROGRAM: THE BIO-RAD D-10™ DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C IN WHOLE BLOOD USING ION-EXCHANGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). EXTENDED PROGRAM: THE BIO-RAD D-10™ DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBINS A2, F AND A1C AND FOR THE DETECTION OF ABNORMAL HEMOGLOBIN IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD D-10 DUAL PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE.,D-100 WASH SOLUTION(D-100 WASH SOLUTION)-THE D 100 HBA1C TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP%) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON D 100 HEMOGLOBIN TESTING SYSTEM. HEMOGLOBIN A1C MEASUREMENTS ARE USED AS AN AID IN DIAGNOSIS OF DIABETES MELLITUS, AS AN AID TO IDENTIFY PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. MEASUREMENT OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG TERM GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE D 100 HBA1C TEST IS INTENDED FOR PROFESSIONAL USE ONLY. CALIBRATORS: THE D 100 HBA1C CALIBRATOR PACK IS FOR THE CALIBRATION OF D 100 HEMOGLOBIN TESTING SYSTEM USED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD ,WHOLE BLOOD PRIMER(WHOLE BLOOD PRIMER)-SHORT PROGRAM: THE BIO-RAD D-10™ DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C IN WHOLE BLOOD USING ION-EXCHANGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). EXTENDED PROGRAM: THE BIO-RAD D-10™ DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBINS A2, F AND A1C AND FOR THE DETECTION OF ABNORMAL HEMOGLOBIN IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD D-10 DUAL PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE.,VARIANT™ II -THALASSEMIA SHORT PROGRAM ANALYTICAL CARTRIDGE(VARIANT™ II -THALASSEMIA SHORT PROGRAM ANALYTICAL CARTRIDGE)-THE VARIANT™ II -THALASSEMIA SHORT

	PROGRAM IS INTENDED FOR SEPARATION AND AREA PERCENT DETERMINATIONS OF HEMOGLOBIN A2 AND F , AND AS AID IN THE IDENTIFICATION OF ABNORMAL HEMOGLOBIN'S IN WHOLE BLOOD USING USING ION-EXCHNGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE VARIANT™ II -THALASSEMIA SHORT PROGRAM IS INTENDED FOR USE ONLY WITH THE BIO-RAD VARIANT™ II HEMOGLOBIN TESTING SYSTEM. FOR IN VITRO DIAGNOSTIC USE.,VARIANT™ II HEMOGLOBIN A1C PROGRAM CALIBRATOR/DILUENT SET(VARIANT™ II HEMOGLOBIN A1C PROGRAM CALIBRATOR/DILUENT SET)-THE BIO-RAD VARIANT™ II HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD VARIANT™ II HEMOGLOBIN A1C PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY., VARIANT™ HEMOGLOBIN A1C PROGRAM ELUTION BUFFER B (VARIANT™ II HEMOGLOBIN A1C PROGRAM ELUTION BUFFER B)-THE BIO-RAD VARIANT™ II HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD VARIANT™ II HEMOGLOBIN A1C PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY., VARIANT™ HEMOGLOBIN A1C PROGRAM ANALYTICAL CARTRIDGE (VARIANT™ HEMOGLOBIN A1C PROGRAM ANALYTICAL CARTRIDGE)-THE BIO-RAD VARIANT™ II HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD VARIANT™ II HEMOGLOBIN A1C PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY., VARIANT™NBS SICKLE CELL PROGRAM WASH SOLUTION (VARIANT™NBS SICKLE CELL PROGRAM WASH SOLUTION)-THE BIO-RAD VARIANT™NBS SICKLE CELL PROGRAM IS INTENDED AS A QUANTITATIVE SCREEN FOR THE PRESENCE OF HEMOGLOBIN F, A, S, D, C AND E IN ELUATES OF NEONATAL BLOOD COLLECTED ON FILTER PAPER BY HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD VARIANT™NBS SICKLE CELL PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY.,VARIANT™NBS SICKLE CELL PROGRAM WHOLE BLOOD PRIMER(VARIANT™NBS SICKLE CELL PROGRAM WHOLE BLOOD PRIMER)-THE BIO-RAD VARIANT™NBS SICKLE CELL PROGRAM IS INTENDED AS A QUANTITATIVE SCREEN FOR THE PRESENCE OF HEMOGLOBIN F, A, S, D, C AND E IN ELUATES OF NEONATAL BLOOD COLLECTED ON FILTER PAPER BY HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD VARIANT™NBS SICKLE CELL PROGRAM IS INTENDED FOR

	PROFESSIONAL USE ONLY.,VARIANT™ II TURBO HBA1C KIT - 2.0 CALIBRATOR/DILUENT SET(VARIANT™ II TURBO HBA1C KIT - 2.0 CALIBRATOR/DILUENT SET)-THE VARIANT™ II TURBO HBA1C KIT- 2.0 IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION- EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON VARIANT™ II TURBO HEMOGLOBIN TESTING SYSTEM AND VARIANT™ II TURBO LINK HEMOGLOBIN TESTING SYSTEM. THIS TEST IS TO BE USED AS AN AID IN DIAGNOSIS OF DIABETES AND AS AND AID IN IDENTIFYING PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. MEASUREMENTS OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG-TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE VARIANT™ II TURBO HBA1C KIT -2.0 IS INTENDED FOR PROFESSIONAL USE ONLY. THE HEMOGLOBIN CAPILLARY COLLECTION SYSTEM (HCCS) IS INTENDED FOR THE COLLECTION OF HUMAN WHOLE BLOOD FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C USING BIO-RAD HPLC METHODS.,D-10™ HEMOGLOBIN A1C PROGRAM ELUTION BUFFER 2(D-10™ HEMOGLOBIN A1C PROGRAM ELUTION BUFFER 2)-THE D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE PERCENT (QUANTITATIVE) DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE D-10™ HEMOGLOBIN TESTING SYSTEM. THE BIO-RAD D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE.,D-10™ ANALYTICAL CARTRIDGE(D-10™ ANALYTICAL CARTRIDGE)-SHORT PROGRAM: THE BIO-RAD D-10™ DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C IN WHOLE BLOOD USING ION-EXCHANGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). EXTENDED PROGRAM: THE BIO-RAD D-10™ DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBINS A2, F AND A1C AND FOR THE DETECTION OF ABNORMAL HEMOGLOBIN IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD D-10 DUAL PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE.,VARIANT™ II -THALASSEMIA SHORT PROGRAM ELUTION BUFFER 1(VARIANT™ II -THALASSEMIA SHORT PROGRAM ELUTION BUFFER 1)-THE VARIANT™ II -THALASSEMIA SHORT PROGRAM IS INTENDED FOR SEPARATION AND AREA PERCENT DETERMINATIONS OF HEMOGLOBIN A2 AND F , AND AS AID IN THE IDENTIFICATION OF ABNORMAL HEMOGLOBIN'S IN WHOLE BLOOD USING USING ION-EXCHNGE HIGH -PERFORMANCE LIQUID

	CHROMATOGRAPHY (HPLC). THE VARIANT™ II -THALASSEMIA SHORT PROGRAM IS INTENDED FOR USE ONLY WITH THE BIO-RAD VARIANT™ II HEMOGLOBIN TESTING SYSTEM. FOR IN VITRO DIAGNOSTIC USE.,WHOLE BLOOD PRIMER(WHOLE BLOOD PRIMER)-THE D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE PERCENT (QUANTITATIVE) DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE D-10™ HEMOGLOBIN TESTING SYSTEM. THE BIO-RAD D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE.,D-10™ ANALYTICAL CARTRIDGE(D-10™ ANALYTICAL CARTRIDGE)-THE D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE PERCENT (QUANTITATIVE) DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE D-10™ HEMOGLOBIN TESTING SYSTEM. THE BIO-RAD D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE.,D-10™ HEMOGLOBIN A1C PROGRAM ELUTION BUFFER 2(D-10™ HEMOGLOBIN A1C PROGRAM ELUTION BUFFER 2)-THE D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH- PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE D-10 HEMOGLOBIN TESTING SYSTEM. HEMOGLOBIN A1C MEASUREMENTS ARE USED AS AN AID IN DIAGNOSIS OF DIABETES MELLITUS, AS AN AID TO IDENTIFY PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES MELLITUS AND FOR THE MONITORING OF LONG-TERM BLOOD GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE D-10™ HEMOGLOBIN A1C PROGRAM IS FOR PROFESSIONAL IN VITRO DIAGNOSTICS USE ONLY.,D-10™ DUAL PROGRAM ELUTION BUFFER 1 (D-10™ DUAL PROGRAM ELUTION BUFFER 1)-SHORT PROGRAM: THE BIO-RAD D-10™ DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C IN WHOLE BLOOD USING ION-EXCHANGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). EXTENDED PROGRAM: THE BIO-RAD D-10™ DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBINS A2, F AND A1C AND FOR THE DETECTION OF ABNORMAL HEMOGLOBIN IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD D-10 DUAL PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE.,D-10™ HEMOGLOBIN A1C PROGRAM ELUTION BUFFER 1(D-10™ HEMOGLOBIN A1C PROGRAM ELUTION

	BUFFER 1)-THE D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH- PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE D-10 HEMOGLOBIN TESTING SYSTEM. HEMOGLOBIN A1C MEASUREMENTS ARE USED AS AN AID IN DIAGNOSIS OF DIABETES MELLITUS, AS AN AID TO IDENTIFY PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES MELLITUS AND FOR THE MONITORING OF LONG-TERM BLOOD GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE D-10™ HEMOGLOBIN A1C PROGRAM IS FOR PROFESSIONAL IN VITRO DIAGNOSTICS USE ONLY.,VARIANT™ II HEMOGLOBIN A1C PROGRAM ELUTION BUFFER A(VARIANT™ II HEMOGLOBIN A1C PROGRAM ELUTION BUFFER A)-THE BIO-RAD VARIANT™ II HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD VARIANT™ II HEMOGLOBIN A1C PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY., WASH/DILUENT SOLUTION SET (WASH/DILUENT SOLUTION SET)-THE VARIANT™ II TURBO HBA1C KIT- 2.0 IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/ MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH- PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON VARIANT™ II TURBO HEMOGLOBIN TESTING SYSTEM AND VARIANT™ II TURBO LINK HEMOGLOBIN TESTING SYSTEM. MEASUREMENT OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG-TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE BIO-RAD VARIANT™ II TURBO HBA1C KIT - 2.0 IS INTENDED FOR PROFESSIONAL USE ONLY.,VARIANT™ II -THALASSEMIA SHORT PROGRAM ELUTION BUFFER 2(VARIANT™ II -THALASSEMIA SHORT PROGRAM ELUTION BUFFER 2)-THE VARIANT™ II -THALASSEMIA SHORT PROGRAM IS INTENDED FOR SEPARATION AND AREA PERCENT DETERMINATIONS OF HEMOGLOBIN A2 AND F , AND AS AID IN THE IDENTIFICATION OF ABNORMAL HEMOGLOBIN'S IN WHOLE BLOOD USING USING ION-EXCHNGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE VARIANT™ II -THALASSEMIA SHORT PROGRAM IS INTENDED FOR USE ONLY WITH THE BIO-RAD VARIANT™ II HEMOGLOBIN TESTING SYSTEM. FOR IN VITRO DIAGNOSTIC USE.,WHOLE BLOOD PRIMER(WHOLE BLOOD PRIMER)-THE BIO-RAD VARIANT™ II HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD VARIANT™ II HEMOGLOBIN A1C PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY.,

	VARIANT™ II TURBO HBA1C KIT - 2.0 ANALYTICAL CARTRIDGE (VARIANT™ II TURBO HBA1C KIT - 2.0 ANALYTICAL CARTRIDGE)-THE VARIANT™ II TURBO HBA1C KIT- 2.0 IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON VARIANT™ II TURBO HEMOGLOBIN TESTING SYSTEM AND VARIANT™ II TURBO LINK HEMOGLOBIN TESTING SYSTEM. THIS TEST IS TO BE USED AS AN AID IN DIAGNOSIS OF DIABETES AND AS AND AID IN IDENTIFYING PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. MEASUREMENTS OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG-TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE VARIANT™ II TURBO HBA1C KIT -2.0 IS INTENDED FOR PROFESSIONAL USE ONLY. THE HEMOGLOBIN CAPILLARY COLLECTION SYSTEM (HCCS) IS INTENDED FOR THE COLLECTION OF HUMAN WHOLE BLOOD FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C USING BIO-RAD HPLC METHODS.,D-10™ DUAL PROGRAM HBA1C CALIBRATOR/DILUENT SET (D-10™ DUAL PROGRAM HBA1C CALIBRATOR/DILUENT SET)-SHORT PROGRAM: THE BIO-RAD D-10™ DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C IN WHOLE BLOOD USING ION-EXCHANGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). EXTENDED PROGRAM: THE BIO-RAD D-10™ DUAL PROGRAM IS INTENDED FOR THE PERCENT DETERMINATION OF HEMOGLOBINS A2, F AND A1C AND FOR THE DETECTION OF ABNORMAL HEMOGLOBIN IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE BIO-RAD D-10 DUAL PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE.,WHOLE BLOOD PRIMER(WHOLE BLOOD PRIMER)-THE VARIANT™ II -THALASSEMIA SHORT PROGRAM IS INTENDED FOR SEPARATION AND AREA PERCENT DETERMINATIONS OF HEMOGLOBIN A2 AND F , AND AS AID IN THE IDENTIFICATION OF ABNORMAL HEMOGLOBIN'S IN WHOLE BLOOD USING USING ION-EXCHNGE HIGH -PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THE VARIANT™ II -THALASSEMIA SHORT PROGRAM IS INTENDED FOR USE ONLY WITH THE BIO-RAD VARIANT™ II HEMOGLOBIN TESTING SYSTEM. FOR IN VITRO DIAGNOSTIC USE.,WHOLE BLOOD PRIMER(WHOLE BLOOD PRIMER)-THE VARIANT™ II TURBO HBA1C KIT- 2.0 IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON VARIANT™ II TURBO HEMOGLOBIN TESTING SYSTEM AND VARIANT™ II TURBO LINK HEMOGLOBIN TESTING SYSTEM. THIS TEST

	IS TO BE USED AS AN AID IN DIAGNOSIS OF DIABETES AND AS AND AID IN IDENTIFYING PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES. MEASUREMENTS OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG-TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE VARIANT™ II TURBO HBA1C KIT -2.0 IS INTENDED FOR PROFESSIONAL USE ONLY. THE HEMOGLOBIN CAPILLARY COLLECTION SYSTEM (HCCS) IS INTENDED FOR THE COLLECTION OF HUMAN WHOLE BLOOD FOR THE PERCENT DETERMINATION OF HEMOGLOBIN A1C USING BIO-RAD HPLC METHODS.,VARIANT™ II TURBO HBA1C KIT - 2.0 ELUTION BUFFER A (VARIANT™ II TURBO HBA1C KIT - 2.0 ELUTION BUFFER A)-THE VARIANT™ II TURBO HBA1C KIT- 2.0 IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/ MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH- PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON VARIANT™ II TURBO HEMOGLOBIN TESTING SYSTEM AND VARIANT™ II TURBO LINK HEMOGLOBIN TESTING SYSTEM. MEASUREMENT OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING LONG-TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE BIO-RAD VARIANT™ II TURBO HBA1C KIT - 2.0 IS INTENDED FOR PROFESSIONAL USE ONLY.,WHOLE BLOOD PRIMER(WHOLE BLOOD PRIMER)-THE D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH- PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE D-10 HEMOGLOBIN TESTING SYSTEM. HEMOGLOBIN A1C MEASUREMENTS ARE USED AS AN AID IN DIAGNOSIS OF DIABETES MELLITUS, AS AN AID TO IDENTIFY PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES MELLITUS AND FOR THE MONITORING OF LONG-TERM BLOOD GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. THE D-10™ HEMOGLOBIN A1C PROGRAM IS FOR PROFESSIONAL IN VITRO DIAGNOSTICS USE ONLY.,D-10™ HEMOGLOBIN A1C PROGRAM ELUTION BUFFER 1(D-10™ HEMOGLOBIN A1C PROGRAM ELUTION BUFFER 1)-THE D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR THE PERCENT (QUANTITATIVE) DETERMINATION OF HEMOGLOBIN A1C (IFCC MMOL/MOL AND NGSP %) IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ON THE D-10™ HEMOGLOBIN TESTING SYSTEM. THE BIO-RAD D-10™ HEMOGLOBIN A1C PROGRAM IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE.

214	IMP/IVD/2019/000184	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVIA AUTOSLIDE RINSE (ADVIA AUTOSLIDE RINSE)-THE MODIFIED WRIGHT METHOD IS FOR IN VITRO DIAGNOSTIC USE IN THE DIFFERENTIAL STAINING OF BLOOD, BONE MARROW, AND BODY FLUID SMEARS ON THE ADVIA® AUTOSLIDE SLIDE MAKER STAINER. STAINED SMEARS ARE EVALUATED TO IDENTIFY AND QUANTIFY CELLS IN WHOLE BLOOD AND OTHER SPECIMENS TO AID CLINICIANS IN THE ASSESSMENT OF VARIOUS CLINICAL CONDITIONS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

215	IMP/IVD/2019/000186	1.License Holder Name: M/S. I-SENS BIOSENSORS INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD B-KETONE TEST STRIPS (KETOSENS)-KETOSENS BLOOD -KETONE TEST STRIPS WORK WITH THE KETOSENS BLOOD -KETONE METERS TO QUANTITATIVELY MEASURE -KETONE IN WHOLE BLOOD. THE KETOSENS BLOOD -KETONE MONITORING SYSTEMS ARE FOR SELF-TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE). THE KETOSENS BLOOD -KETONE MONITORING SYSTEMS SHOULD NOT BE USED FOR THE DIAGNOSIS OF DIABETIC KETOACIDOSIS. -KETONE IN BLOOD SAMPLES REACTS WITH THE CHEMICAL IN THE TEST STRIP TO PRODUCE A SMALL ELECTRICAL CURRENT. THE KETOSENS BLOOD -KETONE METERS DETECT THE ELECTRICAL CURRENT WHICH REFLECTS THE AMOUNT OF -KETONE IN THE BLOOD SAMPLE.,BLOOD GLUCOSE MONITORING SYSTEM(NOCODING 1 PLUS)-NOCODING 1 PLUS BLOOD GLUCOSE MONITORING SYSTEM IS USED FOR THE QUALITATIVE MEASUREMENT OF THE GLUCOSE LEVEL IN CAPILLARY WHOLE BLOOD AS AN AID IN MONITORING DIABETES MANAGEMENT EFFECTIVELY AT HOME OR IN CLINICAL SETTINGS.,BLOOD GLUCOSE TEST STRIPS(CARESENS S)-CARESENS S BLOOD GLUCOSE TEST STRIPS WORK WITH THE CARESENS S FIT BLOOD GLUCOSE METERS TO QUANTITATIVELY MEASURE GLUCOSE IN WHOLE BLOOD. THE CARESENS S FIT BLOOD GLUCOSE MONITORING SYSTEMS ARE FOR SELF-TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE).,BLOOD GLUCOSE MONITORING SYSTEM (CARESENS N)-CARESENS N BLOOD GLUCOSE MONITORING SYSTEM IS USED FOR THE QUANTITATIVE MEASUREMENT OF THE GLUCOSE LEVEL IN CAPILLARY WHOLE BLOOD AS AN AID IN MONITORING DIABETES MANAGEMENT EFFECTIVELY AT HOME OR IN CLINICAL SETTINGS., GLUCOSE CONTROL SOLUTION(CARESENS)-THE CARESENS CONTROL SOLUTION IS RED IN COLOR AND IS TO BE USED TO CHECK THAT THE COOL, NOCODING 1 PLUS, CARESENS II PLUS, CARESENS N, CARESENS N ECO, ACCUSURE SOUL AND ACCUSURE SOUL+ BGMS AND THE CORRESPONDING STRIPS ARE WORKING TOGETHER PROPERLY AND THAT YOU ARE PERFORMING THE TEST CORRECTLY.,BLOOD GLUCOSE MONITORING SYSTEM(CARESENS N ECO)-CARESENS N ECO BLOOD GLUCOSE MONITORING SYSTEM IS USED FOR THE QUANTITATIVE MEASUREMENT OF THE GLUCOSE LEVEL IN CAPILLARY WHOLE BLOOD AS AN AID IN MONITORING DIABETES MANAGEMENT EFFECTIVELY AT HOME OR IN CLINICAL SETTINGS.,BLOOD GLUCOSE METER(CARESENS PRO)-CARESENS PRO BLOOD GLUCOSE MONITORING SYSTEM IS USED FOR THE QUANTITATIVE MEASUREMENT OF THE GLUCOSE LEVEL IN CAPILLARY WHOLE BLOOD AS AN AID IN MONITORING DIABETES

		MANAGEMENT EFFECTIVELY AT HOME OR IN CLINICAL SETTINGS., BLOOD GLUCOSE MONITORING SYSTEM(CARESENS S FIT)-CARESENS S FIT BLOOD GLUCOSE MONITORING SYSTEM IS USED FOR THE QUANTITATIVE MEASUREMENT OF THE GLUCOSE LEVEL IN CAPILLARY WHOLE BLOOD AS AN AID IN MONITORING DIABETES MANAGEMENT EFFECTIVELY AT HOME OR IN CLINICAL SETTINGS., GLUCOSE CONTROL SOLUTIONS(CARESENS S)-THE CARESENS S GLUOCSE CONTROL SOLUTION IS TO BE USED TO CHECK THAT THE CARESENS S FIT METER AND CARESENS S TEST STRIPS ARE WORKING TOGETHER PROPERLY AND THAT YOU ARE PERFORMING THE TEST CORRECTLY.,BLOOD GLUCOSE TEST STRIPS(CARESENS PRO)-CARESENS PRO BLOOD GLUCOSE TEST STRIPS WORK WITH THE CARESENS PRO / CARESENS DUAL BLOOD GLUCOSE METERS TO QUANTITATIVELY MEASURE GLUCOSE IN WHOLE BLOOD. THE CARESENS PRO / CARESENS DUAL BLOOD GLUCOSE MONITORING SYSTEMS ARE FOR SELF-TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE)., GLUCOSE CONTROL SOLUTION(CARESENS PRO)-THE CARESENS PRO CONTROL SOLUTION IS TO BE USED TO CHECK THAT THE CARESENS PRO/CARESENS DUAL METERS AND THE CORRESPONDING STRIPS ARE WORKING TOGETHER PROPERLY AND THAT YOU ARE PERFORMING THE TEST CORRECTLY.
216	IMP/IVD/2019/000186	1.License Holder Name: M/S. I-SENS BIOSENSORS INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(NO CODING 1 BLOOD GLUCOSE TEST STRIPS)-NO CODING 1 BLOOD GLUCOSE TEST STRIPS USED ALONG WITH BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO MONITOR BLOOD GLUCOSE IN HUMAN BLOOD.,BLOOD GLUCOSE TEST STRIPS(CARESENSN BLOOD GLUCOSE TEST STRIPS)-CARESENSN BLOOD GLUCOSE TEST STRIPS USED ALONG WITH BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO MONITOR BLOOD GLUCOSE IN HUMAN BLOOD.

217	IMP/IVD/2019/000187	1.License Holder Name: RAFAEL DIAGNOSTIC LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICRO-ALBUMIN SEMI-QUANTITATIVE RAPID TEST DIPSTICK(BMT)-THE MICRO-ALBUMIN SEMI-QUANTITATIVE RAPID TEST DIPSTICK (URINE) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETECTION OF MICRO-ALBUMIN IN HUMAN URINE.,COVID-19 IGG/IGM RAPID TEST KIT (WHOLE BLOOD/SERUM/PLASMA)(COVID-19 RAPID DIAGNOSTIC KIT (BMT 51090))-THE 2019-NCOV IGG/IGM RAPID TEST CASSETTE IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGG AND IGM ANTIBODIES TO 2019-NCOV IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SPECIMEN,TRANSFERRIN AND FOB COMBO RAPID TEST CASSETTE (BMT)-THE TRANSFERRIN AND FOB COMBO RAPID TEST CASSETTE IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY (NON-INVASIVE ASSAY) FOR THE QUALITATIVE DETECTION OF HUMAN HAEMOGLOBIN AND TRANSFERRIN IN HUMAN FECES SPECIMENS, WHICH MIGHT BE USEFUL FOR THE DIAGNOSIS OF BLEEDING GASTROINTESTINAL DISORDERS.,STREP B RAPID TEST CASSETTE (BMT)-STREP B RAPID TEST CASSETTE (SWAB) IS A RAPID VISUAL IMMUNOASSAY FOR THE QUALITATIVE PRESUMPTIVE DETECTION OF GROUP B STREPTOCOCCUS (GBS) ANTIGENS IN SPECIMENS TAKEN FROM VAGINAL OR RECTAL SWABS OF PREGNANT WOMEN OR GENERAL SWABS FROM NEWBORN. THIS KIT IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF STREP B INFECTION.,STREP B RAPID TEST DIPSTICK(BMT)-STREP B RAPID TEST DIPSTICK (SWAB) IS A RAPID VISUAL IMMUNOASSAY FOR THE QUALITATIVE PRESUMPTIVE DETECTION OF GROUP B STREPTOCOCCUS (GBS) ANTIGENS IN SPECIMENS TAKEN FROM VAGINAL OR RECTAL SWABS OF PREGNANT WOMEN, OR GENERAL SWABS FROM NEWBORN. THIS KIT IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF STRAP B INFECTION.,STREP A RAPID TEST DIPSTICK (CONTROL IN RED)(BMT)-THE STREP A RAPID TEST DIPSTICK IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF STREP A ANTIGENS FROM THROAT SWAB SPECIMENS TO AID IN THE DIAGNOSIS OF GROUP A STREPTOCOCCAL INFECTION.,MALARIA PF/PAN RAPID TEST CASSETTE(BMT)-THE MALARIA PF/PAN RAPID TEST CASSETTE IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF FOUR KINDS OF CIRCULATING PLASMODIUM FALSIPARUM (P.F.) P.VIVAX, P.OVALE (P.O.) AND P. MALARIA (P.M) IN WHOLE BLOOD.,LEPTOSPIRA LGG/LGM RAPID TEST CASSETTE(BMT)-THE LEPTOSPIRA LGG/LGM RAPID TEST CASSETTE IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF LGG/LGM ANTIBODIES OF LEPTOSPIRA

	INTERROGANS IN HUMAN'S WHOLE BLOOD, SERUM & PLASMA., TYPHOID RAPID TEST DIPSTICK(BMT)-THE TYPHOID RAPID TEST DIPSTICK IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF LGG/LGM ANTIBODIES AGAINST SALMONELLA TYPHI (S.THPHI) IN HUMAN WHOLE BLOOD, SERUM & PLASMA. IT IS INTENDED TO BE USED AS A SCREENING TEST AS AN AID IN THE DISGNOSIS OF INFECTION WITH S. TYPHI. ANY REACTIVE SPECIMEN WITH THE TYPHOID RAPID TEST DIPSTICK NEEDS TO BE CONFIRMED WITH ALTERNATIVE TESTING METHOD.,DENGUE NSI RAPID TEST CASSETTE(BMT)-THE DENGUE NSI RAPID TEST CASSETTE IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF NSI ANTIGEN OF DENGUE VIRUS IN HUMAN WHOLE BLOOD SERUM & PLASMA AS AN AID IN THE DIAGNOSIS OF DENGUE INFECTIONS.,DENGUE LGG/LGM RAPID TEST CASSETTE(BMT)-THE DENGUE LGG/LGM RAPID TEST CASSETTE IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF NSI ANTIGEN OF DENGUE VIRUS IN HUMAN WHOLE BLOOD SERUM & PLASMA AS AN AID IN THE DIAGNOSIS OF DENGUE INFECTIONS.,DENGUE LGG/LGM AND NSI COMBO RAPID TEST CASSETTE(BMT)-THE DENGUE LGG/LGM AND NSI COMBO RAPID TEST CASSETTE A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF NSI ANTIGEN AND LGG/LGM ANTIBODIES OF DENGUE VIRUS IN HUMAN WHOLE BLOOD, SERUM & PLASMA AS AN AID IN THE DIAGNOSIS OF DENGUE INFECTIONS.,CHIKUNGUNYA LGG/LGM RAPID TEST CASSETTE(BMT)-THE CHIKANGUNYA LGG/LGM RAPID TEST CASSETTE (WHO BLOOD/SERUM/PLASMA) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF LGG AND LGM ANTIBODIES TO CHIKANGUNYA IN HUMAN'S WHOLE BLOOD, SERUM OR PLASMA. IT IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH CHIK. ANY REACTIVE SPECIMEN WITH THE CHIKANGUNYA LGG/LGM RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS.,ADENOVIRUS RAPID TEST CASSETTE(BMT)-THE ADENOVIRUS RAPID TEST CASSETTE IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ADENOVIRUS IN HUMAN FECES SPECIMENS TO AID IN THE DIAGNOSIS OF ADENOVIRUS INFECTION.,PREGNANCY (HCG) ENHANCED SENSITIVITY RAPID TEST CASSETTE(BMT)-THE HCG PREGNANCY RAPID TEST CASSETTE IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HUMAN CHRIONIC GONADOTROPIN IN URINE OR SERUM OR PLASMA TO AID IN THE EARLY DETECTION OF PREGNANCY.,PREGNANCY (HCG) ENHANCED SENSITIVITY RAPID TEST DIPSTICK(BMT)-THE HCG

		PREGNANCY TEST DIPSTICK IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HUMAN GONADOTROPIN IN URINE TO AID IN THE EARLY DETECTION OF PREGNANCY.
218	IMP/IVD/2019/000188	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RAPIDQC HCT LEVEL B (RAPIDQC HCT LEVEL B)-FOR QUALITY CONTROL OF HEMATOCRIT ANALYZERS,RAPIDQC COMPLETE LEVEL 3(RAPIDQC COMPLETE LEVEL 3)-FOR QUALITY CONTROL OF PH/BLOOD GAS ANALYZERS, ISE ANALYZERS, CO- OXIMETERS, AND METABOLITE ANALYZERS, RAPIDQC COMPLETE LEVEL 1(RAPIDQC COMPLETE LEVEL 1)-FOR QUALITY CONTROL OF PH/BLOOD GAS ANALYZERS, ISE ANALYZERS, CO- OXIMETERS, AND METABOLITE ANALYZERS,CO-OX SLOPE(CO-OX SLOPE)-FOR IN-VITRO DIAGNOSTIC USE FOR CALIBRATION OF THE 800 SERIES CO-OXIMETERS MODULE,RAPIDQC COMPLETE LEVEL 2(RAPIDQC COMPLETE LEVEL 2)-FOR QUALITY CONTROL OF PH/BLOOD GAS ANALYZERS, ISE ANALYZERS, CO- OXIMETERS, AND METABOLITE ANALYZERS,RAPIDQC HCT LEVEL A(RAPIDQC HCT LEVEL A)-FOR QUALITY CONTROL OF HEMATOCRIT ANALYZERS

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

219	IMP/IVD/2019/000189	1.License Holder Name: MOKSHY SURGICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MITE DUST ALLERGY TEST (FASTEP)-USE FOR THE QUALITATIVE DETERMINATION OF DUST MITE SPECIFIC IMMUNOGLOBULIN E (SIGE) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. ,AMPHETAMINE DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASAY FOR THE QUALITATIVE, PRESUMPTIVE DETECTION OF AMPHETAMINE IN HUMAN URINE SPECIMENS, HEMOGLOBIN TEST STRIPS(FASTEP)-FOR PROFESSIONAL IN VITRO DIAGNOSTIC ONLY, USED WITH THE HB HEMOGLOBIN METER TO MEASURE THE HEMOGLOBIN (HB) CONCENTRATION IN CAPILLARY AND VENOUS WHOLE BLOOD.,MORPHINE DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASSAY FOR THE QUANTATIVE, PRESUMTIVE DETECTION OF MORPHINE IN HUMAN URINE SPECIMENS,BACTERAIAL VAGINOSIS PH DIAGONOSTIC TEST (FASTEP)-DEVICE IS USED BY WOMEN OF MENSTRUATING AGE, TO TEST THE ACIDITY OF VAGINAL DISCHARGE. IT IS INTENDED FOR USE BY WOMEN WHO HAVE ANY OF THE FOLLOWING SYMPTOMS: VAGINAL ITCHING, VAGINAL BURNING OR AN ABNORMAL COLOR, ODOR, OR EXCESSIVE AMOUNT OF VAGINAL DISCHARGE. THE TEST MAY HELP DETERMINE IF SYMPTOMS ARE CAUSED BY AN INFECTION.,METHADONE DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASSAY FOR THE QUANTATIVE, PRESUMTIVE DETECTION OF METHADONE IN HUMAN URINE SPECIMENS,IGE ALLERGY TEST(FASTEP)-TYPE I HYPERSENSITIVITY, SUCH AS ALLERGIC ASTHMA, MOST TYPES OF SINUSITIS, ALLERGIC RHINITIS, FOOD ALLERGY, AND SOME TYPES OF CHRONIC URTICARIAL AND ATOPIC DERMATITIS. ALLERGIC CONDITIONS, SUCH AS ANAPHYLACTIC REACTIONS TO CERTAIN DRUGS, BEE STINGS, AND ANTIGEN PREPARATIONS USED IN SPECIFIC DESENSITIZATION IMMUNOTHERAPY. ,COCAINE DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASSAY FOR THE QUANTATIVE, PRESUMTIVE DETECTION OF COCAINE IN HUMAN URINE SPECIMENS,MDMA DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASSAY FOR THE QUANTATIVE, MULTI DRUGS DETECTION OF MDMA IN HUMAN URINE SPECIMENS,MULTI DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASSAY FOR THE QUANTATIVE, MULTI DRUGS DETECTION OF AMPHETAMINE, BARBITUARATES , BENZIODAPINES, COCAINE , MORPHINE , MARIJUANA, TRAMADOL, METHADONE, PHENCYCLIDINE, BUPRENORPHINE, OXYCODONE, METAMPHETAMINE , OPIATES, PROPOXYPHEN , COTININE, MDMA IN HUMAN URINE SPECIMENS, COTININE DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASSAY FOR THE QUANTATIVE, COTININE DETECTION OF COTININE IN HUMAN URINE SPECIMENS,PROPOXYPHEN DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASSAY FOR THE QUANTATIVE, PRESUMTIVE

	DETECTION OF PROPOXYPHEN IN HUMAN URINE SPECIMENS, OPIATES DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASSAY FOR THE QUANTATIVE, PRESUMTIVE DETECTION OF OPIATES IN HUMAN URINE SPECIMENS,METAMPHETAMINE DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASSAY FOR THE QUANTATIVE, PRESUMTIVE DETECTION OF METAMPHETAMINE IN HUMAN URINE SPECIMENS, OXYCODONE DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASSAY FOR THE QUANTATIVE, PRESUMTIVE DETECTION OF OXYCODONE IN HUMAN URINE SPECIMENS,BUPRENORPHINE DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASSAY FOR THE QUANTATIVE, PRESUMTIVE DETECTION OF BUPRENORPHINE IN HUMAN URINE SPECIMENS, PHENCYCLIDINE DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASSAY FOR THE QUANTATIVE, PRESUMTIVE DETECTION OF PHENCYCLIDINE IN HUMAN URINE SPECIMENS,TRAMADOL DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASSAY FOR THE QUANTATIVE, PRESUMTIVE DETECTION OF TRAMADOL IN HUMAN URINE SPECIMENS,MARIJUANA DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASSAY FOR THE QUANTATIVE, PRESUMTIVE DETECTION OF MARIJUANA IN HUMAN URINE SPECIMENS,BENZIODAPINES DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASAY FOR THE QUANTATIVE, PRESUMTIVE DETECTION OF BENZIODAPINE IN HUMAN URINE SPECIMENS,BARBITUARATES DRUG TEST(FASTEP)-A RAPID VISUAL IMMUNOASAY FOR QUANTATIVE , PRESUMTIVE DETECTION OF BARBITUARATES IN HUMAN URINE SPECIMENS

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220	IMP/IVD/2019/000190	1.License Holder Name: ARK DIAGNOSTICS BANGALORE PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DILUENT(DILUENT REAGENT FOR SPINCELL-5 (DIL-5))-THIS PRODUCT IS DESIGNED TO BE USED ON A SPINREACT 5-PART-DIFF HAEMATOLOGY ANALYSER ALONG WITH LYSE AND SHEATH REAGENTS PRODUCED BY SPINREACT, FOR TESTING THE CELL CONTENT IN HUMAN BLOOD., PROBE CLEANER(PROBE CLEANER (PROCLEAN))-PROBE CLEANER IS APPROPRIATE FOR SPINREACT AUTOMATED HEMATOLOGY ANALYZERS. ,RETICULOCYTE REAGENT(RETICULOCYTE REAGENT FOR SPINCELL 5 (RET-5))-STAIN IS USED FOR MEASURING THE CONTENT OF RETICULOCYTE (RETIC) IN HUMAN BLOOD TOGETHER WITH SPINREACT SHEATH ON ADAPTABLE HEMATOLOGY ANALYZERS. ,LYSE(LYSE REAGENT FOR SPINCELL 5 (LYS-5))-THIS PRODUCT IS DESIGNED TO BE USED ON A SPINREACT 5-PART-DIFF HAEMATOLOGY ANALYSER ALONG WITH LYSE AND SHEATH PRODUCED BY SPINREACT, FOR TESTING THE CELL CONTENT IN HUMAN BLOOD. ,SHEATH (SHEATH REAGENT FOR SPINCELL 5 (SHEA-5))-THIS PRODUCT IS DESIGNED TO BE USED ON A SPINREACT 5-PART-DIFF HAEMATOLOGY ANALYSER ALONG WITH LYSE AND SHEATH REAGENTS PRODUCED BY SPINREACT, FOR TESTING THE CELL CONTENT IN HUMAN BLOOD. ,DETERGENT(DETERGENT REAGENT FOR SPINCELL 5 (DET-5))-DETERGENT IS USED WITH MATCHING ANALYZER FOR DAILY MAINTENANCE AND FLOW SYSTEM AND PROBE CLEANING.

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221	IMP/IVD/2019/000191	1.License Holder Name: MATRIX LABS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD(WONDFO SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD))-WONDFO SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD) IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) IGG/IGM ANTIBODY IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SAMPLE. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY SARS-COV-2.,FINECARE™ 2019-NCOV ANTIGEN TEST(FINECARE)-THE FINECARE™ 2019-NCOV ANTIGEN TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA METERS (MODEL NO.: FS-113, FS-114, FS-205) FOR QUALITATIVE DETECTION OF NOVEL CORONAVIRUSES (2019-NCOV) ANTIGEN EXTRACTED FROM THE NASOPHARYNGEAL SWAB OR OROPHARYNGEAL SWAB SPECIMEN. CLINICALLY, THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY 2019-NCOV.,BETA-HCG TEST(BETA-HCG RAPID QUANTITATIVE TEST)-THE FINECARE™ -HCG RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF -HCG IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF EARLY DETECTION OF PREGNANCY.,SARS-COV-2 REAL-TIME RT-PCR ASSAY(WONDFO)-WONDFO SARS-COV-2 REAL-TIME RT-PCR ASSAY IS A REAL-TIME REVERSE TRANSCRIPTION PCR (RT-PCR) ASSAY FOR RAPID, QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) NUCLEIC ACID IN OROPHARYNGEAL SWABS AND NASOPHARYNGEAL SWABS. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY SARS-COV-2.,AMH TEST(AMH RAPID QUANTITATIVE TEST)-THE FINECARETM AMH RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARETM FIA METERS (MODEL NO.: FS-113, FS-114 AND FS-205) FOR QUANTITATIVE MEASUREMENT OF AMH IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS MAINLY USED IN THE ASSESSMENT OF THE OVARIAN RESERVE AND AS AN AID IN THE DIAGNOSIS OF POLYCYSTIC OVARY SYNDROME (PCOS).,PCT(FINECARE PCT RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF PCT IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO DIAGNOSIS SEVERE, BACTERIAL INFECTION AND SEPSIS,TESTOSTERONE TEST

	(TESTOSTERONE RAPID QUANTITATIVE TEST)-THE FINECARETM TESTOSTERONE RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARETM FIA METERS (MODEL NO.: FS-112, FS-113, FS-114 AND FS-205) FOR QUANTITATIVE MEASUREMENT OF TESTOSTERONE IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF DISEASES RELATED TO ABNORMAL TESTOSTERONE LEVELS.,ONE STEP MAU(FINECARE ONE STEP MAU RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF MAU IN HUMAN URINE.THIS TEST IS USED AS AN AID TO DIAGNOSIS OF KIDNEY DAMAGE,E2 TEST(ESTRADIOL (E2) RAPID QUANTITATIVE TEST)-THE FINECARETM ESTRADIOL (E2) RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARETM FIA METERS (MODEL NO.:FS-112, FS-113, FS-114, FS-205) IS FOR QUANTITATIVE MEASUREMENT OF ESTRADIOL (E2) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS USED AS AN AID TO THE EVALUATION OF OVARIAN DISEASES.,D-DIMER(FINECARE D-DIMER RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN WHOLE BLOOD AND PLASMA.THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF THROMBOSIS AND THROMBOTIC DISEASES.,CRP(FINECARE CRP RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF CRP IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS USED AS AN AID TO PREDICT FUTURE CARDIOVASCULAR DISEASES (CVD) AS WELLAS TO SEE INFECTION AND INFLAMMATION.,ACT(ACTIVATED CLOTTING TIME REAGENT KIT (CLOTTING))-QUANTITATIVE MEASUREMENT INTENDED TO PROVIDE MEASUREMENT OF THE TIME IN SECONDS REQUIRED FOR A CLOT TO FORM IN CITRATED VENOUS WHOLE BLOOD WHICH HAS BEEN EXPOSED TO SURFACE ACTIVATOR.,FBI (FIBRINOGEN REAGENT KIT (CLOTTING))-QUANTITATIVE MEASUREMENT OF FIBRINOGEN IN CITRATED VENOUS WHOLE BLOOD.,PT(PROTHROMBIN TIME REAGENT KIT (CLOTTING))-QUANTITATIVE MEASUREMENT OF PROTHROMBIN TIME (PT) AND INTERNATIONAL NORMALIZED RATIO (INR) IN CITRATED VENOUS WHOLE BLOOD.,PRL(FINECARE PRL RAPID QUANTITATIVE TEST)-INTENDED FOR QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.THIS TEST IS USED AS AN AID TO EVALUATE THE FUNCTION OF HYPOTHALAMIC-PITUITARY ANDDIAGNOSE THE HYPOTHALAMIC DISEASES,FSH(FINECARE FSH RAPID QUANTITATIVE TEST)-INTENDED FOR QUANTITATIVE MEASUREMENT OF FOLLICLE-STIMULATING HORMONE (FSH) IN HUMANWHOLE BLOOD, SERUM OR PLASMA. THIS TEST USED AS AN AID TO EVALUATE THE OVARIAN FUNCTIONS IN CLINICAL,T4 (FINECARE T4 RAPID QUANTITATIVE TEST)-QUANTITATIVE

	DETERMINATION OF THYROXINE (TOTAL T4) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO THE ASSESSMENT OF THYROID FUNCTION.,TSH(FINECARE TSH RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN WHOLEBLOOD, SERUM OR PLASMA.THIS TEST IS USED AS AN AID TO ASSIST IN THE ASSESSMENT OF PITUITARY GLAND AND THYROIDFUNCTION.,CK-MB /MYO/CTN I(FINECARE CK-MB/MYO/CTN I RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF CTNI, CK-MBAND MYO INHUMAN WHOLE BLOOD, SERUM OR PLASMA.THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION, NT-PROBNP(FINECARE NT-PROBNP RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF NT-PROBNP IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.THE TEST IS USED AS AN AID FOR THE DIAGNOSIS OF SUSPECTED CONGESTIVE HEART FAILURE.,T3 (FINECARE T3 RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (TOTAL T3) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID TO THE ASSESSMENT OF THYROID FUNCTION,CTNI(FINECARE CTNI RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF CTN I IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION(AMI),HBA1C(FINECARE HBA1C RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C IN HUMAN BLOOD.THE TEST IS USED AS AN AID TO MONITOR LONG-TERM GLYCEMIC STATUS IN PATIENTS WITHDIABETES MELLITUS, SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD)(WONDFO)-WONDFO SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD) IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) IGG/IGM ANTIBODY IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SAMPLE. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY SARS-COV-2.,SARS-COV-2 ANTIBODY TEST(FINECARE)-THE FINECARETM SARS-COV-2 ANTIBODY TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARETM FIA METERS (MODEL CODE: FS-113, FS-114, FS-205) FOR QUALITATIVE DETECTION OF IGG AND IGM ANTIBODIES OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) IN HUMAN SERUM, PLASMA AND WHOLE BLOOD SAMPLE. CLINICALLY, THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY SARS-COV-2.,TT(THROMBIN TIME REAGENT KIT (CLOTTING))-MEASURE THE TIME OF CLOT FORMATION WHEN THROMBIN IS

		ADDED TO CITRATED VENOUS WHOLE BLOOD,APTT(ACTIVATED PARTIAL THROMBOPLASTINTIME REAGENT KIT (CLOTTING))-QUANTITATIVE MEASUREMENT OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) IN CITRATED VENOUS WHOLE BLOOD.,CK-MB(FINECARE CK-MB RAPID QUANTITATIVE TEST)-QUANTITATIVE DETERMINATION OF CK-MB IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION(AMI).,VD (FINECARE VITAMIN D RAPID QUANTITATIVE TEST)-INTENDED FOR USE BY HEALTHCARE PROFESSIONALS FOR IN VITRO QUANTITATIVE DETERMINATION OF TOTAL 25(OH) D2/D3 LEVEL IN HUMAN SERUM/PLASMA. THE TEST IS USED AS AN AID IN MANAGEMENT AND MONITORING OF REGULATING THE CONCENTRATION OF CALCIUM AND PHOSPHATE IN THE BLOODSTREAM AND PROMOTING THE HEALTHY GROWTH AND REMODELING OF BONE,LH(FINECARE LH RAPID QUANTITATIVE TEST)-INTENDED FOR QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN WHOLE BLOOD,SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO DIAGNOSE THE OVULATION CYCLE, PREMATURE OVARIAN FAILURE AND GONADAL HYPOPLASIA.
222	IMP/IVD/2019/000193	1.License Holder Name: ALPS DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLEANER(HC500 CLEANER)-THE HC500 CLEANER IS INTENDED TO CLEAN AND RINSE THE FLUIDIC CHANNELS WITHIN ANALYZER TO ENSURE THE ANALYZER'S PERFORMANCE.,LYSE(HL500 LYSE)-THE PRODUCT IS USED FOR LYSING ERYTHROCYTES, COUNTING AND DIFFERENTIATING THE FIVE MAIN LEUKOCYTES SUBPOPULATIONS AND QUANTITATIVE DETERMINATION HEMOGLOBIN IN BLOOD SAMPLE.,DILUENT(HD500 DILUENT)-THE HD500 DILUENT IS INTENDED TO PERFORM ERYTHROYTES AND PLATELETS MEASUREMENT IN A BLOOD SAMPLE.

223	IMP/IVD/2019/000194	1.License Holder Name: M/S.TRANSASIA BIO-MEDICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ERBA H3 CON H (ERBA H3 CON H)-ERBA H3 CON IS A CONTROL (HIGH LEVEL) DESIGNED TO MONITOR ACCURACY AND PRECISION OF AUTOMATED H360 HEMATOLOGY ANALYZERS. ,ERBA H3 CON N (ERBA H3 CON N)-ERBA H3 CON IS A CONTROL (NORMAL LEVEL) DESIGNED TO MONITOR ACCURACY AND PRECISION OF AUTOMATED H360 HEMATOLOGY ANALYZERS. ,ERBA H3 CON L(ERBA H3 CON L)-ERBA H3 CON IS A CONTROL (LOW LEVEL) DESIGNED TO MONITOR ACCURACY AND PRECISION OF AUTOMATED H360 HEMATOLOGY ANALYZERS. ,ERBA H360 DIL(ERBA H360 DIL)-ERBA H360 DIL IS USED TO DILUTED BLOOD AND PROVIDE A STABLE ENVIRONMENT FOR COUNTING AND SIZING BLOOD CELLS ON HEMATOLOGY ANALYSERS H360. ,ERBA H360 LYSE(ERBA H360 LYSE)-ERBA H360 LYSE IS USED TO DISSOLVE RED BLOOD CELLS FOR COUNTING HEMOGLOBIN AND WHITE BLOOD CELLS ON HEMATOLOGY ANALYSERS H360. ,ERBA H560 LYSE2(ERBA H560 LYSE2)-ERBA H560 LYSE2 IS USED FOR DIFFERENTIATION OF WHITE BLOOD CELLS ON HEMATOLOGY ANALYSERS H560. ,ERBA H560 LYSE1(ERBA H560 LYSE1)-ERBA H560 LYSE1 IS USED TO DISSOLVE RED BLOOD CELLS FOR COUNTING HEMOGLOBIN AND WHITE BLOOD CELLS ON HEMATOLOGY ANALYSERS H560. ,ERBA H560 DIL(ERBA H560 DIL)-ERBA H560 DIL IS USED TO DILUTED BLOOD AND PROVIDE A STABLE ENVIRONMENT FOR COUNTING AND SIZING BLOOD CELLS ON HEMATOLOGY ANALYSERS H560.

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224	IMP/IVD/2019/000195	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: ARK METHOTREXAT E DILUTION BUFFER (ARK METHOTREXAT E DILUTION BUFFER)-BUFFER IS INTENDED FOR DILUTION OF SPECIMENS CONTAINING HIGH CONCENTRATIONS OF METHOTREXATE FOR THE ARK METHOTREXATE ASSAY.,ARK METHOTREXATE CONTROL (ARK METHOTREXATE CONTROL)-ARK METHOTREXATE CONTROL IS INTENDED FOR USE IN QUALITY CONTROL OF THE ARK METHOTREXATE ASSAY, ARK METHOTREXATE ASSAY (ARK METHOTREXATE ASSAY)- THE ARK METHOTREXATE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR THE QUANTITATIVE DETERMINATION OF METHOTREXATE IN HUMAN SERUM OR PLASMA ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS. THE MEASUREMENT OBTAINED ARE USED IN MONITORING LEVELS OF METHOTREXATE TO HELP ENSURE APPROPRIATE THERAPY.SPECIMENS FROM PATIENTS WHO HAVE RECEIVED GLUCARPIDASE (CARBOXYPEPTIDASE G2) AS A HIGH DOSE METHOTREXATE RESCUE THERAPY SHOULD NOT BE TESTED WITH THE ARK METHOTREXATE ASSAY. ,ARK METHOTREXATE CALIBRATOR (ARK METHOTREXATE CALIBRATOR)-ARK METHOTREXATE CALIBRATOR IS INTENDED FOR USE IN CALIBRATION OF THE ARK METHOTREXATE ASSAY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

225	IMP/IVD/2019/000197	1.License Holder Name: TOSOH INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AIA-PACK AFP (ALPHA FETO PROTEIN) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF ALPHA-FETOPROTEIN (AFP) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK LH II (LUTEINIZING HORMONE II)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF LUTEINIZING HORMONE (LH) IN BLOOD SPECIMENS. ,ST AIA-PACK HSE2 (ESTRADIOL) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE HIGH SENSITIVE MEASUREMENT OF ESTRADIOL (E2).,AIA-PACK AFP (ALPHA FETO PROTEIN) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF ALPHA-FETOPROTEIN (AFP).,AIA-PACK FSH (FOLLICLE-STIMULATING HORMONE) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF FOLLICLE-STIMULATING HORMONE (FSH) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK TPOAB/TGAB SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF ANTI-THYROID PEROXIDASE ANTIBODIES (TPOAB) AND ANTI-THYROGLOBULIN ANTIBODIES (TGAB) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK PSA II (PROSTATE SPECIFIC ANTIGEN II) CALIBRATOR SET (TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF PROSTATE SPECIFIC ANTIGEN (PSA).,AIA-PACK FT4 (FREE THYROXINE) CALIBRATOR SET (TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF NON-PROTEIN-BOUND (FREE) THYROXINE (FT4).,AIA-PACK CYSTATIN C CONTROL SET (TOSOH)-FOR THE QUALITY CONTROL FOR THE MEASUREMENT OF CYSTATIN C WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK PSA II (PROSTATE SPECIFIC ANTIGEN II)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF PROSTATE SPECIFIC ANTIGEN (PSA) IN BLOOD SPECIMENS. ,AIA-PACK FSH (FOLLICLE-STIMULATING HORMONE) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF FOLLICLE-STIMULATING HORMONE (FSH).,AIA-PACK CK-MB (CREATINE KINASE MUSCLE BRAIN) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF CREATINE KINASE MB ISOENZYME (CK-MB) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK PAP (PROSTATIC ACID PHOSPHATASE) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF PROSTATIC ACID PHOSPHATASE (PAP).,ST AIA-

	PACK PROG III (PROGESTERONE)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF PROGESTERONE IN BLOOD SPECIMENS. ,AIA-PACK LH II (LUTEINIZING HORMONE II) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF LUTEINIZING HORMONE (LH) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK TPOAB (ANTI-THYROID PEROXIDASE ANTIBODIES) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF ANTI-THYROID PEROXIDASE ANTIBODIES (TPOAB).,ST AIA-PACK FER (FERRITIN)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF FERRITIN (FER) IN BLOOD SPECIMENS. ,AIA-PACK TPOAB (ANTI-THYROID PEROXIDASE ANTIBODIES) CONTROL SET(TOSOH)-FOR THE QUALITY CONTROL FOR THE MEASUREMENT OF ANTI-THYROID PEROXIDASE ANTIBODIES (TPOAB) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK MYOGLOBIN SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF MYOGLOBIN (MYO) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK PROG II (PROGESTERONE)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF PROGESTERONE IN BLOOD SPECIMENS. , ST AIA-PACK PSA II (PROSTATE SPECIFIC ANTIGEN II) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF PROSTATE SPECIFIC ANTIGEN (PSA) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK OSTEOCALCIN (TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF OSTEOCALCIN IN BLOOD SPECIMENS. ,ST AIA-PACK CEA (CARCINOEMBRYONIC ANTIGEN)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN (CEA) IN BLOOD SPECIMENS.,AIA-PACK SUBSTRATE SET II(TOSOH)-FOR IN VITRO DIAGNOSTIC USE WITH TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF VARIOUS ANALYTE ,AIA-PACK DETECTOR STANDARDIZATION TEST CUP(TOSOH)-FOR IN VITRO DIAGNOSTIC USE WITH TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF VARIOUS ANALYTE ,AIA-PACK SAMPLE TREATMENT CUP(TOSOH)-FOR IN VITRO DIAGNOSTIC USE WITH TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF VARIOUS ANALYTE ,ST AIA-PACK OSTEOCALCIN CALIBRATOR SET (TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF OSTEOCALCIN.,AIA-PACK WASH CONCENTRATE(TOSOH)-FOR IN VITRO DIAGNOSTIC USE WITH TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF VARIOUS ANALYTE ,AIA-PACK DILUENT CONCENTRATE(TOSOH)-FOR IN VITRO DIAGNOSTIC USE WITH TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF VARIOUS ANALYTE ,AIA-PACK KL-6

	CONTROL SET(TOSOH)-FOR THE QUALITY CONTROL FOR THE MEASUREMENT OF KL6 WITH THE TOSOH AIA SERIES OF ANALYZER., ST AIA-PACK SHBG CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF SEX HORMONE-BINDING GLOBULIN (SHBG).,ST AIA-PACK SHBG SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF SEX HORMONE-BINDING GLOBULIN (SHBG) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK OSTEOCALCIN SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF OSTEOCALCIN WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK SHBG(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF SEX HORMONE-BINDING GLOBULIN (SHBG) IN BLOOD SPECIMENS. ,AIA-PACK BMG (BETA-2 MICROGLOBULIN) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF BETA2 MICROGLOBULIN (BMG).,AIA-PACK TGAB (ANTI-THYROGLOBULIN ANTIBODIES)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF ANTI-THYROGLOBULIN ANTIBODIES (TGAB) IN BLOOD SPECIMENS. ,AIA-PACK CEA (CARCINOEMBRYONIC ANTIGEN) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN (CEA) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK TGAB (ANTI-THYROGLOBULIN ANTIBODIES) CONJUGATE (TOSOH)-ADDITIONAL CONJUGATE FOR THE MEASUREMENT OF ANTI-THYROGLOBULIN ANTIBODIES (TGAB) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK THYROGLOBULIN CONTROL SET (TOSOH)-FOR THE QUALITY CONTROL FOR THE MEASUREMENT OF THYROGLOBULIN (TG) WITH THE TOSOH AIA SERIES OF ANALYZER., AIA-PACK CA19-9 CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF CA 19-9.,AIA-PACK SHBG CONTROL SET(TOSOH)-FOR THE QUALITY CONTROL FOR THE MEASUREMENT OF SEX HORMONE-BINDING GLOBULIN (SHBG) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK OSTEOCALCIN CONTROL SET(TOSH)-FOR THE QUALITY CONTROL FOR THE MEASUREMENT OF OSTEOCALCIN WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK CTNI 3RD-GEN (CARDIAC TROPONIN I) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF CARDIAC TROPONIN I (CTNI) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK HOMOCYSTEINE SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF HOMOCYSTEINE WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK INTACT PTH (INTACT PARATHYROID HORMONE) CALIBRATOR

	SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF INTACT PARATHYROID HORMONE.,AIA-PACK ACTH (ADRENOCORTICOTROPIC HORMONE) CONTROL SET(TOSOH)-FOR THE QUALITY CONTROL FOR THE MEASUREMENT OF ADRENOCORTICOTROPIC HORMONE (ACTH) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK HGH (HUMAN GROWTH HORMONE) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF HUMAN GROWTH HORMONE (HGH).,AIA-PACK IGE II (IMMUNOGLOBULIN E) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF IMMUNOGLOBULIN E (IGE) .,AIA-PACK B12 (VITAMIN B12) PRETREATMENT SET(TOSOH)-FOR THE PRETREATMENT OF SPECIMEN FOR THE MEASUREMENT OF VITAMIN B12 (B12) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK B12 (VITAMIN B12)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF VITAMIN B12 (B12) IN BLOOD SPECIMENS. ,AIA-PACK FOLATE CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF FOLATE.,AIA-PACK FER (FERRITIN) SAMPLE DILUTING SOLUTION (TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF FERRITIN (FER) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK MYOGLOBIN CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF MYOGLOBIN (MYO).,ST AIA-PACK C-PEPTIDE II(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF C-PEPTIDE IN BLOOD SPECIMENS. ,ST AIA-PACK IRI (IMMUNOREACTIVE INSULIN) (TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF INSULIN (IRI) IN BLOOD SPECIMENS. ,AIA-PACK PRL (PROLACTIN) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF PROLACTIN (PRL) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK PRL (PROLACTIN)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF PROLACTIN (PRL) IN BLOOD SPECIMENS. ,ST AIA-PACK PROG II (PROGESTERONE) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF PROGESTERONE WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK HSE2 (ESTRADIOL) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE HIGH SENSITIVE MEASUREMENT OF ESTRADIOL (E2) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK IE2 (ESTRADIOL) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF ESTRADIOL (E2)., ST AIA-PACK FSH (FOLLICLE-STIMULATING HORMONE)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF FOLLICLE-

	STIMULATING HORMONE (FSH) IN BLOOD SPECIMENS. ,ST AIA-PACK LH II (LUTEINIZING HORMONE II) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF LUTEINIZING HORMONE (LH).,AIA-PACK TGAB (ANTI-THYROGLOBULIN ANTIBODIES) CONTROL SET(TOSOH)-FOR THE QUALITY CONTROL FOR THE MEASUREMENT OF ANTI-THYROGLOBULIN ANTIBODIES (TGAB) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK TGAB (ANTI-THYROGLOBULIN ANTIBODIES) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF ANTI-THYROGLOBULIN ANTIBODIES (TGAB).,AIA-PACK TPOAB (ANTI-THYROID PEROXIDASE ANTIBODIES)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF ANTI-THYROID PEROXIDASE ANTIBODIES (TPOAB) IN BLOOD SPECIMENS. ,ST AIA-PACK FT4 (FREE THYROXINE)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF NON-PROTEIN-BOUND (FREE) THYROXINE (FT4) IN BLOOD SPECIMENS. ,ST AIA-PACK IFT3 (FREE TRIIODOTHYRONINE)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF FREE TRIIODOTHYRONINE (FT3) IN BLOOD SPECIMENS. ,AIA-PACK T4 (THYROXINE) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF THYROXINE (T4).,AIA-PACK TT3 (TOTAL TRIIODOTHYRONINE) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF TOTAL TRIIODOTHYRONINE (TT3) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK TT3 (TOTAL TRIIODOTHYRONINE)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF TOTAL TRIIODOTHYRONINE (TT3) IN BLOOD SPECIMENS. ,ST AIA-PACK TSH (THYROID STIMULATING HORMONE)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF THYROID STIMULATING HORMONE (TSH) IN BLOOD SPECIMENS. ,AIA-PACK CA15-3 SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF BREAST CANCER ANTIGEN (CA 15-3) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK TPOAB (ANTI-THYROID PEROXIDASE ANTIBODIES) CONJUGATE(TOSOH)-ADDITIONAL CONJUGATE FOR THE MEASUREMENT OF ANTI-THYROID PEROXIDASE ANTIBODIES (TPOAB) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK HBA1C (HEMOGLOBIN A1C) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C)., AIA-PACK CA125 CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF CA125.,ST AIA-PACK CA15-3(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF BREAST CANCER ANTIGEN (CA 15-3)

	IN BLOOD SPECIMENS. ,ST AIA-PACK AFP (ALPHA FETO PROTEIN) (TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF ALPHA-FETOPROTEIN (AFP) IN BLOOD SPECIMENS. ,ST AIA-PACK HBA1C (HEMOGLOBIN A1C)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN BLOOD SPECIMENS. ,ST AIA-PACK CYSTATIN C(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF CYSTATIN C IN BLOOD SPECIMENS. ,AIA-PACK PAP (PROSTATE SPECIFIC ANTIGEN) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF PROSTATIC ACID PHOSPHATASE (PAP) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK CYSTATIN C CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF CYSTATIN C.,ST AIA-PACK HCG II (HUMAN CHORIONIC GONADOTROPIN)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HUMAN CHORIONIC GONADOTROPIN (INTACT HCG) IN BLOOD SPECIMENS. , AIA-PACK BMG (BETA-2 MICROGLOBULIN) SAMPLE DILUTING CONCENTRATE(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF BETA2 MICROGLOBULIN (BMG) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK PROG III (PROGESTERONE) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF PROGESTERONE WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK CYSTATIN C SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF CYSTATIN C WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK BHCG II (BETA HUMAN CHORIONIC GONADOTROPIN) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF HUMAN CHORIONIC GONADOTROPIN (BETA HCG).,ST AIA-PACK HCG II (HUMAN CHORIONIC GONADOTROPIN) CALIBRATOR SET (TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF HUMAN CHORIONIC GONADOTROPIN (INTACT HCG).,ST AIA-PACK HCG II (HUMAN CHORIONIC GONADOTROPIN) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF HUMAN CHORIONIC GONADOTROPIN (INTACT HCG) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK BHCG II (BETA HUMAN CHORIONIC GONADOTROPIN)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HUMAN CHORIONIC GONADOTROPIN (BETA HCG) IN BLOOD SPECIMENS.,AIA-PACK PRL (PROLACTIN) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF PROLACTIN (PRL).,ST AIA-PACK BHCG II (BETA HUMAN CHORIONIC GONADOTROPIN) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE

	SAMPLE DILUTION FOR THE MEASUREMENT OF HUMAN CHORIONIC GONADOTROPIN (BETA HCG) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK PROG III (PROGESTERONE) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF PROGESTERONE.,ST AIA-PACK HGH (HUMAN GROWTH HORMONE)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HUMAN GROWTH HORMONE (HGH) IN BLOOD SPECIMENS. ,ST AIA-PACK CK-MB (CREATINE KINASE MUSCLE BRAIN)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF CREATINE KINASE MB ISOENZYME (CK-MB) IN BLOOD SPECIMENS. ,ST AIA-PACK FREE PSA (FREE PROSTATE SPECIFIC ANTIGEN) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF FREE PROSTATE SPECIFIC ANTIGEN (FREE PSA)., ST AIA-PACK PAP (PROSTATIC ACID PHOSPHATASE)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF PROSTATIC ACID PHOSPHATASE (PAP) IN BLOOD SPECIMENS. ,AIA-PACK T4 (THYROXINE) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF THYROXINE (T4) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK HOMOCYSTEINE PRETREATMENT SET(TOSOH)-FOR THE PRETREATMENT OF SPECIMEN FOR THE MEASUREMENT OF HOMOCYSTEINE WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK IFT3 (FREE TRIIODOTHYRONINE) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF FREE TRIIODOTHYRONINE (FT3).,ST AIA-PACK FREE PSA (FREE PROSTATE SPECIFIC ANTIGEN) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF FREE PROSTATE SPECIFIC ANTIGEN (FREE PSA) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK IE2 (ESTRADIOL)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF ESTRADIOL (E2) IN BLOOD SPECIMENS. ,ST AIA-PACK DHEA-S (DEHYDROEPIANDROSTERONE SULPHATE)(TOSOH)-FOR THE QUANTITATIVE MEASUREMENT OF DEHYDROEPIANDROSTERONE SULPHATE (DHEA-S) IN HUMAN SERUM OR HEPARINIZED PLASMA ,AIA-PACK TT3 (TOTAL TRIIODOTHYRONINE) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF TOTAL TRIIODOTHYRONINE (TT3).,ST AIA-PACK KL-6 SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF KL6 WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK FREE PSA (FREE PROSTATE SPECIFIC ANTIGEN)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF FREE PROSTATE SPECIFIC ANTIGEN (FREE PSA) IN

	BLOOD SPECIMENS. ,ST AIA-PACK T4 (THYROXINE)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF THYROXINE (T4) IN BLOOD SPECIMENS.,ST AIA-PACK THYROGLOBULIN SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF THYROGLOBULIN (TG) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK D-DIMER CALIBRATOR SET (TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF D-DIMER.,ST AIA-PACK KL-6 (TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF KL6 IN BLOOD SPECIMENS. ,ST AIA-PACK KL-6 CALIBRATOR SET (TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF KL6.,ST AIA-PACK D-DIMER SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF D-DIMER WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK D-DIMER CONTROL SET(TOSOH)-FOR THE QUALITY CONTROL FOR THE MEASUREMENT OF D-DIMER WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK CEA (CARCINOEMBRYONIC ANTIGEN) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN (CEA).,ST AIA-PACK DHEA-S (DEHYDROEPIANDROSTERONE SULPHATE) SAMPLE DILUTING SOLUTION(TOSOH)-FOR DILUTION OF PATIENT SAMPLES WITH CONCENTRATIONS OF DEHYDROEPIANDROSTERONE SULPHATE (DHEA-S) ABOVE THE UPPER LIMIT OF THE ASSAY RANGE, AIA-PACK TSH (THYROID STIMULATING HORMONE) 3RD-GEN CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF THYROID STIMULATING HORMONE (TSH).,ST AIA-PACK DHEA-S (DEHYDROEPIANDROSTERONE SULPHATE) CALIBRATOR SET (TOSOH)-FOR THE CALIBRATION OF THE ST AIA-PACK DHEA-S (DEHYDROEPIANDROSTERONE SULPHATE),AIA-PACK CA125 SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF CA125 WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK HOMOCYSTEINE CONTROL SET(TOSOH)-FOR THE QUALITY CONTROL FOR THE MEASUREMENT OF HOMOCYSTEINE WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK D-DIMER (TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF D-DIMER IN BLOOD SPECIMENS. ,AIA-PACK CA15-3 CALIBRATOR SET (TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF BREAST CANCER ANTIGEN (CA 15-3).,AIA-PACK TSH (THYROID STIMULATING HORMONE) 3RD-GEN SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF THYROID STIMULATING HORMONE (TSH) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-

	PACK TESTOSTERONE(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF TESTOSTERONE IN BLOOD SPECIMENS. ,ST AIA-PACK BMG (BETA-2 MICROGLOBULIN)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF BETA2 MICROGLOBULIN (BMG) IN BLOOD SPECIMENS.,ST AIA-PACK CTNI 3RD-GEN (CARDIAC TROPONIN I)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF CARDIAC TROPONIN I (CTNI) IN BLOOD SPECIMENS. ,AIA-PACK FER (FERRITIN) CALIBRATOR SET (TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF FERRITIN (FER).,ST AIA-PACK IE2 (ESTRADIOL) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF ESTRADIOL (E2) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK INTACT PTH (INTACT PARATHYROID HORMONE)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF INTACT PARATHYROID HORMONE IN BLOOD SPECIMENS. ,ST AIA-PACK PROG II (PROGESTERONE) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF PROGESTERONE.,ST AIA-PACK ACTH (ADRENOCORTICOTROPIC HORMONE) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF ADRENOCORTICOTROPIC HORMONE (ACTH) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK INTACT PTH (INTACT PARATHYROID HORMONE) CONTROL SET (TOSOH)-FOR THE QUALITY CONTROL FOR THE MEASUREMENT OF INTACT PARATHYROID HORMONE WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK HOMOCYSTEINE CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF HOMOCYSTEINE.,ST AIA-PACK INTACT PTH (INTACT PARATHYROID HORMONE) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF INTACT PARATHYROID HORMONE WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK 25-OH VITAMIN D (TOTAL 25-HYDROXYVITAMIN D)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF TOTAL 25-HYDROXYVITAMIN D (25-OH VITAMIN D) IN BLOOD SPECIMENS. ,ST AIA-PACK BNP (BRAIN NATRIURETIC PEPTIDE)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF BRAIN NATRIURETIC PEPTIDE (BNP) IN BLOOD SPECIMENS.,ST AIA-PACK BNP (BRAIN NATRIURETIC PEPTIDE) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF BRAIN NATRIURETIC PEPTIDE (BNP).,ST AIA-PACK HOMOCYSTEINE(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF HOMOCYSTEINE IN BLOOD SPECIMENS. ,ST AIA-PACK BNP (BRAIN NATRIURETIC PEPTIDE) SAMPLE DILUTING SOLUTION(TOSOH)-FOR

	THE SAMPLE DILUTION FOR THE MEASUREMENT OF BRAIN NATRIURETIC PEPTIDE (BNP) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK 25-OH VITAMIN D (TOTAL 25-HYDROXYVITAMIN D) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF TOTAL 25-HYDROXYVITAMIN D (25-OH VITAMIN D).,AIA-PACK 25-OH VITAMIN D (TOTAL 25-HYDROXY VITAMIN D) CONTROL SET(TOSOH)-FOR THE QUALITY CONTROL FOR THE MEASUREMENT OF TOTAL 25-HYDROXYVITAMIN D (25-OH VITAMIN D) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK BNP (BRAIN NATRIURETIC PEPTIDE) CONTROL SET(TOSOH)-FOR THE QUALITY CONTROL FOR THE MEASUREMENT OF BRAIN NATRIURETIC PEPTIDE (BNP) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK 25-OH VITAMIN D (TOTAL 25-HYDROXYVITAMIN D) PRETREATMENT SET(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF TOTAL 25-HYDROXYVITAMIN D (25-OH VITAMIN D) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK RBC FOLATE HEMOLYZING REAGENT SET(TOSOH)-FOR THE PRETREATMENT OF SPECIMEN FOR THE MEASUREMENT OF RED BLOOD CELL FOLATE (RBC FOLATE) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK ACTH (ADRENOCORTICOTROPIC HORMONE) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF ADRENOCORTICOTROPIC HORMONE (ACTH).,AIA-PACK CORT (CORTISOL) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF CORTISOL.,AIA-PACK CORT (CORTISOL) SAMPLE DILUTING SOLUTION (TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF CORTISOL WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK ACTH (ADRENOCORTICOTROPIC HORMONE)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF ADRENOCORTICOTROPIC HORMONE (ACTH) IN BLOOD SPECIMENS. , AIA-PACK IGE II (IMMUNOGLOBULIN E) SAMPLE DILUTING SOLUTION (TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF IMMUNOGLOBULIN E (IGE) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK IGE II (IMMUNOGLOBULIN E)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF IMMUNOGLOBULIN E (IGE) IN BLOOD SPECIMENS.,AIA-PACK HGH (HUMAN GROWTH HORMONE) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF HUMAN GROWTH HORMONE (HGH) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK CORT (CORTISOL)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF CORTISOL IN BLOOD SPECIMENS. ,AIA-PACK RBC FOLATE PRETREATMENT SET(TOSOH)-

	FOR THE PRETREATMENT OF SPECIMEN FOR THE MEASUREMENT OF RED BLOOD CELL FOLATE (RBC FOLATE) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK RBC FOLATE CALIBRATOR SET (TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF RED BLOOD CELL FOLATE (RBC FOLATE).,AIA-PACK RBC FOLATE(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF RED BLOOD CELL FOLATE (RBC FOLATE) IN BLOOD SPECIMENS. ,AIA-PACK RBC FOLATE SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF RED BLOOD CELL FOLATE (RBC FOLATE) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK B12 (VITAMIN B12) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF VITAMIN B12 (B12).,ST AIA-PACK HSE2 (ESTRADIOL)(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE HIGH SENSITIVE MEASUREMENT OF ESTRADIOL (E2) IN BLOOD SPECIMENS. ,AIA-PACK FOLATE PRETREATMENT SET(TOSOH)-FOR THE PRETREATMENT OF SPECIMEN FOR THE MEASUREMENT OF FOLATE WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK FOLATE(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF FOLATE IN BLOOD SPECIMENS. ,AIA-PACK B12 (VITAMIN B12) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF VITAMIN B12 (B12) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK FOLATE SAMPLE DILUTING SOLUTION (TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF FOLATE WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK THYROGLOBULIN(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF THYROGLOBULIN (TG) IN BLOOD SPECIMENS. ,ST AIA-PACK THYROGLOBULIN CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF THYROGLOBULIN (TG).,AIA-PACK CK-MB (CREATINE KINASE MUSCLE BRAIN) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF CREATINE KINASE MB ISOENZYME (CK-MB).,ST AIA-PACK TESTOSTERONE CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF TESTOSTERONE.,ST AIA-PACK CA19-9(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF CA 19-9 IN BLOOD SPECIMENS.,ST AIA-PACK CA125 (TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF CA125 IN BLOOD SPECIMENS. ,AIA-PACK CA19-9 SAMPLE DILUTING SOLUTION(TOSOH) -FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF CA 19-9 WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK CTNI 3RD-GEN (CARDIAC TROPONIN I) CALIBRATOR SET(TOSOH)-FOR THE

	CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF CARDIAC TROPONIN I (CTNI).,ST AIA-PACK C-PEPTIDE II SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF C-PEPTIDE WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK C-PEPTIDE II CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF C-PEPTIDE.,ST AIA-PACK HBA1C (HEMOGLOBIN A1C) PRETREATMENT SOLUTION(TOSOH)-FOR THE PRETREATMENT OF SPECIMEN FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK MYOGLOBIN(TOSOH)-FOR IN VITRO DIAGNOSTIC USE FOR THE MEASUREMENT OF MYOGLOBIN (MYO) IN BLOOD SPECIMENS. ,AIA-PACK IRI (IMMUNOREACTIVE INSULIN) SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF INSULIN (IRI) WITH THE TOSOH AIA SERIES OF ANALYZER.,ST AIA-PACK TESTOSTERONE SAMPLE DILUTING SOLUTION(TOSOH)-FOR THE SAMPLE DILUTION FOR THE MEASUREMENT OF TESTOSTERONE WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK HBA1C (HEMOGLOBIN A1C) CONTROL SET (TOSOH)-FOR THE QUALITY CONTROL FOR THE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) WITH THE TOSOH AIA SERIES OF ANALYZER.,AIA-PACK IRI (IMMUNOREACTIVE INSULIN) CALIBRATOR SET(TOSOH)-FOR THE CALIBRATION OF THE TOSOH AIA SERIES OF ANALYZER FOR THE MEASUREMENT OF INSULIN (IRI).

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	POINTS OF REFERENCE TO ESTIMATE MYOGLOBIN VALUES. ,LQC PCT-CHECK (AQT90 FLEX LQC PCT-CHECK LEVEL 2)-FOR IN VITRO DIAGNOSTIC USE. FOR USE WITH THE AQT90 FLEX ANALYZER AS AN ASSAYED LIQUID QUALITY CONTROL (LQC) TO MONITOR PRODUCT PERFORMANCE OF THE PARAMETER LISTED IN THE SPECIFICATIONS INSERT. ,TNT TEST KIT(AQT90 FLEX TNT TEST KIT (8 TESTS))-FOR IN VITRO DIAGNOSTIC USE. THE TNT TEST IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TNT IN EDTA OR LITHIUM-HEPARIN WHOLE-BLOOD OR PLASMA SPECIMENS ON THE AQT90 FLEX ANALYZER IN POINT OF CARE AND LABORATORY SETTINGS. IT IS INDICATED FOR USE AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION AND IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES WITH RESPECT TO THEIR RELATIVE RISK OF MORTALITY. THE TNT CAL CARTRIDGES ARE IN VITRO DIAGNOSTIC REAGENTS INTENDED FOR THE CALIBRATION ADJUSTMENT OF THE TNT TEST ON THE AQT90 FLEX ANALYZER BY ESTABLISHING POINTS OF REFERENCE TO ESTIMATE TNT VALUES. ,D-DIMER CAL CARTRIDGE(AQT90 FLEX D-DIMER CAL CARTRIDGE)-FOR IN VITRO DIAGNOSTIC USE. THE D-DIMER CAL CARTRIDGES ARE IN VITRO DIAGNOSTIC REAGENTS INTENDED FOR THE CALIBRATION ADJUSTMENT OF THE D-DIMER TEST ON THE AQT90 FLEX ANALYZER BY ESTABLISHING POINTS OF REFERENCE TO ESTIMATE D-DIMER VALUES. ,PCT CAL CARTRIDGE (AQT90 FLEX PCT CAL CARTRIDGE)-FOR IN VITRO DIAGNOSTIC USE. THE PCT CAL CARTRIDGES ARE IN VITRO DIAGNOSTIC REAGENTS INTENDED FOR THE CALIBRATION ADJUSTMENT OF THE PROCALCITONIN (PCT) TEST ON THE AQT90 FLEX ANALYZER BY ESTABLISHING POINTS OF REFERENCE TO ESTIMATE PCT VALUES. , TNI CAL CARTRIDGE(AQT90 FLEX TNI CAL CARTRIDGE)-FOR IN VITRO DIAGNOSTIC USE. THE TNI CAL CARTRIDGES ARE IN VITRO DIAGNOSTIC REAGENTS INTENDED FOR THE CALIBRATION ADJUSTMENT OF THE TNI TEST ON THE AQT90 FLEX ANALYZER BY ESTABLISHING POINTS OF REFERENCE TO ESTIMATE TNI VALUES. , TNT TEST KIT(AQT90 FLEX TNT TEST KIT)-FOR IN VITRO DIAGNOSTIC USE. THE TNT TEST IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TNT IN EDTA OR LITHIUM-HEPARIN WHOLE-BLOOD OR PLASMA SPECIMENS ON THE AQT90 FLEX ANALYZER IN POINT OF CARE AND LABORATORY SETTINGS. IT IS INDICATED FOR USE AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION AND IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES WITH RESPECT TO THEIR RELATIVE RISK OF MORTALITY. ,CRP TEST KIT(AQT90 FLEX CRP TEST KIT)-FOR IN VITRO DIAGNOSTIC USE. THE CRP TEST IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE

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	DETERMINATION OF C-REACTIVE PROTEIN IN EDTA OR LITHIUM-HEPARIN WHOLE-BLOOD OR PLASMA SPECIMENS ON THE AQT90 FLEX ANALYZER IN POINT-OF-CARE AND LABORATORY SETTINGS. IT IS INTENDED FOR USE AS AN AID IN THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY, AND INFLAMMATORY DISORDERS AND ASSOCIATED DISEASES. THE CRP CAL CARTRIDGE IS AN IN VITRO DIAGNOSTIC REAGENT INTENDED FOR THE CALIBRATION ADJUSTMENT OF THE CRP TEST ON THE AQT90 FLEX ANALYZER BY ESTABLISHING POINTS OF REFERENCE TO ESTIMATE CRP VALUES. ,CKMB TEST KIT(AQT90 FLEX CKMB TEST KIT)-FOR IN VITRO DIAGNOSTIC USE. THE CKMB TEST IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE ISOFORM MB IN EDTA OR LITHIUM HEPARIN WHOLE-BLOOD OR PLASMA SPECIMENS ON THE AQT90 FLEX ANALYZER IN POINT OF CARE AND LABORATORY SETTINGS. IT IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION. THE CKMB CAL CARTRIDGES ARE IN VITRO DIAGNOSTIC REAGENTS INTENDED FOR THE CALIBRATION ADJUSTMENT OF THE CKMB TEST ON THE AQT90 FLEX ANALYZER BY ESTABLISHING POINTS OF REFERENCE TO ESTIMATE CKMB VALUES. ,PCT TEST KIT(AQT90 FLEX PCT (8 TEST) TEST KIT)-FOR IN VITRO DIAGNOSTIC USE. THE PCT TEST IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF PCT IN EDTA OR LITHIUM-HEPARIN WHOLE-BLOOD OR PLASMA SPECIMENS ON THE AQT90 FLEX ANALYZER IN POINT-OF-CARE AND LABORATORY SETTINGS. IT IS INDICATED FOR USE AS AN AID IN THE DIAGNOSIS OF SEPSIS. THE PCT CAL CARTRIDGES ARE IN VITRO DIAGNOSTIC REAGENTS INTENDED FOR THE CALIBRATION ADJUSTMENT OF THE PROCALCITONIN (PCT) TEST ON THE AQT90 FLEX ANALYZER BY ESTABLISHING POINTS OF REFERENCE TO ESTIMATE PCT VALUES. ,TNI TEST KIT(AQT90 FLEX TNI TEST KIT)-FOR IN VITRO DIAGNOSTIC USE. THE TNI TEST IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TNI IN EDTA OR LITHIUM-HEPARIN WHOLE-BLOOD OR PLASMA SPECIMENS ON THE AQT90 FLEX ANALYZER IN POINT OF CARE AND LABORATORY SETTINGS. IT IS INDICATED FOR USE AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION AND IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES WITH RESPECT TO THEIR RELATIVE RISK OF MORTALITY. THE TNI CAL CARTRIDGES ARE IN VITRO DIAGNOSTIC REAGENTS INTENDED FOR THE CALIBRATION ADJUSTMENT OF THE TNI TEST ON THE AQT90 FLEX ANALYZER BY ESTABLISHING POINTS OF REFERENCE TO ESTIMATE TNI VALUES.,LQC MULTI-CHECK(AQT90 FLEX LQC MULTI-CHECK LEVEL 1 (MC1))-FOR IN VITRO DIAGNOSTIC USE. FOR USE WITH THE AQT90 FLEX ANALYZER AS A LIQUID QUALITY CONTROL SERUM

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	(LQC) TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED ON THE SPECIFICATIONS INSERT. ,TNT CAL CARTRIDGE(AQT90 FLEX TNT CAL CARTRIDGE)-FOR IN VITRO DIAGNOSTIC USE. THE TNT CAL CARTRIDGES ARE IN VITRO DIAGNOSTIC REAGENTS INTENDED FOR THE CALIBRATION ADJUSTMENT OF THE TNT TEST ON THE AQT90 FLEX ANALYZER BY ESTABLISHING POINTS OF REFERENCE TO ESTIMATE TNT VALUES. , HCG CAL CARTRIDGE(AQT90 FLEX HCG CAL CARTRIDGE)-FOR IN VITRO DIAGNOSTIC USE. THE HCG CAL CARTRIDGES ARE IN VITRO DIAGNOSTIC REAGENTS INTENDED FOR THE CALIBRATION ADJUSTMENT OF THE HCG TEST ON THE AQT90 FLEX ANALYZER BY ESTABLISHING POINTS OF REFERENCE TO ESTIMATE TOTAL HCG VALUES. ,NT-PROBNP CAL CARTRIDGE(AQT90 FLEX NT-PROBNP CAL CARTRIDGE)-FOR IN VITRO DIAGNOSTIC USE. THE NT-PROBNP CAL CARTRIDGE IS AN IN VITRO DIAGNOSTIC REAGENT INTENDED FOR THE CALIBRATION ADJUSTMENT OF THE NT-PROBNP TEST ON THE AQT90 FLEX ANALYZER BY ESTABLISHING POINTS OF REFERENCE TO ESTIMATE NT-PROBNP VALUES. ,LQC MULTI-CHECK(AQT90 FLEX LQC MULTI-CHECK LEVEL 3 (MC3))-FOR IN VITRO DIAGNOSTIC USE. FOR USE WITH THE AQT90 FLEX ANALYZER AS A LIQUID QUALITY CONTROL SERUM (LQC) TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED ON THE SPECIFICATIONS INSERT. ,CRP CAL CARTRIDGE(AQT90 FLEX CRP CAL CARTRIDGE)-FOR IN VITRO DIAGNOSTIC USE. THE CRP CAL CARTRIDGE IS AN IN VITRO DIAGNOSTIC REAGENT INTENDED FOR THE CALIBRATION ADJUSTMENT OF THE CRP TEST ON THE AQT90 FLEX ANALYZER BY ESTABLISHING OF POINTS OF REFERENCE TO ESTIMATE CRP VALUES. ,LQC PCT-CHECK (AQT90 FLEX LQC PCT-CHECK LEVEL 1)-FOR IN VITRO DIAGNOSTIC USE. FOR USE WITH THE AQT90 FLEX ANALYZER AS AN ASSAYED LIQUID QUALITY CONTROL (LQC) TO MONITOR PRODUCT PERFORMANCE OF THE PARAMETER LISTED IN THE SPECIFICATIONS INSERT. ,NT-PROBNP TEST KIT (AQT90 FLEX NT-PROBNP TEST KIT)-FOR IN VITRO DIAGNOSTIC USE. THE NT-PROBNP TEST IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF N-TERMINAL PRO-B-TYPE NATRIURETIC PEPTIDE IN EDTA OR LITHIUM-HEPARIN WHOLE-BLOOD OR PLASMA SPECIMENS ON THE AQT90 FLEX ANALYZER IN POINT OF CARE AND LABORATORY SETTINGS. IT IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF HEART FAILURE. THE TEST IS ALSO INTENDED FOR USE AS AN AID IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROME AND HEART FAILURE. THE NT-PROBNP CAL CARTRIDGE IS AN IN VITRO DIAGNOSTIC REAGENT INTENDED FOR THE CALIBRATION ADJUSTMENT OF THE NT-PROBNP TEST ON THE AQT90 FLEX ANALYZER BY ESTABLISHING

		POINTS OF REFERENCE TO ESTIMATE NT-PROBNP VALUES. ,ßHCG TEST KIT(AQT90 FLEX HCG TEST KIT)-FOR IN VITRO DIAGNOSTIC USE. THE HCG TEST IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN PLUS BETA SUBUNIT HUMAN CHORIONIC GONADOTROPIN IN EDTA OR LITHIUM-HEPARIN WHOLE BLOOD OR PLASMA SPECIMENS ON THE AQT90 FLEX ANALYZER IN POINT-OF-CARE AND LABORATORY SETTINGS. IT IS INDICATED FOR USE AS AN AID IN THE EARLY DETECTION OF PREGNANCY. IT IS NOT INDICATED AS A SURROGATE MARKER IN THE DIAGNOSIS OR MONITORING OF CANCER PATIENTS.
227	IMP/IVD/2019/000199	1.License Holder Name: BHARAT SERUMS AND VACCINES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACTIM PANCREATITIS (ACTIM PANCREATITIS)-ACTIM PANCREATITIS TEST IS A VISUALLY INTERPRETED, QUALITATIVE IMMUNOCHROMATOGRAPHIC DIPSTICK TEST FOR USE WHEN ACUTE PANCREATITIS IS SUSPECTED. THE TEST IS BASED ON DETECTION OF ELEVATED LEVELS OF TRYPSINOGEN-2 IN URINE.

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228	IMP/IVD/2019/000203	1.License Holder Name: INSTRUMENTATION LABORATORY INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ISE CLEANING (QUANTILAB)-ISE CLEANING IS INTENDED FOR THE DAILY MAINTENANCE OF THE ISE MODULE OF ILAB CHEMISTRY SYSTEMS., ALKALINE PHOSPHATASE(QUANTILAB)-ALKALINE PHOSPHATASE IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM AND PLASMA USING THE ILAB CHEMISTRY SYSTEMS., CHOLINESTERASE(QUANTILAB)-CHOLINESTERASE IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CHOLINESTERASE (PSEUDOCHOLINESTERASE) IN HUMAN SERUM AND PLASMA, USING THE ILAB CHEMISTRY SYSTEM.,CK(QUANTILAB)-CK IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CREATINE KINASE IN HUMAN SERUM USING THE ILAB CHEMISTRY SYSTEMS.,LITHIUM(QUANTILAB)-LITHIUM IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF LITHIUM IN HUMAN SERUM USING THE ILAB CHEMISTRY SYSTEMS,CALCIUM(QUANTILAB)-CALCIUM IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA AND URINE USING THE ILAB CHEMISTRY SYSTEMS.,LDH-P(QUANTILAB)-LDH-P IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF LACTATE DEHYDROGENASE (LDH-P) IN HUMAN SERUM AND PLASMA, USING THE ILAB CHEMISTRY SYSTEMS.,IRON(QUANTILAB)-IRON IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF IRON IN HUMAN SERUM AND PLASMA, USING THE ILAB CHEMISTRY SYSTEMS.
229	IMP/IVD/2019/000204	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:XPRECIA SYSTEMS PT/INR STRIPS(XPRECIA SYSTEMS PT/INR STRIPS)-THE XPRECIA SYSTEMS PT/INR TEST STRIPS ARE DESIGNED ONLY FOR USE WITH THE SIEMENS XPRECIA STRIDE COAGULATION ANALYZERS. THE XPRECIA STRIDE COAGULATION SYSTEM IS INTENDED FOR QUANTITATIVE PROTHROMBIN TIME (PT) TESTING FOR THE MONITORING OF ORAL ANTICOAGULATION THERAPY WITH WARFARIN, A VITAMIN K ANTAGONIST.

230	IMP/IVD/2019/000206	1.License Holder Name: STEDMAN PHARMACEUTICALS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALPHA-AMYLASE LIQUICOLOR [HUMASTAR 300SR, HUMASTAR 600]-ENZYMATIC COLOR TEST FOR THE QUANTITATIVE DETERMINATION OF ALPHA-AMYLASE IN HUMAN SERUM AND HEPARINISED PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,GAMMA-GT LIQUICOLOR-THE GAMMA-GT LIQUICOLOR TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF -GT (L--GLUTAMYL TRANSFERASE) IN HUMAN SERUM AND EDTA-PLASMA,CUVETTE CLEAN FOR HUMASTAR 600/300SR-CUVETTE CLEAN FOR HUMASTAR 600/300SR,CREATININE (ENZYM.) LIQUICOLOR-THE CREATININE (ENZYM) LIQUICOLOR IS AN ENZYMATIC COLORIMETRIC TEST AND HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM AND HEPARINISED PLASMA.,LIPOPROTEIN (A), LP(A) HUMASTAR 600-LATEX ENHANCED IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN (A), (LP(A)), IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,CK NAC ACTIVATED LIQUIUV-THE CK NAC LIQUIUV HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CK (CREATINE KINASE) IN HUMAN SERUM AND HEPARINISED OR EDTA PLASMA.,CK MB LIQUIUV HUMASTAR 600-HOMOGENEOUS TEST FOR THE QUANTITATIVE DETERMINATION OF CK-MB IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,BILIRUBIN DIRECT/TOTAL LIQUICOLOR-THE BILIRUBIN D+T LIQUICOLOR IS A PHOTOMETRIC TEST FOR DIRECT (D) AND TOTAL (T) BILIRUBIN (MODIFIED JENDRASSIK/GRÓF METHOD) BILIRUBIN D+T LIQUICOLOR TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF BILIRUBIN IN HUMAN SERUM AND HEPARINISED PLASMA., CREATININE (ENZYM.) LIQUICOLOR HUMASTAR 600-ENZYMATIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM ON HUMASTAR 300SR AND HUMASTAR 600., CALCIUM LIQUICOLOR-THE CALCIUM LIQUICOLOR TEST IS A PHOTOMETRIC TEST FOR CALCIUM CPC METHOD AND HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF IONIZED CALCIUM IN HUMAN SERUM AND HEPARINISED PLASMA.,GOT (ASAT) IFCC MOD. LIQUIUV [HUMASTAR 300SR, HUMASTAR 600]-ENZYMATIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF GOT (ASAT) IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,LDL CHOLESTEROL LIQUICOLOR-LDL CHOLESTEROL LIQUICOLOR IS A DIRECT HOMOGENEOUS ENZYMATIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF LDL-CHOLESTEROL (LDL) IN HUMAN SERUM.,TRANSFERRIN HUMASTAR

	600-IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF TRANSFERRIN IN HUMAN SERUM ON HUMASTAR 300 SR AND HUMASTAR 600.,CHOLESTEROL LIQUICOLOR-CHOLESTEROL LIQUICOLOR IS A CHOD-PAP-METHOD ENZYMATIC COLORIMETRIC TEST FOR CHOLESTEROL AND HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM, EDTA-PLASMA AND HEPARINISED PLASMA.,LDL CHOLESTEROL LIQUICOLOR HUMASTAR 600-HOMOGENEOUS ENZYMATIC COLOR ASSAY FOR THE QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IN HUMAN SERUM OR PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,BILIRUBIN LIQUICOLOR-BILIRUBIN LIQUICOLOR IS A PHOTOMETRIC COLORIMETRIC TEST FOR TOTAL BILIRUBIN DCA METHOD AND HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF BILIRUBIN IN HUMAN SERUM AND PLASMA (HEPARINISED AND EDTA-PLASMA).,HC5D CBC LYSE-THIS PRODUCT IS INTENDED FOR LYSING THE RED BLOOD CELLS AND WHITE BLOOD CELL,AUTO-BILIRUBIN-D LIQUICOLOR-THE AUTO-BILIRUBIN-D LIQUICOLOR IS A PHOTOMETRIC TEST FOR DIRECT (D) BILIRUBIN AND HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM AND HEPARINIZED PLASMA PARTICULARLY FOR AUTOMATED WORKING TECHNIQUES.,HC5D-CONTROL-HC5D-CONTROL IS AN ASSAYED BLOOD CONTROL MATERIAL INTENDED FOR USE IN THE VERIFICATION OF ACCURACY AND PRECISION OF HUMACOUNT 5D PROVIDING WHITE BLOOD CELL DIFFERENTIATION OF 5-PART WBC'S., AUTO-BILIRUBIN-T LIQUICOLOR-THE AUTO-BILIRUBIN-T LIQUICOLOR IS A PHOTOMETRIC TEST FOR TOTAL (T) BILIRUBIN AND HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM AND HEPARINISED PLASMA PARTICULARLY FOR AUTOMATED WORKING TECHNIQUES.,HC5D CLEAN-THIS PRODUCT IS INTENDED FOR CLEANING THE FLUIDIC SYSTEM OF THE ANALYZER AND REGULAR INSTRUMENT CLEANING., AUTOCAL CALIBRATOR(AUTOCAL)-AUTOCAL IS INTENDED FOR CALIBRATION OF HUMAN METHODS ON CLINICAL CHEMISTRY ANALYZERS OF AUTOHUMALYZER AND HUMASTAR SERIES.,GPT (ALAT) IFCC MOD. LIQUIUV [HUMASTAR 300 SR, HUMASTAR 600]-ENZYMATIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF GPT (ALAT) IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600,AUTO-CREATININE LIQUICOLOR-THE AUTO-CREATININE LIQUICOLOR TEST IS A JAFFÉ-REACTION PHOTOMETRIC COLORIMETRIC TEST FOR KINETIC MEASUREMENT OF CREATININE AND HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, HEPARINISED PLASMA AND URINE PARTICULARLY FOR AUTOMATED WORKING TECHNIQUES.,AUTO-

	BILIRUBIN-T LIQUICOLOR [HUMASTAR 300 SR, HUMASTAR 600]-COLORIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF BILIRUBIN TOTAL IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,ALPHA-AMYLASE LIQUICOLOR-THE ALPHA-AMYLASE LIQUICOLOR HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF THE -AMYLASE IN HUMAN SERUM, HEPARINISED PLASMA AND URINE.,FERRITIN CALIBRATOR HUMASTAR 600-FERRITIN CALIBRATOR 500 IS USED FOR CALIBRATION OF THE TURBIDIMETRIC FERRITIN SYSTEM REAGENT (HUMASTAR 600,URIC ACID LIQUICOLOR PLUS-THE URIC ACID LIQUICOLOR PLUS IS A PAP-METHOD ENZYMATIC COLORIMETRIC TEST (LCF) AND HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM AND PLASMA.,HC-DILUENT FOR HUMACOUNT-THE HC-DILUENT IS USED TO DILUTE WHOLE BLOOD SPECIMENS AND TO RINSE THE FLUIDIC SYSTEM BETWEEN MEASURING PROCEDURES,UREA LIQUICOLOR - R1, R2-UREA LIQUICOLOR HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM AND PLASMA (NO HEPARINIZED PLASMA).,HDL CHOLESTEROL LIQUICOLOR [HUMASTAR 300SR, HUMASTAR 600]-HOMOGENEOUS ENZYMATIC COLOR ASSAY FOR THE QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,TRIGLYCERIDES LIQUICOLOR MONO-THE TRIGLYCERIDES LIQUICOLOR MONO IS A GPO-PAP METHOD ENZYMATIC COLORIMETRIC TEST FOR TRIGLYCERIDES WITH LIPID CLEARING FACTOR (LCF) AND HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM, EDTA-PLASMA AND HEPARINISED PLASMA.,CALCIUM LIQUICOLOR HUMASTAR 600-COLORIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF CALCIUM TOTAL IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600., SERODOS PLUS CONTROL SERA(SERODOS PLUS)-SERODOS PLUS® CONTROL SERA HAVE BEEN DESIGNED FOR CONTROL OF PRECISION AND ACCURACY OF CLINICAL CHEMISTRY METHODS BOTH MANUAL AND AUTOMATED. SERODOS® CONTROL SERA ARE MANUFACTURED FROM HUMAN SERA.,DILUENT, DILUENT -2 [HUMASTAR 300SR, HUMASTAR 600]-THE DILUENT AND DILUENT-2 SOLUTIONS FOR HUMASTAR SYSTEMS HAVE BEEN DESIGNED FOR THE ON BOARD (AND OFFLINE) SAMPLE DILUTION IN THE QUANTITATIVE DETERMINATIONS OF COMPONENTS IN BODY FLUIDS, CALIBRATORS AND CONTROLS AND FOR THE DETERMINATION OF THE REAGENT BLANK ON HUMASTAR 300SR AND HUMASTAR 600.,PHOSPHORUS LIQUIRAPID-PHOSPHORUS LIQUIRAPID IS A PHOTOMETRIC UV TEST FOR THE DETERMINATION OF PHOSPHORUS AND HAS BEEN

	DESIGNED FOR THE QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHORUS IN HUMAN SERUM.,GAMMA-GT LIQUICOLOR [HUMASTAR 300 SR, HUMASTAR 600]-ENZYMATIC COLOR TEST FOR THE QUANTITATIVE DETERMINATION OF GAMMA-GT (GGT) IN HUMAN SERUM OR PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600., MAGNESIUM LIQUICOLOR-PHOTOMETRIC COLORIMETRIC TEST FOR MAGNESIUM WITH LIPID CLEARING FACTOR (LCF),CK NAC ACTIVATED LIQUIUV HUMASTAR 600-ENZYMATIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600., LIPASE LIQUICOLOR-THE LIPASE LIQUICOLOR TEST IS AN ENZYMATIC COLORIMETRIC TEST AND HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF THE LIPASE ACTIVITY IN HUMAN SERUM.,LDH SCE MOD. LIQUIUV [HUMASTAR 300 SR, HUMASTAR 600]-ENZYMATIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE (LDH) IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,LDH SCE MOD. LIQUIUV-THE LDH LIQUIUV HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF LDH IN HUMAN SERUM AND PLASMA (HEPARINIZED AND EDTA-PLASMA).,SPECIAL WASH SOLUTION-THE LIQUID CONCENTRATE INCLUDED IN THIS KIT HAS BEEN PROVIDED ESPECIALLY TO BE EMPLOYED, FOR THE PREPARATION FOR CLEANING SOLUTIONS FOR HUMASTAR 100, 200, 300SR AND ANALYZERS OF THE SAME FAMILY PRODUCED BY HUMAN.,IRON LIQUICOLOR-IRON LIQUICOLOR TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF IONIZED IRON IN HUMAN SERUM AND HEPARINISED PLASMA.,HUMATEX ASO-HUMATEX ASO IS A LATEX AGGLUTINATION TEST FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN O IN HUMAN SERUM.,HEMOGLOBIN LIQUICOLOR-THE HEMOGLOBIN LIQUICOLOR IS A PHOTOMETRIC COLORIMETRIC TEST FOR THE DETERMINATION OF HEMOGLOBIN IN BLOOD (CYANMETHEMOGLOBIN METHOD),FT3 (FREE TRIIODOTHYRONINE) ELISA-ELISA TEST FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM,HDL CHOLESTEROL-THE HDL-CHOLESTEROL TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF HDL-CHOLESTEROL IN HUMAN SERUM, EDTA-PLASMA AND HEPARINISED PLASMA.,TSH (THYROTROPIN) ELISA-ELISA TEST FOR THE QUANTITATIVE DETERMINATION OF THYROTROPIN (TSH) IN HUMAN SERUM, ALBUMIN LIQUICOLOR-ALBUMIN LIQUICOLOR HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM AND PLASMA (HEPARINISED AND EDTA-PLASMA)., IMMUNGLOBULIN M HUMASTAR 600-IMMUNOTURBIDIMETRIC TEST

	FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM ON HUMASTAR 300 SR AND HUMASTAR 600., CK-MB LIQUIUV-CK-MB LIQUIUV HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CK-MB (CREATINE KINASE MB ISOENZYME) IN HUMAN SERUM AND PLASMA (HEPARINISED AND EDTA-PLASMA).,AUTO-BILIRUBIN-D LIQUICOLOR [HUMASTAR 300SR, HUMASTAR 600]-COLORIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF BILIRUBIN DIRECT IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,ALKALINE PHOSPHATASE LIQUICOLOR-THE ALKALINE PHOSPHATASE (AMP) IFCC LIQUICOLOR TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE (AP) IN HUMAN SERUM AND HEPARINISED PLASMA.,FERRITIN HUMASTAR 600-LATEX ENHANCED IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM UND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,GPT (ALAT) IFCC MOD. LIQUIUV-THE GPT (ALAT) IFCC MOD. LIQUIUV TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF GPT (ALANINE AMINOTRANSFERASE) IN HUMAN SERUM AND PLASMA (HEPARINISED AND EDTA-PLASMA).,CRP HUMASTAR 600-IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,GOT (ASAT) IFCC MOD. LIQUIUV-THE GOT (ASAT) IFCC MOD. LIQUIUV TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF GOT (ASPARTATE AMINOTRANSFERASE) IN HUMAN SERUM AND PLASMA (HEPARINISED AND EDTA-PLASMA).,TIBC-REAGENTS FOR SAMPLE PREPARATION FOR THE DETERMINATION OF TOTAL IRON BINDING CAPACITY (TIBC) IN HUMAN SERUM OR HEPARINISED PLASMA,HDL CHOLESTEROL LIQUICOLOR-THE HDL-CHOLESTEROL LIQUICOLOR IS A TEST FOR DIRECT HOMOGENEOUS TEST FOR THE DETERMINATION OF HDL-CHOLESTEROL (ENZYMATIC COLORIMETRIC) AND HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM., IMMUNGLOBULIN G HUMASTAR 600-IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN SERUM ON HUMASTAR 300 SR AND HUMASTAR 600., ALKALINE PHOSPHATASE OPT. LIQUICOLOR-THE ALKALINE PHOSPHATASE (AP) OPT. LIQUICOLOR HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE (AP) IN HUMAN SERUM AND HEPARINISED PLASMA.,IMMUNGLOBULIN A HUMASTAR 600-IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN SERUM ON HUMASTAR 300 SR AND HUMASTAR 600.,

	SERODOS CONTROL SERA(SERODOS)-SERODOS® CONTROL SERA HAVE BEEN DESIGNED FOR CONTROL OF PRECISION AND ACCURACY OF CLINICAL CHEMISTRY METHODS BOTH MANUAL AND AUTOMATED. SERODOS® CONTROL SERA ARE MANUFACTURED FROM HUMAN SERA.,COMBINA 13-URINE TEST STRIPS FOR VISUAL READING OR WITH COMBILYZER13,UREA LIQUIUV-UREA LIQUIUV REAGENT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM, PLASMA, EXCEPT AMMONIUM HEPARINATE PLASMA, OR URINE.,FT4 (FREE THYROXINE) ELISA-ELISA TEST FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM,CREATININE LIQUICOLOR-CREATININE LIQUICOLOR IS A JAFFÉ-REACTION PHOTOMETRIC COLORIMETRIC TEST FOR KINETIC MEASUREMENTS (METHOD WITHOUT DEPROTEINISATION) AND HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, HEPARINISED PLASMA AND URINE.,HUMATEX CRP-HUMATEX CRP IS A LATEX AGGLUTINATION TEST FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM.,COMPLEMENT C4 HUMASTAR 600-IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT 4 (C4) IN HUMAN SERUM ON HUMASTAR 300 SR AND HUMASTAR 600, COMPLEMENT C3 HUMASTAR 600-IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT C3 (C3C) IN HUMAN SERUM ON HUMASTAR 300 SR AND HUMASTAR 600., MICROALBUMIN HUMASTAR 600-IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF MIRCOALBUMIN IN COLLECTED OR SPOT URINE ON HUMASTAR 300 SR AND HUMASTAR 600.,PHOSPHORUS LIQUIRAPID [HUMASTAR 300 SR, HUMASTAR 600]-PHOTOMETRIC UV TEST FOR QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHATE IN HUMAN SERUM ON HUMASTAR 300 SR AND HUMASTAR 600.,CHOLESTEROL LIQUICOLOR [HUMASTAR 300 SR, HUMASTAR 600]-COLORIMETRIC ENZYMATIC TEST FOR THE QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL IN HUMAN SERUM OR PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600., MAGNESIUM LIQUICOLOR [HUMASTAR 300 SR, HUMASTAR 600] - COLORIMETRIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM OR HEPARINISED PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,POTASSIUM LIQUIUV [HUMASTAR 300 SR, HUMASTAR 600]-ENZYMATIC UV-TEST FOR THE QUANTITATIVE DETERMINATION OF POTASSIUM (K) IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,T3 (TOTAL TRIIODOTHYRONINE) ELISA-ELISA TEST FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE (T3) IN HUMAN SERUM OR PLASMA,TRIGLYCERIDES LIQUICOLOR MONO

	[HUMASTAR 300 SR, HUMASTAR 600]-ENZYMATIC COLORIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600,ACID PHOSPHATASE HUMASTAR 600-ENZYMATIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF TOTAL ACID PHOSPHATASE ACTIVITY IN HUMAN SERUM ON HUMASTAR 300 SR AND HUMASTAR 600.,SPECIAL WASH SOLUTION-2-SPECIAL WASH SOLUTION-2 IS USED FOR AUTOMATICALLY PERFORMED AND MANUALLY PROGRAMMED CLEANING PROCEDURES ON THE HUMASTAR 300SR.,REAGENT PACK HUMALYTE PLUS 3-SYSTEM REAGENT PACKFOR FOR HUMALYTE PLUS 3,AUTO-CREATININE LIQUICOLOR HUMASTAR 600-COLORIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,HC-LYSE CF FOR HUMACOUNT-THE HC-LYSE CF IS USED TO PREPARE BLOOD HEMOLYSATE FOR WBC AND HGB MEASUREMENT,TIP CLEANING KIT FOR HUMASTAR 600-TIP CLEANING KIT FOR HUMASTAR 600,HC-CALIBRATOR-HEMATOLOGY CALIBRATOR FOR HUMACOUNT 30TS, 60TS, 80TS AND 5L,HC-CLEANER FOR HUMACOUNT-THE HC-CLEANER IS USED TO PERFOM CLEANING PROCESS OF THE FLUIDS., UREA LIQUIUV HUMASTAR 600-FULLY ENZYMATIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM OR PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600., APOLIPOPROTEIN A1 (APO A1) HUMASTAR 600-IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A1 (APO A1) IN HUMAN SERUM ON HUMASTAR 300 SR AND HUMASTAR 600,HBA1C LIQUIDIRECT HUMASTAR 600-IMMUNOASSAY FOR THE DIRECT PHOTOMETRIC DETERMINATION OF HBA1C IN HUMAN VENOUS BLOOD WITH EDTA ON HUMASTAR 300 SR AND HUMASTAR 600.,HC5D DIFF LYSE-THIS HC5D DIFF LYSE IS INTENDED FOR LYSING THE RED BLOOD CELLS, DETERMINING THE HEMOGLOBIN, WHITE BLOOD CELL CLASSIFICATION AND COUNTING THE TOTAL NUMBER OF WHITE BLOOD CELLS.,HC5D DILUENT-THIS PRODUCT IS INTENDED FOR SAMPLE DILUTION AND PREPARATION OF CELL SUSPENSION,HC5L CONTROL-HC5L-CONTROL IS AN ASSAYED BLOOD CONTROL MATERIAL INTENDED FOR USE IN THE VERIFICATION OF ACCURACY AND PRECISION OF HUMACOUNT 5L PROVIDING WHITE BLOOD CELL DIFFERENTIATION OF 5-PART WBC'S.,LIPASE LIQUICOLOR HUMASTAR 600-ENZYMATIC COLORIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF LIPASE IN HUMAN SERUM OR PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600,T4 (TOTAL THYROXINE) ELISA-ELISA TEST FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE (T4) IN HUMAN SERUM OR

	PLASMA,HC5-CONTROL-HC5-CONTROL IS AN ASSAYED BLOOD CONTROL MATERIAL INTENDED FOR USE IN THE VERIFICATION OF ACCURACY AND PRECISION OF THE HUMACOUNT 5 ANALYZER PROVIDING 5-PART-DIFF WHITE BLOOD CELL DIFFERENTIATION, ALKALINE PHOSPHATASE OPT. LIQUICOLOR [HUMASTAR 300SR, HUMASTAR 600]-ENZYMATIC COLOR TEST FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE (ALP, AP) IN HUMAN SERUM AND HEPARINISED PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,ALKALINE PHOSPHATASE LIQUICOLOR IFCC [HUMASTAR 300SR, HUMASTAR 600]-ENZYMATIC COLOR TEST FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATISE (ALP, AP) IN HUMAN SERUM AND HEPARINISED PLASMA ON HUMASTAR 300SR AND HUMASTAR 600.,IRON TPTZ LIQUICOLOR [HUMASTAR 300 SR, HUMASTAR 600]-COLORIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM OR PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600., HOMOCYSTEINE LIQUIUV (1X250 TESTS) HUMASTAR 600-ENZYMATIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF HOMOCYSTEINE IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,HC-CONTROL FOR HUMACOUNT-HC-CONTROL IS AN ASSAYED BLOOD CONTROL MATERIAL INTENDED FOR USE IN THE VERIFICATION OF ACCURACY AND PRECISION OF HUMACOUNT, HUMACOUNTPLUS, HUMACOUNT 30TS, HUMACOUNT 60TS AND HUMACOUNT 80 TS AS WELL AS FOR FURTHER SELECTED ANALYZERS PROVIDING 3-PART DIFFERENTIAL OF WHITE BLOOD CELLS.,APOLIPOPROTEIN (APO B) HUMASTAR 600-IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN B (APO B) IN HUMAN SERUM ON HUMASTAR 300 SR AND HUMASTAR 600.,SODIUM LIQUICOLOR [HUMASTAR 300SR, HUMASTAR 600]-ENZYMATIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF SODIUM IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,URIC ACID LIQUICOLOR-ENZYMATIC COLORIMETRIC TEST FOR URIC ACID WITH LIPID CLEARING FACTOR (LCF),PANCREAS-AMYLASE LIQUICOLOR HUMASTAR 600-ENZYMATIC COLOR TEST FOR THE QUANTITATIVE DETERMINATION OF PANCREATIC AMYLASE IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,HUMATEX RF-HUMATEX RF IS A LATEX AGGLUTINATION TEST FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS (RF) IN HUMAN SERUM.,CYSTATIN-C LIQUIDIRECT HUMASTAR 600-LATEX ENHANCED IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF CYSTATIN-C IN HUMAN SERUM ON HUMASTAR 300 SR AND HUMASTAR 600.,CUVETTE CLEAN (4X100ML) FOR

	AUTOMATED ANALYZERS-CUVETTE CLEAN FOR AUTOMATED ANALYZERS HAS BEEN DESIGNED FOR THE CLEANING OF THE CUVETTES AFTER TESTING LATEX ENHANCED PARAMETERS ON AUTOMATED ANALYZERS.,URIC ACID LIQUICOLOR PLUS [HUMASTAR 300SR, HUMASTAR 600]-ENZYMATIC COLOR TEST FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,TOTAL PROTEIN LIQUICOLOR-PHOTOMETRIC COLORIMETRIC TEST FOR TOTAL PROTEIN,ANTI-STREPTOLYSIN-O (ASO)[HUMASTAR 300SR, HUMASTAR 600]-LATEX ENHANCED IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF ANTI-STREPTOLYSIN-O (ASO) IN HUMAN SERUM ON HUMASTAR 300 SR AND HUMASTAR 600.,RHEUMATOID FACTORS [HUMASTAR 300 SR, HUMASTAR 600]-IMMUNOTURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS (RF) IN HUMAN SERUM ON HUMASTAR 300 SR AND HUMASTAR 600.,ALBUMIN LIQUICOLOR [HUMASTAR 300SR, HUMASTAR 600]-COLORIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM OR PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.,TOTAL PROTEIN LIQUICOLOR [HUMASTAR 300 SR, HUMASTAR 600]-COLORIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM AND PLASMA ON HUMASTAR 300 SR AND HUMASTAR 600.

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231	IMP/IVD/2019/000207	1.License Holder Name: IDEXX LABORATORIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VETTEST ALT (25)(IDEXX VETTEST ALT (25))-QUANTITATIVELY MEASURES ALANINE AMINOTRANSFERASE (ALT) ACTIVITY IN ANIMAL SERUM OR PLASMA.,CATALYST PHOS (12)(IDEXX CATALYST PHOS (12))-QUANTITATIVELY MEASURES PHOSPHORUS CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST URIC (12)(IDEXX VETTEST URIC (12))-QUANTITATIVELY MEASURES URIC ACID CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST TRIG (12)(IDEXX VETTEST TRIG (12))-QUANTITATIVELY MEASURES TRIGLYCERIDE CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST ALKP (25)(IDEXX VETTEST ALKP (25))-QUANTITATIVELY MEASURES ALKALINE PHOSPHATASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,VETTROL CONTROL (1 VIAL) (IDEXX VETTROL CONTROL (1 VIAL))-LEOPHILIZED BOVINE SERUM CONTROL FLUID FOR QUALITY CONTROL ON CHEMICAL-FREE BIOCHEMICAL CATALYST ANALYZERS CATALYST AND VETTEST., VETTEST EQUINE HEALTH PROFILE (2)(IDEXX VETTEST EQUINE HEALTH PROFILE (2))-"CONSISTS OF TWELVE SEPARATE SLIDES: ALBUMIN (ALB), ALKALINE PHOSPHATASE (ALKP), ASPARTASE AMINOTRANSFERASE (SGOT/AST), CALCIUM (CA), CREATINE KINASE (CK), CREATININE (CREA), GAMMA-GLUTAMYLTRANFERASE (GGT), GLUCOSE (GLU), LACTATE DEHYDROGENASE, TOTAL BILIRUBIN (TBIL), TOTAL PROTEIN (TP), BLOOD UREA NITROGEN (BUN/UREA)", VETTEST PHOS (12)(IDEXX VETTEST PHOS (12))-QUANTITATIVELY MEASURES PHOSPHORUS CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST AST (25)(IDEXX VETTEST AST (25))-QUANTITATIVELY MEASURES ASPARTATE AMINOTRANSFERASE (AST) ACTIVITY IN ANIMAL SERUM OR PLASMA.,VETTEST PHOS (25) (IDEXX VETTEST PHOS (25))-QUANTITATIVELY MEASURES PHOSPHORUS CONCENTRATION IN ANIMAL SERUM OR PLASMA., VETTEST MG (12)(IDEXX VETTEST MG (12))-QUANTITATIVELY MEASURES MAGNESIUM CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST CREA (25)(IDEXX VETTEST CREA (25))-QUANTITATIVELY MEASURES CREATININE CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST CK (12)(IDEXX VETTEST CK (12))-QUANTITATIVELY MEASURES CREATINE KINASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,VETTEST TP (25)(IDEXX VETTEST TP (25))-QUANTITATIVELY MEASURES TOTAL PROTEIN CONCENTRATION IN ANIMAL SERUM OR PLASMA.,CATALYST CHOL (12)(IDEXX CATALYST CHOL (12))-QUANTITATIVELY MEASURES CHOLESTEROL CONCENTRATION IN ANIMAL SERUM OR PLASMA., VETTEST PREANESTHETIC PANEL (4)(IDEXX VETTEST PREANESTHETIC PANEL (4))-"CONSISTS OF SIX SEPARATE SLIDES:

	ALKALINE PHOSPHATASE (ALKP), ALANINE AMINOTRANSFERASE (ALT / SGPT), CREATININE (CREA), GLUCOSE (GLU), TOTAL PROTEIN (TP), BLOOD UREA NITROGEN (BUN/UREA)",VETTES BUN (12)(IDEXX VETTES BUN (12))-QUANTITATIVELY MEASURES UREA CONCENTRATION, REPORTED EITHER AS UREA NITROGEN (BUN) OR AS UREA (UREA) IN ANIMAL SERUM OR PLASMA.,VETTEST CREA (12) (IDEXX VETTEST CREA (12))-QUANTITATIVELY MEASURES CREATININE CONCENTRATION IN ANIMAL SERUM OR PLASMA.., VETTEST LDH (12)(IDEXX VETTEST LDH (12))-QUANTITATIVELY MEASURES LACTATE DEHYDROGENASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,VETTEST GGT (12)(IDEXX VETTEST GGT (12))-QUANTITATIVELY MEASURES GAMMA GLUTAMYLTRANSFERASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,VETTEST GLU (25)(IDEXX VETTEST GLU (25))-QUANTITATIVELY MEASURES GLUCOSE CONCETRATION IN ANIMAL SERUM OR PLASMA.,VETTEST LAC (12) (IDEXX VETTEST LAC (12))-QUANTITATIVELY MEASURES LACTATE CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST ALB (25) (IDEXX VETTEST ALB (25))-QUANTITATIVELY MEASURES ALBUMIN CONCENTRATION IN ANIMAL SERUM OR PLASMA.,CATALYST URINE P:C DILUENT(IDEXX CATALYST URINE P:C DILUENT)-URINE DILUENT TO BE USED WHEN PREPARING SAMPLES TO ANALYSE UPC RATION WITH THE CATALYST ANALYSERS,CATALYST LAC (12)(IDEXX CATALYST LAC (12))-QUANTITATIVELY MEASURES LACTATE CONCENTRATION IN ANIMAL SERUM OR PLASMA.,CATALYST AST (12) (IDEXX CATALYST AST (12))-QUANTITATIVELY MEASURES ASPARTATE AMINOTRANSFERASE (AST) ACTIVITY IN ANIMAL SERUM OR PLASMA.,CATALYST CREA (12)(IDEXX CATALYST CREA (12))-QUANTITATIVELY MEASURES CREATININE CONCENTRATION IN ANIMAL SERUM OR PLASMA.,CATALYST GLU (12)(IDEXX CATALYST GLU (12))-QUANTITATIVELY MEASURES GLUCOSE CONCETRATION IN ANIMAL SERUM OR PLASMA.,CATALYST EQUINE 15 CLIP (12)(IDEXX CATALYST EQUINE 15 CLIP (12))-USED WITH THE IDEXX CATALYST DX™ CHEMISTRY ANALYZER TO DETECT A VARIETY OF ANALYTES IN ANIMAL SERUM OR PLASMA. 12 ANALYTES,CATALYST MG (12)(IDEXX CATALYST MG (12))-QUANTITATIVELY MEASURES MAGNESIUM CONCENTRATION IN ANIMAL SERUM OR PLASMA.,CATALYST NH3 (12) (IDEXX CATALYST NH3 (12))-QUANTITATIVELY MEASURES AMMONIA CONCENTRATION IN ANIMAL SERUM OR PLASMA.,CATALYST LIPA (12)(IDEXX CATALYST LIPA (12))-QUANTITATIVELY MEASURES LIPASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,VETTEST ALT (12) (IDEXX VETTEST ALT (12))-QUANTITATIVELY MEASURES ALANINE AMINOTRANSFERASE (ALT) ACTIVITY IN ANIMAL SERUM OR PLASMA.,CATALYST GGT (12)(IDEXX CATALYST GGT (12))-QUANTITATIVELY MEASURES GAMMA GLUTAMYLTRANSFERASE

	ACTIVITY IN ANIMAL SERUM OR PLASMA.,VETTEST CA (25)(IDEXX VETTEST CA (25))-QUANTITATIVELY MEASURES CALCIUM CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST ALKP (12)(IDEXX VETTEST ALKP (12))-QUANTITATIVELY MEASURES ALKALINE PHOSPHATASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,CATALYST URINE P:C RATIO (6)(IDEXX CATALYST URINE P:C RATIO (6))-USED WITH THE IDEXX CATALYST DX™ CHEMISTRY ANALYZER TO DETECT TWO ANALYTES IN ANIMAL URINE.,CATALYST CK (12)(IDEXX CATALYST CK (12))-QUANTITATIVELY MEASURES CREATINE KINASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,VETTEST ALB (12)(IDEXX VETTEST ALB (12))-QUANTITATIVELY MEASURES ALBUMIN CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST CA (12)(IDEXX VETTEST CA (12))-QUANTITATIVELY MEASURES CALCIUM CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST DIAGNOSTIC HEALTH PROFILE (2)(IDEXX VETTEST DIAGNOSTIC HEALTH PROFILE (2))-"CONSISTS OF TWELVE SEPARATE SLIDES: ALBUMIN (ALB), ALKALINE PHOSPHATASE (ALKP), AMYLASE (AMYL), CALCIUM (CA), GAMMA GLUTAMYLTRANSFERASE (GGT), CREATININE (CREA), GLUCOSE (GLU), LIPASE (LIPA), TOTAL BILIRUBIN (TBIL), TOTAL PROTEIN (TP), BLOOD UREA NITROGEN (BUN/UREA)",VETTEST LIPA (25)(IDEXX VETTEST LIPA (25))-QUANTITATIVELY MEASURES LIPASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,VETTEST TBIL (12)(IDEXX VETTEST TBIL (12))-QUANTITATIVELY MEASURES TOTAL BILIRUBIN CONCENTRATION IN ANIMAL SERUM OR PLASMA.,CATALYST LDH (12)(IDEXX CATALYST LDH (12))-QUANTITATIVELY MEASURES LACTATE DEHYDROGENASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,CATALYST BUN (12)(IDEXX CATALYST BUN (12))-QUANTITATIVELY MEASURES UREA CONCENTRATION, REPORTED EITHER AS BLOOD UREA NITROGEN (BUN) OR AS UREA (UREA) IN ANIMAL SERUM OR PLASMA.,CATALYST ALB (12)(IDEXX CATALYST ALB (12))-QUANTITATIVELY MEASURES ALBUMIN CONCENTRATION IN ANIMAL SERUM OR PLASMA.,CATALYST CHEM 10 CLIP (12)(IDEXX CATALYST CHEM 10 CLIP (12))-USED WITH THE IDEXX CATALYST DX™ CHEMISTRY ANALYZER TO DETECT A VARIETY OF ANALYTES IN ANIMAL SERUM OR PLASMA. 7 ANALYTES,VETTEST GGT (25)(IDEXX VETTEST GGT (25))-QUANTITATIVELY MEASURES GAMMA GLUTAMYLTRANSFERASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,CATALYST PHBR TEST KIT (6 SLIDE/ WASH)(IDEXX CATALYST PHBR TEST KIT (6 SLIDE/ WASH))-QUANTITATIVELY MEASURES QUANTITATIVELY MEASURE PHENOBARBITAL (PHBR) CONCENTRATION IN ANIMAL SERUM AND PLASMA.,CATALYST TRIG (12)(IDEXX CATALYST TRIG (12))-QUANTITATIVELY MEASURES TRIGLYCERIDE CONCENTRATION IN ANIMAL SERUM OR PLASMA., UPRO CONTROL (6 X 2VIALS)(IDEXX UPRO CONTROL (6 X 2VIALS))-

	CONTROL USED TO MONITOR URINE PROTEIN ON THE IDEXX VETTEST AND CATALYST ANALYZERS,CATALYST® QC CLIP (6)(IDEXX CATALYST® QC CLIP (6))-USED WITH THE IDEXX CATALYST DX™ CHEMISTRY ANALYZER IN CONJUNCTION WITH IDEXX VETTROL* CONTROL FLUID,CATALYST TP (12)(IDEXX CATALYST TP (12))-QUANTITATIVELY MEASURES TOTAL PROTEIN CONCENTRATION IN ANIMAL SERUM OR PLASMA.,CATALYST ALKP (12)(IDEXX CATALYST ALKP (12))-QUANTITATIVELY MEASURES ALKALINE PHOSPHATASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,VETTEST URINE P:C RATIO (6)(IDEXX VETTEST URINE P:C RATIO (6))-QUANTITATIVELY MEASURES TWO ANALYTES; CREATININE AND PROTEIN IN ANIMAL URINE.,VETTEST GENERAL HEALTH PROFILE (2)(IDEXX VETTEST GENERAL HEALTH PROFILE (2))-"CONSISTS OF TWELVE SEPARATE SLIDES: ALBUMIN (ALB), ALKALINE PHOSPHATASE (ALKP), ALANINE AMINOTRANSFERASE (ALT / SGPT), AMYLASE (AMYL), CALCIUM (CA), CHOLESTEROL (CHOL), CREATININE (CREA), GLUCOSE (GLU), INORGANIC PHOSPHATE (PHOS), TOTAL BILIRUBIN (TBIL), TOTAL PROTEIN (TP), BLOOD UREA NITROGEN (BUN/UREA)",VETTEST NSAID MONITORING PANEL (4)(IDEXX VETTEST NSAID MONITORING PANEL (4))-"CONSISTS OF FIVE SEPARATE SLIDES: ALKALINE PHOSPHATASE (ALKP), ALANINE AMINOTRANSFERASE (ALT / SGPT), ASPARTATE AMINOTRANSFERASE (AST / SGOT), CREATININE (CREA), BLOOD UREA NITROGEN (BUN/UREA)",CATALYST AMYL (12)(IDEXX CATALYST AMYL (12))-QUANTITATIVELY MEASURES AMYLASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,VETTEST NH3 (12)(IDEXX VETTEST NH3 (12))-QUANTITATIVELY MEASURES AMMONIA CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST LIPA (12) (IDEXX VETTEST LIPA (12))-QUANTITATIVELY MEASURES LIPASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,CATALYST ALT (12)(IDEXX CATALYST ALT (12))-QUANTITATIVELY MEASURES ALANINE AMINOTRANSFERASE (ALT) ACTIVITY IN ANIMAL SERUM OR PLASMA.,CATALYST TBIL (12)(IDEXX CATALYST TBIL (12))-QUANTITATIVELY MEASURES TOTAL BILIRUBIN CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST CK (25)(IDEXX VETTEST CK (25))-QUANTITATIVELY MEASURES CREATINE KINASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,CATALYST URIC (12)(IDEXX CATALYST URIC (12))-QUANTITATIVELY MEASURES URIC ACID CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST AMYL (12)(IDEXX VETTEST AMYL (12))-QUANTITATIVELY MEASURES AMYLASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,VETTEST CHOL (12)(IDEXX VETTEST CHOL (12))-QUANTITATIVELY MEASURES CHOLESTEROL CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST CHOL (25) (IDEXX VETTEST CHOL (25))-QUANTITATIVELY MEASURES CHOLESTEROL CONCENTRATION IN ANIMAL SERUM OR PLASMA.,

	VETTEST AST (12)(IDEXX VETTEST AST (12))-QUANTITATIVELY MEASURES ASPARTATE AMINOTRANSFERASE (AST) ACTIVITY IN ANIMAL SERUM OR PLASMA.,VETTEST TP (12)(IDEXX VETTEST TP (12)) -QUANTITATIVELY MEASURES TOTAL PROTEIN CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTEST GLU (12)(IDEXX VETTEST GLU (12))-QUANTITATIVELY MEASURES GLUCOSE CONCERTATION IN ANIMAL SERUM OR PLASMA.,CATALYST CHEM 17 CLIP (12)(IDEXX CATALYST CHEM 17 CLIP (12))-USED WITH THE IDEXX CATALYST DX™ CHEMISTRY ANALYZER TO DETECT A VARIETY OF ANALYTES IN ANIMAL SERUM OR PLASMA. 14 ANALYTES,CATALYST CHEM 15 CLIP (12)(IDEXX CATALYST CHEM 15 CLIP (12))-USED WITH THE IDEXX CATALYST DX™ CHEMISTRY ANALYZER TO DETECT A VARIETY OF ANALYTES IN ANIMAL SERUM OR PLASMA. 12 ANALYTES,CATALYST DX WHITE OPTICAL SLIDE(IDEXX CATALYST DX WHITE OPTICAL SLIDE)-OPTICAL SLIDE USED FOR THE CALIBRATION OF THE CATALYST ANALYZERS,CATALYST CA (12)(IDEXX CATALYST CA (12))-QUANTITATIVELY MEASURES CALCIUM CONCENTRATION IN ANIMAL SERUM OR PLASMA.,VETTROL™ CONTROL(IDEXX VETTROL™CONTROL)-LEOPHILIZED BOVINE SERUM CONTROL FLUID FOR QUALITY CONTROL ON CHEMICAL-FREE BIOCHEMICAL CATALYST ANALYZERS CATALYST AND VETTEST.,VETTEST AMYL (25)(IDEXX VETTEST AMYL (25))-QUANTITATIVELY MEASURES AMYLASE ACTIVITY IN ANIMAL SERUM OR PLASMA.,VETTEST BUN (25)(IDEXX VETTEST BUN (25))-QUANTITATIVELY MEASURES UREA CONCENTRATION, REPORTED EITHER AS UREA NITROGEN (BUN) OR AS UREA (UREA) IN ANIMAL SERUM OR PLASMA.,VETTEST® QUALITY CONTROL PANEL (4)(IDEXX VETTEST® QUALITY CONTROL PANEL (4))-CONSISTS OF SIX SEPARATE SLIDES: CALCIUM (CA), ALANINE AMINOTRANSFERASE (ALT), AMMONIA (NH3), ALBUMIN (ALB), ALKALINE PHOSPHATASE (ALKP), GLUCOSE (GLU)",VETTEST AVIAN HEALTH PROFILE (4)(IDEXX VETTEST AVIAN HEALTH PROFILE (4))-"CONSISTS OF SIX SEPARATE SLIDES: ALBUMIN (ALB), ASPARTASE AMINOTRANSFERASE, (SGOT/AST), CALCIUM (CA), GLUCOSE (GLU), TOTAL PROTEIN (TP), URIC ACID (URIC)",CATALYST® PHBR CONTROL (6 VIALS)(IDEXX CATALYST® PHBR CONTROL (6 VIALS))-ASSAY CONTROL USED TO MONITOR PHENOBARBITAL ON THE CATALYST* ANALYZER.,VETTEST TBIL (25)(IDEXX VETTEST TBIL (25))-QUANTITATIVELY MEASURES TOTAL BILIRUBIN CONCENTRATION IN ANIMAL SERUM OR PLASMA.,CATALYST NSAID 6 CLIP (12)(IDEXX CATALYST NSAID 6 CLIP (12))-USED WITH THE IDEXX CATALYST DX™ CHEMISTRY ANALYZER TO DETECT A VARIETY OF ANALYTES IN ANIMAL SERUM OR PLASMA. 5 ANALYTES

232	IMP/IVD/2019/000208	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCESS HBS AG CALIBRATORS (ACCESS HBS AG CALIBRATORS)-THE ACCESS HBS AG CALIBRATORS ARE INTENDED FOR USE WITH THE ACCESS HBS AG AND ACCESS HBS AG CONFIRMATORY ASSAYS FOR THE QUALITATIVE DETECTION AND CONFIRMATION, RESPECTIVELY, OF THE PRESENCE OF THE HEPATITIS B VIRUS SURFACE ANTIGEN (HBS AG) IN HUMAN SERUM OR PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS CEA CALIBRATORS(ACCESS CEA CALIBRATORS)-THE ACCESS CEA CALIBRATORS (BSA MATRIX) ARE INTENDED TO CALIBRATE THE ACCESS CEA ASSAY FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) LEVELS IN HUMAN SERUM, USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS HBS AG(ACCESS HBS AG)-THE ACCESS HBS AG ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF THE SURFACE ANTIGEN OF THE HEPATITIS B VIRUS (HBS AG) IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS,ACCESS RUBELLA IGM QC(ACCESS RUBELLA IGM QC)-THE ACCESS RUBELLA IGM QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS RUBELLA IGM ASSAY.,ACCESS HBS AG QC(ACCESS HBS AG QC)-THE ACCESS HBS AG QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS HBS AG AND ACCESS HBS AG CONFIRMATORY ASSAYS,ACCESS CEA DILUENT(ACCESS CEA DILUENT)-THE ACCESS CEA DILUENT (BSA MATRIX) IS INTENDED FOR USE WITH THE ACCESS CEA ASSAY TO DILUTE PATIENT SAMPLES CONTAINING CEA CONCENTRATIONS GREATER THAN THE ACCESS CEA CALIBRATOR S5.,ACCESS CMV IGM(ACCESS CMV IGM)-THE ACCESS CMV IGM ASSAY IS A PARAMAGNETIC-PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS (CMV) IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS. THE ACCESS CMV IGM ASSAY IS INDICATED AS AN AID IN THE DIAGNOSIS OF ACTIVE OR RECENT CMV INFECTION. NOTE: ASSAY PERFORMANCE CHARACTERISTICS HAVE NOT BEEN ESTABLISHED FOR CORD BLOOD, NEONATAL OR INFANT SPECIMENS., ACCESS HAV AB QC(ACCESS HAV AB QC)-THE ACCESS HAV AB QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS HAV AB ASSAY.,ACCESS RUBELLA IGG (ACCESS RUBELLA IGG)-THE ACCESS RUBELLA IGG ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG

	ANTIBODIES TO THE RUBELLA VIRUS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS. THE ACCESS RUBELLA IGG ASSAY AIDS IN THE DIAGNOSIS OF RUBELLA INFECTION AND THE DETERMINATION OF IMMUNITY.,ACCESS TOXO IGM II(ACCESS TOXO IGM II)-THE ACCESS TOXO IGM II ASSAY IS A PARAMAGNETIC-PARTICLE CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF TOXOPLASMA GONDII-SPECIFIC IGM ANTIBODY IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS CMV IGM QC(ACCESS CMV IGM QC) -THE ACCESS CMV IGM QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS CMV IGM ASSAY.,ACCESS RUBELLA IGM (ACCESS RUBELLA IGM)-THE ACCESS RUBELLA IGM ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTI-RUBELLA VIRUS IGM IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS., ACCESS HAV AB CALIBRATORS(ACCESS HAV AB CALIBRATORS)-THE ACCESS HAV AB CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS HAV AB ASSAY FOR THE DETECTION AND THE QUANTITATIVE DETERMINATION OF TOTAL ANTI-HAV ANTIBODY LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS CMV IGG QC(ACCESS CMV IGG QC) -THE ACCESS CMV IGG QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS CMV IGG ASSAY,ACCESS HAV AB (ACCESS HAV AB)-THE ACCESS HAV AB ASSAY IS A PARAMAGNETIC-PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE DETECTION AND THE QUANTITATIVE DETERMINATION OF TOTAL ANTI-HAV ANTIBODY LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS CEA(ACCESS CEA)-THE ACCESS CEA ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) LEVELS IN HUMAN SERUM, USING THE ACCESS IMMUNOASSAY SYSTEMS. CEA MEASURED BY THE ACCESS IMMUNOASSAY SYSTEMS IS USED AS AN AID IN THE MANAGEMENT OF CANCER PATIENTS IN WHOM CHANGING CEA CONCENTRATIONS HAVE BEEN OBSERVED.,ACCESS RUBELLA IGM CALIBRATORS(ACCESS RUBELLA IGM CALIBRATORS)-THE ACCESS RUBELLA IGM CALIBRATORS ARE INTENDED FOR USE WITH THE ACCESS RUBELLA IGM ASSAY FOR THE DETECTION OF ANTI-RUBELLA VIRUS IGM IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS CMV IGG CALIBRATORS(ACCESS CMV IGG CALIBRATORS)-THE ACCESS CMV IGG CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS CMV IGG ASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS (CMV) IN HUMAN SERUM AND PLASMA (EDTA,

	HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS CMV IGM CALIBRATORS(ACCESS CMV IGM CALIBRATORS)-THE ACCESS CMV IGM CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS CMV IGM ASSAY FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS (CMV) IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS TOXO IGM II CALIBRATORS(ACCESS TOXO IGM II CALIBRATORS)-THE ACCESS TOXO IGM II CALIBRATORS ARE INTENDED FOR USE WITH THE ACCESS TOXO IGM II ASSAY FOR THE QUALITATIVE DETECTION OF TOXOPLASMA GONDII-SPECIFIC IGM ANTIBODY IN ADULT HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS TOXO IGG QC(ACCESS TOXO IGG QC)-THE ACCESS TOXO IGG QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS TOXO IGG ASSAY,ACCESS TOXO IGG (ACCESS TOXO IGG)-THE ACCESS TOXO IGG ASSAY IS A PARAMAGNETIC-PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS. THE ACCESS TOXO IGG ASSAY AIDS IN THE DIAGNOSIS OF TOXOPLASMA GONDII INFECTION AND MAY BE USED TO ASSESS THE IMMUNE STATUS OF PREGNANT WOMEN.,ACCESS TOXO IGG CALIBRATORS (ACCESS TOXO IGG CALIBRATORS)-THE ACCESS TOXO IGG CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS TOXO IGG ASSAY FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS HAV IGM QC (ACCESS HAV IGM QC)-THE ACCESS HAV IGM QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS HAV IGM ASSAY.,ACCESS CMV IGG(ACCESS CMV IGG)-THE ACCESS CMV IGG ASSAY IS A PARAMAGNETIC-PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS (CMV) IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN) USING THE ACCESS IMMUNOASSAY SYSTEMS. THE ACCESS CMV IGG ASSAY AIDS IN THE DIAGNOSIS OF CMV INFECTION AND MAY BE USED TO ASSESS THE SEROLOGICAL STATUS OF PREGNANT WOMEN,ACCESS TOXO IGM II QC(ACCESS TOXO IGM II QC)-THE ACCESS TOXO IGM II QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS TOXO IGM II ASSAY,ACCESS HAV IGM CALIBRATORS(ACCESS HAV IGM CALIBRATORS)-THE ACCESS HAV IGM CALIBRATORS ARE INTENDED FOR USE WITH THE ACCESS HAV IGM ASSAY FOR THE DETECTION OF IGM ANTIBODY TO HEPATITIS A VIRUS ANTIGEN IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS

		HAV IGM(ACCESS HAV IGM)-THE ACCESS HAV IGM ASSAY IS A PARAMAGNETIC-PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE DETECTION OF IGM ANTIBODY TO HEPATITIS A VIRUS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS RUBELLA IGG QC(ACCESS RUBELLA IGG QC)-THE ACCESS RUBELLA IGG QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS RUBELLA IGG ASSAY.,ACCESS CEA QC(ACCESS CEA QC)-THE ACCESS CEA QC (BSA MATRIX) CONTROLS ARE INTENDED FOR MONITORING THE SYSTEM PERFORMANCE OF IMMUNOENZYMATIC PROCEDURES FOR THE QUANTITATIVE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN (CEA) USING ACCESS CEA REAGENTS.,ACCESS RUBELLA IGG CALIBRATORS (ACCESS RUBELLA IGG CALIBRATORS)-THE ACCESS RUBELLA IGG CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS RUBELLA IGG ASSAY FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO THE RUBELLA VIRUS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS.
233	IMP/IVD/2019/000211	1.License Holder Name: ADVY CHEMICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QUALITATIVE IMMUNOCHROMATOGRAPHIC DIPSTICK TEST FOR DETECTING THE PRESENCE OF PHOSPHORYLATED IGFBP-1 (INSULIN LIKE GROWTH FACTOR BINDING PROTEIN-1) IN CERVICAL SECRETIONS DURING PREGNANCY(ACTIM PARTUS)-ACTIM® PARTUS TEST IS A VISUALLY INTERPRETED, QUALITATIVE IMMUNOCHROMATOGRAPHIC DIPSTICK TEST FOR DETECTING THE PRESENCE OF PHOSPHORYLATED IGFBP-1 (INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN-1) IN CERVICAL SECRETIONS DURING PREGNANCY. THE TEST IS INTENDED FOR PROFESSIONAL USE TO HELP PREDICT THE RISK OF PRETERM OR IMMINENT DELIVERY WHEN FETAL MEMBRANES ARE INTACT., QUALITATIVE TEST FOR DETECTION OF AMNIOTIC FLUID IN VAGINAL SECRETION(ACTIM PROM)-ACTIM PROM TEST IS A VISUALLY INTERPRETED, QUALITATIVE IMMUNOCHROMATOGRAPHIC DIPSTICK TEST FOR DETECTION OF AMNIOTIC FLUID IN VAGINAL SECRETIONS DURING PREGNANCY. ACTIM PROM DETECTS IGFBP-1, WHICH IS A MAJOR PROTEIN IN AMNIOTIC FLUID AND A MARKER OF THE AMNIOTIC FLUID IN A VAGINAL SAMPLE. THE TEST IS INTENDED FOR PROFESSIONAL USE TO HELP DIAGNOSE THE RUPTURE OF FETAL MEMBRANES (ROM) IN PREGNANT WOMEN.

234	IMP/IVD/2019/000214	1.License Holder Name: ASCENSIA DIABETES CARE INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROL SOLUTIONS (CONTOUR)-CONTOUR CONTROL SOLUTIONS IS AQUEOUS GLUCOSE SOLUTIONS INTENDED FOR USE IN SELFTESTING BY PEOPLE WITH DIABETES AND BY HEALTH CARE PROFESSIONALS AS A QUALITY CONTROL CHECK.,CONTROL SOLUTIONS(CONTOUR TS)-CONTOUR PLUS AND CONTOUR TS CONTROL SOLUTIONS IS AQUEOUS GLUCOSE SOLUTIONS INTENDED FOR USE IN SELF- TESTING BY PEOPLE WITH DIABETES AND BY HEALTH CARE PROFESSIONALS AS A QUALITY CONTROL CHECK.,CONTROL SOLUTIONS(CONTOUR PLUS) -CONTOUR PLUS AND CONTOUR TS CONTROL SOLUTIONS IS AQUEOUS GLUCOSE SOLUTIONS INTENDED FOR USE IN SELF-TESTING BY PEOPLE WITH DIABETES AND BY HEALTH CARE PROFESSIONALS AS A QUALITY CONTROL CHECK.
235	IMP/IVD/2019/000215	1.License Holder Name: QIAGEN INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CAREHPV TEST KIT-IT IS USED FOR THE QUALITATIVE DETECTION OF 14 TYPES OF HPV DNA IN CERVICAL SPECIMENS.
236	IMP/IVD/2019/000217	1.License Holder Name: SIGMA SALES & SERVICES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIP(PRODIGY NO CODING)-PRODIGY® BLOOD GLUCOSE TEST STRIPS ARE USED WITH THE PRODIGY® BLOOD GLUCOSE METERS. THEY ARE INTENDED FOR SELF-TESTING BY PEOPLE WITH DIABETES AT HOME AND HEALTH CARE PROFESSIONALS IN A CLINICAL SETTING TO MONITOR GLUCOSE CONCENTRATIONS IN CAPILLARY WHOLE BLOOD. THEY ARE FOR TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE ONLY). DO NOT USE THEM FOR DIAGNOSIS OF DIABETES OR TESTING ON NEONATES.

237	IMP/IVD/2019/000219	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QUIKLYTE INTEGRATED MULTISENSOR STANDARD B (QUIKLYTE INTEGRATED MULTISENSOR STANDARD B)-IT IS USED FOR THE CALIBRATION OF NA+/K+/CL-/ TCO2 ON DIMENSION CLINICAL CHEMISTRY SYSTEMS WITH THE QUIKLYTE MODULE.,QUICKLYTE® INTEGRATED MULTISENSOR SAMPLE DILUENT(QUICKLYTE® INTEGRATED MULTISENSOR SAMPLE DILUENT)-TO DILUTE THE SAMPLE FOR DIMENSION CLINICAL CHEMISTRY SYSTEMS WITH THE QUIKLYTE MODULE.,QUICKLYTE® INTEGRATED MULTISENSOR STANDARD A(QUICKLYTE® INTEGRATED MULTISENSOR STANDARD A)-IT IS USED FOR THE CALIBRATION OF NA+/K+/CL-/ TCO2 ON DIMENSION CLINICAL CHEMISTRY SYSTEMS WITH THE QUIKLYTE MODULE.,QUICKLYTE® INTEGRATED MULTISENSOR FLUSH SOLUTION(QUICKLYTE® INTEGRATED MULTISENSOR FLUSH SOLUTION)-IT IS USED TO WASH LINES BETWEEN SAMPLES AND TO STABILIZE SENSING DEVICES ON DIMENSION CLINICAL CHEMISTRY SYSTEM WITH THE QUIKLYTE MODULE.

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238	IMP/IVD/2019/000221	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SALICYLATE CALIBRATOR (SALICYLATE CALIBRATOR)-INTENDED FOR USE IN THE CALIBRATION OF THE SALICYLATE ASSAY ON THE ARCHITECT C SYSTEMS,ALINITY C SALICYLATE REAGENT KIT(ALINITY C SALICYLATE REAGENT KIT)-THE ALINITY C SALICYLATE ASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF SALICYLATE IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER., ACETAMINOPHEN L3K(ACETAMINOPHEN L3K)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF ACETAMINOPHEN IN HUMAN SERUM AND PLASMA.,ALINITY C SALICYLATE CALIBRATOR KIT (ALINITY C SALICYLATE CALIBRATOR KIT)-THE ALINITY C SALICYLATE CALIBRATOR IS INTENDED FOR USE IN THE CALIBRATION OF THE ALINITY C SALICYLATE ASSAY ON THE ALINITY C ANALYZER.,SALICYLATE(SALICYLATE)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF SALICYLATE IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY C DIRECT LDL REAGENT KIT(ALINITY C DIRECT LDL REAGENT KIT)-THE ALINITY C DIRECT LDL ASSAY IS USED FOR THE DIRECT, QUANTITATIVE DETERMINATION OF LOW-DENSITY LIPOPROTEIN (LDL) CHOLESTEROL IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,DIRECT LDL (DIRECT LDL)-USED FOR THE DIRECT, QUANTITATIVE DETERMINATION OF LOW-DENSITY LIPOPROTEIN (LDL) CHOLESTEROL IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEM.
239	IMP/IVD/2019/000223	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:XPRECIA SYSTEMS PT CONTROLS(XPRECIA SYSTEMS PT CONTROLS)-THE XPRECIA SYSTEMS PT CONTROLS KIT CONTAINS ASSAYED CONTROLS FOR THE ASSESSMENT OF PRECISION AND ACCURACY IN THE NORMAL (LIQUID QUALITY CONTROL PT1) AND THERAPEUTIC (LIQUID QUALITY CONTROL PT2) RANGE FOR THE PROTHROMBN TIME (PT) TO BE USED WITH XPRECIA SYSTEMS PT/INR STRIPS

240	IMP/IVD/2019/000226	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVIA AUTOSLIDE METHANOL(ADVIA AUTOSLIDE METHANOL)-THE MODIFIED WRIGHT METHOD IS FOR IN VITRO DIAGNOSTIC USE IN THE DIFFERENTIAL STAINING OF BLOOD, BONE MARROW, AND BODY FLUID SMEARS ON THE ADVIA® AUTOSLIDE SLIDE MAKER STAINER. STAINED SMEARS ARE EVALUATED TO IDENTIFY AND QUANTIFY CELLS IN WHOLE BLOOD AND OTHER SPECIMENS TO AID CLINICIANS IN THE ASSESSMENT OF VARIOUS CLINICAL CONDITIONS.,ADVIA AUTOSLIDE WRIGHT–GIEMSA STAIN(ADVIA AUTOSLIDE WRIGHT–GIEMSA STAIN)-THE MODIFIED WRIGHT METHOD IS FOR IN VITRO DIAGNOSTIC USE IN THE DIFFERENTIAL STAINING OF BLOOD, BONE MARROW, AND BODY FLUID SMEARS ON THE ADVIA® AUTOSLIDE SLIDE MAKERSTAINER STAINED SMEARS ARE EVALUATED TO IDENTIFY AND QUANTIFY CELLS IN WHOLE BLOOD AND OTHER SPECIMENS TO AID CLINICIANS IN THE ASSESSMENT OF VARIOUS CLINICAL CONDITIONS ,ADVIA AUTOSLIDE WRIGHT-GIEMSA BUFFER(ADVIA AUTOSLIDE WRIGHT-GIEMSA BUFFER)-THE WRIGHT GIEMSA METHOD IS FOR IN VITRO DIAGNOSTIC USE IN THE DIFFERENTIAL STAINING OF BLOOD, BONE MARROW, AND BODY FLUID SMEARS ON THE ADVIA® AUTOSLIDE SLIDE MAKER STAINER. STAINED SMEARS ARE EVALUATED TO IDENTIFY AND QUANTIFY CELLS IN WHOLE BLOOD AND OTHER SPECIMENS TO AID CLINICIANS IN THE ASSESSMENT OF VARIOUS CLINICAL CONDITIONS. ,HEMATEK STAIN PAK WRIGHT GIEMSA STAIN (HEMATEK STAIN PAK WRIGHT GIEMSA STAIN)-THE HEMATEK® STAIN PAK IS FOR IN VITRO DIAGNOSTIC USE IN THE DIFFERENTIAL STAINING OF BLOOD, BONE MARROW AND BODY FLUID SMEARS ON THE HEMATEK SLIDE STAINER. STAINED SMEARS ARE EVALUATED FOR THE IDENTIFICATION AND QUANTITATION OF CELLS IN WHOLE BLOOD AND OTHER SPECIMENS TO AID CLINICIANS IN THE ASSESSMENT OF VARIOUS CLINICAL CONDITIONS. ,HEMATEK STAIN PAK MODIFIED WRIGHT'S STAIN(HEMATEK STAIN PAK MODIFIED WRIGHT'S STAIN)-THE HEMATEK® STAIN PAK IS FOR IN VITRO DIAGNOSTIC USE IN THE DIFFERENTIAL STAINING OF BLOOD, BONE MARROW AND BODY FLUID SMEARS ON THE HEMATEK SLIDE STAINER. STAINED SMEARS ARE EVALUATED FOR THE IDENTIFICATION AND QUANTITATION OF CELLS IN WHOLE BLOOD AND OTHER SPECIMENS TO AID CLINICIANS IN THE ASSESSMENT OF VARIOUS CLINICAL CONDITIONS.,ADVIA AUTOSLIDE MODIFIED WRIGHT'S STAIN(ADVIA AUTOSLIDE MODIFIED WRIGHT'S STAIN)-THE MODIFIED WRIGHT METHOD IS FOR IN VITRO DIAGNOSTIC USE IN THE DIFFERENTIAL STAINING OF BLOOD, BONE MARROW, AND BODY FLUID SMEARS ON THE ADVIA® AUTOSLIDE SLIDE MAKER STAINER.

	STAINED SMEARS ARE EVALUATED TO IDENTIFY AND QUANTIFY CELLS IN WHOLE BLOOD AND OTHER SPECIMENS TO AID CLINICIANS IN THE ASSESSMENT OF VARIOUS CLINICAL CONDITIONS. ,ADVIA AUTOSLIDE MODIFIED WRIGHT'S BUFFER(ADVIA AUTOSLIDE MODIFIED WRIGHT'S BUFFER)-THE MODIFIED WRIGHT METHOD IS FOR IN VITRO DIAGNOSTIC USE IN THE DIFFERENTIAL STAINING OF BLOOD, BONE MARROW, AND BODY FLUID SMEARS ON THE ADVIA® AUTOSLIDE SLIDE MAKER STAINER. STAINED SMEARS ARE EVALUATED TO IDENTIFY AND QUANTIFY CELLS IN WHOLE BLOOD AND OTHER SPECIMENS TO AID CLINICIANS IN THE ASSESSMENT OF VARIOUS CLINICAL CONDITIONS.

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241	IMP/IVD/2019/000227	1.License Holder Name: SUN BIOSYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CALIBRATION VERIFICATION/LINEARITY TEST KIT(VALIDATE IBC)-VALIDATE IBC CALIBRATION VERIFICATION / LINEARITY TEST KIT SOLUTIONS ARE UNASSAYED AND INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LINEARITY, CALIBRATION VERIFICATION AND VERIFICATION OF REPORTABLE RANGE IN AUTOMATED INSTRUMENT SYSTEMS FOR THE FOLLOWING ANALYTES: TOTAL IRON BINDING CAPACITY (TIBC) AND UNSATURATED IRON BINDING CAPACITY (UIBC)..,CALIBRATION VERIFICATION/LINEARITY TEST KIT(VALIDATE THY)-VALIDATE THY CALIBRATION VERIFICATION / LINEARITY TEST KIT SOLUTIONS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LINEARITY, CALIBRATION VERIFICATION AND VERIFICATION OF REPORTABLE RANGE IN AUTOMATED, SEMI AUTOMATED, AND MANUAL INSTRUMENT SYSTEMS FOR THE FOLLOWING ANALYTES: CORTISOL (COR), TRIIODOTHYRONINE (T3), THYROXINE (T4) AND HUMAN THYROID STIMULATING HORMONE (TSH). FREE THYROXINE (FT4). THE THY SET ALSO CONTAINS FREE TRIIODOTHYRONINE (FT3) AS AN ELEMENT OF THE TOTAL T3 COMPONENT.,CALIBRATION VERIFICATION/LINEARITY TEST KIT (VALIDATE SP 2)-VALIDATE SP 2 CALIBRATION VERIFICATION / LINEARITY TEST KIT SOLUTIONS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LINEARITY, CALIBRATION VERIFICATION AND VERIFICATION OF REPORTABLE RANGE IN AUTOMATED, SEMI-AUTOMATED AND MANUAL INSTRUMENT SYSTEMS FOR THE FOLLOWING ANALYTES: ALBUMIN (ALB), CERULOPLASMIN (CER), C-REACTIVE PROTEIN (CRP), HAPTOGLOBIN (HPT), PREALBUMIN (PAB), AND RHEUMATOID FACTOR (RF).,CALIBRATION VERIFICATION/LINEARITY TEST KIT (VALIDATE SP 1)-VALIDATE SP1 CALIBRATION VERIFICATION / LINEARITY TEST KIT SOLUTIONS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LINEARITY, CALIBRATION VERIFICATION AND VERIFICATION OF REPORTABLE RANGE IN AUTOMATED, SEMI-AUTOMATED AND MANUAL INSTRUMENT SYSTEMS FOR THE FOLLOWING ANALYTES: 1-ANTITRYPSIN (AAT), COMPLEMENT C3 (C3), COMPLEMENT C4 (C4), IMMUNOGLOBULIN A (IGA), IMMUNOGLOBULIN G (IGG), IMMUNOGLOBULIN M (IGM) AND TRANSFERRIN (TRF). ,CALIBRATION VERIFICATION/LINEARITY TEST KIT(VALIDATE LP)-VALIDATE LP CALIBRATION VERIFICATION / LINEARITY TEST KIT SOLUTIONS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LINEARITY, CALIBRATION VERIFICATION AND

	VERIFICATION OF REPORTABLE RANGE IN AUTOMATED, SEMI-AUTOMATED AND MANUAL INSTRUMENT SYSTEMS FOR THE FOLLOWING ANALYTES: HUMAN HIGH DENSITY LIPOPROTEIN (HDL) AND HUMAN LOW DENSITY LIPOPROTEIN (LDL),CALIBRATION VERIFICATION/LINEARITY TEST KIT(VALIDATE OSMO)-VALIDATE UC OSMO CALIBRATION VERIFICATION / LINEARITY TEST KITS SOLUTIONS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LINEARITY, CALIBRATION VERIFICATION AND VERIFICATION OF REPORTABLE RANGE IN AUTOMATED, SEMI-AUTOMATED AND MANUAL INSTRUMENT SYSTEMS FOR THE FOLLOWING ANALYTES: URINE OSMOLALITY (UOSMO) SERUM OSMOLALITY (SOSMO),CALIBRATION VERIFICATION/LINEARITY TEST KIT(VALIDATE GC 2)-GC 2 CALIBRATION VERIFICATION / LINEARITY TEST KIT SOLUTIONS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LINEARITY, CALIBRATION VERIFICATION AND VERIFICATION OF REPORTABLE RANGE IN AUTOMATED, SEMI-AUTOMATED AND MANUAL INSTRUMENT SYSTEMS FOR THE FOLLOWING ANALYTES: AMMONIA (NH3), CARBON DIOXIDE (CO2), ETHYL ALCOHOL (ETOH) AND IRON (FE).,CALIBRATION VERIFICATION/LINEARITY TEST KIT(VALIDATE GC 1)-GC 1 CALIBRATION VERIFICATION / LINEARITY TEST KIT SOLUTIONS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LINEARITY, CALIBRATION VERIFICATION AND VERIFICATION OF REPORTABLE RANGE IN AUTOMATED, SEMI-AUTOMATED AND MANUAL INSTRUMENT SYSTEMS FOR THE FOLLOWING ANALYTES: ALBUMIN (ALB), BLOOD UREA NITROGEN (BUN), CALCIUM (CA), CHLORIDE (CL), CHOLESTEROL (CHOL), CREATININE (CREAT), GLUCOSE (GLU), LACTATE (LAC), LITHIUM (LITH), MAGNESIUM (MG), PHOSPHORUS (PHOS), POTASSIUM (K), SODIUM (NA), TOTAL PROTEIN (TP) AND TRIGLYCERIDE (TRIG)., CALIBRATION VERIFICATION/LINEARITY TEST KIT(VALIDATE UC 5)-VALIDATE UC 5 CALIBRATION VERIFICATION / LINEARITY TEST KITS SOLUTIONS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LINEARITY, CALIBRATION VERIFICATION AND VERIFICATION OF REPORTABLE RANGE IN AUTOMATED, SEMI-AUTOMATED AND MANUAL INSTRUMENT SYSTEMS FOR THE FOLLOWING ANALYTES IN URINE: ALBUMIN (ALB) / MICROALBUMIN (ALB) AND AMYLASE (AMY) / PANCREATIC AMYLASE (PAMY),CALIBRATION VERIFICATION/LINEARITY TEST KIT (VALIDATE UC 4)-VALIDATE UC 4 CALIBRATION VERIFICATION / LINEARITY TEST KITS SOLUTIONS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LINEARITY, CALIBRATION VERIFICATION AND VERIFICATION OF

	REPORTABLE RANGE IN AUTOMATED, SEMI-AUTOMATED AND MANUAL INSTRUMENT SYSTEMS FOR THE FOLLOWING ANALYTES IN URINE: CALCIUM (CA), CREATININE (CREA), MAGNESIUM (MG) AND PHOSPHORUS (PHOS).,CALIBRATION VERIFICATION/LINEARITY TEST KIT(VALIDATE GC 4)-GC 4 CALIBRATION VERIFICATION / LINEARITY TEST KIT SOLUTIONS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LINEARITY, CALIBRATION VERIFICATION AND VERIFICATION OF REPORTABLE RANGE IN AUTOMATED, SEMI-AUTOMATED AND MANUAL INSTRUMENT SYSTEMS FOR THE FOLLOWING ANALYTES: DIRECT BILIRUBIN (DBIL) AND TOTAL BILIRUBIN (TBIL),CALIBRATION VERIFICATION/LINEARITY TEST KIT(VALIDATE GC 3)-GC 3 CALIBRATION VERIFICATION / LINEARITY TEST KIT SOLUTIONS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LINEARITY, CALIBRATION VERIFICATION AND VERIFICATION OF REPORTABLE RANGE IN AUTOMATED, SEMI-AUTOMATED AND MANUAL INSTRUMENT SYSTEMS FOR THE FOLLOWING ANALYTES: ALANINE AMINOTRANSFERASE (ALT), ALKALINE PHOSPHATASE (ALP), AMYLASE (AMY), ASPARTATE AMINOTRANSFERASE (AST), CREATINE KINASE (CK), GAMMA-GLUTAMYL TRANSFERASE (GGT), LACTATE DEHYDROGENASE (LD) AND LIPASE (LIP).,CALIBRATION VERIFICATION/LINEARITY TEST KIT (VALIDATE UC 1)-VALIDATE UC 1 CALIBRATION VERIFICATION / LINEARITY TEST KITS SOLUTIONS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LINEARITY, CALIBRATION VERIFICATION AND VERIFICATION OF REPORTABLE RANGE IN AUTOMATED, SEMI-AUTOMATED AND MANUAL INSTRUMENT SYSTEMS FOR THE FOLLOWING ANALYTES IN URINE: URIC ACID (UA). CHLORIDE (CL), ETHYL ALCOHOL (ETOH), GLUCOSE (GLU), POTASSIUM (K), SODIUM (NA), URINE TOTAL PROTEIN (UTP) AND URINE UREA NITROGEN (UUN

242	IMP/IVD/2019/000228	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALINITY C COMPLEMENT C3 REAGENT KIT(ALINITY C COMPLEMENT C3 REAGENT KIT)-THE ALINITY C COMPLEMENT C3 ASSAY IS USED FOR THE QUANTITATION OF C3 IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER., ALINITY C UREA NITROGEN REAGENT KIT(ALINITY C UREA NITROGEN REAGENT KIT)-THE ALINITY C UREA NITROGEN ASSAY IS USED FOR THE QUANTITATION OF UREA NITROGEN IN HUMAN SERUM, PLASMA, OR URINE ON THE ALINITY C ANALYZER.,CHOLESTEROL (CHOLESTEROL)-THE CHOLESTEROL ASSAY IS USED FOR THE QUANTITATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA., ALINITY C MICROALBUMIN REAGENT KIT(ALINITY C MICROALBUMIN REAGENT KIT)-THE ALINITY C MICROALBUMIN ASSAY IS USED FOR THE QUANTITATIVE MEASUREMENT OF ALBUMIN IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C APOLIPOPROTEIN A1 REAGENT KIT(ALINITY C APOLIPOPROTEIN A1 REAGENT KIT)-THE ALINITY C APOLIPOPROTEIN A1 ASSAY IS USED FOR THE QUANTITATION OF APOLIPOPROTEIN A-I IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C ALKALINE PHOSPHATASE REAGENT KIT(ALINITY C ALKALINE PHOSPHATASE REAGENT KIT)-THE ALINITY C ALKALINE PHOSPHATASE ASSAY IS USED FOR THE QUANTITATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,CALCIUM (CALCIUM)-THE CALCIUM ASSAY IS USED FOR THE QUANTITATION OF CALCIUM IN HUMAN SERUM, PLASMA, OR URINE.,ALINITY C ICT SERUM CALIBRATOR KIT(ALINITY C ICT SERUM CALIBRATOR KIT)-FOR USE IN THE CALIBRATION OF THE SERUM SODIUM, POTASSIUM, AND CHLORIDE ASSAYS.,URINE/CSF PROTEIN(URINE/CSF PROTEIN)-THE URINE/CSF PROTEIN (UPRO) ASSAY IS USED FOR THE QUANTITATION OF PROTEIN IN HUMAN URINE OR CEREBROSPINAL FLUID (CSF).,ALINITY C MICROALBUMIN CONTROLS(ALINITY C MICROALBUMIN CONTROLS)-FOR USE IN THE QUALITY CONTROL OF THE ALINITY C MICROALBUMIN ASSAY ON THE ALINITY C ANALYZER., TOTAL PROTEIN(TOTAL PROTEIN)-THE TOTAL PROTEIN ASSAY IS USED FOR THE QUANTITATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA.,ALINITY C-SERIES ACID PROBE WASH(ALINITY C-SERIES ACID PROBE WASH)-AN ONBOARD SOLUTION USED IN DAILY MAINTENANCE, SELECTED DIAGNOSTIC PROCEDURES, AND IN CONJUNCTION WITH THE SMARTWASH FEATURE TO REDUCE CARRYOVER BETWEEN SPECIFIC ASSAY COMBINATIONS., IMMUNOGLOBULIN M(IMMUNOGLOBULIN M)-THE IMMUNOGLOBULIN M (IGM) ASSAY IS USED FOR THE QUANTITATION OF IGM IN HUMAN SERUM OR PLASMA.,ALINITY C-SERIES ALKALINE WASH(ALINITY C-

	SERIES ALKALINE WASH)-USED BY THE CUVETTE WASHER TO CLEAN THE CUVETTES AFTER SAMPLE ANALYSIS.,UREA NITROGEN(UREA NITROGEN)-THE UREA NITROGEN ASSAY IS USED FOR THE QUANTITATION OF UREA NITROGEN IN HUMAN SERUM, PLASMA, OR URINE.,ALINITY C CREATININE REAGENT KIT(ALINITY C CREATININE REAGENT KIT)-THE ALINITY C CREATININE ASSAY IS USED FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA, OR URINE ON THE ALINITY C ANALYZER.,ALINITY C IMMUNOGLOBULIN M REAGENT KIT(ALINITY C IMMUNOGLOBULIN M REAGENT KIT)-THE ALINITY C IMMUNOGLOBULIN M ASSAY IS USED FOR THE QUANTITATION OF IGM IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C CREATINE KINASE REAGENT KIT(ALINITY C CREATINE KINASE REAGENT KIT)-THE ALINITY C CREATINE KINASE ASSAY IS USED FOR THE QUANTITATION OF CREATINE KINASE IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,PHOSPHORUS(PHOSPHORUS)-THE PHOSPHORUS ASSAY IS USED FOR THE QUANTITATION OF PHOSPHORUS IN HUMAN SERUM, PLASMA, OR URINE,ALINITY C URIC ACID REAGENT KIT (ALINITY C URIC ACID REAGENT KIT)-THE ALINITY C URIC ACID ASSAY IS USED FOR THE QUANTITATION OF URIC ACID IN HUMAN SERUM, PLASMA, OR URINE ON THE ALINITY C ANALYZER.,ALINITY C COMPLEMENT C4 REAGENT KIT(ALINITY C COMPLEMENT C4 REAGENT KIT)-THE ALINITY C COMPLEMENT C4 ASSAY IS USED FOR THE QUANTITATION OF C4 IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C ICT SAMPLE DILUENT(ALINITY C ICT SAMPLE DILUENT)-THE ALINITY C ICT (INTEGRATED CHIP TECHNOLOGY) IS USED FOR THE QUANTITATION OF SODIUM, POTASSIUM, AND CHLORIDE IN HUMAN SERUM, PLASMA, OR URINE ON THE ALINITY C ANALYZER.,ICT SERUM CALIBRATOR(ICT SERUM CALIBRATOR)-FOR USE IN THE CALIBRATION OF THE SERUM SODIUM, POTASSIUM, AND CHLORIDE ASSAYS.,ALINITY C-SERIES ACID WASH (ALINITY C-SERIES ACID WASH)-USED BY THE CUVETTE WASHER TO CLEAN THE CUVETTES AFTER SAMPLE ANALYSIS.,URINE/CSF PROTEIN CALIBRATOR(URINE/CSF PROTEIN CALIBRATOR)-FOR USE IN THE CALIBRATION OF THE URINE/CSF PROTEIN ASSAY.,ALINITY C GAMMA-GLUTAMYL TRANSFERASE REAGENT KIT(ALINITY C GAMMA-GLUTAMYL TRANSFERASE REAGENT KIT)-THE ALINITY C GAMMA-GLUTAMYL TRANSFERASE ASSAY IS USED FOR THE QUANTITATION OF GAMMA-GLUTAMYL TRANSFERASE IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,APOLIPOPROTEIN B (APOLIPOPROTEIN B)-THE APOLIPOPROTEIN B (APOB) ASSAY IS USED FOR THE QUANTITATION OF APOB IN HUMAN SERUM OR PLASMA. ,ALINITY C-SERIES ICT REFERENCE SOLUTION(ALINITY C-SERIES ICT REFERENCE SOLUTION)-USED BY THE ICT MODULE

	BEFORE AND AFTER EACH SAMPLE TO PROVIDE A REFERENCE POTENTIAL THAT IS USED IN RESULT CALCULATION., IMMUNOGLOBULIN G(IMMUNOGLOBULIN G)-THE IMMUNOGLOBULIN G (IGG) ASSAY IS USED FOR THE QUANTITATION OF IGG IN HUMAN SERUM OR PLASMA. ,ALINITY C TRANSFERRIN REAGENT KIT(ALINITY C TRANSFERRIN REAGENT KIT)-THE ALINITY C TRANSFERRIN ASSAY IS USED FOR THE QUANTITATION OF TRANSFERRIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,IMMUNOGLOBULIN A (IMMUNOGLOBULIN A)-THE IMMUNOGLOBULIN A (IGA) ASSAY IS USED FOR THE QUANTITATION OF IGA IN HUMAN SERUM OR PLASMA.,ALINITY C TOTAL PROTEIN REAGENT KIT(ALINITY C TOTAL PROTEIN REAGENT KIT)-THE ALINITY C TOTAL PROTEIN ASSAY IS USED FOR THE QUANTITATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,PREALBUMIN (PREALBUMIN)-THE PREALBUMIN ASSAY IS USED FOR THE QUANTITATION OF PREALBUMIN IN HUMAN SERUM.,ALINITY C CALCIUM REAGENT KIT(ALINITY C CALCIUM REAGENT KIT)-THE ALINITY C CALCIUM ASSAY IS USED FOR THE QUANTITATION OF CALCIUM IN HUMAN SERUM, PLASMA, OR URINE ON THE ALINITY C ANALYZER.,COMPLEMENT C4(COMPLEMENT C4)-THE COMPLEMENT C4 (C4) ASSAY IS USED FOR THE QUANTITATION OF C4 IN HUMAN SERUM OR PLASMA.,ALINITY C CHOLESTEROL REAGENT KIT(ALINITY C CHOLESTEROL REAGENT KIT)-THE ALINITY C CHOLESTEROL ASSAY IS USED FOR THE QUANTITATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER., COMPLEMENT C3(COMPLEMENT C3)-THE COMPLEMENT C3 (C3) ASSAY IS USED FOR THE QUANTITATION OF C3 IN HUMAN SERUM OR PLASMA.,ALINITY C PHOSPHORUS REAGENT KIT(ALINITY C PHOSPHORUS REAGENT KIT)-THE ALINITY C PHOSPHORUS ASSAY IS USED FOR THE QUANTITATION OF PHOSPHORUS IN HUMAN SERUM, PLASMA, OR URINE ON THE ALINITY C ANALYZER.,APOLIPOPROTEIN A1(APOLIPOPROTEIN A1)-THE APOLIPOPROTEIN A1 (APOA) ASSAY IS USED FOR THE QUANTITATION OF APOLIPOPROTEIN A-I IN HUMAN SERUM OR PLASMA.,ALINITY C ACTIVATED ASPARTATE AMINOTRANSFERASE REAGENT KIT(ALINITY C ACTIVATED ASPARTATE AMINOTRANSFERASE REAGENT KIT)-THE ALINITY C ACTIVATED ASPARTATE AMINOTRANSFERASE ASSAY IS USED FOR THE QUANTITATION OF ASPARTATE AMINOTRANSFERASE IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,MAGNESIUM (MAGNESIUM)-THE MAGNESIUM ASSAY IS USED FOR THE QUANTITATION OF MAGNESIUM IN HUMAN SERUM, PLASMA, OR URINE ON THE ARCHITECT C SYSTEMS.,ARCHITECT B.R.A.H.M.S PCT REAGENT KIT(ARCHITECT B.R.A.H.M.S PCT REAGENT KIT)-THE ARCHITECT BRAHMS PCT ASSAY IS A CHEMILUMINESCENT

	MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN SERUM AND PLASMA (LITHIUM HEPARIN AND K2EDTA) ON THE ARCHITECT ISYSTEM.,ALBUMIN BCG(ALBUMIN BCG)-THE ALBUMIN BCG ASSAY IS USED FOR THE QUANTITATION OF ALBUMIN IN HUMAN SERUM OR PLASMA.,ARCHITECT B.R.A.H.M.S PCT CALIBRATORS(ARCHITECT B.R.A.H.M.S PCT CALIBRATORS)-THE ARCHITECT BRAHMS PCT CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN SERUM AND PLASMA.,CREATININE (CREATININE)-THE CREATININE ASSAY IS USED FOR THE QUANTITATION OF CREATININE IN HUMAN SERUM, PLASMA, OR URINE.,ARCHITECT B.R.A.H.M.S PCT CONTROLS(ARCHITECT B.R.A.H.M.S PCT CONTROLS)-THE ARCHITECT B·R·A·H·M·S PCT CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN SERUM AND PLASMA., TRANSFERRIN(TRANSFERRIN)-THE TRANSFERRIN ASSAY IS USED FOR THE QUANTITATION OF TRANSFERRIN IN HUMAN SERUM OR PLASMA.,ALINITY C ALBUMIN BCP REAGENT KIT(ALINITY C ALBUMIN BCP REAGENT KIT)-THE ALINITY C ALBUMIN BCP ASSAY IS USED FOR THE QUANTITATION OF ALBUMIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ACTIVATED ASPARTATE AMINOTRANSFERASE(ACTIVATED ASPARTATE AMINOTRANSFERASE)-THE ACTIVATED ASPARTATE AMINOTRANSFERASE (ACTIVATED AST) ASSAY IS USED FOR THE QUANTITATION OF ASPARTATE AMINOTRANSFERASE IN HUMAN SERUM OR PLASMA.,ALINITY C URINE/CSF PROTEIN REAGENT KIT (ALINITY C URINE/CSF PROTEIN REAGENT KIT)-THE ALINITY C URINE/CSF PROTEIN ASSAY IS USED FOR THE QUANTITATION OF PROTEIN IN HUMAN URINE OR CEREBROSPINAL FLUID (CSF) ON THE ALINITY C ANALYZER. CSF PROTEIN MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CONDITIONS SUCH AS MENINGITIS, BRAIN TUMORS, AND INFECTIONS OF THE CENTRAL NERVOUS SYSTEM.,ALINITY C HAPTOGLOBIN REAGENT KIT(ALINITY C HAPTOGLOBIN REAGENT KIT)-THE ALINITY C HAPTOGLOBIN ASSAY IS USED FOR THE QUANTITATION OF HAPTOGLOBIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C LACTIC ACID REAGENT KIT(ALINITY C LACTIC ACID REAGENT KIT)-THE ALINITY C LACTIC ACID ASSAY IS USED FOR THE QUANTITATION OF LACTIC ACID IN HUMAN PLASMA ON THE ALINITY C ANALYZER., ALINITY C APOLIPOPROTEIN B REAGENT KIT(ALINITY C APOLIPOPROTEIN B REAGENT KIT)-THE ALINITY C APOLIPOPROTEIN

	B ASSAY IS USED FOR THE QUANTITATION OF APOLIPOPROTEIN B (APOB) IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER., ALINITY C LACTATE DEHYDROGENASE REAGENT KIT(ALINITY C LACTATE DEHYDROGENASE REAGENT KIT)-THE ALINITY C LACTATE DEHYDROGENASE ASSAY IS USED FOR THE QUANTITATION OF LACTATE DEHYDROGENASE IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER,ACTIVATED ALANINE AMINOTRANSFERASE (ACTIVATED ALANINE AMINOTRANSFERASE)-THE ACTIVATED ALANINE AMINOTRANSFERASE (ACTIVATED ALT) ASSAY IS USED FOR THE QUANTITATION OF ALANINE AMINOTRANSFERASE IN HUMAN SERUM OR PLASMA.,ALINITY C ALBUMIN BCG REAGENT KIT (ALINITY C ALBUMIN BCG REAGENT KIT)-THE ALINITY C ALBUMIN BCG ASSAY IS USED FOR THE QUANTITATION OF ALBUMIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C IMMUNOGLOBULIN G REAGENT KIT(ALINITY C IMMUNOGLOBULIN G REAGENT KIT)-THE ALINITY C IMMUNOGLOBULIN G (IGG) ASSAY IS USED FOR THE QUANTITATION OF IGG IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C URINE/CSF PROTEIN CALIBRATOR KIT(ALINITY C URINE/CSF PROTEIN CALIBRATOR KIT)-FOR USE IN THE CALIBRATION OF THE ALINITY C URINE/CSF PROTEIN ASSAY ON THE ALINITY C ANALYZER.,MICROALBUMIN CONTROLS (MICROALBUMIN CONTROLS)-FOR USE IN THE QUALITY CONTROL OF THE MICROALBUMIN ASSAY ON THE ARCHITECT C SYSTEMS.,ALINITY C TRIGLYCERIDE REAGENT KIT(ALINITY C TRIGLYCERIDE REAGENT KIT)-THE ALINITY C TRIGLYCERIDE ASSAY IS USED FOR THE QUANTITATION OF TRIGLYCERIDE IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C IMMUNOGLOBULIN A REAGENT KIT(ALINITY C IMMUNOGLOBULIN A REAGENT KIT)-THE ALINITY C IMMUNOGLOBULIN A (IGA) ASSAY IS USED FOR THE QUANTITATION OF IGA IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER., ALINITY C ACTIVATED ALANINE AMINOTRANSFERASE REAGENT KIT (ALINITY C ACTIVATED ALANINE AMINOTRANSFERASE REAGENT KIT) -THE ALINITY C ACTIVATED ALANINE AMINOTRANSFERASE ASSAY IS USED FOR THE QUANTITATION OF ALANINE AMINOTRANSFERASE IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER., ASPARTATE AMINOTRANSFERASE(ASPARTATE AMINOTRANSFERASE)-THE ASPARTATE AMINOTRANSFERASE (AST) ASSAY IS USED FOR THE QUANTITATION OF ASPARTATE AMINOTRANSFERASE IN HUMAN SERUM OR PLASMA. ,ALINITY C MAGNESIUM REAGENT KIT(ALINITY C MAGNESIUM REAGENT KIT)-THE ALINITY C MAGNESIUM ASSAY IS USED FOR THE QUANTITATION OF MAGNESIUM IN HUMAN SERUM, PLASMA, OR URINE ON THE ALINITY C ANALYZER.,ICT REFERENCE SOLUTION(ICT REFERENCE SOLUTION)-FOR USE IN THE QUANTITATION OF SODIUM, POTASSIUM, AND

	CHLORIDE IN HUMAN SERUM, PLASMA, OR URINE.,ALINITY H-SERIES DILUENT(ALINITY H-SERIES DILUENT)-ACTS AS PRIMARY DILUTING FLUID FOR THE RBC MEASUREMENT, THE PLT MEASUREMENT AND THE RETIC MEASUREMENT FOR ALINITY HQ ANALYZER.,CREATINE KINASE(CREATINE KINASE)-THE CREATINE KINASE ASSAY IS USED FOR THE QUANTITATION OF CREATINE KINASE IN HUMAN SERUM OR PLASMA.,ALINITY C MICROALBUMIN CALIBRATORS(ALINITY C MICROALBUMIN CALIBRATORS)-FOR USE IN THE CALIBRATION OF THE ALINITY C MICROALBUMIN ASSAY ON THE ALINITY C ANALYZER., TRIGLYCERIDE(TRIGLYCERIDE)-THE TRIGLYCERIDE ASSAY IS USED FOR THE QUANTITATION OF TRIGLYCERIDE IN HUMAN SERUM OR PLASMA.,ALINITY C ASPARTATE AMINOTRANSFERASE REAGENT KIT (ALINITY C ASPARTATE AMINOTRANSFERASE REAGENT KIT)-THE ALINITY C ASPARTATE AMINOTRANSFERASE ASSAY IS USED FOR THE QUANTITATION OF ASPARTATE AMINOTRANSFERASE IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,LACTATE DEHYDROGENASE (LACTATE DEHYDROGENASE)-THE LACTATE DEHYDROGENASE (LDH) ASSAY IS USED FOR THE QUANTITATION OF LACTATE DEHYDROGENASE IN HUMAN SERUM OR PLASMA.,GAMMA-GLUTAMYL TRANSFERASE (GAMMA-GLUTAMYL TRANSFERASE)-THE GAMMA-GLUTAMYL TRANSFERASE (GGT) ASSAY IS USED FOR THE QUANTITATION OF GAMMA-GLUTAMYL TRANSFERASE IN HUMAN SERUM OR PLASMA.,URIC ACID(URIC ACID)-THE URIC ACID ASSAY IS USED FOR THE QUANTITATION OF URIC ACID IN HUMAN SERUM, PLASMA, OR URINE.,MICROALBUMIN CALIBRATORS(MICROALBUMIN CALIBRATORS)-FOR USE IN THE CALIBRATION OF THE MICROALBUMIN ASSAY ON THE ARCHITECT C SYSTEMS.,ALINITY C PREALBUMIN REAGENT KIT(ALINITY C PREALBUMIN REAGENT KIT)-THE ALINITY C PREALBUMIN ASSAY IS USED FOR THE QUANTITATION OF PREALBUMIN IN HUMAN SERUM ON THE ALINITY C ANALYZER., MICROALBUMIN(MICROALBUMIN)-THE MICROALBUMIN ASSAY IS USED FOR THE QUANTITATIVE MEASUREMENT OF ALBUMIN IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.

243	IMP/IVD/2019/000229	1.License Holder Name: SYSMEX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SG CALIBRATOR(SG CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE ONLY SG CALIBRATOR IS INTENDED FOR USE IN THE CALIBRATION OF URINE SPECIFIC GRAVITY REFRACTOMETER OF FULLY AUTOMATED URINE CHEMISTRY ANALYZER (UC-3500). ,MEDITAPE UC-10S(MEDITAPE UC-10S)-FOR IN VITRO DIAGNOSTIC USE ONLY MEDITAPE UC-10S IS A URINALYSIS TEST STRIP WITH REAGENT PADS FOR THE DETERMINATION OF DIAGNOSTIC PARAMETERS IN HUMAN URINE. MEDITAPE UC-10S TEST STRIPS ARE FOR VISUAL MEASUREMENT AND FOR USE WITH THE FOLLOWING SYSMEX URINE CHEMISTRY ANALYZER ONLY: UC-1000 ,MEDITAPE UC-11A(MEDITAPE UC-11A)-FOR IN VITRO DIAGNOSTIC USE ONLY MEDITAPE UC-11A IS A URINALYSIS TEST STRIP WITH REAGENT PADS FOR THE DETERMINATION OF DIAGNOSTIC PARAMETERS IN HUMAN URINE. , MEDITAPE UC-12S(MEDITAPE UC-12S)-FOR IN VITRO DIAGNOSTIC USE ONLY MEDITAPE UC-12S IS A URINALYSIS TEST STRIP WITH REAGENT PADS FOR THE DETERMINATION OF DIAGNOSTIC PARAMETERS IN HUMAN URINE. MEDITAPE UC-12S TEST STRIPS ARE FOR VISUAL MEASUREMENT AND FOR USE WITH THE FOLLOWING SYSMEX URINE CHEMISTRY ANALYZER ONLY: UC-1000 ,MEDITAPE UC-9A(MEDITAPE UC-9A)-FOR IN VITRO DIAGNOSTIC USE ONLY MEDITAPE UC-9A IS A URINALYSIS TEST STRIP WITH REAGENT PADS FOR THE DETERMINATION OF DIAGNOSTIC PARAMETERS IN HUMAN URINE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

244	IMP/IVD/2019/000230	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTI-IG G - PER (ANTI-IG G - PER)-THESE ANTISERA ARE DESIGNED FOR THE QUALITATIVE DETECTION AND IDENTIFICATION OF "OLIGOCLONAL" BANDS IN THE ELECTROPHORETIC PATTERNS OF CEREBROSPINAL FLUID (CSF) AFTER MIGRATION AND IMMUNOFIXATION PROCEDURES ON AGAROSE GELS IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS. ,MULTI-SYSTEM HB A1C CAPILLARY CONTROLS (10X2)(MULTI-SYSTEM HB A1C CAPILLARY CONTROLS (10X2))-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN GLYCATED HEMOGLOBIN A1C ON CAPILLARY. ,HYDRAGEL 7 HEMOGLOBIN(E)(HYDRAGEL 7 HEMOGLOBIN(E))-THESE DEVICES ARE DESIGNED FOR SEPARATION OF THE NORMAL HEMOGLOBINS (A AND A2) AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS: S OR D AND C OR E, BY ELECTROPHORESIS ON ALKALINE AGAROSE GELS (PH 8.5). ,MULTI-SYSTEM HB A1C CAPILLARY CONTROLS (2)(MULTI-SYSTEM HB A1C CAPILLARY CONTROLS (2))-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN GLYCATED HEMOGLOBIN A1C ON CAPILLARY. ,ENZYCONTROL(ENZYCONTROL)-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN SERUM LACTATE DEHYDROGENASE (LD) ISOENZYMES AND CREATINE KINASE (CK) ISOENZYMES ON AGAROSE GEL. ,HB A1C CAPILLARY CALIBRATORS (2)(HB A1C CAPILLARY CALIBRATORS (2))-THIS DEVICE IS DESIGNED FOR THE CALIBRATION OF CAPILLARY ELECTROPHORETIC QUANTIFICATION OF HUMAN GLYCATED HEMOGLOBIN A1C ACCORDING TO THE IFCC AND NGSP REQUIREMENTS. ,HYDRAGEL 4 BENCE JONES (SM)(HYDRAGEL 4 BENCE JONES (SM))-THESE DEVICES ARE DESIGNED FOR QUALITATIVE DETECTION AND IDENTIFICATION OF BENCE JONES PROTEINS IN HUMAN URINE OR SERUM BY IMMUNOFIXATION ELECTROPHORESIS. ,HYDRASYS WASH SOLUTION (10)(HYDRASYS WASH SOLUTION (10))-USED FOR THE CLEANING OF THE HYDRASYS STAINING COMPARTMENT.,CDT SAMPLES TREATMENT SOLUTION(CDT SAMPLES TREATMENT SOLUTION)-THIS REAGENT IS DESIGNED FOR TREATMENT OF INTERFERING SAMPLES IN THE CAPILLARY ELECTROPHORESIS SYSTEM. ,MINICAP HEMOGLOBIN(E) MAXI-KIT(MINICAP HEMOGLOBIN (E) MAXI-KIT)-THE MINICAP HEMOGLOBIN(E) MAXI-KIT IS DESIGNED FOR THE SEPARATION OF THE NORMAL HEMOGLOBINS (A, A2 AND F) IN HUMAN BLOOD SAMPLES, AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS (S, C, E AND D), BY CAPILLARY

	ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE SEBIA MINICAP AND MINICAP FLEX-PIERCING INSTRUMENTS.,CAPI 3 CDT (CAPI 3 CDT)-THIS DEVICE IS DESIGNED FOR THE SEPARATION OF THE TRANSFERRIN ISOFORMS IN HUMAN SERUM AND THE QUANTIFICATION OF THE CDT (CARBOHYDRATE DEFICIENT TRANSFERRIN) BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 8.8) WITH THE CAPILLARYS 3 INSTRUMENT. THIS DEVICE IS DESIGNED FOR THE SEPARATION OF THE TRANSFERRIN ISOFORMS IN HUMAN SERUM AND THE QUANTIFICATION OF THE DISIALOTRANSFERRIN FRACTION ("CDT-IFCC") BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 8.8) WITH THE CAPILLARYS 3 INSTRUMENT, ,HYDRAGEL 54 PROTEIN(E)(HYDRAGEL 54 PROTEIN(E))-THESE DEVICES ARE INTENDED FOR SEPARATION OF PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 9.2) AGAROSE GELS.,HYDRAGEL 15 ISO-PAL (HYDRAGEL 15 ISO-PAL)-THESE DEVICES ARE DESIGNED FOR THE IDENTIFICATION AND QUANTIFICATION OF ALKALINE PHOSPHATASE (AP) ISOENZYMES IN HUMAN SERUM. ,A1C/CE - CAPILLARY BLOOD SAMPLE KIT (A)(A1C/CE - CAPILLARY BLOOD SAMPLE KIT (A))-THE "A1C/CE – CAPILLARY BLOOD SAMPLE KIT (A)" DEVICE IS DESIGNED FOR COLLECTION, HEMOLYSIS AND TRANSPORTATION OF BLOOD SAMPLES FOR THEIR ANALYSIS WITH THE SEBIA CAPILLARY ELECTROPHORESIS PROCEDURES.,CAPI 3 URINE(CAPI 3 URINE)-THIS DEVICE IS DESIGNED FOR THE PREPARATION OF HUMAN URINE SAMPLES FOR ANALYSIS WITH THE CAPI 3 URINE PROCEDURE. , HYPERGAMMA CONTROL (5)(HYPERGAMMA CONTROL (5))-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN SERUM PROTEINS ON AGAROSE GEL AND IN CAPILLARY. ,CDT CAPILLARYS CALIBRATORS (2 LEVELS)(CDT CAPILLARYS CALIBRATORS (2 LEVELS))-THIS DEVICE IS DESIGNED FOR THE CALIBRATION OF CAPILLARY ELECTROPHORETIC QUANTIFICATION OF HUMAN CDT ACCORDING TO THE IFCC REQUIREMENTS. ,HYPERGAMMA CONTROL (20)(HYPERGAMMA CONTROL (20))-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN SERUM PROTEINS ON AGAROSE GEL AND IN CAPILLARY. , HYDRAGEL 30 ISO-LDH(HYDRAGEL 30 ISO-LDH)-THESE DEVICES ARE DESIGNED FOR THE IDENTIFICATION AND QUANTIFICATION OF THE FIVE LACTATE DEHYDROGENASE (LD) ISOENZYMES IN HUMAN SERUM BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.4) AGAROSE GELS. ,MINICAP HEMOGLOBIN(E) BUFFER(MINICAP HEMOGLOBIN(E) BUFFER)-ALKALINE BUFFER FOR THE SEPARATION OF THE NORMAL HEMOGLOBINS (A, F AND A2) AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS (ESPECIALLY S,

	C, E OR D) BY CAPILLARY ELECTROPHORESIS WITH THE MINICAP AUTOMATIC SYSTEM. ,CAPI 3 PROTEIN(E) 6(CAPI 3 PROTEIN(E) 6)-THIS DEVICE IS DESIGNED FOR THE SEPARATION OF HUMAN SERUM PROTEINS BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.9) WITH THE CAPILLARYS 3 INSTRUMENT. ,HB AFSC CONTROL (HB AFSC CONTROL)-THIS DEVICE IS INTENDED AS AN AID IN CONFIRMING THE IDENTITY OF THE ABNORMAL HEMOGLOBINS SEPARATED BY ELECTROPHORESIS ON AGAROSE GEL AND IN CAPILLARY. ,HYDRAGEL 15 HEMOGLOBIN(E)(HYDRAGEL 15 HEMOGLOBIN(E))-THESE DEVICES ARE DESIGNED FOR SEPARATION OF THE NORMAL HEMOGLOBINS (A AND A2) AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS: S OR D AND C OR E, BY ELECTROPHORESIS ON ALKALINE AGAROSE GELS (PH 8.5). , MINICAP HEMOGLOBIN(E) (MINICAP HEMOGLOBIN(E))-THE MINICAP HEMOGLOBIN(E) KIT IS DESIGNED FOR THE SEPARATION OF THE NORMAL HEMOGLOBINS (A, A2 AND F) IN HUMAN BLOOD SAMPLES, AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS (S, C, E AND D), BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE SEBIA MINICAP AND MINICAP FLEX-PIERCING INSTRUMENTS.,HYDRAGEL 30 ß1-ß2(HYDRAGEL 30 ß1-ß2)-THESE DEVICES ARE INTENDED FOR SEPARATION OF PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.5) AGAROSE GELS. ,HYDRAGEL 2 IF (SM)(HYDRAGEL 2 IF (SM))-THESE DEVICES ARE DESIGNED FOR DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS. ,CAPILLARYS IMMUNOTYPING(CAPILLARYS IMMUNOTYPING)-THIS DEVICE IS DESIGNED FOR THE DETECTION AND THE CHARACTERIZATION OF MONOCLONAL PROTEINS (IMMUNOTYPING) IN HUMAN URINE AND SERUM WITH THE CAPILLARYS SYSTEM, SEBIA, FOR CAPILLARY ELECTROPHORESIS. , DTT DILUENT (IF / IT)(DTT DILUENT (IF / IT))-THE DTT DILUENT (IF / IT) IS INTENDED FOR THE RECONSTITUTION OF A DITHIOTHREITOL (DTT) VIAL FOR THE PREPARATION OF A DTT 0.5 M REDUCING SOLUTION THAT IS USED TO DEPOLYMERIZE MONOCLONAL PROTEINS, FOR THE ANALYSIS.,HYDRAGEL 11 VON WILLEBRAND MULTIMERS(HYDRAGEL 11 VON WILLEBRAND MULTIMERS)-THIS DEVICE IS DESIGNED FOR THE DETECTION AND THE ANALYSIS OF THE DISTRIBUTION OF VON WILLEBRAND FACTOR MULTIMERS IN HUMAN PLASMA BY AGAROSE GEL ELECTROPHORESIS AND IMMUNOFIXATION, WITH THE SEMIAUTOMATED HYDRASYS 2 INSTRUMENT. ,HYDRAGEL 9 IF (SM) MAXI-KIT(HYDRAGEL 9 IF (SM) MAXI-KIT)-THESE DEVICES ARE DESIGNED FOR DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS. ,CAPI 3 IMMUNOTYPING(CAPI 3 IMMUNOTYPING)-THIS DEVICE IS DESIGNED

	FOR THE DETECTION AND THE CHARACTERIZATION OF MONOCLONAL PROTEINS (IMMUNOTYPING) IN HUMAN URINE AND SERUM WITH THE CAPILLARYS 3 INSTRUMENT, SEBIA, FOR CAPILLARY ELECTROPHORESIS. ,CAPILLARYS / MINICAP WASH SOLUTION (2)(CAPILLARYS / MINICAP WASH SOLUTION (2))-USED FOR WASHING THE CAPILLARIES OF CAPILLARYS 2/MINICAP.,K & L FREE LIGHT CHAINS ANTISERA BOX (SM)(K & L FREE LIGHT CHAINS ANTISERA BOX (SM))-THESE DEVICES CONTAIN SPECIFIC ANTISERA WITH OR WITHOUT FIXATIVE SOLUTION FOR AGAROSE GEL IMMUNOFIXATION TECHNIQUES. THEY ARE SPECIFIC FOR THE IMMUNOFIXATION PROCEDURE WITH THE STANDARD MASK IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS. ,NORMAL HB A2 CONTROL (5)(NORMAL HB A2 CONTROL (5))-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN A2 HEMOGLOBIN ON AGAROSE GEL AND IN CAPILLARY. ,(GAM. K. L) ANTISERA AND FIXATIVE SOLUTION BOX (SM)((GAM. K. L) ANTISERA AND FIXATIVE SOLUTION BOX (SM))-THESE DEVICES CONTAIN SPECIFIC ANTISERA WITH OR WITHOUT FIXATIVE SOLUTION FOR AGAROSE GEL IMMUNOFIXATION TECHNIQUES. THEY ARE SPECIFIC FOR THE IMMUNOFIXATION PROCEDURE WITH THE STANDARD MASK IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS. ,PATHOLOGICAL HB A2 CONTROL (PATHOLOGICAL HB A2 CONTROL)-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN A2 HEMOGLOBIN ON AGAROSE GEL AND IN CAPILLARY. ,IF ANTISERA AND FIXATIVE SOLUTION BOX (SM)(IF ANTISERA AND FIXATIVE SOLUTION BOX (SM))-THESE DEVICES CONTAIN SPECIFIC ANTISERA WITH OR WITHOUT FIXATIVE SOLUTION FOR AGAROSE GEL IMMUNOFIXATION TECHNIQUES. THEY ARE SPECIFIC FOR THE IMMUNOFIXATION PROCEDURE WITH THE STANDARD MASK IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS.,FLUIDIL(FLUIDIL)-USED TO DILUTE SAMPLES WITH HINDERED DIFFUSION THROUGH THE SAMPLE APPLICATOR TEETH. ,HYDRAGEL 7 HR ACID VIOLET (HYDRAGEL 7 HR ACID VIOLET)-THESE DEVICES ARE DESIGNED FOR MULTI-FRACTIONATION OF PROTEINS FROM HUMAN SERA OR OTHER BIOLOGICAL FLUIDS, SUCH AS URINE AND CEREBROSPINAL FLUID (CSF), BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.6) AGAROSE GELS. ,A1C/CE LOW VOLUME SAMPLE COLLECTION TUBE (A1C/CE LOW VOLUME SAMPLE COLLECTION TUBE)-USED FOR THE ANALYSIS OF SAMPLES WITH A VOLUME BELOW 100 L.,CSF CONTROL (CSF CONTROL)-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF THE DETECTION OF IMMUNOGLOBULINS G

	CONTAINED IN HUMAN SERUM AND CEREBROSPINAL FLUID BY IMMUNOFIXATION ,HYDRAGEL 30 PROTEIN(E) (HYDRAGEL 30 PROTEIN(E))-THESE DEVICES ARE INTENDED FOR SEPARATION OF PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 9.2) AGAROSE GELS.,HYDRAGEL 15 HR ACID VIOLET(HYDRAGEL 15 HR ACID VIOLET)-THESE DEVICES ARE DESIGNED FOR MULTI-FRACTIONATION OF PROTEINS FROM HUMAN SERA OR OTHER BIOLOGICAL FLUIDS, SUCH AS URINE AND CEREBROSPINAL FLUID (CSF), BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.6) AGAROSE GELS. ,IT / IF CONTROL(IT / IF CONTROL)-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF THE DETECTION AND CHARACTERIZATION OF HUMAN MONOCLONAL IMMUNOGLOBULINS ON AGAROSE GEL AND IN CAPILLARY., HYDRAGEL 15 ß1-ß2(HYDRAGEL 15 ß1-ß2)-THESE DEVICES ARE INTENDED FOR SEPARATION OF PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.5) AGAROSE GELS. ,HYDRAGEL 4 IF (SM) - ACID VIOLET(HYDRAGEL 4 IF (SM) - ACID VIOLET)-THESE DEVICES ARE DESIGNED FOR DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS. ,INTERMEDIATE CDT CONTROL(INTERMEDIATE CDT CONTROL)-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN CDT IN CAPILLARY. ,CAPILLARYS HEMOGLOBIN(E) (CAPILLARYS HEMOGLOBIN(E))-THIS DEVICE IS DESIGNED FOR THE SEPARATION OF THE NORMAL HEMOGLOBINS (A, F AND A2) AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS (ESPECIALLY S, C, E OR D), BY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE CAPILLARYS SYSTEM., HYDRAGEL 7 ISO-PAL(HYDRAGEL 7 ISO-PAL)-THESE DEVICES ARE DESIGNED FOR THE IDENTIFICATION AND QUANTIFICATION OF ALKALINE PHOSPHATASE (AP) ISOENZYMES IN HUMAN SERUM. , DESTAINING SOLUTION (10)(DESTAINING SOLUTION (10))-USED FOR DESTAINING, THAT IS REMOVAL OF EXCESS AND BACKGROUND STAIN FROM THE GELS.,HYDRAGEL 54 ß1-ß2(HYDRAGEL 54 ß1-ß2)-THESE DEVICES ARE INTENDED FOR SEPARATION OF PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.5) AGAROSE GELS. ,CLEAN PROTECT(CLEAN PROTECT)-CLEAN PROTECT CONCENTRATED SOLUTION CONTAINS A PRESERVATIVE.,HYDRAGEL 7 ß1-ß2(HYDRAGEL 7 ß1-ß2)-THESE DEVICES ARE INTENDED FOR SEPARATION OF PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.5) AGAROSE GELS. ,MINICAP PROTEIN(E) 6 (MINICAP PROTEIN (E) 6)-THE MINICAP PROTEIN(E) 6 KIT IS DESIGNED FOR THE SEPARATION OF HUMAN SERUM PROTEINS IN ALKALINE BUFFER (PH

	9.9) BY CAPILLARY ELECTROPHORESIS WITH THE MINICAP SYSTEM., MINICAP HB A1C(MINICAP HB A1C)-THIS DEVICE IS DESIGNED FOR SEPARATION AND QUANTIFICATION OF THE HBA1C GLYCATED FRACTION OF HEMOGLOBIN IN HUMAN BLOOD, BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE MINICAP FLEX-PIERCING INSTRUMENT. ,CAPILLARYS HEMOGLOBIN(E) HEMOLYSING SOLUTION(CAPILLARYS HEMOGLOBIN(E) HEMOLYSING SOLUTION)-THIS REAGENT IS DESIGNED FOR HEMOLYZE RED BLOOD CELLS IN THE CAPILLARYS AUTOMATIC SYSTEM. ,CAPILLARYS PROTEIN(E) 6 (CAPILLARYS PROTEIN(E) 6)-THIS DEVICE IS DESIGNED FOR THE SEPARATION OF HUMAN SERUM AND URINE PROTEINS IN ALKALINE BUFFER (PH 9.9) BY CAPILLARY ELECTROPHORESIS WITH THE CAPILLARYS SYSTEM. ,NORMAL CONTROL (20)(NORMAL CONTROL (20))-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN SERUM PROTEINS ON AGAROSE GEL AND IN CAPILLARY. , CAPILLARYS PROTEIN(E) 6 BUFFER(CAPILLARYS PROTEIN(E) 6 BUFFER)-ALKALINE BUFFER FOR SERUM PROTEINS ANALYSIS (6 FRACTIONS) BY CAPILLARY ELECTROPHORESIS WITH THE CAPILLARYS AUTOMATIC SYSTEM. ,CAPILLARYS HEMOGLOBIN(E) BUFFER(CAPILLARYS HEMOGLOBIN(E) BUFFER)-ALKALINE BUFFER FOR THE SEPARATION OF THE NORMAL HEMOGLOBINS (A, F AND A2) AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS (ESPECIALLY S, C, E OR D) BY CAPILLARY ELECTROPHORESIS WITH THE CAPILLARYS AUTOMATIC SYSTEM.,HYDRAGEL 1 BENCE JONES (SM)(HYDRAGEL 1 BENCE JONES (SM))-THESE DEVICES ARE DESIGNED FOR QUALITATIVE DETECTION AND IDENTIFICATION OF BENCE JONES PROTEINS IN HUMAN URINE OR SERUM BY IMMUNOFIXATION ELECTROPHORESIS. ,MINICAP PROTEIN(E) 6 BUFFER(MINICAP PROTEIN(E) 6 BUFFER)-ALKALINE BUFFER FOR SERUM PROTEINS ANALYSIS (6 FRACTIONS) BY CAPILLARY ELECTROPHORESIS WITH THE MINICAP AUTOMATIC SYSTEM. ,5 VON WILLEBRAND MULTIMERS VISUALIZATION KIT(5 VON WILLEBRAND MULTIMERS VISUALIZATION KIT)-THIS DEVICE IS DESIGNED FOR THE DETECTION AND THE ANALYSIS OF THE DISTRIBUTION OF VON WILLEBRAND FACTOR MULTIMERS IN HUMAN PLASMA BY AGAROSE GEL ELECTROPHORESIS AND IMMUNOFIXATION, WITH THE SEMI AUTOMATED HYDRASYS 2 INSTRUMENT. ,MINICAP FLEX-PIERCING CAPICLEAN(MINICAP FLEX-PIERCING CAPICLEAN)-CAPICLEAN SOLUTION IS USED FOR CLEANING OF THE SAMPLE PROBE IN AUTOMATED INSTRUMENT MINICAP FLEX-PIERCING, SEBIA, FOR CAPILLARY ELECTROPHORESIS, DURING THE CAPICLEAN CLEANING SEQUENCE.,HYDRAGEL 5 VON WILLEBRAND MULTIMERS(HYDRAGEL 5 VON WILLEBRAND MULTIMERS)-THIS DEVICE IS DESIGNED FOR THE

	DETECTION AND THE ANALYSIS OF THE DISTRIBUTION OF VON WILLEBRAND FACTOR MULTIMERS IN HUMAN PLASMA BY AGAROSE GEL ELECTROPHORESIS AND IMMUNOFIXATION, WITH THE SEMIAUTOMATED HYDRASYS 2 INSTRUMENT. ,MINICAP PROTEIN(E) 6 MAXI-KIT(MINICAP PROTEIN(E) 6 MAXI-KIT)-THE MINICAP PROTEIN(E) 6 MAXI-KIT IS DESIGNED FOR THE SEPARATION OF HUMAN SERUM PROTEINS IN ALKALINE BUFFER (PH 9.9) BY CAPILLARY ELECTROPHORESIS WITH THE MINICAP SYSTEM. ,HYDRAGEL 3 CSF ISOFOCUSING(HYDRAGEL 3 CSF ISOFOCUSING)-THESE DEVICES ARE DESIGNED FOR THE QUALITATIVE DETECTION AND IDENTIFICATION OF "OLIGOCLONAL" BANDS IN THE ELECTROPHORETIC PATTERNS OF CEREBROSPINAL FLUID (CSF). ,ACID VIOLET STAINING SOLUTION (ACID VIOLET STAINING SOLUTION)-USED FOR STAINING GELS WITH ELECTROPHORETIC PROTEIN SEPARATIONS. ,HYDRAGEL 9 CSF ISOFOCUSING(HYDRAGEL 9 CSF ISOFOCUSING)-THESE DEVICES ARE DESIGNED FOR THE QUALITATIVE DETECTION AND IDENTIFICATION OF "OLIGOCLONAL" BANDS IN THE ELECTROPHORETIC PATTERNS OF CEREBROSPINAL FLUID (CSF). ,HYDRAGEL 4 IF (SM) MAXI-KIT (HYDRAGEL 4 IF (SM) MAXI-KIT)-THESE DEVICES ARE DESIGNED FOR DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS.,HYDRAGEL 15 HR AMIDOBLACK(HYDRAGEL 15 HR AMIDOBLACK)-THESE DEVICES ARE DESIGNED FOR MULTI-FRACTIONATION OF PROTEINS FROM HUMAN SERA OR OTHER BIOLOGICAL FLUIDS, SUCH AS URINE AND CEREBROSPINAL FLUID (CSF), BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.6) AGAROSE GELS. ,AMIDOBLACK STAINING SOLUTION(AMIDOBLACK STAINING SOLUTION)-USED FOR STAINING GELS WITH ELECTROPHORETIC PROTEIN SEPARATIONS.,HYDRAGEL 7 HR AMIDOBLACK(HYDRAGEL 7 HR AMIDOBLACK)-THESE DEVICES ARE DESIGNED FOR MULTI-FRACTIONATION OF PROTEINS FROM HUMAN SERA OR OTHER BIOLOGICAL FLUIDS, SUCH AS URINE AND CEREBROSPINAL FLUID (CSF), BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.6) AGAROSE GELS. ,CAPILLARYS HB A1C (CAPILLARYS HB A1C)-THE CAPILLARYS HB A1C KIT IS DESIGNED FOR SEPARATION AND QUANTIFICATION OF THE HBA1C GLYCATED FRACTION OF HEMOGLOBIN IN HUMAN BLOOD, BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE CAPILLARYS 2 FLEX-PIERCING INSTRUMENT. ,CAPI 3 HEMOGLOBIN(E) (CAPI 3 HEMOGLOBIN(E))-THIS DEVICE IS DESIGNED FOR THE SEPARATION OF THE NORMAL HEMOGLOBINS (A, A2 AND F) IN HUMAN BLOOD SAMPLES, AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS (S, C, E AND D), BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE SEBIA CAPILLARYS 3 INSTRUMENT. ,CAPICLEAN(CAPICLEAN)-CAPICLEAN

	SOLUTION IS USED FOR CLEANING OF THE SAMPLE PROBE IN AUTOMATED SYSTEMS CAPILLARYS AND MINICAP.,CAPILLARYS 3 WASH SOLUTION (1)(CAPILLARYS 3 WASH SOLUTION (1))-USED FOR THE CLEANING OF THE STAINING COMPARTMENT. ,HYDRAGEL 54 PROTEIN(E) MAXI-KIT(HYDRAGEL 54 PROTEIN(E) MAXI-KIT)-THESE DEVICES ARE INTENDED FOR SEPARATION OF PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 9.2) AGAROSE GELS. ,HYDRAGEL 7 ACID(E) HEMOGLOBIN(E) (HYDRAGEL 7 ACID(E) HEMOGLOBIN(E))-THESE DEVICES ARE DESIGNED FOR SEPARATION OF THE NORMAL HEMOGLOBIN A, ABNORMAL HEMOGLOBINS S AND C AND FETAL HEMOGLOBIN F, BY ELECTROPHORESIS ON ACIDIC AGAROSE GELS. ,HYDRAGEL 7 PROTEIN(E)(HYDRAGEL 7 PROTEIN(E))-THESE DEVICES ARE INTENDED FOR SEPARATION OF PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 9.2) AGAROSE GELS. ,HYDRAGEL 15 ACID(E) HEMOGLOBIN(E) (HYDRAGEL 15 ACID(E) HEMOGLOBIN(E))-THESE DEVICES ARE DESIGNED FOR SEPARATION OF THE NORMAL HEMOGLOBIN A, ABNORMAL HEMOGLOBINS S AND C AND FETAL HEMOGLOBIN F, BY ELECTROPHORESIS ON ACIDIC AGAROSE GELS. ,HYDRAGEL 15 PROTEIN(E) (HYDRAGEL 15 PROTEIN(E))-THESE DEVICES ARE INTENDED FOR SEPARATION OF PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 9.2) AGAROSE GELS. ,ISO-PAL CONTROL(ISO-PAL CONTROL)-THIS DEVICE IS USED AS A "MARKER" FOR IDENTIFICATION OF THE DIFFERENT ALKALINE PHOSPHATASE ISOENZYMES OF THE HUMAN SERUM AND SEPARATED BY ELECTROPHORESIS ON AGAROSE GEL. ,HYDRAGEL 4 IF (SM) - AMIDOBLACK(HYDRAGEL 4 IF (SM) - AMIDOBLACK)-THESE DEVICES ARE DESIGNED FOR DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS. ,CDT MINICAP CALIBRATORS (2 LEVELS)(CDT MINICAP CALIBRATORS (2 LEVELS))-THIS DEVICE IS DESIGNED FOR THE CALIBRATION OF CAPILLARY ELECTROPHORETIC QUANTIFICATION OF HUMAN CDT ACCORDING TO THE IFCC REQUIREMENTS. ,HYDRAGEL 9 IF (SM)(HYDRAGEL 9 IF (SM))-THESE DEVICES ARE DESIGNED FOR DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS. ,HYDRAGEL 2 BENCE JONES (SM)(HYDRAGEL 2 BENCE JONES (SM))-THESE DEVICES ARE DESIGNED FOR QUALITATIVE DETECTION AND IDENTIFICATION OF BENCE JONES PROTEINS IN HUMAN URINE OR SERUM BY IMMUNOFIXATION ELECTROPHORESIS. ,IF SAMPLE DILUENT(IF SAMPLE DILUENT)-THIS REAGENT IS USED FOR SAMPLE DILUTION IN THE IMMUNOFIXATION PROCEDURES. ,HYDRAGEL 15 ISO-LDH(HYDRAGEL 15 ISO-LDH)-

	THESE DEVICES ARE DESIGNED FOR THE IDENTIFICATION AND QUANTIFICATION OF THE FIVE LACTATE DEHYDROGENASE (LD) ISOENZYMES IN HUMAN SERUM BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.4) AGAROSE GELS. ,HB A1C CAPILLARY CALIBRATORS (5X2)(HB A1C CAPILLARY CALIBRATORS (5X2))-THIS DEVICE IS DESIGNED FOR THE CALIBRATION OF CAPILLARY ELECTROPHORETIC QUANTIFICATION OF HUMAN GLYCATED HEMOGLOBIN A1C ACCORDING TO THE IFCC AND NGSP REQUIREMENTS. ,NORMAL CDT CONTROL (5)(NORMAL CDT CONTROL (5))-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN CDT IN CAPILLARY. ,NORMAL CONTROL (5)(NORMAL CONTROL (5))-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN SERUM PROTEINS ON AGAROSE GEL AND IN CAPILLARY. ,MINICAP CDT (MINICAP CDT)-THIS DEVICE IS DESIGNED FOR THE SEPARATION OF HUMAN SERUM TRANSFERRIN ISOFORMS IN ALKALINE BUFFER (PH 8.8) WITH THE MINICAP SYSTEM. THIS DEVICE IS DESIGNED FOR THE SEPARATION AND QUANTIFICATION OF THE DISIALOTRANSFERRIN FRACTION ("CDT-IFCC") IN HUMAN SERUM BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 8.8) WITH THE MINICAP AND MINICAP FLEX-PIERCING INSTRUMENTS. ,HYDRAGEL 1 IF (SM)(HYDRAGEL 1 IF (SM))-THESE DEVICES ARE DESIGNED FOR DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS. ,HYDRAGEL 9 BENCE JONES (SM) MAXI-KIT (HYDRAGEL 9 BENCE JONES (SM) MAXI-KIT)-THESE DEVICES ARE DESIGNED FOR QUALITATIVE DETECTION AND IDENTIFICATION OF BENCE JONES PROTEINS IN HUMAN URINE OR SERUM BY IMMUNOFIXATION ELECTROPHORESIS. ,HB AF CONTROL(HB AF CONTROL)-THE HB AF CONTROL IS DESIGNED FOR THE MIGRATION CONTROL BEFORE STARTING A NEW ANALYSIS SEQUENCE AND FOR THE QUALITATIVE QUALITY CONTROL FOR HUMAN HEMOGLOBINS A AND F, WITH THE SEBIA ELECTROPHORESIS PROCEDURES : - CAPILLARYS NEONAT HB USED WITH THE CAPILLARYS 2 AND CAPILLARYS 2 NEONAT FAST INSTRUMENTS AND, - CAPILLARYS CORD BLOOD USED WITH THE CAPILLARYS 2 AND CAPILLARYS 2 FLEX- PIERCING INSTRUMENTS. ,CAPILLARYS 3 CAPICLEAN (CAPILLARYS 3 CAPICLEAN)-THIS SOLUTION IS USED FOR CLEANING OF THE SAMPLE PROBE IN AUTOMATED SYSTEMS. ,ANTI-IG D 1 ML (SM)(ANTI-IG D 1 ML (SM))-THIS ANTISERUM IS WELL-SUITED FOR ALL PRECIPITATION TECHNIQUES. THE ANTIBODY REACTS IN IMMUNOFIXATION WITH HEAVY CHAINS WITH HUMAN IG D, BUT NOT WITH THE LIGHT CHAINS OF HUMAN IMMUNOGLOBULINS. THE ANTIBODY DOES NOT REACT WITH THE HEAVY CHAINS ON HUMAN IG

	A, IG G OR IG M. ,CAPI 3 HB A1C(CAPI 3 HB A1C)-THIS DEVICE IS DESIGNED FOR SEPARATION AND QUANTIFICATION OF THE HBA1C, GLYCOSYLATED FRACTION OF HEMOGLOBIN IN HUMAN BLOOD, BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE CAPILLARYS 3 SYSTEM. ,CAPILLARYS NEONAT HB(CAPILLARYS NEONAT HB)-THIS DEVICE IS DESIGNED FOR THE SEPARATION OF THE NORMAL HEMOGLOBINS (F AND A) IN BLOOD SAMPLES FROM HUMAN NEW-BORN BABIES, AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS (ESPECIALLY S, C, E, D OR BART'S), BY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE CAPILLARYS 2 SYSTEM.,HYDRAGEL 7 ISO-LDH(HYDRAGEL 7 ISO-LDH) -THESE DEVICES ARE DESIGNED FOR THE IDENTIFICATION AND QUANTIFICATION OF THE FIVE LACTATE DEHYDROGENASE (LD) ISOENZYMES IN HUMAN SERUM BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.4) AGAROSE GELS. ,ANTI-IG E 1 ML (SM)(ANTI-IG E 1 ML (SM))-THIS ANTISERUM IS WELL-SUITED FOR ALL PRECIPITATION TECHNIQUES. THE ANTISERUM REACTS ONLY IN IMMUNOFIXATION WITH HUMAN SERUM WITH HIGH IG E CONCENTRATION. NO REACTIVITY TO LIGHT CHAINS OR HEAVY CHAINS OF OTHER IMMUNOGLOBULINS IS OBSERVED. ,MINICAP CDT MAXI-KIT(MINICAP CDT MAXI-KIT)-THIS DEVICE IS DESIGNED FOR THE SEPARATION OF HUMAN SERUM TRANSFERRIN ISOFORMS IN ALKALINE BUFFER (PH 8.8) WITH THE MINICAP SYSTEM. THIS DEVICE IS DESIGNED FOR THE SEPARATION AND QUANTIFICATION OF THE DISIALOTRANSFERRIN FRACTION ("CDT-IFCC") IN HUMAN SERUM BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 8.8) WITH THE MINICAP AND MINICAP FLEX-PIERCING INSTRUMENTS. ,HYDRAGEL IF K20 (SM) (HYDRAGEL IF K20 (SM))-THESE DEVICES ARE DESIGNED FOR THE DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM BY IMMUNOFIXATION ELECTROPHORESIS ON ALKALINE BUFFERED (PH 9.1) AGAROSE GELS.,MINICAP IMMUNOTYPING(MINICAP IMMUNOTYPING)-THIS DEVICE IS DESIGNED FOR THE DETECTION AND THE CHARACTERIZATION OF MONOCLONAL PROTEINS (IMMUNOTYPING) IN HUMAN URINE AND SERUM WITH THE MINICAP SYSTEM, SEBIA, FOR CAPILLARY ELECTROPHORESIS. ,HYDRAGEL DOUBLE IF K20 (SM)(HYDRAGEL DOUBLE IF K20 (SM))-THESE DEVICES ARE DESIGNED FOR THE DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM BY IMMUNOFIXATION ELECTROPHORESIS ON ALKALINE BUFFERED (PH 9.1) AGAROSE GELS.,HIGH CDT CONTROL(HIGH CDT CONTROL)-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN CDT IN CAPILLARY. ,CAPILLARYS / MINICAP URINE(CAPILLARYS / MINICAP URINE)-THE CAPILLARYS / MINICAP URINE KIT IS DESIGNED FOR THE PREPARATION OF URINE

	SAMPLES BEFORE SEPARATION OF HUMAN URINE PROTEINS IN ALKALINE BUFFER (PH 9.9) WITH THE CAPILLARYS AND MINICAP INSTRUMENTS.,HYDRAGEL HEMOGLOBIN(E) K20(HYDRAGEL HEMOGLOBIN(E) K20)-THIS DEVICE IS DESIGNED FOR SEPARATION OF THE NORMAL HEMOGLOBINS (A AND A2) AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS: S OR D AND C OR E, BY ELECTROPHORESIS ON ALKALINE AGAROSE GELS., HYDRAGEL 2 IF / BJ (HR)(HYDRAGEL 2 IF / BJ (HR))-THE HYDRAGEL 2 IF / BJ (HR) KIT IS DESIGNED FOR DETECTION AND IDENTIFICATION OF MONOCLONAL PROTEINS AND BENCE JONES PROTEINS, MONOCLONAL FREE LIGHT CHAINS KAPPA OR LAMBDA, IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS., HYDRAGEL PROTEIN(E) K20(HYDRAGEL PROTEIN(E) K20)-THE HYDRAGEL PROTEIN(E) K20 KIT IS DESIGNED FOR SEPARATION OF HUMAN SERUM PROTEINS INTO SIX MAJOR FRACTIONS BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.6) AGAROSE GELS. ,HYDRAGEL 2 URINE PROFIL(E) (SM)(HYDRAGEL 2 URINE PROFIL(E) (SM))-THIS DEVICE IS DESIGNED FOR SCREENING OF MAIN URINARY PROTEINS TO TYPE PROTEINURIA (TUBULAR, GLOMERULAR, OR MIXED) AND IMMUNOGLOBULINS (G, A, M OR D/E) IN HUMAN URINE OR SERUM, BY IMMUNOFIXATION ELECTROPHORESIS ON AGAROSE GELS WITH SPECIFIC ANTISERA., HYDRAGEL 4 URINE PROFIL(E) (SM)(HYDRAGEL 4 URINE PROFIL(E) (SM))-THIS DEVICE IS DESIGNED FOR SCREENING OF MAIN URINARY PROTEINS TO TYPE PROTEINURIA (TUBULAR, GLOMERULAR, OR MIXED) AND IMMUNOGLOBULINS (G, A, M OR D/E) IN HUMAN URINE OR SERUM, BY IMMUNOFIXATION ELECTROPHORESIS ON AGAROSE GELS WITH SPECIFIC ANTISERA.,URINE PROFIL(E) ANTISERA BOX (SM)(URINE PROFIL(E) ANTISERA BOX (SM))-THIS DEVICE IS DESIGNED FOR IMMUNOFIXATION OF THE ELECTROPHORESED PROTEINS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

245	IMP/IVD/2019/000231	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HB-CON LOW-THE CONTROL SOLUTION HB-CON IS INTENDED TO BE USED FOR CONTROL OF ACCURACY AND PRECISION OF THE HEMO CONTROL PHOTOMETER AND THE ASSOCIATED HEMOGLOBIN MICROCUVETTE., HEMO_CONTROL HEMOGLOBIN MICROCUVETTE-THE HEMO_CONTROL HEMOGLOBIN MICROCUVETTE IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HEMOGLOBIN IN WHOLE BLOOD AND IS USED WITH THE HEMO CONTROL ANALYZER., HB-CON SET 2-THE CONTROL SOLUTION HB-CON IS INTENDED TO BE USED FOR CONTROL OF ACCURACY AND PRECISION OF THE HEMO CONTROL PHOTOMETER AND THE ASSOCIATED HEMOGLOBIN MICROCUVETTE.,QUO-LAB A1C TEST KIT-THE QUO-LAB A1C TEST KIT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF GLYCATED HEMOGLOBIN (HBA1C) IN WHOLE BLOOD AND IS USED WITH THE QUO-LAB ANALYZER.,QUO-LAB A1C CONTROL KIT-THE QUO-LAB A1C CONTROL KIT IS INTENDED TO CHECK THE GENERAL FUNCTIONALITY AND ACCURACY OF THE QUO-LAB A1C SYSTEM.
246	IMP/IVD/2019/000233	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DCA SYSTEMS HEMOGLOBIN A1C NORMAL/ABNORMAL CONTROL(DCA SYSTEMS HEMOGLOBIN A1C NORMAL/ABNORMAL CONTROL)-THE NORMAL AND ABNORMAL CONTROLS TO MONITOR THE PRECISION AND THE ACCURACY OF THE DCA HEMOGLOBIN A1C IN-VITRO DIAGNOSTICS ASSAY.
247	IMP/IVD/2019/000235	1.License Holder Name: M/S. I-SENS BIOSENSORS INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:A1CARE HBA1C CARTRIDGE(A1CARE HBA1C CARTRIDGE)-IT IS USED WITH A1CARE ANALYZER FOR QUANTITATIVELY MEASUREMENT OF GLYCATED HEMOGLOBIN(HBA1C)

248	IMP/IVD/2019/000236	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SNAPPAK(SNAPPAK)-SNAPPAK IS A FLUID PACK AND WASTE CONTAINER FOR THE AVL 9180, 9180 ELECTROLYTE ANALYZER (9180 EA), AVL 9181 AND IS USED TO WASH AND CALIBRATE THE FOLLOWING ELECTRODES: NA+, K+, LI+, CL-, CA2+.
249	IMP/IVD/2019/000237	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BETA-2-MICROGLOBULIN-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF -2 MICROGLOBULIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

250	IMP/IVD/2019/000238	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CD11B-APC -ALEXA FLUOR 750(CD11B-APC -ALEXA FLUOR 750)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD11B ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,IGG1(MOUSE)-PACIFIC BLUE(IGG1(MOUSE)-PACIFIC BLUE)-THIS MOUSE IGG1 KAPPA PACIFIC BLUE ISOTYPIC CONTROL FROM THE IO TEST LINE IS SUITABLE FOR FLOW CYTOMETRY ANALYSIS OF HUMAN BLOOD SAMPLES. IT PERMITS TO EVALUATE THE NON-SPECIFIC PART OF THE STAINING OBTAINED ON LEUCOCYTES OR PLATELETS WITH SPECIFIC IGG1 KAPPA -ISOTYPE ANTIBODIES CONJUGATED TO PACIFIC BLUE AND BELONGING TO THE IO TEST LINE.,IGG1(MOUSE)-PC5.5(IGG1(MOUSE)-PC5.5)-THIS MOUSE IGG1 PC5.5 ISOTYPIC CONTROL FROM THE IO TEST LINE IS SUITABLE FOR FLOW CYTOMETRY ANALYSIS OF HUMAN BLOOD SAMPLES. IT PERMITS TO EVALUATE THE NON-SPECIFIC PART OF THE STAINING OBTAINED ON LEUCOCYTES OR PLATELETS WITH SPECIFIC IGG1 -ISOTYPE ANTIBODIES CONJUGATED TO PC5.5 AND BELONGING TO THE IO TEST LINE.,IGG1 (MOUSE)-ECD(IGG1 (MOUSE)-ECD)-THIS MOUSE IGG1 ECD ISOTYPIC CONTROL FROM THE IOTEST LINE IS SUITABLE FOR FLOW CYTOMETRY ANALYSIS OF HUMAN BLOOD SAMPLES. IT PERMITS TO EVALUATE THE NON-SPECIFIC PART OF THE STAINING OBTAINED ON LEUCOCYTES OR PLATELETS WITH SPECIFIC IGG1 -ISOTYPE ANTIBODIES CONJUGATED TO ECD AND BELONGING TO THE IOTEST LINE.,ANTI-MYELOPEROXYDASE-PE(ANTI-MYELOPEROXYDASE-PE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE MYELOPEROXIDASE ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,IGG2A(MOUSE)-PE(IGG2A(MOUSE)-PE)-THIS MOUSE IGG2A PE ISOTYPIC CONTROL FROM THE IO TEST LINE IS SUITABLE FOR FLOW CYTOMETRY ANALYSIS OF HUMAN BLOOD SAMPLES. IT PERMITS TO EVALUATE THE NON-SPECIFIC PART OF THE STAINING OBTAINED ON LEUCOCYTES OR PLATELETS WITH SPECIFIC IGG2A -ISOTYPE ANTIBODIES CONJUGATED TO PE AND BELONGING TO THE IO TEST LINE.,CD14-FITC(CD14-FITC)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD14 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD45-FITC CD14-PE(CD45-FITC CD14-PE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE PERMITS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD45 AND CD14 ANTIGENS PRESENT

	IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,IGG2A (MOUSE)-PC5(IGG2A(MOUSE)-PC5)-THIS MOUSE IGG2A PC5 ISOTYPIC CONTROL FROM THE IO TEST LINE IS SUITABLE FOR FLOW CYTOMETRY ANALYSIS OF HUMAN BLOOD SAMPLES. IT PERMITS TO EVALUATE THE NON-SPECIFIC PART OF THE STAINING OBTAINED ON LEUCOCYTES OR PLATELETS WITH SPECIFIC IGG2A -ISOTYPE ANTIBODIES CONJUGATED TO PC5 AND BELONGING TO THE IO TEST LINE.,CD138-PC5(CD138-PC5)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD138 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD79A-APC (CD79A-APC)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD79A ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,IGG2A(MOUSE)-APC(IGG2A(MOUSE)-APC)-THIS MOUSE IGG2A APC ISOTYPIC CONTROL FROM THE IO TEST LINE IS SUITABLE FOR FLOW CYTOMETRY ANALYSIS OF HUMAN BLOOD SAMPLES. IT PERMITS TO EVALUATE THE NON-SPECIFIC PART OF THE STAINING OBTAINED ON LEUCOCYTES OR PLATELETS WITH SPECIFIC IGG2A -ISOTYPE ANTIBODIES CONJUGATED TO APC AND BELONGING TO THE IO TEST LINE.,CD7-APC -ALEXA FLUOR 700(CD7-APC -ALEXA FLUOR 700)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD7 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD13-ECD(CD13-ECD)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD13 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING LOW CYTOMETRY.,IGG1(MOUSE)-APC(IGG1(MOUSE)-APC)-THIS MOUSE IGG1 APC ISOTYPIC CONTROL FROM THE IO TEST LINE IS SUITABLE FOR FLOW CYTOMETRY ANALYSIS OF HUMAN BLOOD SAMPLES. IT PERMITS TO EVALUATE THE NON-SPECIFIC PART OF THE STAINING OBTAINED ON LEUCOCYTES OR PLATELETS WITH SPECIFIC IGG1 -ISOTYPE ANTIBODIES CONJUGATED TO APC AND BELONGING TO THE IO TEST LINE.,CD16-PACIFIC BLUE(CD16-PACIFIC BLUE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD16 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD65-FITC(CD65-FITC)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD65 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD22-APC -ALEXA FLUOR 700(CD22-APC -ALEXA FLUOR 700)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL

	POPULATIONS EXPRESSING THE CD22 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

251	IMP/IVD/2019/000238	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AQUIOS VERSAFIX LYSING REAGENT(AQUIOS VERSAFIX LYSING REAGENT)-AQUIOS VERSAFIX LYSING REAGENT IS INTENDED FOR THE LYSIS OF RED BLOOD CELLS AND THE FIXATION OF WHITE BLOOD CELLS IN THE PREPARATION OF WHOLE BLOOD BIOLOGICAL SAMPLES FOR FLOW CYTOMETRY ANALYSIS ON THE AQUIOS CL FLOW CYTOMETER.,CD33-PE 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD33 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,ANTI-KAPPA-FITC(ANTI-KAPPA-FITC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE KAPPA ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD25/CD4/CD3 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTI PARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD25, CD4 AND CD3 ANTIGENS ON CELLS OF HAEMATOPOEITIC ORIGIN.,ANTI-HLA-DR-PACIFIC BLUE(ANTI-HLA-DR-PACIFIC BLUE, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE HLA-DR ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,GLYCOPHORIN A-PE 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD235A ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD59-FITC(CD59-FITC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD59 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,OPTILYSE C LYSING SOLUTION-THIS REAGENT IS INTENDED FOR THE LYSIS OF RED BLOOD CELLS IN THE PREPARATION OF BIOLOGICAL SAMPLES FOR FLOW CYTOMETRY ANALYSIS AFTER STAINING OF LEUCOCYTES WITH FLUORESCENT ANTIBODIES. USE OF OPTILYSE C IS LIMITED TO SAMPLES FOR ANALYSIS USING BECKMAN COULTER FLOW CYTOMETERS WITH SO-CALLED NO WASH STAINING AND LYSIS PROCEDURES SO LONG AS DULY CALIBRATED FLUORESCENT ANTIBODIES ARE USED FOR THIS PURPOSE.,CD8-APC-ALEXA FLUOR 700(CD8-APC-ALEXA FLUOR 700, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD8

	ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY,INTRAPREP LEUCOCYTIC PERMEABILIZATION REAGENT-INTRAPREP CONSISTS OF TWO READY-TO-USE REAGENTS, WHICH INDUCE PERMEABILITY IN THE CYTOPLASMIC MEMBRANE OF LEUCOCYTES FOR THE DEMONSTRATION OF INTRACELLULAR ANTIGENIC DETEMINANTS BY MEANS OF MONOCLONAL FLUORESCENT ANTIBODIES.INTRAPREP IS USED TO PREPARE BIOLOGICAL SAMPLES FOR ANALYSIS BY FLOW CYTOMETRY.IT HAS BEEN OPTIMIZED IN ORDER TO MINIMIZE THE NON-SPECIFIC IN THE TYPE OF ANALYSIS.,CD3-PC5.5(CD3-PC5.5, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD3 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,FMC7(B-CELLS)-FITC 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE FMC7 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,PERFIX-NC KIT (NO CENTRIFUGE ASSAY KIT)(PERFIX-NC (NO CENTRIFUGE ASSAY KIT))-"PERFIX-NC KIT IS USED TO PREPARE BIOLOGICAL SAMPLES FOR ANALYSIS BY FLOW CYTOMETRY. PERFIX-NC KIT LYSES RED BLOOD CELLS AND INDUCES PERMEABILITY IN THE CYTOPLASMIC MEMBRANE OF LEUKOCYTES SIMULTANEOUSLY FOR THE DEMONSTRATION OF INTRACELLULAR AND EXTRACELLULAR ANTIGENIC DETERMINANTS BY MEANS OF FLUORESCENT PROBES. ", CD3- APC – ALEXA FLUOR 750-THIS FLUOROCHROME CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD 3 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD55-PE(CD55-PE, 100T, CE)-"THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD55 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.",ANTI–FMC7- FITC/ CD 23- PE/ CD 19- ECD-THIS FLUOROCHROME CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY.IT PERMITS THE DETECTION OF THE EXPRESSION OF FMC7, CD 23 AND CD 19 ANTIGENS IN LEUCOCYTES.,CD56-PC5.5(CD56-PC5.5, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD56 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,NEG./NEG./CD45 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE (NEGATIVE CONTROL-FITC / NEGATIVE CONTROL-PE / CD45-ECD) FROM THE IOTEST 3 RANGE IS SUITABLE FOR FLOW CYTOMETRY

	MULTIPARAMETRIC ANALYSIS. IT PERMITS THE DETERMINATION OF NON-SPECIFIC STAINING OF MIXTURES OF CONJUGATED ANTIBODIES BELONGING TO THIS RANGE ON HUMAN,CD16-FITC(CD16-FITC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD16 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD 34-PC5-THIS FLUOROCHROME CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD 34 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD 33-PC5.5(CD 33-PC5.5, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD33 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD16/CD56/CD3 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD16, CD56 AND CD3 ANTIGENS ON LEUCOCYTES,CD20-APC(CD20-APC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD20 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD19- ECD-THE FLUOROCHROME-CONJUGATED ANTIBODY PERMITS THE IDENTIFICATION AND NUMERATION OF PLATELET AND LEUCOVCYTIC POPULATIONS EXPRESSING THE CD 19 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD64-FITC(CD64-FITC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD64 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD 45- APC- ALEXA FLUOR 700-THIS FLUOROCHROME CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD 45 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD19-PC5.5(CD19-PC5.5, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD19 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD34/CD117/CD45 FITC/PE/ECD 25T CE-THIS FLUOROCHROME CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF ANTIGENS CD34, CD117 AND CD45 ON CELLS OF HAEMATOPOEITIC ORIGIN.,CD36-FITC (CD36-FITC, 100T, CE)-"THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS

	EXPRESSING THE CD36 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.",CD56-PC7 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD56 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD15-PACIFIC BLUE(CD15-PACIFIC BLUE, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD15 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD45-PC5 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD45 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD19-PACIFIC BLUE(CD19-PACIFIC BLUE, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD19 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,IGG2A-FITC, 100T CE-THIS MOUSE IGG2A (MOUSE) FITC ISOTYPIC CONTROL FROM THE IOTEST LINE IS SUITABLE FOR FLOW CYTOMETRY ANALYSIS OF HUMAN BLOOD SAMPLES. IT PERMITS TO EVALUATE THE NON-SPECIFIC PART OF THE STAINING OBTAINED ON LEUCOCYTES OR PLATELETS WITH SPECIFIC IGG2A (MOUSE)-ISOTYPE ANTIBODIES CONJUGATED TO FITC AND BELONGING TO THE IOTEST LINE.,CD57-FITC(CD57-FITC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD57 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,NEG./NEG./NEG. FITC/PE/ECD 25T CE-THIS MIXTURE OF CONJUGATED ANTIBODIES (NEGATIVE CONTROL-FITC / NEGATIVE CONTROL-PE / NEGATIVE CONTROL-ECD) FROM THE IOTEST 3 RANGE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETERMINATION OF NON-SPECIFIC STAINING OF MIXTURES OF CONJUGATED ANTIBODIES BELONGING TO THIS RANGE ON HUMAN LEUCOCYTES,CD5-PC5.5(CD5-PC5.5, 50T, CE)-THIS FLUOROCHROME- THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD5 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD34/CD33/CD45 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD34, CD33 AND CD45 ANTIGENS IN LEUCOCYTES.,ANTI-LAMBDA-PE (ANTI-LAMBDA-PE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS

	EXPRESSING THE LAMBDA ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY,CD117-PC5, 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD117 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD38-PC7(CD38-PC7, 50T, CE)-"THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD38 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.",CD3-ECD 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD3 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,ANTI-TCR PAN /-PE(ANTI-TCR PAN /-PE, 50T, CE)-"THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE TCR / ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.",CD19-PC7, 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD19 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD117-PC7(CD117-PC7, 100T, CE)-"THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD117 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.",CD11B-FITC, 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD11B ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD45RA-FITC(CD45RA-FITC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD45RA ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD34-APC, 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD34 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD4-PACIFIC BLUE(CD4-PACIFIC BLUE, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD4 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD56-PE 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD56

	ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD7-PC7(CD7-PC7, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD7 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD15/CD33/CD45 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD15, CD33 AND CD45 ANTIGENS PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD45-KROME ORANGE(CD45-KROME ORANGE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD45 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD (14 + 16)-FITC/CD85K-PE/CD33-PC5 50T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE IDENTIFICATION AND ENUMERATION OF THE MYELOID SUBSET OF CIRCULATING DENDRITIC CELLS (MDC) IN HUMAN BIOLOGICAL.,CD15-FITC(CD15-FITC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD15 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD20-FITC/CD 10-PE/ CD 19-ECD-THIS FLUOROCHROME CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY.IT PERMITS THE DETECTION OF THE EXPRESSION OF CD 20, CD 10, AND CD 19 ANTIGENS ON LEUCOCYTES.,CD11B-PACIFIC BLUE(CD11B-PACIFIC BLUE, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD11B ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD13-PE 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD13 ANTIGENS PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD15-PC5(CD15-PC5, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD15 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,HLA-DR/CD13/CD45 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF HLA-DR, CD13 AND CD45 ANTIGENS IN LEUCOCYTES.,CD117-APC(CD117-APC, 100T, CE)-"THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD117

	ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.",CD25/CD11C/CD19 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD25, CD11C AND CD19 ANTIGENS IN LEUCOCYTES,CD45-PACIFIC BLUE(CD45-PACIFIC BLUE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD45 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD5/CD10/CD19 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD5, CD10 AND CD19 ANTIGENS IN LEUCOCYTES, CD2-PC7(CD2-PC7, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD2 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD45-FITC 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD45 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD45RO-PE(CD45RO-PE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD45RO ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,G./NEG./CD3 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE (NEGATIVE CONTROL-FITC / NEGATIVE CONTROL-PE / CD3-ECD) IS A NEGATIVE CONTROL SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY AS A SUPPORT FOR GATING. IT MAKES POSSIBLE THE DEMONSTRATION OF THE NON-SPECIFIC STAINING OF ALL THE IOTEST 3S WHICH USE CD3-ECD,CD3-PACIFIC BLUE(CD3-PACIFIC BLUE, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD3 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD19-PC5 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD19 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,ANTI-TCR PAN /-FITC(ANTI-TCR PAN /-FITC, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE TCR / ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD5/CD7/CD3

	FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD5, CD7 AND CD3 ANTIGENS ON LEUCOCYTES., CD38-APC-ALEXA FLUOR 750(CD38-APC-ALEXA FLUOR 750, 50T, CE)-"THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD38 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.",CD8/CD4/CD3 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD8, CD4 AND CD3 ANTIGENS ON LEUCOCYTES.,ANTI-HLA-DR-PC7(ANTI-HLA-DR-PC7, 50T, CE)-"THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE HLA-DR ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.",STEM-KIT REAGENTS 50T-STEM-KIT REAGENTS CONSIST OF A TWO-COLOR FLUORESCENT (FITC, PE) MURINE MONOCLONAL ANTIBODY REAGENT, A TWO-COLOR MURINE FLUORESCENT (FITC, PE) ISOCLONIC CONTROL, AN ABSOLUTE COUNT REAGENT, A CELL VIABILITY REAGENT, AND A LYSING REAGENT. IT IS INTENDED? FOR IN VITRO DIAGNOSTIC USE? FOR THE SIMULTANEOUS IDENTIFICATION AND ENUMERATION OF CD45+ AND DUAL-POSITIVE CD45+ CD34+ CELL POPULATION PERCENTAGES AND ABSOLUTE COUNTS IN BIOLOGICAL SPECIMENS BY FLOW CYTOMETRY. BIOLOGICAL SPECIMENS INCLUDE FRESH NORMAL OR MOBILIZED PERIPHERAL WHOLE BLOOD, AND FRESH OR THAWED APHERESIS PRODUCTS, CORD BLOOD AND BONE MARROW. CELL POPULATION MEASUREMENTS MAY BE OBTAINED USING EITHER AN AUTOMATED METHOD OR A MANUAL METHOD FOR GATING AND ANALYSIS. REFER TO THIS STEM-KIT REAGENTS PACKAGE INSERT FOR COMPLETE INSTRUCTIONS IF USING THE MANUAL METHOD. REFER TO THE STEMONETM SYSTEM GUIDE OR THE STEMCXP SYSTEM GUIDE PROVIDED WITH THE STEM ONE SYSTEM SOFTWARE (REF. 6915452) OR STEMCXP SYSTEM SOFTWARE (REF. 628843) RESPECTIVELY, FOR COMPLETE INSTRUCTIONS IF USING THE AUTOMATED METHOD.,CD38-PC5.5(CD38-PC5.5, 50T, CE)-"THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD38 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.",TDT (POOL)-FITC, 50T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE TDT ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW

	CYTOMETRY.,CD20-PACIFIC BLUE(CD20-PACIFIC BLUE, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD20 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD3/HLA-DR FITC/PE 50T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE PERMITS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD3 AND HLA-DR ANTIGENS PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD127-PE(CD127-PE, 100T, CE)-"THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD127 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.",NEG.CTRL IGG1/IGG1 FITC/PE 50T CE-THIS MIXTURE OF MOUSE IGG1-FITC / IGG1-PE ISOTYPIC CONTROLS FROM THE IOTEST RANGE IS SUITABLE FOR FLOW CYTOMETRY ANALYSIS OF HUMAN BLOOD SAMPLES. IT PERMITS THE NON-SPECIFIC PART OF THE STAINING OBTAINED ON LEUCOCYTES OR PLATELETS TO BE DETERMINED WITH COMBINATIONS OF SPECIFIC IGG1-ISOTYPE ANTIBODIES CONJUGATED TO FITC OR PE AND BELONGING TO THE IOTEST RANGE,CD20-APC-ALEXA FLUOR 750(CD20-APC-ALEXA FLUOR 750, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD20 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,CD62P-FITC 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD62P ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD4-APC-ALEXA FLUOR 750 (CD4-APC-ALEXA 750, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD4 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD45-PC7, 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD45 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD19-APC-ALEXA FLUOR 700 (CD19-APC-ALEXA FLUOR 700, 50T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION OF CELL POPULATIONS EXPRESSING THE CD19 ANTIGEN PRESENT IN HUMAN PERIPHERAL BLOOD USING FLOW CYTOMETRY.,IGG1-APC-ALEXA 700, 100T CE-THIS MOUSE IGG1-APC-ALEXA FLUOR 700 ISOTYPIC CONTROL FROM THE IOTEST RANGE IS SUITABLE FOR FLOW CYTOMETRY ANALYSIS OF HUMAN BLOOD SAMPLES. IT PERMITS TO EVALUATE THE NON-SPECIFIC PART OF THE STAINING OBTAINED ON

	LEUCOCYTES OR PLATELETS WITH SPECIFIC IGG1-ISOTYPE ANTIBODIES CONJUGATED TO APC-ALEXA FLUOR 700 AND BELONGING TO THE IOTEST RANGE.,IOTEST 3 LYSING SOLUTION (IOTEST 3 LYSING SOLUTION, 100T, CE)-THE IOTEST 3 LYSING SOLUTION IS INTENDED FOR THE LYSIS OF RED BLOOD CELLS, A PROCEDURE FREQUENTLY UNDERTAKEN IN THE PREPARATION OF BIOLOGICAL SAMPLES – HUMAN PERIPHERAL WHOLE BLOOD IN PARTICULAR – FOR FLOW CYTOMETRY ANALYSIS AFTER STAINING OF THE CYTOPLASMIC MEMBRANE OF LEUCOCYTES USING FLUORESCENT ANTIBODIES,CD71/CD33/CD45 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD71, CD33 AND CD45 ANTIGENS IN LEUCOCYTES,CD61-FITC(CD61-FITC, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD61 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD3/CD19 FITC/PE 50T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE PERMITS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD3 AND CD19 ANTIGENS PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD5-PC7 (CD5-PC7, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD5 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD19-APC, 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD19 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD56-PC5(CD56-PC5, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD56 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,NEG./NEG./CD19 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE (NEGATIVE CONTROL-FITC / NEGATIVE CONTROL-PE / CD19-ECD) IS A NEGATIVE CONTROL SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY AS AN AID TO GATING. IT ENABLES THE DEMONSTRATION OF THE NON-SPECIFIC STAINING OF ALL THE IOTEST 3S WHICH USE CD19-ECD.,CD5-FITC(CD5-FITC, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD5 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD3/CD8 FITC/PE 50T CE-THIS

	FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE PERMITS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD3 AND CD4 ANTIGENS PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD22-PE(CD22-PE, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD22 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD3/CD16+CD56 FITC/PE 50T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE PERMITS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD3, CD16 AND CD56 ANTIGENS PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD138-PE(CD138-PE, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD138 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD38-FITC 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD38 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD1A-PE(CD1A-PE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD1A ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD71-FITC, 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD71 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD2-FITC(CD2-FITC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD2 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD34-FITC, 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD34 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD2-PE(CD2-PE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD2 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD34-PE 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD34 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,INTRAPREP

	PERMEABILIZATION REAGENT(INTRAPREP PERMEABILIZATION REAGENT, 50T, CE)-INTRAPREP CONSISTS OF TWO READY-TO-USE REAGENT, WHICH INDUCE PERMEABILITY IN THE CYTOPLASMIC MEMBRANE OF LEUCOCYTES FOR THE DEMONSTRATION OF INTRACELLULAR ANTIGENIC DETERMINANTS BY MEANS OF MONOCLONAL FLUROSCENT ANTIBODIES . INTRAPREP IS USED TO PREPARE BIOLOGICAL SAMPLES FOR ANALYSIS BY FLOW CYTOMETRY. IT HAS BEEN OPTIMIZED IN ORDER TO MINIMIZE THE NON-SPECIFIC STAINING IN THIS TYPE OF ANALYSIS.,CD3/CD4 FITC/PE 50T CE-THIS CONJUGATED ANTIBODY MIXTURE (NEGATIVE CONTROL-FITC / NEGATIVE CONTROL-ECD) FROM THE IO TEST 3 RANGE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETERMINATION OF NON-SPECIFIC STAINING OF MIXTURES OF CONJUGATED ANTIBODIES BELONGING TO THIS RANGE ON HUMAN LEUCOCYTES,CD25-PE(CD25-PE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD25 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,STEM-COMP REAGENTS 50T-THE STEM-COMP REAGENT CONSISTS OF A TWO COLOR FLUORESCENT REAGENT IMPLEMENTING TWO MONOCLONAL ANTIBODIES. THE ANTIBODIES ARE CONJUGATED TO FLUORESCEIN ISOTHIOCYANATE (FITC) FOR THE FLUORESCENCE 1 CHANNEL (FL1) OF A FLOW CYTOMETER AND R PHYCOERYTHRIN (PE) FOR THE FLUORESCENCE 2 CHANNEL (FL2). THE STEM-COMP REAGENT IS USED TO ADJUST COLOR COMPENSATIONS FOR AUTOMATED OR MANUAL ANALYSIS WITH THE STEM- KIT REAGENTS,CD38-PC5(CD38-PC5, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD38 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD41/GLYCO. A/CD45 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD41, GLYCOPHORIN A (CD235A) AND CD45 ANTIGENS IN CELLS OF HEMATOPOIETIC,CD38-PE(CD38-PE, 100T, CE) -THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD38 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD79A-PE, 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD79A ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD8-PC5(CD8-PC5, 100T, CE)-

	THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD8 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,TCR PAN GAMMA/DELTA-PC5, 50T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE ANTI-TCR PAN ?/? ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD25-PC5(CD25-PC5, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD25 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD (14 + 16)-FITC/CD85K-PE/CD123-PC5 50T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE IDENTIFICATION AND ENUMERATION OF THE PLASMACYTOID SUBSET OF CIRCULATING DENDRITIC CELLS (PDC) IN HUMAN BIOLOGICAL SAMPLES.,CD8-FITC(CD8-FITC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD8 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,HLA-B27/HLA-B7 FITC/PE 50T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE PERMITS THE IDENTIFCATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE HLA-B27 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY. THE ROLE OF THE HLA-B7 SPECIFICITY MONOCLONAL ANTIBODY IS TO DEMONSTRATE THE PRESENCE OF THIS ANTIGEN, THE MAIN CAUSE OF THE CROSS-REACTION OF THE CLONE RECOGNIZING THE HLA-B27 ANTIGEN (1,2). NOT FOR USE IN THE DETERMINATION OF HLA-B TISSUE GROUP.,IOTEST 3 FIXATIVE SOLUTION(IOTEST 3 FIXATIVE SOLUTION, 100T-200T, CE)-THE IOTEST 3 FIXATIVE SOLUTION, WHICH HAS A FORMALDEHYDE BASE, HAS BEEN SPECIALLY DEVELOPED FOR THE FIXING OF LEUCOCYTES. IT IS USED ON ALL LEUCOCYTIC PREPARATIONS WHETHER HAVING UNDERGONE AN ERYTHROCYTE LYSIS STAGE OR OTHERWISE, BEFORE OR AFTER STAINING.,CD45-ECD 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD45 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD4-PE(CD4-PE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD4 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,HLA-DR/CD7/CD45

	FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF HLA-DR/CD7/CD45 ANTIGENS ON LEUCOCYTES., CD4-PC5(CD4-PC5, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD4 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,HLA-DR/CD34/CD45 FITC/PE/ECD 25T CE-THIS FLUOROCHROME CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF HLADR, CD34 AND CD45 ON LEUCOCYTES,CD3-FITC(CD3-FITC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD3 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD14/CD16/CD45 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD14, CD16 AND CD45 ANTIGENS IN LEUCOCYTES, CD14-APC(CD14-APC, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD14 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,VERSALYSE LYSING SOLUTION-THIS REAGENT IS INTENDED FOR THE LYSIS OF RED BLOOD CELLS IN THE PREPARATION OF BIOLOGICAL SAMPLES FOR FLOW CYTOMETRY ANALYSIS.VERSALYSE IS COMPATIBLE WITH ALL TYPES OF CYTOMETERS AND IS USED WITH OR WITHOUT WASHING AFTER INCUBATION, AS LONG AS PROPERLY CALIBRATED FLUORESCENT ANTIBODIES ARE USED IN THE PROTOCOL. VERSALYSE ALSO MAKES IT POSSIBLE TO TREAT SAMPLES EVEN WHEN THEY HAVE BEEN WASHED EARLIER, IN ORDER TO ELIMINATE SERUM IMMUNOGLOBULINS FOR EXAMPLE.,CD117-PE(CD117-PE, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD117 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD103/CD11C/CD19 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD103, CD11C AND CD19 ANTIGENS IN LEUKOCYTES.,CD4-APC(CD4-APC, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD4 ANTIGEN PRESENT IN HUMAN

	BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD10-PE 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD10 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD20-FITC(CD20-FITC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD20 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD34-PC7 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD34 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD3-APC(CD3-APC, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD3 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,IGG1-APC-ALEXA 750, 100T CE-THIS MOUSE IGG1 APC-ALEXA FLUOR 750 ISOTYPIC CONTROL FROM THE IOTEST LINE IS SUITABLE FOR FLOW CYTOMETRY ANALYSIS OF HUMAN BLOOD SAMPLES. IT PERMITS TO EVALUATE THE NON-SPECIFIC PART OF THE STAINING OBTAINED ON LEUCOCYTES OR PLATELETS WITH SPECIFIC IGG1-ISOTYPE ANTIBODIES CONJUGATED TO APC-ALEXA FLUOR 750 AND BELONGING TO THE IOTEST LINE., CD33-PC5(CD33-PC5, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD33 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD19/CD10/CD45 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD19, CD10 AND CD45 ANTIGENS IN LEUCOCYTES., ANTI-HLA-DR-PC5(ANTI-HLA-DR-PC5, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE HLA-DR ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD14/CD13/CD45 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD14, CD13 AND CD45 ANTIGENS IN LEUCOCYTES,CD45-PE(CD45-PE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD45 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CMPO/CCD79A/CCD3

	FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE INTRACELLULAR EXPRESSION OF MYELOPEROXIDASE (MPO), CD79A AND CD3 MOLECULES IN LEUCOCYTES,CD45-PC5.5(CD45-PC5.5, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD45 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD3- PC5-THIS FLUOROCHROME CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD 3 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD2-PC5(CD2-PC5, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD2 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD10-FITC 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD10 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD4-FITC(CD4-FITC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD4 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,ANTI KAPPA FITC/ ANTI-LAMBDA-PE/ CD19-ECD-THIS FLUOROCHROME CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY.IT PERMITS THE DETECTION OF THE EXPRESSION OF THE CD 19 ANTIGEN AND LIGHT KAPPA CHAIN AND LAMBDA CHAIN SURFACE IMMUNOGLOBULIN CHAINS IN LEUCOCYTES.,CD20-PC5(CD20-PC5, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD20 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD41-PE 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY PERMITS THE IDENTIFICATION AND NUMERATION OF PLATELET AND LEUCOCYTIC POPULATIONS EXPRESSING THE CD41 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD16-PE(CD16-PE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD16 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD69-PC5, 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS

	EXPRESSING THE CD69 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD13-PC5(CD13-PC5, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD13 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,STEM-TROL CONTROL CELLS 10T-STEM-TROL CONTROL CELLS IS AN ASSAYED QUALITY CONTROL PRODUCT FOR IMMUNOPHENOTYPING ANALYSIS USING CD45 AND / OR CD34 MONOCLONAL ANTIBODIES REAGENTS AND FLOW CYTOMETRY. IT PROVIDES A POSITIVE CELL CONTROL THAT IS PROCESSED IN THE SAME MANNER AS A BLOOD SPECIMEN WHEN STEM-TROL CONTROL CELLS ARE SPIKED INTO A PERIPHERAL WHOLE BLOOD SAMPLE. THIS ALLOWS VERIFICATION OF REAGENT PERFORMANCE AND THE METHODS USED FOR STAINING TARGETED CELLS (I.E. CD34+ HEMATOPOIETIC PROGENITOR CELLS HPC), LYSING ERYTHROCYTES, AND ANALYZING SAMPLES WITH FLOW CYTOMETRY. REFER TO THE STEM-KIT? REAGENTS (REF. IM3630) PACKAGE INSERT FOR COMPLETE INSTRUCTIONS IF PERFORMING MANUAL ANALYSIS. REFER TO THE STEMONE? SYSTEM GUIDE OR THE STEMCXP SYSTEM GUIDE PROVIDED WITH THE STEMONE SYSTEM SOFTWARE (REF. 6915452) OR STEMCXP SYSTEM SOFTWARE (REF. 628843) RESPECTIVELY, FOR COMPLETE INSTRUCTIONS IF USING THE AUTOMATED ANALYSIS,CD14-PE(CD14-PE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD14 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD5/CD23/CD19 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD5, CD23 AND CD19 ANTIGENS IN LEUCOCYTES.,CD16-PC5(CD16-PC5, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD16 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,MPO-FITC, 100T CE-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE ANTI- MYELOPEROXIDASE ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD14-PC5 (CD14-PC5, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD14 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD38/CD56/CD45 FITC/PE/ECD 25T CE-THIS FLUOROCHROME-CONJUGATED

	ANTIBODY MIXTURE IS SUITABLE FOR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS THE DETECTION OF THE EXPRESSION OF CD38, CD56 AND CD45 ANTIGENS IN LEUCOCYTES., CD19-FITC(CD19-FITC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD19 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD45-APC(CD45-APC, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD45 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD19-PE(CD19-PE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD19 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD20-PC7(CD20-PC7, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD20 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD3-PE(CD3-PE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD3 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD56-APC(CD56-APC, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD56 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD33-APC(CD33-APC, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD33 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD23-FITC(CD23-FITC, 100T, CE) -THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD23 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD8-APC-ALEXA 750(CD8-APC-ALEXA 750, 50T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD8 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD45-APC-ALEXA 750(CD45-APC-ALEXA 750, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD45 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD19-APC-ALEXA 750(CD19-APC-ALEXA 750, 50T, CE)-

	THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD19 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,IGG1(MOUSE)-FITC(NEG.CTRL IGG1(MOUSE)-FITC, 100T, CE)-THIS MOUSE IGG1 FITC ISOTYPIC CONTROL FROM THE IOTEST LINE IS SUITABLE FOR FLOW CYTOMETRY ANALYSIS OF HUMAN BLOOD SAMPLES. IT PERMITS TO EVALUATE THE NON-SPECIFIC PART OF THE STAINING OBTAINED ON LEUCOCYTES OR PLATELETS WITH SPECIFIC IGG1-ISOTYPE ANTIBODIES CONJUGATED TO FITC AND BELONGING TO THE IOTEST LINE,IGG1 (MOUSE)-PE(NEG.CTRL IGG1 (MOUSE)-PE, 100T, CE)-THIS MOUSE IGG1 PC5 ISOTYPIC CONTROL FROM THE IOTEST LINE IS SUITABLE FOR FLOW CYTOMETRY ANALYSIS OF HUMAN BLOOD SAMPLES. IT PERMITS TO EVALUATE THE NON-SPECIFIC PART OF THE STAINING OBTAINED ON LEUCOCYTES OR PLATELETS WITH SPECIFIC IGG1 -ISOTYPE ANTIBODIES CONJUGATED TO PE AND BELONGING TO THE IOTEST LINE.,CD11C-PE(CD11C-PE, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD11C ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD10-PC5(CD10-PC5, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD10 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,IGG1(MOUSE)-PC5(NEG.CTRL IGG1(MOUSE)-PC5, 100T, CE)-THIS MOUSE IGG1 PC5 ISOTYPIC CONTROL FROM THE IOTEST LINE IS SUITABLE FOR FLOW CYTOMETRY ANALYSIS OF HUMAN BLOOD SAMPLES. IT PERMITS TO EVALUATE THE NON-SPECIFIC PART OF THE STAINING OBTAINED ON LEUCOCYTES OR PLATELETS WITH SPECIFIC IGG1 -ISOTYPE ANTIBODIES CONJUGATED TO PC5 AND BELONGING TO THE IOTEST LINE.,CD7-PC5(CD7-PC5, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD7 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY,CD8-APC(CD8-APC, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD8 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,7-AAD VIABILITY DYE(7-AAD VIABILITY DYE, 150T, CE) -7-AAD VIABILITY DYE IS A CHEMICAL COLORING AGENT IN SOLUTION, WHICH IS DESIGNED FOR MONO- OR MULTIPARAMETRIC ANALYSIS USING FLOW CYTOMETRY. IT PERMITS NON-VIABLE CELLS TO BE IDENTIFIED AND TO BE EXCLUDED FROM (VIABLE) CELLS OF

	INTEREST IN THE ANALYSIS OF HUMAN LEUCOCYTES.,CD79B-PE (CD79B-PE, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD79B ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,ANTI-HLA-DR-PE(ANTI-HLA-DR-PE, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE HLA-DR ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD20-PE(CD20-PE, 100T, CE)-THIS FLUROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD20 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD5-PC5(CD5-PC5, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD5 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD5-PE(CD5-PE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD5 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD7-FITC(CD7-FITC, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD7 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.,CD8-PE(CD8-PE, 100T, CE)-THIS FLUOROCHROME-CONJUGATED ANTIBODY ALLOWS THE IDENTIFICATION AND NUMERATION OF CELL POPULATIONS EXPRESSING THE CD8 ANTIGEN PRESENT IN HUMAN BIOLOGICAL SAMPLES USING FLOW CYTOMETRY.

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252	IMP/IVD/2019/000239	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALINITY C LIPID MULTICONSTITUENT CALIBRATOR KIT(ALINITY C LIPID MULTICONSTITUENT CALIBRATOR KIT)-FOR USE IN THE CALIBRATION OF THE ALINITY C APOLIPOPROTEIN A1 (APOA1), APOLIPOPROTEIN B (APOB), DIRECT LOW DENSITY LIPOPROTEIN (DIRECT LDL), AND ULTRA HIGH DENSITY LIPOPROTEIN (ULTRA HDL) ASSAYS ON THE ALINITY C ANALYZER.,LIPID MULTICONSTITUENT CALIBRATOR(LIPID MULTICONSTITUENT CALIBRATOR)-FOR USE IN THE CALIBRATION OF THE APOLIPOPROTEIN A1 (APO A1), APOLIPOPROTEIN B (APO B), LOW DENSITY LIPOPROTEIN (LDL), AND ULTRA HIGH DENSITY LIPOPROTEIN (UHDL) ASSAYS.

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253	IMP/IVD/2019/000240	1.License Holder Name: HELICO INTERNATIONAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CALPROTECTIN RAPID TEST CASSETTE (FECES)-"THE QUALITATIVE DETECTION OF CALPROTECTIN IN HUMAN FECESSPECIMEN. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY. ",PCT RAPID TEST CASSETTE (WHOLE BLOOD /SERUM/PLASMA)(ALLTEST)-A RAPID TEST FOR THE QUALITATIVE DETECTION OF PROCALCITONIN IN HUMAN'S WHOLE BLOOD, SERUM OR PLASMA. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,CARDIAC TROPONIN I RAPID TEST CASSETTE (WHOLE BLOOD/ SERUM/ PLASMA)(ALLTEST)-A RAPID TEST FOR THE DIAGNOSIS OF MYOCARDIAL INFARCTION (MI) TO DETECT CARDIAC TROPONIN I (CTNI) QUALITATIVELY IN WHOLE BLOOD, SERUM OR PLASMA. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY,H. PYLORI ANTIBODY RAPID TEST CASSETTE (WHOLE BLOOD/SERUM/PLASMA)-"THE QUALITATIVE DETECTION OF ANTIBODIES TO HELICOBACTER PYLORI (H. PYLORI) IN WHOLE BLOOD, SERUM OR PLASMA. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY. ",MICRO-ALBUMIN SEMI-QUANTITATIVE RAPID TEST CASSETTE (URINE)-"THE SEMI-QUANTITATIVE DETECTION OF MICRO-ALBUMIN IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY. ",OVULATION (LH) RAPID TEST CASSETTE (URINE)-"THE QUALITATIVE DETECTION OF LUTEINIZING HORMONE (LH) IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY. ",MICRO-ALBUMIN QUALITATIVE RAPID TEST DIPSTICK (URINE)-"THE QUALITATIVE DETECTION OF MICRO-ALBUMIN IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY. ",FSH RAPID TEST CASSETTE (URINE)-"THE QUALITATIVE DETECTION OF FOLLICLE STIMULATING HORMONE (FSH) IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY. ",VAGINAL PH RAPID TEST PANEL (VIGINAL DISCHARGE)-"THE SEMI-QUANTITATIVE DETERMINATION OF PH IN FEMALE VAGINAL SWAB SPECIMENS. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY. ",VITAMIN D RAPID TEST CASSETTE (WHOLE BLOOD)-"THE SEMI-QUANTITATIVE DETECTION OF 25-HYDROXYVITAMIN D IN HUMAN FINGERSTICK WHOLE BLOOD. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY. ",TSH RAPID TEST CASSETTE (WHOLE BLOOD/SERUM/PLASMA)-"THE QUALITATIVE DETECTION OF HUMAN THYROID STIMULATING HORMONE (TSH) IN WHOLE BLOOD,SERUM OR PLASMA. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY. "

254	IMP/IVD/2019/000241	1.License Holder Name: INSTRUMENTATION LABORATORY INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CUVETTE (AVOXIMETER 4000)(CUVETTE QV8)-A WHOLE BLOOD SAMPLE IS INSERTED INTO A TEST CUVETTE BY CONNECTING A LUER LOCK SYRINGE, SLIP SYRINGE OR CAPILLARY TUBE CONTAINING THE WHOLE BLOOD SAMPLE TO THE FILLING PORT AND THEN GENTLY PRESSING THE SYRINGE PLUNGER TO DISPENSE APPROXIMATELY 50 L OF WHOLE BLOOD INTO THE TEST CUVETTE. AIR ESCAPES FROM THE VENT PATCH AT THE END OF THE TEST CUVETTE WHILE THE WHOLE BLOOD SAMPLE IS BEING INSERTED. THE TEST CUVETTE (WITH THE SYRINGE STILL ATTACHED) IS THEN INSERTED INTO THE TEST CHAMBER OF THE INSTRUMENT.,APTT TEST CUVETTE(J103 (HEMOCHRON))-HEMOCHRON APTT TEST CUVETTE-ACTIVATED PARTIAL THROMBOPLASTIN TIME TEST FOR USE WITH FRESH WHOLE BLOOD. FOR EVALUATION OF LOW DOSE HEPARIN. THE HEMOCHRON JR. INSTRUMENTS UTILIZE A MECHANICAL ENDPOINT CLOTTING MECHANISM IN WHICH CLOT FORMATION OCCURS WITHIN THE DISPOSABLE APTT CUVETTE.,ACT+ TEST CUVETTE(JACT+ (HEMOCHRON))-HEMOCHRON ACT+ TEST CUVETTE-SILICA AND KAOLIN BASED ACTIVATED CLOTTING TIME TEST CUVETTE; FOR USE WITH FRESH WHOLE BLOOD.MONITORS MODERATE TO HIGH LEVELS OF HEPARIN.,PT TEST CUVETTE(J201 (HEMOCHRON))-HEMOCHRON PT TEST CUVETTE PROTHROMBIN TIME TEST CUVETTE; FOR USE WITH FRESH WHOLE BLOOD (VENOUS OR FINGERSTICK SAMPLING), VERIFYNOW® ASPIRIN TEST DEVICE KIT(VERIFYNOW® ASPIRIN TEST DEVICE KIT)-THE VERIFYNOW ASPIRIN TEST IS A QUALITATIVE TEST TO AID IN THE DETECTION OF PLATELET DYSFUNCTION DUE TO ASPIRIN INGESTION IN CITRATED WHOLE BLOOD FOR THE POINT OF CARE* OR LABORATORY SETTING. THIS TEST IS NOT FOR USE IN PATIENTS WITH UNDERLYING CONGENITAL PLATELET ABNORMALITIES, PATIENTS WITH NON-ASPIRIN INDUCED ACQUIRED PLATELET ABNORMALITIES OR IN PATIENTS RECEIVING NON-ASPIRIN ANTI-PLATELET AGENTS (MAY BE USED IN PATIENTS TREATED WITH SELECTIVE COX-2 INHIBITORS, E.G., CELECOXIB (CELEBREX®).,ACT-LR TEST CUVETTE(JACT-LR (HEMOCHRON))-HEMOCHRON ACT-LOW RANGE TEST CUVETTE- CELITE BASED ACTIVATED CLOTTING TIME TEST ; FOR USE WITH FRESH WHOLE BLOOD. MONITORS LOW TO MODERATE TO HIGH LEVELS OF HEPARIN.,VERIFYNOW® PRU TEST DEVICE KIT(VERIFYNOW® PRU TEST DEVICE KIT)-THE VERIFYNOW® PRUTEST® IS A WHOLE BLOOD TEST USED IN THE LABORATORY OR POINT OF CARE* SETTING TO MEASURE THE LEVEL OF PLATELET P2Y12 RECEPTOR BLOCKADE.

		FOR IN VITRO DIAGNOSTIC USE. FOR PROFESSIONAL USE ONLY.
255	IMP/IVD/2019/000242	1.License Holder Name: M/S AGAPPE DIAGNOSTICS LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IGE BULK R1(IGE R1 BULK) -QUANTIFICATION OF NON-SPECIFIC IGE IN SERUM.,IGE CALIBRATOR SET(IGE STD-5 NV)-CALIBRATION FOR MEASURING IGE,IGE CALIBRATOR SET(IGE CALIBRATOR)-CALIBRATION FOR MEASURING IGE,IGE BULK R2(IGE R2 BULK)-QUANTIFICTAION OF NON-SPECIFIC IGE IN SERUM

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256	IMP/IVD/2019/000246	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TESTPOINT HIGH CONTROL(TESTPOINT HIGH CONTROL)-ADVIA® TESTPOINT™ HEMATOLOGY CONTROLS ARE HEMATOLOGY REFERENCE MATERIALS FOR MONITORING THE PRECISION AND ACCURACY OF ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS.,3-IN-1 TESTPOINT NORM CONTROL(3-IN-1 TESTPOINT NORM CONTROL)-ADVIA® 3•IN•1 TESTPOINT™ HEMATOLOGY CONTROLS ARE HEMATOLOGY REFERENCE MATERIALS FOR MONITORING THE PRECISION AND ACCURACY OF ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS., SETPOINT CALIBRATOR(SETPOINT CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS.,3-IN-1 TESTPOINT ABN1 CONTROL(3-IN-1 TESTPOINT ABN1 CONTROL)-ADVIA® 3•IN•1 TESTPOINT™ HEMATOLOGY CONTROLS ARE HEMATOLOGY REFERENCE MATERIALS FOR MONITORING THE PRECISION AND ACCURACY OF ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS.,TESTPOINT RETICULOCYTE LOW CONTROL(TESTPOINT RETICULOCYTE LOW CONTROL)-ADVIA® TESTPOINT™ RETICULOCYTE CONTROLS ARE HEMATOLOGY REFERENCE MATERIALS FOR MONITORING THE PERFORMANCE OF THE RETICULOCYTE METHOD ON ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS.,TESTPOINT LOW CONTROL (TESTPOINT LOW CONTROL)-ADVIA® TESTPOINT™ HEMATOLOGY CONTROLS ARE HEMATOLOGY REFERENCE MATERIALS FOR MONITORING THE PRECISION AND ACCURACY OF ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS.,3-IN-1 TESTPOINT ABN2 CONTROL(3-IN-1 TESTPOINT ABN2 CONTROL)-ADVIA® 3•IN•1 TESTPOINT™ HEMATOLOGY CONTROLS ARE HEMATOLOGY REFERENCE MATERIALS FOR MONITORING THE PRECISION AND ACCURACY OF ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS., TESTPOINT CSF CONTROLS(TESTPOINT CSF CONTROLS)-ADVIA® TESTPOINT™ CSF CONTROLS ARE HEMATOLOGY REFERENCE MATERIALS FOR MONITORING THE PRECISION AND ACCURACY OF ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS WHEN ANALYZING CSF SAMPLES.,CSF REAGENT SYSTEM (CSF REAGENT SYSTEM)-THE ADVIA 120/2120/2120I CSF ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF BLOOD CELLS IN CEREBROSPINAL FLUID (CSF) SPECIMENS. THE CSF ASSAY PROVIDES LEUKOCYTE (CSF WBC) AND ERYTHROCYTE (CSF RBC) COUNTS AS WELL AS ABSOLUTE AND PERCENTAGE COUNTS FOR THE CSF WBC DIFFERENTIAL. TO ARRIVE AT A DIAGNOSIS AND A COURSE OF TREATMENT, RESULTS FROM THE CSF ASSAY SHOULD BE USED IN CONJUNCTION WITH OTHER DIAGNOSTIC INFORMATION AND THE

	ATTENDING HEALTHCARE PROFESSIONAL'S EVALUATION OF THE PATIENT'S CONDITION. ,TESTPOINT RETICULOCYTE HIGH CONTROL (TESTPOINT RETICULOCYTE HIGH CONTROL)-ADVIA® TESTPOINT™ RETICULOCYTE CONTROLS ARE HEMATOLOGY REFERENCE MATERIALS FOR MONITORING THE PERFORMANCE OF THE RETICULOCYTE METHOD ON ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS.,TESTPOINT NORM CONTROL(TESTPOINT NORM CONTROL)-ADVIA® TESTPOINT™ HEMATOLOGY CONTROLS ARE HEMATOLOGY REFERENCE MATERIALS FOR MONITORING THE PRECISION AND ACCURACY OF ADVIA 120/2120/2120I HEMATOLOGY SYSTEMS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

257	IMP/IVD/2019/000247	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLIN CHEM CALIBRATOR (CLIN CHEM CALIBRATOR)-CLIN CHEM CAL IS USED FOR THE CALIBRATION OF THE CREATININE (ENZYMATIC), LITHIUM, PANCREATIC AMYLASE, CHOLINESTERASE (CHE), -HYDROXYBUTYRATE DEHYDROGENASE (AHBDH), DIBUCAINE CHE (CHEDI) AND DIBUCAINE CHE (DIBCH) ASSAYS.,ALINITY C CHOLINESTERASE REAGENT KIT(ALINITY C CHOLINESTERASE REAGENT KIT)-THE ALINITY C CHOLINESTERASE ASSAY IS USED FOR THE KINETIC COLORIMETRIC DETERMINATION OF CHOLINESTERASE ACCORDING TO THE DEUTSCHE GESELLSCHAFT FÜR KLINISCHE CHEMIE (DGKC) RECOMMENDATIONS IN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,LIPASE NG OC CTRL 2(LIPASE NG OC CTRL 2)-LIPASE NG OC CTRL 2 MUST BE USED ONLY TO VERIFY THE PERFORMANCE OF LIPASE NG.,ALINITY C FRUCTOSAMINE CONTROL 1 KIT(ALINITY C FRUCTOSAMINE CONTROL 1 KIT)-THE ALINITY C FRUCTOSAMINE CONTROL 1 KIT MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF ALINITY C FRUCTOSAMINE ON THE ALINITY C ANALYZER.,LIPASE NG OC CAL(LIPASE NG OC CAL)-LIPASE NG OC CAL MUST BE USED ONLY FOR THE CALIBRATION OF LIPASE NG., ALINITY C CK-MB CALIBRATOR KIT(ALINITY C CK-MB CALIBRATOR KIT)-THE ALINITY C CK-MB CALIBRATOR IS USED FOR THE CALIBRATION OF THE CKMB ASSAY ON THE ALINITY C ANALYZER., CLIN CHEM CONTROL 2(CLIN CHEM CONTROL 2)-CLIN CHEM CONTROL 2 IS USED TO VERIFY THE PERFORMANCE OF THE FOLLOWING MULTIGENT ASSAYS: CHOLINESTERASE (CHE), COPPER, CREATININE (ENZYMATIC), DIBUCAINE CHE (CHEDI), DIBUCAINE CHE (DIBCH), -HYDROXYBUTYRATE DEHYDROGENASE (AHBDH), IRON, LITHIUM, AND PANCREATIC AMYLASE. ,ALINITY C CK-MB CONTROL KIT(ALINITY C CK-MB CONTROL KIT)-THE ALINITY C CK-MB CONTROL MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF THE ALINITY C CK-MB ASSAY ON THE ALINITY C ANALYZER.,PANCREATIC AMYLASE(PANCREATIC AMYLASE)-THE PANCREATIC AMYLASE ASSAY IS INTENDED FOR THE ENZYMATIC COLORIMETRIC DETERMINATION OF PANCREATIC AMYLASE ACCORDING TO THE IFCC METHOD OF DETERMINATION IN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY C FRUCTOSAMINE REAGENT KIT (ALINITY C FRUCTOSAMINE REAGENT KIT)-THE ALINITY C FRUCTOSAMINE ASSAY IS USED FOR THE KINETIC COLORIMETRIC DETERMINATION OF FRUCTOSAMINE IN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,LIPASE NG OC REAGENT KIT(LIPASE NG OC REAGENT KIT)-THE LIPASE NG OC ASSAY IS AN IN VITRO DIAGNOSTIC TEST USED FOR THE DETERMINATION OF THE LIPASE ACTIVITY IN

	SERUM AND PLASMA BY KINETIC COLORIMETRIC METHOD.,ALINITY C CK-MB REAGENT KIT(ALINITY C CK-MB REAGENT KIT)-THE ALINITY C CK-MB ASSAY IS USED FOR THE KINETIC DETERMINATION OF THE CK-MB AND CK-BB ISOENZYMES OF CREATINE KINASE IN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,CRP CALIBRATOR HS(CRP CALIBRATOR HS)-FOR USE WITH CRP CALIBRATOR SET TO CALIBRATE CRP VARIO ASSAY, HIGH SENSITIVITY METHOD,ALINITY C TOTAL BILE ACIDS CALIBRATOR KIT(ALINITY C TOTAL BILE ACIDS CALIBRATOR KIT)-THE ALINITY C TOTAL BILE ACIDS CALIBRATOR IS USED FOR THE CALIBRATION OF THE ALINITY C TOTAL BILE ACIDS ASSAY ON THE ALINITY C ANALYZER.,CRP VARIO(CRP VARIO)-THE CRP VARIO ASSAY [CRPVA] IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM AND PLASMA (SODIUM AND LITHIUM HEPARIN) USING THE ARCHITECT C SYSTEMS. MEASUREMENT OF C-REACTIVE PROTEIN IS USEFUL IN THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY AND INFLAMMATORY DISORDERS.,ALINITY C FRUCTOSAMINE CONTROL 2 KIT(ALINITY C FRUCTOSAMINE CONTROL 2 KIT)-THE ALINITY C FRUCTOSAMINE CONTROL 2 KIT MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF ALINITY C FRUCTOSAMINE ON THE ALINITY C ANALYZER.,CYSTATIN C CONTROL SET(CYSTATIN C CONTROL SET)-CYSTATIN C CONTROL SET IS USED TO VERIFY THE PERFORMANCE OF THE CYSTATIN C ASSAY. ,ALINITY C TOTAL BILE ACIDS REAGENT KIT(ALINITY C TOTAL BILE ACIDS REAGENT KIT)-THE ALINITY C TOTAL BILE ACIDS ASSAY IS INTENDED FOR THE ENZYMATIC CYCLING COLORIMETRIC DETERMINATION OF TOTAL BILE ACIDS IN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,CYSTATIN C (CYSTATIN C)-THE CYSTATIN C ASSAY IS INTENDED FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF CYSTATIN C IN SERUM OR PLASMA USING THE ARCHITECT C SYSTEMS.,ALINITY C CERULOPLASMIN REAGENT KIT(ALINITY C CERULOPLASMIN REAGENT KIT)-THE ALINITY C CERULOPLASMIN ASSAY IS USED FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF CERULOPLASMIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,CREATININE (ENZYMATIC) (CREATININE (ENZYMATIC))-THE CREATININE (ENZYMATIC) ASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA, AND URINE USING THE ARCHITECT C SYSTEMS.,ALINITY C FRUCTOSAMINE CALIBRATOR KIT(ALINITY C FRUCTOSAMINE CALIBRATOR KIT)-THE ALINITY C FRUCTOSAMINE CALIBRATOR KIT IS USED FOR THE CALIBRATION OF THE ALINITY C FRUCTOSAMINE ASSAY ON THE ALINITY C ANALYZER.,CYSTATIN C CALIBRATOR(CYSTATIN C CALIBRATOR)-CYSTATIN C CALIBRATOR IS

	USED FOR THE CALIBRATION OF THE CYSTATIN C ASSAY.,ALINITY C LAMBDA LIGHT CHAINS REAGENT KIT(ALINITY C LAMBDA LIGHT CHAINS REAGENT KIT)-THE ALINITY C LAMBDA LIGHT CHAINS ASSAY IS USED FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF THE BOUND AND FREE LAMBDA LIGHT CHAINS IN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,KAPPA LIGHT CHAINS(KAPPA LIGHT CHAINS)-THE KAPPA LIGHT CHAINS ASSAY IS INTENDED FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF THE BOUND AND FREE KAPPA LIGHT CHAINS IN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS. ,ALINITY C HBDH REAGENT KIT(ALINITY C HBDH REAGENT KIT)-THE ALINITY C HBDH ASSAY IS USED FOR THE KINETIC DETERMINATION OF -HYDROXYBUTYRATE DEHYDROGENASE (HBDH) ACCORDING TO THE DEUTSCHE GESELLSCHAFT FÜR KLINISCHE CHEMIE (DGKC) RECOMMENDATIONS IN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,UIBC LIQUID(UIBC LIQUID)-THE UIBC LIQUID ASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF UNSATURATED IRON-BINDING CAPACITY (UIBC) IN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY C KAPPA LIGHT CHAINS REAGENT KIT(ALINITY C KAPPA LIGHT CHAINS REAGENT KIT) -THE ALINITY C KAPPA LIGHT CHAINS ASSAY IS USED FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF THE BOUND AND FREE KAPPA LIGHT CHAINS IN SERUM AND PLASMA ON THE ALINITY C ANALYZER.,CK-MB CALIBRATORS(CK-MB CALIBRATORS)-CK-MB CALIBRATOR IS USED FOR THE CALIBRATION OF THE CK-MB ASSAY.,ALINITY C PANCREATIC AMYLASE REAGENT KIT(ALINITY C PANCREATIC AMYLASE REAGENT KIT)-THE ALINITY C PANCREATIC AMYLASE ASSAY IS USED FOR THE ENZYMATIC COLORIMETRIC DETERMINATION OF PANCREATIC AMYLASE ACCORDING TO THE IFCC METHOD OF DETERMINATION IN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,LAMBDA LIGHT CHAINS (LAMBDA LIGHT CHAINS)-THE LAMBDA LIGHT CHAINS ASSAY IS INTENDED FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF THE BOUND AND FREE LAMBDA LIGHT CHAINS IN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY C DIBUCAINE CHE REAGENT KIT(ALINITY C DIBUCAINE CHE REAGENT KIT)-THE ALINITY C DIBUCAINE CHE ASSAY IS INTENDED TO BE USED WITH THE ALINITY C CHOLINESTERASE (CHE) ASSAY FOR THE DETERMINATION OF THE DIBUCAINE NUMBER (DN) WITH BUTYRYLTHIOCHOLINE SUBSTRATE IN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,CK-MB CONTROLS(CK-MB CONTROLS)-CK-MB CONTROL MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF THE CK-MB ASSAY. ,ALINITY C CRP VARIO HIGH SENSITIVITY CALIBRATOR KIT(ALINITY C CRP VARIO HIGH SENSITIVITY

	CALIBRATOR KIT)-ALINITY C CRP VARIO HIGH SENSITIVITY CALIBRATOR KIT IS INTENDED FOR USE IN THE CALIBRATION OF THE ALINITY C CRP VARIO ASSAY, HIGH SENSITIVITY METHOD [CRP16], ON THE ALINITY C ANALYZER.,LITHIUM(LITHIUM)-THE LITHIUM ASSAY IS INTENDED FOR THE QUANTITATION OF LITHIUM IN SERUM OR PLASMA USING THE ARCHITECT C SYSTEMS.,ALINITY C CLINICAL CHEMISTRY CONTROL 2 KIT(ALINITY C CLINICAL CHEMISTRY CONTROL 2 KIT)-THE ALINITY C CLINICAL CHEMISTRY CONTROL 2 KIT IS USED TO VERIFY THE PERFORMANCE OF THE FOLLOWING ALINITY C ASSAYS: CHOLINESTERASE, CREATININE (ENZYMATIC), DIBUCAINE CHE, HBDH, IRON, LITHIUM, AND PANCREATIC AMYLASE., CLIN CHEM CONTROL 1(CLIN CHEM CONTROL 1)-CLIN CHEM CONTROL 1 IS USED TO VERIFY THE PERFORMANCE OF THE FOLLOWING MULTIGENT ASSAYS: CHOLINESTERASE (CHE), COPPER, CREATININE (ENZYMATIC), DIBUCAINE CHE (CHEDI), DIBUCAINE CHE (DIBCH), -HYDROXYBUTYRATE DEHYDROGENASE (AHBDH), IRON, LITHIUM, AND PANCREATIC AMYLASE. ,ALINITY C CLINICAL CHEMISTRY CONTROL 1 KIT(ALINITY C CLINICAL CHEMISTRY CONTROL 1 KIT)-THE ALINITY C CLINICAL CHEMISTRY CONTROL 1 KIT IS USED TO VERIFY THE PERFORMANCE OF THE FOLLOWING ALINITY C ASSAYS: CHOLINESTERASE, CREATININE (ENZYMATIC), DIBUCAINE CHE, HBDH, IRON, LITHIUM, AND PANCREATIC AMYLASE.,CERULOPLASMIN (CERULOPLASMIN)-THE CERULOPLASMIN ASSAY IS INTENDED FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF CERULOPLASMIN IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY C UIBC CALIBRATOR KIT(ALINITY C UIBC CALIBRATOR KIT)-THE ALINITY C UIBC CALIBRATOR IS USED FOR THE CALIBRATION OF THE ALINITY C UIBC ASSAY ON THE ALINITY C ANALYZER.,FRUCTOSAMINE CONTROL 2(FRUCTOSAMINE CONTROL 2)-THE FRUCTOSAMINE CONTROL 2 MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF FRUCTOSAMINE USING THE ARCHITECT CSYSTEMS ,ALINITY C CRP VARIO HS CONTROL KIT(ALINITY C CRP VARIO HS CONTROL KIT)-THE ALINITY C CRP VARIO HS CONTROL IS USED TO VERIFY THE PERFORMANCE OF THE ALINITY C CRP VARIO ASSAY, HIGH SENSITIVITY METHOD [CRP16], ON THE ALINITY C ANALYZER.,IMMUNO CONTROL 1(IMMUNO CONTROL 1)-IMMUNO CONTROL 1 AND IMMUNO CONTROL 2 MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF THE CERULOPLASMIN, CRP VARIO, KAPPA LIGHT CHAINS, AND MULTIGENT LAMBDA LIGHT CHAINS ASSAYS USING IMMUNOTURBIDIMETRIC METHODS.,ALINITY C CRP VARIO WIDE RANGE CALIBRATOR KIT(ALINITY C CRP VARIO WIDE RANGE CALIBRATOR KIT)-ALINITY C CRP VARIO WIDE RANGE CALIBRATOR KIT IS INTENDED FOR USE IN THE CALIBRATION OF THE ALINITY C CRP VARIO ASSAY, WIDE RANGE METHOD [CRP48], ON THE

	ALINITY C ANALYZER.,IRON(IRON)-THE IRON ASSAY IS INTENDED FOR THE DIRECT COLORIMETRIC DETERMINATION OF IRON WITHOUT DEPROTEINIZATION IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY C IMMUNO CONTROL 2 KIT(ALINITY C IMMUNO CONTROL 2 KIT)-THE ALINITY C IMMUNO CONTROL 1 KIT, ALINITY C IMMUNO CONTROL 2 KIT, AND THE ALINITY C IMMUNO CONTROL SET MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF THE ALINITY C CERULOPLASMIN, ALINITY C CRP VARIO, ALINITY C KAPPA LIGHT CHAINS, AND ALINITY C LAMBDA LIGHT CHAINS ASSAYS USING IMMUNOTURBIDIMETRIC METHODS., PLASMAPROTEINS CAL 3X(PLASMAPROTEINS CAL 3X)-CALIBRATOR FOR THE QUANTITATIVE DETERMINATION OF PLASMAPROTEINS. PLASMAPROTEINS CAL 3X MUST BE USED ONLY FOR THE CALIBRATION OF CERULOPLASMIN, KAPPA LIGHT CHAINS,AND LAMBDA LIGHT CHAINS USING IMMUNOTURBIDIMETRIC METHODS., ALINITY C CREATININE (ENZYMATIC) REAGENT KIT(ALINITY C CREATININE (ENZYMATIC) REAGENT KIT)-THE ALINITY C CREATININE (ENZYMATIC) ASSAY IS USED FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA, AND URINE ON THE ALINITY C ANALYZER.,FRUCTOSAMINE CONTROL 1 (FRUCTOSAMINE CONTROL 1)-THE FRUCTOSAMINE CONTROL 1 MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF FRUCTOSAMINE USING THE ARCHITECT CSYSTEMS. ,ALINITY C CRP VARIO REAGENT KIT(ALINITY C CRP VARIO REAGENT KIT)-THE ALINITY C CRP VARIO ASSAY IS USED FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM AND PLASMA WITH VARIABLE ASSAY RANGES [CRP16 AND CRP48] ON THE ALINITY C ANALYZER.,IMMUNO CONTROL 2(IMMUNO CONTROL 2)-IMMUNO CONTROL 1 AND IMMUNO CONTROL 2 MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF THE CERULOPLASMIN, CRP VARIO, KAPPA LIGHT CHAINS, AND MULTIGENT LAMBDA LIGHT CHAINS ASSAYS USING IMMUNOTURBIDIMETRIC METHODS.,ALINITY C IMMUNO CONTROL 1 KIT(ALINITY C IMMUNO CONTROL 1 KIT)-THE ALINITY C IMMUNO CONTROL 1 KIT, ALINITY C IMMUNO CONTROL 2 KIT, AND THE ALINITY C IMMUNO CONTROL SET MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF THE ALINITY C CERULOPLASMIN, ALINITY C CRP VARIO, ALINITY C KAPPA LIGHT CHAINS, AND ALINITY C LAMBDA LIGHT CHAINS ASSAYS USING IMMUNOTURBIDIMETRIC METHODS.,COPPER(COPPER)-THE COPPER ASSAY IS INTENDED FOR THE DIRECT COLORIMETRIC DETERMINATION OF COPPER WITHOUT DEPROTEINIZATION IN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY C PLASMAPROTEINS CAL 3X KIT(ALINITY C PLASMAPROTEINS CAL 3X KIT)-FOR THE QUANTITATIVE DETERMINATION OF PLASMAPROTEINS. THE ALINITY C

	PLASMAPROTEINS CAL 3X MUST BE USED ONLY FOR THE CALIBRATION OF THE ALINITY C CERULOPLASMIN, ALINITY C KAPPA LIGHT CHAINS, AND ALINITY C LAMBDA LIGHT CHAINS ASSAYS USING IMMUNOTURBIDIMETRIC METHODS ON THE ALINITY C ANALYZER.,IMMUNO CONTROL SET(IMMUNO CONTROL SET)-IMMUNO CONTROL SET MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF THE CERULOPLASMIN, CRP VARIO, KAPPA LIGHT CHAINS, AND MULTIGENT LAMBDA LIGHT CHAINS ASSAYS USING IMMUNOTURBIDIMETRIC METHODS.,ALINITY C IMMUNO CONTROL SET(ALINITY C IMMUNO CONTROL SET)-THE ALINITY C IMMUNO CONTROL 1 KIT, ALINITY C IMMUNO CONTROL 2 KIT, AND THE ALINITY C IMMUNO CONTROL SET MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF THE ALINITY C CERULOPLASMIN, ALINITY C CRP VARIO, ALINITY C KAPPA LIGHT CHAINS, AND ALINITY C LAMBDA LIGHT CHAINS ASSAYS USING IMMUNOTURBIDIMETRIC METHODS., DIBUCAINE CHE(DIBUCAINE CHE)-THE DIBUCAINE CHE ASSAY IS USED WITH THE CHOLINESTERASE (CHE) ASSAY FOR THE DETERMINATION OF THE DIBUCAINE NUMBER (DN) WITH THE BUTYRYLTHIOCHOLINE SUBSTRATE IN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY C CLINICAL CHEMISTRY CALIBRATOR KIT(ALINITY C CLINICAL CHEMISTRY CALIBRATOR KIT)-THE ALINITY C CLINICAL CHEMISTRY CALIBRATOR KIT IS USED FOR THE CALIBRATION OF THE ALINITY C CHOLINESTERASE, CREATININE (ENZYMATIC), DIBUCAINE CHE, HBDH, LITHIUM, AND PANCREATIC AMYLASE ASSAYS ON THE ALINITY C ANALYZER.,AMMONIA CONTROLS(AMMONIA CONTROLS)-THE AMMONIA CONTROLS MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF THE AMMONIA ULTRA ASSAY.,ALINITY C UIBC REAGENT KIT(ALINITY C UIBC REAGENT KIT)-THE ALINITY C UIBC ASSAY IS USED FOR THE QUANTITATIVE DETERMINATION OF UNSATURATED IRON-BINDING CAPACITY (UIBC) IN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,HBDH(HBDH)-THE MULTIGENT HBDH ASSAY IS INTENDED FOR THE KINETIC DETERMINATION OF -HYDROXYBUTYRATE DEHYDROGENASE (HBDH) ACCORDING TO THE DEUTSCHE GESELLSCHAFT FUR KLINISCHE CHEMIE (DGKC) RECOMMENDATIONS IN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY C IRON REAGENT KIT(ALINITY C IRON REAGENT KIT)-THE ALINITY C IRON ASSAY IS USED FOR THE DIRECT COLORIMETRIC DETERMINATION OF IRON WITHOUT DEPROTEINIZATION IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,TOTAL BILE ACIDS (TOTAL BILE ACIDS)-THE TOTAL BILE ACIDS ASSAY IS INTENDED FOR THE ENZYMATIC CYCLING COLORIMETRIC DETERMINATION OF TOTAL BILE ACIDS IN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,AMMONIA ULTRA(AMMONIA ULTRA)-THE MULTIGENT

	AMMONIA ULTRA ASSAY IS INTENDED FOR THE QUANTITATIVE ENZYMATIC DETERMINATION OF AMMONIA IN HUMAN PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY C LITHIUM REAGENT KIT (ALINITY C LITHIUM REAGENT KIT)-THE ALINITY C LITHIUM ASSAY IS USED FOR THE QUANTITATION OF LITHIUM IN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,CRP CONTROL HS(CRP CONTROL HS)-CRP CONTROL HS IS USED TO VERIFY THE PERFORMANCE OF CRP VARIO ASSAY, HIGH SENSITIVITY METHOD,ALINITY C AMMONIA ULTRA REAGENT KIT(ALINITY C AMMONIA ULTRA REAGENT KIT)-THE ALINITY C AMMONIA ULTRA ASSAY IS USED FOR THE QUANTITATIVE ENZYMATIC DETERMINATION OF AMMONIA IN HUMAN PLASMA ON THE ALINITY C ANALYZER.,CRP CALIBRATOR WR(CRP CALIBRATOR WR)-FOR USE WITH CRP CALIBRATOR SET TO CALIBRATE CRP VARIO ASSAY, WIDE RANGE METHOD,CHOLINESTERASE(CHOLINESTERASE)-KINETIC COLORIMETRIC ASSAY FOR THE DETERMINATION OF CHOLINESTERASE IN SERUM AND PLASMA ACCORDING TO THE DGKC (DEUTSCHE GESELLSCHAFT FÜR KLINISCHE CHEMIE) RECOMMENDATIONS,CRP CALIBRATOR SET(CRP CALIBRATOR SET)-FOR USE IN THE CALIBRATION OF CRP VARIO ASSAY.,ALINITY C AMMONIA CONTROLS(ALINITY C AMMONIA CONTROLS)-THE ALINITY C AMMONIA CONTROLS MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF THE ALINITY C AMMONIA ULTRA ASSAY ON THE ALINITY C ANALYZER.,BILE ACIDS CONTROLS(BILE ACIDS CONTROLS)-THE BILE ACIDS CONTROLS MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF BILE ACIDS USING THE ARCHITECT C SYSTEMS.,CK-MB(CK-MB)-THE CK-MB ASSAY IS INTENDED FOR THE KINETIC DETERMINATION OF THE CK-MB AND CK-BB ISOENZYMES OF CREATINE KINASE IN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS. ,FRUCTOSAMINE(FRUCTOSAMINE)-THE FRUCTOSAMINE ASSAY IS INTENDED FOR THE KINETIC COLORIMETRIC DETERMINATION OF FRUCTOSAMINE IN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,LIPASE NG OC CTRL 1(LIPASE NG OC CTRL 1)-LIPASE NG OC CTRL 1 MUST BE USED ONLY TO VERIFY THE PERFORMANCE OF THE LIPASE NG.

258	IMP/IVD/2019/000248	1.License Holder Name: DHR HOLDING INDIA PVT. LTD, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AUTOCHECK6+ (AUTOCHECK6+)-THIS AUTOCHECK6+ SOLUTION IS AN ASSAYED QUALITY CONTROL SYSTEM FOR EVALUATING THE QUALITY AND PRECISION OF ALL PARAMETERS LISTED ON THE INSERT SPECIFYING THE CONTROL RANGES. FOR PROFESSIONAL USE.,S1830 CALIBRATION SOLUTION 2(CALIBRATION SOLUTION 2)-FOR CALIBRATION OF PH AND ELECTROLYTE ELECTRODES IN THE ABL800 FLEX ANALYZERS.,AUTOCHECK5+(AUTOCHECK5+)-AUTOCHECK IS AN ASSAYED QUALITY CONTROL SYSTEM FOR EVALUATING THE ACCURACY AND PRECISION OF ALL PARAMETERS LISTED ON THE INSERT SPECIFYING THE CONTROL RANGES. FOR PROFESSIONAL USE.,S4980 RINSE SOLUTION(S4980 RINSE SOLUTION (ABL800))-FOR AUTOMATIC RINSE OF THE MEASURING SYSTEM IN THE ABL800 FLEX ANALYZERS. ,CLEANING SOLUTION WITH ADDITIVE, ABL8XX(CLEANING SOLUTION WITH ADDITIVE, ABL8XX)-FOR CLEANING THE MEASURING SYSTEM OF THE ABL800 SERIES ANALYZERS,AQT90 FLEX SOLUTION PACK(AQT90 SOLUTION PACK)-FOR IN VITRO DIAGNOSTIC USE THE ASSAY BUFFER IN THE SOLUTION PACK IS USED FOR THE OPERATION OF THE AQT90 FLEX ANALYZER. THE PACK ALSO RECEIVES THE DISCARDED CUPS AND LIQUID WASTE. THE SOLUTION PACK IS USED IN CONJUNCTION WITH ANY OF THE TEST KITS AND CONTAINS SUFFICIENT BUFFER FOR UP TO 200 TESTS. ,ABL90 FLEX SOLUTION PACK-SP90 XL(ABL90 FLEX SOLUTION PACK-SP90 XL)-FOR CALIBRATION OF SENSORS, QUALITY CONTROL, EVALUATION OF ACCURACY AND PRECISION, RINSE OF MEASURING SYSTEM AND COLLECTION OF WASTE FROM THE ABL90 FLEX AND ABL90 FLEX PLUS ANALYZERS.,E788 ELECTRODE FOR ABL ANALYZERS – PCO2(ELECTRODE FOR ABL ANALYZERS)-IS USED IN THE ABL700 SERIES AND ABL800 FLEX ANALYZERS ,S1820 CALIBRATION SOLUTION 1(S1820 CALIBRATION SOLUTION 1 (ABL800))-FOR CALIBRATION OF PH, ELECTROLYTE AND METABOLITE ELECTRODES IN THE ABL800 FLEX ANALYZERS,E8088 CREA A ELECTRODE(ELECTRODE FOR ABL ANALYZERS)-IN THE ABL837/827/817 FLEX ANALYZERS,S4987 RINSE SOLUTION II(S4987 RINSE SOLUTION II)-FOR AUTOMATIC RINSE OF THE MEASURING SYSTEM IN THE ABL837/827/817 FLEX ANALYZERS ,AUTOCHECK5+ (S7755 AUTOCHECK5+ – LEVEL 3)-AUTOCHECK IS AN ASSAYED QUALITY CONTROL SYSTEM FOR EVALUATING THE ACCURACY AND PRECISION OF ALL PARAMETERS LISTED ON THE INSERT SPECIFYING THE CONTROL RANGES. FOR PROFESSIONAL USE. ,S8377 CLEANING METABOLITE II(S8377 CLEANING METABOLITE II)-FOR CLEANING THE MEASURING SYSTEM OF THE ABL837/827/817 FLEX ANALYZERS AND

	FOR CHECKING HIGH CREATININE LEVEL. ,E744 ELECTRODE FOR ABL ANALYZERS – CL–(ELECTRODE FOR ABL ANALYZERS)-IS USED IN THE ABL700 SERIES AND ABL800 FLEX ANALYZERS ,E777 ELECTRODE FOR ABL ANALYZERS – PH(ELECTRODE FOR ABL ANALYZERS)-IS USED IN THE ABL700 SERIES AND ABL800 FLEX ANALYZERS ,E755 ELECTRODE FOR ABL ANALYZERS – NA+ (ELECTRODE FOR ABL ANALYZERS)-IS USED IN THE ABL700 SERIES AND ABL800 FLEX ANALYZERS ,E7066 ELECTRODE FOR ABL ANALYZERS – GLUCOSE(ELECTRODE FOR ABL ANALYZERS)-IS USED IN THE ABL700 SERIES AND ABL800 FLEX ANALYZERS , AUTOCHECK5+ (S7745 AUTOCHECK5+ – LEVEL 2)-AUTOCHECK IS AN ASSAYED QUALITY CONTROL SYSTEM FOR EVALUATING THE ACCURACY AND PRECISION OF ALL PARAMETERS LISTED ON THE INSERT SPECIFYING THE CONTROL RANGES. FOR PROFESSIONAL USE. ,E733 ELECTRODE FOR ABL ANALYZERS – CA2+(ELECTRODE FOR ABL ANALYZERS)-IS USED IN THE ABL700 SERIES AND ABL800 FLEX ANALYZERS ,E8089 CREA B ELECTRODE(ELECTRODE FOR ABL ANALYZERS)-IN THE ABL837/827/817 FLEX ANALYZERS,E799 ELECTRODE FOR ABL ANALYZERS – PO2(ELECTRODE FOR ABL ANALYZERS)-IS USED IN THE ABL700 SERIES AND ABL800 FLEX ANALYZERS ,E722 ELECTRODE FOR ABL ANALLYZERS – K+ (ELECTRODE FOR ABL ANALYZERS)-IS USED IN THE ABL700 SERIES AND ABL800 FLEX ANALYZERS ,S1837 CALIBRATION SOLUTION 2 (S1837 CALIBRATION SOLUTION 2)-FOR CLEANING THE MEASURING SYSTEM OF THE ABL837/827/817 FLEX ANALYZERS AND FOR CHECKING HIGH CREATININE LEVEL. ,E1001 REFERENCE ELECTRODE FOR ABL ANALYZERS – REF(ELECTRODE FOR ABL ANALYZERS)-IS USED IN THE ABL700 SERIES AND THE ABL800 FLEX ANALYZERS , AUTOCHECK5+ (S7735 AUTOCHECK5+ – LEVEL 1)-AUTOCHECK IS AN ASSAYED QUALITY CONTROL SYSTEM FOR EVALUATING THE ACCURACY AND PRECISION OF ALL PARAMETERS LISTED ON THE INSERT SPECIFYING THE CONTROL RANGES. FOR PROFESSIONAL USE. ,E7077 ELECTRODE FOR ABL ANALYZERS – LACTATE (ELECTRODE FOR ABL ANALYZERS)-IS USED IN THE ABL700 SERIES AND ABL800 FLEX ANALYZERS ,S1827 CALIBRATION SOLUTION 1 (S1827 CALIBRATION SOLUTION 1)-FOR CALIBRATION OF PH, ELECTROLYTE AND METABOLITE ELECTRODES IN THE ABL837/827/817 FLEX ANALYZERS ,ABL90 FLEX SOLUTION PACK SP90(ABL90 FLEX SP90)-FOR CALIBRATION OF SENSORS, QUALITY CONTROL, EVALUATION OF ACCURACY AND PRECISION, RINSE OF MEASURING SYSTEM AND COLLECTION OF WASTE FROM THE ABL90 FLEX AND ABL90 FLEX PLUS ANALYZERS. ,CLEANING SOLUTION WITH ADDITIVE, ABL8XX(CLEANING SOLUTION WITH ADDITIVE, ABL8XX)-FOR CLEANING THE MEASURING SYSTEM OF THE ABL800

	SERIES ANALYZERS.

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259	IMP/IVD/2019/000249	1.License Holder Name: DHR HOLDING INDIA PVT. LTD, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:D7066 MEMBRANE BOX FOR E7066 ELECTRODE – GLU(D7066 MEMBRANE BOX FOR E7066 ELECTRODE – GLU)-D7066 MEMBRANE BOX FOR GLUCOSE ELECTRODE. 4 PREMEMBRANED ELECTRODE JACKETS EACH FILLED WITH ELECTROLYTE SOLUTION. FOR IN VITRO DIAGNOSTIC USE ONLY.,AUTOCHECK6+ (AUTOCHECK6+)-THIS AUTOCHECK6+ SOLUTION IS AN ASSAYED QUALITY CONTROL SYSTEM FOR EVALUATING THE ACCURACY AND PRECISION OF ALL PARAMETERS LISTED ON THE INSERT SPECIFYING THE CONTROL RANGES. FOR PROFESSIONAL USE,D788 MEMBRANE BOX FOR E788 ELECTRODE – PCO2(D788 MEMBRANE BOX FOR E788 ELECTRODE – PCO2)-D788 MEMBRANE BOX FOR PCO2 ELECTRODE. 4 PREMEMBRANED ELECTRODE JACKETS EACH FILLED WITH ELECTROLYTE SOLUTION. FOR IN VITRO DIAGNOSTIC USE ONLY. ,S4980 RINSE SOLUTION (S4980 RINSE SOLUTION)-FOR AUTOMATIC RINSE OF THE MEASURING SYSTEM IN THE ABL800 FLEX ANALYZERS.,D799 MEMBRANE BOX FOR E799 ELECTRODE – PO2(D799 MEMBRANE BOX FOR E799 ELECTRODE – PO2)-D799 MEMBRANE BOX FOR PO2 ELECTRODE. 4 PREMEMBRANED ELECTRODE JACKETS EACH FILLED WITH ELECTROLYTE SOLUTION. FOR IN VITRO DIAGNOSTIC USE ONLY. ,S1820 CALIBRATION SOLUTION 1(S1820 CALIBRATION SOLUTION 1)-FOR CALIBRATION OF PH, ELECTROLYTE AND METABOLITE ELECTRODES IN THE ABL800 FLEX ANALYZERS ,S5362 HYPOCHLORITE SOLUTION(S5362 HYPOCHLORITE SOLUTION)-HYPOCHLORITE SOLUTION IS INTENDED FOR PROTEIN REMOVAL AND DECONTAMINATION.,ABL90 FLEX SOLUTION PACK SP90(ABL90 FLEX SOLUTION PACK SP90)-FOR CALIBRATION OF SENSORS, QUALITY CONTROL, EVALUATION OF ACCURACY AND PRECISION, RINSE OF MEASURING SYSTEM AND COLLECTION OF WASTE FROM THE ABL90 FLEX AND ABL90 FLEX PLUS ANALYZERS.,D744 MEMBRANE BOX FOR E744 ELECTRODE – CL–(D744 MEMBRANE BOX FOR E744 ELECTRODE – CL–)-D744 MEMBRANE BOX FOR CL- ELECTRODE. 4 PREMEMBRANED ELECTRODE JACKETS EACH FILLED WITH ELECTROLYTE SOLUTION. FOR IN VITRO DIAGNOSTIC USE ONLY. ,S1837 CALIBRATION SOLUTION 2(S1837 CALIBRATION SOLUTION 2)-FOR CLEANING THE MEASURING SYSTEM OF THE ABL837/827/817 FLEX ANALYZERS AND FOR CHECKING HIGH CREATININE LEVEL.,D733 MEMBRANE BOX FOR E733 ELECTRODE – CA2+(D733 MEMBRANE BOX FOR E733 ELECTRODE – CA2+)-D733 MEMBRANE BOX FOR CA2+ ELECTRODE. 4 PREMEMBRANED ELECTRODE JACKETS EACH FILLED WITH ELECTROLYTE SOLUTION. FOR IN VITRO DIAGNOSTIC USE ONLY. ,S1830 CALIBRATION

	SOLUTION 2(S1830 CALIBRATION SOLUTION 2)-FOR CALIBRATION OF PH AND ELECTROLYTE ELECTRODES IN THE ABL800 FLEX ANALYZERS.,D722 MEMBRANE BOX FOR E722 ELECTRODE – K+(D722 MEMBRANE BOX FOR E722 ELECTRODE – K+)-D722 MEMBRANE BOX FOR K+ ELECTRODE. 4 PREMEMBRANED ELECTRODE JACKETS EACH FILLED WITH ELECTROLYTE SOLUTION. FOR IN VITRO DIAGNOSTIC USE ONLY. ,S7570 HIGH METABOLITE QUALICHECK – LEVEL 1(S7570 HIGH METABOLITE QUALICHECK – LEVEL 1)-THIS HIGH METABOLITE QUALICHECK SOLUTION IS AN ASSAYED QUALITY CONTROL SYSTEM FOR EVALUATING THE ACCURACY AND PRECISION OF ALL PARAMETERS LISTED ON THE INSERT SPECIFYING THE CONTROL RANGES. ANALYTES ARE: PO2, CTHB, CGLUCOSE, CLACTATE AND CTBIL. ,D755 MEMBRANE BOX FOR E755 ELECTRODE – NA+(D755 MEMBRANE BOX FOR E755 ELECTRODE – NA+)-D755 MEMBRANE BOX FOR NA+ ELECTRODE. 4 PREMEMBRANED ELECTRODE JACKETS EACH FILLED WITH ELECTROLYTE SOLUTION. FOR IN VITRO DIAGNOSTIC USE ONLY. ,RANGE+ QUALICHECK (RANGE+ QUALICHECK)-FOR IN VITRO DIAGNOSTIC USE. THIS RANGE+ QUALICHECK SOLUTION IS AN ASSAYED QUALITY CONTROL SYSTEM FOR EVALUATING THE ACCURACY AND PRECISION OF ALL PARAMETERS LISTED ON THE INSERT SPECIFYING THE CONTROL RANGES. ANALYTES ARE: PH, PCO2, PO2, CTHB, SO2, FO2HB, FCOHB, FMETHB, FHBF, CK+, CNA+, CCA2+, CCL–, CGLU, CLAC, CTBIL.,D7077 MEMBRANE BOX FOR E7077 ELECTRODE – LAC(D7077 MEMBRANE BOX FOR E7077 ELECTRODE – LAC)-D7077 MEMBRANE BOX FOR LACTATE ELECTRODE. 4 PREMEMBRANED ELECTRODE JACKETS EACH FILLED WITH ELECTROLYTE SOLUTION. FOR IN VITRO DIAGNOSTIC USE ONLY. ,CLEANING SOLUTION WITH ADDITIVE, ABL8XX(CLEANING SOLUTION WITH ADDITIVE, ABL8XX)-FOR CLEANING THE MEASURING SYSTEM OF THE ABL800 SERIES ANALYZERS,AQT90 FLEX CLEANING TUBE SOLUTION(CLEANING SOLUTION TUBES (BOX OF 6 TUBES))-FOR IN VITRO DIAGNOSTIC USE. FOR CLEANING THE SAMPLE-HANDLING PART OF THE LIQUID-TRANSPORT SYSTEM OF THE AQT90 FLEX ANALYZER., QUALICHECK5+ (QUALICHECK5+)-FOR IN VITRO DIAGNOSTIC USE. THIS QUALICHECK+ SOLUTION IS AN ASSAYED QUALITY CONTROL SYSTEM FOR EVALUATING THE ACCURACY AND PRECISION OF ALL PARAMETERS LISTED ON THE INSERT SPECIFYING THE CONTROL RANGES. FOR PROFESSIONAL USE.,SENSOR CASSETTE PACK (SC90) (ABL90 SENSOR CASSETTE PACK)-SENSOR CASSETTE FOR THE ABL90 FLEX ANALYZER FOR MEASURING THE PARAMETERS INDICATED ON THE SENSOR CASSETTE.,S1827 CALIBRATION SOLUTION 1(S1827 CALIBRATION SOLUTION 1)-FOR CALIBRATION OF PH, ELECTROLYTE AND METABOLITE ELECTRODES IN THE

	ABL837/827/817 FLEX ANALYZERS,SENSOR CASSETTE PACK (SC90)(ABL90 SENSOR CASSETTE PACK)-SENSOR CASSETTE FOR THE ABL90 FLEX ANALYZER FOR MEASURING THE PARAMETERS INDICATED ON THE SENSOR CASSETTE.,QUALICHECK4+ (QUALICHECK4+)-FOR IN VITRO DIAGNOSTIC USE. THIS QUALICHECK+ SOLUTION IS AN ASSAYED QUALITY CONTROL SYSTEM FOR EVALUATING THE ACCURACY AND PRECISION OF ALL PARAMETERS LISTED ON THE INSERT SPECIFYING THE CONTROL RANGES. FOR PROFESSIONAL USE.,SENSOR CASSETTE PACK (SC90)(ABL90 SENSOR CASSETTE PACK)-SENSOR CASSETTE FOR THE ABL90 FLEX ANALYZER FOR MEASURING THE PARAMETERS INDICATED ON THE SENSOR CASSETTE.,HEMATOCRIT AND METABOLITE QUALICHECK(HEMATOCRIT AND METABOLITE QUALICHECK)-THIS HEMATOCRIT AND METABOLITE QUALICHECK SOLUTION IS AN ASSAYED QUALITY CONTROL SYSTEM FOR EVALUATING THE ACCURACY AND PRECISION OF ALL PARAMETERS LISTED ON THE INSERT SPECIFYING THE CONTROL RANGES. ,ABL800 FLEX CREA A + B MEMBRANE UNITS(D8088+D8089 CREA MEMBRANE A+B)-MEMBRANE BOX FOR CREA A AND CREA B ELECTRODES D8088 AND D8089 2 CREA A AND 2 CREA B PREMEMBRANED ELECTRODE JACKETS AND 4 CAPSULES OF ELECTROLYTE SOLUTIONS. FOR IN VITRO DIAGNOSTIC USE ONLY. ,S8377 CLEANING METABOLITE II (S8377 CLEANING METABOLITE II)-FOR CLEANING THE MEASURING SYSTEM OF THE ABL837/827/817 FLEX ANALYZERS AND FOR CHECKING HIGH CREATININE LEVEL.,QUALICHECK4+ (S7440 QUALICHECK4+ – LEVEL 2)-FOR IN VITRO DIAGNOSTIC USE. THIS QUALICHECK+ SOLUTION IS AN ASSAYED QUALITY CONTROL SYSTEM FOR EVALUATING THE ACCURACY AND PRECISION OF ALL PARAMETERS LISTED ON THE INSERT SPECIFYING THE CONTROL RANGES. FOR PROFESSIONAL USE. ,AUTOCHECK5+ (AUTOCHECK5+) -AUTOCHECK IS AN ASSAYED QUALITY CONTROL SYSTEM FOR EVALUATING THE ACCURACY AND PRECISION OF ALL PARAMETERS LISTED ON THE INSERT SPECIFYING THE CONTROL RANGES. FOR PROFESSIONAL USE.,S7770 CTHB CALIBRATION SOLUTION FOR ABL700 SERIES(S7770 CTHB CALIBRATION SOLUTION FOR ABL700 SERIES)-CALIBRATION SOLUTION FOR THE OXIMETRY MODULE OF THE ABL700 SERIES, ABL800 FLEX, ABL800 BASIC, ABL80 FLEX CO-OX, THE ABL90 FLEX AND ABL90 FLEX PLUS ANALYZERS. FOR IN VITRO DIAGNOSTIC USE. ,S4987 RINSE SOLUTION II(S4987 RINSE SOLUTION II)-FOR AUTOMATIC RINSE OF THE MEASURING SYSTEM IN THE ABL837/827/817 FLEX ANALYZERS ,SENSOR CASSETTE PACK (SC90)(ABL90 SENSOR CASSETTE PACK)-SENSOR CASSETTE FOR THE ABL90 FLEX ANALYZER FOR MEASURING THE PARAMETERS INDICATED ON THE SENSOR CASSETTE.,D711 MEMBRANE BOX FOR

		E1001 ELECTRODE – REF(D711 MEMBRANE BOX FOR E1001 ELECTRODE – REF)-D711 MEMBRANE BOX FOR REFERENCE ELECTRODE. 4 PREMEMBRANED ELECTRODE JACKETS EACH FILLED WITH ELECTROLYTE SOLUTION. FOR IN VITRO DIAGNOSTIC USE ONLY.
260	IMP/IVD/2019/000250	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RAPID CHEM 744/754 ANALYZER DAILY CLEANING SOLUTION(RAPID CHEM 744/754 ANALYZER DAILY CLEANING SOLUTION)-FOR CLEANING FLUID PATHS TO REMOVE TO REMOVE PROTEIN IN DEPOSITS IN THE RAPIDCHEM ANALYZERS,RAPID CHEM DAILY CLEANING SOLUTION KIT(RAPID CHEM DAILY CLEANING SOLUTION KIT)-USED AS A CALIBRANT FOR CALIBRATION OF RAPIDCHEM CLINICAL LABORATORY ANALYZERS,RAPID CHEM 754 NA+/K+/CL- REAGENT MODULE(RAPID CHEM 754 NA+/K+/CL- REAGENT MODULE)-USED AS A CALIBRANT FOR CALIBRATION OF RAPIDCHEM 700 CLINICAL LABORATORY ANALYZERS,RAPID CHEM TROUBLE SHOOTING KIT (RAPID CHEM TROUBLE SHOOTING KIT)-FOR TROUBLE SHOOTING OPERATIONS TO HELP DIAGNOSE AND CORRECT TECHNICAL PROBLEM IN THE ANALYZERS,RAPID CHEM 744 NA+/K+/CL- REAGENT MODULE(RAPID CHEM 744 NA+/K+/CL- REAGENT MODULE)-USED AS A CALIBRANT FOR CALIBRATION OF RAPIDCHEM 700 CLINICAL LABORATORY ANALYZERS,RAPID CHEM 744/754 ANALYZER URINE DILUENT(RAPID CHEM 744/754 ANALYZER URINE DILUENT)-FOR DILUTION OF URINE SAMPLES FOR IN-VITRO DIAGNOSTICS USE FOR RAPIDCHEM ANALYZER SYSTEM

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

261	IMP/IVD/2019/000255	1.License Holder Name: SYSMEX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CN-COAGWASHER(CN-COAGWASHER)-FOR IN VITRO DIAGNOSTIC USE ONLY, THIS PRODUCT IS USED TO CLEAN THE PIPETTES ON THE CN-SERIES FULLY AUTOMATED BLOOD COAGULATION ANALYZER,FLUOROCELL WPC (FLUOROCELL WPC)-FLUOROCELL WPC IS TO BE USED TO LABEL THE LEUKOCYTES IN DILUTED AND LYSED BLOOD SAMPLES FOR DETECTION OF VARIOUS IMMATURE CELLS IN BLOOD WITH SYSMEX AUTOMATED HEMATOLOGY ANALYZERS.,RET SEARCH (II)(RET SEARCH (II))-FOR IN VITRO DIAGNOSTIC USE ONLY. RET-SEARCH() IS TO BE USED TO DILUTE THE SAMPLE WHILE SIMULTANEOUSLY STAINING THE RETICULOCYTES FOR THE ASSAY OF RETICULOCYTE COUNT AND RETICULOCYTE PERCENT IN BLOOD WITH SELECTED SYSMEX AUTOMATED HEMATOLOGY ANALYSERS. RET-SEARCH() IS A PRE-PACKAGED REAGENT KIT CONSISTING OF RET-SEARCH() DILUENT BUFFER AND RET-SEARCH()DYE.,STROMATOLYSER-NR (STROMATOLYSER-NR)-FOR IN VITRO DIAGNOSTIC USE ONLY. STROMATOLYSER-NR IS TO BE USED TO DILUTE THE SAMPLE WHILE SIMULTANEOUSLY STAINING THE NUCLEATED CELLS FOR THE ASSAY OF NRBC COUNT AND NRBC PERCENT IN BLOOD WITH SELECTED SYSMEX AUTOMATED HEMATOLOGY ANALYSERS. STROMATOLYSER-NR IS A PRE-PACKAGED REAGENT KIT CONSISTING OF STROMATOLYSER-NR LYSING REAGENT BUFFER AND STROMATOLYSER-NR DYE.,STROMATOLYSER-WH(STROMATOLYSER-WH)-STROMATOLYSER-WH IS A REAGENT THAT LYSES RBC FOR ACCURATE WBC COUNT DETERMINATION, WBC TRI-MODAL SIZE DISTRIBUTION ANALYSIS AND HEMOGLOBIN LEVEL MEASUREMENT. THE REAGENT IS COLORLESS TRANSPARENT AND CONTAINS NO CYANIDE OR AZIDE COMPOUND. IT IS INTENDED FOR USE IN CONJUNCTION WITH SELECTED SYSMEX AUTOMATED HEMATOLOGY ANALYZER.,WASH SOLUTION NO. 3(WASH SOLUTION NO. 3)-FOR IN VITRO DIAGNOSTIC USE ONLY. WASH SOLUTION NO. 3 IS A WASH SOLUTION FOR AUTOMATED CLINICAL CHEMISTRY ANALYZER, BX SERIES,LYSERCELL WNR(LYSERCELL WNR)-FOR IN VITRO DIAGNOSTIC USE ONLY. LYSERCELL WNR IS A REAGENT PRODUCT TO BE COMBINED AND USED WITH FLUOROCELL WNR. BY HEMOLYZING RED BLOOD CELLS WITH LYSERCELL WNR AND BY DIFFERENTIATING WHITE BLOOD CELLS (NON-BASOPHIL), BASOPHILS, AND NUCLEATED RED BLOOD CELLS WITH LYSERCELL WNR AND FLUOROCELL WNR, THE WHITE BLOOD CELL COUNT, BASOPHIL COUNT, BASOPHIL PERCENTAGE, NUCLEATED RED BLOOD CELL COUNT, AND NUCLEATED RED BLOOD CELL PERCENTAGE ARE ANALYZED. THIS REAGENT IS TO BE USED BY CONNECTING TO AN

	AUTOMATIC HEMATOLOGY ANALYZER SPECIFIED BY SYSMEX.,LATEX PARTICLE-R(LATEX PARTICLE-R)-LATEX PARTICLE-R IS INTENDED FOR IN VITRO DIAGNOSTIC USE TO ESTABLISH THE OPTICAL AXIS ALIGNMENT FOR THE OPTICAL UNIT OF THE RETICULOCYTE ANALYZER,UFII SEARCH-SED(UFII SEARCH-SED)-UF SEARCH -SED IS TO BE USED TO STAIN FORMED ELEMENTS IN URINE FOR DETERMINATION OF THEIR COUNTS WITH THE SYSMEX FULLY AUTOMATED URINE PARTICLE ANALYZER (UF-1000I AND UF-500I)., UF-CELLSHEATH(UF-CELLSHEATH)-FOR IN VITRO DIAGNOSTIC USE ONLY. UF-CELLSHEATH IS A SHEATH FLUID FOR SYSMEX FULLY AUTOMATED URINE PARTICLE ANALYZERS. THIS REAGENT IS USED IN COMBINATION WITH OTHER REAGENTS TO OBTAIN A COUNT OF THE TARGET SUBSTANCE BY MEANS OF THE FLOW CYTOMETRY METHOD.,CELLPACK DCL(CELLPACK DCL)-WHOLE BLOOD DILUENT FOR USE IN HEMATOLOGY ANALYZERS.,FLUOROCELL WNR (FLUOROCELL WNR)-FLUOROCELL WNR IS TO BE USED TO LABEL THE NUCLEATED CELLS IN DILUTED AND LYSED BLOOD SAMPLES FOR DETERMINATION OF WHITE BLOOD CELL COUNT, NUCLEATED RED BLOOD CELL COUNT AND BASOPHIL COUNT IN BLOOD WITH SYSMEX AUTOMATED HEMATOLOGY ANALYZERS,LYSERCELL WPC (LYSERCELL WPC)- A LYING REAGENT FOR HEMATOLOGY ANALYZERS.,UXII SEARCH-SED(UXII SEARCH-SED)-UX SEARCH -SED IS TO BE USED TO STAIN FORMED ELEMENTS IN URINE FOR DETERMINATION OF THEIR COUNTS WITH THE SYSMEX FULLY AUTOMATED INTEGRATED URINE ANALYZER (UX-2000).,UFII PACK-BAC(UFII PACK-BAC)-A DILUENT FOR FULLY AUTOMATED URINE PARTICLE ANALYZER.,CELLSHEATH(CELLSHEATH)-ELECTROLYTIC SHEATH SOLUTION FOR USE IN HEMATOLOGY ANALYZERS,WASH SOLUTION C-1(WASH SOLUTION C-1)-FOR IN-VITRO DIAGNOSTIC USE ONLY. WASH SOLUTION C-1 IS A WASH SOLUTION FOR AUTOMATED CLINICAL CHEMISTRY ANALYZER, BX SERIES,LYSERCELL WDF (LYSERCELL WDF)-A LYSING REAGENT FOR HEMATOLOGY ANALYZER. FOR IN VITRO DIAGNOSTIC USE ONLY. LYSERCELL WDF IS A REAGENT USED IN COMBINATION WITH FLUOROCELL WDF. BY HEMOLYZING RED BLOOD CELLS WITH LYSERCELL WDF AND DYEING THE WHITE BLOOD CELL COMPONENTS WITH FLUOROCELL WDF, THE COUNTS AND PERCENTAGES OF NEUTROPHILS, LYMPHOCYTES, MONOCYTES, EOSINOPHILS, AND BASOPHILS ARE ANALYZED. THIS REAGENT IS TO BE USED BY CONNECTING TO AN AUTOMATED HEMATOLOGY ANALYZER SPECIFIED BY SYSMEX.,UF-CELLPACK SF (UF-CELLPACK SF)-FOR IN VITRO DIAGNOSTIC USE ONLY. UF-CELLPACK SF IS A DILUENT FOR SYSMEX FULLY AUTOMATED URINE PARTICLE ANALYZERS AND IS INTENDED FOR USE ONLY IN CONJUNCTION WITH UF-FLUOROCELL SF. UF-CELLPACK SF IS USED

	TO MARK FORMED ELEMENTS IN URINE (OR IN BODY FLUID (CEREBROSPINAL FLUID, ETC.) FOR DETERMINATION OF NON-NUCLEATED SPECIMENS (RED BLOOD CELLS, CASTS, ETC.).,UF-CELLPACK CR(UF-CELLPACK CR)-FOR IN VITRO DIAGNOSTIC USE ONLY UF-CELLPACK CR IS A DILUENT FOR SYSMEX FULLY AUTOMATED URINE PARTICLE ANALYZERS AND IS INTENDED FOR USE ONLY IN CONJUNCTION WITH UF-FLUOROCELL CR. UF-CELLPACK CR IS USED TO MARK FORMED ELEMENTS IN URINE (OR IN BODY FLUID (CEREBROSPINAL FLUID, ETC.)) FOR DETERMINATION OF NUCLEATED SPECIMENS (WHITE BLOOD CELLS, EPITHELIAL CELLS AND BACTERIA, ETC.).,STROMATOLYSER-FB(STROMATOLYSER-FB)-LYSING REAGENT FOR ANALYSIS OF BASOPHILS AND WBC.,UFII SEARCH-BAC(UFII SEARCH-BAC)-UF SEARCH -BAC IS TO BE USED TO STAIN BACTERIA IN URINE FOR DETERMINATION OF THE COUNT WITH THE SYSMEX FULLY AUTOMATED URINE PARTICLE ANALYZER (UF-1000I AND UF-500I),FLUOROCELL WDF(FLUOROCELL WDF)-FLUOROCELL WDF IS TO BE USED TO LABEL THE LEUKOCYTES IN DILUTED AND LYSED BLOOD SAMPLES FOR DETERMINATION OF THE WBC DIERENTIAL WITH SYSMEX AUTOMATED HEMATOLOGY ANALYZERS,CA CLEAN II(CA CLEAN II)-THE PRODUCT IS APPLIED TO CLEANSE THE PIPETS USED FOR FULLY AUTOMATED BLOOD COAGULATION ANALYZER,UFII SHEATH(UFII SHEATH)-THE UF II SHEATH IS THE SHEATH FLUID USED IN ORDER TO ANALYZE THE DILUTED AND STAINED SAMPLES BY FLOW CYTOMETRY METHOD.,UF FLUOROCELL CR(UF FLUOROCELL CR)-FOR IN VITRO DIAGNOSTIC USE ONLY. UF-FLUOROCELL CR IS USED TO MARK WHITE BLOOD CELLS, EPITHELIAL CELLS AND BACTERIA, ETC. IN URINE OR IN BODY FLUIDS FOR DETERMINATION OF THEIR COUNTS WITH SYSMEX FULLY AUTOMATED URINE PARTICLE ANALYZERS. UF-FLUOROCELL CR IS INTENDED FOR USE ONLY IN CONJUNCTION WITH SYSMEX DILUENT UF-CELLPACK CR,UFII PACK-SED(UFII PACK-SED)-UFII PACK -SED DILUTES THE ASPIRATED SAMPLE SO THAT ERYTHROCYTES, LEUKOCYTES, EPITHELIAL CELLS, AND CASTS CAN BE MEASURED BY FLOW CYTOMETRY METHOD.,CELLCLEAN(CELLCLEAN)-FOR IN VITRO DIAGNOSTIC USE ONLY. CELLCLEAN IS TO BE USED AS A STRONG ALKALINE DETERGENT TO REMOVE SYSMEX LYSING REAGENTS, CELLULAR RESIDUALS AND BLOOD PROTEINS REMAINING IN THE HYDRAULICS OF SYSMEX FULLY AUTOMATED HEMATOLOGY ANALYZERS. CELLCLEAN IS TO BE USED AS A STRONG ALKALINE DETERGENT TO CLEAN FLUID SYSTEM COMPONENTS OF SYSMEX FULLY AUTOMATED URINE CHEMISTRY ANALYZER, FULLY AUTOMATED URINE PARTICLE ANALYZER AND FULLY AUTOMATED URINE PARTICLE DIGITAL IMAGING DEVICE. NOTE: DO NOT USE FOR UF-500I/1000I AND UX-2000.,STROMATOLYSER-IM

	(STROMATOLYSER-IM)-LYSING REAGENT FOR ANALYSIS OF IMMATURE WBC.,CELLCHECK-400(CELLCHECK-400)-CELLCHECK-400 IS A LATEX PARTICLE REFERENCE USED WITH SYSMEX SEMIAUTOMATED MICROCELLCOUNTERS.,STROMATOLYSER-4DS (STROMATOLYSER-4DS)-STROMATOLYSER-4DS IS TO BE USED TO STAIN THE LEUKOCYTES IN DILUTED AND LYSED BLOOD SAMPLES FOR DETERMINATION OF 4-PART DIFFERENTIAL COUNT, OR 5-PART DIFFERENTIAL COUNT* AND WBC COUNT* WITH SYSMEX AUTOMATED HEMATOLOGY ANALYZERS (*ON XS SERIES ONLY), CONCENTRATED OF PHOSPHATE BUFFER FOR SP PH 6.6, CONCENTRATED OF PHOSPHATE BUFFER FOR SP PH 6.8, CONCENTRATED OF PHOSPHATE BUFFER FOR SP PH 7.0, CONCENTRATED OF PHOSPHATE BUFFER FOR SP PH 7.2 (CONCENTRATED OF PHOSPHATE BUFFER FOR SP PH 6.6, CONCENTRATED OF PHOSPHATE BUFFER FOR SP PH 6.8, CONCENTRATED OF PHOSPHATE BUFFER FOR SP PH 7.0, CONCENTRATED OF PHOSPHATE BUFFER FOR SP PH 7.2)-FOR IN VITRO DIAGNOSTIC USE ONLY CONCENTRATED PHOSPHATE BUER FOR SP IS A REAGENT FOR THE PREPARATION OF BLOOD SMEARS BY THE AUTOMATED HEMATOLOGY SLIDE PREPARATION UNIT SP-50, CELLPACK DFL(CELLPACK DFL)-WHOLE BLOOD DILUENT FOR USE IN HEMATOLOGY ANALYZERS.,STROMATOLYSER-3WP (STROMATOLYSER-3WP)-FOR IN VITRO DIAGNOSTIC USE ONLY. STROMATOLYSER-3WP IS A LYSING REAGENT TO ELIMINATE RED BLOOD CELLS AND CELL STROMA FOR USE IN ACCURATE DETERMINATION OF WBC COUNTS AND TRI-MODAL WBC DISTRIBUTION ANALYSIS. STROMATOLYSER-3WP IS A CLEAR REAGENT MANUFACTURED FOR USE WITH SELECTED SYSMEX AUTOMATED HEMATOLOGY ANALYZERS,POCH-PACK D(POCH-PACK D)-POCH-PACK D IS INTENDED TO BE USED AS A DILUENT FOR THE POCH-100I AUTOMATED HEMATOLOGY ANALYZER,WASH SOLUTION NO. 9(WASH SOLUTION NO. 9)-FOR IN VITRO DIAGNOSTIC USE ONLY. WASH SOLUTION NO. 9 IS A WASH SOLUTION FOR AUTOMATED CLINICAL CHEMISTRY ANALYZER, BX SERIES,STROMATOLYSER-4DL (STROMATOLYSER-4DL)-FOR IN VITRO DIAGNOSTIC USE ONLY. THE STROMATOLYSER-4DL IS A REAGENT THAT LYSES RBC FOR DETERMINATION OF 4-PART DIFFERENTIAL COUNT, OR 5-PART DIFFERENTIAL COUNT* AND WBC COUNT* WITH SYSMEX AUTOMATED HEMATOLOGY ANALYZERS (*ON XS SERIES ONLY).,UXII PACK-BAC(UXII PACK-BAC)-FOR IN VITRO DIAGNOSTIC USE ONLY. UX II PACK-BAC IS A DILUENT TO ANALYZE BACTERIA IN URINE FOR DETERMINATION OF THE BACTERIAL COUNT WITH THE SYSMEX FULLY AUTOMATED INTEGRATED URINE ANALYZER UX-2000, SULFOLYSER(SULFOLYSER)-SULFOLYSER IS A REAGENT FOR THE

	AUTOMATED DETERMINATION OF HEMOGLOBIN CONCENTRATION OF BLOOD WITH SYSMEX AUTOMATED HEMATOLOGY ANALYZERS., CELLPACK DST(CELLPACK DST)-FOR IN VITRO DIAGNOSTIC USE ONLY CELLPACK DST IS A CONCENTRATED DILUENT FOR USE IN SYSMEX AUTOMATED HEMATOLOGY ANALYZERS AND OTHER SYSMEX DEVICES THAT USE DILUTED CELLPACK DST. CELLPACK DST MUST ONLY BE USED WITH THE REAGENT PREPARATION UNITS SPECIFIED BY SYSMEX.,POCH-PACK L(POCH-PACK L)-FOR IN VITRO DIAGNOSTIC USE ONLY. POCH-PACK L IS A REAGENT THAT LYSES RBC FOR ACCURATE WBC COUNT DETERMINATION, WBC TRI-MODAL SIZE DISTRIBUTION ANALYSIS AND HEMOGLOBIN LEVEL MEASUREMENT. THE REAGENT IS COLORLESS TRANSPARENT AND CONTAINS NO CYANIDE OR AZIDE COMPOUND. IT IS INTENDED FOR USE IN CONJUNCTION WITH SELECTED SYSMEX POCH-100I AUTOMATED HEMATOLOGY ANALYZER.,UF-FLUOROCELL SF(UF-FLUOROCELL SF)-FOR IN VITRO DIAGNOSTIC USE ONLY. UF-FLUOROCELL SF IS USED TO MARK FORMED ELEMENTS IN URINE OR IN BODY FLUIDS FOR DETERMINATION OF RED BLOOD CELLS, CASTS, ETC. COUNTS WITH SYSMEX FULLY AUTOMATED URINE PARTICLE ANALYZERS. UF-FLUOROCELL SF IS INTENDED FOR USE ONLY IN CONJUNCTION WITH SYSMEX DILUENT UF-CELLPACK SF,UXII SEARCH-BAC(UXII SEARCH-BAC)-UX SEARCH -BAC IS TO BE USED TO STAIN BACTERIA IN URINE FOR DETERMINATION OF THE COUNT WITH THE SYSMEX FULLY AUTOMATED INTEGRATED URINE ANALYZER (UX-2000),CELLPACK(CELLPACK)-CELLPACK IS A DILUENT USED TO DILUTE ASPIRATED ANALYSIS SAMPLES IN ORDER TO MEASURE AN RBC COUNT, WBC COUNT, HEMOGLOBIN CONCENTRATION AND PLATELET COUNT.,CELLCLEAN AUTO(CELLCLEAN AUTO)-FOR IN VITRO DIAGNOSTIC USE ONLY. CELLCLEAN AUTO IS TO BE USED AS A STRONG ALKALINE DETERGENT TO REMOVE SYSMEX LYSING REAGENT, CELLULAR RESIDUALS AND BLOOD PROTEINS REMAINING IN THE HYDRAULICS OF AUTOMATED HEMATOLOGY ANALYZER XN SERIES, AUTOMATED HEMATOLOGY ANALYZER XN-L SERIES, AUTOMATED HEMATOLOGY SLIDE PREPARATION UNIT SP-10 AND AUTOMATED HEMATOLOGY SLIDE PREPARATION UNIT SP-50.,CA CLEAN I(CA CLEAN I)-THE PRODUCT IS APPLIED TO CLEANSE THE PIPETS USED FOR FULLY AUTOMATED BLOOD COAGULATION ANALYZER.,UXII PACK-SED(UXII PACK-SED)-UXII PACK -SED DILUTES THE ASPIRATED SAMPLE SO THAT ERYTHROCYTES, LEUKOCYTES, EPITHELIAL CELLS, AND CASTS CAN BE MEASURED BY FLOW CYTOMETRY METHOD,UXII SHEATH(UXII SHEATH)-THE UXII SHEATH IS THE SHEATH FLUID USED IN ORDER TO ANALYZE TO DILUTED AND STAINED MATERIALS BY FLOW CYTOMETRY METHOD,FLUOROCELL RET(FLUOROCELL RET)-FLUOROCELL RET IS TO BE USED TO LABEL

	THE RETICULOCYTES IN DILUTED BLOOD SAMPLE FOR THE ASSAY OF RETICULOCYTE COUNT, RETICULOCYTE PERCENT AND PLATELET COUNT IN BLOOD WITH SYSMEX AUTOMATED HEMATOLOGY ANALYZERS.,FLUOROCELL PLT(FLUOROCELL PLT)-FLUOROCELL PLT IS TO BE USED TO LABEL THE PLATELET IN DILUTED BLOOD SAMPLE FOR THE ASSAY OF PLATELET COUNT IN BLOOD WITH SYSMEX AUTOMATED HEMATOLOGY ANALYZERS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

262	IMP/IVD/2019/000256	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARCHITECT C-PEPTIDE CALIBRATORS(ARCHITECT C-PEPTIDE CALIBRATORS)-THE ARCHITECT C-PEPTIDE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM, PLASMA AND URINE. ,ALINITY I C-PEPTIDE REAGENT KIT(ALINITY I C-PEPTIDE REAGENT KIT)-THE ALINITY I C-PEPTIDE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM, PLASMA AND URINE ON THE ALINITY I ANALYZER. THE ALINITY I C-PEPTIDE ASSAY IS TO BE USED AS AN AID IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH ABNORMAL INSULIN SECRETION INCLUDING DIABETES MELLITUS.,ARCHITECT SHBG REAGENT KIT(ARCHITECT SHBG REAGENT KIT)-THE ARCHITECT SHBG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF SEX HORMONE BINDING GLOBULIN (SHBG) IN HUMAN SERUM AND PLASMA ON THE ARCHITECT ISYSTEM,ALINITY I DHEA-S CALIBRATORS(ALINITY I DHEA-S CALIBRATORS)-THE ALINITY I DHEA-S CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) IN HUMAN SERUM AND PLASMA.,ARCHITECT SHBG CONTROLS(ARCHITECT SHBG CONTROLS)-THE ARCHITECT SHBG CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF SHBG IN HUMAN SERUM AND PLASMA.,ALINITY I DHEA-S REAGENT KIT(ALINITY I DHEA-S REAGENT KIT)-THE ALINITY I DHEA-S ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER., ARCHITECT ITHEOPHYLLINE CALIBRATOR(ARCHITECT ITHEOPHYLLINE CALIBRATOR)-THE ARCHITECT ITHEOPHYLLINE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THEOPHYLLINE IN HUMAN SERUM OR PLASMA.,ALINITY I C-PEPTIDE CONTROLS(ALINITY I C-PEPTIDE CONTROLS)-THE ALINITY I C-PEPTIDE CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE

	IN HUMAN SERUM, PLASMA AND URINE.,ALINITY I INTACT PTH CALIBRATORS(ALINITY I INTACT PTH CALIBRATORS)-THE ALINITY I INTACT PTH CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF INTACT PTH IN HUMAN SERUM AND PLASMA., ALINITY I SHBG CONTROLS(ALINITY I SHBG CONTROLS)-THE ALINITY I SHBG CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF SHBG IN HUMAN SERUM AND PLASMA.,ARCHITECT C-PEPTIDE REAGENT KIT(ARCHITECT C-PEPTIDE REAGENT KIT)-THE ARCHITECT C-PEPTIDE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF C PEPTIDE IN HUMAN SERUM, PLASMA AND URINE ON THE ARCHITECT ISYSTEM. ,ALINITY I SHBG CALIBRATORS(ALINITY I SHBG CALIBRATORS)-THE ALINITY I SHBG CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF SHBG IN HUMAN SERUM AND PLASMA.,ARCHITECT SHBG CALIBRATORS(ARCHITECT SHBG CALIBRATORS)-THE ARCHITECT SHBG CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF SHBG IN HUMAN SERUM AND PLASMA.,ALINITY I C-PEPTIDE CALIBRATORS(ALINITY I C-PEPTIDE CALIBRATORS)-THE ALINITY I C-PEPTIDE CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM, PLASMA AND URINE.,ARCHITECT DHEA-S CONTROLS(ARCHITECT DHEA-S CONTROLS)-THE ARCHITECT DHEA-S CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF DHEA-S IN HUMAN SERUM AND PLASMA. ,ALINITY I DHEA-S CONTROLS(ALINITY I DHEA-S CONTROLS)-THE ALINITY I DHEA-S CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) IN HUMAN SERUM AND PLASMA.,ARCHITECT DHEA-S CALIBRATORS(ARCHITECT DHEA-S CALIBRATORS)-THE ARCHITECT DHEA-S CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF DHEA-S IN HUMAN SERUM AND PLASMA.,ALINITY I SHBG REAGENT KIT(ALINITY I SHBG REAGENT KIT) -THE ALINITY I SHBG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF SEX HORMONE BINDING GLOBULIN (SHBG) IN HUMAN SERUM AND PLASMA ON THE ALINITY I

	ANALYZER.,ARCHITECT DHEA-S REAGENT KIT(ARCHITECT DHEA-S REAGENT KIT)-ARCHITECT DHEA-S IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) IN HUMAN SERUM AND PLASMA ON THE ARCHITECT ISYSTEM., ARCHITECT INTACT PTH CALIBRATORS(ARCHITECT INTACT PTH CALIBRATORS)-THE ARCHITECT INTACT PTH CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF INTACT PTH IN HUMAN SERUM AND PLASMA.,ALINITY I INTACT PTH REAGENT KIT(ALINITY I INTACT PTH REAGENT KIT)-THE ALINITY I INTACT PTH ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (PTH) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER,ARCHITECT INTACT PTH REAGENT KIT(ARCHITECT INTACT PTH REAGENT KIT)-THE ARCHITECT INTACT PTH ASSAY IS AN IN VITRO CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (PTH) IN HUMAN SERUM AND PLASMA ON THE ARCHITECT ISYSTEM. ,ARCHITECT INTACT PTH CONTROLS (ARCHITECT INTACT PTH CONTROLS)-THE ARCHITECT INTACT PTH CONTROLS ARE FOR THE USE IN QUALITY CONTROL TO MONITOR THE ACCURACY AND PRECISION OF THE ARCHITECT INTACT PTH ASSAY ON THE ARCHITECT ISYSTEM FOR HUMAN SERUM AND PLASMA. ,ARCHITECT ITHEOPHYLLINE REAGENT KIT(ARCHITECT ITHEOPHYLLINE REAGENT KIT)-THE ARCHITECT ITHEOPHYLLINE ASSAY IS AN IN VITRO CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE MEASUREMENT OF THEOPHYLLINE IN HUMAN SERUM OR PLASMA ON THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY.,ARCHITECT C-PEPTIDE CONTROLS(ARCHITECT C-PEPTIDE CONTROLS)-THE ARCHITECT C-PEPTIDE CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM, PLASMA AND URINE.,ALINITY I INTACT PTH CONTROLS(ALINITY I INTACT PTH CONTROLS)-THE ALINITY I INTACT PTH CONTROLS ARE FOR THE USE IN QUALITY CONTROL TO MONITOR THE ACCURACY AND PRECISION OF THE ALINITY I INTACT PTH ASSAY ON THE ALINITY I ANALYZER FOR HUMAN SERUM AND PLASMA.,ARCHITECT IVANCOMYCIN REAGENT KIT(ARCHITECT IVANCOMYCIN REAGENT KIT)-THE ARCHITECT IVANCOMYCIN ASSAY IS AN IN VITRO CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE MEASUREMENT OF VANCOMYCIN IN HUMAN

		SERUM OR PLASMA ON THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY.,ARCHITECT IVANCOMYCIN CALIBRATOR KIT (ARCHITECT IVANCOMYCIN CALIBRATOR KIT)-THE ARCHITECT IVANCOMYCIN CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF VANCOMYCIN IN HUMAN SERUM OR PLASMA.
263	IMP/IVD/2019/000257	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:N LATEX HCY(N LATEX HCY)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF TOTAL HOMOCYSTEINE (HCY) IN HUMAN SERUM, HEPARINIZED PLASMA AND EDTA PLASMA BY MEANS OF PARTICLE-ENHANCED IMMUNONEPHELOMETRY WITH BN II AND BN PROSPEC SYSTEM. THE DEVICE CAN ASSIST IN THE DIAGNOSIS AND TREATMENT OF PATIENTS SUSPECTED OF HAVING HYPERHOMOCYSTEINEMIA AND HOMOCYSTINURIA.

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264	IMP/IVD/2019/000259	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCESS SHBG QC (ACCESS SHBG QC)-THE ACCESS SHBG ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF SEX HORMONE BINDING GLOBULIN LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS SENSITIVE ESTRADIOL CALIBRATORS(ACCESS SENSITIVE ESTRADIOL CALIBRATORS)-THE ACCESS SENSITIVE ESTRADIOL CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS SENSITIVE ESTRADIOL ASSAY FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEM$., ACCESS INTACT PTH CALIBRATORS(ACCESS INTACT PTH CALIBRATORS)-THE ACCESS INTACT PTH ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (PARATHYRIN, PTH) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS. IT IS INDICATED TO AID IN THE DIFFERENTIAL DIAGNOSIS OF HYPERPARATHYROIDISM, HYPOPARATHYROIDISM, OR HYPERCALCEMIA OF MALIGNANCY AND CAN BE USED INTRAOPERATIVELY. ASSAY RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL DATA TO ASSIST THE CLINICIAN IN MAKING INDIVIDUAL PATIENT MANAGEMENT DECISIONS.,ACCESS SENSITIVE ESTRADIOL CALIBRATOR S0(ACCESS SENSITIVE ESTRADIOL CALIBRATOR S0)-THE ACCESS SENSITIVE ESTRADIOL CALIBRATOR S0 IS INTENDED FOR USE WITH THE ACCESS SENSITIVE ESTRADIOL ASSAY TO DILUTE PATIENT SAMPLES CONTAINING ANALYTE CONCENTRATIONS GREATER THAN THE ANALYTE SPECIFIC S5 CALIBRATOR.,ACCESS SHBG CALIBRATORS (ACCESS SHBG CALIBRATORS)-THE ACCESS SHBG CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS SHBG ASSAY FOR THE QUANTITATIVE DETERMINATION OF SEX HORMONE BINDING GLOBULIN LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS TPO ANTIBODY CALIBRATOR(ACCESS TPO ANTIBODY CALIBRATOR)-THE ACCESS TPO ANTIBODY CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS TPO ANTIBODY ASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROPEROXIDASE ANTIBODY (TPOAB) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS FREE T3 CALIBRATOR(ACCESS FREE T3 CALIBRATOR)-THE ACCESS FREE T3 CALIBRATORS ARE INTENDED

	TO CALIBRATE THE ACCESS FREE T3 ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.

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265	IMP/IVD/2019/000260	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CK_MB RAPID TEST (SUPERVELOCE)-THE CK-MB RAPID TEST CASSETTE (WHOLE BLOOD/SERUM/PLASMA) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HUMAN CK-MB IN WHOLE BLOOD, SERUM OR PLASMA AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (MI). FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,HEV IGG/IGM RAPID TEST CASSETTE (SUPERVELOCE)-THE HEV RAPID TEST CASSETTE IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES (IGG/IGM) TO HEPATITIS E VIRUS (HEV) IN SERUM OR PLASMA. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,LEISHMANIA IGG/IGM RAPID TEST CASSETTE (SUPERVELOCE)-THE LEISHMANIA IGG/IGM RAPID TEST CASSETTE (WHOLE BLOOD/SERUM/PLASMA) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGG AND IGM ANTIBODIES TO LEISHMANIA IN HUMAN'S WHOLE BLOOD, SERUM OR PLASMA. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY., LEPTOSPIRA IGG/IGM RAPID TEST CASSETTE(SUPERVELOCE)-THE LEPTOSPIRA IGG/IGM RAPID TEST CASSETTE (WHOLE BLOOD/SERUM/PLASMA) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGG AND IGM ANTIBODIES TO LEPTOSPIRA INTERROGANS IN HUMAN'S WHOLE BLOOD, SERUM OR PLASMA. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,MYOGLOBIN RAPID TEST(SUPERVELOCE)-THE MYOGLOBIN RAPID TEST CASSETTE (WHOLE BLOOD/SERUM/PLASMA) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HUMAN MYOGOBIN IN WHOLE BLOOD, SERUM OR PLASMA AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (MI). FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,FILARIASIS IGG/IGM RAPID TEST CASSETTE(SUPERVELOCE)-THE FILARIASIS IGG/IGM RAPID TEST CASSETTE (WHOLE BLOOD/SERUM/PLASMA) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGG AND IGM ANTIBODIES TO FILARIASIS PARASITES (W. BANCROFTI AND B. MALAYI) IN WHOLE BLOOD, SERUM, OR PLASMA TO AID IN THE DIAGNOSIS OF FILARIASIS INFECTION. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY., MYOGLOBIN/CK_MB/TROPONIN I COMB RAPID TEST(SUPERVELOCE)-THE MYOGLOBIN/CK-MB/TROPONIN I COMBO RAPID TEST CASSETTE (WHOLE BLOOD/SERUM/PLASMA) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HUMAN MYOGLOBIN, CK-MB AND CARDIAC TROPONIN I (CTNI) IN WHOLE

	BLOOD, SERUM OR PLASMA AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (MI). FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,HAV IGG/ IGM RAPID TEST CASSETTE (SUPERVELOCE)-THE HAV IGG/IGM COMBO RAPID TEST CASSETTE IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGG AND IGM ANTIBODIES TO HEPATITIS A VIRUS (HAV) IN SERUM OR PLASMA SPECIMEN. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,COVID-19 ANTIGEN RAPID TEST(ALL TEST)-"COVID-19 ANTIGEN RAPID TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID PROTEIN ANTIGENS IN SWAB SPECIMEN. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.",PCT RAPID TEST CASSETTE(SUPERVELOCE)-THE PCT RAPID TEST CASSETTE (WHOLE BLOOD / SERUM / PLASMA) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF PROCALCITONIN IN WHOLE BLOOD, SERUM OR PLASMA. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY., 2019-NCOV IGG/IGM RAPID TEST CASSETTE(SUPRVELOCE)-"THE 2019-NCOV IGG/IGM RAPID TEST CASSETTE IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGG AND IGM ANTIBODIES TO 2019-NCOV IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SPECIMEN. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.",FFN RAPID TEST CASSETTE (SUPERVELOCE)-THE FETAL FIBRONECTIN (FFN) RAPID TEST (VAGINAL SECRETION) IS A VISUALLY INTERPRETED, QUALITATIVE IMMUNOCHROMATOGRAPHIC TEST DEVICE FOR DETECTION OF FFN IN VAGINAL SECRETIONS DURING PREGNANCY, WHICH IS A SPECIAL PROTEIN THAT LITERALLY HOLDS YOUR BABY IN PLACE IN THE WOMB. THE TEST IS INTENDED FOR PROFESSIONAL USE TO HELP DIAGNOSE IF THE PRETERM DELIVERY IS LIKELY TO OCCUR IN PREGNANT WOMEN. THE TEST MAY BE RUN ON PATIENTS BETWEEN 24 AND 34 WEEKS GESTATION.,TROPONIN I (CTNL) RAPID TEST ` (SUPERVELOCE)-THE CARDIAC TROPONIN I RAPID TEST CASSETTE (WHOLE BLOOD/SERUM/PLASMA) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HUMAN CARDIAC TROPONIN I IN WHOLE BLOOD, SERUM OR PLASMA AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (MI). FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.

266	IMP/IVD/2019/000261	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DXH 500 SERIES CLEANER(DXH 500 SERIES CLEANER)-A CLEANING AGENT FOR USE ON DXH 500 SERIES SYSTEMS FOR COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES.,CLEARLLAB COMPENSATION BEADS(CLEARLLAB COMPENSATION BEADS)-CLEARLLAB COMPENSATION BEADS ARE TO BE USED IN CONJUNCTION WITH THE CLEARLLAB COMPENSATION KIT TO ESTABLISH COMPENSATION SETTINGS ON THE NAVIOS AND NAVIOS EX FLOW CYTOMETER(S) PRIOR TO MULTICOLOR ANALYSIS WITH THE CLEARLLAB 10C PANELS,CD45-FITC/ (CD56+CD16)-RD1/ CD19-ECD/CD3-PC5(AQUIOS TETRA-2+ PANEL)-AQUIOS TETRA-1 PANEL AND AQUIOS TETRA-2+ PANEL MONOCLONAL ANTIBODY REAGENTS ARE FOR USE ON THE AQUIOS CL FLOW CYTOMETER WITH PERIPHERAL WHOLE BLOOD FOR IMMUNOPHENOTYPING. THESE REAGENTS ARE INDICATED FOR USE IN THE IMMUNOLOGIC ASSESSMENT OF PATIENTS HAVING, OR SUSPECTED OF HAVING, IMMUNE DEFICIENCY. THESE REAGENTS PROVIDE IDENTIFICATION AND ENUMERATION OF : AQUIOS TETRA-1 PANEL MONOCLONAL ANTIBODY REAGENTS -TOTAL CD3+ , CD3+CD4+, CD3+CD8+, CD3+CD4+/CD3+CD8+ (RATIO ONLY) LYMPHOCYTE PERCENTAGES AND ABSOLUTE COUNTS. -CD45+ ABSOLUTE COUNT CD45+ LOW SS (LYMPHOCYTES) PERCENTAGE AND ABSOLUTE COUNT AQUIOS TETRA-2+ PANEL MONOCLONAL ANTIBODY REAGENTS -TOTAL CD3+, CD3-CD19+, CD3-CD56+ AND/OR CD16+ LYMPHOCYTE PERCENTAGES AND ABSOLUTE COUNTS. -CD45+ ABSOLUTE COUNT CD45+ LOW SS (LYMPHOCYTES) PERCENTAGE AND ABSOLUTE COUNT. ,AQUIOS FLOW-COUNT FLUOROSPHERES(AQUIOS FLOW-COUNT FLUOROSPHERES)-AQUIOS FLOW-COUNT FLUOROSPHERES IS A FLUORESCENT MICROSPHERE REAGENT FOR DIRECT DETERMINATION OF LEUKOCYTE ABSOLUTE COUNTS IN BIOLOGICAL SPECIMENS ON THE AQUIOS CL FLOW CYTOMETER.,FLOW-SET PRO FLUOROSPHERES(FLOW-SET PRO FLUOROSPHERES)-FLOW-SET PRO FLUOROSPHERES IS A SUSPENSION OF FLUORESCENT MICROSPHERES USED AS AN AID IN STANDARDIZING FORWARD SCATTER, SIDE SCATTER, AND FLUORESCENCE DETECTORS ON THE CYTOMICS FC 500 (FL1-5), NAVIOS AND NAVIOS EX FLOW CYTOMETERS (FL1-10).,AQUIOS CLEANING AGENT(AQUIOS CLEANING AGENT)-A CLEANING AGENT FOR USE ON THE AQUIOS FLOW CYTOMETER COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES.,AQUIOS IMMUNO-TROL LOW CELLS (PLG/TETRA)(AQUIOS IMMUNO-TROL LOW CELLS (PLG/TETRA))-AQUIOS IMMUNO-TROL LOW CELLS (PLG/TETRA) IS

	AN ASSAYED, LYSABLE WHOLE BLOOD QUALITY CONTROL PRODUCT FOR IMMUNOPHENOTYPING ANALYSIS USING MONOCLONAL ANTIBODY REAGENTS AND FLOW CYTOMETRY. IT PROVIDES A POSITIVE CELL CONTROL THAT IS PROCESSED IN THE SAME MANNER AS A WHOLE BLOOD SAMPLE. THIS ALLOWS VERIFICATION OF INSTRUMENT AND REAGENT PERFORMANCE. IT ALSO VERIFIES THE METHODS USED FOR STAINING TARGETED CELLS, THE LYSING OF ERYTHROCYTES, AND THE ANALYSIS OF SAMPLES BY THE AQUIOS CL FLOW CYTOMETER.,FLOW CLEAN CLEANING AGENT(FLOW CLEAN CLEANING AGENT)-A CLEANING AGENT FOR USE ON THE CYTOMICS FC 500, NAVIOS, NAVIOS EX AND DXFLEX FLOW CYTOMETERS COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES., FLOW-CHECK PRO FLUOROSPHERES(FLOW-CHECK PRO FLUOROSPHERES)-FLOW-CHECK PRO FLUOROSPHERES IS A SUSPENSION OF FLUORESCENT MICROSPHERES USED FOR DAILY VERIFICATION OF THE NAVIOS, NAVIOS EX OR CYTOMICS FC 500 FLOW CYTOMETER OPTICAL ALIGNMENT AND FLUIDICS SYSTEM., AQUIOS IMMUNO-TROL CELLS (PLG/TETRA)(AQUIOS IMMUNO-TROL CELLS (PLG/TETRA))-AQUIOS IMMUNO-TROL CELLS (PLG/TETRA) IS AN ASSAYED, LYSABLE WHOLE BLOOD QUALITY CONTROL PRODUCT FOR IMMUNOPHENOTYPING ANALYSIS USING MONOCLONAL ANTIBODY REAGENTS AND FLOW CYTOMETRY. IT PROVIDES A POSITIVE CELL CONTROL THAT IS PROCESSED IN THE SAME MANNER AS A WHOLE BLOOD SAMPLE. THIS ALLOWS VERIFICATION OF INSTRUMENT AND REAGENT PERFORMANCE. IT ALSO VERIFIES THE METHODS USED FOR STAINING TARGETED CELLS, THE LYSING OF ERYTHROCYTES, AND THE ANALYSIS OF SAMPLES BY THE AQUIOS CL FLOW CYTOMETER.,CD45-FITC/CD4-RD1/ CD8-ECD/CD3-PC5 (AQUIOS TETRA-1 PANEL)-AQUIOS TETRA-1 PANEL AND AQUIOS TETRA-2+ PANEL MONOCLONAL ANTIBODY REAGENTS ARE FOR USE ON THE AQUIOS CL FLOW CYTOMETER WITH PERIPHERAL WHOLE BLOOD FOR IMMUNOPHENOTYPING. THESE REAGENTS ARE INDICATED FOR USE IN THE IMMUNOLOGIC ASSESSMENT OF PATIENTS HAVING, OR SUSPECTED OF HAVING, IMMUNE DEFICIENCY. THESE REAGENTS PROVIDE IDENTIFICATION AND ENUMERATION OF : AQUIOS TETRA-1 PANEL MONOCLONAL ANTIBODY REAGENTS - TOTAL CD3+ , CD3+CD4+, CD3+CD8+, CD3+CD4+/CD3+CD8+ (RATIO ONLY) LYMPHOCYTE PERCENTAGES AND ABSOLUTE COUNTS. - CD45+ ABSOLUTE COUNT CD45+ LOW SS (LYMPHOCYTES) PERCENTAGE AND ABSOLUTE COUNT AQUIOS TETRA-2+ PANEL MONOCLONAL ANTIBODY REAGENTS -TOTAL CD3+, CD3-CD19+, CD3-CD56+ AND/OR CD16+ LYMPHOCYTE PERCENTAGES AND ABSOLUTE COUNTS. -CD45+ ABSOLUTE COUNT CD45+ LOW SS (LYMPHOCYTES) PERCENTAGE AND ABSOLUTE COUNT. ,AQUIOS IMMUNO-TROL LOW

	CELLS(AQUIOS IMMUNO-TROL LOW CELLS)-AQUIOS IMMUNO-TROL LOW CELLS IS AN ASSAYED, LYSABLE WHOLE BLOOD QUALITY CONTROL PRODUCT FOR IMMUNOPHENOTYPING ANALYSIS USING MONOCLONAL ANTIBODY REAGENTS AND FLOW CYTOMETRY. IT PROVIDES A POSITIVE CELL CONTROL THAT IS PROCESSED IN THE SAME MANNER AS A WHOLE BLOOD SAMPLE. THIS ALLOWS VERIFICATION OF INSTRUMENT AND REAGENT PERFORMANCE. IT ALSO VERIFIES THE METHODS USED FOR STAINING TARGETED CELLS, THE LYSING OF ERYTHROCYTES, AND THE ANALYSIS OF SAMPLES BY THE AQUIOS CL FLOW CYTOMETER.,CD45-FITC/CD4-PE (AQUIOS PLG PANEL)-THE AQUIOS PLG PANEL IS FOR USE ON THE AQUIOS CL FLOW CYTOMETER SYSTEM. THE REAGENT COMBINES TWO FLUORESCENT-LABELED MONOCLONAL ANTIBODIES IN A SINGLE REAGENT FORMULATION. IT IS INTENDED “FOR IN VITRO DIAGNOSTIC USE” FOR THE IDENTIFICATION AND ENUMERATION OF CD4+ ABSOLUTE CELL COUNT AND CD4+ LYMPHOCYTE PERCENTAGE WHEN USED IN COMBINATION WITH AQUIOS FLOW-COUNT FLUOROSPHERES AS A SINGLE PLATFORM MEASUREMENT. THIS REAGENT IS INDICATED FOR USE IN THE IMMUNOLOGIC ASSESSMENT OF PATIENTS HAVING, OR SUSPECTED OF HAVING, IMMUNE DEFICIENCY. -CD45+ ABSOLUTE COUNT CD45+ LOW SS (LYMPHOCYTES) PERCENTAGE AND ABSOLUTE COUNT.,AQUIOS IMMUNO-TROL CELLS(AQUIOS IMMUNO-TROL CELLS)-- AQUIOS IMMUNO-TROL CELLS IS AN ASSAYED, LYSABLE WHOLE BLOOD QUALITY CONTROL PRODUCT FOR IMMUNOPHENOTYPING ANALYSIS USING MONOCLONAL ANTIBODY REAGENTS AND FLOW CYTOMETRY. IT PROVIDES A POSITIVE CELL CONTROL THAT IS PROCESSED IN THE SAME MANNER AS A WHOLE BLOOD SAMPLE. THIS ALLOWS VERIFICATION OF INSTRUMENT AND REAGENT PERFORMANCE. IT ALSO VERIFIES THE METHODS USED FOR STAINING TARGETED CELLS, THE LYSING OF ERYTHROCYTES, AND THE ANALYSIS OF SAMPLES BY THE AQUIOS CL FLOW CYTOMETER

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267	IMP/IVD/2019/000262	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DETERMINE HBSAG (DETERMINE HBSAG)-THE DETERMINE HBSAG IS AN IN VITRO, VISUALLY READ, QUALITATIVE IMMUNOASSAY FOR THE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS INTENDED AS AN AID TO DETECT HBSAG FROM INFECTED INDIVIDUALS.,CONTROL SOLUTION (DETERMINE HIV CONTROLS)-DETERMINE HIV CONTROLS IS TO ENSURE THE TEST IS PERFORMING CORRECTLY AND TO VERIFY THE USER'S ABILITY TO PERFORM THE ASSAY PROPERLY AND INTERPRET THE RESULTS,DETERMINE HIV-1/2(DETERMINE HIV-1/2)-THE DETERMINE™ HIV-1/2 IS AN IN VITRO, VISUALLY READ, QUALITATIVE IMMUNOASSAY FOR THE DETECTION OF ANTIBODIESS TO HIV-1 AND HIV-2 IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS INTENDED AS AN AID TO DETECT ANTIBODIES TO HIV-1/HIV-2 FROM INFECTED INDIVIDUALS. THE TEST IS FOR PROFESSIONAL USE ONLY.
268	IMP/IVD/2019/000262	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DETERMINE™ HBSAG 2 (DETERMINE™ HBSAG 2)-DETERMINE™ HBSAG 2 IS AN IN VITRO, VISUALLY READ, QUALITATIVE IMMUNOASSAY FOR THE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG)IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS INTENDED AS AN AID TO DETECT HBSAG FROM INFECTED INDIVIDUALS.,DETERMINE HIV EARLY DETECT(DETERMINE)-DETERMINE™ HIV EARLY DETECT IS AN IN VITRO, VISUALLY READ, QUALITATIVE IMMUNOASSAY FOR THE DETECTION OF ANTIBODIES (AB) TO HIV-1 AND HIV-2 AND THE DETECTION OF NON-IMMUNOCOMPLEXED (FREE) HIV-1 P24 ANTIGEN (AG) IN HUMAN CAPILLARY AND VENOUS WHOLE BLOOD, PLASMA OR SERUM.

269	IMP/IVD/2019/000263	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD BBL SENSI-DISC CLINDAMYCIN - 2 G(BD BBL SENSI-DISC CLINDAMYCIN - 2 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BACTEC MYCOSIS IC/F CULTURE VIALS (PLASTIC)(BD BACTEC MYCOSIS IC/F CULTURE VIALS (PLASTIC))-BD BACTEC™ MYCOSIS IC/F CULTURE VIALS ARE FOR AEROBIC BLOOD CULTURES. PRINCIPAL USE IS WITH THE BD BACTEC FLUORESCENT SERIES INSTRUMENTS FOR THE SELECTIVE CULTURE AND RECOVERY OF YEASTS AND FUNGI FROM BLOOD.,BD BBL SENSI-DISC AMPICILLIN - 10 G (BD BBL SENSI-DISC AMPICILLIN - 10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BACTEC PLATELET ANAEROBIC/ F CULTURE VIALS (PLASTIC)(BD BACTEC PLATELET ANAEROBIC/ F CULTURE VIALS (PLASTIC))-BD BACTEC™ PLATELET ANAEROBIC/F CULTURE VIALS ARE USED WITH THE BD BACTEC FX INSTRUMENT SERIES FOR QUALITY CONTROL TESTING OF LEUKOCYTE REDUCED APHERESIS PLATELET (LRAP) UNITS, BOTH LEUKOCYTE REDUCED SINGLE AND A POOL OF UP TO 6 UNITS OF LEUKOCYTE REDUCED WHOLE BLOOD PLATELET CONCENTRATES (LRWBPC). BD BACTEC ANAEROBIC/F CULTURE VIALS SUPPORT THE GROWTH OF ANAEROBIC MICROORGANISMS. ,BD BBL SENSI-DISC CEFEPIME - 30 G (BD BBL SENSI-DISC CEFEPIME - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS

	INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BACTEC STANDARD ANAEROBIC/F CULTURE VIALS (PLASTIC)(BD BACTEC STANDARD ANAEROBIC/F CULTURE VIALS (PLASTIC))-BD BACTEC™ STANDARD ANAEROBIC/F CULTURE VIALS (PREREDUCED ENRICHED SOYBEAN-CASEIN DIGEST BROTH WITH CO2) ARE FOR ANAEROBIC BLOOD CULTURES. PRINCIPAL USE IS WITH THE BD BACTEC FLUORESCENT SERIES INSTRUMENTS FOR THE QUALITATIVE CULTURE AND RECOVERY OF ANAEROBIC MICROORGANISMS FROM BLOOD.,BD BBL SENSI-DISC NALIDIXIC ACID - 30 G (BD BBL SENSI-DISC NALIDIXIC ACID - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BACTEC STANDARD/10 AEROBIC/F CULTURE VIALS (PLASTIC)(BD BACTEC STANDARD/10 AEROBIC/F CULTURE VIALS (PLASTIC))-BD BACTEC™ STANDARD/10 AEROBIC/F CULTURE VIALS (ENRICHED SOYBEAN-CASEIN DIGEST BROTH WITH CO2) ARE FOR AEROBIC BLOOD CULTURES. PRINCIPAL USE IS WITH THE BD BACTEC FLUORESCENT SERIES INSTRUMENTS FOR THE QUALITATIVE CULTURE AND RECOVERY OF AEROBIC MICROORGANISMS (BACTERIA AND YEAST) FROM BLOOD,BD BBL SENSI-DISC LOMEFLOXACIN - 10 G (BD BBL SENSI-DISC LOMEFLOXACIN - 10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BACTEC PLATELET AEROBIC / F CULTURE VIALS (PLASTIC)(BD BACTEC PLATELET AEROBIC / F CULTURE VIALS (PLASTIC))-BD BACTEC™ PLATELET AEROBIC/F CULTURE VIALS ARE USED WITH THE BD BACTEC FX INSTRUMENT SERIES FOR QUALITY CONTROL TESTING OF LEUKOCYTE REDUCED APHERESIS PLATELET (LRAP) UNITS, BOTH LEUKOCYTE REDUCED SINGLE AND A POOL OF UP TO 6 UNITS OF LEUKOCYTE REDUCED WHOLE BLOOD PLATELET CONCENTRATES (LRWBPC). BD BACTEC PLATELET AEROBIC/F CULTURE VIALS

	SUPPORT THE GROWTH OF AEROBIC MICROORGANISMS (BACTERIA AND FUNGI).,BD BBL SENSI-DISC AZITHROMYCIN - 15 G(BD BBL SENSI-DISC AZITHROMYCIN - 15 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI.,BD BACTEC MYCOSIS IC/F CULTURE VIALS(BD BACTEC MYCOSIS IC/F CULTURE VIALS)-BD BACTEC™ MYCOSIS IC/F CULTURE VIALS ARE FOR AEROBIC BLOOD CULTURES. PRINCIPAL USE IS WITH THE BD BACTEC FLUORESCENT SERIES INSTRUMENTS FOR THE SELECTIVE CULTURE AND RECOVERY OF YEASTS AND FUNGI FROM BLOOD.,BD BBL SENSI-DISC GATIFLOXACIN - 5 G(BD BBL SENSI-DISC GATIFLOXACIN - 5 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC DORIPENEM - 10 G (BD BBL SENSI-DISC DORIPENEM - 10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC OXACILLIN - 1 G(BD BBL SENSI-DISC OXACILLIN - 1 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER

	STREPTOCOCCI. ,BD BBL SENSI-DISC TETRACYCLINE - 30 G(BD BBL SENSI-DISC TETRACYCLINE - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC TOBRAMYCIN - 10 G(BD BBL SENSI-DISC TOBRAMYCIN - 10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC SULFISOXAZOLE - 1.0 MG (BD BBL SENSI-DISC SULFISOXAZOLE - 1.0 MG)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC TICARCILLIN - 75 G(BD BBL SENSI-DISC TICARCILLIN - 75 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC PENICILLIN - 10 UNITS AND 2 UNIT(BD BBL SENSI-DISC PENICILLIN - 10 UNITS AND 2 UNIT)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE

	THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC OXYTETRACYCLINE - 30 G(BD BBL SENSI-DISC OXYTETRACYCLINE - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CEFACLOR - 30 G (BD BBL SENSI-DISC CEFACLOR - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC LINEZOLID - 30 G (BD BBL SENSI-DISC LINEZOLID - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC NITROFURANTOIN - 300 G(BD BBL SENSI-DISC NITROFURANTOIN - 300 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CHLORAMPHENICOL - 30 G

	SENSI-DISC(BD BBL SENSI-DISC CHLORAMPHENICOL - 30 G SENSI-DISC)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC LEVOFLOXACIN - 5 G (BD BBL SENSI-DISC LEVOFLOXACIN - 5 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC MOXALACTAM - 30 G (BD BBL SENSI-DISC MOXALACTAM - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC LINCOMYCIN - 2 G(BD BBL SENSI-DISC LINCOMYCIN - 2 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CEFAZOLIN - 30 G (BD BBL SENSI-DISC CEFAZOLIN - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP.,

	ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC MOXIFLOXACIN-5 G (BD BBL SENSI-DISC MOXIFLOXACIN-5 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC NAFCILLIN - 1 G(BD BBL SENSI-DISC NAFCILLIN - 1 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC METRONIDAZOLE - 80 G (BD BBL SENSI-DISC METRONIDAZOLE - 80 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC MEROPENEM - 10 G(BD BBL SENSI-DISC MEROPENEM - 10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC DOXYCYCLINE - 30 G (BD BBL SENSI-DISC DOXYCYCLINE - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE

	AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC IMIPENEM - 10 G(BD BBL SENSI-DISC IMIPENEM - 10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CHLORAMPHENICOL - 5 G(BD BBL SENSI-DISC CHLORAMPHENICOL - 5 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC OFLOXACIN - 5 G(BD BBL SENSI-DISC OFLOXACIN - 5 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CIPROFLOXACIN - 5 G (BD BBL SENSI-DISC CIPROFLOXACIN - 5 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS

	PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL CEFINASE PAPER DISC, 1/4", IMPREGNATED WITH NITROCEFIN(BD BBL CEFINASE PAPER DISC, 1/4", IMPREGNATED WITH NITROCEFIN)-CEFINASE™ DISCS ARE INTENDED FOR USE IN RAPID TESTING OF ISOLATED COLONIES OF NEISSERIA GONORRHOEAE, STAPHYLOCOCCUS SPECIES, HAEMOPHILUS INFLUENZAE, ENTEROCOCCI AND ANAEROBIC BACTERIA FOR THE PRODUCTION OF B-LACTAMASE. ,BD BBL SENSI-DISC NOVOBIOCIN - 30 G(BD BBL SENSI-DISC NOVOBIOCIN - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC NOVOBIOCIN - 5 G(BD BBL SENSI-DISC NOVOBIOCIN - 5 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CEFTIZOXIME - 30 G (BD BBL SENSI-DISC CEFTIZOXIME - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CEFPODOXIME - 10 G (BD BBL SENSI-DISC CEFPODOXIME - 10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE,

	NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CEFOTAXIME/CLAVULANIC ACID - 30/10 G (BD BBL SENSI-DISC CEFOTAXIME/CLAVULANIC ACID - 30/10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CEFOPERAZONE - 75 G(BD BBL SENSI-DISC CEFOPERAZONE - 75 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CEFIXIME - 5 G (BD BBL SENSI-DISC CEFIXIME - 5 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC MINOCYCLINE - 30 G(BD BBL SENSI-DISC MINOCYCLINE - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC NITROFURANTOIN - 100 G(BD BBL SENSI-DISC NITROFURANTOIN - 100 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST

	PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC NETILMICIN - 30 G(BD BBL SENSI-DISC NETILMICIN - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC NEOMYCIN - 30 G (BD BBL SENSI-DISC NEOMYCIN - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC KANAMYCIN - 30 G(BD BBL SENSI-DISC KANAMYCIN - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC NORFLOXACIN - 10 G (BD BBL SENSI-DISC NORFLOXACIN - 10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND

	OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC BACITRACIN - 10 UNITS AND 2 UNITS(BD BBL SENSI-DISC BACITRACIN - 10 UNITS AND 2 UNITS)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CLOXACILLIN - 1 G(BD BBL SENSI-DISC CLOXACILLIN - 1 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC ERYTHROMYCIN - 2 G(BD BBL SENSI-DISC ERYTHROMYCIN - 2 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CLARITHROMYCIN - 15 G (BD BBL SENSI-DISC CLARITHROMYCIN - 15 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC FURAZOLIDONE - 100 G(BD BBL SENSI-DISC FURAZOLIDONE - 100 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE

	INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC ETHIONAMIDE - 25 G(BD BBL SENSI-DISC ETHIONAMIDE - 25 G)-THESE DISCS ARE USED IN QUALITATIVE SUSCEPTIBILITY TESTING PROCEDURES IN CULTURE MEDIA. THEY SERVE AS A CONVENIENT METHOD FOR ADDITION OF ANTIMICROBIAL AGENTS TO CULTURE MEDIA, ESPECIALLY FOR QUALITATIVE STUDIES OF MYCOBACTERIA AND RELATED ORGANISMS. ,BD BBL SENSI-DISC CEPHALOTHIN - 30 G(BD BBL SENSI-DISC CEPHALOTHIN - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CEFTRIAXONE - 30 G (BD BBL SENSI-DISC CEFTRIAXONE - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC GENTAMICIN - 10 G (BD BBL SENSI-DISC GENTAMICIN - 10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC AMPICILLIN WITH SULBACTAM - 10/10 G(BD BBL SENSI-DISC AMPICILLIN WITH SULBACTAM - 10/10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING

	AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC ERYTHROMYCIN - 15 G(BD BBL SENSI-DISC ERYTHROMYCIN - 15 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BACTEC™ STANDARD/10 AEROBIC/F CULTURE VIALS(BD BACTEC™ STANDARD/10 AEROBIC/F CULTURE VIALS)-BD BACTEC™ STANDARD/10 AEROBIC/F CULTURE VIALS (ENRICHED SOYBEAN-CASEIN DIGEST BROTH WITH CO2) ARE FOR AEROBIC BLOOD CULTURES. PRINCIPAL USE IS WITH THE BD BACTEC FLUORESCENT SERIES INSTRUMENTS FOR THE QUALITATIVE CULTURE AND RECOVERY OF AEROBIC MICROORGANISMS (BACTERIA AND YEAST) FROM BLOOD. ,BD BBL SENSI-DISC CEFUROXIME - 30 G (BD BBL SENSI-DISC CEFUROXIME - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC RIFAMPIN, RA25, 25UG (BD BBL SENSI-DISC RIFAMPIN, RA25, 25UG)-THESE DISCS ARE USED IN QUALITATIVE SUSCEPTIBILITY TESTING PROCEDURES IN CULTURE MEDIA. THEY SERVE AS A CONVENIENT METHOD FOR ADDITION OF ANTIMICROBIAL AGENTS TO CULTURE MEDIA, ESPECIALLY FOR QUALITATIVE STUDIES OF MYCOBACTERIA AND RELATED ORGANISMS.,BD BBL DRYSLIDE NITROCEFIN(BD BBL DRYSLIDE NITROCEFIN)-BBL™ DRYSLIDE™ NITROCEFIN IS USED FOR DETECTING -LACTAMASE PRODUCTION BY BACTERIA.,BD-BBL SENSI- DISC-CEFTAZIDIME AVIBACATAM 20/30 G(BD-BBL SENSI-DISC-CEFTAZIDIME AVIBACATAM 20/30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE

	AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC STREPTOMYCIN - 300 G(BD BBL SENSI-DISC STREPTOMYCIN - 300 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBLTAXO KANAMYCIN DISCS (1 EA.)(BD BBLTAXO KANAMYCIN DISCS (1 EA.))-THESE DISCS ARE RECOMMENDED FOR USE IN THE PRESUMPTIVE IDENTIFICATION OF GRAM-NEGATIVE ANAEROBIC BACILLI BASED ON DIFFERENCES IN SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS. THIS PROCEDURE IS NOT FOR USE FOR THERAPEUTIC PURPOSES.,BD BBL SENSI-DISC RIFAMPIN, RA5, 5UG (BD BBL SENSI-DISC RIFAMPIN, RA5, 5UG)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL GASPAK DRY ANAEROBIC INDICATOR STRIPS(BD BBL GASPAK DRY ANAEROBIC INDICATOR STRIPS)-FOR THE DETECTION OF AN ANAEROBIC ATMOSPHERE WHEN USING GASPAK™ EZ, GASPAK™ PLUS GAS GENERATING SYSTEMS.,BD BACTEC™ PLUS ANAEROBIC/F CULTURE VIALS(BD BACTEC™ PLUS ANAEROBIC/F CULTURE VIALS)-BD BACTEC PLUS ANAEROBIC/F MEDIUM IS USED IN A QUALITATIVE PROCEDURE FOR THE ANAEROBIC CULTURE AND RECOVERY OF MICROORGANISMS (BACTERIA AND YEAST) FROM BLOOD. THE PRINCIPAL USE OF THESE MEDIA IS WITH THE BD BACTEC FLUORESCENT SERIES INSTRUMENTS.,BD BBL SENSI-DISC TRIMETHOPRIM, P5, 5UG (BD BBL SENSI-DISC TRIMETHOPRIM, P5, 5UG)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE

	AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC-TEICOPLANIN -30G(BD BBL SENSI-DISC- TEICOPLANIN -30G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC VANCOMYCIN - 5 G(BD BBL SENSI-DISC VANCOMYCIN - 5 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBLTAXO DIFFERENTIATION DISC FOR VX FACTOR(BD BBLTAXO DIFFERENTIATION DISC FOR VX FACTOR)-BD BBL™ TAXO™ DIFFERENTIATION DISCS ARE USED FOR PRESUMPTIVELY DIFFERENTIATING HAEMOPHILUS SPP. BASED ON THEIR REQUIREMENTS FOR X OR V FACTORS OR BOTH.,BD BBLTAXO DIFFERENTIATION DISC FOR V FACTOR (1 EA.)(BD BBLTAXO DIFFERENTIATION DISC FOR V FACTOR (1 EA.))-BD BBL™ TAXO™ DIFFERENTIATION DISCS ARE USED FOR PRESUMPTIVELY DIFFERENTIATING HAEMOPHILUS SPP. BASED ON THEIR REQUIREMENTS FOR X OR V FACTORS OR BOTH.,BD BBLTAXO DIFFERENTIATION DISC FOR X FACTOR (BD BBLTAXO DIFFERENTIATION DISC FOR X FACTOR)-BD BBL™ TAXO™ DIFFERENTIATION DISCS ARE USED FOR PRESUMPTIVELY DIFFERENTIATING HAEMOPHILUS SPP. BASED ON THEIR REQUIREMENTS FOR X OR V FACTORS OR BOTH.,BD BACTEC™ LYTIC/10 ANAEROBIC/F CULTURE VIALS(BD BACTEC™ LYTIC/10 ANAEROBIC/F CULTURE VIALS)-BD BACTEC™ LYTIC/10 ANAEROBIC/F CULTURE VIALS (PREREDUCED ENRICHED SOYBEAN-

	CASEIN DIGEST BROTH WITH CO2) ARE FOR ANAEROBIC BLOOD CULTURES. PRINCIPAL USE IS WITH THE BD BACTEC FLUORESCENT SERIES INSTRUMENTS FOR THE QUALITATIVE CULTURE AND RECOVERY OF ANAEROBIC MICROORGANISMS FROM BLOOD ,BD BBLTAXO DIFFERENTIATION DISCS FOR SPS(BD BBLTAXO DIFFERENTIATION DISCS FOR SPS)-BBL™ TAXO™ DIFFERENTIATION DISCS SPS (SODIUM POLYANETHOL SULFONATE) ARE USED FOR PRESUMPTIVELY IDENTIFYING PEPTOSTREPTOCOCCUS ANAEROBIUS AND GARDNERELLA VAGINALIS. ,BD BBL SENSI-DISC VANCOMYCIN - 30 G(BD BBL SENSI-DISC VANCOMYCIN - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BACTEC™ STANDARD ANAEROBIC/F CULTURE VIALS(BD BACTEC™ STANDARD ANAEROBIC/F CULTURE VIALS)-BD BACTEC™ STANDARD ANAEROBIC/F CULTURE VIALS (PREREDUCED ENRICHED SOYBEAN-CASEIN DIGEST BROTH WITH CO2) ARE FOR ANAEROBIC BLOOD CULTURES. PRINCIPAL USE IS WITH THE BD BACTEC FLUORESCENT SERIES INSTRUMENTS FOR THE QUALITATIVE CULTURE AND RECOVERY OF ANAEROBIC MICROORGANISMS FROM BLOOD. ,BD BBL SENSI-DISC SULFAMETHOXAZOLE WITH TRIMETHOPRIM - 23.75/1.25 G (BD BBL SENSI-DISC SULFAMETHOXAZOLE WITH TRIMETHOPRIM - 23.75/1.25 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC POLYMYXIN B - 300 UNITS(BD BBL SENSI-DISC POLYMYXIN B - 300 UNITS)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS

	INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC STREPTOMYCIN - 10 G(BD BBL SENSI-DISC STREPTOMYCIN - 10 G) -THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC STREPTOMYCIN - 50 G (BD BBL SENSI-DISC STREPTOMYCIN - 50 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC TICARCILLIN WITH CLAVULANIC ACID - 75/10 G(BD BBL SENSI-DISC TICARCILLIN WITH CLAVULANIC ACID - 75/10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC TIGECYCLINE - 15 G (BD BBL SENSI-DISC TIGECYCLINE - 15 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BACTEC™ MYCO/F LYTIC CULTURE VIALS(BD BACTEC™ MYCO/F LYTIC CULTURE VIALS)- BD BACTEC™ MYCO/F LYTIC CULTURE MEDIUM WHEN USED WITH THE BD BACTEC FLUORESCENT SERIES INSTRUMENTS IS A

	NONSELECTIVE CULTURE MEDIUM TO BE USED AS AN ADJUNCT TO AEROBIC BLOOD CULTURE MEDIA FOR THE RECOVERY OF MYCOBACTERIA, YEAST AND FUNGI FROM BLOOD. THIS MEDIUM MAY ALSO BE USED FOR THE CULTURE OF STERILE BODY FLUIDS WHEN YEAST OR FUNGI ARE SUSPECTED. ,BD BBL SENSI-DISC TETRACYCLINE - 5 G (BD BBL SENSI-DISC TETRACYCLINE - 5 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBLTAXO P DISCS FOR DIFFERENTIATION OF PNEUMOCOCCI (BD BBLTAXO P DISCS FOR DIFFERENTIATION OF PNEUMOCOCCI)-BD BBL™ TAXO™ P DISCS ARE RECOMMENDED FOR USE IN THE PRESUMPTIVE IDENTIFICATION OF PNEUMOCOCCI, AND ARE INTENDED FOR USE WITH PURE CULTURES. ,BD BBL SENSI-DISC SPECTINOMYCIN - 100 G(BD BBL SENSI-DISC SPECTINOMYCIN - 100 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC SULFADIAZINE - 0.25 MG (BD BBL SENSI-DISC SULFADIAZINE - 0.25 MG)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CEFOTAXIME - 30 G (BD BBL SENSI-DISC CEFOTAXIME - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP.,

	PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC PIPERACILLIN - 100 G(BD BBL SENSI-DISC PIPERACILLIN - 100 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL DRYSLIDE OXIDASE(BD BBL DRYSLIDE OXIDASE)-BBL™ DRYSLIDE™ OXIDASE IS USED FOR DETERMINING THE OXIDASE REACTION OF BACTERIA.,BD BBL SENSI-DISC CARBENICILLIN - 100 G(BD BBL SENSI-DISC CARBENICILLIN - 100 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC PIPERACILLIN/TAZOBACTAM - 100/10 G(BD BBL SENSI-DISC PIPERACILLIN/TAZOBACTAM - 100/10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC SULFAMETHIZOLE - 0.25 MG (BD BBL SENSI-DISC SULFAMETHIZOLE - 0.25 MG)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE,

	NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL TAXO N DISCS(BD BBL TAXO N DISCS)-BD BBL™ TAXO™ N DISCS ARE USED IN QUALITATIVE PROCEDURES TO DISTINGUISH THOSE ORGANISMS WHICH PRODUCE OXIDASE. BY THIS REACTION, BD BBL TAXO N DISCS MAY BE USED FOR THE PRESUMPTIVE DIFFERENTIATION OF THE GENUS NEISSERIA FROM OTHER GRAM-NEGATIVE COCCI AND MEMBERS OF THE GENUS PSEUDOMONAS FROM ENTERIC BACILLI. ,BD BBL SENSI-DISC CEFOXITIN - 30 G (BD BBL SENSI-DISC CEFOXITIN - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BACTEC™ PLUS ANAEROBIC/F CULTURE VIALS (PLASTIC) (BD BACTEC™ PLUS ANAEROBIC/F CULTURE VIALS (PLASTIC))-THE BD BACTEC™ PLUS ANAEROBIC/F MEDIUM IS USED IN A QUALITATIVE PROCEDURE FOR THE ANAEROBIC CULTURE AND RECOVERY OF MICROORGANISMS (BACTERIA) FROM BLOOD. THE PRINCIPAL USE OF THIS MEDIUM IS WITH THE BD BACTEC FLUORESCENT SERIES INSTRUMENTS.,BD BACTEC™ LYTIC/10 ANAEROBIC/F CULTURE VIALS (PLASTIC)(BD BACTEC™ LYTIC/10 ANAEROBIC/F CULTURE VIALS (PLASTIC))-BACTEC™ LYTIC/10 ANAEROBIC/F CULTURE VIALS (PREREDUCED ENRICHED SOYBEAN-CASEIN DIGEST BROTH WITH CO2) ARE FOR ANAEROBIC BLOOD CULTURES. PRINCIPAL USE IS WITH THE BACTEC FLUORESCENT SERIES INSTRUMENTS FOR THE QUALITATIVE CULTURE AND RECOVERY OF ANAEROBIC MICROORGANISMS FROM BLOOD.,BD BBL SENSI-DISC COLISTIN - 10 G(BD BBL SENSI-DISC COLISTIN - 10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BACTEC PED PLUS/F CULTURE VIALS (PLASTIC)(BD BACTEC PED PLUS/F CULTURE VIALS (PLASTIC))-BD BACTEC PED PLUS/F CULTURE VIALS (PLASTIC) BD BACTEC PED PLUS/F CULTURE VIALS (PLASTIC) 442020 BD BACTEC PEDS

	PLUS™/F CULTURE VIALS (ENRICHED SOYBEAN-CASEIN DIGEST BROTH WITH CO2) ARE FOR AEROBIC BLOOD CULTURES. PRINCIPAL USE IS WITH THE BD BACTEC FLUORESCENT SERIES INSTRUMENTS FOR THE QUALITATIVE CULTURE AND RECOVERY OF AEROBIC MICROORGANISMS (MAINLY BACTERIA AND YEAST) FROM PEDIATRIC AND NON-PEDIATRIC BLOOD SPECIMENS WHICH ARE GENERALLY LESS THAN 3 ML IN VOLUME.,BD BBL SENSI-DISC AZTREONAM - 30 G (BD BBL SENSI-DISC AZTREONAM - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC CEFTAZIDIME - 30 G(BD BBL SENSI-DISC CEFTAZIDIME - 30 G)-ON RECEIPT STORE DISCS AT -20 TO 8 C. IF THE LABORATORY REFRIGERATOR IS FREQUENTLY OPENED AND CLOSED AND A SUITABLE TEMPERATURE IS NOT MAINTAINED PLACE THERE A SUPPLY SUFFICIENT ONLY FOR USE WITHIN A WEEK. SOME DISCS LIKE BETA LACTAMS SHOULD PREFERABLY BE KEPT FROZEN AT -20C.,BD BBL SENSI-DISC CEFTAZIDIME/CLAVULANIC ACID - 30/10 G(BD BBL SENSI-DISC CEFTAZIDIME/CLAVULANIC ACID - 30/10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC AMOXICILLIN WITH CLAVULANIC ACID - 20/10 G (BD BBL SENSI-DISC AMOXICILLIN WITH CLAVULANIC ACID - 20/10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBLTAXO A DISCS

	FOR DIFFERENTIATION OF GROUP A STREPTOCOCCI (BD BBLTAXO A DISCS FOR DIFFERENTIATION OF GROUP A STREPTOCOCCI)-BD BBL TAXO™ A DISCS ARE FOR THE PRESUMPTIVE IDENTIFICATION OF GROUP A BETA-HEMOLYTIC STREPTOCOCCI BASED ON SUSCEPTIBILITY TO A LOW LEVEL OF BACITRACIN. DISCS ARE INTENDED FOR USE WITH PURE CULTURES, WITH THE EXCEPTION NOTED UNDER “SPECIMENS.”,BD BACTEC™ PEDS PLUS™/ F CULTURE VIALS(BD BACTEC™ PEDS PLUS™/ F CULTURE VIALS)-BD BACTEC PEDS PLUS™/F CULTURE VIALS (ENRICHED SOYBEAN-CASEIN DIGEST BROTH WITH CO2) ARE FOR AEROBIC BLOOD CULTURES. PRINCIPAL USE IS WITH THE BD BACTEC FLUORESCENT SERIES INSTRUMENTS FOR THE QUALITATIVE CULTURE AND RECOVERY OF AEROBIC MICROORGANISMS (MAINLY BACTERIA AND YEAST) FROM PEDIATRIC AND OTHER BLOOD SPECIMENS WHICH ARE GENERALLY LESS THAN 3 ML IN VOLUME.,BD BACTEC™ PLUS AEROBIC/F CULTURE VIALS (PLASTIC)(BD BACTEC™ PLUS AEROBIC/F CULTURE VIALS (PLASTIC))-BD BACTEC PLUS AEROBIC/F MEDIUM IS USED IN A QUALITATIVE PROCEDURE FOR THE AEROBIC CULTURE AND RECOVERY OF MICROORGANISMS (BACTERIA AND YEAST) FROM BLOOD. THE PRINCIPAL USE OF THIS MEDIUM IS WITH THE BD BACTEC FLUORESCENT SERIES INSTRUMENTS,BD BACTEC™ PLUS AEROBIC/F CULTURE VIALS(BD BACTEC™ PLUS AEROBIC/F CULTURE VIALS)-BD BACTEC PLUS AEROBIC/F MEDIUM IS USED IN A QUALITATIVE PROCEDURE FOR THE AEROBIC CULTURE AND RECOVERY OF MICROORGANISMS (BACTERIA AND YEAST) FROM BLOOD. THE PRINCIPAL USE OF THESE MEDIA IS WITH THE BD BACTEC FLUORESCENT SERIES INSTRUMENTS.,BD BBL SENSI-DISC AMPICILLIN - 2 G (BD BBL SENSI-DISC AMPICILLIN - 2 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC FOSFOMYCIN - 200 G(BD BBL SENSI-DISC FOSFOMYCIN - 200 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS

	INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC AMIKACIN - 30 G (BD BBL SENSI-DISC AMIKACIN - 30 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC ERTAPENEM - 10 G(BD BBL SENSI-DISC ERTAPENEM - 10 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI. ,BD BBL SENSI-DISC GENTAMICIN - 120 G(BD BBL SENSI-DISC GENTAMICIN - 120 G)-THESE DISCS ARE USED FOR SEMI-QUANTITATIVE IN VITRO SUSCEPTIBILITY TESTING BY THE AGAR DISC DIFFUSION TEST PROCEDURE OF COMMON, RAPIDLY GROWING AND CERTAIN FASTIDIOUS BACTERIAL PATHOGENS. THESE INCLUDE THE ENTEROBACTERIACEAE, STAPHYLOCOCCUS SPP., PSEUDOMONAS SPP.,ACINETOBACTER SPP., ENTEROCOCCUS SPP., VIBRIO CHOLERAE AND, BY MODIFIED PROCEDURES, HAEMOPHILUS INFLUENZAE, NEISSERIA GONORRHOEAE, STREPTOCOCCUS PNEUMONIAE AND OTHER STREPTOCOCCI.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

270	IMP/IVD/2019/000264	1.License Holder Name: M/S.ROCHE DIABETES CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(ACCU-CHEK GUIDE)-THE ACCU-CHEK GUIDE TEST STRIPS WITH THE ACCU-CHEK GUIDE METER ARE INTENDED TO QUANTITATIVELY MEASURE GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD FROM FINGER, PALM, FOREARM, AND UPPER ARM AS AN AID IN MONITORING THE EFFECTIVENESS OF GLUCOSE CONTROL. THE ACCU-CHEK GUIDE TEST STRIP WITH ACCU-CHEK GUIDE METER ARE INTENDED FOR IN-VITRO DIAGNOSTIC SELF-TESTING BY PEOPLE WITH DIABETES. THE ACCU-CHEK GUIDE TEST STRIP WITH ACCU-CHEK GUIDE METER ARE INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS IN CLINICAL SETTINGS. VENOUS, ARTERIAL, AND NEONATAL BLOOD TESTING IS LIMITED TO HEALTHCARE PROFESSIONAL USE. THIS SYSTEM IS NOT FOR USE IN DIAGNOSIS OF DIABETES MELLITUS, NOR FOR TESTING NEONATE CORD BLOOD SAMPLES.
271	IMP/IVD/2019/000269	1.License Holder Name: MICROGENE DIAGNOSTIC SYSTEMS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOGLOBIN TEST STRIP (ACCUSURE HB)-ACCUSURE HB HEMOGLOBIN TEST STRIPS IS USED ALONG WITH HEMOGLOBIN TEST SYSTEM IS INTENDED TO QUANTITATIVELY MEASURE HEMOGLOBIN IN CAPILLARY AND VENOUS WHOLE BLOOD
272	IMP/IVD/2019/000271	1.License Holder Name: HORIBA INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MINOCAL (BULK) (HORIBA)-MINOCAL IS A MULTIPARAMETER BLOOD CALIBRATOR DESIGNED FOR USE IN THE CALIBRATION OFHORIBA MEDICAL HEMATOLOGY BLOOD CELL COUNTERS USING HORIBA MEDICAL REAGENTS.,MINOTROL (BULK) (HORIBA)-MINOTROL IS A TRI-LEVEL CONTROL INTENDED FOR IN VITRO DIAGNOSTIC USE IN MONITORINGTHE ACCURACY AND PRECISION ON HORIBA MEDICAL HEMATOLOGY BLOOD CELLCOUNTERS USING HORIBA MEDICAL REAGENTS.,DIFFTROL (BULK) (HORIBA)-DIFFTROL IS A TRI-LEVEL CONTROL INTENDED FOR IN VITRO USE IN MONITORING THE ACCURACYAND PRECISION OF HORIBA MEDICAL HEMATOLOGY BLOOD CELL COUNTERS USINGHORIBA MEDICAL REAGENTS

273	IMP/IVD/2019/000272	1.License Holder Name: ASCENSIA DIABETES CARE INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(CONTOUR PLUS)-CONTOUR PLUS TEST STRIPS ARE INTENDED FOR SELF-TESTING BY PEOPLE WITH DIABETES AND BY HEALTH CARE PROFESSIONALS TO MONITOR GLUCOSE CONCENTRATIONS IN WHOLE BLOOD.,BLOOD GLUCOSE TEST STRIPS (CONTOUR TS)-CONTOUR TS TEST STRIPS ARE INTENDED FOR SELF-TESTING BY PEOPLE WITH DIABETES AND BY HEALTH CARE PROFESSIONALS TO MONITOR GLUCOSE CONCENTRATIONS IN WHOLE BLOOD.
274	IMP/IVD/2019/000275	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CK-MB CALIBRATOR-THE CK-MB CALIBRATOR IS A LYOPHILISED HUMAN SERUM CALIBRATOR DESIGNED FOR CALIBRATION OF THE CK-MB REAGENT OSR61155 ON BECKMAN COULTER ANALYSERS,CK-MB CONTROL SERUM LEVEL 1-THE CK-MB CONTROL SERUM LEVEL 1 IS A LYOPHILISED HUMAN SERUM CONTROL DESIGNED TO MONITOR THE ACCURACY AND PRECISION OF THE CK-MB REAGENT OSR61155 ON BECKMAN COULTER ANALYSERS,CK-MB CONTROL SERUM LEVEL 2-THE CK-MB CONTROL SERUM LEVEL 2 IS A LYOPHILISED HUMAN SERUM CONTROL DESIGNED TO MONITOR THE ACCURACY AND PRECISION OF THE CK-MB REAGENT OSR61155 ON BECKMAN COULTER ANALYSERS.
275	IMP/IVD/2019/000283	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HB HEMOGLOBIN CONTROL SOLUTION-HB HEMOGLOBIN CONTROL SOLUTION IS INTENDED FOR USE IN VALIDATING HEMOGLOBIN TESTING USING MISSION HB HEMOGLOBIN TESTING SYSTEM.,CHOL TOTAL CHOLESTEROL TEST STRIPS-FOR ESTIMATION OF CHOLESTEROL, CHOLESTEROL TEST DEVICES-FOR ESTIMATION OF TOTAL CHOLESTEROL, HDL AND TRIGLYCERIDES,HB HAEMOGLOBIN TEST STRIPS-FOR ESTIMATION OF HEMOGLOBIN,URINE ANALYSIS REAGENT STRIPS-FOR ESTIMATION OF GLUCOSE, BILIRUBIN, PH, SPECIFIC GRAVITY, PROTEIN, UROBILINOGEN, NITRITE, KETONE, BLOOD, LEUKOCYTE, ASCORBIC ACID, MICROALBUMIN, CREATININE, CALCIUM ETC. IN URINE,LIQUID URINE CONTROL-FOR QUALITY CONTROL OF URINE ANALYSIS REAGENT STRIPS

276	IMP/IVD/2019/000284	1.License Holder Name: DIASYS DIAGNOSTIC INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GREENCARE A1C HEMOGLOBIN A1C TEST KIT(QDX A1C ADVANCE)-THE GREENCARE A1C HEMOGLOBIN A1C TEST KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF GLYCATED HEMOGLOBIN (HEMOGLOBIN A1C, HBA1C) IN HUMAN BLOOD. IT ALSO PROVIDES THE ESTIMATED AVERAGE GLUCOSE (EAG) VALUE, IN ADDITION TO THE GLYCATED HEMOGLOBIN RESULT, ALLOWING FOR EASIER DIABETES CARE.

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277	IMP/IVD/2019/000287	1.License Holder Name: EDIF MEDICAL SYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOODTROL 22(SFRI)-BLOODTROL 22 IS A COMPATIBLE HEMATOLOGY CONTROL DESIGNED TO EVALUATE THE ACCURACY AND PRECISION OF HAEMATOLOGY CELL COUNTER,ISE CONTROL (NA+, K+, CL-, CA++, PH)(SFRI)-CALIBRATION SOLUTION OF BIOCHEMISTRY ANALYZERS SFRI ISE 2000, 3000,4000,4500, 5000 AND 6000, FOR SODIUM, POTASSIUM, CHLORIDE, CALCIUM AND PH.,K FILLING SOLUTION(SFRI) -FILLING SOLUTION FOR POTASSIUM ELECTRODE OF SFRI ISE.,ISE CONTROL (NA+,K+,CL-, LI+)(SFRI)-QUALITY CONTROL SOLUTION FOR BIOCHEMISTRY ANALYZERS SFRI ISE 4500.,BLOODTROL 16(SFRI)-BLOODTROL 16 IS A COMPATIBLE HEMATOLOGY CONTROL DESIGNED TO EVALUATE THE ACCURACY AND PRECISION OF HAEMATOLOGY CELL COUNTER,SFRI CLEAN EZ 3.3(SFRI)-CLEAN EZ IS A CLEANING REAGENT THAT EFFECTIVELY CLEANS OUT CELL DEBRIS, PROTEINS AND TRIGLYCERIDES BY DETERGENT SOLUBILISATION..,SFRI DILUENT 3.3(SFRI)-DILUENT IS A MEDICAL DEVICE USED FOR BLOOD DILUTING FOR FURTHER TESTING SUCH AS CBC.,SFRI LYSE 5.1(SFRI)-LYSE IS A MEDICAL DEVICE USED FOR LYSING OF CELLS FOR ESTIMATION OF CBC.,SFRI CLEANER 3.1(SFRI)-CLEANER IS USED FOR CLEANING VARIOUS PARTS OF HEAMATOLOGY ANALYZER LIKE PROBE, NEEDLES & TUBING.,SFRI CLAIR 5.1(SFRI)-CLAIR IS A CLEANING REAGENT THAT EFFECTIVELY CLEANS OUT CELL DEBRIS, PROTEINS AND TRIGLYCERIDES BY DETERGENT SOLUBILISATION..,PH NA CL FILLING SOLUTION(SFRI)-FILLING TECHNICAL SOLUTION FOR SODIUM, CHLORIDE AND PH ELECTRODES OF SFRI ISE.,BLOODCAL (SFRI)-BLOODCAL - 1 X 3 ML IS AN ASSAYED HEMATOLOGY CALIBRATOR DESIGNED FOR THE CALIBRATION OF SFRI HEMATOLOGY BLOOD CELL COUNTERS,SFRI REAGENT PACK FOR ISE 4500(SFRI)-SOLUTIONS USED TO DOSE SODIUM, POTASSIUM, CHLORIDE AND LITHIUM IN SERUM SAMPLES WITH SFRI ISE 4500.,NA CONDITIONNER(SFRI)-CLEANING SOLUTION FOR SODIUM ELECTRODE OF SFRI ISE.,WEEKLY CLEANING SOLUTION(SFRI)-CLEANING SOLUTION USED TO RINSE SFRI ISE.,SFRI REAGENT PACK FOR ISE 6000(SFRI)-SOLUTIONS USED TO DOSE SODIUM, POTASSIUM, CHLORIDE AND CALCIUM IN SERUM SAMPLES WITH SFRI ISE 6000. THIS ANALYZER ALSO PERMITS TO DETERMINE THE BLOOD PH AND THE TOTAL CONCENTRATION OF CARBON DIOXIDE (TCO2) , SFRI REAGENT PACK FOR ISE 5000(SFRI)-SOLUTIONS USED TO DOSE SODIUM, POTASSIUM, CHLORIDE AND CALCIUM IN SERUM SAMPLES WITH SFRI ISE 5000. THIS ANALYZER ALSO PERMITS TO DETERMINE THE BLOOD PH.,SFRI REAGENT PACK FOR ISE 4000(SFRI)-SOLUTIONS USED TO DOSE SODIUM, POTASSIUM, CHLORIDE AND

	TOTAL CO2 (TCO2) IN SERUM SAMPLES WITH SFRI ISE 4000., STANDARD C (LITHIUM)(SFRI)-CONTROL SOLUTION OF BIOCHEMISTRY ANALYZERS SFRI ISE 4500.,REFERENCE FILLING SOLUTION(SFRI)-FILLING SOLUTION FOR REFERENCE ELECTRODES OF SFRI ISE.,LITHIUM CONTROL HIGH(SFRI)-CONTROL SOLUTION OF BIOCHEMISTRY ANALYZERS SFRI ISE 4500.,STANDARD TCO2(SFRI)-CO2 CALIBRATION SOLUTION FOR BIOCHEMISTRY ANALYZERS SFRI ISE 4000 AND 6000.,ISE CALIBRATION (NA+, K+,CL-,CA++, PH)(SFRI)-CALIBRATION SOLUTION OF BIOCHEMISTRY ANALYZERS SFRI ISE 2000, 3000,4000,4500, 5000 AND 6000, FOR SODIUM, POTASSIUM, CHLORIDE, CALCIUM AND PH.,SFRI REAGENT PACK FOR ISE 3000 (SFRI)-THE ISE 3000 EMPLOYS ELECTRODES FOR SODIUM, POTASSIUM, CHLORIDE AND CALCIUM THAT ARE SPECIFIC FOR EACH ION OF INTEREST IN THE SAMPLE.,BLOODTROL 22(SFRI)-BLOODTROL 22 IS A COMPATIBLE HEMATOLOGY CONTROL DESIGNED TO EVALUATE THE ACCURACY AND PRECISION OF HAEMATOLOGY CELL COUNTER,BLOODTROL 22(SFRI)-BLOODTROL 22 IS A COMPATIBLE HEMATOLOGY CONTROL DESIGNED TO EVALUATE THE ACCURACY AND PRECISION OF HAEMATOLOGY CELL COUNTER,BLOODTROL 16 (SFRI)-BLOODTROL 16 IS A COMPATIBLE HEMATOLOGY CONTROL DESIGNED TO EVALUATE THE ACCURACY AND PRECISION OF HAEMATOLOGY CELL COUNTER,SFRI CLAIR 3.1(SFRI)-CLAIR IS A CLEANING REAGENT THAT EFFECTIVELY CLEANS OUT CELL DEBRIS, PROTEINS AND TRIGLYCERIDES BY DETERGENT SOLUBILISATION..,SFRI DILUENT 3.1(SFRI)-DILUENT IS A MEDICAL DEVICE USED FOR BLOOD DILUTING FOR FURTHER TESTING SUCH AS CBC.,SFRI QUENCH 5.1(SFRI)-QUENCH IS A REAGENT FOR THE HAEMOLYSE OF ERYTHROCYTES, THE NUMERATION OF LEUCOCYTES, THE DETERMINATION OF PARTIAL LEUCOCYTES DIFFERENTIATION AND THE MEASUREMENT OF HAEMOGLOBIN ON BLOOD CELL COUNTERS..,SFRI DILUENT 5.1(SFRI)-DILUENT IS A MEDICAL DEVICE USED FOR BLOOD DILUTING FOR FURTHER TESTING SUCH AS CBC.,BLOODTROL 16(SFRI)-BLOODTROL 16 IS A COMPATIBLE HEMATOLOGY CONTROL DESIGNED TO EVALUATE THE ACCURACY AND PRECISION OF HAEMATOLOGY CELL COUNTER,SFRI LYSE 3.3(SFRI)-LYSE IS A MEDICAL DEVICE USED FOR LYSING OF CELLS FOR ESTIMATION OF CBC.,BLOODTROL 22(SFRI)-BLOODTROL 22 IS A COMPATIBLE HEMATOLOGY CONTROL DESIGNED TO EVALUATE THE ACCURACY AND PRECISION OF HAEMATOLOGY CELL COUNTER,SFRI LYSE 3.1 (SFRI)-LYSE IS A MEDICAL DEVICE USED FOR LYSING OF CELLS FOR ESTIMATION OF CBC.,SFRI CLAIR 3.3(SFRI)-CLAIR IS A CLEANING REAGENT THAT EFFECTIVELY CLEANS OUT CELL DEBRIS, PROTEINS AND TRIGLYCERIDES BY DETERGENT SOLUBILISATION..,SFRI CLEANER 3.3(SFRI)-CLEANER IS USED FOR CLEANING VARIOUS

		PARTS OF HEAMATOLOGY ANALYZER LIKE PROBE, NEEDLES & TUBING.,CA FILLING SOLUTION(SFRI)-FILLING SOLUTION FOR CALCIUM ELECTRODE OF SFRI ISE 5000 AND 6000,BLOODTROL 16 (SFRI)-BLOODTROL 16 IS A COMPATIBLE HEMATOLOGY CONTROL DESIGNED TO EVALUATE THE ACCURACY AND PRECISION OF HAEMATOLOGY CELL COUNTER,SFRI CLEANEZ 3.1(SFRI)-CLEAN EZ IS A CLEANING REAGENT THAT EFFECTIVELY CLEANS OUT CELL DEBRIS, PROTEINS AND TRIGLYCERIDES BY DETERGENT SOLUBILISATION..,SFRI CLEANER 3.1(SFRI)-CLEANER IS USED FOR CLEANING VARIOUS PARTS OF HEAMATOLOGY ANALYZER LIKE PROBE, NEEDLES & TUBING.,LI FILLING SOLUTION(SFRI)-FILLING SOLUTION FOR LITHIUM ELECTRODE OF SFRI ISE.
278	IMP/IVD/2019/000292	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:G-6-P D CONTROLS, NORMAL, DEFICIENT, INTERMEDIATE (G6888, G5888, G5029)-FOR USE AS CONTROL WITH G6PDH KIT,ACE CONTROLS, NORMAL AND ELEVATED (A6040, A7040)-FOR USE AS CONTROL WITH ACE REAGENT KIT,ACE CALIBRATOR (305-50)-FOR USE AS CALIBRATOR WITH ACE REAGENT KIT
279	IMP/IVD/2019/000293	1.License Holder Name: ESTIMA HEALTHCARE PVT.LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EXTERNAL LIQUID QUALITY CONTROL(MICRO INR EASY CONTROL)-THE MICRO INR EASY CONTROL IS INTENDED FOR QUALITY CONTROL PERFORMED ON THE MICRO INR METER WHEN USED WITH THE MICRO INR DISPOSABLE ANALYTIC STRIPS (CHIPS).,TEST STRIP FOR INR DETERMINATION(MICRO INR CHIP)-THE PRODUCT IS INDICATED FOR MONITORING PROLONGED ORAL ANTICOAGULANT TREATMENTS (VITAMIN K ANTAGONISTS SUCH AS ACNEOCUMAROL, WARFARIN,..) USUALLY INDICATED FOR TREATING THROMBOEMBOLIC DISEASE, ATRIAL FIBRILLATION SURGERY OR IMPLANTATION OF MEDICAL DEVICE FOR IN-VITRO DIAGNOSIS DESIGNED FOR PROFESSIONAL & SELF TESTING USE.

280	IMP/IVD/2019/000294	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCESS AMH(ACCESS AMH)-THE ACCESS AMH ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-MÜLLERIAN HORMONE (AMH) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS AS AN AID IN THE ASSESSMENT OF OVARIAN RESERVE., ACCESS TSH (3RD IS)(ACCESS TSH (3RD IS))-THE ACCESS TSH (3RD IS) ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID-STIMULATING HORMONE (THYROTROPIN, TSH, HTSH) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS. THIS ASSAY IS CAPABLE OF PROVIDING 3RD GENERATION TSH RESULTS.
281	IMP/IVD/2019/000295	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCESS AMH CALIBRATORS(ACCESS AMH CALIBRATORS)-THE ACCESS AMH CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS AMH AND ACCESS AMH ADVANCED ASSAYS.,ACCESS AMH QC(ACCESS AMH QC) -THE ACCESS AMH QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS AMH AND ACCESS AMH ADVANCED ASSAYS

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282	IMP/IVD/2019/000296	1.License Holder Name: TAEVAS LIFE SCIENCES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASPERGILUS GALACTOMANNAN LATERAL FLOW ASSAY(SONA ASPERGILLUS GM LFA)-THE SONA ASPERGILLUS GALACTOMANNAN LATERAL FLOW ASSAY (ASPERGILLUS GM LFA) IS AN IMMUNOCHROMATOGRAPHIC TEST SYSTEM FOR THE QUALITATIVE DETECTION OF ASPERGILLUS GALACTOMANNAN IN SERUM AND BAL SAMPLES. THE SONA ASPERGILLUS GM LFA IS A TEST WHICH, WHEN USED IN CONJUNCTION WITH OTHER DIAGNOSTIC PROCEDURES SUCH AS MICROBIOLOGICAL CULTURE, HISTOLOGICAL EXAMINATION OF BIOPSY SAMPLES, AND RADIOGRAPHIC EVIDENCE, CAN BE USED AS AN AID IN THE DIAGNOSIS OF ASPERGILLOSIS.,CRAG LATERAL FLOW ASSAY(CRAG® LFA)-THE CRAG LATERAL FLOW ASSAY IS AN IMMUNOCHROMATOGRAPHIC TEST SYSTEM FOR THE QUALITATIVE OR SEMI-QUANTITATIVE DETECTION OF THE CAPSULAR POLYSACCHARIDE ANTIGENS OF CRYPTOCOCCUS SPECIES COMPLEX (CRYPTOCOCCUS NEOFORMANS AND CRYPTOCOCCUS GATTII) IN SERUM, PLASMA, WHOLE BLOOD (VENOUS AND FINGER STICK) AND CEREBRAL SPINAL FLUID (CSF). THE CRAG LATERAL FLOW ASSAY IS A PRESCRIPTION-USE LABORATORY ASSAY, WHICH CAN AID IN THE DIAGNOSIS OF CRYPTOCOCCOSIS.
283	IMP/IVD/2019/000298	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DILUENT FOR MYTHIC 22 (DILUENT FOR MYTHIC 22)-ISOTONIC SOLUTION USE FOR THE DIFFERENTIATION OF THE WHITE BLOOD CELLS.,CLEANER FOR MYTHIC 22(CLEANER FOR MYTHIC 22)-THIS SOLUTION IS USED TO CLEAN THE SYSTEM. THE PRESENCE OF AN ENZYME REDUCES THE FORMATION OF PROTEINS DEPOSIT,MYTHIC 18-22 FLUSH - CLEANER (MYTHIC 18-22 FLUSH - CLEANER)-MYTHIC 18-22 FLUSH - CLEANER IS AN EMERGENCY CLEANER, BASED ON HYPOCHLORITE, DESIGNED FOR WASHING AND MAINTENANCE OF MYTHIC HAEMATOLOGY ANALYSERS.

284	IMP/IVD/2019/000299	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREALBUMIN CALIBRATOR(PREALBUMIN CALIBRATOR)-FOR USE IN THE CALIBRATION OF THE PREALBUMIN ASSAY.,ALINITY C PREALBUMIN CALIBRATOR KIT(ALINITY C PREALBUMIN CALIBRATOR KIT)-FOR USE IN THE CALIBRATION OF THE ALINITY C PREALBUMIN ASSAY ON THE ALINITY C ANALYZER.,SPECIFIC PROTEINS MULTICONSTITUENT CALIBRATOR(SPECIFIC PROTEINS MULTICONSTITUENT CALIBRATOR) -FOR USE IN THE CALIBRATION OF THE IMMUNOGLOBULIN A (IGA), IMMUNOGLOBULIN G (IGG), IMMUNOGLOBULIN M (IGM), COMPLEMENT C3 (C3), COMPLEMENT C4 (C4), HAPTOGLOBIN, AND TRANSFERRIN ASSAYS.,ALINITY C SPECIFIC PROTEINS MULTICONSTITUENT CALIBRATOR KIT(ALINITY C SPECIFIC PROTEINS MULTICONSTITUENT CALIBRATOR KIT)-FOR USE IN THE CALIBRATION OF THE IMMUNOGLOBULIN A (IGA), IMMUNOGLOBULIN G (IGG), IMMUNOGLOBULIN M (IGM), COMPLEMENT C3 (C3), COMPLEMENT C4 (C4), HAPTOGLOBIN, AND TRANSFERRIN (TRANSF) ASSAYS ON THE ALINITY C ANALYZER.
285	IMP/IVD/2019/000300	1.License Holder Name: AGD BIOMEDICALS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CRP (BULK)(US TYPE CRP LATEX R1)-US TYPE CRP LATEX R1 AND R2 ARE USED TO MEASURE CRP IN SERUM AND PLASMA SAMPLE.,CRP (BULK)(US TYPE CRP CALIBRATOR A)-ASSAY TO DETERMINE LEVEL OF C-REACTIVE PROTEIN IN SERUM OR PLASMA.,CRP (BULK)(US TYPE CRP LATEX R2) -US TYPE CRP LATEX R1 AND R2 ARE USED TO MEASURE CRP IN SERUM AND PLASMA SAMPLE.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

286	IMP/IVD/2019/000301	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMMULITE INSULIN CONTROLS MODULE (IMMULITE INSULIN CONTROLS MODULE)-IMMULITE INSULIN CONTROLS ARE ASSAYED, BI-LEVEL CONTROLS INTENDED FOR USE WITH THE IMMULITE/IMMULITE 1000, IMMULITE 2000 AND IMMULITE 2500 INSULIN ASSAYS. THEY ARE INTENDED AS AN AID IN MONITORING DAY-TO-DAY ASSAY PERFORMANCE. ,BETA 2 MICROGLOBULIN (IMMULITE 2000 SYSTEM RANGE ASSAYS)(BETA 2 MICROGLOBULIN (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF 2-MICROGLOBULIN (2M) IN SERUM AND URINE, AS AN AID IN CLINICAL DIAGNOSIS OF ACTIVE RHEUMATOID ARTHRITIS AND KIDNEY DISEASE. ,IMMULITE® C-REACTIVE PROTEIN CONTROL MODULE (IMMULITE® C-REACTIVE PROTEIN CONTROL MODULE)-THE IMMULITE® C-REACTIVE PROTEIN CONTROL MODULE IS AN ASSAYED, TRI-LEVEL CONTROL INTENDED FOR USE WITH THE IMMULITE/ IMMULITE 1000 AND IMMULITE 2000 HIGH SENSITIVITY CRP ASSAYS. IT IS INTENDED AS AN AID IN MONITORING DAY-TO-DAY ASSAY PERFORMANCE. ,TURBO TROPONIN I(TURBO TROPONIN I)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF TROPONIN I IN SERUM, HEPARINIZED OR EDTA PLASMA, AS AN AID IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI). , IMMULITE® 2000 SHBG(IMMULITE® 2000 SHBG)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF SHBG IN SERUM, AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF HIRSUTISM. ,HIGH SENSITIVITY CRP (IMMULITE 2000)(HIGH SENSITIVITY CRP (IMMULITE 2000))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS—FOR THE QUANTITATIVE MEASUREMENT OF C-REACTIVE PROTEIN (CRP) IN SERUM OR PLASMA, AS AN AID IN THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY, INFLAMMATORY DISORDERS AND ASSOCIATED DISEASES. MEASUREMENTS MAY ALSO BE USED AS AN AID IN THE IDENTIFICATION OF INDIVIDUALS AT RISK FOR FUTURE CARDIOVASCULAR DISEASE. HIGH SENSITIVITY CRP (HSCRP) MEASUREMENTS, WHEN USED IN CONJUNCTION WITH TRADITIONAL CLINICAL LABORATORY EVALUATION OF ACUTE CORONARY SYNDROME, MAY BE USEFUL AS AN INDEPENDENT MARKER FOR RECURRENT EVENTS IN PATIENTS WITH STABLE CORONARY DISEASE OR ACUTE CORONARY SYNDROME. ,IMMULITE/IMMULITE 1000 TOTAL T3(IMMULITE/IMMULITE 1000 TOTAL T3)-FOR IN VITRO DIAGNOSTIC

	USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF TOTAL CIRCULATING TRIIODOTHYRONIN (T3) IN SERUM AS AN AID IN THE CLINICAL ASSESSMENT OF THYROID STATUS.,EBNA IGG (IMMULITE 2000 SYSTEM RANGE ASSAYS)(EBNA IGG (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO THE EPSTEIN-BARR VIRUS NUCLEAR ANTIGEN (EBNA) IN HUMAN SERUM OR PLASMA (HEPARINIZED OR EDTA). THIS ASSAY MAY ALSO BE USED AS AN AID IN THE DIAGNOSIS OF EBV-ASSOCIATED DISEASES WHEN USED IN CONJUNCTION WITH THE IMMULITE 2000 EBV-VCA IGG AND IMMULITE 2000 EBV-VCA IGM IMMUNOASSAYS. ,IMMULITE®/IMMULITE 1000 IL2R (IMMULITE®/IMMULITE 1000 IL2R)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF SOLUBLE INTERLEUKIN 2 RECEPTOR (IL2R) IN SERUM AND EDTA PLASMA, AS AN AID IN THE STUDY OF INFLAMMATORY DISEASES. ,RUBELLA IGG (QUANT) (IMMULITE 2000 SYSTEM RANGE ASSAYS)(RUBELLA IGG (QUANT) (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM, AS AN AID IN THE DETERMINATION OF IMMUNE STATUS TO RUBELLA, PARTICULARLY FOR WOMEN OF CHILDBEARING AGE. ,IMMULITE® SHBG SAMPLE DILUENT(IMMULITE® SHBG SAMPLE DILUENT)-FOR MANUAL DILUTION OF PATIENT SAMPLES.,IMMULITE® SYSTEMS TSH CONTROL THIRD GENERATION TSH (IMMULITE® SYSTEMS TSH CONTROL THIRD GENERATION TSH)-IMMULITE® SYSTEMS TSH CONTROL THIRD GENERATION TSH CONTROL MODULE IS AN ASSAYED, SINGLE-LEVEL CONTROL INTENDED FOR USE WITH THE IMMULITE/IMMULITE 1000 THIRD GENERATION TSH AND IMMULITE 2000 THIRD GENERATION TSH ASSAYS FOR DETERMINATIONS IN THE NEAR-HYPERTHYROID RANGE. IT IS INTENDED AS AN AID IN MONITORING DAYTO-DAY ASSAY PERFORMANCE AT LOW TSH CONCENTRATIONS. ,IMMULITE® 2000 SYSTEMS ALB ALBUMIN (IMMULITE® 2000 SYSTEMS ALB ALBUMIN)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE DETECTION AND QUANTITATION OF MICROALBUMINURIA, THAT IS, CONCENTRATIONS OF ALBUMIN IN HUMAN URINE NOT DETECTABLE BY CONVENTIONAL DIPSTICK METHODS. IT IS INTENDED FOR USE AS AN AID IN MONITORING THE DEVELOPMENT OF INCIPIENT DIABETIC NEPHROPATHY,IMMULITE® 2000 SYSTEMS IGL IGF-1(IMMULITE® 2000 SYSTEMS IGL IGF-1)-FOR IN VITRO

	DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF INSULIN-LIKE GROWTH FACTOR 1 (IGF-I) IN SERUM OR HEPARIN|ZED PLASMA AS AN AID IN THE EVALUATION OF GROWTH DISORDERS.,IMMULITE® 2000 SYSTEMS CAL CALCITONIN(IMMULITE® 2000 SYSTEMS CAL CALCITONIN)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CALCITONIN (THYROCALCITONIN) IN HUMAN SERUM OR HEPARINIZED PLASMA, AS AN AID IN THE DIAGNOSIS AND TREATMENT OF DISEASES INVOLVING THE THYROID AND PARATHYROID GLANDS, INCLUDING CARCINOMA AND HYPERPARATHYROIDISM., IMMULITE® 2000 SYSTEMS BP3 IGFBP-3 (IMMULITE® 2000 SYSTEMS BP3 IGFBP-3)- FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN 3 (IGFBP-3) IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN THE EVALUATION OF GROWTH DISORDERS. IMMULITE® /IMMULITE® 1000 SYSTEMS CAL CALCITONIN (IMMULITE® /IMMULITE® 1000 SYSTEMS CAL CALCITONIN)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CALCITONIN (THYROCALCITONIN) IN HUMAN SERUM OR HEPARINIZED PLASMA, AS AN AID IN THE DIAGNOSIS AND TREATMENT OF DISEASES INVOLVING THE THYROID AND PARATHYROID GLANDS, INCLUDING CARCINOMA AND HYPERPARATHYROIDISM., IMMULITE® 2000 SYSTEM FBC FREE BETA HCG(IMMULITE® 2000 SYSTEM FBC FREE BETA HCG)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF FREE BETA HCG SUBUNIT IN SERUM.,IMMULITE® /IMMULITE® 1000 SYSTEMS INS INSULIN (IMMULITE® /IMMULITE® 1000 SYSTEMS INS INSULIN)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF INSULIN IN SERUM OR HEPARINIZED PLASMA, FOR THE MANAGEMENT OF DIABETES,IMMULITE® 2000 SYSTEMS INS DIL INSULIN SAMPLE DILUENT(IMMULITE® 2000 SYSTEMS INS DIL INSULIN SAMPLE DILUENT)-FOR ON-BOARD DILUTION OF HIGH SAMPLES.,IMMULITE® 2000 SYSTEMS PEP C-PEPTIDE(IMMULITE® 2000 SYSTEMS PEP C-PEPTIDE)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF C-PEPTIDE IN SERUM, HEPARINIZED PLASMA, OR URINE, AS AN AID IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH ABNORMAL INSULIN SECRETION., IMMULITE®/ IMMULITE® 1000 SYSTEMS ATG ANTI- TG AB(ANTI-THYROGLOBULIN AB) (IMMULITE®/ IMMULITE®

	1000 SYSTEMS ATG ANTI- TG AB(ANTI-THYROGLOBULIN AB)- FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS - FOR THE QUANTITATIVE MEASURMENT OF ANTIBODIES AGAINST THYRODLOBULIN (TG) IN SERUM, EDTA, HYPERINIZED AND CITRATE PLASMA, AS AN AID IN THE CLINICAL DIAGNOSIS OF THYROID DISEASES.,IMMULITE® /IMMULITE® 1000 SYSTEMS GAS GASTRIN(IMMULITE® /IMMULITE® 1000 SYSTEMS GAS GASTRIN)- FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF GASTRIN IN SERUM, AS AN AID IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH DISORDERS ASSOCIATED WITH ABNORMAL GASTRIN PRODUCTION.,IMMULITE® 2000 SYSTEMS HCY DIL HOMOCYSTEINE SAMPLE DILUENT(IMMULITE® 2000 SYSTEMS HCY DIL HOMOCYSTEINE SAMPLE DILUENT)- FOR THE ON-BOARD DILUTION OF HIGH SAMPLES.,IMMULITE® /IMMULITE® 1000 SYSTEMS EPN EPO(IMMULITE® /IMMULITE® 1000 SYSTEMS EPN EPO)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF ERYTHROPOIETIN (EPO) IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN THE DIAGNOSIS OF ANEMIAS AND POLYCYTHEMIAS. WITH THE ADVENT OF THE ADMINISTRATION OF RECOMBINANT EPO AS A BIOLOGICAL THERAPY TO INCREASE RED BLOOD CELL MASS, AN EPO ASSAY MAY BE USED ALSO TO AID IN THE PREDICTION AND MONITORING OF RESPONSE TO RECOMBINANT EPO TREATMENT IN PERSONS WITH ANEMIAS, IMMULITE® 2000 SYSTEM HCG HCG(IMMULITE® 2000 SYSTEM HCG HCG)- FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN SERUM, AND FOR STRICTLY QUALITATIVE DETERMINATIONS IN URINE AS AN AID IN THE DETECTION OF PREGNANCY.,IMMULITE® /IMMULITE® 1000 SYSTEMS PEP C-PEPTIDE(IMMULITE® /IMMULITE® 1000 SYSTEMS PEP C-PEPTIDE)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF C-PEPTIDE IN SERUM, HEPARINIZED PLASMA, OR URINE, AS AN AID IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH ABNORMAL INSULIN SECRETION, IMMULITE® 2000 SYSTEM FSH FSH(IMMULITE® 2000 SYSTEM FSH FSH)- FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF FSH IN SERUM, AS AN AID IN THE DIAGNOSIS AND TREATMENT OF PITUITARY AND GONADAL DISORDERS.,IMMULITE® /IMMULITE® 1000 SYSTEMS MYO MYOGLOBULIN(IMMULITE® /IMMULITE® 1000 SYSTEMS MYO MYOGLOBULIN)-FOR IN VITRO DIAGNOSTIC USE WITH

	THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF MYOGLOBIN IN SERUM AND HEPARINIZED PLASMA, AS AN AID IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI).,IMMULITE®/ IMMULITE® 1000 SYSTEMS COR DIL CORTISOL SAMPLE DILUENT(IMMULITE®/ IMMULITE® 1000 SYSTEMS COR DIL CORTISOL SAMPLE DILUENT)- FOR THE DILUTION OF PATIENT SAMPLES.,IMMULITE® /IMMULITE® 1000 SYSTEMS GAS DIL GASTRIN SAMPLE DILUENT(IMMULITE® /IMMULITE® 1000 SYSTEMS GAS DIL GASTRIN SAMPLE DILUENT)- FOR THE MANUAL DILUTION OF SAMPLES., IMMULITE® 2000 SYSTEMS COR CORTISOL(IMMULITE® 2000 SYSTEMS COR CORTISOL)- FOR IN VITRO DIAGNOSTIC USE WITH THE LMMULITE® 2000 SYSTEMS ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF CORTISOL (HYDROCORTISONE COMPOUND F) IN SERUM, AS AN AID IN THE CLINICAL ASSESSMENT OF ADRENAL STATUS.,IMMULITE® 2000 SYSTEMS EPN EPO(IMMULITE® 2000 SYSTEMS EPN EPO)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF ERYTHROPOIETIN (EPO) IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN THE DIAGNOSIS OF ANEMIAS AND POLYCYTHEMIAS. WITH THE ADVENT OF THE ADMINISTRATION OF RECOMBINANT EPO AS A BIOLOGICAL THERAPY TO INCREASE RED BLOOD CELL MASS, AN EPO ASSAY MAY BE USED ALSO TO AID IN THE PREDICTION AND MONITORING OF RESPONSE TO RECOMBINANT EPO TREATMENT IN PERSONS WITH ANEMIAS, IMMULITE®/ IMMULITE® 1000 SYSTEM GRH GROWTH HORMONE (RECOMBINANAT 98/574)(IMMULITE®/ IMMULITE® 1000 SYSTEM GRH GROWTH HORMONE (RECOMBINANAT 98/574))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF HUMAN GROWTH HORMONE (HGH) IN SERUM, AS AN AID IN PATIENT MANAGEMENT.,IMMULITE® 2000 SYSTEMS FOL FOLIC ACID (IMMULITE® 2000 SYSTEMS FOL FOLIC ACID)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF FOLIC ACID IN SERUM, HEPARINIZED PLASMA OR ASCORBIC ACID-TREATED WHOLE BLOOD, AS AN AID IN CLINICAL DIAGNOSIS AND TREATMENT OF ANEMIA, IMMULITE® / IMMULITE® 1000 SYSTEMS ACT ACTH(IMMULITE® / IMMULITE® 1000 SYSTEMS ACT ACTH)- FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF ADRENOCORTICOTROPIC HORMONE (ACTH) IN EOTA PLASMA AS AN AID IN THE ASSESSMENT OF ADRENAL INSUFFICIENCY AND HYPERSECRETION.,IMMULITE® 2000 SYSTEMS VB VITAMIN B12(IMMULITE® 2000 SYSTEMS VB

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	VITAMIN B12)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF VITAMIN B12 IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN CLINICAL DIAGNOSIS AND TREATMENT OF ANEMIA, IMMULITE®/ IMMULITE@ 1000 SYSTEMS COR CORTISOL(IMMULITE®/ IMMULITE@ 1000 SYSTEMS COR CORTISOL)-FOR IN VITRO DIAGNOSTIC USE WITH THE LMMULITE® AND LMMULITE 1000 ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF CORTISOL (HYDROCORTISONE COMPOUND F) IN SERUM, AS AN AID IN THE CLINICAL ASSESSMENT OF ADRENAL STATUS.,IMMULITE® 2000 SYSTEMS PEP DIL C-PEPTIDE SAMPLE DILUENT(IMMULITE® 2000 SYSTEMS PEP DIL C-PEPTIDE SAMPLE DILUENT)-FOR THE ON-BOARD DILUTION OF URINE SAMPLES AND HIGH SERUM/PLASMA SAMPLES., IMMULITE® / IMMULITE® 1000 SYSTEMS HCY HOMOCYSTEINE(IMMULITE® / IMMULITE® 1000 SYSTEMS HCY HOMOCYSTEINE)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS - FOR THE QUANTITATIVE DETERMINATION OF L-HOMOCYSTEINE IN HUMAN PLASMA OR SERUM. THIS DEVICE CAN ASSIST IN THE DIAGNOSIS AND TREATMENT OF PATIENTS SUSPECTED OF HAVING HYPERHOMOCYSTEINEMIA OR HOMOCYSTINURIA.,IMMULITE® 2000 SYSTEMS PAP PAP(IMMULITE® 2000 SYSTEMS PAP PAP)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF PROSTATIC ACID PHOSPHATASE (PAP) IN SERUM, AS AN AID IN PATIENT MANAGEMENT., IMMULITE®/ IMMULITE® 1000 SYSTEMS ACT DIL ACTH SAMPLE DILUENT (IMMULITE®/ IMMULITE® 1000 SYSTEMS ACT DIL ACTH SAMPLE DILUENT)- FOR THE MANUAL DILUTION OF PATIENT SAMPLES.,IMMULITE® 2000 MULTI-DILUENT 2 DILUENT(IMMULITE® 2000 MULTI-DILUENT 2 DILUENT)-FOR THE ON-BOARD DILUTION OF PATIENT SAMPLES EXCEEDING THE CALIBRATION RANGE OF THE INDICATED IMMULITE® 2000 ASSAYS., IMMULITE® SYSTEMS ACT CONTROL ACTH(IMMULITE® SYSTEMS ACT CONTROL ACTH)-THE IMMULITE ACTH CONTROL MODULE IS ASSAYED BI-LEVEL CONTROL INTENDED FOR USE WITH IMMULITE /IMMULITE 2000 ACTH ASSAYS. IT IS INTENDED AS AN AID IN MONITORING DAY-TO- DAY ASSAY PERFORMANCE.,IMMULITE® 2000 SYSTEMS VAL VALPORIC ACID(IMMULITE® 2000 SYSTEMS VAL VALPORIC ACID)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF VALPROIC ACID IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN MONITORING DRUG THERAPY,IMMULITE® SYSTEMS TG RECOVERY SAMPLE THYROGLOBULIN(IMMULITE® SYSTEMS TG RECOVERY SAMPLE THYROGLOBULIN)-FOR USE USE WITH THE IMMULITE THYROGLOBULIN ASSAY, AS AN AID IN

	DETECTING SAMPLE-SPECIFIC SOURCES OF INTERFACE WITH THE ASSAY.,IMMULITE® 2000 SYSTEMS FER FERRITIN(IMMULITE® 2000 SYSTEMS FER FERRITIN)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF FERRITIN IN SERUM, AS AN AID IN THE CLINICAL DIAGNOSIS OF IRON DEFICIENCY AND OVERLOAD, IGF-1 SAMPLE DILUENT (IMMULITE 2000 SAMPLE DILUENT)(IGF-1 SAMPLE DILUENT (IMMULITE 2000 SAMPLE DILUENT))-FOR THE PRE-TREATMENT OF SAMPLES WHICH IS ACCOMPLISHED IN THE DILUTION WELL, THROUGH THE ON-BOARD DILUTION PROCESS. NOT INTENDED FOR DILUTING SAMPLES EXCEEDING THE CALIBRATION RANGE. 20 ML OF CONCENTRATED (READY- TO-USE) IGF-1-FREE BUFFER MATRIX., IMMULITE® /IMMULITE® 1000 SYSTEMS CAL DIL CALCITONIN SAMPLE DILUENT(IMMULITE® /IMMULITE® 1000 SYSTEMS CAL DIL CALCITONIN SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF PATIENT SAMPLES.,IMMULITE® 1000 PYRILINKS-D CONTROL MODULE (DPD)(IMMULITE® 1000 PYRILINKS-D CONTROL MODULE (DPD))-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 AND IMMULITE 2000 PYRILINKS-D ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE.,IMMULITE® 2000 SYSTEMS GAS GASTRIN(IMMULITE® 2000 SYSTEMS GAS GASTRIN)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF GASTRIN IN SERUM, AS AN AID IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH DISORDERS ASSOCIATED WITH ABNORMAL GASTRIN PRODUCTION,IMMULITE® 2000 SYSTEMS BRM BR-MA (CA 15-3) (IMMULITE® 2000 SYSTEMS BRM BR-MA (CA 15-3))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE@ 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CA 15-3 ANTIGEN IN HUMAN SERUM, AS AN AID IN THE DETECTION OF RECURRENCE IN PREVIOUSLY TREATED STAGE II AND STAGE III BREAST CANCER PATIENTS, AND IN THE MANAGEMENT OF METASTATIC BREAST CANCER PATIENTS BY MONITORING DISEASE PROGRESSION OR RESPONSE TO TREATMENT, SERIAL TESTING FOR PATIENT CA 15-3 VALUES SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL METHODS USED FOR DETECTING EARLY RECURRENCE IN STAGE II AND STAGE III DISEASE AND FOR MONITORING RESPONSE TO TREATMENT IN PATIENTS WITH METASTATIC BREAST CANCER., IMMULITE® /IMMULITE® 1000 SYSTEMS TPI TROPONIN I(IMMULITE® /IMMULITE® 1000 SYSTEMS TPI TROPONIN I)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF TROPONIN I IN SERUM, HEPARINIZED OR EDTA PLASMA, AS AN AID IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI),

	IMMULITE®/IMMULITE 2000 SYSTEMS OV OM-MA (CA 125) (IMMULITE®/IMMULITE 2000 SYSTEMS OV OM-MA (CA 125))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CAI 25 ANTIGEN IN SERUM, AS AN AID IN MONITORING THE RESPONSE TO THERAPY FOR PATIENTS WITH EPITHELIAN OVARIAN CANCER, AND IN DETECTING RESIDUAL OVARIAN CANCER IN PATIENTS WHO HAVE UNDERGONE FIRST-LINE THERAPY AND WOULD BE CONSIDERED FOR DIAGNOSTIC SECOND-LOOK PROCEDURES.,IMMULITE® /IMMULITE® 1000 SYSTEMS TPI DIL TROPONIN I SAMPLE DILUENT(IMMULITE® /IMMULITE® 1000 SYSTEMS TPI DIL TROPONIN I SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF PATIENT SAMPLES, IMMULITE®/IMMULITE 1000 SYSTEMS PSA PSA (IMMULITE®/IMMULITE 1000 SYSTEMS PSA PSA)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF PROSTATE-SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM, AS AN AID IN THE DETECTION OF PROSTATE CANCER WHEN USED IN CONJUNCTION WITH DIGITAL RECTAL EXAMINATION (DRE) IN MEN AGED 50 YEARS OR OLDER. THIS ASSAY IS FURTHER INDICATED AS AN ADJUNCTIVE TEST TO AID IN THE MANAGEMENT OF PROSTATE CANCER PATIENTS. ,IMMULITE® /IMMULITE® 1000 SYSTEMS EPO DIL EPO SAMPLE DILUENT(IMMULITE® /IMMULITE® 1000 SYSTEMS EPO DIL EPO SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF PATIENT SAMPLES,LBP (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS) (LBP (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF LIPOPOLYSACCHARIDE BINDING PROTEIN (LBP) IN SERUM OR PLASMA, AS AN AID IN THE DIAGNOSIS AND PROGNOSIS OF DISEASES THAT ARE INDUCED BY EXPOSURE TO ENDOTOXIN, SUCH AS SEPSIS AND INFECTIOUS COMPLICATIONS OF SURGERY AND TRAUMA. ,IMMULITE® /IMMULITE® 1000 SYSTEMS PEP DIL C-PEPTIDE SAMPLE DILUENT(IMMULITE® /IMMULITE® 1000 SYSTEMS PEP DIL C-PEPTIDE SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF URINE SAMPLES AND HIGH SERUM/PLASMA SAMPLES,IL-8 DILUENT(IL-8 DILUENT)-FOR DILUTION OF SAMPLES FOR THE IMMULITE IL-8 IN VITRO DIAGNOSTIC ASSAYS,IMMULITE® /IMMULITE® 1000 SYSTEMS VB VITAMIN B12(IMMULITE® /IMMULITE® 1000 SYSTEMS VB VITAMIN B12)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF VITAMIN B12 IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN CLINICAL DIAGNOSIS AND TREATMENT OF ANEMIA.,RUBELLA IGM (INT)

	(IMMULITE 2000 SYSTEM RANGE ASSAYS)(RUBELLA IGM (INT) (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM OR PLASMA (EDTA AND HEPARINIZED), AS AN AID IN THE PRESUMPTIVE DIAGNOSIS OF AN ACUTE OR RECENT RUBELLA INFECTION, PARTICULARLY IN WOMEN OF CHILDBEARING AGE ,IMMULITE® /IMMULITE® 1000 SYSTEMS CMB CK-MB (IMMULITE® /IMMULITE® 1000 SYSTEMS CMB CK-MB)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CREATINE KINASE ISOENZYME MB (CK-MB) IN HEPARINIZED PLASMA OR SERUM, AS AN AID IN PATIENT MANAGEMENT AND THE ASSESSMENT OF PROGNOSIS OF MYOCARDIAL INFARCTION.,BETA 2 MICROGLOBULIN DILUENT (IMMULITE SAMPLE DILUENT)(BETA 2 MICROGLOBULIN DILUENT (IMMULITE SAMPLE DILUENT))-FOR DILUTION OF SAMPLES FOR THE IMMULITE BETA 2 MICROGLOBULIN IN VITRO DIAGNOSTIC ASSAYS,(IMMULITE/IMMULITE 1000 SYSTEMS TXU TOXOPLASMA IGM (-CAPTURE))((IMMULITE/IMMULITE 1000 SYSTEMS TXU TOXOPLASMA IGM (-CAPTURE)))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE PRESUMPTIVE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM OR PLASMA (EDTA OR HEPARINIZED), PARTICULARLY FOR WOMEN OF CHILDBEARING AGE. WHEN PERFORMED IN CONJUNCTION WITH A TOXOPLASMA IGG ASSAY, THE IMMULITE/IMMULITE 1000 TOXOPLASMA IGM (-CAPTURE) CAN BE USED AS AN AID IN THE PRESUMPTIVE DIAGNOSIS OF ACUTE, RECENT OR REACTIVATED TOXOPLASMA INFECTION.,IL-10 CONTROLS (IL-10 / IML)(IL-10 CONTROLS (IL-10 / IML))-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 IL-10 ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE,IMMULITE 2000 SYSTEMS DDI D-DIMER(IMMULITE 2000 SYSTEMS DDI D-DIMER)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CROSS-LINKED FIBRIN DEGRADATION PRODUCTS (XL-FDP) CONTAINING D-DIMER IN HUMAN PLASMA (HEPARINIZED OR SODIUM CITRATE).,IMMULITE® 1000 SHBG DILUENT MODULE(IMMULITE® 1000 SHBG DILUENT MODULE)-REQUIRED FOR THE ON-BOARD DILUTION OF PATIENT SAMPLES USING IMMULITE 1000 WINDOWS. SAMPLE DILUENT WEDGES (LSHW) CONTAINING A CONCENTRATED (2.5X) NON-HUMAN PROTEIN/BUFFER MATRIX,IMMULITE® /IMMULITE® 1000 SYSTEMS VB DIL VITAMIN B12 SAMPLE DILUENT(IMMULITE® /IMMULITE® 1000 SYSTEMS VB DIL VITAMIN B12 SAMPLE DILUENT)-FOR THE MANUAL

	DILUTION OF PATIENT SAMPLES.,RUBELLA IGG CONTROLS(RUBELLA IGG CONTROLS)-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 AND IMMULITE 2000 RUBELLA IGG ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE,IMMULITE® 2000 SYSTEMS INS INSULIN(IMMULITE® 2000 SYSTEMS INS INSULIN)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF INSULIN IN SERUM OR HEPARINIZED PLASMA, FOR THE MANAGEMENT OF DIABETES,RUBELLA IGM CONTROLS(RUBELLA IGM CONTROLS)-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 AND IMMULITE 2000 RUBELLA IGM ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE.,IMMULITE® /IMMULITE® 1000 SYSTEMS PAA PAPP-A(IMMULITE® /IMMULITE® 1000 SYSTEMS PAA PAPP-A)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF PREGNANCY-ASSOCIATED PLASMA PROTEIN A (PAPP-A) IN SERUM OR HEPARINIZED PLASMA,IMMULITE® TOTAL IGE (TIE) CONTROL MODULE(IMMULITE® TOTAL IGE (TIE) CONTROL MODULE)-INTENDED FOR USE WITH COAT-A-COUNT IRMA, IMMULITE/IMMULITE 1000 AND IMMULITE 2000 TOTAL IGE ASSAY , AS AN AID IN DAY TO DAY MONITORING OF ASSAY PERFORMANCE.,IMMULITE® /IMMULITE® 1000 SYSTEMS INS DIL INSULIN SAMPLE DILUENT(IMMULITE® /IMMULITE® 1000 SYSTEMS INS DIL INSULIN SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF SAMPLES.,H-PYLORI (IGG) (IMMULITE 2000 SYSTEM RANGE ASSAYS)(H-PYLORI (IGG) (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO HELICOBACTER PYLORI IN HUMAN SERUM FROM SYMPTOMATIC ADULTS, AS AN AID IN THE DIAGNOSIS OF HELICOBACTER PYLORI INFECTION ,IMMULIE ® /IMMULIE ® 1000 SYSTEMS BCG FREE BETA HCG(IMMULIE ® /IMMULIE ® 1000 SYSTEMS BCG FREE BETA HCG)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF FREE BETA-HCG SUBUNIT IN SERUM.,IMMULITE®/ IMMULITE® 1000 SYSTEMS T3 DIL TOTAL T3 SAMPLE DILUENT (IMMULITE®/ IMMULITE® 1000 SYSTEMS T3 DIL TOTAL T3 SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF SAMPLES.,IMMULIE ® /IMMULIE ® 1000 SYSTEMS FSH(IMMULIE ® /IMMULIE ® 1000 SYSTEMS FSH)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF FOLLICLE STIMULATING HORMONE (FSH, FOLLITROPIN) IN SERUM, AS AN AID IN THE DIAGNOSIS AND TREATMENT OF PITUITARY AND GONADAL DISORDERS.,TNF ALPHA DILUENT(TNF ALPHA DILUENT)-FOR

	DILUTION OF SAMPLES FOR THE IMMULITE TNF ALPHA IN VITRO DIAGNOSTIC ASSAYS,IMMULIE ® /IMMULIE ® 1000 SYSTEMS AND ANDROSTENEDIONE(IMMULIE ® /IMMULIE ® 1000 SYSTEMS AND ANDROSTENEDIONE)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF T.4-ANDROSTENEDIONE IN HUMAN SERUM.,NICOTINE METABOLITE (IMMULITE/IMMULITE 1000 SYSTEM RANGE ASSAYS)(NICOTINE METABOLITE (IMMULITE/IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF COTININE AND OTHER PRINCIPAL METABOLITES OF NICOTINE IN SERUM AND URINE, AS AN AID IN DISTINGUISHING TOBACCO SMOKERS FROM NON SMOKERS.,IMMULIE ® /IMMULIE ® 1000 SYSTEMS DHS DHEA-SO4(IMMULIE ® /IMMULIE ® 1000 SYSTEMS DHS DHEA-SO4)-USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF DEHYDROEPIANDROSTERONE SULFATE (DHEA-SO4) IN SERUM.,IMMULITE® 2000 SYSTEMS PSA PSA(IMMULITE® 2000 SYSTEMS PSA PSA)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF PROSTATE-SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM AS AN AID IN THE DETECTION OF PROSTATE CANCER WHEN USED IN CONJUNCTION WITH DIGITAL RECTAL EXAMINATION (DRE) IN MEN AGED 50 YEARS OR OLDER. THIS ASSAY IS FURTHER INDICATED AS AN ADJUNCTIVE TEST TO AID IN THE MANAGEMENT OF PROSTATE CANCER PATIENTS.,IMMULIE ® SYSTEMS FBC CONTROL FREE BETA HCG(IMMULIE ® SYSTEMS FBC CONTROL FREE BETA HCG) -THE IMMULITE® FREE BETA HCG CONTROL MODULE IS AN ASSAYED CONTROL INTENDED FOR USE WITH THE IMMULITE/IMMULITE 1000 (LKBCG) AND IMMULITE 2000 FREE BETA HCG ASSAYS. IT IS INTENDED AS AN AID IN MONITORING DAY-TO-DAY ASSAY PERFORMANCE.,TOXOPLASMA QUANT (IGG) (IMMULITE 2000 SYSTEM RANGE ASSAYS)(TOXOPLASMA QUANT (IGG) (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN SERUM, AS AN AID IN THE DETERMINATION OF SEROLOGICAL STATUS TO TOXOPLASMA GONDII. ,IMMULIE ® /IMMULIE ® 1000 SYSTEMS DHS DIL DHEA –SO4 SAMPLE DILUENT (IMMULIE ® /IMMULIE ® 1000 SYSTEMS DHS DIL DHEA –SO4 SAMPLE DILUENT)-FOR DILUTION OF SAMPLES FOR THE IMMULITE DHEA SO4 IN VITRO DIAGNOSTIC ASSAYS.,H-PYLORI (IGG) (IMMULITE 2000 SYSTEM RANGE ASSAYS) SAMPLE DILUENT(H-PYLORI (IGG) (IMMULITE 2000 SYSTEM RANGE ASSAYS) SAMPLE DILUENT)-FOR

	DILUTION OF SAMPLES FOR THE IMMULITE 1000 INFECTIOUS DISEASE IN VITRO DIAGNOSTIC ASSAYS,IMMULIE ® /IMMULIE ® 1000 SYSTEMS PRG DIL PROGESTERONE SAMPLE DILUENT(IMMULIE ® /IMMULIE ® 1000 SYSTEMS PRG DIL PROGESTERONE SAMPLE DILUENT)-FOR DILUTION OF SAMPLES FOR THE IMMULITE PROGESTERONE IN VITRO DIAGNOSTIC ASSAYS.,NICOTINE METABOLITE (IMMULITE 2000 SYSTEM RANGE ASSAYS)(NICOTINE METABOLITE (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF COTININE AND OTHER PRINCIPAL METABOLITES OF NICOTINE IN SERUM AND URINE, AS AN AID IN DISTINGUISHING TOBACCO SMOKERS FROM NON-SMOKERS.,IMMULIE ® /IMMULIE ® 1000 SYSTEMS PRG PROGESTRORONE(IMMULIE ® /IMMULIE ® 1000 SYSTEMS PRG PROGESTRORONE)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF PROGESTERONE IN SERUM AS AN AID IN THE DIAGNOSIS AND TREATMENT OF DISORDERS OF THE OVARIES OR PLACENTA., IMMULITE® 2000 SYSTEMS FFVB DIL VITAMIN B 12/FOLIC ACID SAMPLE DILUENT(IMMULITE® 2000 SYSTEMS FFVB DIL VITAMIN B 12/FOLIC ACID SAMPLE DILUENT)-FOR ON-BOARD DILUTION OF HIGH SERUM SAMPLES.,IMMULIE ® 1000 SYSTEMS SD2 DIL HCG SAMPLE DILUENT(IMMULIE ® 1000 SYSTEMS SD2 DIL HCG SAMPLE DILUENT)-FOR DILUTION OF SAMPLES FOR THE IMMULITE HCG IN VITRO DIAGNOSTIC ASSAYS.,IL-10 (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)(IL-10 (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF INTERLEUKIN 10 (IL-10) IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN THE STUDY OF INFLAMMATORY DISEASES. ,IMMULIE ® SYSTEMS HCG CONTROL(IMMULIE ® SYSTEMS HCG CONTROL)-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 AND IMMULITE 2000 HCG ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE AT HIGH HCG CONCENTRATIONS., RUBELLA IGM (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)(RUBELLA IGM (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM OR PLASMA (EDTA AND HEPARINIZED), AS AN AID IN THE PRESUMPTIVE DIAGNOSIS OF AN ACUTE OR RECENT RUBELLA INFECTION, PARTICULARLY IN WOMEN OF CHILDBEARING AGE. ,IMMULIE ® 2000 SYSTEMS AND ANDROSTENEDIONE(IMMULIE ® 2000 SYSTEMS AND ANDROSTENEDIONE)-FOR IN VITRO DIAGNOSTIC USE WITH THE

	IMMULITE® 2000 SYSTEMS ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF L'L4 ANDROSTENEDIONE IN HUMAN SERUM., HERPES (I & II IGG) (IMMULITE 2000 SYSTEM RANGE ASSAYS) (HERPES (I & II IGG) (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO HERPES SIMPLEX VIRUS (HSV) TYPES I AND II IN HUMAN SERUM, AS AN AID IN DETERMINATION OF SEROLOGICAL STATUS TO HSV I & II ,SHBG CONTROLS(SHBG CONTROLS)-INTENDED FOR USE WITH IMMULITE 2000 SHBG ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE.,IMMULITE® SYSTEMS SPS CONTROL THIRD GENERATION PSA(IMMULITE® SYSTEMS SPS CONTROL THIRD GENERATION PSA)-THE IMMULITE THIRD GENERATION PSA CONTROL MODULE IS AN ASSAYED, SINGLE-LEVEL PSA CONTROL INTENDED FOR USE WITH THE IMMULITE/IMMULITE 1000 THIRD GENERATION PSA ASSAY. IT IS INTENDED AS AN AID IN MONITORING DAY-TO-DAY ASSAY PERFORMANCE.,IMMULIE ® /IMMULIE ® 1000 SYSTEMS PRL DIL PROLACTIN SAMPLE DILUENT(IMMULIE ® /IMMULIE ® 1000 SYSTEMS PRL DIL PROLACTIN SAMPLE DILUENT)-FOR DILUTION OF SAMPLES FOR THE IMMULITE PROLACTIN IN VITRO DIAGNOSTIC ASSAYS., IMMULITE® 2000 SYSTEMS AF AFP(IMMULITE® 2000 SYSTEMS AF AFP)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF ALPHAFETOPROTEIN (AFP) IN EITHER OF TWO CONTEXTS: (A) SERIAL MEASUREMENTS IN HUMAN SERUM TO AID IN THE MANAGEMENT OF PATIENTS WITH NONSEMINOMATOUS TESTICULAR CANCER; OR (B) MEASUREMENTS IN MATERNAL SERUM AND AMNIOTIC FLUID DURING GESTATIONAL WEEKS 15 THROUGH 20— USED IN CONJUNCTION WITH ULTRASONOGRAPHY OR AMNIOGRAPHY — TO AID IN DETECTION OF FETAL OPEN NEURAL TUBE DEFECTS. ,IMMULIE ® 1000 SYSTEMS TES TOTAL TESTOSTERONE (IMMULIE ® 1000 SYSTEMS TES TOTAL TESTOSTERONE)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF TOTAL TESTOSTERONE IN SERUM AND HEPARINIZED PLASMA, AS AN AID IN THE DIAGNOSIS AND MANAGEMENT OF CONDITIONS INVOLVING EXCESS OR DEFICIENCY OF THIS ANDROGEN.,BETA 2 MICROGLOBULIN CONTROLS(BETA 2 MICROGLOBULIN CONTROLS)-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 BETA 2 MICROGLOBULIN ASSAYS AND IMMULITE 2000 BETA 2 MICROGLOBULIN ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE,IMMULIE ® /IMMULIE ® 1000 SYSTEMS LH(IMMULIE ® /IMMULIE ® 1000 SYSTEMS LH)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE®

	AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF LUTEINIZING HORMONE (LUTROPIN, LH) IN SERUM, AS AN AID IN CLINICAL DIAGNOSIS.,IMMULITE SYSTEMS THYROGLOBULIN TG CONTROLS MODULE (IMMULITE SYSTEMS THYROGLOBULIN TG CONTROLS MODULE)-IMMULITE SYSTEMS THYROGLOBULIN TG CONTROLS MODULE IS AN ASSAYED, TRI-LEVEL THYROGLOBULIN CONTROL INTENDE FOR USE WITH THE IMMULITE/ IMMULITE 1000 AND IMMULITE 2000 THYROGLOBULIN ASSAYS. IT IS INTENDED AS AN AID IN MONITORING DAY-TO-DAY ASSAY PERFORMANCE. ,IMMULIE ® /IMMULIE ® 1000 SYSTEMS FSH DIL FSH SAMPLE DILUENT(IMMULIE ® /IMMULIE ® 1000 SYSTEMS FSH DIL FSH SAMPLE DILUENT)-FOR DILUTION OF SAMPLES FOR THE IMMULITE FSH IN VITRO DIAGNOSTIC ASSAYS.,IMMULITE® 2000 DIGOXIN (DGX)(IMMULITE® 2000 DIGOXIN (DGX))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF DIGOXIN IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN MONITORING THE THERAPEUTIC ADMINISTRATION OF THIS CARDIOGLYCOSIDE, WHILE AVOIDING TOXICITY.,IMMULIE ® 2000 SYSTEMS ATG ANTI-TG AB (ANTI-THYROGLOBULIN AB)(IMMULIE ® 2000 SYSTEMS ATG ANTI-TG AB (ANTI-THYROGLOBULIN AB))-FOR IN VITRO DIAGNOSTIC USE WITH IMMULITE SYSTEMS (2000) -FOR THE QUANTITATIVE MEASUREMENT OF AUTOANTIBODIES TO THYROGLOBULIN (TG) IN SERUM, EDTA OR HEPARINIZED PLASMA, AS AN AID IN THE CLINICAL DIAGNOSIS OF THYROID DISEASES.,TURBO STAT INTACT PTH(TURBO STAT INTACT PTH)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF INTACT PARATHYROID HORMONE (PARATHYRIN, PTH) IN EDTA PLASMA OR SERUM. IT IS INTENDED FOR INTRAOPERATIVE USE.,ACTH IMMULITE 2000 SYSTEM RANGE ASSAYS)(ACTH IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH IMMULITE SYSTEMS (2000) -FOR THE QUANTITATIVE MEASUREMENT OF ADRENOCORTICOTROPIC HORMONE (ACTH) IN EDTA PLASMA, AS AN AID IN THE ASSESSMENT OF ADRENAL INSUFFICIENCY AND HYPERSECRETION., IMMULITE®/IMMULITE 1000 OSTEOCALCIN (OCN) (IMMULITE®/IMMULITE 1000 OSTEOCALCIN (OCN))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF OSTEOCALCIN IN HUMAN SERUM OR HEPARINIZED PLASMA, AS AN AID IN MONITORING MINERAL AND BONE METABOLISM. ,IMMULIE ® 2000 SYSTEM E2 DIL ESTRADIOL SAMPLE DILUENT (IMMULIE ® 2000 SYSTEM E2 DIL ESTRADIOL SAMPLE DILUENT)-FOR DILUTION OF SAMPLES FOR THE ESTRADIOL IMMULITE 2000 IN VITRO DIAGNOSTIC

	ASSAYS.,BETA 2 MICROGLOBULIN (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)(BETA 2 MICROGLOBULIN (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF 2-MICROGLOBULIN (2M) IN SERUM AND URINE, AS AN AID IN CLINICAL DIAGNOSIS OF ACTIVE RHEUMATOID ARTHRITIS AND KIDNEY DISEASE ,IMMULIE ® 2000 SYSTEM DHS DHEA-SO4 (IMMULIE ® 2000 SYSTEM DHS DHEA-SO4)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF DHEA-SO4 IN SERUM.,TURBO MYOGLOBIN(TURBO MYOGLOBIN)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF MYOGLOBIN IN SERUM AND HEPARINIZED PLASMA, AS AN AID IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI). ,MULTI-DILUENT 1 (IMMULITE 2000 SAMPLE DILUENT)(MULTI-DILUENT 1 (IMMULITE 2000 SAMPLE DILUENT))-FOR THE ONBOARD DILUTION OF PATIENT SAMPLES EXCEEDING THE CALIBRATION RANGE OF THE INDICATED IMMULITE 2000 AND IMMULITE 2500 ASSAYS., IMMULITE® OSTEOCALCIN (OCN) CONTROL MODULE(IMMULITE® OSTEOCALCIN (OCN) CONTROL MODULE)-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 OSTEOCALCIN ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE.,IMMULIE ® /IMMULIE ® 1000 SYSTEMS PRL PROLACTIN(IMMULIE ® /IMMULIE ® 1000 SYSTEMS PRL PROLACTIN)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF PROLACTIN IN SERUM, AS AN AID IN THE DIAGNOSIS AND TREATMENT OF PITUITARY DISORDERS.,HIGH SENSITIVITY CRP (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)(HIGH SENSITIVITY CRP (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF C-REACTIVE PROTEIN (CRP) IN SERUM OR PLASMA, AS AN AID IN THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY, INFLAMMATORY DISORDERS AND ASSOCIATED DISEASES. MEASUREMENTS MAY ALSO BE USED AS AN AID IN THE IDENTIFICATION OF INDIVIDUALS AT RISK FOR FUTURE CARDIOVASCULAR DISEASE. HIGH SENSITIVITY CRP (HSCRP) MEASUREMENTS, WHEN USED IN CONJUNCTION WITH TRADITIONAL CLINICAL LABORATORY EVALUATION OF ACUTE CORONARY SYNDROME, MAY BE USEFUL AS AN INDEPENDENT MARKER FOR RECURRENT EVENTS IN PATIENTS WITH STABLE CORONARY DISEASE OR ACUTE CORONARY SYNDROME ,IMMULIE ® /IMMULIE ® 1000 SYSTEMS HCG DIL HCG SAMPLE DILUENT(IMMULIE ® /IMMULIE ®

	1000 SYSTEMS HCG DIL HCG SAMPLE DILUENT)-FOR DILUTION OF SAMPLES FOR THE IMMULITE HCG IN VITRO DIAGNOSTIC ASSAYS.,IMMULITE® 2000 SYSTEMS GIM GIMA (CA 19-9)(IMMULITE® 2000 SYSTEMS GIM GIMA (CA 19-9))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CA 19-9 IN SERUM, AS AN AID IN PATIENT MANAGEMENT.,IMMULIE ® 2000 SYSTEM E2 ESTRADIOL (IMMULIE ® 2000 SYSTEM E2 ESTRADIOL)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF ESTRADIOL IN SERUM, AS AN AID IN THE DIAGNOSIS AND TREATMENT OF VARIOUS SEXUAL DISORDERS.,DIGITOXIN (IMMULITE 2000 SYSTEM RANGE ASSAYS) (DIGITOXIN (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF DIGITOXIN IN SERUM, AS AN AID IN THE THERAPEUTIC ADMINISTRATION OF THIS CARDIOGLYCOSIDE.,IMMULIE ® /IMMULIE ® 1000 SYSTEMS E2 ESTRADIOL(IMMULIE ® /IMMULIE ® 1000 SYSTEMS E2 ESTRADIOL)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF ESTRADIOL (ESTRADIOL-17, E2) IN SERUM, AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF AMENORRHEA, AND MONITORING OF OVULATION INDUCTION WITH AND WITHOUT STIMULATION IN ASSISTED REPRODUCTIVE TECHNOLOGY (ART).,LBP CONTROLS (LBP CONTROLS/IML (INT.)(LBP CONTROLS (LBP CONTROLS/IML (INT.))-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 AND IMMULITE 2000 LBP ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE,IMMULIE ® /IMMULIE ® 1000 SYSTEMS UE3 UNCONJUGATED ESTRIOL(IMMULIE ® /IMMULIE ® 1000 SYSTEMS UE3 UNCONJUGATED ESTRIOL)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF UNCONJUGATED (FREE) ESTRIOL IN SERUM, AS AN AID IN MONITORING FETAL MATURITY AND WELL-BEING IN THE CONTEXT OF HIGH-RISK AND POORLY DATED PREGNANCIES.,LBP (IMMULITE 2000 SYSTEM RANGE ASSAYS)(LBP (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF LIPOPOLYSACCHARIDE BINDING PROTEIN (LBP) IN SERUM OR PLASMA, AS AN AID IN THE DIAGNOSIS AND PROGNOSIS OF DISEASES THAT ARE INDUCED BY EXPOSURE TO ENDOTOXIN, SUCH AS SEPSIS AND INFECTIOUS COMPLICATIONS OF SURGERY AND TRAUMA. ,IMMULIE ® /IMMULIE ® 1000 SYSTEMS SBG SHBG(IMMULIE ® /IMMULIE ® 1000 SYSTEMS SBG SHBG)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND

	IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF SEX HORMONE BINDING GLOBULIN (SHBG) IN SERUM, AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF HIRSUTISM., IMMULITE®/IMMULITE 1000 VALPROIC ACID (VAL) (IMMULITE®/IMMULITE 1000 VALPROIC ACID (VAL))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF VALPROIC ACID IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN MONITORING DRUG THERAPY.,IMMULIE ® /IMMULIE ® 1000 SYSTEMS E2 DIL ESTRADIOL SAMPLE DILUENT(IMMULIE ® /IMMULIE ® 1000 SYSTEMS E2 DIL ESTRADIOL SAMPLE DILUENT)-FOR DILUTION OF SAMPLES FOR THE IMMULITE ESTRADIOL IN VITRO DIAGNOSTIC ASSAYS., IMMULITE® 2000 SYSTEM NT-PROBNP(IMMULITE® 2000 SYSTEM NT-PROBNP)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HEPARINIZED PLASMA, AS AN AID IN THE DIAGNOSIS OF INDIVIDUALS SUSPECTED OF HAVING CONGESTIVE HEART FAILURE. THE TEST IS FURTHER INDICATED FOR THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROME AND CONGESTIVE HEART FAILURE,IMMULIE ® SYSTEMS E2 CONTROL ESTRADIOL (IMMULIE ® SYSTEMS E2 CONTROL ESTRADIOL)-INTENDED FOR USE WITH COAT-A-COUNT ESTRADIOL (BASIC PROCEDURE), IMMULITE/IMMULITE 1000 AND IMMULITE 2000 ESTRADIOL ASSAY, AS AN AID IN MONITORING DAY TO DAY ASSAY PERFORMANCE.,IMMULITE® 2000 SYSTEMS GRH GROWTH HARMONE (RECOMBINANT 98/574)(IMMULITE® 2000 SYSTEMS GRH GROWTH HARMONE (RECOMBINANT 98/574))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF HUMAN GROWTH HORMONE IN SERUM, AS AN AID IN PATIENT MANAGEMENT.,IMMULIE ® /IMMULIE ® 1000 SYSTEMS HCG(IMMULIE ® /IMMULIE ® 1000 SYSTEMS HCG)-FOR IN VITRO DIAGNOSTIC USE WITH IMMULITE AND IMMULITE 1000 ANALYZERS -FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN SERUM AND FOR STRICTLY QUALITATIVE DETERMINATION IN URINE, AS AN AID IN THE DETECTION OF PREGNANCY.,THYROID UPTAKE (IMMULITE 2000 SYSTEM RANGE ASSAYS)(THYROID UPTAKE (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — YIELDS AN INDEX OF THYROID HORMONE CARRIER PROTEIN LEVELS IN SERUM, TO AID IN THE CLINICAL ASSESSMENT OF THYROID STATUS ,FERRITIN DILUENT (IMMULITE SAMPLE DILUENT)(FERRITIN DILUENT (IMMULITE SAMPLE DILUENT))-FOR DILUTION OF SAMPLES FOR THE IMMULITE FERRITIN

	IN VITRO DIAGNOSTIC ASSAYS,THYROID AUTO AB/IML (CONTROLS) (THYROID AUTO AB/IML (CONTROLS))-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 AND IMMULITE 2000 ANTI- TG AB ASSAYS AND WITH IMMULITE/IMMULITE 1000 AND IMMULITE 2000 ANTI-TPO AB ASSAYS, AS AN AID IN MONITORING DAY TO DAY ASSAY PERFORMANCE.,IMMULITE®/IMMULITE 1000 SYSTEMS CEA DIL CEA SAMPLE DILUENT(IMMULITE®/IMMULITE 1000 SYSTEMS CEA DIL CEA SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF PATIENT SAMPLES.,IMMULITE® 2000 SYSTEM TES TOTAL TESTOSTERONE (IMMULITE® 2000 SYSTEM TES TOTAL TESTOSTERONE)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF TOTAL TESTOSTERONE IN SERUM AND HEPARINIZED PLASMA, AS AN AID IN THE DIAGNOSIS AND MANAGEMENT OF CONDITIONS INVOLVING EXCESS OR DEFICIENCY OF THIS ANDROGEN.,IMMULITE® 2000 SYSTEMS HCG DIL HCG SAMPLE DILUENT(IMMULITE® 2000 SYSTEMS HCG DIL HCG SAMPLE DILUENT)-FOR ON-BOARD DILUTION OF HIGH SAMPLES.,THEOPHYLLINE (IMMULITE 2000 SYSTEM RANGE ASSAYS) (THEOPHYLLINE (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF THEOPHYLLINE IN SERUM, AS AN AID IN MONITORING THE THERAPEUTIC ADMINISTRATION OF THIS BRONCHODILATOR., IMMULITE® 2000 ANTI-TPO AB(IMMULITE® 2000 ANTI-TPO AB)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS- FOR THE QUANTITATIVE MEASUREMENT OF ANTITHYROID PEROXIDASE (TPO) ANTIBODIES IN SERUM AND EDTA PLASMA, AS AN AID IN THE CLINICAL DIAGNOSIS OF THYROID DISEASES. ,ECP (IMMULITE 2000 SYSTEM RANGE ASSAYS)(ECP (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF EOSINOPHIL CATIONIC PROTEIN (ECP) IN SERUM , IMMULITE® 2000 SYSTEM PRL PROLACTIN(IMMULITE® 2000 SYSTEM PRL PROLACTIN)- FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF PROLACTIN IN SERUM, AS AN AID IN THE DIAGNOSIS AND TREATMENT OF PITUITARY DISORDERS.,IMMULITE® 2000 SYSTEMS TG DIL THYROGLOBULIN SAMPLE DILUENT(IMMULITE® 2000 SYSTEMS TG DIL THYROGLOBULIN SAMPLE DILUENT)-FOR THE ON-BOARD DILUTION OF PATIENT SAMPLES.,THYROID UPTAKE (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)(THYROID UPTAKE (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000

	ANALYZERS — YIELDS AN INDEX OF THYROID HORMONE CARRIER PROTEIN LEVELS IN SERUM, TO AID IN THE CLINICAL ASSESSMENT OF THYROID STATUS. , IMMULITE® 2000 SYSTEM PRG PROGESTERONE(IMMULITE® 2000 SYSTEM PRG PROGESTERONE)- FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS FOR THE QUANTITATIVE MEASUREMENT OF PROGESTERONE IN SERUM, AS AN AID IN THE DIAGNOSIS AND TREATMENT OF DISORDERS OF THE OVARIES OR PLECENTA.,IMMULITE® 2000 SYSTEMS IPTH INTACT PTH(IMMULITE® 2000 SYSTEMS IPTH INTACT PTH)- FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF INTACT PARATHYROID HORMONE (PARATHYRIN, PTH) IN EDTA PLASMA AND SERUM, AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF HYPERCALCEMIA AND HYPOCALCEMIA.,IMMULITE®/ IMMULITE® 1000 SYSTEMS TG THYROGLOBULIN(IMMULITE®/ IMMULITE® 1000 SYSTEMS TG THYROGLOBULIN)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF THYROGLOBULIN IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN MONITORING PATIENTS WHO HAVE UNDERGONE THYROIDECTOMY. ,IMMULITE® 2000 SYSTEMS F4 FREE T4(IMMULITE® 2000 SYSTEMS F4 FREE T4)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF NON-PROTEIN-BOUND THYROXINE (FREE T4) IN SERUM AND HEPARINIZED PLASMA. MEASUREMENTS OF FREE T4 ARE USED IN THE DIAGNOSIS AND TREATMENT OF THYROID DISEASE. ,IMMULITE® SYSTEMS TBG CONTROL TBG (IMMULITE® SYSTEMS TBG CONTROL TBG)- IMMULITE® SYSTEMS TBG CONTROL TBG IS AN ASSAYED, BI-LEVEL CONTROL INTENDED FOR USE WITH IMMULITE/IMMULITE 2000 TBG ASSAYS. IT IS INTENDED AS AN AID IN MONITORING DAY-TO-DAY ASSAY PERFORMANCE. ,IMMULITE®/IMMULITE 1000 SYSTEMS PSA DIL PSA SAMPLE DILUENT(IMMULITE®/IMMULITE 1000 SYSTEMS PSA DIL PSA SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF PATIENTS SAMPLES.,IMMULITE®/IMMULITE 1000 SYSTEMS OMM DIL OM-MA SAMPLE DILUENT(IMMULITE®/IMMULITE 1000 SYSTEMS OMM DIL OM-MA SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF PATIENTS SAMPLES.,SERUM DRUG CONTROL (GENERAL CONTROLS)(SERUM DRUG CONTROL (GENERAL CONTROLS))-CONTROL (MULTI LEVELS) FOR USE AS AN AID IN DAY TO DAY MONITORING OF PERFORMANCE OF SEVERAL DRUGS AND METABOLITE IN VITRO DIAGNOSTIC ASSAYS ON IMMULITE SYSTEM SERIES.,IMMULITE® 2000 SYSTEMS RTH RAPID TSH(IMMULITE® 2000 SYSTEMS RTH RAPID TSH)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF

	THYROTROPIN (TSH) IN SERUM, AS AN AID IN THE CLINICAL ASSESSMENT OF THYROID STATUS. ,IL-6 (IMMULITE 2000 SYSTEM RANGE ASSAYS)(IL-6 (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF INTERLEUKIN 6 (IL-6) IN SERUM, EDTA OR HEPARINIZED PLASMA, AS AN AID IN THE STUDY OF INFLAMMATORY DISEASES. ,IMMULITE® 2000 SYSTEMS PTH DIL INTACT PTH SAMPLE DILUENT(IMMULITE® 2000 SYSTEMS PTH DIL INTACT PTH SAMPLE DILUENT)-FOR ON-BOARD DILUTION OF HIGH SAMPLES.,EBV VCA IGM (IMMULITE 2000 SYSTEM RANGE ASSAYS)(EBV VCA IGM (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO VIRAL CAPSID ANTIGEN OF EPSTEIN-BARR VIRUS IN HUMAN SERUM OR PLASMA (EDTA AND HEPARINIZED). THIS ASSAY MAY ALSO BE USED AS AN AID IN THE DIAGNOSIS OF EBV-ASSOCIATED DISEASES WHEN USED IN CONJUNCTION WITH THE IMMULITE 2000 EBV-VCA IGG AND IMMULITE 2000 EBV-EBNA IGG IMMUNOASSAYS ,IMMULITE®/ IMMULITE® 1000 SYSTEMS TOTAL T4 DIL TOTAL T4 SAMPLE DILUENT(IMMULITE®/ IMMULITE® 1000 SYSTEMS TOTAL T4 DIL TOTAL T4 SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF SAMPLES.,IMMULITE® 2000 SYSTEM PAA PAPP-A(IMMULITE® 2000 SYSTEM PAA PAPP-A)- FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS ~ FOR THE QUANTITATIVE MEASUREMENT OF PREGNANCY-ASSOCIATED PLASMA PROTEIN A (PAPP-A) IN SERUM OR HEPERINIZED PLASMA.,IMMULITE® 2000 SYSTEMS TSH THIRD GENERATION TSH(IMMULITE® 2000 SYSTEMS TSH THIRD GENERATION TSH)- FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF THYROTROPIN (TSH) IN SERUM. MEASUREMENTS OF THYROID STIMULATING HORMONE PRODUCED BY THE ANTERIOR PITUITARY ARE USED IN THE DIAGNOSIS OF THYROID OR PITUITARY DISORDERS. ,IMMULITE® 2000 SYSTEMS TBG DIL TBG SAMPLE DILUENT(IMMULITE® 2000 SYSTEMS TBG DIL TBG SAMPLE DILUENT)-FOR THE ON-BOARD DILUTION OF HIGH SAMPLES.,IMMULITE®/ IMMULITE® 1000 SYSTEMS TSH THIRD GENERATION TSH (IMMULITE®/ IMMULITE® 1000 SYSTEMS TSH THIRD GENERATION TSH)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF THYROTROPIN (TSH) IN SERUM, AS AN AID IN THE CLINICAL ASSESSMENT OF THYROID STATUS., IMMULITE TURBO HCG(IMMULITE TURBO HCG)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000

	ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN SERUM, HEPARINIZED OR EDTA PLASMA, AS AN AID IN THE DETECTION OF PREGNANCY. , IMMULITE® 2000 SYSTEM UE3 UNCONJUGATED ESTRIOL(IMMULITE® 2000 SYSTEM UE3 UNCONJUGATED ESTRIOL)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF UNCONJUGATED (FREE) ESTRIOL IN SERUM AS AN AID IN MONITORING FETAL MATURITY AND WELL-BEING IN THE CONTEXT OF HIGH-RISK AND POORLY DATED PREGNANCIES.,IMMULITE® 2000 SYSTEM TROPONIN I(IMMULITE® 2000 SYSTEM TROPONIN I)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF TROPONIN I IN SERUM, HEPARINIZED OR EDTA PLASMA, AS AN AID IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI).,IMMULITE® 2000 SYSTEM MYOGLOBIN (IMMULITE® 2000 SYSTEM MYOGLOBIN)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF MYOGLOBIN IN SERUM AND HEPARINIZED PLASMA, AS AN AID IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI).,IMMULITE® 2000 NT PRO-BNP SAMPLE DILUENT(IMMULITE® 2000 NT PRO-BNP SAMPLE DILUENT)-FOR THE ON-BOARD DILUTION OF PATIENT SAMPLES. ONE VIAL OF CONCENTRATED (READY- TO-USE) PROCESSED, NT-PROBNP-FREE NONHUMAN SERUM MATRIX, WITH PRESERVATIVE,TURBO NT PRO-BNP(TURBO NT PRO-BNP)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HEPARINIZED PLASMA, AS AN AID IN THE DIAGNOSIS OF INDIVIDUALS SUSPECTED OF HAVING CONGESTIVE HEART FAILURE. THE TEST IS FURTHER INDICATED FOR THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROME AND CONGESTIVE HEART FAILURE ,TURBO D-DIMER (TURBO D-DIMER)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CROSS-LINKED FIBRIN DEGRADATION PRODUCTS (XL-FDP) CONTAINING D-DIMER IN HUMAN PLASMA (HEPARINIZED OR SODIUM CITRATE). ,IMMULITE® 2000 OSTEOCALCIN (OCN)(IMMULITE® 2000 OSTEOCALCIN (OCN))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF OSTEOCALCIN IN HUMAN SERUM OR HEPARINIZED PLASMA, AS AN AID IN MONITORING MINERAL AND BONE METABOLISM. , IMMULITE®/IMMULITE 2000 PYRILINKS-D(IMMULITE®/IMMULITE 2000 PYRILINKS-D)-FOR IN VITRO DIAGNOSTIC USE WITH THE

	IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF DEOXYPYRIDINOLINE (DPD) IN URINE, AS AN AID IN MONITORING TYPE 1 COLLAGEN RESORPTION CHANGES, ESPECIALLY IN BONE IN POSTMENOPAUSAL WOMEN DIAGNOSED WITH OSTEOPOROSIS AND RECEIVING ANTIRESORPTIVE THERAPY (AMINOBISPHOSPHONATE). ,IMMULITE®/IMMULITE 1000 PHENOBARBITAL (PHE)(IMMULITE®/IMMULITE 1000 PHENOBARBITAL (PHE))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF PHENOBARBITAL IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN MONITORING DRUG THERAPY., IMMULITE®/IMMULITE 1000 ECP(IMMULITE®/IMMULITE 1000 ECP)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF EOSINOPHIL CATIONIC PROTEIN (ECP) IN SERUM. ,IMMULITE® 1000 PYRILINKS-D SAMPLE DILUENT (DPD)(IMMULITE® 1000 PYRILINKS-D SAMPLE DILUENT (DPD))-FOR DILUTION OF SAMPLES FOR THE IMMULITE PYRILINKS-D IN VITRO DIAGNOSTIC ASSAYS,IMMULITE® SYSTEMS DDI CONTROL D-DIMER(IMMULITE® SYSTEMS DDI CONTROL D-DIMER)-IMMULITE D-DIMER CONTROL MODULE IS AN ASSAYED, TRI-LEVEL CONTROL INTENDED FOR USE WITH THE IMMULITE/IMMULITE 1000 TURBO AND IMMULITE 2000 D-DIMER ASSAYS. IT IS INTENDED AS AN AID IN MONITORING DAY-TO-DAY ASSAY PERFORMANCE. ,RUBELLA IGG (RUBELLA QUANT IGG) (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)(RUBELLA IGG (RUBELLA QUANT IGG) (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM, AS AN AID IN THE DETERMINATION OF IMMUNE STATUS TO RUBELLA, PARTICULARLY FOR WOMEN OF CHILDBEARING AGE. , IMMULITE 2000 TSI(IMMULITE 2000 TSI)-THE IMMULITE 2000 TSI ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF THYROID STIMULATING AUTOANTIBODIES SPECIFIC TO TSH RECEPTORS IN HUMAN SERUM (INCLUDING SERUM SEPARATOR TUBES) OR PLASMA (K2-EDTA OR LITHIUM HEPARIN). THE IMMULITE TSI ASSAY IS FOR USE WITH THE IMMULITE® 2000 SYSTEM. THE MEASUREMENT OF THYROID STIMULATING AUTOANTIBODIES, IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS, IS USED AS AN AID IN THE DIAGNOSIS OF PATIENTS SUSPECTED OF HAVING GRAVES' DISEASE. , IMMULITE®/IMMULITE 1000 ATA ANTI-TPO AB (IMMULITE®/IMMULITE 1000 ATA ANTI-TPO AB)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000

	ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF ANTIBODIES AGAINST THYROID PEROXIDASE (TPO) IN SERUM AND EDTA PLASMA, AS AN AID IN THE CLINICAL DIAGNOSIS OF THYROID DISEASES.,IMMULITE® 2000 PHENYTOIN (PHN)(IMMULITE® 2000 PHENYTOIN (PHN))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF PHENYTOIN IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN MONITORING DRUG THERAPY., IMMULITE®/IMMULITE®1000 CMV IGM(IMMULITE®/IMMULITE®1000 CMV IGM)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS (CMV) IN HUMAN SERUM OR PLASMA (EDTA OR HEPARINIZED), AS AN AID IN THE DETERMINATION OF AN ACUTE CMV INFECTION. ,IMMULITE®/IMMULITE® 1000 DIGITOXIN (DGT)(IMMULITE®/IMMULITE® 1000 DIGITOXIN (DGT))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF DIGITOXIN IN SERUM, AS AN AID IN THE THERAPEUTIC ADMINISTRATION OF THIS CARDIOGLYCOSIDE., IMMULITE®/IMMULITE 1000 SYSTEMS SPS THIRD GENERATION PSA (IMMULITE®/IMMULITE 1000 SYSTEMS SPS THIRD GENERATION PSA) -FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF PROSTATE-SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM, AS AN AID IN THE DETECTION OF PROSTATE CANCER WHEN USED IN CONJUNCTION WITH DIGITAL RECTAL EXAMINATION (DRE) IN MEN AGED 50 YEARS OR OLDER. THIS ASSAY IS FURTHER INDICATED AS AN ADJUNCTIVE TEST TO AID IN THE MANAGEMENT OF PROSTATE CANCER PATIENTS. ,PAP (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)(PAP (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF PROSTATIC ACID PHOSPHATASE (PAP) IN SERUM, AS AN AID IN PATIENT MANAGEMENT. ,IMMULITE®/IMMULITE1000 CMV IGG CONTROLS(IMMULITE®/IMMULITE1000 CMV IGG CONTROLS)-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 AND IMMULITE 2000 CMV IGG ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE.,EBV VCA IGG (IMMULITE 2000 SYSTEM RANGE ASSAYS)(EBV VCA IGG (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO VIRAL CAPSID ANTIGEN OF EPSTEIN-BARR VIRUS IN HUMAN SERUM OR PLASMA (EDTA AND HEPARINIZED). THIS ASSAY MAY ALSO BE USED AS AN AID IN THE DIAGNOSIS OF EBV-

	ASSOCIATED DISEASES WHEN USED IN CONJUNCTION WITH THE IMMULITE 2000 EBV-VCA IGM AND IMMULITE 2000 EBV-EBNA IGG IMMUNOASSAYS ,IMMULITE®/IMMULITE 1000 DIGOXIN (DGX) (IMMULITE®/IMMULITE 1000 DIGOXIN (DGX))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF DIGOXIN IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN MONITORING THE THERAPEUTIC ADMINISTRATION OF THIS CARDIOGLYCOSIDE, WHILE AVOIDING TOXICITY.,IL-1 BETA (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)(IL-1 BETA (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF INTERLEUKIN-1 (IL-1) IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN THE CLINICAL ASSESSMENT OF VARIOUS IMMUNOLOGICAL DISEASES. ,IMMULITE® NT-PROBNP CONTROL MODULE(IMMULITE® NT-PROBNP CONTROL MODULE)-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 TURBO AND IMMULITE 2000 NT-PROBNP ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE,IL-6 DILUENT (MONO/POLY)(IL-6 DILUENT (MONO/POLY))-FOR DILUTION OF SAMPLES FOR THE IMMULITEIL-6 IN VITRO DIAGNOSTIC ASSAYS, IMMULITE®/IMMULITE® 1000 H. PYLORI IGG (HPG) CONTROLS (IMMULITE®/IMMULITE® 1000 H. PYLORI IGG (HPG) CONTROLS)-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 AND IMMULITE 2000 H PYLORI IGG ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE,TOXOPLASMA QUANT IGG (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)(TOXOPLASMA QUANT IGG (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES TO TOXOPLASMA GONDII (TOXOPLASMA) IN HUMAN SERUM, AS AN AID IN THE DETERMINATION OF SEROLOGICAL STATUS TO TOXOPLASMA GONDII. ,FERRITIN(IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)(FERRITIN(IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF FERRITIN IN SERUM, AS AN AID IN THE CLINICAL DIAGNOSIS OF IRON DEFICIENCY AND OVERLOAD , IMMULITE® 2000 CARBAMAZEPINE (CMP)(IMMULITE® 2000 CARBAMAZEPINE (CMP))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CARBAMAZEPINE IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN MONITORING THE THERAPEUTIC ADMINISTRATION OF THIS DRUG.,IMMULITE®/IMMULITE 1000

	SYSTEMS GIM GI-MA (CA 19-9)(IMMULITE®/IMMULITE 1000 SYSTEMS GIM GI-MA (CA 19-9))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CA19-9 IN SERUM, AS AN AID IN PATIENT MANAGEMENT.,IMMULITE®/IMMULITE 1000 SYSTEMS BRM DIL BR-MA (CA 15-3) SAMPLE DILUENT(IMMULITE®/IMMULITE 1000 SYSTEMS BRM DIL BR-MA (CA 15-3) SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF PATIENT SAMPLES.,IMMULITE®/ IMMULITE® 1000 SYSTEMS TG DIL THYROGLOBULIN SAMPLE DILUENT (IMMULITE®/ IMMULITE® 1000 SYSTEMS TG DIL THYROGLOBULIN SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF PATIENT SAMPLES.,IMMULITE® 2000 SYSTEMS F PS FREE PSA(IMMULITE® 2000 SYSTEMS F PS FREE PSA)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF FREE, UNCOMPLEXED PROSTATE-SPECIFIC ANTIGEN (PSA), I.E. PSA NOT BOUND TO APLHA1-ANTICHYMOTRYPSIN OR OTHER BINDING PROTEINS, IN SERUM. , IMMULITE® 2000 SYSTEMS CEA CEA(IMMULITE® 2000 SYSTEMS CEA CEA)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN (CEA) IN SERUM, AS AN AID IN THE MANAGEMENT OF CANCER PATIENTS AND IN THE ASSESSMENT OF PROGNOSIS.,IMMULITE®/IMMULITE 1000 PHENYTOIN (PHN) (IMMULITE®/IMMULITE 1000 PHENYTOIN (PHN))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF PHENYTOIN IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN MONITORING DRUG THERAPY.,IMMULITE®/IMMULITE 1000 SYSTEMS SYSTEMS CEA CEA(IMMULITE®/IMMULITE 1000 SYSTEMS SYSTEMS CEA CEA)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE@ AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN (CEA) IN SERUM, AS AN AID IN THE MANAGEMENT OF CANCER PATIENTS AND IN THE ASSESSMENT OF PROGNOSIS.,IMMULITE®/IMMULITE 1000 SYSTEMS OV OM-MA (CA 125)(IMMULITE®/IMMULITE 1000 SYSTEMS OV OM-MA (CA 125))-FOR IN-VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CA125 ANTIGEN IN SERUM, AS AN AID IN MONITORING THE RESPONSE TO THERAPY FOR PATIENTS WITH EPITHELIAN OVARIAN CANCER AND IN DETECTING RESIDUAL OVARIAN CANCER IN PATIENTS WHO HAVE UNDERGONE FIRST-LINE THERAPY AND WOULD BE CONSIDERED FOR DIAGNOSTIC SECOND-LOOK PROCEDURES.,-CAPTURE TOXOPLASMA IGM (TOXO -CAPTURE) (IMMULITE 2000 SYSTEM RANGE ASSAYS)(-CAPTURE

	TOXOPLASMA IGM (TOXO -CAPTURE) (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZER — FOR THE PRESUMPTIVE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM OR PLASMA (EDTA OR HEPARINIZED), PARTICULARLY FOR WOMEN OF CHILDBEARING AGE. WHEN PERFORMED IN CONJUNCTION WITH A TOXOPLASMA IGG ASSAY, THE IMMULITE 2000 TOXOPLASMA IGM (-CAPTURE) CAN BE USED AS AN AID IN THE PRESUMPTIVE DIAGNOSIS OF ACUTE, RECENT OR REACTIVATED TOXOPLASMA INFECTION. ,IMMULITE® 2000 SYSTEMS FT3 FREE T3 (IMMULITE® 2000 SYSTEMS FT3 FREE T3)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF FREE T3 IN SERUM. MEASUREMENTS OF FREE T3 ARE USED IN THE DIAGNOSIS AND TREATMENT OF THYROID DISEASE.,IL-6 (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)(IL-6 (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH IMMULITE AND IMMULITE 1000 ANALYZERS -FOR THE QUANTITATIVE MEASUREMENT OF INTERLEUKIN 6 (IL-6) IN SERUM, EDTA OR HEPARINIZED PLASMA, AS AN AID IN STUDY OF INFLAMMATORY DISEASE., IMMULITE® 2000 SYSTEM LH LH(IMMULITE® 2000 SYSTEM LH LH)- FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF LH IN SERUM AS AN AID IN CLINICAL DIAGNOSIS., IMMULITE®/IMMULITE 1000 TOTAL IGE (TIE)(IMMULITE®/IMMULITE 1000 TOTAL IGE (TIE))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF TOTAL IMMUNOGLOBULIN TYPE E (IGE) IN SERUM. ,IMMULITE®/IMMULITE® 1000 CARBAMAZEPINE (CMP)(IMMULITE®/IMMULITE® 1000 CARBAMAZEPINE (CMP))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CARBAMAZEPINE IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN MONITORING THE THERAPEUTIC ADMINISTRATION OF THIS DRUG., CMV IGG (IMMULITE 2000 SYSTEM RANGE ASSAYS)(CMV IGG (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS (CMV) IN HUMAN SERUM, AS AN AID IN THE DETERMINATION OF SEROLOGICAL STATUS TO CMV. ,IMMULITE® 2000 PHENOBARBITAL (PHE)(IMMULITE® 2000 PHENOBARBITAL (PHE))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF PHENOBARBITAL IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN

	MONITORING DRUG THERAPY.,IMMULITE® TOTAL IGE (TIE) SAMPLE DILUENT(IMMULITE® TOTAL IGE (TIE) SAMPLE DILUENT)-FOR DILUTION OF SAMPLES FOR THE IMMULITE TOTAL IGE IN VITRO DIAGNOSTIC ASSAYS,IMMULITE® SYSTEMS EPO CONTROL EPO (IMMULITE® SYSTEMS EPO CONTROL EPO)-THE IMMULITE EPO CONTROL MODULE IS AN ASSAYED, TRI-LEVEL CONTROL INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 (LKEPN) AND IMMULITE 2000 (L2KEPN) EPO ASSAYS. IT IS INTENDED AS AN AID IN MONITORING DAY-TO-DAY ASSAY PERFORMANCE. ,ALBUMIN (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS) SAMPLE DILUENT(ALBUMIN (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS) SAMPLE DILUENT)-FOR DILUTION OF SAMPLES FOR THE IMMULITE ALBUMIN IN VITRO DIAGNOSTIC ASSAYS, IMMULITE®/IMMULITE 1000 SYSTEMS GIM DIL GI-MA (CA 19-9) SAMPLE DILUENT(IMMULITE®/IMMULITE 1000 SYSTEMS GIM DIL GI-MA (CA 19-9) SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF PATIENT SAMPLES.,CYTOKINE CONTROLS (CYTOKINE /IML) (CYTOKINE CONTROLS (CYTOKINE /IML))-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 AND IMMULITE 2000 IL-6, IMMULITE/IMMULITE 1000 IL-1 AND IL-8, IMMULITE/IMMULITE 1000 AND IMMULITE 2000 IL2R, IMMULITE/IMMULITE 1000 TNF ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE, IMMULITE® 2000 SYSTEMS TT4 TOTAL T4(IMMULITE® 2000 SYSTEMS TT4 TOTAL T4)- FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF TOTAL CIRCULATING THYROXINE (T4) IN SERUM. MEASUREMENTS OF T4 ARE USED IN THE DIAGNOSIS AND TREATMENT OF THYROID DISEASE. ,IMMULITE® 2000 SYSTEMS CAL CONTROL CALCITONIN(IMMULITE® 2000 SYSTEMS CAL CONTROL CALCITONIN)-THE IMMULITE CALCITONIN CONTROL MODULE IS AN ASSAYED, BI-LEVEL CONTROL INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 AND IMMULITE 2000 CALCITONIN ASSAYS. IT IS INTENDED AS AN AID IN MONITORING DAY-TO-DAY ASSAY PERFORMANCE. ,IMMULITE® 2000 SYSTEMS TG THYROGLOBULIN (IMMULITE® 2000 SYSTEMS TG THYROGLOBULIN)- FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF THYROGLOBULIN IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN MONITORING PATIENTS WHO HAVE UNDERGONE THYROIDECTOMY., IMMULITE®/IMMULITE 1000 SYSTEMS AF AFP(IMMULITE®/IMMULITE 1000 SYSTEMS AF AFP)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE@ AND IMMULITE 1000 ANALYZERS FOR THE QUANTITATIVE MEASUREMENT OF ALPHAFETOPROTEIN (AFP) IN EITHER OF TWO CONTEXTS: (A) SERIAL MEASUREMENTS IN HUMAN

	SERUM TO AID IN THE MANAGEMENT OF PATIENTS WITH NONSEMINOMATOUS TESTICULAR CANCER; OR (B) MEASUREMENTS IN MATERNAL SERUM AND AMNIOTIC FLUID DURING GESTATIONAL WEEKS 15 THROUGH 20 — USED IN CONJUNCTION WITH ULTRASONOGRAPHY OR AMNIOGRAPHY — TO AID IN DETECTION OF FETAL OPEN NEURAL TUBE DEFECTS.,IMMULITE® / IMMULITE® 1000 SYSTEMS GH GROWTH HORMONE SAMPLE DILUENT(IMMULITE® / IMMULITE® 1000 SYSTEMS GH GROWTH HORMONE SAMPLE DILUENT)- FOR THE MANUAL DILUTION OF PATIENT SAMPLES., TORCH IGG/IGM DILUENT (IMMULITE 2000 SAMPLE DILUENT)(TORCH IGG/IGM DILUENT (IMMULITE 2000 SAMPLE DILUENT))-FOR DILUTION OF SAMPLES FOR THE IMMULITE 2000 SERIES TORCH IGG/IGM DILUENT IN VITRO DIAGNOSTIC ASSAYS, IMMULITE®/IMMULITE 1000 SYSTEMS BRM BR-MA (CA15-3) (IMMULITE®/IMMULITE 1000 SYSTEMS BRM BR-MA (CA15-3))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE@ AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CA 15-3 ANTIGEN IN HUMAN SERUM, AS AN AID IN THE DETECTION OF RECURRENCE IN PREVIOUSLY TREATED STAGE II AND STAGE III BREAST CANCER PATIENTS, AND IN THE MANAGEMENT OF METASTATIC BREAST CANCER PATIENTS BY MONITORING DISEASE PROGRESSION OR RESPONSE TO TREATMENT. SERIAL TESTING FOR PATIENT CA 15-3 VALUES SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL METHODS USED FOR DETECTING EARLY RECURRENCE IN STAGE II AND STAGE III DISEASE AND FOR MONITORING RESPONSE TO TREATMENT IN PATIENTS WITH METASTATIC BREAST CANCER.,IMMULITE®/IMMULITE1000 CMV IGG (IMMULITE®/IMMULITE1000 CMV IGG)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS (CMV) IN HUMAN SERUM, AS AN AID IN THE DETERMINATION OF SEROLOGICAL STATUS TO CMV. , IMMULITE®/IMMULITE® 1000 H. PYLORI IGG (HPG) (IMMULITE®/IMMULITE® 1000 H. PYLORI IGG (HPG))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO HELICOBACTER PYLORI IN HUMAN SERUM FROM SYMPTOMATIC ADULTS, AS AN AID IN THE DIAGNOSIS OF HELICOBACTER PYLORI INFECTION. ,IMMULITE®/IMMULITE 1000 SYSTEMS F PS FREE PSA(IMMULITE®/IMMULITE 1000 SYSTEMS F PS FREE PSA)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF FREE, UNCOMPLEXED PROSTATE-SPECIFIC ANTIGEN (PSA), I.E. PSA NOT BOUND TO ALPHA 1-

	ANTICHYMOTRYPSIN OR OTHER BINDING PROTEINS, IN SERUM. , IMMULITE® 2000 TOTAL IGE (TIE)(IMMULITE® 2000 TOTAL IGE (TIE)) -FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF IMMUNOGLOBULIN TYPE E (IGE) IN SERUM. ,IMMULITE®/ IMMULITE® 1000 SYSTEMS T3F FREE T3(IMMULITE®/ IMMULITE® 1000 SYSTEMS T3F FREE T3)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF FREE T3 LEVELS IN SERUM, AS AN AID IN THE CLINICAL ASSESSMENT OF THYROID STATUS.,IMMULITE®/ IMMULITE® 1000 SYSTEMS TBG (IMMULITE®/ IMMULITE® 1000 SYSTEMS TBG)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF THYROXINE-BINDING GLOBULIN (TBG) IN SERUM, AS AN AID IN THE DIAGNOSIS AND TREATMENT OF THYROID DISEASES.,IMMULITE®/IMMULITE 1000 PYRILINKS-D (DPD) (IMMULITE®/IMMULITE 1000 PYRILINKS-D (DPD))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF DEOXYPYRIDINOLINE (DPD) IN URINE, AS AN AID IN MONITORING TYPE 1 COLLAGEN RESORPTION CHANGES, ESPECIALLY IN BONE IN POSTMENOPAUSAL WOMEN DIAGNOSED WITH OSTEOPOROSIS AND RECEIVING ANTIRESORPTIVE THERAPY (AMINOBISPHOSPHONATE)., IMMULITE® 2000 SYSTEM FSH DIL FSH SAMPLE DILUENT(IMMULITE® 2000 SYSTEM FSH DIL FSH SAMPLE DILUENT)-FOR THE ON-BOARD DILUTION OF HIGH SAMPLES.,IMMULITE®/ IMMULITE® 1000 SYSTEMS TSH DIL THIRD GENERATION TSH SAMPLE DILUENT (IMMULITE®/ IMMULITE® 1000 SYSTEMS TSH DIL THIRD GENERATION TSH SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF PATIENT SAMPLES.,IMMULITE®/IMMULITE 1000 SYSTEMS AF DIL AFP SAMPLE DILUENT(IMMULITE®/IMMULITE 1000 SYSTEMS AF DIL AFP SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF HIGH SERUM SAMPLES AND AMNIOTIC FLUID SAMPLES.,IMMULITE® SYSTEMS GAS CONTROL GASTRIN(IMMULITE® SYSTEMS GAS CONTROL GASTRIN)-IMMULITE GASTRIN CONTROL MODULE IS AN ASSAYED, BI-LEVEL CONTROL INTENDED FOR USE WITH THE IMMULITE/IMMULITE 1000 AND IMMULITE 2000 GASTRIN ASSAY. IT IS INTENDED AS AN AID IN MONITORING DAY-TO-DAY ASSAY PERFORMANCE. ,IMMULITE® SYSTEMS INS CONTROL INSULIN(IMMULITE® SYSTEMS INS CONTROL INSULIN)-IMMULITE INSULIN CONTROLS ARE ASSAYED BI-LEVEL CONTROLS INTENDED FOR USE WITH THE IMMULITE/IMMULITE 1000 AND IMMULITE 2000 INSULIN ASSAYS. THEY ARE INTENDED AS AN AID IN MONITORING DAY-TO-DAY ASSAY PERFORMANCE. , IMMULITE® 2000 OM-MA SAMPLE DILUENT(IMMULITE® 2000 OM-MA

	SAMPLE DILUENT)-FOR THE ON-BOARD DILUTION OF HIGH SAMPLES., IMMULITE®/ IMMULITE® 1000 SYSTEMS IPT INTACT PTH (IMMULITE®/ IMMULITE® 1000 SYSTEMS IPT INTACT PTH)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF INTACT PARATHYROID HORMONE (PARATHYRIN, PTH) IN EDTA PLASMA OR SERUM, AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF HYPERCALCEMIA AND HYPOCALCEMIA. ,IMMULITE®/ IMMULITE® 1000 SYSTEMS F4 FREE T4(IMMULITE®/ IMMULITE® 1000 SYSTEMS F4 FREE T4)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF NON-PROTEIN-BOUND THYROXINE (FREE T4) LEVELS IN SERUM AND HEPARINIZED PLASMA, AS AN AID IN THE CLINICAL ASSESSMENT OF THYROID STATUS.,IMMULITE® SYSTEMS IGL CONTROL IGF-1(IMMULITE® SYSTEMS IGL CONTROL IGF-1)-IMMULITE® IGF CONTROL MODULE IS AN ASSAYED, BI- LEVEL CONTROL INTENDED FOR THE USE WITH IMMULITE/ IMMULITE 1000 AND IMMULITE 2000 IGFBP- 3 ASSAYS. IT IS INTENDED AS AN AID IN MONITORING DAY-TO-DAY ASSAY PERFORMANCE.,IMMULITE®/ IMMULITE® 1000 SYSTEMS RTH DIL RAPID TSH SAMPLE DILUENT (IMMULITE®/ IMMULITE® 1000 SYSTEMS RTH DIL RAPID TSH SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF PATIENT SAMPLES, IMMULITE® 2000 SYSTEMS HCY HOMOCYSTEINE(IMMULITE® 2000 SYSTEMS HCY HOMOCYSTEINE)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS - FOR THE QUANTITATIVE DETERMINATION L- HOMOCYSTEINE IN HUMAN PLASMA OR SERUM. THIS DEVICE CAN ASSIST IN THE DIAGNOSIS AND TREATMENT OF PATIENTS SUSPECTED OF HAVING HYPERHOMOCYSTEINEMIA OR HOMOCYSTINURIA.,IL-8 (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)(IL-8 (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF INTERLEUKIN 8 (IL-8) IN SERUM OR EDTA PLASMA, AS AN AID IN THE STUDY OF INFLAMMATORY DISEASES. , IMMULITE® 2000 SYSTEMS PRL DIL PROLACTIN SAMPLE DILUENT(IMMULITE® 2000 SYSTEMS PRL DIL PROLACTIN SAMPLE DILUENT)-FOR ON-BOARD DILUTION OF HIGH SAMPLES., IMMULITE® SYSTEMS PAA CONTROL PAPP-A(IMMULITE® SYSTEMS PAA CONTROL PAPP-A)-THE IMMULITE® PAPP-A CONTROL MODULE IS AN ASSAYED, BI-LEVEL CONTROL INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 AND IMMULITE 2000 PAPP-A ASSAYS. IT IS INTENDED AS AN AID IN MONITORING DAY-TO- DAY ASSAY PERFORMANCE.,IMMULITE®/IMMULITE 1000 THEOPHYLLINE (THE) (IMMULITE®/IMMULITE 1000 THEOPHYLLINE (THE))-FOR IN VITRO

	DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF THEOPHYLLINE IN SERUM, AS AN AID IN MONITORING THE THERAPEUTIC ADMINISTRATION OF THIS BRONCHODILATOR., ALBUMIN (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)(ALBUMIN (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE DETECTION AND QUANTITATION OF MICROALBUMINURIA, THAT IS, CONCENTRATIONS OF ALBUMIN IN HUMAN URINE NOT DETECTABLE BY CONVENTIONAL DIPSTICK METHODS. IT IS INTENDED FOR USE AS AN AID IN MONITORING THE DEVELOPMENT OF INCIPIENT DIABETIC NEPHROPATHY. ,IGG/IGM SAMPLE DILUENT (IMMULITE 1000 SAMPLE DILUENT)(IGG/IGM SAMPLE DILUENT (IMMULITE 1000 SAMPLE DILUENT))-FOR DILUTION OF SAMPLES FOR THE IMMULITE 1000 SERIES TORCH IGG/IGM DILUENT IN VITRO DIAGNOSTIC ASSAYS,IMMULITE® 2000 SYSTEMS TSH DIL THIRD GENERATION TSH SAMPLE DILUENT(IMMULITE® 2000 SYSTEMS TSH DIL THIRD GENERATION TSH SAMPLE DILUENT)-FOR THE ON-BOARD DILUTION OF PATIENT SAMPLES.,IL2R (IMMULITE 2000 SYSTEM RANGE ASSAYS)(IL2R (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF SOLUBLE INTERLEUKIN 2 RECEPTOR (IL2R) IN SERUM, AS AN AID IN THE STUDY OF INFLAMMATORY DISEASES ,ANTI CCP IGG (IMMUITE 2000)(ANTI CCP IGG (IMMUITE 2000))-THE IMMULITE® 2000 ANTI-CCP IGG ASSAY IS AN IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE SEMIQUANTITATIVE DETERMINATION OF THE IGG CLASS OF AUTOANTIBODIES SPECIFIC TO CYCLIC CITRULLINATED PEPTIDE (CCP) IN HUMAN SERUM (INCLUDING SERUM SEPARATOR TUBES) OR PLASMA (EDTA OR LITHIUM HEPARIN) ON THE IMMULITE 2000 SYSTEMS ANALYZERS. DETECTION OF ANTI-CCP ANTIBODIES IS USED AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA) AND SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL INFORMATION. AUTOANTIBODY LEVELS REPRESENT ONE PARAMETER IN A MULTI-CRITERIA DIAGNOSTIC PROCESS, ENCOMPASSING BOTH CLINICAL AND LABORATORY-BASED ASSESSMENTS. ,CK-MB (IMMULITE 2000 SYSTEM RANGE ASSAYS)(CK-MB (IMMULITE 2000 SYSTEM RANGE ASSAYS))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF CREATINE KINASE ISOENZYME MB (CK-MB) IN HEPARINIZED PLASMA OR SERUM, AS AN AID IN PATIENT MANAGEMENT AND THE ASSESSMENT OF PROGNOSIS OF MYOCARDIAL INFARCTION ,TOXOPLASMA QUANT. CONTROLS

	(TOXOPLASMA QUANT. IGG)(TOXOPLASMA QUANT. CONTROLS (TOXOPLASMA QUANT. IGG))-INTENDED FOR USE WITH TOXOPLASMA QUANT. IMMULITE ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE,IMMULITE® 2000 ALLERGEN-SPECIFIC IGG (SPG)(IMMULITE® 2000 ALLERGEN-SPECIFIC IGG (SPG))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGG IN HUMAN SERUM AND PLASMA (EDTA OR HEPARINIZED), AS AN AID IN THE CLINICAL DIAGNOSIS OF IGG-MEDIATED ALLERGIC DISORDERS.,TNF ALPHA (MONO/POLY) (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)(TNF ALPHA (MONO/POLY) (IMMULITE/ IMMULITE 1000 SYSTEM RANGE ASSAYS)) -FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF TUMOR NECROSIS FACTOR (TNF) IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN THE CLINICAL ASSESSMENT OF VARIOUS IMMUNOLOGICAL DISEASES. ,CMV IGM (IMMULITE 2000 SYSTEM RANGE ASSAYS)(CMV IGM (IMMULITE 2000 SYSTEM RANGE ASSAYS)) -FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS (CMV) IN HUMAN SERUM OR PLASMA (EDTA OR HEPARINIZED), AS AN AID IN THE DETERMINATION OF AN ACUTE CMV INFECTION. ,FERRITIN CONTROLS(FERRITIN CONTROLS)-INTENDED FOR USE WITH COAT-A-COUNT IRMA, IMMULITE/IMMULITE 1000 AND IMMULITE 2000 FERRITIN ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE, IMMULITE®/ IMMULITE® 1000 SYSTEMS RTH RAPID TSH (IMMULITE®/ IMMULITE® 1000 SYSTEMS RTH RAPID TSH)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF THYROTROPIN (TSH) IN SERUM, AS AN AID IN THE CLINICAL ASSESSMENT OF THYROID STATUS. ,IMMULITE®/ IMMULITE® 1000 SYSTEMS PTH DIL INTACT PTH SAMPLE DILUENT(IMMULITE®/ IMMULITE® 1000 SYSTEMS PTH DIL INTACT PTH SAMPLE DILUENT)-FOR THE MANUAL DILUTION OF SAMPLES.,IMMULITE® 2000 SYSTEMST3 TOTAL T3(IMMULITE® 2000 SYSTEMST3 TOTAL T3)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF TOTAL CIRCULATING TRIIODOTHYRONIN (T3) IN SERUM. MEASUREMENTS OF T3 ARE USED IN THE DIAGNOSIS AND TREATMENT OF THYROID DISEASE., IMMULITE® 2000 SYSTEMS HCG DIL HCG SAMPLE DILUENT (IMMULITE® 2000 SYSTEMS HCG DIL HCG SAMPLE DILUENT)-FOR ON-BOARD DILUTION OF HIGH SAMPLES.,IMMULITE® / IMMULITE® 1000 HERPES I & II IGG (HER)(IMMULITE® / IMMULITE® 1000 HERPES

	I & II IGG (HER))-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE AND IMMULITE 1000 ANALYZERS — FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO HERPES SIMPLEX VIRUS (HSV) TYPES I AND II IN HUMAN SERUM, AS AN AID IN DETERMINATION OF SEROLOGICAL STATUS TO HSV I & II. ,PAP CONTROLS(PAP CONTROLS)-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 AND IMMULITE 2000 PAP ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE,ALBUMIN CONTROLS (ALBUMIN /IML) (ALBUMIN CONTROLS (ALBUMIN /IML))-INTENDED FOR USE WITH IMMULITE/IMMULITE 1000 AND IMMULITE 2000 ALBUMIN ASSAYS AS AN AID IN MONITORING DAY TO DAY ASSAYS PERFORMANCE, IMMULITE®/ IMMULITE® 1000 SYSTEMS T4 TOTAL T4(IMMULITE®/ IMMULITE® 1000 SYSTEMS T4 TOTAL T4)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF TOTAL CIRCULATING THYROXINE (T4) IN SERUM, AS AN AID IN THE CLINICAL ASSESSMENT OF THYROID STATUS. ,IMMULITE® 2000 SYSTEMS CPE CONTROL C-PEPTIDE(IMMULITE® 2000 SYSTEMS CPE CONTROL C-PEPTIDE)-THE C-PEPTIDE CONTROL MODULE IS AN ASSAYED, TRI-LEVEL CONTROL INTENDED FOR USE WITH THE IMMULITEO/IMMULITE 1000 AND IMMULITE 2000 C-PEPTIDE ASSAYS, IT IS INTENDED AS AN AID IN MONITORING DAY-TO-DAY ASSAY PERFORMANCE.,LBP DILUENT(LBP DILUENT)-FOR DILUTION OF SAMPLES FOR THE IMMULITE LBP IN VITRO DIAGNOSTIC ASSAYS,IMMULITE® 2000 SYSTEMS TBG (IMMULITE® 2000 SYSTEMS TBG)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE 2000 SYSTEMS ANALYZERS — FOR THE QUANTITATIVE MEASUREMENT OF THYROXINE-BINDING GLOBULIN (TBG) IN SERUM, AS AN AID IN THE DIAGNOSIS AND TREATMENT OF THYROID DISEASES.,IMMULITE® / IMMULITE@ 1000 SYSTEMS IGL IGF- 1(IMMULITE® / IMMULITE@ 1000 SYSTEMS IGL IGF- 1)-FOR IN VITRO DIAGNOSTIC USE WITH THE IMMULITE® AND IMMULITE 1000 ANALYZERS - FOR THE QUANTITATIVE MEASUREMENT OF INSULIN-LIKEGROWTH FACTOR I (IGF-1) IN SERUM OR HEPARINIZED PLASMA, AS AN AID IN THE EVALUATION OF GROWTH DISORDERS.

287	IMP/IVD/2019/000302	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCESS HCV AB V3 CALIBRATORS(ACCESS HCV AB V3 CALIBRATORS)-THE ACCESS HCV AB V3 CALIBRATORS KIT IS FOR THE CALIBRATION OF THE ACCESS IMMUNOASSAY SYSTEMS WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HCV IN HUMAN SERUM AND PLASMA., ACCESS HCV AB PLUS CALIBRATORS(ACCESS HCV AB PLUS CALIBRATORS)-THE ACCESS HCV AB PLUS CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS HCV AB PLUS ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HCV IN HUMAN SERUM AND PLASMA, USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS HCV AB V3 QC(ACCESS HCV AB V3 QC)-THE ACCESS HCV AB V3 QC IS INTENDED FOR MONITORING THE SYSTEM PERFORMANCE OF THE ACCESS HCV AB V3.,ACCESS HCV AB PLUS(ACCESS HCV AB PLUS)-THE ACCESS HCV AB PLUS ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO THE HEPATITIS C VIRUS IN HUMAN SERUM OR PLASMA, USING THE ACCESS IMMUNOASSAY SYSTEMS. THE ACCESS HCV AB PLUS IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF HCV INFECTION AND AS A SCREENING TEST FOR BLOOD AND PLASMA DONORS. THE ASSAY IS NOT INTENDED FOR THE TESTING OR SCREENING OF POOLED SPECIMENS.,ACCESS HCV AB V3(ACCESS HCV AB V3)-THE ACCESS HCV AB V3 IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO THE HEPATITIS C VIRUS IN HUMAN SERUM OR PLASMA (LITHIUM HEPARIN, K2-EDTA, K3-EDTA, CITRATE, CPDA-1 OR ACD), USING THE ACCESS IMMUNOASSAY SYSTEMS. THE ACCESS HCV AB V3 IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF HCV INFECTION AND AS A SCREENING TEST FOR BLOOD AND PLASMA DONORS. THE ASSAY IS NOT INTENDED FOR THE TESTING OR SCREENING OF POOLED SPECIMENS,ACCESS HIV COMBO CALIBRATORS(ACCESS HIV COMBO CALIBRATORS)-THE ACCESS HIV COMBO ASSAY IS A PARAMAGNETIC-PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HIV-1 P24 ANTIGEN AND ANTIBODIES TO HIV-1 (GROUPS M AND O) AND HIV-2 IN HUMAN SERUM AND PLASMA (LI HEPARIN, K2-EDTA, K3-EDTA AND CPDA-1) USING THE ACCESS IMMUNOASSAY SYSTEMS. THE ACCESS HIV COMBO ASSAY IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF HIV-1 OR HIV-2 INFECTION AND AS SCREENING TEST FOR BLOOD AND PLASMA DONORS. THE ASSAY IS NOT INTENDED FOR THE TESTING OR SCREENING OF POOLED SPECIMENS. AN

	ACCESS HIV COMBO ASSAY RESULT DOES NOT DISTINGUISH BETWEEN THE DETECTION OF HIV-1 P24 ANTIGEN, HIV-1 OR HIV-1-O OR HIV-2 ANTIBODIES.,ACCESS HIV COMBO(ACCESS HIV COMBO)-THE ACCESS HIV COMBO ASSAY IS A PARAMAGNETIC-PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HIV-1 P24 ANTIGEN AND ANTIBODIES TO HIV-1 (GROUPS M AND O) AND HIV-2 IN HUMAN SERUM AND PLASMA (LI HEPARIN, K2-EDTA, K3-EDTA AND CPDA-1), USING THE ACCESS IMMUNOASSAY SYSTEMS. THE ACCESS HIV COMBO ASSAY IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF HIV-1 OR HIV-2 INFECTION AND AS SCREENING TEST FOR BLOOD AND PLASMA DONORS. THE ASSAY IS NOT INTENDED FOR THE TESTING OR SCREENING OF POOLED SPECIMENS. AN ACCESS HIV COMBO ASSAY RESULT DOES NOT DISTINGUISH BETWEEN THE DETECTION OF HIV-1 P24 ANTIGEN, HIV-1 OR HIV-1-O OR HIV-2 ANTIBODIES.,ACCESS HIV COMBO Q.C (ACCESS HIV COMBO Q.C)-THE ACCESS HIV COMBO ASSAY IS A PARAMAGNETIC-PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HIV-1 P24 ANTIGEN AND ANTIBODIES TO HIV-1 (GROUPS M AND O) AND HIV-2 IN HUMAN SERUM AND PLASMA (LI HEPARIN, K2-EDTA, K3-EDTA AND CPDA-1), USING THE ACCESS IMMUNOASSAY SYSTEMS. THE ACCESS HIV COMBO ASSAY IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF HIV-1 OR HIV-2 INFECTION AND AS SCREENING TEST FOR BLOOD AND PLASMA DONORS. THE ASSAY IS NOT INTENDED FOR THE TESTING OR SCREENING OF POOLED SPECIMENS. AN ACCESS HIV COMBO ASSAY RESULT DOES NOT DISTINGUISH BETWEEN THE DETECTION OF HIV-1 P24 ANTIGEN, HIV-1 OR HIV-1-O OR HIV-2 ANTIBODIES,ACCESS HCV AB PLUS QC(ACCESS HCV AB PLUS QC)-THE ACCESS HCV AB PLUS QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS HCV AB PLUS ASSAY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

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	MEROPENEM/MEROPENEM +EDTA)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS /OR FOR DETECTION OF RESISTANCE MECHANISMS.,PYZ(PYZ)-IDENTIFICATION OF MICROORGANISMS,ETEST POSACONAZOLE (ETEST POSACONAZOLE)-ETEST IS AN AGAR-BASED GRADIENT TECHNIQUE FOR QUANTITATIVE ANTIFUNGAL SUSCEPTIBILITY TESTING . THE SYSTEM COMPRISES A PREDEFINED CONCENTRATION GRADIENT OF A SPECIFIC ANTIFUNGAL AGENT WHICH IS USED TO DETERMINE MINIMUM INHIBITORY CONCENTRATION THAT INHIBITS THE GROWTH OF THE TEST ORGANISM UNDER DEFINED TESTING CONDITIONS.,NIT 1 + NIT 2(NIT 1 + NIT 2)-IDENTIFICATION OF MICROORGANISMS,ETEST PIPERACILLIN/TAZOBACTAM(ETEST PIPERACILLIN/TAZOBACTAM)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS /OR FOR DETECTION OF RESISTANCE MECHANISMS.,XYL(XYL)-IDENTIFICATION OF MICROORGANISMS, ETEST ITRACONAZOLE(ETEST ITRACONAZOLE)-ETEST IS AN AGAR-BASED GRADIENT TECHNIQUE FOR QUANTITATIVE ANTIFUNGAL SUSCEPTIBILITY TESTING . THE SYSTEM COMPRISES A PREDEFINED CONCENTRATION GRADIENT OF A SPECIFIC ANTIFUNGAL AGENT WHICH IS USED TO DETERMINE MINIMUM INHIBITORY CONCENTRATION THAT INHIBITS THE GROWTH OF THE TEST ORGANISM UNDER DEFINED TESTING CONDITIONS.,BCP(BCP)-IDENTIFICATION OF MICROORGANISMS,CEFTAZIDIME/CEFTAZIDIME + CLAVULANIC ACID(CEFTAZIDIME/CEFTAZIDIME + CLAVULANIC ACID) -ETEST IS A MANUAL QUANTITAIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS /OR FOR DETECTION OF RESISTANCE MECHANISMS.,ID 32 C(ID 32 C)-IDENTIFICATION SYSTEM FOR YEASTS,ETEST CEFOTAXIME/CEFOTAXIME+CLAVULANIC ACID(ETEST CEFOTAXIME/CEFOTAXIME+CLAVULANIC ACID)-ETEST IS A MANUAL QUANTITAIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS /OR FOR DETECTION OF RESISTANCE MECHANISMS.,API 20 E REAGENT KIT (API 20 E REAGENT KIT)-IDENTIFICATION OF MICROORGANISMS, ETEST MICAFUNGIN(ETEST MICAFUNGIN)-ETEST IS AN AGAR-BASED GRADIENT TECHNIQUE FOR QUANTITATIVE ANTIFUNGAL SUSCEPTIBILITY TESTING . THE SYSTEM COMPRISES A PREDEFINED CONCENTRATION GRADIENT OF A SPECIFIC ANTIFUNGAL AGENT WHICH IS USED TO DETERMINE MINIMUM INHIBITORY CONCENTRATION THAT INHIBITS THE GROWTH OF THE TEST ORGANISM UNDER DEFINED TESTING CONDITIONS.,API SUSPENSION MEDIUM(API SUSPENSION MEDIUM)-MEDIA FOR THE PREPARATION

	OF ORGANISM SUSPENSIONS,ETEST ANIDULAFUNGIN(ETEST ANIDULAFUNGIN)-ETEST IS AN AGAR-BASED GRADIENT TECHNIQUE FOR QUANTITATIVE ANTIFUNGAL SUSCEPTIBILITY TESTING . THE SYSTEM COMPRISES A PREDEFINED CONCENTRATION GRADIENT OF A SPECIFIC ANTIFUNGAL AGENT WHICH IS USED TO DETERMINE MINIMUM INHIBITORY CONCENTRATION THAT INHIBITS THE GROWTH OF THE TEST ORGANISM UNDER DEFINED TESTING CONDITIONS.,ID 32 GN(ID 32 GN)-AUTOMATIC IDENTIFICATION SYSTEM FOR GRAM-NEGATIVE RODS,ETEST CEFTOLOZANE/TAZOBACTAM(ETEST CEFTOLOZANE/TAZOBACTAM)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA,API OF MEDIUM(API OF MEDIUM)-GLUCOSE OXIDATION-FERMENTATION TEST,ETEST OFLOXACIN OF 0.002-32 G/ML(ETEST OFLOXACIN OF 0.002-32 G/ML)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA.,API 50 CHL MEDIUM(API 50 CHL MEDIUM)-FOR THE IDENTIFICATION OF THE GENUS LACTOBACILLUS AND RELATED GENERA,ETEST CEFOTAXIME (ETEST CEFOTAXIME)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA,VITEK MS-FA REAGENTS(VITEK MS-FA REAGENTS)-MASS SPECTROMETRY IS A METHOD FOR THE DETECTION AND IDENTIFICATION OF MOLECULES OF INTEREST BY MEASURING THEIR MONOISOTOPIC MASS. VITEK® MS-FA IS USED TO PRETREAT YEASTS TO FACILITATE THEIR IDENTIFICATION ACCORDING TO THE MALDI-TOF METHOD (MATRIX-ASSISTED LASER DESORPTION IONISATION-TIME OF FLIGHT).,ETEST CEFTRIAXONE(ETEST CEFTRIAXONE)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA.,API 20A(API 20A)-FOR THE BIOCHEMICAL IDENTIFICATION OF ANAEROBES.,ETEST AMOXICILLIN/CLAVULANIC ACID(ETEST AMOXICILLIN/CLAVULANIC ACID)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA,RAPID ID 32 STREP(RAPID ID 32 STREP)-FOR THE IDENTIFICATION OF STREPTOCOCCI AND ENTEROCOCCI, AND THOSE MOST COMMON RELATED ORGANISMS, IN 4 HOURS, WHICH USES 32 MINIATURIZED ENZYMATIC TESTS, AS WELL AS A SPECIFIC DATABASE. ,ETEST MUPIROCIN(ETEST MUPIROCIN)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA.,API 20NE(API 20NE)-FOR THE IDENTIFICATION OF NON-FASTIDIOUS, NON

	ENTERIC GRAM-NEGATIVE RODS COMBINING 8 CONVENTIONAL TESTS, 12 ASSIMILATION TESTS AND A DATABASE.,ETEST NITROFURANTOIN(ETEST NITROFURANTOIN)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA,API CANDIDA(API CANDIDA)-FOR THE IDENTIFICATION IN 18-24 HOURS OF YEASTS , NOTABLY THOSE MOST FREQUENTLY ENCOUNTERED IN CLINICAL MICROBIOLOGY.,ETEST TIGECYCLINE (ETEST TIGECYCLINE)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA.,API NH(API NH)-FOR THE IDENTIFICATION OF NEISSERIA, HAEMOPHILUS AND MORAXELLA CATARRHALIS ,ETEST SPECTINOMYCIN(ETEST SPECTINOMYCIN)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA.,RAPIDEC® CARBA NP (RAPIDEC® CARBA NP)-FOR THE RAPID DETECTION OF CARBAPENEMASEPRODUCING, ENTEROBACTERIACEAE, PSEUDOMONAS AERUGINOSA AND ACINETOBACTER BAUMANNII, USING BACTERIA CULTURED ON AN AGAR MEDIUM.,ETEST METRONIDAZOLE(ETEST METRONIDAZOLE)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA.,VITEK® MS MOULD KIT(VITEK® MS MOULD KIT)-THE VITEK® MS MOULD KIT PROVIDES THE REAGENTS AND CONSUMABLES NEEDED TO PROCESS SAMPLES BY PROTEIN EXTRACTION AND INACTIVATION FOR MOULD IDENTIFICATION FROM AGAR PLATES BY THE VITEK® MS SYSTEM,ETEST AMIKACIN(ETEST AMIKACIN)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA.,API CORYNE(API CORYNE)-FOR THE IDENTIFICATION OF CORYNEFORM BACTERIA IN 24 HOURS, WHICH USES MINIATURIZED TESTS AND A SPECIALLY ADAPTED DATABASE.,ETEST TRIMETHOPRIM /SULFAMETHOXAZOLE(ETEST TRIMETHOPRIM /SULFAMETHOXAZOLE)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA,ETEST POLYMYXIN B (ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST LEVOFLOXACIN(ETEST LEVOFLOXACIN)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA.,ETEST

	MEROPENEM (ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST TETRACYCLINE(ETEST TETRACYCLINE)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA,ETEST MOXIFLOXACIN (ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST GENTAMICIN(ETEST GENTAMICIN)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA,ETEST CASPOFUNGIN (ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIFUNGAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST ERYTHROMYCIN (ETEST ERYTHROMYCIN)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA.,ETEST FLUCONAZOLE (ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIFUNGAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST CEFTAZIDIME(ETEST CEFTAZIDIME)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA,ETEST BENZYLPENICILLIN (ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST CLINDAMYCIN(ETEST CLINDAMYCIN)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA.,ETEST IMIPENEM (ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST FOSFOMYCIN(ETEST FOSFOMYCIN)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA,ETEST CIPROFLOXACIN (ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST CEFOXITIN(ETEST

	CEFOXITIN)-ETEST IS A QUANTITATIVE TECHNIQUE FOR DETERMINING THE ANTIMICROBIAL SUSCEPTIBILITY OF GRAM NEGATIVE AND GRAM POSITIVE AEROBIC BACTERIA,ETEST TEICOPLANIN(ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST SPECTINOMYCIN(ETEST SPECTINOMYCIN)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,ETEST AMPHOTERICIN B(ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIFUNGAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST DAPTOMYCIN (ETEST DAPTOMYCIN)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,ETEST VANCOMYCIN(ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST FLUCYTOSINE (ETEST FLUCYTOSINE)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,ETEST DORIPENEM (ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST CEFIXIME(ETEST CEFIXIME)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,TDA(TDA)-IDENTIFICATION OF MICROORGANISMS, ETEST FLUCONAZOLE(ETEST FLUCONAZOLE)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,VP 1 + VP 2(VP 1 + VP 2)-IDENTIFICATION OF MICROORGANISMS,ETEST TETRACYCLINE(ETEST TETRACYCLINE)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,API 50 CH(API 50 CH)-FOR THE STUDY OF THE CARBOHYDRATE METABOLISM OF MICROORGANISMS,ETEST LEVOFLOXACIN(ETEST LEVOFLOXACIN)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF

	ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,API 50 CHB/E MEDIUM (API 50 CHB/E MEDIUM)-INTENDED FOR THE IDENTIFICATION OF BACILLUS AND RELATED GENERA, AS WELL AS GRAM-NEGATIVE RODS BELONGING TO THE ENTEROBACTERIACEAE AND VIBRIONACEAE FAMILIES.,ETEST ITRACONAZOLE(ETEST ITRACONAZOLE)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,API M MEDIUM(API M MEDIUM)-MOTILITY MEDIUM, ETEST ERYTHROMYCIN(ETEST ERYTHROMYCIN)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,MCFARLAND STANDARDS (MCFARLAND STANDARDS)-STANDARD,ETEST VORICONAZOLE (ETEST VORICONAZOLE)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,VP A + VP B(VP A + VP B)-IDENTIFICATION OF MICROORGANISMS,ETEST CLARITHROMYCIN (ETEST CLARITHROMYCIN)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,API CAMPY(API CAMPY)-FOR THE IDENTIFICATION OF CAMPYLOBACTER, WHICH USES MINIATURIZED TESTS, AS WELL AS A SPECIALLY ADAPTED DATABASE.,ETEST LINEZOLID(ETEST LINEZOLID)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,EHR(EHR)-IDENTIFICATION OF MICROORGANISMS,ETEST MOXIFLOXACIN(ETEST MOXIFLOXACIN)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,ID 32 STAPH (ID 32 STAPH)-IDENTIFICATION SYSTEM FOR STAPHYLOCOCCI,ETEST AZITHROMYCIN(ETEST AZITHROMYCIN)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,ATB FUNGUS 3(ATB FUNGUS 3)-ANTIFUNGAL SUSCEPTIBILITY TEST FOR YEASTS,ETEST TRIMETHOPRIM SULFAMETHOXAZOLE(ETEST TRIMETHOPRIM SULFAMETHOXAZOLE)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF

	RESISTANCE MECHANISMS.,FB(FB)-IDENTIFICATION OF MICROORGANISMS,ETEST AMOXICILLIN/CLAVULANIC ACID(ETEST AMOXICILLIN/CLAVULANIC ACID)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,API 20E(API 20E)-FOR ENTEROBACTERIACEAE AND OTHER NON-FASTIDIOUS, GRAM NEGATIVE RODS WHICH USES 21 MINIATURIZED BIOCHEMICAL TESTS AND A DATABASE.,ETEST TEICOPLANIN(ETEST TEICOPLANIN)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS.,VITEK MS-CHCA MATRIX(VITEK MS-CHCA MATRIX)-THE VITEK® MS-CHCA MATRIX IS USED WITH THE VITEK® MS SYSTEM TO ENABLE THE IDENTIFICATION OF MICROORGANISMS. THE MATRIX ABSORBS ENERGY FROM THE VITEK® MS LASER AND TRANSFERS IT TO THE MICROORGANISMS TO ENABLE IONIZATION.,API STAPH(API STAPH)-FOR THE IDENTIFICATION OF THE GENERA STAPHYLOCOCCUS, MICROCOCCUS AND KOCURIA, WHICH USES MINIATURIZED BIOCHEMICAL TESTS AND A SPECIALLY ADAPTED DATABASE.,RAPID ID 32A(RAPID ID 32A)-FOR THE IDENTIFICATION OF ANAEROBES IN 4 HOURS, WHICH USES 29 MINIATURIZED ENZYMATIC TESTS AND A DATABASE. ,ZYM B(ZYM B)-IDENTIFICATION OF MICROORGANISMS,ZYM A(ZYM A)-IDENTIFICATION OF MICROORGANISMS,ETEST DAPTOMYCIN (ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST COLISTIN (ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST VORICONAZOLE (ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIFUNGAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,ETEST AZITHROMYCIN (ETEST)-ETEST IS A MANUAL QUANTITATIVE TECHNIQUE FOR DETERMINING THE MIC OF ANTIMICROBIAL AGENTS AGAINST MICROORGANISMS AND/OR FOR DETECTION OF RESISTANCE MECHANISMS,VITEK® MS MYCOBACTERIUM/NOCARDIA KIT(VITEK® MS MYCOBACTERIUM/NOCARDIA KIT)-THE VITEK® MS MYCOBACTERIUM/NOCARDIA KIT PROVIDES THE REAGENTS AND CONSUMABLES NEEDED TO PROCESS SAMPLES BY PROTEIN EXTRACTION AND INACTIVATION FOR MYCOBACTERIUM AND NOCARDIA IDENTIFICATION USING THE VITEK® MS SYSTEM,ID 32 E(ID 32 E)-SYSTEM FOR THE IDENTIFICATION OF ENTEROBACTERIACEAE

		AND OTHER NON-FASTIDIOUS GRAM-NEGATIVE RODS,RAPID ID 32 E (RAPID ID 32 E)-RAPID ID 32 E IS A STANDARDIZED SYSTEM FOR THE IDENTIFICATION OF ENTEROBACTERIACEAE IN 4 HOURS, USING 32 MINIATURIZED ENZYMATIC TESTS, AS WELL AS A SPECIFIC DATABASE. THE COMPLETE LIST OF THOSE ORGANISMS THAT IT IS POSSIBLE TO IDENTIFY WITH THIS SYSTEM CAN BE FOUND IN THE IDENTIFICATION TABLE AT THE END OF THIS PACKAGE INSERT. READING AND INTERPRETATION ARE CARRIED OUT AUTOMATICALLY OR MANUALLY. ,API 20 STREP(API 20 STREP)-FOR STREPTOCOCCACEAE AND RELATED ORGANISMS,API 20C AUX(API 20C AUX)-FOR THE PRECISE IDENTIFICATION OF THE MOST FREQUENTLY ENCOUNTERED YEASTS. ,API LISTERIA(API LISTERIA)-FOR THE IDENTIFICATION OF LISTERIA
289	IMP/IVD/2019/000304	1.License Holder Name: PAMMVI EXPORT PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NANO-CHECK TM RAPID NICOTINE TEST(NANO-CHECK TM)-TO DETECT NICOTINE IN URINE SAMPLES

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

290	IMP/IVD/2019/000305	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLUCODOT BLOOD GLUCOSE METER(GLUCO DOT)-THE GLUCO DOT BLOOD GLUCOSE METER IS USED WITH THE GLUCO DOT BLOOD GLUCOSE TEST STRIPS FOR QUANTITATIVELY MEASURING GLUCOSE (SUGAR) IN WHOLE BLOOD OBTAINED FROM THE FINGERTIP, PALM AND FOREARM., GLUCO DOT BLOOD GLUCOSE TEST STRIPS(GLUCO DOT)-THE GLUCO DOT BLOOD GLUCOSE TEST STRIPS ARE USED WITH THE GLUCO DOT BLOOD GLUCOSE METER FOR QUANTITATIVELY MEASURING GLUCOSE (SUGAR) IN WHOLE BLOOD OBTAINED FROM THE FINGERTIP, PALM AND FOREARM.,GLUCO DOT CONTROL SOLUTION (HIGH)(GLUCO DOT)-THE CONTROL SOLUTION IS A DESIRED AQUEOUS GLUCOSE SOLUTION WITH SMALL AMOUNTS OF NON-REACTIVE INGREDIENTS AND FOOD COLORING FOR VERIFYING THE ACCURACY OF THE ENTIRE BLOOD GLUCOSE MONITORING SYSTEM. THE CONTROL SOLUTION TEST EXAMINES THE PERFORMANCE OF THE GLUCOSE METER, TEST STRIP, AND YOUR OPERATING TECHNIQUES.,GLUCO DOT CONTROL SOLUTION (LOW)(GLUCO DOT)-THE CONTROL SOLUTION IS A DESIRED AQUEOUS GLUCOSE SOLUTION WITH SMALL AMOUNTS OF NON-REACTIVE INGREDIENTS AND FOOD COLORING FOR VERIFYING THE ACCURACY OF THE ENTIRE BLOOD GLUCOSE MONITORING SYSTEM. THE CONTROL SOLUTION TEST EXAMINES THE PERFORMANCE OF THE GLUCOSE METER, TEST STRIP, AND YOUR OPERATING TECHNIQUES.,GLUCO DOT CONTROL SOLUTION (NORMAL)(GLUCO DOT)-THE CONTROL SOLUTION IS A DESIRED AQUEOUS GLUCOSE SOLUTION WITH SMALL AMOUNTS OF NON-REACTIVE INGREDIENTS AND FOOD COLORING FOR VERIFYING THE ACCURACY OF THE ENTIRE BLOOD GLUCOSE MONITORING SYSTEM. THE CONTROL SOLUTION TEST EXAMINES THE PERFORMANCE OF THE GLUCOSE METER, TEST STRIP, AND YOUR OPERATING TECHNIQUES.,GLUCO DOT BLOOD GLUCOSE MONITORING SYSTEM(GLUCODOT)-MEASUREMENT OF BLOOD GLUCOSE VALUE
291	IMP/IVD/2019/000306	1.License Holder Name: ARKRAY HEALTHCARE PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIP(GLUCOCARD 01 SENSOR)-FOR QUANTITATIVELY MEASURING THE GLUCOSE LEVEL IN FRESH CAPILLARY WHOLE BLOOD

292	IMP/IVD/2019/000307	1.License Holder Name: ATHENESE-DX PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:UNCUT SHEET FOR COVID-19 IGG/IGM RAPID TEST -UNCUT SHEET FOR COVID-19 IGG/IGM RAPID TEST IS USED TO MANUFACTURE COVID-19 IGG/IGM RAPID TEST. THIS TEST IS INTENDED TO DETECT THE SARS-COV-2 IGG/IGM ANTIBODIES IN HUMAN SERUM, PLASMA OR WHOLE BLOOD BY COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY ASSAY. THE TEST IS USED AS AN AID FOR THE DETECTION OF SARS-COV-2 INFECTION. , HSV–2 IGG/IGM RAPID TEST(ONSITE)-THE HSV-2 IGG/IGM RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION AND DIFFERENTIATION OF ANTIBODIES (IGG AND IGM) TO HERPES SIMPLEX VIRUS 2 (HSV-2) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH HSV-2.,COVID-19 IGG/IGM RAPID TEST(ONSITE)-THE ONSITE COVID-19 IGG/IGM RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE DETECTION OF ANTI-SARS-COV-2 IGG AND IGM ANTIBODIES IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY HEALTHCARE PROFESSIONALS AS AN AID IN THE DIAGNOSIS OF INFECTION WITH SARS-COV-2 CORONAVIRUS, WHICH CAUSES COVID-19 DISEASE.,RUBELLA IGG/IGM RAPID TEST(ONSITE)-THE RUBELLA IGG/IGM RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETECTION AND DIFFERENTIATION OF ANTIBODIES (IGG AND IGM) TO RUBELLA VIRUS IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH RUBELLA VIRUS.,TYPHOID IGG/IGM COMBO RAPID TEST (ONSITE)-THE TYPHOID IGG/IGM COMBO RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE DETECTION AND DIFFERENTIATION OF ANTI-SALMONELLA TYPHI (S. TYPHI) AND PARATYPHI IGG AND IGM IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH S. TYPHI AND PARATYPHI.,LEISHMANIA AB RAPID TEST(ONSITE)-THE LEISHMANIA AB RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES INCLUDING IGG AND IGM TO THE SUBSPECIES OF LEISHMANIA DONOVANI (L. DONOVANI), THE VISCERAL LEISHMANIASIS CAUSATIVE PROTOZOANS, IN HUMAN SERUM OR PLASMA. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO

	AID IN THE DIAGNOSIS OF INFECTION WITH VISCERAL LEISHMANIASIS,HEV IGM RAPID TEST(ONSITE)-THE HEV IGM RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO HEPATITIS E VIRUS (HEV) IN HUMAN SERUM OR PLASMA. IT IS INTENDED TO BE USED AS A SCREENING TEST BY PROFESSIONALS AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH HEV.,TSH ELISA(RECOMBILISA)-"THE TSH ELISA IS A SOLID PHASE ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE LEVELS OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM. IT IS INTENDED TO BE USED BY PROFESSIONALS AS AN AID IN THE DIAGNOSIS OF THYROID DYSFUNCTION.",LEPTOSPIRA IGM ELISA(RECOMBILISA)-THE LEPTOSPIRA IGM ELISA IS A SOLID PHASE ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF IGM ANTI-LEPTOSPIRA INTERROGANS (L. INTERROGANS) IN HUMAN SERUM OR PLASMA. IT IS INTENDED TO BE USED BY PROFESSIONALS AS AN AID IN THE DIAGNOSIS OF ACUTE INFECTION WITH L. INTERROGANS. ANY INTERPRETATION OR USE OF THIS TEST RESULT MUST ALSO RELY ON OTHER CLINICAL FINDINGS AS WELL AS ON THE PROFESSIONAL JUDGMENT OF HEALTH CARE PROVIDERS. ALTERNATIVE TEST METHOD(S) MAY BE CONSIDERED TO CONFIRM THE RESULT OBTAINED BY THIS TEST.,LEISHMANIA IGG/IGM COMBO RAPID TEST(ONSITE)-"THE LEISHMANIA IGG/IGM COMBO RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF IGG AND IGM TO THE SUBSPECIES OF LEISHMANIA DONOVANI (L. DONOVANI), THE VISCERAL LEISHMANIASIS CAUSATIVE PROTOZOANS, IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH VISCERAL LEISHMANIASIS.,TROPONIN I COMBO RAPID TEST (ONSITE)-THE TROPONIN I COMBO RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF CARDIAC TROPONIN I (CTNI) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. ,TORCH PANEL RAPID TEST(ONSITE)-THE TORCH PANEL RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION AND DIFFERENTIATION OF ANTIBODIES (IGG AND IGM) TO TOXOPLASMA GONDII (T. GONDII), RUBELLA VIRUS, CYTOMEGALOVIRUS (CMV), HERPES SIMPLEX VIRUS 1 (HSV-1), AND HERPES SIMPLEX VIRUS 2 (HSV-2) IN HUMAN SERUM, PLASMA, OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE

	DIAGNOSIS OF INFECTION WITH T. GONDII, RUBELLA VIRUS, CMV, HSV-1 AND HSV-2.,TOTAL T3 ELISA(RECOMBILISA)-THE TOTAL T3 ELISA IS A COMPETITIVE, SOLID-PHASE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE (T3) LEVELS IN HUMAN SERUM. IT IS INTENDED TO BE USED BY PROFESSIONALS AS AN AID IN THE DIAGNOSIS OF THYROID DYSFUNCTION.,TOXO IGG/IGM COMBO RAPID TEST(ONSITE)-THE TOXO IGG/IGM COMBO RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF IGM AND IGG ANTIBODIES TO TOXOPLASMA GONDII (T. GONDII) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH T. GONDII.,H. PYLORI AB COMBO RAPID TEST(ONSITE)-THE H. PYLORI AB COMBO RAPID TEST IS A SANDWICH LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES (IGG, IGM AND IGA) AGAINST HELICOBACTER PYLORI (H. PYLORI) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH H. PYLORI.,HAV IGM ELISA(RECOMBILISA)-THE HAV IGM ELISA IS A SOLID-PHASE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF IGM TO HEPATITIS A VIRUS IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR PROFESSIONAL USE ONLY AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HAV.,HAV IGG/IGM RAPID TEST(ONSITE)-THE HAV IGG/IGM RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION AND DIFFERENTIATION OF ANTIBODIES (IGG AND IGM) TO HEPATITIS A VIRUS (HAV) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED AS A SCREENING TEST BY PROFESSIONALS AND PROVIDE A PRELIMINARY RESULT TO AID IN THE DIAGNOSIS OF ACTIVE AND/OR PAST HAV INFECTION.,DENGUE AG ELISA(RECOMBILISA)-THE DENGUE AG ELISA IS A SOLID PHASE ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN (DEN1, 2, 3, 4) IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR PROFESSIONAL USE ONLY AS AN AID IN THE DIAGNOSIS OF AN ACUTE INFECTION WITH DENGUE VIRUSES.,FILARIASIS IGG/IGM COMBO RAPID TEST(ONSITE)-THE FILARIASIS IGG/IGM COMBO RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF IGG AND IGM ANTIBODIES TO LYMPHATIC FILARIAL PARASITES (W.BANCROFTI AND B. MALAYI) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE

	USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH LYMPHATIC FILARIAL PARASITES.,RF RAPID TEST(ONSITE)-THE RF RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ALL SUBTYPES OF RHEUMATOID FACTOR (RF) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD AT A SENSITIVITY OF 8 IU/ML. IT IS INTENDED TO BE USED AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS AND SJÖGREN'S SYNDROME,TYPHOID IGG/IGM RAPID TEST(ONSITE)-THE TYPHOID IGG/IGM RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE QUALITATIVE DETECTION AND DIFFERENTIATION OF ANTI-SALMONELLA TYPHI (S. TYPHI) AND PARATYPHI IGG AND IGM IN HUMAN SERUM OR PLASMA. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH S. TYPHI AND PARATYPHI. ,DENGUE AG RAPID TEST(ONSITE)-"THE DENGUE AG RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN (DEN1, 2, 3, 4) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH DENGUE VIRUS.",DENGUE IGG/IGM COMBO RAPID TEST(ONSITE) -"THE DENGUE IGG/IGM COMBO RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF ANTI–DENGUE VIRUS (DEN1, 2, 3 AND 4) IGG AND IGM IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH DENGUE VIRUSES." ,CHIKUNGUNYA IGM COMBO RAPID TEST(ONSITE)-THE CHIKUNGUNYA IGM COMBO RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTI-CHIKUNGUNYA (CHIK) VIRUS IGM IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH CHIKUNGUNYA VIRUS. DUO DENGUE AG- IGG/IGM RAPID TEST(ONSITE)-THE DUO DENGUE AG-IGG/IGM RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF IGG ANTI-DENGUE VIRUS, IGM ANTI-DENGUE VIRUS AND DENGUE NS1 ANTIGEN (DEN1, 2, 3, 4) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A

	SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH DENGUE VIRUS., LEPTOSPIRA IGG/IGM COMBO RAPID TEST(ONSITE)-THE LEPTOSPIRA IGG/IGM COMBO RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF IGG AND IGM ANTIBODIES TO LEPTOSPIRA INTERROGANS (L. INTERROGANS) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED AS A SCREENING TEST BY PROFESSIONALS, AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH L. INTERROGANS.,TOTAL T4 ELISA (RECOMBILISA)-THE TOTAL T4 ELISA IS A COMPETITIVE SOLID-PHASE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE (TT4) LEVELS IN HUMAN SERUM OR PLASMA (SODIUM CITRATE, EDTA). IT IS INTENDED TO BE USED BY PROFESSIONALS AS AN AID IN THE DIAGNOSIS OF THYROID DYSFUNCTION.,FOB – HI RAPID TEST (ONSITE)-THE FOB-HI RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF FECAL OCCULT BLOOD IN HUMAN FECAL SPECIMENS IN LABORATORIES OR PHYSICIAN OFFICES. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DETECTION OF BLEEDING CAUSED BY A NUMBER OF GASTROINTESTINAL DISORDERS, E.G. DIVERTICULITIS, COLITIS, POLYPS, AND COLORECTAL CANCER.,CMV IGG/IGM RAPID TEST(ONSITE)-THE CMV IGG/IGM RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF IGM AND IGG ANTIBODIES TO CYTOMEGALOVIRUS (CMV) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH CMV.,HAV IGM RAPID TEST (ONSITE)-THE HAV IGM RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO HEPATITIS A VIRUS (HAV) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH HAV.,TOXO IGG/IGM RAPID TEST(ONSITE)-THE TOXO IGG/IGM RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF IGG AND IGM ANTIBODIES TO TOXOPLASMA GONDII (T. GONDII) IN HUMAN SERUM OR PLASMA. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF

	INFECTION WITH T. GONDII.,HEV IGM ELISA(RECOMBILISA)-THE HEV IGM ELISA IS A SOLID-PHASE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTI-HEPATITIS E VIRUS IGM IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR PROFESSIONAL USE ONLY AND TO BE USED AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HEV.,HSV-1 IGG/IGM RAPID TEST (ONSITE)-"THE HSV-1 IGG/IGM RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION AND DIFFERENTIATION OF IGG AND IGM ANTIBODIES TO HERPES SIMPLEX VIRUS 1 (HSV-1) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH HSV-1.",H. PYLORI AG RAPID TEST(ONSITE)-THE H. PYLORI AG RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF H. PYLORI ANTIGEN IN HUMAN FECAL SPECIMEN. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH H. PYLORI ,S. TYPHI/PARATYPHI AG RAPID TEST(ONSITE)-THE S. TYPHI/PARATYPHI AG RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF SALMONELLA TYPHI (S. TYPHI) AND SALMONELLA PARATYPHI (S.PARATYPHI) ANTIGENS IN HUMAN FECAL SPECIMEN, SERUM, PLASMA, WHOLE BLOOD OR BLOOD CULTURE SPECIMEN. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF INFECTION WITH S. TYPHI AND/OR S. PARATYPHI. ,PSA SEMI-QUANTITATIVE RAPID TEST(ONSITE)-THE PSA SEMI-QUANTITATIVE RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETECTION OF PROSTATE SPECIFIC ANTIGEN (PSA) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA AT A CUT-OFF LEVEL OF 4 NG/ML. IT IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND PROVIDES A PRELIMINARY TEST RESULT TO AID IN THE DIAGNOSIS OF PROSTATE CANCER. ,FREE T3 ELISA (RECOMBILISA)-THE FREE T3 ELISA IS COMPETITIVE SOLID-PHASE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) LEVELS IN HUMAN SERUM. IT IS INTENDED TO BE USED BY PROFESSIONALS AS AN AID IN THE DIAGNOSIS OF THYROID DYSFUNCTION.,FREE T4 ELISA (RECOMBILISA)-THE FREE T4 ELISA IS A COMPETITIVE SOLID-PHASE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM. IT IS INTENDED FOR PROFESSIONAL USE ONLY AS AN AID IN THE

	DIAGNOSIS OF THYROID DYSFUNCTION.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

293	IMP/IVD/2019/000308	1.License Holder Name: MERIL DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:25OH VITAMIN D(--)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF 25OH VITAMIN D CONCENTRATION IN HUMAN SERUM OR PLASMA.,ESTRADIOL ELISA(--)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF 17B-ESTRADIOL CONCENTRATION IN HUMAN SERUM OR PLASMA.,ANTI CARDIOLIPIN SCREEN(--)-ANTI CARDIOLIPIN SCREEN IS AN INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGG OR IGM CLASS AUTO-ANTIBODIES DIRECTED AGAINST CARDIOLIPIN- BETA 2-GLYCOPROTEIN COMPLEX IN HUMAN SERUM OR PLASMA. ,ANTI PHOSPHOLIPID SCREEN(--)-ANTI PHOSPHOLIPID SCREEN IS AN INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTO-ANTIBODIES DIRECTED AGAINST BETA2-GLYCOPROTEIN MEDIATED ANIONIC PHOSPHOLIPIDS IN HUMAN SERUM OR PLASMA, INCLUDING CARDIOLIPIN, PHOSPHATIDYL SERINE, PHOSPHATIDYL INOSITOL, PHOSPHATIDIC ACID, PHOSPHATIDYL CHOLINE, LYSO-PHOSPHATIDYL CHOLINE, PHOSPHATIDYL ETHANOLAMINE. , PROLACTIN ELISA (BULK)(--)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF PROLACTIN CONCENTRATION IN HUMAN SERUM.,IGE TOTAL ELISA(--)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF IGE CONCENTRATION IN HUMAN SERUM OR PLASMA.,ANTI CARDIOLIPIN IGG(--)-ANTI CARDIOLIPIN IGG KIT IS AN INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTO-ANTIBODIES DIRECTED AGAINST CARDIOLIPINA-BETA 2-GLYCOPROTEIN COMPLEX IN HUMAN SERUM OR PLASMA. ,PROGESTERONE ELISA(--)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA.,ANA SCREEN(--)-ANA SCREEN KIT IS AN INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) DESIGNED FOR SEMIQUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED AGAINST SM (SMITH), RNP/SM, SCL-70, SS-A (RO) (52KDA E 60KDA), SS-B (LA), JO1, U1-SMRNP, CENP-B, DSDNA, AND HISTONES IN HUMAN SERUM OR PLASMA.,B -HCG ELISA(--)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF BETA-HCG CONCENTRATION IN HUMAN SERUM OR PLASMA.,ANTI CARDIOLIPIN IGM(--)-ANTI CARDIOLIPIN IGM KIT IS AN INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGM

	CLASS AUTO-ANTIBODIES DIRECTED AGAINST CARDIOLIPINA-BETA 2-GLYCOPROTEIN COMPLEX IN HUMAN SERUM OR PLASMA. , TESTOSTERONE ELISA(--)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA.,C-PEPTIDE ELISA(--)-C-PEPTIDE KIT IS A DIRECT SOLID PHASE ENZYME IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM OR PLASMA.,LH ELISA (BULK)(--)-LH ELISA KIT IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THE LUTEINIZING HORMONE (LH) CONCENTRATION IN HUMAN SERUM OR PLASMA.,FSH ELISA (BULK) (--)-FSH ELISA KIT IS A DIRECT SOLID PHASE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN SERUM OR PLASMA.,FT4 ELISA (BULK)(--) -IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) CONCENTRATION IN HUMAN SERUM OR PLASMA.,ANTI CCP(--)-ANTI CCP KIT IS AN IMMUNOENZYMATIC TEST (ELISA), INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES DIRECTED AGAINST CYCLIC CITRULLINATED PEPTIDES, PRESENT IN HUMAN SERUM OR PLASMA.,FT3 ELISA (BULK)(--)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) CONCENTRATION IN HUMAN SERUM AND PLASMA.,FREE TESTOSTERONE ELISA(--)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA.

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294	IMP/IVD/2019/000309	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHEKSTIX POSITIVE AND NEGATIVE CONTROL STRIPS COMBO PACK(CHEKSTIX POSITIVE AND NEGATIVE CONTROL STRIPS COMBO PACK)-URINALYSIS STRIPS-REGENTS STRIPS INTENDED TO PROVIDE DEFINED RESULTS (POSITIVE AND NEGATIVE) FOR GLUCOSE, BILIRUBIN, KETONE (ACETOACETIC ACID), SPECIFIC GRAVITY, BLOOD, PH, PROTEIN, UROBILINOGEN, NITRITE AND LEUKOCYTES,CHEKSTIX POSITIVE CONTROL STRIPS(CHEKSTIX POSITIVE CONTROL STRIPS)-THE QUALITY CONTROL SOLUTION INTENDED TO BE USED FOR QUALITY CONTROL PURPOSES IN THE URINALYSIS IN VITRO DIAGNOSTIC PROCEDURES USING CHEKSTIX URINALYSIS STRIPS,CLINITEK ATLAS POSITIVE CONTROL STRIPS(CLINITEK ATLAS POSITIVE CONTROL STRIPS)-THESE ARE INTENDED TO PRODUCE A POSITIVE CONTROL SOLUTION BY DISSOLVING THE ANALYTE AREAS FOR THE QUALITY CONTROL PURPOSES IN CLINITEK ATLAS IN VITRO DIAGNOSTIC PROCEDURES,CLINITEK ATLAS NEGATIVE CONTROL STRIPS (CLINITEK ATLAS NEGATIVE CONTROL STRIPS)-THESE ARE INTENDED TO PRODUCE A NEGATIVE CONTROL SOLUTION BY DISSOLVING THE ANALYTE AREAS FOR THE QUALITY CONTROL PURPOSES IN CLINITEK ATLAS IN VITRO DIAGNOSTIC PROCEDURES, CLINITEK NOVUS 10 URINALYSIS CASSETTE(CLINITEK NOVUS 10 URINALYSIS CASSETTE)-THE CLINITEK NOVUS 10 URINALYSIS CASSETTE IS FOR IN-VITRO DIAGNOSTICS USE INTENDED FOR THE MEASUREMENT OF BILIRUBIN, BLOOD (OCCULT), GLUCOSE, KETONE (ACETOACETIC ACID), LEUKOCYTES, NITRITE, PH, PROTEIN, AND UROBILINOGEN IN URINE,CLINITEK NOVUS PRO 12 URINALYSIS CASSETTE(CLINITEK NOVUS PRO 12 URINALYSIS CASSETTE)-THE CLINITEK NOVUS PRO 12 URINALYSIS CASSETTE IS FOR IN-VITRO DIAGNOSTICS USE INTENDED FOR THE MEASUREMENT OF ALBUMIN, BILIRUBIN, BLOOD (OCCULT), CREATININE, GLUCOSE, KETONE (ACETOACETIC ACID), LEUKOCYTES, NITRITE, PH, PROTEIN, UROBILINOGEN, ALBUMIN-TO-CREATININE RATIO, AND PROTEIN-TO-CREATININE RATIO IN URINE.,DCA SYSTEMS MICROALBUMIN / CREATININE KIT(DCA SYSTEMS MICROALBUMIN / CREATININE KIT)-THE DCA MICRO ALBUMIN/CREATININE ASSAY IS INTENDED FOR MEASURING LOW CONCENTRATIONS OF ALBUMIN, CREATININE, AND THE ALBUMIN/CREATININE RATIO IN URINE,DCA SYSTEMS HEMOGLOBIN A1C REAGENT KIT(DCA SYSTEMS HEMOGLOBIN A1C REAGENT KIT)-THIS ASSAY IS INTENDED FOR MEASURING THE PERCENT CONCENTRATION OF HEMOGLOBIN A1C IN BLOOD,CLINITEK ATLAS 10 REAGENT PAK(CLINITEK ATLAS 10 REAGENT PAK)-CLINITEK ATLAS 10 REAGENT PAK DETERMINES THE PH AND COLOR

		OF URINE AND TESTS FOR PROTEIN, OCCULT BLOOD, LEUKOCYTES, NITRITE, GLUCOSE, KETONE (ACETOACETIC ACID), BILIRUBIN, AND UROBILINOGEN.,CLINITEK ATLAS PRO 12 REAGENT PAK(CLINITEK ATLAS PRO 12 REAGENT PAK)-CLINITEK ATLAS PRO 12 REAGENT PAK DETERMINES THE PH AND COLOR OF URINE AND TESTS FOR PROTEIN (USING THE PROTEIN–HIGH AND PROTEIN–LOW PADS), CREATININE, OCCULT BLOOD, LEUKOCYTES, NITRITE, GLUCOSE, KETONE (ACETO ACETIC ACID), BILIRUBIN, AND UROBILINOGEN
295	IMP/IVD/2019/000311	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREALBUMIN CALIBRATOR(PREALBUMIN CALIBRATOR)-THE PREALBUMIN CALIBRATOR IS A LIQUID HUMAN SERUM BASED MATRIX CALIBRATOR INTENDED TO BE USED WITH THE PREALBUMIN REAGENT OSR6175 FOR THE QUANTITATIVE DETERMINATION OF PREALBUMIN ON BECKMAN COULTER ANALYSERS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

296	IMP/IVD/2019/000312	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRA ONE STEP TRAMADOL TEST DEVICE (URINE)(TRA ONE STEP TRAMADOL TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 100NG/ML TRAMADOL IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,COT 100 ONE STEP COTININE TEST DEVICE (URINE)(COT 100 ONE STEP COTININE TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 100 NG/ML COTININE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,PCP ONE STEP PHENCYCLIDINE TEST DEVICE (URINE)(PCP ONE STEP PHENCYCLIDINE TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 25 NG/ML PHENCYCLIDINE METABOLITE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,MULTI-DRUG MULTI-LINE TWIST SCREEN TEST DEVICE (ORAL FLUID)(MULTI-DRUG MULTI-LINE TWIST SCREEN TEST DEVICE (ORAL FLUID))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF MULTIPLE DRUGS AND METABOLITES IN HUMAN ORAL FLUIDS. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,BAR ONE STEP BARBITURATES TEST DEVICE (URINE)(BAR ONE STEP BARBITURATES TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 300 NG/ML BARBITURATES IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,MULTI-DRUG ONE STEP MULTI-LINE SCREEN TEST PANEL WITH INTEGRATED E-Z SPLIT KEY CUP (URINE)(MULTI-DRUG ONE STEP MULTI-LINE SCREEN TEST PANEL WITH INTEGRATED E-Z SPLIT KEY CUP (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF MULTI-DRUG IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,AMP ONE STEP AMPHETAMINE DEVICE (URINE)(AMP ONE STEP AMPHETAMINE DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 1000 NG/ML AMPHETAMINES IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY,KET ONE STEP KETAMINE TEST DEVICE (URINE)(KET ONE STEP KETAMINE TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 1000 NG/ML KETAMINE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,COC ONE STEP COCAINE TEST DEVICE (URINE)(COC ONE STEP COCAINE TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE

	DETECTION OF 300NG/ML COCAINE METABOLITE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,MTD ONE STEP METHADONE TEST DEVICE (URINE)(MTD ONE STEP METHADONE TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 300 NG/ML METHADONE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,THC ONE STEP MARIJUANA TEST DEVICE (URINE)(THC ONE STEP MARIJUANA TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 50NG/ML MARIJUANA IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,FTY ONE STEP FENTANYL TEST DEVICE (URINE)(FTY ONE STEP FENTANYL TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 20 NG/ML NORFENTANYL IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY,OPI ONE STEP OPIATE TEST DEVICE (URINE)(OPI ONE STEP OPIATE TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 2000 NG/ML MORPHINE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,BZO ONE STEP BENZODIAZEPINES TEST DEVICE (URINE)(BZO ONE STEP BENZODIAZEPINES TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 300NG/ML BENZODIAZEPINES IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,OXY ONE STEP OXYCODONE TEST STRIP (URINE)(OXY ONE STEP OXYCODONE TEST STRIP (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 100 NG/ML OXYCODONE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,MQL ONE STEP METHAQUALONE TEST STRIP (URINE)(MQL ONE STEP METHAQUALONE TEST STRIP (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 300 NG/ML METHAQUALONE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,MET ONE STEP METHAMPHETAMINE TEST DEVICE (URINE)(MET ONE STEP METHAMPHETAMINE TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 1000 NG/ML METHAMPHETAMINE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,MOP ONE STEP MORPHINE TEST DEVICE (URINE)(MOP ONE STEP MORPHINE TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 300 NG/ML MORPHINE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,MULTI-DRUG ONE STEP SCREEN TEST PANEL (URINE)(MULTI-DRUG ONE STEP SCREEN TEST PANEL (URINE))-A LATERAL FLOW

	CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION MUTI-DRUG IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,BUP ONE STEP BUPRENORPHINE TEST DEVICE ((URINE)(BUP ONE STEP BUPRENORPHINE TEST DEVICE ((URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 10NG/ML BUPRENORPHINE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,MULTI-DRUG ONE STEP MULTI-LINE SCREEN TEST DEVICE (URINE)(MULTI-DRUG ONE STEP MULTI-LINE SCREEN TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION MUTI-DRUG IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,PPX ONE STEP PROPOXYPHENE TEST DEVICE (URINE)(PPX ONE STEP PROPOXYPHENE TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 300 NG/ML PROPOXYPHENE OR NORPROPOXYPHENE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,MDMA ONE STEP ECSTASY TEST DEVICE (URINE)(MDMA ONE STEP ECSTASY TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 500 NG/ML METHYLENEDIOXYMETHAMPHETAMINE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,TCA ONE STEP TRICYCLIC ANTIDEPRESSANTS TEST STRIP (URINE)(TCA ONE STEP TRICYCLIC ANTIDEPRESSANTS TEST STRIP (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 1000NG/ML NORTRIPTYLINE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.

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297	IMP/IVD/2019/000312	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COT ONE STEP COTININE TEST DEVICE (URINE)(COT ONE STEP COTININE TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 200NG/ML COTININE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,K2 ONE STEP SYNTHETIC CANNABINOIDS TEST DEVICE (URINE)(K2 ONE STEP SYNTHETIC CANNABINOIDS TEST DEVICE (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 20NG/ML JWH-018 5-PENTANOIC ACID METABOLITE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,FOB ONE STEP FECAL OCCULT BLOOD TEST STRIP (FECES)(FOB ONE STEP FECAL OCCULT BLOOD TEST STRIP (FECES))-A RAPID, ONE STEP TEST FOR THE QUALITATIVE DETECTION OF HUMAN OCCULT BLOOD IN FECES. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY. , SYPHILIS ULTRA RAPID TEST DEVICE (WHOLE BLOOD/SERUM/PLASMA)(SYPHILIS ULTRA RAPID TEST DEVICE (WHOLE BLOOD/SERUM/PLASMA))-THE SYPHILIS ULTRA RAPID TEST DEVICE (WHOLE BLOOD/SERUM/PLASMA) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES (IGG AND IGM) TO TREPONEMA PALLIDUM (TP) IN WHOLE BLOOD, SERUM OR PLASMA TO AID IN THE DIAGNOSIS OF SYPHILIS.,FOB ONE STEP FECAL OCCULT BLOOD TEST DEVICE (FECES)(FOB ONE STEP FECAL OCCULT BLOOD TEST DEVICE (FECES))-A RAPID, ONE STEP TEST FOR THE QUALITATIVE DETECTION OF HUMAN OCCULT BLOOD IN FECES. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY. ,SYPHILIS ULTRA RAPID TEST STRIP (WHOLE BLOOD/SERUM/PLASMA)(SYPHILIS ULTRA RAPID TEST STRIP (WHOLE BLOOD/SERUM/PLASMA))-SYPHILIS ULTRA RAPID TEST STRIP IS RAPID TEST FOR THE QUALITATIVE DETECTION OF ANTIBODIES (IGG AND IGM) TO TREPONEMA PALLIDUM (TP) IN WHOLE BLOOD, SERUM OR PLASMA, AS AN AID IN THE DIAGNOSIS OF SYPHILIS.,HRN ONE STEP HEROIN TEST STRIP (URINE)(HRN ONE STEP HEROIN TEST STRIP (URINE))-A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 10NG/ML 6-ACETYLMORPHINE IN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.

298	IMP/IVD/2019/000313	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G-6-PDH)-TRINITY BIOTECH GLUCOSE-6-PHOSPHATE DEHYDROGENASE REAGENTS ARE FOR THE QUANTITATIVE, ULTRAVIOLET, KINETIC DETERMINATION OF G-6-PDH IN BLOOD AT 340 NM.,OXALATE URINE CONTROL-N-FOR QUALITY CONTROL OF OXALATE KIT,RED CELL LYSING REAGENT-FOR USE WITH DISCRETE ANALYSER APPLICATIONS.,OXALATE URINE CONTROL-E-FOR QUALITY CONTROL OF OXALATE KIT,ACE REAGENT-ACE REAGENT IS FOR USE IN THE KINETIC DETERMINATION OF ANGIOTENSIN CONVERTING ENZYME (ACE) ACTIVITY IN SERUM OR PLASMA AT 340 NM.,OXALATE STANDARDS-TRINITY BIOTECH OXALATE REAGENTS ARE FOR THE QUANTITATIVE, ENZYMATIC DETERMINATION OF OXALATE IN URINE AT 590 NM.,G-6-PDH DEFICIENCY-TRINITY BIOTECH GLUCOSE-6-PHOSPHATE DEHYDROGENASE REAGENTS ARE FOR THE QUALITATIVE, VISUAL FLUORESCENCE SCREENING OF G-6-PDH IN WHOLE BLOOD.,OXALATE KIT-TRINITY BIOTECH OXALATE REAGENTS ARE FOR THE QUANTITATIVE, ENZYMATIC DETERMINATION OF OXALATE IN URINE AT 590 NM.,OXALATE STANDARD 0.50 MMOL/L-TRINITY BIOTECH OXALATE REAGENTS ARE FOR THE QUANTITATIVE, ENZYMATIC DETERMINATION OF OXALATE IN URINE AT 590 NM.

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299	IMP/IVD/2019/000314	1.License Holder Name: GENWORKS HEALTH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HBA1C CALIBRATOR (HBA1C CALIBRATOR)-HBA1C CALIBRATOR IS COMPOSED OF A SET OF LYOPHILIZED MATERIALS, AIMED AT THE PREPARATION OF CALIBRATION CURVES FOR QUANTITATIVE DETERMINATION OF HBA1C IN HUMAN BLOOD, THROUGH IMMUNOCHEMICAL TECHNIQUES.,CHLORIDE(CHLORIDE)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHLORIDE IN BIOLOGICAL FLUIDS., HBA1C CONTROL SET(HBA1C CONTROL SET)-HBA1C CONTROL SET IS COMPOSED OF A SET OF LYOPHILIZED MATERIALS FOR QUALITY CONTROL OF METHODS FOR DETERMINATION OF HBA1C IN HUMAN BLOOD, THROUGH IMMUNOCHEMICAL TECHNIQUES.,CONTROL (QUANTIPATH CHEMA)-QUALITY CONTROL OF GENERAL CLINICAL CHEMISTRY METHODS FOR THE QUANTITATIVE DETERMINATION OF SUBSTRATES, ELECTROLYTES, LIPIDS, ENZYMES AND PROTEIN ., HBA1C(HBA1C)-REAGENT FOR QUALITATIVE IN VITRO DETERMINATION OF GLYCATED HEMOGLOBIN (HBA1C) IN BIOLOGICAL FLUIDS.,ALKALINE PHOSPHATASE(ALKALINE PHOSPHATASE FL (DGKC))-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IN ALKALINE PHOSPHATASE IN BIOLOGICAL FLUIDS.,LDH(LDH FL (DGKC))-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LDH IN BIOLOGICAL FLUIDS.,TOTAL PROTEIN (TOTAL PROTEINS)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTEINS IN BIOLOGICAL FLUIDS.,IRON (IRON CRX)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IRON IN BIOLOGICAL FLUIDS.,CALIBRATOR(MICROALBUMIN CALIBRATOR)-SET OF SERA FOR THE PREPARATION OF CALIBRATION CURVES FOR QUANTITATIVE DETERMINATION OF ALBUMIN IN URINE.,CHOLESTEROL(CHOLESTEROL FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHOLESTEROL IN BIOLOGICAL FLUIDS.,CALIBRATOR(ASO CALIBRATOR)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ASO IN BIOLOGICAL FLUIDS.,CHOLESTEROL-HDL(HDL-DIRECT FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HDL - CHOLESTEROL IN BIOLOGICAL FLUIDS.,CONTROL(RHEUMATOID FACTOR CONTROL SET)-LIQUID SOLUTIONS FOR QUALITY CONTROL OF METHODS DETERMINATION OF RF,RHEUMATOIDE FACTOR(RHEUMATOID FACTOR FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF RF IN BIOLOGICAL FLUIDS.,GLUCOSE(GLUCOSE FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE IN BIOLOGICAL FLUIDS.,CREATININE(CREATININE-E FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN BIOLOGICAL FLUIDS.,ETHANOL(ETHANOL FL)-REAGENT FOR

	QUANTITATIVE IN VITRO DETERMINATION OF ETHANOL IN BIOLOGICAL FLUIDS.,CK-MB(CK-MB FL (DGKC/IFCC))-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATINE KINASE MB IN BIOLOGICAL FLUIDS.,CALIBRATOR(CRP CALIBRATOR)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN IN BIOLOGICAL FLUIDS.,COPPER(COPPER)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF COPPER IN BIOLOGICAL FLUIDS.,TRANSFERRIN(TRANSFERRIN FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TRANSFERRIN IN BIOLOGICAL FLUIDS.,ALBUMIN(ALBUMIN)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN BIOLOGICAL FLUIDS.,CALIBRATOR(AUTOCAL H)-HUMAN BASED MULTIPARAETRIC CALIBRATION SERUM.,IGG(IGG)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IGG IN BIOLOGICAL FLUIDS.,GPT(GPT-ALT FL (IFCC))-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GPT IN BIOLOGICAL FLUIDS.,GLUCOSE (GLUCOSE UV FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE IN BIOLOGICAL FLUIDS.,AMYLASE (AMYLASE EPS FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF AMYLASE IN BIOLOGICAL FLUIDS.,PHOSPHORUS (PHOSPHORUS UV)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PHOSPHORUS IN BIOLOGICAL FLUIDS.,ZINC (ZINC)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ZINC IN BIOLOGICAL FLUIDS.,URIC ACID(URIC ACID T FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN BIOLOGICAL FLUIDS.,CRP(CRP FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN IN BIOLOGICAL FLUIDS.,IGA(IGA)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IGA IN BIOLOGICAL FLUIDS.,CONTROL (MULTINORM)-QUALITY CONTROL OF GENERAL CLINICAL CHEMISTRY METHODS FOR THE QUANTITATIVE DETERMINATION OF SUBSTRATES, ELECTROLYTES, LIPIDS, ENZYMES AND PROTEIN,IGM (IGM)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IGM IN BIOLOGICAL FLUIDS.,MICROALBUMIN(MICROALBUMIN FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN BIOLOGICAL FLUIDS.,CONTROL(MULTIPATH)-QUALITY CONTROL OF GENERAL CLINICAL CHEMISTRY METHODS FOR THE QUANTITATIVE DETERMINATION OF SUBSTRATES, ELECTROLYTES, LIPIDS, ENZYMES AND PROTEIN,CALIBRATOR(RHEUMATOID FACTOR CALIBRATOR)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF RF IN BIOLOGICAL FLUIDS.,CONTROL (QUANTINORM CHEMA)-QUALITY CONTROL OF GENERAL CLINICAL CHEMISTRY METHODS FOR THE QUANTITATIVE DETERMINATION OF SUBSTRATES, ELECTROLYTES, LIPIDS, ENZYMES AND PROTEIN.,

	CALIBRATOR(REFERENCE P MULTICALIBRATOR)-SET OF SERA FOR THE PREPARATION OF CALIBRATION CURVES FOR QUANTITATIVE DETERMINATION OF PROTEINS IN HUMAN SERUM ., ANTISTREPTOLYSIN O(ASO FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ASO IN BIOLOGICAL FLUIDS.,URIC ACID (URIC ACID AOX FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN BIOLOGICAL FLUIDS.,UREA(UREA UV FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF UREA IN BIOLOGICAL FLUIDS.,TRIGLYCERIDES(TRIGLYCERIDES FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDES IN BIOLOGICAL FLUIDS.,PROTEINS(PROTEINS HS)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PROTEINS IN BIOLOGICAL FLUIDS.,CONTROL(ETHANOL CONTROL SET)-FOR QUALITY CONTROL OF CLINICAL CHEMISTRY FOR DETERMINATION OF ETHANOL.,CK(CK-NAC FL (DGKC/IFCC))-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATINE KINASE IN BIOLOGICAL FLUIDS.,MAGNESIUM(MAGNESIUM XL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF MAGNESIUM IN BIOLOGICAL FLUIDS.,LIPASE(LIPASE FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPASE IN BIOLOGICAL FLUIDS.,IRON(IRON FZ)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IRON IN BIOLOGICAL FLUIDS.,GOT(GOT-AST FL (IFCC))-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GOT IN BIOLOGICAL FLUIDS.,CREATININE (CREATININE)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN BIOLOGICAL FLUIDS., CHOLINESTERASE(CHOLINESTERASE FL (DGKC))-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHOLINESTERASE IN BIOLOGICAL FLUIDS.,TOTAL BILIRUBIN(TOTAL BILIRUBIN FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILIRUBIN IN BIOLOGICAL FLUIDS.,BICARBONATE(BICARBONATE FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE IN BIOLOGICAL FLUIDS.,AMYLASE(AMYLASE FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF AMYLASE IN BIOLOGICAL FLUIDS.,GAMMA-GT(GAMMA-GT FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GAMMA-GT IN BIOLOGICAL FLUIDS.,CALCIUM(CALCIUM ASX)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN BIOLOGICAL FLUIDS.,CHOLESTEROL-LDL(LDL-DIRECT FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LDL - CHOLESTEROL IN BIOLOGICAL FLUIDS.,DIRECT BILIRUBIN(DIRECT BILIRUBIN FL)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF DIRECT BILIRUBIN IN BIOLOGICAL FLUIDS., ALKALINE PHOSPHATASE(ALKALINE PHOSPHATASE FL (IFCC))-

	REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALKALINE PHOSPHATASE IN BIOLOGICAL FLUIDS.

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300	IMP/IVD/2019/000315	1.License Holder Name: BIOMERIEUX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GENOTYPE MTBDRPLUS (HAIN)-FOR THE IDENTIFICATION OF THE MYCOBACTERIUM TUBERCULOSIS COMPLEX AND ITS RESISTANCE TO RIFAMPICIN (RMP) AND ISONIAZID FROM PULMONARY SMEAR-POSITIVE OR NEGATIVE CLINICAL SPECIMENS AND CULTIVATED SAMPLES., GENOTYPE CMDIRECT(GENOTYPE CMDIRECT)-IT IS A QUALITATIVE IN VITRO TEST FOR IDENTIFICATION OF THE MYCOBACTERIUM TUBERCULOSIS COMPLEX AS WELL AS THE FOLLOWING NONTUBERCULOSIS MYCOBACTERIA FROM CLINICAL SPECIMENS MYCOBACTERIUM AVIUM, MYCOBACTERIUM CHELONAE, MYCOBACTERIUM ABSCESSUS COMPLEX, MYCOBACTERIUM FORTUITUM GROUP, MYCOBACTERIUM GORDONAE, MYCOBACTERIUM INTRACELLULARE , MYCOBACTERIUM SCROFULACEUM/M. INTRACELLULARE, MYCOBACTERIUM SZULGAI, MYCOBACTERIUM INTERJECTUM, MYCOBACTERIUM KANSAII, MYCOBACTERIUM MALMOENSE, MYCOBACTERIUM MARINUM/MYCOBACTERIUM ULCERANS, AND MYCOBACTERIUM XENOPI. THE TEST IS INDICATED AS AN AID FOR DIAGNOSIS AND INTENDED FOR USE IN MEDICAL LABORATORIES.,GENOLYSE(HAIN)-THE GENOLYSE DNA EXTRACTION KIT PERMITS THE FAST AND EASY MANUAL EXTRACTION OF BACTERIAL DNA,GENOTYPE NTM-DR (GENOTYPE NTM-DR)-THE GENOTYPE NTM-DR VER 1.0 IS A QUALITATIVE IN VITRO TEST FOR DETECTION OF ANTIBIOTIC RESISTANCE IN MEMBERS OF THE MYCOBACTERIUM AVIUM COMPLEX, THE MYCOBACTERIUM ABSCESSUS COMPLEX AND MYCOBACTERIUM CHELONAE. THE M. AVIUM COMPLEX INCLUDES THE SPECIES M. AVIUM , M. INTRACELLULAR AND M. CHIMAERA. THE M. ABSCESSUS COMPLEX INCLUDES THE SUBSPECIES M. ABSCESSUS SUBSP. ABSCESSUS, M. ABSCESSUS SUBSP, BOLLETII, AND M. ABSCESSUS SUBSP. MASSILIENCE, ANTIBIOTIC RESISTANCES DETECTABLE BY THIS TEST ARE RESISTANCES TO MACROLIDES AND AMINOGLYCOSIDES .,GENOTYPE MYCOBACTERIUM CM(HAIN)-FOR THE IDENTIFICATION OF THE MYCOBACTERIUM TUBERCULOSIS COMPLEX AS WELL AS THE FOLLOWING NONTUBERCULOUS MYCOBACTERIAL SPECIES FROM CULTURED MATERIAL:M. AVIUM, M. CHELONAE, M. ABSCESSUS, M. FORTUITUM, M. GORDONAE, M. INTRACELLULARE, M. SCROFULACEUM, M. INTERJECTUM, M. KANSASII, M. MALMOENSE, M. MARINUM/M. ULCERANS, M. PEREGRINUM, AND M. XENOPI.,GENOTYPE MTBDRSL VER 2.0(HAIN)-FOR THE IDENTIFICATION OF THE MYCOBACTERIUM TUBERCULOSIS COMPLEX AND ITS RESISTANCE TO FLUROQUINOLONES AND AMINOGLYCOSIDES/CYCLIC PEPTIDES FROM SMEAR-POSITIVE OR

		NEGATIVE SPUTUM SPECIMENS AND CULTIVATED SAMPLES., GENOTYPE MYCOBACTERIUM AS(HAIN)-FOR THE IDENTIFICATION OF THE FOLLOWING NONTUBERCULOUS MYCOBACTERIAL SPECIES FROM CULTURED MATERIAL: M. SIMIAE, M. MUCOGENICUM , M. GOODII, M. CELATUM, M. SMEGMATIS, M. GENAVENSE, M. LENTIFLAVUM , M. HECKESHORNENSE, M. SZULGAI/M. INTERMEDIUM, M. PHLEI, M. HAEMOPHILUM, M. KANSASII, M. ULCERANS, M. GASTRI, M. ASIATICUM AND M. SHIMOIDEI.,GXT DNA/RNA EXTRACTION KIT (HAIN)-THE GXT DNA/RNA EXTRACTION KIT PERMITS THE FAST AND EASY AUTOMATED EXTRACTION OF BACTERIAL DNA AND RNA FROM CLINICAL SPECIMENS.,REAGENT SET FOR DNA STRIP KITS(HAIN)-THE REAGENT SET FOR DNA STRIP KITS IS A REAGENT SET FOR USE WITH TEST KITS BASED ON THE DNA STRIP TECHNOLOGY. THE REAGENTS CAN REPLACE OR REPLENISH THE SOLUTIONS PROVIDED WITH DNA STRIP KITS
301	IMP/IVD/2019/000316	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LACTATE(LACTATE)-ENZYMATIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF L-LACTATE IN HUMAN PLASMA AND CEREBROSPINAL FLUID (CSF) ON BECKMAN COULTER ANALYSERS.,CHOLINESTERASE (CHOLINESTERASE)-KINETIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF CHOLINESTERASE, EC 3.1.1.8 (CHE) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.

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302	IMP/IVD/2019/000317	1.License Holder Name: ASPEN LABORATORIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASO/CRP/RF CONTROL, LOW LEVEL-USED TO EVALUATE THE PRECISION AND ACCURACY OF ASO/CRP/RF DETERMINATION IN HUMAN SERUM BY TURBIDITY METHOD,RF TURBI-USED FOR MEASUREMENT OF RF IN HUMAN SERUM/PLASMA,HDL&LDL CAL.-USED TO CALIBRATE HDL/LDL PARAMETERS,CRP TURBI-USED FOR MEASUREMENT OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM/PLASMA,ASO TURBI CALIBRATOR-USED TO CALIBRATE ASO DETERMINATION BY TURBIDITY METHOD, ASO TURBI-USED FOR MEASUREMENT OF ASO IN HUMAN SERUM/PLASMA,RF TURBI CAL.-USED TO CALIBRATE RF DETERMINATION BY TURBIDITY METHOD,CRP TURBI CAL.-USED TO CALIBRATE CRP DETERMINATION BY TURBIDITY METHOD, ASO/CRP/RF CONTROL, HIGH LEVEL-USED TO EVALUATE THE PRECISION AND ACCURACY OF ASO/CRP/RF DETERMINATION IN HUMAN SERUM BY TURBIDITY METHOD
303	IMP/IVD/2019/000318	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ONLYONE(ONLYONE)-LYSING AGENT TO OBTAIN THE MEASUREMENT OF THE HAEMOGLOBIN, COUNTING & DIFFERENTIATION OF THE WHITE BLOOD CELLS.

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304	IMP/IVD/2019/000319	1.License Holder Name: BIOMERIEUX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BACT/ALERT® MP ANTIMICROBIAL SUPPLEMENT KIT(BACT/ALERT® MP ANTIMICROBIAL SUPPLEMENT KIT)-THE BACT/ALERT® MP REAGENT SYSTEM CONSISTS OF THE BACT/ALERT® MP CULTURE BOTTLE WITH A REMOVABLE CLOSURE USED IN CONJUNCTION WITH THE BACT/ALERT® MP ANTIMICROBIAL SUPPLEMENT AND THE BACT/ALERT® MP NUTRIENT SUPPLEMENT. THE BACT/ALERT® MP REAGENT SYSTEM IS DESIGNED FOR USE WITH BACT/ALERT® 3D MYCOBACTERIA DETECTION SYSTEMS FOR RECOVERY AND DETECTION OF MYCOBACTERIA FROM STERILE BODY SPECIMENS OTHER THAN BLOOD, AND FROM DIGESTED/ DECONTAMINATED CLINICAL SPECIMENS,BACT/ALERT® BPN(BACT/ALERT® BPN)-BACT/ALERT® BPN CULTURE BOTTLES (REF 279045) ARE USED WITH THE BACT/ALERT® MICROBIAL DETECTION SYSTEMS FOR QUALITY CONTROL TESTING OF LEUKOCYTE REDUCED APHERESIS PLATELET (LRAP) UNITS, BOTH LEUKOCYTE REDUCED SINGLE AND POOLS OF UP TO SIX (6) UNITS OF LEUKOCYTE REDUCED WHOLE BLOOD PLATELET CONCENTRATES (LRWBPC)1,2 AND POOLS OF UP TO FOUR (4) UNITS OF LEUKOCYTE REDUCED WHOLE BLOOD DERIVED BUFFY COAT PLATELETS (LRWBDBCP). BACT/ALERT BPN CULTURE BOTTLES SUPPORT THE GROWTH OF ANAEROBIC AND FACULTATIVE ANAEROBIC MICROORGANISMS (BACTERIA). , BACT/ALERT® MP(BACT/ALERT® MP)-THE BACT/ALERT® MP REAGENT SYSTEM CONSISTS OF THE BACT/ALERT® MP CULTURE BOTTLE WITH A REMOVABLE CLOSURE USED IN CONJUNCTION WITH THE BACT/ALERT® MP ANTIMICROBIAL SUPPLEMENT AND THE BACT/ALERT® MP NUTRIENT SUPPLEMENT. THE BACT/ALERT® MP REAGENT SYSTEM IS DESIGNED FOR USE WITH BACT/ALERT® 3D MYCOBACTERIA DETECTION SYSTEMS FOR RECOVERY AND DETECTION OF MYCOBACTERIA FROM STERILE BODY SPECIMENS OTHER THAN BLOOD, AND FROM DIGESTED/ DECONTAMINATED CLINICAL SPECIMENS.,BACT/ALERT® FN PLUS(BACT/ALERT® FN PLUS)-BACT/ALERT® MICROBIAL DETECTION SYSTEMS IN QUALITATIVE PROCEDURES FOR RECOVERY AND DETECTION OF ANAEROBIC AND FACULTATIVE ANAEROBIC MICROORGANISMS FROM BLOOD AND OTHER NORMALLY STERILE BODY FLUIDS, BACT/ALERT® BPA(BACT/ALERT® BPA)-BACT/ALERT® BPA CULTURE BOTTLES (REF 279044) ARE USED WITH THE BACT/ALERT® MICROBIAL DETECTION SYSTEMS FOR QUALITY CONTROL TESTING OF LEUKOCYTE REDUCED APHERESIS PLATELET (LRAP) UNITS, BOTH LEUKOCYTE REDUCED SINGLE AND POOLS OF UP TO SIX (6) UNITS OF LEUKOCYTE REDUCED WHOLE BLOOD

	PLATELET CONCENTRATES (LRWBPC)1,2 AND POOLS OF UP TO FOUR (4) UNITS OF LEUKOCYTE REDUCED WHOLE BLOOD DERIVED BUFFY COAT PLATELETS (LRWBDBCP). BACT/ALERT BPA CULTURE BOTTLES SUPPORT THE GROWTH OF AEROBIC MICROORGANISMS (BACTERIA AND FUNGI). ,BACT/ALERT® SN(BACT/ALERT® SN)-BACT/ALERT® SN CULTURE BOTTLES ARE USED WITH THE BACT/ALERT® MICROBIAL DETECTION SYSTEMS IN QUALITATIVE PROCEDURES FOR THE RECOVERY AND DETECTION OF ANAEROBIC AND FACULTATIVE ANAEROBIC MICROORGANISMS (BACTERIA) FROM BLOOD AND OTHER NORMALLY STERILE BODY FLUIDS., BACT/ALERT® SA(BACT/ALERT® SA)-BACT/ALERT® SA CULTURE BOTTLES ARE USED WITH THE BACT/ALERT® MICROBIAL DETECTION SYSTEM IN QUALITATIVE PROCEDURES FOR THE RECOVERY AND DETECTION OF AEROBIC MICROORGANISMS (BACTERIA AND FUNGI) FROM BLOOD AND OTHER NORMALLY STERILE BODY FLUIDS. , BACT/ALERT® PF PLUS(BACT/ALERT® PF PLUS)-BACT/ALERT® PF PLUS CULTURE BOTTLES ARE USED WITH BACT/ALERT® MICROBIAL DETECTION SYSTEMS IN QUALITATIVE PROCEDURES FOR RECOVERY AND DETECTION OF AEROBIC AND FACULTATIVE ANAEROBIC MICROORGANISMS (BACTERIA AND YEAST) FROM BLOOD. , BACT/ALERT® FA PLUS(BACT/ALERT® FA PLUS)-BACT/ALERT® FA PLUS CULTURE BOTTLES ARE USED WITH BACT/ALERT® MICROBIAL DETECTION SYSTEMS IN QUALITATIVE PROCEDURES FOR RECOVERY AND DETECTION OF AEROBIC AND FACULTATIVE ANAEROBIC MICROORGANISMS (BACTERIA AND YEAST) FROM BLOOD AND OTHER NORMALLY STERILE BODY FLUIDS

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305	IMP/IVD/2019/000320	1.License Holder Name: M/S. GOLDEN HARVEST INDUSTRIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CBC-CAL PLUS CALIBRATOR / CBC-CAL PLUS FOR MINDRAY(R&D SYSTEMS)-CBC-CAL PLUS IS DESIGNED FOR USE IN THE CALIBRATION OF BECKMAN COULTER HEMATOLOGY ANALYZERS.,R&D 3K RETIC CONTROL(R&D SYSTEMS)-R & D 3K RETICULOCYTE CONTROL IS A BI-LEVEL CONTROL FOR USE IN MONITORING THE PERFORMANCE OF ABBOTT CELL-DYN(R) HEMATOLOGY INSTRUMENTS. ,R&D 4K RETIC CONTROL (R&D SYSTEMS)-R&D 4K RETIC IS A CONTROL DESIGNED TO MONITOR VALUES OBTAINED BY RETICULOCYTE COUNTING METHODS,CBC-5DMR / R&D CBC-5DMR(R&D SYSTEMS)-CBC-5DMR IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS., CBC-3D FOR MINDRAY(R&D SYSTEMS)-CBC-3D FOR MINDRAY IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

306	IMP/IVD/2019/000322	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ATELLICA IM INTERLEUKIN-6 QUALITY CONTROL (IL6 QC)(ATELLICA IM INTERLEUKIN-6 QUALITY CONTROL (IL6 QC))-THE ATELLICA® IM INTERLEUKIN-6 QUALITY CONTROL MATERIAL (IL6 QC) IS FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND ACCURACY OF THE ATELLICA IM IL6 ASSAY USING THE ATELLICA® IM ANALYZER.,ADVIA CENTAUR ACCP MASTER CURVE MATERIAL (ADVIA CENTAUR ACCP MASTER CURVE MATERIAL)-THE ADVIA CENTAUR® ANTI-CCP IGG (ACCP) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR ACCP ASSAY., ATELLICA IM INTERLEUKIN-6 (IL6) (ATELLICA IM INTERLEUKIN-6 (IL6))-THE ATELLICA® IM INTERLEUKIN-6 (IL6) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF INTERLEUKIN-6 (IL-6) IN SERUM OR PLASMA USING THE ATELLICA® IM ANALYZER. THE ASSAY IS INDICATED AS AN AID IN THE STUDY OF INFLAMMATORY DISEASES.,ADVIA CENTAUR ACCP QUALITY CONTROL(ADVIA CENTAUR ACCP QUALITY CONTROL)-THE ADVIA CENTAUR® ANTI-CCP IGG (ACCP) QUALITY CONTROL MATERIAL IS FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND ACCURACY OF THE ADVIA CENTAUR ACCP ASSAY ON THE ADVIA CENTAUR SYSTEMS.,ADVIA CENTAUR FREE BETA HUMAN CHORIONIC GONADOTROPIN (FBHCG)(ADVIA CENTAUR FREE BETA HUMAN CHORIONIC GONADOTROPIN (FBHCG))-THE ADVIA CENTAUR FREE BETA HUMAN CHORIONIC GONADOTROPIN (FBHCG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE FREE BETA SUBUNIT OF CHORIONIC GONADOTROPIN IN HUMAN SERUM USING THE ADVIA CENTAUR XP AND ADVIA CENTAUR XPT SYSTEMS. THE ADVIA CENTAUR FBHCG ASSAY IS INTENDED FOR USE AS ONE COMPONENT IN COMBINATION WITH OTHER PARAMETERS TO EVALUATE THE RISK OF TRISOMY 21 (DOWN SYNDROME) DURING THE FIRST TRIMESTER OF PREGNANCY. FURTHER TESTING IS REQUIRED FOR DIAGNOSIS OF CHROMOSOMAL ABERRATIONS.,ADVIA CENTAUR ERYTHROPOIETIN (EPO)(ADVIA CENTAUR ERYTHROPOIETIN (EPO))-THE ADVIA CENTAUR® ERYTHROPOIETIN (EPO) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF ERYTHROPOIETIN IN HUMAN SERUM AND PLASMA USING THE ADVIA CENTAUR CP, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. ERYTHROPOIETIN IS USED AS AN AID IN THE DIAGNOSIS OF ANEMIAS AND POLYCYTHEMIAS.,ADVIA CENTAUR PREGNANCY ASSOCIATED PLASMA PROTEIN-A (PAPP-A) ASSAY(ADVIA CENTAUR PREGNANCY

	ASSOCIATED PLASMA PROTEIN-A (PAPP-A) ASSAY)-THE ADVIA CENTAUR PREGNANCY ASSOCIATED PLASMA PROTEIN-A (PAPP-A) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF PREGNANCY-ASSOCIATED PLASMA PROTEIN-A IN HUMAN SERUM USING THE ADVIA CENTAUR XP AND ADVIA CENTAUR XPT SYSTEMS. THE ADVIA CENTAUR PAPP-A ASSAY IS INTENDED FOR USE AS ONE COMPONENT IN COMBINATION WITH OTHER PARAMETERS TO EVALUATE THE RISK OF TRISOMY (DOWN SYNDROME) DURING THE FIRST TRIMESTER OF PREGNANCY. FURTHER TESTING IS REQUIRED FOR DIAGNOSIS OF CHROMOSOMAL ABERRATIONS.,ADVIA CENTAUR ACTIVE-B12 (AB12) MASTER CURVE MATERIAL(ADVIA CENTAUR ACTIVE-B12 (AB12) MASTER CURVE MATERIAL)-THE ADVIA CENTAUR® ACTIVE-B12 (AB12) MASTER CURVE MATERIAL (MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR AB12 (HOLOTRANSCOBALAMIN) ASSAY USING THE ADVIA CENTAUR SYSTEMS.,ADVIA CENTAUR INTERLEUKIN-6 (IL6) (ADVIA CENTAUR INTERLEUKIN-6 (IL6))-THE ADVIA CENTAUR® INTERLEUKIN-6 (IL6) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF INTERLEUKIN-6 (IL-6) IN SERUM OR PLASMA USING THE ADVIA CENTAUR CP, ADVIA CENTAUR XP AND ADVIA CENTAUR XPT SYSTEMS. THE ASSAY IS INDICATED AS AN AID IN THE STUDY OF INFLAMMATORY DISEASES.,ADVIA CENTAUR IL6 QUALITY CONTROL MATERIAL(ADVIA CENTAUR IL6 QUALITY CONTROL MATERIAL)-THE ADVIA CENTAUR® INTERLEUKIN-6 (IL6) QUALITY CONTROL MATERIAL IS FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND ACCURACY OF THE ADVIA CENTAUR IL6 ASSAY USING THE ADVIA CENTAUR SYSTEMS.,ATELLICA IM FREE BETA HUMAN CHORIONIC GONADOTROPIN (FBHCG)(ATELLICA IM FREE BETA HUMAN CHORIONIC GONADOTROPIN (FBHCG))-THE ATELLICA® IM FREE BETA HUMAN CHORIONIC GONADOTROPIN (FBHCG) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE FREE BETA SUBUNIT OF CHORIONIC GONADOTROPIN IN HUMAN SERUM USING THE ATELLICA® IM ANALYZER. THE ATELLICA IM FBHCG ASSAY IS INTENDED FOR USE AS ONE COMPONENT IN COMBINATION WITH OTHER PARAMETERS TO EVALUATE THE RISK OF TRISOMY 21 (DOWN SYNDROME) DURING THE FIRST TRIMESTER OF PREGNANCY. FURTHER TESTING IS REQUIRED FOR DIAGNOSIS OF CHROMOSOMAL ABERRATIONS.,ADVIA CENTAUR CALCITONIN (CALCT)(ADVIA CENTAUR CALCITONIN (CALCT))-THE ADVIA CENTAUR® CALCITONIN (CALCT) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF CALCITONIN IN HUMAN SERUM AND PLASMA (K2-EDTA, K3-EDTA, AND LITHIUM HEPARIN) USING THE

	ADVIA CENTAUR CP, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. CALCITONIN MEASUREMENT IS USED AS AN AID IN THE DIAGNOSIS AND TREATMENT OF DISEASES INVOLVING THE THYROID AND PARATHYROID GLANDS, INCLUDING CARCINOMA AND HYPERPARATHYROIDISM.,ADVIA CENTAUR LIPOPOLYSACCHARIDE BINDING PROTEIN (LBP)(ADVIA CENTAUR LIPOPOLYSACCHARIDE BINDING PROTEIN (LBP))-THE ADVIA CENTAUR® LIPOPOLYSACCHARIDE BINDING PROTEIN (LBP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF LIPOPOLYSACCHARIDE BINDING PROTEIN (LBP) IN HUMAN SERUM AND PLASMA USING THE ADVIA CENTAUR CP, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THE ASSAY IS INDICATED AS AN AID IN THE DIAGNOSIS AND PROGNOSIS OF DISEASES THAT ARE INDUCED BY EXPOSURE TO ENDOTOXIN, SUCH AS SEPSIS AND INFECTIOUS COMPLICATIONS OF SURGERY AND TRAUMA.,ADVIA CENTAUR ACTIVE-B12 (AB12)(ADVIA CENTAUR ACTIVE-B12 (AB12))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF HOLOTRANSCOBALAMIN (HOLOTC) IN HUMAN SERUM USING THE ADVIA CENTAUR CP, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. ACTIVE-B12 (HOLOTRANSCOBALAMIN) IS USED AS AN AID IN THE DIAGNOSIS AND TREATMENT OF VITAMIN B12 DEFICIENCY.,ATELLICA IM ANTI-CCP IGG QUALITY CONTROL (ACCP QC)(ATELLICA IM ANTI-CCP IGG QUALITY CONTROL (ACCP QC))-THE ATELLICA® IM ANTI-CCP IGG QUALITY CONTROL MATERIAL (ACCP QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND ACCURACY OF THE ATELLICA IM ACCP ASSAY USING THE ATELLICA® IM ANALYZER.,ATELLICA IM ACTIVE-B12 MASTER CURVE MATERIAL (AB12 MCM) (ATELLICA IM ACTIVE-B12 MASTER CURVE MATERIAL (AB12 MCM))-THE ATELLICA® IM ACTIVE-B12 MASTER CURVE MATERIAL (AB12 MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA IM AB12 (HOLOTRANSCOBALAMIN) ASSAY USING THE ATELLICA® IM ANALYZER.,ATELLICA IM ANTI-CCP IGG (ACCP)(ATELLICA IM ANTI-CCP IGG (ACCP))-THE ATELLICA® IM ANTI-CCP IGG (ACCP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE SEMI-QUANTITATIVE DETERMINATION OF THE IGG CLASS OF AUTOANTIBODIES SPECIFIC TO CYCLIC CITRULLINATED PEPTIDE (CCP) IN HUMAN SERUM OR PLASMA (K2 EDTA AND LITHIUM HEPARIN) USING THE ATELLICA® IM ANALYZER. DETECTION OF ANTI-CCP ANTIBODIES IS USED AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA) AND SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL INFORMATION. AUTOANTIBODY LEVELS REPRESENT ONE PARAMETER IN A MULTI-CRITERIA DIAGNOSTIC PROCESS, ENCOMPASSING BOTH CLINICAL

	AND LABORATORY-BASED ASSESSMENTS.,ATELLICA IM ANTI-CCP IGG MASTER CURVE MATERIAL (ACCP MCM)(ATELLICA IM ANTI-CCP IGG MASTER CURVE MATERIAL (ACCP MCM))-THE ATELLICA® IM ANTI-CCP IGG MASTER CURVE MATERIAL (ACCP MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA IM ACCP ASSAY USING THE ATELLICA® IM ANALYZER.,ATELLICA IM LIPOPOLYSACCHARIDE BINDING PROTEIN (LBP)(ATELLICA IM LIPOPOLYSACCHARIDE BINDING PROTEIN (LBP))-THE ATELLICA® IM LIPOPOLYSACCHARIDE BINDING PROTEIN (LBP) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF LIPOPOLYSACCHARIDE BINDING PROTEIN (LBP) IN HUMAN SERUM AND PLASMA USING THE ATELLICA® IM ANALYZER. THE ASSAY IS INDICATED AS AN AID IN THE DIAGNOSIS AND PROGNOSIS OF DISEASES THAT ARE INDUCED BY EXPOSURE TO ENDOTOXIN, SUCH AS SEPSIS AND INFECTIOUS COMPLICATIONS OF SURGERY AND TRAUMA.,ADVIA CENTAUR ERYTHROPOIETIN (EPO) QUALITY CONTROL(ADVIA CENTAUR ERYTHROPOIETIN (EPO) QUALITY CONTROL)-THE ADVIA CENTAUR® ERYTHROPOIETIN (EPO) QUALITY CONTROL MATERIAL IS FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND ACCURACY OF THE ADVIA CENTAUR EPO ASSAY USING THE ADVIA CENTAUR SYSTEMS.,ATELLICA IM LIPOPOLYSACCHARIDE BINDING PROTEIN QUALITY CONTROL (LBP QC)(ATELLICA IM LIPOPOLYSACCHARIDE BINDING PROTEIN QUALITY CONTROL (LBP QC))-THE ATELLICA® IM LIPOPOLYSACCHARIDE BINDING PROTEIN QUALITY CONTROL MATERIAL (LBP QC) IS FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND ACCURACY OF THE ATELLICA IM LBP ASSAY USING THE ATELLICA® IM ANALYZER.,ATELLICA IM ACTIVE-B12 (HOLOTRANSCOBALAMIN) (AB12) (ATELLICA IM ACTIVE-B12 (HOLOTRANSCOBALAMIN) (AB12))-THE ATELLICA® IM ACTIVE-B12 (HOLOTRANSCOBALAMIN) (AB12) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF HOLOTRANSCOBALAMIN (HOLOTC) IN HUMAN SERUM USING THE ATELLICA® IM ANALYZER. ACTIVE-B12 (HOLOTRANSCOBALAMIN) IS USED AS AN AID IN THE DIAGNOSIS AND TREATMENT OF VITAMIN B12 DEFICIENCY.,ATELLICA IM PREGNANCY-ASSOCIATED PLASMA PROTEIN-A (PAPP-A)(ATELLICA IM PREGNANCY-ASSOCIATED PLASMA PROTEIN-A (PAPP-A))-THE ATELLICA® IM PREGNANCY-ASSOCIATED PLASMA PROTEIN-A (PAPP-A) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF PREGNANCY-ASSOCIATED PLASMA PROTEIN-A IN HUMAN SERUM USING THE ATELLICA® IM ANALYZER. THE ATELLICA IM PAPP-A ASSAY IS INTENDED FOR USE AS ONE COMPONENT IN COMBINATION WITH OTHER PARAMETERS TO EVALUATE THE RISK OF TRISOMY 21

	(DOWN SYNDROME) DURING THE FIRST TRIMESTER OF PREGNANCY. FURTHER TESTING IS REQUIRED FOR DIAGNOSIS OF CHROMOSOMAL ABERRATIONS.,ATELLICA IM ACTIVE-B12 QUALITY CONTROL (AB12 QC) (ATELLICA IM ACTIVE-B12 QUALITY CONTROL (AB12 QC))-THE ATELLICA® IM ACTIVE-B12 QUALITY CONTROL MATERIAL (AB12 QC) IS FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND ACCURACY OF THE ATELLICA IM AB12 (HOLOTRANSCOBALAMIN) ASSAY USING THE ATELLICA® IM ANALYZER.,ADVIA CENTAUR ACTIVE-B12 (AB12) QUALITY CONTROL(ADVIA CENTAUR ACTIVE-B12 (AB12) QUALITY CONTROL)-THE ADVIA CENTAUR® ACTIVE-B12 (AB12) QUALITY CONTROL MATERIAL IS FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND ACCURACY OF THE ADVIA CENTAUR AB12 (HOLOTRANSCOBALAMIN) ASSAY USING THE ADVIA CENTAUR SYSTEMS.,ADVIA CENTAUR LIPOPOLYSACCHARIDE BINDING PROTEIN (LBP) QUALITY CONTROL MATERIAL(ADVIA CENTAUR LIPOPOLYSACCHARIDE BINDING PROTEIN (LBP) QUALITY CONTROL MATERIAL)-THE ADVIA CENTAUR® LIPOPOLYSACCHARIDE BINDING PROTEIN (LBP) QUALITY CONTROL MATERIAL IS FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND ACCURACY OF THE ADVIA CENTAUR LBP ASSAY USING THE ADVIA CENTAUR SYSTEMS.,ATELLICA IM ERYTHROPOIETIN (EPO)(ATELLICA IM ERYTHROPOIETIN (EPO))-THE ATELLICA® IM ERYTHROPOIETIN (EPO) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF ERYTHROPOIETIN IN HUMAN SERUM AND PLASMA USING THE ATELLICA® IM ANALYZER. MEASUREMENT OF ERYTHROPOIETIN IS USED AS AN AID IN THE DIAGNOSIS OF ANEMIAS AND POLYCYTHEMIAS.,ATELLICA IM ERYTHROPOIETIN QUALITY CONTROL (EPO QC)(ATELLICA IM ERYTHROPOIETIN QUALITY CONTROL (EPO QC))-THE ATELLICA IM® ERYTHROPOIETIN QUALITY CONTROL MATERIAL (EPO QC) IS FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PRECISION AND ACCURACY OF THE ATELLICA IM EPO ASSAY USING THE ATELLICA IM® ANALYZER.,ADVIA CENTAUR ANTI-CCP IGG (ACCP)(ADVIA CENTAUR ANTI-CCP IGG (ACCP))-FOR IN VITRO DIAGNOSTIC USE IN THE SEMI-QUANTITATIVE DETERMINATION OF THE IGG CLASS OF AUTOANTIBODIES SPECIFIC TO CYCLIC CITRULLINATED PEPTIDE (CCP) IN HUMAN SERUM OR PLASMA (K2-EDTA AND LITHIUM HEPARIN) USING THE ADVIA CENTAUR CP, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. DETECTION OF ANTI-CCP ANTIBODIES IS USED AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA) AND SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL INFORMATION. AUTOANTIBODY LEVELS REPRESENT ONE PARAMETER IN A MULTI-CRITERIA DIAGNOSTIC PROCESS, ENCOMPASSING BOTH CLINICAL AND LABORATORY-

	BASED ASSESSMENTS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

307	IMP/IVD/2019/000323	1.License Holder Name: INSTRUMENTATION LABORATORY INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QUANTA LITE® TPO ELISA(QUANTA LITE® TPO ELISA)-QUANTA LITE TPO IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF THYROID PEROXIDASE (TPO) AUTOANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTIBODIES TO HUMAN PEROXIDASE ANTIGEN CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF AUTOIMMUNE THYROID DISEASES SUCH AS HASHIMOTO'S THYROIDITIS AND GRAVES' DISEASE.,NOVA LITE® DAPI ANCA (FORMALIN) KIT(NOVA LITE® DAPI ANCA (FORMALIN) KIT)-NOVA LITE DAPI ANCA (FORMALIN) KIT IS AN INDIRECT IMMUNOFLUORESCENCE ASSAY FOR THE QUALITATIVE DETECTION AND SEMI-QUANTITATIVE DETERMINATION OF ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA) OF IGG ISOTYPES IN HUMAN SERUM BY MANUAL FLUORESCENCE MICROSCOPY OR WITH THE NOVA VIEW AUTOMATED FLUORESCENCE MICROSCOPE. THE PRESENCE OF ANCA, IN CONJUNCTION WITH OTHER SEROLOGICAL, RADIOLOGICAL, HISTOLOGICAL AND CLINICAL FINDINGS AIDS IN THE DIAGNOSIS OF ANCA ASSOCIATED VASCULITIDES.,QUANTA LITE® R H-TTG IGA ELISA(QUANTA LITE® R H-TTG IGA ELISA)-THIS ASSAY IS DESIGNED FOR THE IN-VITRO MEASUREMENT OF SPECIFIC IGA AUTOANTIBODIES AGAINST TISSUE TRANSGLUTAMINASE (TTG) PRESENT IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF COELIAC DISEASE. SUFFICIENT MATERIALS ARE SUPPLIED TO ALLOW A MAXIMUM OF 41 SAMPLES TO BE TESTED IN DUPLICATE OR 89 IN SINGLE, WITH A CALIBRATION CURVE AND 2 CONTROLS.,NOVA LITE® DAPI ANCA (ETHANOL) KIT(NOVA LITE® DAPI ANCA (ETHANOL) KIT)-NOVA LITE DAPI ANCA (ETHANOL) KIT IS AN INDIRECT IMMUNOFLUORESCENCE ASSAY FOR THE QUALITATIVE DETECTION AND SEMI-QUANTITATIVE DETERMINATION OF ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA) OF IGG ISOTYPES IN HUMAN SERUM BY MANUAL FLUORESCENCE MICROSCOPY OR WITH NOVA VIEW AUTOMATED FLUORESCENCE MICROSCOPE. THE PRESENCE OF ANCA, IN CONJUNCTION WITH OTHER SEROLOGICAL, RADIOLOGICAL, HISTOLOGICAL, AND CLINICAL FINDINGS AIDS IN THE DIAGNOSIS OF ANCA ASSOCIATED VASCULITIDES,QUANTA LITE® ANTI-C1Q ELISA (QUANTA LITE® ANTI-C1Q ELISA)-THE QUANTA LITE ANTI-C1Q IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF ANTI-C1Q ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTI-C1Q ANTIBODIES IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS CAN BE USED IN CONJUNCTION

	WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN DETECTING PEOPLE AT RISK OF DEVELOPING GLOMERULONEPHRITIS.,QUANTA LITE® CALPROTECTIN EXTENDED RANGE(QUANTA LITE® CALPROTECTIN EXTENDED RANGE)-QUANTA LITE CALPROTECTIN EXTENDED RANGE IS A QUANTITATIVE ELISA FOR DETECTING CONCENTRATION OF FECAL CALPROTECTIN, WHICH CAN BE USED AS AN IN VITRO DIAGNOSTIC TO AID IN THE DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD), SPECIFICALLY CROHN'S DISEASE AND ULCERATIVE COLITIS, AND TO DIFFERENTIATE IBD FROM IRRITABLE BOWEL SYNDROME (IBS) IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS,QUANTA LITE® RF IGA ELISA(QUANTA LITE® RF IGA ELISA)-QUANTA LITE RF IGA IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF IGA RHEUMATOID FACTOR (RF) ANTIBODIES IN PATIENT SERA. THE PRESENCE OF THESE ANTIBODIES, WHEN CONSIDERED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS, IS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA).,NOVA LITE® DSDNA CRITHIDIA LUCILIAE KIT WITH DAPI (NOVA LITE® DSDNA CRITHIDIA LUCILIAE KIT WITH DAPI)-NOVA LITE DSDNA CRITHIDIA LUCILIAE IS AN INDIRECT IMMUNOFLUORESCENT ASSAY FOR THE SCREENING AND SEMI-QUANTITATIVE DETERMINATION OF ANTI-DOUBLE STRANDED DNA (DSDNA) IN HUMAN SERUM,QUANTA LITE® RNP ELISA(QUANTA LITE® RNP ELISA)-QUANTA LITE RNP IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF RNP ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF RNP ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AND RELATED CONNECTIVE TISSUE DISEASES.,QUANTA LITE® APS/PT IGG(QUANTA LITE® APS/PT IGG)-QUANTA LITE APS/PT IGG AND/OR QUANTA LITE APS/PT IGM KITS ARE SEMI-QUANTITATIVE AND QUALITATIVE ENZYME-LINKED IMMUNOSORBENT ASSAYS (ELISA) FOR THE DETECTION OF IGG AND IGM CLASS ANTIBODIES TO PHOSPHATIDYLSERINE/PROTHROMBIN COMPLEX (PS/PT) IN SERUM OR PLASMA. FOR USE AS AN AID IN THE DIAGNOSIS OF CERTAIN AUTOIMMUNE THROMBOTIC DISORDERS, SUCH AS ANTI-PHOSPHOLIPID SYNDROME (APS) AND THOSE SECONDARY TO SYSTEMIC LUPUS ERYTHEMATOSUS OR OTHER LUPUS-LIKE DISEASES, IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS.,QUANTA FLASH® APL MULTI CONTROLS (QUANTA FLASH® APL MULTI CONTROLS)-THE QUANTA FLASH APL MULTI CONTROLS ARE INTENDED FOR THE QUALITY CONTROL OF THE QUANTA FLASH ANTIBODY-BASED ASSAYS PERFORMED ON THE

	BIO-FLASH SYSTEM. APL LOW CONTROL: CONTROL INTENDED FOR THE ASSESSMENT OF PRECISION AND ACCURACY AT NORMAL OR CUT-OFF ANTIBODY LEVELS. APL HIGH CONTROL: CONTROL INTENDED FOR THE ASSESSMENT OF PRECISION AND ACCURACY AT ABNORMAL ANTIBODY LEVELS.,NOVA LITE® DAPI EMA KIT(NOVA LITE® DAPI EMA KIT)-NOVA LITE DAPI EMA KIT IS AN INDIRECT IMMUNOFLUORESCENCE ASSAY FOR THE QUALITATIVE DETECTION AND SEMI-QUANTITATIVE DETERMINATION OF ANTI-ENDOMYSIAL ANTIBODIES OF IGA ISOTYPES IN HUMAN SERUM BY MANUAL FLUORESCENCE MICROSCOPY OR WITH NOVA VIEW AUTOMATED FLUORESCENCE MICROSCOPE. THE PRESENCE OF ANTI-ENDOMYSIAL ANTIBODIES, IN CONJUNCTION WITH OTHER SEROLOGICAL, RADIOLOGICAL, HISTOLOGICAL, AND CLINICAL FINDINGS, AID IN THE DIAGNOSIS OF CELIAC DISEASE.,QUANTA LITE® RIBOSOME P ELISA (QUANTA LITE® RIBOSOME P ELISA)-QUANTA LITE RIBOSOME P IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF RIBOSOME P ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF RIBOSOME P ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AND OTHER RELATED CONNECTIVE TISSUE DISEASES.,NOVA LITE® RAT LIVER, KIDNEY, STOMACH KIT(NOVA LITE® RAT LIVER, KIDNEY, STOMACH KIT)-THIS PRODUCT IS INTENDED FOR USE IN THE SCREENING AND TITRATION OF CIRCULATING AUTOANTIBODIES IN HUMAN SERUM AS AN AID IN THE DIAGNOSIS AND TREATMENT OF VARIOUS AUTOIMMUNE DISEASES. THE FOUR MAJOR AUTOANTIBODIES DETECTED ARE ANTINUCLEAR ANTIBODIES (ANA), ANTIMITOCHONDRIAL ANTIBODIES (AMA), ANTISMOOTH MUSCLE ANTIBODIES (ASMA) AND ANTIGASTRIC PARIETAL CELL ANTIBODIES (AGPCA).,QUANTA LITE® SM ELISA (QUANTA LITE® SM ELISA)-QUANTA LITE SM IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF SM ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF SM ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AND RELATED CONNECTIVE TISSUE DISEASES.,NOVA LITE® DAPI ANA KIT (NOVA LITE® DAPI ANA KIT)-NOVA LITE DAPI ANA KIT IS AN INDIRECT IMMUNOFLUORESCENCE ASSAY FOR THE QUALITATIVE DETECTION AND SEMI-QUANTITATIVE DETERMINATION OF ANTI-NUCLEAR ANTIBODIES OF THE IGG ISOTYPE IN HUMAN SERUM BY MANUAL FLUORESCENCE MICROSCOPY OR WITH THE NOVA VIEW AUTOMATED FLUORESCENCE MICROSCOPE. THE PRESENCE OF ANTI-NUCLEAR ANTIBODIES CAN BE USED IN CONJUNCTION WITH OTHER

	SEROLOGICAL TESTS AND CLINICAL FINDINGS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS AND OTHER SYSTEMIC RHEUMATIC DISEASES.,QUANTA FLASH® CTD SCREEN PLUS REAGENTS(QUANTA FLASH® CTD SCREEN PLUS REAGENTS)-QUANTA FLASH CTD SCREEN PLUS IS A CHEMILUMINESCENT IMMUNOASSAY (CIA) FOR THE QUALITATIVE DETECTION OF ANTI-NUCLEAR AUTOANTIBODIES (ANA) IN HUMAN SERUM. THE PRESENCE OF ANA IS TO BE USED AS AN AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS, SJÖGREN'S SYNDROME, SCLERODERMA, IDIOPATHIC INFLAMMATORY MYOPATHY AND MIXED CONNECTIVE TISSUE DISEASE IN CONJUNCTION WITH CLINICAL FINDING AND OTHER LABORATORY TESTS. THE ASSAY COLLECTIVELY DETECTS TOTAL ANA AGAINST DSDNA, SM/RNP, RO52, RO60, SS-B, SCL-70, CENTROMERE, MI-2, KU, THTO, RNA POL III, PM/SCL AND PCNA AS WELL AS DIAGNOSTICALLY IMPORTANT ANTIBODIES AGAINST CYTOPLASMIC ANTIGENS SUCH AS JO-1 AND RIBOSOMAL-P PROTEIN.,NOVA LITE® MONKEY OESOPHAGUS IFA KIT(NOVA LITE® MONKEY OESOPHAGUS IFA KIT)-MONKEY OESOPHAGUS SECTIONS ARE INTENDED FOR USE AS A SUBSTRATE FOR THE SCREENING OF ANTIBODIES TO INTRA-EPIDERMAL ANTIGENS OR BASEMENT MEMBRANE ZONES IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF PEMPHIGUS AND BULLOUS PEMPHIGOID RESPECTIVELY. THE SECTIONS CAN ALSO BE USED FOR DETECTION OF ENDOMYSIAL ANTIBODIES AS AN AID IN THE DIAGNOSIS OF COELIAC DISEASE., QUANTA LITE® ASCA IGG ELISA (S. CEREVISIAE)(QUANTA LITE® ASCA IGG ELISA (S. CEREVISIAE))-QUANTA LITE ASCA IGG(S. CEREVISIAE) IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF ANTI-SACCHAROMYCES CEREVISIAE ANTIBODIES (ASCA) OF THE IGG CLASS IN HUMAN SERUM. THE PRESENCE OF ASCA (S. CEREVISIAE) IGG ANTIBODIES, USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, MAY AID IN THE DIAGNOSIS OF PATIENTS WITH CROHN'S DISEASE.,QUANTA FLASH® HMGCR REAGENTS(QUANTA FLASH® HMGCR REAGENTS)-QUANTA FLASH HMGCR IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG AUTOANTIBODIES AGAINST HMGCR (3-HYDROXY-3-METHYLGLUTARYL-COENZYME A REDUCTASE) ANTIGEN IN HUMAN SERUM. THE PRESENCE OF ANTI-HMGCR ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, IS AN AID IN THE DIAGNOSIS OF IDIOPATHIC INFLAMMATORY MYOPATHY (IIM,QUANTA LITE® ASCA IGA ELISA (S. CEREVISIAE)(QUANTA LITE® ASCA IGA ELISA (S. CEREVISIAE))-QUANTA LITE ASCA (S. CEREVISIAE) IGA IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-

	QUANTITATIVE DETECTION OF ANTI-SACCHAROMYCES CEREVISIAE ANTIBODIES (ASCA) OF THE IGA CLASS IN HUMAN SERUM. THE PRESENCE OF ASCA (S. CEREVISIAE) IGA ANTIBODIES, USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, MAY AID IN THE DIAGNOSIS OF PATIENTS WITH CROHN'S DISEASE. THE QUANTA LITE ASCA (S. CEREVISIAE) IGA KIT SHOULD NOT BE USED AS A SCREENING TEST FOR ASCA, SINCE SOME CROHN'S DISEASE PATIENTS DO NOT HAVE ASCA IGA ANTIBODIES. THE QUANTA LITE ASCA (S. CEREVISIAE) IGA ELISA SHOULD BE USED TO COMPLEMENT, BUT NOT TO REPLACE OR TO SUBSTITUTE FOR ASCA IGG ANTIBODY TESTING,QUANTA FLASH® M2 (MIT3) REAGENTS (QUANTA FLASH® M2 (MIT3) REAGENTS)-QUANTA FLASH M2 (MIT3) IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTI-MITOCHONDRIAL ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTI-MITOCHONDRIAL ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, IS AN AID IN THE DIAGNOSIS OF PRIMARY BILIARY CHOLANGITIS. ,QUANTA FLASH® H-TTG IGG REAGENTS(QUANTA FLASH® H-TTG IGG REAGENTS)-THE QUANTA FLASH H-TTG IGG IS A CHEMILUMINESCENT IMMUNOASSAY (CIA) FOR THE SEMI-QUANTITATIVE DETECTION OF IGG ANTI-HUMAN TISSUE TRANSGLUTAMINASE (H-TTG) ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF IGG ANTI-H-TTG ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, CAN AID IN THE DIAGNOSIS OF THE GLUTEN SENSITIVE ENTEROPATHY CELIAC DISEASE, PARTICULARLY IN PATIENTS WITH SELECTIVE IGA DEFICIENCY.,QUANTA FLASH® LKM-1 REAGENTS (QUANTA FLASH® LKM-1 REAGENTS)-QUANTA FLASH LKM-1 IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTI-LIVER/KIDNEY MICROSOME TYPE 1 ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTI-LIVER/KIDNEY MICROSOME TYPE 1 ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, IS AN AID IN THE DIAGNOSIS OF AUTOIMMUNE HEPATITIS TYPE 2. ,QUANTA LITE® JO-1 ELISA(QUANTA LITE® JO-1 ELISA)-QUANTA LITE JO-1 IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF JO-1 ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF JO-1 ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF POLYMYOSITIS AND OTHER RELATED CONNECTIVE TISSUE DISEASES.,QUANTA FLASH® APL CONTROLS (QUANTA FLASH® APL CONTROLS)-THE QUANTA FLASH APL CONTROLS ARE INTENDED FOR THE QUALITY CONTROL OF THE QUANTA FLASH/HEMOSIL ACUSTAR ANTIBODY BASED ASSAYS PERFORMED ON THE BIO-FLASH ACL ACUSTAR

	SYSTEMS. APL LOW CONTROL: CONTROL INTENDED FOR THE ASSESSMENT OF PRECISION AND ACCURACY AT NORMAL OR CUT-OFF ANTIBODY LEVELS. APL HIGH CONTROL: CONTROL INTENDED FOR THE ASSESSMENT OF PRECISION AND ACCURACY AT ABNORMAL ANTIBODY LEVELS. ,QUANTA LITE® ACA IGG III(QUANTA LITE® ACA IGG III)-QUANTA LITE ACA IGG III IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF IGG CARDIOLIPIN ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF CARDIOLIPIN ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN ASSESSING THE RISK OF THROMBOSIS IN INDIVIDUALS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) OR LUPUS-LIKE DISORDERS.,QUANTA FLASH® RF IGA REAGENTS (QUANTA FLASH® RF IGA REAGENTS)-QUANTA FLASH RF IGA IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGA RHEUMATOID FACTOR (RF) ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF IGA ANTI-RF ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, IS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA). ,NOVA LITE® ANA KSL KIT(NOVA LITE® ANA KSL KIT)-NOVA LITE ANA KSL IS AN INDIRECT IMMUNOFLUORESCENT ASSAY FOR THE SCREENING AND SEMI-QUANTITATIVE DETERMINATION OF ANTI-NUCLEAR ANTIBODIES (ANA), ANTI-MITOCHONDRIAL (AMA), ANTI-SMOOTH MUSCLE (ASMA) AND GASTRIC PARIETAL ANTIBODIES (GPA) IN HUMAN SERUM. THE PRESENCE OF ANTI-NUCLEAR ANTIBODIES CAN BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL TESTS AND CLINICAL FINDINGS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) OR OTHER CONNECTIVE TISSUE OR RHEUMATIC DISEASES.,QUANTA FLASH® RF IGM REAGENTS(QUANTA FLASH® RF IGM REAGENTS)-QUANTA FLASH RF IGM IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGM RHEUMATOID FACTOR (RF) ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF IGM ANTI-RF ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, IS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA).,QUANTA LITE® HISTONE ELISA(QUANTA LITE® HISTONE ELISA) -QUANTA LITE HISTONE IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF HISTONE ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF HISTONE ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), DRUG-INDUCED SLE AND RELATED CONNECTIVE TISSUE DISEASES, SUCH AS RHEUMATOID ARTHRITIS, DERMATOMYOSITIS AND SJÖGREN'S

	SYNDROME. DETERMINATION OF THE PATIENT'S HISTONE ANTIBODY STATUS MAY BE USEFUL IN THE DIFFERENTIAL DIAGNOSIS BETWEEN SLE AND DRUG INDUCED SLE.,QUANTA FLASH® CALPROTECTIN REAGENTS(QUANTA FLASH® CALPROTECTIN REAGENTS)-QUANTA FLASH CALPROTECTIN IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FECAL CALPROTECTIN IN EXTRACTED HUMAN STOOL SAMPLES. ELEVATED LEVELS OF FECAL CALPROTECTIN, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, CAN AID IN THE DIAGNOSIS OF INFLAMMATORY BOWEL DISEASE (IBD) (ULCERATIVE COLITIS AND CROHN'S DISEASE), AND IN THE DIFFERENTIATION OF IBD FROM IRRITABLE BOWEL SYNDROME (IBS),QUANTA FLASH® ß2GP1 IGA REAGENTS(QUANTA FLASH® ß2GP1 IGA REAGENTS)-FULLY AUTOMATED CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE MEASUREMENT OF ANTI-ß2 GLYCOPROTEIN-1 (ß2GP1) IGA ANTIBODIES IN HUMAN CITRATED PLASMA AND SERUM ON THE BIO-FLASH® INSTRUMENT, AS AN AID IN THE DIAGNOSIS OF THROMBOTIC DISORDERS RELATED TO PRIMARY AND SECONDARY ANTIPHOSPHOLIPID SYNDROME, WHEN USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS.,NOVA LITE® HEP-2 SELECT® KIT WITH DAPI(NOVA LITE® HEP-2 SELECT® KIT WITH DAPI)-THE HEP-2 SELECT KIT WITH DAPI IS AN INDIRECT IMMUNOFLUORESCENT ASSAY FOR THE SCREENING AND SEMI-QUANTITATIVE DETERMINATION OF ANTI-NUCLEAR ANTIBODIES (ANA) IN HUMAN SERUM WITH MANUAL MICROSCOPY OR WITH THE NOVA VIEW® AUTOMATED FLUORESCENT MICROSCOPE. THE PRESENCE OF ANTI-NUCLEAR ANTIBODIES IS USED IN CONJUNCTION WITH OTHER LABORATORY TESTS AND CLINICAL FINDINGS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS AND OTHER CONNECTIVE TISSUE OR RHEUMATIC DISEASES.,QUANTA FLASH® H-TTG IGA(QUANTA FLASH® H-TTG IGA)-THE QUANTA FLASH H-TTG IGA IS A CHEMILUMINESCENT IMMUNOASSAY (CIA) FOR THE SEMI-QUANTITATIVE DETECTION OF IGA ANTI-HUMAN TISSUE TRANSGLUTAMINASE (H-TTG) ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF IGA ANTI-H-TTG ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, CAN AID IN THE DIAGNOSIS OF THE GLUTEN SENSITIVE ENTEROPATHIES CELIAC DISEASE (CD) AND DERMATITIS HERPETIFORMIS (DH).,QUANTA LITE® CALPROTECTIN ELISA(QUANTA LITE® CALPROTECTIN ELISA)-QUANTA LITE CALPROTECTIN IS A QUANTITATIVE ELISA FOR DETECTING CONCENTRATION OF FECAL CALPROTECTIN. QUANTA LITE CALPROTECTIN CAN BE USED AS AN IN VITRO DIAGNOSTIC TO AID IN THE DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD, CROHN'S DISEASE AND ULCERATIVE COLITIS) AND TO

	DIFFERENTIATE IBD FROM IRRITABLE BOWEL SYNDROME (IBS) IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS., QUANTA FLASH™ ACL IGA REAGENTS(QUANTA FLASH™ ACL IGA REAGENTS)-FULLY AUTOMATED CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE MEASUREMENT OF ANTI-CARDIOLIPIN (ACL) IGA ANTIBODIES IN HUMAN CITRATED PLASMA AND SERUM ON THE BIO-FLASH®, AS AN AID IN THE DIAGNOSIS OF THROMBOTIC DISORDERS RELATED TO PRIMARY AND SECONDARY ANTIPHOSPHOLIPID SYNDROME (APS), WHEN USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS., QUANTA LITE® ENA 4 ELISA SM, RNP, SS-A AND SS-B SCREENING TEST(QUANTA LITE® ENA 4 ELISA SM, RNP, SS-A AND SS-B SCREENING TEST)-QUANTA LITE ENA 4 IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF SM, RNP, SS-A (60KDA AND 52KDA) AND SS-B ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF THESE ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AND RELATED CONNECTIVE TISSUE DISEASES, SUCH AS SJÖGREN'S SYNDROME.,QUANTA LITE®ß2 GPI IGG ELISA(QUANTA LITE®ß2 GPI IGG ELISA)-QUANTA LITE 2 GPI IGG IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF 2 GPI IGG ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF 2 GPI IGG ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF CERTAIN AUTOIMMUNE DISEASE THROMBOTIC DISORDERS, SUCH AS THOSE SECONDARY TO SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) OR OTHER LUPUS-LIKE THROMBOTIC DISEASES.,QUANTA LITE® GP210 ELISA(QUANTA LITE® GP210 ELISA)-THE QUANTA LITE GP210 KIT IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF ANTI-GP210 ANTIBODY OF THE IGG CLASS IN HUMAN SERUM. THIS TEST IS INTENDED TO AID IN THE DIAGNOSIS OF PRIMARY BILIARY CIRRHOSIS (PBC).,QUANTA LITE® SS-A ELISA(QUANTA LITE® SS-A ELISA)-QUANTA LITE SS-A IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF SS-A (60KDA AND 52KDA) ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF SS-A ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AND RELATED CONNECTIVE TISSUE DISEASES, SUCH AS SJOGREN'S SYNDROME.,QUANTA FLASH® DSDNA REAGENTS(QUANTA FLASH® DSDNA REAGENTS)-QUANTA

	FLASH DSDNA IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTI-DOUBLE STRANDED DEOXYRIBONUCLEIC ACID (DSDNA) ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTI-DSDNA ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, IS AN AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS.,QUANTA LITE® M2 EP (MIT3) ELISA(QUANTA LITE® M2 EP (MIT3) ELISA)-QUANTA LITE M2 EP (MIT3) ELISA IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF MITOCHONDRIA ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF MITOCHONDRIA ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF PRIMARY BILIARY CIRRHOSIS.,QUANTA FLASH® JO-1 REAGENTS(QUANTA FLASH® JO-1 REAGENTS)-QUANTA FLASH JO-1 IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTI-JO-1 ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTI-JO-1 ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, IS AN AID IN THE DIAGNOSIS OF IDIOPATHIC INFLAMMATORY MYOPATHY.,QUANTA LITE® ACTIN IGG ELISA (QUANTA LITE® ACTIN IGG ELISA)-QUANTA LITE ACTIN IGG IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF IGG ANTIBODIES TO THE ACTIN COMPONENT OF SMOOTH MUSCLE IN HUMAN SERUM. THE PRESENCE OF ACTIN ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF AUTOIMMUNE LIVER DISEASES SUCH AS AUTOIMMUNE HEPATITIS (AIH) AND PRIMARY BILIARY CIRRHOSIS (PBC).,NOVA LITE® ANCA FORMALIN KIT(NOVA LITE® ANCA FORMALIN KIT)-THIS PRODUCT (KIT OR SUBSTRATE SLIDES) IS INTENDED FOR USE IN THE SCREENING AND TITRATION OF CIRCULATING ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA). THESE ANTIBODIES ARE MARKERS FOR THE DIAGNOSIS AND TREATMENT OF WEGENER'S GRANULOMATOSIS AND OTHER SYSTEMIC VASCULITIDES.,QUANTA LITE® SS-B ELISA(QUANTA LITE® SS-B ELISA)-QUANTA LITE SS-B IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF SS-B ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF SS-B ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AND RELATED CONNECTIVE TISSUE DISEASES, SUCH AS SJOGREN'S SYNDROME.,QUANTA FLASH® RIBOSOMAL P CALIBRATORS(QUANTA FLASH® RIBOSOMAL P CALIBRATORS)-QUANTA FLASH RIBOSOMAL

	P CALIBRATORS ARE INTENDED FOR USE WITH THE QUANTA FLASH RIBOSOMAL P CHEMILUMINESCENT IMMUNOASSAY FOR THE DETERMINATION OF IGG ANTI-RIBOSOMAL P ANTIBODIES IN HUMAN SERUM. EACH CALIBRATOR ESTABLISHES A POINT OF REFERENCE FOR THE WORKING CURVE THAT IS USED TO CALCULATE UNIT VALUES.,QUANTA LITE® PHOSPHATIDYLSERINE IGG ELISA(QUANTA LITE® PHOSPHATIDYLSERINE IGG ELISA)-THIS ASSAY IS INTENDED FOR THE IN-VITRO MEASUREMENT OF IGG ANTI-PHOSPHATIDYLSERINE ANTIBODIES IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF ANTI-PHOSPHOLIPID SYNDROME (APS). SUFFICIENT MATERIALS ARE SUPPLIED TO ALLOW A MAXIMUM OF 41 SAMPLES TO BE TESTED IN DUPLICATE OR 89 IN SINGLE, WITH A CALIBRATION CURVE AND A POSITIVE AND NEGATIVE CONTROL., QUANTA FLASH® SS-B REAGENTS(QUANTA FLASH® SS-B REAGENTS)-QUANTA FLASH SS-B IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTI-SS-B AUTOANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTI-SS-B AUTOANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS IS AN AID IN THE DIAGNOSIS OF SJÖGREN'S SYNDROME AND SYSTEMIC LUPUS ERYTHEMATOSUS.,QUANTA LITE® HA DSDNA ELISA(QUANTA LITE® HA DSDNA ELISA)-THIS ASSAY IS INTENDED FOR THE IN-VITRO MEASUREMENT OF SPECIFIC, HIGH AVIDITY IGG AUTOANTIBODIES AGAINST DOUBLE STRANDED DEOXYRIBONUCLEIC ACID (DSDNA) PRESENT IN HUMAN SERUM, AS AN AID TO THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), IN CONJUNCTION WITH OTHER SEROLOGICAL TEST RESULTS AND CLINICAL FINDINGS. SUFFICIENT MATERIALS ARE SUPPLIED TO ALLOW A MAXIMUM OF 40 SAMPLES TO BE TESTED IN DUPLICATE OR 88 IN SINGLE, WITH A CALIBRATION CURVE AND POSITIVE, NEGATIVE AND SINGLE STRANDED DNA CONTROLS.,QUANTA FLASH® ENA7 REAGENTS (QUANTA FLASH® ENA7 REAGENTS)-QUANTA FLASH ENA7 IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE SCREENING OF IGG AUTOANTIBODIES TO SM, RNP, RO60 (SS-A), RO52/TRIM21, SS-B (LA), SCL-70 (TOPOISOMERASE I) AND JO-1 IN HUMAN SERUM. THE PRESENCE OF THESE AUTOANTIBODIES IS USED AS AN AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), SYSTEMIC SCLEROSIS (SSC), POLYMYOSITIS (PM), DERMATOMYOSITIS (DM), SJÖGREN'S SYNDROME (SJS) AND MIXED CONNECTIVE TISSUE DISEASE (MCTD) IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS.,QUANTA LITE® LKM-1 ELISA(QUANTA LITE® LKM-1 ELISA)-QUANTA LITE LKM-1 IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF LKM-1 ANTIBODIES IN HUMAN

	SERUM. THE PRESENCE OF LKM-1 ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, IS AN AID IN THE DIAGNOSIS OF AUTOIMMUNE HEPATITIS TYPE 2.,QUANTA FLASH® DFS70 CALIBRATORS(QUANTA FLASH® DFS70 CALIBRATORS)-THE QUANTA FLASH DFS70 CALIBRATORS ARE INTENDED FOR USE WITH THE QUANTA FLASH DFS70 CHEMILUMINESCENT IMMUNOASSAY (CIA) ON THE BIO-FLASH INSTRUMENT. EACH CALIBRATOR ESTABLISHES A POINT OF REFERENCE FOR THE WORKING CURVE THAT IS USED TO DETERMINE CHEMILUMINESCENT UNIT (CU) VALUES IN THE MEASUREMENT OF DFS70 ANTIBODIES IN SERUM.,QUANTA LITE® GLIADIN IGG II ELISA (QUANTA LITE® GLIADIN IGG II ELISA)-QUANTA LITE GLIADIN IGG II IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF GLIADIN IGG ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF GLIADIN ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF CELIAC DISEASE., QUANTA FLASH® RO60 REAGENTS(QUANTA FLASH® RO60 REAGENTS)-QUANTA FLASH RO60 IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTI-RO60 AUTOANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTI-RO60 AUTOANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, AIDS IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS AND SJÖGREN'S SYNDROME., QUANTA LITE® PR-3 IGG ELISA(QUANTA LITE® PR-3 IGG ELISA)-QUANTA LITE PR-3 IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF IGG AUTOANTIBODIES TO SERINE PROTEASE 3 (PR-3) IN HUMAN SERUM. THIS TEST IS TO BE USED IN CONJUNCTION WITH OTHER CLINICAL FINDINGS TO AID IN ASSESSMENT OF CERTAIN AUTOIMMUNE VASCULITIDES SUCH AS WEGENER'S GRANULOMATOSIS.,QUANTA LITE® RF IGG ELISA(QUANTA LITE® RF IGG ELISA)-QUANTA LITE RF IGG IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF IGG RHEUMATOID FACTOR (RF) ANTIBODIES IN PATIENT SERA. THE PRESENCE OF THESE ANTIBODIES, WHEN CONSIDERED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS, IS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA).,QUANTA LITE® CENTROMERE ELISA(QUANTA LITE® CENTROMERE ELISA)-QUANTA LITE CENTROMERE (CENP-A & CENP-B) IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF CENTROMERE ANTIBODIES, SPECIFICALLY REACTIVE TO THE CENP-A AND CENP-B ANTIGENS IN HUMAN SERUM. DETECTION OF THESE ANTIBODIES IS AN AID IN DIAGNOSIS OF

	CERTAIN CONNECTIVE TISSUE DISEASES SUCH AS THE CREST VARIANT OF SCLERODERMA.,QUANTA LITE® SP100 ELISA(QUANTA LITE® SP100 ELISA)-THE QUANTA LITE SP100 KIT IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF ANTI-SP100 ANTIBODY OF THE IGG CLASS IN HUMAN SERUM. THIS TEST IS INTENDED TO AID IN THE DIAGNOSIS OF PRIMARY BILIARY CIRRHOSIS (PBC).,QUANTA LITE® C1Q CIC ELISA(QUANTA LITE® C1Q CIC ELISA)-THIS ASSAY IS DESIGNED FOR THE IN-VITRO MEASUREMENT OF CIRCULATING IMMUNE COMPLEXES (CIC) THAT BIND C1Q, PRESENT IN HUMAN SERUM. IT IS INTENDED FOR THE DETERMINATION OF CIC IN SERUM OF PATIENTS WITH VARIOUS AUTOIMMUNE AND OTHER CIC-RELATED DISEASES, AND IS USED IN CONJUNCTION WITH OTHER CLINICAL FINDINGS.,QUANTA FLASH® DGP IGG REAGENTS(QUANTA FLASH® DGP IGG REAGENTS)-THE QUANTA FLASH DGP IGG IS A CHEMILUMINESCENT IMMUNOASSAY (CIA) FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTI-DEAMIDATED GLIADIN PEPTIDE (DGP) ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF IGG ANTI-DGP ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, CAN AID IN THE DIAGNOSIS OF CELIAC DISEASE IN IGA SUFFICIENT AND IGA DEFICIENT PATIENTS, AS WELL AS DERMATITIS HERPETIFORMIS.,QUANTA LITE® GBM ELISA (QUANTA LITE® GBM ELISA)-QUANTA LITE GBM IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF GLOMERULAR BASEMENT MEMBRANE (GBM) IGG ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF GBM ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF AUTOIMMUNE RENAL DISORDERS SUCH AS GOODPASTURE'S SYNDROME.,QUANTA FLASH® DGP SCREEN REAGENTS(QUANTA FLASH® DGP SCREEN REAGENTS)-THE QUANTA FLASH DGP SCREEN IS A CHEMILUMINESCENT IMMUNOASSAY (CIA) FOR THE SEMI-QUANTITATIVE DETECTION OF IGG AND IGA ANTI-DEAMIDATED GLIADIN PEPTIDE (DGP) ANTIBODIES IN HUMAN SERUM ON THE BIO-FLASH® INSTRUMENT. IT IS AN AID IN THE DIAGNOSIS OF CELIAC DISEASE AND DERMATITIS HERPETIFORMIS IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS.,QUANTA LITE® SLA ELISA (SOLUBLE LIVER ANTIGEN)(QUANTA LITE® SLA ELISA (SOLUBLE LIVER ANTIGEN))-QUANTA LITE SLA (SOLUBLE LIVER ANTIGEN) IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF SLA ANTIBODIES OF THE IGG CLASS IN HUMAN SERUM. THE PRESENCE OF SLA ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE

	DIAGNOSIS OF CONDITIONS WITH ELEVATED LEVELS OF SLA ANTIBODY INCLUDING AUTOIMMUNE HEPATITIS (AIH).,QUANTA LITE® PBC SCREEN IGG/IGA ELISA(QUANTA LITE® PBC SCREEN IGG/IGA ELISA)-THE QUANTA LITE PBC SCREEN IGG/IGA ELISA IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF MITOCHONDRIAL ANTIBODIES, GP210 ANTIBODIES AND SP100 ANTIBODIES OF THE IGG AND/OR IGA CLASS IN HUMAN SERUM. THE PRESENCE OF MITOCHONDRIAL, GP210 AND SP100 ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF PRIMARY BILIARY CIRRHOSIS,NOVA LITE® HEP-2 ANA KITS(NOVA LITE® HEP-2 ANA KITS/SUBSTRATE SLIDES)-NOVA LITE HEP-2 IS AN INDIRECT IMMUNOFLUORESCENT ASSAY FOR THE SCREENING AND SEMI-QUANTITATIVE DETERMINATION OF ANTI-NUCLEAR ANTIBODIES (ANA) IN HUMAN SERUM. THE PRESENCE OF ANTI-NUCLEAR ANTIBODIES CAN BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL TESTS AND CLINICAL FINDINGS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) OR OTHER CONNECTIVE TISSUE OR RHEUMATIC DISEASES.,QUANTA LITE® F-ACTIN IGA ELISA(QUANTA LITE® F-ACTIN IGA ELISA)-QUANTA LITE F-ACTIN IGA IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF IGA ANTIBODIES TO THE F-ACTIN COMPONENT OF SMOOTH MUSCLE IN HUMAN SERUM. IN PATIENTS WITH CLINICAL FINDINGS CONSISTENT WITH CELIAC DISEASE, THE PRESENCE ANTI-F-ACTIN IGA ANTIBODIES MAY ASSIST IN ESTIMATING THE LIKELIHOOD OF SIGNIFICANT INTESTINAL VILLOUS ATROPHY.,QUANTA LITE® SCL-70 ELISA(QUANTA LITE® SCL-70 ELISA)-QUANTA LITE SCL-70 IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF SCL-70 ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF SCL-70 ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF SCLERODERMA.,QUANTA FLASH® RIBOSOMAL P CONTROLS(QUANTA FLASH® RIBOSOMAL P CONTROLS)-QUANTA FLASH RIBOSOMAL P CONTROLS ARE INTENDED FOR USE WITH THE QUANTA FLASH RIBOSOMAL P CHEMILUMINESCENT IMMUNOASSAY FOR QUALITY CONTROL IN THE DETERMINATION OF IGG ANTI-RIBOSOMAL P ANTIBODIES IN HUMAN SERUM.,QUANTA LITE® MPO SC ELISA(QUANTA LITE® MPO SC ELISA)-THIS ASSAY IS INTENDED FOR THE IN-VITRO MEASUREMENT OF SPECIFIC IGG AUTOANTIBODIES AGAINST MYELOPEROXIDASE (MPO) PRESENT IN SERUM, AS AN AID TO THE DIAGNOSIS OF CERTAIN TYPES OF AUTOIMMUNE VASCULITIS, INCLUDING CRESCENTRIC GLOMERULONEPHRITIS AND MICROSCOPIC POLYARTERITIS, IN

	CONJUNCTION WITH OTHER CLINICAL FINDINGS. SUFFICIENT MATERIALS ARE SUPPLIED TO ALLOW A MAXIMUM OF 41 SAMPLES TO BE TESTED IN DUPLICATE OR 89 IN SINGLE, WITH A CALIBRATION CURVE AND A POSITIVE AND NEGATIVE CONTROL.,QUANTA LITE® H-TTG SCREEN ELISA(QUANTA LITE® H-TTG SCREEN ELISA)-QUANTA LITE H-TTG SCREEN IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF IGA AND IGG ANTIBODIES TO HUMAN TISSUE TRANSGLUTAMINASE (H-TTG) IN HUMAN SERUM. THE PRESENCE OF THESE ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF IGA SUFFICIENT AND IGA DEFICIENT CELIAC DISEASE AS WELL AS DERMATITIS HERPETIFORMIS.,QUANTA LITE® CCP3 IGG ELISA(QUANTA LITE® CCP3 IGG ELISA)-THE QUANTA LITE CCP3 IGG ELISA IS A SEMIQUANTITATIVE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE DETECTION OF IGG ANTI-CCP3 (CYCLIC CITRULLINATED PEPTIDE 3) ANTIBODIES IN PATIENT SERA OR CITRATED OR EDTA PLASMA. THE PRESENCE OF THESE ANTIBODIES, WHEN CONSIDERED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS, IS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS.,QUANTA FLASH® DGP IGA REAGENTS(QUANTA FLASH® DGP IGA REAGENTS)-THE QUANTA FLASH DGP IGA IS A CHEMILUMINESCENT IMMUNOASSAY (CIA) FOR THE SEMI-QUANTITATIVE DETERMIANTION OF IGA ANTI-DEAMIDATED GLIADIN PEPTIDE (DGP) ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF IGA ANTI-DGP ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, CAN AID IN THE DIAGNOSIS OF THE GLUTEN SENSITIVE ENTEROPATHIES: CELIAC DISEASE AND DERMATITIS HERPETIFORMIS.,QUANTA LITE® INTRINSIC FACTOR ELISA(QUANTA LITE® INTRINSIC FACTOR ELISA)-THE QUANTA LITE INTRINSIC FACTOR ELISA IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF INTRINSIC FACTOR ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF INTRINSIC FACTOR ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF PERNICIOUS ANEMIA.,QUANTA FLASH® ß2GP1-DOMAIN1 CONTROLS(QUANTA FLASH® ß2GP1-DOMAIN1 CONTROLS)-THE QUANTA FLASH ß2GP1-DOMAIN1 CONTROLS ARE INTENDED FOR QUALITY CONTROL PURPOSES OF THE QUANTA FLASH ß2GP1-DOMAIN1 CHEMILUMINESCENT IMMUNOASSAY (CIA) KIT.,QUANTA LITE® SS-A 52 ELISA(QUANTA LITE® SS-A 52 ELISA)-THE QUANTA LITE SS-A 52 ELISA IS A SEMIQUANTITATIVE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE DETECTION OF IGG ANTI-SS-A 52 ANTIBODIES IN PATIENT SERA. THE PRESENCE OF THESE

	ANTIBODIES, WHEN CONSIDERED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS, IS AN AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), SJÖGREN'S SYNDROME (SS), SYSTEMIC SCLEROSIS (SSC), POLYMYOSITIS (PM) AND DERMATOMYOSITIS (DM).,QUANTA FLASH® DGP IGG CONTROLS (QUANTA FLASH® DGP IGG CONTROLS)-THE QUANTA FLASH DGP IGG CONTROLS ARE INTENDED FOR QUALITY CONTROL PURPOSES OF THE QUANTA FLASH DGP IGG CHEMILUMINESCENT IMMUNOASSAY (CIA) KIT RUN ON A BIO-FLASH® INSTRUMENT.,NOVA LITE® ANCA ANTI-NEUTROPHIL CYTOPLASMIC AUTOANTIBODY REAGENTS(NOVA LITE® ANCA ANTI-NEUTROPHIL CYTOPLASMIC AUTOANTIBODY REAGENTS)-AN INDIRECT IMMUNOFLUORESCENT TEST SYSTEM UTILIZING ETHANOL-FIXED HUMAN NEUTROPHIL SUBSTRATE SLIDES FOR DETECTION OF ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA) IN HUMAN SERUM. DETECTION OF ANCA WHEN USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS AIDS IN THE ASSESSMENT OF VARIOUS SYSTEMIC VASCULITIDES., QUANTA LITE® H. PYLORI IGG ELISA(QUANTA LITE® H. PYLORI IGG ELISA)-THE QUANTA LITE H. PYLORI IGG KIT IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO H. PYLORI (HELICOBACTER PYLORI) IN HUMAN SERUM. THIS TEST IS INTENDED TO AID IN THE DIAGNOSIS OF H. PYLORI INFECTIONS IN ADULT PATIENTS WITH CLINICAL SIGNS AND SYMPTOMS OF GASTROINTESTINAL DISEASE.,NOVA LITE® MONKEY OESOPHAGUS IFA KIT(NOVA LITE® MONKEY OESOPHAGUS IFA KIT)-MONKEY OESOPHAGUS SECTIONS ARE INTENDED FOR USE AS A SUBSTRATE FOR THE SCREENING OF ANTIBODIES TO INTRA-EPIDERMAL ANTIGENS OR BASEMENT MEMBRANE ZONES IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF PEMPHIGUS AND BULLOUS PEMPHIGOID RESPECTIVELY. THE SECTIONS CAN ALSO BE USED FOR DETECTION OF ENDOMYSIAL ANTIBODIES AS AN AID IN THE DIAGNOSIS OF COELIAC DISEASE.,QUANTA FLASH® DFS70 CONTROLS(QUANTA FLASH® DFS70 CONTROLS)-THE QUANTA FLASH DFS70 CONTROLS ARE INTENDED FOR QUALITY CONTROL PURPOSES OF THE QUANTA FLASH DFS70 CHEMILUMINESCENT IMMUNOASSAY (CIA) KIT RUN ON A BIO-FLASH INSTRUMENT., QUANTA LITE® RNA POL III ELISA(QUANTA LITE® RNA POL III ELISA)-THE QUANTA LITE RNA POL III ELISA IS A SEMIQUANTITATIVE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE DETECTION OF IGG ANTI-RNA POLYMERASE III ANTIBODIES IN PATIENT SERA. THE PRESENCE OF THESE ANTIBODIES, WHEN CONSIDERED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS, IS AN AID IN THE DIAGNOSIS OF SYSTEMIC SCLEROSIS (SCLERODERMA) WITH INCREASED INCIDENCE OF SKIN

	INVOLVEMENT AND RENAL CRISIS.,QUANTA LITE® CHROMATIN ELISA(QUANTA LITE® CHROMATIN ELISA)-QUANTA LITE CHROMATIN IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF CHROMATIN ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF CHROMATIN ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF DRUG-INDUCED LUPUS (DIL) AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE).,QUANTA LITE® THYROID T ELISA(QUANTA LITE® THYROID T ELISA)-QUANTA LITE THYROID T IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF THYROGLOBULIN AUTOANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTIBODIES TO HUMAN THYROGLOBULIN ANTIGEN CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF HASHIMOTO'S THYROIDITIS.,QUANTA FLASH® DGP IGG CALIBRATORS(QUANTA FLASH® DGP IGG CALIBRATORS)-THE QUANTA FLASH DGP IGG CALIBRATORS ARE INTENDED FOR USE WITH THE QUANTA FLASH DGP IGG CHEMILUMINESCENT IMMUNOASSAY (CIA) ON THE BIO-FLASH® INSTRUMENT. EACH CALIBRATOR ESTABLISHES A POINT OF REFERENCE FOR THE WORKING CURVE THAT IS USED TO DETERMINE CHEMILUMINESCENT UNIT (CU) VALUES IN THE MEASUREMENT OF IGG ANTI-DGP ANTIBODIES IN SERUM.,NOVA LITE® DSDNA CRITHIDIA LUCILIAE KITS/SUBSTRATE SLIDES(NOVA LITE® DSDNA CRITHIDIA LUCILIAE KITS/SUBSTRATE SLIDES)-NOVA LITE DSDNA CRITHIDIA LUCILIAE IS AN INDIRECT IMMUNOFLUORESCENT ASSAY FOR THE SCREENING AND SEMI-QUANTITATIVE DETERMINATION OF ANTI-DOUBLE STRANDED DNA (DSDNA) IN HUMAN SERUM. THE PRESENCE OF ANTI-DOUBLE STRANDED DNA CAN BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL TESTS AND CLINICAL FINDINGS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)., QUANTA FLASH® SM REAGENTS(QUANTA FLASH® SM REAGENTS)-THE QUANTA FLASH SM IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTI-SM ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTI-SM ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, CAN AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE).,QUANTA LITE® ANA ELISA(QUANTA LITE® ANA ELISA)-QUANTA LITE ANA IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF ANTI-NUCLEAR ANTIBODIES (ANA) IN HUMAN SERUM. THE PRESENCE OF ANA CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF RHEUMATIC DISEASES SUCH AS SYSTEMIC LUPUS

	ERYTHEMATOSUS, SJÖGREN'S SYNDROME, SCLERODERMA, AND MIXED CONNECTIVE TISSUE DISEASE. THE ASSAY COLLECTIVELY DETECTS, IN ONE WELL, TOTAL ANA AGAINST CHROMATIN (DSDNA AND HISTONES), SM/RNP, SS-A, SS-B, SCL-70, CENTROMERE AND PCNA AS WELL AS ANTIBODIES AGAINST DIAGNOSTICALLY IMPORTANT CYTOPLASMIC ANTIGENS SUCH AS JO-1, MITOCHONDRIA (M-2) AND RIBOSOMAL-P PROTEIN. SERA POSITIVE FOR UNIDENTIFIED ANTIGENS BY THE TRADITIONAL INDIRECT IMMUNOFLUORESCENT ANTIBODY TEST ON HEP-2 CELLS MAY ALSO BE DETECTED.,QUANTA FLASH® ENA7 CALIBRATORS(QUANTA FLASH® ENA7 CALIBRATORS)-QUANTA FLASH ENA7 CALIBRATORS ARE INTENDED FOR USE WITH THE QUANTA FLASH ENA7 REAGENTS FOR THE DETERMINATION OF IGG AUTOANTIBODIES TO SM, RNP, RO60 (SS-A), RO52/TRIM21, SS-B (LA), SCL-70 (TOPOISOMERASE I) AND JO-1 IN HUMAN SERUM. EACH CALIBRATOR ESTABLISHES A POINT OF REFERENCE FOR THE WORKING CURVE THAT IS USED TO CALCULATE THE UNIT VALUES.,QUANTA LITE® GPA ELISA(QUANTA LITE® GPA ELISA)-QUANTA LITE GPA (GASTRIC PARIETAL CELL ANTIBODY) KIT IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF GASTRIC PARIETAL CELL (H+/K+) ATPASE ANTIBODIES OF THE IGG CLASS IN HUMAN SERUM. THE PRESENCE OF GASTRIC PARIETAL CELL (H+/K+) ATPASE ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF CONDITIONS WITH ELEVATED LEVELS OF ANTI-GASTRIC PARIETAL CELL (H+/K+) ATPASE ANTIBODIES INCLUDING PERNICIOUS ANEMIA.,QUANTA FLASH® RNP REAGENTS(QUANTA FLASH® RNP REAGENTS)-THE QUANTA FLASH RNP IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTI-RIBONUCLEOPROTEIN (RNP) ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTI-RNP ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, CAN AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AND MIXED CONNECTIVE TISSUE DISEASE (MCTD).,QUANTA LITE® ENA 5 ELISA SM, RNP, SS-A, SS-B AND SCL-70 SCREENING TEST(QUANTA LITE® ENA 5 ELISA SM, RNP, SS-A, SS-B AND SCL-70 SCREENING TEST)-QUANTA LITE ENA 5 IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF SM, RNP, SS-A (60KDA AND 52KDA), SS-B AND SCL-70 ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF THESE ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), AND RELATED CONNECTIVE TISSUE DISEASES, SUCH AS SJOGREN'S

	SYNDROME.,QUANTA LITE® H. PYLORI IGA ELISA(QUANTA LITE® H. PYLORI IGA ELISA)-THE QUANTA LITE H. PYLORI IGA KIT IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUALITATIVE DETECTION OF IGA ANTIBODIES TO H. PYLORI (HELICOBACTER PYLORI) IN HUMAN SERUM. THIS TEST IS INTENDED TO AID IN THE DIAGNOSIS OF H. PYLORI INFECTION IN ADULT PATIENTS 18 YEARS OR OLDER WITH CLINICAL SIGNS AND SYMPTOMS OF GASTROINTESTINAL DISEASE. THE QUANTA LITE H. PYLORI IGA SHOULD BE PERFORMED AND INTERPRETED IN CONJUNCTION WITH THE QUANTA LITE H. PYLORI IGG FOR THE DETECTION OF IGG ANTIBODIES TO H. PYLORI.,QUANTA FLASH® GBM REAGENTS(QUANTA FLASH® GBM REAGENTS)-THE QUANTA FLASH GBM IS A CHEMILUMINESCENT IMMUNOASSAY (CIA) FOR THE SEMI-QUANTITATIVE DETECTION OF IGG ANTI-GLOMERULAR BASEMENT MEMBRANE (GBM) AUTOANTIBODIES IN HUMAN SERUM ON THE BIO-FLASH® INSTRUMENT. QUANTA FLASH GBM IS AN AID IN THE DIAGNOSIS OF GOODPASTURE'S SYNDROME IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS.,NOVA LITE® MONKEY OESOPHAGUS IFA KIT/SLIDES(NOVA LITE® MONKEY OESOPHAGUS IFA KIT/SLIDES)-MONKEY OESOPHAGUS SECTIONS ARE INTENDED FOR USE AS A SUBSTRATE FOR THE SCREENING OF ANTIBODIES TO INTRA-EPIDERMAL ANTIGENS OR BASEMENT MEMBRANE ZONES IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF PEMPHIGUS AND BULLOUS PEMPHIGOID RESPECTIVELY. THE SECTIONS CAN ALSO BE USED FOR DETECTION OF ENDOMYSIAL ANTIBODIES AS AN AID IN THE DIAGNOSIS OF COELIAC DISEASE., NOVA LITE® AUTOANTIBODY CONTROLS (AUTO AB PANEL)(NOVA LITE® AUTOANTIBODY CONTROLS (AUTO AB PANEL))-NOVA LITE AUTOANTIBODY CONTROLS ARE FOR USE AS QUALITY CONTROL SAMPLES AND AS AIDS TO IMPROVE USER PROFICIENCY IN DETECTING AUTOANTIBODIES WITH NOVA LITE AUTOANTIBODY IMMUNOFLUORESCENCE TEST KITS.,QUANTA FLASH® MPO REAGENTS(QUANTA FLASH® MPO REAGENTS)-THE QUANTA FLASH MPO IS A CHEMILUMINESCENT IMMUNOASSAY (CIA) FOR THE SEMI-QUANTITATIVE DETECTION OF IGG ANTI-MYELOPEROXIDASE (MPO) AUTOANTIBODIES IN HUMAN SERUM ON THE BIO-FLASH® INSTRUMENT. QUANTA FLASH MPO IS AN AID IN THE DIAGNOSIS OF MICROSCOPIC POLYANGIITIS (MPA) IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS.,QUANTA FLASH® CCP3 REAGENTS(QUANTA FLASH® CCP3 REAGENTS)-QUANTA FLASH CCP3 IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTI-CCP3 ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTI-CCP3 ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY

	TESTS, IS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS.,QUANTA FLASH® CENTROMERE REAGENTS(QUANTA FLASH® CENTROMERE REAGENTS)-QUANTA FLASH CENTROMERE IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTI-CENTROMERE PROTEIN B AUTOANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTI-CENTROMERE PROTEIN B AUTOANTIBODIES IS USED AS AN AID IN THE DIAGNOSIS OF SYSTEMIC SCLEROSIS, IN CONJUNCTION WITH CLINICAL FINDING AND OTHER LABORATORY TESTS.,QUANTA LITE® ENA PROFILE EIA(QUANTA LITE® ENA PROFILE EIA)-THIS KIT IS DESIGNED FOR THE IN-VITRO QUALITATIVE SCREENING OF HUMAN SERUM FOR THE PRESENCE OF SPECIFIC IGG AUTOANTIBODIES AGAINST EXTRACTABLE NUCLEAR ANTIGENS (ENAS) NAMELY; SSA/RO (60 AND 52KD), SSB/LA, SM, SM/RNP, SCL-70 AND JO-1, AS AN AID IN THE DIAGNOSIS OF CERTAIN SYSTEMIC RHEUMATIC DISEASES. SUFFICIENT MATERIALS ARE SUPPLIED TO ALLOW A MAXIMUM OF 12 SAMPLES TO BE TESTED ON EACH OF THE 6 ENAS IN SINGLE, WITH A CUT-OFF AND POSITIVE CONTROL.,QUANTA FLASH® DFS70 REAGENTS(QUANTA FLASH® DFS70 REAGENTS)-THE QUANTA FLASH DFS70 IS A CHEMILUMINESCENT IMMUNOASSAY (CIA) FOR THE SEMI-QUANTITATIVE DETECTION OF AUTOANTIBODIES TO DFS70 IN HUMAN SERUM. THIS TEST IS TO BE USED IN CONJUNCTION WITH CLINICAL FINDINGS TO AID IN ASSESSMENT OF CERTAIN AUTOIMMUNE DISEASES SUCH AS SYSTEMIC LUPUS ERYTHEMATOSUS.,QUANTA LITE® 2 GPI SCREENING ELISA (QUANTA LITE® 2 GPI SCREENING ELISA)-QUANTA LITE 2 GPI SCREEN IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUALITATIVE DETECTION OF IGG, IGM AND IGA ANTIBODIES TO 2 GLYCOPROTEIN I (2 GPI) IN HUMAN SERUM. 2 GPI ANTIBODIES ARE USED AS AN AID IN THE DIAGNOSIS OF CERTAIN AUTOIMMUNE THROMBOTIC DISORDERS, SUCH AS THOSE SECONDARY TO SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) OR OTHER LUPUS-LIKE DISORDERS.,NOVA LITE® IGG F-ACTIN(NOVA LITE® IGG F-ACTIN)-THE NOVA LITE IGG F-ACTIN KIT IS AN INDIRECT IMMUNOFLUORESCENT ASSAY (IFA) ON RAT INTESTINE EPITHELIAL SUBSTRATE FOR THE SCREENING AND SEMI-QUANTITATIVE DETERMINATION OF IGG ANTI-F-ACTIN ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF IGG ANTI-F-ACTIN ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF AUTOIMMUNE LIVER DISEASES SUCH AS AUTOIMMUNE HEPATITIS (AIH) AND PRIMARY BILIARY CIRRHOSIS (PBC).,QUANTA FLASH® RO52 REAGENTS(QUANTA FLASH® RO52 REAGENTS)-QUANTA FLASH RO52 IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-

	QUANTITATIVE DETERMINATION OF IGG ANTI-RO52 AUTOANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTI-RO52 AUTOANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, IS AN AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS, SJÖGREN'S SYNDROME, SYSTEMIC SCLEROSIS, IDIOPATHIC INFLAMMATORY MYOPATHIES.. QUANTA FLASH® 2GP1 -DOMAIN1 REAGENTS(QUANTA FLASH® 2GP1 -DOMAIN1 REAGENTS)-THE QUANTA FLASH ß2GP1-DOMAIN1 IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY (CIA) FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG AUTOANTIBODIES TO ß2GP1-DOMAIN1 IN HUMAN SERUM OR CITRATED PLASMA. THE PRESENCE OF ANTI-ß2GP1-DOMAIN1 AUTOANTIBODIES IS USED IN CONJUNCTION WITH CLINICAL AND OTHER LABORATORY FINDINGS AS AN AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME. THE QUANTA FLASH ß2GP1-DOMAIN1 IS NOT INTENDED TO REPLACE ASSAYS FOR ANTIBODIES AGAINST THE WHOLE ß2GP1 MOLECULE. TESTING FOR ANTIBODIES TO THE WHOLE ß2GP1 MOLECULE IS REQUIRED ACCORDING TO THE CLASSIFICATION CRITERIA FOR ANTIPHOSPHOLIPID SYNDROME.,QUANTA LITE® PHOSPHATIDYLSERINE IGA ELISA (QUANTA LITE® PHOSPHATIDYLSERINE IGA ELISA)-THIS ASSAY IS INTENDED FOR THE IN-VITRO MEASUREMENT OF IGA ANTI-PHOSPHATIDYLSERINE ANTIBODIES IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF ANTI-PHOSPHOLIPID SYNDROME (APS). SUFFICIENT MATERIALS ARE SUPPLIED TO ALLOW A MAXIMUM OF 41 SAMPLES TO BE TESTED IN DUPLICATE OR 89 IN SINGLE, WITH A CALIBRATION CURVE AND A POSITIVE AND NEGATIVE CONTROL. ,QUANTA LITE® HMGCR ELISA (QUANTA LITE® HMGCR ELISA)-THE QUANTA LITE HMGCR ELISA IS A SEMIQUANTITATIVE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE DETECTION OF ANTI-HMGCR (3-HYDROXY-3-METHYLGLUTARYL COENZYME A REDUCTASE) ANTIBODIES (IGG) IN PATIENT SERA. THE PRESENCE OF THESE ANTIBODIES, WHEN CONSIDERED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS, IS AN AID IN THE DIAGNOSIS OF POLYMYOSITIS, PARTICULARLY STATIN-INDUCED NECROTIZING MYOSITIS.,QUANTA LITE® ACA SCREEN III(QUANTA LITE® ACA SCREEN III)-QUANTA LITE ACA SCREEN III IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUALITATIVE DETECTION OF CARDIOLIPIN ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF CARDIOLIPIN ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN ASSESSING THE RISK OF THROMBOSIS IN INDIVIDUALS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) OR LUPUS-LIKE DISORDERS.,QUANTA LITE® ENA 6 ELISA SM, RNP, SS-A, SS-B, SCL-70 & JO-1 SCREENING TEST

	(QUANTA LITE® ENA 6 ELISA SM, RNP, SS-A, SS-B, SCL-70 & JO-1 SCREENING TEST)-QUANTA LITE ENA 6 IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF SM, RNP, SS-A (60KDA AND 52KDA), SS-B, SCL-70 AND JO-1 ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF THESE ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), AND RELATED CONNECTIVE TISSUE DISEASES, SUCH AS SJOGREN'S SYNDROME.,QUANTA FLASH® RIBOSOMAL P REAGENTS(QUANTA FLASH® RIBOSOMAL P REAGENTS)-THE QUANTA FLASH RIBOSOMAL P IS A CHEMILUMINESCENT IMMUNOASSAY (CIA) FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTI-RIBOSOMAL P ANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTI-RIBOSOMAL P ANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, IS AN AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE).,QUANTA LITE® RF IGM ELISA(QUANTA LITE® RF IGM ELISA)-QUANTA LITE RF IGM IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE SEMI-QUANTITATIVE DETECTION OF IGM RHEUMATOID FACTOR (RF) ANTIBODIES IN PATIENT SERA. THE PRESENCE OF THESE ANTIBODIES, WHEN CONSIDERED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS, IS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA).,QUANTA FLASH® PR3 REAGENTS (QUANTA FLASH® PR3 REAGENTS)-THE QUANTA FLASH PR3 IS A CHEMILUMINESCENT IMMUNOASSAY (CIA) FOR THE SEMI-QUANTITATIVE DETECTION OF IGG ANTI-PROTEINASE 3 (PR3) AUTOANTIBODIES IN HUMAN SERUM ON THE BIO-FLASH® INSTRUMENT. QUANTA FLASH PR3 IS AN AID IN THE DIAGNOSIS OF GRANULOMATOSIS WITH POLYANGIITIS (GPA) IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS.,QUANTA FLASH® SCL-70 REAGENTS(QUANTA FLASH® SCL-70 REAGENTS)-QUANTA FLASH SCL-70 IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG ANTI-SCL-70 AUTOANTIBODIES IN HUMAN SERUM. THE PRESENCE OF ANTI-SCL-70 AUTOANTIBODIES, IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS, AIDS IN THE DIAGNOSIS OF SYSTEMIC SCLEROSIS,NOVA LITE® ANA KSL KIT(NOVA LITE® ANA KSL KIT)-NOVA LITE ANA KSL IS AN INDIRECT IMMUNOFLUORESCENT ASSAY FOR THE SCREENING AND SEMI-QUANTITATIVE DETERMINATION OF ANTI-NUCLEAR ANTIBODIES (ANA), ANTI-MITOCHONDRIAL (AMA), ANTI-SMOOTH MUSCLE (ASMA) AND GASTRIC PARIETAL ANTIBODIES (GPA) IN HUMAN SERUM. THE PRESENCE OF ANTI-NUCLEAR ANTIBODIES CAN BE USED IN CONJUNCTION WITH OTHER

		SEROLOGICAL TESTS AND CLINICAL FINDINGS TO AID IN THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) OR OTHER CONNECTIVE TISSUE OR RHEUMATIC DISEASES.,QUANTA FLASH® ENA7 CONTROLS(QUANTA FLASH® ENA7 CONTROLS)-QUANTA FLASH ENA7 CONTROLS ARE INTENDED FOR USE WITH THE QUANTA FLASH ENA7 REAGENTS FOR QUALITY CONTROL IN THE DETERMINATION OF IGG AUTOANTIBODIES TO SM, RNP, RO60 (SS-A), RO52/TRIM21, SS-B (LA), SCL-70 (TOPOISOMERASE I) AND JO-1 IN HUMAN SERUM.,NOVA LITE® ANCA KIT(NOVA LITE® ANCA KIT)-AN INDIRECT IMMUNOFLUORESCENT TEST SYSTEM UTILIZING ETHANOL-FIXED HUMAN NEUTROPHIL SUBSTRATE SLIDES FOR DETECTION OF ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA) IN HUMAN SERUM. DETECTION OF ANCA WHEN USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS AIDS IN THE ASSESSMENT OF VARIOUS SYSTEMIC VASCULITIDES.
308	IMP/IVD/2019/000325	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MYT-CAL(MYT-CAL)-MYT-CAL IS DESIGNED FOR USE IN THE CALIBRATION OF ORPHEE HEMATOLOGY ANALYZERS.,MYT-5D(MYT-5D)-WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MYTHIC 22 HEMATOLOGY CELL COUNTERS.

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309	IMP/IVD/2019/000326	1.License Holder Name: SNIBE DIAGNOSTIC (INDIA) PRIVATE LIMITED. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HSV-2 IGG (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF HSV-2 IGG IN HUMAN SERUM. ,IGG (URINE ANALYSIS) (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN URINE.,RUBELLA IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF RUBELLA IGG IN HUMAN SERUM. ,TGA (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN AUTOANTIBODY (TGA) IN HUMAN SERUM.,PAP (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROSTATIC ACID PHOSPHATASE (PAP) IN HUMAN SERUM. ,DHEA-S (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE (DHEA-S) IN HUMAN SERUM. ,TOXO IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF TOXO IGG IN HUMAN SERUM. ,FREE TESTOSTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE IN HUMAN SERUM.,HSV-1/2 IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF HSV-1/2 IGG IN HUMAN SERUM. ,FREE ESTRIOL (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE ESTRIOL IN HUMAN SERUM.,CMV IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF CMV IGG IN HUMAN SERUM. , INSULIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM.,CA 19-9(CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 19-9 (CA 19-9) IN HUMAN SERUM. ,C-PEPTIDE (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM AND PLASMA.,RUBELLA IGM (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF RUBELLA

	IGM IN HUMAN SERUM. ,CSA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE A (CSA) IN HUMAN WHOLE BLOOD.,CA 15-3(CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 15-3 (CA 15-3) IN HUMAN SERUM. ,INTACT PTH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (INTACT PTH) IN HUMAN SERUM. ,CEA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) IN HUMAN SERUM. ,ANTI-TPO (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-TPO IN HUMAN SERUM.,NSE (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF NEURON SPECIFIC ENOLASE (NSE) IN HUMAN SERUM. ,GAD 65 (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GLUTAMIC ACID DECARBOXYLASE ANTIBODY (GAD65) IN HUMAN SERUM.,CMV IGM (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF CMV IGM IN HUMAN SERUM. ,FK 506 (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FK 506 IN HUMAN WHOLE BLOOD.,AFP (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALPHA-FETOPROTEIN (AFP) IN HUMAN SERUM. ,VITAMIN B12 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM., F-PSA(CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (F-PSA) IN HUMAN SERUM. ,25-OH VITAMIN D (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM. ,CA 125 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 125 IN HUMAN SERUM. , TROPONIN I (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TROPONIN I IN HUMAN SERUM.,TOXO IGM (CLIA)

	(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF TOXO IGM IN HUMAN SERUM. ,ALDOSTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALDOSTERONE (ALD) IN HUMAN SERUM, PLASMA AND TREATED URINE.,HSV-1/2 IGM (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF HSV-1/2 IGM IN HUMAN SERUM. ,CORTISOL (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM OR URINE,TOTAL PSA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROSTATE SPECIFIC ANTIGEN (TOTAL PSA) IN HUMAN SERUM. ,IGG (SERUM ANALYSIS) (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN SERUM.,MAGLUMI LIGHT CHECK(MAGLUMI LIGHT CHECK)-LIGHT CHECK REAGENT REQUIRED TO CHECK THE VALIDITY OF STARTER 1+2 AS WELL AS THE FUNCTIONING OF THE MEASURING AND PIPETTING UNITS. A LIGHT CHECK HAS TO BE CARRIED OUT ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,FT4 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM.,MAGLUMI REACTION MODULE(MAGLUMI REACTION MODULE)-REACTION MODULES REQUIRED FOR THE IMPLEMENTATION OF THE MAGLUMI ASSAYS ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). ,FT3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM.,MAGLUMI SYSTEM TUBING CLEANING SOLUTION(MAGLUMI SYSTEM TUBING CLEANING SOLUTION)-THE MAGLUMI SYSTEM TUBING CLEANING SOLUTION IS USED TO CLEAN THE PIPETTOR AND THE WASHER NEEDLES. IT IS USEFUL TO MINIMIZE REAGENT CARRYOVER BY REDUCING PROTEIN PRECIPITATION IN THE TUBING, AND IMPROVE ROUTINE MAINTENANCE OF THE MAGLUMI SYSTEM. THE KIT CAN ONLY BE USED WITH MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER,PRL (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PRL IN

	HUMAN SERUM.,MAGLUMI WASH CONCENTRATE(MAGLUMI WASH CONCENTRATE)-MAGLUMI WASH CONCENTRATE IS INTENDED TO BE DILUTED FOR PREPARATION OF SYSTEM LIQUID WHICH IS REQUIRED FOR WASHING THE MAGNETIC MIRCOBEADS OF THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER ,FSH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM.,MAGLUMI STARTER 1+2 (MAGLUMI STARTER 1+2)-STARTER REAGENT KIT REQUIRED TO GENERATE THE CHEMILUMINOMETRIC LIGHT SIGNAL NECESSARY FOR THE IMPLEMENTATION OF MAGLUMI ASSAYS ON THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER. ,T4 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM.,LH (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM.,IGE (CLIA)(MAGLUMI) -THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) IN HUMAN SERUM.,FERRITIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM.,IGM (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM. ,CK-MB (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MB ISOENZYME OF CREATINE KINASE (CK-MB) IN HUMAN SERUM., ESTRADIOL (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM.,PRG (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE (PRG) IN HUMAN SERUM.,IGF-I (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN-LIKE GROWTH FACTOR-(IGF-) IN HUMAN SERUM.,ANTI-IA2 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TYROSINE PHOSPHATASE-LIKE PROTEINS ANTIBODY (ANTI-IA2) IN HUMAN SERUM.,AMH (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-MULLERIAN HORMONE (AMH) IN HUMAN SERUM.,TSH (CLIA)

	(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN HUMAN SERUM., TESTOSTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM., T3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) IN HUMAN SERUM.,AI (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANGIOTENSIN (A) IN HUMAN PLASMA.

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310	IMP/IVD/2019/000327	1.License Holder Name: M/S. CPC DIAGNOSTICS PVT, LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EUROLINE LIVER PROFILE (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO FOUR DIFFERENT ANTIGENS: AMA-M2 (PYRUVATE-DEHYDROGENASE-COMPLEX), LKM-1 (LIVER-KIDNEY MICROSOMES; CYTOCHROME P450 II D6), LC-1 (CYTOSOLIC LIVER ANTIGEN TYPE 1; FORMIMINOTRANSFERASE-CYCLODEAMINASE) AND SLA/LP (SOLUBLE LIVER ANTIGEN/LIVER-PANCREAS ANTIGEN) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF PRIMARY BILIARY LIVER CIRRHOSIS (PBC), IN CASE OF AN INCREASE IN TRANSAMINASES FOR UNCLEAR REASONS AND SUSPECTED CASES OF AUTOIMMUNE HEPATITIS (AIH), IIFT: NEUROLOGY MOSAIC 1-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASSES IGA, IGG OR IGM AGAINST NEURAL ANTIGENS IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF DIFFERENT NEUROLOGICAL DISEASES.,IIFT: LIVER MOSAIC 2-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF AUTOIMMUNE HEPATITIS (AIH), PRIMARY BILIARY CHOLANGITIS (PBC), MYASTHENIA GRAVIS AND RHEUMATIC DISEASES,IIFT: NEUROLOGY MOSAIC 17-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASSES IGA, IGG OR IGM AGAINST NEURAL ANTIGENS IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF DIFFERENT NEUROLOGICAL DISEASES.,EUROPLUS KIDNEY (MONKEY) / GBM-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST GLOMERULAR AND ALVEOLAR BASEMENT MEMBRANE IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF GOODPASTURE'S SYNDROME AND GLOMERULONEPHRITIS,ANTI-VZV ELISA (IGG)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTI- BODIES OF THE IGG CLASS AGAINST VARICELLA ZOSTER VIRUS (VZV) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF VARICELLA ZOSTER VIRUS INFECTIONS,IIFT: THROMBOCYTES (HUMAN)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF IDIOPATHIC THROMBOCYTOPENIC PURPURA THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST THROMBOCYTE ANTIGENS IN PATIENT SAMPLES

	TO SUPPORT THE DIAGNOSIS OF IDIOPATHIC THROMBOCYTOPENIC PURPURA (ITP) AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE).,ANTI-VZV ELISA (IGA)-TEST SYSTEM FOR IN VITRO DETERMINATIONS OF ANTIBODIES AGAINST VARICELLA ZOSTER VIRUS (VZV) IN HUMAN SERUM OR PLASMA,IIFT MOSAIC: BASIC PROFILE 3C-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST CELL NUCLEI, MITOCHONDRIA AND SMOOTH MUSCLES IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF MANY AUTOIMMUNE DISEASES, PARTICULARY THOSE OF THE RHEUMATIC FORM.,ANTI-MUMPS VIRUS ELISA (IGM)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IGM CLASS AGAINST MUMPS VIRUS IN SERUM OR PLASMA FOR THE DIAGNOSIS OF MUMPS.,IIFT OESOPHAGUS (MONKEY) IGA-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASSES IGA OR IGG AGAINST ENDOMYSIUM IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF GLUTEN-SENSITIVE ENTEROPATHY (GSE; YOUNG CHILDREN: COELIAC DISEASE, ADULTS: NON-TROPICAL SPRUE) AND DUHRING'S DERMATITIS HERPETIFORMIS.,ANTI-MUMPS VIRUS ELISA (IGG)-THE ELISA TEST KIT PROVIDES SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST MUMPS VIRUS IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF MUMPS,EUROPLUS OESOPHAGUS (MONKEY)/ GLIADIN (GAF-3X) (IGG)-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASSES IGA OR IGG AGAINST ENDOMYSIUM AND GLIADIN IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF GLUTEN-SENSITIVE ENTEROPATHY (GSE; YOUNG CHILDREN: COELIAC DISEASE, ADULTS: NONTROPICAL SPRUE) AND DUHRING'S DERMATITIS HERPETIFORMIS.,ANTI-MEASLES VIRUS ELISA (IGM)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTI- BODIES OF THE IGM CLASS AGAINST MEASLES VIRUS IN SERUM OR PLASMA.,ANTI-HISTONES ELISA (IGG)-MEDICATION-INDUCED LUPUS ERYTHEMATOSUS, LUPUS ERYTHEMATOSUS DISSEMINATUS, RHEUMATOID ARTHRITIS. IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF AUTOIMMUNE DISEASES,ANTI-BORDETELLA FHA ELISA (IGG)-THE ELISA TEST KIT PROVIDES A QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST BORDETELLA FHA (FILAMENTOUS HAEMAGGLUTININ) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF INFECTIONS WITH BORDETELLA

	PERTUSSIS AND PARAPERTUSSIS.,EUROPLUS OESOPHAGUS (MONKEY)/ GLIADIN (GAF-3X) (IGA)-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASSES IGA OR IGG AGAINST ENDOMYSIUM AND GLIADIN IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF GLUTEN-SENSITIVE ENTEROPATHY (GSE; YOUNG CHILDREN: COELIAC DISEASE, ADULTS: NONTROPICAL SPRUE) AND DUHRING'S DERMATITIS HERPETIFORMIS.,ANTI-BORDETELLA FHA ELISA (IGA)-BORDETELLA PERTUSSIS AND PARAPERTUSSIS,IIFT: NMOSD SCREEN1 EUROPATTERN-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST AQUAPORIN-4 (AQP-4) AND MYELIN-OLIGODENDROCYTE GLYCOPROTEIN (MOG) IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF DEMYELINATING DISEASES OF THE CENTRAL NERVOUS SYSTEM.,ANTI-BORDETELLA PERTUSSIS TOXIN ELISA (IGG)-THE ELISA TEST KIT PROVIDES A QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST BORDETELLA PERTUSSIS TOXIN IN SERUM OR PLASMA FOR THE DIAGNOSIS OF BORDETELLA PERTUSSIS INFECTIONS AND WHOOPING COUGH,ANTI-SLA/LP ELISA (IGG)-INCREASE IN TRANSAMINASES FOR UNCLEAR REASONS, SUSPECTED AUTOIMMUNE HEPATITIS. IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE HEPATITIS,EUROLINE PEDIATRICS (IGE)-THE EUROLINE TEST KIT IS DESIGNED FOR SEMIQUANTITATIVE IN VITRO DETERMINATION OF ALLERGEN SPECIFIC IGE (SIGE) IN SERUM OR PLASMA, CONTRIBUTING TO THE DIAGNOSIS OF ALLERGIES. THE EUROLINE TEST KIT IS USED FOR THE DIAGNOSIS OF SENSITISATIONS THAT MAY LEAD TO ALLERGY- ASSOCIATED SYMPTOMS SUCH AS CONJUNCTIVITIS, RHINITIS OR GASTRO-INTESTINAL PROBLEMS, ANTI-RIBOSOMAL P PROTEINS ELISA (IGG)-SYSTEMIC LUPUS ERYTHEMATOSUS IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES,EUROLINE FOOD "INDIA 2" (IGE)-THE EUROLINE TEST KIT IS DESIGNED FOR SEMIQUANTITATIVE IN VITRO DETERMINATION OF ALLERGEN SPECIFIC IGE (SIGE) IN SERUM OR PLASMA, CONTRIBUTING TO THE DIAGNOSIS OF ALLERGIES. THE EUROLINE TEST KIT IS USED FOR THE DIAGNOSIS OF SENSITISATIONS THAT MAY LEAD TO ALLERGY- ASSOCIATED SYMPTOMS SUCH AS CONJUNCTIVITIS, RHINITIS OR GASTROINTESTINAL PROBLEMS.,IIFT MOSAIC: THYROID GLAND (MONKEY) / KIDNEY (RAT)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF AUTOIMMUNE THYROID DISEASES THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST THYROID

	GLAND AND THYROGLOBULIN IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF HASHIMOTO THYROIDITIS AND GRAVES' DISEASE, EUROLINE FOOD INDIA (IGE)-THE EUROLINE TEST KIT IS DESIGNED FOR SEMIQUANTITATIVE IN VITRO DETERMINATION OF ALLERGEN SPECIFIC IGE (SIGE) IN SERUM OR PLASMA CONTRIBUTING TO THE DIAGNOSIS OF ALLERGIES. THE EUROLINE TEST KIT IS USED FOR THE DIAGNOSIS OF SENSITISATIONS THAT MAY LEAD TO ALLERGY-ASSOCIATED SYMPTOMS SUCH AS CONJUNCTIVITIS, RHINITIS OR GASTRO-INTESTINAL PROBLEMS,IIFT: KIDNEY (MONKEY)-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST GLOMERULAR AND ALVEOLAR BASEMENT MEMBRANE IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF GOODPASTURE'S SYNDROME AND GLOMERULONEPHRITIS,EUROLINE AUTOIMMUNE INFLAMMATORY MYOPATHIES 16 AG (IGG)-IN-VITRO DIAGNOSTIC REAGENTSFOR THE DIAGNOSIS OF DERMATO- AND POLYMYOSITIS, IDIOPATHIC MYOSITIS, ANTISYNTHETASE SYNDROME AND OVERLAPPING SYNDROME THE EUROLINE TEST KIT PROVIDES QUALITATIVE IN VITRO DETERMINATION OF HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO 16 DIFFERENT ANTIGENS MI-2, MI-2, TIF1, MDA5, NXP2, SAE1, KU, PM-SCL100, PM-SCL75, JO-1, SRP, PL-7, PL-12, EJ, OJ AND RO-52 IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF DERMATO- AND POLYMYOSITIS, IDIOPATHIC MYOSITIS, ANTISYNTHETASE SYNDROME AND OVERLAPPING SYNDROMES.,IIFT: THYROID GLAND (MONKEY)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF AUTOIMMUNE THYROID DISEASES THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST THYROID GLAND AND THYROGLOBULIN IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF HASHIMOTO THYROIDITIS AND GRAVES' DISEASE,EUROLINE MYOSITIS ANTIGENS PROFILE 3 (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO 11 DIFFERENT ANTIGENS: MI-2, KU, PM-SCL100, PM-SCL75, JO-1, SRP, PL-7, PL-12, EJ, OJ AND RO-52 IN SERUM OR PLASMA FOR THE DIAGNOSIS OF DERMATO- AND POLYMYOSITIS, IDIOPATHIC MYOSITIS, ANTI-SYNTHETASE SYNDROME AND OVERLAPPING SYDROME.,ANTI-TETANUS TOXOID ELISA (IGG)-THE ELISA TEST KIT PROVIDES A QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST TETANUS TOXOID IN SERUM OR PLASMA FOR THE CLARIFICATION OF AN UNCLEAR IMMUNE STATUS.,EUROLINE LIVER PROFILE 2 (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR

	HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO FIVE DIFFERENT ANTIGENS: M2 (PYRUVATE-DEHYDROGENASE-COMPLEX), M2-3E (BPO, FUSION PROTEIN OF THE E2 SUBUNITS OF THE ALPHA-2-OXOACID DEHYDROGENASES OF THE INNER MITOCHONDRIAL MEMBRANE), LKM-1 (LIVER-KIDNEY MICROSOMES; CYTOCHROME P450 II D6), LC-1 (CYTOSOLIC LIVER ANTIGEN TYPE 1; FORMIMINOTRANSFERASE-CYCLODEAMINASE) AND SLA/LP (SOLUBLE LIVER ANTIGEN/LIVER-PANCREAS ANTIGEN) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF PRIMARY BILIARY LIVER CIRRHOSIS, INCREASE IN TRANSAMINASES FOR UNCLEAR REASONS, SUSPECTED AUTOIMMUNE HEPATITIS,ANTI-NUCLEOSOMES ELISA (IGG)-THE ENZYME IMMUNOASSAY (ELISA) PROVIDES SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST NUCLEOSOMES IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS.,EUROLINE PARANEOPLASTIC NEUROLOGIC SYNDROMES 12 AG (IGG)-THE EUROLINE TEST KIT PROVIDES QUALITATIVE IN VITRO DETERMINATION OF HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO 12 DIFFERENT ANTIGENS: AMPHIPHYSIN, CV2, PNMA2 (MA2/TA), RI, YO, HU, RECOVERIN, SOX1, TITIN, ZIC4, GAD65 AND TR (DNER) IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF PARANEOPLASTIC NEUROLOGICAL SYNDROMES (PNS),ANTI-IA2 ELISA (IGG)-THE ELISA TEST KIT PROVIDES A QUANTITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES AGAINST TYROSINE PHOSPHATASE (IA2) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF TYPE 1 DIABETES MELLITUS (INSULIN- DEPENDENT DIABETES MELLITUS, IDDM), EUROLINE NEURONAL ANTIGENS PROFILE 2 (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO THE 6 DIFFERENT ANTIGENS AMPHIPHYSIN, CV2, PNMA2 (MA2/TA), RI, YO AND HU IN SERUM OR PLASMA FOR THE DIAGNOSIS OF PARANEOPLASTIC NEUROLOGICAL SYNDROMES (PNS),ANTI-PCA ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF CHRONIC ATROPHIC GASTRITIS, PERNICIOUS ANEMIA, FUNICULAR MYELOSIS, VARIOUS AUTOIMMUNE ENDOCRINOPATHIES CHRONIC-ATROPHIC GASTRITIS, PERNICIOUS ANEMIA,25-OH VITAMIN D ELISA-THE ELISA TEST KIT PROVIDES QUANTITATIVE VITRO DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM OR PLASMA IN CASES OF SUSPECTED VITAMIN D DEFICIENCY OR OVERDOSING, REDUCED INTESTINAL VITAMIN D UPTAKE, HYPOCALCAEMIA, HYPOPHOSPHATAEMIA, HYPOCALCIURIA, ELEVATED ALKALINE PHOSPHATASE, REDUCED BONE MINERAL CONTENT.,EUROLINE

	NEURONAL ANTIGENS PROFILE PLUS RST (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IGG CLASS TO 9 DIFFERENT ANTIGENS (AMPHIPHYSIN, CV2, PNMA2 (MA2/TA), RI, YO, HU, RECOVERIN, SOX1 AND TITIN) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF THE PARANEOPLASTIC NEUROLOGICAL SYNDROME (PNS),ANTI-TISSUE TRANSGLUTAMINASE ELISA (IGA)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF CELIAC DISEASE,ANTI-GLUTAMIC ACID DECARBOXYLASE (65KDA) (GAD65) IIFT-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN AUTOANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST GAD65 IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS EXCLUSIVELY OF NEUROLOGICAL DISEASES, IN PARTICULAR LIMBIC ENCEPHALITIS AND STIFF-PERSON SYNDROME,ANTI-ß2-GLYCOPROTEIN 1 ELISA (IGM)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF PHOSPHOLIPID SYNDROME,IIFT: OVARY (MONKEY)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF AUTOIMMUNE DISEASES THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASSES IGA, IGG AND IGM AGAINST OVARIAN ANTIGENS IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF AUTOIMMUNE-ASSOCIATED FERTILITY DISORDERS, ANTI-ß2- GLYCOPROTEIN 1 ELISA (IGG) -IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF PHOSPHOLIPID SYNDROME,EUROPLUS GRANULOCYTE MOSAIC 32-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF MICROSCOPIC POLYANGITIS, RAPID PROGRESSIVE GLOMERULONEPHRITIS , GOODPASTURE SYNDROME AND OTHER FORMS OF VASCULITIS THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST GRANULOCYTE CYTOPLASM (ANCA) IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF THE FOLLOWING DISEASES: GRANULOMATOSIS WITH POLYANGIITIS (GPA, WEGENER'S GRANULOMATOSIS), EOSINOPHILE GRANULOMATOSIS WITH POLYANGIITIS (EGPA, CHURG-STRAUSS SYNDROME), MICROSCOPIC POLYANGIITIS (MPA), PRIMARY SCLEROSING CHOLANGITIS AND CHRONIC INFLAMMATORY BOWEL DISEASES (MAINLY ULCERATIVE COLITIS),ANTI-CARDIOLIPIN ELISA (IGM)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGM AGAINST CARDIOLIPIN IN SERUM OR PLASMA FOR THE DIAGNOSIS OF ANTI-PHOSPHOLIPID SYNDROME.,ANTI-INTRINSIC FACTOR ELISA (IGG)-PERNICIOUS ANEMIA IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF CHRONIC ATROPHIC GASTRITIS,

	PERNICIOUS ANEMIA, FUNICULAR MYELOSIS, VARIOUS AUTOIMMUNE ENDOCRINOPATHIES,ANTI-CARDIOLIPIN ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF PHOSPHOLIPID SYNDROME,IIFT: PANCREAS (MONKEY)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF TYPE 1 DIABETES MELLITUS THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST PANCREAS ISLETS (ICA) IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF DIABETES MELLITUS (TYPE I),IIFT MOSAIC: BASIC PROFILE 3A EUROPATTERN-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST CELL NUCLEI, MITOCHONDRIA AND SMOOTH MUSCLES IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF MANY AUTOIMMUNE DISEASES, PARTICULARLY THOSE OF THE RHEUMATIC FORM., MOSAIC: PANCREAS (MONKEY) / CEREBELLUM (MONKEY)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF AUTOIMMUNE DISEASES THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST PANCREAS ISLETS (ICA) IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF DIABETES MELLITUS (TYPE I),IIFT: GRANULOCYTE MOSAIC 13 EUROPATTERN-THIS TEST KIT IS DESIGNED FOR THE QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST GRANULOCYTE CYTOPLASM (ANCA) IN PATIENT SAMPLES FOR THE DIAGNOSIS OF ANCA-ASSOCIATED VASCULITIDES, FOR EXAMPLE GRANULOMATOSIS WITH POLY- ANGIITIS (WEGENER'S GRANULOMATOSIS), MICROSCOPIC POLYANGIITIS, PAUCIIMMUNE NECROTISING GLOMERULONEPHRITIS, POLYARTERITIS NODOSA, CHURG-STRAUSS SYNDROME AND PRIMARY SCLEROSING CHOLANGITIS AND CHRONIC INFLAMMATORY BOWEL DISEASES, MAINLY ULCERATIVE COLITIS.,ANTI-COLLAGEN TYPE VII ELISA (IGG) (NIL)-EPIDERMOLYSIS BULLOSA AQUISITA (EBA),EUROPLUS INTESTINE (MONKEYS)/ GLIADIN (GAF-3X) (IGA)-THIS TEST KIT IS DESIGNED FOR THE QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASSES IGA OR IGG AGAINST ENDOMYSIUM IN PATIENT SAMPLES FOR THE DIAGNOSIS OF GLUTEN-SENSITIVE ENTEROPATHIE (GSE; YOUNG CHILDREN: COELIAC DISEASE, ADULTS: NON-TROPICAL SPRUE) AND DUHRING'S DERMATITIS HERPETIFORMIS.,ANTI-TSH RECEPTOR ELISA (IGG)(NIL)-DIAGNOSIS OR EXCLUSION OF THE TREATMENT OF GRAVES' DISEASE AND THERAPY MONITORING,IIFT: CRITHIDIA LUCILIAE (ANTI-DSDNA)-THIS TEST KIT IS DESIGNED FOR

	THE QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST DSDNA IN PATIENT SAMPLES FOR THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE).,ANTI-WEST NILE VIRUS ELISA (IGG) (NIL)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IGG CLASS AGAINST WEST NILE VIRUS IN SERUM OR PLASMA,IIFT MOSAIC: HEP-20-10 / LIVER (MONKEY)-THIS TEST KIT IS DESIGNED FOR THE QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST CELL NUCLEI IN PATIENT SAMPLES FOR THE DIAGNOSIS OF MANY AUTOIMMUNE DISEASES, PARTICULARLY OF THE RHEUMATIC FORM.,IIFT: HANTAVIRUS MOSAIC 1 (IGM)(NIL)-THIS TEST KIT IS DESIGNED FOR THE QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASSES IGG OR IGM AGAINST HANTAVIRUS IN PATIENT SAMPLES FOR THE DIAGNOSIS OF HAEMORRHAGIC FEVER WITH RENAL SYNDROME, KIDNEY FAILURE, ACUTE RESPIRATORY DISTRESS SYNDROME AND HANTAVIRUS PULMONARY SYNDROME, IIFT - MOSAIC: DESMOGLEIN 1/DESMOGLEIN 3-IN VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE BULLOUS DERMATOSES,IIFT MOSAIC: STOMACH (RAT) / VSM47 CELLS (ANTI-F-ACTIN)(NIL)-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF AUTOIMMUNE HEPATITIS (AIH), PRIMARY BILIARY CHOLANGITIS (PBC), MYASTHENIA GRAVIS AND RHEUMATIC DISEASES,IIFT: LIVER MOSAIC 8-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF AUTOIMMUNE HEPATITIS (AIH), PRIMARY BILIARY CHOLANGITIS (PBC), MYASTHENIA GRAVIS AND RHEUMATIC DISEASES.,AVIDITY: ANTI-WEST NILE VIRUS ELISA (IGG) (NIL)-THIS TEST KIT IS INTENDED FOR THE AVIDITY DETERMINATION OF IGG CLASS ANTIBODIES AGAINST WEST NILE VIRUS IN HUMAN SERUM OR PLASMA,ANTI-PHOSPHOLIPASE A2 RECEPTOR (PLA2R) IIFT-THIS TEST KIT IS DESIGNED FOR THE QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST PHOSPHOLIPASE A2 RECEPTOR (PLA2R) IN PATIENT SAMPLES FOR THE DIAGNOSIS OF PRIMARY MEMBRANOUS NEPHROPATHY.,ANTI-EBNA-1 ELISA (IGG)(NIL)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST

	EPSTEIN-BARR VIRUS NUCLEAR ANTIGEN 1 (EBNA-1) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF INFECTIOUS MONONUCLEOSIS.,IIFT: GRANULOCYTE MOSAIC 13-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF MICROSCOPIC POLYANGITIS, RAPID PROGRESSIVE GLOMERULONEPHRITIS, GOOD PASTURE SYNDROME AND OTHER FORMS OF VASCULITIS,IIFT: SPERMATOZOA (HUMAN) (NIL)-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASSES IGA, IGG UND IGM AGAINST HUMAN SPERMATOZOA IN SERUM OR PLASMA SAMPLES TO SUPPORT THE DIAGNOSIS OF IMMUNOLOGICAL FERTILITY DISORDERS,IIFT: AUTOIMMUNE ENCEPHALITIS MOSAIC 1-TEST SYSTEM FOR IN VITRO DETERMINATIONS IVD OF AUTOANTIBODIES AGAINST GLUTAMATE RECEPTORS (TYPES NMDA, AMPA1, AMPA2), CASPR2, LGI1 AND GABARB1/B2 IN HUMAN SERUM OR PLASMA FOR THE DIAGNOSIS OF AUTOIMMUNE ENCEPHALITIS.,EUROPLUS GRANULOCYTE MOSAIC 25 (NIL)- THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST GRANULOCYTE CYTOPLASM (ANCA) IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF THE FOLLOWING DISEASES: GRANULOMATOSIS WITH POLYANGIITIS (GPA, WEGENER'S GRANULOMATOSIS), EOSINOPHILE GRANULOMATOSIS WITH POLYANGIITIS (EGPA, CHURG-STRAUSS SYNDROME), MICROSCOPIC POLYANGIITIS (MPA), PRIMARY SCLEROSING CHOLANGITIS AND CHRONIC INFLAMMATORY BOWEL DISEASES (MAINLY ULCERATIVE COLITIS),ANTI-AQUAPORIN-4 IIFT-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST AQUAPORIN-4 (AQP-4) IN PATIENT SAMPLES FOR THE DIAGNOSIS OF NEUROMYELITIS OPTICA (NMO, OPTICOSPINAL ENCEPHALOMYELITIS, DEVIC'S SYNDROME).,ANTI-ENA SLE PROFILE 2-ELISA (IGG)(NIL)-THE ENZYME IMMUNOASSAY (ELISA) PROVIDES SEMIQUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST 8 DIFFERENT ANTIGENS (DOUBLE-STRANDED DNA (DSDNA), HISTONES, NUCLEOSOMES, NRNP/SM, SM, SS-A, SS-B, SCL-70) IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF THE SHARP SYNDROME (MCTD), LUPUS ERYTHEMATOSUS DISSEMINATUS, SJOGREN'S SYNDROME AND PROGRESSIVE SYSTEMIC SCLEROSIS.,IIFT: NMOSD SCREEN 1-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST AQUAPORIN-4 (AQP-4) AND/OR MYELIN-OLIGODENDROCYTE GLYCOPROTEIN (MOG) IN PATIENT SAMPLES TO SUPPORT THE

	DIAGNOSIS OF DEMYELINATING DISEASES OF THE CENTRAL NERVOUS SYSTEM.,IGA RHEUMATOID FACTOR ELISA(NIL)-THE ELISA TEST KIT PROVIDES SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO DETERMINATION OF HUMAN IGA RHEUMATOID FACTORS (AUTOANTIBODIES OF THE IGA CLASS AGAINST HUMAN IGG) IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF AUTOIMMUNE DISEASES, ESPECIALLY CASES OF SUSPECTED RHEUMATOID ARTHRITIS AND FURTHER RHEUMATIC DISEASES,ANA SCREEN ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES,IIFT: STOMACH (MONKEY)(NIL)-THIS TEST KIT PROVIDES QUALITATIVE OR SEMI-QUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBIN CLASS IGG AGAINST PARIETAL CELLS IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF CHRONIC-ATROPHIC GASTRITIS, PERNICIOUS ANAEMIA, FUNICULAR MYELOSIS, VARIOUS AUTOIMMUNE ENDOCRINOPATHIES, ANTI-DSDNA-NCX ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES,IIFT MOSAIC: BASIC PROFILE 2(NIL)-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST CELL NUCLEI, MITOCHONDRIA AND SMOOTH MUSCLES IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF MANY AUTOIMMUNE DISEASES, PARTICULARY THOSE OF THE RHEUMATIC FORM.,ANTI-ACETYLCHOLINE RECEPTOR ELISA (IGG)-THE ELISA TEST KIT PROVIDES A QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST ACETYLCHOLINE RECEPTORS IN SERUM OR PLASMA FOR THE DIAGNOSIS OF MYASTHENIA GRAVIS.,ANTI-PM-SCL-ELISA (IGG)(NIL)-OVERLAP SYNDROME: SYMPTOMS OF POLYMYOSITIS (PM), DERMATOMYOSITIS (DM), AND PROGRESSIVE SYSTEMIC SCLEROSIS (SCL),ANTI-CCP ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF RHEUMATOID ARTHRITIS,ANTI-HANTA VIRUS POOL 1 "EURASIA" ELISA (IGM)(NIL)-THE ENZYME IMMUNOASSAY (ELISA) PROVIDES SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGM AGAINST HANTAVIRUS (STRAINS: HANTAAN, DOBRAVA AND PUUMALA) IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF HAEMORRHAGIC FEVER WITH RENAL SYNDROME, KIDNEY FAILURE, ACUTE RESPIRATORY DISTRESS SYNDROME AND HANTAVIRUS PULMONARY SYNDROME. ,ANTI-PR3-HN-HR ELISA (IGG)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST PROTEINASE 3 (PR3) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF GRANULOMATOSIS WITH POLYANGIITIS (WEGENER'S) (GPA),ANTI-WEST NILE VIRUS ELISA

	(IGM)(NIL)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IGM CLASS AGAINST WEST NILE VIRUS IN SERUM OR PLASMA,ANTI-PLA2R ELISA (IGG) -IN VITRO DIAGNOSTICS REAGENTS FOR THE DETERMINATION OF AUTOANTIBODIES OF THE IGG CLASS AGAINST PLA2R RECEPTORS., IIFT: NERVES (MONKEY)(NIL)-THIS TEST KIT IS DESIGNED FOR THE QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASSES IGA, IGG OR IGM AGAINST MEDULLATED NERVES IN PATIENT SAMPLES FOR THE DIAGNOSIS OF NEUROLOGICAL DISEASES (E.G. IGM GAMMOPATHY-ASSOCIATED NEUROPATHY, GUILLAIN-BARRE SYNDROME AND MULTIPLE SCLEROSIS),EUROLINE-FOOD PROFILE 216 (IGG)-THE EUROLINE-FOOD TEST PROVIDES SEMIQUANTITATIVE IN VITRO DETERMINATION OF THE FOOD- SPECIFIC IMMUNOGLOBULIN CLASS IGG IN SERUM OR PLASMA AND CONTRIBUTES TO THE DIAGNOSIS OF INTOLERANCES AGAINST FOODS AND FOOD ADDITIVES WHICH MAY LEAD TO UNSPECIFIC HEALTH PROBLEMS, BY DETECTION OF IGG ANTIBODIES (E.G. GASTROINTESTINAL DISORDERS, INFLAMMATORY SKIN DISEASES, MIGRAINE, CHRONIC FATIGUE SYNDROME, ETC.), ANTI-LC-1 ELISA (IGG)(NIL)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IGG CLASS AGAINST LIVER CYTOSOL ANTIGEN TYPE 1 (LC-1) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF INCREASE IN TRANSAMINASES FOR UNCLEAR REASONS AND SUSPECTED AUTOIMMUNE HEPATITIS.,EUROLINE ANA PROFILE ET MI-2 ET KU, DFS70 (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IGG CLASS TO 18 DIFFERENT ANTIGENS: MI-2, KU, NRNP/SM, SM, SS-A, RO-52, SS-B, SCL-70, PM-SCL100, JO-1, CENP B, PCNA, DSDNS, NUCLEOSOMES, HISTONES, RIB. P-PROT., AMA-M2 AND DFS70 IN SERUM OR PLASMA FOR THE DIAGNOSIS OF SHARP SYNDROME (MCTD), SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), SJOGREN'S SYNDROME, PROGRESSIVE SYSTEMIC SCLEROSIS, POLY-/DERMATOMYOSITIS, OVERLAP SYNDROME, LIMITED FORM OF PROGRESSIVE SYSTEMIC SCLEROSIS (CREST SYNDROME) AND PRIMARY BILIARY LIVER CIRRHOSIS.,ANTI-SACCHAROMYCES CEREVISIAE ELISA (IGA)(NIL)-SUSPECTED CROHN' S DISEASE,ANTI-BORDETELLA PERTUSSIS ELISA (IGM)-BORDETELLA PERTUSSIS INFECTIONS, WHOOPING COUGH,ANTI-GABA B RECEPTOR IIFT(NIL)-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST NEURONAL ANTIGENS IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF NEUROLOGICAL DISEASES (ENCEPHALITIS),EUROLINE ANA PROFILE ET MI-2 ET KU (IGG)-THE EUROLINE TEST KIT PROVIDES A

	QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO THE 17 DIFFERENT ANTIGENS MI-2, KU, NRNPSM, SM, SS-A (NATIVE), RO-52, SS-B, SCL-70, PM-SCL100, JO-1, CENP B, PCNA, DSDNA, NUCLEOSOMES, HISTONES, RIBOSOMAL P- PROTEIN AND AMA M2 IN SERUM OR PLASMA FOR THE DIAGNOSIS OF SHARP SYNDROME (MCTD), LUPUS ERYTHEMATOSUS DISSEMINATUS (SLE), SJOGREN'S SYNDROME, PROGRESSIVE SYSTEMIC SCLEROSIS, POLY-/DERMATOMYOSITIS, OVERLAP SYNDROMES, LIMITED FORM OF PROGRESSIVE SYSTEMIC SCLEROSIS (CREST SYNDROME) AND PRIMARY BILIARY CHOLANGITIS.,ANTI-MPO ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF WEGENER'S GRANULOMATOSIS, MICROSCOPIC POLYANGITIS, RAPID PROGRESSIVE GLOMERULONEPHRITIS, GOODPASTURE SYNDROME AND OTHER FORMS OF VASCULITIS,EUROLINE INHALATION INDIA (IGE)-THE EUROLINE TEST KIT IS DESIGNED FOR SEMIQUANTITATIVE IN VITRO DETERMINATION OF ALLERGEN SPECIFIC IGE (SIGE) IN SERUM OR PLASMA, CONTRIBUTING TO THE DIAGNOSIS OF ALLERGIES. THE EUROLINE TEST KIT IS USED FOR THE DIAGNOSIS OF SENSITISATIONS THAT MAY LEAD TO ALLERGY- ASSOCIATED SYMPTOMS SUCH AS CONJUNCTIVITIS, RHINITIS OR GASTRO-INTESTINAL PROBLEMS., EUROLINE ANA PROFILE 3 PLUS DFS70 (IGG)-HE EUROLINE TEST KIT PROVIDES AUTOANTIBODIES OF THE IGG CLASS TO 16 DIFFERENT ANTIGENS NRNP, SM, , SS-B, SCL-70, PM-SCL, JO-1, CENP B, PCNA, DSDNA, NUCLEOSOMES, HISTONES, RIBOSOMAL P-PROTEIN, AMA M2 AND DFS70 IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF SHARP SYNDROME (MCTD), SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), SJOGREN'S SYNDROME, PROGRESSIVE SYSTEMIC SCLEROSIS, POLY-/DERMATOMYOSITIS, OVERLAP SYNDROMES LIMITED FORM OF PROGRESSIVE SYSTEMIC SCLEROSIS (CREST SYNDROME) AND PRIMARY BILIARY LIVER CHOLANGITIS,EUROLINE INHALATION "INDIA 2" (IGE)-THE EUROLINE TEST KIT IS DESIGNED FOR SEMIQUANTITATIVE IN VITRO DETERMINATION OF ALLERGEN SPECIFIC IGE (SIGE) IN SERUM OR PLASMA, CONTRIBUTING TO THE DIAGNOSIS OF ALLERGIES. THE EUROLINE TEST KIT IS USED FOR THE DIAGNOSIS OF SENSITISATIONS THAT MAY LEAD TO ALLERGY-ASSOCIATED SYMPTOMS SUCH AS CONJUNCTIVITIS, RHINITIS OR GASTROINTESTINAL PROBLEMS,EUROLINE AUTOIMMUNE LIVER DISEASES 14 AG (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO 14 DIFFERENT ANTIGENS (AMA-M2, M2-3E, SP100, PML, GP210, LKM-1, LC-1, SLA/LP, SS-A, RO-52, SCL-70, CENP A, CENP B AND PGDH) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF PRIMARY BILIARY LIVER CIRRHOSIS, INCREASE IN

	TRANSAMINASES FOR UNCLEAR REASONS, SUSPECTED AUTOIMMUNE HEPATITIS AND OVERLAP SYNDROMES.,IIFT MOSAIC: BASIC PROFILE 3A-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST CELL NUCLEI, MITOCHONDRIA AND SMOOTH MUSCLES IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF MANY AUTOIMMUNE DISEASES, PARTICULARY THOSE OF THE RHEUMATIC FORM., EUROLINE ANA PROFILE 3 (IGG)-THE EUROLINE TEST KIT PROVIDES QUALITATIVE IN VITRO DETERMINATION OF HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO THE 15 DIFFERENT ANTIGENS NRNP, SM, SS-A, RO-52, SS-B, SCL-70, PM-SCL, JO-1, CENP B, PCNA, DSDNA, NUCLEOSOMES, HISTONES, RIBOSOMAL P-PROTEIN AND AMA M2 IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF SHARP SYNDROME (MCTD), SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), SJOGREN'S SYNDROME, PROGRESSIVE SYSTEMIC SCLEROSIS, POLY-/DERMATOMYOSITIS, OVERLAP SYNDROMES, LIMITED FORM OF PROGRESSIVE SYSTEMIC SCLEROSIS (CREST SYNDROME), PRIMARY BILIARY CHOLANGITIS. ,IIFT: GLUTAMATE RECEPTOR MOSAIC 3-TEST SYSTEM FOR IN VITRO DETERMINATIONS IVD OF AUTOANTIBODIES AGAINST GLUTAMATE RECEPTOR (TYPE NMDA) IN HUMAN SERUM, PLASMA OR CEREBROSPINAL FLUID.,EUROLINE - AUTOIMMUNE LIVER DISEASES-(IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE HEPATITIS, PRIMARY BILIARY CIRRHOSIS, OVERLAP SYNDROMES THE EUROLINE TEST KIT PROVIDES QUALITATIVE IN VITRO DETERMINATION OF HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO 9 DIFFERENT ANTIGENS: AMA-M2 (PYRUVATE DEHYDROGENASE COMPLEX), M2-3E (BPO, FUSION PROTEIN OF THE E2 SUBUNITS OF THE ALPHA-2-OXOACID DEHYDROGENASES OF THE INNER MITOCHONDRIAL MEMBRANE), SP100 (NUCLEAR GRANULA PROTEIN, NUCLEAR DOTS), PML (PROMYELOCYTIC LEUKAEMIA PROTEIN, NUCLEAR DOTS), GP210 (INTEGRAL PROTEIN OF THE NUCLEAR MEMBRANE, NUCLEAR PORE COMPLEX), LKM-1 (LIVER-KIDNEY MICROSOMES; CYTOCHROME P450 II D6), LC-1 (CYTOSOLIC LIVER ANTIGEN TYPE 1; FORMIMINOTRANSFERASE CYCLODEAMINASE), SLA/LP (SOLUBLE LIVER ANTIGEN/LIVER-PANCREAS ANTIGEN) AND RO-52 IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF PRIMARY BILIARY LIVER CHOLANGITIS, INCREASE IN TRANSAMINASES FOR UNCLEAR REASONS, SUSPECTED AUTOIMMUNE HEPATITIS. ,IIFT: CRITHIDIA LUCILIAE (ANTI-DSDNA) EUROPATTERN-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST

	DSDNA IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE),EUROLINE ANTI- MPO, -PR3 AND GBM (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF WEGENER'S GRANULOMATOSIS, MICROSCOPIC POLYANGITIS, RAPID PROGRESSIVE GLOMERULONEPHRITIS, GOODPASTURE SYNDROME AND OTHER FORMS OF VASCULITIS,ANTI-GLUTAMATE RECEPTOR (TYPE NMDA) IIFT-TEST SYSTEM FOR IN VITRO DETERMINATIONS IVD OF AUTOANTIBODIES AGAINST GLUTAMATE RECEPTOR (TYPE NMDA) IN HUMAN SERUM, PLASMA OR CEREBROSPINAL FLUID FOR THE DIAGNOSIS OF AUTOIMMUNE ENCEPHALITIS,IIFT: ANTI-VGKC ASSOCIATED PROTEINS MOSAIC 1-IN VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF AUTOIMMUNE ENCEPHALITIS,ANTI-MEASLES VIRUS ELISA (IGG)-THE ELISA TEST KIT PROVIDES A QUANTITATIVE OR SEMIQUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IGG CLASS AGAINST MEASLES VIRUS IN SERUM OR PLASMA.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

311	IMP/IVD/2019/000328	1.License Holder Name: SOWAR PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CREATINE KINASE-MB/CARDIAC TROPONIN I/MYOGLOBIN(CK-MB/CTNL/MYO FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-CK-MB/CTNL/MYO FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CK-MB/CTNL/MYO IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI). UNSTABLE ANGINA, ACUTE MYOCARDITIS, AND ACUTE CORONARY SYNDROME (ACS).,HCG+(ONE STEP TEST FOR HCG+ (COLLOIDAL GOLD))-PREGNANCY MONITORING,BETA 2 MICROGLOBULIN (BETA 2 - MG)(BETA 2 MG FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-BETA 2 MG FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF BETA 2-MICROGLOBULIN IN SERUM, PLASMA OR WHOLE BLOOD. MEASUREMENT OF BETA 2-MG IS USEFUL FOR THE DETECTION AND EVALUATION OF GLOMERULAR FITRATION RATE, RENTAL TRANSPLANTATION AND RENTAL FUNCTION.,NEUTROPHILS GILATINASE ASSOCIATED LIPOCALIN (NGAL)(ONE STEP TEST FOR NGAL (COLLOIDAL GOLD))-AS AID IN THE DIAGNOSIS OF ACUTE KIDNEY INJURY,RISK CLASSIFICATION AND TREATMENT MONITORING,D-DIMER(D-DIMER FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-D-DIMER FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF D-DIMER IN PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF DEEP-VEIN THROMBOSIS OR PULMONARY EMBOLISM,TSH(ONE STEP TEST FOR TSH (COLLOIDAL GOLD))-THYROID FUNCTION MONITORING,T3(T3 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-T3 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T3 IN SERUM AND PLASMA. IT CAN BE USED THE MONITORING OF HYPERTHYROIDISM HYPOTHYROIDISM, AND ALSO USE AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA,MICROALBUMINURIA (MALB)(ONE STEP TEST FOR MALB (COLLOIDAL GOLD))-AS AN AID IN THE DIAGNOSIS OF KIDNEY DISEASE AND INCREASED CARDIOVASCULAR RISK IN DIABETIC NEPHROPATHY,NEUTROPHILS GELATINASE ASSOCIATED LIPOCALIN (NGAL)(NGAL (IMMUNOFLUORESCENCE ASSAY))-NGAL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF NEUTROPHILS GELATINASE ASSOCIATED LIPOCALN (NGAL) IN SERUM AND URINE.

	THIS TEST IS USED AS AN AID IN THE EARLY DIAGNOSIS OF ACUTE KIDNEY INJURY (AKI), RISK CLASSIFICATION AND TREATMENT MONITORING,HIGH SENSITIVITY C-REACTIVE PROTEIN(HS-CRP) (ONE STEP TEST FOR HS-CRP (COLLOIDAL GOLD))-AS AN AID IN THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY AND INFLAMMATORY DISORDERS,LH(LH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-LH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF LH IN HUMAN SERUM AND PLASMA. THIS TEST IS USED TO DETERMINE MENOPAUSE, PINPOINT OVULATION AND MOTHER ENDOCRINE THERAPY,N-TERMINAL PROHORMONE OF BRAIN NATRIURETIC PEPTIDE (NT-PROBNP)(ONE STEP TEST FOR NT-PROBNP (COLLOIDAL GOLD))-AS AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF) ,FSH(FSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-FSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY)) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM AND PLASMA. FSH TESTING IS USED FOR WOMEN SUSPECTED OF HAVING POLYCYSTIC OVARY SYNDROME , AND IN INDIVIDUAL UNDERGOING EVALUATION OF INFERTILITY, ALSO USED FOR EVALUATION OF INDIVIDUALS WITH SUSPECTED PITUITIRY DISORDERS OR DISEASE OF THE OVARIES,CYSTATIN C (CYSC)(ONE STEP TEST FOR CYSC (COLLOIDAL GOLD))-AS AN AID IN THE ASSESSMENT AND EVALUTION OF INDEX OF GLOMERULAR FILTRATION RATE AND HAS IMPORTANT APPLICATION VALUE IN RENAL FUNCTION, KIDNEY DAMAGE AND RENAL TRANSPLANTATION, HIGH SENSITIVITY C-REACTIVE PROTEIN (HS-CRP)(HS CRP+CRP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-HS CRP+CRP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM, PLASMA, WHOLE BLOOD OR FIGURE TIP BLOOD. MEASUREMENT OF CRP IS USEFUL FOR DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY AND INFLAMMATORY DISORDERS. MEASUREMENT OF HIGH SENSIVITY CRP (HS-CPR), WHEN USE IN CONJUNCTION WITH TRADITIONAL CLINICAL LABORATORY EVALUATION OF ACUTE CORONARY SYNDROME (ACS), MAY BE USEFUL AS AN INDEPENDENT MARKER OF PROGNOSIS FOR RECURRENT EVENTS IN PATIENTS WITH STABLE CORONARY DISEASE OR ACS.,2 MICROGLOBULIN (2 MG)(ONE STEP TEST FOR 2 MICROGLOBULIN (COLLOIDAL GOLD))-AS AN AID IN THE DETECTION AND EVALUATION OF GLOMERULAR FILTRATION RATE, RENAL TRANSPLANTATION AND RENAL FUNCTION,CARDIAC TROPONIN I (CARDIAC TROPONIN I FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-CARDIAC TROPONIN I FAST TEST KIT

	(IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNL) IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS AND ACUTE CORONARY SYNDROME (ACS),CREATINE KINASE-MB/CARDIAC TROPONIN I/MYOGLOBIN(ONE STEP TEST FOR CK-MB/CTNI/MYO (COLLOIDAL GOLD))-AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFRACTION(AMI), AND ACUTE MYOCARDIAL SYNDROME(ACS),HBA1C(HBA1C FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-HBA1C FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE MEASUREMENT OF HBA1C IN WHOLE BLOOD. THIS TEST IS USED AS AN AID FOR MONITORING GLYCEMIC CONTROL IN DIABETICS. IN ADDITION, IT CAN IDENTIFY AT PEOPLE AT RISK OF DEVELOPING THE DISEASE AND ONGOING MONITORING,CARDIAC TROPONIN I(CARDIAC TROPONIN I FAST TEST KIT)-AS AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY AND ACUTE MYOCARDIAL SYNDROME(ACS),25-OH-VD(25-OH-VD FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-25-OH-VD FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF 25-OH-VD IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST MAY HELP UNDERSTAND THE METABOLIC CHANGES OF BONE.,HBA1C(ONE STEP TEST FOR HBA1C (COLLOIDAL GOLD))-DIABETES MONITORING,AMH(AMH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-AMH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF AMH IN HUMAN SERUM AND PLASMA SAMPLES. THIS TEST CAN BE USED AS AN AID IN INDICATING OVARIAN FUNCTIONAL RESERVE, AND ALSO HELP TO DIAGNOSE MENSTRUAL DISORDERS OR TO MONITOR THE HEALTH OF WOMEN., N-TERMINAL PROHORMONE OF BRAIN NATRIURETIC PEPTIDE(NT-PROBNP)/CARDIAC TROPONIN I(NT-PROBNP/CTNI)(ONE STEP TEST FOR NT-PROBNP/CTNI (COLLOIDAL GOLD))-AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE(HF),ACUTE MYOCARDIAL INFRACTION(AMI) AND ACUTE MYOCARDIAL SYNDROME(ACS),FERRITIN FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY)(FERRITIN FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-FERRITIN FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA SAMPLES.IT CAN BE USED AS AN AID IN THE QUANTIFICATION OF HUMAN FERRITIN AND THE DIAGNOSIS OF IRON

	DEFICIENCY ANEMIA OR IRON OVERLOAD RELATED DISEASES, PROCALCITONIN (PCT)(ONE STEP TEST FOR PCT(COLLOIDAL GOLD))-AS AN AID IN THE ASSESSMENT AND EVALUTION OF PATIENT SUSPECTED BACTERIAL INFECTION TRAUMA OR SHOCK,N-TERMINAL PROHORMONE OF BRAIN NATRIURETIC PEPTIDE (NT- PROBNP)(NT -PRO BNP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-NT -PRO BNP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF N TERMINAL B-TYPE NATRIURETIC PEPTIDE PRECURSOR/CARDIAC TROPONIN I (NT -PRO BNP) IN SERUM, PLASMA AND WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF).,D-DIMER(ONE STEP TEST FOR D-DIMER (COLLOIDAL GOLD))-RAPID SCREENING FOR DVT & PE, CYSTATIN C(CYSC FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-CYSC FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CYSTATIN C (CYSC) IN SERUM, PLASMA OR WHOLE BLOOD. THE TEST RESULT IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF INDEX OF GLOMERULAR FILTRATION RATE, AND HAS IMPORTANT APPLICATION VALUE IN RENTAL FUNCTION, KIDNEY DAMAGE AND RENTAL TRANSPLANTATION.,ONE STEP TEST FOR NOVEL CORONAVIRUS (2019-NCOV) IGM/IGG ANTIBODY (COLLOIDAL GOLD) (GETEIN)-ONE STEP TEST FOR NOVEL CORONAVIRUS (2019-NCOV) IGM/IGG ANTIBODY (COLLOIDAL GOLD) IS INTENDED FOR THE QUALITATIVE DETECTION OF 2019-NOVEL CORONAVIRUS IGM AND IGG ANTIBODY IN SERUM, PLASMA, FINGERTIP BLOOD OR WHOLE BLOOD SAMPLES OF PNEUMONITIS PATIENTS OR SUSPECTED CASES, HCG+BETA(HCG+BETA FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-HCG+BETA FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONATROPIN (HCG) IN SERUM. THIS TEST IS USED AS AN AID IN PREGNANCY TEST.,PROCALCITONIN (PCT)(PCT FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-PCT FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN SERUM, PLASMA AND WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF BACTERIAL INFECTION, TRAUMA AND SHOCK.,IL-6 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY)(IL-6 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-IL-6 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF INTERLEUKIN 6(IL-6) IN HUMAN SERUM, PLASMA, WHOLE BLOOD AND PERIPHERAL BLOOD SAMPLES. IL-6 IS AN EARLY MARKER IN ACUTE INFLAMMATION AND THIS TEST

	CAN BE USED AS AN AID IN THE INFLAMMATORY DISEASES., MICROALBUMINURIA (MALB)(MALB FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-MALB FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF MICROALBUMINURIA (MALB) IN URINE . AN ELEVATED MALB CONCENTRATION BELOW BELOW THE PROTEINURIC LEVEL HAS LONG BEEN RECOGNIZED AS A MARKER OF KIDNEY AND INCREASED CARDIOVASCULAR RISK IN DIABETIC NEPHROPATHY.,TSH(TSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-TSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN SERUM, PLASMA. THIS TEST IS USED IN THE SCREENING, CLINICAL DIAGNOSIS, PROGNOSIS AND THERAPEUTIC EFFECT EVALUATION THYROID DISEASE.,T4(T4 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-T4 (THYROXINE) FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T4 IN SERUM AND PLASMA. IT CAN BE USED THE MONITORING OF HYPERTHYROIDISM HYPOTHYROIDISM, AND ALSO USE AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA,PRL(PRL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-PRL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN SERUM OR PLASMA SAMPLES. THIS TEST CAN BE USED AS AN AID IN THE DIAGNOSIS OF MALE AND FEMALE INFERTILITY AND PITUITIARY DYSFUNCTION, MONITORING OF MALE AND FEMALE GONADAL DISORDERS AND MANAGEMENT OF AMENORRHEA AND GALACTORRHEA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

312	IMP/IVD/2019/000331	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SERUM PROTEIN MULTI-CALIBRATOR 1(SERUM PROTEIN MULTI-CALIBRATOR 1)-THE SERUM PROTEIN MULTI-CALIBRATOR IS INTENDED TO BE USED WITH THE IMMUNO-TURBIDIMETRIC REAGENTS LISTED IN THE TABLE BELOW FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G, IMMUNOGLOBULIN A, IMMUNOGLOBULIN M, COMPLEMENT 3, COMPLEMENT 4, TRANSFERRIN, C-REACTIVE PROTEIN, ANTI-STREPTOLYSIN O AND FERRITIN ON BECKMAN COULTER ANALYSERS. THE MATERIAL IS PREPARED FROM HUMAN SERUM WITH THE CONSTITUENT VALUES ADJUSTED WHERE NECESSARY BY THE ADDITION OF ANALYTICAL GRADE CHEMICALS AND APPROPRIATE SERUM PROTEINS.,SERUM PROTEIN MULTI-CALIBRATOR 2(SERUM PROTEIN MULTI- CALIBRATOR 2)-THE SERUM PROTEIN MULTI-CALIBRATOR 2 IS INTENDED TO BE USED WITH THE BECKMAN COULTER IMMUNO-TURBIDIMETRIC REAGENTS LISTED IN THE TABLE BELOW FOR THE QUANTITATIVE DETERMINATION OF -1 ACIDGLYCOPROTEIN, -1 ANTITRYPSIN, -2 MICROGLOBULIN, CERULOPLASMIN AND HAPTOGLOBIN ON BECKMAN COULTER ANALYSERS. THE MATERIAL IS PREPARED FROM HUMAN SERUM WITH THE CONSTITUENT VALUES ADJUSTED WHERE NECESSARY BY THE ADDITION OF ANALYTICAL GRADE CHEMICALS AND APPROPRIATE SERUM PROTEINS.

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313	IMP/IVD/2019/000332	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CARBON DIOXIDE CALIBRATOR(CARBON DIOXIDE CALIBRATOR)-FOR USE IN THE CALIBRATION OF THE CARBON DIOXIDE ASSAY.,ALINITY C BILIRUBIN CALIBRATOR KIT (ALINITY C BILIRUBIN CALIBRATOR KIT)-FOR USE IN THE CALIBRATION OF THE ALINITY C BILIRUBIN ASSAYS ON THE ALINITY C ANALYZER.,ALINITY C MULTICONSTITUENT CALIBRATOR KIT(ALINITY C MULTICONSTITUENT CALIBRATOR KIT)-FOR USE IN THE CALIBRATION OF THE ALINITY C ALBUMIN, CALCIUM, CHOLESTEROL, CREATININE, GLUCOSE, LACTIC ACID, MAGNESIUM, PHOSPHORUS, TOTAL PROTEIN, TRIGLYCERIDE, UREA NITROGEN, AND URIC ACID ASSAYS.,ALINITY C IRON CALIBRATOR KIT(ALINITY C IRON CALIBRATOR KIT)-FOR USE IN THE CALIBRATION OF THE ALINITY C IRON ASSAY ON THE ALINITY C ANALYZER.,ALINITY C CARBON DIOXIDE CALIBRATOR KIT(ALINITY C CARBON DIOXIDE CALIBRATOR KIT)-FOR USE IN THE CALIBRATION OF THE ALINITY C CARBON DIOXIDE ASSAY ON THE ALINITY C ANALYZER.,BILLRUBIN CALIBRATOR(BILLRUBIN CALIBRATOR)-FOR USE IN THE CALIBRATION OF THE BILIRUBIN ASSAYS.,MULTICONSITITUENT CALIBRATOR(MULTICONSITITUENT CALIBRATOR)-FOR USE IN THE CALIBRATION OF THE ALBUMIN, CALCIUM, CHOLESTEROL, CREATININE, GLUCOSE, IRON, LACTIC ACID, MAGNESIUM, PHOSPHORUS, TOTAL PROTEIN, TRIGLYCERIDE, UREA NITROGEN, AND URIC ACID ASSAYS.
314	IMP/IVD/2019/000334	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ISOFLOW SHEATH FLUID (ISOFLOW SHEATH FLUID)-A NON-FLUORESCENT, AZIDE FREE BALANCED ELECTROLYTE SOLUTION FOR USE ON COULTER FLOW CYTOMETERS WITH LIGHT SCATTER AND FLUORESCENT APPLICATIONS.,DXFLEX SHEATH FLUID(DXFLEX SHEATH FLUID)-A NONIONIC, NON-FLUORESCENT, AND AZIDE-FREE SHEATH FLUID FOR USE ON BECKMAN COULTER DXFLEX FLOW CYTOMETERS.

315	IMP/IVD/2019/000337	1.License Holder Name: SIRUS BIOCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOLATEX®LP(A) [LIPOPROTEIN(A)](CRM®DIAGNOSTIC SYSTEMS LIPOPROTEIN(A)[LP (A)])-DIAGNOSTIC REAGENT FOR QUANTITATIVE DETERMINATION OF HUMAN LIPOPROTEIN (A) [LP(A)] IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS,BIOLATEX®IGE (IMMUNOGLOBULIN E) (CRM®DIAGNOSTIC SYSTEMS IGE (IMMUNOGLOBULIN E))-DIAGNOSTIC REAGENT FOR QUANTITATIVE DETERMINATION OF HUMAN IGE IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS, BIOLATEX®FERRITIN(CRM®DIAGNOSTIC SYSTEMS FERRITIN)-DIAGNOSTIC REAGENT FOR QUANTITATIVE DETERMINATION OF HUMAN FERRITIN IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS, BIOLATEX®ASO (ANTISTREPTOLYSIN O)(CRM®DIAGNOSTIC SYSTEMS ASO (ANTISTREPTOLYSIN O))-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ASO IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS,BIOLATEX®RF (RHEUMATOID FACTOR) (CRM®DIAGNOSTIC SYSTEMS RF (RHEUMATOID FACTOR))-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF RF IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS,BIOLATEX® MICROALBUMIN(CRM®DIAGNOSTIC SYSTEMS MICROALBUMIN)-DIAGNOSTIC REAGENT FOR QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN URINE ON PHOTOMETRIC SYSTEMS,BIOLATEX® CYSTATIN C(CRM®DIAGNOSTIC SYSTEMS CYSTATIN C)-DIAGNOSTIC REAGENT FOR QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS,BIOLATEX®CRP (C-REACTIVE PROTEIN) (CRM®DIAGNOSTIC SYSTEMS (C-REACTIVE PROTEIN))-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CRP IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS
316	IMP/IVD/2019/000338	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASO(ASO)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF ASO (ANTI-STREPTOLYSIN O) ANTIBODIES IN HUMAN SERUM ON BECKMAN COULTER ANALYSERS.

317	IMP/IVD/2019/000339	1.License Holder Name: ARKRAY HEALTHCARE PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URINALYSIS REAGENT STRIPS FOR 10 PARAMETERS(ORINASYSB10 +)-TO DETECT THE GLUCOSE, KETONE, SG, BLOOD, PH, PROTEIN, NITRITE, BILIRUBIN, UROBILINOGEN AND LEUKOCYTE IN URINE ,URINALYSIS REAGENT STRIPS FOR 11 PARAMETERS(ORINASYS S11)-TO DETECT THE GLUCOSE, ASCORBIC ACID, KETONE, SG, BLOOD, PH, PROTEIN, NITRITE, BILIRUBIN, UROBILINOGEN AND LEUKOCYTE IN URINE , URINALYSIS REAGENT STRIPS FOR 2 PARAMETERS(ORINASYS GP)-TO DETECT THE GLUCOSE AND PROTEIN IN URINE ,URINALYSIS REAGENT STRIPS FOR 2 PARAMETERS(ORINASYS GK)-TO DETECT THE GLUCOSE AND KETONE IN URINE,URINALYSIS REAGENT STRIPS FOR 4 PARAMETERS(ORINASYS 4S)-TO DETECT THE GLUCOSE, PROTEIN, PH AND SG IN URINE ,URINALYSIS REAGENT STRIPS FOR 10 PARAMETERS(ORINASYSB10)-TO DETECT THE GLUCOSE, KETONE, SG, BLOOD, PH, PROTEIN, NITRITE, BILIRUBIN, UROBILINOGEN AND LEUKOCYTE IN URINE
318	IMP/IVD/2019/000340	1.License Holder Name: RGB HEALTHCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS (SAFE-ACCU2)-FOR QUANTITATIVELY MEASURING GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD AND VENOUS WHOLE BLOOD. THE SAFE-ACCU2 TEST STRIP AND THE ASSOCIATED METER ARE INTENDED FOR USE OUTSIDE THE BODY BY PEOPLE WITH DIABETES AND HEALTH CARE PROFESSIONALS IN THE CLINICAL SETTING, AS AN AID TO MONITOR THE EFFECTIVENESS OF DIABETES CONTROL. IT SHOULD NOT BE USED FOR THE DIAGNOSIS OR FOR THE TESTING OF NEWBORNS.
319	IMP/IVD/2019/000340	1.License Holder Name: RGB HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIP(BLOOD GLUCOSE TEST STRIP)-THE DNURSE SP1 BLOOD GLUCOSE TEST STRIP IS TO BE USED WITH THE DNURSE SP1 BLOOD GLUCOSE METER TO QUANTITATIVE MEASURE GLUCOSE IN HUMAN WHOLE BLOOD TAKEN FROM THE FINGERTIPS OR FROM THE VEIN

320	IMP/IVD/2019/000340	1.License Holder Name: RGB HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE METER (SAFE-ACCU2)-THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD SAMPLE TAKEN FROM FINGERTIP AND IN VENOUS WHOLE BLOOD SAMPLE,BLOOD GLUCOSE METER (BEATO)-THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD SAMPLE TAKEN FROM FINGERTIP AND IN VENOUS WHOLE BLOOD SAMPLE.
321	IMP/IVD/2019/000341	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TSH ELISA-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUANTITATIVE DETERMINATION OF TSH (THYROID STIMULATING HORMONE) IN HUMAN SERUM,FT3 ELISA-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUANTITATIVE DETERMINATION OF FT3 (FREE TRIIODOTHYRONINE) IN HUMAN SERUM,FT4 ELISA-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUANTITATIVE DETERMINATION OF FT4 (FREE THYROXINE) IN HUMAN SERUM,T3 ELISA-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUANTITATIVE DETERMINATION OF T3 (TRIIODOTHYRONINE) IN HUMAN SERUM,T4 ELISA-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUANTITATIVE DETERMINATION OF T4 (THYROXINE) IN HUMAN SERUM
322	IMP/IVD/2019/000342	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HBA1C CONTROL KIT-USED FOR PRECISION OF AUTOMATED HBA1C ANALYZERS , GLYCOSYLATED HEMOGLOBIN TEST REAGENT KIT-USED FOR ESTIMATION OF GLYCATED HEMOGLOBIN (HBA1C) VALUES USING AUTOMATED HBA1C ANALYZERS,LYSE FOR HEMATOLOGY ANALYZERS USE-TO LYSE THE CELLS FOR FURTHER TESTING USING HEMATOLOGY ANALYZER, SUCH AS COMPLETE BLOOD COUNT (CBC).,DILUENT FOR HEMATOLOGY ANALYZERS USE-TO DILUTE BLOOD FOR FURTHER TESTING, SUCH AS COMPLETE BLOOD COUNT (CBC).,HBA1C CALIBRATOR KIT-USED FOR PRECISION OF AUTOMATED HBA1C ANALYZERS,STAIN FOR HEMATOLOGY ANALYZERS USE-USED AS CONSUMABLE IN HEMATOLOGY ANALYZER FOR ESTIMATION OF VARIOUS HEMATOLOGY PARAMETERS, SUCH AS COMPLETE BLOOD COUNT (CBC).

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323	IMP/IVD/2019/000343	1.License Holder Name: ASPEN DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REAGENT STRIPS FOR URINALYSIS, DIRUI H11-FOR DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH AND ASCORBIC ACID IN URINE, CONTROL LIQUID FOR TURBIDITY-USED FOR URINE ANALYZERS TURBIDIMETERS QUALITY CONTROL,REAGENT STRIPS FOR URINALYSIS, DIRUI H2-CR-FOR DETECTION OF MICROALBUMIN AND CREATINE RATIO IN URINE,URINALYSIS CONTROL-USED FOR QUALITY CONTROL DURING TEST ON AUTOMATED URINE ANALYZERS,REAGENT STRIPS FOR URINALYSIS, DIRUI FUS-10-FOR DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY AND PH IN URINE,FOCUS-USED FOR FOCUS OF FUS SEDIMENT ANALYZERS ,CALIBRATION LIQUID FOR TURBIDITY-USED FOR URINE ANALYZERS TURBIDIMETERS CALIBRATION,POSITIVE CONTROL-USED FOR QUALITY CONTROL OF FUS SEDIMENT ANALYZERS ,REAGENT STRIPS FOR URINALYSIS, DIRUI H10-800-FOR DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY AND PH IN URINE,COLOR CONTROL-USED FOR URINE ANALYZERS COLOR QUALITY CONTROL ,REAGENT STRIPS FOR URINALYSIS, DIRUI FUS-11-FOR DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH AND ASCORBIC ACID IN URINE,CALIBRATION LIQUID FOR SPECIFIC GRAVITY-USED FOR URINE ANALYZERS REFRACTOMETERS CALIBRATION,STANDARD SOLUTION-USED FOR STANDARDIZATION OF FUS SEDIMENT ANALYZERS,CONTROL LIQUID FOR SPECIFIC GRAVITY-USED FOR URINE ANALYZERS REFRACTOMETERS CONTROL,CLEANING LIQUID (CONCENTRATED TYPE)-USED FOR CLEANING OF VARIOUS PARTS OF AUTOMATED URINE ANALYZERS,REAGENT STRIPS FOR URINALYSIS, DIRUI H11-800-FOR DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH AND ASCORBIC ACID IN URINE,REAGENT STRIPS FOR URINALYSIS, DIRUI H10-FOR DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY AND PH IN URINE, CLEANING LIQUID FOR REFRACTOMETER AND TURBIDIMETER-USED FOR CLEANING OF URINE ANALYZERS REFRACTOMETERES AND TURBIDIMETERS,REAGENT STRIPS FOR URINALYSIS, DIRUI H11-MA-FOR DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH AND MICROALBUMIN IN URINE,REAGENT STRIPS FOR URINALYSIS,

	DIRUI H11-MA (N)-FOR DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH AND MICROALBUMIN IN URINE,NEGATIVE CONTROL-USED FOR QUALITY CONTROL OF FUS SEDIMENT ANALYZERS,DETERGENT-USED TO RINSE THE PIPELINE AND FLOW CELL OF FUS SEDIMENT ANALYZERS,SHEATH-USED TO WRAP SAMPLE TO FORM A SHEATH FLOW TO CONDUCT URINE PHYSICAL COMPONENT COUNTING ON FUS SEDIMENT ANALYZERS,DILUENT-USED FOR DILUTING SAMPLES ON FUS SEDIMENT ANALYZERS

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324	IMP/IVD/2019/000344	1.License Holder Name: M/S. CPC DIAGNOSTICS PVT, LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EUROREALTIME SARS-COV-2-THIS TEST IS USED FOR MOLECULAR DIAGNOSTIC IN VITRO DETECTION OF RNA OF THE CORONAVIRUS SARS-COV-2 FROM THROAT SWABS. THE PCR-BASED TEST SUPPORTS DIAGNOSTICS OF SARS-COV-2 INFECTIONS.,CSF: ANTI-CMV ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF CMV INFECTIONS, ANTI-SARS-COV-2 ELISA (IGG)-THE ENZYME IMMUNOASSAY (ELISA) PROVIDES SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST SARS-COV-2 IN SERUM, EDTA, HEPARIN OR CITRATE PLASMA TO SUPPORT THE DIAGNOSIS OF SARS-COV-2 INFECTION AND CONSTITUTES A SUPPLEMENT TO THE DIRECT PATHOGEN DETECTION. MOREOVER, SEROLOGY CAN BE APPLIED TO COLLECT EPIDEMIOLOGICAL DATA., ANTI-HSV-1/2 POOL ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR DETECTION OF TOXOPLASMOSIS THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTI- BODIES OF THE IGG CLASS AGAINST HSV-1 AND HSV-2 IN SERUM OR PLASMA,ANTI-SARS-COV-2 ELISA (IGA)-THE ENZYME IMMUNOASSAY (ELISA) PROVIDES SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGA AGAINST SARS-COV-2 IN SERUM, EDTA, HEPARIN OR CITRATE PLASMA TO SUPPORT THE DIAGNOSIS OF SARS-COV-2 INFECTION AND CONSTITUTES A SUPPLEMENT TO THE DIRECT PATHOGEN DETECTION.,ANTI-TOXOPLASMA GONDII ELISA (IGM)-IN-VITRO DIAGNOSTIC REAGENTS FOR DETECTION OF TOXOPLASMOSIS ,ANTI-TREPONEMA PALLIDUM SCREEN ELISA (IGGM)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IGG/IGM CLASS AGAINST TREPONEMA PALLIDUM IN SERUM OR PLASMA FOR THE DIAGNOSIS OF ASSOCIATED DISEASES: LUES,ANTI-CHLAMYDIA TRACHOMATIS ELISA (IGM)-IN-VITRO DIAGNOSTIC REAGENTS FOR DETECTION OF TRACHOMA, INFECTIONS OF THE UROGENITAL TRACT AND LYMPHOGRANULOMA VENEREUM,ANTI-HSV-1/HSV-2 GG2 EUROLINE-WB (IGG)-THE EUROLINE-WB TEST KIT PROVIDES A QUALITATIVE IN-VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST HERPES SIMPLEX 1 VIRUS AND AGAINST THE HERPES SIMPLEX 2 VIRUS TYPE SPECIFIC GLYCOPROTEIN G-2 FOR THE DIAGNOSIS OF INFECTIONS WITH HERPES SIMPLEX VIRUSES,ANTI-TOXOPLASMA GONDII ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR DETECTION OF TOXOPLASMOSIS,ANTI-CHLAMYDIA TRACHOMATIS ELISA (IGA)-IN-VITRO DIAGNOSTIC REAGENTS FOR DETECTION OF TRACHOMA,

	INFECTIONS OF THE UROGENITAL TRACT AND LYMPHOGRANULOMA VENEREUM,ANTI-HSV-2 (GG2) ELISA (IGG)- THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTI- BODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST THE HSV-2 SPECIFIC GLYCOPROTEIN G2 IN SERUM OR PLASMA FOR THE DIAGNOSIS OF HSV-2 INFECTIONS,EUROLINE ANTI-TO.R.C.H. PROFILE (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO 5 DIFFERENT TO.R.C.H. ANTIGENS, I. E. TOXOPLASMA GONDII, RUBELLA VIRUS, CMV, HSV-1 AND HSV-2 IN SERUM OR PLASMA FOR THE DIAGNOSIS OF INFECTIONS THE EUROLINE ANTI-TO.R.C.H. PROFILE (IGG AND IGM), BASED ON HIGHLY PURIFIED RECOMBINANT AND NATIVE ANTIGENS, ALLOWS SCREENING FOR SPECIFIC ANTI-BODIES AGAINST THE PATHOGENS TOXOPLASMA GONDII, RUBELLA VIRUS, CMV, HSV 1 AND HSV 2 WITH ONE TEST STRIP. THE DETECTION OF ANTIBODIES OF CLASSES IGG AND IGM PROVIDES USEFUL INFORMATION FOR DETERMINING THE IMMUNITY STATUS, ASSESSING THE RISK IN PREGNANCY AND PERFORMING CONTINUATIVE MONITORING DURING PRENATAL CARE, ANTI-HSV-2 (GG2) ELISA (IGM)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGM AGAINST THE HSV-2 SPECIFIC GLYCOPROTEIN G2 IN SERUM OR PLASMA FOR THE DIAGNOSIS OF HSV-2 INFECTIONS,ANTI-HSV-1/HSV-2 GG2 EUROLINE-WB (IGM)-THE TEST KIT PROVIDES A QUALITATIVE IN-VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGM AGAINST HERPES SIMPLEX 1 VIRUS AND AGAINST THE HERPES SIMPLEX 2 VIRUS TYPE SPECIFIC GLYCOPROTEIN G-2 IN SERUM OR PLASMA FOR THE DIAGNOSIS OF HERPES SIMPLEX VIRUS INFECTION,ANTI-HSV-1 (GC1) ELISA (IGM)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGM AGAINST THE HSV-1 SPECIFIC GLYCOPROTEIN C1 IN SERUM OR PLASMA FOR THE DIAGNOSIS OF HERPES SIMPLEX 1 INFECTIONS,AVIDITY: ANTI-TOXOPLASMA GONDII ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR DETECTION OF TOXOPLASMOSIS, ANTI-CHLAMYDIA TRACHOMATIS ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR DETECTION OF TRACHOMA, INFECTIONS OF THE UROGENITAL TRACT AND LYMPHOGRANULOMA VENEREUM., EUROLINE ANTI-TO.R.C.H. PROFILE (IGM)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGM TO 5 DIFFERENT TO.R.C.H. ANTIGENS, I.E. TOXOPLASMA GONDII, RUBELLA VIRUS, CMV, HSV-1 AND HSV-2 IN SERUM OR PLASMA FOR THE DIAGNOSIS OF INFECTIONS THE EUROLINE ANTI-TO.R.C.H. PROFILE (IGG AND IGM),

	BASED ON HIGHLY PURIFIED RECOMBINANT AND NATIVE ANTIGENS, ALLOWS SCREENING FOR SPECIFIC ANTIBODIES AGAINST THE PATHOGENS TOXOPLASMA GONDII, RUBELLA VIRUS, CMV, HSV-1 AND HSV-2 WITH ONE TEST STRIP. THE DETECTION OF ANTIBODIES OF CLASSES IGG AND IGM PROVIDES USEFUL INFORMATION FOR DETERMINING THE IMMUNITY STATUS, ASSESSING THE RISK IN PREGNANCY AND PERFORMING CONTINUATIVE MONITORING DURING PRENATAL CARE,ANTI-RUBELLA VIRUS ELISA (IGM)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGM AGAINST RUBELLA VIRUS IN SERUM OR PLASMA FOR THE DIAGNOSIS OF RUBELLA,DENGUE VIRUS NS 1 ELISA-THE ELISA TEST KIT PROVIDES SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO DETERMINATION OF DENGUE VIRUS NS1 IN SERUM OR PLASMA TO SUPPORT DIAGNOSIS OF DENGUE FEVER (DF), DENGUE HAEMORRHAGIC FEVER (DHF) AND DENGUE SHOCK SYNDROME (DSS),ANTI-RUBELLA VIRUS GLYCOPROTEIN ELISA (IGM)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGM CLASS AGAINST RUBELLA VIRUS GLYCOPROTEINS IN SERUM OR PLASMA FOR THE DIAGNOSIS OF RUBELLA,CSF: ANTI-TOXOPLASMA GONDII ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR DETECTION OF TOXOPLASMOSIS,ANTI-RUBELLA VIRUS ELISA (IGG)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IGG CLASS AGAINST RUBELLA VIRUS IN SERUM OR PLASMA FOR THE DIAGNOSIS OF RUBELLA,AVIDITY: ANTI-CMV ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF CMV INFECTIONS,CSF: ANTI-RUBELLA VIRUS ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF RUBELLA INFECTIONS,ANTI-HSV-1/2 POOL ELISA (IGM)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF HERPES SIMPLEX INFECTIONS,AVIDITY: ANTI-RUBELLA VIRUS ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF RUBELLA INFECTIONS ,ANTI-HSV-1 (GC1) ELISA (IGG)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST THE HSV-1 SPECIFIC GLYCOPROTEIN C1 IN SERUM OR PLASMA FOR THE DIAGNOSIS OF HERPES SIMPLEX-1 VIRUS INFECTIONS,ANTI-CMV ELISA (IGG)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST CMV IN SERUM OR PLASMA FOR THE DIAGNOSIS OF THE INFECTION WITH CYTOMEGALOVIRUS,ANTI-CMV ELISA (IGM)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE IN VITRO ASSAY FOR HUMAN

		ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGM AGAINST CMV IN SERUM OR PLASMA FOR THE DIAGNOSIS OF THE INFECTION WITH CYTOMEGALOVIRUS.
325	IMP/IVD/2019/000345	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:D-DIMER CONTROL(D-DIMER CONTROL)-THE D-DIMER CONTROL IS A LYOPHILISED CONTROL IN A HUMAN SERUM MATRIX INTENDED TO BE USED TO MONITOR THE ANALYTICAL PERFORMANCE OF THE D-DIMER OSR60135 ON BECKMAN COULTER ANALYSERS.,D-DIMER (D-DIMER)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA ON BECKMAN COULTER AU ANALYSERS.,D-DIMER CALIBRATOR(D-DIMER CALIBRATOR)-THE D-DIMER CALIBRATOR IS A LYOPHILISED CALIBRATOR IN A HUMAN SERUM MATRIX INTENDED TO BE USED WITH THE D-DIMER OSR60135 FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA ON BECKMAN COULTER ANALYSERS.
326	IMP/IVD/2019/000346	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ISO FLOW SHEATH FLUID (ISO FLOW SHEATH FLUID)-A NON-FLUORESCENT, AZIDE FREE BALANCED ELECTROLYTE SOLUTION FOR USE ON COULTER FLOW CYTOMETERS WITH LIGHT SCATTER AND FLUORESCENT APPLICATIONS.

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327	IMP/IVD/2019/000347	1.License Holder Name: HORIBA INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PENTRA GLUCOSE HK CP (ABX)-"ABX PENTRA GLUCOSE HK CP REAGENT IS INTENTED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF GLUCOSE IN HUMAN SERUM, PLASMA AND URINE USING GLUCOSE HEXOKINASE METHOD BY COLORIMETRY. GLUCOSE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CARBOHYDRATE METABOLISM DISORDERS INCLUDING DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, AND IDIOPATHIC HYPOGLYCEMIA, AND OF PANCREATIC ISLET CELL CARCINOMA." ,ABX PENTRA LACTIC ACID(HORIBA MEDICAL)-ABX PENTRA LACTIC ACID REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF LACTIC ACID IN PLASMA BY COLORIMETRY., PENTRA GLUCOSE PAP CP(ABX)-"ABX PENTRA GLUCOSE PAP CP REAGENT IS INTENTED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF GLUCOSE IN HUMAN SERUM, PLASMA AND URINE USING GLUCOSE OXIDASE METHOD BY COLORIMETRY. GLUCOSE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CARBOHYDRATE METABOLISM DISORDERS INCLUDING DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, AND IDIOPATHIC HYPOGLYCEMIA, AND OF PANCREATIC ISLET CELL CARCINOMA." ,ABX PENTRA PHOSPHORUS CP(HORIBA MEDICAL)-ABX PENTRA PHOSPHORUS CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF PHOSPHORUS IN HUMAN SERUM, PLASMA AND URINE BASED ON A UV METHOD USING PHOSPHOMOLYBDATE. ,ABX PENTRA ALBUMIN CP(HORIBA MEDICAL)-ABX PENTRA ALBUMIN CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ALBUMIN IN SERUM PLASMA BY COLORIMETRY.,ABX PENTRA URIC ACID CP(HORIBA MEDICAL)-ABX PENTRA URIC ACID CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA AND URINE BASED ON THE ENZYMATIC DETERMINATION OF URIC ACID USING A CHROMOGENIC SYSTEM IN THE PRESENCE OF PEROXIDASE AND URICASE (TRINDER METHOD)., ABX PENTRA CALCIUM AS CP(HORIBA MEDICAL)-ABX PENTRA CALCIUM AS CP REAGENT, WITH ASSOCIATED CALIBRATOR AND CONTROLS, IS A DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA AND URINE BASED ON A COLOURIMETRIC METHOD, USING THE PENTRA C400 CLINICAL CHEMISTRY ANALYZER.,ABX PENTRA TRIGLYCERIDES CP (HORIBA MEDICAL)-ABX PENTRA TRIGLYCERIDES CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC

	DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA BASED ON AN ENZYMATIC COLORIMETRIC ASSAY. MEASUREMENTS OBTAINED BY THIS DEVICE ARE USED IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH DIABETES MELLITUS, NEPHROSIS, LIVER OBSTRUCTION, OTHER DISEASES INVOLVING LIPID METABOLISM, OR VARIOUS ENDOCRINE DISORDERS.,ABX PENTRA TOTAL PROTEIN CP(HORIBA MEDICAL)-ABX PENTRA TOTAL PROTEIN CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF TOTAL PROTEIN IN SERUM AND PLASMA BY COLORIMETRY. MEASUREMENTS OBTAINED BY THIS DEVICE ARE USED IN THE DIAGNOSIS AND TREATMENT OF A VARIETY OF DISEASES INVOLVING THE LIVER, KIDNEY, OR BONE MARROW AS WELL AS OTHER METABOLIC OR NUTRITIONAL DISORDERS.

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328	IMP/IVD/2019/000348	1.License Holder Name: INSTRUMENTATION LABORATORY INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AST/GOT LIQUID (QUANTILAB)-AST/GOT LIQUID IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ASPARTATE AMINOTRANSFERASE (AST OR GLUTAMIC OXALACETIC TRANSAMINASE, GOT) IN HUMAN SERUM AND PLASMA USING THE ILAB CHEMISTRY SYSTEMS.,ALBUMIN(QUANTILAB)-:ALBUMIN ASSAY IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ALBUMIN IN HUMAN SERUM AND PLASMA USING THE ILAB CHEMISTRY SYSTEMS.,CHOLESTEROL(QUANTILAB)-CHOLESTEROL IS INTENDED FOR QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA USING THE ILAB CHEMISTRY SYSTEMS.,TRIGLYCERIDES (QUANTILAB)-TRIGLYCERIDES IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA, USING THE ILAB CHEMISTRY SYSTEMS, TOTAL BILIRUBIN(QUANTILAB)-:TOTAL BILIRUBIN IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM AND PLASMA USING THE ILAB CHEMISTRY SYSTEMS. ,TOTAL PROTEIN(QUANTILAB)-TOTAL PROTEIN IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM AND PLASMA USING THE ILAB CHEMISTRY SYSTEMS. ,PHOSPHORUS(QUANTILAB)-: PHOSPHORUS IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF INORGANIC PHOSPHORUS IN HUMAN SERUM, PLASMA AND URINE USING THE ILAB CHEMISTRY SYSTEMS,AMYLASE(QUANTILAB)-AMYLASE IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF AMYLASE IN HUMAN SERUM, PLASMA AND URINE USING THE ILAB CHEMISTRY SYSTEMS.,CREATININE ENZYMATIC(QUANTILAB)-CREATININE ENZYMATIC IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE USING THE ILAB CHEMISTRY SYSTEM.,G-GT LIQUID(QUANTILAB)-GT LIQUID IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF GAMMA-GLUTAMYL TRANSFERASE (-GT) IN HUMAN SERUM AND PLASMA USING THE ILAB CHEMISTRY SYSTEMS.,CREATININE(QUANTILAB)-CREATININE IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA OR URINE USING THE ILAB CHEMISTRY SYSTEM. ,ALT/GPT LIQUID (QUANTILAB)-:ALT/GPT LIQUID IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ALANINE

	AMINOTRANSFERASE (ALT OR GLUTAMIC PYRUVATE TRANSAMINASE, GPT) IN HUMAN SERUM AND PLASMA USING THE ILAB CHEMISTRY SYSTEMS.,LDL CHOLESTEROL(QUANTILAB)-:LDL CHOLESTEROL IS INTENDED FOR THE DIRECT QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF LOW-DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN HUMAN SERUM AND PLASMA USING ILAB CHEMISTRY SYSTEMS. REFERRIL HDL-LDL CHOLESTEROL IS A CALIBRATOR INTENDED FOR THE CALIBRATION OF THE HIGH-DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) AND THE LOW-DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) ASSAY USING THE ILAB CHEMISTRY SYSTEMS.,HDL CHOLESTEROL(QUANTILAB)-:HDL CHOLESTEROL IS INTENDED FOR THE DIRECT QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF HIGH-DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) IN HUMAN SERUM AND PLASMA USING ILAB CHEMISTRY SYSTEMS. REFERRIL HDL CHOLESTEROL IS A CALIBRATOR INTENDED FOR THE CALIBRATION OF THE HIGH-DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) ASSAY USING THE ILAB CHEMISTRY SYSTEMS.,GLUCOSE (OXIDASE)(QUANTILAB)-: GLUCOSE (OXIDASE) IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF GLUCOSE IN HUMAN SERUM, PLASMA, URINE AND CEREBROSPINAL FLUID (CFS) USING THE ILAB CHEMISTRY SYSTEMS,LIPASE(QUANTILAB)-LIPASE IS INTENDED FOR QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF PANCREATIC LIPASE IN HUMAN SERUM AND PLASMA USING THE ILAB CHEMISTRY SYSTEMS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

329	IMP/IVD/2019/000350	1.License Holder Name: PASSIM MEDICHEM AGENCIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS (GLUCOSE DEHYDROGENASE FAD-DEPENDENT)(DR. ODIN ACCUGENCE)-FOR IN VITRO DIAGNOSTIC USE. ACCUGENCE R BLOOD GLUCOSE TEST STRIPS (GLUCOSE DEHYDROGENASE FAD-DEPENDENT) ARE USED TO MEASURE THE AMOUNT OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD OR VENOUS WHOLE BLOOD, WHICH IS USED TO MONITOR HOW WELL THE DIABETES CONTROL PROGRAMS WORK. ACCUGENCE R BLOOD GLUCOSE TEST STRIPS (GLUCOSE DEHYDROGENASE FAD-DEPENDENT) CAN BE USED ONLY OUTSIDE THE BODY. FOR SELF-TESTING AND PROFESSIONAL USE. BLOOD GLUCOSE TEST STRIPS (GLUCOSE OXIDASE)(DR. ODIN ACCUGENCE)-FOR IN VITRO DIAGNOSTIC USE. ACCUGENCE R BLOOD GLUCOSE TEST STRIPS (GLUCOSE OXIDASE) ARE USED TO MEASURE THE AMOUNT OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD, WHICH IS USED TO MONITOR HOW WELL THE DIABETES CONTROL PROGRAMS WORK. ACCUGENCE R BLOOD GLUCOSE TEST STRIPS (GLUCOSE OXIDASE) CAN BE USED ONLY OUTSIDE THE BODY. FOR SELF-TESTING AND PROFESSIONAL USE.
330	IMP/IVD/2019/000351	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ICHEM VELOCITY WASH SOLUTION(ICHEM VELOCITY WASH SOLUTION)-THE ICHEMVELOCITY WASH SOLUTION IS A BUFFER SOLUTION FOR ROUTINE RINSE OF ICHEMVELOCITY URINE CHEMISTRY SYSTEM. THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC USE WITH THE ICHEMVELOCITY.,DXH 500 SERIES DILUENT(DXH 500 SERIES DILUENT)-FOR USE AS AN ISOTONIC BUFFERED DILUENT USED IN CONJUNCTION WITH A CYANIDE-FREE LYTIC AGENT FOR COUNTING AND SIZING BLOOD CELLS ON THE DXH 500 SERIES SYSTEMS. USE ONLY WITH DXH 500 SERIES LYSE REAGENT.,IQ LAMINA (IQ LAMINA)-IQ LAMINA IS INTENDED FOR IN VITRO DIAGNOSTIC USE WITH IQ200 SERIES ANALYZERS.

331	IMP/IVD/2019/000352	1.License Holder Name: AMINDO BIOLOGICS PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTI CARDIOLIPIN IGM-ANTI CARDIOLIPIN IGM KIT IS AN INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS AUTO-ANTIBODIES DIRECTED AGAINST CARDIOLIPINA-2-GLYCOPROTEIN COMPLEX IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF INCREASED RISK OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERITEMATOSUS (SLE) OR SIMILAR DISORDERS. ANTI CARDIOLIPIN IGM KIT IS INTENDED FOR LABORATORY USE ONLY.,ANTI DEAMIDATED GLIADIN PEPTIDE (DGP) IGA-"ANTI DEAMIDATED GLIADIN PEPTIDE (DPG) IGA KIT IS A SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS ANTIBODIES DIRECTED AGAINST DEAMIDATED GLIADIN PEPTIDES (DGP) IN HUMAN SERUM OR PLASMA. ANTI DEAMIDATED GLIADIN PEPTIDE (DPG) IGA IS INTENDED FOR LABORATORY USE ONLY." ,17OH PROGESTERONE ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF 17OH PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. 17OH PROGESTERONE ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,DHEA-S ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF DEHYDRO-EPIANDROSTERONE SULFATE (DHEA-S) CONCENTRATION IN HUMAN SERUM OR PLASMA. DHEA-S ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,ANTI BETA 2 GLYCOPROTEIN 1 SCREEN-"ANTI BETA 2 GLYCOPROTEIN 1 SCREEN IS AN INDIRECT ENZYMELINKED IMMUNOSORBENT ASSAY (ELISA) KIT DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGG OR IGM CLASS ANTIBODIES DIRECTED AGAINST THE 2-GLYCOPROTEIN 1 IN HUMAN SERUM OR PLASMA. ANTI BETA 2 GLYCOPROTEIN 1 SCREEN IS INTENDED FOR LABORATORY USE ONLY." ,ALDOSTERONE ELISA-"COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF ALDOSTERONE CONCENTRATION IN HUMAN SERUM, HUMAN PLASMA OR URINE. ALDOSTERONE ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.",ANTI BETA 2 GLYCOPROTEIN 1 IGM-"ANTI BETA 2 GLYCOPROTEIN 1 IGM KIT IS AN INDIRECT ENZYMELINKED IMMUNOSORBENT ASSAY (ELISA) DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS ANTIBODIES DIRECTED AGAINST THE 2-GLYCOPROTEIN 1 IN HUMAN SERUM OR PLASMA. ANTI BETA 2 GLYCOPROTEIN 1 IGM KIT IS INTENDED FOR LABORATORY USE ONLY." ,ANTI DSDNA IGG-"ANTI DSDNA IGG KIT IS AN INDIRECT SOLID

	PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES DIRECTED AGAINST DSDNA IN HUMAN SERUM OR PLASMA. ANTI DSDNA IGG IS INTENDED FOR LABORATORY USE ONLY",ANTI PHOSPHOLIPID SCREEN-ANTI PHOSPHOLIPID SCREEN IS AN INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTO-ANTIBODIES DIRECTED AGAINST 2-GLYCOPROTEIN MEDIATED ANIONIC PHOSPHOLIPIDS IN HUMAN SERUM OR PLASMA, INCLUDING CARDIOLIPIN, PHOSPHATIDYL SERINE, PHOSPHATIDYL INOSITOL, PHOSPHATIDIC ACID, PHOSPHATIDYL CHOLINE, LYSO-PHOSPHATIDYL CHOLINE, PHOSPHATIDYL ETHANOLAMINE. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF INCREASED RISK OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERITEMATOSUS (SLE) OR SIMILAR DISORDERS. ANTI PHOSPHOLIPID SCREEN KIT IS INTENDED FOR LABORATORY USE ONLY.,ANA SCREEN-"ANA SCREEN KIT IS AN INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) DESIGNED FOR SEMIQUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED AGAINST SM (SMITH), RNP/SM, SCL-70, SS-A (RO) (52KDA E 60KDA), SS-B (LA), JO1, U1-SMRNP, CENP-B, DSDNA, AND HISTONES IN HUMAN SERUM OR PLASMA. ANA SCREEN KIT IS INTENDED FOR LABORATORY USE ONLY.",ANTI CARDIOLIPIN IGG-ANTI CARDIOLIPIN IGG KIT IS AN INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTO-ANTIBODIES DIRECTED AGAINST CARDIOLIPINA-2- GLYCOPROTEIN COMPLEX IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF INCREASED RISK OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERITEMATOSUS (SLE) OR SIMILAR DISORDERS. ANTI CARDIOLIPIN IGG KIT IS INTENDED FOR LABORATORY USE ONLY.,PROGESTERONE ELISA-"COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. PROGESTERONE ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.",URINARY CORTISOL ELISA-"COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE CORTISOL CONCENTRATION IN URINE. URINARY CORTISOL ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.",FERRITIN ELISA-"IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FERRITIN CONCENTRATION IN HUMAN SERUM OR PLASMA. FERRITIN ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.",THYROGLOBULIN ELISA-"IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF

	THYROGLOBULIN CONCENTRATION IN HUMAN SERUM. THYROGLOBULIN ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.",ANTI BETA 2 GLYCOPROTEIN 1 IGG-"ANTI BETA 2 GLYCOPROTEIN 1 IGG IS AN INDIRECT ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) KIT DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES DIRECTED AGAINST THE 2-GLYCOPROTEIN 1 IN HUMAN SERUM OR PLASMA. ANTI BETA 2 GLYCOPROTEIN 1 IGG IS INTENDED FOR LABORATORY USE ONLY" ,ANTI CARDIOLIPIN SCREEN-"ANTI CARDIOLIPIN SCREEN IS AN INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGG OR IGM CLASS AUTO-ANTIBODIES DIRECTED AGAINST CARDIOLIPIN- 2-GLYCOPROTEIN COMPLEX IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF INCREASED RISK OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERITEMATOSUS (SLE) OR SIMILAR DISORDERS. ANTI CARDIOLIPIN SCREEN KIT IS INTENDED FOR LABORATORY USE ONLY." ,ANTI TISSUE TRANSGLUTAMINASE IGG-"ANTI TISSUE TRANSGLUTAMINASE IGG IS AN INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) KIT DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES DIRECTED AGAINST TISSUE TRANSGLUTAMINASE IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF CELIAC DISEASE AND DERMATITIS HERPETIFORMIS. ANTI TISSUE TRANSGLUTAMINASE IGG KIT IS INTENDED FOR LABORATORY USE ONLY." ,ANTI PR-3 (C-ANCA) -"ANTI PR-3 (C-ANCA) IS AN INDIRECT SOLID PHASE ENZYME IMMUNOASSAY (ELISA) FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST PROTEINASE 3 (PR-3) IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF CERTAIN AUTOIMMUNE VASCULITIDES SUCH AS WEGENER´S GRANULOMATOSIS. ANTI PR-3 (C-ANCA) KIT IS INTENDED FOR LABORATORY USE ONLY.",ANTI MPO (P-ANCA)-"ANTI MPO (P-ANCA) KIT IS AN INDIRECT SOLID PHASE ENZYME IMMUNOASSAY (ELISA) FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST MYELOPEROXIDASE (MPO) IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF CERTAIN AUTOIMMUNE VASCULITITES SUCH AS WEGENER´S GRANULOMATOSIS. ANTI MPO (P-ANCA) KIT IS INTENDED FOR LABORATORY USE ONLY.",25OH VITAMIN D-"IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF 25OH VITAMIN D CONCENTRATION IN HUMAN SERUM OR PLASMA.

	25OH VITAMIN D KIT IS INTENDED FOR LABORATORY USE ONLY." , ANDROSTENEDIONE ELISA-"COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF ANDROSTENEDIONE CONCENTRATION IN HUMAN SERUM OR PLASMA. ANDROSTENEDIONE ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.",FREE ESTRIOL ELISA-"COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE ESTRIOL CONCENTRATION IN HUMAN SERUM OR PLASMA. FREE ESTRIOL ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.",ANTI DEAMIDATED GLIADIN PEPTIDE (DGP) IGG-"ANTI DEAMIDATED GLIADIN PEPTIDE (DGP) IGG IS AN INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) KIT DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES DIRECTED AGAINST DEAMIDATED GLIADIN PEPTIDES (DGP) IN HUMAN SERUM OR PLASMA. ANTI DEAMIDATED GLIADIN PEPTIDE (DGP) IGG KIT IS INTENDED FOR LABORATORY USE ONLY." , TESTOSTERONE ELISA-"COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. TESTOSTERONE ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.",FREE TESTOSTERONE ELISA-"COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. SECOND GENERATION KIT. FREE TESTOSTERONE ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.",ANTI TISSUE TRANSGLUTAMINASE IGA-"ANTI TISSUE TRANSGLUTAMINASE IGA IS AN INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) KIT DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS ANTIBODIES DIRECTED AGAINST TISSUE TRANSGLUTAMINASE IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF CELIAC DISEASE AND DERMATITIS HERPETIFORMIS. ANTI TISSUE TRANSGLUTAMINASE IGA KIT IS INTENDED FOR LABORATORY USE ONLY." ,ANTI CP IGG-"ANTI CP IGG IS AN INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) KIT DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES DIRECTED AGAINST CITRULLINATED PEPTIDES (CP) IN HUMAN SERUM OR PLASMA. ANTI CP IGG KIT IS INTENDED FOR LABORATORY USE ONLY." ,TOTAL ESTRIOL ELISA-"COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF TOTAL ESTRIOL CONCENTRATION IN HUMAN SERUM OR PLASMA. TOTAL ESTRIOL KIT ELISA IS INTENDED FOR LABORATORY USE ONLY.",CH50-"IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE

		DETERMINATION OF COMPLEMENT FUNCTIONALITY IN HUMAN SERUM. CH50 KIT IS INTENDED FOR LABORATORY USE ONLY."
332	IMP/IVD/2019/000353	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AQUIOS SHEATH SOLUTION(AQUIOS SHEATH SOLUTION)-A NON-FLUORESCENT, AZIDE FREE BALANCED ELECTROLYTE SOLUTION FOR USE ON AQUIOS FLOW CYTOMETERS WITH LIGHT SCATTER AND FLUORESCENT APPLICATIONS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

333	IMP/IVD/2019/000354	1.License Holder Name: DHR HOLDING INDIA PVT. LTD, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABL80 SC80(SC80 200/60 FULL)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80 (SC80 200/60 BG/HCT)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS., ABL80 SC80(SC80 300/60 BG/HCT)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80(SC80 50/60 BG/HCT)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80(SC80 50/30 FULL + LAC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80 (SC80 100/60 BG/HCT)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS., ABL80 SC80(SC80 200/30 FULL + LAC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80(SC80 25/30 FULL + LAC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING

	ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80(SC80 300/60 FULL)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80(SC80 600/15 BG/HCT)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80 (SC80 300/30 FULL)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS., ABL80 SC80(SC80 25/60 FULL)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS., ABL80 SC80(SC80 600/15 FULL + LAC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80(SC80 100/30 FULL + LAC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80(SC80 300/15 FULL)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80(SC80 50/60 FULL)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80(SC80 600/15 FULL)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE

	(CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80(SC80 25/60 BG/HCT)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80 (SC80 100/60 FULL)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS., ABL80 SC80(SC80 300/15 FULL + LAC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80(SC80 300/30 FULL + LAC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURE PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, HEMATOCRIT, GLUCOSE (CGLU), AND LACTATE (CLAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.

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334	IMP/IVD/2019/000357	1.License Holder Name: M/S. GOLDEN HARVEST INDUSTRIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL BILE ACIDS(TBA) KIT(ENZYMATIC CYCLING ASSAY)(MINDRAY)-IN VITRO TEST .FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILE ACID CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,M-18CFL LYSE(MINDRAY)-FOR USE ON MINDRAY BC-1800/BC-2800/BC-2600 HEMATOLOGY ANALYZER. ,M-58LH LYSE (MINDRAY)-M-58 LH LYSE APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT BREAKS DOWN RED BLOOD CELL MEMBRANE AND CONVERTS HEMOGLOBIN TO A HEMOGLOBIN COMPLEX TO DETERMINE THE HG8.,CREATINE KINASE KIT (IFCC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATININE CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,M-58LEO(II) LYSE (MINDRAY)-M-58 LEO (II) LYSE APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT COOPERATES WITH THE M-58 LEO (I) LYSE TO 4 DIFFERENTIATE W8C'S ,COMPLEMENT C3 KIT (IMMUNOTURBIDIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF C3 CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,M-68LN LYSE(MINDRAY)-THE M-68LN LYSE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF NRBC-RELATED PARAMETERS TOGETHER WITH M-68FN DYE.,V-28D DILUENT(MINDRAY)-AN AZIDE-FREE FILTERED ISOTONIC SOLUTION FOR USE IN BLOOD CELL COUNTING AND SIZING. USE AS DIRECTED IN INSTRUMENT OPERATION MANUAL.,BILIRUBINDIRECT (BIL-D) KIT(DSA METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF D-BIL CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,M-50 LEO (I) LYSE (MINDRAY)-M-50 LEO (I) LYSE APPLIES TO 5 PART DIFFERNTIAL AUTO HEMATOLOGY ANALYSER. IT IS USED TO LYSE RED BLOOD CELLS AND 4 DIFFERENTIATES WBC'S ,TRIGLYCERIDES(TG) KIT (GPO-POD METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TG CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM ,ADENOSINE DEAMINASE (ADA) KIT (ENZYMATIC COLORIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ADA ACTIVITY IN SERUM ON PHOTOMETRIC SYSTEMS.,LIPASE(LIP)KIT(ENZYMATIC COLORIMETRIC ASSAY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LIP CONCENTRATION IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEM ,PREALBUMIN CALIBRATOR (MINDRAY)-PRE ALBUMIN CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF SPECIFIC

	PROTEINS ON MINDRAY BS MEASUREMENT SYSTEM ,M-68LB LYSE (MINDRAY)-THE M-68LB LYSE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN WBC COUNTING AND MEASUREMENT OF BASOPHIL- RELATED PARAMETERS.,-HYDROXYBUTYRATE DEHYDROGENASE KIT (DGKC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF A HBDH ACTIVITY IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,ALANINE AMINOTRANSFERASE KIT (IFCC METHOD)(MINDRAY)-ALT REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE ACTIVITY IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEM.,TRF CONTROL (MINDRAY)-TRF CONTROL IS USED IN TRANSFERRRIN PROTEINS QUALITY CONTROL BY MONITORING PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY. , FRUCTOSAMINE(FUN)KIT(COLORIMETRIC ASSAY)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF FRUCTOSAMINE CONCENTRATION IN SERUM, HEPARIN PLASMA ON PHOTOMETRIC SYSTEMS. ,LIPIDS CALIBRATOR(MINDRAY)-LIPID CALIBRATOR IS USED FOR CALIBRATION OF QUANTITATIVE DETERMINATION OF LIPID ANALYTES ON MINDRAY BS MEASUREMENT SYSTEM ,M-58LEO(I)LYSE (MINDRAY)-M-58 LEO (I) LYSE APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT BREAKS DOWN RED BLOOD CELL MEMBRANE AND COOPERATES WITH THE M-58 LEO (II) LYSE TO 4 DIFFERENTIATE W8C'S .,HDL-CHOLESTEROL KIT (DIRECT METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BIL-D CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM ,BILIRUBIN TOTAL KIT (VOX METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BIL - T CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,V-28E E-Z CLEANSER(MINDRAY)-INTENDED FOR CLEANING THE HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATION MANUAL.,CREATININE KIT (SARCOSINE OXIDASE METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATININE CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,M-68FR DYE(MINDRAY)-THE M-68FR DYE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF RET-RELATED PARAMETERS TOGETHER WITH M-68DR DILUENT., MULTI CONTROL SERA P(MINDRAY)-MULTI CONTROL SERA P IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION ON MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY,URIC ACID(UA) KIT(URICASE-PEROXIDASE METHOD)(MINDRAY)-IN VITRO

	TEST FOR THE QUANTITATIVE DETERMINATION OF UA CONCENTRATION IN SERUM, PLASMA AND URINE ON PHOTOMETRIC SYSTEM ,M-50D DILUENT (MINDRAY)-M-50 D DILUENTS APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLOGY ANALYZER. IT IS USED TO PROVIDE A STABLE ENVIRONMENT FOR COUNTING AND SIZING BLOOD CELLS,HBA1C CALIBRATOR(MINDRAY)-HBA1C CALIBRATOR IS USED FOR CALIBRATION OF QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C ANALYTE ON MINDRAY BS MEASUREMENT SYSTEM. ,V-52LH LYSE(MINDRAY)-V-52LH LYSE APPLIES TO BC- 5000VET VETERINARY AUTO HEMATOLOGY ANALYZER MANUFACTURED BY MINDRAY, IT DISSOLVES RBCS, REALIZES WBC COUNTING, BASOPHIL DIFFERENTIAL AND HEMOGLOBIN MEASUREMENT.,BILIRUBIN DIRECT KIT (VOX METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BIL-D CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM ,MULTI CONTROL SERA N(MINDRAY)-MULTI CONTROL SERA N IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION ON MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY,IRON(FE)KIT(COLORIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM AND HEPARIN PLASMA ON PHOTOMETRIC SYSTEM, MR BUFFER SOLUTION(MINDRAY)-MR BUFFER SOLUTION APPLIES TO MINDRAY BS SERIES AUTO CHEMISTRY ANALYZERS. IT IS USED TO DILUTE SAMPLES BEFORE THEY ARE DISPOSED TO THE ELECTRODES FLOWCELL. USE THE MR BUFFER SOLUTION AS INSTRUCTED BY THE OPERATOR'S MANUAL OF THE ANALYZER.,LIPOPROTEIN(A) CALIBRATOR(MINDRAY)-LIPOPORTEIN (A) CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF LIPID ANALYTE ON MIND RAY BS MEASUREMENT SYSTEM,BC-5D ((HIGH/NORMAL/LOW)*2/EN3ML*6)(MINDRAY)-BC - 50 IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS ,M-68DR DILUENT(MINDRAY)-THE M-68DR DILUENT APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF RET-RELATED PARAMETERS TOGETHER WITH M-68FR DYE. ,CARBON DIOXIDE(CO2)KIT(ENZYMATIC METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF C02 CONCENTRATION IN SERUM AND HEPARIN PLASMA ON PHOTOMETRIC SYSTEM,M-53 LEO (I) LYSE (MINDRAY)-M-53LEO(I) LYSE BREAKS DOWN RED BLOOD CELL MEMBRANE AND COOPERATES WITH THE M-53LEO(II) LYSE TO 4-DIFFERENTIATE WBCS. ,CK-MB CALIBRATOR(MINDRAY)-CK-MB CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF

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	CARDIAC ANALYTE ON MINDRAY BS MEASUREMENT SYSTEM,M-58LBA LYSE(MINDRAY)-M-58 L8A LYSE APPLIES TO MINDRAY BC-5600 , 8C-5800 AUTO HEMATOLOGY ANALYZER. IT BREAKS DOWN RED BLOOD CELL MEMBRANE AND 2 DIFFERENTIATES W8C'S TO BASOPHILS AND OTHER W8C'S,BC-RET (MINDRAY)-BC-RET IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.,APOLIPOPROTEIN B KIT (TURBIDEMETRY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF APOB CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,M-58D DILUENT(MINDRAY)-M-58 D DILUENTS APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT PROVIDE A STABLE ENVIRONMENT FOR COUNTING AND SIZINQ BLOOD CELLS.,M-53 CLEANSER (MINDRAY)-AN-AZIDE FREE FILTERED SOLUTION FOR USE IN CLEANING HEMATOLOGY ANALYZER,M-52LH LYSE(MINDRAY)-M-52 LH LYSE FUTHER PROCESS THE BLOOD CELL THAT HAVE BEEN PROCESSED BY M-52 DIFF LYSE. IT TURNS HEMOGLOBIN INTO METHEMOGLOBIN, WHICH THEN MEASURED BY THE COLORIMETRIC METHOD. IT IS ALSO PROCESSES W8C'S TO INTENSIFY THE DIFFERENCE BETWEEN BASOPHILES AND OTHER W8C SUB POPULATIONS AND IN CORPORATE CYTOMETRY TO REALIZE BASOPHIL ANALYSIS,M-53P PROBE CLEANSER(MINDRAY)-M-53P PROBE CLEANSER APPLIES TO MINDRAY BC-5300, BC-5380 BC-5100, BC-5180, ULTIMA 5 AUTO HEMATOLOGY ANALYZER. IT IS USED TO CLEAN THE ANALYZER REGULARLY. USE THE M-53P PROBE CLEANER AS INSTRUCTED BY THE OPERATOR'S MANUAL OF THE ANALYZER. ,CD80 DETERGENT (MINDRAY)-CLEAN SAMPLE AND REAGENT PROBES, MIXERS AND CUVETTES OF THE CHEMISTRY ANALYZER MANUFACTURED BY MINDRAY. ,V28P PROBE CL(MINDRAY)-INTENDED FOR CLEANING THE HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATION MANUAL. ,M-52D DILUENT(MINDRAY)-M-52 D DILUENT PROIVDE STABLE SOLUTION ENVIRONMENT FOR BLOOD CELLS, DILUTE BLOOD SAMPLE, GENERATES SHEATH FLUID AND PROVIDE CONDUCTANCE IN BLOOD CELL ANALYSIS PROCESS,M-50P PROBE CLEANSER (MINDRAY)-M-50 P PROBE CLEANSER APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLOGY ANALYZER. IT IS USED TO CLEAN THE ANALYZER REGULARLY ,M-52DIFF LYSE (MINDRAY)-M-52 DIFF LYSE DISSOLVES RBCS IN THE BLOOD CELL ANALYSIS PROCESS. IT PROCESSES W8CS TO INTENSIFY THE DIFFERENCE OF THE WBC SUB POPULATIONS AND IN CORPORATE LASER SCATTER AND FLOW CYTOMETRY TO REALIZE DIFF CHANNEL WBC ANALYSIS,HIGH SENSITIVITY C-REACTION PROTEIN (HS-CRP) KIT (PARTICLE-ENHANCED IMMUNOTURBIDIMETRIC ASSAY METHOD)

	(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CRP CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS.,M-53 LEO (II) LYSE (MINDRAY)-M-53LEO(II) LYSE COOPERATES WITH THE M-53LEO(I) LYSE TO 4- DIFFERENTIATE WBCS.,M-18P PROBE CLEANSER(MINDRAY)-FOR USE ON MINDRAY BC-1800/BC- 2800/BC-2600 HEMATOLOGY ANALYZER. FOR USE AS A CLEANING REAGENT FOR HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,M-53 LH LYSE(MINDRAY)-M-53LH LYSE BREAKS DOWN RED BLOOD CELL MEMBRANE AND CONVERTS HEMOGLOBIN TO A HEMOGLOBIN COMPLEX TO DETERMINE THE HGB. IT 2- DIFFERENTIATES WBCS TO BASO AND OTHER WBCS, AND DETERMINES WBCS AMOUNT.,M-50LBA LYSE (MINDRAY)-M-50 LBA LYSE APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLOGY ANALYZER. IT IS USED TO LYSE RED BLOOD CELLS AND COUNT WBC'S AND BASOPHILS. , HEMOGLOBIN A1C(HBA1C)KIT(ENZYMATIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF HBA1C CONCENTRATION IN HUMAN WHOLE BLOOD ON PHOTOMETRIC SYSTEMS ,LDL-CHOLESTEROL KIT (DIRECT METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LDLCHOLESTEROL CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,IMMUNOGLOBULIN A(IGA) KIT(IMMUNOTURBIDIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGA CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM ,UREA KIT (UREASE-GLDH, UV METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF UREA CONCENTRATION IN SERUM, PLASMA AND URINE ON PHOTOMETRIC SYSTEM,ALKALINE PHOSPHATASE KIT (IFCC MODIFIED METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALP ACTIVITY IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,CHOLINESTERASE(CHE)KIT (BUTYRYLTHIOCHOLINE MINDRAY METHOD)(MINDRAY)-CHE REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CHE ACTIVITY IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEM,MULTI SERA CALIBRATOR(10×3ML)(MINDRAY)-MULTI SERA CALIBRATOR IS USED FOR CALIBRATION OF QUANTITATIVE DETERMINATION OF ROUTINE CHEMISTRY ANALYSTES ON MINDRAY BS MEASUREMENT SYSTEM,LIPOPROTEIN(A) CONTROL N&P(MINDRAY)-LIPOPROTEIN (A) N & P IS USED IN LIPID ANALYTE QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY,M-50 LH LYSE(MINDRAY)-M-50 LH LYSE APPLIES TO 5 PART DIFFERNTIAL AUTO HEMATOLOGY ANALYSER. IT IS USED TO LYSE RED BLOOD CELLS AND DETERMINE THE HGB,CREATINE KINASE-MB KIT (IFCC

	METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE- MB (CK-MB) ACTIVITY IN SERUM ON PHOTOMETRIC SYSTEMS.,ASPARTATE AMINOTRANSFERASE KIT (IFCC METHOD)(MINDRAY)-AST REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OR PLASMA ON PHOTOMETRIC SYSTEM IN SERUM AST ACTIVITY,CLINCHEM MULTI CONTROL (LEVEL 1)(MINDRAY)-CLINCHEM MULTI CONTROL (LEVEL 1) IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,M-68DS DILUENT(MINDRAY)-THE M-68DS DILUENT APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF PARAMETERS RELATED TO RBC, PLT, WBC, RET AND NRBC. M- 68DS DILUENT ALSO APPLIES TO SC- 120 AUTO SLIDE MAKER & STAINER AND CRP-M100 SPECIFIC PROTEIN ANALYZER MANUFACTURED BY MINDRAY. IT PARTICIPATES IN THE CLEANING OF RELATED COMPONENTS OF THE AUTO SLIDE MAKER & STAINER AND SPECIFIC PROTEIN ANALYZER.,M-68LD LYSE(MINDRAY)-THE M-68LD LYSE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN WBC DIFFERENTIATION IN THE DIFF CHANNEL TOGETHER WITH M-68FD DYE.,IMMUNOGLOBULIN M (IGM) KIT (IMMUNOTURBIDIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGM CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM.,M-30E E-Z CLEANSER (MINDRAY)-FOR USE ON MINDRAY BC-3000/BC-3000PLUS/BC-3000CT/ BC-3200 HEMATOLOGY ANALYZER. FOR USE AS A CLEANING REAGENT FOR CLEANING HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL. ,BILIRUBINTOTAL (BIL-T) KIT(DSA METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TC CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM ,CLINCHEM MULTI CONTROL (LEVEL 2)(MINDRAY)-CLINCHEM MULTI CONTROL (LEVEL 2) IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY. ,M-18R RINSE(MINDRAY)-FOR USE ON MINDRAY BC-1800/BC- 2800/BC-2600 HEMATOLOGY ANALYZER. FOR USE AS AN AZIDE- FREE, FILTERED ISOTONIC SOLUTION FOR COUNTING AND SIZING BLOOD CELLS. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,PROBE CLEANSER (MINDRAY)-PROBE CLEANSER APPLIES TO MINDRAY BC-20, BC-21, BC-10, BC- 11, BC-6800, BC-6600, BC-5000, BC-5150, BC-5390 CRP, BC-5180 CRP, BC-30S, BC-31S, BC-20S, BC- 21S, BC-5120, BC-5130, BC-5310 CRP,

	BC-5100 CRP, BC-5140, BC- 30, BC-31, BC-6000, BC- 6000PLUS, BC-6100, BC- 6100PLUS, BC-6200, BC- 6600PLUS, BC-6700PLUS, BC-6800PLUS AUTO HEMATOLOGY ANALYZER, BC-5000VET VETERINARY AUTO HEMATOLOGY ANALYZER, SC- 120 AUTO SLIDE MAKER & STAINER AND CRP-M100 SPECIFIC PROTEIN ANALYZER. IT IS USED TO CLEAN THE INSTRUMENT REGULARLY.,MR SERUM STANDARD(MINDRAY)-MR SERUM STANDARD IS INTENDED FOR USE AS CALIBRATOR FOR IN VITRO TESTING FOR THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM, AND CHLORIDE CONCENTRATION IN SERUM AND PLASMA SAMPLE ON ION-SELECTIVE ELECTRODE ON ISE MODULES ON BS SERIES AUTOMATIC CHEMISTRY ANALYZERS). BEFORE CARRYING OUT CLINICAL PRACTICE, PARAMETERS OF THE CHEMISTRY ANALYZER NEED TO BE CALIBRATED AS INSTRUCTED IN INSTRUMENT MANUAL. ,BC-6D (MINDRAY)-BC-5D IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS,M-50 CLEANSER (MINDRAY)-M-50 CLEANSER APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLGY ANALYZER. IT IS AN ISOTONIC , CLEANING SOLUTION USE TO CLEAN THE ANALYSER ,SC-CAL PLUS CALIBRATOR(MINDRAY)-SC CAL PLUS IS DESIGNED FOR USE IN THE CALIBRATION OF HEMATOLOGY ANALYZER,M-30D DILUENT (MINDRAY)-IT IS USE ON MINDRAY THREE PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS USE AS AZIDE FREE, FILTERED ISOTONIC SOLUTION FOR COUNTING AND SIZING OF BLOOD CELLS, M-50 LEO (II) LYSE (MINDRAY)-M-50 LEO (II) LYSE APPLIES TO 5 PART DIFFERNTIAL AUTO HEMATOLOGY ANALYSER. IT IS USED TO LYSE RED BLOOD CELLS AND 4 DIFFERENTIATES WBC'S, IMMUNOGLOBULIN G(IGG) KIT(IMMUNOTURBIDIMETRIC METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGG CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,M-53D DILUENT (MINDRAY)-M-53D DILUENT PROVIDES A STABLE ENVIRONMENT FOR COUNTING AND SIZING BLOOD CELLS.,M-30R RINSE(MINDRAY)-IT IS USE ON MINDRAY THREE PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS USE AS AZIDE FREE, FILTERED ISOTONIC SOLUTION FOR CLEANING HEMATOLOGY ANALYSER,M-68FD DYE(MINDRAY)-THE M-68FN DYE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF NRBC-RELATED PARAMETERS TOGETHER WITH M-68LN LYSE.,M-30CFL LYSE(MINDRAY)-FOR USE ON MINDRAY THREE PART DIFFERENTIAL HEMATOLOGY ANALYZER FOR USE AS A CYANIDE FREE LYTIC REAGENT FOR QUANTITATIVELY DETERMINING HEMOGLOBIN AND FOR COUNTING AND SIZING LEUKOCYTES ,

	LACTATE DEHYDROGENASE KIT (IFCC METHOD)(MINDRAY)-LDH REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. ,MR URINE QUALITY CONTROL(MINDRAY)-MR URINE QUALITY CONTROL IS AN ELECTROLYTE REFERENCE URINE CONTROL USED TO MONITOR THE URINE MODE PERFORMANCE OF ION- SELECTIVE ELECTRODE ON ISE MODULES ON AUTOMATIC CHEMISTRY ANALYZERS. DAILY USE OF THIS URINE CONTROL PROVIDES QUALITY CONTROL DATA FOR CONFIRMING THE PRECISION AND ACCURACY OF URINE SAMPLE TESTS.,M30P PROBE CLEANSER(MINDRAY)-FOR USE ON MINDRAY BC- 3000PLUS/BC-3000CT/BC-3200 HEMATOLOGY ANALYZER. FOR USE AS AN AZIDE-FREE, FILTERED ISOTONIC SOLUTION FOR COUNTING AND SIZING BLOOD CELLS. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,MAGNESIUMMG KITXYLIDYL BLUE METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF MG CONCENTRATION IN SERUM, PLASMA AND URINE ON PHOTOMETRIC SYSTEM ,MICROALBUMIN (MALB) KIT (IMMUNOTURBIDIMETRIC ASSAY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF MALB CONCENTRATION IN URINE ON PHOTOMETRIC SYSTEMS.,M-68LH LYSE(MINDRAY)-THE M-68LH LYSE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT IS FORMULATED TO MEASURE THE HEMOGLOBIN-RELATED PARAMETERS,GAMMA–GLUTAMYLTRANSFERASE KIT (SZASZ METHOD / IFCC STAND)(MINDRAY)-GGT REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF GAMMA-GLUTAMYLTRANSFERASE ACTIVITY IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,PHOSPHORUS(P) KIT (PHOSPHOMOLYBDATE METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF P CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,V-28CFL LYSE(MINDRAY)-A CYANIDE FREE LYSE REAGENT, INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN AND LEUKOCYTE COUNTING AND SIZING ,M-58 CLEANSER (MINDRAY)-PROBE CLEANSER APPLIES TO MINDRAY BC-5600, BC-5800, BC-3300, BC-3600 AUTO HEMATOLOGY ANALYZER. IT IS USED TO CLEAN THE ANALYZER REGULARLY. USE THE PROBE CLEANER AS INSTRUCTED BY THE OPERATOR'S MANUAL OF THE ANALYZER. ,M-68FN DYE(MINDRAY)-THE M-68FN DYE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF NRBC-RELATED PARAMETERS TOGETHER WITH M-68LN LYSE.,S30 CALIBRATOR (MINDRAY)-S30 CALIBRATOR IS INTENDED FOR USE AS CALIBRATOR FOR WBC, RBC, HGB, MCV AND PLT PARAMETERS ON HEMATOLOGY ANALYZERS. BEFORE CARRYING OUT CLINICAL PRACTICE,

	PARAMETERS OF THE HEMATOLOGY ANALYZER NEED TO BE CALIBRATED AS INSTRUCTED IN INSTRUMENT MANUAL. ,MR NA/K CHECK SOLUTION(MINDRAY)-MR NA/K CHECK SOLUTION IS A KIND OF MAINTENANCES SOLUTIONS USED TO MONITOR THE SODIUM/POTASSIUM ION-SELECTIVE PERFORMANCE OF ION-SELECTIVE ELECTRODE INSTALLED IN ISE MODULES ON AUTOMATIC CHEMISTRY ANALYZERS.,MR DETERGENT(MR DETERGENT)-MR DETERGENT SOLUTION APPLIES TO MINDRAY BS SERIES AUTO CHEMISTRY ANALYZERS. IT IS USED TO CLEAN THE ELECTRODES FLOW CELL AS WELL AS THE PIPELINE OF THE ISE MODULE. , PREALBUMIN KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF PA CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS.,M-18E E-Z CLEANSER(MINDRAY)-FOR USE ON MINDRAY BC-1800/BC- 2800/BC-2600 HEMATOLOGY ANALYZER. FOR USE AS A CLEANING REAGENT FOR CLEANING HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,B30 CONTROL 6 X 3.0ML TRI-PACK(MINDRAY)-B30 CONTROL IS A HEMATOLOGY REFERENCE CONTROL USED TO MONITOR THE PERFORMANCE OF BC SERIES OF HEMATOLOGY ANALYZER. THE MEAN VALUES AND EXPECTED RANGE OF THE PARAMETER ARE DISPLAYED IN QUALITY CONTROL GRAPHS WITH UPPER AND LOWER CONTROL LIMITS. CLINICAL LABORATORIES USE STABLIZED BLOOD CELL SUSPENSION TO MONITOR CORRESPONDING PARAMETER. DAILY USE OF THIS WHOLE BLOOD CONTROL PROVIDES CONTROL DATA FOR CONFRIMING THE PRECISION AND ACCURACY OF INSTRUMENT ,LIPOPROTEIN (A) KIT (TURBIDIMETRY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LP(A) CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS.,V-28R RINSE(MINDRAY)-AN AZIDE-FREE FILTERED ISOTONIC SOLUTION FOR USE IN BLOOD CELL COUNTING AND SIZING. USE AS DIRECTED IN INSTRUMENT OPERATION MANUAL. ,HEMATOLOGY CONTROL BC-3D(MINDRAY)-BC-3D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,ALBUMIN(ALB) KIT (BROMOCRESOL GREEN METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALB CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM.,SPECIFIC PROTEINS CALIBRATOR (MINDRAY)-SPECIFIC PROTEINS CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF SPECIFIC PROTEINS ON MINDRAY BS MEASUREMENT SYSTEM,CALCIUM(CA) KIT(ARSENAZO III METHOD)(MINDRAY)-IN VITRO TEST FOR THE

	QUANTITATIVE DETERMINATION OF CA CONCENTRATION IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEM,V-52D DILUENT (EN/20L×1)(MINDRAY)-V-52D DILUENT APPLIES TO BC- 5000VET VETERINARY AUTO HEMATOLOGY ANALYZER MANUFACTURED BY MINDRAY, IT IS USED IN SAMPLE DILUTION, BLOOD CELL COUNTING, VOLUME MEASUREMENT AND HEMOGLOBIN MEASUREMENT.,V-52DIFF LYSE(EN/300ML×4)(MINDRAY)-V-52DIFF APPLIES TO BC-5000VET VETERINARY AUTO HEMATOLOGY ANALYZER MANUFACTURED BY MINDRAY, IT DISSOLVES RBCS AND DIFFERENTIATES WBCS.,COMPLEMENT C4 KIT (TURBIDIMETRY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF C4 CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,M-18D DILUENT(MINDRAY)-FOR USE ON MINDRAY BC-1800/BC- 2800/BC-2600 HEMATOLOGY ANALYZER. FOR USE AS AN AZIDE- FREE, FILTERED ISOTONIC SOLUTION FOR COUNTING AND SIZING BLOOD CELLS. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,APOLIPOPROTEIN A1 KIT (TURBIDEMETRY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF APOA1 CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,TOTAL PROTEIN(TP)KIT (BIURET METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TP CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM ,-AMYLASE(-AMY) KIT (IFCC METHOD) (MINDRAY)-A AMY REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF A AMYLASE ACTIVITY IN SERUM. PLASMA OR URINE ON PHOTOMETRIC SYSTEM ,TOTAL CHOLESTEROL(TC) KIT (CHOD-POD METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TC CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM ,MR URINE STANDARD (MINDRAY)-MR URINE STANDARD IS INTENDED FOR USE AS CALIBRATOR FOR IN VITRO TESTING FOR THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM, AND CHLORIDE CONCENTRATION IN URINE SAMPLE ON ION-SELECTIVE ELECTRODE ON ISE MODULES ON BS SERIES AUTOMATIC CHEMISTRY ANALYZERS. BEFORE CARRYING OUT CLINICAL PRACTICE, PARAMETERS OF THE CHEMISTRY ANALYZER NEED TO BE CALIBRATED AS INSTRUCTED IN INSTRUMENT MANUAL. ,C-REACTIVE PROTEIN KIT (TURBIDIMETRY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CRP CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM

335	IMP/IVD/2019/000358	1.License Holder Name: BIO-RAD LABORATORIES (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIACLON ANTI-JKA (DIACLON ANTI-JKA)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES, EXTENDED PARTIAL RHD TYPING SET(EXTENDED PARTIAL RHD TYPING SET)-THESE CARDS OR ANTISERA ARE USED FOR THE TYPING OF D ANTIGENS ON RED CELLS,DIACLON ANTI-AB(DIACLON ANTI-AB)-THIS ANTI SERA IS FOR THE DETECTION OF THE AB (ABO3) ANTIGEN ON HUMAN RED BLOOD CELLS,DIACLON ANTI-D(DIACLON ANTI-D)-THIS ANTI SERA IS FOR THE DETECTION OF THE D (RH1) ANTIGEN ON HUMAN RED BLOOD CELLS.,ID-CARD FYB(ID-CARD FYB)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,DIACLON ANTI-JKB (DIACLON ANTI-JKB)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,ID-ANTIGEN PROFILE III(ID-ANTIGEN PROFILE III)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,DIACLON ANTI-P1(DIACLON ANTI-P1)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,ANTI-FYA(ANTI-FYA)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,DIACLON ANTI-N(DIACLON ANTI-N)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,ANTI-S(ANTI-S)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,ID-DIACLON ANTI D(ID-DIACLON ANTI D)-THESE CARDS OR ANTISERA ARE USED FOR THE TYPING OF D ANTIGENS ON RED CELLS,DIACLON ANTI-E(DIACLON ANTI-E)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,DIACLON ANTI-C (DIACLON ANTI-C)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,ID-ANTI-

	FYB(ID-ANTI-FYB)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,DIACLON ANTI-C(DIACLON ANTI-C)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES., DIACLON ANTI-LEA(DIACLON ANTI-LEA)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,ANTI-FYB(ANTI-FYB)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,ID-ANTI-S(ID-ANTI-S)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,DIACLON ANTI-B(DIACLON ANTI-B)-THIS ANTI SERA IS FOR THE DETECTION OF THE B (ABO2) ANTIGEN ON HUMAN RED BLOOD CELLS,ANTI-KPA(ANTI-KPA)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,DIACLON ANTI-M(DIACLON ANTI-M)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,ANTI-S(ANTI-S)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,ANTI-LUB(ANTI-LUB)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,ID-ANTI-FYA(ID-ANTI-FYA)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,ANTI-JKB(ANTI-JKB)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,DIACLON ANTI-P1(DIACLON ANTI-P1)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,DIACLON ANTI-M(DIACLON ANTI-M)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,DIACLON ANTI-LEB (DIACLON ANTI-LEB)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS

	PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,ANTI-K (ANTI-K)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,ID-ANTI-S(ID-ANTI-S)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,ANTI-KPB(ANTI-KPB)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,DIACLON ANTI-CDE (DIACLON ANTI-CDE)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,ID-PARTIAL RHD TYPING SET(ID-PARTIAL RHD TYPING SET)-THESE CARDS OR ANTISERA ARE USED FOR THE TYPING OF D ANTIGENS ON RED CELLS,ABO/RH(ABO/RH)-THIS ANTI SERA IS FOR THE DETECTION OF THE AB (ABO3) ANTIGEN ON HUMAN RED BLOOD CELLS,ANTI-LUA(ANTI-LUA)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES., DIACLON ANTI H(DIACLON ANTI H)-TYPING OF A1 AND A2 SUBGROUPS WITH THE HELP OF ANTISERA IN TUBE AND SLIDE AND BY CARD PREFILLED WITH ANTISERA.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

336	IMP/IVD/2019/000359	1.License Holder Name: M/S. CPC DIAGNOSTICS PVT, LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTI- GLUTAMATE RECEPTOR (TYPE NMDA) IIFT EURO PATTERN-IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE NEUROLOGICAL DISEASES.,ANTI- ZINC FINGER PROTEIN ZIC4 IIFT-IN- VITRO DIAGNOSTIC REAGENTS FOR DIAGNOSIS OF PARANEOPLASTIC CEREBELLAR DEGENERATION WITH SMALL CELL LUNG CARCINOMA AND FOR DIFFERENTIAL DIAGNOSIS OF OTHER PARANEOPLASTIC NEUROLOGICAL SYNDROMES.,EURO PLUS GRANULOCYTE MOSAIC 25 EURO PATTERN- IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE VASCULITIS DISEASES.,ANCA PROFILE ELISA (IGG)- IN- VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF WEGENER'S GRANULOMATOSIS MICROSCOPIC POLYANGITIS, RAPID PROGRESSIVE GLOMERULONEPHRITIS GOOD PASTURE SYNDROME AND OTHER FORMS OF VASCULITIS,IIFT NEUROLOGY MOSAIC 2- IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF NEUROLOGICAL DISEASES,IIFT MOSAIC BASIC PROFILE 2 EURO PATTERN-IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUE RHEUMATOLOGICAL DISEASES,ANTI-DESMOGLEIN 3 ELISA (IGG)-IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF PEMPHIGUS FOLIACEUS, PEMPHIGUS VULGARIS. ,ANTI-- DPPX IIFT-IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF AUTOIMMUNE ENCEPHALITIS.,ANTI-IGLON FAMILY MEMBER 5 (IGLON5) IIFT-IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF AUTOIMMUNE NEUROLOGICAL DISEASES.,IIFT NEUROLOGY MOSAIC 14- IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF AUTOIMMUNE NEUROLOGICAL DISEASES,IIFT INTESTINE (MONKEY) IGA-IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF GLUTENSENSITIVE ENTEROPATHY, DUHRING'S DERMATITIS HERPETIFORMIS,IIFT NEUROLOGY MOSAIC - 16- IN- VITRO DIAGNOSTICS REAGENTS FOR THE DETECTION OF AUTOIMMUNE NEUROLOGICAL DISEASES.,IIFT CIBD PROFILE 3- IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF ANTIBODIES IN CHRONIC INFLAMMATORY BOWEL DISEASE.,EUROPLUS STOMACH (MONKEY) / INTRISIC FACTOR-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF PERNICIOUS ANEMIA, CHRONIC ATROPHIC GASTRITIS.,ANTI-F-ACTIN IIFT-IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES,ANTI- DNER IIFT- IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF AUTOIMMUNE NEUROLOGICAL DISEASES.,ANTI-DFS70 ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES ,ANTI- TG ELISA (IGG)- IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE THYROID DISEASES,ANTI-PHOSPHOLIPASE A2 RECEPTOR (PLA2R) IIFT EURO PATTERN-IN-

	VITRO DIAGNOSTIC REAGENTS FOR PRIMARY MEMBRANOUS NEPHROPATHY,ANTI- TRANSCRIPTION INTERMEDIARY FACTOR 1-GAMMA (TIF1-GAMMA) IIFT-IN- VITRO DIAGNOSTIC REAGENTS FOR DIFFERNTIAL DIAGNOSIS OF MYOSITIS AND DERMATOMYOSYTIS.,IIFT LIVER MOSAIC 8 EURO PATTERN- IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE LIVER DISEASES.,ANTI-SS-A ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES ,ANTI-DESMOGLEIN 1 ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF PEMPHIGUS FOLIACEUS, PEMPHIGUS VULGARIS. , IIFT HEP-2 EURO PATTERN- IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE RHEUMATOLOGICAL DISEASES,IIFT DERMATOLOGY MOSAIC 7-IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE BULLOUS DERMATOSES,IIFT : OESOPHAGUS (MONKEY)- IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF PEMPHIGUS FOLIACEUS, PEMPHIGUS VULGARIS.,IIFT MOSAIC HEART (MONKEY) / SKELETAL MUSCLE (MONKEY)- IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF MYASTHENIA GRAVIS.,IIFT SALT SPLIT SKIN (MONKEY)-IN- VITRO DIAGNOSTIC REAGENTS FOR BULLOUS PEMPHIGOID ANTIGENS,IIFT KIDNEY (RAT)-IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES,EUROPLUS KIDNEY (RAT) / M2-IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES, STOMACH (RAT)- IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES,IIFT MOSAIC STOMACH (RAT) / VSM47 - CELLS (ANTI-F- ACTIN)-IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES,IIFT : AUTOIMMUNE ENCEPHALITIS MOSAIC 6- IN VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF NEUROLOGICAL DISEASES (ENCEPHALITIS).,EUROPLUS INTENSTINE (MONKEY) / GLIADIN (GAF- 3X) (IGG)-IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF GLUTENSENSITIVE ENTEROPATHY, DUHRING'S DERMATITIS HERPETIFORMIS,ANTI-SS-B ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES ,ANTI-SACCHAROMYCES CEREVISIAE IIFT (IGA)-IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF CHRONIC DETECTION OF CHRONIC INFLAMMATORY BOWEL DISEASE,ANTI-SCL-70 ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES ,IIFT HEP-20-10 EURO PATTERN- IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE RHEMATOLOGICAL DISEASES,IIFT OESOPHAGUS (MONKEY) IGG- IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF GLUTENSENSITIVE ENTEROPATHY. DUHRING'S DERMATITIS HERPETIFORMIS DERMATITIS HERPETIFORMIS,ANA SCREEN 9 ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES ,ANTI- GAD ELISA (IGG)- IN-VITRO DIAGNOSTIC REAGENTS FOR THE DIAGNOSIS OF DIABETES MELLITUS,ANTI-LKM-1 ELISA (IGG)- IN- VITRO DIAGNOSTIC

	REAGENTS FOR AUTOIMMUNE LIVER DISEASES,IIFT NEUROLOGY MOSAIC 8-IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF NEUROLOGICAL DISEASES.,AMA/ ASMA IIFT (KR/SR) EURO PATTERN- IN- VITRO DIAGNOTIC REAGENTS FOR AUTOIMMNUE DISEASES,ANTI-BP180-NC16A-4X ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF BULLOUS PEMPHIGOID ,IIFT MOSAIC KIDNEY (RAT) / STOMACH (RAT)- IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES,IIFT AUTOIMMUNE ENCEPHALITIS MOSAIC 6 EURO PATTERN- IN- VITRO DIAGNOSTIC REAGENTS FOR NEUROLOGICAL DISEASES.,DERMATOLOGY PROFILE ELISA (IGG)- IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE BULLOUS DERMATOSES ,ANTI-ENA SLE PROFILE 2 ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES ,ANTI- MYELIN-OLIGODENDROCYTE GLYCOPROTEIN (MOG) IIFT-IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF AUTOIMMUNE NEUROLOGICAL DISEASES.,ANTI- INTRINSIC FACTOR IIFT- IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF PERNICIOUS ANEMIA CHRONIC ATROPHIC GASTRITIS.,ANTI- THSD7A IIFT- IN-VITRO DIAGNOSTIC REAGENTS FOR ANTIBODIES AGAINST THSD7A., IIFT GRANULOCYTE MOSAIC 2 EURO PATTERN- IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE VASCULITIS DISEASES, ANTI-NRNP/SM ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES ,ANTI-CEP-1-ELISA (IGG)-IN VITRO DIAGNOSTICS REAGENTS FOR THE DETERMINATION OF AUTOANTIBODIES OF THE IGG CLASS AGAINST CEP-1 IN SERUM OR PLASMA FOR THE DIAGNOSIS OF RHEUMOID ARTHRITIS. ,ANTI-ENA PROFILEPLUS 1 ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES ,IIFT CRITHIDIA LUCILIAE SENSITIVE (ANTI-DSDNA) EURO PATTERN- IN- VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE RHEUMATOLOGICAL DISEASES,ANTI-ENA PROFILEPLUS 2 ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES ,ANTI-ENA POOLPLUS ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES ,ANTI-SACCHAROMYCES CEREVISIAE IIFT (IGG)-IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF CHRONIC INFLAMMATORY BOWEL DISEASE,IIFT COELIAC DISEASE SCREEN (EM) EURO PATTERN (IGA)-IN- VITRO DIAGNOSTIC REAGENTS FOR COELIAC DISEASES, ANTI- F- ACTIN IIFT EURO PATTERN- IN- VITRO DIAGNOSTIC REAGENTS FOR AUTO IMMUNE LIVER DISEASES,IIFT MOSAIC : GLUTAMATE RECEPTOR (TYPE AMPA1)/ GLUTAMATE RECEPTOR (TYPE AMPA2)- IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF AUTOIMMUNE NEUROLOGICAL DISEASES.,ANTI-BP230-CF ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF BULLOUS PEMPHIGOID ,ANTI-SM ELISA (IGG)-IN-

	VITRO DIAGNOSTIC REAGENTS FOR AUTOIMMUNE DISEASES ,ANTI-TPO ELISA (IGG)- IN- VITRO DIAGNOSTI REAGENTS FOR AUTOIMMUNE THYROID DISEASES,ANTI- GBM ELISA (IGG)- IN- VITRO DIAGNOSTIC REAGNETS FOR THE DIAGNOSIS OF WEGENER'S GRANULOMATOSIS, MIRCOSCOPIC POLYANGITIS, RAPID PROGRESSIVE GLOMERULONEPHRITIS GOODPASTURE SYNDROME AND OTHER FORMS OF VASCULITIS,ANTI- AQUAPORIN - 4- IIFT EUROPATTERN-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF NEUROMYELITIS OPTICA (NMO, OPTICOSPINAL ENCEPHALOMYELITIS, DEVIC'S SYNDROME),IIFT MEMBRANOUS NEPHROPATHY MOSAIC 1-IN- VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF MEMBRANOUS NEPHROPATHY.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

337	IMP/IVD/2019/000361	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COBAS® AMPLIPREP/COBAS® TAQMAN® SPECIMEN DILUENT KIT(COBAS® AMPLIPREP/COBAS® TAQMAN® SPECIMEN DILUENT KIT)-SAMPLE PREPARATION REAGENT TO DILUTE SPECIMENS (SAMPLES) PRIOR TO SAMPLE PREPARATION AND LYSIS,COBAS® AMPLIPREP/COBAS® TAQMAN® HBV TEST, VERSION 2.0(COBAS® AMPLIPREP/COBAS® TAQMAN® HBV TEST, VERSION 2.0)-THE COBAS® AMPLIPREP/COBAS® TAQMAN® HBV TEST, VERSION 2.0 (V2.0) IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF HEPATITIS B VIRUS (HBV) DNA IN HUMAN PLASMA AND SERUM, USING THE COBAS® AMPLIPREP INSTRUMENT FOR AUTOMATED SPECIMEN PROCESSING AND THE COBAS® TAQMAN® ANALYZER OR COBAS® TAQMAN® 48 ANALYZER FOR AUTOMATED AMPLIFICATION AND DETECTION. THIS TEST IS INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF PATIENTS WITH CHRONIC HBV INFECTION UNDERGOING ANTI-VIRAL THERAPY. THE ASSAY CAN BE USED TO MEASURE HBV DNA LEVELS AT BASELINE AND DURING TREATMENT TO AID IN ASSESSING RESPONSE TO TREATMENT. THE RESULTS FROM THE COBAS® AMPLIPREP/COBAS® TAQMAN® HBV TEST, V2.0 MUST INTERPRETED WITHIN THE CONTEXT OF ALL RELEVANT CLINICAL AND LABORATORY FINDINGS. THE COBAS® AMPLIPREP/COBAS® TAQMAN® HBV TEST, V2.0 IS NOT INTENDED FOR USE AS A SCREENING TEST FOR THE PRESENCE OF HBV IN BLOOD OR BLOOD PRODUCTS OR AS A DIAGNOSTIC TEST TO CONFIRM THE PRESENCE OF HBV INFECTION.,COBAS® PCR URINE SAMPLE KIT(COBAS® PCR URINE SAMPLE KIT)-THE COBAS® PCR URINE SAMPLE KIT IS USED TO COLLECT AND TRANSPORT URINE SPECIMENS. THE COBAS® PCR MEDIA SERVES AS A NUCLEIC ACID STABILIZING TRANSPORT AND STORAGE MEDIUM FOR URINE SPECIMENS.,COBAS® AMPLIPREP/COBAS® TAQMAN® HCV QUANTITATIVE TEST, VERSION 2.0(COBAS® AMPLIPREP/COBAS® TAQMAN® HCV QUANTITATIVE TEST, VERSION 2.0)-THE COBAS® AMPLIPREP/COBAS® TAQMAN® HCV QUANTITATIVE TEST, V2.0 IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF HEPATITIS C VIRUS (HCV) RNA GENOTYPES 1 TO 6 IN HUMAN EDTA PLASMA OR SERUM USING THE COBAS® AMPLIPREP INSTRUMENT FOR AUTOMATED SPECIMEN PROCESSING AND THE COBAS® TAQMAN® ANALYZER OR THE COBAS® TAQMAN® 48 ANALYZER FOR AUTOMATED AMPLIFICATION AND DETECTION. THE TEST IS INTENDED FOR USE IN THE MANAGEMENT OF PATIENTS WITH CHRONIC HCV IN CONJUNCTION WITH CLINICAL AND LABORATORY MARKERS OF INFECTION. THE TEST CAN BE USED TO PREDICT THE

	PROBABILITY OF SUSTAINED VIROLOGIC RESPONSE (SVR) EARLY DURING A COURSE OF ANTIVIRAL THERAPY, AND TO ASSESS VIRAL RESPONSE TO ANTIVIRAL TREATMENT (RESPONSE GUIDED THERAPY) AS MEASURED BY CHANGES OF HCV RNA LEVELS IN SERUM OR EDTA PLASMA. THE COBAS® AMPLIPREP/COBAS® TAQMAN® HCV QUANTITATIVE TEST, V2.0 IS NOT INTENDED FOR USE AS A SCREENING TEST FOR THE PRESENCE OF HCV IN BLOOD OR BLOOD PRODUCTS OR AS A DIAGNOSTIC TEST TO CONFIRM THE PRESENCE OF HCV INFECTION.,COBAS® AMPLIPREP/COBAS® TAQMAN® CMV TEST(COBAS® AMPLIPREP/COBAS® TAQMAN® CMV TEST)-"THE COBAS® AMPLIPREP/COBAS® TAQMAN® CMV TEST IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF CYTOMEGALOVIRUS DNA IN EDTA HUMAN PLASMA USING THE COBAS® AMPLIPREP INSTRUMENT FOR AUTOMATED SPECIMEN PROCESSING AND THE COBAS® TAQMAN® ANALYZER OR COBAS® TAQMAN® 48 ANALYZER FOR AUTOMATED AMPLIFICATION AND DETECTION. THE TEST CAN QUANTITATE CMV DNA OVER THE RANGE OF 150 - 10,000,000 COPIES/ML. ONE COPY OF CMV DNA (AS DEFINED BY THE COBAS® AMPLIPREP/COBAS® TAQMAN® CMV TEST) IS EQUIVALENT TO 0.91 INTERNATIONAL UNIT (IU) [1.1 CP/IU] ON THE FIRST WHO INTERNATIONAL STANDARD FOR HUMAN CYTOMEGALOVIRUS FOR NUCLEIC ACID AMPLIFICATION TECHNIQUES (NIBSC 09/162).40 THE TEST IS INTENDED TO BE USED IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS IN THE DIAGNOSIS AND MANAGEMENT OF CMV INFECTION IN PATIENTS AT RISK FOR CMV DISEASE. THE COBAS® AMPLIPREP/COBAS® TAQMAN® CMV TEST IS NOT INTENDED FOR USE AS A SCREENING TEST FOR THE PRESENCE OF CMV IN BLOOD OR BLOOD PRODUCTS OR AS A DIAGNOSTIC TEST TO CONFIRM THE PRESENCE OF CMV INFECTION. THE RESULTS FROM THE COBAS® AMPLIPREP/COBAS® TAQMAN® CMV TEST MUST BE INTERPRETED WITHIN THE CONTEXT OF ALL RELEVANT CLINICAL AND LABORATORY FINDINGS." ,COBAS® AMPLIPREP/COBAS® TAQMAN® HCV QUALITATIVE TEST, VERSION 2.0(COBAS® AMPLIPREP/COBAS® TAQMAN® HCV QUALITATIVE TEST, VERSION 2.0)-THE COBAS® AMPLIPREP/COBAS® TAQMAN® HCV QUALITATIVE TEST, V2.0 IS A QUALITATIVE IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DETECTION OF HEPATITIS C VIRUS (HCV) RNA GENOTYPES 1 TO 6 IN HUMAN EDTA PLASMA OR SERUM USING THE COBAS® AMPLIPREP INSTRUMENT FOR AUTOMATED SPECIMEN PROCESSING AND THE COBAS® TAQMAN® ANALYZER OR THE COBAS® TAQMAN® 48 ANALYZER FOR AUTOMATED AMPLIFICATION AND DETECTION. THE COBAS® AMPLIPREP/COBAS® TAQMAN® HCV QUALITATIVE TEST, V2.0 IS INDICATED FOR

	PATIENTS WHO HAVE CLINICAL AND/OR BIOCHEMICAL EVIDENCE OF LIVER DISEASE AND ANTIBODY EVIDENCE OF HCV INFECTION, AND WHO ARE SUSPECTED TO BE ACTIVELY INFECTED WITH HCV. THE TEST CAN BE USED TO CONFIRM ANTIBODY POSITIVE SPECIMENS. DETECTION OF HCV RNA INDICATES THAT THE VIRUS IS REPLICATING AND THEREFORE IS EVIDENCE OF ACTIVE INFECTION. THE COBAS® AMPLIPREP/COBAS® TAQMAN® HCV QUALITATIVE TEST, V2.0 IS NOT INTENDED FOR USE AS A SCREENING TEST FOR THE PRESENCE OF HCV IN BLOOD OR BLOOD PRODUCTS.,COBAS® SARS-COV-2 (COBAS® SARS-COV-2)-COBAS® SARS-COV-2 FOR USE ON THE COBAS® 6800/8800 SYSTEMS IS A REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACIDS FROM SARS-COV-2 IN HEALTHCARE PROVIDER-INSTRUCTED SELF-COLLECTED ANTERIOR NASAL (NASAL) SWAB SPECIMENS (COLLECTED ON SITE), AND HEALTHCARE PROVIDER-COLLECTED NASAL, NASOPHARYNGEAL, AND OROPHARYNGEAL SWAB SPECIMENS COLLECTED FROM ANY INDIVIDUALS, INCLUDING THOSE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER, AND/THOSE WITHOUT SYMPTOMS OR OTHER REASONS TO SUSPECT COVID-19. RESULTS ARE FOR THE DETECTION OF SARS-COV-2 RNA. THE SARS-COV-2 RNA IS GENERALLY DETECTABLE IN IN RESPIRATORY SAMPLES DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS ARE INDICATIVE OF SARS-COV-2 RNA DETECTION, BUT MAY NOT REPRESENT THE PRESENCE OF SARS-COV-2 RNA; CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR PATIENT MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. COBAS® SARS-COV-2 IS INTENDED FOR USE BY TRAINED CLINICAL LABORATORY PERSONNEL SPECIFICALLY INSTRUCTED AND TRAINED IN THE TECHNIQUES OF REAL-TIME PCR AND IN VITRO DIAGNOSTIC PROCEDURES.,COBAS® AMPLIPREP/COBAS® TAQMAN® HIV-1 TEST, VERSION 2.0(COBAS® AMPLIPREP/COBAS® TAQMAN® HIV-1 TEST, VERSION 2.0)-THE COBAS® AMPLIPREP/COBAS® TAQMAN® HIV-1 TEST, VERSION 2.0 (V2.0) IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) RNA IN HUMAN EDTA PLASMA OR FROM A COBAS® PLASMA SEPARATION CARD (PSC) DRIED PLASMA SPOT USING THE COBAS® AMPLIPREP INSTRUMENT

	FOR AUTOMATED SPECIMEN PROCESSING AND THE COBAS® TAQMAN® ANALYZER OR COBAS® TAQMAN® 48 ANALYZER FOR AUTOMATED AMPLIFICATION AND DETECTION. THE TEST CAN QUANTITATE HIV-1 RNA OVER THE RANGE OF 20 - 10,000,000 COPIES/ML (33 TO 1.67 X 107 INTERNATIONAL UNITS [IU]/ML IN EDTA PLASMA AND 738 – 10,000,000 COPIES/ML (1230 TO 1.67 X 107 INTERNATIONAL UNITS [IU]/ML) IN A PSC DRIED PLASMA SPOT). ONE COPY OF HIV-1 RNA IS EQUIVALENT TO 1.67 IU BASED ON THE WHO 1ST INTERNATIONAL STANDARD FOR HIV-1 RNA FOR NUCLEIC ACID-BASED TECHNIQUES (NAT) (NIBSC 97/656)36. THIS TEST IS INTENDED FOR USE IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS OF DISEASE PROGRESS FOR THE CLINICAL MANAGEMENT OF HIV-1 GROUP M AND HIV-1 GROUP O INFECTED PATIENTS. THE TEST CAN BE USED TO ASSESS PATIENT PROGNOSIS BY MEASURING THE BASELINE HIV-1 RNA LEVEL OR TO MONITOR THE EFFECTS OF ANTIRETROVIRAL THERAPY BY MEASURING CHANGES IN HIV-1 RNA LEVELS DURING THE COURSE OF ANTIRETROVIRAL TREATMENT. THE COBAS AMPLIPREP/COBAS TAQMAN HIV-1 TEST V2.0 IS NOT INTENDED FOR USE AS A SCREENING TEST FOR THE PRESENCE OF HIV-1 IN BLOOD OR BLOOD PRODUCTS OR AS A DIAGNOSTIC TEST TO CONFIRM THE PRESENCE OF HIV-1 INFECTION.,COBAS® 4800 CDIFF CONTROLS AND COFACTOR KIT(COBAS® 4800 CDIFF CONTROLS AND COFACTOR KIT)-CONTROL KIT FOR COBAS 4800 CDIFF TEST,COBAS SARS-COV-2 & INFLUENZA A/B(COBAS SARS-COV-2 & INFLUENZA A/B)-COBAS® SARS-COV-2 & INFLUENZA A/B ASSAY FOR USE ON THE COBAS® 6800/8800 SYSTEMS (COBAS® SARS-COV-2 & INFLUENZA A/B) IS AN AUTOMATED MULTIPLEX REAL-TIME RT-PCR ASSAY INTENDED FOR SIMULTANEOUS QUALITATIVE DETECTION AND DIFFERENTIATION OF SARS-COV-2, INFLUENZA A VIRUS, AND/OR INFLUENZA B VIRUS RNA IN HEALTHCARE PROVIDER-COLLECTED NASAL AND NASOPHARYNGEAL SWAB SPECIMENS, AND SELF-COLLECTED NASAL SWAB SPECIMENS (COLLECTED IN A HEALTHCARE SETTING WITH INSTRUCTION BY A HEALTHCARE PROVIDER) FROM INDIVIDUALS SUSPECTED OF RESPIRATORY VIRAL INFECTION CONSISTENT WITH COVID- 19 BY THEIR HEALTHCARE PROVIDER. COBAS® SARS-COV-2 & INFLUENZA A/B IS INTENDED FOR USE AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF SARS-COV-2 , INFLUENZA A, AND INFLUENZA B IN HUMANS AND IS NOT INTENDED TO DETECT INFLUENZA C. TESTING IS LIMITED TO LABORATORIES CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C. §263A, THAT MEET REQUIREMENTS TO PERFORM MODERATE OR HIGH COMPLEXITY TESTS. RNA FROM SARS-COV-2, INFLUENZA A, AND

	INFLUENZA B IS GENERALLY DETECTABLE IN RESPIRATORY SPECIMENS DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS ARE INDICATIVE OF THE PRESENCE OF SARS-COV-2, INFLUENZA A, AND/OR INFLUENZA B RNA; CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. TESTING FACILITIES WITHIN THE UNITED STATES AND ITS TERRITORIES ARE REQUIRED TO REPORT ALL SARS-COV-2 RESULTS TO THE APPROPRIATE PUBLIC HEALTH AUTHORITIES. NEGATIVE RESULTS DO NOT PRECLUDE INFECTION FROM SARS-COV-2, INFLUENZA A, AND/OR INFLUENZA B AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER PATIENT MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. COBAS® SARS-COV-2 & INFLUENZA A/B IS INTENDED FOR USE BY QUALIFIED CLINICAL LABORATORY PERSONNEL SPECIFICALLY INSTRUCTED AND TRAINED IN THE TECHNIQUES OF REAL-TIME PCR AND ON THE USE OF THE COBAS® 6800/8800 SYSTEMS. IN THE US, COBAS® SARS-COV-2 & INFLUENZA A/B IS ONLY FOR USE UNDER THE FOOD AND DRUG ADMINISTRATION'S EMERGENCY USE AUTHORIZATION.,COBAS® 4800 CDIFF AMPLIFICATION/DETECTION KIT(COBAS® 4800 CDIFF AMPLIFICATION/DETECTION KIT)-THE COBAS® CDIFF TEST ON THE COBAS® 4800 SYSTEM IS AN AUTOMATED, QUALITATIVE IN VITRO DIAGNOSTIC TEST, THAT UTILIZES REAL-TIME POLYMERASE CHAIN REACTION (PCR), FOR THE DIRECT DETECTION OF THE TOXIN B (TCDB) GENE OF TOXIGENIC CLOSTRIDIUM DIFFICILE (C. DIFFICILE) IN UNFORMED (LIQUID OR SOFT) STOOL SPECIMENS OBTAINED FROM PATIENTS SUSPECTED OF HAVING C. DIFFICILE INFECTION (CDI). THE COBAS® CDIFF TEST IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF CDI IN HUMANS IN CONJUNCTION WITH CLINICAL AND EPIDEMIOLOGICAL RISK FACTORS.,COBAS® PCR MEDIA UNI SWAB SAMPLE KIT(COBAS® PCR MEDIA UNI SWAB SAMPLE KIT)-THE COBAS® PCR MEDIA UNI SWAB SAMPLE KIT IS USED TO COLLECT AND TRANSPORT HUMAN SPECIMENS. THE COBAS® PCR MEDIA SERVES AS A NUCLEIC ACID STABILIZING TRANSPORT AND STORAGE MEDIUM FOR HUMAN SPECIMENS.,COBAS® TAQSCREEN DPX CONTROL KIT(COBAS® TAQSCREEN DPX CONTROL KIT)-COBAS® TAQSCREEN DPX CONTROL KIT TO BE USED WITH THE COBAS® TAQSCREEN DPX TEST.,COBAS® HPV POSITIVE CONTROL KIT (COBAS® HPV POSITIVE CONTROL KIT)-COBAS® HPV POSITIVE CONTROL KIT IS USED TO MONITOR FOR FAILURES OF RRT-PCR

	REAGENTS AND REACTION CONDITIONS.,COBAS® PCR MEDIA DUAL SWAB SAMPLE KIT(COBAS® PCR MEDIA DUAL SWAB SAMPLE KIT)-THE COBAS® PCR MEDIA DUAL SWAB SAMPLE KIT IS USED TO COLLECT AND TRANSPORT ENDOCERVICAL AND VAGINAL SWAB SPECIMENS. THE COBAS® PCR MEDIA SERVES AS A NUCLEIC ACID STABILIZING TRANSPORT AND STORAGE MEDIUM FOR GYNECOLOGICAL SPECIMENS. NOTE: THIS KIT HAS BEEN VALIDATED FOR USE WITH THE FOLLOWING TESTS: COBAS® CT/NG V2.0 TEST COBAS® CT/NG FOR USE ON COBAS® 6800/8800 SYSTEMS REFER TO THE ASSAY-SPECIFIC INSTRUCTIONS FOR USE FOR PARTICULAR SPECIMEN CLAIMS.,COBAS SARS-COV-2 & INFLUENZA A/B CONTROL KIT(COBAS SARS-COV-2 & INFLUENZA A/B CONTROL KIT)-THE COBAS® SARS-COV-2 & INFLUENZA A/B CONTROL KIT IS USED TO MONITOR FOR FAILURES OF RRT-PCR REAGENTS AND REACTION CONDITIONS ,COBAS® 4800 SYSTEM LIQUID CYTOLOGY PREPARATION KIT(COBAS® 4800 SYSTEM LIQUID CYTOLOGY PREPARATION KIT)-LIQUID CYTOLOGY PREPARATION KIT FOR COBAS 4800 TEST,COBAS® HPV(COBAS® HPV)-COBAS® HPV FOR USE ON THE COBAS® 6800/8800 SYSTEMS (COBAS® HPV) IS AN AUTOMATED QUALITATIVE IN VITRO TEST FOR THE DETECTION OF HUMAN PAPILLOMAVIRUS (HPV) DNA IN PATIENT SPECIMENS. THE TEST UTILIZES AMPLIFICATION OF TARGET DNA BY THE POLYMERASE CHAIN REACTION (PCR) AND NUCLEIC ACID HYBRIDIZATION FOR THE DETECTION OF 14 HIGH-RISK (HR) HPV TYPES IN A SINGLE ANALYSIS. THE TEST SPECIFICALLY IDENTIFIES HPV16 AND HPV18 WHILE CONCURRENTLY DETECTING THE OTHER HIGH RISK TYPES (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, AND 68) AT CLINICALLY RELEVANT INFECTION LEVELS. SPECIMENS ARE LIMITED TO CERVICAL CELLS COLLECTED IN ROCHE CELL COLLECTION MEDIUM (ROCHE MOLECULAR SYSTEMS, INC.), COBAS® PCR CELL COLLECTION MEDIA (ROCHE MOLECULAR SOLUTIONS, INC.), PRESERVCYT® SOLUTION (HOLOGIC CORP.) AND SUREPATH™ PRESERVATIVE FLUID (BD DIAGNOSTICS-TRIPATH). INDICATIONS FOR USE OF COBAS® HPV ARE: A. COBAS® HPV IS INDICATED FOR USE IN SCREENING PATIENTS WITH ATYPICAL SQUAMOUS CELLS OF UNDETERMINED SIGNIFICANCE (ASC-US) CERVICAL CYTOLOGY RESULTS TO DETERMINE THE NEED FOR REFERRAL TO COLPOSCOPY. B. COBAS® HPV IS INDICATED FOR USE IN SCREENING PATIENTS WITH ASC-US CERVICAL CYTOLOGY RESULTS TO ASSESS THE PRESENCE OR ABSENCE OF HR HPV GENOTYPES 16 AND 18. C. COBAS® HPV IS INDICATED FOR USE ADJUNCTIVELY WITH CERVICAL CYTOLOGY TO ASSESS THE PRESENCE OR ABSENCE OF HR HPV TYPES. D. COBAS® HPV IS INDICATED FOR USE ADJUNCTIVELY WITH CERVICAL CYTOLOGY TO ASSESS THE PRESENCE OR ABSENCE OF

	HPV GENOTYPES 16 AND 18. E. COBAS® HPV IS INDICATED FOR USE AS A FIRST-LINE PRIMARY SCREENING TEST TO IDENTIFY WOMEN AT INCREASED RISK FOR THE DEVELOPMENT OF CERVICAL CANCER OR PRESENCE OF HIGH-GRADE DISEASE. F. COBAS® HPV IS INDICATED FOR USE AS A FIRST-LINE PRIMARY SCREENING TEST TO ASSESS THE PRESENCE OR ABSENCE OF HPV GENOTYPES 16 AND 18. THE RESULTS FROM COBAS® HPV, TOGETHER WITH THE PHYSICIAN'S ASSESSMENT OF CYTOLOGY HISTORY, OTHER RISK FACTORS, AND PROFESSIONAL GUIDELINES, MAY BE USED TO GUIDE PATIENT MANAGEMENT. THE RESULTS OF COBAS® HPV ARE NOT INTENDED TO PREVENT WOMEN FROM PROCEEDING TO COLPOSCOPY.,COBAS® AMPLIPREP/COBAS® TAQMAN® WASH REAGENT(COBAS® AMPLIPREP/COBAS® TAQMAN® WASH REAGENT)-SAMPLE PREPARATION REAGENT THAT REMOVES UNBOUND SUBSTANCES AND IMPURITIES AND REDUCES THE SALT CONCENTRATION BEFORE PCR IS INITIATED.,COBAS® TAQSCREEN CADAVERIC SPECIMEN DILUENT KIT(COBAS® TAQSCREEN CADAVERIC SPECIMEN DILUENT KIT)-CADAVERIC SPECIMEN DILUENT TO BE USED WITH COBAS® TAQSCREEN MPX TEST, V2.0,COBAS 4800 SYSTEM SAMPLE PREP BUFFER(COBAS 4800 SYSTEM SAMPLE PREP BUFFER)-SUREPATH SPECIMENS MUST BE TREATED WITH COBAS SAMPLE PREP BUFFER TO REVERSE MATRIX-INDUCED CROSS LINKS PRIOR TO HPV TESTING ON THE COBAS 4800 SYSTEM.,COBAS® SARS-COV-2 & INFLUENZA A/B(COBAS® SARS-COV-2 & INFLUENZA A/B)-THE COBAS® SARS-COV-2 & INFLUENZA A/B NUCLEIC ACID TEST FOR USE ON THE COBAS® LIAT® SYSTEM (COBAS® SARS-COV-2 & INFLUENZA A/B) IS AN AUTOMATED MULTIPLEX REAL-TIME RT-PCR ASSAY INTENDED FOR THE SIMULTANEOUS RAPID IN VITRO QUALITATIVE DETECTION AND DIFFERENTIATION OF SARS-COV-2, INFLUENZA A, AND INFLUENZA B VIRUS RNA IN HEALTHCARE PROVIDER-COLLECTED NASOPHARYNGEAL AND NASAL SWABS AND SELF-COLLECTED NASAL SWABS (COLLECTED IN A HEALTHCARE SETTING WITH INSTRUCTION BY A HEALTHCARE PROVIDER) FROM INDIVIDUALS SUSPECTED OF A VIRAL RESPIRATORY INFECTION. COBAS® SARS-COV-2 & INFLUENZA A/B IS INTENDED FOR USE IN THE SIMULTANEOUS RAPID IN VITRO DETECTION AND DIFFERENTIATION OF SARS-COV-2, INFLUENZA A VIRUS, AND INFLUENZA B VIRUS NUCLEIC ACID IN CLINICAL SPECIMENS AND IS NOT INTENDED TO DETECT INFLUENZA C VIRUS. SARS-COV-2, INFLUENZA A AND INFLUENZA B VIRAL RNA IS GENERALLY DETECTABLE IN RESPIRATORY SPECIMENS DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS ARE INDICATIVE OF ACTIVE INFECTION BUT DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER PATHOGENS NOT DETECTED BY THE TEST. CLINICAL

	CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. NEGATIVE RESULTS DO NOT PRECLUDE INFECTION FROM SARS-COV-2, INFLUENZA A, AND/OR INFLUENZA B AND SHOULD NOT BE USED AS THE SOLE BASIS FOR DIAGNOSIS, TREATMENT OR OTHER PATIENT MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND/OR EPIDEMIOLOGICAL INFORMATION. COBAS® SARS-COV-2 & INFLUENZA A/B IS INTENDED FOR USE BY HEALTH PROFESSIONALS OR TRAINED OPERATORS WHO ARE PROFICIENT IN USING THE COBAS® LIAT® SYSTEM AT THE POINT OF CARE (POC) OR IN A CLINICAL LABORATORY SETTING.,COBAS® TAQSCREEN DPX TEST (COBAS® TAQSCREEN DPX TEST)-THE COBAS® TAQSCREEN DPX TEST, FOR USE ON THE COBAS S 201 SYSTEM, IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DIRECT QUANTITATION OF PARVOVIRUS B19 (B19V) GENOTYPES 1, 2, AND 3 DNA AND THE DIRECT QUALITATIVE DETECTION OF HEPATITIS A VIRUS (HAV) GENOTYPES I, II, AND III RNA IN HUMAN PLASMA. THE COBAS® TAQSCREEN DPX TEST IS INTENDED FOR USE AS AN IN-PROCESS TEST TO QUANTIFY PARVOVIRUS B19 DNA ALONE OR TO SIMULTANEOUSLY QUANTIFY PARVOVIRUS B19 DNA AND DETECT HEPATITIS A VIRUS RNA IN PLASMA INTENDED FOR FURTHER MANUFACTURE. PLASMA FROM WHOLE BLOOD (RECOVERED PLASMA) OR COLLECTED BY APHERESIS (SOURCE PLASMA) MAY BE USED. PLASMA FROM ALL DONORS OR MANUFACTURING POOLS MAY BE TESTED AS INDIVIDUAL SPECIMENS OR IN POOLS COMPRISED OF ALIQUOTS OF INDIVIDUAL SPECIMENS. THIS TEST IS NOT INTENDED FOR USE ON SAMPLES OF CORD BLOOD. THIS TEST IS NOT INTENDED FOR USE AS AN AID IN DIAGNOSIS.,COBAS® SARS-COV-2 & INFLUENZA A/B QUALITY CONTROL KIT(COBAS® SARS-COV-2 & INFLUENZA A/B QUALITY CONTROL KIT)-THE COBAS® SARS-COV-2 & INFLUENZA A/B CONTROL KIT IS USED TO MONITOR FOR FAILURES OF RRT-PCR REAGENTS AND REACTION CONDITIONS,COBAS® 4800 HSV 1 AND 2 AMPLIFICATION/DETECTION KIT(COBAS® 4800 HSV 1 AND 2 AMPLIFICATION/DETECTION KIT)-THE COBAS® HSV 1 AND 2 TEST ON THE COBAS® 4800 SYSTEM IS AN AUTOMATED, QUALITATIVE IN VITRO DIAGNOSTIC TEST, THAT UTILIZES REAL-TIME POLYMERASE CHAIN REACTION (PCR), FOR THE DIRECT DETECTION AND TYPING OF HERPES SIMPLEX VIRUS 1 AND 2 (HSV-1 AND HSV-2) DNA IN CLINICIAN-COLLECTED ANOGENITAL LESION SPECIMENS FROM SYMPTOMATIC MALE AND FEMALE PATIENTS. THE COBAS® HSV 1 AND 2 TEST IS INTENDED FOR USE AS AN AID IN DIAGNOSIS OF ANOGENITAL HSV-1 AND HSV-2 INFECTIONS IN SYMPTOMATIC

	PATIENTS. ,COBAS® BUFFER NEGATIVE CONTROL KIT(COBAS® BUFFER NEGATIVE CONTROL KIT)-COBAS® BUFFER NEGATIVE CONTROL KIT CAN BE USED WITH THE MULTIPLE REAGENTS., COBAS® 4800 CT/NG AMPLIFICATION/DETECTION KIT(COBAS® 4800 CT/NG AMPLIFICATION/DETECTION KIT)-"THE COBAS® 4800 CT/NG TEST IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUALITATIVE DETECTION OF CHLAMYDIA TRACHOMATIS (CT) AND/OR NEISSERIA GONORRHOEAE (NG) IN PATIENT SPECIMENS. THE TEST UTILIZES AMPLIFICATION OF TARGET DNA BY THE POLYMERASE CHAIN REACTION (PCR) AND NUCLEIC ACID HYBRIDIZATION FOR THE DETECTION OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE DNA IN ENDOCERVICAL SWAB SPECIMENS, CLINICIAN-COLLECTED VAGINAL SWAB SPECIMENS, CLINICIAN-INSTRUCTED SELF-COLLECTED VAGINAL SWAB SPECIMENS, AND MALE AND FEMALE URINE IN COBAS® PCR MEDIA (ROCHE MOLECULAR SYSTEMS, INC.), AND CERVICAL SPECIMENS IN PRESERVCYT® SOLUTION (HOLOGIC, INC.). THIS TEST IS INTENDED TO BE USED AS A DIAGNOSTIC AS WELL AS A SCREENING TOOL IN BOTH SYMPTOMATIC AND ASYMPTOMATIC POPULATIONS." ,COBAS TAQSCREEN MPX TEST, V2.0(COBAS TAQSCREEN MPX TEST, V2.0)-THE COBAS" TAQSCREEN MPX TEST, VERSION 2.0 (V2.0) FOR USE WITH THE COBAS S 201 SYSTEM, IS A QUALITATIVE IN VITRO TEST FOR THE DIRECT DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE I (HIV-I) GROUP M RNA, HIV-I GROUP O RNA, HUMAN IMMUNODEFICIENCY VIRUS TYPE 2 (HIV-2) RNA, HEPATITIS C VIRUS (HCV) RNA AND HEPATITIS B VIRUS (HBV) DNA IN HUMAN PLASMA. THIS TEST IS INTENDED FOR USE TO SCREEN DONOR SAMPLES FOR HIV-I GROUP M RNA, HCV RNA AND HBV DNA IN PLASMA SPECIMENS FROM INDIVIDUAL HUMAN DONORS, INCLUDING DONORS OF WHOLE BLOOD, BLOOD COMPONENTS, SOURCE PLASMA AND OTHER LIVING DONORS. THIS TEST IS ALSO INTENDED FOR USE IN TESTING PLASMA SPECIMENS TO SCREEN INDIVIDUAL ORGAN AND TISSUE DONORS WHEN SPECIMENS ARE OBTAINED WHILE THE DONOR'S HEART IS STILL BEATING, AND IN TESTING BLOOD SERUM AND PLASMA FROM CADAVERIC (NON-HEART-BEATING) DONORS. THIS TEST IS NOT INTENDED FOR USE ON SAMPLES OF CORD BLOOD. PLASMA FROM ALL DONORS MAY BE SCREENED AS INDIVIDUAL SPECIMENS. FOR DONATIONS OF WHOLE BLOOD AND BLOOD COMPONENTS, PLASMA SPECIMENS MAY BE TESTED INDIVIDUALLY OR IN POOLS COMPRISED OF NOT MORE THAN 6 INDIVIDUAL SPECIMENS. FOR DONORS OF HEMATOPOIETIC STEM/PROGENITOR CELLS (HPCS) SOURCED FROM BONE MARROW, PERIPHERAL BLOOD OR CORD BLOOD, AND FOR DONORS OF DONOR LYMPHOCYTES FOR INFUSION (DLI), PLASMA MAY BE TESTED IN POOLS COMPRISED OF NOT MORE THAN 6

	INDIVIDUAL SPECIMENS. FOR DONATIONS OF SOURCE PLASMA, SAMPLE MAY BE TESTED IN POOLS COMPRISED OF NOT MORE THAN 96 INDIVIDUAL SPECIMENS. WHEREAS THIS TEST CAN DETECT HIV -1 GROUP O RNA AND HIV -2 RNA, DETECTION OF HIV -1 GROUP O RNA AND HIV -2 RNA IN DONOR SPECIMENS NEGATIVE FOR ANTI-HIV-1 GROUP 0 ANTIBODIES OR ANTI-HIV-2 ANTIBODIES, RESPECTIVELY, HAS NOT BEEN DEMONSTRATED IN CLINICAL STUDIES THIS TEST IS INTENDED TO BE USED IN CONJUNCTION WITH LICENSED SEROLOGY TESTS FOR HIV, HCV AND HBV. FOR AN INDIVIDUAL SPECIMEN, RESULTS ARE SIMULTANEOUSLY DETECTED AND DISCRIMINATED FOR HIV, HCV AND HBV. THE COBAS? TAQSCREEN MPX TEST, V2.0 CAN BE CONSIDERED A SUPPLEMENTAL TEST THAT CONFIRMS HIV INFECTION FOR SPECIMENS THAT ARE REPEATEDLY REACTIVE ON A LICENSED DONOR SCREENING TEST FOR ANTIBODIES TO HIV AND REACTIVE ON THE COBAS• TAQSCREEN MPX TEST, V2.0. THE COBAS• TAQSCREEN MPX TEST, V2.0 CAN BE CONSIDERED A SUPPLEMENTAL TEST THAT CONFIRMS HCV INFECTION FOR SPECIMENS THAT ARE REPEATEDLY REACTIVE ON A LICENSED DONOR SCREENING TEST FOR ANTIBODIES TO HCV AND REACTIVE ON THE COBAS• TAQSCREEN MPX TEST, V2.0. THE COBAS• TAQSCREEN MPX TEST, V2. 0 CAN BE CONSIDERED A SUPPLEMENTAL TEST THAT CONFIRMS HBV INFECTION FOR SPECIMENS THAT ARE REPEATEDLY REACTIVE ON A LICENSED DONOR SCREENING TEST FOR HEPATITIS B SURFACE ANTIGEN, AND REACTIVE ON THE COBAS• TAQSCREEN MPX TEST, V2. 0. THIS TEST IS NOT INTENDED FOR USE AS AN AID IN DIAGNOSIS OF INFECTION WITH HIV, HCV OR HBV.,COBAS® SARS-COV-2 CONTROL KIT(COBAS® SARS-COV-2 CONTROL KIT)-INTENDED USE: NON-INFECTIOUS PLASMID DNA THAT INCLUDE THE FOLLOWING SEQUENCES: SARS-COV-2 SEQUENCE, PAN-SARBECOVIRUS 1 SEQUENCE, AND PAN-SARBECOVIRUS SEQUENCE. THE POSITIVE CONTROL IS USED TO MONITOR FOR FAILURES OF RRT-PCR REAGENTS AND REACTION CONDITIONS. CHANGE IN MATERIAL OF CONSTRUCTION: FURTHER, WITH RESPECT TO THE MATERIAL OF CONSTRUCTION, THE REPETITION OF THE WORDINGS " 0.01% NON-INFECTIOUS PLASMID DNA (MICROBIAL) CONTAINING PAN-SARBECOVIRUS SEQUENCE" IS NOTED BY THIS OFFICE.,COBAS® FACTOR II AND FACTOR V TEST(COBAS® FACTOR II AND FACTOR V TEST)-THE COBAS® FACTOR II AND FACTOR V TEST IS AN IN VITRO DIAGNOSTIC DEVICE THAT USES REAL-TIME POLYMERASE CHAIN REACTION (PCR) FOR THE DETECTION AND GENOTYPING OF THE HUMAN FACTOR II (PROTHROMBIN) G20210A MUTATION AND THE HUMAN FACTOR V LEIDEN MUTATION, FROM GENOMIC DNA OBTAINED FROM K2EDTA WHOLE BLOOD SPECIMENS, AS AN AID IN DIAGNOSIS OF PATIENTS WITH SUSPECTED THROMBOPHILIA. THE

	COBAS® FACTOR II AND FACTOR V TEST AND THE COBAS Z 480 ANALYZER ARE USED TOGETHER FOR AUTOMATED AMPLIFICATION AND DETECTION.,COBAS® 4800 SYSTEM INTERNAL CONTROL KIT 1 (COBAS® 4800 SYSTEM INTERNAL CONTROL KIT 1)-THE CT/NG INTERNAL CONTROL REAGENT IS INCLUDED IN THE COBAS 4800 CT/NG TEST AND IS INTRODUCED INTO EACH SAMPLE ON THE COBAS X 480 INSTRUMENT DURING SAMPLE PROCESSING,COBAS® TAQSCREEN MPX CONTROL KIT, V2.0(COBAS® TAQSCREEN MPX CONTROL KIT, V2.0)-COBAS TAQSCREEN MPX CONTROL KIT, V 2.0 IS USED IN CONJUNCTION WITH COBAS TAQSCREEN MPX TEST, V 2.0 , COBAS® 4800 SYSTEM SAMPLE PREPARATION KIT(COBAS® 4800 SYSTEM SAMPLE PREPARATION KIT)-IT CONSISTS OF THE ELUTION BUFFER AND MAGNETIC GLASS PARTICLES (MGP) REAGENT. THE ELUTION BUFFER IS A SAMPLE PREPARATION REAGENT USED TO SOLUBILIZE PREPARED NUCLEIC ACIDS AT THE END OF THE SAMPLE PREP PROCESS PRIOR TO PCR SET UP . THE MAGNETIC GLASS PARTICLES (MGP) REAGENT IS A SAMPLE PREPARATION REAGENT USED TO BIND THE RELEASED NUCLEIC ACIDS RELEASED BY THE ADDITION OF PROTEINASE AND LYSIS REAGENT TO THE SAMPLE, COBAS® HIV-1/HIV-2 QUALITATIVE CONTROL KIT(COBAS® HIV-1/HIV-2 QUALITATIVE CONTROL KIT)-THE COBAS HIV-1/HIV-2 QUALITATIVE CONTROL KIT IS TO BE USED IN CONJUNCTION WITH THE COBAS® HIV-1/HIV-2 QUALITATIVE TEST ON COBAS® 6800 AND COBAS® 8800 SYSTEMS,COBAS® 4800 SYSTEM LYSIS KIT 1 (COBAS® 4800 SYSTEM LYSIS KIT 1)-SAMPLE PREPARATION PROCESS TO LYSE VIRUSES, DENATURE PROTEINS AND INACTIVE NUCLEASES.,COBAS® HIV-1/HIV-2 QUALITATIVE(COBAS® HIV-1/HIV-2 QUALITATIVE)-COBAS® HIV-1/HIV-2 QUALITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEMS IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUALITATIVE DETECTION AND DIFFERENTIATION OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) TYPE 1 (HIV-1) AND TYPE 2 (HIV-2) IN HUMAN SERUM, PLASMA, AND DRIED BLOOD SPOTS (DBS). THE TEST IS INTENDED TO BE USED AS AN AID IN DIAGNOSIS OF HIV-1/HIV-2. DETECTION OF HIV-1 OR HIV-2 NUCLEIC ACID IS INDICATIVE OF HIV-1 OR HIV-2 INFECTION, RESPECTIVELY. THE PRESENCE OF HIV-1 OR HIV-2 NUCLEIC ACID IN THE PLASMA OR SERUM OF INDIVIDUALS WITHOUT ANTIBODIES TO HIV-1 OR HIV-2 IS INDICATIVE OF ACUTE OR PRIMARY INFECTION. IN INFANTS BORN TO HIV-INFECTED MOTHERS AND WHO HAVE MATERNAL ANTIBODIES TO HIV-1 OR HIV-2, THE PRESENCE OF HIV NUCLEIC ACID IS INDICATIVE OF ACTIVE INFECTION. COBAS® HIV-1/HIV-2 QUALITATIVE MAY ALSO BE USED TO CONFIRM HIV-1 OR HIV-2 INFECTION IN AN INDIVIDUAL WITH SPECIMENS REACTIVE FOR HIV-1 OR HIV-2 ANTIBODIES OR ANTIGENS.,COBAS® 4800 SYSTEM

	WASH BUFFER KIT(COBAS® 4800 SYSTEM WASH BUFFER KIT)-SAMPLE PREPARATION REAGENT THAT REMOVES UNBOUND SUBSTANCES AND IMPURITIES AND REDUCES THE SALT CONCENTRATION BEFORE PCR IS INITIATED.,COBAS® 4800 HPV AMPLIFICATION/DETECTION KIT(COBAS® 4800 HPV AMPLIFICATION/DETECTION KIT)-THE COBAS® 4800 HUMAN PAPILLOMAVIRUS (HPV) TEST IS A QUALITATIVE IN VITRO TEST FOR THE DETECTION OF HUMAN PAPILLOMAVIRUS IN PATIENT SPECIMENS. THE TEST UTILIZES AMPLIFICATION OF TARGET DNA BY THE POLYMERASE CHAIN REACTION (PCR) AND NUCLEIC ACID HYBRIDIZATION FOR THE DETECTION OF 14 HIGH-RISK (HR) HPV TYPES IN A SINGLE ANALYSIS. THE TEST SPECIFICALLY IDENTIFIES HPV16 AND HPV18 WHILE CONCURRENTLY DETECTING THE OTHER HIGH RISK TYPES (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 AND 68) AT CLINICALLY RELEVANT INFECTION LEVELS. SPECIMENS ARE LIMITED TO CERVICAL CELLS COLLECTED IN ROCHE CELL COLLECTION MEDIUM (ROCHE MOLECULAR SYSTEMS, INC.), COBAS® PCR CELL COLLECTION MEDIA (ROCHE MOLECULAR SYSTEMS, INC.), PRESERVCYT® SOLUTION (HOLOGIC CORP.) AND SUREPATHTM PRESERVATIVE FLUID (BD DIAGNOSTICS-TRIPATH). INDICATIONS FOR USE OF THE COBAS® 4800 HPV TEST ARE: (A) THE COBAS® 4800 HPV TEST IS INDICATED FOR USE IN SCREENING PATIENTS WITH ASC-US (ATYPICAL SQUAMOUS CELLS OF UNDETERMINED SIGNIFICANCE) CERVICAL CYTOLOGY RESULTS TO DETERMINE THE NEED FOR REFERRAL TO COLPOSCOPY. (B) THE COBAS® 4800 HPV TEST IS INDICATED FOR USE IN SCREENING PATIENTS WITH ASC-US CERVICAL CYTOLOGY RESULTS TO ASSESS THE PRESENCE OR ABSENCE OF HIGH-RISK HPV GENOTYPES 16 AND 18. (C) THE COBAS® 4800 HPV TEST IS INDICATED FOR USE ADJUNCTIVELY WITH CERVICAL CYTOLOGY TO ASSESS THE PRESENCE OR ABSENCE OF HIGH RISK HPV TYPES. (D) THE COBAS® 4800 HPV TEST IS INDICATED FOR USE ADJUNCTIVELY WITH CERVICAL CYTOLOGY TO ASSESS THE PRESENCE OR ABSENCE OF HPV GENOTYPES 16 AND 18. (E) THE COBAS® 4800 HPV TEST IS INDICATED FOR USE AS A FIRST-LINE PRIMARY SCREENING TEST TO IDENTIFY WOMEN AT INCREASED RISK FOR THE DEVELOPMENT OF CERVICAL CANCER OR PRESENCE OF HIGH-GRADE DISEASE. (F) THE COBAS® 4800 HPV TEST IS INDICATED FOR USE AS A FIRST-LINE PRIMARY SCREENING TEST TO ASSESS THE PRESENCE OR ABSENCE OF HPV GENOTYPES 16 AND 18. THE RESULTS FROM THE COBAS® HPV TEST, TOGETHER WITH THE PHYSICIAN'S ASSESSMENT OF CYTOLOGY HISTORY, OTHER RISK FACTORS, AND PROFESSIONAL GUIDELINES, MAY BE USED TO GUIDE PATIENT MANAGEMENT. THE RESULTS OF THE COBAS® HPV TEST ARE NOT INTENDED TO PREVENT WOMEN FROM PROCEEDING TO

	COLPOSCOPY.,COBAS® 4800 MRSA/SA AMPLIFICATION/DETECTION KIT (COBAS® 4800 MRSA/SA AMPLIFICATION/DETECTION KIT)-THE COBAS® MRSA/SA TEST ON THE COBAS® 4800 SYSTEM IS AN AUTOMATED, REAL-TIME PCR ASSAY FOR THE RAPID IN VITRO QUALITATIVE DETECTION OF METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) AND STAPHYLOCOCCUS AUREUS (SA) DNA FROM NASAL SWABS TO AID IN THE PREVENTION AND CONTROL OF MRSA AND SA INFECTIONS IN HEALTHCARE SETTINGS. THE COBAS® MRSA/SA TEST IS NOT INTENDED TO DIAGNOSE, GUIDE OR MONITOR TREATMENT FOR MRSA OR SA INFECTIONS, OR PROVIDE RESULTS OF SUSCEPTIBILITY TO METHICILLIN. A NEGATIVE RESULT DOES NOT PRECLUDE MRSA/SA NASAL COLONIZATION. CONCOMITANT CULTURES ARE NECESSARY TO RECOVER ORGANISMS FOR EPIDEMIOLOGY TYPING OR FOR FURTHER SUSCEPTIBILITY TESTING. ,COBAS® 4800 HPV CONTROLS KIT(COBAS® 4800 HPV CONTROLS KIT)-COBAS® 4800 HPV CONTROLS KIT IS USED WITH THE MAIN KIT, THE POSITIVE CONTROL IS USED TO MONITOR FOR FAILURES OF RRT-PCR REAGENTS AND REACTION CONDITIONS,COBAS® 4800 MRSA/SA CONTROLS AND COFACTOR KIT(COBAS® 4800 MRSA/SA CONTROLS AND COFACTOR KIT)-COBAS® 4800 MRSA/SA CONTROLS AND COFACTOR KIT USED WITH MRSA. ,COBAS® NHP NEGATIVE CONTROL KIT(COBAS® NHP NEGATIVE CONTROL KIT)-THE COBAS NHP NEGATIVE CONTROL KIT IS TO BE USED IN CONJUNCTION WITH THE COBAS®MPX/CMV/HCV/HBV/HIV/ HIV-1/HIV-2 QUALITATIVE TEST ON COBAS® 6800 AND COBAS® 8800 SYSTEMS,COBAS® TAQSCREEN WASH REAGENT(COBAS® TAQSCREEN WASH REAGENT) -SAMPLE PREPARATION REAGENT THAT REMOVES UNBOUND SUBSTANCES AND IMPURITIES AND REDUCES THE SALT CONCENTRATION BEFORE PCR IS INITIATED.,COBAS® SPECIMEN PRE-EXTRACTION REAGENT(COBAS® SPECIMEN PRE-EXTRACTION REAGENT)-THE COBAS® SPECIMEN PRE EXTRACTION KIT IS TO BE USED IN CONJUNCTION WITH THE COBAS® HIV-1/HIV-2 QUALITATIVE,COBAS® 4800 SYSTEM CONTROL DILUENT KIT (COBAS® 4800 SYSTEM CONTROL DILUENT KIT)-CONTROL DILUENT FOR COBAS 4800 CT/NG TEST,COBAS® 4800 HSV 1 AND 2 CONTROLS AND COFACTOR KIT(COBAS® 4800 HSV 1 AND 2 CONTROLS AND COFACTOR KIT)-COBAS® 4800 HSV 1 AND 2 CONTROLS AND COFACTOR KIT ,COBAS® 4800 CT/NG CONTROLS KIT(COBAS® 4800 CT/NG CONTROLS KIT)-COBAS® 4800 CT/NG CONTROLS KIT USED WITH COBAS® 4800 CT/NG AMPLIFICATION/DETECTION KIT

338	IMP/IVD/2019/000362	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URISCAN 10 SGL STRIP(YD DIAGNOSTIC)-DETERMINATION OF THE FOLLOWING PARAMETERS IN URINE: BLOOD, BILIRUBIN, UROBILINOGEN, KETONES (ACETOACETIC ACID), PROTEIN, NITRITE, GLUCOSE, PH, S.G (SPECIFIC GRAVITY), LEUCOCYTES.,URISCAN SUPER CASSETTE ACR(YD DIAGNOSTIC)-DETERMINATION OF THE FOLLOWING PARAMETERS IN URINE: BLOOD, BILIRUBIN, UROBILINOGEN, KETONES (ACETOACETIC ACID), PROTEIN, NITRITE, GLUCOSE, PH, LEUCOCYTES,MICROALBUMIN, CREATININEAND ASCORBIC ACID,URITROL LIQUID 1, 2(YD DIAGNOSTIC)-ASSAYED QUALITY CONTROL URINE TO MONITOR AND MAINTAIN THE ACCURACY AND PRECISION OF THE URINE STRIPS AND THE ANALYZERS,URISCAN 11 STRIP(YD DIAGNOSTIC)-DETERMINATION OF THE FOLLOWING PARAMETERS IN URINE: BLOOD, BILIRUBIN, UROBILINOGEN, KETONES (ACETOACETIC ACID), PROTEIN, NITRITE, GLUCOSE, PH, S.G (SPECIFIC GRAVITY), LEUCOCYTES AND ASCORBIC ACID.,URITROL LIQUID PLUS(YD DIAGNOSTIC)-ASSAYED QUALITY CONTROL URINE TO MONITOR AND MAINTAIN THE ACCURACY AND PRECISION OF THE URINE STRIPS AND THE ANALYZERS,URISCAN 11 ACR STRIPS(YD DIAGNOSTIC)-DETERMINATION OF THE FOLLOWING PARAMETERS IN URINE: BLOOD, KETONES, PROTEIN, NITRITE, GLUCOSE, PH, SPECIFIC GRAVITY, LEUCOCYTES,MICROALBUMIN, CREATININE, ASCORBIC ACID,URISCAN SUPER CASSETTE(YD DIAGNOSTIC)-DETERMINATION OF THE FOLLOWING PARAMETERS IN URINE: BLOOD, BILIRUBIN, UROBILINOGEN, KETONES (ACETOACETIC ACID), PROTEIN, NITRITE, GLUCOSE, PH, LEUCOCYTES AND ASCORBIC ACID.,URISCAN 6 L STRIP (YD DIAGNOSTIC)-DETERMINATION OF THE FOLLOWING PARAMETERS IN URINE: BLOOD, PROTEIN, NITRITE, GLUCOSE, PH, LEUCOCYTES.,URISCAN 9 SG STRIP(YD DIAGNOSTIC)-DETERMINATION OF THE FOLLOWING PARAMETERS IN URINE: BLOOD, BILIRUBIN, UROBILINOGEN, KETONES (ACETOACETIC ACID), PROTEIN, NITRITE, GLUCOSE, PH, S.G,URITROL 1, 2, 3(YD DIAGNOSTIC) -ASSAYED QUALITY CONTROL URINE TO MONITOR AND MAINTAIN THE ACCURACY AND PRECISION OF THE URINE STRIPS AND THE ANALYZERS,URISCAN 2 ACR STRIPS(YD DIAGNOSTIC)-DETERMINATION OF THE FOLLOWING PARAMETERS IN URINE: MICROALBUMIN, CREATININE

339	IMP/IVD/2019/000364	1.License Holder Name: BIOSYSTEMS DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRI LEVEL QUALITY CONTROL KIT(EASY QC- TRI LEVEL QUALITY CONTROL KIT)-USED TO ESTABLISH THE PERFORMANCE OF ELECTROLYTE ANALYSERS USING CONTROLS.,CLEANING SOLUTION KIT(ISE MODULE CLEANING SOLUTION KIT)-USED TO REMOVE THE PROTEIN DEPOSITS FROM THE FLUID AND THE SENSOR PATH ON THE ISE MODULE.,BI LEVEL QUALITY CONTROL KIT(EASY QC-BI LEVEL QUALITY CONTROL KIT)-USED TO MONITOR THE PERFORMANCE OF THE EASYLYTE ANALYSER.,URINE DILUENT (ISE MODULE URINE DILUENT)-THE ISE MODULE URINE DILUENT IS USED TO DILUTE URINE SAMPLES PRIOR TO ANALYSIS.,URINE DILUENT (ISE MODULE URINE DILUENT)-THE ISE MODULE URINE DILUENT IS USED TO DILUTE URINE SAMPLES PRIOR TO ANALYSIS.,NA/K/CL/LI REAGENT PACK (ISE REAGENT PACK NA/K/CL/LI)-THE PACK IS INTENDED FOR USE TO CALIBRATE THE NA, K, CL & LI SENSORS. IT CONTAINS BUFFERED CALIBRANT & A WASTE CONTAINER TO COLLECT WASTE.
340	IMP/IVD/2019/000366	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NA/K/CL/LI REAGENT PACK(ISE REAGENT PACK NA/K/CL/LI)-THE ISE MODULE REAGENT PACK IS USED TO MEASURE THE CONCENTRATION OF SODIUM, POTASSIUM, CHLORIDE AND LITHIUM IN SERUM SAMPLES.
341	IMP/IVD/2019/000367	1.License Holder Name: M/S ONE ABOVE HEALTHCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS (ONE ABOVE BLOOD GLUCOSE TEST STRIP)-USE TO DETECT BLOOD GLUCOSE

342	IMP/IVD/2019/000368	1.License Holder Name: OPERON BIOTECH AND HEALTH CARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PT-INR TEST STRIPS (QLABS)-THE QLABS® PT-INR TEST STRIPS ARE DESIGNED TO PROVIDE QUANTITATIVE MEASUREMENTS OF PROTHROMBIN TIME (PT) AND INTERNATIONAL NORMALIZED RATIO (INR) IN FRESH CAPILLARY WHOLE BLOOD OR FRESH VENOUS WHOLE BLOOD.,COAG PANEL 2 TEST STRIPS(QLABS)-THE QLABS® COAG PANEL 2 TEST STRIPS ARE DESIGNED TO PROVIDE QUANTITATIVE DETERMINATION OF PROTHROMBIN TIME (PT)/ INTERNATIONAL NORMALIZED RATIO (INR) AND ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) IN FRESH CAPILLARY WHOLE BLOOD OR FRESH VENOUS WHOLE BLOOD.

343	IMP/IVD/2019/000369	1.License Holder Name: M/S. CPC DIAGNOSTICS PVT, LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTI-ß2-GLYCOPROTEIN 1 ELISA (IGAGM)-ANTI-PHOSPHOLIPID SYNDROME,ANTI-EBV-CA ELISA (IGM)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGM AGAINST EPSTEIN-BARR VIRUS CAPSID ANTIGEN (EBV-CA) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF INFECTIOUS MONONUCLEOSIS, BURKITT`S LYMPHOMA AND NASOPHARYNGEAL CARCINOMA,EUROLINE COELIAC DISEASE PROFILE (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST THE TWO ANTIGENS TISSUE TRANSGLUTAMINASE (TTG) AND GLIADIN (GAF-3X) (GLIADIN-ANALOGUE FUSION PEPTIDE) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF GLUTEN-SENSITIVE ENTEROPATHY AND DERMATITIS HERPETIFORMIS DUHRING., EUROLINE ANTI-MI-2 ALFA, -MI-2 BETA, -KU, - DFS70 (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IGG CLASS TO 4 DIFFERENT ANTIGENS: MI-2, MI-2, KU AND DFS70 IN SERUM OR PLASMA FOR THE DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), DERMATOMYOSITIS AND OTHER DISEASES ASSOCIATED WITH ANTI-DFS70,EUROLINE CYTOPLASM PROFILE (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO 10 DIFFERENT ANTIGENS AMA-M2, M2-3E, RIB. P-PROTEIN, JO-1, SRP, PL-7, PL-12, EJ, OJ AND RO-52 IN SERUM OR PLASMA FOR THE DIAGNOSIS OF PRIMARY BILIARY CIRRHOSIS, SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AND POLY-/DERMATOMYOSITIS.,EUROLINE-FOOD PROFILE108 (IGG)-THE EUROLINE-FOOD TEST PROVIDES SEMIQUANTITATIVE IN VITRO DETERMINATION OF THE FOOD-SPECIFIC IMMUNOGLOBULIN CLASS IGG IN SERUM OR PLASMA AND CONTRIBUTES TO THE DIAGNOSIS OF INTOLERANCES AGAINST FOODS AND FOOD ADDITIVES. THE TEST IS A MULTI-PARAMETER TEST WHICH CONTAINS OPTIMISED COMBINATIONS OF RELEVANT FOODS AND THEIR RESPECTIVE ADDITIVES AND THEREFORE ENABLES SIMULTANEOUS ANALYSES OF IGG AGAINST BOTH., EUROLINE SYSTEMIC SCLEROSIS (NUCLEOLI) PROFILE (IGG)-THE EUROLINE TEST KIT PROVIDES QUALITATIVE IN VITRO DETERMINATION OF HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO THE 13 DIFFERENT ANTIGENS SCL-70, CENP A, CENP B, RP11 AND RP155 (RNA POLYMERASE III SUBUNITS), FIBRILLARIN, NOR90, TH/TO, PM-SCL100, PM-SCL75, KU, PDGFR (PLATELET DERIVED GROWTH FACTOR RECEPTOR) AND RO-

	52 IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF PROGRESSIVE SYSTEMIC SCLEROSIS (SSC, DIFFUSE AND LIMITED FORM) AND OVERLAP SYNDROMES,EUROLINE ANTI-MPO, -PR3 (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST THE 2 DIFFERENT ANTIGENS MYELOPEROXIDASE (MPO) AND PROTEINASE 3 (PR3) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF GRANULOMATOSIS WITH POLYANGIITIS (WEGENER'S) (GPA) AND MICROSCOPIC ARTERITIS.,EUROLINE-ATOPY (IGE)-THE EUROLINE TEST KIT IS USED FOR THE DIAGNOSIS OF SENSITISATIONS THAT MAY LEAD TO ALLERGY- ASSOCIATED SYMPTOMS SUCH AS CONJUNCTIVITIS, RHINITIS OR GASTROINTESTINAL PROBLEMS. THESE SYMPTOMS CAN BE CAUSED BY MISGUIDED IMMUNE REACTIONS LEADING TO INCREASED IMMUNOGLOBULIN CLASS E (IGE) ANTIBODY CONCENTRATIONS, WHICH ARE MEASURED BY USING THIS TEST.,EUROLINE ANTI-GANGLIOSIDES-PROFILE 2 (IGM)-THE EUROLINE TEST KIT PROVIDES QUALITATIVE IN VITRO DETERMINATION OF HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGM TO THE SEVEN GANGLIOSIDES GM1, GM2, GM3, GD1A, GD1B, GT1B AND GQ1B IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF GUILLAIN-BARRE SYNDROME (GBS), CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP), MULTIFOCAL MOTOR NEUROPATHY (MMN), SENSORY NEUROPATHY AND MILLER-FISHER SYNDROME (MFS; A SUBTYPE OF GBS),EUROLINE ANTI-GANGLIOSIDES-PROFILE 2 (IGG)-THE EUROLINE TEST KIT PROVIDES QUALITATIVE IN VITRO DETERMINATION OF HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO THE SEVEN GANGLIOSIDES GM1, GM2, GM3, GD1A, GD1B, GT1B AND GQ1B IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF GUILLAIN-BARRE SYNDROME (GBS), CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP), MULTIFOCAL MOTOR NEUROPATHY (MMN), SENSORY NEUROPATHY AND MILLER-FISHER SYNDROME (MFS; A SUBTYPE OF GBS),ANTI-GLIADIN (GAF-3X) ELISA (IGG)-GLUTEN-SENSITIVE ENTEROPATHY (COELIAC DISEASE), DERMATITIS HERPETIFORMIS DUHRING. ,PNF-H ELISA-THIS ELISA TEST KIT IS DESIGNED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PHOSPHORYLATED NEUROFILAMENT HEAVY CHAIN (PNF-H) IN CEREBROSPINAL FLUID (CSF) OR SERUM SAMPLES OF HUMAN ORIGIN,TOTAL-TAU ELISA-THIS ELISA TEST KIT PROVIDES A QUANTITATIVE IN VITRO DETERMINATION OF TOTAL TAU IN PATIENT CSF FOR THE DIAGNOSIS OF NEURONAL APOPTOSIS,ANTI-GLIADIN (GAF-3X) ELISA (IGA)-GLUTEN-SENSITIVE ENTEROPATHY (COELIAC DISEASE), DERMATITIS HERPETIFORMIS DUHRING,P-TAU ELISA-THIS ELISA TEST KIT PROVIDES A QUANTITATIVE IN VITRO

	DETERMINATION OF THREONINE 181, PHOSPHORYLATED TAU (PTAU181) IN HUMAN CEREBROSPINAL FLUID (CSF),EUROLINE COELIAC DISEASE PROFILE (IGA)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGA AGAINST THE TWO ANTIGENS TISSUE TRANSGLUTAMINASE (TTG) AND GLIADIN (GAF-3X) (GLIADIN-ANALOGUE FUSION PEPTIDE) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF GLUTEN-SENSITIVE ENTEROPATHY AND DERMATITIS HERPETIFORMIS DUHRING.,BETA-AMYLOID (1-42) ELISA-THIS ELISA TEST KIT IS DESIGNED FOR THE QUANTITATIVE DETERMINATION OF BETA-AMYLOID (1-42) IN CEREBROSPINAL FLUID (CSF) OF PATIENTS, TO BE USED ONLY AS AN ADDITIONAL DIAGNOSTIC TOOL IN SUSPECTED CLINICAL AMYLOID PATHOLOGY OF THE BRAIN,TOTAL IGE ELISA-THE ELISA TEST KIT PROVIDES QUANTITATIVE IN VITRO DETERMINATION OF TOTAL IGE CONCENTRATION IN SERUM OR PLASMA.,UROMODULIN-ELISA-THIS ELISA TEST KIT PROVIDES QUANTITATIVE IN VITRO DETERMINATION OF UROMODULIN IN SERUM OR HEPARIN PLASMA AS A PARAMETER OF RENAL FUNCTION,INTACT-PTH ELISA-THIS ELISA TEST KIT IS DESIGNED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF INTACT PARATHYROID HORMONE (IPTH) IN HUMAN SERUM OR PLASMA FOR THE DIAGNOSIS OF FUNCTIONAL DISORDER OF THE PARATHYROID GLANDS WITH AN INCREASED LEVEL OF PARATHYROID HORMONE (HYPERPARATHYROIDISM) OR LOW PARATHYROID HORMONE LEVELS (HYPOPARAT-HYROIDISM),EUROLINE ANTI-ENA PROFILEPLUS 1 (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IGG CLASS TO 7 DIFFERENT ANTIGENS NRNP/SM, SM, SS-A, RO-52, SS-B, SCL-70 AND JO-1 IN SERUM OR PLASMA FOR THE DIAGNOSIS OF SHARP SYNDROME (MCTD), LUPUS ERYTHEMATOSUS DISSEMINATUS, SJOGREN'S SYNDROME, PROGRESSIVE SYSTEMIC SCLEROSIS AND POLY-/DERMATOMYOSITIS.,BETA-AMYLOID (1-40) ELISA-THIS ELISA TEST KIT IS DESIGNED FOR THE QUANTITATIVE DETERMINATION OF BETA-AMYLOID (1-40) IN CEREBROSPINAL FLUID (CSF) TO BE USED ONLY AS AN ADDITIONAL DIAGNOSTIC TOOL IN SUSPECTED CLINICAL AMYLOID PATHOLOGY OF THE BRAIN,CXCL13-ELISA-THIS ELISA TEST KIT PROVIDES QUANTITATIVE IN VITRO DETERMINATION OF CXCL13 IN HUMAN CEREBROSPINAL FLUID (CSF) OF PATIENTS WITH SUSPECTED ENCEPHALITIS, ESPECIALLY IN CASES OF SUSPECTED BORRELIOSIS WITH INVOLVEMENT OF THE CENTRAL NERVOUS SYSTEM (NEUROBORRELIOSIS),EUROARRAY HLA-B57:01 DIRECT-MOLECULAR GENETIC TEST SYSTEM FOR IN VITRO DETERMINATIONS OF HLA-B*57:01-ALLELES (NOT FOR TISSUE TYPING). THE TEST SYSTEM IS EXCLUSIVELY DESIGNED FOR THE

	MOLECULAR GENETIC IN VITRO DETERMINATION OF HLA-B*57:01 ALLELES FOR ASSESSMENT OF THE RISK OF A HYPERSENSITIVITY REACTION TO DRUGS CONTAINING ABACAVIR SULPHATE WHICH IS ASSOCIATED WITH THE HLA-B*57:01 ALLELE. IT SHOULD NOT BE USED FOR TISSUE TYPING,EUROLINE ANA-PROFILE 1 (IGG)-THE EUROLINE TEST KIT PROVIDES QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO THE 12 DIFFERENT ANTIGENS NRNP, SM, SS-A, RO-52, SS-B, SCL-70, JO-1, CENP B, DSDNA, NUCLEOSOMES, HISTONES AND RIBOSOMAL P-PROTEINS IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF SHARP SYNDROME (MCTD), LUPUS ERYTHEMATOSUS DISSEMINATUS, SJOGREN'S SYNDROME, PROGRESSIVE SYSTEMIC SCLEROSIS, POLY-/DERMATOMYOSITIS AND LIMITED FORM OF PROGRESSIVE SYSTEMIC SCLEROSIS (CREST SYNDROME).,EUROARRAY HLA-CW6- THE TEST SYSTEM IS EXCLUSIVELY DESIGNED FOR THE MOLECULAR GENETIC IN VITRO DETERMINATION OF DISEASE-ASSOCIATED HLA-C*06 ALLELES FOR THE DIAGNOSIS OF PSORIASIS WITH SKIN MANIFESTATIONS (IN PARTICULAR PSORIASIS VULGARIS TYPE 1, PSORIASIS GUTTATA, PSORIASIS VULGARIS TYPE 2), JOINT MANIFESTATIONS (IN PARTICULAR ARTHRITIS PSORIATICA) ETC. IT SHOULD NOT BE USED FOR TISSUE TYPING.,IIFT: ANA-MOSAIC 1A EUROPATTERN-THIS TEST KIT IS DESIGNED FOR THE QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASS IGG AGAINST CELL NUCLEI IN PATIENT SAMPLES FOR THE DIAGNOSIS OF MANY AUTOIMMUNE DISEASES, PARTICULARLY THOSE OF THE RHEUMATIC FORM.,CSF-ANTI-VZV ELISA (IGG)-THE ELISA TEST KIT PROVIDES A QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IGG CLASS AGAINST VZV IN CEREBROSPINAL FLUID (CSF).,ANTI ECHINOCOCCUS IGG-THE ELISA TEST KIT PROVIDES SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST ECHINOCOCCUS IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF ECHINOCOCCOSIS AND HYDATIDOSIS,ANTI-JO-1 ELISA (IGG)-POLYMYOSITIS, DERMATOMYOSITIS,IGM-RHEUMATOID FACTOR ELISA-THE ELISA TEST KIT PROVIDES SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO DETERMINATION OF HUMAN IGM RHEUMATOID FACTORS (AUTOANTIBODIES OF THE IGM CLASS AGAINST HUMAN IGG) IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF AUTOIMMUNE DISEASES, ESPECIALLY CASES OF SUSPECTED RHEUMATOID ARTHRITIS AND FURTHER RHEUMATIC DISEASES.,ANTI-EBV-CA ELISA (IGG)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST EBV-CA

	IN SERUM OR PLASMA FOR THE DIAGNOSIS OF INFECTIOUS MONONUCLEOSIS, BURKITT`S LYMPHOMA AND NASOPHARYNGEAL CARCINOMA. ,CSF ANTI-EBV-CA -ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF INFECTIOUS MONONUCLEOSIS, BURKITT'S LYMPHOMA, NASOPHARYNGEAL CARCINOMA,EUROLINE ANA PROFILE 23 (IGG)-THE EUROLINE TEST KIT HUMAN AUTOANTIBODIES OF THE DIFFERENT ANTIGENS: DSDNA, NUCLEOSOMES, HISTONES, SS-A, RO-52, SS-B, NRNP/SM, SM, MI-2, MI-2, KU, CENP A, CENP B, SP100, PML, SCL-70, PM-SCL100, PM-SCL75, RP11, RP155, GP210, PCNA AND DFS70 IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF SHARP SYNDROME (MCTD), SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), SJOGREN'S SYNDROME, PROGRESSIVE SYSTEMIC SCLEROSIS, POLY-/DERMATOMYOSITIS, OVERLAP SYNDROME, LIMITED FORM OF PROGRESSIVE SYSTEMIC SCLEROSIS (CREST SYNDROME) AND PRIMARY BILIARY LIVER CHOLANGITIS.,CSF: ANTI-MEASLES VIRUS ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF MEASLES,ANTI-BRUCELLA ABORTUS ELISA (IGM)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTI-BODIES OF THE IMMUNOGLOBULIN CLASS IGM AGAINST BRUCELLA ABORTUS IN SERUM OR PLASMA FOR THE DIAGNOSIS OF BRUCELLOSIS,ANTI-VZV ELISA (IGM)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IGM CLASS AGAINST VARICELLA ZOSTER VIRUS (VZV) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF VARICELLA ZOSTER VIRUS INFECTIONS.,ANTI-VZV GLYCOPROTEIN ELISA (IGM)-VARICELLA ZOSTER VIRUS INFECTION, EUROLINE ANTI-EBV PROFILE 2 (IGM)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IGM CLASS TO FIVE DIFFERENT EBV ANTIGENS: VCA GP125, VCA P19, EBNA-1, P22 AND EA-D IN SERUM OR PLASMA FOR THE DIAGNOSIS OF INFECTIONS WITH EPSTEIN-BARR VIRUS (INFECTIOUS MONONUCLEOSIS, BURKITT S LYMPHOMA, NASOPHARYNGEAL CARCINOMA),EUROLINE ANTI-EBV PROFILE 2 (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IGG CLASS IN SERUM OR PLASMA TO FIVE DIFFERENT EBV ANTIGENS: VCA GP125, VCA P19, EBNA-1, P22 AND EA-D FOR THE DIAGNOSIS OF INFECTIONS WITH EPSTEIN-BARR VIRUS (INFECTIOUS MONONUCLEOSIS, BURKITT S LYMPHOMA, NASOPHARYNGEAL CARCINOMA),ANTI-MUMPS VIRUS AT ELISA (IGG) -THE ELISA TEST KIT PROVIDES SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST MUMPS VIRUSES (ANTIGEN AT OF STRAINS ATCC VR106 AND JERYL LYNN) IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF MUMPS,EUROLINE

	HANTAVIRUS PROFILE 1 (IGM)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGM TO THREE DIFFERENT HANTAVIRUS SEROTYPES: PUUMALA (PUUV), DOBRAVA (DOBV) AND HANTAAN (HTNV) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF HANTAVIRUS INFECTIONS,ANTI-DIPHTHERIA TOXOID ELISA (IGG)-THE ELISA TEST KIT PROVIDES A QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST DIPHTHERIA TOXOID IN SERUM OR PLASMA FOR THE CLARIFICATION OF AN UNKNOWN IMMUNE STATUS.,ANTI-HELICOBACTER PYLORI ELISA (IGG)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST HELICOBACTER PYLORI IN SERUM OR PLASMA FOR THE DIAGNOSIS OF INFECTIONS WITH HELICOBACTER PYLORI, CHRONIC ACTIVE GASTRITIS (ANTRAL GASTRITIS), PEPTIC ULCER AND DUODENAL ULCER,EUROLINE HANTAVIRUS PROFILE 1 (IGG)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO THREE DIFFERENT HANTAVIRUS SEROTYPES: PUUMALA (PUUV), DOBRAVA (DOBV) AND HANTAAN (HTNV) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF HANTAVIRUS INFECTIONS,EUROARRAY HLA-DQ2/DQ8 H-THE EUROARRAY HLA-DQ2/DQ8-H DIRECT TEST SYSTEM ENABLES FAST AND EASY HLA-DQ2/DQ8 DETECTION TO ASSESS THE GENETIC PREDISPOSITION TO COELIAC DISEASE AND OTHER HLA-DQ2/DQ8-ASSOCIATED DISEASES. IN ORDER TO PROVIDE AN IMPROVED RISK ASSESSMENT, DIFFERENTIATION IS MADE BETWEEN THE HOMO- OR HETEROZYGOUS PRESENCE OF THE ALLELES CODING FOR THE ALPHA- AND BETA-SUBUNITS OF HLA-DQ2.2 AND DQ2.5. IN THE DIRECT METHOD FULL BLOOD SAMPLES CAN BE USED DIRECTLY WITHOUT THE NEED OF SEPARATE DNA ISOLATION,ANTI-BRUCELLA ABORTUS ELISA (IGG)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG CLASS AGAINST BRUCELLA ABORTUS IN SERUM OR PLASMA FOR THE DIAGNOSIS OF BRUCELLOSIS,ANTI-HELICOBACTER PYLORI ELISA (IGA)-INFECTION WITH HELICOBACTER PYLORI, CHRONIC ACTIVE GASTRITIS (ANTRAL GASTRITIS), PEPTIC ULCER, DUODENAL ULCER.,LIVER PROFILE 3G (NIL)-THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG TO FOUR DIFFERENT ANTIGENS: AMA-M2 (PYRUVATE-DEHYDROGENASE-COMPLEX), LKM-1 (LIVER-KIDNEY MICROSOMES; CYTOCHROME P450 II D6), LC-1 (CYTOSOLIC LIVER ANTIGEN TYPE 1; FORMIMINOTRANSFERASE-CYCLODEAMINASE) AND SLA/LP

	(SOLUBLE LIVER ANTIGEN/LIVER-PANCREAS ANTIGEN) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF PRIMARY BILIARY LIVER CIRRHOSIS (PBC), IN CASE OF AN INCREASE IN TRANSAMINASES FOR UNCLEAR REASONS AND SUSPECTED CASES OF AUTOIMMUNE HEPATITIS (AIH), EUROARRAY HLA-DQ2/DQ8 -THE EUROARRAY HLA-DQ2/DQ8 DIRECT TEST SYSTEM ENABLES FAST AND EASY HLA-DQ2/DQ8 DETECTION TO ASSESS THE GENETIC PREDISPOSITION TO COELIAC DISEASE AND OTHER HLA-DQ2/DQ8-ASSOCIATED DISEASES. IN THE DIRECT METHOD FULL BLOOD SAMPLES CAN BE USED DIRECTLY WITHOUT THE NEED OF SEPARATE DNA ISOLATION.,ANTI-TISSUE TRANSGLUTAMINASE ELISA (IGG)-GLUTEN-SENSITIVE ENTEROPATHY (COELIAC DISEASE), DERMATITIS HERPETIFORMIS DUHRING. ,AVIDITY: ANTI-MEASLES VIRUS ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF MEASLES,CSF: ANTI-MUMPS VIRUS ELISA (IGG)-IN-VITRO DIAGNOSTIC REAGENTS FOR THE DETECTION OF MUMPS AND EPIDEMIC PAROTITIS,ANTI-CARDIOLIPIN ELISA (IGA)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTI- BODIES OF THE IMMUNOGLOBULIN CLASS IGA AGAINST CARDIOLIPIN IN SERUM OR PLASMA FOR THE DIAGNOSIS OF ANTI-PHOSPHOLIPID SYNDROME (APS),EUROARRAY HLA-B27 DIRECT-THE TEST SYSTEM IS EXCLUSIVELY DESIGNED FOR THE MOLECULAR GENETIC IN VITRO DETERMINATION OF DISEASE-ASSOCIATED HLA-B*27 ALLELES FOR THE DIAGNOSIS OF RHEUMATIC DISEASES, ESPECIALLY BECHTEREW'S DISEASE (SPONDYLITIS ANKYLOSANS, ANKYLOSING SPONDYLITIS, AS), URETHRO-OCULO-ARTICULAR SYNDROME (REITER'S DISEASE, COMBINATION OF SYMPTOMS FROM URETHRITIS, CONJUNCTIVITIS/UVEITIS, ARTHRITIS), REACTIVE ARTHRITIS (PARA-/POSTINFECTIOUS ARTHRITIS), ACUTE UVEITIS ANTERIOR OR ACUTE IRIDOCYCLITIS, PERIARTHRITIS (PERIARTHROPATHIA) HUMEROSCAPULARIS, ARTHRITIS PSORIATICA (PSORIASIS ARTHRITIS), JUVENILE IDIOPATHIC ARTHRITIS AND ENTEROPATHIES (CHRONIC-INFLAMMATORY BOWEL DISEASES, IBD). IT SHOULD NOT BE USED FOR TISSUE TYPING.,EUROLINE NEURONAL ANTIGENS PROFILE PLUS RST (IGG)(NIL)-IN VITRO DIAGNOSTIC REAGENTS FOR DIAGNOSIS OF PARANEOPLASTIC NEUROLOGICAL SYNDROMES (PNS) THE EUROLINE TEST KIT PROVIDES A QUALITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IGG CLASS TO 9 DIFFERENT ANTIGENS (AMPHIPHYSIN, CV2, PNMA2 (MA2/TA), RI, YO, HU, RECOVERIN, SOX1 AND TITIN) IN SERUM OR PLASMA FOR THE DIAGNOSIS OF THE PARANEOPLASTIC NEUROLOGICAL SYNDROME (PNS),ANTI-CCD ABSORBENT-ANTI-CCD ABSORBENT IS A SUPPLEMENTARY REAGENT DESIGNED FOR THE INCUBATION WITH EUROIMMUN ALLERGY PROFILES (PRODUCT

	CLASSIFICATION DQ, DP, DF, DE). THE ABSORBENT IS USED IN CASE IGE ANTIBODIES AGAINST CROSS-REACTIVE CARBOHYDRATE DETERMINANTS (CCDS) WERE DETECTED IN THE PATIENT SAMPLE (ANTI-CCD IGE ANTIBODIES). THE PRESENCE OF THESE ANTIBODIES IS INDICATED BY A POSITIVE CCD BAND ON THE ALLERGY PROFILES., EUROARRAY LACTOSE INTOLERANCE-THE EUROARRAY LACTOSE INTOLERANCE DIRECT ENABLES FAST AND SIMPLE DETERMINATION OF TWO POLYMORPHISMS 13910C/T AND 22018G/A IN THE PROMOTER REGION OF THE LACTASE GENE IN ONE TEST REACTION. THE DIRECT METHOD ENABLES DIRECT USAGE OF WHOLE BLOOD SAMPLES AND DOES NOT REQUIRE A SEPARATE DNA ISOLATION., ANTI-ß2-GLYCOPROTEIN 1 ELISA (IGA)-ANTI-PHOSPHOLIPID SYNDROME,ANTI-BORDETELLA PERTACTIN ELISA (IGG)- INDICATION: BORDETELLA PERTUSSIS INFECTIONS, WHOOPING COUGH,ANTI M2-3E ELISA (IGG)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN ANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST THE MITOCHONDRIAL ANTIGENS M2 IN SERUM OR PLASMA TO SUPPORT THE DIAGNOSIS OF PRIMARY BILIARY CIRRHOSIS (PBC) AND OVERLAP SYNDROME WITH AUTOIMMUNE HEPATITIS.,BIOCHIP SEQUENCE EBV (AVIDITY DETERMINATION)-THIS TEST KIT PROVIDES QUALITATIVE OR SEMIQUANTITATIVE IN VITRO DETERMINATION OF HUMAN ANTIBODIES OF IMMUNOGLOBULIN CLASSES IGG OR IGM AGAINST EBV-CA, GP125, P19, EBV-EA AND EBNA (C3C) IN PATIENT SAMPLES TO SUPPORT THE DIAGNOSIS OF INFECTIOUS MONONUCLEOSIS, BURKITT`S LYMPHOMA AND NASOPHARYNGEAL CARCINOMA,ANTI-CARDIOLIPIN ELISA (IGAGM)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IGAGM CLASS AGAINST CARDIOLIPIN IN SERUM OR PLASMA FOR THE DIAGNOSIS OF ANTI-PHOSPHOLIPID SYNDROME (APS),ANTI-CENTROMERE ELISA (IGG)-THE ELISA TEST KIT PROVIDES A SEMIQUANTITATIVE OR QUANTITATIVE IN VITRO ASSAY FOR HUMAN AUTOANTIBODIES OF THE IMMUNOGLOBULIN CLASS IGG AGAINST CENTROMERES IN SERUM OR PLASMA FOR THE DIAGNOSIS OF THE LIMITED FORM OF THE PROGRESSIVE SYSTEMIC SCLEROSIS (CREST SYNDROME).

344	IMP/IVD/2019/000370	1.License Holder Name: SVR BIOTECH 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REAGENT STRIPS FOR URINALYSIS(MR 2 ITEMS(CRE/MALB))-DETECTION OF MICROALBUMIN & CREATININE,REAGENT STRIPS FOR URINALYSIS (MR U11)-DETECTION OF ASCORBIC ACID & GLUCOSE & BILIRUBIN & KETONE & SG & BLOOD & PH &PROTEIN &UROBILINOGEN & NITRITE & LEUCOCYTEE,REAGENT STRIPS FOR URINALYSIS(MR 8 ITEMS)-DETECTION OF GLUCOSE & BILIRUBIN & KETONE & SG & BLOOD & PH &PROTEIN &UROBILINOGEN ,REAGENT STRIPS FOR URINALYSIS(MR URISTIK5 ITEMS)-DETECTION OF GLUCOSE & KETONE & BLOOD & PH &PROTEIN ,REAGENT STRIPS FOR URINALYSIS(MR U13CR)-DETECTION OF MICROALBUMIN & CREATININE&ASCORBIC ACID & GLUCOSE & BILIRUBIN & KETONE & SG & BLOOD & PH &PROTEIN & UROBILINOGEN & NITRITE & LEUCOCYTEE,REAGENT STRIPS FOR URINALYSIS(MR 4 ITEMS(BLD))-DETECTION OF GLUCOSE & BLOOD & PH &PROTEIN,REAGENT STRIPS FOR URINALYSIS(MR 4 ITEMS(SG))-DETECTION OF GLUCOSE & SG& PH &PROTEIN,REAGENT STRIPS FOR URINALYSIS(MR A10)-DETECTION OF GLUCOSE & BILIRUBIN & KETONE & SG & BLOOD & PH &PROTEIN &UROBILINOGEN & NITRITE & LEUCOCYTEE,REAGENT STRIPS FOR URINALYSIS(MR 1 ITEM (KETONE))-DETECTION OF KETONE,REAGENT STRIPS FOR URINALYSIS(MR 3 ITEMS)-DETECTION OF GLUCOSE & PH &PROTEIN, REAGENT STRIPS FOR URINALYSIS(MR 1 ITEM(GLUCOSE))-DETECTION OF GLUCOSE,REAGENT STRIPS FOR URINALYSIS(MR 1 ITEM (PROTEIN))-DETECTION OF PROTEIN,REAGENT STRIPS FOR URINALYSIS(MR 2 ITEMS(GLU/PRO))-DETECTION OF GLUCOSE &PROTEIN

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345	IMP/IVD/2019/000371	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONDITIONING NA SOLUTION(BIOLYTE)-REAGENTS FOR USE WITH BIOLYTE 2000 FOR CONDITIONING OF SODIUM ELECTRODES,REAGENT PACK FOR ELECTROLYTE ANALYZER(BIOLYTE)-QUANTITATIVE DETERMINATION OF ELECTROLYTES IN HUMAN SERUM/PLASMA/WHOLE BLOOD USING BIOLYTE 2000 ANALYZER, WASHING SOLUTION(BIOLYTE)-WASHING FLOW PATH SOLUTION FOR BIOLYTE V ELECTROLYTE ANALYZER,CLEANING SOLUTION FOR ELECTROLYTE ANALYZER(BIOLYTE)-REGENTS FOR USE WITH BIOLYTE 2000 FOR CLEANING TUBING,REAGENT PACK FOR ELECTROLYTE ANALYZER(BIOLYTE)-QUANTITATIVE DETERMINATION OF ELECTROLYTES USING BIOLYTE V ANALYZER IN HUMAN SERUM /PLASMA/WHOLE BLOOD
346	IMP/IVD/2019/000373	1.License Holder Name: ARKRAY HEALTHCARE PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:POCKETCHEM A1C TEST KIT(POCKETCHEM A1C TEST KIT)-THE POCKETCHEM™ A1C TEST KIT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF GLYCATED HEMOGLOBIN (HBA1C) IN WHOLE BLOOD AND IS USED WITH THE POCKETCHEM™ A1C ANALYZER.,POCKETCHEM A1C CONTROL KIT(POCKETCHEM A1C CONTROL KIT)-THE POCKETCHEM™ A1C CONTROL KIT IS INTENDED TO BE USED TO CHECK THE GENERAL FUNCTIONALITY AND ACCURACY OF THE WITH POCKETCHEM™ A1C TEST SYSTEM.
347	IMP/IVD/2019/000374	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AQUIOS LYSING REAGENT KIT(AQUIOS LYSING REAGENT KIT)-AQUIOS LYSING REAGENT KIT IS USED AS PART OF THE AQUIOS FLOW CYTOMETER SYSTEM. THE KIT CONSISTS OF TWO REAGENTS USED BY AQUIOS FLOW CYTOMETERS TO PREPARE WHOLE BLOOD SAMPLES FOR ANALYSIS OF WHITE BLOOD CELLS.,AQUIOS SODIUM HYPOCHLORITE SOLUTION(AQUIOS SODIUM HYPOCHLORITE SOLUTION)-AQUIOS SODIUM HYPOCHLORITE SOLUTION IS A CLEANING AGENT USED AS PART OF AN AQUIOS FLOW CYTOMETER SYSTEM. THE SOLUTION MAINTAINS AQUIOS INSTRUMENTS IN OPTIMAL CONDITION.

348	IMP/IVD/2019/000376	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCESS TSH (3RD IS) (REAGENT PACK)(ACCESS TSH (3RD IS) (REAGENT PACK))-THE ACCESS TSH (3RD IS) ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID-STIMULATING HORMONE (THYROTROPIN, TSH, HTSH) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS. THIS ASSAY IS CAPABLE OF PROVIDING 3RD GENERATION TSH RESULTS.,ACCESS PCT CALIBRATORS(ACCESS PCT CALIBRATORS)-THE ACCESS PCT CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS PCT ASSAY FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS TSH (3RD IS) (CALIBRATORS)(ACCESS TSH (3RD IS) (CALIBRATORS))-THE ACCESS TSH (3RD IS) CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS TSH (3RD IS) ASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID-STIMULATING HORMONE (THYROTROPIN, TSH, HTSH) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS PCT (REAGENT PACK)(ACCESS PCT (REAGENT PACK))-THE ACCESS PCT ASSAY IS A PARAMAGNETIC, CHEMILUMINESCENT IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS. MEASUREMENT OF PCT IN CONJUNCTION WITH OTHER LABORATORY FINDINGS AND CLINICAL ASSESSMENTS AIDS IN THE RISK ASSESSMENT OF CRITICALLY ILL PATIENTS FOR PROGRESSION TO SEVERE SEPSIS AND SEPTIC SHOCK.,ACCESS PAPP-A CALIBRATOR(ACCESS PAPP-A CALIBRATOR)-THE ACCESS PAPP-A CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS PAPP-A ASSAY FOR THE QUANTITATIVE DETERMINATION OF PREGNANCY ASSOCIATED PLASMA PROTEIN A LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS HSTNI (REAGENT PACK)(ACCESS HSTNI (REAGENT PACK))-THE ACCESS HSTNI ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR HIGH SENSITIVITY QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS TO AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (MI).,ACCESS PAPP-A QC(ACCESS PAPP-A QC)-THE ACCESS PAPP-A QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS PAPP-A ASSAY.,ACCESS PAPP-A REAGENT(ACCESS PAPP-A

		REAGENT)-THE ACCESS PAPP-A ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PREGNANCY ASSOCIATED PLASMA PROTEIN A LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS HSTNI CALIBRATOR(ACCESS HSTNI CALIBRATOR)-THE ACCESS HSTNI CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS HSTNI ASSAY FOR HIGH SENSITIVITY QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) LEVELS IN HUMAN SERUM AND PLASMA USING THE ACCESS IMMUNOASSAY SYSTEMS.
349	IMP/IVD/2019/000377	1.License Holder Name: M/S. SPECTRUM DIAGNOSTICS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE MONITORING SYSTEM(GLUCODR. SUPERSENSOR (AGM-2200))-BLOOD GLUCOSE METER IS USED WITH AGM-2200 TESTING STRIPS FOR QUANTITATIVELY MEASURING GLUCOSE IN FRESH CAPILLARY, VENOUS WHOLE BLOOD (INVITRO DIAGNOSTIC USE).,BLOOD GLUCOSE TEST STRIP(GLUCODR. AUTOTM A BLOOD GLUCOSE TEST STRIP)-UESD WITH AGM-4000, GLUCODR. AUTOTM A BLOOD GLUCOSE TEST METER FOR QUANTITATIVELY MEASURING GLUCOSE IN FRESH CAPILLARY, VENOUS WHOLE BLOOD(IN VITRO DIAGNOSTIC USE),BLOOD GLUCOSE MONITORING SYSTEM(GLUCODR. AUTO A (AGM-4000))-BLOOD GLUCOSE METER IS USED WITH AGM-4000 TESTING STRIPS FOR QUANTITATIVELY MEASURING GLUCOSE IN FRESH CAPILLARY, VENOUS WHOLE BLOOD (INVITRO DIAGNOSTIC USE).,BLOOD GLUCOSE TEST STRIP(GLUCODR. SUPERSENSOR BLOOD GLUCOSE TEST STRIP)-USED WITH AGM-2200, GLUCODR. SUPERSENSOR BLOOD GLUCOSE TEST METER IS USED FOR QUANTITATIVELY MEASURING GLUCOSE IN FRESH CAPILLARY, VENOUS WHOLE BLOOD (IN VITRO DIAGNOSTIC USE).

350	IMP/IVD/2019/000378	1.License Holder Name: ANAND BROTHERS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CALPREST(CALPREST)-CALPREST IS A QUANTITATIVE ENZYME-LINKED IMMUNOASSAY FOR THE DETECTION OF CALPROTECTIN IN FAECES. TO SUPPORT THE DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD, CROHN'S DISEASE AND ULCERATIVE COLITIS) AND TO DIFFERENTIATE IBD FROM IRRITABLE BOWEL SYNDROME (IBS) IN CONJUCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS.,CALPREST TURBO (CALPREST TURBO)-CALPREST TURBO IS TURBIDMETRIC TEST FOR QUANTITATIVE DETECTION OF CALPROTECTIN IN STOOL.,CALFAST (CALFAST)-CALFAST IS A RAPID, QUANTITATIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF CALPROTECTIN IN FAECES. WHICH CAN BE USED AS IN VITRO DIAGNOSTIC TO AID IN THE DIAGNOSIS AND DISEASE MONITORING OF INFLAMMATORY BOWEL DISEASES (IBD), SPECIFICALLY CROHN'S DISEASE AND ULCERATIVE COLITIS AND TO DIFFERENTIATE IBD FROM IRRITABLE BOWEL SYNDROME (IBS) IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS.

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351	IMP/IVD/2019/000379	1.License Holder Name: SYSMEX INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREALBUMIN FS (PREALBUMIN FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PREALBUMIN IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C ,CHOLINESTERASE FS (CHOLINESTERASE FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHOLINESTERASE (CHE) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,TRULAB BICARBONATE (TRULAB BICARBONATE)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE ,TRUCAL APO A1/B(TRUCAL APO A1/B)-CALIBRATOR FOR USE WITH DIASYS TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF APOLIPOPROTEIN A1 AND APOLIPOPROTEIN B ON PHOTOMETRIC SYSTEMS ,ß-HYDROXYBUTYRATE FS(ß-HYDROXYBUTYRATE FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF -HYDROXYBUTYRATE IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C ,TRUCAL PROTEIN(TRUCAL PROTEIN)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS SERUM PROTEINS ON PHOTOMETRIC SYSTEMS ,TRUCAL LIPID(TRUCAL LIPID)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPIDS AND LP-PLA2 ON PHOTOMETRIC SYSTEMS ,COMPLEMENT C3C FS(COMPLEMENT C3C FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF COMPLEMENT COMPONENT C3C IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,ETHANOL FS(ETHANOL FS) -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ETHANOL IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,TRULAB PROTEIN LEVEL 1(TRULAB PROTEIN LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS SERUM PROTEINS,TRULAB P(TRULAB P)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES,TRUCAL CRP 150(TRUCAL CRP 150)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF C REACTIVE PROTEIN (CRP) ON PHOTOMETRIC SYSTEMS,IMMUNOGLOBULIN E FS(IMMUNOGLOBULIN E FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IMMUNOGLOBULIN E (IGE) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,TRUCAL ALBUMIN U/CSF HIGH (TRUCAL ALBUMIN U/CSF HIGH)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN URINE AND

	CSF ON PHOTOMETRIC SYSTEMS ,TRUCAL ASO(TRUCAL ASO)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF ANTISTREPTOLYSIN O (ASO) ON PHOTOMETRIC SYSTEMS,COMPLEMENT C4 FS(COMPLEMENT C4 FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF COMPLEMENT COMPONENT C4 IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,TRUCAL CK-MB(TRUCAL CK-MB)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF CK-MB ACTIVITY ON PHOTOMETRIC SYSTEMS , MYOGLOBIN FS(MYOGLOBIN FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF MYOGLOBIN IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C ,TRUCAL MYOGLOBIN (TRUCAL MYOGLOBIN)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF MYOGLOBIN ON PHOTOMETRIC SYSTEMS ,NEFA FS(NEFA FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF NON-ESTERIFIED FATTY ACIDS (NEFA) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C ,IMMUNOGLOBULIN A FS(IMMUNOGLOBULIN A FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,TRULAB URINE LEVEL 1 (TRULAB URINE LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES ,-HYDROXYBUTYRATE 21 FS(-HYDROXYBUTYRATE 21 FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF -HYDROXYBUTYRATE IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,FERRITIN FS (FERRITIN FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF FERRITIN IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,TRULAB CYSTATIN C LEVEL 1(TRULAB CYSTATIN C LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF CYSTATIN C ,APOLIPOPROTEIN A1 FS (APOLIPOPROTEIN A1 FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF APOLIPOPROTEIN A1 (APO A1) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,TRULAB CYSTATIN C LEVEL 2(TRULAB CYSTATIN C LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING THE ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF CYSTATIN C ,APOLIPOPROTEIN B FS(APOLIPOPROTEIN B FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF APOLIPOPROTEIN B (APO B) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,ALBUMIN IN URINE/ CSF FS (MICROALBUMIN)(ALBUMIN IN URINE/ CSF FS (MICROALBUMIN))-

	DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN URINE, CSF, SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,TRULAB PROTEIN LEVEL 2(TRULAB PROTEIN LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS SERUM PROTEINS ,ANTISTREPTOLYSIN O FS(ANTISTREPTOLYSIN O FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ANTISTREPTOLYSIN O (ASO) IN SERUM ON BIOMAJESTY JCA-BM6010/C,TRUCAL FERRITIN (TRUCAL FERRITIN)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF FERRITIN ON PHOTOMETRIC SYSTEMS ,TRULAB ALBUMIN U/CSF LEVEL 2(TRULAB ALBUMIN U/CSF LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN URINE ,TRULAB CRP LEVEL 2 (TRULAB CRP LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP),TRULAB CRP LEVEL 1(TRULAB CRP LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING THE ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP),ETHANOL STANDARD FS(ETHANOL STANDARD FS)-AQUEOUS STANDARD SOLUTIONS IN DIFFERENT CONCENTRATIONS,LACTATE FS(LACTATE FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LACTATE IN PLASMA ON DIASYS BIOMAJESTY JCA-BM6010/C,TRULAB ETHANOL(TRULAB ETHANOL)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF ETHANOL,TRULAB URINE LEVEL 2(TRULAB URINE LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES ,TRULAB L LEVEL 1 (TRULAB L LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ANALYTICAL ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF LIPIDS ,TRUCAL CYSTATIN C(TRUCAL CYSTATIN C)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF CYSTATIN C ON PHOTOMETRIC SYSTEMS , TRULAB N(TRULAB N)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES ,LP(A) 21 FS(LP(A) 21 FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPOPROTEIN (A) [LP(A)] IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,BICARBONATE STANDARD FS (BICARBONATE STANDARD FS)-STANDARD FOR USE IN TESTS FOR

	QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE ON PHOTOMETRIC SYSTEMS,TRUCAL CRP(TRUCAL CRP)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF C REACTIVE PROTEIN (CRP) ON PHOTOMETRIC SYSTEMS, CYSTATIN C FS(CYSTATIN C FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CYSTATIN C IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,TRULAB LP(A) LEVEL 2 (TRULAB LP(A) LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF [LP(A)] ,IMMUNOGLOBULIN G FS (IMMUNOGLOBULIN G FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,TRUCAL ALBUMIN U/CSF(TRUCAL ALBUMIN U/CSF)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN URINE AND CSF ON PHOTOMETRIC SYSTEM,PHOSPHOLIPIDS FS (PHOSPHOLIPIDS FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHOLINE-CONTAINING PHOSPHOLIPIDS IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C ,TRULAB L LEVEL 2(TRULAB L LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ANALYTICAL ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF LIPIDS , IMMUNOGLOBULIN M FS(IMMUNOGLOBULIN M FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,RHEUMATOID FACTOR FS(RHEUMATOID FACTOR FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF RHEUMATOID FACTOR (RF) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C ,TRANSFERRIN FS (TRANSFERRIN FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TRANSFERRIN (TRF) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C ,TRULAB LP(A) LEVEL 1 (TRULAB LP(A) LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF [LP(A)] ,TRUCAL LP(A) 21(TRUCAL LP(A) 21)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPOPROTEIN (A) [LP(A)] ON PHOTOMETRIC SYSTEMS ,TRUCAL U(TRUCAL U)-MULTI-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES ON PHOTOMETRIC SYSTEMS ,TRUCAL CRP HIGH(TRUCAL CRP HIGH)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF C REACTIVE PROTEIN (CRP) ON PHOTOMETRIC SYSTEMS,TRULAB ALBUMIN U/CSF LEVEL 1(TRULAB ALBUMIN U/CSF LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL

	FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN URINE ,TRUCAL RF(TRUCAL RF)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF RHEUMATOID FACTOR (RF) ON PHOTOMETRIC SYSTEMS ,TRUCAL PROTEIN HIGH (TRUCAL PROTEIN HIGH)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS SERUM PROTEINS ON PHOTOMETRIC SYSTEMS

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	BIOMAJESTY JCA-BM6010/C.,CREATININE FS(CREATININE FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN SERUM, PLASMA OR URINE ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN SERUM, PLASMA OR URINE ON BIOMAJESTY JCA-BM6010/C,IRON FS FERENE(IRON FS FERENE)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IRON IN SERUM OR PLASMA ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IRON IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C.,URIC ACID FS TOOS(URIC ACID FS TOOS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN SERUM OR PLASMA OR URINE ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN SERUM OR PLASMA OR URINE ON BIOMAJESTY JCA-BM6010/C.,UREA FS(UREA FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF UREA IN SERUM, PLASMA OR URINE ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF UREA IN SERUM, PLASMA OR URINE ON BIOMAJESTY JCA-BM6010/C.,BILIRUBIN AUTO DIRECT FS(BILIRUBIN AUTO DIRECT FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF DIRECT BILIRUBIN IN SERUM OR PLASMA ON SYSMEX BX-SERIES -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF DIRECT BILIRUBIN IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,ALAT (GPT) FS (IFCC MOD.)(ALAT (GPT) FS (IFCC MOD.))--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALAT (GPT) IN SERUM OR PLASMA ON SYSMEX BX-SERIES -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALAT (GPT) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,ALBUMIN FS(ALBUMIN FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN SERUM OR PLASMA ON SYSMEX BX-SERIES -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,ALKALINE PHOSPHATASE (IFCC MOD. 37°C)(ALKALINE PHOSPHATASE (IFCC MOD. 37°C))--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALKALINE PHOSPHATASE (AP) IN SERUM OR PLASMA ON SYSMEX BX-SERIES -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALKALINE PHOSPHATASE (AP) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,CHOLESTEROL FS (CHOLESTEROL FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHOLESTEROL IN SERUM OR PLASMA ON

	SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHOLESTEROL IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C.,MAGNESIUM XL FS(MAGNESIUM XL FS) --DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF MAGNESIUM IN SERUM OR PLASMA ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF MAGNESIUM IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C.,LIPASE DC FS(LIPASE DC FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPASE IN SERUM OR PLASMA ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPASE IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C.,BICARBONATE FS(BICARBONATE FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE/TOTAL CO2 IN SERUM OR PLASMA ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE/TOTAL CO2 IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,BILIRUBIN AUTO TOTAL FS (BILIRUBIN AUTO TOTAL FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILIRUBIN IN SERUM OR PLASMA ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILIRUBIN IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C.,LDH FS IFCC (LDH FS IFCC)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LACTATE DEHYDROGENASE (LDH) IN SERUM OR PLASMA ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LACTATE DEHYDROGENASE (LDH) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,LDL-C SELECT FS(LDL-C SELECT FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN SERUM OR PLASMA ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C.,TRIGLYCERIDES FS(TRIGLYCERIDES FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDES IN SERUM OR PLASMA ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDES IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,CRP FS`(CRP FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM OR PLASMA ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM OR

	PLASMA ON BIOMAJESTY JCA-BM6010/C.,GLUCOSE HEXOKINASE FS (GLUCOSE HEXOKINASE FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE IN SERUM, PLASMA OR URINE ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE IN SERUM, PLASMA OR URINE ON BIOMAJESTY JCA-BM6010/C.,CK-MB FS(CK-MB FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CK-MB IN SERUM OR PLASMA ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CK-MB IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C.,PANCREATIC AMYLASE CC FS(PANCREATIC AMYLASE CC FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PANCREATIC AMYLASE IN SERUM OR PLASMA ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PANCREATIC AMYLASE IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C,GAMMA – GT FS (SZASZ MOD. /IFCC STAND.)(GAMMA – GT FS (SZASZ MOD. /IFCC STAND.))--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GAMMA-GLUTAMYLTRANSFERASE (GAMMA-GT) IN SERUM OR PLASMA ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GAMMA-GLUTAMYLTRANSFERASE (GAMMA-GT) IN SERUM OR PLASMA ON BIOMAJESTY JCA-BM6010/C.,CREATININE PAP FS(CREATININE PAP FS)--DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN SERUM, PLASMA OR URINE ON SYSMEX BX-SERIES. -DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN SERUM, PLASMA OR URINE ON BIOMAJESTY JCA-BM6010/C.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

353	IMP/IVD/2019/000380	1.License Holder Name: M/S.TRANSASIA BIO-MEDICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TSH ELISA(ERBALISA TSH)-THYROID STIMULATING HORMONE TEST KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF THYROID STIMULATING HORMONE IN BLOOD SERUM/PLASMA.,THYROXINE, FREE (FT4) ELISA (ERBALISA THRYOXINE FREE (FT4))-THE FT4 ELISA KIT IS USED FOR THE QUANTITATIVE MEASUREMENT OF FREE THYROXINE (FT4) IN HUMAN SERUM.,LH ELISA(ERBALISA LH)-THE ERBALISA LH ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM USING STREPTAVIDIN BIOTIN TECHNOLOGY.,ESTRADIOL ELISA(ERBALISA ESTRADIOL)-THE ESTRADIOL (E2) ELISA KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL (E2) CONCENTRATION IN HUMAN SERUM AND PLASMA.,FSH ELISA(ERBALISA FSH)-THE ERBALISA FSH ELISA IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN SERUM USING STREPTAVIDIN BIOTIN TECHNOLOGY,VITAMIN B12 ELISA(ERBALISA VITAMIN B12)-THE VITAMIN B12 ELISA TEST KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM AND PLASMA.,PROLACTIN ELISA(ERBALISA PROLACTIN)-THE ERBALISA PROLACTIN ELISA IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF PROLACTIC IN HUMAN SERUM USING STREPTAVIDIN BIOTIN TECHNOLOGY.,FERRITIN ELISA(ERBALISA FERRITIN)-THE FERRITIN SA ELISA KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF FERRITIN IN HUMAN SERUM OR PLASMA.,TRIIODOTHYRONINE (T3) ELISA(ERBALISA TRIIODOTHYRONINE (T3))-TOTAL TRIIODOTHYRONINE TEST KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TOTAL TRIIODOTHYRONINE IN BLOOD SERUM/PLASMA.,PROGESTERONE ELISA(ERBALISA PROGESTERONE)-THE PROGESTERONE ELISA KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF PROGESTERONE IN HUMAN SERUM OR PLASMA.,THYROXINE (T4) ELISA(ERBALISA THYROXINE (T4))-TOTAL THYROXINE TEST KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TOTAL THYROXINE IN BLOOD SERUM/PLASMA.,C-PEPTIDE ELISA(ERBALISA C-PEPTIDE)-THE C-PEPTIDE ELISA KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN C-PEPTIDE LEVELS IN HUMAN SERUM.,25(OH) VITAMIN D ELISA(ERBALISA 25(OH) VITAMIN D)-THE 25(OH) VITAMIN D ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25-OH VITAMIN D IN HUMAN SERUM AND PLASMA.,FOLATE ELISA(ERBALISA FOLATE)-THE FOLATE ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF FOLATE CONCENTRATION IN HUMAN SERUM.,

		HGH(ERBALISA HUMAN GROWTH HORMONE (HGH))-THE HGH ELISA KIT IS USED FOR THE QUANTITATIVE MEASUREMENT OF HGH IN HUMAN SERUM OR PLASMA.,INSULIN ELISA(ERBALISA INSULIN)-THE INSULIN ELISA KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF INSULIN IN HUMAN SERUM OR PLASMA,IGE ELISA (ERBALISA IGE)-THE IGE ELISA KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF IGE IN HUMAN SERUM.,DHEA-S ELISA(ERBALISA DHEA-S)-THE DHEA-S ELISA KIT IS USED FOR THE QUANTITATIVE MEASUREMENT OF DHEA-S IN HUMAN SERUM AND PLASMA.,HCG ELISA(ERBALISA HCG)-THE HCG ELISA KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HCG IN HUMAN SERUM OR PLASMA.,TRIIODOTHYRONINE, FREE (FT3) ELISA (ERBALISA TRIIODOTHYRONINE FREE (FT3))-THE FT3 ELISA KIT IS USED FOR THE QUANTITATIVE MEASUREMENT OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM OR PLASMA., TESTOSTERONE FREE ELISA(ERBALISA FREE TESTOSTERONE)-THE FREE TESTOSTERONE ELISA KIT IS INTENDED FOR THE MEASUREMENT OF FREE TESTOSTERONE IN SERUM OR PLASMA.
354	IMP/IVD/2019/000381	1.License Holder Name: PERKINELMER INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SERO MATERNAL HEALTH CONTROL – EARLY L-1, L-2, L-3(SERO MATERNAL HEALTH CONTROL – EARLY L-1, L-2, L-3)-SERO MATERNAL HEALTH CONTROL – EARLY IS A LYOPHILIZED HUMAN CONTROL SERUM MANUFACTURED UNDER STRICT QUALITY CONTROL STANDARDS. IT IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR PRECISION AND TRUENESS OF LABORATORY MEASUREMENT PROCEDURES FOR THE ANALYTES DESCRIBED IN THIS PACKAGE INSERT IN QUANTITATIVE MANUAL, SEMI-AUTOMATED AND AUTOMATED IMMUNOASSAYS. THREE LEVELS OF CONTROLS ARE AVAILABLE TO ALLOW PERFORMANCE MONITORING WITHIN THE CLINICAL RANGE.

355	IMP/IVD/2019/000382	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HBA1C ADVANCED (HBA1C ADVANCED)-THE HBA1C (HEMOGLOBIN A1C) ADVANCED ASSAY ON THE BECKMAN COULTER DXC 700 AU CHEMISTRY ANALYZER, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF MMOL/MOL HBA1C (IFCC) OR %HBA1C (DCCT/NGSP) CONCENTRATION IN HUMAN VENOUS WHOLE BLOOD. THE DETERMINATION OF HBA1C IS USED AS AN AID IN THE DIAGNOSIS OF DIABETES MELLITUS, FOR THE MONITORING OF LONG-TERM BLOOD GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS AND IDENTIFYING PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES MELLITUS. FOR IN VITRO DIAGNOSTIC USE ONLY.,HBA1C(HBA1C)-THE HBA1C (HEMOGLOBIN A1C) REAGENT, WHEN USED IN CONJUNCTION WITH BECKMAN COULTER SYSTEMS, HBA1C CALIBRATORS, AND SYNCHRON AND AU HEMOLYZING REAGENT, IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C CONCENTRATION IN HUMAN WHOLE BLOOD. THE ABSOLUTE HBA1C AND TOTAL HEMOGLOBIN (THB) VALUES GENERATED AS PART OF THE HBA1C ASSAY ARE INTENDED FOR USE IN THE CALCULATION OF THE HBA1C/TOTAL HEMOGLOBIN RATIO, AND MUST NOT BE USED INDIVIDUALLY FOR DIAGNOSTIC PURPOSES.

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356	IMP/IVD/2019/000383	1.License Holder Name: LAB X 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STA® - STACLOT® HEPARIN 1-CLOTTING ASSAY OF HEPARINS (UFH AND LMWH) BY ANTI-XA METHOD,PTT AUTOMATE 5-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),NÉOPLASTINE® CI PLUS 2, 5, 10-DETERMINATION OF PROTHROMBIN TIME (PT),STA® - DESORB U-DESORBING SOLUTION FOR USE WITH ANALYZERS OF THE STA® LINE,STA®- HBPM/LMWH CONTROL-CONTROL PLASMAS FOR ASSAYS OF LOW MOLECULAR WEIGHT HEPARINS (LMWH) USING ANTI-XA METHOD,STA® - HEPANORM® H-CALIBRATION PLASMA FOR ASSAY OF UNFRACTIONATED HEPARIN (UFH) USING ANTI-XA METHOD,STA® - DEFICIENT XI-DEFICIENT PLASMA FOR FACTOR XI ASSAY,CK PREST® 2, 5-DETERMINATION OF THE KAOLIN-ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),FDP PLASMA-QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF FDP IN PLASMA BY LATEX AGGLUTINATION,PTT-LA-LUPUS ANTICOAGULANT-SENSITIVE APTT REAGENT,STA® - CEPHASCREEN 4-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - LIATEST® FREE PROTEIN S 6-IMMUNO-TURBIDIMETRIC ASSAY OF FREE PROTEIN S,SYSTEM CONTROL N+ P-CONTROL PLASMAS FOR ASSAYS OF COAGULATION PARAMETERS,STA® - LIATEST® D-DI PLUS-IMMUNO-TURBIDIMETRIC ASSAY OF D-DIMER,ASSERACHROM® HPIA - IG G-DETECTION OF ANTI-HEPARIN-PF4 ANTIBODIES OF IGG CLASS BY ENZYME IMMUNOASSAY,ASSERACHROM® HPIA-DETECTION OF ANTI-HEPARIN-PF4 ANTIBODIES BY ENZYME IMMUNOASSAY,STA® - LIQUID FIB-QUANTITATIVE DETERMINATION OF FIBRINOGEN,STA® - LIATEST® VWF : AG-IMMUNO-TURBIDIMETRIC ASSAY OF VON WILLEBRAND FACTOR,STA® - MULTI HEP CALIBRATOR-CALIBRATION PLASMAS FOR ASSAYS OF HEPARINS (UFH AND LMWH) USING ANTI-XA METHOD,STA®- LIQUID ANTI-XA4, 8-COLORIMETRIC ASSAY OF HEPARINS (UFH AND LMWH), FONDAPARINUX AND RIVAROXABAN,STA® - LIATEST® FM-IMMUNO-TURBIDIMETRIC ASSAY OF FIBRIN MONOMERS,STA® - LIATEST® CONTROL N+P-CONTROL PLASMAS FOR IMMUNO-TURBIDIMETRIC ASSAYS,STA®- LIATEST® FREE PROTEIN S 2-IMMUNO-TURBIDIMETRIC ASSAY OF FREE PROTEIN S,COAG CONTROL N+ P-CONTROL PLASMAS FOR COAGULATION TESTS,UNICALIBRATOR-CALIBRATION PLASMA FOR FUNCTIONAL ASSAYS OF COAGULATION PARAMETERS,STA® - DEFICIENT V-SUBSTRATE PLASMA FOR FACTOR V ASSAY,STA® - DEFICIENT IX-IMMUNO-DEPLETED PLASMA FOR FACTOR IX ASSAY,STA® - QUALITY HNF/UFH-CONTROL PLASMAS FOR ASSAYS OF UNFRACTIONATED HEPARINS (UFH) USING ANTI-XA METHOD,STA® - PTT A 5-DETERMINATION OF ACTIVATED

	PARTIAL THROMBOPLASTIN TIME (APTT),STA® - ROUTINE QC 2 ML-CONTROL PLASMAS FOR COAGULATION TESTS,STA® - THROMBIN 2, 10-DETERMINATION OF THROMBIN TIME,POOL NORM-NORMAL HUMAN PLASMA POOL,STA® - STACHROM® PROTEIN C-COLORIMETRIC ASSAY OF PROTEIN C,STA® - CEPHASCREEN 10-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - OWREN - KOLLER-OWREN-KOLLER BUFFER SOLUTION FOR COAGULATION TESTS,STA® - UNICALIBRATOR-CALIBRATION PLASMA FOR FUNCTIONAL ASSAYS OF COAGULATION PARAMETERS, STA® - VWF:AG CALIBRATOR-CALIBRATION PLASMA FOR THE IMMUNO-TURBIDIMETRIC ASSAY OF VWF:AG,D-DI TEST®-LATEX AGGLUTINATION SLIDE TEST FOR THE QUALITATIVE AND SEMI - QUANTITATIVE DETERMINATION OF D-DIMER,STA® - SYSTEM CONTROL N+P-CONTROL PLASMAS FOR ASSAYS OF COAGULATION PARAMETERS,STA®- QUALITY HBPM/LMWH-CONTROL PLASMA FOR ASSAYS OF LOW MOLECULAR WEIGHT HEPARINS (LMWH) USING STA® - ROTACHROM® HEPARIN,STA® - STACLOT® PROTEIN S-CLOTTING ASSAY OF PROTEIN S,STA® - DEFICIENT VII-IMMUNO-DEPLETED PLASMA FOR FACTOR VII ASSAY,STA® - FM CALIBRATOR-CALIBRATION PLASMAS FOR THE IMMUNO-TURBIDIMETRIC ASSAY OF FIBRIN MONOMERS,STA® - STACHROM® ATIII 3, 6-COLORIMETRIC ASSAY OF ANTITHROMBIN,STACLOT® LA-DETECTION OF LUPUS ANTICOAGULANTS,STA® - CONTROL LA 1+2-CONTROL PLASMAS FOR LUPUS ANTICOAGULANT (LA) TESTS,STA® - FM CONTROL-CONTROL PLASMAS FOR THE IMMUNO-TURBIDIMETRIC ASSAY OF FIBRIN MONOMERS,STA® - STACLOT® PROTEIN C 1-CLOTTING ASSAY OF PROTEIN C,STA® - DEFICIENT II-SUBSTRATE PLASMA FOR FACTOR LL ASSAY,STA® - DEFICIENT VIII-IMMUNO-DEPLETED PLASMA FOR FACTOR VIII ASSAY,STA® - DEFICIENT X-IMMUNO-DEPLETED PLASMA FOR FACTOR X ASSAY,STA® - CK PREST 5-DETERMINATION OF THE KAOLIN-ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - STACLOT® APC-R-ASSESSMENT OF ACTIVATED PROTEIN C RESISTANCE,STA® - IMMUNODEF VIII-IMMUNO-DEPLETED PLASMA FOR FACTOR VIII ASSAY,STA® - STACLOT®DRVV SCREEN 2, 5-DETECTION OF LUPUS ANTICOAGULANTS,STA® - STACLOT®DRVV CONFIRM-DETECTION OF LUPUS ANTICOAGULANTS,STA® - NEOPLASTINE® R15-DETERMINATION OF PROTHROMBIN TIME (PT),STA® - IMMUNODEF IX-IMMUNO-DEPLETED PLASMA FOR FACTOR IX ASSAY,STA® - COAG CONTROL N+P-CONTROL PLASMAS FOR COAGULATION TESTS,STA® - CACL2 0.025 M-CALCIUM CHLORIDE SOLUTION,STA® - HEPANORM® HBPM/LMWH-CALIBRATION PLASMAS FOR ASSAYS OF LOW MOLECULAR WEIGHT HEPARINS (LMWH) USING ANTI-XA METHOD,STA® - IMMUNODEF XII-IMMUNO-DEPLETED PLASMA FOR

		FACTOR XII ASSAY,STA® - D-DI CONTROL-QUALITY CONTROL FOR IMMUNO-TURBIDIMETRIC ASSAY OF D-DIMER,STA® - NEOPTIMAL® 5, 10, 20-DETERMINATION OF PROTHROMBIN TIME (PT),STA® - HEPARIN CONTROL-CONTROL PLASMAS FOR ASSAYS OF UNFRACTIONATED HEPARINS (UFH) USING ANTI-XA METHOD
357	IMP/IVD/2019/000384	1.License Holder Name: SYSMEX INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LA CONTROL HIGH(LA CONTROL HIGH)-LA CONTROL HIGH IS A HIGH POSITIVE CONTROL PLASMA FOR USE IN LUPUS ANTICOAGULATION CLOTTING TEST ASSAYS.,LA CONTROL LOW(LA CONTROL LOW)-LA CONTROL LOW IS A LOW POSITIVE CONTROL PLASMA FOR USE IN LUPUS ANTICOAGULANT CLOTTING TEST ASSAYS.,LA 2 CONFIRMATION REAGENT(LA 2 CONFIRMATION REAGENT)-LA 2 CONFIRMATION REAGENT PHOSPHOLIPID-RICH DRVV REAGENT FOR THE SPECIFIC CORRECTION OF LUPUS ANTICOAGULANTS.,LA 1 SCREENING REAGENT(LA 1 SCREENING REAGENT)-LA1 SCREENING REAGENT SIMPLIFIED DRVV REAGENT TO SCREEN FOR THE PRESENCE OF LUPUS ANTICOAGULANTS.

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358	IMP/IVD/2019/000385	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PHENCYCLIDINE (PHENCYCLIDINE)-THE MULTIGENT PHENCYCLIDINE ASSAY IS INTENDED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF PHENCYCLIDINE IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,CANNABINOIDS 40 CONTROL (CANNABINOIDS 40 CONTROL)-THE MULTIGENT CANNABINOIDS CALIBRATORS AND CONTROLS ARE INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF THE MULTIGENT CANNABINOIDS ASSAY, WHICH DETECTS CANNABINOIDS (THC) IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,TOBRAMYCIN CALIBRATORS(TOBRAMYCIN CALIBRATORS)-THE MULTIGENT TOBRAMYCIN CALIBRATORS ARE INTENDED FOR USE IN THE CALIBRATION OF THE MULTIGENT TOBRAMYCIN ASSAY ON THE ARCHITECT C SYSTEMS.,ALINITY C ECSTASY QUAL CALIBRATOR KIT (ALINITY C ECSTASY QUAL CALIBRATOR KIT)-THE ALINITY C ECSTASY QUAL CALIBRATOR IS INTENDED FOR THE CALIBRATION OF THE ALINITY C ECSTASY ASSAY, WHICH DETECTS 3,4-METHYLENEDIOXYMETHAMPHETAMINE (MDMA) IN HUMAN URINE ON THE ALINITY C ANALYZER.,ECSTASY 500 CALIBRATORS(ECSTASY 500 CALIBRATORS)-THE MULTIGENT ECSTASY CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE MULTIGENT ECSTASY ASSAY, WHICH DETECTS 3,4-METHYLENEDIOXYMETHAMPHETAMINE (MDMA) IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,ALINITY C CANNABINOIDS QUAL CALIBRATOR KIT(ALINITY C CANNABINOIDS QUAL CALIBRATOR KIT)-THE ALINITY C CANNABINOIDS QUAL CALIBRATOR IS INTENDED FOR THE CALIBRATION OF THE ALINITY C CANNABINOIDS ASSAY, WHICH DETECTS CANNABINOIDS (THC) IN HUMAN URINE ON THE ALINITY C ANALYZER.,DOA MC II CONTROL SET(DOA MC II CONTROL SET)-THE MULTIGENT DOA MC II CONTROL SET IS INTENDED FOR THE QUALITY CONTROL OF THE MULTIGENT COCAINE AND ECSTASY ASSAYS ON THE ARCHITECT C SYSTEMS., ALINITY C OPIATES REAGENT KIT(ALINITY C OPIATES REAGENT KIT)-THE ALINITY C OPIATES ASSAY IS USED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF OPIATES IN HUMAN URINE ON THE ALINITY C ANALYZER.,ECSTASY(ECSTASY)-THE MULTIGENT ECSTASY ASSAY IS INTENDED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF ECSTASY IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,ALINITY C CARBAMAZEPINE REAGENT KIT(ALINITY C CARBAMAZEPINE REAGENT KIT)-THE ALINITY C CARBAMAZEPINE ASSAY IS USED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CARBAMAZEPINE IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ECSTASY 750

	CALIBRATORS(ECSTASY 750 CALIBRATORS)-THE MULTIGENT ECSTASY CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE MULTIGENT ECSTASY ASSAY, WHICH DETECTS 3,4-METHYLENEDIOXYMETHAMPHETAMINE (MDMA) IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,ALINITY C CANNABINOIDS SEMIQUANT 100 CALIBRATOR KIT(ALINITY C CANNABINOIDS SEMIQUANT 100 CALIBRATOR KIT)-THE ALINITY C CANNABINOIDS SEMIQUANT 100 CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE ALINITY C CANNABINOIDS ASSAY, WHICH DETECTS CANNABINOIDS (THC) IN HUMAN URINE ON THE ALINITY C ANALYZER.,ECSTASY 250 CALIBRATORS(ECSTASY 250 CALIBRATORS)-THE MULTIGENT ECSTASY CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE MULTIGENT ECSTASY ASSAY, WHICH DETECTS 3,4-METHYLENEDIOXYMETHAMPHETAMINE (MDMA) IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,ALINITY C OPIATES SEMIQUANT CALIBRATOR KIT(ALINITY C OPIATES SEMIQUANT CALIBRATOR KIT)-THE ALINITY C OPIATES SEMIQUANT CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE ALINITY C OPIATES ASSAY, WHICH DETECTS OPIATES IN HUMAN URINE ON THE ALINITY C ANALYZER., ECSTASY 1000 CALIBRATORS(ECSTASY 1000 CALIBRATORS)-THE MULTIGENT ECSTASY CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE MULTIGENT ECSTASY ASSAY, WHICH DETECTS 3,4-METHYLENEDIOXYMETHAMPHETAMINE (MDMA) IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,ALINITY C OPIATES QUAL CALIBRATOR KIT(ALINITY C OPIATES QUAL CALIBRATOR KIT)-THE ALINITY C OPIATES QUAL CALIBRATOR IS INTENDED FOR THE CALIBRATION OF THE ALINITY C OPIATES ASSAY, WHICH DETECTS OPIATES IN HUMAN URINE ON THE ALINITY C ANALYZER., PROPOXYPHENE(PROPOXYPHENE)-THE MULTIGENT PROPOXYPHENE ASSAY IS INTENDED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF PROPOXYPHENE IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,ALINITY C ECSTASY REAGENT KIT(ALINITY C ECSTASY REAGENT KIT)-THE ALINITY C ECSTASY ASSAY IS USED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF ECSTASY IN HUMAN URINE ON THE ALINITY C ANALYZER.,TRICYCLIC ANTIDEPRESSANTS(TRICYCLIC ANTIDEPRESSANTS)-THE MULTIGENT TRICYCLIC ANTIDEPRESSANTS ASSAY (TCA) IS INTENDED FOR THE SEMIQUANTITATIVE DETERMINATION OF TRICYCLIC ANTIDEPRESSANTS IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY C TRICYCLIC ANTIDEPRESSANTS REAGENT KIT(ALINITY C TRICYCLIC ANTIDEPRESSANTS REAGENT KIT)-THE ALINITY C TRICYCLIC ANTIDEPRESSANTS ASSAY IS USED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF TRICYCLIC

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	ANTIDEPRESSANTS IN HUMAN SERUM OR PLASMA USING 300 NG/ML AS A CUTOFF CALIBRATOR ON THE ALINITY C ANALYZER., TOBRAMYCIN(TOBRAMYCIN)-THE MULTIGENT TOBRAMYCIN ASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOBRAMYCIN IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY C COCAINE REAGENT KIT(ALINITY C COCAINE REAGENT KIT)-THE ALINITY C COCAINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR THE QUALITATIVE AND/OR SEMI-QUANTITATIVE DETERMINATION OF BENZOYLECGONINE (COCAINE METABOLITE) IN HUMAN URINE AT A CUTOFF CONCENTRATION OF EITHER 150 NG/ML OR 300 NG/ML ON THE ALINITY C ANALYZER.,SERUM BENZODIAZEPINES(SERUM BENZODIAZEPINES)-THE MULTIGENT SERUM BENZODIAZEPINES ASSAY IS INTENDED FOR THE SEMIQUANTITATIVE DETERMINATION OF BENZODIAZEPINES IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY C CANNABINOIDS CONTROL 2 KIT (ALINITY C CANNABINOIDS CONTROL 2 KIT)-THE ALINITY C CANNABINOIDS CONTROL 2 CONTROLS ARE INTENDED FOR THE QUALITY CONTROL OF THE ALINITY C CANNABINOIDS ASSAY, WHICH DETECTS CANNABINOIDS (THC) IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C TOX QUAL CALIBRATORS(ALINITY C TOX QUAL CALIBRATORS)-FOR THE CALIBRATION OF THE ALINITY C SERUM BENZODIAZEPINES ASSAY AND THE ALINITY C TRICYCLIC ANTIDEPRESSANTS ASSAY ON THE ALINITY C ANALYZER.,ALINITY C ECSTASY SEMIQUANT CALIBRATOR KIT(ALINITY C ECSTASY SEMIQUANT CALIBRATOR KIT)-THE ALINITY C ECSTASY SEMIQUANT CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE ALINITY C ECSTASY ASSAY, WHICH DETECTS 3,4-METHYLENEDIOXYMETHAMPHETAMINE (MDMA) IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C DOA MC I CONTROLS(ALINITY C DOA MC I CONTROLS)-THE ALINITY C DOA MC I CONTROLS ARE USED FOR THE QUALITY CONTROL OF DRUG OF ABUSE (DOA) ASSAYS FOR AMPHETAMINE/METHAMPHETAMINE, BARBITURATES, COCAINE METABOLITES, METHADONE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE IN HUMAN URINE ON THE ALINITY C ANALYZER., ALINITY C TDM MULTICONSTITUENT CALIBRATOR KIT(ALINITY C TDM MULTICONSTITUENT CALIBRATOR KIT)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF THE ALINITY C AMIKACIN, CARBAMAZEPINE, DIGOXIN, GENTAMICIN, PHENOBARBITAL, PHENYTOIN, THEOPHYLLINE, VALPROIC ACID, AND VANCOMYCIN HUMAN SERUM OR PLASMA ASSAYS ON THE ALINITY C ANALYZER., ALINITY C BENZODIAZEPINES QUAL CALIBRATOR KIT(ALINITY C BENZODIAZEPINES QUAL CALIBRATOR KIT)-THE ALINITY C BENZODIAZEPINES SEMIQUANT CALIBRATORS ARE INTENDED FOR

	THE CALIBRATION OF THE ALINITY C BENZODIAZEPINES ASSAY WHICH DETECTS BENZODIAZEPINES IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C CANNABINOIDS CONTROL 1 KIT (ALINITY C CANNABINOIDS CONTROL 1 KIT)-THE ALINITY C CANNABINOIDS CONTROL 1 CONTROLS ARE INTENDED FOR THE QUALITY CONTROL OF THE ALINITY C CANNABINOIDS ASSAY, WHICH DETECTS CANNABINOIDS (THC) IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C TOX SEMIQUANT CALIBRATORS(ALINITY C TOX SEMIQUANT CALIBRATORS)-FOR THE CALIBRATION OF THE ALINITY C SERUM BENZODIAZEPINES ASSAY AND THE ALINITY C TRICYCLIC ANTIDEPRESSANTS ASSAY ON THE ALINITY C ANALYZER., ALINITY C CANNABINOIDS REAGENT KIT(ALINITY C CANNABINOIDS REAGENT KIT)-THE ALINITY C CANNABINOIDS ASSAY IS USED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF CANNABINOIDS (THC) IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C DOA MC NEGATIVE CALIBRATOR KIT(ALINITY C DOA MC NEGATIVE CALIBRATOR KIT)-THE ALINITY C DOA MC NEGATIVE CALIBRATOR IS USED FOR THE CALIBRATION OF DRUG OF ABUSE (DOA) ASSAYS FOR AMPHETAMINE/METHAMPHETAMINE, BARBITURATES, CANNABINOIDS, COCAINE METABOLITES, ECSTASY, METHADONE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C CANNABINOIDS SEMIQUANT 200 CALIBRATOR KIT(ALINITY C CANNABINOIDS SEMIQUANT 200 CALIBRATOR KIT)-THE ALINITY C CANNABINOIDS SEMIQUANT 200 CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE ALINITY C CANNABINOIDS ASSAY, WHICH DETECTS CANNABINOIDS (THC) IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C TOX CONTROLS(ALINITY C TOX CONTROLS)-FOR THE QUALITY CONTROL OF THE ALINITY C SERUM BENZODIAZEPINES ASSAY AND ALINITY C TRICYCLIC ANTIDEPRESSANTS ASSAY ON THE ALINITY C ANALYZER., CANNABINOIDS 200 CALIBRATOR(CANNABINOIDS 200 CALIBRATOR) -THE MULTIGENT CANNABINOIDS CALIBRATORS AND CONTROLS ARE INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF THE MULTIGENT CANNABINOIDS ASSAY, WHICH DETECTS CANNABINOIDS (THC) IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,ALINITY C BENZODIAZEPINES REAGENT KIT(ALINITY C BENZODIAZEPINES REAGENT KIT)-THE ALINITY C BENZODIAZEPINES ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR THE QUALITATIVE AND/OR SEMIQUANTITATIVE DETERMINATION OF THE PRESENCE OF BENZODIAZEPINES AND THEIR METABOLITES IN HUMAN URINE AT A CUTOFF CONCENTRATION OF 200 NG/ML (0.700 MOL/L) ON THE ALINITY C ANALYZER.,COCAINE REAGENT (COCAINE REAGENT)-THE COCAINE ASSAY IS INTENDED FOR THE

	QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF BENZOYLECGONINE (COCAINE METABOLITE) IN HUMAN URINE ON THE ARCHITECT CSYSTEMS.,ALINITY C SERUM BENZODIAZEPINES REAGENT KIT(ALINITY C SERUM BENZODIAZEPINES REAGENT KIT)-THE ALINITY C SERUM BENZODIAZEPINES ASSAY IS USED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF BENZODIAZEPINES IN HUMAN SERUM OR PLASMA WITH A 50 NG/ML CUTOFF ON THE ALINITY C ANALYZER.,ETHANOL 100 CAL(ETHANOL 100 CAL)-INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF THE MULTIGENT ETHANOL ASSAY, WHICH IS USED FOR THE QUANTITATIVE DETERMINATION OF ETHANOL (ETHYL ALCOHOL OR ALCOHOL) IN HUMAN URINE, SERUM, OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY C BENZODIAZEPINES SEMIQUANT CALIBRATOR KIT(ALINITY C BENZODIAZEPINES SEMIQUANT CALIBRATOR KIT)-THE ALINITY C BENZODIAZEPINES QUAL CALIBRATOR IS INTENDED FOR THE CALIBRATION OF THE ALINITY C BENZODIAZEPINES ASSAY WHICH DETECTS BENZODIAZEPINES IN HUMAN URINE ON THE ALINITY C ANALYZER.,BARBITURATES REAGENT(BARBITURATES REAGENT)-THE MULTIGENT BARBITURATES ASSAY IS INTENDED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF BARBITURATES IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,METHADONE REAGENT(METHADONE REAGENT)-THE MULTIGENT METHADONE ASSAY IS INTENDED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF METHADONE IN HUMAN URINE ON THE ARCHITECT C SYSTEMS. ,BENZODIAZEPINES REAGENT (BENZODIAZEPINES REAGENT)-THE MULTIGENT BENZODIAZEPINES ASSAY IS INTENDED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF BENZODIAZEPINES IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,AMIKACIN(AMIKACIN)-THE MULTIGENT AMIKACIN ASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF AMIKACIN IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ETHANOL 300 CONTROL(ETHANOL 300 CONTROL)-INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF THE MULTIGENT ETHANOL ASSAY, WHICH IS USED FOR THE QUANTITATIVE DETERMINATION OF ETHANOL (ETHYL ALCOHOL OR ALCOHOL) IN HUMAN URINE, SERUM, OR PLASMA ON THE ARCHITECT C SYSTEMS.,TOX CALIBRATOR 2(TOX CALIBRATOR 2)-FOR THE CALIBRATION OF THE MULTIGENT SERUM BENZODIAZEPINES AND TRICYCLIC ANTIDEPRESSANTS (TCA) ASSAYS.,ETHANOL NEG CAL(ETHANOL NEG CAL)-NTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF THE MULTIGENT ETHANOL ASSAY, WHICH IS USED FOR THE QUANTITATIVE DETERMINATION OF ETHANOL (ETHYL ALCOHOL OR ALCOHOL) IN HUMAN URINE, SERUM, OR PLASMA ON THE ARCHITECT C SYSTEMS.,DOA MC I CAL 4(DOA MC

	I CAL 4)-THE MULTIGENT DOA MC I CALIBRATORS AND CONTROLS ARE INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF DRUG OF ABUSE ASSAYS FOR AMPHETAMINE/ METHAMPHETAMINE, BARBITURATES, BENZODIAZEPINES, COCAINE METABOLITES, METHADONE, PHENCYCLIDINE, PROPOXYPHENE, AND OPIATES IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,OPIATES 150 CAL (OPIATES 150 CAL)-THE MULTIGENT OPIATES LOW CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE MULTIGENT OPIATES ASSAY, WHICH DETECTS OPIATES IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,DOA MC NEG CAL(DOA MC NEG CAL)-THE MULTIGENT DOA MC NEG CAL IS INTENDED FOR THE CALIBRATION OF DRUG OF ABUSE ASSAYS FOR AMPHETAMINE/METHAMPHETAMINE, BARBITURATES, BENZODIAZEPINES, CANNABINOIDS, COCAINE METABOLITES, ECSTASY, METHADONE, PHENCYCLIDINE, PROPOXYPHENE, AND OPIATES IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,DOA MC I CAL 2(DOA MC I CAL 2)-THE MULTIGENT DOA MC I CALIBRATORS AND CONTROLS ARE INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF DRUG OF ABUSE ASSAYS FOR AMPHETAMINE/ METHAMPHETAMINE, BARBITURATES, BENZODIAZEPINES, COCAINE METABOLITES, METHADONE, PHENCYCLIDINE, PROPOXYPHENE, AND OPIATES IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,OPIATES 300 CAL(OPIATES 300 CAL) -THE MULTIGENT OPIATES LOW CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE MULTIGENT OPIATES ASSAY, WHICH DETECTS OPIATES IN HUMAN URINE ON THE ARCHITECT C SYSTEMS., TOX NEGATIVE CALIBRATOR(TOX NEGATIVE CALIBRATOR)-FOR THE CALIBRATION OF THE MULTIGENT SERUM BENZODIAZEPINES AND TRICYCLIC ANTIDEPRESSANTS (TCA) ASSAYS.,TOX CALIBRATOR 3 (TOX CALIBRATOR 3)-FOR THE CALIBRATION OF THE MULTIGENT SERUM BENZODIAZEPINES AND TRICYCLIC ANTIDEPRESSANTS (TCA) ASSAYS.,CANNABINOIDS 125 CONTROL(CANNABINOIDS 125 CONTROL)-THE MULTIGENT CANNABINOIDS CALIBRATORS AND CONTROLS ARE INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF THE MULTIGENT CANNABINOIDS ASSAY, WHICH DETECTS CANNABINOIDS (THC) IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,CANNABINOIDS 75 CONTROL(CANNABINOIDS 75 CONTROL)-THE MULTIGENT CANNABINOIDS CALIBRATORS AND CONTROLS ARE INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF THE MULTIGENT CANNABINOIDS ASSAY, WHICH DETECTS CANNABINOIDS (THC) IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,CANNABINOIDS 60 CONTROL(CANNABINOIDS 60 CONTROL)-THE MULTIGENT CANNABINOIDS CALIBRATORS AND CONTROLS ARE INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF THE MULTIGENT CANNABINOIDS ASSAY, WHICH

	DETECTS CANNABINOIDS (THC) IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,CANNABINOIDS 20 CALIBRATOR(CANNABINOIDS 20 CALIBRATOR)-THE MULTIGENT CANNABINOIDS CALIBRATORS AND CONTROLS ARE INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF THE MULTIGENT CANNABINOIDS ASSAY, WHICH DETECTS CANNABINOIDS (THC) IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,CANNABINOIDS 100 CALIBRATOR(CANNABINOIDS 100 CALIBRATOR)-THE MULTIGENT CANNABINOIDS CALIBRATORS AND CONTROLS ARE INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF THE MULTIGENT CANNABINOIDS ASSAY, WHICH DETECTS CANNABINOIDS (THC) IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,CANNABINOIDS 50 CALIBRATORS(CANNABINOIDS 50 CALIBRATORS)-THE MULTIGENT CANNABINOIDS CALIBRATORS AND CONTROLS ARE INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF THE MULTIGENT CANNABINOIDS ASSAY, WHICH DETECTS CANNABINOIDS (THC) IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,ALINITY C DOA MC QUAL CALIBRATOR 2 KIT(ALINITY C DOA MC QUAL CALIBRATOR 2 KIT)-THE ALINITY C DOA MC QUAL CALIBRATOR 2 IS USED FOR THE CALIBRATION OF DRUG OF ABUSE (DOA) ASSAYS FOR AMPHETAMINE/METHAMPHETAMINE, BARBITURATES, COCAINE METABOLITES, METHADONE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C DOA MC QUAL LOW CALIBRATOR 1 KIT(ALINITY C DOA MC QUAL LOW CALIBRATOR 1 KIT)-THE ALINITY C DOA MC QUAL LOW CALIBRATOR 1 IS USED FOR THE CALIBRATION OF DRUG OF ABUSE (DOA) ASSAYS FOR AMPHETAMINE/ METHAMPHETAMINE AND COCAINE METABOLITES IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C DOA MC NEGATIVE CALIBRATOR KIT(ALINITY C DOA MC NEGATIVE CALIBRATOR KIT)-THE ALINITY C DOA MC NEGATIVE CALIBRATOR IS USED FOR THE CALIBRATION OF DRUG OF ABUSE (DOA) ASSAYS FOR AMPHETAMINE/METHAMPHETAMINE, BARBITURATES, BENZODIAZEPINES, CANNABINOIDS, COCAINE METABOLITES, ECSTASY, METHADONE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE IN HUMAN URINE ON THE ALINITY C ANALYZER., ALINITY C DOA MC II CONTROLS(ALINITY C DOA MC II CONTROLS)-THE ALINITY C DOA MC II CONTROLS ARE USED FOR THE QUALITY CONTROL OF DRUG OF ABUSE (DOA) ASSAYS FOR COCAINE METABOLITES AND ECSTASY IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C AMPHETAMINE/METHAMPHETAMINE REAGENT KIT(ALINITY C AMPHETAMINE/METHAMPHETAMINE REAGENT KIT)-THE ALINITY C AMPHETAMINE/METHAMPHETAMINE ASSAY IS USED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF AMPHETAMINE/METHAMPHETAMINE IN HUMAN

	URINE ON THE ALINITY C ANALYZER.,ALINITY C METHADONE REAGENT KIT(ALINITY C METHADONE REAGENT KIT)-THE ALINITY C METHADONE ASSAY IS USED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF METHADONE IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C DOA MC I CONTROLS (ALINITY C DOA MC I CONTROLS)-THE ALINITY C DOA MC I CONTROLS ARE USED FOR THE QUALITY CONTROL OF DRUG OF ABUSE (DOA) ASSAYS FOR AMPHETAMINE/METHAMPHETAMINE, BARBITURATES, BENZODIAZEPINES, COCAINE METABOLITES, METHADONE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C PROPOXYPHENE REAGENT KIT (ALINITY C PROPOXYPHENE REAGENT KIT)-THE ALINITY C PROPOXYPHENE ASSAY IS USED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF PROPOXYPHENE IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C PHENCYCLIDINE REAGENT KIT(ALINITY C PHENCYCLIDINE REAGENT KIT)-THE ALINITY C PHENCYCLIDINE ASSAY IS USED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF PHENCYCLIDINE IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C BARBITURATES REAGENT KIT(ALINITY C BARBITURATES REAGENT KIT)-THE ALINITY C BARBITURATES ASSAY IS USED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF BARBITURATES IN HUMAN URINE ON THE ALINITY C ANALYZER.,ALINITY C DOA MC SEMIQUANT CALIBRATOR KIT(ALINITY C DOA MC SEMIQUANT CALIBRATOR KIT)-THE ALINITY C DOA MC SEMIQUANT CALIBRATORS ARE USED FOR THE CALIBRATION OF DRUG OF ABUSE (DOA) ASSAYS FOR AMPHETAMINE/ METHAMPHETAMINE, BARBITURATES, COCAINE METABOLITES, METHADONE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE IN HUMAN URINE ON THE ALINITY C ANALYZER., ALINITY C DOA MC III CONTROLS(ALINITY C DOA MC III CONTROLS)-THE ALINITY C DOA MC III CONTROLS ARE USED FOR THE QUALITY CONTROL OF DRUG OF ABUSE (DOA) ASSAYS FOR AMPHETAMINE/METHAMPHETAMINE AND OPIATES IN HUMAN URINE ON THE ALINITY C ANALYZER.,CANNABINOIDS(CANNABINOIDS)-THE MULTIGENT CANNABINOIDS ASSAY IS INTENDED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF CANNABINOIDS (THC) IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,ETHANOL 50 CONTROL(ETHANOL 50 CONTROL)-INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF THE MULTIGENT ETHANOL ASSAY, WHICH IS USED FOR THE QUANTITATIVE DETERMINATION OF ETHANOL (ETHYL ALCOHOL OR ALCOHOL) IN HUMAN URINE, SERUM, OR PLASMA ON THE ARCHITECT C SYSTEMS.,OPIATES REAGENT(OPIATES REAGENT)-THE MULTIGENT OPIATES ASSAY IS INTENDED FOR THE QUALITATIVE AND

	SEMIQUANTITATIVE DETERMINATION OF OPIATES IN HUMAN URINE ON THE ARCHITECT C SYSTEMS. ,ETHANOL REAGENT(ETHANOL REAGENT)-THE MULTIGENT ETHANOL ASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ETHANOL IN HUMAN URINE, SERUM, OR PLASMA ON THE ARCHITECT C SYSTEMS.,AMPHETAMINE/ METHAMPHETAMINE REAGENT(AMPHETAMINE/ METHAMPHETAMINE REAGENT)-THE MULTIGENT AMPHETAMINE/METHAMPHETAMINE ASSAY IS INTENDED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF AMPHETAMINE/ METHAMPHETAMINE IN HUMAN URINE ON THE ARCHITECT C SYSTEMS. ,TOX CALIBRATOR 1(TOX CALIBRATOR 1)-FOR THE CALIBRATION OF THE MULTIGENT SERUM BENZODIAZEPINES AND TRICYCLIC ANTIDEPRESSANTS (TCA) ASSAYS.,TDM MULTICONSTITUENT CALIBRATOR(TDM MULTICONSTITUENT CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF THE AMIKACIN, CARBAMAZEPINE, DIGOXIN, GENTAMICIN, PHENOBARBITAL, PHENYTOIN, QUINIDINE, THEOPHYLLINE, VALPROIC ACID, AND VANCOMYCIN HUMAN SERUM OR PLASMA ASSAYS ON THE ARCHITECT C SYSTEMS.,DOA MC I CAL 1 (DOA MC I CAL 1)-THE MULTIGENT DOA MC I CALIBRATORS AND CONTROLS ARE INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF DRUG OF ABUSE ASSAYS FOR AMPHETAMINE/ METHAMPHETAMINE, BARBITURATES, BENZODIAZEPINES, COCAINE METABOLITES, METHADONE, PHENCYCLIDINE, PROPOXYPHENE, AND OPIATES IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,DOA MC I CONTROL SET(DOA MC I CONTROL SET)-THE MULTIGENT DOA MC I CALIBRATORS AND CONTROLS ARE INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF DRUG OF ABUSE ASSAYS FOR AMPHETAMINE/ METHAMPHETAMINE, BARBITURATES, BENZODIAZEPINES, COCAINE METABOLITES, METHADONE, PHENCYCLIDINE, PROPOXYPHENE, AND OPIATES IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,TOX CONTROLS SET(TOX CONTROLS SET)-FOR THE QUALITY CONTROL OF THE MULTIGENT SERUM BENZODIAZEPINES AND TRICYCLIC ANTIDEPRESSANTS (TCA) ASSAYS.,DOA MC I CAL 3(DOA MC I CAL 3)-THE MULTIGENT DOA MC I CALIBRATORS AND CONTROLS ARE INTENDED FOR THE CALIBRATION AND QUALITY CONTROL OF DRUG OF ABUSE ASSAYS FOR AMPHETAMINE/ METHAMPHETAMINE, BARBITURATES, BENZODIAZEPINES, COCAINE METABOLITES, METHADONE, PHENCYCLIDINE, PROPOXYPHENE, AND OPIATES IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,OPIATES 1000 CAL(OPIATES 1000 CAL)-THE MULTIGENT OPIATES LOW CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE MULTIGENT OPIATES ASSAY, WHICH DETECTS OPIATES IN HUMAN URINE ON THE ARCHITECT C SYSTEMS, OPIATES 500 CAL(OPIATES 500 CAL)-THE MULTIGENT OPIATES LOW

	CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE MULTIGENT OPIATES ASSAY, WHICH DETECTS OPIATES IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

359	IMP/IVD/2019/000387	1.License Holder Name: COMPACT DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CORTISOL (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM OR URINE.,VITAMIN B12 (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM.,FK 506 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FK 506 IN HUMAN WHOLE BLOOD.,DHEA-S (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE (DHEA-S) IN HUMAN SERUM.,FERRITIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM. ,ANTI-IA2 (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TYROSINE PHOSPHATASE-LIKE PROTEINS ANTIBODY (ANTI-IA2) IN HUMAN SERUM.,INSULIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM.,OSTEOCALCIN (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF OSTEOCALCIN (BGP) IN HUMAN SERUM. ,PROINSULIN (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROINSULIN IN HUMAN SERUM.,A II (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANGIOTENSIN II (A II) IN HUMAN PLASMA.,FSH (CLIA)(MAGLUMI)-THE KIS IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM.,HCG/B-HCG (CLIA) (MAGLUMI)-THE KIS IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (B-SUBUNIT) (HCG/B-HCG) IN HUMAN SERUM.,C-PEPTIDE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM AND PLASMA.,GH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GROWTH HORMONE (GH) IN HUMAN SERUM.,DIGOXIN (CLIA)

	(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN IN HUMAN SERUM.,17 OH PROGESTERONE (CLIA)(MAGLUMI) -THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 17-OH PROGESTERON IN HUMAN SERUM. ,TRAB (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TSH RECEPTOR ANTIBODIES (TRAB) IN HUMAN SERUM.,IGF-I (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN-LIKE GROWTH FACTOR- I (IGF - I) IN HUMAN SERUM. ,ANTI-TPO (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-TPO IN HUMAN SERUM.,ICA (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO ISLET CELLS OF PANCREAS (ICA) IN HUMAN SERUM. , LIGHT CHECK(MAGLUMI)-LIGHT CHECK REAGENT REQUIRED TO CEHCK THE VALIDITY OF STARTER 1+2 AS WELL AS THE FUNCTIONING OF THE MEASURING AND PIPETTING UNITS. ,IGE (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) IN HUMAN SERUM.,IAA (CLIA)(MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN AUTOANTIBODIES (IAA) IN HUMAN SERUM. ,REV T3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF REVERSE TRIIODOTHYRONINE (REV T3) IN HUMAN SERUM. ,FT4 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM., REACTION MODULE(MAGLUMI)-REACTION MODULES REQUIRED FOR THE IMPLEMENTATION OF THE MAGLUMI ASSAYS ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,TMA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID MICROSOMAL AUTOANTIBODY (TMA) IN HUMAN SERUM. ,FA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLIC ACID (FA) IN HUMAN SERUM.,T4 (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM.,TESTOSTERONE (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE

	IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM.,T3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) IN HUMAN SERUM.,TSH (CLIA)(MAGLUMI)-THE KIS IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN HUMAN SERUM.,25 OH VITAMIN D (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM.,MYOGLOBIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM,PRG (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE (PRG) IN HUMAN SERUM.,FREE TESTOSTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE IN HUMAN SERUM.,LH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM.,PRL (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PRL IN HUMAN SERUM.,CK-MB (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MB ISOENZYME OF CREATINE KINASE (CK-MB) IN HUMAN SERUM.,SYSTEM TUBING CLEANING SOLUTION(MAGLUMI)-THE MAGLUMI SYSTEM TUBING CLEANING SOLUTION IS USED TO CLEAN THE PIPETTOR AND THE WASHER NEEDLES. IT IS USEFUL TO MINIMIZE REAGENT CARRYOVER BY REDUCING PROTEIN PRECIPITATION IN THE TUBING, AND IMPROVE ROUTINE MAINTENANCE OF THE MAGLUMI SYSTEM. THE KIT CAN ONLY BE USED WITH MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER, WITH TUBING CLEANING PROGRAM.,INTACT PTH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (INTACT PTH) IN HUMAN SERUM.,TGA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN AUTOANTIBODY (TGA) IN HUMAN SERUM. ,WASH CONCENTRATE (MAGLUMI)-MAGLUMI WASH CONCENTRATE IS INTENDED TO BE DILUTED FOR PREPARATION OF SYSTEM LIQUID WHICH IS REQUIRED FOR WASHING THE MAGNETIC MICROBEADS OF THE MAGLUMI

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO/WHO-UMC CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

	FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER.,AMH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-MULLERIAN HORMONE (AMH) IN HUMAN SERUM.,LP-PLA2 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN - ASSOCIATED PHOSPHOLIPASE A2 (LP-PLA2) IN HUMAN SERUM.,IGM (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM.,IGA (SERUM ANALYSIS) (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN SERUM.,CSA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE A (CSA) IN HUMAN WHOLE BLOOD. ,IGG (SERUM ANALYSIS) (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN SERUM.,ESTRADIOL (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM. ,GAD65 (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GLUTAMIC ACID DECARBOXYLASE ANTIBODY (GAD65) IN HUMAN SERUM.,A I (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANGIOTENSIN I (A I) IN HUMAN PLASMA.,ACTH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ADRENOCORTICOTROPIC HORMONE (ACTH) IN HUMAN PLASMA.,FT3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM.,ALDOSTERONE (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALDOSTERONE (ALD) IN HUMAN SERUM, PLASMA AND TREATED URINE. ,STARTER 1+2(MAGLUMI)-STARTER REAGENT KIT REQUIRED TO GENERATE THE CHEMILUMINOMETRIC LIGHT SIGNAL NECESSARY FOR THE IMPLEMENTATION OF MAGLUMI ASSAYS ON THE MAGLUMI FULLY AUTO CHEMILUMINESCENCE IMMUNOASSAY CLIA ANALYZER.

360	IMP/IVD/2019/000388	1.License Holder Name: THERMO FISHER SCIENTIFIC INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUSCEPTIBILITY, RAPID GROWING MYCOBACTERIA, NOCARDIA, OTHER AEROBIC ACTINOMYCETES(SENSITITRE)-THE SENSITITRE MYCOBACTERIUM TUBERCULOSIS SUSCEPTIBILITY PLATE PACKAGED KIT IS INTENDED FOR SUSCEPTIBILITY TESTING OF CLINICAL ISOLATES OF RAPIDLY GROWING MYCOBACTERIA SPECIES,SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE(SENSITITRE)-THE SENSITITRE MIC AND BREAKPOINT SUSCEPTIBILITY SYSTEM IS AN IN VITRO DIAGNOSTIC PRODUCT FOR CLINICAL SUSCEPTIBILITY TESTING OF NON-FASTIDIOUS GRAM-NEGATIVE ISOLATES, COMPRISING OF ENTEROBACTERIACEAE, PSEUDOMONAS AERUGINOSA, AND OTHER NON-ENTEROBACTERIACEAE AND OF NON-FASTIDIOUS GRAM POSITIVE ISOLATES, COMPRISING OF STAPHYLOCOCCUS SP., ENTEROCOCCUS SP., AND BETA HAEMOLYTIC STREPTOCOCCI OTHER THAN S. PNEUMONIAE. THE SENSITITRE ESBL CONFIRMATORY TEST PLATE IS AN IN VITRO DIAGNOSTIC PRODUCT FOR DETECTION OF ESBLS IN CLINICAL ISOLATES OF KLEBSIELLA PNEUMONIAE, KLEBSIELLA OXYTOCA AND ESCHERICHIA COLI. MIC AND ESBL PLATES CAN EITHER BE READ MANUALLY OR AUTOMATICALLY ON THE SENSITITRE AUTOREADER /OPTIREAD . TREK DIAGNOSTIC SYSTEMS PRODUCTS HAVE ONLY BEEN VALIDATED WITH TREK MANUFACTURED BROTHS. ,SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE(SENSITITRE)-THE SENSITITRE MIC AND BREAKPOINT SUSCEPTIBILITY SYSTEM IS AN IN VITRO DIAGNOSTIC PRODUCT FOR CLINICAL SUSCEPTIBILITY TESTING OF NON-FASTIDIOUS GRAM NEGATIVE ISOLATES, COMPRISING OF ENTEROBACTERIACEAE, PSEUDOMONAS AERUGINOSA, AND OTHER NON-ENTEROBACTERIACEAE AND OF NON-FASTIDIOUS GRAM POSITIVE ISOLATES, COMPRISING OF STAPHYLOCOCCUS SP., ENTEROCOCCUS SP., AND BETA HAEMOLYTIC STREPTOCOCCI OTHER THAN S. PNEUMONIAE. THE SENSITITRE ESBL CONFIRMATORY TEST PLATE IS AN IN VITRO DIAGNOSTIC PRODUCT FOR DETECTION OF ESBLS IN CLINICAL ISOLATES OF KLEBSIELLA PNEUMONIAE, KLEBSIELLA OXYTOCA AND ESCHERICHIA COLI. MIC AND ESBL PLATES CAN EITHER BE READ MANUALLY OR AUTOMATICALLY ON THE SENSITITRE AUTOREADER / OPTIREAD AND/OR ARIS. THERMO SCIENTIFIC MANUFACTURED BROTHS HAVE ONLY BEEN VALIDATED WITH SENSITITRE PRODUCTS.,SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE(SENSITITRE)-THE SENSITITRE MIC AND BREAKPOINT SUSCEPTIBILITY SYSTEM IS AN IN VITRO DIAGNOSTIC PRODUCT FOR CLINICAL SUSCEPTIBILITY TESTING OF NON-FASTIDIOUS GRAM NEGATIVE ISOLATES, COMPRISING OF

	ENTEROBACTERIACEAE, PSEUDOMONAS AERUGINOSA, AND OTHER NON-ENTEROBACTERIACEAE AND OF NON-FASTIDIOUS GRAM POSITIVE ISOLATES, COMPRISING OF STAPHYLOCOCCUS SP., ENTEROCOCCUS SP., AND BETA HAEMOLYTIC STREPTOCOCCI OTHER THAN S. PNEUMONIAE. THE SENSITITRE ESBL CONFIRMATORY TEST PLATE IS AN IN VITRO DIAGNOSTIC PRODUCT FOR DETECTION OF ESBLS IN CLINICAL ISOLATES OF KLEBSIELLA PNEUMONIAE, KLEBSIELLA OXYTOCA AND ESCHERICHIA COLI. MIC AND ESBL PLATES CAN EITHER BE READ MANUALLY OR AUTOMATICALLY ON THE SENSITITRE AUTOREADER /OPTIREAD. TREK DIAGNOSTIC SYSTEMS PRODUCTS HAVE ONLY BEEN VALIDATED WITH TREK MANUFACTURED BROTHS. ,SUSCEPTIBILITY SLOW GROWING NON TUBERCULOSIS MYCOBACTERIA(SENSITITRE)-THE THERMO FISHER SCIENTIFIC SENSITITRE MYCO SLOMYCO AST SUSCEPTIBILITY PLATE PACKAGED KIT IS INTENDED FOR SUSCEPTIBILITY TESTING OF CLINICAL ISOLATES OF SLOW GROWING MYCOBACTERIA SPECIES. SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE(SENSITITRE)-THE SENSITITRE MIC AND BREAKPOINT SUSCEPTIBILITY SYSTEM IS AN IN VITRO DIAGNOSTIC PRODUCT FOR CLINICAL SUSCEPTIBILITY TESTING OF NON-FASTIDIOUS GRAM NEGATIVE ISOLATES, COMPRISING OF ENTEROBACTERIACEAE, PSEUDOMONAS AERUGINOSA, AND OTHER NON-ENTEROBACTERIACEAE AND OF NON-FASTIDIOUS GRAM POSITIVE ISOLATES, COMPRISING OF STAPHYLOCOCCUS SP., ENTEROCOCCUS SP., AND BETA HAEMOLYTIC STREPTOCOCCI OTHER THAN S. PNEUMONIAE. THE SENSITITRE ESBL CONFIRMATORY TEST PLATE IS AN IN VITRO DIAGNOSTIC PRODUCT FOR DETECTION OF ESBLS IN CLINICAL ISOLATES OF KLEBSIELLA PNEUMONIAE, KLEBSIELLA OXYTOCA AND ESCHERICHIA COLI. MIC AND ESBL PLATES CAN EITHER BE READ MANUALLY OR AUTOMATICALLY ON THE SENSITITRE AUTOREADER /OPTIREAD. TREK DIAGNOSTIC SYSTEMS PRODUCTS HAVE ONLY BEEN VALIDATED WITH TREK MANUFACTURED BROTHS. ,SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE(SENSITITRE)-THE SENSITITRE MIC AND BREAKPOINT SUSCEPTIBILITY SYSTEM IS AN IN VITRO DIAGNOSTIC PRODUCT FOR CLINICAL SUSCEPTIBILITY TESTING OF NON-FASTIDIOUS GRAM NEGATIVE ISOLATES, COMPRISING OF ENTEROBACTERIACEAE, PSEUDOMONAS AERUGINOSA, AND OTHER NON-ENTEROBACTERIACEAE AND OF NON-FASTIDIOUS GRAM POSITIVE ISOLATES, COMPRISING OF STAPHYLOCOCCUS SP., ENTEROCOCCUS SP., AND BETA HAEMOLYTIC STREPTOCOCCI OTHER THAN S. PNEUMONIAE. THE SENSITITRE ESBL CONFIRMATORY TEST PLATE IS AN IN VITRO DIAGNOSTIC PRODUCT FOR DETECTION OF ESBLS IN CLINICAL ISOLATES OF KLEBSIELLA PNEUMONIAE, KLEBSIELLA OXYTOCA AND ESCHERICHIA COLI. MIC AND ESBL

	PLATES CAN EITHER BE READ MANUALLY OR AUTOMATICALLY ON THE SENSITITRE AUTOREADER / OPTIREAD AND/OR ARIS. THERMO SCIENTIFIC MANUFACTURED BROTHS HAVE ONLY BEEN VALIDATED WITH SENSITITRE PRODUCTS.,SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE(SENSITITRE)-THE SENSITITRE MIC AND BREAKPOINT SUSCEPTIBILITY SYSTEM IS AN IN VITRO DIAGNOSTIC PRODUCT FOR CLINICAL SUSCEPTIBILITY TESTING OF NON-FASTIDIOUS GRAM NEGATIVE ISOLATES, COMPRISING OF ENTEROBACTERIACEAE, PSEUDOMONAS AERUGINOSA, AND OTHER NON-ENTEROBACTERIACEAE AND OF NON-FASTIDIOUS GRAM POSITIVE ISOLATES, COMPRISING OF STAPHYLOCOCCUS SP., ENTEROCOCCUS SP., AND BETA HAEMOLYTIC STREPTOCOCCI OTHER THAN S. PNEUMONIAE. THE SENSITITRE ESBL CONFIRMATORY TEST PLATE IS AN IN VITRO DIAGNOSTIC PRODUCT FOR DETECTION OF ESBLS IN CLINICAL ISOLATES OF KLEBSIELLA PNEUMONIAE, KLEBSIELLA OXYTOCA AND ESCHERICHIA COLI. MIC AND ESBL PLATES CAN EITHER BE READ MANUALLY OR AUTOMATICALLY ON THE SENSITITRE AUTOREADER / OPTIREAD AND/OR ARIS. THERMO SCIENTIFIC MANUFACTURED BROTHS HAVE ONLY BEEN VALIDATED WITH SENSITITRE PRODUCTS.,SUSCEPTIBILITY NON-FASTIDIOUS GRAM POSITIVE(SENSITITRE)-THE SENSITITRE MIC AND BREAKPOINT SUSCEPTIBILITY SYSTEM IS AN IN VITRO DIAGNOSTIC PRODUCT FOR CLINICAL SUSCEPTIBILITY TESTING OF NON-FASTIDIOUS GRAM NEGATIVE ISOLATES, COMPRISING OF ENTEROBACTERIACEAE, PSEUDOMONAS AERUGINOSA, AND OTHER NON-ENTEROBACTERIACEAE AND OF NON-FASTIDIOUS GRAM POSITIVE ISOLATES, COMPRISING OF STAPHYLOCOCCUS SP., ENTEROCOCCUS SP., AND BETA HAEMOLYTIC STREPTOCOCCI OTHER THAN S. PNEUMONIAE. THE SENSITITRE ESBL CONFIRMATORY TEST PLATE IS AN IN VITRO DIAGNOSTIC PRODUCT FOR DETECTION OF ESBLS IN CLINICAL ISOLATES OF KLEBSIELLA PNEUMONIAE, KLEBSIELLA OXYTOCA AND ESCHERICHIA COLI. MIC AND ESBL PLATES CAN EITHER BE READ MANUALLY OR AUTOMATICALLY ON THE SENSITITRE AUTOREADER / OPTIREAD AND/OR ARIS. THERMO SCIENTIFIC MANUFACTURED BROTHS HAVE ONLY BEEN VALIDATED WITH SENSITITRE PRODUCTS.,SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE(SENSITITRE)-THE SENSITITRE MIC AND BREAKPOINT SUSCEPTIBILITY SYSTEM IS AN IN VITRO DIAGNOSTIC PRODUCT FOR CLINICAL SUSCEPTIBILITY TESTING OF NON-FASTIDIOUS GRAM NEGATIVE ISOLATES, COMPRISING OF ENTEROBACTERIACEAE, PSEUDOMONAS AERUGINOSA, AND OTHER NON-ENTEROBACTERIACEAE AND OF NON-FASTIDIOUS GRAM POSITIVE ISOLATES, COMPRISING OF STAPHYLOCOCCUS SP., ENTEROCOCCUS SP., AND BETA HAEMOLYTIC STREPTOCOCCI OTHER

	THAN S. PNEUMONIAE. THE SENSITITRE ESBL CONFIRMATORY TEST PLATE IS AN IN VITRO DIAGNOSTIC PRODUCT FOR DETECTION OF ESBLS IN CLINICAL ISOLATES OF KLEBSIELLA PNEUMONIAE, KLEBSIELLA OXYTOCA AND ESCHERICHIA COLI. MIC AND ESBL PLATES CAN EITHER BE READ MANUALLY OR AUTOMATICALLY ON THE SENSITITRE AUTOREADER / OPTIREAD AND/OR ARIS. THERMO SCIENTIFIC MANUFACTURED BROTHS HAVE ONLY BEEN VALIDATED WITH SENSITITRE PRODUCTS.,YEASTONE YO2IVD SUSCEPTIBILITY CANDIDA SPECIES(SENSITITRE)-THE THERMO SCIENTIFIC™ SENSITITRE™ YEASTONE™ SUSCEPTIBILITY PLATE IS AN IN VITRO DIAGNOSTIC MICROBROTH DILUTION METHOD IN A DRIED 96-WELL MICROPLATE FORMAT THAT PROVIDES QUANTITATIVE MINIMUM INHIBITORY CONCENTRATION (MIC) RESULTS FOR NON-FASTIDIOUS YEAST INCLUDING CANDIDA SPECIES, CRYPTOCOCCUS SPECIES, ASPERGILLUS SPECIES AND MISCELLANEOUS OTHER RAPID-GROWING YEAST SPECIES.,GPALL1F SUSCEPTIBILITY NON FASTIDOUS, GRAM POSITIVE(SENSITITRE)-THE SENSITITRE MIC AND BREAKPOINT SUSCEPTIBILITY SYSTEM IS AN IN VITRO DIAGNOSTIC PRODUCT FOR CLINICAL SUSCEPTIBILITY TESTING OF NON-FASTIDIOUS GRAM NEGATIVE ISOLATES, COMPRISING OF ENTEROBACTERIACEAE, PSEUDOMONAS AERUGINOSA, AND OTHER NON-ENTEROBACTERIACEAE AND OF NON-FASTIDIOUS GRAM POSITIVE ISOLATES, COMPRISING OF STAPHYLOCOCCUS SP., ENTEROCOCCUS SP., AND BETA HAEMOLYTIC STREPTOCOCCI OTHER THAN S. PNEUMONIAE. THE SENSITITRE ESBL CONFIRMATORY TEST PLATE IS AN IN VITRO DIAGNOSTIC PRODUCT FOR DETECTION OF ESBLS IN CLINICAL ISOLATES OF KLEBSIELLA PNEUMONIAE, KLEBSIELLA OXYTOCA AND ESCHERICHIA COLI. MIC AND ESBL PLATES CAN EITHER BE READ MANUALLY OR AUTOMATICALLY ON THE SENSITITRE AUTOREADER / OPTIREAD AND/OR ARIS. THERMO SCIENTIFIC MANUFACTURED BROTHS HAVE ONLY BEEN VALIDATED WITH SENSITITRE PRODUCTS.,SUSCEPTIBILITY NON-FASTIDIOUS ESBL CONFIRMATORY TESTING GRAM NEGATIVE(SENSITITRE)-THE SENSITITRE MIC AND BREAKPOINT SUSCEPTIBILITY SYSTEM IS AN IN VITRO DIAGNOSTIC PRODUCT FOR CLINICAL SUSCEPTIBILITY TESTING OF NON-FASTIDIOUS GRAM NEGATIVE ISOLATES, COMPRISING OF ENTEROBACTERIACEAE, PSEUDOMONAS AERUGINOSA, AND OTHER NON-ENTEROBACTERIACEAE AND OF NON-FASTIDIOUS GRAM POSITIVE ISOLATES, COMPRISING OF STAPHYLOCOCCUS SP., ENTEROCOCCUS SP., AND BETA HAEMOLYTIC STREPTOCOCCI OTHER THAN S. PNEUMONIAE. THE SENSITITRE ESBL CONFIRMATORY TEST PLATE IS AN IN VITRO DIAGNOSTIC PRODUCT FOR DETECTION OF ESBLS IN CLINICAL ISOLATES OF KLEBSIELLA PNEUMONIAE, KLEBSIELLA OXYTOCA AND ESCHERICHIA COLI. MIC

	AND ESBL PLATES CAN EITHER BE READ MANUALLY OR AUTOMATICALLY ON THE SENSITITRE AUTOREADER / OPTIREAD AND/OR ARIS. THERMO SCIENTIFIC MANUFACTURED BROTHS HAVE ONLY BEEN VALIDATED WITH SENSITITRE PRODUCTS., IDENTIFICATION NON-FASTIDIOUS GRAM POSITIVE(SENSITITRE)-THE SENSITITRE GPID PLATE IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE AUTOMATED IDENTIFICATION OF GRAM-POSITIVE BACTERIA., SUSCEPTIBILITY NON-FASTIDIOUS GRAM NEGATIVE(SENSITITRE)-THE SENSITITRE MIC AND BREAKPOINT SUSCEPTIBILITY SYSTEM IS AN IN VITRO DIAGNOSTIC PRODUCT FOR CLINICAL SUSCEPTIBILITY TESTING OF NON-FASTIDIOUS GRAM NEGATIVE ISOLATES, COMPRISING OF ENTEROBACTERIACEAE, PSEUDOMONAS AERUGINOSA, AND OTHER NON-ENTEROBACTERIACEAE AND OF NON-FASTIDIOUS GRAM POSITIVE ISOLATES, COMPRISING OF STAPHYLOCOCCUS SP., ENTEROCOCCUS SP., AND BETA HAEMOLYTIC STREPTOCOCCI OTHER THAN S. PNEUMONIAE. THE SENSITITRE ESBL CONFIRMATORY TEST PLATE IS AN IN VITRO DIAGNOSTIC PRODUCT FOR DETECTION OF ESBLS IN CLINICAL ISOLATES OF KLEBSIELLA PNEUMONIAE, KLEBSIELLA OXYTOCA AND ESCHERICHIA COLI. MIC AND ESBL PLATES CAN EITHER BE READ MANUALLY OR AUTOMATICALLY ON THE SENSITITRE AUTOREADER / OPTIREAD AND/OR ARIS. THERMO SCIENTIFIC MANUFACTURED BROTHS HAVE ONLY BEEN VALIDATED WITH SENSITITRE PRODUCTS., SUSCEPTIBILITY FASTIDIOUS STREPTOCOCCUS SPECIES (SENSITITRE)-THE SENSITITRE HAEMOPHILUS INFLUENZAE STREPTOCOCCUS PNEUMONIAE PLATES ARE IN VITRO DIAGNOSTIC PRODUCTS FOR CLINICAL SUSCEPTIBILITY TESTING OF HAEMOPHILUS INFLUENZAE, STREPTOCOCCUS PNEUMONIAE AND STREPTOCOCCUS SPECIES.,SUSCEPTIBILITY YEAST ISOLATES (SENSITITRE YEASTONE)-THE THERMO FISHER SCIENTIFIC SENSITITRE YEASTONE SUSCEPTIBILITY PLATE PACKAGES KIT IS INTENDED FOR SUSCEPTIBILITY TESTING OF CLINICAL ISOLATES OF NON – FASTIDIOUS YEASTS INCLUDING CANDIDA SPECIES, CRYPTOCOCCUS SPECIES AND ASPERGILLUS SPECIES AND MISCELLANEOUS OTHER RAPIDLY GROWING YEAST SPECIES., IDENTIFICATION NON-FASTIDIOUS GRAM NEGATIVE(SENSITITRE)-THE SENSITITRE® GNID PLATE IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE AUTOMATED IDENTIFICATION OF GRAM-NEGATIVE BACTERIA.

361	IMP/IVD/2019/000389	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:C.K. PREST® - DETERMINATION OF THE KAOLIN-ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - SYSTEM CONTROL N + P-CONTROL PLASMA FOR COAGULATION TESTS,STA® - UNICALIBRATOR-CALIBRATION PLASMA FOR FUNCTIONAL ASSAYS OF COAGULATION PARAMETERS,STA® - COAG CONTROL N + P-CONTROL PLASMA FOR COAGULATION TESTS,STA® - IMMUNODEF VIII-IMMUNO-DEPLETED PLASMA FOR FACTOR VIII ASSAY, NEOPLASTINE® CL PLUS -DETERMINATION OF PROTHROMBIN TIME (PT),COAG CONTROL N + P-CONTROL PLASMA FOR COAGULATION TESTS,STA® - NÉOPLASTINE® R -DETERMINATION OF PROTHROMBIN TIME (PT),STA® - C.K. PREST® -DETERMINATION OF THE KAOLIN-ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)
362	IMP/IVD/2019/000390	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST (VERI-Q BALANCE)-BLOOD GLUCOSE TEST STRIPS USED TO TESTING OF GLUCOSE LEVEL IN WHOLE BLOOD,LIPID TEST STRIPS (TC, TG, HDL, LDL)(VERI-Q MULTI)-LIPID TEST STRIPS USED TO TESTING OF TOTAL CHOLESTEROL, TRIGLYCERIDE, HIGH DENSITY LIPOPROTEIN, LOW DENSITY LIPOPROTEIN IN WHOLE BLOOD,HEMOGLOBIN STRIPS (VERI-Q HB MATE)-HEMOGLOBIN TEST STRIPS USED TO TESTING OF HEMOGLOBIN LEVEL IN WHOLE BLOOD

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

363	IMP/IVD/2019/000391	1.License Holder Name: TOSOH INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HUMAN CHORIONIC GONADOTROPIN (BHCG) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CHORIONIC GONADOTROPIN (HCG) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,FREE BETA HUMAN CHORIONIC GONADOTROPIN (F-BHCG) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE BETA CHORIONIC GONADOTROPIN SUBUNIT CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,FERTILITY VAST (LH+FSH+PRL+BHCG) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF HCG, PRL, LH AND FSH CONCENTRATION IN HUMAN SERUM AND PLASMA BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY.,ESTRADIOL ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL ESTRADIOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,INSULIN ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF INSULIN LEVELS IN HUMAN SERUM,17-OH PROGESTERONE ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF 17-OH PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY.,UNCONJUGATED ESTRIOL (U-E3) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF ESTRIOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,PROLACTIN (PRL) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,THYROGLOBULIN (TG) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) LEVELS IN HUMAN SERUM.,ANTI-THROGLOBULIN (ANTI-TG) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) AUTOANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,FOLLICLE STIMULATING HORMONE (FSH) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY ,ANTI-THYROPEROXIDASE (ANTI-TPO) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF THYROID PEROXIDASE (TPO)

	AUTOANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,LUTEINIZING HORMONE (LH) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,TOTAL TRIIODOTHYRONINE (T3) UPTAKE ELISA(ACCUBIND)-FOR THE MEASUREMENT OF TOTAL AMOUNT OF BINDING SITES AVAILABLE FOR THE THYROID HORMONES IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,THYROTROPIN (TSH) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF THYROTROPIN (TSH) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,FREE THYROXINE (FT4) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,CORTISOL ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL CORTISOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,THYROID BINDING GLOBULIN (TBG) ELISA (ACCUBIND)-THE QUANTITATIVE DETERMINATION OF TBG THYROXINE BINDING GLOBULIN CONCENTRATION IN HUMAN SERUM, PLASMA OR WHOLE BLOOD BY A MICROPLATE ENZYME LABELED IMMUNOASSAY.,HUMAN GROWTH HORMONE (HGH) ELISA(ACCUBIND) -FOR THE QUANTITATIVE DETERMINATION OF GROWTH HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,FREE TESTOSTERONE ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,THYROID VAST (T3+T4+TSH) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE, TOTAL TRIIODOTHYRONINE, & THYROID STIMULATING HORMONE CONCENTRATION FOR A COMPREHENSIVE THYROID STATUS OF HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,FREE THYROID VAST (FT3+FT4+TSH) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE, FREE TRIIODOTHYRONINE, & THYROID STIMULATING HORMONE CONCENTRATION FOR A COMPREHENSIVE THYROID STATUS OF HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,25-OH VITAMIN D TOTAL ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY.,MYOGLOBIN ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING MYOGLOBIN CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,TOTAL THYROXINE (T4) ELISA

	(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE (TT4) CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,FREE TRIIODOTHYRONINE (FT3) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,TOTAL T3 TEST SYSTEM ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE (TT3) CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,FREE TESTOSTERONE CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,FREE TRIIODOTHYRONINE (FT3) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA).,TESTOSTERONE CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,CREATINE KINASE (CK) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING CREATINE KINASE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,ESTRADIOL CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL ESTRADIOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY, IMMUNOGLOBULIN E (IGE) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,DIGOXIN ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL DIGOXIN CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,FREE PROSTATE SPECIFIC ANTIGEN (FPSA) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (FPSA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY.,SOLUBLE TRANSFERRIN RECEPTOR CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF STFR CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE ASSAY (CLIA), TOTAL THYROXINE (T4) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),TROPONIN I CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING TROPONIN-I

	CONCENTRATIONS IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,CANCER ANTIGEN 15-3 (CA 15-3) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 15-3 (CA 15-3) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE ASSAY,CANCER ANTIGEN 125 (CA-125) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 125 (CA-125) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE ASSAY,CANCER ANTIGEN 19-9 (CA 19-9) CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 19-9 (CA 19-9) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE ASSAY,VITAMIN B12 CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,DIGOXIN CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL DIGOXIN CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,PROSTATE SPECIFIC ANTIGEN (TPSA) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROSTATE SPECIFIC ANTIGEN (TPSA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,C-PEPTIDE ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING C-PEPTIDE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,FERTILITY VAST (LH+FSH+PRL+BHCG) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF HCG, PRL, LH AND FSH CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),FERRITIN ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING FERRITIN CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,CARCINOEMBRYONIC ANTIGEN (CEA) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,HIGH SENSITIVITY C-REACTIVE PROTEIN (HS CRP) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,FERRITIN CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING FERRITIN CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),TESTOSTERONE ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL

	TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,H.PYLORI IGM CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF ANTI-H. PYLORI SPECIFIC ANTIBODIES OF THE IGM ANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,FREE PROSTATE SPECIFIC ANTIGEN (FPSA) CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (FPSA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY, CANCER ANTIGEN 19-9 (CA 19-9) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 19-9 (CA 19-9) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,HIGH SENSITIVITY C-REACTIVE PROTEIN (HS CRP) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CRP C-REACTIVE PROTEIN CONCENTRATION IN HUMAN SERUM, PLASMA OR WHOLE BLOOD BY A MICROPLATE IMMUNOENZYMOMETRIC CHEMILUMINESCENCE ASSAY, UNCONJUGATED ESTRIOL (U-E3) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL ESTRIOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,INSULIN/C-PEPTIDE MAPS CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF INSULIN OR C-PEPTIDE LEVELS IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,IMMUNOGLOBULIN E (IGE) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,C-PEPTIDE CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING C-PEPTIDE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY.,CANCER ANTIGEN 15-3 (CA 15-3) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 15-3 (CA 15-3) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,CANCER PANEL VAST (AFP+CEA+PSA) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF AFP, CEA AND PSA CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE ASSAY, MYOGLOBIN CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING MYOGLOBIN CONCENTRATION IN HUMAN SERUM, PLASMA AND URINE BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,H.PYLORI IGG CLIA(ACCULITE) -FOR THE QUANTITATIVE DETERMINATION OF ANTI-H.PYLORI SPECIFIC ANTIBODIES OF THE IGG ANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,

	DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE CONCENTRATION (DHEA-$) IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,PROGESTERONE CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,TUMOR MARKER QUALITY CONTROL MATERIAL(ACCUBIND)-THE TUMOR MARKER PANEL CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE CONSISTENCY OF PERFORMANCE OF LABORATORY TEST PROCEDURES ASSOCIATED WITH DETERMINATION AND MONITORING OF THE TUMOR MARKER STATUS. ,CREATINE KINASE (CK) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING CREATINE KINASE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,MULTI LIGAND QUALITY CONTROL MATERIAL(ACCUBIND)-THE MULTI LIGAND CONTROLS ARE INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE CONSISTENCY OF PERFORMANCE OF LABORATORY TEST PROCEDURES ASSOCIATED WITH DETERMINATION AND MONITORING OF THE CLINICAL STATUS. ,PROGESTERONE ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,CARCINOEMBRYONIC ANTIGEN (CEA) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE ASSAY (CLIA),H.PYLORI IGG ELISA(ACCUBIND) -FOR THE QUANTITATIVE DETERMINATION OF ANTI-H.PYLORI SPECIFIC ANTIBODIES OF THE IGG ANTIBODIES IN HUMAN SERUM OR PLASMA BY MICROPLATE ENZYME IMMUNOASSAY,CANCER ANTIGEN 125 (CA-125) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 125 (CA-125) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,CORTISOL CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL CORTISOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),HUMAN GROWTH HORMONE (HGH) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF GROWTH HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY, CANCER PANEL VAST (AFP+CEA+PSA) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF AFP, CEA AND PSA

	CONCENTRATION IN HUMAN SERUM AND PLASMA BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,17-OH PROGESTERONE CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL 17 HYDROXY PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,H. PYLORI IGA CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF ANTI-H.PYLORI SPECIFIC ANTIBODIES OF THE IGA ANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,THYROGLOBULIN (TG) CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN LEVELS IN HUMAN SERUM,LUTEINIZING HORMONE (LH) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),INSULIN CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF INSULIN CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),HUMAN CHORIONIC GONADOTROPIN (BHCG) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CHORIONIC GONADOTROPIN (HCG) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),FOLLICLE STIMULATING HORMONE (FSH) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,ANTI-THYROPEROXIDASE (ANTI-TPO) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF THYROID PEROXIDASE (TPO) AUTOANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),FREE THYROID VAST (FT3+FT4+TSH) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE, FREE TRIIODOTHYRONINE, THYROID STIMULATING HORMONE CONCENTRATION FOR A COMPREHENSIVE THYROID STATUS OF HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,FREE BETA HUMAN CHORIONIC GONADOTROPIN (F-BHCG) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE BETA CHORIONIC GONADOTROPIN SUBUNIT CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,PROLACTIN (PRL) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),ANTI-THYROGLOBULIN (ANTI-TG) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN AUTOANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE

	CHEMILUMINESCENCE IMMUNOASSAY (CLIA),ALPHA FETO PROTEIN (AFP) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF ALPHA FETOPROTEIN (AFP) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,INSULIN/C-PEPTIDE MAPS ELISA(ACCUBIND)-MONOBIND INSULIN/C-PEPTIDE MAPS ELISA TEST IS INTENDED TO BE USED FOR THE QUANTITATIVE DETERMINATION OF INSULIN OR C-PEPTIDE LEVELS IN HUMAN SERUM.,ALPHA FETO PROTEIN (AFP) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF ALPHA FETOPROTEIN (AFP) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,25-OH VITAMIN D TOTAL CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY.,TOTAL TRIIODOTHYRONINE (T3) UPTAKE CLIA(ACCULITE)-FOR THE MEASUREMENT OF TOTAL AMOUNT OF BINDING SITES AVAILABLE FOR THE THYROID HORMONES IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),PROSTATE SPECIFIC ANTIGEN (TPSA) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROSTATE SPECIFIC ANTIGEN (TPSA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,TROPONIN I ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING TROPONIN I CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY.,H.PYLORI IGM ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF ANTI-H.PYLORI SPECIFIC ANTIBODIES OF THE IGM ANTIBODIES IN HUMAN SERUM OR PLASMA BY MICROPLATE ENZYME IMMUNOASSAY,TOTAL T3 TEST SYSTEM CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),FREE THYROXINE (FT4) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),SOLUBLE TRANSFERRIN RECEPTOR ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF STFR CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY.,THYROTROPIN (TSH) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF THYROTROPIN CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),THYROID VAST (T3+T4+TSH) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE, TOTAL TRIIODOTHYRONINE, THYROID STIMULATING HORMONE CONCENTRATION FOR A

	COMPREHENSIVE THYROID STATUS OF HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,VITAMIN B12 ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,H.PYLORI IGA ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF ANTI-H.PYLORI SPECIFIC ANTIBODIES OF THE IGA ANTIBODIES IN HUMAN SERUM OR PLASMA BY MICROPLATE ENZYME IMMUNOASSAY,THYROID BINDING GLOBULIN (TBG) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TBG THYROXINE BINDING GLOBULIN CONCENTRATION IN HUMAN SERUM, PLASMA OR WHOLE BLOOD BY A MICROPLATE ENZYME LABELED CHEMILUMINESCENSE IMMUNOASSAY,FOLATE ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FOLATE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

364	IMP/IVD/2019/000392	1.License Holder Name: MATRIX LABS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DILUENT(DILUENT)-USED TO DILUTE AND LIQUEFY THE FECES SAMPLE, SO THAT THE SAMPLE CAN BE TESTED BYAVE IVD(IN VITRODIAGNOSTIC) REAGENT OR AVE-56 SERIES FULLY AUTOMATED FECES ANALYZER.,FECAL OCCULT BLOOD AND TRANSFERRIN RAPID TEST KIT(COLLOIDAL GOLD)(FECAL OCCULT BLOOD AND TRANSFERRIN RAPID TEST KIT (COLLOIDAL GOLD))-USED TO DETECT HEMOGLOBIN AND TRANSFERRIN IN HUMAN FECES SAMPLE, CLINICALLY USED TO EVALUATE GASTROINTESTINAL BLEEDING. ,BUFFER(BUFFER)-FOR AVE-772 FULLY AUTOMATED INTEGRATED URINE ANALYZER ONLY, QC FOR URINE ANALYZER(CALIBRATOR FOR URINE FORMED ELEMENTS ANALYZER)-FOR SENSITIVITY AND ACCURACY CALIBRATION OF AVE SERIES URINE FORMED ELEMENTS ANALYZER ONLY,FECAL OCCULT BLOOD RAPID TEST KIT(DUPLEX)(FECAL OCCULT BLOOD RAPID TEST KIT(DUPLEX)-USED TO DETECT HEMOGLOBIN IN HUMAN FECES SAMPLE, CLINICALLY USED TO EVALUATE GASTROINTESTINAL BLEEDING,URINE TEST STRIP(URINE TEST STRIP)-APPLICABLE FOR ASCORBIC ACID IN URINE(VITAMINC), BILIRUBIN(BIL),OCCULT BLOOD(BLD), GLUCOSE(GLU), LEUKOCYTE (LEU), NITRITE(NIT),PH VALUE (PH),PROTEIN(PRO),SPECIFIC GRAVITY OF URINE(SG),UROBILINOGEN(URO),ACETONE BODY(KET), CREATININE(CRE),MICROALBUMINURIA (ALB),CALCIUM ION(CA) SEMI QUANTITATIVE ANALYSIS OF FOURTEEN CHEMICAL INDEXES. IT IS SUITABLE FOR THE EXAMINATION OF CLINICAL URINE SAMPLES IN MEDICAL,CLEANSER I CLEANSER II(CLEANSER)-FOR AVE-772 FULLY AUTOMATED INTEGRATED URINE ANALYZER ONLY,FECAL OCCULT BLOOD RAPID TEST KIT(COLLOIDAL GOLD)(FECAL OCCULT BLOOD RAPID TEST KIT(COLLOIDAL GOLD))-USED TO DETECT HEMOGLOBIN IN HUMAN FECES SAMPLE, CLINICALLY USED TO EVALUATE GASTROINTESTINAL BLEEDING.,TRANSFERRIN RAPID TEST KIT (COLLOIDAL GOLD)(TRANSFERRIN RAPID TEST KIT (COLLOIDAL GOLD))-USED TO DETECT TRANSFERRIN IN HUMAN FECES SAMPLE, CLINICALLY USED TO EVALUATE GASTROINTESTINAL BLEEDING.

365	IMP/IVD/2019/000393	1.License Holder Name: NISHA SALES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STA®- LIATEST® FREE PROTEIN S 2-IMMUNO-TURBIDIMETRIC ASSAY OF FREE PROTEIN S, STA® - LIATEST® CONTROL N+P-CONTROL PLASMAS FOR IMMUNO-TURBIDIMETRIC ASSAYS,STA® - DEFICIENT VIII-IMMUNO-DEPLETED PLASMA FOR FACTOR VIII ASSAY,STA® - DEFICIENT II-SUBSTRATE PLASMA FOR FACTOR LL ASSAY,STA® - HEPANORM® H-CALIBRATION PLASMA FOR ASSAY OF UNFRACTIONATED HEPARIN (UFH) USING ANTI-XA METHOD,STA® - DESORB U-DESORBING SOLUTION FOR USE WITH ANALYZERS OF THE STA® LINE, ASSERACHROM® HPIA-DETECTION OF ANTI-HEPARIN-PF4 ANTIBODIES BY ENZYME IMMUNOASSAY,STA® - FM CALIBRATOR-CALIBRATION PLASMAS FOR THE IMMUNO-TURBIDIMETRIC ASSAY OF FIBRIN MONOMERS,UNICALIBRATOR-CALIBRATION PLASMA FOR FUNCTIONAL ASSAYS OF COAGULATION PARAMETERS,STA® - STACHROM® PROTEIN C-COLORIMETRIC ASSAY OF PROTEIN C,STA® - IMMUNODEF XII-IMMUNO-DEPLETED PLASMA FOR FACTOR XII ASSAY,STA® - STACHROM® ATIII 3, 6-COLORIMETRIC ASSAY OF ANTITHROMBIN,STA® - QUALITY HNF/UFH-CONTROL PLASMAS FOR ASSAYS OF UNFRACTIONATED HEPARINS (UFH) USING ANTI-XA METHOD,STA® - PTT A 5-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - MULTI HEP CALIBRATOR-CALIBRATION PLASMAS FOR ASSAYS OF HEPARINS (UFH AND LMWH) USING ANTI-XA METHOD,STA® - LIQUID FIB-QUANTITATIVE DETERMINATION OF FIBRINOGEN,STA®- LIQUID ANTI-XA 4, 8-COLORIMETRIC ASSAY OF HEPARINS (UFH AND LMWH), FONDAPARINUX AND RIVAROXABAN,STA® - OWREN - KOLLER-OWREN-KOLLER BUFFER SOLUTION FOR COAGULATION TESTS,STA® - LIATEST® VWF : AG-IMMUNO-TURBIDIMETRIC ASSAY OF VON WILLEBRAND FACTOR,FDP PLASMA-QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF FDP IN PLASMA BY LATEX,COAG CONTROL N+ P-CONTROL PLASMAS FOR COAGULATION TESTS, ASSERACHROM® HPIA - IG G-DETECTION OF ANTI-HEPARIN-PF4 ANTIBODIES OF IGG CLASS BY ENZYME IMMUNOASSAY,CK PREST® 2, 5-DETERMINATION OF THE KAOLIN-ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),D-DI TEST®-LATEX AGGLUTINATION SLIDE TEST FOR THE QUALITATIVE AND SEMI - QUANTITATIVE DETERMINATION OF D-DIMER,STA® - COAG CONTROL N+P-CONTROL PLASMAS FOR COAGULATION TESTS,STA® - STACLOT® PROTEIN S-CLOTTING ASSAY OF PROTEIN S,PTT AUTOMATE 5-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), NÉOPLASTINE® CI PLUS 2, 5, 10-DETERMINATION OF PROTHROMBIN TIME (PT),STA® - CONTROL LA 1+2-CONTROL PLASMAS FOR LUPUS

	ANTICOAGULANT (LA) TESTS,SYSTEM CONTROL N+ P-CONTROL PLASMAS FOR ASSAYS OF COAGULATION PARAMETERS,STA® - DEFICIENT V-SUBSTRATE PLASMA FOR FACTOR V ASSAY,STACLOT® LA-DETECTION OF LUPUS ANTICOAGULANTS,STA® - DEFICIENT XI-DEFICIENT PLASMA FOR FACTOR XI ASSAY,STA® - IMMUNODEF IX-IMMUNO-DEPLETED PLASMA FOR FACTOR IX ASSAY,PTT-LA-LUPUS ANTICOAGULANT-SENSITIVE APTT REAGENT,STA® - DEFICIENT IX-IMMUNO-DEPLETED PLASMA FOR FACTOR IX ASSAY,STA® - STACLOT® APC-R-ASSESSMENT OF ACTIVATED PROTEIN C RESISTANCE,STA® - D-DI CONTROL-QUALITY CONTROL FOR IMMUNO-TURBIDIMETRIC ASSAY OF D-DIMER,STA® - THROMBIN 2, 10-DETERMINATION OF THROMBIN TIME,STA® - VWF:AG CALIBRATOR-CALIBRATION PLASMA FOR THE IMMUNO-TURBIDIMETRIC ASSAY OF VWF:AG,STA® - STACLOT®DRVV CONFIRM-DETECTION OF LUPUS ANTICOAGULANTS,STA® - LIATEST® D-DI PLUS-IMMUNO-TURBIDIMETRIC ASSAY OF D-DIMER, STA® - STACLOT® HEPARIN 1-CLOTTING ASSAY OF HEPARINS (UFH AND LMWH) BY ANTI-XA METHOD,STA® - DEFICIENT VII-IMMUNO-DEPLETED PLASMA FOR FACTOR VII ASSAY,STA® - NEOPLASTINE® R15-DETERMINATION OF PROTHROMBIN TIME (PT),STA® - HEPARIN CONTROL-CONTROL PLASMAS FOR ASSAYS OF UNFRACTIONATED HEPARINS (UFH) USING ANTI-XA METHOD,STA® - FM CONTROL-CONTROL PLASMAS FOR THE IMMUNO-TURBIDIMETRIC ASSAY OF FIBRIN MONOMERS,STA®- HBPM/LMWH CONTROL-CONTROL PLASMAS FOR ASSAYS OF LOW MOLECULAR WEIGHT HEPARINS (LMWH) USING ANTI-XA METHOD,STA® - IMMUNODEF VIII-IMMUNO-DEPLETED PLASMA FOR FACTOR VIII ASSAY,STA® - SYSTEM CONTROL N+P-CONTROL PLASMAS FOR ASSAYS OF COAGULATION PARAMETERS,STA® - HEPANORM® HBPM/LMWH-CALIBRATION PLASMAS FOR ASSAYS OF LOW MOLECULAR WEIGHT HEPARINS (LMWH) USING ANTI-XA METHOD ,STA® - CEPHASCREEN 4-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - STACLOT®DRVV SCREEN 2, 5-DETECTION OF LUPUS ANTICOAGULANTS,STA® - DEFICIENT X-IMMUNO-DEPLETED PLASMA FOR FACTOR X ASSAY,STA® - CEPHASCREEN 10-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - CACL2 0.025 M-CALCIUM CHLORIDE SOLUTION,STA® - LIATEST® FREE PROTEIN S 6-IMMUNO-TURBIDIMETRIC ASSAY OF FREE PROTEIN S, STA® - STACLOT® PROTEIN C 1-CLOTTING ASSAY OF PROTEIN C, STA® - NEOPTIMAL® 5, 10, 20-DETERMINATION OF PROTHROMBIN TIME (PT),STA®- QUALITY HBPM/LMWH-CONTROL PLASMA FOR ASSAYS OF LOW MOLECULAR WEIGHT HEPARINS (LMWH) USING STA® - ROTACHROM® HEPARIN,STA® - UNICALIBRATOR-CALIBRATION PLASMA FOR FUNCTIONAL ASSAYS OF COAGULATION

		PARAMETERS,STA® - ROUTINE QC 2 ML-CONTROL PLASMAS FOR COAGULATION TESTS,POOL NORM-NORMAL HUMAN PLASMA POOL, STA® - CK PREST 5-DETERMINATION OF THE KAOLIN-ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - LIATEST® FM-IMMUNO-TURBIDIMETRIC ASSAY OF FIBRIN MONOMERS
366	IMP/IVD/2019/000394	1.License Holder Name: SOWAR PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TT(THROMBIN TIME REAGENT KIT (CLOTTING))-MEASURE THE TIME OF CLOT FORMATION WHEN THROMBIN IS ADDED TO CITRATED VENOUS WHOLE BLOOD., ACT(ACTIVATED CLOTTINGTIME REAGENT KIT (CLOTTING))-QUANTITATIVE MEASUREMENT INTENDED TO PROVIDE MEASUREMENT OF THE TIME IN SECONDS REQUIRED FOR A CLOT TO FORM IN CITRATED VENOUS WHOLE BLOOD WHICH HAS BEEN EXPOSED TO SURFACE ACTIVATOR,PT(PROTHROMBIN TIME REAGENT KIT (CLOTTING))-QUANTITATIVE MEASUREMENT OF PROTHROMBIN TIME (PT) AND INTERNATIONAL NORMALIZED RATIO (INR) IN CITRATED VENOUS WHOLE BLOOD.,APTT(ACTIVATED PARTIAL THROMBOPLASTIN TIME REAGENT KIT (CLOTTING))-QUANTITATIVE MEASUREMENT OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) IN CITRATED VENOUS WHOLE BLOOD.,FBI(FIBRINOGEN REAGENT KIT (CLOTTING))-QUANTITATIVE MEASUREMENT OF FIBRINOGEN IN CITRATED VENOUS WHOLE BLOOD.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

367	IMP/IVD/2019/000395	1.License Holder Name: MATRIX LABS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CMV IGM CLIA MICROPARTICLES(CMV IGM CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF CMV IGM (SPECIFIC IGM ANTIBODIES TO CYTOMEGALOVIRUS) IN HUMAN SERUM OR PLASMA.,C-PEPTIDE CLIA MICROPARTICLES(C-PEPTIDE CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETECTION OF C-PEPTIDE IN HUMAN SERUM.,CMV IGG CLIA MICROPARTICLES(CMV IGG CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF CMV IGG (SPECIFIC IGG ANTIBODIES TO CYTOMEGALOVIRUS) IN HUMAN SERUM OR PLASMA.,RENIN CLIA MICROPARTICLES(RENIN CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF RENIN IN HUMAN PLASMA (EDTA),SHBG CLIA MICROPARTICLES(SHBG CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF SHBG (SEX HORMONE-BINDING GLOBULIN) IN HUMAN SERUM.,HS-CRP CLIA MICROPARTICLES(HS-CRP CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF HS-CRP (HIGH-SENSITIVITY C-REACTIVE PROTEIN) IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN OR SODIUM CITRATE).,COL IV CLIA MICROPARTICLES(COL IV CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF COL IV (COLLAGEN IV) IN HUMAN SERUM.,DILUENT UNIVERSAL(DILUENT UNIVERSAL)-USED IN CONJUGATION WITH IMMUNE DETECTION KITS FOR THE DILUTION OF CLINICAL SAMPLES.,HEV IGM CLIA MICROPARTICLES(HEV IGM CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUALITATIVE DETECTION OF HEV IGM (IGM ANTIBODY TO HEPATITIS E VIRUS) IN HUMAN SERUM OR PLASMA (EDTA, HEPARIN OR SODIUM CITRATE).,PRL CLIA MICROPARTICLES(PRL CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF PRL (PROLACTIN) CONCENTRATION IN HUMAN

	SERUM,TOXO IGM CLIA MICROPARTICLES(TOXO IGM CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF TOXO IGM (SPECIFIC IGM ANTIBODIES TO TOXOPLASMA GONDII) IN HUMAN SERUM OR PLASMA.,TSH CLIA MICROPARTICLES(TSH CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF TSH (THYROID STIMULATING HORMONE) IN HUMAN SERUM.,RUBELLA IGM CLIA MICROPARTICLES(RUBELLA IGM CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF RUBELLA IGM (SPECIFIC IGM ANTIBODIES TO RUBELLA VIRUS) IN HUMAN SERUM OR PLASMA,ANTI-TG CLIA MICROPARTICLES(ANTI-TG CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF ANTI-TG (ANTIBODY TO THYROGLOBULIN) IN HUMAN SERUM., RUBELLA IGG CLIA MICROPARTICLES(RUBELLA IGG CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF RUBELLA IGG (SPECIFIC IGG ANTIBODIES TO RUBELLA VIRUS) IN HUMAN SERUM OR PLASMA., OSTEOCALCIN CLIA MICROPARTICLES(OSTEOCALCIN CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETECTION OF OSTEOCALCIN IN HUMAN SERUM OR PLASMA (EDTA OR HEPARIN).,SARS-COV-2 IGM CLIA MICROPARTICLES(AUTOBIO)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUALITATIVE DETEC- TION OF SARS-COV-2 IGM (IGM ANTIBODIES TO SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2) IN HUMAN SERUM AND PLASMA., CHEMILUMINESCENT SUBSTRATESUBSTRATEA+SUBSTRATE B) (CHEMILUMINESCENT SUBSTRATESUBSTRATEA+SUBSTRATE B))-CHEMILUMINESCENT SUBSTRATE IS USED IN CONJUNCTION WITH MATCHING REAGENT KITS WHICH BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) TECHNOLOGY IN THE DETECTION OF MEASURAND FOR IN VITRO DIAGNOSTIC,PIIINP CLIA MICROPARTICLES(PIIINP CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF PIIINP (PROCOLLAGEN III N-

	TERMINAL PEPTIDE) IN HUMAN SERUM.,T3 CLIA MICROPARTICLES(T3 CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF T3 (TRIIODOTHYRONINE) IN HUMAN SERUM.,HA CLIA MICROPARTICLES (HA CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF HA (HYALURONIC) IN HUMAN SERUM.,HGH CLIA MICROPARTICLES(HGH CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETECTION OF HGH (HUMAN GROWTH HORMONE) CONCENTRATION IN HUMAN SERUM AND PLASMA (HEPARIN),TOXO IGG CLIA MICROPARTICLES(TOXO IGG CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF TOXO IGG (SPECIFIC IGG ANTIBODIES TO TOXOPLASMA GONDII) IN HUMAN SERUM OR PLASMA.,FOLATE CLIA MICROPARTICLES(FOLATE CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETECTION OF FOLIC ACID CONCENTRATION IN HUMAN SERUM.,HAV IGM CLIA MICROPARTICLES(HAV IGM CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUALITATIVE DETECTION OF HAV IGM (IGM ANTIBODY TO HEPATITIS A VIRUS) IN HUMAN SERUM OR PLASMA (EDTA, HEPARIN OR SODIUM CITRATE).,25-OH VITAMIN D CLIA MICROPARTICLES(25-OH VITAMIN D CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM OR PLASMA (EDTA OR HEPARIN).,SARS-COV-2 IGG CLIA MICROPARTICLES (AUTOBIO)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUALITATIVE DETEC- TION OF SARS-COV-2 IGG (IGG ANTIBODIES TO SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2) IN HUMAN SERUM AND PLASMA,SYSTEM WASH(SYSTEM WASH)-SYSTEM WASH IS A CONCENTRATE WHICH USED FOR CLEANING SAMPLE PIPETTOR DURING THE REACTION PROCESS IN THE DETECTION OF MEASURAND FOR IN VITRO DIAGNOSTIC DETECTION ASSAY.,17-OHP CLIA MICROPARTICLES(17-OHP CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE

	DETERMINATION OF 17-OHP (17-HYDROXYPROGESTERONE) IN HUMAN SERUM.,INSULIN CLIA MICROPARTICLES(INSULIN CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETECTION OF INSULIN IN HUMAN SERUM.,LN CLIA MICROPARTICLES(LN CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF LN (LAMININ) IN HUMAN SERUM.,PTH CLIA MICROPARTICLES(PTH CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETECTION OF PTH IN HUMAN SERUM OR PLASMA (EDTA),HEV IGG CLIA MICROPARTICLES(HEV IGG CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUALITATIVE DETECTION OF HEV IGG (IGG ANTIBODY TO HEPATITIS E VIRUS) IN HUMAN SERUM OR PLASMA (EDTA, HEPARIN OR SODIUM CITRATE).,CK-MB CLIA MICROPARTICLES(CK-MB CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE-MB (CK-MB) CONCENTRATION IN HUMAN SERUM AND PLASMA (HEPARIN), CHOLYLGLYCINE CLIA MICROPARTICLES(CHOLYLGLYCINE CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF CHOLYLGLYCINE IN HUMAN SERUM.,CTNI CLIA MICROPARTICLES(CTNI CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) CONCENTRATION IN HUMAN SERUM AND PLASMA (HEPARIN OR SODIUM CITRATE), DHEA-S CLIA MICROPARTICLES(DHEA-S CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF DHEA-S (DEHYDROEPIANDROSTERONE SULFATE) IN HUMAN SERUM.,ACTH CLIA MICROPARTICLES(ACTH CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF ACTH (ADRENOCORTICOTROPIC HORMONE) IN HUMAN PLASMA (EDTA),HSV-2 IGG CLIA(HSV-2 IGG CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETECTION OF HSV-2 IGG (IGG ANTIBODIES TO HERPES SIMPLEX

	VIRUS TYPE 2) IN HUMAN SERUM OR PLASMA (EDTA, HEPARIN OR SODIUM CITRATE).,FT4 CLIA MICROPARTICLES(FT4 CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF FT4 (FREE THYROXINE) IN HUMAN SERUM.,CA50 CLIA(CA50 CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLEIMMUNOASSAY(CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF CA50 (CANCER ANTIGEN 50)IN HUMAN SERUM.,CALCITONIN CLIA MICROPARTICLES(CALCITONIN CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETECTION OF CALCITONIN IN HUMAN SERUM.,HSV-1 IGM CLIA(HSV-1 IGM CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETECTION OF HSV-1 IGM (IGM ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE 1) IN HUMAN SERUM OR PLASMA (EDTA, HEPARIN OR SODIUM CITRATE).,FT3 CLIA MICROPARTICLES (FT3 CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF FT3 (FREE TRIIODOTHYRONINE) IN HUMAN SERUM.,AFP CLIA(AFP CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF AFP (ALPHA-FETOPROTEIN) IN HUMAN SERUM.,ANGIOTENSIN II CLIA MICROPARTICLES (ANGIOTENSIN II CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF ANGIOTENSIN II IN HUMAN PLASMA (EDTA).,HSV-2 IGM CLIA(HSV-2 IGM CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETECTION OF HSV-2 IGM (IGM ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE 2) IN HUMAN SERUM OR PLASMA (EDTA, HEPARIN OR SODIUM CITRATE).,LH CLIA MICROPARTICLES(LH CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF LH (LUTEINIZING HORMONE) CONCENTRATION IN HUMAN SERUM., FERRITIN CLIA (FERRITIN CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLEIMMUNOASSAY (CLIA MICROPARTICLES) FOR THEQUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM.,T4 CLIA MICROPARTICLES(T4 CLIA

	MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF T4 (THYROXINE) IN HUMAN SERUM,CA125 CLIA (CA125 CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLEIMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OFCA125 (CANCER ANTIGEN 125) IN HUMAN SERUM.,MYO CLIA MICROPARTICLES(MYO CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN (MYO) CONCENTRATION IN HUMAN SERUM AND PLASMA (EDTA, HEPARIN OR SODIUM CITRATE).,CA19-9 CLIA(CA19-9 CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FORTHE QUANTITATIVE DETERMINATION OFCA19-9 (CANCER ANTIGEN 19-9) IN HUMAN SERUM.,AMH CLIA MICROPARTICLES(AMH CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETECTION OF ANTIMÜLLERIANHORMONE (AMH) IN HUMAN SERUM,CEA CLIA(CEA CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLEIMMUNOASSAY(CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF CEA (CARCINOEMBRYONIC ANTIGEN) IN HUMAN SERUM.,TESTOSTERONE CLIA MICROPARTICLES(TESTOSTERONE CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLEIMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE CONCENTRATION IN HUMAN SERUM.,CA15-3 CLIA(CA15-3 CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLEIMMUNOASSAY(CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OFCA15-3 (CANCER ANTIGEN 15-3) IN HUMAN SERUM.,CORTISOL CLIA MICROPARTICLES(CORTISOL CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM OR PLASMA (EDTA).,HSV-1 IGG CLIA(HSV-1 IGG CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETECTION OF HSV-1 IGG (IGG ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE 1) IN HUMAN SERUM OR PLASMA (EDTA, HEPARIN OR SODIUM CITRATE).,ALDOSTERONE CLIA MICROPARTICLES (ALDOSTERONE CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA

	MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF ALDOSTERONE IN HUMAN SERUM OR PLASMA (EDTA).,TPSA CLIA MICROPARTICLES(TPSA CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF TPSA (TOTAL PROSTATIC SPECIFIC ANTIGEN) IN HUMAN SERUM., VITAMIN B12 CLIA MICROPARTICLES(VITAMIN B12 CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETECTION OF VITAMIN B12 CONCENTRATION IN HUMAN SERUM.,SARS-COV-2 NAB Q CLIA MICROPARTICLES(SARS-COV-2 NAB Q CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF SARS-COV-2 NEUTRALIZATION ANTIBODIES (ANTIBODIES TO SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2) IN HUMAN SERUM AND PLASMA.,PRG CLIA MICROPARTICLES(PRG CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF PRG (PROGESTERONE) CONCENTRATION IN HUMAN SERUM.,TORCH IGG CONTROL(TORCH IGG CONTROL)-THIS PRODUCT IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURE FOR ANALYTES LISTED IN THIS INSTRUCTION FOR USE.,ANTI-TPO CLIA MICROPARTICLES(ANTI-TPO CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF ANTI-TPO (ANTIBODY TO THYROID PEROXIDASE) IN HUMAN SERUM., TUMOR MARKER CONTROL II(TUMOR MARKER CONTROL II)-THIS PRODUCT IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURE FOR ANALYTES LISTED IN THIS INSTRUCTION FOR USE.,FSH CLIA MICROPARTICLES(FSH CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF FSH (FOLLICLE-STIMULATING HORMONE) CONCENTRATION IN HUMAN SERUM.,HE4 CLIA MICROPARTICLES(HE4 CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF HE4(HUMAN EPIDIDYMAL PROTEIN 4) IN HUMAN SERUM.,TG CLIA MICROPARTICLES(TG CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE

	QUANTITATIVE DETERMINATION OF TG (THYROGLOBULIN) IN HUMAN SERUM,ADENOVIRUS IGM CLIA MICROPARTICLES(ADENOVIRUS IGM CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUALITATIVE DETERMINATION OF ADENOVIRUS IGM (IGM ANTIBODIES TO ADENOVIRUS) IN HUMAN SERUM OR PLASMA.,WASH BUFFER(WASH BUFFER)-WASH BUFFER IS USED FOR CLEANING DURING THE REACTION PROCESS IN THE DETECTION OF MEASURAND FOR IN VITRO DIAGNOSTIC DETECTION ASSAY.,SARS-COV-2 IGM II CLIA MICROPARTICLES(SARS-COV-2 IGM II CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUALITATIVE DETECTION OF SARS-COV-2 IGM (IGM ANTIBODIES TO SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2) IN HUMAN SERUM AND PLASMA.,E2 CLIA MICROPARTICLES(E2 CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF E2 (ESTRADIOL) CONCENTRATION IN HUMAN SERUM.,PCT CLIA MICROPARTICLES(PCT CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF PCT (PROCALCITONIN) IN HUMAN SERUM AND PLASMA (HEPARIN, EDTA).,IGF-1 CLIA MICROPARTICLES(IGF-1 CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF INSULIN-LIKE GROWTH FACTOR I (IGF-I) CONCENTRATION IN HUMAN SERUM AND PLASMA (HEPARIN).,P-AFP CLIA MICROPARTICLES(P-AFP CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF P-AFP (PREGNANCY ALPHA FETOPROTEIN) IN HUMAN SERUM., BETA2-MICROGLOBULIN CLIA MICROPARTICLES(BETA2-MICROGLOBULIN CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF 2-MICROGLOBULIN IN HUMAN SERUM.,TORCH IGM CONTROL(TORCH IGM CONTROL)-THIS PRODUCT IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURE FOR ANALYTES LISTED IN THIS INSTRUCTION FOR USE.,FREE BETA HCG CLIA MICROPARTICLES(FREE BETA HCG CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF

	FREE BETA HCG (FREE HUMAN CHORIONIC GONADOTROPIN) IN HUMAN SERUM.,UE3 CLIA MICROPARTICLES(UE3 CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETECTION OF UE3 IN HUMAN SERUM.,BETA-HCG CLIA MICROPARTICLES(BETA-HCG CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF -HCG (-HUMAN CHORIONIC GONADOTROPIN) IN HUMAN SERUM,FPSA CLIA MICROPARTICLES(FPSA CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF FPSA (FREE PROSTATIC SPECIFIC ANTIGEN) IN HUMAN SERUM.,PAPP-A CLIA MICROPARTICLES(PAPP-A CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF PAPP-A (PREGNANCY ASSOCIATED PLASMA PROTEIN A) IN HUMAN SERUM.,TB-IGRA CLIA MICROPARTICLES(TB-IGRA CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) USING SPECIFIC ANTIGEN REPRESENTING TO MYCOBACTERIUM TUBERCULOSIS PEPTIDES TO STIMULATE CELLS IN FRESH PERIPHERAL VENOUS ANTICOAGULANT BLOOD TO RELEASE INTERFERON-GAMMA (INTERFERON GAMMA RELEASE ASSAY, IGRA). DETECTION OF INTERFERON-GAMMA IS USED TO IDENTIFY SPECIFIC T-CELLS IMMUNOLOGICAL REACTION TO THOSE PEPTIDE ANTIGENS THAT ARE ASSOCIATED WITH MYCOBACTERIUM TUBERCULOSIS INFECTION.,PROGRP CLIA MICROPARTICLES(PROGRP CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF PROGRP(PRO-GASTRIN-RELEASING PEPTIDE) IN HUMAN SERUM.,RSV IGM CLIA MICROPARTICLES(RSV IGM CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUALITATIVE DETECTION OF RSV IGM (IGM ANTIBODIES TO RESPIRATORY SYNCYTIAL VIRUS) IN HUMAN SERUM AND PLASMA.,ENTEROVIRUS 71 IGM CLIA MICROPARTICLES(ENTEROVIRUS 71 IGM CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUALITATIVE DETERMINATION OF ENTEROVIRUS 71 IGM (IGM ANTIBODIES TO ENTEROVIRUS) IN HUMAN SERUM OR PLASMA.,NT-PROBNP CLIA MICROPARTICLES(NT-PROBNP CLIA MICROPARTICLES)-THIS ASSAY

		IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF NT-PROBNP (N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE) IN HUMAN SERUM AND PLASMA.,SARS-COV-2 IGG II CLIA MICROPARTICLES(SARS-COV-2 IGG II CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUALITATIVE DETECTION OF SARS-COV-2 IGG (IGG ANTIBODIES TO SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2) IN HUMAN SERUM AND PLASMA.,ANTI-SARS-COV-2 RBD CLIA MICROPARTICLES(ANTI-SARS-COV-2 RBD CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DETERMINATION OF ANTIBODIES (INCLUDING IGG) TO SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) SPIKE (S) PROTEIN RECEPTOR BINDING DOMAIN (RBD) IN HUMAN SERUM AND PLASMA., FOLATE CLIA MICROPARTICLES(FOLATE CLIA MICROPARTICLES)-THIS ASSAY IS BASED ON A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CLIA MICROPARTICLES) FOR THE QUANTITATIVE DE TERMINATION OF FOLATE CONCENTRATION IN HUMAN SERUM.
368	IMP/IVD/2019/000396	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MYOGLOBIN CALIBRATOR (MYOGLOBIN CALIBRATOR)-THE MYOGLOBIN CALIBRATOR IS A BUFFER BASED MATRIX CONTAINING HUMAN MYOGLOBIN INTENDED TO BE USED WITH THE MYOGLOBIN REAGENT OSR6168 FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN ON BECKMAN COULTER ANALYSERS.,MYOGLOBIN(MYOGLOBIN)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM ON BECKMAN COULTER ANALYSERS.

369	IMP/IVD/2019/000397	1.License Holder Name: SNIBE DIAGNOSTIC (INDIA) PRIVATE LIMITED. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EBV NA IGA(MAGLUMI EBV NA IGA (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV NA IGA IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER , APOLIPOPROTEIN (APOLIPOPROTEIN E ASSAY KIT (IMMUNOTURBIDIMETRIC))-THE SNIBE BIOSSAYSTM APOE REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN E IN HUMAN SERUM.,PROGRP(MAGLUMI PROGRP (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGRP IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER ,DIRECT RENIN CLIA TEST(MAGLUMI DIRECT RENIN (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF RENIN IN HUMAN EDTA-PLASMA SPECIMENS, EBV EA IGG(MAGLUMI EBV EA IGG (CLIA))-THE KIT IS AN IN VITROCHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV EA IGG IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER ,ANTI-RIB-P IGG (CLIA)(MAGLUMI ANTI-RIB-P IGG (CLIA))-THE KIT IS AN IN VITROCHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGGANTIBODIES TO RIB-P (ANTI-RIB-PIGG) IN HUMAN SERUMAND PLASMA USING THE MAGLUMI SERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,2-MICROGLOBULIN(MAGLUMI 2-MG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 2 -MICROGLOBULIN (2 -MG) IN HUMAN SERUM OR URINE USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,GLUCOSE (GLUCOSE ASSAY KIT (HEXOKINASE))-THE SNIBE BIOSSAYSTM GLU REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM. ,EBV VCA IGA(MAGLUMI EBV VCA IGA (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV VCA IGA IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER ,INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN 3 CLIA TEST(MAGLUMI IGFBP-3 (CLIA))-THE KIT IS AN IN-VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF

	INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN 3 (IGFBP-3) IN HUMAN SERUM,TG(MAGLUMI TG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,LACTATE(LACTATE (LOX-PAP))-THE SNIBE BIOSSAYSTMLAC REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LACTATE IN HUMAN PLASMA,EBV EA IGA (MAGLUMI EBV EA IGA (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV EA IGA IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,TRANSFERRIN(TRANSFERRIN (IMMUNOTURBIDIMETRIC))-THE SNIBEBIOSSAYSTMTRF REAGENT ISINTENDED FOR QUANTITATIVE DETERMINATION OFTRANSFERRININ HUMAN SERUM. ,HER-2(MAGLUMI HER-2 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HER-2 IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER ,ANTI-CYCLIC CITRULLINATED PEPTIDES CLIA TEST(MAGLUMI ANTI-CCP (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG AUTO ANTIBODIES TO CYCLIC CITRULLINATED PEPTIDES (ANTI-CCP) IN HUMAN SERUM AND PLASMA,EBV NA IGG(MAGLUMI EBV NA IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV NA IGG IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER ,ANTBODY TO ISLET CELLS OF PANCREAS CLIA TEST(MAGLUMI ICA (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO ISLET CELLS OF PANCREAS (ICA) IN HUMAN SERUM,HCG(MAGLUMI HCG/-HCG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (-SUBUNIT) (HCG/-HCG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,CANCER ANTIGEN 72-4 CLIA TEST (MAGLUMI CA 72-4 (CLIA))-THE KIT IS AN IN-VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 72-4 (CA 72-4) IN HUMAN SERUM,BNP(MAGLUMI BNP (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF BNP IN HUMAN EDTA PLASMA WITH THE

	MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER ,HYALURONIC ACID CLIA TEST(MAGLUMI HA (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HYALURONIC ACID (HA) IN HUMAN SERUM,FREE -HCG(MAGLUMI FREE -HCG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE -CHAINS OF HUMAN CHORIONIC GONADOTROPIN (FREE -HCG) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,ANTI-SS-B IGG (CLIA)(MAGLUMI ANTI-SS-B IGG (CLIA))-THE KIT IS AN IN VITROCHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGGANTIBODIES TO SS-B(ANTI-SS-BIGG) IN HUMAN SERUMAND PLASMA USING THE MAGLUMI SERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS)., EBV VCA IGG(MAGLUMI EBV VCA IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV VCA IGG IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER ,HE4 CLIA TEST(MAGLUMI HE4 (CLIA))-THE KIT IS AN IN-VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HE4 IN HUMAN SERUM AND PLASMA,PAPP-A(MAGLUMI PAPP-A (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PLASMA PROTEIN A (PAPP-A) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,ANTI-SS-A IGG (CLIA)(MAGLUMI ANTI-SS-A IGG (CLIA))-THE KIT IS AN IN VITROCHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGGANTIBODIES TO SS-A(ANTI-SS-AIGG) IN HUMAN SERUMAND PLASMA USING THE MAGLUMI SERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS)., EBV VCA IGM(MAGLUMI EBV VCA IGM (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV VCA IGM IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER ,CANCER ANTIGEN 242 CLIA TEST (MAGLUMI CA 242 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 242 (CA 242) IN HUMAN

	SERUM,AFP(MAGLUMI AFP (PRENATAL SCREENING) (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF AFP IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,EXTRACTABLE NUCLEAR ANTIGENS CLIA TEST(MAGLUMI ENA SCREEN (CLIA))-THE KIT IS AN IN-VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES TO EXTRACTABLE NUCLEAR ANTIGENS (ENA) IN HUMAN SERUM AND PLASMA, CALCITONIN(MAGLUMI CALCITONIN (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CALCITONIN (CT) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,ALKALINE WASH SOLUTION(ALKALINE WASH)-ALKALINE WASH IS USED TO WASH THE PIPING, REAGENT PROBE AND ASSAY CUP OF AUTOMATIC BIOCHEMISTRY ANALYZER., COLLAGEN TYPE N-PEPTIDE (PP N-P) CLIA TEST(MAGLUMI PP N-P (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF COLLAGEN TYPE N-PEPTIDE (PP N-P) IN HUMAN SERUM,OSTEOCALCIN CLIA TEST (MAGLUMI OSTEOCALCIN (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF OSTEOCALCIN (BGP) IN HUMAN SERUM, CYFRA21-1 CLIA TEST(MAGLUMI CYFRA21-1 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CYFRA21-1 IN HUMAN SERUM, MYOGLOBIN CLIA TEST(MAGLUMI MYOGLOBIN (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM, ANTI-JO-1 IGG (CLIA)(MAGLUMI ANTI-JO-1 IGG (CLIA))-THE KIT IS AN IN VITROCHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGGANTIBODIES TO JO-1(ANTI-JO-1IGG) IN HUMAN SERUMAND PLASMA USING THE MAGLUMI SERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,C-REACTIVE PROTEIN CLIA TEST(MAGLUMI CRP (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM,IL-6 (CLIA)(MAGLUMI IL-6 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IL-6 IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING

	MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS)., ANTI-SM IGG (CLIA)(MAGLUMI ANTI-SM IGG (CLIA))-THE KIT IS AN IN VITROCHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGGANTIBODIES TO SM(ANTI-SMIGG) IN HUMAN SERUMAND PLASMA USING THE MAGLUMI SERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,H. PYLORI IGA CLIA TEST(MAGLUMI H.PYLORI IGA (CLIA))-THE KIT IS AN IN-VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF H. PYLORI IGA IN HUMAN SERUM, PROCALCITONIN CLIA TEST(MAGLUMI PCT (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PCT IN HUMAN SERUM AND PLASMA,H.PYLORI IGM CLIA TEST(MAGLUMI H.PYLORI IGM (CLIA))-THE KIT IS AN IN-VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF H. PYLORI IGM IN HUMAN SERUM,CANCER ANTIGEN 50 CLIA TEST(MAGLUMI CA 50 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 50 (CA 50) IN HUMAN SERUM,PEPSINOGEN 2 CLIA TEST(MAGLUMI PG 2 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN (PG) IN HUMAN SERUM,S-100 CLIA TEST(MAGLUMI S-100 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF S-100(S100 A1B AND S100 BB) IN HUMAN SERUM,DIGOXIN CLIA TEST(MAGLUMI DIGOXIN (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN IN HUMAN SERUM, PROINSULIN CLIA TEST(MAGLUMI PROINSULIN (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROINSULIN IN HUMAN SERUM, LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 CLIA TEST (MAGLUMI LP-PLA2 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 (LP-PLA2) IN HUMAN SERUM,H-FABP CLIA TEST(MAGLUMI H-FABP (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN H-FABP IN HUMAN SERUM AND PLASMA,CARDIAC TROPONIN I CLIA TEST (MAGLUMI HS-CTNI (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN HUMAN SERUM

	AND PLASMA,17-OH PROGESTERONE CLIA TEST(MAGLUMI 17-OH PROGESTERONE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 17-OH PROGESTERONE IN HUMAN SERUM, ANDROSTENEDIONE CLIA TEST(MAGLUMI ANDROSTENEDIONE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANDROSTENEDIONE IN HUMAN SERUM AND PLASMA,LAMININ CLIA TEST(MAGLUMI LAMININ (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LAMININ (LN) IN HUMAN SERUM,D-DIMER CLIA TEST(MAGLUMI D-DIMER (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA, ANGIOTENSIN CLIA TEST(MAGLUMI™ A (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANGIOTENSIN (A) IN HUMAN PLASMA,INSULIN AUTOANTIBODIES CLIA TEST(MAGLUMI IAA (CLIA)) -THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN AUTOANTIBODIES (IAA) IN HUMAN SERUM,H.PYLORI IGG CLIA TEST(MAGLUMI H.PYLORI IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF H.PYLORI IGG IN HUMAN SERUM,GASTRIN-17 CLIA TEST(MAGLUMI GASTRIN-17 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GASTRIN-17 IN HUMAN SERUM,TISSUE POLYPEPTIDE ANTIGEN CLIA TEST(MAGLUMI TPA-SNIBE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TISSUE POLYPEPTIDE ANTIGEN (TPA-SNIBE) IN HUMAN SERUM,BILE ACID (BILE ACID ASSAY KIT (ENZYME CYCLING))-THE SNIBE BIOSSAYSTM TBA REAGENT IS INTENDED FOR QUANTITATIVE DETERMI-NATION OF TOTAL BILE ACIDS IN HUMAN SERUM.,ANTI-NRNP/SM IGG (CLIA) (MAGLUMI ANTI-NRNP/SM IGG (CLIA))-THE KIT IS AN IN VITROCHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGGANTIBODIES TO NRNP/SM(ANTI-NRNP/SMIGG) IN HUMAN SERUMAND PLASMA USING THE MAGLUMI SERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,TOTAL PROTEIN (TOTAL PROTEIN ASSAY KIT (BIURET))-THE SNIBE BIOSSAYSTM TP REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM.,CREATINE KINASE (NAC ACTIVATED)(CREATINE KINASE (NAC ACTIVATED) ASSAY KIT (IFCC))-THE SNIBE BIOSSAYSTM CK REAGENT

	IS INTENDED FOR QUANTITATIVE DETERMINATION OF CREATINE KINASE IN HUMAN SERUM. ,ALPHA-AMYLASE(ALPHA-AMYLASE ASSAY KIT (EPS-G7))-THE SNIBE BIOSSAYSTM ALPHA-AMY REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF -AMYLASE IN HUMAN SERUM.,ACID WASH SOLUTION(ACID WASH)-ACID WASH IS USED TO CLEAN CROSS CONTAMINATION OF AUTOMATIC BIOCHEMISTRY ANALYZER.,CREATININE (CREATININE ASSAY KIT (PAP))-THE SNIBE BIOSSAYSTM CR REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM., ALBUMIN(ALBUMIN ASSAY KIT (BCG))-THE SNIBE BIOSSAYSTM ALB REAGENT IS INTENDED FOR THE IN VITRO DIRECT QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM. ,CREATINE KINASE-MB ISOZYME(CREATINE KINASE-MB ISOZYME ASSAY KIT (IMMUNOSUPPRESSION))-THE SNIBE BIOSSAYSTM CK-MB REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CREATINE KINASE-MB IN HUMAN SERUM,ALANINE AMINOTRANSFERASE (ALANINE AMINOTRANSFERASE ASSAY KIT (IFCC))-THE SNIBE BIOSSAYSTM ALT REAGENT IS INTENDED FOR QUANTITATIVE DETERMI-NATION OF ALANINE AMINOTRANSFERASE IN HUMAN SERUM.,URIC ACID(URIC ACID ASSAY KIT (URICASE- PAP))-THE SNIBE BIOSSAYSTM UA REAGENT IS INTENDED FOR QUANTITATIVE DETERMINA-TION OF URIC ACID IN HUMAN SERUM. , APOLIPOPROTEIN B(APOLIPOPROTEIN B (IMMUNOTURBIDIMETRIC))-THE SNIBE BIOSSAYSTM APOB REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN B IN HUMAN SERUM.,UREA ASSAY (UREA ASSAY KIT (UREASE KINETIC))-THE SNIBE BIOSSAYSTM UREA REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM. ,CUVETTE(CUVETTE)-CUVETTES REQUIRED FOR THE IMPLEMENTATION OF THE ASSAYS ON THE BIOSSAYS 240 AUTOMATIC BIOCHEMISTRY ANALYZER., HITERGENT WASH SOLUTION(HITERGENT)-HITERGENT IS USED TO WASH THE PENTROUGH, REAGENT PROBE, STIRRING ARM AND ASSAY CUP OF AUTOMATIC BIOCHEMISTRY ANALYZER.,ISE CLEANER SOLUTION(ISE CLEANER)-ISE CLEANER IS USED TO WASH THE ISE OF AUTOMATIC BIOCHEMISTRY ANALYZER.,ANTI-HISTONES IGG (CLIA) (MAGLUMI ANTI-HISTONES IGG (CLIA))-THE KIT IS AN IN VITROCHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGGANTIBODIES TO HISTONES(ANTI-HISTONESIGG) IN HUMAN SERUMAND PLASMA USING THE MAGLUMI SERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,INORGANIC PHOSPHORUS(INORGANIC PHOSPHORUS (MOLYBDATE))-THE SNIBEBIOSSAYSTM PHOS

	REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHORUS (PHOS) IN HUMAN SERUM.,ALPHA-HYDROXYBUTYRATE DEHYDROGENASE(ALPHA-HYDROXYBUTYRATE DEHYDROGENASE ASSAY KIT (DGKC))-THE SNIBE BIOSSAYSTM ALPHA-HBDH REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALPHA-HYDROXYBUTYRATE DEHYDROGENASE IN HUMAN SERUM.,LACTATE DEHYDROGENASE(LACTATE DEHYDROGENASE ASSAY KIT (LP))-THE SNIBE BIOSSAYSTM LDH REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE IN HUMAN SERUM. ,LIPOPROTEIN (A) (LIPOPROTEIN (A) ASSAY KIT (IMMUNOTURBIDIMETRIC))-THE SNIBE BIOSSAYSTM LP(A) REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LIPOPROTEIN(A) IN HUMAN SERUM., TRIGLYCERIDES (TRIGLYCERIDES ASSAY KIT (GPO- PAP))-THE SNIBE BIOSSAYSTM TG REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF TRIGLYCERIDE IN HUMAN SERUM.,DIRECT BILIRUBIN (DIRECT BILIRUBIN ASSAY KIT (VANADATE))-THE SNIBE BIOSSAYSTM DBIL REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM. ,IRON (IRON (FERENE))-THE SNIBEBIOSSAYSTMIRONREAGENT IS USED FOR QUANTITATIVE DETERMINATION OFIRON IN HUMAN SERUM. ,TSH RECEPTOR ANTIBODIES CLIA TEST(MAGLUMI TRAB (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TSH RECEPTOR ANTIBODIES (TRAB) IN HUMAN SERUM,APOLIPOPROTEIN A1(APOLIPOPROTEIN A1 (IMMUNOTURBIDIMETRIC))-THE SNIBE BIOSSAYSTM APOA1 REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A1 IN HUMAN SERUM.,ASPARTATE AMINOTRANSFERASE(ASPARTATE AMINOTRANSFERASE ASSAY KIT (IFCC))-THE SNIBE BIOSSAYSTM AST REAGENT IS INTENDED FOR QUANTITATIVE DE-TERMINATION OF ASPARTATE AMINOTRANSFERASE IN HUMAN SERUM. ,SQUAMOUS CELL CARCINOMA ANTIGEN CLIA TEST(MAGLUMI SCCA (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF SQUAMOUS CELL CARCINOMA ANTIGEN (SCCA) IN HUMAN SERUM,CALCIUM(CALCIUM (OCPC))-THE SNIBE BIOSSAYSTM CA REAGENT IS USED FOR QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM.,IMMUNOGLOBULIN-A(IMMUNOGLOBULIN-A (IMMUNOTURBIDIMETRIC))-THE SNIBE BIOSSAYSTMIGA REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN-A IN HUMAN SERUM.,TOTAL CHOLESTEROL(TOTAL CHOLESTEROL ASSAY KIT (CHOD-PAP))-THE SNIBE BIOSSAYSTM TC REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL IN HUMAN SERUM.,

	ALKALINE PHOSPHATASE(ALKALINE PHOSPHATASE ASSAY KIT (IFCC))-THE SNIBE BIOSSAYSTM ALP REAGENT IS INTENDED FOR QUANTITATIVE DETER-MINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM.,LDL CHOLESTEROL(LOW DENSITY LIPOPROTEIN CHOLESTEROL ASSAY KIT (CAT))-THE SNIBE BIOSSAYSTM LDL-C REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL IN HUMAN SERUM.,HDL CHOLESTEROL(HIGH DENSITY LIPOPROTEIN CHOLESTEROL ASSAY KIT (PPD))-THE SNIBE BIOSSAYSTM HDL-C REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL IN HUMAN SERUM.,IMMUNOGLOBULIN-G (IMMUNOGLOBULIN-G(IMMUNOTURBIDIMETRIC))-THE SNIBE BIOSSAYSTMIGG REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN-G IN HUMAN SERUM., IMMUNOGLOBULIN-M(IMMUNOGLOBULIN-M (IMMUNOTURBIDIMETRIC))-THE SNIBE BIOSSAYSTM IGM REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN-M IN HUMAN SERUM.,ANTI-M2-3E IGG (CLIA) (MAGLUMI ANTI-M2-3E IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO M2-3E(ANTI-M2-3E IGG) IN HUMAN SERUMAND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS)., THYROID MICROSOMAL AUTOANTIBODY CLIA TEST(MAGLUMI TMA (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID MICROSOMAL AUTOANTIBODY (TMA) IN HUMAN SERUM,HOMOCYSTEINE (HOMOCYSTEINE ASSAY KIT (ENZYME CYCLING))-THE SNIBE BIOSSAYSTM HCY REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF HOMOCYSTEINE IN HUMAN SERUM. ,FOLIC ACID CLIA TEST(MAGLUMI FA (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLIC ACID (FA) IN HUMAN SERUM,ANTI-CENTROMERES IGG (CLIA)(MAGLUMI ANTI-CENTROMERES IGG (CLIA)) -THE KIT IS AN IN VITROCHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGGANTIBODIES TO CENTROMERES(ANTI-CENTROMERESIGG) IN HUMAN SERUMAND PLASMA USING THE MAGLUMI SERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS)., IMMUNOGLOBULIN A CLIA TEST(MAGLUMI IGA (URINE ANALYSIS)

	(CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN URINE,ANTI-SCL-70 IGG (CLIA)(MAGLUMI ANTI-SCL-70 IGG (CLIA))-THE KIT IS AN IN VITROCHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGGANTIBODIES TO SCL-70 (ANTI-SCL-70 IGG) IN HUMAN SERUMAND PLASMA USING THE MAGLUMI SERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS)., REVERSE TRIIODOTHYRONINE CLIA TEST(MAGLUMI REV T3 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF REVERSE TRIIODOTHYRONINE (REVT3) IN HUMAN SERUM,ISE-REAGENT PACK (ISE-REAGENT PACK)-ISE REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF K+, NA+, CL- AND CA2+ IN HUMAN SERUM USING THE AUTOMATIC BIOCHEMISTRY ANALYZER BC1200 ELECTROLYTE MODULE, ELECTROLYTE ANALYZER (E1200) AND INTEGRATED SYSTEM (BIOLUMI 8000).,SEX HARMONE-BINDING GLOBULIN CLIA TEST(MAGLUMI SHBG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF SEX HARMONE-BINDING GLOBULIN IN HUMAN SERUM AND PLASMA,PEPSINOGEN 1 CLIA TEST(MAGLUMI PG 1 (CLIA)) -THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN (PG) IN HUMAN SERUM,ALBUMIN CLIA TEST(MAGLUMI ALBUMIN (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN URINE, IMMUNOGLOBULIN A CLIA TEST(MAGLUMI IGA (SERUM ANALYSIS) (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN SERUM,COLLAGEN CLIA TEST(MAGLUMI C (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TYPE COLLAGEN (C) IN HUMAN SERUM,GROWTH HORMONE CLIA TEST(MAGLUMI GH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GROWTH HORMONE (GH) IN HUMAN SERUM,N-TERMINAL PROHORMONE B-TYPE NATRIURETIC PEPTIDE CLIA TEST(MAGLUMI NT-PROBNP (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF N-TERMINAL PROHORMONE B-TYPE NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM,ANTI-DOUBLE-STRANDED DNA CLIA TEST(MAGLUMI ANTI-DSDNA IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY

		FOR THE QUANTITATIVE DETERMINATION OF IGG AUTO ANTIBODIES TO DOUBLE-STRANDED DNA (ANTI-DSDNA IGG) IN HUMAN SERUM AND PLASMA,CHAGAS CLIA TEST(MAGLUMI CHAGAS (CLIA))-THE KIT IS AN IN-VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG ANTIBODIES TO TRYPANOSOMACRUZI (T. CRUZI) IN HUMAN SERUM AND PLASMA, ANTINUCLEAR ANTIBODIES CLIA TEST(MAGLUMI ANA SCREEN (CLIA) -THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTINUCLEAR ANTIBODIES (ANA) IN HUMAN SERUM AND PLASMA, ADRENOCORTICOTROPIC HORMONE CLIA TEST(MAGLUMI ACTH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ADRENOCORTICOTROPIC HORMONE (ACTH) IN HUMAN PLASMA, CHOLYLGLYCINE CLIA TEST(MAGLUMI CHOLYLGLYCINE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CHOLYLGLYCINE (CG) IN HUMAN SERUM,TOTAL BILIRUBIN(TOTAL BILIRUBIN ASSAY KIT (VANADATE))-THE SNIBE BIOSSAYSTM TBIL REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM.,GAMMA-GLUTAMYL TRANSFERASE(GAMMA-GLUTAMYL TRANSFERASE ASSAY KIT (IFCC))-THE SNIBE BIOSSAYSTM GGT REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF GAMMA-GLUTAMYL TRANSFERASE IN HUMAN SERUM.
370	IMP/IVD/2019/000398	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONDITIONING NA SOLUTION(CONDITIONING NA SOLUTION)-USED FOR CONDITIONING SODIUM ELECTRODE IN ANALYZERS. FOR IN VITRO DIAGNOSTIC USE ONLY.,CLEANING SOLUTION(CLEANING SOLUTION)-USED FOR CLEANING SAMPLE PROBES, TUBING AND ELECTRODES IN ANALYZERS. FOR IN VITRO DIAGNOSTIC USE ONLY.,REAGENT PACK (REAGENT PACK)-USED FOR THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM, CHLORIDE OR LITHIUM IN SERUM, PLASMA, URINE, WHOLE BLOOD & CSF USING THE BIOLYTE ANALYZER. FOR IN VITRO DIAGNOSTIC USE ONLY.

371	IMP/IVD/2019/000399	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COULTER AC•T 5DIFF FIX (COULTER AC•T 5DIFF FIX)-FOR USE AS A LEUKOCYTE REAGENT TO DIFFERENTIATE SUBPOPULATIONS OF WHITE BLOOD CELLS ON COULTER AC•T 5DIFF HEMATOLOGY ANALYZERS. INTENDED FOR USE ONLY WITH SPECIFIC AC•T 5DIFF REAGENTS. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE.,COULTER AC•T 5DIFF WBC LYSE(COULTER AC•T 5DIFF WBC LYSE)-FOR USE AS AN ERYTHROCYTE LYTIC REAGENT FOR LEUKOCYTE COUNTING AND BASOPHIL DIFFERENTIATION ON COULTER AC•T 5DIFF HEMATOLOGY ANALYZERS. INTENDED FOR USE ONLY WITH SPECIFIC AC•T 5DIFF REAGENTS. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

372	IMP/IVD/2019/000400	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALINITY C ASO-RF CONTROL II KIT(ALINITY C ASO-RF CONTROL II KIT)-THE ALINITY C ASO-RF CONTROL II (HIGH LEVEL) IS INTENDED FOR USE IN MONITORING THE QUALITY CONTROL OF RESULTS OBTAINED WITH THE ALINITY C ASO AND ALINITY C RF ASSAYS BY TURBIDIMETRY., QUANTIA DIGITOXIN CONTROL(QUANTIA DIGITOXIN CONTROL)-THE QUANTIA DIGITOXIN CONTROL IS INTENDED FOR USE IN MONITORING THE QUALITY CONTROL OF RESULTS OBTAINED WITH THE QUANTIA DIGITOXIN ASSAY BY TURBIDIMETRY.,ALINITY C FERRITIN/MYOGLOBIN/IGE CONTROL KIT(ALINITY C FERRITIN/MYOGLOBIN/IGE CONTROL KIT)-THE ALINITY C FERRITIN/MYOGLOBIN/IGE CONTROL KIT IS INTENDED FOR USE IN MONITORING THE QUALITY CONTROL OF RESULTS OBTAINED WITH THE ALINITY C MYOGLOBIN ASSAY BY TURBIDIMETRY. THIS CONTROL IS INTENDED TO BE USED TOGETHER WITH THE ALINITY C MYOGLOBIN REAGENT ON THE ALINITY C ANALYZER.,QUANTIA D-DIMER CONTROL(QUANTIA D-DIMER CONTROL)-THE QUANTIA D-DIMER CONTROL IS INTENDED FOR USE IN MONITORING THE QUALITY CONTROL OF RESULTS OBTAINED WITH THE QUANTIA D-DIMER ASSAY BY TURBIDIMETRY.,ALINITY C MYOGLOBIN STANDARD (ALINITY C MYOGLOBIN STANDARD)-THE ALINITY C MYOGLOBIN STANDARD IS INTENDED FOR USE IN ESTABLISHING THE CALIBRATION FOR THE ALINITY C MYOGLOBIN ASSAY BY TURBIDIMETRY. THIS STANDARD IS INTENDED TO BE USED TOGETHER WITH THE ALINITY C MYOGLOBIN REAGENTS. CAREFULLY READ THE INSTRUCTIONS WITH THE CORRESPONDING REAGENTS BEFORE USE.,QUANTIA ASO(QUANTIA ASO)-THE QUANTIA ASO REAGENTS ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN-O IN HUMAN SERUM USING THE ABBOTT ARCHITECT C SYSTEMS.,ALINITY C A-1-AGP REAGENT KIT(ALINITY C A-1-AGP REAGENT KIT)-THE ALINITY C A-1-AGP ASSAY IS USED FOR THE QUANTITATIVE DETERMINATION OF A-1-ACID GLYCOPROTEIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,QUANTIA IGE(QUANTIA IGE)-THE QUANTIA IGE REAGENTS ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) IN HUMAN SERUM OR PLASMA USING THE ABBOTT ARCHITECT C SYSTEMS.,ALINITY C LP(A) REAGENT KIT(ALINITY C LP(A) REAGENT KIT)-THE ALINITY C LP(A) ASSAY IS USED FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN(A) IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER. ,QUANTIA DIGITOXIN STANDARD (QUANTIA DIGITOXIN STANDARD)-THE QUANTIA DIGITOXIN CALIBRATOR IS INTENDED FOR USE IN ESTABLISHING THE

	CALIBRATION FOR THE QUANTIA DIGITOXIN ASSAY BY TURBIDIMETRY.,ALINITY C BETA 2-MICROGLOBULIN REAGENT KIT (ALINITY C BETA 2-MICROGLOBULIN REAGENT KIT)-THE ALINITY C 2-MICROGLOBULIN REAGENTS ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF 2-MICROGLOBULIN (2M) IN HUMAN SERUM, PLASMA, OR URINE SAMPLES USING THE ALINITY C ANALYZER.,QUANTIA MYOGLOBIN(QUANTIA MYOGLOBIN)-THE QUANTIA MYOGLOBIN REAGENTS ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM OR PLASMA USING THE ARCHITECT C SYSTEMS.,ALINITY C ASO STANDARD(ALINITY C ASO STANDARD)-THE ALINITY C ASO STANDARD IS USED FOR ESTABLISHING THE CALIBRATION CURVE FOR THE ALINITY C ASO ASSAY BY TURBIDIMETRY ON THE ALINITY C ANALYZER. THIS STANDARD IS INTENDED TO BE USED TOGETHER WITH THE ALINITY C ASO REAGENTS.,QUANTIA MYOGLOBIN STANDARD (QUANTIA MYOGLOBIN STANDARD)-THE QUANTIA MYOGLOBIN CALIBRATOR IS INTENDED FOR USE IN ESTABLISHING THE CALIBRATION FOR THE QUANTIA MYOGLOBIN ASSAY BY TURBIDIMETRY.,ALINITY C LP(A) CONTROL KIT(ALINITY C LP(A) CONTROL KIT)-THE ALINITY C LP(A) CONTROL I AND ALINITY C LP(A) CONTROL II ARE INTENDED FOR USE AS ASSAYED QUALITY CONTROL MATERIALS FOR THE QUANTITATIVE MONITORING OF LIPOPROTEIN (A) WITH THE ALINITY C LP(A) REAGENTS BY TURBIDIMETRY ON THE ALINITY C ANALYZER.,QUANTIA A-1-AGP REAGENT KIT(QUANTIA A-1-AGP REAGENT KIT)-THE QUANTIA A-1-AGP REAGENTS ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF A-1-ACID GLYCOPROTEIN IN HUMAN SERUM OR PLASMA USING THE ABBOTT ARCHITECT C SYSTEMS.,ALINITY C RF REAGENT KIT(ALINITY C RF REAGENT KIT)-THE ALINITY C RF ASSAY IS USED FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS (RF) IN HUMAN SERUM ON THE ALINITY C ANALYZER.,QUANTIA ß2-MICROGLOBULIN STANDARD(QUANTIA ß2-MICROGLOBULIN STANDARD)-THE QUANTIA ß2-MICROGLOBULIN STANDARD IS INTENDED FOR USE IN ESTABLISHING THE CALIBRATION FOR THE QUANTIA ß2-MICROGLOBULIN ASSAY BY TURBIDIMETRY. THIS STANDARD IS INTENDED TO BE USED TOGETHER WITH THE QUANTIA ß2-MICROGLOBULIN REAGENTS.,ALINITY C PROTEINS CONTROL KIT (ALINITY C PROTEINS CONTROL KIT)-THE ALINITY C PROTEINS CONTROL IS INTENDED FOR USE IN MONITORING THE QUALITY CONTROL OF RESULTS OBTAINED WITH THE ALINITY C (A-1-AGP, A1-ANTITRYPSIN, BETA 2MICROGLOBULIN) ASSAYS BY TURBIDIMETRY. THIS CONTROL IS INTENDED TO BE USED TOGETHER WITH THE ALINITY C (A-1-AGP, A1- ANTITRYPSIN, BETA 2MICROGLOBULIN) REAGENTS ON THE ALINITY C ANALYZER. CAREFULLY READ THE

	INSTRUCTIONS WITH THE CORRESPONDING REAGENTS BEFORE USE., QUANTIA ß2-MICROGLOBULIN(QUANTIA ß2-MICROGLOBULIN)-THE QUANTIA ß2-MICROGLOBULIN REAGENTS ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF ß2-MICROGLOBULIN (ß2M) IN HUMAN SERUM, PLASMA, OR URINE SAMPLES USING THE ABBOTT ARCHITECT C SYSTEMS.,ALINITY C ASO REAGENT KIT(ALINITY C ASO REAGENT KIT)-THE ALINITY C ASO ASSAY IS USED FOR THE QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN-O IN HUMAN SERUM ON THE ALINITY C ANALYZER.,QUANTIA ASO STANDARD (QUANTIA ASO STANDARD)-THE QUANTIA ASO CALIBRATOR IS INTENDED FOR USE IN ESTABLISHING THE CALIBRATION FOR THE QUANTIA ASO ASSAY BY TURBIDIMETRY., ALINITY C ASO-RF CONTROL I KIT(ALINITY C ASO-RF CONTROL I KIT)-THE ALINITY C ASO-RF CONTROL I IS INTENDED FOR USE IN MONITORING THE QUALITY CONTROL OF RESULTS OBTAINED WITH THE ALINITY C ASO AND ALINITY C RF ASSAYS BY TURBIDIMETRY., QUANTIA LP(A) CALIBRATOR(QUANTIA LP(A) CALIBRATOR)-THE QUANTIA LP(A) CALIBRATOR IS INTENDED FOR USE IN ESTABLISHING THE CALIBRATION FOR THE QUANTIA LP(A) ASSAY BY TURBIDIMETRY.,ALINITY C PROTEINS STANDARD(ALINITY C PROTEINS STANDARD)-THE ALINITY C PROTEINS STANDARD IS INTENDED FOR USE IN ESTABLISHING THE CALIBRATION FOR THE ALINITY C (A-1-AGP, A1-ANTITRYPSIN) ASSAYS BY TURBIDIMETRY. THIS STANDARD IS INTENDED TO BE USED TOGETHER WITH THE ALINITY C (A-1-AGP, A1-ANTITRYPSIN) REAGENTS ON THE ALINITY C ANALYZER. CAREFULLY READ THE INSTRUCTIONS WITH THE CORRESPONDING REAGENTS BEFORE USE.,QUANTIA D-DIMER STANDARD (QUANTIA D-DIMER STANDARD)-THE QUANTIA D-DIMER CALIBRATOR IS INTENDED FOR USE IN ESTABLISHING THE CALIBRATION FOR THE QUANTIA D-DIMER ASSAY BY TURBIDIMETRY.,ALINITY C RF STANDARD(ALINITY C RF STANDARD)-THE ALINITY C RF STANDARD IS USED FOR ESTABLISHING THE CALIBRATION CURVE FOR THE ALINITY C RF ASSAY BY TURBIDIMETRY ON THE ALINITY C ANALYZER. THIS STANDARD IS INTENDED TO BE USED TOGETHER WITH THE ALINITY C RF REAGENTS.,QUANTIA FERRITIN/MYOGLOBIN/IGE CONTROL(QUANTIA FERRITIN/MYOGLOBIN/IGE CONTROL)-THE QUANTIA FERRITIN/MYOGLOBIN/IGE CONTROL IS INTENDED FOR USE IN MONITORING THE QUALITY CONTROL OF RESULTS OBTAINED WITH THE QUANTIA (FERRITIN, MYOGLOBIN, AND IGE) ASSAYS BY TURBIDIMETRY.,ALINITY C BETA 2-MICROGLOBULIN STANDARD (ALINITY C BETA 2-MICROGLOBULIN STANDARD)-THE ALINITY C 2-MICROGLOBULIN STANDARD IS INTENDED FOR USE IN ESTABLISHING THE CALIBRATION FOR THE ALINITY C 2-MICROGLOBULIN ASSAY

	BY TURBIDIMETRY. THIS STANDARD IS INTENDED TO BE USED TOGETHER WITH THE ALINITY C 2-MICROGLOBULIN REAGENTS., QUANTIA PROTEINS STANDARD (QUANTIA PROTEINS STANDARD)-THE QUANTIA PROTEINS CALIBRATOR IS INTENDED FOR USE IN ESTABLISHING THE CALIBRATION FOR THE QUANTIA (A1AGP, A1AT) ASSAYS BY TURBIDIMETRY.,ALINITY C MYOGLOBIN REAGENT KIT (ALINITY C MYOGLOBIN REAGENT KIT)-THE ALINITY C MYOGLOBIN ASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,QUANTIA LP(A)(QUANTIA LP(A))-THE QUANTIA LP(A) REAGENTS ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN(A) IN HUMAN SERUM OR PLASMA USING THE ABBOTT ARCHITECT C SYSTEMS. ,ALINITY C A1-ANTITRYPSIN REAGENT KIT(ALINITY C A1-ANTITRYPSIN REAGENT KIT)-THE ALINITY C A1-ANTITRYPSIN ASSAY IS USED FOR THE QUANTITATIVE DETERMINATION OF ALPHA1-ANTITRYPSIN IN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,QUANTIA D-DIMER(QUANTIA D-DIMER)-THE QUANTIA D-DIMER REAGENTS ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN CITRATED PLASMA USING THE ABBOTT ARCHITECT C SYSTEMS.,ALINITY C LP(A) CALIBRATORS(ALINITY C LP(A) CALIBRATORS)-THE ALINITY C LP(A) CALIBRATORS ARE FOR USE IN ESTABLISHING THE CALIBRATION CURVE FOR THE ALINITY C LP(A) REAGENTS BY TURBIDIMETRY ON THE ALINITY C ANALYZER.,QUANTIA LP(A) CONTROL(QUANTIA LP(A) CONTROL)-THE QUANTIA LP(A) CONTROL IS INTENDED FOR USE IN MONITORING THE QUALITY CONTROL OF RESULTS OBTAINED WITH THE QUANTIA LP(A) ASSAY BY TURBIDIMETRY.,QUANTIA DIGITOXIN (QUANTIA DIGITOXIN)-THE QUANTIA DIGITOXIN REAGENTS ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF DIGITOXIN IN HUMAN SERUM USING THE ABBOTT ARCHITECT C SYSTEMS.,QUANTIA FERRITIN(QUANTIA FERRITIN)-AUTOMATED LATEX ENHANCED IMMUNOASSAY FOR THE QUANTITATIVE IN VITRO DETERMINATION OF FERRITIN IN HUMAN SERUM OR EDTA PLASMA USING THE ARCHITECT C SYSTEMS.,QUANTIA ASO-RF CONTROL II(QUANTIA ASO-RF CONTROL II)-THE QUANTIA ASO-RF CONTROL II (HIGH LEVEL) IS INTENDED FOR USE IN MONITORING THE QUALITY CONTROL OF RESULTS OBTAINED WITH THE QUANTIA (ASO, RF) ASSAYS BY TURBIDIMETRY.,QUANTIA FERRITIN STANDARD (QUANTIA FERRITIN STANDARD)-THE QUANTIA FERRITIN CALIBRATOR IS INTENDED FOR USE IN ESTABLISHING THE CALIBRATION FOR THE QUANTIA FERRITIN ASSAY BY TURBIDIMETRY.,QUANTIA ASO-RF CONTROL I(QUANTIA ASO-RF CONTROL I)-THE QUANTIA ASO-RF CONTROL I (LOW LEVEL) IS INTENDED FOR USE IN MONITORING THE QUALITY CONTROL OF

		RESULTS OBTAINED WITH THE QUANTIA (ASO, RF) ASSAYS BY TURBIDIMETRY.,QUANTIA IGE STANDARD (QUANTIA IGE STANDARD)-THE QUANTIA IGE CALIBRATOR IS INTENDED FOR USE IN ESTABLISHING THE CALIBRATION FOR THE QUANTIA IGE ASSAY BY TURBIDIMETRY.,QUANTIA A1-ANTITRYPSIN(QUANTIA A1-ANTITRYPSIN)-QUANTIA A1-ANTITRYPSIN REAGENTS ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF ALPHA1-ANTITRYPSIN IN SERUM OR PLASMA USING THE ABBOTT ARCHITECT C SYSTEMS., QUANTIA RF STANDARD (QUANTIA RF STANDARD)-THE QUANTIA RF CALIBRATOR IS INTENDED FOR USE IN ESTABLISHING THE CALIBRATION CURVE FOR THE QUANTIA RF ASSAY BY TURBIDIMETRY.,QUANTIA PROTEINS CONTROLS(QUANTIA PROTEINS CONTROLS)-THE QUANTIA PROTEINS CONTROL IS INTENDED FOR USE IN MONITORING THE QUALITY CONTROL OF RESULTS OBTAINED WITH THE QUANTIA (A1AGP, A1AT, ß2M) ASSAYS BY TURBIDIMETRY. , QUANTIA RF(QUANTIA RF)-THE QUANTIA RF REAGENTS ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS (RF) IN HUMAN SERUM USING THE ABBOTT ARCHITECT C SYSTEMS.
373	IMP/IVD/2019/000401	1.License Holder Name: PERKINELMER HEALTH SCIENCES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRISOMY 21 (DOWN SYNDROME), IVD CONTROL(SERO MATERNAL HEALTH CONTROL – EARLY L-1, L-2, L-3)-SERO MATERNAL HEALTH CONTROL – EARLY IS A LYOPHILIZED HUMAN CONTROL SERUM MANUFACTURED UNDER STRICT QUALITY CONTROL STANDARDS. IT IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR PRECISION AND TRUENESS OF LABORATORY MEASUREMENT PROCEDURES FOR THE ANALYTES DESCRIBED IN THIS PACKAGE INSERT IN QUANTITATIVE MANUAL, SEMI-AUTOMATED AND AUTOMATED IMMUNOASSAYS. THREE LEVELS OF CONTROLS ARE AVAILABLE TO ALLOW PERFORMANCE MONITORING WITHIN THE CLINICAL RANGE.

374	IMP/IVD/2019/000402	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COULTER DIFF AC.T TAINER REAGENT KIT(COULTER DIFF AC.T TAINER REAGENT KIT)-FOR USE ON COULTER AC.T DIFF AND AC.T DIFF 2 HEMATOLOGY ANALYZERS ONLY. REFER TO YOUR INSTRUMENT PRODUCT MANUALS.,COULTER DXH RETIC PACK(COULTER DXH RETIC PACK)-FOR USE ON UNICEL DXH COULTER CELLULAR ANALYSIS SYSTEMS FOR CLEANING RED CELLS AND STAINING RETICULOCYTES. USE ONLY WITH DXH DILUENT.,COULTER DXH CLEANER 5L(COULTER DXH CLEANER 5L)-A CLEANING AGENT FOR USE ON UNICEL DXH COULTER CELLULAR ANALYSIS SYSTEMS FOR COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES.,AC.T RINSE SHUTDOWN DILUENT (AC.T RINSE SHUTDOWN DILUENT)-FOR USE AS A SHUTDOWN DILUENT FOR COULTER AC.T 8, AC.T 10, AC.T DIFF, AND AC.T DIFF 2 HEMATOLOGY ANALYZER COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES, INCLUDING APERTURES AND PROBE. REFER TO YOUR INSTRUMENT PRODUCT MANUALS.,COULTER CLENZ CLEANING AGENT 5L(COULTER CLENZ CLEANING AGENT 5L)-FOR USE AS A CLEANING AGENT FOR COULTER HEMATOLOGY ANALYZER COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES, INCLUDING APERTURES AND BLOOD SAMPLING VALVES. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE. NOT INTENDED FOR USE ON THE COULTER LH 780 HEMATOLOGY ANALYZER.,COULTER DXH DILUENT(COULTER DXH DILUENT)-FOR USE AS AN ISOTONIC BUFFERED DILUENT IN CONJUNCTION WITH A CYANIDE-FREE LYTIC AGENT FOR COUNTING AND SIZING BLOOD CELLS ON ALL UNICEL DXH COULTER CELLULAR ANALYSIS SYSTEMS. USE ONLY WITH COULTER DXH CELL LYSE. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE. FOR USE AS A RINSING AGENT ON THE UNICEL DXH SLIDEMAKER STAINERS.,COULTER LH SERIES PAK REAGENT KIT (COULTER LH SERIES PAK REAGENT KIT)-FOR USE ON COULTER HMX, LH 500, LH 750, AND LH 780 HEMATOLOGY ANALYZERS TO LYSE ERYTHROCYTES AND PRESERVE LEUKOCYTES. USE WITH ONLY LH SERIES OR ISOTON 4 DILUENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE., COULTER CLENZ CLEANING AGENT 500 ML(COULTER CLENZ CLEANING AGENT 500 ML)-FOR USE AS A CLEANING AGENT FOR COULTER HEMATOLOGY ANALYZER COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES, INCLUDING APERTURES AND BLOOD SAMPLING VALVES. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE. NOT INTENDED FOR USE ON THE COULTER LH 780 HEMATOLOGY ANALYZER.,

	COULTER ACT 5 DIFF DILUENT (COULTER ACT 5 DIFF DILUENT)-FOR USE AS A STABILIZED SALINE SOLUTION, CONTAINING AN ORGANIC BUFFER AND PRESERVATIVE, FOR COUNTING AND SIZING BLOOD CELLS ON COULTER AC•T 5DIFF HEMATOLOGY ANALYZERS. INTENDED FOR USE ONLY WITH SPECIFIC AC•T 5DIFF REAGENTS. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE.,COULTER LH SERIES RETIC PAK REAGENT KIT (COULTER LH SERIES RETIC PAK REAGENT KIT)-FOR USE ON THE COULTER LH 750 AND LH 780 HEMATOLOGY ANALYZERS FOR CLEANING RED CELLS AND STAINING RETICULOCYTES. USE WITH ONLY LH SERIES OR ISOTON 4 DILUENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP.,COULTER CLENZ CLEANING AGENT 10L(COULTER CLENZ CLEANING AGENT 10L)-FOR USE AS A CLEANING AGENT FOR COULTER HEMATOLOGY ANALYZER COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES, INCLUDING APERTURES AND BLOOD SAMPLING VALVES. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE. NOT INTENDED FOR USE ON THE COULTER LH 780 HEMATOLOGY ANALYZER.,AC.T PAK REAGENT KIT(AC.T PAK REAGENT KIT)-FOR USE ON COULTER AC.T 8 AND AC.T 10 HEMATOLOGY ANALYZERS ONLY. REFER TO YOUR INSTRUMENT PRODUCT MANUALS. REAGENT 1- COULTER BALANCED ELECTROLYTE SOLUTION . FOR USE AS AN ISOTONIC BUFFERED DILUENT FOR COUNTING AND SIZING BLOOD CELLS REAGENT 2- COULTER LYTIC REAGENT FOR USE AS A LYTIC AGENT FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN AND FOR LEUKOCYTE COUNTING AND SIZING.,COULTER ISOTON III DILUENT (COULTER ISOTON III DILUENT)-FOR USE AS AN ISOTONIC BUFFERED DILUENT IN CONJUNCTION WITH A LYTIC REAGENT FOR COUNTING AND SIZING BLOOD CELLS ON COULTER HMX HEMATOLOGY ANALYZERS. USE WITH ONLY COULTER LYSE S III DIFF LYTIC REAGENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE.,COULTER HMX PAK REAGENT KIT (COULTER HMX PAK REAGENT KIT)-FOR USE ON COULTER HMX HEMATOLOGY ANALYZERS TO LYSE ERYTHROCYTES AND PRESERVE LEUKOCYTES. USE WITH ONLY ISOTON III OR ISOTON 4 DILUENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS., COULTER LH SERIES CLEANER 5L (COULTER LH SERIES CLEANER 5L) -FOR USE AS A CLEANING AGENT FOR COULTER LH 500, LH 750, AND LH 780 HEMATOLOGY ANALYZER COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES, INCLUDING APERTURES AND BLOOD SAMPLING VALVES. REFER TO YOUR INSTRUMENT ONLINE HELP OR PRODUCT MANUALS.,COULTER LH SERIES CLEANER 10L (COULTER LH SERIES CLEANER 10L)-FOR USE AS A CLEANING AGENT

	FOR COULTER LH 500, LH 750, AND LH 780 HEMATOLOGY ANALYZER COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES, INCLUDING APERTURES AND BLOOD SAMPLING VALVES. REFER TO YOUR INSTRUMENT ONLINE HELP OR PRODUCT MANUALS.,COULTER ACT 5 DIFF HGB LYSE (COULTER ACT 5 DIFF HGB LYSE)-FOR USE AS AN ERYTHROCYTE LYTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN ON COULTER AC•T 5DIFF HEMATOLOGY ANALYZERS. INTENDED FOR USE ONLY WITH SPECIFIC AC•T 5DIFF REAGENTS. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE.,COULTER ACT 5 DIFF RINSE (COULTER ACT 5 DIFF RINSE)-FOR USE AS A RINSING AGENT ON COULTER AC•T 5DIFF HEMATOLOGY ANALYZERS. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE.,ACCESS WASH BUFFER II(ACCESS WASH BUFFER II)-ACCESS WASH BUFFER II IS INTENDED FOR USE WITH THE ACCESS IMMUNOASSAY SYSTEMS AND SPECIFIC ACCESS IMMUNOASSAY REAGENTS. ,IMMAGE IMMUNOCHEMISTRY SYSTEMS WASH SOLUTION (IMMAGE IMMUNOCHEMISTRY SYSTEMS WASH SOLUTION)-WASH SOLUTION IS INTENDED FOR USE WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND REAGENTS FOR THE QUANTITATIVE DETERMINATIONS OF COMPONENTS IN BIOLOGICAL FLUIDS.,COULTER DXH DIFF PACK (COULTER DXH DIFF PACK)-FOR USE ON UNICEL DXH COULTER CELLULAR ANALYSIS SYSTEMS TO LYSE ERYTHOCYTES AND PRESERVE LEUKOCYTES. USE ONLY WITH COULTER DXH DILUENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS POSSIBLE.,COULTER AC.T TRAINER REAGENT KIT(COULTER AC.T TRAINER REAGENT KIT)-FOR USE ON COULTER AC.T 8 AND AC.T 10 HEMATOLOGY ANALYZERS ONLY. REFER TO YOUR INSTRUMENT PRODUCT MANUALS.,COULTER ISOTON 4 DILUENT(COULTER ISOTON 4 DILUENT)-FOR USE AS AN ISOTONIC BUFFERED DILUENT IN CONJUNCTION WITH A CYANIDE-FREE LYTIC AGENT FOR COUNTING AND SIZING BLOOD CELLS ON COULTER HMX, LH 500*, LH 750†, AND LH 780 HEMATOLOGY ANALYZERS. USE ONLY WITH COULTER LYSE S 4 LYTIC REAGENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE. ,COULTER LH 700 SERIES DILUENT(COULTER LH 700 SERIES DILUENT)-FOR FOR USE AS AN ENHANCED LOW FORMALDEHYDE-PRODUCING ISOTONIC BUFFERED DILUENT IN CONJUNCTION WITH A LYTIC REAGENT FOR COUNTING AND SIZING BLOOD CELLS ON COULTER HMX, LH 500, LH 750, AND LH 780 HEMATOLOGY ANALYZERS. USE WITH ONLY COULTER LYSE S III DIFF LYTIC REAGENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE.,UNICEL DXL ACCESS WASH BUFFER II(UNICEL DXL ACCESS WASH BUFFER II)-ACCESS WASH BUFFER II IS INTENDED FOR

	USE WITH THE ACCESS IMMUNOASSAY SYSTEMS AND SPECIFIC ACCESS IMMUNOASSAY REAGENTS. ,COULTER DIFF ACT PAK REAGENT KIT(COULTER DIFF ACT PAK REAGENT KIT)-FOR USE ON COULTER AC•T DIFF AND AC•T DIFF 2 HEMATOLOGY ANALYZERS ONLY. REFER TO YOUR INSTRUMENT PRODUCT MANUALS,COULTER DXH CLEANER 10L(COULTER DXH CLEANER 10L)-A CLEANING AGENT FOR USE ON UNICEL DXH COULTER CELLULAR ANALYSIS SYSTEMS FOR COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES., COULTER LYSE SIII DIFF LYTIC REAGENT 1 L(COULTER LYSE SIII DIFF LYTIC REAGENT 1 L)-FOR USE AS AN ERYTHROCYTE LYTIC AGENT FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN AND FOR LEUKOCYTE COUNTING AND SIZING ON COULTER HMX, LH 500, LH 750, AND LH 780 HEMATOLOGY ANALYZERS. USE WITH ONLY ISOTON III OR LH SERIES DILUENT . REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/ OR ONLINE HELP, AS APPLICABLE., COULTER LYSE S III DIFF LYTIC REAGENT 5L(COULTER LYSE S III DIFF LYTIC REAGENT 5L)-FOR USE AS AN ERYTHROCYTE LYTIC AGENT FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN AND FOR LEUKOCYTE COUNTING AND SIZING ON COULTER HMX LH 500, LH 750, AND LH 780 HEMATOLOGY ANALYZERS. USE WITH ONLY ISOTON III OR LH SERIES DILUENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

375	IMP/IVD/2019/000403	1.License Holder Name: M/S. RECKON DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NGAL FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY) (GP)-NGAL FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF NEUTROPHILS GELATINASE ASSOCIATED LIPOCALIN (NGAL) IN SERUM AND URINE. THIS TEST IS USED AS AN AID IN THE EARLY DIAGNOSIS OF ACUTE KIDNEY INJURY (AKI), RISK CLASSIFICATION AND TREATMENT MONITORING.,PRL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY)(GP)-PRL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PROLACTIN(PRL) IN SERUM, PLASMA. THIS TEST IS USED AS AN AID IN THE DIAGNOSIS OF MALE AND FEMALE INFERTILITY AND PITUITARY DYSFUNCTION, MONITORING OF MALE AND FEMALE GONADAL DISORDERS AND MANAGEMENT OF AMENORRHEA AND GALACTORRHEA.,NT-PROBNP FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-NT-PROBNP FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF N-TERMINAL B-TYPE NATRIURETIC PEPTIDE PRECURSOR (NT-PROBNP) IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF).,LH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) (GP)-LH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF LH IN SERUM, PLASMA. THIS TEST IS USED TO DETERMINE MENOPAUSE, PINPOINT OVULATION AND MONITOR ENDOCRINE THERAPY.,NT-PROBNP/CTNI FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP) -NT-PROBNP/CTNL FAST TEST KTT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF N-TERMINAL B- TYPE NATRIURETIC PEPTIDE PRECURSOR/CARDIAC TROPONIN I (NT-PROBNP/ CTNL) IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF), ACUTE MYOCARDIAL INFARCTION (AMI) AND ACUTE CORONARY SYNDROME (ACS).,FSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY)(GP)-FSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM AND PLASMA. FSH TEST IS USED FOR WOMEN SUSPECTED OF HAVING POLYCYSTIC OVARY SYNDROME, AND IN INDIVIDUALS UNDERGOING EVALUATION FOR INFERTILITY, ALSO USED FOR EVALUATION OF INDIVIDUALS WITH SUSPECTED PITUITARY DISORDERS OR DISEASES OF THE OVARIES.,HBA1C FAST TEST KIT (IMUMUNOFLUORESCENCE

	ASSAY)(GP)-HBA1C FAST TEST KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HBA1C IN WHOLE BLOOD. THIS TEST IS USED AS AN AID FOR MONITORING GLYCEMIC CONTROL IN DIABETICS. IN ADDITION, IT CAN IDENTIFY PEOPLE AT RISK OF DEVELOPING THE DISEASE AND ONGOING MONITORING.,AMH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY)(GP)-AMH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF AMH IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN INDICATING OVARIAN FUNCTIONAL RESERVE, AND ALSO HELP TO DIAGNOSE MENSTRUAL DISORDERS OR TO MONITOR THE HEALTH OF WOMEN., D-DIMER FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-D-DIMER FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF D-DIMER IN PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF DEEP-VEIN THROMBOSIS OR PULMONARY EMBOLISM.,IL-6 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY)(GP)-IL-6 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF INTERLEUKIN 6(IL-6) IN HUMAN SERUM,PLASMA,WHOLE BLOOD AND PERIPHERAL BLOOD SAMPLES. IL-6 IS AN EARLY MARKER IN ACUTE INFLAMMATION AND THIS TEST CAN BE USED AS AN AID IN THE INFLAMMATORY DISEASES.,MALB FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-MALB FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF MICROALBUMINURIA (MALB) IN URINE. AN ELEVATED MALB CONCENTRATION BELOW THE PROTEINURIC LEVEL HAS LONG BEEN RECOGNIZED AS A MARKER OF KIDNEY DISEASE AND INCREASED CARDIOVASCULAR RISK IN DIABETIC NEPHROPATHY.,PROGESTERONE(PROG) FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY)(GP)-PROGESTERONE(PROG) FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PROGESTERONE(PROG) IN SERUM, PLASMA. THIS TEST IS USED TO MEASURE OVARIAN FUNCTION AND CAN DETERMINE IF A WOMAN HAS OVULATED AND WHEN THE OVULATION OCCURRED.,CYSC FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-CYSC FAST TEST KIT {LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CYSTATIN C (CYSC) IN SERUM, PLASMA OR WHOLE BLOOD. THE TEST RESULT IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF INDEX OF GLOMERULAR FILTRATION RATE, AND HAS IMPORTANT APPLICATION VALUE IN RENAL FUNCTION, KIDNEY DAMAGE AND RENAL TRANSPLANTATION.,SAA FAST TEST KIT (IMUMUNOFLUORESCE NCE

	ASSAY)(GP)-INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF SAA IN SERUM,PLASMA, WHOLE BLOOD AND FINGER TIP BLOOD.,T4 FAST TEST KIT(IMUMUNOFLUORESCENCE ASSAY)(GP)-T4 (THYRXINE) FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T4 IN SERUM AND PLASMA. IT CAN BE USED IN THE MONITORING OF HYPERTHYROID-ISM AND HYPOTHYROIDISM, AND ALSO USED AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA.,FERRITIN FAST TEST KIT(FERRITIN FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-FERRITIN FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA SAMPLES.,TSH FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-TSH FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN SERUM AND PLASMA. THIS TEST IS USED IN THE SCREENING, CLINICAL DIAGNOSIS, PROGNOSIS AND THERAPEUTIC EFFECT EVALUATION OF THYROID DISEASES.,PCT FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-PCT FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF BACTERIAL INFECTION, TRAUMA OR SHOCK.,T3 FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-T3 (TRIIODOTHYRONINE) FAST TEST KIT(LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T3 IN SERUM AND PLASMA. IT CAN BE USED IN THE MONITORING OF HYPERTHYROIDISM AND HYPOTHYROIDISM, AND ALSO USED AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA.,CK-MB/CTNI/MYO FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP) -CK-MB/CTNL/MYO FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CK-MB/CTNL/ MYO IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS AND ACUTE CORONARY SYNDROME (ACS).,HCG+BETA () FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-HCG+ BETA() FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN SERUM OR PLASMA. THIS TEST IS USED AS AN AID IN PREGNANCY TEST.,CARDIAC TROPONIN I FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-CARDIAC

	TROPONIN I FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNL) IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS AND ACUTE CORONARY SYNDROME (ACS).,HS-CRP+CRP FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-HS-CRP+CRP FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM, PLASMA WHOLE BLOOD, OR FINGERTIP BLOOD. MEASUREMENT OF CRP IS USEFUL FOR THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY AND INFLAMMATORY DISORDERS. MEASUREMENT OF HIGH SENSITIVITY CRP (HS-CRP), WHEN USED IN CONJUNCTION WITH TRADITIONAL CLINICAL LABORATORY EVALUATION OF ACUTE CORONARY SYNDROMES (ACS), MAY BE USEFUL AS AN INDEPENDENT MARKER OF PROGNOSIS FOR RECURRENT EVENTS IN PATIENTS WITH STABLE CORONARY DISEASE OR ACS.,BETA2(2)-MG FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-BETA2(2)-MG FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF BETA2(2)-MICROGLOBULIN IN SERUM, PLASMA OR WHOLE BLOOD. MEASUREMENT OF BETA2(2)-MG IS USEFUL FOR THE DETECTION AND EVALUATION OF GLOMERULAR FILTRATION RATE, RENAL TRANSPLANTATION AND RENAL FUNCTION.,25-OH-VD FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-25-OH-VD FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF 25-OH-VD IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST MAY HELP UNDERSTAND THE METABOLIC CHANGES OF BONE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

376	IMP/IVD/2019/000404	1.License Holder Name: M/S AVANTOR PERFORMANCE MATERIALS INDIA LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TSH TEST SYSTEM (ELISA KIT) (BULK)-USED QUANTITATIVE DETERMINATION OF TSH IN HUMAN SERUM.,FREE T3 TEST SYSTEM (ELISA KIT) (BULK)-USED QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE IN HUMAN SERUM.,TOTAL T3 TEST SYSTEM (ELISA KIT) (BULK)-USED QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE IN HUMAN SERUM.,FSH TEST SYSTEM (ELISA KIT) (BULK)-USED QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE IN HUMAN SERUM.,PRL TEST SYSTEM (ELISA KIT) (BULK)-USED QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM.,LH TEST SYSTEM (ELISA KIT) (BULK)-USED QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE IN HUMAN SERUM.,FREE T4 TEST SYSTEM (ELISA KIT) (BULK)-USED QUANTITATIVE DETERMINATION OF FREE THYROXINE IN HUMAN SERUM.,TOTAL T4 TEST SYSTEM (ELISA KIT) (BULK)-USED QUANTITATIVE DETERMINATION OF TOTAL THYROXINE IN HUMAN SERUM.
377	IMP/IVD/2019/000405	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROSCAN MH BROTH WITH 3% LHB-25ML(MICROSCAN MH BROTH WITH 3% LHB-25ML)-FOR USE WITH MICROSCAN MICROSTREP PLUS TYPE 3 PANELS. MICROSCAN MICROSTREP PLUS PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY OF AEROBIC NON-ENTEROCOCCAL STREPTOCOCCI (INCLUDING STREPTOCOCCUS PNEUMONIAE) AND HAEMOPHILUS SPP.,MICROSCAN HTM BROTH-25ML(MICROSCAN HTM BROTH-25ML)-FOR USE WITH MICROSCAN MICROSTREP PLUS TYPE 3 PANELS. MICROSCAN MICROSTREP PLUS PANELS ARE DESIGNED FOR USE IN DETERMINING ANTIMICROBIAL AGENT SUSCEPTIBILITY OF AEROBIC NON-ENTEROCOCCAL STREPTOCOCCI (INCLUDING STREPTOCOCCUS PNEUMONIAE) AND HAEMOPHILUS SPP

378	IMP/IVD/2019/000406	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:C1 CALIBRATION SOLUTION 1(C1 CALIBRATION SOLUTION 1)-C1 CALIBRATION SOLUTION 1 FOR COBAS B 121 SYSTEM.,COBAS B 123 SENSOR CARTRIDGE BG/ISE(COBAS B 123 SENSOR CARTRIDGE BG/ISE)-SENSOR CARTRIDGE FOR THE COBAS B 123 POC SYSTEM TO MEASURE PH, BLOOD GASES (PO2, PCO2), ELECTROLYTES (NA+,K+, CA2+, CL-) AND HEMATOCRIT (HCT),GLU / LAC/UREA (BUN) CASSETTE(GLU / LAC/UREA (BUN) CASSETTE)-SENSOR CASSETTE FOR ROCHE OMNI S 6 SYSTEM, COBAS B 221 SYSTEMS FOR THE DETERMINATION OF GLUCOSE, LACTATE AND UREA/BUN,COBAS B 123 SENSOR CARTRIDGE BG/ISE/GLU/LAC(COBAS B 123 SENSOR CARTRIDGE BG/ISE/GLU/LAC)-SENSOR CARTRIDGE FOR THE COBAS B 123 POC SYSTEM TO MEASURE PH, BLOOD GASES (PO2, PCO2), ELECTROLYTES (NA+, K+, CA2+, CL-), HEMATOCRIT (HCT) AND METABOLITES (GLU, LAC),COBAS B 123 FLUID PACK(COBAS B 123 FLUID PACK)-THE COBAS B 123 FLUID PACKS ARE AN ACCESSORY TO THE COBAS B123 POC SYSTEM. THE COBAS B123 POC SYSTEM IS A FULLY AUTOMATED POC SYSTEM FOR IN VITRO MEASUREMENT OF PH, BLOOD GASES (BG), ELECTROLYTES (ISE), HEMATOCRIT (HCT), METABOLITES (GLU, LAC), TOTAL HEMOGLOBIN (THB), HEMOGLOBIN DERIVATIVES (O2HB, HHB, METHB), OXYGEN SATURATION (SO2) AND NEONATAL BILIRUBIN (BILI).,HB - CALIBRATOR(HB - CALIBRATOR)-HB-CALIBRATOR SOLUTION FOR COBAS B 221 SYSTEM.,S2 FLUID PACK(S2 FLUID PACK)-S2 FLUID PACK FOR COBAS B 221 SYSTEM., COBAS B 123 FLUID PACK COOX(COBAS B 123 FLUID PACK COOX)-THE COBAS B 123 FLUID PACKS ARE AN ACCESSORY TO THE COBAS B123 POC SYSTEM. THE COBAS B123 POC SYSTEM IS A FULLY AUTOMATED POC SYSTEM FOR IN VITRO MEASUREMENT OF PH, BLOOD GASES (BG), ELECTROLYTES (ISE), HEMATOCRIT (HCT), METABOLITES (GLU, LAC), TOTAL HEMOGLOBIN (THB), HEMOGLOBIN DERIVATIVES (O2HB, HHB, METHB), OXYGEN SATURATION (SO2) AND NEONATAL BILIRUBIN (BILI).,URINE DILUENT(URINE DILUENT)-THE URINE DILUENT IS INTENDED TO BE USED FOR THE DILUTION OF URINE PRIOR TO THE MEASUREMENT WITH 9180 ELECTROLYTE ANALYZER. ,S3 FLUID PACK A(S3 FLUID PACK A)-S3 FLUID PACK A FOR COBAS B 221 SYSTEM.,S1 RINSE SOLUTION(S1 RINSE SOLUTION)-S1 RINSE SOLUTION FOR COBAS B 221 SYSTEM.,C3 FLUID PACK(C3 FLUID PACK)-C3 FLUID PACK FOR COBAS B 121 SYSTEM., DEPROTEINIZER(DEPROTEINIZER)-THE DEPROTEINIZER IS A CLEANING SOLUTION AND IS INTENDED TO BE USED FOR PERIODIC EXTERNAL CLEANING OR FOR DECONTAMINATION OF THE MEASURING SYSTEMS FOR COBAS B 121 SYSTEM, COBAS B 221

	SYSTEM, 9180 ELECTROLYTE ANALYZER.,GLU/LAC CASSETTE (GLU/LAC CASSETTE)-SENSOR CASSETTE FOR ROCHE OMNI S 6 SYSTEM, COBAS B 221 SYSTEM FOR THE DETERMINATION OF GLUCOSE AND LACTATE,C2 CALIBRATION SOLUTION 2(C2 CALIBRATION SOLUTION 2)-C2 CALIBRATION SOLUTION 2 FOR COBAS B 121 SYSTEM.,SODIUM ELECTRODE CONDITIONER(SODIUM ELECTRODE CONDITIONER)-THE SODIUM ELECTRODE CONDITIONER IS USED FOR THE CONDITIONING OF THE SODIUM ELECTRODE OF THE 9180 ELECTROLYTE ANALYZER.,CLEANING SOLUTION(CLEANING SOLUTION)-THE CLEANING SOLUTION IS INTENDED TO BE USED FOR CLEANING OF THE 9180 ELECTROLYTE ANALYZER.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

379	IMP/IVD/2019/000408	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COULTER AC.T PAK REAGENT KIT(COULTER AC.T PAK REAGENT KIT)-FOR USE ON COULTER AC•T 8 AND AC•T 10 HEMATOLOGY ANALYZERS ONLY. REFER TO YOUR INSTRUMENT PRODUCT MANUALS. REAGENT 1 - COULTER BALANCED ELECTROLYTE SOLUTION FOR USE AS AN ISOTONIC BUFFERED DILUENT FOR COUNTING AND SIZING BLOOD CELLS. REAGENT 2 - COULTER LYTIC REAGENT FOR USE AS A LYTIC AGENT FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN AND FOR LEUKOCYTE COUNTING AND SIZING. ,COULTER CLENZ CLEANING AGENT 5L(COULTER CLENZ CLEANING AGENT 5L)-FOR USE AS A CLEANING AGENT FOR COULTER HEMATOLOGY ANALYZER COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES, INCLUDING APERTURES AND BLOOD SAMPLING VALVES. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE. NOT INTENDED FOR USE ON THE COULTER LH 780 HEMATOLOGY ANALYZER.,COULTER ISOTON 4 DILUENT (COULTER ISOTON 4 DILUENT)-FOR USE AS AN ISOTONIC BUFFERED DILUENT IN CONJUNCTION WITH A CYANIDE-FREE LYTIC AGENT FOR COUNTING AND SIZING BLOOD CELLS ON COULTER HMX, LH 500*, LH 750†, AND LH 780 HEMATOLOGY ANALYZERS. USE ONLY WITH COULTER LYSE S 4 LYTIC REAGENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE. , COULTER CLENZ CLEANING AGENT 1L(COULTER CLENZ CLEANING AGENT 1L)-FOR USE AS A CLEANING AGENT FOR COULTER HEMATOLOGY ANALYZER COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES, INCLUDING APERTURES AND BLOOD SAMPLING VALVES. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE. NOT INTENDED FOR USE ON THE COULTER LH 780 HEMATOLOGY ANALYZER.,UNICEL DXL ACCESS WASH BUFFER II(UNICEL DXL ACCESS WASH BUFFER II)-ACCESS WASH BUFFER II IS INTENDED FOR USE WITH THE ACCESS IMMUNOASSAY SYSTEMS AND SPECIFIC ACCESS IMMUNOASSAY REAGENTS. ,COULTER ACT RINSE SHUTDOWN DILUENT(COULTER ACT RINSE SHUTDOWN DILUENT)-FOR USE AS A SHUTDOWN DILUENT FOR COULTER AC•T 8, AC•T 10, AC•T DIFF, AND AC•T DIFF 2 HEMATOLOGY ANALYZER COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES, INCLUDING APERTURES AND PROBE. REFER TO YOUR INSTRUMENT PRODUCT MANUALS.,COULTER DXH DILUENT (COULTER DXH DILUENT)-FOR USE AS AN ISOTONIC BUFFERED DILUENT IN CONJUNCTION WITH A CYANIDE-FREE LYTIC AGENT FOR COUNTING AND SIZING BLOOD CELLS ON ALL UNICEL DXH COULTER

	CELLULAR ANALYSIS SYSTEMS. USE ONLY WITH COULTER DXH CELL LYSE. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE. FOR USE AS A RINSING AGENT ON THE UNICEL DXH SLIDEMAKER STAINERS.,COULTER LH 700 SERIES DILUENT (COULTER LH 700 SERIES DILUENT)-FOR USE AS AN ENHANCED LOW FORMALDEHYDE-PRODUCING ISOTONIC BUFFERED DILUENT IN CONJUNCTION WITH A LYTIC REAGENT FOR COUNTING AND SIZING BLOOD CELLS ON COULTER HMX, LH 500, LH 750, AND LH 780 HEMATOLOGY ANALYZERS. USE WITH ONLY COULTER LYSE S III DIFF LYTIC REAGENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE. ,IMMAGE IMMUNOCHEMISTRY SYSTEMS WASH SOLUTION (IMMAGE IMMUNOCHEMISTRY SYSTEMS WASH SOLUTION)-WASH SOLUTION IS INTENDED FOR USE WITH IMMAGE IMMUNOCHEMISTRY SYSTEMS AND REAGENTS FOR THE QUANTITATIVE DETERMINATIONS OF COMPONENTS IN BIOLOGICAL FLUIDS.,ACCESS WASH BUFFER II (ACCESS WASH BUFFER II)-ACCESS WASH BUFFER II IS INTENDED FOR USE WITH THE ACCESS IMMUNOASSAY SYSTEMS AND SPECIFIC ACCESS IMMUNOASSAY REAGENTS. ,COULTER ACT RINSE SHUTDOWN DILUENT(COULTER ACT RINSE SHUTDOWN DILUENT)-FOR USE AS A SHUTDOWN DILUENT FOR COULTER AC•T 8, AC•T 10, AC•T DIFF, AND AC•T DIFF 2 HEMATOLOGY ANALYZER COMPONENTS THAT COME IN CONTACT WITH BLOOD SAMPLES, INCLUDING APERTURES AND PROBE. REFER TO YOUR INSTRUMENT PRODUCT MANUALS.,COULTER ISOTON III DILUENT (COULTER ISOTON III DILUENT)-FOR USE AS AN ISOTONIC BUFFERED DILUENT IN CONJUNCTION WITH A LYTIC REAGENT FOR COUNTING AND SIZING BLOOD CELLS ON COULTER HMX HEMATOLOGY ANALYZERS. USE WITH ONLY COULTER LYSE S III DIFF LYTIC REAGENT. REFER TO YOUR INSTRUMENT PRODUCT MANUALS AND/OR ONLINE HELP, AS APPLICABLE. ,COULTER DIFF AC•T PAK REAGENT KIT(COULTER DIFF AC•T PAK REAGENT KIT)-FOR USE ON COULTER AC•T DIFF AND AC•T DIFF 2 HEMATOLOGY ANALYZERS ONLY. REFER TO YOUR INSTRUMENT PRODUCT MANUALS. REAGENT 1 - COULTER BALANCED ELECTROLYTE SOLUTION FOR USE AS AN ISOTONIC BUFFERED DILUENT FOR COUNTING AND SIZING BLOOD CELLS. REAGENT 2 - COULTER LYTIC REAGENT FOR USE AS A LYTIC AGENT FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN AND FOR LEUKOCYTE COUNTING AND SIZING.

380	IMP/IVD/2019/000409	1.License Holder Name: LIFESIGN HEALTHCARE PVT.LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STA® - STACLOT®DRVV CONFIRM-DETECTION OF LUPUS ANTICOAGULANTS,STA® - STACHROM® PROTEIN C-COLORIMETRIC ASSAY OF PROTEIN C, ASSERACHROM® HPIA-DETECTION OF ANTI-HEPARIN-PF4 ANTIBODIES BY ENZYME IMMUNOASSAY,STA® - SYSTEM CONTROL N+P-CONTROL PLASMAS FOR ASSAYS OF COAGULATION PARAMETERS,STA® - HEPARIN CONTROL-CONTROL PLASMAS FOR ASSAYS OF UNFRACTIONATED HEPARINS (UFH) USING ANTI-XA METHOD,STA® - NEOPLASTINE® R15-DETERMINATION OF PROTHROMBIN TIME (PT),STA® - DEFICIENT IX-IMMUNO-DEPLETED PLASMA FOR FACTOR IX ASSAY,STA® - DESORB U-DESORBING SOLUTION FOR USE WITH ANALYZERS OF THE STA® LINE,STA® - CEPHASCREEN 4-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),ASSERACHROM® HPIA - IG G-DETECTION OF ANTI-HEPARIN-PF4 ANTIBODIES OF IGG CLASS BY ENZYME IMMUNOASSAY,STA® - MULTI HEP CALIBRATOR-CALIBRATION PLASMAS FOR ASSAYS OF HEPARINS (UFH AND LMWH) USING ANTI-XA METHOD,STA® - QUALITY HNF/UFH-CONTROL PLASMAS FOR ASSAYS OF UNFRACTIONATED HEPARINS (UFH) USING ANTI-XA METHOD,STA®- LIATEST® FREE PROTEIN S 2-IMMUNO-TURBIDIMETRIC ASSAY OF FREE PROTEIN S,PTT AUTOMATE 5-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - DEFICIENT X-IMMUNO-DEPLETED PLASMA FOR FACTOR X ASSAY,STA® - DEFICIENT VII-IMMUNO-DEPLETED PLASMA FOR FACTOR VII ASSAY,STA® - DEFICIENT VIII-IMMUNO-DEPLETED PLASMA FOR FACTOR VIII ASSAY,STA® - LIATEST® FREE PROTEIN S 6-IMMUNO-TURBIDIMETRIC ASSAY OF FREE PROTEIN S,STA® - STACLOT®DRVV SCREEN 2, 5-DETECTION OF LUPUS ANTICOAGULANTS,STA® - LIQUID FIB-QUANTITATIVE DETERMINATION OF FIBRINOGEN,STA® - STACLOT® PROTEIN S-CLOTTING ASSAY OF PROTEIN S,STA® - LIATEST® D-DI PLUS-IMMUNO-TURBIDIMETRIC ASSAY OF D-DIMER,NÉOPLASTINE® CI PLUS 2, 5, 10-DETERMINATION OF PROTHROMBIN TIME (PT),STA® - DEFICIENT V-SUBSTRATE PLASMA FOR FACTOR V ASSAY,STA® - THROMBIN 2, 10-DETERMINATION OF THROMBIN TIME,STA®- LIQUID ANTI-XA4, 8-COLORIMETRIC ASSAY OF HEPARINS (UFH AND LMWH), FONDAPARINUX AND RIVAROXABAN,FDP PLASMA-QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF FDP IN PLASMA BY LATEX AGGLUTINATION,PTT-LA-LUPUS ANTICOAGULANT-SENSITIVE APTT REAGENT,UNICALIBRATOR-CALIBRATION PLASMA FOR FUNCTIONAL ASSAYS OF COAGULATION PARAMETERS,STA® - ROUTINE QC 2 ML-CONTROL PLASMAS FOR COAGULATION TESTS,

	STA® - STACLOT® APC-R-ASSESSMENT OF ACTIVATED PROTEIN C RESISTANCE,COAG CONTROL N+ P-CONTROL PLASMAS FOR COAGULATION TESTS,STA® - DEFICIENT II-SUBSTRATE PLASMA FOR FACTOR LL ASSAY,SYSTEM CONTROL N+ P-CONTROL PLASMAS FOR ASSAYS OF COAGULATION PARAMETERS,STA®- HBPM/LMWH CONTROL-CONTROL PLASMAS FOR ASSAYS OF LOW MOLECULAR WEIGHT HEPARINS (LMWH) USING ANTI-XA METHOD,STA® - CEPHASCREEN 10-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - LIATEST® CONTROL N+P-CONTROL PLASMAS FOR IMMUNO-TURBIDIMETRIC ASSAYS,STA® - STACLOT® HEPARIN 1-CLOTTING ASSAY OF HEPARINS (UFH AND LMWH) BY ANTI-XA METHOD,STA® - DEFICIENT XI-DEFICIENT PLASMA FOR FACTOR XI ASSAY,STA® - OWREN - KOLLER-OWREN-KOLLER BUFFER SOLUTION FOR COAGULATION TESTS,STA® - VWF: AG CALIBRATOR-CALIBRATION PLASMA FOR THE IMMUNO-TURBIDIMETRIC ASSAY OF VWF:AG,STA® - UNICALIBRATOR-CALIBRATION PLASMA FOR FUNCTIONAL ASSAYS OF COAGULATION PARAMETERS,STA®- QUALITY HBPM/LMWH-CONTROL PLASMA FOR ASSAYS OF LOW MOLECULAR WEIGHT HEPARINS (LMWH) USING STA® - ROTACHROM® HEPARIN,STA® - LIATEST® VWF : AG-IMMUNO-TURBIDIMETRIC ASSAY OF VON WILLEBRAND FACTOR, STACLOT® LA-DETECTION OF LUPUS ANTICOAGULANTS,POOL NORM-NORMAL HUMAN PLASMA POOL,STA® - LIATEST® FM-IMMUNO-TURBIDIMETRIC ASSAY OF FIBRIN MONOMERS,STA® - PTT A 5-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - CACL2 0.025 M-CALCIUM CHLORIDE SOLUTION,STA® - IMMUNODEF XII-IMMUNO-DEPLETED PLASMA FOR FACTOR XII ASSAY,STA® - STACLOT® PROTEIN C 1-CLOTTING ASSAY OF PROTEIN C,STA® - D-DI CONTROL-QUALITY CONTROL FOR IMMUNO-TURBIDIMETRIC ASSAY OF D-DIMER,STA® - IMMUNODEF IX-IMMUNO-DEPLETED PLASMA FOR FACTOR IX ASSAY,STA® - HEPANORM® HBPM/LMWH-CALIBRATION PLASMAS FOR ASSAYS OF LOW MOLECULAR WEIGHT HEPARINS (LMWH) USING ANTI-XA METHOD , STA® - IMMUNODEF VIII-IMMUNO-DEPLETED PLASMA FOR FACTOR VIII ASSAY,STA® - COAG CONTROL N+P-CONTROL PLASMAS FOR COAGULATION TESTS,STA® - HEPANORM® H-CALIBRATION PLASMA FOR ASSAY OF UNFRACTIONATED HEPARIN (UFH) USING ANTI-XA METHOD,STA® - CK PREST 5-DETERMINATION OF THE KAOLIN-ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - FM CONTROL-CONTROL PLASMAS FOR THE IMMUNO-TURBIDIMETRIC ASSAY OF FIBRIN MONOMERS,STA® - FM CALIBRATOR-CALIBRATION PLASMAS FOR THE IMMUNO-TURBIDIMETRIC ASSAY OF FIBRIN MONOMERS,STA® - CONTROL LA 1+2-CONTROL PLASMAS FOR LUPUS ANTICOAGULANT (LA) TESTS,STA® - STACHROM® ATIII 3, 6-

	COLORIMETRIC ASSAY OF ANTITHROMBIN,STA® - NEOPTIMAL® 5, 10, 20-DETERMINATION OF PROTHROMBIN TIME (PT),D-DI TEST®-LATEX AGGLUTINATION SLIDE TEST FOR THE QUALITATIVE AND SEMI - QUANTITATIVE DETERMINATION OF D-DIMER,CK PREST® 2, 5-DETERMINATION OF THE KAOLIN-ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)

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381	IMP/IVD/2019/000410	1.License Holder Name: VECTOR BIOTEK PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HCG+ BETA FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-HCG+BETA FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN SERUM OR PLASMA. THIS TEST IS USED AS AN AID IN PREGNANCY TEST.,CK-MB/CTNI/MYO FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-CK-MB/CTNL/MYO FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CK-MB/CTNL/ MYO IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS AND ACUTE CORONARY SYNDROME (ACS).,NGAL FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-NGAL FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF NEUTROPHILS GELATINASE ASSOCIATED LIPOCALIN (NGAL) IN SERUM AND URINE. THIS TEST IS USED AS AN AID IN THE EARLY DIAGNOSIS OF ACUTE KIDNEY INJURY (AKI), RISK CLASSIFICATION AND TREATMENT MONITORING.,MALB FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-MALB FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF MICROALBUMINURIA (MALB) IN URINE. AN ELEVATED MALB CONCENTRATION BELOW THE PROTEINURIC LEVEL HAS LONG BEEN RECOGNIZED AS A MARKER OF KIDNEY DISEASE AND INCREASED CARDIOVASCULAR RISK IN DIABETIC NEPHROPATHY.,T4 FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-T4 (THYRXINE) FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T4 IN SERUM AND PLASMA. IT CAN BE USED IN THE MONITORING OF HYPERTHYROID-ISM AND HYPOTHYROIDISM, AND ALSO USED AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA.,HS-CRP+CRP FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-HS-CRP+CRP FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM, PLASMA WHOLE BLOOD, OR FINGERTIP BLOOD. MEASUREMENT OF CRP IS USEFUL FOR THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY AND INFLAMMATORY DISORDERS. MEASUREMENT OF HIGH SENSITIVITY CRP (HS-CRP), WHEN USED IN CONJUNCTION WITH TRADITIONAL CLINICAL LABORATORY EVALUATION OF ACUTE CORONARY SYNDROMES

	(ACS), MAY BE USEFUL AS AN INDEPENDENT MARKER OF PROGNOSIS FOR RECURRENT EVENTS IN PATIENTS WITH STABLE CORONARY DISEASE OR ACS.,NT-PROBNP/CTNI FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-NT-PROBNP/CTNL FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF N-TERMINAL B- TYPE NATRIURETIC PEPTIDE PRECURSOR/CARDIAC TROPONIN I (NT-PROBNP/ CTNL) IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF), ACUTE MYOCARDIAL INFARCTION (AMI) AND ACUTE CORONARY SYNDROME (ACS).,T3 FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-T3 (TRIIODOTHYRONINE) FAST TEST KIT(LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T3 IN SERUM AND PLASMA. IT CAN BE USED IN THE MONITORING OF HYPERTHYROIDISM AND HYPOTHYROIDISM, AND ALSO USED AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA.,CARDIAC TROPONIN I FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-CARDIAC TROPONIN I FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNL) IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS AND ACUTE CORONARY SYNDROME (ACS).,CYSC FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY(GP)-CYSC FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CYSTATIN C (CYSC) IN SERUM, PLASMA OR WHOLE BLOOD. THE TEST RESULT IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF INDEX OF GLOMERULAR FILTRATION RATE, AND HAS IMPORTANT APPLICATION VALUE IN RENAL FUNCTION, KIDNEY DAMAGE AND RENAL TRANSPLANTATION.,BETA 2-MG FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-BETA2,-MG FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF BETA 2-MICROGLOBULIN (BETA2,-MG) IN SERUM, PLASMA OR WHOLE BLOOD. MEASUREMENT OF BETA2,-MG IS USEFUL FOR THE DETECTION AND EVALUATION OF GLOMERULAR FILTRATION RATE, RENAL TRANSPLANTATION AND RENAL FUNCTION.,NT-PROBNP FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-NT-PROBNP FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF N-TERMINAL B-TYPE NATRIURETIC PEPTIDE PRECURSOR (NT-PROBNP) IN SERUM,

	PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF).,HBA1C FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-HBA1C FAST TEST KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HBA1C IN WHOLE BLOOD. THIS TEST IS USED AS AN AID FOR MONITORING GLYCEMIC CONTROL IN DIABETICS. IN ADDITION, IT CAN IDENTIFY PEOPLE AT RISK OF DEVELOPING THE DISEASE AND ONGOING MONITORING.,25-OH-VDFAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-25-OH-VD FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF 25-OH-VD IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST MAY HELP UNDERSTAND THE METABOLIC CHANGES OF BONE.,PCT FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-PCT FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF BACTERIAL INFECTION, TRAUMA OR SHOCK.,TSH FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-TSH FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN SERUM AND PLASMA. THIS TEST IS USED IN THE SCREENING, CLINICAL DIAGNOSIS, PROGNOSIS AND THERAPEUTIC EFFECT EVALUATION OF THYROID DISEASES.,D-DIMER FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY)(GP)-D-DIMER FAST TEST KIT (LMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF D-DIMER IN PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF DEEP-VEIN THROMBOSIS OR PULMONARY EMBOLISM.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MANUFACTURING UNIT MINISTRY OF HEALTH, GOVERNMENT OF INDIA

382	IMP/IVD/2019/000411	1.License Holder Name: MICROGENE DIAGNOSTIC SYSTEMS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CAREUS DENGUE IGM/IGG (CAREUS)-USED FOR THE RAPID QUALITATIVE DETECTION OF ANTIBODIES TO DENGUE VIRUS IN SERUM , PLASMA OR WHOLE BLOOD AS AN AID IN THE DIAGNOSIS OF DENGUE VIRUS INFECTION , CAREUS DENGUE NS1(CAREUS)-USED FOR THE RAPID QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN TO DENGUE VIRUS IN SERUM , PLASMA OR WHOLE BLOOD AS AN AID IN THE DIAGNOSIS OF DENGUE VIRUS INFECTION ,CAREUS DENGUE COMBO NS1 & IGM/IGG(CAREUS) -RAPID TEST USED FOR THE QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN AND OR ANTIBODIES TO DENGUE VIRUS IN SERUM , PLASMA OR WHOLE BLOOD AS AN AID IN THE DIAGNOSIS OF DENGUE VIRUS INFECTION

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

383	IMP/IVD/2019/000412	1.License Holder Name: DHR HOLDING INDIA PVT. LTD, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABL80 SC80(SC PH/LYTES)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURES PH, PCO2, CCA2+, CCL-, CK+, CAN+, HEMATOCRIT, GLUCOSE (GLU) AND LACTATE (LAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,SC9 SENSOR CASSETTE WITH BGEL(SC9 SENSOR CASSETTE)-THE ABL9 IS A PORTABLE, AUTOMATED ANALYZER THAT MEASURES PH, BLOOD GASES, ELECTROLYTES, LACTATE AND HEMATOCRIT IN WHOLE BLOOD. THE ABL9 IS INTENDED FOR USE BY TRAINED TECHNOLOGISTS, NURSES, PHYSICIANS AND THERAPISTS. IT IS INTENDED FOR USE IN OR NEAR A POINT-OF-CARE SETTING OR IN A HOSPITAL LABORATORY ENVIRONMENT.,ABL80 SC80(SC80 FULL-NO GLU, QC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURES PH, PCO2, CCA2+, CCL-, CK+, CAN+, HEMATOCRIT, GLUCOSE (GLU) AND LACTATE (LAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS,ABL80 SC80 (SC80 100/30 BG/HCT, QC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURES PH, PCO2, CCA2+, CCL-, CK+, CAN+, HEMATOCRIT, GLUCOSE (GLU) AND LACTATE (LAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS., ABL80 SC80 CO-OX(SC80 CO-OX, QC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURES PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, CGLU, CTHB, SO2, PO2HB, FCOHB, FMETHB AND FHHB. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS,SP9 SOLUTION PACK(SP9 SOLUTION PACK)-THE ABL9 IS A PORTABLE AUTOMATED ANALYZER THAT MEASURES PH, BLOOD GASES, ELECTROLYTES, LACTATE AND HEMATOCRIT IN WHOLE BLOOD. THE ABL9 IS INTENDED FOR USE BY TRAINED TECHNOLOGISTS, NURSES, PHYSICIANS AND THERAPISTS. IT IS INTENDED FOR USE IN OR NEAR A POINT-OF-CARE SETTING OR IN A HOSPITAL LABORATORY ENVIRONMENT.,ABL80 SP80 CO-OX(ABL80 SP80 CO-OX)-THE SOLUTION PACK PROVIDES THE NECESSARY REAGENTS, PACKAGED IN SEALED FOIL POUCHES, FOR USE IN THE CALIBRATION AND AUTOMATIC QUALITY CONTROL OF THE SENSORS,SC9 SENSOR CASSETTE(SC9 SENSOR CASSTTE)-THE ABL9 IS A PORTABLE, AUTOMATED ANALYZER THAT MEASURES PH, BLOOD GASES, ELECTROLYTES, LACTATE AND HEMATOCRIT IN WHOLE BLOOD. THE ABL9 IS INTENDED FOR USE BY TRAINED TECHNOLOGISTS, NURSES,

	PHYSICIANS AND THERAPISTS. IT IS INTENDED FOR USE IN OR NEAR A POINT-OF-CARE SETTING OR IN A HOSPITAL LABORATORY ENVIRONMENT.,ABL80 SC80 CO-OX(SC80 CO-OX FULL, NO GLU, NO QC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURES PH, PCO2, PO2, CCA2+, CCL-, CK+, CNA+, CGLU, CTHB, SO2, PO2HB, FCOHB, FMETHB AND FHHB. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS,ABL80 SC80(SC80 100/30 FULL, NO QC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURES PH, PCO2, CCA2+, CCL-, CK+, CAN+, HEMATOCRIT, GLUCOSE (GLU) AND LACTATE (LAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS,ABL80 SP80(SP80 SOLUTION PACK)-THE SOLUTION PACK PROVIDES THE NECESSARY REAGENTS, PACKAGED IN SEALED FOIL POUCHES, FOR USE IN THE CALIBRATION AND AUTOMATIC QUALITY CONTROL OF THE SENSORS,ABL80 SC80(SC80 300/30 FULL, QC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURES PH, PCO2, CCA2+, CCL-, CK+, CAN+, HEMATOCRIT, GLUCOSE (GLU) AND LACTATE (LAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80 (SC80 FULL +LAC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURES PH, PCO2, CCA2+, CCL-, CK+, CAN+, HEMATOCRIT, GLUCOSE (GLU) AND LACTATE (LAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80 (SC80 BG/HCT)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURES PH, PCO2, CCA2+, CCL-, CK+, CAN+, HEMATOCRIT, GLUCOSE (GLU) AND LACTATE (LAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL80 SC80 (SC80 FULL)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURES PH, PCO2, CCA2+, CCL-, CK+, CAN+, HEMATOCRIT, GLUCOSE (GLU) AND LACTATE (LAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.,ABL 80 SC80 (SC80 25/30 FULL-NO GLU, QC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURES PH, PCO2, CCA2+, CCL-, CK+, CAN+, HEMATOCRIT, GLUCOSE (GLU) AND LACTATE (LAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS., ABL80 SC80(SC80 25/30 FULL, QC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURES PH, PCO2, CCA2+, CCL-, CK+, CAN+, HEMATOCRIT, GLUCOSE (GLU) AND LACTATE (LAC) AS WELL

		AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS,SP80 CLEANING PACK(SP80 CLEANING PACK)-CLEANING PACK USED IN CONJUNCTION WITH A CLEANING CASSETTE AND FLUID PATH OBSTRUCTION KIT IF NECESSARY, TO FLUSH AND CLEAN THE INTERNAL FLUIDIC LINES WITHIN ALL VERSIONS OF THE ABL80 ANALYZERS. SEE SC80 CLEANING CASSETTE FOR ADDITIONAL INFORMATION.,ABL80 SC80(SC80 FULL-NO GLU, NO QC)-THE SENSOR CASSETTE INCLUDES SENSORS THAT MEASURES PH, PCO2, CCA2+, CCL-, CK+, CAN+, HEMATOCRIT, GLUCOSE (GLU) AND LACTATE (LAC) AS WELL AS THE SAMPLE INLET. THE CASSETTE ATTACHES TO THE FRONT OF THE ANALYZER, PROVIDING ELECTRONIC AND FLUIDIC CONNECTIONS.
384	IMP/IVD/2019/000413	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URINE CALIBRATOR (URINE CALIBRATOR)-THE URINE CALIBRATOR IS A LIQUID HUMAN URINE CALIBRATOR INTENDED TO BE USED WITH THE BECKMAN COULTER SYSTEM REAGENTS LISTED BELOW ON BECKMAN COULTER ANALYSERS.,HDL/LDL CHOLESTEROL CONTROL SERUM(HDL/LDL CHOLESTEROL CONTROL SERUM)-THE HDL/LDL-CHOLESTEROL CONTROL SERUM IS A LYOPHILISED HUMAN SERUM CONTROL DESIGNED TO MONITOR THE ANALYTICAL PERFORMANCE OF THE HDL AND LDL CHOLESTEROL REAGENTS, OSR6187 AND OSR6183 RESPECTIVELY, ON BECKMAN COULTER ANALYSERS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

385	IMP/IVD/2019/000415	1.License Holder Name: DHR HOLDING INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PLASMA/LOW HB MICROCUVETTE(HEMOCUE PLASMA/LOW HB MICROCUVETTE)-"THE SYSTEM SHALL BE USED FOR QUANTITATIVE DETERMINATION OF LOW LEVELS OF HEMOGLOBIN IN PLASMA, SERUM, AQUEOUS SOLUTIONS OR STORED/BANKED ERYTHROCYTES USING A SPECIALLY DESIGNED PHOTOMETER, THE HEMOCUE® PLASMA/LOW HB PHOTOMETER AND SPECIALLY DESIGNED MICROCUVETTES, HEMOCUE® PLASMA/LOW HB MICROCUVETTES. ",WBC DIFF MICROCUVETTE(HEMOCUE WBC DIFF MICROCUVETTE)-THE HEMOCUE WBC DIFF SYSTEM IS AN IN-VITRO DIAGNOSTIC SYSTEM DESIGNED FOR QUANTITATIVE DETERMINATION OF WHITE BLOOD CELLS (WBC) IN CAPILLARY OR VENOUS WHOLE BLOOD. THE SYSTEM PROVIDES VALUES FOR A TOTAL WHITE BLOOD CELL COUNT AND A DIFFERENTIAL COUNT INCLUDING NEUTROPHIL COUNT, LYMPHOCYTE COUNT, MONOCYTE COUNT, EOSINOPHIL COUNT AND BASOPHIL COUNT.,GLUCOSE 201 MICROCUVETTE(HEMOCUE GLUCOSE 201 MICROCUVETTE)-QUANTITATIVE DETERMINATION OF GLUCOSE IN WHOLE BLOOD USING A SPECIALLY DESIGNED ANALYZER, THE HEMOCUE GLUCOSE 201. THE QUANTITATIVE DETERMINATION OF THE INSTANT BLOOD GLUCOSE CONCENTRATION IN CIRCULATION SUPPLEMENTS THE CLINICAL EVIDENCE IN THE DIAGNOSIS AND TREATMENT OF THE DIABETIC PATIENT AS WELL AS IN THE MONITORING OF NEONATAL BLOOD GLUCOSE LEVELS. TO ESTABLISH HEMOCUE GLUCOSE REFERENCE VALUES AND AN INTERVENTION LEVEL, NEONATAL BLOOD SAMPLES SHOULD BE EVALUATED AGAINST A SUITABLE LABORATORY METHOD, TAKING INTO CONSIDERATION THE DIFFERENCE BETWEEN WHOLE BLOOD AND PLASMA REFERENCE VALUES. HEMOCUE GLUCOSE 201 MICROCUVETTES ARE FOR IN VITRO DIAGNOSTIC USE ONLY. THE HEMOCUE GLUCOSE 201 ANALYZER IS ONLY TO BE USED WITH HEMOCUE GLUCOSE 201 MICROCUVETTES. FOR PROFESSIONAL USE ONLY.,URINE ALBUMIN MICROCUVETTES(HEMOCUE® URINE ALBUMIN MICROCUVETTES)-"THE SYSTEM SHALL BE USED FOR SCREENING, MONITORING AND TO SUPPLEMENT THE CLINICAL EVIDENCE IN THE DIAGNOSIS AND TREATMENT OF MICROALBUMINURIA THE TEST SHOULD BE USED FOR: -PATIENTS WITH DIABETES -PATIENTS WITH HYPERTENSION -PREGNANT WOMEN -THE GENERAL POPULATION INTENDED USER THE HEMOCUE® ALBUMIN 201 SYSTEM IS FOR PROFESSIONAL USE ONLY.",WBC MICROCUVETTE(HEMOCUE WBC MICROCUVETTE)-THE HEMOCUE WBC SYSTEM IS INDICATED FOR USE FOR QUANTITATIVE DETERMINATION OF WHITE BLOOD CELL (WBC) COUNT IN CAPILLARY

	OR VENOUS WHOLE BLOOD. THE HEMOCUE WBC SYSTEM IS FOR IN VITRO DIAGNOSTIC USE ONLY. THE HEMOCUE WBC ANALYZER IS ONLY TO BE USED WITH HEMOCUE WBC MICROCUVETTES. THE HEMOCUE WBC SYSTEM IS INDICATED FOR USE IN CLINICAL LABORATORIES AND FOR POINT-OF-CARE SETTINGS.,HB 301 MICROCUVETTE(HEMOCUE HB 301 MICROCUVETTE)-"THE HEMOCUE® HB 301 SYSTEM IS DESIGNED FOR QUANTITATIVE POINT-OF-CARE WHOLE BLOOD (CAPILLARY, VENOUS OR ARTERIAL) HEMOGLOBIN DETERMINATION IN PRIMARY CARE OR BLOOD DONATION SETTINGS USING A SPECIALLY DESIGNED ANALYZER, THE HEMOCUE® HB 301 ANALYZER, AND SPECIALLY DESIGNED MICROCUVETTES, THE HEMOCUE® HB 301 MICROCUVETTES. THE HEMOCUE® HB 301 SYSTEM IS FOR IN VITRO DIAGNOSTIC USE ONLY. THE HEMOCUE® HB 301 ANALYZER IS ONLY TO BE USED WITH HEMOCUE® HB 301 MICROCUVETTES.,GLUCOSE 201 RT MICROCUVETTE(HEMOCUE GLUCOSE 201 RT MICROCUVETTE)-"THE HEMOCUE® GLUCOSE 201 RT SYSTEM IS USED FOR QUANTITATIVE DETERMINATION OF GLUCOSE IN WHOLE BLOOD, SUPPLEMENTING THE CLINICAL EVIDENCE IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH DIABETES AS WELL AS MONITORING OF NEONATAL BLOOD GLUCOSE LEVELS. THE SYSTEM SHOULD NOT BE USED ON CRITICALLY ILL NEONATES IN NEONATAL INTENSIVE CARE SETTINGS. THE HEMOCUE® GLUCOSE 201 RT SYSTEM IS FOR IN VITRO DIAGNOSTIC USE ONLY. THE HEMOCUE® GLUCOSE 201 RT ANALYZER IS ONLY TO BE USED WITH HEMOCUE® GLUCOSE 201 RT MICROCUVETTES. FOR PROFESSIONAL USE ONLY.,HB 201 MICROCUVETTE(HEMOCUE HB 201 MICROCUVETTE)-"THE HEMOCUE® HB 201+ SYSTEM IS INTENDED FOR QUANTITATIVE DETERMINATION OF HEMOGLOBIN IN CAPILLARY, VENOUS AND ARTERIAL WHOLE BLOOD, USING A SPECIALLY DESIGNED ANALYZER, THE HEMOCUE® HB 201+ ANALYZER, AND SPECIALLY DESIGNED MICROCUVETTES, THE HEMOCUE® HB 201 MICROCUVETTES. HEMOCUE® HB 201 MICROCUVETTES ARE FOR IN VITRO DIAGNOSTIC USE ONLY. THE HB 201+ ANALYZER IS ONLY TO BE USED WITH HEMOCUE® HB 201 MICROCUVETTES. "

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

386	IMP/IVD/2019/000418	1.License Holder Name: SYSMEX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ISE CLEANER(ISE CLEANER)-ISE CLEANER IS A SOLUTION INTENDED FOR THE CLEANING OF ISE MODULE ON SYSMEX CLINICAL CHEMISTRY ANALYZER BX SERIES,H SOLUTION(H SOLUTION)-H SOLUTION IS A SOLUTION INTENDED FOR THE CALIBRATION OF ISE MODULE ON SYSMEX CLINICAL CHEMISTRY ANALYZER BX SERIES,L SOLUTION(L SOLUTION)-L SOLUTION IS A SOLUTION INTENDED FOR THE CALIBRATION OF ISE MODULE ON SYSMEX CLINICAL CHEMISTRY ANALYZER BX SERIES,NA ELECTRODE(NA ELECTRODE)-NA ELECTRODE IS AN ION SELECTIVE ELECTRODE INTENDED FOR THE QUANTITATIVE DETERMINATION OF SODIUM (NA) ON FURUNO ANALYZER INSTRUMENT,CL ELECTRODE(CL ELECTRODE)-CL ELECTRODE IS AN ION SELECTIVE ELECTRODE INTENDED FOR THE QUANTITATIVE DETERMINATION OF CHLORIDE (CL) ON FURUNO ANALYZER INSTRUMENT.,K ELECTRODE(K ELECTRODE)-K ELECTRODE IS AN ION SELECTIVE ELECTRODE INTENDED FOR THE QUANTITATIVE DETERMINATION OF POTASSIUM (K) ON FURUNO ANALYZER INSTRUMENT,REF SOLUTION(REF SOLUTION)-REF SOLUTION IS A SOLUTION INTENDED FOR THE PRIMING OF ISE ELECTRODE REF ON SYSMEX CLINICAL CHEMISTRY ANALYZER BX SERIES.,REF ELECTRODE(REF ELECTRODE)-REF ELECTRODE IS AN ION SELECTIVE ELECTRODE INTENDED FOR THE QUANTITATIVE DETERMINATION OF SODIUM (NA), POTASSIUM (K), AND CHLORIDE (CL) ON FURUNO ANALYZER INSTRUMENT,DILUENT(DILUENT)-DILUENT IS A SOLUTION INTENDED FOR DILUTING URINE SAMPLE ON SYSMEX CLINICAL CHEMISTRY ANALYZER BX SERIES,ETCHING (ETCHING)-ETCHING IS A SOLUTION INTENDED FOR THE TREATMENT OF ISE ELECTRODE NA ON SYSMEX CLINICAL CHEMISTRY ANALYZER BX SERIES.

387	IMP/IVD/2019/000419	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARCHITECT STAT TROPONIN-I CALIBRATORS(ARCHITECT STAT TROPONIN-I CALIBRATORS)-THE ARCHITECT STAT TROPONIN-I CALIBRATORS ARE FOR CALIBRATION OF THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN-I IN HUMAN SERUM AND PLASMA.,IMMUNOGLOBULIN A(IMMUNOGLOBULIN A)-THE IMMUNOGLOBULIN A (IGA) ASSAY IS USED FOR THE QUANTITATION OF IGA IN HUMAN SERUM OR PLASMA.,HGB/WIC LYSE(HGB/WIC LYSE)-LYSE THE RBC AND MINIMIZE THE RESULTANT STROMA. STRIP THE WHITE CELL CYTOPLASM. CONVERT HGB TO MODIFIED HEMIGLOBINCYANIDE COMPLEX.,IMMUNOGLOBULIN M (IMMUNOGLOBULIN M)-THE IMMUNOGLOBULIN M (IGM) ASSAY IS USED FOR THE QUANTITATION OF IGM IN HUMAN SERUM OR PLASMA.,ARCHITECT ANTI-TG REAGENT(ARCHITECT ANTI-TG)-ARCHITECT ANTI-TG IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF THE IGG CLASS OF THYROGLOBULIN AUTOANTIBODIES (ANTI-TG) IN HUMAN SERUM AND PLASMA ON THE ARCHITECT ISYSTEM. THE ARCHITECT ANTI-TG ASSAY IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF AUTOIMMUNE THYROID DISEASE.,COMPLEMENT C3 (COMPLEMENT C3)-THE COMPLEMENT C3 (C3) ASSAY IS USED FOR THE QUANTITATION OF C3 IN HUMAN SERUM OR PLASMA., ARCHITECT T-UPTAKE CONTROLS(ARCHITECT T-UPTAKE CONTROLS) -THE ARCHITECT T-UPTAKE CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THE TOTAL BINDING CAPACITY OF HUMAN SERUM OR PLASMA FOR THYROID HORMONE THYROXINE (T4).,PREALBUMIN(PREALBUMIN)-THE PREALBUMIN ASSAY IS USED FOR THE QUANTITATION OF PREALBUMIN IN HUMAN SERUM.,ARCHITECT STAT MYOGLOBIN CALIBRATORS(ARCHITECT STAT MYOGLOBIN CALIBRATORS)-THE ARCHITECT STAT MYOGLOBIN CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM AND PLASMA.,COMPLEMENT C4 (COMPLEMENT C4)-THE COMPLEMENT C4 (C4) ASSAY IS USED FOR THE QUANTITATION OF C4 IN HUMAN SERUM OR PLASMA., ARCHITECT STAT CK-MB REAGENT(ARCHITECT STAT CK-MB)-ARCHITECT STAT CK-MB IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF THE MB ISOENZYME OF CREATINE KINASE (CK-MB) IN HUMAN SERUM

	AND PLASMA ON THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY. CK-MB VALUES ARE USED TO ASSIST IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (MI).,IMMUNOGLOBULIN G (IMMUNOGLOBULIN G)-THE IMMUNOGLOBULIN G (IGG) ASSAY IS USED FOR THE QUANTITATION OF IGG IN HUMAN SERUM OR PLASMA.,DILUENT/SHEATH(DILUENT/SHEATH)-PREPARES EACH CELL FOR COUNTING AND SIZING, ACTING AS THE PRIMARY DILUTING FLUID FOR THE RBC/PLT AND RETC. ACT AS THE DILUENT FOR THE RBCS, PLTS, AND HEMOGLOBIN.,APOLIPOPROTEIN B (APOLIPOPROTEIN B)-THE APOLIPOPROTEIN B (APOB) ASSAY IS USED FOR THE QUANTITATION OF APOB IN HUMAN SERUM OR PLASMA.,HAPTOGLOBIN(HAPTOGLOBIN)-THE HAPTOGLOBIN ASSAY IS USED FOR THE QUANTITATION OF HAPTOGLOBIN IN HUMAN SERUM OR PLASMA.,APOLIPOPROTEIN A1(APOLIPOPROTEIN A1)-THE APOLIPOPROTEIN A1 (APOA) ASSAY IS USED FOR THE QUANTITATION OF APOLIPOPROTEIN A-I IN HUMAN SERUM OR PLASMA.,RETICULOCYTE REAGENT(RETICULOCYTE REAGENT)-STAINS THE NUCLEIC ACIDS OF CELLS PRESENT IN THE RETICULOCYTE DILUTION AND PRIMES THE RETICULOCYTE REAGENT SYRINGE AND TUBING.,ACID WASH(ACID WASH)-ACID WASH IS INTENDED FOR USE WITH THE ARCHITECT CSYSTEMS,WBC REAGENT, PART B(WBC REAGENT, PART B)-ACTS AS THE DILUTING FLUID FOR THE WBC DILUTION, AND MAINTAINS WBC INTEGRITY AND MORPHOLOGY. LYSES RBCS, AND STAINS DNA IN EXPOSED NUCLEI OF ANY NRBCS.,ARCHITECT STAT CK-MB CALIBRATORS(ARCHITECT STAT CK-MB CALIBRATORS)-THE ARCHITECT STAT CK-MB CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CK-MB IN HUMAN SERUM AND PLASMA.,CN-FREE HGB/WIC LYSE(CN-FREE HGB/WIC LYSE)-LYSE THE RED BLOOD CELLS, STRIP THE WHITE CELL CYTOPLASM. CONVERT HGB TO A SINGLE CHROMAGEN.,CN-FREE HEMOGLOBIN REAGENT(CN-FREE HEMOGLOBIN REAGENT)-ACTS AS LYSING AGENT IN THE HEMOGLOBIN (HGB) DILUTION. CONVERTS HGB TO A SINGLE CHROMOGEN.,DETERGENT(DETERGENT)-PROVIDES OPTICALLY CLEAR SOLUTION USED TO OBTAIN THE ZERO REFERENCE DURING HGB MEASUREMENT CYCLE. PROVIDE PROPER MENISCUS FORMATION IN METERING TUBES.,ARCHITECT ANTI-TG CONTROLS (ARCHITECT ANTI-TG CONTROLS)-THE ARCHITECT ANTI-TG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM (REAGENTS, CALIBRATORS AND INSTRUMENT) WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THE IGG CLASS OF THYROGLOBULIN AUTOANTIBODIES (ANTI-TG) IN HUMAN

	SERUM AND PLASMA.,DILUENT(DILUENT)-ACT AS DILUENT FOR THE WBCS, RBCS, PLTS,AND HGB. MAINTAIN THE CELL VOLUME OF EACH RBC AND PLT.,RHEUMATOID FACTOR(RHEUMATOID FACTOR)-THE RHEUMATOID FACTOR (RF) ASSAY IS USED FOR THE QUANTITATION OF RHEUMATOID FACTOR IN HUMAN SERUM.,ALKALINE PHOSPHATASE(ALKALINE PHOSPHATASE)-THE ALKALINE PHOSPHATASE ASSAY IS USED FOR THE QUANTITATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR PLASMA.,ARCHITECT ANTI-TPO REAGENT(ARCHITECT ANTI-TPO)-ARCHITECT ANTI-TPO IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF THE IGG CLASS OF THYROID PEROXIDASE AUTOANTIBODIES (ANTI-TPO) IN HUMAN SERUM AND PLASMA ON THE ARCHITECT ISYSTEM. THE ARCHITECT ANTI-TPO ASSAY IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF THYROID DISEASE.,ICT SAMPLE DILUENT(ICT SAMPLE DILUENT)-THE ARCHITECT CSYSTEMS ICT (INTEGRATED CHIP TECHNOLOGY) IS USED FOR THE QUANTITATION OF SODIUM, POTASSIUM, AND CHLORIDE IN HUMAN SERUM, PLASMA, OR URINE.,ALKALINE WASH (ALKALINE WASH)-FOR THE USE OF ALKALINE WASH WITH THE ARCHITECT CSYSTEMS.,SHEATH(SHEATH)-OSMOTICALLY LYSE THE RED CELLS. MAINTAIN THE LIGHT SCATTERING PROPERTIES OF THE WBCS.,ALBUMIN BCP(ALBUMIN BCP)-THE ALBUMIN BCP ASSAY IS USED FOR THE QUANTITATION OF ALBUMIN IN HUMAN SERUM OR PLASMA.,ACID PHOSPHATASE(ACID PHOSPHATASE)-THE ACID PHOSPHATASE ASSAY IS USED FOR THE QUANTITATION OF ACID PHOSPHATASE IN HUMAN SERUM.,ARCHITECT T-UPTAKE REAGENT (ARCHITECT T-UPTAKE)-THE ARCHITECT T-UPTAKE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF THE TOTAL BINDING CAPACITY OF HUMAN SERUM OR PLASMA FOR THE THYROID HORMONE, THYROXINE (T4). THE ARCHITECT T-UPTAKE ASSAY SHOULD BE USED IN CONJUNCTION WITH TOTAL T4 TO YIELD A CALCULATED FREE THYROXINE INDEX (FTI), AS AN AID IN THE ASSESSMENT OF THYROID FUNCTION STATUS. ,ARCHITECT ANTI-TG CALIBRATORS(ARCHITECT ANTI-TG CALIBRATORS)-THE ARCHITECT ANTI-TG CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THE IGG CLASS OF THYROGLOBULIN AUTOANTIBODIES (ANTI-TG) IN HUMAN SERUM AND PLASMA., ARCHITECT CORTISOL REAGENT(ARCHITECT CORTISOL)-ARCHITECT CORTISOL IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM, PLASMA OR URINE ON THE ARCHITECT ISYSTEM. THE ARCHITECT CORTISOL ASSAY IS INTENDED FOR USE AS AN AID IN

	THE DIAGNOSIS AND TREATMENT OF ADRENAL DISORDERS.,WBC LYSE(WBC LYSE)-ACT AS THE DILUENT FOR THE WBC. OSMOTICALLY LYSE THE RED CELLS. ACT AS A DILUENT FOR RETICULOCYTES., ARCHITECT ANTI-TPO CONTROLS(ARCHITECT ANTI-TPO CONTROLS)-THE ARCHITECT ANTI-TPO CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM (REAGENTS, CALIBRATORS AND INSTRUMENT) WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THE IGG CLASS OF THYROID PEROXIDASE AUTOANTIBODIES (ANTI-TPO) IN HUMAN SERUM AND PLASMA.,CN-FREE HGB/NOC LYSE(CN-FREE HGB/NOC LYSE)-LYSE THE RED BLOOD CELLS. STRIP THE WHITE CELL CYTOPLASM. CONVERT HGB TO A STABLE CHROMAGEN COMPLEX.,ARCHITECT STAT TROPONIN-I REAGENT(ARCHITECT STAT TROPONIN-I)-ARCHITECT STAT TROPONIN-I IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN-I IN HUMAN SERUM AND PLASMA ON THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY. TROPONIN-I VALUES ARE USED TO ASSIST IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (MI) AND IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES (INCLUDING UNSTABLE ANGINA AND NON-ST ELEVATION) WITH RESPECT TO RELATIVE RISK OF MORTALITY, MYOCARDIAL INFARCTION, OR INCREASED PROBABILITY OF ISCHEMIC EVENTS.,RETICULOCYTE REAGENT (RETICULOCYTE REAGENT)-CELL-DYN WHEN RETICULOCYTE REAGENT USED IN COMBINATION WITH CELL-DYN RUBY CELL-DYN 3200, OR CELL-DYN 3700 RETICULOCYTE SOFTWARE, ENABLES A WHOLE BLOOD SPECIMEN TO BE ANALYZED FOR RETICULOCYTES., ARCHITECT CORTISOL CALIBRATORS(ARCHITECT CORTISOL CALIBRATORS)-THE ARCHITECT CORTISOL CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM, PLASMA OR URINE.,ARCHITECT T-UPTAKE CALIBRATORS(ARCHITECT T-UPTAKE CALIBRATORS)-THE ARCHITECT T-UPTAKE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THE TOTAL BINDING CAPACITY OF HUMAN SERUM OR PLASMA FOR THYROID HORMONE THYROXINE (T4).,ARCHITECT STAT MYOGLOBIN REAGENT (ARCHITECT STAT MYOGLOBIN)-ARCHITECT STAT MYOGLOBIN IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM AND PLASMA ON THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY. MYOGLOBIN VALUES ARE USED TO ASSIST IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (MI).,ARCHITECT

	ANTI-TPO CALIBRATORS(ARCHITECT ANTI-TPO CALIBRATORS)-THE ARCHITECT ANTI-TPO CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THE IGG CLASS OF THYROID PEROXIDASE AUTOANTIBODIES (ANTI-TPO) IN HUMAN SERUM AND PLASMA., ENZYMATIC CLEANER CONCENTRATE(ENZYMATIC CLEANER CONCENTRATE)-CELL-DYN ENZYMATIC CLEANER CONCENTRATE IS A SPECIAL CLEANING AGENT FOR USE ON CELL-DYN HEMATOLOGY ANALYZERS. ANALYZERS SHOULD BE CLEANED ON THE SCHEDULE RECOMMENDED IN THE APPROPRIATE CELL-DYN OPERATOR'S MANUAL, OR WHENEVER A REPEATED CLOG OR OBSTRUCTED APERTURE IS SUSPECTED. CELL-DYN ENZYMATIC CLEANER CONCENTRATE WAS SPECIFICALLY DEVELOPED FOR THE REMOVAL OF PROTEIN BUILDUP AND DEBRIS (CLOGS) IN COUNTING ORIFICES, FLOW CELLS, AND ASSOCIATED ANALYZER TUBING. CELL-DYN ENZYMATIC CLEANER CONCENTRATE IS LESS HARMFUL TO DELICATE PLASTIC AND CERAMIC PARTS THAN IS BLEACH (SODIUM HYPOCHLORITE).,WBC REAGENT, PART A(WBC REAGENT, PART A)-ACTS AS THE DILUTING FLUID FOR THE WBC DILUTION, AND MAINTAINS WBC INTEGRITY AND MORPHOLOGY. LYSES RBCS, AND STAINS DNA IN EXPOSED NUCLEI OF ANY NRBCS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

388	IMP/IVD/2019/000420	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD BBL CATALASE REAGENT DROPPERS(BD BBL CATALASE REAGENT DROPPERS)-BD BBL CATALASE REAGENT DROPPERS ARE USED FOR DETERMINING THE PRESENCE OF CATALASE PRODUCED BY BACTERIA.,BD BBL VOGES-PROSKAUER A REAGENT, DROPPERS(BD BBL VOGES-PROSKAUER A REAGENT, DROPPERS)-BD BBL™ VOGES-PROSKAUER REAGENT DROPPERS ARE INTENDED FOR USE IN THE VOGES-PROSKAUER TEST, ONE OF SEVERAL QUALITATIVE TESTS USED TO DISTINGUISH BETWEEN MEMBERS OF THE ENTEROBACTERIACEAE,BD BBL LACTOPHENOL COTTON BLUE STAIN DROPPERS(BD BBL LACTOPHENOL COTTON BLUE STAIN DROPPERS)-BD BBL™ LACTOPHENOL COTTON BLUE STAIN DROPPERS ARE INTENDED FOR USE AS A STAIN IN THE EXAMINATION OF FUNGI,BD BBL INDIA INK REAGENT DROPPERS(BD BBL INDIA INK REAGENT DROPPERS)-BD BBL™ INDIA INK REAGENT DROPPERS ARE USED TO ENHANCE THE MICROSCOPIC DETECTION OF CRYPTOCOCCUS SPP. IN WET PREPARATIONS,BD BBL CALCOFLUOR WHITE REAGENT DROPPERS (BD BBL CALCOFLUOR WHITE REAGENT DROPPERS)-BD BBL™ CALCOFLUOR WHITE REAGENT DROPPERS ARE USED IN THE RAPID FLUORESCENT MICROSCOPIC DETECTION OF FUNGI IN DIRECT SMEARS,BD BBL INDOLE REAGENT DROPPER(BD BBL INDOLE REAGENT DROPPER)-BD BBL™ INDOLE REAGENT DROPPERS (MODIFIED KOVACS' REAGENT) ARE USED IN DETERMINING THE ABILITY OF BACTERIA TO PRODUCE INDOLE BY THE DEAMINATION OF TRYPTOPHAN,BD BBL DMACA INDOLE REAGENT DROPPERS(BD BBL DMACA INDOLE REAGENT DROPPERS)-FOR THE DETECTION OF INDOLE PRODUCTION AS AN AID IN THE IDENTIFICATION OF AEROBIC, ANAEROBIC, OR FACULTATIVELY ANAEROBIC ORGANISMS, BD BBL VOGES-PROSKAUER B REAGENT, DROPPERS(BD BBL VOGES-PROSKAUER B REAGENT, DROPPERS)-BD BBL™ VOGES-PROSKAUER REAGENT DROPPERS ARE INTENDED FOR USE IN THE VOGES-PROSKAUER TEST, ONE OF SEVERAL QUALITATIVE TESTS USED TO DISTINGUISH BETWEEN MEMBERS OF THE ENTEROBACTERIACEAE,BD BBL NITRATE A REAGENT, DROPPERS(BD BBL NITRATE A REAGENT, DROPPERS)-BD BBL™ NITRATE REAGENT A DROPPERS ARE FOR USE IN DETERMINING THE ABILITY OF BACTERIA TO REDUCE NITRATE TO NITRITE OR FREE NITROGEN GAS.,BD BBL PYR REAGENT DROPPERS (BD BBL PYR REAGENT DROPPERS)-BD BBL™ PYR REAGENT DROPPERS ARE USED IN THE RAPID PRESUMPTIVE IDENTIFICATION OF GROUP A B-HEMOLYTIC STREPTOCOCCI AND GROUP D ENTEROCOCCI.,BD BBL OXIDASE REAGENT DROPPERS(BD BBL OXIDASE REAGENT DROPPERS)-BD BBL™ OXIDASE REAGENT

		DROPPERS ARE USED IN THE KOVACS OXIDASE TEST AS A QUALITATIVE REACTION IN THE IDENTIFICATION OF NONFERMENTERS AND MISCELLANEOUS GRAM-NEGATIVE BACTERIA,BD BBL NITRATE B REAGENT, DROPPERS(BD BBL NITRATE B REAGENT, DROPPERS)-BD BBL NITRATE REAGENT B DROPPERS ARE FOR USE IN DETERMINING THE ABILITY OF BACTERIA TO REDUCE NITRATE TO NITRITE OR FREE NITROGEN GAS.
389	IMP/IVD/2019/000421	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE MONITORING SYSTEM FOR U-RIGHT TD4285A(OZOCHECK)-THIS SYSTEM IS INTENDED FOR USE OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) BY PEOPLE WITH DIABETES AT HOME AND BY HEALTH ,GLUCOSE TEST STRIPS FOR U-RIGHT TD4285A(OZOCHECK)-STRIPS FOR ESTIMATION OF GLUCOSE LEVELS USED IN BLOOD GLUCOSE MONITORING SYSTEM
390	IMP/IVD/2019/000422	1.License Holder Name: SYSMEX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SHEATH FLUID(SHEATH FLUID)-FOR IN VITRO DIAGNOSTIC USE ONLY. SHEATH FLUID IS INTENTED TO ENSURE THAT THE SAMPLE INTRODUCED TO TH FLOW CYTOMETER WILL RUN UNDER HYDRODYNAMIC FOCUSING. SHEATH FLUID PERMITS THE SYSTEM TO RUN UNDER CONTROLLED CONDITIONS WITH PARTICLES PASSING THROUGH THE FLOW CELL IN SINGLE FILE ORDER.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

391	IMP/IVD/2019/000423	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD PHOENIX EMERGE AST BROTH(BD PHOENIX EMERGE AST BROTH)-THE BD PHOENIX™ AUTOMATED MICROBIOLOGY SYSTEM IS INTENDED FOR THE RAPID IDENTIFICATION (ID) AND ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) OF CLINICALLY SIGNIFICANT BACTERIA. THE BD PHOENIX SYSTEM PROVIDES RAPID RESULTS FOR MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-POSITIVE BACTERIA AS WELL AS MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM-NEGATIVE BACTERIA OF HUMAN ORIGIN. THE BD PHOENIX SYSTEM IS ALSO INTENDED FOR THE RAPID IDENTIFICATION OF YEAST AND YEAST-LIKE ORGANISMS.,BD PHOENIX™ ID BROTH (BD PHOENIX™ ID BROTH) -THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM IS INTENDED FOR THE RAPID IDENTIFICATION (ID) AND ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) OF CLINICALLY SIGNIFICANT BACTERIA. THE PHOENIX SYSTEM PROVIDES RAPID RESULTS FOR MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM POSITIVE BACTERIA AS WELL AS AEROBIC AND FACULTATIVE ANAEROBIC GRAM-NEGATIVE BACTERIA OF HUMAN ORIGIN. THE PHOENIX SYSTEM IS ALSO INTENDED FOR THE RAPID IDENTIFICATION OF YEAST AND YEAST-LIKE ORGANISMS. ,BD BBL SALINE, NORMAL(BD BBL SALINE, NORMAL)-SALINE, NORMAL (PHYSIOLOGICAL) IS USED IN PROCEDURES THAT REQUIRE THE USE OF AN ISOTONIC DILUENT., COLUMBIA AGAR WITH 5% SHEEP BLOOD(COLUMBIA AGAR WITH 5% SHEEP BLOOD)-COLUMBIA AGAR WITH 5% SHEEP BLOOD IS A HIGHLY NUTRITIOUS GENERAL PURPOSE MEDIUM FOR THE ISOLATION AND CULTIVATION OF NONFASTIDIOUS AND FASTIDIOUS MICROORGANISMS FROM A VARIETY OF CLINICAL AND NONCLINICAL MATERIAL.,BD BBL™ CHOCOLATE II AGAR(BD BBL™ CHOCOLATE II AGAR)-BD BBL CHOCOLATE II AGAR IS AN IMPROVED MEDIUM FOR USE IN QUALITATIVE PROCEDURES FOR THE ISOLATION AND CULTIVATION OF FASTIDIOUS MICROORGANISMS, ESPECIALLY NEISSERIA AND HAEMOPHILUS SPECIES, FROM A VARIETY OF CLINICAL SPECIMENS,DIFCO™ EGG YOLK ENRICHMENT 50%(DIFCO™ EGG YOLK ENRICHMENT 50%)-DIFCO™ EGG YOLK ENRICHMENT 50% IS A CONCENTRATED EGG YOLK EMULSION RECOMMENDED FOR USE IN A VARIETY OF MEDIA SUCH AS DIFCO™ SFP AGAR BASE AND DIFCO™ MCCLUNG TOABE AGAR BASE FOR THE ISOLATION AND IDENTIFICATION OF CLOSTRIDIUM SPECIES ON THE BASIS OF THEIR LECITHINASE ACTIVITY.,BD BBL™ TRYPTICASE SOY AGAR WITH 5% SHEEP BLOOD(BD BBL™ TRYPTICASE SOY AGAR WITH 5% SHEEP BLOOD)-BD BBL TRYPTICASE SOY AGAR IS USED FOR CULTIVATING FASTIDIOUS MICROORGANISMS AND FOR THE VISUALIZATION OF

	HEMOLYTIC REACTIONS PRODUCED BY MANY BACTERIAL SPECIES. PLATES LABELED “DEEP FILL” CONTAIN AN ADDITIONAL VOLUME OF MEDIUM TO REDUCE THE EFFECTS OF DRYING DURING PROLONGED INCUBATION.,BD PHOENIX™ AST-S BROTH(BD PHOENIX™ AST-S BROTH)-THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM IS INTENDED FOR THE RAPID IDENTIFICATION (ID) AND ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) OF CLINICALLY SIGNIFICANT BACTERIA. THE PHOENIX SYSTEM PROVIDES RAPID RESULTS FOR MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM POSITIVE BACTERIA AS WELL AS AEROBIC AND FACULTATIVE ANAEROBIC GRAM-NEGATIVE BACTERIA OF HUMAN ORIGIN. THE PHOENIX SYSTEM IS ALSO INTENDED FOR THE RAPID IDENTIFICATION OF YEAST AND YEAST-LIKE ORGANISMS. ,BD BBL™ COLUMBIA AGAR WITH 5% SHEEP BLOOD(BD BBL™ COLUMBIA AGAR WITH 5% SHEEP BLOOD)-BD BBL COLUMBIA AGAR WITH 5% SHEEP BLOOD IS A HIGHLY NUTRITIOUS GENERAL PURPOSE MEDIUM FOR THE ISOLATION AND CULTIVATION OF NONFASTIDIOUS AND FASTIDIOUS MICROORGANISMS FROM A VARIETY OF CLINICAL AND NONCLINICAL MATERIAL,BD BBL™ MGIT™ MYCOBACTERIA GROWTH INDICATOR TUBES, 4 ML (100/SP)/ (25/SP)(BD BBL™ MGIT™ MYCOBACTERIA GROWTH INDICATOR TUBES, 4 ML (100/SP)/ (25/SP))-THE BBL™ MGIT™ MYCOBACTERIA GROWTH INDICATOR TUBE SUPPLEMENTED WITH BBL™ MGIT™ OADC ENRICHMENT AND BBL™ MGIT™ PANTA™ ANTIBIOTIC MIXTURE, WHEN APPROPRIATE, IS INTENDED FOR THE DETECTION AND RECOVERY OF MYCOBACTERIA. ACCEPTABLE SPECIMEN TYPES ARE DIGESTED AND DECONTAMINATED CLINICAL SPECIMENS (EXCEPT URINE) AND STERILE BODY FLUIDS (EXCEPT BLOOD).,BBL™ HEMOGOBIN SOLUTION 2%(BBL™ HEMOGOBIN SOLUTION 2%)-BD BBL™ HEMOGLOBIN PRODUCTS ARE USED IN PREPARING MICROBIOLOGICAL CULTURE MEDIA.,BD BACTEC™ MGIT™ 960 SUPPLEMENT KIT(BD BACTEC™ MGIT™ 960 SUPPLEMENT KIT)-THE BD BBL™ MGIT™ MYCOBACTERIA GROWTH INDICATOR TUBE SUPPLEMENTED WITH BD BACTEC™ MGIT™ GROWTH SUPPLEMENT AND BD BBL™ MGIT™ PANTA™ ANTIBIOTIC MIXTURE IS INTENDED FOR THE DETECTION AND RECOVERY OF MYCOBACTERIA USING THE BD BACTEC™ MGIT™ 960 AND BD BACTEC™ MGIT™ 320 SYSTEMS. ACCEPTABLE SPECIMEN TYPES ARE DIGESTED AND DECONTAMINATED CLINICAL SPECIMENS (EXCEPT URINE), AND STERILE BODY FLUIDS (EXCEPT BLOOD). ,BD BACTEC ™ MGIT™ 960 CALIBRATOR KIT(BD BACTEC ™ MGIT™ 960 CALIBRATOR KIT)-ALL BD BACTEC MGIT INSTRUMENTS ARE CALI¬BRATED AT THE FACTORY PRIOR TO SHIPMENT. IN ADDITION, ONCE PER HOUR, EACH DETECTOR IN THE DETECTOR ASSEMBLY READS THE CALIBRATOR TUBE PRESENT IN ITS ROW. AFTER THE CALIBRATOR TUBE IS READ,

	THE READ¬INGS ARE USED BY THE BUILT-IN-TEST TO VERIFY THAT THE DETECTION INSTRUMENT IS IN CALIBRATION.,BD BACTEC™ MGIT™ 960 SIRE KIT(BD BACTEC™ MGIT™ 960 SIRE KIT)-THE BD BACTEC™ MGIT™ 960 SIRE KIT IS A RAPID QUALITATIVE PROCEDURE FOR SUSCEPTIBILITY TESTING OF MYCOBACTERIUM TUBERCULOSIS, FROM CULTURE, TO STREPTOMYCIN (STR), ISONIAZID (INH), RIFAMPIN (RIF) AND ETHAMBUTOL (EMB). THE BD BACTEC MGIT 960 STR 4.0 KIT AND THE BD BACTEC MGIT 960 INH 0.4 KIT ARE FOR TESTING AT HIGHER DRUG CONCENTRATIONS. THE BD BACTEC MGIT 960 SUSCEPTIBILITY TEST KITS ARE USED WITH THE BD BACTEC MGIT 960 AND BD BACTEC MGIT 320 SYSTEMS ,BD DIRECTIGEN™ MENINGITIS COMBO KIT (90 DETERMINATIONS)(BD DIRECTIGEN™ MENINGITIS COMBO KIT (90 DETERMINATIONS))-THE BD DIRECTIGEN™ MENINGITIS COMBO TEST IS A PRESUMPTIVE LATEX AGGLUTINATION TEST FOR THE DIRECT QUALITATIVE DETECTION OF ANTIGENS TO H. INFLUENZAE TYPE B, S. PNEUMONIAE, N. MENINGITIDIS GROUPS A, B, C, Y OR W135 AND ESCHERICHIA COLI K1 IN CEREBROSPINAL FLUID (CSF), SERUM OR URINE. THE TEST CAN ALSO BE USED FOR THE DIRECT QUALITATIVE DETECTION OF ANTIGENS TO GROUP B STREPTOCOCCUS IN CSF AND SERUM. IN ADDITION, THE TEST KIT PROVIDES CONFIRMATION AND SEROGROUPING CAPABILITIES FROM SUSPECTED COLONIES OF H. INFLUENZAE TYPE B, S. PNEUMONIAE, GROUP B STREPTOCOCCUS, AND N. MENINGITIDIS GROUPS A / Y, B OR C / W135. VISIBLE AGGLUTINATION OCCURS WHEN A SAMPLE CONTAINING ANY OF THESE BACTERIAL ANTIGENS IS REACTED WITH ITS RESPECTIVE ANTIBODY-COATED LATEX BEADS.,BD BBL™ MGIT™ MYCOBACTERIA GROWTH INDICATOR TUBES, 7 ML(BD BBL™ MGIT™ MYCOBACTERIA GROWTH INDICATOR TUBES, 7 ML)-THE BD BBL™ MGIT™ MYCOBACTERIA GROWTH INDICATOR TUBE SUPPLEMENTED WITH BD BACTEC™ MGIT™ GROWTH SUPPLEMENT AND BD BBL™ MGIT™ PANTA™ ANTIBIOTIC MIXTURE IS INTENDED FOR THE DETECTION AND RECOVERY OF MYCOBACTERIA USING THE BD BACTEC™ MGIT™ 960 AND BD BACTEC™ MGIT™ 320 SYSTEMS. ACCEPTABLE SPECIMEN TYPES ARE DIGESTED AND DECONTAMINATED CLINICAL SPECIMENS (EXCEPT URINE), AND STERILE BODY FLUIDS (EXCEPT BLOOD). ,BD PHOENIX™ AST BROTH(BD PHOENIX™ AST BROTH)-THE BD PHOENIX AUTOMATED MICROBIOLOGY SYSTEM IS INTENDED FOR THE RAPID IDENTIFICATION (ID) AND ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) OF CLINICALLY SIGNIFICANT BACTERIA. THE PHOENIX SYSTEM PROVIDES RAPID RESULTS FOR MOST AEROBIC AND FACULTATIVE ANAEROBIC GRAM POSITIVE BACTERIA AS WELL AS AEROBIC AND FACULTATIVE ANAEROBIC GRAM-NEGATIVE BACTERIA OF HUMAN ORIGIN. THE PHOENIX SYSTEM IS ALSO INTENDED FOR THE RAPID

	IDENTIFICATION OF YEAST AND YEAST-LIKE ORGANISMS. , CHOCOLATE II AGAR(CHOCOLATE II AGAR)-CHOCOLATE II AGAR IS AN IMPROVED MEDIUM FOR USE IN QUALITATIVE PROCEDURES FOR THE ISOLATION AND CULTIVATION OF FASTIDIOUS MICROORGANISMS, ESPECIALLY NEISSERIA AND HAEMOPHILUS SPECIES, FROM A VARIETY OF CLINICAL SPECIMENS.,TRYPTICASE™ SOY AGAR WITH 5% SHEEP BLOOD(TRYPTICASE™ SOY AGAR WITH 5% SHEEP BLOOD)-TRYPTICASE SOY AGAR WITH 5% OR 10% SHEEP BLOOD IS USED FOR CULTIVATING FASTIDIOUS MICROORGANISMS AND FOR THE VISUALIZATION OF HEMOLYTIC REACTIONS PRODUCED BY MANY BACTERIAL SPECIES,BD BBL™ CRYSTAL ENTERIC/NONFERMENTER ID SYSTEM(BD BBL™ CRYSTAL ENTERIC/NONFERMENTER ID SYSTEM)-THE BD BBL CRYSTAL™ ENTERIC/NONFERMENTER (E/NF) IDENTIFICATION (ID) SYSTEM IS FOR THE IDENTIFICATION OF AEROBIC GRAM-NEGATIVE BACTERIA THAT BELONG TO THE FAMILY ENTEROBACTERIACEAE AS WELL AS SOME OF THE MORE FREQUENTLY ISOLATED GLUCOSE FERMENTING AND NON-FERMENTING GRAM-NEGATIVE BACILLI.,BD BBL™ CRYSTAL™ NEISSERIA/HAEMOPHILUS ID SYSTEM(BD BBL™ CRYSTAL™ NEISSERIA/HAEMOPHILUS ID SYSTEM)-THE BD BBL™ CRYSTAL™ NEISSERIA/HAEMOPHILUS (N/H) IDENTIFICATION (ID) SYSTEM IS A MINIATURIZED IDENTIFICATION METHOD EMPLOYING MODIFIED CONVENTIONAL, FLUOROGENIC AND CHROMOGENIC SUBSTRATES. IT IS INTENDED FOR THE IDENTIFICATION OF FREQUENTLY ISOLATED NEISSERIA AND HAEMOPHILUS AS WELL AS SEVERAL OTHER FASTIDIOUS BACTERIA.,BD BACTEC™ MGIT™ 960 PZA SUSCEPTIBILITY TEST MEDIUM(BD BACTEC™ MGIT™ 960 PZA SUSCEPTIBILITY TEST MEDIUM)-THE BD BACTEC™ MGIT™ 960 PZA KIT IS A RAPID QUALITATIVE PROCEDURE FOR SUSCEPTIBILITY TESTING OF MYCOBACTERIUM TUBERCULOSIS, FROM CULTURE, TO PYRAZINAMIDE (PZA). THE BD BACTEC MGIT 960 PZA KIT IS USED WITH THE BD BACTEC MGIT SYSTEM.,BD DIFCO™ ANTIMICROBIC VIAL P (BD DIFCO™ ANTIMICROBIC VIAL P)-DIFCO™ ANTIMICROBIC VIAL P, CONTAINING POLYMYXIN B, IS USED FOR THE PREPARATION OF SELECTIVE MICROBIOLOGICAL CULTURE MEDIA.,BBL™ MGIT™ PANTA™, LYOPHILIZED(BBL™ MGIT™ PANTA™, LYOPHILIZED)-THE BD BBL™ MGIT™ MYCOBACTERIA GROWTH INDICATOR TUBE SUPPLEMENTED WITH BD BBL™ MGIT™ OADC ENRICHMENT AND BD BBL™ MGIT™ PANTA™ ANTIBIOTIC MIXTURE, WHEN APPROPRIATE, IS INTENDED FOR THE DETECTION AND RECOVERY OF MYCOBACTERIA. ACCEPTABLE SPECIMEN TYPES ARE DIGESTED AND DECONTAMINATED CLINICAL SPECIMENS (EXCEPT URINE) AND STERILE BODY FLUIDS (EXCEPT BLOOD). ,BD BACTEC™ MGIT™960 PZA KIT(BD BACTEC™ MGIT™960 PZA KIT)-THE BD BACTEC™ MGIT™

	960 PZA KIT IS A RAPID QUALITATIVE PROCEDURE FOR SUSCEPTIBILITY TESTING OF MYCOBACTERIUM TUBERCULOSIS, FROM CULTURE TO PYRAZINAMIDE (PZA). THE BD BACTEC MGIT 960 PZA KIT IS USED WITH THE BD BACTEC MGIT SYSTEM. ,BD BBL™ GRAM SLIDE (BD BBL™ GRAM SLIDE)-THE BD BBL™ GRAM SLIDE IS USED FOR EVALUATING AND CONTROLLING THE QUALITY OF GRAM STAIN REAGENTS AND TECHNIQUES.,BD BBL™ CRYSTAL™ RAPID GRAM-POSITIVE ID SYSTEM(BD BBL™ CRYSTAL™ RAPID GRAM-POSITIVE ID SYSTEM)-THE BD BBL™ CRYSTAL™ RAPID GRAM-POSITIVE (RGP) IDENTIFICATION SYSTEM (ID) IS A MINIATURIZED IDENTIFICATION METHOD EMPLOYING MODIFIED CONVENTIONAL, FLUOROGENIC AND CHROMOGENIC SUBSTRATES. IT IS INTENDED FOR THE IDENTIFICATION OF AEROBIC GRAM-POSITIVE BACTERIA, BBL™ LOWENSTEIN-JENSEN MEDIUM SLANTS(BBL™ LOWENSTEIN-JENSEN MEDIUM SLANTS)-BD BBL™ LOWENSTEIN-JENSEN MEDIUM IS USED FOR THE CULTIVATION OF MYCOBACTERIUM TUBERCULOSIS AND OTHER MYCOBACTERIAL SPECIES,BD DIFCO™ NOVOBIOCIN ANTIMICROBIC SUPPLEMENT(BD DIFCO™ NOVOBIOCIN ANTIMICROBIC SUPPLEMENT)-FOR USE IN PREPARATION OF SELECTIVE MICROBIOLOGICAL CULTURE MEDIA. ,DIFCO™ GLYCEROL (DIFCO™ GLYCEROL)-HIGHLY PURIFIED ALCOHOL USED AS A FIXATIVE, IN BACTERIAL PRESERVATION MEDIA AND IN THE ISOLATION AND CULTIVATION OF MANY ORGANISMS.,BBL™ LOWENSTEIN-JENSEN MEDIUM SLANTS(BBL™ LOWENSTEIN-JENSEN MEDIUM SLANTS)-BD BBL™ LOWENSTEIN-JENSEN MEDIUM IS USED FOR THE CULTIVATION OF MYCOBACTERIUM TUBERCULOSIS AND OTHER MYCOBACTERIAL SPECIES.,BD BBL™ CRYSTAL™ GRAM POSITIVE ID KIT(BD BBL™ CRYSTAL™ GRAM POSITIVE ID KIT)-THE BD BBL™ CRYSTAL™ GRAM-POSITIVE (GP) IDENTIFICATION (ID) SYSTEM IS A MINIATURIZED IDENTIFICATION METHOD EMPLOYING MODIFIED CONVENTIONAL, FLUOROGENIC AND CHROMOGENIC SUBSTRATES. IT IS INTENDED FOR THE IDENTIFICATION OF FREQUENTLY ISOLATED AEROBIC GRAM-POSITIVE BACTERIA.,BD BBL™ CRYSTAL™ ANR, GP, RGP, N/H ID INOCULUM FLUID(BD BBL™ CRYSTAL™ ANR, GP, RGP, N/H ID INOCULUM FLUID)-THE BBL™ CRYSTAL™INOCULUM BROTH IS USED WITH THE ANAERODE ID KIT,NEISERRIA/ HAEMOPHILUS ID KIT, GRAM-POSITIVE ID KIT AND THE RAPID GRAM-POSITIVE ID KIT,BD BBL™ CRYSTAL™ ENTERIC/ID INOCULUM FLUID(BD BBL™ CRYSTAL™ ENTERIC/ID INOCULUM FLUID)-THE BD BBL™ CRYSTAL™ ENTERIC/NONFERMENTER (E/NF) IDENTIFICATION (ID) SYSTEM IS FOR THE IDENTIFICATION OF AEROBIC GRAM-NEGATIVE BACTERIA THAT BELONG TO THE FAMILY ENTEROBACTERIACEAE AS WELL AS SOME OF THE MORE FREQUENTLY ISOLATED GLUCOSE FERMENTING AND NON-FERMENTING GRAM-NEGATIVE BACILLI.,BD BBL™ MGIT™

	OADC ENRICHMENT(BD BBL™ MGIT™ OADC ENRICHMENT)-THE BD BBL™ MGIT™ MYCOBACTERIA GROWTH INDICATOR TUBE SUPPLEMENTED WITH BD BBL™ MGIT™ OADC ENRICHMENT AND BD BBL™ MGIT™ PANTA™ ANTIBIOTIC MIXTURE, WHEN APPROPRIATE, IS INTENDED FOR THE DETECTION AND RECOVERY OF MYCOBACTERIA. ACCEPTABLE SPECIMEN TYPES ARE DIGESTED AND DECONTAMINATED CLINICAL SPECIMENS (EXCEPT URINE) AND STERILE BODY FLUIDS (EXCEPT BLOOD).,BD BACTEC™ MGIT™960 IR KIT(BD BACTEC™ MGIT™960 IR KIT)-THE BD BACTEC™ MGIT™ 960 SIRE KIT IS A RAPID QUALITATIVE PROCEDURE FOR SUSCEPTIBILITY TESTING OF MYCOBACTERIUM TUBERCULOSIS, FROM CULTURE, TO STREPTOMYCIN (STR), ISONIAZID (INH), RIFAMPIN (RIF) AND ETHAMBUTOL (EMB). THE BD BACTEC MGIT 960 STR 4.0 KIT AND THE BD BACTEC MGIT 960 INH 0.4 KIT ARE FOR TESTING AT HIGHER DRUG CONCENTRATIONS. THE BD BACTEC MGIT 960 SUSCEPTIBILITY TEST KITS ARE USED WITH THE BD BACTEC MGIT 960 AND BD BACTEC MGIT 320 SYSTEMS. ,BD BBL™ CRYSTAL™ ANAEROBE ID SYSTEM (BD BBL™ CRYSTAL™ ANAEROBE ID SYSTEM)-THE BBL CRYSTAL™ ANAEROBE (ANR) IDENTIFICATION (ID) SYSTEM IS A MINIATURIZED IDENTIFICATION METHOD EMPLOYING MODIFIED CONVENTIONAL, FLUOROGENIC AND CHROMOGENIC SUBSTRATES. IT IS INTENDED FOR THE IDENTIFICATION OF FREQUENTLY ISOLATED ANAEROBIC BACTERIA.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

392	IMP/IVD/2019/000424	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARTHRITIS LIA(IMTEC)-IMTEC-ARTHRITIS-LIA IS AN IVD INTENDED FOR THE QUALITATIVE DETECTION OF 10 DIFFERENT AUTOANTIBODIES IN HUMAN SERUM AND PLASMA AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS.,GAMMA-GT LIQUICOLOR M - TEST-GAMMA-GT LIQUICOLOR HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF GAMMA-GT (L-GAMMA-GLUTAMYL TRANSFERASE) IN HUMAN SERUM AND EDTA-PLASMA.,ANA LIA XL (IMTEC)-IMTEC-ANA-LIA XL IS AN IVD ASSAY FOR THE QUALITATIVE DETERMINATION OF 18 IGG CLASS ANTIBODIES AGAINST DSDNA, NUCLEOSOME, HISTONES, SMD1, PCNA, RIBOSOMAL P0 (RPP), SS-A/RO 60, SS-A/RO 52, SS-B/LA, CENP-B, SCL70, U1-SNRNP, AMA M2, JO-1, PM-SCL, MI-2, KU AND DFS70 IN HUMAN SERUM OR PLASMA., CALIBRATOR FOR HEMATOLOGY ANALYZER-THE HC-CALIBRATOR HAS BEEN DESIGNED FOR VERIFICATION OF PRECISION AND ACCURACY OF THE HUMAN 3-AND 5-PART DIFFERENTIAL HEMATOLOGY SYSTEM.,HEMOSTAT D-DIMER-THE HUMAN HEMOSTAT D-DIMER IS AN ASSAY FOR QUANTITATIVE DETERMINATION OF D-DIMER IN CITRATED PLASMA. IT IS INTENDED FOR PROFESSIONAL USE AS AN AID IN DIAGNOSIS OF THROMBOEMBOLIC EVENTS E.G. EXCLUSION OF DVT (DEEP VEIN THROMBOSIS) AND PE (PULMONARY EMBOLISM). IT IS SUITABLE FOR SEMI-AUTOMATED AND AUTOMATED APPLICATIONS,TRANSFERRIN-THE TRANSFERRIN TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF TRANSFERRIN IN HUMAN SERUM.,LIPASE LIQUICOLOR-LIPASE LIQUICOLOR HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF THE LIPASE ACTIVITY IN HUMAN SERUM.,IMTEC-GASTRO LIA-THE IMTEC-GASTRO-LIA TEST (ITC30701) HAS BEEN DESIGNED AS A LINE IMMUNO ASSAY (LIA) FOR THE DETECTION OF ANTIBODIES IN GASTROINTESTINAL DISEASES OF DIFFERENT SPECIFICITY AND SUBCLASSES (IGA AND IGG).,HUMATEX CRP-HUMATEX RF HAS BEEN DESIGNED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS (RF) IN HUMAN SERUM.,RF STANDARD-STANDARD FOR THE DETERMINATION OF RHEUMATOID FACTORS (RF),COMPLEMENT C4-THE C3/C4/TRF STANDARD IS USED FOR CALIBRATION OF THE IMMUNOTURBIDIMETRIC COMPLEMENT C3/C4 AND TRANSFERRIN ASSAYS.,HEMOSTAT APTT-EL-HEMOSTAT APTT-EL HAS BEEN DESIGNED FOR THE DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME IN HUMAN PLASMA (CITRATE PLASMA)., HEMOSTAT THROMBOPLASTIN-SI-HEMOSTAT

	THROMBOPLASTINLIQUID AND HEMOSTAT THROMBOPLASTIN-SI HAVE BEEN DESIGNED FOR THE MANUAL AND AUTOMATED DETERMINATION OF THE PROTHROMBIN TIME (QUICK, PT).,HC5D DILUENT-THE HC5D CBC DILUENT IS INTENDED TO BE USED WITH THE HUMACOUNT 5D ANALYZER FOR SAMPLE DILUTION AND PREPARATION OF CELL SUSPENSION BEFORE RUNNING THE SAMPLES.,SLE LATEX TEST-SLE LATEX TEST HAS BEEN DESIGNED FOR THE QUALITATIVE DETECTION OF AUTO ANTIBODIES DIRECTED AGAINST DEOXYRIBONUCLEO PROTEIN (DNP) ASSOCIATED WITH SYSTEMIC LUPUS ERYTHEMATODES (SLE).,COMPLEMENT C3-THE COMPLEMENT C3 TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT C3 IN HUMAN SERUM.,HC5D CBC LYSE-THE HC5D CBC LYSE IS INTENDED TO BE USED WITH THE HUMACOUNT 5D ANALYZER FOR LYSING THE RED BLOOD CELLS AND WHITE BLOOD CELL CLASSIFICATION.,FERRITIN-THE FERRITIN TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM.,BILIRUBIN LIQUICOLOR-BILIRUBIN LIQUICOLOR DCA TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF BILIRUBIN IN HUMAN SERUM AND PLASMA (HEPARINISED AND EDTA-PLASMA).,CYSTATIN-C LIQUIDIRECT-CYSTATIN-C LIQUIDIRECT TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CYSTATIN-C IN HUMAN SERUM., MICROALBUMIN STANDARD-THE MICROALBUMIN STANDARD IS USED FOR CALIBRATION OF THE IMMUNOTURBIDIMETRIC MICROALBUMIN ASSAYS.,HC5D-CONTROL-HC5D-CONTROL IS AN ASSAYED BLOOD CONTROL MATERIAL INTENDED FOR USE IN THE VERIFICATION OF ACCURACY AND PRECISION OF HUMACOUNT 5D PROVIDING WHITE BLOOD CELL DIFFERENTIATION OF 5-PART WBC'S.,PHOSPHORUS LIQUIRAPID-PHOSPHORUS LIQUIRAPID TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHORUS IN HUMAN SERUM.,IRON LIQUICOLOR-IRON LIQUICOLOR TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF IONIZED IRON IN HUMAN SERUM AND HEPARINISED PLASMA.,CK MB LIQUIUV-CK-MB LIQUIUV HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CK-MB (CREATINE KINASE MB ISOENZYME) IN HUMAN SERUM AND PLASMA (HEPARINISED AND EDTA-PLASMA).,LDH LIQUIUV-LDH LIQUIUV HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF LDH IN HUMAN SERUM AND PLASMA (HEPARINIZED AND EDTA-PLASMA)., ALBUMIN LIQUICOLOR-PHOTOMETRIC COLORIMETRIC TEST FOR ALBUMIN BCG-METHOD,DAILY CLEANING SOLUTION HUMALYTE PLUS-DAILY CLEANING SOLUTION FOR HUMALYTE PLUS, LIPOPROTEIN-(A)-LIPOPROTEIN (A) TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN (A) (LP(A)) IN

	HUMAN SERUM AND PLASMA (EDTA).,C3/C4/TRF STANDARD-THE C3/C4/TRF STANDARD IS USED FOR CALIBRATION OF THE IMMUNOTURBIDIMETRIC COMPLEMENT C3/C4 AND TRANSFERRIN ASSAYS.,TSH ELISA-HUMAN TSH ELISA HAS BEEN DESIGNED AS A SANDWICH ELISA TEST FOR THE QUANTITATIVE DETERMINATION OF THYREOTROPIN (TSH) IN HUMAN SERUM.,MICROALBUMIN-THE MICROALBUMIN TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN URINE.,IMTEC - VASCULITIS LIA-IMTEC-VASCULITIS-LIA TEST (ITC82040) HAS BEEN DESIGENED AS A LINE IMMUNO ASSAY (LIA) FOR THE DETECTION OF ANTIBODIES IN AUTOIMMUNE VASCULITIS AND GOODPASTURE'S SYNDROME., HUMATEX ASO-HUMATEX ASO HAS BEEN DESIGNED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF ANTIBODIES AGAINST STREPTOLYSIN O (ASO) IN HUMAN SERUM., HUMATEX RF-HUMATEX RF HAS BEEN DESIGNED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS (RF) IN HUMAN SERUM.,IMTEC MYOSITIS-LIA PL-MYOSITIS-LIA PL TEST (ITC60201) HAS BEEN DESIGNED AS A LINE IMMUNOASSAY (LIA) FOR THE DETECTION OF MYOSITIS-SPECIFIC ANTIBODY (MSA) AND MYOSITIS-ASSOCIATED ANTIBODY (MAA) PROFILES.,IMTEC- ANA LIA MAXX-IMTEC-ANA-LIA MAXX (ITC92005) HAS BEEN DESIGNED AS A LINE IMMUNO ASSAY (LIA) FOR THE DETECTION OF ANTINUCLEAR ANTIBODY (ANA) PROFILES., APOLIPOPROTEIN-B-APOLIPOPROTEIN B TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN B (APO B) IN HUMAN SERUM.,25-OH VITAMIN D-ELISA FOR THE QUANTITATIVE MEASUREMENT OF 25-OH VITAMIN D IN HUMAN SERUM.,HEMOSTAT CONTROL PLASMA NORMAL-HEMOSTAT CONTROL PLASMA NORMAL AND HEMOSTAT CONTROL PLASMA ABNORMAL HAVE BEEN DESIGNED FOR QUALITY CONTROL OF THE HEMOSTAT TESTS THROMBOPLASTINLIQUID, THROMBOPLASTIN-SI, APTT-EL, FIBRINOGEN AND THROMBIN TIME,MAGNESIUM LIQUICOLOR-MAGNESIUM LIQUICOLOR HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF IONIZED MAGNESIUM IN HUMAN SERUM AND PLASMA (EXCEPT EDTA-PLASMA).,HEMOSTAT FIBRINOGEN-HEMOSTAT FIBRINOGEN HAS BEEN DESIGNED FOR THE MANUAL AND AUTOMATED DETERMINATION OF FIBRINOGEN IN HUMAN PLASMA (CITRATE PLASMA).,IMMUNOGLOBULINS DIRECT IGM REAGENT KIT-THE IMMUNOGLOBULINS DIRECT IGA, IGG, IGM MULTIPURPOSE REAGENTS HAVE BEEN DESIGNED FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF THE IMMUNOGLOBULINS A (IGA), G (IGG) AND M (IGM) IN HUMAN SERUM., IMMUNOGLOBULINS DIRECT IGG REAGENT KIT-THE IMMUNOGLOBULINS DIRECT IGA, IGG, IGM MULTIPURPOSE REAGENTS

	HAVE BEEN DESIGNED FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF THE IMMUNOGLOBULINS A (IGA), G (IGG) AND M (IGM) IN HUMAN SERUM., PANCREAS-AMYLASE LIQUICOLOR-PANCREAS-AMYLASE LIQUICOLOR TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF THE PANCREAS-AMYLASE ACTIVITY IN HUMAN SERUM.,LDL CHOLESTEROL LIQUICOLOR-LDL-CHOLESTEROL LIQUICOLOR REAGENT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IN HUMAN SERUM.,ANTI-STREPTOLYSIN-O-THE HUMAN ANTI-STREPTOLYSIN-O (ASO) LATEX-ENHANCED TURBIDIMETRIC TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF ANTI-STREPTOLYSIN-O (ASO) IN HUMAN SERUM.,RHEUMATOID FACTORS-RHEUMATOID FACTORS (RF) TURBIDIMETRIC TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS (RF) IN HUMAN SERUM., T3 ELISA-THE HUMAN T3 ELISA TEST HAS BEEN DESIGNED AS A COMPETITIVE ELISA TEST FOR THE QUANTITATIVE DETERMINATION OF T3 IN HUMAN SERUM OR PLASMA (EDTA, HEPARIN).,ALKALINE PHOSPHATASE LIQUICOLOR-ALKALINE PHOSPHATASE (AP) OPT. LIQUICOLOR HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE (AP) IN HUMAN SERUM AND HEPARINISED PLASMA.,CALCIUM LIQUICOLOR-THE CALCIUM LIQUICOLOR TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF IONIZED CALCIUM IN HUMAN SERUM AND HEPARINISED PLASMA.,URIC ACID LIQUICOLOR-URIC ACID LIQUICOLOR HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM, HEPARINISED OR EDTA PLASMA AND URINE.,GLUCOSE LIQUICOLOR-GLUCOSE LIQUICOLOR HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN WHOLE BLOOD , SERUM AND PLASMA.,HC-LYSE-CF-USED TO PREPARE BLOOD HEMOLYSATE FOR WBC AND HGB MEASUREMENT.,REAGENT PACK HUMALYTE PLUS 3-REAGENT PACK FOR HUMALYTE PLUS3,TRIGLYCERIDES LIQUICOLOR-TRIGLYCERIDES LIQUICOLORMONO HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM, EDTA-PLASMA AND HEPARINISED PLASMA,HC-CLEANER-USED TO PERFORM CLEANING PROCESS OF THE FLUIDICS.,APOLIPOPROTEIN-A1/B STANDARD-THE APO A1/B STANDARD IS USED FOR CALIBRATION OF THE IMMUNOTURBIDIMETRIC APOLIPOPROTEIN A1 (APO A1) AND APOLIPOPROTEIN B (APO B) ASSAYS.,HEMOSTAT CONTROL PLASMA ABNORMAL-HEMOSTAT CONTROL PLASMA NORMAL AND HEMOSTAT CONTROL PLASMA ABNORMAL HAVE BEEN DESIGNED FOR QUALITY CONTROL OF THE HEMOSTAT TESTS THROMBOPLASTINLIQUID,

	THROMBOPLASTIN-SI, APTT-EL, FIBRINOGEN AND THROMBIN TIME., WASH ADDITIVE-THE WASH ADDITIVE IS USED TO PREPARE THE WASH SOLUTION FOR HUMASTAR ANALYZERS.,ALKALINE PHOSPHATASE LIQUICOLOR IFCC-ALKALINE PHOSPHATASE (AMP) IFCC LIQUICOLOR TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE (AP) IN HUMAN SERUM AND HEPARINISED PLASMA.,CUVETTE CLEAN-THE CUVETTE CLEAN FOR AUTOMATED ANALYZERS HAS BEEN DESIGNED FOR THE CLEANING OF THE CUVETTES AFTER TESTING LATEX ENHANCED TESTS ON AUTOMATED ANALYZERS.,CRP REAGENT KIT-CRP MULTIPURPOSE REAGENTS HAVE BEEN DESIGNED FOR THE QUANTITATIVE I MMUNOTURBIDIMETRIC DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM AND PLASMA., IMMUNOGLOBULINS DIRECT IGA REAGENT KIT-THE IMMUNOGLOBULINS DIRECT IGA, IGG, IGM MULTIPURPOSE REAGENTS HAVE BEEN DESIGNED FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF THE IMMUNOGLOBULINS A (IGA), G (IGG) AND M (IGM) IN HUMAN SERUM., CK-MB CONTROL-CK-MB CONTROL AND CK-MB CALIBRATOR SERA HAVE BEEN DESIGNED FOR CONTROL OF PRECISION AND ACCURACY OF CK-MB LIQUIUV METHOD BOTH MANUAL AND AUTOMATED.,CK-MB CALIBRATOR-CK-MB CONTROL AND CK-MB CALIBRATOR SERA HAVE BEEN DESIGNED FOR CONTROL OF PRECISION AND ACCURACY OF CK-MB LIQUIUV METHOD BOTH MANUAL AND AUTOMATED.,CK NAC ACTIVATED LIQUIUV-CK NAC-ACT. LIQUIUV HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CK (CREATINE KINASE) IN HUMAN SERUM AND HEPARINISED OR EDTA PLASMA.,GPT(ALAT) IFCC MOD. LIQUIUV-GPT (ALAT) IFCC MOD. LIQUIUV HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF GPT (ALANINE AMINOTRANSFERASE) IN HUMAN SERUM AND PLASMA (HEPARINISED AND EDTA-PLASMA).,COMBINA 13-COMBINA 13 HAS BEEN DESIGNED AS URINE TEST STRIPS FOR THE RAPID DETERMINATION OF UROBILINOGEN, BILIRUBIN, KETONES, CREATININE, HEMOGLOBIN/BLOOD, PROTEIN, MICROALBUMIN, NITRITE, LEUCOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH AND ASCORBIC ACID.,TIBC-TIBC MULTIPURPOSE REAGENTS HAVE BEEN DESIGNED FOR SAMPLE PREPARATION FOR THE QUANTITATIVE DETERMINATION OF TOTAL IRON BINDING CAPACITY (TIBC) IN HUMAN SERUM AND HEPARINISED PLASMA.,I.M. QUICK TEST-IM QUICK TEST HAS BEEN DESIGNED FOR THE QUALITATIVE DETECTION OF HETEROPHILIC ANTIBODIES ASSOCIATED WITH ACUTE INFECTIOUS MONONUCLEOSIS (IM) IN HUMAN SERUM.,ANTI-STREPTOLYSIN-O STANDARD-THE ASO STANDARD IS USED FOR CALIBRATION OF THE IMMUNOTURBIDIMETRIC ANTI-STREPTOLYSIN-

	O ASSAYS.,HDL CHOLESTEROL-HDL-CHOLESTEROL HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF HDL-CHOLESTEROL IN HUMAN SERUM, EDTA-PLASMA AND HEPARINISED PLASMA.,HC5D DIFF LYSE-THE HC5D DIFF LYSE IS INTENDED TO BE USED WITH THE HUMACOUNT 5D ANALYZER FOR LYSING THE RED BLOOD CELLS, DETERMINING THE HEMOGLOBIN, WHITE BLOOD CELL CLASSIFICATION AND COUNTING THE TOTAL NUMBER OF WHITE BLOOD CELLS.,GLYCOHAEMOGLOBIN HBA1 TEST-GLYCOHEMOGLOBIN HBA1 TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF HBA1 IN HUMAN EDTA-BLOOD., CREATININE ENZYM LIQUICOLOR-CREATININE (ENZYM) LIQUICOLOR TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM AND HEPARINISED PLASMA., LIPOPROTEIN-(A) STANDARD-THE LIPOPROTEIN (A) STANDARD IS USED FOR CALIBRATION OF THE IMMUNOTURBIDIMETRIC LIPOPROTEIN (A) ASSAYS.,UREA LIQUICOLOR (R2)-UREA LIQUICOLOR HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM AND PLASMA (NO HEPARINIZED PLASMA).,AUTO-CREATININE LIQUICOLOR-AUTO-CREATININE LIQUICOLOR TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, HEPARINISED PLASMA AND URINE PARTICULARLY FOR AUTOMATED WORKING TECHNIQUES.,UREA LIQUICOLOR (R1)-UREA LIQUICOLOR HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM AND PLASMA (NO HEPARINIZED PLASMA)., IMTEC - LIVER LIA S-THE IMTEC-LIVER-LIA S TEST (ITC66205) HAS BEEN DESIGNED AS A LINE IMMUNO ASSAY (LIA) FOR THE DETECTION OF AUTOANTIBODIES IN AUTOIMMUNE LIVER DISEASES OF DIFFERENT SPECIFICITY.,SERODOS-SERODOS CONTROL SERA HAS BEEN DESIGNED FOR CONTROL OF PRECISION AND ACCURACY OF CLINICAL CHEMISTRY METHODS BOTH MANUAL AND AUTOMATED., FERRITIN CALIBRATOR SET-THE FERRITIN TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM.,TURBIDOS CONTROL-THE TURBIDOS CONTROL SERA HAVE BEEN DESIGNED FOR CONTROL OF PRECISION AND ACCURACY OF CLINICAL CHEMISTRY METHODS BOTH MANUAL AND AUTOMATED., AUTOCAL-THE AUTOCAL MULTICALIBRATOR HAS BEEN DESIGNED FOR THE CALIBRATION OF HUMAN CLINICAL CHEMISTRY REAGENTS ON PREFERABLY HUMAN ANALYSERS.,SERODOS PLUS-SERODOS PLUS CONTROL SERA HAS BEEN DESIGNED FOR CONTROL OF PRECISION AND ACCURACY OF CLINICAL CHEMISTRY METHODS BOTH MANUAL AND AUTOMATED.,CK NAC ACTIVATED-THE CK NAC-ACT. HUMAZYM TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CK (CREATINE KINASE) IN HUMAN SERUM AND

	PLASMA (HEPARINIZED AND EDTA-PLASMA).,CK-MB NAC-ACTIVATED-THE CK-MB NAC-ACT. TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CK-MB (CREATINE KINASE) IN HUMAN SERUM AND PLASMA (HEPARINISED AND EDTA-PLASMA)., SPECIAL WASH SOLUTION-SPECIAL WASH SOLUTION FOR HUMASTAR 100 AND 200,UREA LIQUICOLOR-UREA LIQUICOLOR HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM AND PLASMA (NO HEPARINIZED PLASMA).,CRP STANDARD-CRP MULTIPURPOSE REAGENTS HAVE BEEN DESIGNED FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM AND PLASMA., POTASSIUM LIQUIRAPID-POTASSIUM LIQUIRAPID HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF IONISED POTASSIUM IN HUMAN SERUM AND LITHIUM-HEPARIN PLASMA.,GOT (ASAT) IFCC MOD. LIQUIUV-GOT (ASAT) IFCC MOD. LIQUIUV HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF GOT (ASPARTATE AMINOTRANSFERASE) IN HUMAN SERUM AND PLASMA (HEPARINISED AND EDTA-PLASMA).,UREA LIQUIUV-UREA LIQUIUV REAGENT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM, PLASMA, EXCEPT AMMONIUM HEPARINATE PLASMA, OR URINE.,URIC ACID LIQUICOLOR PLUS-URIC ACID LIQUICOLORPLUS TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM AND PLASMA.,BILIRUBIN D+T LIQUICOLOR-BILIRUBIN D+T LIQUICOLOR TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF BILIRUBIN IN HUMAN SERUM AND HEPARINISED PLASMA. IT MAY BE EMPLOYED FOR MANUAL WORKING TECHNIQUES.,T4 ELISA-THE HUMAN T4 ELISA TEST HAS BEEN DESIGNED AS A COMPETITIVE ELISA TEST FOR THE QUANTITATIVE DETERMINATION OF L-THYROXINE (T4) IN HUMAN SERUM OR PLASMA (EDTA, HEPARIN).,TIP CLEANING KIT-THE TIP CLEANING KIT FOR HS600 HAS BEEN DESIGNED FOR CLEANING THE NEADLES OF THE HUMASTAR 600.,TOTAL PROTEIN LIQUICOLOR-TOTAL PROTEIN LIQUICOLOR TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF INORGANIC TOTAL PROTEIN IN HUMAN SERUM., IRON TPTZ LIQUICOLOR-THE IRON TPTZ LIQUICOLOR HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF THE IRON CONCENTRATION IN HUMAN SERUM OR HEPARINISED PLASMA., ALPHA-AMYLASE LIQUICOLOR-ALPHA-AMYLASE LIQUICOLOR MULTIPURPOSE REAGENTS HAVE BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF ALPHA-AMYLASE IN HUMAN SERUM AND HEPARINISED PLASMA,HC-DILUENT-ISOTONIC SALINE SOLUTION, USED TO DILUTE WHOLE BLOOD SAMPLES AND TO RINSE THE FLUIDIC SYSTEM BETWEEN MEASURING PROCEDURES.,

	CHOLESTEROL LIQUICOLOR-CHOLESTEROL LIQUICOLOR TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM, EDTA-PLASMA AND HEPARINISED PLASMA.,AUTO-BILIRUBIN-T LIQUICOLOR-AUTO-BILIRUBIN-T LIQUICOLOR REAGENT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM AND HEPARINISED PLASMA PARTICULARLY FOR AUTOMATED WORKING TECHNIQUES.,AUTO-BILIRUBIN-D LIQUICOLOR-AUTO-BILIRUBIN-D LIQUICOLOR REAGENT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM AND HEPARINISED PLASMA PARTICULARLY FOR AUTOMATED WORKING TECHNIQUES,HDL CHOLESTEROL LIQUICOLOR-HDL-CHOLESTEROL LIQUICOLOR REAGENT HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM., CREATININE LIQUICOLOR-CREATININE LIQUICOLOR TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, HEPARINISED PLASMA AND URINE., APOLIPOPROTEIN A1-APOLIPOPROTEIN B TEST HAS BEEN DESIGNED FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN B (APO B) IN HUMAN SERUM.,HC5D CLEAN-THE HC5D CBC CLEAN IS INTENDED TO BE USED WITH THE HUMACOUNT 5D ANALYZER FOR CLEANING THE FLUIDIC SYSTEM OF THE ANALYZER AND REGULAR INSTRUMENT CLEANING.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

393	IMP/IVD/2019/000425	1.License Holder Name: TOSOH INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MYOSITIS PLUS IMMUNOBLOT(ORGENTEC)-MYOSITIS PLUS IMMUNOBLOT ASSAY IS A MEMBRANE BASED ENZYME IMMUNOASSAY FOR THE SEMI-QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES TO AMA-M2, JO-1, PM-SCI-100, PL-7, PL-12, MI-2, KU (P70/80), RIB-P AND SRP IN HUMAN SERUM OR PLASMA.,ANTI-INTRINSIC FACTOR (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST INTRINSIC FACTOR IN HUMAN SERUM OR PLASMA,LIVER-9-LINE 2ND GENERATION IMMUNOBLOT(ORGENTEC)-LIVER-9-LINE 2ND GENERATION IMMUNOBLOT ASSAY IS A MEMBRANE BASED ENZYME IMMUNOASSAY FOR THE SEMIQUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES TO AMA-M2, SP100, GP210, SLA/LP, LKM-1, LC1, F-ACTIN, ACTININ AND TROPOMYOSIN IN HUMAN SERUM OR PLASMA.,ANTI-RNP-70 (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST RNP 70 IN HUMAN SERUM OR PLASMA, ANCA-3-LINE IMMUNOBLOT(ORGENTEC)-ANCA-3-LINE IMMUNOBLOT ASSAY IS A MEMBRANE BASED ENZYME IMMUNOASSAY FOR THE SEMI-QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES TO PR3, MPO AND GBM IN HUMAN SERUM OR PLASMA.,ALEGRIA ANTI NUCLEAR ANTIBODIES (ANA DETECT) (ORGENTEC)-FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-A-52 (RO-52), SS-A-60 (RO-60), SS-B (LA), RNP/SM, RNP-70, RNP-A, RNP-C, SM-BB, SM-D, SM-E, SM-F, SM-G, SCL-70, JO-1, DSDNA, SSDNA, POLYNUCLEOSOMES, MONONUCLEOSOMES, HISTONE COMPLEX, HISTONE H1, HISTONE H2A, HISTONE H2B, HISTONE 3, HISTONE H4, PM-SCL-100 AND CENTROMERE B IN HUMAN SERUM OR PLASMA SAMPLES.,NUCLEO-9-LINE IMMUNOBLOT(ORGENTEC)-NUCLEO-9-LINE IMMUNOBLOT ASSAY IS A MEMBRANE BASED ENZYME IMMUNOASSAY FOR THE SEMI-QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES TO DSDNA, NUCLEOSOMES, SS-A (52 A 60 KDA), SS-B, SM, RNP/SM, SCL-70, JO-1 AND CENTROMERE B IN HUMAN SERUM OR PLASMA.,ANTI-DOUBLE STRANDED DNA (DSDNA) IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS AUTOANTIBODIES AGAINST DOUBLE STRANDED DNA IN HUMAN SERUM OR PLASMA,GASTRO-5-LINE IMMUNOBLOT(ORGENTEC)-GASTRO-5-LINE IMMUNOBLOT ASSAY IS A MEMBRANE BASED ENZYME IMMUNOASSAY FOR THE SEMI-QUANTITATIVE MEASUREMENT OF IGG AND IGA CLASS AUTOANTIBODIES TO INTRINSIC FACTOR, PARIETAL CELL H+/K+ ATPASE, TISSUE TRANSGLUTAMINASE, MANNAN FROM SACCHAROMYCES

	CEREVISIAE AND GLIADIN IN HUMAN SERUM OR PLASMA., RHEUMATOID FACTOR SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG, IGM AND IGA CLASS RHEUMATOID FACTOR IN HUMAN SERUM OR PLASMA SAMPLES,THYROGLOBULIN ELISA (ORGENTEC)-THYROGLOBULIN IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF THYROGLOBULIN IN HUMAN SERUM OR PLASMA.,ALEGRIA ANTI-DOUBLE STRANDED DNA (DSDNA) IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS AUTOANTIBODIES AGAINST DOUBLE-STRANDED DNA (DSDNA) IN HUMAN SERUM OR PLASMA,MICRO-ALBUMIN ELISA (ORGENTEC)-MICRO-ALBUMIN IS A COMPETITIVE ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF HUMAN ALBUMIN IN URINE.,ALEGRIA ANTI-ALPHA-FODRIN IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST ALPHA-FODRIN IN HUMAN SERUM OR PLASMA SAMPLES, FERRITIN ELISA(ORGENTEC)-FERRITIN IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF FERRITIN IN HUMAN SERUM OR PLASMA.,ANTI NUCLEAR ANTIBODIES (ANA) COMBI (ORGENTEC)-FOR THE QUALITATIVE MEASUREMENT OF ANA AUTOANTIBODIES DIRECTED AGAINST RNP-70, RNP/SM, SM, SS-A (52 AND 60 KDA), SS-B, SCL-70, CENTROMERE B AND JO-1 IN HUMAN SERUM OR PLASMA, ANA-9-LINE IMMUNOBLOT(ORGENTEC)-ANA-9-LINE IMMUNOBLOT ASSAY IS A MEMBRANE BASED ENZYME IMMUNOASSAY FOR THE SEMI-QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES TO EXTRACTABLE NUCLEAR ANTIGENS SS-A 52, SS-A 60, SS B, RNP/SM, SM, CENTROMERE B, JO-1, SCL-70 AND RIBOSOMAL P PROTEINS IN HUMAN SERUM OR PLASMA.,ALEGRIA ANTI-PHOSPHATIDYL SERINE IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS AUTOANTIBODIES AGAINST PHOSPHATIDYL SERINE IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-SINGLE STRANDED DNA (SSDNA) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SINGLE-STRANDED DNA (SSDNA) IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-PROTHROMBIN IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST PROTHROMBIN IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-PROTHROMBIN IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS AUTOANTIBODIES AGAINST PROTHROMBIN IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-PROTHROMBIN IGA(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES AGAINST PROTHROMBIN IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-CARDIOLIPIN IGA (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES

	AGAINST CARDIOLIPIN IN HUMAN SERUM OR PLASMA SAMPLES, ALEGRIA ANTI-RIBONUCLEOPROTEINS/SMITH ANTIGEN (RNP/SM) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST RNP/SM IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-GLOMERULAR BASEMENT MEMBRANE (GBM) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST GLOMERULAR BASEMENT MEMBRANE (GBM) IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-JO-1(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST JO-1 IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-SCL-70 (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SCL-70 IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-C1Q (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST C1Q IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-CARDIOLIPIN IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM OR PLASMA SAMPLES, ALEGRIA ANTI-PHOSPHATIDIC ACID IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST PHOSPHATIDIC ACID IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-GLIADIN SCREEN (ORGENTEC)-FOR THE SIMULTANEOUS QUANTITATIVE MEASUREMENT OF IGG AND IGA CLASS AUTOANTIBODIES AGAINST GLIADIN IN HUMAN SERUM OR PLASMA,ANTI-GLIADIN IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST GLIADIN IN HUMAN SERUM OR PLASMA.,ANTI-SJOGREN ANTIGEN (SS-A) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-A (52 AND 60 KDA) IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-PROTHROMBIN SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG, IGA AND IGM CLASS AUTOANTIBODIES AGAINST PROTHROMBIN IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-SJOGREN ANTIGEN (SS-B) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-B (LA) IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-CATHEPSIN G (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST CATHEPSIN G IN HUMAN SERUM OR PLASMA SAMPLES, ALEGRIA ANTI-GLIADIN IGA (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES AGAINST GLIADIN IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-RIBONUCLEOPROTEIN/SMITH ANTIGEN (RNP/SM) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST RNP/SM IN HUMAN SERUM OR PLASMA SAMPLES,

	CALPROTECTIN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL SAMPLES TO BE USED IN THE ASSESSMENT OF INTESTINAL INFLAMMATORY DISORDERS,ALEGRIA ANTI-SJOGREN ANTIGEN 60 (SS-A 60) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-A 60 IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-LC1(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES AGAINST THE LIVER CYTOSOLIC PROTEIN TYPE 1 (LC1) IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA RHEUMATOID FACTOR SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG, IGA AND IGM CLASS RHEUMATOID FACTOR (RF) IN HUMAN SERUM OR PLASMA SAMPLES, ANTI-DOUBLE STRANDED DNA (DSDNA) SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG, IGM AND IGA CLASS AUTOANTIBODIES AGAINST DOUBLE-STRANDED DNA IN HUMAN SERUM OR PLASMA,ANTI-TISSUE-TRANSGLUTAMINASE IGA (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM OR PLASMA,ALEGRIA RHEUMATOID FACTOR IGA (ORGENTEC) -FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS RHEUMATOID FACTOR (RF) IN HUMAN SERUM OR PLASMA SAMPLES, ALEGRIA ANTI-TISSUE-TRANSGLUTAMINASE IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-RNP-70 (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST RNP-70 IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-TISSUE-TRANSGLUTAMINASE IGG(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES TO TISSUE-TRANSGLUTAMINASE (TTG) IN HUMAN SERUM OR PLASMA, ALEGRIA RHEUMATOID FACTOR IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS RHEUMATOID FACTOR (RF) IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA LACTOFERRIN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF LACTOFERRIN IN HUMAN STOOL SAMPLES TO BE USED IN THE ASSESSMENT OF INTESTINAL INFLAMMATORY DISORDERS,ANTI-BETA-2-GLYCOPROTEIN I IGA (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF I IGA CLASS AUTOANTIBODIES AGAINST BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA,ANTI-TISSUE-TRANSGLUTAMINASE SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGA CLASS AUTOANTIBODIES TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM OR PLASMA,ANTI-PROTHROMBIN IGG/IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTOANTIBODIES AGAINST

	PROTHROMBIN IN HUMAN SERUM OR PLASMA,ANTI-GLOMERULAR BASEMENT MEMBRANE (GBM) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES TO GLOMERULAR BASEMENT MEMBRANE (GBM) IN HUMAN SERUM OR PLASMA, ALEGRIA ANTI-BACTERICIDAL PERMEABILITY INCREASING PROTEIN (BPI) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST BACTERICIDAL PERMEABILITY-INCREASING PROTEIN (BPI) IN HUMAN SERUM OR PLASMA SAMPLES, ALEGRIA ANTI-ELASTASE (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST ELASTASE IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA 25-OH VITAMIN D3/D2 CONTROL SET(ORGENTEC)-25-OH VITAMIN D3/D2 CONTROL SET CONTAINS EXTERNAL CONTROL MATERIALS WITH DEFINED CONCENTRATIONS OF 25-OH VITAMIN D3/D2 FOR THE QUANTITATIVE ALEGRIA 25-OH VITAMIN D3/D2 ASSAY,ALEGRIA POSITIVE CONTROL(ORGENTEC)-ALEGRIA POSITIVE CONTROL IS AN ELISA BASED ALEGRIA TEST STRIP INTENDED FOR QUALITY CONTROL OF THE ALEGRIA SYSTEM AND ALEGRIA REAGENTS, ALEGRIA ANTI-CYCLIC CITRULLINATED PEPTIDES HIGH SENSITIVE (CCP HS)(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST CYCLIC CITRULLINATED PEPTIDES (CCP) IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ALPHA-1-ANTITRYPSIN(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF ALPHA-1 ANTITRYPSIN IN HUMAN STOOL SAMPLES,ANTI-INSULIN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST INSULIN IN HUMAN SERUM OR PLASMA,ANTI-DEAMIDATED GLIADIN PROTEIN (DGP) IGG (ORGENTEC)-FOR THE QUANTITATIVE DETECTION OF ANTIBODIES (IGG) AGAINST DEAMIDATED GLIADIN PROTEIN EPITOPES (DGP) IN HUMAN SERUM OR PLASMA,ANTI-DEAMIDATED GLIADIN PROTEIN (DGP) IGA (ORGENTEC)-FOR THE QUANTITATIVE DETECTION OF ANTIBODIES (IGA) AGAINST DEAMIDATED GLIADIN PROTEIN EPITOPES (DGP) IN HUMAN SERUM OR PLASMA,ALEGRIA NEGATIVE CONTROL(ORGENTEC)-ALEGRIA NEGATIVE CONTROL IS AN ELISA BASED ALEGRIA TEST STRIP INTENDED FOR QUALITY CONTROL OF THE ALEGRIA SYSTEM AND ALEGRIA REAGENTS,ANTI MITOCHONDRIAL ANTIBODIES - M2 (AMA-M2) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST MITOCHONDRIAL M2 SUBTYPE ANTIGEN IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-MYELOPEROXIDASE (MPO) (PANCA) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST MYELOPEROXIDASE (MPO) IN HUMAN SERUM OR PLASMA,ANTI-RIBOSOMAL P PROTEINS (RIB-P) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS

	AUTOANTIBODIES AGAINST RIBOSOMAL P PROTEINS IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-GLYCOPROTEIN 210 (GP210) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES AGAINST THE NUCLEAR CORE GLYCOPROTEIN 210 (GP210) IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-PROTEINASE 3 HIGH SENSITIVE (PR3 HS) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST PROTEINASE 3 (PR3) IN HUMAN SERUM OR PLASMA,ANTI NUCLEAR ANTIBODIES (ANA) DETECT (ORGENTEC)-FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-A-52 (RO-52), SS-A-60 (RO-60), SS-B (LA), RNP/SM, RNP-70, RNP-A, RNP-C, SM-BB, SM-D, SM-E, SM-F, SM-G, SCL-70, JO-1, DSDNA, SSDNA, SSDNA, POLYNUCLEOSOMES, MONONUCLEOSOMES, HISTONE COMPLEX, HISTONE H1, HISTONE H2A, HISTONE H2B, HISTONE 3, HISTONE H4, PM-SCL-100 AND CENTROMERE B IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-PROTHROMBIN IGA (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES AGAINST PROTHROMBIN IN HUMAN SERUM OR PLASMA,ANTI-BETA-2-GLYCOPROTEIN I IGG/IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF I IGG AND IGM CLASS AUTOANTIBODIES AGAINST BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-LACTOFERRIN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST LACTOFERRIN IN HUMAN SERUM OR PLASMA SAMPLES, ANTI-CYCLIC CITRULLINATED PEPTIDES HIGH SENSITIVE (CCP HS) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST CYCLIC CITRULLINATED PEPTIDES (CCP) IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-BETA-2-GLYCOPROTEIN I IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS AUTOANTIBODIES AGAINST BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-DOUBLE STRANDED DNA (DSDNA) IGA (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES AGAINST DOUBLE STRANDED DNA IN HUMAN SERUM OR PLASMA, ALEGRIA ANTI-BETA-2-GLYCOPROTEIN I SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG, IGA AND IGM CLASS AUTOANTIBODIES AGAINST BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-PHOSPHATIDYL SERINE IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST PHOSPHATIDYL SERINE IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI MITOCHONDRIAL ANTIBODIES - M2 (AMA-M2) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST MITOCHONDRIAL M2 SUBTYPE ANTIGEN IN HUMAN SERUM

	OR PLASMA SAMPLES,ALEGRIA ANTI-RIBOSOMAL P PROTEINS (RIB-P)(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST RIBOSOMAL P PROTEINS IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-DOUBLE STRANDED DNA (DSDNA) IGG(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST DOUBLE-STRANDED DNA IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-LYSOZYME (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST LYSOZYME IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-SP100 (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES AGAINST THE NUCLEAR BODY PROTEIN SP100 IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-PHOSPHOLIPID SCREEN IGG/IGM (ORGENTEC)-FOR SCREENING THE PRESENCE OF IGG AND IGM CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN, PHOSPHATIDYL SERINE, PHOSPHATIDYL INOSITOL, PHOSPHATIDIC ACID AND BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-SACCHAROMYCES CEREVISIAE AUTOANTIBODIES (ASCA) IGA (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS ANTI-SACCHAROMYCES CEREVISIAE AUTOANTIBODIES (ASCA) IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-PROTEINASE 3 (PR3) (CANCA)(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST PROTEINASE 3 (PR3) IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-BETA-2-GLYCOPROTEIN I IGA (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES AGAINST BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-PHOSPHATIDIC ACID IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS AUTOANTIBODIES AGAINST PHOSPHATIDIC ACID IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-PHOSPHATIDYL SERINE IGG/IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTOANTIBODIES AGAINST PHOSPHATIDYL SERINE IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-BETA-2-GLYCOPROTEIN I IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-TISSUE-TRANSGLUTAMINASE IGA (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES AGAINST TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM OR PLASMA SAMPLES, ALEGRIA ANTI-CARDIOLIPIN SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG, IGA AND IGM CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-CATHEPSIN G (ORGENTEC)-FOR THE

	QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST CATHEPSIN G IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-TISSUE-TRANSGLUTAMINASE SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGA CLASS AUTOANTIBODIES AGAINST TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-CARDIOLIPIN IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-SMIT ANTIGEN (SM) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SM IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA 25-OH VITAMIN D3/D2(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF THE TOTAL CONCENTRATION OF 25-(OH)-VITAMIN D2 AND 25-(OH)-VITAMIN D3 IN HUMAN SERUM OR PLASMA SAMPLES (EDTA PLASMA, HEPARIN PLASMA, CITRATE PLASMA),ANTI-PHOSPHATIDYL INOSITOL IGG/IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTOANTIBODIES AGAINST PHOSPHATIDYL INOSITOL IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-NUCLEOSOME (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST NUCLEOSOMES IN HUMAN SERUM OR PLASMA SAMPLES, ALEGRIA ANTI-SJOGREN ANTIGEN (SS-B) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-B IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-SINGLE STRANDED DNA (SSDNA) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SINGLE-STRANDED DNA IN HUMAN SERUM OR PLASMA,ANTI-SJOGREN ANTIGEN 60 (SS-A 60) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES TO SS-A 60 IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-PHOSPHOLIPID SCREEN IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN, PHOSPHATIDYL SERINE, PHOSPHATIDYL INOSITOL, PHOSPHATIDIC ACID AND BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA SAMPLES, ALEGRIA ANTI-HISTONE(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST HISTONE IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA EXTRACTABLE NUCLEAR ANTIGENS (ENA) SCREEN (ORGENTEC)-FOR THE QUALITATIVE SCREENING OF IGG CLASS AUTOANTIBODIES AGAINST EXTRACTABLE NUCLEAR ANTIGENS (ENA): SS-A 60, SS-A 52, SS-B, SM, RNP/SM, SCL-70, AND JO-1, IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-SJOGREN ANTIGEN (SS-A) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-A 60 AND SS-A 52 IN HUMAN SERUM OR PLASMA

	SAMPLES.,ALEGRIA ANTI-GLIADIN SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGA CLASS AUTOANTIBODIES AGAINST GLIADIN IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-ANNEXIN V IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST ANNEXIN V IN HUMAN SERUM OR PLASMA SAMPLES, ALEGRIA ANTI-PHOSPHATIDYL INOSITOL IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST PHOSPHATIDYL INOSITOL IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-PARIETAL CELL (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST THE ALPHA AND BETA-SUBUNITS OF THE PARIETAL CELL H+/K+-ATPASE IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-ANNEXIN V IGM(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS AUTOANTIBODIES AGAINST ANNEXIN V IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-SJOGREN ANTIGEN 52 (SS-A 52) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES TO SS-A 52 IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-DOUBLE STRANDED DNA (DSDNA) IGA (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES AGAINST DOUBLE-STRANDED DNA (DSDNA) IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-LACTOFERRIN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST LACTOFERRIN IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-THYROGLOBULIN (TG)(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST THYROGLOBULIN (TG) IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES HIGH SENSITIVE (ANCASCREEN HS) (ALEGRIA)-FOR THE QUALITATIVE SCREENING OF IGG CLASS AUTOANTIBODIES AGAINST PR3 AND MPO IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-PROTEINASE 3 HIGH SENSITIVE (PR3 HS)(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST PROTEINASE 3 (PR3) IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-C1Q (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST C1Q IN HUMAN SERUM OR PLASMA,ALEGRIA CALPROTECTIN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL SAMPLES TO BE USED IN THE ASSESSMENT OF INTESTINAL INFLAMMATORY DISORDERS,ANTI-ALPHA-FODRIN IGG/IGA (ORGENTEC)-FOR THE FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGA CLASS AUTOANTIBODIES AGAINST ALPHA-FODRIN IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-PHOSPHATIDYL INOSITOL IGM (ORGENTEC)-FOR THE QUANTITATIVE

	MEASUREMENT OF IGM CLASS AUTOANTIBODIES AGAINST PHOSPHATIDYL INOSITOL IN HUMAN SERUM OR PLASMA SAMPLES, ANTI-PARIETAL CELL (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST THE ALPHA- AND BETA-SUBUNITS OF THE PARIETAL CELL H+/K+-ATPASE IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-DOUBLE STRANDED DNA (DSDNA) IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST DOUBLE-STRANDED DNA (DSDNA) IN HUMAN SERUM OR PLASMA SAMPLES, ALEGRIA ANTI-MYELOPEROXIDASE (MPO) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST MYELOPEROXIDASE (MPO) IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-INSULIN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES AGAINST INSULIN IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA RHEUMATOID FACTOR IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS RHEUMATOID FACTOR (RF) IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-MUTATED CITRULLINATED VIMENTIN (MCV) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST MUTATED CITRULLINATED VIMENTIN (MCV) IN HUMAN SERUM OR PLASMA, EXTRACTABLE NUCLEAR ANTIGEN-4-PROFILE (ENA-4-PROFILE) (ORGENTEC)-FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES DIRECTED AGAINST THE EXTRACTABLE NUCLEAR ANTIGENS SS-A (52 AND 60 KDA, RO), SS-B (LA), SM AND RNP/SM IN HUMAN SERUM OR PLASMA,ANTI-PROTEINASE 3 (PR3) (CANCA) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST PROTEINASE 3 (PR3) IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-PROTHROMBIN SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG, IGM AND IGA CLASS AUTOANTIBODIES AGAINST PROTHROMBIN IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-MUTATED CITRULLINATED VIMENTIN (MCV) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST MUTATED CITRULLINATED VIMENTIN (MCV) IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-ANNEXIN V IGG/IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTOANTIBODIES AGAINST ANNEXIN V IN HUMAN SERUM OR PLASMA,ANTI-SACCHAROMYCES CEREVISIAE AUTOANTIBODIES (ASCA) IGG/IGA (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGA CLASS ANTI-SACCHAROMYCES CEREVISIAE ANTIBODIES (ASCA) IN HUMAN SERUM OR PLASMA,ANTI-THYROID PEROXIDASE (TPO) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST THYROID PEROXIDASE (TPO) IN HUMAN

	SERUM OR PLASMA.,ANTI-BETA-2-GLYCOPROTEIN I SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF I IGG, IGM AND IGA CLASS AUTOANTIBODIES AGAINST BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA.,ALEGRIA ANTI-DEAMIDATED GLIADIN PROTEIN EPITOPES (DGP) IGA(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS ANTIBODIES AGAINST DEAMIDATED GLIADIN PROTEIN EPITOPES (DGP) IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-THYROGLOBULIN (TG) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST THYROGLOBULIN (TG) IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-CARDIOLIPIN SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG, IGM AND IGA CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM OR PLASMA SAMPLES,EXTRACTABLE NUCLEAR ANTIGEN-6-PROFILE (ENA-6-PROFILE) (ORGENTEC)-FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES DIRECTED AGAINST THE EXTRACTABLE NUCLEAR ANTIGENS SS-A (52 AND 60 KDA, RO), SS-B (LA), SM, RNP/SM, SCL-70, AND JO-1 IN HUMAN SERUM OR PLASMA,ANTI-CENTROMERE B (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST CENTROMERE B IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-LIVER-KIDNEY MICROSOMES (LKM-1) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES AGAINST TYPE 1 LIVER-KIDNEY MICROSOMES (LKM-1) IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-CENTROMERE B (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST CENTROMERE B IN HUMAN SERUM OR PLASMA SAMPLES, ANTI NUCLEAR ANTIBODIES (ANA) SCREEN (ORGENTEC)-FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-A 60, SSA 52, SS-B, RNP-70, SM, RNP/SM, SCL-70, CENTROMERE B, JO-1 IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-DEAMIDATED GLIADIN PROTEIN (DGP) SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGA CLASS ANTIBODIES AGAINST DEAMIDATED GLIADIN PROTEIN EPITOPES (DGP) IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-PHOSPHOLIPID SCREEN IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN, PHOSPHATIDYL SERINE, PHOSPHATIDYL INOSITOL, PHOSPHATIDIC ACID AND BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA SAMPLES, RHEUMATOID FACTOR IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS RHEUMATOID FACTOR IN HUMAN SERUM OR PLASMA SAMPLES,RHEUMATOID FACTOR IGA (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS RHEUMATOID FACTOR IN HUMAN SERUM OR PLASMA SAMPLES,

	RHEUMATOID FACTOR IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS RHEUMATOID FACTOR IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-SOLUBLE LIVER ANTIGEN (SLA) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES AGAINST SOLUBLE LIVER ANTIGEN (SLA) IN HUMAN SERUM OR PLASMA SAMPLES.,ALEGRIA ANTI-GLIADIN IGG (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST GLIADIN IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-DEAMIDATED GLIADIN PROTEIN EPITOPES (DGP) IGG(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES AGAINST DEAMIDATED GLIADIN PROTEIN EPITOPES (DGP) IN HUMAN SERUM OR PLASMA SAMPLES, EXTRACTABLE NUCLEAR ANTIGENS (ENA) COMBI (ORGENTEC)-FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST EXTRACTABLE NUCLEAR ANTIGENS (ENA): SS-A (52 AND 60 KDA), SS-B, SM, RNP/SM, SCL-70, AND JO-1, IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-CARDIOLIPIN IGG/IGM (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM OR PLASMA,ANTI-CARDIOLIPIN IGA (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM OR PLASMA SAMPLES, ALEGRIA ANTI-ALPHA-FODRIN IGA (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES AGAINST ALPHA-FODRIN IN HUMAN SERUM OR PLASMA SAMPLES, ANTI-JO-1 (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST JO-1 IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-SJOGREN ANTIGEN 52 (SS-A 52) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-A 52 IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-DEAMIDATED GLIADIN PROTEIN EPITOPES (DGP) SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA AND IGG CLASS ANTIBODIES AGAINST DEAMIDATED GLIADIN PROTEIN EPITOPES (DGP) IN HUMAN SERUM OR PLASMA SAMPLES, ANTI-SCL-70 (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SCL-70 IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI NUCLEAR ANTIBODIES (ANA) SCREEN (ORGENTEC)-FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-A 60, SS-A 52, SS-B, RNP-70, SM, RNP/SM, SCL-70, CENTROMERE B, JO-1 IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-SMIT ANTIGEN (SM) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SM IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-SACCHAROMYCES CEREVISIAE AUTOANTIBODIES (ASCA) IGG

	(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTI-SACCHAROMYCES CEREVISIAE AUTOANTIBODIES (ASCA) IN HUMAN SERUM OR PLASMA SAMPLES,25-OH VITAMIN D3/D2 (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF TOTAL CONCENTRATION OF 25-(OH)-VITAMIN D2 AND 25-(OH)-VITAMIN D3 IN HUMAN SERUM OR PLASMA SAMPLES (EDTA PLASMA, HEPARIN PLASMA, CITRATE PLASMA),ANTI-HISTONE (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES TO HISTONE IN HUMAN SERUM OR PLASMA,EXTRACTABLE NUCLEAR ANTIGEN (ENA) SCREEN (ORGENTEC)-FOR THE QUALITATIVE SCREENING OF IGG CLASS AUTOANTIBODIES AGAINST EXTRACTABLE NUCLEAR ANTIGENS (ENA): SS-A 60, SS-A 52, SS-B, SM, RNP/SM, SCL-70, AND JO-1, IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-INTRINSIC FACTOR (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST INTRINSIC FACTOR IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-PHOSPHATIDIC ACID IGG/IGM(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTOANTIBODIES AGAINST PHOSPHATIDIC ACID IN HUMAN SERUM OR PLASMA,ANTI-ELASTASE(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST ELASTASE IN HUMAN SERUM OR PLASMA,ALEGRIA ANTI-DOUBLE STRANDED DNA (DSDNA) SCREEN (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG, IGM, IGA CLASS AUTOANTIBODIES AGAINST DOUBLE-STRANDED (DSDNA) IN HUMAN SERUM OR PLASMA SAMPLES,ALEGRIA ANTI-THYROID PEROXIDASE (TPO)(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST THYROID PEROXIDASE (TPO) IN HUMAN SERUM OR PLASMA SAMPLES,ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA) COMBI (ORGENTEC)-FOR THE QUALITATIVE MEASUREMENT OF ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA) DIRECTED AGAINST PR3, MPO, BPI, ELASTASE, CATHEPSIN G, LYSOZYME AND LACTOFERRIN IN HUMAN SERUM OR PLASMA,ANTI-GLIADIN IGA(ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES AGAINST GLIADIN IN HUMAN SERUM OR PLASMA,ANTI-NUCLEOSOME (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST NUCLEOSOMES IN HUMAN SERUM OR PLASMA,ANTI-BACTERICIDAL PERMEABILITY INCREASING PROTEIN (BPI) (ORGENTEC)-FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST BACTERICIDAL PERMEABILITY INCREASING PROTEIN, BPI, IN HUMAN SERUM OR PLASMA,ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES SCREEN HIGH SENSITIVE (ANCASCREEN HS) (ORGENTEC)-FOR THE QUALITATIVE

		MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST PR3 AND MPO IN HUMAN SERUM OR PLASMA
394	IMP/IVD/2019/000426	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HAPTOGLOBIN (HAPTOGLOBIN)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF HAPTOGLOBIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,ALPHA-1-ACIDGLYCOPROTEIN(ALPHA-1-ACIDGLYCOPROTEIN)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF -1 ACIDGLYCOPROTEIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS
395	IMP/IVD/2019/000427	1.License Holder Name: M/S AGAPPE DIAGNOSTICS LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LYSE REAGENT FOR 5 PART DIFFERENTIAL HEMATOLOGY ANALYZER(LYSE 5D)-TO BE USED FOR BLOOD CELL COUNTING SIZING AND WBC DIFFERENTIATION HEMOGLOBIN DETERMINATION ON MISPA COUNT PLUS HEMATOLOGY ANALYZER.

396	IMP/IVD/2019/000428	1.License Holder Name: BIOSYSTEMS DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHOLESTEROL STANDARD(CHOLESTEROL STANDARD)-USED TO STANDARDIZE THE CHOLESTEROL KIT.,CALCIUM ARSENAZO(CALCIUM ARSENAZO)-REAGENTS FOR MEASUREMENT OF CALCIUM ARSENAZO CONCENTRATION IN SERUM,ALKALINE WASHING SOLUTION (ALKALINE WASHING SOLUTION)-WASHING SOLUTION TO CLEAN THE INTERNAL PARTS OF THE INSTRUMENTS.,BILIRUBIN (DIRECT) (BILIRUBIN (DIRECT))-REAGENTS FOR MEASUREMENT OF BILIRUBIN DIRECT CONCENTRATION IN SERUM,GLUCOSE / UREA / CREATININE STANDARD(GLUCOSE / UREA / CREATININE STANDARD)-USED TO STANDARDIZE THE GLUCOSE/UREA/CREATININE KIT. ,PROTEIN CONTROL SERUM II(PROTEIN CONTROL SERUM II)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE, BETA-HYROXYBUTYRATE(BETA-HYROXYBUTYRATE)-REAGENTS FOR MEASUREMENT OF BETA-HYDROXYBUTYRATE CONCENTRATION IN SERUM OR PLASMA.,FRUCTOSE STANDARD(FRUCTOSE STANDARD)-BEING USED TO STANDARDIZE THE FRUCTOSE KIT, FRUCTOSAMINE CONTROL SERUM(FRUCTOSAMINE CONTROL SERUM)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE.,17-HYDROXYCORICOSTEROIDS(17-HYDROXYCORICOSTEROIDS)-REAGENTS FOR MEASUREMENT OF 17-OH CONCENTRATION IN URINE,HEMOGLOBIN A1C CONTROL (NORMAL)(HEMOGLOBIN A1C CONTROL (NORMAL))-THE HEMOGLOBIN A1C CONTROL IS INTENDED FOR QUALITY CONTROL PURPOSES ONLY AND IS SUPPLIED WITH SUGGESTED INTERVALS OF ACCEPTABLE VALUES.,CREATINE KINASE (CK)(CREATINE KINASE (CK))-REAGENTS FOR MEASUREMENT OF CREATINE KINASE CONCENTRATION IN SERUM,OXALATE CONTROL URINE(OXALATE CONTROL URINE)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE.,FIBRINOGEN(FIBRINOGEN)-REAGENTS FOR MEASUREMENT OF FIBRINOGEN CONCENTRATION IN SERUM, URIC ACID STANDARD(URIC ACID STANDARD)-USED TO STANDARDIZE THE URIC ACID KIT.,ASMA POSITIVE CONTROL(ASMA POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,ALBUMIN STANDARD(ALBUMIN STANDARD)-USED TO STANDARDIZE THE ALBUMIN KIT., HEMOGLOBIN A1C DIRECT (HBA1C-DIR)(HEMOGLOBIN A1C DIRECT (HBA1C-DIR))-REAGENTS FOR MEASUREMENT OF HBA1C DIRECT CONCENTRATION IN SERUM,TRIGLYCERIDES STANDARD (TRIGLYCERIDES STANDARD)-USED TO STANDARDIZE THE CHOLESTEROL KIT.,COAGULATION CALIBRATOR(COAGULATION CALIBRATOR)-BEING USED TO STANDARDIZE THE COAGULATION

	KITS,OXALATE(OXALATE)-REAGENTS FOR MEASUREMENT OF OXALATE CONCENTRATION IN URINE.,HOMOCYSTEINE (HOMOCYSTEINE)-REAGENTS FOR MEASUREMENT OF HOMOCYSTEINE CONCENTRATION IN SERUM,PROTEIN (TOTAL) STANDARD(PROTEIN (TOTAL) STANDARD)-USED TO STANDARDIZE THE ALBUMIN KIT.,ANTI-TTRANSGLUTAMINASE IGG ANTIBODIES ((ANTI-TTG IGG)(ANTI-TTRANSGLUTAMINASE IGG ANTIBODIES ((ANTI-TTG IGG))-REAGENTS FOR MEASUREMENT OF TTG IGG CONCENTRATION IN SERUM,CALCIUM / MAGNESIUM STANDARD (CALCIUM / MAGNESIUM STANDARD)-USED TO STANDARDIZE THE CALCIUM/MAGNESIUM KIT. ,CHOLESTEROL LDL DIRECT (CHOLESTEROL LDL DIRECT)-REAGENTS FOR MEASUREMENT OF CHOLESTEROL LDL DIRECT CONCENTRATION IN SERUM, UNSATURATED IRON BINDING CAPACITY(UNSATURATED IRON BINDING CAPACITY)-REAGENTS FOR MEASUREMENT OF UIBC CONCENTRATION IN SERUM OR HEPARINIZED PLASMA.,PREVECAL PROTEINS(PREVECAL PROTEINS)-EXTERNAL QUALITY CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE, ANTI-NUCLEASOME ANTIBODIES (NCL)(ANTI-NUCLEASOME ANTIBODIES (NCL))-REAGENTS FOR MEASUREMENT OF NUCLEOSOME CONCENTRATION IN SERUM,FERTILITY BIOCHEMISTRY CONTROL(FERTILITY BIOCHEMISTRY CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE, COMPLEMENT COMPONENT C4(COMPLEMENT COMPONENT C4)-REAGENTS FOR MEASUREMENT OF C4 CONCENTRATION IN SERUM, PREALBUMIN(PREALBUMIN)-REAGENTS FOR MEASUREMENT OF PREALBUMIN CONCENTRATION IN SERUM,APCA POSITIVE CONTROL (APCA POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURES,ANTI-THYROGLOBULIN ANTIBODIES (ANTI-TG)(ANTI-THYROGLOBULIN ANTIBODIES (ANTI-TG))-REAGENTS FOR MEASUREMENT OF THYROGLOBULIN CONCENTRATION IN SERUM,ANTI-INSULIN ANTIBODIES (INS)(ANTI-INSULIN ANTIBODIES (INS))-REAGENTS FOR MEASUREMENT OF INSULIN CONCENTRATION IN SERUM,OXALATE PRETREATMENT REAGENTS(OXALATE PRETREATMENT REAGENTS)-REAGENTS FOR MEASUREMENT OF OXALATE CONCENTRATION IN SERUM,CONCENTRATED SYSTEM LIQUID(CONCENTRATED SYSTEM LIQUID)-SOLUTION BEING USED TO CLEAN THE INTERNAL PART OF THE INSTRUMENT,BIOCHEMISTRY CONTROL SERUM II (BIOCHEMISTRY CONTROL SERUM II)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,CALCIUM CRESOLPHTHALEIN(CALCIUM CRESOLPHTHALEIN)-REAGENTS FOR MEASUREMENT OF CALCIUM CRESOLPHTHALEIN CONCENTRATION IN SERUM,ALKALINE PHOSPHATASE (ALP)-DEA(ALKALINE

	PHOSPHATASE (ALP)-DEA)-REAGENTS FOR MEASUREMENT OF ALKALINE PHOSPHATASE DEA CONCENTRATION IN SERUM,ALBUMIN (ALBUMIN)-REAGENTS FOR MEASUREMENT OF ALBUMIN CONCENTRATION IN SERUM,RHEUMATOID CONTROL SERUM II (RHEUMATOID CONTROL SERUM II)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,CHOLESTEROL HDL DIRECT(CHOLESTEROL HDL DIRECT)-REAGENTS FOR MEASUREMENT OF CHOLESTEROL HDL DIRECT CONCENTRATION IN SERUM,TRIGLYCERIDES(TRIGLYCERIDES)-REAGENTS FOR MEASUREMENT OF TRIGLYCERIDES CONCENTRATION IN SERUM, ANTI-SKIN ANTIBODIES (ASA)(ANTI-SKIN ANTIBODIES (ASA))-REAGENTS FOR MEASUREMENT OF SKIN ANTIBODIES CONCENTRATION IN SERUM,BETA 2 MICROGLOBULIN STANDARD (BETA 2 MICROGLOBULIN STANDARD)-BEING USED TO STANDARDIZE THE BETA 2 MICROGLOBULIN KIT,C-REACTIVE PROTEIN-ER (CRP-ER) (C-REACTIVE PROTEIN-ER (CRP-ER))-REAGENTS FOR MEASUREMENT OF CRP ER CONCENTRATION IN SERUM,ETHANOL(ETHANOL)-REAGENTS FOR MEASUREMENT OF ETHANOL CONCENTRATION IN SERUM,BIOCHEMISTRY CONTROL SERUM (HUMAN) II(BIOCHEMISTRY CONTROL SERUM (HUMAN) II)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,LACTATE DEHYDROGENASE (LDH) – IFCC(LACTATE DEHYDROGENASE (LDH) – IFCC)-REAGENTS FOR MEASUREMENT OF LDH IFCC CONCENTRATION IN SERUM,A-AMYLASE PANCREATIC(A-AMYLASE PANCREATIC)-REAGENTS FOR MEASUREMENT OF A AMYLASE PANCREATIC CONCENTRATION IN SERUM.,RHEUMATOID FACTORS (RF) STANDARD(RHEUMATOID FACTORS (RF) STANDARD)-BEING USED TO STANDARDIZE THE RF KIT,CHOLESTEROL(CHOLESTEROL)-REAGENTS FOR MEASUREMENT OF CHOLESTEROL CONCENTRATION IN SERUM,PBS (10X)(PBS (10X))-AUXILLIARY REAGENT BEING USED FOR THE MEASUREMENT OF AUTOIMMUNE PARAMETERS IN SERUM, HOMOCYSTEINE CONTROL I(HOMOCYSTEINE CONTROL I)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE, PHOSPHORUS(PHOSPHORUS)-REAGENTS FOR MEASUREMENT OF PHOSPHORUS CONCENTRATION IN SERUM,IGG FITC/EVANS(IGG FITC/EVANS)-AUXILLIARY REAGENT BEING USED FOR THE MEASUREMENT OF AUTOIMMUNE PARAMETERS IN SERUM,ANTI-STREPTOLYSIN O (ASO)(ANTI-STREPTOLYSIN O (ASO))-REAGENTS FOR MEASUREMENT OF ASO CONCENTRATION IN SERUM,ANA HO POSITIVE CONTROL(ANA HO POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE, ANGIOTENSIN CONVERTING ENZYME (ACE)(ANGIOTENSIN CONVERTING ENZYME (ACE))-REAGENTS FOR MEASUREMENT OF ACE CONCENTRATION IN SERUM,ANTI-MPO ANTIBODIES(ANTI-MPO

	ANTIBODIES)-REAGENTS FOR MEASUREMENT OF MPO CONCENTRATION IN SERUM,IMMUNOGLOBULIN A (IGA) (IMMUNOGLOBULIN A (IGA))-REAGENTS FOR MEASUREMENT OF IGA CONCENTRATION IN SERUM, URINE,MAGNESIUM(MAGNESIUM)-REAGENTS FOR MEASUREMENT OF A MAGNESIUM CONCENTRATION IN SERUM,ANTI-TTRANSGLUTAMINASE IGA ANTIBODIES (ANTI-TTG IGA)(ANTI-TTRANSGLUTAMINASE IGA ANTIBODIES (ANTI-TTG IGA))-REAGENTS FOR MEASUREMENT OF TTG IGA CONCENTRATION IN SERUM,ANTI-ENDOMYSIUM ANTIBODIES (AEA)(ANTI-ENDOMYSIUM ANTIBODIES (AEA))-REAGENTS FOR MEASUREMENT OF ENDOMYSIUM ANTIBODIES CONCENTRATION IN SERUM,CONTROL URINE(CONTROL URINE)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,AMA POSITIVE CONTROL(AMA POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,THROMBIN TIME (TT)(THROMBIN TIME (TT))-REAGENTS FOR MEASUREMENT OF CLOT FORMATION IN BLOOD,ALBUMIN (MICROALBUMINURIA) STANDARD(ALBUMIN (MICROALBUMINURIA) STANDARD)-BEING USED TO STANDARDIZE THE MICROALBUMINUREA KIT,CARBON DIOXIDE (CO2)(CARBON DIOXIDE (CO2))-REAGENTS FOR MEASUREMENT OF CO2 CONCENTRATION IN SERUM,APOLIPOPROTEIN B STANDARD (APOLIPOPROTEIN B STANDARD)-BEING USED TO STANDARDIZE THE APO B KIT,BETA 2 MICROGLOBULIN(BETA 2 MICROGLOBULIN)-REAGENTS FOR MEASUREMENT OF BETA2 MICROGLOBULIN CONCENTRATION IN SERUM,BILIRUBIN (TOTAL AND DIRECT) (BILIRUBIN (TOTAL AND DIRECT))-REAGENTS FOR MEASUREMENT OF BILIRUBIN TOTAL AND DIRECT CONCENTRATION IN SERUM, MOUNTING MEDIUM(MOUNTING MEDIUM)-AUXILLIARY REAGENT BEING USED FOR THE MEASUREMENT OF AUTOIMMUNE PARAMETERS IN SERUM,PROTEIN CONTROL SERUM I(PROTEIN CONTROL SERUM I)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,CK-MB CONTROL SERUM II(CK-MB CONTROL SERUM II)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,ANTI-PHOSPHOLIPID IGG/IGM (APLA)(ANTI-PHOSPHOLIPID IGG/IGM (APLA))-REAGENTS FOR MEASUREMENT OF PHOSPHOLIPIDS CONCENTRATION IN SERUM,AKA POSITIVE CONTROL(AKA POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURES,FERRITIN STANDARD(FERRITIN STANDARD)-BEING USED TO STANDARDIZE THE FERRITIN KIT,ANTI-RIBOSOMAL P ANTIBODIES (RIB P)(ANTI-RIBOSOMAL P ANTIBODIES (RIB P))-REAGENTS FOR MEASUREMENT OF RIBOSOMAL P PROTEIN CONCENTRATION IN SERUM,ALKALINE PHOSPHATASE (ALP)-AMP(ALKALINE PHOSPHATASE (ALP)-AMP)-REAGENTS FOR MEASUREMENT OF ALKALINE PHOSPHATASE AMP

	CONCENTRATION IN SERUM,ANTI-HISTONES ANTIBODIES (HIST)(ANTI-HISTONES ANTIBODIES (HIST))-REAGENTS FOR MEASUREMENT OF HISTONES CONCENTRATION IN SERUM,ANTI-THYROID ANTIBODIES (ATA)(ANTI-THYROID ANTIBODIES (ATA))-REAGENTS FOR MEASUREMENT OF THYROID ANTIBODIES CONCENTRATION IN SERUM,C-REACTIVE PROTEIN (CRP)(C-REACTIVE PROTEIN (CRP))-REAGENTS FOR MEASUREMENT OF CRP CONCENTRATION IN SERUM, ANTI-DEAMIDATED GLIADIN PEPTIDES IGG (DGP – IGG)(ANTI-DEAMIDATED GLIADIN PEPTIDES IGG (DGP – IGG))-REAGENTS FOR MEASUREMENT OF DEAMINATED GLIADIN IGG CONCENTRATION IN SERUM,BIOCHEMISTRY CALIBRATOR (HUMAN)(BIOCHEMISTRY CALIBRATOR (HUMAN))-BEING USED TO STANDARDIZE THE BIOCHEMICAL PARAMETERS,RHEUMATOID CONTROL SERUM I (RHEUMATOID CONTROL SERUM I)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,ANA CE POSITIVE CONTROL(ANA CE POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE, PROTHROMBIN TIME (PT)(PROTHROMBIN TIME (PT))-REAGENTS FOR MEASUREMENT OF CLOT FORMATION IN BLOOD.,ANTI-GLIADIN ANTIBODIES (AGA-IGG/IGA)(ANTI-GLIADIN ANTIBODIES (AGA-IGG/IGA))-REAGENTS FOR MEASUREMENT OF GLIADIN CONCENTRATION IN SERUM,IRON-CHROMAZUROL(IRON-CHROMAZUROL)-REAGENTS FOR MEASUREMENT OF IRON CHROMAZOUL CONCENTRATION IN SERUM,A-AMYLASE EPS(A-AMYLASE EPS)-REAGENTS FOR MEASUREMENT OF A AMYLASE EPS CONCENTRATION IN SERUM.,CHOLESTEROL HDL/LDL CALIBRATOR (CHOLESTEROL HDL/LDL CALIBRATOR)-BEING USED TO STANDARDIZE THE HDL/LDL KITS,AUTOANTIBODIES-MSL/MSK/MSS (AA-MSL/MSK/MSS)(AUTOANTIBODIES-MSL/MSK/MSS (AA-MSL/MSK/MSS))-REAGENTS FOR MEASUREMENT OF AUTO ANTIBODIES CONCENTRATION IN SERUM,HEMOGLOBIN A1C CONTROL(ELEVATED)(HEMOGLOBIN A1C CONTROL(ELEVATED))-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,LKM POSITIVE CONTROL(LKM POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURES,AMMONIA/ETHANOL/CO2 CONTROL L2 (AMMONIA/ETHANOL/CO2 CONTROL L2)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,ALBUMIN (MICROALBUMINURIA)(ALBUMIN (MICROALBUMINURIA))-REAGENTS FOR MEASUREMENT OF MICROALBUMINUREA CONCENTRATION IN SERUM, PLASMA, URINE,LAMBDA(LAMBDA)-REAGENTS FOR MEASUREMENT OF ETHANOL CONCENTRATION IN SERUM,ANTI-KERATIN ANTIBODIES (AKA)(ANTI-KERATIN ANTIBODIES (AKA))-REAGENTS FOR MEASUREMENT OF KERATIN ANTIBODIES

	CONCENTRATION IN SERUM,ADENOSINE DEAMINASE (ADA)(ADENOSINE DEAMINASE (ADA))-REAGENTS FOR MEASUREMENT OF ADENOSINE DEAMINASE CONCENTRATION IN SERUM.,ANTI-SC170 ANTIBODIES(ANTI-SC170 ANTIBODIES)-REAGENTS FOR MEASUREMENT OF SCL70 CONCENTRATION IN SERUM,ANTI-DSDNA ANTIBODIES(ANTI-DSDNA ANTIBODIES)-REAGENTS FOR MEASUREMENT OF DSDNA CONCENTRATION IN SERUM, COMPLEMENT COMPONENT C3(COMPLEMENT COMPONENT C3)-REAGENTS FOR MEASUREMENT OF C3 CONCENTRATION IN SERUM, ANTI – STREPTOLYSIN O (ASO) STANDARD(ANTI – STREPTOLYSIN O (ASO) STANDARD)-BEING USED TO STANDARDIZE THE ASO KIT, ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)(ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT))-REAGENTS FOR MEASUREMENT OF CLOT FORMATION IN BLOOD,PREVECAL ANCA (PREVECAL ANCA)-EXTERNAL QUALITY CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE, AUTOANTIBODIES DUO-HEP2/ML(DUO-HEP2/ML)(AUTOANTIBODIES DUO-HEP2/ML(DUO-HEP2/ML))-REAGENTS FOR MEASUREMENT OF ANA CONCENTRATION IN SERUM,ASPARATE AMINOTRANSFERASE (AST/GOT)(ASPARATE AMINOTRANSFERASE (AST/GOT))-REAGENTS FOR MEASUREMENT OF AST/GOT CONCENTRATION IN SERUM, PREVECAL ANA(PREVECAL ANA)-EXTERNAL QUALITY CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE, PREVECAL BIOCHEMISTRY HUMAN(PREVECAL BIOCHEMISTRY HUMAN)-EXTERNAL QUALITY CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,CALCIUM-MTB (CALCIUM-MTB)-REAGENTS FOR MEASUREMENT OF CALCIUM MTB CONCENTRATION IN SERUM,PROTEIN (TOTAL)(PROTEIN (TOTAL))-REAGENTS FOR MEASUREMENT OF PROTEIN TOTAL CONCENTRATION IN SERUM,HOMOCYSTEINE CONTROL II (HOMOCYSTEINE CONTROL II)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,WASHING SOLUTION(WASHING SOLUTION)-WASHING SOLUTION BEING USED TO CLEAN THE INTERNAL PART OF THE INSTRUMENT,ANTI-PR3 ANTIBODIES(ANTI-PR3 ANTIBODIES)-REAGENTS FOR MEASUREMENT OF PROTEINASE3 CONCENTRATION IN SERUM,ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA)(ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA))-REAGENTS FOR MEASUREMENT OF ANCA CONCENTRATION IN SERUM,LACTATE DEHYDROGENASE (LDH)(LACTATE DEHYDROGENASE (LDH))-REAGENTS FOR MEASUREMENT OF LDH CONCENTRATION IN SERUM,CITRATE (CITRATE)-REAGENTS FOR MEASUREMENT OF CITRATE CONCENTRATION IN SERUM,CK-MB CONTROL SERUM I(CK-MB CONTROL SERUM I)-CONTROL TO VERIFY THE PERFORMANCE OF THE

	MEASUREMENT PROCEDURE,KAPPA/LAMBDA CALIBRATOR (KAPPA/LAMBDA CALIBRATOR)-BEING USED TO STANDARDIZE THE KAPPA/LAMBDA KIT,IMMUNOGLOBULIN G (IGG)(IMMUNOGLOBULIN G (IGG))-REAGENTS FOR MEASUREMENT OF IGG CONCENTRATION IN SERUM,URINE,ANTI-STREPTOLYSIN O (ASO) CONTROL +(ANTI-STREPTOLYSIN O (ASO) CONTROL +)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURES,5-AMINOLEVULINIC ACID (ALA) / PORPHOBILINOGEN (PBG)(5-AMINOLEVULINIC ACID (ALA) / PORPHOBILINOGEN (PBG))-REAGENTS FOR MEASUREMENT OF 5-ALA PBG CONCENTRATION IN URINE,GLOMERULAR BASEMENT MEMBRANE ANTIBODIES (GBMA)(GLOMERULAR BASEMENT MEMBRANE ANTIBODIES (GBMA))-REAGENTS FOR MEASUREMENT OF GBM CONCENTRATION IN SERUM, ANA-SCREENING(ANA-SCREENING)-REAGENTS FOR MEASUREMENT OF ANTI NUCLEAR ANTIBODIES CONCENTRATION IN SERUM, APOLIPOPROTEIN B (APO B)(APOLIPOPROTEIN B (APO B))-REAGENTS FOR MEASUREMENT OF APO B CONCENTRATION IN SERUM,AICA POSITIVE CONTROL(AICA POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURES,CREATININE(CREATININE)-REAGENTS FOR MEASUREMENT OF CREATININE CONCENTRATION IN SERUM,ASCA –IGG/IGA (ASCA)(ASCA –IGG/IGA (ASCA))-REAGENTS FOR MEASUREMENT OF ASCA CONCENTRATION IN SERUM,FRUCTOSE (FRUCTOSE)-REAGENTS FOR MEASUREMENT OF FRUCTOSE CONCENTRATION IN SERUM,BIOCHEMISTRY CALIBRATOR (BIOCHEMISTRY CALIBRATOR)-BEING USED TO STANDARDIZE THE BIOCHEMICAL PARAMETERS,ENA 6-SCREENING(ENA 6-SCREENING)-REAGENTS FOR MEASUREMENT OF A ENA ANTIBODIES CONCENTRATION IN SERUM,PHOSPHORUS STANDARD(PHOSPHORUS STANDARD)-BEING USED TO STANDARDIZE THE PHOSPHORUS KIT, ZINC(ZINC)-REAGENTS FOR MEASUREMENT OF ZINC CONCENTRATION IN SERUM,COAGULATION CONTROL II (COAGULATION CONTROL II)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,ACID PHOSPHATASE (ACP)(ACID PHOSPHATASE (ACP))-REAGENTS FOR MEASUREMENT OF ACID PHOSPHATASE CONCENTRATION IN SERUM, CHOLESTEROL HDL(CHOLESTEROL HDL)-REAGENTS FOR MEASUREMENT OF CHOLESTEROL HDL CONCENTRATION IN SERUM, URIC ACID(URIC ACID)-REAGENTS FOR MEASUREMENT OF URIC ACID CONCENTRATION IN SERUM,NDNA POSITIVE CONTROL(NDNA POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,AMMONIA(AMMONIA)-REAGENTS FOR MEASUREMENT OF AMMONIA CONCENTRATION IN SERUM, PROTEIN (URINE)(PROTEIN (URINE))-REAGENTS FOR MEASUREMENT

	OF PROTEIN URINE CONCENTRATION IN URINE,CHOLESTEROL LDL PRECIPITATING REAGENT(CHOLESTEROL LDL PRECIPITATING REAGENT)-REAGENTS FOR MEASUREMENT OF CHOLESTEROL LDL PRECIPITATING REAGENT CONCENTRATION IN SERUM,UREA/BUN-COLOR(UREA/BUN-COLOR)-REAGENTS FOR MEASUREMENT OF UREA BUN COLOUR CONCENTRATION IN SERUM,BIOCHEMISTRY CONTROL URINE II(BIOCHEMISTRY CONTROL URINE II)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE OF COMPLETE BIOCHEMICAL PARAMETERS,FIBRINOGEN STANDARD (FIBRINOGEN STANDARD)-BEING USED TO STANDARDIZE THE FIBRINOGEN KIT,HOMOCYSTEINE STANDARDS(HOMOCYSTEINE STANDARDS)-BEING USED TO STANDARDIZE THE HOMOCYSTEINE KIT,RHEUMATOID FACTORS (RF) – SLIDE(RHEUMATOID FACTORS (RF) – SLIDE)-REAGENTS FOR MEASUREMENT OF RF CONCENTRATION IN SERUM,METANEPHRINES(METANEPHRINES)-REAGENTS FOR MEASUREMENT OF METANEPHRINES CONCENTRATION IN URINE, VANILMANDELIC ACID(VANILMANDELIC ACID)-REAGENTS FOR MEASUREMENT OF VANILMANDELIC ACID CONCENTRATION IN URINE,CRP-ER STANDARD(CRP-ER STANDARD)-BEING USED TO STANDARDIZE THE CRP ER KIT.,CREATINE KINASE-MB (CK-MB) (CREATINE KINASE-MB (CK-MB))-REAGENTS FOR MEASUREMENT OF CREATINE KINASE MB CONCENTRATION IN SERUM,BIOCHEMISTRY CONTROL SERUM (HUMAN) I(BIOCHEMISTRY CONTROL SERUM (HUMAN) I)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,TRANSFERRIN(TRANSFERRIN)-REAGENTS FOR MEASUREMENT OF TRANSFERRIN CONCENTRATION IN SERUM,GBMA POSITIVE CONTROL(GBMA POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURES,ANTI-ANNEXIN V IGG/IGM (ANX)(ANTI-ANNEXIN V IGG/IGM (ANX))-REAGENTS FOR MEASUREMENT OF ANNEXIN CONCENTRATION IN SERUM,ANA NU POSITIVE CONTROL(ANA NU POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,IRON-FERROZINE(IRON-FERROZINE)-REAGENTS FOR MEASUREMENT OF IRON FERROZINE CONCENTRATION IN SERUM,KAPPA(KAPPA)-REAGENTS FOR MEASUREMENT OF KAPPA CONCENTRATION IN SERUM,ANA SP POSITIVE CONTROL(ANA SP POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE, BILIRUBIN STANDARD(BILIRUBIN STANDARD)-BEING USED TO STANDARDIZE THE BILIRUBIN KIT,TOTAL BILE ACIDS(TOTAL BILE ACIDS)-REAGENTS FOR MEASUREMENT OF TOTAL BILE ACIDS CONCENTRATION IN SERUM,CHOLESTEROL HDL PRECIPITATING REAGENT(CHOLESTEROL HDL PRECIPITATING REAGENT)-REAGENTS FOR MEASUREMENT OF CHOLESTEROL HDL PRECIPITATING

	REAGENT CONCENTRATION IN SERUM,ANTI-DEAMIDATED GLIADIN PEPTIDES IGA (DGP – IGA)(ANTI-DEAMIDATED GLIADIN PEPTIDES IGA (DGP – IGA))-REAGENTS FOR MEASUREMENT OF DEAMINATED GLIADIN IGA CONCENTRATION IN SERUM,ENA – 6 PROFILE(ENA – 6 PROFILE)-REAGENTS FOR MEASUREMENT OF A ENA ANTIBODIES CONCENTRATION IN SERUM,GLUCOSE(GLUCOSE)-REAGENTS FOR MEASUREMENT OF GLUCOSE CONCENTRATION IN SERUM, FRUCTOSAMINE(FRUCTOSAMINE)-REAGENTS FOR MEASUREMENT OF FRUCTOSAMINE CONCENTRATION IN SERUM,LIPID CONTROL SERUM II(LIPID CONTROL SERUM II)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,17-KETOSTEROIDS(17-KETOSTEROIDS)-REAGENTS FOR MEASUREMENT OF 17-KETOSTEROIDES CONCENTRATION IN URINE,IGA FITC/EVANS (IGA FITC/EVANS)-AUXILLIARY REAGENT BEING USED FOR THE MEASUREMENT OF AUTOIMMUNE PARAMETERS IN SERUM,ALANINE AMINOTRANSFERASE (ALT/GPT)(ALANINE AMINOTRANSFERASE (ALT/GPT))-REAGENTS FOR MEASUREMENT OF ALT/GPT CONCENTRATION IN SERUM,C-REACTIVE PROTEIN HS (CRP-HS)(C-REACTIVE PROTEIN HS (CRP-HS))-REAGENTS FOR MEASUREMENT OF CRP HS CONCENTRATION IN SERUM,HEMOGLOBIN A2 CONTROL (HEMOGLOBIN A2 CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,ENA 4-PROFILE (ENA 4-PROFILE)-REAGENTS FOR MEASUREMENT OF A ENA ANTIBODIES CONCENTRATION IN SERUM,GLUCOSE-HEXOKINASE (GLUCOSE-HEXOKINASE)-REAGENTS FOR MEASUREMENT OF GLUCOSE HEXOKINASE CONCENTRATION IN SERUM,BETA 2 MICROGLOBULIN CONTROL URINE(BETA 2 MICROGLOBULIN CONTROL URINE)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,CRP / CRP – HS STANDARD(CRP / CRP – HS STANDARD)-BEING USED TO STANDARDIZE THE CRP/HSCRP KITS, ANTI-SM/RNP ANTIBODIES(ANTI-SM/RNP ANTIBODIES)-REAGENTS FOR MEASUREMENT OF SM CONCENTRATION IN SERUM,CREATININE ENZYMATIC(CREATININE ENZYMATIC)-REAGENTS FOR MEASUREMENT OF CREATININE ENZYMATIC CONCENTRATION IN SERUM,ADENOSINE DEAMINASE (ADA) STANDARD(ADENOSINE DEAMINASE (ADA) STANDARD)-BEING USED TO STANDARDIZE THE ADA KIT,COAGULATION CONTROL I(COAGULATION CONTROL I)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,UREA/BUN-UV(UREA/BUN-UV)-REAGENTS FOR MEASUREMENT OF UREA BUN UV CONCENTRATION IN SERUM, BIOCHEMISTRY CONTROL URINE(BIOCHEMISTRY CONTROL URINE)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,RHEUMATOID FACTORS (RF)(RHEUMATOID FACTORS (RF))-REAGENTS FOR MEASUREMENT OF RHEUMATOID FACTORS

	CONCENTRATION IN SERUM,CONCENTRATED WASHING SOLUTION (CONCENTRATED WASHING SOLUTION)-WASHING SOLUTION BEING USED TO CLEAN THE INTERNAL PART OF THE INSTRUMENT, AMMONIA/ETHANOL/CO2 CONTROL L1(AMMONIA/ETHANOL/CO2 CONTROL L1)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,BIOCHEMISTRY CONTROL SERUM I (BIOCHEMISTRY CONTROL SERUM I)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,ASA-IS POSITIVE CONTROL(ASA-IS POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURES, CANCA POSITIVE CONTROL(CANCA POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE, PREVECAL NDNA(PREVECAL NDNA)-EXTERNAL QUALITY CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE, C-REACTIVE PROTEIN (CRP) CONTROL +(C-REACTIVE PROTEIN (CRP) CONTROL +)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURES,ASTMA POSITIVE CONTROL(ASTMA POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURES,ANTI-GBM ANTIBODIES –EIA (GBM) (ANTI-GBM ANTIBODIES –EIA (GBM))-REAGENTS FOR MEASUREMENT OF GBM CONCENTRATION IN SERUM,RHEUMATOID FACTORS (RF) CONTROL +(RHEUMATOID FACTORS (RF) CONTROL +)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURES, APOLIPOPROTEIN A-I (APO A-I)(APOLIPOPROTEIN A-I (APO A-I))-REAGENTS FOR MEASUREMENT OF APO A1 CONCENTRATION IN SERUM,ANTI-NUCLEAR ANTIBODIES HEP-2 (ANA-HEP-2)(ANTI-NUCLEAR ANTIBODIES HEP-2 (ANA-HEP-2))-REAGENTS FOR MEASUREMENT OF ANA HEP2 IN SERUM,ANTI-SMOOTH MUSCLE ANTIBODIES (ASMA)(ANTI-SMOOTH MUSCLE ANTIBODIES (ASMA))-REAGENTS FOR MEASUREMENT OF ANTI SMOOTH MUSCLE ANTIBODIES CONCENTRATION IN SERUM,ATA POSITIVE CONTROL (ATA POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURES,HEMOGLOBIN A2 (HEMOGLOBIN A2)-REAGENTS FOR MEASUREMENT OF HEMOGLOBIN A2 CONCENTRATION IN URINE,ANTI-NDNA ANTIBODIES (NDNA) (ANTI-NDNA ANTIBODIES (NDNA))-REAGENTS FOR MEASUREMENT OF NDNA CONCENTRATION IN SERUM,FIBRINOGEN CLAUSS (FIBRINOGEN CLAUSS)-REAGENTS FOR MEASUREMENT OF CLOT FORMATION IN BLOOD,5-HYDROXYINDOLEACETIC ACID (5-HIAA)(5-HYDROXYINDOLEACETIC ACID (5-HIAA))-REAGENTS FOR MEASUREMENT OF 5-H1AA CONCENTRATION IN URINE,PREVECAL BIOCHEMISTRY(PREVECAL BIOCHEMISTRY)-EXTERNAL QUALITY CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,ANTI-JO1 ANTIBODIES(ANTI-JO1 ANTIBODIES)-

	REAGENTS FOR MEASUREMENT OF ANTI JO1 CONCENTRATION IN SERUM,BETA 2 MICROGLOBULIN CONTROLS(BETA 2 MICROGLOBULIN CONTROLS)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,ANTI-MITOCHONDRIAL ANTIBODIES (AMA)(ANTI-MITOCHONDRIAL ANTIBODIES (AMA))-REAGENTS FOR MEASUREMENT OF MITOCHONDRIAL ANTIBODIES CONCENTRATION IN SERUM,IGG FITC/EVANS (M)(IGG FITC/EVANS (M))-AUXILLIARY REAGENT BEING USED FOR THE MEASUREMENT OF AUTOIMMUNE PARAMETERS IN SERUM,ANTI-B2-GLYCOPROTEIN 1 IGG/IGM (B2-GP1)(ANTI-B2-GLYCOPROTEIN 1 IGG/IGM (B2-GP1))-REAGENTS FOR MEASUREMENT OF BETA 2 GLYCOPROTEIN CONCENTRATION IN SERUM,ANTI-ISLET CELL ANTIBODIES (AICA)(ANTI-ISLET CELL ANTIBODIES (AICA))-REAGENTS FOR MEASUREMENT OF ISLET CELL ANTIBODIES CONCENTRATION IN SERUM,FIBRINOGEN CONTROL PLASMA (FIBRINOGEN CONTROL PLASMA)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE, AMMONIA/ETHANOL/CO2 CALIBRATOR(AMMONIA/ETHANOL/CO2 CALIBRATOR)-BEING USED TO STANDARDIZE THE AMMONIA, ETHANOL & CO2 KIT,PREVECAL CELIAC(PREVECAL CELIAC)-EXTERNAL QUALITY CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,ANTI-CENTROMERE B ANTIBODIES (CENP-B)(ANTI-CENTROMERE B ANTIBODIES (CENP-B))-REAGENTS FOR MEASUREMENT OF CENTROMERE ANTIBODIES CONCENTRATION IN SERUM,LACTATE(LACTATE)-REAGENTS FOR MEASUREMENT OF LACTATE CONCENTRATION IN SERUM,APOLIPOPROTEIN A-I STANDARD(APOLIPOPROTEIN A-I STANDARD)-BEING USED TO STANDARDIZE THE APO A1 KIT,PROTEIN (URINE) STANDARD (PROTEIN (URINE) STANDARD)-BEING USED TO STANDARDIZE THE PROTEIN URINE KIT,ANTI-THYROID PEROXIDASE ANTIBODIES (ANTI-TPO)(ANTI-THYROID PEROXIDASE ANTIBODIES (ANTI-TPO))-REAGENTS FOR MEASUREMENT OF THYROPEROXIDASE CONCENTRATION IN SERUM,IMMUNOGLOBULIN M (IGM) (IMMUNOGLOBULIN M (IGM))-REAGENTS FOR MEASUREMENT OF IGM CONCENTRATION IN SERUM,URINE,PROTEIN CALIBRATORS(PROTEIN CALIBRATORS)-BEING USED TO STANDARDIZE THE IMMUNOTURBIDIMETRY KITS.,FERRITIN(FERRITIN)-REAGENTS FOR MEASUREMENT OF FERRITIN CONCENTRATION IN SERUM,ADA CONTROLS(ADA CONTROLS)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,ZINC STANDARD(ZINC STANDARD)-BEING USED TO STANDARDIZE THE ZINC KIT,ACID WASHING SOLUTION(ACID WASHING SOLUTION)-SOLUTION TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,ANTI-ADRENAL CORTEX ANTIBODIES (AACA)(ANTI-

	ADRENAL CORTEX ANTIBODIES (AACA))-REAGENTS FOR MEASUREMENT OF ADRENAL CORTEX ANTIBODIES CONCENTRATION IN SERUM,OXALATE CONTROL URINE II(OXALATE CONTROL URINE II) -CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURES,ASA-BM POSITIVE CONTROL(ASA-BM POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURES,CHOLINESTERASE (CHE) (CHOLINESTERASE (CHE))-REAGENTS FOR MEASUREMENT OF CHOLINESTERASE CONCENTRATION IN SERUM,A- 1- ACID GLYCOPROTEIN(A- 1- ACID GLYCOPROTEIN)-REAGENTS FOR MEASUREMENT OF A 1-ACID GLYCOPROTEIN CONCENTRATION IN SERUM.,A-AMYLASE DIRECT(A-AMYLASE DIRECT)-REAGENTS FOR MEASUREMENT OF A AMYLASE DIRECT CONCENTRATION IN SERUM., ANTI-SM ANTIBODIES(ANTI-SM ANTIBODIES)-REAGENTS FOR MEASUREMENT OF NRNP/SM CONCENTRATION IN SERUM,TOTAL IRON BINDING CAPACITY (TIBC)(TOTAL IRON BINDING CAPACITY (TIBC))-REAGENTS FOR MEASUREMENT OF TIBC CONCENTRATION IN SERUM,AUTOANTIBODIES RL/RK/RS (AA-RL/RK/RS) (AUTOANTIBODIES RL/RK/RS (AA-RL/RK/RS))-REAGENTS FOR MEASUREMENT OF AUTO ANTIBODIES CONCENTRATION IN SERUM, AACA POSITIVE CONTROL(AACA POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURES,C-REACTIVE PROTEIN (CRP) – SLIDE(C-REACTIVE PROTEIN (CRP) – SLIDE)-REAGENTS FOR MEASUREMENT OF CRP CONCENTRATION IN SERUM,LIPASE(LIPASE)-REAGENTS FOR MEASUREMENT OF LIPASE CONCENTRATION IN SERUM,CREATININE KINASE – MB (CKMB) STANDARD(CREATININE KINASE – MB (CKMB) STANDARD)-BEING USED TO STANDARDIZE THE CKMB KIT,ANTI-SSA (RO) ANTIBODIES (ANTI-SSA (RO) ANTIBODIES)-REAGENTS FOR MEASUREMENT OF SSA CONCENTRATION IN SERUM,ANTI-STRIATED MUSCLE ANTIBODIES (ASTMA)(ANTI-STRIATED MUSCLE ANTIBODIES (ASTMA))-REAGENTS FOR MEASUREMENT OF ASTMA CONCENTRATION IN SERUM, FITC/EVANS (R)(FITC/EVANS (R))-AUXILLIARY REAGENT BEING USED FOR THE MEASUREMENT OF AUTOIMMUNE PARAMETERS IN SERUM,ANTI-SSB (LA) ANTIBODIES(ANTI-SSB (LA) ANTIBODIES)-REAGENTS FOR MEASUREMENT OF SSB CONCENTRATION IN SERUM, LIPID CONTROL SERUM I(LIPID CONTROL SERUM I)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE, ANTI-STREPTOLYSIN O (ASO) – SLIDE(ANTI-STREPTOLYSIN O (ASO) – SLIDE)-REAGENTS FOR MEASUREMENT OF ASO CONCENTRATION IN SERUM,G-GLUTAMYLTRANSFERASE (G-GT)(G-GLUTAMYLTRANSFERASE (G-GT))-REAGENTS FOR MEASUREMENT OF GGT CONCENTRATION IN SERUM,ANTI-CARDIOLIPIN ANTIBODIES (ACA-IGG/IGM)(ANTI-CARDIOLIPIN ANTIBODIES (ACA-IGG/IGM))-

	REAGENTS FOR MEASUREMENT OF CARDIOLIPIN CONCENTRATION IN SERUM,PREVECAL RHEUMA(PREVECAL RHEUMA)-EXTERNAL QUALITY CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,BILIRUBIN (TOTAL)(BILIRUBIN (TOTAL))-REAGENTS FOR MEASUREMENT OF BILIRUBIN TOTAL CONCENTRATION IN SERUM,AEA POSITIVE CONTROL(AEA POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,HEMOGLOBIN A1C –DIRECT (HBA1C-DIR) STANDARDS(HEMOGLOBIN A1C –DIRECT (HBA1C-DIR) STANDARDS) -BEING USED TO STANDARDIZE THE HBA1C KIT,P ANCA POSITIVE CONTROL(P ANCA POSITIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,NEGATIVE CONTROL(NEGATIVE CONTROL)-CONTROL TO VERIFY THE PERFORMANCE OF THE MEASUREMENT PROCEDURE,ANTI-CITRULLINATED PROTEIN ANTIBODIES (ACPA)(ANTI-CITRULLINATED PROTEIN ANTIBODIES (ACPA))-REAGENTS FOR MEASUREMENT OF CITRULLINATED PROTEIN CONCENTRATION IN SERUM

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397	IMP/IVD/2019/000429	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PBS POWDER(IMMUNO CONCEPTS (IC))-PHOSPHATE BUFFERED SALINE (PBS) USED FOR RINSING/WASHING SLIDES AND MICROWELL STRIPS IN IMMUNOASSAY TEST SYSTEM SUCH AS ANA - RO TEST SYSTEM, HISTOFLUOR® RODENT LKS FLUORESCENT ANTIBODY TEST SYSTEM (HISTOFLUOR®)-THIS IS AN INDIRECT FLUORESCENT ANTIBODY TEST FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETECTION OF IGG AUTOANTIBODIES IN HUMAN SERUM BY MANUAL FLUORESCENT MICROSCOPY OR WITH THE IMAGE NAVIGATOR® FLUORESCENCE SEMI-AUTOMATED MICROSCOPE. THIS TEST SYSTEM IS TO BE USED AS AN AID IN THE DETECTION OF ANTI-MITOCHONDRIAL (AMA), ANTI-PARIETAL CELL (APCA), AND ANTI-SMOOTH MUSCLE (ASMA) AUTOANTIBODIES ASSOCIATED WITH TYPE 1 AUTOIMMUNE HEPATITIS, PRIMARY BILIARY CHOLANGITIS, AND PERNICIOUS ANEMIA/AUTOIMMUNE GASTRITIS IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. A TRAINED OPERATOR MUST CONFIRM RESULTS GENERATED WITH THE IMAGE NAVIGATOR® SEMI-AUTOMATED DEVICE AND SOFTWARE.,ANCA FORMALIN FLUORESCENT TEST SYSTEM(IMMUNO CONCEPTS OR IC)-INDIRECT FLUORESCENT ANTIBODY TEST FOR THE SEMI QUANTITATIVE DETECTION OF ANTINEUTROPHIL CYTOPLASMIC AUTO ANTIBODIES (ANCA) IN HUMAN SERUM ON FORMALIN FIXED SLIDE,ANCA ETHANOL FLUORESCENT TEST SYSTEM(IMMUNO CONCEPTS OR IC)-INDIRECT FLUORESCENT ANTIBODY TEST FOR THE SEMI QUANTITATIVE DETECTION OF ANTINEUTROPHIL CYTOPLASMIC AUTO ANTIBODIES (ANCA) IN HUMAN SERUM ON ETHANOL FIXED SLIDE,ANA SAMPLE DILUENT(IMMUNO CONCEPTS OR IC)-BUFFER USED AS A DILUENT FOR PATIENT SAMPLES/SERUM IN ANA - RO TEST SYSTEM,ANA-RO IGG FLUORESCENT TEST SYSTEM(HEP 2000 (R))-INDIRECT FLUORESCENT ANTIBODY TEST FOR THE SEMI - QUANTITATIVE DETECTION OF IGG ANTINUCLEAR ANTIBODY (ANA) IN HUMAN SERUM,NDNA FLUORESCENT TEST SYSTEM (IMMUNOCONCEPTS OR IC)-INDIRECT FLUORESCENT ANTIBODY TEST FOR THE SEMI QUANTITATIVE DETECTION OF ANTI- NDNA ANTIBODY IN HUMAN SERUM

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398	IMP/IVD/2019/000431	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ICHEM 10SG URINE CHEMISTRY STRIPS (ICHEM 10SG URINE CHEMISTRY STRIPS)-THE ICHEM100 URINE CHEMISTRY ANALYZER (ICHEM100) IS A SEMI-AUTOMATED BENCHTOP URINE CHEMISTRY ANALYZER INTENDED FOR THE IN VITRO MEASUREMENT OF THE FOLLOWING ANALYTES: GLUCOSE, PROTEIN, BILIRUBIN, UROBILINOGEN, PH, SPECIFIC GRAVITY, BLOOD, KETONES, NITRITE, LEUKOCYTE ESTERASE, ASCORBIC ACID, AND COLOR. THE ICHEM100 IS INTENDED FOR USE ONLY WITH ICHEM 10 SG URINE CHEMISTRY STRIPS AND IS INTENDED FOR USE EXCLUSIVELY BY HEALTHCARE PROFESSIONALS.,ICHEM VELOCITY URINE CHEMISTRY STRIPS (ICHEM VELOCITY URINE CHEMISTRY STRIPS)-THE ICHEMVELOCITY STRIPS ARE MANUFACTURED FOR USE ONLY WITH THE ICHEMVELOCITY URINE CHEMISTRY SYSTEM AND ARE INTENDED FOR USE EXCLUSIVELY BY HEALTHCARE PROFESSIONALS. THESE QUALITATIVE OR SEMI-QUANTITATIVE MEASUREMENTS CAN BE USED ALONG WITH OTHER DIAGNOSTIC TOOLS IN THE EVALUATION OF RENAL, URINARY, AND METABOLIC DISORDERS.,VCHEM 10SG URINE CHEMISTRY STRIPS (VCHEM 10SG URINE CHEMISTRY STRIPS)-VCHEM URINE CHEMISTRY STRIPS ARE INTENDED FOR IN VITRO MEASUREMENT OF THE FOLLOWING ANALYTES IN URINE: GLUCOSE, PROTEIN, BILIRUBIN, UROBILINOGEN, PH, SPECIFIC GRAVITY, BLOOD, KETONES, NITRITE, LEUKOCYTES, AND ASCORBIC ACID. VCHEM URINE CHEMISTRY STRIPS ARE INTENDED FOR VISUAL USE ONLY.

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399	IMP/IVD/2019/000432	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RAPIDLAB® 348EX CA++ STARTER KIT(RAPIDLAB® 348EX CA++ STARTER KIT)-TO SUPPORT THE INITIALIZATION OF RAPIDLAB 348EX BLOOD GAS ANALYZER., ADVIA CENTAUR WASH 1(ADVIA CENTAUR WASH 1)-ADVIA CENTAUR WASH 1 IS A SYSTEM FLUID USED FOR WASHING CUVETTES BETWEEN REACTION STEPS. FOR SOME ASSAYS, IT IS USED FOR PARTICLE RESUSPENSION.,RAPIDLAB® 1200 ELECTRODE FILL SOLUTION NA+, K+, CA++, CL-(RAPIDLAB® 1200 ELECTRODE FILL SOLUTION NA+, K+, CA++, CL-)-INTENDED FOR MAINTENANCE OF THE NA/K/K/CA/CL ELECTRODES/ SENSORS OF RAPIDLAB 1200 SYSTEM SERIES, REFERENCE ELECTRODE FILL SOLUTION(REFERENCE ELECTRODE FILL SOLUTION)-THE REFERENCE ELECTRODE FILL SOLUTION IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR USE WITH RAPIDLAB® SERIES ANALYZERS. ,CONDITIONER(CONDITIONER)-INTENDED TO CLEAN AND CONDITION THE PH AND SODIUM SENSORS OF THE PH/BLOOD GAS/ELECTROLYTE ANALYZER,RAPIDLAB® 1200 SYSTEMS REAGENT CARTRIDGE(RAPIDLAB® 1200 SYSTEMS REAGENT CARTRIDGE)-FOR THE CALIBRATION OF RAPIDLAB1200 SYSTEM SERIES,NA / K / CL FILL SOLUTION(NA / K / CL FILL SOLUTION)-INTENDED FOR MAINTENANCE OF THE NA/K/CA/CL ELECTRODES/SENSORS OF THE RAPIDLAB 1200 SYSTEM SERIES, RAPID LAB PH SENSOR FILL SOLUTION(RAPID LAB PH SENSOR FILL SOLUTION)-INTENDED FOR MAINTENANCE OF THE PH ELECTRODES/SENSORS OF THE RAPIDLAB1200 SYSTEM SERIES,AQC CARTRIDGE KIT(AQC CARTRIDGE KIT)-FOR QUALITY CONTROL OF PH/BLOOD GAS/ELECTROLYTE ANALYZERS,RAPIDLAB® 1200 SYSTEMS WASH CARTRIDGE(RAPIDLAB® 1200 SYSTEMS WASH CARTRIDGE)-INTENDED TO WASH THE PROBES AND SAMPLE PATHS OF THE PH/BLOOD GAS/ELECTROLYTE ANALYZER,RAPIDLAB® 1200 PH ELECTRODE FILL SOLUTION(RAPIDLAB® 1200 PH ELECTRODE FILL SOLUTION)-INTENDED FOR MAINTENANCE OF THE PH ELECTRODES/SENSORS OF THE RAPIDLAB1200 SYSTEM SERIES, READY SENSOR GOLD REFERENCE SENSOR INNER (READY SENSOR GOLD REFERENCE SENSOR INNER)-KCL SOLUTION FOR USE IN CONTACT WITH POTASSIUM ELECTRODE.,RAPIDLAB® 1200 SERIES CO-OX SAMPLE CHAMBER(RAPIDLAB® 1200 SERIES CO-OX SAMPLE CHAMBER)-FOR IN VITRO DIAGNOSTIC USE IN THE MEASUREMENT OF THE TOTAL HEMOGLOBIN AND HEMOGLOBIN FRACTIONS IN THE HUMAN SAMPLES USING RAPID LAB SYSTEMS,REFERENCE SENSOR MOLAR KCL SATURATED WITH AGCL(REFERENCE SENSOR MOLAR KCL SATURATED WITH AGCL)-INTENDED TO MAINTAIN A SATURATED SOLUTION OF KCL IN THE REFERENCE SAMPLE SOLUTION CHAMBER

	BLOOD GAS ANALYZER,RAPIDPOINT®500 MEASUREMENT CARTRIDGE(RAPIDPOINT®500 MEASUREMENT CARTRIDGE)-THE RAPIDPOINT 500 MEASUREMENT CARTRIDGES ARE INTENDED FOR USE IN IN VITRO-DIAGNOSTICS AND ARE INTENDED FOR DETERMINATION IN PLEURAL FLUID SAMPLES FOR PH PARAMETER, 6.8/7.3 BUFFER PACK(6.8/7.3 BUFFER PACK)-PROVIDES THE CALIBRATION POINT FOR PH, ELECTROLYTE AND HEMATOCRIT CALIBRATIONS,READY SENSOR™ GOLD REFERENCE SENSOR REFILL (READY SENSOR™ GOLD REFERENCE SENSOR REFILL)-INTENDED TO MAINTAIN CONTACT WITH REFERENCE ELECTRODE TO MAINTAIN CONSTANT VOLTAGE,RAPID POINT 400/405/500 WASH/WASTE CARTRIDGE KIT(RAPID POINT 400/405/500 WASH/WASTE CARTRIDGE KIT)-INTENDED TO CLEAN THE SAMPLE PATH AND WASTE FLUID WITHOUT CONTACTING SYSTEM COMPONENTS FOR RAPIDPOINT 400/500 SERIES SYSTEMS.,RAPID LAB WASH AND CD PACK(RAPID LAB WASH AND CD PACK)-INTENDED TO WASH THE PROBES AND SAMPLE PATHS OF THE PH/BLOOD GAS/ELECTROLYTE ANALYZER,RAPIDPOINT® 405 MEASUREMENT CARTRIDGE (RAPIDPOINT® 405 MEASUREMENT CARTRIDGE)-THE RAPIDPOINT 405 MEASUREMENT CARTRIDGES ARE INTENDED FOR USE IN IN VITRO-DIAGNOSTICS AND ARE INTENDED FOR DETERMINATION IN PLEURAL FLUID SAMPLES FOR THE PH PARAMETER: PO2, PCO2, PH, SODIUM, POTASSIUM, IONIZED CALCIUM, CHLORIDE, GLUCOSE & TOTAL HEMOGLOBIN AND FRACTIONS: FO2HB, FCOHB, FHHB., HEMATOCRIT (HCT) SLOPE AMPOULES(HEMATOCRIT (HCT) SLOPE AMPOULES)-INTENDED TO PROVIDE THE SLOPE POINT FOR HCT CALIBRATION DURING THE IN VITRO DIAGNOSTIC PROCEDURES ON PH/BLOOD GAS/ELECTROLYTE ANALYZERS,RAPIDLAB® 348EX CL-STARTER KIT(RAPIDLAB® 348EX CL- STARTER KIT)-INTENDED TO SUPPORT THE INITIALIZATION OF RAPIDLAB 348EX BLOOD GAS ANALYZER,RAPID LAB® 1200 DEPROTEINIZER PACK 10 UDC(RAPID LAB® 1200 DEPROTEINIZER PACK 10 UDC)-INTENDED TO REMOVE THE PROTEIN BUILDUPS FROM THE SAMPLE PATHS OF THE PH/BLOOD GAS/ELECTROLYTE ANALYZERS AS PART OF PREVENTIVE MAINTENANCE

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400	IMP/IVD/2019/000434	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACET2 CALIBRATOR (ACET2 CALIBRATOR)-ACET2 CALIBRATOR IS FOR USE IN THE CALIBRATION OF THE ACETAMINOPHEN GEN 2 ROCHE ASSAY., CYCLOSPORINE CALIBRATORS(CYCLOSPORINE CALIBRATORS)-CYCLOSPORINE CALIBRATORS IS FOR USE IN THE CALIBRATION OF QUANTITATIVE DETERMINATION OF CYCLOSPORINE USING THE COBAS INTEGRA CYCLOSPORINE REAGENT ON COBAS INTEGRA ANALYZERS.,CYCLOSPORINE SAMPLE PRETREATMENT REAGENT (CYCLOSPORINE SAMPLE PRETREATMENT REAGENT)-THE COBAS INTEGRA CYCLOSPORINE SAMPLE PRETREATMENT REAGENT IS AN IN VITRO DIAGNOSTIC REAGENT INTENDED FOR USE WITH THE COBAS INTEGRA CYCLOSPORINE ASSAY ON THE COBAS INTEGRA ANALYZERS AS AN ALTERNATIVE TO METHANOLIC EXTRACTION OF SAMPLES.,CYCLOSPORINE CALIBRATOR 0 NG/ML(CYCLOSPORINE CALIBRATOR 0 NG/ML)-CYCLOSPORINE CALIBRATOR 0 NG/ML IS FOR USE IN THE CALIBRATION OF THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE USING THE COBAS INTEGRA CYCLOSPORINE REAGENT ON COBAS INTEGRA ANALYZERS.

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401	IMP/IVD/2019/000435	1.License Holder Name: IRIS HEALTHCARE TECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIATROHYPOCLEAN CC (DIATRON)-USED FOR HARD CLEANING PROCEDURE TO REMOVE PROTEIN AND LIPIDS FROM SAMPLE TUBES, CHAMBERS AND APERTURES.,DIATRODIFF-5P(DIATRON)-USED FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC) AND LEUKOCYTE 5-PART DIFFERENTIATION (LYM, MONO, NEU, EO, BA) MEASUREMENT.,DIATRO CLEANER(DIATRON)-USED TO CLEAN THE TUBING, COUNTING CHAMBERS AND APERTURES.,DIATRODIL-DIFF(DIATRON)-USED TO DILUTE WHOLE BLOOD SAMPLES AND RINSE THE FLUIDI SYSTEM BETWEEN MEASURING CYCLES.,DIATRO LYSE-DIFF(DIATRON)-USED FOR CREATING THE HEMOLYSATES FOR 3-PART WBC DIFFERENTIAL, TOTAL WBC COUNT AND HGB DETERMINATION.,DIATRO DIL-5P (DIATRON)-USED TO DILUTE WHOLE BLOOD SAMPLES AND RINSE THE FLUIDI SYSTEM BETWEEN MEASURING CYCLES., DIATROHYPOCLEAN(DIATRON)-OPTIONAL REAGENT. USED FOR SERVICE MAINTENANCE FOR REMOVING DEBRIS FROM TUBING AND CHAMBERS.,DIATRO LYSE 5P(DIATRON)-USED AS LYSING AGENT FOR STROMATOLYSIS OF ERYTHROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE 5-PART DIFFERENTIATION (LYM, MONO, NEU, EO, BA) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD., DIATROCAL HEMATOLOGY CALIBRATOR(DIATRON)-USED FOR PERFORMING CALIBRATION OF ICOUNT3 CP.
402	IMP/IVD/2019/000436	1.License Holder Name: ASCENSIA DIABETES CARE INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(CONTOUR)-CONTOUR TEST STRIPS ARE INTENDED FOR SELF-TESTING BY PEOPLE WITH DIABETES AND BY HEALTH CARE PROFESSIONALS TO MONITOR GLUCOSE CONCENTRATIONS IN WHOLE BLOOD.
403	IMP/IVD/2019/000437	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROSCAN PROMPT INOCULATION SYSTEM-D(MICROSCAN PROMPT INOCULATION SYSTEM-D)-THE PROMPT INOCULATION SYSTEMS-D IS USED TO STANDARDIZE INOCULA FOR MICRO DILUTION ANTIMICROBIAL SUSCEPTIBILITY TESTS.

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404	IMP/IVD/2019/000438	1.License Holder Name: FUJIFILM INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FUJI DRI CHEM SLIDE TBIL-P III(FUJI DRI CHEM SLIDE TBIL-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF TOTAL BILIRUBIN CONCENTRATION IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE MG-P III(FUJI DRI CHEM SLIDE MG-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF MAGNESIUM CONCENTRATION IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE LIP-P(FUJI DRI CHEM SLIDE LIP-P)-USE FOR THE QUANTITATIVE MEASURMENT OF PANCREATIC LIPASE (LIP) IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE GGT-P III(FUJI DRI CHEM SLIDE GGT-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF Y-GLUTAMYLTRANFERASE ACTIVITY IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE DBIL-P II(FUJI DRI CHEM SLIDE DBIL-P II)-USE FOR THE QUANTITATIVE MEASURMENT OF DIRECT BILIRUBIN CONCENTRATION IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE IP-P (FUJI DRI CHEM SLIDE IP-P)-USE FOR THE QUANTITATIVE MEASURMENT OF INORGANIC PHOSPHORUS CONCENTRATION IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE GOT/AST-P III(FUJI DRI CHEM SLIDE GOT/AST-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF GLUTAMIC OXALACETIC TRANSAMINASE (ASPARTATE AMINOTRANSFERASE) ACTIVITY IN PLASMA OR SERUM, FUJI DRI CHEM SLIDE NA-K-CL(FUJI DRI CHEM SLIDE NA-K-CL)-USE FOR THE QUANTITATIVE MEASURMENT OF SODIUM, POTASSIUM AND CHLORIDE IN CONCENTRATION IN WHOLE BLOOD, PLASMA OR SERUM,FUJI DRI CHEM SLIDE CPK-P III(FUJI DRI CHEM SLIDE CPK-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF CREATINE PHOSPHOKINASE ACTIVITY IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE CA-P III(FUJI DRI CHEM SLIDE CA-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF CALCIUM CONCENTRATION IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE CRE-P III(FUJI DRI CHEM SLIDE CRE-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF CREATINE CONCENTRATION IN PLASMA OR SERUM,FUJI DRI CHEM REFERENCE FLUID RE(FUJI DRI CHEM REFERENCE FLUID RE)-FOR IN-VITRO BLOOD TESTING PURPOSES,FUJI DRI CHEM SLIDE TCO2-P(FUJI DRI CHEM SLIDE TCO2-P)-USE FOR THE QUANTITATIVE MEASURMENT OF TOTAL CARBON DIOXIDE (CO2) CONCENTRATION IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE LAP-P(FUJI DRI CHEM SLIDE LAP-P)-USE FOR THE QUANTITATIVE MEASURMENT OF LEUCINE AMINOPEPTIDASE ACTIVITY IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE BUN-P III(FUJI DRI CHEM SLIDE BUN-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF UREA NITROGEN CONCENTRATION IN PLASMA OR SERUM,FUJI DRI CHEM CONTROL QP-H(FUJI DRI CHEM CONTROL QP-H)-FOR IN-VITRO BLOOD TESTING PURPOSES,FUJI DRI

	CHEM SLIDE CHE-P(FUJI DRI CHEM SLIDE CHE-P)-USE FOR THE QUANTITATIVE MEASURMENT OF CHLOINESTERASE ACTIVITY IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE CKMB-P(FUJI DRI CHEM SLIDE CKMB-P)-USE FOR THE QUANTITATIVE MEASURMENT OF CREATINE PHOSPHOKINASE ISOENZYME MB ACTIVITY IN PLASMA OR SERUM,FUJI DRI CHEM DILUENT DL (CRP)(FUJI DRI CHEM DILUENT DL (CRP))-FOR IN-VITRO BLOOD TESTING PURPOSES,FUJI DRI CHEM CONTROL QP-L(FUJI DRI CHEM CONTROL QP-L)-FOR IN-VITRO BLOOD TESTING PURPOSES,FUJI DRI CHEM SLIDE AMYL-P III(FUJI DRI CHEM SLIDE AMYL-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF AMYLASE ACTIVITY IN PLASMA OR SERUM,FUJI DRI CHEM CONTROL QN(FUJI DRI CHEM CONTROL QN)-FOR IN-VITRO BLOOD TESTING PURPOSES,FUJI DRI CHEM SLIDE GPT/ALT-P III(FUJI DRI CHEM SLIDE GPT/ALT-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF GLUTAMIC PYRUVIC TRANSAMINASE (ALANINE AMINOTRANSFERASE) ACTIVITY IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE HDL-C-P III D(FUJI DRI CHEM SLIDE HDL-C-P III D)-USE FOR THE QUANTITATIVE MEASURMENT OF HIGH DENSITY LIPOPROTIN CHOLESTROL IN PLASMA OR SERUM,FUJI DRI CHEM ELECTROLYTE CONTROL QE(FUJI DRI CHEM ELECTROLYTE CONTROL QE)-FOR IN-VITRO BLOOD TESTING PURPOSES,FUJI DRI CHEM SLIDE GLU-P III(FUJI DRI CHEM SLIDE GLU-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF GLUCOSE CONCENTRATION IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE TP-P III(FUJI DRI CHEM SLIDE TP-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF TOTAL PROTEIN CONCENTRATION IN PLASMA OR SERUM,FUJI DRI CHEM CALIBRATOR CP (CRP)(FUJI DRI CHEM CALIBRATOR CP (CRP))-TO CALIBRATE C-REACTIVE PROTEIN TEST ,FUJI DRI CHEM SLIDE NH3-P II(FUJI DRI CHEM SLIDE NH3-P II)-USE FOR THE QUANTITATIVE MEASURMENT OF AMMONIA CONCENTRATION IN PLASMA OR SERUM, FUJI DRI CHEM SLIDE LDH-P III(FUJI DRI CHEM SLIDE LDH-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF LACTATE DEHYDROGENASE ACTIVITY IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE ALB-P(FUJI DRI CHEM SLIDE ALB-P)-USE FOR THE QUANTITATIVE MEASUREMENT OF ALBUMIN CONCENTRATION IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE ALP-P III(FUJI DRI CHEM SLIDE ALP-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF ALKALINE PHOSPHATISE IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE CRP-S III(FUJI DRI CHEM SLIDE CRP-S III)-USE FOR THE QUANTITATIVE MEASURMENT OF HUMAN CRP (C-REACTIVE PROTEIN) CONCENTRATION IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE TCHO-P III(FUJI DRI CHEM SLIDE TCHO-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF TOTAL CHOLESTEROL CONCENTRATION IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE TG-P

		III(FUJI DRI CHEM SLIDE TG-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF TRIGLYCERIDE CHOLESTEROL CONCENTRATION IN PLASMA OR SERUM,FUJI DRI CHEM SLIDE UA-P III(FUJI DRI CHEM SLIDE UA-P III)-USE FOR THE QUANTITATIVE MEASURMENT OF URIC ACID CONCENTRATION IN PLASMA OR SERUM
405	IMP/IVD/2019/000438	1.License Holder Name: FUJIFILM INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FUJI DRI-CHEM SLIDE V-LIP-P(FUJI DRI-CHEM SLIDE V-LIP-P)-QUANTITATIVE MEASUREMENT OF PANCREATIC LIPASE (LIP) IN CANINE PLASMA OR SERUM. FOR VETERINARY USE ONLY. ,FUJI DRI-CHEM IMMUNO AU CARTRIDGE V-COR(FUJI DRI-CHEM IMMUNO AU CARTRIDGE V-COR)-QUANTITATIVE MEASUREMENT OF CORTISOL (COR) CONCENTRATION IN CANINE PLASMA OR SERUM. ,FUJI DRI-CHEM SLIDE V-AMY-P(FUJI DRI-CHEM SLIDE V-AMY-P)-QUANTITATIVE MEASUREMENT OF AMYLASE ACTIVITY IN PLASMA OR SERUM. FOR VETERINARY USE ONLY. ,FUJI DRI-CHEM IMMUNO AU CARTRIDGE VC-TSH(FUJI DRI-CHEM IMMUNO AU CARTRIDGE VC-TSH)-"QUANTITATIVE MEASUREMENT OF TSH CONCENTRATION IN CANINE PLASMA OR SERUM. " ,FUJI DRI-CHEM SLIDE VC-CRP-P(FUJI DRI-CHEM SLIDE VC-CRP-P)-QUANTITATIVE MEASUREMENT OF CANINE CRP(C-REACTIVE-PROTEIN) CONCENTRATION IN PLASMA OR SERUM. FOR VETERINARY USE ONLY. ,FUJI DRI-CHEM IMMUNO AU CARTRIDGE V-BA(FUJI DRI-CHEM IMMUNO AU CARTRIDGE V-BA)-"QUANTITATIVE MEASUREMENT OF BILE ACIDS (BA) CONCENTRATION IN PLASMA OR SERUM FROM CANINE AND FELINE. " ,FUJI DRI-CHEM IMMUNO AU CARTRIDGE V-T4 (FUJI DRI-CHEM IMMUNO AU CARTRIDGE V-T4)-QUANTITATIVE MEASUREMENT OF THYROXINE (T4) CONCENTRATION IN PLASMA OR SERUM FROM CANINE AND FELINE.

406	IMP/IVD/2019/000439	1.License Holder Name: GASTROLAB INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QUANTON CAL(QUANTON CAL)-QUANTONCAL® IS AN IN-VITRO DIAGNOSTIC DEVICE (IVD) CONSISTING OF AN IMMUNOLOGICAL RAPID TEST AND A SMARTPHONE APP. THE QUANTONCAL® TEST SYSTEM IS INTENDED FOR SELF-TESTING BY PATIENTS WITH INFLAMMATORY BOWEL DISEASES (IBD, E. G. CROHN'S DISEASE OR ULCERATIVE COLITIS), WHO ARE UNDER THE CARE OF A HEALTHCARE PRACTITIONER. QUANTONCAL® IS FOR THE QUANTITATIVE DETERMINATION OF THE INFLAMMATORY MARKER CALPROTECTIN IN FAECES AND AIDS THE HEALTHCARE PRACTITIONER IN ASSESSING THE INFLAMMATORY ACTIVITY IN THE INTESTINE OF IBD PATIENTS.
407	IMP/IVD/2019/000440	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HOMOCYSTEINE CONTROL KIT (HOMOCYSTEINE CONTROL KIT)-THE HOMOCYSTEINE CONTROL KIT IS INTENDED FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHODS AS SPECIFIED IN THE VALUE SHEETS.,HOMOCYSTEINE CALIBRATOR KIT (HOMOCYSTEINE CALIBRATOR KIT)-THE HOMOCYSTEINE CALIBRATOR KIT IS INTENDED FOR USE IN THE CALIBRATION OF QUANTITATIVE ROCHE METHODS ON ROCHE CLINICAL CHEMISTRY ANALYZERS AS SPECIFIED IN THE VALUE SHEETS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

408	IMP/IVD/2019/000441	1.License Holder Name: ANAND BROTHERS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PROLACTIN IRMA KIT (PROLACTIN IRMA KIT)-IMMUNORADIOMETRIC ASSAY FOR THE IN VITRO DETERMINATION OF PROLACTIN IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,DHEA RIA KIT(DHEA RIA KIT)-RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF DEHYDROEPIANDROSTERONE IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE.,CORTISOL RIA KIT(CORTISOL RIA KIT)-RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF CORTISOL IN HUMAN SERUM, PLASMA AND URINE. FOR IN VITRO DIAGNOSTIC USE.,ANGIOTENSIN I (PLASMA RENIN ACTIVITY) RIA KIT (ANGIOTENSIN I (PLASMA RENIN ACTIVITY) RIA KIT)-RADIOIMMUNOASSAY OF ANGIOTENSIN I FOR THE IN VITRO DETERMINATION OF PLASMA RENIN ACTIVITY (PRA) IN HUMAN PLASMA. FOR IN VITRO DIAGNOSTIC USE.,IGF-1 IRMA KIT(IGF-1 IRMA KIT)-IMMUNORADIOMETRIC ASSAY FOR THE IN VITRO DETERMINATION OF INSULIN–LIKE GROWTH FACTOR I IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,ACTIVE FREE TESTOSTERONE RIA KIT(ACTIVE FREE TESTOSTERONE RIA KIT)-RADIOIMMUNOASSAY FOR THE QUANTITATIVE MEASUREMENT OF FREE TESTOSTERONE IN HUMAN SERUM. THIS ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE.,TOTAL T4 RIA KIT(TOTAL T4 RIA KIT) -RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF FREE TOTAL THYROXINE (TT4) IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,ACTIVE(R) IGFBP-3 IRMA KIT(ACTIVE(R) IGFBP-3 IRMA KIT)-IMMUNORADIOMETRIC KIT FOR THE QUANTITATIVE MEASUREMENT OF IGFBP-3 IN HUMAN SERUM. THIS ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE.,17 -HYDROXYPROGESTERONE RIA KIT(17 -HYDROXYPROGESTERONE RIA KIT)-RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF 17-HYDROXYPROGESTERONE IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,C-PEPTIDE IRMA(C-PEPTIDE IRMA)-IMMUNORADIOMETRIC ASSAY FOR THE IN VITRO DETERMINATION OF C-PEPTIDE IN HUMAN SERUM, PLASMA AND URINE. FOR IN VITRO DIAGNOSTIC USE.,DIHYDROTESTOSTERONE (ACTIVE (R) DHT) (DIHYDROTESTOSTERONE (ACTIVE (R) DHT))-RADIOIMMUNOASSAY FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF DIHYDROTESTOSTERONE (DHT) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE.,SHBG IRMA KIT(SHBG IRMA KIT)-IMMUNORADIOMETRIC ASSAY FOR THE IN VITRO DETERMINATION OF SEX HORMONE BINDING GLOBULIN IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE.,LH IRMA KIT(LH IRMA KIT)-IMMUNORADIOMETRIC ASSAY FOR THE IN VITRO DETERMINATION OF LUTEINIZING

	HORMONE IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,ESTRADIOL RIA KIT(ESTRADIOL RIA KIT)-RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF ESTRADIOL IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE. ,GH IRMA KIT(GH IRMA KIT)-IMMUNORADIOMETRIC ASSAY FOR THE IN VITRO DETERMINATION OF GROWTH HORMONE IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,25-OH VITAMIN D TOTAL RIA KIT(25-OH VITAMIN D TOTAL RIA KIT)-RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF 25-HYDROXYVITAMIN D3 AND D2 (25-OH-D3 AND 25-OH-D2) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE.,TESTOSTERONE DIRECT RIA KIT(TESTOSTERONE DIRECT RIA KIT)-RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF TOTAL TESTOSTERONE IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,ANTI-HTG IRMA KIT(ANTI-HTG IRMA KIT)-IMMUNORADIOMETRIC ASSAY FOR THE IN VITRO DETERMINATION OF ANTI-HTG IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,FSH IRMA KIT(FSH IRMA KIT)-IMMUNORADIOMETRIC ASSAY FOR THE IN VITRO DETERMINATION OF FSH IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE,PTH IRMA KIT(PTH IRMA KIT)-IMMUNORADIOMETRIC ASSAY FOR THE IN VITRO DETERMINATION OF PARATHYROID HORMONE IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,UNCONJUGATED ESTRIOL(UNCONJUGATED ESTRIOL)-RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF UNCONJUGATED ESTRIOL IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE.,TOTAL T3 RIA KIT(TOTAL T3 RIA KIT)-RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF TOTAL TRIIODOTHYRONINE (TT3) IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,FT3 RIA KIT(FT3 RIA KIT)-RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF FREE TRIIODOTHYRONINE IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,ESTRONE RIA KIT(ESTRONE RIA KIT)-RADIOIMMUNOASSAY FOR THE QUANTITATIVE MEASUREMENT OF ESTRONE IN HUMAN SERUM OR PLASMA. THIS ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE.,PROGESTERONE RIA KIT (PROGESTERONE RIA KIT)-RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF PROGESTERONE IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,ANDROSTENEDIONE RIA (ANDROSTENEDIONE RIA)-RADIOIMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF ANDROSTENEDIONE IN HUMAN SERUM OR PLASMA. THIS ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE.,TSH IRMA KIT(TSH IRMA KIT)-IMMUNORADIOMETRIC ASSAY FOR THE IN VITRO DETERMINATION OF THYROID-STIMULATING HORMONE IN HUMAN SERUM AND PLASMA.

	FOR IN VITRO DIAGNOSTIC USE.,DHEA SULFATE KIT(DHEA SULFATE KIT)-RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,ALDOSTERONE RIA KIT (ALDOSTERONE RIA KIT)-RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF ALDOSTERONE IN HUMAN SERUM, PLASMA AND URINE. FOR IN VITRO DIAGNOSTIC USE.,ANTI - TPO RIA KIT(ANTI - TPO RIA KIT)-RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF ANTIBODIES AGAINST THYROID PEROXIDASE (ANTI-TPO) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE.,FERRITIN IRMA KIT (FERRITIN IRMA KIT)-IMMUNORADIOMETRIC ASSAY FOR THE IN VITRO DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,ALBUMIN RIA KIT(ALBUMIN RIA KIT)-RADIOIMMUNOASSAY FOR IN VITRO DETERMINATION OF ALBUMIN IN HUMAN URINE. FOR IN VITRO DIAGNOSTIC USE.,INSULIN IRMA KIT (INSULIN IRMA KIT)-IMMUNORADIOMETRIC ASSAY FOR THE IN VITRO DETERMINATION OF INSULIN IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,FT4 RIA KIT(FT4 RIA KIT)-RADIOIMMUNOASSAY FOR THE IN VITRO DETERMINATION OF FREE THYROXINE IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE.,ACTH IRMA KIT(ACTH IRMA KIT)-IMMUNORADIOMETRIC ASSAY FOR THE IN VITRO DETERMINATION OF ACTH IN HUMAN PLASMA. FOR IN VITRO DIAGNOSTIC USE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

409	IMP/IVD/2019/000444	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VYSIS LSI 21 SPECTRUMORANGE PROBE(VYSIS LSI 21 SPECTRUMORANGE PROBE) -VYSIS LSI 21 SPECTRUMORANGE DNA PROBE HYBRIDIZES TO THE BAND REGION 21Q22.13 - Q22.2 (LOCI D21S259, D21S341 AND D21S342) OF HUMAN CHROMOSOME 21. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,VYSIS PARAFFIN PRETREATMENT IV & POST-HYBRIDIZATION WASH BUFFER KIT(VYSIS PARAFFIN PRETREATMENT IV & POST-HYBRIDIZATION WASH BUFFER KIT)-TO PREPARE PARAFFIN EMBEDDED LUNG CANCER TISSUE SECTIONS FIXED ON POSITIVELY CHARGED SLIDES FOR USE IN FLUORESCENCE IN SITU HYBRIDIZATION (FISH) WITH VYSIS DNA FISH PROBES.,VYSIS LSI D13S319 (13Q14.3) SPECTRUMORANGE PROBE(VYSIS LSI D13S319 (13Q14.3) SPECTRUMORANGE PROBE)-VYSIS LSI D13S319 (13Q14.3) SPECTRUMORANGE DNA PROBE HYBRIDIZES TO THE BAND 13Q14.3, LOCUS D13S319 OF HUMAN CHROMOSOME 13. THE HYBRIDIZED PROBE FLUORESCES WITH BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES. IN INTERPHASE NUCLEI OF NORMAL CELLS, THE PROBE GENERALLY APPEARS AS TWO DISTINCT SIGNALS. OCCASIONALLY, IT MAY APPEAR AS THREE OR FOUR SIGNALS DEPENDING UPON THE CONDENSATION OF THE DNA AND THE RELATIVE DISTANCES BETWEEN CHROMATIDS. THE SIGNALS MAY ALSO APPEAR DIFFUSE OR SPLIT. IN A NORMAL METAPHASE, LSI D13S319 MAY APPEAR AS ONE OR TWO SIGNALS ON EACH CHROMOSOME 13.,VYSIS CLL FISH PROBE KIT(VYSIS CLL FISH PROBE KIT)-THE VYSIS CLL FISH PROBE KIT IS A TEST TO DETECT DELETION OF THE LSI TP53, LSI ATM, AND LSI D13S319 PROBE TARGETS AND GAIN OF THE D12Z3 SEQUENCE PROBE TARGET VIA FLUORESCENCE IN SITU HYBRIDIZATION (FISH) IN PERIPHERAL BLOOD SPECIMENS FROM PATIENTS WITH B-CELL CHRONIC LYMPHOCYTIC LEUKEMIA (CLL).,VYSIS LSI BCR/ABL ES DUAL COLOR SINGLE FUSION PROBES(VYSIS LSI BCR/ABL ES DUAL COLOR SINGLE FUSION PROBES)-VYSIS LSI BCR/ABL ES DUAL COLOR SINGLE FUSION PROBES HYBRIDIZE TO CHROMOSOME 22Q11.2 (BREAKPOINT CLUSTER REGION SPECTRUMGREEN) AND TO CHROMOSOME 9Q34 (ABL ONCOGENE SPECTRUMORANGE). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES, CEP 8 SPECTRUM ORANGE DNA PROBE KIT(CEP 8 SPECTRUM ORANGE DNA PROBE KIT)-THE CEP 8 SPECTRUM ORANGE DNA PROBE KIT IS INTENDED TO DETECT AT RICH ALPHA SATELLITE SEQUENCES IN THE

	CENTROMERE REGION OF CHROMOSOME 8 IN CONJUNCTION WITH ROUTINE DIAGNOSTIC CYTOGENETIC TESTING.,VYSIS LSI EWSR1 (22Q12) DUAL COLOR BREAK APART REARRANGEMENT PROBE (VYSIS LSI EWSR1 (22Q12) DUAL COLOR BREAK APART REARRANGEMENT PROBE)-VYSIS LSI EWSR1 (22Q12) DUAL COLOR BREAK APART REARRANGEMENT PROBE HYBRIDIZES TO THE BAND 22Q12 (SPECTRUMGREEN ON THE 3' (TELOMERIC) SIDE AND SPECTRUMORANGE ON THE 5' (CENTROMERIC) SIDE OF THE EWSR1 GENE BREAKPOINTS). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES,PATHVYSION HER-2 DNA PROBE KIT II(PATHVYSION HER-2 DNA PROBE KIT II)-THE PATHVYSION HER-2 DNA PROBE KIT II (PATHVYSION KIT II) IS DESIGNED TO DETECT AMPLIFICATION OF THE HER-2/NEU GENE VIA FLUORESCENCE IN SITU HYBRIDIZATION (FISH) IN FORMALIN-FIXED, PARAFFIN-EMBEDDED HUMAN BREAST AND GASTRIC CANCER TISSUE SPECIMENS.,VYSIS LSI FOXO1 (TEL) SPECTRUMORANGE PROBE(VYSIS LSI FOXO1 (TEL) SPECTRUMORANGE PROBE)-THE SPECTRUMORANGE VYSIS LSI FOXO1 (TEL) FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE IS TARGETED TO THE 13Q14 REGION ON CHROMOSOME 13. THE PROBE IS APPROXIMATELY 655KB IN SIZE AND IS LOCATED TELOMERIC OF THE FOXO1 GENE. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND METAPHASE CHROMOSOMES., PROBECHEK HER-2/NEUCONTROL SLIDES FOR FISH USING PATHVYSION HER-2DNA PROBE KIT(PROBECHEK HER-2/NEU CONTROL SLIDES FOR FISH USING PATHVYSION HER-2DNA PROBE KIT)-THE PROBECHEK HER-2/NEU CONTROL SLIDES ARE PARAFFIN EMBEDDED, FIXED,CULTURED CELL SPECIMENS APPLIED TO MICROSCOPE SLIDES. THE PROBECHEK HER-2/NEU CONTROL SLIDES ARE DESIGNED FOR USE AS FISH ASSAY CONTROLS FOR APPROPRIATE HYBRIDIZATION CONDITIONS AND AS CONTROLS FOR PROPER PREPARATION OF REAGENTS DURING ROUTINE USE OF THE PATHVYSION HER-2 DNA PROBES ON CLINICAL SPECIMENS.,VYSIS LSI DDIT3 (TEL) SPECTRUMGREEN PROBE(VYSIS LSI DDIT3 (TEL) SPECTRUMGREEN PROBE)-THE VYSIS LSI DDIT3 (TEL) SPECTRUMGREEN FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE IS TARGETED TO THE 12Q13 REGION ON CHROMOSOME 12. THE PROBE IS APPROXIMATELY 663 KB IN SIZE AND IS LOCATED TELOMERIC OF THE DDIT3 GENE. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES,VYSIS CEP X SPECTRUM ORANGE/Y SPECTRUM GREEN DNA PROBE KIT (VYSIS CEP X SPECTRUM ORANGE/Y SPECTRUM GREEN DNA PROBE

	KIT)-THE CEP X SPECTRUM ORANGE / Y SPECTRUM GREEN DNA PROBE KIT IS INTENDED TO DETECT ALPHA SATELLITE SEQUENCES IN THE CENTROMERE REGION OF CHROMOSOME X AND SATELLITE III DNA AT THE YQ12 REGION OF CHROMOSOME Y IN CONJUNCTION WITH ROUTINE DIAGNOSTIC CYTOGENETIC TESTING.,VYSIS WILLIAMS REGION LSI ELN SPECTRUMORANGE/D7S486, D7S522 SPECTRUMGREEN PROBES(VYSIS WILLIAMS REGION LSI ELN SPECTRUMORANGE/D7S486, D7S522 SPECTRUMGREEN PROBES)-VYSIS WILLIAMS REGION LSI ELN SPECTRUMORANGE/D7S486, D7S522 SPECTRUMGREEN PROBES HYBRIDIZE TO THE BAND 7Q11.2, LOCI ELN, LIMK1, AND D7S613 (SPECTRUMORANGE LSI ELASTIN) AND TO THE BAND 7Q31, LOCI D7S486 AND D7S522 OF HUMAN CHROMOSOME 7. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES,PATHVYSION HER-2 DNA PROBE KIT(PATHVYSION HER-2 DNA PROBE KIT)-THE PATHVYSION HER-2 DNA PROBE KIT (PATHVYSION KIT) IS DESIGNED TO DETECT AMPLIFICATION OF THE HER-2/NEU GENE VIA FLUORESCENCE IN SITU HYBRIDIZATION (FISH) IN FORMALIN-FIXED, PARAFFIN-EMBEDDED HUMAN BREAST CANCER TISSUE SPECIMENS.,VYSIS LSI RUNX1/ RUNX1T1 DUAL COLOR DUAL FUSION PROBES(VYSIS LSI RUNX1/ RUNX1T1 DUAL COLOR DUAL FUSION PROBES)-VYSIS LSI RUNX1/RUNX1T1 DUAL COLOR DUAL FUSION PROBES HYBRIDIZE TO CHROMOSOME 8Q21.3 (RUNX1T1 (ETO) SPECTRUMORANGE) AND CHROMOSOME 21Q22 (RUNX1 (AML1) SPECTRUMGREEN) . THIS PROBE IS USEFUL FOR THE DETECTION OF THE TRANSLOCATION T(8; 21)(Q21.3;Q22). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES,ABBOTT REALTIME SARS-COV-2 AMPLIFICATION REAGENT KIT(ABBOTT REALTIME SARS-COV-2 AMPLIFICATION REAGENT KIT)-THE ABBOTT REALTIME SARS-COV-2 ASSAY IS A REAL-TIME (RT) REVERSE TRANSCRIPTASE (RT) POLYMERASE CHAIN REACTION (PCR) TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN NASOPHARYNGEAL (NP) AND OROPHARYNGEAL (OP) SWABS FROM PATIENTS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER.,VYSIS LSI TCF3/ PBX1 DUAL COLOR, DUAL FUSION TRANSLOCATION PROBE(VYSIS LSI TCF3/ PBX1 DUAL COLOR, DUAL FUSION TRANSLOCATION PROBE)-VYSIS LSI TCF3/PBX1 DUAL COLOR, DUAL FUSION TRANSLOCATION PROBE HYBRIDIZES TO CHROMOSOME 19P13.3 (TCF3 - SPECTRUM GREEN) AND CHROMOSOME 1Q23 (PBX1 - SPECTRUM ORANGE). THE PBX1 PROBE IS 635 KB IN SIZE AND COVERS THE ENTIRE PBX1 GENE ON CHROMOSOME 1Q23. THE TCF3 PROBE IS 730 KB IN SIZE AND THE

	GREEN PROBE EXTENDS BEYOND THE TCF3 GENE TO COVER A LARGER REGION ON CHROMOSOME 19P13.3.,ABBOTT REALTIME SARS-COV-2 CONTROL KIT(ABBOTT REALTIME SARS-COV-2 CONTROL KIT)-THE ABBOTT REALTIME SARS-COV-2 CONTROLS ARE USED TO ESTABLISH RUN VALIDITY OF THE ABBOTT REALTIME SARS-COV-2 ASSAY WHEN USED FOR THE DIRECT, QUALITATIVE DETECTION OF SARS-COV-2 RNA FROM NASOPHARYNGEAL AND OROPHARYNGEAL SWABS. ,VYSIS LSI ETV6 SPECTRUMORANGE PROBE(VYSIS LSI ETV6 SPECTRUMORANGE PROBE)-THE SPECTRUMORANGE VYSIS LSI ETV6 FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE IS TARGETED TO THE 12P13 REGION ON CHROMOSOME 12. THE PROBE IS ~1.3 MB IN SIZE AND SPANS THE ENTIRE ETV6 GENE. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,CT/NG AMPLIFICATION REAGENT KIT(ABBOTT REALTIME CT/NG AMPLIFICATION REAGENT KIT)-THE ABBOTT REALTIME CT/NG ASSAY IS AN IN VITRO POLYMERASE CHAIN REACTION (PCR) ASSAY FOR THE DIRECT, QUALITATIVE DETECTION OF THE PLASMID DNA FOR C. TRACHOMATIS AND THE GENOMIC DNA OF N. GONORRHOEAE IN FEMALE ENDOCERVICAL OR VAGINAL SWAB SPECIMENS.,VYSIS LSI FUS (TEL) SPECTRUMGREEN PROBE(VYSIS LSI FUS (TEL) SPECTRUMGREEN PROBE)-THE VYSIS LSI FUS (TEL) SPECTRUMGREEN FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE IS TARGETED TO THE 16P11 REGION ON CHROMOSOME 16. THE PROBE IS APPROXIMATELY 505 KB IN SIZE AND IS LOCATED TELOMERIC OF THE FUS GENE. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES,ANEUVYSION MULTICOLOR DNA PROBE KIT(ANEUVYSION MULTICOLOR DNA PROBE KIT)-THE ANEUVYSION (VYSIS CEP 18, X, Y-ALPHA SATELLITE, LSI 13 AND 21) MULTICOLOR PROBE PANEL IS INTENDED TO USE CEP 18/X/Y PROBE TO DETECT ALPHA SATELLITE SEQUENCES IN THE CENTROMERE REGIONS OF CHROMOSOMES 18, X, AND Y, AND LSI 13/21 PROBE TO DETECT THE 13Q14 REGION AND THE 21Q22.13 TO 21Q22.2 REGION.,VYSIS LSI SRY SPECTRUM ORANGE/CEP X SPECTRUM GREEN PROBES(VYSIS LSI SRY SPECTRUM ORANGE/CEP X SPECTRUM GREEN PROBES)-VYSIS LSI SRY SPECTRUM ORANGE/CEP X SPECTRUM GREEN PROBES HYBRIDIZE TO BAND YP11.3 OF THE HUMAN Y CHROMOSOME (LSI SRY SPECTRUMORANGE) AND TO THE CENTROMERE, BAND REGION XP11.1-Q11.1, LOCUS DXZ1 (CEP X SPECTRUMGREEN) OF THE HUMAN X CHROMOSOME. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES,PROBECHEK PRENATAL POSITIVE CONTROL SLIDES

	(PROBECHEK PRENATAL POSITIVE CONTROL SLIDES)-THE PROBECHEK PRENATAL CONTROL SLIDES ARE FIXED CELL SPECIMENS APPLIED TO MICROSCOPE SLIDES THAT ARE DESIGNED FOR USE AS CONTROLS FOR INTERPHASE FISH, AS A TEACHING TOOL FOR FISH SIGNAL ENUMERATION, AND FOR USER TRAINING AND LABORATORY QUALITY CONTROL.,VYSIS LSI SS18 (TEL) SPECTRUMORANGE PROBE(VYSIS LSI SS18 (TEL) SPECTRUMORANGE PROBE)-THE VYSIS LSI SS18 (TEL) SPECTRUMORANGE FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE IS TARGETED TO THE 18Q11.2 REGION ON CHROMOSOME 18. THE PROBE IS APPROXIMATELY 650 KB IN SIZE AND POSITIONED TELOMERIC TO THE SS18 GENE. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND METAPHASE CHROMOSOMES.,CMV CALIBRATOR(ABBOTT REALTIME CMV CALIBRATOR KIT)-THE ABBOTT REALTIME CMV CALIBRATORS ARE FOR CALIBRATION OF THE ABBOTT REALTIME CMV ASSAY WHEN USED FOR THE QUANTITATION OF CYTOMEGALOVIRUS (CMV) DNA IN HUMAN PLASMA OR WHOLE BLOOD.,VYSIS LSI FOXO1 (CEN) SPECTRUMGREEN PROBE(VYSIS LSI FOXO1 (CEN) SPECTRUMGREEN PROBE)-THE SPECTRUMGREEN VYSIS LSI FOXO1 (CEN) FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE IS TARGETED TO THE 13Q14 REGION ON CHROMOSOME 13. THE PROBE IS APPROXIMATELY 724 KB IN SIZE AND IS LOCATED CENTROMERIC OF THE FOXO1 GENE. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND METAPHASE CHROMOSOMES.,CMV CONTROLS(ABBOTT REALTIME CMV CONTROL KIT)-THE ABBOTT REALTIME CMV CONTROLS ARE USED TO ESTABLISH RUN VALIDITY OF THE ABBOTT REALTIME CMV ASSAY WHEN USED FOR THE QUANTITATION OF CYTOMEGALOVIRUS (CMV) DNA IN HUMAN PLASMA OR WHOLE BLOOD.,VYSIS LSI MALT1 DUAL COLOR BREAK APART REARRANGEMENT PROBE(VYSIS LSI MALT1 DUAL COLOR BREAK APART REARRANGEMENT PROBE)-VYSIS LSI MALT1 DUAL COLOR BREAK APART REARRANGEMENT PROBE HYBRIDIZES TO THE BAND 18Q21(SPECTRUMGREEN ON THE 3' (TELOMERIC) SIDE AND SPECTRUMORANGE ON THE 5' (CENTROMERIC) SIDE OF THE MALT1 LOCUS BREAKPOINTS). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,CT/NG CONTROL(ABBOTT REALTIME CT/NG CONTROL KIT)-THE ABBOTT REALTIME CT/NG CONTROLS ARE USED TO ESTABLISH RUN VALIDITY AND FOR THE QUALITATIVE DETECTION OF THE PLASMID DNA OF CHLAMYDIA TRACHOMATIS AND THE GENOMIC DNA OF NEISSERIA GONORRHOEAE IN FEMALE ENDOCERVICAL OR VAGINAL SWAB SPECIMENS.,VYSIS LSI CCND1

	(CEN) SPECTRUMGREEN PROBE(VYSIS LSI CCND1 (CEN) SPECTRUMGREEN PROBE)-THE VYSIS LSI CCND1 (CEN) SPECTRUMGREEN FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE IS TARGETED TO THE 11Q13 REGION ON CHROMOSOME 11. THE PROBE IS APPROXIMATELY 665 KB IN SIZE AND IS LOCATED CENTROMERIC OF THE CCND1 GENE. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES,CMV AMPLIFICATION REAGENT KIT(ABBOTT REALTIME CMV AMPLIFICATION REAGENT KIT)-THE ABBOTT REALTIME CMV ASSAY IS AN IN VITRO POLYMERASE CHAIN REACTION (PCR) ASSAY FOR THE QUANTITATION OF CYTOMEGALOVIRUS (CMV) DNA IN HUMAN PLASMA OR WHOLE BLOOD.,VYSIS LSI SS18 (CEN) SPECTRUMGREEN PROBE(VYSIS LSI SS18 (CEN) SPECTRUMGREEN PROBE)-THE VYSIS LSI SS18 (CEN) SPECTRUMGREEN FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE IS TARGETED TO THE 18Q11.2 REGION ON CHROMOSOME 18. THE PROBE IS APPROXIMATELY 1044 KB IN SIZE AND POSITIONED CENTROMERIC TO THE SS18 GENE. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND METAPHASE CHROMOSOMES.,VYSIS LSI D20S108 (20Q12) SPECTRUMORANGE PROBE(VYSIS LSI D20S108 (20Q12) SPECTRUMORANGE PROBE)-VYSIS LSI D20S108 (20Q12) SPECTRUMORANGE DNA PROBE HYBRIDIZES TO BAND 20Q12, LOCUS D20S108 ON HUMAN CHROMOSOME 20. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,VYSIS LSI HIRA SPECTRUMORANGE PROBE(VYSIS LSI HIRA SPECTRUMORANGE PROBE)-THE VYSIS LSI HIRA SPECTRUMORANGE FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE IS TARGETED TO THE 22Q11.2 REGION ON CHROMOSOME 22. THE PROBE IS APPROXIMATELY 117 KB IN SIZE AND CONTAINS PART OF THE HIRA GENE. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND METAPHASE CHROMOSOMES.,VYSIS INTELLIFISH UNIVERSAL FFPE TISSUE PRETREATMENT AND WASH REAGENTS(VYSIS INTELLIFISH UNIVERSAL FFPE TISSUE PRETREATMENT AND WASH REAGENTS)-VYSIS INTELLIFISH UNIVERSAL FFPE TISSUE PRETREATMENT AND WASH REAGENT KIT, VYSIS INTELLIFISH UNIVERSAL FFPE TISSUE PRETREATMENT PROTEASE (FOR 50 ML) AND VYSIS INTELLIFISH UNIVERSAL FFPE TISSUE PRETREATMENT PROTEASE (FOR 500 ML) ARE USED TO PREPARE FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS FIXED ON POSITIVELY CHARGED SLIDES FOR USE IN FLUORESCENCE IN SITU HYBRIDIZATION (FISH) WITH VYSIS DNA FISH PROBES.,VYSIS

	LSI TRA/D DUAL COLOR BREAK APART REARRANGEMENT PROBE (VYSIS LSI TRA/D DUAL COLOR BREAK APART REARRANGEMENT PROBE)-VYSIS LSI TRA/D DUAL COLOR BREAK APART REARRANGEMENT PROBE HYBRIDIZES TO CHROMOSOME 14Q11.2 IN BOTH SPECTRUMORANGE AND SPECTRUMGREEN. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,VYSIS ALK BREAK APART FISH PROBE KIT(VYSIS ALK BREAK APART FISH PROBE KIT)-THE VYSIS ALK BREAK APART FISH PROBE KIT IS A QUALITATIVE TEST TO DETECT REARRANGEMENTS INVOLVING THE ALK GENE VIA FLUORESCENCE IN SITU HYBRIDIZATION (FISH) IN FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) NON SMALL CELL LUNG CANCER (NSCLC) TISSUE SPECIMENS TO AID IN IDENTIFYING THOSE PATIENTS ELIGIBLE FOR TREATMENT WITH XALKORI® (CRIZOTINIB).,VYSIS LSI SNRPN SPECTRUMORANGE/CEP 15 SPECTRUMAQUA/ PML SPECTRUMGREEN PROBES(VYSIS LSI SNRPN SPECTRUMORANGE/CEP 15 SPECTRUMAQUA/ PML SPECTRUMGREEN PROBES)-THE SPECTRUMORANGE SNRPN PROBE HYBRIDIZES TO 15Q11.2. THE PROBE IS 125 KB IN SIZE AND SPANS THE SNRPN GENE. THE CEP 15 PROBE IS LABELED IN SPECTRUMAQUA AND HYBRIDIZES TO THE CENTROMERIC REGION OF CHROMOSOME 15 AND ACTS AS A CONTROL PROBE. THE PML SPECTRUMGREEN PROBE HYBRIDIZES TO THE 15Q22-24 REGION AND IS 180 KB IN SIZE. THE PROBE MAY BE USED WITH METAPHASE CHROMOSOMES OR INTERPHASE NUCLEI. THE SIGNALS MAY ALSO APPEAR DIFFUSE OR SPLIT DEPENDING UPON THE CONDENSATION OF THE DNA AND THE RELATIVE DISTANCES BETWEEN CHROMATIDS. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,VYSIS LSI ETV6 (TEL) / RUNX1 (AML1) ES DUAL COLOR SINGLE FUSION PROBE(VYSIS LSI ETV6 (TEL) / RUNX1 (AML1) ES DUAL COLOR SINGLE FUSION PROBE)-VYSIS LSI ETV6 (TEL) / RUNX1 (AML1) ES DUAL COLOR SINGLE FUSION PROBE HYBRIDIZES TO CHROMOSOME 12P13 (SPECTRUMGREEN TEL - ETV6) AND TO CHROMOSOME 21Q22 (SPECTRUMORANGE AML1). THE HYBRIDIZED PROBE FLUORESCES WITH BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,VYSIS LSI DDIT3 (CEN) SPECTRUMORANGE PROBE(VYSIS LSI DDIT3 (CEN) SPECTRUMORANGE PROBE)-THE VYSIS LSI DDIT3 (CEN) SPECTRUMORANGE PROBE FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE IS TARGETED TO THE 12Q13 REGION ON CHROMOSOME 12. THE PROBE IS APPROXIMATELY 700 KB IN SIZE AND IS LOCATED CENTROMERIC OF THE DDIT3 GENE. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN

	INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES,DAPI I COUNTERSTAIN (DAPI I COUNTERSTAIN)-DAPI COUNTERSTAIN IN ANTIFADE MOUNTING SOLUTION IS A MIXTURE CONTAINING 4',6-DIAMINO-2 PHENYLINDOLE AND 1,4-PHEYLENEDIAMINE IN A PHOSPHATE BUFFERED SALINE AND GLYCEROL MIXTURE. WHEN USED AS A COUNTERSTAIN IN FISH ASSAYS, THE DAPI APPEARS AS A VIVID BLUE COLOR ON INTERPHASE AND METAPHASE CELLS.,VYSIS LSI FUS (CEN) SPECTRUMORANGE PROBE(VYSIS LSI FUS (CEN) SPECTRUMORANGE PROBE)-THE SPECTRUMORANGE VYSIS LSI FUS (CEN) FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE IS TARGETED TO THE 16P11 REGION ON CHROMOSOME 16. THE PROBE IS APPROXIMATELY 275 KB IN SIZE AND IS LOCATED CENTROMERIC OF THE FUS GENE. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES,20X SSC(20X SSC)-20X SSC, 500G (SALINE SODIUM CITRATE) IS A SALT POWDER MIXTURE CONTAINING SODIUM CHLORIDE AND SODIUM CITRATE. IT IS USED TO MAKE 20X SSC SOLUTION AND SUBSEQUENT DILUTIONS FOR DENATURING AND WASH SOLUTIONS.,VYSIS LSI IGH/BCL2 DUAL COLOR DUAL FUSION PROBES(VYSIS LSI IGH/BCL2 DUAL COLOR DUAL FUSION PROBES)-VYSIS LSI IGH/BCL2 DUAL COLOR DUAL FUSION PROBES HYBRIDIZE TO CHROMOSOME 14Q32 (IGH SPECTRUMGREEN) AND CHROMOSOME 18Q21 (BCL2 SPECTRUMORANGE). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,VP 2000 PRETREATMENT REAGENT(VP 2000 PRETREATMENT REAGENT)-VP 2000 REAGENTS ARE SPECIFICALLY DESIGNED FOR AUTOMATED DEPARAFFINIZATION AND PRETREATMENT PROTOCOLS FOR VYSIS FISH ASSAYS,VYSIS LSI IGH/MYC/CEP 8 TRI-COLOR DUAL FUSION PROBES(VYSIS LSI IGH/MYC/CEP 8 TRI-COLOR DUAL FUSION PROBES)-VYSIS LSI IGH/MYC/CEP 8 TRI-COLOR DUAL FUSION PROBES REAGENT HYBRIDIZES TO THE BAND 14Q32 (IGH) IN SPECTRUMGREEN, BAND 8Q24 (MYC) IN SPECTRUMORANGE AND THE CENTROMERE OF CHROMOSOME 8 IN SPECTRUMAQUA. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,DAPI II COUNTERSTAIN (DAPI II COUNTERSTAIN)-DAPI II COUNTERSTAIN IN ANTIFADE MOUNTING SOLUTION IS A MIXTURE CONTAINING 4',6-DIAMINO-2 PHENYLINDOLE AND 1,4-PHEYLENEDIAMINE IN A PHOSPHATE BUFFERED SALINE AND GLYCEROL MIXTURE. WHEN USED AS A COUNTERSTAIN IN FISH ASSAYS, THE DAPI APPEARS AS A VIVID BLUE COLOR ON INTERPHASE AND METAPHASE CELLS.,VYSIS MET SPECTRUMRED PROBE(VYSIS MET SPECTRUMRED PROBE)-THE VYSIS LSI MET

	SPECTRUMRED FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE IS TARGETED TO THE 7Q31.2 REGION ON CHROMOSOME 7. THE PROBE IS ~456 KB IN SIZE AND SPANS THE ENTIRE MET GENE. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,PROTEASE II(PROTEASE II)-IT IS USED TO PREPARE THE SPECIMEN FOR THE USE IN FLUORESCENCE IN SITU HYBRIDIZATION (FISH) WITH VYSIS DNA PROBES ON VP2000 PROCESSOR.,VYSIS LSI RUNX1 SPECTRUMGREEN PROBE(VYSIS LSI RUNX1 SPECTRUMGREEN PROBE)-SPECTRUMGREEN FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE IS TARGETED TO THE 21Q22 REGION ON CHROMOSOME 21. THE PROBE IS ~1.4 MB IN SIZE AND SPANS THE ENTIRE RUNX1 GENE. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,VYSIS INTELLIFISH UNIVERSAL FFPE TISSUE PRETREATMENT PROTEASE (FOR 50 ML)(VYSIS INTELLIFISH UNIVERSAL FFPE TISSUE PRETREATMENT PROTEASE (FOR 50 ML))-VYSIS INTELLIFISH UNIVERSAL FFPE TISSUE PRETREATMENT AND WASH REAGENT KIT AND VYSIS INTELLIFISH UNIVERSAL FFPE TISSUE PRETREATMENT PROTEASE (FOR 50 ML) ARE USED TO PREPARE FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS FIXED ON POSITIVELY CHARGED SLIDES FOR USE IN FLUORESCENCE IN SITU HYBRIDIZATION (FISH) WITH VYSIS DNA FISH PROBES. THIS IS FOR MANUAL ASSAY.,VYSIS LSI 13 (RB1) 13Q14 SPECTRUMORANGE PROBE (VYSIS LSI 13 (RB1) 13Q14 SPECTRUMORANGE PROBE)-VYSIS LSI 13 (RB1) 13Q14 SPECTRUMORANGE DNA PROBE HYBRIDIZES TO BAND 13Q14 OF HUMAN CHROMOSOME 13. THE HYBRIDIZED PROBE FLUORESCES WITH BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,DAPI III COUNTERSTAIN (DAPI III COUNTERSTAIN)-DAPI III COUNTERSTAIN IN ANTIFADE MOUNTING SOLUTION IS A MIXTURE CONTAINING 4',6-DIAMINO-2 PHENYLINDOLE AND 1,4-PHEYLENEDIAMINE IN A PHOSPHATE BUFFERED SALINE AND GLYCEROL,VYSIS LSI CCND1 (TEL) SPECTRUMORANGE PROBE(VYSIS LSI CCND1 (TEL) SPECTRUMORANGE PROBE)-THE VYSIS LSI CCND1 (TEL) SPECTRUMORANGE FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBE IS TARGETED TO THE 11Q13 REGION ON CHROMOSOME 11. THE PROBE IS APPROXIMATELY 532 KB IN SIZE AND CONTAINS THE CCND1 GENE. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,ANTIFADE II SOLUTION(ANTIFADE II SOLUTION)-ANTIFADE II IS A MOUNTING SOLUTION THAT IS USED TO PREVENT THE RAPID PHOTOBLEACHING OF AMCA, TEXAS RED,

	RHODAMINE, FLUORESCEIN, AND OTHER FLUOROCHROMES,VYSIS LSI MYB (6Q23) SPECTRUMAQUA PROBE(VYSIS LSI MYB (6Q23) SPECTRUMAQUA PROBE)-VYSIS LSI MYB (6Q23) SPECTRUMAQUA DNA PROBE HYBRIDIZES TO HUMAN CHROMOSOME 6Q23. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES. IN INTERPHASE NUCLEI OF NORMAL CELLS, THE PROBE GENERALLY APPEARS AS TWO DISTINCT SIGNALS. THE PROBE MAY ALSO APPEAR AS THREE OR FOUR SIGNALS, DEPENDING UPON DNA CONDENSATION, AND RELATIVE DISTANCE BETWEEN CHROMATIDS. THE SIGNALS MAY ALSO APPEAR AS DIFFUSE OR SPLIT SIGNALS. IN A NORMAL METAPHASE, THE PROBE MAY APPEAR AS ONE OR TWO SIGNALS ON EACH CHROMOSOME 6.,NP-40(NP-40)-NP-40 IS A NON-IONIC SURFACTANT THAT IS USED IN THE AQUEOUS POST-HYBRIDIZATION WASH SOLUTION,HCV REAL TIME CALIBRATOR KIT(ABBOTT REAL TIME HCV CALIBRATOR KIT)- THE ABBOTT REAL TIME HCV CALIBRATORS ARE FOR CALIBRATION OF THE ABBOTT REAL TIME HCV ASSAY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS C VIRUS (HCV) RNA IN HUMAN SERUM AND PLASMA (EDTA) FROM HCV INFECTED INDIVIDUALS. ,VYSIS LSI EGFR SPECTRUMORANGE/CEP 7 SPECTRUMGREEN PROBES(VYSIS LSI EGFR SPECTRUMORANGE/CEP 7 SPECTRUMGREEN PROBES)-VYSIS LSI EGFR SPECTRUMORANGE/CEP 7 SPECTRUMGREEN PROBES HYBRIDIZE TO THE BAND REGION 7P11.2 - 7P12 IN SPECTRUMORANGE AND THE CENTROMERE OF CHROMOSOME 7 (7P11.1-Q11,1, D7Z1 LOCUS) IN SPECTRUMGREEN. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,HIV-1 REAL TIME RNA QUANTITATION KIT(ABBOTT REAL TIME HIV-1 AMPLIFICATION REAGENT KIT)-THE ABBOTT REAL TIME HIV-1 ASSAY IS AN IN VITRO REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) ASSAY FOR THE QUANTITATION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) IN WHOLE BLOOD SPOTTED ON CARDS AS DRIED BLOOD SPOTS (DBS) OR HUMAN PLASMA FROM HIV-1 INFECTED INDIVIDUALS.,VYSIS PARAFFIN PRETREATMENT REAGENT KIT(VYSIS PARAFFIN PRETREATMENT REAGENT KIT)-TO PREPARE PARAFFIN-EMBEDDED TISSUE SECTIONS FIXED ON POSITIVELY CHARGED SLIDES FOR THE USE IN FLUORESCENCE IN SITU HYBRIDIZATION (FISH) WITH VYSIS PROBES.,HBV REAL TIME CALIBRATOR KIT (ABBOTT REAL TIME HBV CALIBRATOR KIT)-THE ABBOTT REAL TIME HBV CALIBRATORS ARE FOR CALIBRATION OF THE ABBOTT REAL TIME HBV ASSAY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS B VIRUS (HBV) DNA IN HUMAN SERUM

	AND PLASMA FROM HBV INFECTED INDIVIDUALS.,VYSIS LSI IGH DUAL COLOR BREAK APART REARRANGEMENT PROBE(VYSIS LSI IGH DUAL COLOR BREAK APART REARRANGEMENT PROBE)-VYSIS LSI IGH DUAL COLOR BREAK APART REARRANGEMENT PROBE HYBRIDIZES TO THE BAND 14Q32.3 (SPECTRUMGREEN ON THE TELOMERIC SIDE AND SPECTRUMORANGE ON THE CENTROMERIC SIDE OF THE IGH LOCUS BREAKPOINTS). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,HBV REAL TIME CONTROL KIT (ABBOTT REAL TIME HBV CONTROL KIT)-THE ABBOTT REAL TIME HBV CONTROLS ARE USED TO ESTABLISH RUN VALIDITY OF THE ABBOTT REAL TIME HBV ASSAY WHEN USED FOR THE QUANTITATION OF HEPATITIS B VIRUS (HBV) DNA IN HUMAN SERUM AND PLASMA FROM HBV INFECTED INDIVIDUALS.,VYSIS CEP HYBRIDIZATION BUFFER(VYSIS CEP HYBRIDIZATION BUFFER)-VYSIS CEP HYBRIDIZATION BUFFER IS A SOLUTION CONTAINING SODIUM CHLORIDE, SODIUM CITRATE AND DEXTRAN SULFATE IN FORMAMIDE. IT IS USED TO RECONSTITUTE VYSIS CHROMOSOME ENUMERATOR PROBE (CEP) DNA PROBES TO FACILITATE THE HYBRIDIZATION OF THE PROBE TO THE TARGET DNA.,HIV-1 REAL TIME CONTROL KIT (ABBOTT REAL TIME HIV-1 CONTROL KIT)-THE ABBOTT REAL TIME HIV-1 CONTROLS ARE USED TO ESTABLISH RUN VALIDITY OF THE ABBOTT REALTIME HIV-1 ASSAY WHEN USED FOR THE QUANTITATIVE DETERMINATION HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) RNA IN HUMAN PLASMA FROM HIV-1 INFECTED INDIVIDUALS.,VYSIS LSI MYC DUAL COLOR BREAK APART REARRANGEMENT PROBE (VYSIS LSI MYC DUAL COLOR BREAK APART REARRANGEMENT PROBE)-VYSIS LSI MYC DUAL COLOR BREAK APART REARRANGEMENT PROBE HYBRIDIZES TO THE BAND REGION 8Q24. THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,PROTEINASE K, RECOMBINANT, PCR GRADE (ABBOTT PROTEINASE K)- THE GENERAL PURPOSE REAGENT CONTAINS PROTEINASE K, RECOMBINANT, PCR GRADE, FROM PICHIA PASTORIS.,VYSIS LSI IGH/FGFR3 DUAL COLOR DUAL FUSION PROBES (VYSIS LSI IGH/FGFR3 DUAL COLOR DUAL FUSION PROBES)-VYSIS LSI IGH/FGFR3 DUAL COLOR DUAL FUSION PROBES HYBRIDIZE TO CHROMOSOME 14Q32 (IGH SPECTRUMGREEN) AND CHROMOSOME 4P16 (FGFR3 SPECTRUMORANGE). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES,ABBOTT MSAMPLE PREPARATION SYSTEM DBS BUFFER KIT(ABBOTT MSAMPLE PREPARATION SYSTEM DBS BUFFER KIT)-THE ABBOTT MSAMPLE PREPARATION SYSTEM DBS BUFFER KIT IS USED TO ELUTE

	NUCLEIC ACID FROM DRIED BLOOD SPOTS.,VYSIS D7S486/CEP 7 FISH PROBE KIT(VYSIS D7S486/CEP 7 FISH PROBE KIT)-THE VYSIS D7S486/CEP 7 FISH PROBE KIT IS A DEVICE INTENDED FOR SPECIMEN CHARACTERIZATION AND DETECTS THE LSI D7S486 PROBE TARGET ON CHROMOSOME 7Q31 AND THE CEP 7 PROBE TARGET ON CHROMOSOME 7P11.1-Q11.1 IN BONE MARROW AND PERIPHERAL BLOOD SPECIMENS FROM PATIENTS WITH ACUTE MYELOID LEUKEMIA OR MYELODYSPLASTIC SYNDROME.,REAL TIME HCV GENOTYPE II CONTROL KIT(ABBOTT REAL TIME HCV GENOTYPE II CONTROL KIT)-THE ABBOTT REALTIME HCV GENOTYPE II CONTROLS ARE USED TO ESTABLISH RUN VALIDITY OF THE ABBOTT REAL TIME HCV GENOTYPE II ASSAY WHEN USED FOR DETERMINING THE GENOTYPE(S) OF HEPATITIS C VIRUS (HCV) IN PLASMA AND SERUM FROM HCV-INFECTED INDIVIDUALS.,VYSIS LSI 1P36 SPECTRUMORANGE/1Q25 SPECTRUMGREEN PROBES AND VYSIS LSI 19Q13 SPECTRUMORANGE/19P13 SPECTRUMGREEN PROBES(VYSIS LSI 1P36 SPECTRUMORANGE/1Q25 SPECTRUMGREEN PROBES AND VYSIS LSI 19Q13 SPECTRUMORANGE/19P13 SPECTRUMGREEN PROBES)-VYSIS LSI 1P36 SPECTRUMORANGE/1Q25 SPECTRUMGREEN PROBES AND VYSIS LSI 19Q13 SPECTRUMORANGE/19P13 SPECTRUMGREEN PROBES CONSIST OF TWO SEPARATE PROBE MIXTURES: ONE PROBE SET/VIAL CONTAINS LSI 1P36 SPECTRUMORANGE AND LSI 1Q25 SPECTRUMGREEN, AND THE OTHER PROBE SET/VIAL CONTAINS LSI 19Q13 SPECTRUMORANGE AND LSI 19P13 SPECTRUMGREEN. THE HYBRIDIZED PROBES FLUORESCE WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,HIV-1 REAL TIME CALIBRATOR KIT(ABBOTT REAL TIME HIV-1 CALIBRATOR KIT)-THE ABBOTT REAL TIME HIV-1 CALIBRATORS ARE FOR CALIBRATION OF THE ABBOTT REAL TIME HIV-1 ASSAY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) RNA IN HUMAN PLASMA FROM HIV-1 INFECTED INDIVIDUALS.,VYSIS LSI BCL2 DUAL COLOR BREAK APART REARRANGEMENT PROBE(VYSIS LSI BCL2 DUAL COLOR BREAK APART REARRANGEMENT PROBE)-VYSIS LSI BCL2 DUAL COLOR BREAK APART REARRANGEMENT PROBE HYBRIDIZES TO THE BAND 18Q21 (SPECTRUMGREEN ON THE 3' (CENTROMERIC) SIDE AND SPECTRUMORANGE ON THE 5' (TELOMERIC) SIDE OF THE BCL 2 LOCUS BREAKPOINTS). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,HCV REAL TIME CONTROL KIT(ABBOTT REAL TIME HCV CONTROL KIT)-THE ABBOTT REAL TIME HCV CONTROLS ARE USED TO ESTABLISH RUN VALIDITY OF THE ABBOTT REAL TIME HCV

	ASSAY WHEN USED FOR THE QUANTITATION OF HEPATITIS C VIRUS (HCV) RNA IN HUMAN SERUM AND PLASMA (EDTA) FROM HCV INFECTED INDIVIDUALS ,VYSIS LSI IGH/MAF DUAL COLOR DUAL FUSION PROBES(VYSIS LSI IGH/MAF DUAL COLOR DUAL FUSION PROBES)-VYSIS LSI IGH/MAF DUAL COLOR DUAL FUSION PROBES HYBRIDIZE TO CHROMOSOME 14Q32 (IGH SPECTRUMGREEN) AND CHROMOSOME 16Q23 (MAF SPECTRUMORANGE). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,REAL TIME HCV GENOTYPE II AMPLIFICATION REAGENT KIT(ABBOTT REAL TIME HCV GENOTYPE II AMPLIFICATION REAGENT KIT)-THE ABBOTT REAL TIME HCV GENOTYPE II IS AN IN VITRO REVERSE TRANSCRIPTION-POLYMERASE CHAIN REACTION (RT-PCR) ASSAY FOR DETERMINING THE GENOTYPE(S) OF HEPATITIS C VIRUS (HCV) IN PLASMA AND SERUM FROM HCV-INFECTED INDIVIDUALS.,VYSIS LSI TP53 SPECTRUMORANGE/ CEP 17 SPECTRUMGREEN PROBE(VYSIS LSI TP53 SPECTRUMORANGE/ CEP 17 SPECTRUMGREEN PROBE)-VYSIS LSI TP53 SPECTRUMORANGE/CEP 17 SPECTRUMGREEN PROBES HYBRIDIZE TO CHROMOSOME 17. THE SPECTRUMORANGE TP53 PROBE HYBRIDIZES TO 17P13.1. THE PROBE IS 170 KB IN SIZE AND COVERS THE ENTIRE TP53 GENE. THE CEP 17 IS LABELED IN SPECTRUMGREEN AND HYBRIDIZES TO THE 17P11.1-Q11.1 REGION OF CHROMOSOME 17,REAL TIME HIV-1 QUALITATIVE AMPLIFICATION REAGENT KIT(ABBOTT REAL TIME HIV-1 QUALITATIVE AMPLIFICATION REAGENT KIT)-THE ABBOTT REALTIME HIV-1 QUALITATIVE IS AN IN VITRO AMPLIFICATION ASSAY FOR THE QUALITATIVE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) NUCLEIC ACIDS FROM HUMAN PLASMA AND DRIED BLOOD SPOTS (DBS).,VYSIS LSI IGH/CCND1 DUAL COLOR DUAL FUSION PROBES(VYSIS LSI IGH/CCND1 DUAL COLOR DUAL FUSION PROBES)-VYSIS LSI IGH/CCND1 DUAL COLOR DUAL FUSION PROBES HYBRIDIZE TO CHROMOSOME 14Q32.3 (IGH SPECTRUMGREEN) AND CHROMOSOME 11Q13 (CCND1 SPECTRUMORANGE). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,HBV REAL TIME DNA QUANTITATION KIT(ABBOTT REAL TIME HBV AMPLIFICATION REAGENT KIT)-ABBOTT REAL TIME HBV IS AN IN VITRO POLYMERASE CHAIN REACTION (PCR) ASSAY FOR THE QUANTITATION OF HEPATITIS B VIRUS (HBV) DNA IN HUMAN PLASMA OR SERUM FROM HBVINFECTED INDIVIDUALS.,VYSIS LSI BCL6 DUAL COLOR BREAK APART REARRANGEMENT PROBE(VYSIS LSI BCL6 DUAL COLOR BREAK APART REARRANGEMENT PROBE)-VYSIS LSI BCL6 DUAL COLOR BREAK APART DNA PROBE HYBRIDIZES TO THE BAND 3Q27. THE 5' BCL6 SPECTRUMORANGE™ PROBE IS ~349 KB IN

	SIZE AND FLANKS THE ABR OF BCL6. THE 3' BCL6 SPECTRUMGREEN™ PROBE IS APPROXIMATELY 600KB IN SIZE AND FLANKS THE MBR REGION OF BCL6. THERE IS AN APPROXIMATE 269 KB GAP BETWEEN THE TWO PROBES.,HCV REAL TIME DNA QUANTITATION KIT(ABBOTT REAL TIME HCV AMPLIFICATION REAGENT KIT)-THE ABBOTT REAL TIME HCV ASSAY IS AN IN VITRO REVERSE TRANSCRIPTION-POLYMERASE CHAIN REACTION (RT-PCR) ASSAY FOR THE QUANTITATION OF HEPATITIS C VIRAL RIBONUCLEIC ACID (HCV RNA) IN HUMAN SERUM AND PLASMA FROM HCV-INFECTED INDIVIDUALS., VYSIS LSI MLL DUAL COLOR BREAK APART REARRANGEMENT PROBE (VYSIS LSI MLL DUAL COLOR BREAK APART REARRANGEMENT PROBE)-VYSIS LSI MLL DUAL COLOR BREAK APART REARRANGEMENT PROBE HYBRIDIZES TO THE BAND 11Q23 (SPECTRUMGREEN ON THE CENTROMERIC SIDE AND SPECTRUMORANGE ON THE TELOMERIC SIDE OF THE MLL GENE BREAKPOINT). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,REAL TIME HIV-1 QUALITATIVE CONTROL KIT(ABBOTT REAL TIME HIV-1 QUALITATIVE CONTROL KIT)-THE ABBOTT REALTIME HIV-1 QUALITATIVE CONTROLS ARE USED TO ESTABLISH RUN VALIDITY OF THE ABBOTT REALTIME HIV-1 QUALITATIVE ASSAY WHEN USED FOR THE QUALITATIVE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) NUCLEIC ACIDS FROM HUMAN PLASMA AND DRIED BLOOD SPOTS (DBS).,VYSIS LSI BCR/ABL1/ASS1TRI-COLOR DUAL FUSION PROBES(VYSIS LSI BCR/ABL1/ASS1TRI-COLOR DUAL FUSION PROBES)-VYSIS LSI BCR/ABL1/ASS1TRI-COLOR DUAL FUSION PROBES HYBRIDIZE TO CHROMOSOME 22Q11.2 (BREAKPOINT CLUSTER REGION - SPECTRUM GREEN), CHROMOSOME 9Q34 (ABL1 ONCOGENE - SPECTRUM ORANGE AND ASS1 GENE LOCUS - SPECTRUM AQUA). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,VYSIS LSI IGH/BCL2 DUAL COLOR DUAL FUSION PROBES(VYSIS LSI IGH/BCL2 DUAL COLOR DUAL FUSION PROBES)-VYSIS LSI IGH/BCL2 DUAL COLOR DUAL FUSION PROBES HYBRIDIZE TO CHROMOSOME 14Q32 (IGH SPECTRUMGREEN) AND CHROMOSOME 18Q21 (BCL2 SPECTRUMORANGE). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES,VYSIS EGR1 FISH PROBE KIT-SC (VYSIS EGR1 FISH PROBE KIT-SC)-THE VYSIS EGR1 FISH PROBE KIT –SC(SPECIMEN CHARACTERIZATION) DETECTS THE LSI EGR1 PROBE TARGET ON CHROMOSOME 5Q IN BONE MARROW SPECIMENS. THE VYSIS EGR1 FISH PROBE KIT – SC ASSAY RESULTS CHARACTERIZE BONE MARROW SPECIMENS FROM

	PATIENTS WITH ACUTE MYELOID LEUKEMIA OR MYELODYSPLASTIC SYNDROME,VYSIS LSI/WCP HYBRIDIZATION BUFFER(VYSIS LSI/WCP HYBRIDIZATION BUFFER)-VYSIS LSI/WCP HYBRIDIZATION BUFFER IS A SOLUTION CONTAINING SODIUM CHLORIDE, SODIUM CITRATE AND DEXTRAN SULFATE IN FORMAMIDE. IT IS USED TO RECONSTITUTE VYSIS LOCUS SPECIFIC IDENTIFIER (LSI) DNA PROBES TO FACILITATE THE HYBRIDIZATION OF THE PROBE TO THE TARGET DNA.,VP 2000 REAGENTS PROTEASE BUFFER(VP 2000 REAGENTS PROTEASE BUFFER)-VP 2000 REAGENTS ARE SPECIFICALLY DESIGNED FOR AUTOMATED DEPARAFFINIZATION AND PRETREATMENT PROTOCOLS FOR VYSIS FISH ASSAYS. THE PROTEASE BUFFER IS 0.01 N HYDROCHLORIDE ACID. ,VYSIS FISH PRETREATMENT REAGENT KIT (VYSIS FISH PRETREATMENT REAGENT KIT)-TO PREPARE CELLS RECOVERED FROM URINE PELLETS FIXED ONTO SLIDES FOR USE IN FLUORESCENCE IN SITU HYBRIDIZATION (FISH) WITH VYSIS PROBES., VYSIS PROTEASE I(VYSIS PROTEASE I)-IT IS USED TO PREPARE THE SPECIMEN FOR THE USE IN FLUORESCENCE IN SITU HYBRIDIZATION (FISH) WITH VYSIS DNA PROBES.,ANTIFADE SOLUTION(ANTIFADE SOLUTION)-ANTIFADE SOLUTION IS A MOUNTING SOLUTION CONTAINING A MIXTURE OF 1,4-PHEYLENEDIAMINE IN A PHOSPHATE BUFFERED SALINE AND GLYCEROL. ,VYSIS LSI CBFB DUAL COLOR BREAK APART REARRANGEMENT PROBE(VYSIS LSI CBFB DUAL COLOR BREAK APART REARRANGEMENT PROBE)-VYSIS LSI CBFB DUAL COLOR BREAK APART REARRANGEMENT PROBE HYBRIDIZES TO THE BAND 16Q22 (SPECTRUMRED ON THE CENTROMERIC SIDE AND SPECTRUMGREEN ON THE TELOMERIC SIDE OF THE CBF GENE BREAKPOINT). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,VYSIS INTELLIFISH UNIVERSAL FFPE TISSUE PRETREATMENT PROTEASE (VYSIS INTELLIFISH UNIVERSAL FFPE TISSUE PRETREATMENT PROTEASE)-VYSIS INTELLIFISH UNIVERSAL FFPE TISSUE PRETREATMENT AND WASH REAGENT KIT AND VYSIS INTELLIFISH UNIVERSAL FFPE TISSUE PRETREATMENT PROTEASE (FOR 500 ML) ARE USED TO PREPARE FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS FIXED ON POSITIVELY CHARGED SLIDES FOR THE USE IN FLUORESCENCE IN SITU HYBRIDIZATION (FISH) WITH VYSIS DNA FISH PROBES. THIS IS FOR AUTOMATED ASSAY ON VP2000 PROCESSOR. ,VYSIS LSI PML/RARA DUAL COLOR DUAL FUSION PROBES(VYSIS LSI PML/RARA DUAL COLOR DUAL FUSION PROBES)-VYSIS LSI PML/RARA DUAL COLOR DUAL FUSION PROBES HYBRIDIZES TO CHROMOSOME 15Q22-24 (PML SPECTRUMORANGE) AND CHROMOSOME 17Q21 (RETINOIC ACID RECEPTOR SPECTRUMGREEN). THE HYBRIDIZED PROBE FLUORESCES WITH

	MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES.,VYSIS LSI BCR/ABL DUAL COLOR DUAL FUSION PROBES(VYSIS LSI BCR/ABL DUAL COLOR DUAL FUSION PROBES)-VYSIS LSI BCR/ABL DUAL COLOR DUAL FUSION PROBES HYBRIDIZES TO CHROMOSOME 22Q11.2 (BREAKPOINT CLUSTER REGION SPECTRUMGREEN) AND TO CHROMOSOME 9Q34 (ABL ONCOGENE SPECTRUMORANGE). THE HYBRIDIZED PROBE FLUORESCES WITH MODERATE TO BRIGHT INTENSITY BOTH IN INTERPHASE NUCLEI AND ON METAPHASE CHROMOSOMES,VYSIS INTELLIFISH HYBRIDIZATION BUFFER (VYSIS INTELLIFISH HYBRIDIZATION BUFFER)-THE VYSIS INTELLIFISH HYBRIDIZATION BUFFER IS USED WITH FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBES TO FACILITATE FISH HYBRIDIZATION OF THE VYSIS FISH PROBES TO THE TARGET AND FACILITATES HYBRIDIZATION WITHIN 1-3 HOURS, ALLOWING LABORATORIES TO GENERATE FISH RESULTS IN A SINGLE DAY.,VYSIS INTELLIFISH HYBRIDIZATION BUFFER (VYSIS INTELLIFISH HYBRIDIZATION BUFFER)-THE VYSIS INTELLIFISH HYBRIDIZATION BUFFER IS USED WITH FLUORESCENCE IN SITU HYBRIDIZATION (FISH) PROBES TO FACILITATE FISH HYBRIDIZATION OF THE VYSIS FISH PROBES TO THE TARGET AND FACILITATES HYBRIDIZATION WITHIN 1-3 HOURS, ALLOWING LABORATORIES TO GENERATE FISH RESULTS IN A SINGLE DAY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

410	IMP/IVD/2019/000445	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CORE TDM MULTI-CALIBRATOR(CORE TDM MULTI-CALIBRATOR)-THE CORE TDM MULTI-CALIBRATOR IS INTENDED TO BE USED WITH THE REAGENTS LISTED IN THE TABLE BELOW FOR THE QUANTITATIVE DETERMINATION OF CARBAMAZEPINE, PHENOBARBITAL, PHENYTOIN, THEOPHYLLINE AND VALPROIC ACID ON BECKMAN COULTER ANALYSERS., PHENOBARBITAL(PHENOBARBITAL)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PHENOBARBITAL IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,OPIATES(OPIATES)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND SEMI-QUANTITATIVE ASSAY OF OPIATES IN HUMAN URINE ON BECKMAN COULTER AU ANALYSERS,ANTIBIOTIC TDM MULTI-CALIBRATOR(ANTIBIOTIC TDM MULTI-CALIBRATOR)-THE ANTIBIOTIC TDM MULTI-CALIBRATOR IS INTENDED TO BE USED WITH THE GENTAMYCIN REAGENT OSR6420 FOR THE QUANTITATIVE DETERMINATION OF GENTAMYCIN ON BECKMAN COULTER ANALYSERS.,DAU NEGATIVE CALIBRATOR(DAU NEGATIVE CALIBRATOR)-THE DAU NEGATIVE CALIBRATOR IS A HUMAN URINE BASED LIQUID CALIBRATOR INTENDED TO BE USED WITH DAU REAGENTS LISTED IN THE TABLE BELOW FOR THE SEMI-QUANTITATIVE DETERMINATION OF DRUGS OF ABUSE IN HUMAN URINE ON BECKMAN COULTER ANALYSERS., AMPHETAMINES/ECSTASY(AMPHETAMINES/ECSTASY)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND SEMI-QUANTITATIVE ASSAY OF AMPHETAMINES AND ECSTASY IN HUMAN URINE ON BECKMAN COULTER AU ANALYSERS.,VALPROIC ACID(VALPROIC ACID)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VALPROIC ACID IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS,DIGOXIN (DIGOXIN)-IMMUNO-INHIBITION TEST FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN IN HUMAN SERUM ON BECKMAN COULTER ANALYSERS,GENTAMYCIN(GENTAMYCIN)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GENTAMYCIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS,BARBITURATES(BARBITURATES)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND SEMI-QUANTITATIVE ASSAY OF BARBITURATE IN HUMAN URINE ON BECKMAN COULTER AU ANALYSERS. THE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS

	SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.1 CLINICAL CONSIDERATION AND PROFESSIONAL JUDGEMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN USING A PRELIMINARY POSITIVE RESULT.,METHADONE(METHADONE)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND SEMI-QUANTITATIVE ASSAY OF METHADONE IN HUMAN URINE ON BECKMAN COULTER AU ANALYSERS.,DAU THC 100 CALIBRATOR(DAU THC 100 CALIBRATOR)-THE DAU THC CALIBRATORS ARE HUMAN URINE BASED LIQUID CALIBRATORS INTENDED TO BE USED WITH THE THC REAGENT OSR6322 FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF THC IN HUMAN URINE ON BECKMAN COULTER ANALYSERS.,EDDP(EDDP)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND SEMI-QUANTITATIVE ASSAY OF EDDP (2-ETHYLIDINE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE) IN HUMAN URINE ON BECKMAN COULTER AU ANALYSERS,BENZODIAZEPINES (BENZODIAZEPINES)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND SEMI-QUANTITATIVE ASSAY OF BENZODIAZEPINES IN HUMAN URINE ON BECKMAN COULTER AU ANALYSERS,DIGITOXIN(DIGITOXIN)-IMMUNO-INHIBITION TEST FOR THE QUANTITATIVE DETERMINATION OF DIGITOXIN IN HUMAN SERUM ON BECKMAN COULTER ANALYSERS,COCAINE(COCAINE)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND SEMI-QUANTITATIVE ASSAY OF THE COCAINE METABOLITE BENZOYLECGONINE IN HUMAN URINE ON BECKMAN COULTER AU ANALYSERS,PHENYTOIN(PHENYTOIN)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PHENYTOIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,DAU THC 75 CALIBRATOR(DAU THC 75 CALIBRATOR)-THE DAU THC CALIBRATORS ARE HUMAN URINE BASED LIQUID CALIBRATORS INTENDED TO BE USED WITH THE THC REAGENT OSR6322 FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF THC IN HUMAN URINE ON BECKMAN COULTER ANALYSERS.,DAU HIGH MULTI-DRUG CALIBRATOR(DAU HIGH MULTI-DRUG CALIBRATOR)-THE DAU MULTI-DRUG CALIBRATORS ARE HUMAN URINE BASED LIQUID CALIBRATORS INTENDED TO BE USED WITH DAU REAGENTS LISTED IN THE TABLE BELOW FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF DRUGS OF ABUSE IN HUMAN URINE ON BECKMAN COULTER ANALYSERS., DAU SPECIALITY CONTROL(DAU SPECIALITY CONTROL)-THE DAU SPECIALITY CONTROL IS A HUMAN URINE BASED LIQUID CONTROL DESIGNED TO MONITOR THE ANALYTICAL PERFORMANCE OF THE DAU REAGENTS ON BECKMAN COULTER ANALYSERS.,DAU THC 50 CALIBRATOR(DAU THC 50 CALIBRATOR)-THE DAU THC

	CALIBRATORS ARE HUMAN URINE BASED LIQUID CALIBRATORS INTENDED TO BE USED WITH THE THC REAGENT OSR6322 FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF THC IN HUMAN URINE ON BECKMAN COULTER ANALYSERS.,THEOPHYLLINE (THEOPHYLLINE)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THEOPHYLLINE IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS,DAU METHADONE HIGH CALIBRATOR(DAU METHADONE HIGH CALIBRATOR)-THE DAU METHADONE CALIBRATORS ARE HUMAN URINE BASED LIQUID CALIBRATORS INTENDED TO BE USED WITH THE METHADONE REAGENT OSR6319 FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF METHADONE IN HUMAN URINE ON BECKMAN COULTER ANALYSERS.,DAU INTERMEDIATE MULTI-DRUG CALIBRATOR(DAU INTERMEDIATE MULTI-DRUG CALIBRATOR)-THE DAU MULTI-DRUG CALIBRATORS ARE HUMAN URINE BASED LIQUID CALIBRATORS INTENDED TO BE USED WITH DAU REAGENTS LISTED IN THE TABLE BELOW FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF DRUGS OF ABUSE IN HUMAN URINE ON BECKMAN COULTER ANALYSERS.,DAU SECONDARY CUT-OFF MULTI-DRUG CALIBRATOR(DAU SECONDARY CUT-OFF MULTI-DRUG CALIBRATOR)-THE DAU MULTI-DRUG CALIBRATORS ARE HUMAN URINE BASED LIQUID CALIBRATORS INTENDED TO BE USED WITH DAU REAGENTS LISTED IN THE TABLE BELOW FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF DRUGS OF ABUSE IN HUMAN URINE ON BECKMAN COULTER ANALYSERS, CARBAMAZEPINE(CARBAMAZEPINE)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CARBAMAZEPINE IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,DIGITOXIN CALIBRATOR(DIGITOXIN CALIBRATOR)-THE DIGITOXIN CALIBRATOR IS A LIQUID HUMAN SERUM BASED MATRIX CALIBRATOR INTENDED TO BE USED WITH THE DIGITOXIN REAGENT OSR6403 FOR THE QUANTITATIVE DETERMINATION OF DIGITOXIN ON BECKMAN COULTER ANALYSERS., DAU METHADONE CUT-OFF CALIBRATOR(DAU METHADONE CUT-OFF CALIBRATOR)-THE DAU METHADONE CALIBRATORS ARE HUMAN URINE BASED LIQUID CALIBRATORS INTENDED TO BE USED WITH THE METHADONE REAGENT OSR6319 FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF METHADONE IN HUMAN URINE ON BECKMAN COULTER ANALYSERS.,DAU PRIMARY CUT-OFF MULTI-DRUG CALIBRATOR(DAU PRIMARY CUT-OFF MULTI-DRUG CALIBRATOR)-THE DAU MULTI-DRUG CALIBRATORS ARE HUMAN URINE BASED LIQUID CALIBRATORS INTENDED TO BE USED WITH DAU REAGENTS FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF DRUGS OF ABUSE IN HUMAN URINE ON

	BECKMAN COULTER ANALYSERS,DAU MULTI-DRUG CONTROL(DAU MULTI-DRUG CONTROL)-THE DAU MULTI-DRUG CONTROL IS A HUMAN URINE BASED LIQUID CONTROL DESIGNED TO MONITOR THE ANALYTICAL PERFORMANCE OF THE DAU REAGENTS LISTED IN THE TABLE BELOW ON BECKMAN COULTER ANALYSERS.,DAU THC 50 CONTROL(DAU THC 50 CONTROL)-THE DAU THC CONTROLS ARE HUMAN URINE BASED LIQUID CONTROLS DESIGNED TO MONITOR THE ANALYTICAL PREFORMANCE OF THE THC REAGENT OSR6322 ON BECKMAN COULTER ANALYSERS.,THC(THC)-HOMOGENEOUS ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND SEMI-QUANTITATIVE ASSAY OF CANNABINOIDS (THC) IN HUMAN URINE ON BECKMAN COULTER AU ANALYSERS.,DAU METHADONE INTERMEDIATE CALIBRATOR(DAU METHADONE INTERMEDIATE CALIBRATOR)-THE DAU METHADONE CALIBRATORS ARE HUMAN URINE BASED LIQUID CALIBRATORS INTENDED TO BE USED WITH THE METHADONE REAGENT OSR6319 FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF METHADONE IN HUMAN URINE ON BECKMAN COULTER ANALYSERS.,DAU THC 25 CALIBRATOR(DAU THC 25 CALIBRATOR)-THE DAU THC CALIBRATORS ARE HUMAN URINE BASED LIQUID CALIBRATORS INTENDED TO BE USED WITH THE THC REAGENT OSR6322 FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF THC IN HUMAN URINE ON BECKMAN COULTER ANALYSERS,DAU THC 25 CONTROLS(DAU THC 25 CONTROLS)-THE DAU THC CONTROLS ARE HUMAN URINE BASED LIQUID CONTROLS DESIGNED TO MONITOR THE ANALYTICAL PREFORMANCE OF THE THC REAGENT OSR6322 ON BECKMAN COULTER ANALYSERS.,DIGOXIN CALIBRATOR(DIGOXIN CALIBRATOR) -THE DIGOXIN CALIBRATOR IS A LIQUID HUMAN SERUM BASED MATRIX CALIBRATOR INTENDED TO BE USED WITH THE DIGOXIN REAGENT OSR6404 FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN ON BECKMAN COULTER ANALYSERS.

411	IMP/IVD/2019/000448	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:H 560 DIL 5 P(H 560 DIFF 5 P)-H 560 DIL 5 P DILUENT IS A BUFFERED, STABILIZED AND MICROFILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN (HGB) CONCENTRATION ON H 560 HEMATOLOGY ANALYZERS.,H 560 DIFF 5 P(H 560 DIFF 5 P)-H 560 DIFF 5 P LYSING REAGENT IS A STABILIZED AND MICRO-FILTERED REAGENT FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC) AND LEUKOCYTE 5-PART DIFFERENTIATION (LYM, MONO, NEU, EO, BA) MEASUREMENT IN HUMAN BLOOD ON H 560 HEMATOLOGY ANALYZERS,H 560 HEMO CONTROL KIT(H 560 HEMO CONTROL KIT)-H 560 HEMO CONTROL KIT IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS.,H 560 HEMO CONTROL NORMAL(H 560 HEMO CONTROL NORMAL)-H 560 HEMO CONTROL NORMAL IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS,H 560 HEMO CONTROL LOW(H 560 HEMO CONTROL LOW)-H 560 HEMO CONTROL LOW IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.,H 3P REAGENT SMART PACK(H 3P REAGENT SMART PACK)-H 3P REAGENT SMART PACK WBC-3-DIFF REAGENT SET IS A REAGENT SET FOR COUNTING OF ERYTHTROCYTES (RBC), PLATELETS (PLT), FOR HAEMOGLOBIN (HGB) MEASUREMENT, AND FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE 3-PART DIFFERENTIATION (LYM, MID, GRA) IN HUMAN BLOOD ON AQUILA/ A60 HEMATOLOGY ANALYZERS.,H 380 DIL 3P(H 380 DIL 3P)-H 380 DIL 3P DILUENT IS A BUFFERED, STABILIZED AND MICROFILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN (HGB) CONCENTRATION ON H 380 HEMATOLOGY ANALYZERS.,H 380 CLEANER(H 380 CLEANER)-H 380 CLEANER CLEANING REAGENT IS A STABILIZED AND MICRO- FILTERED DETERGENT SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT

	PRECIPITATES AND LIPOPROTEIN DEPOSITS ON H 380 HEMATOLOGY ANALYZERS.,H 380 HEMO CONTROL HIGH(H 380 HEMO CONTROL HIGH)-H 380 HEMO CONTROL HIGH IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS,H 560 LYSE 5 P(H 560 LYSE 5 P)-H 560 LYSE 5 PLYSING REAGENT IS A STABILIZED AND MICROFILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE 5-PART DIFFERENTIATION (LYM, MONO, NEU, EO, BA) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON H 560 HEMATOLOGY ANALYZERS,H 380 HEMO CONTROL KIT(H 380 HEMO CONTROL KIT)-H 380 HEMO CONTROL KIT IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.,H 560 HEMO CONTROL HIGH(H 560 HEMO CONTROL HIGH)-H 560 HEMO CONTROL HIGH IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS,H 380 HEMO CONTROL LOW(H 380 HEMO CONTROL LOW)-H 380 HEMO CONTROL LOW IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS,H HYPOCLEAN(H HYPOCLEAN)-H HYPOCLEAN HYPOCHLORITE CLEANING CONCENTRATE IS A STABILIZED AND MICRO-FILTERED HYPOCHLORITE SOLUTION FOR INTENSIVE OXIDATIVE CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON H 560 / H 380 HEMATOLOGY ANALYZERS.,H 380 HEMO CONTROL NORMAL(H 380 HEMO CONTROL NORMAL)-H 380 HEMO CONTROL NORMAL IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS,H 380 LYSE DIFF 3 P(H 380 LYSE DIFF 3 P)-H 380 LYSE DIFF 3 P LYSING REAGENT IS A STABILIZED AND MICRO- FILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE THREE-PART DIFFERENTIATION (LYM, MID, GRAN) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON H 380 HEMATOLOGY ANALYZERS.,H HEMO CALIBRATOR(H HEMO CALIBRATOR)-H HEMO CALIBRATOR IS DESIGNED FOR USE IN THE CALIBRATION OF HEMATOLOGY ANALYZERS

412	IMP/IVD/2019/000449	1.License Holder Name: RAGOK MEDICARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ONE STEP METHAMPHETAMINE URINE TEST(WONDFO)-QUALITATIVE DETECTION OF METHAMPHETAMINE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL,ONE STEP MARIJUANA URINE TEST(WONDFO)-QUALITATIVE DETECTION OF MARIJUANA AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL ,ONE STEP PROPOXYPHENE URINE TEST(WONDFO)-QUALITATIVE DETECTION OF PROPOXYPHENE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL,ONE STEP MORPHINE URINE TEST(WONDFO)-QUALITATIVE DETECTION OF MORPHINE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL,ONE STEP OXYCODONE URINE TEST(WONDFO)-QUALITATIVE DETECTION OF OXYCODONE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL,ONE STEP MULTI-DRUG URINE T-CUP (+ ADULTERATION AND TEMPERATURE CONTROL)(WONDFO)-WONDFO ONE STEP MULTI-DRUG URINE T-CUP IS RAPID URINE SCREENING TEST. THE TEST IS A LATERAL FLOW, ONE-STEP IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC DRUGS AND THEIR METABOLITES IN HUMAN URINE,ONE STEP MULTI DRUG URINE TEST PANEL(WONDFO)-WONDFO ONE STEP MULTI-DRUG URINE TEST PANEL IS CONSISTED OF INDIVIDUAL ONE-STEP IMMUNOASSAYS. THE TEST IS A LATERAL FLOW, ONE-STEP IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC DRUGS AND THEIR METABOLITES IN HUMAN URINE,ONE STEP OPIATE URINE TEST(WONDFO)-QUALITATIVE DETECTION OF OPIATE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL (300 NG/ML, 2000 NG/ML),ONE STEP AMPHETAMINE URINE TEST(WONDFO)-QUALITATIVE DETECTION OF AMPHETAMINE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,ONE STEP BENZODIAZEPINES URINE TEST(WONDFO)-QUALITATIVE DETECTION OF BENZODIAZEPINES AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL,ONE STEP BARBITURATES URINE TEST(WONDFO)-QUALITATIVE DETECTION OF BARBITURATES AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL.,ONE STEP BUPRENORPHINE URINE TEST(WONDFO)-QUALITATIVE DETECTION OF BUPRENORPHINE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL,ONE STEP TRAMADOL URINE TEST(WONDFO)-THE WONDFO ONE STEP TRAMADOL URINE TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE DETECTION OF TRAMADOL IN HUMAN URINE AT THE CUT-OFF

	CONCENTRATION OF 1000 NG/ML.,ONE STEP COCAINE URINE TEST (WONDFO)-QUALITATIVE DETECTION OF COCAINE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL,ONE STEP COTININE URINE TEST(WONDFO)-QUALITATIVE DETECTION OF COTININE AND ITS PRINCIPAL METABOLITES IN HUMAN URINE AT SPECIFIED CUT-OFF LEVEL

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

413	IMP/IVD/2019/000450	1.License Holder Name: BIOMERIEUX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREGNANCY ASSOCIATED PLASMA PROTEIN A ASSAY KIT(HYBIOME)-FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF PREGNANCY ASSOCIATED PLASMA PROTEIN A IN HUMAN SERUM.,ANTI-CYCLIC CITRULLINATED PEPTIDE ANTIBODY ASSAY KIT(HYBIOME)-FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CALCITONIN IN HUMAN SERUM.,COLLAGEN TYPE IV ASSAY KIT(HYBIOME)-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF COLLAGEN TYPE IV (C) IN HUMAN SERUM,PROCOLLAGEN III N-TERMINAL PEPTIDE ASSAY KIT (HYBIOME)-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PROCOLLAGEN N-TERMINAL PEPTIDEP NPIN HUMAN SERUM., CHOLYLGLYCINE ASSAY KIT(HYBIOME)-FOR QUANTATIVE MEASUREMENT OF CHOLYLGLYCINE IN HUMAN SERUM.,N TERMINAL PEPTIDE BONE GAMMA-CARBOXYGLUTAMIC ACID-CONTAINING PROTEINS ASSAY KIT(HYBIOME)-FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF N-BGP IN HUMAN SERUM,ANTI-DOUBLESTRANDED DEOXYRIBONUCLEIC ACID ANTIBODY ASSAY KIT (HYBIOME)-FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ANTI-DOUBLESTRANDED DEOXYRIBONUCLEIC ACID ANTIBODY (ANTI-DSDNA) IN HUMAN SERUM.,ANTI-MYELOPEROXIDASE ASSAY KIT(HYBIOME)-FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ANTI-MYELOPEROXIDASE ANTIBODIES IN HUMAN SERUM,HYALURONIC ACID ASSAY KIT (HYBIOME)-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HYALURONIC ACIDHAIN HUMAN SERUM,LAMININ ASSAY KIT (HYBIOME)-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF LAMININLN IN HUMAN SERUM,INSULIN ASSAY KIT(HYBIOME)-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF INSULIN (INS) IN HUMAN SERUM.,THE MB ISOENZYME OF CREATINE KINASE ASSAY KIT (HYBIOME)-FOR IN-VITRO QUANTITATIVE DETERMINATION OF THE MB ISOENZYME OF CREATINE KINASE (CK-MB) IN HUMAN SERUM,C-PEPTIDE ASSAY KIT(HYBIOME)-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF C- PEPTIDE (C-P) IN HUMAN SERUM.,ANTI-PROTEINASE 3 ASSAY KIT(HYBIOME)-FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ANTI-PR3 IN HUMAN SERUM., HUMAN CHORIONIC GONADOTROPIN ASSAY KIT(HUMAN CHORIONIC GONADOTROPIN ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN HUMAN SERUM.,THYROGLOBULIN ASSAY KIT(THYROGLOBULIN ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) IN HUMAN SERUM.,THYROXINE ASSAY KIT(THYROXINE ASSAY KIT)-

	IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETECTION OF TOTAL THYROXINE (T4) IN HUMAN SERUM.,PROGESTERONE ASSAY KIT (PROGESTERONE ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PROGESTERONEPIN HUMAN SERUM.,THYROID STIMULATING HORMONE ASSAY KIT(THYROID STIMULATING HORMONE ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM.,FREE TRIIODOTHYRONINE ASSAY KIT(FREE TRIIODOTHYRONINE ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETECTION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM.,FREE THYROXINE ASSAY KIT(FREE THYROXINE ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETECTION OF FREE THYROXINE (FT4) IN HUMAN SERUM.,TESTOSTERONE ASSAY KIT(TESTOSTERONE ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TESTOSTERONE (T) IN HUMAN SERUM.,PARATHYROID HORMONE ASSAY KIT(PARATHYROID HORMONE ASSAY KIT)-FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF PARATHYROID HORMONE IN HUMAN SERUM,ESTRADIOL ASSAY KIT (ESTRADIOL ASSAY KIT)-IMMUNOASSAY FOR THE IN-VITRO QUANTITATIVE DETERMINATION OF ESTRADIOL (E2) IN HUMAN SERUM.,LUTEINIZING HORMONE ASSAY KIT(LUTEINIZING HORMONE ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM., PROLACTIN ASSAY KIT(PROLACTIN ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN HUMAN SERUM.,HUMAN CHORIONIC GONADOTROPHIN B-SUBUNIT ASSAY KIT(HUMAN CHORIONIC GONADOTROPIN ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CHORIONIC GONADOTROPIN -SUBUNIT-HCGIN HUMAN SERUM.,FERRITIN ASSAY KIT(FERRITIN ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FERRITIN (FER) IN HUMAN SERUM.,25-OH VITAMIN D ASSAY KIT(25-OH VITAMIN D ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D25-OH VDIN HUMAN SERUM., SUBSTRATE SOLUTION(SUBSTRATE SOLUTION)-THIS REAGENT IS DESIGNED TO WORK TOGETHER WITH MANY OTHER REAGENTS (SUCH AS PRIMARY ANTIBODY, SECONDARY ANTIBODY, STANDARD SUBSTANCE, AND STOPPING SOLUTION E.G.), SO AS TO COMPLETE IN VITRO TEST BASED ON IMMUNITY PRINCIPLE.,SAMPLE DILUENT (SAMPLE DILUENT)-USED FOR THE DILUTING OR LIQUEFYING OF SPECIMEN TO BE DETECTED, SO THAT THE SPECIMEN COULD BE MEASURED BY ON THE EQUIPMENT.,CLEANING SOLUTION(CLEANING SOLUTION)-FOR THE CLEANING OF REACTION SYSTEM DURING THE

	INSPECTION PROCESS, SO AS TO PERFORM IN VITRO TEST ON THE SUBSTANCE BEING TESTED.,FOLLICLE STIMULATING HORMONE ASSAY KIT(FOLLICLE STIMULATING HORMONE ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONEFSHIN HUMAN SERUM.,IGM ANTIBODY TO HEPATITIS E VIRUS ASSAY KIT(IGM ANTIBODY TO HEPATITIS E VIRUS ASSAY KIT)-FOR QUALITATIVE MEASUREMENT OF IGM ANTIBODIES TO HEPATITIS E VIRUS IN HUMAN SERUM (PLASMA)., IGG ANTIBODY TO HEPATITIS E VIRUS ASSAY KIT(IGG ANTIBODY TO HEPATITIS E VIRUS ASSAY KIT)-FOR QUALITATIVE MEASUREMENT OF IGG ANTIBODIES TO HEPATITIS E VIRUS IN HUMAN SERUM (PLASMA)., TRIIODOTHYRONINE ASSAY KIT(TRIIODOTHYRONINE ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETECTION OF THE TOTAL TRIIODOTHYRONINE (T3) IN HUMAN SERUM.,ANTIBODY TO THYROID PEROXIDASE ASSAY KIT(ANTIBODY TO THYROID PEROXIDASE ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETECTION OF ANTIBODY TO THYROID PEROXIDASE (ANTI-TPO) IN HUMAN SERUM.,ANTIBODY TO THYROGLOBULIN (ANTI-TG) ASSAY KIT(ANTIBODY TO THYROGLOBULIN (ANTI-TG) ASSAY KIT)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETECTION OF ANTIBODY TO THYROGLOBULIN (ANTI-TG) IN HUMAN SERUM.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

414	IMP/IVD/2019/000452	1.License Holder Name: RAPHA DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REAGENT STRIPS FOR URINALYSIS (DIRUI 5 ITEMS)-DIRUI 5 ITEMS REAGENT STRIPS FOR URINALYSIS ARE MADE FOR URINALYSIS OF BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. IT IS USED FOR QUALITATIVE AND SEMI-QUANTITATIVE TEST OF GLUCOSE, PH , PROTEIN, KETONE AND BLOOD IN URINE. THE STRIPS ARE FOR PROFESSIONAL USE ONLY., REAGENT STRIPS FOR URINALYSIS(DIRUI H11-MA)-DIRUI H11-MA REAGENT STRIPS FOR URINALYSIS ARE MADE FOR URINALYSIS OF BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. IT IS USED FOR QUALITATIVE AND SEMI-QUANTITATIVE TEST OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUCOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH & MICROALBUMIN IN URINE. THE STRIPS ARE FOR PROFESSIONAL USE ONLY. DIRUI H11-MA REAGENT STRIPS FOR URINALYSIS CAN BE READ VISUALLY AND INSTRUMENTALLY USING H-50, H-100, H-300 & H-500 URINE ANALYZERS, WHICH IS ALSO MANUFACTURED BY M/S. DIRUI INDUSTRIAL CO. LTD.,REAGENT STRIPS FOR URINALYSIS(DIRUI 2 ITEMS (GLU, KET))-DIRUI 2 ITEMS (GLU, KET) REAGENT STRIPS FOR URINALYSIS ARE MADE FOR URINALYSIS OF BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. IT IS USED FOR QUALITATIVE AND SEMI-QUANTITATIVE TEST OF GLUCOSE & KETONE IN URINE. THE STRIPS ARE FOR PROFESSIONAL USE ONLY.,REAGENT STRIPS FOR URINALYSIS (DIRUI 2 ITEMS (PRO, GLU))-DIRUI 2 ITEMS (PRO, GLU) REAGENT STRIPS FOR URINALYSIS ARE MADE FOR URINALYSIS OF BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. IT IS USED FOR QUALITATIVE AND SEMI-QUANTITATIVE TEST OF GLUCOSE & PROTEIN IN URINE. THE STRIPS ARE FOR PROFESSIONAL USE ONLY. , REAGENT STRIPS FOR URINALYSIS (DIRUI 4 ITEMS)-DIRUI 4 ITEMS REAGENT STRIPS FOR URINALYSIS ARE MADE FOR URINALYSIS OF BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. IT IS USED FOR QUALITATIVE AND SEMI-QUANTITATIVE TEST OF GLUCOSE, PH , SPECIFIC GRAVITY AND PROTEIN IN URINE. THE STRIPS ARE FOR PROFESSIONAL USE ONLY. , REAGENT STRIPS FOR URINALYSIS (DIRUI 1 ITEM (GLU))-DIRUI 1 ITEM (GLU) REAGENT STRIPS FOR URINALYSIS ARE MADE FOR URINALYSIS OF BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. IT IS USED FOR QUALITATIVE AND SEMI-QUANTITATIVE TEST OF GLUCOSE IN URINE. THE STRIPS ARE FOR PROFESSIONAL USE ONLY. ,REAGENT STRIPS FOR

	URINALYSIS (DIRUI A10)-DIRUI A10 REAGENT STRIPS FOR URINALYSIS ARE MADE FOR URINALYSIS OF BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. IT IS USED FOR QUALITATIVE AND SEMI-QUANTITATIVE TEST OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUCOCYTES, GLUCOSE, SPECIFIC GRAVITY AND PH IN URINE. THE STRIPS ARE FOR PROFESSIONAL USE ONLY. , REAGENT STRIPS FOR URINALYSIS (DIRUI H10)-DIRUI H10 REAGENT STRIPS FOR URINALYSIS ARE MADE FOR URINALYSIS OF BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. IT IS USED FOR QUALITATIVE AND SEMI-QUANTITATIVE TEST OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUCOCYTES, GLUCOSE, SPECIFIC GRAVITY AND PH IN URINE. THE STRIPS ARE FOR PROFESSIONAL USE ONLY. DIRUI H10 REAGENT STRIPS FOR URINALYSIS CAN BE READ VISUALLY AND INSTRUMENTALLY USING H-50, H-100, H-300 & H-500 URINE ANALYZERS, WHICH IS ALSO MANUFACTURED BY M/S. DIRUI INDUSTRIAL CO. LTD. ,REAGENT STRIPS FOR URINALYSIS (DIRUI 8 ITEMS)-DIRUI 8 ITEMS REAGENT STRIPS FOR URINALYSIS ARE MADE FOR URINALYSIS OF BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. IT IS USED FOR QUALITATIVE AND SEMI-QUANTITATIVE TEST OF UROBILINOGEN, PROTEIN, PH , BLOOD, SPECIFIC GRAVITY, KETONE, BILRUBIN & GLUCOSE IN URINE. THE STRIPS ARE FOR PROFESSIONAL USE ONLY.

CENTRAL DRUG STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

415	IMP/IVD/2019/000453	1.License Holder Name: INSTRUMENTATION LABORATORY INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOSIL FDP(HEMOSIL)-AUTOMATED LATEX ENHANCED IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FIBRIN(OGEN) DEGRADATION PRODUCTS (FDP) IN HUMAN CITRATED PLASMA ON ACL TOP® FAMILY SYSTEMS.,HEMOSIL HIT-AB (PF4-H)(HEMOSIL)- FULLY AUOTOMATED LATEX ENHANCED IMMUNOASSAY FOR THE SEMI-QUANTITATIVE DETECTION OF TOTAL IMMUNOGLOBULIN IN HUMAN CITRATED PLASMA THAT REACTS WITH PLATLET FACTOR 4(PF4) WHEN COMPLEXED WITH TO HEPARIN ON THE ACL TOP FAMILY. HEPARIN ASSOCIATED ANTIBODIES ARE COMMONLY FOUND IN PATIENTS WITH HEPARIN INDUCED THROMBOCYTOPENIA OR THROMBOSIS (HIT).,HEMOSIL ACUSTAR - VON WILLEBRAND FACTOR COLLAGEN BINDING ACTIVITY(HEMOSIL)-THE HEMOSIL ACUSTAR VON WILLEBRAND FACTORCOLLAGEN BINDING ACTIVITY ASSAY (HEMOSIL ACUSTAR VWF : CB) IS A FULLY AUTOMATED CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VON WILLEBRAND FACTOR COLLAGEN BINDING ACTIVITY IN HUMAN CITRATED PLASMA ON THE ACL ACUSTAR. THE HEMOSIL ACUSTAR VWF:CB ASSAY IS INDICATED FOR USE ON PATIENTS WHO ARE SUSPECTED OF HAVING VON WILLEBRAND DISEASE (VWD).

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

416	IMP/IVD/2019/000454	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLEARLLAB CONTROL CELLS NORMAL(CLEARLLAB CONTROL CELLS NORMAL)-CLEARLLAB CONTROL CELLS NORMAL AND CLEARLLAB CONTROL CELLS ABNORMAL ARE STABILIZED PREPARATIONS OF ASSAYED, LYSABLE WHOLE BLOOD INTENDED AS PROCESS CONTROLS FOR THE VERIFICATION OF THE CLEARLLAB 10C PANELS ON THE NAVIOS AND NAVIOS EX FLOW CYTOMETERS. PARAMETERS ASSAYED INCLUDE: KAPPA, LAMBDA, CD5, CD200, CD38, CD20, CD19, CD45, TCR, CD4, CD2, CD56, CD3, CD7, CD8, CD16, CD10, CD13, CD64, CD14, HLA-DR, CD11B, CD15, CD33, CD34, CD117, AND CD123. THEY PROVIDE POSITIVE CELL CONTROLS THAT ARE PROCESSED IN THE SAME MANNER AS A WHOLE BLOOD SAMPLE. THIS ALLOWS VERIFICATION OF REAGENT PERFORMANCE AND THE METHODS USED FOR STAINING TARGETED CELLS, LYSING ERYTHROCYTES, AND ANALYZING SAMPLES WITH FLOW CYTOMETRY,CLEARLLAB CONTROL CELLS ABNORMAL (CLEARLLAB CONTROL CELLS ABNORMAL)-CLEARLLAB CONTROL CELLS NORMAL AND CLEARLLAB CONTROL CELLS ABNORMAL ARE STABILIZED PREPARATIONS OF ASSAYED, LYSABLE WHOLE BLOOD INTENDED AS PROCESS CONTROLS FOR THE VERIFICATION OF THE CLEARLLAB 10C PANELS ON THE NAVIOS AND NAVIOS EX FLOW CYTOMETERS. PARAMETERS ASSAYED INCLUDE: KAPPA, LAMBDA, CD5, CD200, CD38, CD20, CD19, CD45, TCR, CD4, CD2, CD56, CD3, CD7, CD8, CD16, CD10, CD13, CD64, CD14, HLA-DR, CD11B, CD15, CD33, CD34, CD117, AND CD123. THEY PROVIDE POSITIVE CELL CONTROLS THAT ARE PROCESSED IN THE SAME MANNER AS A WHOLE BLOOD SAMPLE. THIS ALLOWS VERIFICATION OF REAGENT PERFORMANCE AND THE METHODS USED FOR STAINING TARGETED CELLS, LYSING ERYTHROCYTES, AND ANALYZING SAMPLES WITH FLOW CYTOMETRY

417	IMP/IVD/2019/000457	1.License Holder Name: IMMUCOR INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SSO TYPING KIT [628927] (IMMUCOR)-DNA TYPING OF CLASS I AND CLASS II HLA ALLIES, TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR AND RECIPIENT MATCHING.,SSO TYPING KIT [628921(IMMUCOR)-DNA TYPING OF CLASS I AND CLASS II HLA ALLIES, TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR AND RECIPIENT MATCHING.,SSO TYPING KIT [628923](IMMUCOR)-DNA TYPING OF CLASS I AND CLASS II HLA ALLIES, TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR AND RECIPIENT MATCHING.,SSO TYPING KIT [628930](IMMUCOR)-DNA TYPING OF CLASS I AND CLASS II HLA ALLIES, TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR AND RECIPIENT MATCHING.,SSO TYPING KIT [628911](IMMUCOR)-DNA TYPING OF CLASS I AND CLASS II HLA ALLIES, TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR AND RECIPIENT MATCHING.,SSO TYPING KIT [628915](IMMUCOR)-DNA TYPING OF CLASS I AND CLASS II HLA ALLIES, TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR AND RECIPIENT MATCHING.,SSO TYPING KIT [628075](IMMUCOR)-DNA TYPING OF CLASS I AND CLASS II HLA ALLIES, TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR AND RECIPIENT MATCHING.,SSO TYPING KIT [628511](IMMUCOR)-DNA TYPING OF CLASS I AND CLASS II HLA ALLIES, TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR AND RECIPIENT MATCHING.,ANTIBODY KIT(LIFECODES CLASS I ID)-LIFECODES CLASS I ID IS A BEAD-BASED IMMUNOASSAY USED TO QUALITATIVELY DETECT PANEL REACTIVE HLA IGG ANTIBODIES (PRA).,ANTIBODY KIT (LIFECODES CLASS II IDV2)-LIFECODES CLASS II IDV2 IS A BEAD-BASED IMMUNOASSAY USED TO QUALITATIVELY DETECT PANEL REACTIVE HLA IGG ANTIBODIES (PRA).,ANTIBODY KIT(LIFECODES LIFESCREEN DELUXE)-LIFECODES LIFESCREEN DELUXE IS A QUALITATIVE BEAD-BASED IMMUNOASSAY USED TO DETECT IGG ANTIBODIES TO HLA CLASS I AND CLASS II MOLECULES.
418	IMP/IVD/2019/000458	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PIMA CD4 (CARTRIDGE) (PIMA CD4 (CARTRIDGE))-PIMA CD4 IS AN AUTOMATED, IMAGE-BASED, IMMUNE HAEMATOLOGY TEST INTENDED FOR THE RAPID IN VITRO QUANTITATIVE MEASUREMENT OF CDG+/CD++ T CELLS (T-HELPER CELLS) IN CAPILLARY OR VENOUS WHOLE BLOOD

419	IMP/IVD/2019/000459	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AMYL2(AMYL2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF AMYLASE IN HUMAN SERUM, PLASMA AND URINE.,NAOHD(NAOHD)-WASH SOLUTION FOR REAGENT PROBES AND REACTION CELLS.,LDHI2 (LDHI2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE IN HUMAN SERUM AND PLASMA.,CREJ2 (CREJ2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE.,MG2(MG2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM, PLASMA AND URINE.,SI2(SI2)-IN VITRO TEST FOR THE SEMI-QUANTITATIVE DETERMINATION OF THE LIPEMIA INDEX, HEMOLYSIS INDEX AND ICTERUS INDEX IN HUMAN SERUM AND PLASMA.,GGT-2(GGT-2)-N VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF GLUTAMYLTRANSFERASE (GGT) IN HUMAN SERUM AND PLASMA.,ECO-D(ECO-D)-ECOTERGENT IS AN ADDITIVE TO THE REACTION BATH TO REDUCE SURFACE TENSION.,CHE2(CHE2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CHOLINESTERASE IN HUMAN SERUM AND PLASMA.,SMS(SMS)-WASH SOLUTION FOR REAGENT PROBES AND REACTION CELLS.,HBDH2(HBDH2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF HYDROXYBUTYRATE DEHYDROGENASE (HBDH) IN SERUM AND PLASMA.,BILD2(BILD2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN SERUM AND PLASMA.,ALP2(ALP2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM AND PLASMA.,IRON2(IRON2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM AND PLASMA.,TRSF2(TRSF2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TRANSFERRIN IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS. ,LDLC3(LDLC3)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LDL-CHOLESTEROL IN HUMAN SERUM AND PLASMA.,UA2(UA2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA AND URINE ON ROCHE/HITACHI COBAS C SYSTEMS. ,CK(CK)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE (CK) IN HUMAN SERUM AND PLASMA.,UREAL(UREAL)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF UREA/UREA NITROGEN IN HUMAN SERUM, PLASMA AND URINE ON ROCHE/HITACHI COBAS C SYSTEMS.,APOBT (APOBT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN B IN HUMAN SERUM AND PLASMA.,FRA(FRA)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF GLYCATED

	PROTEINS (FRUCTOSAMINE) IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS. ,CA2(CA2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA AND URINE.,GLUC3(GLUC3)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM, PLASMA, URINE AND CSF ON ROCHE/HITACHI COBAS C SYSTEMS. ,APOAT(APOAT)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A1 IN HUMAN SERUM AND PLASMA.,TRIGL(TRIGL)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS. ,PREA(PREA)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF PREALBUMIN IN HUMAN SERUM AND PLASMA.,CHOL2(CHOL2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,PHOS2 (PHOS2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF PHOSPHORUS IN HUMAN SERUM, PLASMA AND URINE.,TP2(TP2)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM AND PLASMA ON ROCHE/HITACHI COBAS C SYSTEMS.,NACL(NACL)-DILUENT NACL 9 % IS USED AS A SAMPLE DILUENT IN CONJUNCTION WITH ASSAY REAGENTS.,ELECSYS PROLACTIN II(ELECSYS PROLACTIN II)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM AND PLASMA. THE ELECTROCHEMILUMINESCENCE IMMUNOASSAY “ECLIA” IS INTENDED FOR USE ON ELECSYS AND COBAS E IMMUNOASSAY ANALYZERS. ,HDLC4(HDLC4)-IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF THE HDLCHOLESTEROL CONCENTRATION IN HUMAN SERUM AND PLASMA.,CO2-L(CO2-L)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BICARBONATE (HCO3-) IN HUMAN SERUM AND PLASMA.

420	IMP/IVD/2019/000460	1.License Holder Name: PAMED SERVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FREE TESTOSTERONE ELISA(DIAMETRA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. SECOND GENERATION KIT FREE TESTOSTERONE ELISA KIT INTENDED FOR LABORATORY USE ONLY.,CORTISOL SALIVA ELISA(DIAMETRA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF CORTISOL CONCENTRATION IN SALIVA. CORTISOL SALIVA ELISA KIT INTENDED FOR LABORATORY USE ONLY.,ANTI TISSUE TRANSGLUTAMINASE IGA(DIAMETRA)-INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) KIT DESIGNED FOR THE QUANTITIVE MEASUREMENT OF IGA CLASS ANTIBODIES DIRECTED AGAINST TISSUE TRANSGLUTAMINASE IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF CELIAC DISEASE AND DERMATITIS HERPETIFORMIS. ANTI TISSUE TRANSGULAMINASE IGA KIT IS INTENDED FOR LABORATORY USE ONLY.,PROLACTIN ELIA(DIAMETRA)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF PROLACTIN CONCENTRATION IN HUMAN SERUM OR PLASMA. PORLACTIN ELISA KIT INTENDED FOR LABORATORY USE ONLY., CORTISOL ELISA(DIAMETRA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF CORTIZOL CONCENTRATION IN HUMAN SERUM OR PLASMA. CORTIZOL ELISA KIT IS INTENDED FOR LABORATORY USE ONLY., TESTOSTERONE ELISA(DIAMETRA)-COMPETITIVE IMMUNE ENZYMATIC COLORIMETRIC METHOD FOR QUANTITIVE DETERMINATION OF TOTAL TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. TESTOSTERONE ELISA KIT IS INTENDED FOR LABORATORY USE ONLY,T4 ELISA(DIAMETRA)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF THROXINE (T4) CONCENTRATION IN HUMAN SERUM AND PLASMA. T4 ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,ALDOSTERONE ELISA(DIAMETRA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF ALDOSTERONE CONCENTRATION IN HUMAN SERUM PLASMA OR URINE. ALDOSTERONE ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,DHEA-S ELISA(DIAMETRA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD OF QUANTITATIVE DETERMINATION OF DEHYDRO-EPIANDROSTERONE SULFATE (DHEA-S) CONCENTRATION IN HUMAN SERUM OR PLASMA. DHEA-S ELISA KIT IS INTENDED FOR LABORATORY USE ONLY,ANTI

	TG ELISA(DIAMETRA)-INDIRECT IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF ANTI-TG CONCENTRATION IN HUMAN SERUM OR PLASMA. ANTI TG ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,THROGLOBULIN ELISA (DIAMETRA)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF THROGLOBULIN CONCENTRATION IN HUMAN SERUM. THROGLOBULIN ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,TOTAL ESTRIOL ELISA (DIAMETRA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF TOTAL ESTRIOL CONCENTRATION IN HUMAN SERUM OR PLASMA. TOTAL ESTRIOL ELISA KIT INTENDED FOR LABORATORY USE ONLY.,DHEA-S SALIVA ELISA(DIAMETRA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF DHEA-S CONCENTRATION IN SALIVA. DHEA-S SALIVA ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,25OH VITAMIN D(DIAMETRA)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF 25OH VITAMIN D CONCENTRATION IN HUMAN SERUM OR PLASMA. 25 OH VITAMIN D KIT IS INTENDED FOR LABORATORY USE ONLY.,ANTI PHOSPHOLIPID SCREEN(DIAMETRA)-ANTI PHOSPHOLIPID SCREEN IS AN INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITIVE MEASUREMENT OF IGG AND IGM CLASS AUTOANTIBODIES DIRECTED AGAINST B-2 GLYCOPROTEIN MEDIATED ANIONIC PHOSPHOLIPIDS IN HUMAN SERUM OR PLASMA,INCLUDING CARDIOLIPIN, PHOSPHATIDIC ACID, PHOSPHATIDYL CHOLINE, LYSO-PHOSPHAATIDYL CHOLINE. PHOSPHATIDYL ETHANOLAMINE. THE ASSYA IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AB AIDIN THE DIAGNOSIS OF INCREASED RISK OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERITEMATOSUS(SLE) OR SIMILAR DISORDERS. ANTI PHOSPHOLIPIDS SCREEN KIT IS INTENDED FOR LABORATORY USE ONLY.,FREE ESTRIOL ELISA(DIAMETRA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE ESTRIOL CONCENTRATION IN HUMAN SERUM OR PLASMA. FREE ESTRIOL ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,T3 ELISA(DIAMETRA)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) CONCENTRATION IN HUMAN SERUM AND PLASMA. T3 ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,17 OH PROGESTERONE ELISA(DIAMETRA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD OF QUANTITATIVE DETERMINATION OF 17OH PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. 17OH PROGESTERONE ELISA KIT IS INTENDED FOR LABORATORY USE ONLY,ANDROSTENDIONE ELISA

	(DIAMETRA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF ANDROSTENEDIONE CONCENTRATION IN HUMAN SERUM OR PLASMA. ANDROSTENEDIONE ELISA KIT INTENDED FOR LABORATORY USE ONLY.,PROGESTERONE ELISA(DIAMETRA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. PROGESTERONE ELISA KIT INTENDED FOR LABORATORY USE ONLY.,ESTRADIOL ELISA (DIAMETRA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF 17-B-ESTRADIOL CONCENTRATION IN HUMAN SERUM OR PLASMA. ESTRADIOL KIT IS INTENDED FOR LABORATORY USE ONLY.,INSULIN ELISA(DIAMETRA)-DIRECT SOLID PHASE ENZYME IMMUNOASSSAY FOR QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM OR PLASMA. INSULIN ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,TSH ELISA (DIAMETRA)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH, THROTROPIN) CONCENTRATION IN HUMAN SERUM OR PLASMA. TSH ELISA KIT INTENDED FOR LABORATORY USE ONLY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

421	IMP/IVD/2019/000461	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAGNA PURE 96 DNA AND VIRAL NA LARGE VOLUME KIT(MAGNA PURE 96 DNA AND VIRAL NA LARGE VOLUME KIT)-THE MAGNA PURE 96 DNA AND VIRAL NA LARGE VOLUME KIT IS A REAGENT KIT THAT IS USED IN COMBINATION WITH THE MAGNA PURE 96 SYSTEM FOR ISOLATION AND PURIFICATION OF TOTAL NUCLEIC ACIDS (DNA/RNA) FROM BIOLOGICAL SPECIMENS FOR IN VITRO DIAGNOSTIC PURPOSES. ANY IVD APPLICATION USING THE SAMPLE PREPARATION PROCEDURE IN CONJUNCTION WITH ANY DOWNSTREAM IVD NUCLEIC ACID TESTING SHOULD BE EVALUATED WITH REGARD TO THE INDIVIDUAL IVD PARAMETERS. ,MAGNA PURE 96 SYSTEM FLUID (INTERNAL)(MAGNA PURE 96 SYSTEM FLUID (INTERNAL))-THE MAGNA PURE 96 INSTRUMENT IS DESIGNED TO PERFORM AUTOMATED PURIFICATION OF NUCLEIC ACIDS FOR IN VITRO DIAGNOSTIC PURPOSES. THE MAGNA PURE 96 INSTRUMENT IS INTENDED TO BE USED IN COMBINATION WITH SPECIFIED MAGNA PURE 96 KITS. THE MAGNA PURE 96 SYSTEM IS INTENDED TO BE USED WITH THE DEFINED ROBOTIC WORKSTATION, COMPUTER (CONTROL UNIT) WITH OPERATING SOFTWARE, SOFTWARE PROTOCOL, SAMPLE PREPARATION KIT AND CONSUMABLES AND BY PROFESSIONAL USERS.,MAGNA PURE 24 TOTAL NA ISOLATION KIT(MAGNA PURE 24 TOTAL NA ISOLATION KIT)-THE MAGNA PURE 24 SYSTEM IS AN AUTOMATED NUCLEIC ACID PURIFICATION SYSTEM CONSISTING OF THE MAGNA PURE 24 INSTRUMENT, SOFTWARE, CONSUMABLES AND REAGENTS. THE MAGNA PURE 24 SYSTEM IS INTENDED FOR USE BY PROFESSIONAL USERS FOR THE PURIFICATION OF NUCLEIC ACIDS FROM BIOLOGICAL SAMPLES FOR IN VITRO DIAGNOSTIC PURPOSES. THE MAGNA PURE 24 TOTAL NA ISOLATION KIT IS FOR USE WITH THE MAGNA PURE 24 SYSTEM.,MAGNA PURE 96 SYSTEM FLUID (EXTERNAL)(MAGNA PURE 96 SYSTEM FLUID (EXTERNAL))-THE MAGNA PURE 96 INSTRUMENT IS DESIGNED TO PERFORM AUTOMATED PURIFICATION OF NUCLEIC ACIDS FOR IN VITRO DIAGNOSTIC PURPOSES. THE MAGNA PURE 96 INSTRUMENT IS INTENDED TO BE USED IN COMBINATION WITH SPECIFIED MAGNA PURE 96 KITS. THE MAGNA PURE 96 SYSTEM IS INTENDED TO BE USED WITH THE DEFINED ROBOTIC WORKSTATION, COMPUTER (CONTROL UNIT) WITH OPERATING SOFTWARE, SOFTWARE PROTOCOL, SAMPLE PREPARATION KIT AND CONSUMABLES AND BY PROFESSIONAL USERS.,MAGNA PURE 24 MGP SET(MAGNA PURE 24 MGP SET)-USED FOR ADDITIONAL ISOLATIONS OF NUCLEIC ACIDS FROM SMALL, LARGE, AND EXTRA-LARGE SAMPLE VOLUMES,MAGNA PURE 96 DNA AND VIRAL NA SMALL VOLUME KIT(MAGNA PURE 96

	DNA AND VIRAL NA SMALL VOLUME KIT)-THE MAGNA PURE 96 DNA AND VIRAL NA SMALL VOLUME KIT IS A REAGENT KIT THAT IS USED IN COMBINATION WITH THE MAGNA PURE 96 SYSTEM FOR ISOLATION AND PURIFICATION OF TOTAL NUCLEIC ACIDS (DNA/RNA) FROM BIOLOGICAL SPECIMENS FOR IN VITRO DIAGNOSTIC PURPOSES. ANY IVD APPLICATION USING THE SAMPLE PREPARATION PROCEDURE IN CONJUNCTION WITH ANY DOWNSTREAM IVD NUCLEIC ACID TESTING SHOULD BE EVALUATED WITH REGARD TO THE INDIVIDUAL IVD PARAMETERS. ,MAGNA PURE 96 DNA TISSUE LYSIS BUFFER(MAGNA PURE 96 DNA TISSUE LYSIS BUFFER)-MAGNA PURE 96 DNA TISSUE LYSIS BUFFER IS USED IN COMBINATION WITH THE MAGNA PURE 96 SYSTEM FOR ISOLATION AND PURIFICATION OF TOTAL NUCLEIC ACIDS (DNA/RNA) FROM BIOLOGICAL SPECIMENS FOR IN VITRO DIAGNOSTIC PURPOSES. ANY IVD APPLICATION USING THE SAMPLE PREPARATION PROCEDURE, IN CONJUNCTION WITH ANY DOWNSTREAM IVD NUCLEIC ACID TESTING, SHOULD BE EVALUATED WITH REGARD TO THE INDIVIDUAL IVD PARAMETER.,MAGNA PURE 96 BACTERIA LYSIS BUFFER(MAGNA PURE 96 BACTERIA LYSIS BUFFER)-MAGNA PURE 96 EXTERNAL LYSIS BUFFER IS A REAGENT THAT IS USED IN COMBINATION WITH THE MAGNA PURE 96 SYSTEM FOR ISOLATION AND PURIFICATION OF TOTAL NUCLEIC ACIDS (DNA/RNA) FROM BIOLOGICAL SPECIMENS FOR IN VITRO DIAGNOSTIC PURPOSES. ANY IVD APPLICATION USING THE SAMPLE PREPARATION PROCEDURE IN CONJUNCTION WITH ANY DOWNSTREAM IVD NUCLEIC ACID TESTING SHOULD BE EVALUATED WITH REGARD TO THE INDIVIDUAL IVD PARAMETER.,MAGNA PURE 96 EXTERNAL LYSIS BUFFER(MAGNA PURE 96 EXTERNAL LYSIS BUFFER)-MAGNA PURE 96 EXTERNAL LYSIS BUFFER IS A REAGENT THAT IS USED IN COMBINATION WITH THE MAGNA PURE 96 SYSTEM FOR ISOLATION AND PURIFICATION OF TOTAL NUCLEIC ACIDS (DNA/RNA) FROM BIOLOGICAL SPECIMENS FOR IN VITRO DIAGNOSTIC PURPOSES. ANY IVD APPLICATION USING THE SAMPLE PREPARATION PROCEDURE IN CONJUNCTION WITH ANY DOWNSTREAM IVD NUCLEIC ACID TESTING SHOULD BE EVALUATED WITH REGARD TO THE INDIVIDUAL IVD PARAMETER.

422	IMP/IVD/2019/000462	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRINICLOT THROMBIN TIME 1ML-THE TRINICLOT THROMBIN TIME IS INTENDED FOR THE DETERMINATION OF FUNCTIONAL FIBRINOGEN IN HUMAN PLASMA., TRINICLOT PT HTF 6ML-TRINICLOT PT HTF IS A TISSUE THROMBOPLASTIN REAGENT DERIVED FROM CULTURED HUMAN CELLS FOR USE IN DETERMINATION OF THE PROTHROMBIN TIME (PT) IN HUMAN PLASMA.,TRINICLOT PT EXCEL 6ML-TRINICLOT PT EXCEL IS A TISSUE THROMBOPLASTIN REAGENT (RABBIT BRAIN). TRINICLOT PT EXCEL IS USED IN A MODIFIED ONE-STAGE PROTHROMBIN TIME TEST.,TRINICHECK LEVEL 2-TRINICHECK LEVEL 2 AND TRINICHECK LEVEL 3 ARE LYOPHILIZED HUMAN PLASMAS IN WHICH FACTORS II, VII, IX, AND X HAVE BEEN SELECTIVELY AND PARTIALLY REMOVED TO BE USED AS ABNORMAL CONTROLS IN THE PROTHROMBIN TIME (PT) AND ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) TEST PROCEDURES.,TRINICHROM ANTITHROMBIN IIA-TRINICHROM ANTITHROMBIN (AT) IIA IS FOR THE QUANTITATIVE DETERMINATION OF AT ACTIVITY IN HUMAN PLASMA BY A CHROMOGENIC ASSAY., TRINICLOT FACTOR XII-TRINICLOT FACTOR VIII, IX, XI OR XII DEFICIENT HUMAN PLASMA ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF FACTOR IN HUMAN PLASMA BY CLOTTING ASSAY.,TRINICHROM ANTITHROMBIN XA-TRINICHROM ANTITHROMBIN XA (ANTI-XA) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ANTITHROMBIN (AT) ACTIVITY IN HUMAN CITRATED PLASMA BY CHROMOGENIC ASSAY.,TRINICLOT FACTOR V-TRINICLOT FACTOR II, V, VII OR X DEFICIENT HUMAN PLASMA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF FACTOR IN HUMAN PLASMA BY CLOTTING ASSAY.,TRINICLOT FACTOR VIII-TRINICLOT FACTOR VIII, IX, XI OR XII DEFICIENT HUMAN PLASMA ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF FACTOR IN HUMAN PLASMA BY CLOTTING ASSAY.,TRINICLOT APTT HS 3ML-TRINICLOT APTT HS IS A PHOSPHOLIPID REAGENT WITH PARTICULATE ACTIVATOR FOR THE DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT).,TRINICLOT FACTOR XI -TRINICLOT FACTOR VIII, IX, XI OR XII DEFICIENT HUMAN PLASMA ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF FACTOR IN HUMAN PLASMA BY CLOTTING ASSAY.,TRINICLOT FACTOR IX-TRINICLOT FACTOR VIII, IX, XI OR XII DEFICIENT HUMAN PLASMA ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF FACTOR IN HUMAN PLASMA BY CLOTTING ASSAY.,TRINICHECK D-DIMER 3 -TRINICHECK D-DIMER 3 IS INTENDED FOR THE QUALITY CONTROL OF THE TRINILIA D-DIMER, AND FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA.,TRINICLOT APTT S

	3ML-TRINICLOT APTT S IS A TEST KIT FOR USE IN THE DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) AND CONSISTS OF A PHOSPHOLIPID REAGENT WITH PARTICULATE ACTIVATOR AND A CALCIUM CHLORIDE REAGENT., TRINICLOT PT HTF 20ML-TRINICLOT PT HTF IS A TISSUE THROMBOPLASTIN REAGENT DERIVED FROM CULTURED HUMAN CELLS FOR USE IN DETERMINATION OF THE PROTHROMBIN TIME (PT) IN HUMAN PLASMA.,TRINICHECK LEVEL 1-TRINICHECK LEVEL 1 IS A LYOPHILIZED HUMAN PLASMA WITH CHARACTERISTICS SIMILAR TO THOSE OF FRESH NORMAL PLASMA TO BE USED AS A NORMAL CONTROL IN THE PROTHROMBIN TIME (PT), ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), AND FIBRINOGEN ASSAY PROCEDURES.,TRINICLOT PT EXCEL S 20ML-TRINICLOT PT EXCEL S IS A TISSUE THROMBOPLASTIN REAGENT (RABBIT BRAIN) FOR USE IN THE DETERMINATION OF PROTHROMBIN TIME (PT) TESTS., TRINIVERICAL-THE TRINIVERICAL CALIBRATOR SET IS A SET OF LABELLED HUMAN PLASMAS FOR USE WITH THE DESTINY MAX AND DESTINY PLUS SYSTEMS IN THE IN VITRO QUANTIFICATION OF THE PROTHROMBIN AND ACTIVATED PARTIAL THROMBOPLASTIN COAGULATION ASSAYS. THE TRINIVERICAL CALIBRATOR SET CAN ALSO BE USED TO VERIFY CONTINUED SYSTEM AND REAGENT ACCURACY AFTER CALIBRATION.,TRINILIA D-DIMER-TRINILIA D-DIMER KIT IS A POLYSTYRENE, MICROPARTICLE, AGGLUTINATION ASSAY FOR THE QUANTITATIVE DETERMINATION OF FIBRIN DEGRADATION PRODUCTS CONTAINING DDIMER IN CITRATED HUMAN PLASMA USING AUTOMATED COAGULATION ANALYZERS., TRINICLOT APTT S 10ML-TRINICLOT APTT S IS A TEST KIT FOR USE IN THE DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) AND CONSISTS OF A PHOSPHOLIPID REAGENT WITH PARTICULATE ACTIVATOR AND A CALCIUM CHLORIDE REAGENT.,TRINICHECK ABNORMAL CONTROL-TRINICHECK ABNORMAL CONTROL IS FOR USE AS AN ASSAYED PLASMA CONTROL IN THE TESTING OF COAGULATION FACTORS AND OTHER PLASMA COMPONENTS INVOLVED IN HAEMOSTASIS., TRINICLOT CALCIUM CHLORIDE 0.025M-TRINICLOT CALCIUM CHLORIDE 0.025 M IS A GENERAL PURPOSE LABORATORY REAGENT DESIGNED FOR USE IN COAGULATION ASSAYS SUCH AS APTT AND PROTEIN C CLOTTING.,TRINICAL FIBRINOGEN-TRINICLOT FIBRINOGEN KIT IS INTENDED FOR QUANTITATIVE DETERMINATION OF FIBRINOGEN IN PLASMA.,TRINICHECK LUPUS POSITIVE CONTROL-TRINICHECK LUPUS POSITIVE CONTROL IS AN ASSAYED ABNORMAL PLASMA FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF ASSAYS FOR THE DETECTION OF LUPUS ANTICOAGULANT IN HUMAN PLASMA,TRINICHROM FACTOR VIII:C-TRINICHROM FACTOR

	VIII:C IS DESIGNED FOR THE QUANTITATIVE DETERMINATION OF FACTOR VIII:C IN HUMAN PLASMA AND FACTOR VIII CONCENTRATE BY CHROMOGENIC ASSAY,TRINICLOT FACTOR X-TRINICLOT FACTOR II, V, VII OR X DEFICIENT HUMAN PLASMA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF FACTOR IN HUMAN PLASMA BY CLOTTING ASSAY.,DT FLUID-TO CLEAN MEDICAL INSTRUMENTS (DT100, DESTINY MAX AND DESTINY PLUS) TO MAKE THEM SUITABLE FOR AN IN VITRO DIAGNOSTIC PROCEDURE,TRINICLOT AUTOMATED APTT 3ML-TRINICLOT AUTOMATED APTT IS A PLATELET FACTOR 3 REAGENT (PARTIAL THROMBOPLASTIN) PLUS PARTICULATE ACTIVATOR FOR THE DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIMES.,TRINICLOT PT EXCEL S 6ML-TRINICLOT PT EXCEL S IS A TISSUE THROMBOPLASTIN REAGENT (RABBIT BRAIN) FOR USE IN THE DETERMINATION OF PROTHROMBIN TIME (PT) TESTS.,TRINICLOT APTT HS 10ML-TRINICLOT APTT HS IS A PHOSPHOLIPID REAGENT WITH PARTICULATE ACTIVATOR FOR THE DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT).,TRINICLOT FACTOR VII-TRINICLOT FACTOR II, V, VII OR X DEFICIENT HUMAN PLASMA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF FACTOR IN HUMAN PLASMA BY CLOTTING ASSAY.,TRINICHECK CONTROL 3 (ASSAYED)-TRINICHECK CONTROL 2 AND TRINICHECK CONTROL 3 ARE LYOPHILIZED HUMAN PLASMAS IN WHICH FACTORS II, VII, IX, AND X HAVE BEEN SELECTIVELY AND PARTIALLY REMOVED WHICH ARE INTENDED TO BE USED AS ASSAYED CONTROL LEVELS FOR THE FOLLOWING QUANTITATIVE ASSAYS; PROTHROMBIN TIME (PT), ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), FIBRINOGEN (CLAUSS METHOD), THROMBIN TIME (TT), FACTORS II, V, VII, VIII, IX, X, XI, XII ANTITHROMBIN (AT) AND PROTEIN C.,DT WASH-TO CLEAN PROBE OF MEDICAL INSTRUMENTS (DT100, DESTINY MAX AND DESTINY PLUS) TO MAKE THEM SUITABLE FOR AN INVITRO DIAGNOSTIC PROCEDURE, TRINICLOT IMIDAZOLE BUFFER-TRINICLOT IMIDAZOLE BUFFER IS A GENERAL PURPOSE LABORATORY REAGENT DESIGNED FOR USE IN COAGULATION ASSAYS SUCH AS FIBRINOGEN AND FACTOR ASSAYS., TRINICLOT AUTOMATED APTT 6ML-TRINICLOT AUTOMATED APTT IS A PLATELET FACTOR 3 REAGENT (PARTIAL THROMBOPLASTIN) PLUS PARTICULATE ACTIVATOR FOR THE DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIMES.,TRINICHECK D-DIMER 1-TRINICHECK D-DIMER 1 IS INTENDED FOR THE QUALITY CONTROL OF THE TRINILIA D-DIMER, AND FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA.,TRINICAL REFERENCE PLASMA-TRINICAL REFERENCE PLASMA IS AN ASSAYED HUMAN PLASMA THAT HAS BEEN LYOPHILIZED TO MAINTAIN THE INTEGRITY OF THE CONSTITUENTS. IT IS INTENDED FOR USE AS A

	REFERENCE PLASMA FOR THE QUANTITATION OF COAGULATION PROTEINS, AS WELL AS A CONTROL IN ROUTINE COAGULATION ASSAYS.,TRINICLOT FIBRINOGEN 6ML-TRINICLOT FIBRINOGEN KIT IS INTENDED FOR QUANTITATIVE DETERMINATION OF FIBRINOGEN IN PLASMA.,TRINICHECK LEVEL 3-TRINICHECK LEVEL 2 AND TRINICHECK LEVEL 3 ARE LYOPHILIZED HUMAN PLASMAS IN WHICH FACTORS II, VII, IX, AND X HAVE BEEN SELECTIVELY AND PARTIALLY REMOVED, TO BE USED AS ABNORMAL CONTROLS IN THE PROTHROMBIN TIME (PT) AND ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) TEST PROCEDURES.,TRINICHECK CONTROL 2 (ASSAYED)-TRINICHECK CONTROL 2 AND TRINICHECK CONTROL 3 ARE LYOPHILIZED HUMAN PLASMAS IN WHICH FACTORS II, VII, IX, AND X HAVE BEEN SELECTIVELY AND PARTIALLY REMOVED WHICH ARE INTENDED TO BE USED AS ASSAYED CONTROL LEVELS FOR THE FOLLOWING QUANTITATIVE ASSAYS; PROTHROMBIN TIME (PT), ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), FIBRINOGEN (CLAUSS METHOD), THROMBIN TIME (TT), FACTORS II, V, VII, VIII, IX, X, XI, XII ANTITHROMBIN (AT) AND PROTEIN C.,TRINICHECK D-DIMER 2-TRINICHECK D-DIMER 2 IS INTENDED FOR THE QUALITY CONTROL OF THE TRINILLA D-DIMER, AND FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA.,TRINICLOT THROMBIN TIME 4ML-THE TRINICLOT THROMBIN TIME IS INTENDED FOR THE DETERMINATION OF FUNCTIONAL FIBRINOGEN IN HUMAN PLASMA.,TRINICHECK CONTROL 1 (ASSAYED)-TRINICHECK CONTROL 1 IS A LYOPHILIZED HUMAN PLASMA WITH CHARACTERISTICS SIMILAR TO THOSE OF FRESH NORMAL PLASMA WHICH IS INTENDED TO BE USED AS AN ASSAYED CONTROL LEVEL FOR THE FOLLOWING QUANTITATIVE ASSAYS; PROTHROMBIN TIME (PT), ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), FIBRINOGEN (CLAUSS METHOD), THROMBIN TIME (TT), FACTORS II, V, VII, VIII, IX, X, XI, XII, ANTITHROMBIN (AT), PROTEIN C, PROTEIN S AND PLASMINOGEN., TRINICLOT FIBRINOGEN KIT-TRINICLOT FIBRINOGEN KIT IS INTENDED FOR QUANTITATIVE DETERMINATION OF FIBRINOGEN IN PLASMA., TRINICLOT FACTOR II-TRINICLOT FACTOR II, V, VII OR X DEFICIENT HUMAN PLASMA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF FACTOR IN HUMAN PLASMA BY CLOTTING ASSAY.

423	IMP/IVD/2019/000463	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VERSANT ® HCV GENOTYPE 2.0 ASSAY (LIPA)(VERSANT ® HCV GENOTYPE 2.0 ASSAY (LIPA))-THE VERSANT® HCV GENOTYPE 2.0 ASSAY (LIPA) IS A LINE PROBE ASSAY, FOR IN VITRO DIAGNOSTIC USE, WHICH IDENTIFIES HEPATITIS C VIRUS (HCV) GENOTYPES 1 TO 6 AND SUBTYPES A AND B OF GENOTYPE 1 IN HUMAN SERUM OR EDTA PLASMA SAMPLES. ADDITIONAL SUBTYPE INFORMATION IS AVAILABLE IN A MAJORITY OF CASES. THE PRODUCT IS INTENDED TO BE USED TO GUIDE THE SELECTION OF TREATMENT TYPE AND LENGTH FOR INDIVIDUALS BEING CONSIDERED FOR ANTIVIRAL TREATMENT WHO ARE CHRONICALLY INFECTED WITH HCV. THUS THE KIT IS INTENDED TO BE USED WITH SAMPLES KNOWN TO BE POSITIVE FOR HCV RNA. THE VERSANT HCV GENOTYPE 2.0 ASSAY (LIPA) IS NOT INTENDED TO BE USED AS A SCREENING TEST FOR HCV OR AS A DIAGNOSTIC TEST TO CONFIRM THE PRESENCE OF HCV. FOR IN VITRO DIAGNOSTIC USE., VERSANT HCV AMPLIFICATION 2.0 KIT (LIPA)(VERSANT HCV AMPLIFICATION 2.0 KIT (LIPA))-THE VERSANT® HCV AMPLIFICATION 2.0 KIT (LIPA) IS DESIGNED FOR USE IN REVERSE TRANSCRIPTION AND AMPLIFICATION OF THE 5' UNTRANSLATED REGION (5'UTR) AND CORE REGION OF THE HEPATITIS C VIRUS (HCV) GENOME. FOR IN VITRO DIAGNOSTIC USE.,VERSANT HCV CONTROL 2.0 KIT (LIPA) (VERSANT HCV CONTROL 2.0 KIT (LIPA))-THE VERSANT® HCV CONTROL 2.0 KIT (LIPA) IS DESIGNED FOR USE WITH THE VERSANT HCV AMPLIFICATION 2.0 KIT (LIPA) AND THE VERSANT HCV GENOTYPE 2.0 ASSAY (LIPA) PRODUCTS. THE CONTROLS ARE USED FOR MONITORING PERFORMANCE OF ALL STEPS OF THE VERSANT HCV GENOTYPE 2.0 ASSAY. THE VERSANT HCV CONTROL 2.0 KIT (LIPA) IS FOR IN VITRO DIAGNOSTIC USE.
424	IMP/IVD/2019/000468	1.License Holder Name: ARKRAY HEALTHCARE PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GENEDRIVE® HCV ID KIT (GENEDRIVE® HCV ID KIT)-GENEDRIVE HCV ID KIT IS AN IN VITRO DIAGNOSTIC TEST FOR THE RAPID QUALITATIVE DETECTION OF HEPATITIS C VIRUS (HCV) RNA IN HUMAN WHOLE BLOOD DERIVED EDTA PLASMA USING THE GENEDRIVE INSTRUMENT.

425	IMP/IVD/2019/000469	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRINICLOT OWREN'S BUFFER-TRINICLOT OWREN'S BUFFER IS A BUFFER SOLUTION INTENDED FOR USE AS A DILUENT FOR REAGENTS AND PATIENT SAMPLES IN COAGULATION TESTS.,TRINICLOT PS II-TRINICLOT PS II IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF THE FUNCTIONAL PROTEIN S LEVEL BASED ON THE PRINCIPLE OF FACTOR VA INHIBITION ,TRINICLOT PC II-TRINICLOT PC II KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF THE THE FUNCTIONAL PROTEIN C LEVEL BASED ON THE PROLONGATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),TRINICAL PC/PS-TRINICAL PC/PS IS PLASMA INTENDED FOR USE AS CALIBRATION PLASMA FOR THE FUNCTIONAL ASSAYS OF PROTEIN C AND PROTEIN S BY CLOTTING METHOD,TRINILIA D-DIMER II-TRINILIA D-DIMER II KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN PLASMA BY THE IMMUNOTURBIDI METRIC METHOD. IT CAN BE USED TO AID IN THE DIAGNOSIS OF DEEP VEIN THROMBOSIS AND PULMONARY EMBOLISM DISEASE., TRINICHECK LIA CONTROL SET-TRINICHECK LIA CONTROL SET PROVIDES A NORMAL PLASMA AND AN ABNORMAL PLASMA INTENDED FOR THE QUALITY CONTROL OF THE FOLLOWING ANTIGENIC ASSAYS BY THE IMMUNETURBIDIMETRIC METHOD: VON WILLEBRAND FACTOR, FREE PROTEIN S AND D-DIMER.

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426	IMP/IVD/2019/000470	1.License Holder Name: LIFESCAN MEDICAL DEVICES INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TEST STRIPS (ONETOUCH ULTRA)(ONETOUCH ULTRA)-ONETOUCH® ULTRA™ TEST STRIPS ARE USED WITH THE ONETOUCH® ULTRA™ FAMILY OF METERS FOR QUANTITATIVELY MEASURING GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD. THE ONETOUCH® ULTRA™ TEST STRIPS AND ASSOCIATED METERS ARE INTENDED FOR USE BY PEOPLE WITH DIABETES AT HOME AND HEALTH CARE PROFESSIONALS IN THE CLINICAL SETTING. ONETOUCH® ULTRA™ TEST STRIPS AND ASSOCIATED METERS ARE FOR USE IN FINGERTIP, PALM, AND FOREARM TESTING.,TEST STRIPS (ONETOUCH SELECT PLUS) (ONETOUCH SELECT PLUS)-THE ONETOUCH SELECT® PLUS TEST STRIPS ARE USED WITH THE ONETOUCH SELECT® PLUS FAMILY OF BLOOD GLUCOSE MONITORING SYSTEMS (ONETOUCH SELECT® PLUS, ONETOUCH SELECT PLUS SIMPLE®) FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE (SUGAR) IN FRESH CAPILLARY WHOLE BLOOD SAMPLES DRAWN FROM THE FINGERTIPS. THE ONETOUCH SELECT® PLUS FAMILY OF BLOOD GLUCOSE MONITORING SYSTEMS IS INTENDED TO BE USED BY A SINGLE PATIENT AND SHOULD NOT BE SHARED. THE ONETOUCH SELECT® PLUS FAMILY OF BLOOD GLUCOSE MONITORING SYSTEMS IS NOT TO BE USED FOR THE DIAGNOSIS OF OR SCREENING OF DIABETES OR FOR NEONATAL USE., TEST STRIPS (ONETOUCH SELECT)(ONETOUCH SELECT)-ONETOUCH® SELECT™ TEST STRIPS ARE USED WITH THE ONETOUCH® SELECTSIMPLE™ METER FOR QUANTITATIVELY MEASURING GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD. THE ONETOUCH® SELECT™ TEST STRIPS AND METER ARE INTENDED FOR SELF TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) BY PEOPLE WITH DIABETES AT HOME AND HEALTHCARE PROFESSIONALS IN THE CLINICAL SETTING, AS AN AID TO MONITOR THE EFFECTIVENESS OF DIABETES CONTROL. ONETOUCH® SELECT™ TEST STRIPS AND METER ARE FOR USE ON THE FINGER, PALM, AND FOREARM.,TEST STRIPS (ONETOUCH VERIO®) (ONETOUCH VERIO®)-THE ONETOUCH VERIO® TEST STRIPS WHEN USED WITH THE ONETOUCH VERIO® FAMILY OF BLOOD GLUCOSE MONITORING SYSTEMS (ONETOUCH VERIO®, ONETOUCH VERIO FLEX™) IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE (SUGAR) IN FRESH CAPILLARY WHOLE BLOOD. VENOUS WHOLE BLOOD SAMPLES MAY BE USED BY HEALTHCARE PROFESSIONALS WITH SOME SYSTEMS. REFER TO YOUR USER GUIDE THAT CAME WITH YOUR METER FOR SAMPLE INFORMATION. THE ONETOUCH VERIO® FAMILY OF BLOOD GLUCOSE MONITORING SYSTEMS ARE INTENDED

	FOR SELF-TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) BY PEOPLE WITH DIABETES AT HOME AND BY HEALTHCARE PROFESSIONALS IN A CLINICAL SETTING AS AN AID TO MONITOR THE EFFECTIVENESS OF DIABETES CONTROL. THE ONETOUCH VERIO® FAMILY OF BLOOD GLUCOSE MONITORING SYSTEMS IS NOT TO BE USED FOR THE DIAGNOSIS OF OR SCREENING OF DIABETES OR FOR NEONATAL USE.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

427	IMP/IVD/2019/000474	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EUROTROL EPOC GAS-ISE METABOLITES - LEVEL 2(EUROTROL EPOC GAS-ISE METABOLITES - LEVEL 2)-EUROTROL EPOC GAS-ISE METABOLITES IS A SINGLE USE, ASSAYED BLOOD GAS, ELECTROLYTE AND METABOLITE REFERENCE MATERIAL FOR THE QUALITATIVE VERIFICATION OF THE PRECISION AND ACCURACY OF THE EPOC BLOOD ANALYSIS SYSTEM. THE PRODUCT IS AN IN VITRO DIAGNOSTIC DEVICE, INTENDED FOR PROFESSIONAL LABORATORY PERSONNEL. EUROTROL EPOC GAS-ISE METABOLITES IS DESIGNED TO TEST THE FOLLOWING ELECTROLYTES: PH, PO2, PCO2, NA+, K+, CA2+, MG2+, CL-, GLUCOSE LACTATE, UREA, CREATININE AND TCO2,EUROTROL EPOC GAS-ISE METABOLITES - LEVEL 3(EUROTROL EPOC GAS-ISE METABOLITES - LEVEL 3)-EUROTROL EPOC GAS-ISE METABOLITES IS A SINGLE USE, ASSAYED, BLOOD GAS, ELECTROLYTE AND METABOLITE REFERENCE MATERIAL FOR THE QUALITATIVE VERIFICATION OF THE PRECISION AND ACCURACY OF THE EPOC BLOOD ANALYSIS SYSTEM. THE PRODUCT IS AN IN VITRO DIAGNOSTIC DEVICE, INTENDED FOR PROFESSIONAL LABORATORY PERSONNEL. EUROTROL EPOC GAS-ISE METABOLITES IS DESIGNED TO TEST THE FOLLOWING ANALYTES: PH, PO2, PCO2, NA+, K+, CA2+, MG2+, CL- , GLUCOSE LACTATE, UREA, CREATININE AND TCO2.,EUROTROL EPOC GAS-ISE METABOLITES - LEVEL 6(EUROTROL EPOC GAS-ISE METABOLITES - LEVEL 6)-EUROTROL EPOC GAS-ISE METABOLITES IS A SINGLE USE, ASSAYED, BLOOD GAS, ELECTROLYTE AND METABOLITE REFERENCE MATERIAL FOR THE QUALITATIVE VERIFICATION OF THE PRECISION AND ACCURACY OF THE EPOC BLOOD ANALYSIS SYSTEM. THE PRODUCT IS AN IN VITRO DIAGNOSTIC DEVICE, INTENDED FOR PROFESSIONAL LABORATORY PERSONNEL. EUROTROL EPOC GAS-ISE METABOLITES IS DESIGNED TO TEST THE FOLLOWING ANALYTES: PH, PO2, PCO2, NA+, K+, CA2+, MG2+, CL- , GLUCOSE LACTATE, UREA, CREATININE AND TCO2.,EPOC HEMATOCRIT VERIFICATION FLUIDS(EPOC HEMATOCRIT VERIFICATION FLUIDS)-EPOC HEMATOCRIT VERIFICATION FLUIDS IS AN ASSAYED HEMOTOCRIT REFERENCE MATERIAL, TO VERIFY THE PRECISION AND ACCURACY OF THE EPOC BLOOD ANALYSIS SYSTEM FOR THE MEASUREMENT OF HEMATOCRIT.,EUROTROL HCT CONTROL - LEVEL B(EUROTROL HCT CONTROL - LEVEL B)-EUROTROL HCT CONTROL - LEVEL B IS AN ASSAYED HEMOTOCRIT REFERENCE MATERIAL, TO VERIFY THE PRECISION AND ACCURACY OF THE EPOC BLOOD ANALYSIS SYSTEM FOR THE MEASUREMENT OF HEMATOCRIT. ,EUROTROL HCT CONTROL - LEVEL C(EUROTROL HCT CONTROL - LEVEL C)-EUROTROL HCT CONTROL - LEVEL C IS AN ASSAYED HEMOTOCRIT REFERENCE

	MATERIAL, TO VERIFY THE PRECISION AND ACCURACY OF THE EPOC BLOOD ANALYSIS SYSTEM FOR THE MEASUREMENT OF HEMATOCRIT. ,EUROTROL HCT CONTROL - LEVEL A(EUROTROL HCT CONTROL - LEVEL A)-EUROTROL HCT CONTROL - LEVEL A IS AN ASSAYED HEMOTOCRIT REFERENCE MATERIAL, TO VERIFY THE PRECISION AND ACCURACY OF THE EPOC BLOOD ANALYSIS SYSTEM FOR THE MEASUREMENT OF HEMATOCRIT. ,EUROTROL EPOC GAS-ISE METABOLITES - LEVEL 1(EUROTROL EPOC GAS-ISE METABOLITES - LEVEL 1)-EUROTROL EPOC GAS-ISE METABOLITES IS A SINGLE USE, ASSAYED BLOOD GAS, ELECTROLYTE AND METABOLITE REFERENCE MATERIAL FOR THE QUALITATIVE VERIFICATION OF THE PRECISION AND ACCURACY OF THE EPOC BLOOD ANALYSIS SYSTEM. THE PRODUCT IS AN IN VITRO DIAGNOSTIC DEVICE,INTENDED FOR PROFESSIONAL LABORATORY PERSONNEL. EUROTROL EPOC GAS-ISE METABOLITES IS DESIGNED TO TEST THE FOLLOWING ANALYTES: PH, PO2, PCO2, NA+, K+, CA2+, MG2+, CL-, GLUCOSE LACTATE, UREA, CREATININE AND TCO2,EUROTROL EPOC CALIBRATION VERIFICATION FLUIDS(EUROTROL EPOC CALIBRATION VERIFICATION FLUIDS)-EUROTROL EPOC CALIBRATION VERIFICATION FLUIDS IS A SINGLE USE, ASSAYED, BLOOD GAS, ELECTROLYTE AND METABOLITE REFERENCE MATERIAL FOR THE QUALITATIVE VERIFICATION OF THE PRECISION AND ACCURACY OF THE EPOC BLOOD ANALYSIS SYSTEM. THE PRODUCT IS AN IN VITRO DIAGNOSTIC DEVICE, INTENDED FOR PROFESSIONAL LABORATORY PERSONNEL. EUROTROL EPOC CALIBRATION VERIFICATION FLUIDS IS DESIGNED TO TEST THE FOLLOWING ANALYTES: PH, PO2, PCO2, NA+, K+, CA2+, MG2+, CL- , GLUCOSE LACTATE, UREA, CREATININE AND TCO2

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

428	IMP/IVD/2019/000475	1.License Holder Name: THERMO FISHER SCIENTIFIC INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMMUNOCAP TOTAL IGE CALIBRATOR STRIP(IMMUNOCAP™)-"IMMUNOCAP TOTAL IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF CIRCULATING TOTAL IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TOTAL IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIAN 1000,PHADIA 2500 OR PHADIA 5000.",ELIA RO60 WELL (ELIA™)-ELIA RO60 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED RO60 IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SJOGREN'S SYNDROME AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA RO60 USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP TOTAL IGE CALIBRATORS (IMMUNOCAP™)-"IMMUNOCAP TOTAL IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF CIRCULATING TOTAL IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TOTAL IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIAN 1000,PHADIA 2500 OR PHADIA 5000.",ELIA IGA CONJUGATE (ELIA™)-ELIA CELIKEY IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM AND PLASMA. ELIA CELIKEY IGA IS BASED ON RECOMBINANT HUMAN TISSUE TRANSGLUTAMINASE AS ANTIGEN AND IS USEFUL AS AN AID IN THE CLINICAL DIAGNOSIS OF PATIENTS WITH CELIAC DISEASE. ELIA CELIKEY IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,DEVELOPMENT SOLUTION (IMMUNOCAP™)-DEVELOPMENT SOLUTION IS TO BE USED IN IMMUNOCAP OR ELIA ASSAYS.,ELIA IGM CONJUGATE 200(ELIA™)-"ELIA CARDIOLIPIN IGM IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGM ANTIBODIES DIRECTED TO CARDIOLIPIN IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME (APS) AND TO EVALUATE THE THROMBOTIC RISK IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA CARDIOLIPIN IGM USES THE THE ELIA IGM METHOD ON THE PHADIA INSTRUMENTS." ,WASHING SOLUTION (IMMUNOCAP™)-WASHING SOLUTION IS TO BE USED IN IMMUNOCAP

	OR ELIA ASSAYS,ELIA IGG CONJUGATE 50 (ELIA™)-ELIA DSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO DSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA DSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP TOTAL IGE CONJUGATE 100(IMMUNOCAP™)-"IMMUNOCAP TOTAL IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF CIRCULATING TOTAL IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TOTAL IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIAN 1000,PHADIA 2500 OR PHADIA 5000.",ELIA CALPROTECTIN WELL (ELIA™)-ELIA CALPROTECTIN IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN USES THE ELIA CALPROTECTIN METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP TOTAL IGE (IMMUNOCAP™)-"IMMUNOCAP TOTAL IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF CIRCULATING TOTAL IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TOTAL IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIAN 1000,PHADIA 2500 OR PHADIA 5000.",ELIA PARIETAL CELL WELL (ELIA™)-ELIA PARIETAL CELL IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF PERNICIOUS ANEMIA ELIA PARIETAL CELL USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP TOTAL IGE CURVE CONTROLS (IMMUNOCAP™)-"IMMUNOCAP TOTAL IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF CIRCULATING TOTAL IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TOTAL IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIAN 1000,PHADIA 2500 OR PHADIA 5000.",ELIA SMDP WELL (ELIA™)-ELIA SMDP IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG

	ANTIBODIES DIRECTED TO SM IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS DISEASE ERYTHEMATOUS (SLE) . ELIA SMDP USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,STOP SOLUTION(IMMUNOCAP™)-STOP SOLUTION IS TO BE USED IN IMMUNOCAP OR ELIA ASSAYS.,ELIA IGA CALIBRATOR WELL (ELIA™)-ELIA CELIKEY IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM AND PLASMA. ELIA CELIKEY IGA IS BASED ON RECOMBINANT HUMAN TISSUE TRANSGLUTAMINASE AS ANTIGEN AND IS USEFUL AS AN AID IN THE CLINICAL DIAGNOSIS OF PATIENTS WITH CELIAC DISEASE. ELIA CELIKEY IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,QUALITY CLUB TOTAL IGE(IMMUNOCAP™)-"QUALITY CLUB TOTAL IGE IS A QUALITY ASSESSMENT PROGRAM FOR IMMUNOCAP TOTAL IGE USERS. THE INDIVIDUAL LABORATORY'S CONTINUOUS PERFORMANCE IS MONITORED BY COMPARISON OF TEST RESULTS GENERATED FROM OTHER IMMUNOCAP TOTAL IGE USERS",ELIA SYMPHONY WELL (ELIA™)-"ELIA SYMPHONY IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF ANTINUCELAR IGG ANTIBODIES IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), MIXEDE CONNECTIVE TISSUE DISEASE (MCTD), SJOGREN'S SYNDROME, SCLERODERMA AND POLYMYOSITIS/DERMATOMYOSITIS. ELIA SYMPHONY USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP IGE/ECP/TRYPTASE SAMPLE DILUENT(IMMUNOCAP™)-"TO BE USED WITH IN VITRO TEST FOR QUANTITATIVE MEASUREMENT OF IGE/ECP/TRYPTASE IN PHADIA INSTRUMENT",ELIA RNP70 WELL (ELIA™)-"ELIA RNP70 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO RNP70 IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF MIXED CONNECTIVE TISSUE DISEASE (MCTD) AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA RNP70 USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP TOTAL IGE CONTROL LMH (IMMUNOCAP™)-"IMMUNOCAP TOTAL IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF CIRCULATING TOTAL IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TOTAL IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIAN 1000,PHADIA 2500 OR PHADIA 5000.",ELIA IGA CURVE CONTROL STRIPS (ELIA™)-ELIA CELIKEY IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE

	MEASUREMENT OF IGA ANTIBODIES DIRECTED TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM AND PLASMA. ELIA CELIKEY IGA IS BASED ON RECOMBINANT HUMAN TISSUE TRANSGLUTAMINASE AS ANTIGEN AND IS USEFUL AS AN AID IN THE CLINICAL DIAGNOSIS OF PATIENTS WITH CELIAC DISEASE. ELIA CELIKEY IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP TOTAL IGE CURVE CONTROLS STRIPS (IMMUNOCAP™)-"IMMUNOCAP TOTAL IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF CIRCULATING TOTAL IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TOTAL IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIAN 1000,PHADIA 2500 OR PHADIA 5000.",ELIA STOOL EXTRACTION KIT 2(ELIA™)-ELIA CALPROTECTIN 2 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN 2 USES THE ELIA CALPROTECTIN 2 METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP TOTAL IGE ANTI-IGE(IMMUNOCAP™)-"IMMUNOCAP TOTAL IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF CIRCULATING TOTAL IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TOTAL IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIAN 1000,PHADIA 2500 OR PHADIA 5000.",ELIA CALPROTECTIN 2 CALIBRATOR STRIPS(ELIA™)-ELIA CALPROTECTIN 2 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN 2 USES THE ELIA CALPROTECTIN 2 METHOD ON THE PHADIA INSTRUMENTS. , IMMUNOCAP TOTAL IGE CONJUGATE 400(IMMUNOCAP™)-"IMMUNOCAP TOTAL IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF CIRCULATING TOTAL IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TOTAL IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIAN 1000,PHADIA 2500

	OR PHADIA 5000.",ELIA CARDIOLIPIN IGM WELL(ELIA™)-"ELIA CARDIOLIPIN IGM IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGM ANTIBODIES DIRECTED TO CARDIOLIPIN IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME (APS) AND TO EVALUATE THE THROMBOTIC RISK IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA CARDIOLIPIN IGM USES THE THE ELIA IGM METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN F44, STRAWBERRY(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ANTI-IGA POSITIVE CONTROL 250(ELIA™)-ELIA ANTI-IGA IS INTENDEED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO IGA IN HUMAN SERUM OR PLASMA. ELIA ANTI-IGA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN M228, ASPERGILLUS FLAVUS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ß2-GLYCOPROTEIN I IGG WELL (ELIA™)-"ELIA ß2-GLYCOPROTEIN I IGG IS INTENDED FOR THE INVITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO ß2-GLYCOPROTEIN IIN HUMAN SERUM AND PLASMA AS AN AID IN THE DIAGNOSIS OF ANTIPHOPHOLIPID SYNDROME (APS)TO EVALUATE THE THROMBOTIC RISK IN PATEINTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA ß2-GLYCOPROTEIN I IGG USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN F35, POTATO(IMMUNOCAP) -IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES.

	IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN 2 CONJUGATE 50(ELIA™)-ELIA CALPROTECTIN 2 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN 2 USES THE ELIA CALPROTECTIN 2 METHOD ON THE PHADIA INSTRUMENTS. , IMMUNOCAP ALLERGEN T20, MESQUITE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGA CONJUGATE 200 (ELIA™)-ELIA CELIKEY IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM AND PLASMA. ELIA CELIKEY IGA IS BASED ON RECOMBINANT HUMAN TISSUE TRANSGLUTAMINASE AS ANTIGEN AND IS USEFUL AS AN AID IN THE CLINICAL DIAGNOSIS OF PATIENTS WITH CELIAC DISEASE. ELIA CELIKEY IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F221, COFFEE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ECP CURVE CONTROL(IMMUNOCAP™) -IMMUNOCAP ECP IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF EOSINOPHIL CATIONIC PROTEIN (ECP) IN HUMAN SERUM. IMMUNOCAP ECP IS TO BE USED WITH INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN T18, EUCALYPTUS, GUM-TREE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN

	CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN CURVE CONTROL (ELIA™)-ELIA CALPROTECTIN IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN USES THE ELIA CALPROTECTIN METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F256, WALNUT (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA RIB-P WELL (ELIA™)-ELIA RIB-P IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO RIB-P IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF RHEUMATOID ARTHRITIS. ELIA RF IGM USES THE ELIA IGM METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F7, OAT(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA QUALITY CLUB AUTOIMMUNITY(ELIA™)-"ELIA QUALITY CLUB AUTOIMMUNITY IS A QUALITY ASSESSMENT PROGRAM FOR PHADIA INSTRUMENT USERS. THE INDIVIDUAL LABORATORY'S CONTINUOUS PERFORMANCE IS MONITORED BY COMPARISON OF TEST RESULTS GENERATED FROM OTHER PHADIA INSTRUMENT USERS." ,IMMUNOCAP ALLERGEN F91, MANGO (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES.

	IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN NEGATIVE CONTROL 250 (ELIA™)-ELIA CALPROTECTIN 2 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN 2 USES THE ELIA CALPROTECTIN 2 METHOD ON THE PHADIA INSTRUMENTS. , IMMUNOCAP ALLERGEN F17, HAZEL NUT(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CCP POSITIVE CONTROL 100(ELIA™)-"ELIA CCP IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO CCP IN HUMAN SERUM AND PLASMA. THE PRESENCE OF ANTI-CCP ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS AS AN AID IN THE CLINICAL DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA). ELIA CCP USES THE THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS." , IMMUNOCAP ALLERGEN F280, BLACK PEPPER(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN CONJUGATE (ELIA™)-ELIA CALPROTECTIN IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN USES THE ELIA CALPROTECTIN METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F75, EGG YOLK(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER

	CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ANTI-IGA WELL (ELIA™)-ELIA ANTI-IGA IS INTENDEED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGAG ANTIBODIES DIRECTED TO IGA IN HUMAN SERUM OR PLASMA. ELIA ANTI-IGA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F342, OLIVE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP SPECIFIC IGE CONJUGATE 400 (IMMUNOCAP™)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN M210, TRICHOPHYTON MENT. VAR GOETZII(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP SPECIFIC IGE CALIBRATORS 0-100,(IMMUNOCAP™)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP

	ALLERGEN W20, NETTLE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA GASTRIC POSITIVE CONTROL 250 (ELIA™)-ELIA INTRINSIC FACTOR IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO INTRINSIC FACTOR IN HUMAN SERUM AND PLASMA TO AID IN THE CLINICAL DIAGNOSIS OF PERNICIOUS ANEMIA. ELIA INTRINSIC FACTOR USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F40, TUNA (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ECP CONJUGATE 50(IMMUNOCAP™)-IMMUNOCAP ECP IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF EOSINOPHIL CATIONIC PROTEIN (ECP) IN HUMAN SERUM. IMMUNOCAP ECP IS TO BE USED WITH INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F263, GREEN PEPPER (UNRIPE SEED)(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ECP CURVE CONTROL STRIP(IMMUNOCAP™)-IMMUNOCAP ECP IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF EOSINOPHIL CATIONIC PROTEIN (ECP) IN HUMAN SERUM. IMMUNOCAP ECP IS TO BE USED WITH INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F210, PINEAPPLE(IMMUNOCAP)-

	IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ECP CONTROL(IMMUNOCAP™)-IMMUNOCAP ECP CONTROL IS USED FOR MONITORING IMMUNOCAP ECP MEASUREMENTS PERFORMANCE IN PHADIA INSTRUMENTS., IMMUNOCAP ALLERGEN T19, ACACIA(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ECP (IMMUNOCAP™)-IMMUNOCAP ECP IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF EOSINOPHIL CATIONIC PROTEIN (ECP) IN HUMAN SERUM. IMMUNOCAP ECP IS TO BE USED WITH INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP RARE ALLERGEN C209, CHYMOPAPAIN(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,QUALITY CLUB ECP(IMMUNOCAP™)-QUALITY CLUB ECP IS A QUALITY ASSESSMENT PROGRAM FOR IMMUNOCAP ECP USERS. THE INDIVIDUAL LABORATORY'S CONTINUOUS PERFORMANCE IS MONITORED BY COMPARISON OF TEST RESULTS GENERATED FROM OTHER IMMUNOCAP ECP USERS,IMMUNOCAP ALLERGEN G12, CULTIVATED RYE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER

	CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA PCNA WELL (ELIA™)-ELIA PCNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO PCNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA PCNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN FX15, FRUITS (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP SPECIFIC IGE CALIBRATOR STRIP 0-100(IMMUNOCAP™)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F83, CHICKEN (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP SPECIFIC IGE CONJUGATE 100 (IMMUNOCAP™)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500

	OR PHADIA 5000.,IMMUNOCAP ALLERGEN C202, SUXAMETHONIUM (SUCCINYLCHOLINE)(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGA CALIBRATOR STRIPS(ELIA™)-ELIA CELIKEY IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM AND PLASMA. ELIA CELIKEY IGA IS BASED ON RECOMBINANT HUMAN TISSUE TRANSGLUTAMINASE AS ANTIGEN AND IS USEFUL AS AN AID IN THE CLINICAL DIAGNOSIS OF PATIENTS WITH CELIAC DISEASE. ELIA CELIKEY IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F293, PAPAYA(IMMUNOCAP) -IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA RF IGA WELL (ELIA™)-ELIA RF IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA RHEUMATOID FACTOR IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS. ELIA RF IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F218, PAPRIKA, SWEET PEPPER(IMMUNOCAP)- IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGG/IGA/IGM NEGATIVE CONTROL 100 (ELIA™)-ELIA DSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO DSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF

	SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA DSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN E213, PARROT FEATHERS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGM CONJUGATE(ELIA™)-"ELIA CARDIOLIPIN IGM IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGM ANTIBODIES DIRECTED TO CARDIOLIPIN IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME (APS) AND TO EVALUATE THE THROMBOTIC RISK IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA CARDIOLIPIN IGM USES THE THE ELIA IGM METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN I206, COCKROACH, AMERICAN(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGG CALIBRATORS(ELIA™)-ELIA DSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO DSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA DSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN T12, WILLOW (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP SPECIFIC IGE CONJUGATE 0-100 (IMMUNOCAP™)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN

	SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN GX2, GRASS POLLEN (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGG CURVE CONTROL STRIPS (ELIA™)-ELIA DSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO DSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA DSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN C8, CHLORHEXIDINE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA U1RNP WELL (ELIA™)-"ELIA U1RNP IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO U1RNP IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF MIXED CONNECTIVE TISSUE DISEASE (MCTD) AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA U1RNP USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN HX2, HOUSE DUST(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500

	OR PHADIA 5000.,ELIA ASCA IGG WELL (ELIA™)-"ELIA ASCA IGG IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO MANNAN OF SACCHAROMYCES CEREVISIAE IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF CROHN'S DISEASE. ELIA ASCA IGG USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN F87, MELON(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA MI-2 WELL (ELIA™)-ELIA MI-2 IS INTENDED FOR THE INVITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO MI-2 IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF IDOPATHIC (AUTOIMMUNE) MYOSITIS (IM). ELIA MI-2 USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN T2, GREY ALDER(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGM CONJUGATE 50(ELIA™)-"ELIA CARDIOLIPIN IGM IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGM ANTIBODIES DIRECTED TO CARDIOLIPIN IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME (APS) AND TO EVALUATE THE THROMBOTIC RISK IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA CARDIOLIPIN IGM USES THE THE ELIA IGM METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN G8, MEADOW GRASS, KENTUCKY BLUE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS

	PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA APS POSITIVE CONTROL 100(ELIA™)-"ELIA CARDIOLIPIN IGM IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGM ANTIBODIES DIRECTED TO CARDIOLIPIN IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME (APS) AND TO EVALUATE THE THROMBOTIC RISK IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA CARDIOLIPIN IGM USES THE THE ELIA IGM METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN I6, COCKROACH, GERMAN(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN 2 WELL (ELIA™)-ELIA CALPROTECTIN 2 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN 2 USES THE ELIA CALPROTECTIN 2 METHOD ON THE PHADIA INSTRUMENTS. , IMMUNOCAP ALLERGEN F259, GRAPE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN CURVE CONTROL STRIPS (ELIA™)-ELIA CALPROTECTIN IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN USES THE ELIA CALPROTECTIN METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F284, TURKEY MEAT(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED

	IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CELIKEY IGG WELL(ELIA™)-ELIA CELIKEY IGG IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM AND PLASMA. ELIA CELIKEY IGG IS BASED ON RECOMBINANT HUMAN TISSUE TRANSGLUTAMINASE AS ANTIGEN AND IS USEFUL AS AN AID IN THE CLINICAL DIAGNOSIS OF PATIENTS WITH CELIAC DISEASE. ELIA CELIKEY IGG USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN M2, CLADOSPORIUM HERBARUM(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA RNA POL III WELL (ELIA™)-ELIA RNA POL III IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO RNA POLYMERASE III (RNA POL III) IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC SCLEROSIS (DIFFUSE FORM). ELIA RNA POL III USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN E85, CHICKEN FEATHERS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA PM-SCL WELL (ELIA™)-ELIA PM-SCL IS INTENDED FOR THE INVITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO PM-SCL IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF POLYMYOSITIS/SCLERODERMA OVERLAP SYNDROME. ELIA PM-SCL USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN W11, SALTWORT (PRICKLY), RUSSIAN THISTLE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE

	CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGG/IGA/IGM NEGATIVE CONTROL 250 (ELIA™)-ELIA DSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO DSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA DSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN W13, COCKLEBUR(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA RO WELL (ELIA™)-"ELIA RO IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO RO IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SJÖGREN'S SYNDROME AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA RO USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN M207, ASPERGILLUS NIGER(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGG CALIBRATOR STRIPS (ELIA™)-ELIA DSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO DSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA DSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F15, WHITE BEAN (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF

	IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGG CONJUGATE 200 (ELIA™)-ELIA DSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO DSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA DSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN K71, CASTOR BEAN(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA RF POSITIVE CONTROL 100 (ELIA™)-ELIA RF IGM IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGM RHEUMATOID FACTOR IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS. ELIA RF IGM USES THE ELIA IGM METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN W14, COMMON PIGWEED(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA SSDNA WELL (ELIA™)-ELIA SSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO SSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF DRUG INDUCED LUPUS DISEASE (DIL). THE TEST IS NOT DEFINITIVE IN ISOLATION BUT HAS TO BE SEEN AS ONE PARAMETER IN A MULTICRITERION PROCESS. ELIA SSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F95, PEACH(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN

	CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA SAMPLE DILUENT (ELIA™)-ELIA DSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO DSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA DSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. , IMMUNOCAP ALLERGEN F215, LETTUCE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA STOOL EXTRACTION KIT (ELIA™)-ELIA CALPROTECTIN IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN USES THE ELIA CALPROTECTIN METHOD ON THE PHADIA INSTRUMENTS. , IMMUNOCAP ALLERGEN F92, BANANA(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA LA WELL (ELIA™)-"ELIA LA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO LA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SJÖGREN'S SYNDROME AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA LA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN T21, MELALEUCA, CAJEPUT-TREE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES.

	IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ANA POSITIVE CONTROL 250 (ELIA™)-ELIA DSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO DSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA DSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F45, YEAST(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA RF IGM WELL (ELIA™)-ELIA RF IGM IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGM RHEUMATOID FACTOR IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS. ELIA RF IGM USES THE ELIA IGM METHOD ON THE PHADIA INSTRUMENTS. , IMMUNOCAP ALLERGEN F85, CELERY(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA THYROID POSITIVE CONTROL 250 (ELIA™)-ELIA ANTI-TPO IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO THYROID PEROXIDASE (TPO) IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF THYROID DISEASES SUCH AS AUTOIMMUNE THYROIDITIS AND GRAVES' DISEASE. ELIA ANTI-TPO USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F49, APPLE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS

	PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA RO52 WELL (ELIA™)-ELIA RO52 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED RO52 IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SJOGREN'S SYNDROME AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA RO52 USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN E6, GUINEA PIG EPITHELIUM(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN CALIBRATORS(ELIA™)-ELIA CALPROTECTIN IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN USES THE ELIA CALPROTECTIN METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F315, GREEN BEAN (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ANTI-TPO WELL (ELIA™)-ELIA ANTI-TPO IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO THYROID PEROXIDASE (TPO) IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF THYROID DISEASES SUCH AS AUTOIMMUNE THYROIDITIS AND GRAVES' DISEASE. ELIA ANTI-TPO USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN H2, HOUSE DUST (HOLLISTER-STIER LABS.)(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE

	USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA M2 POSITIVE CONTROL 250(ELIA™)-ELIA M2 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO M2 IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF PRIMARY BILIARY CIRRHOSIS. ELIA M2 USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN I208, ALLERGEN COMPONENT RAPI M 1 PHOSPHOLIPASE A2, HONEY BEE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA FIBRILLARIN WELL(ELIA™)-ELIA FIBRILLARIN IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO FIBRILLARIN IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC SCLEROSIS (SSC). ELIA FIBRILLARIN USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN T3, COMMON SILVER BIRCH (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN 2 CONJUGATE 200(ELIA™)-ELIA CALPROTECTIN 2 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN 2 USES THE ELIA CALPROTECTIN 2 METHOD ON THE PHADIA INSTRUMENTS. , IMMUNOCAP ALLERGEN G6, TIMOTHY(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE

	USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN CONJUGATE 200 (ELIA™)-ELIA CALPROTECTIN IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN USES THE ELIA CALPROTECTIN METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F287, RED KIDNEY BEAN(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA PR3S WELL(ELIA™)-"ELIA PR3S IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO PROTEINASE 3 (PR3) IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF GRANULOMATOSIS WITH POLYANGIITIS (GPA, FORMALLY CALLED WEGENER'S GRANULOMATOSIS). ELIA PR3S USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP PHADIATOP (IMMUNOCAP)-PHADIATOP IS AN IN VITRO QUALITATIVE ASSAY FOR THE DIFFERENTIAL DETERMINATION OF IGE ANTIBODIES SPECIFIC TO INHALANT ALLERGENS IN HUMAN SERUM AND PLASMA. PHADIATOP IS TO BE USED IN PHADIA INSTRUMENT SYSTEM. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS INTENDED FOR USE IN CLINICAL LABORATORIES, AS WELL AS, PHYSICIAN OFFICE LABORATORIES., ELIA GLIADIN IGG WELL (ELIA™)-ELIA GLIADIN IGG IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO GLIADIN IN SERUM OR PLASMA TO AID IN THE DIAGNOSIS OF CELIAC DISEASE. ELIA GLIADIN IGG USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN T70, MULBERRY(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA

	250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN POSITIVE CONTROL 250 (ELIA™)-ELIA CALPROTECTIN 2 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN 2 USES THE ELIA CALPROTECTIN 2 METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN W1, COMMON RAGWEED(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN EXTRACTION BUFFER (ELIA™)-ELIA CALPROTECTIN IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN USES THE ELIA CALPROTECTIN METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN C260, MORPHINE (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA SSDNA POSITIVE CONTROL 250(ELIA™)-ELIA SSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO SSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF DRUG INDUCED LUPUS DISEASES (DIL). THE TEST IS NOT DEFINITIVE IN ISOLATION BUT HAS TO BE SEEN AS ONE PARAMETER IN A MULTICRITERION PROCESS. ELIA SSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F25, TOMATO(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES.

	IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN CALIBRATOR WELL (ELIA™)-ELIA CALPROTECTIN IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN USES THE ELIA CALPROTECTIN METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN W230, ALLERGEN COMPONENT NAMB A 1 RAGWEED(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ECP CALIBRATORS STRIPS (IMMUNOCAP™)-IMMUNOCAP ECP IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF EOSINOPHIL CATIONIC PROTEIN (ECP) IN HUMAN SERUM. IMMUNOCAP ECP IS TO BE USED WITH INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN TX7, TREE POLLEN(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP SPECIFIC IGE CONTROL M(IMMUNOCAP™)-"IMMUNOCAP SPECIFIC IGE CONTROLS ARE USED FOR MONITORING IMMUNOCAP SPECIFIC IGE MEASUREMENTS PERFORMANCE IN PHADIA INSTRUMENTS", IMMUNOCAP ALLERGEN F212, MUSHROOM (CHAMPIGNON) (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500

	OR PHADIA 5000.,IMMUNOCAP SPECIFIC IGE 0-100(IMMUNOCAP™)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F20, ALMOND (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CELIAC POSITIVE CONTROL 250(ELIA™)-ELIA CELIKEY IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM AND PLASMA. ELIA CELIKEY IGA IS BASED ON RECOMBINANT HUMAN TISSUE TRANSGLUTAMINASE AS ANTIGEN AND IS USEFUL AS AN AID IN THE CLINICAL DIAGNOSIS OF PATIENTS WITH CELIAC DISEASE. ELIA CELIKEY IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F18, BRAZIL NUT (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ECP ANTI-ECP(IMMUNOCAP™)-IMMUNOCAP ECP IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF EOSINOPHIL CATIONIC PROTEIN (ECP) IN HUMAN SERUM. IMMUNOCAP ECP IS TO BE USED WITH INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN M227, MALASSEZIA SPP.(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS

	INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP SPECIFIC IGE CURVE CONTROLS,(IMMUNOCAP™)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN EX1, ANIMAL PROTEINS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGM CURVE CONTROL STRIPS(ELIA™)-"ELIA CARDIOLIPIN IGM IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGM ANTIBODIES DIRECTED TO CARDIOLIPIN IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME (APS) AND TO EVALUATE THE THROMBOTIC RISK IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA CARDIOLIPIN IGM USES THE THE ELIA IGM METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN F23, CRAB(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CENP WELL (ELIA™)-"ELIA CENP IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO CENP IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SCLERODERMA (CREST SYNDROME). ELIA CENP USES THE ELIA IGG

	METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN F26, PORK(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGG CONJUGATE (ELIA™)-ELIA DSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO DSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA DSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN E4, COW DANDER(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA RF IGG WELL (ELIA™)-ELIA RF IGG IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG RHEUMATOID FACTOR IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS. ELIA RF IGG USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F79, GLUTEN(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CCP IGA WELL (ELIA™)-ELIA CCP IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO CCP IN HUMAN SERUM AND PLASMA.THE PRESENCE OF ANTI-CCP IGA ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS AS AN AID IN THE CLINICAL DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA). ELIA CCP IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,

	IMMUNOCAP ALLERGEN G10, JOHNSON GRASS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN 2 EXTRACTION BUFFER (ELIA™)-ELIA CALPROTECTIN 2 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN 2 USES THE ELIA CALPROTECTIN 2 METHOD ON THE PHADIA INSTRUMENTS. , IMMUNOCAP ALLERGEN C6, AMOXICILLOYL(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ANCA/GBM POSITIVE CONTROL 250(ELIA™)-"ELIA MPOS IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO MYELOPEROXIDASE (MPO) IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF MICROSCOPIC POLYANGIITIS (MPA). ELIA MPOS USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN F208, LEMON(IMMUNOCAP) -IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA SCL-70S WELL (ELIA™)-ELIA SCL-70S IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO SCL-70 IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SCLERODERMA (DIFFUSE FORM). ELIA SCL-70S USES THE ELIA IGGMETHOD ON THE PHADIA

	INSTRUMENTS. ,IMMUNOCAP ALLERGEN W6, MUGWORT(IMMUNOCAP) -IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGM CALIBRATORS(ELIA™)-"ELIA CARDIOLIPIN IGM IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGM ANTIBODIES DIRECTED TO CARDIOLIPIN IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME (APS) AND TO EVALUATE THE THROMBOTIC RISK IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA CARDIOLIPIN IGM USES THE THE ELIA IGM METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN E71, MOUSE EPITHELIUM(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA APS POSITIVE CONTROL 250(ELIA™)-"ELIA CARDIOLIPIN IGM IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGM ANTIBODIES DIRECTED TO CARDIOLIPIN IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME (APS) AND TO EVALUATE THE THROMBOTIC RISK IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA CARDIOLIPIN IGM USES THE THE ELIA IGM METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN F245, EGG(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ASCA POSTIVE CONTROL 100 (ELIA™)-"ELIA ASCA IGG IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES

	DIRECTED TO MANNAN OF SACCHAROMYCES CEREVISIAE IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF CROHN'S DISEASE. ELIA ASCA IGG USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN F201, PECAN NUT(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP SPECIFIC IGE ANTI-IGE (IMMUNOCAP™)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN FX5, FOOD(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP TRYPTASE CONJUGATE 50 (IMMUNOCAP™)-IMMUNOCAP TRYPTASE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF TRYPTASE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TRYPTASE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250 OR PHADIA 1000.,IMMUNOCAP ALLERGEN C2, PENICILLOYL V(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED

	IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP TRYPTASE(IMMUNOCAP™)-IMMUNOCAP TRYPTASE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF TRYPTASE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TRYPTASE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250 OR PHADIA 1000.,IMMUNOCAP ALLERGEN F244, CUCUMBER(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA RF POSTIVE CONTROL 250 (ELIA™)-ELIA RF IGM IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGM RHEUMATOID FACTOR IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS. ELIA RF IGM USES THE ELIA IGM METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN G4, MEADOW FESCUE (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN NEGATIVE CONTROL 100 (ELIA™)-ELIA CALPROTECTIN IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN USES THE ELIA CALPROTECTIN METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN G17, BAHIA GRASS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED

	IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP SPECIFIC IGE CURVE CONTROL STRIP(IMMUNOCAP™)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F235, LENTIL(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN CALIBRATOR STRIPS(ELIA™)-ELIA CALPROTECTIN IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN USES THE ELIA CALPROTECTIN METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP PHADIATOP(IMMUNOCAP)-IMMUNOCAP PHADIATOP IS AN IN VITRO QUALITATIVE AND SEMIQUANTITATIVE ASSAY FOR GRADED DETERMINATION OF IGE ANTIBODIES SPECIFIC TO INHALANT ALLERGENS IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP PHADIATOP IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ANTI-TG WELL (ELIA™)-ELIA ANTI-TG IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO THYROGLOBULIN (TG) IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF THYROID DISEASES SUCH AS AUTOIMMUNE THYROIDITIS AND GRAVES' DISEASE. ELIA ANTI-TG USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. , IMMUNOCAP ALLERGEN E215, PIGEON FEATHERS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE

	QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ß2-GLYCOPROTEIN I IGM(ELIA™)-"ELIA ß2-GLYCOPROTEIN I IGM IS INTENDED FOR THE INVITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO ß2-GLYCOPROTEIN I IN HUMAN SERUM AND PLASMA AS AN AID IN THE DIAGNOSIS OF ANTIPHOPHOLIPID SYNDROME (APS)TO EVALUATE THE THROMBOTIC RISK IN PATEINTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA ß2-GLYCOPROTEIN I IGM USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN F202, CASHEW NUT(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,"QUALITY CLUB SPECIFIC IGE"(IMMUNOCAP™)-"QUALITY CLUB SPECIFIC IGE IS A QUALITY ASSESSMENT PROGRAM FOR IMMUNOCAP SPECIFIC IGE USERS. THE INDIVIDUAL LABORATORY'S CONTINUOUS PERFORMANCE IS MONITORED BY COMPARISON OF TEST RESULTS GENERATED FROM OTHER IMMUNOCAP SPECIFIC IGE USERS.", IMMUNOCAP ALLERGEN F88, MUTTON(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP TRYPTASE CALIBRATOR STRIP(IMMUNOCAP™)-IMMUNOCAP TRYPTASE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF TRYPTASE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TRYPTASE IS TO BE USED WITH THE

	INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250 OR PHADIA 1000.,IMMUNOCAP ALLERGEN F84, KIWI FRUIT(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ECP CALIBRATORS(IMMUNOCAP™)-IMMUNOCAP ECP IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF EOSINOPHIL CATIONIC PROTEIN (ECP) IN HUMAN SERUM. IMMUNOCAP ECP IS TO BE USED WITH INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN C261, PHOLCODINE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP TRYPTASE CURVE CONTROL STRIP(IMMUNOCAP™)-IMMUNOCAP TRYPTASE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF TRYPTASE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TRYPTASE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250 OR PHADIA 1000.,IMMUNOCAP ALLERGEN C73, INSULIN HUMAN(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP SPECIFIC IGE CONTROL H (IMMUNOCAP™)-"IMMUNOCAP SPECIFIC IGE CONTROLS ARE USED FOR MONITORING IMMUNOCAP SPECIFIC IGE MEASUREMENTS

	PERFORMANCE IN PHADIA INSTRUMENTS",IMMUNOCAP ALLERGEN K82, LATEX(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP SPECIFIC IGE NEGATIVE CONTROL (IMMUNOCAP™)-"IMMUNOCAP SPECIFIC IGE CONTROLS ARE USED FOR MONITORING IMMUNOCAP SPECIFIC IGE MEASUREMENTS PERFORMANCE IN PHADIA INSTRUMENTS",IMMUNOCAP ALLERGEN C5, AMPICILLOYL(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP TRYPTASE CALIBRATORS(IMMUNOCAP™)-IMMUNOCAP TRYPTASE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF TRYPTASE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TRYPTASE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250 OR PHADIA 1000., IMMUNOCAP ALLERGEN F93, CACAO(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGM CALIBRATOR STRIPS(ELIA™)-"ELIA CARDIOLIPIN IGM IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGM ANTIBODIES DIRECTED TO CARDIOLIPIN IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME (APS) AND TO EVALUATE THE THROMBOTIC RISK IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA CARDIOLIPIN IGM USES THE THE

	ELIA IGM METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN FX21, FRUITS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP TRYPTASE CONTROL(IMMUNOCAP™)-IMMUNOCAP TRYPTASE CONTROL IS USED FOR MONITORING IMMUNOCAP TRYPTASE MEASUREMENTS PERFORMANCE IN PHADIA INSTRUMENTS., IMMUNOCAP ALLERGEN F94, PEAR(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP SPECIFIC IGE CONTROL L(IMMUNOCAP™)-"IMMUNOCAP SPECIFIC IGE CONTROLS ARE USED FOR MONITORING IMMUNOCAP SPECIFIC IGE MEASUREMENTS PERFORMANCE IN PHADIA INSTRUMENTS", IMMUNOCAP ALLERGEN T14, COTTONWOOD(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP TRYPTASE CURVE CONTROL (IMMUNOCAP™)-IMMUNOCAP TRYPTASE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF TRYPTASE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TRYPTASE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250 OR PHADIA 1000.,IMMUNOCAP PHADIATOP INFANT(IMMUNOCAP)-IMMUNOCAP PHADIATOP INFANT IS AN IN VITRO QUALITATIVE AND SEMIQUANTITATIVE ASSAY FOR GRADED

	DETERMINATION OF IGE ANTIBODIES, IN HUMAN SERUM OR PLASMA, SPECIFIC TO ALLERGENS THAT ARE RELEVANT IN THE DEVELOPMENT OF ATOPY IN SMALL CHILDREN. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP PHADIATOP INFANT IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGA CALIBRATORS(ELIA™)-ELIA CELIKEY IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM AND PLASMA. ELIA CELIKEY IGA IS BASED ON RECOMBINANT HUMAN TISSUE TRANSGLUTAMINASE AS ANTIGEN AND IS USEFUL AS AN AID IN THE CLINICAL DIAGNOSIS OF PATIENTS WITH CELIAC DISEASE. ELIA CELIKEY IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN G5, RYE-GRASS (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGA CURVE CONTROLS(ELIA™)-ELIA CELIKEY IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM AND PLASMA. ELIA CELIKEY IGA IS BASED ON RECOMBINANT HUMAN TISSUE TRANSGLUTAMINASE AS ANTIGEN AND IS USEFUL AS AN AID IN THE CLINICAL DIAGNOSIS OF PATIENTS WITH CELIAC DISEASE. ELIA CELIKEY IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN T7, OAK (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA DSDNA WELL (ELIA™)-ELIA DSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO DSDNA IN HUMAN SERUM AND PLASMA AS

	AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA DSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN M36, ASPERGILLUS TERREUS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP TRYPTASE ANTI-TRYPTASE(IMMUNOCAP™)-IMMUNOCAP TRYPTASE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF TRYPTASE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP TRYPTASE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250 OR PHADIA 1000.,IMMUNOCAP ALLERGEN F89, MUSTARD(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CTD SCREEN WELL(ELIA™)-"ELIA CTD SCREEN IS INTENDED FOR THE IN VITRO QUALITATIVE MEASUREMENT OF ANTINUCLEAR IGG ANTIBODIES IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), MIXED CONNECTIVE TISSUE DISEASE (MCTD), SJÖGREN'S SYNDROME, SCLERODERMA AND POLYMYOSITIS/DERMATOMYOSITIS. ELIA CTD SCREEN USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN F24, SHRIMP(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA

	250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CELIAC POSITIVE CONTROL 100(ELIA™)-ELIA CELIKEY IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM AND PLASMA. ELIA CELIKEY IGA IS BASED ON RECOMBINANT HUMAN TISSUE TRANSGLUTAMINASE AS ANTIGEN AND IS USEFUL AS AN AID IN THE CLINICAL DIAGNOSIS OF PATIENTS WITH CELIAC DISEASE. ELIA CELIKEY IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F279, CHILIPEPPER (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA M2 WELL(ELIA™)-ELIA M2 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO M2 IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF PRIMARY BILIARY CIRRHOSIS. ELIA M2 USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F78, ALLERGEN COMPONENT NBOS D 8 CASEIN, MILK (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGM CALIBRATOR WELL(ELIA™)-"ELIA CARDIOLIPIN IGM IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGM ANTIBODIES DIRECTED TO CARDIOLIPIN IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME (APS) AND TO EVALUATE THE THROMBOTIC RISK IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA CARDIOLIPIN IGM USES THE THE ELIA IGM METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN W10, GOOSEFOOT, LAMB'S QUARTERS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE

	MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN POSITIVE CONTROL 100 (ELIA™)-ELIA CALPROTECTIN IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN USES THE ELIA CALPROTECTIN METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F80, LOBSTER(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ANA POSITIVE CONTROL 100 (ELIA™)-ELIA DSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO DSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA DSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F291, CAULIFLOWER (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA INTRINSIC FACTOR WELL (ELIA™)-ELIA INTRINSIC FACTOR IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO INTRINSIC FACTOR IN HUMAN SERUM AND PLASMA TO AID IN THE CLINICAL DIAGNOSIS OF PERNICIOUS ANEMIA. ELIA INTRINSIC FACTOR USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN MX4, MOULDS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN

	CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGG CALIBRATOR WELL (ELIA™)-ELIA DSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO DSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA DSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F268, CLOVE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ASCA POSTIVE CONTROL 250 (ELIA™)-"ELIA ASCA IGG IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO MANNAN OF SACCHAROMYCES CEREVISIAE IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF CROHN'S DISEASE. ELIA ASCA IGG USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS." , IMMUNOCAP ALLERGEN T8, ELM(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGM CURVE CONTROL(ELIA™)-"ELIA CARDIOLIPIN IGM IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGM ANTIBODIES DIRECTED TO CARDIOLIPIN IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME (APS) AND TO EVALUATE THE THROMBOTIC RISK IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA CARDIOLIPIN IGM USES THE THE ELIA IGM METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN F27, BEEF(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE

	CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ANCA/GBM POSITIVE CONTROL 100(ELIA™)-"ELIA MPOS IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO MYELOPEROXIDASE (MPO) IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF MICROSCOPIC POLYANGIITIS (MPA). ELIA MPOS USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN MX1, MOULDS (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ASCA IGA WELL (ELIA™)-"ELIA ASCA IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO MANNAN OF SACCHAROMYCES CEREVISIAE IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF CROHN'S DISEASE. ELIA ASCA IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN T16, WHITE PINE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN 2 CALIBRATOR WELL(ELIA™)-ELIA CALPROTECTIN 2 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN 2 USES THE ELIA CALPROTECTIN 2 METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN M1, PENICILLIUM CHRYSOGENUM(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE

	CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ANTI-IGA POSITIVE CONTROL 100(ELIA™)-ELIA ANTI-IGA IS INTENDEED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO IGA IN HUMAN SERUM OR PLASMA. ELIA ANTI-IGA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN G2, BERMUDA GRASS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGG CURVE CONTROL (ELIA™)-ELIA DSDNA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO DSDNA IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA DSDNA USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. , IMMUNOCAP ALLERGEN I71, MOSQUITO(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA GLIADINDP IGA WELL (ELIA™)-ELIA GLIADIN IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO GLIADIN IN SERUM OR PLASMA TO AID IN THE DIAGNOSIS OF CELIAC DISEASE. ELIA GLIADIN IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN C1, PENICILLOYL G (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS

	PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA M2 POSITIVE CONTROL 100(ELIA™)-ELIA M2 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO M2 IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF PRIMARY BILIARY CIRRHOSIS. ELIA M2 USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN RX3, REGIONAL (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA JO-1 WELL (ELIA™)-ELIA JO-1 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO JO-1 IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF POLYMYOSITIS / DERMATOMYOSITIS. ELIA JO-1 USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN E82, RABBIT EPITHELIUM(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA GLIADIN IGA WELL (ELIA™)-ELIA GLIADIN IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO GLIADIN IN SERUM OR PLASMA TO AID IN THE DIAGNOSIS OF CELIAC DISEASE. ELIA GLIADIN IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F9, RICE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA IGA CONJUGATE 50 (ELIA™)-ELIA CELIKEY IGA IS INTENDED FOR THE IN

	VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM AND PLASMA. ELIA CELIKEY IGA IS BASED ON RECOMBINANT HUMAN TISSUE TRANSGLUTAMINASE AS ANTIGEN AND IS USEFUL AS AN AID IN THE CLINICAL DIAGNOSIS OF PATIENTS WITH CELIAC DISEASE. ELIA CELIKEY IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN D3, HOUSE DUST MITE (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN 2 CURVE CONTROL STRIPS (ELIA™)-ELIA CALPROTECTIN 2 IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN 2 USES THE ELIA CALPROTECTIN 2 METHOD ON THE PHADIA INSTRUMENTS. , IMMUNOCAP ALLERGEN W9, PLANTAIN (ENGLISH), RIBWORT (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CCP WELL(ELIA™)-"ELIA CCP IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO CCP IN HUMAN SERUM AND PLASMA. THE PRESENCE OF ANTI-CCP ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS AS AN AID IN THE CLINICAL DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA). ELIA CCP USES THE THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN T9, OLIVE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES.

	IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CARDIOLIPIN IGG WELL(ELIA™)-ELIA CARDIOLIPIN IGG IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO CARDIOLIPIN IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME (APS) AND TO EVALUATE THE THROMBOTIC RISK IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA CARDIOLIPIN IGG USES THE THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F216, CABBAGE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA MPOS WELL (ELIA™)-"ELIA MPOS IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO MYELOPEROXIDASE (MPO) IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF MICROSCOPIC POLYANGIITIS (MPA). ELIA MPOS USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN F12, PEA(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA GLIADINDP IGG WELL (ELIA™)-ELIA GLIADIN IGG IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO GLIADIN IN SERUM OR PLASMA TO AID IN THE DIAGNOSIS OF CELIAC DISEASE. ELIA GLIADIN IGG USES THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F10, SESAME SEED(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED

	IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CALPROTECTIN CONJUGATE 50 (ELIA™)-ELIA CALPROTECTIN IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN STOOL AS AN AID IN THE CLINICAL DIAGNOSIS OF INFLAMMATORY BOWEL DISEASES (IBD). ELIA CALPROTECTIN USES THE ELIA CALPROTECTIN METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN G1, SWEET VERNAL GRASS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CELIKEY IGA WELL(ELIA™)-ELIA CELIKEY IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM AND PLASMA. ELIA CELIKEY IGA IS BASED ON RECOMBINANT HUMAN TISSUE TRANSGLUTAMINASE AS ANTIGEN AND IS USEFUL AS AN AID IN THE CLINICAL DIAGNOSIS OF PATIENTS WITH CELIAC DISEASE. ELIA CELIKEY IGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN E1, CAT DANDER(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CCP POSITIVE CONTROL 250(ELIA™)-"ELIA CCP IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED TO CCP IN HUMAN SERUM AND PLASMA. THE PRESENCE OF ANTI-CCP ANTIBODIES CAN BE USED IN CONJUNCTION WITH CLINICAL FINDINGS AND OTHER LABORATORY TESTS AS AN AID IN THE CLINICAL DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA). ELIA CCP USES THE THE ELIA IGG METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN F8, MAIZE, CORN (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN

	VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA CARDIOLIPIN IGA WELL(ELIA™)-ELIA CARDIOLIPIN IGA IS INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO CARDIOLIPIN IN SERUM AND PLASMA TO AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME (APS) AND TO EVALUATE THE THROMBOTIC RISK IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA CARDIOLIPIN IGA USES THE THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS. ,IMMUNOCAP ALLERGEN F13, PEANUT(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA ß2-GLYCOPROTEIN I IGA WELL (ELIA™)-"ELIA ß2-GLYCOPROTEIN I I IGA IS INTENDED FOR THE INVITRO QUANTITATIVE MEASUREMENT OF IGA ANTIBODIES DIRECTED TO ß2-GLYCOPROTEIN IIN HUMAN SERUM AND PLASMA AS AN AID IN THE DIAGNOSIS OF ANTIPHOPHOLIPID SYNDROME (APS)TO EVALUATE THE THROMBOTIC RISK IN PATEINTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE). ELIA ß2-GLYCOPROTEIN IIGA USES THE ELIA IGA METHOD ON THE PHADIA INSTRUMENTS." ,IMMUNOCAP ALLERGEN F33, ORANGE(IMMUNOCAP) -IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ELIA GBM WELL (ELIA™)-"THE ELIA GBM WELLS ARE PART OF THE ELIA IGG SYSTEM. THEY ARE INTENDED FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES TO 3 CHAIN OF COLLAGEN IV IN HUMAN SERUM AND PLASMA AS AN AID IN THE CLINICAL DIAGNOSIS OF GOODPASTURE SYNDROME AND ANTI-GBM DISEASE. ELIA GBM USES THE ELIA IGG METHOD ON THE PHADIA

	INSTRUMENTS." ,IMMUNOCAP ALLERGEN WX1, WEED POLLEN (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,SPECIFIC IGG/IGG4 CONTROL L(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGG/IGG4 CONTROLS ARE USED FOR MONITORING IMMUNOCAP SPECIFIC IGG MEASUREMENTS PERFORMANCE IN PHADIA INSTRUMENTS.,IMMUNOCAP ALLERGEN G13, VELVET GRASS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ANTIGEN GM24, STACHYBOTRYS ATRA(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGG IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF SPECIFIC IGG ANTIBODIES IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUNCTION WITH OTHER CLINICAL FINDINGS AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGG IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN I1, HONEY BEE VENOM(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,SPECIFIC IGG CURVE CONTROL STRIP (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGG IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF SPECIFIC IGG ANTIBODIES IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUNCTION WITH OTHER CLINICAL FINDINGS AND IS TO BE USED IN CLINICAL LABORATORIES.

	IMMUNOCAP SPECIFIC IGG IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F214, SPINACH (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ANTIGEN GMX6, MOULDS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGG IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF SPECIFIC IGG ANTIBODIES IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUNCTION WITH OTHER CLINICAL FINDINGS AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGG IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN E3, HORSE DANDER(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IGA/IGG CALIBRATOR(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGG IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF SPECIFIC IGG ANTIBODIES IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUNCTION WITH OTHER CLINICAL FINDINGS AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGG IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F41, SALMON(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA

	250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ANTIGEN GM22, MICROPOLYSPORA FAENI(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGG IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF SPECIFIC IGG ANTIBODIES IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUNCTION WITH OTHER CLINICAL FINDINGS AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGG IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN M5, CANDIDA ALBICANS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,SPECIFIC IGG CONJUGATE 50(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGG IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF SPECIFIC IGG ANTIBODIES IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUNCTION WITH OTHER CLINICAL FINDINGS AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGG IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F36, COCONUT(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,SPECIFIC IGG/IGG4 I1 CONTROL H(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGG/IGG4 CONTROLS ARE USED FOR MONITORING IMMUNOCAP SPECIFIC IGG MEASUREMENTS PERFORMANCE IN PHADIA INSTRUMENTS.,IMMUNOCAP ALLERGEN M4, MUCOR RACEMOSUS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED

	IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,SPECIFIC IGG M3 CONTROL H(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGG/IGG4 CONTROLS ARE USED FOR MONITORING IMMUNOCAP SPECIFIC IGG MEASUREMENTS PERFORMANCE IN PHADIA INSTRUMENTS., IMMUNOCAP ALLERGEN RX2, REGIONAL(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,SPECIFIC IGA/IGG SAMPLE DILUENT(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGG IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF SPECIFIC IGG ANTIBODIES IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUNCTION WITH OTHER CLINICAL FINDINGS AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGG IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F309, CHICK PEA(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ANTIGEN GE92, PARROT SERUM PROTEINS, FEATHERS AND DROPPINGS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGG IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF SPECIFIC IGG ANTIBODIES IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUNCTION WITH OTHER CLINICAL FINDINGS AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGG IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN H1, HOUSE DUST (GREER LABS. INC.)(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO

	DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,ANTIGEN GM23, THERMOACTINOMYCES VULGARIS (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGG IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF SPECIFIC IGG ANTIBODIES IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUNCTION WITH OTHER CLINICAL FINDINGS AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGG IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN E5, DOG DANDER (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,SPECIFIC IGG CALIBRATOR STRIP(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGG IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF SPECIFIC IGG ANTIBODIES IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN CONJUNCTION WITH OTHER CLINICAL FINDINGS AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGG IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F6, BARLEY(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,MAINTENANCE SOLUTION KIT(NIL)-MAINTENANCE SOLUTION KIT IS INTENDED FOR CLEANING OF PHADIA™ INSTRUMENTS.,IMMUNOCAP ALLERGEN F37, BLUE MUSSEL (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN

	SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN M3, ASPERGILLUS FUMIGATUS(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F2, MILK(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F254, PLAICE (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F1, EGG WHITE (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN D1, HOUSE DUST MITE (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST

	SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F262, AUBERGINE, EGGPLANT(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F3, FISH (COD) (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F269, BASIL(IMMUNOCAP) -IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN M6, ALTERNARIA ALTERNATA(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F81, CHEESE, CHEDDAR

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	TYPE(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F316, RAPE SEED (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F4, WHEAT(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F47, GARLIC(IMMUNOCAP) -IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN D2, HOUSE DUST MITE (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500

	OR PHADIA 5000.,IMMUNOCAP ALLERGEN F48, ONION(IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F31, CARROT (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F203, PISTACHIO (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN F14, SOYBEAN (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.,IMMUNOCAP ALLERGEN D201, HOUSE DUST MITE (IMMUNOCAP)-IMMUNOCAP SPECIFIC IGE IS AN IN VITRO TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN SPECIFIC IGE IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN AID IN THE CLINICAL DIAGNOSIS OF IGE MEDIATED ALLERGIC DISORDERS IN CONJUNCTION WITH OTHER CLINICAL FINDINGS, AND IS TO BE USED IN CLINICAL LABORATORIES. IMMUNOCAP SPECIFIC IGE IS TO BE USED WITH THE INSTRUMENTS

	PHADIA 100, PHADIA 200, PHADIA 250, PHADIA 1000, PHADIA 2500 OR PHADIA 5000.

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429	IMP/IVD/2019/000477	1.License Holder Name: DIATEK HEALTHCARE PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:T3(CLIA)(MAGLUMI T3 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) IN HUMAN SERUM.,HCG/BETA HCG (CLIA)(MAGLUMI HCG/BETA HCG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (BETA SUB UNIT) IN HUMAN SERUM., ANTI-TPO (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI TPO IN HUMAN SERUM.,LH (CLIA)(MAGLUMI LH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LH IN HUMAN SERUM,VITAMIN B 12 (CLIA)(MAGLUMI VITAMIN B 12 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN 12 IN HUMAN SERUM.,STARTER 1+2(MAGLUMI)-STARTER REAGENT KIT REQUIRED TO GENERATE THE CHEMILUMINOMETRIC LIGHT SIGNAL NECESSARY FOR THE IMPLEMENTATION OF MAGLUMI ASSAYS ON THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER.,IGE (CLIA)(MAGLUMI IGE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGE IN HUMAN SERUM.,ALBUMIN (CLIA)(MALIUMI ALBUMIN (CLIA))-THE KIT IS AN CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM.,25-OH VITAMIN D (CLIA)(MAGLUMI 25-OH VITAMIN D (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D,17 OH-PROGESTERONE (CLIA)(MAGLUMI 17 OH-PROGESTERONE (CLIA))-THE KIT IS AN CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 17 OH-PROGESTERONE IN HUMAN SERUM.,FT4 (CLIA)(MAGLUMI FT4 (CLIA))-THE KIT IS IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR QUANTITATIVE DETERMINATION FREE THYROXINE IN HUMAN SERUM.,TSH (CLIA)(MAGLUMI TSH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TSH IN HUMAN SERUM.,LIGHT CHECK(MAGLUMI)-LIGHT CHECK REAGENT REQUIRED TO CHECK THE VALIDITY OF STARTER 1+2 AS WELL AS THE FUNCTIONING OF THE MEASURING AND PIPETTING UNITS. A LIGHT CHECK HAS TO BE CARRIED OUT ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER EITHER ONCE DAILY PRIOR TO STARTING THE FIRST MEASUREMENT OR WHENEVER A NEW LOT OF STARTER

	REAGENTS IS USED. THIS CONTROL PROGRAM CHECKS THE PROPER FUNCTIONING OF THE INSTRUMENT AND STARTER REAGENTS TO AVOID DATA ERROR DUE TO INSTRUMENT DEFECTS OR MISLOCATED OR EXPIRED STARTER REAGENTS.,GAD 65 (CLIA)(MAGLUMI GAD 65 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GLUTAMIC ACID DECARBOXYLASE ANTIBODY (GAD 65) IN HUMAN SERUM.,FA (CLIA) (MAGLUMI FA (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLIC ACID (FA) IN HUMAN SERUM.,FERRITIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM.,C-PEPTIDE (CLIA)(MAGLUMI C-PEPTIDE (CLIA))-THE KIT IS IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM.,FREE ESTRIOL (CLIA)(MAGLUMI FREE ESTRIOL (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE ESTRIOL IN HUMAN SERUM.,PRG (CLIA) (MAGLUMI PRG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM.,REACTION MODULE(MAGLUMI)-REACTION MODULES REQUIRED FOR THE IMPLEMENTATION OF THE MAGLUMI ASSAYS ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,CK-MB (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CK-MB IN HUMAN SERUM.,ESTRADIOL (CLIA)(MAGLUMI ESTRADIOL (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM. ,INSULIN (CLIA)(MAGLUMI INSULIN (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM., TESTOSTERONE (CLIA)(MAGLUMI TESTOSTERONE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM.,CORTISOL (CLIA)(MAGLUMI CORTISOL (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM., FREE TESTOSTERONE (CLIA)(MAGLUMI FREE TESTOSTERONE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE IN HUMAN SERUM.,DHEA-S (CLIA)(MAGLUMI DHEA-S (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE

	(DHEA-S) IN HUMAN SERUM.,T4 (CLIA)(MAGLUMI T4 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNO ASSAY FOR THE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM.,SYSTEM TUBING CLEANING SOLUTION(MAGLUMI)-THE MAGLUMI SYSTEM TUBING CLEANING SOLUTION IS USED TO CLEAN THE PIPETTOR AND THE WASHER NEEDLES. IT IS USEFUL TO MINIMIZE REAGENT CARRYOVER BY REDUCING PROTEIN PRECIPITATION IN THE TUBING, AND IMPROVE ROUTINE MAINTENANCE OF THE MAGLUMI SYSTEM. THE KIT CAN ONLY BE USED WITH MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER, WITH TUBING CLEANING PROGRAM.,PRL (CLIA)(MAGLUMI PRL (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM., FT3 (CLIA)(MAGLUMI FT3 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM.,MYOGLOBIN (CLIA)(MAGLUMI)-INTENDED USE: THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM, INTACT PTH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (INTACT PTH) IN HUMAN SERUM,FSH (CLIA)(MAGLUMI FSH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM.,GH (CLIA)(MAGLUMI GH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GROWTH HORMONE (GH) IN HUMAN SERUM.,PCT (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PCT (PROCALCITONIN) IN HUMAN SERUM.,WASH CONCENTRATE(MAGLUMI)-MAGLUMI WASH CONCENTRATE IS INTENDED TO BE DILUTED FOR PREPARATION OF SYSTEM LIQUID WHICH IS REQUIRED FOR WASHING THE MAGNETIC MIRCOBEADS OF THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER,AMH (CLIA)(MAGLUMI AMH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI MULLERIAN HORMONE (AMH) IN HUMAN SERUM.

430	IMP/IVD/2019/000478	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:THINPREP ORANGE G SOLUTION(THINPREP ORANGE G SOLUTION)-THINPREP ORANGE G SOLUTION IS INTENDED TO BE USED IN A PAPANICOLAOU STAINING PROCEDURE IN CONJUNCTION WITH THINPREP NUCLEAR STAIN, THINPREP RINSE SOLUTION, THINPREP BLUING SOLUTION, AND THINPREP EA SOLUTION.,THINPREP NUCLEAR STAIN SOLUTION (THINPREP NUCLEAR STAIN SOLUTION)-THINPREP NUCLEAR STAIN IS INTENDED TO BE USED IN A PAPANICOLAOU STAINING PROCEDURE IN CONJUNCTION WITH THINPREP RINSE SOLUTION, THINPREP BLUING SOLUTION, THINPREP ORANGE G SOLUTION, AND THINPREP EA SOLUTION.,THINPREP EA SOLUTION (THINPREP EA SOLUTION)-THINPREP EA SOLUTION IS INTENDED TO BE USED IN A PAPANICOLAOU STAINING PROCEDURE IN CONJUNCTION WITH THINPREP NUCLEAR STAIN, THINPREP RINSE SOLUTION, THINPREP BLUING SOLUTION, AND THINPREP ORANGE G SOLUTION.,THINPREP RINSE SOLUTION(THINPREP RINSE SOLUTION)-THINPREP RINSE SOLUTION IS INTENDED TO BE USED IN A PAPANICOLAOU STAINING PROCEDURE IN CONJUNCTION WITH THINPREP NUCLEAR STAIN, THINPREP BLUING SOLUTION, THINPREP ORANGE G SOLUTION, AND THINPREP EA SOLUTION.,THINPREP BLUING SOLUTION (THINPREP BLUING SOLUTION)-THINPREP BLUING SOLUTION IS INTENDED TO BE USED IN A PAPANICOLAOU STAINING PROCEDURE IN CONJUNCTION WITH THINPREP NUCLEAR STAIN, THINPREP RINSE SOLUTION, THINPREP ORANGE G SOLUTION, AND THINPREP EA SOLUTION. ,THINPREP CYTOLYT SOLUTION(THINPREP CYTOLYT SOLUTION)-CYTOLYT® SOLUTION IS A WATER-BASED, BUFFERED CELL WASH SOLUTION DESIGNED TO LYSE RED BLOOD CELLS, PREVENT PROTEIN PRECIPITATION, DISSOLVE MUCUS, AND PRESERVE MORPHOLOGY OF GENERAL CYTOLOGY CELLULAR SAMPLES PRIOR TO SLIDE PREPARATION WITH A THINPREP® PROCESSOR.,THINPREP PRESERVCYT SOLUTION(THINPREP PRESERVCYT SOLUTION)-PRESERVCYT® SOLUTION IS DESIGNED FOR USE WITH THE THINPREP® PROCESSOR. PRESERVCYT SOLUTION IS A METHANOL-BASED TRANSPORT MEDIUM AND PRESERVATIVE FOR CYTOLOGIC SAMPLES.,THINPREP PAP TEST PRESERVCYT SOLUTION(THINPREP PAP TEST PRESERVCYT SOLUTION)-IT IS DESIGNED FOR USE WITH THE THINPREP® PROCESSORS. PRESERVCYT SOLUTION IS A METHANOL-BASED REAGENT THAT SERVES AS A TRANSPORT, PRESERVATIVE, AND ANTIBACTERIAL MEDIUM FOR GYNECOLOGIC SAMPLES.

431	IMP/IVD/2019/000479	1.License Holder Name: GASTROLAB INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SCHEBO PANCREATIC ELASTASE 1 QUICK(NA)-QUANTITATIVE RAPID TEST BASED ON MONOCLONAL ANTIBODIES. TO MEASURE ELASTASE 1 IN STOOL FOR THE DIAGNOSIS/EXCLUSION OF AN EXOCRINE PANCREATIC INSUFFICIENCY.,SCHEBO PANCREATIC ELASTASE 1 ELISA STOOL TEST(NA)-QUANTITATIVE ELISA TEST BASED ON MONOCLONAL ANTIBODIES. TO MEASURE ELASTASE 1 IN STOOL FOR THE DIAGNOSIS/EXCLUSION OF AN EXOCRINE PANCREATIC INSUFFICIENCY.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

432	IMP/IVD/2019/000480	1.License Holder Name: WELDON BIOTECH INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ICHROMA™ FERRITIN (ICHROMA™ FERRITIN)-ICHROMA™ FERRITIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN QUANTIFIES HUMAN FERRITIN,COVID-19 AB(ICHROMA)-ICHROMA™ COVID-19 AB IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE DETERMINATION OF IGG/IGM ANTIBODIES AGAINST 'NOVEL CORONAVIRUS' IN HUMAN WHOLE BLOOD / SERUM /PLASMA. IT IS HELPFUL AS AN AID IN THE SCREENING OF EARLY MILD, ASYMPTOMATIC OR ACUTE PATIENTS FOR IDENTIFICATION OF 'NOVEL CORONAVIRUS (E.G., SARS-COV-2)' INFECTION WITH HIGH SENSITIVITY. ,ICHROMA™RF IGM(ICHROMA™RF IGM)-ICHROMA™RFIGMIS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF RF IGMINHUMANWHOLE BLOOD/SERUM/ PLASMA.IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF RHEUMATOID ARTHRITIS.,B-HCG(ICHROMA)-ICHROMA™ -HCG IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL -HCG IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF TOTAL BETA HUMAN CHORIONIC GONADOTROPIN (TOTAL -HCG) LEVEL IN HUMAN. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA™ TSH(ICHROMA™ TSH)-ICHROMA™ TSH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TSH IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF MEASUREMENT IN THE ASSESSMENT OF THYROID FUNCTION.,ANTI-CCP PLUS(ICHROMA)-ICHROMA™ ANTI-CCP PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE OR SEMI-QUANTITATIVE DETERMINATION OF HUMAN IGG AUTOANTIBODIES TO CYCLIC CITRULLINATED PEPTIDES (CCP) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA) IN COMBINATION WITH OTHER CLINICAL AND LABORATORY FINDINGS. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA™ TESTOSTERONE(ICHROMA™ TESTOSTERONE)-ICHROMA™ TESTOSTERONE IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ANDROGEN LEVEL.,DENGUE NS1 AG(ICHROMA)-ICHROMA™ DENGUE NS1 AG IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE DETERMINATION OF NS1 ANTIGEN IN HUMAN WHOLE BLOOD/SERUM/PLASMA DURING DENGUE VIRUS INFECTION. IT IS USEFUL AS AN AID IN SCREENING OF

	EARLY DENGUE VIRUS INFECTION. FOR IN VITRO DIAGNOSTIC USE ONLY.,ICHROMA™ FSH(ICHROMA™ FSH)-ICHROMA™ FSH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE(FSH) IN HUMAN SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF CONCENTRATION OF FSH.,NT-PRO BNP (ICHROMA)-ICHROMA™ NT-PROBNP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF NT-PROBNP IN HUMAN WHOLE BLOOD/ SERUM/PLASMA. IT IS USEFUL AS AN AID IN THE DIAGNOSIS OF PERSONS SUSPECTED OF HAVING CONGESTIVE HEART FAILURE. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA™ PROGESTERONE(ICHROMA™ PROGESTERONE)-ICHROMA™ PROGESTERONE IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THE CAUSE OF INFERTILITY, TRACK OVULATION, DIAGNOSE AN ECTOPIC OR FAILING PREGNANCY, MONITOR THE HEALTH OF A PREGNANCY.,TSH PLUS (ICHROMA)-ICHROMA™ TSH PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TSH IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF MEASUREMENT IN THE ASSESSMENT OF THYROID FUNCTION. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA™ ANTI-CCP(ICHROMA™ ANTI-CCP)-ICHROMA™ ANTI-CCP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE OR SEMI-QUANTITATIVE DETERMINATION OF HUMAN IGG AUTOANTIBODIES TO CYCLIC CITRULLINATED PEPTIDES (CCP) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA) IN COMBINATION WITH OTHER CLINICAL AND LABORATORY FINDINGS.,COVID-19 AG (ICHROMA)-ICHROMA™ COVID-19 AG IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE DETECTION OF NOVEL CORONA VIRUS (SARS-COV-2, 2019-NCOV) IN HUMAN NASOPHARYNGEAL SWAB. IT IS HELPFUL AS AN AID IN THE SCREENING OF EARLY MILD, ASYMPTOMATIC, OR ACUTE PATIENTS FOR IDENTIFICATION OF 'NOVEL CORONAVIRUS' INFECTION. , ICHROMA™ PRL(ICHROMA™ PRL)-ICHROMA™ PRL IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF HYPOTHALAMIC-PITUITARY DISORDERS.,ST2(ICHROMA)-ICHROMA™ ST2 IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE SOLUBLE SUPPRESSOR OF TUMORIGENICITY 2 (ST2) LEVEL IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS

	AN AID IN MANAGEMENT AND ASSESSING THE PROGNOSIS OF PATIENTS DIAGNOSED WITH CHRONIC HEART FAILURE (CHF). FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA™ AFP(ICHROMA™ AFP)-ICHROMA™AFP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF ALPHA FETO PROTEIN (AFP) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF PRIMARY HEPATOCELLULAR CARCINOMA AND NON SEMINOMATOUS TESTICULAR CANCER., CARDIAC TRIPLE(ICHROMA)-ICHROMA™ CARDIAC TRIPLE IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONINI (TNI), CREATINE KINASE (CKMB) AND MYOGLOBIN IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION (AMI) AND ACUTE CORONARY SYNDROME (ACS). FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA™ IFOB NEO(ICHROMA™ IFOB NEO)-ICHROMA™ IFOBIS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN IN HUMAN FECES. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF COLORECTAL CANCER.,AMH(ICHROMA)-ICHROMA™ AMH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF AMH (ANTI-MÜLLERIAN HORMONE) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF PREMATURE OVARIAN INSUFFICIENCY, MENOPAUSE AND OVARIAN RESERVE. FOR IN VITRO DIAGNOSTIC USE ONLY. , ICHROMA™ HBA1C(ICHROMA™ HBA1C)-ICHROMA™ HBA1C IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF HBA1C(HEMOGLOBIN A1C) IN HUMAN WHOLE BLOOD. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THE LONG-TERM GLYCEMIC STATUS IN PATIENTS WITH DIABETES MELLITUS,TOTAL IGE(ICHROMA)-ICHROMA™ TOTAL IGE IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL IGE IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN DIAGNOSIS AND MANAGEMENT OFALLEGIC DISEASE. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA™ MICROALBUMIN(ICHROMA™ MICROALBUMIN)-ICHROMA™ MICROALBUMIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF MICROALBUMIN IN HUMAN URINE. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF KIDNEY DAMAGE FROM DIABETES.,DENGUE IGG/IGM(ICHROMA)-ICHROMA™ DENGUE IGG/IGM IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE DETERMINATION OF IGG/IGM ANTIBODIES AGAINST DENGUE VIRUS IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID

	IN SCREENING OF DENGUE VIRUS INFECTION. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA™ CK-MB(ICHROMA™ CK-MB)-ICHROMA™ CK-MB IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE ISOENZYME-MB (CK-MB) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAC INFARCTION (AMI) AND ACUTE CORONARY SYNDROME (ACS).,TN-I PLUS(ICHROMA)-ICHROMA™ TN I PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN-I (TN-I) IN HUMAN WHOLE BLOOD/ SERUM/PLASMA IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION (AMI) FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA™ CEA(ICHROMA™ CEA)-ICHROMA™ CEA IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CEA IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF CANCER PATIENTS.,IL-6(ICHROMA)-ICHROMA™ IL-6 IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETECTION OF IL-6 IN HUMAN WHOLE BLOOD /SERUM/PLASMA. IT IS HELPFUL AS AN AID IN MANAGEMENT AND MONITORING OF INFLAMMATORY DISEASE. FOR IN VITRO DIAGNOSTIC USE ONLY. , ICHROMA™ LH(ICHROMA™ LH)-ICHROMA™ LH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF EVALUATING FERTILITY ISSUES, FUNCTION OF REPRODUCTIVE ORGANS (OVARIES OR TESTICLES), OR DETECTION OF THE OVULATION.,H.PYLORI SA(ICHROMA)-ICHROMA™ H. PYLORI SA (H. PYLORI STOOL ANTIGEN) IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE DETERMINATION OF H. PYLORI ANTIGEN IN HUMAN FECES. IT IS USEFUL AS AN AID IN THE DIAGNOSIS OF H. PYLORI INFECTION AND TO DEMONSTRATE LOSS OF H. PYLORI ANTIGEN FOLLOWING TREATMENT. FOR IN VITRO DIAGNOSTIC USE ONLY.,ICHROMA™ VITAMIN D(ICHROMA™ VITAMIN D)-ICHROMA™ VITAMIN D IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25(OH)D2/D3 LEVEL IN REGULATING THE CONCENTRATION OF CALCIUM AND PHOSPHATE IN THE BLOODSTREAM AND PROMOTING THE HEALTHY GROWTH AND REMODELING OF BONE. HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF BONE,CALPROTECTIN (ICHROMA)-ICHROMA™ CALPROTECTIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR QUANTITATIVE DETERMINATION OF CALPROTECTIN (MRP8/14; S100A8/S100A9) IN HUMAN FECES. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THE

	REFLEX GASTROINTESTINAL INFLAMMATION CAUSED BY SEVERAL PATHOLOGIES (INFLAMMATORY BOWEL DISEASE, COLORECTAL CANCER AND SOME ENTEROPATHIES). FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA™ -HCG(ICHROMA™ -HCG)-ICHROMA™ -HCG IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL -HCG IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF TOTAL BETA HUMAN CHORIONIC GONADOTROPIN (TOTAL -HCG) LEVEL IN HUMAN.,ICHROMA™ MYOGLOBIN(ICHROMA™ MYOGLOBIN)-ICHROMA™ MYOGLOBIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN WHOLE BLOOD/ SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION (AMI).,ICHROMA™ D-DIMER(ICHROMA™ D-DIMER)-ICHROMA™ D-DIMER IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN WHOLE BLOOD / PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF POST THERAPEUTIC EVALUATION OF THROMBOEMBOLIC DISEASE PATIENTS.,ICHROMA™ PCT PLUS(ICHROMA™ PCT PLUS)-ICHROMA™ PCT PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF BACTERIAL INFECTION AND SEPSIS.,ICHROMA™ T4(ICHROMA™ T4)-ICHROMA™ T4 IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THYROID DISORDER.,ICHROMA™ ASO(ICHROMA™ ASO)-ICHROMA™ ASO IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF ANTI STREPTOLYSIN O (ASO) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF SCARLET FEVER, RHEUMATIC FEVER AND POST INFECTIOUS GLOMERULONEPHRITIS ALONG WITH SEVERAL OTHER CONDITIONS.,ICHROMA™ T3(ICHROMA™ T3)-ICHROMA™ T3 IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (TOTAL T3) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF THYROID DISORDERS., ICHROMA™ PSA(ICHROMA™ PSA)-ICHROMA™ PSA IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROSTATE SPECIFIC ANTIGEN (PSA) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF PROSTATE CANCER OR OTHER

	PROSTATE DISORDERS.,ICHROMA™ CRP(ICHROMA™ CRP)-ICHROMA™ CRP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CRP IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF AUTOIMMUNE DISEASES AND INFECTIOUS PROCESSES, SUCH AS RHEUMATOID ARTHRITIS,ICHROMA™ PCT (ICHROMA™ PCT)-ICHROMA™ PCT IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF BACTERIAL INFECTION AND SEPSIS.,ICHROMA™ CYSTATIN C (ICHROMA™ CYSTATIN C)-ICHROMA™ CYSTATIN C IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF RENAL DISEASE.,ICHROMA™ CORTISOL(ICHROMA™ CORTISOL)-ICHROMA™ CORTISOL IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF CONCENTRATION OF CORTISOL.,ICHROMA™ HSCRP(ICHROMA™ HSCRP)-ICHROMA™ HSCRP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CRP IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF RISK OF CARDIOVASCULAR DISEASES.,ICHROMA™ TN-I (ICHROMA™ TN-I)-ICHROMA™ TN-I IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN-I (TN-I) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION (AMI).

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

433	IMP/IVD/2019/000481	1.License Holder Name: DHR HOLDING INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOCUE HBA1C 501 TEST CARTRIDGE(HEMOCUE HBA1C 501 TEST CARTRIDGE)-THE HEMOCUE® HBA1C 501 TEST CARTRIDGE, TOGETHER WITH THE HEMOCUE® HBA1C 501 ANALYZER, WHICH ARE PARTS OF THE HEMOCUE® HBA1C 501 SYSTEM PROVIDES A CONVENIENT METHOD FOR MEASURING HEMOGLOBIN A1C (HBA1C %) IN BOTH CAPILLARY AND ANTICOAGULATED VENOUS WHOLE BLOOD SAMPLES. THE TEST IS USED FOR MONITORING GLYCEMIC CONTROL IN PATIENTS WITH DIABETES MELLITUS AND AS A SUPPLEMENT OF THE CLINICAL EVIDENCE IN THE DIAGNOSIS OF DIABETES AS WELL AS IN IDENTIFYING PATIENTS AT RISK FOR DEVELOPING DIABETES. , HEMOCUE HBA1C 501 DAILY CHECK CARTRIDGE(HEMOCUE HBA1C 501 DAILY CHECK CARTRIDGE)-HEMOCUE HBA1C 501 CHECK CARTRIDGE FOR QUALITY CONTROL WHICH SCREENS THE OPTICAL AND OPERATION SYSTEM OF ANALYZER ,HEMOCUE HBA1C 501 MONTHLY CHECK CARTRIDGE(HEMOCUE HBA1C 501 MONTHLY CHECK CARTRIDGE)-HEMOCUE HBA1C 501 CHECK CARTRIDGE FOR QUALITY CONTROL WHICH SCREENS THE OPTICAL AND OPERATION SYSTEM OF ANALYZER
434	IMP/IVD/2019/000482	1.License Holder Name: M/S. GERMON STEELS GLOBAL PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(GMATE)-THE GMATE® BLOOD GLUCOSE TEST STRIP IS INTENDED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD. THE GMATE® BLOOD GLUCOSE TEST STRIP IS INTENDED FOR SELF-TESTING USE OUTSIDE THE BODY (FOR IN VITRO DIAGNOSTIC USE) BY PEOPLE WITH DIABETES AT HOME OR BY HEALTH PROFESSIONALS IN A CLINICAL SETTING AS AN AID TO MONITOR THE EFFECTIVENESS OF DIABETES CONTROL.

435	IMP/IVD/2019/000483	1.License Holder Name: BIO-RAD LABORATORIES (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AUTOIMMUNE EIA ANTI GLIADIN IGA TEST(AUTOIMMUNE EIA ANTI GLIADIN IGA TEST)-THE BIO-RAD AUTOIMMUNE EIA ANTI-GLIADIN IGA TEST IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE SEMI-QUANTITATIVE AND QUALITATIVE DETECTION OF IGA ANTIBODIES AGAINST GLIADIN IN HUMAN SERUM. THE ASSAY IS AN AID IN THE DIAGNOSIS OF CELIAC DISEASE (GLUTEN-SENSITIVE ENTEROPATHY) AND SHOULD BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL TESTS AND CLINICAL FINDINGS. FOR IN VITRO DIAGNOSTIC USE,AUTOIMMUNE EIA ANTI SACCHAROMYCES CEREVISIAE ANTIBODIES (ASCA) IGG TEST (AUTOIMMUNE EIA ANTI SACCHAROMYCES CEREVISIAE ANTIBODIES (ASCA) IGG TEST)-THE BIO-RAD AUTOIMMUNE EIA ANTI-SACCHAROMYCES CEREVISIAE ANTIBODIES (ASCA) IGG TEST IS A SOLID PHASE ENZYME IMMUNOASSAY (ELISA) EMPLOYING PURIFIED MANNAN FOR THE SEMI-QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTI-SACCHAROMYCES CEREVISIAE ANTIBODIES (ASCA) IN HUMAN SERUM. ASCA RECOGNIZE SPECIFICALLY MANNAN, A COMPONENT OF THE OUTER CELL WALL OF YEAST.,AUTOIMMUNE EIA ANTI GLIADIN IGG TEST(AUTOIMMUNE EIA ANTI GLIADIN IGG TEST)-THE BIO-RAD AUTOIMMUNE EIA ANTI-GLIADIN IGG TEST IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE SEMI-QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTIBODIES AGAINST GLIADIN IN HUMAN SERUM. THE ASSAY IS AN AID IN THE DIAGNOSIS OF CELIAC DISEASE (GLUTENSENSITIVE ENTEROPATHY) AND SHOULD BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL TESTS AND CLINICAL FINDINGS. FOR IN VITRO DIAGNOSTIC USE.,AUTOIMMUNE EIA ANTI SACCHAROMYCES CEREVISIAE ANTIBODIES (ASCA) IGA TEST(AUTOIMMUNE EIA ANTI SACCHAROMYCES CEREVISIAE ANTIBODIES (ASCA) IGA TEST)-THE BIO-RAD AUTOIMMUNE EIA ANTI-SACCHAROMYCES CEREVISIAE ANTIBODIES (ASCA) IGA TEST IS A SOLID PHASE ENZYME IMMUNOASSAY (ELISA) EMPLOYING PURIFIED MANNAN FOR THE SEMI-QUANTITATIVE AND QUALITATIVE DETECTION OF IGA ANTI-SACCHAROMYCES CEREVISIAE ANTIBODIES (ASCA) IN HUMAN SERUM. ASCA RECOGNIZE SPECIFICALLY MANNAN, A COMPONENT OF THE OUTER CELL WALL OF YEAST. THE BIO-RAD ASCA IGA TEST KIT SHOULD NOT BE USED AS A SCREENING TEST FOR ASCA, SINCE SOME CROHN'S DISEASE PATIENTS DO NOT HAVE ASCA IGA ANTIBODIES. THE BIO-RAD ASCA IGA TEST SHOULD BE USED TO SUPPLEMENT, NOT REPLACE, ASCA IGG TESTING. THE ASSAY IS AN AID IN THE DIAGNOSIS OF CROHN'S DISEASE AND SHOULD BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL TESTS AND CLINICAL

	FINDINGS. FOR IN VITRO DIAGNOSTIC USE.,AUTOIMMUNE EIA ANTI TISSUE TRANSGLUTAMINASE (TTG) IGA TEST(AUTOIMMUNE EIA ANTI TISSUE TRANSGLUTAMINASE (TTG) IGA TEST)-THE BIO-RAD AUTOIMMUNE EIA ANTI-TISSUE TRANSGLUTAMINASE (TTG) IGA TEST IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE SEMI-QUANTITATIVE AND QUALITATIVE DETECTION OF IGA ANTIBODIES AGAINST TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM. THE ASSAY IS AN AID IN THE DIAGNOSIS OF CELIAC DISEASE (GLUTENSENSITIVE ENTEROPATHY) AND SHOULD BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL TESTS AND CLINICAL FINDINGS,AUTOIMMUNE EIA ANTI TISSUE TRANSGLUTAMINASE (TTG) IGG TEST(AUTOIMMUNE EIA ANTI TISSUE TRANSGLUTAMINASE (TTG) IGG TEST)-THE BIO-RAD AUTOIMMUNE EIA ANTI-TISSUE TRANSGLUTAMINASE (TTG) IGG TEST IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE SEMI-QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTIBODIES AGAINST TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM. THE ASSAY IS AN AID IN THE DIAGNOSIS OF CELIAC DISEASE (GLUTENSENSITIVE ENTEROPATHY) AND SHOULD BE USED IN CONJUNCTION WITH OTHER SEROLOGICAL TESTS AND CLINICAL FINDINGS. FOR IN VITRO DIAGNOSTIC USE.,AUTOIMMUNE EIA ANTIMYELOPEROXIDASE (MPO) TEST(AUTOIMMUNE EIA ANTIMYELOPEROXIDASE (MPO) TEST)-THE BIO-RAD AUTOIMMUNE EIA ANTI-MYELOPEROXIDASE (MPO) TEST IS A SOLID PHASE ENZYME IMMUNOASSAY EMPLOYING PURIFIED NATIVE MYELOPEROXIDASE (MPO) FROM HUMAN PERIPHERAL BLOOD POLYMORPHONUCLEAR CELLS FOR THE SEMI-QUANTITATIVE AND QUALITATIVE DETECTION OF ANTIBODIES AGAINST MPO IN HUMAN SERUM. THE ASSAY IS AN AID IN THE DIAGNOSIS OF AUTOIMMUNE SYSTEMIC VASCULITIS, SUCH AS MICROSCOPIC POLYANGIITIS AND GLOMERULONEPHRITIS, AND SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS ,AUTOIMMUNE EIA ANTIPROTEINASE 3 (PR3) TEST (AUTOIMMUNE EIA ANTIPROTEINASE 3 (PR3) TEST)-THE BIO-RAD AUTOIMMUNE EIA ANTI-PROTEINASE 3 (PR3) TEST IS A SOLID PHASE ENZYME IMMUNOASSAY EMPLOYING HIGHLY PURIFIED NATIVE HUMAN PROTEINASE 3 (PR3) FROM HUMAN NEUTROPHIL GRANULOCYTES FOR THE SEMI-QUANTITATIVE AND QUALITATIVE DETECTION OF ANTIBODIES AGAINST PROTEINASE 3 IN HUMAN SERUM. THE ASSAY IS AN AID IN THE DIAGNOSIS OF WEGENER'S GRANULOMATOSIS AND SHOULD BE USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS.

436	IMP/IVD/2019/000484	1.License Holder Name: ACCUREX BIOMEDICALS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IL-6 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY)(GP)-IL-6 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITROQUANTITATIVE DETERMINATION OF INTERLEUKIN 6(IL-6) IN HUMAN SERUM,PLASMA,WHOLE BLOOD ANDPERIPHERAL BLOOD SAMPLES. IL-6 IS AN EARLY MARKER IN ACUTE INFLAMMATION AND THIS TEST CAN BE USED ASAN AID IN THE INFLAMMATORY DISEASES.,D-DIMER(D-DIMER FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY))-RAPID SCREENING FOR DVT & PE ,HBA1C(HBA1C FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY))-DIABETES MONITORING ,PROCALCITONIN (PCT)(PCT FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY))-AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED BACTERIAL INFECTION, TRAUMA OR SHOCK ,CREATINE KINASE-MB/CARDIAC TROPONIN I/MYOGLOBIN(CK-MB/CTNI/MYO FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY))-AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION(AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS AND ACUTE MYOCARDIAL SYNDROME(ACS) , 25-OH-VD(25-OH-VDFAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY))-BONE TURNOVER MARKER ,"N-TERMINAL PROHORMONE OF BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) "(NT-PROBNP FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY))-AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE(HF) , CARDIAC TROPONIN I(CARDIAC TROPONIN I FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY))-AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY UNSTABLE ANGINA, ACUTE MYOCARDITIS AND ACUTE MYOCARDIAL SYNDROME(ACS) ,T4(T4 FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY))-THYROID FUNCTION MONITORING ,ONE STEP TEST FOR NOVEL CORONAVIRUS (2019-NCOV) IGM / IGG ANTIBODY (COLLOIDAL GOLD)(GETEIN)-ONE STEP TEST FOR NOVEL CORONAVIRUS (2019-NCOV) IGM/IGG ANTIBODY (COLLOIDAL GOLD) IS INTENDED FOR THE QUALITATIVE DETECTION OF 2019-NOVEL CORONAVIRUS IGM AND IGG ANTIBODY IN SERUM, PLASMA, FINGERTIP BLOOD OR WHOLE BLOOD SAMPLES OF PNEUMONITIS PATIENTS OR SUSPECTED CASES.,HIGH SENSITIVITY C-REACTIVE PROTEIN (HS-CRP)(HS-CRP+CRP FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY))-AS AN AID IN THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY AND INFLAMMATORY DISORDERS ,T3(T3FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY))-THYROID FUNCTION MONITORING ,TSH(TSH FAST TEST KIT (IMUMUNOFLUORESCENCE

	ASSAY))-THYROID FUNCTION MONITORING ,MICROALBUMINURIA (MALB)(MALB FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY))-AS AN AID IN THE DIAGNOSIS OF KIDNEY DISEASES AND INCREASED CARDIOVASCULAR RISK IN DIABETIC NEPHROPATHY

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

437	IMP/IVD/2019/000485	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEOMASS AAAC(NA)-LABSYSTEMS DIAGNOSTICS' NEOMASS AAAC KIT IS FOR THE QUANTITATIVE MEASUREMENT OF AMINO ACIDS, FREE CARNITINE AND ACYLCARNITINES IN BLOOD SAMPLES DRIED ON FILTER PAPER AS A PRIMARY TEST FOR SCREENING OF NEWBORNS FOR INBORN ERRORS OF METABOLISM.,NEONATAL IRT FEIA(NA)-LABSYSTEMS DIAGNOSTICS' NEONATAL IRT FEIA (FLUOROMETRIC ENZYME IMMUNOASSAY) KIT IS FOR THE QUANTITATIVE DETERMINATION OF HUMAN IMMUNOREACTIVE TRYPSINOGEN (IRT) IN BLOOD SAMPLES DRIED ON FILTER PAPER AS A PRIMARY TEST FOR SCREENING OF BABIES FOR CYSTIC FIBROSIS (CF).,NEONATAL PHENYLALANINE(NA)-LABSYSTEMS DIAGNOSTICS' NEONATAL PHENYLALANINE' IS DESIGNED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PHENYLALANINE CONCENTRATION IN BLOOD SPECIMENS DRIED ON FILTER PAPER INTENDED FOR NEWBORN SCREENING FOR PHENYLKETONURIA (PKU).,NEONATAL GALACTOSE(NA)-LABSYSTEMS DIAGNOSTICS' NEONATAL GALACTOSE KIT IS INTENDED FOR THE QUANTITATIVE FLUOROMETRIC DETERMINATION OF THE TOTAL GALACTOSE FROM DRIED BLOOD SPOT SAMPLES. THE TEST IS BASED ON THE COMBINED DETERMINATION OF FREE AND GALACTOSE LIBERATED FROM THE CLEAVAGE OF THE GALACTOSE-1-PHOSPHATE.,NEOMASS AAAC PLUS(NA)-LABSYSTEMS DIAGNOSTICS' NEOMASS AAAC PLUS KIT IS FOR THE QUANTITATIVE MEASUREMENT OF AMINO ACIDS, FREE CARNITINE, ACYLCARNITINES, ARGININOSUCCINIC ACID AND SUCCINYLACETONE IN BLOOD SAMPLES DRIED ON FILTER PAPER AS A PRIMARY TEST FOR SCREENING OF NEWBORNS FOR INBORN ERRORS OF METABOLISM.,NEONATAL G6PD(NA)-LABSYSTEMS DIAGNOSTICS' NEONATAL G6PD TEST IS DESIGNED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE ACTIVITY IN BLOOD SAMPLES DRIED ON FILTER PAPER INTENDED FOR NEWBORN SCREENING OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE DEFICIENCY.,NEONATAL 17- OH PROGESTERONE FEIA(NA)-LABSYSTEMS DIAGNOSTICS NEONATAL 17- OH PROGESTERONE FEIA TEST IS A SIMPLE COMPETITION FLUOROMETRIC ENZYME IMMUNOASSAY ENABLING THE QUANTIFICATION OF 17- HYDROXYPROGESTRONE STEROID PRESENT IN BLOOD SAMPLES DRIED ON FILTER PAPER.,NEONATAL HTSH FEIA PLUS(NA)-LABSYSTEMS DIAGNOSTICS' NEONATAL HTSH FEIA PLUS (FLUOROMETRIC ENZYME IMMUNOASSAY) KIT IS FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROTROPIN (HTSH) IN BLOOD SAMPLES DRIED ON FILTER PAPER AS A PRIMARY TEST FOR

		SCREENING OF BABIES FOR CONGENITAL HYPOTHYROIDISM (CH). NEONATAL T4 FEIA(NA)-THIS NEONATAL T4 FEIA KIT IS FOR THE QUANTITATIVE MEASUREMENT OF TOTAL THYROXINE CONCENTRATION IN BLOOD SAMPLES DRIED ON FILTER PAPER AS A PRIMARY TEST FOR SCREENING OF BABIES FOR CONGENITAL HYPOTHYROIDISM (CH).,NEONATAL GALT(NA)-LABSYSTEMS DIAGNOSTICS' NEONATAL GALT TEST IS DESIGNED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF GALACTOSE-1-PHOSPHATE URIDYLTRANSFERASE (GALT) ACTIVITY IN BLOOD SAMPLES DRIED ON FILTER PAPER INTENDED FOR SCREENING NEWBORNS FOR CLASSIC GALACTOSEMIA CAUSED BY GALACTOSE-1-PHOSPHATE URIDYLTRANSFERASE DEFICIENCY.,NEONATAL BIOTINIDASE(NA)-NEONATAL BIOTINIDASE KIT IS FOR ENZYMATIC DETERMINATION OF HUMAN BIOTINIDASE ENZYME ACTIVITY FROM BLOOD SAMPLES DRIED ON FILTER PAPER. INTENDED FOR NEWBORN SCREENING FOR BIOTINIDASE DEFICIENCY.
438	IMP/IVD/2019/000486	1.License Holder Name: M/S.ROCHE DIABETES CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(ACCU CHEK ACTIVE)-THE ACCU-CHEK ACTIVE TEST STRIPS ARE INTENDED FOR QUANTITATIVE BLOOD GLUCOSE TESTS IN FRESH CAPILLARY BLOOD. IF THE TEST STRIP IS REMOVED FROM THE METER TO APPLY BLOOD, VENOUS BLOOD ANTICOAGULATED WITH LITHIUM HEPARIN OR AMMONIUM HEPARIN OR EDTA, ARTERIAL BLOOD AND BLOOD FROM NEONATES MAY ALSO BE TESTED. THE TEST STRIPS MAY ONLY BE USED TOGETHER WITH ACCU CHEK ACTIVE METERS. THE SYSTEM COMPRISES THE METER AND TEST STRIPS AND IS SUITABLE FOR SELF-TESTING AND FOR PROFESSIONAL USE. PEOPLE WITH DIABETES CAN USE THIS SYSTEM TO SELF-TEST THEIR BLOOD GLUCOSE. HEALTHCARE PROFESSIONALS CAN USE THIS SYSTEM TO CHECK PATIENTS' BLOOD GLUCOSE VALUES AND THEY CAN USE IT IN SUSPECTED CASES OF DIABETES AND IN EMERGENCY DIAGNOSTICS. THE SYSTEM MUST NOT BE USED TO DIAGNOSE OR RULE OUT DIABETES.

439	IMP/IVD/2019/000487	1.License Holder Name: SYSMEX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CD4 EASY COUNT KIT (CD4 EASY COUNT KIT)-FOR IN VITRO DIAGNOSTIC USE. THE CD4 EASY COUNT KIT IS A MANUAL, TWO COMPONENT, QUANTITATIVE IVD TEST FOR SUBPOPULATION LABELING OF LYMPHOCYTES IN ADULT VENOUS EDTA WHOLE BLOOD, AND SUBSEQUENT ENUMERATION WITH THE SYSMEX PARTEC CYFLOW COUNTER IVD FLOW CYTOMETER. THE CD4 CELL CONCENTRATION OF BLOOD SAMPLES IS A USEFUL INDICATOR FOR THE INITIATION OR FOLLOW-UP OF TREATMENT FOR HIV POSITIVE PATIENTS IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS THE TEST IS INTENDED TO BE PERFORMED BY TRAINED HEALTHCARE PROFESSIONALS..,CD4% EASY COUNT KIT(CD4% EASY COUNT KIT)-THE CD4% EASY COUNT KIT IS A MANUAL, FOUR-COMPONENT, QUANTITATIVE IVD TEST FOR LABELLING OF LEUKOCYTES AND A SUBPOPULATION OF LYMPHOCYTES IN ADULT VENOUS EDTA WHOLE BLOOD, WHICH CAN THEN BE ENUMERATED WITH THE SYSMEX PARTEC CYFLOW COUNTER IVD FLOW CYTOMETER. THE CD4 T CELL CONCENTRATION AND CD4% OF LYMPHOCYTES IN BLOOD SAMPLES ARE USEFUL INDICATORS FOR THE INITIATION OR FOLLOW-UP OF TREATMENT FOR HIV POSITIVE PATIENTS IN CONJUCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. THE TEST IS INTENDED TO BE PERFORMED BY TRAINED HEALTHCARE PROFESSIONALS.
440	IMP/IVD/2019/000488	1.License Holder Name: BIOSYSTEMS DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ISE CALIBRATING KIT (DIESTRO)-USED TO CALIBRATE AND WASH THE ION-PH ANALYZER. PACK CONTAINS SOLUTIONS FOR TWO-POINT CALIBRATION.,ISE CALIBRATING PACK(DIESTRO)-USED TO CALIBRATE AND WASH THE ION-PH ANALYZER. PACK CONTAINS SOLUTIONS FOR TWO-POINT CALIBRATION.,DIESTRO TRILEVEL(DIESTRO)-IT IS INTENDED FOR USE AS A CONTROL MATERIAL TO MONITOR THE MEASUREMENT OF NA, K, CL, CA AND LI.,ISE CLEANING SOLUTION(DIESTRO)-SOLUTION DESIGNED TO MAKE THE CLEANING AND DECONTAMINATION OF THE ANALYZER.,SODIUM CONDITIONER(DIESTRO)-SOLUTION DESIGNED TO CONDITIONING THE SODIUM ELECTRODE.,ISE URINE DILUENT (DIESTRO)-SOLUTION DESIGNED TO DILUTE THE URINE WHEN THIS WILL BE USED AS A SAMPLE.

441	IMP/IVD/2019/000489	1.License Holder Name: INBIOS INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SCRUB TYPHUS DETECT IGM ELISA(INBIOS)-THE SCRUB TYPHUS DETECT™ IGM ELISA TEST FOR EXPOSURE TO ORIENTIA TSUTSUGAMUSHI (OT; FORMERLY RICKETTSIA) IS AN ELISA ASSAY SYSTEM FOR THE DETECTION OF IGM ANTIBODIES IN HUMAN SERUM TO OT-DERIVED RECOMBINANT ANTIGEN.,JE DETECT™ IGM ELISA(JE DETECT™ IGM ANTIBODY CAPTURE ELISA)-THE JE DETECT™ IGM ELISA TEST FOR EXPOSURE TO JAPANESE ENCEPHALITIS VIRUS (JEV) IS AN ELISA ASSAY SYSTEM FOR THE DETECTION OF IGM ANTIBODIES IN HUMAN SERUM TO JEV-DERIVED RECOMBINANT ANTIGEN (JERA) (1-4).,KALAZAR DETECT™ RAPID TEST(INBIOS)-THE KALAZAR DETECT™ TEST FOR VISCERAL LEISHMANIASIS (VL) IS A RAPID IMMUNOCHROMATOGRAPHIC STRIP ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO MEMBERS OF L. DONOVANI IN HUMAN SERUM TO AID IN THE PRESUMPTIVE DIAGNOSIS OF VL.,SCOV-2 DETECTTM IGG ELISA(INBIOS)-THE SCOV-2 DETECT™ IGG ELISA IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM.,WEST NILE DETECT IGM CAPTURE ELISA(INBIOS)-THE WEST NILE DETECTTM IGM CAPTURE ELISA IS DESIGNED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO WEST NILE RECOMBINANT ANTIGENS (WNRA) IN HUMAN SERUM.,SCOV-2 DETECT IGM ELISA(INBIOS)-THE SCOV-2 DETECT™ IGM ELISA IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM.,DENV DETECT NS1 ELISA(INBIOS)-THE DENV DETECTTM NS1 ELISA IS FOR THE EARLY DETECTION OF DENGUE VIRUS (DENV) NS1 ANTIGEN IN HUMAN SERUM. THIS TEST IS FOR THE PRESUMPTIVE CLINICAL LABORATORY DIAGNOSIS OF DENGUE VIRUS INFECTION. THIS ASSAY IS INTENDED FOR USE IN PATIENTS WITH CLINICAL SYMPTOMS CONSISTENT WITH EITHER DENGUE FEVER OR DENGUE HEMORRHAGIC FEVER.
442	IMP/IVD/2019/000492	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IQ LAMINA (IQ LAMINA)-IQ LAMINA IS INTENDED FOR IN VITRO DIAGNOSTIC USE WITH IQ200 SERIES ANALYZERS

443	IMP/IVD/2019/000494	1.License Holder Name: LIFESCAN MEDICAL DEVICES INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROL SOLUTION (ONETOUCH SELECT)(ONETOUCH SELECT)-: FOR USE WITH THE ONETOUCH® SELECTSIMPLE™ BLOOD GLUCOSE METERS TO CHECK THAT THE METER AND TEST STRIPS ARE WORKING TOGETHER PROPERLY AND THAT YOU ARE PERFORMING THE TEST CORRECTLY., CONTROL SOLUTION (ONETOUCH SELECT® PLUS)(ONETOUCH SELECT®PLUS)-FOR USE WITH THE ONETOUCH SELECT® PLUS FAMILY OF BLOOD GLUCOSE METERS (ONETOUCH SELECT PLUS SIMPLE®, ONETOUCH SELECT® PLUS) AND ONETOUCH SELECT® PLUS TEST STRIPS TO CHECK THAT THE METER AND TEST STRIPS ARE WORKING TOGETHER PROPERLY AND THAT THE TEST IS PERFORMING CORRECTLY.,CONTROL SOLUTIONS (ONETOUCH VERIO®)(ONETOUCH VERIO®)-: FOR USE WITH THE ONETOUCH VERIO® FAMILY OF BLOOD GLUCOSE METERS (ONETOUCH VERIO®, ONETOUCH VERIO FLEX™) AND ONETOUCH VERIO® TEST STRIPS TO CHECK THAT THE METER AND TEST STRIPS ARE WORKING TOGETHER PROPERLY AND THAT YOU ARE DOING THE TEST CORRECTLY., CONTROL SOLUTION (ONETOUCH ULTRA)(ONETOUCH ULTRA)-ONETOUCH® ULTRA™ CONTROL SOLUTION IS USED WITH ONETOUCH® ULTRA™ BRAND SYSTEMS, TO CHECK THAT THE METER AND TEST STRIPS ARE WORKING TOGETHER AS A SYSTEM AND THAT YOU ARE PERFORMING THE TEST CORRECTLY. IT IS VERY IMPORTANT THAT YOU DO CONTROL SOLUTION TESTS ROUTINELY TO MAKE SURE YOU ARE GETTING ACCURATE RESULTS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

444	IMP/IVD/2019/000495	1.License Holder Name: THERMO FISHER SCIENTIFIC INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HBA1C CALIBRATOR(NIL)-FOR IN VITRO DIAGNOSTIC USE ONLY. HBA1C CALIBRATOR IS USED AS A STOCK CALIBRATOR FOR QUANTITATION OF HBA1C AND HB ON KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS USING A THERMO FISHER SCIENTIFIC OY DEFINED METHOD HBA1C (CODES 981947 AND 981948).,GLUCOSE (GOD-POD)(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF GLUCOSE CONCENTRATION IN HUMAN SERUM OR PLASMA ON KONELAB AND INDIKO ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES.,GAMMA-GT (IFCC)(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF GAMMA-GT ((-GLUTAMYL)-PEPTIDE: AMINO ACID -GLUTAMYLTRANSFERASE (GGT), EC 2.3.2.2) ACTIVITY IN HUMAN SERUM OR PLASMA ON KONELAB AND INDIKO ANALYZERS., HBA1C(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD ON KONELAB™AND INDIKO™ANALYZERS. THE RESULTS ARE UTILIZED IN THE LONG-TERM MONITORING OF GLYCEMIA. ANY REFERENCE TO THE KONELAB™SYSTEMS ALSO REFERS TO THE T SERIES.,CRP(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CRP IN HUMAN SERUM AND PLASMA ON KONELAB AND INDIKO ANALYZERS.,STFR CONTROL(NA) -STFR CONTROL IS INTENDED FOR USE AS AN ASSAYED CONTROL PREPARATION TO MONITOR TRUENESS OF SOLUBLE TRANSFERRIN RECEPTOR (STFR) TEST ON THERMO SCIENTIFIC™ KONELAB™AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY. ANY REFERENCE TO THE KONELAB™SYSTEMS ALSO REFERS TO THE T SERIES. , SPECITROL(NIL)-SPECITROL IS USED AS AN ASSAYED CONTROL SERUM TO MONITOR PRECISION OF SPECIFIC PROTEIN TESTS DEFINED BY THERMO FISHER SCIENTIFIC OY ON KONELAB™ AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS.,D-DIMER(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF D-DIMER CONCENTRATION IN HUMAN PLASMA ON THERMO SCIENTIFIC™ KONELAB™(60, 30, 20XT) AND INDIKO™ ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES.,GLUCOSE (HK)(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE GLUCOSE CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE ON THERMO SCIENTIFIC™ INDIKO™ AND KONELAB™ ANALYZERS.,SPECICAL(NA)-SPECICAL IS USED AS A STOCK CALIBRATOR FOR BOTH QUANTIFICATION OF SPECIFIC PROTEINS IN SERUM AND PLASMA BY

	IMMUNOTURBIDIMETRY AND FOR ANTIGEN EXCESS DETECTION WITH KONELAB™ AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES ,LDH (SCE)(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LDH (L-LACTATE: NAD OXIDOREDUCTASE EC 1.1.1.27) ACTIVITY IN HUMAN SERUM ON THERMO SCIENTIFIC™ INDIKO™ AND KONELAB™ ANALYZERS., LIPOPROTEIN (A) CALIBRATOR(NA)-LIPOPROTEIN(A) CALIBRATOR IS USED AS A CALIBRATOR FOR QUANTIFICATION OF LIPOPROTEIN(A) IN SERUM AND PLASMA BY IMMUNOTURBIDIMETRY WITH KONELAB™CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,LDH (IFCC)(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LDH (L-LACTATE: NAD OXIDOREDUCTASE EC 1.1.1.27) IN HUMAN SERUM OR PLASMA ON THERMO SCIENTIFIC™ INDIKO™ AND KONELAB™ ANALYZERS.,LIPOTROL HDL/LDL ABNORMAL(NA)-LIPOTROL HDL/LDL ABNORMAL IS A CONTROL SERUM TO MONITOR TRUENESS AND PRECISION OF HDL-CHOLESTEROL AND LDL-CHOLESTEROL METHODS DEFINED BY THERMO FISHER- SCIENTIFIC OY ON KONELAB AND INDIKO CLINICAL CHEMISTRY ANALYZERS. ,LIPASE (COLORIMETRIC)(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE LIPASE (EC 3.1.1.3; TRIACYLGLYCEROL ACYLHYDROLASE) CONCENTRATION IN HUMAN SERUM AND HUMAN PLASMA ON THERMO SCIENTIFIC™ KONELAB™ AND INDIKO™ ANALYZERS., LIPOPROTEIN (A) CONTROL(NA)-LIPOPROTEIN(A) CONTROL IS INTENDED FOR USE ON KONELAB™CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY AS A QUALITY CONTROL TO MONITOR PRECISION OF THE LIPOPROTEIN(A) TEST. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,IRON(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE IRON CONCENTRATION IN HUMAN SERUM OR PLASMA ON KONELAB AND INDIKO ANALYZERS.,MAGNESIUM(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE MAGNESIUM CONCENTRATION IN HUMAN SERUM OR PLASMA ON THERMO SCIENTIFIC™ INDIKO AND KONELAB ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,HBA1C CONTROL NORMAL(NIL)-FOR IN VITRO DIAGNOSTIC USE ONLY. HBA1C CONTROL NORMAL IS INTENDED FOR USE ON KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS AS A PRECISION CONTROL SAMPLE FOR THE HBA1C TEST.,RHEUMATOID

	FACTORS 2 (RF 2)(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS IN HUMAN SERUM AND PLASMA ON THERMO SCIENTIFIC™ KONELAB™ AND INDIKO™ ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,FERRITIN CONTROL HIGH (NIL)-FERRITIN CONTROL HIGH IS INTENDED FOR USE AS AN ASSAYED CONTROL PREPARATION TO MONITOR TRUENESS OF FERRITIN TEST ON THERMO SCIENTIFIC™ KONELAB™ AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY.,CK-MB CONTROL(NA)-CK-MBCONTROL IS INTENDED FOR USE AS A CK-MB AND CK PRECISION CONTROL ON KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,CK (IFCC)(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CREATINE KINASE (ATP: CREATINE N-PHOSPHOTRANSFERASE (CK), EC 2.7.3.2) ACTIVITY IN HUMAN SERUM OR PLASMA ON THERMO SCIENTIFIC™ INDIKO™AND KONELAB™ANALYZERS.,APOA1/APO B CALIBRATOR (NA)-FOR IN VITRO DIAGNOSTIC USE ONLY. APO A1/APO B CALIBRATOR IS USED AS A STOCK CALIBRATOR FOR QUANTIFICATION OF APOLIPOPROTEIN A1 AND B IN SERUM AND PLASMA BY IMMUNOTURBIDIMETRY WITH KONELAB™ AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS USING THE APOLIPOPROTEIN A1 (CODE 981929) AND APOLIPOPROTEIN B (CODE 981930) METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES , RHEUMATOID FACTORS CONTROL(NIL)-RHEUMATOID FACTORS CONTROL IS INTENDED FOR USE ON THERMO SCIENTIFIC™ KONELAB™AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS AS A QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF RHEUMATOID FACTORS TEST.,TRANSFERRIN(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TRANSFERRIN IN HUMAN SERUM AND PLASMA ON KONELAB AND INDIKO ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,CREATININE (JAFFÉ)(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA OR URINE ON THERMO SCIENTIFIC™ KONELAB™ AND INDIKO™ ANALYZERS.,STFR CALIBRATION SET(NA)-STFR CALIBRATION SET IS USED AS A CALIBRATION SET FOR QUANTIFICATION OF SOLUBLE TRANSFERRIN RECEPTOR (STFR) IN SERUM AND PLASMA BY IMMUNOTURBIDIMETRY ON THERMO SCIENTIFIC™ KONELAB™ AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS USING METHODS

	DEFINED BY THERMO FISHER SCIENTIFIC OY. ANY REFERENCE TO THE KONELAB™SYSTEMS ALSO REFERS TO THE T SERIES. ,CRP HIGH SENSITIVITY(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LOW CONCENTRATIONS OF CRP IN HUMAN SERUM AND PLASMA ON THERMO SCIENTIFIC™ KONELAB™ AND INDIKO™ ANALYZERS.,HEMOLYZING REAGENT(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) ON KONELAB™AND INDIKO™ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES,ALKALINE PHOSPHATASE (SCE)(NIL)-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE (ORTHOPHOSPHORIC - MONOESTER PHOSPHO-HYDROLASE, ALKALINE OPTIMUM, EC 3.1.3.1) ACTIVITY IN HUMAN SERUM OR PLASMA ON KONELAB™ANALYZERS ACCORDING TO SCE METHOD. ALL TEST RESULTS MUST BE INTERPRETED WITH REGARD TO THE CLINICAL CONTEXT.,COMPLEMENT C4(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF COMPLEMENT C4 IN HUMAN SERUM AND PLASMA ON THERMO SCIENTIFIC™KONELAB™ AND INDIKO™ ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. , TRIGLYCERIDES(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE TRIGLYCERIDES CONCENTRATION IN HUMAN SERUM AND PLASMA ON KONELAB AND INDIKO ANALYZERS.,COMPLEMENT C3(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF COMPLEMENT C3 IN HUMAN SERUM AND PLASMA ON THERMO SCIENTIFIC™KONELAB™ AND INDIKO™ ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,TOTAL PROTEIN PLUS(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN CONCENTRATION IN HUMAN SERUM OR PLASMA ON KONELAB AND INDIKO ANALYZERS.,ANTISTREPTOLYSIN O(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN O (ASO) IN HUMAN SERUM ON KONELAB AND INDIKO ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T-SERIES ,CK-MB CONTROL HIGH(NIL)-CK-MB CONTROL HIGH IS INTENDED FOR USE AS A CK-MBAND CK PRECISION CONTROL ON KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY. ,IMMUNOGLOBULIN G (IGG)(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G IN HUMAN SERUM AND PLASMA ON KONELAB AND INDIKO ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,CRP CONTROL(NIL)-CRP

	CONTROL IS INTENDED FOR USE ON KONELAB™AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS AS A QUALITY CONTROL SERUM TO MONITOR TRUENESS OF THERMO FISHER SCIENTIFIC OY DEFINED METHODS CRP (CODES 981699 AND 981933) AND CRP PLUS (CODES 981794 AND 981934).,CRP PLUS CALIBRATOR(NA)-CRP PLUS CALIBRATOR IS USED AS A STOCK CALIBRATOR FOR QUANTIFICATION OF CRP IN SERUM AND PLASMA BY IMMUNOTURBIDIMETRY WITH KONELAB™ AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS USING A THERMO FISHER SCIENTIFIC OY DEFINED METHOD CRP PLUS, CODE 981794 (KONELAB), AND CODE 981934 (KONELAB AND INDIKO). ,HDL/LDL CALIBRATOR(NIL)-FOR IN VITRO DIAGNOSTIC USE ONLY. HDL/LDL CALIBRATOR IS INTENDED FOR THE CALIBRATION OF HDL- AND LDL-CHOLESTEROL DIRECT METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY ON KONELAB™ AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS., IMMUNOGLOBULIN A (IGA)(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A IN HUMAN SERUM AND PLASMA ON KONELAB AND INDIKO ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,ECAL(NIL)-ECAL IS USED AS A MULTICALIBRATOR FOR ENZYME TESTS ON KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY.,IMMUNOGLOBULIN M (IGM)(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M IN HUMAN SERUM AND PLASMA ON KONELAB AND INDIKO ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,SCAL(NIL)-SCAL IS USED AS A MULTICALIBRATOR FOR SUBSTRATE TESTS ON KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY.,LIPOPROTEIN (A)(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN(A) IN HUMAN SERUM, LI-HEPARIN PLASMA AND EDTA PLASMA ON KONELAB™(20XT, 30, 60) INSTRUMENTS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES ,CRP HIGH SENSITIVITY CONTROL(NIL)-CRP HIGH SENSITIVITY CONTROL IS INTENDED FOR USE ON THERMO SCIENTIFIC™ KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS AS A QUALITY CONTROL SERUM TO MONITOR PRECISION OF THERMO FISHER SCIENTIFIC OY DEFINED CRP HIGH SENSITIVITY (981798) TEST.,CHOLINESTERASE(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CHOLINESTERASE (EC 3.1.1.8; SCHE) ACTIVITY IN HUMAN SERUM OR PLASMA ON THERMO SCIENTIFIC™ INDIKO™ AND KONELAB™ ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO

	REFERS TO THE T SERIES.,ALBUMIN U CONTROL HIGH(NIL)-ALBUMIN U CONTROL HIGH IS INTENDED FOR USE ON KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS AS A QUALITY CONTROL SAMPLE TO MONITOR TRUENESS OF THERMO FISHER SCIENTIFIC OY DEFINED ALBUMIN MST (CODE 981927) URINE ALBUMIN METHOD. , HBA1C PRETREATMENT LIQUID(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) ON KONELAB™AND INDIKO™ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES,FERRITIN CONTROL(NIL)-FERRITIN CONTROL IS INTENDED FOR USE AS AN ASSAYED CONTROL PREPARATION TO MONITOR TRUENESS OF FERRITIN TEST ON THERMO SCIENTIFIC™KONELAB™AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY.,STFR(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE SOLUBLE TRANSFERRIN RECEPTOR (STFR) CONCENTRATION IN HUMAN SERUM AND PLASMA ON THERMO SCIENTIFIC™ KONELAB™(60, 30, 20XT) AND INDIKO™ ANALYZERS. ANY REFERENCE TO THE KONELAB™SYSTEMS ALSO REFERS TO THE T SERIES. ,CHOLESTEROL (NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CHOLESTEROL CONCENTRATION IN HUMAN SERUM OR PLASMA ON KONELAB AND INDIKO ANALYZERS., APOLIPO-PROTEIN A1(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A1 (APO A1) IN HUMAN SERUM AND PLASMA ON KONELAB AND INDIKO ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,ALBUMIN U CALIBRATOR(NIL)-ALBUMIN U CALIBRATOR IS USED AS A STOCK CALIBRATOR FOR QUANTIFICATION OF ALBUMIN IN URINE BY IMMUNOTURBIDIMETRY WITH KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS USING THERMO FISHER SCIENTIFIC OY DEFINED METHOD ALBUMIN MST (CODE 981927).,HDL-CHOLESTEROL PLUS(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF HDL-CHOLESTEROL IN HUMAN SERUM AND LI-HEPARIN PLASMA ON KONELAB AND INDIKO ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,ALBUMIN U CONTROL(NIL)-ALBUMIN U CONTROL IS INTENDED FOR USE ON KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS AS A QUALITY CONTROL SAMPLE TO MONITOR TRUENESS OF THERMO FISHER SCIENTIFIC OY DEFINED ALBUMIN MST (CODE 981927) URINE ALBUMIN METHOD. ,CK-MB(NA)-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THE B SUBUNIT OF THE ISOENZYME CK-MB OF CREATINE KINASE (ATP: CREATINE N-PHOSPHOTRANSFERASE (CK), EC 2.7.3.2) ACTIVITY IN HUMAN SERUM OR PLASMA ON KONELAB AND INDIKO ANALYZERS.

	ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,ABTROL(NIL)-ABTROL IS A CONTROL SERUM TO MONITOR TRUENESS AND PRECISION OF THE ANALYTES LISTED IN THE SEPARATE ABTROL VALUE SHEET. THE GIVEN VALUES ARE VALID FOR KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY., PHOSPHORUS(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE INORGANIC PHOSPHATE CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE ON KONELAB™AND INDIKO™ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES ,CALCIUM(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE CALCIUM CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE ON KONELAB AND INDIKO ANALYZERS., CREATININE (ENZYMATIC)(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CREATININE CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE ON KONELAB AND INDIKO ANALYZERS, USING ENZYMATIC METHOD. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES ,ALT/GPT (IFCC)(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE (L-ALANINE: 2-OXOGLUTARATE AMINOTRANSFERASE (ALT), EC 2.6.1.2) ACTIVITY IN HUMAN SERUM OR PLASMA ON THERMO SCIENTIFIC™ INDIKO™ AND KONELAB™ ANALYZERS.,ACID PHOSPHATASE(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL AND NONPROSTATIC (TARTRATE RESISTANT) ACID PHOSPHATASE (EC 3.1.3.2; ACP) ACTIVITY IN HUMAN SERUM ON KONELAB™ ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,CRP CONTROL HIGH(NIL)-CRP CONTROL HIGH IS INTENDED FOR USE ON KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS AS A QUALITY CONTROL SERUM TO MONITOR TRUENESS OF THERMO FISHER SCIENTIFIC OY DEFINED METHODS CRP (CODES 981699 AND 981933) AND CRP PLUS (CODES 981794 AND 981934).,LIPOPROTEIN (A) CONTROL HIGH(NA)-LIPOPROTEIN(A) CONTROL HIGH IS INTENDED FOR USE ON KONELAB™ CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY AS A QUALITY CONTROL TO MONITOR PRECISION OF THE LIPOPROTEIN(A) TEST. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,UTROL HIGH (NIL)-UTROL HIGH IS INTENDED FOR USE ON KONELAB™AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY AS AN ASSAYED CONTROL PREPARATION TO MONITOR PRECISION OF THE ANALYTES

	LISTED IN THE ANALYZER SPECIFIC VALUE SHEETS., APOLIPOPROTEIN B(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE APOLIPOPROTEIN B (APO B) IN HUMAN SERUM AND PLASMA ON KONELAB AND INDIKO ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,UREA(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF UREA CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE ON THERMO SCIENTIFIC™ INDIKO™ AND KONELAB™ ANALYZERS.,STFR CONTROL HIGH(NA)-STFR CONTROL HIGH IS INTENDED FOR USE AS AN ASSAYED CONTROL PREPARATION TO MONITOR TRUENESS OF SOLUBLE TRANSFERRIN RECEPTOR (STFR) TEST ON THERMO SCIENTIFIC™ KONELAB™AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY. ANY REFERENCE TO THE KONELAB™SYSTEMS ALSO REFERS TO THE T SERIES. ,NORTROL(NIL)-NORTROL IS A CONTROL SERUM TO MONITOR TRUENESS AND PRECISION OF THE ANALYTES LISTED IN THE SEPARATE NORTROL VALUE SHEET. THE GIVEN VALUES ARE VALID FOR KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY.,CRP PLUS(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CRP IN HUMAN SERUM AND PLASMA ON KONELAB AND INDIKO ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,AMYLASE (IFCC) (NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF -AMYLASE (1,4--D-GLUCAN GLUCANOHYDROLASE, EC 3.2.1.1) ACTIVITY IN HUMAN SERUM, PLASMA OR URINE ON THERMO SCIENTIFIC™ INDIKO™ AND KONELAB™ ANALYZERS.,BICARBONATE(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF BICARBONATE (CO2) CONCENTRATION IN HUMAN SERUM OR PLASMA ON THERMO SCIENTIFIC™ INDIKO™ AND KONELAB™ ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,URIC ACID (AOX)(NIL)-FOR IN VITRO USE IN THE QUANTITATIVE DETERMINATION OF URIC ACID CONCENTRATION IN HUMAN SERUM, PLASMA OR URINE ON KONELAB AND INDIKO ANALYZERS.,BILIRUBIN DIRECT(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF DIRECT (CONJUGATED) BILIRUBIN CONCENTRATION IN HUMAN SERUM OR PLASMA ON THERMO SCIENTIFIC™ INDIKO AND KONELAB ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,CRP CALIBRATION SET(NIL)-CRP CALIBRATION SET IS USED AS A CALIBRATION SET FOR QUANTIFICATION OF CRP IN SERUM AND PLASMA BY IMMUNOTURBIDIMETRY WITH KONELAB™AND

	INDIKO™CLINICAL CHEMISTRY ANALYZERS USING A THERMO FISHER SCIENTIFIC OY DEFINED METHOD CRP, CODE 981699 (KONELAB), AND CODE 981933 (KONELAB AND INDIKO).,ALBUMIN BCG(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM OR PLASMA ON KONELAB AND INDIKO ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,FERRITIN CALIBRATION SET(NIL)-FERRITIN CALIBRATION SET IS USED AS A CALIBRATION SET FOR QUANTIFICATION OF FERRITIN IN SERUM AND PLASMA BY IMMUNOTURBIDIMETRY ON THERMO SCIENTIFIC™ KONELAB™AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY.,ANTISTREPTOLYSIN O CALIBRATOR(NA)-ANTISTREPTOLYSIN O CALIBRATOR IS USED AS A STOCK CALIBRATOR FOR QUANTIFICATION OF ANTISTREPTOLYSIN O IN SERUM AND PLASMA BY IMMUNOTURBIDIMETRY WITH KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS USING THE ANTISTREPTOLYSIN O (CODE 981802) METHOD DEFINED BY THERMO FISHER SCIENTIFIC OY. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES ,UTROL(NIL)-UTROL IS INTENDED FOR USE ON KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY AS AN ASSAYED CONTROL PREPARATION TO MONITOR PRECISION OF THE ANALYTES LISTED IN THE ANALYZER SPECIFIC VALUE SHEETS.,LIPOTROL(NA)-LIPOTROL IS A CONTROL SERUM TO MONITOR TRUENESS AND PRECISION OF LIPID AND APOLIPOPROTEIN METHODS DEFINED BY THERMO FISHER SCIENTIFIC™ ON INDIKO™ AND KONELAB™ CLINICAL CHEMISTRY ANALYZERS. ,ALBUMIN (BCP)(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF THE ALBUMIN IN HUMAN SERUM OR PLASMA ON THERMO SCIENTIFIC™ KONELAB™ ANALYZERS.,LDL-CHOLESTEROL(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF LDL-CHOLESTEROL IN HUMAN SERUM AND PLASMA ON THERMO SCIENTIFIC INDIKO AND KONELAB ANALYZERS. ,AST/GOT (IFCC)(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE (LASPARTATE: 2-OXOGLUTARATE AMINOTRANSFERASE (AST), EC 2.6.1.1) ACTIVITY IN HUMAN SERUM OR PLASMA ON THERMO SCIENTIFIC™ INDIKO™ AND KONELAB™ ANALYZERS.,ALBUMIN MST(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM, PLASMA AND IN LOW ALBUMIN CONCENTRATION IN URINE (E.G. MICROALBUMINURIA) ON KONELAB ANALYZER AND IN LOW ALBUMIN CONCENTRATION IN URINE (E.G. MICROALBUMINURIA) ON INDIKO ANALYZER. ANY REFERENCE TO THE KONELAB SYSTEMS

	ALSO REFERS TO THE T SERIES. ,SPECITROL HIGH(NIL)-SPECITROL HIGH IS USED AS AN ASSAYED CONTROL SERUM TO MONITOR PRECISION OF SPECIFIC PROTEIN TESTS ON KONELAB™AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY.,BILIRUBIN TOTAL (NBD)(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM OR PLASMA ON KONELAB AND INDIKO ANALYZERS. ANY REFERENCE TO KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,HBA1C CONTROL ABNORMAL(NIL)-FOR IN VITRO DIAGNOSTIC USE ONLY. HBA1C CONTROL ABNORMAL IS INTENDED FOR USE ON KONELAB™AND INDIKO™CLINICAL CHEMISTRY ANALYZERS AS A PRECISION CONTROL SAMPLE FOR THE HBA1C TEST. ,FERRITIN(NA)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF FERRITIN CONCENTRATION IN HUMAN SERUM AND PLASMA ON KONELAB™(60, 30, 20XT) ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES. ,ALKALINE PHOSPHATASE (IFCC) PLUS (NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE (ORTHOPHOSPHORIC - MONOESTER PHOSPHO-HYDROLASE, ALKALINE OPTIMUM, EC 3.1.3.1) ACTIVITY IN HUMAN SERUM OR PLASMA ON THERMO SCIENTIFIC™ INDIKO™ AND KONELAB™ ANALYZERS ACCORDING TO THE IFCC METHOD (1).,D-DIMER(NIL)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF D-DIMER CONCENTRATION IN HUMAN PLASMA ON THERMO SCIENTIFIC™ KONELAB™(60, 30, 20XT) AND INDIKO™ ANALYZERS. ANY REFERENCE TO THE KONELAB SYSTEMS ALSO REFERS TO THE T SERIES.,U/CSF PROTEIN(NIL)-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THE TOTAL PROTEIN CONCENTRATION IN HUMAN URINE AND CEREBROSPINAL FLUID ON THERMO SCIENTIFICTM INDIKOTM AND KONELABTM ANALYZERS. ALL TEST RESULTS MUST BE INTERPRETED WITH REGARD TO THE CLINICAL CONTEXT.,D-DIMER CONTROL HIGH(NIL)-D-DIMER CONTROL HIGH IS INTENDED FOR USE AS AN ASSAYED CONTROL PREPARATION TO MONITOR PRECISION OF D-DIMER TEST ON THERMO SCIENTIFIC™ KONELAB™AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY.,D-DIMER CONTROL(NIL)-D-DIMER CONTROL IS INTENDED FOR USE AS AN ASSAYED CONTROL PREPARATION TO MONITOR PRECISION OF D-DIMER TEST ON THERMO SCIENTIFIC™ KONELAB™AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY.,D-DIMER CALIBRATION SET(NIL)-D-DIMER CALIBRATION SET IS USED AS A CALIBRATION SET FOR QUANTIFICATION OF D-DIMER IN PLASMA BY IMMUNOTURBIDIMETRY

	ON THERMO SCIENTIFIC™ KONELAB™AND INDIKO™ CLINICAL CHEMISTRY ANALYZERS USING METHODS DEFINED BY THERMO FISHER SCIENTIFIC OY.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

445	IMP/IVD/2019/000496	1.License Holder Name: B & E DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,"HEMATOLOGY CONTROL" ("HEMATOLOGY CONTROL")-TO MONITOR THE INSTRUMENT PERFORMANCE, ALSO BE AVAILABLE FOR INTERNAL QUALITY CONTROL AND EXTERNAL QUALITY ASSESSMENT.,CELLLYSE (CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,"CALIBRATION PACK FOR ELECTROLYTE ANALYZER"("CALIBRATION PACK FOR ELECTROLYTE ANALYZER")-FOR CALIBRATION OF ION CONCENTRATION, SODIUM, POTASSIUM, CHLORIDE, CALCIUM, PH & TCO2 IN DIFFERENT ELECTROLYTE ANALYZER,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE

	COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,"HEMATOLOGY CONTROL"("HEMATOLOGY CONTROL")-TO MONITOR THE INSTRUMENT PERFORMANCE, ALSO BE AVAILABLE FOR INTERNAL QUALITY CONTROL AND EXTERNAL QUALITY ASSESSMENT.,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,"CALIBRATION PACK FOR ELECTROLYTE ANALYZER"("CALIBRATION PACK FOR ELECTROLYTE ANALYZER")-FOR CALIBRATION OF ION CONCENTRATION, SODIUM, POTASSIUM, CHLORIDE, CALCIUM, PH & TCO2 IN DIFFERENT ELECTROLYTE ANALYZER,"CALIBRATION PACK FOR ELECTROLYTE ANALYZER" ("CALIBRATION PACK FOR ELECTROLYTE ANALYZER")-FOR CALIBRATION OF ION CONCENTRATION, SODIUM, POTASSIUM, CHLORIDE, CALCIUM, PH & TCO2 IN DIFFERENT ELECTROLYTE ANALYZER,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL

	CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,"CALIBRATION PACK FOR ELECTROLYTE ANALYZER" ("CALIBRATION PACK FOR ELECTROLYTE ANALYZER")-FOR CALIBRATION OF ION CONCENTRATION, SODIUM, POTASSIUM, CHLORIDE, CALCIUM, PH & TCO2 IN DIFFERENT ELECTROLYTE ANALYZER,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL CELL COUNT,"CALIBRATION PACK FOR ELECTROLYTE ANALYZER" ("CALIBRATION PACK FOR ELECTROLYTE ANALYZER")-FOR CALIBRATION OF ION CONCENTRATION, SODIUM, POTASSIUM, CHLORIDE, CALCIUM, PH & TCO2 IN DIFFERENT ELECTROLYTE ANALYZER,CELLLYSE(CELLLYSE)-IT'S USED BY AUTOMATED HEMATOLOGY ANALYZER AS A HEMOLYZING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTE COUNT, MONOCYTE CELL COUNT, EOSINOPHIL CELL COUNT, NEUTROPHIL

		CELL COUNT
446	IMP/IVD/2019/000497	1.License Holder Name: ABBOTT HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FREESTYLE OPTIUM BLOOD BETA-KETONE TEST STRIPS-USED FOR QUANTITATIVE MEASUREMENT OF BETA KETONE (BETA HYDROXYBUTYRATE) IN FRESH CAPILLARY BLOOD SAMPLES,FREESTYLE OPTIUM H BLOOD BETA-KETONE TEST STRIPS-USED FOR QUANTITATIVE MEASUREMENT OF BETA KETONE (BETA HYDROXYBUTYRATE) IN FRESH CAPILLARY AND VENOUS WHOLE BLOOD SAMPLES, FREESTYLE OPTIUM BLOOD GLUCOSE TEST STRIPS-USED FOR QUANTITATIVE MEASUREMENT OF GLUCOSE (SUGAR) IN FRESH CAPILLARY BLOOD SAMPLES,FREESTYLE OPTIUM H BLOOD GLUCOSE TEST STRIPS-USED FOR QUANTITATIVE MEASUREMENT OF GLUCOSE (D GLUCOSE) IN FRESH CAPILLARY, VENOUS, ARTERIAL AND NEONATAL WHOLE BLOOD SAMPLES
447	IMP/IVD/2019/000498	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALINITY I STAT CK-MB CONTROLS(ALINITY I STAT CK-MB CONTROLS)-THE ALINITY I STAT CK-MB CONTROLS ARE FOR VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CK-MB IN HUMAN SERUM AND PLASMA.,ALINITY I STAT MYOGLOBIN CONTROLS(ALINITY I STAT MYOGLOBIN CONTROLS)-THE ALINITY I STAT MYOGLOBIN CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM AND PLASMA.

448	IMP/IVD/2019/000500	1.License Holder Name: BIOLINE DIAGNOSTICS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HB HEMOGLOBIN TEST STRIPS(HB HEMOGLOBIN TEST STRIPS)-THE HB HEMOGLOBIN TEST STRIPS (WHOLE BLOOD) ARE FIRM PLASTIC STRIPS ONTO WHICH A MULTILAYER DRY REAGENT IS AFFIXED AND ARE INTENDED TO BE READ ON THE QUIK-CHECK® HB HEMOGLOBIN METER. THE TEST STRIPS FUNCTION BY LYSING ERYTHROCYTES AND CONVERTING THE RELEASED HEMOGLOBIN INTO METHEMOGLOBIN. THIS TEST IS FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN (HB) AND CALCULATED HEMATOCRIT (HCT) IN CAPILLARY AND VENOUS WHOLE BLOOD. THE TEST STRIPS ARE FOR PROFESSIONAL USE ONLY. ,PT/INR TEST STRIPS(PT/INR TEST STRIPS)-USE WITH THE PT/INR MONITORING SYSTEM TO MONITOR BLOOD CLOTTING TIME IN PATIENTS STABILIZED ON COUMARIN-TYPE (E.G. WARFARIN) ANTICOAGULATION THERAPY. ,ULTRA HEMOGLOBIN TEST STRIPS (ULTRA HEMOGLOBIN TEST STRIPS)-QUANTITATIVE DETERMINATION OF HEMOGLOBIN LEVEL IN FRESH FINGERTIP CAPILLARY OR VENOUS WHOLE BLOOD ,3D HEMATOLOGY REAGENT (MI-PO CLEANER)(3D HEMATOLOGY REAGENT (MI-PO CLEANER))-USE IN CONJUNCTION WITH HA-360 3-DIFF AUTOMATIC HEMATOLOGY ANALYZER FOR BLOOD CELL ANALYSIS ,3D HEMATOLOGY REAGENT (CYTO-DILUENT) (3D HEMATOLOGY REAGENT (CYTO-DILUENT))-USE IN CONJUNCTION WITH HA-360 3-DIFF AUTOMATIC HEMATOLOGY ANALYZER FOR BLOOD CELL ANALYSIS. ,3D HEMATOLOGY REAGENT (CYTO-LYSER) (3D HEMATOLOGY REAGENT (CYTO-LYSER))-USE IN CONJUNCTION WITH HA-360 3-DIFF AUTOMATIC HEMATOLOGY ANALYZER FOR BLOOD CELL ANALYSIS. ,CHOL TOTAL CHOLESTEROL TEST STRIPS (CHOL TOTAL CHOLESTEROL TEST STRIPS)-MEASURE THE TOTAL CHOLESTEROL CONCENTRATION IN WHOLE BLOOD.

449	IMP/IVD/2020/000006	1.License Holder Name: M/S. PEERLESS BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:3D HEMATOLOGY REAGENT (MI-PO CLEANER)(MISSION)-MISSION® 3D HEMATOLOGY REAGENT (MI-PO CLEANER) IS INTENDED FOR USE IN CONJUNCTION WITH MISSION® HA-360 3-DIFF AUTOMATIC HEMATOLOGY ANALYZER FOR HUMAN BLOOD CELL ANALYSIS, ROUTINE/ PERIODIC CLEANING AND SYSTEM MAINTENANCE.,URINALYSIS REAGENT STRIPS FOR 2 PARAMETER (GLUCOSE AND PROTEIN)(MISSION)-TO DETECT THE GLUCOSE AND PROTEIN IN URINE,3D HEMATOLOGY REAGENT (CYTO-DILUENT)(MISSION)-MISSION® 3D HEMATOLOGY REAGENT (CYTO-DILUENT) IS INTENDED FOR USE IN CONJUNCTION WITH MISSION® HA-360 3-DIFF AUTOMATIC HEMATOLOGY ANALYZER FOR HUMAN BLOOD CELL ANALYSIS. IT IS USED TO DILUTE AND PREPARE THE HUMAN BLOOD SPECIMENS FOR ANALYSIS.,URINALYSIS REAGENT STRIPS FOR 4 PARAMETER (GLUCOSE, PROTEIN, PH AND SG)(MISSION)-TO DETECT GLUCOSE, PROTEIN, PH AND SG IN URINE,3D HEMATOLOGY REAGENT (CYTO-LYSER)(MISSION)-MISSION® 3D HEMATOLOGY REAGENT (CYTO-LYSER) IS INTENDED FOR HUMAN BLOOD CELL ANALYSIS USING IN CONJUNCTION WITH MISSION® HA-360 3-DIFF AUTOMATIC HEMATOLOGY ANALYZER. IT CAN LYSE THE RBC AND RELEASE HEMOGLOBIN. IT CAN ALSO MODIFY THE WBC.,BLOOD KETONE TEST STRIPS(ON CALL)-TO MEASURE KETONE LEVEL IN BLOOD,HBA1C TEST KIT(THE ON CALL® A1C)-THE ON CALL® A1C TEST KIT IS USED WITH THE ON CALL® A1C ANALYZER TO QUANTITATIVELY DETERMINE THE HEMOGLOBIN A1C (HBA1C) LEVEL (PERCENTAGE OR MMOL/MOL) IN CAPILLARY OR VENOUS WHOLE BLOOD. THE ON CALL® A1C TEST KIT INCLUDES THE CARTRIDGES AND REAGENT 1 & 2. THEY USE BORONATE AFFINITY ASSAY TO SEPARATE THE GLYCATED HEMOGLOBIN FRACTION FROM THE NONGLYCATED FRACTION. THE ON CALL® A1C TEST KIT IS FOR PROFESSIONAL USE ONLY.,BLOOD GLUCOSE TEST STRIPS (ON CALL EXTRA)-TO MEASURE GLUCOSE LEVEL IN CAPILLARY BLOOD,NUCLEIC ACID EXTRACTION KIT(PROMOTOR NUCLEIC ACID EXTRACTION KIT)-THE PROMOTOR® NUCLEIC ACID EXTRACTION KIT IS DESIGNED TO BE USED WITH THE PROMOTOR® NES-32 NUCLEIC ACID EXTRACTION SYSTEM FOR EXTRACTING DNA OR RNA FROM VARIOUS SPECIMENS, SUCH AS SERUM, PLASMA, SWAB, SPUTUM. EXTRACTED NUCLEIC ACID CAN BE USED IN BIOLOGICAL APPLICATIONS AND CLINICAL MOLECULAR DIAGNOSTICS, SUCH AS, NUCLEIC ACID TESTING, GENE CLONING AND SEQUENCING, PCR, MOLECULAR HYBRIDIZATION, ETC.,URINALYSIS REAGENT STRIPS FOR 14 PARAMETER (GLUCOSE, ASCORBIC ACID, PROTEIN, PH, KETONE, LEUKOCYTES,NITRITE, SG, BILIRUBIN,

	UROBILINOGEN, ALBUMIN, CREATININE, CALCIUM AND BLOOD) (MISSION)-TO DETECT GLUCOSE, ASCORBIC ACID, PROTEIN, PH, KETONE, LEUKOCYTES, NITRITE, SG, BILIRUBIN, UROBILINOGEN, ALBUMIN, CREATININE, CALCIUM AND BLOOD,BLOOD GLUCOSE MONITORING SYSTEM(ON CALL PLUS)-TO MEASURE GLUCOSE LEVEL IN CAPILLARY BLOOD.,BLOOD GLUCOSE TEST STRIPS(ON CALL PLUS)-TO MEASURE GLUCOSE LEVEL IN CAPILLARY BLOOD,SARS-COV-2 ANTIGEN RAPID TEST(FLOWFLEX SARS-COV-2 ANTIGEN RAPID TEST)-A RAPID TEST FOR THE QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID ANTIGENS IN NASAL AND NASOPHARYNGEAL SWAB SPECIMENS. ,URINALYSIS REAGENT STRIPS FOR 3 PARAMETER (GLUCOSE, PROTEIN AND KETONE) (MISSION)-TO DETECT GLUCOSE, PROTEIN AND KETONE IN URINE, BLOOD GLUCOSE MONITORING SYSTEM(ON CALL EXTRA)-TO MEASURE GLUCOSE LEVEL IN CAPILLARY BLOOD,LIQUID URINE CONTROL(MISSION)-TO VALIDATE THE VISUAL AND ANALYZER READING OF URINALYSIS,CHOL TOTAL CHOLESTEROL TESTING STRIPS(QUICK CHECK ULTRA)-TO MEASURE TOTAL CHOLESTEROL LEVEL IN CAPILLARY AND VENOUS BLOOD,URINALYSIS REAGENT STRIPS FOR 2 PARAMETER (ALBUMIN AND CREATININE)(MISSION)-TO DETECT THE ALBUMIN AND CREATININE,URINALYSIS REAGENT STRIPS FOR 10 PARAMETER (GLUCOSE, PROTEIN, PH, KETONE, LEUKOCYTES, NITRITE, SG, BILIRUBIN, UROBILINOGEN AND BLOOD) (MISSION)-TO DETECT GLUCOSE, PROTEIN, PH, KETONE, LEUKOCYTES, NITRITE, SG, BILIRUBIN, UROBILINOGEN AND BLOOD IN URINE,URINALYSIS REAGENT STRIPS FOR 1 PARAMETER (GLUCOSE) (MISSION)-TO DETECT THE GLUCOSE IN URINE,URINALYSIS REAGENT STRIPS FOR 2 PARAMETER (GLUCOSE AND KETONE)(MISSION)-TO DETECT THE GLUCOSE AND KETONE IN URINE,HB HEMOGLOBIN TEST STRIPS(QUICK CHECK PLUS)-TO DETECT THE HEMOGLOBIN (HB) AND CALCULATED HAEMATOCRIT (HCT) IN CAPILLARY AND VENOUS WHOLE BLOOD

450	IMP/IVD/2020/000007	1.License Holder Name: SENTIER CONSULTING AND HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IVD STRIPS FOR DETECTION OF IGG IN WHOLE BLOOD AND SERUM(IMMUNE CHECK IGG)-FOR DETECTION OF TOTAL IGG IN HUMAN WHOLE BLOOD AND SERUM,ALLERGY DETECTION PANEL FOR FOOD AND INHALED ALLERGENS(PROTIA ALLERGY-Q 96M)-FOR DETECTION OF ALLERGENS IN HUMAN SERUM COMING FROM FOOD AND INHALED ALLERGENS,INHALENT PANEL FOR DETECTION OF INHALED ALLERGENS(PROTIA ALLERGY-Q 64)-FOR DIAGNOSIS OF ALLERGY GENERATED THROUGH INHALATION,IVD STRIPS FOR DETECTION OF IGG-F IN WHOLE BLOOD OR SERUM(IMMUNECHECK IGG-F)-TOTAL IGG MEASUREMENT,ATOPY PANEL FOR DETECTION OF SKIN ALLERGIES (PROTIA ALLERGY-Q)-DIAGNOSIS OF ALLERGIES OF SKIN,FOOD PANEL FOR DETECTION OF FOOD ALLERGIES(PROTIA ALLERGY-Q 64) -FOR DIAGNOSIS OF FOOD ALLERGENS IN HUMAN SERUM

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

451	IMP/IVD/2020/000008	1.License Holder Name: IRIS HEALTHCARE TECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BETA-HYDROXYBUTYRATE, ENZYMATIC, UV(DIALAB)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF BETA-HYDROXYBUTYRATE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,GLUCOSE, GOD-PAP(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF GLUCOSE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,BILE ACID STANDARD(DIALAB)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF BILE ACIDS IN SERUM OR PLASMA.,POTASSIUM, ENZYMATIC(DIALAB)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF POTASSIUM IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS.,BILE ACIDS, ENZYMATIC CYCLING(DIALAB)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF BILE ACIDS IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,LACTATE, ENZYMATIC, UV(DIALAB)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF LACTATE IN HUMAN PLASMA OR CSF ON PHOTOMETRIC SYSTEMS., CHOLINESTERASE, OPT. DGKC(DIALAB)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF CHOLINESTERASE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,SODIUM, ENZYMATIC(DIALAB)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF SODIUM IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS.,BETA-HYDROXYBUTYRATE STANDARD(DIALAB)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF BETA-HYDROXYBUTYRATE IN SERUM OR PLASMA.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

452	IMP/IVD/2020/000009	1.License Holder Name: SPECTRUM MEDICAL INDUSTRIES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AMMONIA(MEDICON)-FOR QUANTITATIVE DETERMINATION OF AMMONIA ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,TRIGLYCERIDES(MEDICON)-FOR QUANTITATIVE DETERMINATION OF TRIGLYCERIDES ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,AST/GOT(MEDICON)-INTENDED USE: FOR QUANTITATIVE DETERMINATION OF AST/GOT ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,PROTIEN STANDARD(MEDICON)-FOR QUANTITATIVE DETERMINATION OF PROTIEN STANDARD ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,MAGNESIUM(MEDICON)-FOR QUANTITATIVE DETERMINATION OF MAGNESIUM ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,URINARY PROTIEN-CSF(MEDICON)-FOR QUANTITATIVE DETERMINATION OF URINARY PROTIEN-CSF ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,MEDI-CAL(MEDICON)-FOR QUANTITATIVE DETERMINATION OF MEDI-CAL ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,RF CALIBRATOR(MEDICON)-RF CALIBRATOR,ALKALINE PHOSPHATASE (ALP)(MEDICON)-FOR QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHASE(ALP) ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,HBA1C CONTROL (MEDICON)-HBA1C CONTROL,CRP CALIBRATOR(MEDICON)-CRP SINGLE CALIBRATOR,UIBC(MEDICON)-FOR QUANTITATIVE DETERMINATION OF UIBC ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,A- AMYLASE(MEDICON)-FOR QUANTITATIVE DETERMINATION OF A-AMYLASE ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,CHOLESTEROL(MEDICON)-FOR QUANTITATIVE DETERMINATION OF CHOLESTEROL ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,CLINICAL CHEMISTRY CONTROL L-1 (MEDICON)-CLINICAL CHEMISTRY CONTROL L-1,IMMUNOLOGY CONTROL LEVEL-2(MEDICON)-IMMUNOLOGY CONTROL LEVEL-2, HBA1C WITH HBA1C DENATURENT(MEDICON)-FOR QUANTITATIVE DETERMINATION OF HBA1C WITH HBA1C DENATURANT ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,CK-MB CONTROL(MEDICON)-CK-MB CONTROL,CLINICAL CHEMISTRY CONTROL L-2(MEDICON)-CLINICAL CHEMISTRY CONTROL L-2,CK-MB(MEDICON)-FOR QUANTITATIVE DETERMINATION OF CK-MB ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,AMMONIA CONTROL(MEDICON)-AMMONIA CONTROL,LDH P-L(MEDICON)-FOR QUANTITATIVE DETERMINATION OF LDH P-L ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,CRP CALIBRATOR (MEDICON)-CRP CALIBRATOR,CALCIUM(MEDICON)-FOR QUANTITATIVE DETERMINATION OF CALCIUM ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,ALBUMIN(MEDICON)-FOR QUANTITATIVE DETERMINATION OF ALBUMIN ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,CREATININE(MEDICON)-FOR

	QUANTITATIVE DETERMINATION OF CREATININE ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,CRP (MEDICON)-FOR QUANTITATIVE DETERMINATION OF CRP LIQUID ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,UREA(MEDICON)-FOR QUANTITATIVE DETERMINATION OF UREA ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,TOTAL PROTIEN (MEDICON)-FOR QUANTITATIVE DETERMINATION OF TOTAL PROTIEN ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,RF HIGH CALIBRATOR (MEDICON)-RF SINGLE POINT CALIBRATOR,TOTAL BILIRUBIN (MEDICON)-FOR QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,CK-MB CALIBRATOR(MEDICON)-CK-MB CALIBRATOR,IMMUNOLOGY CONTROL LEVEL-3(MEDICON)-IMMUNOLOGY CONTROL LEVEL-3, ALT/GPT(MEDICON)-FOR QUANTITATIVE DETERMINATION OF ALT/GPT ACTIVITY IN SERUM/PLASMA/URINE SAMPLE, MICROALBUMIN(MEDICON)-FOR QUANTITATIVE DETERMINATION OF MICROALBUMIN ACTIVITY IN SERUM/PLASMA/URINE SAMPLE, LIPASE(MEDICON)-FOR QUANTITATIVE DETERMINATION OF LIPASE ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,DIRECT BILIRUBIN (MEDICON)-FOR QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,HDL-CHOLESTEROL(MEDICON)-FOR QUANTITATIVE DETERMINATION OF HDL-CHOLESTEROL ACTIVITY IN SERUM/PLASMA/URINE SAMPLE, AMMONIA CALIBRATOR(MEDICON)-AMMONIA CALIBRATOR,LDL-CHOLESTEROL(MEDICON)-FOR QUANTITATIVE DETERMINATION OF LDL-CHOLESTEROL ACTIVITY IN SERUM/PLASMA/URINE SAMPLE, MICROALBUMIN CALIBRATOR(MEDICON)-MICROALBUMIN CALIBRATOR,IRON(MEDICON)-FOR QUANTITATIVE DETERMINATION OF IRON ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,IMMUNOLOGY CONTROL LEVEL-1(MEDICON)-IMMUNOLOGY CONTROL LEVEL-1,RF LATEX(MEDICON)-FOR QUANTITATIVE DETERMINATION OF RF LATEX ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,GGT(MEDICON)-FOR QUANTITATIVE DETERMINATION OF CREATININE ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,HBA1C CALIBRATOR(MEDICON)-HBA1C CALIBRATOR,URIC ACID(MEDICON)-FOR QUANTITATIVE DETERMINATION OF URIC ACID ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,CK(MEDICON)-FOR QUANTITATIVE DETERMINATION OF CK ACTIVITY IN SERUM/PLASMA/URINE SAMPLE,PHOSPHORUS (MEDICON)-FOR QUANTITATIVE DETERMINATION OF PHOSPHORUS ACTIVITY IN SERUM/PLASMA/URINE SAMPLE

453	IMP/IVD/2020/000010	1.License Holder Name: QIAGEN INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARTUS HBV QS-RGQ KIT (ARTUS HBV QS-RGQ KIT)-THE ARTUS HBV QS-RGQ KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF HEPATITIS B VIRUS (HBV) DNA IN HUMAN EDTA PLASMA. THIS DIAGNOSTIC TEST KIT UTILIZES THE POLYMERASE CHAIN REACTION (PCR) AND IS CONFIGURED FOR USE WITH THE QIASYMPHONY SP/AS AND ROTOR-GENE Q INSTRUMENTS. THE ARTUS HBV QS-RGQ KIT IS INTENDED FOR USE IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS FOR DISEASE PROGNOSIS AND FOR USE AS AN AID IN ASSESSING VIRAL RESPONSE TO ANTIVIRAL TREATMENT AS MEASURED BY CHANGES IN HUMAN EDTA PLASMA HBV DNA LEVELS. THE ARTUS HBV QS-RGQ KIT IS NOT INTENDED TO BE USED AS A SCREENING TEST FOR HBV OR AS A DIAGNOSTIC TEST TO CONFIRM THE PRESENCE OF HBV INFECTION.,ARTUS HCV QS-RGQ KIT(ARTUS HCV QS-RGQ KIT)-THE ARTUS HCV QS-RGQ KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF HEPATITIS C VIRUS (HCV) RNA IN HUMAN EDTA PLASMA. THIS DIAGNOSTIC TEST KIT UTILIZES THE REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) AND IS CONFIGURED FOR USE WITH THE QIASYMPHONY SP/AS AND ROTOR-GENE Q INSTRUMENTS. THE ARTUS HCV QS RGQ KIT IS INTENDED FOR USE IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS FOR DISEASE PROGNOSIS AND FOR USE AS AN AID IN ASSESSING VIRAL RESPONSE TO ANTIVIRAL TREATMENT AS MEASURED BY CHANGES IN HUMAN EDTA PLASMA HCV RNA LEVELS. THE ARTUS HCV QS-RGQ KIT IS NOT INTENDED TO BE USED AS A SCREENING TEST FOR HCV OR AS A DIAGNOSTIC TEST TO CONFIRM THE PRESENCE OF HCV INFECTION.,ARTUS HBV RG PCR KIT (ARTUS HBV RG PCR KIT)-THE ARTUS HBV RG PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF HEPATITIS B VIRUS (HBV) DNA IN HUMAN PLASMA. THIS DIAGNOSTIC TEST KIT UTILIZES THE POLYMERASE CHAIN REACTION (PCR) AND IS CONFIGURED FOR USE WITH ROTOR-GENE Q INSTRUMENTS., QIASTAT-DX RESPIRATORY SARS-COV-2 PANEL(QIASTAT-DX RESPIRATORY SARS-COV-2 PANEL)-THE QIASTAT-DX RESPIRATORY SARS-COV-2 PANEL IS A QUALITATIVE TEST INTENDED FOR ANALYZING NASOPHARYNGEAL SWAB (NPS) SAMPLES FOR THE PRESENCE OF VIRAL OR BACTERIAL NUCLEIC ACIDS. THE QIASTAT-DX RESPIRATORY SARS-COV-2 PANEL IS ABLE TO ACCEPT BOTH DRY SWABS AND TRANSPORT MEDIUM LIQUID SAMPLES. THE ASSAY IS DESIGNED FOR USE WITH THE QIASTAT-DX ANALYZER 1.0 FOR INTEGRATED NUCLEIC ACID EXTRACTION AND MULTIPLEX REAL-

	TIME RT-PCR DETECTION.,ARTUS HCV RG RT-PCR KIT(ARTUS HCV RG RT-PCR KIT)-THE ARTUS HCV RG RT-PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF HEPATITIS C VIRUS (HCV) RNA IN HUMAN PLASMA. THIS DIAGNOSTIC TEST KIT UTILIZES THE REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) AND IS CONFIGURED FOR USE WITH ROTOR-GENE Q INSTRUMENTS. THE TEST CAN QUANTITATE HCV RNA OVER THE RANGE OF 65 – 1 X 106 HCV IU/ML. THE ARTUS HCV RG RT-PCR KIT IS INTENDED FOR USE IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS FOR DISEASE PROGNOSIS AND FOR USE AS AN AID IN ASSESSING VIRAL RESPONSE TO ANTIRETROVIRAL TREATMENT AS MEASURED BY CHANGES IN EDTA PLASMA HCV RNA LEVELS. THE ARTUS HCV RG RT-PCR KIT IS NOT INTENDED TO BE USED AS A SCREENING TEST FOR HCV OR AS A DIAGNOSTIC TEST TO CONFIRM THE PRESENCE OF HCV INFECTION., ARTUS HI VIRUS-1 RG RT-PCR KIT(ARTUS HI VIRUS-1 RG RT-PCR KIT)-THE ARTUS HI VIRUS-1 RG RT-PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) RNA IN HUMAN PLASMA. THIS DIAGNOSTIC TEST KIT UTILIZES THE REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) AND IS CONFIGURED FOR USE WITH ROTOR-GENE Q INSTRUMENTS. THE TEST CAN QUANTITATE HIV-1 RNA OVER THE RANGE OF 120 – 1 X 108 HIV-1 IU/ML. PLASMA SAMPLES CONTAINING GROUP M SUBTYPES A–H HAVE BEEN VALIDATED FOR USE IN THE ASSAY. THE ARTUS HI VIRUS-1 RG RT-PCR KIT IS INTENDED FOR USE IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS FOR DISEASE PROGNOSIS AND FOR USE AS AN AID IN ASSESSING VIRAL RESPONSE TO ANTIRETROVIRAL TREATMENT AS MEASURED BY CHANGES IN EDTA PLASMA HIV-1 RNA LEVELS. THE ARTUS HI VIRUS-1 RG RT-PCR KIT IS NOT INTENDED TO BE USED AS A SCREENING TEST FOR HIV OR AS A DIAGNOSTIC TEST TO CONFIRM THE PRESENCE OF HIV INFECTION.,ARTUS HI VIRUS-1 QS-RGQ KIT(ARTUS HI VIRUS-1 QS-RGQ KIT)-THE ARTUS HI VIRUS-1 QS-RGQ KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) RNA IN HUMAN BIOLOGICAL SAMPLES. THIS DIAGNOSTIC TEST KIT UTILIZES THE REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) AND IS CONFIGURED FOR USE WITH THE QIASYMPHONY SP/AS AND ROTOR-GENE Q INSTRUMENTS. SAMPLE CONTAINING GROUP M SUBTYPES A–H HAVE BEEN VALIDATED FOR USE IN THE ASSAY. THE ARTUS HI VIRUS-1 QS-RGQ KIT IS INTENDED FOR USE IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS FOR DISEASE PROGNOSIS AND FOR USE AS

		AN AID IN ASSESSING VIRAL RESPONSE TO ANTIRETROVIRAL TREATMENT AS MEASURED BY CHANGES IN HUMAN EDTA PLASMA HIV-1 RNA LEVELS. THE ARTUS HI VIRUS-1 QS-RGQ KIT IS NOT INTENDED TO BE USED AS A SCREENING TEST FOR HIV OR AS A DIAGNOSTIC TEST TO CONFIRM THE PRESENCE OF HIV INFECTION.
454	IMP/IVD/2020/000011	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HDL-CHOLESTEROL CALIBRATOR(HDL-CHOLESTEROL CALIBRATOR)-THE HDL-CHOLESTEROL CALIBRATOR IS A LYOPHILISED HUMAN SERUM CALIBRATOR INTENDED TO BE USED WITH THE HDL-CHOLESTEROL REAGENT OSR6187/OSR6287/OSR6687 FOR THE QUANTITATIVE DETERMINATION OF HDL-CHOLESTEROL ON BECKMAN COULTER ANALYSERS.,HDL-CHOLESTEROL(HDL-CHOLESTEROL)-ENZYMATIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF HDL-CHOLESTEROL IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,LDL-CHOLESTEROL CALIBRATOR(LDL-CHOLESTEROL CALIBRATOR)-THE LDL-CHOLESTEROL CALIBRATOR IS A LYOPHILISED HUMAN SERUM CALIBRATOR INTENDED TO BE USED WITH THE LDL-CHOLESTEROL REAGENT OSR6183/OSR6283 FOR THE QUANTITATIVE DETERMINATION OF LDL-CHOLESTEROL ON BECKMAN COULTER ANALYSERS.,LDL-CHOLESTEROL(LDL-CHOLESTEROL)-ENZYMATIC COLOUR TEST FOR THE QUANTITATIVE DETERMINATION OF LDL-CHOLESTEROL IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,CREATININE (ENZYMATIC)(CREATININE (ENZYMATIC))-ENZYMATIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE ON BECKMAN COULTER AU ANALYSERS.

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455	IMP/IVD/2020/000012	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALINITY I TACROLIMUS WHOLE BLOOD PRECIPITATION REAGENT(ALINITY I TACROLIMUS WHOLE BLOOD PRECIPITATION REAGENT)-THE ALINITY I TACROLIMUS WHOLE BLOOD PRECIPITATION REAGENT IS FOR THE EXTRACTION OF TACROLIMUS FROM SAMPLES (HUMAN WHOLE BLOOD PATIENT SPECIMENS, CONTROLS AND ALINITY I TACROLIMUS CALIBRATORS) TO BE TESTED ON THE ALINITY I ANALYZER., ARCHITECT TACROLIMUS WHOLE BLOOD PRECIPITATION REAGENT (ARCHITECT TACROLIMUS WHOLE BLOOD PRECIPITATION REAGENT)-ARCHITECT TACROLIMUS WHOLE BLOOD PRECIPITATION REAGENT IS FOR THE EXTRACTION OF TACROLIMUS FROM SAMPLES (HUMAN WHOLE BLOOD PATIENT SPECIMENS, CONTROLS AND ARCHITECT TACROLIMUS CALIBRATORS) TO BE TESTED ON THE ARCHITECT ISYSTEM.,ALINITY I SIROLIMUS WHOLE BLOOD PRECIPITATION REAGENT(ALINITY I SIROLIMUS WHOLE BLOOD PRECIPITATION REAGENT)-THE ALINITY I SIROLIMUS WHOLE BLOOD PRECIPITATION REAGENT IS FOR THE EXTRACTION OF SIROLIMUS FROM SAMPLES (HUMAN WHOLE BLOOD PATIENT SPECIMENS, CONTROLS AND ALINITY I SIROLIMUS CALIBRATORS) TO BE TESTED ON THE ALINITY I ANALYZER.,ARCHITECT SIROLIMUS WHOLE BLOOD PRECIPITATION REAGENT(ARCHITECT SIROLIMUS WHOLE BLOOD PRECIPITATION REAGENT)-THE ARCHITECT SIROLIMUS WHOLE BLOOD PRECIPITATION REAGENT IS FOR THE EXTRACTION OF SIROLIMUS FROM SAMPLES (HUMAN WHOLE BLOOD PATIENT SPECIMENS, CONTROLS AND ARCHITECT SIROLIMUS CALIBRATORS) TO BE TESTED ON THE ARCHITECT ISYSTEM.,ALINITY I CYCLOSPORINE WHOLE BLOOD PRECIPITATION REAGENT KIT(ALINITY I CYCLOSPORINE WHOLE BLOOD PRECIPITATION REAGENT KIT)-THE ALINITY I CYCLOSPORINE WHOLE BLOOD PRECIPITATION REAGENT KIT IS FOR THE EXTRACTION OF CYCLOSPORINE FROM SAMPLES (HUMAN WHOLE BLOOD PATIENT SPECIMENS, CONTROLS AND ALINITY I CYCLOSPORINE CALIBRATORS) TO BE TESTED ON THE ALINITY I ANALYZER.,ARCHITECT CYCLOSPORINE WHOLE BLOOD PRECIPITATION REAGENT KIT(ARCHITECT CYCLOSPORINE WHOLE BLOOD PRECIPITATION REAGENT KIT)-THE ARCHITECT CYCLOSPORINE WHOLE BLOOD PRECIPITATION REAGENT KIT IS FOR THE EXTRACTION OF CYCLOSPORINE FROM SAMPLES (HUMAN WHOLE BLOOD PATIENT SPECIMENS, CONTROLS AND ARCHITECT CYCLOSPORINE CALIBRATORS) TO BE TESTED ON THE ARCHITECT ISYSTEM.

456	IMP/IVD/2020/000013	1.License Holder Name: SHIVA SCIENTIFIC COMPANY 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HISTO SPOT B 4D(HISTO SPOT B 4D)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR MOLECULAR GENETIC TYPING OF HLA-B WITH THE SSO TECHNIQUE. ,HISTO SPOT COELIAC DISEASE (HISTO SPOT COELIAC DISEASE)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR THE DETECTION OF HLA ALLELES ASSOCIATED WITH COELIAC DISEASE WITH THE SSO TECHNIQUE.,HISTO SPOT A 4D(HISTO SPOT A 4D)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR MOLECULAR GENETIC TYPING OF HLA-A WITH THE SSO TECHNIQUE. , HISTO SPOT DQB1 4D/DQA1(HISTO SPOT DQB1 4D/DQA1)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR MOLECULAR GENETIC TYPING OF HLA-DQB1 AND HLA DQA1 WITH THE SSO TECHNIQUE,HISTO SPOT DRB1 4D(HISTO SPOT DRB1 4D)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR MOLECULAR GENETIC TYPING OF HLA-DRB1 WITH THE SSO TECHNIQUE,HISTO SPOT C 4D(HISTO SPOT C 4D)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR MOLECULAR GENETIC TYPING OF HLA-C WITH THE SSO TECHNIQUE. , HISTO SPOT REAGENT KIT(HISTO SPOT REAGENT KIT)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TESTS KIT WITH REAGENTS TO BE USED TOGETHER WITH THE KITS FROM THE BAG PRODUCT LINE HISTO SPOT® FOR MOLECULAR GENETIC HLA TYPING/DETECTION OF DISEASE ASSOCIATED HLA ALLELES USING THE SSO TECHNIQUE.
457	IMP/IVD/2020/000014	1.License Holder Name: ASPEN DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HB HAEMOGLOBIN TEST STRIPS-FOR ESTIMATION OF HEMOGLOBIN,URINE ANALYSIS REAGENT STRIPS-FOR ESTIMATION OF GLUCOSE, BILIRUBIN, PH, SPECIFIC GRAVITY, PROTEIN, UROBILINOGEN, NITRITE, KETONE, BLOOD, LEUKOCYTE, ASCORBIC ACID, MICROALBUMIN, CREATININE, CALCIUM ETC. IN URINE,CHOLESTEROL TEST DEVICES-FOR ESTIMATION OF TOTAL CHOLESTEROL, HDL AND TRIGLYCERIDES, LIQUID URINE CONTROL-FOR QUALITY CONTROL OF URINE ANALYSIS REAGENT STRIPS,CHOL TOTAL CHOLESTEROL TEST STRIPS-FOR ESTIMATION OF CHOLESTEROL

458	IMP/IVD/2020/000015	1.License Holder Name: ASPEN DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SMART CHECK BLOOD GLUCOSE TEST STRIPS(GLUCO CHEK)-MEASUREMENT OF BLOOD GLUCOSE VALUE,AP-PLUS BLOOD GLUCOSE METER(AP+PLUS)-IT IS A DEVICE TO MEASURE THE CONCENTRATION OF GLUCOSE IN BLOOD.,AP-PLUS BLOOD GLUCOSE TEST STRIPS(AP+PLUS)-MEASUREMENT OF BLOOD GLUCOSE VALUE,SMART CHEK BLOOD GLUCOSE METER(GLUCO CHEK)-IT IS DEVICE TO MEASURE THE CONCENTRATION OF GLUCOSE IN BLOOD.,AP-PLUS BLOOD GLUCOSE MONITORING SYSTEM(AP+PLUS)-IT IS A DEVICE TO MEASURE THE CONCENTRATION OF GLUCOSE IN BLOOD.,SMART CHEK BLOOD GLUCOSE MONITORING SYSTEM(GLUCO CHEK)-IT IS DEVICE TO MEASURE THE CONCENTRATION OF GLUCOSE IN BLOOD

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459	IMP/IVD/2020/000016	1.License Holder Name: M/S.ROCHE DIABETES CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE MONITORING STRIPS(ACCU CHEK PERFORMA TEST STRIPS)-THE ACCUCHEK PERFORMA TEST STRIPS ARE INTENDED TO BE USED WITH THE ACCUCHEK PERFORMA, ACCUCHEK PERFORMA NANO AND ACCUCHEK PERFORMA SOLO BLOOD GLUCOSE METERS TO QUANTITATIVELY MEASURE GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD AS AN AID IN MONITORING THE EFFECTIVENESS OF CONTROLLING GLUCOSE. TESTING SITES FOR THE ACCUCHEK PERFORMA AND ACCUCHEK PERFORMA NANO METERS INCLUDE THE FINGER, PALM, FOREARM AND UPPER ARM. THE TESTING SITE FOR THE ACCU-CHEK PERFORMA SOLO METERS IS THE FINGERTIP. THE ACCUCHEK PERFORMA TEST STRIPS, USED WITH THE ACCUCHEK PERFORMA AND ACCUCHEK PERFORMA NANO METERS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS IN CLINICAL SETTINGS AND BY PEOPLE WITH DIABETES AT HOME. THE ACCU-CHEK PERFORMA SOLO METERS ARE FOR HOME USE ONLY. HEALTHCARE PROFESSIONALS CAN USE VENOUS, ARTERIAL AND NEONATAL BLOOD WITH THE ACCU-CHEK PERFORMA AND ACCU-CHEK PERFORMA NANO METERS. THE SYSTEMS ARE NOT FOR USE IN DIAGNOSIS OR SCREENING OF DIABETES MELLITUS, NOR FOR TESTING NEONATE CORD BLOOD SAMPLES. VENOUS, ARTERIAL AND NEONATAL BLOOD TESTING IS LIMITED TO HEALTHCARE PROFESSIONAL USE ONLY. ,BLOOD GLUCOSE MONITORING STRIPS(ACCU-CHEK AVIVA TEST STRIPS)-THE ACCU-CHEK AVIVA TEST STRIPS ARE INTENDED TO BE USED WITH THE ACCU-CHEK AVIVA, ACCU-CHEK AVIVA NANO, ACCU-CHEK AVIVA CONNECT, ACCU-CHEK AVIVA COMBO, ACCU-CHEK AVIVA EXPERT, ACCU-CHEK AVIVA INSIGHT, AND ACCU-CHEK AVIVA SOLO BLOOD GLUCOSE METERS TO QUANTITATIVELY MEASURE GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD AS AN AID IN MONITORING THE EFFECTIVENESS OF CONTROLLING GLUCOSE. TESTING SITES FOR THE ACCU-CHEK AVIVA, ACCU-CHEK AVIVA NANO AND ACCU-CHEK AVIVA CONNECT METERS INCLUDE THE FINGER, PALM, FOREARM, AND UPPER ARM. THE TESTING SITE FOR THE ACCU-CHEK AVIVA COMBO, ACCU-CHEK AVIVA EXPERT, ACCU-CHEK AVIVA INSIGHT AND ACCU-CHEK AVIVA SOLO METERS IS THE FINGERTIP. THE ACCU-CHEK AVIVA TEST STRIP, USED WITH THE ACCU-CHEK AVIVA, ACCU-CHEK AVIVA NANO, AND ACCU-CHEK AVIVA CONNECT METERS, ARE INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS IN CLINICAL SETTINGS AND BY PEOPLE WITH DIABETES AT HOME. THE ACCU-CHEK AVIVA COMBO, ACCU-CHEK

	AVIVA EXPERT, ACCU-CHEK AVIVA INSIGHT AND ACCU-CHEK AVIVA SOLO METERS ARE FOR HOME USE ONLY. HEALTHCARE PROFESSIONALS CAN USE VENOUS, ARTERIAL, AND NEONATAL BLOOD WITH THE ACCU-CHEK AVIVA AND ACCU-CHEK AVIVA NANO METERS. HEALTHCARE PROFESSIONALS CAN USE CAPILLARY AND VENOUS BLOOD WITH THE ACCU-CHEK AVIVA CONNECT METER. THE SYSTEMS ARE NOT FOR USE IN DIAGNOSIS OR SCREENING OF DIABETES MELLITUS, NOR FOR TESTING NEONATE CORD BLOOD SAMPLES. VENOUS, ARTERIAL, AND NEONATAL BLOOD TESTING IS LIMITED TO HEALTHCARE PROFESSIONAL USE ONLY.

460	IMP/IVD/2020/000017	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALLERGEN- ASPERGILLUS NIGER(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM , ALLERGEN- PEANUT(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- SORGHUM HALEPENSE (JOHNSON GRASS)(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- ORANGE(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- SOYA BEAN(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- COTTON SEED(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- BORMUS INERMIS (BROME GRASS)(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- ANTHOXANTHUM ODORATUM (SWEET VERNAL GRASS)(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- YEAST(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- CLOVES(RADIM Q)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- HELIANTHUS ANNUUS(SUNFLOWER)(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- AVENA SATIVA (CULTIVATED OAT)(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- HOLCUS LANATUS (VELVET GRASS)(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- BLATELLA GERMANICA (COCKROACH) (RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM , ALLERGEN- CHICK PEA(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- CURD(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- GARLIC(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,BIOTINYLATED ALLERGENS (RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- AMBROSIA ELATIOR (COMMON RAGWEED) (RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM , ALLERGENP BASIC KIT 96 TESTS AB (RADIM)-QUANTITATIVE DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- POTATO(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- MUCOR MUCEDO(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN P IGE CALIBRATION SET AB(RADIM)-QUANTITATIVE DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- WHOLE EGG(HEN)(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- SPINACH(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- TARTRAZINE(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- CABBAGE(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- PIGEON DROPPINGS(RADIM)-DETERMINATION OF SPECIFIC IGE IN

	HUMAN SERUM ,ALLERGEN- PIGEON FEATHERS(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN-YOGURT(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- TOMATO(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- COCONUT(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN-ONION(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM , ALLERGEN- BANANA(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM,ALLERGEN- TULIPA SPP. (TULIP)(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN P TOTAL IGE (RADIM)-QUANTITATIVE DETERMINATION OF TOTAL IMMUNOGLOBULIN E (IGE) IN HUMAN SERUM. ,ALLERGEN- OATS (RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM , ALLERGEN- DERMATO PHAGOIDES FARINAE(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN-WALNUT(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- SORBIC ACID(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN-LOLIUM PERENNE (RYE-GRASS)(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- CYNODON DACTYLON (BERMUDA GRASS)(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN-HEENA(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM , ALLERGEN- ASPERGILLUS FUMIGATUS(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- COFFEE(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN-FISH (COD)(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- COCOA(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- ALMOND(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN-CHICKEN MEAT(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- COW MILK(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN-GLUTEN(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN-SESAME SEED(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- CHOCOLATE(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- LEMON(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN-GINGER(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- PHRAGMITES COMMUNIS (COMMON REED)(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN-CANDIDA ALBICANS(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- TEA(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- SUNFLOWER SEED (RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,

	ALLERGEN- MUSHROOMS(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- CORIANDER(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- CASEIN (BOVINE) (RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM , ALLERGEN- PEA(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- CARROT(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- DOG DANDER(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- APPLE(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM , ALLERGEN- FRANSERIA ACANTHICARPA (FALSE RAGWEED)(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- SUNFLOWER SEED(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- HORSE DANDER(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- CARDAMON(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- BASIL(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- MILLET(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- CAULIFLOWER(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- DERMATO PHAGOIDES PTEONYSSINUS(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- MAIZE(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN- DOG EPITHELIUM(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM ,ALLERGEN-TOBACCO DUST(RADIM)-DETERMINATION OF SPECIFIC IGE IN HUMAN SERUM

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461	IMP/IVD/2020/000018	1.License Holder Name: CRESCENT ORGANICS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:I-STAT PT/INR CARTRIDGE(I-STAT PT/INR CARTRIDGE)-I-STAT PT, A PROTHROMBIN TIME TEST IS USEFUL FOR MONITORING PATIENTS RECEIVING ORAL ANTICOAGULATION THERAPY SUCH AS COUMADIN OR WARFARIN.,I-STAT CHEM8+ CARTRIDGE(I-STAT CHEM8+ CARTRIDGE)-THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM, POTASSIUM, CHLORIDE (BUN/UREA), GLUCOSE, HEMOCRIT, IONIZED CALCIUM, TCO2, CREATININE IN ARTERIAL OR VENOUS WHOLE BLOOD.,I-STAT CTNI CARTRIDGE(I-STAT CTNI CARTRIDGE)-THE I-STAT® CARDIAC TROPONIN I (CTNI) TEST IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF CARDIAC TROPONIN I (CTNI) IN WHOLE BLOOD OR PLASMA. MEASUREMENTS OF CARDIAC TROPONIN I ARE USED IN THE DIAGNOSIS AND TREATMENT OF MYOCARDIAL INFARCTION AND AS AN AID IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES WITH RESPECT TO THEIR RELATIVE RISK OF MORTALITY.,I-STAT CG4+ CARTRIDGE(I-STAT CG4+ CARTRIDGE)-THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM, IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PO2, PH, PCO2, TCO2, LACTATE IN ARTERIAL OR VENOUS WHOLE BLOOD.,I-STAT CG8+ CARTRIDGE(I-STAT CG8+ CARTRIDGE)-THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM POTASSIUM, GLUCOSE, HEMATOCRIT, PO2, IONIZED CALCIUM, PH, PCO2, TCO2 IN ARTERIAL, VENOUS OR CAPILLARY WHOLE BLOOD.,I-STAT EC8+ CARTRIDGE(I-STAT EC8+ CARTRIDGE)-THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM POTASSIUM, CHLORIDE, (BUN/UREA), GLUCOSE, HEMATOCRIT, PH, PCO2, TCO2 IN ARTERIAL VENOUS OR CAPILLARY WHOLE BLOOD.,I-STAT CREATININE CARTRIDGE(I-STAT CREATININE CARTRIDGE)-THE TEST FOR CREATININE, AS PART OF THE I- STAT® SYSTEM, IS FOR THE QUANTITATIVE DETERMINA-TION OF CREATININE IN WHOLE BLOOD ON THE I-STAT HANDHELD.,I-STAT BNP CARTRIDGE(I-STAT BNP CARTRIDGE)-THE I-STAT® BNP TEST IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF B-TYPE NATRIURETIC PEPTIDE (BNP) IN WHOLE BLOOD OR PLASMA SAMPLES USING EDTA AS THE ANTICOAGULANT. BNP MEASUREMENTS CAN BE USED AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF THE SEVERITY OF CONGESTIVE HEART FAILURE.,I-STAT EG7+ CARTRIDGE(I-STAT EG7+ CARTRIDGE)-THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM IS INTENDED FOR USE IN

	THE IN VITRO QUANTIFICATION OF SODIUM POTASSIUM, HEMATOCRIT, PO2, IONIZED CALCIUM, PH, PCO2, TCO2 IN ARTERIAL, VENOUS OR CAPILLARY WHOLE BLOOD.,I-STAT CK-MB CARTRIDGE(I-STAT CK-MB CARTRIDGE)-THE I-STAT® CK-MB TEST IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE MEASUREMENT OF CREATINE KINASE MB MASS IN WHOLE BLOOD OR PLASMA SAMPLES. CK-MB MEASUREMENTS CAN BE USED AS AN AID IN THE DIAGNOSIS AND TREATMENT OF MYOCARDIAL INFARCTION (MI).,I-STAT EC4+CARTRIDGE(I-STAT EC4+CARTRIDGE)-THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM POTASSIUM, CHLORIDE, (BUN/UREA) GLUCOSE, HEMATOCRIT, IN ARTERIAL, VENOUS OR CAPILLARY WHOLE BLOOD.,I-STAT KAOLIN ACT CARTRIDGE(I-STAT KAOLIN ACT CARTRIDGE)-I-STAT KAOLIN ACTIVATED CLOTTING TIME (KAOLIN ACT) TEST IS AN IN VITRO DIAGNOSTIC TEST THAT USES FRESH, WHOLE BLOOD TO MONITOR HIGH DOSE HEPARIN ANTICOAGULATION FREQUENTLY ASSOCIATED WITH CARDIOVASCULAR SURGERY.,I-STAT E3+ CARTRIDGE(I-STAT E3+ CARTRIDGE)-THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM POTASSIUM, HEMATOCRIT IN ARTERIAL, VENOUS, OR CAPILLARY WHOLE BLOOD.,I-STAT G3+ CARTRIDGE(I-STAT G3+ CARTRIDGE)-THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF PO2, PH, PCO2, TCO2 IN ARTERIAL OR VENOUS WHOLE BLOOD.,I-STAT EG6+ CARTRIDGE(I-STAT EG6+ CARTRIDGE)-THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM POTASSIUM, PO2, HEMATOCRIT, PH, PCO2, TCO2 IN ARTERIAL VENOUS OR CAPILLARY WHOLE BLOOD.,I-STAT TOTAL -HCG CARTRIDGE(I-STAT TOTAL -HCG CARTRIDGE)-THE I-STAT® TOTAL BETA HUMAN CHORIONIC GONADOTROPIN (-HCG) TEST IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE AND QUALITATIVE DETERMINATION OF -HCG IN VENOUS WHOLE BLOOD OR PLASMA SAMPLES USING I-STAT1 ANALYZER SYSTEMS. THE TEST IS INTENDED TO BE USED AS AN AID IN THE EARLY DETECTION OF PREGNANCY AND IS FOR PRESCRIPTION USE ONLY.,I-STAT CELITE® ACT CARTRIDGE(I-STAT CELITE® ACT CARTRIDGE)-I-STAT CELITE ACTIVATED CLOTTING TIME (CELITE ACT) TEST IS AN IN VITRO DIAGNOSTIC TEST THAT USES FRESH, WHOLE BLOOD AND IS USEFUL FOR MONITORING PATIENTS RECEIVING HEPARIN FOR TREATMENT OF PULMONARY EMBOLISM OR VENOUS THROMBOSIS AND FOR MONITORING ANTICOAGULATION THERAPY IN PATIENTS UNDERGOING MEDICAL PROCEDURES SUCH AS CATHETERIZATION, CARDIAC SURGERY, SURGERY, ORGAN TRANSPLANT AND DIALYSIS.,

		I-STAT 6+ CARTRIDGE(I-STAT 6+ CARTRIDGE)-THE TEST FOR SODIUM, AS PART OF THE I-STAT SYSTEM IS INTENDED FOR USE IN THE IN VITRO QUANTIFICATION OF SODIUM POTASSIUM, CHLORIDE, (BUN/UREA) GLUCOSE, HEMATOCRIT, IN ARTERIAL, VENOUS OR CAPILLARY WHOLE BLOOD
462	IMP/IVD/2020/000019	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARCHITECT IDIGOXIN (ARCHITECT IDIGOXIN)-THE ARCHITECT IDIGOXIN ASSAY IS AN IN VITRO CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE MEASUREMENT OF DIGOXIN IN HUMAN SERUM OR PLASMA ON THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY.,ARCHITECT IDIGOXIN CALIBRATORS (ARCHITECT IDIGOXIN CALIBRATORS)-THE ARCHITECT IDIGOXIN CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN IN HUMAN SERUM OR PLASMA.

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463	IMP/IVD/2020/000020	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PANBIO SARS-COV-2 IGG ELISA(PANBIO SARS-COV-2 IGG ELISA)-THE PANBIO SARS-COV-2 IGG ELISA TEST IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) INTENDED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA. THE PANBIO SARS-COV-2 IGG ELISA TEST IS TO BE USED AS AN AID IN THE IDENTIFICATION OF INDIVIDUALS WITH AN IMMUNE RESPONSE TO SARS-COV-2, INDICATING RECENT OR PRIOR INFECTION OF SARS-COV-2. THE PANBIO SARS-COV-2 IGG ELISA TEST CAN ALSO BE USED AS AN AID IN THE DIAGNOSIS OF COVID-19 DURING THE LATE ACUTE PHASE OF SARS-COV-2 INFECTION IN CONJUNCTION WITH CLINICAL PRESENTATIONS AND OTHER LABORATORY TESTS.,ALERE NT-PROBNP FOR ALINITY I REAGENT KIT(NA)-THE ALERE NT-PROBNP FOR ALINITY I ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE (NTPROBNP) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ALERE NT-PROBNP FOR ARCHITECT CALIBRATOR (NA)-THE ALERE NT-PROBNP FOR ARCHITECT CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE (NTPROBNP) IN HUMAN SERUM AND PLASMA., ALERE NT-PROBNP FOR ARCHITECT CONTROL (NA)-THE ALERE NT-PROBNP FOR ARCHITECT CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE (NTPROBNP) IN HUMAN SERUM AND PLASMA, ALERE NT-PROBNP FOR ALINITY I CONTROLS(NA)-THE ALERE NT-PROBNP FOR ALINITY I CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM AND PLASMA.,ALERE NT-PROBNP FOR ALINITY I CALIBRATORS(NA)-THE ALERE NT-PROBNP FOR ALINITY I CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM AND PLASMA.,ALERE NT-PROBNP FOR ARCHITECT REAGENT KIT(NA)-THE ALERE NT-PROBNP FOR ARCHITECT ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE IN VITRO

	QUANTITATIVE DETERMINATION OF N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE IN HUMAN SERUM AND PLASMA ON THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY

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464	IMP/IVD/2020/000021	1.License Holder Name: INDRA CHEMICAL MANUFACTURING PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASO CALIBRATOR (DIALAB)-LIQUID HUMAN BASED CALIBRATOR FOR USE AS A CALIBRATOR IN IMMUNOTURBIDIMETRIC ASSAYS FOR ASO , BILIRUBIN AUTO DIRECT DCA(DIALAB)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF BILIRUBIN AUTO DIRECT IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,CRP 5+1 (DIALAB)-DIAGNOSTIC REAGENT FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CRP (C-REACTIVE PROTEIN) IN HUMAN SERUM BY TURBIDIMETRIC ASSAY ,UIBC FERENE(DIALAB)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF UNSATURATED IRON BINDING CAPACITY IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,ASO 5+1 (DIALAB)-DIAGNOSTIC REAGENT FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ASO (ANTI-STREPTOLYSIN O) IN HUMAN SERUM BY TURBIDIMETRIC ASSAY , BILIRUBIN AUTO TOTAL DCA(DIALAB)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF BILIRUBIN AUTO TOTAL IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,LDL CALIBRATOR (LDL CHOLESTEROL CALIBRATOR) (DIALAB)-LYOPHILIZED HUMAN BASED CALIBRATOR FOR THE USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF LOW DENSITY LIPOPROTEINS CHOLESTEROL (LDL-C) ON PHOTOMETRIC SYSTEMS. ,HBA1C DIRECT CONTROL SET (DIALAB)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF HBA1C USING HBA1C CONTROL FOR ESTIMATION IN BLOOD ON PHOTOMETRIC SYSTEMS.,IRON FERENE (DIALAB)-DIAGNOSTIC REAGENT FOR THE QUANTITATIVE IN VITRO DETERMINATION OF IRON IN HUMAN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS , LDH-L (IFCC)(DIALAB)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF LACTATE DEHYDROGENASE (LDH-L) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,CRP CALIBRATOR HIGH(DIALAB)-LIQUID HUMAN BASED CALIBRATOR FOR USE AS A CALIBRATOR IN IMMUNOTURBIDIMETRIC ASSAYS FOR CRP , MAGNESIUM, XYLIDYL BLUE(DIALAB)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF MAGNESIUM IN HUMAN SERUM, PLASMA, CEREBROSPINAL FLUID OR URINE ON PHOTOMETRIC SYSTEMS, MICROALBUMIN 5+1 (DIALAB)-DIAGNOSTIC REAGENT FOR THE QUANTITATIVE IN VITRO DETERMINATION OF MICROALBUMIN IN HUMAN URINE BY TURBIDIMETRIC ASSAY,TRIPLE CONTROL (ASO, CRP,RF)(DIALAB)-LIQUID HUMAN BASED CONTROL SERUM FOR USE AS A CONTROL IN IMMUNOTURBIDIMETRIC ASSAYS FOR ASO, CRP AND RF.,GLUCOSE HEXOKINASE (DIALAB)-DIAGNOSTIC REAGENT FOR INVITRO QUANTITATIVE ESTIMATION OF GLUCOSE IN HUMAN

	SERUM OR PLASMA USING PHOTOMETIC SYSTEM,UREA UV AUTO, UREASE/GLDH(DIALAB)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF UREA IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS,RF 5+1 (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF RF (RHEUMATOID FACTOR) IN HUMAN SERUM BY TURBIDIMETRIC ASSAY,HBA1C DIRECT CALIBRATOR 5 LEVEL SERIES(DIALAB)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF HBA1C USING HBA1C CALIBRATOR FOR ESTIMATION IN BLOOD ON PHOTOMETRIC SYSTEMS.,ALPHA-AMYLASE CNP-G3 (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALPHA-AMYLASE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,GLUCOSE, GOD-PAP(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE INVITRO DETERMINATION OF GLUCOSE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEM,RF CALIBRATOR HIGH(DIALAB)-LIQUID HUMAN BASED CALIBRATOR FOR USE AS A CALIBRATOR IN IMMUNOTURBIDIMETRIC ASSAYS FOR RF ,URIC ACID TBHBA ENZYMATIC (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE INVITRO DETERMINATION OF URIC ACID IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,LIPASE ENZYMATIC, COLORIMETRIC (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPASE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,PROTEIN TOTAL STANDARD (DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. ,HBALC DIRECT (DIALAB)- DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HBALC IN HUMAN BLOOD BY TURBIDIMETRIC ASSAY,TRIGLYCERIDE STANDARD(DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDE IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS.,CK-NAC (CREATINE KINASE - NAC) OPT. DGKC / IFCC (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATINKINASE (CK-NAC) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS ,TRIGLYCERIDE, GPO-PAP(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. ,HDL CALIBRATOR (HDL CHOLESTEROL CALIBRATOR) (DIALAB)-LYOPHILIZED HUMAN BASED CALIBRATOR FOR THE USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF HIGH DENSITY LIPOPROTEINS CHOLESTEROL (HDL-C) ON PHOTOMETRIC ,GAMMA GT, SZASZ STAND . TO IFCC (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE INVITRO

	DETERMINATION OF GAMMA GT IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. ,DIACAL CK-MB (DIALAB)-LYOPHILIZED CALIBRATION SERUM FOR THE USE IN TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CK-MB ACTIVITY ON PHOTOMETRIC SYSTEMS. ,ALKALINE PHOSPHATASE, MOD IFCC (DAILAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF ALKALINE PHOSPHATASE (ALP) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. ,CHOLESTEROL LDL DIRECT ENZYMATIC SELECTIVE PROTECTION (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,CREATININE, MOD JAFFE (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS,CK-MB (CREATINE KINASE-MB) OPT.DGKC/IFCC(DIALAB)-DIAGNOSTIC REAGENT FOR INVITRO QUANTITATIVE ESTIMATION OF CK-MB IN HUMAN SERUM OR PLASMA USING PHOTOMETIC SYSTEM ,ALBUMIN, BCG(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE INVITRO DETERMINATION OF ALBUMIN IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEM, HEMOLYSIS REAGENT (DIALAB)-FOR THE PREPARATION OF SAMPLES USED IN THE DIALAB HBA1C DIRECT ASSAY ,ALBUMIN STANDRAD (DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS. , CARBON DIOXIDE (CO2, BICARBONATE) PEP-C (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE (CO2) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,CALCIUM STANDARD(DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS.,CHOLESTEROL HDL DIRECT IMMUNOINHIBITION (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,CHOLESTEROL STANDARD(DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CHOLESTEROL IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS.,GPT (ALT) MOD IFCC (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION GPT (ALT) IN HUMAN SERUM ON PHOTOMETRIC METHOD. ,PROTEIN TOTAL, BIURET(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE INVITRO DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC

		SYSTEMS,PHOSPHORUS INORGANIC MOLYBDATE(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE INVITRO DETERMINATION OF PHOSPHORUS IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEM,CREATININE STANDRAD(DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS.,GLUCOSE STANDRAD (DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS. ,CALCIUM, ARSENAZO (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS. ,CHOLESTEROL, CHOD-PAP(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE INVITRO DETERMINATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. ,GOT (AST) MOD IFCC (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE INVITRO DETERMINATION GOT (AST) IN HUMAN SERUM ON PHOTOMETRIC METHOD.
465	IMP/IVD/2020/000022	1.License Holder Name: ACCUREX BIOMEDICALS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLYCOHEMOGLOBIN TEST KIT(XPRESSA1C)-HBA1C TEST
466	IMP/IVD/2020/000024	1.License Holder Name: M/S. ASHISH INTERCHEM PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIP(EVOLVE FL)-THE BLOOD GLUCOSE TEST STRIPS ASSOCIATED WITH THE SERIES BLOOD GLUCOSE METERS ARE DESIGNED TO QUANTITATIVELY MEASURE THE CONCENTRATION OF GLUCOSE IN CAPILLARY WHOLE BLOOD BY PERSONS WITH DIABETES OR BY HEALTHCARE PROFESSIONALS FOR MONITORING GLUCOSE AT HOME OR IN HEALTHCARE FACILITIES. THE BLOOD MONITORING SYSTEM IS NOT INTENDED FOR THE DIAGNOSIS OR DIABETES MELLITUS SCREENING.

467	IMP/IVD/2020/000025	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHEMISTRY CALIBRATOR (CHEMCAL)-CALIBRATORS FOR CLINICAL CHEMISTRY ASSAYS FOR USE IN MEDICAL LABORATORIES.,CHEMISTRY CONTROL, LEVEL 2 (PATHOLYTE LEVEL 2)-CONTROL SERA FOR INTERNAL QUALITY CONTROL OR EXTERNAL QUALITY ASSESEMENT IN MEDICAL LABORATORIES,CHEMISTRY CONTROL, LEVEL 1(NORMALYTE LEVEL 1)-CONTROL SERA FOR INTERNAL QUALITY CONTROL OR EXTERNAL QUALITY ASSESEMENT IN MEDICAL LABORATORIES
468	IMP/IVD/2020/000026	1.License Holder Name: AKIVA MEDICAL DEVICES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE MONITORING STRIPS(GLUCO DR. S (AGM-513S))-TEST STRIPS ARE FOR TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE). SELF-TESTING BLOOD GLUCOSE REGULARLY CAN HELP YOU KNOW HOW WELL YOUR DIABETES IS BEING CONTROLLED. DIABETES SHOULD BE MANAGED UNDER THE GUIDANCE OF A DOCTOR OR HEALTHCARE PROFESSIONAL.,BLOOD GLUCOSE MONITORING STRIPS(GLUCO DR. AUTO A (AGM-4000))-TEST STRIPS ARE FOR TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE). SELF-TESTING BLOOD GLUCOSE REGULARLY CAN HELP YOU KNOW HOW WELL YOUR DIABETES IS BEING CONTROLLED. DIABETES SHOULD BE MANAGED UNDER THE GUIDANCE OF A DOCTOR OR HEALTHCARE PROFESSIONAL.,BLOOD GLUCOSE MONITORING STRIPS(GLUCO DR. SUPER SENSOR (AGM-2200))-TEST STRIPS ARE FOR TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE). SELF-TESTING BLOOD GLUCOSE REGULARLY CAN HELP YOU KNOW HOW WELL YOUR DIABETES IS BEING CONTROLLED. DIABETES SHOULD BE MANAGED UNDER THE GUIDANCE OF A DOCTOR OR HEALTHCARE PROFESSIONAL.,BLOOD GLUCOSE MONITORING STRIPS(GLUCO DR (AGM-2100))-TEST STRIPS ARE FOR TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE). SELF-TESTING BLOOD GLUCOSE REGULARLY CAN HELP YOU KNOW HOW WELL YOUR DIABETES IS BEING CONTROLLED. DIABETES SHOULD BE MANAGED UNDER THE GUIDANCE OF A DOCTOR OR HEALTHCARE PROFESSIONAL.

469	IMP/IVD/2020/000027	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INFINITY AMMONIA REAGENT(INFINITY AMMONIA REAGENT)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF AMMONIA (NH3) CONCENTRATIONS IN HUMAN PLASMA FOR USE ON THE BECKMAN COULTER A CHEMISTRY ANALYZERS.,INFINITY LITHIUM REAGENT (INFINITY LITHIUM REAGENT)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF LITHIUM CONCENTRATIONS IN HUMAN PLASMA FOR USE ON THE BECKMAN COULTER AU CHEMISTRY ANALYZERS
470	IMP/IVD/2020/000028	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SALICYLATE CALIBRATOR (SALICYLATE CALIBRATOR)-THE COBAS SALICYLATE CALIBRATOR IS INTENDED FOR USE ON ROCHE CLINICAL CHEMISTRY ANALYZERS FOR THE QUANTITATIVE DETERMINATION OF SALICYLATE IN SERUM AND PLASMA.

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471	IMP/IVD/2020/000029	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CRP CONTROL US-CRP CONTROL US IS USED TO VERIFY THE PERFORMANCE OF THE CRP ULTRA TEST WITH ULTRASENSITIVE METHOD. CONTROL MATERIALS SHOULD BE TREATED AS A PATIENT SAMPLE AND THE TEST PERFORMED ACCORDING TO THE INDICATED ANALYTICAL PROCEDURE. FOR IN VITRO DIAGNOSTIC USE ONLY,CRP CALIBRATOR SET (UD)-CRP CALIBRATOR SET (UD) SHOULD BE USED ONLY FOR THE PREPARATION OF THE CALIBRATION CURVE FOR THE CRP ULTRA TEST ON VITROS® SYSTEMS WITH STANDARD METHOD AND ULTRASENSITIVE METHOD. FOR IN VITRO DIAGNOSTIC USE ONLY., CRP ULTRA (MP)-LATEX IMMUNOASSAY FOR THE DETERMINATION OF THE C-REACTIVE PROTEIN (CRP) CONCENTRATION IN SERUM AND PLASMA ON SUITABLE VITROS® SYSTEM. CRP (C-REACTIVE PROTEIN) IS AN ACUTE PHASE PROTEIN WHOSE CONCENTRATION IS OBSERVED TO INCREASE AS A RESULT OF THE INFLAMMATORY PROCESS, MOST NOTABLY IN RESPONSE TO PNEUMOCOCCAL (BACTERIAL) INFECTION, HISTOLYTIC DISEASE AND A VARIETY OF OTHER DISEASE STATES. CRP IS USED AS A MARKER OR GENERAL DIAGNOSTIC INDICATOR OF INFECTIONS AND INFLAMMATION, IN ADDITION TO SERVING AS A MONITOR OF PATIENT RESPONSE TO PHARMACOLOGICAL THERAPY AND SURGERY. THE ASSAY IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE ONLY.,IMMUNO CONTROL SET-IMMUNO CONTROL SET MUST BE USED ONLY TO VERIFY THE PERFORMANCE OF THE TESTS WITH IMMUNOTURBIDIMETRIC METHOD. FOR IN VITRO DIAGNOSTIC USE ONLY.

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472	IMP/IVD/2020/000030	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVIA CENTAUR INSULIN (IRI) CALIBRATOR(ADVIA CENTAUR INSULIN (IRI) CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR® SYSTEMS INSULIN ASSAYS. ,ATELLICA IM INSULIN MASTER CURVE MATERIAL (IRI MCM)(ATELLICA IM INSULIN MASTER CURVE MATERIAL (IRI MCM))-THE ATELLICA® IM INSULIN MASTER CURVE MATERIAL (IRI MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA® IM IRI ASSAY.,ATELLICA IM C-PEPTIDE (CPS)(ATELLICA IM C-PEPTIDE (CPS))-THE ATELLICA® IM CPEPTIDE (CPS) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CPEPTIDE IN HUMAN SERUM AND URINE USING THE ATELLICA® IM ANALYZER. THIS ASSAY CAN BE USED TO AID IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH ABNORMAL INSULIN SECRETION INCLUDING DIABETES MELLITUS. ,ADVIA CENTAUR C-PEPTIDE MASTER CURVE MATERIAL (CPS MCM)(ADVIA CENTAUR C-PEPTIDE MASTER CURVE MATERIAL (CPS MCM))-THE ADVIA CENTAUR® C-PEPTIDE (CPS) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR C-PEPTIDE ASSAY., ADVIA CENTAUR INSULIN (IRI)(ADVIA CENTAUR INSULIN (IRI))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF INSULIN IN SERUM USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THIS ASSAY CAN BE USED TO AID IN THE DIAGNOSIS AND TREATMENT OF DIABETES MELLITUS AND HYPOGLYCEMIA. ,ATELLICA IM INSULIN (IRI)(ATELLICA IM INSULIN (IRI))-THE ATELLICA® IM INSULIN (IRI) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM USING THE ATELLICA® IM ANALYZER. THIS ASSAY CAN BE USED TO AID IN THE DIAGNOSIS AND TREATMENT OF DIABETES MELLITUS AND HYPOGLYCEMIA. ,ADVIA CENTAUR INSULIN (IRI) DILUENT(ADVIA CENTAUR INSULIN (IRI) DILUENT)-THE ADVIA CENTAUR IRI DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY ,ADVIA CENTAUR C-PEPTIDE (CPS)(ADVIA CENTAUR C-PEPTIDE (CPS))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN SERUM OR URINE USING THE ADVIA CENTAUR®, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THIS ASSAY CAN BE USED TO AID IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH ABNORMAL INSULIN SECRETION INCLUDING DIABETES MELLITUS.,ADVIA CENTAUR INSULIN MASTER CURVE MATERIAL (IRI MCM)(ADVIA CENTAUR INSULIN MASTER CURVE

	MATERIAL (IRI MCM))-THE ADVIA CENTAUR® INSULIN (IRI) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR INSULIN ASSAY. ,ADVIA CENTAUR C-PEPTIDE (CPS) CALIBRATOR(ADVIA CENTAUR C-PEPTIDE (CPS) CALIBRATOR)-FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ADVIA CENTAUR® SYSTEMS C-PEPTIDE ASSAYS.,ATELLICA IM C-PEPTIDE MASTER CURVE MATERIAL (CPS MCM)(ATELLICA IM C-PEPTIDE MASTER CURVE MATERIAL (CPS MCM))-THE ATELLICA® IM C-PEPTIDE MASTER CURVE MATERIAL (CPS MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA® IM CPS ASSAY. ,ATELLICA IM INSULIN (IRI) CALIBRATOR(ATELLICA IM INSULIN (IRI) CALIBRATOR)-THE ATELLICA IM INSULIN CALIBRATOR (IRI CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM IRI ASSAY USING THE ATELLICA™ IM ANALYZER. ,ATELLICA IM C-PEPTIDE (CPS) CALIBRATOR(ATELLICA IM C-PEPTIDE (CPS) CALIBRATOR)-THE ATELLICA IM CPEPTIDE CALIBRATOR (CPS CAL) IS FOR IN VITRO DIAGNOSTIC USE IN CALIBRATING THE ATELLICA IM CPS ASSAY USING THE ATELLICA IM ANALYZER. ,ATELLICA IM INSULIN (IRI) DILUENT(ATELLICA IM INSULIN (IRI) DILUENT)-THE ATELLICA IM IRI DILUENT IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE ASSAY.

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473	IMP/IVD/2020/000031	1.License Holder Name: ANAND BROTHERS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DILUENT(HD300 DILUENT)-THE HD300 DILUENT IS INTENDED TO PERFORM ERYTHROCYTES AND PLATELETS MEASUREMENT IN A BLOOD SAMPLE,CLEANER(HC300 CLEANER)-THE HC300 CLEANER IS INTENDED TO CLEAN AND RINSE THE FLUIDIC CHANNELS WITHIN ANALYZER TO ENSURE THE ANALYZER'S PERFORMANCE.,CLEANER (HC500 CLEANER)-CLEANER IS INTENDED TO CLEAN AND RINSE THE FLUIDIC CHANNELS WITHIN ANALYZER TO ENSURE THE ANALYZER'S PERFORMANCE.,DILUENT(HD500 DILUENT)-DILUENT IS INTENDED TO PERFORM ERYTHROCYTES AND PLATELETS MEASUREMENT IN BLOOD SAMPLE,LYSE(HL500 LYSE)-LYSE IS USED FOR LYSING ERYTHROCYTES, COUNTING AND DIFFERENTIATING THE FIVE MAIN LEUKOCYTES SUBPOPULATIONS AND QUANTITATIVE DETERMINATION HEMOGLOBIN IN A BLOOD SAMPLE,LYSE(HL300 LYSE)-THE PRODUCT IS USED FOR LYSING ERYTHROCYTES, COUNTING AND DIFFERENTIATING THE FIVE MAIN LEUKOCYTES SUBPOPULATIONS AND QUANTITATIVE DETERMINATION HEMOGLOBIN IN A BLOOD SAMPLE
474	IMP/IVD/2020/000032	1.License Holder Name: VORTEX MEDSOLUTIONS PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FERRITIN RAPID TEST (FRT-CHECK - 1)-FRT-CHECK-1 IS A RAPID QUALITATIVE TEST KIT FOR THE DETECTION OF FERRITIN IN WHOLE BLOOD, PLASMA OR SERUM. THE KIT IS INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTH PROFESSIONALS.,TSH RAPID TEST(TSH -CHECK- 1 (ADULT VERSION))-TSH-CHECK-1 ADULT IS A RAPID QUALITATIVE TEST KIT FOR THE DETECTION OF THYROID STIMULATING HORMONE IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES. THE KIT IS INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTH PROFESSIONALS.,TSH RAPID TEST (TSH -CHECK- 1 (PAEDIATRIC VERSION))-TSH-CHECK-1 PAEDIATRIC IS A RAPID QUALITATIVE TEST KIT FOR THE DETECTION OF THYROID STIMULATING HORMONE IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES TO BE USED AS A SCREENING TEST FOR THE NEW-BORNS AND CHILDREN. THE KIT IS INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTH PROFESSIONALS,IGE RAPID TEST(IGE-CHECK-1)-IGE-CHECK-1 IS A RAPID QUALITATIVE TEST KIT FOR THE DETECTION OF IGE IN WHOLE BLOOD, PLASMA OR SERUM. THE KIT IS INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTH PROFESSIONALS.

475	IMP/IVD/2020/000033	1.License Holder Name: BIO-RAD LABORATORIES (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KALLESTAD ANTI CCP II MICROPLATE EIA(KALLESTAD ANTI CCP II MICROPLATE EIA)-THE KALLESTAD® ANTI-CCP II TEST KIT IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR DETECTION AND SEMI-QUANTITATION OF IGG ANTIBODIES TO CYCLIC CITRULLINATED PEPTIDES (CCP) IN HUMAN SERUM OR PLASMA. THE ASSAY IS USED TO DETECT ANTIBODIES IN A SINGLE SPECIMEN. THE RESULTS OF THE ASSAY ARE TO BE USED AS AN AID TO THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA), IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. THE ANALYSIS SHOULD BE PERFORMED BY TRAINED LABORATORY PROFESSIONALS. FOR IN VITRO DIAGNOSTIC USE

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476	IMP/IVD/2020/000034	1.License Holder Name: ARK DIAGNOSTICS BANGALORE PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAGNESIUM(SPINREACT)-QUANTITATIVE DETERMINATION OF MAGNESIUM XILYDIL IN USE OF VITRO DIAGNOSTICS,GPT (ALT)(SPINREACT)-QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE GPT IN USE OF VITRO DIAGNOSTICS,BILIRUBIN DIRECT(SPINREACT)-QUANTITATIVE DETERMINATION OF BILIRUBIN DIRECT IN USE OF VITRO DIAGNOSTICS,LIPOPROTEIN (A)(SPINREACT)-QUANTITATIVE DETERMINATION OF LIPOPROTEIN A IN USE OF VITRO DIAGNOSTICS, TIBC(SPINREACT)-QUANTITATIVE DETERMINATION OF TIBC IN USE OF VITRO DIAGNOSTICS,CALCIUM(SPINREACT)-QUANTITATIVE DETERMINATION OF CACIUM IN USE OF VITRO DIAGNOSTICS, AMYLASE(SPINREACT)-QUANTITATIVE DETERMINATION OF ALPHA-AMYLASE IN USE OF VITRO DIAGNOSTICS,CHOLESTEROL (SPINREACT)-QUANTITATIVE DETERMINATION OF CHOLESTEROL IN USE OF VITRO DIAGNOSTICS,FRUCTOSAMINE(SPINREACT)-QUANTITATIVE DETERMINATION OF FRUCTOSAMINE IN USE OF VITRO DIAGNOSTICS,PROTEIN URINE & CSF(SPINREACT)-QUANTITATIVE DETERMINATION OF TOTAL URINARY & CSF PROTEIN IN USE OF VITRO DIAGNOSTICS,COMPLEMENT C4(SPINREACT)-QUANTITATIVE DETERMINATION OF COMPLEMENT C4 IN USE OF VITRO DIAGNOSTICS,IGA(SPINREACT)-QUANTITATIVE DETERMINATION OF HUMAN IMMUNOGLOBULIN A IN USE OF VITRO DIAGNOSTICS,UREA (SPINREACT)-QUANTITATIVE DETERMINATION OF UREA IN USE OF VITRO DIAGNOSTICS,BILIRUBIN TOTAL(SPINREACT)-QUANTITATIVE DETERMINATION OF BILIRUBIN TOTAL IN USE OF VITRO DIAGNOSTICS,IM-LATEX(SPINREACT)-QUANTITATIVE DETERMINATION OF HETEROPHILE ANTIBODIES IN USE OF VITRO DIAGNOSTICS,LIPASE(SPINREACT)-QUANTITATIVE DETERMINATION OF LIPASE IN USE OF VITRO DIAGNOSTICS,LDH – P(SPINREACT)-QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE IN USE OF VITRO DIAGNOSTICS,PCR ULTRA(SPINREACT)-QUANTITATIVE DETERMINATION OF LOW LEVELS OF C-REACTIVE PROTEIN IN USE OF VITRO DIAGNOSTICS,URIC ACID(SPINREACT)-QUANTITATIVE DETERMINATION OF URIC ACID IN USE OF VITRO DIAGNOSTICS, SPINTROL H CALIBRATOR(SPINREACT)-SERUM CALIBRATOR FOR CLINICAL CHEMISTRY ASSAYS IN USE OF VITRO DIAGNOSTICS, CREATININE(SPINREACT)-QUANTITATIVE DETERMINATION OF CREATININE IN USE OF VITRO DIAGNOSTICS,SPINTROL H PATHOLOGIC(SPINREACT)-SERUM CONTROL MULTICOMPONENT FOR CLINICAL CHEMISTRY ASSAYS IN USE OF VITRO DIAGNOSTICS,RF (SPINREACT)-QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS IN USE OF VITRO DIAGNOSTICS,ALKALINE PHOSPHATASE

	(SPINREACT)-QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN USE OF VITRO DIAGNOSTICS,SPINTROL H NORMAL (SPINREACT)-SERUM CONTROL MULTICOMPONENT FOR CLINICAL CHEMISTRY ASSAYS IN USE OF VITRO DIAGNOSTICS,IRON (SPINREACT)-QUANTITATIVE DETERMINATION OF IRON IN USE OF VITRO DIAGNOSTICS,FERRITIN(SPINREACT)-QUANTITATIVE DETERMINATION OF FERRITIN IN USE OF VITRO DIAGNOSTICS, LACTATE(SPINREACT)-QUANTITATIVE DETERMINATION OF LACTATE IN USE OF VITRO DIAGNOSTICS,MICROALBUMIN(SPINREACT)-QUANTITATIVE DETERMINATION OF MICROALBUMIN IN USE OF VITRO DIAGNOSTICS,CERULOPLASMIN(SPINREACT)-QUANTITATIVE DETERMINATION OF CERULOPLASMINE IN USE OF VITRO DIAGNOSTICS,GOT (AST)(SPINREACT)-QUANTITATIVE DETERMINATION OF ASPIRATE AMINOTRANSFERASE GOT IN USE OF VITRO DIAGNOSTICS,IGG(SPINREACT)-QUANTITATIVE DETERMINATION OF HUMAN IMMUNOGLOBULIN G IN USE OF VITRO DIAGNOSTICS,LDL CHOLESTEROL(SPINREACT)-QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IN USE OF VITRO DIAGNOSTICS,COMPLEMENT C3(SPINREACT)-QUANTITATIVE DETERMINATION OF COMPLEMENT C3 IN USE OF VITRO DIAGNOSTICS,CRP(SPINREACT)-QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN USE OF VITRO DIAGNOSTICS,PHOSPHORUS (SPINREACT)-QUANTITATIVE DETERMINATION OF PHOSPHORUS IN USE OF VITRO DIAGNOSTICS,TRIGLYCERIDES(SPINREACT)-QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN USE OF VITRO DIAGNOSTICS,HDL CHOLESTEROL(SPINREACT)-QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN USE OF VITRO DIAGNOSTICS,TOTAL PROTEIN(SPINREACT)-QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN USE OF VITRO DIAGNOSTICS, ASO(SPINREACT)-QUANTITATIVE DETERMINATION OF ANTI-STERPTOLYSIN O IN USE OF VITRO DIAGNOSTICS,CHOLINESTERASE (SPINREACT)-QUANTITATIVE DETERMINATION OF CHOLINESTERASE IN USE OF VITRO DIAGNOSTICS,CHLORIDE(SPINREACT)-QUANTITATIVE DETERMINATION OF CHLORIDE IN USE OF VITRO DIAGNOSTICS,GAMMA GT(SPINREACT)-QUANTITATIVE DETERMINATION OF GAMMA-GLUTAMYLTRANSFERASE IN USE OF VITRO DIAGNOSTICS,IGM(SPINREACT)-QUANTITATIVE DETERMINATION OF HUMAN IMMUNOGLOBULIN M IN USE OF VITRO DIAGNOSTICS,ALBUMIN(SPINREACT)-QUANTITATIVE DETERMINATION OF ALBUMIN,TOTAL LIPIDS(SPINREACT)-QUANTITATIVE DETERMINATION OF TOTAL LIPIDS IN USE OF VITRO DIAGNOSTICS,CK-NAC(SPINREACT)-QUANTITATIVE DETERMINATION OF CREATINE KINASE IN USE OF VITRO DIAGNOSTICS,CK-MB (SPINREACT)-QUANTITATIVE DETERMINATION OF CREATINE KINASE

		MB IN USE OF VITRO DIAGNOSTICS
477	IMP/IVD/2020/000035	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EASYTOUCH SIMPLE BLOOD GLUCOSE TEST STRIPS-INTENDED FOR THE PRELIMINARY SELF TESTING OF GLUCOSE LEVELS IN BLOOD,EASYTOUCH SIMPLE BLOOD GLUCOSE TEST METER(OZOCHECK)-INTENDED FOR THE PRELIMINARY SELF TESTING OF GLUCOSE LEVELS IN BLOOD

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478	IMP/IVD/2020/000036	1.License Holder Name: VANGUARD DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:D-CHECK 5DIFF 4,5 ML L (D-CHECK 5DIFF 4,5 ML L)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK 5DIFF PLUS 4,5ML H(D-CHECK 5DIFF PLUS 4,5ML H)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS,D-CHECK 5DIFF 3 ML L(D-CHECK 5DIFF 3 ML L)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK D 2,5L(D-CHECK D 2,5L)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR ACCURACY AND PRECISION OF AUTOMATED AND SEMI- AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK 5DIFF 3 ML H(D-CHECK 5DIFF 3 ML H)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK D N(D-CHECK D N)-D-CHECK DIS A CONTROL DESIGNED TO MONITOR ACCURACY AND PRECISION OF AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK D L(D-CHECK D L)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR ACCURACY AND PRECISION OF AUTOMATED AND SEMI- AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK 5DIFF PLUS 3 ML N(D-CHECK 5DIFF PLUS 3 ML N)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK 5DIFF PLUS 4,5 ML L(D-CHECK 5DIFF PLUS 4,5 ML L)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK D PLUS 4H(D-CHECK D PLUS 4H)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK D PLUS 2,5L(D-CHECK D PLUS 2,5L)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK D 4N (D-CHECK D 4N)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR

	VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK 5DIFF 4,5 ML N(D-CHECK 5DIFF 4,5 ML N)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK 5DIFF 3 ML N(D-CHECK 5DIFF 3 ML N)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK 5DIFF PLUS 4,5ML N(D-CHECK 5DIFF PLUS 4,5ML N)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK 5DIFF 4,5 ML H(D-CHECK 5DIFF 4,5 ML H)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK 5DIFF PLUS 3 ML L(D-CHECK 5DIFF PLUS 3 ML L)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS,D-CHECK D 2,5N (D-CHECK D 2,5N)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK D PLUS 4L(D-CHECK D PLUS 4L)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK D PLUS 4N(D-CHECK D PLUS 4N)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS,D-CHECK 5DIFF PLUS 3 ML H(D-CHECK 5DIFF PLUS 3 ML H)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK D 2,5H(D-CHECK D 2,5H)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK D H(D-CHECK D H)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR. ACCURACY AND PRECISION OF AUTOMATED AND SEMI- AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK D 4L(D-CHECK D 4L)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK D 4H

		(D-CHECK D 4H)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK D PLUS 2,5N(D-CHECK D PLUS 2,5N)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.,D-CHECK D PLUS 2,5H(D-CHECK D PLUS 2,5H)-D-CHECK D IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY. TABLE FOR SPECIFIC INSTRUMENT MODELS.
479	IMP/IVD/2020/000037	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CELL WASH SOLUTION I/ NAOH-D(CELL WASH SOLUTION I/ NAOH-D)-CELL WASH SOLUTION I/ NAOH-D IS USED AS ALKALINE WASH SOLUTION FOR REACTION CELLS ON ROCHE/HITACHI SYSTEMS.,CLEANCELL M(CLEANCELL M)-SYSTEM SOLUTION FOR CLEANING THE DETECTION UNIT OF ELECSYS OR COBAS E IMMUNOASSAY ANALYZERS.

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480	IMP/IVD/2020/000039	1.License Holder Name: ZYMOGEN LIFESCIENCES PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:"MASSCHECK® STEROID PANEL 2 SERUM CONTROL LEVEL III (LYOPH.) RECONSTITUTE WITH 3.0 ML DIST. WATER"(MASSCHECK® STEROID PANEL 2 SERUM CONTROL, LEVEL III (LYOPH.))-QUALITY CONTROL SAMPLE FOR LC-MS/MS FOR THE ANALYSIS OF STEROIDS ,"MASSCHECK® STEROID PANEL 1 SERUM CONTROL LEVEL II 5 X 3.0 ML (LYOPH.) "(MASSCHECK® STEROID PANEL 1 SERUM CONTROL LEVEL II (LYOPH.))-QUALITY CONTROL SAMPLE FOR LC-MS/MS FOR THE ANALYSIS OF STEROIDS ,"MASSCHECK® STEROID PANEL 1 SERUM CONTROL LEVEL III 5 X 3.0 ML (LYOPH.) "(MASSCHECK® STEROID PANEL 1 SERUM CONTROL LEVEL III (LYOPH.))-QUALITY CONTROL SAMPLE FOR LC-MS/MS FOR THE ANALYSIS OF STEROIDS ,WASH BUFFER 1 MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE(WASH BUFFER 1 MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE)-USED DURING SAMPLE PREPARATION FOR WASHING OF SAMPLES FOR THE DETERMINATION OF CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN ,"MASSCHECK® STEROID PANEL 2 SERUM CONTROL LEVEL I (LYOPH.) RECONSTITUTE WITH 3.0 ML DIST. WATER "(MASSCHECK® STEROID PANEL 2 SERUM CONTROL LEVEL I (LYOPH.))-QUALITY CONTROL SAMPLE FOR LC-MS/MS FOR THE ANALYSIS OF STEROIDS ,"MASSCHECK® CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN URINE CONTROL LEVEL II 5 X 2.0 ML (LYOPH.)"("MASSCHECK® CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN URINE CONTROL LEVEL II")-QUALITY CONTROL SAMPLE FOR LC-MS/MS FOR THE ANALYSIS OF BIOGENIC AMINES ,"MASSCHECK® STEROID PANEL 1 SERUM CONTROL LEVEL I 5 X 3.0 ML (LYOPH.) "(MASSCHECK® STEROID PANEL 1 SERUM CONTROL LEVEL I (LYOPH.))-QUALITY CONTROL SAMPLE FOR LC-MS/MS FOR THE ANALYSIS OF STEROIDS ,LC-MS/MS REAGENT KIT MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD(MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD REAGENT KIT FOR LC MS/MS, ANALYSIS OF CYLOSPORINE A, TACROLIMUS, SIROLIMUS & EVEROLIMUS IN WHOLE BLOOD)-THIS REAGENT KIT IS USED FOR THE QUANTITATIVE DETECTION OF CYCLOSPORIN A, EVEROLIMUS, SIROLIMUS (RAPAMYCIN) AND TACROLIMUS (FK-506) IN PATIENT EDTA WHOLE BLOOD SAMPLES VIA LC-MS/MS. IT IS INDICATED AS A MONITORING TEST FOR PATIENTS TREATED WITH IMMUNOSUPPRESSANTS AND AS AN AID TO ENSURE DRUG LEVELS WITHIN THE THERAPEUTIC RANGE,"SYSTEM CHECK SOLUTION MASSCHROM® STEROID PANEL 2 1 X 1 ML"(SYSTEM CHECK SOLUTION MASSCHROM® STEROID PANEL 2)-STARTUP ACCESSORY

	FOR LC-MS/MS STATUS CHECK FOR THE ANALYSIS OF STEROIDS , WASH BUFFER 2 MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE(WASH BUFFER 2 MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE)-USED DURING SAMPLE PREPARATION FOR WASHING OF SAMPLES FOR THE DETERMINATION OF CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN ,"INTERNAL STANDARD SET MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD 4 X 93004; 1 X 93006 (LYPH)"("INTERNAL STANDARD SET MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD ")-USED DURING SAMPLE PREPARATION FOR THE QUANTIFICATION OF IMMUNOSUPPRESSANTS,"MOBILE PHASE A MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD 1000 ML"(MOBILE PHASE A MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-MOBILE PHASE FOR LC-MS/MS USED WITH THE 93000 & 93000/1200 KIT, MASSCHROM® BIOGENIC AMINES/METABOLITES IN URINE SAMPLE PREP SET CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN INCLUDING SAMPLE CLEAN UP COLUMNS FOR 96 ANALYSES (MASSCHROM® BIOGENIC AMINES/METABOLITES IN URINE SAMPLE PREP SET CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN INCLUDING SAMPLE CLEAN UP COLUMNS)-THE MASSCHROM® BIOGENIC AMINES/METABOLITES IN URINE SYSTEM – CHROMATOGRAPHIC PLATFORM IN COMBINATION WITH THE SAMPLE PREP SET CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN IN URINE IS AN IN-VITRO DIAGNOSTIC PRODUCT FOR USE IN CLINICAL LABORATORIES TO QUANTITATIVELY DETERMINE ADRENALINE (SYN. EPINEPHRINE), NORADRENALINE (SYN. NOREPINEPHRINE), DOPAMINE, METANEPHRINE, NORMETANEPHRINE, 3-METHOXYTYRAMINE AND SEROTONIN IN HUMAN URINE SAMPLES THROUGH LIQUID CHROMATOGRAPHY WITH TANDEM MASS SPECTROMETRY (LC- MS/MS). THE KIT IS USED AS A TEST FOR PATIENTS IN WHOM THE URINE LEVELS OF THESE BIOGENIC AMINES ARE OF CLINICAL IMPORTANCE. ,"MOBILE PHASE B MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD 1000 ML"(MOBILE PHASE B MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-MOBILE PHASE FOR LC-MS/MS USED WITH THE 93000 & 93000/1200 KIT," NEUTRALISATION BUFFER MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE(NEUTRALISATION BUFFER MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE)-USED DURING SAMPLE PREPARATION FOR NEUTRALISATION OF SAMPLES FOR THE ANAYSIS OF CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN ,"RINSING SOLUTION MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD 1000 ML"(RINSING SOLUTION MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-

	NEEDLE RINSING SOLUTION FOR THE INJECTOR,"MASSCHECK® STEROID PANEL 2 SERUM CONTROL LEVEL II (LYOPH.) RECONSTITUTE WITH 3.0 ML DIST. WATER"(MASSCHECK® STEROID PANEL 2 SERUM CONTROL LEVEL II (LYOPH.))-QUALITY CONTROL SAMPLE FOR LC-MS/MS FOR THE ANALYSIS OF STEROIDS ," EXTRACTION BUFFER MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD 40 ML"(EXTRACTION BUFFER MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-USED DURING SAMPLE PREPARATION FOR EXTRACTION OF ANALYTES,LC-MS/MS REAGENT KIT INCLUDING STEROID 96 SPE WELL PLATE MASSCHROM® STEROIDS IN SERUM/PLASMA(LC-MS/MS REAGENT KIT INCLUDING STEROID 96 SPE WELL PLATE MASSCHROM® STEROIDS IN SERUM/PLASMA)-THIS REAGENT KIT IS USED FOR THE QUANTITATIVE DETECTION OF ALDOSTERONE, CORTISOL, CORTISONE, CORTI-COSTERONE, 11-DEOXYCORTISOL, ANDROSTENEDIONE, DEHYDROEPIANDROSTERONE (DHEA), DEHYDRO-EPIANDRO-STERONE SULFATE (DHEAS), DIHYDRO-TESTOSTERONE, ESTRADIOL, 17-HYDROXYPROGESTERONE, PROGESTERONE AND TESTOSTERONE IN PATIENT SERUM AND PLASMA SAMPLES VIA LC-MS/MS (LIQUID CHROMATOGRAPHY-MASS SPECTROMETRY). THE KIT IS INTENDED AS A TEST FOR PATIENTS REQUIRING MONITORING OF THE RELEVANT STEROID HORMONE LEVELS,"PRECIPITATION REAGENT MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD 100 ML "(PRECIPITATION REAGENT MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-USED DURING SAMPLE PREPARATION FOR PRECIPITATION OF IMMUNOSUPPRESSANTS,"TUNING MIX – SUCCINYLACETONE MASSCHROM® AMINO ACIDS AND ACYLCARNITINES ANALYTE AND INTERNAL STANDARD (NON DERIVATISED) 1 X 1 ML"("TUNING MIX – SUCCINYLACETONE MASSCHROM® AMINO ACIDS AND ACYLCARNITINES ANALYTE AND INTERNAL STANDARD (NON DERIVATISED)")-ACCESSORY FOR THE TUNING OF LC-MS/MS INSTRUMENTS FOR SUCCINYLACETONE ,"6PLUS1® MULTILEVEL WHOLE BLOOD CALIBRATOR SET MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD 7 X 2.0 ML (LYOPH.)" (6PLUS1® MULTILEVEL WHOLE BLOOD CALIBRATOR SET MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-USED FOR CALIBRATION OF THE INSTRUMENT (= LC-MS/MS),"MASSCHECK® AMINO ACIDS, ACYLCARNITINES INCL. SUCCINYLACETONE DRIED BLOOD SPOT CONTROL BI-LEVEL (I+II) 2 X 3 SPOTS"("MASSCHECK® AMINO ACIDS, ACYLCARNITINES INCL. SUCCINYLACETONE DRIED BLOOD SPOT CONTROL BI-LEVEL (I+II)")-QUALITY CONTROL SAMPLE FOR LC-MS/MS ,"ANALYTICAL COLUMN MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD 1 PC. - EQUILIBRATED AND TESTED"(ANALYTICAL

	COLUMN MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-USED FOR SEPARATION OF IMMUNOSUPPRESSANTS IN SAMPLES," RINSING SOLUTION MASSCHROM® STEROIDS IN SERUM/PLASMA 1000 ML"(RINSING SOLUTION MASSCHROM® STEROIDS IN SERUM/PLASMA)-NEEDLE RINSING SOLUTION FOR THE INJECTOR ," TRAP COLUMN MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD 1 PC. - EQUILIBRATED AND TESTED"(TRAP COLUMN MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-USED FOR SEPARATION OF IMMUNOSUPPRESSANTS IN SAMPLES," MASSCHECK® AMINO ACIDS, ACYLCARNITINES INCL. SUCCINYLACETONE DRIED BLOOD SPOT CONTROL, LEVEL I 1 X 3 SPOTS"("MASSCHECK® AMINO ACIDS, ACYLCARNITINES INCL. SUCCINYLACETONE DRIED BLOOD SPOT CONTROL, LEVEL I")-QUALITY CONTROL SAMPLE FOR LC-MS/MS ,"TUNING MIX MASSTOX® IMMUNOSUPPRESSANTS ANALYTES AND INTERNAL STANDARDS 1 X 1 ML"(TUNING MIX MASSTOX® IMMUNOSUPPRESSANTS ANALYTES AND INTERNAL STANDARDS)-ACCESSORY FOR THE TUNING OF LC-MS/MS INSTRUMENTS FOR THE ANALYSIS OF IMMUNOSUPPRESSANTS,"PROTECTIVE SHEETS FOR 96 WELL PLATES MASSCHROM® AMINO ACIDS AND ACYLCARNITINES FROM DRIED BLOOD 10 PCS."(PROTECTIVE SHEETS FOR 96 WELL PLATES MASSCHROM® AMINO ACIDS AND ACYLCARNITINES FROM DRIED BLOOD)-COVERING SHEETS FOR WELL PLATES ,6PLUS1® MULTILEVEL URINE CALIBRATOR SET MASSCHROM® CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN IN URINE 7 X 2.0 ML (LYOPH.)(6PLUS1® MULTILEVEL URINE CALIBRATOR SET MASSCHROM® CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN IN URINE)-USED FOR CALIBRATION OF THE INSTRUMENT (= LC-MS/MS) ,"PIERCEABLE ADHESIVE SEALS FOR 96 WELL PLATES MASSCHROM® AMINO ACIDS AND ACYLCARNITINES FROM DRIED BLOOD 10 PCS."(PIERCEABLE ADHESIVE SEALS FOR 96 WELL PLATES MASSCHROM® AMINO ACIDS AND ACYLCARNITINES FROM DRIED BLOOD)-COVERING SHEETS FOR WELL PLATES ,96 SPE WELL PLATE MASSCHROM® BIOGENIC AMINES/METABOLITES IN URINE("96 SPE WELL PLATE MASSCHROM® BIOGENIC AMINES/METABOLITES IN URINE")-USED FOR BINDING AND ELUTION OF BIOGENIC AMINES ," TUNING MIX MASSCHROM® AMINO ACIDS AND ACYLCARNITINES ANALYTES AND INTERNAL STANDARDS (NON DERIVATISED) 2 ML" ("TUNING MIX MASSCHROM® AMINO ACIDS AND ACYLCARNITINES ANALYTES AND INTERNAL STANDARDS (NON DERIVATISED)")-ACCESSORY FOR THE TUNING OF LC-MS/MS INSTRUMENTS FOR ALL THE ANALYTES OF AMINO ACIDS AND ACYLCARNITINES ,PIERCEABLE ADHESIVE SEALS FOR 96 WELL PLATES MASSCHROM® BIOGENIC AMINES/METABOLITES IN URINE(PIERCEABLE ADHESIVE SEALS FOR

	96 WELL PLATES MASSCHROM® BIOGENIC AMINES/METABOLITES IN URINE)-COVERING SHEETS FOR WELL PLATES ,"96 WELL FILTER PLATES MASSCHROM® AMINO ACIDS AND ACYLCARNITINES FROM DRIED BLOOD (NON DERIVATISED) 5 PCS."(96 WELL FILTER PLATES MASSCHROM® AMINO ACIDS AND ACYLCARNITINES FROM DRIED BLOOD (NON DERIVATISED))-MICROTITTER PLATES FOR SAMPLE PREPARTION ,MASSCHECK® CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN URINE CONTROL LEVEL I 5 X 2.0 ML (LYOPH.)("MASSCHECK® CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN URINE CONTROL LEVEL I")-QUALITY CONTROL SAMPLE FOR LC-MS/MS FOR THE ANALYSIS OF BIOGENIC AMINES ,LC-MS/MS REAGENT KIT INCLUDING SAMPLE CLEAN UP COLUMNS MASSCHROM® STEROIDS IN SERUM/PLASMA FOR 96 ANALYSES(LC-MS/MS REAGENT KIT INCLUDING SAMPLE CLEAN UP COLUMNS MASSCHROM® STEROIDS IN SERUM/PLASMA)-THIS REAGENT KIT IS USED FOR THE QUANTITATIVE DETECTION OF ALDOSTERONE, CORTISOL, CORTISONE, CORTI-COSTERONE, 11-DEOXYCORTISOL, ANDROSTENEDIONE, DEHYDROEPIANDROSTERONE (DHEA), DEHYDRO-EPIANDRO-STERONE SULFATE (DHEAS), DIHYDRO-TESTOSTERONE, ESTRADIOL, 17-HYDROXYPROGESTERONE, PROGESTERONE AND TESTOSTERONE IN PATIENT SERUM AND PLASMA SAMPLES VIA LC-MS/MS (LIQUID CHROMATOGRAPHY-MASS SPECTROMETRY). THE KIT IS INTENDED AS A TEST FOR PATIENTS REQUIRING MONITORING OF THE RELEVANT STEROID HORMONE LEVELS ,TUNING MIX ANALYTES AND INTERNAL STANDARDS MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE(TUNING MIX ANALYTES AND INTERNAL STANDARDS MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE)-ACCESSORY FOR THE TUNING OF LC-MS/MS INSTRUMENTS ," MASSCHECK® AMINO ACIDS, ACYLCARNITINES INCL. SUCCINYLACETONE DRIED BLOOD SPOT CONTROL, LEVEL II 1 X 3 SPOTS"("MASSCHECK® AMINO ACIDS, ACYLCARNITINES INCL. SUCCINYLACETONE DRIED BLOOD SPOT CONTROL, LEVEL II")-QUALITY CONTROL SAMPLE FOR LC-MS/MS ,"INTERNAL STANDARD MIX MASSCHROM® STEROIDS IN SERUM/PLASMA 1 X 5 ML" (INTERNAL STANDARD MIX MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED DURING SAMPLE PREPARATION FOR THE QUANTIFICATION OF STEROIDS ,"TUNING MIX MASSCHROM® STEROID PANEL 2 ANALYTES AND INTERNAL STANDARDS 1 X 1 ML" (TUNING MIX MASSCHROM® STEROID PANEL 2 ANALYTES AND INTERNAL STANDARDS)-ACCESSORY FOR THE TUNING OF LC-MS/MS INSTRUMENTS ,"SYSTEM CHECK SOLUTION MASSCHROM® STEROID PANEL 1 1 X 1 ML"(SYSTEM CHECK SOLUTION MASSCHROM® STEROID PANEL 1)-STARTUP ACCESSORY FOR LC-MS/MS STATUS

	CHECK FOR THE ANALYSIS OF STEROIDS ,"EXTRACTION BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA 45 ML"(EXTRACTION BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED DURING SAMPLE PREPARATION FOR THE EXTRACTION OF STEROIDS ," RECONSTITUTION BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA 10 ML"(RECONSTITUTION BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED DURING SAMPLE PREPARATION FOR DETERMINATION OF STEROIDS ,"WASTE PLATES MASSCHROM® STEROIDS IN SERUM/PLASMA 3 PCS."(WASTE PLATES MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED FOR COLLECTION OF WASTE SOLUTIONS DURING SAMPLE PREPARATION ,"TUNING MIX MASSCHROM® STEROID PANEL 1 ANALYTES AND INTERNAL STANDARDS 1 X 1 ML"(TUNING MIX MASSCHROM® STEROID PANEL 1 ANALYTES AND INTERNAL STANDARDS)-ACCESSORY FOR THE TUNING OF LC-MS/MS INSTRUMENT FOR THE ANALYSIS OF STEROIDS ,SYSTEM CHECK SOLUTION MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE(SYSTEM CHECK SOLUTION MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE)-STARTUP ACCESSORY FOR LC-MS/MS STATUS CHECK FOR THE DETERNIMATION OF BIOGENIC AMINES ,"STEROID 96 SPE WELL PLATE MASSCHROM® STEROIDS IN SERUM/PLASMA 1 PC."(STEROID 96 SPE WELL PLATE MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED FOR BINDING AND ELUTION OF STEROIDS ,ADJUSTMENT REAGENT MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE(ADJUSTMENT REAGENT MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE)-USED DURING SAMPLE PREPARATION FOR PH ADJUSTMENT ,"SAMPLE CLEAN UP COLUMNS MASSCHROM® STEROIDS IN SERUM/PLASMA 96 PCS."(SAMPLE CLEAN UP COLUMNS MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED FOR BINDING AND ELUTION OF STEROIDS ," EQUILIBRATION REAGENT 2 MASSCHROM® STEROIDS IN SERUM/PLASMA 80 ML"(EQUILIBRATION REAGENT 2 MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED DURING SAMPLE PREPARATION FOR RECONSTITUTION OF STEROIDS TO MAXIMIZE THE RECOVERY AND ACTIVITY ,COLLECTION PLATES MASSCHROM® BIOGENIC AMINES/METABOLITES IN URINE("COLLECTION PLATES MASSCHROM® BIOGENIC AMINES/METABOLITES IN URINE")-MICROTITTER PLATES FOR COLLECTION OF BIOGENIC AMINES , DILUTION BUFFER MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE(DILUTION BUFFER MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE)-USED DURING SAMPLE PREPARATION FOR DILUTION OF SAMPLES FOR THE ANALYSIS OF CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN ,"RINSING SOLUTION, MASSCHROM®

	AMINO ACIDS AND ACYLCARNITINES FROM DRIED BLOOD (NON DERIVATISED) 1000 ML"(MASSCHROM® AMINO ACIDS AND ACYLCARNITINES FROM DRIED BLOOD (NON DERIVATISED))-NEEDLE RINSING SOLUTION FOR THE INJECTOR ,SAMPLE CLEAN UP COLUMNS MASSCHROM® BIOGENIC AMINES/METABOLITES IN URINE ("SAMPLE CLEAN UP COLUMNS MASSCHROM® BIOGENIC AMINES/METABOLITES IN URINE")-USED DURING SAMPLE PREPARATION FOR BINDING AND ELUTION OF SAMPLES FOR THE ANALYSIS OF CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN ,"MOBILE PHASE B MASSCHROM® STEROIDS IN SERUM/PLASMA 1000 ML"(MOBILE PHASE B MASSCHROM® STEROIDS IN SERUM/PLASMA)-MOBILE PHASE FOR LC-MS/MS USED WITH THE 72072/96, 72072/480 OR 72072/C KIT ,"MOBILE PHASE A MASSCHROM® STEROIDS IN SERUM/PLASMA 900 ML"(MOBILE PHASE A MASSCHROM® STEROIDS IN SERUM/PLASMA)-MOBILE PHASE FOR LC-MS/MS USED WITH THE 72072/96, 72072/480 OR 72072/C KIT ,"INTERNAL STANDARD MIX MASSCHROM® CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN IN URINE ("INTERNAL STANDARD MIX MASSCHROM® CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN IN URINE")-INTERNAL STANDARD FOR SAMPLE PREPARATION USED WITH REAGENT KIT FOR TANDEM MASS SPECTROMETRY (LC-MS/MS) ANALYSIS OF CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN ,"EQUILIBRATION REAGENT 1 MASSCHROM® STEROIDS IN SERUM/PLASMA 80 ML" (EQUILIBRATION REAGENT 1 MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED DURING SAMPLE PREPARATION FOR RECONSTITUTION OF STEROIDS TO MAXIMIZE THE RECOVERY AND ACTIVITY. ,"ELUTION BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA 50 ML"(ELUTION BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED DURING SAMPLE PREPARATION FOR THE ELUTION OF STEROIDS ,ELUTION BUFFER MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE(ELUTION BUFFER MASSCHROM® CATECHOLAMINES, METANEPHRINES, SEROTONIN IN URINE)-USED DURING SAMPLE PREPARATION FOR ELUTION OF CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN ,"INTERNAL STANDARD MASSCHROM® AMINO ACIDS AND ACYLCARNITINES FROM DRIED BLOOD (NON DERIVATISED) 57004 = 4 X 25 ML 57004/T = 1 X 25 ML"(INTERNAL STANDARD MASSCHROM® AMINO ACIDS AND ACYLCARNITINES FROM DRIED BLOOD (NON DERIVATISED))-INTERNAL STANDARD FOR SAMPLE PREPARATION USED WITH LC-MS/MS REAGENT KIT MASS CHROM AMINO ACID & ACYLCARNITINE FROM DRIED BLOOD (NON DERIVATISED) DURING SAMPLE PREPARATION ,"6PLUS1® MULTILEVEL SERUM CALIBRATOR SET MASSCHROM® STEROID

	PANEL 2 7 X 3.0 ML (LYOPH.) "(6PLUS1® MULTILEVEL SERUM CALIBRATOR SET STEROID PANEL 2 (LYOPH.))-USED FOR CALIBRATION OF THE INSTRUMENT (= LC-MS/MS) ,"EXTRACTION BUFFER, SUCCINYLACETONE (NON DERIVATISED) MASSCHROM® AMINO ACIDS AND ACYLCARNITINES 18 ML "("EXTRACTION BUFFER, SUCCINYLACETONE (NON DERIVATISED) MASSCHROM® AMINO ACIDS AND ACYLCARNITINES ")-BUFFER FOR THE EXTRACTION OF SUCCINYLACETONE FROM DRIED BLOOD SPOTS. ,"WASH BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA 70 ML"(WASH BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED FOR WASHING OF STEROID SAMPLES DURING SAMPLE PREPARATION ,"INTERNAL STANDARD SUCCINYLACETONE (NON DERIVATISED) MASSCHROM® AMINO ACIDS AND ACYLCARNITINES 18 ML"("INTERNAL STANDARD SUCCINYLACETONE (NON DERIVATISED) MASSCHROM® AMINO ACIDS AND ACYLCARNITINES")-INTERNAL STANDARD FOR SAMPLE PREPARATION USED WITH LC-MS/MS REAGENT KIT MASS CHROM AMINO ACID & ACYLCARNITINE FROM DRIED BLOOD (NON DERIVATISED) FOR DETERMIANTION OF SUCCINYLACETOE DURING SAMPLE PREPARATION,"6PLUS1® MULTILEVEL SERUM CALIBRATOR SET MASSCHROM® STEROID PANEL 1 7 X 3.0 ML (LYOPH.) "(6PLUS1® MULTILEVEL SERUM CALIBRATOR SET MASSCHROM® STEROID PANEL 1 (LYOPH.))-USED FOR CALIBRATION OF THE INSTRUMENT (= LC-MS/MS) ,SUCCINYLACETONE (NON DERIVATISED) UPGRADE SET MASSCHROM® AMINO ACIDS AND ACYLCARNITINES FROM DRIED BLOOD (NON DERIVATISED) WITH 96 WELL PLATES FOR 960 ANALYSES(LC-MS/MS SUCCINYLACETONE UPGRADE SET MASSCHROM® AMINO ACIDS AND ACYLCARNITINES FROM DRIED BLOOD (NON DERIVATISED))-UPGRADE SET CONSISTING OF INTERNAL STANDARD, EXTRACTION BUFFER AND ACCESSORIES. USED FOR SAMPLE PREPARATION FOR THE ANALYSIS OF SUCCINYLACETONE ,MASSCHROM® BIOGENIC AMINES/METABOLITES IN URINE SAMPLE PREP SET CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN INCLUDING 96 SPE WELL PLATE(MASSCHROM® BIOGENIC AMINES/ METABOLITES IN URINE SAMPLE PREP SET CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN INCLUDING 96 SPE WELL PLATE)-THE MASSCHROM® BIOGENIC AMINES/METABOLITES IN URINE SYSTEM – CHROMATOGRAPHIC PLATFORM IN COMBINATION WITH THE SAMPLE PREP SET CATECHOLAMINES, FREE METANEPHRINES, SEROTONIN IN URINE IS AN IN-VITRO DIAGNOSTIC PRODUCT FOR USE IN CLINICAL LABORATORIES TO QUANTITATIVELY DETERMINE ADRENALINE (SYN. EPINEPHRINE), NORADRENALINE (SYN. NOREPINEPHRINE), DOPAMINE, METANEPHRINE, NORMETANEPHRINE, 3-METHOXYTYRAMINE AND SEROTONIN IN HUMAN URINE SAMPLES

		THROUGH LIQUID CHROMATOGRAPHY WITH TANDEM MASS SPECTROMETRY (LC- MS/MS). THE KIT IS USED AS A TEST FOR PATIENTS IN WHOM THE URINE LEVELS OF THESE BIOGENIC AMINES ARE OF CLINICAL IMPORTANCE.,LC-MS/MS REAGENT KIT MASSCHROM® AMINO ACIDS & ACYLCARNITINES FROM DRIED BLOOD (NON DERIVATISED)(LC-MS/MS REAGENT KIT MASSCHROM® AMINO ACIDS & ACYLCARNITINES FROM DRIED BLOOD (NON DERIVATISED))-THIS CHROMSYSTEMS REAGENT KIT IS DESIGNED FOR THE SEMI-QUANTITATIVE DETERMINATION OF AMINO ACIDS & ACYLCARNITINES IN DRIED BLOOD SPOTS FOR THE NEWBORN SCREENING OF AMINO AND FATTY ACID META-BOLIC DISORDERS VIA TANDEM MASS SPECTROMETRY (= LC-MS/MS).,"PIERCEABLE ADHESIVE SEALS MASSCHROM® STEROIDS IN SERUM/PLASMA FOR 96 SPE WELL PLATES 3 PCS."(PIERCEABLE ADHESIVE SEALS MASSCHROM® STEROIDS IN SERUM/PLASMA FOR 96 SPE WELL PLATES)-COVERING SHEETS FOR WELL PLATES ,MOBILE PHASE, MASSCHROM® AMINO ACIDS AND ACYLCARNITINES FROM DRIED BLOOD (NON DERIVATISED) 57001 = 1 X 1000 ML 57002 = 10 X 1000 ML (MOBILE PHASE, MASSCHROM® AMINO ACIDS AND ACYLCARNITINES FROM DRIED BLOOD (NON DERIVATISED))-MOBILE PHASE FOR LC-MS/MS USED WITH THE 57000 &/OR 57000/F KITS. ," STEROID COLLECTION PLATES MASSCHROM® STEROIDS IN SERUM/PLASMA 3 PCS."(STEROID COLLECTION PLATES MASSCHROM® STEROIDS IN SERUM/PLASMA)-MICROTITTER PLATES FOR COLLECTION OF STEROIDS ,"ANALYTICAL COLUMN MASSCHROM® STEROIDS IN SERUM/PLASMA 1 PC. - EQUILIBRATED AND TESTED"(ANALYTICAL COLUMN MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED FOR SEPARATION OF STEROIDS IN SAMPLES ,"MASSCHECK® IMMUNOSUPPRESSANTS WHOLE BLOOD CONTROL FOUR-LEVEL (I+II+III+IV) 4 X 2 X 2.0 ML (LYOPH.)"(MASSCHECK® IMMUNOSUPPRESSANTS WHOLE BLOOD CONTROL FOUR-LEVEL (I+II+III+IV))-QUALITY CONTROL SAMPLE FOR LC-MS/MS
481	IMP/IVD/2020/000040	1.License Holder Name: BIODX HEALTHCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LYSE(ZYBIO)-FOR CELL CLASSIFICATION COUNT OR HEMOGLOBIN QUANTITATIVE MEASUREMENT.,DILUENT(ZYBIO)-THE DILUENT IS USED FOR COUNTING AND SIZING BLOOD CELLS.,LYSE(ZYBIO)-FOR CELL CLASSIFICATION COUNT OR HEMOGLOBIN QUANTITATIVE MEASUREMENT.

482	IMP/IVD/2020/000041	1.License Holder Name: IMMUNOSHOP INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CRP -NEPHSTAR (GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN C-REACTIVE PROTEIN (CRP) IN SERUM AS AN AID IN DIAGNOSIS AND TREATMENT OF INFLAMMATORY CONDITIONS, BACTERIAL INFECTION AS WELL AS CARDIAC DISEASES ,CYS C - OMLIPO (GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN CYSTATIN C CYS CIN SERUM , PLASMA AS AN AID IN DIAGNOSIS AND TREATMENT OF RENAL DISEASES., HBA1C -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN HAEMOGLOBIN A1C (HBA1C) PERCENTAGE TO TOTAL HAEMOGLOBIN IN WHOLE BLOOD AS AN AID IN DIAGNOSIS OF DIABETIC MELLITUS.,TRF -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN TRANSFERRIN (TRF) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL TRF METABOLISM, D-DIMER - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN D-DIMER (DD) IN HUMAN CITRATED PLASMA ,CRP - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN C-REACTIVE PROTEIN(CRP) IN SERUM AS AN AID IN DIAGNOSIS AND TREATMENT OF INFLAMMATORY CONDITIONS, BACTERIAL INFECTION AS WELL AS CARDIAC DISEASES. ,BCRP -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN C-REACTIVE PROTEIN (CRP) IN WHOLE BLOOD AS AN AID IN DIAGNOSIS AND TREATMENT OF INFLAMMATORY CONDITIONS, BACTERIAL INFECTION AS WELL AS CARDIAC DISEASES.,C4 -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN COMPLEMENT 4 (C4) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL C4 METABOLISM., CER -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN CERULOPLASMIN (CER) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL CER METABOLISM. ,USCRP - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN ULTRASENSITIVE C-REACTIVE PROTEIN (USCRP) IN SERUM AS AN AID IN DIAGNOSIS AND TREATMENT OF INFLAMMATORY CONDITIONS, BACTERIAL INFECTION AS WELL AS CARDIAC DISEASES ,RF - NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF

	HUMAN RHEUMATOID FACTOR (RF) IN SERUM AS AN AID IN DIAGNOSIS OF RHEUMATOID ARTHRITIS.,HPT - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN HAPTOGLOBIN (HPT) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL HPT METABOLISM.,SARS-COV-2 IGG/IGM KIT(GOLDSITE)-THIS KIT IS USED FOR QUALITATIVE DETERMINATION OF THE IGG AND IGM ANTIBODIES TO THE NOVEL CORONAVIRUS SARS-COV-2 IN HUMAN WHOLE BLOOD OR SERUM OR PLASMA AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS DISEASE 2019 (COVID-19).,MALB - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN MICRO ALBUMIN (MALB) IN URINE AS AN AID IN DIAGNOSIS OF ABNORMAL MALB METABOLISM.,HPT - NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN HAPTOGLOBIN (HPT) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL HPT METABOLISM,SAA - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN SERUM AMYLOID A (SAA) IN SERUM, PLASMA OR WHOLE BLOOD.,IGA -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN IMMUNOGLOBULIN A (IGA) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL IGA METABOLISM.,ALB - OMLIPO (GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN ALBUMIN (ALB) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL ALB METABOLISM.,HBA1C - OMLIPO (GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN HAEMOGLOBIN A1C (HBA1C) IN WHOLE BLOOD.,C1IN - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED ON PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN C1-INACTIVATOR(C1IN) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL C1IN METABOLISM.,CYS C -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN CYSTATIN C CYS C IN SERUM , PLASMA AS AN AID IN DIAGNOSIS AND TREATMENT OF RENAL DISEASES,PAB -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN PREALBUMIN (PAB) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL PAB METABOLISM., IGM - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN IMMUNOGLOBULIN M (IGM) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL IGM METABOLISM.,CER - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN CERULOPLASMIN (CER) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL CER

	METABOLISM.,IGG -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN IMMUNOGLOBULIN G (IGG) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL IGG METABOLISM.,AT3 - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN ANTITHROMBIN (AT-, AT3) IN PLASMA (SODIUM CITRATE AS ANTICOAGULANT) AS AN AID IN DIAGNOSIS OF ABNORMAL AT- METABOLISM.,IGA - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN IMMUNOGLOBULIN A (IGA) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL IGA METABOLISM.,AMG - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN A2 MACROGLOBULIN (AMG) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL AMG METABOLISM.,USCRP -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN ULTRASENSITIVE C-REACTIVE PROTEIN (USCRP) IN SERUM AS AN AID IN DIAGNOSIS AND TREATMENT OF INFLAMMATORY CONDITIONS, BACTERIAL INFECTION AS WELL AS CARDIAC DISEASES. ,AAG - OMLIPO (GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN 1-ACID GLYCOPROTEIN (AAG) IN SERUM AS AN AID IN DIAGNOSIS AND TREATMENT OF INFLAMMATORY CONDITIONS, BACTERIAL INFECTION AS WELL AS CARDIAC DISEASES.,RBP -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN RETINOL BINDING PROTEIN (RBP) IN SERUM.,AMG -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN A2 MACROGLOBULIN (AMG) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL AMG METABOLISM.,PAB - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN PREALBUMIN (PAB) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL PAB METABOLISM., APO A1 - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN APOLIPOPROTEIN A1 (APO A1) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL APO A1 METABOLISM.,APO A1 -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN APOLIPOPROTEIN A1 (APO A1) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL APO A1 METABOLISM.,C4 - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN COMPLEMENT 4 (C4) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL C4 METABOLISM., APO B - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR

	QUANTITATIVE DETERMINATION OF HUMAN APOLIPOPROTEIN B (APO B) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL APO B METABOLISM.,IGM -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN IMMUNOGLOBULIN M (IGM) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL IGM METABOLISM.,ASO - NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN ANTI-STREPTOLYSIN O (ASO) IN SERUM AS AN AID IN DETERMINATION OF LEVELS OF STREPTOCOCCAL INFECTION.,IGG - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN IMMUNOGLOBULIN G (IGG) IN SERUM/ URINE AS AN AID IN DIAGNOSIS OF ABNORMAL IGG METABOLISM., BCRP - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN C-REACTIVE PROTEIN (CRP) IN WHOLE BLOOD AS AN AID IN DIAGNOSIS AND TREATMENT OF INFLAMMATORY CONDITIONS, BACTERIAL INFECTION AS WELL AS CARDIAC DISEASES. ,APO B -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN APOLIPOPROTERIN B (APO B) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL APO B METABOLISM.,D-DIMER -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN D-DIMER (DD) IN HUMAN CITRATED PLASMA. ,AAT - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN 1-ANTITRYPSIN (AAT) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL AAT METABOLISM.,ALB -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN ALBUMIN (ALB) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL ALB METABOLISM., RBP - NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN RETINOL BINDING PROTEIN (RBP) IN SERUM.,AAG - NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN1-ACID GLYCOPROTEIN (AAG) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL AAG METABOLISM.,AT3 - NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN ANTITHROMBIN (AT-, AT3) IN PLASMA(SODIUM CITRATE AS ANTICOAGULANT) AS AN AID IN DIAGNOSIS OF ABNORMAL AT-METABOLISM.,LIPOPROTEIN(A) -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED USED ON NEPHSTAR® PROTEIN ANALYSIS

	SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN LIPOPROTEIN(A) (LP(A)) IN SERUM.,RF - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN SERUM AS AN AID IN DIAGNOSIS OF RHEUMATOID ARTHRITIS.,LIPOPROTEIN(A) - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN LIPOPROTEIN(A) (LP(A)) IN SERUM.,MALB -NEPHSTAR (GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN MICRO ALBUMIN (MALB) IN URINE AS AN AID IN DIAGNOSIS OF ABNORMAL MALB METABOLISM.,TRF - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN TRANSFERRIN (TRF) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL TRF METABOLISM. ,AAT -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN 1-ANTITRYPSIN (AAT) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL AAT METABOLISM, SAA -NEPHSTAR (GOLDSITE)-THIS PRODUCT IS USED USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN AMYLOID A (SAA) IN SERUM, PLASMA OR WHOLE BLOOD. ,A1M - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN 1 MICROGLOBULIN (A1M) IN URINE.,C3 -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN COMPLEMENT 3 (C3) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL C3 METABOLISM.,C3 - OMLIPO (GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN COMPLEMENT 3 (C3) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL C3 METABOLISM.,A1M -NEPHSTAR (GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN 1 MICROGLOBULIN (A1M) IN URINE.,ASO - OMLIPO(GOLDSITE)-THIS PRODUCT IS USED FOR QUANTITATIVE DETERMINATION OF HUMAN ANTI-STREPTOLYSIN O (ASO) IN SERUM AS AN AID IN DETERMINATION OF LEVELS OF STREPTOCOCCAL INFECTION.,C1IN -NEPHSTAR(GOLDSITE)-THIS PRODUCT IS USED ON NEPHSTAR® PROTEIN ANALYSIS SYSTEM FOR QUANTITATIVE DETERMINATION OF HUMAN C1-INACTIVATOR(C1IN) IN SERUM AS AN AID IN DIAGNOSIS OF ABNORMAL C1IN METABOLISM.

483	IMP/IVD/2020/000042	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD FACSFLOW SHEATH FLUID(BD FACSFLOW SHEATH FLUID)-OPTIMIZED SHEATH FLUID FOR USE ON FLOW CYTOMETERY INSTRUMENTS,BD FACS RINSE SOLUTION(BD FACS RINSE SOLUTION)-MAINTENANCE SOLUTION FOR FLOW CYTOMETERS,BD FACS SHUTDOWN SOLUTION(BD FACS SHUTDOWN SOLUTION)-MAINTENANCE SOLUTION FOR BD FACSCANTO FLOW CYTOMETERS,BD FACS SHEATH SOLUTION WITH SURFACTANT(BD FACS SHEATH SOLUTION WITH SURFACTANT)-OPTIMIZED SHEATH FLUID FOR USE ON FLOW CYTOMETRY INSTRUMENTS WITH BD HIGH THROUGHPUT SAMPLER,BD FACS CLEAN SOLUTION(BD FACS CLEAN SOLUTION)-DECONTAMINATION SOLUTION FOR USE WITH FLOW CYTOMETERS

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

484	IMP/IVD/2020/000045	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CRP LATEX (CRP LATEX)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS. THE NORMAL APPLICATION IS TO BE USED FOR THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY, INFLAMMATORY DISORDERS AND ASSOCIATED DISEASES. THE HIGHLY SENSITIVE APPLICATION IS NOT A GENERAL SCREENING TEST FOR INFECTION/INFLAMMATION.,RF LATEX (RF LATEX)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF RF (RHEUMATOID FACTOR) ANTIBODIES IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,FERRITIN(FERRITIN)-IMMUNO-TURBIDIMETRIC TEST FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER AU ANALYSERS.,CRP LATEX CALIBRATOR HIGHLY SENSITIVE SET(CRP LATEX CALIBRATOR HIGHLY SENSITIVE SET)-THE CRP CALIBRATOR (LATEX) IS A LIQUID HUMAN SERUM BASED MATRIX CALIBRATOR INTENDED TO BE USED WITH THE HIGHLY SENSITIVE APPLICATION OF THE CRP LATEX REAGENT OSR6199 FOR THE QUANTITATIVE DETERMINATION OF CRP ON BECKMAN COULTER AU ANALYSERS.,CRP LATEX CALIBRATOR NORMAL (N) SET(CRP LATEX CALIBRATOR NORMAL (N) SET)-THE CRP CALIBRATOR (LATEX) IS A LIQUID HUMAN SERUM BASED MATRIX CALIBRATOR INTENDED TO BE USED WITH THE NORMAL APPLICATION OF THE CRP (LATEX) REAGENT OSR6199 FOR THE QUANTITATIVE DETERMINATION OF CRP ON BECKMAN COULTER AU ANALYSERS.,RF LATEX CALIBRATOR(RF LATEX CALIBRATOR)-THE RF LATEX CALIBRATOR IS A LIQUID HUMAN SERUM BASED MATRIX CALIBRATOR INTENDED TO BE USED WITH THE RF LATEX REAGENT OSR61105 FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR ON BECKMAN COULTER ANALYSERS.

485	IMP/IVD/2020/000046	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMBITROL TS + LEVEL 2 (COMBITROL TS + LEVEL 2)-COMBITROL TS+, A MULTI-ANALYTE CONTROL, IS INTENDED FOR USE AS CONTROL MATERIAL TO MONITOR THE MEASUREMENT OF PH, PCO2, PO2, SO2, NA+, K+, CL-, ICA2+, HCT AND THB ON ROCHE OMNI C, ROCHE OMNI S, COBAS B ANALYZERS, AS WELL AS GLUCOSE AND LACTATE ON ROCHE OMNI S AND COBAS B ANALYZERS.,AUTO-TROL PLUS B LEVEL 3(AUTO-TROL PLUS B LEVEL 3)-AUTO-TROL PLUS B, A MULTI-ANALYTE CONTROL, IS INTENDED FOR USE AS CONTROL MATERIAL TO MONITOR THE MEASUREMENT OF PH, PCO2, PO2, SO2, NA+, K+, CL-, ICA2+, HCT, THB AND HB DERIVATIVES AS WELL AS GLUCOSE, LACTATE, UREA/BUN AND BILIRUBIN ON ROCHE OMNI S AND COBAS B ANALYZERS WITH AN OXIMETER MODULE.,AUTO-TROL TS+ LEVEL 3 (AUTO-TROL TS+ LEVEL 3)-AUTO-TROL TS+, A MULTI-ANALYTE CONTROL, IS INTENDED FOR USE AS CONTROL MATERIAL TO MONITOR THE MEASUREMENT OF PH, PCO2, PO2, SO2, NA+, K+, CL-, ICA2+, HCT AND THB ON ROCHE OMNI C, ROCHE OMNI S, COBAS B AND COBAS B ANALYZERS, AS WELL AS GLUCOSE AND LACTATE ON ROCHE OMNI S AND COBAS B ANALYZERS. THIS CONTROL MATERIAL IS PACKAGED FOR USE WITH THE AUTO QC MODULE, AN OPTION TO THE ROCHE OMNI C, ROCHE OMNI S, COBAS B ANALYZERS., COMBITROL TS+ LEVEL 1(COMBITROL TS+ LEVEL 1)-COMBITROL TS+, A MULTI-ANALYTE CONTROL, IS INTENDED FOR USE AS CONTROL MATERIAL TO MONITOR THE MEASUREMENT OF PH, PCO2, PO2, SO2, NA+, K+, CL-, ICA2+, HCT AND THB ON ROCHE OMNI C, ROCHE OMNI S, COBAS B ANALYZERS, AS WELL AS GLUCOSE AND LACTATE ON ROCHE OMNI S AND COBAS B ANALYZERS.,AUTO-TROL PLUS B LEVEL 1(AUTO-TROL PLUS B LEVEL 1)-AUTO-TROL PLUS B, A MULTI-ANALYTE CONTROL, IS INTENDED FOR USE AS CONTROL MATERIAL TO MONITOR THE MEASUREMENT OF PH, PCO2, PO2, SO2, NA+, K+, CL-, ICA2+, HCT, THB AND HB DERIVATIVES AS WELL AS GLUCOSE, LACTATE, UREA/BUN AND BILIRUBIN ON ROCHE OMNI S AND COBAS B ANALYZERS WITH AN OXIMETER MODULE.,COMBITROL PLUS B LEVEL 1(COMBITROL PLUS B LEVEL 1)-COMBITROL PLUS B IS A MULTI-ANALYTE CONTROL INTENDED FOR USE AS CONTROL MATERIAL TO MONITOR THE MEASUREMENT OF PH, PCO2, PO2, SO2, NA+, K+, CL-, ICA2+, HCT, THB AND HB DERIVATIVES AS WELL AS GLUCOSE, LACTATE, UREA/BUN AND BILIRUBIN ON ROCHE OMNI S OR COBAS B ANALYZERS WITH AN OXIMETER MODULE, AND COBAS B POC ANALYZERS.,COMBITROL TS+ LEVEL 3(COMBITROL TS+ LEVEL 3)-COMBITROL TS+, A MULTI-ANALYTE CONTROL, IS INTENDED FOR USE AS CONTROL MATERIAL TO MONITOR THE MEASUREMENT OF

	PH, PCO2, PO2, SO2, NA+, K+, CL-, ICA2+, HCT AND THB ON ROCHE OMNI C, ROCHE OMNI S, COBAS B ANALYZERS, AS WELL AS GLUCOSE AND LACTATE ON ROCHE OMNI S AND COBAS B ANALYZERS.,AUTO-TROL TS+ LEVEL 1(AUTO-TROL TS+ LEVEL 1)-AUTO-TROL TS+, A MULTI-ANALYTE CONTROL, IS INTENDED FOR USE AS CONTROL MATERIAL TO MONITOR THE MEASUREMENT OF PH, PCO2, PO2, SO2, NA+, K+, CL-, ICA2+, HCT AND THB ON ROCHE OMNI C, ROCHE OMNI S, COBAS B ANALYZERS, AS WELL AS GLUCOSE AND LACTATE ON ROCHE OMNI S AND COBAS B ANALYZERS. THIS CONTROL MATERIAL IS PACKAGED FOR USE WITH THE AUTO QC MODULE, AN OPTION TO THE ROCHE OMNI C, ROCHE OMNI S, COBAS B ANALYZERS.,AUTO-TROL TS+ LEVEL 2(AUTO-TROL TS+ LEVEL 2)-AUTO-TROL TS+, A MULTI-ANALYTE CONTROL, IS INTENDED FOR USE AS CONTROL MATERIAL TO MONITOR THE MEASUREMENT OF PH, PCO2, PO2, SO2, NA+, K+, CL-, ICA2+, HCT AND THB ON ROCHE OMNI C, ROCHE OMNI S, COBAS B AND COBAS B ANALYZERS, AS WELL AS GLUCOSE AND LACTATE ON ROCHE OMNI S AND COBAS B ANALYZERS. THIS CONTROL MATERIAL IS PACKAGED FOR USE WITH THE AUTO QC MODULE, AN OPTION TO THE ROCHE OMNI C, ROCHE OMNI S, COBAS B ANALYZERS.,COBAS B123 AUTOCVC PACK(COBAS B123 AUTOCVC PACK)-THE COBAS B 123 AUTOCVC PACK IS A MULTI-ANALYTE CONTROL, INTENDED FOR USE IN CALIBRATION VERIFICATION OF THE MEASURING RANGE ESTABLISHED BY COBAS B 123 POC SYSTEMS FOR PH, PCO2, PO2, SO2, NA+, K+, CL-, ICA2+, HCT, THB AND HB DERIVATIVES AS WELL AS GLUCOSE, LACTATE AND BILIRUBIN ON COBAS B 123 POC SYSTEMS WITH AN AUTOQC MODULE.,COMBITROL PLUS B LEVEL 3(COMBITROL PLUS B LEVEL 3)-COMBITROL PLUS B IS A MULTI-ANALYTE CONTROL INTENDED FOR USE AS CONTROL MATERIAL TO MONITOR THE MEASUREMENT OF PH, PCO2, PO2, SO2, NA+, K+, CL-, ICA2+, HCT, THB AND HB DERIVATIVES AS WELL AS GLUCOSE, LACTATE, UREA/BUN AND BILIRUBIN ON ROCHE OMNI S OR COBAS B ANALYZERS WITH AN OXIMETER MODULE, AND COBAS B POC ANALYZERS.,COBAS B 123 AUTOQC PACK TRI-LEVEL(COBAS B 123 AUTOQC PACK TRI-LEVEL)-THE COBAS B 123 AUTOQC PACK TRI-LEVEL IS A MULTI-ANALYTE CONTROL INTENDED FOR USE AS CONTROL MATERIAL TO MONITOR THE MEASUREMENT OF PH, PCO2, PO2, SO2, NA+, K+, CL-, ICA2+, HCT, THB AND HB DERIVATIVES AS WELL AS GLUCOSE, LACTATE AND BILIRUBIN ON COBAS B POC SYSTEMS WITH AN AUTOQC MODULE.,AUTO-TROL PLUS B LEVEL 2(AUTO-TROL PLUS B LEVEL 2)-AUTO-TROL PLUS B, A MULTI-ANALYTE CONTROL, IS INTENDED FOR USE AS CONTROL MATERIAL TO MONITOR THE MEASUREMENT OF PH, PCO2, PO2, SO2, NA+, K+, CL-, ICA2+,HCT, THB AND HB DERIVATIVES AS WELL AS GLUCOSE, LACTATE, UREA/BUN AND BILIRUBIN ON ROCHE

		OMNI S AND COBAS B ANALYZERS WITH AN OXIMETER MODULE., ISETROL(ISETROL)-ISETROL (ISETROL ELECTROLYTE CONTROLS) IS INTENDED FOR USE AS CONTROL MATERIAL TO MONITOR THE MEASUREMENTS OF NA+, K+, LI+, CL–, CA 2+.,COMBITROL PLUS B LEVEL 2(COMBITROL PLUS B LEVEL 2)-COMBITROL PLUS B IS A MULTI-ANALYTE CONTROL INTENDED FOR USE AS CONTROL MATERIAL TO MONITOR THE MEASUREMENT OF PH, PCO2, PO2, SO2, NA+, K+, CL-, ICA2+, HCT, THB AND HB DERIVATIVES AS WELL AS GLUCOSE, LACTATE, UREA/BUN AND BILIRUBIN ON ROCHE OMNI S OR COBAS B ANALYZERS WITH AN OXIMETER MODULE, AND COBAS B POC ANALYZERS.
486	IMP/IVD/2020/000047	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL BILIRUBIN(TOTAL BILIRUBIN)-THE TOTAL BILIRUBIN ASSAY IS USED FOR THE QUANTITATIVE ANALYSIS OF TOTAL BILIRUBIN IN HUMAN SERUM OR PLASMA OF ADULTS AND NEONATES ON THE ARCHITECT C SYSTEMS.,ICT CLEANING FLUID(ICT CLEANING FLUID)-FOR USE AS A CLEANING SOLUTION TO REMOVE PROTEIN FROM THE ICT UNIT AND C SYSTEM PROBES.,DETERGENT B(DETERGENT B)-DETERGENT B IS ONE OF THE ON-BOARD DETERGENT SOLUTIONS (AFTER DILUTION TO 10%) USED TO WASH THE REAGENT PROBES DURING NORMAL OPERATION ON THE ARCHITECT C SYSTEM.,LIPASE CALIBRATOR (LIPASE CALIBRATOR)-FOR USE IN THE CALIBRATION OF THE LIPASE ASSAY.,LIPASE(LIPASE)-THE LIPASE ASSAY IS USED FOR THE QUANTITATION OF LIPASE IN HUMAN SERUM OR PLASMA.

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487	IMP/IVD/2020/000048	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CRP CONTROL(AFINION™ CRP CONTROL)-THE AFINION™ CRP CONTROL KIT CONTAINS ASSAYED HUMAN SERUM CONTROLS AT TWO CONCENTRATION LEVELS OF C-REACTIVE PROTEIN (CRP).,LIPID PANEL CONTROL (AFINION™ LIPID PANEL CONTROL)-THE AFINION™ LIPID PANEL CONTROL KIT IS INTENDED FOR USE AS ASSAYED CONTROL MATERIAL FOR TOTAL CHOLESTEROL (CHOL), HIGH-DENSITY LIPOPROTEIN (HDL) CHOLESTEROL AND TRIGLYCERIDES (TRIG)., HBA1C(AFINION™ HBA1C)-AFINION™ HBA1C IS AN IN VITRO DIAGNOSTIC TEST FOR QUANTITATIVE DETERMINATION OF GLYCATED HEMOGLOBIN (HEMOGLOBIN A1C, HBA1C) IN HUMAN WHOLE BLOOD.,D-DIMER(NYCOCARD™ D-DIMER)-NYCOCARD™ D-DIMER IS AN IN VITRO TEST FOR THE RAPID DETERMINATION OF THE FIBRIN DEGRADATION PRODUCT D-DIMER IN PLASMA.,CRP (NYCOCARD™ CRP)-NYCOCARD™ CRP IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN WHOLE BLOOD AND IN HUMAN SERUM AND PLASMA.,CRP(AFINION™ CRP)-AFINION™ CRP IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN WHOLE BLOOD AND IN HUMAN SERUM AND PLASMA.,ACR CONTROL(AFINION™ ACR CONTROL)-THE AFINION™ ACR CONTROL KIT CONTAINS LIQUID PREPARATIONS OF ALBUMIN AND CREATININE IN CITRATE BUFFER,ACR(AFINION™ ACR)-AFINION™ ACR IS AN IN VITRO DIAGNOSTIC TEST FOR QUANTITATIVE DETERMINATION OF ALBUMIN, CREATININE AND ALBUMIN/CREATININE RATIO (ACR) IN HUMAN URINE.,HBA1C CONTROL(AFINION™ HBA1C CONTROL)-AFINION™ HBA1C CONTROL KIT CONTAINS LIQUID PREPARATIONS OF STABILIZED PORCINE WHOLE BLOOD (CONTROL C I) AND HUMAN WHOLE BLOOD (CONTROL C II), RESPECTIVELY.,LIPID PANEL(AFINION™ LIPID PANEL) -THE AFINION™ LIPID PANEL IS AN IN VITRO DIAGNOSTIC TEST FOR QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL (CHOL), HIGH-DENSITY LIPOPROTEIN (HDL) CHOLESTEROL AND TRIGLYCERIDES (TRIG) IN WHOLE BLOOD, SERUM AND PLASMA., HBA1C CONTROL(NYCOCARD™ HBA1C CONTROL)-THE NYCOCARD™ HBA1C CONTROL CONTAINS LIQUID PREPARATIONS OF STABILIZED BOVINE HAEMOGLOBIN,U-ALBUMIN CONTROL(NYCOCARD™ U-ALBUMIN CONTROL)-THE NYCOCARD™ U-ALBUMIN CONTROL KIT CONSISTS OF TWO CONTROL MATERIALS BASED ON HUMAN URINE., U-ALBUMIN(NYCOCARD U-ALBUMIN)-NYCOCARD™ U-ALBUMIN IS A RAPID IN VITRO TEST FOR MEASUREMENT OF LOW ALBUMIN CONCENTRATIONS IN HUMAN URINE,HBA1C(NYCOCARD™ HBA1C)-

		NYCOCARD™ HBA1C IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR QUANTITATIVE DETERMINATION OF GLYCATED HEMOGLOBIN (HBA1C) IN HUMAN WHOLE BLOOD.
488	IMP/IVD/2020/000055	1.License Holder Name: ASPEN DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROLS-CONTROLS ARE INTENDED FOR USE TO MONITOR TEST CARTRIDGE PERFORMANCE AT MULTIPLE POINTS.,TEST CARTRIDGE-THE TEST CARTRIDGE ARE INTENDED TO USE WITH EDAN I15 BLOOD GAS AND CHEMISTRY ANALYSIS SYSTEM. EACH DISPOSABLE CARTRIDGE ANALYZE BLOOD SAMPLE AND GIVEREPORT IN TERMS OF BLOOD ELECTROLYTES, BLOOD GASES AND BLOOD CHEMICALS, ETC., CALIBRANT FLUID PACK-CALIBRANT FLUID PACK CONTAIN CALIBRANT SOLUTION AND INTENDED TO BE USED TOGETHER WITH EDAN I15 BLOOD GAS AND CHEMISTRY ANALYSIS SYSTEM TO PERFORM SENSOR/CARTRIDGE CALIBRATION
489	IMP/IVD/2020/000056	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD ONCLARITY HPV CERVICAL BRUSH COLLECTION KIT(BD ONCLARITY HPV CERVICAL BRUSH COLLECTION KIT)-THE BD ONCLARITY™ HPV CERVICAL BRUSH COLLECTION KIT FOR THE BD ONCLARITY™ HPV ASSAY IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CERVICAL BRUSH SPECIMENS TO THE LABORATORY FOR TESTING WITH THE BD ONCLARITY™ HPV ASSAY ON THE BD VIPER™ LT SYSTEM.
490	IMP/IVD/2020/000057	1.License Holder Name: MEDISOFT PLUS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(ASHTON INTERNATIONAL LTD (UK))-DIAGNOSIS OR SCREENING OF DIABETES MELLITUS IN WHOLE HUMAN BLOOD COLLECTED FROM FINGER TIPS.
491	IMP/IVD/2020/000058	1.License Holder Name: ABBOTT HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FREESTYLE OPTIUM NEO H BLOOD GLUCOSE TEST STRIPS-BLOOD GLUCOSE TEST STRIPS ARE USED FOR IN -VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS. THIS SYSTEM MAY BE USED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE (D-GLUCOSE) IN FRESH CAPILLARY (I.E. FROM THE FINGER), VENOUS, ARTERIAL AND NEONATAL WHOLE BLOOD SAMPLES

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492	IMP/IVD/2020/000059	1.License Holder Name: KIN DIAGNOSTICS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IL-6(ICHROMA)-"ICHROMA™ IL-6 IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETECTION OF IL-6 IN HUMAN WHOLE BLOOD /SERUM/PLASMA. IT IS HELPFUL AS AN AID IN MANAGEMENT AND MONITORING OF INFLAMMATORY DISEASE. FOR IN VITRO DIAGNOSTIC USE ONLY. ",ICHROMA T3(ICHROMA T3)-ICHROMA T3 IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (TOTAL T3) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF THYROID DISORDERS. FOR IN VITRO DIAGNOSTIC USE ONLY. ,AMH(ICHROMA)-ICHROMA™ AMH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF AMH (ANTI-MÜLLERIAN HORMONE) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF PREMATURE OVARIAN INSUFFICIENCY, MENOPAUSE AND OVARIAN RESERVE. FOR IN VITRO DIAGNOSTIC USE ONLY, ICHROMA MICROALBUMIN(ICHROMA MICROALBUMIN)-ICHROMA MICROALBUMIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF MICROALBUMIN IN HUMAN URINE. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF KIDNEY DAMAGE FROM DIABETES. FOR IN VITRO DIAGNOSTIC USE ONLY. ,TN-I PLUS(ICHROMA)-ICHROMA™ TN-I PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN-I (TN-I) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION (AMI). FOR IN VITRO DIAGNOSTIC USE ONLY,ICHROMA PROGESTERONE(ICHROMA PROGESTERONE)-ICHROMA PROGESTERONE IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THE CAUSE OF INFERTILITY, TRACK OVULATION, DIAGNOSE AN ECTOPIC OR FAILING PREGNANCY, MONITOR THE HEALTH OF A PREGNANCY. FOR IN VITRO DIAGNOSTIC USE ONLY. , CARDIAC TRIPLE(ICHROMA)-ICHROMA™ CARDIAC TRIPLE IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONINI (TN I), CREATINE KINASE (CKMB) AND MYOGLOBIN IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION (AMI) AND ACUTE CORONARY SYNDROME (ACS). FOR IN VITRO DIAGNOSTIC USE ONLY,ICHROMA TN-I(ICHROMA TN-I)-ICHROMA TN-I IS A

	FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN-I (TN-I) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION (AMI). FOR IN VITRO DIAGNOSTIC USE ONLY.,NT-PROBNP(ICHROMA)-ICHROMA™ NT-PROBNP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF NT-PROBNP IN HUMAN WHOLE BLOOD/ SERUM/PLASMA. IT IS USEFUL AS AN AID IN THE DIAGNOSIS OF PERSONS SUSPECTED OF HAVING CONGESTIVE HEART FAILURE. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA PRL(ICHROMA PRL)-ICHROMA PRL IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF HYPOTHALAMIC-PITUITARY DISORDERS. FOR IN VITRO DIAGNOSTIC USE ONLY. ,TOTAL IGE(ICHROMA)-ICHROMA™ TOTAL IGE IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL IGE IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN DIAGNOSIS AND MANAGEMENT OF ALLERGIC DISEASE. FOR IN VITRO DIAGNOSTIC USE ONLY.,ICHROMA HSCRP(ICHROMA HSCRP)-ICHROMA HSCRP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CRP IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF RISK OF CARDIOVASCULAR DISEASES. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA TSH(ICHROMA TSH)-ICHROMA™ TSH PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TSH IN HUMAN WHOLE BLOOD/ SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF MEASUREMENT IN THE ASSESSMENT OF THYROID FUNCTION. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA MYOGLOBIN(ICHROMA MYOGLOBIN)-ICHROMA MYOGLOBIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN WHOLE BLOOD/ SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION (AMI). FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA FSH(ICHROMA FSH)-ICHROMA FSH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE(FSH) IN HUMAN SERUM/ PLASMA.IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF CONCENTRATION OF FSH. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA ANTI-CCP PLUS(ICHROMA ANTI-CCP PLUS)-"ICHROMA™ ANTI-CCP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE OR SEMI-QUANTITATIVE DETERMINATION OF HUMAN IGG AUTOANTIBODIES TO CYCLIC

	CITRULLINATED PEPTIDES (CCP) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA) IN COMBINATION WITH OTHER CLINICAL AND LABORATORY FINDINGS. FOR IN VITRO DIAGNOSTIC USE ONLY.",ICHROMA HBA1C(ICHROMA HBA1C)-ICHROMA HBA1C IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF HBA1C(HEMOGLOBIN A1C) IN HUMAN WHOLE BLOOD. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THE LONG-TERM GLYCEMIC STATUS IN PATIENTS WITH DIABETES MELLITUS. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA D-DIMER (ICHROMA D-DIMER)-ICHROMA D-DIMER IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN WHOLE BLOOD / PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF POST THERAPEUTIC EVALUATION OF THROMBOEMBOLIC DISEASE PATIENTS. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA PCT(ICHROMA PCT)-ICHROMA PCT IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF BACTERIAL INFECTION AND SEPSIS. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA CRP (ICHROMA CRP)-ICHROMA CRP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CRP IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF AUTOIMMUNE DISEASES AND INFECTIOUS PROCESSES, SUCH AS RHEUMATOID ARTHRITIS. FOR IN VITRO DIAGNOSTIC USE ONLY.,ICHROMA PCT PLUS(ICHROMA PCT PLUS)-"ICHROMA™ PCT PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF BACTERIAL INFECTION AND SEPSIS. FOR IN VITRO DIAGNOSTIC USE ONLY." , ICHROMA RF IGM(ICHROMA RF IGM)-ICHROMA RF IGM IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF RF IGM IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF RHEUMATOID ARTHRITIS. FOR IN VITRO DIAGNOSTIC USE ONLY. , ICHROMA VITAMIN D(ICHROMA VITAMIN D)-ICHROMA VITAMIN D IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25(OH)D2/D3 LEVEL IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF REGULATING THE CONCENTRATION OF CALCIUM AND PHOSPHATE IN THE BLOODSTREAM AND PROMOTING THE HEALTHY GROWTH AND REMODELING OF BONE. FOR IN VITRO

	DIAGNOSTIC USE ONLY. ,ICHROMA ASO(ICHROMA ASO)-ICHROMA™ ASO IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF ANTI STREPTOLYSIN O (ASO) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF SCARLET FEVER, RHEUMATIC FEVER AND POST INFECTIOUS GLOMERULONEPHRITIS ALONG WITH SEVERAL OTHER CONDITIONS. ,ICHROMA TESTOSTERONE(ICHROMA TESTOSTERONE)-ICHROMA TESTOSTERONE IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ANDROGEN LEVEL. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA LH(ICHROMA LH)-ICHROMA LH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF EVALUATING FERTILITY ISSUES, FUNCTION OF REPRODUCTIVE ORGANS (OVARIES OR TESTICLES), OR DETECTION OF THE OVULATION. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA T4(ICHROMA T4)-ICHROMA T4 IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THYROID DISORDER. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ICHROMA BETA-HCG(ICHROMA BETA-HCG)-ICHROMA B-HCG IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL BETA-HCG IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF TOTAL BETA HUMAN CHORIONIC GONADOTROPIN (TOTAL B-HCG) LEVEL IN HUMAN. FOR IN VITRO DIAGNOSTIC USE ONLY ,ICHROMA FERRITIN(ICHROMA FERRITIN)-ICHROMA FERRITIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN QUANTIFIES HUMAN FERRITIN. FOR IN VITRO DIAGNOSTIC USE ONLY.,ICHROMA CALPROTECTIN(ICHROMA CALPROTECTIN)-"ICHROMA™ CALPROTECTIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR QUANTITATIVE DETERMINATION OF CALPROTECTIN (MRP8/14; S100A8/S100A9) IN HUMAN FECES. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THE REFLEX GASTROINTESTINAL INFLAMMATION CAUSED BY SEVERAL PATHOLOGIES (INFLAMMATORY BOWEL DISEASE, COLORECTAL CANCER AND SOME ENTEROPATHIES). FOR IN VITRO DIAGNOSTIC USE ONLY.",COVID-19 AB(ICHROMA)-ICHROMA™ COVID-19 AB IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE

	DETERMINATION OF IGG/IGM ANTIBODIES AGAINST 'NOVEL CORONAVIRUS' IN HUMAN WHOLE BLOOD / SERUM /PLASMA. IT IS HELPFUL AS AN AID IN THE SCREENING OF EARLY MILD, ASYMPTOMATIC OR ACUTE PATIENTS FOR IDENTIFICATION OF 'NOVEL CORONAVIRUS (E.G., SARS-COV-2)' INFECTION WITH HIGH SENSITIVITY. ,ICHROMA CORTISOL(ICHROMA CORTISOL)-"ICHROMA™ CORTISOL IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF CONCENTRATION OF CORTISOL. FOR IN VITRO DIAGNOSTIC USE ONLY.",ICHROMA CYSTATIN C(ICHROMA CYSTATIN C)-ICHROMA CYSTATIN C IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF RENAL DISEASE. FOR IN VITRO DIAGNOSTIC USE ONLY.,ICHROMA CK-MB(ICHROMA CK-MB)-"ICHROMA™ CK-MB IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE ISOENZYME-MB (CK-MB) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAC INFARCTION (AMI) AND ACUTE CORONARY SYNDROME (ACS). FOR IN VITRO DIAGNOSTIC USE ONLY."

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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493	IMP/IVD/2020/000060	1.License Holder Name: M/S. GOLDEN HARVEST INDUSTRIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAGLUMI C-PEPTIDE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI TSH(CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI LIGHT CHECK(MAGLUMI)-IT IS USED TO CHECK THE VALIDITY OF STARTER REAGENTS STARTER 1 AND 2 AS WELL AS THE FUNCTIONING OF THE MEASURING AND PIPETTING UNITS OF MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER.,MAGLUMI WASH CONCENTRATE(MAGLUMI)-IT IS INTENDED TO BE DILUTED FOR PREPARATION OF MAGLUMI WASH/SYSTEM LIQUID WHICH IS REQUIRED FOR WASHING THE MAGNETIC MIRCOBEADS OF THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER.,MAGLUMI INTACT PTH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (INTACT PTH) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI A (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANGIOTENSIN II (AII) IN HUMAN PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI EBV VCA IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV VCA IGG IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE

	IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI ALBUMIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN URINE USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI VITAMIN B12 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI EBV VCA IGA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV VCA IGA IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI FREE TESTOSTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI CORTISOL (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM OR URINE USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI TMA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID MICROSOMAL AUTOANTIBODY (TMA) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI

	CK-MB (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MB ISOENZYME OF CREATINE KINASE (CK-MB) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI STARTER 1+2(MAGLUMI)-IT IS USED TO GENERATE THE CHEMILUMINOMETRIC LIGHT SIGNAL IN MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER.,MAGLUMI T3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI SYSTEM TUBING CLEANING SOLUTION(MAGLUMI)-USED TO CLEAN THE PIPETTOR AND THE WASHER NEEDLES FOR MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER., MAGLUMI REV T3(CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF REVERSE TRIIODOTHYRONINE (REVT3) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI TGA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN AUTOANTIBODY (TGA) IN HUMAN SERUM USING MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI PROINSULIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROINSULIN IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI FT3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM USING THE MAGLUMI

	SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI IGA (URINE ANALYSIS) (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN URINE USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI FT4 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI DHEA-S (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE (DHEA-S) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI IGF-I (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN-LIKE GROWTH FACTOR-I(IGF-I) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI T4 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI LH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS,

	MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI GAD 65 (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GLUTAMIC ACID DECARBOXYLASE ANTIBODY (GAD65) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI H-FABP(CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN H-FABP IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS), MAGLUMI EBV VCA IGM (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV VCA IGM IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI TESTOSTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI FA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLIC ACID (FA) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI FSH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI ACTH (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF

	ADRENOCORTICOTROPIC HORMONE (ACTH) IN HUMAN PLASMA WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI LAMININ (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LAMININ (LN) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI LP-PLA2 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 (LP-PLA2) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS)., MAGLUMI AMH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-MULLERIAN HORMONE (AMH) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS), MAGLUMI DIRECT RENIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF RENIN IN HUMAN EDTA-PLASMA SPECIMENS USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI PRL (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PRL IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI MYOGLOBIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI

	800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI IAA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN AUTOANTIBODIES (IAA) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI HA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HYALURONIC ACID (HA) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI PIIIP N-P (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF COLLAGEN TYPE III N-PEPTIDE (PIIIP N-P) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMITM ANTI-TPO (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-TPO IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,MAGLUMI IGE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI GH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GROWTH HORMONE (GH) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI TRAB(CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TSH RECEPTOR ANTIBODIES (TRAB) IN HUMAN SERUM USING THE

	MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMITM AI (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANGIOTENSIN I(AI) IN HUMAN PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER, MAGLUMI CHOLYLGLYCINE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CHOLYLGLYCINE (CG) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI EBV EA IGA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV EA IGA IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI OSTEOCALCIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF OSTEOCALCIN (BGP) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI IGM (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI INSULIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI 25-OH VITAMIN D (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE

	QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI EBV EA IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV EA IGG IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI FREE ESTRIOL (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE ESTRIOL IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI ALDOSTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALDOSTERONE (ALD) IN HUMAN SERUM, PLASMA AND TREATED URINE WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI HCG/-HCG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (-SUBUNIT) (HCG/-HCG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI IGFBP-3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN 3 (IGFBP-3) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI REACTION MODULE(MAGLUMI)-REACTION MODULES REQUIRED FOR THE IMPLEMENTATION OF THE MAGLUMI ASSAYS ON THE MAGLUMI SERIES FULLY-AUTO

	CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,MAGLUMI ESTRADIOL (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI PCT (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PCT IN HUMAN SERUM AND PLASMA WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI PRG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE (PRG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI C IV (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TYPE IV COLLAGEN (CIV) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MAGLUMI IGG (URINE ANALYSIS) (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN URINE USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,MAGLUMI EBV NA IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV NA IGG IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).

494	IMP/IVD/2020/000061	1.License Holder Name: M/S.ROCHE DIABETES CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(ACCU-CHEK AVIVA)-THE ACCU-CHEK AVIVA TEST STRIPS ARE INTENDED TO BE USED WITH THE ACCU-CHEK AVIVA, ACCU-CHEK AVIVA NANO, ACCU-CHEK AVIVA CONNECT, ACCU-CHEK AVIVA COMBO, ACCU-CHEK AVIVA EXPERT, ACCU-CHEK AVIVA INSIGHT, AND ACCU-CHEK AVIVA SOLO BLOOD GLUCOSE METERS TO QUANTITATIVELY MEASURE GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD AS AN AID IN MONITORING THE EFFECTIVENESS OF CONTROLLING GLUCOSE. TESTING SITES FOR THE ACCU-CHEK AVIVA, ACCU-CHEK AVIVA NANO AND ACCU-CHEK AVIVA CONNECT METERS INCLUDE THE FINGER, PALM, FOREARM, AND UPPER ARM. THE TESTING SITE FOR THE ACCU-CHEK AVIVA COMBO, ACCU-CHEK AVIVA EXPERT, ACCU-CHEK AVIVA INSIGHT AND ACCU-CHEK AVIVA SOLO METERS IS THE FINGERTIP. THE ACCU-CHEK AVIVA TEST STRIP, USED WITH THE ACCU-CHEK AVIVA, ACCU-CHEK AVIVA NANO, AND ACCU-CHEK AVIVA CONNECT METERS, ARE INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS IN CLINICAL SETTINGS AND BY PEOPLE WITH DIABETES AT HOME. THE ACCU-CHEK AVIVA COMBO, ACCU-CHEK AVIVA EXPERT, ACCU-CHEK AVIVA INSIGHT AND ACCU-CHEK AVIVA SOLO METERS ARE FOR HOME USE ONLY. HEALTHCARE PROFESSIONALS CAN USE VENOUS, ARTERIAL, AND NEONATAL BLOOD WITH THE ACCU-CHEK AVIVA AND ACCU-CHEK AVIVA NANO METERS. HEALTHCARE PROFESSIONALS CAN USE CAPILLARY AND VENOUS BLOOD WITH THE ACCU-CHEK AVIVA CONNECT METER. THE SYSTEMS ARE NOT FOR USE IN DIAGNOSIS OR SCREENING OF DIABETES MELLITUS, NOR FOR TESTING NEONATE CORD BLOOD SAMPLES. VENOUS, ARTERIAL, AND NEONATAL BLOOD TESTING IS LIMITED TO HEALTHCARE PROFESSIONAL USE ONLY.
495	IMP/IVD/2020/000062	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DXH 500 SERIES LYSE (DXH 500 SERIES LYSE)-ERYTHROCYTE LYTIC AGENT FOR QUANTITATIVE DETERMINATION OF HEMOGLOBIN, AND THE COUNTING, SIZING AND OPTICAL MEASUREMENT OF LEUKOCYTES ON DXH 500 SERIES SYSTEMS. USE ONLY WITH DXH 500 SERIES DILUENT AND DXH 500 SERIES CLEANER.

496	IMP/IVD/2020/000063	1.License Holder Name: NEMPRO CARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIP(AKKISCAN)-THE BLOOD GLUCOSE TEST STRIPS ASSOCIATED WITH THE SERIES BLOOD GLUCOSE METERS ARE DESIGNED TO QUANTITATIVELY MEASURE THE CONCENTRATION OF GLUCOSE IN CAPILLARY WHOLE BLOOD BY PERSONS WITH DIABETES OR BY HEALTHCARE PROFESSIONALS FOR MONITORING GLUCOSE AT HOME OR IN HEALTHCARE FACILITIES.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

497	IMP/IVD/2020/000067	1.License Holder Name: ANAND BROTHERS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLUEDIVER DOT APS IGG (BLUEDIVER DOT APS IGG)-BLUEDIVER DOT APS IGG IS AN IMMUNODOT KIT INTENDED FOR THE DETECTION IN HUMAN SERA OF IGG AUTOANTIBODIES AGAINST CARDIOLIPIN /B2-GPI COMPLEX AND B2-GPI (ISOTALTED PROTEIN),BLUEDIVER DOT LIVER 10 IGG (BLUEDIVER DOT LIVER 10 IGG)-BLUEDIVER DOT LIVER 10 IGG IS AN IMMUNODOT KIT INTENDED FOR THE DETECTION IN HUMAN SERA OF IGG AUTOANTIBODIES AGAINST M2/NPDC, M2/OGDC-E2, M2/BCOADCE2, M2/PDC-E2, GP210, SP100, LKM1, LC1 SLA AND F-ACTIN,BLUEDOT ANCA + GBM IGG(BLUEDOT ANCA + GBM IGG)-DETECTION IN HUMAN SERA OF IGG AUTOANTIBODIES AGAINST THE MYELOPEROXYDASE (MPO) AND PROTEINASE 3 (PR3) & GLOMERULAR BASEMENT MEMBRANE.,BLUEDIVER DOT ANCA+GBM IGG(BLUEDIVER DOT ANCA+GBM IGG)-BLUEDIVER DOT ANCA+GBM IGG IS AN INNUNODOT KIT INTENDED FOR THE DETECTION IN HUMAN SERA OF IGG AUTOANITBODIES AGAINST MPO AND PR3 AND GBM, BLUEDIVER DOT ASCA IGG + IGA(BLUEDIVER DOT ASCA IGG + IGA)-BLUEDIVER DOT ASCA IGG + IGA IS AN IMMUNODOT KIT INTENDED FOR THE DETECTION IN HUMAN SERA OF IGG AND IGA AUTOANTIBODIES AGAINST THE SACCHAROMYCES CEREVISIEA (MANNAN).,BLUEDIVER DOT GASTRITIS IGG(BLUEDIVER DOT GASTRITIS IGG)-BLUEDIVER DOT GASTRITIS IGG IS AN IMMUNODOT KIT INTENDED FOR THE DETECTION IN HUMAN SERA OF IGA AUTOANTIBODIES AGAINST THE INTRINSIC FACTOR AND THE PCA, BLUEWELL ENDOMYSIUM IGA(BLUEWELL ENDOMYSIUM IGA)-DETECTION OF IGA ANTIBODIES TO GLIADIN ACTIVATED ENDOMYCIAL EXTRACT IN HUMAN SERUM.,BLUEDOT POLYMYOSITIS/SCLERODERMA 8 IGG(BLUEDOT POLYMYOSITIS/SCLERODERMA 8 IGG)-DETECTION IN HUMAN SERA OF IGG AUTOANTIBODIES AGAINST JO-1, PL-7, PL-12, SRP-54, MI-2, KU, PM-SCL, SCL-70.,BLUEDOT LIVER 5 IGG(BLUEDOT LIVER 5 IGG)-DETECTION IN HUMAN SERA OF IGG AUTOANTIBODIES AGAINST M2/NPDC, LKM1, LC1, SLA AND F-ACTIN.,BLUEDIVER DOT ANA12 IGG (BLUEDIVER DOT ANA12 IGG)-BLUEDIVER DOT ANA12 IGG IS AN IMMUNODOT KIT INTENDED FOR THE DETECTION IN HUMAN SERA OF IGG AUTOANTIBODIES AGAINST SM, RNP, SM/RNP, SSA/RO6KD, SSB (LA), JO-1(HISTIDYL-T-RNA SYNTHETASE), SCL-70 (DNA TOPISOMERASE-I) PM-SCL 100 KU, CENP/A/B (CENTROMERE A/B PROTEINS) PCNA AND RIBOSOME PO.,BLUEDIVER DOT LIVER 5 IGG (BLUEDIVER DOT LIVER 5 IGG)-BLUEDIVER DOT LIVER 5 IGG IS AN IMMUNODOT KIT INTENDED FOR THE DETECTION IN HUMAN SERA OF IGG AUTOANTIBODIES AGAINST M2/NPDC, LKM1, LC1 SLA AND F-

		ACTIN.,BLUEDIVER DOT CELIAC IGA(BLUEDIVER DOT CELIAC IGA)-BLUEDIVER DOT CELIAC IGA IS AN IMMUNODOT KIT INTENDED FOR THE DETECTION IN HUMAN SERA OF IGA AUTOANTIBODIES AGAINST DEAMIDATED GLIANDIN AND TISSUE TRANSGLUTAMINASE.,BLUEDOT ANA8 IGG(BLUEDOT ANA8 IGG)-DETECTION IN HUMAN SERA OF IGG AUTOANTIBODIES AGAINST SM, SM/RNP, SSA/RO 60KD, SSB(LA), JO-1, SCL-70, PM-SCL 100 AND CENP-A/B.,BLUEDIVER QUANTRIX ANA25 IGG(BLUEDIVER QUANTRIX ANA25 IGG)-BLUEDIVER QUANTRIX ANA25 SCREEN IGG IS AN IMMUNODOT KIT INTENDED FOR THE DETECTION IN HUMAN SERA OF IGG AUTOANTIBODIES AGAINST NUCLEOSOME, DSDNA, HISTONES, SM RNP, (68KD/A/C), SM/RNP, SSA/RO60KD, SSA/RO52KD, SSB, SCL-70, KU, PM-SCL 100, MI-2, JO-1, PL-7, PL-12, SRP, RIBOSOMES, CENP-A/B, PCNA, SP100, GP210, M2RECOMBINANT, M2/NPDC AND F-ACTIN
498	IMP/IVD/2020/000067	1.License Holder Name: ANAND BROTHER'S 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLUEDOT POLYMYOSITIS/SCLERODERMA 12 IGG KIT(BLUEDOT)-BLUEDOT POLYMYOSITIS/SCLERODERMA12 IGG IS AN IMMUNODOT KIT INTENDED FOR THE DETECTION IN HUMAN SERA OF IGG AUTOANTIBODIES AGAINST JO-1, PL-7, PL-12, EJ, SRP, MI-2, MDA-5, TIF1-Y, KU, PM-SCL 100, SCL-70 AND SSA/RO52 ANTIGENS.,BLUE DOT MYOSITIS 7 IGG KIT(BLUEDOT)-BLUEDOT MYOSITIS7 IGG IS AN IMMUNODOT KIT INTENDED FOR THE DETECTION IN HUMAN SERA OF IGG AUTOANTIBODIES AGAINST MI-2, MDA-5, TIF1-Y, HMGCR, SAE1, SAE2 AND NXP-2 ANTIGENS.,BLUEDIVER DOT MYOSITIS 12 SAE IGG KIT(BLUEDIVER DOT)-BLUEDIVER DOT MYOSITIS12 SAE IGG IS AN IMMUNODOT KIT INTENDED FOR THE DETECTION IN HUMAN SERA OF IGG AUTOANTIBODIES AGAINST JO-1, PL-7, PL-12, EJ, SRP, MI-2, MDA-5, TIF1-Y, SSA/RO52KD, SAE1, SAE2 AND NXP-2.,BLUEDOT LIVER 7 IGG KIT(BLUEDOT)-BLUEDOT LIVER7 IGG IS AN IMMUNODOT KIT INTENDED FOR THE DETECTION IN HUMAN SERA OF IGG AUTOANTIBODIES AGAINST M2/NPDC, GP210, SP100, LKM1, LC1, SLA AND F-ACTIN.

499	IMP/IVD/2020/000068	1.License Holder Name: BIOGENEX LIFE SCIENCES PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANDROGEN RECEPTOR (ANTI-ANDROGEN RECEPTOR)-THIS ANTIBODY IS FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OFHUMAN ANDROGEN RECEPTOR ANTIGENIN FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) TISSUE SECTIONS., CYTOKERATIN 20(ANTI-CYTOKERATIN 20)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF CYTOKERATIN 20 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,INHIBIN ALPHA(ANTI-INHIBIN-ALPHA)-THIS ANTIBODY IS FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF INHIBIN-ALPHA IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,EZ-AR™ EZ-AR™ 1 EZ-AR™ 2 EZ-AR™ 3 EZ-AR™ 4(EZ -AR SOLUTIONS)-THE EZ-AR™ SOLUTIONS ARE DESIGNED TO DEPARAFFINIZE, REHYDRATE AND RECOVER ANTIGENICITY OF EPITOPES IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. THESE PRODUCTS ARE FOR LABORATORY USE ONLY.,SUPER SENSITIVE WASH BUFFER(SUPER SENSITIVE™ WASH BUFFER (20X))-THE CONCENTRATED WASH BUFFER IS A GENERAL PURPOSE REAGENT SUITABLE FOR DIAGNOSTIC HISTOPATHOLOGY, LABORATORY AND RESEARCH USE., BCL6(ANTI-BCL6)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF BCL6 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,SUPER SENSITIVE LINK LABEL IHC DET (SUPER SENSITIVE™* LINK LABEL IHC DETECTION SYSTEM)-THE BIOGENEX SUPER SENSITIVE™ LINK LABEL IHC DETECTION SYSTEMS IS A SECONDARY IMMUNOHISTOCHEMICAL DETECTION SYSTEM EMPLOYING AN INDIRECT BIOTIN-STREPTAVIDIN AMPLIFIED STAINING SYSTEM.,ER ALPHA(ANTI- ER)-FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF ER IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. EVALUATION MUST BE PERFORMED BY A QUALIFIED PATHOLOGIST.,CYTOKERATIN, HMW(ANTI-CYTOKERATIN, HIGH MW)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF HIGH MOLECULAR WEIGHT CYTOKERATIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS., CYTOKERATIN 19(ANTI-CYTOKERATIN 19)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF CYTOKERATIN 19 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE

	SECTIONS.,PMS2(ANTI-PMS2)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF PMS2 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,CYTOKERATIN, PAN (ANTI-CYTOKERATIN PAN)-THIS ANTIBODY IS FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF CYTOKERATIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS .,C-ERBB2 (HER-2/NEU)(ANTI-C-ERBB-2 (HER-2/NEU))-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF HER-2 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,MUC5AC(ANTI-MUC5AC)-THIS ANTIBODY IS FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF MUC5AC IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,MUC4 (ANTI-MUC4)-THIS ANTIBODY IS FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF MUC4 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,GFAP (ANTI-GLIAL FIBRILLARY ACIDIC PROTEIN (GFAP))-THIS ANTIBODY IS FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF GLIAL FIBRILLARY ACIDIC PROTEIN (GFAP) IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,E-CADHERIN(ANTI-E-CADHERIN)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF E-CADHERIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,CYTOKERATIN COCKTAIL(ANTI-CYTOKERATIN COCKTAIL) -THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF CYTOKERATIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,SYNAPTOPHYSIN(ANTI-SYNAPTOPHYSIN)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF SYNAPTOPHYSIN PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,P53 PROTEIN(ANTI-P53 PROTEIN)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF P53 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,CDX-2 (ANTI-CDX-2)-THIS ANTIBODY IS FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF CDX2 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,DYSTROPHIN 1 & DYSTROPHIN 2(ANTI-DYSTROPHIN)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC

	USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF DYSTROPHIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,CYTOKERATIN 5 & 6(ANTI-CYTOKERATIN 5&6)-FOR IN-VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF CYTOKERATIN 5&6 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. EVALUATION MUST BE PERFORMED BY A QUALIFIED PATHOLOGIST.,KI-67 AG(ANTI-KI-67 ANTIGEN, PROLIFERATING CELL)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF KI-67 ANTIGEN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,BETA-CATENIN(ANTI-HUMAN BETA CATENIN)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF BETA CATENIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,CYTOKERATIN 7(ANTI-CYTOKERATIN 7)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF CYTOKERATIN 7 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,B CELL(ANTI B CELL)-THIS ANTIBODY IS FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OFHUMAN MB2 ANTIGENIN FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) TISSUE SECTIONS.,ESTROGEN RECEPTOR ALPHA(ANTI- ESTROGEN RECEPTOR-ALPHA)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF ESTROGEN RECEPTOR -ALPHA IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,MLH 1(ANTI-MLH1)-THIS ANTIBODY IS FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF HUMAN MISMATCH PROTEIN REPAIR (MLH1) MOLECULE IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,DESMIN(ANTI-DESMIN)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF DESMIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,SUPER SENSITIVE POLYMER HRP(SUPER SENSITIVE™ POLYMER-HRP IHC DETECTION SYSTEM)-THE BIOGENEX SUPER SENSITIVE™ DETECTION SYSTEMS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE FOR THE CHROMOGENIC DETECTION OF ANTIGEN-ANTIBODY BINDING REACTIONS IN TISSUE SPECIMENS., PROGESTERONE RECEPTOR(ANTI-PROGESTERONE RECEPTOR)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF PROGESTERONE RECEPTOR IN FORMALIN-FIXED, PARAFFIN-

	EMBEDDED TISSUE SECTIONS.,EBER PROBE(EBER PROBE)-BIOGENEX EBER PROBE IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS PROBE IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF EBV ENCODED RNA IN FORMALIN FIXED; PARAFFIN EMBEDDED HUMAN TISSUES AND/OR FROZEN TISSUES BY IN SITU HYBRIDIZATION.,NSE(ANTI-NEURON SPECIFIC ENOLASE)-THIS ANTIBODY IS FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF NEURON SPECIFIC ENOLASE (NSE) IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,CHROMOGRAININ A(ANTI-CHROMOGRANIN A)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF SECRETORY STORAGE GRANULES IN ENDOCRINE CELLS IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,MSH2 (ANTI-HUMAN MSH2)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OFMSH2IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,ACTIN(ANTI-ACTIN, SMOOTH MUSCLE)-THIS ANTIBODY IS FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OFHUMAN ALPHA SMOOTH MUSCLE ACTIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) TISSUE SECTIONS.,CALRETININ(ANTI-CALRETININ)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF CALRETININ ANTIGEN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,P504S/AMACR (ANTI-P504S / AMACR)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF P504S/AMACR IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,PR (INSITE)(ANTI-PROGESTERONE RECEPTOR (INSITE® PR))-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF PROGESTERONE RECEPTOR IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,NAPSIN A(ANTI- NAPSIN A)-THIS ANTIBODY IS FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF HUMAN NAPSIN A MOLECULE IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,ER-BETA(ANTI-ESTROGEN RECEPTOR-BETA)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF ESTROGEN RECEPTOR B PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,CALPONIN(ANTI-CALPONIN)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO

	DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF PHOSPHORYLATED TYROSINE IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,LAMBDA LIGHT CHAIN(ANTI-LAMBDA LIGHT CHAIN)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF LAMBDA LIGHT CHAINS IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,EZ-DEWAX(EZ-DEWAXTM SOLUTION)-THE CONCENTRATED DEWAX™ SOLUTION IS A GENERAL PURPOSE REAGENT SUITABLE FOR DIAGNOSTIC HISTOPATHOLOGY, LABORATORY AND RESEARCH USE.,SUPER SENSITIVE ONE STEP POLYMER(SUPER SENSITIVE™* ONE-STEP POLYMER-HRP DETECTION SYSTEM)-THE BIOGENEX SUPER SENSITIVE™ ONE-STEP POLYMER-HRP DETECTION SYSTEM REPRESENTS STATE-OF-ART TECHNOLOGY IN THE DETECTION OF ANTIGEN-ANTIBODY BINDING REACTIONS, SUCH AS IN IMMUNOHISTOCHEMICAL STAINING APPLICATIONS.,MITF(ANTI-MITF)-THIS ANTIBODY IS FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF MITF IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,TDT(ANTI-TERMINAL DEOXYNUCLEOTIDYL TRANSFERASE (TDT))-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF TDT IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,PEPSIN 4-PACK KIT & PROTEASE XXIV, CONFEZIONE DA 4(DIGESTIVE ENZYME PRETREATMENT)-ENZYME DIGESTION KITS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE FOR ENZYMATIC PRETREATMENT OF FORMALIN-FIXED TISSUE SECTIONS PRIOR TO IMMUNOHISTOCHEMISTRY (IHC) OR IN SITU HYBRIDIZATION (ISH).,VIMENTIN(ANTI-VIMENTIN)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF VIMENTIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,MYF4(ANTI-MYF-4)-THIS ANTIBODY IS FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF MYF4 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,KAPPA LIGHT CHAIN(ANTI-KAPPA LIGHT CHAIN)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF KAPPA LIGHT CHAIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.,CYTOKERATIN 20(ANTI-HUMAN CYTOKERATIN 20)-THIS ANTIBODY IS CURRENTLY AVAILABLE FOR IN VITRO DIAGNOSTIC USE. THIS ANTIBODY IS DESIGNED FOR THE SPECIFIC LOCALIZATION OF CYTOKERATIN 20 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.

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500	IMP/IVD/2020/000069	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARCHITECT CYCLOSPORINE CALIBRATORS (ARCHITECT CYCLOSPORINE CALIBRATORS)-THE ARCHITECT CYCLOSPORINE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE IN HUMAN WHOLE BLOOD.,ALINITY I TACROLIMUS REAGENT KIT(ALINITY I TACROLIMUS REAGENT KIT)-THE ALINITY I TACROLIMUS ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF TACROLIMUS IN HUMAN WHOLE BLOOD ON THE ALINITY I ANALYZER.,ARCHITECT CYCLOSPORINE REAGENT KIT(ARCHITECT CYCLOSPORINE)-THE ARCHITECT CYCLOSPORINE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE IN HUMAN WHOLE BLOOD ON THE ARCHITECT ISYSTEM. THE ARCHITECT CYCLOSPORINE ASSAY IS USED AS AN AID IN THE MANAGEMENT OF HEART, LIVER AND KIDNEY TRANSPLANT PATIENTS RECEIVING CYCLOSPORINE THERAPY., ALINITY I SIROLIMUS REAGENT KIT(ALINITY I SIROLIMUS REAGENT KIT)-THE ALINITY I SIROLIMUS ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF SIROLIMUS IN HUMAN WHOLE BLOOD ON THE ALINITY I ANALYZER.,ARCHITECT TACROLIMUS CALIBRATORS(ARCHITECT TACROLIMUS CALIBRATORS)-THE ARCHITECT TACROLIMUS CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TACROLIMUS IN HUMAN WHOLE BLOOD.,ALINITY I SIROLIMUS CALIBRATORS(ALINITY I SIROLIMUS CALIBRATORS)-THE ALINITY I SIROLIMUS CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF SIROLIMUS IN HUMAN WHOLE BLOOD., ARCHITECT SIROLIMUS CALIBRATORS(ARCHITECT SIROLIMUS CALIBRATORS)-THE ARCHITECT SIROLIMUS CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF SIROLIMUS IN HUMAN WHOLE BLOOD.,ALINITY I TACROLIMUS CALIBRATORS(ALINITY I TACROLIMUS CALIBRATORS)-THE ALINITY I TACROLIMUS CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TACROLIMUS IN HUMAN WHOLE BLOOD.,ARCHITECT TACROLIMUS REAGENT KIT(ARCHITECT TACROLIMUS)-THE ARCHITECT TACROLIMUS ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF

		TACROLIMUS IN HUMAN WHOLE BLOOD ON THE ARCHITECT ISYSTEM. THE ARCHITECT TACROLIMUS ASSAY IS TO BE USED AS AN AID IN THE MANAGEMENT OF LIVER AND KIDNEY ALLOGRAFT PATIENTS RECEIVING TACROLIMUS THERAPY,ARCHITECT SIROLIMUS REAGENT KIT(ARCHITECT SIROLIMUS)-THE ARCHITECT SIROLIMUS ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF SIROLIMUS IN HUMAN WHOLE BLOOD ON THE ARCHITECT ISYSTEM. THE ARCHITECT SIROLIMUS ASSAY IS TO BE USED AS AN AID IN THE MANAGEMENT OF RENAL TRANSPLANT PATIENTS RECEIVING SIROLIMUS THERAPY.
501	IMP/IVD/2020/000070	1.License Holder Name: QIAGEN INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:THERASCREEN EGFR RGQ PCR KIT(THERASCREEN EGFR RGQ PCR KIT)-THERASCREEN EGFR RGQ PCR KIT IS AN IN VITRO DIAGNOSTIC TEST FOR THE DETECTION OF 29 SOMATIC MUTATIONS IN THE EGFR GENE. IT PROVIDES A QUALITATIVE ASSESSMENT OF THE MUTATION STATUS IN TUMOR SAMPLES FROM NON-SMALL CELL LUNG CANCER (NSCLC) PATIENTS. RESULTS ARE INTENDED TO AID THE CLINICIAN IN IDENTIFYING PATIENTS WITH NSCLC WHO MAY BENEFIT FROM TREATMENT WITH EGFR TYROSINE KINASE INHIBITORS. THE THERASCREEN EGFR RGQ PCR KIT WILL TEST DNA SAMPLES EXTRACTED FROM FORMALIN-FIXED, PARAFFIN EMBEDDED (FFPE) TUMOR TISSUE FROM NSCLC PATIENTS AND RUN ON A ROTOR-GENE Q MDX INSTRUMENT. IT IS TO BE USED BY TRAINED PERSONNEL IN A PROFESSIONAL LABORATORY ENVIRONMENT. THE THERASCREEN EGFR RGQ PCR KIT IS INTENDED FOR IN VITRO DIAGNOSTIC USE.,THERASCREEN KRAS RGQ PCR KIT(THERASCREEN KRAS RGQ PCR KIT)-THE THERASCREEN KRAS RGQ PCR KIT IS A REAL-TIME QUALITATIVE PCR ASSAY FOR THE DETECTION OF 7 SOMATIC MUTATIONS IN CODONS 12 AND 13 OF THE HUMAN KRAS ONCOGENE USING THE ROTOR-GENE Q MDX INSTRUMENT. THE KIT IS INTENDED FOR USE WITH DNA EXTRACTED FROM FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) SAMPLES OF COLORECTAL CANCER (CRC) OR NON-SMALL CELL LUNG CANCER (NSCLC) SAMPLES ACQUIRED BY RESECTION, CORE NEEDLE BIOPSY (CNB) OR FINE NEEDLE ASPIRATION (FNA). THE PATIENT'S MUTATION STATUS WILL BE CONSIDERED BY A CLINICIAN ALONGSIDE OTHER DISEASE FACTORS TO MAKE A THERAPY DECISION. NO TREATMENT DECISION FOR CANCER PATIENTS SHOULD BE BASED ON KRAS MUTATION STATUS ALONE. THE THERASCREEN KRAS RGQ PCR KIT IS NOT INTENDED TO DIAGNOSE CRC, NSCLC, OR ANY OTHER DISEASE.

502	IMP/IVD/2020/000071	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CRYPTOCOCCAL CAPSULAR POLYSACCHARIDE DETECTION K-SET (LATERAL FLOW ASSAY)(FUNGIXPERT)-THE PRODUCT IS USED FOR THE QUALITATIVE OR SEMI-QUANTITATIVE DETECTION OF THE CAPSULAR POLYSACCHARIDE ANTIGENS OF CRYPTOCOCCUS SPECIES IN SERUM AND CEREBRAL SPINAL FLUID (CSF), THE ASSAY IS A PRESCRIPTION-USE LABORATORY ASSAY WHICH CAN AID IN THE DIAGNOSIS OF CRYPTOCOCCOSIS.

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503	IMP/IVD/2020/000072	1.License Holder Name: MINDRAY MEDICAL INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CA15-3 CALIBRATORS (MINDRAY)-MINDRAY CA15-3 CALIBRATORS (CA15-3 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE CANCER ANTIGEN 15-3 (CA15-3) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,ALPHA-FETOPROTEIN (CLIA)(MINDRAY)-THE CL-SERIES AFP ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ALPHA-FETOPROTEIN (AFP) IN HUMAN SERUM OR PLASMA.,CA125 CALIBRATORS(MINDRAY)-MINDRAY CA125 CALIBRATORS (CA125 CAL) ARE INTENDED TO CALIBRATE QUANTITATIVE CANCER ANTIGEN 125 (CA125) ASSAY ON THE MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,UIBC CONTROL (MINDRAY)-UIBC CONTROL IS USED IN UNSATURATED IRON BINDING CAPACITY QUALITY CONTROL BY MONITORING PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,TUMOR MARKER MULTI CONTROL (H) (MINDRAY)-TUMOR MARKER MULTI CONTROL (H) IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY & PRECISION OF MINDRAY CL SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF TUMOR MARKER ANALYTES., MICROALBUMIN KIT (IMMUNOTURBIDIMETRIC ASSAY METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF MALB CONCENTRATION IN URINE ON PHOTOMETRIC SYSTEMS., AFP CALIBRATORS(MINDRAY)-MINDRAY AFP CALIBRATORS (AFP CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE ALPHA-FETOPROTEIN (AFP) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,RBP CONTROL (MINDRAY)-RBP CONTROL IS USED FOR RETINOL BINDING PROTEIN (RBP) QUALITY CONTROL BY MONITORING PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,TUMOR MARKER MULTI CONTROL (L)(MINDRAY)-TUMOR MARKER MULTI CONTROL (L) IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY & PRECISION OF MINDRAY CL SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF TUMOR MARKER ANALYTES., TOTAL PROTEIN IN URINE/CSF(TPUC) KIT (PYROGALLOL RED-MOLYBDATE METHOD)T(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TPUC CONCENTRATION IN URINE OR CEREBROSPINAL FLUID ON PHOTOMETRIC SYSTEMS.,SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 IGM (CLIA)

	(MINDRAY)-THE MINDRAY SARS-COV-2 IGM ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF SARS-COV-2 IGM ANTIBODIES IN HUMAN SERUM OR PLASMA FROM SUSPECTED COVID-19 PATIENTS.,MYOGLOBIN KIT (PARTICLE EHANCED LMMUNOTURBIDIMETRI ASSAY METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF MYO CONCENTRATION IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 IGG (CLIA)(MINDRAY)-THE MINDRAY SARS-COV-2 IGG ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF SARS-COV-2 IGG ANTIBODIES IN HUMAN SERUM OR PLASMA FROM SUSPECTED COVID-19 PATIENTS., IMMUNOGLOBUBIN E KIT (PARTICLE-ENHANCED IMMUNOTURBIDIMETRIC ASSAY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGE CONCENTRATION IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,CEA CALIBRATORS(MINDRAY)-MINDRAY CEA CALIBRATORS (CEA CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE CARCINOEMBRYONIC ANTIGEN (CEA) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE,ANTISTEPTOLYSIN "0" KIT KIT (LATEX IMMUNOTURBIDIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ASO CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS.,FREE PSA CALIBRATORS (MINDRAY)-MINDRAY FREE PSA CALIBRATORS (FPSA CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE FREE PROSTATE SPECIFIC ANTIGEN (FPSA) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,MULTIMMUN CONTROL(MINDRAY)-MULTIMMUN CONTROL IS USED FOR HUMAN FERRITIN (FER)/IMMUNOGLOBULIN E (IGE)/MYOGLOBIN (MYO) ANALYTE QUALITY CONTROL BY MONITORING PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,CA19-9 CALIBRATORS(MINDRAY)-MINDRAY CA19-9 CALIBRATORS (CA19-9 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE CARBOHYDRATE ANTIGEN 19-9 (CA19-9) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,TRANSFERRIN KIT (IMMUNOTURBIDIMETRIC ASSAY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TRF CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS.,TOTAL PSA CALIBRATORS(MINDRAY)-MINDRAY TOTAL PSA CALIBRATORS (T-PSA CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE TOTAL PROSTATE SPECIFIC ANTIGEN (T-PSA) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,MALB CONTROL(MINDRAY)-MALB CONTROL IS USED IN MICROALBUMIN QUALITY CONTROL BY

	MONITORING PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY.,CALCITONIN CALIBRATORS (MINDRAY)-MINDRAY CALCITONIN CALIBRATORS (CT CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE CALCITONIN ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,CA72-4 CALIBRATORS(MINDRAY)-MINDRAY CA72-4 CALIBRATORS (CA72-4 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE CANCER ANTIGEN 72-4 (CA72-4) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,TUMOR MARKER CONTROL II(H)(MINDRAY)-MINDRAY TUMOR MARKER MULTI CONTROL II IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF TUMOUR MARKER ANALYTES.,UNSATURATED IRON BINDING CAPACITY KIT (COLORIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF UIBC CONCENTRATION IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,TROPONIN I CALIBRATORS(MINDRAY)-MINDRAY TROPONIN I CALIBRATORS (TNI CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE TROPONIN I (TNI) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,DETERGENT C(MINDRAY)-DETERGENT C APPLIES TO MINDRAY ANALYZERS. ITIS USED TO CLEAN THE PROBES OF ANALYZERS REGULARLY.,BNP CALIBRATORS(MINDRAY)-MINDRAY BNP CALIBRATORS (BNP CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE BTYPE NATRIURETIC PEPTIDE (BNP) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,G6PD CONTROL(MINDRAY)-G6PD CONTROL IS USED FOR GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD) QUALITY CONTROL BY MONITORING PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY.,NSE CONTROL (H)(MINDRAY)-MINDRAY NSE CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF NSE ANALYTE.,CARBON DIOXIDE (CO2) KIT (ENZYMATIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CO2 CONCENTRATION IN SERUM AND HEPARIN PLASMA ON PHOTOMETRIC SYSTEMS.,NSE CONTROL (L)(MINDRAY)-MINDRAY NSE CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF NSE ANALYTE.,M-5 LEO (II) LYSE

	(MINDRAY)-M-5LEO(II) LYSE COOPERATES WITH THE M-5LEO(I) LYSE TO 4-DIFFERENTIATE WBCS.,TUMOR MARKER CONTROL II(L) (MINDRAY)-MINDRAY TUMOR MARKER MULTI CONTROL II IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TESTABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF TUMOUR MARKER ANALYTES.,RETINOL BINDING PROTEIN KIT (PARTICLE - ENHANCED IMMUNOTURBIDIMETRIC ASSAY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF RBP CONCENTRATION IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS., TROPONIN I (CLIA)(MINDRAY)-THE CL-SERIES TNI ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TNI IN HUMAN SERUM OR PLASMA.,M-5 LEO (I) LYSE(MINDRAY)-M-5LEO(I) LYSE BREAKS DOWN RED BLOOD CELL MEMBRANE AND COOPERATES WITH THE M-5LEO(II) LYSE TO 4-DIFFERENTIATE WBCS.,B-TYPE NATRIURETIC PEPTIDE(CLIA) (MINDRAY)-THE CL-SERIES BNP ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF B-TYPE NATRIURETIC PEPTIDE (BNP) IN HUMAN EDTA PLASMA., ADENOSINE DEAMINASE KITENZYMATIC COLORIMETRIC METHOD (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ADA ACTIVITY IN SERUM ON PHOTOMETRIC SYSTEMS.,ANTI-MULLERIAN HORMONE (CLIA)(MINDRAY)-THE CL-SERIES AMH ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF AMH IN HUMAN SERUM OR PLASMA.,CYSTATIN C KIT (LATEX IMMUNOTURBIDIMETRIC METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CYSC CONCENTRATION IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,CYSTATIN C CONTROL(MINDRAY)-CYSTATIN C CONTROL IS USED IN CYSTATIN C (CYSC) QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,C-REACTIVE PROTEIN CALIBRATOR(MINDRAY)-C-REACTIVE PROTEIN CALIBRATOR IS USED FOR CALIBRATION OF QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) ANALYTE ON MINDRAY BS MEASUREMENT SYSTEM.,2-MG CONTROL(MINDRAY)-2-MG CONTROL IS USED IN 2-MICROGLOBULIN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,HCY CONTROL(MINDRAY)-HCY CONTROL IS USED FOR HOMOCYSTEINE (HCY) QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,2-MICROGLOBULIN CALIBRATOR (FOR SERUM)

	(MINDRAY)-2-MICROGLOBULIN CALIBRATOR IS USED FOR CALIBRATION OF QUANTITATIVE DETERMINATION OF 2-MICROGLOBULIN (2-MG) ANALYTE IN THE SERUM ON MINDRAY BS MEASUREMENT SYSTEM.,FRUCTOSAMINE (FUN) KIT (COLORIMETRIC ASSAY)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF FRUCTOSAMINE CONCENTRATION IN SERUM, HEPARIN PLASMA ON PHOTOMETRIC SYSTEMS.,ASO/CRP/RF TRIPLE CONTROL(MINDRAY)-ASO/CRP/RF TRIPLE CONTROL IS USED IN RHEUMATISM ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,-AMYLASE KIT (IFCC METHOD)(MINDRAY)--AMY REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF AMYLASE (1, 4-D-GLUCANOHYDROLASES) ACTIVITY IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS.,CLINCHEM MULTI CONTROL(LEVEL 2) (MINDRAY)-CLINCHEM MULTI CONTROL (LEVEL 2) IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,TOTAL PROTEIN KIT (BIURET METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TP CONCENTRATION IN SERUM AND PLASMA ON MINDRAY BS SERIES SYSTEMS.,FULL RANGE C-REACTIVE PROTEIN KIT (LATEX IMMUNOTURBIDIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CRP CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS.,GLUCOSE-6-PHOSPHATE DEHYDROGENASE KIT (UV ENZYMATIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF G6PD IN HUMAN ERYTHROCYTES ON PHOTOMETRIC SYSTEMS.,CYSTATIN C CALIBRATOR(MINDRAY)-CYSTATIN C CALIBRATOR IS USED FOR CALIBRATION OF QUANTITATIVE DETERMINATION OF CYSTATIN C (CYSC) ANALYTE ON MINDRAY BS MEASUREMENT SYSTEM., RHEUMATOID FACTOR KIT (IMMUNOTURBIDIMETRIC METHOD (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF RF CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS. , FREE PROSTATE SPECIFIC ANTIGEN (CLIA)(MINDRAY)-THE CL-SERIES FPSA ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (FREE PSA, FPSA) IN HUMAN SERUM.THE CL-SERIES FPSA ASSAY CAN BE USED WITH THE T-PSA AS AN AID IN DISTINGUISHING PROSTATE CANCER FROM BENIGN PROSTATIC CONDITIONS. PROSTATE BIOPSY IS REQUIRED FOR THE DIAGNOSIS OF PROSTATE CANCER.,-HYDROXYBUTYRATE KIT (ENZYMATIC COLORIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE

	DETERMINATION OF -HB CONCENTRATION IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,CYFRA 21-1 (CLIA)(MINDRAY)-HE CL-SERIES CYFRA 21-1 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF CYTOKERATIN 19 FRAGMENT (CYFRA 21-1) IN HUMAN SERUM OR PLASMA,ANGIOTENSIN CONVERTING ENZYME KIT (ENZYMATIC COLORIMETRIC ASSAY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ACE IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS.,CANCER ANTIGEN 72-4 (CLIA)(MINDRAY)-THE CL-SERIES CA72-4 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 72-4 (CA72-4) IN HUMAN SERUM OR PLASMA., CANCER ANTIGEN 125 (CLIA)(MINDRAY)-THE CL-SERIES CA125 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 125 (CA125) IN HUMAN SERUM OR PLASMA.,ANTI-TP CALIBRATORS(MINDRAY)-MINDRAY ANTI-TP CALIBRATORS (ANTI-TP CAL) ARE INTENDED TO CALIBRATE THE QUALITATIVE ANTIBODY TO TREPONEMA PALLIDUM (ANTI-TP) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,CANCER ANTIGEN 15-3 (CLIA)(MINDRAY)-THE CL-SERIES CA15-3 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 15-3 (CA15-3) IN HUMAN SERUM OR PLASMA.,D-DIMER KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF D-DIMER CONCENTRATION IN HUMAN CITRATED PLASMA ON PHOTOMETRIC SYSTEMS.,TPUC CONTROL(MINDRAY)-TPUC CONTROL IS USED FOR TOTAL PROTEIN IN URINE/CSF (TPUC) QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,CLINCHEM MULTI CONTROL(LEVEL 1) (MINDRAY)-CLINCHEM MULTI CONTROL (LEVEL 1) IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,NSE CALIBRATORS(MINDRAY)-MINDRAY NSE CALIBRATORS (NSE CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE NEURON-SPECIFIC ENOLASE (NSE) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,CARBOHYDRATE ANTIGEN 19-9 (CLIA)(MINDRAY)-THE CL-SERIES CA19-9 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF CARBOHYDRATE ANTIGEN 19-9 (CA19-9) IN HUMAN SERUM OR PLASMA.,ANTI- TP POSITIVE CONTROL(MINDRAY)-MINDRAY ANTI-TP CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND

	PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUALITATIVE MEASUREMENT OF ANTI-TP ANALYTE.,NEURON-SPECIFIC ENOLASE (CLIA)(MINDRAY)-THE CL-SERIES NSE ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF NEURON-SPECIFIC ENOLASE (NSE) IN HUMAN SERUM,2-MICROGLOBULIN CALIBRATOR (FOR URINE)(MINDRAY)-2-MICROGLOBULIN CALIBRATOR IS USED FOR CALIBRATION OF QUANTITATIVE DETERMINATION OF 2-MICROGLOBULIN (2-MG) ANALYTE IN THE URINE ON MINDRAY BS MEASUREMENT SYSTEM.,2-MICROGLOBULIN KIT (LATEX IMMUNOTURBIDIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF 2-MG CONCENTRATION IN SERUM OR URINE ON PHOTOMETRIC SYSTEMS.,LACTATE DEHYDROGENASE KIT (IFCC METHOD)(MINDRAY)-LDH REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,D-DIMER CONTROL(MINDRAY)-D-DIMER CONTROL IS USED FOR D-DIMER QUALITY CONTROL BY MONITORING PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,FERRITIN KIT (PARTICLE-ENHANCED IMMUNOTURBIDIMETRIC ASSAY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF FER CONCENTRATION IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS., CHOLINESTERASE CHEKIT (DGKC METHOD)(MINDRAY)-CHE REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CHE ACTIVITY IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,TOTAL PROSTATE SPECIFIC ANTIGEN (CLIA)(MINDRAY)-THE CL-SERIES T-PSA ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROSTATE SPECIFIC ANTIGEN (TOTAL PSA, T-PSA) IN HUMAN SERUM OR PLASMA. THE CL-SERIES T-PSA ASSAY CAN BE USED AS AN ADJUNCTIVE TEST TO AID IN THE MANAGEMENT OF PROSTATE CANCER PATIENTS. IT CAN ALSO BE USED AS AN AID IN THE DETECTION OF PROSTATE CANCER WHEN USED IN CONJUNCTION WITH DIGITAL RECTAL EXAM (DRE). PROSTATIC BIOPSY IS REQUIRED FOR DIAGNOSIS OF CANCER., HOMOCYSTEINE (HCY) KIT (ENZYMATIC CYCLING METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF HCY CONCENTRATION IN SERUM OR HEPARIN PLASMA ON PHOTOMETRIC SYSTEMS.,TRF CONTROL(MINDRAY)-TRF CONTROL IS USED IN TRANSFERRRIN PROTEINS QUALITY CONTROL BY MONITORING PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY.,CARCINOEMBRYONIC ANTIGEN (CLIA)(MINDRAY)-THE CL-SERIES CEA ASSAY IS A

		CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) IN HUMAN SERUM OR PLASMA.,-HB CONTROL(MINDRAY)--HB CONTROL IS USED FOR -HYDROXYBUTYRATE (-HB) QUALITY CONTROL BY MONITORING PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,ANTI- TP NEGATIVE CONTROL(MINDRAY)-MINDRAY ANTI-TP CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUALITATIVE MEASUREMENT OF ANTI-TP ANALYTE.,CALCIUM KIT (ARSENAZO METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CA CONCENTRATION IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS.,PHOSPHORUS KIT (PHOSPHOMOLYBDATE METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF P CONCENTRATION IN SERUM, PLASMA OR URINE ON MINDRAY BS SERIES SYSTEMS.,CYFRA 21-1 CALIBRATORS(MINDRAY)-MINDRAY CYFRA 21-1 CALIBRATORS (CYFRA 21-1 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE HUMAN CYTOKERATIN 19 FRAGMENTS (CYFRA 21-1) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,ACE CONTROL(MINDRAY)-ACE CONTROL IS USED FOR ANGIOTENSIN CONVERTING ENZYME (ACE) QUALITY CONTROL BY MONITORING PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.
504	IMP/IVD/2020/000073	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DXH 500 SERIES CONTROL(DXH 500 SERIES CONTROL)-DXH 500 SERIES CONTROL IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS.,DXH 500 SERIES CALIBRATOR(DXH 500 SERIES CALIBRATOR)-DXH 500 SERIES CALIBRATOR IS DESIGNED FOR THE DETERMINATION OF CALIBRATION FACTORS FOR THE DXH 500 SERIES SYSTEMS IN CONJUNCTION WITH SPECIFIC DXH 500 SERIES REAGENTS.
505	IMP/IVD/2020/000074	1.License Holder Name: SHREYA CORPORATION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EBSENSOR GLUCOSE TEST STRIP-EBSENSOR BLOOD GLUCOSE MONITORING TEST STRIP

506	IMP/IVD/2020/000074	1.License Holder Name: SHREYA CORPORATION LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLUCOMETER DEVICE E-BG(EBSENSOR)-BLOOD GLUCOSE MONITORING SYSTEM FOR SELF TESTING
507	IMP/IVD/2020/000076	1.License Holder Name: M/S ONE ABOVE HEALTHCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIP(GLYCOCHEK)-WORK WITH BLOOD GLUCOSE METER TO MEASURE THE CONCENTRATION OF GLUCOSE IN CAPILLARY WHOLE BLOOD

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

508	IMP/IVD/2020/000077	1.License Holder Name: M/S PAREKH INTEGRATED SERVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTIPLE THERAPEUTIC DRUGS/DRUGS OF ABUSE IVD, CONTROL(QUIDEL TRIAGE® TOX DRUG SCREEN, 94600 CONTROL 1)-THE QUIDEL TRIAGE TOX DRUG SCREEN, 94600 CONTROLS ARE TO BE USED WITH THE QUIDEL TRIAGE TOX DRUG SCREEN, 94600 TESTS AND QUIDEL TRIAGE METERPRO TO ASSIST THE LABORATORY IN MONITORING TEST PERFORMANCE.,MULTIPLE CARDIAC MARKER IVD, CONTROL(QUIDEL TRIAGE® TOTAL 5 CONTROL 1)-THE QUIDEL TRIAGE TOTAL 5 CONTROLS ARE ASSAYED MATERIALS TO BE USED WITH THE QUIDEL TRIAGE CARDIAC PANEL, QUIDEL TRIAGE PROFILER SOB PANEL, QUIDEL TRIAGE BNP TEST, QUIDEL TRIAGE DDIMER TEST, AND QUIDEL TRIAGE METERS TO ASSIST THE LABORATORY IN MONITORING TEST PERFORMANCE.,TROPONIN I IVD, CONTROL (QUIDEL TRIAGETRUE™ HIGH SENSITIVITY TROPONIN I CONTROL 2)-THE QUIDEL TRIAGETRUE HIGH SENSITIVITY TROPONIN I CONTROLS ARE ASSAYED MATERIALS TO BE USED WITH THE QUIDEL TRIAGETRUE HIGH SENSITIVITY TROPONIN I TEST, AND QUIDEL TRIAGE® METERPRO TO ASSIST THE END USER IN MONITORING TEST PERFORMANCE,MULTIPLE THERAPEUTIC DRUGS/DRUGS OF ABUSE IVD, CONTROL(QUIDEL TRIAGE® TOX DRUG SCREEN CONTROL 1)-THE QUIDEL TRIAGE TOX DRUG SCREEN CONTROLS ARE TO BE USED WITH THE QUIDEL TRIAGE TOX DRUG SCREEN TESTS AND QUIDEL TRIAGE METERS TO ASSIST THE END USER IN MONITORING PRODUCT PERFORMANCE.,MULTIPLE THERAPEUTIC DRUGS/DRUGS OF ABUSE IVD, CONTROL(QUIDEL TRIAGE® TOX DRUG SCREEN, 94600 CONTROL 2)-THE QUIDEL TRIAGE TOX DRUG SCREEN, 94600 CONTROLS ARE TO BE USED WITH THE QUIDEL TRIAGE TOX DRUG SCREEN, 94600 TESTS AND QUIDEL TRIAGE METERPRO TO ASSIST THE LABORATORY IN MONITORING TEST PERFORMANCE.,MULTIPLE CARDIAC MARKER IVD, CONTROL(QUIDEL TRIAGE® TOTAL 3 CONTROL 1)-THE QUIDEL TRIAGE TOTAL 3 CONTROLS ARE ASSAYED MATERIALS TO BE USED WITH THE QUIDEL TRIAGE TROPONIN I TEST, QUIDEL TRIAGE BNP TEST, QUIDEL TRIAGE CARDIO2 PANEL AND QUIDEL TRIAGE CARDIO3 PANEL DEVICES AND THE QUIDEL TRIAGE METER TO ASSIST THE END USER IN MONITORING PRODUCT PERFORMANCE.,MULTIPLE DRUGS OF ABUSE IVD, KIT, FLUORESCENT IMMUNOASSAY(QUIDEL TRIAGE® TOX DRUG SCREEN, 94600)-THE QUIDEL TRIAGE TOX DRUG SCREEN, 94600 IS A FLUORESCENCE IMMUNOASSAY TO BE USED WITH THE QUIDEL TRIAGE METERPRO FOR THE QUALITATIVE DETERMINATION OF THE PRESENCE OF DRUGS AND/OR METABOLITES IN HUMAN URINE OF UP TO 9 DRUG

	ASSAYS AT OR ABOVE THE THRESHOLD CONCENTRATIONS. THIS TEST PROVIDES ONLY A PRELIMINARY RESULT. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT MUST BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY IN EVALUATING A PRELIMINARY POSITIVE RESULT. A MORE SPECIFIC ALTERNATE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY / MASS SPECTROSCOPY (GC/MS), LIQUID CHROMATOGRAPHY / MASS SPECTROSCOPY / MASS SPECTROSCOPY (LC-MS/MS) AND HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ARE COMMON CONFIRMATORY METHODS.,MULTIPLE CARDIAC MARKER IVD, CONTROL(QUIDEL TRIAGE® TOTAL 5 CONTROL 2)-THE QUIDEL TRIAGE TOTAL 5 CONTROLS ARE ASSAYED MATERIALS TO BE USED WITH THE QUIDEL TRIAGE CARDIAC PANEL, QUIDEL TRIAGE PROFILER SOB PANEL, QUIDEL TRIAGE BNP TEST, QUIDEL TRIAGE D DIMER TEST, AND QUIDEL TRIAGE METERS TO ASSIST THE LABORATORY IN MONITORING TEST PERFORMANCE.,TROPONIN I IVD, KIT, FLUORESCENT IMMUNOASSAY(QUIDEL TRIAGETRUE™ HIGH SENSITIVITY TROPONIN I TEST)-THE QUIDEL TRIAGETRUE HIGH SENSITIVITY TROPONIN I TEST IS A FLUORESCENCE IMMUNOASSAY TO BE USED WITH THE TRIAGE® METERPRO FOR THE QUANTITATIVE DETERMINATION OF TROPONIN I IN EDTA ANTICOAGULATED WHOLE BLOOD AND PLASMA SPECIMENS. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION. (MI),MULTIPLE THERAPEUTIC DRUGS/DRUGS OF ABUSE IVD, CONTROL(QUIDEL TRIAGE® TOX DRUG SCREEN CONTROL 2)-THE QUIDEL TRIAGE TOX DRUG SCREEN CONTROLS ARE TO BE USED WITH THE QUIDEL TRIAGE TOX DRUG SCREEN TESTS AND QUIDEL TRIAGE METERS TO ASSIST THE END USER IN MONITORING PRODUCT PERFORMANCE.,TROPONIN I IVD, CONTROL(QUIDEL TRIAGETRUE™ HIGH SENSITIVITY TROPONIN I CONTROL 1)-THE QUIDEL TRIAGETRUE HIGH SENSITIVITY TROPONIN I CONTROLS ARE ASSAYED MATERIALS TO BE USED WITH THE QUIDEL TRIAGETRUE HIGH SENSITIVITY TROPONIN I TEST, AND QUIDEL TRIAGE® METERPRO TO ASSIST THE END USER IN MONITORING TEST PERFORMANCE,B-TYPE NATRIURETIC PROTEIN/N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE IVD, CALIBRATOR(QUIDEL TRIAGE® BNP CALIBRATORS)-THE QUIDEL TRIAGE BNP CALIBRATORS ARE INTENDED TO CALIBRATE THE QUIDEL TRIAGE BNP TEST FOR THE QUANTITATIVE DETERMINATION OF BNP LEVELS IN HUMAN EDTA PLASMA USING THE BECKMAN COULTER ACCESS FAMILY OF IMMUNOASSAY SYSTEMS.,B-TYPE NATRIURETIC PROTEIN/N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE IVD, CONTROL(QUIDEL TRIAGE® BNP CONTROL 1)-THE QUIDEL TRIAGE BNP CONTROLS ARE ASSAYED MATERIALS TO BE

	USED WITH THE QUIDEL TRIAGE BNP TEST AND QUIDEL TRIAGE METER TO ASSIST THE END USER IN MONITORING PRODUCT PERFORMANCE.,MULTIPLE CARDIAC MARKER IVD, CONTROL(QUIDEL TRIAGE® TOTAL 5 CALIBRATION VERIFICATION)-THE QUIDEL TRIAGE TOTAL 5 CALIBRATION VERIFICATION MATERIALS ARE TO BE USED WITH THE QUIDEL TRIAGE CARDIAC PANEL, QUIDEL TRIAGE PROFILER SOB PANEL, QUIDEL TRIAGE BNP TEST, QUIDEL TRIAGE D-DIMER TEST AND QUIDEL TRIAGE METERS TO VERIFY THE CALIBRATION OF THE TEST DEVICES THROUGHOUT THE MEASURABLE RANGE.,MULTIPLE CARDIAC MARKER IVD, KIT, FLUORESCENT IMMUNOASSAY(QUIDEL TRIAGE® PROFILER SOB PANEL)-THE QUIDEL TRIAGE PROFILER SOB (SHORTNESS OF BREATH) PANEL IS A FLUORESCENCE IMMUNOASSAY TO BE USED WITH THE QUIDEL TRIAGE METERS FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE MB, MYOGLOBIN, TROPONIN I, BTYPE NATRIURETIC PEPTIDE, AND CROSSLINKED FIBRIN DEGRADATION PRODUCTS CONTAINING DDIMER IN EDTA ANTICOAGULATED WHOLE BLOOD AND PLASMA SPECIMENS. THE TEST IS USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (INJURY), AN AID IN THE DIAGNOSIS AND ASSESSMENT OF SEVERITY OF HEART FAILURE, AN AID IN THE RISK STRATIFICATION OF PATIENTS WITH HEART FAILURE, AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF HAVING DISSEMINATED INTRAVASCULAR COAGULATION OR THROMBOEMBOLIC EVENTS INCLUDING PULMONARY EMBOLISM AND AN AID IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES.,B-TYPE NATRIURETIC PROTEIN/N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE IVD, KIT, FLUORESCENT IMMUNOASSAY(QUIDEL TRIAGE® NT-PROBNP TEST)-THE QUIDEL TRIAGE NT-PROBNP TEST IS A FLUORESCENCE IMMUNOASSAY TO BE USED WITH THE QUIDEL TRIAGE METER FOR THE QUANTITATIVE DETERMINATION OF N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN EDTA ANTICOAGULATED WHOLE BLOOD AND PLASMA SPECIMENS. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF INDIVIDUALS SUSPECTED OF HAVING CONGESTIVE HEART FAILURE (ALSO REFERRED TO AS HEART FAILURE). THE TEST IS ALSO TO BE USED AS AN AID FOR THE RISK STRATIFICATION OF PATIENTS WITH HEART FAILURE AND THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES (ACS). THE TEST MAY ALSO SERVE AS AN AID IN THE ASSESSMENT OF INCREASED RISK FOR CARDIOVASCULAR EVENTS AND MORTALITY IN PATIENTS AT RISK FOR HEART FAILURE WHO HAVE STABLE CORONARY ARTERY DISEASE.,B-TYPE NATRIURETIC PROTEIN/N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE IVD, KIT,

	FLUORESCENT IMMUNOASSAY(QUIDEL TRIAGE® BNP REAGENTS)-THE QUIDEL TRIAGE BNP TEST IS INTENDED FOR USE WITH THE BECKMAN COULTER ACCESS FAMILY OF IMMUNOASSAY SYSTEMS FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF B-TYPE NATRIURETIC PEPTIDE (BNP) IN PLASMA SPECIMENS USING EDTA AS THE ANTICOAGULANT. THE TEST IS INTENDED TO BE USED FOR THE FOLLOWING INDICATIONS: -AS AN AID IN THE DIAGNOSIS OF CONGESTIVE HEART FAILURE (ALSO REFERRED TO AS HEART FAILURE) -AS AN AID IN THE ASSESSMENT OF SEVERITY OF CONGESTIVE HEART FAILURE -FOR THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES -FOR THE RISK STRATIFICATION OF PATIENTS WITH HEART FAILURE,MULTIPLE DRUGS OF ABUSE IVD, KIT, FLUORESCENT IMMUNOASSAY(QUIDEL TRIAGE® TOX DRUG SCREEN)-THE QUIDEL TRIAGE TOX DRUG SCREEN IS A FLUORESCENCE IMMUNOASSAY TO BE USED WITH THE QUIDEL TRIAGE METERS FOR THE QUALITATIVE DETERMINATION OF THE PRESENCE OF DRUG AND/OR THE MAJOR METABOLITES ABOVE THE THRESHOLD CONCENTRATIONS OF UP TO 10 DISTINCT DRUG CLASSES, INCLUDING ASSAYS FOR ACETAMINOPHEN/PARACETAMOL, AMPHETAMINES, METHAMPHETAMINES, BARBITURATES, BENZODIAZEPINES, COCAINE, METHADONE, OPIATES, PHENCYCLIDINE, THS AND TRICYCLIC ANTIDEPRESSANTS IN URINE. THE ACETAMINOPHEN/PARACETAMOL ASSAY WILL YIELD POSITIVE RESULTS WHEN ACETAMINOPHEN/PARACETAMOL IS INGESTED AT OR ABOVE THERAPEUTIC DOSES. THIS TEST PROVIDES ONLY A PRELIMINARY RESULT. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT MUST BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY IN EVALUATING A PRELIMINARY POSITIVE RESULT. IN ORDER TO OBTAIN A CONFIRMED ANALYTICAL RESULT, A MORE SPECIFIC ALTERNATE CHEMICAL METHOD IS NEEDED. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS), LIQUID CHROMATOGRAPHY/ MASS SPECTROMETRY/ MASS SPECTROMETRY (LC/MS/MS) AND HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) ARE COMMON CONFIRMATORY METHODS.A QUANTITATIVE SERUM ACETAMINOPHEN/PARACETAMOL MEASUREMENT IS THE COMMON CONFIRMATORY METHOD FOR PRELIMINARY POSITIVE ACETAMINOPHEN/PARACETAMOL RESULTS.,B-TYPE NATRIURETIC PROTEIN/N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE IVD, KIT, FLUORESCENT IMMUNOASSAY(QUIDEL TRIAGE® BNP TEST)-THE QUIDEL TRIAGE BNP TEST IS A RAPID, POINT OF CARE FLUORESCENCE IMMUNOASSAY TO BE USED WITH THE QUIDEL TRIAGE METERS FOR THE QUANTITATIVE MEASUREMENT OF B-TYPE

	NATRIURETIC PEPTIDE (BNP) IN EDTA ANTICOAGULATED WHOLE BLOOD OR PLASMA SPECIMENS. THE TEST IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS AND ASSESSMENT OF SEVERITY OF CONGESTIVE HEART FAILURE (ALSO REFERRED TO AS HEART FAILURE). THE TEST ALSO IS USED FOR THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES AND FOR THE RISK STRATIFICATION OF PATIENTS WITH HEART FAILURE.,B-TYPE NATRIURETIC PROTEIN/N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE IVD, CONTROL(QUIDEL TRIAGE® BNP QC CONTROLS)-THE QUIDEL TRIAGE BNP QC CONTROLS ARE INTENDED FOR MONITORING THE PERFORMANCE OF THE QUIDEL TRIAGE BNP TEST USING THE BECKMAN COULTER ACCESS FAMILY OF IMMUNOASSAY SYSTEMS.,B-TYPE NATRIURETIC PROTEIN/N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE IVD, CONTROL(QUIDEL TRIAGE® NT-PROBNP CONTROL 2)-THE QUIDEL TRIAGE NT-PROBNP CONTROLS ARE ASSAYED MATERIALS TO BE USED WITH THE QUIDEL TRIAGE NT-PROBNP TEST AND THE QUIDEL TRIAGE METER TO ASSIST THE END USER IN MONITORING PRODUCT PERFORMANCE.,MULTIPLE CARDIAC MARKER IVD, KIT, FLUORESCENT IMMUNOASSAY(QUIDEL TRIAGE® CARDIAC PANEL)-THE QUIDEL TRIAGE CARDIAC PANEL IS A FLUORESCENCE IMMUNOASSAY TO BE USED WITH THE QUIDEL TRIAGE METERS FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE MB (CK-MB), MYOGLOBIN AND TROPONIN I IN EDTA ANTICOAGULATED WHOLE BLOOD OR PLASMA SPECIMENS. THE TEST IS USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (INJURY).,MULTIPLE CARDIAC MARKER IVD, KIT, FLUORESCENT IMMUNOASSAY(QUIDEL TRIAGE® CARDIO3 PANEL)-THE QUIDEL TRIAGE CARDIO3 PANEL IS A FLUORESCENCE IMMUNOASSAY TO BE USED WITH THE QUIDEL TRIAGE METERS FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE MB, TROPONIN I, AND B-TYPE NATRIURETIC PEPTIDE IN EDTA ANTICOAGULATED WHOLE BLOOD AND PLASMA SPECIMENS. THE QUIDEL TRIAGE CARDIO3 PANEL IS TO BE USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (INJURY), AN AID IN THE DIAGNOSIS AND ASSESSMENT OF SEVERITY OF CONGESTIVE HEART FAILURE (ALSO REFERRED TO AS HEART FAILURE), AN AID IN THE RISK STRATIFICATION OF PATIENTS WITH HEART FAILURE, AND AN AID IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES.,B-TYPE NATRIURETIC PROTEIN/N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE IVD, CONTROL (QUIDEL TRIAGE® BNP CALIBRATION VERIFICATION)-THE QUIDEL TRIAGE BNP CALIBRATION VERIFICATION MATERIALS ARE TO BE USED WITH THE QUIDEL TRIAGE BNP TEST AND QUIDEL TRIAGE METER TO VERIFY THE CALIBRATION OF THE QUIDEL TRIAGE BNP

	TEST THROUGHOUT THE MEASURABLE RANGE.,MULTIPLE CARDIAC MARKER IVD, CONTROL(QUIDEL TRIAGE® TOTAL 3 CONTROL 2)-THE QUIDEL TRIAGE TOTAL 3 CONTROLS ARE ASSAYED MATERIALS TO BE USED WITH THE QUIDEL TRIAGE TROPONIN I TEST, QUIDEL TRIAGE BNP TEST, QUIDEL TRIAGE CARDIO2 PANEL AND QUIDEL TRIAGE CARDIO3 PANEL DEVICES AND THE QUIDEL TRIAGE METER TO ASSIST THE END USER IN MONITORING PRODUCT PERFORMANCE.,TROPONIN I IVD, KIT, FLUORESCENT IMMUNOASSAY(QUIDEL TRIAGE® TROPONIN I TEST)-THE QUIDEL TRIAGE TROPONIN I TEST IS A FLUORESCENCE IMMUNOASSAY TO BE USED WITH THE QUIDEL TRIAGE METERS FOR THE QUANTITATIVE DETERMINATION OF TROPONIN I IN EDTA ANTICOAGULATED WHOLE BLOOD AND PLASMA SPECIMENS. THE TEST IS USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (INJURY).,MULTIPLE CARDIAC MARKER IVD, KIT, FLUORESCENT IMMUNOASSAY(QUIDEL TRIAGE® CARDIO2 PANEL)-THE QUIDEL TRIAGE CARDIO2 PANEL IS A FLUORESCENCE IMMUNOASSAY TO BE USED WITH THE QUIDEL TRIAGE METERS FOR THE RAPID QUANTITATIVE DETERMINATION OF TROPONIN I AND B-TYPE NATRIURETIC PEPTIDE IN EDTA ANTICOAGULATED WHOLE BLOOD AND PLASMA SPECIMENS. THE QUIDEL TRIAGE CARDIO2 PANEL IS TO BE USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (INJURY), AN AID IN THE DIAGNOSIS AND ASSESSMENT OF SEVERITY OF CONGESTIVE HEART FAILURE (ALSO REFERRED TO AS HEART FAILURE), AN AID IN THE RISK STRATIFICATION OF PATIENTS WITH HEART FAILURE, AND AN AID IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROMES.,B-TYPE NATRIURETIC PROTEIN/N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE IVD, CONTROL(QUIDEL TRIAGE® NT-PROBNP CONTROL 1)-THE QUIDEL TRIAGE NT-PROBNP CONTROLS ARE ASSAYED MATERIALS TO BE USED WITH THE QUIDEL TRIAGE NT-PROBNP TEST AND THE QUIDEL TRIAGE METER TO ASSIST THE END USER IN MONITORING PRODUCT PERFORMANCE.,B-TYPE NATRIURETIC PROTEIN/N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE IVD, CONTROL(QUIDEL TRIAGE® BNP CONTROL 2)-THE QUIDEL TRIAGE BNP CONTROLS ARE ASSAYED MATERIALS TO BE USED WITH THE QUIDEL TRIAGE BNP TEST AND QUIDEL TRIAGE METER TO ASSIST THE END USER IN MONITORING PRODUCT PERFORMANCE.,D-DIMER IVD. REAGENT(QUIDEL TRIAGE® D-DIMER TEST)-THE QUIDEL TRIAGE D-DIMER TEST IS A FLUORESCENCE IMMUNOASSAY TO BE USED WITH THE QUIDEL TRIAGE METERS FOR THE QUANTITATIVE DETERMINATION OF CROSS-LINKED FIBRIN DEGRADATION PRODUCTS CONTAINING D-DIMER IN EDTA ANTICOAGULATED WHOLE BLOOD AND PLASMA SPECIMENS. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF

	PATIENTS SUSPECTED OF HAVING DISSEMINATED INTRAVASCULAR COAGULATION OR THROMBOEMBOLIC EVENTS INCLUDING PULMONARY EMBOLISM.

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509	IMP/IVD/2020/000078	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: INTACT PTH ELISA-COLORIMETRIC IMMUNOENZYMATIC METHOD FOR QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (PTH) CONCENTRATION IN HUMAN SERUM AND PLASMA. , ANTI CCP-FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES DIRECTED AGAINST CYCLIC CITRULLINATED PEPTIDES, PRESENT IN HUMAN SERUM OR PLASMA. , FREE TESTOSTERONE ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. , FSH ELISA-DIRECT SOLID PHASE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE-STIMULATING HORMON (FSH) IN HUMAN SERUM OR PLASMA. , ANDROSTENEDIONE SALIVA ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF ANDROSTENEDIONE CONCENTRATION IN SALIVA. , ANTI DEAMIDATED GLIADIN PEPTIDE (DGP) IGA-SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS ANTIBODIES DIRECTED AGAINST DEAMIDATED GLIADIN PEPTIDES (DGP) IN HUMAN SERUM OR PLASMA. , TESTOSTERONE ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. , T4 ELISA-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF THYROXINE (T4) CONCENTRATION IN HUMAN SERUM AND PLASMA. , CIC C1Q ELISA-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF CIC C1Q CONCENTRATION IN HUMAN SERUM OR PLASMA. , LH ELISA-SOLID PHASE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THE LUTEINIZING HORMONE (LH) CONCENTRATION IN HUMAN SERUM OR PLASMA. , IGF-1-IMMUNOENZYMATIC COLORIMETRIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN INSULIN-LIKE GROWTH FACTOR 1 (IGF-1) CONCENTRATION IN HUMAN SERUM. , 25OH VITAMIN D-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF 25OH VITAMIN D CONCENTRATION IN HUMAN SERUM OR PLASMA. , ANTI MPO (P-ANCA)-INDIRECT SOLID PHASE ENZYME IMMUNOASSAY (ELISA) FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST MYELOPEROXIDASE (MPO) IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF CERTAIN AUTOIMMUNE VASCULITITES SUCH

	AS WEGENER´S GRANULOMATOSIS. , ANTI PR-3 (C-ANCA)-INDIRECT SOLID PHASE ENZYME IMMUNOASSAY (ELISA) FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST PROTEINASE 3 (PR-3) IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF CERTAIN AUTOIMMUNE VASCULITIDES SUCH AS WEGENER´S GRANULOMATOSIS. , ANTI BETA 2 GLYCOPROTEIN 1 SCREEN-INDIRECT ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) KIT DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGG OR IGM CLASS ANTIBODIES DIRECTED AGAINST THE 2-GLYCOPROTEIN 1 IN HUMAN SERUM OR PLASMA. , HGH ELISA-DIRECT SOLID PHASE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE MEASUREMENT OF GROWTH HORMONE IN HUMAN SERUM OR PLASMA. , ANTI CP IGG-INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) KIT DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES DIRECTED AGAINST CITRULLINATED PEPTIDES (CP) IN HUMAN SERUM OR PLASMA. , ANTI GAD-IN VITRO QUANTITATIVE ELISA TEST FOR THE DETERMINATION OF AUTOANTIBODIES TO GLUTAMIC ACID DECARBOXYLASE (GAD65 ABS) IN HUMAN SERUM OF PREDIABETIC HIGH RISK INDIVIDUALS AS WELL AS IDDM DIABETIC PATIENTS. , ANA SCREEN-INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) DESIGNED FOR SEMI-QUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED AGAINST SM (SMITH), RNP/SM, SCL-70, SS-A (RO) (52KDA E 60KDA), SS-B (LA), JO-1, U1-SMRNP, CENP-B, DSDNA, AND HISTONES IN HUMAN SERUM OR PLASMA. , TOTAL ESTRIOL ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF TOTAL ESTRIOL CONCENTRATION IN HUMAN SERUM OR PLASMA. , PROLACTIN ELISA-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF PROLACTIN CONCENTRATION IN HUMAN SERUM. , CIC C3D ELISA-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF CIRCULATING IMMUNE COMPLEX C3D (CIC C3D) CONCENTRATION IN HUMAN SERUM OR PLASMA. , ANTI CARDIOLIPIN SCREEN-INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTO-ANTIBODIES DIRECTED AGAINST CARDIOLIPINA-2-GLYCOPROTEIN COMPLEX IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF INCREASED RISK OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERITEMATOSUS (SLE) OR SIMILAR DISORDERS. , ANTI DEAMIDATED GLIADIN PEPTIDE (DGP) IGG-INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) KIT DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS

	ANTIBODIES DIRECTED AGAINST DEAMIDATED GLIADIN PEPTIDES (DGP) IN HUMAN SERUM OR PLASMA. , TSH ELISA-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH, THYROTROPIN) CONCENTRATION IN HUMAN SERUM OR PLASMA. , CORTISOL SALIVA ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF CORTISOL CONCENTRATION IN SALIVA. , URINARY CORTISOL ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE CORTISOL CONCENTRATION IN URINE. , FT3 ELISA-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) CONCENTRATION IN HUMAN SERUM AND PLASMA. , FERRITIN ELISA-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FERRITIN CONCENTRATION IN HUMAN SERUM OR PLASMA. , ANTI TG ELISA-INDIRECT IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF ANTI-TG CONCENTRATION IN HUMAN SERUM OR PLASMA. , ANTI TPO ELISA-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF ANTI-TPO CONCENTRATION IN HUMAN SERUM OR PLASMA. , ANTI DSDNA IGG-INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES DIRECTED AGAINST DSDNA IN HUMAN SERUM OR PLASMA. , ANTI BETA 2 GLYCOPROTEIN 1 IGM-INDIRECT ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS ANTIBODIES DIRECTED AGAINST THE 2-GLYCOPROTEIN 1 IN HUMAN SERUM OR PLASMA. , ANTI PHOSPHOLIPID SCREEN-INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTO-ANTIBODIES DIRECTED AGAINST 2-GLYCOPROTEIN MEDIATED ANIONIC PHOSPHOLIPIDS IN HUMAN SERUM OR PLASMA, INCLUDING CARDIOLIPIN, PHOSPHATIDYL SERINE, PHOSPHATIDYL INOSITOL, PHOSPHATIDIC ACID, PHOSPHATIDYL CHOLINE, LYSO- PHOSPHATIDYL CHOLINE, PHOSPHATIDYL ETHANOLAMINE. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF INCREASED RISK OF THROMBOSIS IN PATIENTS WITH SYSTEMATIC LUPUS ERITEMATOSUS (SLE) OR SIMILAR DISORDERS. , SHBG-DIRECT IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF SHBG CONCENTRATION IN HUMAN SERUM OR PLASMA. , CORTISOL ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF CORTISOL CONCENTRATION IN HUMAN SERUM OR PLASMA. ,

	ANDROSTENEDIONE ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF ANDROSTENEDIONE CONCENTRATION IN HUMAN SERUM OR PLASMA. , PROGESTERONE ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. , ANTI TISSUE TRANSGLUTAMINASE IGA-INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) KIT DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS ANTIBODIES DIRECTED AGAINST TISSUE TRANSGLUTAMINASE IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF CELIAC DISEASE AND DERMATITIS HERPETIFORMIS , ANTI TISSUE TRANSGLUTAMINASE IGG-INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) KIT DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES DIRECTED AGAINST TISSUE TRANSGLUTAMINASE IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF CELIAC DISEASE AND DERMATITIS HERPETIFORMIS. ,CH50-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF COMPLEMENT FUNCTIONALITY IN HUMAN SERUM., DHEA-S ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF DEHYDRO-EPIANDROSTERONE SULFATE (DHEA-S) CONCENTRATION IN HUMAN SERUM OR PLASMA. , ANTI BETA 2 GLYCOPROTEIN 1 IGG-INDIRECT ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) KIT DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES DIRECTED AGAINST THE 2-GLYCOPROTEIN 1 IN HUMAN SERUM OR PLASMA. , T3 ELISA-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) CONCENTRATION IN HUMAN SERUM AND PLASMA. , ANTI CARDIOLIPIN IGG-INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTO-ANTIBODIES DIRECTED AGAINST CARDIOLIPINA-2-GLYCOPROTEIN COMPLEX IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF INCREASED RISK OF THROMBOSIS IN PATIENTS WITH SYSTEMATIC LUPUS ERITEMATOSUS (SLE) OR SIMILAR DISORDERS. , ESTRADIOL ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF 17-ESTRADIOL CONCENTRATION IN HUMAN SERUM OR PLASMA. , ANTI CARDIOLIPIN IGM-INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS AUTO-ANTIBODIES DIRECTED AGAINST CARDIOLIPINA-2-GLYCOPROTEIN

	COMPLEX IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF INCREASED RISK OF THROMBOSIS IN PATIENTS WITH SYSTEMATIC LUPUS ERITEMATOSUS (SLE) OR SIMILAR DISORDERS. , TESTOSTERONE SALIVA ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF TESTOSTERONE CONCENTRATION IN SALIVA. , IA2-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF AUTOANTIBODIES TO PROTEIN TYROSINE PHOSPHATASE (IA2 ABS) IN HUMAN SERUM OR PLASMA. , C-PEPTIDE ELISA-DIRECT SOLID PHASE ENZYME IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM OR PLASMA. , TSH RECEPTOR AB-INTENDED FOR USE BY PROFESSIONAL PERSONS ONLY FOR THE QUANTITATIVE DETERMINATION OF THYROTROPIN RECEPTOR AUTOANTIBODIES IN HUMAN SERUM. , INSULIN ELISA-DIRECT SOLID PHASE ENZYME IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM OR PLASMA. , ALDOSTERONE ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF ALDOSTERONE CONCENTRATION IN HUMAN SERUM, HUMAN PLASMA OR URINE. , THYROGLOBULIN ELISA-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITA-TIVE DETERMINATION OF THYROGLOBULIN CONCENTRATION IN HUMAN SERUM. , DHEA-S SALIVA ELISA-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF DHEA-S CONCENTRATION IN SALIVA. , FT4 ELISA-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) CONCENTRATION IN HUMAN SERUM OR PLASMA. , 17OH PROGESTERONE ELISA -COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF 17OH PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA.

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510	IMP/IVD/2020/000079	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVIA CENTAUR HERPES-2 IGG QUALITY CONTROL (HSV2 QC)(ADVIA CENTAUR HERPES-2 IGG QUALITY CONTROL (HSV2 QC))-THE ADVIA CENTAUR® HERPES-2 IGG (HSV2) QUALITY CONTROL IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ADVIA CENTAUR HERPES-2 IGG (HSV2) ASSAY ON ADVIA CENTAUR SYSTEMS.,ADVIA CENTAUR HERPES-1 IGG QUALITY CONTROL (HSV1 QC)(ADVIA CENTAUR HERPES-1 IGG QUALITY CONTROL (HSV1 QC))-THE ADVIA CENTAUR® HERPES-1 IGG (HSV1) QUALITY CONTROL IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ADVIA CENTAUR HERPES-1 IGG (HSV1) ASSAY ON ADVIA CENTAUR SYSTEMS. ,ADVIA CENTAUR HERPES-1 IGG (HSV1)(ADVIA CENTAUR HERPES-1 IGG (HSV1))-THE ADVIA CENTAUR® HERPES-1 IGG (HSV1) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF IGG ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE 1 (HSV-1) IN HUMAN SERUM AND PLASMA (EDTA AND LITHIUM HEPARIN) USING THE ADVIA CENTAUR CP, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THIS ASSAY IS INTENDED FOR USE AS AN AID IN THE DETERMINATION OF SEROLOGICAL STATUS TO HSV-1 AND IN THE DIAGNOSIS OF HERPES SIMPLEX VIRUS INFECTION.,ADVIA CENTAUR HERPES-2 IGG (HSV2)(ADVIA CENTAUR HERPES-2 IGG (HSV2))-THE ADVIA CENTAUR® HERPES-2 IGG (HSV2) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUALITATIVE DETERMINATION OF IGG ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE 2 (HSV-2) IN HUMAN SERUM AND PLASMA (EDTA AND LITHIUM HEPARIN) USING THE ADVIA CENTAUR CP, ADVIA CENTAUR XP, AND ADVIA CENTAUR XPT SYSTEMS. THIS ASSAY IS INTENDED FOR USE AS AN AID IN THE DETERMINATION OF SEROLOGICAL STATUS TO HSV-2 AND IN THE DIAGNOSIS OF HERPES SIMPLEX VIRUS INFECTION.

511	IMP/IVD/2020/000081	1.License Holder Name: PASSIM MEDICHEM AGENCIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST METER(NA)-WORK WITH BLOOD GLUCOSE TEST STRIP TO MEASURE THE CONCENTRATION OF GLUCOSE IN CAPILLARY WHOLE BLOOD, BLOOD GLUCOSE TEST STRIP-WORK WITH BLOOD GLUCOSE METER TO MEASURE THE CONCENTRATION OF GLUCOSE IN CAPILLARY WHOLE BLOOD,BLOOD GLUCOSE TEST METER(NA)-WORK WITH BLOOD GLUCOSE TEST STRIP TO MEASURE THE CONCENTRATION OF GLUCOSE IN CAPILLARY WHOLE BLOOD,BLOOD GLUCOSE TEST STRIP-WORK WITH BLOOD GLUCOSE METER TO MEASURE THE CONCENTRATION OF GLUCOSE IN CAPILLARY WHOLE BLOOD

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

512	IMP/IVD/2020/000082	1.License Holder Name: QIAGEN INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IPSOGEN CALR RGQ PCR KIT(IPSOGEN CALR RGQ PCR KIT)-THE IPSOGEN CALR RGQ PCR KIT IS AN IN VITRO REAL-TIME PCR TEST INTENDED FOR THE DETECTION OF CALR MUTATIONS IN GENOMIC DNA FROM WHOLE BLOOD OF SUBJECTS SUSPECTED OF MYELOPROLIFERATIVE NEOPLASMS (MPN). THE IPSOGEN CALR RGQ PCR KIT ALSO ENABLES THE IDENTIFICATION OF THE TWO MAJOR CALR MUTATIONS (TYPE 1 AND TYPE 2) AND IS FOR USE WITH THE QIAGEN ROTOR-GENE Q MDX 5PLEX HRM PLATFORM,QIAAMP DSP DNA FFPE TISSUE KIT(QIAAMP DSP DNA FFPE TISSUE KIT)-THE QIAAMP DSP DNA FFPE TISSUE KIT IS A SYSTEM THAT USES SILICA-MEMBRANE TECHNOLOGY FOR ISOLATION AND PURIFICATION OF GENOMIC DNA FROM FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) BIOLOGICAL SPECIMENS., IPSOGEN BCR-ABL1 MBCR RGQ RT-PCR KIT(IPSOGEN BCR-ABL1 MBCR RGQ RT-PCR KIT)-THE IPSOGEN BCR-ABL1 MBCR RGQ RT-PCR KIT IS A QUANTITATIVE IN VITRO DIAGNOSTIC TEST FOR THE MEASURE OF THE BCR-ABL1 FUSION GENE B3A2 (E14A2) AND B2A2 (E13A2) TRANSCRIPTS IN TOTAL RNA EXTRACTED FROM WHOLE BLOOD. , IPSOGEN JAK2 RGQ PCR KIT(IPSOGEN JAK2 RGQ PCR KIT)-THE IPSOGEN JAK2 RGQ PCR KIT IS AN IN VITRO QUANTITATIVE TEST FOR THE DETECTION OF THE JAK2 V617F/G1849T ALLELE IN GENOMIC DNA EXTRACTED FROM WHOLE BLOOD. THE TEST IS INTENDED TO BE AN AID IN THE DIAGNOSIS OF MYELOPROLIFERATIVE NEOPLASM (MPN) IN CONJUNCTION WITH OTHER CLINICOPATHOLOGICAL FACTORS.,IPSOGEN CALR RGQ PCR KIT(IPSOGEN CALR RGQ PCR KIT) -THE IPSOGEN CALR RGQ PCR KIT IS AN IN VITRO REAL-TIME PCR TEST INTENDED FOR THE DETECTION OF CALR MUTATIONS IN GENOMIC DNA FROM WHOLE BLOOD OF SUBJECTS SUSPECTED OF MYELOPROLIFERATIVE NEOPLASMS (MPN). THE IPSOGEN CALR RGQ PCR KIT ALSO ENABLES THE IDENTIFICATION OF THE TWO MAJOR CALR MUTATIONS (TYPE 1 AND TYPE 2), AND IS FOR USE WITH THE QIAGEN ROTOR-GENE Q MDX 5PLEX HRM PLATFORM.

513	IMP/IVD/2020/000083	1.License Holder Name: INBIOS INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HAV AB(DIA.PRO)-COMPETITIVE ENZYME IMMUNOASSAY (ELISA) FOR THE DETERMINATION OF ANTIBODIES TO HEPATITIS A VIRUS IN HUMAN PLASMA AND SERA,HEV IGM(DIA.PRO)-ENZYME IMMUNOASSAY (ELISA) FOR THE DETERMINATION OF IGM ANTIBODIES TO HEPATITIS E VIRUS IN HUMAN SERUM AND PLASMA,HEV IGG(DIA.PRO)-THIRD GENERATION ENZYME IMMUNOASSAY FOR THE DETERMINATION OF IGG ANTIBODIES TO HEPATITIS E VIRUS IN HUMAN SERUM AND PLASMA,HDV AB(DIA.PRO)-COMPETITIVE ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO HEPATITIS DELTA VIRUS IN HUMAN SERUM AND PLASMA,HDV IGM (DIA.PRO)-“CAPTURE” ENZYME IMMUNOASSAY (ELISA) FOR THE DETERMINATION OF IGM ANTIBODIES TO HEPATITIS DELTA VIRUS IN HUMAN PLASMA AND SERA,HAV IGM(DIA.PRO)-“CAPTURE” ENZYME IMMUNO ASSAY (ELISA) FOR THE DETERMINATION OF IGM CLASS ANTIBODIES TO HEPATITIS A VIRUS IN HUMAN PLASMA AND SERA, HDV AG(DIA.PRO)-ENZYME IMMUNOASSAY FOR THE DETERMINATION OF HEPATITIS DELTA VIRUS IN HUMAN SERUM AND PLASMA

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

514	IMP/IVD/2020/000084	1.License Holder Name: WELDON BIOTECH INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTI-CENTROMERE B (ORGENTEC)-ANTI-CENTROMERE B IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST CENTROMERE B IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-DGP IGA(ORGENTEC)-ANTI-DGP IGA IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE DETECTION OF IGA ANTIBODIES AGAINST DEAMIDATED GLIADIN PROTEIN EPITOPES (DGP) IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-PROTHROMBIN IGG/IGM(ORGENTEC)-ANTI-PROTHROMBIN IGG/IGM IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTOANTIBODIES AGAINST PROTHROMBIN IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-C1Q (ORGENTEC)-ANTI-C1Q IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST C1Q IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY., AMA-M2(ORGENTEC)-AMA-M2 IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST MITOCHONDRIAL M2 SUBTYPE ANTIGEN IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,FERRITIN(ORGENTEC)-FERRITIN IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF FERRITIN IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-ANNEXIN V IGG/IGM(ORGENTEC)-ANTI-ANNEXIN V IGG/IGM IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTOANTIBODIES AGAINST ANNEXIN V IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-HISTONE(ORGENTEC)-ANTI-HISTONE IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES TO HISTONE IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-MPO (PANCA)(ORGENTEC)-ANTI-MPO IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST MYELOPEROXIDASE (MPO) IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,CALPROTECTIN (ORGENTEC)-CALPROTECTIN IS AN ELISA-BASED TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF CALPROTECTIN IN HUMAN

	STOOL SAMPLES TO BE USED IN THE ASSESSMENT OF INTESTINAL INFLAMMATORY DISORDERS. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-GLIADIN IGA (ORGENTEC)-ANTI-GLIADIN IGA IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES AGAINST GLIADIN IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY., ANTI-ALPHA-FODRIN IGG/IGA(ORGENTEC)-ANTI-ALPHA FODRIN IGG/IGA IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGA CLASS AUTOANTIBODIES AGAINST ALPHA-FODRIN IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY., THYROGLOBULIN(ORGENTEC)-THYROGLOBULIN IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF THYROGLOBULIN IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY, MICRO-ALBUMIN(ORGENTEC)-MICRO-ALBUMIN IS A COMPETITIVE ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF HUMAN ALBUMIN IN URINE. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY,ANTI-TISSUE-TRANSGLUTAMINASE IGA(ORGENTEC)-ANTI-TISSUE-TRANSGLUTAMINASE IGA IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-GLIADIN IGG(ORGENTEC)-ANTI-GLIADIN IGG IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST GLIADIN IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-CARDIOLIPIN IGG/IGM(ORGENTEC)-ANTI-CARDIOLIPIN IGG/IGM IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-INSULIN(ORGENTEC)-ANTI-INSULIN IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST INSULIN IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-TPO (ORGENTEC)-ANTI-TPO IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST THYROID PEROXIDASE (TPO) IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANA DETECT(ORGENTEC)-ANASCREEN IS AN

	ELISA-BASED TEST SYSTEM FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-A 60, SS-A 52, SS-B, RNP-70, SM, RNP/SM, SCL-70, CENTROMERE B, JO-1 IN HUMAN SERUM OR PLASMA SAMPLES. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-SS-A (ORGENTEC)-ANTI-SS-A IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-A (52 AND 60 KDA) IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-INTRINSIC FACTOR-ANTI-INTRINSIC FACTOR IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST INTRINSIC FACTOR IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-CARDIOLIPIN IGA(ORGENTEC)-ANTI-CARDIOLIPIN IGA IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-PHOSPHOLIPID SCREEN IGG/IGM (ORGENTEC)-ANTI-PHOSPHOLIPID SCREEN IGG/IGM IS AN ELISA TEST SYSTEM TO SCREEN FOR THE PRESENCE OF IGG AND IGM CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN, PHOSPHATIDYL SERINE, PHOSPHATIDYL INOSITOL, PHOSPHATIDIC ACID AND BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY., ANTI-TISSUE-TRANSGLUTAMINASE IGG(ORGENTEC)-ANTI-TISSUE-TRANSGLUTAMINASE IGG IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES TO TISSUE-TRANSGLUTAMINASE (TTG) IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,25-OH VITAMIN D3/D2(ORGENTEC)-25-OH VITAMIN D3/D2 FOR ALEGRIA® IS AN ELISA BASED TEST SYSTEM INTENDED FOR THE QUANTITATIVE MEASUREMENT OF TOTAL CONCENTRATION OF 25-(OH)-VITAMIN D2 AND 25-(OH)-VITAMIN D3 IN HUMAN SERUM OR PLASMA SAMPLES (EDTA PLASMA, HEPARIN PLASMA, CITRATE PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-DGP IGG (ORGENTEC)- ANTI-DGP IGG IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE DETECTION OF IGG ANTIBODIES AGAINST DEAMIDATED GLIADIN PROTEIN EPITOPES (DGP) IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-CATHEPSIN G(ORGENTEC)-ANTI-CATHEPSIN G IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST

	CATHEPSIN G IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY, ANTI-CCP HS (HIGH SENSITIVE)(ORGENTEC)-ANTI-CCP HS® (HIGH SENSITIVE) IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST CYCLIC CITRULLINATED PEPTIDES (CCP) IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-TG(ORGENTEC)-ANTI-TG IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST THYROGLOBULIN (TG) IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-DSDNA (ORGENTEC)-ANTI-DSDNA IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST DOUBLE-STRANDED DNA IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY., ANASCREEN(ORGENTEC)-ANASCREEN IS AN ELISA-BASED TEST SYSTEM FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-A 60, SS-A 52, SS-B, RNP-70, SM, RNP/SM, SCL-70, CENTROMERE B, JO-1 IN HUMAN SERUM OR PLASMA SAMPLES. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-BPI(ORGENTEC)-ANTI-BPI IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST BACTERICIDAL PERMEABILITY INCREASING PROTEIN, BPI, IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ENASCREEN(ORGENTEC)-ENASCREEN IS AN ELISA-BASED TEST SYSTEM FOR THE QUALITATIVE SCREENING OF IGG CLASS AUTOANTIBODIES AGAINST EXTRACTABLE NUCLEAR ANTIGENS (ENA): SS-A 60, SS-A 52, SS-B, SM, RNP/SM, SCL-70, AND JO-1, IN HUMAN SERUM OR PLASMA SAMPLES. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY., ASCA IGG/IGA(ORGENTEC)-ASCA IGG/IGA IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGA CLASS ANTI-SACCHAROMYCES CEREVISIAE ANTIBODIES (ASCA) IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-JO-1 (ORGENTEC)-ANTI-JO-1 IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST JO-1 IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY., ANTI-RNP/SM(ORGENTEC)-ANTI-RNP/SM IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST RNP/SM IN HUMAN SERUM OR PLASMA.

	THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-BETA-2-GLYCOPROTEIN IGA (ORGENTEC)-ANTI-BETA-2-GLYCOPROTEIN I IGA IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF I IGA CLASS AUTOANTIBODIES AGAINST BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,RHEUMATOID FACTOR IGM(ORGENTEC)-RHEUMATOID FACTOR IGM IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS RHEUMATOID FACTOR IN HUMAN SERUM OR PLASMA SAMPLES. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY,ANTI-GBM(ORGENTEC)-ANTI-GBM IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES TO GLOMERULAR BASEMENT MEMBRANE (GBM) IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ENACOMBI (ORGENTEC)-ENACOMBI IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST EXTRACTABLE NUCLEAR ANTIGENS (ENA): SS-A (52 AND 60 KDA), SS-B, SM, RNP/SM, SCL-70, AND JO-1, IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-ELASTASE(ORGENTEC)-ANTI-ELASTASE IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST ELASTASE IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY,RHEUMATOID FACTOR IGG(ORGENTEC)-RHEUMATOID FACTOR IGG IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS RHEUMATOID FACTOR IN HUMAN SERUM OR PLASMA SAMPLES. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-SS-B(ORGENTEC)-ANTI-SS-B IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-B (LA) IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-BETA-2-GLYCOPROTEIN IGG/IGM (ORGENTEC)-ANTI-BETA-2-GLYCOPROTEIN I IGG/IGM IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF I IGG AND IGM CLASS AUTOANTIBODIES AGAINST BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-SCL-70 (ORGENTEC)-ANTI-SCL-70 IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SCL-70 IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY,

		ANTI-PARIETAL CELL(ORGENTEC)-ANTI-PARIETAL CELL IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST THE ALPHA- AND BETA-SUBUNITS OF THE PARIETAL CELL H+/K+-ATPASE IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-PR3 (CANCA)(ORGENTEC)-ANTI-PR3 IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST PROTEINASE 3 (PR3) IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-LACTOFERRIN(ORGENTEC)-ANTI-LACTOFERRIN IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST LACTOFERRIN IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY,ANTI-CARDIOLIPIN SCREEN(ORGENTEC)-ANTI-CARDIOLIPIN SCREEN IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG, IGM AND IGA CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ANTI-SM(ORGENTEC)-ANTI-SM IS AN ELISA TEST SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SM IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ENA-6-PROFILE(ORGENTEC)-ENA-6-PROFILE IS AN ELISA TEST SYSTEM FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES DIRECTED AGAINST THE EXTRACTABLE NUCLEAR ANTIGENS SS-A (52 AND 60 KDA, RO), SS-B (LA), SM, RNP/SM, SCL-70, AND JO-1 IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.
515	IMP/IVD/2020/000085	1.License Holder Name: BIOSENSE TECHNOLOGIES PVT LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLYCOHEMOGLOBIN TEST STRIP KIT(A1CHEK)-USED TO DETECT THE PERCENTAGE OF GLYCATED HEMOGLOBIN IN HUMAN BLOOD

516	IMP/IVD/2020/000086	1.License Holder Name: COMPACT DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FIBRINOGEN REAGENT (FIBRINOGEN REAGENT KIT)-FOR THE DETERMINATION OF FIBRINOGEN BASED IN PLASMA.,PT REAGENT(TECHNOPLASTIN HIS FOR CEVERON)-PT REAGENT IS USED FOR THE DETERMINATION OF THE PROTHROMBIN TIME IN PLASMA.,APTT REAGENT(DAPTTIN TC, SIRON LS,)-APTT REAGENT IS USED FOR THE DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME IN PLASMA.,THROMBIN TIME REAGENT(THROMBIN REAGENT)-THROMBIN REAGENT IS USED FOR THE DETERMINATION OF THE THROMBIN TIME (TT),D-DIMER KIT (TECHNOLEIA,)-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN PLASMA

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517	IMP/IVD/2020/000087	1.License Holder Name: SOWAR PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROL BLOOD (NORMACONT3+ KIT K1 (NIC-032K1))-NORMACONT3+ IS A 3 LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,CONTROL BLOOD(NORMACONT3+ (NIC-0P32N))-NORMACONT3+ IS A 3 LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,DILUENT (NORMA-IDIL5 5L)-NORMA-IDIL5 DILUENT IS A BUFFERED, STABILIZED AND MICRO-FILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, AND THE MEASUREMENT OF THROMBOCYTES (PLT) CONCENTRATION ON NORMA ICON-5 HEMATOLOGY ANALYZERS. ,CONTROL BLOOD (NORMACONT3+ (NIC-0P32H))-NORMACONT3+ IS A 3 LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,CONTROL BLOOD(NORMACONT3+ (NIC-0P32L))-NORMACONT3+ IS A 3 LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,CALIBRATOR (NORMACAL3 (NIC-CAL32))-NORMACAL3 IS DESIGNED FOR USE IN THE CALIBRATION OF NORMA HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. , REAGENT PACK(NORMA-IRP31 (IC-91711))-NORMA-IRP31 IS A SET OF REAGENTS INTENDED TO BE USED ON NORMA ICON-3 HAEMATOLOGY ANALYSERS. NORMA-IRP31 REAGENTS SHOULD NOT BE REPLACED WITH THIRD PARTY REAGENTS. ERRONEOUS RESULTS MAY BE OBTAINED IF THE THIRD PARTY REAGENT IS APPLIED., CLEANER(NORMA-ICLEAN5 5L)-NORMA-ICLEAN5 OP IS A BUFFERED, STABILIZED AND MICRO-FILTERED ELECTROLYTE SOLUTION USED FOR CONDITIONING OF SPECIFIC TUBING SECTIONS IN NORMA ICON-5 OP HAEMATOLOGY ANALYSERS. ,CONTROL BLOOD (NORMACONT5+ NORMAL 3ML (NIC-0P53N))-NORMACONT5+ IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES

	ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. , REAGENT PACK(NORMA IRP51 (100T))-NORMA IRP51 IS A SET OF REAGENTS INTENDED TO BE USED ON NORMA ICON-5 HAEMATOLOGY ANALYSERS. NORMA-IRP51 REAGENTS SHOULD NOT BE REPLACED WITH THIRD PARTY REAGENTS. ERRONEOUS RESULTS MAY BE OBTAINED IF THE THIRD PARTY REAGENT IS APPLIED. , REAGENT PACK(NORMA-IRP51 OP (IC-91771))-NORMA-IRP51 OP IS A SET OF REAGENTS INTENDED TO BE USED ON NORMA ICON-5 OP HAEMATOLOGY ANALYSERS. ,REAGENT PACK(NORMA-IRP52 OP (IC-91772))-NORMA-IRP52 OP IS A SET OF REAGENTS INTENDED TO BE USED ON NORMA ICON-5 OP HAEMATOLOGY ANALYSERS. ,LYSE (NORMA-ILYSE5 OP (IC-21771))-NORMA-ILYSE5 OP LYSING REAGENT IS A STABILIZED AND MICRO-FILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE FIVE-PART DIFFERENTIATION (LYM, MID, NEU, EOS, BAS) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON NORMA ICON-5 OP HAEMATOLOGY ANALYSERS. ,LYSE(NORMA-ILYSE5 1L)-NORMA-ILYSE5 OP LYSING REAGENT IS A STABILIZED AND MICRO-FILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE FIVE-PART DIFFERENTIATION (LYM, MID, NEU, EOS, BAS) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON NORMA ICON-5 OP HAEMATOLOGY ANALYSERS. ,REAGNT PACK(NORMA IRP54 (400T))-NORMA IRP54 IS A SET OF REAGENTS INTENDED TO BE USED ON NORMA ICON-5 HAEMATOLOGY ANALYSERS. NORMA-IRP54 REAGENTS SHOULD NOT BE REPLACED WITH THIRD PARTY REAGENTS. ERRONEOUS RESULTS MAY BE OBTAINED IF THE THIRD PARTY REAGENT IS APPLIED. ,DILUENT(NORMA-IDIL5 10L)-NORMA-IDIL5 OP DILUENT IS A BUFFERED, STABILIZED AND MICRO-FILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, AND THE MEASUREMENT OF THROMBOCYTES (PLT) CONCENTRATION ON NORMA ICON-5 OP HEMATOLOGY ANALYZERS. ,CLEANER(NORMA-ICLEAN5 OP (IC-51771))-NORMA-ICLEAN5 OP IS A BUFFERED, STABILIZED AND MICRO-FILTERED ELECTROLYTE SOLUTION USED FOR CONDITIONING OF SPECIFIC TUBING SECTIONS IN NORMA ICON-5 OP HAEMATOLOGY ANALYSERS. ,CLEANER(NORMA-ICLEAN5 OP (IC-51775))-NORMA-ICLEAN5 OP IS A BUFFERED, STABILIZED AND MICRO-FILTERED ELECTROLYTE SOLUTION USED FOR CONDITIONING OF SPECIFIC

	TUBING SECTIONS IN NORMA ICON-5 OP HAEMATOLOGY ANALYSERS. ,DILUENT(NORMA-IDIL5 OP (IC-11775))-NORMA-IDIL5 OP DILUENT IS A BUFFERED, STABILIZED AND MICRO-FILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, AND THE MEASUREMENT OF THROMBOCYTES (PLT) CONCENTRATION ON NORMA ICON-5 OP HEMATOLOGY ANALYZERS. ,CONTROL BLOOD(NORMACONT5+ LOW 3ML (NIC-0P53L))-NORMACONT5+ IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,CONTROL BLOOD (NORMACONT3+ KIT K4 (NIC-032K4))-NORMACONT3+ IS A 3 LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,CONTROL BLOOD(NORMACONT3+ KIT KN (NIC-032KN))-NORMACONT3+ IS A 3 LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. , CONTROL BLOOD(NORMACONT3+ KIT KH (NIC-032KH))-NORMACONT3+ IS A 3 LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,DILUENT(NORMA-IDIL3 (IC-11731))-NORMA-IDIL3 DILUENT IS A BUFFERED, STABILIZED AND MICRO-FILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN (HGB) CONCENTRATION ON NORMA ICON-3 HAEMATOLOGY ANALYSERS. ,LYSE(NORMA-ILYSE3 (IC-21731))-NORMA-ILYSE3 LYSING REAGENT IS A STABILIZED AND MICRO-FILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE THREE-PART DIFFERENTIATION (LYM, MID, GRAN) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON NORMA ICON-3 HAEMATOLOGY ANALYSERS. NORMA-ILYSE3 LYSING REAGENT SHOULD ONLY BE USED WITH NORMA REAGENTS. ERRONEOUS

	RESULTS MAY BE OBTAINED IF THE REAGENT IS APPLIED WITH THIRD PARTY REAGENTS.,DILUENT(NORMA-IDIL5 OP (IC-11771))-NORMA-IDIL5 OP DILUENT IS A BUFFERED, STABILIZED AND MICRO-FILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, AND THE MEASUREMENT OF THROMBOCYTES (PLT) CONCENTRATION ON NORMA ICON-5 OP HEMATOLOGY ANALYZERS. ,HYPOCHLORITE CLEANER(NORMA-IHCLEAN (IC-81730))-NORMA-IHCLEAN HYPOCHLORITE CLEANING REAGENT IS A STABILIZED AND MICRO-FILTERED HYPOCHLORITE SOLUTION FOR INTENSIVE OXIDATIVE CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON NORMA HAEMATOLOGY ANALYSERS, CONTROL BLOOD(NORMACONT3+ KIT K2 (NIC-032K2))-NORMACONT3+ IS A 3 LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,CLEANER(NORMA-ISOL3 (IC-41735))-NORMA-ISOL3 IS A BUFFERED, STABILIZED AND MICRO-FILTERED ELECTROLYTE SOLUTION USED FOR CONDITIONING OF SPECIFIC TUBING SECTIONS IN NORMA ICON-3 HAEMATOLOGY ANALYSERS. , CLEANER(NORMA-ISOL3 (IC-41731))-NORMA-ISOL3 IS A BUFFERED, STABILIZED AND MICRO-FILTERED ELECTROLYTE SOLUTION USED FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, ON NORMA ICON-3 HAEMATOLOGY ANALYSERS. NORMA-ISOL3 SYSTEM SOLUTION SHOULD ONLY BE USED WITH NORMA REAGENTS. ERRONEOUS RESULTS MAY BE OBTAINED IF THE REAGENT IS APPLIED WITH THIRD PARTY REAGENTS.,CONTROL BLOOD (NORMACONT5+ HIGH 3ML (NIC-0P53H))-NORMACONT5+ IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. , DILUENT(NORMA-IDIL3 (IC-11735))-NORMA-IDIL3 DILUENT IS A BUFFERED, STABILIZED AND MICRO-FILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN (HGB) CONCENTRATION ON NORMA ICON-3 HAEMATOLOGY ANALYSERS. NORMA-IDIL3 DILUENT SHOULD ONLY BE USED WITH NORMA REAGENTS. ERRONEOUS RESULTS MAY BE

	OBTAINED IF THE REAGENT IS APPLIED WITH THIRD PARTY REAGENTS.,HYPOCHLORITE CLEANER(NORMA-IHCLEAN (IC-81731))-ORMA-IHCLEAN HYPOCHLORITE CLEANING REAGENT IS A STABILIZED AND MICRO-FILTERED HYPOCHLORITE SOLUTION FOR INTENSIVE OXIDATIVE CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON NORMA HAEMATOLOGY ANALYSERS. NORMA-IHCLEAN HYPOCHLORITE CLEANING REAGENT SHOULD ONLY BE USED WITH NORMA REAGENTS. ERRONEOUS RESULTS MAY BE OBTAINED IF THE REAGENT IS APPLIED WITH THIRD PARTY REAGENTS.,CONTROL BLOOD(NORMACONT5+ KIT KL (6L) (NIC-053KL))-NORMACONT5+ IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,CONTROL BLOOD(NORMACONT3+ KIT K3 (NIC-032K3))-NORMACONT3+ IS A 3 LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,CONTROL BLOOD(NORMACONT5+ KIT K1 (2L, 2N,2H) (NIC-053K1))-NORMACONT5+ IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,REAGENT PACK (NORMA-IRP35 (IC-91715))-NORMA-IRP35 IS A SET OF REAGENTS INTENDED TO BE USED ON NORMA ICON-3 HAEMATOLOGY ANALYSERS. NORMA-IRP35 REAGENTS SHOULD NOT BE REPLACED WITH THIRD PARTY REAGENTS. ERRONEOUS RESULTS MAY BE OBTAINED IF THE THIRD PARTY REAGENT IS APPLIED.,CONTROL BLOOD(NORMACONT5+ KIT KH (6H) (NIC-053KH))-NORMACONT5+ IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,CONTROL BLOOD(NORMACONT3+ KIT KL (NIC-032KL))-NORMACONT3+ IS A 3 LEVEL CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,CONTROL BLOOD(NORMACONT5+ KIT KN (6N) (NIC-053KN))-NORMACONT5+ IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.

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518	IMP/IVD/2020/000088	1.License Holder Name: QIAGEN INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QUANTIFERON CONTROL PANEL(QUANTIFERON CONTROL PANEL)-THE QUANTIFERON CONTROL PANEL CONTAINS A SET OF 3 INTERFERON- (IFN-) CONTROLS FOR OPTIONAL USE WITH QUANTIFERON CELL-MEDIATED IMMUNE (CMI) ASSAYS. THE IFN- CONTROLS ARE PROVIDED AT THREE LEVELS (1, 2 AND 3) WITHIN THE LINEAR RANGE OF THE QUANTIFERON ELISA.,QUANTIFERON MONITOR LYOSPHERE (QUANTIFERON MONITOR LYOSPHERE)-THE QUANTIFERON MONITOR (QFM) LYOPHILIZED STIMULANTS (LYOSPHERES) ARE INTENDED FOR USE ONLY WITH THE QUANTIFERON MONITOR ASSAY. QFM ASSAY USES LYOPHILIZED STIMULANTS (QFM LYOSPHERE), WHICH ARE ADDED TO HEPARINIZED WHOLE BLOOD.,QUANTIFERON CMV (QUANTIFERON CMV)-QUANTIFERON-CMV IS AN IN VITRO ASSAY USING A PEPTIDE COCKTAIL SIMULATING HUMAN CYTOMEGALOVIRUS (CMV) PROTEINS TO STIMULATE CELLS IN HEPARINIZED WHOLE BLOOD. DETECTION OF INTERFERON-GAMMA (IFN- GAMMA) BY ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) IS USED TO QUANTIFY IN VITRO RESPONSES TO THESE PEPTIDE ANTIGENS THAT ARE ASSOCIATED WITH IMMUNE CONTROL OF CMV INFECTION. LOSS OF THIS IMMUNE FUNCTION MAY BE ASSOCIATED WITH DEVELOPMENT OF CMV DISEASE. THE INTENDED USE OF QUANTIFERON-CMV IS TO MONITOR A PATIENT'S LEVEL OF ANTI-CMV IMMUNITY. QUANTIFERON-CMV IS NOT A TEST FOR DETERMINING CMV INFECTION AND SHOULD NOT BE USED TO EXCLUDE CMV INFECTION.,QUANTIFERON MONITOR ELISA (QUANTIFERON MONITOR ELISA)-THE QUANTIFERON MONITOR ASSAY (QFM) IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO DETECT CELL-MEDIATED IMMUNE FUNCTION THROUGH THE MEASUREMENT OF INTERFERON GAMMA (IFN-) IN PLASMA BY ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOLLOWING INCUBATION OF HEPARINIZED WHOLE BLOOD WITH INNATE AND ADAPTIVE IMMUNE RESPONSE STIMULANTS. THE ASSAY IS USED TO DETECT CELL MEDIATED IMMUNE RESPONSE IN THE IMMUNOSUPPRESSED SOLID ORGAN TRANSPLANT POPULATION. QFM IS INTENDED FOR USE IN CONJUNCTION WITH RISK ASSESSMENT AND OTHER MEDICAL AND DIAGNOSTIC EVALUATIONS.,PARTOSURE TEST(PARTOSURE TEST)-THE PARTOSURE TEST IS A RAPID, NON-INSTRUMENTED, QUALITATIVE IMMUNOCHROMATOGRAPHIC TEST FOR THE IN VITRO DETECTION OF PLACENTAL ALPHA MICROGLOBULIN- 1 (PAMG-1) IN VAGINAL SECRETIONS OF PREGNANT WOMEN. THE DEVICE IS DESIGNED AS AN AID TO RAPIDLY ASSESS THE RISK OF PRETERM DELIVERY IN 7 OR 14 DAYS FROM THE TIME OF CERVICOVAGINAL

		SAMPLE COLLECTION IN PREGNANT WOMEN WITH SIGNS AND SYMPTOMS OF EARLY PRETERM LABOR, INTACT AMNIOTIC MEMBRANES, AND MINIMAL CERVICAL DILATATION (3 CM), SAMPLED BETWEEN 20 WEEKS, 0 DAYS AND 36 WEEKS, 6 DAYS GESTATION,QUANTIFERON-TB GOLD(QUANTIFERON-TB GOLD)-QUANTIFERON®-TB GOLD (QFT) IS A QUALITATIVE IN VITRO DIAGNOSTIC TEST USING A PEPTIDE COCKTAIL SIMULATING ESAT-6, CFP-10 AND TB7.7 PROTEINS TO STIMULATE CELLS IN HEPARINISED WHOLE BLOOD. DETECTION OF INTERFERON-(IFN-) BY ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) IS USED TO IDENTIFY IN VITRO RESPONSES TO THESE PEPTIDE ANTIGENS THAT ARE ASSOCIATED WITH MYCOBACTERIUM TUBERCULOSIS INFECTION.
519	IMP/IVD/2020/000095	1.License Holder Name: QIAGEN INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QUANTIFERON TB GOLD PLUS(QUANTIFERON TB GOLD PLUS)-QUANTIFERON TB GOLD PLUS (QFT-PLUS) ASSAY IS AN IN VITRO DIAGNOSTIC TEST USING A PEPTIDE COCKTAIL SIMULATING ESAT-6 AND CFP-10 PROTEINS TO STIMULATE CELLS IN HEPARINIZED WHOLE BLOOD. DETECTION OF INTERFERON- (IFN-) BY ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) IS USED TO IDENTIFY IN VITRO RESPONSES TO THOSE PEPTIDE ANTIGENS THAT ARE ASSOCIATED WITH MYCOBACTERIUM TUBERCULOSIS INFECTION. QUANTIFERON-TB GOLD PLUS IS AN INDIRECT TEST FOR M. TUBERCULOSIS INFECTION (INCLUDING DISEASE) AND IS INTENDED FOR USE IN ONJUNCTION WITH RISK ASSESSMENT, RADIOGRAPHY, AND OTHER MEDICAL DEVICES AND DIAGNOSTIC EVALUATIONS.
520	IMP/IVD/2020/000097	1.License Holder Name: ANALYTICAL AUTOMATION (INDIA) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DILUENT(HD500 DILUENT , HD300 DILUENT)-DILUENT IS INTENDED TO PERFORM ERYTHROCYTES AND PLATELETS MEASUREMENT IN BLOOD SAMPLE, CLEANER(HC500 CLEANER, HC300 CLEANER)-CLEANER IS INTENDED TO CLEAN AND RINSE THE FLUIDIC CHANNELS WITHIN ANALYZER TOENSURE THE ANALYZER'S PERFORMANCE.,LYSE(HL500 LYSE , HL300 LYSE)-LYSE IS USED FOR LYSING ERYTHROCYTES, COUNTING AND DIFFERENTIATING THE FIVE MAIN LEUKOCYTES SUBPOPULATIONS AND QUANTITATIVE DETERMINATION HEMOGLOBIN IN A BLOOD SAMPLE

521	IMP/IVD/2020/000100	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PYRIDOXAL PHOSPHATE LIQUID(PYRIDOXAL PHOSPHATE LIQUID)-KINETIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE, EC 2.6.1.2 (ALT), IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.,P-5-P(P-5-P)-KINETIC UV TEST FOR THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE, EC 2.6.1.2 (ALT), IN HUMAN SERUM AND PLASMA ON BECKMAN COULTER ANALYSERS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

522	IMP/IVD/2020/000102	1.License Holder Name: VISION BIOCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTIPLE CLINICAL CHEMISTRY ANALYTE IVD, CONTROL(RAMP PROCALCITON IN CONTROLS LEVEL2)-THE RAMP PROCALCITONIN CONTROLS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF THE ACCURACY OF THE RAMP PROCALCITONIN ASSAY. THIS MATERIAL CAN BE USED TO MONITOR THE CONTROL OF ACCURACY OR THE CONTROL OF REPRODUCIBILITY OF THE RAMP PROCALCITONIN ASSAY.,"MULTIPLE CARDIAC MARKER IVD, CONTROL"(RAMP CARDIAC CONTROLS)-THE RAMP CARDIAC CONTROLS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF CARDIAC MARKERS ON THE RAMP® PLATFORM.,IVD TEST REAGENT/KITS, IMMUNOASSAY, PROTEIN, PROCALCITONIN(RAMP PROCALCITONIN ASSAY)-"THE RAMP PROCALCITONIN ASSAY IS A QUANTITATIVE IMMUNOCHROMATOGRAPHIC TEST INDICATED FOR USE AS AN IN VITRO DIAGNOSTIC PRODUCT USED WITH A RAMP INSTRUMENT TO MEASURE LEVELS OF THE PROHORMONE PROCALCITONIN (PCT) IN HUMAN EDTA ANTICOAGULATED WHOLE BLOOD. THE RAMP PROCALCITONIN ASSAY IS INTENDED TO BE USED IN CONJUNCTION WITH OTHER LABORATORY FINDINGS AND CLINICAL ASSESSMENTS AS AN AID IN THE RISK ASSESSMENT OF PROGRESSION TO SEVERE SEPSIS AND SEPTIC SHOCK.,D-DIMER IVD, KIT, IMMUNOCHROMATOGRAPHIC TEST (JCT), RAPID(RAMP D- DIMER ASSAY)-THE RAMP D-DIMER ASSAY IS A QUANTITATIVE IMMUNOCHROMATOGRAPHIC TEST INDICATED FOR USE AS AN IN VITRO DIAGNOSTIC PRODUCT USED IN THE QUANTIFICATION OF THE FIBRIN DEGRADATION PRODUCT (FOP) D-DIMER IN HUMAN EDTA ANTI-COAGULATED WHOLE BLOOD.,TROPONIN I IVD, KIT, IMMUNOCHROMATOGRAPHIC TEST (ICT), RAPID(RAMP TROPONIN I ASSAY)-"THE RAMP TROPONIN I ASSAY IS A QUANTITATIVE IMMUNOCHROMATOGRAPHIC TEST INDICATED FOR USE AS AN IN VITRO DIAGNOSTIC PRODUCT USED TO MEASURE CARDIAC TROPONIN I LEVELS IN EDTA WHOLE BLOOD. MEASUREMENT OF CARDIAC TROPONIN I AIDS IN THE RAPID DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI). THE RAMP® TROPONIN I ASSAY IS INTENDED TO BE USED ONLY TO PRIORITIZED PATIENT MANAGEMENT FOR THOSE SUSPECTED OF AMI.",MULTIPLE CLINICAL CHEMISTRY ANALYTE IVD, CONTROL(RAMP PROCALCITON IN CONTROLS LEVEL 1)-THE RAMP PROCALCITONIN CONTROLS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF THE ACCURACY OF THE RAMP PROCALCITONIN ASSAY. THIS MATERIAL CAN BE USED TO MONITOR THE CONTROL OF ACCURACY

	OR THE CONTROL OF REPRODUCIBILITY OF THE RAMP PROCALCITONIN ASSAY.,B-TYPE NATRIURETIC PROTEIN/N-TERMINAL PRO B- TYPE NATRIURETIC PEPTIDE IVD, KIT, IMMUNOCHROMATOGRAPHIC TEST (JCT), RAPID(RAMP NT- PROBNP ASSAY)-"THE RAMP NT-PROBNP ASSAY IS A QUANTITATIVE IMMUNOCHROMATOGRAPHIC TEST INDICATED FOR USE AS AN IN VITRO DIAGNOSTIC PRODUCT TO MEASURE N- TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) LEVELS IN EDTA WHOLE BLOOD. THE RAMP NT-PROBNP ASSAY CAN BE USED IN THE CLINICAL LABORATORY AND AT THE POINT-OF CARE WHERE MEASUREMENT OF NT-PROBNP AIDS IN THE DIAGNOSIS AND ASSESSMENT OF SEVERITY IN INDIVIDUALS SUSPECTED OF HAVING CONGESTIVE HEART FAILURE (CHF) AND MAY AID IN THE RISK STRATIFICATION OF PATIENTS WITH ACUTE CORONARY SYNDROME AND HEART FAILURE. THE TEST MAY ALSO SERVE AS AN AID IN THE ASSESSMENT OF INCREASED RISK OF CARDIOVASCULAR EVENTS AND MORTALITY IN PATIENTS AT RISK FOR HEART FAILURE WHO HAVE STABLE CORONARY ARTERY DISEASE.",MYOGLOBIN IVD, KIT, IMMUNOCHROMATOGRAPHIC TEST (ICT), RAPID(RAMP MYOGLOBIN ASSAY)-THE RAMP MYOGLOBIN ASSAY IS A QUANTITATIVE IMMUNOCHROMATOGRAPHIC TEST INDICATED FOR USE AS AN IN VITRO DIAGNOSTIC PRODUCT USED TO MEASURE MYOGLOBIN LEVELS IN EDTA WHOLE BLOOD. MEASUREMENT OF MYOGLOBIN AIDS IN THE RAPID DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION., CREATINE KINASE MYOCARDIAL ISOENZYME (CKMB) IVD, KIT, IMMUNOCHROMATOGRAPHIC TEST (ICT) RAPID(RAMP CK- MB ASSAY)-"THE RAMP CK-MB ASSAY IS A QUANTITATIVE IMMUNOCHROMATOGRAPHIC TEST INDICATED FOR USE AS AN IN VITRO ' DIAGNOSTIC PRODUCT USED TO MEASURE CK- MB LEVELS IN EDTAWHOLE BLOOD. MEASUREMENT OF CK-MB AIDS IN THE RAPID DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI). THE RAMP® CK-MB ASSAY IS INTENDED TO BE USED ONLY TO PRIORITIZE PATIENT MANAGEMENT FOR THOSE SUSPECTED OF AMI."

523	IMP/IVD/2020/000104	1.License Holder Name: STERANCO HEALTHCARE PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTIPLE COAGULATION FACTOR IVD, CONTROL(HAEMONETICS® TEG® HEMOSTASIS SYSTEM QC LEVEL 1)-THE TEG® 6S HEMOSTASIS ANALYZER IS A NON-INVASIVE DIAGNOSTIC INSTRUMENT DESIGNED TO MONITOR AND ANALYZE THE COAGULATION STATE OF A BLOOD SAMPLE IN ORDER TO ASSIST IN THE ASSESSMENT OF PATIENT CLINICAL HEMOSTASIS CONDITIONS. THE TEG 6S ANALYZER IS INDICATED FOR USE WITH ADULT PATIENTS WHERE AN EVALUATION OF BLOOD COAGULATION PROPERTIES IS DESIRED. RESULTS FROM THE TEG 6S ANALYZER SHOULD NOT BE THE SOLE BASIS FOR A PATIENT DIAGNOSIS, BUT SHOULD BE EVALUATED TOGETHER WITH THE PATIENT'S MEDICAL HISTORY, THE CLINICAL PICTURE AND, IF NECESSARY, OTHER COAGULATION TESTS. ,PLATELET AGGREGATION STUDY IVD (HAEMONETICS TEG HAEMOSTASIS SYSTEM PLATELET MAPPING ADP & AA)-REAGENT TO MEASURE PLATELET INHIBITION AND TOTAL PLATELET FUNCTION. AIDS IN ANTI-PLATELET THERAPY DECISIONS FOR ADP & GP IIB/IIIA INHIBITORS.,PLATELET AGGREGATION STUDY IVD, REAGENT(HAEMONETICS® TEG® HEMOSTASIS SYSTEM PLATELET MAPPING ADP,AA)-THE TEG® 6S HEMOSTASIS ANALYZER IS A NON-INVASIVE DIAGNOSTIC INSTRUMENT DESIGNED TO MONITOR AND ANALYZE THE COAGULATION STATE OF A BLOOD SAMPLE IN ORDER TO ASSIST IN THE ASSESSMENT OF PATIENT CLINICAL HEMOSTASIS CONDITIONS. THE TEG 6S ANALYZER IS INDICATED FOR USE WITH ADULT PATIENTS WHERE AN EVALUATION OF BLOOD COAGULATION PROPERTIES IS DESIRED.,MULTIPLE COAGULATION FACTOR IVD, CONTROL(HAEMONETICS TEG HAEMOSTASIS SYSTEM LEVEL I CONTROL)-NORMAL RANGE BIOLOGICAL CONTROL UNIT. A WHOLE BLOOD COAGULATION CONTROL THAT CONTAINS A PREPARATION OF ANIMAL CITRATED PLASMA, ACTIVATOR, PRESERVATIVE & BUFFER. IT HAS BEEN FORMULATED SPECIFICALLY AS A QUALITY CONTROL FOR THE TEG ANALYSER.,MULTIPLE COAGULATION FACTOR IVD, CONTROL (HAEMONETICS® TEG® HEMOSTASIS SYSTEM QC LEVEL 2)-THE TEG® 6S HEMOSTASIS ANALYZER IS A NON-INVASIVE DIAGNOSTIC INSTRUMENT DESIGNED TO MONITOR AND ANALYZE THE COAGULATION STATE OF A BLOOD SAMPLE IN ORDER TO ASSIST IN THE ASSESSMENT OF PATIENT CLINICAL HEMOSTASIS CONDITIONS. THE TEG 6S ANALYZER IS INDICATED FOR USE WITH ADULT PATIENTS WHERE AN EVALUATION OF BLOOD COAGULATION PROPERTIES IS DESIRED. RESULTS FROM THE TEG 6S ANALYZER SHOULD NOT BE THE SOLE BASIS FOR A PATIENT DIAGNOSIS, BUT SHOULD BE EVALUATED TOGETHER WITH THE PATIENT'S MEDICAL

	HISTORY, THE CLINICAL PICTURE AND, IF NECESSARY, OTHER COAGULATION TESTS. ,MULTIPLE COAGULATION FACTOR IVD, CONTROL(HAEMONETICS TEG HAEMOSTASIS SYSTEM LEVEL II CONTROL)-ABNORMAL RANGE BIOLOGICAL CONTROL UNIT. A WHOLE BLOOD COAGULATION CONTROL THAT CONTAINS A PREPARATION OF ANIMAL CITRATED PLASMA, ACTIVATOR, PRESERVATIVE & BUFFER. IT HAS BEEN FORMULATED SPECIFICALLY AS A QUALITY CONTROL FOR THE TEG ANALYSER.,MULTIPLE COAGULATION FACTOR IVD, REAGENT(HAEMONETICS® TEG® HEMOSTASIS SYSTEM CITRATED K, KH, RT, FF)-THE TEG® 6S HEMOSTASIS ANALYZER IS A NON-INVASIVE DIAGNOSTIC INSTRUMENT DESIGNED TO MONITOR AND ANALYZE THE COAGULATION STATE OF A BLOOD SAMPLE IN ORDER TO ASSIST IN THE ASSESSMENT OF PATIENT CLINICAL HEMOSTASIS CONDITIONS., MULTIPLE COAGULATION FACTOR IVD,REAGENT(HAEMONETICS TEG HAEMOSTASIS SYSTEM DISPOSABLE CUPS & PINS HEPARINASE)-EACH CUP CONTAINS ENOUGH HEPARINASE TO REVERSE 6IU OF HEPARIN.,ACTIVATED CLOTTING TIME (ACT) IVD(HAEMONETICS TEG HAEMOSTASIS SYSTEM RAPID TEG REAGENT)-REAGENT THAT ACTIVATES AND ACCELERATES THE CLOTTING PROCESS. USED IN TRAUMA PATIENTS,FIBRINOGEN ASSAY (FACTOR I) IVD (HAEMONETICS TEG HAEMOSTASIS SYSTEM FUNCTIONAL FIBRINOGEN REAGENT)-FIBRINOGEN TEST TO MONITOR THE CONTRIBUTION OF FIBRINOGEN IN CLOT FORMATION.,KAOLIN (HAEMONETICS TEG HAEMOSTASIS KAOLIN)-A STANDARDIZED REAGENT THAT ACTIVATES THE BLOOD SAMPLE THROUGH THE INTRINSIC PATHWAY FOR CLOT ACTIVATION,CALCIUM CHLORIDE COAGULATION IVD(HAEMONETICS TEG HAEMOSTASIS SYSTEM 0.2 M CACL2 (5ML))-USED TO RECALCIFY SAMPLES THAT HAVE BEEN ANTICOAGULATED WITH SODIUM CITRATE

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524	IMP/IVD/2020/000129	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LABGUN™ COVID-19 RT-PCR KIT (LABGUN™ COVID-19 RT-PCR KIT)-QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN NASOPHARYNGEAL, OR OROPHARYNGEAL, ANTERIOR NASAL AND MID-TURBINATE NASAL SWABS, AS WELL AS NASOPHARYNGEAL WASH/ASPIRATE OR NASAL ASPIRATE SPECIMENS AND SPUTUM, FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. , LABGUN COVID-19 ASSAY(LABGUN COVID-19 ASSAY)-THE LABGUNTM COVID-19 ASSAY IS A REAL TIME RT-PCR IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE DETECTION OF SARS-COV-2 RNA FROM SPUTUM, BRONCHOALVEOLAR LAVAGE FLUID AND OROPHARYNGEAL, NASOPHARYNGEAL SWAB SPECIMENS FROM INDIVIDUALS WHO MEET COVID-19 CLINICAL AND/OR EPIDEMIOLOGICAL CRITERIA.,LABGUN™ COVID-19 ASSAY PLUS (LABGUN™ COVID-19 ASSAY PLUS)-LABGUN™ COVID-19 ASSAY PLUS IS A REAL-TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RRT-PCR) TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN NASOPHARYNGEAL OR OROPHARYNGEAL SWABS, AND SPUTUM, FROM INDIVIDUALS WITH SIGNS AND SYMPTOMS OF INFECTION WHO ARE SUSPECTED OF COVID-19.,LABGUN™ COVID-19 EXOFAST RT- PCR KIT(LABGUN™ COVID-19 EXOFAST RT- PCR KIT)-LABGUN™ COVID-19 EXOFAST RT- PCR KIT IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME REVERSE-TRANSCRIPTION PCR TECHNOLOGY, FOR THE AMPLIFICATION AND DETECTION OF RDRP GENE AND N GENE OF SARS-COV-2 FROM SPUTUM AND OROPHARYNGEAL, NASOPHARYNGEAL SWAB. THE KIT AIDS TO DIAGNOSE COVID-19.

525	IMP/IVD/2020/000131	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 NUCLEIC ACID DETECTION KIT-KIT USED FOR THE DETECTION OF NUCLEIC ACID RNA OF NOVEL CORONAVIRUS 2019-NCOV IN HUMAN SPECIMENS SUCH AS NASOPHARYNGEAL SWABS, THROAT SWAB, NASOPHARYNGEAL SECRETION OR BRONCHOALVEOLAR LAVAGE FLUID ETC.,MAGABIO PLUS VIRUS DNA/RNA PURIFICATION KIT-FOR EXTRACTION OF DNA/RNA FROM VIRUS IN HUMAN SERUM, PLASMA, BLOOD, SALIVA, SWAB, SPUTUM, ALVEOLAR, LAVAGE AND CELL FREE FLUIDS.,BIOSPIN VIRUS DNA/RNA EXTRACTION KIT-SIMULTANEOUS PURIFICATION OF VIRAL RNA AND DNA FROM PLASMA, SERUM, AND CELL FREE BODY FLUIDS.
526	IMP/IVD/2020/000134	1.License Holder Name: INVITROGEN BIOSERVICES INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TAQPATH™ COVID-19 COMBO KIT(APPLIED BIOSYSTEMS)-THE TAQPATH™ COVID-19 COMBO KIT IS A REAL-TIME RT-PCR TEST INTENDED FOR THE PRESUMPTIVE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN UPPER AND LOWER RESPIRATORY SPECIMENS (SUCH AS NASOPHARYNGEAL SWABS, NASOPHARYNGEAL, AND BRONCHOALVEOLAR LAVAGE) COLLECTED FROM INDIVIDUALS WHO MEET CDC CRITERIA FOR SARS-COV-2 TESTING.
527	IMP/IVD/2020/000139	1.License Holder Name: ATHENESE-DX PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIASURE SARS-COV-2 REAL TIME PCR DETECTION KIT(VIASURE)-VIASURE SARS-COV-2 REAL TIME PCR DETECTION KIT IS DESIGNED FOR THE SPECIFIC IDENTIFICATION AND DIFFERENTIATION OF 2019 NOVEL CORONAVIRUS (SARS-COV-2) IN RESPIRATORY SAMPLES FROM PATIENTS WITH SIGNS AND SYMPTOMS OF COVID-19 INFECTION. THIS TEST IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF SARS-COV-2 IN COMBINATION WITH CLINICAL AND EPIDEMIOLOGICAL RISK FACTORS. RNA IS EXTRACTED FROM RESPIRATORY SPECIMENS, AMPLIFIED USING RT-PCR AND DETECTED USING FLUORESCENT REPORTER DYE PROBES SPECIFIC FOR SARS-COV-2.

528	IMP/IVD/2020/000143	1.License Holder Name: ALTONA DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHIKUNGUNYA RT-PCR KIT 2.0(REALSTAR®)-THE REALSTAR® CHIKUNGUNYA RT-PCR KIT 2.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE QUALITATIVE DETECTION OF CHIKUNGUNYA VIRUS (CHIKV) SPECIFIC RNA.,SARS-COV-2 RT-PCR KIT 1.0 (REALSTAR)-THE REALSTAR® SARS-COV-2 RT-PCR KIT 1.0 IS A REAGENT SYSTEM, BASED ON REAL- TIME PCR TECHNOLOGY, FOR THE QUALITATIVE DETECTION AND DIFFERENTIATION OF LINEAGE B-BETACORONAVIRUS (B-COV) AND SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) SPECIFIC RNA,DENGUE RT-PCR KIT 3.0(REALSTAR®)-THE REALSTAR® DENGUE RT-PCR KIT 3.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REALTIME PCR TECHNOLOGY, FOR THE QUALITATIVE DETECTION OF DENGUE VIRUS (DENV) SPECIFIC RNA.,ALTOSTAR® PURIFICATION KIT 1.5 (ALTOSTAR®)-THE ALTOSTAR® PURIFICATION KIT 1.5 USES MAGNETIC PARTICLE TECHNOLOGY AND IS INTENDED TO BE USED FOR THE AUTOMATED ISOLATION AND PURIFICATION OF NUCLEIC ACIDS FROM SPECIFIED BIOLOGICAL SPECIMENS FOR IN VITRO DIAGNOSTIC PURPOSES. THE PRODUCT IS DESIGNED FOR USE WITH THE ALTOSTAR® AUTOMATION SYSTEM AM16, THE ALTOSTAR® INTERNAL CONTROL 1.5 AND ALTONA DIAGNOSTICS' KITS AND REAGENTS SPECIFIED FOR USE WITH THE ALTOSTAR® PURIFICATION KIT 1.5,ALTOSTAR® INTERNAL CONTROL 1.5(ALTOSTAR®)-THE ALTOSTAR® INTERNAL CONTROL 1.5 IS INTENDED TO BE USED AS A NUCLEIC ACID PURIFICATION, AMPLIFICATION AND DETECTION CONTROL FOR IN VITRO DIAGNOSTIC PURPOSES. IT IS DESIGNED FOR USE WITH THE ALTOSTAR® PURIFICATION KIT 1.5 AND ALTONA DIAGNOSTICS REAL-TIME PCR KITS SPECIFIED FOR USE WITH THE ALTOSTAR® INTERNAL CONTROL 1.5.,HBV PCR KIT 1.5(ALTOSTAR®)-THE ALTOSTAR® HBV PCR KIT 1.5 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE DETECTION AND QUANTIFICATION OF HUMAN HEPATITIS B VIRUS (HBV) SPECIFIC DNA (GENOTYPES A TO H) IN HUMAN EDTA PLASMA. THE ALTOSTAR® HBV PCR KIT 1.5 IS CONFIGURED FOR USE WITH THE CFX96™ DEEP WELL DX SYSTEM (BIO-RAD) IN COMBINATION WITH THE ALTOSTAR® AUTOMATION SYSTEM AM16, THE ALTOSTAR® PURIFICATION KIT 1.5 AND THE ALTOSTAR® INTERNAL CONTROL 1.5. THE RESULTS GENERATED WITH THE ALTOSTAR® HBV PCR KIT 1.5 HAVE TO BE INTERPRETED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS. THE ALTOSTAR® HBV PCR KIT 1.5 IS INTENDED FOR USE BY PROFESSIONAL USERS TRAINED IN MOLECULAR BIOLOGICAL TECHNIQUES.,HCV RT-PCR KIT 1.5

	(ALTOSTAR®)-THE ALTOSTAR® HCV RT-PCR KIT 1.5 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE DETECTION AND QUANTIFICATION OF HUMAN HEPATITIS C VIRUS (HCV) SPECIFIC RNA (GENOTYPES 1 TO 6) IN HUMAN EDTA PLASMA. THE ALTOSTAR® HCV RT-PCR KIT 1.5 IS CONFIGURED FOR USE WITH THE CFX96™ DEEP WELL DX SYSTEM (BIO-RAD) IN COMBINATION WITH THE ALTOSTAR® AUTOMATION SYSTEM AM16, THE ALTOSTAR® PURIFICATION KIT 1.5 AND THE ALTOSTAR® INTERNAL CONTROL 1.5. THE RESULTS GENERATED WITH THE ALTOSTAR® HCV RT-PCR KIT 1.5 HAVE TO BE INTERPRETED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS. THE ALTOSTAR® HCV RT-PCR KIT 1.5 IS INTENDED FOR USE BY PROFESSIONAL USERS TRAINED IN MOLECULAR BIOLOGICAL TECHNIQUES.,ADENOVIRUS PCR KIT 1.0(REALSTAR®)-THE REALSTAR® ADENOVIRUS PCR KIT 1.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REALTIME PCR TECHNOLOGY, FOR THE DETECTION AND QUANTIFICATION OF HUMAN ADENOVIRUS (HADV) SPECIFIC DNA.,BORDETELLA PCR KIT 1.0(REALSTAR®)-THE REALSTAR® BORDETELLA PCR KIT 1.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REALTIME PCR TECHNOLOGY, FOR THE QUALITATIVE DETECTION AND DIFFERENTIATION OF BORDETELLA PERTUSSIS AND BORDETELLA PARAPERTUSSIS SPECIFIC DNA.,HEV RT-PCR KIT 2.0 (REALSTAR®)-THE REALSTAR® HEV RT-PCR KIT 2.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REALTIME PCR TECHNOLOGY, FOR THE DETECTION AND QUANTIFICATION OF HEPATITIS E VIRUS (HEV) SPECIFIC RNA.,MERS -COV RT-PCR KIT 1.0(REALSTAR®)-THE REALSTAR® MERS-COV RT-PCR KIT 1.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE QUALITATIVE DETECTION OF MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS (MERS-COV) SPECIFIC RNA.,PARVOVIRUS B19 PCR KIT 1.0(REALSTAR®)-THE REALSTAR® PARVOVIRUS B19 PCR KIT 1.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE DETECTION AND QUANTIFICATION OF PARVOVIRUS B19 SPECIFIC DNA.,RSV RT-PCR KIT 3.0(REALSTAR®)-THE REALSTAR® RSV RT-PCR KIT 3.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE QUALITATIVE DETECTION OF RESPIRATORY SYNCYTIAL VIRUS (RSV) SPECIFIC RNA. FURTHERMORE, THE TEST ALLOWS THE DIFFERENTIATION BETWEEN RSV SUBTYPE A (RSV A) AND RSV SUBTYPE B (RSV B) SPECIFIC RNA.,CLOSTRIDIUM DIFFICILE PCR KIT 2.0(REALSTAR®)-THE REALSTAR® CLOSTRIDIUM DIFFICILE PCR KIT 2.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE QUALITATIVE DETECTION AND DIFFERENTIATION OF TOXIN A (TCDA) AND TOXIN B (TCDB) SPECIFIC

		DNA OF CLOSTRIDIUM DIFFICILE.
529	IMP/IVD/2020/000145	1.License Holder Name: ERIS LIFESCIENCES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 NUCLEIC ACID DETECTION KIT (FLUORESCENT PCR)-SIMULTANEOUS DETECTION OF THE THREE GENES OF ORF1AB / E / N IN 2019-NCOV, MEETING THE REQUIREMENTS OF RELEVANT DOCUMENTS OF THE WORLD HEALTH ORGANIZATION (WHO),SARS-COV-2 IGM/IGG ANTIBODY KIT-FOR IN VITRO QUALITATIVE DETERMINATION OF SARS-COV-2 IGM/IGG ANTIBODIES IN NOVEL CORONAVIRUS-INFECTED SUSPECTED PNEUMONIA CASES, SUSPECTED CLUSTERED CASES, AND OTHER SERUM, PLASMA OR WHOLE BLOOD SAMPLES TO BE SCREENED FOR NOVEL CORONAVIRUS INFECTION
530	IMP/IVD/2020/000147	1.License Holder Name: M/S. CPC DIAGNOSTICS PVT, LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IFLASH-2019-NCOV NAB (IFLASH)-THE IFLASH-2019-NCOV NEUTRALIZATION ANTIBODY (NAB) ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF 2019-NCOV NEUTRALIZATION ANTIBODY IN HUMAN SERUM AND PLASMA USING THE AUTOMATED IFLASH IMMUNOASSAY ANALYZER. IT IS INTENDED TO BE USED FOR EVALUATION OF NEUTRALIZING ANTIBODIES IN PATIENTS WHO HAD RECOVERED FROM COVID-19 OR MONITOR NEUTRALIZATION ANTIBODIES IN PEOPLE WHO HAD COVID-19 VACCINATION. IFLASH-2019-NCOV NEUTRALIZATION ANTIBODY (NAB) ASSAY IS NOT INTENDED TO BE USED FOR DIAGNOSE OR TO EXCLUDE 2019-NCOV OR SARS-COV-2 INFECTION., SARS-COV-2 IGG(IFLASH)-THE IFLASH-SARS-COV-2 IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR QUALITATIVE DETERMINATION OF IGG ANTIBODY TO SARS-COV-2 IN HUMAN SERUM OR PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER. THE IFLASH-SARS-COV-2 IGG AIDS IN THE DIAGNOSIS OF SARS-COV-2 INFECTION AND THE DETERMINATION OF IMMUNITY.,SARS-COV-2 IGM(IFLASH)-THE IFLASH-SARS-COV-2 IGM ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR QUALITATIVE DETERMINATION OF IGM ANTIBODY TO SARS-COV-2 IN HUMAN SERUM OR PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER. THE IFLASH-SARS-COV-2 IGM AIDS IN THE DIAGNOSIS OF SARS-COV-2 INFECTION AND THE DETERMINATION OF IMMUNITY.

531	IMP/IVD/2020/000157	1.License Holder Name: APOLLO HOSPITALS ENTERPRISE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID 19 TEST KIT-COVID 19 TEST KIT
532	IMP/IVD/2020/000160	1.License Holder Name: GASTROLAB INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MUTACLEAN® MAG SWAB/RESPIRA EXTRACTION KIT-THE MUTACLEAN® MAG SWAB/RESPIRA NUCLEIC ACID EXTRACTION KIT IS DESIGNED FOR RAPID MANUAL AND AUTOMATED PURIFICATION OF NUCLEIC ACIDS FROM RESPIRATORY SAMPLES (E. G. ORAL SWABS, BRONCHOALVEOLAR LAVAGE, SPUTUM).,MUTAPLEX CORONAVIRUS (MUTAPLEX CORONAVIRUS)-THE MUTAPLEX® CORONAVIRUS (SARSCOV- 2) REAL TIME RT-PCR KIT IS A SCREENING ASSAY FOR THE SIMULTANEOUS DETECTION OF RNA OF NOVEL CORONAVIRUS (SARS-COV-2) AND OTHER BETACORONAVIRUSES (E.G. MERS-COV, SARS-COV) EXTRACTED FROM BIOLOGICAL SPECIMENS.
533	IMP/IVD/2020/000161	1.License Holder Name: M/S SOLUTION ONE, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALLPLEX™ 2019-NCOV ASSAY(ALLPLEX™)-ALLPLEXTM 2019-NCOV ASSAY IS IN VITRO DIAGNOSTIC MEDICAL DEVICE DESIGNED FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS (2019-NCOV) WITH REAL-TIME REVERSE TRANSCRIPTION PCR FROM SPUTUM, NASOPHARYNGEAL ASPIRATE, THROAT & NASOPHARYNGEAL SWAB, AND BRONCHOALVEOLAR LAVAGE.

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534	IMP/IVD/2020/000167	1.License Holder Name: MYLAN PHARMACEUTICALS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD)(WONDFO)-SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD) IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) IGG/IGM ANTIBODY IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SAMPLE. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY SARS-COV-2. THE TEST PROVIDES PRELIMINARY TEST RESULTS. NEGATIVE RESULTS DON'T PRECLUDE SARS-COV-2 INFECTION AND THEY CANNOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISION. FOR IN VITRO DIAGNOSTIC USE ONLY. FOR PROFESSIONAL USE ONLY.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

535	IMP/IVD/2020/000168	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD™ UNIVERSAL VIRAL TRANSPORT, 1 ML VIAL(BD™ UNIVERSAL VIRAL TRANSPORT, 1 ML VIAL)-BD™ UNIVERSAL VIRAL TRANSPORT SYSTEM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. THIS SYSTEM CAN BE PROCESSED USING STANDARD CLINICAL LABORATORY OPERATING PROCEDURES FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL AND UREAPLASMAL CULTURE.,BD™ UNIVERSAL VIRAL TRANSPORT KIT, 3 ML, FLOCKED FLEXIBLE MINITIP (BD™ UNIVERSAL VIRAL TRANSPORT KIT, 3 ML, FLOCKED FLEXIBLE MINITIP)-BD™ UNIVERSAL VIRAL TRANSPORT SYSTEM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. THIS SYSTEM CAN BE PROCESSED USING STANDARD CLINICAL LABORATORY OPERATING PROCEDURES FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL AND UREAPLASMAL CULTURE.,BD™ UNIVERSAL VIRAL TRANSPORT KIT, 3 ML, FLOCKED REGULAR AND FLEXIBLE MINITIP(BD™ UNIVERSAL VIRAL TRANSPORT KIT, 3 ML, FLOCKED REGULAR AND FLEXIBLE MINITIP)-BD™ UNIVERSAL VIRAL TRANSPORT SYSTEM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. THIS SYSTEM CAN BE PROCESSED USING STANDARD CLINICAL LABORATORY OPERATING PROCEDURES FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL AND UREAPLASMAL CULTURE.,BD™ UNIVERSAL VIRAL TRANSPORT KIT, 1ML, FLOCKED FLEXIBLE MINITIP(BD™ UNIVERSAL VIRAL TRANSPORT KIT, 1ML, FLOCKED FLEXIBLE MINITIP)-BD™ UNIVERSAL VIRAL TRANSPORT SYSTEM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. THIS SYSTEM CAN BE PROCESSED USING STANDARD CLINICAL LABORATORY OPERATING PROCEDURES FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL AND UREAPLASMAL CULTURE.,BD™ UNIVERSAL VIRAL TRANSPORT COMBO KIT; 3 ML VIAL WITH 1 STERILE REGULAR POLYESTER-TIPPED PLASTIC SWAB AND 1 STERILE WIRE/PLASTIC POLYESTER MINITIP SWAB WITH SCORED SHAFTS(BD™ UNIVERSAL VIRAL TRANSPORT COMBO KIT; 3 ML VIAL WITH 1 STERILE REGULAR POLYESTER-TIPPED PLASTIC SWAB AND 1 STERILE WIRE/PLASTIC POLYESTER MINITIP

	SWAB WITH SCORED SHAFTS)-BD™ UNIVERSAL VIRAL TRANSPORT SYSTEM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. THIS SYSTEM CAN BE PROCESSED USING STANDARD CLINICAL LABORATORY OPERATING PROCEDURES FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL AND UREAPLASMAL CULTURE.,BD™ UNIVERSAL VIRAL TRANSPORT STANDARD KIT; 3 ML VIAL WITH 2 STERILE REGULAR POLYESTER-TIPPED PLASTIC SWABS WITH SCORED SHAFT(BD™ UNIVERSAL VIRAL TRANSPORT STANDARD KIT; 3 ML VIAL WITH 2 STERILE REGULAR POLYESTER-TIPPED PLASTIC SWABS WITH SCORED SHAFT)-BD™ UNIVERSAL VIRAL TRANSPORT SYSTEM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. THIS SYSTEM CAN BE PROCESSED USING STANDARD CLINICAL LABORATORY OPERATING PROCEDURES FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL AND UREAPLASMAL CULTURE.,BD™ UNIVERSAL VIRAL TRANSPORT KIT, 3 ML VIAL(BD™ UNIVERSAL VIRAL TRANSPORT KIT, 3 ML VIAL)-BD™ UNIVERSAL VIRAL TRANSPORT SYSTEM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. THIS SYSTEM CAN BE PROCESSED USING STANDARD CLINICAL LABORATORY OPERATING PROCEDURES FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL AND UREAPLASMAL CULTURE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

536	IMP/IVD/2020/000169	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD MAX ENTERIC PARASITE PANEL(BD MAX ENTERIC PARASITE PANEL)-THE BD MAX ENTERIC PARASITE PANEL PERFORMED ON THE BD MAX SYSTEM IS AN AUTOMATED IN VITRO DIAGNOSTIC TEST FOR THE DIRECT QUALITATIVE DETECTION OF ENTERIC PARASITIC PATHOGENS. THE BD MAX ENTERIC PARASITE PANEL DETECTS NUCLEIC ACIDS FROM: • GIARDIA LAMBLIA • CRYPTOSPORIDIUM (C. HOMINIS AND C. PARVUM ONLY) • ENTAMOEBA HISTOLYTICA TESTING IS PERFORMED ON UNPRESERVED OR 10% FORMALIN-FIXED STOOL SPECIMENS FROM SYMPTOMATIC PATIENTS WITH SUSPECTED GASTROENTERITIS, ENTERITIS OR COLITIS. THE ASSAY IS INTENDED TO AID IN THE DIAGNOSIS OF GASTROINTESTINAL INFECTION WHEN USED IN CONJUNCTION WITH CLINICAL EVALUATION AND OTHER LABORATORY FINDINGS. THE TEST IS PERFORMED DIRECTLY ON THE SPECIMEN, UTILIZING REAL-TIME POLYMERASE CHAIN REACTION (PCR) FOR THE AMPLIFICATION OF SPECIFIC TARGETS. THE TEST UTILIZES FLUOROGENIC GENE-SPECIFIC HYBRIDIZATION PROBES FOR DETECTION OF THE AMPLIFIED DNA. THIS TEST IS INTENDED FOR USE, IN CONJUNCTION WITH CLINICAL PRESENTATION, LABORATORY FINDINGS, AND EPIDEMIOLOGICAL INFORMATION, AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF GIARDIA LAMBLIA, CRYPTOSPORIDIUM HOMINIS AND C. PARVUM, AS WELL AS ENTAMOEBA HISTOLYTICA INFECTIONS. RESULTS OF THIS TEST SHOULD NOT BE USED AS THE SOLE BASIS FOR DIAGNOSIS, TREATMENT, OR OTHER PATIENT MANAGEMENT DECISION. POSITIVE RESULTS DO NOT RULE OUT CO-INFECTION WITH OTHER ORGANISMS THAT ARE NOT DETECTED BY THIS TEST, AND MAY NOT BE THE SOLE OR DEFINITIVE CAUSE OF PATIENT ILLNESS. NEGATIVE RESULTS IN THE SETTING OF CLINICAL ILLNESS COMPATIBLE WITH GASTROENTERITIS AND/OR COLITIS MAY BE DUE TO INFECTION BY PATHOGENS THAT ARE NOT DETECTED BY THIS TEST OR NON-INFECTIOUS CAUSES SUCH AS ULCERATIVE COLITIS, IRRITABLE BOWEL SYNDROME, OR CROHN'S DISEASE.,BDMAX EXK TNA-3(BDMAX EXK TNA-3)-THE BD MAX EXK TNA-3 IS INTENDED TO EXTRACT TOTAL NUCLEIC ACID (TNA) FROM SWAB SPECIMENS IN UNIVERSAL TRANSPORT MEDIUM (UTM). THE TNA EXTRACTION TUBE CONTAINS A SPECIMEN PROCESSING CONTROL SEQUENCE FROM A PROPRIETARY ARMORED RNA QUANT® (ASURAGEN, INC.).* THE BD MAX EXK TNA-3 HAS NOT BEEN VALIDATED FOR USE WITH ANY SPECIFIC TEST METHOD.,BD MAX EXTENDED ENTERIC BACTERIAL PANEL(BD MAX EXTENDED ENTERIC BACTERIAL PANEL)-THE BD MAX™ EXTENDED ENTERIC BACTERIAL PANEL PERFORMED ON THE BD MAX SYSTEM, IS AN AUTOMATED IN

	VITRO DIAGNOSTIC TEST FOR THE DIRECT QUALITATIVE DETECTION AND DIFFERENTIATION OF ENTERIC BACTERIAL PATHOGENS. IT IS USED IN CONJUNCTION WITH THE BD MAX ENTERIC BACTERIAL PANEL AS AN OPTIONAL MASTER MIX. THE BD MAX EXTENDED ENTERIC BACTERIAL PANEL DETECTS NUCLEIC ACIDS FROM • PLESIOMONAS SHIGELLOIDES • VIBRIO (V. VULNIFICUS, V. PARAHAEMOLYTICUS, AND V. CHOLERAE) • ENTEROTOXIGENIC ESCHERICHIA COLI (ETEC) HEAT-LABILE ENTEROTOXIN (LT)/ HEAT-STABLE ENTEROTOXIN (ST) GENES • YERSINA ENTEROCOLITICA TESTING IS PERFORMED ON UNPRESERVED SOFT TO DIARRHEAL OR CARY-BLAIR PRESERVED STOOL SPECIMENS FROM SYMPTOMATIC PATIENTS WITH SUSPECTED ACUTE GASTROENTERITIS, ENTERITIS OR COLITIS. THE TEST IS PERFORMED DIRECTLY ON THE SPECIMEN, UTILIZING REAL-TIME POLYMERASE CHAIN REACTION (PCR) FOR THE AMPLIFICATION OF RELEVANT GENE TARGET DNA. THE TEST UTILIZES FLUOROGENIC GENE-SPECIFIC HYBRIDIZATION PROBES FOR THE DETECTION OF THE AMPLIFIED DNA. THIS TEST IS INTENDED FOR USE, IN CONJUNCTION WITH CLINICAL PRESENTATION, LABORATORY FINDINGS, AND EPIDEMIOLOGICAL INFORMATION, AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF PLESIOMONAS SHIGELLOIDES, VIBRIO (V. VULNIFICUS, V. PARAHAEMOLYTICUS, AND V. CHOLERAE) ENTEROTOXIGENIC ESCHERICHIA COLI (ETEC) LT/ST AND YERSINIA ENTEROCOLITICA INFECTIONS. RESULTS OF THIS TEST SHOULD NOT BE USED AS THE SOLE BASIS FOR DIAGNOSIS, TREATMENT, OR OTHER PATIENT MANAGEMENT DECISIONS. POSITIVE RESULTS DO NOT RULE OUT CO-INFECTION WITH OTHER ORGANISMS THAT ARE NOT DETECTED BY THIS TEST, AND MAY NOT BE THE SOLE OR DEFINITIVE CAUSE OF PATIENT ILLNESS. NEGATIVE RESULTS IN THE SETTING OF CLINICAL ILLNESS COMPATIBLE WITH GASTROENTERITIS MAY BE DUE TO INFECTION BY PATHOGENS THAT ARE NOT DETECTED BY THIS TEST OR NON-INFECTIOUS CAUSES SUCH AS ULCERATIVE COLITIS, IRRITABLE BOWEL SYNDROME, OR CROHN'S DISEASE.,BD MAX PCR CARTRIDGES(BD MAX PCR CARTRIDGES)-THE BD MAX PCR CARTRIDGES IS AN IVD ACCESSORY THAT IS USED IN CONJUNCTION WITH THE BD MAX INSTRUMENT AND USED WITH ALL OF THE BD MAX ASSAYS. IT IS A PLASTIC, MICROFLUIDIC CARTRIDGE INTO WHICH THE SAMPLE IS LOADED AND THE PCR REACTION TAKES PLACE.,BD MAX ENTERIC BACTERIAL PANEL(BD MAX ENTERIC BACTERIAL PANEL)-THE BD MAX™ ENTERIC BACTERIAL PANEL PERFORMED ON THE BD MAX SYSTEM IS AN AUTOMATED IN VITRO DIAGNOSTIC TEST FOR THE DIRECT QUALITATIVE DETECTION AND DIFFERENTIATION OF ENTERIC BACTERIAL PATHOGENS. THE BD MAX ENTERIC BACTERIAL PANEL DETECTS NUCLEIC ACIDS FROM: • SALMONELLA SPP. •

	CAMPYLOBACTER SPP. (JEJUNI AND COLI) • SHIGELLA SPP. / ENTEROINVASIVE E. COLI (EIEC) • SHIGA TOXIN 1 (STX1) / SHIGA TOXIN 2 (STX2) GENES (FOUND IN SHIGA TOXIN-PRODUCING E. COLI [STEC]) AS WELL AS SHIGELLA DYSENTERIAE, WHICH CAN POSSESS A SHIGA TOXIN GENE (STX) THAT IS IDENTICAL TO THE STX1 GENE OF STEC. TESTING IS PERFORMED ON UNPRESERVED SOFT TO DIARRHEAL STOOL SPECIMENS OR CARY-BLAIR PRESERVED STOOL SPECIMENS FROM SYMPTOMATIC PATIENTS WITH SUSPECTED ACUTE GASTROENTERITIS, ENTERITIS OR COLITIS. THE TEST IS PERFORMED DIRECTLY ON THE SPECIMEN, UTILIZING REAL-TIME POLYMERASE CHAIN REACTION (PCR) FOR THE AMPLIFICATION OF SPAO, A CAMPYLOBACTER SPECIFIC TUF GENE SEQUENCE, IPAH AND STX1/STX2. THE TEST UTILIZES FLUOROGENIC SEQUENCE-SPECIFIC HYBRIDIZATION PROBES FOR DETECTION OF THE AMPLIFIED DNA. THIS TEST IS INTENDED FOR USE, IN CONJUNCTION WITH CLINICAL PRESENTATION, LABORATORY FINDINGS, AND EPIDEMIOLOGICAL INFORMATION, AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF SALMONELLA, SHIGELLA/EIEC, CAMPYLOBACTER AND SHIGA TOXIN-PRODUCING E. COLI (STEC) INFECTIONS. RESULTS OF THIS TEST SHOULD NOT BE USED AS THE SOLE BASIS FOR DIAGNOSIS, TREATMENT, OR OTHER PATIENT MANAGEMENT DECISIONS. POSITIVE RESULTS DO NOT RULE OUT CO-INFECTION WITH OTHER ORGANISMS THAT ARE NOT DETECTED BY THIS TEST, AND MAY NOT BE THE SOLE OR DEFINITIVE CAUSE OF PATIENT ILLNESS. NEGATIVE RESULTS IN THE SETTING OF CLINICAL ILLNESS COMPATIBLE WITH GASTROENTERITIS MAY BE DUE TO INFECTION BY PATHOGENS THAT ARE NOT DETECTED BY THIS TEST OR NON-INFECTIOUS CAUSES SUCH AS ULCERATIVE COLITIS, IRRITABLE BOWEL SYNDROME, OR CROHN'S DISEASE.,BD MAX STAPHSR(BD MAX STAPHSR)-THE BD MAX™ STAPHSR ASSAY PERFORMED ON THE BD MAX SYSTEM IS AN AUTOMATED QUALITATIVE IN VITRO DIAGNOSTIC TEST FOR THE DIRECT DETECTION AND DIFFERENTIATION OF STAPHYLOCOCCUS AUREUS (SA) DNA AND METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) DNA FROM NASAL SWABS IN PATIENTS AT RISK FOR NASAL COLONIZATION. THE TEST UTILIZES REAL-TIME POLYMERASE CHAIN REACTION (PCR) FOR THE AMPLIFICATION OF MRSA/SA DNA AND FLUOROGENIC TARGET-SPECIFIC HYBRIDIZATION PROBES FOR THE DETECTION OF THE AMPLIFIED DNA. THE BD MAX STAPHSR ASSAY IS INTENDED TO AID IN THE PREVENTION AND CONTROL OF MRSA AND SA INFECTIONS IN HEALTHCARE SETTINGS. IT IS NOT INTENDED TO DIAGNOSE MRSA OR SA INFECTIONS NOR GUIDE OR MONITOR TREATMENT FOR MRSA/SA INFECTIONS. A NEGATIVE RESULT DOES NOT PRECLUDE NASAL COLONIZATION. CONCOMITANT CULTURES ARE NECESSARY TO RECOVER

	ORGANISMS FOR EPIDEMIOLOGICAL TYPING OR FOR FURTHER SUSCEPTIBILITY TESTING,BD MAX CDIFF(BD MAX CDIFF)-THE BD MAX™ CDIFF ASSAY PERFORMED ON THE BD MAX SYSTEM IS AN AUTOMATED IN VITRO DIAGNOSTIC TEST FOR THE DIRECT, QUALITATIVE DETECTION OF THE CLOSTRIDIOIDES DIFFICILE TOXIN B GENE (TCDB) IN HUMAN LIQUID OR SOFT STOOL SPECIMENS FROM PATIENTS SUSPECTED OF HAVING CLOSTRIDIOIDES DIFFICILE INFECTION (CDI). THE TEST, PERFORMED DIRECTLY ON THE SPECIMEN, UTILIZES REAL-TIME POLYMERASE CHAIN REACTION (PCR) FOR THE AMPLIFICATION OF CLOSTRIDIOIDES DIFFICILE TOXIN B GENE DNA AND FLUOROGENIC TARGET-SPECIFIC HYBRIDIZATION PROBES FOR THE DETECTION OF THE AMPLIFIED DNA. THE BD MAX CDIFF ASSAY IS INTENDED TO AID IN THE DIAGNOSIS OF CDI,BD MAX™ MRSA XT(BD MAX™ MRSA XT)-THE BD MAX™ MRSA XT ASSAY PERFORMED ON THE BD MAX SYSTEM IS AN AUTOMATED QUALITATIVE IN VITRO DIAGNOSTIC TEST FOR THE DIRECT DETECTION OF METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) DNA FROM NASAL SWABS IN PATIENTS AT RISK FOR NASAL COLONIZATION. THE TEST UTILIZES REAL-TIME POLYMERASE CHAIN REACTION (PCR) FOR THE AMPLIFICATION OF MRSA DNA AND FLUOROGENIC TARGET-SPECIFIC HYBRIDIZATION PROBES FOR THE DETECTION OF THE AMPLIFIED DNA. THE BD MAX MRSA XT ASSAY IS INTENDED TO AID IN THE PREVENTION AND CONTROL OF MRSA INFECTIONS IN HEALTHCARE SETTINGS. IT IS NOT INTENDED TO DIAGNOSE MRSA INFECTIONS NOR GUIDE OR MONITOR TREATMENT FOR MRSA INFECTIONS. A NEGATIVE RESULT DOES NOT PRECLUDE NASAL COLONIZATION. CONCOMITANT CULTURES ARE NECESSARY TO RECOVER ORGANISMS FOR EPIDEMIOLOGICAL TYPING OR FOR FURTHER SUSCEPTIBILITY TESTING.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

537	IMP/IVD/2020/000170	1.License Holder Name: GLAND PHARMA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (2019-NCOV) RT- PCR DETECTION KIT(FOSUN 2019-NCOV QPCR)-THIS PRODUCT IS INTENDED FOR THE RAPID DETECTION OF 2019-NCOV BY TAQMAN MULTIPLEX REAL-TIME PCR IN HUMAN THROAT SWAB OR SPUTUM SAMPLES.,NUCLEIC ACID EXTRACTION AND PURIFICATION KIT(FOSUN ULTRAPURE NA)-THIS PRODUCT IS INTENDED FOR THE EXTRACTION, ENRICHMENT AND PURIFICATION OF NUCLEIC ACIDS (DNA/RNA) FROM SERUM, PLASMA, WHOLE BLOOD, NASAL SWAB, PHARYNGEAL SWAB, NASOPHARYNGEAL SWAB AND UROGENITAL SWAB SAMPLES. THE PURIFIED NUCLEIC ACID IS USED FOR MOLECULAR DIAGNOSTIC APPLICATION, AND NOT INTENDED FOR THE DIRECT DIAGNOSIS, PREVENTION, OR TREAT OF A DISEASE.,NOVEL CORONAVIRUS (2019-NCOV) IGG/IGM RAPID TEST KIT(FOSUN 2019-NCOV IGM/IGG RAPID)-THE PRODUCT IS A SOLID PHASE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE RAPID, QUALITATIVE/ SEMI-QUANTITATIVE AND DIFFERENTIAL DETECTION OF IGG AND IGM ANTIBODIES TO 2019-NCOV IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.,PRESERVATION BUFFER (1XHANK'S) (FOSUN SWAB BUFFER-HANK'S)-THIS PRODUCT IS INTENDED FOR THE COLLECTION, PRESERVATION AND TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING CELL OR TISSUE USED FOR PATHOGEN ANALYSIS FROM THE COLLECTION SITE TO THE LABORATORY. IT IS ALSO SUITABLE FOR CELL CULTURE APPLICATION. THE PRODUCT IS USED FOR IN VITRO DIAGNOSTIC APPLICATION AND NOT INTENDED FOR THE PREVENTION OR TEST OF A DISEASE.,NUCLEIC ACID EXTRACTION AND PURIFICATION KIT (FOSUN MAGPURE NA)-THIS PRODUCT IS INTENDED FOR THE EXTRACTION, ENRICHMENT AND PURIFICATION OF NUCLEIC ACIDS (DNA/RNA) FROM SERUM, PLASMA, WHOLE BLOOD, URINE, SPUTUM, CEREBROSPINAL FLUID, PLEURAL EFFUSION, MILK, NOSE SWAB, OROPHARYNGEAL SWAB, NASOPHARYNGEAL SWAB AND UROGENITAL SWAB SAMPLES. THE PURIFIED NUCLEIC ACID IS USED FOR MOLECULAR DIAGNOSTIC APPLICATION, AND NOT INTENDED FOR THE DIRECT DIAGNOSIS, PREVENTION, OR TREAT OF A DISEASE. , PRESERVATION BUFFER (5XHANK'S)(FOSUN SWAB BUFFER-HANK'S)-THIS PRODUCT IS INTENDED FOR THE COLLECTION, PRESERVATION AND TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING CELL OR TISSUE USED FOR PATHOGEN ANALYSIS FROM THE COLLECTION SITE TO THE LABORATORY. IT IS ALSO SUITABLE FOR CELL CULTURE APPLICATION. THE PRODUCT IS USED FOR IN VITRO DIAGNOSTIC APPLICATION AND NOT INTENDED FOR THE PREVENTION OR TEST OF A DISEASE.

538	IMP/IVD/2020/000171	1.License Holder Name: DEEP MEDITECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLUCO DOT BLOOD GLUCOSE TEST STRIPS(GLUCO DOT)-THE GLUCO DOT BLOOD GLUCOSE TEST STRIPS ARE USED WITH THE GLUCO DOT BLOOD GLUCOSE METER FOR QUANTITATIVELY MEASURING GLUCOSE (SUGAR) IN WHOLE BLOOD OBTAINED FROM THE FINGERTIP, PALM AND FOREARM.,GLUCO DOT CONTROL SOLUTION (HIGH)(GLUCO DOT) -THE CONTROL SOLUTION IS A DESIRED AQUEOUS GLUCOSE SOLUTION WITH SMALL AMOUNTS OF NON-REACTIVE INGREDIENTS AND FOOD COLORING FOR VERIFYING THE ACCURACY OF THE ENTIRE BLOOD GLUCOSE MONITORING SYSTEM. THE CONTROL SOLUTION TEST EXAMINES THE PERFORMANCE OF THE GLUCOSE METER, TEST STRIP, AND YOUR OPERATING TECHNIQUES.,GLUCO DOT CONTROL SOLUTION (LOW)(GLUCO DOT)-THE CONTROL SOLUTION IS A DESIRED AQUEOUS GLUCOSE SOLUTION WITH SMALL AMOUNTS OF NON-REACTIVE INGREDIENTS AND FOOD COLORING FOR VERIFYING THE ACCURACY OF THE ENTIRE BLOOD GLUCOSE MONITORING SYSTEM. THE CONTROL SOLUTION TEST EXAMINES THE PERFORMANCE OF THE GLUCOSE METER, TEST STRIP, AND YOUR OPERATING TECHNIQUES.,GLUCO DOT CONTROL SOLUTION (NORMAL)(GLUCO DOT)-THE CONTROL SOLUTION IS A DESIRED AQUEOUS GLUCOSE SOLUTION WITH SMALL AMOUNTS OF NON-REACTIVE INGREDIENTS AND FOOD COLORING FOR VERIFYING THE ACCURACY OF THE ENTIRE BLOOD GLUCOSE MONITORING SYSTEM. THE CONTROL SOLUTION TEST EXAMINES THE PERFORMANCE OF THE GLUCOSE METER, TEST STRIP, AND YOUR OPERATING TECHNIQUES.

539	IMP/IVD/2020/000175	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NUCLEIC ACID EXTRACTION REAGENT(NA)-IT IS USED FOR THE EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS FROM HUMAN WHOLE BLOOD, PLASMA /SERUM, ORAL SWAB, SALIVA, SPUTUM, ALVEOLAR LAVAGE FLUID AND OTHER SAMPLES. THE PROCESSED PRODUCTS ARE USED FOR CLINICAL IN VITRO DETECTION.,NOVEL CORONAVIRUS 2019-NCOV PNEUMONIA NUCLEIC ACID DETECTION KIT(NA)-THIS KIT IS USED FOR QUANTITATIVE DETECTION IN VITRO OF ORF1AB AND N GENES OF NOVEL CORONAVIRUS 2019-NCOV WHICH WERE FOUND IN THROAT SWAB, SPUTUM AND ALVEOLAR LAVAGE FLUID SAMPLES OF SUSPECTED CASES OF PNEUMONIA, SUSPECTED CASES OF CLUSTERING, AND OTHER PATIENTS WHO NEED TO CARRY OUT DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS OF NOVEL CORONAVIRUS 2019-NCOV INFECTION.
540	IMP/IVD/2020/000176	1.License Holder Name: GENETIX BIOTECH ASIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IVD KIT FOR COVID-19 (GENESIG® REAL-TIME PCR CORONAVIRUS COVID-19 (CE IVD) KIT)-INTENDED TO BE USED TO ACHIEVE QUALITATIVE DETECTION OF SARS-COV-2 VIRAL RNA EXTRACTED FROM NASOPHARYNGEAL SWABS, OROPHARYNGEAL SWABS AND SPUTUM FROM PATIENTS IN ASSOCIATION WITH A CE IVD EXTRACTION SYSTEM AND THE DESIGNATED PCR PLATFORMS. THE KIT IS INTENDED FOR USE BY LABORATORY TRAINED PERSONNEL
541	IMP/IVD/2020/000179	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTI-SARS-COV-2 RAPID TEST(NA)-THIS ASSAY IS BASED ON A COLLOIDAL GOLD METHOD FOR THE RAPID, QUALITATIVE DETERMINATION OF ANTI-SARS-COV-2 (IGG/IGM ANTIBODIES OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.

542	IMP/IVD/2020/000180	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 S-RBD IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN-VITRO CHEMILUMINESCENCE IMMUNO ASSAY FOR THE QUANTITATIVE DETERMINATION OF S-RBD IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,MAGLUMI 2019-NCOV IGM (CLIA)(NA)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGM ANTIBODIES TO NOVEL CORONAVIRUS (2019-NCOV IGM) IN HUMAN SERUM OR PLASMA., SARS-COV-2 NEUTRALIZING ANTIBODY (CLIA)(MAGLUMI® SARS-COV-2 NEUTRALIZING ANTIBODY (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF NEUTRALIZING ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER, AND THE ASSAY IS USED FOR AN AID IN IDENTIFYING INDIVIDUALS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS-COV-2, INDICATING RECENT OR PRIOR INFECTION.,MAGLUMI STARTER KIT 1+2(NA)-THE STARTER KIT IS REQUIRED TO REACT WITH LABELED ABEI, WHICH WILL GENERATE THE LIGHT SIGNAL. (ACCESSORIES OF CORONAVIRUS IVD KITS "MAGLUMI 2019-NCOV IGM (CLIA) & MAGLUMI 2019-NCOV IGG (CLIA)". ,MAGLUMI 2019-NCOV IGG (CLIA)(NA)-VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG ANTIBODIES TO NOVEL CORONAVIRUS (2019-NCOV IGG) IN HUMAN SERUM OR PLASMA.,MAGLUMI WASH CONCENTRATES (NA)-WASH LIQUID IS REQUIRED TO WASH CUVETTES AND PIPETTING. (ACCESSORIES OF CORONAVIRUS IVD KITS "MAGLUMI 2019-NCOV IGM (CLIA) & MAGLUMI 2019-NCOV IGG (CLIA)".,MAGLUMI LIGHT CHECK(NA)-LCS (LC-LE AND LC-RI), TOGETHER WITH BGW, ARE USED TO CHECK WHETHER THE ANALYZER IS IN GOOD STATUS EVERY MORNING. (ACCESSORIES OF CORONAVIRUS IVD KITS "MAGLUMI 2019-NCOV IGM (CLIA) & MAGLUMI 2019-NCOV IGG (CLIA)".,MAGLUMI TUBING CLEANING SOLUTION(NA)-THE MAGLUMI SYSTEM TUBING CLEANING SOLUTION IS USEFUL TO MINIMIZE REAGENT CARRYOVER BY REDUCING PROTEIN IN THE TUBING, AND IMPROVE ROUTINE MAINTENANCE OF THE MAGLUMI SYSTEM. (ACCESSORIES OF CORONAVIRUS IVD KITS "MAGLUMI 2019-NCOV IGM (CLIA) & MAGLUMI 2019-NCOV IGG (CLIA)".

543	IMP/IVD/2020/000181	1.License Holder Name: THERMO FISHER SCIENTIFIC INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROTESTTM M4RT® (REMEL)-"REMEL MICROTEST™ M4RT® IS A LIQUID MEDIUM RECOMMENDED FOR THE TRANSPORT OF CLINICAL SPECIMENS TO THE LABORATORY FOR MICROBIOLOGICAL PROCEDURES FOR VIRAL AND CHLAMYDIAL AGENTS" ,MICROTEST M4-RT TUBE FOR THE TRANSPORT OF VIRUS AND CHLAMYDIA(REMEL)-REMEL MICROTEST M4RT IS A LIQUID MEDIUM RECOMMENDED FOR THE TRANSPORT OF CLINICAL SPECIMENS TO THE LABORATORY FOR MICROBIOLOGICAL PROCEDURES FOR VIRAL AND CHLAMYDIAL AGENTS.,YEASTONE BROTH(SENSITITRE)-A MEDIUM FOR THE SUSPENSION OF MICRO-ORGANISMS ISOLATED FROM CLINICAL SAMPLES FOR THE INOCULATION OF THE SENSITITRE YEASTONE PANELS AS PART OF THE THERMO FISHER SENSITITRE SYSTEM FOR IN VITRO ANTIMICROBIAL SUSCEPTIBILITY TESTING.,MICROTEST M4RT FOR THE TRANSPORT OF VIRUSES AND CHLAMYDIA(REMEL)-REMEL MICROTEST M4RT IS A LIQUID MEDIUM RECOMMENDED FOR THE TRANSPORT OF CLINICAL SPECIMENS TO THE LABORATORY FOR MICROBIOLOGICAL PROCEDURES FOR VIRAL AND CHLAMYDIAL AGENTS.,CATION ADJUSTED MULLER-HINTON BROTH WITH TES (SENSITITRE)-A MEDIUM FOR THE SUSPENSION OF MICRO-ORGANISMS ISOLATED FROM CLINICAL SAMPLES FOR THE INOCULATION OF THE SENSITITRE NON-FASTIDIOUS AND RAPID MYCOBACTERIA PANELS AS PART OF THE THERMO FISHER SENSITITRE SYSTEM FOR IN VITRO ANTIMICROBIAL SUSCEPTIBILITY TESTING.,MICROTEST M4RT KIT W/ MICROTIP FLOCKED KIT. FOR THE TRANSPORT OF VIRUSES AND CHLAMYDIA(REMEL)-REMEL MICROTEST M4RT IS A LIQUID MEDIUM RECOMMENDED FOR THE TRANSPORT OF CLINICAL SPECIMENS TO THE LABORATORY FOR MICROBIOLOGICAL PROCEDURES FOR VIRAL AND CHLAMYDIAL AGENTS.,REDOX1(VERSATREK)-A BOTTLE CONTAINING CULTURE MEDIA WHICH CAN BE USED MANUALLY OR IN THE VERSATREK SYSTEM FOR CULTIVATING AND RECOVERING MICROORGANISMS, ESPECIALLY BACTERIA AND YEASTS FROM BLOOD AND OTHER NORMALLY STERILE BODY FLUIDS.,MICROTEST M4 FOR THE TRANSPORT OF VIRUS AND CHLAMYDIA(REMEL)-REMEL MICROTEST M4 IS A LIQUID MEDIUM RECOMMENDED FOR THE TRANSPORT OF CLINICAL SPECIMENS TO THE LABORATORY FOR MICROBIOLOGICAL PROCEDURES FOR VIRUS, CHLAMYDIA AND MYCOPLASMAS, WHICH INCLUDES MYCOPLASMAS AND UREAPLASMA SPECIES,FOR THE TRANSPORT OF VIRUS.(M4RT MICROTEST)-REMEL MICROTEST M4RT IS A LIQUID MEDIUM RECOMMENDED FOR THE TRANSPORT OF CLINICAL SPECIMENS TO THE LABORATORY FOR MICROBIOLOGICAL

	PROCEDURES FOR VIRUS.,MICROTEST M4 -RT FOR THE TRANSPORT OF VIRUS AND CHLAMYDIA(REMEL)-REMEL MICROTEST M4RT IS A LIQUID MEDIUM RECOMMENDED FOR THE TRANSPORT OF CLINICAL SPECIMENS TO THE LABORATORY FOR MICROBIOLOGICAL PROCEDURES FOR VIRAL AND CHLAMYDIAL AGENTS.,FOR THE TRANSPORT OF VIRUS AND CHLAMYDIA(M4RT MICROTEST)-REMEL MICROTEST M4RT IS A LIQUID MEDIUM RECOMMENDED FOR THE TRANSPORT OF CLINICAL SPECIMENS TO THE LABORATORY FOR MICROBIOLOGICAL PROCEDURES FOR VIRUS AND CHLAMYDIA., MICROTEST M4RT KIT SWABS (FLOCKED) FOR THE TRANSPORT OF VIRUS AND CHLAMYDIA(REMEL)-REMEL MICROTEST M4RT IS A LIQUID MEDIUM RECOMMENDED FOR THE TRANSPORT OF CLINICAL SPECIMENS TO THE LABORATORY FOR MICROBIOLOGICAL PROCEDURES FOR VIRAL AND CHLAMYDIAL AGENTS.,MYCO PVNA (VERSATREK)-A BOTTLE CONTAINING ANTIBIOTICS USED IN THE VERSATREK SYSTEM FOR THE RECOVERY OF MYCOBACTERIA FROM STERILE BODY SPECIMENS AND FROM DIGESTED DECONTAMINATED CLINICAL SPECIMENS.,M4RT KIT SWAB (1 MALE AND 1 FEMALE) (MICROTEST)-REMEL MICROTEST M4RT IS A LIQUID MEDIUM RECOMMENDED FOR THE TRANSPORT OF CLINICAL SPECIMENS TO THE LABORATORY FOR MICROBIOLOGICAL PROCEDURES FOR VIRAL AND CHLAMYDIAL AGENTS.,REDOX2(VERSATREK)-A BOTTLE CONTAINING CULTURE MEDIA WHICH CAN BE USED MANUALLY OR IN THE VERSATREK SYSTEM FOR CULTIVATING AND RECOVERING MICROORGANISMS, ESPECIALLY BACTERIA AND YEASTS FROM BLOOD AND OTHER NORMALLY STERILE BODY FLUIDS.,MICROTEST M4RT KIT SWAB (2 FEMALE) FOR THE TRANSPORT OF VIRUSES AND CHLAMYDIA(REMEL)-REMEL MICROTEST M4RT IS A LIQUID MEDIUM RECOMMENDED FOR THE TRANSPORT OF CLINICAL SPECIMENS TO THE LABORATORY FOR MICROBIOLOGICAL PROCEDURES FOR VIRAL AND CHLAMYDIAL AGENTS.,MYCO(VERSATREK)-THE VERSATREK MYCO WITH VERSATREK GS AND EITHER VERSATREK AS OR VERSATREK PVNA ADDED AS A SELECTIVE GROWTH MEDIUM FOR USE WITH EITHER THE VERSATREK OR ESP II CULTURE SYSTEM FOR THE RECOVERY OR MYCOBACTERIA FROM STERILE BODY SPECIMENS AND FROM DIGESTED DECONTAMINATED CLINICAL SPECIMENS.,MYCO SUSCEPTIBILITY KIT (VERSATREK)-THE VERSATREK MYCO SUSCEPTIBILITY KIT IS INTENDED FOR QUALITATIVE IN VITRO SUSCEPTIBILITY TESTING OF ISOLATED COLONIES OF MYCOBACTERIUM TUBERCULOSIS WITH RIFAMPICIN, ETHAMBUTOL AND ISONIAZID ON THE VERSATREK INSTRUMENT, APPROPRIATE INOCULUM SOURCES ARE PREPARED FROM GROWTH ON SOLID AGAR SUCH AS MIDDLEBROOK 7H10 OR LOWENSTEIN JENSEN SLATES OR MIDDLEBROOK 7H9 BROTH.,HTM BROTH

	(SENSITITRE)-A MEDIUM FOR THE SUSPENSION OF MICRO-ORGANISMS ISOLATED FROM CLINICAL SAMPLES FOR THE INOCULATION OF THE SENSITITRE HEMOPHILUS PANELS AS PART OF THE THERMO FISHER SENSITITRE SYSTEM FOR IN VITRO ANTIMICROBIAL SUSCEPTIBILITY TESTING.,MYCO GS (VERSATREK)-A BOTTLE CONTAINING GROWTH SUPPLEMENT USED IN THE VERSATREK SYSTEM FOR THE RECOVERY OF MYCOBACTERIA FROM STERILE BODY SPECIMENS AND FROM DIGESTED DECONTAMINATED CLINICAL SPECIMENS.,MYCO PZA KIT (VERSATREK)-THE VERSATREK MYCO PZA KIT IS USED WITH THE ESP CULTURE SYSTEM II OR WITH THE VERSATREK MICROBIAL DETECTION SYSTEM. THE VERSATREK PZA KIT FINAL TEST CONCENTRATION IS 300MCG/ML FOR PZA,MYCO AS(VERSATREK)-A BOTTLE CONTAINING ANTIBIOTICS USED IN THE VERSATREK SYSTEM FOR THE RECOVERY OF MYCOBACTERIA FROM STERILE BODY SPECIMENS AND FROM DIGESTED DECONTAMINATED CLINICAL SPECIMENS.,REDOX2 EZ DRAW(VERSATREK)-A BOTTLE CONTAINING CULTURE MEDIA WHICH CAN BE USED MANUALLY OR IN THE VERSATREK SYSTEM FOR CULTIVATING AND RECOVERING MICROORGANISMS, ESPECIALLY BACTERIA AND YEASTS FROM BLOOD AND OTHER NORMALLY STERILE BODY FLUIDS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

544	IMP/IVD/2020/000184	1.License Holder Name: SNIBE DIAGNOSTIC (INDIA) PRIVATE LIMITED. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAGLUMI 2019-NCOV IGM (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGM ANTIBODIES TO NOVEL CORONAVIRUS (2019-NCOV IGM) IN HUMAN SERUM OR PLASMA,SARS-COV-2 RT-PCR(MOLECISION SARS-COV-2 RT-PCR)-THE SARS-COV-2 RT-PCR ASSAY IS USED FOR QUALITATIVE DETECTION OF SARS-COV-2 FROM OROPHARYNGEAL SWABS, NASOPHARYNGEAL SWABS AND BALF (BRONCHOALVEOLAR LAVAGE FLUID) OF SUSPECTED CASES OF COVID-19. ,MAGLUMI 2019-NCOV IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG ANTIBODIES TO NOVEL CORONAVIRUS (2019-NCOV IGG) IN HUMAN SERUM OR PLASMA,SARS-COV-2 AG (CLIA)(MAGLUMI SARS-COV-2 AG (CLIA))-THE KIT IS A CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF SARS-COV-2 NUCLEOCAPSID PROTEIN (SARS-COV-2 AG) IN NASOPHARYNGEAL SWAB AND OROPHARYNGEAL SWAB USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER ,8-STRIP TIP (MOLECISION 8-STRIP TIP)-8-STRIP TIP IS REQUIRED FOR THE IMPLEMENTATION OF THE NUCLEIC ACID EXTRACTION ON FULLY-AUTO NUCLEIC ACID PURIFICATION SYSTEM MOLECISION MP-32 (SNIBE) OR GENEPURE PRO NPA-32P (BIOER),SARS-COV-2 S-RBD IGG (CLIA)(MAGLUMI SARS-COV-2 S-RBD IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF S-RBD IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER ,SARS-COV-2 NEUTRALIZING ANTIBODY (CLIA)(MAGLUMI SARS-COV-2 NEUTRALIZING ANTIBODY (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF NEUTRALIZING ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA,NUCLEIC ACID EXTRACTION KIT(MOLECISION NUCLEIC ACID EXTRACTION KIT)-THE NUCLEIC ACID EXTRACTION KIT IS INTENDED FOR ISOLATING NUCLEIC ACIDS (NA) FROM SAMPLE MATERIALS FOR AN IN VITRO TESTING,SAMPLE EXTRACTION SOLUTION(MAGLUMI SAMPLE EXTRACTION SOLUTION)-THE SAMPLE EXTRACTION SOLUTION IS INTENDED FOR PRE-TREATING DRY NASOPHARYNGEAL SWAB AND OROPHARYNGEAL SWAB SAMPLES FOR IMMUNOASSAY,96-WELL DEEP-WELL PLATE(MOLECISION 96-WELL DEEP-WELL PLATE)-96-WELL DEEP-WELL PLATE IS REQUIRED FOR THE IMPLEMENTATION OF

		THE NUCLEIC ACID EXTRACTION ON FULLY-AUTO NUCLEIC ACID PURIFICATION SYSTEM MOLECISION MP-32 (SNIBE) OR GENEPURE PRO NPA-32P (BIOER)
545	IMP/IVD/2020/000185	1.License Holder Name: PERKINELMER INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERKINELMER® SARS-COV-2 REAL-TIME RT-PCR ASSAY(PERKINELMER® SARS-COV-2 REAL-TIME RT-PCR ASSAY)-THE SARS-COV-2 REAL-TIME RT-PCR ASSAY IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DETECTION OF SARS-COV-2 RNA IN HUMAN OROPHARYNGEAL SWAB, NASOPHARYNGEAL SWAB, BRONCHOALVEOLAR LAVAGE (BAL), SPUTUM, PLASMA OR SERUM. THE TEST IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF SARS-COV-2 INFECTION., PERKINELMER® NUCLEIC ACID EXTRACTION KIT(PERKINELMER® NUCLEIC ACID EXTRACTION KIT)-THE PERKINELMER® NUCLEIC ACID KIT IS DESIGNED FOR DNA/RNA EXTRACTION AND PURIFICATION FROM OROPHARYNGEAL SWAB, NASOPHARYNGEAL SWAB, PLASMA AND SERUM SPECIMENS USING MAGNETIC BEADS. THE KIT IS INTENDED TO BE USED FOR IN VITRO DIAGNOSTICS WITH PERKINELMER DIAGNOSTIC ASSAYS, FOR EXAMPLE THE PERKINELMER® SARS-COV-2 REAL-TIME RT-PCR ASSAY.
546	IMP/IVD/2020/000186	1.License Holder Name: KRYPTON BIOMEDICAL PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GENEFINDER™(COVID-19 PLUS REAL AMP KIT)-GENEFINDER™ COVID-19 PLUS REAL AMP KIT IS THE ONE-STEP REVERSE TRANSCRIPTION REAL-TIME PCR KIT DESIGNED TO DETECT NOVEL CORONA VIRUS (COVID-19) QUALITATIVELY THROUGH REVERSE TRANSCRIPTION REACTION AND REAL-TIME POLYMERASE CHAIN REACTION.,VIRAL DNA/RNA EXTRACTION KIT(GENEFINDER™)-GENEFINDER VIRAL DNA/RNA EXTRACTION KIT IS DESIGNED TO EXTRACT AND ISOLATE VIRAL DNA/RNA FROM HUMAN SAMPLE USING AUTOMATED GENEFINDER EX-MATE 32 PLUS AND EX-MATE 32 SYSTEM.
547	IMP/IVD/2020/000194	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOCELL COVID-19 IGM ELISA TEST- THE PRODUCT INTENDS FOR THE QUALITATIVE DETECTION OF COVID-19 IGM ANTIBODIES IN SERUM SPECIMENS FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER.

548	IMP/IVD/2020/000197	1.License Holder Name: P. VISHRAM DISTRIBUTORS PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 IGG / IGM ANTIBODY TEST DIAGNOSTIC KIT(DEEP BLUE)-COVID-19 (SARS-COV-2) IGG/IGM TEST IS USED FOR QUALITATIVE DETECTION OF NOVEL CORONAVIRUS IGG/IGM ANTIBODIES IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD IN VITRO
549	IMP/IVD/2020/000199	1.License Holder Name: KRYPTON BIOMEDICAL PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALLPLEX 2019-NCOV ASSAY(ALLPLEX)-ALLPLEX 2019-NCOV ASSAY IS IN VITRO DIAGNOSTIC MEDICAL DEVICE DESIGNED FOR QUALITATIVE DETECTION OF NOVEL CORONA VIRUS (2019-NCOV) WITH REAL-TIME REVERSE TRANSCRIPTION PCR FROM SPUTUM, NASOPHARYNGEAL ASPIRATE, OROPHARYNGEAL (THROAT) & NASOPHARYNGEAL SWAB, AND BRONCHOALVEOLAR LAVAGE.
550	IMP/IVD/2020/000203	1.License Holder Name: IMMUNOSHOP INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:2019-NCOV IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG ANTIBODIES TO NOVEL CORONAVIRUS (2019-NCOV IGG) IN HUMAN SERUM OR PLASMA.,2019-NCOV IGM (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGM ANTIBODIES TO NOVEL CORONAVIRUS (2019-NCOV IGM) IN HUMAN SERUM OR PLASMA.
551	IMP/IVD/2020/000204	1.License Holder Name: FISHER BIOPHARMA SERVICES (INDIA) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TAQPATH™ COVID-19 COMBO KIT(APPLIED BIOSYSTEMS)-THE TAQPATH™ COVID-19 COMBO KIT IS A REAL-TIME RT-PCR TEST INTENDED FOR THE PRESUMPTIVE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN UPPER AND LOWER RESPIRATORY SPECIMENS (SUCH AS NASOPHARYNGEAL SWABS, NASOPHARYNGEAL, AND BRONCHOALVEOLAR LAVAGE) COLLECTED FROM INDIVIDUALS WHO MEET CDC CRITERIA FOR SARS-COV-2 TESTING.

552	IMP/IVD/2020/000213	1.License Holder Name: SHRIYA PHARMA & SURGICAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS IGM ANTIBODY TEST CASSETTE(LIVZON)-THIS PRODUCT IS USED FOR IN VITRO QUALITATIVE DETECTION OF CORONAVIRUS (SARSCOV-2) IGM/IGG ANTIBODY IN HUMAN SERUM, PLASMA AND WHOLE BLOOD SAMPLES.,NOVEL CORONAVIRUS (COVID 19) -DILUENT(LIVZON)-THIS PRODUCT IS USED FOR IN VITRO QUALITATIVE DETECTION OF CORONAVIRUS (SARSCOV-2) IGM/IGG ANTIBODY IN HUMAN SERUM, PLASMA AND WHOLE BLOOD SAMPLES.,NOVEL CORONAVIRUS IGG ANTIBODY TEST CASSETTE(LIVZON)-THIS PRODUCT IS USED FOR IN VITRO QUALITATIVE DETECTION OF CORONAVIRUS (SARSCOV-2) IGM/IGG ANTIBODY IN HUMAN SERUM, PLASMA AND WHOLE BLOOD SAMPLES.
553	IMP/IVD/2020/000214	1.License Holder Name: INDELOX GLOBAL DISTRIBUTION PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 IGM & IGG RAPID TEST(EDAN SARS-COV-2 (COVID-19) IGM & IGG RAPID TEST)-THE PRODUCT IS USED FOR IN VITRO QUANTITATIVE DETECTION OF SARS-COV-2 IGG & IGM ANTIBODY IN HUMAN SERUM,PLASMA, OR WHOLE BLOOD. CORONAVIRUS BELONGS TO CORONAVIRIDAE , NIDOVIRALES AND IS DIVIDED INTO , AND GENUSES. AND GENUSES CAN ONLY MAKE MAMMAL SICK AND Y GENUS MAINLY CAUSES BIRDS TO BE INFECTED . COV IS MAINLY TRANSMITTED THROUGH DIRECT CONTAINING SECRETA OR TRANSMITTED BY AEROSOL OR SPRAY. BUT THERE IS ALSO EVIDENCE CERTIFYING IT CAN BE TRANSMITTED BY THE FECAL-ORAL ROUTE. BY NOW THERE HAS BEEN ALREADY UP TO 7 TYPES OF HCOVS THAT CAN CAUSE HUMAN RESPIRATORY DISEASE. HCOV-229E, HCOV-OC43,SARS-COV, HCOV-NL63, HCOV-HKU1, MERS-COV AND SARS –COV2, SO HCOV IS THE MAJOR CAUSATIVE AGENT TO CAUSE HUMAN RESPIRATORY TRACT INFECTION . THEREIN, THE COVID-19 WAS DISCOVERED DUE TO VIRAL PNEUMONIA CASE IN WUHAN, OF WHICH THE CLINICAL MANIFESTATION INCLUDES FEVER AND FATIGUE ETC. CONSTITUTIONAL SYMPTOMS, ACCOMPANIED BY DRY COUGH AND DYSPNEA, ETC. IT CAN EVOLVES SEVERE PNEUMONIA, RESPIRATORY FAILURE , ACUTE RESPIRATORY DISTRESS SYNDROME, SEPTIC SHOCK, MULTIPLE ORGAN FAILURE AND SEVERE ACID-BASE UNBALANCE ETC, AND EVEN LIFE –THREATENING.

554	IMP/IVD/2020/000216	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EXTRACTION KIT(ZYBIO)-FOR THE EXTRACTION, ENRICHMENT AND PURIFICATION OF NUCLEIC ACID (DNA/RNA) IN SAMPLES. ITS PROCESSED PRODUCTS ARE FOR CLINICAL IN VITRO DIAGNOSTICS.,SARS COV 2 IGM/IGG ANTIBODY A SSAY KIT (COLLOIDAL GOLD METHOD)(ZYBIO)-THIS KIT IS USED FOR THE QUALITATIVE DETECTION OF SPECIFIC IGM ANTIBODIES AND IGG ANTIBODIES AGAINST NOVEL CORONAVIRUS (SARS-COV-2) IN HUMAN SPECIMENS (SERUM, PLASMA, WHOLE BLOOD).,SARS-COV-2 NUCLEIC ACID DETECTION KIT (PCRFLUORESCENT PROBE METHOD) (ZYBIO)-THIS KIT IS USED IN QUALITATIVE DETECTION OF SARS-COV-2 RNA IN NASAL /THROAT SWAB, ALVEOLAR LAVAGE FLUIDS SPECIMENS FROM SUSPECTED COVID-19 CASES, SUSPECTED CLUSTERED CASES, OTHER CASES REQUIRING SARS-COV-2 DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS. IT CAN SPECIFICALLY DETECT THE TARGET GENES (ORF 1AB AND N GENES) OF SARS-COV-2 AND IS APPLIED IN CLINICAL DIAGNOSIS OF SARS-COV-2 INFECTION.
555	IMP/IVD/2020/000217	1.License Holder Name: KRISHGEN BIOSYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 IGG/IGM RAPID TEST KIT(ELABSCIENCE)-COVID-19 IGG/IGM RAPID TEST (WHOLE BLOOD/ SERUM/PLASMA) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGG AND IGM ANTIBODIES TO COVID-19 IN HUMAN WHOLE BLOOD, SERUM OR PLASMA AS AN AID IN THE DIAGNOSIS OF PRIMARY AND SECONDARY COVID-19 INFECTIONS.
556	IMP/IVD/2020/000220	1.License Holder Name: PTS DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIBODY TEST STRIPS (COLLOIDAL GOLD METHOD)(NA)-THE SARS-COV-2 ANTIBODY TEST STRIP IS FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIBODY IN HUMAN SERUM, PLASMA OR WHOLE BLOOD SAMPLE. IT IS INTENDED FOR USE OUTSIDE THE BODY ONLY IN VITRO DIAGNOSTIC USEFOR PROFESSIONAL USE

557	IMP/IVD/2020/000223	1.License Holder Name: M/S.TRANSASIA BIO-MEDICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LYE-1(LYE-1)-IT IS USED TO LYSE (DESTROY) RED BLOOD CELLS FOR HEMOGLOBIN DETERMINATIONS OR AID IN THE COUNTING OF WHITE BLOOD CELLS. ,LYC-2(LYC-2)-IT IS USED TO LYSE (DESTROY) RED BLOOD CELLS AND MAINTAIN THE MORPHOLOGY OF CELLS BEFORE BLOOD CELL ANALYSIS, SO AS TO FACILITATE THE COUNTING OF WHITE BLOOD CELLS. ,LYA-3(LYA-3)-IT IS USED TO BREAK DOWN RED BLOOD CELL AND COOPERATE WITH THE LYA-2 LYSE TO 4-DIFFERENTIATE WBCS. , CLE-P (CLE-P)-IT'S USED ON HEMATOLOGY ANALYZERS FOR REGULAR CLEANING AND WASHING OF THE PROBE AND TUBING SYSTEM WITHIN MACHINES. ,LYA-1(LYA-1)-IT IS USED TO BREAK DOWN RED BLOOD CELL MENBRANCE AND CONVERT HEMOGLOBIN TO A HEMOGLOBIN COMPLEX TO DETERMINE THE HGB. IT 2-DIFFERENTIATES WBCS TO BASO AND OTHER WBCS, AND DETERMINES WBCS AMOUNT. ,LYC-1(LYC-1)-IT IS USED TO LYSE (DESTROY) RED BLOOD CELLS FOR HEMOGLOBIN DETERMINATIONS OR AID IN THE COUNTING OF WHITE BLOOD CELLS. ,DIL-C(DIL-C)-IT IS USED FOR BLOOD CELL ANALYSIS, SAMPLE DILUTION AND CELL SUSPENSION PREPARATION. ,DIL-E(DIL-E)-IT IS USED FOR BLOOD CELL ANALYSIS, SAMPLE DILUTION AND CELL SUSPENSION PREPARATION. ,LYA-2(LYA-2)-IT IS USED TO BREAK DOWN RED BLOOD CELL AND COOPERATE WITH THE LYA-3 LYSE TO 4-DIFFERENTIATE WBCS. ,DIL-A(DIL-A)-IT IS USED FOR BLOOD CELL ANALYSIS, SAMPLE DILUTION AND CELL SUSPENSION PREPARATION.
558	IMP/IVD/2020/000224	1.License Holder Name: 3I MOLECULAR SOLUTIONS AND HEALTHCARE SERVICES PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALLPLEX™ 2019-NCOV ASSAY(ALLPLEX™)-:ALLPLEXTM 2019-NCOV ASSAY IS IN VITRO DIAGNOSTIC MEDICAL DEVICE DESIGNED FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS (2019-NCOV) WITH REAL-TIME REVERSE TRANSCRIPTION PCR FROM SPUTUM, NASOPHARYNGEAL ASPIRATE, THROAT & NASOPHARYNGEAL SWAB, AND BRONCHOALVEOLAR LAVAGE.

559	IMP/IVD/2020/000225	1.License Holder Name: DIATEK HEALTHCARE PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:D-DIMER DETECTION KIT (NEPHELOMETRY)(D-DIMER DETECTION KIT)-FOR IN VITRO DETERMINATION OF D-DIMER,RHEUMATOID FACTOR (RF) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF RF IN HUMAN SERUM,IMMUNOGLOBULIN IGG DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF IGG IN HUMAN SERUM, IMMUNOGLOBULIN IGM DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF IGM IN HUMAN SERUM,ELECTROLYTE REAGENT (MODEL NO DS-REF)(GENRUI)-REAGENT USED IN ELECTROLYTE ANALYSER,ANTI-STREPTOLYSIN O (ASO) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF ASO IN HUMAN SERUM, DEPROTEINIZER(GENRUI)-REAGENT USED FOR CLEANING ELECTROLYTE ANALYSER,CYSTATIN C (CYS-C) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM,ELECTROLYTE REAGENT (MODEL NO DS-ISE)(GENRUI)-REAGENT USED IN ELECTROLYTE ANALYSER,COMPLEMENT C4(C4) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF C4 IN HUMAN SERUM,COMPLEMENT C3 (C3) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF C3 IN HUMAN SERUM,GLYCATED HEMOGLOBIN (HBA1C) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF HBA1C IN HUMAN SERUM,C-REACTIVE PROTEIN (CRP) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF CRP,QC SOLUTION(GENRUI)-REAGENT USED FOR QC OF ELECTROLYTE ANALYSER,ELECTROLYTE REAGENT (MODEL NO DS-I (NO.3))(GENRUI)-REAGENT PACK FOR USE IN ELECTROLYTE ANALYSER,HIGH SENSITIVE C- REACTIVE PROTEIN (HS-CRP) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF HS- CRP,PVC ELECTRODE ACTIVATING SOLUTION(GENRUI)-REAGENT USED FOR ELECTROLYTE ANALYSER,CLEANING SOLUTION(GENRUI)-REAGENT USED FOR CLEANING ELECTROLYTE ANALYSER,ANTI-CYCLIC CITRULLINATED PEPTIDE ANTIBODY (CCP) DETECTION KIT (NEPHELOMETRY)(GENRUI) -FOR IN VITRO QUANTITATIVE DETERMINATION OF CCP IN HUMAN SERUM,IMMUNOGLOBULIN IGA DETECTION KIT (NEPHELOMETRY) (GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF IGA IN HUMAN SERUM,HUMAN MICRO-ALBUMINURIA (MALB) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE

		DETERMINATION OF MICRO-ALBUMINURIA IN HUMAN URINE
560	IMP/IVD/2020/000227	1.License Holder Name: QIAGEN INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CAREHPV TEST KIT-IT IS USED FOR THE QUALITATIVE DETECTION OF 14 TYPES OF HPV DNA IN CERVICAL SPECIMENS.
561	IMP/IVD/2020/000228	1.License Holder Name: ACCREDITED CONSULTANT PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:2019-NCOV IGG/IGM RAPID TEST CASSETTE(ALLTEST)-A RAPID TEST FOR THE QUALITATIVE DETECTION OF IGG AND IGM ANTIBODIES TO 2019-NCOV IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SPECIMENS.

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562	IMP/IVD/2020/000236	1.License Holder Name: COSMIC SCIENTIFIC TECHNOLOGIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEUTROPHILS GELATINASE ASSOCIATED LIPOCALIN (NGAL)(ONE STEP TEST FOR NGAL (COLLOIDAL GOLD))-ONE STEP TEST FOR MALB (COLLOIDAL GOLD) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF NEUTROPHILS GELATINASE ASSOCIATED LIPOCALN (NGAL) IN SERUM AND URINE. THIS TEST IS USED AS AN AID IN THE EARLY DIAGNOSIS OF ACUTE KIDNEY INJURY (AKI), RISK CLASSIFICATION AND TREATMENT MONITORING.,ONE STEP TEST FOR NOVEL CORONAVIRUS (2019-NCOV) IGM/IGG ANTIBODY (COLLOIDAL GOLD) (GETEIN)-ONE STEP TEST FOR NOVEL CORONAVIRUS (2019-NCOV) IGM/IGG ANTIBODY (COLLOIDAL GOLD) IS INTENDED FOR THE QUALITATIVE DETECTION OF 2019-NOVEL CORONAVIRUS IGM AND IGG ANTIBODY IN SERUM, PLASMA, FINGERTIP BLOOD OR WHOLE BLOOD SAMPLES OF PNEUMONITIS PATIENTS OR SUSPECTED CASES.,CREATINE KINASE-MB/CARDIAC TROPONIN I/MYOGLOBIN (CK-MB/CTNL/MYO FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY)) -CK-MB/CTNL/MYO FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CK-MB/CTNL/MYO IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS, AND ACUTE CORONARY SYNDROME (ACS).,NOVEL CORONAVIRUS (2019-NCOV) REAL-TIME RT-PCR KIT(GETEIN)-NOVEL CORONAVIRUS (2019-NCOV) REAL-TIME RT-PCR KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF 2019-NOVEL CORONAVIRUS IN RESPIRATORY SPECIMENS (LIKE NASOPHARYNGEAL OR OROPHARYNGEAL SWABS, BRONCHOALVEOLAR LAVAGE) OF PNEUMONITIS PATIENTS OR SUSPECTED CASES.,D-DIMER (ONE STEP TEST FOR D-DIMER (COLLOIDAL GOLD))-- ONE STEP TEST FOR D-DIMER (COLLOIDAL GOLD) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF D-DIMER IN PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF DEEP-VEIN THROMBOSIS OR PULMONARY EMBOLISM.,HCG+BETA (HCG+BETA FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-HCG+BETA FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONATROPIN (HCG) IN SERUM. THIS TEST IS USED AS AN AID IN PREGNANCY TEST.,BETA 2 MICROGLOBULIN (BETA 2 - MG)(BETA 2 MG FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-BETA 2 MG FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN

	VITRO QUANTITATIVE DETERMINATION OF BETA 2-MICROGLOBULIN IN SERUM, PLASMA OR WHOLE BLOOD. MEASUREMENT OF BETA 2-MG IS USEFUL FOR THE DETECTION AND EVALUATION OF GLOMERULAR FITRATION RATE, RENTAL TRANSPLANTATION AND RENTAL FUNCTION.,CARDIAC TROPONIN I (CARDIAC TROPONIN I FAST TEST KIT (COLLOIDAL GOLD))-CARDIAC TROPONIN I FAST TEST KIT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNL) IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS AND ACUTE CORONARY SYNDROME (ACS),TSH(TSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-TSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN SERUM, PLASMA. THIS TEST IS USED IN THE SCREENING, CLINICAL DIAGNOSIS, PROGNOSIS AND THERAPEUTIC EFFECT EVALUATION THYROID DISEASE.,FSH(FSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-FSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY)) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM AND PLASMA. FSH TESTING IS USED FOR WOMEN SUSPECTED OF HAVING POLYCYSTIC OVARY SYNDROME , AND IN INDIVIDUAL UNDERGOING EVALUATION OF INFERTILITY, ALSO USED FOR EVALUATION OF INDIVIDUALS WITH SUSPECTED PITUITIRY DISORDERS OR DISEASE OF THE OVARIES,CYSTATIN C(CYSC FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-CYSC FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CYSTATIN C (CYSC) IN SERUM, PLASMA OR WHOLE BLOOD. THE TEST RESULT IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF INDEX OF GLOMERULAR FILTRATION RATE, AND HAS IMPORTANT APPLICATION VALUE IN RENTAL FUNCTION, KIDNEY DAMAGE AND RENTAL TRANSPLANTATION.,NEUTROPHILS GELATINASE ASSOCIATED LIPOCALIN (NGAL)(NGAL (IMMUNOFLUORESCENCE ASSAY))-NGAL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF NEUTROPHILS GELATINASE ASSOCIATED LIPOCALN (NGAL) IN SERUM AND URINE. THIS TEST IS USED AS AN AID IN THE EARLY DIAGNOSIS OF ACUTE KIDNEY INJURY (AKI), RISK CLASSIFICATION AND TREATMENT MONITORING,PROCALCITONIN (PCT)(ONE STEP TEST FOR PCT FAST TEST KIT (COLLOIDAL GOLD))-ONE STEP TEST FOR PCT (COLLOIDAL GOLD) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN SERUM, PLASMA AND WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION

	OF PATIENTS SUSPECTED OF BACTERIAL INFECTION, TRAUMA AND SHOCK.,MICROALBUMINURIA (MALB)(ONE STEP TEST FOR MALB (COLLOIDAL GOLD))-ONE STEP TEST FOR MALB (COLLOIDAL GOLD) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF MICROALBUMINURIA (MALB) IN URINE . AN ELEVATED MALB CONCENTRATION BELOW BELOW THE PROTEINURIC LEVEL HAS LONG BEEN RECOGNIZED AS A MARKER OF KIDNEY AND INCREASED CARDIOVASCULAR RISK IN DIABETIC NEPHROPATHY.,HCG+BETA (ONE STEP TEST FOR HCG+BETA (COLLOIDAL GOLD))-ONE STEP TEST FOR HCG+BETA (COLLOIDAL GOLD) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONATROPIN (HCG) IN SERUM. THIS TEST IS USED AS AN AID IN PREGNANCY TEST.,PRL(PRL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))- PRL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN SERUM OR PLASMA SAMPLES. THIS TEST CAN BE USED AS AN AID IN THE DIAGNOSIS OF MALE AND FEMALE INFERTILITY AND PITUITIARY DYSFUNCTION, MONITORING OF MALE AND FEMALE GONADAL DISORDERS AND MANAGEMENT OF AMENORRHEA AND GALACTORRHEA,HBA1C(HBA1C FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-HBA1C FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE MEASUREMENT OF HBA1C IN WHOLE BLOOD. THIS TEST IS USED AS AN AID FOR MONITORING GLYCEMIC CONTROL IN DIABETICS. IN ADDITION, IT CAN IDENTIFY AT PEOPLE AT RISK OF DEVELOPING THE DISEASE AND ONGOING MONITORING,TSH(ONE STEP TEST FOR TSH(COLLOIDAL GOLD))-ONE STEP TEST FOR TSH (COLLOIDAL GOLD) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN SERUM, PLASMA. THIS TEST IS USED IN THE SCREENING, CLINICAL DIAGNOSIS, PROGNOSIS AND THERAPEUTIC EFFECT EVALUATION THYROID DISEASE,CREATINE KINASE-ISOENZYME MB (CK-MB)(CK-MB FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-- CK-MB FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CK-MB IN SERUM , PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS, AND EVALUATION OF MYOCARDIAL SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI). UNSTABLE ANGINA, ACUTE MYOCARDITIS, AND ACUTE CORONARY SYNDROME (ACS),HBA1C(ONE STEP TEST FOR HBA1C (COLLOIDAL GOLD))-ONE STEP TEST FOR HBA1C (COLLOIDAL GOLD) IS INTENDED FOR IN VITRO QUANTITATIVE MEASUREMENT OF HBA1C IN WHOLE BLOOD. THIS TEST IS USED AS AN AID FOR MONITORING GLYCEMIC CONTROL IN DIABETICS. IN ADDITION, IT CAN IDENTIFY AT PEOPLE

	AT RISK OF DEVELOPING THE DISEASE AND ONGOING MONITORING, N-TERMINAL PROHORMONE OF BRAIN NATRIURETIC PEPTIDE (NT-PROBNP/CTNL)(NT -PRO BNP/CTNL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))- NT -PRO BNP/CTNL (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF N TERMINAL B TYPE NATRIURETIC PEPTIDE PRECURSOR/CARDIAC TROPONIN I (NT -PRO BNP/CTNL) IN SERUM, PLASMA AND WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF), ACUTE MYOCARDIAL INFARCTION (AMI) AND ACUTE CORONARY SYNDROME (ACS),25-OH-VD(25-OH-VD FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-25-OH-VD FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF 25-OH-VD IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST MAY HELP UNDERSTAND THE METABOLIC CHANGES OF BONE.,N-TERMINAL PROHORMONE OF BRAIN NATRIURETIC PEPTIDE (NT- PROBNP)(ONE STEP TEST FOR NT -PRO BNP (COLLOIDAL GOLD))-ONE STEP TEST FOR NT -PRO BNP/CTNL (COLLOIDAL GOLD) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF N TERMINAL B TYPE NATRIURETIC PEPTIDE PRECURSOR/CARDIAC TROPONIN I (NT -PRO BNP/CTNL) IN SERUM, PLASMA AND WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF), ACUTE MYOCARDIAL INFARCTION (AMI) AND ACUTE CORONARY SYNDROME (ACS),AMH (AMH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-AMH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF AMH IN HUMAN SERUM AND PLASMA SAMPLES. THIS TEST CAN BE USED AS AN AID IN INDICATING OVARIAN FUNCTIONAL RESERVE, AND ALSO HELP TO DIAGNOSE MENSTRUAL DISORDERS OR TO MONITOR THE HEALTH OF WOMEN.,CREATINE KINASE-MB/CARDIAC TROPONIN I/MYOGLOBIN (ONE STEP TEST FOR CK-MB/CTNL/MYO (COLLOIDAL GOLD))-ONE STEP TEST FOR CK-MB/CTNL/MYO (COLLOIDAL GOLD) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CK-MB/CTNL/MYO IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI). UNSTABLE ANGINA, ACUTE MYOCARDITIS, AND ACUTE CORONARY SYNDROME (ACS). ,CARDIAC TROPONIN I (CARDIAC TROPONIN I FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-CARDIAC TROPONIN I FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNL) IN SERUM, PLASMA OR WHOLE

	BLOOD. THIS TEST IS USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS AND ACUTE CORONARY SYNDROME (ACS),HIGH SENSITIVITY C-REACTIVE PROTEIN (HS-CRP)(HS CRP+CRP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-HS CRP+CRP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM, PLASMA, WHOLE BLOOD OR FIGURE TIP BLOOD. MEASUREMENT OF CRP IS USEFUL FOR DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY AND INFLAMMATORY DISORDERS. MEASUREMENT OF HIGH SENSIVITY CRP (HS-CPR), WHEN USE IN CONJUNCTION WITH TRADITIONAL CLINICAL LABORATORY EVALUATION OF ACUTE CORONARY SYNDROME (ACS), MAY BE USEFUL AS AN INDEPENDENT MARKER OF PROGNOSIS FOR RECURRENT EVENTS IN PATIENTS WITH STABLE CORONARY DISEASE OR ACS.,HIGH SENSITIVITY C-REACTIVE PROTEIN (HS-CRP)(ONE STEP TEST FOR HS CRP+CRP (COLLOIDAL GOLD))-ONE STEP TEST FOR HS CRP+CRP (COLLOIDAL GOLD) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM, PLASMA, WHOLE BLOOD OR FINGURETIP BLOOD. MEASUREMENT OF CRP IS USEFUL FOR DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY AND INFLAMMATORY DISORDERS. MEASUREMENT OF HIGH HIGH SENSIVITY CRP (HS-CPR), WHEN USE IN CONJUNCTION WITH TRADITIONAL CLINICAL LABORATORY EVALUATION OF ACUTE CORONARY SYNDROME (ACS), MAY BE USEFUL AS AN INDEPENDENT MARKER OF PROGNOSIS FOR RECURRENT EVENTS IN PATIENTS WITH STABLE CORONARY DISEASE OR ACS. ,LH(LH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-LH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF LH IN HUMAN SERUM AND PLASMA. THIS TEST IS USED TO DETERMINE MENOPAUSE, PINPOINT OVULATION AND MOTHER ENDOCRINE THERAPY., MICROALBUMINURIA (MALB)(MALB FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-MALB FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF MICROALBUMINURIA (MALB) IN URINE . AN ELEVATED MALB CONCENTRATION BELOW BELOW THE PROTEINURIC LEVEL HAS LONG BEEN RECOGNIZED AS A MARKER OF KIDNEY AND INCREASED CARDIOVASCULAR RISK IN DIABETIC NEPHROPATHY.,BETA 2 MICROGLOBULIN (BETA 2 - MG)(ONE STEP TEST FOR BETA 2 MG (COLLOIDAL GOLD))-ONE STEP TEST FOR TSH (COLLOIDAL GOLD) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF BETA 2-MICROGLOBULIN IN SERUM, PLASMA OR

	WHOLE BLOOD. MEASUREMENT OF BETA 2-MG IS USEFUL FOR THE DETECTION AND EVALUATION OF GLOMERULAR FITRATION RATE, RENTAL TRANSPLANTATION AND RENTAL FUNCTION. ,D-DIMER (D-DIMER FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-D-DIMER FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF D-DIMER IN PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF DEEP-VEIN THROMBOSIS OR PULMONARY EMBOLISM,T3(T3 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-T3 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T3 IN SERUM AND PLASMA. IT CAN BE USED THE MONITORING OF HYPERTHYROIDISM HYPOTHYROIDISM, AND ALSO USE AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA.,N-TERMINAL PROHORMONE OF BRAIN NATRIURETIC PEPTIDE (NT- PROBNP)(NT -PRO BNP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-NT -PRO BNP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF N TERMINAL B-TYPE NATRIURETIC PEPTIDE PRECURSOR/CARDIAC TROPONIN I (NT -PRO BNP) IN SERUM, PLASMA AND WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF).,PROCALCITONIN (PCT)(PCT FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-PCT FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN SERUM, PLASMA AND WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF BACTERIAL INFECTION, TRAUMA AND SHOCK.,CREATINE KINASE-ISOENZYME MB (CK-MB)(ONE STEP TEST FOR CK-MB (COLLOIDAL GOLD))-CK-MB FAST TEST KIT (COLLOIDAL GOLD) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CK-MB IN SERUM , PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS, AND EVALUATION OF MYOCARDIAL SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI). UNSTABLE ANGINA, ACUTE MYOCARDITIS, AND ACUTE CORONARY SYNDROME (ACS),N-TERMINAL PROHORMONE OF BRAIN NATRIURETIC PEPTIDE (NT- PROBNP/CTNL)(ONE STEP TEST FOR NT -PRO BNP/CTNL (COLLOIDAL GOLD))-ONE STEP TEST FOR NT -PRO BNP/CTNL (COLLOIDAL GOLD) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF N TERMINAL B TYPE NATRIURETIC PEPTIDE PRECURSOR/CARDIAC TROPONIN I (NT -PRO BNP/CTNL) IN SERUM, PLASMA AND WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND

		EVALUATION OF HEART FAILURE (HF), ACUTE MYOCARDIAL INFARCTION (AMI) AND ACUTE CORONARY SYNDROME (ACS),T4(T4 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-T4 (THYROXINE) FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T4 IN SERUM AND PLASMA. IT CAN BE USED THE MONITORING OF HYPERTHYROIDISM HYPOTHYROIDISM, AND ALSO USE AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA.,CYSTATIN C(ONE STEP TEST FOR CYSC (COLLOIDAL GOLD))-ONE STEP TEST FOR CYSC (COLLOIDAL GOLD) FOR IN VITRO QUANTITATIVE DETERMINATION OF ONE STEP TEST FOR CYSC IN SERUM, PLASMA OR WHOLE BLOOD. THE TEST RESULT IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF INDEX OF GLOMERULAR FILTRATION RATE, AND HAS IMPORTANT APPLICATION VALUE IN RENTAL FUNCTION, KIDNEY DAMAGE AND RENTAL TRANSPLANTATION.
563	IMP/IVD/2020/000237	1.License Holder Name: ACCREDITED CONSULTANT PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 IGG/IGM TEST (HUMASIS)-HUMASIS COVID-19 IGG/IGM TEST IS ONE STEP IN VITRO DIAGNOSTIC TEST BASED ON AN IMMUNOCHROMATOGRAPHIC ASSAY. IT IS DESIGNED FOR QUALITATIVE DETECTION OF IMMUNOGLOBULIN G AND IMMUNOGLOBULIN M ANTIBODY OF NOVEL CORONAVIRUS (COVID-19) IN HUMAN BLOOD.
564	IMP/IVD/2020/000238	1.License Holder Name: INBIOS INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (2019-NCOV) NUCLEIC ACID DIAGNOSTIC KIT-NOVEL CORONAVIRUS (2019-NCOV) NUCLEIC ACID DIAGNOSTIC KIT (PCR-FLUORESCENCE PROBING) IS USED FOR QUALITATIVE DETECTION OF THE ORF1AB AND N GENES OF NOVEL CORONAVIRUS (2019-NCOV) IN NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, ALVEOLAR LAVAGE FLUID, SPUTUM, SERUM, WHOLE BLOOD AND FECES FROM SUSPECTED PNEUMONIA CASES WITH NOVEL CORONAVIRUS INFECTION, PATIENTS WITH SUSPECTED CLUSTERS OF NOVEL CORONAVIRUS INFECTION, AND OTHER PATIENTS REQUIRING DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS OF NOVEL CORONAVIRUS INFECTION

565	IMP/IVD/2020/000239	1.License Holder Name: ALPS DIAGNOSTICS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CALIBRANT FLUID PACK (CALIBRANT FLUID PACK (CP100, CP50))-CALIBRANT FLUID PACK CONTAIN CALIBRANT SOLUTION AND INTENDED TO BE USED TOGETHER WITH EDAN I15 BLOOD GAS AND CHEMISTRY ANALYSIS SYSTEM TO PERFORM SENSOR/CARTRIDGE CALIBRATION ,TEST CARTRIDGE(TEST CARTRIDGE (BG3,BG4,BG8,BG9,BG10,BC4))-THE TEST CARTRIDGE ARE INTENDED TO USE WITH EDAN I15 BLOOD GAS AND CHEMISTRY ANALYSIS SYSTEM. EACH DISPOSABLE CARTRIDGE ANALYZE BLOOD SAMPLE AND GIVE REPORT IN TERMS OF BLOOD ELECTROLYTES, BLOOD GASES AND BLOOD CHEMICALS, ETC. , CONTROLS(CONTROLS (CONTROL-LEVEL 1, CONTROL-LEVEL 2, CONTROL-LEVEL 3))-CONTROLS ARE INTENDED FOR USE TO MONITOR TEST CARTRIDGE PERFORMANCE AT MULTIPLE POINTS.
566	IMP/IVD/2020/000240	1.License Holder Name: M/S AGAPPE DIAGNOSTICS LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID 19 IGG/IGM RAPID TEST CASSETTE -TO DETECT SARS -COV- 2 IGG/IGM IN HUMAN BLOOD /SERUM/PLASMA
567	IMP/IVD/2020/000243	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BASE POINT COVID-19 LGG/LGM RAPID TEST DEVICE-BASEPOINT™ COVID-19 IGG/IGM RAPID TEST DEVICE IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) IGG/IGM ANTIBODIES IN HUMAN VENOUS WHOLE BLOOD, FINGERSTICK WHOLE BLOOD, SERUM OR PLASMA SAMPLE. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY SARS-COV-2. THE TEST PROVIDES PRELIMINARY TEST RESULTS. NEGATIVE RESULTS DON'T PRECLUDE SARS-COV-2 INFECTION AND THEY CANNOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISION.

568	IMP/IVD/2020/000249	1.License Holder Name: DHR HOLDING INDIA PVT. LTD, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TECHNOPATH MULTI-CHECK CARDIAC LEVEL 1(TECHNOPATH MULTI-CHECK CARDIAC LEVEL 1)-FOR IN VITRO DIAGNOSTIC USE. FOR USE WITH THE AQT90 FLEX ANALYZER AS AN ASSAYED LIQUID CONTROL (LQC) SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE PARAMETERS LISTED IN THE SPECIFICATION INSERT., TECHNOPATH MULTI-CHECK CARDIAC LEVEL 3(TECHNOPATH MULTI-CHECK CARDIAC LEVEL 3`)-FOR IN VITRO DIAGNOSTIC USE. FOR USE WITH THE AQT90 FLEX ANALYZER AS AN ASSAYED LIQUID CONTROL (LQC) SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE PARAMETERS LISTED IN THE SPECIFICATION INSERT.,TECHNOPATH MULTI-CHECK CARDIAC LEVEL 2(TECHNOPATH MULTI-CHECK CARDIAC LEVEL 2)-FOR IN VITRO DIAGNOSTIC USE. FOR USE WITH THE AQT90 FLEX ANALYZER AS AN ASSAYED LIQUID CONTROL (LQC) SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE PARAMETERS LISTED IN THE SPECIFICATION INSERT.

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569	IMP/IVD/2020/000251	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MEASLES VIRUS IGG (NOVALISA®)-"THE MEASLES VIRUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST MEASLES VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN). MEASLES VIRUS IGG AVIDITY CAN BE DETERMINED WITH ASSAY AVIDITY MEASLES VIRUS IGG (PRODUCT CODE: AMEA7330).",DENGUE IGM VIRUS(NOVALISA®)-THE DENGUE VIRUS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST DENGUE VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN). ,VARICELLA-ZOSTER VIRUS (VZV) IGM(NOVALISA®)-THE VARICELLA-ZOSTER VIRUS (VZV) IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST VARICELLA-ZOSTER VIRUS (VZV) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,CHIKUNGUNYA VIRUS IGM -CAPTURE (NOVALISA®)-THE CHIKUNGUNYA VIRUS IGM -CAPTURE ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST CHIKUNGUNYA VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN). ,MYCOPLASMA PNEUMONIAE IGG (NOVALISA®)-THE MYCOPLASMA PNEUMONIAE IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST MYCOPLASMA PNEUMONIAE IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,DENGUE IGG VIRUS (NOVALISA®)-THE DENGUE VIRUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST DENGUE VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN). , TRICHINELLA SPIRALIS IGG(NOVALISA®)-THE TRICHINELLA SPIRALIS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST TRICHINELLA SPIRALIS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)., CHIKUNGUNYA VIRUS IGG CAPTURE(NOVALISA®)-THE CHIKUNGUNYA VIRUS IGG CAPTURE ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CHIKUNGUNYA VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN). ,RESPIRATORY SYNCYTIAL VIRUS IGG(NOVALISA®)-THE RESPIRATORY SYNCYTIAL VIRUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST RESPIRATORY SYNCYTIAL VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,COXIELLA BURNETII (Q-FEVER) PHASE 1 IGG (NOVALISA®)-THE COXIELLA BURNETII (Q-FEVER) PHASE 1 IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST COXIELLA BURNETII (Q-FEVER) PHASE 1 IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,CANDIDA

	ALBICANS IGA(NOVALISA®)-THE CANDIDA ALBICANS IGA ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGA CLASS ANTIBODIES AGAINST CANDIDA ALBICANS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,RESPIRATORY SYNCYTIAL VIRUS IGA (NOVALISA®)-THE RESPIRATORY SYNCYTIAL VIRUS IGA ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGA CLASS ANTIBODIES AGAINST RESPIRATORY SYNCYTIAL VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,VARICELLA-ZOSTER VIRUS (VZV) IGG(NOVALISA®)-THE VARICELLA-ZOSTER VIRUS (VZV) IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST VARICELLA-ZOSTER VIRUS (VZV) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,RESPIRATORY SYNCYTIAL VIRUS IGM(NOVALISA®)-THE RESPIRATORY SYNCYTIAL VIRUS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST RESPIRATORY SYNCYTIAL VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,ASPERGILLUS FUMIGATUS IGM(NOVALISA®)-THE ASPERGILLUS FUMIGATUS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST ASPERGILLUS FUMIGATUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,BORDETELLA PERTUSSIS IGA(NOVALISA®)-THE BORDETELLA PERTUSSIS IGA ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGA CLASS ANTIBODIES AGAINST BORDETELLA PERTUSSIS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,BORDETELLA PERTUSSIS IGG(NOVALISA®)-THE BORDETELLA PERTUSSIS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST BORDETELLA PERTUSSIS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,PARVOVIRUS B19 IGM(NOVALISA®)-THE PARVOVIRUS B19 IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST PARVOVIRUS B19 IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,TAENIA SOLIUM IGG (NOVALISA®)-THE TAENIA SOLIUM IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST TAENIA SOLIUM IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)., BRUCELLA IGG(NOVALISA®)-THE BRUCELLA IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST BRUCELLA IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,BORRELIA BURGDORFERI IGM(NOVALISA®)-THE BORRELIA BURGDORFERI IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST BORRELIA BURGDORFERI IN HUMAN SERUM, PLASMA (CITRATE, HEPARIN) AND CSF (CEREBROSPINAL FLUID). FOR THE DETERMINATION OF INTRATHECALLY PRODUCED IGG ANTIBODIES A

	SEPARATE INSTRUCTION FOR USE FOR CSF (BORL0040) CAN BE OBTAINED AT NOVATEC.,CHAGAS(NOVALISA®)-THE CHAGAS (TRYPANOSOMA CRUZI) IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CHAGAS (TRYPANOSOMA CRUZI) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,PARAINFLUENZA VIRUS 1,2,3 IGA(NOVALISA®)-THE PARAINFLUENZA VIRUS 1, 2, 3 IGA-ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGA CLASS ANTIBODIES AGAINST PARAINFLUENZA VIRUS 1, 2, 3 IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,MYCOPLASMA PNEUMONIAE IGM(NOVALISA®)-THE MYCOPLASMA PNEUMONIAE IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST MYCOPLASMA PNEUMONIAE IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,LEPTOSPIRA IGG(NOVALISA®)-THE LEPTOSPIRA IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST LEPTOSPIRA SPP. IN HUMAN SERUM OR PLASMA (HEPARIN).,RHEUMATOID FACTOR IGM(NOVALISA®)-THE RHEUMATOID FACTOR IGM ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGM RHEUMATOID FACTORS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,MYCOPLASMA PNEUMONIAE IGA(NOVALISA®)-THE MYCOPLASMA PNEUMONIAE IGA ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGA CLASS ANTIBODIES AGAINST MYCOPLASMA PNEUMONIAE IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,COXIELLA BURNETII (Q-FEVER) PHASE 2 IGM (NOVALISA®)-"THE COXIELLA BURNETII (Q-FEVER) PHASE 2 IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST COXIELLA BURNETII (Q-FEVER) PHASE 2 IN THE EARLY STAGES OF INFECTION IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)",ADENOVIRUS IGM(NOVALISA®)-"THE ADENOVIRUS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST ADENOVIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).",EPSTEIN-BARR VIRUS (VCA) IGG(NOVALISA®)-"THE EPSTEIN-BARR VIRUS (VCA) IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST EPSTEIN-BARR VIRUS VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN). EPSTEIN-BARR VIRUS (VCA) IGG AVIDITY CAN BE DETERMINED WITH ASSAY AVIDITY EPSTEIN-BARR VIRUS (VCA) IGG ELISA (PRODUCT NUMBER: AEBV7150).",LEISHMANIA INFANTUM IGG(NOVALISA®)-THE LEISHMANIA INFANTUM IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST LEISHMANIA INFANTUM IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,ADENOVIRUS IGA(NOVALISA®)-"THE ADENOVIRUS IGA

	ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGA CLASS ANTIBODIES AGAINST ADENOVIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).",HELICOBACTER PYLORI IGG PLUS (NOVALISA®)-THE HELICOBACTER PYLORI IGG PLUS ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST HELICOBACTER PYLORI IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,HELICOBACTER PYLORI IGA PLUS (NOVALISA®)-THE HELICOBACTER PYLORI IGA PLUS ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGA CLASS ANTIBODIES AGAINST HELICOBACTER PYLORI IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,BORDETELLA PERTUSSIS IGM (NOVALISA®)-THE BORDETELLA PERTUSSIS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST BORDETELLA PERTUSSIS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,EPSTEIN-BARR VIRUS (EBNA) IGG(NOVALISA®)-THE EPSTEIN-BARR VIRUS (EBNA) IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST EPSTEIN-BARR VIRUS (EBNA) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,ENTAMOEBA HISTOLYTICA IGG(NOVALISA®)-THE ENTAMOEBA HISTOLYTICA IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST ENTAMOEBA HISTOLYTICA IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,HELICOBACTER PYLORI IGG(NOVALISA®)-THE HELICOBACTER PYLORI IGG ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST HELICOBACTER PYLORI IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,CANDIDA ALBICANS IGG(NOVALISA®)-THE CANDIDA ALBICANS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CANDIDA ALBICANS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)., EPSTEIN-BARR VIRUS (VCA) IGM(NOVALISA®)-THE EPSTEIN-BARR VIRUS (VCA) IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST EPSTEIN-BARR VIRUS VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,HELICOBACTER PYLORI IGA (NOVALISA®)-THE HELICOBACTER PYLORI IGA ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGA CLASS ANTIBODIES AGAINST HELICOBACTER PYLORI IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,LEPTOSPIRA IGM(NOVALISA®)-THE LEPTOSPIRA IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST LEPTOSPIRA SPP. IN HUMAN SERUM OR PLASMA (HEPARIN).,ADENOVIRUS IGG (NOVALISA®)-"THE ADENOVIRUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST

	ADENOVIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)."BORRELIA BURGDORFERI IGG(NOVALISA®)-THE BORRELIA BURGDORFERI IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST BORRELIA BURGDORFERI IN HUMAN SERUM, PLASMA (CITRATE, HEPARIN) AND CSF (CEREBROSPINAL FLUID). FOR THE DETERMINATION OF INTRATHECALLY PRODUCED IGG ANTIBODIES A SEPARATE INSTRUCTION FOR USE FOR CSF (BORL0040) CAN BE OBTAINED AT NOVATEC.,BORDETELLA PERTUSSIS TOXIN (PT) IGG(NOVALISA®)-THE B. PERTUSSIS TOXIN (PT) IGG ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST B. PERTUSSIS TOXIN (PT) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,BRUCELLA IGM(NOVALISA®)-THE BRUCELLA IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST BRUCELLA IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,CANDIDA ALBICANS IGM(NOVALISA®)-THE CANDIDA ALBICANS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST CANDIDA ALBICANS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)., CLOSTRIDIUM TETANI TOXIN 5S IGG PLUS(NOVALISA®)-"THE CLOSTRIDIUM TETANI TOXIN 5S IGG PLUS ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CLOSTRIDIUM TETANI TOXIN IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)."CORYNEBACTERIUM DIPHTERIAE TOXIN IGG (NOVALISA®)-THE CORYNEBACTERIUM DIPHTHERIAE TOXIN IGG ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CORYNEBACTERIUM DIPHTHERIAE TOXIN IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)., PARVOVIRUS B19 IGG(NOVALISA®)-THE PARVOVIRUS B19 IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST PARVOVIRUS B19 IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,ASCARIS LUMBRICOIDES IGG (NOVALISA®)-THE ASCARIS LUMBRICOIDES IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST ASCARIS LUMBRICOIDES IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,ASPERGILLUS FUMIGATUS IGG(NOVALISA®)-THE ASPERGILLUS FUMIGATUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST ASPERGILLUS FUMIGATUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,COXIELLA BURNETII (Q-FEVER) PHASE 2 IGG(NOVALISA®) -THE COXIELLA BURNETII (Q-FEVER) PHASE 2 IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST COXIELLA BURNETII (Q-FEVER) PHASE 2 IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,ECHINOCOCCUS IGG(NOVALISA®)-

	THE ECHINOCOCCUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST ECHINOCOCCUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)., RUBELLA VIRUS IGG(NOVALISA®)-"THE RUBELLA VIRUS IGG ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST RUBELLA VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN). RUBELLA IGG AVIDITY CAN BE DETERMINED WITH ASSAY AVIDITY RUBELLA VIRUS IGG (PRODUCT CODE: ARUB7400).",MUMPS VIRUS IGG(NOVALISA®)-THE MUMPS VIRUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST MUMPS VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,MUMPS VIRUS IGM(NOVALISA®)-THE MUMPS VIRUS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST MUMPS VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,MEASLES VIRUS IGM(NOVALISA®)-"THE MEASLES VIRUS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST MEASLES VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN). ",SCHISTOSOMA MANSONI IGG(NOVALISA®)-THE SCHISTOSOMA MANSONI IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST SCHISTOSOMA MANSONI IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,CLOSTRIDIUM TETANI TOXIN 5S IGG(NOVALISA®)-"THE CLOSTRIDIUM TETANI TOXIN 5S IGG ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CLOSTRIDIUM TETANI TOXIN IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).",PARAINFLUENZA VIRUS 1,2,3 IGG(NOVALISA®) -THE PARAINFLUENZA VIRUS 1, 2, 3 IGG-ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST PARAINFLUENZA VIRUS 1, 2, 3 IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,CLOSTRIDIUM TETANI TOXIN IGG(NOVALISA®)- "THE CLOSTRIDIUM TETANI TOXIN IGG ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CLOSTRIDIUM TETANI TOXIN IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).",CHAGAS (TRYPANOSOMA CRUZI) IGG (NOVALISA®)-THE CHAGAS ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES AGAINST CHAGAS (TRYPANOSOMA CRUZI) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,CORYNEBACTERIUM DIPHTERIAE TOXIN 5S IGG (NOVALISA®)-THE CORYNEBACTERIUM DIPHTHERIAE TOXIN 5S IGG ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CORYNEBACTERIUM DIPHTHERIAE TOXIN IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)., CORYNEBACTERIUM DIPHTERIAE TOXIN 5S IGG PLUS(NOVALISA®)-

		THE CORYNEBACTERIUM DIPHTHERIAE TOXIN 5S IGG PLUS ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CORYNEBACTERIUM DIPHTHERIAE TOXIN IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,VARICELLA-ZOSTER VIRUS (VZV) IGA(NOVALISA®)-THE VARICELLA-ZOSTER VIRUS (VZV) IGA ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGA CLASS ANTIBODIES AGAINST VARICELLA-ZOSTER VIRUS (VZV) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).
570	IMP/IVD/2020/000252	1.License Holder Name: VORTEX MEDSOLUTIONS PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOTYPESC™ (HEMOTYPESC™)-HEMOTYPESC™ IS A CLASS B RAPID TEST KIT INTENDED TO DETERMINE THE PRESENCE OF HEMOGLOBINS A, S AND C IN WHOLE BLOOD. THE KIT IS INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTH PROFESSIONALS.
571	IMP/IVD/2020/000254	1.License Holder Name: PERKINELMER INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREECLAMPSIA DETECTION KIT (DOT BLOT DIFFUSION)(PREECLAMPSIA DETECTION KIT (DOT BLOT DIFFUSION))-THIS KIT IS INTENDED TO AID IN PREECLAMPSIA DIAGNOSIS BY QUALITATIVE DETECTION OF CONGOPHILIA (SELECTIVE BINDING OF CONGO RED TO MISFOLDED PROTEINS) IN URINE. THE RESULT SHOULD BE INTERPRETED ALONG WITH CLINICAL FINDINGS AND OTHER LABORATORY TEST RESULTS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY.
572	IMP/IVD/2020/000255	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIBODY TEST (COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY)(LEPU)-THE PRODUCT IS INTENDED FOR THE QUALITATIVE DETECTION OF ANTIBODY CONTENT AGAINST COVID-19 IN CLINICAL SAMPLES (SERUM/PLASMA/ WHOLE BLOOD).

573	IMP/IVD/2020/000256	1.License Holder Name: INSTRUMENTATION LABORATORY INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOSIL ACUSTAR ANTI-(BETA)2GPI DOMAIN 1 REAGENT(HEMOSIL)-THE HEMOSIL ACUSTAR ANTI-ß2GPI DOMAIN 1 IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY (CIA) FOR THE SEMI-QUANTITATIVE DETERMINATION OF IGG AUTOANTIBODIES TO ß2GPI DOMAIN 1 IN HUMAN SERUM OR CITRATED PLASMA. THE PRESENCE OF ANTI-ß2GPI DOMAIN 1 AUTOANTIBODIES IS USED IN CONJUNCTION WITH CLINICAL AND OTHER LABORATORY FINDINGS AS AN AID IN THE DIAGNOSIS OF ANTIPHOSPHOLIPID SYNDROME. THE HEMOSIL ACUSTAR ANTI-ß2GPI DOMAIN 1 IS NOT INTENDED TO REPLACE ASSAYS FOR ANTIBODIES AGAINST THE WHOLE ß2GPI MOLECULE. TESTING FOR ANTIBODIES TO THE WHOLE ß2GPI MOLECULE IS REQUIRED ACCORDING TO THE CLASSIFICATION CRITERIA FOR ANTIPHOSPHOLIPID SYNDROME.
574	IMP/IVD/2020/000257	1.License Holder Name: IMPERIAL LIFE SCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REAL-TIME FLUORESCENT RT-PCR KIT FOR DETECTING 2019-NCOV(BGI)-THE KIT IS A QUALITATIVE IN VITRO NUCLEIC ACID AMPLIFICATION ASSAY TO DETECT THE NEW CORONAVIRUS IDENTIFIED IN CHINA IN 2019 USING REVERSE TRANSCRIPTION PCR IN SPECIMEN OF THROAT SWAB AND BRONCHOALVEOLAR LAVAGE FLUID (BALF) FROM SUSPECTS.
575	IMP/IVD/2020/000259	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIGHTMIX MODULAR SARBECOVIRUS E-GENE(LIGHTMIX MODULAR SARBECOVIRUS E-GENE)-THIS PRODUCT IS INTENDED TO BE USED TO DIAGNOSE AN INFECTION BY DETECTION OF THE VIRAL GENOME IN A TOTAL-NA NUCLEIC ACID EXTRACT OBTAINED FROM RESPIRATORY TRACT SPECIMEN FROM PATIENTS WITH SIGNIFICANT RESPIRATORY SYMPTOMS. THIS ASSAY HAS BEEN DEVELOPED FOR USE IN MULTIPLEX PCR AND CAN BE RUN COMBINED WITH A CONTROL REACTION.

576	IMP/IVD/2020/000260	1.License Holder Name: KRISHGEN BIOSYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIRAL RNA EXTRACTION KIT-VIRAL RNA EXTRACTION KIT IS USED FOR ISOLATING THE VIRAL RNA PLASMA, WHOLE BLOOD, CELL-FREE BODY FLUIDS (INCLUDING PLASMA, SERUM, URINE, CSF AND CELL CULTURE SUPERNATANT), VIRAL STOCK SOLUTION AND INFECTED TISSUES.,COVID-19 REAL TIME PCR KIT(-)-COVID-19 REAL TIME PCR KIT IS A REAL TIME PCR KIT FOR THE QUANTITATIVE DETECTION OF COVID-19 BY ISOLATING THE VIRAL RNA FROM THROAT AND NASAL SWABS.

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577	IMP/IVD/2020/000262	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTICHEM HSTN (MULTICHEM HSTN)-MULTICHEM HSTN IS INTENDED FOR USE AS A SINGLE LEVEL ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF HIGH SENSITIVE TROPONIN APPLICATIONS ON AUTOMATED ANALYSERS FOR THE ANALYTE TROPONIN I AS IISTED IN THE PACKAGE INSERT.,MULTICHEM A1C(MULTICHEM A1C)-MULTICHEM A1C CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTE, HBA1C AS LISTED IN THE PACKAGE INSERT.,MULTICHEM WBT(MULTICHEM WBT) -MULTICHEM WBT IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,MULTICHEM S PLUS (ASSAYED) LEVEL 1(MULTICHEM S PLUS (ASSAYED) LEVEL 1)-MULTICHEM S PLUS (ASSAYED) IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,MULTICHEM P (MULTICHEM P)-MULTICHEM P IS INTENDED FOR USE AS A SINGLE LEVEL ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,MULTICHEM IA PLUS (MULTICHEM IA PLUS)-MULTICHEM IA PLUS IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,MULTICHEM S PLUS (ASSAYED) LEVEL 2(MULTICHEM S PLUS (ASSAYED) LEVEL 2)-MULTICHEM S PLUS (ASSAYED) IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,MULTICHEM U(MULTICHEM U)-MULTICHEM U IS INTENDED FOR USE AS AN ASSAYED URINE QUALITY CONTROL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT., MULTICHEM S PLUS (UNASSAYED) LEVEL 2(MULTICHEM S PLUS (UNASSAYED) LEVEL 2)-MULTICHEM S PLUS (UNASSAYED) IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT., MULTICHEM S PLUS (ASSAYED) LEVEL 3(MULTICHEM S PLUS (ASSAYED) LEVEL 3)-MULTICHEM S PLUS (ASSAYED) IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR

	THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,MULTICHEM S PLUS (UNASSAYED) LEVEL 1(MULTICHEM S PLUS (UNASSAYED) LEVEL 1)-MULTICHEM S PLUS (UNASSAYED) IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,MULTICHEM S PLUS (UNASSAYED) LEVEL 3 (MULTICHEM S PLUS (UNASSAYED) LEVEL 3)-MULTICHEM S PLUS (UNASSAYED) IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.

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578	IMP/IVD/2020/000263	1.License Holder Name: M/S. CPC DIAGNOSTICS PVT, LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:2019-NCOV IGM CONTROL-2019-NCOV IGM CONTROL IS USED TO CHECK THE RELIABILITY OF 2019-NCOV IGM ASSAY. THE PERFORMANCE OF 2019-NCOV IGM CONTROL HAS NOT BEEN EVALUATED FOR OTHER ASSAYS OR INSTRUMENTS,IFLASH-JO-1 IGG(YHLO)-THE IFLASH-JO-1 IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODY TO JO-1 IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,2019-NCOV IGG CONTROL-2019-NCOV IGG CONTROL IS USED TO CHECK THE RELIABILITY OF 2019-NCOV IGG ASSAY. THE PERFORMANCE OF 2019-NCOV IGG CONTROL HAS NOT BEEN EVALUATED FOR OTHER ASSAYS OR INSTRUMENTS., IFLASH-GADA(YHLO)-THE IFLASH-GADA ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF GLUTAMIC ACID DECARBOXYLASE ANTIBODY (GADA) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER., IFLASH-IAA(YHLO)-THE IFLASH-IAA ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUALITATIVE DETERMINATION OF ANTI-INSULIN ANTIBODY IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-GBM IGG(YHLO)-THE IFLASH-GBM IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODY TO GLOMERULAR BASEMENT MEMBRANE IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-SCL-70 IGG(YHLO)-THE IFLASH-SCL-70 IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODY TO SCL-70 IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER. , IFLASH-ZNT8A(YHLO)-THE IFLASH-ZNT8A ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO ZINC TRANSPORTER 8 IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-ANTI-TSHR(YHLO)-THE IFLASH-ANTI-TSHR ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTI-TSHR IN HUMAN SERUM USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-PTH(YHLO)-"THE IFLASH-PTH ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PARATHYROID HORMONE (PTH) IN HUMAN SERUM AND PLASMA

	USING THE IFLASHIMMUNOASSAY ANALYZER", IFLASH-IA-2A(YHLO)-THE IFLASH-IA-2A ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODY OF PROTEIN TYROSINE PHOSPHATASE IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-BETA 2-GLYCOPROTEIN I IGA (YHLO)-THE IFLASH-BETA 2-GLYCOPROTEIN I IGA ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF BETA 2-GLYCOPROTEIN I IGA IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-ANTI-TPO(YHLO)-THE IFLASH-ANTI-TPO ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO THYROID PEROXIDASE (TPO) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-RA33 IGG(YHLO)-THE IFLASH-RA33 IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF RA33 IGG IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-DHEA-S(YHLO)-"THE IFLASH-DHEA-S ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF DHEA-S IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH-RF(YHLO)-THE IFLASH-RF ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-RNP70 IGG (YHLO)-THE IFLASH-RNP70 IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODY TO RNP70 IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-LH KIT(IFLASH)-THE IFLASH-LH ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER,IFLASH-PR3 IGG(YHLO)-THE IFLASH-PR3 IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODY TO PROTEINASE 3 IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,AMH CONTROL (ANTI MULLERIAN HORMONE CONTROL) (YHLO)-AMH CONTROL IS TO BE USED AS A MEANS OF CHECKING THE RELIABILITY OF AMH ASSAY. THE PERFORMANCE OF AMH CONTROL HAS NOT BEEN ESTABLISHED FOR OTHER ASSAYS OR INSTRUMENT.,

	IFLASH – TSH KIT(IFLASH)-THE IFLASH-TSH ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE (TSH)IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER,IFLASH-ANTI-CARDIOLIPIN (YHLO)-THE IFLASH-ANTI-CARDIOLIPIN ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTI-CARDIOLIPIN ANTIBODY IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-ACTH(YHLO)-"THE IFLASH-ACTH ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ADRENOCORTICOTROPIC HORMONE (ACTH) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER",IFLASH-FSH KIT(IFLASH)-THE IFLASH-FSH ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-ANTI-TG(YHLO)-THE IFLASH-ANTI-TG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO THYROGLOBULIN (TG) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-RF IGM(YHLO)-THE IFLASH-RF IGM ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF IGM ANTIBODY TO RHEUMATOID FACTOR (RF) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,PCT CONTROL (PROCALCITONIN CONTROL)(YHLO)-PCT CONTROL IS USED AS A MEANS OF CHECKING THE RELIABILITY OF PCT ASSAY. THE PERFORMANCE OF PCT CONTROL HAS NOT BEEN EVALUATED FOR OTHER ASSAYS OR INSTRUMENTS.,IFLASH-SS-B IGG (YHLO)-THE IFLASH-SS-B IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODY TO SS-B IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER., IFLASH-RF IGG(YHLO)-THE IFLASH-RF IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODY TO RHEUMATOID FACTOR (RF) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER., IFLASH-ANA(YHLO)-THE IFLASH-ANA ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTI-NUCLEAR ANTIBODIES IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER., IFLASH-CARDIOLIPIN IGA

	(YHLO)-THE IFLASH-CARDIOLIPIN IGA ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF CARDIOLIPIN IGA IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER., IFLASH-BETA 2-GLYCOPROTEIN I IGM(YHLO)-THE IFLASH-BETA 2-GLYCOPROTEIN I IGM ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF BETA 2-GLYCOPROTEIN I IGM IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH – T3 KIT(IFLASH)-THE IFLASH-T3 ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE (T3) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH – 25-OH VITAMIN D KIT(IFLASH)-THE IFLASH-25 OH VITAMIN D ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF 25OH VITAMIN D IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-BETA2-GLYCOPROTEIN I IGG(YHLO)-THE IFLASH-2-GLYCOPROTEIN I IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF 2-GLYCOPROTEIN I IGG IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH – PCT KIT(IFLASH)-THE IFLASH–PCT ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PCT IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-AMA-M2(YHLO)-THE IFLASH-AMA-M2 ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTI-MITOCHONDRIAL ANTIBODIES SUBTYPE M2 IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER,IFLASH – TRIGGER SOLUTION(1×)(IFLASH) -FOR USE IN THE IFLASH IMMUNOASSAY ANALYZER (IFLASH 3000/ IFLASH 1800) TO CLEAN THE CHEMILUMINESCENT SYSTEM., IMMUNOASSAY MULTI CONTROL(YHLO)-IMMUNOASSAY MULTI CONTROL IS USED AS A MEANS OF CHECKING THE RELIABILITY OF IMMUNOASSAYS LISTED IN ANALYTES PART. THE PERFORMANCE OF IMMUNOASSAY MULTI CONTROL HAS NOT BEEN EVALUATED FOR OTHER ASSAYS OR INSTRUMENT.,IFLASH – INSULIN KIT(IFLASH)-THE IFLASH-INSULIN ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-INHIBIN B KIT (IFLASH)-THE IFLASH-INHIBIN B ASSAY IS A PARAMAGNETIC

	PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF INHIBIN B IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER,IFLASH – PRE TRIGGER SOLUTION (1×)(IFLASH)-FOR USE IN THE IFLASH IMMUNOASSAY ANALYZER (IFLASH 3000/ IFLASH 1800) TO CLEAN THE CHEMILUMINESCENT SYSTEM.,IFLASH – ANTI-CCP KIT(IFLASH)-THE IFLASH-ANTI-CCP ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO CYCLIC CITRULLINATED PEPTIDE IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH – WASH BUFFER(10×)(IFLASH)-FOR USE IN THE IFLASH IMMUNOASSAY ANALYZER (IFLASH 3000/ IFLASH 1800) TO CLEAN THE PIPELINE SYSTEM.,IFLASH – FT3 KIT(IFLASH)-THE IFLASH-FT3 ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER, IFLASH-SMA IGG(YHLO)-THE IFLASH-SMA IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUALITATIVE DETERMINATION OF ANTIBODY TO SMOOTH MUSCLE IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-ANTI-BETA 2-GLYCOPROTEIN I (YHLO)-THE IFLASH-ANTI-BETA 2-GLYCOPROTEIN I ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTI-BETA 2-GLYCOPROTEIN I IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-ICA (YHLO)-THE IFLASH-ICA ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUALITATIVE DETERMINATION OF ISLET CELL ANTIBODY (ICA) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-HCG(YHLO)-"THE IFLASH-HCG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN HUMAN SERUM AND PLASMA USINGTHE IFLASH IMMUNOASSAY ANALYZER. DO NOT USE IT TO EVALUATE THE RISK OF TRISOMY 21 (DOWNSYNDROME)",IFLASH-DSDNA IGG(YHLO)-THE IFLASH-DSDNA IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODY TO SYSTEMIC LUPUS ERYTHEMTOSUS (SLE) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER., IFLASH – FOLATE KIT(IFLASH)-THE IFLASH-FOLATE ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FOLATE IN

	HUMAN SERUM, PLASMA AND ERYTHROCYTE USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-BNP (YHLO)-THE IFLASH-BNP ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF BNP IN HUMAN AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-MYOGLOBIN(YHLO)-THE IFLASH-MYOGLOBIN ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH-MPO IGG(YHLO)-THE IFLASH-MPO IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODY TO MYELOPEROXIDASE IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,INHIBIN B CONTROL(YHLO)-INHIBIN B CONTROL IS USED AS A MEANS OF CHECKING THE RELIABILITY OF INHIBIN B ASSAY. THE PERFORMANCE OF INHIBIN B CONTROL HAS NOT BEEN ESTABLISHED FOR OTHER ASSAYS OR INSTRUMENTS.,IFLASH – PIIIPN-P KIT (IFLASH)-THE IFLASH-PIIIPN-P ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PIIIPN-P IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER,IFLASH – COL IV KIT(IFLASH)-THE IFLASH-COI IVASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF COI IV IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER,IFLASH – FERRITIN KIT (IFLASH)-THE IFLASH-FERRITIN ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FERRITIN SPECIFIC ANTIGEN IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH – LAMININ KIT(IFLASH)-THE IFLASH-LAMININ ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF LAMININ IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER,IFLASH-SS-A IGG(YHLO)-THE IFLASH-SS-A IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODY TO SS-A IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH – CORTISOL KIT(IFLASH)-THE IFLASH-CORTISOL ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER,IFLASH – FT4 KIT (IFLASH)-THE IFLASH-FT4 ASSAY IS A PARAMAGNETIC PARTICLE

	CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH – VITAMIN B12 KIT(IFLASH)-THE IFLASH-VITAMIN B12 ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH – HA KIT(IFLASH)-THE IFLASH-HA ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF HA IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER., IFLASH-PROGESTERONE KIT(IFLASH)-THE IFLASH-PROGESTERONE ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER,IFLASH-CARDIOLIPIN IGM(YHLO)-THE IFLASH-CARDIOLIPIN IGM ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTI-CARDIOLIPIN ANTIBODY IGM IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER. , IFLASH-SM IGG(YHLO)-THE IFLASH-SM IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODY TO SM PROTEINS IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER.,IFLASH – PROLACTIN KIT(IFLASH)-THE IFLASH-PROLACTIN ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER,IFLASH – T4 KIT (IFLASH)-THE IFLASH-T4 ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE (T4) IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER,IFLASH-TESTOSTERONE KIT(IFLASH)-THE IFLASH-TESTOSTERONE ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM AND (OR) PLASMA USING THE IFLASH IMMUNOASSAY ANLAYZER.,IFLASH – WASH BUFFER(1×)(IFLASH)-FOR USE IN THE IFLASH IMMUNOASSAY ANALYZER (IFLASH 3000/ IFLASH 1800) TO CLEAN THE PIPELINE SYSTEM,IFLASH-AMH KIT (IFLASH)-THE IFLASH-AMH ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF AMH IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER,IFLASH-CARDIOLIPIN IGG(YHLO)-

	THE IFLASH-CARDIOLIPIN IGG ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODY TO CARDIOLIPIN IN HUMAN SERUM AND PLASMA USING THE IFLASH IMMUNOASSAY ANALYZER., IFLASH – C-PEPTIDE KIT(IFLASH)-THE IFLASH-C-PEPTIDE ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM, PLASMA AND URINE USING THE IFLASH IMMUNOASSAY ANALYZER,IFLASH – E2 KIT(IFLASH)-THE IFLASH-E2 ASSAY IS A PARAMAGNETIC PARTICLE CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF E2 IN HUMAN SERUM AND (OR) PLASMA USING THE IFLASH IMMUNOASSAY ANLAYZER

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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579	IMP/IVD/2020/000264	1.License Holder Name: SHIVA SCIENTIFIC COMPANY 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIROQ SARS COV-2 (VIROQ SARS COV-2)-THE VIROQ SARS-COV-2 KIT IS USED FOR QUALITATIVE DETECTION OF SARS-COV-2 RNA IN RESPIRATORY SPECIMENS SUCH AS SPUTUM OR SWABS BASED ON REVERSE TRANSCRIPTION OF THE RNA AND SUBSEQUENT AMPLIFICATION IN REAL-TIME PCR. THE TEST IS PERFORMED BY QUALIFIED PERSONNEL IN SPECIALISED LABS.,HISTO TYPE DR/DQB(HISTO TYPE DR/DQB)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR LOW RESOLUTION MOLECULAR GENETIC TYPING OF THE HLA-DR AND DQB WITH THE (SSP)-PCR TECHNIQUE.,HISTO TYPE DR LOW(HISTO TYPE DR LOW)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR LOW RESOLUTION MOLECULAR GENETIC TYPING OF THE HLA-DR ALLELES WITH THE (SSP)-PCR TECHNIQUE. ,HISTO TYPE ABC(HISTO TYPE ABC)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR LOW RESOLUTION MOLECULAR GENETIC TYPING OF THE HLA-A, B AND C ALLELES WITH THE (SSP)-PCR TECHNIQUE.,HISTO TYPE ABDR (HISTO TYPE ABDR)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR LOW RESOLUTION MOLECULAR GENETIC TYPING OF THE HLA-A, B AND DR ALLELES WITH THE (SSP)-PCR TECHNIQUE. ,RABBIT COMPLEMENT(RABBIT COMPLEMENT)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE REAGENT FOR USE IN THE MICROLYMPHOCYTOTOXICITY TEST TO DETECT HLA-ANTIGENS ON HUMAN LYMPHOCYTES.,HISTO TYPE B LOW(HISTO TYPE B LOW)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR LOW RESOLUTION MOLECULAR GENETIC TYPING OF THE HLA-B ALLELES WITH THE (SSP)-PCR TECHNIQUE. ,HISTO TYPE A LOW(HISTO TYPE A LOW)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR LOW RESOLUTION MOLECULAR GENETIC TYPING OF THE HLA-A ALLELES WITH THE (SSP)-PCR TECHNIQUE.,HAPPY TAQ (HAPPY TAQ)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE THERMOSTABLE DNA POLYMERASE TO BE USED TOGETHER WITH THE KITS FROM THE BAG PRODUCT LINE HISTO TYPE FOR MOLECULAR GENETIC HLA TYPING USING THE SEQUENCE SPECIFIC PRIMER (SSP)-PCR.,HISTO TYPE CELIAC DISEASE(HISTO TYPE CELIAC DISEASE)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR THE DETECTION OF HLA ALLELES ASSOCIATED WITH CELIAC DISEASE WITH THE (SSP)-PCR TECHNIQUE. ,HISTO TYPE B27 LOW(HISTO TYPE B27 LOW)-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR THE DETECTION OF HLA-B27 WITH THE (SSP)-PCR TECHNIQUE.,HISTO

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		TRAY ABC 72 (10)(HISTO TRAY ABC 72 (10))-IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE TEST KIT FOR SEROLOGICAL TISSUE TYPING OF HLA CLASS I ANTIGENS.
580	IMP/IVD/2020/000268	1.License Holder Name: PROVIDENCE INTERNATIONAL LABS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:2019-NCOV IGG/IGM RAPID TEST DEVICE(COVID-19 RAPID IGM/IGG COMBINED ANTIBODY ASSAY PRE-SCREENING KIT)-2019-NCOV IGG/IGM RAPID TEST DEVICE IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGG/IGM ANTIBODY OF WUHAN NEW CORONAVIRUS IN HUMAN WHOLE BLOOD, SERUM OR PLASMA AS AN AID IN THE DIAGNOSIS OF 2019-NCOV INFECTIONS.
581	IMP/IVD/2020/000271	1.License Holder Name: SD BIOSENSOR HEALTHCARE PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCUPREP DX VIRAL RNA EXTRACTION KIT(NA)-IT IS AN IN VITRO DIAGNOSTIC KIT DESIGNED FOR THE EXTRACTION OF VIRAL RNA FROM VARIOUS HUMAN SAMPLES SUCH AS SERUM, PLASMA AND CSF.
582	IMP/IVD/2020/000276	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COBAS LIPID CONTROL (COBAS LIPID CONTROL)-COBAS LIPID CONTROL SOLUTION IS USED FOR PERFORMING QUALITY CONTROL OF TOTAL CHOLESTEROL (TC), HIGH DENSITY LIPOPROTEIN (HDL), CHOLESTEROL AND TRIGLYCERIDES (TG) WITH COBAS LIPID PANEL TEST ON THE COBAS B 101 INSTRUMENT.,COBAS CRP CONTROL(COBAS CRP CONTROL)-COBAS CRP CONTROL SOLUTION IS USED FOR PERFORMING QUALITY CONTROL OF CRP WITH COBAS CRP REAGENT DISCS ON THE COBAS B 101 INSTRUMENT

583	IMP/IVD/2020/000277	1.License Holder Name: M/S HEMOGENOMICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID19 IGG/IGM RAPID GOLD(:PCL COVID19 IGG/IGM RAPID GOLD)-PCL COVID19 IGG/IGM RAPID GOLD IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR QUALITATIVE DETECTION OF IGG AND IGM ANTIBODIES OF COVID19 INFECTION IN HUMAN SERUM, PLASMA, VENOUS BLOOD AND CAPILLARY BLOOD.,NCOV ONE STEP RT- PCR KIT(PCL MDTM NCOV)-ONE STEP RC PTR KIT FOR DETECTION OF RNA OF SARS-COV-2(COVID-19),COVID19 AG RAPID FIA(PCL COVID19 AG RAPID FIA)-:FOR DETECTION OF SARS-COV-2(COVID-19) ANTIGEN IN SPUTUM OR NASOPHARYNGEAL / OROPHARYNGEAL SWAB SAMPLES OF HUMAN.

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584	IMP/IVD/2020/000278	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:H-FABP RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF H-FABP IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION., SARS-COV-2 ANTIBODY TEST-SARS-COV-2 ANTIBODY TEST IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) IGG/IGM ANTIBODY IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SAMPLE.,CRP RAPID QUANTITATIVE TEST(-)-QUANTITATIVE DETERMINATION OF CRP IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS USED AS AN AID TO PREDICT FUTURE CARDIOVASCULAR DISEASES (CVD) AS WELL AS TO SEE INFECTION AND INFLAMMATION.,TROPONIN I RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF CTN I IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI).,CK-MB RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF CK-MB IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI).,ONE STEP PCT RAPID QUANTITATIVE TEST-QUANTITATIVE MEASUREMENT OF PROCALCITONIN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS USED AS AN AID TO DIAGNOSE AND CONTROL THE TREATMENT OF SEVERE, BACTERIAL INFECTION AND SEPSIS.",TSH RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID TO ASSIST IN THE ASSESSMENT OF PITUITARY GLAND AND THYROID FUNCTION.,PCT RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF PCT IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO DIAGNOSIS SEVERE, BACTERIAL INFECTION AND SEPSIS.,CTNI-NTPROBNP RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF CTN I AND NT-PROBNP IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION AND SUSPECTED CONGESTIVE HEART FAILURE.,ONE STEP D-DIMER RAPID QUANTITATIVE TEST-QUANTITATIVE ANALYSIS OF CROSS-LINKED FIBRIN DEGRADATION PRODUCTS CONTAINING D-DIMER IN HUMAN WHOLE BLOOD OR PLASMA. THE TEST IS USED AS AN AID IN DETECTING THE PRESENCE AND ASSESSING THE DEGREE OF INTRAVASCULAR COAGULATION OR THROMBOEMBOLIC EVENTS INCLUDING PULMONARY EMBOLISM.,D-

	DIMER RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN WHOLE BLOOD AND PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF THROMBOSIS AND THROMBOTIC DISEASES.,NT-PROBNP RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF NT-PROBNP IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS USED AS AN AID FOR THE DIAGNOSIS OF SUSPECTED CONGESTIVE HEART FAILURE.,CK-MB/ MYO/ CTN I RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF CTNI, CK-MB AND MYO IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION.,LH RAPID QUANTITATIVE TEST-INTENDED FOR QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) INHUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO DIAGNOSE THE OVULATION CYCLE, PREMATURE OVARIAN FAILURE AND GONADAL HYPOPLASIA.,VITAMIN D RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF TOTAL 25(OH) D2/D3 LEVEL IN HUMAN SERUM OR PLASMA. RESULTS ARE TO BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST THE CLINICIAN IN THE ASSESSMENT OF VITAMIN D SUFFICIENCY.,T3 RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (TOTAL T3) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID TO THE ASSESSMENT OF THYROID FUNCTION.,FSH RAPID QUANTITATIVE TEST-INTENDED FOR QUANTITATIVE MEASUREMENT OF FOLLICLE-STIMULATING HORMONE (FSH) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST USED AS AN AID TO EVALUATE THE OVARIAN FUNCTIONS IN CLINICAL.,ONE STEP MAU RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF MAU IN HUMAN URINE. THIS TEST IS USED AS AN AID TO DIAGNOSIS OF KIDNEY DAMAGE.,B-HCG RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF B-HCG IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF EARLY DETECTION OF PREGNANCY,HBA1C RAPID QUANTITATIVE TEST-USED QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C IN HUMAN BLOOD. THE TEST IS USED AS AN AID TO MONITOR LONG-TERM GLYCEMIC STATUS IN PATIENTS WITH DIABETES MELLITUS.,T4 RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF THYROXINE (TOTAL T4) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID TO THE ASSESSMENT OF THYROID FUNCTION.,PROGESTERONE RAPID QUANTITATIVE TEST-INTENDED FOR QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM, WHOLE BLOOD OR PLASMA. THE TEST IS USED AS AN AID TO THE TRACK OVULATION.,MYO RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF

		MYOGLOBIN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS USED AS AN AID TO ASSIST IN THE DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI).,BNP RAPID QUANTITATIVE TEST-INTENDED FOR QUANTITATIVE DETERMINATION OF BRAIN NATRIURETIC PEPTIDES (BNP) IN HUMAN WHOLE BLOOD OR PLASMA. THIS TEST IS USED AS AN AID TO PREDICT THE RISK OF HEART FAILURE.,NGAL RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF NEUTROPHIL GELATINASE ASSOCIATED LIPOCALIN (NGAL) CONCENTRATION IN HUMAN URINE. THE TEST IS USED AS AN AID FOR THE DIAGNOSIS OF KIDNEY INJURIES.,CRP-PCT RAPID QUANTITATIVE TEST-QUANTITATIVE DETERMINATION OF CRP AND PCT IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THIS TEST IS USED AS AN AID TO SEE INFECTION AND INFLAMMATION AND USED TO AID IN THE EARLY DETECTION OF CLINICALLY RELEVANT BACTERIAL INFECTIONS.
585	IMP/IVD/2020/000279	1.License Holder Name: RAYMED TRADING GROUP PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTIBODY TEST COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY(SARS-COV-2)-THE PRODUCT IS INTENDED FOR THE QUALITATIVE DETECTION OF ANTIBODY CONTENT AGAINST SARS-COV-2 IN CLINICAL SAMPLES (SERUM/PLASMA/WHOLE BLOOD.
586	IMP/IVD/2020/000280	1.License Holder Name: IMPERIAL LIFE SCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIRUS DNA/RNA EXTRACTION KIT-TO EXTRACT VIRAL DNA/RNA FROM VARIOUS SAMPLE TYPES INCLUDING COVID-19
587	IMP/IVD/2020/000281	1.License Holder Name: M/S ARACION TECHNOLOGY PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 IGM ANTIBODY RAPID TEST KIT(HECIN)-HECIN COVID-19 IGM ANTIBODY RAPID TEST KIT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE DETECTION OF COVID-19 IGM ANTIBODY IN WHOLE BLOOD, SERUM, PLASMA AND FINGERTIP BLOOD. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY 2019-NCOV. THE TEST PROVIDES PRELIMINARY TEST RESULTS. NEGATIVE RESULTS DON'T PRECLUDE COVID-19 INFECTION AND THEY CANNOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISION.

588	IMP/IVD/2020/000282	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MOLECUTECH REAL-TIME COVID-19(YD)-MOLECUTECH® REAL-TIME COVID-19 TEST IS A REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN SPUTUM, BRONCHIAL ALVEOLAR LAVAGE FLUID, OROPHARYNGEAL AND NASOPHARYNGEAL SWAB SAMPLES FROM INDIVIDUALS WITH SIGNS AND SYMPTOMS OF INFECTION WHO ARE SUSPECTED OF COVID-19. TESTING IS LIMITED TO LABORATORIES - CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C. §263A, TO PERFORM HIGH COMPLEXITY TESTS.
589	IMP/IVD/2020/000283	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS DETECTION KIT (VERI-Q PCR 316)-THIS KIT IS USED IN QUALITATIVE DETECTION OF NOVEL CORONA VIRUS IN NASAL /THROAT SWAB, ALVEOLAR LAVAGE FLUIDS SPECIMENS FROM SUSPECTED COVID-19 CASES, SUSPECTED CLUSTERED CASES, OTHER CASES REQUIRING COVID-19 DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS. ,VIRAL DNA/RNA PREP KIT - AIRWAY CLINICAL SAMPLE (VERI-Q PREP M16)-KIT WILL BE USE WITH NOVEL CORONA VIRUS KIT FOR SAMPLE PREPARATION KIT
590	IMP/IVD/2020/000285	1.License Holder Name: BILCARE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ONE STEP TEST FOR NOVEL CORONAVIRUS(2019-NCOV) IGM/IGG ANTIBODY (COLLOIDAL GOLD)(ONE STEP TEST FOR NOVEL CORONAVIRUS(2019-NCOV) IGM/IGG ANTIBODY (COLLOIDAL GOLD))-ONE STEP TEST FOR NOVEL CORONAVIRUS (2019-NCOV) IGM/IGG ANTIBODY (COLLOIDAL GOLD) IS INTENDED FOR THE QUALITATIVE DETECTION OF 2019-NOVEL CORONAVIRUS IGM AND IGG ANTIBODY IN SERUM, PLASMA, FINGERTIP BLOOD OR WHOLE BLOOD SAMPLES OF PNEUMONITIS PATIENTS OR SUSPECTED CASES.

591	IMP/IVD/2020/000286	1.License Holder Name: COSARA DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (2019-NCOV) TEST KIT(LOGIX SMART)-THE LOGIX SMART 2019 NOVEL CORONAVIRUS (2019-NCOV) KIT TEST, BASED ON REAL-TIME PCR (QPCR) TECHNOLOGY, FOR THE QUALITATIVE DETECTION OF THE 2019 NOVEL CORONAVIRUS (2019-NCOV)
592	IMP/IVD/2020/000289	1.License Holder Name: SOLUMED INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD)(WONDFO)-SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD) IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARSCOV- 2) IGG/IGM ANTIBODY IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SAMPLE. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY SARS-COV- 2. THE TEST PROVIDES PRELIMINARY TEST RESULTS. NEGATIVE RESULTS DON'T PRECLUDE SARS-COV-2 INFECTION AND THEY CANNOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISION. FOR IN VITRO DIAGNOSTIC USE ONLY. FOR PROFESSIONAL USE ONLY.
593	IMP/IVD/2020/000290	1.License Holder Name: INVEX HEALTH PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS- COV-2 ANTIBODY TEST (LATERAL FLOW METHOD)(WONDFO)-WONDFO SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD) IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) IGG/IGM ANTIBODY IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SAMPLE. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY SARS-COV-2. THE TEST PROVIDES PRELIMINARY TEST RESULTS. NEGATIVE RESULTS DON'T PRECLUDE SARS-COV-2 INFECTION AND THEY CANNOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISION.

594	IMP/IVD/2020/000291	1.License Holder Name: HARMONY LIFESCIENCE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HUMASIS COVID-19 IGG/IGM TEST (HUMASIS COVID-19 IGG/IGM TEST)-HUMASIS COVID-19 IGG/IGM TEST IS ONE STEP IN VITRO DIAGNOSTIC TEST BASED ON AN IMMUNOCHROMATOGRAPHIC ASSAY. IT IS DESIGNED FOR QUALITATIVE DETECTION OF IMMUNOGLOBULIN G AND IMMUNOGLOBULIN M ANTIBODY OF NOVEL CORONAVIRUS (COVID-19) IN HUMAN BLOOD.
595	IMP/IVD/2020/000292	1.License Holder Name: INBIOS INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ONE STEP TEST FOR NOVEL CORONAVIRUS (2019-NCOV) IGM/IGG ANTIBODY (COLLOIDAL GOLD)-ONE STEP TEST FOR NOVEL CORONAVIRUS (2019-NCOV) IGM/IGG ANTIBODY (COLLOIDAL GOLD) IS INTENDED FOR THE QUALITATIVE DETECTION OF 2019-NOVEL CORONAVIRUS IGM AND IGG ANTIBODY IN SERUM, PLASMA, FINGERTIP BLOOD OR WHOLE BLOOD SAMPLES OF PNEUMONITIS PATIENTS OR SUSPECTED CASES.
596	IMP/IVD/2020/000293	1.License Holder Name: MEDSMART LOGISTICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONA VIRUS NUCLEIC ACID DIAGNOSTIC KIT-NOVEL CORONA VIRUS NUCLEIC ACID DIAGNOSTIC KIT
597	IMP/IVD/2020/000294	1.License Holder Name: BRAVO PHRMACEUTICLS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOSYNEX COVID-19 BSS (BIOSYNEX)-RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGG AND IGM. ANTIBODIES TO SARS-COV-2 IN HUMAN WHOLE BLOOD, SERUM OR PLASMA AS AN AID IN THE DIAGNOSIS OF PRIMARY AND SECONDARY SARS-COV-2 INFECTIONS.

598	IMP/IVD/2020/000295	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABBOTT M SAMPLE PREPARATION SYSTEM DNA(ABBOTT M SAMPLE PREPARATION SYSTEM DNA)-THE ABBOTT M SAMPLE PREPARATION SYSTEM DNA IS USED FOR THE LABORATORY ISOLATION OF NUCLEIC ACIDS FROM BIOLOGICAL SAMPLES THAT IS FUNCTIONAL IN STANDARD POLYMERASE CHAIN REACTION (PCR) REACTIONS.,ABBOTT M SAMPLE PREPARATION SYSTEM BULK MLYSIS DNA BUFFER KIT (ABBOTT M SAMPLE PREPARATION SYSTEM BULK MLYSIS DNA BUFFER KIT)-THE ABBOTT MSAMPLE PREPARATION SYSTEM DNA BULK LYSIS BUFFER KIT IS A GENERAL LABORATORY REAGENT USED FOR SAMPLE LYSIS DURING LABORATORY ISOLATION OF NUCLEIC ACIDS FROM BIOLOGICAL SAMPLES,ABBOTT M SAMPLE PREPARATION SYSTEM(ABBOTT M SAMPLE PREPARATION SYSTEM)-THE ABBOTT MSAMPLE PREPARATION SYSTEM IS USED FOR THE LABORATORY ISOLATION OF NUCLEIC ACIDS FROM BIOLOGICAL SAMPLES THAT IS FUNCTIONAL IN STANDARD POLYMERASE CHAIN REACTION (PCR) REACTIONS
599	IMP/IVD/2020/000296	1.License Holder Name: IMPERIAL LIFE SCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 LGG/LGM RAPID TEST CASSETTE(NEWSCEN)-COVID-19 LGG/LGM RAPID TEST CASSETTE IS FOR THE DETECTION OF LGG/LGM IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT CANNOT BE USED AS THE BASIS FOR THE DIAGNOSIS AND EXCLUSIVE OF COVID-19

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600	IMP/IVD/2020/000298	1.License Holder Name: M/S GENES 2 ME PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIAGNOSTIC KIT FOR IGM/IGG ANTIBODY TO CORONAVIRUS (SARS-COV-2) (LATERAL FLOW)(LIVZON)-THIS PRODUCT IS USED FOR IN VITRO QUALITATIVE DETECTION OF CORONAVIRUS (SARS-COV-2) IGM/IGG ANTIBODY IN HUMAN SERUM, PLASMA AND VENOUS WHOLE BLOOD SAMPLES. NEGATIVE RESULTS DO NOT RULE OUT SARS-COV-2 INFECTION, PARTICULARLY IN THOSE WHO HAVE BEEN IN CONTACT WITH THE VIRUS. FOLLOW-UP TESTING WITH A MOLECULAR DIAGNOSTIC SHOULD BE CONSIDERED TO RULE OUT INFECTION IN THESE INDIVIDUALS. RESULTS FROM ANTIBODY TESTING SHOULD NOT BE USED AS THE SOLE BASIS TO DIAGNOSE OR EXCLUDE SARS-COV-2 INFECTION OR TO INFORM INFECTION STATUS. NOT FOR THE SCREENING OF THE GENERAL POPULATION. FOR PROFESSIONAL USE ONLY.
601	IMP/IVD/2020/000299	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (2019-NCOV)REAL TIME MULTIPLEX RT-PCR KIT (DETECTION FOR 3 GENES)(LIFERIVER)-NOVEL CORONAVIRUS(2019-NCOV)REAL TIME MULTIPLEX RT-PCR KIT (DETECTION FOR 3 GENES) IS USED FOR THE IN VITRO QUALITATIVE DETECTION OF 2019NOVEL CORONAVIRUS (2019-NCOV) RNA IN UPPER RESPIRATORY TRACT SPECIMENS (NASOPHARYNGEAL AND OROPHARYNGEAL EXTRACTS) AND LOWER RESPIRATORY TRACT SPECIMENS (BRONCHOALVEOLAR LAVAGE FLUID (BALF)AND DEEP COUGH SPUTUM) BY REAL TIME PCR SYSTEMS. IT IS CONSIDERED AS AN AID IN THE DIAGNOSIS OF THE 2019-NCOV INFECTION.,VIRAL RNA ISOLATION KIT (PRELOADED FOR AUTO-EXTRACTION)(LIFERIVER)-VIRAL RNA ISOLATION KIT (PRELOADED FOR AUTO-EXTRACTION) UTILIZES MAGNETIC PARTICLE TECHNOLOGY FOR ISOLATION AND PURIFICATION OF PATHOGEN'S NUCLEIC ACIDS FROM BIOLOGICAL SPECIMENS. THIS KIT CAN BE USED IN COMBINATION WITH AUTOMATED NUCLEIC ACID EXTRACTION SYSTEMS. THE PRODUCT IS INTENDED TO BE USED BY PROFESSIONAL USERS, SUCH AS TECHNICIANS AND PHYSICIANS WHO ARE TRAINED IN MOLECULAR BIOLOGICAL TECHNIQUES. VIRAL RNA ISOLATION KIT (PRELOADED FOR AUTO-EXTRACTION) IS INTENDED FOR IN VITRO DIAGNOSTIC USE.

602	IMP/IVD/2020/000300	1.License Holder Name: QIAGEN INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QIAMP VIRAL RNA MINI KIT(QIAMP VIRAL RNA MINI KIT)-QIAAMP VIRAL RNA MINI KITS PROVIDE THE FASTEST AND EASIEST WAY TO PURIFY VIRAL RNA FOR RELIABLE USE IN AMPLIFICATION TECHNOLOGIES. VIRAL RNA CAN BE PURIFIED FROM PLASMA (TREATED WITH ANTICOAGULANTS OTHER THAN HEPARIN), SERUM AND OTHER CELLFREE BODY FLUIDS. THE QIAAMP VIRAL RNA MINI KIT IS INTENDED FOR MOLECULAR BIOLOGY APPLICATIONS. THIS PRODUCT IS NOT INTENDED FOR THE DIAGNOSIS, PREVENTION, OR TREATMENT OF A DISEASE.,QIAAMP DSP DNA BLOOD MINI KIT(QIAAMP DSP DNA BLOOD MINI KIT)-THE QIAAMP DSP DNA BLOOD MINI KIT IS A SYSTEM FOR ISOLATION AND PURIFICATION OF GENOMIC DNA FROM BIOLOGICAL SPECIMENS. THE QIAAMP DSP DNA BLOOD MINI KIT IS INTENDED FOR IN VITRO DIAGNOSTIC USE.,ARTUS SARS-COV- 2 PREP& UM KIT(ARTUS)-THE ARTUS SARS-COV-2 PREP& UM KIT IS A REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN NASOPHARYNGEAL SWABS (NPS), NASAL SWABS, AND OROPHARYNGEAL SWABS FROM INDIVIDUALS WITH SIGNS AND SYMPTOMS OF INFECTION OR WHO ARE SUSPECTED OF COVID-19. IT IS INTENDED AS AN AID IN THE DIAGNOSIS OF COVID-19 IN THE ACUTE PHASE OF INFECTION IN COMBINATION WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. THE ARTUS SARS-COV-2 PREP& UM KIT IS TO BE USED IN A MOLECULAR BIOLOGY LABORATORY ENVIRONMENT BY PROFESSIONAL USERS, SUCH AS TRAINED CLINICAL LABORATORY PERSONNEL SPECIFICALLY INSTRUCTED IN THE TECHNIQUES OF REAL-TIME PCR AND IN VITRO DIAGNOSTIC PROCEDURES. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR PATIENT MANAGEMENT DECISIONS. THE ARTUS SARS-COV-2 PREP& UM KIT IS INTENDED TO BE USED WITH THE ROTOR-GENE Q (RGQ) MDX SYSTEM OR THE ABI 7500 FAST DX AS RT-PCR INSTRUMENTS.,ARTUS VZV RG PCR KIT & ARTUS VZV QS-RGQ KIT(ARTUS VZV RG PCR KIT & ARTUS VZV QS-RGQ KIT)-THE ARTUS VZV RG PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF VZV DNA IN HUMAN CEREBRAL SPINAL FLUID (CSF). THIS DIAGNOSTIC TEST KIT UTILIZES THE POLYMERASE CHAIN REACTION (PCR) AND IS CONFIGURED FOR USE WITH ROTOR-GENE Q INSTRUMENTS., QIASYMPHONY DSP VIRUS / PATHOGEN MINI KIT(QIASYMPHONY DSP VIRUS / PATHOGEN MINI KIT)-THE QIASYMPHONY DSP VIRUS/PATHOGEN MINI KIT UTILIZE MAGNETIC-PARTICLE TECHNOLOGY FOR AUTOMATED ISOLATION AND PURIFICATION OF

		NUCLEIC ACIDS FROM BIOLOGICAL SPECIMENS.,QIAAMP DSP VIRUS KIT(QIAAMP DSP VIRUS KIT)-THE QIAAMP DSP VIRUS KIT IS A GENERIC SYSTEM THAT USES SILICA-MEMBRANE TECHNOLOGY (QIAAMP TECHNOLOGY) FOR ISOLATION AND PURIFICATION OF VIRAL NUCLEIC ACIDS FROM HUMAN PLASMA OR SERUM SAMPLES FOR IN VITRO DIAGNOSTIC PURPOSES.,EZ1 DSP VIRUS KIT(EZ1 DSP VIRUS KIT)-THE EZ1 DSP VIRUS KIT UTILIZES MAGNETIC-PARTICLE TECHNOLOGY FOR AUTOMATED ISOLATION AND PURIFICATION OF VIRAL NUCLEIC ACIDS AND BACTERIAL DNA FROM BIOLOGICAL SPECIMENS.,QIASYMPHONY DSP VIRUS / PATHOGEN MIDI KIT (QIASYMPHONY DSP VIRUS / PATHOGEN MIDI KIT)-THE QIASYMPHONY DSP VIRUS/PATHOGEN MIDI KIT UTILIZE MAGNETIC-PARTICLE TECHNOLOGY FOR AUTOMATED ISOLATION AND PURIFICATION OF NUCLEIC ACIDS FROM BIOLOGICAL SPECIMENS.,ARTUS HSV-1/2 RG PCR KIT & ARTUS HSV-1/2 QS-RGQ KIT(ARTUS HSV-1/2 RG PCR KIT & ARTUS HSV-1/2 QS-RGQ KIT)-THE ARTUS HSV-1/2 RG-PCR & ARTUS HSV-1/2 QS-RGQ KIT IS A REAL-TIME DETECTION AND DISCRIMINATION OF VIRUS DNA HUMAN HERPES SIMPLEX 1 AND 2 IN HUMAN CEREBROSPINAL FLUID SAMPLE (CSF) OF INDIVIDUALS INFECTED.,ARTUS BK VIRUS RG PCR KIT & ARTUS BK VIRUS QS-RGQ KIT(ARTUS BK VIRUS RG PCR KIT & ARTUS BK VIRUS QS-RGQ KIT)-AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF BK VIRUS (BKV) DNA IN HUMAN EDTA PLASMA OR URINE. THE ARTUS BK VIRUS RGQ KIT IS INTENDED FOR USE IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS FOR DISEASE PROGNOSIS.
603	IMP/IVD/2020/000301	1.License Holder Name: BILCARE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD)(SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD))-THIS PRODUCT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) IGG/IGM ANTIBODY IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SAMPLE. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY SARS-COV-2. THE TEST PROVIDES PRELIMINARY TEST RESULTS. NEGATIVE RESULTS DON'T PRECLUDE SARS-COV-2 INFECTION ANDTHEY CANNOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISION.

604	IMP/IVD/2020/000302	1.License Holder Name: AR KAY MEDICOS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HUMASIS COVID-19 IGG/IGM TEST(HUMASIS COVID-19 IGG/IGM TEST)-HUMASIS COVID-19 IGG/IGM TEST IS ONE STEP IN VITRO DIAGNOSTIC TEST BASED ON AN IMMUNOCHROMATOGRAPHIC ASSAY. IT IS DESIGNED FOR QUALITATIVE DETECTION OF IMMUNOGLOBULIN G AND IMMUNOGLOBULIN M ANTIBODY OF NOVEL CORONAVIRUS (COVID-19) IN HUMAN BLOOD.
605	IMP/IVD/2020/000303	1.License Holder Name: BIOINNOVATIONS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IVD KIT FOR COVID-19 (GENESIG® REAL-TIME PCR CORONAVIRUS COVID-19 (CE IVD) KIT)-INTENDED TO BE USED TO ACHIEVE QUALITATIVE DETECTION OF SARS-COV-2 VIRAL RNA EXTRACTED FROM NASOPHARYNGEAL SWABS, OROPHARYNGEAL SWABS AND SPUTUM FROM PATIENTS IN ASSOCIATION WITH A CE IVD EXTRACTION SYSTEM AND THE DESIGNATED PCR PLATFORMS. THE KIT IS INTENDED FOR USE BY LABORATORY TRAINED PERSONNEL
606	IMP/IVD/2020/000304	1.License Holder Name: CONCEPT HEALTHCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QSARS-COV-2 IGG/IGM RAPID TEST(CELLEX)-THE QSARS-COV-2 IGG/IGM RAPID TEST IS INTENDED FOR RAPID AND QUALITATIVE DETECTION OF ANTIBODIES INDICATIVE OF SARS-COV-2 INFECTION AND USED AS AN AID FOR DIAGNOSIS OF SARS-COV-2 INFECTION.

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607	IMP/IVD/2020/000305	1.License Holder Name: ADT INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:2019-NCOV (CORONA VIRUS RT PCR KIT)(LYTESTARTM 2019-NCOV RT-PCR KIT 2.0)-THE LYTESTAR™ 2019-NCOV RT-PCR KIT 2.0 IS INTENDED FOR THE SPECIFIC DETECTION OF SARS-COV-2 RNA IN HUMAN RESPIRATORY SPECIMENS (BRONCHOALVEOLAR LAVAGE, TRACHEAL ASPIRATE, SPUTUM, NASOPHARYNGEAL AND OROPHARYNGEAL SWABS PLACED IN VTM, NASOPHARYNGEAL WASH/ASPIRATE, AND NASAL WASH/ASPIRATE). THE LYTESTAR™ 2019-NCOV RT-PCR KIT 2.0 IS A DUAL TARGET ASSAY COMPRISING A SCREENING ASSAY TARGETING THE E GENE AND A CONFIRMATION ASSAY TARGETING THE RDRP GENE.,2019-NCOV (CORONA VIRUS RT PCR KIT)(LYTESTARTM SARS-COV-2 RT-PCR KIT 1.0 S)-THE LYTESTARTM SARS-COV-2 RT-PCR KIT 1.0 S IS BASED ON WHO RECOMMENDATIONS FOR A BROADER SCREENING TEST KIT WITH A SCREENING ASSAY FOR SARS-RELATED CORONAVIRUSES BASED ON THE E GENE. THE KIT INCLUDES AN INTERNAL CONTROL TO IDENTIFY POSSIBLE PCR INHIBITION.,2019-NCOV (CORONA VIRUS RT PCR KIT)(LYTESTARTM 2019-NCOV RT-PCR KIT 1.0)-THE LYTESTARTM 2019-NCOV RT-PCR KIT 1.0 IS BASED ON WHO RECOMMENDATIONS FOR A BROADER SCREENING TEST AND A HIGHLY SPECIFIC CONFIRMATION TEST AND IS DESIGNED AS A DUAL TARGET KIT WITH A SCREENING ASSAY FOR SARS-RELATED CORONAVIRUSES BASED ON THE E GENE AND A HIGHLY SPECIFIC CONFIRMATORY ASSAY ONLY FOR 2019-NCOV (SARS-COV-2), BASED ON THE RDRP-GENE. THE KIT INCLUDES AN INTERNAL CONTROL TO IDENTIFY POSSIBLE PCR INHIBITION.
608	IMP/IVD/2020/000306	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:2019-NCOV AB TEST (COLLOIDAL GOLD)(NA)-THE KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF IGM AND IGG ANTIBODIES AGAINST 2019 NOVEL CORONAVIRUS (2019-NCOV) IN HUMAN SERUM/PLASMA/VENOUS WHOLE BLOOD SPECIMEN AND FOR THE AUXILIARY DIAGNOSIS OF 2019-NCOV INFECTION.

609	IMP/IVD/2020/000308	1.License Holder Name: CORE DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIAGNOSTIC KIT FOR IGM/IGG ANTIBODY TO CORONAVIRUS (SARS-COV-2) (LATERAL FLOW)(LIVZON)-THIS PRODUCT IS USED FOR IN VITRO QUALITATIVE DETECTION OF CORONAVIRUS (SARS-COV-2) IGM/IGG ANTIBODY IN HUMAN SERUM, PLASMA AND VENOUS WHOLE BLOOD SAMPLES. NEGATIVE RESULTS DO NOT RULE OUT SARS-COV-2 INFECTION, PARTICULARLY IN THOSE WHO HAVE BEEN IN CONTACT WITH THE VIRUS. FOLLOW-UP TESTING WITH A MOLECULAR DIAGNOSTIC SHOULD BE CONSIDERED TO RULE OUT INFECTION IN THESE INDIVIDUALS. RESULTS FROM ANTIBODY TESTING SHOULD NOT BE USED AS THE SOLE BASIS TO DIAGNOSE OR EXCLUDE SARS-COV-2 INFECTION OR TO INFORM INFECTION STATUS. NOT FOR THE SCREENING OF THE GENERAL POPULATION. FOR PROFESSIONAL USE ONLY.
610	IMP/IVD/2020/000309	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GENBODY COVID-19 IGM/IGG(GENBODY)-GENBODY COVID-19 IGM/IGG DEVICE IS A CHROMATOGRAPHIC IMMUNOASSAY KIT FOR THE RAPID AND DIFFERENTIAL DETECTION OF IMMUNOGLOBULIN M (LGM) AND IMMUNOGLOBULIN G (IGG) AGAINST COVID-19 USING SERUM, PLASMA AND WHOLE BLOOD.
611	IMP/IVD/2020/000310	1.License Holder Name: LIFECELL INTERNATIONAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IN VITRO POLYMERASE CHAIN REACTION (PCR) ASSAY FOR CO V I D 19(GENEFINDERTM COVID-19 PLUS REALAMP KIT)-THIS KIT BASED ON THE R EVERSE TRANSCRIPTION AND REAL TIME POLYMERASE CHAIN REACTION FROM RNA EXTRACTED FROM RESPIRATORY SPECIMENS SUCH AS ALVEOLAR LAVAGE FLUID, THROAT SWAB, SPUTUM. THIS PRODUCT CAN QUALITATIVELY DETECT COVID 19 USING REACTION

612	IMP/IVD/2020/000311	1.License Holder Name: M/S ARACION TECHNOLOGY PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:2019-NCOV AB TEST (COLLOIDAL GOLD)(--)- THE KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF IGM AND IGG ANTIBODIES AGAINST 2019 NOVEL CORONAVIRUS (2019-NCOV) IN HUMAN SERUM/PLASMA/VENOUS WHOLE BLOOD SPECIMEN. IT IS ONLY USED AS A SUPPLEMENTARY DETECTION INDICATOR FOR SUSPECTED NUCLEIC ACID NEGATIVE RESULTS OR IN CONJUNCTION WITH NUCLEIC ACID DETECTION IN THE DIAGNOSIS OF SUSPECTED CASES. IT CANNOT BE USED AS A BASIS FOR THE DIAGNOSIS AND EXCLUSION OF COVID-19. IT IS NOT SUITABLE FOR GENERAL SCREENING. A POSITIVE TEST RESULT REQUIRES FURTHER CONFIRMATION. A NEGATIVE TEST RESULT DOES NOT RULE OUT THE POSSIBILITY OF INFECTION. THIS PRODUCT IS LIMITED TO CLINICAL USE AND EMERGENCY RESERVE DURING THE COVID-19 EPIDEMIC OUTBREAK SINCE DECEMBER 2019, AND CANNOT BE USED IN THE CLINIC AS A CONVENTIONAL IN VITRO DIAGNOSTIC REAGENT. THE TEST RESULTS OF THIS KIT ARE FOR CLINICAL REFERENCE ONLY. IT IS RECOMMENDED TO CONDUCT A COMPREHENSIVE ANALYSIS OF THE CONDITION BASED ON THE PATIENT'S CLINICAL MANIFESTATIONS AND OTHER LABORATORY TESTS.
613	IMP/IVD/2020/000314	1.License Holder Name: MERIDIAN MEDICARE LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 ASSAY SOLUTION(GEN BODY)-GENBODY COVID-19 IGM/IGG DEVICE IS A CHROMATICGRAPHIC IMMUNOASSAY KIT FOR THE RAPID AND DIFFERENTIAL DETECTION OF IMMUNOGLOBULIN M & G (IGM & IGG) AGAINST COVID-19 USING SERUM, PLASMA & WHOLE BLOOD.,COVID-19 IGG(GEN BODY)-GENBODY COVID-19 IGG DEVICE IS A CHROMATICGRAPHIC IMMUNOASSAY KIT FOR THE RAPID AND DIFFERENTIAL DETECTION OF IMMUNOGLOBULIN G (IGG)AGAINST COVID-19 USING SERUM, PLASMA & WHOLE BLOOD.,COVID-19 IGM (GEN BODY)-GENBODY COVID-19 IGM DEVICE IS A CHROMATICGRAPHIC IMMUNOASSAY KIT FOR THE RAPID AND DIFFERENTIAL DETECTION OF IMMUNOGLOBULIN M (IGM)AGAINST COVID-19 USING SERUM, PLASMA & WHOLE BLOOD.

614	IMP/IVD/2020/000315	1.License Holder Name: DEEP MEDITECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIGEN RAPID TEST(FLOWFLEX)-A RAPID TEST FOR THE QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID ANTIGENS IN NASAL AND NASOPHARYNGEAL SWAB SPECIMENS.,LIQUID URINE CONTROL-FOR QUALITY CONTROL OF URINE ANALYSIS REAGENT STRIPS, PROMOTOR NUCLEIC ACID EXTRACTION KIT(PROMOTOR)-THE PROMOTOR® NUCLEIC ACID EXTRACTION KIT IS DESIGNED TO BE USED WITH THE PROMOTOR® N ES-32 NUCLEIC ACID EXTRACTION SYSTEM FOR EXTRACTING DNA OR RNA FROM VARIOUS SPECIMENS, SUCH AS SERUM, PLASMA, SWAB, SPUTUM. EXTRACTED NUCLEIC ACID CAN BE USED IN BIOLOGICAL APPLICATIONS AND CLINICAL MOLECULAR DIAGNOSTICS, SUCH AS, NUCLEIC ACID TESTING, GENE CLONING AND SEQUENCING, PCR, MOLECULAR HYBRIDIZATION, ETC., CHOLESTEROL TEST DEVICES-FOR ESTIMATION OF TOTAL CHOLESTEROL, HDL AND TRIGLYCERIDES,VIRAL NUCLEIC ACID ISOLATION KIT-VIRAL NUCLEIC ACID ISOLATION KIT IS DESIGNED FOR RAPID ISOLATION AND PURIFICATION OF NUCLEIC ACIDS FROM SERUM, PLASMA OR SWAB.,HB HAEMOGLOBIN TEST STRIPS-FOR ESTIMATION OF HEMOGLOBIN,NUCLEIC ACID (RNA) EXTRACTION KIT (MAGNETIC BEADS)-KIT FOR EXTRACTION OF RNA FROM VARIOUS SPECIMENS, SUCH AS SERUM, PLASMA, SWAB AND FECES.,CHOL TOTAL CHOLESTEROL TEST STRIPS-FOR ESTIMATION OF CHOLESTEROL,WHOLE BLOOD GENOMIC DNA EXTRACTION KIT (MAGNETIC BEADS)-KIT FOR DNA EXTRACTION FROM WHOLE BLOOD SPECIMENS USING MAGNETIC BEADS METHOD.,URINE ANALYSIS REAGENT STRIPS-FOR ESTIMATION OF GLUCOSE, BILIRUBIN, PH, SPECIFIC GRAVITY, PROTEIN, UROBILINOGEN, NITRITE, KETONE, BLOOD, LEUKOCYTE, ASCORBIC ACID, MICROALBUMIN, CREATININE, CALCIUM ETC. IN URINE,NUCLEIC ACID (DNA) EXTRACTION KIT (MAGNETIC BEADS)-KIT FOR EXTRACTION OF DNA FROM VARIOUS SPECIMENS, SUCH AS SERUM, PLASMA, SWAB, FECES AND URINE.

615	IMP/IVD/2020/000317	1.License Holder Name: AADIVIGHNESH CHEM. PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REAL-TIME PCR CORONAVIRUS (SARS-COV-2) DETECTION TEST(QUANTI VIRUS™)-THE QUANTIVIRUS™ REAL-TIME RT- PCR CORONAVIRUS (SARS-COV-2) DETECTION TEST IS A REAL-TIME REVERSE TRANSCRIPTION (RT)-PCR IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE DETECTION OF VIRAL NUCLEIC ACID FROM THE SARS-COV-2 IN RESPIRATORY SPECIMENS FROM INDIVIDUALS. THE QUANTIVIRUS™ KIT IS TO BE USED BY TRAINED LABORATORY PROFESSIONALS FOR THE DETECTION OF SARS-COV-2 VIRAL RNA.
616	IMP/IVD/2020/000318	1.License Holder Name: TARA MEDICOS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QSARS-COV-2 IGG/IGM CASSETTE RAPID TEST(CELLEX QSARS-COV-2 IGG/IGM CASSETTE RAPID TEST)-THE CELLEX QSARS-COV-2 IGG/IGM CASSETTE RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF 2019-NCOV IGM/IGG ANTIBODIES IN SERUM, PLASMA OR WHOLE BLOOD SPECIMENS. IT IS INTENDED TO BE USED AS A SCREENING TEST AND AID IN THE DIAGNOSIS OF SARS-COV-2 VIRAL INFECTIONS. ANY REACTIVE SPECIMEN WITH THE CELLEX QSARS-COV-2 IGG/IGM CASSETTE RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S).
617	IMP/IVD/2020/000320	1.License Holder Name: HUMOLE DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALLPLEX 2019-NCOV ASSAY(ALLPLEX)-ALLPLEX 2019-NCOV ASSAY IS IN VITRO DIAGNOSTIC MEDICAL DEVICE DESIGNED FOR QUALITATIVE DETECTION OF NOVEL CORONA VIRUS (2019-NCOV) WITH REAL-TIME REVERSE TRANSCRIPTION PCR FROM SPUTUM, NASOPHARYNGEAL ASPIRATE, OROPHARYNGEAL (THROAT) & NASOPHARYNGEAL SWAB, AND BRONCHOALVEOLAR LAVAGE.

618	IMP/IVD/2020/000321	1.License Holder Name: INSTRUMENTATION LABORATORY INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOSIL HOMOCYSTEINE (HEMOSIL)-AUTOMATED LATEX ENHANCED IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL L-HOMOCYSTEINE IN HUMAN CITRATED PLASMA ON IL COAGULATION SYSTEMS.,HEMOSIL ACUSTAR ANTI-CARDIOLIPIN IGM(HEMOSIL)-FULLY AUTOMATED CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE MEASUREMENT OF ANTICARDIOLIPIN (ACL) IGM ANTIBODIES IN HUMAN CITRATED PLASMA AND SERUM ON THE ACL ACUSTAR, AS AN AID IN THE DIAGNOSIS OF THROMBOTIC DISORDERS RELATED TO PRIMARY AND SECONDARY ANTIPHOSPHOLIPID SYNDROME (APS) WHEN USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS.,HEMOSIL D-DIMER 500(HEMOSIL)-AUTOMATED LATEX ENHANCED IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN CITRATED PLASMA ON IL COAGULATION SYSTEMS FOR USE IN CONJUNCTION WITH A CLINICAL PRETEST PROBABILITY (PTP) ASSESSMENT MODEL TO EXCLUDE VENOUS THROMBOEMBOLISM (VTE) IN OUTPATIENTS SUSPECTED OF DEEP VENOUS THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE).,HEMOSIL ACUSTAR D-DIMER(HEMOSIL)-FULLY AUTOMATED CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN CITRATED PLASMA ON THE ACL ACUSTAR AS AN AID IN THE DIAGNOSIS OF VENOUS THROMBOEMBOLISM (VTE) [DEEP VEIN THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE)].,HEMOSIL D-DIMER HS(HEMOSIL)-HEMOSIL D-DIMER HS IS AN AUTOMATED LATEX ENHANCED IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMANCITRATED PLASMA ON THE ACL TOP® FAMILY AND ACL TOP FAMILY 50 SERIES FOR USE, IN CONJUNCTION WITH A CLINICAL PRETEST PROBABILITY (PTP) ASSESSMENT MODEL TO EXCLUDE VENOUS THROMBOEMBOLISM (VTE) IN OUTPATIENTS SUSPECTED OF DEEP VENOUSTHROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE).,HEMOSIL ACUSTAR HIT-IGG(PF4-H)(HEMOSIL)-FULLY AUTOMATED CHEMILUMINESCENT IMMUNOASSAY FOR THE DETECTION OF IGG ANTIBODIES IN HUMAN CITRATED PLASMA AND SERUM THAT REACT WITH PLATELET FACTOR 4 (PF4) WHEN COMPLEXED TO HEPARIN ON THE ACL ACUSTAR™. HEPARIN-ASSOCIATED ANTIBODIES ARE COMMONLY FOUND IN PATIENTS WITH HEPARIN INDUCED THROMBOCYTOPENIA OR THROMBOSIS (HIT)., HEMOSIL VON WILLEBRAND FACTOR ACTIVITY(HEMOSIL)-AUTOMATED LATEX ENHANCED IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VON WILLEBRAND FACTOR

	ACTIVITY (VWF ACTIVITY) IN HUMAN CITRATED PLASMA ON IL COAGULATION SYSTEMS.,HEMOSIL FREE PROTEIN S(HEMOSIL)-AUTOMATED LATEX LIGAND IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE PROTEIN S IN HUMAN CITRATED PLASMA ON IL COAGULATION SYSTEMS.,HEMOSIL ACUSTAR ANTI-CARDIOLIPIN IGG(HEMOSIL)-FULLY AUTOMATED CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI- QUANTITATIVE MEASUREMENT OF ANTI-CARDIOLIPIN (ACL) IGG ANTIBODIES IN HUMAN CITRATED PLASMA AND SERUM ON THE ACL ACUSTAR, AS AN AID IN THE DIAGNOSIS OF THROMBOTIC DISORDERS RELATED TO PRIMARY AND SECONDARY ANTIPHOSPHOLIPID SYNDROME (APS) WHEN USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS.,HEMOSIL ACUSTAR ANTI-(BETA)2 GLYCOPROTEIN I IGM(HEMOSIL)-FULLY AUTOMATED CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE MEASUREMENT OF ANTI-ß2 GLYCOPROTEIN-I (ANTI-ß2GPI) IGM ANTIBODIES IN HUMAN CITRATED PLASMA AND SERUM ON THE ACL ACUSTAR AS AN AID IN THE DIAGNOSIS OF THROMBOTIC DISORDERS RELATED TO PRIMARY AND SECONDARY ANTIPHOSPHOLIPID SYNDROME (APS) WHEN USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS.,HEMOSIL ACUSTAR ANTI-(BETA)2 GLYCOPROTEIN I IGG(HEMOSIL)-FULLY AUTOMATED CHEMILUMINESCENT IMMUNOASSAY FOR THE SEMI-QUANTITATIVE MEASUREMENT OF ANTI-ß2 GLYCOPROTEIN-I (ANTI-ß2GPI) IGG ANTIBODIES IN HUMAN CITRATED PLASMA AND SERUM ON THE ACL ACUSTAR, AS AN AID IN THE DIAGNOSIS OF THROMBOTIC DISORDERS RELATED TO PRIMARY AND SECONDARY ANTIPHOSPHOLIPID SYNDROME (APS) WHEN USED IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS.,HEMOSIL D-DIMER(HEMOSIL) -AUTOMATED LATEX ENHANCED IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN CITRATED PLASMA ON IL COAGULATION SYSTEMS FOR USE IN CONJUNCTION WITH A CLINICAL PRETEST PROBABILITY (PTP) ASSESSMENT MODEL TO EXCLUDE VENOUS THROMBOEMBOLISM (VTE) IN OUTPATIENTS SUSPECTED OF DEEP VENOUS THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE).,HEMOSIL ACUSTAR VON WILLEBRAND FACTOR RISTOCETIN COFACTOR ACTIVITY(HEMOSIL)-THE HEMOSIL ACUSTAR VON WILLEBRAND FACTOR RISTOCETIN COFACTOR ACTIVITY (HEMOSIL ACUSTAR VWF:RCO) ASSAY IS A FULLY AUTOMATED CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VON WILLEBRAND FACTOR RISTOCETIN COFACTOR ACTIVITY IN HUMAN CITRATED PLASMA ON THE ACL ACUSTAR™. THE HEMOSIL ACUSTAR VWF:RCO ASSAY IS INDICATED FOR USE ON PATIENTS WHO, BASED ON THEIR CLINICAL SIGNS, ARE

		SUSPECTED OF HAVING VON WILLEBRAND DISEASE.,HEMOSIL FACTOR XIII ANTIGEN(HEMOSIL)-AUTOMATED LATEX ENHANCED IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FACTOR XIII ANTIGEN (FXIII AG) IN HUMAN CITRATED PLASMA ON IL COAGULATION SYSTEMS.,HEMOSIL ACUSTAR VON WILLEBRAND FACTOR ANTIGEN(HEMOSIL)-THE HEMOSIL ACUSTAR VON WILLEBRAND FACTOR ANTIGEN (HEMOSIL ACUSTAR VWF:AG) ASSAY IS A FULLY AUTOMATED CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VON WILLEBRAND FACTOR ANTIGEN IN HUMAN CITRATED PLASMA ON THE ACL ACUSTAR™. THE HEMOSIL ACUSTAR VON WILLEBRAND FACTOR ANTIGEN ASSAY IS INDICATED FOR USE ON PATIENTS WHO, BASED ON THEIR CLINICAL SIGNS, ARE SUSPECTED OF HAVING VON WILLEBRAND DISEASE.
619	IMP/IVD/2020/000322	1.License Holder Name: KDH BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PNEUMOSLIDE IGM (PNEUMOSLIDE IGM (VIRCELL))-INDIRECT IMMUNOFLUORESCENT ASSAY KIT TO TEST SIMULANEOUSLY IGM ANTIBODIES AGAINST THE MAIN ETIOLOGICAL AGENTS OF INFECTIOUS DISEASE OF THE RESPAIRTORY TRACT.,COVID19 VIRCLIA IGG MONOTEST(VIRCELL)-INDIRECT CHEMILUMINESCENT IMMUNOASSAY (CLIA) TO TEST IGG ANTIBODIES AGAINST SARSCOV2 IN HUMAN SERUM/PLASMA., COVID19 ELISA IGG(VIRCELL)-INDIRECT IMMUNOENZYME ASSAY TO TEST IGG ANTIBODIES AGAINST SARSCOV2 IN HUMAN SERUM/PLASMA,COVID19 ELISA IGM+IGA(VIRCELL)-INDIRECT IMMUNOENZYME ASSAY TO TEST IGM+IGA ANTIBODIES AGAINST SARSCOV2 IN HUMAN SERUM/PLASMA,SARS-COV-2 REALTIME PCR KIT(VIRCELL)-REAL TIME RT-PCR KIT TO DETECT NUCLEIC ACID FROM SARS-COV-2 IN HUMAN RESPIRATORY SAMPLES. THE TEST IS A QUALITATIVE ASSAY TO AID IN THE DIAGNOSIS OF 2019 NOVEL CORONAVIRUS DISEASE (COVID-19).,COVID19 VIRCLIA IGM+IGA MONOTEST(VIRCELL)-INDIRECT CHEMILUMINESCENT IMMUNOASSAY (CLIA) TO TEST IGM+IGA ANTIBODIES AGAINST SARSCOV2 IN HUMAN SERUM/PLASMA.

620	IMP/IVD/2020/000323	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD)(NA)-WONDFO SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD) IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) IGG/IGM ANTIBODY IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SAMPLE. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY SARS-COV-2.
621	IMP/IVD/2020/000324	1.License Holder Name: TRUE HEALTHCARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use::HUMASIS COVID-19 IGG/IGM TEST(:HUMASIS COVID-19 IGG/IGM TEST)-:HUMASIS COVID-19 IGG/IGM TEST IS ONE STEP IN VITRO DIAGNOSTIC TEST BASED ON AN IMMUNOCHROMATOGRAPHIC ASSAY. IT IS DESIGNED FOR QUALITATIVE DETECTION OF IMMUNOGLOBULIN G AND IMMUNOGLOBULIN M ANTIBODY OF NOVEL CORONAVIRUS (COVID-19) IN HUMAN BLOOD.
622	IMP/IVD/2020/000329	1.License Holder Name: CORE DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIBODY TEST(LATERAL FLOW METHOD)-THIS PRODUCT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) IGG/IGM ANTIBODY IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SAMPLE. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY SARS-COV-2. THE TEST PROVIDES PRELIMINARY TEST RESULTS. NEGATIVE RESULTS DON'T PRECLUDE SARS-COV-2 INFECTION AND THEY CANNOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISION.

623	IMP/IVD/2020/000330	1.License Holder Name: BIOHOUSE SOLUTIONS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: IGM-IGG RAPID TEST (COVID-19)-BIOMEDOMICS RAPID IGM-IGG COMBINED ANTIBODY TEST FOR COVID-19 IS USED TO QUALITATIVELY DETECT IGG AND IGM ANTIBODIES OF THE NOVEL CORONAVIRUS IN HUMAN SERUM, PLASMA OR WHOLE BLOOD IN VITRO.

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624	IMP/IVD/2020/000334	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COBAS LIPID PANEL (COBAS LIPID PANEL)-THE COBAS B 101 IS AN IN VITRO DIAGNOSTIC TEST SYSTEM DESIGNED TO QUANTITATIVELY DETERMINE TOTAL CHOLESTEROL (TC), HIGHDENSITY LIPOPROTEIN CHOLESTEROL (HDL), AND TRIGLYCERIDES (TG) IN HUMAN CAPILLARY AND VENOUS WHOLE BLOOD OR PLASMA BY PHOTOMETRIC TRANSMISSION MEASUREMENT. A CALCULATED VALUE FOR LOWDENSITY LIPOPROTEIN (LDL), NONHDL AND A TC/HDL RATIO IS PROVIDED BY THE COBAS B 101 SYSTEM. THE SYSTEM IS INTENDED FOR PROFESSIONAL USE IN A CLINICAL LABORATORY SETTING, OR POINT OF CARE (POC) LOCATIONS.,COBAS CRP TEST(COBAS CRP TEST)-THE ROCHE COBAS B 101 IS AN IN VITRO DIAGNOSTIC TEST SYSTEM DESIGNED TO QUANTITATIVELY DETERMINE THE CREACTIVE PROTEIN (CRP) IN HUMAN CAPILLARY WHOLE BLOOD AND SERUM, EDTA K2/K3 AND LITHIUM HEPARIN ANTICOAGULATED WHOLE BLOOD AND PLASMA BY PHOTOMETRIC MEASUREMENT. MEASUREMENT OF CRP IS OF USE FOR THE EVALUATION OF INFLAMMATORY DISORDERS AND ASSOCIATED DISEASES, INFECTION AND TISSUE INJURY. THE SYSTEM IS INTENDED FOR USE IN POINTOFCARE (POC) SETTINGS SUCH AS PHARMACIES, PHYSICIAN OFFICES, PHYSICIAN OFFICE LABORATORIES, CLINICS AND HOSPITALS, AND CLINICAL LABORATORY SETTINGS. ,COBAS HBA1C TEST(COBAS HBA1C TEST)-THE COBAS B 101 IS AN IN VITRO DIAGNOSTIC TEST SYSTEM DESIGNED TO QUANTITATIVELY DETERMINE THE % HEMOGLOBIN A1C (DCCT/NGSP) AND MMOL/MOL HEMOGLOBIN A1C (IFCC) IN HUMAN CAPILLARY AND VENOUS WHOLE BLOOD BY PHOTOMETRIC TRANSMISSION MEASUREMENT. AN ESTIMATED AVERAGE GLUCOSE LEVEL (EAG) IS CALCULATED BY THE COBAS B 101 SYSTEM. THE SYSTEM IS INTENDED FOR PROFESSIONAL USE IN A CLINICAL LABORATORY SETTING, OR POINT OF CARE (POC) LOCATIONS. HBA1C DETERMINATIONS ARE USEFUL FOR MONITORING OF LONGTERM BLOOD GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS. MOREOVER, THIS TEST IS TO BE USED AS AN AID IN DIAGNOSIS OF DIABETES AND IDENTIFYING PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES.

625	IMP/IVD/2020/000337	1.License Holder Name: INSTRUMENTATION LABORATORY INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOSIL ACUSTAR ADAMTS13 ACTIVITY(HEMOSIL)-THE HEMOSIL ACUSTAR ADAMTS13 ACTIVITY IS A QUANTITATIVE, FULLY AUTOMATED, CHEMILUMINESCENT IMMUNOASSAY (CIA) FOR THE MEASUREMENT OF ADAMTS13 ACTIVITY. THE ASSAY IS FOR USE IN HUMAN 3.2% OR 3.8% CITRATED PLASMA ON THE ACL ACUSTAR ® IN A LABORATORY SETTING BY HEALTHCARE PROFESSIONALS. THE ASSAY RESULTS AID IN THE DIAGNOSIS AND MONITORING OF THROMBOTIC THROMBOCYTOPENIC PURPURA (TTP). THE RESULTS SHOULD BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS. FOR USE IN ADULT POPULATION. FOR PRESCRIPTION USE ONLY

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626	IMP/IVD/2020/000338	1.License Holder Name: IMMUNOSHOP INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:THYROID PEROXIDASE ANTIBODY (ELECTROCHEMILUMINESCENCE IMMUNOASSAY) (LIFOTRONIC)-"IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF ANTIBODY TO THYROID PEROXIDASE IN HUMAN SERUM AND PLASMA.",SARS-COV-2 IGM ASSAY KITS(LIFOTRONIC)-FOR AUXILIARY DIAGNOSIS OF CORONAVIRUS DISEASE COVID-19. , CALCITONIN (ELECTROCHEMILUMINESCENCE IMMUNOASSAY) (LIFOTRONIC)-IT'S USED FOR QUANTITATIVE DETERMINATION OF CALCITONIN IN HUMAN SERUM OR PLASMA IN VITRO, WHICH MAINLY ASSISTS IN DIAGNOSIS OF PARATHYROID FUNCTION,D-DIMER ASSAY KITS(LIFOTRONIC)-THE D-DIMER ASSAY KITS IS TO BE USED WITH FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVE MEASUREMENT OF THE CONTENT OF D-DIMER IN WHOLE BLOOD, SERUM, PLASMA.,PROCALCITONIN (PCT) ASSAY KITS (LIFOTRONIC)-THE PCT ASSAY KITS IS TO BE USED WITH FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVE MEASUREMENT OF THE CONTENT OF PCT IN WHOLE BLOOD, SERUM, PLASMA. PCT IS A PEPTIDEPRECURSOROF THE HORMONECALCITONIN, THE LATTER BEING INVOLVED WITHCALCIUMHOMEOSTASIS. IT IS COMPOSED OF 116 AMINO ACIDSAND IS PRODUCED BY PARAFOLLICULAR CELLS(C CELLS) OF THE THYROIDAND BY THE NEUROENDOCRINE CELLSOF THE LUNG AND THE INTESTINE,HEART FATTY ACID-BINDING PROTEIN(H-FABP) ASSAY KITS(LIFOTRONIC)-THE H-FABP ASSAY KITS IS USED WITH FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVELY MEASUREMENT OF THE CONTENT OF H-FABP IN WHOLE BLOOD, SERUM, PLASMA.,CREATINE KINASE MB (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF CREATINE KINASE MB IN HUMAN SERUM AND PLASMA.,HBA1C ASSAY KITS(LIFOTRONIC)-THE HBA1C ASSAY KITS IS USED WITH FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVELY MEASUREMENT OF THE CONTENT OF HBA1C IN WHOLE BLOOD. ,TOTAL TRIIODOTHYRONINE KIT ELECTROCHEMILUMINESCENCE IMMUNOASSAY(LIFOTRONIC)-"IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE IN HUMAN SERUM AND PLASMA.", CYSTATIN C (CYS-C) ASSAY KITS(LIFOTRONIC)-THE CYS-C ASSAY KITS IS TO BE USED WITH LIFOTRONIC FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVE MEASUREMENT OF THE CONTENT OF CYS-C IN WHOLE BLOOD, SERUM, PLASMA.,LUTEINIZING HORMONE

	(ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE(LH) IN HUMAN SERUM AND PLASMA. THE RESULTS MAINLY USED TO EVALUATE PITUITARY ENDOCRINE FUNCTION.,HYPERSENSITIVITY C-REACTIVE PROTEIN (HS-CRP) ASSAY KITS(LIFOTRONIC)-THE HS-CRP ASSAY KITS IS USED WITH LIFOTRONIC FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVELY MEASUREMENT OF THE CONTENT OF CRP IN WHOLE BLOOD, SERUM, PLASMA.,"N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE(ELECTROCHEMILUMINESCENCE IMMUNOASSAY)"(LIFOTRONIC)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE IN HUMAN PLASMA.,N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) ASSAY KITS(LIFOTRONIC)-THE NT-PROBNP ASSAY KITS IS TO BE USED WITH LIFOTRONIC FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVE MEASUREMENT OF THE CONTENT OF NT-PROBNP IN WHOLE BLOOD, SERUM, PLASMA. ,PARATHYROID HORMONE (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IT'S USED FOR QUANTITATIVE DETERMINATION OF PARATHYROID HORMONE IN HUMAN SERUM OR PLASMA IN VITRO.,- HUMAN CHORIONIC GONADOTROPHIN (-HCG) ASSAY KITS(LIFOTRONIC)-"THE -HCG ASSAY KITS IS USED WITH FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVELY MEASUREMENT OF THE CONTENT OF -HCG IN WHOLE BLOOD, SERUM, PLASMA." ,PROGESTERONE (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM AND PLASMA.THE RESULTS CAN BE USED IN THE AUXILIARY DIAGNOSIS FOR PREMONITORY ABORTION.,THYROID STIMULATING HORMONE (TSHASSAY KIT(LIFOTRONIC)-"THYROID STIMULATING HORMONE (TSHASSAY KITS IS TO BE USED WITH LIFOTRONIC FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVE MEASUREMENT OF THE CONTENT OF TSH.. THE RESULTS CAN BE USED IN THE PRELIMINARY SCREENING TEST OF THYROID FUNCTION." ,FOLLICLE-STIMULATING HORMONE (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF FOLLICLE-STIMULATING HORMONE (FSH) IN HUMAN SERUM AND PLASMA. THE RESULTS MAINLY USED TO EVALUATE PITUITARY ENDOCRINE FUNCTION.,THYROXINET4ASSAY KITS(LIFOTRONIC)-"THYROXINE T4ASSAY KITS IS TO BE USED WITH LIFOTRONIC FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVE MEASUREMENT OF THE CONTENT OF THYROXINE.",

	TOTAL THYROXINE KIT ELECTROCHEMILUMINESCENCE IMMUNOASSAY(LIFOTRONIC)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TOTAL THYROXINE IN HUMAN SERUM AND PLASMA,C-REACTIVE PROTEIN (CRP) ASSAY KITS (LIFOTRONIC)-"THE CRP ASSAY KITS IS USED WITH FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVELY MEASUREMENT OF THE CONTENT OF CRP IN WHOLE BLOOD, SERUM, PLASMA." ,MYOGLOBIN (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM AND PLASMA. THE RESULTS CAN BE USED IN ASSISTING DIAGNOSIS OF MYOCARDIAL INJURY., MICROALBUMIN (MALB) ASSAY KITS(LIFOTRONIC)-THE MALB ASSAY KITS IS TO BE USED WITH LIFOTRONIC FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVE MEASUREMENT OF THE CONTENT OF MALB IN URINE. ,HUMAN CHORIONIC GONADOTROPIN (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN IN HUMAN SERUM AND PLASMA., TRIIODOTHYRONINET3) ASSAY KITS(LIFOTRONIC)-"TRIIODOTHYRONINE T3 ASSAY KITS IS TO BE USED WITH LIFOTRONIC FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER, APPLICABLE TO QUANTITATIVE MEASUREMENT OF THE CONTENT OF T3.",INTERLEUKIN-6 (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF INTERLEUKIN-6 (IL-6) IN HUMAN SERUM AND PLASMA. THIS ASSAY CAN BE USED TO AID IN THE MANAGEMENT OF CRITICALLY ILL PATIENTS AS AN EARLY INDICATOR FOR ACUTE INFLAMMATION.,HBA1C REAGENT KITS(HPLC) (LIFOTRONIC)-APPLICABLE TO QUANTITATIVE EXAMINATION THE CONTENT OF HBA1C IN THE WHOLE BLOOD OF HUMAN BODY WITH LIFOTRONIC H SERIES HEMOGLOBIN ANALYZER. IT ADOPTS HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) METHOD TO MEASURE THE LEVEL OF HBALAB, HBALC AND HBA0. AND THE ANALYZER CALCULATES THE REST ITEMS. ,ESTRADIOL (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF 17-ESTRADIOL (E2) IN HUMAN SERUM AND PLASMA, WHICH IS CLINICALLY USED FOR AUXILIARY DIAGNOSIS OF OVARIAN DISEASES.,CARDIAC TROPONIN (CTNI) ASSAY KITS(LIFOTRONIC)-CTNI ASSAY KITS IS TO BE USED WITH FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVELY MEASUREMENT OF THE CONTENT OF CTNI IN WHOLE BLOOD, SERUM,

	PLASMA. ,FOLATE (ELECTROCHEMILUMINESCENCE IMMUNOASSAY) (LIFOTRONIC)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN SERUM.,CREATINE KINASE MB (CK-MB) ASSAY KITS (LIFOTRONIC)-THE CK-MB ASSAY KITS IS USED WITH FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVELY MEASUREMENT OF THE CONTENT OF CK-MB IN WHOLE BLOOD, SERUM, PLASMA.,THYROID STIMULATING HORMONE (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF THYROTROPIN IN HUMAN SERUM AND PLASMA.,MYOGLOBIN (MYO) ASSAY KITS (LIFOTRONIC)-THE MB ASSAY KITS IS USED WITH FA SERIES LATERAL FLOW IMMUNOASSAY ANALYZER. APPLICABLE TO QUANTITATIVELY MEASUREMENT OF THE CONTENT OF MB IN WHOLE BLOOD, SERUM, PLASMA.,FREE THYROXINE KITELECTROCHEMILUMINESCENCE IMMUNOASSAY (LIFOTRONIC)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FREE THYROXINE IN HUMAN SERUM AND PLASMA.,SARS-COV-2 IGG ASSAY KITS(LIFOTRONIC)-FOR AUXILIARY DIAGNOSIS OF CORONAVIRUS DISEASE COVID-19. ,HIGH-SENSITIVITY C-REACTIVE PROTEIN (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM AND PLASMA,FREE TRIIODOTHYRONINE KIT ELECTROCHEMILUMINESCENCE IMMUNOASSAY(LIFOTRONIC)-"IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE IN HUMAN SERUM AND PLASMA.",C-PEPTIDE (ELECTROCHEMILUMINESCENCE IMMUNOASSAY) (LIFOTRONIC)-"IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM AND PLASMA.", FERRITIN (ELECTROCHEMILUMINESCENCE IMMUNOASSAY) (LIFOTRONIC)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA. IT'S MAINLY USED FOR IRON-METABOLISM-RELATED DISEASES, SUCH AS HEMOCHROMATOSIS AND IRON-DEFICIENCY ANEMIA,INSULIN (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM AND PLASMA. DETERMINATION OF INSULIN IS USED FOR EVALUATION OF PANCREATIC ISLET FUNCTION.,PROLACTIN (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-"IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN HUMAN SERUM AND PLASMA. IT IS MAINLY USED TO EVALUATE THE ENDOCRINE FUNCTION OF PITUITARY IN CLINIC, AND CAN NOT BE USED FOR THE AUXILIARY DIAGNOSIS OF HYPOPHYSOMA.",

	TESTOSTERONE (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM AND PLASMA. CLINICALLY USED FOR THE AUXILIARY DIAGNOSIS OF DISEASES WITH ABNORMAL LEVEL OF TESTOSTERONE,THYROGLOBULIN (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THYROGLOBULIN IN HUMAN SERUM AND PLASMA. DETERMINATION OF TG IS USED AS AN AID IN MONITORING AFTER THYROID ABLATION,LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 (ELECTROCHEMINLUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF LP-PLA2 IN HUMAN SERUM AND PLASMA.,TROPONIN I (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I IN HUMAN SERUM AND PLASMA. THIS ASSAY IS INTENDED TO AUXILIARY DIAGNOSIS OF MYOCARDIAL INFARCTION, THYROGLOBULIN ANTIBODY (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ANTIBODIES TO THYROGLOBULIN IN HUMAN SERUM AND PLASMA. DETERMINATION OF ANTI-TG IS USED AS AN AID IN THE DETECTION OF AUTOIMMUNE THYROID DISEASES.,25-OH VITAMIN D TOTAL (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF TOTAL 25-HYDROXY VITAMIN D IN HUMAN SERUM AND PLASMA. THE RESULTS CAN BE USED IN ASSISTING DIAGNOSIS OF VITMAIN D SUFFICIENCY.,PROCALCITONIN (ELECTROCHEMILUMINESCENCE IMMUNOASSAY)(LIFOTRONIC)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PCT (PROCALCITONIN) IN HUMAN SERUM AND PLASMA.

627	IMP/IVD/2020/000339	1.License Holder Name: CLINIEXPERTS SERVICES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TELL ME FAST COVID19 ANTIGEN TEST CASSETTE/STRIP FORMAT(BIOCAN)-BIOCAN TELL ME FAST COVID-19 ANTIGEN TEST IS A RAPID QUALITATIVE MEMBRANE-BASED IMMUNOCHROMATOGRAPHIC IN VITRO ASSAY INTENDED FOR DETECTION OF SARS-COV-2 (COVID19) ANTIGENS WITH HUMAN NASAL SWAB, NASOPHARYNGEAL SWAB AND THROAT (OROPHARYNGEAL) SWABS. THIS TEST IS INTENDED FOR IN VITRO DIAGNOSTIC USE AT POINT OF CARE SETTINGS, LABORATORIES AND SELF-TESTING (HOME) AND IS A PRELIMINARY SCREENING TEST AND FINAL DIAGNOSIS SHOULD BE BASED AFTER EXAMINATION WITH OTHER QUALIFIED ASSAYS LIKE MOLECULAR DIAGNOSTICS TEST., TELL ME FAST CORONAVIRUS (COVID-19) IGG/IGM ANTIBODY TEST CASSETTE/STRIP FORMAT(BIOCAN)-BIOCAN TELL ME FAST CORONAVIRUS (COVID-19) IGG/IGM ANTIBODY RAPID TEST IS A RAPID, QUALITATIVE, MEMBRANE-BASED IMMUNOCHROMATOGRAPHIC IN VITRO ASSAY INTENDED FOR DETECTION AND DIFFERENTIATION OF NOVEL CORONAVIRUS (COVID-19) IGG & IGM ANTIBODIES WITH HUMAN SERUM, PLASMA OR WHOLE BLOOD SAMPLES (INCLUDING FINGER PRICK). THIS TEST IS INTENDED FOR LABORATORY IN VITRO DIAGNOSTIC USE AND IS A PRELIMINARY SCREENING TEST AND FINAL DIAGNOSIS SHOULD BE BASED AFTER EXAMINATION WITH OTHER QUALIFIED ASSAYS.
628	IMP/IVD/2020/000341	1.License Holder Name: INBIOS INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CELLEX QSARS-COV-2 IGG/IGM CASSETTE RAPID TEST(CELLEX)-THE CELLEX QSARS-COV-2 IGG/IGM CASSETTE RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR QUALITATIVE DETECTION OF ANTIBODIES TO 2019 NOVEL CORONAVIRUS (SARS-COV-2) IN SERUM PLASMA OR WHOLE BLOOD SPECIMENS.

629	IMP/IVD/2020/000342	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD MAX ENTERIC VIRAL PANEL (BD MAX ENTERIC VIRAL PANEL)-THE BD MAX™ ENTERIC VIRAL PANEL PERFORMED ON THE BD MAX SYSTEM, IS AN AUTOMATED IN VITRO DIAGNOSTIC TEST FOR THE DIRECT QUALITATIVE DETECTION AND DIFFERENTIATION OF ENTERIC VIRAL PATHOGENS. THE BD MAX ENTERIC VIRAL PANEL DETECTS NUCLEIC ACIDS FROM • NOROVIRUS GI & GII • ROTAVIRUS A • ADENOVIRUS F40/41 • SAPOVIRUS (GENOGROUPS I, II, IV, V) • HUMAN ASTROVIRUS (HASTRO) TESTING IS PERFORMED ON UNPRESERVED SOFT TO DIARRHEAL OR CARY-BLAIR PRESERVED STOOL SPECIMENS FROM SYMPTOMATIC PATIENTS WITH SUSPECTED ACUTE GASTROENTERITIS, ENTERITIS OR COLITIS. THE TEST IS PERFORMED DIRECTLY ON THE SPECIMEN, UTILIZING REAL-TIME POLYMERASE CHAIN REACTION (PCR) FOR THE AMPLIFICATION OF RELEVANT GENE TARGET DNA/RNA. THE TEST UTILIZES FLUOROGENIC GENE-SPECIFIC HYBRIDIZATION PROBES FOR THE DETECTION OF THE AMPLIFIED DNA. THIS TEST IS INTENDED FOR USE, IN CONJUNCTION WITH CLINICAL PRESENTATION, LABORATORY FINDINGS, AND EPIDEMIOLOGICAL INFORMATION, AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF NOROVIRUS GI & GII, ROTAVIRUS A, ADENOVIRUS F40/41, SAPOVIRUS (GENOGROUPS I, II, IV, V), AND HASTRO INFECTIONS. RESULTS OF THIS TEST SHOULD NOT BE USED AS THE SOLE BASIS FOR DIAGNOSIS, TREATMENT, OR OTHER PATIENT MANAGEMENT DECISIONS. POSITIVE RESULTS DO NOT RULE OUT CO-INFECTION WITH OTHER ORGANISMS THAT ARE NOT DETECTED BY THIS TEST, AND MAY NOT BE THE SOLE OR DEFINITIVE CAUSE OF PATIENT ILLNESS. NEGATIVE RESULTS IN THE SETTING OF CLINICAL ILLNESS COMPATIBLE WITH GASTROENTERITIS MAY BE DUE TO INFECTION BY PATHOGENS THAT ARE NOT DETECTED BY THIS TEST OR NON-INFECTIOUS CAUSES SUCH AS ULCERATIVE COLITIS, IRRITABLE BOWEL SYNDROME, OR CROHN'S DISEASE.,BD SARS-COV-2 REAGENTS FOR BD MAX SYSTEM(BD SARS-COV-2 REAGENTS FOR BD MAX SYSTEM)-THE BD SARS-COV-2 REAGENTS FOR BD MAX™ SYSTEM IS A REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN NASAL, NASOPHARYNGEAL, AND OROPHARYNGEAL SWAB SAMPLES FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. RESULTS ARE FOR THE IDENTIFICATION OF SARS-COV-2 RNA. THE SARS-COV-2 RNA IS GENERALLY DETECTABLE IN UPPER RESPIRATORY SAMPLES DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS ARE INDICATIVE OF THE PRESENCE OF SARS-COV-2 RNA; CLINICAL CORRELATION WITH

	PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR PATIENT MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. THE BD SARS-COV-2 REAGENTS FOR BD MAX SYSTEM IS INTENDED FOR USE BY QUALIFIED AND TRAINED CLINICAL LABORATORY PERSONNEL SPECIFICALLY INSTRUCTED AND TRAINED IN THE TECHNIQUES OF REAL-TIME PCR, IN VITRO DIAGNOSTIC PROCEDURES, AND USE OF THE BD MAX SYSTEM.,BD SARS-COV-2 REAGENTS FOR BD MAX SYSTEM(BD SARS-COV-2 REAGENTS FOR BD MAX SYSTEM)-THE BD SARS-COV-2 REAGENTS FOR BD MAX™ SYSTEM IS A REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN NASAL, NASOPHARYNGEAL AND OROPHARYNGEAL SWAB SAMPLES FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. RESULTS ARE FOR THE IDENTIFICATION OF SARS-COV-2 RNA. THE SARS-COV-2 RNA IS GENERALLY DETECTABLE IN UPPER RESPIRATORY SAMPLES DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS ARE INDICATIVE OF THE PRESENCE OF SARS-COV-2 RNA; CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR PATIENT MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. THE BD SARS-COV-2 REAGENTS FOR BD MAX SYSTEM IS INTENDED FOR USE BY QUALIFIED AND TRAINED CLINICAL LABORATORY PERSONNEL. SPECIFICALLY INSTRUCTED AND TRAINED IN THE TECHNIQUES OF REAL-TIME PCR, IN VITRO DIAGNOSTIC PROCEDURES, AND USE OF THE BD MAX SYSTEM.

630	IMP/IVD/2020/000343	1.License Holder Name: ADVY CHEMICAL PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (2019-NCOV) REAL TIME MULTIPLEX RT-PCR KIT(NOVEL CORONAVIRUS (2019-NCOV) REAL TIME MULTIPLEX RT-PCR KIT)-NOVEL CORONAVIRUS(2019-NCOV)REAL TIME MULTIPLEX RT-PCR KIT (DETECTION FOR 3 GENES) IS USED FOR THE IN VITRO QUALITATIVE DETECTION OF 2019 NOVEL CORONAVIRUS (2019-NCOV) RNA IN UPPER RESPIRATORY TRACT SPECIMENS (NASOPHARYNGEAL AND OROPHARYNGEAL EXTRACTS) AND LOWER RESPIRATORY TRACT SPECIMENS (BRONCHOALVEOLAR LAVAGE FLUID (BALF)AND DEEP COUGH SPUTUM) BY REAL TIME PCR SYSTEMS. IT IS CONSIDERED AS AN AID IN THE DIAGNOSIS OF THE 2019-NCOV INFECTION.
631	IMP/IVD/2020/000344	1.License Holder Name: TATA INTERNATIONAL LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD)(SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD))-THIS PRODUCT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) IGG/IGM ANTIBODY IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SAMPLE. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY SARS-COV-2. THE TEST PROVIDES PRELIMINARY TEST RESULTS. NEGATIVE RESULTS DON'T PRECLUDE SARS-COV-2 INFECTION AND THEY CANNOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISION.
632	IMP/IVD/2020/000346	1.License Holder Name: SYNERGY SCIENTIFIC SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID 19 IGM/IGG-WHEN THE HUMAN BODY COMES INTO CONTACT WITH EXTERNAL ANTIGENS, THE ANTIBODY IGM IS PRODUCED FIRST, FOLLOWED BY A LARGE AMOUNT OF ANTIBODY IGG. THIS TEST IS USED FOR QUALITATIVE DETECTION OF 2019-NEW CORONAVIRUS IGG / IGM IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD FOR THE AUXILIARY DIAGNOSIS OF NEW CORONAVIRUS INFECTION IN CLINICAL.

633	IMP/IVD/2020/000348	1.License Holder Name: M/S. ELDER PROJECTS LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (2019-NCOV) DIAGNOSTIC KIT(SANSURE)-NOVEL CORONAVIRUS (2019-NCOV) NUCLEIC ACID DIAGNOSTIC KIT (PCR-FLUORESCENCE PROBING) IS USED FOR QUALITATIVE DETECTION OF THE ORF1AB AND N GENES OF NOVEL CORONAVIRUS (2019-NCOV) IN NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, ALVEOLAR LAVAGE FLUID, SPUTUM, SERUM, WHOLE BLOOD AND FECES FROM SUSPECTED PNEUMONIA CASES WITH NOVEL CORONAVIRUS INFECTION, PATIENTS WITH SUSPECTED CLUSTERS OF NOVEL CORONAVIRUS INFECTION, AND OTHER PATIENTS REQUIRING DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS OF NOVEL CORONAVIRUS INFECTION.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

634	IMP/IVD/2020/000349	1.License Holder Name: IMMUNOSHOP INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAGLUMI - ANTI-SM IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO SM (ANTI-SM IGG) IN HUMAN SERUM AND PLASMA., CORTISOL (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM OR URINE , MAGLUMI SARS-COV-2 NEUTRALIZING ANTIBODY(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF NEUTRALIZING ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER, AND THE ASSAY IS USED FOR AN AID IN IDENTIFYING INDIVIDUALS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS-COV-2, INDICATING RECENT OR PRIOR INFECTION. THE KIT SHOULD NOT BE USED TO DIAGNOSE ACUTE SARS-COV-2 INFECTION.,IGG (SERUM ANALYSIS) (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN SERUM. , MAGLUMI - FREE -HCG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE -CHAINS OF HUMAN CHORIONIC GONADOTROPIN (FREE -HCG) IN HUMAN SERUM.,25-OH VITAMIN D (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM. ,MAGLUMI - PAPP-A (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PREGNANCY-ASSOCIATED PLASMA PROTEIN A (PAPPA) IN HUMAN SERUM.,RUBELLA IGG (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF RUBELLA IGG IN HUMAN SERUM. ,MAGLUMI - SARS-COV-2 S-RBD IGG (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF S-RBD IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,CUVETTE(BIOSSAYS)-"CUVETTES REQUIRED FOR THE IMPLEMENTATION OF THE ASSAYSON THE BIOSSAYS 240 AUTOMATIC BIOCHEMISTRY ANALYZER." ,MAGLUMI - BNP (CLIA)(MAGLUMI)-THE BNP (CLIA) KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF BNP IN HUMAN EDTA PLASMA. NATRIURETIC

	PEPTIDES ARE A FAMILY OF STRUCTURALLY SIMILAR PEPTIDE HORMONES WITH THE FUNCTION OF NATRIURESIS, PROMOTING VASODILATION AND INHIBITING RENIN. BNP EXISTS WIDELY IN BRAIN, HEART, LUNG, DIGESTIVE TRACT AND SO ON. AMONG THEM, THE HEART CONTENT IS THE HIGHEST, AND THE SYNTHESIS AND SECRETION OF BNP IN THE HEART IS MAINLY IN THE VENTRICLE. BNP IS A 32 AMINO ACID PEPTIDE WITH A CENTRAL LOOP CONTAINING 17 AMINO-ACIDS LINKED BY A DISULFIDE BOND BETWEEN 2 CYSTEINE RESIDUES.,RUBELLA IGM (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF RUBELLA IGM IN HUMAN SERUM. ,IL-6 (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IL-6 IN HUMAN SERUM AND PLASMA. ,INTACT PTH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (INTACT PTH) IN HUMAN SERUM. ,ANTI-CCP (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG AUTOANTIBODIES TO CYCLIC CITRULLINATED PEPTIDES (ANTI-CCP) IN HUMAN SERUM AND PLASMA. ,TSH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN HUMAN SERUM. ,ANTI-RIB-P IGG (CLIA)(MAGLUMI) -THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO RIB-P (ANTI-RIB-P IGG) IN HUMAN SERUM AND PLASMA. ,CMV IGM(CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF CMV IGM IN HUMAN SERUM. ,HER-2 (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HER-2 IN HUMAN SERUM AND PLASMA. ,LH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM. ,ANTI-SS-B IGG (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO SS-B (ANTI-SS-B IGG) IN HUMAN SERUM AND PLASMA. ,LACTATE DEHYDROGENASE ASSAY KIT (LP)(BIOSSAYS)- THE SNIBE BIOSSAYSTM LDH REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE IN HUMAN SERUM. ,ENA SCREEN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES TO

	EXTRACTABLE NUCLEAR ANTIGENS (ENA) IN HUMAN SERUM AND PLASMA. ,-HYDROXYBUTYRATE DEHYDROGENASE ASSAY KIT (DGKC)(BIOSSAYS)-THE SNIBE BIOSSAYSTM -HBDH REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALPHA-HYDROXYBUTYRATE DEHYDROGENASE IN HUMAN SERUM. ,ANTI-HISTONES IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO HISTONES (ANTI-HISTONES IGG) IN HUMAN SERUM AND PLASMA. ,GLUCOSE ASSAY KIT (HEXOKINASE)(BIOSSAYS)-THE SNIBE BIOSSAYSTM GLU REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM. ,ANTI-SCL-70 IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO SCL-70 (ANTI-SCL-70 IGG) IN HUMAN SERUM AND PLASMA. ,STARTER 1+2 (MAGLUMI)-STARTER REAGENT KIT REQUIRED TO GENERATE THE CHEMILUMINOMETRIC LIGHT SIGNAL NECESSARY FOR THE IMPLEMENTATION OF MAGLUMI ASSAYS ON THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER. ,ANA SCREEN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTINUCLEAR ANTIBODIES (ANA) IN HUMAN SERUM AND PLASMA. ,WASH CONCENTRATE(MAGLUMI)-MAGLUMI WASH CONCENTRATE IS INTENDED TO BE DILUTED FOR PREPARATION OF SYSTEM LIQUID WHICH IS REQUIRED FOR WASHING THE MAGNETIC MIRCOBEADS OF THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER. ,ANTI-CENTROMERES IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CENTROMERES (ANTI-CENTROMERES IGG) IN HUMAN SERUM AND PLASMA. ,VITAMIN B12 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM. ,ANTI-M2-3E IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO M2-3E (ANTI-M2-3E IGG) IN HUMAN SERUM AND PLASMA. ,HSV-1/2 IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF HSV-1/2 IGG IN HUMAN SERUM. ,ANTI-DSDNA IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG AUTOANTIBODIES TO DOUBLE-STRANDED DNA (ANTI-DSDNA IGG) IN HUMAN SERUM AND PLASMA. ,C-PEPTIDE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO

	CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM AND PLASMA., ANTI-JO-1 IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO JO-1 (ANTI-JO-1 IGG) IN HUMAN SERUM AND PLASMA. ,EBV EA IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV EA IGG IN HUMAN SERUM. , ANTI-SS-A IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO SS-A (ANTI-SS-A IGG) IN HUMAN SERUM AND PLASMA. ,IGG (URINE ANALYSIS) (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN URINE. ,ANTI-NRNP/SM IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO NRNP/SM (ANTI-NRNP/SM IGG) IN HUMAN SERUM AND PLASMA. ,DIGOXIN(CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN IN HUMAN SERUM.,ALBUMIN (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN URINE. ,WASTE BAG(MAGLUMI)-"THE MAGLUMI WASTE BAG IS USED FOR COLLECTING WASTE PRODUCED DURING THE TESTS ON MAGLUMI FULLYAUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER. " ,2-MG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 2-MICROGLOBULIN (2-MG) IN HUMAN SERUM OR URINE. ,ALBUMIN ASSAY KIT (BCG)(BIOSSAYS)-THE SNIBE BIOSSAYSTM ALB REAGENT IS INTENDED FOR THE IN VITRO DIRECT QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM. ,FT4 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM. ,TOXO IGM (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF TOXO IGM IN HUMAN SERUM. ,CMV IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF CMV IGG IN HUMAN SERUM. ,GH (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GROWTH HORMONE (GH). ,TOTAL BILIRUBIN ASSAY KIT (VANADATE) (BIOSSAYS)-THE SNIBE BIOSSAYSTM TBIL REAGENT IS INTENDED

	FOR QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM. ,ISE CLEANER(BIOSSAYS)-ISE CLEANER IS USED TO WASH THE ISE OF AUTOMATIC BIOCHEMISTRY ANALYZER. ,FREE TESTOSTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE IN HUMAN SERUM. , ASPARTATE AMINOTRANSFERASE ASSAY KIT (IFCC)(BIOSSAYS)-THE SNIBE BIOSSAYSTM AST REAGENT IS INTENDED FOR QUANTITATIVE DE-TERMINATION OF ASPARTATE AMINOTRANSFERASE IN HUMAN SERUM. ,INSULIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM. ,APOLIPOPROTEIN E ASSAY KIT (IMMUNOTURBIDIMETRIC)(BIOSSAYS)-THE SNIBE BIOSSAYSTM APOE REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN E IN HUMAN SERUM. , HITERGENT(BIOSSAYS)-HITERGENT IS USED TO WASH THE PENTROUGH, REAGENT PROBE, STIRRING ARM AND ASSAY CUP OF AUTOMATIC BIOCHEMISTRY ANALYZER. ,FREE ESTRIOL (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE ESTRIOL IN HUMAN SERUM. ,EBV VCA IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV VCA IGG IN HUMAN SERUM. , URIC ACID ASSAY KIT (URICASE-PAP)(BIOSSAYS)-THE SNIBE BIOSSAYSTM UA REAGENT IS INTENDED FOR QUANTITATIVE DETERMINA-TION OF URIC ACID IN HUMAN SERUM. ,EBV VCA IGA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV VCA IGA IN HUMAN SERUM. ,FERRITIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM. , IRON (FERENE)(BIOSSAYS)-THE SNIBE BIOSSAYSTM FE REAGENT IS USED FOR QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM. ,MYOGLOBIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM. ,NT-PROBNP (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF N-TERMINAL PROHORMONE B-TYPE NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM. ,INORGANIC PHOSPHORUS (MOLYBDATE)(BIOSSAYS)-THE SNIBE BIOSSAYSTM PHOS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHORUS (PHOS) IN HUMAN SERUM. ,FA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE

	QUANTITATIVE DETERMINATION OF FOLIC ACID (FA) IN HUMAN SERUM.,PCT (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PCT IN HUMAN SERUM, PLASMA AND WHOLE BLOOD. ,HIGH DENSITY LIPOPROTEIN CHOLESTEROL ASSAY KIT (PPD)(BIOSSAYS)-THE SNIBE BIOSSAYSTM HDL-C REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL IN HUMAN SERUM. ,ESTRADIOL (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM. ,GAD 65 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GLUTAMIC ACID DECARBOXYLASE ANTIBODY (GAD65) IN HUMAN SERUM. ,PRG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE (PRG) IN HUMAN SERUM. ,ANTI-TPO (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-TPO IN HUMAN SERUM. ,TESTOSTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM. ,TRIGLYCERIDES ASSAY KIT (GPO-PAP)(BIOSSAYS)-THE SNIBE BIOSSAYSTM TG REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF TRIGLYCERIDE IN HUMAN SERUM. ,TROPONIN I (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TROPONIN I IN HUMAN SERUM. ,TOTAL CHOLESTEROL ASSAY KIT (CHOD-PAP)(BIOSSAYS)-THE SNIBE BIOSSAYSTM TC REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL IN HUMAN SERUM. ,A (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANGIOTENSIN (A) IN HUMAN PLASMA ,TRAB (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TSH RECEPTOR ANTIBODIES (TRAB) IN HUMAN SERUM. ,TGA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN AUTOANTIBODY (TGA) IN HUMAN SERUM. ,TG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) IN HUMAN SERUM. , CALCITONIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE

	DETERMINATION OF CALCITONIN (CT) IN HUMAN SERUM. ,TMA (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID MICROSOMAL AUTOANTIBODY (TMA) IN HUMAN SERUM. , FSH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM. ,-AMYLASE ASSAY KIT (EPS-G7)(BIOSSAYS)-THE SNIBE BIOSSAYSTM -AMY REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF -AMYLASE IN HUMAN SERUM. , CHOLYLGLYCINE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CHOLYLGLYCINE (CG) IN HUMAN SERUM. ,REV T3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF REVERSE TRIIODOTHYRONINE (REVT3) IN HUMAN SERUM. ,TOTAL PROTEIN ASSAY KIT (BIURET)(BIOSSAYS)-THE SNIBE BIOSSAYSTM TP REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM. ,DIRECT BILIRUBIN ASSAY KIT (VANADATE)(BIOSSAYS)-THE SNIBE BIOSSAYSTM DBIL REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM. ,CALCIUM (OCPC)(BIOSSAYS)-THE SNIBE BIOSSAYSTM CA REAGENT IS USED FOR QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM. ,HS-CTNI (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN HUMAN SERUM AND PLASMA. , ALKALINE PHOSPHATASE ASSAY KIT (IFCC)(BIOSSAYS)-THE SNIBE BIOSSAYSTM ALP REAGENT IS INTENDED FOR QUANTITATIVE DETER-MINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM. ,IGM (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM. ,C (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TYPE COLLAGEN (C) IN HUMAN SERUM. ,FT3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM. ,ALDOSTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALDOSTERONE (ALD) IN HUMAN SERUM, PLASMA AND TREATED URINE. ,AMH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-MULLERIAN HORMONE (AMH) IN HUMAN SERUM. ,LIPOPROTEIN(A) ASSAY KIT

	(IMMUNOTURBIDIMETRIC)(BIOSSAYS)-THE SNIBE BIOSSAYSTM LP(A) REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LIPOPROTEIN(A) IN HUMAN SERUM. ,ANTI-IA2 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TYROSINE PHOSPHATASE-LIKE PROTEINS ANTIBODY (ANTI-IA2) IN HUMAN SERUM. ,CK-MB (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MB ISOENZYME OF CREATINE KINASE (CK-MB) IN HUMAN SERUM. , LAMININ (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LAMININ (LN) IN HUMAN SERUM. ,ALANINE AMINOTRANSFERASE ASSAY KIT (IFCC)(BIOSSAYS)-THE SNIBE BIOSSAYSTM ALT REAGENT IS INTENDED FOR QUANTITATIVE DETERMI-NATION OF ALANINE AMINOTRANSFERASE IN HUMAN SERUM. ,HOMOCYSTEINE ASSAY KIT (ENZYME CYCLING)(BIOSSAYS)-THE SNIBE BIOSSAYSTM HCY REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF HOMOCYSTEINE IN HUMAN SERUM. ,HA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HYALURONIC ACID (HA) IN HUMAN SERUM. , ALKALINE WASH(BIOSSAYS)-ALKALINE WASH IS USED TO WASH THE PIPING, REAGENT PROBE AND ASSAY CUP OF AUTOMATIC BIOCHEMISTRY ANALYZER. ,BILE ACID ASSAY KIT (ENZYME CYCLING)(BIOSSAYS)-THE SNIBE BIOSSAYSTM TBA REAGENT IS INTENDED FOR QUANTITATIVE DETERMI-NATION OF TOTAL BILE ACIDS IN HUMAN SERUM. ,REACTION MODULE(MAGLUMI)-REACTION MODULES REQUIRED FOR THE IMPLEMENTATION OF THE MAGLUMI ASSAYS ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER. ,17 OH-PROGESTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 17-OH PROGESTERONE IN HUMAN SERUM. ,CRP (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM. ,IGA (URINE ANALYSIS)(CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN URINE. ,IAA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN AUTOANTIBODIES (IAA) IN HUMAN SERUM. ,HSV-2 IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF HSV-2 IGG IN HUMAN SERUM. ,LOW

	DENSITY LIPOPROTEIN CHOLESTEROL ASSAY KIT (CAT)(BIOSSAYS)-THE SNIBE BIOSSAYSTM LDL-C REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL IN HUMAN SERUM. ,ICA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO ISLET CELLS OF PANCREAS (ICA) IN HUMAN SERUM. ,EBV NA IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV NA IGG IN HUMAN SERUM. ,UREA ASSAY KIT (UREASE KINETIC)(BIOSSAYS)-THE SNIBE BIOSSAYSTM UREA REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM. ,CSA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE A (CSA) IN HUMAN WHOLE BLOOD.,DIRECT RENIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF RENIN IN HUMAN EDTA-PLASMA SPECIMENS. ,FK506 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FK 506 IN HUMAN WHOLE BLOOD.,CREATININE ASSAY KIT (PAP)(BIOSSAYS)-THE SNIBE BIOSSAYSTM CR REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM. ,HSV-1/2IGM (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF HSV-1/2 IGM IN HUMAN SERUM. ,IGA (SERUM ANALYSIS) (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN SERUM.,D-DIMER (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA. ,PROINSULIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROINSULIN IN HUMAN SERUM. ,ACID WASH(BIOSSAYS)-ACID WASH IS USED TO CLEAN CROSS CONTAMINATION OF AUTOMATIC BIOCHEMISTRY ANALYZER. ,TOXO IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF TOXO IGG IN HUMAN SERUM. , LIGHT CHECK(MAGLUMI)-LIGHT CHECK REAGENT REQUIRED TO CHECK THE VALIDITY OF STARTER 1+2 AS WELL AS THE FUNCTIONING OF THE MEASURING AND PIPETTING UNITS. A LIGHT CHECK HAS TO BE CARRIED OUT ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER EITHER ONCE DAILY PRIOR TO STARTING THE FIRST MEASUREMENT OR

	WHENEVER A NEW LOT OF STARTER REAGENTS IS USED. THIS CONTROL PROGRAM CHECKS THE PROPER FUNCTIONING OF THE INSTRUMENT AND STARTER REAGENTS TO AVOID DATA ERROR DUE TO INSTRUMENT DEFECTS OR MISLOCATED OR EXPIRED STARTER REAGENTS. ,IGE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) IN HUMAN SERUM. ,T3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) IN HUMAN SERUM. ,DHEA-S (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE (DHEA-S) IN HUMAN SERUM. ,IGF-(CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN-LIKE GROWTH FACTOR-(IGF-) IN HUMAN SERUM. ,-GLUTAMYL TRANSFERASE ASSAY KIT (IFCC)(BIOSSAYS)-THE SNIBE BIOSSAYSTM GGT REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF -GLUTAMYL TRANSFERASE IN HUMAN SERUM. , LP-PLA2 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 (LP-PLA2) IN HUMAN SERUM. ,OSTEOCALCIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF OSTEOCALCIN (BGP) IN HUMAN SERUM. ,CREATINE KINASE-MB ISOZYME ASSAY KIT (IMMUNOSUPPRESSION)(BIOSSAYS)-THE SNIBE BIOSSAYSTM CK-MB REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CREATINE KINASE-MB IN HUMAN SERUM. ,PP N-P (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF COLLAGEN TYPE N-PEPTIDE (PP N-P) IN HUMAN SERUM. ,T4 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM. ,EBV VCA IGM (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV VCA IGM IN HUMAN SERUM. ,ACTH (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ADRENOCORTICOTROPIC HORMONE (ACTH) IN HUMAN PLASMA. , SYSTEM TUBING CLEANING SOLUTION(MAGLUMI)-THE MAGLUMI SYSTEM TUBING CLEANING SOLUTION IS USED TO CLEAN THE PIPETTOR AND THE WASHER NEEDLES. IT IS USEFUL TO MINIMIZE REAGENT CARRYOVER BY REDUCING PROTEIN PRECIPITATION IN

		THE TUBING, AND IMPROVE ROUTINE MAINTENANCE OF THE MAGLUMI SYSTEM. THE KIT CAN ONLY BE USED WITH MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER, WITH TUBING CLEANING PROGRAM. ,HCG/-HCG (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (-SUBUNIT) (HCG/-HCG) IN HUMAN SERUM. ,CREATINE KINASE (NAC ACTIVATED) ASSAY KIT (IFCC) (BIOSSAYS)-THE SNIBE BIOSSAYSTM CK REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CREATINE KINASE IN HUMAN SERUM. ,EBV EA IGA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV EA IGA IN HUMAN SERUM. ,A (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANGIOTENSIN (A) IN HUMAN PLASMA. ,PRL (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PRL IN HUMAN SERUM. ,ISE-REAGENT PACK(BIOSSAYS)-ISE REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF K+, NA+, CL- AND CA2+ IN HUMAN SERUM USING THE AUTOMATIC BIOCHEMISTRY ANALYZER BC1200 ELECTROLYTE MODULE, ELECTROLYTE ANALYZER (E1200) AND INTEGRATED SYSTEM (BIOLUMI 8000).
635	IMP/IVD/2020/000350	1.License Holder Name: SANYA HOSPITALITY PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD)(WONDFO)-WONDFOSARS-COV-2 ANTIBODY TEST (LATERAL FLOW METHOD) IS AN IMMUNE CHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2)IGG/IGM ANTIBODY IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SAMPLE. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF CORONAVIRUSINFECTION DISEASE (COVID-19), WHICH IS CAUSED BY SARS-COV-2.
636	IMP/IVD/2020/000351	1.License Holder Name: RENAISSANCE PHARMACEUTICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIAGNOSTIC KIT FOR IGM/IGG ANTIBODY TO CORONAVIRUS (SARS-COV-2) (LATERAL FLOW)(LIVZON)-THIS PRODUCT IS USED FOR IN VITRO QUALITATIVE DETECTION OF CORONAVIRUS (SARS-COV-2) IGM/IGG ANTIBODY IN HUMAN SERUM, PLASMA AND VENOUS WHOLE BLOOD SAMPLES.

637	IMP/IVD/2020/000354	1.License Holder Name: GASTROLAB INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SCHEBO SARS COV2 QUICK-THE SCHEBO® • SARS-COV-2 QUICK™ IS A VISUAL IMMUNOCHROMATOGRAPHIC RAPID TEST FOR THE QUALITATIVE DETECTION OF SARS-COV-2 IGM- AND IGG-ANTIBODIES FROM HUMAN SERUM, PLASMA AND WHOLE BLOOD SAMPLES.
638	IMP/IVD/2020/000356	1.License Holder Name: BIO SCIENCE SALES CORPORATION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 IGG / IGM AB DIAGNOSTIC TEST KIT (COLOIDAL GOLD)(SARS-COV-2 IGG / IGM AB DIAGNOSTIC TEST KIT (COLOIDAL GOLD))-FOR IN VITRO QUALITATIVE DETERMINATION OF THE CONTENT OF SARS-COV-2 IGG/IGM ANTIBODY IN HUMAN SERUM, PLASMA AND WHOLE BLOOD
639	IMP/IVD/2020/000358	1.License Holder Name: DOCTOR'S ANALYTICAL LABORATORIES PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TELL ME FAST CORONAVIRUS (COVID-19) IGG/IGM ANTIBODY RAPID TEST , CASSETTE/STRIP FORMAT(BIOCAN)-BIOCAN TELL ME FAST CORONAVIRUS (COVID-19) IGG/IGM ANTIBODY RAPID TEST IS A RAPID, QUALITATIVE, MEMBRANE-BASED IMMUNOCHROMATOGRAPHIC IN VITRO ASSAY INTENDED FOR DETECTION AND DIFFERENTIATION OF NOVEL CORONAVIRUS (COVID-19) IGG & IGM ANTIBODIES WITH HUMAN SERUM, PLASMA OR WHOLE BLOOD SAMPLES (INCLUDING FINGER PRICK). THIS TEST IS INTENDED FOR LABORATORY IN VITRO DIAGNOSTIC USE AND IS A PRELIMINARY SCREENING TEST AND FINAL DIAGNOSIS SHOULD BE BASED AFTER EXAMINATION WITH OTHER QUALIFIED ASSAYS.
640	IMP/IVD/2020/000359	1.License Holder Name: VINCLAN TECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (2019-NCOV) RT-PCR DETECTION KIT(NOVEL CORONAVIRUS (2019-NCOV) RT-PCR DETECTION KIT)-THIS PRODUCT IS INTENDED FOR THE RAPID DETECTION OF 2019-NCOV IN HUMAN THROAT SWAB OR SPUTUM SAMPLES

641	IMP/IVD/2020/000360	1.License Holder Name: KIN DIAGNOSTICS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SGTI-FLEX COVID-19 IGM/IGG(SGTI-FLEX COVID-19 IGM/IGG)-SGTI-FLEX COVID-19 IGM/IGG TEST IS AN IMMUNOASSAY FOR QUALITATIVE DETECTION OF LGM OR IGG ANTIBODIES TO COVID-19 IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS USEFUL AS A SCREENING TEST FOR COVID-19
642	IMP/IVD/2020/000361	1.License Holder Name: BIOGENY DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URINE REAGENT STRIPS (URIT 14G)-URIT 14G URINE REAGENT STRIPS PROVIDE TESTS FOR THE SEMI-QUANTITATIVE MEASUREMENT OF LEUKOCYTES, KETONE, NITRITE, UROBILINOGEN, BILIBRUBIN, GLUCOSE, PROTEIN, SPECIFIC GRAVITY, PH, BLOOD, ASCORBIC ACID, MICROALBUMIN, CALCIUM AND CREATININE IN URINE.,URINE REAGENT STRIPS (URIT 10G)-URIT 10G URINE REAGENT STRIPS PROVIDE TESTS FOR THE SEMI-QUANTITATIVE MEASUREMENT OF LEUKOCYTES, KETONE, NITRITE, UROBILINOGEN, BILIRUBIN, PROTEIN, GLUCOSE, SPECIFIC GRAVITY, BLOOD AND PH IN URINE.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

643	IMP/IVD/2020/000364	1.License Holder Name: M/S.ROCHE DIABETES CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QUALITY CONTROL SOLUTION(ACCU-CHEK AVIVA CONTROL)-FOR PERFORMANCE CHECKS ON THE ACCU-CHEK AVIVA, ACCU-CHEK AVIVA NANO, ACCU-CHEK AVIVA CONNECT, ACCU-CHEK AVIVA COMBO, ACCU-CHEK AVIVA EXPERT & ACCU-CHEK AVIVA INSIGHT SYSTEMS WITH THE ACCU-CHEK AVIVA TEST STRIPS. TESTING CONTROL SOLUTIONS WITH KNOWN GLUCOSE LEVELS ESTABLISHES THAT THE OPERATOR AND THE SYSTEM ARE PERFORMING ACCEPTABLY. CONTROL RESULTS MUST BE WITHIN THE DEFINED ACCEPTABLE RANGES BEFORE VALID PATIENT TESTING IS ALLOWED. ,QUALITY CONTROL SOLUTION(ACCU-CHEK PERFORMA CONTROL)-FOR PERFORMANCE CHECKS ON THE ACCU-CHEK PERFORMA SYSTEM WITH THE ACCU-CHEK PERFORMA TEST STRIPS; AND FOR PERFORMANCE CHECKS ON THE ACCU-CHEK PERFORMA AND THE ACCU-CHEK INFORM II SYSTEMS WITH THE ACCU-CHEK INFORM II TEST STRIPS. TESTING CONTROL SOLUTIONS WITH KNOWN GLUCOSE LEVELS ESTABLISHES THAT THE OPERATOR AND THE SYSTEM ARE PERFORMING ACCEPTABLY. CONTROL RESULTS MUST BE WITHIN THE DEFINED ACCEPTABLE RANGES BEFORE VALID PATIENT TESTING IS ALLOWED.,QUALITY CONTROL SOLUTION(ACCU-CHEK ACTIVE CONTROL)-THE CONTROL SOLUTION IS INTENDED FOR PERFORMING CONTROL TESTS ON ACCU-CHEK ACTIVE BLOOD GLUCOSE METERS AND ACCU-CHEK ACTIVE TEST STRIPS.
644	IMP/IVD/2020/000366	1.License Holder Name: MDAAC INTERNATIONAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COYOTE SARS-COV-2 DIRECT DETECT QPCR ASSAY(DIRECTDETECTTM SARS-COV-2 DETECTION KIT)-DETECTION OF COVID-19
645	IMP/IVD/2020/000367	1.License Holder Name: MDAAC INTERNATIONAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 IGM/IGG ANTIBODY RAPID TEST(NOVA TEST)-DETECTION OF COVID-19

646	IMP/IVD/2020/000368	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PANBIO™ COVID-19 IGG/IGM RAPID TEST DEVICE(PANBIO™ COVID-19 IGG/IGM RAPID TEST DEVICE)-"PANBIO™ COVID-19 IGG/IGM RAPID TEST DEVICE (FINGERSTICK WHOLE BLOOD/ VENOUS WHOLE BLOOD/SERUM/PLASMA) IS FOR PROFESSIONAL USE ONLY AND IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF SARS-COV-2 INFECTION. THE PRODUCT MAY BE USED IN ANY LABORATORY AND NON-LABORATORY ENVIRONMENT. THE TEST PROVIDE PRELIMINARY TEST RESULTS. "
647	IMP/IVD/2020/000373	1.License Holder Name: M/S AGAPPE DIAGNOSTICS LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 FLUORESCENT PCR KIT-TO IDENTIFY AND SPECIFY THE SARS-COV-2 , RNA EXTRACTION KIT-FOR EXTRACTION OF RNA FOR COVID 19 TESTING . USED AS PART OF THE PCR TESTING OF COVID 19
648	IMP/IVD/2020/000375	1.License Holder Name: NUCLEUS18 TURNKEY PROJECTS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 RAPID ANTIBOBY TEST IVD COLLOIDAL GOLD METHOD(INNOVITA)-FOR TESTING OF CORONA VIRUS INFECTION DISEASE (COVID-19) WHICH IS CAUSED BY SARS-COV-2
649	IMP/IVD/2020/000376	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL BILIRUBIN(TOTAL BILIRUBIN)-THE TOTAL BILIRUBIN ASSAY IS USED FOR THE QUANTITATIVE ANALYSIS OF TOTAL BILIRUBIN IN HUMAN SERUM OR PLASMA OF ADULTS AND NEONATES ON THE ARCHITECT C SYSTEMS.

650	IMP/IVD/2020/000377	1.License Holder Name: M/S PAREKH INTEGRATED SERVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LYRA SARS-COV-2 ASSAY (LYRA SARS-COV-2 ASSAY)-THE LYRA SARS-COV-2 ASSAY IS A REAL-TIME RT-PCR ASSAY INTENDED FOR THE IN VITRO QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS COV-2 IN NASAL, NASOPHARYNGEAL (NP) OR OROPHARYNGEAL (OP) SWAB SPECIMENS FROM PATIENTS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. THE ASSAY TARGETS THE NON-STRUCTURAL POLYPROTEIN (PP1AB) OF THE SARS-COV-2 VIRUS. THE AUTHORIZED TESTING CONSISTS OF NUCLEIC ACID EXTRACTION ON THE BIOMERIEUX NUCLISENS® EASYMAG® SYSTEM OR EMAG SYSTEM, FOLLOWED BY RT-PCR ON THE FDA-CLEARED REAL-TIME PCR INSTRUMENT.,LYRA DIRECT SARS-COV-2 ASSAY(LYRA DIRECT SARS-COV-2 ASSAY)-THE LYRA DIRECT SARS-COV-2 ASSAY IS A REAL-TIME RT-PCR ASSAY INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN NASAL (NS), NASOPHARYNGEAL (NP), OR OROPHARYNGEAL (OP) DIRECT SWAB SPECIMENS FROM PATIENTS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER.

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651	IMP/IVD/2020/000378	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD VIPER LT SYSTEM PCR ACCESSORY KIT(BD VIPER LT SYSTEM PCR ACCESSORY KIT)-THE PCR ACCESSORY KIT IS USED IN CONJUNCTION WITH THE VIPER LT INSTRUMENT AND HPV ONCLARITY ASSAY AND REAGENT. THE PROVIDED PLATE SEALS ARE USED DURING THE ASSAY RUN SET UP AND IS PLACED ON THE FILLED PCR PLATE BY THE INSTRUMENT PRIOR TO ENTERING THE READER,BD BBL GRAM STAIN CRYSTAL VIOLET(BD BBL GRAM STAIN CRYSTAL VIOLET)-GRAM STAIN KITS AND REAGENTS ARE USED TO STAIN MICROORGANISMS FROM CULTURES OR SPECIMENS BY THE DIFFERENTIAL GRAM METHOD.,BD VIPER LT PCR TUBE/TRAY KIT(BD VIPER LT PCR TUBE/TRAY KIT)-THE BD VIPER LT PCR TUBE/TRAY KIT IS USED IN CONJUNCTION WITH THE VIPER LT INSTRUMENT AND HPV ONCLARITY ASSAY AND REAGENTS. EMPTY PCR TUBES AS PROVIDED IN THIS KIT ARE USED TO COMPLETELY FILL THE PCR PLATE IF LESS THAN A FULL PLATE OF TUBES IS BEING RUN.,BD BBL GRAM IODINE (STABILIZED)(BD BBL GRAM IODINE (STABILIZED))-GRAM STAIN KITS AND REAGENTS ARE USED TO STAIN MICROORGANISMS FROM CULTURES OR SPECIMENS BY THE DIFFERENTIAL GRAM METHOD.,BD ONCLARITY HPV ASSAY LBC DILUENT TUBES(BD ONCLARITY HPV ASSAY LBC DILUENT TUBES)-THE BD ONCLARITY HUMAN PAPILLOMAVIRUS (HPV) LIQUID-BASED CYTOLOGY (LBC) DILUENT TUBES ARE DESIGNED TO ALLOW FOR DETECTION OF HUMAN PAPILLOMAVIRUS IN GYNECOLOGICAL SPECIMENS THAT ARE COLLECTED IN BD SUREPATH™ PRESERVATIVE FLUID OR PRESERVCYT® SOLUTION AND TESTED WITH THE BD ONCLARITY HPV ASSAY ON THE BD VIPER™ LT SYSTEM USING AN ALIQUOT THAT IS REMOVED PRIOR TO OR AFTER PROCESSING FOR GYNECOLOGICAL TESTING.,BD BBL GRAM STAIN KIT(BD BBL GRAM STAIN KIT)-GRAM STAIN KITS AND REAGENTS ARE USED TO STAIN MICROORGANISMS FROM CULTURES OR SPECIMENS BY THE DIFFERENTIAL GRAM METHOD.,CONTROL SET FOR THE BD ONCLARITY HPV ASSAY(CONTROL SET FOR THE BD ONCLARITY HPV ASSAY)-THE CONTROL SET FOR THE BD ONCLARITY HPV ASSAY CONTAINS POSITIVE AND NEGATIVE CONTROLS THAT ARE INTENDED FOR QUALITY CONTROL USE WHEN TESTING WITH THE BD ONCLARITY HPV ASSAY ON THE BD VIPER LT INSTRUMENT.,BD BBL GRAM SAFRANIN(BD BBL GRAM SAFRANIN)-GRAM STAIN KITS AND REAGENTS ARE USED TO STAIN MICROORGANISMS FROM CULTURES OR SPECIMENS BY THE DIFFERENTIAL GRAM METHOD.,BD ONCLARITY HPV SELF-COLLECTION DILUENT TUBE(BD ONCLARITY HPV SELF-COLLECTION DILUENT TUBE)-BD ONCLARITY HPV SELF-COLLECTION DILUENT TUBE IS INTENDED FOR THE TRANSFER AND

		RESUSPENSION OF SELF COLLECTED VAGINAL SPECIMENS IN THE LABORATORY FOR TESTING WITH THE BD ONCLARITY HPV ASSAY., BD BBL GRAM DECOLORIZER(BD BBL GRAM DECOLORIZER)-GRAM STAIN KITS AND REAGENTS ARE USED TO STAIN MICROORGANISMS FROM CULTURES OR SPECIMENS BY THE DIFFERENTIAL GRAM METHOD.
652	IMP/IVD/2020/000380	1.License Holder Name: ALMIGHTY TECHSERV 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NUCLEIC ACID EXTRACTION KIT(KBM)-FOR NUCLEIC ACID EXTRACTION OR PURIFICATION KIT. APPLICATION IN PCR, RT-PCR, REAL TIME QPCR AND INFECTIOUS DISEASE RESEARCH.
653	IMP/IVD/2020/000381	1.License Holder Name: M/S. ELDER PROJECTS LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (2019- NCOV) ANTIBODY TEST KIT (COLLOIDAL GOLD METHOD) (NOVEL CORONAVIRUS (SARS- COV-2) ANTIBODY (IGG/IGM) TEST)-THIS KIT IS USED FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS (2019-NCOV) ANTIBODIES IN HUMAN SERUM, PLASMA AND VENOUS WHOLE BLOOD SAMPLES IN VITRO. IT IS ONLY USED AS A SUPPLEMENTARY INDICATOR FOR SUSPECTED CASES OF NOVEL CORONAVIRUS NUCLEIC ACID TESTING OR IN CONJUNCTION WITH NUCLEIC ACID DETECTION IN THE DIAGNOSIS OF SUSPECTED CASES, AND IT CANNOT BE USED AS A BASIS FOR THE DIAGNOSIS AND CONCLUSION OF PNEUMONIA CAUSED BY NOVEL CORONAVIRUS, AND NOT SUITABLE FOR GENERAL POPULATION SCREENING. IT IS ONLY FOR MEDICAL INSTITUTIONS.

654	IMP/IVD/2020/000382	1.License Holder Name: KDH BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CANDIDA MANNAN ASSAY(DYNAMIKER CANDIDA MANNAN ASSAY)-DYNAMIKER CANDIDA MANNAN ASSAY IS BASED ON COMPETITIVE ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA). IT IS USED FOR QUANTITATIVE DETECTION OF CANDIDA MANNAN ANTIGEN IN HUMAN SERUM, OFFERING A DIAGNOSTIC REFERENCE FOR CANDIDA INFECTION. THE KIT IS INTENDED FOR PROFESSIONAL USE ONLY., NOVEL CORONAVIRUS (2019-NCOV) RT-PCR KIT (DYNAMIKER)-NOVEL CORONAVIRUS (2019-NCOV) RT-PCR KIT IS A POLYMERASE CHAIN REACTION IVD TEST TO DETECT RNA OF 2019-NCOV IN SAMPLES LIKE UPPER RESPIRATORY TRACT SAMPLES (THROAT SWABS, NASAL SWABS, ETC), LOWER RESPIRATORY TRACT SAMPLES (RESPIRATORY TRACT EXTRACTS, BRONCHIAL LAVAGE FLUID, ALVEOLAR LAVAGE FLUID, DEEP SPUTUM, ETC), CONJUNCTIVAL SWABS, STOOL SPECIMENS, ANTICOAGULANT AND SERUM, CRYPTOCOCCAL ANTIGEN LATERAL FLOW ASSAY(DYNAMIKER CRYPTOCOCCAL ANTIGEN LATERAL FLOW ASSAY)-RAPID IMMUNOCHROMATOGRAPHIC TEST FOR THE DETECTION OF CAPSULAR POLYSACCHARIDE ANTIGENS OF CRYPTOCOCCUS SPECIES COMPLEX CRYPTOCOCCUS NEOFORMANS AND CRYPTOCOCCUS GATTII IN HUMAN SERUM AND CEREBRAL SPINAL FLUID (CSF).,2019-NCOV IGG/IGM RAPID TEST(DYNAMIKER)-THE 2019-NCOV IGG/IGM RAPID TEST IS BASED ON RAPID IMMUNOCHROMATOGRAPHIC TEST. IT IS USED FOR THE DETECTION OF 2019 NOVEL CORONAVIRUS (2019-NCOV) IGG AND IGM ANTIBODY IN HUMAN WHOLE BLOOD/SERUM/PLASMA, OFFERING A DIAGNOSTIC REFERENCE FOR COVID-19,ASPERGILLUS GALACTOMANNAN ASSAY(DYNAMIKER ASPERGILLUS GALACTOMANNAN ASSAY)-DYNAMIKER ASPERGILLUS GALACTOMANNAN ASSAY IS BASED ON SANDWICH ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA). IT IS USED FOR THE DETECTION OF ASPERGILLUS GALACTOMANNAN ANTIGEN IN HUMAN SERUM AND BRONCHOALVEOLAR LAVAGE FLUID (BAL), OFFERING A DIAGNOSTIC REFERENCE FOR ASPERGILLUS INFECTION. THE KIT IS INTENDED FOR PROFESSIONAL USE ONLY.,FUNGUS 1-3 BETA- D GLUCAN ASSAY (DYNAMIKER FUNGUS 1-3 BETA- D GLUCAN ASSAY)-(1 3) BETA D GLUCAN IS THE MAIN CELL WALL COMPONENT OF MOST FUNGI, SUCH AS CANDIDA , ASPERGILLUS AND FUSARIUM , ETC. AND DOES NOT EXIST IN BACTERIA, VIRUS OR HUMAN FUNGUS (1 3) BETA D GLUCAN ASSAY IS BASED ON SPECTROPHOTOMETRY FOR THE QUANTITATIVE DETECTION OF (1 3) BETA D GLUCAN IN HUMAN SERUM. IT OFFERS A DIAGNOSTIC REFERENCE FOR INVASIVE FUNGAL DISEASES. THE KIT

		IS INTENDED FOR PROFESSIONAL USE ONLY.
655	IMP/IVD/2020/000383	1.License Holder Name: BIODX HEALTHCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 IGM/IGG ANTIBODY ASSAY KIT (COLLOIDAL GOLD METHOD)(SARS-COV-2 IGM/IGG ANTIBODY ASSAY KIT (COLLOIDAL GOLD METHOD))-THIS KIT IS USED FOR THE QUALITATIVE DETECTION OF SPECIFIC IGM ANTIBODIES AND IGG ANTIBODIES AGAINST NOVEL CORONAVIRUS (SARS-COV-2) IN HUMAN SPECIMENS (SERUM, PLASMA, WHOLE BLOOD).,SARS-COV-2 IGM IGG ANTIBODY ASSAY KIT (COLLOIDAL GOLD METHOD)(ZYBIO)-QUALITATIVE DETECTION OF SPECIFIC IGM ANTIBODIES AND IGG ANTIBODIES AGAINST NOVEL CORONAVIRUS (SARS-COV-2) IN HUMAN SPECIMENS (SERUM, PLASMA, WHOLE BLOOD) ,SARS-COV-2 ANTIGEN ASSAY KIT (COLLOIDAL GOLD METHOD)(SARS-COV-2 ANTIGEN ASSAY KIT (COLLOIDAL GOLD METHOD))-THIS KIT IS USED FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIGENS TO SARS-COV-2 PRESENT IN HUMAN OROPHARYNGEAL SWAB, NASOPHARYNX SWAB.,NUCLEIC ACID EXTRACTION KIT(MAGNETIC BEAD METHOD)(ZYBIO)-FOR THE EXTRACTION, ENRICHMENT AND PURIFICATION OF NUCLEIC ACID (DNA/RNA) IN SAMPLES. ITS PROCESSED PRODUCTS ARE FOR CLINICAL IN VITRO DIAGNOSTICS ,SARS-COV-2 NUCLEIC ACID DETECTION KIT (PCR-FLUORESCENT PROBE METHOD)(ZYBIO)-THIS KIT IS USED INQUALITATIVE DETECTION IN VITRO OF SARS-COV-2 RNA IN SPUTUM, THROAT SWAB, ALVEOLAR LAVAGE FLUIDS SPECIMENS FROM SUSPECTED COVID-19 CASES, SUSPECTED CLUSTERED CASES, OTHER CASES REQUIRING SARS-COV-2 DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS
656	IMP/IVD/2020/000384	1.License Holder Name: NAMOHA BIO PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 RT PCR KIT (CAREGENE N-COV RT-PCR KIT, CAREGENE COVID-19 RT-PCR KIT)-CAREGENE N-COV RT-PCR KIT & CAREGENE COVID-19 RT-PCR KIT ARE IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR QUALITATIVE DETECTION OF CORONAVIRUS DISEASE (COVID-19) FROM RNA EXTRACTED FROM HUMAN NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB AND SPUTUM USING REAL-TIME RT-PCR (REVERSE TRANSCRIPTION-POLYMERASE CHAIN REACTION).

657	IMP/IVD/2020/000385	1.License Holder Name: BHARAT PARENTERALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:N - COV RT PCR KIT (CAREGENE TM N-COV RT – PCR KIT)-CAREGENE TM N-COV RT – PCR KIT IS IN AN IN VITRO DIAGNOSTIC FOR QUALITATIVE DETECTION OF NOVEL; CORONAVIRUS (COVID - 19) FROM RNA EXTRCATED FROM HUMAN NASOPHARYNGEAL SWAB, ORROPHARYNGEAL SWAB AND SPUTUM USING REAL TIME RT - PCR (REVERSE TRANSCRIPTION - POLYMERASE CHAIN REACTION).
658	IMP/IVD/2020/000386	1.License Holder Name: A. MENARINI INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RADI COVID-19 DETECTION KIT(RADI COVID-19 DETECTION KIT)-THE RADI COVID-19 DETECTION KIT IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE, BASED ON REAL TIME RT-PCR TECHNOLOGY UTILIZING REVERSE-TRANSCRIPTASE (RT) REACTION TO CONVERT RNA INTO COMPLEMENTARY DNA (CDNA). IT IS INTENDED FOR THE PRESUMPTIVE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE COVID-19 IN UPPER AND LOWER RESPIRATORY SPECIMENS.,RADI PREP SWAB AND STOOL DNA/RNA KIT(RADI PREP SWAB AND STOOL DNA/RNA KIT)-THE RADI PREP SWAB AND STOOL DNA / RNA KIT IS A REAGENT USED TO EXTRACT NUCLEIC ACIDS FROM BACTERIA AND VIRUSES PRESENT IN SAMPLES COLLECTED FROM HUMAN FECES, ANUS, VAGINA, OR PHARYNX USING COTTON SWABS. THE EXTRACTED NUCLEIC ACID CAN BE USED IN ALL EXPERIMENTS THAT REQUIRE NUCLEIC ACIDS, SUCH AS REAL-TIME PCR AND NGS. THE KIT IS FOR USE BY A LABORATORY PROFESSIONAL.
659	IMP/IVD/2020/000387	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INVISORB SPIN UNIVERSAL KIT(INVISORB SPIN UNIVERSAL KIT)-THE INVISORB SPIN UNIVERSAL KIT IS DESIGNED FOR EXTRACTION AND PURIFICATION OF DNA/RNA FROM 200 MICROLITER SAMPLE MATERIAL (FOR BLOOD SAMPLE ONLY 100 MICROLITER) USING THE RTA SPIN FILTER SYSTEM WITH CAPPED SPIN COLUMNS

660	IMP/IVD/2020/000388	1.License Holder Name: LAB X 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:K-ASSAY COAGULATION CONTROL (K240C-10M)-QUALITY CONTROL FOR MONITORING THE PERFORMANCE OF QUANTATIVE DETERMINATION OF COAGULATION FACTOR XIII.,K-ASSAY FACTOR-XIII (KAI-205)-QUANTATIVE DETERMINATION OF COAGULATION FACTOR-XIII IN PLASMA,K-ASSAY FACTOR-XIII CALIBRATOR (KAI-206C)-CALIBRATION OF QUANTATIVE DETERMINATION OF COAGULATION FACTOR-XIII IN PLASMA
661	IMP/IVD/2020/000389	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 IGG ASSAY KITS (LATERAL FLOW IMMUNOASSAY)(NA)-IMMUNOASSAY FOR IN VITRO QUALITATIVE DETERMINATION OF ANTI-SARS-COV-2 IGG ANTIBODIES IN HUMAN BLOOD SAMPLE.,SARS-COV-2 IGM ASSAY KITS (LATERAL FLOW IMMUNOASSAY)(NA)-IMMUNOASSAY FOR IN VITRO QUALITATIVE DETERMINATION OF ANTI-SARS-COV-2 IGM ANTIBODIES IN HUMAN BLOOD SAMPLE.
662	IMP/IVD/2020/000390	1.License Holder Name: SAFFRON NATURELE PRODUCTS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: COVID-19 IGG-IGM RAPID TEST CASSETTE(NA)-THE COVID-19 IGG/IGM RAPID TEST CASSETTE IS A LATERAL FLOW CHROMATOGRAPHY IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTI-BODIES (IGG AND IGM) TO NOVEL CORONAVIRUS IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT PROVIDES AN AID IN THE DIAGNOSIS OF INFECTION WITH NOVEL CORONAVIRUS.

663	IMP/IVD/2020/000391	1.License Holder Name: RIHIM PHARMA INTERNATIONAL LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABTES™COVID-19 QPCR I KIT(ABTES™)-THE ABTES™ COVID-19 QPCR I KIT IS A QUALITATIVE REAL-TIME POLYMERASE CHAIN REACTION (QPCR) KIT WHICH ENABLES SIMULTANEOUS DETECTION OF TWO COVID-19- SPECIFIC SIGNATURE REGIONS FROM ITS NON-STRUCTURE POLYPEPTIDE (ORF1A) IN A SINGLE REACTION. IT ALSO INCLUDES DETECTION OF HUMAN HOUSEKEEPING GENE, GAPDH, AS AN INTERNAL CONTROL (IC) TO IDENTIFY POSSIBLE PCR INHIBITIONS FROM SAMPLE PROCESSING. THE KIT CONTAINS ALL THE NECESSARY PCR REAGENTS FOR RAPID, SENSITIVE AND SPECIFIC DETECTION USING TARGET-SPECIFIC PRIMERS AND DOUBLE-LABELED HYDROLYSIS PROBES. THIS KIT HAS BEEN VALIDATED ON SAMPLES EXTRACTED FROM SPUTUM, NASOPHARYNGEAL AND THROAT SWABS.
664	IMP/IVD/2020/000392	1.License Holder Name: HORIBA INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 REAL-TIME PCR KIT (L) (EXAMPLAR)-EXAMPLAR COVID-19 REAL-TIME PCR KIT (L) IS A KIT FOR THE IN VITRO QUALITATIVE DETECTION OF SARS-COV-2 RESPONSIBLE FOR COVID-19 IN RESPIRATORY SPECIMENS. THE PRIMER AND PROBE SETS ARE DESIGNED FOR THE UNIVERSAL DETECTION OF BETACORONAVIRUSES (E GENE) AND FOR SPECIFIC DETECTION OF COVID-19 (RDRP GENE). FOR IN VITRO DIAGNOSTIC USE ONLY. ,VIRAL RNA EXTRACTION KIT (NUACTOR)-NUACTOR VIRAL RNA EXTRACTION KIT IS A CARTRIDGE TYPE EXTRACTION KIT INTENDED FOR VIRAL RNA PURIFICATION FROM HUMAN SERUM/PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.
665	IMP/IVD/2020/000394	1.License Holder Name: GENETIX BIOTECH ASIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID 19 IGG/IGM RAPID TEST KIT(SGTI-FLEX COVID-19 IGM/IGG KIT)-SGTI-FLEX COVID-19 IGM/IGG TEST IS AN IMMUNOASSAY FOR QUALITATIVE DETECTION OF LGM OR IGG ANTIBODIES TO COVID-19 IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS USEFUL AS A SCREENING TEST FOR COVID-19.

666	IMP/IVD/2020/000395	1.License Holder Name: PREMIER NUTRACEUTICALS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (SARS-COV-2) ANTIBODY (IGG/IGM) TEST-THE NOVEL CORONAVIRUS (SARS-COV-2) ANTIBODY (IGG/IGM) TEST IS A DEVICE THAT UTILIZES IMMUNOCHROMATOGRAPHY FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS IGM/IGG ANTIBODY IN A SERUM, PLASMA OR WHOLE BLOOD SPECIMEN. THE TEST IS IN A CASSETTE FORMAT AND INTENDED FOR PROFESSIONAL USE ONLY. THE DEVICE IS FOR IN VITRO DIAGNOSTIC USE.

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667	IMP/IVD/2020/000396	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URINE CROSSLAPS® ELISA (CTX-I)-THE URINE CROSSLAPS® (CTX-I) EIA IS AN ENZYME IMMUNOSORBENT ASSAY FOR QUANTITATIVE DETERMINATION OF DEGRADATION PRODUCTS OF C-TERMINAL TELOPEPTIDES OF TYPE-I COLLAGEN IN HUMAN URINE. THE URINE CROSSLAPS® (CTX-I)EIA ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN INDICATION OF HUMAN BONE RESORPTION AND MAY BE USED AS AN AID IN MONITORING BONE RESORPTION CHANGES AND PREDICTING SKELETAL RESPONSE (BONE MINERAL DENSITY) IN POSTMENOPAUSAL WOMEN UNDERGOING ANTI-RESORPTIVE THERAPIES. ,25-HYDROXY VITAMIN D RIA(25-HYDROXY VITAMIN D RIA)-THE IDS 25-HYDROXY VITAMIN D RIA KIT IS A LIQUID PHASE RADIOIMMUNOASSAY INTENDED FOR THE QUANTITATIVE DETERMINATION OF 25-HYDROXYVITAMIN D (25-OH D) AND OTHER HYDROXYLATED METABOLITES IN HUMAN SERUM OR PLASMA. RESULTS ARE TO BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST THE CLINICIAN IN THE ASSESSMENT OF VITAMIN D SUFFICIENCY.,URINE BETA CROSSLAPS (CTX-I) ELISA-THE URINE BETA CROSSLAPS® (CTX-I)ELISA IS AN ENZYME IMMUNOLOGICAL TEST FOR THE QUANTIFICATION OF DEGRADATION PRODUCTS OF C-TERMINAL TELOPEPTIDES OF TYPE-I COLLAGEN IN HUMAN URINE,1,25-DIHYDROXY VITAMIN D EIA-THE IDS 1,25-DIHYDROXY VITAMIN D EIA KIT IS A COMPLETE ASSAY SYSTEM INTENDED FOR THE PURIFICATION OF 1,25-DIHYDROXYVITAMIN D (1,25D) IN HUMAN SERUM OR PLASMA BY IMMUNOEXTRACTION FOLLOWED BY QUANTITATION BY ENZYMEIMMUNOASSAY. RESULTS ARE TO BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST THE CLINICIAN IN THE ASSESSMENT OF 1,25D DEFICIENCY ASSOCIATED WITH RENAL DISEASE IN ADULT POPULATIONS.,25-HYDROXY VITAMIN DS EIA-THE 25-HYDROXY VITAMIN DS EIA ASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF 25-HYDROXYVITAMIN D [25(OH)D] AND OTHER HYDROXYLATED METABOLITES IN HUMAN SERUM OR PLASMA. RESULTS ARE TO BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY DATA TO ASSIST THE CLINICIAN IN THE ASSESSMENT OF VITAMIN D SUFFICIENCY.,SERUM CROSSLAPS® ELISA (CTX-I)-THE SERUM CROSSLAPS® (CTX-I) ELISA IS AN ENZYME IMMUNOLOGICAL TEST FOR THE QUANTIFICATION OF DEGRADATION PRODUCTS OF C-TERMINAL TELOPEPTIDES OF TYPE I COLLAGEN IN HUMAN SERUM AND PLASMA. THE SERUM CROSSLAPS® (CTX-I) ELISA ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN INDICATION OF HUMAN BONE RESORPTION AND MAY BE USED AS AN

	AID IN MONITORING BONE RESORPTION CHANGES AND PREDICTING SKELETAL RESPONSE (BONE MINERAL DENSITY) IN POSTMENOPAUSAL WOMEN UNDERGOING ANTI RESORPTIVE THERAPIES ,OSTASE® BAP EIA-THE OSTASE® BAP EIA IMMUNOENZYMETRIC ASSAY IS AN IN VITRO DEVICE INDICATED FOR THE QUANTITATIVE MEASUREMENT OF BONE-SPECIFIC ALKALINE PHOSPHATASE (BAP), AN INDICATOR OF OSTEOBLASTIC ACTIVITY, IN HUMAN SERUM. THIS DEVICE IS INTENDED TO BE USED AS AN AID IN THE MANAGEMENT OF POSTMENOPAUSAL OSTEOPOROSIS AND PAGET'S DISEASE.,N MID OSTEOCALCIN® ELISA-THE N-MID® OSTEOCALCIN ELISA IS AN ENZYME IMMUNOLOGICAL TEST FOR THE QUANTITATIVE MEASUREMENT OF OSTEOCALCIN, AN INDICATOR OF OSTEOBLASTIC ACTIVITY IN HUMAN SERUM AND PLASMA AND IS INTENDED TO BE USED AS AN AID IN THE PREVENTION OF OSTEOPOROSIS,ALPHACROSSLAPS® ELISA (CTX-I)-THE ALPHA CROSSLAPS® (CTX-I) EIA IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUANTIFICATION OF NON-ISOMERIZED FRAGMENTS OF C-TERMINAL TELOPEPTIDES OF TYPE-I COLLAGEN (CTX-I) IN HUMAN URINE. THE ALPHA CROSSLAPS® (CTX-I) EIA IS INTENDED FOR USE AS AN INDICATOR OF DEGRADATION OF NON-ISOMERIZED BONE COLLAGEN AND MAY BE USED AS AN AID IN THE IDENTIFICATION OF SKELETAL METASTASES IN PATIENTS WITH BREAST AND PROSTATE CANCER ,BONE TRACP (TRACP 5B) ELISA-THE BONETRAP® ASSAY IS A SPECIFIC METHOD TO DETECT TRACP 5B ACTIVITY FRESHLY LIBERA- TED FROM OSTEOCLASTS. IT IS INTENDED FOR USE AS AN INDICATOR OF BONE RESORPTION AND CAN BE USED AS AN AID IN MONITORING BONE RESORPTION CHANGES IN POST-MENOPAUSAL WOMEN AND INDIVIDUALS DIAGNOSED WITHOSTEOPOROSIS UNDERGOING ANTI-RESORPTIVE THERAPIES (HRT AND BISPHOSPHONATES) (4, 6-18). IN VITRO,TRACP 5B ACTIVITY REFLECTS THE NUMBER OF OSTEOCLASTS (15,19), AND THEREFORE THE BONETRAP® ASSAY CAN BE CONVENIENTLY USED TO DETERMINE OSTEOCLAST NUMBER IN HUMAN OSTEOCLAST CULTURES

668	IMP/IVD/2020/000397	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMATOLOGY CONTROL-HEMATOLOGY CONTROL IS USED FOR THE QUALITY CONTROL OF HEMATOLOGY ANALYZER,HEMATOLOGY ANALYZER LYSE-TO LYSE THE CELLS FOR FURTHER TESTING USING HEMATOLOGY ANALYZER, SUCH AS COMPLETE BLOOD COUNT (CBC),HEMATOLOGY ANALYZER DILUENT-TO DILUTE BLOOD FOR FURTHER TESTING USING HEMATOLOGY ANALYZER, SUCH AS COMPLETE BLOOD COUNT (CBC), CLEANSER-FOR CLEANING VARIOUS PARTS OF HEMATOLOGY ANALYZER LIKE PROBE, NEEDLES, BATH, TUBING ETC.,HEMATOLOGY CALIBRATOR-HEMATOLOGY CALIBRATOR IS USED IN THE CALIBRATION OF HEMATOLOGY ANALYZER

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669	IMP/IVD/2020/000398	1.License Holder Name: ASVIN DIAGNOSTICS PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IGE TURBI (IGE TURBI)-QUANTITATIVE DETECTION OF ALLERGY LEVEL IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,CRP LATEX(CRP LATEX)-QUALITATIVE MEASUREMENT OF CRP (C-REACTIVE PROTEIN) IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,CRP TURBI (CRP TURBI)-QUANTITATIVE MEASUREMENT OF CRP IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,HDLC-D(HDLC-D)-QUANTITATIVE DETERMINATION OF HIGH DENSITY LIPO PROTEINS IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,CK NAC-LQ (CK NAC-LQ)-QUANTITATIVE DETERMINATION OF CREATININE KINEASE (CK) IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,URIC ACID(URIC ACID)-QUANTITATIVE DETERMINATION OF IN URIC ACID SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,ASO LATEX (ASO LATEX)-QUALITATIVE MEASUREMENT OF ASO (ANTI-STREPTOLYSIS O) IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,GOT/AST LQ(GOT/AST LQ)-QUANTITATIVE DETERMINATION OF GOT/AST IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,LDLC-D(LDLC-D)-QUANTITATIVE DETERMINATION OF LOW DENSITY LIPO PROTEINS IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,CHLORIDE (CHLORIDE)-QUANTITATIVE DETERMINATION OF CHLORIDE IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,AMYLASE LQ(AMYLASE LQ)-QUANTITATIVE DETERMINATION OF AMYLASE IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,CREATININE TR(CREATININE TR)-QUANTITATIVE DETERMINATION OF CREATININE IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,CHOLESTEROL (CHOLESTEROL)-QUANTITATIVE DETERMINATION OF CHOLESTEROL IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,RF LATEX(RF LATEX)-QUALITATIVE MEASUREMENT OF RF (RHEUMATOID FACTORS) IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,RF TURBI(RF TURBI)-QUANTITATIVE MEASUREMENT OF RF IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY , TRIGLYCERIDES LS(TRIGLYCERIDES LS)-QUANTITATIVE DETERMINATION OF IN TRIGLYCERIDES SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,URIC ACID LS(URIC ACID LS)-QUANTITATIVE DETERMINATION OF IN URIC ACID SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,TRIGLYCERIDES (TRIGLYCERIDES)-QUANTITATIVE DETERMINATION OF IN TRIGLYCERIDES SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,TOTAL LIPIDS(TOTAL LIPIDS)-QUANTITATIVE DETERMINATION OF TOTAL LIPIDS IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,GPT/ALT (GPT/ALT)-QUANTITATIVE

	DETERMINATION OF GPT/ALT IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY , GPT/ALT LQ(GPT/ALT LQ)-QUANTITATIVE DETERMINATION OF GPT/ALT LQ IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,UREA UV LQ(UREA UV LQ)-QUANTITATIVE DETERMINATION OF IN UREA SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,CK MB CONTROL(CK MB CONTROL)-SERUM CONTROL FOR CK MB CLINICAL CHEMISTRY ASSAYS. ,FERRITIN TURBI(FERRITIN TURBI)-QUANTITATIVE DETERMINATION OF FERRITIN IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,BILIRUBIN T-DMSO(BILIRUBIN T-DMSO)-QUANTITATIVE DETERMINATION OF BILIRUBIN T- DMSO IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,CREATININE - J(CREATININE - J)-QUANTITATIVE DETERMINATION OF CREATININE IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,LP(A) TURBI(LP(A) TURBI)-QUANTITATIVE MEASUREMENT OF LIPO PROTEIN A IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,AMMONIA (NH3) (AMMONIA (NH3))-QUANTITATIVE DETERMINATION OF AMMONIA IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY , CHOLESTEROL LS(CHOLESTEROL LS)-QUANTITATIVE DETERMINATION OF CHOLESTEROL IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,CK –MB LQ(CK –MB LQ)-QUANTITATIVE DETERMINATION OF CREATININE KINEASE(MB) IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,MAGNESIUM (MAGNESIUM)-QUANTITATIVE DETERMINATION OF MAGNESIUM IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,PHOSPHORUS UV (PHOSPHORUS UV)-QUANTITATIVE DETERMINATION OF PHOSPHORUS IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,MICROALBUMIN TURBI (MICROALBUMIN TURBI)-QUANTITATIVE DETERMINATION OF MICROALBUMIN IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,ASO TURBI (ASO TURBI)-QUANTITATIVE MEASUREMENT OF ASLO IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,GOT/AST(GOT/AST)-QUANTITATIVE DETERMINATION OF GOT/AST IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,CHE/COLINESTERASE (CHE/COLINESTERASE)-QUANTITATIVE DETERMINATION OF CHOLINESTERASE/CHE IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,IRON FZ(IRON FZ)-QUANTITATIVE DETERMINATION OF IRON IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,PHOSPHOLIPIDS(PHOSPHOLIPIDS)-QUANTITATIVE DETERMINATION OF PHOSPHOLIPIDS IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,TIBC(TIBC)-QUANTITATIVE DETERMINATION OF IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,CALCIUM A-III(CALCIUM A-III)-QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM ONLY FOR IN

		VITRO USE IN CLINICAL CHEMISTRY ,PROTEIN U & CFS(PROTEIN U & CFS)-QUANTITATIVE DETERMINATION OF PROTEIN U & CFS IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,ALBUMIN (ALBUMIN)-QUANTITATIVE DETERMINATION OF ALBUMIN IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY,BILIRUBIN D-DMSO (BILIRUBIN D-DMSO)-QUANTITATIVE DETERMINATION OF BILIRUBIN D-DMSO IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY , Y- GT LQ(Y- GT LQ)-QUANTITATIVE DETERMINATION OF GAMMA GULTAMYLTRASNFERASE IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY,LDH LQ(LDH LQ)-QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,ACP(ACP)-QUANTITATIVE DETERMINATION OF ACID PHOSPHATES IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,TOTAL PROTEIN (TOTAL PROTEIN)-QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,ALP LQ(ALP LQ)-QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATES IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY ,LIPASE LQ(LIPASE LQ)-QUANTITATIVE DETERMINATION OF LIPASE IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY
670	IMP/IVD/2020/000402	1.License Holder Name: N.W. OVERSEAS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIBODY TEST (COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY)(LEPU)-THE PRODUCT IS INTENDED FOR THE QUALITATIVE DETECTION OF ANTIBODY CONTENT AGAINST SARS-COV-2 IN CLINICAL SAMPLES (SERUM/PLASMA/WHOLE BLOOD).
671	IMP/IVD/2020/000404	1.License Holder Name: BIOPLUS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CELLEX QSARS- COV-2 IGG/IGM CASSETTE RAPID TEST-THE CELLEX QSARS-COV-2 IGG/IGM CASSETTE RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR QUALITATIVE DETECTION OF ANTIBODIES TO 2019 NOVEL CORONAVIRUS (SARS-COV-2) IN SERUM,PLASMA OR WHOLE BLOOD SPECIMENS.

672	IMP/IVD/2020/000406	1.License Holder Name: S A DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (2019-NCOV) IGM/IGG ANTIBODY TEST KIT (COLLOIDAL GOLD) (GENRUI)-FOR IN VITRO QUALITATIVELY DETECTING NOVEL CORONAVIRUS (2019-NCOV) IGM AND IGG ANTIBODIES IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.
673	IMP/IVD/2020/000407	1.License Holder Name: CRONIES PHARMA AND BIO-SCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DOW QUICKFINDER ™ 2019-NCOV REAL TIME PCR KIT(DOW QUICKFINDER ™ 2019-NCOV REAL TIME PCR KIT)-DOW QUICKFINDER™ 2019-NCOV REAL TIME PCR KIT IS INTENDED FOR THE QUALITATIVE DETERMINATION OF CORONA VIRUS FROM PHLEGM, OROPHARYNGEAL AND NASOPHARYNGEAL SWAB USING REAL-TIME REVERSE-TRANSCRIPTION PCR METHOD. "DOW QUICKFINDERTM 2019-NCOV REAL-TIME PCR KIT IS A PRODUCT THAT CAN DETECT THREE SPECIFIC TARGET REGIONS OF N GENE AMONG SPECIFIC TARGET GENES IN CORONA 19 USING REAL-TIME POLYMERASE CHAIN REACTION. THE REAL-TIME POLYMERASE CHAIN REACTION METHOD USES FLUORESCENT MATERIALS TO MEASURE THE SIGNALS FROM EACH CYCLE OF PCR IN REAL TIME TO COMPENSATE FOR THE SHORTCOMINGS OF THE END-POINT DETECTION OF EXISTING PCR, AND DETECTS PCR AMPLIFICATION PRODUCTS THROUGH FLUORESCENCE. CDNA SYNTHESIS AND TARGET REGION DETECTION CAN BE PERFORMED SIMULTANEOUSLY WITH A SINGLE PCR USING A ONE-STEP METHOD, THEREBY DETECTING CORONA 19 IN A SHORTER TIME COMPARED TO THE TIME REQUIRED FOR THE EXISTING TEST. THIS PRODUCT EXTRACTS RNA FROM HUMAN SAMPLES (SPUTUM, OROPHARYNGEAL AND NASOPHARYNGEAL SMEARS, ETC.) AND THEN USES REAL-TIME REVERSE-TRANSCRIPTION PCR TO DETECT 3 OF THE N GENES OF CORONA19 VIRUS. IT IS A MEDICAL DEVICE FOR IN VITRO DIAGNOSIS THAT HELPS TO DIAGNOSE CORONA19 VIRUS INFECTION BY DETECTING THE TARGET REGION."
674	IMP/IVD/2020/000411	1.License Holder Name: ALLIANZ BIOINNOVATION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIRAL RNA EXTRACTION KIT(RIBOSPIN™ VRD -GENEALL)-EXTRACTION OF VIRAL RNA FROM PATIENT SAMPLE

675	IMP/IVD/2020/000412	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SCRUB TYPHUS RAPID (IMMUNEMED)-"IMMUNEMED SCRUB TYPHUS RAPID" IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR QUALITATIVE DETECTION OF IGM & IGG ANTIBODIES TO ORIENTIA TSUTSUGAMUSHI IN THE PATIENT'S SERUM, PLASMA OR WHOLE BLOOD.

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676	IMP/IVD/2020/000413	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QMS TACROLIMUS IMMUNOASSAY CALIBRATOR(QMS TACROLIMUS IMMUNOASSAY CALIBRATOR SET)-THE QMS TACROLIMUS CALIBRATOR SET IS INTENDED FOR USE IN CALIBRATION OF THE QMS TACROLIMUS IMMUNOASSAY,CEDIA CYCLOSPORIN PLUS ASSAY (CEDIA CYCLOSPORIN PLUS ASSAY)-THE CEDIA® CYCLOSPORINE PLUS ASSAY IS FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CYCLOSPORINE IN HUMAN WHOLE BLOOD USING AUTOMATED CLINICAL CHEMISTRY ANALYZERS AS AN AID IN THE MANAGEMENT OF CYCLOSPORINE THERAPY IN KIDNEY, LIVER, AND HEART TRANSPLANTS,CEDIA MYCOPHENOLIC ACID ASSAY(CEDIA MYCOPHENOLIC ACID ASSAY)-THE CEDIA® MYCOPHENOLIC ACID (MPA) ASSAY IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE QUANTITATIVE MEASUREMENT OF MYCOPHENOLIC ACID IN HUMAN PLASMA USING AUTOMATED CLINICAL CHEMISTRY ANALYZERS AS AN AID IN THE MANAGEMENT OF MYCOPHENOLIC ACID THERAPY IN RENAL AND CARDIAC TRANSPLANT PATIENTS.,QMS TACROLIMUS IMMUNOASSAY (QMS TACROLIMUS IMMUNOASSAY)-THE QMS TACROLIMUS IMMUNOASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TACROLIMUS IN HUMAN WHOLE BLOOD ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS. THE RESULTS OBTAINED ARE USED AS AN AID IN THE MANAGEMENT OF KIDNEY, LIVER, AND HEART TRANSPLANT PATIENTS RECEIVING TACROLIMUS THERAPY. THIS IN VITRO DIAGNOSTIC DEVICE IS INTENDED FOR CLINICAL LABORATORY USE ONLY.,MAS LIQUID MYCOPHENOLIC ACID CONTROL LEVEL 1(MAS LIQUID MYCOPHENOLIC ACID CONTROL LEVEL 1)-MAS MYCOPHENOLIC ACID (MPA) CONTROLS ARE INTENDED FOR USE AS ASSAYED QUALITY CONTROL MATERIAL FOR VALIDATION OF MPA ASSAYS.,CEDIA MYCOPHENOLIC ACID CALIBRATORS(CEDIA MYCOPHENOLIC ACID CALIBRATORS)-THE CEDIA MYCOPHENOLIC ACID (MPA) CALIBRATORS ARE INTENDED FOR USE IN THE CALIBRATION OF THE CEDIA MPA ASSAY.,MAS LIQUID MYCOPHENOLIC ACID CONTROL LEVEL 3(MAS LIQUID MYCOPHENOLIC ACID CONTROL LEVEL 3)-MAS MYCOPHENOLIC ACID (MPA) CONTROLS ARE INTENDED FOR USE AS ASSAYED QUALITY CONTROL MATERIAL FOR VALIDATION OF MPA ASSAYS.,QMS EVEROLIMUS IMMUNOASSAY REAGENT(QMS EVEROLIMUS IMMUNOASSAY REAGENT)-THE QMS EVEROLIMUS ASSAY IS TO BE USED FOR THE QUANTITATIVE DETERMINATION OF EVEROLIMUS IN HUMAN WHOLE BLOOD ON AUTOMATED CLINICAL CHEMISTRY

	ANALYZERS.,QMS EVEROLIMUS IMMUNOASSAY CALIBRATOR(QMS EVEROLIMUS IMMUNOASSAY CALIBRATOR SET)-THE QMS EVEROLIMUS CALIBRATOR SET IS INTENDED FOR USE IN CALIBRATION OF THE QMS EVEROLIMUS ASSAY.,QMS EVEROLIMUS IMMUNOASSAY CONTROL(QMS EVEROLIMUS IMMUNOASSAY CONTROL SET)-THE QMS EVEROLIMUS CONTROL SET IS INTENDED FOR USE IN QUALITY CONTROL OF THE QMS EVEROLIMUS ASSAY.,MAS LIQUID MYCOPHENOLIC ACID CONTROL LEVEL 2(MAS LIQUID MYCOPHENOLIC ACID CONTROL LEVEL 2)-MAS MYCOPHENOLIC ACID (MPA) CONTROLS ARE INTENDED FOR USE AS ASSAYED QUALITY CONTROL MATERIAL FOR VALIDATION OF MPA ASSAYS,CEDIA CYCLOSPORINE PLUS HIGH RANGE CALIBRATORS(CEDIA CYCLOSPORINE PLUS HIGH RANGE CALIBRATORS)-THE CEDIA CYCLOSPORINE PLUS HIGH RANGE CALIBRATORS ARE USED TO CALIBRATE THE CEDIA CYCLOSPORINE PLUS HIGH RANGE ASSAY IN HUMAN WHOLE BLOOD. EACH CALIBRATOR SET IS SOLD SEPARATELY AND MAY BE USED WITH ANY REAGENT LOT.

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677	IMP/IVD/2020/000420	1.License Holder Name: BIO-RAD LABORATORIES (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KALLESTAD CRITHIDIA LUCILIAE, 4 WELL KIT, 24 TESTS(KALLESTAD CRITHIDIA LUCILIAE, 4 WELL KIT, 24 TESTS)-AN INDIRECT FLUORESCENT ANTIBODY PROCEDURE FOR THE DETECTION AND SEMI-QUANTITATION OF HUMAN NATIVE NDNA AUTO-ANTIBODIES.,KALLESTAD HEP-2, 12 WELL KIT, 240 TESTS(KALLESTAD HEP-2, 12 WELL KIT, 240 TESTS)-AN INDIRECT FLUORESCENT ANTIBODY PROCEDURE FOR THE DETECTION AND SEMI-QUANTITATION OF HUMAN AUTO-ANTIBODIES.,KALLESTAD CRITHIDIA LUCILIAE, 8 WELL KIT, 48 TESTS (KALLESTAD CRITHIDIA LUCILIAE, 8 WELL KIT, 48 TESTS)-AN INDIRECT FLUORESCENT ANTIBODY PROCEDURE FOR THE DETECTION AND SEMI-QUANTITATION OF HUMAN NATIVE NDNA AUTO-ANTIBODIES.,KALLESTAD HEP-2, 12 WELL KIT, 60 TESTS (KALLESTAD HEP-2, 12 WELL KIT, 60 TESTS)-AN INDIRECT FLUORESCENT ANTIBODY PROCEDURE FOR THE DETECTION AND SEMI-QUANTITATION OF HUMAN AUTO-ANTIBODIES.,KALLESTAD MOUSE STOMACH KIDNEY, 8 WELL KIT, 48 TESTS(KALLESTAD MOUSE STOMACH KIDNEY, 8 WELL KIT, 48 TESTS)-AN INDIRECT FLUORESCENT ANTIBODY PROCEDURE FOR THE DETECTION AND SEMI-QUANTITATION OF HUMAN AUTO-ANTIBODIES.,KALLESTAD HEP-2, 6 WELL KIT, 48 TESTS(KALLESTAD HEP-2, 6 WELL KIT, 48 TESTS)-AN INDIRECT FLUORESCENT ANTIBODY PROCEDURE FOR THE DETECTION AND SEMI-QUANTITATION OF HUMAN AUTO-ANTIBODIES.

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678	IMP/IVD/2020/000421	1.License Holder Name: HEALTH ARX TECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIAPLEXQ™ NOVEL CORONAVIRUS (2019-NCOV) DETECTION KIT(SOLGENT CO., LTD.)-DIAPLEXQ™ NOVEL CORONAVIRUS (2019-NCOV) DETECTION KIT IS A REAL-TIME RT-PCR TEST INTENDED FOR THE PRESUMPTIVE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN RESPIRATORY SPECIMENS SUCH AS NASOPHARYNGEAL SWAB OR OROPHARYNGEAL SWAB OR SPUTUM FROM INDIVIDUALS SUSPECTED OF COVID-19 THAT MEET THE CDC SARS-COV-2 CLINICAL CRITERIA. RESULTS ARE FOR THE PRESUMPTIVE DETECTION AND IDENTIFICATION OF SARS-COV-2 RNA. THE SARS-COV-2 RNA IS GENERALLY DETECTABLE IN RESPIRATORY SPECIMENS DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS ARE INDICATIVE OF ACTIVE INFECTION WITH SARS-COV -2 BUT DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. BASIC PRINCIPAL OF THIS KIT IS REAL-TIME PCR METHOD, WHICH IS ABLE TO DETECT SPECIFIC TARGET GENE INTO TOTAL RNA. THIS IS A ONESTEP MULTIPLEX RT-QPCR BASED DETECTION WITH HIGH-SPECIFICITY & IS INTENDED FOR USE BY TRAINED CLINICAL LABORATORY PROFESSIONALS.
679	IMP/IVD/2020/000422	1.License Holder Name: PREMAS LIFE SCIENCES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NX-48S VIRAL NA KIT(NX-48S VIRAL NA KIT)-A REAGENT FOR EXTRACTING SPECIFIC GENES (DNA, RNA) FOR GENETIC TESTING IN HUMAN-DERIVED SPECIMENS
680	IMP/IVD/2020/000423	1.License Holder Name: ALMIGHTY TECHSERV 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSMISSION MEDIA-VIRUS SPECIMEN COLLECTION TUBE WITH SWABS

681	IMP/IVD/2020/000424	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREALBUMIN CALIBRATOR(PREALBUMIN CALIBRATOR)-FOR USE IN THE CALIBRATION OF THE PREALBUMIN ASSAY.,SPECIFIC PROTEINS MULTICONSTITUENT CALIBRATOR(SPECIFIC PROTEINS MULTICONSTITUENT CALIBRATOR)-FOR USE IN THE CALIBRATION OF THE IMMUNOGLOBULIN A (IGA), IMMUNOGLOBULIN G (IGG), IMMUNOGLOBULIN M (IGM), COMPLEMENT C3 (C3), COMPLEMENT C4 (C4), HAPTOGLOBIN, AND TRANSFERRIN ASSAYS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

682	IMP/IVD/2020/000425	1.License Holder Name: HOTGEN BIOTECH INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS 2019-NCOV ANTIBODY TEST (UP-CONVERTING PHOSPHOR IMMUNOCHROMATOGRAPHIC TECHNOLOGY)(NOVEL CORONAVIRUS 2019-NCOV ANTIBODY TEST (UP-CONVERTING PHOSPHOR IMMUNOCHROMATOGRAPHIC TECHNOLOGY))-WHOLE BLOOD SAMPLES. IT IS ONLY USED AS A SUPPLEMENTARY DETECTION INDICATOR FOR SUSPECTED CASES OF NOVEL CORONAVIRUS NUCLEIC ACID NEGATIVE DETECTION OR IN CONJUNCTION WITH NUCLEIC ACID DETECTION IN SUSPECTED CASES. IT CANNOT BE USED AS A BASIS FOR THE DIAGNOSIS AND EXCLUSION OF PNEUMONITIS INFECTED BY NEW CORONAVIRUS. IT IS NOT SUITABLE FOR SCREENING OF THE GENERAL POPULATION,LUTEINIZING HORMONE TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE IN HUMAN SERUM AND PLASMA.,INTERLEUKIN-6 TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF IL-6 IN HUMAN SERUM, PLASMA AND WHOLE BLOOD. THE RESULT OBTAINED WITH THE ASSAY IS USED TO ASSIST IN THE DIAGNOSIS OF INFLAMMATION AND AN EARLY ALARM SIGNAL OF INFECTION.,25-HYDROXY - VITAMIN D TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THE 25-OH -VD IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD. 25-OH-VD VALUES ARE USED TO ASSIST IN DIAGNOSIS OF THE RISK OF VITAMIN D DEFICIENCY DISEASES ETC.,INTERLEUKIN-6 TEST (UP-CONVERTING PHOSPHOR TECHNOLOGY)-INTENDED FOR QUANTITATIVE MEASUREMENT OF HUMAN INTERLEUKIN 6 (IL-6) IN SERUM BY A COMBINATION OF UP-CONVERTING PHOSPHOR TECHNOLOGY (UPT) EMPLOYING IMMUNOCHROMATOGRAPHY AS AN AIDING TOOL FOR EARLY DIAGNOSIS OF INFECTION.,TRIIODOTHYRONINE TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE IN HUMAN SERUM AND PLASMA.,LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 TEST (UP-CONVERTING PHOSPHOR TECHNOLOGY)-INTENDED FOR QUANTITATIVE MEASUREMENT OF HUMAN LIPOPROTEIN ASSOCIATED PHOSPHOLIPASE A2 (LP-PLA2) IN PLASMA BY A COMBINATION OF UP-CONVERTING PHOSPHOR TECHNOLOGY (UPT) EMPLOYING IMMUNECHROMATOGRAPHY AS AN AIDING TOOL FOR RISK STRATIFICATION OF ATHEROSCLEROSIS.,N-TERMINAL PRO-B-TYPE NATRIURETIC PEPTIDE RAPID TEST (COLLOIDAL GOLD)-INTENDED FOR SEMI-QUANTITATIVE MEASUREMENT OF HUMAN N-TERMINAL PRO B-TYPE NATRIURETIC

	PEPTIDE (NT-PROBNP) IN SERUM OR PLASMA EMPLYING COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY AS AN AIDING TOOL FOR DIAGNOSIS OF CONGESTIVE HEART FAILURE (CHF) .,CARDIAC TROPONIN- I TEST(UP-CONVERTING PHOSPHOR TECHNOLOGY)-INTENDED FOR QUANTITATIVE MEASUREMENT OF HUMAN CTNI IN SERUM OR PLASMA BY A COMBINATION OF UP-CONVERTING PHOSPHOR TECHNOLOGY (UPT) EMPLOYING IMMUNOCHROMATOGRAPHY AS AN AIDING TOOL FOR EARLY DIAGNOSIS OF HEART ATTACK.,THYROXINE TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TOTAL THYROXINE IN HUMAN SERUM AND PLASMA.,ANTI-MULLERIAN HORMONE TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF AMH IN HUMAN SERUM. THE RESULT OBTAINED WITH THE ASSAY IS USED AS AN AID IN THE ASSESSMENT OF OVARIAN RESERVE.,C REACTIVE PROTEIN (CRP) TEST (UP-CONVERTING PHOSPHOR TECHNOLOGY)-INTENDED FOR QUANTITATIVE MEASUREMENT OF HUMAN C REACTIVE PROTEIN (CRP) IN SERUM OR PLASMA BY A COMBINATION OF UP-CONVERTING PHOSPHOR TECHNOLOGY (UPT) EMPLOYING IMMUNOCHROMATOGRAPHY AS AN AIDING TOOL FOR INFLAMMATORY CONDITIONS AND RISK STRATIFICATION FOR CARDIAC EVENTS.,N-TERMINAL PRO-B-TYPE NATRIURETIC PEPTIDE TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF N-TERMINAL PRO-B-TYPE NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD. NT-PROBNP VALUES ARE USED TO ASSIST IN DIAGNOSIS OF CARDIAC FAILURE.,LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 TEST(CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THE LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 (LP-PLA2) IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD. LP-PLA2 VALUES ARE USED TO ASSESS THE RISK OF ATHEROSCLEROSIS FOR PATIENT., ANTI-CYCLIC CITRULLINATED PEPTIDE RAPID TEST (COLLOIDAL GOLD)-INTENDED FOR SEMI-QUANTITATIVE MEASUREMENT OF HUMAN ANTI-CYCLIC CITRULLINATED PEPTIDE ANTIBODY (ANTI-CCP) IN SERUM AND PLASMA EMPLOYING COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY AS AN AIDING TOOL FOR DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA) .,D-DIMER TEST (UP-CONVERTING PHOSPHOR TECHNOLOGY)-INTENDED FOR QUANTITATIVE MEASUREMENT OF D-DIMER IN PLASMA BY A COMBINATION OF UP-CONVERTING PHOSPHOR TECHNOLOGY (UPT) EMPLOYING IMMUNOCHROMATOGRAPHY AS AN AIDING TOOL FOR DIAGNOSTIC CRITERIA OF ACUTE PULMONARY EMBOLISM AND DEEP VEIN

	THROMBOSIS.,CREATINE KINASE MB TEST(CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THE MB ISOENZYME OF CREATINE KINASE (CK-MB) IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD. CK-MB VALUES ARE USED TO ASSIST IN DIAGNOSIS OF MYOCARDIAL INFARCTION (MI), MYOPATHY, ETC.,PROCALCITONIN RAPID TEST(COLLOIDAL GOLD)-INTENDED FOR SEMI-QUANTITATIVE MEASUREMENT OF HUMAN PROCALCITONIN (PCT) IN SERUM AND PLASMA EMPLOYING COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY AS AN AIDING TOOL FOR DIAGNOSIS OF SEVERE BACTERIAL INFECTION AND SEPSIS., PROCALCITONIN TEST (UP-CONVERTING PHOSPHOR TECHNOLOGY)-INTENDED FOR QUANTITATIVE MEASUREMENT OF HUMAN PROCALCITONIN (PCT) IN SERUM AND PLASMA EMPLOYING A COMBINATION OF UP-CONVERTING PHOSPHOR TECHNOLOGY (UPT) AND IMMUNOCHROMATOGRAPHY AS AN AIDING DIAGNOSTIC TOOL FOR SEVERE BACTERIAL INFECTION AND SEPSIS.,D-DIMER TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA AND WHOLE BLOOD. D-DIMER VALUES ARE USED TO ASSIST IN DIAGNOSIS OF VENOUS THROMBOSIS AND DIC, AND MONITOR PROGNOSIS OF THROMBOLYTIC THERAPY.,PROCALCITONIN TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THE PROCALCITONIN(PCT) IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD. PROCALCITONIN VALUES ARE USED TO ASSIST IN DIAGNOSIS OF BACTERIAL INFECTIOUS DISEASES ETC.,ANTI-CYCLIC CITRULLINATED PEPTIDE TEST (ENZYME-LINKED IMMUNOSORBENT ASSAY)-INTENDED FOR IN-VITRO QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF ANTI-CYCLIC CITRULLINATED PEPTIDE (ANTI-CCP) IN HUMAN SERUM OR PLASMA SAMPLE, MAINLY USED FOR CLINICAL DIAGNOSIS OF RHEUMATOID ARTHRITIS(RA).,THYROID-STIMULATING HORMONE TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THYROTROPIN IN HUMAN SERUM AND PLASMA.,C-REACTIVE PROTEIN TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THE C-REACTIVE PROTEIN IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD. C-REACTIVE PROTEIN VALUES ARE USED TO THE INDEX OF NONSPECIFIC INFLAMMATION, ETC.,ANTI-MULLERIAN HORMONE TEST (UP-CONVERTING PHOSPHOR TECHNOLOGY)-INTENDED FOR IN VITRO QUANTITATIVE MEASUREMENT OF ANTI MULLERIAN HORMONE (AMH) IN HUMAN SERUM. IT IS MAINLY USED FOR THE AUXILIARY JUDGMENT OF FEMALE OVARIAN RESERVE FUNCTION.,LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 QUANTITATIVE TEST(ENZYME-LINKED

	IMMUNOSORBENT ASSAY)-INTENDED FOR IN-VITRO QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 IN HUMAN PLASMA SAMPLE. STUDY INDICATES THAT LP-PLA2 CAN BE USED FOR EVALUATING ATHEROSCLEROSIS RISK.,MYOGLOBIN TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF MYOGLOBIN (MYO) IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD. MYO VALUES ARE USED TO ASSIST IN DIAGNOSIS OF MYOCARDIAL INFARCTION (MI).,N-TERMINAL PRO-B-TYPE NATRIURETIC PEPTIDE (NT-PROBNP) TEST (UP-CONVERTING PHOSPHOR TECHNOLOGY)-INTENDED FOR QUANTITATIVE MEASUREMENT OF HUMAN NT-PRO BNP IN SERUM AND PLASMA EMPLOYING COMBINATION OF UP-CONVERTING PHOSPHOR TECHNOLOGY (UPT) AND IMMUNOCHROMATOGRAPHY AS AN AIDING DIAGNOSTIC TOOL FOR CONGESTIVE HEART FAILURE (CHF).,HIGH SENSITIVE CARDIAC TROPONIN-I TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THE CARDIAC TROPONIN-I (CTNI) IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD. CTNI VALUES ARE USED TO ASSIST IN DIAGNOSIS OF MYOCARDIAL INFARCTION (MI).,FETAL FIBRONECTIN RAPID TEST (COLLOIDAL GOLD)-INTENDED FOR QUALITATIVE DETERMINATION OF HUMAN FETAL FIBRONECTIN (FFN) IN CERVICOVAGINAL SECRETIONS EMPLOYING COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY AS AN AIDING TOOL FOR RISK ESTIMATION OF PRETERM LABOR.,FREE THYROXINE TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FREE TYROXINE IN HUMAN SERUM AND PLASMA.,FREE TRIIODOTHYRONINE TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE IN HUMAN SERUM AND PLASMA.,PROLACTIN TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM AND PLASMA.,CREATINE KINASE MB (CK-MB) TEST (UP-CONVERTING PHOSPHOR TECHNOLOGY)-INTENDED FOR QUANTITATIVE MEASUREMENT OF HUMAN CARDIAC CREATINE KINASE MB (CK-MB) IN SERUM AND PLASMA BY A COMBINATION OF UP-CONVERTING PHOSPHOR TECHNOLOGY (UPT) EMPLOYING IMMUNOCHROMATOGRAPHY AS AN AIDING TOOL FOR EARLY DIAGNOSIS OF MYOCARDIAL INFARCTION AND VIRAL MYOCARDITIS.,MYOGLOBIN (MYO) TEST (UP-CONVERTING PHOSPHOR TECHNOLOGY)-INTENDED FOR QUANTITATIVE MEASUREMENT OF HUMAN CARDIAC MYOGLOBIN (MYO) IN SERUM OR PLASMA BY A COMBINATION OF UP-CONVERTING PHOSPHOR TECHNOLOGY (UPT)

		EMPLOYING IMMUNOCHROMATOGRAPHY AS AN AIDING TOOL FOR MYOCARDIAL INFARCTION (AMI) RISK ASSESSMENT.,ANTI-MULLERIAN HORMONE TEST (ENZYME-LINKED IMMUNOSORBENT ASSAY)-INTENDED FOR IN-VITRO QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF ANTI-MULLERIAN HORMONE IN HUMAN SERUM SAMPLE, MAINLY USED FOR CLINICAL DIAGNOSIS OF OVARIAN RESERVE FUCTION.,ANTI-CYCLIC CITRULLINATED PEPTIDE TEST (UP-CONVERTING PHOSPHOR TECHNOLOGY)-INTENDED FOR QUANTITATIVE MEASUREMENT OF HUMAN ANTI-CCP IN SERUM EMPLOYING A COMBINATION OF UP-CONVERTING PHOSPHOR TECHNOLOGY (UPT) AND IMMUNOCHROMATOGRAPHY AS AN AIDING DIAGNOSTIC TOOL FOR RHEUMATOID ARTHRITIS.,FOLLICLE-STIMULATING HORMONE TEST (CHEMILUMINESCENCE IMMUNOASSAY)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FOLLICLE-STIMULATING HORMONE IN HUMAN SERUM AND PLASMA.
683	IMP/IVD/2020/000426	1.License Holder Name: INVITROGEN BIOSERVICES INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TAQMAN™ MGB PROBE (APPLIED BIOSYSTEMS)-APPLIED BIOSYSTEMS TAQMAN MGB (MINOR GROOVE BINDER) PROBES ARE DUAL-LABELED PROBES USED FOR REAL-TIME PCR APPLICATIONS USING TAQMAN CHEMISTRY., TAQPATH™ COVID-19 CE-IVD RT-PCR KIT(APPLIED BIOSYSTEMS)-TAQPATH™ COVID-19 CE-IVD RT-PCR KIT CONTAINS THE REAGENTS AND CONTROLS FOR A REAL-TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN NASOPHARYNGEAL SWAB, NASOPHARYNGEAL ASPIRATE, AND BRONCHOALVEOLAR LAVAGE (BAL) SPECIMENS FROM INDIVIDUALS SUSPECTED OF COVID-19.,SEQUENCE DETECTION PRIMER(APPLIED BIOSYSTEMS)-SEQUENCE DETECTION PRIMERS ARE UNLABELED PRIMERS THAT CAN BE USED WITH TAQMAN PROBES OR SYBR GREEN DYE FOR YOUR REAL-TIME PCR RESEARCH APPLICATIONS

684	IMP/IVD/2020/000431	1.License Holder Name: IRIS HIGHTECH PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS COV 2 RAPID ANTIBODY TEST/ COVID 19 TEST-OUR “COV-2 RAPID TEST” IS INTENDED FOR THE DETECTION OF “CORONA 2019” / SARS-COV-2 VIRUS - ANTIBODIES. TWO BIOMARKERS ARE USED, ONE IS IGM, THE OTHER IS IGG. THE RAPID TEST IS AN IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY INTENDED FOR THE QUALITATIVE DETECTION OF THE CONCENTRATION OF IGM / IGG ANTIBODIES IN CAPILLARY OR WHOLE BLOOD OR SERUM. MEASUREMENTS OF IGM / IGG ANTIBODIES ARE TO BE USED IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WHO HAVE BEEN EXPOSED TO THE SARS-COV-2 VIRUS, AS WELL AS ASSIST IN PREVENTING THE SPREAD OF THE DISEASE.
685	IMP/IVD/2020/000433	1.License Holder Name: INBIOS INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SMART DETECTTM SARS-COV-2 RRT-PCR KIT(INBIOS)-SMART DETECTTM SARS-COV-2 RRT-PCR KIT IS A REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SEVERE ACUTE RESPIRATORY SYNDROMERELATED CORONAVIRUS 2 (SARS-COV-2) IN HUMAN NASOPHARYNGEAL SWAB, ANTERIOR NASAL SWAB AND MIDTURBINATE NASAL SWAB SPECIMENS FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER.
686	IMP/IVD/2020/000434	1.License Holder Name: GREINER BIO-ONE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIRUS STABILIZATION TUBE(VACUETTE® VIRUS STABILIZATION TUBE)-VACUETTE® VIRUS STABILIZATION TUBES ARE INTENDED FOR THE TRANSPORT AND STORAGE OF NASOPHARYNGEAL AND OROPHARYNGEAL SWAB SPECIMENS. THE PRODUCT IS TO BE USED BY HEALTHCARE PROFESSIONALS FOR SARS-COV-2 TESTING ONLY.

687	IMP/IVD/2020/000435	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VITROS IMMUNODIAGNOSTIC PRODUCTS ANTISARS-COV-2 TOTAL CONTROLS-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR USE IN MONITORING THE PERFORMANCE OF THE SUITABLE VITROS SYSTEMS WHEN USED FOR THE DETERMINATION OF ANTIBODIES TO SARS-COV-2.,VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 TOTAL REAGENT PACK-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 TOTAL REAGENT PACK TEST WHEN USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 TOTAL CALIBRATOR IS FOR THE QUALITATIVE MEASUREMENT OF TOTAL ANTIBODY (INCLUDING IGG AND IGM) TO SARS-COV-2 IN HUMAN SERUM AND PLASMA (K2 EDTA) SAMPLES FROM PATIENTS SUSPECTED OF COVID-19 BY A HEALTHCARE PROVIDER, USING SUITABLE VITROS SYSTEMS. ,VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 TOTAL CALIBRATOR-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 TOTAL REAGENT PACK TEST WHEN USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 TOTAL CALIBRATOR IS FOR THE QUALITATIVE MEASUREMENT OF TOTAL ANTIBODY (INCLUDING IGG AND IGM) TO SARS-COV-2 IN HUMAN SERUM AND PLASMA (K2 EDTA) SAMPLES FROM PATIENTS SUSPECTED OF COVID-19 BY A HEALTHCARE PROVIDER, USING SUITABLE VITROS SYSTEMS.
688	IMP/IVD/2020/000439	1.License Holder Name: DIAGNOSTIC BIOSYSTEMS (INDIA) 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ZENA MAX COVID-19 QPCR DETECTION KIT-THIS ASSAY IS AN IN-VITRO PCR TEST FOR THE QUALITATIVE IDENTIFICATION OF CORONA VIRUS 2019 COVID-19 RNA IN HUMAN SAMPLES SUCH AS NASOPHARYNGEAL SWABS OR BRONCHOALVEOLAR LAVAGE (BAL). IT IS BASED ON THE HYDROLYSIS PROBE DETECTION METHOD AND IS A HIGHLY SENSITIVE ONE-STEP RT-QPCR KIT.

689	IMP/IVD/2020/000441	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD BBL COAGULASE PLASMA, RABBIT(BD BBL COAGULASE PLASMA, RABBIT)-BD BBL™ COAGULASE PLASMA, RABBIT ARE USED TO QUALITATIVELY DETERMINE THE PATHOGENICITY OF STAPHYLOCOCCI USING THE DIRECT TUBE METHOD.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP O FACTOR 35(BD DIFCO™ SALMONELLA O ANTISERUM GROUP O FACTOR 35)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD BBL COAGULASE PLASMA, RABBIT WITH EDTA(BD BBL COAGULASE PLASMA, RABBIT WITH EDTA)-BD BBL COAGULASE PLASMA, RABBIT WITH EDTA ARE USED TO QUALITATIVELY DETERMINE THE PATHOGENICITY OF STAPHYLOCOCCI USING THE DIRECT TUBE METHOD.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP B FACTORS 1,4,12,27(BD DIFCO™ SALMONELLA O ANTISERUM GROUP B FACTORS 1,4,12,27)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ LISTERIA O ANTISERUM POLY SEROTYPES 1, 4(BD DIFCO™ LISTERIA O ANTISERUM POLY SEROTYPES 1, 4)-BD DIFCO™ LISTERIA O ANTISERA TYPES 1, 4 AND POLY ARE USED FOR IDENTIFYING LISTERIA MONOCYTOGENES IN THE SLIDE AGGLUTINATION TEST. BD DIFCO LISTERIA O ANTIGENS TYPES 1 AND 4 (SLIDE) ARE USED AS POSITIVE CONTROLS IN THE SLIDE AGGLUTINATION TEST,BD DIFCO™ SHIGELLA ANTISERUM POLY GROUP A (BD DIFCO™ SHIGELLA ANTISERUM POLY GROUP A)-BD DIFCO™ SHIGELLA ANTISERA POLY ARE USED FOR THE IDENTIFICATION OF SHIGELLA SPECIES BY THE SLIDE AGGLUTINATION TEST.,BD DIFCO™ BORDETELLA PERTUSSIS ANTISERUM(BD DIFCO™ BORDETELLA PERTUSSIS ANTISERUM)-BD DIFCO™ BORDETELLA PERTUSSIS ANTISERUM AND BD DIFCO BORDETELLA PARAPERTUSSIS ANTISERUM ARE RECOMMENDED FOR USE IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF BORDETELLA PERTUSSIS AND BORDETELLA PARAPERTUSSIS. BD DIFCO BORDETELLA PERTUSSIS ANTIGEN IS USED TO DEMONSTRATE A POSITIVE QUALITY CONTROL TEST IN THE SLIDE AGGLUTINATION TEST.,BD DIFCO™ VIBRIO CHOLERA ANTISERUM OGAWA(BD DIFCO™ VIBRIO CHOLERA ANTISERUM OGAWA)-BD DIFCO™ VIBRIO CHOLERAE ANTISERA ARE RECOMMENDED FOR USE IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION AND SEROTYPING OF VIBRIO CHOLERAE,BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 27(BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 27)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE

	AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 2 (BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 2)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SHIGELLA ANTISERUM POLY GROUP A1(BD DIFCO™ SHIGELLA ANTISERUM POLY GROUP A1)-BD DIFCO™ SHIGELLA ANTISERA POLY ARE USED FOR THE IDENTIFICATION OF SHIGELLA SPECIES BY THE SLIDE AGGLUTINATION TEST.,BD DIFCO™ SALMONELLA H ANTISERUM 1 COMPLEX(BD DIFCO™ SALMONELLA H ANTISERUM 1 COMPLEX)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 23(BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 23)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA H ANTISERUM SINGLE FACTOR 2(BD DIFCO™ SALMONELLA H ANTISERUM SINGLE FACTOR 2)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP E4 FACTORS 1, 3, 19(BD DIFCO™ SALMONELLA O ANTISERUM GROUP E4 FACTORS 1, 3, 19)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 9(BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 9)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP E3 FACTORS 3,15, 34(BD DIFCO™ SALMONELLA O ANTISERUM GROUP E3 FACTORS 3,15, 34)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA H ANTISERUM D(BD DIFCO™ SALMONELLA H ANTISERUM D)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ E. COLI O ANTISERUM 0157 (BD DIFCO™ E. COLI O ANTISERUM 0157)-BD DIFCO™ E. COLI O ANTISERUM O157 AND BD DIFCO E. COLI H ANTISERUM H7 ARE USED IN TUBE AGGLUTINATION TESTS FOR IDENTIFYING ESCHERICHIA COLI O157:H7.,BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 7(BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 7)-BD DIFCO™

	SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA H ANTISERUM G COMPLEX(BD DIFCO™ SALMONELLA H ANTISERUM G COMPLEX)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS,BD DIFCO™ SALMONELLA O ANTISERUM POLY B(BD DIFCO™ SALMONELLA O ANTISERUM POLY B)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA H ANTISERUM POLY A(BD DIFCO™ SALMONELLA H ANTISERUM POLY A)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP C3 FACTORS (8), 20(BD DIFCO™ SALMONELLA O ANTISERUM GROUP C3 FACTORS (8), 20)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 8(BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 8)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP F FACTOR 11(BD DIFCO™ SALMONELLA O ANTISERUM GROUP F FACTOR 11)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM POLY A (BD DIFCO™ SALMONELLA O ANTISERUM POLY A)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS,BD DIFCO™ VIBRIO CHOLERA ANTISERUM POLY, HIKOJIMA, INABA, OGAWA(BD DIFCO™ VIBRIO CHOLERA ANTISERUM POLY, HIKOJIMA, INABA, OGAWA)-BD DIFCO™ VIBRIO CHOLERAE ANTISERA ARE RECOMMENDED FOR USE IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION AND SEROTYPING OF VIBRIO CHOLERAE.,BD DIFCO™ SHIGELLA ANTISERUM POLY GROUP B(BD DIFCO™ SHIGELLA ANTISERUM POLY GROUP B)-BD DIFCO™ SHIGELLA ANTISERA POLY ARE USED FOR THE IDENTIFICATION OF SHIGELLA SPECIES BY THE SLIDE AGGLUTINATION TEST.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP I FACTOR 16(BD DIFCO™ SALMONELLA O ANTISERUM GROUP I FACTOR 16)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD

	DIFCO™ SALMONELLA H ANTISERUM POLY C(BD DIFCO™ SALMONELLA H ANTISERUM POLY C)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP C2 FACTORS 6, 8(BD DIFCO™ SALMONELLA O ANTISERUM GROUP C2 FACTORS 6, 8)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP E FACTORS 1/3/10/15/19/34(BD DIFCO™ SALMONELLA O ANTISERUM GROUP E FACTORS 1/3/10/15/19/34)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ ALKALESCENS-DISPAR ANTISERUM POLY CONTAINS TYPES 1-4(BD DIFCO™ ALKALESCENS-DISPAR ANTISERUM POLY CONTAINS TYPES 1-4)-BD DIFCO ALKALESCENS-DISPAR ANTISERUM POLY IS USED FOR THE IDENTIFICATION OF ALKALESCENS-DISPAR GROUP OF MICROORGANISMS BY THE SLIDE AGGLUTINATION TEST.,BD DIFCO™ SALMONELLA H ANTISERUM POLY D(BD DIFCO™ SALMONELLA H ANTISERUM POLY D)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP D1 FACTORS 1,9,12(BD DIFCO™ SALMONELLA O ANTISERUM GROUP D1 FACTORS 1,9,12)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP E1 FACTOR 3,10(BD DIFCO™ SALMONELLA O ANTISERUM GROUP E1 FACTOR 3,10)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA H ANTISERUM B(BD DIFCO™ SALMONELLA H ANTISERUM B)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ E. COLI H ANTISERUM H7(BD DIFCO™ E. COLI H ANTISERUM H7)-BD DIFCO™ E. COLI O ANTISERUM O157 AND BD DIFCO E. COLI H ANTISERUM H7 ARE USED IN TUBE AGGLUTINATION TESTS FOR IDENTIFYING ESCHERICHIA COLI O157:H7.,BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 4(BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 4)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA H ANTISERUM SINGLE FACTOR 5(BD DIFCO™ SALMONELLA H ANTISERUM SINGLE

	FACTOR 5)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM POLY G(BD DIFCO™ SALMONELLA O ANTISERUM POLY G)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM POLY A-I & VI(BD DIFCO™ SALMONELLA O ANTISERUM POLY A-I & VI) -BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA H ANTISERUM SINGLE FACTOR M(BD DIFCO™ SALMONELLA H ANTISERUM SINGLE FACTOR M)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP D2 FACTORS (9), 46(BD DIFCO™ SALMONELLA O ANTISERUM GROUP D2 FACTORS (9), 46)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERUM GROUP W135(BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERUM GROUP W135)-BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERA ARE RECOMMENDED FOR USE IN SLIDE AGGLUTINATION TESTS FOR SEROTYPING NEISSERIA MENINGITIDIS,BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERUM POLY CONTAINS GROUP A,B,C,D(BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERUM POLY CONTAINS GROUP A,B,C,D)-BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERA ARE RECOMMENDED FOR USE IN SLIDE AGGLUTINATION TESTS FOR SEROTYPING NEISSERIA MENINGITIDIS.,BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERUM GROUP X(BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERUM GROUP X)-BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERA ARE RECOMMENDED FOR USE IN SLIDE AGGLUTINATION TESTS FOR SEROTYPING NEISSERIA MENINGITIDIS.,BD DIFCO™ VIBRIO CHOLERA ANTISERUM INABA(BD DIFCO™ VIBRIO CHOLERA ANTISERUM INABA)-BD DIFCO™ VIBRIO CHOLERAE ANTISERA ARE RECOMMENDED FOR USE IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION AND SEROTYPING OF VIBRIO CHOLERAE.,BD DIFCO™ SALMONELLA O ANTISERUM POLY C(BD DIFCO™ SALMONELLA O ANTISERUM POLY C)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA H ANTISERUM K(BD DIFCO™ SALMONELLA H ANTISERUM K)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA

	BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ SALMONELLA H ANTISERUM Z(BD DIFCO™ SALMONELLA H ANTISERUM Z)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ SALMONELLA H ANTISERUM A(BD DIFCO™ SALMONELLA H ANTISERUM A)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERUM GROUP Y(BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERUM GROUP Y)-BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERA ARE RECOMMENDED FOR USE IN SLIDE AGGLUTINATION TESTS FOR SEROTYPING NEISSERIA MENINGITIDIS,BD DIFCO™ SHIGELLA ANTISERUM POLY GROUP C1(BD DIFCO™ SHIGELLA ANTISERUM POLY GROUP C1)-BD DIFCO™ SHIGELLA ANTISERA POLY ARE USED FOR THE IDENTIFICATION OF SHIGELLA SPECIES BY THE SLIDE AGGLUTINATION TEST.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP M FACTOR 28(BD DIFCO™ SALMONELLA O ANTISERUM GROUP M FACTOR 28)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SHIGELLA ANTISERUM POLY GROUP D(BD DIFCO™ SHIGELLA ANTISERUM POLY GROUP D)-BD DIFCO™ SHIGELLA ANTISERA POLY ARE USED FOR THE IDENTIFICATION OF SHIGELLA SPECIES BY THE SLIDE AGGLUTINATION TEST.,BD DIFCO™ SALMONELLA H ANTISERUM SINGLE FACTOR 6(BD DIFCO™ SALMONELLA H ANTISERUM SINGLE FACTOR 6)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP G FACTORS 13, 22, 23, 36, 37(BD DIFCO™ SALMONELLA O ANTISERUM GROUP G FACTORS 13, 22, 23, 36, 37)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS,BD DIFCO™ SHIGELLA ANTISERUM POLY GROUP C (BD DIFCO™ SHIGELLA ANTISERUM POLY GROUP C)-BD DIFCO™ SHIGELLA ANTISERA POLY ARE USED FOR THE IDENTIFICATION OF SHIGELLA SPECIES BY THE SLIDE AGGLUTINATION TEST.,BD DIFCO™ SALMONELLA H ANTISERUM POLY A-Z(BD DIFCO™ SALMONELLA H ANTISERUM POLY A-Z)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ SHIGELLA ANTISERUM POLY GROUP C2(BD DIFCO™ SHIGELLA ANTISERUM POLY GROUP C2) -BD DIFCO™ SHIGELLA ANTISERA POLY ARE USED FOR THE IDENTIFICATION OF SHIGELLA SPECIES BY THE SLIDE

	AGGLUTINATION TEST.,BD DIFCO™ SALMONELLA H ANTISERUM C(BD DIFCO™ SALMONELLA H ANTISERUM C)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERUM GROUP A(BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERUM GROUP A)-BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERA ARE RECOMMENDED FOR USE IN SLIDE AGGLUTINATION TESTS FOR SEROTYPING NEISSERIA MENINGITIDIS,BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 12(BD DIFCO™ SALMONELLA O ANTISERUM FACTOR 12)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERUM GROUP C(BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERUM GROUP C)-BD DIFCO™ NEISSERIA MENINGITIDIS ANTISERA ARE RECOMMENDED FOR USE IN SLIDE AGGLUTINATION TESTS FOR SEROTYPING NEISSERIA MENINGITIDIS,BD DIFCO™ SALMONELLA H ANTISERUM I (BD DIFCO™ SALMONELLA H ANTISERUM I)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM GROUP A FACTORS 1,2,12(BD DIFCO™ SALMONELLA O ANTISERUM GROUP A FACTORS 1,2,12)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA H ANTISERUM EH(BD DIFCO™ SALMONELLA H ANTISERUM EH)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.,BD DIFCO™ SALMONELLA O ANTISERUM POLY D(BD DIFCO™ SALMONELLA O ANTISERUM POLY D)-BD DIFCO™ SALMONELLA O ANTISERA ARE USED IN SLIDE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY SOMATIC (O) ANTIGENS.,BD DIFCO™ SALMONELLA H ANTISERUM POLY B(BD DIFCO™ SALMONELLA H ANTISERUM POLY B)-BD DIFCO SALMONELLA H ANTISERA ARE USED IN TUBE AGGLUTINATION TESTS FOR THE IDENTIFICATION OF SALMONELLA BY FLAGELLAR (H) ANTIGENS.

690	IMP/IVD/2020/000442	1.License Holder Name: KOPRAN LABORATORIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:H10-800 URINALYSIS REAGENT STRIPS_WECOMPRESS(DIRUI)-FOR THE DETERMINATION OF KIDNEY FAILURE, DIABETES OR RELATED KIDNEY DAMAGE,ALT ALANINE AMINOTRANSFERASE(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF ALT ACTIVITY IN HUMAN SERUM ,ISE REFERENCE SOLUTION(DIRUI)-"THIS PRODUCT IS USED TO DETERMINE THE ELECTRIC POTENTIAL OF A REFERENCE ELECTRODE",IGG IMMUNOGLOBULIN G(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT CONTENT OF IGG OF HUMAN SERUM.,ISE BLOOD SAMPLE CALIBRATOR(DIRUI)-"THIS PRODUCT IS APPLICABLE TO THE ION-SELECTIVE ELECTRODE MODULE OF CS SERIES AUTO CHEMISTRY ANALYZER FOR MEASURING ELECTROLYTE",GLU-HK GLUCOSE HEXO KINASE(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF THE GLUCOSE CONCENTRATION CONTAINED IN HUMAN SERUM, PLASMA OR URINE.,H SERIES URINE ANALYZER CONTROL LIQUID FOR TURBIDITY(DIRUI)-"FOR MONITORING ACCURACY OF TURBIDITY DURING ANALYSIS",D-BILL DIRECT BILIRUBIN(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF D-BILIRUBIN CONCENTRATION OF HUMAN SERUM OR PLASMA,CS-ACIDIC DETERGENT(DIRUI)-"FOR CLEANING REAGENT PROBE AND REACTION CUVETTE OF CS SERIES AUTO-CHEMISTRY ANALYZER",CA-ARS CALCIUM ARSENAZO(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CALCIUM CONCENTRATION OF SERUM, PLASMA OR URINE.,8 ITEMS URINALYSIS REAGENT STRIPS(DIRUI)-FOR THE DETERMINATION OF KIDNEY FAILURE, DIABETES OR RELATED KIDNEY DAMAGE,PHOS PHOSPHORUS(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF PHOSPHORUS CONCENTRATION IN HUMAN SERUM OR PLASMA,BF DETERGENT(DIRUI)-"IT IS USED TO REMOVE LYSE, CELL RESIDUE AND PROTEIN IN THE ANALYZER",AST ASPARTATE AMINOTRANSFERASE (DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF ASPARTATE AMINOTRANSFERASE IN HUMAN SERUM,CS-ANTI-BACTERIAL PHOSPHOR-FREE DETERGENT(DIRUI)-"FOR CLEANING REAGENT PROBE, INCUBATION BATH AND REACTION CUVETTE OF CS SERIES AUTO-CHEMISTRY ANALYZER",FMN FRUCTOSAMINE(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF FRUCTOSAMINE CONCENTRATION IN HUMAN SERUM.,ISE DILUENT (DIRUI)-FOR THE DILUTING SAMPLE,GLDH GLUTAMATE DEHYDROGENASE(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF GLUTAMATE DEHYDROGENASE ACTIVITY OF HUMAN SERUM,ISE INTERNAL STANDARD SOLUTION(DIRUI)-"THE PRODUCT APPLIES TO ISE PART OF CS SERIAL AUTO CHEMISTRY ANALYZER",RF RHEUMATOID FACTOR(DIRUI)-IN VITRO QUANTITATIVE

	DETERMINATION OF RHEUMATOID FACTOR CONTENT IN HUMAN SERUM.,H12-800MA(DIRUI)-FOR THE DETERMINATION OF KIDNEY FAILURE, DIABETES OR RELATED KIDNEY DAMAGE,ALB ALBUMIN (DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF ALBUMIN OF CONCENTRATION SERUM OR PLASMA,BF-FDT LYSE(DIRUI)-"FOR THE DISSOLUTION OF RED BLOOD CELL, DYE OF CELL, CONTENT DETECTION OF LYMPHOCYTE, MONOCYTE, EOSINOPHIL AND NEUTROPHIL",BUN BLOOD UREA NITROGEN(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF UREA CONCENTRATION OF HUMAN SERUM, PLASMA, OR URINE.,ISE BLOOD QUALITY CONTROL (HIGH AND LOW)(DIRUI)-"THIS PRODUCT IS APPLICABLE TO THE ION-SELECTIVE ELECTRODE MODULE OF CS SERIES AUTO CHEMISTRY ANALYZER FOR MEASURING ELECTROLYTE",ADA ADENOSINE DEAMINASE ACTIVITY(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF ADENOSINE DEAMINASE ACTIVITY IN HUMAN SERUM OR PLASMA ,H SERIES URINE ANALYZER CALIBRATION LIQUID FOR SPECIFIC GRAVITY(DIRUI)-"FOR CALIBRATION OF SPECIFIC GRAVITY DURING ANALYSIS",HBDH -ALPHA HYDROXYBUTYRATE DEHYDROGENASE(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF THE ACTIVITY OF -HYDROXYBUTYRATE DEHYDROGENASE-HBDHIN SERUM OR PLASMA,H14 CA URINALYSIS REAGENT STRIPS(DIRUI)-FOR THE DETERMINATION OF KIDNEY FAILURE, DIABETES OR RELATED KIDNEY DAMAGE,MALB MICROALBUMIN(DIRUI)-QUANTITATIVE MEASUREMENT OF MICROALBUMIN CONTENT IN HUMAN URINE.,ISE STANDARD SOLUTION(DIRUI)-"THIS PRODUCT IS APPLICABLE TO THE ION-SELECTIVE ELECTRODE MODULE OF CS SERIES AUTO CHEMISTRY ANALYZER FOR MEASURING ELECTROLYTE",CK CREATININE KINASE(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF CREATININE KINASE (CK) OF HUMAN SERUM OR PLASMA.,H13-CR (DIRUI)-FOR THE DETERMINATION OF KIDNEY FAILURE, DIABETES OR RELATED KIDNEY DAMAGE,FER FERRITIN(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF FERRITIN IN HUMAN SERUM,CS-ISE DETERGENT(DIRUI)-CLEANING OF ANALYSER SYSTEM,CK- MB CREATINIE KINASE ISOENZYME(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF ACTIVITY OF CK-MB ISOENZYME IN HUMAN SERUM .,5 ITEMS URINALYSIS REAGENT STRIPS(DIRUI)-FLOW TO CONDUCT URINE PHYSICAL COMPONENT COUNTING,TC CHOLESTEROL(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OFTOTAL CHOLESTEROL IN HUMAN SERUM,H SERIES URINE ANALYZER CALIBRATION LIQUID FOR TURBIDITY (DIRUI)-FOR CALIBRATION OF TURBIDITY DURING ANALYSIS,LDH LACTATE DEHYDROGENASE(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF THE ACTIVITY OF LDH IN HUMAN SERUM OR

	PLASMA.,CLINICAL CHEMICAL QUALITY CONTROL SERUM(DIRUI)-"QUALITY CONTROL SERUM IS USED FOR THE DETERMINATION OF ACCURACY OR REPEATABILITY OF CLINICAL CHEMICAL ITEMS.",HDL-C HIGH DENSITY LIPOPROTEIN(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF HIGH DENSITY LIPOPROTEIN-CHOLESTEROL (HDL-C) CONCENTRATION OF HUMAN SERUM,SHEATH(DIRUI)-USED TO WRAP THE SAMPLE TO FORM A SHEATH,IGM IMMUNOGLOBULIN M (DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT CONTENT OF IGM OF HUMAN SERUM.,KIT FOR URINE SEDIMENT ANALYSER(DIRUI)-FOR SEDIMENT ANALYSIS IN URINE,ASO ANTI-STREPTOLYSIN O(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF ANTI-STREPTOLYSIN O IN HUMAN SERUM OR PLASMA.,BF DILUENT(DIRUI)-FOR DILUTING SAMPLE,MG- XB MAGNESIUM(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF MAGNESIUM CONCENTRATION IN HUMAN SERUM OR PLASMA,URINE SEDIMENT ANALYZER DETERGENT(DIRUI)-"FOR CLEANING PIPE LINES AND FLOW CELL DURING ANALYSIS", GLU-OX GLUCOSE(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF THE GLUCOSE CONCENTRATION CONTAINED IN HUMAN SERUM, PLASMA OR URINE.,CLINICAL CHEMICAL CALIBRATION SERUM(DIRUI) -"CALIBRATION SERUM IS USED FOR THE DETERMINATION OF ACCURACY OR REPEATABILITY OF CLINICAL CHEMICAL ITEMS.",LDL-C LOW DENSITY LIPOPROTEIN(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF LOW DENSITY LIPOPROTEIN-CHOLESTEROL (LDL-C) CONCENTRATION OF HUMAN SERUM,H 10 URINALYSIS STRIPS(DIRUI)-FOR THE DETERMINATION OF KIDNEY FAILURE, DIABETES OR RELATED KIDNEY DAMAGE,TP TOTAL PROTEIN(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF TOTAL PROTEIN CONTENT OF HUMAN SERUM OR PLASMA,H11-800(DIRUI)-FOR THE DETERMINATION OF KIDNEY FAILURE, DIABETES OR RELATED KIDNEY DAMAGE,ZN ZINC(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF ZINC IN HUMAN SERUM, CLEANING LIQUID(DIRUI)-"FOR CLEANING PIPE LINES AND FLOW CELL DURING ANALYSIS",GGT GAMMA GLUTAMYL TRANSFERASE (DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF THE ACTIVITY OF GGT IN HUMAN SERUM AND PLASMA.,URINALYSIS CONTROL NEGATIVE(DIRUI)-"URINALYSIS CONTROL IS USED FOR QUALITY CONTROL URINALYSIS STRIP AND ANALYZER",ALP ALKALINE PHOSPHATASE(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF THE ACTIVITY OF ALP IN HUMAN SERUM OR PLASMA,BF-6500 LYSE _SLS-I_(DIRUI)-"FOR RED BLOOD CELLS DISSOLUTION AND HAEMOGLOBIN RELEASING, CONTENT DETECTION OF HAEMOGLOBIN",C4 COMPLEMENT 4(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF COMPLEMENT 4 REAGENT OF HUMAN SERUM OR PLASMA,BF-FDO LYSE(DIRUI)-"FOR THE DISSOLUTION OF RED

	BLOOD CELL, DYE OF CELL, CONTENT DETECTION OF LYMPHOCYTE, MONOCYTE, EOSINOPHIL AND NEUTROPHIL",P-AMY PANCREATIC AMYLASE(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF PANCREATIC AMYLASE IN HUMAN SERUM, CONTROL FOR AUTOMATIC HEMATOLOGY ANALYZER _5-PART_ (DIRUI)-"IT IS USED FOR MONITORING OR EVALUATION TEST RESULT ACCURACY OF 5-PART HEMATOLOGY ANALYZER",APO B APOLIPOPROTEIN B(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF APOLIPOPROTEIN B (APO B) CONTENT IN HUMAN SERUM, URINALYSIS CONTROL POSITIVE(DIRUI)-"URINALYSIS CONTROL IS USED FOR QUALITY CONTROL URINALYSIS STRIP AND ANALYZER", APO A1 APOLIPOPROTEIN A1(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF APOLIPOPROTEIN A1APO A1CONTENT IN HUMAN SERUM,CS-ALKALINE DETERGENT(DIRUI)-"FOR CLEANING REAGENT PROBE AND REACTION CUVETTE OF CS SERIES AUTO-CHEMISTRY ANALYZER",PA PREALBUMIN(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF PREALBUMIN CONTENT OF HUMAN SERUM OR PLASMA.,H SERIES URINE ANALYZER CONTROL LIQUID FOR SPECIFIC GRAVITY(DIRUI)-"FOR LEVEL 3 QC DETERMINATION OF SG DURING ANALYSIS",LP (A) LIPOPROTEIN (A)(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF LIPOPROTEIN (A) CONTENT IN HUMAN SERUM , CLEANING LIQUID FOR REFRACTOMETER AND TURBIDIMETER(DIRUI)-CLEANING OF ANALYSER SYSTEM,T - BILL TOTAL BILIRUBIN(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF TOTAL BILIRUBIN IN HUMAN SERUM,DILUENT(DIRUI)-FOR DILUTING SAMPLE,HBA1C GLYCOHEMOGLOBIN A1C(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF GLYCOHEMOGLOBIN CONTENT IN HUMAN BLOOD.,H SERIES URINE ANALYZER COLOR CONTROL(DIRUI) -"FOR COLOR CONTROL DETERMINATION DURING ANALYSIS",CYC- C CYSTATIN C(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF CYSTATIN C CONTENT IN HUMAN SERUM OR PLASMA.,TRF TANSFERRIN(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF TRANSFERRIN IN HUMAN SERUM ,TBV TOTAL BILIRUBIN(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF TOTAL BILIRUBIN IN HUMAN SERUM,IGA IMMUNOGLOBULIN A(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT CONCENTRATION OF IGA OF HUMAN SERUM,UA URIC ACID(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF URIC ACID IN HUMAN SERUM,CRE- ENZYME CREATININE(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF CREATININE CONCENTRATION OF HUMAN SERUM, PLASMA OR URINE,TG TRIGLYCERIDE(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF TRIGLYCERIDES CONCENTRATION OF HUMAN SERUM OR PLASMA.,CO2 CARBON DIOXIDE(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF CARBON

	DIOXIDE CONTENT IN HUMAN SERUM OR PLASMA,MB MYOGLOBIN (DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF MYOGLOBIN IN HUMAN SERUM,LPS LIPASE (DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF LIPASE IN HUMAN SERUM,DBV DIRECT BILIRUBIN(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF DIRECT BILIRUBIN IN HUMAN SERUM,CA-CPC CALCIUM(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CALCIUM CONCENTRATION OF SERUM, PLASMA OR URINE,AMY AMYLASE(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF - AMYLASE ACTIVITY OF HUMAN SERUM OR URINE.,ALPHA 1 - MG 1 MICROGLOBULIN(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF 2-MICROGLOBULIN IN HUMAN SERUM,C3 COMPLEMENT 3(DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF COMPLEMENT 3 REAGENT OF HUMAN SERUM OR PLASMA, CHOLINESTERASE(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF CHOLINESTERASE IN HUMAN SERUM,FE FERRUS(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF FERRUS IN HUMAN SERUM,TIBC TOTAL IRON BINDING CAPACITY(DIRUI)-IN VITRO QUANTITATIVE DETERMINATION OF CONCENTRATION OF TIBC IN HUMAN SERUM,HCY HOMOCYSTEINE (DIRUI)-IN VITRO QUANTITATIVE MEASUREMENT OF HOMOCYSTEINE CONTENT IN HUMAN SERUM OR PLASMA

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691	IMP/IVD/2020/000443	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABBOTT MULTI COLLECT SPECIMEN COLLECTION KIT(ABBOTT MULTI COLLECT SPECIMEN COLLECTION KIT)-THE ABBOTT MULTI-COLLECT SPECIMEN COLLECTION KIT IS INTENDED FOR THE COLLECTION AND TRANSPORTATION OF URINE SPECIMENS, AND OF ENDOCERVICAL, MALE URETHRAL, AND VAGINAL SWAB SPECIMENS FOR THE DETECTION OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE.,ALINITY M SPECIMEN DILUTION KIT I(ALINITY M SPECIMEN DILUTION KIT I)-THE ALINITY M SPECIMEN DILUTION KIT I IS INTENDED TO ALLOW DILUTION OF SPECIMENS FOR TESTING ON THE AUTOMATED ALINITY M SYSTEM FOR MEASUREMENT OF NUCLEIC ACID,ABBOTT CERVI-COLLECT SPECIMEN COLLECTION KIT (ABBOTT CERVI-COLLECT SPECIMEN COLLECTION KIT)-THE ABBOTT CERVI-COLLECT SPECIMEN COLLECTION KIT IS INTENDED FOR THE COLLECTION AND TRANSPORTATION OF CERVICAL SPECIMENS FOR THE DETECTION OF HUMAN PAPILLOMAVIRUS (HPV) PER THE INSTRUCTIONS PROVIDED.,ALINITY M CERVI-COLLECT SPECIMEN COLLECTION KIT(ALINITY M CERVI-COLLECT SPECIMEN COLLECTION KIT)-ALINITY M CERVI-COLLECT SPECIMEN COLLECTION KIT IS INTENDED FOR THE COLLECTION AND TRANSPORTATION OF CERVICAL SPECIMENS FOR THE DETECTION OF HUMAN PAPILLOMAVIRUS (HPV). THE COLLECTED SPECIMENS ARE INTENDED TO BE TESTED ON THE AUTOMATED ALINITY M SYSTEM.,ABBOTT MULTI COLLECT SPECIMEN COLLECTION KIT (P/CAP)(ABBOTT MULTI COLLECT SPECIMEN COLLECTION KIT (P/CAP))-THE ABBOTT MULTI-COLLECT SPECIMEN COLLECTION KIT (LIST NO. 9K12-02) IS INTENDED FOR THE COLLECTION AND TRANSPORTATION OF URINE SPECIMENS, AND OF ENDOCERVICAL, MALE URETHRAL, AND VAGINAL SWAB SPECIMENS FOR THE DETECTION OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE.,ALINITY M MULTI-COLLECT SPECIMEN COLLECTION KIT(ALINITY M MULTI-COLLECT SPECIMEN COLLECTION KIT)-THE ALINITY M MULTI-COLLECT SPECIMEN COLLECTION KIT IS INTENDED FOR THE COLLECTION AND TRANSPORTATION OF MALE AND FEMALE URINE SPECIMENS, ENDOCERVICAL SWAB SPECIMENS, AND VAGINAL SWAB SPECIMENS TO STABILIZE NUCLEIC ACID FROM THESE SPECIMENS. THE COLLECTED SPECIMENS ARE INTENDED TO BE TESTED ON THE AUTOMATED ALINITY M SYSTEM.

692	IMP/IVD/2020/000444	1.License Holder Name: DIASYS DIAGNOSTIC INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIBODY TEST (COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY)(LEPU)-THE PRODUCT IS INTENDED FOR THE QUALITATIVE DETECTION OF ANTIBODY CONTENT AGAINST SARS-COV-2 IN CLINICAL SAMPLES (SERUM/PLASMA/WHOLE BLOOD).
693	IMP/IVD/2020/000449	1.License Holder Name: WOCKHARDT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE MONITORING SYSTEM(SUGARCHEK ADVANCE (URIGHT TD-4279))-TO DETERMINE THE CONCENTRATION OF GLUCOSE IN BLOOD,BLOOD GLUCOSE TEST STRIPS(SUGARCHEK ADVANCE (U RIGHT TD-4279))-USED FOR QUANTITATIVE MEASUREMENT OF GLUCOSE IN HUMAN WHOLE BLOOD.,BLOOD GLUCOSE MONITORING SYSTEM(SUGARCHEK (ACHTUNG TD-4207))-TO DETERMINE THE CONCENTRATION OF GLUCOSE IN BLOOD,BLOOD GLUCOSE TEST STRIPS(SUGARCHEK (ACHTUNG TD-4207))-USED FOR QUANTITATIVE MEASUREMENT OF GLUCOSE IN HUMAN WHOLE BLOOD.
694	IMP/IVD/2020/000450	1.License Holder Name: INDIAN ORTHOCARE SURGICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM (VTM) KIT(MOLE BIOSCIENCE)-THIS KIT IS USED FOR SAMPLE COLLECTION, TRANSMISSION AND PRESERVATION.
695	IMP/IVD/2020/000451	1.License Holder Name: JETTALABS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CORONA VIRUS IGG/IGM TEST CASSETTE (OZO)-THIS PRODUCT IS USED FOR IN VITRO QUALITATIVE DETECTION OF CORONA VIRUS (SARSCOV-2) IGM/IGG ANTIBODY IN THE HUMAN SERUM, PLASMA AND WHOLE BLOOD SAMPLES.

696	IMP/IVD/2020/000452	1.License Holder Name: PROSPER CHANNEL LIFESCIENCE INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONA VIRUS (2019-NCOV)RT-PCR DETECTION KIT(FOSUN 2019-NCOV QPCR)-THIS PRODUCT IS INTENDED FOR THE RAPID DETECTION OF 2019-NCOV IN HUMAN THROAT SWAB OR SPUTUM SAMPLES.CORONAVIRUS IS A +SSRNA VIRUS WITH ENVELOPE. ITS DIAMETER IS ABOUT 80-120 NM. THIS KIT IS INTENDED FOR THE DETECTION OF 2019-NCOV AND IS HELPFUL FOR CLINICAL DIAGNOSIS OF 2019-NCOV INFECTION.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

697	IMP/IVD/2020/000453	1.License Holder Name: KIN DIAGNOSTICS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RF KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN RF,C3 KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN C3,C4 KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN C4,C1IN KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN C1IN,LAM KIT (NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN LAM,MALB KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN MALB, BMG KIT-QUANTITATIVE DETERMINATION OF HUMAN BMG,KAP KIT (NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN KAP,AMG KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN AMG , CYS C KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN CYS C ,D-DIMER KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN D-DIAMR ,APO A1 KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN APO A1,AAG KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN AAG ,BCRP KIT (NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN BCRP ,CER KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN CER , HBA1C KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN HBA1C ,IGM KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN IGM ,USCRP KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN USCRP ,PAB KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN PAB ,RBP KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN RBP ,ALB KIT (NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN ALB ,APO B KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN APO B , IGG KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN IGG , ASO KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN ASO ,HPT KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN HPT ,1 MICROGLOBULIN KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN 1 MICROGLOBULIN ,TRF KIT (NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN TRF ,SAA KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN SAA , IGA KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN IGA, LIPOPROTEIN(A) KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN LIPOPROTEIN(A) ,AT3 KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN AT3 ,CRP KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN CRP ,AAT KIT (NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN AAT

698	IMP/IVD/2020/000454	1.License Holder Name: THERMO FISHER SCIENTIFIC INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: LABTYPE™ SSO CLASS I B LOCUS TYPING TEST(LABTYPE)-DNA TYPING OF HLA CLASS I OR CLASS II ALLELES,LABTYPE™ XR CLASS I B LOCUS TYPING TEST (LABTYPE)-FOR USE TO DETERMINE HLA A, B, C AND DRB1 LOCUS TYPING TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR RECIPIENT MATCHING.,LABSCREEN™ SINGLE ANTIGEN HLA CLASS I SUPPLEMENT - GROUP 1(LABSCREEN)-LABSCREEN PRODUCTS ARE INTENDED FOR USE IN DETECTION OF HLA ANTIBODY USING FLOW CYTOMETRIC TECHNOLOGY,CLASS I COMPLEMENT (NIL)- FOR USE IN COMPLEMENT DEPENDENT CYTOTOXIC ASSAYS FOR DETERMINING HLA CLASS I CELL SURFACE ANTIGENS.,MICRO SSP™ HLA CLASS I DNA TYPING TRAY - AB(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,MICRO SSP™ AMBISTRIPS™ HLA CLASS I - B27+ B73(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,LABTYPE™ CWD CLASS I A LOCUS TYPING TEST(LABTYPE)-FOR USE TO DETERMINE HLA A, B, C AND DRB1 LOCUS TYPING TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR RECIPIENT MATCHING.,FLOWPRA™ SPECIFIC HLA CLASS II ANTIBODY DETECTION TEST(FLOWPRA)-THE FLOWPRA® SPECIFIC TESTS ARE INTENDED FOR USE IN FLOW CYTOMETRIC DETECTION OF HLA ANTIBODIES AND THEIR SPECIFICITIES.,TERASAKI HLA-ABC FIRST TISSUE TYPING TRAY(TERASAKI)-FOR USE IN DETERMINING HLA CELL SURFACE ANTIGENS WITH A COMPLEMENT DEPENDENT MICROLYMPHOCYTOTOXIC TEST,LYOPHILIZED CLASS I COMPLEMENT (NIL)- FOR USE IN COMPLEMENT DEPENDENT CYTOTOXIC ASSAYS FOR DETERMINING HLA CLASS I CELL SURFACE ANTIGENS.,MICRO SSP™ HLA CLASS I A LOCUS SPECIFIC DNA TYPING TRAY(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,LABSCREEN™ MIXED CLASS I & II(LABSCREEN)-LABSCREEN PRODUCTS ARE INTENDED FOR USE IN DETECTION OF HLA ANTIBODY USING FLOW CYTOMETRIC TECHNOLOGY,LABTYPE™ SSO MICA (LABTYPE)-DNA TYPING OF HLA CLASS I OR CLASS II ALLELES, LABTYPE™ XR CLASS I C LOCUS TYPING TEST(LABTYPE)-FOR USE TO DETERMINE HLA A, B, C AND DRB1 LOCUS TYPING TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR RECIPIENT MATCHING.,MICRO SSP™ AMBISTRIPS™ HLA CLASS II -DRB50110N (MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES., FLOWPRA™ SPECIFIC HLA CLASS I ANTIBODY DETECTION TEST (FLOWPRA)-THE FLOWPRA® SPECIFIC TESTS ARE INTENDED FOR USE IN FLOW CYTOMETRIC DETECTION OF HLA ANTIBODIES AND THEIR SPECIFICITIES.,MICRO SSP™ GENERIC HLA CLASS II DNA TYPING TRAY - DQB1 ONLY(MICRO SSP)-DNA TYPING OF CLASS I OR

	CLASS II HLA ALLELES.,MICRO SSP™ ALLELE SPECIFIC HLA CLASS I DNA TYPING TRAY - B*57(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,TERASAKI HLA-ABC THIRD TISSUE TYPING TRAY(TERASAKI)-FOR USE IN DETERMINING HLA CELL SURFACE ANTIGENS WITH A COMPLEMENT DEPENDENT MICROLYMPHOCYTOTOXIC TEST,TERASAKI HLA-ABC SECOND TISSUE TYPING TRAY(TERASAKI)-FOR USE IN DETERMINING HLA CELL SURFACE ANTIGENS WITH A COMPLEMENT DEPENDENT MICROLYMPHOCYTOTOXIC TEST,PE CONJUGATED GOAT ANTI-HUMAN IGG(LABSCREEN)-FOR USE IN THE DETECTION OF HUMAN IGG IN THE LABSCREEN™ AND LABSCREEN™ MULTI ASSAYS.,FLOWPRA™ SINGLE ANTIGEN HLA CLASS I ANTIBODY DETECTION TEST (FLOWPRA)-THE FLOWPRA® SPECIFIC TESTS ARE INTENDED FOR USE IN FLOW CYTOMETRIC DETECTION OF HLA ANTIBODIES AND THEIR SPECIFICITIES.,MICRO SSP™ HLA CLASS I C LOCUS SPECIFIC DNA TYPING TRAY(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,MICRO SSP™ GENERIC HLA CLASS II DRB/DQB1/DPB1 DNA TYPING TRAY(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,LABTYPE™ XR CLASS II DRB1 TYPING TEST(LABTYPE)-FOR USE TO DETERMINE HLA A, B, C AND DRB1 LOCUS TYPING TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR RECIPIENT MATCHING.,LABTYPE™ CWD CLASS I B LOCUS TYPING TEST (LABTYPE)-FOR USE TO DETERMINE HLA A, B, C AND DRB1 LOCUS TYPING TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR RECIPIENT MATCHING.,LABTYPE™ XR CLASS I A LOCUS TYPING TEST (LABTYPE)-FOR USE TO DETERMINE HLA A, B, C AND DRB1 LOCUS TYPING TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR RECIPIENT MATCHING.,MICRO SSP™ GENERIC HLA CLASS I AND II ABDR DNA TYPING TRAY(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,LABTYPE™ CWD CLASS I C LOCUS TYPING TEST(LABTYPE)-FOR USE TO DETERMINE HLA A, B, C AND DRB1 LOCUS TYPING TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR RECIPIENT MATCHING.,MICRO SSP™ AMBISTRIPS™ HLA CLASS II -DRB40103N(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,PE-CONJUGATED STREPTAVIDIN(LABTYPE)-FOR USE IN DETECTION OF BIOTINYLATED PROTEINS AND NUCLEIC ACIDS IN LAB TYPE SSO TYPING TESTS AND LAB TYPE XR AND CWD DNA TYPING TEST ASSAY,LABSCREEN™ SINGLE ANTIGEN HLA CLASS II SUPPLEMENT - GROUP 1(LABSCREEN)-LABSCREEN PRODUCTS ARE INTENDED FOR USE IN DETECTION OF HLA ANTIBODY USING FLOW CYTOMETRIC TECHNOLOGY,MICRO SSP™ GENERIC HLA CLASS I AND II DNA TYPING TRAY - ABDRDQ(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,LABSCREEN™ PRA CLASS II(LABSCREEN)-LABSCREEN PRODUCTS ARE INTENDED FOR USE IN DETECTION OF

	HLA ANTIBODY USING FLOW CYTOMETRIC TECHNOLOGY, LABSCREEN™ MICA SINGLE ANTIGEN - GROUP 1(LABSCREEN)-LABSCREEN PRODUCTS ARE INTENDED FOR USE IN DETECTION OF HLA ANTIBODY USING FLOW CYTOMETRIC TECHNOLOGY,MICRO SSP™ GENERIC HLA CLASS I DNA TYPING TRAY(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,FLOWPRA™ CLASS I & II NEGATIVE CONTROL(FLOWPRA)-THE FLOWPRA® SCREENING TEST IS INTENDED FOR USE IN FLOW CYTOMETRIC DETECTION OF HLA-SPECIFIC ANTIBODIES IN SERUM OF PRE AND POST-TRANSPLANT ORGAN RECIPIENTS.,CLASS II COMPLEMENT(NIL)- FOR USE IN COMPLEMENT DEPENDENT CYTOTOXIC ASSAYS FOR DETERMINING HLA CLASS II CELL SURFACE ANTIGENS.,LABSCREEN™ SINGLE ANTIGEN HLA CLASS I - COMBI(LABSCREEN)-LABSCREEN PRODUCTS ARE INTENDED FOR USE IN DETECTION OF HLA ANTIBODY USING FLOW CYTOMETRIC TECHNOLOGY,FLOWPRA™ CLASS II POSITIVE CONTROL(FLOWPRA)-THE FLOWPRA™ SCREENING TEST IS INTENDED FOR USE IN FLOW CYTOMETRIC DETECTION OF HLA- SPECIFIC ANTIBODIES IN SERUM OF PRE AND POST-TRANSPLANT ORGAN RECIPIENTS.,LABTYPE™ CWD CLASS II DRB1 TYPING TEST(LABTYPE)-FOR USE TO DETERMINE HLA A, B, C AND DRB1 LOCUS TYPING TO AID IN TRANSFUSION AND TRANSPLANTATION DONOR RECIPIENT MATCHING.,LABSCREEN™ SINGLE ANTIGEN HLA CLASS II - GROUP 1 (LABSCREEN)-LABSCREEN PRODUCTS ARE INTENDED FOR USE IN DETECTION OF HLA ANTIBODY USING FLOW CYTOMETRIC TECHNOLOGY,FLOWPRA™ HLA CLASS II SCREENING TEST(FLOWPRA) -THE FLOWPRA™ SCREENING TEST IS INTENDED FOR USE IN FLOW CYTOMETRIC DETECTION OF HLA-SPECIFIC ANTIBODIES IN SERUM OF PRE AND POST-TRANSPLANT ORGAN RECIPIENTS.,MICRO SSP™ AMBISTRIPS™ HLA CLASS I - B27+ B81(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,FLOWPRA™ HLA CLASS I & II SCREENING TEST(FLOWPRA)-THE FLOWPRA™ SCREENING TEST IS INTENDED FOR USE IN FLOW CYTOMETRIC DETECTION OF HLA-SPECIFIC ANTIBODIES IN SERUM OF PRE AND POST-TRANSPLANT ORGAN RECIPIENTS.,FLOWPRA™ CONTROL BEADS(FLOWPRA)-FLOWPRA™ CONTROL BEADS ARE INTENDED FOR USE AS BLANK CONTROL BEADS IN THE FLOWPRA™ CLASS I AND/OR II SCREENING TESTS TO INDICATE THE BACKGROUND LEVEL OF THE TESTING SERUM.,FLOWPRA™ WASH BUFFER (10X)(FLOWPRA)-THE FLOWPRA™ WASH BUFFER IS INTENDED FOR USE WITH FLOWPRA™ SCREENING TESTS WHEN A LARGER VOLUME OF WASH BUFFER THAN THAT NORMALLY SUPPLIED WITH THE TEST IS REQUIRED.,LABTYPE™ SSO CLASS I A LOCUS TYPING TEST(LABTYPE)-DNA TYPING OF HLA CLASS I OR CLASS II ALLELES,FLOWPRA™ SINGLE ANTIGEN HLA CLASS II ANTIBODY DETECTION TEST(FLOWPRA)-THE FLOWPRA®

	SPECIFIC TESTS ARE INTENDED FOR USE IN FLOW CYTOMETRIC DETECTION OF HLA ANTIBODIES AND THEIR SPECIFICITIES., TERASAKI HLA CLASS II TISSUE TYPING TRAY(TERASAKI)-FOR USE IN DETERMINING HLA CELL SURFACE ANTIGENS WITH A COMPLEMENT DEPENDENT MICROLYMPHOCYTOTOXIC TEST,MICRO SSP™ HLA CLASS I B LOCUS SPECIFIC DNA TYPING TRAY(MICRO SSP) -DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,LABSCREEN NEGATIVE CONTROL(LABSCREEN)-THIS REAGENT IS FOR USE AS AN INDICATOR OF THE NON-SPECIFIC BACKGROUND SIGNAL OF EACH LABSCREEN™ AND LABSCREEN™ MULTI* BEAD (HLA-COATED BEADS, AS WELL AS NEGATIVE AND POSITIVE CONTROL BEADS) WHEN REACTING WITH A SERUM SAMPLE THAT DOES NOT CONTAIN ANY ANTI-HLA CLASS I OR CLASS II ANTIBODY. THIS REAGENT MAY ONLY BE USED WITH LABSCREEN™ PRODUCTS.,LABSCREEN™ PRA CLASS I(LABSCREEN)-LABSCREEN PRODUCTS ARE INTENDED FOR USE IN DETECTION OF HLA ANTIBODY USING FLOW CYTOMETRIC TECHNOLOGY,MICRO SSP™ AMBISTRIPS™ HLA CLASS II -DRB50103N (MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES., FLOWPRA™ REAGENT PACK(FLOWPRA)-THE FLOWPRA™ REAGENT PACK CONTAINS ANCILLARY REAGENTS USED WITH THE FLOWPRA™ SPECIFIC AND FLOWPRA™ SCREENING TESTS FOR DETECTION OF HLA ANTIBODIES AND THEIR SPECIFICITIES.,MICRO SSP™ GENERIC HLA CLASS II DNA TYPING TRAY - DRB ONLY(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,MICRO SSP™ GENERIC HLA CLASS II DNA TYPING TRAY(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,MICRO SSP™ HIGH RESOLUTION HLA CLASS II DNA TYPING TRAY - DPA1/DPB1(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,LYOPHILIZED CLASS II COMPLEMENT (NIL)- FOR USE IN COMPLEMENT DEPENDENT CYTOTOXIC ASSAYS FOR DETERMINING HLA CLASS II CELL SURFACE ANTIGENS.,LABTYPE™ SSO CLASS II DRB1 TYPING TEST(LABTYPE)- DNA TYPING OF HLA CLASS I OR CLASS II ALLELES,LABTYPE™ SSO CLASS I BW4 SUPPLEMENT TYPING TEST(LABTYPE)-DNA TYPING OF HLA CLASS I OR CLASS II ALLELES,FLOWPRA™ CLASS L POSITIVE CONTROL(FLOWPRA)-THE FLOWPRA™ SCREENING TEST IS INTENDED FOR USE IN FLOW CYTOMETRIC DETECTION OF HLA- SPECIFIC ANTIBODIES IN SERUM OF PRE AND POST-TRANSPLANT ORGAN RECIPIENTS.,MICRO SSP™ HIGH RESOLUTION HLA CLASS II DNA TYPING TRAY(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,LABTYPE™ SSO CLASS II DRB3,4,5 TYPING TEST(LABTYPE)- DNA TYPING OF HLA CLASS I OR CLASS II ALLELES,FLOWPRA™ HLA CLASS I SCREENING TEST(FLOWPRA)-THE FLOWPRA™ SCREENING TEST IS INTENDED FOR USE IN FLOW CYTOMETRIC DETECTION OF HLA- SPECIFIC ANTIBODIES IN SERUM OF PRE AND POST-

		TRANSPLANT ORGAN RECIPIENTS., LABTYPE™ SSO CLASS II DQA1/DQB1 TYPING TEST(LABTYPE)-DNA TYPING OF HLA CLASS I OR CLASS II ALLELES,LABTYPE™ SSO CLASS I EXON 4-7 SUPPLEMENT TYPING TEST - 20 TESTS(LABTYPE)-DNA TYPING OF HLA CLASS I OR CLASS II ALLELES,LABTYPE™ SSO CLASS I C LOCUS TYPING TEST (LABTYPE)-DNA TYPING OF HLA CLASS I OR CLASS II ALLELES, LABTYPE™ SSO CLASS II DPA1/DPB1 TYPING TEST(LABTYPE)-DNA TYPING OF HLA CLASS I OR CLASS II ALLELES,LABTYPE™ SSO CLASS I B7 SUPPLEMENT TYPING TEST TESTS(LABTYPE)-DNA TYPING OF HLA CLASS I OR CLASS II ALLELES,MICRO SSP™ AMBISTRIPS™ NEGATIVE CONTROL(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.,MICRO SSP™ HIGH RESOLUTION HLA CLASS II DNA TYPING TRAY - DQA1(MICRO SSP)-DNA TYPING OF CLASS I OR CLASS II HLA ALLELES.
699	IMP/IVD/2020/000455	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRINICLOT LUPUS CONFIRM-TRINICLOT LUPUS SCREEN AND TRINICLOT LUPUS CONFIRM ARE SIMPLIFIED DILUTE RUSSELL VIPER VENOM TIME (DRVVT) REAGENTS, INTENDED TO SPECIFICALLY DETECT LUPUS ANTICOAGULANTS (LAS), A TYPE OF ANTIPHOSPHOLIPID ANTIBODY. THE REAGENTS ARE SIMPLE ONE-STEP-CLOTTING TESTS THAT CAN BE PERFORMED EITHER MANUALLY OR ON AUTOMATED COAGULATION INSTRUMENTS,TRINILIZE PAI-1 ACTIVITY-TRINILIZE PAI-1 ACTIVITY IS A BIO-IMMUNOASSAY (BIA) FOR THE QUANTITATIVE DETERMINATION OF ACTIVE HUMAN PLASMINOGEN ACTIVATOR INHIBITOR, TYPE 1 (PAI-1) IN HUMAN PLASMA,TRINICLOT LUPUS SCREEN-TRINICLOT LUPUS SCREEN AND TRINICLOT LUPUS CONFIRM ARE SIMPLIFIED DILUTE RUSSELL VIPER VENOM TIME (DRVVT) REAGENTS, INTENDED TO SPECIFICALLY DETECT LUPUS ANTICOAGULANTS (LAS), A TYPE OF ANTIPHOSPHOLIPID ANTIBODY. THE REAGENTS ARE SIMPLE ONE-STEP-CLOTTING TESTS THAT CAN BE PERFORMED EITHER MANUALLY OR ON AUTOMATED COAGULATION INSTRUMENTS,TRINILIZE PAI-1 ANTIGEN-TRINILIZE PAI-1 ANTIGEN IS AN ENZYME IMMUNOASSAY (ELISA) FOR THE QUANTITATIVE DETERMINATION OF HUMAN PLASMINOGEN ACTIVATOR INHIBITOR, TYPE 1 (PAI-1) ANTIGEN IN HUMAN PLASMA

700	IMP/IVD/2020/000456	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALINITY H-SERIES CONTROL 29-P(ALINITY H-SERIES CONTROL 29-P)-ALINITY H-SERIES CONTROL 29P IS A WHOLE BLOOD HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR RESULTS OBTAINED ON ALINITY H-SERIES SYSTEMS.,ALINITY H-SERIES HEMCAL(ALINITY H-SERIES HEMCAL)-ALINITY H-SERIES HEMCAL IS A WHOLE BLOOD CALIBRATOR USED TO CALIBRATE ALINITY H-SERIES SYSTEMS. CALIBRATION VALUES ARE PROVIDED FOR WBC, RBC, HGB, MCV, PLT, AND MPV PARAMETERS.
701	IMP/IVD/2020/000457	1.License Holder Name: TWINS DIGITAL SERVICES INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KETONE TEST STRIPS (PROCHECK ADVANCE)-PROCHECK ADVANCE BETA-KETONE TEST STRIP IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF BETA-KETONE IN VENOUS WHOLE BLOOD AND FRESH CAPILLARY WHOLE BLOOD FROM FINGER. ,BLOOD GLUCOSE TEST STRIP (PROCHECK ADVANCE)-PROCHECK ADVANCE BLOOD GLUCOSE TEST STRIPS, WHEN USE TOGETHER WITH PROCHECK ADVANCE MULTI-FUNCTIONAL MONITORING SYSTEM, ALLOW YOUR BLOOD GLUCOSE LEVELS TO BE MEASURED BY YOURSELF AT HOME OR BY HEALTHCARE PROFESSIONALS. IT USES FRESH CAPILLARY WHOLE BLOOD SAMPLES FROM THE FINGER, AND FROM VENOUS WHOLE BLOOD. THIS SYSTEM IS NOT INTENDED FOR USE IN THE DIAGNOSIS OR SCREENING OF DIABETES MELLITUS. IT CAN BE USED ON NEONATES. PROFESSIONALS MAY USE TEST STRIPS TO TEST CAPILLARY AND VENOUS BLOOD SAMPLE; HOME USE IS LIMITED TO CAPILLARY WHOLE BLOOD TESTING.,MULTI-FUNCTIONAL MONITORING SYSTEM (GLUCOMETER)(PROCHECK ADVANCE)-THIS SYSTEM IS INTENDED FOR USE OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) TO QUANTITATIVELY MEASURE THE BLOOD GLUCOSE, -KETONE OR TOTAL CHOLESTEROL LEVELS IN WHOLE BLOOD. IT IS FOR HOME USE OR FOR HEALTHCARE PROFESSIONAL USE. IT SHOULD NOT BE USED FOR DIAGNOSIS OR SCREENING OF DISEASES.

702	IMP/IVD/2020/000458	1.License Holder Name: BIOTRON HEALTHCARE (INDIA) PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REAL-TIME FLUORESCENT ISOTHERMAL ASSAY KIT FOR COVID 19 DETECTION (IAMP COVID-19 DETECTION KIT)-IAMP COVID-19 DETECTION KIT IS A MULTIPLEXED, REAL-TIME FLUORESCENT RT-ISOTHERMAL ASSAY BASED ON ATILA'S PROPRIETARY ISOTHERMAL AMPLIFICATION TECHNOLOGY INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN NASOPHARYNGEAL SWABS, OROPHARYNGEAL SWABS OR BAL FROM INDIVIDUALS WITH SIGNS AND SYMPTOMS OF INFECTION WHO ARE SUSPECTED OF COVID-19.
703	IMP/IVD/2020/000459	1.License Holder Name: JETTALABS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (2019-NCOV) NUCLEIC ACID DIAGNOSTIC KIT-NOVEL CORONAVIRUS (2019-NCOV) NUCLEIC ACID DIAGNOSTIC KIT (PCR-FLUORESCENCE PROBING) IS USED FOR QUALITATIVE DETECTION OF THE ORF1AB AND N GENES OF NOVEL CORONAVIRUS (2019-NCOV) IN NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, ALVEOLAR LAVAGE FLUID, SPUTUM, SERUM, WHOLE BLOOD AND FECES FROM SUSPECTED PNEUMONIA CASES WITH NOVEL CORONAVIRUS INFECTION, PATIENTS WITH SUSPECTED CLUSTERS OF NOVEL CORONAVIRUS INFECTION, AND OTHER PATIENTS REQUIRING DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS OF NOVEL CORONAVIRUS INFECTION.
704	IMP/IVD/2020/000460	1.License Holder Name: M/S.TRANSASIA BIO-MEDICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 IGG ELISA (ERBALISA COVID-19 IGG)-THE ERBALISA COVID-19 IGG KIT IS INTENDED FOR THE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 (COVID-19) IN HUMAN SERUM OR PLASMA.

705	IMP/IVD/2020/000462	1.License Holder Name: ALLIED BIOTECHNOLOGY INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SMART DETECT SARS-COV- 2 RRT-PCR KIT-SMART DETECT SARS-COV-2 RRT-PCR KIT IS A REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SEVERE ACUTE RESPIRATORY SYNDROME-RELATED CORONAVIRUS 2 (SARS-COV-2) IN HUMAN NASOPHARYNGEAL SWAB, ANTERIOR NASAL SWAB AND MID-TURBINATE NASAL SWAB SPECIMENS FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER.
706	IMP/IVD/2020/000465	1.License Holder Name: 365 MEDICAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID 19 REAL TIME PCR KIT(SARS-COV-2/SARS-COV MULTIPLEX REAL-TIME PCR DETECTION KIT)-THE SARS-COV-2/SARS-COV MULTIPLEX REAL-TIME PCR DETECTION KIT IS DESIGNED TO DETECT COVID-19 VIRUS IN HUMAN BIOLOGICAL SAMPLES(NASOPHARYNGEAL SWABS, OROPHARYNGEAL SWABS, BRONCHOALVEOLAR LAVAGE, ENDOTRACHEAL ASPIRATE, NASOPHARYNGEAL ASPIRATE, SPUTUM). THE KIT IS INTENDED FOR USE BY LABORATORY TRAINED PERSONNEL.
707	IMP/IVD/2020/000468	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FTD™ SARS-COV-2(FTD™ SARS-COV-2)-FTD SARS-COV-2 IS A SEMI-AUTOMATED QUALITATIVE IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DETECTION OF ORF1AB AND N GENE OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) NUCLEIC ACIDS IN NASOPHARYNGEAL AND OROPHARYNGEAL SWABS OF PATIENTS WITH SIGNS AND SYMPTOMS OF SARS-COV-2 INFECTION IN CONJUNCTION WITH CLINICAL AND EPIDEMIOLOGICAL RISK FACTORS, WHO ARE SUSPECTED OF CORONAVIRUS DISEASE 2019 (COVID-19). THE KIT IS INTENDED FOR PROFESSIONAL USE BY LABORATORY PERSONNEL TRAINED IN REAL-TIME PCR AT A LEVEL 2 BIOSAFETY LABORATORY OR EQUIVALENT PER LOCAL REGULATIONS. THE TEST IS INTENDED AS AN AID IN THE DIAGNOSIS OF INFECTIONS CAUSED BY THE NEW HUMAN CORONAVIRUS SARS-COV-2. FOR IN VITRO DIAGNOSTIC USE.

708	IMP/IVD/2020/000469	1.License Holder Name: ASPEN DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TUMOR MARKER CONTROL II (L)(MINDRAY)-MINDRAY TUMOR MARKER MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF TUMOR MARKER ANALYTES.,IMMUNOASSAY MULTI CONTROL (H)(MINDRAY)-MINDRAY IMMUNOASSAY MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF IMMUNOASSAY MULTI ANALYTES., TOTAL PROSTATE SPECIFIC ANTIGEN (CLIA)(MINDRAY)-THE CL-SERIES T-PSA ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROSTATE SPECIFIC ANTIGEN (TOTAL PSA, T-PSA) IN HUMAN SERUM OR PLASMA.,ACTH CONTROL (H)(MINDRAY)-MINDRAY ACTH CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF ACTH ANALYTE.,CARCINOEMBRYONIC ANTIGEN (CLIA)(MINDRAY)-THE CL-SERIES CEA ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) IN HUMAN SERUM OR PLASMA.,THYROID-STIMULATING HORMONE (CLIA)(MINDRAY)-THE CL-SERIES TSH ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN HUMAN SERUM.,TOTAL PSA CALIBRATORS (MINDRAY)-MINDRAY TOTAL PSA CALIBRATORS (T-PSA CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE TOTAL PROSTATE SPECIFIC ANTIGEN (T-PSA) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,IMMUNOASSAY MULTI CONTROL (L)(MINDRAY)-MINDRAY IMMUNOASSAY MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF IMMUNOASSAY MULTI ANALYTES.,TUMOR MARKER CONTROL II (H)(MINDRAY)-MINDRAY TUMOR MARKER MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY

	ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF TUMOR MARKER ANALYTES., SYSTEM DETECTION SOLUTION(MINDRAY)-FOR USE WITH THE CL-SERIES ANALYZER IN SYSTEM MAINTENANCE.,CANCER ANTIGEN 125 (CLIA)(MINDRAY)-THE CL-SERIES CA125 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 125 (CA125) IN HUMAN SERUM OR PLASMA.,FREE TRIIODOTHYRONINE (CLIA)(MINDRAY)-THE CL-SERIES FT3 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM.,CARDIAC MARKER MULTI CONTROL (H)(MINDRAY)-MINDRAY CARDIAC MARKER MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF CARDIAC MARKER ANALYTES.,FOLATE CALIBRATORS(MINDRAY)-MINDRAY FOLATE CALIBRATORS (FOLATE CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE FOLATE ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,TROPONIN I CALIBRATORS(MINDRAY)-MINDRAY TROPONIN I CALIBRATORS (TNI CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE TROPONIN I (TNI) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,SAMPLE DILUENT(MINDRAY)-MINDRAY SAMPLE DILUENT IS INTENDED FOR DILUTION OF SAMPLES IN WHICH ANALYTE CONCENTRATION HAS EXCEEDED THE MEASURING RANGE OF RESPECTIVE CHEMILUMINESCENT IMMUNOASSAY REAGENTS.,B-TYPE NATRIURETIC PEPTIDE (CLIA)(MINDRAY)-THE CL-SERIES BNP ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF B-TYPE NATRIURETIC PEPTIDE (BNP) IN HUMAN EDTA PLASMA.,ANTIBODY TO THYROID PEROXIDASE (CLIA)(MINDRAY)-THE CL-SERIES ANTI-TPO ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OFANTI-TPO IN HUMAN SERUM OR PLASMA.,BNP CALIBRATORS(MINDRAY)-MINDRAY BNP CALIBRATORS (BNP CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE B-TYPE NATRIURETIC PEPTIDE (BNP) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,PROCALCITONIN (CLIA)(MINDRAY)-THECL-SERIESPROCALCITONIN ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONINPCT IN HUMAN SERUM OR PLASMA.,TROPONIN I (CLIA)(MINDRAY)-THE CL-SERIES TNI ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TNI IN HUMAN SERUM OR

	PLASMA.,TOTAL THYROXINE (CLIA)(MINDRAY)-THE CL-SERIES T4 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE (T4) LEVELS IN HUMAN SERUM OR PLASMA.,CARDIAC MARKER MULTI CONTROL (L)(MINDRAY)-MINDRAY CARDIAC MARKER MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF CARDIAC MARKER ANALYTES.,25-OH-VITAMIN D TOTAL (CLIA)(MINDRAY)-THE CL-SERIES VD-T ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF 25-OH-VITAMIN D TOTAL IN HUMAN SERUM OR PLASMA. ,ALFA-FETOPROTEIN (CLIA) (MINDRAY)-THE CL-SERIES AFP ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ALPHA-FETOPROTEIN (AFP) IN HUMAN SERUM OR PLASMA., LUTEINIZING HORMONE (CLIA)(MINDRAY)-THE CL-SERIES LH ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM OR PLASMA.,CA125 CALIBRATORS(MINDRAY)-MINDRAY CA125 CALIBRATORS (CA125 CAL) ARE INTENDED TO CALIBRATE QUANTITATIVE CANCER ANTIGEN 125 (CA125) ASSAY ON THE MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,FREE T4 CALIBRATORS(MINDRAY)-MINDRAY FREE T4 CALIBRATORS (FT4 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE FREE THYROXINE (FT4) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,CEA CALIBRATORS(MINDRAY)-MINDRAY CEA CALIBRATORS (CEA CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE CARCINOEMBRYONIC ANTIGEN (CEA) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,ANTI-TPO CALIBRATORS(MINDRAY)-MINDRAY ANTI-TPO CALIBRATORS (ANTI-TPO CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE ANTIBODIES TO THYROID PEROXIDASE (ANTI-TPO) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,AFP CALIBRATORS(MINDRAY)-MINDRAY AFP CALIBRATORS (AFP CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE ALPHA-FETOPROTEIN (AFP) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,M-6DR DILUENT(MINDRAY)-FOR THE MEASUREMENT OF RET-RELATED PARAMETERS TOGETHER WITH M-6FR DILUENT.,TRIGLYCERIDES (TG) KIT (GPO-POD METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TG CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,CK-MB CALIBRATORS

	(MINDRAY)-MINDRAY CK-MB CALIBRATORS (CK-MB CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE CREATINE KINASE MB (CK-MB) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,M-68FR DYE(MINDRAY)-THE M-68FR DYE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF RET-RELATED PARAMETERS TOGETHER WITH M-68DR DILUENT.,ESTRIOL CALIBRATORS(MINDRAY)-MINDRAY ESTRIOL CALIBRATORS (E3 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE ESTRIOL (E3) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,HEMOGLOBIN A1C (HBA1C) KIT (ENZYMATIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF HBA1C CONCENTRATION IN HUMAN WHOLE BLOOD ON PHOTOMETRIC SYSTEMS.,MYOGLOBIN (CLIA)-THE CL-SERIES MYOGLOBIN ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OFMYOGLOBIN (MYO) IN HUMAN SERUM OR PLASMA.,M-68DR DILUENT(MINDRAY)-THE M-68DR DILUENT APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF RET-RELATED PARAMETERS TOGETHER WITH M-68FR DYE.,FSH CALIBRATORS(MINDRAY)-MINDRAY FSH CALIBRATORS (FSH CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE FOLLICLE STIMULATING HORMONE (FSH) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,CARBON DIOXIDE (CO2) KIT (ENZYMATIC METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF C02 CONCENTRATION IN SERUM AND HEPARIN PLASMA ON PHOTOMETRIC SYSTEM,LH CALIBRATORS(MINDRAY)-MINDRAY LH CALIBRATORS (LH CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE LUTEINIZING HORMONE (LH) ASSAY ON MINDRAY CL-SERIES CHEMILUMINES-CENCE IMMUNOASSAY ANALYZER.,M-68FN DYE(MINDRAY)-THE M-68FN DYE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF NRBC-RELATED PARAMETERS TOGETHER WITH M-68LN LYSE.,PCT CONTROL (L)(MINDRAY)-USED IN IN VITRO DIAGNOSTICS (FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF PCT).,CK KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATININE CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,PTH CALIBRATORS(MINDRAY)-MINDRAY PTH CALIBRATORS (PTH CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE PTH ASSAY ON MINDRAY CL-SERIES

	CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,D-BIL KIT (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BIL-D CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,FERRITIN (CLIA)(MINDRAY)-THE CL-SERIES FERR ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FERRITIN (FERR) IN HUMAN SERUM OR PLASMA,M-30R RINSE(MINDRAY)-IT IS USE ON MINDRAY THREE PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS USE AS AZIDE FREE, FILTERED ISOTONIC SOLUTION FOR CLEANING HEMATOLOGY ANALYSER,M-6LN LYSE(MINDRAY)-FOR THE MEASUREMENT OF NRBC-RELATED PARAMETERS TOGETHER WITH M-6FN DYE,PHOSPHORUS (P) KIT (PHOSPHOMOLYBDATE METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF P CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM, THYROGLOBULIN (CLIA)(MINDRAY)-THE CL-SERIES TG ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) IN HUMAN SERUM OR PLASMA.,M-68DS DILUENT(MINDRAY)-THE M-68DS DILUENT APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF PARAMETERS RELATED TO RBC, PLT, WBC, RET AND NRBC. M-68DS DILUENT ALSO APPLIES TO SC-120 AUTO SLIDE MAKER & STAINER AND CRP-M100 SPECIFIC PROTEIN ANALYZER MANUFACTURED BY MINDRAY. IT PARTICIPATES IN THE CLEANING OF RELATED COMPONENTS OF THE AUTO SLIDE MAKER & STAINER AND SPECIFIC PROTEIN ANALYZER., TOTAL HCG CALIBRATORS(MINDRAY)-MINDRAY TOTAL HCG CALIBRATORS (HCG CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE TOTAL HUMAN CHORIONIC GONADOTROPHIN (TOTAL HCG) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,M-53 CLEANSER (1LX4)(MINDRAY)-AN-AZIDE FREE FILTERED SOLUTION FOR USE IN CLEANING HEMATOLOGY ANALYZER,INSULIN CALIBRATORS(MINDRAY)-MINDRAY INSULIN CALIBRATORS (INSULIN CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE INSULIN ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER., CHOLINESTERASE (CHE) KIT (BUTYRYLTHIOCHOLINE METHOD) (MINDRAY)-CHE REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CHE ACTIVITY IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEM,M-6LD LYSE(MINDRAY)-FOR USE IN WBC DIFFERENTIATION IN THE DIFF CHANNEL TOGETHER WITH M-6FD LYSE.,IMMUNOGLOBULIN A (IGA) KIT (IMMUNOTURBIDIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGA CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,THYROGLOBULIN CALIBRATORS(MINDRAY)-

	MINDRAY THYROGLOBULIN CALIBRATORS (TG CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE THYROGLOBULIN (TG) ASSAY ON MINDRAY CL-SERIESCHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,REAGENT MODULE (CALA, CALB, WASTE)(MINDRAY)-FOR USE WITH THE ISE MODULE DAILY RINSE CLEANING DILUENT,FREE THYROXINE (CLIA)(MINDRAY)-THE CL-SERIES FT4 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM OR PLASMA.,MR BUFFER SOLUTION(MINDRAY)-MR BUFFER SOLUTION APPLIES TO MINDRAY BS SERIES AUTO CHEMISTRY A NALYZERS. IT IS USED TO DILUTE SAMPLES BEFORE THEY ARE DISPOSED TO THE ELECTRODES FLOWCELL. USE THE MR BUFFER SOLUTION AS INSTRUCTED BY THE OPERATOR'S MANUAL OF T HE ANALYZER., ANTI-TG CALIBRATORS(MINDRAY)-MINDRAY ANTI-TG CALIBRATORS (ANTI-TG CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE ANTIBODY TO THYROGLOBULIN (ANTI-TG) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,M-68LB LYSE(MINDRAY)-THE M-68LB LYSE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN WBC COUNTING AND MEASUREMENT OF BASOPHIL-RELATED PARAMETERS.,TOTAL T3 CALIBRATORS(MINDRAY)-MINDRAY TOTAL T3 CALIBRATORS (T3 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE TOTAL TRIIODOTHYRONINE (T3) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,M-53 LEO (II) LYSE(MINDRAY)-M-53LEO(II) LYSE COOPERATES WITH THE M-53LEO(I) LYSE TO 4-DIFFERENTIATE WBCS.,LIVER FIBROSIS MULTI CONTROL (L)(MINDRAY)-MINDRAY LIVER FIBROSIS MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF LIVER FIBROSIS ANALYTES.,TOTAL CHOLESTEROL (TC) KIT (CHOD-POD METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TC CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,ACTH CALIBRATORS(MINDRAY)-MINDRAY ACTH CALIBRATORS (ACTH CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE ADRENOCORTICOTROPIC HORMONE (ACTH) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,M-18D DILUENT(MINDRAY)-FOR USE ON MINDRAY BC-1800/BC-2800/BC-2600 HEMATOLOGY ANALYZER. FOR USE AS AN AZIDE-FREE, FILTERED ISOTONIC SOLUTION FOR COUNTING AND SIZING BLOOD CELLS. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,SUBSTRATE SOLUTION(MINDRAY)-MINDRAY SUBSTRATE SOLUTION IS INTENDED FOR USE WITH THE MINDRAY CL-

	SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND SPECIFIC MINDRAY IMMUNOASSAY REAGENTS.,PRE ALBUMIN CALIBRATOR(MINDRAY)-PRE ALBUMIN CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF SPECIFIC PROTEINS ON MINDRAY BS MEASUREMENT SYSTEM,TOTAL TRIIODOTHYRONINE (CLIA)(MINDRAY)-THE CL-SERIES T3 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE (T3) IN HUMAN SERUM.,IRON (FE) KIT (COLORIMETRIC METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM AND HEPARIN PLASMA ON PHOTOMETRIC SYSTEM, DEHYDROEPIANDROSTERONE SULFATE (CLIA)(MINDRAY)-THE CL-SERIES DHEA-S ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) IN HUMAN SERUM OR PLASMA.,M-68FD DYE(MINDRAY)-THE M-68FD DYE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN WBC DIFFERENTIATION IN THE DIFF CHANNEL TOGETHER WITH M-68LD LYSE,PROGESTERONE CALIBRATORS (MINDRAY)-MINDRAY PROGESTERONE CALIBRATORS (PROG CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE PROGESTERONE (PROG) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER. ,RHEUMATOID FACTOR (RF) KIT (PARTICLE-ENHANCED IMMUNOTURBIDIMETRIC ASSAY METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF RF CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM, METABOLIC MULTI CONTROL (L)(MINDRAY)-MINDRAY METABOLIC MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF PTH, CT, 25-OH-VITAMIN D TOTAL, VB12, FOLATE, FERRITIN ANALYTES.,HBA1C CONTROL N(MINDRAY)-HBA1C CONTROL N IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,FREE T3 CALIBRATORS(MINDRAY)-MINDRAY FREE T3 CALIBRATORS (FT3 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE FREE TRIIODOTHYRONINE (FT3) ASSAY ON MINDRAY CL-SERIESCHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,IGM KIT (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGM CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM., DHEA-S CALIBRATORS(MINDRAY)-MINDRAY DHEA-S CALIBRATORS (DHEA-S CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE

	DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,TOTAL BILE ACIDS (TBA) KIT (ENZYMATIC CYCLING ASSAY)(MINDRAY)-IN VITRO TEST .FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILE ACID CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,C-PEPTIDE (CLIA) (MINDRAY)-THE CL-SERIES C-PEPTIDE ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE (C-PEPTIDE) IN HUMAN SERUM, PLASMA OR URINE.,S30 CALIBRATOR(MINDRAY)-S30 CALIBRATOR IS INTENDED FOR USE AS CALIBRATOR FOR WBC, RBC, HGB, MCV AND PLT PARAMETERS ON HEMATOLOGY ANALYZERS. BEFORE CARRYING OUT CLINICAL PRACTICE, PARAMETERS OF THE HEMATOLOGY ANALYZER NEED TO BE CALIBRATED AS INSTRUCTED IN INSTRUMENT MANUAL.,ESTRIOL (CLIA)(MINDRAY)-THE CL-SERIES E3 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ESTRIOL (E3) IN HUMAN SERUM., M-18CFL LYSE(MINDRAY)-FOR USE ON MINDRAY BC-1800/BC-2800/BC-2600 HEMATOLOGY ANALYZER. FOR USE AS A CYANIDE-FREE LYTIC REAGENT FOR QUANTITATIVELY DETERMINING HEMOGLOBIN AND FOR COUNTING AND SIZING LEUKOCYTES. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,THYROID FUNCTION MULTI CONTROL (L)(MINDRAY)-MINDRAY THYROID FUNCTION MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF THYROID FUNCTION ANALYTES.,V-28D DILUENT (MINDRAY)-AN AZIDE-FREE FILTERED ISOTONIC SOLUTION FOR USE IN BLOOD CELL COUNTING AND SIZING. USE AS DIRECTED IN INSTRUMENT OPERATION MANUAL.,WASH BUFFER(MINDRAY)-MINDRAY WASH BUFFER IS INTENDED FOR USE WITH THE CL-SERIES IMMUNOASSAY SYSTEMS AND SPECIFIC CL-SERIES IMMUNOASSAY REAGENTS. ,SPECIFIC PROTEINS CALIBRATOR(MINDRAY)-SPECIFIC PROTEINS CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF SPECIFIC PROTEINS ON MINDRAY BS MEASUREMENT SYSTEM,REPRODUCTIVE MULTI CONTROL (H)(MINDRAY)-MINDRAY REPRODUCTIVE MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF REPRODUCTIVE HORMONE ANALYTES.,LIPIDS CALIBRATOR (MINDRAY)-LIPID CALIBRATOR IS USED FOR CALIBRATION OF

	QUANTITATIVE DETERMINATION OF LIPID ANALYTES ON MINDRAY BS MEASUREMENT SYSTEM,REPRODUCTIVE MULTI CONTROL (L)-MINDRAY REPRODUCTIVE MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF REPRODUCTIVE HORMONE ANALYTES.,M-53 LEO (I) LYSE (MINDRAY)-M-53LEO(I) LYSE BREAKS DOWN RED BLOOD CELL MEMBRANE AND COOPERATES WITH THE M-53LEO(II) LYSE TO 4-DIFFERENTIATE WBCS.,ACTH CONTROL (L) (MINDRAY)-MINDRAY ACTH CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF ACTH ANALYTE.,KIT,CLEANING SOLUTION, ISE(MINDRAY)-INTENDED FOR CLEANING THE CHEMISTRY ANALYZER ,HEMOGLOBIN A1C CONTROL(MINDRAY)-QUALITY CONTROL OVER THE TEST ON HBA1C IN WHOLE BLOOD TO MONITOR AND ASSESS THE ACCURACY OF THE TEST KIT,MULTI CONTROL SERA N(MINDRAY)-MULTI CONTROL SERA N IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION ON MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY,ADRENOCORTICOTROPIC HORMONE (CLIA)(MINDRAY)-THE CL-SERIES ACTH ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ADRENOCORTICOTROPIC HORMONE (ACTH) IN HUMAN EDTA PLASMA.,SC-CAL PLUS CALIBRATOR(MINDRAY)-SC CAL PLUS IS DESIGNED FOR USE IN THE CALIBRATION OF HEMATOLOGY ANALYZER,FOLLICLE STIMULATING HORMONE (CLIA) (MINDRAY)-THE CL-SERIES FSH ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN SERUM OR PLASMA.,LIPOPROTEIN (A) CONTROL N&P(MINDRAY)-LIPOPROTEIN (A) N & P IS USED IN LIPID ANALYTE QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY,TSH CALIBRATORS(MINDRAY)-MINDRAY TSH CALIBRATORS (TSH CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE THYROID-STIMULATING HORMONE (TSH) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,M-58D DILUENT (MINDRAY)-M-58 D DILUENTS APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT PROVIDE A STABLE ENVIRONMENT FOR COUNTING AND SIZINQ BLOOD CELLS.,ELUENT A (MINDRAY)-THIS PRODUCT APPLIES TO MINDRAY H50/H50P

	AUTOMATED GLYCOHEMOGLOBIN ANALYZER. THE PRODUCTPARTICIPATES IN THE MEASUREMENT OF HBA1C IN BLOOD SAMPLES,M30P PROBE CL(MINDRAY)-FOR USE ON MINDRAY BC-3000PLUS/BC-3000CT/BC-3200 HEMATOLOGY ANALYZER. FOR USE AS AN AZIDE-FREE, FILTERED ISOTONIC SOLUTION FOR COUNTING AND SIZING BLOOD CELLS. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,THYROID FUNCTION MULTI CONTROL (H)(MINDRAY)-MINDRAY THYROID FUNCTION MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF THYROID FUNCTION ANALYTES.,M-58LBA LYSE (MINDRAY)-M-58 L8A LYSE APPLIES TO MINDRAY BC-5600 , 8C-5800 AUTO HEMATOLOGY ANALYZER. IT BREAKS DOWN RED BLOOD CELL MEMBRANE AND 2 DIFFERENTIATES W8C'S TO BASOPHILS AND OTHER W8C'S,FOLATE (CLIA)(MINDRAY)-THE CL-SERIES FOLATE ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN SERUM, PLASMA OR RED BLOOD CELLS.,M-53D DILUENT(MINDRAY)-M-53D DILUENT PROVIDES A STABLE ENVIRONMENT FOR COUNTING AND SIZING BLOOD CELLS., VITAMIN B12 CALIBRATORS(MINDRAY)-MINDRAY VITAMIN B12 CALIBRATORS (VB12 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE VB12 ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,LPA KIT (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LP(A) CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS.,M-6FN DYE(MINDRAY)-FOR THE MEASUREMENT OF NRBC-RELATED PARAMETERS TOGETHER WITH M-6LN LYSE.,GGT KIT(MINDRAY)-GGT REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF GAMMA-GLUTAMYLTRANSFERASE ACTIVITY IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. ,M-6LH LYSE(MINDRAY)-FOR THE MEASUREMENT OF THE HAEMOGLOBIN-RELATED PARAMETERS., IMMUNOGLOBULIN G (IGG) KIT (IMMUNOTURBIDIMETRIC METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF IGG CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM, TOTAL T4 CALIBRATORS(MINDRAY)-MINDRAY TOTAL T4 CALIBRATORS (T4 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE TOTAL THYROXINE (T4) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,M-68LN LYSE(MINDRAY)-THE M-68LN LYSE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN THE MEASUREMENT OF NRBC-RELATED PARAMETERS TOGETHER WITH M-68FN DYE.,M-6FR DYE(MINDRAY)-FOR THE MEASUREMENT

	OF RET-RELATED PARAMETERS TOGETHER WITH M-6DR DILUENT.,M-30CFL LYSE(MINDRAY)-FOR USE ON MINDRAY THREE PART DIFFERENTIAL HEMATOLOGY ANALYZER FOR USE AS A CYANIDE FREE LYTIC REAGENT FOR QUANTITATIVELY DETERMINING HEMOGLOBIN AND FOR COUNTING AND SIZING LEUKOCYTES,DS DILUENT(MINDRAY)-FOR THE MEASUREMENT OF PARAMETERS RELATED TO RBC, PLT, WBC, RET AND NRBC,M-58LEO(I) LYSE (MINDRAY)-M-58 LEO (I) LYSE APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT BREAKS DOWN RED BLOOD CELL MEMBRANE AND COOPERATES WITH THE M-58 LEO (II) LYSE TO 4 DIFFERENTIATE W8C'S .,RED BLOOD CELL FOLATE RELEASING REAGENT(MINDRAY)-RED BLOOD CELL FOLATE RELEASING REAGENT IS USED FOR THE PRETREATMENT OF WHOLE BLOOD SAMPLES TO RELEASE FOLATES IN ERYTHROCYTES (RED BLOOD CELLS, RBC), IN ORDER TO TESTING THE FOLATE CONCENTRATION IN ERYTHROCYTES USING THE FOLATE (CLIA) REAGENT KIT., LIPOPROTEIN (A) CALIBRATOR(MINDRAY)-LIPOPORTEIN (A) CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF LIPID ANALYTE ON MIND RAY BS MEASUREMENT SYSTEM,CORTISOL CALIBRATORS(MINDRAY)-MINDRAY CORTISOL CALIBRATORS (CORTISOL CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE CORTISOL ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,CRP KIT (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CRP CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM, PROLACTIN CALIBRATORS(MINDRAY)-MINDRAY PROLACTIN CALIBRATORS (PRL CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE PROLACTIN (PRL) ASSAYON MINDRAY CL-SERIES CHEMILUMINES-CENCE IMMUNOASSAY ANALYZER.,M-18R RINSE (MINDRAY)-FOR USE ON MINDRAY BC-1800/BC-2800/BC-2600 HEMATOLOGY ANALYZER. FOR USE AS AN AZIDE-FREE, FILTERED ISOTONIC SOLUTION FOR COUNTING AND SIZING BLOOD CELLS. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL., TESTOSTERONE CALIBRATORS(MINDRAY)-MINDRAY TESTOSTERONE CALIBRATORS (TESTO CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE TESTOSTERONE (TESTO) ASSAY ON MINDRAY CL-SERIES CHEMILUMINES-CENCE IMMUNOASSAY ANALYZER. ,M-50 LEO (II) LYSE (MINDRAY)-M-50 LEO (II) LYSE APPLIES TO 5 PART DIFFERNTIAL AUTO HEMATOLOGY ANALYSER. IT IS USED TO LYSE RED BLOOD CELLS AND 4 DIFFERENTIATES WBC'S,CORTISOL (CLIA) (MINDRAY)-THE CL-SERIES CORTISOL ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM, PLASMA OR URINE.,FRUCTOSAMINE (FUN) KIT (COLORIMETRIC ASSAY)(MINDRAY)

	-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF FRUCTOSAMINE CONCENTRATION IN SERUM, HEPARIN PLASMA ON PHOTOMETRIC SYSTEMS.,ESTRADIOL CALIBRATORS(MINDRAY)-MINDRAY ESTRADIOL CALIBRATORS (E2 CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE ESTRADIOL (E2) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,M-53 LH LYSE(MINDRAY)-M-53LH LYSE BREAKS DOWN RED BLOOD CELL MEMBRANE AND CONVERTS HEMOGLOBIN TO A HEMOGLOBIN COMPLEX TO DETERMINE THE HGB. IT 2-DIFFERENTIATES WBCS TO BASO AND OTHER WBCS, AND DETERMINES WBCS AMOUNT., CREATINE KINASE MB (CLIA)(MINDRAY)-THE CL-SERIES CREATINE KINASE MB ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY(CLIA) FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE MB (CK-MB) IN HUMAN SERUM OR PLASMA,V-28R RINSE(MINDRAY)-AN AZIDE-FREE FILTERED ISOTONIC SOLUTION FOR USE IN BLOOD CELL COUNTING AND SIZING. USE AS DIRECTED IN INSTRUMENT OPERATION MANUAL.,25-OH-VITAMIN D TOTAL CALIBRATORS (MINDRAY)-MINDRAY 25-OH-VITAMIN D TOTAL CALIBRATORS (VD-T CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE 25-OH-VITAMIN D TOTAL ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,V28P PROBE CL (MINDRAY)-INTENDED FOR CLEANING THE HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATION MANUAL.,PCT CONTROL (H)(MINDRAY)-USED IN IN VITRO DIAGNOSTICS (FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF PCT).,M-52D DILUENT(MINDRAY)-M-52 D DILUENT PROIVDE STABLE SOLUTION ENVIRONMENT FOR BLOOD CELLS, DILUTE BLOOD SAMPLE, GENERATES SHEATH FLUID AND PROVIDE CONDUCTANCE IN BLOOD CELL ANALYSIS PROCESS,ANTIBODY TO THYROGLOBULIN (CLIA)(MINDRAY)-THE CL-SERIES ANTI-TG ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO THYROGLOBULIN (ANTI-TG) IN HUMAN SERUM OR PLASMA.,DETERGENT (INDIRECT) (INTERNATIONAL)(MINDRAY)-MR DETERGENT SOLUTION APPLIES TO MINDRAY BS SERIES AUTO CHEMISTRY ANALYZERS. IT IS USED TO CLEAN THE ELECTRODES FLOW CELL AS WELL AS THE PIPELINE OF THE ISE MODULE. ,C-PEPTIDE CALIBRATORS(MINDRAY)-MINDRAY C-PEPTIDE CALIBRATORS (C-PEPTIDE CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE C-PEPTIDE ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,V-52DIFF LYSE (EN/300ML×4)(MINDRAY)-V-52DIFF APPLIES TO BC-5000VET

	VETERINARY AUTO HEMATOLOGY ANALYZER MANUFACTURED BY MINDRAY, IT DISSOLVES RBCS AND DIFFERENTIATES WBCS.,ELUENT B(MINDRAY)-THIS PRODUCT APPLIES TO MINDRAY H50/H50P AUTOMATED GLYCOHEMOGLOBIN ANALYZER. THE PRODUCTPARTICIPATES IN THE MEASUREMENT OF HBA1C IN BLOOD SAMPLES,M-50P PROBE CLEANSER (MINDRAY)-M-50 P PROBE CLEANSER APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLOGY ANALYZER. IT IS USED TO CLEAN THE ANALYZER REGULARLY,SYSTEM WASH SOLUTION(MINDRAY)-SYSTEM WASH SOLUTION IS USED TO PRIME THE SUBSTRATE DISPENSING TUBE IN ORDER TO CLEAN THE TUBES.,HBDH KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF A HBDH ACTIVITY IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,FERRITIN CALIBRATORS(MINDRAY)-MINDRAY FERRITIN CALIBRATORS (FERR CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE FERRITIN (FERR) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,UREA KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF UREA CONCENTRATION IN SERUM, PLASMA AND URINE ON PHOTOMETRIC SYSTEM, PARATHYROID HORMONE (CLIA)(MINDRAY)-THE CL-SERIES PTH ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PTH IN HUMAN SERUM OR PLASMA.,URIC ACID (UA) KIT (URICASE-PEROXIDASE METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF UA CONCENTRATION IN SERUM, PLASMA AND URINE ON PHOTOMETRIC SYSTEM,M-6FD DYE(MINDRAY)-FOR USE IN WBC DIFFERENTIATION IN THE DIFF CHANNEL TOGETHER WITH M-6LD LYSE.AS PER PRODUCT INSERT,V-52D DILUENT (EN/20L×1) (MINDRAY)-V-52D DILUENT APPLIES TO BC-5000VET VETERINARY AUTO HEMATOLOGY ANALYZER MANUFACTURED BY MINDRAY, IT IS USED IN SAMPLE DILUTION, BLOOD CELL COUNTING, VOLUME MEASUREMENT AND HEMOGLOBIN MEASUREMENT.,INSULIN (CLIA) (MINDRAY)-THE CL-SERIES INSULIN ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OFINSULIN IN HUMAN SERUM OR PLASMA.,MR URINE QUALITY CONTROL(MINDRAY)-MR URINE QUALITY CONTROL IS AN ELECTROLYTE REFERENCE URINE CONTROL USED TO MONITOR THE URINE MODE PERFORMANCE OF ION-SELECTIVE ELECTRODE ON ISE MODULES ON AUTOMATIC CHEMISTRY ANALYZERS. DAILY USE OF THIS URINE CONTROL PROVIDES QUALITY CONTROL DATA FOR CONFIRMING THE PRECISION AND ACCURACY OF URINE SAMPLE TESTS. ,VITAMIN B12 (CLIA)(MINDRAY)-THE CL-SERIES VITAMIN B12 (VB12) ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN

	SERUM OR PLASMA.,M-50LBA LYSE(MINDRAY)-M-50 LBA LYSE APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLOGY ANALYZER. IT IS USED TO LYSE RED BLOOD CELLS AND COUNT WBC'S AND BASOPHILS.,ESTRADIOL (CLIA)(MINDRAY)-THE CL-SERIES E2 ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL (E2) IN HUMAN SERUM.,-AMYLASE (-AMY) KIT (IFCC METHOD)(MINDRAY)--AMY REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF A AMYLASE ACTIVITY IN SERUM. PLASMA OR URINE ON PHOTOMETRIC SYSTEM,MYO CALIBRATORS(MINDRAY)-MINDRAY MYOGLOBIN CALIBRATORS (MYO CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE MYOGLOBIN (MYO) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,ALT KIT(MINDRAY) -ALT REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE ACTIVITY IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEM.,HYALURONIC ACID (CLIA)(MINDRAY)-THE CL-SERIES HA ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF HYALURONIC ACID (HA) IN HUMAN SERUM.,V-28E E-Z CLEAN(MINDRAY)-INTENDED FOR CLEANING THE HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATION MANUAL.,PROGESTERONE (CLIA)(MINDRAY)-THE CL-SERIES PROG ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE (PROG) IN HUMAN SERUM.,MR URINE STANDARD(MINDRAY)-MR URINE STANDARD IS INTENDED FOR USE AS CALIBRATOR FOR IN VITRO TESTING FOR THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM, AND CHLORIDE CONCENTRATION IN URINE SAMPLE ON ION-SELECTIVE ELECTRODE ON ISE MODULES ON BS SERIES AUTOMATIC CHEMISTRY ANALYZERS. BEFORE CARRYING OUT CLINICAL PRACTICE, PARAMETERS OF THE CHEMISTRY ANALYZER NEED TO BE CALIBRATED AS INSTRUCTED IN INSTRUMENT MANUAL.,PCT CALIBRATORS(MINDRAY)-USED IN IN VITRO DIAGNOSTICS(TO CALIBRATE THE QUANTITATIVE PROCALCITONIN (PCT) ASSAY ON MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER).,NA/K CHECK SOLUTION (INTERNATIONAL)(MINDRAY)-MR NA/K CHECK SOLUTION IS A KIND OF MAINTENANCES SOLUTIONS USED TO MONITOR THE SODIUM/POTASSIUM ION-SELECTIVE PERFORMANCE OF ION-SELECTIVE ELECTRODE INSTALLED IN ISE MODULES ON AUTOMATIC CHEMISTRY ANALYZERS. ,TOTAL HUMAN CHORIONIC GONADOTROPIN (CLIA)(MINDRAY)-THE CL-SERIES TOTAL HCG ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL HUMAN CHORIONIC GONADOTROPIN (TOTAL HCG) IN HUMAN SERUM.,CK-MB

	KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE-MB (CK-MB) ACTIVITY IN SERUM ON PHOTOMETRIC SYSTEMS.,COLLAGEN TYPE IV (CLIA) (MINDRAY)-THE CL-SERIES C IV ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF COLLAGEN TYPE IV (C IV) IN HUMAN SERUM.,BC-5D ((HIGH/NORMAL/LOW)*2/EN3ML*6)(MINDRAY)-BC - 5D IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS,HEMOGLOBIN A1C CALIBRATOR(MINDRAY)-TEST AND CALIBRATE HBA1C IN WHOLE BLOOD TO GUARANTEE THAT THE TEST RESULT IS ACCURATE,PA (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF PA CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS. , TESTOSTERONE (CLIA)(MINDRAY)-THE CL-SERIES TESTO ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE (TESTO) IN HUMAN SERUM AND PLASMA. ,V-52LH LYSE (EN/90ML×4)(MINDRAY)-V-52LH LYSE APPLIES TO BC-5000VET VETERINARY AUTO HEMATOLOGY ANALYZER MANUFACTURED BY MINDRAY, IT DISSOLVES RBCS, REALIZES WBC COUNTING, BASOPHIL DIFFERENTIAL AND HEMOGLOBIN MEASUREMENT.,LIVER FIBROSIS MULTI CONTROL (H) (MINDRAY)-MINDRAY LIVER FIBROSIS MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF LIVER FIBROSIS ANALYTES.,ALP KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALP ACTIVITY IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,LAMININ (CLIA)(MINDRAY)-THE CL-SERIES LAMININ ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF LAMININLN IN HUMAN SERUM.,M-30D DILUENT(MINDRAY)-IT IS USE ON MINDRAY THREE PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS USE AS AZIDE FREE, FILTERED ISOTONIC SOLUTION FOR COUNTING AND SIZING OF BLOOD CELLS,PROLACTIN (CLIA)(MINDRAY)-THE CL-SERIES PRL ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN HUMAN SERUM OR PLASMA., LDL KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LDLCHOLESTEROL CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,HEMOLYSIS SOLUTION(MINDRAY)-THIS PRODUCT APPLIES TO MINDRAY H50/H50P AUTOMATED GLYCOHEMOGLOBIN ANALYZER. USED FORPRE-TREATMENT OF BLOOD SAMPLES BEFORE HBA1C ANALYSIS.,CREA KIT(MINDRAY)-IN VITRO TEST FOR THE

	QUANTITATIVE DETERMINATION OF CREATININE CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,METABOLIC MULTI CONTROL (H)(MINDRAY)-MINDRAY METABOLIC MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF PTH, CT, 25-OH-VITAMIN D TOTAL, VB12, FOLATE, FERRITIN ANALYTES.,M-50 LEO (I) LYSE (MINDRAY)-M-50 LEO (I) LYSE APPLIES TO 5 PART DIFFERNTIAL AUTO HEMATOLOGY ANALYSE_R. IT IS USED TO LYSE RED BLOOD CELLS AND 4 DIFFERENTIATES WBC'S,ANTI-THYROID ANTIBODIES CONTROL (H)(MINDRAY)-MINDRAY ANTI-THYROID ANTIBODIES CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF ANTI-THYROID ANTIBODIES ANALYTES.,HDL KIT (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BIL-D CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,ANTI-THYROID ANTIBODIES CONTROL (L) (MINDRAY)-MINDRAY ANTI-THYROID ANTIBODIES CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF ANTI-THYROID ANTIBODIES ANALYTES.,HBA1C CONTROL P(MINDRAY)-HBA1C CONTROL P IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF CLINICAL LABORATORY.,C4 KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF C4 CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,APOB KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF APOB CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,MULTI CONTROL SERA P (MINDRAY)-MULTI CONTROL SERA P IS USED IN ROUTINE CHEMISTRY ANALYTES QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION ON MINDRAY BS MEASUREMENT SYSTEM AND TEST ABILITY OF LABORATORY,M-52LH LYSE(MINDRAY)-M-52 LH LYSE FUTHER PROCESS THE BLOOD CELL THAT HAVE BEEN PROCESSED BY M-52 DIFF LYSE. IT TURNS HEMOGLOBIN INTO METHEMOGLOBIN, WHICH THEN MEASURED BY THE COLORIMETRIC METHOD. IT IS ALSO PROCESSES W8C'S TO INTENSIFY THE DIFFERENCE BETWEEN BASOPHILES AND OTHER W8C SUB POPULATIONS AND IN CORPORATE CYTOMETRY TO REALIZE BASOPHIL ANALYSIS,TOTAL

	PROTEIN (TP) KIT (BIURET METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF TP CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,MULTI SERA CALIBRATOR(MINDRAY)-MULTI SERA CALIBRATOR IS USED FOR CALIBRATION OF QUANTITATIVE DETERMINATION OF ROUTINE CHEMISTRY ANALYSTES ON MINDRAY BS MEASUREMENT SYSTEM, CK-MB CALIBRATOR(MINDRAY)-CK-MB CALIBRATOR IS USED FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF CARDIAC ANALYTE ON MINDRAY BS MEASUREMENT SYSTEM,DIRECT BILIRUBIN (D-BIL) KIT (DSA METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF D-BIL CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,CREATININE KIT (MODIFIED JAFFE METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CREATININE CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,REAGENT, M-30E E-Z CLEANSER(MINDRAY)-FOR USE ON MINDRAY BC-3000/BC-3000PLUS/BC-3000CT/ BC-3200 HEMATOLOGY ANALYZER. FOR USE AS A CLEANING REAGENT FOR CLEANING HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,ALBUMIN (ALB) KIT (BCG METHOD)(MINDRAY) -IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ALB CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM.,M-18E E-Z CLEANSER(MINDRAY)-FOR USE ON MINDRAY BC-1800/BC-2800/BC-2600 HEMATOLOGY ANALYZER. FOR USE AS A CLEANING REAGENT FOR CLEANING HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,MAGNESIUM (MG) KIT (XYLIDYL BLUE METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF MG CONCENTRATION IN SERUM, PLASMA AND URINE ON PHOTOMETRIC SYSTEM,M-52DIFF LYSE(MINDRAY)-M-52 DIFF LYSE DISSOLVES RBCS IN THE BLOOD CELL ANALYSIS PROCESS. IT PROCESSES W8CS TO INTENSIFY THE DIFFERENCE OF THE WBC SUB POPULATIONS AND IN CORPORATE LASER SCATTER AND FLOW CYTOMETRY TO REALIZE DIFF CHANNEL WBC ANALYSIS,M-68LH LYSE(MINDRAY)-THE M-68LH LYSE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT IS FORMULATED TO MEASURE THE HEMOGLOBIN-RELATED PARAMETERS,MR SERUM STANDARD(MINDRAY)-R SERUM STANDARD IS INTENDED FOR USE AS CALIBRATOR FOR IN VITRO TESTING FOR THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM, AND CHLORIDE CONCENTRATION IN SERUM AND PLASMA SAMPLE ON ION-SELECTIVE ELECTRODE ON ISE MODULES ON BS SERIES AUTOMATIC CHEMISTRY ANALYZERS). BEFORE CARRYING OUT CLINICAL PRACTICE, PARAMETERS OF THE CHEMISTRY ANALYZER NEED TO BE CALIBRATED AS INSTRUCTED IN

	INSTRUMENT MANUAL.,M-58LEO(II) LYSE (MINDRAY)-M-58 LEO (II) LYSE APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT COOPERATES WITH THE M-58 LEO (I) LYSE TO 4 DIFFERENTIATE W8C'S,M-50 CLEANSER(MINDRAY)-M-50 CLEANSER APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLGY ANALYZER. IT IS AN ISOTONIC , CLEANING SOLUTION USE TO CLEAN THE ANALYSER,TOTAL BILIRUBIN (T-BIL) KIT (DSA METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BIL - T CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,BC-RET(MINDRAY)-BC-RET IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.,CD80 DETERGENT (MINDRAY)-CLEAN SAMPLE AND REAGENT PROBES, MIXERS AND CUVETTES OF THE CHEMISTRY ANALYZER MANUFACTURED BY MINDRAY.,M-50D DILUENT (MINDRAY)-M-50 D DILUENTS APPLIES TO MINDRAY 5 PART DIFFERENTIAL AUTO HEMATOLOGY ANALYZER. IT IS USED TO PROVIDE A STABLE ENVIRONMENT FOR COUNTING AND SIZING BLOOD CELLS,ISE-URINE DILUENT(MINDRAY)-ISE URINE DILUENT IS INTENDED FOR USE AS DILUENT FOR URINE BEFORE TEST ON ISE MODULES ON MINDRAY BS SERIES CHEMISTRY ANALYZERS., APOA1 KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF APOA1 CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,M-58 CLEANSER (MINDRAY)-PROBE CLEANSER APPLIES TO MINDRAY BC-5600, BC-5800, BC-3300, BC-3600 AUTO HEMATOLOGY ANALYZER. IT IS USED TO CLEAN THE ANALYZER REGULARLY. USE THE PROBE CLEANER AS INSTRUCTED BY THE OPERATOR'S MANUAL OF THE ANALYZER. ,M-68LD LYSE (MINDRAY)-THE M-68LD LYSE APPLIES TO MINDRAY BC-6800/BC-6600 AUTO HEMATOLOGY ANALYZER. IT PARTICIPATES IN WBC DIFFERENTIATION IN THE DIFF CHANNEL TOGETHER WITH M-68FD DYE.,M-50 LH LYSE(MINDRAY)-M-50 LH LYSE APPLIES TO 5 PART DIFFERNTIAL AUTO HEMATOLOGY ANALYSER. IT IS USED TO LYSE RED BLOOD CELLS AND DETERMINE THE HGB,V-28CFL LYSE (MINDRAY)-A CYANIDE FREE LYSE REAGENT, INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN AND LEUKOCYTE COUNTING AND SIZING,LIPASE (LIP) KIT (ENZYMATIC COLORIMETRIC ASSAY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF LIP CONCENTRATION IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEM,ANTIBODIES AGAINST STREPTOLYSIN O (ASO) KIT (PARTICLE-ENHANCED IMMUNOTURBIDIMETRIC ASSAY METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ASO CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,LDH KIT(MINDRAY)-LDH REAGENT IS

	INTENDED FOR QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. ,BC-6D (MINDRAY)-BC-6D IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS. ,AST KIT(MINDRAY)-AST REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OR PLASMA ON PHOTOMETRIC SYSTEM IN SERUM AST ACTIVITY,T-BIL KIT(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF BIL - T CONCENTRATION IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEM,M-18P PROBE CLEANSER(MINDRAY)-FOR USE ON MINDRAY BC-1800/BC-2800/BC-2600 HEMATOLOGY ANALYZER. FOR USE AS A CLEANING REAGENT FOR HEMATOLOGY ANALYZER PERIODICALLY. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL.,M-58LH LYSE -M-58 LH LYSE APPLIES TO MINDRAY BC-5600 , BC-5800 AUTO HEMATOLOGY ANALYZER. IT BREAKS DOWN RED BLOOD CELL MEMBRANE AND CONVERTS HEMOGLOBIN TO A HEMOGLOBIN COMPLEX TO DETERMINE THE HG8., PROBE CLEANSER (M-68/EN)(MINDRAY)-PROBE CLEANSER APPLIES TO MINDRAY BC-20, BC-21, BC-10, BC-11, BC-6800, BC-6600, BC-5000, BC-5150, BC-5390 CRP, BC-5180 CRP, BC-30S, BC-31S, BC-20S, BC-21S, BC-5120, BC-5130, BC-5310 CRP, BC-5100 CRP, BC-5140, BC-30, BC-31, BC-6000, BC-6000PLUS, BC-6100, BC-6100PLUS, BC-6200, BC-6600PLUS, BC-6700PLUS, BC-6800PLUS AUTO HEMATOLOGY ANALYZER, BC-5000VET VETERINARY AUTO HEMATOLOGY ANALYZER, SC-120 AUTO SLIDE MAKER & STAINER AND CRP-M100 SPECIFIC PROTEIN ANALYZER. IT IS USED TO CLEAN THE INSTRUMENT REGULARLY.,B55 CONTROL (MINDRAY)-B55 HEMATOLOGY CONTROL IS A HEMATOLOGY REFERENCE CONTROL USED TO MONITOR THE PERFORMANCE OF BC SERIES HEMATOLOGY ANALYZERS. THE REFERENCE VALUES AND EXPECTED RANGES OF PARAMETERS ARE DISPLAYED IN THE QUALITY CONTROL GRAPHS WITH UPPER AND LOWER CONTROL LIMITS. CLINICAL LABORATORIES USE STABILIZED, SIMULATED BLOOD CELL SUSPENSION TO MONITOR CORRESPONDING PARAMETERS. DAILY USE OF THIS WHOLE BLOOD CONTROL PROVIDES QUALITY CONTROL DATA FOR CONFIRMING THE PRECISION AND ACCURACY OF INSTRUMENT. ,CALCIUM(CA) KIT (ARSENAZO III METHOD)(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CA CONCENTRATION IN SERUM,PLASMA OR URINE ON PHOTOMETRIC SYSTEM,COMPLEMENT C3 KIT (IMMUNOTURBIDIMETRIC METHOD) (MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF C3 CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEM,M-53P CLEANSER(MINDRAY)-M-53P PROBE CLEANSER APPLIES TO

		MINDRAY BC-5300, BC-5380 BC-5100, BC-5180, ULTIMA 5 AUTO HEMATOLOGY ANALYZER. IT IS USED TO CLEAN THE ANALYZER REGULARLY. USE THE M-53P PROBE CLEANER AS INSTRUCTED BY THE OPERATOR'S MANUAL OF THE ANALYZER.
709	IMP/IVD/2020/000470	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NUCLISWAB(NUCLISWAB) -NUCLISWAB IS A TRANSPORT SYSTEM USED FOR COLLECTION AND TRANSPORT OF CELLS FROM CLINICAL SAMPLES OR FROM ENVIRONMENT, FOR ISOLATION OF NUCLEIC ACIDS THAT WILL BE USED IN NUCLEIC ACID AMPLIFICATION TESTS.
710	IMP/IVD/2020/000471	1.License Holder Name: IMPERIAL LIFE SCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 FLUORESCENT PCR(MACCURA)-FOR IN VITRO QUALITATIVE DETECTION OF SARS-COV-2 (ALSO KNOWN AS 2019-NCOV) ORF1AB, E, AND N GENE IN OROPHARYNGEAL SWABS AND SPUTUM SPECIMENS OF SUSPECTED SARS-COV-2-INFECTED PNEUMONIA CASES, SUSPECTED CLUSTERED INFECTION CASES, AND OTHERS WHO NEED SARS-COV-2 INFECTION DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS.,MAG-BIND RNA EXTRACTION KIT(MACCURA)-FOR EXTRACTION, ENRICHMENT, PURIFICATION AND OTHER STEPS OF NUCLEIC ACID WHICH IS USED FOR IN VITRO CLINICAL TESTS.

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711	IMP/IVD/2020/000474	1.License Holder Name: POINT OF CARE BIOMEDICAL PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIPID/GLU PANEL(SKYLA HI LIPID/GLU PANEL)-HE SKYLA HI LIPID PANEL PLUS USED WITH SKYLA HI ANALYZER IS INTENDED TO BE USED FOR THE QUANTITATIVE DETERMINATION OF BLOOD GLUCOSE (GLU), HIGH-DENSITY LIPOPROTEIN (HDL), TOTAL CHOLESTEROL (TC), AND TRIGLYCERIDE (TG) IN BOTH OF FINGER-PRICK WHOLE BLOOD, VENOUS WHOLE BLOOD, PLASMA OR SERUM.,HEMOGLOBIN A1C REAGENT KIT(SKYLA HI HEMOGLOBIN A1C REAGENT KIT)-THE SKYLATM HI HEMOGLOBIN A1C REAGENT KIT IS AN IMMUNOASSAY USED WITH SKYLATM HI ANALYZER PROVIDES QUANTITATIVE MEASUREMENT OF THE PERCENT CONCENTRATION OF GLYCATED HEMOGLOBIN (%HBA1C) IN BOTH OF CAPILLARY BLOOD TAKEN FROM THE FINGER-PRICK, AND VENOUS WHOLE BLOOD.,CRP REAGENT KIT(SKYLA HI CRP REAGENT KIT)-THE SKYLA HI CRP REAGENT KIT IS AN IMMUNOASSAY USED WITH SKYLA HI ANALYZER PROVIDES QUANTITATIVE MEASUREMENT OF C-REACTIVE PROTEIN (CRP) CONCENTRATION IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD.

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712	IMP/IVD/2020/000476	1.License Holder Name: INVITROGEN BIOSERVICES INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TAQMAN® FAST VIRUS 1-STEP MASTER MIX(APPLIED BIOSYSTEMS)-THE TAQMAN® FAST VIRUS 1-STEP MASTER MIX CAN BE USED WITH ANY TAQMAN® PRIMER AND PROBE SET FOR REAL-TIME RT-PCR OF DNA AND RNA SAMPLES. DURING THERMAL CYCLING, THE REVERSE TRANSCRIPTION STEP DOES NOT AFFECT PERFORMANCE WITH DNA TARGETS.,MAGMAX VIRAL/PATHOGEN BULK KIT 1000 PREPS (APPLIED BIOSYSTEMS)-THE MAGMAX VIRAL/PATHOGEN NUCLEIC ACID ISOLATION KIT IS DESIGNED TO RECOVER RNA AND DNA FROM VIRUS AND GRAM-NEGATIVE BACTERIA IN SAMPLES SUCH AS BLOOD, SWABS, URINE, AND VIRAL TRANSPORT MEDIA (VTM)., MAGMAX™ VIRAL/PATHOGEN II (MVP II) NUCLEIC ACID ISOLATION KIT 2,000 PREPS(APPLIED BIOSYSTEMS)-THE MAGMAX VIRAL/PATHOGEN II (MVP II) NUCLEIC ACID ISOLATION KIT IS SPECIFICALLY DESIGNED TO RECOVER RNA AND DNA FROM VIRAL PARTICLES CONTAINED IN VIRAL TRANSPORT MEDIA (VTM). THE KIT UTILIZES MAGMAX MAGNETIC-BEAD TECHNOLOGY, ENSURING REPRODUCIBLE RECOVERY OF HIGH-QUALITY NUCLEIC ACID,5X MAGMAX PATHOGEN RNA/DNA KIT(APPLIED BIOSYSTEMS)-THE APPLIED BIOSYSTEMS® MAGMAX™ PATHOGEN RNA/DNA KIT ENABLES PURIFICATION OF RNA AND DNA FROM VIRUSES AND EASY-TO-LYSE BACTERIA AND PARASITES, USING MAGNETIC PARTICLE TECHNOLOGY IN A 96-WELL FORMAT.
713	IMP/IVD/2020/000477	1.License Holder Name: V S YARNS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCO COVID-19 IGM/IGG RAPID TEST(ACCO COVID-19 IGM/IGG RAPID TEST)-ACCO COVID-19 IGM/IGG DEVICE IS A CHROMATOGRAPHIC IMMUNOASSAY KIT FOR THE RAPID AND DIFFERENTIAL DETECTION OF IMMUNOGLOBULIN M (LGM) AND IMMUNOGLOBULIN G (IGG) AGAINST COVID- 19 USING SERUM, PLASMA AND WHOLE BLOOD

714	IMP/IVD/2020/000478	1.License Holder Name: INVITROGEN BIOSERVICES INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAGMAX VIRAL/PATHOGEN KIT(APPLIED BIOSYSTEMS)-THE APPLIED BIOSYSTEMS™ MAGMAX™ VIRAL/PATHOGEN NUCLEIC ACID ISOLATION KIT IS DEVELOPED FOR SCALABLE, RAPID PURIFICATION OF HIGH QUALITY NUCLEIC ACID (RNA AND DNA) FROM VIRUS AND EASY TO LYSE BACTERIA IN BIOFLUID AND TRANSPORT MEDIA SAMPLES.
715	IMP/IVD/2020/000479	1.License Holder Name: M/S HEMOGENOMICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PROCLEIX ULTRIO ELITE ASSAY KIT (A QUALITATIVE IN-VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DETECTION OF HIV 1 & 2 RNA, HCV RNA AND HBV DNA IN PLASMA AND SERUM SPECIMENS FROM HUMAN DONORS) (PROCLEIX ULTRIO ELITE)-THE PROCLEIX ULTRIO ELITE ASSAY IS A QUALITATIVE IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND HUMAN IMMUNODEFICIENCY VIRUS TYPE 2 (HIV) RNA, HEPATITIS C VIRUS (HCV) RNA, AND/OR HEPATITIS B VIRUS (HBV) DNA IN PLASMA AND SERUM SPECIMENS FROM HUMAN DONORS, TESTED INDIVIDUALLY OR IN POOLS. IT IS ALSO INTENDED FOR USE IN TESTING PLASMA AND SERUM TO SCREEN ORGAN AND TISSUE DONORS, INCLUDING CADAVERIC (NONHEART- BEATING) DONORS , PROCLEIX ULTRIO PLUS ASSAY KIT (A QUALITATIVE IN-VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DETECTION OF HIV 1 RNA, HCV RNA AND HBV DNA IN PLASMA AND SERUM SPECIMENS FROM HUMAN DONORS)(PROCLEIX ULTRIO PLUS)-THE PROCLEIX ULTRIO PLUS ASSAY IS A QUALITATIVE IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) RNA, HEPATITIS C VIRUS (HCV) RNA, AND/OR HEPATITIS B VIRUS (HBV) DNA IN PLASMA AND SERUM SPECIMENS FROM HUMAN DONORS, TESTED INDIVIDUALLY OR IN POOLS. IT IS ALSO INTENDED FOR USE IN TESTING PLASMA AND SERUM TO SCREEN ORGAN AND TISSUE DONORS, INCLUDING CADAVERIC (NON-HEART-BEATING) DONORS

716	IMP/IVD/2020/000481	1.License Holder Name: DEEP MEDITECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IST CARD-USED FOR IDENTIFICATION AND ANTIMICROBIAL MIC DETERMINATIONS, ANAEROBIC BLOOD CULTURE BOTTLE-USED FOR QUALITATIVE DETECTION OF MICROBIAL IN HUMAN BLOOD OR OTHER BODY FLUIDS UNDER NORMAL STERILE CONDITIONS,CHILDREN'S BLOOD CULTURE BOTTLE-USED FOR QUALITATIVE DETECTION OF MICROBIAL IN HUMAN BLOOD OR OTHER BODY FLUIDS UNDER NORMAL STERILE CONDITIONS,AEROBIC BLOOD CULTURE BOTTLE-USED FOR QUALITATIVE DETECTION OF MICROBIAL IN HUMAN BLOOD OR OTHER BODY FLUIDS UNDER NORMAL STERILE CONDITIONS
717	IMP/IVD/2020/000482	1.License Holder Name: GENAXY SCIENTIFIC PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DNA & RNA ISOLATION KITS(FAVORGEN)-FOR ISOLATION OF DNA & RNA FROM VARIOUS SAMPLES
718	IMP/IVD/2020/000483	1.License Holder Name: BYUNGMAN ELECTRIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 REAL-TIME RT-PCR KIT(PAXVIEW)-THE PAXVIEW® COVID-19 REAL-TIME RT-PCR KIT DETECTS THE NOVEL CORONAVIRUS, COVID-19 USING ONE-STEP REALTIME RT-PCR IN A SINGLE TUBE. THE TARGET GENES FOR THE DETECTION OF THE VIRUS ARE ORF1AB AND N GENE. THE SEQUENCE OF PRIMERS AND PROBES FOR THE AMPLIFICATION WERE ADAPTED FROM SOURCES PUBLISHED BY CHINA CDC AND WHO.WE RECOMMEND USE VIRAL RNA EXTRACTED FROM OROPHARYNGEAL SWAB, NASOPHARYNGEAL SWAB, SPUTUM AND BRONCHOALVEOLAR LAVAGE(BAL) SAMPLE.
719	IMP/IVD/2020/000484	1.License Holder Name: INBIOS INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAT-NAT® COVID-19 HK-THE STAT-NAT® COVID-19 HK KIT IS A LYOPHILIZED REAL-TIME RT-PCR QUALITATIVE ASSAY BASED ON NUCLEIC ACID AMPLIFICATION FOR THE IDENTIFICATION OF THE NOVEL CORONAVIRUS SARS-COV-2 RNA IN HUMAN RESPIRATORY TRACT SPECIMENS

720	IMP/IVD/2020/000485	1.License Holder Name: DEEP MEDITECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 NUCLEIC ACID DETECTION KIT (PCR-FLUORESCENT PROBE METHOD)-FOR DETECTION OF SARS-COV-2 RNA IN SPUTUM, THROAT SWAB, ALVEOLAR LAVAGE FLUIDS SPECIMENS

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721	IMP/IVD/2020/000486	1.License Holder Name: LAB X 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHOLESTEROL LS(LAB KIT)-CHEMELEX LABKIT BRAND CHOLESTEROL LS IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CHOLESTEROL. ,COMPLEMENT C3(LABKIT)-QUANTITATIVE DETERMINATION OF COMPLEMENT C3 IN HUMAN SAMPLES,IRON-FZ (LAB KIT)-CHEMELEX LABKIT BRAND IRON-FZ IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF IRON. , HDLC-D(LABKIT)-QUANTITATIVE DETERMINATION OF CHOLESTEROL HDL IN HUMAN SAMPLES,BILIRUBIN T-DMSO(LAB KIT)-CHEMELEX LABKIT BRAND BILIRUBIN T-DMSO IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF DIRECT BILIRUBIN. ,LABTROL H PATHOLOGICAL(LABKIT)-LABTROL PATHOLOGICAL IS MULTI PARAMETRIC CONTROL SERA INTENDED FOR ACCURACY CONTROL OF LABKIT CLINICAL CHEMISTRY REAGENTS. THE CONCENTRATION AND ACTIVITIES ARE IN THE PATHOLOGICAL RANGE (BOVIN SOURCE),IGM(LAB KIT)-CHEMELEX LABKIT BRAND IGM IN INTENDED FOR IVD HUMAN IMMUNOGLOBULIN M (IGM) ,APO B(LABKIT)-QUANTITATIVE DETERMINATION OF HUMAN APOLIPOPROTEIN B (APO B),CK-NAC LQ(LAB KIT)-CHEMELEX LABKIT BRAND CK-NAC LQ IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF CK-NAC. ,CRP- TURBI(LABKIT)-QUANTITATIVE DETERMINATION OF C REACTIVE PROTEIN IN HUMAN SAMPLES.,TRIGLYCERIDES(LAB KIT)-CHEMELEX LABKIT BRAND TRIGLYCERIDES IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF TRIGLYCERIDES. ,LIPASE -LQ (LABKIT)-QUANTITATIVE DETERMINATION OF THE LIPASE ACTIVITY IN HUMAN SAMPLES.,URIC ACID-LS(LAB KIT)-CHEMELEX LABKIT BRAND URIC ACID LS IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF URIC ACID. ,CRP LATEX KIT (LABKIT)-QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SAMPLES,IGA(LAB KIT)-CHEMELEX LABKIT BRAND IGA IN INTENDED FOR IVD HUMAN IMMUNOGLOBULIN A (IGA) ,ASO- TURBI (LABKIT)-QUANTITATIVE DETERMINATION OF ASO IN HUMAN SAMPLES,BILIRUBIN T&D-DMSO(LAB KIT)-CHEMELEX LABKIT BRAND BILIRUBIN T&D-DMSO IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF DIRECT AND TOTAL BILIRUBIN. , COMPLEMENT C4(LABKIT)-QUANTITATIVE DETERMINATION OF COMPLEMENT C4 IN HUMAN SAMPLES,CHLORIDE(LAB KIT)-CHEMELEX LABKIT BRAND CHLORIDE IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF CHLORIDE. ,LABTROL H NORMAL(LABKIT)-LABTROL NORMAL IS MULTI PARAMETRIC CONTROL SERA INTENDED FOR ACCURACY

	CONTROL OF LABKIT CLINICAL CHMISTRY REAGENTS.THE CONCENTRATION & ACTIVITIES ARE IN THE NORMAL RANGE OR AT THE NORMAL THRESHOLD (BOVINE SOURCE).,MAGNESIUM(LAB KIT)-CHEMELEX LABKIT BRAND MAGNESIUM IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF MAGNESIUM.,CHE CHOLINSTERASE(LABKIT)-QUANTITATIVE DETERMINATION OF THE CHOLINESTERASE ACTIVITY IN HUMAN SAMPLES.,CALCIUM-AIII(LAB KIT)-CHEMELEX LABKIT BRAND CALCIUM-AIII IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CALCIUM. ,AMYLASE-LQ(LABKIT)-QUANTITATIVE DETERMINATION OF THE ALPHA AMYLASE ACTIVITY IN HUMAN SAMPLES,LDH-LQ(LAB KIT)-CHEMELEX LABKIT BRAND LDH-LQ IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF LACTATE DEHYDROGENASE (LDH). ,TIBC(LABKIT)-QUANTITATIVE DETERMINATION OF IRON TIBC IN HUMAN SAMPLES.,UREA-UV-LQ(LAB KIT)-CHEMELEX LABKIT BRAND UREA UV-LQ IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF UREA. ,RF LATEX KIT(LABKIT)-QUALITATIVE DETERMINATION OF RHEUMATID FACTOR IN HUMAN IN HUMAN SAMPLE,LP(A) TURBI(LAB KIT)-CHEMELEX LABKIT BRAND LP (A) TURBI IN INTENDED FOR IVD QUANTITATIVE MEASURE THE LP(A). , LABTROL H CAL(LABKIT)-LABTROL H CALIBRATOR IS MULTI PARAMETRIC CALIBRATOR INTENDED FOR ACCURACY CALIBRATION OF LABKIT REAGENTS (BOVINE SOURCE).,CO2 LQ(LAB KIT)-CHEMELEX LABKIT BRAND CO2 LQ IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF CARBON DIOXIDE.,ASO LATEX KIT(LABKIT)-QUANTITATIVE DETERMINATION OF ASO IN HUMAN SAMPLES,PROT-CAL(LAB KIT)-CHEMELEX LABKIT BRAND PROT-CAL IN INTENDED FOR IVD QUANTITATIVE DETERMINATION OF PROTEINS (PROT),ACP ACID PHOSPHATASE (LABKIT)-QUANTITATIVE DETERMINATION OF ACID PHOSPHATASE (ACP) ACTIVITY IN HUMAN SAMPLES.,CK-MB LQ(LAB KIT)-CHEMELEX LABKIT BRAND CK-MB LQ IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF CK-MB. ,APO A1(LABKIT)-QUANTITATIVE DETERMINATION OF HUMAN APOLIPOPROTEIN A1 (APO A1),ALBUMIN(LAB KIT)-CHEMELEX LABKIT BRAND ALBUMIN IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF ALBUMIN.,PROTEIN U & CSF(LABKIT)-QUANTITATIVE DETERMINATION OF TOTAL URINARY & CSF PROTEIN IN HUMAN SAMPLES.,TOTAL PROTEINS(LAB KIT)-CHEMELEX LABKIT BRAND TOTAL PROTEIN IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF TOTAL PROTEINS. ,LDLC-D (LABKIT)-QUANTITATIVE DETERMINATION OF CHOLESTROL LDL IN HUMAN SAMPLES,GAMMA-GT-LQ(LAB KIT)-CHEMELEX LABKIT

	BRAND -GT LQ IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF GAMMA-GLUTAMYL TRANSFERASE (-GT) ,RF - TURBI(LABKIT)-QUANTITATIVE DETERMINATION OF RHEUMATID FACTOR IN HUMAN SAMPLES., TRIGLYCERIDES-LS(LAB KIT)-CHEMELEX LABKIT BRAND TRIGLYCERIDES IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF TRIGLYCERIDES. ,APO - CAL (LABKIT)-SERUM CALIBRATOR FOR APO A1/B TURBIDIMETRY ASSAY, TOTAL LIPIDS(LAB KIT)-CHEMELEX LABKIT BRAND TOTAL LIPIDS IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF TOTAL LIPIDS. ,MICROALBUMIN-TURBI(LAB KIT)-CHEMELEX LABKIT BRAND MICROALBUMIN TURBI IN INTENDED FOR IVD QUANTITATIVE MEASURE THE MICROALBUMIN.,IGE-TURBI(LAB KIT)-CHEMELEX LABKIT BRAND IGE TURBI IN INTENDED FOR IVD QUANTITATIVE MEASURE THE IGE. ,ALP LQ(LAB KIT)-CHEMELEX LABKIT BRAND ALP-LQ IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF ALKALINE PHOSPHATASE (ALP),GOT/AST-LQ(LAB KIT)-CHEMELEX LABKIT BRAND GOT/AST-LQ IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF GOT/AST. ,CREATININE-J(LAB KIT)-CHEMELEX LABKIT BRAND CREATININE-J IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CREATININE. ,BILIRUBIN D-DMSO(LAB KIT)-CHEMELEX LABKIT BRAND BILIRUBIN D-DMSO IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF DIRECT BILIRUBIN. ,LACTATE-LQ(LAB KIT)-CHEMELEX LABKIT BRAND LACTATE IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF LACTATE. ,GPT/ALT-LQ(LAB KIT)-CHEMELEX LABKIT BRAND GPT/ALT-LQ IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF GPT/ALT. ,CHOLESTEROL(LAB KIT)-CHEMELEX LABKIT BRAND CHOLESTEROL IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTICS DETERMINATION OF CHOLESTEROL. ,IGG(LAB KIT)-CHEMELEX LABKIT BRAND IGG IN INTENDED FOR IVD HUMAN IMMUNOGLOBULIN G (IGG) , PHOSPHORUS-UV(LAB KIT)-CHEMELEX LABKIT BRAND PHOSPHORUS-UV IN INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF PHOSPHORUS.

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722	IMP/IVD/2020/000488	1.License Holder Name: ALPHA AGENCIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RT PCR KIT(LILIF COVID 19 REAL TIME RT PCR KIT)-SPUTUM, BRONCHOALVEOLAR LAVAGE FLUID (BAL) IN PATIENTS WITH SUSPECTED RESPIRATORY INFECTIONS, OR NASOPH ARYNGEAL SWAB (NS) AND OROPHARYNGEAL SWAB (OS) COLLECTED SIMULTANEOUSLY IN THE UPPER RESPIRATORY TRAC T IN VITRO DIAGNOSTIC MEDICAL DEVICE THAT HELPS TO DIAGNOSE NEW CORONAVIRUS INFECTION (COVID-19) BY QUALITATIVELY DETECTING GENES (RDRP GENE, E GENE, AND N GENE) OF NEW CORONAVIRUS (2019-NCOV) FROM THE SAMPLE., RNA/DNA EXTRACTION KIT(PATHO GENE-SPIN VIRAL DNA/RNA EXTRACTION KIT)-PATHOGEN DETECTION, PCR, RT-PCR, QUANTITATIVE PCR (QPCR, QRT- PCR)
723	IMP/IVD/2020/000489	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MEDONIC LYSE L-2 (MEDONIC M51 LYSE L-2 500 ML)-USED IN IN-VITRO DIAGNOSTIC, EASY CLEANER (BOULE EASY CLEANER)-USED IN IN-VITRO DIAGNOSTIC ,MEDONIC DILUENT (MEDONIC M51-D DILUENT 20 L)-USED IN IN-VITRO DIAGNOSTIC,MEDONIC LYSE L-1(MEDONIC M51 LYSE L-1 200 ML)-USED IN IN-VITRO DIAGNOSTIC

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724	IMP/IVD/2020/000490	1.License Holder Name: CEPHEID INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:XPERT XPRESS SARS-COV-2(XPERT XPRESS SARS-COV-2)-THE XPERT XPRESS SARS-COV-2 TEST IS A RAPID, REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN UPPER RESPIRATORY SPECIMENS (SUCH AS NASOPHARYNGEAL, OROPHARYNGEAL, NASAL, OR MID-TURBINATE SWAB AND/OR NASAL WASH/ ASPIRATE) COLLECTED FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. TESTING OF NASOPHARYNGEAL, OROPHARYNGEAL, NASAL, OR MID-TURBINATE SWAB AND NASAL WASH/ASPIRATE SPECIMENS USING THE XPERT XPRESS SARSCOV-2 TEST RUN ON THE GENEXPERT DX AND GENEXPERT INFINITY SYSTEMS IS LIMITED TO LABORATORIES CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C. § 263A, TO PERFORM HIGH AND MODERATE COMPLEXITY TESTS. TESTING OF NASOPHARYNGEAL, NASAL, OR MIDTURBINATE SWAB SPECIMENS USING THE XPERT XPRESS SARS-COV-2 TEST RUN ON THE GENEXPERT XPRESS SYSTEM (TABLET AND HUB CONFIGURATIONS) IS AUTHORIZED TO BE DISTRIBUTED AND USED IN PATIENT CARE SETTINGS OUTSIDE OF THE CLINICAL LABORATORY ENVIRONMENT. RESULTS ARE FOR THE DETECTION OF SARS-COV-2 RNA. THE SARS-COV-2 RNA IS GENERALLY DETECTABLE IN UPPER RESPIRATORY SPECIMENS DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS ARE INDICATIVE OF ACTIVE INFECTION WITH SARS-COV2; CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. LABORATORIES WITHIN THE UNITED STATES AND ITS TERRITORIES ARE REQUIRED TO REPORT ALL POSITIVE RESULTS TO THE APPROPRIATE PUBLIC HEALTH AUTHORITIES. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER PATIENT MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. TESTING WITH THE XPERT XPRESS SARS-COV-2 TEST IS INTENDED FOR USE BY TRAINED OPERATORS WHO ARE PROFICIENT IN PERFORMING TESTS USING EITHER GENEXPERT DX, GENEXPERT INFINITY AND/OR GENEXPERT XPRESS SYSTEMS. THE XPERT XPRESS SARS-COV-2 TEST IS ONLY FOR USE UNDER THE FOOD AND DRUG ADMINISTRATION'S EMERGENCY USE

	AUTHORIZATION. ,XPERT XPRESS FLU/RSV(XPERT XPRESS FLU/RSV) -REAL-TIME, REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION (RT-PCR) ASSAY INTENDED FOR THE IN VITRO QUALITATIVE DETECTION AND DIFFERENTIATION OF INFLUENZA A, INFLUENZA B, AND RESPIRATORY SYNCYTIAL VIRUS (RSV) VIRAL RNA. THE XPERT XPRESS FLU/RSV ASSAY USES NASOPHARYNGEAL (NP) SWAB AND NASAL SWAB (NS) SPECIMENS COLLECTED FROM PATIENTS WITH SIGNS AND SYMPTOMS OF RESPIRATORY INFECTION. THE XPERT XPRESS FLU/RSV ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF INFLUENZA AND RESPIRATORY SYNCYTIAL VIRUS INFECTIONS IN CONJUNCTION WITH CLINICAL AND EPIDEMIOLOGICAL RISK FACTORS. NEGATIVE RESULTS DO NOT PRECLUDE INFLUENZA VIRUS OR RSV INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER PATIENT MANAGEMENT DECISIONS. PERFORMANCE CHARACTERISTICS FOR INFLUENZA A WERE ESTABLISHED DURING THE 2015-2016 INFLUENZA SEASON FOR NP SWAB SPECIMENS AND THE 2016-2017 INFLUENZA SEASON FOR NS SPECIMENS. WHEN OTHER NOVEL INFLUENZA A VIRUSES ARE EMERGING, PERFORMANCE CHARACTERISTICS MAY VARY. IF INFECTION WITH A NOVEL INFLUENZA A VIRUS IS SUSPECTED BASED ON CURRENT CLINICAL AND EPIDEMIOLOGICAL SCREENING CRITERIA RECOMMENDED BY PUBLIC HEALTH AUTHORITIES, SPECIMENS SHOULD BE COLLECTED WITH APPROPRIATE INFECTION CONTROL PRECAUTIONS FOR NOVEL VIRULENT INFLUENZA VIRUSES AND SENT TO STATE OR LOCAL HEALTH DEPARTMENTS FOR TESTING. VIRAL CULTURE SHOULD NOT BE ATTEMPTED IN THESE CASES UNLESS A BSL 3+ FACILITY IS AVAILABLE TO RECEIVE AND CULTURE SPECIMENS.

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725	IMP/IVD/2020/000491	1.License Holder Name: ASPEN DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REFILL SOLUTION (ISE)-INTENDED TO PROVIDE PROPER FUNCTIONING OF ELECTRODES USED FOR ESTIMATION OF SODIUM, POTASSIUM, CHLORIDE, CALCIUM PH & LITHIUM PARAMETERS IN SERUM/PLASMA/ OTHER BODY FLUIDS.,ELECTROLYTES QUALITY CONTROL (ISE)-INTENDED FOR QUALITY CONTROL OF REAGENT KITS INTENDED FOR ESTIMATION OF SODIUM, POTASSIUM, CHLORIDE, CALCIUM PH & LITHIUM PARAMETERS IN SERUM/PLASMA/ OTHER BODY FLUIDS., CALIBRATION STANDARD SOLUTION (ISE)-REAGENT KIT INTENDED FOR THE ESTIMATION OF SODIUM, POTASSIUM, CHLORIDE, CALCIUM PH & LITHIUM PARAMETERS IN SERUM/PLASMA/ OTHER BODY FLUIDS,CONDITIONING SOLUTION-INTENDED TO MAINTAIN ELECTRODES OF ELECTROLYTE ANALYZERS ,DE-PROTEINIZER-INTENDED TO MAINTAIN ELECTRODES ON ELECTROLYTE ANALYZERS
726	IMP/IVD/2020/000493	1.License Holder Name: HOLLY DRUGS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19(SARS-COV-2) NUCLEIC ACID TEST KIT (PCR-FLUORESCENCE PROBE METHOD) (SARS-COV-2 NUCLEIC ACID TEST KIT)-THE KIT IS USED FOR THE IN VITRO DETECTION OF SUSPECTED CASES AND SUSPECTED CLUSTERED CASES OF 2019-NCOV, AS WELL AS 2019-NCOV NUCLEIC ACID IN OROPHARYNGEAL SWABS, NASOPHARYNGEAL SWABS OR SPUTUM SPECIMENS OF OTHER PATIENTS WHO NEED TO GO THROUGH INFECTION DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS OF 2019-NCOV, AND IT IS FOR THE AUXILIARY DIAGNOSIS OF 2019-NCOV.
727	IMP/IVD/2020/000495	1.License Holder Name: CLINIEXPERTS SERVICES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 COLLOIDAL GOLD IMMUNOASSAY TESTING KIT, IGG/IGM COMBINED(EDINBURGH GENETICS)-THIS KIT IS USED TO QUALITATIVELY DETECT IGG AND IGM ANTIBODIES OF THE COVID-19 NOVEL CORONAVIRUS IN HUMAN SERUM, PLASMA OR WHOLE BLOOD IN VITRO.,COMPLETE WHOLE BLOOD COLLECTION KIT(EDINBURGH GENETICS)-EDINBURGH GENETICS COMPLETE WHOLE BLOOD COLLECTION KIT IS A SINGLE-USE DEVICE INTENDED TO BE USED BY HEALTHCARE PROFESSIONALS AND RESEARCHERS TO COLLECT FINGERPRICK WHOLE BLOOD SAMPLES.

728	IMP/IVD/2020/000496	1.License Holder Name: GODOLO & GODOLO EXPORTS PVT LTD . 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIAGNOVITAL SARS-COV-2 REAL TIME PCR KIT(DIAGNOVITAL)-THE USE OF REAL-TIME RT-PCR ASSAYS IS FOR THE IN VITRO QUALITATIVE DETECTION OF 2019-NOVEL CORONAVIRUS (SARS-COV-2) IN RESPIRATORY SPECIMENS. THE SARS-COV-2 PRIMER AND PROBE SETS ARE DESIGNED FOR THE SPECIFIC DETECTION OF SARS-COV-2.
729	IMP/IVD/2020/000498	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALINITY H-SERIES WRIGHT-GIEMSA STAIN(ALINITY H-SERIES WRIGHT-GIEMSA STAIN)-THE MAJOR FUNCTION OF THE ALINITY H-SERIES WRIGHT-GIEMSA STAIN SOLUTIONS IS TO PROVIDE A ROMANOWSKY DYE (A VARIETY OF THIAZINES AND EOSINS) THAT IS REQUIRED TO STAIN BLOOD FILMS. THESE DYES IMPART COLORATION TO CELLS AND OTHER BLOOD ELEMENTS TO ENABLE THE DIFFERENTIAL IDENTIFICATION OF CELLS AND QUALITY ASSESSMENT OF THEIR MORPHOLOGY FOR DIAGNOSTIC PURPOSES. THE ALINITY HS SLIDE MAKER STAINER MODULE SUPPORTS THE ALINITY H-SERIES WRIGHT-GIEMSA STAIN., ALINITY H-SERIES MAY-GRUNWALD-GIEMSA STAIN(ALINITY H-SERIES MAY-GRUNWALD-GIEMSA STAIN)-THE MAJOR FUNCTION OF THE STAIN SOLUTIONS IS TO PROVIDE ROMANOWSKY DYES (A VARIETY OF THIAZINES AND EOSINS) THAT ARE REQUIRED TO STAIN BLOOD FILMS. THESE DYES IMPART COLORATION TO CELLS AND OTHER BLOOD ELEMENTS TO ENABLE THE DIFFERENTIAL IDENTIFICATION OF CELLS AND QUALITY ASSESSMENT OF THEIR MORPHOLOGY FOR DIAGNOSTIC PURPOSES.,ALINITY H-SERIES SMEAR FIX(ALINITY H-SERIES SMEAR FIX)-THE SMEAR FIX REAGENT IS USED FOR THE FOLLOWING FUNCTIONS FIXES AND PROVIDES PERMEABILITY OF THE CELLS IN PREPARATION FOR STAINING. PRESERVES THE MORPHOLOGY OF THE CELLS.
730	IMP/IVD/2020/000501	1.License Holder Name: BIOHOUSE SOLUTIONS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAT-NAT COVID-19 B (STAT-NAT COVID-19 B)-THE STAT-NAT COVID-19 B KIT IS A LYOPHILIZED REAL-TIME RT-PCR QUALITATIVE ASSAY BASED ON NUCLEIC ACID AMPLIFICATION FOR THE IDENTIFICATION OF THE NOVEL CORONAVIRUS SARS-COV-2 RNA IN HUMAN RESPIRATORY TRACT SPECIMENS. THIS ASSAY IS AN AID IN THE DIAGNOSIS OF SARS-COV-2 INFECTION.

731	IMP/IVD/2020/000502	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AXIS SHIELD HOMOCYSTEINE CONTROLS (AXIS SHIELD HOMOCYSTEINE CONTROLS)-THE AXIS SHIELD HOMOCYSTEINE CONTROL KIT IS INTENDED TO BE USED AS AN ASSAYED QUALITY CONTROL SERUM WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF TOTAL L-HOMOCYSTEINE IN HUMAN SERUM OR PLASMA. ,AXIS SHIELD LIQUID STABLE (LS) 2-PART HOMOCYSTEINE REAGENT(AXIS SHIELD LIQUID STABLE (LS) 2-PART HOMOCYSTEINE REAGENT)-THE LIQUID STABLE (LS) 2-PART HOMOCYSTEINE REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF TOTAL HOMOCYSTEINE IN HUMAN SERUM AND PLASMA. THE DEVICE CAN ASSIST IN THE DIAGNOSIS AND TREATMENT OF PATIENTS SUSPECTED OF HAVING HYPERHOMOCYSTEINEMIA AND HOMOCYSTINURIA.
732	IMP/IVD/2020/000509	1.License Holder Name: CYGEN PHARMA & SURGICALS (A UNIT OF CYGEN CONSULTANCY PVT LTD) 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALLPLEX® 2019-NCOV ASSAY (ALLPLEX®)-ALLPLEXTM 2019-NCOV ASSAY IS IN VITRO DIAGNOSTIC MEDICAL DEVICE DESIGNED FOR QUALITATIVE DETECTION OF NOVEL CORONA VIRUS (2019-NCOV) WITH REAL-TIME REVERSE TRANSCRIPTION PCR FROM SPUTUM, NASOPHARYNGEAL ASPIRATE, THROAT & NASOPHARYNGEAL SWAB, AND BRONCHOALVEOLAR LAVAGE.
733	IMP/IVD/2020/000510	1.License Holder Name: DEEP MEDITECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTI-SARS-COV-2 RAPID TEST-FOR THE RAPID, QUALITATIVE DETERMINATION OF ANTI-SARS-COV-2 (IGG/IGM ANTIBODIES OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.
734	IMP/IVD/2020/000511	1.License Holder Name: STAG GLOBAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 TEST KIT-GENEFINDER COVID-19 PLUS REALAMP KIT IS THE ONE-STEP REVERSE TRANSCRIPTION REAL-TIME PCR KIT DESIGNED TO DETECT NOVEL CORONA VIRUS (COVID-19) QUALITATIVELY THROUGH REVERSE TRANSCRIPTION REACTION AND REAL-TIME POLYMERASE CHAIN REACTION.

735	IMP/IVD/2020/000512	1.License Holder Name: JAYA SURGICAL AND PHARMA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (2019-NCOV) NUCLEIC ACID DIAGNOSTIC KIT-NOVEL CORONAVIRUS (2019-NCOV) NUCLEIC ACID DIAGNOSTIC KIT (PCR-FLUORESCENCE PROBING) IS USED FOR QUALITATIVE DETECTION OF THE ORF1AB AND N GENES OF NOVEL CORONAVIRUS (2019- NCOV) IN NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, ALVEOLAR LAVAGE FLUID, SPUTUM, SERUM, WHOLE BLOOD AND FECES FROM SUSPECTED PNEUMONIA CASES WITH NOVEL CORONAVIRUS INFECTION, PATIENTS WITH SUSPECTED CLUSTERS OF NOVEL CORONAVIRUS INFECTION, AND OTHER PATIENTS REQUIRING DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS OF NOVEL CORONAVIRUS INFECTION
736	IMP/IVD/2020/000513	1.License Holder Name: BHARAT PARENTERALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RADI PREP SWAB AND STOOL DNA/RNA KIT(RADI PREP SWAB AND STOOL DNA/RNA KIT)-THE RADI PREP SWAB AND STOOL DNA / RNA KIT IS A REAGENT USED TO EXTRACT NUCLEIC ACIDS FROM BACTERIA AND VIRUSES PRESENT IN SAMPLES COLLECTED FROM HUMAN FECES, ANUS, VAGINA, OR PHARYNX USING COTTON SWABS. THE EXTRACTED NUCLEIC ACID CAN BE USED IN ALL EXPERIMENTS THAT REQUIRE NUCLEIC ACIDS, SUCH AS REAL-TIME PCR AND NGS. THE KIT IS FOR USE BY A LABORATORY PROFESSIONAL.,RADI COVID-19 DETECTION KIT(RADI COVID-19 DETECTION KIT)-THE RADI COVID-19 DETECTION KIT IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE, BASED ON REAL TIME RT-PCR TECHNOLOGY UTILIZING REVERSE-TRANSCRIPTASE (RT) REACTION TO CONVERT RNA INTO COMPLEMENTARY DNA (CDNA). IT IS INTENDED FOR THE PRESUMPTIVE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE COVID-19 IN UPPER AND LOWER RESPIRATORY SPECIMENS.

737	IMP/IVD/2020/000514	1.License Holder Name: INVITROGEN BIOSERVICES INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TAQPATH™ COVID-19 CE-IVD RT-PCR KIT(APPLIED BIOSYSTEMS)-TAQPATH™ COVID-19 CE-IVD RT-PCR KIT CONTAINS THE REAGENTS AND CONTROLS FOR A REAL-TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN NASOPHARYNGEAL SWAB, NASOPHARYNGEAL ASPIRATE, AND BRONCHOALVEOLAR LAVAGE (BAL) SPECIMENS FROM INDIVIDUALS SUSPECTED OF COVID-19.
738	IMP/IVD/2020/000515	1.License Holder Name: LAB X 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MOLECUTECH REAL-TIME COVID-19(YD)-MOLECUTECH® REAL-TIME COVID-19 TEST IS A REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN SPUTUM, BRONCHIAL ALVEOLAR LAVAGE FLUID, OROPHARYNGEAL AND NASOPHARYNGEAL SWAB SAMPLES FROM INDIVIDUALS WITH SIGNS AND SYMPTOMS OF INFECTION WHO ARE SUSPECTED OF COVID-19. TESTING IS LIMITED TO LABORATORIES - CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C. §263A, TO PERFORM HIGH COMPLEXITY TESTS.
739	IMP/IVD/2020/000518	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALINITY H-SERIES AUTOCLEAN SOLUTION(ALINITY H-SERIES AUTOCLEAN SOLUTION)-ALINITY H-SERIES AUTOCLEAN SOLUTION IS INTENDED TO CLEAN AND SANITIZE THE ALINITY HQ MODULE.

740	IMP/IVD/2020/000523	1.License Holder Name: ANAND BROTHERS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HBA1C (GHB) CONTROL KIT(HBA1C (GHB) CONTROL KIT)-HBA1C (GHB) CONTROLS ARE INTENDED TO MONITOR THE PERFORMANCE OF GLYCATED HEMOGLOBIN ASSAYS.,PREMIER WASH REAGENT(PREMIER WASH REAGENT)-THE PREMIER DILUENT REAGENT IS INTENDED FOR USE WITH TRINITY BIOTECH PREMIER HB9210TM HBAIC ANALYZER ONLY. THE PREMIER SYSTEM IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN HUMAN CAPILLARY AND VENOUS WHOLE BLOOD. HBA1C IS USED FOR THE MONITORING OF LONG-TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETS MELLITUS.,PREMIER AFFINITY A1C(PREMIER AFFINITY A1C)-PREMIER AFFINITY AIC SET IS INTENDED FOR USE WITH TRINITY BIOTECH PREMIER HB9210TM ANALYZER ONLY. THE PREMIER AFFINITY AIC IS INTENDED FOR THE QUANTITATIVE MEASUEMENT OF HEMOGLOBIN AIC (HBA1C) IN HUMAN CAPILLARY AND VENOUS WHOLE BLOOD., PREMIER BUFFER B REAGENT(PREMIER BUFFER B REAGENT)-THIS REAGENT IS INTENDED FOR USE WITH TRINITY BIOTECH PREMIER HB9210TM HBAIC ANALYZER ONLY. THE PREMIER HB9210TM SYSTEM IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN HUMAN CAPILLARY AND VENOUS WHOLE BLOOD. HBA1C IS USED FOR THE MONITORING OF LONG TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETS MELLITUS., PREMIER DILUENT REAGENT(PREMIER DILUENT REAGENT)-THE PREMIER DILUENT REAGENT IS INTENDED FOR USE WITH TRINITY BIOTECH PREMIER HB9210TM HBAIC ANALYZER ONLY. THE PREMIER SYSTEM IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN HUMAN CAPILLARY AND VENOUS WHOLE BLOOD. HBA1C IS USED FOR THE MONITORING OF LONG-TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETS MELLITUS., HBA1C (GHB) CALIBRATOR KIT(HBA1C (GHB) CALIBRATOR KIT)-HBAIC (GHB) CALIBRATORS ARE INTENDED TO MONITOR THE PERFORMANCE OF GLYCATED HEMOGLOBIN ASSAYS. CALIBRATORS ARE FOR THE CALIBRATION OF QUANTITATIVE HBAIC AFFINITY ASSAY SYSTEMS.,PREMIER BUFFER A REAGENT(PREMIER BUFFER A REAGENT)-THIS REAGENT IS INTENDED FOR USE WITH TRINITY BIOTECH PREMIER HB9210TM HBAIC ANALYZER ONLY. THE PREMIER HB9210TM SYSTEM IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN HUMAN CAPILLARY AND VENOUS WHOLE BLOOD. HBA1C IS USED FOR THE MONITORING OF LONG TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETS MELLITUS.

741	IMP/IVD/2020/000524	1.License Holder Name: ANAND BROTHERS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACETYLCHOLINE RECEPTOR-AB (ARAB) RRA(ACETYLCHOLINE RECEPTOR-AB (ARAB) RRA)-RADIO RECEPTOR ASSAY FOR THE IN-VITRO-DIAGNOSTIC SEMI-QUANTITATIVE DETERMINATION OF AUTOANTIBODIES AGAINST THE ACETYLCHOLINE RECEPTOR IN HUMAN SERUM AND PASMA
742	IMP/IVD/2020/000525	1.License Holder Name: PERKINELMER INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHEMAGIC VIRAL DNA/RNA 300 KIT H96(CHEMAGIC VIRAL DNA/RNA 300 KIT H96)-THE CHEMAGIC VIRAL DNA/RNA KITS ARE DESIGNED FOR SIMULTANEOUS PURIFICATION OF VIRAL DNA OR RNA FROM PLASMA, SERUM, NASO OR OROPHARYNGEAL SWABS, BAL AND SPUTUM SAMPLES
743	IMP/IVD/2020/000526	1.License Holder Name: IMPERIAL LIFE SCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PCLMD NCOV ONE STEP RT-PCR KIT(PCL)-THE PCLMD NCOV ONE STEP RT-PCR KIT IS A QUALITATIVE REAL-TIME REVERSE TRANSCRIPTION PCR (RT-PCR) IVD MEDICAL DEVICE FOR THE DETECTION OF SARS-COV-2 IN HUMAN NASOPHARYNGEAL SPECIMEN.

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744	IMP/IVD/2020/000527	1.License Holder Name: INNVOLUTION HEALTHCARE PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GB SARS-COV-2 REAL-TIME RT-PCR(GB SARS-COV-2 REAL-TIME RT-PCR)-THE GB SARS-COV-2 REAL-TIME RT-PCR IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST (NAT) FOR THE QUALITATIVE DETECTION OF 2019 NOVEL CORONAVIRUS (SARS-COV-2) IN RESPIRATORY TRACT SPECIMENS (I.E., NASOPHARYNGEAL/ OROPHARYNGEAL SWAB OR SPUTUM SPECIMENS), SERUM OR PLASMA.,GB SARS-COV-2 REAL-TIME RT-PCR(GB SARS-COV-2 REAL-TIME RT-PCR)-THE GB SARS-COV-2 REAL-TIME RT-PCR IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST (NAT) FOR THE QUALITATIVE DETECTION OF 2019 NOVEL CORONAVIRUS (SARS-COV-2) IN RESPIRATORY TRACT SPECIMENS (I.E., NASOPHARYNGEAL/ OROPHARYNGEAL SWAB OR SPUTUM SPECIMENS), SERUM OR PLASMA.,VIRAL DNA/RNA MINI KIT (VIRAL DNA/RNA MINI KIT)-FOR ISOLATION OF VIRAL RNA/ VIRAL NUCLEIC ACID FROM CELL-FREE FLUID SUCH AS, SERUM, PLASMA, BODY FLUID AND CELL CULTURE SUPERNATANT, AND FROM TRANSPORT MEDIUM OF SWABS
745	IMP/IVD/2020/000528	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIAGNOVITAL® SARS-COV-2 REAL TIME PCR KIT(DIAGNOVITAL®SARS-COV-2 REAL TIME PCR KIT)-DIAGNOVITAL® SARS-COV-2 REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION ASSAY FOR QUALITATIVE DETECTION OF 2019-NOVEL CORONAVIRUS (SARS-COV-2) IN RESPIRATORY SPECIMENS USING RTA VIRAL NUCLEIC ACID ISOLATION KIT AND BIO-RAD CFX96-IVD OR ROTOR-GENE 3000/6000 OR APPLIED BIOSYSTEMS 7500 OR QUANTSTUDIO 5 REAL-TIME PCR DETECTION SYSTEMS FOR AMPLIFICATION, DETECTION AND ANALYSIS.
746	IMP/IVD/2020/000531	1.License Holder Name: BILCARE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REAL-Q 2019-NCOV DETECTION KIT (REAL-Q 2019-NCOV DETECTION KIT)-IT IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE THAT QUALITATIVELY DETECTS THE GENE (E GENE, RDRP GENE) OF THE CORONAVIRUS DISEASE (COVID-19) IN SAMPLES (SPUTUM, OROPHARYNGEAL AND NASOPHARYNGEAL SPECIMENS) OF PATIENTS WITH RESPIRATORY INFECTIONS USING REAL-TIME POLYMERASE CHAIN REACTION

747	IMP/IVD/2020/000532	1.License Holder Name: MATRIX HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ONLYONE(ONLYONE)-LYSING AGENT TO OBTAIN THE MEASUREMENT OF THE HAEMOGLOBIN,COUNTING AND DIFFERENTIATION OF THE WHITE BLOOD CELLS.,CLEANER FOR MYTHIC 22(CLEANER FOR MYTHIC 22)-THIS SOLUTION IS USED TO CLEAN THE SYSTEM.THE PRESENCE OF AN ENZYME REDUCES THE FORMATION OF PROTEINS DEPOSIT., DILUENT FOR MYTHIC 22(DILUENT FOR MYTHIC 22)-ISOTONIC SOLUTION USE FOR THE DIFFERENTIATION OF THE WHITE BLOOD CELLS,MYTHIC 18-22 FLUSH CLEANER(MYTHIC 18-22 FLUSH CLEANER)-MYTHIC 18-22 FLUSH CLEANER IS AN EMERGENCY CLEANER ,BASED ON HYPOCHLORITE, DESIGNED FOR WASHING AND MAINTENANCE OF MYTHIC HAEMATOLOGY ANALYSERS.,MYTHIC 18-22 ENZYMATIC CLEANING SOLUTION(MYTHIC 18-22 ENZYMATIC CLEANING SOLUTION)-THIS SOLUTION IS USED TO CLEAN THE SYSTEM.THE PRESENCE OF AN ENZYME REDUCES THE FORMATION OF PROTEINS DEPOSIT,MYTHIC 18 DILUENT(MYTHIC 18 DILUENT)-ISOTONIC SOLUTION USE FOR THE DIFFERENTIATION OF THE WHITE BLOOD CELLS.,MYTHIC 18 CYANIDE FREE LYTIC SOLUTION(MYTHIC 18 CYANIDE FREE LYTIC SOLUTION)-LYSING AGENT TO OBTAIN THE MEASUREMENT OF THE HAEMOGLOBIN,COUNTING AND DIFFERENTIATION OF THE WHITE BLOOD CELLS.,MYT-CAL(MYT-CAL)-MYT-CAL IS DESIGNED FOR USE IN THE CALIBRATION OF ORPHEE HAEMATOLOGY ANALYZERS.
748	IMP/IVD/2020/000534	1.License Holder Name: MCW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NCOVID-19 IGG&IGM POCT (NCOVID-19 IGG&IGM POCT)-THE NCOVID-19 IGG&IGM POCT KIT ADOPTS THE SOLID PHASE COLLOIDAL GOLD IMMUNOCHROMATOGRAPHIC TECHNOLOGY FOR THE QUALITATIVE DETERMINATION OF IGM/IGG ANTIBODIES AGAINST SARS-COV-2 IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD. THIS ASSAY IS USED AS A DIAGNOSTIC AID WHEN ASSESSING IMMUNITY STATUS OF PATIENTS RELATED TO COVID-19 INFECTION. THIS PRODUCT MUST BE USED IN STRICT COMPLIANCE WITH THE INSTRUCTIONS GIVEN IN THIS DOCUMENT BY PROFESSIONAL USERS

749	IMP/IVD/2020/000536	1.License Holder Name: PERKINELMER INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERKINELMER® NEW CORONAVIRUS NUCLEIC ACID DETECTION KIT(PERKINELMER® NEW CORONAVIRUS NUCLEIC ACID DETECTION KIT)-AS PER EMERGENCY USE AUTHORIZATION (EUA) FROM USFDA, THIS TEST IS ALSO FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 VIRUS IN POOLED SAMPLES CONTAINING UP TO 5 INDIVIDUAL UPPER RESPIRATORY SWAB SPECIMENS(OROPHARYNGEAL, NASOPHARYNGEAL,OR ANTERIOR NASAL SWABS), WHERE EACH SPECIMEN IS COLLECTED UNDER OBSERVATION OR BY A HEALTHCARE PROVIDER USING INDIVIDUAL VIALS CONTAINING TRANSPORT MEDIA.
750	IMP/IVD/2020/000538	1.License Holder Name: BRINTON PHARMACEUTICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REAL-TIME FLUORESCENT RT-PCR KIT FOR DETECTING 2019-NCOV(BGI)-THE KIT IS QUALITATIVE IN VITRO NUCLEIC ACID AMPLIFICATION ASSAY TO DETECT THE NEW CORONAVIRUS IDENTIFIED IN CHINA IN 2019 USING REVERSE TRANSCRIPTION PCR IN SPECIMEN OF THE THROAT SWAB AND BRONCHOALVEOLAR LAVAGE FLUID (BALF).
751	IMP/IVD/2020/000539	1.License Holder Name: CLINIEXPERTS SERVICES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REALCYCLER CORO-G V. 5.3(REALCYCLER)-REALCYCLER CORO-G V.5.3 IS AN IN VITRO DIAGNOSTIC KIT OF REAGENTS WHICH ALLOWS THE DETECTION OF CORONAVIRUS SARS-COV-2 AND SARBECOVIRUSRNA IN CLINICAL SAMPLES.

752	IMP/IVD/2020/000548	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG REAGENT PACK-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG REAGENT PACK WHEN USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG CALIBRATOR IS A CHEMILUMINESCENT IMMUNOASSAY TEST INTENDED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM USING VITROS IMMUNODIAGNOSTIC AND INTEGRATED SYSTEMS,VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG CALIBRATOR-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG REAGENT PACK WHEN USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 IGG CALIBRATOR IS A CHEMILUMINESCENT IMMUNOASSAY TEST INTENDED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM USING VITROS IMMUNODIAGNOSTIC AND INTEGRATED SYSTEMS.,VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 TOTAL CALIBRATOR-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 TOTAL REAGENT PACK TEST WHEN USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 TOTAL CALIBRATOR IS FOR THE QUALITATIVE MEASUREMENT OF TOTAL ANTIBODY (INCLUDING IGG, IGA AND IGM) TO SARS-COV-2 IN HUMAN SERUM AND PLASMA (K2 EDTA) SAMPLES FROM PATIENTS SUSPECTED OF COVID-19 BY A HEALTHCARE PROVIDER, USING VITROS IMMUNODIAGNOSTIC AND INTEGRATED SYSTEMS.,VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 TOTAL REAGENT PACK-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 TOTAL REAGENT PACK TEST WHEN USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-SARS-COV-2 TOTAL CALIBRATOR IS FOR THE QUALITATIVE MEASUREMENT OF TOTAL ANTIBODY (INCLUDING IGG, IGA AND IGM) TO SARS-COV-2 IN HUMAN SERUM AND PLASMA (K2 EDTA) SAMPLES FROM PATIENTS SUSPECTED OF COVID-19 BY A HEALTHCARE PROVIDER, USING VITROS IMMUNODIAGNOSTIC AND INTEGRATED SYSTEMS.,VITROS IMMUNODIAGNOSTIC PRODUCTS ANTISARS-COV-2 TOTAL CONTROLS-FOR IN VITRO DIAGNOSTIC AND LABORATORY

		PROFESSIONAL USE. FOR USE IN MONITORING THE PERFORMANCE OF THE VITROS IMMUNODIAGNOSTIC AND INTEGRATED SYSTEMS WHEN USED FOR THE DETERMINATION OF ANTIBODIES TO SARS-COV-2.
753	IMP/IVD/2020/000549	1.License Holder Name: LOFTEN INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 MULTI REAL-TIME RT-PCR KIT(LILIF)-LILIF™ COVID-19 MULTI REAL-TIME RT-PCR KIT IS IN VITRO DIAGNOSTIC MEDICAL DEVICE BASED ON REAL-TIME REVERSE TRANSCRIPTION PCR METHOD INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE 2019-NCOV IN NASOPHARYNGEAL/OROPHARYNGEAL SWABS AND SPUTA FROM INDIVIDUALS WITH SIGNS AND SYMPTOMS OF INFECTION WHO ARE SUSPECTED OF COVID-19,COVID-19 REAL-TIME RT-PCR KIT(LILIF)-LILIF™ COVID-19 REAL-TIME RT-PCR KIT IS IN VITRO DIAGNOSTIC MEDICAL DEVICE BASED ON REAL-TIME REVERSE TRANSCRIPTION PCR METHOD INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE 2019-NCOV IN NASOPHARYNGEAL/OROPHARYNGEAL SWABS AND SPUTA FROM INDIVIDUALS WITH SIGNS AND SYMPTOMS OF INFECTION WHO ARE SUSPECTED OF COVID-19
754	IMP/IVD/2020/000550	1.License Holder Name: KIN DIAGNOSTICS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 REAL TIME PCR KIT(POWERCHEK™ SARS-COV-2 REAL-TIME PCR KIT)-"THE POWERCHEK™ SARS-COV-2 REAL-TIME PCR KIT IS A REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 THAT CAUSES CORONAVIRUS DISEASE 2019 (COVID-19) IN CLINICAL SPECIMENS, INCLUDING UPPER AND LOWER RESPIRATORY SPECIMENS (SUCH AS NASOPHARYNGEAL/ OROPHARYNGEAL SWABS, BRONCHOALVEOLAR LAVAGE FLUID, AND SPUTUM) OBTAINED FROM INDIVIDUALS WITH SIGNS AND SYMPTOMS OF INFECTION WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. RESULTS ARE FOR THE IDENTIFICATION OF SARS-COV-2 RNA. THE SARS-COV-2 RNA IS GENERALLY DETECTABLE IN UPPER AND LOWER RESPIRATORY SPECIMENS DURING INFECTION. POSITIVE RESULTS ARE INDICATIVE OF THE PRESENCE OF SARS-COV-2 RNA, CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS."

755	IMP/IVD/2020/000551	1.License Holder Name: GRAVITY GLOBAL HOSPITALITY PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: COVID-19 QPCR MULTI TESTING KIT(1COPY TM)-1COPY™ COVID-19 QPCR KIT IS AN IN-VITRO DIAGNOSTIC MEDICAL DEVICE FOR QUALITATIVE ANALYSIS OF E GENE AND RDRP GENE FOR CORONAVIRUS (COVID-19) IN EXTRACTED RNA FROM SPUTUM, NASOPHARYNGEAL SWAB AND OROPHARYNGEAL SWAB OF PATIENTS WITH SUSPECTED RESPIRATORY INFECTIONS.
756	IMP/IVD/2020/000554	1.License Holder Name: TOSOH INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 (COVID-19) IGG(NOVALISA®)-THE SARS-COV-2 (COVID-19) IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST SARS COV-2 IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN) TO SUPPORT THE DIAGNOSIS OF COVID-19 DISEASE AND CONSTITUTES A SUPPLEMENT TO DIRECT PATHOGEN DETECTION. IN ADDITION, SEROLOGY CAN BE USED TO COLLECT EPIDEMIOLOGICAL INFORMATION ON THE PREVALENCE OF SARS COV-2.,SARS-COV-2 (COVID-19) IGA (NOVALISA®)-THE SARS-COV-2 (COVID-19) IGA ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGA CLASS ANTIBODIES AGAINST SARSCOV2 IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN) TO SUPPORT THE DIAGNOSIS OF COVID-19 DISEASE AND CONSTITUTES A SUPPLEMENT TO DIRECT PATHOGEN DETECTION.,SARS-COV-2 (COVID-19) IGM (NOVALISA®)-THE SARS-COV-2 (COVID-19) IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST SARSCOV2 IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN) TO SUPPORT THE DIAGNOSIS OF COVID-19 DISEASE AND CONSTITUTES A SUPPLEMENT TO DIRECT PATHOGEN DETECTION.

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757	IMP/IVD/2020/000555	1.License Holder Name: MERIDIAN BIOTECH 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALLPLEX™ SARS-COV-2/FLUA/FLUB/RSV ASSAY(ALLPLEX™)-MULTIPLEX REAL-TIME ONE-STEP RT-PCR SYSTEM FOR DETECTION OF SARS-COV-2, INFLUENZA A VIRUS, INFLUENZA B VIRUS, AND HUMAN RESPIRATORY SYNCYTIAL VIRUS FROM NASOPHARYNGEAL ASPIRATE, NASOPHARYNGEAL SWAB, BRONCHOALVEOLAR LAVAGE, AND SALIVA. THE DETECTION OF SARS-COV-2 IS ADDITIONALLY VALIDATED ON OROPHARYNGEAL (THROAT) SWAB AND SPUTUM., ALLPLEX™ 2019- NCOV ASSAY(ALLPLEX™)-ALLPLEX™ 2019-NCOV ASSAY IS IN VITRO DIAGNOSTIC MEDICAL DEVICE DESIGNED FOR QUALITATIVE DETECTION OF NOVEL CORONA VIRUS (2019-NCOV) WITH REAL-TIME REVERSE TRANSCRIPTION PCR FROM SPUTUM, NASOPHARYNGEAL ASPIRATE, THROAT & NASOPHARYNGEAL SWAB, AND BRONCHOALVEOLAR LAVAGE.,ALLPLEX™ SARS-COV-2 MASTER ASSAY(ALLPLEX™)-ALLPLEX™ SARS-COV-2 MASTER ASSAY IS IN VITRO DIAGNOSTIC MEDICAL DEVICE DESIGNED FOR QUALITATIVE DETECTION OF SARS-COV-2 AND VARIANTS OF S GENE (HV69/70DEL, Y144DEL, E484K, N501Y, P681H) WITH REAL-TIME REVERSE TRANSCRIPTION PCR FROM NASOPHARYNGEAL ASPIRATE, NASOPHARYNGEAL SWAB, BRONCHOALVEOLAR LAVAGE, OROPHARYNGEAL (THROAT) SWAB, SPUTUM, AND SALIVA., ALLPLEX™ 2019-NCOV ASSAY(ALLPLEX™)-ALLPLEX™ 2019-NCOV ASSAY IS AN IN VITRO DIAGNOSTIC (IVD) REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF SARS-COV-2 VIRAL NUCLEIC ACIDS IN HUMAN NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, ANTERIOR NASAL SWAB, MID-TURBINATE NASAL SWAB, NASOPHARYNGEAL WASH/ASPIRATE, NASAL ASPIRATE, BRONCHOALVEOLAR LAVAGE (BAL) AND SPUTUM SPECIMENS FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTH CARE PROVIDER.

758	IMP/IVD/2020/000564	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERKINELMER® NEW CORONAVIRUS NUCLEIC ACID DETECTION KIT(PERKINELMER® NEW CORONAVIRUS NUCLEIC ACID DETECTION KIT)-THE PERKINELMER® NEW CORONAVIRUS NUCLEIC ACID DETECTION KIT IS A REAL-TIME RTPCR IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARSCOV- 2 VIRUS IN HUMAN OROPHARYNGEAL SWAB AND NASOPHARYNGEAL SWAB SPECIMENS COLLECTED FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER.
759	IMP/IVD/2020/000565	1.License Holder Name: NOVOMED INCORPORATION PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GA COV-2 IGG-ENZYME IMMUNOASSAY FOR THE DETERMINATION OF IGG ANTIBODIES TO SARS-CORONAVIRUS 2 (SARS-COV-2) IN HUMAN SERUM AND PLASMA FOR THE MONITORING OF IMMUNE RESPONSE IN COVID-19 DISEASE. ,GA COV-2 IGG +-ENZYME IMMUNOASSAY FOR THE CONFIRMATION OF POSITIVE IGG ANTIBODIES AGAINST SARS-COV-2 IN HUMAN SERUM AND PLASMA FOR THE MONITORING OF IMMUNE RESPONSE IN COVID-19 DISEASE. ,GA COV-2 IGM-ENZYME IMMUNOASSAY FOR THE DETERMINATION OF IGM ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA FOR THE MONITORING OF IMMUNE RESPONSE IN COVID-19 DISEASE.

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760	IMP/IVD/2020/000568	1.License Holder Name: GRIFOLS INDIA HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PROCLEIX ULTRIO ELITE ASSAY KIT (A QUALITATIVE IN-VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DETECTION OF HIV 1 & 2 RNA, HCV RNA AND HBV DNA IN PLASMA AND SERUM SPECIMENS FROM HUMAN DONORS) (PROCLEIX ULTRIO ELITE)-THE PROCLEIX ULTRIO ELITE ASSAY IS A QUALITATIVE IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND HUMAN IMMUNODEFICIENCY VIRUS TYPE 2 (HIV) RNA, HEPATITIS C VIRUS (HCV) RNA, AND/OR HEPATITIS B VIRUS (HBV) DNA IN PLASMA AND SERUM SPECIMENS FROM HUMAN DONORS, TESTED INDIVIDUALLY OR IN POOLS. IT IS ALSO INTENDED FOR USE IN TESTING PLASMA AND SERUM TO SCREEN ORGAN AND TISSUE DONORS, INCLUDING CADAVERIC (NONHEART- BEATING) DONORS , PROCLEIX ULTRIO PLUS ASSAY KIT (A QUALITATIVE IN-VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DETECTION OF HIV 1 RNA, HCV RNA AND HBV DNA IN PLASMA AND SERUM SPECIMENS FROM HUMAN DONORS)(PROCLEIX ULTRIO PLUS)-THE PROCLEIX ULTRIO PLUS ASSAY IS A QUALITATIVE IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) RNA, HEPATITIS C VIRUS (HCV) RNA, AND/OR HEPATITIS B VIRUS (HBV) DNA IN PLASMA AND SERUM SPECIMENS FROM HUMAN DONORS, TESTED INDIVIDUALLY OR IN POOLS. IT IS ALSO INTENDED FOR USE IN TESTING PLASMA AND SERUM TO SCREEN ORGAN AND TISSUE DONORS, INCLUDING CADAVERIC (NON-HEART-BEATING) DONORS
761	IMP/IVD/2020/000570	1.License Holder Name: M/S VANMAUR ENTERPRISE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SAMPLE PRESERVATION SOLUTION (VIRAL TRANSPORT MEDIUM)(LONGSEE)-SAMPLE PRESERVATION,RNA EXTRACTION KIT(LONGSEE)-RAPID EXTRACTION OF HIGH PURITY VIRAL NUCLEIC ACID RNA

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762	IMP/IVD/2020/000571	1.License Holder Name: M/S.ROCHE DIABETES CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(ACCU CHEK INSTANT)-THE ACCUCHEK INSTANT TEST STRIPS WITH THE ACCUCHEK INSTANT AND ACCU-CHEK INSTANT $ METERS ARE INTENDED TO QUANTITATIVELY MEASURE GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD FROM THE FINGER, PALM, FOREARM, AND UPPER ARM AS AN AID IN MONITORING THE EFFECTIVENESS OF GLUCOSE CONTROL. THE ACCUCHEK INSTANT TEST STRIPS WITH THE ACCUCHEK INSTANT AND ACCU-CHEK INSTANT S METERS ARE INTENDED FOR IN VITRO DIAGNOSTIC SELF-TESTING BY PEOPLE WITH DIABETES. THE ACCUCHEK INSTANT TEST STRIPS WITH THE ACCUCHEK INSTANT AND ACCU-CHEK INSTANT $ METERS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS IN CLINICAL SETTINGS. VENOUS, ARTERIAL, AND NEONATAL BLOOD TESTING IS LIMITED TO HEALTHCARE PROFESSIONAL USE. THIS SYSTEM IS NOT FOR USE IN DIAGNOSIS OF DIABETES MELLITUS, NOR FOR TESTING NEONATE CORD BLOOD SAMPLES.
763	IMP/IVD/2020/000574	1.License Holder Name: ALLIED BIOTECHNOLOGY INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NUCLEIC ACID EXTRACTION OR PURIFICATION REAGENT(COMMAXP VIRUS DNA/RNA EXTRACTION)-INTENDED FOR DNA/RNA EXTRACTIONS FROM BLOOD TISSUE ORGANS ENVIORNMENTAL SAMPLE SALIVA NASAL LIQUID AND SWAB SAMPLE,TRANSPORT MEDIUM(BIOCOMMA TRANSPORT AND PRESERVATION MEDIUM)-INTENDED FOR THE COLLECTION STORAGE AND TRANSPORT OFVIRUSES, MYCOPLASMA, CHLAMYDIAE OR UREAPLASMA SPECIMENS FROM THE COLLECTION SITE TO THE TESTING LABORATORY.

764	IMP/IVD/2020/000576	1.License Holder Name: M/S.ROCHE DIABETES CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(ACCU CHEK INSTANT)-THE ACCU CHEK INSTANT TEST STRIPS WITH THE ACCU CHEK INSTANT AND ACCU-CHEK INSTANT S METERS ARE INTENDED TO QUANTITATIVELY MEASURE GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD FROM THE FINGER, PALM, FOREARM, AND UPPER ARM AS AN AID IN MONITORING THE EFFECTIVENESS OF GLUCOSE CONTROL. THE ACCU CHEK INSTANT TEST STRIPS WITH THE ACCU CHEK INSTANT AND ACCU-CHEK INSTANT S METERS ARE INTENDED FOR IN VITRO DIAGNOSTIC SELF-TESTING BY PEOPLE WITH DIABETES. THE ACCU CHEK INSTANT TEST STRIPS WITH THE ACCU CHEK INSTANT AND ACCU-CHEK INSTANT S METERS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS IN CLINICAL SETTINGS. VENOUS, ARTERIAL, AND NEONATAL BLOOD TESTING IS LIMITED TO HEALTHCARE PROFESSIONAL USE. THIS SYSTEM IS NOT FOR USE IN DIAGNOSIS OF DIABETES MELLITUS, NOR FOR TESTING NEONATE CORD BLOOD SAMPLES.

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765	IMP/IVD/2020/000578	1.License Holder Name: SOWAR PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:E PLUS CASSETTES(OPTI MEDICAL)-CASSETTE IS USED WITH THE OPTI LION ANALYZER TO DETECT NA, K, CL, CA & PH IN WHOLE BLOOD, SERUM OR PLASMA.,E-BUN CASSETTES(OPTI MEDICAL)-CASSETTE IS USED WITH THE OPTI CCA ANALYZER W|TH TOUCH SCREEN TO DETECT PH, PCO2, PO2, BUN/UREA, NA, K, THB, SO2 IN WHOLE BLOOD, SERUM OR PLASMA., OPTI CHECK PLUS LEVEL 2(OPTI MEDICAL)-LIQUID QUALITY CONTROL VIALS USED TO CHECK THE ACCURACY OF THE OPTI CCA ANALYZERS PCO2 & PO2, NA, K, CL, CA, & GLU, SENSORS,E-GLU CASSETTES(OPTI MEDICAL)-CASSETTE IS USED WITH THE OPTI CCA ANALYZER TO DETECT PH, PCO2, PO¬2, GLU, NA, K, THB & SO2 IN WHOLE BLOOD. SERUM OR PLASMA.,B LAC CASSETTES(OPTI MEDICAL)-CASSETTE IS USED WITH THE OPTI CCA ANALYZER WITH TOUCH SCREEN TO DETECT PH, PCO2, PO2, & LACTATE IN WHOLE BLOOD, SERUM OR PLASMA.,OPTI CHECK PLUS LEVEL 3(OPTI MEDICAL)-LIQUID QUALITY CONTROL VIALS USED TO CHECK THE ACCURACY OF THE OPTI CCA ANALYZERS PCO2 & PO2, NA, K, CL, CA, & GLU, SENSORS,E-CL CASSETTES(OPTI MEDICAL)-CASSETTE IS USED WITH THE OPTI CCA ANALYZER TO DETECT PH, PCO2, PO2, CL, NA, K, THB & SO2 IN WHOLE BLOOD, SERUM OR PLASMA.,OPTI CHECK LYTES LEVEL 3(OPTI MEDICAL)-LIQUID QUALITY CONTROL VIALS USED TO CHECK THE ACCURACY OF THE OPTI LION INSTRUMENTS NA, K, CL, CA & PH SENSORS,OPTI CHECK LYTES LEVEL 1(OPTI MEDICAL)-LIQUID QUALITY CONTROL VIALS USED TO CHECK THE ACCURACY OF THE OPTI LION INSTRUMENTS NA, K, CL, CA & PH SENSORS,OPTI CHECK LEVEL 2(OPTI MEDICAL)-LIQUID QUALITY CONTROL VIALS USED TO CHECK THE ACCURACY OF THE OPTI CCA ANALYZER'S PCO2 & PO2, NA, K, CL & CA SENSORS,OPTI CHECK LEVEL 1(OPTI MEDICAL)-LIQUID QUALITY CONTROL VIALS USED TO CHECK THE ACCURACY OF THE OPTI CCA ANALYZER'S PCO2 & PO2, NA, K, CL & CA SENSORS,OPTI CHECK LYTES LEVEL 2(OPTI MEDICAL)-LIQUID QUALITY CONTROL VIALS USED TO CHECK THE ACCURACY OF THE OPTI LION INSTRUMENTS NA, K, CL, CA & PH SENSORS,OPTI CHECK LEVEL 3(OPTI MEDICAL)-LIQUID QUALITY CONTROL VIALS USED TO CHECK THE ACCURACY OF THE OPTI CCA ANALYZER'S PCO2 & PO2, NA, K, CL & CA SENSORS,B-TYPE CASSETTES(OPTI MEDICAL)-CASSETTE IS USED WITH THE OPTI CCA ANALYZER TO DETECT PH, PCO2, PO2, THB & SO2 IN WHOLE BLOOD, SERUM OR PLASMA.,OPTI CHECK PLUS LEVEL 1(OPTI MEDICAL)-LIQUID QUALITY CONTROL VIALS USED TO CHECK THE ACCURACY OF THE OPTI CCA ANALYZER'S PCO2 & CLASS B PO2, NA, K, CL, CA & GLU SENSORS,E-CA CASSETTES(OPTI MEDICAL)-CASSETTE IS USED WITH THE OPTI

		CCA ANALYZER TO DETECT PH, PCO2, PO2, CA, NA, K, THB & SO2 IN WHOLE BLOOD, SERUM OR PLASMA.,B-60 CASSETTES(OPTI MEDICAL) -CASSETTE IS USED WITH THE OPTI CCA ANALYZER TO DETECT PH, PCO2 & PO2 IN WHOLE BLOOD, SERUM OR PLASMA.,E CASSETTES (OPTI MEDICAL)-CASSETTE IS USED WITH THE OPTI CCA ANALYZER TO DETECT PH, PH, PCO2, PO2, THB, SO2
766	IMP/IVD/2020/000580	1.License Holder Name: ARTEC DIAGNOSTIC SYSTEM 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:U-TOP COVID-19 DETECTION KIT FOR SARS-COV2 (COVID-19) REAL TIME PCR KIT(U-TOP)-THE U-TOP COVID-19 DETECTION KIT IS A ONE-STEP REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN OROPHARYNGEAL AND NASOPHARYNGEAL SWAB SPECIMENS, ANTERIOR NASAL AND MID-TURBINATE NASAL SWABS, NASOPHARYNGEAL WASH/ASPIRATE OR NASAL ASPIRATE SPECIMENS AND SPUTUM FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. TESTING IS LIMITED TO LABORATORIES CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C. §263A, TO PERFORM HIGH COMPLEXITY TESTS.
767	IMP/IVD/2020/000581	1.License Holder Name: M/S HEMOGENOMICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 RT PCR ASSAY (A NUCLEIC ACID AMPLIFICATION IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE DETECTION OF RNA FROM SARS-COV-2)(APTIMA™ SARS-COV-2 ASSAY)-THE APTIMA™ SARS-COV-2 ASSAY IS A NUCLEIC ACID AMPLIFICATION IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE DETECTION OF RNA FROM SARS-COV-2 ISOLATED AND PURIFIED FROM NASOPHARYNGEAL (NP), NASAL, MID-TURBINATE AND OROPHARYNGEAL (OP) SWAB SPECIMENS, NASOPHARYNGEAL WASH/ ASPIRATE OR NASAL ASPIRATES OBTAINED FROM INDIVIDUALS MEETING COVID-19 CLINICAL AND/OR EPIDEMIOLOGICAL CRITERIA.

768	IMP/IVD/2020/000585	1.License Holder Name: RANDOX LABORATORIES INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LACTATE DEHYDROGENASE (LDH) -A LACTATE DEHYDROGENASE TEST SYSTEM IS A DEVICE INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF LACTATE DEHYDROGENASE ACTIVITY IN SERUM AND PLASMA.,H-FABP CONTROL (H-FABP CONTROL) -THE H-FABP CONTROL (H-FABP CONTROL) IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. THE H-FABP CONTROL IS FOR THE CONTROL OF ACCURACY , AMMONIA (NH3) -THE AMMONIA (NH3) DEVICE IS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF AMMONIA IN PLASMA , COAGULATION CONTROLS-THE COAGULATION CONTROLS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. THE COAGULATION CONTROLS ARE FOR THE CONTROL OF ACCURACY,C-REACTIVE PROTEIN (CRP)-THE C-REACTIVE PROTEIN (CRP) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN CONCENTRATION IN SERUM AND PLASMA. THIS PRODUCT IS SUITABLE FOR MANUAL USE AND ON AUTOMATED INSTRUMENTS. ,ACID WASH SOLUTION (AWS) -ACID WASH SOLUTION (AWS) THIS PRODUCT SHOULD BE USED IN CONJUNCTION WITH RX DAYTONA PLUS REAGENTS TO CLEAN PROBES AND CUVETTES.,C-REACTIVE PROTEIN (CRP)-THE C-REACTIVE PROTEIN (CRP) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN CONCENTRATION IN SERUM AND PLASMA. THIS PRODUCT IS SUITABLE FOR MANUAL USE AND ON AUTOMATED INSTRUMENTS. ,CRP CONTROL (HS & LIQUID) (CRP CONTROL) -THE CRP CONTROL (HS & LIQUID) (CRP CONTROL) IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. THE CRP CONTROL (HS & LIQUID) IS FOR THE CONTROL OF ACCURACY,TOTAL PROTEIN (UP) -THE TOTAL PROTEIN (UP) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTEIN IN URINE AND C.S.F. THIS PRODUCT IS SUITABLE FOR MANUAL USE AND ON SEMI-AUTOMATED INSTRUMENTS.,CK-MB CONTROL -THE CK-MB CONTROL IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. THE HUMAN ASSAYED MULTI-SERA IS FOR THE CONTROL OF ACCURACY ,LACTATE DEHYDROGENASE (LDH) -A LACTATE DEHYDROGENASE TEST SYSTEM IS A DEVICE INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF LACTATE DEHYDROGENASE ACTIVITY IN SERUM AND PLASMA.,SERUM DILUENT -SERUM DILUENT (DIL SM) IS FOR RECONSTITUTION OF RANDOX QUALITY CONTROL SERA.,-GT (GGT)-A -GT (GGT) TEST SYSTEM IS A DEVICE INTENDED FOR THE QUANTITATIVE IN VITRO

	DETERMINATION OF L- -GLUTAMYLTRANSERASE (--GT) ACTIVITY IN SERUM AND PLASMA. THIS PRODUCT IS SUITABLE FOR USE ON RE SERIES INSTRUMENTS.,ALDOLASE CONTROL (ALS CONTROL)-THE ALDOLASE CONTROL (ALS CONTROL) IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF THE ALDOLASE ASSAY AD189,IMMUNOASSAY PREMIUM -THE IMMUNOASSAY PREMIUM DEVICE IS INTENDED FOR IN VITRO DIAGNOSTIC USE, IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. THE IMMUNOASSAY PREMIUM AND IMMUNOASSAY PREMIUM PLUS IS FOR THE CONTROL OF ACCURACY. ,BUTYRYL CHOLINESTERASE (CHE) -THE BUTYRYL CHOLINESTERASE (CHE) DEVICE FOR THE QUANTITATIVE IN VITRO DETERMINATION OF BUTYRYL CHOLINESTERASE IN SERUM AND PLASMA,LDL CHOLESTEROL (LDL) -THE LDL CHOLESTEROL (LDL) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF LDL-CHOLESTEROL CONCENTRATION IN HUMAN SERUM AND PLASMA. ,FRUCTOSAMINE (FRUC)-THE FRUCTOSAMINE (FRUC) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF FRUCTOSAMINE CONCENTRATION IN SERUM AND PLASMA,RHEUMATOID FACTOR (RF) -THE RHEUMATOID FACTOR (RF) TEST SYSTEM IS A DEVICE INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF RHEUMATOID FACTORS (RF) CONCENTRATION IN SERUM. SUITABLE FOR USE OF RX SERIES INSTRUMENTS.,THERAPEUTIC DRUG CALIBRATOR (TDM CAL)-THERAPEUTIC DRUG CALIBRATOR (TDM CAL) IS INTENDED FOR USE IN THE CALIBRATION OF THERAPEUTIC DRUG ASSAYS.,HAEMOGLOBIN A1C CONTROL SET (HBA1C CONTROL) -THE HAEMOGLOBIN A1C CONTROL SET (HBA1C CONTROL) IS INTENDED FOR IN VITRO DIAGNOSTIC USE, IN THE QUALITY CONTROL OF HBA1C ON CLINICAL CHEMISTRY SYSTEMS. ,BUFFER AND L SOLUTION-THE ISE BUFFER & L SOLUTIONS ARE REQUIRED FOR THE RUNNING OF THE ISE UNIT ON THE RX MODENA ANALYSER.,LIQUID ASSAYED SPECIFIC PROTEIN CONTROL (SP CONTROL) -THE LIQUID ASSAYED SPECIFIC PROTEIN CONTROL (SP CONTROL) IS INTENDED FOR IN VITRO DIAGNOSTIC USE, IN THE QUALITY CONTROL OF SERUM ON CLINICAL CHEMISTRY SYSTEMS. THE ASSAYED LIQUID PROTEIN CONTROLS ARE FOR THE CONTROL OF ACCURACY. ,CRP CALIBRATOR SERIES-THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF CRP ASSAYS ON CLINICAL CHEMISTRY SYSTEMS. CONSTITUENT CONCENTRATIONS ARE AVAILABLE AT 6 LEVELS. ,SERUM IRON (FE) -THE SERUM IRON (FE) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF IRON CONCENTRATION IN SERUM AND PLASMA. THIS PRODUCT IS SUITABLE FOR MANUAL USE AND ON SEMI-AUTOMATED INSTRUMENTS. ,CARBAMAZEPINE (CBZ)-THE CARBAMAZEPINE (CBZ)

	DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CARBAMAZEPINE CONCENTRATION IN SERUM AND PLASMA,SERUM IRON (FE) -THE SERUM IRON (FE) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF IRON CONCENTRATION IN SERUM AND PLASMA. THIS PRODUCT IS SUITABLE FOR MANUAL USE AND ON SEMI-AUTOMATED INSTRUMENTS.,ACID WASH SOLUTION (AWS)-ACID WASH SOLUTION (AWS) THIS PRODUCT SHOULD BE USED IN CONJUNCTION WITH RX DAYTONA PLUS REAGENTS TO CLEAN PROBES AND CUVETTES., RHEUMATOID FACTOR (RF) -THE RHEUMATOID FACTOR (RF) TEST SYSTEM IS A DEVICE INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF RHEUMATOID FACTORS (RF) CONCENTRATION IN SERUM. SUITABLE FOR USE OF RX SERIES INSTRUMENTS, ALDOLASE (AD) -THE ALDOLASE (AD) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ALDOLASE CONCENTRATION IN SERUM AND PLASMA,SERUM IRON (FE)-THE SERUM IRON (FE) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF IRON CONCENTRATION IN SERUM AND PLASMA. THIS PRODUCT IS SUITABLE FOR MANUAL USE AND ON SEMI-AUTOMATED INSTRUMENTS.,ANTI-STREPTOLYSIN (ASO) -THE ANTI-STREPTOLYSIN (ASO) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ANTI-STREPTOLYSIN-O CONCENTRATION IN SERUM ,MICROALBUMIN (MALB) -THE MICROALBUMIN (MALB) REAGENT DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF MICROALBUMIN IN URINE.,CK-MB CALIBRATION SERUM -THIS PRODUCT IS INTENDED FOR USE IN THE CALIBRATION OF CK-MB ASSAYS ON CLINICAL CHEMISTRY SYSTEMS ,DIRECT BILIRUBIN-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF DIRECT BILIRUBIN IN SERUM AND PLASMA. ,IGE CALIBRATOR SERIES (IGE CAL SET)-IGE CALIBRATOR SERIES (IGE CAL SET) IS FOR USE AS A CALIBRATOR IN CLINICAL CHEMISTRY ASSAYS,ASPARTATE AMINOTRANSFERASE-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ASPARTATE AMINOTRANSFERASE (AST) CONCENTRATION IN SERUM AND PLASMA. ,THERAPEUTIC DRUG CONTROL (TDM CONTROL)-THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC USE, IN THE QUALITY CONTROL OF DRUG RESIDUE ANALYSIS ON CLINICAL CHEMISTRY SYSTEMS,UREA-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF UREA IN SERUM, PLASMA AND URINE.THIS PRODUCT IS SUITABLE FOR MANUAL USE. ,RX WASH CONCENTRATE (WASH CONC. 1) -RX WASH CONCENTRATE (WASH CONC. 1) IS A CLEANING SOLUTION FOR THE RX SERIES THAT SHOULD BE CONNECTED VIA WASH LINE 1. THIS PRODUCT HAS BEEN DESIGNED PARTICULARLY FOR THE RX SERIES ANALYSERS AND IS A

	PHOSPHATE FREE SOLUTION WITH AN ANTIBACTERIAL EFFECT. , CALIBRATION SERUM -CALIBRATION SERUM IS FOR USE AS A CALIBRATOR IN CLINICAL CHEMISTRY ASSAYS. RANDOX CALIBRATION SERA ARE BASED ON LYOPHILISED HUMAN SERUM. THE CONCENTRATIONS AND ACTIVITIES ARE SUITABLE FOR CALIBRATION OF CLINICAL CHEMISTRY ASSAYS ON A WIDE RANGE OF AUTOMATIC ANALYSERS. CONSTITUENT CONCENTRATIONS ARE AVAILABLE AT 2 LEVELS. ,VALPROIC ACID (VPA)-VALPROIC ACID (VPA) REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF VALPROIC ACID IN HUMAN SERUM,ALBUMIN (ALB)-AN ALBUMIN TEST SYSTEM IS A DEVICE INTENDED FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF ALBUMIN CONCENTRATION IN SERUM AND PLASMA.,APOLIPOPROTEIN A1 (APO A-1)-THE APOLIPOPROTEIN A1 (APO A-1) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF APOLIPOPROTEIN A1 CONCENTRATION IN SERUM AND PLASMA,CREATININE (CREA)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CREATININE IN SERUM PLASMA AND URINE.,TRI-LEVEL CARDIAC CONTROL (CRD CONTROL 1, 2, 3)-THE TRI-LEVEL CARDIAC CONTROL (CRD CONTROL 1, 2, 3) IS INTENDED FOR IN VITRO DIAGNOSTIC USE, IN THE QUALITY CONTROL OF CARDIAC MARKERS ON CLINICAL CHEMISTRY AND IMMUNOASSAY SYSTEMS.,HDL- CHOLESTROL (HDL)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF HDL- CHOLESTROL IN SERUM AND PLASMA. ,PHENYTOIN (PHT)-THE PHENYTOIN (PHT) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PHENYTOIN CONCENTRATION IN SERUM AND PLASMA,HDL- CHOLESTROL (HDL)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF HDL- CHOLESTROL IN SERUM AND PLASMA. THE PRODUCT IS SUITABLE FOR MANUAL USE AND ON RX MONZA ANALYSER.,RHEUMATOID FACTOR STANDARD -THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTICS USE, IN THE CALIBRATION OF RF ON CLINICAL CHEMISTRY ANALYSERS.,TOTAL PROTIEN-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTIEN CONCENTRATION IN SERUM AND PLASMA. ,SODIUM (NA) -THE SODIUM (NA) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF SODIUM CONCENTRATION IN SERUM AND PLASMA,URIC ACID (UA)-THE URIC ACID (UA) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID CONCENTRATION IN SERUM, PLASMA AND URINE.,H-FABP -THE H-FABP DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF H-FABP CONCENTRATION IN SERUM AND PLASMA.,ALANINE AMINOTRANSFERASE (ALT)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF ALKALINE PHOSPHATASE IN SERUM AND PLASMA. ,CREATINE KINASE (CK-NAC)

	-THE CREATINE KINASE (CK-NAC) REAGENT FAMILY ARE FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CREATINE KINASE IN SERUM OR PLASMA,GLUCOSE (GLUC -HK)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF GLUCOSE IN SERUM PLASMA AND URINE. ,DETERGENT -DETERGENT IS A CLEANING SOLUTION OF PHOSPHOROUS FREE ANTIBACTERIAL DETERGENT USED FOR DECONTAMINATION OF THE ANALYSER SAMPLE PROBE AND WATER BATH. ,TOTAL PROTIEN 2 (TP 2)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTIEN CONCENTRATION IN SERUM AND PLASMA.,IMMUNOGLOBULIN E (IGE) -THE IMMUNOGLOBULIN E (IGE) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF IGE CONCENTRATION IN SERUM AND PLASMA, ALBUMIN (ALB)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF ALBUMIN CONCENTRATION IN SERUM AND PLASMA. THIS PRODUCT IS SUITABLE FOR MANUAL USE AND ON RX MONZA ANALYSER.,IMMUNOASSAY SPECIALITY CONTROL -THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC USE, IN THE QUALITY CONTROL OF THE ACCURACY OF IMMUNOASSAYS ON CLINICAL CHEMISTRY SYSTEMS. THIS MATERIAL CAN BE USED TO MONITOR THE CONTROL OF ACCURACY OR THE CONTROL OF REPRODUCIBILITY OF IMMUNOASSAYS.,CREATININE (CREA)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CREATININE IN SERUM PLASMA AND URINE. ,ANTI-STREPTOLYSIN (ASO) -THE ANTI-STREPTOLYSIN (ASO) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ANTI-STREPTOLYSIN-O CONCENTRATION IN SERUM ,TOTAL BILIRUBIN 2 (T BIL 2)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILIRUBIN CONCENTRATION IN SERUM AND PLASMA.,WASH SOLUTION-WASH SOLUTION THIS PRODUCT SHOULD BE USED IN CONJUNCTION WITH RX MODENA REAGENTS TO CLEAN PROBES AND CUVETTES.,TOTAL BILIRUBIN (T BIL)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILIRUBIN CONCENTRATION IN SERUM AND PLASMA. THIS PRODUCT IS SUITABLE FOR MANUAL USE.,CSF CONTROL (CSF CONTROL)-THE CSF CONTROL (CSF CONTROL) IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. THE CSF CONTROL IS FOR THE CONTROL OF ACCURACY,ALKALINE PHOSPHATASE (ALP)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF ALKALINE PHOSPHATASE IN SERUM AND PLASMA. ,LIQUID PROTEIN CALIBRATORS-LIQUID PROTEIN CALIBRATORS ARE AN IN VITRO DIAGNOSTIC PRODUCT USED FOR THE CALIBRATION OF VARIOUS ASSAYS. ,GLUCOSE (GLUC -PAP)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF GLUCOSE IN SERUM PLASMA AND URINE. ,CREATINE KINASE (CK-NAC)-THE CREATINE KINASE (CK-NAC) REAGENT FAMILY ARE FOR THE

	QUANTITATIVE IN VITRO DETERMINATION OF CREATINE KINASE IN SERUM OR PLASMA,UREA-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF UREA IN SERUM, PLASMA AND URINE.,RX WASH CONCENTRATE (WASH CONC. 3) -RX WASH CONCENTRATE (WASH CONC. 3) IS A CLEANING SOLUTION FOR THE RX SERIES THAT SHOULD BE CONNECTED VIA WASH LINE 3. THIS PRODUCT HAS BEEN DESIGNED PARTICULARLY FOR THE RX SERIES ANALYSERS AND IS A PHOSPHATE FREE SOLUTION WITH AN ANTIBACTERIAL EFFECT., ALANINE AMINOTRANSFERASE (ALT)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF ALANINE AMINOTRANSFERASE (ALT) IN SERUM AND PLASMA. THE PRODUCT IS SUITABLE FOR MANUAL USE AND ON THE RX MONZA ANALYSER,D-3 HYDROXYBUTYRATE (RANBUT) -THE D-3 HYDROXYBUTYRATE (RANBUT) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF D-3-HYDROXYBUTYRATE IN SERUM AND PLASMA.,DIRECT BILIRUBIN-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF DIRECT BILIRUBIN IN SERUM AND PLASMA. THIS PRODUCT IS SUITABLE FOR MANUAL USE.,RX WASH CONCENTRATE (WASH CONC. 2) -RX WASH CONCENTRATE (WASH CONC. 2) IS A CLEANING SOLUTION FOR THE RX SERIES THAT SHOULD BE CONNECTED VIA WASH LINE 2. THIS PRODUCT HAS BEEN DESIGNED PARTICULARLY FOR THE RX SERIES ANALYSERS AND IS A PHOSPHATE FREE SOLUTION WITH AN ANTIBACTERIAL EFFECT.,ALKALINE PHOSPHATASE (ALP)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF ALKALINE PHOSPHATASE IN SERUM AND PLASMA.,ALKALINE DETERGENT -ALKALINE DETERGENT SOLUTION WHICH IS FLUSHED THROUGH THE INTERNAL FLUIDICS OF THE ANALYSER TO DECONTAMINATE THE CUVETTE WASH HEADS AND CUVETTES,AMYLASE (AMY)-THE AMYLASE (AMY) REAGENT DEVICE IS REQUIRED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF AMYLASE IN SERUM, PLASMA OR URINE,LIPOPROTEIN (A) CALIBRATOR-LIPOPROTEIN (A) CALIBRATOR IS FOR USE AS A CALIBRATOR IN CLINICAL CHEMISTRY ASSAYS. RANDOX LIPOPROTEIN (A) CALIBRATOR ARE BASED ON LYOPHILISED HUMAN SERUM. ,TOTAL BILIRUBIN (T BIL)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILIRUBIN CONCENTRATION IN SERUM AND PLASMA.,G6P-DH CONTROLS-G6P-DH CONTROLS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. G6P-DH CONTROLS IS FOR THE CONTROL OF ACCURACY.,TRIGLYCERIDES (TRIGS) -THE TRIGLYCERIDES (TRIGS) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDE CONCENTRATION IN SERUM AND PLASMA,HUMAN ASSAYED MULTI-SERA LEVEL 3 (HUM ASY CONTROL 3)(NA)-THE HUMAN ASSAYED MULTI-SERA (HUM ASY CONTROL) IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE

	QUALITY CONTROL OF DIAGNOSTIC ASSAYS. THE HUMAN ASSAYED MULTI-SERA IS FOR THE CONTROL OF ACCURACY,ASPARTATE AMINOTRANSFERASE (AST)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ASPARTATE AMINOTRANSFERASE (AST) CONCENTRATION IN SERUM AND PLASMA. THIS PRODUCT IS SUITABLE FOR MANUAL USE AND ON THE RX MONZA ANALYSER., BILE ACIDS (TBA)-THE BILE ACIDS (TBA) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILE ACIDS IN SERUM AND PLASMA ,TRIGLYCERIDES (TRIGS) -THE TRIGLYCERIDES (TRIGS) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDE CONCENTRATION IN SERUM AND PLASMA,HAEMATOLOGY CONTROL 1,2,3 (HAEM CNTL 1,2,3) -THE HAEMATOLOGY CONTROL 1,2,3 (HAEM CNTL 1,2,3) IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. THE HAEMATOLOGY CONTROL 1,2,3 IS FOR THE CONTROL OF ACCURACY,CALCIUM (CA)-THE CALCIUM (CA) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN SERUM, PLASMA AND URINE,MATERNAL CONTROL - LEVEL 2 (MATERNAL CONTROL 2)(NA)-THE MATERNAL CONTROL PRODUCT IS INTENDED FOR IN VITRO USE, IN THE QUALITY CONTROL OF ALPHA-FETOPROTEIN, FREE BETA HCG, FREE ESTRIOL, HUMAN CHORIONIC GONADOTROPIN, INHIBIN A AND PAPP-A METHODS ON CLINICAL CHEMISTRY SYSTEMS,AMYLASE (AMY) -THE AMYLASE (AMY) REAGENT DEVICE IS REQUIRED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF AMYLASE IN SERUM, PLASMA OR URINE, ISE CALIBRATOR B (CAL B) -ISE CALIBRATOR B (CAL B) USED AS A SECOND CALIBRATOR IN A TWO-POINT CALIBRATION. CALIBRATOR B IS ASPIRATED FROM A SAMPLE CUP AT POSITION 18 ON THE ANALYSER ASP TRAY AT LEAST ONCE EVERY 8 HOURS DEPENDING ON THE LABORATORIES SCHEDULE. THIS PRODUCT IS SUITABLE FOR USE ON THE RX SERIES INSTRUMENTS WHICH INCLUDES THE RX DAYTONA AND THE RX IMOLA. ,TRIGLYCERIDES (TRIGS) -THE TRIGLYCERIDES (TRIGS) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDE CONCENTRATION IN SERUM AND PLASMA,MICROALBUMIN LIQUID CONTROL (MALB CONTROL)-THE MICROALBUMIN LIQUID CONTROL (MALB CONTROL) IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. ,UREA-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF UREA IN SERUM, PLASMA AND URINE., 2 MICROGLOBULIN (B2M)-THE 2 MICROGLOBULIN (B2M) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF 2 MICROGLOBULIN CONCENTRATION IN SERUM AND PLASMA,TOTAL-IRON BINDING CAPACITY (TIBC-THE TOTAL-IRON BINDING CAPACITY (TIBC) REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO

	DETERMINATION OF TOTAL IRON-BINDING CAPACITY (TIBC) CONCENTRATION IN SERUM,C1 SOLUTION (C1 SOLN) -C1 SOLUTION (C1 SOLN) HAS BEEN DESIGNED PARTICULARLY FOR THE RX DAYTONA ANALYSER AND IS A WEAK BLEACH SOLUTION., CHOLESTEROL (CHOL)-THE CHOLESTEROL (CHOL) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CHOLESTEROL IN SERUM AND PLASMA,C1 SOLUTION (C1 SOLN)-C1 SOLUTION (C1 SOLN) HAS BEEN DESIGNED PARTICULARLY FOR THE RX DAYTONA ANALYSER AND IS A WEAK BLEACH SOLUTION.,LIPASE (LI)-A LIPASE TEST SYSTEM IS A DEVICE INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF LIPASE IN HUMAN SERUM AND PLASMA., ISE DETERGENT -ISE DETERGENT IS REQUIRED FOR MAINTENANCE OF THE ISE UNIT ON THE RX MODENA ANALYSER.,TOTAL-IRON BINDING CAPACITY (TIBC)-THE TOTAL-IRON BINDING CAPACITY (TIBC) REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TOTAL IRON-BINDING CAPACITY (TIBC) CONCENTRATION IN SERUM. ,ISE URINE DILUENT (ISE DIL URN)-ISE URINE DILUENT (ISE DIL URN) IS REQUIRED FOR URINE SAMPLES. URINE SAMPLES MUST BE DILUTED BY A FACTOR OF 10 TO PERFORM URINE MEASUREMENT. THE HOST ANALYSER WILL MIX THE DILUENT AND SAMPLE BEFORE DISPENSING THE DILUTED SAMPLE INTO THE ISE MODULE. ,URIC ACID (UA) -THE URIC ACID (UA) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID CONCENTRATION IN SERUM, PLASMA AND URINE. ,: LIPOPROTEIN (A) (LP(A))-THE LIPOPROTEIN (A) (LP(A)) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF LIPOPROTEIN CONCENTRATION IN SERUM AND PLASMA ,HOMOCYSTEINE (HCY)-A HOMOCYSTEINE TEST SYSTEM IS A DEVICE INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF HOMOCYSTEINE CONCENTRATION IN HUMAN SERUM,CREATINE KINASE (CK-MB)-THE CREATINE KINASE (CK-MB) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CK-MB CONCENTRATION IN SERUM AND PLASMA,CALCIUM (CA)-THE CALCIUM (CA) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN SERUM, PLASMA AND URINE, FERRITIN (FERR) -THE FERRITIN (FERR) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF FERRITIN CONCENTRATION IN SERUM AND PLASMA,HAEMOGLOBIN A1C (HBA1C) -A HAEMOGLOBIN A1C TEST SYSTEM IS A DEVICE INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF HAEMOGLOBIN A1C CONCENTRATION IN WHOLE BLOOD, FRUCTOSAMINE CONTROL (FRUC CONTROL) -THE FRUCTOSAMINE CONTROL (FRUC CONTROL) IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. THE

	FRUCTOSAMINE CONTROL IS FOR THE CONTROL OF ACCURACY, IMMUNOASSAY PREMIUM PLUS -IMMUNOASSAY PREMIUM PLUS IS INTENDED FOR IN VITRO DIAGNOSTIC USE, IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. THE IMMUNOASSAY PREMIUM AND IMMUNOASSAY PREMIUM PLUS IS FOR THE CONTROL OF ACCURACY., URINALYSIS CONTROL (URNAL CONTROL) -THE URINALYSIS CONTROL IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. THE URINALYSIS CONTROL IS FOR THE CONTROL OF ACCURACY,DIRECT LDL/HDL CHOLESTEROL CALIBRATOR (D LDL/HDL CAL)-DIRECT LDL/HDL CHOLESTEROL CALIBRATOR (D LDL/HDL CAL) IS INTENDED FOR IN VITRO USE, IN THE CALIBRATION OF RANDOX HDL & LDL CHOLESTEROL CLEARANCE METHODS. THIS CALIBRATION MATERIAL IS BASED ON LYOPHILISED HUMAN SERUM.,SLDL-EX “SEIKEN” (SLDL) -THE SLDL-EX “SEIKEN” (SLDL) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF SLDL-EX “SEIKEN” CONCENTRATION IN SERUM AND PLASMA,AMYLASE (AMY)-THE AMYLASE (AMY) REAGENT DEVICE IS REQUIRED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF AMYLASE IN SERUM, PLASMA OR URINE,COPPER (CU) -THE COPPER (CU) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF COPPER IN SERUM AND PLASMA ,INORGANIC PHOSPHORUS (PHOS)-THE INORGANIC PHOSPHOROUS (PHOS) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF INORGANIC PHOSPHOROUS IN SERUM, PLASMA AND URINE,BUFFER AND L SOLUTION -THE ISE BUFFER & L SOLUTIONS ARE REQUIRED FOR THE RUNNING OF THE ISE UNIT ON THE RX MODENA ANALYSER., GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G-6-PDH)-THE GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G-6-PDH) IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE IN ERYTHROCYTES,CO2 TOTAL (CO2) -THE CO2 TOTAL (CO2) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CARBON DIOXIDE IN SERUM AND PLASMA ,HUMAN ASSAYED MULTI-SERA LEVEL 2 (HUM ASY CONTROL 2)(NA)-THE HUMAN ASSAYED MULTI-SERA (HUM ASY CONTROL) IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. THE HUMAN ASSAYED MULTI-SERA IS FOR THE CONTROL OF ACCURACY,MATERNAL CONTROL - LEVEL 1 (MATERNAL CONTROL 1)(NA)-THE MATERNAL CONTROL PRODUCT IS INTENDED FOR IN VITRO USE, IN THE QUALITY CONTROL OF ALPHA-FETOPROTEIN, FREE BETA HCG, FREE ESTRIOL, HUMAN CHORIONIC GONADOTROPIN, INHIBIN A AND PAPP-A METHODS ON CLINICAL CHEMISTRY SYSTEMS,MATERNAL CONTROL - LEVEL 3 (MATERNAL CONTROL 3)(NA)-THE MATERNAL CONTROL

	PRODUCT IS INTENDED FOR IN VITRO USE, IN THE QUALITY CONTROL OF ALPHA-FETOPROTEIN, FREE BETA HCG, FREE ESTRIOL, HUMAN CHORIONIC GONADOTROPIN, INHIBIN A AND PAPP-A METHODS ON CLINICAL CHEMISTRY SYSTEMS,COMPLEMENT C4 (C4)-THE COMPLEMENT C4 (C4) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF COMPLEMENT C4 CONCENTRATION IN SERUM AND PLASMA,LACTATE (LAC)-THE LACTATE (LAC) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF L-LACTATE IN PLASMA AND CSF. THIS PRODUCT IS SUITABLE FOR MANUAL USE AND ON SEMI- AUTOMATED INSTRUMENTS., COMPLEMENT C3 (C3)-THE COMPLEMENT C3 (C3) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF COMPLEMENT C3 CONCENTRATION IN SERUM AND PLASMA,ISE CALIBRATOR A (CAL A)-ISE CALIBRATOR A (CAL A) USED AS A WASH SOLUTION AND SINGLE POINT CALIBRATOR. CALIBRATOR A IS PUMPED INTO THE SAMPLE PORT BY THE CALIBRATOR A PUMP AND THEN POSITIONED IN FRONT OF THE SENSOR. THIS PRODUCT IS SUITABLE FOR USE ON THE RX SERIES INSTRUMENTS WHICH INCLUDES THE RX DAYTONA AND THE RX IMOLA.,SALINE DILUENT (NS)-SALINE DILUENT (NS) SHOULD BE USED IN CONJUNCTION WITH RX DAYTONA PLUS REAGENTS TO DILUTE SAMPLES PRIOR TO ASSAY.,BILE ACIDS (TBA)-THE BILE ACIDS (TBA) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILE ACIDS IN SERUM AND PLASMA ,ISE ELECTRODE-ISE ELECTRODE IS A FOR THE QUANTITATIVE IN VITRO DETERMINATION OF SODIUM, POTASSIUM AND CHLORIDE IN SERUM, PLASMA AND URINE.,BLOOD GAS CONTROL (BG CONTROL)-THE BLOOD GAS CONTROL (BG CONTROL) ARE INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. THE BLOOD GAS CONTROL (BG CONTROL) ARE FOR THE CONTROL OF ACCURACY,RX MODENA ISE ELECTRODE-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF SODIUM, POTASSIUM AND CHLORIDE IN SERUM, PLASMA AND URINE. THIS PRODUCT IS SUITABLE FOR USE ON THE RX MODENA.,ISE CLEANING SOLUTION (SOLN WASH)-ISE CLEANING SOLUTION (SOLN WASH) SHOULD BE RUN ONCE A DAY TO PREVENT PROTEIN BUILD UP OR AT 8-HOUR INTERVALS IF THE ISE MODULE PERFORMS MORE THAN 50 SAMPLES PER DAY. CLEANING SOLUTION MAY BE ASPIRATED FROM A SAMPLE CUP, BUT THE CUP MUST BE COVERED BETWEEN USE TO ELIMINATE EVAPORATION AND ENSURE ACCURACY ,ASSAYED URINE CONTROL-THE ASSAYED URINE CONTROL IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUALITY CONTROL OF DIAGNOSTIC ASSAYS. THE ASSAYED URINE CONTROL IS FOR THE CONTROL OF ACCURACY.,LACTATE (LAC)-THE LACTATE (LAC) DEVICE IS INTENDED FOR THE QUANTITATIVE IN

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		VITRO DETERMINATION OF L-LACTATE IN PLASMA AND CSF. THIS PRODUCT IS SUITABLE FOR MANUAL USE AND ON SEMI- AUTOMATED INSTRUMENTS. ,MAGNESIUM (MG)-THE MAGNESIUM (MG) DEVICE IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF MAGNESIUM CONCENTRATION IN SERUM, PLASMA AND URINE. ,LIPID CONTROL (LPD CONTROL)-LIPID CONTROL (LPD CONTROL) IS SUPPLIED AT 3 LEVELS, LEVEL 1, 2 AND 3. TARGET VALUES AND RANGES ARE SUPPLIED FOR THE ANALYTES LISTED IN THE VALUES SECTION AT BOTH LEVELS.,NORMAL SALINE (NS)-NORMAL SALINE (NS) PRODUCT SHOULD BE USED IN CONJUNCTION WITH RX SERIES REAGENTS TO DILUTE SAMPLES PRIOR TO ASSAY.,HEMOGLOBIN A1C CALIBRATOR -THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF HBA1C ON CLINICAL CHEMISTRY SYSTEMS
769	IMP/IVD/2020/000587	1.License Holder Name: ACCUREX BIOMEDICALS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: URIC ACID TEST STRIP (BENECHECK)-THE URIC ACID TEST STRIP IS INTENDED TO MEASURE THE URIC ACID LEVELS IN FINGERTIP CAPILLARY WHOLE BLOOD FOR SELF-TESTING WITH THE METER.

770	IMP/IVD/2020/000591	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANA SCREEN 8 IGG-IN VITRO DIAGNOSTIC TEST FOR DETERMINATION OF ANTI NUCLEAR ANTIBODIES IN HUMAN SERUM/PLASMA,SS-A/RO 60 IGG-IN VITRO DIAGNOSTIC TEST FOR DETERMINATION OF SSA/RO60 AUTO ANTIBODIES IN HUMAN SERUM/PLASMA,ß2-GLYCOPROTEIN 1 (ß2GP1) IGG-IN VITRO DIAGNOSTIC TEST FOR DETERMINATION OF ß2GP1 IGG AUTO ANTIBODIES IN HUMAN SERUM/PLASMA,DSDNA IGG-IN VITRO DIAGNOSTIC TEST FOR DETERMINATION OF DSDNA IGG AUTO ANTIBODIES IN HUMAN SERUM/PLASMA,TISSUE TRANSGLUTAMINASE (TTG) IGA-IN VITRO DIAGNOSTIC TEST FOR DETERMINATION OF TTG IGA AUTO ANTIBODIES IN HUMAN SERUM/PLASMA,PROTEINASE 3 (PR3) IGG-IN VITRO DIAGNOSTIC TEST FOR DETERMINATION OF PR3 AUTO ANTIBODIES IN HUMAN SERUM/PLASMA,MYELOPEROXIDASE (MPO) IGG-IN VITRO DIAGNOSTIC TEST FOR DETERMINATION OF MPO AUTO ANTIBODIES IN HUMAN SERUM/PLASMA,ß2-GLYCOPROTEIN 1 (ß2GP1) IGM-IN VITRO DIAGNOSTIC TEST FOR DETERMINATION OF ß2GP1 1 IGM AUTO ANTIBODIES IN HUMAN SERUM/PLASMA,CARDIOLIPIN IGM-IN VITRO DIAGNOSTIC TEST FOR DETERMINATION OF CARDIOLIPIN IGM AUTO ANTIBODIES IN HUMAN SERUM/PLASMA,CARDIOLIPIN IGG-IN VITRO DIAGNOSTIC TEST FOR DETERMINATION OF CARDIOLIPIN IGG AUTO ANTIBODIES IN HUMAN SERUM/PLASMA
771	IMP/IVD/2020/000592	1.License Holder Name: BRUNDAS TRADING CONSORTIUM PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DILUENT(ZYBIO)-THE DILUENT IS USED FOR COUNTING AND SIZING BLOOD CELLS.,LYSE (ZYBIO)-FOR CELL CLASSIFICATION COUNT OR HEMOGLOBIN QUANTITATIVE MEASUREMENT.,LYSE(ZYBIO)-FOR CELL CLASSIFICATION COUNT OR HEMOGLOBIN QUANTITATIVE MEASUREMENT.

772	IMP/IVD/2020/000597	1.License Holder Name: ASVINS LIFETECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:U-TOP™ COVID-19 DETECTION KIT-THE U-TOP COVID-19 DETECTION KIT IS A ONE-STEP REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN OROPHARYNGEAL AND NASOPHARYNGEAL SWAB SPECIMENS, ANTERIOR NASAL AND MID-TURBINATE NASAL SWABS, NASOPHARYNGEAL WASH/ASPIRATE OR NASAL ASPIRATE SPECIMENS AND SPUTUM FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER.
773	IMP/IVD/2020/000598	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REACELL PANEL FOR ANTIBODY IDENTIFICATION(REACELL PANEL)-REACELL PANEL ARE USED FOR ANTIBODY IDENTIFICATION..,REACELL I, II, III FOR ANTIBODY DETECTION(REACELL I, II, III)-REACELL I, II, III ARE USED FOR ANTIBODY DETECTION.,REA IQC TB (TOTAL BLOOD) KIT FOR BLOOD GROUPING(REA IQC TB KIT)-REA IQC TOTAL BLOOD KIT FOR INTERNAL QUALITY CONTROL FOR IMMUNOHAEMATOLOGY TESTING.
774	IMP/IVD/2020/000600	1.License Holder Name: TOPAIM PROPERTIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (2019-NCOV) RT – PCR DETECTION KIT(FOSUN 2019 – NCOV QPCR)-THIS PRODUCT IS INTENDED FOR THE RAPID DETECTION OF 2019-NCOV BY TAQMAN MULTIPLEX REAL-TIME PCR IN HUMAN THROAT SWAB OR SPUTUM SAMPLES

775	IMP/IVD/2020/000602	1.License Holder Name: KDH BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:H.PYLORI(CERTEST H. PYLORI)-FOR THE QUALITATIVE DETECTION OF HELICOBACTER PYLORI IN STOOL SAMPLES.,CRYPTO(CERTEST CRYPTO)-FOR THE QUALITATIVE DETECTION OF CRYPTOSPORIDIUM IN STOOL SAMPLES.,RSV(CERTEST RSV)-FOR THE QUALITATIVE DETECTION OF RESPIRATORY SYNCYTICAL VIRUS ANTIGEN FROM NASAL SWAB, NASOPHARYANGEAL WASH OR ASPIRATE SPECIMENS.,GIARDIA (CERTEST GIARDIA)-FOR THE QUALITATIVE DETECTION OF GIARDIA IN STOOL SAMPLES.,ADENOVIRUS RESP(CERTEST ADENOVIRUS RESP)-FOR THE QUALITATIVE DETECTION OF ADENOVIRUS FROM NASAL SWAB, NASOPHARYNGEAL WASH OR ASPIRATE SPECIMENS., STREP A(CERTEST STREP A)-FOR THE QUALITATIVE DETECTION OF GROUP A STREPTOCOCCAL FROM THROAT SWABS AND SUSPECTED GROUP A STREPTOCOCCAL COLONIES RECOVERED FROM CULTURE., LEGIONELLA(CERTEST LEGIONELLA)-FOR THE QUALITATIVE DETECTION OF LEGIONELLA PNEUMOPHILLA IN HUMAN URINE SAMPLES.,NOROVIRUS GL + GLL(CERTEST NOROVIRUS GL + GLL)-FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF NOROVIRUS GENOGROUP I AND II (GL AND GLL) IN STOOL SAMPLES., CALPROTECTIN TURBILATEX COMBO(CALPROTECTIN TURBILATEX COMBO)-CALPROTECTIN TURBILATEX IS A LATEX TURBIDIMETRIC ASSAY ONLY FOR THE QUANTITATIVE DETECTION OF CALPROTECTIN IN HUMAN SOLID STOOL SAMPLES (NOT TO BE USED FOR BODY FLUID AS BLOOD, SERUM, PLASMA, URINE, CEREBROSPINAL FLUID, ORAL FLUID, SYNOVIAL FLUID OR EMPYEMA FLUID).,CALPROTECTIN 50 + 200(CERTEST CALPROTECTIN 50 + 200)-FOR THE SIMULTANEOUS SEMI-QUANTITATIVE DETECTION OF HUMAN CALPROTECTIN (HCP) IN STOOL SAMPLES,YERSINIA ENTERCOLITICA 0 : 3 + 0 : 9(CERTEST YERSINIA ENTERCOLITICA 0 : 3 + 0 : 9)-FOR THE SIMULTANEOUS QUALTIATIVE DETECTION OF YERSINA ENTEROCOLITICA SEROTYPES 0 : 3 AND 0 : 9 IN STOOL SAMPLES AND YERSINIA SUSPECTED COLONIES IN STOOL CULTURE., CALPROTECTIN TURBILATEX SAMPLE COLLECTION VIALS(SAMPLE DILUTION VIALS MC)-SAMPLE DILUENT VIALS IS A SINGLE USE VIAL CONTAINING DILUENT FOR FAECAL SAMPLES DILUTION. FOR PROFESSIONAL IN VITRO DIAGNOSTICS USE ONLY.,CLOSTRIDIUM DIFFICILE GDH + TOXIN A + B(CERTEST CLOSTRIDIUM DIFFICILE GDH + TOXIN A + B)-FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF CLOSTRIDUM DIFFICILE GLUTAMATE DEHYDROGENASE (GDH), TOXIN A AND TOXIN B IN STOOL SAMPLES.,ADENOVIRUS(CERTEST ADENOVIRUS)-FOR THE QUALITATIVE DETECTION OF ADENOVIRUS IN STOOL SAMPLES.,EHEC VT1 + VT2(CERTEST EHEC VT1 + VT2)-FOR

	THE SIMULTANEOUS QUALITATIVE DETECTION OF VEROXINS 1 AND 2 (VT1 AND VT2) PRODUCED BY E. COLI IN STOOL SAMPLE AND E. COLI SUSPECTED COLONIES IN STOOL CULTURE.,CRYPTO + GIARDIA (CERTEST CRYPTO + GIARDIA)-FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF CRYPTOSPORIDIUM AND GIARDIA IN STOOL SAMPLES.,CAMPYLOBACTER(CERTEST CAMPYLOBACTER)-FOR THE QUALITATIVE DETECTION OF CAMPYLOBACTER SPP. STOOL SAMPLES AND CAMPYLOBACTER SPP. SUSPECTED COLONIES IN STOOL CULTURE.,LISTERIA(CERTEST LISTERIA)-FOR THE QUALITATIVE DETECTION OF LISTERIA MONOCYTOGENES IN STOOL SAMPLES.,ROTA + ADENO + ASTRO + NORO GI/GII(CERTEST ROTA + ADENO + ASTRO + NORO GI/GII)-FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF ROTAVIRUS, ADENOVIRUS, ASTROVIRUS AND NOROVIRUS IN STOOLS SAMPLES. ,ROTAVIRUS (CERTEST ROTAVIRUS)-FOR THE QUALITATIVE DETECTION OF ROTAVIRUS IN STOOL SAMPLES. ,ENTAMOEBA(CERTEST ENTAMOEBA)-FOR THE QUALITATIVE DETECTION OF ENTAMOEBA SPP. IN STOOL SAMPLES.,FOB(CERTEST FOB)-FOR THE SEMI-QUANTITATIVE DETERMINATION OF HUMAN HEAMOGLOBIN (HHB) IN STOOL SAMPLES.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

776	IMP/IVD/2020/000603	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALINITY C TOBRAMYCIN REAGENT KIT(ALINITY C TOBRAMYCIN REAGENT KIT)-THE ALINITY C TOBRAMYCIN ASSAY IS USED FOR THE QUANTITATIVE DETERMINATION OF TOBRAMYCIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C ETHANOL REAGENT KIT (ALINITY C ETHANOL REAGENT KIT)-THE ALINITY C ETHANOL ASSAY IS USED FOR THE QUANTITATIVE DETERMINATION OF ETHANOL IN HUMAN URINE, SERUM, OR PLASMA ON THE ALINITY C ANALYZER., ALINITY C DIGOXIN REAGENT KIT(ALINITY C DIGOXIN REAGENT KIT)-THE ALINITY C DIGOXIN ASSAY IS USED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF DIGOXIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C PHENOBARBITAL REAGENT KIT (ALINITY C PHENOBARBITAL REAGENT KIT)-THE ALINITY C PHENOBARBITAL ASSAY IS FOR IN VITRO DIAGNOSTIC USE FOR THE QUANTITATIVE MEASUREMENT OF PHENOBARBITAL IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C TOBRAMYCIN CALIBRATORS(ALINITY C TOBRAMYCIN CALIBRATORS) -THE ALINITY C TOBRAMYCIN CALIBRATORS ARE INTENDED FOR USE IN THE CALIBRATION OF THE ALINITY C TOBRAMYCIN ASSAY ON THE ALINITY C ANALYZER.,ALINITY C VANCOMYCIN REAGENT KIT (ALINITY C VANCOMYCIN REAGENT KIT)-THE ALINITY C VANCOMYCIN ASSAY IS USED FOR THE QUANTITATIVE DETERMINATION OF VANCOMYCIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C PHENYTOIN REAGENT KIT(ALINITY C PHENYTOIN REAGENT KIT)-THE ALINITY C PHENYTOIN ASSAY IS USED FOR IN VITRO DIAGNOSTIC USE FOR THE QUANTITATIVE MEASUREMENT OF PHENYTOIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C TDM MULTICONSTITUENT CALIBRATOR KIT(ALINITY C TDM MULTICONSTITUENT CALIBRATOR KIT)-FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF THE ALINITY C DIGOXIN, GENTAMICIN, PHENYTOIN, AND VANCOMYCIN HUMAN SERUM OR PLASMA ASSAYS ON THE ALINITY C ANALYZER., ALINITY C ETHANOL CALIBRATOR KIT(ALINITY C ETHANOL CALIBRATOR KIT)-THE ALINITY C ETHANOL CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE ALINITY C ETHANOL ASSAY, WHICH IS USED FOR THE QUANTITATIVE DETERMINATION OF ETHANOL (ETHYL ALCOHOL OR ALCOHOL) IN HUMAN URINE, SERUM, OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C VALPROIC ACID REAGENT KIT(ALINITY C VALPROIC ACID REAGENT KIT)-THE ALINITY C VALPROIC ACID ASSAY IS USED FOR THE QUANTITATIVE IN VITRO MEASUREMENT OF VALPROIC ACID IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C ETHANOL CONTROL KIT

		(ALINITY C ETHANOL CONTROL KIT)-THE ALINITY C ETHANOL CONTROLS ARE INTENDED FOR THE QUALITY CONTROL OF THE ALINITY C ETHANOL ASSAY, WHICH IS USED FOR THE QUANTITATIVE DETERMINATION OF ETHANOL (ETHYL ALCOHOL OR ALCOHOL) IN HUMAN URINE, SERUM, OR PLASMA ON THE ALINITY C ANALYZER., ALINITY C AMIKACIN REAGENT KIT(ALINITY C AMIKACIN REAGENT KIT)-THE ALINITY C AMIKACIN ASSAY IS USED FOR THE QUANTITATIVE DETERMINATION OF AMIKACIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C THEOPHYLLINE REAGENT KIT(ALINITY C THEOPHYLLINE REAGENT KIT)-THE ALINITY C THEOPHYLLINE ASSAY IS FOR IN VITRO DIAGNOSTIC USE FOR THE QUANTITATIVE MEASUREMENT OF THEOPHYLLINE IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.,ALINITY C GENTAMICIN REAGENT KIT(ALINITY C GENTAMICIN REAGENT KIT)-THE ALINITY C GENTAMICIN ASSAY IS USED FOR THE QUANTITATIVE DETERMINATION OF GENTAMICIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.
777	IMP/IVD/2020/000607	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HBA1C LIQUID CONTROLS (EXTENDSURE HBA1C LIQUID CONTROLS)-THE CONTROLS ARE DESIGNED FOR USE AS QUALITY CONTROL MATERIALS TO MONITOR THE ACCURACY AND PRECISION OF LABORATORY TESTING PROCEDURES FOR HBA1C QUANTITATION FOR THE FOLLOWING ASSAY TYPES: ION EXCHANGE, HPLC, IMMUNOASSAY AND ENZYMATIC PROCEDURES.
778	IMP/IVD/2020/000608	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERKINELMER® NUCLEIC ACID EXTRACTION KIT(PERKINELMER® NUCLEIC ACID EXTRACTION KIT)-THE PERKINELMER® NUCLEIC ACID KIT IS DESIGNED FOR DNA/RNA EXTRACTION AND PURIFICATION FROM OROPHARYNGEAL SWAB, NASOPHARYNGEAL SWAB, PLASMA AND SERUM SPECIMENS USING MAGNETIC BEADS. THE KIT IS INTENDED TO BE USED FOR IN VITRO DIAGNOSTICS WITH PERKINELMER DIAGNOSTIC ASSAYS, FOR EXAMPLE THE PERKINELMER® SARS-COV-2 REAL-TIME RT-PCR ASSAY.

779	IMP/IVD/2020/000609	1.License Holder Name: M/S AVANTOR PERFORMANCE MATERIALS INDIA LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 RT-PCR KIT 1.0(REALSTAR®)-REALSTAR® SARS-COV-2 RT-PCR KIT 1.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE QUALITATIVE DETECTION OF LINEAGE B-BETA CORONAVIRUS (LINEAGE B-COV) AND SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) SPECIFIC RNA.

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780	IMP/IVD/2020/000615	1.License Holder Name: INSTRUMENTATION LABORATORY INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOSIL FACTOR X DEFICIENT PLASMA(HEMOSIL)-HUMAN PLASMA IMMUNODEPLETED OF FACTOR X FOR THE QUANTITATIVE DETERMINATION OF FACTOR X ACTIVITY IN CITRATED PLASMA, BASED ON THE PROTHROMBIN TIME (PT) ASSAY, ON IL COAGULATION SYSTEMS.,HEMOSIL REFERENCE EMULSION(HEMOSIL)-REFERENCE EMULSION - FOR USE WITH ACL CLASSIC (100-7000) INSTRUMENTS,HEMOSIL RECOMBIPLASTIN 2G (20 ML)(HEMOSIL)-A HIGH SENSITIVITY THROMBOPLASTIN REAGENT BASED ON RECOMBINANT HUMAN TISSUE FACTOR (RTF) FOR THE QUANTITATIVE DETERMINATION IN HUMAN CITRATED PLASMA OF PROTHROMBIN TIME (PT) AND FIBRINOGEN ON IL COAGULATION SYSTEMS. THE PRODUCT IS USED FOR THE EVALUATION OF THE EXTRINSIC COAGULATION PATHWAY AND THE MONITORING OF ORAL ANTICOAGULANT THERAPY (OAT).,HEMOSIL PROCLOT DILUENT (HEMOSIL)-PROCLOT DILUENT - FOR USE WITH PROCLOT. FOR USE WITH PROCLOT. COMPOSITION: HEPES BUFFER, POLYBRENE AND PRESERVATIVE. ,HEMOSIL FACTOR V LEIDEN (APC RESISTANCE V) (HEMOSIL)-FOR DETERMINATION OF RESISTANCE TO ACTIVATED PROTEIN C, CAUSED BY THE FACTOR V:Q 506 (FACTOR V LEIDEN) MUTATION, IN PLASMA FROM UNTREATED INDIVIDUALS AND FROM PATIENTS ON ORAL ANTI-COAGULANT(OAT) OR HEPARIN THERAPY., HEMOSIL RINSE, 4 LITERS(HEMOSIL)-FOR USE WITH THE ACL TOP® FAMILY INSTRUMENTS. CONTENTS: SURFACTANT AND PRESERVATIVE. ,HEMOSIL PT-FIBRINOGEN HS PLUS(HEMOSIL)-A VERY HIGH SENSITIVITY CALCIUM THROMBOPLASTIN FOR SIMULTANEOUS DETERMINATIONS OF PROTHROMBIN TIME (PT) AND FIBRINOGEN (FIB), FOR EVALUATION OF THE EXTRINSIC COAGULATION PATHWAY AND MONITORING ORAL ANTICOAGULANT THERAPY INHUMAN CITRATED PLASMA ON THE IL COAGULATION SYSTEMS.,HEMOSIL SAMPLE DILUENT(HEMOSIL)-SAMPLE DILUENT - FOR USE WITH ACL CLASSIC (100-7000) INSTRUMENTS FOR THE CALIBRATION OF BOTH PT AND FIBRINOGEN ASSAYS,HEMOSIL FACTOR XII DEFICIENT PLASMA(HEMOSIL)-HUMAN PLASMA IMMUNODEPLETED OF FACTOR XII FOR THE QUANTITATIVE DETERMINATION OF FACTOR XII (FXII) ACTIVITY IN CITRATED PLASMA, BASED ON ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) ASSAY, ON IL COAGULATION SYSTEMS.,HEMOSIL RECOMBIPLASTIN 2G (20 ML)(HEMOSIL)-A HIGH SENSITIVITY THROMBOPLASTIN REAGENT BASED ON RECOMBINANT HUMAN TISSUE FACTOR (RTF) FOR THE QUANTITATIVE DETERMINATION IN HUMAN CITRATED PLASMA OF PROTHROMBIN TIME (PT) AND

	FIBRINOGEN ON IL COAGULATION SYSTEMS. THE PRODUCT IS USED FOR THE EVALUATION OF THE EXTRINSIC COAGULATION PATHWAY AND THE MONITORING OF ORAL ANTICOAGULANT THERAPY (OAT), ELECTRACHROME FACTOR VIII(HEMOSIL)-FOR THE PHOTOMETRIC DETERMINATION OF FACTOR VIII ACTIVITY IN HUMAN CITRATED PLASMA. THIS INCLUDES DETECTION OF FACTOR VIII DEFICIENCY, MONITORING PATIENTS ON REPLACEMENT THERAPY AND FOR POTENCY ESTIMATION OFFACTOR VIII CONCENTRATES.,HEMOSIL CLEANING SOLUTION(HEMOSIL)-CLEANING SOLUTION - FOR USE WITH IL 1300 FAMILY BLOOD GAS ANALYZERS AND ACL FAMILY, ACL FUTURA, ACL ADVANCE AND ACL TOP INSTRUMENTS (CLEAN A)., HEMOSIL READIPLASTIN (20ML)(HEMOSIL)-HEMOSIL READIPLASTIN IS AN IN VITRO DIAGNOSTIC THROMBOPLASTIN REAGENT, BASED ON RECOMBINANT HUMAN TISSUE FACTOR, FOR THE QUANTITATIVE DETERMINATION, IN HUMAN CITRATED PLASMA, OF PROTHROMBIN TIME (PT) AND FIBRINOGEN, ON THE ACL TOP FAMILY AND ACL TOP FAMILY 50 SERIES OF ANALYZERS. THE PRODUCT IS INTENDED TO BE USED FOR THE EVALUATION OF THE EXTRINSIC COAGULATION PATHWAY AND THE MONITORING OF ORAL VITAMIN K ANTAGONIST THERAPY.,HEMOSIL WASH-R EMULSION(HEMOSIL)-OPTICAL REFERENCE FOR NEPHELOMETRIC ANALYSIS AND WASHING SOLUTION ON ACL ELITE/ELITE PRO SYSTEMS.,HEMOSIL RECOMBIPLASTIN 2G (5 X 8 ML)(HEMOSIL)-A HIGH SENSITIVITY THROMBOPLASTIN REAGENT BASED ON RECOMBINANT HUMAN TISSUE FACTOR (RTF) FOR THE QUANTITATIVE DETERMINATION IN HUMAN CITRATED PLASMA OF PROTHROMBIN TIME (PT) AND FIBRINOGEN ON IL COAGULATION SYSTEMS. THE PRODUCT IS USED FOR THE EVALUATION OF THE EXTRINSIC COAGULATION PATHWAY AND THE MONITORING OF ORAL ANTICOAGULANT THERAPY (OAT)., HEMOSIL FACTOR DILUENT (HEMOSIL)-FOR USE WITH IL COAGULATION SYSTEMS. COMPOSITION: SALINE SOLUTION AND LESS THAN 0.1% OF SODIUM AZIDE. ,HEMOSIL DRVVT SCREEN (HEMOSIL)-THE DRVVT SCREEN AND HEMOSIL DRVVT CONFIRM ASSAYS ARE QUALITATIVE IN-VITRO DIAGNOSTIC PRODUCTS TO AID IN THE DETECTION OF LUPUS ANTICOAGULANTSIN HUMAN CITRATED PLASMA BY THE DILUTED RUSSELL'S VIPER VENOM METHOD, ON IL COAGULATION SYSTEMS. THE HEMOSIL DRVVT SCREEN AND HEMOSIL DRVVT CONFIRM ASSAYS ARE INTENDED TO EVALUATE PATIENTS WHO HAVE UNEXPLAINED PROLONGED APTT TEST RESULTS. THE HEMOSIL DRVVT SCREEN AND HEMOSIL DRVVT CONFIRM ASSAYS SHOULD BE USED IN PARALLEL AS AN INTEGRATED TEST FOR LUPUS ANTICOAGULANT DETECTION.,GEM ® CVP 5 (CALIBRATION VALUATION PRODUCT) TBILI(GEM PREMIER 5000 SYSTEM)-EXTERNAL CALIBRATION VALUATION PRODUCT

	USED TO COMPLETE THE CALIBRATION PROCESS OF GEM PREMIER 4000 AND GEM PREMIER 5000* ANALYZERS PRIOR TO USE WITH PATIENT SAMPLES FOR TOTAL BILIRUBIN (TBILI) TESTING.,HEMOSIL DIRECT THROMBIN INHIBITOR ASSAY(HEMOSIL)-THE HEMOSIL DIRECT THROMBIN INHIBITOR (DTI) ASSAY IS AN IN VITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE DIRECT THROMBIN INHIBITOR DABIGATRAN IN CITRATED HUMAN PLASMA ON THE ACL TOP FAMILY OF ANALYZERS. THE PRODUCT IS INTENDED TO BE USED FOR THE MEASUREMENT OF ACTIVE DABIGATRAN LEVELS IN SITUATIONS WHERE MEASUREMENT IS WARRANTED.,GEM PREMIER 5000 PAK PH, PCO2, PO2, NA+, K+, CA++, CL-, GLU, LAC, HCT, THB, O2HB, COHB, HHB, METHB, SO2 - 75 TEST(GEM PREMIER 5000 PAK)-SENSOR AND REAGENT CARTRIDGE FOR USE WITH THE IL GEM PREMIER 5000 ANALYZER.,HEMOSIL SYNTHAFAX(HEMOSIL)-A HIGH QUALITY SYNTHETIC PHOSPHOLIPIDS REAGENT FOR THE IN VITRO DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME(APTT) IN HUMAN CITRATED PLASMA ON IL COAGULATION SYSTEMS. THE PRODUCT IS USED FOR THE EVALUATION OF THE INTRINSIC COAGULATION PATHWAY, APTT SUBSTITUTION TEST AND THE MONITORING OF HEPARIN THERAPY. , HEMOSIL FACTOR VIII DEFICIENT PLASMA(HEMOSIL)-HEMOSIL FACTOR VIII DEFICIENT PLASMA IS HUMAN PLASMA, DEPLETED OF FACTOR VIII, WHICH IS INTENDED FOR THE IN VITRO DIAGNOSTIC QUANTITATIVE DETERMINATION OF FACTOR VIII ACTIVITY IN CITRATED PLASMA, BASED ON THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) ASSAY, ON THE ACL TOP® FAMILY/ACL TOP FAMILY 50 SERIES† ANALYZERS. HEMOSIL FACTOR VIII DEFICIENT PLASMA IS INDICATED FOR USE ON PATIENTS WHO ARE SUSPECTED OF CONGENITAL OR ACQUIRED DEFICIENCY BASED ON THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) ASSAY RESULTS.,HEMOSIL FACTOR VII DEFICIENT PLASMA(HEMOSIL)-HUMAN PLASMA IMMUNODEPLETED OF FACTOR VII FOR THE QUANTITATIVE DETERMINATION OF FACTOR VII ACTIVITY IN CITRATED PLASMA, BASED ON THE PROTHROMBIN TIME (PT) ASSAY, ON IL COAGULATION SYSTEMS.,GEM PREMIER 5000 PAK PH, PCO2, PO2, NA+, K+, CA++, CL-, HCT, THB, O2HB, COHB, HHB, METHB, SO2 - 75 TEST(GEM PREMIER 5000 PAK)-SENSOR AND REAGENT CARTRIDGE FOR USE WITH THE IL GEM PREMIER 5000 ANALYZER., HEMOSIL APTT-SP(HEMOSIL)-FOR THE IN VITRO DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) IN CITRATED PLASMA ON IL COAGULATION SYSTEMS AS A GENERAL SCREENING PROCEDURE FOR THE EVALUATION OF THE INTRINSIC COAGULATION PATHWAY AND TO MONITOR PATIENTS RECEIVING HEPARIN ANTICOAGULANT THERAPY.,GEM PREMIER 5000 PAK PH, PCO2, PO2,

	HCT, TBILI, THB, O2HB, COHB, HHB, METHB, SO2 - 75 TEST(GEM PREMIER 5000 PAK)-SENSOR AND REAGENT CARTRIDGE FOR USE WITH THE IL GEM PREMIER 5000 ANALYZER.,HEMOSIL PROCLOT (HEMOSIL)-AUTOMATED FUNCTIONAL CLOTTING PROTEIN C ASSAY FOR THE QUANTITATIVE DETERMINATION OF PROTEIN C IN HUMAN CITRATED PLASMA ON THE IL COAGULATION SYSTEMS,HEMOSIL QFA THROMBIN (BOVINE) (HEMOSIL)-FOR THE QUANTITATIVE DETERMINATION OF FIBRINOGEN, BASED ON THE CLAUSS METHOD, IN HUMAN CITRATED PLASMA ON THE IL COAGULATION SYSTEMS., HEMOSIL LIQUID ANTITHROMBIN(HEMOSIL)-AUTOMATED CHROMOGENIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTITHROMBIN IN HUMAN CITRATED PLASMA ON THE IL COAGULATION SYSTEMS.,GEM PREMIER 5000 PAK PH, PCO2, PO2, NA+, K+, CA++, CL-, GLU, LAC, HCT, TBILI, THB, O2HB, COHB, HHB, METHB, SO2 - 75 TEST(GEM PREMIER 5000 PAK)-SENSOR AND REAGENT CARTRIDGE FOR USE WITH THE IL GEM PREMIER 5000 ANALYZER.,HEMOSIL FACTOR V DEFICIENT PLASMA(HEMOSIL)-HUMAN PLASMA IMMUNODEPLETED OF FACTOR V FOR THE QUANTITATIVE DETERMINATION OF FACTOR V ACTIVITY IN CITRATED PLASMA, BASED ON THE PROTHROMBIN TIME (PT) ASSAY, ON IL COAGULATION SYSTEMS.,GEM PREMIER 5000 PAK PH, PCO2, PO2, NA+, K+, CA++, CL-, HCT, TBILI, THB, O2HB, COHB, HHB, METHB, SO2 - 75 TEST(GEM PREMIER 5000 PAK)-SENSOR AND REAGENT CARTRIDGE FOR USE WITH THE IL GEM PREMIER 5000 ANALYZER., HEMOSIL FIBRINOGEN-C (10X2ML)(HEMOSIL)-FOR THE QUANTITATIVE DETERMINATION OF FIBRINOGEN, BASED ON THE CLAUSS METHOD, IN HUMAN CITRATED PLASMA ON IL COAGULATION SYSTEMS.,HEMOSIL LIQUID ANTITHROMBIN(HEMOSIL)-AUTOMATED CHROMOGENIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTITHROMBIN IN HUMAN CITRATED PLASMA ON THE ACL TOP® SYSTEMS.,HEMOSIL HEPARIN(HEMOSIL)-AUTOMATED CHROMOGENIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF UNFRACTIONATED HEPARIN (UFH) AND LOW MOLECULAR WEIGHT HEPARIN (LMWH) ACTIVITY IN HUMAN CITRATED PLASMA ON THE IL COAGULATION SYSTEMS.,HEMOSIL LIQUID ANTITHROMBIN(HEMOSIL) -AUTOMATED CHROMOGENIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTITHROMBIN IN HUMAN CITRATED PLASMA ON THE IL COAGULATION SYSTEMS.,HEMOSIL FACTOR IX DEFICIENT PLASMA(HEMOSIL)-HUMAN PLASMA IMMUNODEPLETED OF FACTOR IX FOR THE QUANTITATIVE DETERMINATION OF FACTOR IX ACTIVITY IN CITRATED PLASMA, BASED ON ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) ASSAY, ON IL COAGULATION SYSTEMS.,GEM PREMIER 5000 PAK PH, PCO2, PO2, HCT, THB, O2HB, COHB, HHB, METHB, SO2 - 75 TEST(GEM PREMIER 5000 PAK)-SENSOR

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	AND REAGENT CARTRIDGE FOR USE WITH THE IL GEM PREMIER 5000 ANALYZER.,HEMOSIL SYNTHASIL(HEMOSIL)-A HIGH QUALITY SYNTHETIC PHOSPHOLIPID REAGENT FOR THE IN VITRO DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) IN HUMAN CITRATED PLASMA ON IL COAGULATION SYSTEMS. THE PRODUCT IS USED FOR THE EVALUATION OF THE INTRINSIC COAGULATION PATHWAY, APTT SUBSTITUTION TEST AND THE MONITORING OF HEPARIN THERAPY. ,HEMOSIL LIQUID ANTI-XA (HEMOSIL)-AUTOMATED CHROMOGENIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF UNFRACTIONATED HEPARIN (UFH) AND LOW MOLECULAR WEIGHT HEPARIN (LMWH) ACTIVITY IN HUMAN CITRATED PLASMA ON IL COAGULATION SYSTEMS, (ACL TOP® FAMILY, ACL TOP FAMILY 50 SERIES AND ACL ELITE®/ELITE PRO/8/9/10000) WHEN USED IN CONJUNCTION WITH HEMOSIL HEPARIN CALIBRATORS. THIS ASSAY IS ALSO INTENDED FOR THE MEASUREMENT OF DIRECT FXA INHIBITOR CONCENTRATIONS (E.G. RIVAROXABAN, APIXABAN) IN HUMAN CITRATED PLASMA ON ACL TOP FAMILY AND ACL TOP FAMILY 50 SERIES SYSTEMS WHEN USED IN CONJUNCTION WITH HEMOSIL RIVAROXABAN CALIBRATORS (FOR RIVAROXABAN TESTING) AND HEMOSIL APIXABAN CALIBRATORS (FOR APIXABAN TESTING).,HEMOSIL PROTEIN S ACTIVITY(HEMOSIL)-AUTOMATED COAGULATION FUNCTIONAL ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE PROTEIN S IN HUMAN CITRATED PLASMA ON THE ACL TOP® FAMILY, ACL TOP FAMILY 50 SERIES, ACL ELITE®/ELITE PRO AND ACL 7000 SYSTEMS AS AN AID IN THE DIAGNOSIS OF HEREDITARY AND ACQUIRED PROTEIN S DEFICIENCY.,HEMOSIL PLASMINOGEN(HEMOSIL)-AUTOMATED CHROMOGENIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF PLASMINOGEN IN HUMAN CITRATED PLASMA ON IL COAGULATION SYSTEMS.,HEMOSIL SILICA CLOTTING TIME(HEMOSIL)-FOR THE DETECTION OF LUPUS ANTICOAGULANTS IN HUMAN CITRATED PLASMA ON THE IL COAGULATION SYSTEMS BY THE USE OF SCREENING (SCT SCREEN) AND CONFIRMATORY (SCT CONFIRM) REAGENTS SENSITIZED TO PHOSPHOLIPID DEPENDENT ANTIBODIES., HEMOSIL FACTOR VIII DEFICIENT PLASMA(HEMOSIL)-HUMAN PLASMA IMMUNODEPLETED OF FACTOR VIII FOR THE QUANTITATIVE DETERMINATION OF FACTOR VIII (FVIII) ACTIVITY IN CITRATED PLASMA, BASED ON ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) ASSAY, ON IL COAGULATION SYSTEMS.,HEMOSIL PLASMIN INHIBITOR(HEMOSIL)-AUTOMATED CHROMOGENIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF PLASMIN INHIBITOR IN HUMAN CITRATED PLASMA ON IL COAGULATION SYSTEMS,HEMOSIL FACTOR XI DEFICIENT PLASMA(HEMOSIL)-HUMAN PLASMA IMMUNODEPLETED OF FACTOR XI FOR THE QUANTITATIVE

		DETERMINATION OF FACTOR XI ACTIVITY IN CITRATED PLASMA, BASED ON THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) ASSAY, ON IL COAGULATION SYSTEMS.,HEMOSIL THROMBIN TIME (HEMOSIL)-FOR THE QUANTITATIVE DETERMINATION OF THROMBIN TIME (TT) IN HUMAN CITRATED PLASMA ON IL COAGULATION SYSTEMS.,HEMOSIL FACTOR II DEFICIENT PLASMA(HEMOSIL)-HUMAN PLASMA IMMUNODEPLETED OF FACTOR II FOR THE QUANTITATIVE DETERMINATION OF FACTOR II ACTIVITY IN CITRATED PLASMA, BASED ON THE PROTHROMBIN TIME (PT) ASSAY, ON IL COAGULATION SYSTEMS.,HEMOSIL PROTEIN C(HEMOSIL)-AUTOMATED CHROMOGENIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF PROTEIN C IN HUMAN CITRATED PLASMA ON ILCOAGULATION SYSTEMS.
781	IMP/IVD/2020/000616	1.License Holder Name: BANGALORE MEDICAL SYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PROCLEIX ULTRIO ELITE ASSAY KIT (A QUALITATIVE IN-VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DETECTION OF HIV 1 & 2 RNA, HCV RNA AND HBV DNA IN PLASMA AND SERUM SPECIMENS FROM HUMAN DONORS) (PROCLEIX ULTRIO ELITE)-THE PROCLEIX ULTRIO ELITE ASSAY IS A QUALITATIVE IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND HUMAN IMMUNODEFICIENCY VIRUS TYPE 2 (HIV) RNA, HEPATITIS C VIRUS (HCV) RNA, AND/OR HEPATITIS B VIRUS (HBV) DNA IN PLASMA AND SERUM SPECIMENS FROM HUMAN DONORS, TESTED INDIVIDUALLY OR IN POOLS. IT IS ALSO INTENDED FOR USE IN TESTING PLASMA AND SERUM TO SCREEN ORGAN AND TISSUE DONORS, INCLUDING CADAVERIC (NONHEART- BEATING) DONORS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

782	IMP/IVD/2020/000617	1.License Holder Name: MATRIX LABS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ß-THALASSAEMIA & HBA1C CONTROL MATERIAL(LIFOTRONIC)-HBA1C CONTROL MATERIAL IS INTENDED FOR THE SYSTEM QUALITY CONTROL FOR ACCURACY AND REPEATABILITY.,ß-THALASSAEMIA & HBA1C CALIBRATOR(LIFOTRONIC)-HBA1C CALIBRATOR IS INTENDED FOR THE PERCENT DETERMINATION OF HBA2/HBF/HBA1C IN HUMAN BLOOD USING HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC),HBA1C REAGENT KITS (HPLC)(LIFOTRONIC)-APPLICABLE TO QUANTITATIVE EXAMINATION THE CONTENT OF HBA1C IN THE WHOLE BLOOD OF HUMAN BODY WITH LIFOTRONIC H SERIES HEMOGLOBIN ANALYZER. IT ADOPTS HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) METHOD TO MEASURE THE LEVEL OF HBA1AB, HBA1C AND HBA0. AND THE ANALYZER CALCULATES THE REST ITEMS.,HBA1C CALIBRATOR(LIFOTRONIC)-HBA1C CALIBRATOR IS INTENDED FOR THE PERCENT DETERMINATION OF HBA1C IN HUMAN BLOOD USING HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC).,HBA1C CONTROL MATERIAL (LIFOTRONIC)-HBA1C CONTROL MATERIAL IS INTENDED FOR THE SYSTEM QUALITY CONTROL FOR ACCURACY AND REPEATABILITY. ß-THALASSAEMIA & HBA1C REAGENT KIT (HPLC)(LIFOTRONIC)-BETA-THALASSEMIA ANALYSIS MODE IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY FOR THE SEPARATION AND AREA PERCENT DETERMINATIONS OF HEMOGLOBIN HBA2HBF AND HBA1C AND AS AN AID IN THE PRESUMPTIVE IDENTIFICATION OF ABNORMAL HUMAN HEMOGLOBINS IN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC). THIS RESULT CAN BE USED FOR REFERENCE OF CLINICAL -THALASSAEMIA DIAGNOSE

783	IMP/IVD/2020/000618	1.License Holder Name: KABS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TEST FOR HUMAN IGG AUTOANTIBODIES TO CYCLIC CITRULLINATED PEPTIDES(ICHROMA™ ANTI-CCP)-ICHROMA™ ANTI-CCP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE OR SEMI-QUANTITATIVE DETERMINATION OF HUMAN IGG AUTOANTIBODIES TO CYCLIC CITRULLINATED PEPTIDES (CCP) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA) IN COMBINATION WITH OTHER CLINICAL AND LABORATORY FINDINGS ,TEST FOR PROCALCITONIN (ICHROMA™ PCT)-ICHROMA™ PCT IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF BACTERIAL INFECTION AND SEPSIS ,TEST FOR PROLACTIN (ICHROMA™ PRL)-ICHROMA™ PRL IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF HYPOTHALAMIC-PITUITARY DISORDERS ,TEST FOR TESTOSTERONE(ICHROMA™ TESTOSTERONE)-ICHROMA™ TESTOSTERONE IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ANDROGEN LEVEL ,TEST FOR ANTI STREPTOLYSIN O(ICHROMA™ ASO)-ICHROMA™ ASO IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF ANTI STREPTOLYSIN O (ASO) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF SCARLET FEVER, RHEUMATIC FEVER AND POST INFECTIOUS GLOMERULONEPHRITIS ALONG WITH SEVERAL OTHER CONDITIONS ,TEST FOR T4(ICHROMA™ T4)-ICHROMA™ T4 IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THYROID DISORDER,TEST FOR CYSTATIN C(ICHROMA™ CYSTATIN C)-ICHROMA™ CYSTATIN C IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF RENAL DISEASE,TEST FOR T3(ICHROMA™ T3)-ICHROMA™ T3 IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (TOTAL T3) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF THYROID DISORDERS ,

	TEST FOR FOLLICLE STIMULATING HORMONE(ICHROMA™ FSH)-ICHROMA™ FSH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE(FSH) IN HUMAN SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF CONCENTRATION OF FSH , TEST FOR PROGESTERONE(ICHROMA™ PROGESTERONE)-ICHROMA™ PROGESTERONE IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THE CAUSE OF INFERTILITY, TRACK OVULATION, DIAGNOSE AN ECTOPIC OR FAILING PREGNANCY, MONITOR THE HEALTH OF A PREGNANCY ,TEST FOR LUTEINIZING HORMONE (ICHROMA™ LH)-ICHROMA™ LH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF EVALUATING FERTILITY ISSUES, FUNCTION OF REPRODUCTIVE ORGANS (OVARIES OR TESTICLES), OR DETECTION OF THE OVULATION ,TEST FOR MICROALBUMINURIA(ICHROMA™ MICROALBUMIN)-ICHROMA™ MICROALBUMIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF MICROALBUMIN IN HUMAN URINE. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF KIDNEY DAMAGE FROM DIABETES,TEST FOR CRP(ICHROMA™ CRP)-ICHROMA™ CRP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CRP IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF AUTOIMMUNE DISEASES AND INFECTIOUS PROCESSES, SUCH AS RHEUMATOID ARTHRITIS ,TEST FOR MYOGLOBIN(ICHROMA™ MYOGLOBIN)-ICHROMA™ MYOGLOBIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN WHOLE BLOOD/ SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION (AMI),TEST FOR TOTAL 25(OH)D2/D3(ICHROMA™ VITAMIN D)-ICHROMA™ VITAMIN D IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25(OH)D2/D3 LEVEL IN REGULATING THE CONCENTRATION OF CALCIUM AND PHOSPHATE IN THE BLOODSTREAM AND PROMOTING THE HEALTHY GROWTH AND REMODELING OF BONE. HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF BONE ,TEST FOR CREATINE KINASE ISOENZYME-MB(ICHROMA™ CK-MB)-ICHROMA™ CK-MB IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE ISOENZYME-

		MB (CK-MB) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAC INFARCTION (AMI) AND ACUTE CORONARY SYNDROME (ACS),TEST FOR FERRITIN(ICHROMA™ FERRITIN)-ICHROMA™ FERRITIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN QUANTIFIES HUMAN FERRITIN ,TEST FOR HBA1C(ICHROMA™ HBA1C)-ICHROMA™ HBA1C IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF HBA1C(HEMOGLOBIN A1C) IN HUMAN WHOLE BLOOD. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THE LONG-TERM GLYCEMIC STATUS IN PATIENTS WITH DIABETES MELLITUS,TEST FOR RF IGM(ICHROMA™ RF IGM)-ICHROMA™RF IGMIS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF RF IGMIN HUMANWHOLE BLOOD/SERUM/ PLASMA.IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF RHEUMATOID ARTHRITIS ,TEST FOR TOTAL BETA HUMAN CHORIONIC GONADOTROPIN(ICHROMA™ -HCG)-ICHROMA™ -HCG IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL -HCG IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF TOTAL BETA HUMAN CHORIONIC GONADOTROPIN (TOTAL -HCG) LEVEL IN HUMAN ,TEST FOR THYROID STIMULATING HORMONE(ICHROMA™ TSH)-ICHROMA™ TSH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TSH IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF MEASUREMENT IN THE ASSESSMENT OF THYROID FUNCTION,TEST FOR CORTISOL (ICHROMA™ CORTISOL)-ICHROMA™ CORTISOL IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF CONCENTRATION OF CORTISOL
784	IMP/IVD/2020/000619	1.License Holder Name: LAJ EXPORTS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID 19 RAPID TEST KIT (BIOHIT)-SARS COV 2 TO TEST IGM/IGG ANTIBODY TEST KIT (COLLOIDAL GOLD METHOD) IS INTENDED FOR THE IN VITRO QUALITATIVE DETECTION OF SARS COV 2 IGM/IGG ANTIBODIES FROM THE HUMAN SERUM. PLASMA AND WHOLE BLOOD SAMPLES

785	IMP/IVD/2020/000620	1.License Holder Name: ANAND BROTHERS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLINREP® COMPLETE KIT FOR VMA, HVA AND 5-HIAA IN URINE(CLINREP® COMPLETE KIT FOR VMA, HVA AND 5-HIAA IN URINE)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF VMA, HVA AND 5-HIAA FROM HUMAN URINE BY HPLC COUPLED WITH ELECTROCHEMICAL DETECTION,CLINREP® COMPLETE KIT FOR CATECHOLAMINES IN URINE(CLINREP® COMPLETE KIT FOR CATECHOLAMINES IN URINE)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF CATECHOLAMINES FROM HUMAN URINE BY HPLC COUPLED WITH ELECTROCHEMICAL DETECTION., CLINREP®COMPLETE KIT FOR VITAMIN C IN PLASMA (CLINREP®COMPLETE KIT FOR VITAMIN C IN PLASMA)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF VITAMIN C FROM HUMAN PLASMA OR SERUM BY HPLC COUPLED WITH UV DETECTION,CLINREP® COMPLETE KIT FOR VITAMIN B1 IN WHOLE BLOOD(CLINREP® COMPLETE KIT FOR VITAMIN B1 IN WHOLE BLOOD)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF VITAMIN B1 FROM HUMAN WHOLE BLOOD BY HPLC COUPLED WITH FLUORESCENCE DETECTION, CLINREP®COMPLETE KIT FOR METANEPHRINES IN URINE (CLINREP®COMPLETE KIT FOR METANEPHRINES IN URINE)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF METANEPHRINES FROM HUMAN URINE BY HPLC COUPLED WITH ELECTROCHEMICAL DETECTION,CLINMASS® COMPLETE KIT FOR 25-OH-VITAMIN D2/D3 IN PLASMA AND SERUM (CLINMASS® COMPLETE KIT FOR 25-OH-VITAMIN D2/D3 IN PLASMA AND SERUM)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF 25-OH-VITAMIN D2/D3 FROM HUMAN PLASMA OR SERUM BY ON-LINE SPE HPLC COUPLED WITH TANDEM MASS- SPECTROMETRY (LC-MS/MS), CLINMASS® COMPLETE KIT FOR FREE METANEPHRINES IN PLASMA, ON-LINE(CLINMASS® COMPLETE KIT FOR FREE METANEPHRINES IN PLASMA, ON-LINE)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF THE PLASMA FREE METANEPHRINES BY ON-LINE SPE HPLC COUPLED WITH TANDEM MASS- SPECTROMETRY (LC-MS/MS),CLINMASS® COMPLETE KIT FOR STEROIDS IN SERUM / PLASMA(CLINMASS® COMPLETE KIT FOR STEROIDS IN SERUM / PLASMA)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF 8 STEROIDS FROM HUMAN SERUM OR

	PLASMA BY HPLC COUPLED WITH TANDEM MASS- SPECTROMETRY (LC-MS/MS),CLINMASS® COMPLETE KIT FOR HOMOCYSTEINE IN PLASMA / SERUM(CLINMASS® COMPLETE KIT FOR HOMOCYSTEINE IN PLASMA / SERUM)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF HOMOCYSTEINE (TOTAL HOMOCYSTEINE) FROM HUMAN PLASMA OR SERUM BY HPLC COUPLED WITH TANDEM MASS- SPECTROMETRY (LC-MS/MS).,CLINMASS® COMPLETE KIT, ADVANCED, FOR METHYLMALONIC ACID IN SERUM / PLASMA / URINE(CLINMASS® COMPLETE KIT, ADVANCED, FOR METHYLMALONIC ACID IN SERUM / PLASMA / URINE)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF METHYLMALONIC ACID (MMA) FROM HUMAN SERUM, PLASMA OR URINE BY HPLC COUPLED WITH TANDEM MASS- SPECTROMETRY (LC-MS/MS),CLINEASY® COMPLETE KIT FOR 5-AMINOLEVULINIC ACID AND PORPHOBILINOGENE IN URINE(CLINEASY® COMPLETE KIT FOR 5-AMINOLEVULINIC ACID AND PORPHOBILINOGENE IN URINE)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (INITIAL TESTING FOR PORPHYRIAS) OF 5-AMINOLEVULINIC ACID AND PORPHOBILINOGEN BY PHOTOMETRIC DETECTION,CLINREP® COMPLETE KIT FOR VITAMIN B2 IN WHOLE BLOOD(CLINREP® COMPLETE KIT FOR VITAMIN B2 IN WHOLE BLOOD)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF VITAMIN B2 FROM HUMAN WHOLE BLOOD BY HPLC COUPLED WITH FLUORESCENCE DETECTION, CLINREP® COMPLETE KIT FOR VITAMIN B6 IN PLASMA / WHOLE BLOOD(CLINREP® COMPLETE KIT FOR VITAMIN B6 IN PLASMA / WHOLE BLOOD)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF VITAMIN B6 FROM HUMAN PLASMA OR WHOLE BLOOD BY HPLC COUPLED WITH FLUORESCENCE DETECTION,CLINSPOT® COMPLETE KIT FOR AMINO ACIDS AND ACYLCARNITINES IN DRIED BLOOD SPOTS (DBS (CLINSPOT® COMPLETE KIT FOR AMINO ACIDS AND ACYLCARNITINES IN DRIED BLOOD SPOTS (DBS)-IN VITRO DIAGNOSTIC TEST INTENDED FOR THE SEMI-QUANTITATIVE DETERMINATION OF AMINO ACIDS AND ACYLCARNITINES FOR NEONATAL SCREENING ON INHERITED METABOLIC DISORDERS. THE DETERMINATION IS PERFORMED BY LC-MS/MS FROM DRIED BLOOD SPOT SPECIMEN,CLINREP® COMPLETE KIT FOR PORPHYRINS IN URINE(CLINREP® COMPLETE KIT FOR PORPHYRINS IN URINE)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIFFERENTIAL DIAGNOSIS) OF DIFFERENT PORPHYRINS FROM HUMAN URINE BY HPLC COUPLED WITH FLUORESCENCE DETECTION,CLINREP® COMPLETE KIT FOR 25-OH-

	VITAMIN D2/D3 IN PLASMA AND SERUM BY UHPLC(CLINREP® COMPLETE KIT FOR 25-OH-VITAMIN D2/D3 IN PLASMA AND SERUM BY UHPLC)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF 25-OH-VITAMIN D2/D3 FROM HUMAN PLASMA OR SERUM BY UHPLC COUPLED WITH UV DETECTION,CLINEASY® COMPLETE KIT FOR PORPHYRINS IN URINE(CLINEASY® COMPLETE KIT FOR PORPHYRINS IN URINE)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (INITIAL TESTING FOR PORPHYRIAS) OF TOTAL URINARY PORPHYRINS (TUP) BY PHOTOMETRIC DETECTION., CLINREP® COMPLETE KIT FOR VITAMIN A AND E IN SERUM / PLASMA (CLINREP® COMPLETE KIT FOR VITAMIN A AND E IN SERUM / PLASMA)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF VITAMINS A AND E FROM HUMAN SERUM OR PLASMA BY HPLC COUPLED WITH UV DETECTION, CLINSPOT® COMPLETE KIT FOR AMINO ACIDS AND ACYLCARNITINES IN DRIED BLOOD SPOTS (DBS) WITH FILTER-PLATES(CLINSPOT® COMPLETE KIT FOR AMINO ACIDS AND ACYLCARNITINES IN DRIED BLOOD SPOTS (DBS) WITH FILTER-PLATES)-IN VITRO DIAGNOSTIC TEST INTENDED FOR THE SEMI-QUANTITATIVE DETERMINATION OF AMINO ACIDS AND ACYLCARNITINES FOR NEONATAL SCREENING ON INHERITED METABOLIC DISORDERS. THE DETERMINATION IS PERFORMED BY LC-MS/MS FROM DRIED BLOOD SPOT SPECIMEN, CLINREP® COMPLETE KIT FOR 25-OH VITAMIN D2/D3 IN PLASMA AND SERUM(CLINREP® COMPLETE KIT FOR 25-OH VITAMIN D2/D3 IN PLASMA AND SERUM)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF 25-OH-VITAMIN D2/D3 FROM HUMAN PLASMA OR SERUM BY HPLC COUPLED WITH UV DETECTION,CLINREP®CHROMATOGRAPHY KIT FOR VITAMIN B1, B2 AND B6 IN HUMAN PLASMA / WHOLE BLOOD (CLINREP®CHROMATOGRAPHY KIT FOR VITAMIN B1, B2 AND B6 IN HUMAN PLASMA / WHOLE BLOOD)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF VITAMINS B1, B2 AND B6 FROM HUMAN PLASMA OR WHOLE BLOOD BY HPLC COUPLED WITH FLUORESCENCE DETECTION, CLINEASY® COMPLETE KIT FOR PORPHOBILINOGENE IN URINE (CLINEASY® COMPLETE KIT FOR PORPHOBILINOGENE IN URINE)-IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (INITIAL TESTING FOR PORPHYRIAS) OF PORPHOBILINOGEN BY PHOTOMETRIC DETECTION

786	IMP/IVD/2020/000620	1.License Holder Name: ANAND BROTHER'S 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLINREP COMPLETE KIT FOR CATECHOLAMINES IN PLASMA(CLINREP COMPLETE KIT FOR CATECHOLAMINES IN PLASMA)-THE COMPLETE KITS IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE DETERMINATION (AID FOR DIAGNOSIS) OF CATECHOLAMINES FROM HUMAN PLASMA BY HPLC COUPLED WITH ELECTROCHEMICAL DETECTION.,CLINMASS TDM PLATFORM AND ADD-ON SET FOR IMMUNOSUPPRESSANTS IN WHOLE BLOOD(CLINMASS TDM PLATFORM AND ADD-ON SET FOR IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-IN VITRO DIAGNOSTIC TEST INTENDED FOR THERAPEUTIC DRUG MONITORING (TDM) BY QUANTITATIVE DETERMINATION OF THE IMMUNOSUPPRESSANTS CYCLOSPORINE A, TACROLIMUS, SIROLIMUS AND EVEROLIMUS FROM HUMAN BLOOD ON HPLC SYSTEMS COUPLED WITH TANDEM MASS-SPECTROMETRY (LC-MS/MS),CLINMASS ADD-ON SET, ON-LINE, FOR BENZODIAZEPINES IN SERUM / PLASMA(CLINMASS ADD-ON SET, ON-LINE, FOR BENZODIAZEPINES IN SERUM / PLASMA)-THE ON-LINE ADD-ON SET IS AN IN VITRO DIAGNOSTIC TEST AND HAS TO BE USED WITH THE CLINMASS® ON-LINE TDM PLATFORM (ORDER NO. MS9050). IT IS INTENDED FOR THERAPEUTIC DRUG MONITORING (TDM) BY QUANTITATIVE DETERMINATION OF BENZODIAZEPINES FROM HUMAN SERUM OR PLASMA ON HPLC SYSTEMS COUPLED WITH TANDEM MASS-SPECTROMETRY (LC-MS/MS),CLINMASS® TDM PLATFORM (ORDER NO. MS9000), WITH CLINMASS® ADD-ON SET FOR ANTIMYCOTICS IN WHOLE BLOOD(CLINMASS® TDM PLATFORM (ORDER NO. MS9000), WITH CLINMASS® ADD-ON SET FOR ANTIMYCOTICS IN WHOLE BLOOD)-THE CLINMASS® TDM PLATFORM (ORDER NO. MS9000) AND THE CLINMASS® ADD-ON SET WITH ORDER NO. MS9600 ARE IN VITRO DIAGNOSTIC TESTS. THE ADD-ON SET IS INTENDED FOR THERAPEUTIC DRUG MONITORING (TDM) BY QUANTITATIVE DETERMINATION OF THE ANTIMYCOTIC DRUGS AND METABOLITES 5-FLUOROCYTOSINE, FLUCONAZOLE, HYDROXY-ITRACONAZOLE, ISAVUCONAZOLE, ITRACONAZOLE, KETOCONAZOLE, POSACONAZOLE AND VORICONAZOLE FROM HUMAN SERUM OR PLASMA ON HPLC SYSTEMS COUPLED WITH TANDEM MASS-SPECTROMETRY (LC-MS/MS).

787	IMP/IVD/2020/000621	1.License Holder Name: ID VET INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MYCOPLASMA GALLISEPTICUM(ID SCREEN® MYCOPLASMA GALLISEPTICUM INDIRECT)-RECOMBINANT PROTEIN-BASED INDIRECT ELISA FOR THE DETECTION OF ANTI-MYCOPLASMA GALLISEPTICUM (MG) ANTIBODIES IN CHICKEN AND TURKEY SERA.,WEST NILE (ID SCREEN®WEST NILE COMPETITION MULTI-SPECIES)-KIT FOR THE DETECTION OF WEST NILE VIRUS ANTI-PR-E ANTIBODIES IN EQUINE AND AVIAN SERA BY COMPETITIVE ELISA.,INFECTIOUS BURSAL DISEASE(ID SCREEN® IBD INDIRECT)-THIS INDIRECT ELISA DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST THE INFECTIOUS BURSAL DISEASE (IBD) VIRUS, ALSO KNOWN AS GUMBORO DISEASE.IT IS A QUANTITATIVE TEST FOR THE DETECTION OF IBDV-SPECIFIC ANTIBODIES IN CHICKEN SERA., PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME VIRUS (ID SCREEN® PRRS INDIRECT)-INDIRECT ELISA FOR THE DETECTION OF ANTIBODIES DIRECTED AGAINST EUROPEAN AND AMERICAN PRRSV STRAINS IN SERUM AND PLASMA,NEWCASTLE DISEASE(ID SCREEN® NEWCASTLE DISEASE INDIRECT CONVENTIONAL VACCINES)-THIS INDIRECT ELISA DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST THE NEWCASTLE DISEASE VIRUS (NDV).IT IS A QUANTITATIVE TEST FOR THE DETECTION OF NDV-SPECIFIC ANTIBODIES IN CHICKEN AND TURKEY SERA.THIS TEST CAN BE USED FOR MONITORING VACCINATION WITH CONVENTIONAL VACCINES (ATTENUATED OR KILLED).,BOVINE LUEKOSIS VIRUS(ID SCREEN® BLV COMPETITION)-THIS DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTI-GP51 ANTIBODIES IN BOVINE OR BUFFALO SERA (INDIVIDUAL AND POOLS OF 10 SAMPLES),MYCOPLASMA GALLISEPTICUM/SYNOVIAE(ID SCREEN® MG/MS INDIRECT)-RECOMBINANT PROTEIN-BASED INDIRECT ELISA FOR THE DETECTION OF ANTI-MYCOPLASMA GALLISEPTICUM (MG) AND MYCOPLASMA SYNOVIAE (MS) ANTIBODIES IN CHICKEN AND TURKEY SERA.,PESTE DES PETITS RUMINANTS(ID SCREEN®PPR COMPETITION)-KIT FOR THE DETECTION OF ANTIBODIES AGAINST THE PESTE DES PETITS RUMINANTS (PPR) VIRUS IN SERUM AND PLASMA FROM SHEEP, GOAT AND OTHER SUSCEPTIBLE SPECIES BY COMPETITIVE ELISA,AVIAN INFLUENZA(ID SCREEN® INFLUENZA A ANTIBODY COMPETITION MULTI-SPECIES)-THIS DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST THE INTERNAL NUCLEOCAPSID OF THE INFLUENZA A VIRUS.IT CAN BE USED WITH PIGS, HORSES OR BIRDS SERUM OR PLASMA BUT ALSO WITH PORCINE ORAL FLUID.,INFECTIOUS BOVINE RHINOTRACHEITIS (ID SCREEN® IBR GE COMPETITION)-COMPETITIVE ELISA FOR THE

	DETECTION OF ANTIBODIES AGAINST THE GE PROTEIN OF THE BHV-1 VIRUS IN BOVINE SERUM, PLASMA AND MILK (INDIVIDUAL, BULK OR CONDENSED MILK SAMPLES),AVAIN INFLUENZA(ID SCREEN® INFLUENZA A NUCLEOPROTEIN INDIRECT)-THIS INDIRECT ELISA DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST THE NUCLEOPROTEIN OF THE INFLUENZA A VIRUS.IT IS A QUANTITATIVE TEST FOR THE DETECTION OF SPECIFIC ANTIBODIES IN SERUM OR PLASMA FROM CHICKEN OR TURKEY.,RUMINANT IFN-G (ID SCREEN®RUMINANT IFN-G)-KIT FOR THE DETECTION OF BOVINE, OVINE AND CAPRINE INTERFERON GAMMA (IFN-G) BY SANDWICH ELISA,NEWCASTLE DISEASE(ID SCREEN® NEWCASTLE DISEASE INDIRECT)-THIS INDIRECT ELISA DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST THE NEWCASTLE DISEASE VIRUS (NDV). IT IS A QUANTITATIVE TEST FOR THE DETECTION OF NDVSPECIFIC ANTIBODIES IN CHICKEN OR TURKEY SERUM. THIS TEST ALLOWS FOR MONITORING OF VACCINATION WITH RECOMBINANT HVT-ND VACCINES.,BLUETONGUE(ID SCREEN® BLUETONGUE COMPETITION)-THIS DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST THE BLUETONGUE VIRUS VP7 PROTEIN. IT CAN BE USED WITH SHEEP, GOAT, CATTLE, BUFFALO OR DEER SERUM OR PLASMA.,INFECTIOUS LARYNGOTRACHEITIS(ID SCREEN® ILT INDIRECT)-THIS INDIRECT ELISA DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST THE AVIAN INFECTIOUS LARYNGOTRACHEITIS (ILT) VIRUS.IT IS A QUANTITATIVE TEST FOR THE DETECTION OF ILT-SPECIFIC ANTIBODIES IN CHICKEN SERA.,BRUCELLOSIS(ID SCREEN® BRUCELLOSIS SERUM INDIRECT MULTI-SPECIES)-THIS DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST BRUCELLA ABORTUS (BOVINE), MELITENSIS (OVINE AND CAPRINE) AND SUIS (PIGS). IT CAN BE USED IN BOVINE, OVINE, CAPRINE AND PIGS INDIVIDUAL SERUM AND PLASMA OR IN BOVINE POOLS UP TO 10.,AVIAN METAPHEUMOVIRUS (ID SCREEN® AVIAN METAPHEUMOVIRUS INDIRECT)-THIS INDIRECT ELISA DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST AVIAN METAPNEUMOVIRUS, RESPONSIBLE OF RHINOTRACHEITIS IN TURKEY (TRT) AND SWOLLEN HEAD SYNDROME IN CHICKEN (SHS). FOUR SUBTYPES OF THE VIRUS HAVE BEEN IDENTIFIED: SUBTYPES A AND B, PREDOMINANT IN EUROPE, SUBTYPE C DETECTED IN USA, AND SUBTYPE D ONLY DETECTED IN FRANCE. IT IS A QUANTITATIVE TEST FOR THE DETECTION OF ANTIBODIES SPECIFICALLY DIRECTED AGAINST THE SUBTYPES A AND B OF AMPV IN CHICKEN AND TURKEY SERUM., PARATUBERCULOSIS(ID SCREEN® PARATUBERCULOSIS INDIRECT SCREENING TEST)-THIS DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST MYCOBACTERIUM AVIUM SUBSP.

	PARATUBERCULOSIS (MAP). IT CAN BE USED WITH GOAT, SHEEP, CATTLE OR BUFFALO SERUM OR PLASMA OR WITH BOVINE MILK (INDIVIDUAL AND BULK MILKS).,AVAIN ENCEPHALOMYELITIS(ID SCREEN® AVAIN ENCEPHALOMYELITIS INDIRECT)-THIS INDIRECT ELISA DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST THE AVIAN ENCEPHALOMYELITIS VIRUS (AEV).IT IS A QUANTITATIVE TEST FOR THE DETECTION OF ANTIBODIES SPECIFICALLY DIRECTED AGAINST AEV IN CHICKEN SERUM OR PLASMA.,INFECTIOUS BOVINE RHINOTRACHEITIS(ID SCREEN® IBR INDIRECT)-INDIRECT ELISA FOR THE DETECTION OF ANTIBODIES DIRECTED AGAINST BHV-1 IN SERUM OR PLASMA,MYCOPLAMA SYNOVIAE(ID SCREEN® MYCOPLAMA SYNOVIAE INDIRECT)-RECOMBINANT PROTEIN-BASED INDIRECT ELISA FOR THE DETECTION OF ANTI-MYCOPLASMA SYNOVIAE (MS) ANTIBODIES IN CHICKEN AND TURKEY SERA.,BRUCELLOSIS(ID SCREEN® BRUCELLOSIS MILK INDIRECT)-INDIRECT ELISA FOR THE DETECTION OF ANTIBODIES AGAINST BRUCELLA ABORTUS OR MELITENSIS IN BOVINE, OVINE AND CAPRINE MILK.,AVIAN INFLUENZA(ID SCREEN® INFLUENZA H9 INDIRECT)-THIS INDIRECT ELISA IS DESIGNED TO DETECT THE ANTIBODIES DIRECTED AGAINST THE H9 HEMAGGLUTININ OF THE INFLUENZA A VIRUS IN THE SERUM OR THE PLASMA OF CHICKENS OR TURKEYS. IT CAN BE USED FOR THE MONITORING OF THE VACCINATION WITH H9 VACCINES.,NEOSPORA CANINUM (ID SCREEN®NEOSPORA CANINUM INDIRECT)-INDIRECT ELISA FOR THE DETECTION OF ANTIBODIES AGAINST N.CANINUM IN SERUM, PLASMA OR MILK FROM CATTLE, SHEEP OR GOATS,AVIAN INFLUENZA(ID SCREEN® INFLUENZA H5 INDIRECT)-THIS INDIRECT ELISA IS DESIGNED TO DETECT THE ANTIBODIES DIRECTED AGAINST THE H5 HEMAGGLUTININ OF THE INFLUENZA A VIRUS IN THE SERUM OR THE PLASMA OF CHICKENS OR TURKEYS. IT CAN BE USED FOR THE MONITORING OF THE VACCINATION WITH H5 VACCINES.,EQUINE INFECTIOUS ANEMIA(ID SCREEN® EQUINE INFECTIOUS ANEMIA DOUBLE ANTIGEN)-KIT FOR THE DETECTION OF P 26 (GENE GAG) ANTIBODIES DIRECTED AGAINST THE EQUINE INFECTIOUS ANEMIA VIRUS BY INDIRECT ELISA IN HORSE SERUM,INFECTIOUS BRONCHITIS (ID SCREEN® INFECTIOUS BRONCHITIS INDIRECT)-THIS INDIRECT ELISA DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST THE INFECTIOUS BRONCHITIS VIRUS (IBV) IT IS A QUANTITATIVE TEST FOR THE DETECTION OF IBVSPECIFIC ANTIBODIES IN CHICKEN SERA.,INFECTIOUS BOVINE RHINOTRACHEITIS(ID SCREEN® IBR GB COMPETITION)-COMPETITIVE ELISA FOR THE DETECTION OF ANTI-GB ANTIBODIES IN SERUM, PLASMA AND MILK FROM CATTLE AND BUFFALO,INFECTIOUS LARYNGOTRACHEITIS(ID SCREEN® ILT GB INDIRECT)-THIS INDIRECT

	ELISA DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST THE GB PROTEIN OF THE AVIAN INFECTIOUS LARYNGOTRACHEITIS (ILT) VIRUS IN CHICKEN SERUM OR PLASMA. THIS TEST ALLOWS FOR MONITORING OF VACCINATION WITH RECOMBINANT FP-ILTGB VACCINES.,PESTE DES PETITS RUMINANTS (ID SCREEN® PPR ANTIGEN CAPTURE)-SANDWICH ELISA FOR THE DETECTION OF PPR VIRUS,SALMONELLOSIS(ID SCREEN® AVIAN SALMONELLA INDIRECT GROUP D)-THIS INDIRECT ELISA DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST SALMONELLA ENTERITIDIS (SE), AND OTHER AVIAN SALMONELLAS BELONGING TO GROUPS D.IT IS A QUANTITATIVE TEST FOR THE DETECTION OF SALMONELLASPECIFIC ANTIBODIES IN CHICKEN SERA.,TOXOPLASMOSIS(ID SCREEN® TOXOPLASMOSIS INDIRECT MULTI-SPECIES)-KIT FOR THE DETECTION OF ANTIBODIES DIRECTED AGAINST TOXOPLASMA GONDII BY INDIRECT ELISA IN SERA, PLASMA AND MEAT JUICE,INFECTIOUS BURSAL DISEASE(ID SCREEN® IBD VP2)-THIS INDIRECT ELISA DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST THE INFECTIOUS BURSAL DISEASE (IBD) VIRUS, ALSO KNOWN AS GUMBORO DISEASE.IT IS A QUANTITATIVE TEST FOR THE DETECTION OF IBD-SPECIFIC ANTIBODIES IN SERA FROM CHICKENS VACCINATED WITH RECOMBINANT HVT-VP2 VECTOR VACCINES.,CLASSICAL SWINE FEVER (ID SCREEN® CLASSICAL SWINE FEVER E2 COMPETITION)-KIT FOR THE DETECTION OF ANTI-E2 ANTIBODIES IN SWINE SAMPLES (SERUM OR PLASMA).,PASTEURELLA MULTOCIDA(ID SCREEN® PASTEURELLA MULTOCIDA CHICKEN AND TURKEY INDIRECT)-THIS INDIRECT ELISA DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST PASTEURELLA MULTOCIDA IN CHICKEN AND TURKEY SERA.,CHLAMYDOPHILA ABORTUS(ID SCREEN®CHLAMYDOPHILA ABORTUS INDIRECT MULTI-SPECIES)-KIT FOR THE DETECTION OF ANTIBODIES DIRECTED AGAINST CHLAMYDOPHILA ABORTUS IN RUMINANTS, SWINE AND HORSES, SALMONELLOSIS(ID SCREEN® AVIAN SALMONELLA INDIRECT - GROUPS B AND D)-THIS INDIRECT ELISA DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST SALMONELLA ENTERITIDIS (SE), S. THYPHIMURIUM (ST), AND OTHER AVIAN SALMONELLAS BELONGING TO GROUPS B AND D. IT IS A QUANTITATIVE TEST FOR THE DETECTION OF SALMONELLASPECIFIC ANTIBODIES IN CHICKEN SERA.,AVIAN REOVIRUS(ID SCREEN® AVIAN REOVIRUS INDIRECT)-THIS INDIRECT ELISA DIAGNOSTIC KIT IS DESIGNED TO DETECT ANTIBODIES DIRECTED AGAINST AVIAN REOVIRUS (REO), ALSO CALLED VIRAL ARTHRITIS.IT IS A QUANTITATIVE TEST FOR THE DETECTION OF REOSPECIFIC ANTIBODIES IN CHICKEN SERUM.,INFECTIOUS LARYNGOTRACHEITIS

		(ID SCREEN® ILT GL INDIRECT)-THIS INDIRECT ELISA KIT IS DESIGNED TO DETECT SPECIFIC ANTIBODIES AGAINST GI PROTEIN FROM THE AVIAN INFECTIOUS LARYNGOTRACHEITIS (ILT) VIRUS IN CHICKEN SERUM.THIS TEST IS DESIGNED FOR ANIMALS VACCINATED WITH RECOMBINANT HVT-ILTGI VECTOR VACCINE.
788	IMP/IVD/2020/000622	1.License Holder Name: ARKRAY HEALTHCARE PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LACTATE PRO2 TEST STRIP(LACTATE PRO2 TEST STRIP)-SELF-TESTING OF LACTATE LEVEL IN WHOLE BLOOD

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789	IMP/IVD/2020/000623	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FRUCTOSAMINE CONTROL SET(FRUCTOSAMINE CONTROL SET)-FRUCTOSAMINE CONTROL SET MUST BE USED ONLY TO MONITOR THE ACCURACY AND PRECISION OF FRUCTOSAMINE KINETIC COLORIMETRIC DIRECT DETERMINATION.,ACID PHOSPHATASE(ACID PHOSPHATASE)-KINETIC DETERMINATION OF TOTAL ACID PHOSPHATASE (ACP) WITH 1-NAPHTILPHOSPHATE/ FAST RED IN SERUM. KINETIC DETERMINATION OF NON PROSTATIC ACID PHOSPHATASE (ACP-NPP) WITH 1-NAPHTYLPHOSPHATE/ FAST RED/ TARTRATE IN SERUM.,FRUCTOSAMINE LIQUID(FRUCTOSAMINE LIQUID)-FRUCTOSAMINE LIQUID IS INTENDED TO BE USED IN THE KINETIC COLORIMETRIC DETERMINATION OF FRUCTOSAMINE CONCENTRATION IN HUMAN SERUM OR PLASMA.,LP(A) ULTRA(LP(A) ULTRA)-QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF LIPOPROTEIN (A) [LP(A)] IN SERUM AND PLASMA,CLIN CHEM CAL (CLIN CHEM CAL)-CLIN CHEM CAL MUST BE USED ONLY FOR THE CALIBRATION OF CLINICAL CHEMISTRY TESTS. FOR IN VITRO DIAGNOSTIC USE ONLY.,SYPHILIS TP LATEX(SYPHILIS TP LATEX)-THE SYPHILIS TP LATEX ASSAY IS AN IN VITRO DIAGNOSTIC TEST USED FOR THE DETERMINATION ON AU SYSTEMS OF THE ANTI-TREPONEMA PALLIDUM (TP) ANTIBODY IN SERUM AND LI-HEPARIN OR EDTA PLASMA BY IMMUNOTURBIDIMETRIC METHOD. THE ASSAY IS INTENDED FOR PROFESSIONAL USE ONLY. SYPHILIS IS A SEXUALLY TRANSMITTED DISEASE CAUSED BY THE SPIROCHETAL BACTERIUM TREPONEMA PALLIDUM SUBSPECIES PALLIDUM. THE ROUTE OF TRANSMISSION OF SYPHILIS IS ALMOST ALWAYS THROUGH SEXUAL CONTACT, ALTHOUGH THERE ARE EXAMPLES OF CONGENITAL SYPHILIS VIA TRANSMISSION FROM MOTHER TO CHILD IN UTERO.,TOTAL BILE ACIDS CONTROL SET(TOTAL BILE ACIDS CONTROL SET)-TOTAL BILE ACIDS CONTROL SET MUST BE USED ONLY TO VERIFY THE PERFORMANCE OF THE TOTAL BILE ACIDS LIQUID TEST. USE THE CONTROL MATERIAL LIKE THE SPECIMENS, ACCORDING TO THE INDICATED ANALYTICAL PROCEDURE.,SYPHILIS TP CAL SET(SYPHILIS TP CAL SET)-TO PREPARE THE CALIBRATION CURVE FOR SYPHILIS TP LATEX TEST REF A53709. USE THE CALIBRATOR ACCORDING TO THE INDICATED ANALYTICAL PROCEDURE.,ALBUMIN BCP(ALBUMIN BCP)-THE ALBUMIN BCP (6X20 ML) ASSAY IS AN IN VITRO DIAGNOSTIC TEST USED FOR THE DETERMINATION OF ALBUMIN IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR PROFESSIONAL USE ONLY. FOR IN VITRO DIAGNOSTIC USE ONLY.,SYPHILIS TP CONTROL SET(SYPHILIS TP CONTROL SET)-SYPHILIS TP CONTROL SET MUST ONLY BE USED TO

	VERIFY THE PERFORMANCE OF THE SYPHILIS TP LATEX TEST REF A53709. USE THE CONTROL ACCORDING TO THE INDICATED ANALYTICAL PROCEDURE.,TOTAL BILE ACIDS LIQUID(TOTAL BILE ACIDS LIQUID)-THE TOTAL BILE ACIDS LIQUID ASSAY IS INTENDED FOR THE ENZYMATIC CYCLING COLORIMETRIC DETERMINATION OF TOTAL BILE ACIDS IN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR PROFESSIONAL USE ONLY.,LP(A) CONTROL SET(LP(A) CONTROL SET)-LP(A) CONTROL SET MUST ONLY BE USED TO VERIFY THE PERFORMANCE OF THE LP(A) TEST. USE THE CONTROL MATERIAL LIKE THE SPECIMENS, ACCORDING TO THE INDICATED ANALYTICAL PROCEDURE.,FRUCTOSAMINE CALIBRATOR(FRUCTOSAMINE CALIBRATOR)-FRUCTOSAMINE CALIBRATOR MUST BE USED ONLY FOR THE CALIBRATION OF FRUCTOSAMINE KINETIC COLORIMETRIC DIRECT DETERMINATION.,LP(A) CAL SET(LP(A) CAL SET)-LP(A) CAL SET SHOULD BE USED AS CALIBRATION CURVE FOR THE LP(A) ULTRA TEST. USE THE CALIBRATOR ACCORDING TO THE INDICATED ANALYTICAL PROCEDURE.,IMMUNO CONTROL SET(IMMUNO CONTROL SET)-IMMUNO CONTROL SET IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION FOR THE QUANTITATIVE METHOD AS SPECIFIED IN THE ASSIGNED CONCENTRATION TABLE. USE THE CONTROL MATERIAL LIKE THE SPECIMENS, ACCORDING TO THE INDICATED ANALYTICAL PROCEDURE

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790	IMP/IVD/2020/000627	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VENTANA ANTI-PMS2 (A16-4) MOUSE MONOCLONAL PRIMARY ANTIBODY(VENTANA ANTI-PMS2 (A16-4) MOUSE MONOCLONAL PRIMARY ANTIBODY)-VENTANA ANTI-PMS2 (A16-4) MOUSE MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-PMS2 (A16-4) ANTIBODY) IS INTENDED FOR THE QUALITATIVE DETECTION OF PMS2 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. VENTANA ANTI-PMS2 (A16-4) ANTIBODY IS READY TO USE ON BENCHMARK ULTRA, XT AND GX INSTRUMENTS WITH THE OPTIVIEW DAB IHC DETECTION KIT, OPTIVIEW AMPLIFICATION KIT AND ANCILLARY REAGENTS. VENTANA ANTI-PMS2 (A16-4) ANTIBODY IS PART OF THE VENTANA MMR IHC PANEL WHICH INCLUDES VENTANA ANTI-MLH1 (M1) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-MSH2 (G219-1129) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-MSH6 (SP93) RABBIT MONOCLONAL PRIMARY ANTIBODY AND VENTANA ANTI-BRAF V600E (VE1) MOUSE MONOCLONAL PRIMARY ANTIBODY. THE VENTANA MMR IHC PANEL IS INDICATED FOR THE DETECTION OF MISMATCH REPAIR PROTEIN DEFICIENCY AS A TEST FOR THE IDENTIFICATION OF INDIVIDUALS AT RISK FOR LYNCH SYNDROME IN PATIENTS DIAGNOSED WITH COLORECTAL CANCER (CRC), AND, WITH BRAF V600E STATUS, AS AN AID TO DIFFERENTIATE BETWEEN SPORADIC AND PROBABLE LYNCH SYNDROME CRC IN THE ABSENCE OF MLH1 PROTEIN EXPRESSION. THESE PRODUCTS SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA PD-L1 (SP263) ASSAY (VENTANA PD-L1 (SP263) ASSAY)-VENTANA PD-L1 (SP263) ASSAY IS INTENDED FOR THE QUALITATIVE DETECTION OF THE PROGRAMMED DEATH LIGAND 1 (PD-L1) PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) NON-SMALL CELL LUNG CANCER (NSCLC), UROTHELIAL CARCINOMA (UC) AND OTHER TUMOR TISSUES STAINED WITH OPTIVIEW DAB IHC DETECTION KIT ON A BENCHMARK IHC/ISH INSTRUMENT. NSCLC: PD-L1 EXPRESSION IN TUMOR CELL (TC) MEMBRANE AS DETECTED BY VENTANA PD-L1 (SP263) ASSAY IN NSCLC IS INDICATED AS AN AID IN IDENTIFYING PATIENTS FOR TREATMENT WITH KEYTRUDA® (PEMBROLIZUMAB). PD-L1 EXPRESSION IN TUMOR CELL (TC) MEMBRANE AS DETECTED BY VENTANA PD-L1 (SP263) ASSAY IN NSCLC MAY BE ASSOCIATED WITH ENHANCED SURVIVAL FROM OPDIVO® (NIVOLUMAB). UROTHELIAL CARCINOMA: PD-L1 HIGH STATUS AS DETERMINED BY VENTANA PD-L1 (SP263) ASSAY WAS ASSOCIATED WITH INCREASED OBJECTIVE

	RESPONSE RATE (ORR) IN A SINGLE ARM STUDY OF IMFINZI™ (DURVALUMAB). PD-L1 STATUS IS DETERMINED BY THE PERCENTAGE OF TUMOR CELLS WITH ANY MEMBRANE STAINING ABOVE BACKGROUND OR BY THE PERCENTAGE OF TUMOR-ASSOCIATED IMMUNE CELLS WITH STAINING (IC+) AT ANY INTENSITY ABOVE BACKGROUND. THE PERCENT OF TUMOR AREA OCCUPIED BY ANY TUMOR-ASSOCIATED IMMUNE CELLS (IMMUNE CELLS PRESENT, ICP) IS USED TO DETERMINE IC+, WHICH IS THE PERCENT AREA OF ICP EXHIBITING PD-L1 POSITIVE IMMUNE CELL STAINING. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS.,VENTANA ANTI-BRAF V600E (VE1) MOUSE MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-BRAF V600E (VE1) MOUSE MONOCLONAL PRIMARY ANTIBODY)-VENTANA ANTI-BRAF V600E (VE1) MOUSE MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-BRAF V600E (VE1) ANTIBODY) IS INTENDED FOR THE QUALITATIVE DETECTION OF BRAF V600E PROTEIN IN FORMALIN-FIXED, PARAFFINEMBEDDED TISSUE SECTIONS. VENTANA ANTI-BRAF V600E (VE1) ANTIBODY IS READY TO USE ON BENCHMARK ULTRA, XT AND GX INSTRUMENTS WITH THE OPTIVIEW DAB IHC DETECTION KIT AND ANCILLARY REAGENTS. VENTANA ANTI-BRAF V600E (VE1) ANTIBODY IS PART OF THE VENTANA MMR IHC PANEL WHICH INCLUDES VENTANA ANTI-MLH1 (M1) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-PMS2 (A16-4) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-MSH2 (G219-1129) MOUSE MONOCLONAL PRIMARY ANTIBODY AND VENTANA ANTI-MSH6 (SP93) RABBIT MONOCLONAL PRIMARY ANTIBODY. THE VENTANA MMR IHC PANEL IS INDICATED FOR THE DETECTION OF MISMATCH REPAIR PROTEIN DEFICIENCY AS A TEST FOR THE IDENTIFICATION OF INDIVIDUALS AT RISK FOR LYNCH SYNDROME IN PATIENTS DIAGNOSED WITH COLORECTAL CANCER (CRC), AND, WITH BRAF V600E STATUS, AS AN AID TO DIFFERENTIATE BETWEEN SPORADIC AND PROBABLE LYNCH SYNDROME CRC IN THE ABSENCE OF MLH1 PROTEIN EXPRESSION. THESE PRODUCTS SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA PD-L1 (SP142) ASSAY (VENTANA PD-L1 (SP142) ASSAY)-VENTANA PD-L1 (SP142) ASSAY IS INTENDED FOR THE IMMUNOHISTOCHEMICAL ASSESSMENT OF THE PROGRAMMED DEATH-LIGAND 1 (PD-L1) PROTEIN IN TUMOR CELLS AND TUMOR INFILTRATING IMMUNE CELLS IN FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) TUMOR TISSUE STAINED WITH OPTIVIEW DAB IHC DETECTION KIT AND OPTIVIEW AMPLIFICATION

	KIT ON A VENTANA BENCHMARK IHC/ISH INSTRUMENT. DETERMINATION OF PD-L1 STATUS IS INDICATION-SPECIFIC AND EVALUATION IS BASED ON EITHER THE PROPORTION OF TUMOR AREA OCCUPIED BY PD-L1 EXPRESSING TUMOR-INFILTRATING IMMUNE CELLS (% IC) OF ANY INTENSITY OR THE PERCENTAGE OF PD-L1 EXPRESSING TUMOR CELLS (% TC) OF ANY INTENSITY. PD-L1 EXPRESSION MAY BE ASSOCIATED WITH IMPROVED PATIENT OUTCOMES OBSERVED IN CLINICAL TRIALS. SEE THE TECENTRIQ (ATEZOLIZUMAB) PRODUCT LABEL FOR THE SIGNIFICANCE OF PD-L1 EXPRESSION LEVELS IN SPECIFIC CLINICAL SETTINGS. PD-L1 EXPRESSION IN TC OR IC DETERMINED BY VENTANA PD-L1 (SP142) ASSAY IN NSCLC TISSUE MAY BE ASSOCIATED WITH ENHANCED OVERALL SURVIVAL. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE,VENTANA ANTI-MSH6 (SP93) RABBIT MONOCLONAL PRIMARY ANTIBODY(VENTANA ANTI-MSH6 (SP93) RABBIT MONOCLONAL PRIMARY ANTIBODY)-VENTANA ANTI-MSH6 (SP93) RABBIT MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-MSH6 (SP93) ANTIBODY) IS INTENDED FOR THE QUALITATIVE DETECTION OF MSH6 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. VENTANA- ANTI-MSH6 (SP93) ANTIBODY IS READY TO USE ON BENCHMARK ULTRA, XT AND GX INSTRUMENTS WITH THE OPTIVIEW DAB IHC DETECTION KIT AND ANCILLARY REAGENTS. VENTANA ANTI-MSH6 (SP93) ANTIBODY IS PART OF THE VENTANA MMR IHC PANEL WHICH INCLUDES VENTANA ANTI-MLH1 (M1) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-PMS2 (A16-4) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-MSH2 (G219-1129) MOUSE MONOCLONAL PRIMARY ANTIBODY AND VENTANA ANTI-BRAF V600E (VE1) MOUSE MONOCLONAL PRIMARY ANTIBODY. THE VENTANA MMR IHC PANEL IS INDICATED FOR THE DETECTION OF MISMATCH REPAIR PROTEIN DEFICIENCY AS A TEST FOR THE IDENTIFICATION OF INDIVIDUALS AT RISK FOR LYNCH SYNDROME IN PATIENTS DIAGNOSED WITH COLORECTAL CANCER (CRC), AND, WITH BRAF V600E STATUS, AS AN AID TO DIFFERENTIATE BETWEEN SPORADIC AND PROBABLE LYNCH SYNDROME CRC IN THE ABSENCE OF MLH1 PROTEIN EXPRESSION. THESE PRODUCTS SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA HER2 DUAL ISH DNA PROBE COCKTAIL(VENTANA HER2 DUAL ISH DNA PROBE COCKTAIL)-THE VENTANA HER2 DUAL ISH DNA PROBE COCKTAIL IS INTENDED TO DETERMINE HER2 GENE STATUS BY ENUMERATION OF THE RATIO OF THE HER2 GENE TO CHROMOSOME 17 BY LIGHT MICROSCOPY. THE HER2 AND CHROMOSOME 17 PROBES

	ARE DETECTED USING TWO-COLOR CHROMOGENIC IN SITU HYBRIDIZATION (ISH) IN FORMALIN-FIXED, PARAFFIN-EMBEDDED HUMAN BREAST AND GASTRIC CARCINOMA TISSUE SPECIMENS, INCLUDING THE GASTROESOPHAGEAL JUNCTION, FOLLOWING STAINING ON BENCHMARK IHC/ISH INSTRUMENTS. THE VENTANA HER2 DUAL ISH DNA PROBE COCKTAIL IS INDICATED AS AN AID IN THE ASSESSMENT OF PATIENTS FOR WHOM HERCEPTIN (TRASTUZUMAB) IS BEING CONSIDERED. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA ANTI-MLH1 (M1) MOUSE MONOCLONAL PRIMARY ANTIBODY(VENTANA ANTI-MLH1 (M1) MOUSE MONOCLONAL PRIMARY ANTIBODY)-VENTANA ANTI-MLH1 (M1) MOUSE MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-MLH1 (M1) ANTIBODY) IS INTENDED FOR THE QUALITATIVE DETECTION OF MLH1 PROTEIN IN FORMALINFIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. VENTANA ANTI-MLH1 (M1) ANTIBODY IS READY TO USE ON BENCHMARK ULTRA, XT AND GX INSTRUMENTS WITH THE OPTIVIEW DAB IHC DETECTION KIT AND ANCILLARY REAGENTS. VENTANA ANTI-MLH1 (M1) ANTIBODY IS PART OF THE VENTANA MMR IHC PANEL WHICH INCLUDES VENTANA ANTI-PMS2 (A16-4) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-MSH2 (G219-1129) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-MSH6 (SP93) RABBIT MONOCLONAL PRIMARY ANTIBODY AND VENTANA ANTI-BRAF V600E (VE1) MOUSE MONOCLONAL PRIMARY ANTIBODY. THE VENTANA MMR IHC PANEL IS INDICATED FOR THE DETECTION OF MISMATCH REPAIR PROTEIN DEFICIENCY AS A TEST FOR THE IDENTIFICATION OF INDIVIDUALS AT RISK FOR LYNCH SYNDROME IN PATIENTS DIAGNOSED WITH COLORECTAL CANCER (CRC), AND, WITH BRAF V600E STATUS, AS AN AID TO DIFFERENTIATE BETWEEN SPORADIC AND PROBABLE LYNCH SYNDROME CRC IN THE ABSENCE OF MLH1 PROTEIN EXPRESSION. THESE PRODUCTS SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,INFORM® HPV II FAMILY 6 PROBE(INFORM® HPV II FAMILY 6 PROBE)-VENTANA MEDICAL SYSTEMS' (VENTANA) INFORM HPV II FAMILY 6 PROBE IS TO BE USED IN CONJUNCTION WITH ISH IVIEW BLUE PLUS DETECTION KIT AND OTHER ACCESSORY REAGENTS TO STAIN NEUTRAL BUFFERED FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE SECTIONS ON THE BENCHMARK IHC/ISH INSTRUMENTS. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. POSITIVE RESULTS AID IN

	THE CLASSIFICATION OF NORMAL AND ABNORMAL SPECIMENS, AND SERVE AS AN ADJUNCT TO CONVENTIONAL HISTOPATHOLOGY TESTS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,VENTANA ANTI-MSH2 (G219-1129) MOUSE MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-MSH2 (G219-1129) MOUSE MONOCLONAL PRIMARY ANTIBODY)-VENTANA ANTI-MSH2 (G219-1129) MOUSE MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-MSH2 (G219-1129) ANTIBODY) IS INTENDED FOR THE QUALITATIVE DETECTION OF MSH2 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. VENTANA ANTI- MSH2 (G219-1129) ANTIBODY IS READY TO USE ON BENCHMARK ULTRA, XT AND GX INSTRUMENTS WITH THE OPTIVIEW DAB IHC DETECTION KIT AND ANCILLARY REAGENTS. VENTANA ANTI-MSH2 (G219-1129) ANTIBODY IS PART OF THE VENTANA MMR IHC PANEL WHICH INCLUDES VENTANA ANTI-MLH1 (M1) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-PMS2 (A16-4) MOUSE MONOCLONAL PRIMARY ANTIBODY, VENTANA ANTI-MSH6 (SP93) RABBIT MONOCLONAL PRIMARY ANTIBODY AND VENTANA ANTI-BRAF V600E (VE1) MOUSE MONOCLONAL PRIMARY ANTIBODY. THE VENTANA MMR IHC PANEL IS INDICATED FOR THE DETECTION OF MISMATCH REPAIR PROTEIN DEFICIENCY AS A TEST FOR THE IDENTIFICATION OF INDIVIDUALS AT RISK FOR LYNCH SYNDROME IN PATIENTS DIAGNOSED WITH COLORECTAL CANCER (CRC), AND, WITH BRAF V600E STATUS, AS AN AID TO DIFFERENTIATE BETWEEN SPORADIC AND PROBABLE LYNCH SYNDROME CRC IN THE ABSENCE OF MLH1 PROTEIN EXPRESSION. THESE PRODUCTS SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,INFORM KAPPA PROBE(INFORM KAPPA PROBE)-"VENTANA MEDICAL SYSTEMS, INC.'S (VENTANA) INFORM KAPPA PROBE IS INTENDED TO DETECT CYTOPLASMIC MRNA FOR KAPPA IMMUNOGLOBULIN LIGHT CHAIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SAMPLES. IT IS TYPICALLY USED IN CONJUNCTION WITH THE INFORM LAMBDA PROBE FOR LAMBDA IMMUNOGLOBULIN LIGHT CHAIN. THE COMBINED ASSAYS ASSIST DISTINCTION BETWEEN POLYCLONAL (KAPPA POSITIVE, LAMBDA POSITIVE MRNA) PROLIFERATIONS ASSOCIATED WITH BENIGN REACTIVE PLASMA CELL AND B-CELL LYMPHOID PROLIFERATIONS.

	AND MONOCLONAL (EITHER KAPPA POSITIVE AND LAMBDA NEGATIVE, OR KAPPA NEGATIVE AND LAMBDA POSITIVE) PROLIFERATIONS ASSOCIATED WITH NEOPLASTIC PLASMA CELL AND B-CELL LYMPHOID PROLIFERATIONS.1,2,3 INFORM KAPPA PROBE IS TO BE USED IN CONJUNCTION WITH ISH IVIEWBLUE DETECTION KIT, AND OTHER ACCESSORY REAGENTS TO STAIN SECTIONS THAT ARE FIXED IN NEUTRAL BUFFERED FORMALIN, PARAFFIN EMBEDDED TISSUE, OR CYTOLOGICAL SPECIMEN SLIDES ON THE BENCHMARK, BENCHMARK XT, OR BENCHMARK ULTRA AUTOMATED SLIDE STAINERS. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. POSITIVE RESULTS AID IN THE CLASSIFICATION OF NORMAL AND ABNORMAL SPECIMENS, AND SERVE AS AN ADJUNCT TO CONVENTIONAL HISTOPATHOLOGY OR CYTOPATHOLOGY TESTS. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE." ,INFORM HER2 DUAL ISH DNA PROBE COCKTAIL(INFORM HER2 DUAL ISH DNA PROBE COCKTAIL)-THE INFORM HER2 DUAL ISH DNA PROBE COCKTAIL IS DESIGNED TO QUANTITATIVELY DETECT AMPLIFICATION BY LIGHT MICROSCOPY OF THE HER2 GENE VIA TWO-COLOR CHROMOGENIC IN SITU HYBRIDIZATION (ISH) IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SPECIMENS OF HUMAN BREAST CANCER AND GASTRIC CANCER, INCLUDING THE GASTROESOPHAGEAL JUNCTION, FOLLOWING STAINING ON VENTANA AUTOMATED SLIDE STAINERS. THE INFORM HER2 DUAL ISH DNA PROBE COCKTAIL IS INDICATED AS AN AID IN THE ASSESSMENT OF BREAST AND GASTRIC CANCER PATIENTS FOR WHOM HERCEPTIN (TRASTUZUMAB) TREATMENT IS BEING CONSIDERED AND FOR BREAST CANCER PATIENTS FOR WHOM KADCYLA (TRASTUZUMAB EMTANSINE (T-DM1)) TREATMENT IS BEING CONSIDERED. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,INFORM EBER (EPSTEIN-BARR VIRUS EARLY RNA) PROBE (INFORM EBER (EPSTEIN-BARR VIRUS EARLY RNA) PROBE)- "VENTANA MEDICAL SYSTEMS, INC.'S (VENTANA) INFORM EBER (EPSTEIN-BARR VIRUS EARLY RNA) PROBE (INFORM EBER PROBE) IS INTENDED TO IDENTIFY, BY IN SITU HYBRIDIZATION (ISH) AND LIGHT MICROSCOPY, CELLS EXPRESSING EPSTEIN-BARR ENCODED RNA (EBER) IN SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. INFORM EBER PROBE SPECIFICALLY HYBRIDIZES TO EBER RNA TRANSCRIPTS. POSITIVE RESULTS AID IN THE IDENTIFICATION

	OF CELLS INFECTED WITH EPSTEIN-BARR VIRUS. THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION AND PROPER CONTROLS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.",INFORM® HPV III FAMILY 16 PROBE (B)(INFORM® HPV III FAMILY 16 PROBE (B))-VENTANA MEDICAL SYSTEMS' (VENTANA) INFORM HPV III FAMILY 16 PROBE (B) IS TO BE USED IN CONJUNCTION WITH THE ISH IVIEW BLUE PLUS DETECTION KIT AND OTHER ACCESSORY REAGENTS TO STAIN NEUTRAL BUFFERED FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE SECTIONS ON THE VENTANA BENCHMARK IHC/ISH INSTRUMENTS. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. POSITIVE RESULTS AID IN THE CLASSIFICATION OF NORMAL AND ABNORMAL SPECIMENS, AND SERVE AS AN ADJUNCT TO CONVENTIONAL HISTOPATHOLOGY TESTS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE,INFORM CYTOPLASMIC LAMBDA MRNA PROBE(INFORM CYTOPLASMIC LAMBDA MRNA PROBE)-"VENTANA MEDICAL SYSTEMS, INC.'S (VENTANA) INFORM CYTOPLASMIC LAMBDA MRNA PROBE (INFORM LAMBDA PROBE) IS INTENDED TO DETECT CYTOPLASMIC MRNA FOR LAMBDA IMMUNOGLOBULIN LIGHT CHAIN IN FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE SAMPLES. IT IS TYPICALLY USED IN CONJUNCTION WITH THE INFORM KAPPA PROBE FOR KAPPA IMMUNOGLOBULIN LIGHT CHAIN. THE COMBINED ASSAYS ASSIST DISTINCTION BETWEEN POLYCLONAL (KAPPA POSITIVE, LAMBDA POSITIVE MRNA) PROLIFERATIONS ASSOCIATED WITH BENIGN REACTIVE PLASMA CELL AND BCELL LYMPHOID PROLIFERATIONS; AND MONOCLONAL (EITHER KAPPA POSITIVE AND LAMBDA NEGATIVE, OR KAPPA NEGATIVE AND LAMBDA POSITIVE) PROLIFERATIONS ASSOCIATED WITH NEOPLASTIC PLASMA CELL AND B-CELL LYMPHOID PROLIFERATIONS.1,2,3 INFORM LAMBDA PROBE IS TO BE USED IN CONJUNCTION WITH ISH IVIEWBLUE DETECTION KIT, AND OTHER ACCESSORY REAGENTS TO STAIN SECTIONS THAT ARE FIXED IN NEUTRAL BUFFERED FORMALIN, PARAFFIN-EMBEDDED TISSUE, OR CYTOLOGICAL SPECIMEN SLIDES ON THE BENCHMARK, BENCHMARK XT, OR BENCHMARK ULTRA AUTOMATED SLIDE STAINERS. LIGHT MICROSCOPY IS USED TO DETECT THE STAINING REACTION. POSITIVE RESULTS AID IN THE CLASSIFICATION OF NORMAL AND ABNORMAL SPECIMENS, AND

	SERVE AS AN ADJUNCT TO CONVENTIONAL HISTOPATHOLOGY OR CYTOPATHOLOGY TESTS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED PATHOLOGIST WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. THIS PRODUCT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE.,ULTRAVIEW SISH DNP DETECTION KIT(ULTRAVIEW SISH DNP DETECTION KIT)-VENTANA MEDICAL SYSTEMS' (VENTANA) ULTRAVIEW SISH DNP DETECTION KIT IS AN INDIRECT, BIOTIN-FREE SYSTEM FOR DETECTING DNP LABELED PROBES. THE KIT IS INTENDED TO IDENTIFY TARGETS BY SILVER IN SITU HYBRIDIZATION (ISH) IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE THAT ARE STAINED ON VENTANA BENCHMARK SERIES INSTRUMENTS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY HISTOLOGICAL EXAMINATION AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED READER WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. THIS DETECTION KIT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. ,INFORM HER2 DNA PROBE(INFORM HER2 DNA PROBE)-THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) INFORM HER2 DNA PROBE IS DESIGNED TO DETECT AMPLIFICATION OF THE HER2 GENE VIA CHROMOGENIC SILVER IN SITU HYBRIDIZATION (SISH) IN FORMALIN FIXED, PARAFFIN EMBEDDED HUMAN BREAST CANCER TISSUE SPECIMENS FOLLOWING STAINING ON A VENTANA AUTOMATED SLIDE STAINER USING LIGHT MICROSCOPY. THE INFORM HER2 DNA PROBE IS INDICATED AS AN AID IN THE ASSESSMENT OF PATIENTS FOR WHOM HERCEPTIN (TRASTUZUMAB) TREATMENT IS BEING CONSIDERED. INFORMHER2DNAPROBE INFORM HER2 DNA PROBE HAS BEEN SHOWN TO DETECT AMPLIFICATION OF THE HER2 GENE VIA CHROMOGENIC IN-SITU HYBRIDIZATION IN FORMALIN FIXED, PARAFFIN EMBEDDED, HUMAN GASTRIC TISSUE ON VENTANA BENCHMARK, BENCHMARK LT, AND BENCHMARK XT INSTRUMENTS USING LIGHT MICROSCOPY.,VENTANA ANTI-ALK (D5F3) RABBIT MONOCLONAL PRIMARY ANTIBODY(VENTANA ANTI-ALK (D5F3) RABBIT MONOCLONAL PRIMARY ANTIBODY)-VENTANA ANTI-ALK (D5F3) RABBIT MONOCLONAL PRIMARY ANTIBODY (VENTANA ANTI-ALK (D5F3)) IS INTENDED FOR LABORATORY USE IN THE DETECTION OF THE ANAPLASTIC LYMPHOMA KINASE (ALK) PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED NON-SMALL CELL LUNG CARCINOMA (NSCLC) TISSUE STAINED WITH THE BENCHMARK

		IHC/ISH INSTRUMENTS. IT IS INDICATED AS AN AID IN IDENTIFYING PATIENTS ELIGIBLE FOR TREATMENT WITH XALKORI® (CRIZOTINIB), ZYKADIA® (CERITINIB), OR ALECENSA® (ALECTINIB). THIS PRODUCT SHOULD BE INTERPRETED BY A QUALIFIED PATHOLOGIST IN CONJUNCTION WITH HISTOLOGICAL EXAMINATION, RELEVANT CLINICAL INFORMATION, AND PROPER CONTROLS. THIS ANTIBODY IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE,INFORM CHROMOSOME 17 PROBE(INFORM CHROMOSOME 17 PROBE)-"THIS REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE. VENTANA MEDICAL SYSTEMS' (VENTANA) INFORM CHROMOSOME 17 PROBE IS DESIGNED TO HYBRIDIZE TO THE CENTROMERIC REGION OF CHROMOSOME 17 ALLOWING DETERMINATION OF PLOIDY STATUS OF CHROMOSOME 17 VIA CHROMOGENIC SILVER IN SITU HYBRIDIZATION (SISH) IN FORMALIN-FIXED, PARAFFIN-EMBEDDED HUMAN BREAST CANCER TISSUE SPECIMENS FOLLOWING STAINING ON VENTANA AUTOMATED SLIDE STAINER INSTRUMENTS USING LIGHT MICROSCOPY.,ULTRAVIEW RED ISH DIG DETECTION KIT (ULTRAVIEW RED ISH DIG DETECTION KIT)-"VENTANA MEDICAL SYSTEMS' (VENTANA) ULTRAVIEW RED ISH DIG DETECTION KIT IS AN INDIRECT, BIOTIN-FREE SYSTEM FOR DETECTING DIG LABELED PROBES. THE KIT IS INTENDED TO IDENTIFY TARGETS BY CHROMOGENIC RED IN SITU HYBRIDIZATION (ISH) IN SECTIONS OF FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE THAT ARE STAINED ON VENTANA BENCHMARK SERIES INSTRUMENTS. THE CLINICAL INTERPRETATION OF ANY STAINING, OR THE ABSENCE OF STAINING, MUST BE COMPLEMENTED BY HISTOLOGICAL EXAMINATION AND EVALUATION OF PROPER CONTROLS. EVALUATION MUST BE MADE BY A QUALIFIED READER WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS. THIS DETECTION KIT IS INTENDED FOR IN VITRO DIAGNOSTIC (IVD) USE."
791	IMP/IVD/2020/000628	1.License Holder Name: AGD BIOMEDICALS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CYANIDE-FREE REAGENT USED FOR LYSING ERYTHROCYTES-CYANIDE-FREE REAGENT USED FOR LYSING ERYTHROCYTES, COUNTING AND DIFFERENTIATING THE FIVE MAIN LEUKOCYTES SUB POPULATIONS AND QUANTITATIVE DETERMINATION HEMOGLOBIN IN A BLOOD SAMPLE IN COMBINATION 5DIFF DILUENT ON 5 PART DIFFERENTIAL HEMATOLOGY ANALYZERS.

792	IMP/IVD/2020/000629	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALINITY C LACTIC ACID REAGENT KIT(ALINITY C LACTIC ACID REAGENT KIT)-THE ALINITY C LACTIC ACID ASSAY IS USED FOR THE QUANTITATION OF LACTIC ACID IN HUMAN PLASMA ON THE ALINITY C ANALYZER.,LACTIC ACID ASSAY(LACTIC ACID ASSAY)-THE LACTIC ACID ASSAY IS USED FOR THE QUANTITATION OF LACTIC ACID IN HUMAN PLASMA.
793	IMP/IVD/2020/000638	1.License Holder Name: ORANGE BIOSCIENCE PRODUCTS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIAGNOSTIC REAGENT SOLUTION(HURO PATH LYSIS SOLUTION(HEMOLICS))-IN CASE THE SPECIMEN IS NOT SMEARED DUE TO ITS EXCESSIVE BLOOD CONCENTRATE SPECIMEN BY CENTRIFUGATION AT DIFFERENT PROTOCOL,DIAGNOSTIC REAGENT SOLUTION(HURO PATH SOLUTION: BODY FLUID)-THIS USED FOR SUPERIOR CELLULAR PRESERVATION BY PREVENTING DEGENERATION OF PROTEIN WHICH IS FURTHER PUT ON MEMBRANE FILTRATION IN SLIDE PROCESSOR, DIAGNOSTIC REAGENT SOLUTION(HURO PATH LYSIS SOLUTION (CONTRO-REAGENT))-IN CASE THE SPECIMEN IS NOT SMEARED DUE TO ITS EXCESSIVE BLOOD CONCENTRATE SPECIMEN BY CENTRIFUGATION AT DIFFERENT PROTOCOL,DIAGNOSTIC REAGENT SOLUTION(HURO PATH SOLUTION: FNA)-THIS USED TO CLEAR BACK GROUND OF CELLULAR SMEAR BY ELIMINATING BLOOD AND FLUID OF TISSUE WHICH IS FURTHER PUT ON MEMBRANE FILTRATION IN SLIDE PROCESSOR,DIAGNOSTIC REAGENT SOLUTION(HURO PATH SOLUTION: GYN)-THIS USED FOR PRESERVATION OF CELL FOR CERVIX SMEAR WHICH IS FURTHER PUT ON MEMBRANE FILTRATION IN SLIDE PROCESSOR,DIAGNOSTIC REAGENT SOLUTION(HURO PATH LYSIS SOLUTION(DILUENT))-INCASE THE SPECIMEN IS NOT SMEARED DUE TO ITS EXCESSIVE DENSITY, MIX DILENT.DILUENT IN SPECIMEN VERSUS SPECIMEN 1:3 IN QUANTITY AND SMEAR AGAIN,DIAGNOSTIC REAGENT SOLUTION(HURO PATH SOLUTION: SPUTUM)-THIS USED FOR PRESERVATION OF CELL FOR SPUTUM SMEAR WHICH IS FURTHER PUT ON MEMBRANE FILTRATION IN SLIDE PROCESSOR, DIAGNOSTIC REAGENT SOLUTION(HURO PATH SOLUTION: URINE)-THIS USED FOR MINIMIZING CYTOLOGICAL DEGENERATION WHICH IS FURTHER PUT ON MEMBRANE FILTRATION IN SLIDE PROCESSOR

794	IMP/IVD/2020/000640	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABBOTT REALTIME MTB AMPLIFICATION REAGENT KIT(ABBOTT REALTIME MTB AMPLIFICATION REAGENT KIT)-THE ABBOTT REALTIME MTB ASSAY IS AN IN VITRO POLYMERASE CHAIN REACTION (PCR) ASSAY FOR THE QUALITATIVE DETECTION OF MTB COMPLEX DNA IN SMEAR POSITIVE OR SMEAR NEGATIVE SPECIMENS OF SPUTUM OR BRONCHIAL ALVEOLAR LAVAGE AND N-ACETYL-L-CYSTEINE (NALC)-PREPARED SEDIMENTS PREPARED FROM SPUTUM AND BRONCHIAL ALVEOLAR LAVAGE COLLECTED FROM INDIVIDUALS SUSPECTED OF HAVING TUBERCULOSIS (TB).,ABBOTT REALTIME MTB CONTROL KIT (ABBOTT REALTIME MTB CONTROL KIT)-THE ABBOTT REALTIME MTB CONTROLS ARE USED TO ESTABLISH RUN VALIDITY OF THE ABBOTT REALTIME MTB ASSAY WHEN USED FOR THE QUALITATIVE DETECTION OF MYCOBACTERIUM TUBERCULOSIS (MTB) DNA IN CLINICAL SPECIMENS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

795	IMP/IVD/2020/000653	1.License Holder Name: INVITROGEN BIOSERVICES INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:96 WELL RETAINER & BASE STD CE-IVD(APPLIED BIOSYSTEMS)-THIS IS A 96-WELL STANDARD RETAINER & BASE SET DESIGNED FOR USE WITH THE 3500 DX3500XL DX GENETIC ANALYZER AS ACCESSORIES. THE 96-WELL STANDARD RETAINER & BASE SET IS A RE-USABLE PLASTIC CONSUMABLE THAT STABILIZES THE POSITION OF THE SAMPLE CONTAINING PLATE ON THE INSTRUMENT. THE 96-WELL STANDARD RETAINER & BASE SET IS TO BE USED TOGETHER WITH 3500DX/ 3500XL DX GENETIC ANALYZERS INSTRUMENT.,96-WELL CALIBRATION NED IVD(APPLIED BIOSYSTEMS)-THE 96-WELL SPECTRAL CALIBRATION PLATE WITH NED™ DYE IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH STANDARD 96-WELL BLOCK. DYE CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE 96-WELL SPECTRAL CALIBRATION PLATE WITH NED™ DYE IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,TB, ARRAY CALIBRATION VIC DYE, IVD(APPLIED BIOSYSTEMS)-ARRAY CARD CALIBRATION WITH VIC DYE. FOR IN VITRO DIAGNOSTIC USE. THE TB, ARRAY CALIBRATION VIC DYE,IVD IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,96 WELL RETAINER & BASE FAST CE-IVD(APPLIED BIOSYSTEMS)-THIS IS A 96-WELL FAST (0.1ML) RETAINER & BASE SET DESIGNED FOR USE WITH THE 3500 DX3500XL DX GENETIC ANALYZER. SEPTA AND PLATE BASE RETAINER KITS FOR 8 TUBE STRIP, 96 AND 384-WELL PLATES USED WITH THE 3500 DX SERIES GENETIC ANALYZERS. THE 96-WELL FAST (0.1ML) RETAINER & BASE SET IS TO BE USED TOGETHER WITH 3500DX/ 3500XL DX GENETIC ANALYZERS INSTRUMENT.,FAST 96W BACKGND IVD(APPLIED BIOSYSTEMS)-THE FAST 96-WELL BACKGROUND PLATE IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH 96-WELL FAST BLOCK. BACKGROUND CALIBRATION SHOULD BE RUN AT LEAST EVERY SIX MONTHS. THE FAST 96-WELL BACKGROUND PLATE IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,GS600LIZV2-DX (APPLIED BIOSYSTEMS)-THE GENESCAN™ 600 LIZ™ SIZE STANDARD V2.0 DX IS A FIVE DYE–LABELED, HIGH-DENSITY SIZE STANDARD FOR THE REPRODUCIBLE SIZING OF FRAGMENT ANALYSIS DATA. THIS PRODUCT CAN BE USED AS A TRADITIONAL SIZE STANDARD ON ALL

	OF THE APPLIED BIOSYSTEMS™ CAPILLARY ELECTROPHORESIS SYSTEMS. USE THIS SIZE STANDARD FOR FRAGMENTS BETWEEN 20 AND 600 BP. THE STANDARD CONTAINS 36 LIZ DYE–LABELED, SINGLE-STRANDED DNA FRAGMENTS. SINCE THE STANDARD IS LABELED WITH THE FIFTH DYE, USERS CAN GENOTYPE A GREATER NUMBER OF MARKERS IN A GIVEN LANE, COMPARED TO THE FOUR-DYE SYSTEM. THE GENESCAN™ 600 LIZ™ SIZE STANDARD V2.0 DX IS TO BE USED TOGETHER WITH 3500DX/ 3500XL DX GENETIC ANALYZERS INSTRUMENT.,384-WELL ROI AND BACKGROUND PLATES, IVD(APPLIED BIOSYSTEMS)-THE 384-WELL ROI & BACKGROUND CALIBRATION KIT IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH 384-WELL BLOCK. REGION OF INTEREST (ROI) AND BACKGROUND CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE 384-WELL ROI & BACKGROUND CALIBRATION KIT IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,FAST 96-WELL CALIBRATION PLATE W/ROX, IVD (APPLIED BIOSYSTEMS)-THE FAST 96-WELL DYE CALIBRATION PLATE (ROX™) IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH FAST 96-WELL BLOCK. DYE CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE FAST 96-WELL DYE CALIBRATION PLATE (ROX™) IS TO BE USED TOGETHER WITH QUANTSTUDIO DX INSTRUMENT. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,ARRAY CARD RNASE P VERIF IVD(APPLIED BIOSYSTEMS)-THE KIT, RNASE P ARRAY CARD INSTRUMENT VERIFICATION REAGENTS IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION. FOR IN VITRO DIAGNOSTIC USE. ,FAST 96-WELL CALIBRATION PLATE W/TAMRA, IVD(APPLIED BIOSYSTEMS)-THE FAST 96-WELL DYE CALIBRATION PLATE (TAMRA™) IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH FAST 96-WELL BLOCK. DYE CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE FAST 96-WELL DYE CALIBRATION PLATE (TAMRA™) IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,ARRAY CARD CALIBRATION IVD(APPLIED BIOSYSTEM$)-ARRAY CARD SPECTRAL CALIBRATION DYE KIT: • ARRAY CALIBRATION WITH FAM™ DYE • ARRAY CALIBRATION WITH VIC® DYE • ARRAY CALIBRATION WITH ROX™ DYE • ARRAY CALIBRATION WITH ROI DYE • ARRAY BACKGROUND BUFFER • ARRAY

	CALIBRATION WITH FAM™/ROX™ DYE • ARRAY CALIBRATION WITH VIC®/ROX™ DYE FOR IN VITRO DIAGNOSTIC USE. THE ARRAY CARD SPECTRAL CALIBRATION DYE KIT IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,96-WELL 0.2ML CALIBRATION PLATE 2 (ABY, JUN, AND MUSTANG PURPLE DYES) (APPLIED BIOSYSTEMS)-USE THE 96WELL 0.2ML SPECTRAL CALIBRATION PLATES FOR SPECTRAL NORMALIZATION OF THE QUANTSTUDIO™ 5 DX REALTIME PCR INSTRUMENT. PERFORM DYE CALIBRATION AS PART OF ROUTINE INSTRUMENT MAINTENANCE AS DESCRIBED IN THE QUANTSTUDIO™ 5 DX REALTIME PCR INSTRUMENT MAINTENANCE AND ADMINISTRATION USER GUIDE.,96-WELL 0.2ML CALIBRATION PLATE 1 (FAM, VIC, ROX, AND SYBR DYES) (APPLIED BIOSYSTEMS)-USE THE 96WELL 0.2ML SPECTRAL CALIBRATION PLATES FOR SPECTRAL NORMALIZATION OF THE QUANTSTUDIO™ 5 DX REALTIME PCR INSTRUMENT. PERFORM DYE CALIBRATION AS PART OF ROUTINE INSTRUMENT MAINTENANCE AS DESCRIBED IN THE QUANTSTUDIO™ 5 DX REALTIME PCR INSTRUMENT MAINTENANCE AND ADMINISTRATION USER GUIDE., POP - 6 (384) POLYMER 3500DX SERIES(APPLIED BIOSYSTEMS)-THE POLYMER IS THE SEPARATION MATRIX FOR CAPILLARY ELECTROPHORESIS. IT IS SUPPLIED AS A READY-TO-USE POUCH WITH A RADIO FREQUENCY IDENTIFICATION (RFID) TAG INCORPORATED INTO THE LABEL. THE INSTRUMENT USES THE RFID TAG TO TRACK POLYMER USAGE AND EXPIRATION. THIS PRODUCT IS INDICATED FOR IN VITRO DIAGNOSTIC USE WITH THE 3500 DX/3500XL DX GENETIC ANALYZER,DS-33 MATRIX STD-DX(APPLIED BIOSYSTEMS)-THE DS-33 MATRIX STANDARD KIT DX (DYE SET G5) IS USED TO GENERATE THE "MULTICOMPONENT MATRIX" REQUIRED WHEN ANALYZING 6-FAM™, VIC™, NED™, PET™, AND LIZ™ DYE-LABELED DNA FRAGMENTS ON THE APPLIED BIOSYSTEMS™ 3500 DX SERIES GENETIC ANALYZERS. THE DATA COLLECTION SOFTWARE FOR THESE INSTRUMENTS USES THE MULTICOMPONENT MATRIX TO AUTOMATICALLY ANALYZE THE FIVE DIFFERENT-COLORED FLUORESCENT DYE–LABELED SAMPLES IN A SINGLE CAPILLARY., TAQMAN RNASE P FAST 384W VERIF PLATE IVD(APPLIED BIOSYSTEMS)-THE 384-WELL RNASEP VERIFICATION PLATE IS USED TO VERIFY YOUR REAL-TIME PCR INSTRUMENT WITH 384-WELL BLOCK. CONFIRM THE PERFORMANCE OF YOUR INSTRUMENT BY RUNNING THE RNASEP ASSAY. THE 384-WELL RNASEP VERIFICATION PLATE IS PRELOADED WITH THE NECESSARY REAGENTS TO DETECT AND QUANTITATE GENOMIC COPIES OF THE HUMAN RNASE P GENE, A SINGLE-COPY GENE ENCODING THE RNA MOIETY OF THE RNASE P

	ENZYME. EACH WELL CONTAINS PRELOADED REACTION MIX (1X TAQMAN® UNIVERSAL PCR MASTER MIX, RNASE P PRIMERS, AND FAM™ DYE-LABELED PROBE) AND TEMPLATE. THE 384-WELL RNASEP VERIFICATION PLATE IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,96-WELL CALIBRATION CY5 IVD(APPLIED BIOSYSTEMS)-THE 96-WELL SPECTRAL CALIBRATION PLATE WITH CY™ 5 DYE IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH STANDARD 96-WELL BLOCK. DYE CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE 96-WELL SPECTRAL CALIBRATION PLATE WITH CY™ 5 DYE IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,FG, CAPILLARY ARRAY 24-CAP 50 CM CE-IVD(APPLIED BIOSYSTEMS)-THE CAPILLARY ARRAY FOR THE 3500 DX/3500XL DX GENETIC ANALYZER IS AVAILABLE IN 8CAPILLARIES OR 24CAPILLARIES. THIS PRODUCT IS INDICATED FOR IN VITRO DIAGNOSTIC USE WITH THE 3500 DX/3500XL DX GENETIC ANALYZER,384-WELL CALIBRATION PLATE W/FAM, IVD(APPLIED BIOSYSTEMS)-THE 384-WELL DYE CALIBRATION PLATE (FAM™) IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH 384-WELL BLOCK. DYE CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE 384-WELL DYE CALIBRATION PLATE (FAM™) IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,FAST 96-WELL NORMALIZATION PLATES, IVD(APPLIED BIOSYSTEMS)-THE FAST 96-WELL NORMALIZATION KIT IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH FAST 96-WELL BLOCK. NORMALIZATION PLATES ARE USED TO CALIBRATE DIFFERENT INSTRUMENTS. THE KIT CONTAINS ONE FAM™/ROX™ NORMALIZATION PLATE AND ONE VIC®/ROX™ NORMALIZATION PLATE. THE FAST 96-WELL NORMALIZATION PLATES WITH FAM™/ROX™ AND VIC™/ROX™ DYES IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,ARRAY CARD BACKGROUND BUFFER, KIT IVD(APPLIED BIOSYSTEMS)-THE ARRAY CARD BACKGROUND BUFFER KIT CONSISTS OF 6 TUBES OF BACKGROUND BUFFER AND 6-PACK ARRAY CARD KIT (EMPTY). THE ARRAY CARD BACKGROUND BUFFER KIT IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION

	AND MAINTENANCE FOR PROPER OPERATION.,POP - 7 (384) POLYMER 3500DX SERIES(APPLIED BIOSYSTEMS)-THE POLYMER IS THE SEPARATION MATRIX FOR CAPILLARY ELECTROPHORESIS. IT IS SUPPLIED AS A READY-TO-USE POUCH WITH A RADIO FREQUENCY IDENTIFICATION (RFID) TAG INCORPORATED INTO THE LABEL. THE INSTRUMENT USES THE RFID TAG TO TRACK POLYMER USAGE AND EXPIRATION. THIS PRODUCT IS INDICATED FOR IN VITRO DIAGNOSTIC USE WITH THE 3500 DX/3500XL DX GENETIC ANALYZER, SEQUENCING STANDARD V3.1 3500 DX SERIES(APPLIED BIOSYSTEMS)-THE SEQUENCING STANDARD KIT INCLUDES FOUR TUBES THAT CONTAIN LYOPHILIZED DNA OF A KNOWN 1202-BASE PAIR SEQUENCE, PREPARED WITH BIGDYE™ TERMINATOR V3.1. EACH TUBE CONTAINS ENOUGH DNA TO PERFORM: • ONE SPECTRAL CALIBRATION OR PERFORMANCE CHECK, AND/OR • ONE CONTROL SEQUENCING RUN THIS PRODUCT IS INDICATED FOR IN VITRO DIAGNOSTIC USE WITH THE 3500 DX/3500XL DX GENETIC ANALYZER CS2 AND 3500 DX/3500XL DX GENETIC ANALYZER,SEQUENCING STANDARD V1.1 3500DX SERIES(APPLIED BIOSYSTEMS)-THE SEQUENCING STANDARD KIT INCLUDES FOUR TUBES THAT CONTAIN LYOPHILIZED DNA OF A KNOWN 1200-BASE PAIR SEQUENCE, PREPARED WITH BIGDYE™ TERMINATOR V1.1. EACH TUBE CONTAINS ENOUGH DNA TO PERFORM: • ONE SPECTRAL CALIBRATION OR PERFORMANCE CHECK, AND/OR • ONE CONTROL SEQUENCING RUN THIS PRODUCT IS INDICATED FOR IN VITRO DIAGNOSTIC USE WITH THE 3500 DX/3500XL DX GENETIC ANALYZER CS2 AND 3500 DX/3500XL DX GENETIC ANALYZER,TB, ARRAY FAM/ROX NORMALIZATION, IVD(APPLIED BIOSYSTEMS)-ARRAY CARD SPECTRAL CALIBRATION WITH FAM™/ROX™ DYE. FOR IN VITRO DIAGNOSTIC USE. THE TB, ARRAY FAM/ROX NORMALIZATION, IVD IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION., CATHODE BUFFER CONTAINER 3500DX SERIES(APPLIED BIOSYSTEMS)-THE CATHODE BUFFER CONTAINER (CBC) CONTAINS 1X RUNNING BUFFER FOR CAPILLARY ELECTROPHORESIS. THE CONTAINER HAS TWO COMPARTMENTS: THE LEFT COMPARTMENT PROVIDES THE CATHODE BUFFER FOR ELECTROPHORESIS; THE RIGHT COMPARTMENT PROVIDES FOR A CAPILLARY WASH AND SPENT POLYMER WASTE EJECTION FUNCTIONALITY BETWEEN INJECTIONS. THE CBC IS A READY-TO-USE, DISPOSABLE CONTAINER WITH A RADIO FREQUENCY IDENTIFICATION (RFID) TAG INCORPORATED INTO THE LABEL. THE INSTRUMENT USES THE RFID TAG TO TRACK BUFFER USAGE AND EXPIRATION. THIS PRODUCT IS INDICATED FOR IN VITRO DIAGNOSTIC USE WITH THE 3500

	DX/3500XL DX GENETIC ANALYZER,BTL HI-DI FORMAMIDE 5ML (CE-IVD)(APPLIED BIOSYSTEMS)-THE HI-DI™ FORMAMIDE IS A HIGHLY DE-IONIZED FORMAMIDE, FORMULATED WITH A STABILIZER, FOR USE AS AN INJECTION SOLVENT ON APPLIED BIOSYSTEMS® 3500 DX SERIES GENETIC ANALYZERS. THIS HIGHLY DEIONIZED FORMAMIDE IS USED TO RESUSPEND SAMPLES BEFORE ELECTROKINETIC INJECTION IN CAPILLARY ELECTROPHORESIS SYSTEMS AND IS APPROPRIATE FOR ALL APPLICATIONS. IT IS PROVIDED IN A 5 ML BOTTLE FORMAT TO MINIMIZE FREEZE-THAW CYCLES.,ANODE BUFFER CONTAINER 3500DX SERIES(APPLIED BIOSYSTEMS)-THE ANODE BUFFER CONTAINER (ABC) CONTAINS 1X RUNNING BUFFER FOR CAPILLARY ELECTROPHORESIS. THE ABC IS A READY-TO-USE, DISPOSABLE CONTAINER WITH A RADIO FREQUENCY IDENTIFICATION (RFID) TAG INCORPORATED INTO THE LABEL. THE INSTRUMENT USES THE RFID TAG TO TRACK BUFFER USAGE AND EXPIRATION. THIS PRODUCT IS INDICATED FOR IN VITRO DIAGNOSTIC USE WITH THE 3500 DX/3500XL DX GENETIC ANALYZER,TAQMAN RNASE P 96W INSTRUMENT VERIF PLATE IVD(APPLIED BIOSYSTEMS)-THE 96-WELL RNASEP VERIFICATION PLATE IS USED TO VERIFY YOUR REAL-TIME PCR INSTRUMENT WITH STANDARD 96-WELL BLOCK. CONFIRM THE PERFORMANCE OF YOUR INSTRUMENT BY RUNNING THE RNASEP ASSAY. THE 96-WELL RNASEP VERIFICATION PLATE IS PRELOADED WITH THE NECESSARY REAGENTS TO DETECT AND QUANTITATE GENOMIC COPIES OF THE HUMAN RNASE P GENE, A SINGLE-COPY GENE ENCODING THE RNA MOIETY OF THE RNASE P ENZYME. EACH WELL CONTAINS PRELOADED REACTION MIX (1X TAQMAN® UNIVERSAL PCR MASTER MIX, RNASE P PRIMERS, AND FAM™ DYE-LABELED PROBE) AND TEMPLATE. THE 96-WELL RNASEP VERIFICATION PLATE IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,384-WELL NORMALIZATION PLATES, IVD(APPLIED BIOSYSTEMS)-THE 384-WELL NORMALIZATION KIT IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH 384-WELL BLOCK. NORMALIZATION PLATES ARE USED TO CALIBRATE DIFFERENT INSTRUMENTS. THE KIT CONTAINS ONE FAM™/ROX™ NORMALIZATION PLATE AND ONE VIC®/ROX™ NORMALIZATION PLATE. THE 384-WELL NORMALIZATION KIT IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,POP - 7 (960) POLYMER 3500DX SERIES(APPLIED BIOSYSTEMS)-THE POLYMER IS THE SEPARATION MATRIX FOR CAPILLARY ELECTROPHORESIS. IT IS SUPPLIED AS A READY-TO-USE POUCH

	WITH A RADIO FREQUENCY IDENTIFICATION (RFID) TAG INCORPORATED INTO THE LABEL. THE INSTRUMENT USES THE RFID TAG TO TRACK POLYMER USAGE AND EXPIRATION. THIS PRODUCT IS INDICATED FOR IN VITRO DIAGNOSTIC USE WITH THE 3500 DX/3500XL DX GENETIC ANALYZER,DS-33 GS INSTALL KIT-DX (APPLIED BIOSYSTEMS)-THE DS-33 GENESCAN™ INSTALLATION KIT DX CONSISTS OF POOLED PCR PRODUCTS LABELED WITH 6-FAM™, VIC™, NED™, AND PET™ DYES. TO GENERATE THE POOLED PRODUCTS, CEPH INDIVIDUAL 1347-02 GENOMIC DNA IS AMPLIFIED WITH 8 FLUORESCENT PCR PRIMER PAIRS, WHICH AMPLIFY SELECTED MICROSATELLITE LOCI. DS-33 GENESCAN™ INSTALLATION KIT DX IS TO BE USED TOGETHER WITH 3500DX/ 3500XL DX GENETIC ANALYZERS INSTRUMENT.,FG, CAPILLARY ARRAY 24-CAP 36 CM CE-IVD(APPLIED BIOSYSTEMS)-THE CAPILLARY ARRAY FOR THE 3500 DX/3500XL DX GENETIC ANALYZER IS AVAILABLE IN 8CAPILLARIES OR 24CAPILLARIES. THIS PRODUCT IS INDICATED FOR IN VITRO DIAGNOSTIC USE WITH THE 3500 DX/3500XL DX GENETIC ANALYZER,TB, ARRAY CALIBRATION FAM DYE, IVD(APPLIED BIOSYSTEM)-ARRAY CARD CALIBRATION WITH FAM DYE. THE TB, ARRAY CALIBRATION FAM DYE, IVD IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,FAST 96-WELL CALIBRATION PLATE W/VIC, IVD(APPLIED BIOSYSTEMS)-THE FAST 96-WELL DYE CALIBRATION PLATE (VIC®) IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH FAST 96-WELL BLOCK. DYE CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE FAST 96-WELL SPECTRAL CALIBRATION PLATE WITH VIC™ DYE IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,96 WELL CALIBRATION PLATE W/VIC, IVD(APPLIED BIOSYSTEMS)-THE 96-WELL DYE CALIBRATION PLATE (VIC®) IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH STANDARD 96-WELL BLOCK. DYE CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE 96-WELL SPECTRAL CALIBRATION PLATE WITH VIC™ DYE IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,96 WELL CALIBRATION PLATE W/ROX, IVD(APPLIED BIOSYSTEMS)-THE 96-WELL DYE CALIBRATION PLATE (ROX™) IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH STANDARD 96-WELL BLOCK. DYE CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE 96-WELL SPECTRAL CALIBRATION PLATE WITH ROX™ DYE IS TO BE USED

	TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION,FAST 96-WELL CALIBRATION PLATE W/FAM, IVD(APPLIED BIOSYSTEMS)-THE FAST 96-WELL ROI & BACKGROUND CALIBRATION KIT IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH FAST 96-WELL BLOCK. REGION OF INTEREST (ROI) AND BACKGROUND CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE FAST 96W ROI AND BACKGND IVD IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,384-WELL CALIBRATION PLATE W/ROX, IVD(APPLIED BIOSYSTEMS)-THE 384-WELL DYE CALIBRATION PLATE (ROX™) IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH 384-WELL BLOCK. DYE CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE 384-WELL SPECTRAL CALIBRATION PLATE WITH ROX™ DYE IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,POP - 6 (960) POLYMER 3500DX SERIES(APPLIED BIOSYSTEMS)-THE POLYMER IS THE SEPARATION MATRIX FOR CAPILLARY ELECTROPHORESIS. IT IS SUPPLIED AS A READY-TO-USE POUCH WITH A RADIO FREQUENCY IDENTIFICATION (RFID) TAG INCORPORATED INTO THE LABEL. THE INSTRUMENT USES THE RFID TAG TO TRACK POLYMER USAGE AND EXPIRATION. THIS PRODUCT IS INDICATED FOR IN VITRO DIAGNOSTIC USE WITH THE 3500 DX/3500XL DX GENETIC ANALYZER,CONDITIONING REAGENT 3500DX SERIES(APPLIED BIOSYSTEMS)-THE CONDITIONING REAGENT IS USED TO PRIME THE POLYMER PUMP, WASH THE POLYMER PUMP BETWEEN POLYMER TYPE CHANGES, AND PERFORM INSTRUMENT SHUTDOWN PROCEDURES. IT IS SUPPLIED AS A READY-TO-USE POUCH WITH A RADIO FREQUENCY IDENTIFICATION (RFID) TAG INCORPORATED INTO THE LABEL. THE INSTRUMENT USES THE RFID TAG TO TRACK THE CONDITIONING REAGENT USAGE AND EXPIRATION. THIS PRODUCT IS INDICATED FOR IN VITRO DIAGNOSTIC USE WITH THE 3500 DX/3500XL DX GENETIC ANALYZER,FAST 96-WELL CALIBRATION PLATE, W/CY5 IVD(APPLIED BIOSYSTEMS)-THE FAST 96-WELL SPECTRAL CALIBRATION PLATE WITH CY®5 DYE IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH FAST 96-WELL BLOCK. DYE CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE FAST 96-WELL SPECTRAL CALIBRATION PLATE WITH CY®5 DYE IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER

	OPERATION.,384-WELL CALIBRATION PLATE W/TAMRA, IVD(APPLIED BIOSYSTEMS)-THE 384-WELL DYE CALIBRATION PLATE (TAMRA™) IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH 384-WELL BLOCK. DYE CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE 384-WELL DYE CALIBRATION PLATE (TAMRA™) IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,SEPTA, 384 WELL CE-IVD, 3500(APPLIED BIOSYSTEMS)-THIS IS SEPTA 384-WELL IS DESIGNED FOR USE WITH THE 3500 DX3500XL DX GENETIC ANALYZER. SEPTA AND PLATE BASE RETAINER KITS FOR 8 TUBE STRIP, 96 AND 384-WELL PLATES USED WITH THE 3500 DX SERIES GENETIC ANALYZERS.,FG, CAPILLARY ARRAY 8-CAP 50 CM CE-IVD (APPLIED BIOSYSTEMS)-THE CAPILLARY ARRAY FOR THE 3500 DX/3500XL DX GENETIC ANALYZER IS AVAILABLE IN 8CAPILLARIES OR 24CAPILLARIES. THIS PRODUCT IS INDICATED FOR IN VITRO DIAGNOSTIC USE WITH THE 3500 DX/3500XL DX GENETIC ANALYZER,96-WELL 0.2ML CALIBRATION PLATE 3 (TAMRA, NED, AND CY®5 DYES)(APPLIED BIOSYSTEMS)-USE THE 96WELL 0.2ML SPECTRAL CALIBRATION PLATES FOR SPECTRAL NORMALIZATION OF THE QUANTSTUDIO™ 5 DX REALTIME PCR INSTRUMENT. PERFORM DYE CALIBRATION AS PART OF ROUTINE INSTRUMENT MAINTENANCE AS DESCRIBED IN THE QUANTSTUDIO™ 5 DX REALTIME PCR INSTRUMENT MAINTENANCE AND ADMINISTRATION USER GUIDE.,TB, ARRAY CALIBRATION ROX DYE,IVD(APPLIED BIOSYSTEMS)-ARRAY CARD SPECTRAL CALIBRATION WITH ROX™ DYE. FOR IN VITRO DIAGNOSTIC USE. THE TB, ARRAY CALIBRATION ROX DYE,IVD IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,96 WELL CALIBRATION PLATE W/FAM, IVD(APPLIED BIOSYSTEMS)-THE 96-WELL DYE CALIBRATION PLATE (FAM™) IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH STANDARD 96-WELL BLOCK. DYE CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE 96-WELL SPECTRAL CALIBRATION PLATE WITH FAM™ DYE IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,8 TUBE & RETAINER FAST STD CE-IVD(APPLIED BIOSYSTEMS)-THIS IS AN 8-TUBE FAST (0.1ML) RETAINER & BASE SET DESIGNED FOR USE WITH THE 3500 DX3500XL DX GENETIC ANALYZER. SEPTA AND PLATE BASE RETAINER KITS FOR 8 TUBE STRIP, 96 AND 384-WELL PLATES USED WITH THE 3500 DX SERIES GENETIC ANALYZERS. THE 8-TUBE FAST (0.1ML) RETAINER & BASE

	SET IS TO BE USED TOGETHER WITH 3500DX/ 3500XL DX GENETIC ANALYZERS INSTRUMENT.,SEPTA, 8 STRIP CE-IVD 3500(APPLIED BIOSYSTEMS)-THIS IS SEPTA 8-STRIP DESIGNED FOR USE WITH THE 3500 DX3500XL DX GENETIC ANALYZER. SEPTA AND PLATE BASE RETAINER KITS FOR 8 TUBE STRIP, 96 AND 384-WELL PLATES USED WITH THE 3500 DX SERIES GENETIC ANALYZERS. THE SEPTA 8-STRIP IS TO BE USED TOGETHER WITH 3500DX/ 3500XL DX GENETIC ANALYZERS INSTRUMENT.,96 WELL CALIBRATION PLATE W/TAMRA, IVD(APPLIED BIOSYSTEMS)-THE 96-WELL DYE CALIBRATION PLATE (TAMRA™) IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH STANDARD 96-WELL BLOCK. DYE CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE 96-WELL DYE CALIBRATION PLATE (TAMRA™) IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,TB, ARRAY VIC/ROX NORMALIZATION, IVD(APPLIED BIOSYSTEMS)-ARRAY CARD SPECTRAL CALIBRATION WITH VIC®/ROX™ DYE. FOR IN VITRO DIAGNOSTIC USE. THE ARRAY CARD BACKGROUND BUFFER KIT IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,384 WELL CALIBRATION PLATE W/VIC IVD(APPLIED BIOSYSTEMS)-THE 384-WELL DYE CALIBRATION PLATE (VIC®) IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH 384-WELL BLOCK. DYE CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE 384-WELL DYE CALIBRATION PLATE (VIC®) IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,96W BACKGND IVD (APPLIED BIOSYSTEMS)-THE 96-WELL BACKGROUND PLATE IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH 96-WELL STANDARD BLOCK. BACKGROUND CALIBRATION SHOULD BE RUN AT LEAST EVERY SIX MONTHS. 96-WELL BACKGROUND CALIBRATION PLATE IS TO BE USED TOGETHER WITH QUANTSTUDIO DX INSTRUMENT.,FAST 96-WELL ROI AND BACKGROUND PLATES, IVD (APPLIED BIOSYSTEMS)-THE FAST 96-WELL ROI & BACKGROUND CALIBRATION KIT IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH FAST 96-WELL BLOCK. REGION OF INTEREST (ROI) AND BACKGROUND CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE FAST 96W ROI AND BACKGND IVD IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,96 WELL ROI AND

	BACKGROUND PLATES, IVD(APPLIED BIOSYSTEMS)-THE 96-WELL ROI & BACKGROUND CALIBRATION KIT IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH STANDARD 96-WELL BLOCK. REGION OF INTEREST (ROI) AND BACKGROUND CALIBRATION SHOULD BE RUN AFTER LAMP CHANGE. THE 96-WELL REGION OF INTEREST (ROI) AND BACKGROUND PLATES IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,384 WELL RETAINER & BASE STD CE-IVD(APPLIED BIOSYSTEMS)-THIS IS A 384-WELL STANDARD RETAINER & BASE SET DESIGNED FOR USE WITH THE 3500 DX3500XL DX GENETIC ANALYZER. SEPTA AND PLATE BASE RETAINER KITS FOR 8 TUBE STRIP, 96 AND 384-WELL PLATES USED WITH THE 3500 DX SERIES GENETIC ANALYZERS. THE 384-WELL STANDARD RETAINER & BASE SET IS TO BE USED TOGETHER WITH 3500DX/ 3500XL DX GENETIC ANALYZERS INSTRUMENT.,8 TUBE & RETAINER STD CE-IVD(APPLIED BIOSYSTEMS)-THIS IS AN 8-TUBE STANDARD RETAINER & BASE SET DESIGNED FOR USE WITH THE 3500 DX3500XL DX GENETIC ANALYZER. SEPTA AND PLATE BASE RETAINER KITS FOR 8 TUBE STRIP, 96 AND 384-WELL PLATES USED WITH THE 3500 DX SERIES GENETIC ANALYZERS. THE 8-TUBE STANDARD RETAINER & BASE SET IS TO BE USED TOGETHER WITH 3500DX/ 3500XL DX GENETIC ANALYZERS INSTRUMENT.,SEPTA, 96 WELL CE-IVD 3500(APPLIED BIOSYSTEMS)-THIS IS A SEPTA 96-WELL DESIGNED FOR USE WITH THE 3500 DX3500XL DX GENETIC ANALYZER AS ACCESSORIES. THE SEPTA 96-WELL IS A SINGLE USE CONSUMABLE THAT RESIDES ON TOP OF THE SAMPLE PLATE BUT UNDERNEATH THE CLIP.,TAQMAN RNASE P FAST 96W VERIF PLATE, IVD(APPLIED BIOSYSTEMS)-THE FAST 96-WELL RNASEP VERIFICATION PLATE IS USED TO VERIFY YOUR REAL-TIME PCR INSTRUMENT WITH FAST 96-WELL BLOCK. CONFIRM THE PERFORMANCE OF YOUR INSTRUMENT BY RUNNING THE RNASEP ASSAY. THE FAST 96-WELL RNASEP VERIFICATION PLATE IS PRELOADED WITH THE NECESSARY REAGENTS TO DETECT AND QUANTITATE GENOMIC COPIES OF THE HUMAN RNASE P GENE, A SINGLE-COPY GENE ENCODING THE RNA MOIETY OF THE RNASE P ENZYME. EACH WELL CONTAINS PRELOADED REACTION MIX (1X TAQMAN® UNIVERSAL PCR MASTER MIX, RNASE P PRIMERS, AND FAM™ DYE-LABELED PROBE) AND TEMPLATE. FAST 96-WELL RNASEP VERIFICATION PLATE IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,384W BACKGND IVD (APPLIED BIOSYSTEMS)-THE 384-WELL BACKGROUND PLATE IS

		USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH 384-WELL BLOCK. BACKGROUND CALIBRATION SHOULD BE RUN AT LEAST EVERY SIX MONTHS. THE 384-WELL BACKGROUND PLATE IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,96 WELL NORMALIZATION PLATES, IVD(APPLIED BIOSYSTEMS)-THE 96-WELL NORMALIZATION KIT IS USED TO MAINTAIN YOUR REAL-TIME PCR INSTRUMENT WITH STANDARD 96-WELL BLOCK. NORMALIZATION PLATES ARE USED TO CALIBRATE DIFFERENT INSTRUMENTS. THE KIT CONTAINS ONE FAM™/ROX™ NORMALIZATION PLATE AND ONE VIC®/ROX™ NORMALIZATION PLATE. THE 96-WELL NORMALIZATION KIT IS TO BE USED TOGETHER WITH QUANTSTUDIO™ DX REALTIME PCR SYSTEM. THE QUANTSTUDIO™ DX INSTRUMENT REQUIRES REGULAR CALIBRATION AND MAINTENANCE FOR PROPER OPERATION.,FG, CAPILLARY ARRAY 8-CAP 36 CM CE-IVD(APPLIED BIOSYSTEMS)-THE CAPILLARY ARRAY FOR THE 3500 DX/3500XL DX GENETIC ANALYZER IS AVAILABLE IN 8CAPILLARIES OR 24CAPILLARIES. THIS PRODUCT IS INDICATED FOR IN VITRO DIAGNOSTIC USE WITH THE 3500 DX/3500XL DX GENETIC ANALYZER,SEPTA CATHODE BUFFER CNTR CE-IVD 3500(APPLIED BIOSYSTEMS)-THIS IS A SEPTA CATHODE BUFFER CONTAINER INTENDED FOR USE WITH THE 3500 DX3500XL DX GENETIC ANALYZER.
796	IMP/IVD/2020/000654	1.License Holder Name: HORIBA INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABX PENTRA LDL CAL (HORIBA MEDICAL)-CALIBRATOR FOR THE MEASUREMENT OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDLC) BY COLORIMETRY. , ABX PENTRA LDL DIRECT CP(HORIBA MEDICAL)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN SERUM OR PLASMA BY COLORIMETRY. ,ABX PENTRA HDL DIRECT CP(HORIBA MEDICAL)-"DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF HIGH-DENSITY LIPOPROTEIN CHOLESTEROL (HDL -C) IN HUMAN SERUM OR PLASMA BY COLORIMETRY.",ABX PENTRA HDL CAL(HORIBA MEDICAL)-CALIBRATOR FOR THE MEASUREMENT OF HIGH-DENSITY LIPOPROTEIN CHOLESTEROL (HDLC) BY COLORIMETRY. ,ABX PENTRA HDL DIRECT 100 CP(HORIBA MEDICAL)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HIGH-DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) IN HUMAN SERUM OR PLASMA BY COLORIMETRY.

797	IMP/IVD/2020/000657	1.License Holder Name: MILI HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (2019-NCOV) NUCLEIC ACID DIAGNOSTIC KIT (PCR-FLUORESCENCE PROBING)(NIL)-NOVEL CORONAVIRUS(2019-NCOV) NUCLEIC ACID DIAGNOSTIC KIT (PCR-FLUORESCENCE PROBING) IS USED FOR QUALITATIVE DETECTION OF THE ORF1AB AND N GENES OF NOVEL CORONAVIRUS (2019-NCOV) IN NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, ALVEOLAR LAVAGE FLUID, SPUTUM, SERUM, WHOLE BLOOD, FECES FROM SUSPECTED PNEUMONIA CASES WITH NOVEL CORONAVIRUS INFECTION, IN PATIENTS WITH SUSPECTED CLUSTERS OF NOVEL CORONAVIRUS INFECTION, AND OTHER PATIENTS REQUIRING DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS OF NOVEL CORONAVIRUS INFECTION.
798	IMP/IVD/2020/000658	1.License Holder Name: WOCKHARDT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 RT-PCR TEST KIT(COVIWOK)-COVID-19 REAL TIME PCR TEST KIT IS A RT-PCR TEST INTENDED FOR THE PRESUMPTIVE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE 2019-NCOV IN NASOPHARYNGEAL SAMPLES FROM INDIVIDUALS WITH SIGNS AND SYMPTOMS OF INFECTION WHO ARE SUSPECTED OF COVID-19

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799	IMP/IVD/2020/000663	1.License Holder Name: GENWORKS HEALTH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SFRI CLAIR 5.1(NA)-SFRI CLAIR 5.1 IS TO BE USED TO RINSE SFRI'S BLOOD CELL COUNTERS., DILUCLAIR H18(NA)-DILUCLAIR H18 IS TO BE USED TO RINSE SFRI'S BLOOD CELL COUNTERS.,BLOODTROL 22(NA)-BLOODTROL 22 IS A COMPATIBLE HEMATOLOGY CONTROL DESIGNED TO EVALUATE THE ACCURACY AND PRECISION OF BOTH HEMIX 5-60 AND COUNTENDER 80+ BLOOD CELL COUNTERS.,LYSOGLOBINE H18(NA)-LYSOGLOBINE H18 IS USED BY SFRI'S BLOOD CELL COUNTER AS A LYSIS REAGENT, SFRI DILUENT 5.1(NA)-SFRI DILUENT 5.1 IS USED BY SFRI'S 5 PART DIFF BLOOD CELL COUNTERS AS A DILUING REAGENT.,SFRI QUENCH 5.1(NA)-SFRI QUENCH 5.1 IS USED BY SFRI'S 5 PART DIFF BLOOD CELL COUNTER REAGENT.,DILUTERGE H18(NA)-DILUTERGE H18 IS TO BE USED TO RINSE SFRI'S BLOOD CELL COUNTERS,BLOODTROL 16(NA)-BLOODTROL 16 IS A COMPATIBLE HEMATOLOGY CONTROL DESIGNED TO EVALUATE THE ACCURACY AND PRECISION OF SFRI 3-PART DIFF BLOOD CELL COUNTERS.,SFRI LYSE 5.1(NA)-SFRI LYSE 5.1 IS USED BY SFRI'S 5 PART DIFF'S BLOOD CELL COUNTER AS A LYSIS REAGENT., HEMACLAIR H18(NA)-HÉMACLAIR H18 IS TO BE USED TO RINSE SFRI'S BLOOD CELL COUNTERS.,DILUTON H18(NA)-DILUTON H18 IS USED BY SFRI'S BLOOD CELL COUNTER AS A DILUTING REAGENT.,BLOODCAL (NA)-BLOODCAL IS AN ASSAYED HEMATOLOGY CALIBRATOR DESIGNED FOR THE CALIBRATION OF SFRI HEMATOLOGY BLOOD CELL COUNTERS H18 LIGHT, COUNTENDER 80+, COUNTENDER 20+, COUNTENDER 30, HEMIX 3-30 AND HEMIX 5-60.
800	IMP/IVD/2020/000664	1.License Holder Name: GENERICARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE MONITORING SYSTEM(SUGARTRACK)-SELF-TESTING OF GLUCOSE LEVELS IN THE BLOOD,BLOOD GLUCOSE STRIPS(SUGARTRACK)-SELF-TESTING OF GLUCOSE LEVELS IN BLOOD (PRELIMINARY)

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801	IMP/IVD/2020/000665	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOLINE HIV 1/2 3.0 (BIOLINE HIV 1/2 3.0)-THE BIOLINE HIV-1/2 3.0 KIT IS A RAPID, QUALITATIVE TEST FOR THE DETECTION OF ANTIBODIES TO ALL ISOTYPES (IGG, IGM, IGA) SPECIFIC TO HIV-1 INCLUDING SUBTYPE-O AND HIV-2 SIMULTANEOUSLY IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE BIOLINE HIV 1/2 3.0 KIT IS INTENDED ONLY FOR PROFESSIONAL USE AND FOR IN VITRO DIAGNOSTIC USE. THIS TEST MAY NOT BE SUITABLE FOR DIAGNOSIS OF EARLY INFECTION OR BLOOD DONATION SCREENING. POSITIVE SAMPLES SHOULD BE CONFIRMED BY A SUPPLEMENTAL ASSAY SUCH AS ELISA OR WESTERN BLOT TEST.,SD UROCOLOR 10(SD UROCOLOR)-SD UROCOLOR IS A SEMI-QUANTITATIVE DETERMINATION OF BLOOD, BILIRUBIN, UROBILINOGEN, KETONE, PROTEIN, NITRITE, GLUCOSE, PH, SPECIFIC GRAVITY, AND LEUCOCYTES IN HUMAN URINE,SD BIOLINE TB AG MPT64 RAPID(SD BIOLINE TB AG MPT64 RAPID)-THE SD BIOLINE TB AG MPT64 RAPID IS A CHROMATOGRAPHIC IMMUNOASSAY FOR THE DETECTION OF ANTIGEN MPT64 MYOBACTERIUM TUBERCULOSIS COMPLEX IN SAMPLES FROM LIQUID OR SOLID CULTURE MEDIA,PANBIO DENGUE EARLY ELISA (PANBIO DENGUE EARLY ELISA)-THE PANBIO DENGUE EARLY ELISA IS A DENGUE NS1 ANTIGEN CAPTURE ELISA. IT IS FOR THE QUALITATIVE DETECTION OF NS1 ANTIGEN IN SERUM, USED AS AN AID IN THE CLINICAL LABORATORY DIAGNOSIS OF PATIENTS WITH CLINICAL SYMPTOMS CONSISTENT WITH DENGUE FEVER. THE PANBIO DENGUE EARLY ELISA SHOULD BE USED IN CONJUNCTION WITH OTHER DENGUE SEROLOGY,PANBIO LEPTOSPIRA IGM ELISA (PANBIO LEPTOSPIRA IGM ELISA)-THE PANBIO LEPTOSPIRA IGM ELISA IS FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO LEPTOSPIRA IN SERUM AS AN AID IN THE CLINICAL LABORATORY DIAGNOSIS OF PATIENTS WITH CLINICAL SYMPTOMS CONSISTENT WITH LEPTOSPIROSIS,PANBIO DENGUE IGM CAPTURE ELISA(PANBIO DENGUE IGM CAPTURE ELISA)-THE PANBIO DENGUE IGM CAPTURE ELISA IS FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO DENGUE ANTIGEN IN SERUM AS AN AID IN THE CLINICAL LABORATORY DIAGNOSIS OF PATIENTS WITH CLINICAL SYMPTOMS CONSISTENT WITH DENGUE FEVER. THE PANBIO DENGUE IGM CAPTURE ELISA SHOULD BE USED IN CONJUNCTION WITH OTHER DENGUE SEROLOGY ,SD BIOLINE LEPTOSPIRA IGG/IGM(SD BIOLINE LEPTOSPIRA IGG/IGM)-THE SD BIOLINE LEPTOSPIRA IGG/IGM KIT IS A RAPID QUALITATIVE TEST FOR THE DETECTION OF ANTIBODIES OF IGG AND IGM SPECIFIC TO LEPTOSPIRA INTERROGANS IN HUMAN SERUM OR PLASMA ,PANBIO DENGUE IGG CAPTURE ELISA(PANBIO

		DENGUE IGG CAPTURE ELISA)-THE PANBIO DENGUE IGG CAPTURE ELISA IS FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO DENGUE VIRUS (SEROTYPES 1-4) IN SECONDARY DENGUE INFECTIONS. THIS TEST IS INTENDED AS AN AID IN THE CLINICAL LABORATORY DIAGNOSIS OF SECONDARY DENGUE VIRUS INFECTION, AND CAN BE USED IN CONJUNCTION WITH THE PANBIO DENGUE IGM CAPTURE ELISA FOR PRESUMPTIVE DIFFERENTIATION BETWEEN PRIMARY AND SECONDARY INFECTION. THIS TEST SHOULD ONLY BE USED WITH SAMPLES FROM PATIENTS WITH CLINICAL SYMPTOMS CONSISTENT WITH DENGUE FEVER. POSITIVE RESULTS MUST BE CONFIRMED BY VIRUS ISOLATION, PAIRED SERA ANALYSIS, ANTIGEN DETECTION BY IMMUNOHISTOCHEMISTRY OR VIRAL NUCLEIC ACID DETECTION FOR CONFIRMATION OF DENGUE VIRUS INFECTION
802	IMP/IVD/2020/000666	1.License Holder Name: HORIBA INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:"ABX PENTRA ENZYMATIC CREATININE CP"(HORIBA MEDICAL)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN SERUM, PLASMA AND URINE BY COLORIMETRY.

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803	IMP/IVD/2020/000671	1.License Holder Name: JAINAM BIOMEDICAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMMUNOGLOBULIN G KIT (IGG KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN BLOOD OR SERUM OR PLASMA AS AN AID IN DIAGNOSIS OF ABNORMAL IGG METABOLISM.,ANTI-STREPTOLYSIN O KIT(ASO KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF ANTI-STREPTOLYSIN O (ASO) IN HUMAN SERUM AS AN AID IN DETERMINATION OF LEVELS OF STREPTOCOCCAL INFECTION., HAEMOGLOBIN A1C KIT(HBA1C KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF HAEMOGLOBIN A1C (HBA1C) IN HUMAN BLOOD AS AN AID IN DIAGNOSIS OF ABNORMAL HBA1C METABOLISM.,ANTI-CYCLIC CITRULLINATED PEPTIDE KIT(ANTI-CCP KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF ANTI-CYCLIC CITRULLINATED PEPTIDE ANTIBODY (ANTI-CCP) IN HUMAN SERUM AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA).,BETA 2-MICROGLOBULIN KIT(BMG KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF 2-MICROGLOBULIN (BMG) IN HUMAN SERUM OR PLASMA OR URINE AS AN AID IN DIAGNOSIS OF ABNORMAL BMG METABOLISM, COMPLEMENT 3 KIT(C3 KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF COMPLEMENT 3 (C3) IN HUMAN SERUM OR PLASMA AS AN AID IN DIAGNOSIS OF ABNORMAL C3 METABOLISM.,ALPHA 1 MICROGLOBULIN(A1M KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF 1 MICROGLOBULIN (A1M) IN HUMAN URINE.,C-REACTIVE PROTEIN KIT(CRP KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM OR PLASMA AS AN AID IN DIAGNOSIS AND MONITORING OF INFLAMMATORY CONDITIONS, BACTERIAL INFECTION AS WELL AS CARDIAC DISEASES.,CYSTATIN C KIT(CYS C KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF HUMAN CYSTATIN C (CYS C) IN HUMAN SERUM OR PLASMA AS AN AID IN DIAGNOSIS AND TREATMENT OF RENAL DISEASES.,FULL RANGE C-REACTIVE PROTEIN KIT(FR-CRP KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF FULL RANGE C-REACTIVE PROTEIN (FR-CRP) IN HUMAN WHOLE BLOOD OR SERUM OR PLASMA AS AN AID IN

	DIAGNOSIS AND TREATMENT OF INFLAMMATORY CONDITIONS, BACTERIAL INFECTION AS WELL AS CARDIAC DISEASES, ULTRASENSITIVE C-REACTIVE PROTEIN KIT(USCRP KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF ULTRASENSITIVE C-REACTIVE PROTEIN (USCRP) IN HUMAN SERUM OR PLASMA AS AN AID IN DIAGNOSIS AND MONITORING OF INFLAMMATORY CONDITIONS, BACTERIAL INFECTION AS WELL AS CARDIAC DISEASES., IMMUNOGLOBULIN M KIT(IGM KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM OR PLASMA AS AN AID IN DIAGNOSIS OF ABNORMAL IGM METABOLISM., SERUM AMYLOID A KIT(SAA KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF SERUM AMYLOID A (SAA) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,COMPLEMENT 4 KIT(C4 KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF COMPLEMENT 4 (C4) IN HUMAN SERUM OR PLASMA AS AN AID IN DIAGNOSIS OF ABNORMAL C4 METABOLISM., URINE MICRO ALBUMIN KIT(MALB KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF MICRO ALBUMIN (MALB) IN HUMAN URINE AS AN AID IN DIAGNOSIS OF ABNORMAL MALB METABOLISM.,RHEUMATOID FACTOR KIT(RF KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN HUMAN SERUM AS AN AID IN DIAGNOSIS OF RHEUMATOID ARTHRITIS.,D-DIMER KIT(DD KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF D-DIMER (DD) IN HUMAN PLASMA.,IMMUNOGLOBULIN A KIT(IGA KIT)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN BLOOD (OR SERUM OR PLASMA) AS AN AID IN THE DIAGNOSIS OF ABNORMAL IGA METABOLISM.

804	IMP/IVD/2020/000672	1.License Holder Name: SIRUS BIOCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SCOV-2 IGG ELISA KIT (SCOV-2 DETECTTM IGG ELISA)-THE SCOV-2 DETECT™ IGG ELISA IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM. THE SCOV-2 DETECT™ IGG ELISA IS INTENDED AS AN AID IN IDENTIFYING INDIVIDUALS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS-COV-2, INDICATING RECENT OR PRIOR INFECTION.
805	IMP/IVD/2020/000674	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIAZYME PROCALCITONIN (PCT) CONTROL SET(DIAZYME PROCALCITONIN (PCT) CONTROL SET)-THE DIAZYME PROCALCITONIN (PCT) CONTROL SET IS INTENDED FOR USE AS QUALITY CONTROL FOR THE DIAZYME PCT ASSAY. FOR IN VITRO DIAGNOSTIC USE ONLY.,DIAZYME PROCALCITONIN (PCT)CALIBRATOR SET(DIAZYME PROCALCITONIN (PCT)CALIBRATOR SET)-THE DIAZYME PROCALCITONIN (PCT) CALIBRATOR SET IS INTENDED FOR USE IN THE CALIBRATION OF THE DIAZYME PCT ASSAY. FOR IN VITRO DIAGNOS-TIC USE ONLY., DIAZYME PROCALCITONIN (PCT) ASSAY(DIAZYME PROCALCITONIN (PCT) ASSAY)-DIAZYME PCT ASSAY IS A LATEX PARTICLE ENHANCED IMMUNOTURBIDIMETRIC METHOD INTENDED FOR THE QUANTITATIVE DETERMINATION OF PCT IN HUMAN SERUM, EDTA OR LITHIUM HEPARIN PLASMA.
806	IMP/IVD/2020/000675	1.License Holder Name: ARKRAY HEALTHCARE PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URINE TEST STRIPS (AUTION STICKS)-DETERMINATION OF GLUCOSE, PROTEIN, BILIRUBIN, UROBILINOGEN, CREATININE, PH, BLOOD, KETONES, NITRITE ANDLEUKOCYTES IN URINE.

807	IMP/IVD/2020/000676	1.License Holder Name: NANDAN EXPORTS AND IMPORTS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:1COPY™ COVID-19 QPCR TRIPLEX KIT(1COPY™)-1COPY™ COVID-19 QPCR TRIPLEX KIT IS A REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN NASOPHARYNGEAL, OROPHARYNGEAL, ANTERIOR NASAL, MID-TURBINATE NASAL SWAB SPECIMENS AS WELL AS NASOPHARYNGEAL WASH/ASPIRATE AND NASAL ASPIRATE SPECIMENS COLLECTED FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDERS.1COPY™ COVID-19 QPCR TRIPLEX KIT IS INTENDED FOR USE BY QUALIFIED CLINICAL LABORATORY PERSONNEL SPECIFICALLY INSTRUCTED AND TRAINED IN THE TECHNIQUES OF REAL-TIME PCR AND IN VITRO DIAGNOSTIC PROCEDURES.,1COPY™ COVID-19 QPCR KIT(1COPY™)-1 COPY™ COVID-19 QPCR KIT IS AN IN-VITRO DIAGNOSTIC MEDICAL DEVICE FOR QUALITATIVE ANALYSIS OF E GENE AND RDRP GENE FOR CORONAVIRUS (COVID-19) IN EXTRACTED RNA FROM SPUTUM, NASOPHARYNGEAL SWAB AND OROPHARYNGEAL SWAB OF PATIENTS WITH SUSPECTED RESPIRATORY INFECTIONS.
808	IMP/IVD/2020/000677	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCESS SARS-COV-2 IGG QC(ACCESS SARS-COV-2 IGG QC)-THE ACCESS SARS-COV-2 IGG QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS SARS-COV-2 IGG ASSAY. THE ACCESS SARS-COV-2 IGG QC IS FOR USE ON THE ACCESS FAMILY OF IMMUNOASSAY SYSTEMS ONLY. ,ACCESS SARS-COV-2 IGG CALIBRATOR(ACCESS SARS-COV-2 IGG CALIBRATOR)-THE ACCESS SARS-COV-2 IGG CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS SARS-COV-2 IGG ASSAY FOR THE IN VITRO QUALITATIVE DETECTION OF SARS-COV-2 IGG ANTIBODIES IN HUMAN SERUM, SERUM SEPARATOR TUBES AND PLASMA (LITHIUM HEPARIN, DIPOTASSIUM EDTA, TRIPOTASSIUM EDTA, AND SODIUM CITRATE) FOR USE ON THE ACCESS FAMILY OF IMMUNOASSAY SYSTEMS ONLY.

809	IMP/IVD/2020/000682	1.License Holder Name: BIO-RAD LABORATORIES (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 DDPCR KIT (SARS-COV-2 DDPCR KIT)-QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN NASOPHARYNGEAL, ANTERIOR NASAL AND MID-TURBINATE NASAL SWAB SPECIMENS AS WELL AS NASOPHARYNGEAL WASH/ASPIRATE AND NASAL ASPIRATE SPECIMENS COLLECTED FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. EMERGENCY USE OF THIS TEST IS LIMITED TO AUTHORIZED LABORATORIES.

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810	IMP/IVD/2020/000687	1.License Holder Name: M/S. CPC DIAGNOSTICS PVT, LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: B·R·A·H·M·S CGA II KRYPTOR(B·R·A·H·M·S CGA II KRYPTOR)-THE B·R·A·H·M·S CGA II KRYPTOR TEST IS AN AUTOMATED IMMUNOFLUORESCENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF CHROMOGRANIN A (CGA) IN HUMAN SERUM OR PLASMA (EDTA). , BRAHMS PCT SENSITIVE KRYPTOR QC(B.R.A.H.M.S PCT SENSITIVE KRYPTOR QC)-TO RE-ADJUST THE STANDARD CURVE STORED BY B. R.A.H.M.S KRYPTOR COMPACT/ KRYPTOR COMPACT PLUS/ KRYPTOR GOLD,BRAHMS PCT SENSITIVE KRYPTOR CAL(B.R.A.H.M.S PCT SENSITIVE KRYPTOR CAL)-TO RE-ADJUST THE STANDARD CURVE STORED BY B.R.A.H.M.S KRYPTOR COMPACT/ KRYPTOR COMPACT PLUS/ KRYPTOR GOLD,B·R·A·H·M·S PLGF PLUS KRYPTOR CAL (B·R·A·H·M·S PLGF PLUS KRYPTOR CAL)-TO READJUST THE STANDARD CURVE MEMORIZED IN B·R·A·H·M·S KRYPTOR COMPACT PLUS.,B.R.A.H.M.S KRYPTOR COMPACT SOLUTION 2(B.R.A.H.M.S KRYPTOR COMPACT SOLUTION 2)-B.R.A.H.M.S KRYPTOR COMPACT SOLUTION 2 IS DESIGNED TO RECONSTITUTE THE LYOPHILIZED CONJUGATES FROM B.R.A.H.M.S KRYPTOR COMPACT/KRYPTOR COMPACT PLUS KITS,B.R.A.H.M.S PCT-Q(B.R.A.H.M.S PCT-Q)-THE B·R·A·H·M·S PCT-Q IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE SEMI-QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF PROCALCITONIN (PCT) IN HUMAN SERUM AND PLASMA., B·R·A·H·M·S PAPP-A KRYPTOR CAL(B·R·A·H·M·S PAPP-A KRYPTOR CAL)-TO READJUST THE STANDARD CURVE STORED BY B·R·A·H·M·S KRYPTOR COMPACT / KRYPTOR COMPACT PLUS / KRYPTOR GOLD , B·R·A·H·M·S UE3 KRYPTOR CAL(B·R·A·H·M·S UE3 KRYPTOR CAL)-TO READJUST THE STANDARD CURVE MEMORIZED IN B·R·A·H·M·S KRYPTOR COMPACT PLUS.,B·R·A·H·M·S CGA II KRYPTOR CAL (B·R·A·H·M·S CGA II KRYPTOR CAL)-TO READJUST THE STANDARD CURVE MEMORIZED IN B·R·A·H·M·S KRYPTOR COMPACT / KRYPTOR COMPACT PLUS / KRYPTOR GOLD,B.R.A.H.M.S KRYPTOR COMPACT SOLUTION 1(B.R.A.H.M.S KRYPTOR COMPACT SOLUTION 1)-B.R.A.H.M. S KRYPTOR COMPACT SOLUTION 1 IS DESIGNED TO RECONSTITUTE THE LYOPHILIZED CONJUGATES FROM B.R.A.H.M.S KRYPTOR COMPACT/KRYPTOR COMPACT PLUS KITS AND TO RINSE THE TIP, B·R·A·H·M·S AFP KRYPTOR DILUENT(B·R·A·H·M·S AFP KRYPTOR DILUENT)-DILUENT FOR AMNIOTIC FLUID SAMPLES,B·R·A·H·M·S COPEPTIN PROAVP KRYPTOR CAL(B·R·A·H·M·S COPEPTIN PROAVP KRYPTOR CAL)-TO RE-ADJUST STANDARD CURVE MEMORIZED IN B·R·A·H·M·S KRYPTOR COMPACT PLUS,BRAHMS PCT SENSITIVE KRYPTOR(B.R.A.H.M.S PCT SENSITIVE KRYPTOR)-THE B·R·A·H·M·S PCT SENSITIVE KRYPTOR TEST IS AN AUTOMATED IMMUNO

	FLUORESCENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF PROCALCITONIN (PCT) IN HUMAN SERUM OR HUMAN PLASMA (EDTA, HEPARIN) SAMPLES.,B·R·A·H·M·S SFLT-1 KRYPTOR(B·R·A·H·M·S SFLT-1 KRYPTOR)-B·R·A·H·M·S SFLT-1 KRYPTOR IS AN AUTOMATED IMMUNOFLUORESCENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF SFLT-1 (SOLUBLE FMS-LIKE TYROSINE KINASE 1, ALSO KNOWN AS VEGF RECEPTOR-1) IN HUMAN SERUM AND EDTA PLASMA,B·R·A·H·M·S COPEPTIN PROAVP KRYPTOR(B·R·A·H·M·S COPEPTIN PROAVP KRYPTOR)-B·R·A·H·M·S COPEPTIN PROAVP KRYPTOR IS AN AUTOMATED IMMUNOFLUORESCENT ASSAY TO DETERMINE THE CONCENTRATION OF COPEPTIN (C-TERMINAL PROVASOPRESSIN CT-PROAVP) IN HUMAN SERUM AND HUMAN PLASMA (EDTA, HEPARIN)., B·R·A·H·M·S HCG+ KRYPTOR QC HIGH(B·R·A·H·M·S HCG+ KRYPTOR QC HIGH)-QUALITY CONTROL ON BOARD OF B·R·A·H·M·S KRYPTOR COMPACT/ KRYPTOR COMPACT PLUS/KRYPTOR GOLD.,B.R.A.H.M.S KRYPTOR COMPACT SOLUTION 3(B.R.A.H.M.S KRYPTOR COMPACT SOLUTION 3)-B.R.A.H.M.S KRYPTOR COMPACT SOLUTION 3 IS DESIGNED FOR WASHING OF THE B.R.A.H.M.S KRYPTOR COMPACT/KRYPTOR COMPACT PLUS FLUIDIC SYSTEM,B·R·A·H·M·S AFP KRYPTOR CAL(B·R·A·H·M·S AFP KRYPTOR CAL)-TO READJUST THE STANDARD CURVE STORED BY B·R·A·H·M·S KRYPTOR COMPACT / KRYPTOR COMPACT PLUS / KRYPTOR GOLD.,B.R.A.H.M.S KRYPTOR COMPACT SOLUTION 4(B.R.A.H.M.S KRYPTOR COMPACT SOLUTION 4) -B.R.A.H.M.S KRYPTOR COMPACT SOLUTION 4 IS DESIGNED FOR WASHING OF THE B.R.A.H.M.S KRYPTOR COMPACT/KRYPTOR COMPACT PLUS FLUIDIC SYSTEM,B·R·A·H·M·S AFP KRYPTOR (B·R·A·H·M·S AFP KRYPTOR)-"B·R·A·H·M·S AFP KRYPTOR IS A KIT DESIGNED FOR B·R·A·H·M·S KRYPTOR AUTOMATED IMMUNOFLUORESCENT ASSAYS OF ALPHA-FETOPROTEIN (AFP) IN SERUM, HEPARIN PLASMA OR AMNIOTIC FLUID. THE TEST IS INTENDED TO BE USED FOR THE DETERMINATION OF AFP AS AN IN-VITRO TUMOR MARKER AND FOR THE RISK ASSESSMENT OF FETAL CHROMOSOMAL ABNORMALITIES AND NEURAL TUBE DEFECTS. ", B·R·A·H·M·S TM1 KRYPTOR QC(B·R·A·H·M·S TM1 KRYPTOR QC)-MULTIPARAMETRIC QUALITY CONTROL FOR TUMOR MARKERS ON B·R·A·H·M·S KRYPTOR COMPACT/ KRYPTOR COMPACT PLUS/KRYPTOR GOLD.,B·R·A·H·M·S CGA II KRYPTOR QC(B·R·A·H·M·S CGA II KRYPTOR QC)-QUALITY CONTROL ON BOARD OF BRAHMS KRYPTOR COMPACT/KRYPTOR COMPACT PLUS/KRYPTOR GOLD, B·R·A·H·M·S PLGF PLUS KRYPTOR QC(B·R·A·H·M·S PLGF PLUS KRYPTOR QC)-QUALITY CONTROL ON BOARD OF B·R·A·H·M·S KRYPTOR COMPACT PLUS FOR THE ASSAY,B·R·A·H·M·S UE3 KRYPTOR (B·R·A·H·M·S UE3 KRYPTOR)-B·R·A·H·M·S UE3 KRYPTOR IS AN

	AUTOMATED IMMUNOFLUORESCENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF UE3 (UNCONJUGATED ESTRIOL) IN HUMAN SERUM.,B·R·A·H·M·S GM KRYPTOR QC(B·R·A·H·M·S GM KRYPTOR QC)-MULTIPARAMETRIC QUALITY CONTROL FOR PRENATAL SCREENING ON B·R·A·H·M·S KRYPTOR COMPACT/ KRYPTOR COMPACT PLUS/KRYPTOR GOLD,B·R·A·H·M·S SFLT-1 KRYPTOR CAL(B·R·A·H·M·S SFLT-1 KRYPTOR CAL)-TO READJUST THE STANDARD CURVE MEMORIZED IN B·R·A·H·M·S KRYPTOR COMPACT PLUS.,B·R·A·H·M·S FREE BETA-HCG KRYPTOR(B·R·A·H·M·S FREE BETA-HCG KRYPTOR)-THE B·R·A·H·M·S FREE HCG KRYPTOR TEST IS AN AUTOMATED IMMUNOFLUORESCENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF FREE BETA SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN HORMONE (HCG) IN HUMAN SERUM. THE TEST IS INTENDED TO BE USED FOR THE DETERMINATION OF FREE HCG AS IN VITRO TUMOR MARKER AND FOR NON-INVASIVE RISK ASSESSMENT OF FETAL CHROMOSOMAL ABNORMALITIES.,B·R·A·H·M·S HCG+ KRYPTOR CAL(B·R·A·H·M·S HCG+ KRYPTOR CAL)-TO READJUST THE STANDARD CURVE STORED BY B·R·A·H·M·S KRYPTOR COMPACT / KRYPTOR COMPACT PLUS / KRYPTOR GOLD.,B·R·A·H·M·S SFLT-1 KRYPTOR QC(B·R·A·H·M·S SFLT-1 KRYPTOR QC)-QUALITY CONTROL ON BOARD OF B·R·A·H·M·S KRYPTOR COMPACT PLUS FOR THE ASSAY,B·R·A·H·M·S FREE BETA-HCG KRYPTOR CAL(B·R·A·H·M·S FREE BETA-HCG KRYPTOR CAL)-TO READJUST THE STANDARD CURVE STORED BY B·R·A·H·M·S KRYPTOR COMPACT / KRYPTOR COMPACT PLUS / KRYPTOR GOLD.,B.R.A.H.M.S KRYPTOR BUFFER(B.R.A.H.M.S KRYPTOR BUFFER)-B.R.A.H.M.S KRYPTOR BUFFER IS DESIGNED TO PREPARE THE B.R.A.H.M.S KRYPTOR COMPACT/ KRYPTOR COMPACT PLUS SYSTEM LIQUID, B·R·A·H·M·S COPEPTIN PROAVP KRYPTOR QC(B·R·A·H·M·S COPEPTIN PROAVP KRYPTOR QC)-QUALITY CONTROL ON BOARD OF B·R·A·H·M·S KRYPTOR COMPACT PLUS FOR THE ASSAY,B·R·A·H·M·S PAPP-A KRYPTOR(B·R·A·H·M·S PAPP-A KRYPTOR)-B·R·A·H·M·S PAPP - A KRYPTOR IS AN AUTOMATED IMMUNOFLUORESCENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF PAPP - A (PREGNANCY ASSOCIATED PLASMA PROTEIN-A) IN HUMAN SERUM. ,B·R·A·H·M·S HCG+ KRYPTOR CAROV(B·R·A·H·M·S HCG+ KRYPTOR CAROV)-CHECKING THE SAMPLING TIP (CARRY-OVER) OF THE B·R·A·H·M·S KRYPTOR / KRYPTOR COMPACT / KRYPTOR COMPACT PLUS/ KRYPTOR GOLD AFTER MEASUREMENT OF HCG+. THE KIT IS USED WITH THE APPROPRIATE B·R·A·H·M·S KRYPTOR / KRYPTOR COMPACT / KRYPTOR COMPACT PLUS/KRYPTOR GOLD REAGENTS, B·R·A·H·M·S HCG+ KRYPTOR QC(B·R·A·H·M·S HCG+ KRYPTOR QC)-QUALITY CONTROL ON BOARD OF B·R·A·H·M·S KRYPTOR COMPACT/ KRYPTOR COMPACT PLUS/KRYPTOR GOLD.,B·R·A·H·M·S HCG+

		KRYPTOR(B·R·A·H·M·S HCG+ KRYPTOR)-B·R·A·H·M·S HCG+ KRYPTOR IS A KIT DESIGNED FOR B·R·A·H·M·S KRYPTOR AUTOMATED IMMUNOFLUORESCENT ASSAYS OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN SERUM. THE TEST IS INTENDED TO BE USED FOR THE DETERMINATION OF HCG AS AN IN VITRO TUMOR MARKER AND FOR NONINVASIVE RISK ASSESSMENT OF FETAL CHROMOSOMAL ABNORMALITIES.,B·R·A·H·M·S UE3 KRYPTOR QC (B·R·A·H·M·S UE3 KRYPTOR QC)-QUALITY CONTROL ON BOARD OF B·R·A·H·M·S KRYPTOR COMPACT PLUS FOR THE ASSAY,B·R·A·H·M·S PLGF PLUS KRYPTOR(B·R·A·H·M·S PLGF PLUS KRYPTOR)-B·R·A·H·M·S PLGF PLUS KRYPTOR IS AN AUTOMATED IMMUNOFLUORESCENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF HUMAN PLGF (PLACENTAL GROWTH FACTOR) IN HUMAN SERUM AND EDTA PLASMA.
811	IMP/IVD/2020/000693	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCESS ACTIVE-B12 QC (ACCESS ACTIVE-B12 QC)-THE ACCESS ACTIVE-B12 QC IS INTENDED FOR MONITORING SYSTEM PERFORMANCE OF THE ACCESS ACTIVE-B12 ASSAY USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS ACTIVE-B12 CALIBRATOR(ACCESS ACTIVE-B12 CALIBRATOR)-THE ACCESS ACTIVE-B12 CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS ACTIVE-B12 ASSAY FOR THE QUANTITATIVE DETERMINATION OF HOLOTC LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS.,ACCESS ACTIVE- B-12(ACCESS ACTIVE- B-12)-THE ACCESS ACTIVE-B12 ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HOLOTC LEVELS IN HUMAN SERUM USING THE ACCESS IMMUNOASSAY SYSTEMS.

812	IMP/IVD/2020/000694	1.License Holder Name: BI-BIOTECH INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOCORE 2019-NCOV REAL TIME PCR KIT(BIOCORE 2019-NCOV REAL TIME PCR KIT)-BIOCORE 2019-NCOV REAL TIME PCR KIT IS A REVERSE-TRANSCRIPTION REAL TIME PCR TEST INTENDED FOR QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE 2019-NCOV IN UPPER RESPIRATORY SPECIMENS (SUCH AS NASAL, MID-TURBINATE, OROPHARYNGEAL, AND NASOPHARYNGEAL SWABS) AND LOWER RESPIRATORY SPECIMENS (SUCH AS SPUTUM, BRONCHIOALVEOLAR LAVAGE (BAL), AND TRACHEAL ASPIRATES) FROM PATIENTS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. TESTING IS LIMITED TO LABORATORIES CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C. §263A, TO PERFORM HIGH COMPLEXITY TESTS. RESULTS ARE FOR THE IDENTIFICATION OF 2019-NCOV RNA. THE 2019-NCOV RNA IS GENERALLY DETECTABLE IN RESPIRATORY SPECIMENS DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS ARE INDICATIVE OF THE PRESENCE OF SARS-COV-2 RNA. CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. LABORATORIES WITHIN THE UNITED STATES AND ITS TERRITORIES ARE REQUIRED TO REPORT ALL POSITIVE RESULTS TO THE APPROPRIATE PUBLIC HEALTH AUTHORITIES. NEGATIVE RESULTS DO NOT PRECLUDE 2019-NCOV INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR PATIENT MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. THE BIOCORE 2019-NCOV REAL TIME PCR KIT IS INTENDED FOR USE BY TRAINED CLINICAL LABORATORY PERSONNEL SPECIFICALLY INSTRUCTED AND TRAINED IN THE TECHNIQUES OF REAL-TIME PCR AND IN VITRO DIAGNOSTIC PROCEDURES. THE BIOCORE 2019-NCOV REAL TIME PCR KIT IS ONLY FOR USE UNDER THE FOOD AND DRUG ADMINISTRATION'S EMERGENCY USE AUTHORIZATION

813	IMP/IVD/2020/000696	1.License Holder Name: SYSMEX INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTERNAL STANDARD (INTERNAL STANDARD)-INTERNAL STANDARD SOLUTION FOR USE ON AUTOMATIC CLINICAL CHEMISTRY ANALYZERS FOR THE QUANTITATIVE DETERMINATION OF ELECTROLYTES CONCENTRATION (SODIUM, POTASSIUM, AND CHLORIDE) IN HUMAN SERUM, PLASMA, OR URINE SAMPLES.,ISE BUFFER (IS)(ISE BUFFER (IS))-BUFFER SOLUTION FOR SAMPLE DILUTION ON AUTOMATIC CLINICAL CHEMISTRY ANALYZERS FOR THE QUANTITATIVE DETERMINATION OF ELECTROLYTES CONCENTRATION (SODIUM, POTASSIUM AND CHLORIDE) IN HUMAN SERUM, PLASMA, OR URINE SAMPLES.,ISE SERUM STANDARD SET (NA)(ISE SERUM STANDARD SET (NA))-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CERTAIN ELECTROLYTES IN HUMAN SERUM AND PLASMA ON AUTOMATIC CLINICAL CHEMISTRY ANALYZERS.,ISE DETERGENT SOLUTION(ISE DETERGENT SOLUTION)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CERTAIN ELECTROLYTES IN HUMAN SERUM, PLASMA AND URINE ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS,ISE URINE STANDARD SET(ISE URINE STANDARD SET)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF CERTAIN ELECTROLYTES IN HUMAN URINE ON AUTOMATIC CLINICAL CHEMISTRY ANALYZERS

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814	IMP/IVD/2020/000699	1.License Holder Name: GASTROLAB INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOHIT CELIAC QUICK TEST (BIOHIT CELIAC QUICK TEST 602070)-THE BIOHIT CELIAC QUICK TEST IS AN IMMUNOCHROMATOGRAPHIC TEST DESIGNED FOR THE QUALITATIVE DETECTION OF ANTIBODIES (IGA/IGG/IGM) AGAINST HUMAN TISSUE TRANSGLUTAMINASE IN WHOLE HUMAN BLOOD.,GASTROPANEL® STABILIZER(GASTROPANEL® STABILIZER)-GASTROPANEL® STABILIZER IS AN ADDITIVE FOR THE STABILIZATION OF EDTA PLASMA SAMPLES TO BE ANALYZED WITH THE GASTROPANEL® KITS. ,LACTOSE INTOLERANCE QUICK TEST (BIOHIT LIQT 602010)-THE BIOHIT LACTOSE INTOLERANCE QUICK TEST IS BASED ON BIOCHEMICAL REACTIONS THAT QUALITATIVELY DETERMINE HYPOLAC-TASIA FROM BIOPSY SPECIMENS., GASTROPANEL® HELICOBACTER PYLORI(GASTROPANEL® HELICOBACTER PYLORI)-GASTROPANEL® HELICOBACTER PYLORI TEST IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUANTITATIVE DETECTION OF HUMAN IGG CLASS ANTIBODIES TO HELICOBACTER PYLORI IN EDTA PLASMA. THE TEST IS INTENDED FOR DIAGNOSIS OF HELICOBACTER PYLORI INFECTION IN ADULT PATIENTS WITH UPPER ABDOMINAL SYMPTOMS (DYSPEPSIA). THE KIT IS USED AS PART OF GASTROPANEL®. FOR IN VITRO DIAGNOSTIC USE. ,HELICOBACTER PYLORI QUICK TEST(BIOHIT HPQT 602015)-THE HELICOBACTER PYLORI QUICK TEST KIT IS BASED ON A BIOCHEMICAL REACTION TO QUALITATIVELY DETERMINE H. PYLORI UREASE ACTIVITY DIRECTLY FROM BIOPSY SPECIMENS IN NEAR PATIENT TESTING (NPT) SETTINGS.,GASTROPANEL® GASTRIN-17 (GASTROPANEL® GASTRIN-17)-GASTROPANEL® GASTRIN-17 IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUANTITATIVE MEASUREMENT OF GASTRIN-17 (G-17) IN HUMAN EDTA PLASMA SAMPLES. THE KIT IS USED AS A PART OF GASTROPANEL®. FOR IN VITRO DIAGNOSTIC USE.,BIOHIT COLONVIEW QUICK TEST-COLONVIEW HB AND HB/HP FECAL OCCULT BLOOD TEST IS A VISUAL, IMMUNOCHROMATOGRAPHIC QUICK TEST (FIT) FOR THE QUALITATIVE DETECTION OF HUMAN HEMOGLOBIN (HB) AND HEMOGLOBIN/HAPTOGLOBIN COMPLEX (HB/HP) IN STOOL SAMPLES.,GASTROPANEL® PEPSINOGEN II(GASTROPANEL® PEPSINOGEN II)-GASTROPANEL® PEPSINOGEN II (PGII) KIT IS A MICROPLATE-BASED QUANTITATIVE ENZYME IMMUNOASSAY (ELISA) FOR THE DETERMINATION OF HUMAN PEPSINOGEN II FROM PLASMA SAMPLES. THE KIT IS USED AS A PART OF GASTROPANEL®. FOR IN VITRO DIAGNOSTIC USE. ,GASTROPANEL® PEPSINOGEN I (GASTROPANEL® PEPSINOGEN I)-THE GASTROPANEL® PEPSINOGEN I (PGI) KIT IS A MICROPLATE-BASED QUANTITATIVE

	ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE DETERMINATION OF HUMAN PEPSINOGEN I FROM EDTA PLASMA SAMPLES. THE KIT IS USED AS PART OF GASTROPANEL®. FOR IN VITRO DIAGNOSTIC USE.

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815	IMP/IVD/2020/000700	1.License Holder Name: HORIBA INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABX PENTRA CK 2 CONTROL(HORIBA MEDICAL)-"ABX PENTRA CK 2 CONTROL IS A QUALITY CONTROL USED TO MONITOR THE PERFORMANCE OF ABX PENTRA CK NAC CP, REF.A11A01632 AND ABX PENTRA CK-MB RTU, REF.A11A01643 DETERMINATIONS BY OPTIMISED UV TEST. " ,ABX PENTRA FRUCTO CONTROL P(HORIBA MEDICAL)-"THE ABX PENTRA FRUCTO CONTROL P IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF HORIBA MEDICAL METHODS (BY COLORIMETRY) ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS WITH THE FOLLOWING REAGENTS: ABX PENTRA FRUCTOSAMINE (A11A01679) ABX PENTRA FRUCTOSAMINE CP (1300063534) " ,ABX PENTRA N CONTROL (HORIBA MEDICAL)-"THE ABX PENTRA N CONTROL IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF HORIBA MEDICAL METHODS, LISTED IN THE ANNEX, ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS. " ,ABX PENTRA FRUCTO CONTROL N(HORIBA MEDICAL)-"THE ABX PENTRA FRUCTO CONTROL N IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF HORIBA MEDICAL METHODS (BY COLORIMETRY) ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS WITH THE FOLLOWING REAGENTS: ABX PENTRA FRUCTOSAMINE (A11A01679) ABX PENTRA FRUCTOSAMINE CP (1300063534) " ,ABX PENTRA FRUCTO CAL(HORIBA MEDICAL)-"ABX PENTRA FRUCTO CAL IS USED FOR THE CALIBRATION OF METHODS ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS WITH THE FOLLOWING REAGENT(S): ABX PENTRA FRUCTOSAMINE (A11A01679) ABX PENTRA FRUCTOSAMINE CP (1300063534) " ,ABX PENTRA MULTICAL(HORIBA MEDICAL)-ABX PENTRA MULTICAL IS USED FOR THE CALIBRATION OF QUANTITATIVE HORIBA MEDICAL METHODS, LISTED IN THE ANNEX, ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYSERS. , ABX PENTRA P CONTROL(HORIBA MEDICAL)-"THE ABX PENTRA P CONTROL IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF HORIBA MEDICAL METHODS, LISTED IN THE ANNEX, ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS. " ,ABX PENTRA FRUCTOSAMINE CP(HORIBA MEDICAL)-"ABX PENTRA FRUCTOSAMINE CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF GLYCATED PROTEIN (FRUCTOSAMINE) IN SERUM AND PLASMA BY COLORIMETRY. " ,ABX PENTRA P MULTICONTROL(HORIBA MEDICAL)-THE ABX PENTRA P MULTICONTROL IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF HORIBA MEDICAL METHODS, LISTED IN THE ANNEX, ON HORIBA MEDICAL

	CLINICAL CHEMISTRY ANALYZERS. ,ABX PENTRA N MULTICONTROL (HORIBA MEDICAL)-THE ABX PENTRA N MULTICONTROL IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF HORIBA MEDICAL METHODS, LISTED IN THE ANNEX, ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

816	IMP/IVD/2020/000703	1.License Holder Name: BIOGENESIS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:D-DIMER CONTROL-MATERIAL FOR THE QUALITY CONTROL OF D-DIMER IN HUMAN PLASMA.,MICROALBUMIN-SET OF IMMUNOTURBIDIMETRIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN URINE,D-DIMER-FOR THE DETERMINATION OF D-DIMER IN HUMAN PLASMA.,AST/SGOT-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE IN HUMAN SERUM OR PLASMA FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,D-DIMER CALIBRATOR-MATERIAL FOR THE PREPARATION OF CALIBRATION CURVES FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA., ALBUMIN-REAGENT FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM OR PLASMA FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,CRP CALIBRATOR-CALIBRATION MATERIAL FOR THE PREPARATION OF CALIBRATION CURVES FOR THE QUANTITATIVE DETERMINATION OF CRP IN HUMAN SERUM.,LDH P-L-SET OF REAGENTS FOR THE ENZYMATIC DETERMINATION OF LDH IN HUMAN SERUM AND PLASMA,CK-MB CALIBRATOR-CALIBRATOR MATERIAL FOR THE PREPARATION OF REFERENCE CURVES FOR THE DETERMINATION OF CK-MB ASSAYS., URIC ACID-REAGENT FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA OR URINE FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,CRP-FOR THE QUANTITATIVE DETERMINATION OF CRP IN HUMAN SERUM OR PLASMA.,ACE CONTROL-MATERIAL FOR THE QUALITY CONTROL OF THE DETERMINATION OF ANGIOTENSINE CONVERTING ENZYME,CK-MB-DETERMINATION OF THE ACTIVITY OF CREATINE KINASE-MB (CK-MB) IN HUMAN SERUM OR PLASMA.,MALB/UPROT CONTROL-CONTROL MATERIAL FOR INTERNAL QUALITY CONTROL OF MICROALBUMIN AND URINE ALBUMIN ASSAY,CK-MB CONTROL-MATERIAL FOR THE QUALITY CONTROL OF THE DETERMINATION OF CK-MB IN HUMAN SERUM OR PLASMA.,TRIGLYCERIDES-REAGENTS FOR THE ENZYMATIC QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM OR PLASMA FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,CYSTATIN C CALIBRATOR-MATERIAL FOR THE PREPARATION OF CALIBRATION CURVES FOR THE QUANTITATIVE DETERMINATION OF CYSTATIN C, CALCIUM-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CA IN HUMAN SERUM, PLASMA AND URINE,AMMONIA CALIBRATOR-CALIBRATOR MATERIAL FOR THE PREPARATION OF REFERENCE CURVES FOR THE QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN PLASMA,CHOLESTEROL-REAGENTS FOR THE QUANTITATIVE

	DETERMINATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,DIRECT BILIRUBIN-SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM AND PLASMA,IGE CONTROL-MATERIAL FOR THE INTERNAL QUALITY CONTROL OF TOTAL IMMUNOGLOBULIN E IN HUMAN SERUM.,PHOSPHORUS-REAGENT FOR THE QUANTITATIVE DETERMINATION OF PHOSPHOROUS IN HUMAN SERUM, PLASMA AND URINE,IMMUNOLOGY CONTROL 1-MATERIAL FOR THE INTERNAL QUALITY CONTROL OF THE PERFORMANCE OF MEDICON SPECIAL PROTEINS REAGENTS,UREA-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM, PLASMA OR URINE FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS, AMMONIA-SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN PLASMA,ACE-SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF ACE IN HUMAN SERUM,LP(A) CALIBRATOR-CALIBRATION MATERIAL FOR THE PREPARATION OF CALIBRATION CURVES FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN (A) BY IMMUNOTURBIDIMETRY IN HUMAN SERUM,ACE CALIBRATOR-CALIBRATOR MATERIAL FOR THE PREPARATION OF REFERENCE CURVES FOR THE DETERMINATION OF ANGIOTENSIN CONVERTING ENZYME (ACE) IN HUMAN SERUM OR PLASMA,AMMONIA CONTROL-MATERIAL FOR THE QUALITY CONTROL OF THE DETERMINATION OF AMMONIA,IRON-REAGENT FOR THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM OR PLASMA,G-6-PDH-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE ACTIVITY IN HUMAN BLOOD FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS.,IRON-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM OR PLASMA FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,ALT/SGPT-SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF ALT IN HUMAN SERUM OR PLASMA.,TOTAL BILIRUBIN-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM OR PLASMA FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,ALPHA-AMYLASE-REAGENT FOR THE DETERMINATION OF ALPHA-AMYLASE ACTIVITY IN HUMAN SERUM, PLASMA OR URINE FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,TOTAL BILIRUBIN-SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM AND PLASMA,CHOLESTEROL-CHOLESTEROL REAGENT FOR THE ENZYMATIC DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA.,GGT-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF L-GAMMA GLUTAMYL

	TRANSFERASE (-GLUTAMYLTRANSPEPTIDASE) IN HUMAN SERUM OR PLASMA FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,LP(A) CONTROL LOW-MATERIAL FOR THE INTERNAL QUALITY CONTROL OF THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN LP(A),LDL-CHOLESTEROL- REAGENT FOR THE DETERMINATION OF LDL IN HUMAN SERUM OR PLASMA,LP(ALPHA)-SET OF IMMUNOTURBIDIMETRIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF LP(ALPHA) IN HUMAN SERUM.,RF-IMMUNOTURBIDIMETRIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR IN HUMAN SERUM OR PLASMA,CREATININE-CREATININE SET OF REAGENTS FOR THE ENZYMATIC DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE.,DIRECT BILIRUBIN-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM OR PLASMA FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,MICROALBUMIN CALIBRATOR-CALIBRATION MATERIAL FOR THE PREPARATION OF CALIBRATION CURVES FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF MICROALBUMIN IN URINE,IGE-SET OF IMMUNOTURBIDIMETRIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF IGE IN HUMAN SERUM.,UREA-SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM, PLASMA AND URINE,CERULOPLASMIN-SET OF IMMUNOTURBIDIMETRIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF CERULOPLASMIN IN HUMAN SERUM AND PLASMA.,HDL-CHOLESTEROL-REAGENT FOR THE ENZYMATIC DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA., CREATININE-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA OR URINE FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,CYSTATIN C CONTROL-MATERIAL FOR THE QUALITY CONTROL OF THE DETERMINATION OF CYSTATIN C,IGE CALIBRATOR-MATERIAL FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF TOTAL IMMUNOGLOBULIN E IN HUMAN SERUM,UIBC-SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF UIBC IN HUMAN SERUM OR PLASMA,ALBUMIN-REAGENT FOR THE DETERMINATION OF ALBUMIN IN HUMAN SERUM AND PLASMA,TOTAL PROTEIN-REAGENT FOR THE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA, FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS.,URIC ACID-SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA AND URINE,ETHANOL CALIBRATOR-CALIBRATION MATERIAL FOR THE PREPARATION OF CALIBRATION CURVES FOR THE QUANTITATIVE DETERMINATION OF ETHANOL IN SERUM,CLINICAL CHEMISTRY

	CONTROL LEV.1-MATERIAL FOR THE INTERNAL QUALITY CONTROL OF THE RESULTS,CHOLINESTERASE-SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF CHOLINESTERASE IN HUMAN SERUM AND PLASMA,ADA CONTROL-ATERIAL FOR THE QUALITY CONTROL OF THE QUANTITATIVE DETERMINATION OF ADA IN HUMAN SERUM OR PLEURITIC FLUID,ALT/SGPT-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE IN HUMAN SERUM OR PLASMA FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,ETHANOL CONTROL-MATERIAL FOR THE QUALITY CONTROL OF THE DETERMINATION OF ETHANOL ,MEDI-CAL-MATERIAL FOR USE AS CALIBRATOR IN CLINICAL CHEMISTRY ASSAYS,TRIGLYCERIDES-SET OF REAGENTS FOR THE ENZYMATIC DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA,STFR CALIBRATOR-MATERIAL FOR THE PREPARATION OF REFERENCE CURVES FOR THE QUANTITATIVE DETERMINATION OF SOLUBLE TRANSFERRIN RECEPTORS (STFR) IN HUMAN SERUM OR PLASMA,CLINICAL CHEMISTRY CONTROL LEV.2-MATERIAL FOR THE INTERNAL QUALITY CONTROL OF THE RESULTS, CERULOPLASMIN-SET OF IMMUNOTURBIDIMETRIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF CERULOPLASMIN IN HUMAN SERUM AND PLASMA,FERRITIN CALIBRATOR-MATERIAL,ALKALINE PHOSPHATASE (ALP)-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE (ALP) IN HUMAN SERUM OR PLASMA WITH BIOCHEMISRY AUTOMATED ANALYZERS, GGT-SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF GGT IN HUMAN SERUM AND PLASMA.,ACE-SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF ACE IN HUMAN SERUM, IMMUNOLOGY CONTROL 2-MATERIAL FOR THE INTERNAL QUALITY CONTROL OF THE PERFORMANCE OF MEDICON SPECIAL PROTEINS REAGENTS,LDH P->L-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF L-LACTATE DEHYDROGENASE IN HUMAN SERUM AND PLASMA SAMPLES FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,PROTEIN STANDARD-MEDICON PROTEIN STANDARD CALIBRATOR IS A HUMAN PLASMA CALIBRATOR INTENDED TO BE USED FOR THE QUANTITATIVE DETERMINATION OF A1-ANTITRYPSIN, A2-MACROGLOBULIN, A1-ACID GLYCOPROTEIN, CERULO PLASMIN, HAPTOGLOBIN, TRANSFERRIN, IGA, IGG, IGM, C3, C4, PREALBUMIN, KAPPA LIGHT CHAINS, LAMBDA LIGHT CHAINS ON BIOCHEMICAL ANALYZERS ,RF CALIBRATOR-A HUMAN PLASMA CALIBRATOR INTENDED TO BE USED FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR,STFR-SET OF IMMUNOTURBIDIMETRIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF STFR IN HUMAN SERUM OR PLASMA, MAGNESIUM-REAGENT FOR THE QUANTITATIVE DETERMINATION OF

	MAGNESIUM IN HUMAN SERUM,CK-MB CONTROL-MATERIAL FOR THE QUALITY CONTROL OF THE DETERMINATION OF CK-MB IN HUMAN SERUM OR PLASMA,ALKALINE PHOSPHATASE (ALP)-SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF ALP IN HUMAN SERUM AND PLASMA.,URINARY PROTEIN-CSF-REAGENT FOR THE ENZYMATIC DETERMINATION OF TOTAL PROTEIN IN HUMAN URINE AND CSF,G-6-PDH CONTROL-LYOPHILIZED QUALITY CONTROL MATERIAL FROM HEMOLYSED HUMAN BLOOD FOR THE QUALITY CONTROL OF THE G-6-PDH DETERMINATION. ,FERRITIN-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF IRON DEFICIENCY ANEMIA.,ADA CALIBRATOR-MATERIAL FOR THE CALIBRATION OF THE QUANTITATIVE DETERMINATION OF ADA IN HUMAN SERUM OR PLEURITIC FLUID,TOTAL PROTEIN-SET OF REAGENTS FOR THE ENZYMATIC DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA,LP(A) CONTROL HIGH-MATERIAL FOR THE INTERNAL QUALITY CONTROL OF THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN LP(A),HDL-CHOLESTEROL-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF HDL-CHOLESTEROL IN HUMAN SERUM OR PLASMA FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,ADA-SET OF REAGENTS FOR THE ENZYMATIC DETERMINATION OF ADA IN HUMAN SERUM OR PLEURITIC FLUID,CYSTATIN C-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM OR PLASMA, ETHANOL-SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF ETHANOL IN HUMAN SERUM AND PLASMA, TOTAL PROTEIN-REAGENT FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM AND PLASMA.,STFR CONTROL-MATERIAL FOR THE INTERNAL QUALITY CONTROL OF SOLUBLE TRANSFERRIN RECEPTORS (STFR) IN HUMAN SERUM OR PLASMA,CK-REAGENTS FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE (CK) IN HUMAN SERUM OR PLASMA FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,CALCIUM-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA, OR URINE FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS,LDH L->P-REAGENT FOR THE ENZYMATIC DETERMINATION OF LDH-L IN HUMAN SERUM AND CSF., LACTATE-SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF LACTATE IN HUMAN PLASMA,AST/SGOT-AST/SGOT SET OF REAGENTS FOR THE QUANTITATIVE DETERMINATION OF AST IN HUMAN SERUM AND PLASMA ., PHOSPHORUS-REAGENT FOR THE QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHORUS IN HUMAN SERUM, PLASMA OR URINE FOR MANUAL USE OR WITH AUTOMATED BIOCHEMISTRY ANALYZERS

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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817	IMP/IVD/2020/000709	1.License Holder Name: HORIBA INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABX PENTRA UREA CP (HORIBA MEDICAL)-"ABX PENTRA UREA CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF UREA/UREA NITROGEN (AN END-PRODUCT OF NITROGEN METABOLISM) IN HUMAN SERUM, PLASMA AND URINE BASED ON AN ENZYMATIC UV TEST USING UREASE AND GLUTAMATE DEHYDROGENASE. MEASUREMENTS OBTAINED BY THIS DEVICE ARE USED IN THE DIAGNOSIS AND TREATMENT OF CERTAIN RENAL AND METABOLIC DISEASES." ,ABX PENTRA URINARY PROTEINS CP (HORIBA MEDICAL)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTEINS IN URINE BY COLORIMETRY. ,ABX PENTRA CK NAC CP(HORIBA MEDICAL)-ABX PENTRA CK NAC CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF THE TOTAL CREATINE KINASE IN HUMAN SERUM AND PLASMA BASED ON AN OPTIMIZED UV TEST. MEASUREMENTS OF CREATINE PHOSPHOKINASE AND ITS ISOENZYMES ARE USED IN THE DIAGNOSIS AND TREATMENT OF MYOCARDIAL INFARCTION AND MUSCLE DISEASES SUCH AS PROGRESSIVE, DUCHENNE-TYPE MUSCULAR DYSTROPHY. ,ABX PENTRA CO2 CAL(HORIBA MEDICAL)-ABX PENTRA CO2 CAL IS USED TO CALIBRATE ABX PENTRA CO2 RTU, REF. A11A01645. ,ABX PENTRA IG A CP(HORIBA MEDICAL)-"ABX PENTRA IGA CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN SERUM AND PLASMA BY TURBIDIMETRY. MEASUREMENT OF THIS IMMUNOGLOBULIN AIDS IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S LACK OF ABILITY TO RESIST INFECTIOUS AGENTS." ,ABX PENTRA MICRO ALB 2 CAL(HORIBA MEDICAL)-ABX PENTRA MICRO ALB 2 CAL IS USED TO CALIBRATE ABX PENTRA MICRO ALBUMIN 2 CP, ,ABX PENTRA CHOLESTEROL CP (HORIBA MEDICAL)-"ABX PENTRA CHOLESTEROL CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA BASED ON AN ENZYMATIC PHOTOMETRIC TEST (TRINDER'S REACTION). CHOLESTEROL MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF DISORDERS INVOLVING EXCESS CHOLESTEROL IN THE BLOOD AND LIPID AND LIPOPROTEIN METABOLISM DISORDERS." ,ABX PENTRA TPU CAL(HORIBA MEDICAL) -ABX PENTRA TPU CAL IS USED TO CALIBRATE ABX PENTRA URINARY PROTEINS CP, REF. A11A01642. ,ABX PENTRA AST CP (HORIBA MEDICAL)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ASPARTATE AMINOTRANSFERASE (AST)

	IN SERUM OR PLASMA BY COLORIMETRY. ,ABX PENTRA AMYLASE CP (HORIBA MEDICAL)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF AMYLASE IN SERUM, PLASMA AND URINE BY COLORIMETRY. ,ABX PENTRA SP CONTROL LOW(HORIBA MEDICAL)-"THE ABX PENTRA SP CONTROL LOW IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF HORIBA MEDICAL METHODS (BY IMMUNOTURBIDIMETRY) ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS WITH THE FOLLOWING REAGENTS: ABX PENTRA IGA CP (A11A01923) ABX PENTRA IGG CP (A11A01924) ABX PENTRA IGM CP (A11A01925) ABX PENTRA TRANSFERRIN CP (A11A01926)" ,ABX PENTRA IG G CP(HORIBA MEDICAL)-ABX PENTRA IGG CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN SERUM AND PLASMA BY TURBIDIMETRY. MEASUREMENT OF THIS IMMUNOGLOBULIN AIDS IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S LACK OF ABILITY TO RESIST INFECTIOUS AGENTS. ,ABX PENTRA LIPASE CP(HORIBA MEDICAL)-"ABX PENTRA LIPASE CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF LIPASE IN SERUM OR PLASMA. LIPASE MEASUREMENTS ARE USED IN DIAGNOSIS AND TREATMENT OF DISEASES OF THE PANCREAS SUCH AS ACUTE PANCREATITIS AND OBSTRUCTION OF THE PANCREATIC DUCT.",ABX PENTRA CO2 RTU (HORIBA MEDICAL)-ABX PENTRA CO2 RTU REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CARBON DIOXIDE IN HUMAN SERUM AND PLASMA BASED ON AN ENZYMATIC TEST USING PHOSPHOENOLPYRUVATE (PEP), PHOSPHORENOLPYRUVATE CARBOXYLASE (PEPC) AND AN ANALOG OF NADH. BICARBONATE/CARBON MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF NUMEROUS POTENTIALLY SERIOUS DISORDERS ASSOCIATED WITH CHANGES IN BODY ACIDBASE BALANCE.,ABX PENTRA IRON CP(HORIBA MEDICAL)-ABX PENTRA IRON CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF IRON (NONHEME) IN HUMAN SERUM AND PLASMA BASED ON A PHOTOMETRIC TEST (FERENE METHOD). IRON (NON-HEME) MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF DISEASES SUCH AS IRON DEFICIENCY ANEMIA AND HEMOCHROMATOSIS.,ABX PENTRA LDH CP (HORIBA MEDICAL)-ABX PENTRA LDH CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF LACTATE DEHYDROGENASE (LDH) IN SERUM OR PLASMA. LACTATE DEHYDROGENASE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIVER DISEASES SUCH AS ACUTE VIRAL HEPATITIS, CIRRHOSIS, AND METASTATIC CARCINOMA OF THE LIVER,

	CARDIAC DISEASES SUCH AS MYOCARDIAL INFARCTION, AND TUMORS OF THE LUNG OR KIDNEYS. ,ABX PENTRA CK-MB RTU (HORIBA MEDICAL)-ABX PENTRA CK-MB RTU REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CKMB IN SERUM BY COLORIMETRY. MEASUREMENTS OF CREATINE KINASE ARE USED IN THE DIAGNOSIS AND TREATMENT OF MYOCARDIAL INFARCTION AND MUSCLE DISEASES SUCH AS PROGRESSIVE, DUCHENNE-TYPE MUSCULAR DYSTROPHY.,ABX PENTRA CO2 CONTROL(HORIBA MEDICAL)-"THE ABX PENTRA CO2 CONTROL IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF HORIBA MEDICAL METHODS (BY COLORIMETRY) ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS WITH THE FOLLOWING REAGENTS: ABX PENTRA CO2 RTU (A11A01645)" ,ABX PENTRA BILIRUBIN, DIRECT CP(HORIBA MEDICAL)-ABX PENTRA BILIRUBIN, DIRECT CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM AND PLASMA BASED ON A PHOTOMETRIC TEST USING 2,4-DICHLOROANILINE (DCA). MEASUREMENTS OF THE LEVELS OF BILIRUBIN (DIRECT OR TOTAL), AN ORGANIC COMPOUND FORMED DURING THE NORMAL AND ABNORMAL DESTRUCTION OF RED BLOOD CELLS, ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIVER, HEMOLYTIC HEMATOLOGICAL, AND METABOLIC DISORDERS, INCLUDING HEPATITIS AND GALL BLADDER BLOCK. ,ABX PENTRA MAGNESIUM RTU(HORIBA MEDICAL)-ABX PENTRA MAGNESIUM RTU REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF MAGNESIUM IN HUMAN SERUM AND PLASMA BASED ON A PHOTOMETRIC TEST USING XYLIDYL BLUE. MAGNESIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF HYPOMAGNESEMIA (ABNORMALLY LOW PLASMA LEVELS OF MAGNESIUM) AND HYPERMAGNESEMIA (ABNORMALLY HIGH PLASMA LEVELS OF MAGNESIUM). ,ABX PENTRA BILIRUBIN, TOTAL CP(HORIBA MEDICAL)-ABX PENTRA BILIRUBIN, TOTAL CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM AND PLASMA BASED ON A PHOTOMETRIC TEST USING 2,4-DICHLOROANILINE (DCA) AND DETERGENTS. MEASUREMENTS OF THE LEVELS OF BILIRUBIN (DIRECT OR TOTAL), AN ORGANIC COMPOUND FORMED DURING THE NORMAL AND ABNORMAL DESTRUCTION OF RED BLOOD CELLS, ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIVER, HEMOLYTIC, HEMATOLOGICAL, AND METABOLIC DISORDERS, INCLUDING HEPATITIS AND GALL BLADDER BLOCK. ,ABX PENTRA MICRO ALBUMIN 2 CP(HORIBA MEDICAL)-"DIAGNOSTIC REAGENT USED TO MEASURE BY IMMUNOCHEMICAL TECHNIQUES THE ALBUMIN (A

	PLASMA PROTEIN) IN URINE. MEASUREMENT OF ALBUMIN AIDS IN THE DIAGNOSIS OF KIDNEY AND INTESTINAL DISEASES. DIAGNOSTIC REAGENT USED TO MEASURE BY IMMUNOCHEMICAL TECHNIQUES THE ALBUMIN (A PLASMA PROTEIN) IN URINE. MEASUREMENT OF ALBUMIN AIDS IN THE DIAGNOSIS OF KIDNEY AND INTESTINAL DISEASES." ,ABX PENTRA SP CAL(HORIBA MEDICAL)-ABX PENTRA SP CAL IS USED TO CALIBRATE ABX PENTRA IGA CP, REF. A11A01923, ABX PENTRA IGG CP, REF. A11A01924, ABX PENTRA IGM CP, REF. A11A01925 AND ABX PENTRA TRANSFERRIN CP, REF. A11A01926 ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYSERS. ,ABX PENTRA ALT CP(HORIBA MEDICAL)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALANINE AMINO TRANSFERASE (ALT) IN SERUM OR PLASMA BY COLORIMETRY. ,ABX PENTRA ALP CP(HORIBA MEDICAL)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALKALINE PHOSPHATASE (ALP) IN SERUM OR PLASMA BY COLORIMETRY. ,ABX PENTRA GGT CP(HORIBA MEDICAL)-ABX PENTRA GGT CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF GAMMAGLUTAMYLTRANSFERASE (GGT) IN SERUM OR PLASMA. GAMMA-GLUTAMYLTRANSPEPTIDASE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIVER DISEASES SUCH AS ALCOHOLIC CIRRHOSIS AND PRIMARY AND SECONDARY LIVER TUMORS ,ABX PENTRA IG M CP(HORIBA MEDICAL) -ABX PENTRA IGM CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN SERUM AND PLASMA BY TURBIDIMETRY. MEASUREMENT OF THIS IMMUNOGLOBULIN AIDS IN THE DIAGNOSIS OF ABNORMAL PROTEIN METABOLISM AND THE BODY'S LACK OF ABILITY TO RESIST INFECTIOUS AGENTS. ,ABX PENTRA SP CONTROL HIGH(HORIBA MEDICAL)-THE ABX PENTRA SP CONTROL HIGH IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF HORIBA MEDICAL METHODS (BY IMMUNOTURBIDIMETRY) ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS WITH THE FOLLOWING REAGENTS: ABX PENTRA IGA CP (A11A01923) ABX PENTRA IGG CP (A11A01924) ABX PENTRA IGM CP (A11A01925) ABX PENTRA TRANSFERRIN CP (A11A01926) ,ABX PENTRA TRANSFERRIN CP (HORIBA MEDICAL)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TRANSFERRIN IN SERUM AND PLASMA BY TURBIDIMETRY.

818	IMP/IVD/2020/000710	1.License Holder Name: GENETIX BIOTECH ASIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 REAL TIME PCR KIT(REAL-Q 2019-NCOV DETECTION KIT)-IT IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE THAT QUALITATIVELY DETECTS THE GENE (E GENE, RDRP GENE) OF THE CORONAVIRUS DISEASE (COVID-19) IN SAMPLES (SPUTUM, OROPHARYNGEAL AND NASOPHARYNGEAL SPECIMENS) OF PATIENTS WITH RESPIRATORY INFECTIONS USING REAL-TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION. THE REAL-Q 2019-NCOV DETECTION KIT IS INTENDED FOR USE BY QUALIFIED AND TRAINED CLINICAL LABORATORY PERSONNEL SPECIFICALLY INSTRUCTED AND TRAINED IN THE TECHNIQUES OF REAL-TIME PCR AND IN VITRO DIAGNOSTIC PROCEDURES.
819	IMP/IVD/2020/000712	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONCENTRATED CLEANSER-USED ON 5-PART HEMATOLOGY ANALYZER FOR DAILY MAINTENANCE AND SYSTEM CLEANING,DILUENT-USED ON AUTO HEMATOLOGY ANALYZER FOR WHITE BLOOD CELL COUNTING, DIFFERENTIATING AND HEMOGLOBIN MEASUREMENT.,CLEANSER-USED ON 5-PART HEMATOLOGY ANALYZER FOR CLEANING AND WASHING TUBING SYSTEM, REMOVING BLOOD RESIDUAL AND OTHER PARTICLES TO ENSURE BLOOD CELL COUNTING,HEMATOLOGY CALIBRATOR-USED IN THE CALIBRATION OF PARAMETERS INCLUDING WBC, RBC,HGB,MCV AND PLT OF HEMATOLOGY ANALYZERS,LYSE (RL-86H)-USED ON 5-PART HEMATOLOGY ANALYZER FOR WHITE BLOOD CELL COUNTING, VOLUME AND HEMOGLOBIN MEASUREMENT,HEMATOLOGY CONTROL-USED TO MONITOR THE PERFORMANCE OFHEMATOLOGY ANALYZERS,LYSE (RL-86D)-USED ON 5-PART HEMATOLOGY ANALYZER FOR WHITE BLOOD CELL COUNTING, WHITE BLOOD CELL DIFFERENTIATING AND VOLUME MEASUREMENT

820	IMP/IVD/2020/000715	1.License Holder Name: DHR HOLDING INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CUESEE® HBA1C (CUESEE® HBA1C)-CUESEE® HBA1C IS AN ASSAYED REAL GLYCOHAEMOGLOBIN CONTROL INTENDED FOR PROFESSIONAL USE IN THE VERIFICATION OF THE PRECISION AND ACCURACY OF HBA1C INSTRUMENTS. THE PURPOSE OF THIS QUALITY CONTROL IS TO VALIDATE THE CALIBRATION AND OTHER PERFORMANCE RELATED CHARACTERISTICS.,EUROTROL HEMOTROL(EUROTROL HEMOTROL)-EUROTROL HEMOTROL® IS AN ASSAYED QUALITY CONTROL MATERIAL FOR PROFESSIONAL USE TO VERIFY THE PERFORMANCE CHARACTERISTICS OF THE HEMOCUE HB 201 SYSTEMS. HEMOTROL® IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN.,EUROTROL PLASMA/LOW HB CONTROL(EUROTROL PLASMA/LOW HB CONTROL)-EUROTROL PLASMA/LOW HB CONTROL IS AN ASSAYED HEMATOLOGY CONTROL INTENDED FOR PROFESSIONAL USE IN THE VERIFICATION OF THE PRECISION AND ACCURACY OF THE HEMOCUE® PLASMA/LOW HB SYSTEM., EUROTROL ALBUTROL(EUROTROL ALBUTROL)-EUROTROL ALBUTROL® IS AN ASSAYED ALBUMIN CONTROL INTENDED FOR PROFESSIONAL USE IN THE VERIFICATION OF THE PRECISION AND ACCURACY OF THE HEMOCUE® ALBUMIN 201 SYSTEM. EUROTROL ALBUTROL® IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN.,EUROTROL HB 301 CONTROL(EUROTROL HB 301 CONTROL)-EUROTROL HB 301 CONTROL IS AN ASSAYED HEMOGLOBIN CONTROL INTENDED FOR PROFESSIONAL USE IN THE VERIFICATION OF THE PRECISION AND ACCURACY OF THE HEMOCUE® HB 301 SYSTEM.,EUROTROL GLUCOTROL-NG(EUROTROL GLUCOTROL-NG)-EUROTROL GLUCOTROL-NG IS AN ASSAYED GLUCOSE CONTROL INTENDED FOR PROFESSIONAL USE IN THE VERIFICATION OF THE PRECISION AND ACCURACY OF THE HEMOCUE® GLUCOSE SYSTEMS.

821	IMP/IVD/2020/000716	1.License Holder Name: SYSMEX INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BM TEST HBA1C REAGENT 1(BM TEST HBA1C REAGENT 1)-KIT FOR THE QUANTITATIVE MEASUREMENT OF THE PERCENTAGE OF GLYCATED HEMOGLOBIN LEVELS IN HUMAN WHOLE BLOOD,BM TEST HBA1C REAGENT 2(BM TEST HBA1C REAGENT 2)-KIT FOR THE QUANTITATIVE MEASUREMENT OF THE PERCENTAGE OF GLYCATED HEMOGLOBIN LEVELS IN HUMAN WHOLE BLOOD.,BM TEST HBA1C CONTROL(BM TEST HBA1C CONTROL)-CONTROL FOR QUANTITATIVE IN VITRO DETERMINATION OF HBA1C IN BLOOD ON BIOMAJESTY SYSTEM,BM TEST HBA1C DILUENT(BM TEST HBA1C DILUENT)-DILUENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HBA1C IN BLOOD ON BIOMAJESTY SYSTEM,BM TEST HBA1C CALIBRATOR(BM TEST HBA1C CALIBRATOR)-CALIBRATOR FOR QUANTITATIVE IN VITRO DETERMINATION OF HBA1C IN BLOOD ON BIOMAJESTY SYSTEMS.

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822	IMP/IVD/2020/000717	1.License Holder Name: BIOGENESIS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHOLESTEROL REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF TC ACTIVITY IN HUMAN SERUM,DIRUI H10-800 (30,100,125)-FOR THE DETERMINATION OF PARAMETERS RELATED TO KIDNEY IN URINE., CS-ISE DETERGENT-FOR CLEANING ISE ELECTRODE OF CS SERIES AUTO-CHEMISTRY ANALYZER,ALPHA-HYDROXYBUTYRIC DEHYDROGENASE REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF ALPHA-HYDROXYBUTYRIC DEHYDROGENASE REAGENT KIT ACTIVITY IN HUMAN SERUM,LACTATE DEHYDROGENASE REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF LDH ACTIVITY IN HUMAN SERUM,CYSTATIN C REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF CYS-C ACTIVITY IN HUMAN SERUM.,LIPOPROTEIN (A) REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF LP(A) ACTIVITY IN HUMAN SERUM, 5-NUCLEOTINASE REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF 5'NT ACTIVITY IN HUMAN SERUM.,ALBUMIN REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF ALB ACTIVITY IN HUMAN SERUM,IMMUNOGLOBULIN G KIT-IN VITRO QUANTITATIVE MEASUREMENT OF IGG ACTIVITY IN HUMAN SERUM, PREALBUMIN REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF PA ACTIVITY IN HUMAN SERUM,CREATININE REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF CRE ACTIVITY IN HUMAN SERUM,TOTAL PROTEIN REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF TP ACTIVITY IN HUMAN SERUM, GLYCOHEMOGLOBIN A1C REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF HBA1C ACTIVITY IN HUMAN SERUM,DIRUI H11-800 (30,100,125)-FOR THE DETERMINATION OF PARAMETERS RELATED TO KIDNEY IN URINE.,URIC ACID REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF UA ACTIVITY IN HUMAN SERUM, ADENOSINE DEAMINASE REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF ADA ACTIVITY IN HUMAN SERUM.,CREATINE KINASE REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF CK ACTIVITY IN HUMAN SERUM,ISE BLOOD SAMPLE CALIBRATOR-FOR THE CALIBRATION OF ISE MODULE,ISE DILUENT-THE PRODUCT APPLIES TO ISE PART OF CS SERIAL AUTO CHEMISTRY ANALYZER FOR MEASURING ION SELECTIVE MODULE & DILUTING SAMPLE & STANDARD LIQUID.,IMMUNOGLOBULIN A KIT-IN VITRO QUANTITATIVE MEASUREMENT OF IGA ACTIVITY IN HUMAN SERUM, CLINICAL CHEMICAL CALIBRATION SERUM-CALIBRATION SERUM IS USED FOR THE DETERMINATION OF ACCURACY OR REPEATABILITY OF CLINICAL CHEMICAL ITEMS.,COMPLEMENT 4 REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF C4 ACTIVITY IN HUMAN

	SERUM,ALKALINE PHOSPHATASE REAGENT-IN VITRO QUANTITATIVE MEASUREMENT OF ALP ACTIVITY IN HUMAN SERUM, IMMUNOGLOBULIN M KIT-IN VITRO QUANTITATIVE MEASUREMENT OF IGM ACTIVITY IN HUMAN SERUM,TRANSFERRIN REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF TRF ACTIVITY IN HUMAN SERUM,ISE REFERENCE SOLUTION-THIS PRODUCT IS USED TO DETERMINE THE ELECTRIC POTENTIAL OF A REFERENCE ELECTRODE.,ISE STANDARD SOLUTION (HIGH)-THIS PRODUCT IS APPLICABLE TO THE ION-SELECTIVE ELECTRODE MODULE OF CS SERIES AUTO CHEMISTRY ANALYZER FOR MEASURING ELECTROLYTE.,RHEUMATOID FACTOR KIT-IN VITRO QUANTITATIVE MEASUREMENT OF RF ACTIVITY IN HUMAN SERUM,DIRECT BILIRUBIN REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF DB ACTIVITY IN HUMAN SERUM,DIRECT BILIRUBIN KIT-IN VITRO QUANTITATIVE MEASUREMENT OF DB-V ACTIVITY IN HUMAN SERUM, ANTI-STREPTOLYSIN O KIT-IN VITRO QUANTITATIVE MEASUREMENT OF ASO ACTIVITY IN HUMAN SERUM.,URINALYSIS CONTROL (POSITIVE)-URINALYSIS CONTROL IS USED FOR QUALITY CONTROL URINALYSIS STRIP AND ANALYZER,LOW DENSITY LIPOPROTEIN CHOLESTEROL REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF LDL-C ACTIVITY IN HUMAN SERUM,ISE BLOOD QUALITY CONTROL (HIGH)-THIS PRODUCT IS APPLICABLE TO THE ION-SELECTIVE ELECTRODE MODULE OF CS SERIES AUTO CHEMISTRY ANALYZER FOR MEASURING ELECTROLYTE., APOLIPOPROTEIN A1 REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF APOA1 ACTIVITY IN HUMAN SERUM,ISE INTERNAL STANDARD SOLUTION-THE PRODUCT APPLIES TO ISE PART OF CS SERIAL AUTO CHEMISTRY ANALYZER.,CHOLINESTERASE REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF CHE ACTIVITY IN HUMAN SERUM,ALANINE AMINOTRANSFERASE LIQUID-IN VITRO QUANTITATIVE MEASUREMENT OF ALT ACTIVITY IN HUMAN SERUM., MAGNESIUM REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF MG ACTIVITY IN HUMAN SERUM.,TOTAL BILIRUBIN REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF TB ACTIVITY IN HUMAN SERUM,APOLIPOROTEIN B REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF APOB ACTIVITY IN HUMAN SERUM,GLUTAMYL TRANSFERASE REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF GGT ACTIVITY IN HUMAN SERUM,URINALYSIS CONTROL (NEGATIVE)-URINALYSIS CONTROL IS USED FOR QUALITY CONTROL URINALYSIS STRIP AND ANALYZER,CARBON DIOXIDE REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF CO2 ACTIVITY IN HUMAN SERUM,CHLORIDE REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF CL ACTIVITY IN HUMAN SERUM, KIT FOR URINE SEDIMENT ANALYZER-STANDARD SOLUTION IS USED

	FOR CALIBRATING THE ANALYSER , CONTROL IS USED FOR QUALITY CONTROL THE ANALYSER, FOCUS IS FOR MAKING THE FOCUS TEST, HOMOCYSTEINE REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF HCY ACTIVITY IN HUMAN SERUM,ZINC REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF ZN ACTIVITY IN HUMAN SERUM,LYSE-FOR RED BLOOD CELLS DISSOLUTION AND HAEMOGLOBIN RELEASING, CONTENT DETECTION OF HAEMOGLOBIN.,INORGANIC PHOSPHORUS REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF P ACTIVITY IN HUMAN SERUM, DIRUI-H10 (100)-FOR THE DETERMINATION OF PARAMETERS RELATED TO KIDNEY IN URINE,TRIGLYCERIDES REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF TG ACTIVITY IN HUMAN SERUM,ISE BLOOD QUALITY CONTROL (LOW)-THIS PRODUCT IS APPLICABLE TO THE ION-SELECTIVE ELECTRODE MODULE OF CS SERIES AUTO CHEMISTRY ANALYZER FOR MEASURING ELECTROLYTE.,BILE ACID REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF TBA ACTIVITY IN HUMAN SERUM OR PLASMA.,CS ALKALINE DETERGENT-FOR CLEANING REAGENT PROBE AND REACTION CUVETTE OF CS SERIES AUTO-CHEMISTRY ANALYZER., UREA REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF BUN ACTIVITY IN HUMAN SERUM,MICROALBUMIN REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF MALB ACTIVITY IN HUMAN SERUM.,CALCIUM REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF CA ACTIVITY IN HUMAN SERUM,CREATINE KINASE MB ISOENZYME REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF CK-MB ACTIVITY IN HUMAN SERUM,COMPLEMENT 3 REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF C3 ACTIVITY IN HUMAN SERUM.,PANCREATIC AMYLASE REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF P-AMY ACTIVITY IN HUMAN SERUM.,CS-ACIDIC DETERGENT-FOR CLEANING REAGENT PROBE AND REACTION CUVETTE OF CS SERIES AUTO-CHEMISTRY ANALYZER,CLEANSER-FOR CLEANING THE TUBINGS INSIDE THE HEMATOLOGY ANALYZER.,CS-ANTI-BACTERIAL PHOSPHOR-FREE DETERGENT-FOR CLEANING REAGENT PROBE, INCUBATION BATH AND REACTION CUVETTE OF CS SERIES AUTO-CHEMISTRY ANALYZER,CLINICAL CHEMICAL QUALITY CONTROL SERUM-QUALITY CONTROL SERUM IS USED FOR THE DETERMINATION OF ACCURACY OR REPEATABILITY OF CLINICAL CHEMICAL ITEMS.,ASPARTATE AMINOTRANSFERASE REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF AST ACTIVITY IN HUMAN SERUM.,DILUENT-FOR DILUTING THE SAMPLE.,TOTAL BILIRUBIN KIT-IN VITRO QUANTITATIVE MEASUREMENT OF TB-V ACTIVITY IN HUMAN SERUM, AMYLASE REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF AMY ACTIVITY IN HUMAN SERUM.,GLUTAMATE DEHYDROGENASE

	REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF GLDH ACTIVITY IN HUMAN SERUM.,HIGH DENSITY LIPOPROTEIN CHOLESTEROL REAGENT KIT-IN VITRO QUANTITATIVE MEASUREMENT OF HDL-C ACTIVITY IN HUMAN SERUM.,ISE STANDARD SOLUTION (LOW)-THIS PRODUCT IS APPLICABLE TO THE ION-SELECTIVE ELECTRODE MODULE OF CS SERIES AUTO CHEMISTRY ANALYZER FOR MEASURING ELECTROLYTE.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

823	IMP/IVD/2020/000718	1.License Holder Name: SEBIA DIAGNOSTICS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYDRAGEL 15 HR ACID VIOLET(HYDRAGEL 15 HR ACID VIOLET)-THESE DEVICES ARE DESIGNED FOR MULTI-FRACTIONATION OF PROTEINS FROM HUMAN SERA OR OTHER BIOLOGICAL FLUIDS, SUCH AS URINE AND CEREBROSPINAL FLUID (CSF), BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.6) AGAROSE GELS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMIAUTOMATED HYDRASYS INSTRUMENT. THE HYDRASYS INSTRUMENT ALLOWS ALL. FOR IN VITRO DIAGNOSTIC USE. ,MINICAP PROTEIN(E) 6 MAXI-KIT(MINICAP PROTEIN(E) 6 MAXI-KIT)-E MINICAP PROTEIN(E) 6 KIT IS DESIGNED FOR THE SEPARATION OF HUMAN SERUM PROTEINS IN ALKALINE BUFFER (PH 9.9) BY CAPILLARY ELECTROPHORESIS WITH THE MINICAP SYSTEM. NORMAL SERUM PROTEINS SEPARATE INTO SIX MAJOR FRACTIONS. THE MINICAP PERFORMS ALL SEQUENCES AUTOMATICALLY TO OBTAIN A PROTEIN PROFILE FOR QUALITATIVE OR QUANTITATIVE ANALYSIS. THE PROTEINS, SEPARATED IN SILICA CAPILLARIES, ARE DIRECTLY DETECTED AT AN ABSORBANCE OF 200 NM. THE ELECTROPHOREGRAMS CAN BE INTERPRETED VISUALLY TO SCREEN FOR ANY PATTERN ABNORMALITIES. DIRECT DETECTION PROVIDES ACCURATE RELATIVE QUANTIFICATION OF INDIVIDUAL PROTEIN FRACTIONS. FOR IN VITRO DIAGNOSTIC USE ,HYDRAGEL 7 HEMOGLOBIN(E)(HYDRAGEL 7 HEMOGLOBIN(E))-THESE DEVICES ARE DESIGNED FOR SEPARATION OF THE NORMAL HEMOGLOBINS (A AND A2) AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS: S OR D AND C OR E, BY ELECTROPHORESIS ON ALKALINE AGAROSE GELS (PH 8.5). ,5 VON WILLEBRAND MULTIMERS VISUALIZATION KIT(5 VON WILLEBRAND MULTIMERS VISUALIZATION KIT)-THIS DEVICE IS DESIGNED FOR THE DETECTION AND THE ANALYSIS OF THE DISTRIBUTION OF VON WILLEBRAND FACTOR MULTIMERS IN HUMAN PLASMA BY AGAROSE GEL ELECTROPHORESIS AND IMMUNOFIXATION, WITH THE SEMI AUTOMATED HYDRASYS 2 INSTRUMENT. ,HYDRAGEL 4 IF (SM) - AMIDOBLACK(HYDRAGEL 4 IF (SM) - AMIDOBLACK)-THE HYDRAGEL 1 IF, 2 IF, 4 IF AND 9 IF KITS ARE DESIGNED FOR DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS. THE PROTEINS, SEPARATED BY ELECTROPHORESIS ON ALKALINE BUFFERED AGAROSE GELS, ARE INCUBATED WITH INDIVIDUAL ANTISERA THAT ARE SPECIFIC AGAINST GAMMA (IG G), ALPHA (IG A) AND MU (IG M) HEAVY CHAINS, AND KAPPA (FREE AND BOUND) AND LAMBDA (FREE AND BOUND)

	LIGHT CHAINS, RESPECTIVELY. AFTER REMOVING THE NON-REACTED PROTEINS, THE IMMUNOPRECIPITATES ARE STAINED EITHER WITH ACID VIOLET OR AMIDO BLACK. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY FOR THE PRESENCE OF SPECIFIC REACTIONS WITH THE SUSPECT MONOCLONAL PROTEINS. EACH AGAROSE GEL IS INTENDED TO RUN : - ONE SAMPLE IN THE HYDRAGEL 1 IF KIT, - TWO SAMPLES IN THE HYDRAGEL 2 IF KIT, - FOUR SAMPLES IN THE HYDRAGEL 4 IF KITS, - NINE SAMPLES IN THE HYDRAGEL 9 IF KITS. TO ACCOMMODATE DIVERSE USER PREFERENCES, THE HYDRAGEL 4 IF KITS ARE AVAILABLE EITHER WITH ACID VIOLET OR WITH AMIDOBLACK. FOR IN VITRO DIAGNOSTIC USE ,HB A1C CAPILLARY CALIBRATORS (5X2)(HB A1C CAPILLARY CALIBRATORS (5X2))-THIS DEVICE IS DESIGNED FOR THE CALIBRATION OF CAPILLARY ELECTROPHORETIC QUANTIFICATION OF HUMAN GLYCATED HEMOGLOBIN A1C ACCORDING TO THE IFCC AND NGSP REQUIREMENTS ,CAPILLARYS PROTEIN(E) 6(CAPILLARYS PROTEIN (E) 6)-THE CAPILLARYS PROTEIN(E) 6 KIT IS DESIGNED FOR THE SEPARATION OF HUMAN SERUM AND URINE PROTEINS IN ALKALINE BUFFER (PH 9.9) BY CAPILLARY ELECTROPHORESIS WITH THE CAPILLARYS SYSTEM. NORMAL SERUM PROTEINS SEPARATE INTO SIX MAJOR FRACTIONS. URINE PROTEINS SEPARATE INTO FIVE ZONES, AFTER THE PREPARATION OF URINE SAMPLES WITH THE CAPILLARYS / MINICAP URINE KIT (SEE THE INSTRUCTION SHEETS OF THE CAPILLARYS / MINICAP URINE KIT, SEBIA, PN 2013). THE CAPILLARYS PERFORMS ALL SEQUENCES AUTOMATICALLY TO OBTAIN A PROTEIN PROFILE FOR QUALITATIVE OR QUANTITATIVE ANALYSIS. THE PROTEINS, SEPARATED IN SILICA CAPILLARIES, ARE DIRECTLY DETECTED AT AN ABSORBANCE OF 200 NM. THE ELECTROPHOREGRAMS CAN BE INTERPRETED VISUALLY TO SCREEN FOR ANY PATTERN ABNORMALITIES. DIRECT DETECTION PROVIDES ACCURATE RELATIVE QUANTIFICATION OF INDIVIDUAL PROTEIN FRACTIONS. FOR IN VITRO DIAGNOSTIC USE ,A1C/CE - CAPILLARY BLOOD SAMPLE KIT (A)(A1C/CE - CAPILLARY BLOOD SAMPLE KIT (A)) -THE "A1C/CE – CAPILLARY BLOOD SAMPLE KIT (A)" DEVICE IS DESIGNED FOR COLLECTION, HEMOLYSIS AND TRANSPORTATION OF BLOOD SAMPLES FOR THEIR ANALYSIS WITH THE SEBIA CAPILLARY ELECTROPHORESIS PROCEDURES. ,HYDRAGEL 5 VON WILLEBRAND MULTIMERS(HYDRAGEL 5 VON WILLEBRAND MULTIMERS)-THE HYDRAGEL 5 VON WILLEBRAND MULTIMERS AND HYDRAGEL 11 VON WILLEBRAND MULTIMERS KITS ARE DESIGNED FOR THE DETECTION AND THE ANALYSIS OF THE DISTRIBUTION OF VON WILLEBRAND FACTOR MULTIMERS IN HUMAN PLASMA BY AGAROSE GEL ELECTROPHORESIS AND IMMUNOFIXATION, WITH THE SEMIAUTOMATED HYDRASYS 2 INSTRUMENT. THE SEMI-AUTOMATED

	HYDRASYS 2 INSTRUMENT PERFORMS ALL THE STEPS NEEDED TO OBTAIN GELS READY FOR QUALITATIVE ANALYSIS. PLASMA PROTEINS ARE SEPARATED ACCORDING TO THEIR MOLECULAR WEIGHT IN NEUTRAL BUFFER (PH 7.0) CONTAINING AN ANIONIC DETERGENT. AFTER IMMUNOPRECIPITATION OF PROTEINS IN THE GEL WITH A SPECIFIC ANTISERUM, VON WILLEBRAND FACTOR MULTIMERS ARE VISUALIZED USING A PEROXIDASE-LABELLED ANTIBODY. EACH AGAROSE GEL IS INTENDED TO RUN : - 5 SAMPLES IN THE HYDRAGEL 5 VON WILLEBRAND MULTIMERS KIT, - 11 SAMPLES IN THE HYDRAGEL 11 VON WILLEBRAND MULTIMERS KIT. FOR IN VITRO DIAGNOSTIC USE ONLY. ,CAPILLARYS HEMOGLOBIN(E) (CAPILLARYS HEMOGLOBIN(E))-THE CAPILLARYS HEMOGLOBIN(E) KIT IS DESIGNED FOR THE SEPARATION OF THE NORMAL HEMOGLOBINS (A, F AND A2) AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS (ESPECIALLY S, C, E OR D), BY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE CAPILLARYS 2 SYSTEM. FOR IN VITRO DIAGNOSTIC USE.,HYDRAGEL 15 HR AMIDOBLACK(HYDRAGEL 15 HR AMIDOBLACK)-THESE DEVICES ARE DESIGNED FOR MULTI-FRACTIONATION OF PROTEINS FROM HUMAN SERA OR OTHER BIOLOGICAL FLUIDS, SUCH AS URINE AND CEREBROSPINAL FLUID (CSF), BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.6) AGAROSE GELS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMIAUTOMATED HYDRASYS INSTRUMENT. THE HYDRASYS INSTRUMENT ALLOWS ALL. FOR IN VITRO DIAGNOSTIC USE ,HIGH CDT CONTROL(HIGH CDT CONTROL)-THE HIGH CDT CONTROL IS DESIGNED FOR THE QUALITY CONTROL OF QUANTIFICATION OF HUMAN TRANSFERRIN ISOFORMS WITH THE SEBIA CAPILLARYS CDT, CAPI 3 CDT AND MINICAP CDT CAPILLARY ELECTROPHORESIS PROCEDURES. IT SHOULD BE USED LIKE A HUMAN SERUM. THE VALUES OBTAINED MUST FALL WITHIN THE RANGE PROVIDED WITH EACH BATCH OF CONTROL. FOR IN VITRO DIAGNOSTIC USE. ,CAPILLARYS NEONAT HB(CAPILLARYS NEONAT HB)-THIS DEVICE IS DESIGNED FOR THE SEPARATION OF THE NORMAL HEMOGLOBINS (F AND A) IN BLOOD SAMPLES FROM HUMAN NEW-BORN BABIES, AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS (ESPECIALLY S, C, E, D OR BART'S), BY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE CAPILLARYS 2 SYSTEM ,CDT SAMPLES TREATMENT SOLUTION(CDT SAMPLES TREATMENT SOLUTION)-THIS REAGENT IS DESIGNED FOR TREATMENT OF INTERFERING SAMPLES IN THE CAPILLARY ELECTROPHORESIS SYSTEM. ,NORMAL HB A2 CONTROL (5)(NORMAL HB A2 CONTROL (5))-THE NORMAL HB A2 CONTROL IS DESIGNED : - FOR THE QUALITY CONTROL OF HEMOGLOBIN A2 QUANTIFICATION, - FOR THE MIGRATION CONTROL OF THE HUMAN HEMOGLOBIN

	PATTERN WITH HYDRAGEL HEMOGLOBIN(E)* AND CAPILLARYS / CAPI 3 / MINICAP HEMOGLOBIN(E)* ELECTROPHORESIS PROCEDURES. IT SHOULD BE USED AS NORMAL HUMAN BLOOD. THE VALUES OBTAINED MUST FALL WITHIN THE RANGE PROVIDED WITH EACH BATCH OF HB A2 CONTROL. ,HYDRAGEL 54 PROTEIN(E) (HYDRAGEL 54 PROTEIN(E))-THE HYDRAGEL 54 PROTEIN(E) KIT IS DESIGNED FOR SEPARATION OF HUMAN SERUM PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 9.1) AGAROSE GELS. BY DESIGN, THE NORMAL HUMAN SERUM PROTEINS SEPARATE INTO FIVE MAJOR FRACTIONS. THE KIT IS USED IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS INSTRUMENT. THE SEPARATED PROTEINS ARE STAINED WITH AMIDOBLACK. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY FOR PATTERN ABNORMALITIES. DENSITOMETRY PROVIDES ACCURATE RELATIVE QUANTIFICATION OF INDIVIDUAL ZONES. EACH AGAROSE GEL IS INTENDED TO RUN 54 SAMPLES. FOR IN VITRO DIAGNOSTIC USE ,MINICAP PROTEIN(E) 6 BUFFER(MINICAP PROTEIN(E) 6 BUFFER)-ALKALINE BUFFER FOR SERUM PROTEINS ANALYSIS (6 FRACTIONS) BY CAPILLARY ELECTROPHORESIS WITH THE MINICAP AUTOMATIC SYSTEM ,MINICAP PROTEIN(E) 6(MINICAP PROTEIN(E) 6)-E MINICAP PROTEIN(E) 6 KIT IS DESIGNED FOR THE SEPARATION OF HUMAN SERUM PROTEINS IN ALKALINE BUFFER (PH 9.9) BY CAPILLARY ELECTROPHORESIS WITH THE MINICAP SYSTEM. NORMAL SERUM PROTEINS SEPARATE INTO SIX MAJOR FRACTIONS. THE MINICAP PERFORMS ALL SEQUENCES AUTOMATICALLY TO OBTAIN A PROTEIN PROFILE FOR QUALITATIVE OR QUANTITATIVE ANALYSIS. THE PROTEINS, SEPARATED IN SILICA CAPILLARIES, ARE DIRECTLY DETECTED AT AN ABSORBANCE OF 200 NM. THE ELECTROPHOREGRAMS CAN BE INTERPRETED VISUALLY TO SCREEN FOR ANY PATTERN ABNORMALITIES. DIRECT DETECTION PROVIDES ACCURATE RELATIVE QUANTIFICATION OF INDIVIDUAL PROTEIN FRACTIONS. FOR IN VITRO DIAGNOSTIC USE ,CSF CONTROL(CSF CONTROL)-THE CSF CONTROL IS DESIGNED FOR THE QUALITY CONTROL OF THE DETECTION OF IMMUNOGLOBULINS G CONTAINED IN HUMAN SERUM AND CEREBROSPINAL FLUID BY IMMUNOFIXATION WITH HYDRAGEL CSF* AND HYDRAGEL CSF ISOFOCUSING* PROCEDURES. THE CSF CONTROL SHOULD BE USED AS A HUMAN SERUM. ,HYDRAGEL 7 PROTEIN(E)(HYDRAGEL 7 PROTEIN(E))-HE HYDRAGEL 7 PROTEIN(E) AND HYDRAGEL PROTEIN(E) 15/30 GELS ARE INTENDED FOR SEPARATION OF HUMAN SERUM PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 9.1) AGAROSE GELS. BY DESIGN, THE NORMAL HUMAN SERUM PROTEINS SEPARATE INTO FIVE MAJOR FRACTIONS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMI-AUTOMATED

	HYDRASYS INSTRUMENT. THE SEPARATED PROTEINS ARE STAINED WITH AMIDOBLACK. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY FOR PATTERN ABNORMALITIES. DENSITOMETRY PROVIDES ACCURATE RELATIVE QUANTIFICATION OF INDIVIDUAL ZONES. EACH AGAROSE GEL IS INTENDED TO RUN: • 7 SAMPLES IN THE HYDRAGEL 7 PROTEIN(E) KIT, . FOR IN VITRO DIAGNOSTIC USE , HYDRAGEL 15 ISO-LDH(HYDRAGEL 15 ISO-LDH)-THESE DEVICES ARE DESIGNED FOR THE IDENTIFICATION AND QUANTIFICATION OF THE FIVE LACTATE DEHYDROGENASE (LD) ISOENZYMES IN HUMAN SERUM BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.4) AGAROSE GELS. ,HYPERGAMMA CONTROL SERUM (20) (HYPERGAMMA CONTROL SERUM (20))-THIS SERUM IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN SERUM PROTEINS ON HYDRAGEL AND CAPILLARYS & MINICAP. THE VALUES OBTAINED MUST FALL WITHIN THE MEAN } 2 SD CONFIDENCE RANGE PROVIDED WITH EACH BATCH OF CONTROL SERUM. THE CONTROL SERUM CAN BE USED FOR THE QUALITY CONTROL OF SERUM FREE LIGHT CHAINS QUANTIFICATION WITH SEBIA FLC KAPPA AND SEBIA FLC LAMBDA KITS ,CAPILLARYS IMMUNOTYPING(CAPILLARYS IMMUNOTYPING)-THE CAPILLARYS IMMUNOTYPING KIT IS DESIGNED FOR THE DETECTION AND THE CHARACTERIZATION OF MONOCLONAL PROTEINS (IMMUNOTYPING) IN HUMAN URINE AND SERUM WITH THE CAPILLARYS SYSTEM, SEBIA, FOR CAPILLARY ELECTROPHORESIS. IT IS USED IN CONJUNCTION WITH THE CAPILLARYS PROTEIN(E) 6 KIT, SEBIA, DESIGNED FOR PROTEINS SEPARATION INTO 6 MAJOR FRACTIONS IN ALKALINE BUFFER (PH 9.9). THE CAPILLARYS PERFORMS ALL PROCEDURAL SEQUENCES AUTOMATICALLY TO OBTAIN A PROTEIN PROFILE FOR QUALITATIVE ANALYSIS. EACH URINE OR SERUM SAMPLE IS MIXED WITH INDIVIDUAL ANTISERA THAT ARE SPECIFIC AGAINST GAMMA (IG G), ALPHA (IG A) AND MU (IG M) HEAVY CHAINS, AND KAPPA (FREE AND BOUND) LIGHT CHAINS AND LAMBDA (FREE AND BOUND) LIGHT CHAINS, RESPECTIVELY. THE PROTEINS, SEPARATED IN SILICA CAPILLARIES, ARE DIRECTLY DETECTED BY THEIR ABSORBANCE AT 200 NM. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY TO DETECT THE PRESENCE OF SPECIFIC REACTIONS WITH THE SUSPECT MONOCLONAL PROTEINS. FOR IN VITRO DIAGNOSTIC USE ,MINICAP HEMOGLOBIN(E)(MINICAP HEMOGLOBIN(E))-THE MINICAP HEMOGLOBIN(E) KIT IS DESIGNED FOR THE SEPARATION OF THE NORMAL HEMOGLOBINS (A, A2 AND F) IN HUMAN BLOOD SAMPLES, AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS (S, C, E AND D), BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE SEBIA MINICAP AND MINICAP FLEX-PIERCING INSTRUMENTS. FOR IN VITRO DIAGNOSTIC USE. ,MINICAP

	HEMOGLOBIN(E) MAXI-KIT(MINICAP HEMOGLOBIN(E) MAXI-KIT)-THE MINICAP HEMOGLOBIN(E) MAXI-KIT IS DESIGNED FOR THE SEPARATION OF THE NORMAL HEMOGLOBINS (A, A2 AND F) IN HUMAN BLOOD SAMPLES, AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS (S, C, E AND D), BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE SEBIA MINICAP AND MINICAP FLEX-PIERCING INSTRUMENTS ,CAPI 3 URINE (CAPI 3 URINE)-THIS DEVICE IS DESIGNED FOR THE PREPARATION OF HUMAN URINE SAMPLES FOR ANALYSIS WITH THE CAPI 3 URINE PROCEDURE. ,NORMAL CONTROL SERUM (5)(NORMAL CONTROL SERUM (5))-THIS SERUM IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN SERUM PROTEINS, LIPOPROTEINS, CHOLESTEROL AND APOLIPOPROTEINS ON HYDRAGEL AND FOR SERUM PROTEINS ON CAPILLARYS & MINICAP. IT IS USED AS A "MARKER" FOR IDENTIFICATION OF THE DIFFERENT ISOENZYMES SEPARATED BY ELECTROPHORETIC METHODS. THE VALUES OBTAINED MUST FALL WITHIN THE MEAN } 2 SD CONFIDENCE RANGE PROVIDED WITH EACH BATCH OF CONTROL SERUM. THE CONTROL SERUM CAN BE USED FOR THE QUALITY CONTROL OF SERUM FREE LIGHT CHAINS QUANTIFICATION WITH SEBIA FLC KAPPA AND SEBIA FLC LAMBDA KITS ,MULTI-SYSTEM HB A1C CAPILLARY CONTROLS (2)(MULTI-SYSTEM HB A1C CAPILLARY CONTROLS (2))-THE MULTI-SYSTEM HB A1C CAPILLARY CONTROLS (2) ARE DESIGNED FOR THE MIGRATION CONTROL AND QUALITY CONTROL OF HUMAN GLYCATED HEMOGLOBIN A1C QUANTIFICATION WITH SEBIA CAPILLARY ELECTROPHORESIS PROCEDURES : - CAPILLARYS HB A1C PERFORMED WITH THE CAPILLARYS 2 FLEX-PIERCING AUTOMATED INSTRUMENT, - CAPI 3 HB A1C PERFORMED WITH THE CAPILLARYS 3 AUTOMATED INSTRUMENT AND, - MINICAP HB A1C PERFORMED WITH THE MINICAP FLEX-PIERCING AUTOMATED INSTRUMENT. THE HB A1C CAPILLARY CONTROLS ARE DESIGNED FOR LABORATORY USE. THEY SHOULD BE USED LIKE HUMAN BLOODS. THE VALUES OBTAINED MUST FALL WITHIN THE RANGE DETERMINED FOR EACH BATCH.,MINICAP HEMOGLOBIN(E) BUFFER (MINICAP HEMOGLOBIN(E) BUFFER)-ALKALINE BUFFER FOR THE SEPARATION OF THE NORMAL HEMOGLOBINS (A, F AND A2) AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS (ESPECIALLY S, C, E OR D) BY CAPILLARY ELECTROPHORESIS WITH THE MINICAP AUTOMATIC SYSTEM. ,CAPILLARYS PROTEIN(E) 6 BUFFER(CAPILLARYS PROTEIN(E) 6 BUFFER)-ALKALINE BUFFER FOR SERUM PROTEINS ANALYSIS (6 FRACTIONS) BY CAPILLARY ELECTROPHORESIS WITH THE CAPILLARYS AUTOMATIC SYSTEM. , HYDRAGEL 2 IF (SM)(HYDRAGEL 2 IF (SM))-THE HYDRAGEL 1 IF, 2 IF, 4 IF AND 9 IF KITS ARE DESIGNED FOR DETECTION OF MONOCLONAL

	PROTEINS IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS. THE PROTEINS, SEPARATED BY ELECTROPHORESIS ON ALKALINE BUFFERED AGAROSE GELS, ARE INCUBATED WITH INDIVIDUAL ANTISERA THAT ARE SPECIFIC AGAINST GAMMA (IG G), ALPHA (IG A) AND MU (IG M) HEAVY CHAINS, AND KAPPA (FREE AND BOUND) AND LAMBDA (FREE AND BOUND) LIGHT CHAINS, RESPECTIVELY. AFTER REMOVING THE NON-REACTED PROTEINS, THE IMMUNOPRECIPITATES ARE STAINED EITHER WITH ACID VIOLET OR AMIDO BLACK. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY FOR THE PRESENCE OF SPECIFIC REACTIONS WITH THE SUSPECT MONOCLONAL PROTEINS. EACH AGAROSE GEL IS INTENDED TO RUN : - ONE SAMPLE IN THE HYDRAGEL 1 IF KIT, - TWO SAMPLES IN THE HYDRAGEL 2 IF KIT, - FOUR SAMPLES IN THE HYDRAGEL 4 IF KITS, - NINE SAMPLES IN THE HYDRAGEL 9 IF KITS. TO ACCOMMODATE DIVERSE USER PREFERENCES, THE HYDRAGEL 4 IF KITS ARE AVAILABLE EITHER WITH ACID VIOLET OR WITH AMIDOBLACK. FOR IN VITRO DIAGNOSTIC USE ,HYDRAGEL 9 IF (SM) (HYDRAGEL 9 IF (SM))-THE HYDRAGEL 1 IF, 2 IF, 4 IF AND 9 IF KITS ARE DESIGNED FOR DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS. THE PROTEINS, SEPARATED BY ELECTROPHORESIS ON ALKALINE BUFFERED AGAROSE GELS, ARE INCUBATED WITH INDIVIDUAL ANTISERA THAT ARE SPECIFIC AGAINST GAMMA (IG G), ALPHA (IG A) AND MU (IG M) HEAVY CHAINS, AND KAPPA (FREE AND BOUND) AND LAMBDA (FREE AND BOUND) LIGHT CHAINS, RESPECTIVELY. AFTER REMOVING THE NON-REACTED PROTEINS, THE IMMUNOPRECIPITATES ARE STAINED EITHER WITH ACID VIOLET OR AMIDO BLACK. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY FOR THE PRESENCE OF SPECIFIC REACTIONS WITH THE SUSPECT MONOCLONAL PROTEINS. EACH AGAROSE GEL IS INTENDED TO RUN : - ONE SAMPLE IN THE HYDRAGEL 1 IF KIT, - TWO SAMPLES IN THE HYDRAGEL 2 IF KIT, - FOUR SAMPLES IN THE HYDRAGEL 4 IF KITS, - NINE SAMPLES IN THE HYDRAGEL 9 IF KITS. TO ACCOMMODATE DIVERSE USER PREFERENCES, THE HYDRAGEL 4 IF KITS ARE AVAILABLE EITHER WITH ACID VIOLET OR WITH AMIDOBLACK. FOR IN VITRO DIAGNOSTIC USE ,HYDRAGEL 11 VON WILLEBRAND MULTIMERS (HYDRAGEL 11 VON WILLEBRAND MULTIMERS)-THE HYDRAGEL 5 VON WILLEBRAND MULTIMERS AND HYDRAGEL 11 VON WILLEBRAND MULTIMERS KITS ARE DESIGNED FOR THE DETECTION AND THE ANALYSIS OF THE DISTRIBUTION OF VON WILLEBRAND FACTOR

	MULTIMERS IN HUMAN PLASMA BY AGAROSE GEL ELECTROPHORESIS AND IMMUNOFIXATION, WITH THE SEMIAUTOMATED HYDRASYS 2 INSTRUMENT. THE SEMI-AUTOMATED HYDRASYS 2 INSTRUMENT PERFORMS ALL THE STEPS NEEDED TO OBTAIN GELS READY FOR QUALITATIVE ANALYSIS. PLASMA PROTEINS ARE SEPARATED ACCORDING TO THEIR MOLECULAR WEIGHT IN NEUTRAL BUFFER (PH 7.0) CONTAINING AN ANIONIC DETERGENT. AFTER IMMUNOPRECIPITATION OF PROTEINS IN THE GEL WITH A SPECIFIC ANTISERUM, VON WILLEBRAND FACTOR MULTIMERS ARE VISUALIZED USING A PEROXIDASE-LABELLED ANTIBODY. EACH AGAROSE GEL IS INTENDED TO RUN : - 5 SAMPLES IN THE HYDRAGEL 5 VON WILLEBRAND MULTIMERS KIT, - 11 SAMPLES IN THE HYDRAGEL 11 VON WILLEBRAND MULTIMERS KIT. FOR IN VITRO DIAGNOSTIC USE ONLY. ,MINICAP CDT(MINICAP CDT)-THIS DEVICE IS DESIGNED FOR THE SEPARATION OF HUMAN SERUM TRANSFERRIN ISOFORMS IN ALKALINE BUFFER (PH 8.8) WITH THE MINICAP SYSTEM. THIS DEVICE IS DESIGNED FOR THE SEPARATION AND QUANTIFICATION OF THE DISIALOTRANSFERRIN FRACTION ("CDT-IFCC") IN HUMAN SERUM BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 8.8) WITH THE MINICAP AND MINICAP FLEXPIERCING INSTRUMENTS. ,HYPERGAMMA CONTROL SERUM (5)(HYPERGAMMA CONTROL SERUM (5))-THIS SERUM IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN SERUM PROTEINS ON HYDRAGEL AND CAPILLARYS & MINICAP. THE VALUES OBTAINED MUST FALL WITHIN THE MEAN } 2 SD CONFIDENCE RANGE PROVIDED WITH EACH BATCH OF CONTROL SERUM. THE CONTROL SERUM CAN BE USED FOR THE QUALITY CONTROL OF SERUM FREE LIGHT CHAINS QUANTIFICATION WITH SEBIA FLC KAPPA AND SEBIA FLC LAMBDA KITS ,HYDRAGEL 7 HR ACID VIOLET(HYDRAGEL 7 HR ACID VIOLET)-THESE DEVICES ARE DESIGNED FOR MULTI-FRACTIONATION OF PROTEINS FROM HUMAN SERA OR OTHER BIOLOGICAL FLUIDS, SUCH AS URINE AND CEREBROSPINAL FLUID (CSF), BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.6) AGAROSE GELS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMIAUTOMATED HYDRASYS INSTRUMENT. THE HYDRASYS INSTRUMENT ALLOWS ALL. FOR IN VITRO DIAGNOSTIC USE ,HYDRAGEL 7 ACID(E) HEMOGLOBIN(E)(HYDRAGEL 7 ACID(E) HEMOGLOBIN(E))-THESE DEVICES ARE DESIGNED FOR SEPARATION OF THE NORMAL HEMOGLOBIN A, ABNORMAL HEMOGLOBINS S AND C AND FETAL HEMOGLOBIN F, BY ELECTROPHORESIS ON ACIDIC AGAROSE GELS. ,ANTI-IG D 1 ML (SM)(ANTI-IG D 1 ML (SM))-THIS ANTISERUM IS WELL-SUITED FOR ALL PRECIPITATION TECHNIQUES. THE ANTIBODY REACTS IN IMMUNOFIXATION WITH HEAVY CHAINS WITH HUMAN IG D, BUT NOT

	WITH THE LIGHT CHAINS OF HUMAN IMMUNOGLOBULINS. THE ANTIBODY DOES NOT REACT WITH THE HEAVY CHAINS ON HUMAN IG A, IG G OR IG M. ,HYDRAGEL 2 BENCE JONES (SM)(HYDRAGEL 2 BENCE JONES (SM))-THE HYDRAGEL 1 BENCE JONES, HYDRAGEL 2 BENCE JONES, HYDRAGEL 4 BENCE JONES AND HYDRAGEL 9 BENCE JONES KITS ARE DESIGNED FOR QUALITATIVE DETECTION AND IDENTIFICATION OF BENCE JONES PROTEINS, MONOCLONAL FREE LIGHT CHAINS KAPPA OR LAMBDA, IN HUMAN URINE OR SERUM, BY IMMUNOFIXATION ELECTROPHORESIS. THE DETECTION OF BENCE JONES PROTEINS SERVES AS A QUALITATIVE AID IN THE IDENTIFICATION OF MONOCLONAL GAMMOPATHIES. EACH AGAROSE GEL IS INTENDED TO RUN : - ONE SAMPLE IN THE HYDRAGEL 1 BENCE JONES KIT, - TWO SAMPLES IN THE HYDRAGEL 2 BENCE JONES KIT, - FOUR SAMPLES IN THE HYDRAGEL 4 BENCE JONES KIT, - NINE SAMPLES IN THE HYDRAGEL 9 BENCE JONES KITS. FOR IN VITRO DIAGNOSTIC USE. ,CAPILLARYS / MINICAP URINE(CAPILLARYS / MINICAP URINE)-THE CAPILLARYS / MINICAP URINE KIT IS DESIGNED FOR THE PREPARATION OF URINE SAMPLES BEFORE SEPARATION OF HUMAN URINE PROTEINS IN ALKALINE BUFFER (PH 9.9) WITH THE CAPILLARYS AND MINICAP INSTRUMENTS.,HYDRAGEL 2 IF / BJ (HR) (HYDRAGEL 2 IF / BJ (HR))-THE HYDRAGEL 2 IF / BJ (HR) KIT IS DESIGNED FOR DETECTION AND IDENTIFICATION OF MONOCLONAL PROTEINS AND BENCE JONES PROTEINS, MONOCLONAL FREE LIGHT CHAINS KAPPA OR LAMBDA, IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS.,HYDRAGEL PROTEIN(E) K20 (HYDRAGEL PROTEIN(E) K20)-THE HYDRAGEL PROTEIN(E) K20 KIT IS DESIGNED FOR SEPARATION OF HUMAN SERUM PROTEINS INTO SIX MAJOR FRACTIONS BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.6) AGAROSE GELS.,HYDRAGEL IF K20 (SM)(HYDRAGEL IF K20 (SM))-THESE DEVICES ARE DESIGNED FOR THE DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM BY IMMUNOFIXATION ELECTROPHORESIS ON ALKALINE BUFFERED (PH 9.1) AGAROSE GELS.,HYDRAGEL DOUBLE IF K20 (SM)(HYDRAGEL DOUBLE IF K20 (SM))-THESE DEVICES ARE DESIGNED FOR THE DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM BY IMMUNOFIXATION ELECTROPHORESIS ON ALKALINE BUFFERED (PH 9.1) AGAROSE GELS.,HYDRAGEL HEMOGLOBIN(E) K20(HYDRAGEL HEMOGLOBIN(E) K20)-THIS DEVICE IS DESIGNED FOR SEPARATION OF THE NORMAL HEMOGLOBINS (A AND A2) AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS: S OR D AND C OR E, BY ELECTROPHORESIS ON ALKALINE AGAROSE GELS.,ACID VIOLET STAINING SOLUTION (ACID VIOLET STAINING SOLUTION)-USED FOR STAINING GELS WITH ELECTROPHORETIC PROTEIN SEPARATIONS,HYDRAGEL 9 IF (SM) MAXI-KIT(HYDRAGEL 9 IF (SM) MAXI-KIT)-THE HYDRAGEL 1 IF, 2 IF, 4

	IF AND 9 IF KITS ARE DESIGNED FOR DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS. THE PROTEINS, SEPARATED BY ELECTROPHORESIS ON ALKALINE BUFFERED AGAROSE GELS, ARE INCUBATED WITH INDIVIDUAL ANTISERA THAT ARE SPECIFIC AGAINST GAMMA (IG G), ALPHA (IG A) AND MU (IG M) HEAVY CHAINS, AND KAPPA (FREE AND BOUND) AND LAMBDA (FREE AND BOUND) LIGHT CHAINS, RESPECTIVELY. AFTER REMOVING THE NON-REACTED PROTEINS, THE IMMUNOPRECIPITATES ARE STAINED EITHER WITH ACID VIOLET OR AMIDO BLACK. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY FOR THE PRESENCE OF SPECIFIC REACTIONS WITH THE SUSPECT MONOCLONAL PROTEINS. EACH AGAROSE GEL IS INTENDED TO RUN : - ONE SAMPLE IN THE HYDRAGEL 1 IF KIT, - TWO SAMPLES IN THE HYDRAGEL 2 IF KIT, - FOUR SAMPLES IN THE HYDRAGEL 4 IF KITS, - NINE SAMPLES IN THE HYDRAGEL 9 IF KITS. TO ACCOMMODATE DIVERSE USER PREFERENCES, THE HYDRAGEL 4 IF KITS ARE AVAILABLE EITHER WITH ACID VIOLET OR WITH AMIDOBLACK. FOR IN VITRO DIAGNOSTIC USE ,ANTI-IG G - PER(ANTI-IG G - PER)-THESE ANTISERA ARE DESIGNED FOR THE QUALITATIVE DETECTION AND IDENTIFICATION OF "OLIGOCLONAL" BANDS IN THE ELECTROPHORETIC PATTERNS OF CEREBROSPINAL FLUID (CSF) AFTER MIGRATION AND IMMUNOFIXATION PROCEDURES ON AGAROSE GELS IN CONJUNCTION WITH THE SEMIAUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS. ,HYDRAGEL 7 ß1-ß2 (HYDRAGEL 7 ß1-ß2)-THESE DEVICES ARE INTENDED FOR SEPARATION OF PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.5) AGAROSE GELS. ,ANTI-IG E 1 ML (SM)(ANTI-IG E 1 ML (SM))-THIS ANTISERUM IS WELL-SUITED FOR ALL PRECIPITATION TECHNIQUES. THE ANTISERUM REACTS ONLY IN IMMUNOFIXATION WITH HUMAN SERUM WITH HIGH IG E CONCENTRATION. NO REACTIVITY TO LIGHT CHAINS OR HEAVY CHAINS OF OTHER IMMUNOGLOBULINS IS OBSERVED , CAPILLARYS HEMOGLOBIN(E) BUFFER(CAPILLARYS HEMOGLOBIN(E) BUFFER)-ALKALINE BUFFER FOR THE SEPARATION OF THE NORMAL HEMOGLOBINS (A, F AND A2) AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS (ESPECIALLY S, C, E OR D) BY CAPILLARY ELECTROPHORESIS WITH THE CAPILLARYS AUTOMATIC SYSTEM. ,MINICAP FLEX-PIERCING CAPICLEAN(MINICAP FLEX-PIERCING CAPICLEAN)-CAPICLEAN SOLUTION IS USED FOR CLEANING OF THE SAMPLE PROBE IN AUTOMATED INSTRUMENT MINICAP FLEX-PIERCING, SEBIA, FOR CAPILLARY ELECTROPHORESIS, DURING THE CAPICLEAN CLEANING SEQUENCE. NOTE : A CAPICLEAN

	CLEANING SEQUENCE INCLUDES THE SAMPLE PROBE CLEANING WITH THE CAPICLEAN REAGENT AND THE CAPILLARIES CLEANING WITH THE MINICAP WASH SOLUTION. FOR IN VITRO DIAGNOSTIC USE. ,CAPILLARYS / MINICAP WASH SOLUTION (2)(CAPILLARYS / MINICAP WASH SOLUTION (2))-USED FOR WASHING THE CAPILLARIES OF CAPILLARYS 2/MINICAP,CAPI 3 CDT(CAPI 3 CDT)-THIS DEVICE IS DESIGNED FOR THE SEPARATION OF THE TRANSFERRIN ISOFORMS IN HUMAN SERUM AND THE QUANTIFICATION OF THE CDT (CARBOHYDRATE DEFICIENT TRANSFERRIN) BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 8.8) WITH THE CAPILLARYS 3 INSTRUMENT. THIS DEVICE IS DESIGNED FOR THE SEPARATION OF THE TRANSFERRIN ISOFORMS IN HUMAN SERUM AND THE QUANTIFICATION OF THE DISIALOTRANSFERRIN FRACTION ("CDT-IFCC") BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 8.8) WITH THE CAPILLARYS 3 INSTRUMENT,HYDRAGEL 9 BENCE JONES (SM) MAXI-KIT(HYDRAGEL 9 BENCE JONES (SM) MAXI-KIT)-THE HYDRAGEL 1 BENCE JONES, HYDRAGEL 2 BENCE JONES, HYDRAGEL 4 BENCE JONES AND HYDRAGEL 9 BENCE JONES KITS ARE DESIGNED FOR QUALITATIVE DETECTION AND IDENTIFICATION OF BENCE JONES PROTEINS, MONOCLONAL FREE LIGHT CHAINS KAPPA OR LAMBDA, IN HUMAN URINE OR SERUM, BY IMMUNOFIXATION ELECTROPHORESIS. THE DETECTION OF BENCE JONES PROTEINS SERVES AS A QUALITATIVE AID IN THE IDENTIFICATION OF MONOCLONAL GAMMOPATHIES. EACH AGAROSE GEL IS INTENDED TO RUN : - ONE SAMPLE IN THE HYDRAGEL 1 BENCE JONES KIT, - TWO SAMPLES IN THE HYDRAGEL 2 BENCE JONES KIT, - FOUR SAMPLES IN THE HYDRAGEL 4 BENCE JONES KIT, - NINE SAMPLES IN THE HYDRAGEL 9 BENCE JONES KITS. FOR IN VITRO DIAGNOSTIC USE. ,HYDRAGEL 30 PROTEIN(E)(HYDRAGEL 30 PROTEIN(E))-THE HYDRAGEL 7 PROTEIN(E) AND HYDRAGEL PROTEIN (E) 15/30 GELS ARE INTENDED FOR SEPARATION OF HUMAN SERUM PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 9.1) AGAROSE GELS. BY DESIGN, THE NORMAL HUMAN SERUM PROTEINS SEPARATE INTO FIVE MAJOR FRACTIONS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS INSTRUMENT. THE SEPARATED PROTEINS ARE STAINED WITH AMIDOBLACK. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY FOR PATTERN ABNORMALITIES. DENSITOMETRY PROVIDES ACCURATE RELATIVE QUANTIFICATION OF INDIVIDUAL ZONES. EACH AGAROSE GEL IS INTENDED TO RUN: • 30 SAMPLES IN THE HYDRAGEL 30 PROTEIN(E) KIT. FOR IN VITRO DIAGNOSTIC USE ,HYDRAGEL 7 ISO-CK(HYDRAGEL 7 ISO-CK)-THE HYDRAGEL 7, 15 AND 30 ISO-CK KITS ARE DESIGNED FOR THE IDENTIFICATION AND QUANTIFICATION OF THE THREE CREATINE

	KINASE (CK) ISOENZYMES IN HUMAN SERUM BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.4) AGAROSE GELS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS SYSTEM. THE RESULTING GELS ARE READY FOR VISUAL EXAMINATION AND DENSITOMETRY TO OBTAIN ACCURATE RELATIVE QUANTIFICATION OF INDIVIDUAL ZONES. EACH AGAROSE GEL IS INTENDED TO RUN: • 7 SAMPLES IN THE HYDRAGEL 7 ISO-CK KIT, • 15 SAMPLES IN THE HYDRAGEL 15 ISO-CK KIT, • 30 SAMPLES IN THE HYDRAGEL 30 ISO-CK KIT. FOR IN VITRO DIAGNOSTIC USE., HYDRAGEL 15 LIPOPROTEIN(E)(HYDRAGEL 15 LIPOPROTEIN(E))-THE HYDRAGEL 7, 15 AND 30 LIPOPROTEIN(E) KITS ARE DESIGNED FOR DETERMINATION OF LIPOPROTEIN PROFILES IN HUMAN SERUM. EACH AGAROSE GEL IS INTENDED TO RUN: • 7 SAMPLES WITH THE HYDRAGEL 7 LIPOPROTEIN(E) KIT, • 15 SAMPLES WITH THE HYDRAGEL 15 LIPOPROTEIN(E) KIT, • 30 SAMPLES WITH THE HYDRAGEL 30 LIPOPROTEIN(E) KIT. FOR IN VITRO DIAGNOSTIC USE., HYDRAGEL 30 ISO-CK(HYDRAGEL 30 ISO-CK)-THE HYDRAGEL 7, 15 AND 30 ISO-CK KITS ARE DESIGNED FOR THE IDENTIFICATION AND QUANTIFICATION OF THE THREE CREATINE KINASE (CK) ISOENZYMES IN HUMAN SERUM BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.4) AGAROSE GELS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS SYSTEM. THE RESULTING GELS ARE READY FOR VISUAL EXAMINATION AND DENSITOMETRY TO OBTAIN ACCURATE RELATIVE QUANTIFICATION OF INDIVIDUAL ZONES. EACH AGAROSE GEL IS INTENDED TO RUN: • 7 SAMPLES IN THE HYDRAGEL 7 ISO-CK KIT, • 15 SAMPLES IN THE HYDRAGEL 15 ISO-CK KIT, • 30 SAMPLES IN THE HYDRAGEL 30 ISO-CK KIT. FOR IN VITRO DIAGNOSTIC USE., HYDRAGEL 7 LIPOPROTEIN(E)(HYDRAGEL 7 LIPOPROTEIN(E))-THE HYDRAGEL 7, 15 AND 30 LIPOPROTEIN(E) KITS ARE DESIGNED FOR DETERMINATION OF LIPOPROTEIN PROFILES IN HUMAN SERUM. EACH AGAROSE GEL IS INTENDED TO RUN: • 7 SAMPLES WITH THE HYDRAGEL 7 LIPOPROTEIN(E) KIT, • 15 SAMPLES WITH THE HYDRAGEL 15 LIPOPROTEIN(E) KIT, • 30 SAMPLES WITH THE HYDRAGEL 30 LIPOPROTEIN(E) KIT. FOR IN VITRO DIAGNOSTIC USE., HYDRAGEL 15 ISO-CK(HYDRAGEL 15 ISO-CK)-THE HYDRAGEL 7, 15 AND 30 ISO-CK KITS ARE DESIGNED FOR THE IDENTIFICATION AND QUANTIFICATION OF THE THREE CREATINE KINASE (CK) ISOENZYMES IN HUMAN SERUM BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.4) AGAROSE GELS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS SYSTEM. THE RESULTING GELS ARE READY FOR VISUAL EXAMINATION AND DENSITOMETRY TO OBTAIN ACCURATE RELATIVE QUANTIFICATION OF INDIVIDUAL ZONES. EACH AGAROSE

	GEL IS INTENDED TO RUN: • 7 SAMPLES IN THE HYDRAGEL 7 ISO-CK KIT, • 15 SAMPLES IN THE HYDRAGEL 15 ISO-CK KIT, • 30 SAMPLES IN THE HYDRAGEL 30 ISO-CK KIT. FOR IN VITRO DIAGNOSTIC USE., HYDRAGEL 30 LIPOPROTEIN(E)(HYDRAGEL 30 LIPOPROTEIN(E))-THE HYDRAGEL 7, 15 AND 30 LIPOPROTEIN(E) KITS ARE DESIGNED FOR DETERMINATION OF LIPOPROTEIN PROFILES IN HUMAN SERUM. EACH AGAROSE GEL IS INTENDED TO RUN: • 7 SAMPLES WITH THE HYDRAGEL 7 LIPOPROTEIN(E) KIT, • 15 SAMPLES WITH THE HYDRAGEL 15 LIPOPROTEIN(E) KIT, • 30 SAMPLES WITH THE HYDRAGEL 30 LIPOPROTEIN(E) KIT. FOR IN VITRO DIAGNOSTIC USE, HB A1C CAPILLARY CALIBRATORS (2)(HB A1C CAPILLARY CALIBRATORS (2))-THIS DEVICE IS DESIGNED FOR THE CALIBRATION OF CAPILLARY ELECTROPHORETIC QUANTIFICATION OF HUMAN GLYCATED HEMOGLOBIN A1C ACCORDING TO THE IFCC AND NGSP REQUIREMENTS ,CAPI 3 PROTEIN(E) 6(CAPI 3 PROTEIN(E) 6)-HE CAPI 3 PROTEIN(E) 6 KIT IS DESIGNED FOR THE SEPARATION OF HUMAN SERUM PROTEINS BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.9) WITH THE CAPILLARYS 3 INSTRUMENT. NORMAL SERUM PROTEINS SEPARATE INTO SIX MAJOR FRACTIONS. THE CAPILLARYS 3 INSTRUMENT PERFORMS ALL SEQUENCES AUTOMATICALLY TO OBTAIN A PROTEIN PROFILE FOR QUALITATIVE OR QUANTITATIVE ANALYSIS. THE PROTEINS, SEPARATED IN SILICA CAPILLARIES, ARE DIRECTLY DETECTED AT AN ABSORBANCE OF 200 NM. THE ELECTROPHOREGRAMS CAN BE INTERPRETED VISUALLY TO SCREEN FOR ANY PATTERN ABNORMALITIES. DIRECT DETECTION PROVIDES ACCURATE RELATIVE QUANTIFICATION OF INDIVIDUAL PROTEIN FRACTIONS. FOR IN VITRO DIAGNOSTIC USE. ,CAPI 3 HEMOGLOBIN(E)(CAPI 3 HEMOGLOBIN(E))-THE CAPI 3 HEMOGLOBIN (E) KIT IS DESIGNED FOR THE SEPARATION OF THE NORMAL HEMOGLOBINS (A, A2 AND F) IN HUMAN BLOOD SAMPLES, AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS (S, C, E AND D), BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE SEBIA CAPILLARYS 3 INSTRUMENT. THE CAPILLARYS 3 INSTRUMENT IS AN AUTOMATED ANALYZER WHICH PERFORMS A COMPLETE HEMOGLOBIN PROFILE FOR THE QUANTITATIVE ANALYSIS OF THE NORMAL HEMOGLOBIN FRACTIONS A, A2 AND F AND FOR THE DETECTION OF MAJOR HEMOGLOBIN VARIANTS S, C, E AND D. THE ASSAY IS PERFORMED ON THE HEMOLYSATE OF WHOLE BLOOD SAMPLES COLLECTED IN TUBES CONTAINING KEDTA AS ANTICOAGULANT. FOR IN VITRO DIAGNOSTIC USE. ,MULTI-SYSTEM HB A1C CAPILLARY CONTROLS (10X2)(MULTI-SYSTEM HB A1C CAPILLARY CONTROLS (10X2))-THE MULTI-SYSTEM HB A1C CAPILLARY CONTROLS (2) ARE DESIGNED FOR THE MIGRATION CONTROL AND QUALITY CONTROL OF HUMAN GLYCATED

	HEMOGLOBIN A1C QUANTIFICATION WITH SEBIA CAPILLARY ELECTROPHORESIS PROCEDURES : - CAPILLARYS HB A1C PERFORMED WITH THE CAPILLARYS 2 FLEX-PIERCING AUTOMATED INSTRUMENT, - CAPI 3 HB A1C PERFORMED WITH THE CAPILLARYS 3 AUTOMATED INSTRUMENT AND, - MINICAP HB A1C PERFORMED WITH THE MINICAP FLEX-PIERCING AUTOMATED INSTRUMENT. THE HB A1C CAPILLARY CONTROLS ARE DESIGNED FOR LABORATORY USE. THEY SHOULD BE USED LIKE HUMAN BLOODS. THE VALUES OBTAINED MUST FALL WITHIN THE RANGE DETERMINED FOR EACH BATCH., HYDRAGEL 54 PROTEIN(E) MAXI-KIT(HYDRAGEL 54 PROTEIN(E) MAXI-KIT)-THE HYDRAGEL 54 PROTEIN(E) KIT IS DESIGNED FOR SEPARATION OF HUMAN SERUM PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 9.1) AGAROSE GELS. BY DESIGN, THE NORMAL HUMAN SERUM PROTEINS SEPARATE INTO FIVE MAJOR FRACTIONS. THE KIT IS USED IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS INSTRUMENT. THE SEPARATED PROTEINS ARE STAINED WITH AMIDOBLACK. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY FOR PATTERN ABNORMALITIES. DENSITOMETRY PROVIDES ACCURATE RELATIVE QUANTIFICATION OF INDIVIDUAL ZONES. EACH AGAROSE GEL IS INTENDED TO RUN 54 SAMPLES. FOR IN VITRO DIAGNOSTIC USE ,CAPILLARYS 3 CAPICLEAN(CAPILLARYS 3 CAPICLEAN)-FOR THE SAMPLE PROBE CLEANING IN AUTOMATED INSTRUMENT FOR CAPILLARY ELECTROPHORESIS CAPILLARYS 3, SEBIA, DURING THE CAPICLEAN CLEANING SEQUENCE. FOR IN VITRO DIAGNOSTIC USE. ,HYDRAGEL 7 ISO-PAL(HYDRAGEL 7 ISO-PAL)-THESE DEVICES ARE DESIGNED FOR THE IDENTIFICATION AND QUANTIFICATION OF ALKALINE PHOSPHATASE (AP) ISOENZYMES IN HUMAN SERUM. ,HYDRAGEL 1 BENCE JONES (SM)(HYDRAGEL 1 BENCE JONES (SM))-THE HYDRAGEL 1 BENCE JONES, HYDRAGEL 2 BENCE JONES, HYDRAGEL 4 BENCE JONES AND HYDRAGEL 9 BENCE JONES KITS ARE DESIGNED FOR QUALITATIVE DETECTION AND IDENTIFICATION OF BENCE JONES PROTEINS, MONOCLONAL FREE LIGHT CHAINS KAPPA OR LAMBDA, IN HUMAN URINE OR SERUM, BY IMMUNOFIXATION ELECTROPHORESIS. THE DETECTION OF BENCE JONES PROTEINS SERVES AS A QUALITATIVE AID IN THE IDENTIFICATION OF MONOCLONAL GAMMOPATHIES. EACH AGAROSE GEL IS INTENDED TO RUN : - ONE SAMPLE IN THE HYDRAGEL 1 BENCE JONES KIT, - TWO SAMPLES IN THE HYDRAGEL 2 BENCE JONES KIT, - FOUR SAMPLES IN THE HYDRAGEL 4 BENCE JONES KIT, - NINE SAMPLES IN THE HYDRAGEL 9 BENCE JONES KITS. FOR IN VITRO DIAGNOSTIC USE. ,MINICAP IMMUNOTYPING(MINICAP IMMUNOTYPING)-THE MINICAP IMMUNOTYPING KIT IS DESIGNED FOR THE DETECTION AND THE CHARACTERIZATION OF MONOCLONAL

	PROTEINS (IMMUNOTYPING) IN HUMAN URINE AND SERUM WITH THE MINICAP SYSTEM, SEBIA, FOR CAPILLARY ELECTROPHORESIS. IT IS USED IN CONJUNCTION WITH THE MINICAP PROTEIN(E) 6 KIT, SEBIA, DESIGNED FOR PROTEINS SEPARATION INTO 6 MAJOR FRACTIONS IN ALKALINE BUFFER (PH 9.9). THE MINICAP PERFORMS ALL PROCEDURAL SEQUENCES AUTOMATICALLY TO OBTAIN A PROTEIN PROFILE FOR QUALITATIVE ANALYSIS. EACH URINE OR SERUM SAMPLE IS MIXED WITH INDIVIDUAL ANTISERA THAT ARE SPECIFIC AGAINST GAMMA (IG G), ALPHA (IG A) AND MU (IG M) HEAVY CHAINS, AND KAPPA AND LAMBDA (FREE AND BOUND) LIGHT CHAINS, RESPECTIVELY. THE PROTEINS, SEPARATED IN SILICA CAPILLARIES, ARE DIRECTLY DETECTED BY THEIR ABSORBANCE AT 200 NM. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY TO DETECT THE PRESENCE OF SPECIFIC REACTIONS WITH THE SUSPECTED MONOCLONAL PROTEINS. FOR IN VITRO DIAGNOSTIC USE ,HB AFSC CONTROL(HB AFSC CONTROL)-THE HB AFSC CONTROL IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC SEPARATIONS OF HUMAN HEMOGLOBINS WITH HYDRAGEL HEMOGLOBIN(E)*, HYDRAGEL ACID(E) HEMOGLOBIN(E)*, CAPILLARYS / CAPI 3 / MINICAP HEMOGLOBIN(E)*, CAPILLARYS NEONAT HB* AND CAPILLARYS CORD BLOOD* PROCEDURES. IT SHOULD BE USED AS NORMAL HUMAN BLOOD. IT IS RECOMMENDED TO INCLUDE ONE TRACK OF HB AFSC CONTROL INTO EACH RUN ON HYDRAGEL 7 & 15 HEMOGLOBIN(E) AND HYDRAGEL 7 & 15 ACID(E) HEMOGLOBIN(E) GELS OR ONE ANALYSIS WITH CAPILLARYS, CAPI 3 AND MINICAP HEMOGLOBIN(E) PROCEDURE ,HYDRAGEL 30 ß1-ß2(HYDRAGEL 30 ß1-ß2)-THESE DEVICES ARE INTENDED FOR SEPARATION OF PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.5) AGAROSE GELS. ,PATHOLOGICAL HB A2 CONTROL(PATHOLOGICAL HB A2 CONTROL)-THE PATHOLOGICAL HB A2 CONTROL IS DESIGNED FOR THE QUALITY CONTROL OF QUANTIFICATION OF HUMAN HEMOGLOBIN A2 WITH HYDRAGEL HEMOGLOBIN(E)* AND CAPILLARYS / CAPI 3 / MINICAP HEMOGLOBIN (E)* ELECTROPHORESIS PROCEDURES. IT SHOULD BE USED AS NORMAL HUMAN BLOOD. THE VALUES OBTAINED MUST FALL WITHIN THE RANGE PROVIDED WITH EACH BATCH OF HB A2 CONTROL. , HYDRASYS WASH SOLUTION (10)(HYDRASYS WASH SOLUTION (10))-USED FOR THE CLEANING OF THE HYDRASYS STAINING COMPARTMENT,HYDRAGEL 9 CSF ISOFOCUSING(HYDRAGEL 9 CSF ISOFOCUSING)-THE HYDRAGEL 3 CSF ISOFOCUSING AND HYDRAGEL 9 CSF ISOFOCUSING KITS ARE DESIGNED FOR THE QUALITATIVE DETECTION AND IDENTIFICATION OF "OLIGOCLONAL" BANDS IN THE ELECTROPHORETIC PATTERNS OF CEREBROSPINAL FLUID (CSF) AND CONFIRMATION OF THEIR IMMUNOGLOBULIN CHARACTER. THE

	PROCEDURE INCLUDES ISOELECTROFOCUSING ON AGAROSE GEL, PERFORMED ON THE SEMI-AUTOMATIC HYDRASYS SYSTEM, FOLLOWED BY IMMUNOFIXATION WITH ANTI-IG G ANTISERUM. THE USE OF ENZYME LABELED ANTI-IG G ANTISERUM PERMITS TO DETECT ONLY THE "TRUE" IG G OLIGOCLONAL BANDING AT INCREASED SENSITIVITY OF DETECTION SO THAT THE ANALYSIS CAN BE GENERALLY PERFORMED ON UNCONCENTRATED CSF. THE IG G IMMUNOFIXATION PATTERNS OF CSF AND SERUM FROM THE SAME PATIENT ARE THEN VISUALLY COMPARED. THIS ALLOWS DETECTION OF OLIGOCLONAL BANDING THAT REPRESENTS INTRATHECAL SYNTHESIS OF IMMUNOGLOBULINS. THE HYDRAGEL 3 CSF ISOFOCUSING AND HYDRAGEL 9 CSF ISOFOCUSING KITS ARE INDICATED WHEN CERTAIN DISEASES OF THE CENTRAL NERVOUS SYSTEM (CNS), SUCH AS MULTIPLE SCLEROSIS, ARE SUSPECTED AND THE DETECTION OF OLIGOCLONAL BANDING AND INFLAMMATORY PROCESSES (INTRATHECAL SYNTHESIS OF IMMUNOGLOBULINS) CAN AID TO THE DIAGNOSIS. FOR IN VITRO DIAGNOSTIC USE. ,HYDRAGEL 54 ß1-ß2(HYDRAGEL 54 ß1-ß2)-THESE DEVICES ARE INTENDED FOR SEPARATION OF PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.5) AGAROSE GELS. ,HYDRAGEL 2 URINE PROFIL(E) (SM)(HYDRAGEL 2 URINE PROFIL(E) (SM))-THIS DEVICE IS DESIGNED FOR SCREENING OF MAIN URINARY PROTEINS TO TYPE PROTEINURIA (TUBULAR, GLOMERULAR, OR MIXED) AND IMMUNOGLOBULINS (G, A, M OR D/E) IN HUMAN URINE OR SERUM, BY IMMUNOFIXATION ELECTROPHORESIS ON AGAROSE GELS WITH SPECIFIC ANTISERA. , MINICAP CDT MAXI-KIT(MINICAP CDT MAXI-KIT)-THIS DEVICE IS DESIGNED FOR THE SEPARATION OF HUMAN SERUM TRANSFERRIN ISOFORMS IN ALKALINE BUFFER (PH 8.8) WITH THE MINICAP SYSTEM. THIS DEVICE IS DESIGNED FOR THE SEPARATION AND QUANTIFICATION OF THE DISIALOTRANSFERRIN FRACTION ("CDT-IFCC") IN HUMAN SERUM BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 8.8) WITH THE MINICAP AND MINICAP FLEXPIERCING INSTRUMENTS. ,URINE PROFIL(E) ANTISERA BOX (SM) (URINE PROFIL(E) ANTISERA BOX (SM))-THIS DEVICE IS DESIGNED FOR IMMUNOFIXATION OF THE ELECTROPHORESED PROTEINS, INTERMEDIATE CDT CONTROL(INTERMEDIATE CDT CONTROL)-THE INTERMEDIATE CDT CONTROL IS DESIGNED FOR THE QUALITY CONTROL OF QUANTIFICATION OF HUMAN TRANSFERRIN ISOFORMS WITH THE SEBIA CAPILLARYS CDT, CAPI 3 CDT AND MINICAP CDT CAPILLARY ELECTROPHORESIS PROCEDURES. IT SHOULD BE USED LIKE A HUMAN SERUM. THE VALUES OBTAINED MUST FALL WITHIN THE RANGE PROVIDED WITH EACH BATCH OF CONTROL. FOR IN VITRO DIAGNOSTIC USE. ,CDT CAPILLARYS CALIBRATORS (2 LEVELS)

	(CDT CAPILLARYS CALIBRATORS (2 LEVELS))-THIS DEVICE IS DESIGNED FOR THE CALIBRATION OF CAPILLARY ELECTROPHORETIC QUANTIFICATION OF HUMAN CDT ACCORDING TO THE IFCC REQUIREMENTS. ,HYDRAGEL 1 IF (SM)(HYDRAGEL 1 IF (SM))-THE HYDRAGEL 1 IF, 2 IF, 4 IF AND 9 IF KITS ARE DESIGNED FOR DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS. THE PROTEINS, SEPARATED BY ELECTROPHORESIS ON ALKALINE BUFFERED AGAROSE GELS, ARE INCUBATED WITH INDIVIDUAL ANTISERA THAT ARE SPECIFIC AGAINST GAMMA (IG G), ALPHA (IG A) AND MU (IG M) HEAVY CHAINS, AND KAPPA (FREE AND BOUND) AND LAMBDA (FREE AND BOUND) LIGHT CHAINS, RESPECTIVELY. AFTER REMOVING THE NON-REACTED PROTEINS, THE IMMUNOPRECIPITATES ARE STAINED EITHER WITH ACID VIOLET OR AMIDO BLACK. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY FOR THE PRESENCE OF SPECIFIC REACTIONS WITH THE SUSPECT MONOCLONAL PROTEINS. EACH AGAROSE GEL IS INTENDED TO RUN : - ONE SAMPLE IN THE HYDRAGEL 1 IF KIT, - TWO SAMPLES IN THE HYDRAGEL 2 IF KIT, - FOUR SAMPLES IN THE HYDRAGEL 4 IF KITS, - NINE SAMPLES IN THE HYDRAGEL 9 IF KITS. TO ACCOMMODATE DIVERSE USER PREFERENCES, THE HYDRAGEL 4 IF KITS ARE AVAILABLE EITHER WITH ACID VIOLET OR WITH AMIDOBLACK. FOR IN VITRO DIAGNOSTIC USE ,MINICAP HB A1C (MINICAP HB A1C)-THE MINICAP HB A1C KIT IS DESIGNED FOR SEPARATION AND QUANTIFICATION OF THE HBA1C GLYCATED FRACTION OF HEMOGLOBIN IN HUMAN BLOOD, BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE MINICAP FLEX-PIERCING INSTRUMENT. THE MINICAP HB A1C PROCEDURE PERFORMED WITH THE MINICAP FLEX-PIERCING INSTRUMENT HAS BEEN CERTIFIED BY THE NATIONAL GLYCOHEMOGLOBIN STANDARDIZATION PROGRAM (NGSP). FOR IN VITRO DIAGNOSTIC USE ,HYDRAGEL 15 ACID(E) HEMOGLOBIN(E)(HYDRAGEL 15 ACID(E) HEMOGLOBIN(E))-THESE DEVICES ARE DESIGNED FOR SEPARATION OF THE NORMAL HEMOGLOBIN A, ABNORMAL HEMOGLOBINS S AND C AND FETAL HEMOGLOBIN F, BY ELECTROPHORESIS ON ACIDIC AGAROSE GELS. ,CAPI 3 HB A1C(CAPI 3 HB A1C)-THIS DEVICE IS DESIGNED FOR SEPARATION AND QUANTIFICATION OF THE HBA1C, GLYCOSYLATED FRACTION OF HEMOGLOBIN IN HUMAN BLOOD, BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE CAPILLARYS 3 SYSTEM. ,DTT DILUENT (IF / IT)(DTT DILUENT (IF / IT))-THE DTT DILUENT (IF / IT) IS INTENDED FOR THE RECONSTITUTION OF A DITHIOTHREITOL (DTT) VIAL FOR THE PREPARATION OF A DTT 0.5 M REDUCING SOLUTION THAT IS USED

	TO DEPOLYMERIZE MONOCLONAL PROTEINS, FOR THE ANALYSIS , HYDRAGEL 15 PROTEIN(E)(HYDRAGEL 15 PROTEIN(E))-THE HYDRAGEL 7 PROTEIN(E) AND HYDRAGEL PROTEIN(E) 15/30 GELS ARE INTENDED FOR SEPARATION OF HUMAN SERUM PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 9.1) AGAROSE GELS. BY DESIGN, THE NORMAL HUMAN SERUM PROTEINS SEPARATE INTO FIVE MAJOR FRACTIONS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS INSTRUMENT. THE SEPARATED PROTEINS ARE STAINED WITH AMIDOBLACK. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY FOR PATTERN ABNORMALITIES. DENSITOMETRY PROVIDES ACCURATE RELATIVE QUANTIFICATION OF INDIVIDUAL ZONES. EACH AGAROSE GEL IS INTENDED TO RUN: • 15 SAMPLES IN THE HYDRAGEL 15 PROTEIN(E) KIT, FOR IN VITRO DIAGNOSTIC USE ,IF SAMPLE DILUENT(IF SAMPLE DILUENT)-THIS REAGENT IS USED FOR SAMPLE DILUTION IN THE IMMUNOFIXATION PROCEDURES., HYDRAGEL 7 ISO-LDH(HYDRAGEL 7 ISO-LDH)-THESE DEVICES ARE DESIGNED FOR THE IDENTIFICATION AND QUANTIFICATION OF THE FIVE LACTATE DEHYDROGENASE (LD) ISOENZYMES IN HUMAN SERUM BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.4) AGAROSE GELS. ,CDT MINICAP CALIBRATORS (2 LEVELS)(CDT MINICAP CALIBRATORS (2 LEVELS))-THE CDT MINICAP CALIBRATORS (2 LEVELS) ARE DESIGNED FOR THE CALIBRATION OF THE QUANTIFICATION METHOD OF THE CDT-IFCC FRACTION (CALIBRATED DISIALOTRANSFERRIN) WITH THE SEBIA MINICAP CDT-IFCC CAPILLARY ELECTROPHORESIS PROCEDURE PERFORMED WITH THE MINICAP AND MINICAP FLEX-PIERCING AUTOMATED INSTRUMENTS. THEY ALLOW TO OBTAIN CONSISTENT RESULTS WITH THE RECOMMENDATIONS OF THE IFCC WORKING GROUP FOR STANDARDIZATION OF CDT MEASUREMENT (1, 2). THEY SHOULD BE USED AS HUMAN SERA. WARNING : THE CALIBRATORS ARE SPECIFIC FOR THE MINICAP CDT-IFCC PROCEDURE. FOR IN VITRO DIAGNOSTIC USE.. ,HYDRAGEL 4 URINE PROFIL(E) (SM)(HYDRAGEL 4 URINE PROFIL(E) (SM))-THIS DEVICE IS DESIGNED FOR SCREENING OF MAIN URINARY PROTEINS TO TYPE PROTEINURIA (TUBULAR, GLOMERULAR, OR MIXED) AND IMMUNOGLOBULINS (G, A, M OR D/E) IN HUMAN URINE OR SERUM, BY IMMUNOFIXATION ELECTROPHORESIS ON AGAROSE GELS WITH SPECIFIC ANTISERA , CAPILLARYS 3 WASH SOLUTION (1)(CAPILLARYS 3 WASH SOLUTION (1))-USED FOR THE CLEANING OF THE STAINING COMPARTMENT., HYDRAGEL 4 IF (SM) MAXI-KIT(HYDRAGEL 4 IF (SM) MAXI-KIT)-THE HYDRAGEL 1 IF, 2 IF, 4 IF AND 9 IF KITS ARE DESIGNED FOR DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS. THE KITS ARE USED

	IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS. THE PROTEINS, SEPARATED BY ELECTROPHORESIS ON ALKALINE BUFFERED AGAROSE GELS, ARE INCUBATED WITH INDIVIDUAL ANTISERA THAT ARE SPECIFIC AGAINST GAMMA (IG G), ALPHA (IG A) AND MU (IG M) HEAVY CHAINS, AND KAPPA (FREE AND BOUND) AND LAMBDA (FREE AND BOUND) LIGHT CHAINS, RESPECTIVELY. AFTER REMOVING THE NON-REACTED PROTEINS, THE IMMUNOPRECIPITATES ARE STAINED EITHER WITH ACID VIOLET OR AMIDO BLACK. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY FOR THE PRESENCE OF SPECIFIC REACTIONS WITH THE SUSPECT MONOCLONAL PROTEINS. EACH AGAROSE GEL IS INTENDED TO RUN : - ONE SAMPLE IN THE HYDRAGEL 1 IF KIT, - TWO SAMPLES IN THE HYDRAGEL 2 IF KIT, - FOUR SAMPLES IN THE HYDRAGEL 4 IF KITS, - NINE SAMPLES IN THE HYDRAGEL 9 IF KITS. TO ACCOMMODATE DIVERSE USER PREFERENCES, THE HYDRAGEL 4 IF KITS ARE AVAILABLE EITHER WITH ACID VIOLET OR WITH AMIDOBLACK. FOR IN VITRO DIAGNOSTIC USE. ,CLEAN PROTECT (CLEAN PROTECT)-CLEAN PROTECT CONCENTRATED SOLUTION CONTAINS A PRESERVATIVE,HYDRAGEL 15 ß1-ß2(HYDRAGEL 15 ß1-ß2)-THESE DEVICES ARE INTENDED FOR SEPARATION OF PROTEINS IN HUMAN SERUM AND URINE BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.5) AGAROSE GELS. ,HYDRAGEL 4 IF (SM) - ACID VIOLET(HYDRAGEL 4 IF (SM) - ACID VIOLET)-THE HYDRAGEL 1 IF, 2 IF, 4 IF AND 9 IF KITS ARE DESIGNED FOR DETECTION OF MONOCLONAL PROTEINS IN HUMAN SERUM AND URINE BY IMMUNOFIXATION ELECTROPHORESIS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS. THE PROTEINS, SEPARATED BY ELECTROPHORESIS ON ALKALINE BUFFERED AGAROSE GELS, ARE INCUBATED WITH INDIVIDUAL ANTISERA THAT ARE SPECIFIC AGAINST GAMMA (IG G), ALPHA (IG A) AND MU (IG M) HEAVY CHAINS, AND KAPPA (FREE AND BOUND) AND LAMBDA (FREE AND BOUND) LIGHT CHAINS, RESPECTIVELY. AFTER REMOVING THE NON-REACTED PROTEINS, THE IMMUNOPRECIPITATES ARE STAINED EITHER WITH ACID VIOLET OR AMIDO BLACK. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY FOR THE PRESENCE OF SPECIFIC REACTIONS WITH THE SUSPECT MONOCLONAL PROTEINS. EACH AGAROSE GEL IS INTENDED TO RUN : - ONE SAMPLE IN THE HYDRAGEL 1 IF KIT, - TWO SAMPLES IN THE HYDRAGEL 2 IF KIT, - FOUR SAMPLES IN THE HYDRAGEL 4 IF KITS, - NINE SAMPLES IN THE HYDRAGEL 9 IF KITS. TO ACCOMMODATE DIVERSE USER PREFERENCES, THE HYDRAGEL 4 IF KITS ARE AVAILABLE EITHER WITH ACID VIOLET OR WITH AMIDOBLACK. FOR IN VITRO DIAGNOSTIC USE ,DESTAINING SOLUTION (10)(DESTAINING SOLUTION (10))-USED FOR DESTAINING,

	THAT IS REMOVAL OF EXCESS AND BACKGROUND STAIN FROM THE GELS,HYDRAGEL 15 HEMOGLOBIN(E)(HYDRAGEL 15 HEMOGLOBIN(E)) -THESE DEVICES ARE DESIGNED FOR SEPARATION OF THE NORMAL HEMOGLOBINS (A AND A2) AND FOR THE DETECTION OF THE MAJOR HEMOGLOBIN VARIANTS: S OR D AND C OR E, BY ELECTROPHORESIS ON ALKALINE AGAROSE GELS (PH 8.5). ,HYDRAGEL 7 HR AMIDOBLACK(HYDRAGEL 7 HR AMIDOBLACK)-THESE DEVICES ARE DESIGNED FOR MULTI-FRACTIONATION OF PROTEINS FROM HUMAN SERA OR OTHER BIOLOGICAL FLUIDS, SUCH AS URINE AND CEREBROSPINAL FLUID (CSF), BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.6) AGAROSE GELS. THE KITS ARE USED IN CONJUNCTION WITH THE SEMIAUTOMATED HYDRASYS INSTRUMENT. THE HYDRASYS INSTRUMENT ALLOWS ALL. FOR IN VITRO DIAGNOSTIC USE. ,ISO-PAL CONTROL(ISO-PAL CONTROL)-THIS DEVICE IS USED AS A "MARKER" FOR IDENTIFICATION OF THE DIFFERENT ALKALINE PHOSPHATASE ISOENZYMES OF THE HUMAN SERUM AND SEPARATED BY ELECTROPHORESIS ON AGAROSE GEL. , NORMAL CONTROL (20)(NORMAL CONTROL (20))-THIS SERUM IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN SERUM PROTEINS, LIPOPROTEINS, CHOLESTEROL AND APOLIPOPROTEINS ON HYDRAGEL AND FOR SERUM PROTEINS ON CAPILLARYS & MINICAP. IT IS USED AS A "MARKER" FOR IDENTIFICATION OF THE DIFFERENT ISOENZYMES SEPARATED BY ELECTROPHORETIC METHODS. THE VALUES OBTAINED MUST FALL WITHIN THE MEAN } 2 SD CONFIDENCE RANGE PROVIDED WITH EACH BATCH OF CONTROL SERUM. THE CONTROL SERUM CAN BE USED FOR THE QUALITY CONTROL OF SERUM FREE LIGHT CHAINS QUANTIFICATION WITH SEBIA FLC KAPPA AND SEBIA FLC LAMBDA KITS ,HB AF CONTROL(HB AF CONTROL)-HE HB AF CONTROL IS DESIGNED FOR THE MIGRATION CONTROL BEFORE STARTING A NEW ANALYSIS SEQUENCE AND FOR THE QUALITATIVE QUALITY CONTROL FOR HUMAN HEMOGLOBINS A AND F, WITH THE SEBIA ELECTROPHORESIS PROCEDURES : - CAPILLARYS NEONAT HB USED WITH THE CAPILLARYS 2 AND CAPILLARYS 2 NEONAT FAST INSTRUMENTS AND, - CAPILLARYS CORD BLOOD USED WITH THE CAPILLARYS 2 AND CAPILLARYS 2 FLEX- PIERCING INSTRUMENTS ,K & L FREE LIGHT CHAINS ANTISERA BOX (SM)(K & L FREE LIGHT CHAINS ANTISERA BOX (SM))-THESE DEVICES CONTAIN SPECIFIC ANTISERA WITH OR WITHOUT FIXATIVE SOLUTION FOR AGAROSE GEL IMMUNOFIXATION TECHNIQUES. THEY ARE SPECIFIC FOR THE IMMUNOFIXATION PROCEDURE WITH THE STANDARD MASK IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS. ,(GAM. K. L) ANTISERA AND FIXATIVE SOLUTION BOX (SM)((GAM. K. L) ANTISERA AND FIXATIVE

	SOLUTION BOX (SM))-THESE DEVICES CONTAIN SPECIFIC ANTISERA WITH OR WITHOUT FIXATIVE SOLUTION FOR AGAROSE GEL IMMUNOFIXATION TECHNIQUES. THEY ARE SPECIFIC FOR THE IMMUNOFIXATION PROCEDURE WITH THE STANDARD MASK IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS. ,IF ANTISERA AND FIXATIVE SOLUTION BOX (SM)(IF ANTISERA AND FIXATIVE SOLUTION BOX (SM))-THESE DEVICES CONTAIN SPECIFIC ANTISERA WITH OR WITHOUT FIXATIVE SOLUTION FOR AGAROSE GEL IMMUNOFIXATION TECHNIQUES. THEY ARE SPECIFIC FOR THE IMMUNOFIXATION PROCEDURE WITH THE STANDARD MASK IN CONJUNCTION WITH THE SEMI-AUTOMATED HYDRASYS ELECTROPHORESIS APPARATUS. , HYDRAGEL 15 ISO-PAL(HYDRAGEL 15 ISO-PAL)-THESE DEVICES ARE DESIGNED FOR THE IDENTIFICATION AND QUANTIFICATION OF ALKALINE PHOSPHATASE (AP) ISOENZYMES IN HUMAN SERUM. , AMIDOBLACK STAINING SOLUTION(AMIDOBLACK STAINING SOLUTION)-USED FOR STAINING GELS WITH ELECTROPHORETIC PROTEIN SEPARATIONS.,HYDRAGEL 3 CSF ISOFOCUSING(HYDRAGEL 3 CSF ISOFOCUSING)-THE HYDRAGEL 3 CSF ISOFOCUSING AND HYDRAGEL 9 CSF ISOFOCUSING KITS ARE DESIGNED FOR THE QUALITATIVE DETECTION AND IDENTIFICATION OF "OLIGOCLONAL' BANDS IN THE ELECTROPHORETIC PATTERNS OF CEREBROSPINAL FLUID (CSF) AND CONFIRMATION OF THEIR IMMUNOGLOBULIN CHARACTER. THE PROCEDURE INCLUDES ISOELECTROFOCUSING ON AGAROSE GEL, PERFORMED ON THE SEMI-AUTOMATIC HYDRASYS SYSTEM, FOLLOWED BY IMMUNOFIXATION WITH ANTI-IG G ANTISERUM. THE USE OF ENZYME LABELED ANTI-IG G ANTISERUM PERMITS TO DETECT ONLY THE "TRUE" IG G OLIGOCLONAL BANDING AT INCREASED SENSITIVITY OF DETECTION SO THAT THE ANALYSIS CAN BE GENERALLY PERFORMED ON UNCONCENTRATED CSF. THE IG G IMMUNOFIXATION PATTERNS OF CSF AND SERUM FROM THE SAME PATIENT ARE THEN VISUALLY COMPARED. THIS ALLOWS DETECTION OF OLIGOCLONAL BANDING THAT REPRESENTS INTRATHECAL SYNTHESIS OF IMMUNOGLOBULINS. THE HYDRAGEL 3 CSF ISOFOCUSING AND HYDRAGEL 9 CSF ISOFOCUSING KITS ARE , HYDRAGEL 30 ISO-LDH(HYDRAGEL 30 ISO-LDH)-THESE DEVICES ARE DESIGNED FOR THE IDENTIFICATION AND QUANTIFICATION OF THE FIVE LACTATE DEHYDROGENASE (LD) ISOENZYMES IN HUMAN SERUM BY ELECTROPHORESIS ON ALKALINE BUFFERED (PH 8.4) AGAROSE GELS. ,CAPICLEAN(CAPICLEAN)-CAPICLEAN SOLUTION IS USED FOR CLEANING OF THE SAMPLE PROBE IN AUTOMATED SYSTEMS CAPILLARYS AND MINICAP, SEBIA, FOR CAPILLARY ELECTROPHORESIS, DURING THE CAPICLEAN CLEANING SEQUENCE. NOTE : A CAPICLEAN CLEANING SEQUENCE INCLUDES THE SAMPLE

	PROBE CLEANING WITH THE CAPICLEAN REAGENT AND THE CAPILLARIES CLEANING WITH THE CAPILLARYS / MINICAP WASH SOLUTION. FOR IN VITRO DIAGNOSTIC USE. ,CAPILLARYS HEMOGLOBIN(E) HEMOLYSING SOLUTION(CAPILLARYS HEMOGLOBIN (E) HEMOLYSING SOLUTION)-THIS REAGENT IS DESIGNED FOR HEMOLYZE RED BLOOD CELLS IN THE CAPILLARYS AUTOMATIC SYSTEM. ,ENZYCONTROL(ENZYCONTROL)-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF ELECTROPHORETIC QUANTIFICATION OF HUMAN SERUM LACTATE DEHYDROGENASE (LD) ISOENZYMES AND CREATINE KINASE (CK) ISOENZYMES ON AGAROSE GEL. ,HYDRAGEL 4 BENCE JONES (SM)(HYDRAGEL 4 BENCE JONES (SM))-THE HYDRAGEL 1 BENCE JONES, HYDRAGEL 2 BENCE JONES, HYDRAGEL 4 BENCE JONES AND HYDRAGEL 9 BENCE JONES KITS ARE OF DESIGNED FOR QUALITATIVE DETECTION AND IDENTIFICATION OF BENCE JONES PROTEINS, MONOCLONAL FREE LIGHT CHAINS KAPPA OR LAMBDA, IN HUMAN URINE OR SERUM, BY IMMUNOFIXATION ELECTROPHORESIS. THE DETECTION OF BENCE JONES PROTEINS SERVES AS A QUALITATIVE AID IN THE IDENTIFICATION MONOCLONAL GAMMOPATHIES. EACH AGAROSE GEL IS INTENDED TO RUN : - ONE SAMPLE IN THE HYDRAGEL 1 BENCE JONES KIT, - TWO SAMPLES IN THE HYDRAGEL 2 BENCE JONES KIT, - FOUR SAMPLES IN THE HYDRAGEL 4 BENCE JONES KIT, - NINE SAMPLES IN THE HYDRAGEL 9 BENCE JONES KITS. FOR IN VITRO DIAGNOSTIC USE. ,CAPILLARYS HB A1C(CAPILLARYS HB A1C)-THE CAPILLARYS HB A1C KIT IS DESIGNED FOR SEPARATION AND QUANTIFICATION OF THE HBA1C GLYCATED FRACTION OF HEMOGLOBIN IN HUMAN BLOOD, BY CAPILLARY ELECTROPHORESIS IN ALKALINE BUFFER (PH 9.4) WITH THE CAPILLARYS 2 FLEX-PIERCING INSTRUMENT. THE CAPILLARYS HB A1C KIT IS DESIGNED FOR LABORATORY USE. THE CAPILLARYS 2 FLEX-PIERCING INSTRUMENT IS AN AUTOMATED ANALYZER WHICH PERFORMS A COMPLETE HEMOGLOBIN PROFILE FOR THE QUANTITATIVE ANALYSIS OF HBA1C FRACTION. THE HEMOGLOBINS, SEPARATED IN SILICA CAPILLARIES, ARE DIRECTLY DETECTED BY THEIR ABSORBANCE AT 415 NM. THE ASSAY IS PERFORMED ON THE HEMOLYSATE OF WHOLE BLOOD SAMPLES COLLECTED IN TUBES CONTAINING K2EDTA OR K3EDTA AS ANTICOAGULANT. QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C IS EFFECTIVE IN MONITORING MIDDLE-TERM BLOOD GLUCOSE CONTROL IN DIABETIC INDIVIDUALS. QUANTITATIVE MEASUREMENT OF HEMOGLOBIN A1C CAN BE USED AS AN AID IN THE DIAGNOSIS OF DIABETES MELLITUS AND AS AN AID IN THE IDENTIFICATION OF PATIENTS AT RISK FOR DEVELOPING DIABETES MELLITUS. THE CAPILLARYS HB A1C PROCEDURE PERFORMED WITH THE

	CAPILLARYS 2 FLEX-PIERCING INSTRUMENT HAS BEEN CERTIFIED BY THE NATIONAL GLYCOHEMOGLOBIN STANDARDIZATION PROGRAM (NGSP). FOR IN VITRO DIAGNOSTIC USE ,IT / IF CONTROL(IT / IF CONTROL)-THIS DEVICE IS DESIGNED FOR THE QUALITY CONTROL OF THE DETECTION AND CHARACTERIZATION OF HUMAN MONOCLONAL IMMUNOGLOBULINS ON AGAROSE GEL AND IN CAPILLARY. ,A1C/CE LOW VOLUME SAMPLE COLLECTION TUBE(A1C/CE LOW VOLUME SAMPLE COLLECTION TUBE)-USED FOR THE ANALYSIS OF SAMPLES WITH A VOLUME BELOW 100 L,NORMAL CDT CONTROL (5)(NORMAL CDT CONTROL (5))-THE NORMAL CDT CONTROL IS DESIGNED FOR THE NORMALIZATION OF CAPILLARIES OF THE SEBIA CAPILLARYS AND MINICAP CAPILLARY ELECTROPHORESIS SYSTEMS AND FOR THE QUALITY CONTROL OF QUANTIFICATION OF HUMAN TRANSFERRIN ISOFORMS WITH CAPILLARYS CDT, CAPI 3 CDT AND MINICAP CDT ELECTROPHORESIS PROCEDURES. THE VALUES OBTAINED MUST FALL WITHIN THE RANGE PROVIDED WITH EACH BATCH OF CDT CONTROL. NOTE : THE CDT CONTROL VALUES DO NOT DEPEND ON THE BATCH OF CDT CONTROLS / CALIBRATORS DILUENT USED TO RECONSTITUTE THE VIAL. ,FLUIDIL(FLUIDIL)-USED TO DILUTE SAMPLES WITH HINDERED DIFFUSION THROUGH THE SAMPLE APPLICATOR TEETH. ,CAPI 3 IMMUNOTYPING(CAPI 3 IMMUNOTYPING) -THE CAPI 3 IMMUNOTYPING KIT IS DESIGNED FOR THE DETECTION AND THE CHARACTERIZATION OF MONOCLONAL PROTEINS (IMMUNOTYPING) IN HUMAN URINE AND SERUM WITH THE CAPILLARYS 3 INSTRUMENT, SEBIA, FOR CAPILLARY ELECTROPHORESIS. IT IS USED IN CONJUNCTION WITH THE CAPI 3 PROTEIN(E) 6 KIT, SEBIA, DESIGNED FOR PROTEINS SEPARATION INTO 6 MAJOR FRACTIONS IN ALKALINE BUFFER (PH 9.9). THE CAPILLARYS 3 INSTRUMENT PERFORMS ALL PROCEDURAL SEQUENCES AUTOMATICALLY TO OBTAIN A PROTEIN PROFILE FOR QUALITATIVE ANALYSIS. EACH URINE OR SERUM SAMPLE IS MIXED WITH INDIVIDUAL ANTISERA THAT ARE SPECIFIC AGAINST GAMMA (IG G), ALPHA (IG A) AND MU (IG M) HEAVY CHAINS, AND KAPPA (FREE AND BOUND) LIGHT CHAINS AND LAMBDA (FREE AND BOUND) LIGHT CHAINS, RESPECTIVELY. THE PROTEINS, SEPARATED IN SILICA CAPILLARIES, ARE DIRECTLY DETECTED BY THEIR ABSORBANCE AT 200 NM. THE ELECTROPHOREGRAMS ARE EVALUATED VISUALLY TO DETECT THE PRESENCE OF SPECIFIC REACTIONS WITH THE SUSPECT MONOCLONAL PROTEINS. FOR IN VITRO DIAGNOSTIC USE

824	IMP/IVD/2020/000721	1.License Holder Name: MICROLYN HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KIT FOR URINE SEDIMENT ANALYZER(DIRUI)-THE NEGATIVE CONTROL, POSITIVE CONTROL, AND STANDARD SOLUTION IS USED FOR QC DURING TEST. FOCUS IS USED FOR THE POSITION DETERMINATION OF FOCUS PLANE BEFORE TEST.,ISE BLOOD QUALITY CONTROL (HIGH)(DIRUI)-THIS PRODUCT IS APPLICABLE TO THE ION-SELECTIVE ELECTRODE MODULE OF CS SERIES AUTO CHEMISTRY ANALYZERS FOR MEASURING ELECTROLYTES. ,COLOR CONTROL (RED)(DIRUI)-H SERIES URINE ANALYZER COLOR CONTROL IS USED FOR DIRUI'S H SERIES URINE ANALYZER COLOR QUALITY CONTROL.,TOTAL BILIRUBIN REAGENT KIT(DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF T-BILIRUBIN OF HUMAN SERUM/PLASMA. ,BF-DILUENT(DIRUI)-IT IS USED FOR DILUTING SAMPLE.,DILUENT(DIRUI)-FOR DILUTING SAMPLE.,URIC ACID REAGENT KIT(DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE MEASUREMENT URIC ACID CONTENT OF HUMAN SERUM OR URINE.,CALIBRATOR FOR AUTOMATIC HEMATOLOGY ANALYZER(DIRUI)-IT IS USED FOR CALIBRATING WBC, RBC,MCV/HCT, PLT OFAUTOMATIC HAEMATOLOGY ANALYZER(5-PART).,DIRUI H12- MA (100)(DIRUI)-DIRUI H SERIES URINALYSIS STRIPS ARE MADE FOR URINALYSIS BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO FOR DIAGNOSTICS. THE STRIPS ARE FOR PROFESSIONAL USE ONLY., CLINICAL CHEMICAL QUALITY CONTROL SERUM(DIRUI)-THE SERUM INCLUDES LEVEL 1 & LEVEL 2 USED FOR THE QUALITY CONTROL OF CLINICAL ANALYSIS DETERMINATION OF MANY BIOCHEMICAL ITEMS. ,ISE BLOOD QUALITY CONTROL (LOW)(DIRUI)-THIS PRODUCT IS APPLICABLE TO THE IONSELECTIVE ELECTRODE MODULE OF CS SERIES AUTO CHEMISTRY ANALYZERS FOR MEASURING ELECTROLYTES. ,LYSE(DIRUI)-IT IS USED FOR DISSOLVING RBC, DETECTING TOTAL NUMBER OF WBC, THREE-PART WBC COUNT AND THE CONTENT OF HAEMOGLOBIN. ,ALKALINE PHOSPHATES REAGENT KIT(DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE DETERMINATION OF THE ACTIVITY OF ALKALINE PHOPHATASE IN HUMAN SERUM/PLASMA. ,ISE DILUENT(DIRUI)-TO DILUTE THE SAMPLE AND STANDARD SOLUTION IN ISE MODULE., CALIBRATION LIQUID FOR SPECIFIC GRAVITY(DIRUI)-H SERIES URINE ANALYZER CALIBRATION LIQUID FOR SPECIFIC GRAVITY IS USED FOR DIRUI'S H SERIES URINE ANALYZER'S REFRACTOMETER'S CALIBRATION.,TOTAL BILIRUBIN KIT(DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE DETERMINATION OF THE CONTENT OF T- BILIRUBIN OF HUMAN SERUM. ,BF DETERGENT(DIRUI)

	-TO CLEAN THE DETECTION PART, ROTARY VALVE, WHOLE-BLOOD SUCKING PIPE, AND HAEMOGLOBIN COLORIMETRIC CELL OF AN ANALYZER, AND AVOID PROTEIN ACCUMULATION.,CONTROL LIQUID FOR SPECIFIC GRAVITY(DIRUI)-H SERIES URINE ANALYZER CONTROL LIQUID FOR SPECIFIC GRAVITY IS USED FOR DIRUI'S H SERIES URINE ANALYZER'S REFRACTOMETER'SQUALITY CONTROL.,TRIGLYCERIDES REAGENT KIT(DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA. ,DIRUI H10- 800 (30, 100, 125)(DIRUI)-SPECIAL DIRUI REAGENT STRIPS OF H-800 ARE USEDFOR THE DETERMINATION OF LEUKOCYTES, NITRITE, UROBILINOGEN, PROTEIN, PH,BLOOD, SPECIFIC GRAVITY, KETONE(ACETOACETIC ACID), BILIRUBINAND GLUCOSE IN URINE.,DILUENT(DIRUI)-IT IS USED FOR DILUTING BLOOD SAMPLE.,DIRUI H11- 800 (30, 100, 125)(DIRUI)-SPECIAL DIRUI REAGENT STRIPS OF H-800 ARE USED FOR THE DETERMINATION OF LEUKOCYTES,NITRITE UROBILINOGEN, PROTEIN, PH, BLOOD, SPECIFIC GRAVITY, KETONE (ACETOACETIC ACID), BILIRUBIN, GLUCOSE AND ASCORBIC ACID IN URINE.,ISE REFERENCE SOLUTION(DIRUI)-TO DETERMINE THE REFERENCE ELECTRODE POTENTIAL IN ISE MODULE.,INORGANIC PHOSPHORUS REAGENT KIT (DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHORUS IN HUMAN SERUM, PLASMA OR URINE. ,TOTAL PROTEIN REAGENT KIT(DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE DETERMINATION OF THE TOTAL PROTEIN CONTENT OF HUMAN SERUM OR PLASMA. ,DIRECT BILIRUBIN REAGENT KIT(DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF DBILIRUBIN OF HUMAN SERUM/PLASMA. ,DIRUI 2 ITEMS (PRO, GLU) (100)(DIRUI)-THESE STRIPS ARE USED FOR TESTING PROTEIN AND GLUCOSE IN URINE. THE STRIPS ARE FOR PROFESSIONAL USE ONLY., CALIBRATION LIQUID FOR TURBIDITY(DIRUI)-H SERIES URINE ANALYZERCALIBRATION LIQUID FOR TURBIDITY IS USED FOR DIRUI'S H SERIES URINE ANALYSERTUBIDIMETER CALIBRATION.,ISE BLOOD SAMPLE CALIBRATOR(DIRUI)-THIS PRODUCT IS APPLICABLE TO THE ION-SELECTIVE ELECTRODE MODULE OF CS SERIES AUTO CHEMISTRY ANALYZERS FOR MEASURING ELECTROLYTE IN ORDER TO ELIMINATE ERROR OF MEASURED RESULTS. ,CS-ACIDIC DETERGENT(DIRUI)-FOR CLEANING REAGENT PROBE AND REACTION CUVETTE OF THE CS SERIES AUTO-CHEMISTRY ANALYZER.,ISE INTERNAL STANDARD SOLUTION(DIRUI)-TO COMPENSATE FOR SYSTEM DRIFT AND RINSE THE MATCHING CUVETTES AND FLOW CELL. ,ISE STANDARD SOLUTION (HIGH)(DIRUI)-THIS PRODUCT IS APPLICABLE TO THE IONSELECTIVE ELECTRODE MODULE OF CS

	SERIES AUTO CHEMISTRY ANALYZERS FOR MEASURING ELECTRODES. ,CS- ALKALINE DETERGENT(DIRUI)-FOR CLEANING SAMPLE PROBE AND REACTION CUVETTE OF THE CS SERIES AUTO-CHEMISTRY ANALYZER.,CONTROL LIQUID FOR TURBIDITY(DIRUI)-H SERIES URINE ANALYZER CONTROL LIQUID FOR TURBIDITY IS USED FOR DIRUI'S H SERIES URINE ANALYSER TURBIDITY QUALITY CONTROL.,DIRUI H11- MA(N) (100)(DIRUI)-DIRUI H11-MA(N) SERIES URINALYSIS STRIPS ARE MADE FOR URINALYSIS BOTH QUALITATIVE AND SEMIQUANTITATIVE, WHICH ARE IN VITRO FOR DIAGNOSTICS. THE STRIPS ARE FOR PROFESSIONAL USE ONLY. IT IS THE PRIMARY TESTING FOR THE DISEASE ON ABNORMAL KIDNEYS, DIABETES, SERIOUS INFECTION AND ABNORMAL LIVER FUNCTIONS.,ALBUMIN REAGENT KIT(DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE DETERMINATION OF ALBUMIN CONCENTRATION IN HUMAN SERUM OR PLASMA. ,COLOR CONTROL (GREEN)(DIRUI)-H SERIES URINE ANALYZER COLOR CONTROL IS USED FOR DIRUI'S H SERIES URINE ANALYZER COLOR QUALITY CONTROL.,SHEATH(DIRUI) -USED TO WRAP THE SAMPLE TO FORM A SHEATH FLOW TO CONDUCT URINE.,CONTROL FOR AUTOMATIC HEMATOLOGY ANALYZER(DIRUI)-IT IS USED FOR MONITORING OR EVALUATING TEST RESULT ACCURACY OF 5-PART HAEMATOLOGY ANALYZER.,ISE INTERNAL STANDARD LIQUID(DIRUI)-THE PRODUCT APPLIES TO ISE MODULE OF CS SERIES AUTO CHEMISTRY ANALYZERS FOR MEASURING POTENTIAL BY REFERENCE ELECTRODE.,URINALYSIS CONTROL (NEGATIVE)(DIRUI)-URINALYSIS CONTROL (REFERRED TO AS CONTROL) IS USED FOR QUALITY CONTROL OF URINALYSIS STRIPS AND ANALYZERS. IT CAN CONDUCT QUALITY CONTROL FOR 13 ITEMS OF STRIPS, SUCH AS GLUCOSE, BILIRUBIN, KETONE, SPECIFIC GRAVITY, BLOOD, PH, PROTEIN, UROBILINOGEN, NITRITE, LEUCOCYTES, MICROALBUMIN, CREATNINIE AND CA. ,CALIBRATOR FOR HEMATOLOGY ANALYZER(DIRUI)-TO CALIBRATE THE BLOOD CELL ANALYSING SYSTEM FOR HAEMATOLOGY TESTING.,DIRUI H13-CR (25, 50,100)(DIRUI)-H13-CR STRIPS FOR URINALYSIS IS USED FOR BOTH QUALITATIVE AND SEMIQUANTITATIVE TEST OF UROBILINOGEN, BILIRUBIN, KETONE (ACETOACETICACID), BLOOD, PROTEIN, NITRITE, LEUKOCYTE, GLUCOSE, PH, SPECIFIC GRAVITY, ASCORBIC ACID, MICROALBUMIN AND CREATININE IN URINE.,LOW DENSITY LIPOPROTEIN CHOLESTEROL REAGENT KIT(DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE MEASUREMENT OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) CONCENTRATION CONTENT IN HUMAN SERUM. ,DIRECT BILIRUBIN KIT(DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE DETERMINATION OF THE CONCENTRATION OF DBILIRUBIN OF HUMAN SERUM/PLASMA. ,DIRUI H12- 800MA (30, 100,

	125)(DIRUI)-SPECIAL DIRUI REAGENT STRIPS OF H-800 ARE USED FOR THE DETERMINATION OF LEUKOCYTES, NITRITE, UROBILINOGEN, PROTEIN, PH,BLOOD, SPECIFIC GRAVITY, KETONE (ACETOACETIC ACID), BILIRUBIN, GLUCOSEMICROALBUMIN AND ASCORBIC ACID IN URINE.,CS- ALKALINE DETERGENT-II(DIRUI)-FOR CLEANING SAMPLE PROBE, REAGENT PROBE AND REACTION CUVETTE OF THE CS SERIES AUTO- CHEMISTRY ANALYZER.,URINALYSIS CONTROL (POSITIVE) (DIRUI)-URINALYSIS CONTROL (REFERRED TO AS CONTROL) IS USED FOR QUALITY CONTROL OF URINALYSIS STRIPS AND ANALYZERS. IT CAN CONDUCT QUALITY CONTROL FOR 13 ITEMS OF STRIPS, SUCH AS GLUCOSE, BILIRUBIN, KETONE, SPECIFIC GRAVITY, BLOOD, PH, PROTEIN, UROBILINOGEN, NITRITE,LEUCOCYTES, MICROALBUMIN, CREATNINIE AND CA. ,GAMMA-GLUTAMYL TRANSFERASE REAGENT KIT(DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE DETERMINATION OF THE ACTIVITY OF GLUTAMYL TRANSFERASE IN HUMAN SERUM/PLASMA. ,CS-ANTI- BACTERIAL PHOSPHOR-FREE DETERGENT(DIRUI)-FOR CLEANING REAGENT PROBE, REACTION CUVETTE AND SOAKING REACTION CUP OF THE CS SERIES AUTO- CHEMISTRY ANALYZER. ,CLEANING LIQUID FOR REFRACTOMETER AND TURBIDIMETER(DIRUI)-TO CLEAN THE REFRACTOMETER AND TURBIDIMETER OF H SERIES URINE ANALYZER.,CLEANING LIQUID (CONCENTRATED TYPE)(DIRUI)-IT IS USED FOR CLEANING AND RINSING OF TUBING SYSTEM. IT WILL EFFECTIVELY CLEAN THE REMAINED URINE AND OTHER TEST-INTERFERING PARTICLES TO AVOID CROSS- CONTAMINATION AMONG URINE SAMPLE.,ISE STANDARD SOLUTION (LOW)(DIRUI)-THIS PRODUCT IS APPLICABLE TO THE ION-SELECTIVE ELECTRODE MODULE OF CS SERIES AUTO CHEMISTRY ANALYZERS FOR MEASURING ELECTRODES. ,CLEANSER(DIRUI)-TO CLEAN AND WASH THE DETECTION PART AND FLUID SYSTEM OF THE HAEMATOLOGY ANALYZER.,DIRUI- H11(100)(DIRUI)-DIRUI H SERIES URINALYSIS STRIPS ARE MADE FOR URINALYSIS BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO FOR DIAGNOSTICS AND ARE USED FOR THE DETERMINATION OF LEUKOCYTES, NITRITE, UROBILINOGEN, PROTEIN, PH, BLOOD, SPECIFIC GRAVITY, KETONE (ACETOACETICACID), BILIRUBIN, GLUCOSE AND ASCORBIC ACID IN URINE.,DIRUI- H10(100)(DIRUI)-DIRUI H SERIES URINALYSIS STRIPS ARE MADE FOR URINALYSIS BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO FOR DIAGNOSTICS AND ARE USED FOR THE DETERMINATION OF LEUKOCYTES, NITRITE, UROBILINOGEN, PROTEIN, PH, BLOOD, SPECIFIC GRAVITY, KETONE (ACETOACETIC ACID), BILIRUBIN, AND GLUCOSE IN URINE., ASPARTATE AMINOTRANSFERASE REAGENT KIT(DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE

		DETERMINATION OF THE ACTIVITY OF AST ACTIVITY IN HUMAN SERUM/PLASMA. ,DIRUI H11- MA (100)(DIRUI)-DIRUI H11-MA SERIES URINALYSIS STRIPS ARE MADE FOR URINALYSIS BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO FOR DIAGNOSTICS. THE STRIPS ARE FOR PROFESSIONAL USE ONLY. IT IS THE PRIMARY TESTING FOR THE DISEASE ON ABNORMAL KIDNEYS,DIABETES, SERIOUS INFECTION AND ABNORMAL LIVER FUNCTIONS.,CLINICAL CHEMICAL CALIBRATION SERUM(DIRUI)-THE SERUM INCLUDES LEVEL 1 & LEVEL 2 USED FOR THE CALIBRATION OF CLINICAL ANALYSIS DETERMINATION OF MANY BIOCHEMICAL ITEMS. , CLEANSER(DIRUI)-IT IS USED TO CLEAN THE PIPELINE OF HAEMATOLOGY ANALYZER TO AVOID CROSS- CONTAMINATION CAUSED BY BLOOD RESIDUE OR OTHER PARTICLES. ,CALCIUM REAGENT KIT(DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE DETERMINATION OF CALCIUM CONCENTRATION OF HUMAN SERUM, PLASMA OR URINE. ,MAGNESIUM REAGENT KIT (DIRUI)-THIS REAGENT IS APPLIED TO THE IN- VITRO QUANTITATIVE DETERMINATION OF MAGNESIUM CONCENTRATION IN HUMAN SERUM OR PLASMA. ,DILUENT(DIRUI)-THE PRODUCT APPLIES TO ISE MODULE OF CS SERIES AUTO CHEMISTRY ANALYZERS FOR DILUTING THE SAMPLE AND STANDARD SOLUTION. ,DETERGENT(DIRUI)-TO RINSE THE PIPELINE AND FLOW CELL.,COLOR CONTROL (BLUE) (DIRUI)-H SERIES URINE ANALYZER COLOR CONTROL IS USED FOR DIRUI'S H SERIES URINE ANALYZER COLOR QUALITY CONTROL.,CS-ISE DETERGENT(DIRUI)-FOR CLEANING ISE ELECTRODE OF CS SERIES AUTO- CHEMISTRY ANALYZER.
825	IMP/IVD/2020/000727	1.License Holder Name: ANAND BROTHERS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FUNGITELL KIT (FUNGITELL KIT)-THE FUNGITELL IS A PROTEASE ZYMOGEN BASED COLORIMETRIC ASSAY FOR THE QUALITATIVE DETECTION OF (1->3)-BD GLUCAN IN THE SERUM OF PATIENT WITH SYMPTOMS OF OR MEDICAL CONDITIONS PREDISPOSING THE PATIENT TO INVASIVE FUNGAL INFECTION

826	IMP/IVD/2020/000727	1.License Holder Name: ANAND BROTHER'S 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FUNGITELL STAT (FUNGITELL STAT®)-THE FUNGITELL STAT® ASSAY IS PROTEASE ZYMOGEN-BASED COLORIMETRIC ASSAY FOR THE QUALITATIVE DETECTION OF (1-->3)- B-D- GLUCAN IN THE SERUM OF PATIENTS WITH SYMPTOMS OF, OR MEDICAL CONDITIONS PREDISPOSING THE PATIENT TO INVASIVE FUNGAL INFECTION.
827	IMP/IVD/2020/000728	1.License Holder Name: EUROFINS AMAR IMMUNODIAGNOSTICS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 (COVID-19) (GSD NOVAPRIME®)-THE GSD NOVAPRIME® SARS-COV-2 (COVID-19) RT-PCR IS INTENDED FOR THE QUALITATIVE DETERMINATION OF SARS-COV-2 (SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2) GENOMIC RNA EXTRACTED FROM HUMAN RESPIRATORY (NASAL WASH/SWAB, NASOPHARYNGEAL WASH/SWAB, OROPHARYNGEAL SWAB AND BRONCHOALVEOLAR LAVAGE) SPECIMEN TYPES
828	IMP/IVD/2020/000729	1.License Holder Name: SBGLOBAL DISTRIBUTION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GENEFINDER™ COVID-19 PLUS REALAMP KIT-IN-VITRO DIAGNOSTIC USE AND PROFESSIONAL USE ONLY AND INTENDED TO BE USED IN LABORATORIES, CLINICS, AND HOSPITALS

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

829	IMP/IVD/2020/000730	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARCHITECT IPHENYTOIN REAGENT KIT(ARCHITECT IPHENYTOIN REAGENT KIT)-THE ARCHITECT IPHENYTOIN ASSAY IS AN IN VITRO CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE MEASUREMENT OF PHENYTOIN, AN ANTICONVULSANT DRUG, IN HUMAN SERUM OR PLASMA ON THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY.,ARCHITECT IVALPROIC ACID REAGENT (ARCHITECT IVALPROIC ACID)-THE ARCHITECT IVALPROIC ACID ASSAY IS AN IN VITRO CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE MEASUREMENT OF VALPROIC ACID, AN ANTICONVULSANT DRUG, IN HUMAN SERUM OR PLASMA ON THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY.,ARCHITECT IPHENOBARBITAL REAGENT(ARCHITECT IPHENOBARBITAL)-THE ARCHITECT IPHENOBARBITAL ASSAY IS AN IN VITRO CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE MEASUREMENT OF PHENOBARBITAL, AN ANTICONVULSANT AND SEDATIVE-HYPNOTIC DRUG, IN HUMAN SERUM OR PLASMA ON THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY. THE MEASUREMENTS OBTAINED ARE USED IN THE DIAGNOSIS AND TREATMENT OF PHENOBARBITAL OVERDOSE AND IN MONITORING LEVELS OF PHENOBARBITAL TO HELP ENSURE APPROPRIATE THERAPY.,ARCHITECT IPHENOBARBITAL CALIBRATORS(ARCHITECT IPHENOBARBITAL CALIBRATORS)-THE ARCHITECT IPHENOBARBITAL CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PHENOBARBITAL IN HUMAN SERUM OR PLASMA.,ARCHITECT IVALPROIC ACID CALIBRATORS(ARCHITECT IVALPROIC ACID CALIBRATORS)-THE ARCHITECT IVALPROIC ACID CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF VALPROIC ACID IN HUMAN SERUM OR PLASMA., ARCHITECT IPHENYTOIN CALIBRATORS(ARCHITECT IPHENYTOIN CALIBRATORS)-THE ARCHITECT IPHENYTOIN CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PHENYTOIN IN HUMAN SERUM OR PLASMA.

830	IMP/IVD/2020/000732	1.License Holder Name: GENWORKS HEALTH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:25-OH VITAMIN D (CLIA) (MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM USING THE MAGLUMISERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). ,A-I (CLIA)(MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANGIOTENSIN (A) IN HUMAN PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). ,EBV VCA IGM (CLIA) (MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV VCA IGM IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). ,LAMININ (CLIA)(MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LAMININ (LN) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,AMH (CLIA) (MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-MULLERIAN HORMONE (AMH) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). ,FSH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,LH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE

	QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,DIRECT RENIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF RENIN IN HUMAN EDTA-PLASMA SPECIMENS USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,TMA (CLIA)(MAGLUMI)- THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID MICROSOMAL AUTOANTIBODY (TMA) IN HUMAN SERUM USING THE MAGLUMISERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,EBV EA IGA (CLIA) (MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV EA IGA IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS) ,TRAB (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TSH RECEPTOR ANTIBODIES (TRAB) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,VITAMIN B12 (CLIA)(MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM USING THE MAGLUMISERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). ,TSH (CLIA)(MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN HUMAN SERUM USING THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 8 MAGLUMI 1000, MAGLUMI 1000 PLUS,

	MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND M 4000 PLUS).,REV T3 (CLIA)(MAGLUMI)- THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF REVERSE TRIIODOTHYRONINE(REVT3)IN HUMAN SERUM USING THE MAGLUMISERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,CHOLYGLYCINE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CHOLYLGLYCINE (CG) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),PCT (CLIA)(MAGLUMI)- THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PCT IN HUMAN SERUM, PLASMA AND WHOLE BLOOD WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,PROINSULIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROINSULIN IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,EBV EA IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCEIMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV EA IGG IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,LP-PLA2 (CLIA)(MAGLUMI)- THE KIT IS AN IN VITROCHEMILUMINESCENTIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 (LP-PLA2) IN HUMAN SERUMUSING THE MAGLUMISERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). , INSULIN (CLIA)(MAGLUMI)- THE KIT IS AN IN VITRO

	CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,C IV (CLIA)(MAGLUMI)- THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TYPE COLLAGEN (C) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,HA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HYALURONIC ACID (HA) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,ACTH (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ADRENOCORTICOTROPIC HORMONE (ACTH) IN HUMAN PLASMA WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,CORTISOL (CLIA)(MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM OR URINE USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). ,FA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLIC ACID (FA) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,ANTI- IA2 (CLIA)(MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TYROSINE PHOSPHATASE-LIKE PROTEINS ANTIBODY (ANTI-IA2) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZERS (INCLUDING

	MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). , ALDOSTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALDOSTERONE (ALD) IN HUMAN SERUM, PLASMA AND TREATED URINE WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,T4 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION THYROXINE (T4) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,OSTEOCALCIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF OSTEOCALCIN (BGP) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,NT-PROBNP (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF N-TERMINAL PROHORMONE B-TYPE NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,D- DIMER (CLIA)(MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA USING THE MAGLUMISERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,CRP (CLIA)(MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAYFOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,GAD 65 (CLIA)(MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE

	IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GLUTAMIC ACID DECARBOXYLASE ANTIBODY (GAD65) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,H PYLORI IGG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF H.PYLORI IGG IN HUMAN SERUM AND PLASMA WITH MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,PG I M(CLIA)(MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN (PG) IN HUMAN SERUMUSING THE MAGLUMISERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,PRL (CLIA)(MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PRL IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,TG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,PG II (CLIA)(MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OFPEPSINOGEN (PG) IN HUMAN SERUMUSING THE MAGLUMISERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI4000 PLUS).,HS-CTNL (CLIA) (MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I(CTNI)IN HUMAN SERUMANDPLASMAUSING THE MAGLUMISERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING

	MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS)., GASTRIN- 17 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GASTRIN-17 IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,CALCITONIN (CLIA) (MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CALCITONIN (CT)IN HUMAN SERUMUSING THE MAGLUMISERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,TROPONIN I (CLIA) (MAGLUMI)- THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TROPONIN I IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,ALBUMIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN URINE USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,EBV VCA IGA (CLIA)(MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV VCA IGA IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). ,IGE (CLIA) (MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E(IGE) IN HUMAN SERUM USING THE MAGLUMISERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,IAA (CLIA) (MAGLUMI)- THE KIT IS AN IN

	VITROCHEMILUMINESCENCEIMMUNOASSAYFOR THE QUANTITATIVE DETERMINATION OF INSULIN AUTOANTIBODIES (IAA) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,17 OH- PROGESTER ONE (CLIA)(MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCEIMMUNO ASSAY FOR THE QUANTITATIVE DETERMINATION OF 17-OH PROGESTERONEIN HUMAN SERUM USING THE MAGLUMISERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000AND MAGLUMI 4000 PLUS). , PRG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE (PRG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,ICA (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO ISLET CELLS OF PANCREAS (ICA) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZERS (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,ANTI-TPO (CLIA) (MAGLUMI)- THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAYFOR THE QUANTITATIVE DETERMINATION OF ANTI-TPO IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). ,FERRITIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,FK 506 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FK 506 IN HUMAN WHOLE BLOOD USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE

	IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,IGF-I (CLIA) (MAGLUMI)- THE KIT IS AN IN VITROCHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN-LIKE GROWTH FACTOR-(IGF-) IN HUMAN SERUM USING THE MAGLUMISERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). , DHEA- S (CLIA) (MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE (DHEA-S) IN HUMAN SERUM USING THE MAGLUMISERIES FULLY-AUTOCHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). , TESTOSTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,A II (CLIA) (MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANGIOTENSIN (A) IN HUMAN PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). ,EBV EA IGA (CLIA)(MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV EA IGA IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). ,FREE ESTRIOL (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE ESTRIOL IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,C-PEPTIDE

	(CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,EBV NA IGG (CLIA) (MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF EBV NA IGG IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS). ,FREE TESTOSTERONE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,CK-MB (CLIA)(MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAYFOR THE QUANTITATIVE DETERMINATION OF MB ISOENZYME OF CREATINE KINASE (CK-MB) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,INTACT PTH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (INTACT PTH) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,IGM (CLIA)(MAGLUMI)-THE KIT IS AN IN VITROCHEMILUMINESCENCEIMMUNOASSAYFOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,ESTRADIOL (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-

	AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,PIIIP N-P (CLIA)(MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF COLLAGEN TYPE N-PEPTIDE (PP N-P) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,T3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION TRIIODOTHYRONINE (T3) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINES IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,IGA (SERUM ANALYSIS) (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,IGA (URINE ANALYSIS) (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN URINE USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,CSA (CLIA)(MAGLUMI)- THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CYCLOSPORINE A (CSA) IN HUMAN WHOLE BLOOD WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,FT4 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION THYROXINE (FT4) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS),MYOGLOBIN (CLIA)

	(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,TGA (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN AUTOANTIBODY (TGA) IN HUMAN SERUM USING MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,HCG/B-HCG (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (B-SUBUNIT) (HCG/B-HCG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,FT3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (FT3) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMIN IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS)., DIGOXIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,GH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GROWTH HORMONE (GH) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,IGG (URINE ANALYSIS) (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN URINE USING THE MAGLUMI SERIES FULLY-AUTO

		CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,IGG (SERUM ANALYSIS) (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).
831	IMP/IVD/2020/000733	1.License Holder Name: RMD MEDIAIDS LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(GLUCOCARE SENSE / MAKESURE / OK METER MATCH)-GLUCOCARE SENSE / MAKESURE / OK METER MATCH- BLOOD GLUCOSE TEST STRIPS ARE INTENDED FOR SELF-TESTING BY PEOPLE WITH DIABETES AT HOME AND HEALTH CARE PROFESSIONALS IN A CLINICAL SETTING TO MONITOR GLUCOSE CONCENTRATIONS IN CAPILLARY WHOLE BLOOD. THEY ARE FOR TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE ONLY). DO NOT USE THEM FOR DIAGNOSIS OF DIABETES OR TESTING ON NEONATES.,BLOOD GLUCOSE TEST STRIPS(GLUCOCARE ULTIMA)-GLUCOCARE ULTIMA- BLOOD GLUCOSE TEST STRIPS ARE INTENDED FOR SELF-TESTING BY PEOPLE WITH DIABETES AT HOME AND HEALTH CARE PROFESSIONALS IN A CLINICAL SETTING TO MONITOR GLUCOSE CONCENTRATIONS IN CAPILLARY WHOLE BLOOD. THEY ARE FOR TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE ONLY). DO NOT USE THEM FOR DIAGNOSIS OF DIABETES OR TESTING ON NEONATES
832	IMP/IVD/2020/000734	1.License Holder Name: MERIDIAN BIOTECH 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PHASIFY™ VIRAL RNA EXTRACTION KIT(PHASIFY™)-THE PHASIFY™ VIRAL RNA EXTRACTION KIT IS DESIGNED FOR MAXIMUM YIELD OF VIRAL RNA FROM VIRAL TRANSPORT MEDIA (INCL. PBS AND SALINE) SAMPLESAND HAS DEMONSTRATED SUPERIOR RECOVERY AGAINST SOLID PHASE EXTRACTION METHOD.

833	IMP/IVD/2020/000736	1.License Holder Name: ARK DIAGNOSTIC SYSTEM PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CK-NAC (SPINREACT)-IN-VITRO DETERMINATION OF CREATINE KINASE IN SERUM OR PLASMA, BILIRUBIN TOTAL(SPINREACT)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF BILIRUBIN IN SERUM AND PLASMA.,CK-MB (SPINREACT)-IN-VITRO DETERMINATION OF CREATINE KINASE IN SERUM OR PLASMA,CK-NAC (SPINREACT)-IN-VITRO DETERMINATION OF CREATINE KINASE IN SERUM OR PLASMA,GOT/AST(SPINREACT)-IN-VITRO DETERMINATION OF GLUTAMATE OXALOACETATE ACTIVITY IN SERUM OR PLASMA,LP (A) CONTROL (SPINREACT)-TO EVALUATE THE PRECISION AND ACCURACY OF LP(A) DETERMINATIONS IN HUMAN SERUM BY TURBIDIMETRY METHODS , SPINTROL H PATHOLOGIC(SPINREACT)-SPINTROL PATHOLOGICAL IS A HUMAN LYOPHILIZED SERUM. WITH MOST CONSTITUENT CONCENTRATIONS AND ACTIVITIES IN THE NORMAL OR PATHOLOGIC RANGE. IT'S INTENDED FOR CONTROL OF ACCURACY FOR USE WITH MANUAL AND AUTOMATED ANALYTICAL PROCEDURES.,CRP TURBI LATEX(SPINREACT)-CRP-TURBILATEX IS A QUANTITATIVE TURBIDIMETRIC TEST FOR THE MEASUREMENT OF CREACTIVE PROTEIN (CRP) IN HUMAN SERUM OR PLASMA. LATEX PARTICLES COATED WITH SPECIFIC ANTI- HUMAN CRP ARE AGGLUTINATED WHEN MIXED WITH SAMPLES CONTAINING CRP. THE AGGLUTINATION CAUSES AN ABSORBANCE CHANGE, DEPENDENT UPON THE CRP CONTENTS OF THE PATIENT SAMPLE THAT CAN BE QUANTIFIED BY COMPARISON FROM A CALIBRATOR OF KNOWN CRP CONCENTRATION.,LIPOPROTEIN (A) CALIBRATOR (SPINREACT)-TO CALIBRATE LP(A) DETERMINATIONS BY TURBIDIMETRY METHOD, TRIGLYCERIDES(SPINREACT)-IN-VITRO DETERMINATION OF TRIGLYCERIDES IN SERUM OR PLASMA,IRON(SPINREACT)-QUANTITATIVE IN-VITRO DETERMINATION OF IRON IN SERUM OR HEPARINIZED PLASMA,TRIGLYCERIDES (SPINREACT)-IN-VITRO DETERMINATION OF TRIGLYCERIDES IN SERUM OR PLASMA,TIBC (SPINREACT)-REAGENT TO MEASURE THE TOTAL IRON-BINDING CAPACITY (TIBC) IN SERUM.,SPINTROL H CAL(SPINREACT)-SPINTROL H CAL IS A HUMAN LYOPHILISED SERUM. THE CONCENTRATIONS AND ACTIVITIES HAVE BEEN SELECTED SO AS TO ENSURE OPTIMUM CALIBRATION FOR USE IN MANUAL AND AUTOMATIC ANALYSERS., PHOSPHORUS (SPINREACT)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF PHOSPHORUS IN SERUM AND URINE.,RF TURBI LATEX (SPINREACT)-IN-VITRO DETERMINATION OF RHEUMATOID FACTORS (RF) IN SERUM,LDH (SPINREACT)-IN-VITRO DETERMINATION OF LACTATE DEHYDROGENASE (LDH) ACTIVITY IN SERUM,RF LATEX (SPINREACT)-IN-VITRO DETERMINATION OF

	RHEUMATOID FACTORS (RF) IN SERUM,URIC ACID(SPINREACT)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF URIC ACID IN SERUM AND PLASMA,CYSTATIN C CALIBRATOR (SPINREACT)-TO CALIBRATE CYSTAIN DETERMINATION BY TURBIDIMETRY METHOD. , ALKALINE PHOSPHATASE (SPINREACT)-IN-VITRO DETERMINATION OF ALKALINE PHOSPHATASE IN SERUM OR PLASMA,FERRITIN CALIBRATOR (SPINREACT)-TO CALIBRATE OF FERRITIN DETERMINATIONS BY TURBIDIMETRY METHODS ,URINE & CSF TOTAL PROTEINS (SPINREACT)-IN-VITRO DETERMINATION OF TOTAL URINARY AND CSF PROTEIN,BILIRUBIN TOTAL CALIBRATOR (SPINREACT)-FOR CALIBRATION OF BILIRUBIN DETERMINATION BY TURBIDIMETRY METHOD.,CYSTAIN-C(SPINREACT)-THE C-CYS IS A QUANTITATIVE TURBIDIMETRIC TEST FOR THE MEASUREMENT OF CYSTATIN C IN SERUM OR PLASMA. LATEX PARTICLES COATED WITH POLYCLONAL RABBIT ANTI-CYSTATIN C ANTIBODIES ARE AGGLUTINATED WHEN MIXED WITH SAMPLES CONTAINING CYSTATIN C. THE AGGLUTINATION CAUSES AN ABSORBANCE CHANGE, DEPENDENT UPON THE C-CYS CONTENTS OF THE PATIENT SAMPLE. CYSTATIN C CONCENTRATION IS THEN DETERMINED BY INTERPOLATION FROM A CALIBRATION CURVE PREPARED FROM CALIBRATORS OF KNOWN CONCENTRATIONS.,UREA B(SPINREACT)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF UREA IN SERUM, PLASMA AND URINE.,HOMOCYSTEIN CALIBRATOR (SPINREACT)-HOMOCYSTEIN CALIBRATORS ARE USED WITH HOMOCYSTEIN REAGENT FOR THE PREPARATION OF THE CALIBRATION CURVE FOR DETERMINATION OF HOMOCYSTEIN ASSAY IN HUMAN SERUM OR PLASMA. REAGENTS: HOMOCYSTEIN CALIBRATORS ARE A LYOPHILIZED MATERIAL PREPARED WITH HUMAN SERUM BASE.,HOMOCYSTEIN CONTROL(SPINREACT)-HOMOCYSTEIN CONTROL KIT IS USED AS QUALITY CONTROL SERUM FOR QUANTITATIVE MEASUREMENT OF TOTAL L-HOMOCYSTEIN IN HUMAN SERUM OR PLASMA AND FOR QUALITY CONTROL PROCEDURES IN EXAMINING THE ACCURACY AND PRECISION OF QUANTITATIVE HOMOCYSTEIN ASSAYS.,TBA CALIBRATOR (SPINREACT)-TO CALIBRATE LIPID DETERMINATIONS BY TURBIDIMETRY METHODS,GLUCOSE(SPINREACT)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF GLUCOSE IN SERUM OR PLASMA,HOMOCYSTEIN(SPINREACT)-HOMOCYSTEINE IS A THIOL-CONTAINING AMINO ACID PRODUCED BY THE INTRACELLULAR DEMETHYLATION OF METHIONINE. TOTAL HOMOCYSTEINE (TCCY) REPRESENTS THE SUM OF ALL FORMS OF HCY INCLUDING FORMS OF OXIDIZED, PROTEIN BOUND AND FREE. ELEVATED LEVEL OF THCY HAS EMERGED AS AN IMPORTANT RISK FACTOR IN THE ASSESSMENT OF CARDIOVASCULAR DISEASE. EXCESS HCY IN THE BLOOD STREAM

	MAY CAUSE INJURIES TO ARTERIAL VESSELS DUE TO ITS IRRITANT NATURE, AND RESULT IN INFLAMMATION AND PLAQUE FORMATION, WHICH MAY EVENTUALLY CAUSE BLOCKAGE OF BLOOD FLOW TO THE HEART.,LIPASE-LQ(SPINREACT)-IN-VITRO ENZYMATIC DETERMINATION OF LIPASE IN SERUM OR PLASMA,CHOLINESTERASE (SPINREACT)-IN-VITROMEASUREMENT OF CHOLINESTERASE IN SERUM OR HEPARINIZED PLASMA,ACID PHOSPHATASE (SPINREACT)-IN-VITRO KINETIC DETERMINATION OF ACID PHOSPHATASE IN SERUM,CHOLESTEROL(SPINREACT)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CHOLESTEROL IN SERUM AND PLASMA, CREATININE(SPINREACT)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CREATININE IN SERUM, PLASMA, OR URINE, PHOSPHOLIPIDS(SPINREACT)-QUANTITATIVE IN-VITRO DETERMINATION OF PHOSPHOLIPIDS IN SERUM OR PLASMA, BILIRUBIN TOTAL & DIRECT(SPINREACT)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF BILIRUBIN IN SERUM AND PLASMA.,LDH (SPINREACT)-IN-VITRO DETERMINATION OF LACTATE DEHYDROGENASE (LDH) ACTIVITY IN SERUM,CRP LATEX(SPINREACT) -C-REACTIVE PROTEIN (CRP) IS A PROTEIN FOUND IN THE BLOOD, THE LEVELS OF WHICH RISE IN RESPONSE TO INFLAMMATION (I.E. C-REACTIVE PROTEIN IS AN ACUTE-PHASE PROTEIN). ITS PHYSIOLOGICAL ROLE IS TO BIND TO PHOSPHOCHOLINE EXPRESSED ON THE SURFACE OF DEAD OR DYING CELLS (AND SOME TYPES OF BACTERIA) IN ORDER TO ACTIVATE THE COMPLEMENT SYSTEM VIA THE C1Q COMPLEX,LDLC-D (SPINREACT)-FOR QUANTITATIVE MEASUREMENT OF LDL CHOLESTEROL IN SERUM OR PLASMA SAMPLES,FERRITIN CONTROL (SPINREACT)-TO EVALUATE THE PRECISION AND ACCURACY OF FERRITIN DETERMINATIONS IN HUMAN SERUM BY TURBIDIMETRY METHODS ,CYSTATIN C CONTROL (SPINREACT)-TO EVALUATE PRECISION AND ACCURACY OF CYSTAIN DETERMINATIONS IN HUMAN PLASMA OR SERUM BY TURBIDIMETRY METHOD ,CALCIUM(SPINREACT)-QUANTITATIVE IN-VITRO DETERMINATION OF CALCIUM IN SERUM OR HEPARINIZED PLASMA AND URINE,GLUCOSE HEXOKINASE (HK) (GLUCOSE HEXOKINASE)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF GLUCOSE IN SERUM OR PLASMA,FERRITIN (SPINREACT)-IN-VITRO DETERMINATION OF FERRITIN IN SERUM ,LIPOPROTEIN (A) (SPINREACT)-IN-VITRO DETERMINATION OF LIPOPROTEIN (A) IN HUMAN SERUM OR PLASMA ,GLYCATED HAEMOGLOBIN(SPINREACT)-IN-VITRO DETERMINATION OF GLYCATED HAEMOGLOBIN IN HUMAN BLOOD,HDLC-D(SPINREACT)-QUANTITATIVE IN-VITRO DETERMINATION OF HDL CHOLESTEROL IN SERUM OR PLASMA, ALKALINE PHOSPHATASE(SPINREACT)-IN-VITRO DETERMINATION OF ALKALINE PHOSPHATASE IN SERUM OR PLASMA,COMPLEMENT

	C3(SPINREACT)-IN-VITRO MEASUREMENT OF COMPLEMENT C3 IN HUMAN SERUM OR PLASMA ,TOTAL PROTEIN (SPINREACT)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF TOTAL PROTEIN IN SERUM AND PLASMA.,CALCIUM (SPINREACT)-QUANTITATIVE IN-VITRO DETERMINATION OF CALCIUM IN SERUM OR HEPARINIZED PLASMA AND URINE,ASO TURBI LATEX (SPINREACT)-IN-VITRO DETERMINATION OF ANTI-STREPTOLYSIN O (ASO) IN HUMAN SERUM OR PLASMA,CERULOPLASMIN(SPINREACT)-IN-VITRO MEASUREMENT OF CERULOPLASMIN IN HUMAN SERUM OR PLASMA,UREA-UV (SPINREACT)-IN-VITRO ENZYMATIC DETERMINATION OF UREA IN SERUM OR PLASMA,ASO CALIBRATOR(SPINREACT)-TO CALIBRATE ASO DETERMINATIONS BY TURBIDIMETRY METHOD,GPT/ALT (SPINREACT)-IN-VITRO DETERMINATION OF ALANINE AMINOTRANSFERASE ACTIVITY IN SERUM OR PLASMA,CK-MB (SPINREACT)-IN-VITRO DETERMINATION OF CREATINE KINASE IN SERUM OR PLASMA,RF CALIBRATOR (SPINREACT)-TO CALIBRATE RF DETERMINATIONS BY TURBIDIMETRY METHOD,GLYCATED HAEMOGLOBIN CONTROL(SPINREACT)-TO EVALUATE PRECISION AND ACCURACY OF GLYCATED HAEMOGLOBIN DETERMINATIONS IN HUMAN BLOOD BY TURBIDIMETRY METHODS ,GPT/ALT(SPINREACT)-IN-VITRO DETERMINATION OF ALANINE AMINOTRANSFERASE ACTIVITY IN SERUM OR PLASMA,BILIRUBIN DIRECT(SPINREACT)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF BILIRUBIN IN SERUM AND PLASMA.,GOT/AST (SPINREACT)-IN-VITRO DETERMINATION OF GLUTAMATE OXALOACETATE ACTIVITY IN SERUM OR PLASMA,GLYCATED HAEMOGLOBIN CALIBRATOR (SPINREACT)-TO CALIBRATE GLYCATED HAEMOGLOBIN DETERMINATIONS BY TURBIDIMETRY METHODS ,MICROALBUMIN CONTROL(SPINREACT)-TO EVALUATE THE PRECISION AND ACCURACY OF MICROALBUMIN DETERMINATIONS IN HUMAN URINE BY TURBIDIMETRY METHOD ,MICROALBUMIN CALIBRATOR (SPINREACT)-TO CALIBRATE MICROALBUMIN DETERMINATION BY TURBIDIMETRY METHOD.,UREA UV(SPINREACT)-IN-VITRO ENZYMATIC DETERMINATION OF UREA IN SERUM OR PLASMA, SPINTROL H NORMAL(SPINREACT)-SPINTROL NORMAL IS A HUMAN LYOPHILIZED SERUM. WITH MOST CONSTITUENT CONCENTRATIONS AND ACTIVITIES IN THE NORMAL OR PATHOLOGIC RANGE. IT'S INTENDED FOR CONTROL OF ACCURACY FOR USE WITH MANUAL AND AUTOMATED ANALYTICAL PROCEDURES.,HDL/LDL CALIBRATOR (SPINREACT)-THE CALIBRATOR IS FOR DETERMINATION OF HDLC CONCENTRATION IN HUMAN SERUM.,MAGNESIUM(SPINREACT)-QUANTITATIVE IN-VITRO DETERMINATION OF MAGNESIUM IN SERUM, PLASMA OR URINE.,MICROALBUMIN (SPINREACT)-IN-VITRO DETERMINATION OF MICROALBUMIN IN HUMAN URINE ,LIPIDS

	CONTROL (SPINREACT)-TO EVALUATE THE PRECISION AND ACCURACY OF LIPID DETERMINATIONS BY TURBIDIMETRY METHODS ,TOTAL BILE ACIDS(SPINREACT)-FASTING SERUM BILE ACIDS CAN BE USED IN THE DIAGNOSIS AND PROGNOSIS OF LIVER DISEASE. LEVELS RISE IN MANY LIVER DISEASES, FOR EXAMPLE HEPATITIS AND LIVER SCLEROSIS. ABNORMAL LEVELS IN FASTING PATIENTS OR IMMEDIATELY AFTER A MEAL CAN BE USED TO DETECT LIVER DISEASE AND DAMAGE, IMPAIRED LIVER FUNCTION, INTESTINAL DYSFUNCTION AND PERHAPS A GALL BLADDER BLOCKAGE. BILE ACID MEASUREMENT MAY DETECT SOME FORMS OF LIVER DISEASE EARLIER THAN STANDARD LIVER TESTS BECAUSE BILE ACIDS LEVELS CORRESPOND TO LIVER FUNCTION, RATHER THAN LIVER DAMAGE IN VETERINARY MEDICINE, BILE ACID MEASUREMENT IS CONSIDERED TO BE A SUPERIOR INDICATOR OF LIVER DISEASE. FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF TOTAL BILE ACIDS IN SERUM AND PLASMA.,GAMMA GT (SPINREACT)-IN-VITRO DETERMINATION OF GAMMA-GLUTAMYL TRANSFERASE (GAMMA-GT) IN SERUM,SERUM PROTEIN CALIBRATOR (SPINREACT)-IN-VITRO DETERMINATION OF PLASMA PROTEINS ,GAMMA GT (SPINREACT)-IN-VITRO DETERMINATION OF GAMMA-GLUTAMYL TRANSFERASE (GAMMA-GT) IN SERUM,AMYLASE(SPINREACT)-IN-VITRO DETERMINATION OF AMYLASE IN SERUM OR URINE,COMPLEMENT C4 (SPINREACT)-IN-VITRO MEASUREMENT OF COMPLEMENT C4 IN HUMAN SERUM OR PLASMA ,ALBUMIN (SPINREACT)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN SERUM OR PLASMA.,ASO LATEX (SPINREACT)-IN-VITRO DETERMINATION OF ANTI-STREPTOLYSIN O (ASO) IN SERUM,LACTATE(SPINREACT)-FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF LACTATE IN PLASMA,URINE & CSF TOTAL PROTEINS (SPINREACT)-IN-VITRO DETERMINATION OF TOTAL URINARY AND CSF PROTEIN,SERUM PROTEIN CONTROL(SPINREACT)-IN-VITRO DETERMINATION OF PLASMA PROTEINS

834	IMP/IVD/2020/000739	1.License Holder Name: ACCUREX BIOMEDICALS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URINE REAGENT STRIPS (URIT 14G)-USED FOR THE SEMI-QUANTITATIVE MEASUREMENT OF LEUKOCYTES, KETONE, NITRITE, UROBILINOGEN, BILIBRUBIN, GLUCOSE, PROTEIN, SPECIFIC GRAVITY, PH, BLOOD, ASCORBIC ACID, MICROALBUMIN, CALCIUM AND CREATININE IN URINE.,URINE REAGENT STRIPS(URIT 11G)-USED FOR THE SEMI-QUANTITATIVE MEASUREMENT OF LEUKOCYTES, KETONE, NITRITE, UROBILINOGEN, BILIRUBIN, PROTEIN, GLUCOSE, SPECIFIC GRAVITY, BLOOD, PH AND ASCORBIC ACID IN URINE.,URINE REAGENT STRIPS (URIT 10G)-USED FOR THE SEMI-QUANTITATIVE MEASUREMENT OF LEUKOCYTES, KETONE, NITRITE, UROBILINOGEN, BILIRUBIN, PROTEIN, GLUCOSE, SPECIFIC GRAVITY, BLOOD AND PH IN URINE.
835	IMP/IVD/2020/000741	1.License Holder Name: ACER BIOMEDICALS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GAS ANALYZER CONTROL(WONDFO)-THE WONDFO® BLOOD GAS ANALYZER CONTROL (HEREINAFTER REFERRED TO AS “ANALYZER CONTROL’) ALONG WITH WONDFO® BLOOD GAS ANALYZER (HEREINAFTER REFERRED TO AS “ANALYZER”, MODEL CODE: BGA-101) IS INTENDED FOR MONITORING AND EVALUATING THE PRECISION OF THE RESULT OF PH (ALKALINITY AND ACIDITY), PCO2 (PARTIAL PRESSURE OF CARBON DIOXIDE), PO2 (OXYGEN PARTIAL PRESSURE), NA+ (SODIUM ION CONCENTRATION), CL- (CHLORIDE ION CONCENTRATION), K+ (POTASSIUM ION CONCENTRATION), CA++ (CALCIUM CONCENTRATION), HCT (HEMATOCRIT), GLU (GLUCOSE CONCENTRATION) AND LAC (LACTIC ACID CONCENTRATION) IN THE PATIENT’S ARTERIAL WHOLE BLOOD.,BLOOD GAS ANALYZER TEST CARD(WONDFO)-WONDFO® BLOOD GAS ANALYZER TEST CARD (ELECTROCHEMICAL METHOD, HEREINAFTER REFERRED TO AS “TEST CARD”) IS USED AS A SET WITH WONDFO® BLOOD GAS ANALYZER (HEREINAFTER REFERRED TO AS “ANALYZER”, MODEL CODE: BGA-101), WHICH APPLIES TO THE MEASUREMENT OF PH (PH), CARBON DIOXIDE PARTIAL PRESSURE (PCO2), OXYGEN PARTIAL PRESSURE (PO2), POTASSIUM ION (K+), SODIUM ION (NA+), CALCIUM ION (CA++), CHLORIDE ION (CL-), HEMATOCRIT (HCT), GLUCOSE (GLU) AND LACTIC ACID (LAC) CONCENTRATION IN THE PATIENT’S ARTERIAL WHOLE BLOOD SPECIMEN.

836	IMP/IVD/2020/000742	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD FOX PCR EXTRACTION TUBES(BD FOX PCR EXTRACTION TUBES)-THE BD VIPER LT SYSTEM, USED IN CONJUGATION WITH APPROPRIATE IN VITRO DIAGNOSTIC (IVD) ASSAYS, IS INTENDED FOR THE AUTOMATED EXTRACTION OF NUCLEIC ACIDS FROM MULTIPLE SPECIMEN TYPES AS WELL AS AMPLIFICATION AND DETECTION OF TARGET NUCLEIC ACID SEQUENCES BY EITHER STRAND DISPLACEMENT AMPLIFICATION (SDA) OR POLYMERASE CHAIN REACTION (PCR) TECHNOLOGIES. ,BD MAX SAMPLE TREATMENT REAGENT (STR)(BD MAX SAMPLE TREATMENT REAGENT (STR))-BD MAX STR IS A REAGENT INTENDED TO LIQUEFY SPUTUM SPECIMENS AND REDUCE THE VIABILITY OF MYCOBACTERIUM TUBERCULOSIS COMPLEX PRIOR TO FURTHER PROCESSING ON THE BD MAX SYSTEM.,BD VIPER PCR EXTRACTION REAGENT TROUGH WITH PIERCING TOOL(BD VIPER PCR EXTRACTION REAGENT TROUGHS WITH PIERCING TOOL)-THE BD VIPER LT SYSTEM, USED IN CONJUGATION WITH APPROPRIATE IN VITRO DIAGNOSTIC (IVD) ASSAYS, IS INTENDED FOR THE AUTOMATED EXTRACTION OF NUCLEIC ACIDS FROM MULTIPLE SPECIMEN TYPES AS WELL AS AMPLIFICATION AND DETECTION OF TARGET NUCLEIC ACID SEQUENCES BY EITHER STRAND DISPLACEMENT AMPLIFICATION (SDA) OR POLYMERASE CHAIN REACTION (PCR) TECHNOLOGIES.,BD ONCLARITY HPV ASSAY REAGENT PACK(BD ONCLARITY HPV ASSAY REAGENT PACK)-THE BD ONCLARITY™ HPV ASSAY IS AN AMPLIFIED DNA TEST FOR THE QUALITATIVE DETECTION OF HIGH RISK TYPES OF HUMAN PAPILLOMAVIRUS (HPV). THE ASSAY DETECTS ALL HIGH RISK HPV TYPES (16,18,31,33,35,39,45,51,52,56,58,59,66 AND 68) AND PROVIDES THE CAPABILITY FOR INDIVIDUALLY GENOTYPING SIX HIGH RISK TYPES (HPV 16,18,31,45,51 AND 52) AND THREE GENOTYPE GROUPS (33/58, 35/39/68 AND 56/59/66). CERVICAL SPECIMENS THAT ARE TESTED WITH THE BD ONCLARITY HPV ASSAY INCLUDE THE BD ONCLARITY HPV CERVICAL BRUSH COLLECTION KIT, BD SUREPATH™ VIAL, AND PRESERVCYT® SOLUTION (USING AN ALIQUOT THAT IS REMOVED PRIOR TO OR AFTER PROCESSING FOR EITHER THE BD SUREPATH OR THINPREP®PAP TEST. THE BD ONCLARITY HPV ASSAY IS PERFORMED WITH THE BD VIPER™ LT SYSTEM THE BD ONCLARITY HPV ASSAY IS INDICATED WITH USE OF BD SUREPATH™ VIAL, AND PRESERVCYT® SOLUTION: (A) IN WOMEN WITH ASC-US (ATYPICAL SQUAMOUS CELLS OF UNDETERMINED SIGNIFICANCE) CERVICAL CYTOLOGY TEST RESULTS, THE BD ONCLARITY HPV ASSAY CAN BE USED TO DETECT HIGH-RISK HPV GENOTYPES 16,18,31,33,35,39,45,51,52,56,58,59,66 AND 68. THIS INFORMATION TOGETHER WITH PHYSICIAN'S ASSESSMENT OF

		SCREENING HISTORY, OTHER RISK FACTORS, AND PROFESSIONAL GUIDELINES, MAY BE USED TO GUIDE PATIENT MANAGEMENT. THE RESULTS OF THIS TEST ARE NOT INTENDED TO PREVENT WOMEN FROM PROCEEDING TO COLPOSCOPY. (B) THE BD ONCLARITY HPV ASSAY CAN BE USED TOGETHER WITH CERVICAL CYTOLOGY TO ADJUNCTIVELY SCREEN TO DETECT HIGH RISK HPV TYPES 16,18,31,33,35,39,45,51,52,56,58,59,66 AND 68. THIS INFORMATION, TOGETHER WITH THE PHYSICIAN'S ASSESSMENT OF SCREENING HISTORY, OTHER FACTORS, AND PROFESSIONAL GUIDELINES, MAY BE USED TO GUIDE PATIENT MANAGEMENT. (C) THE BD ONCLARITY HPV ASSAY CAN BE USED AS A FIRST-LINE PRIMARY CERVICAL CANCER SCREENING TEST TO DETECT HIGH RISK HPV TYPES 16,18,31,33,35,39,45,51,52,56,58,59,66 AND 68. WOMEN WHO TEST NEGATIVE FOR THE HIGH RISK HPV TYPES BY THE BD ONCLARITY HPV ASSAY SHOULD BE FOLLOWED UP IN ACCORDANCE WITH THE PHYSICIAN'S ASSESSMENT OF SCREENING AND MEDICAL HISTORY, OTHER RISK FACTORS, AND PROFESSIONAL GUIDELINES. THIS INFORMATION, TOGETHER WITH THE PHYSICIAN'S ASSESSMENT OF SCREENING HISTORY, OTHER FACTORS, AND PROFESSIONAL GUIDELINES, MAY BE USED TO GUIDE PATIENT MANAGEMENT.
837	IMP/IVD/2020/000751	1.License Holder Name: TRUE HEALTHCARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:1COPY™ COVID-19 QPCR MULTI KIT(1COPY™ COVID-19 QPCR MULTI KIT)-1COPY™ COVID-19 QPCR MULTI KIT IS A REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN NASOPHARYNGEAL, OROPHARYNGEAL, ANTERIOR NASAL, MID-TURBINATE NASAL SWAB SPECIMENS AS WELL AS NASOPHARYNGEAL WASH/ASPIRATE AND NASAL ASPIRATE SPECIMENS COLLECTED FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER.

838	IMP/IVD/2020/000752	1.License Holder Name: GRIFOLS INDIA HEALTHCARE PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CARDS FOR DETERMINING THE BLOOD GROUP BY COLUMN AGGLUTINATION(DG GEL COOMB$)-THE DG GEL COOMBS CARD IS USED FOR THE DIRECT AND INDIRECT ANTIGLOBULIN TEST OF HUMAN BLOOD SAMPLES, IN GEL TECHNIQUE. THE INDIRECT ANTIGLOBULIN TESTS INCLUDE SCREENING AND IDENTIFICATION OF UNEXPECTED ANTIBODIES, CROSSMATCH TESTS, AUTOCONTROL AND RED BLOOD CELL TYPING., ANTIBODY IDENTIFICATION PANEL REAGENT RED BLOOD CELL IVD, KIT AGGLUTINATION(DG GEL NEUTRAL)-THE DG GEL NEUTRAL CARD IS USED FOR SALINE AND ENZYMATIC TESTS AND FOR ITS USE AS A CONTROL MICROTUBE, IN GEL TECHNIQUE. THE SALINE AND ENZYMATIC TECHNIQUE TESTS INCLUDE: SCREENING AND IDENTIFICATION OF UNEXPECTED ANTIBODIES, CROSSMATCH TESTS, AUTOCONTROL, RED BLOOD CELL TYPING AND DETERMINATION OF THE REVERSE ABO GROUP.,REAGENT RED BLOOD CELLS(IDENTISERA DIANA)-IDENTISERA DIANA REAGENT RED BLOOD CELLS ARE USED FOR THE IDENTIFICATION OF UNEXPECTED ANTIBODIES IN GEL TECHNIQUE.,CARDS FOR DETERMINING THE BLOOD GROUP BY COLUMN AGGLUTINATION(DG GEL ABO/RH (2D))-THE DG GEL ABO/RH (2D) CARD IS USED FOR DETERMINING THE ANTIGENS OF THE ABO AND RH (D) SYSTEM AND THE REVERSE ABO GROUP, IN GEL TECHNIQUE.,DILUENT, BLOOD CELL(DG GEL SOL)-DG GEL SOL IS A REAGENT FOR PREPARING RED BLOOD CELL SUSPENSIONS AND PLASMA / SERUM DILUTIONS USED IN GEL TECHNIQUES.,CARDS FOR DETERMINING THE BLOOD GROUP BY COLUMN AGGLUTINATION(DG GEL CT)-THE DG GEL CT CARD IS USED FOR CONFIRMING THE BLOOD GROUPS OF THE ABO AND RH (D) SYSTEMS, ABO AND RH (D) ISOGROUP COMPATIBILITY TESTS, SCREENING OF UNEXPECTED ANTIBODIES (SALINE, ENZYMATIC AND LISS-COOMBS TECHNIQUES), CROSSMATCH TESTS (SALINE, ENZYMATIC AND LISS COOMBS TECHNIQUES) AND AUTOCONTROL (SALINE, ENZYMATIC AND LISS-COOMBS TECHNIQUES), IN GEL TECHNIQUE.,REAGENT RED BLOOD CELLS(SERASCAN DIANA 4)-SERASCAN DIANA 4 REAGENT RED BLOOD CELLS ARE USED FOR THE SCREENING OF UNEXPECTED ANTIBODIES IN GEL TECHNIQUE.,REAGENT RED BLOOD CELLS (SERIGRUP DIANA A1/B)-SERIGRUP DIANA A1/B REAGENT RED BLOOD CELLS ARE USED FOR THE DETERMINATION OF THE REVERSE ABO GROUP IN GEL TECHNIQUE.,REAGENT RED BLOOD CELLS (SERASCAN DIANA 3)-SERASCAN DIANA 3 REAGENT RED BLOOD CELLS ARE USED FOR THE SCREENING OF UNEXPECTED ANTIBODIES IN GEL TECHNIQUE.,CARDS FOR DETERMINING THE BLOOD GROUP BY COLUMN AGGLUTINATION(DG GEL CONFIRM)-THE DG GEL CONFIRM

	CARD IS USED FOR CONFIRMING THE BLOOD GROUPS OF THE ABO AND RH (D) SYSTEM, IN GEL TECHNIQUE.,REAGENT RED BLOOD CELLS (SERASCAN DIANA 2)-SERASCAN DIANA 2 REAGENT RED BLOOD CELLS ARE USED FOR THE SCREENING OF UNEXPECTED ANTIBODIES IN GEL TECHNIQUE.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

839	IMP/IVD/2020/000753	1.License Holder Name: MEX INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CREAT CONTROL LEVEL 2 NORMAL(STAT SENSOR)-THE STATSENSOR CREATININE CONTROL SOLUTION IS USED AS A QUALITY CONTROL CHECK TO ENSURE THAT THE NOVA STATSENSOR FAMILY, ACIST STATSENSOR, AND EZ CHEM CREATININE METERS (COLLECTIVELY REFERRED TO AS THE CREATININE METER) AND THE CREATININE METER TEST STRIPS ARE WORKING PROPERLY AS A SYSTEM. THE STATSENSOR FAMILY OF METERS HAS STATSENSOR AS PART OF THEIR BRAND NAME.,CREAT-TEST STRIPS(STAT SENSOR)-USE ONLY FOR QUANTITATIVE TESTS FOR THE NOVA STATSENSOR FAMILY, ACIST STATSENSOR, AND EZ CHEM CREATININE METERS (COLLECTIVELY REFERRED TO AS THE CREATININE METER). THE CREATININE METER IS INTENDED TO THE QUANTITATIVELY MEASURE CREATININE IN WHOLE BLOOD. THE CREATININE METER IS PLASMA CALIBRATED TO ALLOW EASY COMPARISON OF RESULTS WITH LABORATORY METHODS. NOVA STATSENSOR CREATININE TEST STRIPS ARE FOR TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE).,CREAT- TEST STRIPS(STAT SENSOR-I)-USE ONLY FOR QUANTITATIVE TESTS FOR THE NOVA STATSENSOR-I FAMILY CREATININE METERS (COLLECTIVELY REFERRED TO AS THE CREATININE METER). THE CREATININE METER IS INTENDED TO THE QUANTITATIVELY MEASURE CREATININE IN WHOLE BLOOD. THE CREATININE METER IS PLASMA CALIBRATED TO ALLOW EASY COMPARISON OF RESULTS WITH LABORATORY METHODS. NOVA STATSENSOR-I CREATININE TEST STRIPS ARE FOR TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE).,CREAT CONTROL LEVEL 1 LOW(STAT SENSOR)-THE STATSENSOR CREATININE CONTROL SOLUTION IS USED AS A QUALITY CONTROL CHECK TO ENSURE THAT THE NOVA STATSENSOR FAMILY, ACIST STATSENSOR, AND EZ CHEM CREATININE METERS (COLLECTIVELY REFERRED TO AS THE CREATININE METER) AND THE CREATININE METER TEST STRIPS ARE WORKING PROPERLY AS A SYSTEM. THE STATSENSOR FAMILY OF METERS HAS STATSENSOR AS PART OF THEIR BRAND NAME.,CREAT CONTROL LEVEL 3 HIGH(STAT SENSOR)-THE STATSENSOR CREATININE CONTROL SOLUTION IS USED AS A QUALITY CONTROL CHECK TO ENSURE THAT THE NOVA STATSENSOR FAMILY, ACIST STATSENSOR, AND EZ CHEM CREATININE METERS (COLLECTIVELY REFERRED TO AS THE CREATININE METER) AND THE CREATININE METER TEST STRIPS ARE WORKING PROPERLY AS A SYSTEM. THE STATSENSOR FAMILY OF METERS HAS STATSENSOR AS PART OF THEIR BRAND NAME.,CREAT LINEARITY (LEVEL 1, LEVEL 2, LEVEL 3, LEVEL 4, LEVEL5)(STAT SENSOR)-TO CHECK THE LINEARITY OF THE NOVA STATSENSOR

		FAMILY, ACIST STATSENSOR, AND EZ CHEM CREATININE METERS (COLLECTIVELY REFERRED TO AS THE CREATININE METER). THE STATSENSOR FAMILY OF METERS HAS STATSENSOR AS PART OF THEIR BRAND NAME.
840	IMP/IVD/2020/000758	1.License Holder Name: ANALYTICAL AUTOMATION (INDIA) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MYTHIC 18-22 ENZYMATIC CLEANING SOLUTION(MYTHIC 18-22 ENZYMATIC CLEANING SOLUTION)-THIS SOLUTION IS USED TO CLEAN THE SYSTEM. THE PRESENCE OF AN ENZYME REDUCES THE FORMATION OF PROTEINS DEPOSIT.,MYTHIC 18 CYANIDE FREE LYTIC SOLUTION (MYTHIC 18 CYANIDE FREE LYTIC SOLUTION)-LYSING AGENT TO OBTAIN THE MEASUREMENT OF THE HAEMOGLOBIN, COUNTING AND DIFFERENTIATION OF THE WHITE BLOOD CELLS.,MYTHIC 18 DILUENT (MYTHIC 18 DILUENT)-ISOTONIC SOLUTION USE FOR THE DIFFERENTIATION OF THE WHITE BLOOD CELLS,MYTHIC 18-22 FLUSH CLEANER(MYTHIC 18- 22 FLUSH CLEANER)-MYTHIC 18-22 FLUSH-CLEANER IS AN EMERGENCY CLEANER, BASED ON HYPOCHLORITE, DESIGNED FOR WASHING AND MAINTENANCE OF MYTHIC HAEMATOLOGY ANALYZERS.
841	IMP/IVD/2020/000760	1.License Holder Name: M/S HEMOGENOMICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 TMA RT PCR ASSAY (A NUCLEIC ACID AMPLIFICATION IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE DETECTION OF RNA FROM SARS-COV-2)(APTIMA SARS-COV-2 ASSAY)-THE APTIMA SARS COV-2 ASSAY IS A NUCLEIC ACID AMPLIFICATION IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE DETECTION OF RNA FROM SARS-COV-2 ISOLATED AND PURIFIED FROM NASOPHARYNGEAL (NP) , NASAL, MID-TURBINATE AND OROPHARYNGEAL (OP) SWAB SPECIMENS, NASOPHARYNGEAL WASH/ASPIRATE OR NASAL ASPIRATES OBTAINED FROM INDIVIDUALS MEETING COVID-19 CLINICAL AND/OR EPIDEMIOLOGICAL CRITERIA

842	IMP/IVD/2020/000762	1.License Holder Name: BIOTROL LABORATORIES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HUMAN CHORIONIC GONADOTROPHIN (HCG) DIAGNOSTIC TEST KIT (COLLOIDAL GOLD IMMUNOCHOROMATOGRAPHIC ASSAY)(WH ACCU TEST)-ONE STEP PREGNANCY TEST IS AN IMMUNOASSAY DESIGNED FOR THE QUALITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IS USED FOR EARLY DETECTION FOR PREGNANCY.

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843	IMP/IVD/2020/000764	1.License Holder Name: IMMUNOSHOP INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:A1M KIT - GPP-100 (GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF 1 MICROGLOBULIN (A1M) IN HUMAN URINE. ,FR-CRP KIT - GPP-100 (GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF FULL RANGE C-REACTIVE PROTEIN (FR-CRP) IN HUMAN WHOLE BLOOD OR SERUM OR PLASMA AS AN AID IN DIAGNOSIS AND TREATMENT OF INFLAMMATORY CONDITIONS, BACTERIAL INFECTION AS WELL AS CARDIAC DISEASES.,IGA KIT - GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN BLOOD (OR SERUM OR PLASMA) AS AN AID IN THE DIAGNOSIS OF ABNORMAL IGA METABOLISM. ,D-DIMER - GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF D-DIMER (DD) IN HUMAN PLASMA. ,ASO KIT - GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF ANTI-STREPTOLYSIN O (ASO) IN HUMAN SERUM AS AN AID IN DETERMINATION OF LEVELS OF STREPTOCOCCAL INFECTION. ,ANTI-CCP KIT -GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF ANTI-CYCLIC CITRULLINATED PEPTIDE ANTIBODY (ANTI-CCP) IN HUMAN SERUM AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA). ,TRF KIT - GPP-100 (GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF TRANSFERRIN (TRF) IN HUMAN SERUM AS AN AID IN THE DIAGNOSIS OF ABNORMAL TRF METABOLISM. ,USCRP KIT -GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF ULTRASENSITIVE C-REACTIVE PROTEIN (USCRP) IN HUMAN SERUM OR PLASMA AS AN AID IN DIAGNOSIS AND MONITORING OF INFLAMMATORY CONDITIONS, BACTERIAL INFECTION AS WELL AS CARDIAC DISEASES.,HBA1C KIT - GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF HAEMOGLOBIN A1C (HBA1C) IN HUMAN BLOOD AS AN AID IN DIAGNOSIS OF ABNORMAL HBA1C METABOLISM. ,CRP KIT -GPP-100 (GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM OR PLASMA AS AN AID IN DIAGNOSIS AND MONITORING OF INFLAMMATORY CONDITIONS,

	BACTERIAL INFECTION AS WELL AS CARDIAC DISEASES.,MALB KIT-GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF MICRO ALBUMIN (MALB) IN HUMAN URINE AS AN AID IN DIAGNOSIS OF ABNORMAL MALB METABOLISM.,CYS C KIT - GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF HUMAN CYSTATIN C (CYS C) IN HUMAN SERUM OR PLASMA AS AN AID IN DIAGNOSIS AND TREATMENT OF RENAL DISEASES. ,URINE IGG KIT - GPP-100 (GOLDSITE)-THIS PRODUCT IS USED ON THE GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN URINE AS AN AID IN DIAGNOSIS OF ABNORMAL IGG METABOLISM. ,C3 KIT - GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF COMPLEMENT 3 (C3) IN HUMAN SERUM OR PLASMA AS AN AID IN DIAGNOSIS OF ABNORMAL C3 METABOLISM. ,BMG KIT - GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF 2-MICROGLOBULIN (BMG) IN HUMAN SERUM OR PLASMA OR URINE AS AN AID IN DIAGNOSIS OF ABNORMAL BMG METABOLISM. ,C4 KIT- GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF COMPLEMENT 4 (C4) IN HUMAN SERUM OR PLASMA AS AN AID IN DIAGNOSIS OF ABNORMAL C4 METABOLISM. , SAA KIT - GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF SERUM AMYLOID A (SAA) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,RF KIT - GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN HUMAN SERUM AS AN AID IN DIAGNOSIS OF RHEUMATOID ARTHRITIS.,IGG KIT - GPP-100 (GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN BLOOD OR SERUM OR PLASMA AS AN AID IN DIAGNOSIS OF ABNORMAL IGG METABOLISM. ,URINE TRF KIT - GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF TRANSFERRIN (TRF) IN HUMAN URINE AS AN AID IN DIAGNOSIS OF ABNORMAL TRF METABOLISM. ,IGM KIT - GPP-100(GOLDSITE)-THIS PRODUCT IS USED ON GPP-100 SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM OR PLASMA AS AN AID IN DIAGNOSIS OF ABNORMAL IGM METABOLISM.

844	IMP/IVD/2020/000770	1.License Holder Name: SOWAR PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CARTRIDGE(E|1 CARTRIDGE 300 OQC)-MEASUREMENT OF ELECTROLYTES, CARTRIDGE(E|1 CARTRIDGE 600 OQC)-MEASUREMENT OF ELECTROLYTES,QC MATERIAL(E|1 QC LEVEL 2)-QUALITY CONTROL MATERIAL,QC MATERIAL(E|1 QC LEVEL 3)-QUALITY CONTROL MATERIAL,CARTRIDGE(E|1 CARTRIDGE 150)-MEASUREMENT OF ELECTROLYTES,QC MATERIAL(E|1 QC LEVEL 1)-QUALITY CONTROL MATERIAL,CARTRIDGE(E|1 CARTRIDGE 150 OQC)-MEASUREMENT OF ELECTROLYTES,CARTRIDGE(E|1 CARTRIDGE 300)-MEASUREMENT OF ELECTROLYTES,CARTRIDGE(E|1 CARTRIDGE 600)-MEASUREMENT OF ELECTROLYTES,CAPILLARY TUBES(E|1 CAPILLARY TUBES)-CONTAINER FOR BLOOD SAMPLES
845	IMP/IVD/2020/000771	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 RT-QPCR REAGENT KIT(SARS-COV-2 RT-QPCR REAGENT KIT)-THE KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF SARS-COV-2 (SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2) NUCLEIC ACIDS IN RNA EXTRACTED FROM THE HUMAN OROPHARYNGEAL SWAB AND NASOPHARYNGEAL SWAB SPECIMENS AS AN AID IN DIAGNOSING PATIENTS SUSPECTED OF COVID-19 (CORONAVIRUS DISEASE) BY THEIR HEALTHCARE PROVIDER.

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846	IMP/IVD/2020/000772	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CELL-DYN EMERALD 22 EASY CLEANER(CELL-DYN EMERALD 22 EASY CLEANER)-CELL-DYN EMERALD 22 EASY CLEANER IS A SPECIAL CLEANING AGENT FOR USE ON CELL-DYN EMERALD 22 ANALYZER AND THE CELL-DYN EMERALD 22 AL (AUTOLOADER) ANALYZER. SYSTEM SHOULD BE CLEANED ON THE SCHEDULE RECOMMENDED IN THE APPROPRIATE CELL-DYN EMERALD 22 OPERATOR'S MANUAL, CELL-DYN EMERALD 22 AL OPERATOR'S MANUAL, OR WHENEVER A REPEATED CLOG OR OBSTRUCTED APERTURE IS SUSPECTED. CELL-DYN EMERALD 22 EASY CLEANER WAS SPECIFICALLY DEVELOPED FOR THE REMOVAL OF PROTEIN BUILDUP AND DEBRIS (CLOGS) IN COUNTING ORIFICES, FLOW CELLS, AND ASSOCIATED ANALYZER TUBING. INTENDED TO BE USED IN VITRO FOR THE EXAMINATION OF SPECIMENS DERIVED FROM THE HUMAN BODY.,CELL-DYN EMERALD 22 DILUENT(CELL-DYN EMERALD 22 DILUENT)-DILUENT FOR COUNTING AND SIZING BLOOD CELLS ON THE CELL-DYN EMERALD 22 ANALYZER AND THE CELL-DYN EMERALD 22 AL (AUTOLOADER) ANALYZER.

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847	IMP/IVD/2020/000773	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD UNIVERSAL VIRAL TRANSPORT FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL, AND UREAPLASMAL SPECIMEN 3ML VIAL, STANDARD KIT(BD UNIVERSAL VIRAL TRANSPORT FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL, AND UREAPLASMAL SPECIMEN 3ML VIAL, STANDARD KIT)-BD™ UNIVERSAL VIRAL TRANSPORT SYSTEM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. THIS SYSTEM CAN BE PROCESSED USING STANDARD CLINICAL LABORATORY OPERATING PROCEDURES FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL AND UREAPLASMAL CULTURE.,BD BBL CULTURESWAB STERILE SINGLE SWAB(BD BBL CULTURESWAB STERILE SINGLE SWAB)-BD BBL™ CULTURESWAB™ STERILE SWABS IN TUBE ARE STERILE AND READY-FOR-USE SYSTEMS INTENDED FOR CLINICAL SAMPLES DRAWING. THE SWAB IS SUITABLE FOR SHORT CONTACT WITH THE HUMAN BODY. THE PRODUCT SHOULD BE USED AS DIRECTED,BD UNIVERSAL VIRAL TRANSPORT FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL, AND UREAPLASMAL SPECIMEN 3ML VIAL(BD UNIVERSAL VIRAL TRANSPORT FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL, AND UREAPLASMAL SPECIMEN 3ML VIAL)-BD™ UNIVERSAL VIRAL TRANSPORT SYSTEM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. THIS SYSTEM CAN BE PROCESSED USING STANDARD CLINICAL LABORATORY OPERATING PROCEDURES FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL AND UREAPLASMAL CULTURE,BD BBL CULTURESWAB PLUS AMIES W/O CHARCOAL SINGLE(BD BBL CULTURESWAB PLUS AMIES W/O CHARCOAL SINGLE)-BD BBL™ CULTURESWAB™ ARE STERILE READY-TO-USE SYSTEMS INTENDED FOR THE COLLECTION, TRANSPORT, AND PRESERVATION OF CLINICAL SPECIMENS FOR BACTERIOLOGICAL EXAMINATIONS.,BD UNIVERSAL VIRAL TRANSPORT FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL, AND UREAPLASMAL SPECIMEN 1ML VIAL(BD UNIVERSAL VIRAL TRANSPORT FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL, AND UREAPLASMAL SPECIMEN 1ML VIAL)-BD™ UNIVERSAL VIRAL TRANSPORT SYSTEM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. THIS SYSTEM CAN BE PROCESSED USING STANDARD CLINICAL LABORATORY

	OPERATING PROCEDURES FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL AND UREAPLASMAL CULTURE,FLOQSWABS (FLOQSWABS)-COPAN FLOQSWABS® IN POUCH ARE STERILE AND READY-FOR-USE SYSTEMS INTENDED FOR CLINICAL SAMPLES DRAWING. THE SWAB IS SUITABLE FOR SHORT CONTACT WITH THE HUMAN BODY. PRODUCT SHOULD BE USED AS DIRECTED,BD UNIVERSAL VIRAL TRANSPORT FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL, AND UREAPLASMAL SPECIMEN 3ML VIAL, FLOCK REG AND FLEX MINI(BD UNIVERSAL VIRAL TRANSPORT FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL, AND UREAPLASMAL SPECIMEN 3ML VIAL, FLOCK REG AND FLEX MINI)-BD™ UNIVERSAL VIRAL TRANSPORT SYSTEM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. THIS SYSTEM CAN BE PROCESSED USING STANDARD CLINICAL LABORATORY OPERATING PROCEDURES FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL AND UREAPLASMAL CULTURE.,BD UNIVERSAL VIRAL TRANSPORT FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL, AND UREAPLASMAL SPECIMEN 1ML VIAL, FLOCK FLEX MINI(BD UNIVERSAL VIRAL TRANSPORT FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL, AND UREAPLASMAL SPECIMEN 1ML VIAL, FLOCK FLEX MINI)-BD™ UNIVERSAL VIRAL TRANSPORT SYSTEM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. THIS SYSTEM CAN BE PROCESSED USING STANDARD CLINICAL LABORATORY OPERATING PROCEDURES FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL AND UREAPLASMAL CULTURE,BD UNIVERSAL VIRAL TRANSPORT FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL, AND UREAPLASMAL SPECIMEN 3ML VIAL, FLOCK FLEX MINI(BD UNIVERSAL VIRAL TRANSPORT FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL, AND UREAPLASMAL SPECIMEN 3ML VIAL, FLOCK FLEX MINI)-BD™ UNIVERSAL VIRAL TRANSPORT SYSTEM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. THIS SYSTEM CAN BE PROCESSED USING STANDARD CLINICAL LABORATORY OPERATING PROCEDURES FOR VIRAL, CHLAMYDIAL, MYCOPLASMAL AND UREAPLASMAL CULTURE.

848	IMP/IVD/2020/000774	1.License Holder Name: M/S.ROCHE DIABETES CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QUALITY CONTROL SOLUTION(ACCU-CHEK INSTANT CONTROL)-THE CONTROL SOLUTION IS INTENDED FOR PERFORMING CONTROL TESTS ON ACCUCHEK INSTANT AND ACCU-CHEK INSTANT S BLOOD GLUCOSE METERS AND ACCUCHEK INSTANT TEST STRIPS. TESTING CONTROL SOLUTIONS WITH KNOWN GLUCOSE LEVELS ESTABLISHES THAT THE OPERATOR AND THE SYSTEM ARE PERFORMING ACCEPTABLY. CONTROL RESULTS MUST BE WITHIN THE DEFINED ACCEPTABLE RANGES BEFORE VALID PATIENT TESTING IS ALLOWED.

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849	IMP/IVD/2020/000776	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CELL DYN HEM CAL PLUS CALIBRATOR(CELL DYN HEM CAL PLUS CALIBRATOR)-CELL-DYN HEMCAL PLUS CALIBRATOR IS A WHOLE BLOOD CALIBRATOR USED TO CALIBRATE CELL-DYN HEMATOLOGY SYSTEMS. CALIBRATION VALUES ARE PROVIDED FOR WBC, RBC, HGB, MCV, PLT, AND MPV PARAMETERS.,CELL-DYN 22 PLUS CONTROL(CELL-DYN 22 PLUS CONTROL)-CELL-DYN 22 PLUS CONTROL IS AN ASSAYED HEMATOLOGY CONTROL FOR EVALUATING THE ACCURACY AND PRECISION OF THE CELL-DYN EMERALD 22 SYSTEM.,CELL DYN 29 PLUS CONTROL (WITH RECTIC)(CELL DYN 29 PLUS CONTROL (WITH RECTIC))-CELL-DYN 29 PLUS CONTROL (WITH RETIC) IS A WHOLE BLOOD HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR RESULTS OBTAINED ON CELL-DYN HEMATOLOGY SYSTEMS.,CELL DYN RECTIC PLUS CONTROL(CELL DYN RECTIC PLUS CONTROL)-CELL-DYN RETIC PLUS CONTROL IS A HEMATOLOGY QUALITY CONTROL MATERIAL USED TO MONITOR RETICULOCYTE VALUES ON THE CELL-DYN RUBY AND CELL-DYN 3700 SYSTEMS., CELL-DYN 22 PLUS CALIBRATOR (CELL-DYN 22 PLUS CALIBRATOR)-CELL-DYN 22 PLUS CALIBRATOR IS MANUFACTURED FOR THE CALIBRATION OF THE CELL-DYN EMERALD 22 SYSTEM. ASSAYED PARAMETERS INCLUDE: WBC(109/L), RBC (1012/L), HGB (G/DL), MCV (FL), PLT (109/L).,CELL-DYN 18 PLUS CONTROL (CELL-DYN 18 PLUS CONTROL)-CELL-DYN 18 PLUS CONTROL IS AN ASSAYED HEMATOLOGY CONTROL FOR EVALUATING THE ACCURACY AND PRECISION OF HEMATOLOGY INSTRUMENTS THAT PROVIDE A WHITE BLOOD CELL DIFFERENTIAL.,CELL-DYN 26 PLUS CONTROL(CELL-DYN 26 PLUS CONTROL)-CELL-DYN 26 PLUS TRI-LEVEL CONTROL IS AN ASSAYED HEMATOLOGY CONTROL FOR EVALUATING THE ACCURACY AND PRECISION OF HEMATOLOGY INSTRUMENTS THAT PROVIDE A WHITE BLOOD CELL DIFFERENTIAL.,CELL-DYN 18 PLUS CALIBRATOR(CELL-DYN 18 PLUS CALIBRATOR)-CELL-DYN 18 PLUS CALIBRATOR IS MANUFACTURED FOR CALIBRATING MULTI-PARAMETER HEMATOLOGY ANALYZERS.

850	IMP/IVD/2020/000783	1.License Holder Name: SIRUS BIOCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FT4(ACCUDIAG)-FREE T4 ELISA KIT DETERMINES THE LEVELS OF FT4 ARE THOUGHT TO REFLECT THE AMOUNT OF T4 AVAILABLE TO THE CELLS AND MAY THEREFORE DETERMINE THE CLINICAL METABOLIC STATUS OF T4,T4 (ACCUDIAG)-FOR THE QUANTITATIVE MEASUREMENT OF TOTAL THYROXINE (T4) IN HUMAN SERUM.,FT3(ACCUDIAG)-FREE T3 ELISA KIT DETERMINES THE LEVELS OF FT3 ARE THOUGHT TO REFLECT THE AMOUNT OF T3 AVAILABLE TO THE CELLS AND MAY THEREFORE DETERMINE THE CLINICAL METABOLIC STATUS OF T3,T3(ACCUDIAG)-FOR THE QUANTITATIVE MEASUREMENT OF TOTAL TRIIODOTHYRONINE (T3) IN HUMAN SERUM.,TSH(ACCUDIAG)-FOR QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM
851	IMP/IVD/2020/000784	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CELL-DYN IMMUNO PLT (CD61) REAGENT(CELL-DYN IMMUNO PLT (CD61) REAGENT)-CELL-DYN IMMUNOPLT (CD61) REAGENT IS A ONE-COLOR DIRECT IMMUNOFL UORESCENCE REAGENT FOR ENUMERATING PLATELETS (PLT) IN HUMAN WHOLE BLOOD, WHEN USED IN COMBINATION WITH THE CELL-DYN SAPPHIRE SYSTEM. THE IMMUNOPLT (CD61) REAGENT IS FOR IN VITRO DIAGNOSTIC USE ONLY.
852	IMP/IVD/2020/000785	1.License Holder Name: BIOSENSE TECHNOLOGIES PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD LIPID TEST STRIPS AND CONTROL SOLUTION(NIL)-THE BLOOD LIPID MONITORING SYSTEM IS INTENDED FOR QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL (TC) AND HIGH DENSITY LIPO PROTEIN CHOLESTEROL (HDL) AND TRIGLYCERIDES (TG) AND RATIO OF TC-HDL AND LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL) IN PERIPHERAL HUMAN BLOOD, PLASMA,SERUM .
853	IMP/IVD/2020/000786	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID -19 AG RESPI-STRIP -IN VITRO RAPID DIAGNOSTIC TEST FOR THE DETECTION OF SARS-COV-2 ANTIGEN IN NASOPHARYNGEAL SECRETIONS"

854	IMP/IVD/2020/000787	1.License Holder Name: HIDDENITE BEVERAGES PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: PCR(QPCR) ASSAY FOR DETECTION OF 2019 NOVEL CORONAVIRUS(COVID-19)(ABTESTM COVID-19 QPCR I KIT)-THE ABTES COVID-19QPCR I KIT IS A QUALITATIVE REAL -TIME POLYMERASE CHAIN REACTION (QPCR) KIT WHICH ENABLES SIMULTANEOUS DETECTION OF TWO COVID-19-SPECFIC SIGNATURE REGIONS FROM ITS NON-STRUCTURE POLYPEPTIDE(ORF1A) IN A SINGLE REACTION
855	IMP/IVD/2020/000788	1.License Holder Name: YPSOMED INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MYLIFE AVEO BLOOD GLUCOSE MONITORING SYSTEM(MYLIFE AVEO)-QUANTITATIVE MEASUREMENT OF GLUCOSE IN CAPILLARY AND VENOUS WHOLE BLOOD,MYLIFE AVEO BLOOD GLUCOSE TEST STRIPS(MYLIFE AVEO)-QUANTITATIVE MEASUREMENT OF GLUCOSE IN CAPILLARY AND VENOUS WHOLE BLOOD
856	IMP/IVD/2020/000790	1.License Holder Name: GASTROLAB INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PEPTEST(PEPTEST)-RAPID ASSAY FOR THE DETECTION OF PEPSIN IN SALIVA.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

857	IMP/IVD/2020/000791	1.License Holder Name: THERMO FISHER SCIENTIFIC INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EVEROLIMUS IMMUNOASSAY CALIBRATOR SET(QMS)-THE QMS EVEROLIMUS CALIBRATOR SET IS INTENDED FOR USE IN CALIBRATION OF THE QMS EVEROLIMUS ASSAY.,ETHYL ALCOHOL ASSAY(DRI)-THE DRI® ETHYL ALCOHOL ASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ALCOHOL IN HUMAN URINE, SERUM OR PLASMA. ,LIQUIMMUNE LIQUID ASSAYED IMMUNOASSAY CONTROL(MAS)-MAS® LIQUIMMUNE® IS INTENDED FOR USE IN THE CLINICAL LABORATORY AS A CONSISTENT TEST SAMPLE OF KNOWN CONCENTRATION FOR MONITORING ASSAY CONDITIONS IN MANY IMMUNOLOGICAL DETERMINATIONS. INCLUDE LIQUIMMUNE WITH PATIENT SERUM SPECIMENS WHEN ASSAYING FOR ANY OF THE LISTED CONSTITUENTS. ASSAY VALUES ARE PROVIDED FOR THE SPECIFIC SYSTEMS LISTED. THE USER CAN COMPARE OBSERVATIONS WITH EXPECTED RANGES AS A MEANS OF ASSURING CONSISTENT PERFORMANCE OF REAGENT AND INSTRUMENT.,COTININE CALIBRATOR KIT(DRI)-THE DRI® COTININE CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE DRI COTININE ASSAY. THE DRI COTININE CONTROLS ARE INTENDED FOR THE VALIDATION OF DRI COTININE ASSAY CALIBRATION. THESE CALIBRATORS AND CONTROLS SHOULD BE USED FOR IN VITRO DIAGNOSTIC USE ONLY FOR THE DETECTION OF COTININE IN HUMAN URINE. ,PRIMARY DUA CONTROL SET(MCG)-THE MGC PRIMARY DAU CONTROL SET CONSISTS OF UNASSAYED HIGH AND LOW CONTROLS INTENDED FOR USE IN THE VALIDATION OF DRUG OF ABUSE ASSAYS IN HUMAN URINE.,BARBITURATE ASSAY(DRI)-THE DRI ® BARBITURATE ASSAY IS INTENDED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF BARBITURATES IN HUMAN URINE WITH 200 NG/ML AS CUTOFF CALIBRATOR. ,VANCOMYCIN IMMUNOASSAY CALIBRATORS SET(QMS)-THE QMS VANCOMYCIN CALIBRATOR SET IS INTENDED FOR USE IN CALIBRATION OF THE QMS VANCOMYCIN ASSAY. ,DIGOXIN ASSAY(DRI)-THE DRI® DIGOXIN ASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF DIGOXIN IN HUMAN SERUM OR PLASMA. ,THEOPHYLLINE II ASSAY(CEDIA)-THE CEDIA® THEOPHYLLINE II ASSAY IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE QUANTITATION OF THEOPHYLLINE IN HUMAN SERUM OR PLASMA. MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF THEOPHYLLINE OVERDOSE AND IN MONITORING LEVELS OF THEOPHYLLINE TO ENSURE PROPER THERAPY. ,ECSTASY ASSAY(DRI)-THE DRI® ECSTASY ENZYME IMMUNOASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR THE QUALITATIVE OR

	SEMIQUANTITATIVE DETERMINATION OF ECSTASY DRUGS IN HUMAN URINE. THE ASSAY PROVIDES A SIMPLE AND RAPID ANALYTICAL SCREENING PROCEDURE FOR DETECTING ECSTASY DRUGS AT A CUTOFF LEVEL OF 500 NG/ML. ,MYCOPHENOLIC ACID CALIBRATOR (CEDIA)-THE CEDIA® MYCOPHENOLIC ACID (MPA) CALIBRATORS ARE INTENDED FOR USE IN THE CALIBRATION OF THE CEDIA MPA ASSAY. , DRI 50MG/DL ALCOHOL CONTROL(DRI)-THE DRI® ETHYL ALCOHOL CALIBRATORS AND CONTROLS ARE INTENDED FOR IN-VITRO DIAGNOSTIC USE FOR THE CALIBRATION AND VALIDATION OF THE ETHYL ALCOHOL ASSAY, WHICH IS USED FOR THE QUANTITATIVE DETERMINATION OF ETHYL ALCOHOL IN HUMAN URINE, SERUM OR PLASMA. ,THC 100 NG/ML CALIBRATOR(DRI)-THE DRI® THC (11-NOR- 9-THC-9-CARBOXYLIC ACID) URINE CALIBRATORS AND CONTROLS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE FOR THE CALIBRATION AND VALIDATION OF THE DRI CANNABINOID (THC) ASSAY WHICH DETECTS THC IN HUMAN URINE. ,METHAQUQLONE ASSAY(DRI)-THE DRI® METHAQUALONE ASSAY IS INTENDED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF METHAQUALONE IN HUMAN URINE. ,AMIKACIN IMMUNOASSAY CALIBRATORS SET(QMS)-THE QMS AMIKACIN CALIBRATOR SET IS INTENDED FOR USE IN CALIBRATION OF THE QMS AMIKACIN ASSAY. , AMIKACIN IMMUNOASSAY (QMS)-THE QMS AMIKACIN ASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF AMIKACIN IN HUMAN SERUM OR PLASMA ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS. ,CYCLOSPORINE PLUS ASSAY(CEDIA)-THE CEDIA® CYCLOSPORINE PLUS ASSAY IS FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CYCLOSPORINE IN HUMAN WHOLE BLOOD USING AUTOMATED CLINICAL CHEMISTRY ANALYZERS AS AN AID IN THE MANAGEMENT OF CYCLOSPORINE THERAPY IN KIDNEY, LIVER, AND HEART TRANSPLANTS. ,COCAINE METABOLITE ASSAY(DRI)-THE DRI™ COCAINE METABOLITE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR THE QUALITATIVE AND/OR SEMI-QUANTITATIVE DETERMINATION OF BENZOYLECGONINE (COCAINE METABOLITE) IN HUMAN URINE AT A CUTOFF CONCENTRATION OF EITHER 150 NG/ML OR 300 NG/ML. THE SEMI-QUANTITATIVE MODE IS FOR THE PURPOSE OF ENABLING LABORATORIES TO DETERMINE AN APPROPRIATE DILUTION OF THE SPECIMEN FOR CONFIRMATION BY A CONFIRMATORY METHOD SUCH AS LIQUID CHROMATOGRAPHY/TANDEM MASS SPECTROMETRY (LC-MS/MS) OR PERMITTING LABORATORIES TO ESTABLISH QUALITY CONTROL PROCEDURES. ,COTININE LOW CONTROL(DRI)-THE DRI® COTININE CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE DRI COTININE ASSAY. THE DRI COTININE CONTROLS ARE INTENDED FOR THE VALIDATION OF DRI COTININE ASSAY CALIBRATION. THESE

	CALIBRATORS AND CONTROLS SHOULD BE USED FOR IN VITRO DIAGNOSTIC USE ONLY FOR THE DETECTION OF COTININE IN HUMAN URINE. ,VANCOMYCIN IMMUNOASSAY (QMS)-THE QMS VANCOMYCIN ASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF VANCOMYCIN IN HUMAN SERUM OR PLASMA ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS. ,PHENCYCLIDINE ASSAY(DRI)-THE DRI® PHENCYCLIDINE ASSAY IS INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF PHENCYCLIDINE IN HUMAN URINE. ,COTININE HIGH CONTROL(DRI)-THE DRI® COTININE CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE DRI COTININE ASSAY. THE DRI COTININE CONTROLS ARE INTENDED FOR THE VALIDATION OF DRI COTININE ASSAY CALIBRATION. THESE CALIBRATORS AND CONTROLS SHOULD BE USED FOR IN VITRO DIAGNOSTIC USE ONLY FOR THE DETECTION OF COTININE IN HUMAN URINE. ,PAR TDM LIQUID ASSAYED THERAPEUTIC DRUG CONTROL(MAS)-MAS PAR TDM IS INTENDED FOR USE AS A CONSISTENT TEST SAMPLE OF KNOWN CONCENTRATION FOR MONITORING ASSAY CONDITIONS IN MANY CLINICAL LABORATORY DETERMINATIONS. INCLUDE PAR TDM WITH PATIENT SERUM SPECIMENS WHEN ASSAYING FOR ANY OF THE LISTED CONSTITUENTS. ASSAY VALUES ARE PROVIDED FOR SPECIFIC SYSTEMS LISTED. THE USER CAN COMPARE OBSERVATIONS WITH EXPECTED RANGES AS A MEANS OF ASSURING CONSISTENT PERFORMANCE OF REAGENT AND INSTRUMENTS ,THC 20 NG/ML CALIBRATOR(DRI)-THE DRI® THC (11-NOR- 9-THC-9-CARBOXYLIC ACID) URINE CALIBRATORS AND CONTROLS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE FOR THE CALIBRATION AND VALIDATION OF THE DRI CANNABINOID (THC) ASSAY WHICH DETECTS THC IN HUMAN URINE. ,CARDIOIMMUNE XL LIQUID ASSAYED CARDIAC MARKER CONTROLS(MAS)-MAS® CARDIOIMMUNE® XL IS INTENDED FOR USE IN THE CLINICAL LABORATORY AS AN ASSAYED CONTROL SERUM FOR MONITORING ASSAY CONDITIONS IN SPECIFIC CARDIAC MARKER DETERMINATIONS.,TACROLIMUS IMMUNOASSAY (QMS)-THE QMS TACROLIMUS IMMUNOASSAY IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TACROLIMUS IN HUMAN WHOLE BLOOD ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS. THE RESULTS OBTAINED ARE USED AS AN AID IN THE MANAGEMENT OF KIDNEY, LIVER, AND HEART TRANSPLANT PATIENTS RECEIVING TACROLIMUS THERAPY. THIS IN VITRO DIAGNOSTIC DEVICE IS INTENDED FOR CLINICAL LABORATORY USE ONLY. ,BENZODIAZEPINE ASSAY(DRI)-THE DRI® BENZODIAZEPINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR THE QUALITATIVE AND/OR SEMI-QUANTITATIVE DETERMINATION OF THE PRESENCE OF BENZODIAZEPINES AND THEIR METABOLITES IN HUMAN URINE AT A

	CUTOFF CONCENTRATION OF 200 NG/ML. THE ASSAY IS INTENDED TO BE USED IN LABORATORIES AND PROVIDES A RAPID ANALYTICAL SCREENING PROCEDURE TO DETECT BENZODIAZEPINES IN HUMAN URINE. THE ASSAY IS DESIGNED FOR USE WITH A NUMBER OF CLINICAL CHEMISTRY ANALYZERS. THIS ASSAY IS CALIBRATED AGAINST OXAZEPAM. THIS PRODUCT IS INTENDED TO BE USED BY TRAINED PROFESSIONALS ONLY. ,DOA TOTAL LIQUID ASSAYED DRUGS OF ABUSE CONTROL(MAS)-THERMO SCIENTIFIC MAS DOA TOTAL IS INTENDED FOR USE AS AN ASSAYED CONTROL FOR MONITORING ASSAY CONDITIONS IN SEMI-QUANTITATIVE AND QUALITATIVE ANALYSIS OF PATIENTS URINE SPECIMENS FOR DRUGS AND DRUG METABOLITES. THESE CONTROLS ARE HUMAN URINE BASED AND ARE COMPOSED OF D-METHAMPHETAMINE, SECOBARBITAL, NITRAZEPAM, OXAZEPAM, BUPRENORPHINE, BENZOYLECGONINE, COTININE, ETHYL GLUCORONIDE, ETHANOL, LSD, METHADONE, EDDP, METHAQUALONE, MORPHINE, OXYCODONE, PHENYLCYCLIDINE, PROPOXYPHENE, NORTRIPTYLINE AND L--9-THC-COOH. DOA TOTAL PROVIDES AN ESTIMATION OF THE PRECISION OF A DEVICE TEST SYSTEM AND TO DETECT AND MONITOR SYSTEMATIC DEVIATIONS FROM ACCURACY RESULTING FROM REAGENT OR INSTRUMENT DEFECTS. ,EVEROLIMUS IMMUNOASSAY(QMS)-THE QMS® EVEROLIMUS ASSAY IS TO BE USED FOR THE QUANTITATIVE DETERMINATION OF EVEROLIMUS IN HUMAN WHOLE BLOOD ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS. THE QMS EVEROLIMUS ASSAY IS INTENDED TO BE USED AS AN AID IN THE MANAGEMENT OF PATIENTS RECEIVING EVEROLIMUS THERAPY FOR THOSE ORGAN TRANSPLANT PROCEDURES INDICATED IN THE CHART FOR EACH SPECIFIC COUNTRY. THE CHART BELOW INDICATES BY AN “X” WHERE MARKET APPROVAL FOR THE DRUG HAS BEEN GRANTED FOR THE GIVEN TRANSPLANT TYPE. ,URICHEMTRAK LIQUID ASSAYED URINE CONTROL(MAS)-MAS® URICHEMTRAK IS INTENDED FOR USE IN THE CLINICAL LABORATORY AS A CONSISTENT TEST SAMPLE OF KNOWN CONCENTRATION FOR MONITORING ASSAY CONDITIONS IN MANY URINE DETERMINATIONS. ,ECSTASY 1000 NG/ML CALIBRATOR(DRI)-THE DRI® ECSTASY CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE DRI ECSTASY ENZYME IMMUNOASSAY. THE DRI ECSTASY CONTROLS ARE UNASSAYED CONTROLS INTENDED FOR THE VALIDATION OF DRI ECSTASY ENZYME IMMUNOASSAY CALIBRATIONS. THESE CALIBRATORS AND CONTROLS ARE FOR IN VITRO DIAGNOSTIC USE ONLY FOR THE DETECTION OF ECSTASY DRUGS IN HUMAN URINE. ,THC 125NG/ML CONTROL(DRI)-THE DRI® THC (11-NOR- 9-THC-9-CARBOXYLIC ACID) URINE CALIBRATORS AND CONTROLS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE FOR THE CALIBRATION AND VALIDATION OF

	THE DRI CANNABINOID (THC) ASSAY WHICH DETECTS THC IN HUMAN URINE. ,DIABETES LIQUID ASSAYED DIABETES CONTROL(MAS)-MAS® DIABETES IS INTENDED FOR USE AS AN ASSAYED CONTROL MATERIAL FOR MONITORING GLYCOSYLATED HEMOGLOBIN (A1C) ASSAY PROCEDURES. ,CARDIOIMMUNE ULTRA LOW LIQUID ASSAYED CARDIAC MARKER CONTROLS(MAS)-MAS® CARDIOIMMUNE® ULTRA LOW IS INTENDED FOR USE IN THE CLINICAL LABORATORY AS AN ASSAYED CONTROL SERUM FOR MONITORING ASSAY CONDITIONS IN SPECIFIC CARDIAC MARKER DETERMINATIONS.,OMNICORE LIQUID ASSAYED INTEGRATED CHEMISTRY CONTROL(MAS)-THERMO SCIENTIFIC MAS® OMNI•CORE™ IS INTENDED FOR USE AS AN ASSAYED CONTROL FOR MONITORING ASSAY CONDITIONS IN MANY CLINICAL LABORATORY DETERMINATIONS. INCLUDE OMNI•CORE WITH PATIENT SERUM SPECIMENS WHEN ASSAYING FOR ANY OF THE CONSTITUENTS.,EVEROLIMUS IMMUNOASSAY CONTROLS SET(QMS)-THE QMS® EVEROLIMUS CONTROL SET IS INTENDED FOR USE IN QUALITY CONTROL OF THE QMS EVEROLIMUS ASSAY. ,CARDIAC TDM MULTI-CALIBRATORS(CEDIA)-THE CEDIA® CARDIAC TDM MULTI-CALS ARE USED TO CALIBRATE THE CEDIA ASSAYS FOR N-ACETYLPROCAINAMIDE, AND PROCAINAMIDE IN HUMAN SERUM AND PLASMA. ,OPIATES ASSAY(DRI)-THE DRI OPIATE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR THE QUALITATIVE OR SEMI-QUANTITATIVE DETERMINATION OF OPIATES IN HUMAN URINE WITH 300 NG/ML OR 2000 NG/ML AS A CUTOFF CALIBRATOR. ,OMNIIMMUNE LIQUID ASSAYED INTEGRATED IMMUNOASSAY CONTROLS(MAS)-THERMO SCIENTIFIC MAS® OMNI•IMMUNE™ IS INTENDED FOR USE AS AN ASSAYED CONTROL FOR MONITORING ASSAY CONDITIONS IN MANY CLINICAL LABORATORY DETERMINATIONS. ,COTININE ASSAY(DRI)-THE DRI® COTININE ASSAY IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF COTININE IN HUMAN URINE AT A CUTOFF LEVEL OF 500 NG/ML. THIS ASSAY IS INTENDED AS AN AID IN THE DETECTION OF COTININE AFTER USE OR EXPOSURE TO TOBACCO PRODUCTS. ,CARBAMAZEPINE II ASSAY(CEDIA)-THE CEDIA® CARBAMAZEPINE II ASSAY IS AN IN-VITRO DIAGNOSTIC MEDICAL DEVICE INTENDED FORQUANTITATION OF CARBAMAZEPINE IN HUMAN SERUM OR PLASMA. ,METHADONE ASSAY(DRI)-THE DRI® METHADONE ASSAY IS INTENDED FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF METHADONE IN HUMAN URINE. ,PROPOXYPHENE ASSAY(DRI)-THE DRI® PROPOXYPHENE ASSAY IS INTENDED FOR QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF PROPOXYPHENE IN HUMAN URINE. ,ECSTASY 250 NG/ML CALIBRATOR(DRI)-THE DRI® ECSTASY CALIBRATORS

	ARE INTENDED FOR THE CALIBRATION OF THE DRI ECSTASY ENZYME IMMUNOASSAY. THE DRI ECSTASY CONTROLS ARE UNASSAYED CONTROLS INTENDED FOR THE VALIDATION OF DRI ECSTASY ENZYME IMMUNOASSAY CALIBRATIONS. THESE CALIBRATORS AND CONTROLS ARE FOR IN VITRO DIAGNOSTIC USE ONLY FOR THE DETECTION OF ECSTASY DRUGS IN HUMAN URINE. ,DRI 100MG/DL ALCOHOL CALIBRATOR(DRI)-THE DRI® ETHYL ALCOHOL CALIBRATORS AND CONTROLS ARE INTENDED FOR IN-VITRO DIAGNOSTIC USE FOR THE CALIBRATION AND VALIDATION OF THE ETHYL ALCOHOL ASSAY, WHICH IS USED FOR THE QUANTITATIVE DETERMINATION OF ETHYL ALCOHOL IN HUMAN URINE, SERUM OR PLASMA. ,THC 50 NG/ML CALIBRATOR(DRI)-THE DRI® THC (11-NOR- 9-THC-9-CARBOXYLIC ACID) URINE CALIBRATORS AND CONTROLS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE FOR THE CALIBRATION AND VALIDATION OF THE DRI CANNABINOID (THC) ASSAY WHICH DETECTS THC IN HUMAN URINE. ,AMPHETAMINE ASSAY(DRI)-THE DRI® AMPHETAMINES ASSAY IS INTENDED FOR THE QUALITATIVE OR SEMI-QUANTITATIVE DETERMINATION OF AMPHETAMINES IN HUMAN URINE. THE ASSAY RANGE IS 0-2000 NG/ML WITH CUTOFF LEVELS OF 500 AND 1000 NG/ML. THE ASSAY PROVIDES A SIMPLE AND RAPID ANALYTICAL SCREENING PROCEDURE FOR DETECTING AMPHETAMINES IN URINE. ,DRI 300MG/DL ALCOHOL CONTROL(DRI)-THE DRI® ETHYL ALCOHOL CALIBRATORS AND CONTROLS ARE INTENDED FOR IN-VITRO DIAGNOSTIC USE FOR THE CALIBRATION AND VALIDATION OF THE ETHYL ALCOHOL ASSAY, WHICH IS USED FOR THE QUANTITATIVE DETERMINATION OF ETHYL ALCOHOL IN HUMAN URINE, SERUM OR PLASMA. ,THC 200 NG/ML CALIBRATOR(DRI)-THE DRI® THC (11-NOR- 9-THC-9-CARBOXYLIC ACID) URINE CALIBRATORS AND CONTROLS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE FOR THE CALIBRATION AND VALIDATION OF THE DRI CANNABINOID (THC) ASSAY WHICH DETECTS THC IN HUMAN URINE. ,NEGATIVE ALCOHOL CALIBRATOR(DRI)-THE DRI® ETHYL ALCOHOL CALIBRATORS AND CONTROLS ARE INTENDED FOR IN-VITRO DIAGNOSTIC USE FOR THE CALIBRATION AND VALIDATION OF THE ETHYL ALCOHOL ASSAY, WHICH IS USED FOR THE QUANTITATIVE DETERMINATION OF ETHYL ALCOHOL IN HUMAN URINE, SERUM OR PLASMA. ,THC 40NG/ML CONTROL(DRI)-THE DRI® THC (11-NOR- 9-THC-9-CARBOXYLIC ACID) URINE CALIBRATORS AND CONTROLS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE FOR THE CALIBRATION AND VALIDATION OF THE DRI CANNABINOID (THC) ASSAY WHICH DETECTS THC IN HUMAN URINE. ,THC 60NG/ML CONTROL(DRI)-THE DRI® THC (11-NOR- 9-THC-9-CARBOXYLIC ACID) URINE CALIBRATORS AND CONTROLS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE FOR THE CALIBRATION

	AND VALIDATION OF THE DRI CANNABINOID (THC) ASSAY WHICH DETECTS THC IN HUMAN URINE. ,THC 75NG/ML CONTROL(DRI)-THE DRI® THC (11-NOR- 9-THC-9-CARBOXYLIC ACID) URINE CALIBRATORS AND CONTROLS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE FOR THE CALIBRATION AND VALIDATION OF THE DRI CANNABINOID (THC) ASSAY WHICH DETECTS THC IN HUMAN URINE. ,PHENYTOIN II ASSAY(CEDIA)-THE CEDIA® PHENYTOIN II ASSAY IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE QUANTITATION OF PHENYTOIN IN HUMAN SERUM OR PLASMA. MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PHENYTOIN OVERDOSE AND IN MONITORING LEVELS OF PHENYTOIN TO ENSURE PROPER THERAPY. ,PHENOBARBITAL II ASSAY(CEDIA)-PHENOBARBITAL II ASSAY IS AN IN VITRO MEDICAL DEVICE INTENDED FOR THE QUANTITATION OF PHENOBARBITAL IN HUMAN SERUM OR PLASMA. ,MULTI-DRUG URINE CALIBRATOR(DRI)-THE DRI® MULTI-DRUG CALIBRATORS ARE INTENDED FOR THE CALIBRATION AND VALIDATION OF DRUGS OF ABUSE ENZYME IMMUNOASSAYS FOR THE DETECTION OF AMPHETAMINES, BARBITURATES, BENZODIAZEPINES, COCAINE METABOLITES, METHADONE, METHAQUALONE, MORPHINE, PHENCYCLIDINE AND PROPOXYPHENE IN HUMAN URINE. ,LIQUID ASSAYED MYCOPHENOLIC ACID CONTROL (MAS)-MAS MYCOPHENOLIC ACID (MPA) CONTROLS ARE INTENDED FOR USE AS ASSAYED QUALITY CONTROL MATERIAL FOR VALIDATION OF MPA ASSAYS. , CANNABINOIDA (THC) ASSAY(DRI)-THE DRI® CANNABINOID ASSAY IS INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF CANNABINOIDS (THC) IN HUMAN URINE. , MYCOPHENOLIC ACID ASSAY(CEDIA)-THE CEDIA® MYCOPHENOLIC ACID (MPA) ASSAY IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE QUANTITATIVE MEASUREMENT OF MYCOPHENOLIC ACID IN HUMAN PLASMA USING AUTOMATED CLINICAL CHEMISTRY ANALYZERS AS AN AID IN THE MANAGEMENT OF MYCOPHENOLIC ACID THERAPY IN RENAL AND CARDIAC TRANSPLANT PATIENTS. ,ECSTASY 500 NG/ML CALIBRATOR(DRI)-THE DRI® ECSTASY CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE DRI ECSTASY ENZYME IMMUNOASSAY. THE DRI ECSTASY CONTROLS ARE UNASSAYED CONTROLS INTENDED FOR THE VALIDATION OF DRI ECSTASY ENZYME IMMUNOASSAY CALIBRATIONS. THESE CALIBRATORS AND CONTROLS ARE FOR IN VITRO DIAGNOSTIC USE ONLY FOR THE DETECTION OF ECSTASY DRUGS IN HUMAN URINE. ,ECSTASY 750 NG/ML CALIBRATOR(DRI)-THE DRI® ECSTASY CALIBRATORS ARE INTENDED FOR THE CALIBRATION OF THE DRI ECSTASY ENZYME IMMUNOASSAY. THE DRI ECSTASY CONTROLS ARE UNASSAYED CONTROLS INTENDED FOR

	THE VALIDATION OF DRI ECSTASY ENZYME IMMUNOASSAY CALIBRATIONS. THESE CALIBRATORS AND CONTROLS ARE FOR IN VITRO DIAGNOSTIC USE ONLY FOR THE DETECTION OF ECSTASY DRUGS IN HUMAN URINE. ,CYCLOSPORINE PLUS HIGH RANGE CALIBRATOR(CEDIA)-THE CEDIA CYCLOSPORINE PLUS HIGH RANGE CALIBRATORS ARE USED TO CALIBRATE THE CEDIA CYCLOSPORINE PLUS HIGH RANGE ASSAY IN HUMAN WHOLE BLOOD. ,VALPROIC ACID II ASSAY(CEDIA)-THE CEDIA® VALPROIC ACID II ASSAY IS AN IN-VITRO DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THEQUANTITATION OF VALPROIC ACID IN HUMAN SERUM OR PLASMA. ,NEGATIVE URINE CALIBRATOR(DRI)-THE DRI® MULTI-DRUG CALIBRATORS ARE INTENDED FOR THE CALIBRATION AND VALIDATION OF DRUGS OF ABUSE ENZYME IMMUNOASSAYS FOR THE DETECTION OF AMPHETAMINES, BARBITURATES, BENZODIAZEPINES, COCAINE METABOLITES, METHADONE, METHAQUALONE, MORPHINE, PHENCYCLIDINE AND PROPOXYPHENE IN HUMAN URINE. , TACROLIMUS IMMUNOASSAY CALIBRATOR SET(QMS)-THE QMS® TACROLIMUS CALIBRATOR SET IS INTENDED FOR USE IN CALIBRATION OF THE QMS® TACROLIMUS IMMUNOASSAY 10015556. ,ANTIBIOTIC TDM MULTI CALIBRATORS(CEDIA)-THE CEDIA® ANTIBIOTIC TDM MULTI-CALS ARE USED TO CALIBRATE THE CEDIA ASSAYS FOR TOBRAMYCIN AND GENTAMICIN IN HUMAN SERUM AND PLASMA. ,ALCOHOL AMMONIA LIQUID ASSAYED ALCOHOL/ AMMONIA CONTROL(MAS)-MAS® ALCOHOL/AMMONIA IS INTENDED FOR USE IN THE CLINICAL LABORATORY AS A QUANTITATIVE CONTROL FOR MONITORING TEST PROCEDURES USED TO ASSAY HUMAN SERUM AND/OR PLASMA SPECIMENS FOR ALCOHOL AND/OR AMMONIA. INCLUDE ALCOHOL/ AMMONIA WITH PATIENT SERUM OR PLASMA SPECIMENS WHEN ASSAYING FOR ALCOHOL AND/OR AMMONIA.,CSF LIQUID ASSAYED CEREBROSPINAL FLUID CONTROL (MAS)-MAS® CSF IS INTENDED FOR USE IN THE CLINICAL LABORATORY AS A CONSISTENT TEST SAMPLE OF KNOWN CONCENTRATION FOR MONITORING ASSAY CONDITIONS IN MANY CEREBROSPINAL FLUID DETERMINATIONS. ,CORE TDM MULTI-CAL (CEDIA)-THE CEDIA® CORE TDM MULTI-CALS ARE USED TO CALIBRATE THE CEDIA ASSAYS FOR CARBAMAZEPINE, PHENOBARBITAL, PHENYTOIN, THEOPHYLLINE, AND VALPROIC ACID IN HUMAN SERUM AND PLASMA.

858	IMP/IVD/2020/000792	1.License Holder Name: IMMUCOR INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTI-D IGM(NOVACLONE ANTI-D IGM + IGG MONOCLONAL BLEND)-NOVACLONE™ ANTI-D IGM + IGG MONOCLONAL BLEND IS A “LOW PROTEIN” BLOOD GROUPING REAGENT USED TO DETECT THE RH D (RH1) BLOOD GROUP ANTIGEN ON HUMAN RED BLOOD CELLS BY DIRECT AND INDIRECT HEMAGGLUTINATION TESTS. THE TEST USED WITH THESE BLOOD GROUPING REAGENTS IS BASED ON THE PRINCIPLE OF DIRECT HEMAGGLUTINATION.,ANTI-A,B(NOVACLONE ANTI-A,B MURINE MONOCLONAL)-NOVACLONE™ ANTI-A,B MURINE MONOCLONAL PROVIDES A SPECIFIC QUALITATIVE TEST FOR THE DETECTION OF HUMAN BLOOD GROUP ANTIGENS – A AND B. THE TEST USED WITH THESE BLOOD GROUPING REAGENTS IS BASED ON THE PRINCIPLE OF DIRECT HEMAGGLUTINATION. INCUBATION OF TEST RED CELLS WITH NOVACLONE™ ANTI-A, ANTI-B OR ANTI-A,B MURINE MONOCLONAL BLOOD GROUPING REAGENT WILL RESULT IN A SPECIFIC ANTIGEN-ANTIBODY REACTION IF THE CORRESPONDING ANTIGEN IS PRESENT ON THE RED CELLS.,ANTI A(NOVACLONE ANTI-A MURINE MONOCLONAL)-NOVACLONE ANTI-A MURINE MONOCLONAL PROVIDES A SPECIFIC QUALITATIVE TEST FOR THE DETECTION OF HUMAN BLOOD GROUP ANTIGEN – A. THE TEST USED WITH THESE BLOOD GROUPING REAGENTS IS BASED ON THE PRINCIPLE OF DIRECT HEMAGGLUTINATION. INCUBATION OF TEST RED CELLS WITH NOVACLONE™ ANTI-A, ANTI-B OR ANTI-A,B MURINE MONOCLONAL BLOOD GROUPING REAGENT WILL RESULT IN A SPECIFIC ANTIGEN-ANTIBODY REACTION IF THE CORRESPONDING ANTIGEN IS PRESENT ON THE RED CELLS.,ANTI-D IGM(NOVACLONE ANTI-D IGM + IGG MONOCLONAL BLEND (GALILEO))-NOVACLONE™ ANTI-D IGM + IGG MONOCLONAL BLEND IS A “LOW PROTEIN” BLOOD GROUPING REAGENT USED TO DETECT THE RH D (RH1) BLOOD GROUP ANTIGEN ON HUMAN RED BLOOD CELLS BY DIRECT AND INDIRECT HEMAGGLUTINATION TESTS. THE TEST USED WITH THESE BLOOD GROUPING REAGENTS IS BASED ON THE PRINCIPLE OF DIRECT HEMAGGLUTINATION.,ANTI-B(NOVACLONE ANTI-B MURINE MONOCLONAL)-NOVACLONE ANTI-B MURINE MONOCLONAL PROVIDES A SPECIFIC QUALITATIVE TEST FOR THE DETECTION OF HUMAN BLOOD GROUP ANTIGEN – B. THE TEST USED WITH THESE BLOOD GROUPING REAGENTS IS BASED ON THE PRINCIPLE OF DIRECT HEMAGGLUTINATION. INCUBATION OF TEST RED CELLS WITH NOVACLONE™ ANTI-A, ANTI-B OR ANTI-A,B MURINE MONOCLONAL BLOOD GROUPING REAGENT WILL RESULT IN A SPECIFIC ANTIGEN-ANTIBODY REACTION IF THE CORRESPONDING ANTIGEN IS PRESENT ON THE RED CELLS.,ANTI HUMAN GLOBULIN(NOVACLONE ANTI-IGG -

		C3D POLYSPECIFIC MURINE MONOCLONAL BLEND)-ANTI-HUMAN GLOBULIN IS USED IN A DIRECT ANTIGLOBULIN TEST (DAT) TO DETECT ANTIBODIES (IGG) AND/OR COMPLEMENT (C3D) BOUND TO HUMAN RED CELLS IN VIVO. DIRECT ANTIGLOBULIN TEST RESULT MAY SUPPORT THE DIAGNOSIS OF AUTOIMMUNE HEMOLYTIC ANEMIA (AIHA), HEMOLYTIC DISEASE OF THE NEWBORN (HDN) AND DELAYED HEMOLYTIC TRANSFUSION REACTIONS. THE INDIRECT ANTIGLOBULIN TEST (IAT) IS USED TO DETECT IGG AND/OR COMPLEMENT (C3D) BOUND TO HUMAN RED CELLS IN VITRO AND IS THE BASIS FOR A WIDE VARIETY OF IMMUNOHEMATOLOGY TESTS INCLUDING TESTS FOR WEAK D; PRE-TRANSFUSION COMPATIBILITY TESTING (CROSSMATCH); THE DETECTION AND IDENTIFICATION OF UNEXPECTED BLOOD GROUP ANTIBODIES AND RED CELLS ANTIGEN TYPING.
859	IMP/IVD/2020/000793	1.License Holder Name: EFFIBAR INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 RT-PCR KIT (ACCUPOWER® SARS-COV-2 REAL-TIME RT-PCR KIT)-ACCUPOWER ® SARS-COV-2 REAL-TIME RT-PCR KIT IS AN IN VITRO DIAGNOSTIC KIT THAT HELPS DIAGNOSE COVID-19 INFECTIONS (CORONAVIRUS DISEASE19).THIS KIT IS DESIGNED FOR THE DETECTION OF SARS-COV-2 (E GENE AND RDRP GENE) RNA FROM A COVID-19 (CORONAVIRUS DISEASE-19) SUSPECTED PATIENT'S SAMPLE SUCH AS SPUTUM, NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB THROUGH REAL-TIME POLYMERASE CHAIN REACTION (PCR).

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

860	IMP/IVD/2020/000797	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHOLESTECH LDX® TC (CHOLESTECH LDX® TC)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL, IN WHOLE BLOOD.,CHOLESTECH LDX® LIPID PROFILE •GLU(CHOLESTECH LDX® LIPID PROFILE •GLU)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL, HDL (HIGH-DENSITY LIPOPROTEIN) CHOLESTEROL, TRIGLYCERIDES AND GLUCOSE IN WHOLE BLOOD.,CHOLESTECH LDX® TC•HDL•GLU (CHOLESTECH LDX® TC•HDL•GLU)- FOR THE QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL, HDL (HIGH-DENSITY LIPOPROTEIN) CHOLESTEROL, GLUCOSE IN WHOLE BLOOD., CHOLESTECH LDX® MULTIANALYTE CONTROL(CHOLESTECH LDX® MULTIANALYTE CONTROL)-ASSAYED QUALITY CONTROL MATERIAL FOR USE WITH THE CHOLESTECH LDX™ SYSTEM.,CHOLESTECH LDX® TC•HDL(CHOLESTECH LDX® TC•HDL)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL, HDL (HIGH-DENSITY LIPOPROTEIN) CHOLESTEROL, IN WHOLE BLOOD.,CHOLESTECH LDX® TC•GLU(CHOLESTECH LDX® TC•GLU)- FOR THE QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL, AND GLUCOSE IN WHOLE BLOOD.,CHOLESTECH LDX® LIPID PROFILE(CHOLESTECH LDX® LIPID PROFILE)- FOR THE QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL, HDL (HIGH-DENSITY LIPOPROTEIN) CHOLESTEROL, TRIGLYCERIDES IN WHOLE BLOOD.,CHOLESTECH LDX® MULTIANALYTE CALIBRATION VERIFICATION(CHOLESTECH LDX® MULTIANALYTE CALIBRATION VERIFICATION)-ASSAYED CALIBRATION VERIFICATION MATERIAL IS DESIGNED TO BE USED FOR VERIFYING THE REPORTABLE RANGE OF TESTS ON THE CHOLESTECH LDX™ SYSTEM.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

861	IMP/IVD/2020/000799	1.License Holder Name: HORIBA INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABX PENTRA CHLORIDE-E (HORIBA MEDICAL)-ABX PENTRA CHLORIDE-E IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF CHLORIDE BY POTENTIOMETRY USING ION SELECTIVE ELECTRODE WITH ASSOCIATED REFERENCE SOLUTION, CALIBRATORS AND CONTROLS. MEASUREMENTS OF CHLORIDE ARE USED IN DIAGNOSIS AND TREATMENT OF DISEASES INVOLVING ELECTROLYTE IMBALANCE.,ABX PENTRA REFERENCE-E (HORIBA MEDICAL)-ABX PENTRA REFERENCE-E IS AN ION SELECTIVE ELECTRODE INTENDED FOR THE QUANTITATIVE DETERMINATION OF SODIUM (NA+), POTASSIUM (K+) AND CHLORIDE (CL-) ON INSTRUMENT EQUIPPED WITH ISE MODULE OPTION. ,ABX PENTRA DUMMY-E(HORIBA MEDICAL)-ELECTRODE USED WHEN CLEANING THE ISE MODULE. ,ABX PENTRA POTASSIUM-E(HORIBA MEDICAL)-ABX PENTRA POTASSIUM-E IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF POTASSIUM BY POTENTIOMETRY USING ION SELECTIVE ELECTRODE WITH ASSOCIATED REFERENCE SOLUTION, CALIBRATORS AND CONTROLS. MEASUREMENTS OF POTASSIUM ARE USED IN DIAGNOSIS AND TREATMENT DISEASES INVOLVING ELECTROLYTE IMBALANCE.,ABX PENTRA SODIUM-E(HORIBA MEDICAL)-ABX PENTRA SODIUM-E IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF SODIUM BY POTENTIOMETRY USING ION SELECTIVE ELECTRODE WITH ASSOCIATED REFERENCE SOLUTION, CALIBRATORS AND CONTROLS. MEASUREMENTS OF SODIUM ARE USED IN DIAGNOSIS AND TREATMENT DISEASES INVOLVING ELECTROLYTE IMBALANCE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

862	IMP/IVD/2020/000801	1.License Holder Name: ARKRAY HEALTHCARE PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ELUENT 90A(ELUENT 90A)-ELUENT 90A IS INTENDED FOR THE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD FOR USE WITH ADAM A1C HA-8190V. FOR IN VITRO DIAGNOSTIC USE ONLY., WASHING SOLUTION CONCENTRATION(WASHING SOLUTION CONCENTRATION)-WASHING SOLUTION CONCENTRATION USED FOR WASHING THE FLOW LINES, MEASURING SECTION, AND MEASUREMENT SENSOR AFTER THE LOADED SAMPLES ARE MEASURED. ,ELUENT 90CV(ELUENT 90CV)-ELUENT 90CV IS INTENDED FOR THE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD FOR USE WITH ADAM A1C HA-8190V. FOR IN VITRO DIAGNOSTIC USE ONLY,CALIBRATOR 90(CALIBRATOR 90)-CALIBRATOR 90 IS INTENDED FOR CALIBRATION FOR ADAMS A1C H-8190V.,AUTION EYE SHEATH SOLUTION(AUTION EYE SHEATH SOLUTION)-AUTION EYE SHEATH SOLUTION IS USED FOR DETERMINATION OF FORMED ELEMENTS IN HUMAN URINE, HEMOLYSIS WASHING SOLUTION 90H(HEMOLYSIS WASHING SOLUTION 90H)-HEMOLYSIS WASHING SOLUTION 90H IS INTENDED FOR THE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD FOR USE WITH ADAM A1C HA-8190V. USE THIS PRODUCT TO DILUTE WHOLE BLOOD SAMPLES, AND WASH THE TUBES IN WHICH SAMPLE FLOWS. FOR IN-VITRO DIAGNOSTIC USE ONLY ,COLUMN UNIT 90(COLUMN UNIT 90)-COLUMN UNIT 90 IS INTENDED FOR THE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD FOR USE WITH ADAM A1C HA-8190V. FOR IN VITRO DIAGNOSTIC USE ONLY,ELUENT 90B(ELUENT 90B)-ELUENT 90B IS INTENDED FOR THE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD FOR USE WITH ADAM A1C HA-8190V. FOR IN VITRO DIAGNOSTIC USE ONLY.,DILUENT 90(DILUENT 90)-DILUENT 90 IS INTENDED FOR THE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD FOR USE WITH ADAM A1C HA-8190V. THIS SET DISSOLVES AND DILUTES COMMERCIALLY AVAILABLE FREEZE-DRIED CONTROLS SPECIFIED BY YOUR DISTRIBUTOR AND DILUTES WHOLE BLOOD SAMPLES. FOR IN VITRO DIAGNOSTIC USE ONLY.,ELUENT 90CV-S(ELUENT 90CV-S)-ELUENT 90CV-S IS INTENDED FOR THE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD FOR USE WITH ADAM A1C HA-8190V. FOR IN VITRO DIAGNOSTIC USE ONLY, CONCENTRATED WASHING SOLUTION 3(CONCENTRATED WASHING SOLUTION 3)-CONCENTRATED WASHING SOLUTION 3 USED FOR CLEANING THE NOZZLE AND TUBING OF FULLY-AUTOMATIC AUTION ANALYZERS, WHICH IS A CONCENTRATE 10 FOLD-CONCENTRATION,

		STANDARD SOLUTION SET(STANDARD SOLUTION SET)-THIS STANDARD SOLUTION IS INTENDED FOR THE USE AS THE EXCLUSIVE STANDARD SOLUTION OF ARKRAY, INC'S OSMOTIC PRESSURE ANALYZERS.
863	IMP/IVD/2020/000805	1.License Holder Name: BI-BIOTECH INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIAPLEXQTH NOVEL CORONAVIRUS (2019-NCOV) DETECTION KIT(DIAPLEXQTH NOVEL CORONAVIRUS (2019-NCOV) DETECTION KIT)-THE DIAPLEXQ™ NOVEL CORONAVIRUS (2019-NCOV) DETECTION KIT IS A REAL-TIME REVERSE TRANSCRIPTASE (RT)-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN NASOPHARYNGEAL SWABS, OROPHARYNGEAL (THROAT) SWABS, ANTERIOR NASAL SWABS, MID-TURBINATE NASAL SWABS, NASAL ASPIRATES, NASAL WASHES, BRONCHOALVEOLAR LAVAGE (BAL) FLUID AND SPUTUM FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. RESULTS ARE FOR THE IDENTIFICATION OF SARS-COV-2 RNA. THE SARS-COV-2 RNA IS GENERALLY DETECTABLE IN RESPIRATORY SPECIMENS DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS ARE INDICATIVE OF THE PRESENCE OF SARS-COV-2 RNA; CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR PATIENT MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. THE DIAPLEXQ™ NOVEL CORONAVIRUS (2019-NCOV) DETECTION KIT IS INTENDED FOR USE BY QUALIFIED CLINICAL LABORATORY PERSONNEL SPECIFICALLY INSTRUCTED AND TRAINED IN THE TECHNIQUES OF REAL-TIME PCR AND IN VITRO DIAGNOSTIC PROCEDURES.

864	IMP/IVD/2020/000806	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIATROCAL HEMATOLOGY CALIBRATOR(NA)-DIATROCAL HEMATOLOGY CALIBRATOR IS DESIGNED FOR USE IN THE CALIBRATION OF HEMATOLOGY ANALYZERS,DIACON 5 HEMATOLOGY CONTROL SET (NA)-DIACON 5 HEMATOLOGY CONTROL IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS.,DIACON 3 HEMATOLOGY CONTROL SET(NA)-DIACON 3 HEMATOLOGY CONTROL IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS.,LYCEL DIFF D5P(NA)-DIATRO•DIFF-5P WBC DIFFERENTIATION REAGENT IS A STABILIZED AND MICRO-FILTERED REAGENT FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC) AND LEUKOCYTE 5-PART DIFFERENTIATION (LYM, MONO, NEU, EO, BA) MEASUREMENT IN HUMAN BLOOD ON DIATRON ABACUS 5 HEMATOLOGY ANALYZERS., RINCEL D(NA)-DIATRO•CLEANER CLEANING REAGENT IS A STABILIZED AND MICROFILTERED DETERGENT SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON DIATRON JUNIOR, ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 3CT, ABACUS 380 HEMATOLOGY ANALYZERS., D151-PW-1000- PRE-WEIGHED SUBSTANCE(NA)-THE COMPONENTS OF THE PRE-FORMULATED POWDER & LIQUID MIX SET SHOULD BE DISSOLVED IN THE PRESCRIBED VOLUME PURIFIED (DEIONIZED) WATER AT ONCE.,CALIBRATION SET(NA)-50 G/L SODIUM NITRITE AQUEOUS SOLUTION FOR STRAY LIGHT TESTS. UV/VIS STANDARD SET: POTASSIUM DICHROMATE CALIBRATION SOLUTION SET FOR CHECKING THE ABSORBANCE OF SPECTROPHOTOMETERS.,LYCEL D5P(NA)-DIATRO•LYSE-5P LYSING REAGENT IS A STABILIZED AND MICROFILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE 5-PART DIFFERENTIATION (LYM, MONO, NEU, EO, BA) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON DIATRON ABACUS 5 HEMATOLOGY ANALYZERS.,DILUCEL D(NA)-DIATRO•DIL-5P DILUENT IS A BUFFERED, STABILIZED AND MICROFILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF

	HEMOGLOBIN (HGB) CONCENTRATION ON DIATRON ABACUS 5, ABACUS 380 HEMATOLOGY ANALYZERS.,LYCEL D(NA)-DIATRO•LYSE-DIFF LYSING REAGENT IS A STABILIZED AND MICRO-FILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE THREE-PART DIFFERENTIATION (LYM, MID, GRAN) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON DIATRON JUNIOR, ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 380, ABACUS 3CT HEMATOLOGY ANALYZERS.,PROBECEL D(NA)-DIATRO•HYPOCLEAN HYPOCHLORITE CLEANING REAGENT IS A STABILIZED AND MICRO-FILTERED HYPOCHLORITE SOLUTION FOR INTENSIVE OXIDATIVE CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON DIATRON ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 3CT, ABACUS 380 HEMATOLOGY ANALYZERS.,EZCEL D(NA)-DIATRO•CLENZ ENZYMATIC CLEANER REAGENT IS A STABILIZED AND MICRO-FILTERED PROTEOLYTIC ENZYME SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON DIATRON ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 3CT, ABACUS 380 HEMATOLOGY ANALYZERS.,CUVETTE CLEANER KIT(NA)-THE "CUVETTE WASH" SOLUTION IS USED FOR THE AUTOMATIC DECONTAMINATION AND CLEANING OF CUVETTES AFTER EACH USE AND FOR THE REMOVAL OF ANY BLOOD COMPONENT AND LIPOPROTEIN DEPOSITS.,ADDITIVE FOR WASH SOLUTION(NA)-CLEANING SOLUTION ADDITIVE, CONTAINING CONCENTRATED DETERGENTS, FOR REGULAR CLEANING AND RINSING OF CLINICAL CHEMISTRY ANALYZERS' PROBES, TUBINGS AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS.,CLEANING SOLUTION KIT(NA)-CLEANING SOLUTIONS, CONTAINING STABILIZED AND MICRO-FILTERED HYPOCHLORITE AND DETERGENTS, FOR REGULAR CLEANING AND RINSING OF CLINICAL CHEMISTRY ANALYZERS' PROBES, TUBINGS AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS,PROBECEL DC(NA)-DIATRO•HYPOCLEAN CC HYPOCHLORITE CLEANING CONCENTRATE IS A STABILIZED AND MICRO-FILTERED CONCENTRATED HYPOCHLORITE SOLUTION FOR INTENSIVE OXIDATIVE CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON ALL HEMATOLOGY ANALYZERS.

865	IMP/IVD/2020/000808	1.License Holder Name: GLOBE BIO MEDICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TEST STRIPS(FORA 6 BLOOD GLUCOSE TEST STRIP, FORA 6 BLOOD GLUCOSE, HEMATOCRIT AND HEMOGLOBIN TEST STRIP, FORA 6 B-KETONE TEST STRIP, FORA 6 TOTAL CHOLESTEROL TEST STRIP, FORA 6 URIC ACID TEST STRIP)-TEST STRIPS TO BE USED TOGETHER WITH MULTI FUNCTIONAL MONITORING SYSTEM.
866	IMP/IVD/2020/000809	1.License Holder Name: PTS DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:A1CNOW® SELF CHECK (A1CNOW)-THE A1CNOW® SELF CHECK TEST SYSTEM PROVIDES QUANTITATIVE MEASUREMENT OF GLYCATED HAEMOGLOBIN LEVELS IN CAPILLARY (FINGERPRICK) BLOOD SAMPLES. THE TEST IS FOR HOME USE TO MONITOR GLYCEMIC CONTROL IN PEOPLE WITH DIABETES.,A1CNOW+PROFESSIONAL(A1CNOW+)-THE A1CNOW®+ TEST PROVIDES A QUANTITATIVE MEASUREMENT OF THE PERCENT OF GLYCATED HEMOGLOBIN (% A1C) LEVELS IN CAPILLARY (FINGERSTICK) OR VENOUS WHOLE BLOOD SAMPLES. THE TEST IS FOR PROFESSIONAL USE TO MONITOR GLYCEMIC CONTROL IN PEOPLE WITH DIABETES.

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867	IMP/IVD/2020/000811	1.License Holder Name: EZYBUY 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREGNANCY KIT (ELUCIGENE QST*R-PL)-ELUCIGENE QST*R-PL KIT IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE ROUTINE DIAGNOSIS OF SIX MOST COMMON AUTOSOMAL TRISOMIES ASSOCIATED WITH PREGNANCY LOSS: TRISOMY 13 (PATAU SYNDROME), TRISOMY 15, TRISOMY 16, TRISOMY 18 (EDWARDS' SYNDROME), TRISOMY 21 (DOWN'S SYNDROME) AND TRISOMY 22. THE KIT ALSO INCLUDES X AND Y CHROMOSOME MARKERS AND THE TA9FL MARKER FOR SEX STATUS. THE TARGET POPULATION IS INDIVIDUALS WHO HAVE EXPERIENCED A SPONTANEOUS MISCARRIAGE.,ANEUPLOIDY KIT(ELUCIGENE QST*R-PLUS V2)-ELUCIGENE QST*R-PLUS V2 KIT IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE ROUTINE DIAGNOSIS OF THREE MOST COMMON AUTOSOMAL TRISOMIES ASSOCIATED WITH PREGNANCY LOSS: TRISOMY 13 (PATAU SYNDROME), TRISOMY 18 (EDWARDS' SYNDROME) AND TRISOMY 21 (DOWN'S SYNDROME) THE KIT ALSO INCLUDES X AND Y CHROMOSOME MARKERS AND THE TA9FL MARKER FOR SEX STATUS. THE TARGET POPULATION ARE PREGNANT WOMEN THAT HAVE BEEN ASSESSED AS BEING 'HIGH RISK' OF CARRYING AN AFFECTED FOETUS BY EITHER BIOCHEMICAL OR ULTRASOUND DIAGNOSTIC PROCEDURES OR ASSESSED TO BE 'AT RISK' DUE TO PREVIOUS FAMILY HISTORY OR MATERNAL AGE. THE KIT IS INTENDED FOR USE ON PREGNANT FEMALES IN THE PRE-NATAL PHASE.,ANEUPLOIDY KIT(ELUCIGENE QST*R-XY V2)-ELUCIGENE QST*R-XY V2 KIT IS AN IN VITRO DIAGNOSTIC PRODUCT FOR THE ROUTINE DIAGNOSIS AND SEX CHROMOSOME (X AND Y) ANEUPLOIDY. THE TARGET POPULATION ARE PREGNANT WOMEN THAT HAVE BEEN ASSESSED AS BEING 'HIGH RISK' OF CARRYING AN AFFECTED FOETUS BY EITHER BIOCHEMICAL OR ULTRASOUND DIAGNOSTIC PROCEDURES OR ASSESSED TO BE 'AT RISK' DUE TO PREVIOUS FAMILY HISTORY OR MATERNAL AGE. THE KIT IS INTENDED FOR USE ON PREGNANT FEMALES IN THE PRE-NATAL PHASE.

868	IMP/IVD/2020/000815	1.License Holder Name: OSB AGENCIES PRIVATE LIMIATED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MEBRIGHT SARS-COV-2 KIT(MEBRIGHT)-THE MEBRIGHTTM SARS-COV-2 KIT IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE INTENDED TO BE USED BY HEALTHCARE PROFESSIONALS FOR THE QUALITATIVE DETECTION OF SARS-COV-2 VIRAL RNA FROM UPPER RESPIRATORY TRACT SPECIMEN (NASOPHARYNGEAL SWAB) OR LOWER RESPIRATORY TRACT SPECIMEN (SPUTUM OR ALVEOLAR LAVAGE FLUID) BY REVERSE TRANSCRIPTION PCR (RT-PCR) METHOD. DETECTION OF SARS-COV-2 VIRAL RNA IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF COVID-19.
869	IMP/IVD/2020/000816	1.License Holder Name: BIO SCIENCE SALES CORPORATION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DILUENT FOR MYTHIC 22 (DILUENT FOR MYTHIC 22)-ISOTONIC SOLUTION USE FOR THE DIFFERENTIATION OF THE WHITE BLOOD CELLS.,CLEANER FOR MYTHIC 22(CLEANER FOR MYTHIC 22)-THIS SOLUTION IS USED TO CLEAN THE SYSTEM.THE PRESENCE OF AN ENZYME REDUCES THE FORMATION OF PROTEINS DEPOSIT.,MYTHIC 18-22 FLUSH CLEANER (MYTHIC 18-22 FLUSH CLEANER)-AN EMERGENCY CLEANER ,BASED ON HYPOCHLORITE, DESIGNED FOR WASHING AND MAINTENANCE OF MYTHIC HAEMATOLOGY ANALYSERS.

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870	IMP/IVD/2020/000818	1.License Holder Name: BIOMERIEUX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHROMID® CARBA SMART AGAR(CHROMID® CARBA SMART AGAR)-SELECTIVE CHROMOGENIC MEDIA FOR THE SCREENING OF CARBAPENEMASE-PRODUCING ENTEROBACTERIACEAE (CPE),COLUMBIA AGAR + 5% SHEEP BLOOD(COLUMBIA AGAR + 5% SHEEP BLOOD)-ISOLATION OF FASTIDIOUS BACTERIA. DECTION OF HEMOLYSIS.,CHROMID™ ESBL AGAR(CHROMID™ ESBL AGAR)-SELECTIVE CHROMOGENIC MEDIUM FOR THE SCREENING OF EXTENDED SPECTRUM -LACTAMASE-PRODUCING ENTEROBACTERIA (ESBL),MULLER HINTON E AGAR (MULLER HINTON E AGAR)-STUDY OF ANTIMICROBIAL SUSCEPTIBILITY,MAC CONKEY AGAR(MAC CONKEY AGAR)-SELECTIVE ISOLATION OF ENTEROBACTERIA AND ESCHERICHIA COLI,CLED AGAR(CLED AGAR)-ISOLATION OF MICRO-ORGANISMS OF THE URINARY TRACT,CHROMID® CPS® ELITE AGAR TRANSLUCENT MEDIUM(CHROMID® CPS® ELITE AGAR TRANSLUCENT MEDIUM)-ISOLATION, ENUMERATION AND DIRECT AND PRESUMPTIVE IDENTIFICATION OF URINARY TRACT INFECTION ORGANISMS, CHROMID™ VRE AGAR(CHROMID™ VRE AGAR)-SELECTIVE CHROMOGENIC MEDIUM FOR THE DETECTION AND DIFFERENTIATION OF ENTEROCOCCUS FAECIUM AND E. FAECALIS SHOWING ACQUIRED VANCOMYCIN RESISTANCE (VRE)
871	IMP/IVD/2020/000819	1.License Holder Name: DIAGNOSTIC BIOSYSTEMS (INDIA) 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIVA DECLOAKER, 20X-FOR IN VITRO DIAGNOSTIC USE, DIVA DECLOAKER, 20X IS A BUFFERED SOLUTION THAT IS INTENDED FOR LABORATORY USE IN HEATINDUCED ANTIGEN RETRIEVAL OF FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) TISSUES FOR IMMUNOHISTOCHEMISTRY (IHC) PROCEDURES.,MACH 2 UNIVERSAL HRP POLYMER DETECTION (KIT) (BIOCARE MEDICAL, USA)-FOR IN VITRO DIAGNOSTIC USE,DA VINC GREEN DILUENT-FOR IN VITRO DIAGNOSTIC USE,BACKGROUND SNIPER-FOR IN VITRO DIAGNOSTIC USE, BACKGROUND SNIPER IS A BLOCKING REAGENT THAT IS INTENDED FOR LABORATORY USE IN REDUCING NONSPECIFIC BACKGROUND STAINING OBSERVED IN IMMUNOHISTOCHEMISTRY (IHC) PROCEDURE ON FORMALIN-FIXED PARAFFINEMBEDDED (FFPE) HUMAN TISSUES.,BETAZOID DAB CHROMOGEN KIT-FOR IN VITRO DIAGNOSTIC USE,TBS AUTOMATION WASH BUFFER, 20X-FOR IN VITRO DIAGNOSTIC USE

872	IMP/IVD/2020/000825	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REAL TIME PCR KIT FOR NOVEL CORONAVIRUS 2019-NCOV (ORF1AB, N-THIS KIT IS USED FOR IN VITRO QUALITATIVE DETECTION OF NOVEL CORONAVIRUS 2019-NCOV IN RESPIRATORY SPECIMENS INCLUDING OROPHARYNGEAL SWAB, SPUTUM, BRONCHOALVEOLAR LAVAGE FLUID AND NASOPHARYNGEAL SWAB.

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873	IMP/IVD/2020/000826	1.License Holder Name: IMMUNOSHOP INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AESKULISA ß2-GLYCO-GM (AESKU)-"AESKULISA CARDIOLIPIN-GM IS A SOLID PHASE ENZYME IMMUNOASSAY EMPLOYING HIGHLY PURIFIED CARDIOLIPIN PLUS NATIVE HUMAN ß2-GLYCOPROTEIN I FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG AND /OR IGM ANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM. ANTI-CARDIOLIPIN ANTIBODIES MAINLY RECOGNIZE SPECIFIC EPITOPES ON A COMPLEX COMPOSED OF CARDIOLIPIN AND ß2-GLYCOPROTEIN I WHICH ARE ONLY EXPRESSED WHEN ß2-GLYCOPROTEIN I INTERACTS WITH CARDIOLIPIN. THE ASSAY IS AN AID IN THE DIAGNOSIS AND RISK ESTIMATION OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)." ,AESKULISA PHOSPHOLIPID-SCREEN (AESKU)-"AESKULISA PHOSPHOLIPID-SCREEN IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE COMBINED QUALITATIVE DETECTION OF IGG AND IGM ANTIBODIES AGAINST PHOSPHOLIPIDS IN HUMAN SERUM. EACH WELL IS COATED WITH HIGHLY PURIFIED HUMAN ß2-GLYCOPROTEIN I, CARDIOLIPIN AND PHOSPHATIDYLCHOLIN, -ETHANOLAMIN, -INOSITOL, -SERINE AND SPHINGOMYELIN. THE ASSAY IS AN AID IN THE DIAGNOSIS AND RISK ESTIMATION OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS.",AESKULISA SNRNP-C(AESKU)-"AESKULISA SNRNP-C IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF ANTIBODIES AGAINST THE SNRNP COMPLEX IN HUMAN SERUM. THE ASSAY EMPLOYS NATIVE HUMAN U1-SNRNP COMPLEX HIGHLY PURIFIED FROM THE CELL-LINE HELA. THE U1-SNRNP COMPLEX COMPRISES THE SMITH ANTIGEN (SM) AND RNPS, THE 70KDA U1-SPECIFIC PROTEIN PLUS PROTEIN A AND C. THE ASSAY IS A TOOL FOR THE DIAGNOSIS OF MIXED CONNECTIVE TISSUE DISEASES (MCTD) AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)" ,AESKULISA A-TPO (AESKU)-"AESKULISA A-TPO IS A SOLID PHASE ENZYME IMMUNOASSAY EMPLOYING RECOMBINANT HUMAN THYROID PEROXIDASE (TPO) FROM AN EUKARYOTIC EXPRESSION SYSTEM FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF ANTIBODIES AGAINST TPO IN HUMAN SERUM. ONLY RECOMBINANT HUMAN ANTIGEN EXPRESSED IN EUKARYOTIC CELLS DISPLAYS SPECIFIC CONFORMATIONAL EPITOPES THAT ARE ACCESSIBLE FOR HUMAN ANTI-TPO AUTOANTIBODIES. THE ASSAY IS A TOOL IN THE DIAGNOSIS OF AUTOIMMUNE THYROID DISEASES." ,AESKULISA ENA-6S(AESKU)-"AESKULISA ENA-6S IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE COMBINED QUALITATIVE DETECTION OF IGG ANTIBODIES AGAINST SIX CELLULAR AND NUCLEAR ANTIGENS IN

	HUMAN SERUM. EACH WELL IS COATED WITH RECOMBINANT SS-B, SS-A 52 KDA, SCL 70, JO-1 AND HIGHLY PURIFIED NATIVE HUMAN SNRNP/SM, SM AND SS-A 60 KDA. THE ASSAY IS A TOOL IN THE DIFFERENTIAL DIAGNOSIS OF SYSTEMIC RHEUMATIC DISEASES." , AESKULISA ANNEXIN V-GM(AESKU)-"AESKULISA ANNEXIN V-GM IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG AND/OR IGM ANTIBODIES AGAINST ANNEXIN V IN HUMAN SERUM. THE ASSAY EMPLOYS NATIVE HUMAN ANNEXIN V. THE ASSAY IS A TOOL IN THE DIAGNOSIS OF THE ANTIPHOSPHOLIPID SYNDROME." ,AESKULISA CARDIOLIPIN-GM (AESKU)-"AESKULISA CARDIOLIPIN-GM IS A SOLID PHASE ENZYME IMMUNOASSAY EMPLOYING HIGHLY PURIFIED CARDIOLIPIN PLUS NATIVE HUMAN ß2-GLYCOPROTEIN I FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG AND /OR IGM ANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM. ANTI-CARDIOLIPIN ANTIBODIES MAINLY RECOGNIZE SPECIFIC EPITOPES ON A COMPLEX COMPOSED OF CARDIOLIPIN AND ß2-GLYCOPROTEIN I WHICH ARE ONLY EXPRESSED WHEN ß2-GLYCOPROTEIN I INTERACTS WITH CARDIOLIPIN. THE ASSAY IS AN AID IN THE DIAGNOSIS AND RISK ESTIMATION OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)." ,AESKULISA ANA-HEP2 QUANTITATIVE (AESKU)-"AESKULISA ANA-HEP-2 QUANTITATIVE IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTIBODIES AGAINST HEP2 CELLS IN HUMAN SERUM. EACH WELL IS COATED WITH LYSED HEP2 CELLS. THE TEST COLLECTIVELY DETECTS, IN ONE WELL, TOTAL ANAS AGAINST DOUBLE STRANDED DNA (DSDNA), HISTONES, SS-A (RO), SS-B (LA), SM, SNRNP/SM, SCL-70, PM-SCL, JO-1 AND CENTROMERIC ANTIGENS ALONG WITH SERA POSITIVE FOR HEP2 IMMUNOFLUORESCENCE TEST (IFT). THE ASSAY IS A TOOL IN THE DIAGNOSIS OF SYSTEMIC RHEUMATIC DISEASES LIKE SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), MIXED CONNECTIVE TISSUE DISEASES (MCTD), SCLERODERMA, SJÖGREN`S SYNDROME, POLYMYOSITIS AND DERMATOMYOSITIS.', AESKULISA ANA-8PRO(AESKU)-AESKULISA ANA-8PRO IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE SEPARATE QUALITATIVE DETECTION OF IGG ANTIBODIES AGAINST EIGHT CELLULAR AND NUCLEAR ANTIGENS IN HUMAN SERUM. THE WELLS ARE SEPARATELY COATED WITH RECOMBINANT 70 KDA U1 SNRNP, SS-B, SS-A 52 KDA, SCL 70, CENTROMERE PROTEIN B (CENPB), JO-1 AND HIGHLY PURIFIED NATIVE HUMAN SNRNP/SM, SM AND SS-A 60 KDA. THE ASSAY IS A TOOL IN THE DIFFERENTIAL DIAGNOSIS OF SYSTEMIC RHEUMATIC DISEASES. ,AESKULISA PHOSPHOLIPID-8PRO-GM (AESKU)-"AESKULISA PHOSPHOLIPID-8PRO-GM IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE SEPARATE QUALITATIVE

	DETECTION OF IGG AND/OR IGM ANTIBODIES AGAINST PHOSPHOLIPIDS IN HUMAN SERUM. THE ASSAY EMPLOYS HIGHLY PURIFIED HUMAN ß2-GLYCOPROTEIN I, CARDIOLIPIN + ß2-GLYCOPROTEIN I, CARDIOLIPIN AND PHOSPHATIDYLCHOLINE, -ETHANOLAMINE, -INOSITOL, -SERINE AND SPHINGOMYELIN. THE ASSAY IS AN AID IN THE DIAGNOSIS AND RISK ESTIMATION OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS." ,AESKULISA SCL-70(AESKU)-"AESKULISA SCL-70 IS A SOLID PHASE ENZYME IMMUNOASSAY WITH HUMAN RECOMBINANT 70 KDA FRAGMENT OF DNA TOPOISOMERASE I FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF ANTIBODIES AGAINST SCL-70 (70 KDA SCLERODERMA ANTIGEN) IN HUMAN SERUM. THE ASSAY IS A TOOL IN THE DIFFERENTIAL DIAGNOSIS OF SYSTEMIC SCLEROSIS." ,AESKULISA DSDNA-G (AESKU)-"AESKULISA DSDNA-G IS A SOLID PHASE ENZYME IMMUNOASSAY WITH HUMAN RECOMBINANT DOUBLE-STRANDED DNA (DSDNA) FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTIBODIES AGAINST DSDNA IN HUMAN SERUM. ANTI-DSDNA ANTIBODIES MAINLY RECOGNIZE THE PHOSPHAT UNITS OF THE DNA, THUS THESE AUTOANTIBODIES ALSO BIND SINGLE STRANDED DNA (SSDNA). TO ENSURE CORRECT QUANTITATION OF ANTI-DSDNA ANTIBODIES THE USED ANTIGEN HAS BEEN PROVEN TO BE FREE OF CONTAMINATION WITH SSDNA. THE ASSAY IS A TOOL IN THE DIFFERENTIAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)." ,AESKULISA JO-1 (AESKU)-"AESKULISA JO-1 IS A SOLID PHASE ENZYME IMMUNOASSAY WITH RECOMBINANT HUMAN HISTIDYL-TRNA-SYNTHETASE (HRS) FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF ANTIBODIES AGAINST JO-1 (NAMED AFTER THE PROTOTYPE PATIENT) IN HUMAN SERUM. HUMAN SERA WITH ANTI-JO-1 ANTIBODIES SOLELY RECOGNIZE HRS OF HIGHER EUKARYOTES AND REACT WITH HIGHEST AFFINITY WITH THE HUMAN ENZYME. THE ASSAY IS A TOOL IN THE DIAGNOSIS OF POLYMYOSITIS AND DERMATOMYOSITIS." ,AESKULISA PHOSPHOLIPID-SCREEN-GM (AESKU)-"AESKULISA PHOSPHOLIPID-SCREEN-GM IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE SEPARATE QUALITATIVE AND QUANTITATIVE DETECTION OF IGG AND/OR IGM ANTIBODIES AGAINST PHOSPHOLIPIDS IN HUMAN SERUM. EACH WELL IS COATED WITH HIGHLY PURIFIED BOVINE CARDIOLIPIN + ß2-GLYCOPROTEIN I, PHOSPHATIDYL- SERINE, -INOSITOL, - ETHANOLAMIN, - CHOLINE AND SPHINGOMYELIN. THE ASSAY IS AN AID IN THE DIAGNOSIS AND RISK ESTIMATION OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS AND ANTIPHOSPHOLIPID SYNDROME (APS)." ,AESKULISA SS-A(AESKU)-"AESKULISA SS-A IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE AND

	QUALITATIVE DETECTION OF ANTIBODIES AGAINST RO / SS-A IN HUMAN SERUM. THE ASSAY EMPLOYS HUMAN RO/SS-A ANTIGEN COMPOSED OF HIGHLY PURIFIED NATIVE 60KDA AND RECOMBINANT HUMAN 52 KDA RO/SS-A PROTEIN. ANTI-SS-A ANTIBODIES ARE SPECIES-SPECIFIC (DIRECTED AGAINST HUMAN PROTEIN ONLY) AND PREFERENTIALLY REACT WITH THE NATIVE 60KDA MOLECULE WHERE AS MOST ANTIBODIES TO THE 52 KDA PROTEIN PREFER THE DENATURED MOLECULE. THE ASSAY IS A TOOL IN THE DIAGNOSIS OF SJÖGREN`S SYNDROME (SS) AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)." ,AESKUSLIDES NDNA(AESKU)-AESKUSLIDES NDNA (CRITHIDIA LUCILIAE) IS AN INDIRECT IMMUNOFLUORESCENCE ASSAY TO DETECT IGG ANTIBODIES TO NATIVE DOUBLE HELIX DNA IN HUMAN SERUM. ,AESKULISA SS-A-52 (AESKU)-"AESKULISA SS-A-52 IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF ANTIBODIES AGAINST THE 52 KDA RO/ SS-A IN HUMAN SERUM. THE ASSAY EMPLOYS RECOMBINANT HUMAN 52KDA RO/SS-A PROTEIN. MOST ANTIBODIES AGAINST 52 KDA SS-A PREFER THE DENATURED MOLECULE. THE ASSAY IS A TOOL IN THE DIAGNOSIS OF SJÖGREN`S SYNDROME (SS) AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)." ,AESKULISA CARDIOLIPIN-CHECK(AESKU)-"AESKULISA CARDIOLIPIN-CHECK IS A SOLID PHASE ENZYME IMMUNOASSAY EMPLOYING HIGHLY PURIFIED CARDIOLIPIN PLUS NATIVE HUMAN ß2-GLYCOPROTEIN I FOR THE COMBINED QUANTITATIVE AND QUALITATIVE DETECTION OF IGA, IGG AND IGM ANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM. ANTICARDIOLIPIN ANTIBODIES MAINLY RECOGNIZE SPECIFIC EPITOPES ON A COMPLEX COMPOSED OUT OF CARDIOLIPIN AND ß2-GLYCOPROTEIN I WHICH ARE EXPRESSED ONLY WHEN ß2-GLYCOPROTEIN I INTERACTS WITH CARDIOLIPIN. THE ASSAY IS AN AID IN THE DIAGNOSIS AND RISK ESTIMATION OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)."., AESKULISA SS-B(AESKU)-"AESKULISA SS-B IS A SOLID PHASE ENZYME IMMUNOASSAY EMPLOYING HUMAN RECOMBINANT LA-ANTIGEN/ SS-B FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF ANTIBODIES AGAINST LA-ANTIGEN / SS-B IN HUMAN SERUM. THE ASSAY IS A TOOL IN THE DIAGNOSIS OF SJÖGREN`S SYNDROME (SS) AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)." , AESKULISA MPO(AESKU)-"AESKULISA MPO IS A SOLID PHASE ENZYME IMMUNOASSAY EMPLOYING HIGHLY PURIFIED NATIVE MYELOPEROXIDASE (MPO) FROM HUMAN PERIPHERAL BLOOD POLYMORPHNUCLEAR CELLS FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF ANTIBODIES AGAINST MPO IN HUMAN SERUM. ANTI-MPO ANTIBODIES RECOGNIZE SPECIFIC

	CONFORMATIONAL EPITOPES ONLY ACCESSIBLE ON NATIVE MPO. THE ASSAY IS A TOOL IN THE DIFFERENTIAL DIAGNOSIS OF AUTOIMMUNE SYSTEMIC VASCULITIS." ,AESKULISA TTG-GA NEW GENERATION(AESKU)-"THE AESKULISA TTG-GA NEW GENERATION IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE SEPERATE QUANTITATIVE AND QUALITATIVE DETECTION OF IGA AND/OR IGG ANTIBODIES AGAINST NEOEPITOPES OF TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM. THE ASSAY EMPLOYING HUMAN RECOMBINANT TRANSGLUTAMINASE CROSSLINKED WITH GLIADIN-SPECIFIC PEPTIDES DISPLAYS NEOEPITOPES OF TTG WHICH ENSURES A SIGNIFICANTLY INCREASED SENSITIVITY AND SPECIFICITY OF THE TEST. THE ASSAY IS A TOOL FOR THE DIAGNOSIS AND MONITORING OF CELIAC DISEASE (GLUTEN-SENSITIVE ENTEROPATHY).",AESKULISA PHOSPHOLIPID-SCREEN-A (AESKU)-"AESKULISA PHOSPHOLIPID-SCREEN-A IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE COMBINED QUALITATIVE AND QUANTITATIVE DETECTION OF IGA ANTIBODIES AGAINST PHOSPHOLIPIDS IN HUMAN SERUM. EACH WELL IS COATED WITH HIGHLY PURIFIED BOVINE CARDIOLIPIN, ß2-GLYCOPROTEIN I, PHOSPHATIDYL- SERINE, -INOSITOL, ETHANOLAMINE, -CHOLINE AND SPHINGOMYELIN. THE ASSAY IS AN AID IN THE DIAGNOSIS AND RISK ESTIMATION OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS AND ANTIPHOSPHOLIPID SYNDROME (APS)." , AESKULISA TTG-A NEW GENERATION(AESKU)-THE AESKULISA TTG-A NEW GENERATION IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGA ANTIBODIES AGAINST NEO-EPITOPES OF TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM. THE ASSAY EMPLOYING HUMAN RECOMBINANT TRANSGLUTAMINASE CROSSLINKED WITH GLIADIN-SPECIFIC PEPTIDES DISPLAYS NEO-EPITOPES OF TTG WHICH ENSURES A SIGNIFICANTLY INCREASED SENSITIVITY AND SPECIFICITY OF THE TEST. THE ASSAY IS A TOOL FOR THE DIAGNOSIS AND MONITORING OF CELIAC DISEASE (GLUTEN-SENSITIVE ENTEROPATHY).",AESKUSLIDES ANCA ETHANOL(AESKU)-"AESKUSLIDES ANCA IS AN INDIRECT IMMUNOFLUORESCENCE ASSAY TO DETECT ANTI-NEUTROPHIL CYTOPLASMIC AUTOANTIBODIES (ANCA) IN HUMAN SERUM. THE ASSAY IS A TOOL FOR THE DIFFERENTIAL DIAGNOSIS OF ANCA-ASSOCIATED VASCULITIDES (AAV) SUCH AS GRANULOMATOSIS WITH POLYANGIITIS (WEGENER'S)1, MICROSCOPIC POLYANGIITIS AND CHURG-STRAUSS SYNDROME.",AESKULISA CELICHECK NEW GENERATION(AESKU)-AESKULISA CELICHECK NEW GENERATION IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE COMBINED QUANTITATIVE AND QUALITATIVE DETECTION OF IGA AND IGG

	ANTIBODIES AGAINST NEOEPITOPES OF TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM. THE ASSAY EMPLOYING HUMAN RECOMBINANT TTG CROSSLINKED WITH GLIADIN-SPECIFIC PEPTIDES DISPLAYS NEO-EPITOPES OF TTG WHICH ENSURES A SIGNIFICANTLY INCREASED SENSITIVITY AND SPECIFICITY OF THE TEST. THE ASSAY IS A TOOL FOR THE DIAGNOSIS AND MONITORING OF CELIAC DISEASE (GLUTEN-SENSITIVE ENTEROPATHY).",AESKUSLIDES ANA-HEP-2(AESKU)-"AESKUSLIDES ANA-HEP-2 IS AN INDIRECT IMMUNOFLUORESCENCE ASSAY TO DETECT NUCLEAR AND / OR CYTOPLASMIC AUTOANTIBODIES IN HUMAN SERUM. THE ASSAY IS A TOOL IN THE DIFFERENTIAL DIAGNOSIS OF SYSTEMIC RHEUMATIC DISEASES LIKE SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), MIXED CONNECTIVE TISSUE DISEASES (MCTD), SCLERODERMA, SJÖGREN'S SYNDROME (SS), POLYMYOSITIS AND DERMATOMYOSITIS.",AESKULISA TTG-G NEW GENERATION(AESKU)-"THE AESKULISA TTG-G NEW GENERATION IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTIBODIES AGAINST NEO-EPITOPES OF TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM. THE ASSAY EMPLOYING HUMAN RECOMBINANT TRANSGLUTAMINASE CROSSLINKED WITH GLIADIN-SPECIFIC PEPTIDES DISPLAYS NEO-EPITOPES OF TTG WHICH ENSURES A SIGNIFICANTLY INCREASED SENSITIVITY AND SPECIFICITY OF THE TEST. THE ASSAY IS A TOOL FOR THE DIAGNOSIS AND MONITORING OF CELIAC DISEASE (GLUTEN-SENSITIVE ENTEROPATHY)., AESKULISA CENP-B(AESKU)-AESKULISA CENP-B IS A SOLID PHASE ENZYME IMMUNOASSAY EMPLOYING PURIFIED RECOMBINANT HUMAN 80 KDA CENTROMERE PROTEIN B (CENP-B) FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTIBODIES AGAINST CENP-B IN HUMAN SERUM. THE ASSAY ENSURES THE HIGHEST SPECIFICITY AND SENSITIVITY FOR THE DETECTION OF ANTIBODIES AGAINST CENTROMERE PROTEIN B, WHICH SERVES AS AN AID IN THE DIAGNOSIS OF SYSTEMIC SCLEROSIS AND CREST SYNDROME.,AESKULISA VASCULITIS SCREEN(AESKU)-"AESKULISA VASCULITIS-SCREEN IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE COMBINED QUANTITATIVE AND QUALITATIVE DETECTION OF ANTIBODIES AGAINST PR3 AND MPO IN HUMAN SERUM. EACH WELL IS COATED WITH NATIVE HUMAN PROTEINASE 3 (PR3) PLUS NATIVE MYELOPEROXIDASE (MPO), BOTH HIGHLY PURIFIED FROM HUMAN PERIPHERAL BLOOD POLYMORPHNUCLEAR CELLS. ANTI-PR3 AND ANTI-MPO ANTIBODIES RECOGNIZE SPECIFICIALLY CONFORMATIONAL EPITOPES ONLY ACCESSIBLE ON THE NATIVE TARGET ANTIGEN. THE ASSAY IS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF AUTOIMMUNE VASCULITIS." ,AESKULISA DSDNA-M

	(AESKU)-"AESKULISA DSDNA-M IS A SOLID PHASE ENZYME IMMUNOASSAY WITH HUMAN RECOMBINANT DOUBLE-STRANDED DNA (DSDNA) FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGM ANTIBODIES AGAINST DSDNA IN HUMAN SERUM. ANTI-DSDNA ANTIBODIES MAINLY RECOGNIZE THE PHOSPHATE UNITS OF THE DNA, THUS THESE AUTOANTIBODIES ALSO BIND SINGLE-STRANDED DNA (SSDNA). TO ENSURE CORRECT QUANTITATION OF ANTI-DSDNA ANTIBODIES THE USED ANTIGEN HAS BEEN PROVEN TO BE FREE OF CONTAMINATION WITH SSDNA. THE ASSAY IS A TOOL IN THE DIFFERENTIAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE).",AESKULISA ENA-6PRO(AESKU)-AESKULISA ENA-6PRO IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE SEPARATE SEMIQUANTITATIVE DETECTION OF IGG ANTIBODIES AGAINST SIX CELLULAR AND NUCLEAR ANTIGENS IN HUMAN SERUM. THE WELLS ARE COATED WITH RECOMBINANT SS-B, SS-A 52 KDA, SCL 70, JO-1 AND HIGHLY PURIFIED NATIVE HUMAN SNRNP/SM, SM AND SS-A 60 KDA. THE ASSAY IS A TOOL IN THE DIFFERENTIAL DIAGNOSIS OF SYSTEMIC RHEUMATIC DISEASES.,AESKULISA GBM(AESKU)-"AESKULISA GBM IS A SOLID PHASE ENZYME IMMUNOASSAY EMPLOYING RECOMBINANT HUMAN GLOMERULAR BASEMENT MEMBRANE PROTEIN (GBM) FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG ANTIBODIES AGAINST GBM IN HUMAN SERUM. THE ASSAY IS AN AID IN THE DIAGNOSIS OF GOODPASTURE SYNDROME.",AESKULISA U1-70(AESKU)-AESKULISA U1-70 IS A SOLID PHASE ENZYME IMMUNOASSAY EMPLOYING RECOMBINANT HUMAN 70 KDA PROTEIN OF THE U1-SNRNP COMPLEX FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF ANTIBODIES AGAINST THE 70 KDA U1-RNP IN HUMAN SERUM. THE ASSAY IS A TOOL IN THE DIAGNOSIS OF MIXED CONNECTIVE TISSUE DISEASES (MCTD) AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)., AESKULISA CARDIOLIPIN-A(AESKU)-AESKULISA CARDIOLIPIN-A IS A SOLID PHASE ENZYME IMMUNOASSAY EMPLOYING HIGHLY PURIFIED CARDIOLIPIN PLUS NATIVE HUMAN ß2-GLYCOPROTEIN I FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGA ANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM. ANTI-CARDIOLIPIN ANTIBODIES MAINLY RECOGNIZE SPECIFIC EPITOPES ON A COMPLEX COMPOSED OUT OF CARDIOLIPIN AND ß2-GLYCOPROTEIN I WHICH ARE EXPRESSED ONLY WHEN ß2-GLYCOPROTEIN I INTERACTS WITH CARDIOLIPIN. THE ASSAY IS AN AID IN THE DIAGNOSIS AND RISK ESTIMATION OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE).,AESKULISA DSDNA-A(AESKU)-"AESKULISA DSDNA-A IS A SOLID PHASE ENZYME IMMUNOASSAY WITH HUMAN RECOMBINANT DOUBLE-STRANDED DNA (DSDNA) FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF IGA ANTIBODIES

	AGAINST DSDNA IN HUMAN SERUM. ANTI-DSDNA ANTIBODIES MAINLY RECOGNIZE THE PHOSPHAT UNITS OF THE DNA, THUS THESE AUTOANTIBODIES ALSO BIND SINGLE STRANDED DNA (SSDNA). TO ENSURE CORRECT QUANTITATION OF ANTI-DSDNA ANTIBODIES THE USED ANTIGEN HAS BEEN PROVEN TO BE FREE OF CONTAMINATION WITH SSDNA. THE ASSAY IS A TOOL IN THE DIFFERENTIAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE).",AESKULISA SM (AESKU)-"AESKULISA SM IS A SOLID PHASE ENZYME IMMUNOASSAY WITH HIGHLY PURIFIED NATIVE SMITH ANTIGEN (SM) FROM HUMAN EUKARYOTIC CELLS (HELA) FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF ANTIBODIES AGAINST SM IN HUMAN SERUM. ANTI-SM ANTIBODIES RECOGNIZE SPECIFIC CONFORMATIONAL EPITOPES ONLY ACCESSIBLE ON NATIVE HUMAN SM. THE ASSAY IS A TOOL IN THE DIFFERENTIAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE).",AESKULISA ANA HEP-2 (AESKU)-"AESKULISA ANA-HEP-2 IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE COMBINED QUALITATIVE DETECTION OF IGG ANTIBODIES AGAINST HEP2 CELLS IN HUMAN SERUM. EACH WELL IS COATED WITH LYSED HEP2 CELLS. THE TEST COLLECTIVELY DETECTS, IN ONE WELL, TOTAL ANAS AGAINST DOUBLE STRANDED DNA (DSDNA), HISTONES, SS-A (RO), SS-B (LA), SM, SNRNP/SM, SCL-70, PM-SCL, JO-1 AND CENTROMERIC ANTIGENS ALONG WITH SERA POSITIVE FOR HEP2 IMMUNOFLUORESCENCE TEST (IFT). THE ASSAY IS A TOOL IN THE DIAGNOSIS OF SYSTEMIC RHEUMATIC DISEASES LIKE SYSTEMIC LUPUS ERYTHEMATOSUS (SLE), MIXED CONNECTIVE TISSUE DISEASES (MCTD), SCLERODERMA, SJÖGREN`S SYNDROME, POLYMYOSITIS AND DERMATOMYOSITIS.",AESKULISA SS-A-60 (AESKU)-"AESKULISA SS-A-60 IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF ANTIBODIES AGAINST THE 60 KDA RO/SS-A IN HUMAN SERUM. THE ASSAY EMPLOYS HIGHLY PURIFIED HUMAN NATIVE 60KDA RO/SS-A PROTEIN. ANTIBODIES AGAINST SS-A ARE SPECIES-SPECIFIC (DIRECTED AGAINST HUMAN PROTEIN ONLY) AND PREFERENTIALLY REACT WITH THE NATIVE 60KDA MOLECULE. THE ASSAY IS A TOOL IN THE DIAGNOSIS OF SJÖGREN`S SYNDROME (SS) AND SYSTEMIC LUPUS ERYTHEMATOSUS (SLE).",AESKULISA DSDNA-CHECK(AESKU)-"AESKULISA DSDNA-CHECK IS A SOLID PHASE ENZYME IMMUNOASSAY WITH HUMAN RECOMBINANT DOUBLE-STRANDED DNA (DSDNA) FOR THE COMBINED QUANTITATIVE AND QUALITATIVE DETECTION OF IGG, IGA AND IGM ANTIBODIES AGAINST DSDNA IN HUMAN SERUM. ANTI-DSDNA ANTIBODIES MAINLY RECOGNIZE THE PHOSPHATE UNITS OF THE DNA, THUS THESE AUTOANTIBODIES ALSO BIND SINGLE STRANDED DNA (SSDNA). TO ENSURE CORRECT QUANTITATION OF ANTI-DSDNA ANTIBODIES THE

		USED ANTIGEN HAS BEEN PROVEN TO BE FREE OF CONTAMINATION WITH SSDNA. THE ASSAY IS A TOOL IN THE DIFFERENTIAL DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE).",AESKULISA ANA-8S (AESKU)-"AESKULISA ANA-8S IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE COMBINED QUALITATIVE DETECTION OF IGG ANTIBODIES AGAINST EIGHT CELLULAR AND NUCLEAR ANTIGENS IN HUMAN SERUM. EACH WELL IS COATED WITH RECOMBINANT 70 KDA U1-SNRNP, SS-B, SS-A 52 KDA, SCL 70, CENTROMERE PROTEIN B (CENPB), JO-1 AND HIGHLY PURIFIED NATIVE HUMAN SNRNP/SM, SM AND SS-A 60 KDA. THE ASSAY IS A TOOL IN THE DIFFERENTIAL DIAGNOSIS OF SYSTEMIC RHEUMATIC DISEASES.",AESKULISA PR3 SENSITIVE(AESKU)-"AESKULISA PR3 SENSITIVE IS A SOLID PHASE ENZYME IMMUNOASSAY EMPLOYING HIGHLY PURIFIED NATIVE HUMAN PROTEINASE 3 (PR3) FROM HUMAN NEUTROPHIL GRANULOCYTES FOR THE QUANTITATIVE AND QUALITATIVE DETECTION OF ANTIBODIES AGAINST PROTEINASE 3 IN HUMAN SERUM. ANTI-PR3 ANTIBODIES RECOGNIZE SPECIFICIALLY CONFORMATIONAL EPITOPES ONLY ACCESSIBLE ON NATIVE PR3. THE ASSAY IS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF AUTOIMMUNE VASCULITIS." ,AESKUSLIDES RLKS (WRAPPED)(AESKU) -THE ABOVE AESKUSLIDES REFERENCES ARE AN INDIRECT IMMUNOFLUORESCENCE ASSAYS TO DETECT AUTOANTIBODIES AGAINST FOR EXAMPLE MITOCHONDRIAL (AMA), SMOOTH MUSCLE (ASMA), LIVER KIDNEY MICROSOMAL (LKM) OR CIRCULATING PARIETAL CELLS (APCA) IN HUMAN SERUM.
874	IMP/IVD/2020/000827	1.License Holder Name: NIHON KOHDEN INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMATOLOGY CONTROL (MEK-5D)(NIHON KOHDEN)-FOR CHECKING THE PERFORMANCE OF BLOOD SAMPLE.,HEMATOLOGY CONTROL (MEK-3D)(NIHON KOHDEN) -FOR CHECKING THE PERFORMANCE OF BLOOD SAMPLE., HEMATOLOGY CALIBRATOR (MEK-CAL)(NIHON KOHDEN)- CALIBRATOR-FOR CALIBRATING THE EQUIPMENT.

875	IMP/IVD/2020/000828	1.License Holder Name: DSS IMAGETECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS- COV-2 RT PCR (MASTER DIAGNÓSTICA SAR-COV-2 RT PCR KIT)-QUALITATIVE DETECTION OF THE RNA OF THE SEVERE ACUTE RESPIRATORY SYNDROME-RELATED CORONAVIRUS 2, TAKING AS STARTING SAMPLE THE RNA FROM HUMAN CLINICAL SAMPLES OF DIFFERENT ORIGIN, SUCH AS, NASO- AND OROPHARYNGEAL SWABS AND BRONCHOALVEOLAR LAVAGES (BAL). IT IS BASED ON A MULTIPLEX ONE-STEP REAL-TIME RT-PCR ASSAY, USING PRIMERS AND FLUORESCENCE-LABELED PROBES SPECIFIC FOR THE GENE TARGETS N AND E FROM SARS-COV-2, FOLLOWING THE METHODOLOGY RECOMMENDED BY THE WHO.
876	IMP/IVD/2020/000829	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CELL-DYN EMERALD CLEANER(CELL-DYN EMERALD CLEANER)-CELL-DYN EMERALD CLEANER IS AN ENZYMATIC CLEANER USED TO CLEAN THE MEASUREMENT SYSTEM AND THE FLUIDICS OF CELL-DYN EMERALD HEMATOLOGY ANALYZER.,CELL-DYN EMERALD DILUENT(CELL-DYN EMERALD DILUENT)-INTENDED TO BE USED AS THE DILUENT FOR WBC, RBC, PLT AND HEMOGLOBIN MEASUREMENTS,CELL-DYN EMERALD CN-FREE LYSE(CELL-DYN EMERALD CN-FREE LYSE)-INTENDED TO RAPIDLY LYSE THE RBC AND MINIMIZE RESULTANT CELL STROMA.

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877	IMP/IVD/2020/000830	1.License Holder Name: ANAND BROTHERS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LEPTOSPIRA IGG (NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST LEPTOSPIRA SPP. IN HUMAN SERUM OR PLASMA (HEPARIN),COXIELLA BURNETI (Q-FEVER) PHASE 1 IGG(NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST COXIELLA BURNETII (Q-FEVER) PHASE 1 IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,CLOSTRIDIUM TETANI TOXIN IGG (NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CLOSTRIDIUM TETANI TOXIN IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)., CORYNEBACTERIUM DIPHTHERIAE TOXIN IGG(NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CORYNEBACTERIUM DIPHTHERIAE TOXIN IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN), VARICELLA-ZOSTER VIRUS (VZV) IGM(NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST VARICELLA-ZOSTER VIRUS (VZV) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,LEPTOSPIRA IGM (NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST LEPTOSPIRA SPP. IN HUMAN SERUM OR PLASMA (HEPARIN),MUMPS VIRUS IGM (NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST MUMPS VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,PARVOVIRUS B 19 IGG(NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST PARVOVIRUS B19 IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,BRUCELLA IGG(NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST BRUCELLA IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,EPSTEIN-BARR VIRUS (VCA) IGG(NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST EPSTEIN-BARR VIRUS VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,MUMPS VIRUS IGG (NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST MUMPS VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,ENTAMOEBA HISTOLYTICA IGG(NOVALISA®)-ENZYME IMMUNOASSAY FOR QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST ENTAMOEBA HISTOLYTICA IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,ECHINOCOCCUS IGG(NOVALISA®)-ENZYME

	IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST ECHINOCOCCUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,VARICELLA-ZOSTER VIRUS (VZV) IGG (NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST VARICELLA-ZOSTER VIRUS (VZV) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,TAENIA SOLIUM IGG(NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST TAENIA SOLIUM IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,MEASLES VIRUS IGG(NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST MEASLES VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,LEISHMANIA INFANTUM IGG (NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST LEISHMANIA INFANTUM IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)., PARVOVIRUS B 19 IGM(NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST PARVOVIRUS B19 IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,MEASLES VIRUS IGM(NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST MEASLES VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,BRUCELLA IGM(NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST BRUCELLA IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,EPSTEIN-BARR VIRUS (VCA) IGM (NOVALISA®)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST EPSTEIN-BARR VIRUS VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).

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878	IMP/IVD/2020/000831	1.License Holder Name: FINOVA HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URINE STRIP(BIOWAY)-FOR SEMI-QUANTITATIVE DETECTION IN URINE URIC BRAVERY, GLUCOSE, KETONE BODY, BILIRUBIN, ASCORBIC ACID, PROTEIN, NITRITE, PH VALUE, OCCULT BLOOD, SPECIFIC GRAVITY, WHITE BLOOD CELLS, CALCIUM, CREATININE, AND TRACE ALBUMIN PROJECT CLINICALLY, IT IS MAINLY USED FOR THE DIAGNOSIS OF NEPHROPATHY, DIABETES, URINARY INFECTION AND OTHER DISEASES (SUCH AS LIVER METABOLISM),URINE STRIP(BIOWAY)-FOR SEMI-QUANTITATIVE DETECTION IN URINE URIC BRAVERY, GLUCOSE, KETONE BODY, BILIRUBIN, ASCORBIC ACID, PROTEIN, NITRITE, PH VALUE, OCCULT BLOOD, SPECIFIC GRAVITY, WHITE BLOOD CELLS, CALCIUM, CREATININE, AND TRACE ALBUMIN PROJECT CLINICALLY, IT IS MAINLY USED FOR THE DIAGNOSIS OF NEPHROPATHY, DIABETES, URINARY INFECTION AND OTHER DISEASES (SUCH AS LIVER METABOLISM),URINE STRIP(BIOWAY)-FOR SEMI-QUANTITATIVE DETECTION IN URINE URIC BRAVERY, GLUCOSE, KETONE BODY, BILIRUBIN, ASCORBIC ACID, PROTEIN, NITRITE, PH VALUE, OCCULT BLOOD, SPECIFIC GRAVITY, WHITE BLOOD CELLS, CALCIUM, CREATININE, AND TRACE ALBUMIN PROJECT CLINICALLY, IT IS MAINLY USED FOR THE DIAGNOSIS OF NEPHROPATHY, DIABETES, URINARY INFECTION AND OTHER DISEASES (SUCH AS LIVER METABOLISM),URINE STRIP(BIOWAY)-FOR SEMI-QUANTITATIVE DETECTION IN URINE URIC BRAVERY, GLUCOSE, KETONE BODY, BILIRUBIN, ASCORBIC ACID, PROTEIN, NITRITE, PH VALUE, OCCULT BLOOD, SPECIFIC GRAVITY, WHITE BLOOD CELLS, CALCIUM, CREATININE, AND TRACE ALBUMIN PROJECT CLINICALLY, IT IS MAINLY USED FOR THE DIAGNOSIS OF NEPHROPATHY, DIABETES, URINARY INFECTION AND OTHER DISEASES (SUCH AS LIVER METABOLISM)

879	IMP/IVD/2020/000832	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EMIT TOX SERUM TRICYCLIC ANTIDEPRESSANTS ASSAY(EMIT TOX SERUM TRICYCLIC ANTIDEPRESSANTS ASSAY)-THE EMIT TOX SERUM TRICYCLIC ANTIDEPRESSANTS ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUALITATIVE ANALYSIS OF SPECIFIC TRICYCLIC ANTIDEPRESSANTS IN HUMAN SERUM OR PLASMA. THIS ASSAY IS DESIGNED FOR USE WITH MOST CHEMISTRY ANALYZERS.,EMIT ETHOSUXIMIDE ASSAY(EMIT ETHOSUXIMIDE ASSAY)-THE EMIT ETHOSUXIMIDE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF ETHOSUXIMIDE IN HUMAN SERUM OR PLASMA.,EMIT 2000 TOBRAMYCIN CALIBRATORS(EMIT 2000 TOBRAMYCIN CALIBRATORS)-THE EMIT 2000 TOBRAMYCIN CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT 2000 TOBRAMYCIN ASSAY.,EMIT TOX SERUM TRICYCLIC ANTIDEPRESSANTS CALIBRATOR/CONTROLS (EMIT TOX SERUM TRICYCLIC ANTIDEPRESSANTS CALIBRATOR/CONTROLS)-THE EMIT TOX SERUM TRICYCLIC ANTIDEPRESSANTS CALIBRATOR/CONTROLS ARE INTENDED FOR USE WITH THE EMIT TOX SERUM TRICYCLIC ANTIDEPRESSANTS ASSAY FOR THE QUALITATIVE ANALYSIS OF SPECIFIC TRICYCLIC ANTIDEPRESSANTS IN HUMAN SERUM OR PLASMA.,EMIT DISOPYRAMIDE ASSAY(EMIT DISOPYRAMIDE ASSAY)-THE EMIT DISOPYRAMIDE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF DISOPYRAMIDE IN HUMAN SERUM OR PLASMA.,EMIT 2000 QUINIDINE CALIBRATORS(EMIT 2000 QUINIDINE CALIBRATORS)-THE EMIT 2000 QUINIDINE CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT 2000 QUINIDINE ASSAY.,EMIT 2000 QUINIDINE ASSAY(EMIT 2000 QUINIDINE ASSAY)-THE EMIT 2000 QUINIDINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF QUINIDINE IN HUMAN SERUM OR PLASMA. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU CLINICAL CHEMISTRY SYSTEMS.,EMIT II PLUS CANNABINOID ASSAY(EMIT II PLUS CANNABINOID ASSAY)-THE EMIT II PLUS CANNABINOID ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 20 NG/ML, 50 NG/ML (SAMHSA INITIAL TEST CUTOFF LEVEL), OR 100 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF CANNABINOIDS IN HUMAN URINE. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON AU CLINICAL CHEMISTRY SYSTEMS.,EMIT 2000 TOBRAMYCIN ASSAY(EMIT 2000 TOBRAMYCIN ASSAY)-THE EMIT 2000 TOBRAMYCIN ASSAY IS A HOMOGENEOUS

	ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF TOBRAMYCIN IN HUMAN SERUM OR PLASMA. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU CLINICAL CHEMISTRY SYSTEMS.,EMIT ANTIEPILEPTIC DRUG CALIBRATORS(EMIT ANTIEPILEPTIC DRUG CALIBRATORS)-THE EMIT ANTIEPILEPTIC DRUG CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT ANTIEPILEPTIC DRUG ASSAYS AS A REFERENCE IN MEASURING ETHOSUXIMIDE AND PRIMIDONE CONCENTRATIONS IN HUMAN SERUM OR PLASMA.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

880	IMP/IVD/2020/000832	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EMIT 2000 VALPROIC ACID CALIBRATORS(EMIT 2000 VALPROIC ACID CALIBRATORS)-THE EMIT 2000 VALPROIC ACID CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT 2000 VALPROIC ACID ASSAY.,EMIT LSD 0 NG/ML CALIBRATOR(EMIT LSD 0 NG/ML CALIBRATOR)-THE EMIT LSD CALIBRATORS ARE FOR USE ONLY WITH THE EMIT II LSD ASSAY.,EMIT 2000 CARBAMAZEPINE ASSAY(EMIT 2000 CARBAMAZEPINE ASSAY) -THE EMIT® 2000 CARBAMAZEPINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF CARBAMAZEPINE IN HUMAN SERUM OR PLASMA. MEASUREMENTS OF CARBAMAZEPINE ARE USED AS AN AID IN MONITORING THERAPEUTIC ADMINISTRATION OF THIS DRUG. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS.,EMIT II LSD ASSAY(EMIT II LSD ASSAY)-THE EMIT II LSD ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 0.5 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF LYSERGIC ACID DIETHYLAMIDE (LSD) IN HUMAN URINE.,EMIT 2000 THEOPHYLLINE CALIBRATORS(EMIT 2000 THEOPHYLLINE CALIBRATORS)-THE EMIT ® 2000 THEOPHYLLINE CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT® 2000 THEOPHYLLINE ASSAY., EMIT 2000 PROCAINAMIDE CALIBRATORS(EMIT 2000 PROCAINAMIDE CALIBRATORS)-THE EMIT 2000 PROCAINAMIDE CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT 2000 PROCAINAMIDE ASSAY.,EMIT 2000 PHENOBARBITAL ASSAY(EMIT 2000 PHENOBARBITAL ASSAY)-THE EMIT® 2000 PHENOBARBITAL ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF PHENOBARBITAL IN HUMAN SERUM OR PLASMA. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS.,EMIT LSD 1.5 NG/ML CALIBRATOR(EMIT LSD 1.5 NG/ML CALIBRATOR)-THE EMIT LSD CALIBRATORS ARE FOR USE ONLY WITH THE EMIT® II LSD ASSAY,EMIT 2000 PHENOBARBITAL CALIBRATORS (EMIT 2000 PHENOBARBITAL CALIBRATORS)-THE EMIT 2000 PHENOBARBITAL CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT 2000 PHENOBARBITAL ASSAY.,EMIT 2000 PROCAINAMIDE ASSAY(EMIT 2000 PROCAINAMIDE ASSAY)-THE EMIT 2000 PROCAINAMIDE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF PROCAINAMIDE IN HUMAN SERUM OR PLASMA. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU®

	CLINICAL CHEMISTRY SYSTEMS.,EMIT 2000 VALPROIC ACID ASSAY (EMIT 2000 VALPROIC ACID ASSAY)-THE EMIT® 2000 VALPROIC ACID ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE ANALYSIS OF VALPROIC ACID IN HUMAN SERUM OR PLASMA. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS.,EMIT II PLUS PHENCYCLIDINE ASSAY (EMIT II PLUS PHENCYCLIDINE ASSAY)-THE EMIT II PLUS PHENCYCLIDINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 25 NG/ML CUTOFF (SAMHSA INITIAL TEST CUTOFF LEVEL). THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF PHENCYCLIDINE IN HUMAN URINE. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS. THE EMIT® II PLUS PHENCYCLIDINE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.1 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,EMIT 2000 CARBAMAZEPINE CALIBRATORS(EMIT 2000 CARBAMAZEPINE CALIBRATORS)-THE EMIT 2000 CARBAMAZEPINE CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT 2000 CARBAMAZEPINE ASSAY.,EMIT LSD CONTROL LEVEL 1(EMIT LSD CONTROL LEVEL 1)-THE EMIT LSD CONTROLS ARE INTENDED FOR USE IN VERIFYING THE CORRECT FUNCTIONING AND TO CONFIRM CALIBRATION OF THE EMIT® II LSD ASSAY.,EMIT 2000 PHENYTOIN ASSAY(EMIT 2000 PHENYTOIN ASSAY)-THE EMIT® 2000 PHENYTOIN ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF PHENYTOIN IN HUMAN SERUM OR PLASMA. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS.,EMIT AMIKACIN ASSAY(EMIT AMIKACIN ASSAY)-THE EMIT AMIKACIN ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF AMIKACIN IN HUMAN SERUM OR PLASMA.,EMIT 2000 THEOPHYLLINE ASSAY(EMIT 2000 THEOPHYLLINE ASSAY)-THE EMIT® 2000 THEOPHYLLINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF THEOPHYLLINE IN HUMAN SERUM OR PLASMA. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY

	SYSTEMS.,EMIT LSD CONTROL LEVEL 2(EMIT LSD CONTROL LEVEL 2)-THE EMIT LSD CONTROLS ARE INTENDED FOR USE IN VERIFYING THE CORRECT FUNCTIONING AND TO CONFIRM CALIBRATION OF THE EMIT® II LSD ASSAY.,EMIT 2000 PHENYTOIN CALIBRATORS(EMIT 2000 PHENYTOIN CALIBRATORS)-THE EMIT® 2000 PHENYTOIN CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT® 2000 PHENYTOIN ASSAY.,EMIT LIDOCAINE ASSAY(EMIT LIDOCAINE ASSAY) -THE EMIT LIDOCAINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF LIDOCAINE IN HUMAN SERUM OR PLASMA.,EMIT CALIBRATOR/CONTROL LEVEL 1(EMIT CALIBRATOR/CONTROL LEVEL 1)-THE EMIT® CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS AMPHETAMINES, BARBITURATE, BENZODIAZEPINE, CANNABINOID, COCAINE METABOLITE, ECSTASY, METHADONE, METHAQUALONE, MONOCLONAL AMPHETAMINE/METHAMPHETAMINE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE ASSAYS. THESE STANDARDS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED UPON SPECIFIED ASSAY CUTOFF LEVELS FOR THE EMIT® II PLUS DRUGS-OF-ABUSE ASSAYS., EMIT LSD 0.5 NG/ML CALIBRATOR(EMIT LSD 0.5 NG/ML CALIBRATOR) -THE EMIT LSD CALIBRATORS ARE FOR USE ONLY WITH THE EMIT® II LSD ASSAY,EMIT® 2000 N-ACETYLPROCAINAMIDE CALIBRATORS (EMIT® 2000 N-ACETYLPROCAINAMIDE CALIBRATORS)-THE EMIT® 2000 N-ACETYLPROCAINAMIDE CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT® 2000 N-ACETYLPROCAINAMIDE ASSAY.,EMIT LSD 2.5 NG/ML CALIBRATOR(EMIT LSD 2.5 NG/ML CALIBRATOR)-THE EMIT LSD CALIBRATORS ARE FOR USE ONLY WITH THE EMIT® II LSD ASSAY,EMIT II PLUS BARBITURATE ASSAY(EMIT II PLUS BARBITURATE ASSAY)-THE EMIT® II PLUS BARBITURATE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 200 NG/ML OR 300 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF BARBITURATES IN HUMAN URINE. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS. THE EMIT ® II PLUS BARBITURATE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.1 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED., EMIT METHOTREXATE ASSAY(EMIT METHOTREXATE

	ASSAY)-THE EMIT METHOTREXATE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF METHOTREXATE IN HUMAN SERUM OR PLASMA.,EMIT CALIBRATOR/CONTROL LEVEL 5(EMIT CALIBRATOR/CONTROL LEVEL 5)-THE EMIT® CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS AMPHETAMINES, BARBITURATE, BENZODIAZEPINE, CANNABINOID, COCAINE METABOLITE, ECSTASY, METHADONE, METHAQUALONE, MONOCLONAL AMPHETAMINE/METHAMPHETAMINE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE ASSAYS. THESE STANDARDS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED UPON SPECIFIED ASSAY CUTOFF LEVELS FOR THE EMIT® II PLUS DRUGS-OF-ABUSE ASSAYS., EMIT II PLUS AMPHETAMINES ASSAY(EMIT II PLUS AMPHETAMINES ASSAY)-THE EMIT® II PLUS AMPHETAMINES ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 300 NG/ML, 500 NG/ML (SAMHSA INITIAL TEST CUTOFF LEVEL) OR 1000 NG/ML CUTOFF.1 THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMI-QUANTITATIVE ANALYSES OF AMPHETAMINES IN HUMAN URINE. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS. THE EMIT ® II PLUS AMPHETAMINES ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.2 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,EMIT ETHYL ALCOHOL 100 MG/DL CALIBRATOR(EMIT ETHYL ALCOHOL 100 MG/DL CALIBRATOR)-THE EMIT® ETHYL ALCOHOL CALIBRATORS AND CONTROLS ARE FOR USE WITH THE EMIT® ETHYL ALCOHOL ASSAYS.,EMIT II PLUS ETHYL ALCOHOL ASSAY(EMIT II PLUS ETHYL ALCOHOL ASSAY)-THE EMIT® II PLUS ETHYL ALCOHOL ASSAY IS INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF ETHYL ALCOHOL (ETHANOL) IN HUMAN URINE, SERUM, OR PLASMA. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS,EMIT TOX™ SERUM BENZODIAZEPINE ASSAY(EMIT TOX™ SERUM BENZODIAZEPINE ASSAY)-THE EMIT® TOX™ SERUM BENZODIAZEPINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSIS OF SPECIFIC BENZODIAZEPINES IN HUMAN SERUM OR PLASMA. THIS ASSAY IS DESIGNED FOR USE WITH

	MOST CHEMISTRY ANALYZERS. THE EMIT® TOX™ SERUM BENZODIAZEPINE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,EMIT TOX™ SERUM CALIBRATORS(EMIT TOX™ SERUM CALIBRATORS)-THE EMIT® TOX™ SERUM CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT® TOX™ SERUM BARBITURATE AND BENZODIAZEPINE ASSAYS AS A REFERENCE FOR THE SEMIQUANTITATIVE ANALYSIS OF BARBITURATES AND BENZODIAZEPINES IN HUMAN SERUM,EMIT TOX™ SERUM BARBITURATE ASSAY(EMIT TOX™ SERUM BARBITURATE ASSAY)-THE EMIT® TOX™ SERUM BARBITURATE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSIS OF SPECIFIC BARBITURATES IN HUMAN SERUM OR PLASMA. THIS ASSAY IS DESIGNED FOR USE WITH MOST CHEMISTRY ANALYZERS. THE EMIT® TOX™ SERUM BARBITURATE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG OF ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,EMIT ETHYL ALCOHOL HIGH CONTROL(EMIT ETHYL ALCOHOL HIGH CONTROL)-THE EMIT® ETHYL ALCOHOL CALIBRATORS AND CONTROLS ARE FOR USE WITH THE EMIT® ETHYL ALCOHOL ASSAYS.,EMIT II PLUS PROPOXYPHENE ASSAY(EMIT II PLUS PROPOXYPHENE ASSAY)-THE EMIT® II PLUS PROPOXYPHENE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 300 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF PROPOXYPHENE IN HUMAN URINE. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS. THE EMIT® II PLUS PROPOXYPHENE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS

	CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,EMIT II PLUS METHAQUALONE ASSAY(EMIT II PLUS METHAQUALONE ASSAY)-THE EMIT II PLUS METHAQUALONE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 300 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF METHAQUALONE IN HUMAN URINE. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS. THE EMIT ® II PLUS METHAQUALONE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD. OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,EMIT ETHYL ALCOHOL LOW CONTROL(EMIT ETHYL ALCOHOL LOW CONTROL)-THE EMIT® ETHYL ALCOHOL CALIBRATORS AND CONTROLS ARE FOR USE WITH THE EMIT® ETHYL ALCOHOL ASSAYS,EMIT CALIBRATOR/CONTROL LEVEL 4(EMIT CALIBRATOR/CONTROL LEVEL 4)-THE EMIT® CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS AMPHETAMINES, BARBITURATE, BENZODIAZEPINE, CANNABINOID, COCAINE METABOLITE, ECSTASY, METHADONE, METHAQUALONE, MONOCLONAL AMPHETAMINE/METHAMPHETAMINE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE ASSAYS. THESE STANDARDS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED UPON SPECIFIED ASSAY CUTOFF LEVELS FOR THE EMIT® II PLUS DRUGS-OF-ABUSE ASSAYS., EMIT II PLUS OPIATE ASSAY(EMIT II PLUS OPIATE ASSAY)-THE EMIT® II PLUS OPIATE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 300 NG/ML OR 2000 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF OPIATES IN HUMAN URINE. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS. THE EMIT® II PLUS OPIATE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS

	SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.1 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,EMIT® 2000 N-ACETYLPROCAINAMIDE ASSAY(EMIT® 2000 N-ACETYLPROCAINAMIDE ASSAY)-THE EMIT® 2000 N-ACETYLPROCAINAMIDE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF N-ACETYLPROCAINAMIDE IN HUMAN SERUM OR PLASMA. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS.,EMIT ETHYL ALCOHOL NEGATIVE CALIBRATOR(EMIT ETHYL ALCOHOL NEGATIVE CALIBRATOR)-THE EMIT® ETHYL ALCOHOL CALIBRATORS AND CONTROLS ARE FOR USE WITH THE EMIT® ETHYL ALCOHOL ASSAYS., EMIT® 2000 GENTAMICIN PLUS ASSAY(EMIT® 2000 GENTAMICIN PLUS ASSAY)-THE EMIT® 2000 GENTAMICIN PLUS ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF GENTAMICIN IN HUMAN SERUM OR PLASMA. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS. MEASUREMENTS OBTAINED FROM THIS DEVICE ARE USED IN THE DIAGNOSIS AND TREATMENT OF GENTAMICIN OVERDOSE AND IN MONITORING LEVELS OF GENTAMICIN TO ASSURE APPROPRIATE THERAPY.,EMIT® TOX SALICYLIC ACID CALIBRATORS(EMIT® TOX SALICYLIC ACID CALIBRATORS)-THE EMIT® TOX ™ SALICYLIC ACID CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT® TOX™ SALICYLIC ACID ASSAY.,EMIT® TOX SALICYLIC ACID ASSAY(EMIT® TOX SALICYLIC ACID ASSAY)-THE EMIT® TOX™ SALICYLIC ACID ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF SALICYLIC ACID IN HUMAN SERUM OR PLASMA. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS.,EMIT® TOX ACETAMINOPHEN ASSAY(EMIT® TOX ACETAMINOPHEN ASSAY)-THE EMIT® TOX™ ACETAMINOPHEN ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF ACETAMINOPHEN IN HUMAN SERUM OR PLASMA. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS.,EMIT® 2000 GENTAMICIN CALIBRATORS(EMIT® 2000 GENTAMICIN CALIBRATORS)-THE EMIT® 2000 GENTAMICIN PLUS CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT® 2000 GENTAMICIN PLUS ASSAY.,EMIT® TOX ACETAMINOPHEN CALIBRATORS(EMIT® TOX ACETAMINOPHEN CALIBRATORS)-THE

	EMIT® TOX™ ACETAMINOPHEN CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT® TOX™ ACETAMINOPHEN ASSAY.,EMIT® 2000 VANCOMYCIN CALIBRATORS(EMIT® 2000 VANCOMYCIN CALIBRATORS)-THE EMIT® 2000 VANCOMYCIN CALIBRATORS ARE INTENDED FOR USE WITH THE EMIT® 2000 VANCOMYCIN ASSAY, AS A REFERENCE FOR USE IN DETERMINING VANCOMYCIN LEVELS IN HUMAN SERUM OR PLASMA.,EMIT CALIBRATOR/CONTROL LEVEL 0 (EMIT CALIBRATOR/CONTROL LEVEL 0)-THE EMIT® CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS AMPHETAMINES, BARBITURATE, BENZODIAZEPINE, CANNABINOID, COCAINE METABOLITE, ECSTASY, METHADONE, METHAQUALONE, MONOCLONAL AMPHETAMINE/METHAMPHETAMINE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE ASSAYS. THESE STANDARDS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED UPON SPECIFIED ASSAY CUTOFF LEVELS FOR THE EMIT® II PLUS DRUGS-OF-ABUSE ASSAYS., EMIT II PLUS BENZODIAZEPINE ASSAY(EMIT II PLUS BENZODIAZEPINE ASSAY)-THE EMIT ® II PLUS BENZODIAZEPINE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 200 NG/ML OR 300 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF BENZODIAZEPINES IN HUMAN URINE. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS. THE EMIT ® II PLUS BENZODIAZEPINE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.1 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,EMIT® 2000 VANCOMYCIN ASSAY(EMIT® 2000 VANCOMYCIN ASSAY)-THE EMIT® 2000 VANCOMYCIN ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY INTENDED FOR USE IN THE QUANTITATIVE ANALYSIS OF VANCOMYCIN IN HUMAN SERUM OR PLASMA. MEASUREMENTS OBTAINED BY THIS ASSAY ARE USED IN THE DIAGNOSIS AND TREATMENT OF VANCOMYCIN OVERDOSE AND IN MONITORING THE LEVEL OF VANCOMYCIN TO ENSURE APPROPRIATE THERAPY.,EMIT II PLUS COCAINE METABOLITE ASSAY(EMIT II PLUS COCAINE METABOLITE ASSAY)-THE EMIT® II PLUS COCAINE METABOLITE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 150 NG/ML OR 300 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN

	THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF BENZOYLECGONINE (COCAINE METABOLITE) IN HUMAN URINE. EMIT® II PLUS ASSAYS ARE DESIGNED FOR USE WITH A NUMBER OF CHEMISTRY ANALYZERS. THE EMIT® II PLUS COCAINE METABOLITE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.1 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,EMIT II PLUS METHADONE ASSAY(EMIT II PLUS METHADONE ASSAY)-THE EMIT® II PLUS METHADONE ASSAY IS A HOMOGENEOUS ENZYME IMMUNOASSAY WITH A 150 NG/ML OR 300 NG/ML CUTOFF. THE ASSAY IS INTENDED FOR USE IN THE QUALITATIVE AND SEMIQUANTITATIVE ANALYSES OF METHADONE IN HUMAN URINE. THESE REAGENTS ARE PACKAGED SPECIFICALLY FOR USE ON A VARIETY OF AU® CLINICAL CHEMISTRY SYSTEMS. THE EMIT ® II PLUS METHADONE ASSAY PROVIDES ONLY A PRELIMINARY ANALYTICAL TEST RESULT. A MORE SPECIFIC ALTERNATIVE CHEMICAL METHOD MUST BE USED TO OBTAIN A CONFIRMED ANALYTICAL RESULT. GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS) IS THE PREFERRED CONFIRMATORY METHOD.1 OTHER CHEMICAL CONFIRMATION METHODS ARE AVAILABLE. CLINICAL CONSIDERATION AND PROFESSIONAL JUDGMENT SHOULD BE APPLIED TO ANY DRUG-OF-ABUSE TEST RESULT, PARTICULARLY WHEN PRELIMINARY POSITIVE RESULTS ARE USED.,EMIT CALIBRATOR/CONTROL LEVEL 3(EMIT CALIBRATOR/CONTROL LEVEL 3)-THE EMIT® CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS AMPHETAMINES, BARBITURATE, BENZODIAZEPINE, CANNABINOID, COCAINE METABOLITE, ECSTASY, METHADONE, METHAQUALONE, MONOCLONAL AMPHETAMINE/METHAMPHETAMINE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE ASSAYS. THESE STANDARDS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED UPON SPECIFIED ASSAY CUTOFF LEVELS FOR THE EMIT® II PLUS DRUGS-OF-ABUSE ASSAYS., EMIT CALIBRATOR/CONTROL LEVEL 2(EMIT CALIBRATOR/CONTROL LEVEL 2)-THE EMIT® CALIBRATORS/CONTROLS ARE USED IN THE CALIBRATION OF THE EMIT® II PLUS AMPHETAMINES, BARBITURATE, BENZODIAZEPINE, CANNABINOID, COCAINE METABOLITE, ECSTASY, METHADONE, METHAQUALONE, MONOCLONAL

	AMPHETAMINE/METHAMPHETAMINE, OPIATES, PHENCYCLIDINE, AND PROPOXYPHENE ASSAYS. THESE STANDARDS MAY ALSO BE USED AS QUALITY CONTROL MATERIALS BASED UPON SPECIFIED ASSAY CUTOFF LEVELS FOR THE EMIT® II PLUS DRUGS-OF-ABUSE ASSAYS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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881	IMP/IVD/2020/000833	1.License Holder Name: IMMUNOSHOP INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FREE TESTOSTERONE ELISA(DIASOURCE)-"FOR THE DIRECT QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE BY ENZYME IMMUNOASSAY IN HUMAN SERUM." ,DHT ELISA(DIASOURCE)-"FOR THE DIRECT QUANTITATIVE DETERMINATION OF DIHYDROTESTOSTERONE BY ENZYME IMMUNOASSAY IN HUMAN SERUM." ,DHEA ELISA(DIASOURCE)-"FOR THE DIRECT QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE (DHEA) IN HUMAN SERUM BY AN ENZYME IMMUNOASSAY." ,25OH VITAMIN D TOTAL ELISA(DIASOURCE)-IMMUNOENZYMETRIC ASSAY FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF 25-HYDROXYVITAMIN D2 AND D3 (25OH-D2 AND 25OH-D3) IN SERUM.,IL-6-ELISA(DIASOURCE)-"IMMUNOENZYMETRIC ASSAY FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF HUMAN INTERLEUKIN-6 (IL-6) IN SERUM.",17-A-OH PROGESTERONE ELISA(DIASOURCE)-"THE DIASOURCE 17-OH PROGESTERONE ENZYME IMMUNOASSAY KIT PROVIDES MATERIALS FOR THE QUANTITATIVE DETERMINATION OF 17--OH PROGESTERONE IN SERUM OR PLASMA (EDTA-, HEPARIN- OR CITRATE PLASMA).",METANEPHRINE URINE ELISA FAST TRACK (DIASOURCE)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF METANEPHRINE IN URINE,TNF--ELISA (DIASOURCE)-IMMUNOENZYMETRIC ASSAY FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF HUMAN TUMOR NECROSIS FACTOR (TNF-) IN SERUM.,QUANTITATIVE FECAL CALPROTECTIN ELISA(DIASOURCE)-"THIS TEST KIT IS INTENDED FOR USE IN THE QUANTITATIVE DETERMINATION OF HUMAN CALPROTECTIN (NEUTROPHIL CYTOPLASMIC PROTEIN S100A8/A9) LEVELS IN STOOL SAMPLES. THE TEST IS USEFUL FOR DETECTING INFLAMMATORY BOWEL DISEASE (IBD) SUCH AS ULCERATIVE COLITIS AND CROHN'S DISEASE.",CORTISOL ELISA(DIASOURCE)-"FOR THE DIRECT QUANTITATIVE DETERMINATION OF CORTISOL BY ENZYME IMMUNOASSAY IN HUMAN SERUM.",DIASPOT MULTIQUANT NEPTUNE ANA25 SCREEN IGG(DIASOURCE)-"DIASPOT MULTIQUANT NEPTUNE ANA25 SCREEN IGG IS AN IMMUNODOT KIT INTENDED FOR THE DETECTION IN HUMAN SERA OF IGG AUTOANTIBODIES AGAINST NUCLEOSOME, DSDNA, HISTONES, SM, RNP (68KD/A/C), SM/RNP, SSA/RO 60KD, SSA/RO 52KD, SSB, SCL-70, KU, PM-SCL 100, MI-2, JO-1, PL-7, PL-12, SRP, RIBOSOMES, CENP-A/B, PCNA, SP100, GP210, M2 RECOMBINANT, M2/NPDC AND F-ACTIN ANTIGENS.",1,25(OH)2 VITAMIN D ELISA(DIASOURCE)-IMMUNOENZYMETRIC ASSAY FOR THE IN VITRO QUANTITATIVE MEASUREMENT OF 1,25(OH)2 VITAMIN D IN SERUM.

882	IMP/IVD/2020/000835	1.License Holder Name: BIO SCIENCE SALES CORPORATION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ONLYONE(ONLYONE)-LYSING AGENT TO OBTAIN THE MEASUREMENT OF THE HAEMOGLOBIN,COUNTING AND DIFFERENTIATION OF THE WHITE BLOOD CELLS.

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883	IMP/IVD/2020/000837	1.License Holder Name: HORIBA INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABX PENTRA FERRITIN 2 CP(HORIBA MEDICAL)-ABX PENTRA FERRITIN 2 CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF FERRITIN IN SERUM AND PLASMA BY LATEX-ENHANCED IMMUNOTURBIDIMETRIC ASSAY. ,ABX PENTRA ASO 2 CAL (HORIBA MEDICAL)-ABX PENTRA ASO 2 CAL IS USED TO CALIBRATE ABX PENTRA ASO 2 CP, REF. 1300022598. ,ABX PENTRA LOW CRP CONTROL(HORIBA MEDICAL)-ABX PENTRA LOW CRP CONTROL IS A QUALITY CONTROL USED TO MONITOR THE PERFORMANCE OF ABX PENTRA CRP CP (HIGH SENSITIVE METHOD), REF.A11A01611 DETERMINATION AT LOW CONCENTRATION BY LATEX-ENHANCED IMMUNOTURBIDIMETRIC ASSAY. ,ABX PENTRA RF CP(HORIBA MEDICAL)-THE RHEUMATOID FACTOR ASSAY IS USED FOR THE QUANTITATION OF RHEUMATOID FACTOR IN HUMAN SERUM. MEASUREMENT OF RHEUMATOID FACTOR MAY AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS. ,ABX PENTRA FERRITIN CAL (HORIBA MEDICAL)-"ABX PENTRA FERRITIN CAL IS USED FOR THE CALIBRATION OF METHODS ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS WITH THE FOLLOWING REAGENT(S): ABX PENTRA FERRITIN 2 CP (A11A01900) " ,ABX PENTRA MYOGLOBIN CAL (HORIBA MEDICAL)-ABX PENTRA MYOGLOBIN CAL IS USED TO CALIBRATE ABX PENTRA MYOGLOBIN 2 CP, REF. A11A01904. ,ABX PENTRA MYOGLOBIN 2 CP(HORIBA MEDICAL)-ABX PENTRA MYOGLOBIN 2 CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF MYOGLOBIN IN SERUM PLASMA BY LATEX-ENHANCED IMMUNOTURBIDIMETRIC ASSAY. ,ABX PENTRA ASO 2 CP(HORIBA MEDICAL)-"ABX PENTRA ASO 2 CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ANTI-STREPTOLYSIN O (ASO) IN SERUM AND PLASMA BY LATEXENHANCED IMMUNOTURBIDIMETRIC ASSAY. THE IDENTIFICATION AIDS IN THE DIAGNOSIS OF DISEASE CAUSED BY BACTERIA BELONGING TO THE GENUS STREPTOCOCCUS AND PROVIDES EPIDEMIOLOGICAL INFORMATION ON THESE DISEASES. PATHOGENIC STREPTOCOCCI ARE ASSOCIATED WITH INFECTIONS, SUCH AS SORE THROAT, IMPETIGO (AN INFECTION CHARACTERIZED BY SMALL PUSTULES ON THE SKIN), URINARY TRACT INFECTIONS, RHEUMATIC FEVER, AND KIDNEY DISEASE.,ABX PENTRA RF CAL(HORIBA MEDICAL)-"ABX PENTRA RF CAL IS USED FOR THE CALIBRATION OF METHODS ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS WITH THE FOLLOWING REAGENT(S): ABX PENTRA RF CP (A11A01613) " ,ABX PENTRA CRP CAL(HORIBA MEDICAL)-ABX PENTRA CRP CAL IS USED TO CALIBRATE ABX

		PENTRA CRP CP, REF. A11A01611. ,ABX PENTRA IMMUNO II CONTROL L/ H(HORIBA MEDICAL)-"THE ABX PENTRA IMMUNO II CONTROL L/H IS FOR USE IN QUALITY CONTROL BY MONITORING ACCURACY AND PRECISION OF HORIBA MEDICAL METHODS (BY IMMUNOTURBIDIMETRY) ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS WITH THE FOLLOWING REAGENTS: ABX PENTRA FERRITIN 2 CP (A11A01900) ABX PENTRA MYOGLOBIN 2 CP (A11A01904) " ,ABX PENTRA IMMUNO I CONTROL L/ H(HORIBA MEDICAL)-"ABX PENTRA IMMUNO I CONTROL L/H IS A QUALITY CONTROL USED TO MONITOR BY TURBIDIMETRY THE PERFORMANCE OF: ABX PENTRA ASO 2 CP, REF.1300022598 ABX PENTRA CRP CP, REF.A11A01611 ABX PENTRA RF CP, REF.A11A01613 " ,ABX PENTRA CRP CP(HORIBA MEDICAL)-ABX PENTRA CRP CP REAGENT IS INTENDED FOR USE FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF THE C-REACTIVE PROTEIN IN HUMAN SERUM AND PLASMA BASED ON AN IMMUNOTURBIDIMETRIC ASSAY. MEASUREMENT OF C-REACTIVE PROTEIN AIDS IN EVALUATION OF INJURY TO BODY TISSUE.,ABX PENTRA CRP HS CAL(HORIBA MEDICAL)-ABX PENTRA CRP HS CAL IS USED TO CALIBRATE ABX PENTRA CRP CP (HIGH SENSITIVE METHOD), REF. A11A01611.
884	IMP/IVD/2020/000838	1.License Holder Name: SYSMEX INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REVOHEM EPINEPHRINE (REVOHEM EPINEPHRINE)-FOR IN-VITRO DIAGNOSTIC USE MEASUREMENT OF PLATELET AGGREGATION,REVOHEM ADP (REVOHEM ADP)-FOR IN-VITRO DIAGNOSTIC USE MEASUREMENT OF PLATELET AGGREGATION,REVOHEM RISTOCETIN(REVOHEM RISTOCETIN)-FOR IN-VITRO DIAGNOSTIC USE MEASUREMENT OF PLATELET AGGREGATION,REVOHEM ARACHIDONIC ACID(REVOHEM ARACHIDONIC ACID)-FOR IN-VITRO DIAGNOSTIC USE MEASUREMENT OF PLATELET AGGREGATION,REVOHEM COLLAGEN(REVOHEM COLLAGEN)-FOR IN-VITRO DIAGNOSTIC USE MEASUREMENT OF PLATELET AGGREGATION

885	IMP/IVD/2020/000839	1.License Holder Name: VEDAS HEALTHCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIRECT BILIRUBIN (D-BIL) (BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN (D-BIL) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,CREATINE KINASE-MB (CK-MB)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE-MB (CK-MB) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY,ADENOSINE DEAMINASE (ADA)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF ADENOSINE DEAMINASE (ADA) ACTIVITY IN HUMAN SERUM OR PLASMA SAMPLES. FOR IN VITRO DIAGNOSTIC USE ONLY., COMPLEMENT 3 (C3)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT 3 (C3) IN HUMAN SERUM OR PLASMA SAMPLES. FOR IN VITRO DIAGNOSTIC USE ONLY., IRON (FE)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF IRON (FE) IN HUMAN SERUM OR PLASMA FOR IN VITRO DIAGNOSTIC USE ONLY.,NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN (NGAL)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF NEUTROPHIL GELATINASE ASSOCIATED LIPOCALIN (NGAL) IN HUMAN URINE OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,BICARBONATE (CO2)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF BICARBONATE (CO2) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,ALBUMIN (ALB)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN (ALB) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,TOTAL PROTEIN (TP)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN (TP) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,1,5-ANHYDROGLUCITOL (1,5-AG)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF 1,5-ANHYDROGLUCITOL (1,5-AG) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,CHOLESTEROL (CHO)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL (CHO) IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,CREATININE (CRE)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CREATININE (CRE) IN HUMAN SERUM, PLASMA OR URINE. FOR IN VITRO DIAGNOSTIC USE ONLY.,URIC ACID (UA)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF URIC ACID (UA) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,CREATINE KINASE-NAC (CK-NAC)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE-NAC (CK-NAC) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,D-DIMER (D-D) (BSBE

	(GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF D-DIMER (D-D) IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,C-REACTIVE PROTEIN (CRP)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,CYSTATIN C (CYS C) (BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CYSTATIN C (CYS C) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,COMPLEMENT 4 (C4)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT 4 (C4) IN HUMAN SERUM OR PLASMA SAMPLES. FOR IN VITRO DIAGNOSTIC USE ONLY., ALANINE AMINOTRANSFERASE (ALT) / GLUTAMATE PYRUVATE TRANSAMINASE (GPT)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE (ALT) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY., FRUCTOSAMINE (FRUC)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF FRUCTOSAMINE (FRUC) IN HUMAN SERUM FOR IN VITRO DIAGNOSTIC USE ONLY.,LACTATE (LAC) (BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF LACTATE (LAC) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,ALPHA-AMYLASE (AMY)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF ALPHA– AMYLASE IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,D-3-HYDROXYBUTYRATE (-HB) (BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF D-3-HYDROXYBUTYRATE (-HB) IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,ALKALINE PHOSPHATASE (ALP)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE (ALP) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,UREA (UREA)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF UREA (UREA) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,CALCIUM (CA)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CALCIUM (CA) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,LIPASE (LPS)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF LIPASE (LPS) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,COPPER (CU) (BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF COPPER (CU) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G-6-PD) (BSBE (GCELL))-REAGENT

	FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G-6-PD) IN HUMAN BLOOD. FOR IN VITRO DIAGNOSTIC USE ONLY.,GLUTAMATE OXALOACETATE TRANSAMINASE (GOT) / ASPARTATE AMINOTRANSFERASE (AST) (BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF GLUTAMATE OXALOACETATE TRANSAMINASE (GOT/AST) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,TOTAL BILE ACID (TBA) (BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILE ACID (TBA) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,TRIGLYCERIDES (TG) (BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES (TG) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,HOMOCYSTEINE (HCY)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF HOMOCYSTEINE (HCY) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,MAGNESIUM (MG)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM (MG) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,HEMOGLOBIN A1C (HBA1C)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C)/ TOTAL HEMOGLOBIN RATIO (%) IN HUMAN BLOOD FOR IN VITRO DIAGNOSTIC USE ONLY.,ANGIOTENSIN CONVERTING ENZYME (ACE) (BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF ANGIOTENSIN CONVERTING ENZYME (ACE) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,ZINC (ZN) (BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF ZINC (ZN) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY., MICROALBUMIN (MALB)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF MICROALBUMIN (MALB) IN HUMAN URINE SAMPLES. FOR IN VITRO DIAGNOSTIC USE ONLY., CHOLINESTERASE (CHE) (BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CHOLINESTERASE (CHE) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY,HIGH DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,APOLIPOPROTEIN B (APO-B)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN B (APO-B) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY., GLYCATED ALBUMIN (GA)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF GLYCATED ALBUMIN (GA) IN HUMAN SERUM AND PLASMA OR IN VITRO DIAGNOSTIC USE ONLY., GAMMA-GLUTAMYL TRANSFERASE (-GT/GGT)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF GAMMA-

	GLUTAMYL TRANSFERASE (GAMMA-GT/GGT) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,RHEUMATOID FACTOR (RF)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,INORGANIC PHOSPHORUS (IP) (BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHORUS (IP) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,TOTAL BILIRUBIN (T-BIL) (BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN (T-BIL) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,LIPOPROTEIN (A) (LP(A))(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN (A) (LP(A)) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY., LACTATE DEHYDROGENASE-L (LDH)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE-L (LDH) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,APOLIPOPROTEIN A1 (APO-A1)(BSBE (GCELL))-REAGENT FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A1 (APO-A1) IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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886	IMP/IVD/2020/000840	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ID NOW STREP A 2(ID NOW STREP A 2)-ID NOW™ STREP A 2 IS A RAPID, INSTRUMENT-BASED, MOLECULAR IN VITRO DIAGNOSTIC TEST UTILIZING ISOTHERMAL NUCLEIC ACID AMPLIFICATION TECHNOLOGY FOR THE QUALITATIVE DETECTION OF STREPTOCOCCUS PYOGENES, GROUP A STREPTOCOCCUS BACTERIAL NUCLEIC ACID IN THROAT SWAB SPECIMENS OBTAINED FROM PATIENTS WITH SIGNS AND SYMPTOMS OF PHARYNGITIS. IT IS INTENDED TO AID IN THE RAPID DIAGNOSIS OF GROUP A STREPTOCOCCUS BACTERIAL INFECTIONS.,ID NOW COVID-19(ID NOW™ COVID-19)-IT IS A RAPID MOLECULAR IN VITRO DIAGNOSTIC TEST UTILIZING AN ISOTHERMAL NUCLEIC ACID AMPLIFICATION TECHNOLOGY INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 VIRAL RNA IN DIRECT NASAL, NASOPHARYNGEAL OR THROAT SWABS FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. WITHIN THE FIRST SEVEN DAYS OF THE ONSET OF SYMPTOMS.,ID NOW RSV(ID NOW RSV)-THE ID NOW™ RSV ASSAY PERFORMED ON THE ID NOW INSTRUMENT IS A RAPID MOLECULAR IN VITRO DIAGNOSTIC TEST UTILIZING AN ISOTHERMAL NUCLEIC ACID AMPLIFICATION TECHNOLOGY FOR THE QUALITATIVE DETECTION OF RESPIRATORY SYNCYTIAL VIRUS (RSV) VIRAL RNA IN DIRECT NASOPHARYNGEAL SWABS AND NASOPHARYNGEAL SWABS ELUTED IN VIRAL TRANSPORT MEDIA FROM PATIENTS WITH SIGNS AND SYMPTOMS OF RESPIRATORY INFECTION. IT IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF RSV IN CHILDREN,ID NOW COVID-19 CONTROL SWAB KIT(ID NOW COVID-19 CONTROL SWAB KIT) -CONTROL SWABS INTENDED FOR USE ONLY WITH ID NOW COVID-19 PRODUCT. REFER TO THE ID NOW COVID-19 PRODUCT INSERT FOR INSTRUCTION FOR USE

887	IMP/IVD/2020/000841	1.License Holder Name: IMMUNOSHOP INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 IGG/IGM RAPID TEST CASSETTE(SIENNA)-NOVEL CORONAVIRUS(2019-NCOV) NUCLEIC ACID DIAGNOSTIC KIT (PCR-FLUORESCENCE PROBING) IS USED FOR QUALITATIVE DETECTION OF THE ORF1AB AND N GENES OF NOVEL CORONAVIRUS (2019-NCOV) IN NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, ALVEOLAR LAVAGE FLUID, SPUTUM, SERUM, WHOLE BLOOD, FECES FROM SUSPECTED PNEUMONIA CASES WITH NOVEL CORONAVIRUS INFECTION, IN PATIENTS WITH SUSPECTED CLUSTERS OF NOVEL CORONAVIRUS INFECTION, AND OTHER PATIENTS REQUIRING DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS OF NOVEL CORONAVIRUS INFECTION.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

888	IMP/IVD/2020/000842	1.License Holder Name: WELDON BIOTECH INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 IGM (COVID-19 IGM)-THE PRODUCT IS INTENDED FOR THE DETERMINATION IGM ANTIBODIES TO COVID19 IN HUMAN PLASMA AND SERA. THE KIT IS INTENDED FOR THE MONITORING OF THE IMMUNE RESPONSE TO COVID-19, IN THE EARLY STAGE OF THE INFECTION AS ITS MARKER IN ADDITION TO PCR,HSV1&2 IGG(HSV1&2 IGG)-"ENZYME IMMUNOASSAY (ELISA) FOR THE QUANTITATIVE/QUALITATIVE DETERMINATION OF IGG ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE 1 AND 2 IN HUMAN SERUM AND PLASMA.",HSV2 IGG(HSV2 IGG)-ENZYME IMMUNOASSAY (ELISA) FOR THE QUANTITATIVE/QUALITATIVE DETERMINATION OF IGG ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE 2 IN HUMAN SERUM AND PLASMA., HSV1 IGG(HSV1 IGG)-ENZYME IMMUNOASSAY (ELISA) FOR THE QUANTITATIVE/QUALITATIVE DETERMINATION OF IGG ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE 1 IN HUMAN SERUM AND PLASMA., HTLV I&II AB VERSION ULTRA(HTLV I&II AB VERSION ULTRA)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO HUMAN T-CELL LYMPHOTROPIC VIRUS TYPE I&II IN SERUM AND PLASMA.,TOXO IGG(TOXO IGG)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE/QUALITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,RUB IGG(RUB IGG)-ENZYME IMMUNOASSAY (ELISA) FOR THE QUANTITATIVE/QUALITATIVE DETERMINATION OF IGG ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM AND PLASMA., HSV1&2 IGM(HSV1&2 IGM)-“CAPTURE” ENZYME IMMUNO ASSAY (ELISA) FOR THE DETERMINATION OF IGM ANTIBODIES TO HERPES SIMPLEX VIRUS TYPES 1&2 IN HUMAN PLASMA AND SERA.,CHIKV IGM (CHIKV IGM)-ENZYME IMMUNOASSAY (ELISA) FOR THE QUANTITATIVE/QUALITATIVE DETERMINATION OF IGM ANTIBODIES TO CHIK VIRUS IN HUMAN SERUM AND PLASMA.,HEV IGM(HEV IGM)-ENZYME IMMUNOASSAY (ELISA) FOR THE DETERMINATION OF IGM ANTIBODIES TO HEPATITIS E VIRUS IN HUMAN SERUM AND PLASMA, TOXO IGM(TOXO IGM)-“CAPTURE” ENZYME IMMUNO ASSAY (ELISA) FOR THE DETERMINATION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN PLASMA AND SERA.,CMV IGM(CMV IGM)-“CAPTURE” ENZYME IMMUNO ASSAY (ELISA) FOR THE DETERMINATION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN PLASMA AND SERA.,HSV2 IGM(HSV2 IGM)-“CAPTURE” ENZYME IMMUNO ASSAY (ELISA) FOR THE DETERMINATION OF IGM ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE 2 IN HUMAN PLASMA AND SERA.,HSV1 IGM(HSV1 IGM)-“CAPTURE” ENZYME IMMUNO ASSAY (ELISA) FOR THE DETERMINATION OF IGM ANTIBODIE TO HERPES

	SIMPLEX VIRUS TYPE 1 IN HUMAN PLASMA AND SERA.,HDV IGM(HDV IGM)-“CAPTURE” ENZYME IMMUNOASSAY (ELISA) FOR THE DETERMINATION OF IGM ANTIBODIES TO HEPATITIS DELTA VIRUS IN HUMAN PLASMA AND SERA.,RUB IGM(RUB IGM)-“CAPTURE” ENZYME IMMUNO ASSAY (ELISA) FOR THE DETERMINATION OF IGM ANTIBODIES TO RUBELLA VIRUS IN HUMAN PLASMA AND SERA.,CMV IGG(CMV IGG)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE/QUALITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM AND PLASMA.,HAV IGM (HAV IGM)-“CAPTURE” ENZYME IMMUNOASSAY (ELISA) FOR THE DETERMINATION OF IGM CLASS ANTIBODIES TO HEPATITIS A VIRUS IN HUMAN PLASMA AND SERA,T.CRUZI AB(T.CRUZI AB)-THIRD GENERATION ENZYME IMMUNOASSAY FOR THE DETERMINATION OF ANTIBODIES TO TRIPANOSOMA CRUZI IN SERUM AND PLASMA.,HAV AB(HAV AB)-COMPETITIVE ENZYME IMMUNOASSAY (ELISA) FOR THE DETERMINATION OF ANTIBODIES TO HEPATITIS A VIRUS IN HUMAN PLASMA AND SERA.,COVID-19 IGG (COVID-19 IGG)-THE PRODUCT IS INTENDED FOR THE DETERMINATION OF IGG ANTIBODIES TO COVID19-SPECIFIC NUCLEOCAPSID (‘’CORE’’) AND SPIKE ANTIGENS IN HUMAN PLASMA AND SERA (COVID -19 IGG). THE KIT IS INTENDED FOR MONITORING THE IMMUNE RESPONSE TO COVID-19. THE IGG ASSAY IS RECOMMENDED IN PARTICULAR FOR TESTING: (A) INFECTED INDIVIDUALS IN FOLLOW-UP SEROLOGICAL TESTING AND WHEN RECOVERED FROM THE INFECTION, NEGATIVE FOR COVID-19 PCR, TO ASSURE THEY DEVELOPED IGG ANTIBODIES TO THE VIRUS, CONFIRMING A FULL RECOVERY FROM THE INFECTION; (B) HEALTH-CARE WORKERS AT RISK OF COVID-19 INFECTION TO VERIFY WHETHER OR NOT THEY DEVELOPED IGG ANTIBODIES TO THE VIRUS; (C) INDIVIDUALS FROM NORMAL POPULATION TO STUDY THEIR ACQUIRED IMMUNE STATUS AGAINST COVID-19 INFECTION. (D) HUMAN ANTIBODIES DONORS FOR FOR TESTING IGG TITERS IN THE IDENTIFICATION OF HYPER-IMMUNE SERA AS A POSSIBLE IMMUNOTHERAPEUTIC APPROACH TO THE TREATMENT OF THE DISEASE

889	IMP/IVD/2020/000845	1.License Holder Name: BIOSYSTEMS DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CYBOW 10 M(CYBOW 10 M)-URINE STRIPS FOR THE MEASUREMENT OF GLUCOSE, PROTEINS, KETONES, PH, UROBILINOGEN, LEUCOCYTES, NITRITE, BILIRUBIN, SPECIFIC GRAVITY AND BLOOD IN URINE.,CYBOW 11 M(CYBOW 11 M)-URINE STRIPS FOR THE MEASUREMENT OF GLUCOSE, PROTEINS, KETONES, PH, UROBILINOGEN, LEUCOCYTES, NITRITE, BILIRUBIN, SPECIFIC GRAVITY, BLOOD AND ASA IN URINE.,CYBOW 2 GK(CYBOW 2 GK)-URINE STRIPS FOR THE MEASUREMENT OF GLUCOSE AND KETONES IN URINE.,CYBOW 10(CYBOW 10)-URINE STRIPS FOR THE MEASUREMENT OF GLUCOSE, PROTEINS, KETONES, PH, UROBILINOGEN, LEUCOCYTES, NITRITE, BILIRUBIN, SPECIFIC GRAVITY AND BLOOD IN URINE.,CYBOW 11(CYBOW 11)-URINE STRIPS FOR THE MEASUREMENT OF GLUCOSE, PROTEINS, KETONES, PH, UROBILINOGEN, LEUCOCYTES, NITRITE, BILIRUBIN, SPECIFIC GRAVITY, BLOOD AND ASA IN URINE.,CYBOW 2 AC(CYBOW 2 AC)-URINE STRIPS FOR THE MEASUREMENT OF MICROALBUMIN AND CREATININE IN URINE. ,CYBOW 12 AC (CYBOW 12 AC)-URINE STRIPS FOR THE MEASUREMENT OF GLUCOSE, PROTEINS, KETONES, PH, UROBILINOGEN, LEUCOCYTES, NITRITE, BILIRUBIN, SPECIFIC GRAVITY, BLOOD, MICROALBUMIN AND CREATININE IN URINE., CYBOW 3 GK(CYBOW 3 GK)-URINE STRIPS FOR THE MEASUREMENT OF GLUCOSE, PROTEINS AND KETONES IN URINE.,CYBOW 2 GP (CYBOW 2 GP)-URINE STRIPS FOR THE MEASUREMENT OF GLUCOSE AND PROTEINS IN URINE.,CYBOW 5(CYBOW 5)-URINE STRIPS FOR THE MEASUREMENT OF GLUCOSE, PROTEINS, KETONES, PH AND BLOOD IN URINE.
890	IMP/IVD/2020/000847	1.License Holder Name: PERKINELMER HEALTH SCIENCES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHEMAGIC™ VIRAL DNA/RNA 300 KIT H96(CHEMAGIC™ VIRAL DNA/RNA 300 KIT H96)-THE CHEMAGIC™ VIRAL DNA/RNA 300 KIT H96 IS TO BE USED FOR THE EXTRACTION AND PURIFICATION OF DNA AND RNA FROM HUMAN PLASMA, SERUM, NASO- OR OROPHARYNGEAL SWABS, BRONCHOALVEOLAR LAVAGE (BAL) AND SPUTUM USING THE CHEMAGIC 360 INSTRUMENT.

891	IMP/IVD/2020/000849	1.License Holder Name: ARK DIAGNOSTIC SYSTEM PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIATRO LYSE- DIFF WITH HK(DIATRON)-FOR LYSING RBC IN DILUTED BLOOD SAMPLE AND DIFFERENTIAL COUNT OF WBC,DIATRO DIL-5P(DIATRON)-DIATRO•DIL-5P DILUENT IS A BUFFERED, STABILIZED AND MICROFILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN (HGB) CONCENTRATION ON DIATRON ABACUS 5, ABACUS 380 HEMATOLOGY ANALYZERS. DIATRO•DIL-5P DILUENT SHOULD BE USED WITH ONLY DIATRON REAGENTS.,DIATRO LYSE- 5P WITH HK (DIATRON)-FOR LYSING RBC IN DILUTED BLOOD SAMPLE AND DIFFERENTIAL COUNT OF WBC,DIATRO CLEANER (DIATRON)-THE STANDARD DETERGENT-BASED CLEANING SOLUTION FOR DIATRON ANALYZERS.,DIATRO HYPOCLEAN CC(DIATRON)-DIATRO•HYPOCLEAN CC HYPOCHLORITE CLEANING CONCENTRATE IS A STABILIZED AND MICRO-FILTERED CONCENTRATED HYPOCHLORITE SOLUTION FOR INTENSIVE OXIDATIVE CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON ALL HEMATOLOGY ANALYZERS.,DIATRO DIL DIFF(DIATRON)-FOR DILUTING BLOOD SPECIMEN FOR CELL COUNTING,DIATRO DIFF-5P(DIATRON)-FOR LYSING RBC IN DILUTED BLOOD SAMPLE AND DIFFERENTIAL COUNT OF WBC,DIATRO CLEANER(DIATRON)-THE STANDARD DETERGENT-BASED CLEANING SOLUTION FOR DIATRON ANALYZERS.
892	IMP/IVD/2020/000850	1.License Holder Name: DIA SURE IMMUNODIAGNOSTIC LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 RAPID TEST CASSETTE-THE COVID-19 RAPID TEST IS A QUALITATIVE LATERAL FLOW IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION OF IGM AND IGG ANTIBODIES TO SARS-COV-2 IN WHOLE BLOOD, SERUM OR PLASMA SPECIMENS.

893	IMP/IVD/2020/000851	1.License Holder Name: BIOGENESIS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URIC ACID LR-KIT FOR MEASUREMENT OF URIC ACID IN SERUM,PLASMA AND URINE., ASO/CRP/RF NORMAL CONTROL-NORMAL CONTROL , FOR IN VITRO USE, FOR MONITORING THE QUALITY CONTROL OF RESULTS OBTAINED IN THE MEASURING OF THE ANTISTREPTOLYSIN-0, C-REACTIVE PROTEIN AND RHEUMATOID FACTORS IN TURBIDIMETRY., ALKALINE PHOSPHATASE LR-KIT FOR MEASUREMENT OF ALKALINE PHOSPHATASE IN SERUM OR PLASMA.,HOMOCYSTEIN LR-THE LIQUID STABLE (LS) 2-PART HOMOCYSTEINE REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF TOTAL HOMOCYSTEINE IN HUMAN SERUM AND PLASMA. THE DEVICE CAN ASSIST IN THE DIAGNOSIS AND TREATMENT OF PATIENTS SUSPECTED OF HAVING HYPERHOMOCYSTEINEMIA AND HOMOCYSTINURIA. ,UREA UV LR-KIT FOR MEASUREMENT OF UREA IN SERUM, PLASMA AND URINE.,SERA CONTROL P-SERACONTROL IS A MULTIPARAMETRIC CONTROL WHICH INTENDED USE IS CONTROL FOR CLINICAL CHEMISTRY ASSAY.,TRIGLYCERIDES LR-KIT FOR MEASUREMENT OF TRIGLYCERIDES IN SERUM OR PLASMA.,RF-QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS (RF).,ALT-GPT LR-KIT FOR MEASUREMENT OF ALANINE-AMINOTRANSFERASE IN SERUM OR PLASMA.,DIRECT FREE CALCIUM-FREE CALCIUM TEST IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF FREE CALCIUM (IONIZED CALCIUM) IN HUMAN SERUM OR PLASMA.,AST-GOT LR-KIT FOR MEASUREMENT OF ASPARTATE-AMINOTRANSFERASE IN SERUM OR PLASMA.,MICROALBUMIN CONTROL-THE CONTROL IS A SOLUTION CONTAINING HUMAN ALBUMIN USED TO EVALUATE THE PRECISION AND ACCURACY OF MICROALBUMIN DETERMINATIONS IN HUMAN URINE BY TURBIDIMETRY METHOD. ,POTASSIUM LR-KIT FOR MEASUREMENT OF POTASSIUM IN SERUM, PLASMA OR URINE.,BICARBONATE-(CO2) CONTROL SET-USED FOR CHECKING THE FUNCTIONALITY OF THE BICARBONATE.,GAMMA GT LR-KIT FOR MEASUREMENT OF GAMMA GLUTAMYL TRANSFERASE (GGT) IN SERUM OR PLASMA. ,LDH LR-KIT FOR MEASUREMENT OF LACTATE DEHYDROGENASE IN SERUM OR PLASMA. KINETIC OPTIMIZED METHOD SCE.,LACTATE-KIT FOR MEASUREMENT OF LACTATE IN SERUM.,SODIUM LR-GESAN LIQUID STABLE ENZYMATIC SODIUM ASSAY IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF SODIUM IN SERUM., URINARY PROTEINS LR-KIT FOR MEASUREMENT OF TOTAL PROTEIN IN URINE AND CSF.,ASO/CRP/RF HIGH CONTROL-HIGH CONTROL, FOR IN VITRO USE, FOR MONITORING THE QUALITY CONTROL OF THE ANTISTREPTOLYSIN-0, C- REACTIVE PROTEIN AND RHEUMATOID

	FACTORS RESULTS IN TURBIDIMETRY.,DIRECT BILIRUBIN LR-KIT FOR MEASUREMENT OF DIRECT BILIRUBIN IN SERUM OR PLASMA.,TOTAL BILIRUBIN LR-KIT FOR MEASUREMENT OF TOTAL BILIRUBIN IN SERUM OR PLASMA.,BICARBONATE(CO2)-QUANTITATIVE DETERMINATION OF BICARBONATE (CO2) IN SERUM AND PLASMA., MAGNESIUM LR-KIT FOR MEASUREMENT OF MAGNESIUM IN SERUM, PLASMA AND URINE.,FREE CALCIUM CONTROL SET-THIS CONTROL IS FOR IN VITRO USE IN THE CALIBRATION OF CALCIUM FREE.,COPPER-KIT FOR THE QUANTITATIVE IN VITRO DETERMINATION OF COPPER IN SERUM AND PLASMA.,FERRITIN (TURB.)-THE REAGENTS FERRITIN ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM OR PLASMA MEASUREMENTS OF FERRITIN ARE USEFUL IN THE EVALUATION AND MONITORINGOF ANEMIAS. REFER TO THE CLINICAL CHEMISTRY PUBLICATION "EFFECTS OF DISEASE ON CLINICAL LABORATORY TESTS"1 FOR A SUMMARY OF CAUSES OF INCREASED OR DECREASED FERRITIN CONCENTRATION.,CHLORIDE LR-KIT FOR MEASUREMENT OF CHLORIDES IN SERUM, PLASMA AND URINE.,BILE ACID-TOTAL BILE ACID ASSAY KIT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF SERUM TOTAL BILE ACIDS (TBA).,HDL- LDL CALIBRATOR-THIS PRODUCT IS INTENDED FOR IN VITRO USE IN THE CALIBRATION OF HDL AND LDL CHOLESTEROL.,ASO-QUANTITATIVE DETERMINATION OF ANTI-STREPTOLYSIN O (ASO).,CK NAC LR-KIT FOR MEASUREMENT OF CREATINE KINASE IN SERUM OR PLASMA. , CREATININE LR-KIT FOR MEASUREMENT OF CREATININE IN SERUM, PLASMA AND URINE.,ALBUMIN LR-KIT FOR MEASUREMENT OF ALBUMIN IN SERUM OR PLASMA. ,LDL DIRECT CHOLESTEROL LR-KIT FOR ENZYMATIC MEASUREMENT OF LOW-DENSITY LIPOPROTEIN (CHOLESTEROL LDL) IN SERUM OR PLASMA. ,CHOLINESTERASE LR-KIT FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CHOLINESTERASE IN SERUM OR PLASMA.,URINARY PROTEINS CONTROL-INTENDED FOR QUALITY CONTROL OF URINE IN CHEMICAL CHEMISTRY SYSTEM.,MICROALBUMIN-MICROALBUMIN-TURBILATEX IS A QUANTITATIVE TURBIDIMETRIC TEST FOR THE MEASUREMENT OF MICROALBUMIN (MALB) IN HUMAN URINE.,TOTAL PROTEIN LR-KIT FOR MEASUREMENT OF TOTAL PROTEIN IN SERUM OR PLASMA.,LP(A) CONTROL-QUANTITATIVE DETERMINATION OF LIPOPROTEIN (A)., HOMOCYSTEINE CONTROL SET-THE HOMOCYSTEINE CONTROL KIT IS INTENDED TO BE USED AS AN ASSAYED QUALITY CONTROL SERUM WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF TOTAL L-HOMOCYSTEINE IN HUMAN SERUM OR PLASMA.,HBA1C LYSANT-AUXILIARY REAGENT USED FOR SAMPLES PREPARATION FOR HBA1C DIRECT ASSAY GESAN KIT.,LIPIDIC CONTROL SET-INTENDED FOR IN VITRO USE IN THE QUALITY CONTROL OF DIRECT HDL-C AND DIRECT

	LDL-C.,FERRITIN CALIBRATOR SET-CALIBRATION SET, FOR IN VITRO DIAGNOSTIC USE, USE FOR RUNNING THE CALIBRATION CURVE FOR QUANTITATIVE DETERMINATION OF FERRITINE IN SERUM.,LP(A) CALIBRATOR-QUANTITATIVE DETERMINATION OF LIPOPROTEIN (A)., HBA1C DIRECT-FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN BLOOD.,HBA1C CALIBRATOR SET-PREPARATION OF REFERENCE CURVES FOR QUANTITATIVE DETERMINATION OF HBA1C IN HUMAN BLOOD BY TURBIDIMETRIC IMMUNOASSAY.,SERA CAL-SERACAL IS A MULTIPARAMETRIC CALIBRATOR INTENDED FOR CALIBRATION OF CHEMICAL CLINICAL ASSAY. ,LP(A)-IT IS A QUANTITATIVE TURBIDIMETRIC TEST FOR THE MEASUREMENT OF LP(A) IN HUMAN SERUM OR PLASMA., CHOLESTEROL LR-KIT FOR MEASUREMENT OF CHOLESTEROL IN SERUM OR PLASMA.,CRP ANTISERUM CONTROL SET-THE CRP CONTROL KIT IS INTENDED TO BE USED AS AN ASSAYED QUALITY CONTROL SERUM WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF C-REACTIVE PROTEIN IN SERUM.,IRON LR-KIT FOR MEASUREMENT OF IRON IN SERUM OR PLASMA.,FRUCTOSAMINE CONTROL SET-THIS PRODUCT IS INTENDED FOR IN QUALITY CONTROL OF FRUCTOSAMINE DETERMINATION.,SERA CONTROL N-SERACONTROL IS A MULTIPARAMETRIC CONTROL WHICH INTENDED USE IS CONTROL FOR CLINICAL CHEMISTRY ASSAY.,LIPASE LR-KIT FOR MEASUREMENT OF LIPASE IN SERUM.,AMYLASE LR-KIT FOR MEASUREMENT OF AMYLASE IN SERUM, PLASMA AND URINE.,CRP ANTISERUM CALIBRATOR-PREPARATION OF REFERENCE CURVES FOR QUANTITATIVE IMMUNOCHEMICAL DETERMINATION OF C-REACTIVE PROTEIN (CRP).,CRP-THE REAGENT CRP ARE INTENDED FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN SERUM.,HBA1C CONTROL SET-ACCURACY CONTROL IN THE NORMAL RANGE FOR QUANTITATIVE DETERMINATION OF HBA1C IN HUMAN BLOOD.,BILE ACID CONTROL SET-USED IN QUALITY CONTROL PROCEDURES OF TOTAL BILE ACID DETERMINATION., PHOSPHOROUS LR-KIT FOR MEASUREMENT OF INORGANIC PHOSPHOROUS IN SERUM OR PLASMA.,CALCIUM ARSENAZO LR-KIT FOR MEASUREMENT OF CALCIUM IN SERUM, PLASMA AND URINE., HDL DIRECT CHOLESTEROL LR -KIT FOR ENZYMATIC MEASUREMENT OF HIGH-DENSITY LIPOPROTEIN (CHOLESTEROL HDL) IN SERUM OR PLASMA.,FERRITIN CONTROL-FERRITINE CONTROL SET USED FOR MONITORING THE QUALITY CONTROL OF THE RESULTS OBTAINED WITH THE CORRESPONDING REAGENTS IN TURBIDIMETRY.,ZINC-QUANTITATIVE DETERMINATION OF ZINC.

894	IMP/IVD/2020/000853	1.License Holder Name: HEALTHCUBED INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL CHOLESTEROL TEST STRIP(BENECHECK TOTAL CHOLESTEROL TEST STRIP)-MEASURING TOTAL CHOLESTEROL LEVEL IN CAPILLARY WHOLE BLOOD FROM FINGERTIP THE METER CAN BE USED BY LAYPERSONS OR HEALTHCARE PROFESSIONALS IN VITRO DIAGNOSTIC USE ONLY,HB HEMOGLOBIN TEST STRIP (BENECHECK HB HAEMOGLOBIN TEST STRIP)- MEASURING HAEMOGLOBIN LEVEL IN CAPILLARY WHOLE BLOOD FROM FINGERTIP THE METER CAN BE USED BY LAYPERSONS OR HEALTHCARE PROFESSIONALS IN VITRO DIAGNOSTIC USE ONLY,URIC ACID TEST STRIP(BENECHECK URIC ACID TEST STRIP)- MEASURING URIC ACID LEVEL IN CAPILLARY WHOLE BLOOD FROM FINGERTIP THE METER CAN BE USED BY LAYPERSONS OR HEALTHCARE PROFESSIONALS IN VITRO DIAGNOSTIC USE ONLY
895	IMP/IVD/2020/000856	1.License Holder Name: BIO SCIENCE SALES CORPORATION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MYT-CAL(MYT-CAL)-MYT-CAL IS DESIGNED FOR USE IN THE CALIBRATION OF ORPHEE HAEMATOLOGY ANALYZERS.,MYT-5D(MYT-5D)-WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MYTHIC 22 HAEMATOLOGY CELL COUNTERS.
896	IMP/IVD/2020/000857	1.License Holder Name: KRIYA DESIGN TECHNOLOGIES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIP(RIGHTEST)-USED TO MEASURE BLOOD GLUCOSE LEVEL IN THE WHOLE BLOOD.

897	IMP/IVD/2020/000861	1.License Holder Name: INSTRUMENTATION LABORATORY INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALBUMIN(QUANTILAB)-ALBUMIN IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ALBUMIN IN HUMAN SERUM USING THE ILAB CHEMISTRY SYSTEMS,URIC ACID(QUANTILAB)-URIC ACID ASSAY IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA AND URINE USING THE ILAB CHEMISTRY SYSTEMS.,REFERRIL CK-MB (QUANTILAB)-REFERRIL CK-MB IS A CALIBRATOR INTENDED TO USE IN THE CALIBRATION OF CREATINE KINASE B (CK-MB) ON ILAB CHEMISTRY SYSTEMS.,DIRECT BILIRUBIN(QUANTILAB)-DIRECT BILIRUBIN ASSAY IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM AND PLASMA USING THE ILAB CHEMISTRY SYSTEMS., AMYLASE(QUANTILAB)-AMYLASE IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF -AMYLASE IN HUMAN SERUM, PLASMA AND URINE USING THE ILAB CHEMISTRY SYSTEMS.,TIBC(QUANTILAB)-TIBC IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF TOTAL IRON BINDING CAPACITY (TIBC) IN HUMAN SERUM AND PLASMA USING USING THE ILAB CHEMISTRY SYSTEMS, IN CONJUNCTION WITH IRON ASSAY.,UREA NITROGEN(QUANTILAB)-UREA NITROGEN IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF UREA NITROGEN AND UREA IN HUMAN SERUM, PLASMA AND URINE USING THE ILAB CHEMISTRY SYSTEMS., MAGNESIUM(QUANTILAB)-MAGNESIUM IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF MAGNESIUM IN HUMAN SERUM, PLASMA AND URINE USING THE ILAB CHEMISTRY SYSTEMS.,CALCIUM ARSENAZO(QUANTILAB)-CALCIUM ARSENAZO IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA AND URINE USING THE ILAB CHEMISTRY SYSTEMS.

898	IMP/IVD/2020/000862	1.License Holder Name: POLETUS MEDIA MAGIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 AB(ICHROMA™ COVID-19 AB)-ICHROMA™ COVID-19 AB IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE DETERMINATION OF IGG/IGM ANTIBODIES AGAINST 'NOVEL CORONAVIRUS' IN HUMAN WHOLE BLOOD /SERUM/ PLASMA. IT IS HELPFUL AS AN AID IN THE SCREENING OF EARLY MILD, ASYMPTOMATIC OR ACUTE PATIENTS FOR IDENTIFICATION OF 'NOVEL CORONAVIRUS (EG, SARS-COV-2)' INFECTION WITH HIGH SENSITIVITY.
899	IMP/IVD/2020/000863	1.License Holder Name: PREMAS LIFE SCIENCES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 PCR DIAGNOSTIC KIT(KAIRA 2019-NCOV DETECTION KIT)-THE KAIRA 2019-NCOV DETECTION KIT IS DESIGNED FOR QUALITATIVE DETECTION OF COVID- 19 VIRUS (SARS-COV-2) RNA IN THE SPECIMENS OF SUSPECTED RESPIRATORY DISEASE PATIENTS (SPUTUM, ORAL SWAB, NASAL SWAB) IN IN VITRO SETTINGS, BY REAL-TIME POLYMERASE CHAIN REACTION (RT-PCR), ASSISTING DIAGNOSIS OF COVID-19. FOR PROFESSIONAL USE ONLY.
900	IMP/IVD/2020/000864	1.License Holder Name: SYSMEX INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REAGENT PROBE WASH 2 (REAGENT PROBE WASH 2)-FOR IN VITRO DIAGNOSTIC USE AS A CLEANING AGENT ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS.,LAMP COOLANT C(LAMP COOLANT C)-LAMP COOLANT CONTAINING ANTI RUST AGENT,REAGENT PROBE WASH 1(REAGENT PROBE WASH 1)-FOR IN VITRO DIAGNOSTIC USE AS A CLEANING AGENT ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS,REAGENT PROBE WASH K(REAGENT PROBE WASH K)-FOR IN VITRO DIAGNOSTIC USE AS A CLEANING AGENT ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS,REAGENT PROBE WASH S(REAGENT PROBE WASH S)-FOR IN VITRO DIAGNOSTIC USE AS A CLEANING AGENT ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS,CUVETTE WASH SOLUTION 7(CUVETTE WASH SOLUTION 7)-FOR IN VITRO DIAGNOSTIC USE AS A CLEANING AGENT ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS,CUVETTE CONDITIONER EX(CUVETTE CONDITIONER EX)-FOR IN VITRO DIAGNOSTIC USE AS A CLEANING AGENT ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS.

901	IMP/IVD/2020/000873	1.License Holder Name: BIOMERIEUX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHROMID S. AUREUS ELITE AGAR(CHROMID S. AUREUS ELITE AGAR)-CHROMOGENIC MEDIUM FOR THE SELECTIVE ISOLATION AND THE DIRECT IDENTIFICATION OF S. AUREUS.,XLD AGAR(XLD AGAR)-SELECTIVE ISOLATION OF SALMONELLA AND SHIGELLA.,TRYPCASE SOY AGAR (TRYPCASE SOY AGAR)-ISOLATION OF NONFASTIDIOUS MICROORGANISMS.,CHROMID® CPS® ELITE AGAR TRANSLUCENT MEDIUM(CHROMID® CPS® ELITE AGAR TRANSLUCENT MEDIUM)-FOR ISOLATION, ENUMERATION AND DIRECT AND PRESUMPTIVE IDENTIFICATION OF URINARY TRACT INFECTION ORGANISMS, SABOURAUD DEXTROSE AGAR(SABOURAUD DEXTROSE AGAR)-MEDIUM FOR THE CULTURE AND ENUMERATION OF YEASTS, MOULDS AND DERMATOPHYTES.,CHOCOLATE AGAR + POLYVITEX (CHOCOLATE AGAR + POLYVITEX)-ISOLATION OF FASTIDIOUS BACTERIA.,MUELLER HINTON 2 AGAR + 5% SHEEP BLOOD(MUELLER HINTON 2 AGAR + 5% SHEEP BLOOD)-SUSCEPTIBILITY OF PNEUMOCOCCI AND OTHER STREPTOCOCCI TO ANTIBIOTICS, CHROMID™ VRE AGAR(CHROMID™ VRE AGAR)-SELECTIVE CHROMOGENIC MEDIUM FOR THE DETECTION AND DIFFERENTIATION OF ENTEROCOCCUS FAECIUM AND E. FAECALIS SHOWING ACQUIRED VANCOMYCIN RESISTANCE (VRE),CLED AGAR(CLED AGAR)-ISOLATION OF MICRO-ORGANISMS OF THE URINARY TRACT, SABOURAUD CHLORAMPHENICOL 2 AGAR(SABOURAUD CHLORAMPHENICOL 2 AGAR)-SELECTIVE CULTURE OF FUNGI, MUELLER HINTON E AGAR(MUELLER HINTON E AGAR)-STUDY OF ANTIMICROBIAL SUSCEPTIBILITY,MAC CONKEY AGAR(MAC CONKEY AGAR)-SELECTIVE ISOLATION OF ENTEROBACTERIA AND ESCHERICHIA COLI,CHROMID™ ESBL AGAR(CHROMID™ ESBL AGAR)-SELECTIVE CHROMOGENIC MEDIUM FOR THE SCREENING OF EXTENDED SPECTRUM -LACTAMASE-PRODUCING ENTEROBACTERIA (ESBL),HEKTOEN AGAR(HEKTOEN AGAR)-SELECTIVE ISOLATION OF SALMONELLA AND SHIGELLA.,TRYPCASE SOY AGAR(TRYPCASE SOY AGAR)-ISOLATION OF NONFASTIDIOUS MICROORGANISMS.,CHROMID™ MRSA SMART AGAR(CHROMID™ MRSA SMART AGAR)-CHROMOGENIC MEDIUM FOR THE SCREENING OF METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA), SABOURAUD LIQUID BROTH(SABOURAUD LIQUID BROTH)-CULTURE OF YEASTS AND MOLDS.,TRYPCASE SOY BROTH(TRYPCASE SOY BROTH)-CULTURE OF NON-FASTIDIOUS MICROORGANISMS., CHROMID CANDIDA AGAR(CHROMID CANDIDA AGAR)-CHROMOGENIC MEDIUM FOR THE SELECTIVE ISOLATION OF YEASTS AND THE DIRECT IDENTIFICATION OF CANDIDA ALBICANS.,TRYPCASE SOY AGAR + 5%

	SHEEP BLOOD(TRYPCASE SOY AGAR + 5% SHEEP BLOOD)-ISOLATION OF BACTERIA. DETERMINATION OF HEMOLYSIS., THIOGLYCOLLATE BROTH + RESAZURIN(THIOGLYCOLLATE BROTH + RESAZURIN)-STERILITY TESTING. ENRICHMENT OF NON-FASTIDIOUS BACTERIA.,COLUMBIA AGAR + 5% SHEEP BLOOD(COLUMBIA AGAR + 5% SHEEP BLOOD)-ISOLATION OF FASTIDIOUS BACTERIA AND DECTION OF HEMOLYSIS.

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902	IMP/IVD/2020/000878	1.License Holder Name: IMMUNOSHOP INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEV-IGM (WANTAI)-WANTAI HEV-IGM ELISA IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF IGM-CLASS ANTIBODIES TO HEPATITIS E VIRUS IN HUMAN SERUM OR PLASMA. IT IS INTENDED TO BE USED IN CLINICAL LABORATORIES FOR DIAGNOSIS AND MANAGEMENT OF PATIENTS RELATED TO INFECTION WITH HEPATITIS E VIRUS. ,HEV-IGG (WANTAI)-WANTAI HEV-IGG ELISA IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF IGG-CLASS ANTIBODIES TO HEPATITIS E VIRUS IN HUMAN SERUM OR PLASMA. IT IS INTENDED TO BE USED AS AN AID IN SUPPLEMENTARY DIAGNOSIS TO ACUTE HEPATITIS E INFECTION AND PREVALENCE STUDIES AMONG THE POPULATION. , HEV-AG(WANTAI)-WANTAI HEV-AG ELISA PLUS IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUALITATIVE DETECTION OF HEPATITIS E VIRUS ANTIGEN IN HUMAN SERUM OR PLASMA SPECIMENS. IT IS INTENDED FOR USE IN CLINICAL LABORATORIES FOR DIAGNOSIS AND MANAGEMENT OF PATIENTS RELATED TO INFECTION WITH HEPATITIS E VIRUS.,SARS-COV-2 AB ELISA(WANTAI)-"WANTAI SARS-COV-2 AB ELISA IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR QUALITATIVE DETECTION OF TOTAL ANTIBODIES TO SARS-COV-2 VIRUS IN HUMAN SERUM OR PLASMA SPECIMENS. THE KIT IS INTENDED FOR SCREENING OF PATIENTS SUSPECTED FOR INFECTION WITH SARS-COV-2 VIRUS, AND AS AN AID IN THE DIAGNOSIS OF THE CORONAVIRUS DISEASE 2019 (COVID-19)." ,HAV-IGM (WANTAI)-THIS ELISA KIT IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) FOR QUALITATIVE DETECTION OF IGM-CLASS ANTIBODIES TO HEPATITIS A VIRUS IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR USE IN CLINICAL LABORATORIES FOR DIAGNOSIS OF ACUTE HEPATITIS A AND MANAGEMENTS OF PATIENTS RELATED TO INFECTION WITH HEPATITIS A VIRUS. ,HAV-IGM (CASSETTE)(WANTAI)-THIS TEST IS A SINGLE USE, RAPID DEVICE INTENDED FOR QUALITATIVE DETECTION OF IGM-CLASS ANTIBODIES TO HEPATITIS A VIRUS (HAV) IN SERUM OR PLASMA SAMPLES. IT IS INTENDED TO BE USED IN CLINICAL LABORATORIES FOR DIAGNOSIS OF ACUTE HEPATITIS A AND MANAGEMENT OF PATIENTS RELATED TO INFECTION WITH HEPATITIS A VIRUS. ,HEV-IGM (CASSETTE)(WANTAI)-THIS TEST IS A SINGLE USE, RAPID DEVICE INTENDED FOR QUALITATIVE DETECTION OF IGM-CLASS ANTIBODIES TO HEPATITIS E VIRUS (HEV) IN SERUM OR PLASMA SAMPLES. IT IS INTENDED TO BE USED IN CLINICAL LABORATORIES FOR DIAGNOSIS OF ACUTE HEPATITIS E AND MANAGEMENT OF PATIENTS RELATED TO

		INFECTION WITH HEPATITIS E VIRUS. ,ROTAVIRUS ANTIGEN (CASSETTE)(WANTAI)-THIS RAPID TEST, WITH HIGH SENSITIVITY AND SPECIFICITY, ADOPTS IMMUNOCHROMATOGRAPHIC COLLOIDAL GOLD SYSTEM FOR QUALITATIVE DETECTION OF ROTAVIRUS GROUP A IN HUMAN STOOL SAMPLES. THE OPERATION IS EASY AND SAFE AND THE RESULT IS RELIABLE. THE WHOLE OPERATIONAL PROCESS TAKES ONLY 10 MINUTES. IT IS INTENDED FOR CLINICAL DIAGNOSIS IN HOSPITALS, CLINICS, AND REMOTE AREAS. NO SPECIAL EQUIPMENTS OR INSTRUMENTS ARE REQUIRED FOR THIS ASSAY.
903	IMP/IVD/2020/000880	1.License Holder Name: BIO-RAD LABORATORIES (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KALLESTAD ANTI NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA) TEST SYSTEM (KALLESTAD ANTI NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA) TEST SYSTEM)-AN INDIRECT IMMUNOFLUORESCENCE ANTIBODY TEST FOR THE DETECTION AND SEMI - QUANTITATION OF ANTI – NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA) IN HUMAN SERUM. ANCA ARE FOUND IN THE SERA OF PATIENTS WITH NECROTIZING VASCULITIDES AND HENCE, SERVE AS AN AID TO CLINICAL AND OTHER LABORATORY FINDING IN THE DIAGNOSIS OF THESE DISORDERS

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

904	IMP/IVD/2020/000885	1.License Holder Name: INKARP INSTRUMENTS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIACON 5 HEMATOLOGY CONTROL SET (2L-2N-2H)(DIATRON)-DIACON 5 HEMATOLOGY CONTROL IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.,DIATRO•CLENZ(DIATRON)-DIATRO•CLENZ ENZYMATIC CLEANER REAGENT IS A STABILIZED AND MICRO-FILTERED PROTEOLYTIC ENZYME SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON DIATRON ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 3CT, ABACUS 380 HEMATOLOGY ANALYZERS.,DIATROCAL HEMATOLOGY CALIBRATOR(DIATRON)-DIATROCAL HEMATOLOGY CALIBRATOR IS DESIGNED FOR USE IN THE CALIBRATION OF HEMATOLOGY ANALYZERS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS.,DIATRO•HYPOCLEAN CC(DIATRON)-DIATRO•HYPOCLEAN CC HYPOCHLORITE CLEANING CONCENTRATE IS A STABILIZED AND MICRO-FILTERED CONCENTRATED HYPOCHLORITE SOLUTION FOR INTENSIVE OXIDATIVE CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON ALL HEMATOLOGY ANALYZERS.,DIATRO•CLEANER(DIATRON)-DIATRO•CLEANER CLEANING REAGENT IS A STABILIZED AND MICROFILTERED DETERGENT SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON DIATRON JUNIOR, ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 3CT, ABACUS 380 HEMATOLOGY ANALYZERS.,DIATRO•LYSE-BASO(DIATRON)-DIATRO•LYSE-BASO LYSING REAGENT IS A STABILIZED AND MICROFILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF BASOPHIL LEUKOCYTES (BAS) IN HUMAN BLOOD ON DIATRON ABACUS JUNIOR 5 HEMATOLOGY ANALYZERS.,DIATRO•CLENZ (DIATRON)-DIATRO•CLENZ ENZYMATIC CLEANER REAGENT IS A STABILIZED AND MICRO-FILTERED PROTEOLYTIC ENZYME SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON DIATRON ABACUS JUNIOR 30, ABACUS JUNIOR 5,

	ABACUS 3CT, ABACUS 380 HEMATOLOGY ANALYZERS.,DIACON 3 HEMATOLOGY CONTROL SET (2L-2N-2H)(DIATRON)-DIACON 3 HEMATOLOGY CONTROL IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN ALSO BE USED FOR MANUAL METHODS. PLEASE REFER TO THE ASSAY TABLE FOR SPECIFIC INSTRUMENT MODELS,DIATRO•LYSE-DIFF WITH HK(DIATRON)-DIATRO•LYSE-DIFF LYSING REAGENT IS A STABILIZED AND MICROFILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE THREE-PART DIFFERENTIATION (LYM, MID, GRAN) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON DIATRON JUNIOR, ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 380, ABACUS 3CT HEMATOLOGY ANALYZERS.,DIATRO•LYSE-EO(DIATRON)-DIATRO•LYSE-EO LYSING REAGENT IS A STABILIZED AND MICROFILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF EOSINOPHIL LEUKOCYTES (EOS) IN HUMAN BLOOD ON DIATRON ABACUS JUNIOR 5 HEMATOLOGY ANALYZERS.,DIATRO•DIFF-5P (DIATRON)-DIATRO•DIFF-5P WBC DIFFERENTIATION REAGENT IS A STABILIZED AND MICRO-FILTERED REAGENT FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC) AND LEUKOCYTE 5-PART DIFFERENTIATION (LYM, MONO, NEU, EO, BA) MEASUREMENT IN HUMAN BLOOD ON DIATRON ABACUS 5 HEMATOLOGY ANALYZERS., DIATRO•DIL-5P(DIATRON)-DIATRO•DIL-5P DILUENT IS A BUFFERED, STABILIZED AND MICROFILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN(HGB) CONCENTRATION ON DIATRON ABACUS 5 HEMATOLOGY ANALYZERS.,DIATRO•DIL-DIFF(DIATRON)-DIATRO•DIL-DIFF DILUENT IS A BUFFERED, STABILIZED AND MICROFILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN (HGB) CONCENTRATION ON DIATRON JUNIOR, ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 380, ABACUS 3CT HEMATOLOGY ANALYZERS.,DIATRO•CLEANER(DIATRON)-DIATRO•CLEANER CLEANING REAGENT IS A STABILIZED AND MICROFILTERED DETERGENT SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS'

	CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON DIATRON JUNIOR, ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 3CT, ABACUS 380 HEMATOLOGY ANALYZERS,DIATRO•LYSE-DIFF (DIATRON)-DIATRO•LYSE-DIFF LYSING REAGENT IS A STABILIZED AND MICROFILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE THREE-PART DIFFERENTIATION (LYM, MID, GRAN) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON DIATRON JUNIOR, ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 380, ABACUS 3CT HEMATOLOGY ANALYZERS.,DIATRO•HYPOCLEAN (DIATRON)-DIATRO•HYPOCLEAN HYPOCHLORITE CLEANING REAGENT IS A STABILIZED AND MICRO-FILTERED HYPOCHLORITE SOLUTION FOR INTENSIVE OXIDATIVE CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON DIATRON ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 3CT, ABACUS 380 HEMATOLOGY ANALYZERS., DIATRO•LYSE-5P WITH HK(DIATRON)-DIATRO•LYSE-5P LYSING REAGENT IS A STABILIZED AND MICROFILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE 5-PART DIFFERENTIATION (LYM, MONO, NEU, EO, BA) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON DIATRON ABACUS 5 HEMATOLOGY ANALYZERS,DIATRO•CLENZ CC (DIATRON)-DIATRO•CLENZ CC ENZYMATIC CLEANER CONCENTRATE IS A STABILIZED AND MICRO-FILTERED CONCENTRATED PROTEOLYTIC ENZYME SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON ALL HEMATOLOGY ANALYZERS

905	IMP/IVD/2020/000886	1.License Holder Name: REDCELLS DIAGNOSTICS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CREATININE(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA, OR URINE.FOR IN VITRO DIAGNOSTIC USE ONLY.,MALB/UPROT CONTROL(MEDICON)-CONTROL MATERIAL FOR INTERNAL QUALITY CONTROL OF MICROALBUMIN AND URINARY PROTEIN ASSAY WITH MEDICON REAGENTS.,CRP LATEX CALIBRATOR (MEDICON)-CALIBRATION MATERIAL FOR THE PREPARATION OF CALIBRATION CURVES FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM,TRIGLYCERIDES(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,STFR CALIBRATOR (MEDICON)-MATERIAL FOR THE PREPARATION OF REFERENCE CURVES FOR THE QUANTITATIVE DETERMINATION OF SOLUBLE TRANSFERRIN RECEPTORS (STFR) IN HUMAN SERUM.,FERRITIN CALIBRATOR (MEDICON)-CALIBRATION MATERIAL FOR THE PREPARATION OF CALIBRATION CURVES FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM OR PLASMA.,AMMONIA CALIBRATOR (MEDICON)-CALIBRATOR MATERIAL FOR THE PREPARATION OF REFERENCE CURVES FOR THE QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN PLASMA.,TOTAL PROTEIN(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,-AMYLASE(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF A-AMYLASE ACTIVITY IN HUMAN SERUM, PLASMA OR URINE. FOR IN VITRO DIAGNOSTIC USE ONLY.,STFR CONTROL(MEDICON)-MATERIAL FOR THE INTERNAL QUALITY CONTROL OF SOLUBLE TRANSFERRIN RECEPTORS (STFR) IN HUMAN SERUM OR PLASMA.,TOTAL BILIRUBIN(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,LIPASE (MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF LIPASE IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY., ALDOLASE(MEDICON)-A SET OF REAGENTS FOR THE ENZYMATIC DETERMINATION OF ALDOLASE IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,ALBUMIN (MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,LDH P L (MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF L-LACTATE DEHYDROGENASE IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,RF-LATEX (RF)(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR

	IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,LDL-CHOLESTEROL(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF LDL-CHOLESTEROL IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,ASO CALIBRATOR(MEDICON)-CALIBRATOR MATERIAL FOR THE PREPARATION OF REFERENCE CURVES FOR THE DETERMINATION OF ANTISTREPTOLYSIN-O (ASO) IN HUMAN SERUM.,CRP-LATEX (MEDICON)-A SET OF REAGENTS FOR THE DETERMINATION OF CRP-LATEX IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,STFR (MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF STFR IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,RF CALIBRATOR(MEDICON)-HUMAN PLASMA CALIBRATOR INTENDED TO BE USED FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR.,CREATININE(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA OR URINE. FOR IN VITRO DIAGNOSTIC USE ONLY., MAGNESIUM(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM, PLASMA, OR URINE. FOR IN VITRO DIAGNOSTIC USE ONLY.,CHOLESTEROL (MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,DIRECT BILIRUBIN(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY., AMMONIA CONTROL(MEDICON)-MATERIAL FOR THE QUALITY CONTROL OF THE DETERMINATION OF AMMONIA. ,DIRECT BILIRUBIN (MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,NH3 (AMMONIA)(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF AMMONIA (NH3) IN HUMAN PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,CLINICAL CHEMISTRY CONTROL LEV.1(MEDICON)-MATERIAL FOR THE INTERNAL QUALITY CONTROL OF THE TEST RESULTS.,URINARY PROTEIN - CSF(MEDICON) -REAGENT FOR THE ENZYMATIC DETERMINATION OF TOTAL PROTEIN IN HUMAN URINE AND CSF. FOR IN VITRO DIAGNOSTIC USE ONLY., IMMUNOLOGY CONTROL LEVEL-3(MEDICON)-MATERIAL FOR THE INTERNAL QUALITY CONTROL OF THE PERFORMANCE OF MEDICON SPECIAL PROTEINS REAGENTS.,GGT(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF L-GAMMA GLUTAMYL TRANSFERASE (-GLUTAMYLTRANSPEPTIDASE) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,ALT/GPT (MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE (ALT/GPT) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,IGE CALIBRATOR

	(MEDICON)-MATERIAL FOR THE CALIBRATION OF QUANTITATIVE DETERMINATION OF TOTAL IMMUNOGLOBULIN E (IGE) IN HUMAN SERUM.,G-6-PDH CONTROL(MEDICON)-LYOPHILIZED QUALITY CONTROL MATERIAL FROM HEMOLYSED HUMAN BLOOD FOR THE QUALITY CONTROL OF THE G-6-PDH DETERMINATION.,IMMUNOLOGY CONTROL LEVEL-2(MEDICON)-MATERIAL FOR THE INTERNAL QUALITY CONTROL OF THE PERFORMANCE OF MEDICON SPECIAL PROTEINS REAGENTS.,TRIGLYCERIDES(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,LDH L P (MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF L-LACTATE DEHYDROGENASE IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,IGE(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF IGE IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,IMMUNOLOGY CONTROL LEVEL-1(MEDICON)-MATERIAL FOR THE INTERNAL QUALITY CONTROL OF THE PERFORMANCE OF MEDICON SPECIAL PROTEINS REAGENTS.,TRANSFERRIN(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF TRANSFERRIN IN HUMAN SERUM AND PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,CRP CALIBRATOR(MEDICON)-CALIBRATION MATERIAL FOR THE PREPARATION OF CALIBRATION CURVES FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM.,MEDI-CAL(MEDICON)-MATERIAL FOR USE AS CALIBRATOR IN CLINICAL CHEMISTRY ASSAYS,CRP(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CPR IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,TOTAL BILIRUBIN (MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,MICROALBUMIN(MEDICON)-REAGENT FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF MINUTE AMOUNTS OF ALBUMIN IN HUMAN URINE. FOR IN VITRO DIAGNOSTIC USE ONLY.,IRON(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,PHOSPHORUS (MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHORUS IN HUMAN SERUM, PLASMA, OR URINE. FOR IN VITRO DIAGNOSTIC USE ONLY.,MICROALBUMIN CALIBRATOR (MEDICON)-CALIBRATION MATERIAL FOR THE PREPARATION OF CALIBRATION CURVES FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF MICROALBUMIN IN URINE.,URIC ACID(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA, OR URINE. FOR IN VITRO DIAGNOSTIC USE ONLY.,ALKALINE

	PHOSPHATASE (ALP)(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE (ALP) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY., MICROALBUMIN(MEDICON)-REAGENT FOR THE QUANTITATIVE IMMUNOTURBIDIMETRIC DETERMINATION OF MINUTE AMOUNTS OF ALBUMIN IN HUMAN URINE. FOR IN VITRO DIAGNOSTIC USE ONLY.,CK (MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE (CK) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,CALCIUM(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA, OR URINE. FOR IN VITRO DIAGNOSTIC USE ONLY.,UREA (MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM, PLASMA, OR URINE. FOR IN VITRO DIAGNOSTIC USE ONLY.,PROTEIN STANDARD(MEDICON)-MEDICON PROTEIN STANDARD CALIBRATOR IS A HUMAN PLASMA CALIBRATOR INTENDED TO BE USED FOR THE QUANTITATIVE DETERMINATION OF A1-ANTITRYPSIN, A2-MACROGLOBULIN, A1-ACID GLYCOPROTEIN, CERULOPLASMIN, HAPTOGLOBIN, TRANSFERRIN, IGA, IGG, IGM, C3, C4, PREALBUMIN, KAPPA LIGHT CHAINS AND LAMBDA LIGHT CHAINS.,CHOLESTEROL(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,AST/GOT (MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE (AST/GOT) IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,HDL-CHOLESTEROL (MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF HDLCHOLESTEROL IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,CLINICAL CHEMISTRY CONTROL LEV.2 (MEDICON)-MATERIAL FOR THE INTERNAL QUALITY CONTROL OF THE TEST RESULTS.,G6PDH(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF G-6-PDH IN HUMAN BLOOD. FOR IN VITRO DIAGNOSTIC USE ONLY.,FERRITIN(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,UIBC(MEDICON)-REAGENT FOR QUANTITATIVE DETERMINATION OF UNSATURATED IRON BINDING CAPACITY IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.,ASO(MEDICON)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF ASO IN HUMAN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

906	IMP/IVD/2020/000887	1.License Holder Name: M/S. I-SENS BIOSENSORS INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GAS AND ELECTROLYTE ANALYZER REAGENT(CAREPAK 110 CARTRIDGE)-THE CAREPAK 110 CARTRIDGE IS A REAGENT FOR THE I- SMARTCARE 10 BLOOD GAS ANALYZER INTENDED TO BE USED FOR THE MEASUREMENT OF GAS (PCO2, PO2), PH, ELECTROLYTES (NA+, K+, CA2+, CL-), HEMATOCRIT (HCT) AND METABOLITES (GLU, LAC) IN THE SAMPLE OF HEPARINIZED WHOLE BLOOD OF HUMANS.,BLOOD GAS AND ELECTROLYTE ANALYZER REAGENT(I-SMART 300 CARTRIDGE)-THIS PRODUCT IS A REAGENT FOR IN VITRO DIAGNOSTIC ANALYZER INTENDED TO BE USED FOR THE MEASUREMENT OF PH, BLOOD GAS (PCO2, PO2), ELECTROLYTE(CNA+ CK+, CCA2+, CCL-) AND HEMATOCRIT(HCT) IN THE SAMPLE OF WHOLE BLOOD.THE QUANTITATIVE MEASUREMENT IS BASED ON THE ELECTROCHEMICAL POTENTIAL (ION-SELECTIVE ELECTRODE) AND THE MEASURING CURRENT AND THE CONDUCTIVITY MEASUREMENT

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907	IMP/IVD/2020/000896	1.License Holder Name: PTS DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHOLESTEROL TEST STRIPS(PTS PANELS)-PTS PANELS® CHOLESTEROL TEST STRIPS ARE FOR THE QUANTITATIVE DETERMINATION OF TOTAL CHOLESTEROL IN VENOUS WHOLE BLOOD AND CAPILLARY WHOLE BLOOD FROM THE FINGERTIP. CHOLESTEROL MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF DISORDERS INVOLVING EXCESS CHOLESTEROL IN THE BLOOD AND LIPID AND LIPOPROTEIN METABOLISM DISORDERS. THIS SYSTEM IS INTENDED FOR PROFESSIONAL USE.,TRIGLYCERIDES TEST STRIPS(PTS PANELS)-PTS PANELS® TRIGLYCERIDES TEST STRIPS ARE INTENDED TO MEASURE TRIGLYCERIDE IN WHOLE BLOOD FOR USE IN THE DIAGNOSIS AND TREATMENT OF DIABETES MELLITUS, NEPHROSIS, LIVER OBSTRUCTION, AND OTHER DISEASES INVOLVING LIPID METABOLISM, OR VARIOUS ENDOCRINE DISORDERS. THIS TESTING SYSTEM IS INTENDED FOR PROFESSIONAL USE.,LIPID PANEL TEST STRIP(PTS PANELS)-PTS PANELS® LIPID PANEL TEST STRIPS MEASURE TOTAL CHOLESTEROL, HDL CHOLESTEROL AND TRIGLYCERIDES IN WHOLE BLOOD. LIPID MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIPOPROTEIN METABOLISM AND LIPID DISORDERS (SUCH AS DIABETES MELLITUS), ATHEROSCLEROSIS, AND VARIOUS RENAL AND LIVER DISEASES.,HDL CHOLESTEROL TEST STRIPS(PTS PANELS)-PTS PANELS HDL CHOLESTEROL TEST STRIPS ARE INTENDED TO MEASURE HIGH-DENSITY LIPOPROTEIN (HDL) CHOLESTEROL. LIPOPROTEIN MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIPID DISORDERS (SUCH AS DIABETES MELLITUS), ATHEROSCLEROSIS, AND VARIOUS LIVER AND RENAL DISEASES. THIS SYSTEM IS INTENDED FOR PROFESSIONAL USE.,MULTI-CHEMISTRY CONTROLS(PTS PANELS)-FOR USE WITH PTS PANELS® PROFESSIONAL TEST STRIPS AS QUALITY CONTROL MATERIALS TO ESTIMATE PRECISION AND TO DETECT SYSTEMATIC ANALYTICAL DEVIATIONS OF YOUR TEST SYSTEM.,EGLU TEST STRIPS(PTS PANELS)-THE CARDIOCHEK PLUS GLUCOSE TEST SYSTEM IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN WHOLE BLOOD FOR USE BY HEALTHCARE PROFESSIONALS. GLUCOSE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CARBOHYDRATE METABOLISM DISORDERS INCLUDING DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, AND IDIOPATHIC HYPOGLYCEMIA, AND OF PANCREATIC ISLET CELL CARCINOMA.,HDL CHOLESTEROL CONTROLS(PTS PANELS)-FOR USE WITH PTS PANELS® PROFESSIONAL TEST STRIPS AS QUALITY CONTROL MATERIALS TO ESTIMATE PRECISION AND TO DETECT

		SYSTEMATIC ANALYTICAL DEVIATIONS OF YOUR TEST SYSTEM.
908	IMP/IVD/2020/000897	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(OMNITEST 3)-OMNITEST® 3 TEST STRIPS ARE ONLY TO BE USED WITH OMNITEST® 3 BLOOD GLUCOSE METER FOR THE QUANTITATIVELY MEASUREMENT OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD. OMNITEST® 3 COULD BE USED FOR SELF-MONITORING OF BLOOD GLUCOSE LEVEL BY DIABETES PATIENTS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

909	IMP/IVD/2020/000905	1.License Holder Name: DIAGNOSTIC BIOSYSTEMS (INDIA) 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ZYTOLIGHT FISH-TISSUE IMPLEMENTATION KIT-THE ZYTOLIGHT FISH-TISSUE IMPLEMENTATION KIT IS INTENDED TO BE USED IN COMBINATION WITH ZYTOLIGHT FISH PROBES FOR THE DETECTION OF GENETIC ABERRATIONS, E.G., TRANSLOCATIONS, DELETIONS, AMPLIFICATIONS, AND CHROMOSOMAL ANEUPLOIDIES, IN FORMALIN-FIXED, PARAFFIN-EMBEDDED SPECIMENS BY FLUORESCENCE IN SITU HYBRIDIZATION (FISH).,ZYTOLIGHT SPEC ERBB2/CEN17 DUAL COLOR PROBE KIT-THE ZYTOLIGHT SPEC ERBB2/CEN 17 DUAL COLOR PROBE KIT IS INTENDED TO BE USED FOR THE QUALITATIVE DETECTION OF HUMAN ERBB2 GENE AMPLIFICATIONS AS WELL AS THE DETECTION OF CHROMOSOME 17 ALPHA SATELLITES IN FORMALIN-FIXED, PARAFFIN-EMBEDDED SPECIMENS SUCH AS HUMAN BREAST CANCER OR GASTRIC CANCER TISSUES BY FLUORESCENCE IN SITU HYBRIDIZATION (FISH)., ZYTOFAST PLUS CISH IMPLEMENTATION KIT HRP-DAB-THE ZYTOFAST PLUS CISH IMPLEMENTATION KIT HRP-DAB IS INTENDED TO BE USED IN COMBINATION WITH DIGOXIGENIN-LABELED ZYTOFAST PROBES FOR THE QUALITATIVE DETECTION AND DISCRIMINATION OF HUMAN PATHOGEN VIRUSES, E.G., HPV, EBV, CMV, AND THE DETERMINATION OF LYMPHOCYTE CLONALITY BY DETECTING IG-KAPPA () AND IG-LAMBDA () LIGHT CHAIN MRNA IN FORMALIN-FIXED, PARAFFIN-EMBEDDED SPECIMENS BY CHROMOGENIC IN SITU HYBRIDIZATION (CISH).,ZYTOLIGHT GLIOMA 1P/19Q PROBE SET-THE ZYTOLIGHT GLIOMA 1P/19Q PROBE SET IS INTENDED TO BE USED FOR THE QUALITATIVE DETECTION OF DELETIONS INVOLVING THE HUMAN CHROMOSOMAL REGION 1P36.31 AS WELL AS DELETIONS INVOLVING THE HUMAN CHROMOSOMAL REGION 19Q13.32-Q13.33 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED SPECIMENS BY FLUORESCENCE IN SITU HYBRIDIZATION (FISH), ZYTOLIGHT ANEUPLOIDY PANEL X/Y AND 13/18/21-THE ZYTOLIGHT ANEUPLOIDY PANEL X/Y AND 13/18/21 IS INTENDED TO BE USED FOR THE QUALITATIVE DETECTION OF ALPHA SATELLITES OF CHROMOSOME X AND THE CLASSICAL SATELLITES III OF CHROMOSOME Y AS WELL AS ALPHA SATELLITES OF CHROMOSOME 18 AND HUMAN CHROMOSOME 13 AND 21 SPECIFIC SEQUENCES IN CYTOLOGIC OR FORMALIN-FIXED, PARAFFIN-EMBEDDED SPECIMENS BY FLUORESCENCE IN SITU HYBRIDIZATION (FISH).

910	IMP/IVD/2020/000910	1.License Holder Name: DIAGNOSTIC BIOSYSTEMS USA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BUFFER SOLUTION(10X CITRATE BUFFER)-FOR IN VITRO DIAGNOSTIC USE,10X CITRATE BUFFER FOR HEAT INDUCED EPITOPE RECOVERY.,MOUSE MONOCLONAL ANTIBODIES-S 100(S-100)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALINFIXED, PARAFFIN EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. THIS ANTIBODY IS SPECIFIC AGAINST AN EPITOPE LOCATED ON THE CHAIN,MOUSE MONOCLONAL ANTIBODIES-TTF-1 (THYROID TRANSCRIPTION FACTOR-1))(TTF-1 (THYROID TRANSCRIPTION FACTOR-1))-THIS PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALINFIXED, PARAFFIN EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON (S) WHEN EVALUATING AND INTERPRETING RESULTS. THIS ANTIBODY IS SPECIFIC TO A 40 KDA PROTEIN, WHICH IS IDENTIFIED AS THYROID TRANSCRIPTION FACTOR (TTF1). TTF1 IS EXPRESSED IN EPITHELIAL CELLS OF THE THYROID GLAND AND LUNG. TTF1 STAINS PRIMARY LUNG ADENOCARCINOMA AND SMALL CELL CARCINOMA BUT DOES NOT STAIN COLON AND BREAST CARCINOMA.,MOUSE MONOCLONAL ANTIBODIES-DOG1(DOG1)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALIN-¬FIXED, PARAFFIN-¬ EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. DOG1 MAY AID IN THE DIAGNOSIS OF GASTROINTESTINAL STROMAL TUMORS, INCLUDING PDGFRA MUTANTS THAT FAIL TO EXPRESS CKIT ANTIGEN, AND LEAD TO APPROPRIATE TREATMENT WITH IMATINIB MESYLATE, AN INHIBITOR OF THE CKIT TYROSINE KINASE.,MONOCLONAL

	ANTIBODIES-CYTOKERATIN(CYTOKERATIN)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALIN-FIXED,PARAFFIN EMBEDDED TISSUE SECTIONS TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. AE1/AE3 IS A BROAD SPECTRUM ANTI PAN-¬KERATIN ANTIBODY COCKTAIL, WHICH DIFFERENTIATES EPITHELIAL TUMORS FROM NON-¬EPITHELIAL TUMORS E.G. SQUAMOUS VS. ADENOCARCINOMA OF THE LUNG, LIVER CARCINOMA, BREAST CANCER, AND ESOPHAGEAL CANCER., MONOCLONAL ANTIBODIES-P53(P53)-THIS PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. THIS ANTIBODY REACTS WITH THE MUTANT AS WELL AS THE WILD FORM OF P53. ITS EPITOPE MAPS WITHIN N-TERMINUS (AA 37-45) OF P53. P53 IS A TUMOR SUPPRESSOR GENE EXPRESSED IN A WIDE VARIETY OF TISSUE TYPES AND IS INVOLVED IN CELL GROWTH, REPLICATION, AND APOPTOSIS.,BUFFER SOLUTION(IMMUNO WASH BUFFER, 10X)-FOR IN VITRO DIAGNOSTIC USE, IMMUNO WASH BUFFER, 10X IS SPECIFICALLY DESIGNED TO REMOVE LOOSELY BOUND ANTIBODIES EFFECTIVELY AND EFFICIENTLY AND TO PROVIDE CLEANER BACKGROUND STAINING.,MONOCLONAL ANTIBODIES-OCT-3/4(OCT-3/4)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALINFIXED, PARAFFIN EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. OCT-3/4 (ALSO KNOWN AS POU5F1) IS A TRANSCRIPTION FACTOR THAT HAS BEEN RECOGNIZED AS FUNDAMENTAL IN THE MAINTENANCE OF PLURIPOTENCY IN EMBRYONIC STEM CELLS AND PRIMORDIAL GERM CELLS. IT HAS BEEN PROPOSED AS A USEFUL MARKER FOR GERM CELL TUMORS,MONOCLONAL ANTIBODIES-EGFR

	(EGFR)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALINFIXED, PARAFFIN EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. THIS ANTIBODY IS SPECIFIC TO A 170 KDA PROTEIN. EGF-RECEPTOR IS A MEMBER OF THE TYPE I FAMILY OF GROWTH FACTOR RECEPTORS. THE ANTIBODY RECOGNIZES AN EPITOPE MAPPING IN THE EXTRACELLULAR DOMAIN OF EGFR. OVEREXPRESSION OF EGFR HAS BEEN REPORTED IN TUMORS OF BREAST, BRAIN, BLADDER, LUNG, STOMACH, HEAD AND NECK, ESOPHAGUS, CERVIX, VULVA, OVARY AND ENDOMETRIUM. EGFR IS OVER EXPRESSED IN SQUAMOUS CELL CARCINOMA.,MOUSE MONOCLONAL ANTIBODIES-BCL-2 ONCOPROTEIN(BCL-2 ONCOPROTEIN)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALIN-¬FIXED, PARAFFIN-¬ EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON (S) WHEN EVALUATING AND INTERPRETING RESULTS. THIS ANTIBODY RECOGNIZES A PROTEIN OF 25-¬26KDA, IDENTIFIED AS BCL-¬2 ALPHA ONCOPROTEIN,MOUSE MONOCLONAL ANTIBODIES-CYTOKERATIN 19(CYTOKERATIN 19)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALINFIXED, PARAFFIN EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. ANTI-CK19 IS A USEFUL MARKER FOR DETECTION OF TUMOR CELLS IN LYMPH NODES, PERIPHERAL BLOOD, BONE MARROW AND BREAST CANCER, MONOCLONAL ANTIBODIES-P16(P16)-THIS PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS'

	CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. P16 IS A MITOTIC INHIBITOR PROTEIN. IT COMPETES WITH D-TYPE CYCLINS TO BIND TO CDK4 AND CDK6. IT ACTS AS TUMOR SUPPRESSOR AND INHIBITS THE PROGRESSION OF CELLS THROUGH THE G1 PHASE OF THE CELL CYCLE,BUFFER SOLUTION(10X TRIS-EDTA RETRIEVAL BUFFER)-FOR IN VITRO DIAGNOSTIC USE, 10X TRIS-EDTA RETRIEVAL BUFFER BUFFER FOR HEAT INDUCED EPITOPE RECOVERY.,MONOCLONAL ANTIBODIES-CYTOKERATIN 20(CYTOKERATIN 20)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALINFIXED, PARAFFIN EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. THIS ANTIBODY REACTS WITH CYTOKERATIN POLYPEPTIDE OF 46 KDA IN IMMUNOBLOT ANALYSES,RABBIT MONOCLONAL ANTIBODIES-SYNAPTOPHYSIN (SYNAPTOPHYSIN)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALINFIXED, PARAFFIN EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. THIS ANTIBODY RECOGNIZES A PROTEIN OF 38KDA, IDENTIFIED AS SYNAPTOPHYSIN. IT LABELS NORMAL NEUROENDOCRINE CELLS OF HUMAN ADRENAL MEDULLA, CAROTID BODY, SKIN, PITUITARY GLAND, THYROID, LUNG, PANCREAS, GASTROINTESTINAL MUCOSA, PANETH'S CELLS IN THE GASTROINTESTINAL TRACT AND GASTRIC PARIETAL CELLS,RABBIT MONOCLONAL ANTIBODIES -KI-67 ANTIGEN(KI-67 ANTIGEN)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON (S) WHEN EVALUATING AND INTERPRETING RESULTS. KI67 IS A NUCLEAR PROTE N, WHICH IS EXPRESSED IN PROLIFERATING CELLS.

	KI67 IS PREFERENTIALLY EXPRESSED DURING LATE G1, S, M, AND G2PHASES OF THE CELL CYCLE, WHILE CELLS IN THE 0 (QUIESCENT) PHASE ARE NEGATIVE FOR THIS PROTEIN.,RABBIT MONOCLONAL ANTIBODIES-ESTROGEN(ESTROGEN RECEPTOR(ER))-THIS PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. THIS ANTIBODY RECOGNIZES A PROTEIN OF 67KDA, WHICH IS IDENTIFIED AS ESTROGEN RECEPTOR (ER). ER CONTENT OF BREAST CANCER TISSUE IS AN IMPORTANT PARAMETER IN THE PREDICTION OF PROGNOSIS AND RESPONSE TO ENDOCRINE THERAPY,MOUSE MONOCLONAL ANTIBODIES-GATA3(GATA3)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALIN-¬FIXED, PARAFFIN-¬ EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. GATA3 BINDING PROTEIN 3 OR GATA3 EXPRESSION IS PRIMARILY SEEN IN BREAST CARCINOMA AND UROTHELIAL CARCINOMA,MOUSE MONOCLONAL ANTIBODIES-VIMENTIN(VIMENTIN)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALINFIXED, PARAFFIN EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. THIS ANTIBODY REACTS WITH THE 57 KDA INTERMEDIATE FILAMENT PROTEIN PRESENT IN THE CELLS OF MESENCHYMAL ORIGIN,MOUSE MONOCLONAL ANTIBODIES-CYTOKERATIN 7(CYTOKERATIN 7)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALINFIXED, PARAFFIN EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS'

	CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. CYTOKERATIN 7 IS USEFUL IN DISTINGUISHING OVARIAN CARCINOMAS,RABBIT MONOCLONAL ANTIBODIES-P63(P63)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALINFIXED, PARAFFIN EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. P63 IS A HOMOLOG OF THE TUMOR SUPPRESSOR P53, IT IS IDENTIFIED IN BASAL CELLS IN THE EPITHELIAL LAYERS OF A VARIETY OF TISSUES, INCLUDING EPIDERMIS, CERVIX, UROTHELIUM, BREAST AND PROSTATE. P63, VITAL FOR THE DEVELOPMENT OF THE PROSTATE AND SELECTIVELY EXPRESSED BY NORMAL PROSTATE BASAL CELLS, HAS BEEN SHOWN TO BE A PROMISING COMPLEMENTARY BASAL CELL SPECIFIC MARKER TO HIGH MOLECULAR WEIGHT-CYTOKERATIN (HMW-CK), FOR THE DIFFERENTIAL DIAGNOSIS OF BENIGN PROSTATIC LESIONS AND PROSTATIC CARCINOMA. P63 HAS ALSO BEEN SHOWN TO BE A SENSITIVE MARKER FOR LUNG SQUAMOUS CELL CARCINOMAS (SQCC), WITH A SENSITIVITY OF ~90% . SPECIFICITY FOR LUNG SQCC, VS. LUNG ADENOCARCINOMA (LADC), IS APPROXIMATELY 80. IN BREAST TISSUE, P63 HAS BEEN IDENTIFIED IN MYOEPITHELIAL CELLS OF NORMAL DUCTS,DAB DETECTION KIT(POLYVUE™ PLUS)-THE MOUSE/RABBIT POLYVUE PLUS™ HRP/DAB DETECTION SYSTEM IS A NONBIOTIN, TWOSTEP DETECTION SYSTEM SUITABLE FOR LABELING ANTIGENS IN FORMALINFIXED PARAFFINEMBEDDED TISSUES AND CRYOSTAT SECTIONS. THE POLYVUE PLUS™ DETECTION SYSTEM MAY ALSO BE USED WITH BLOOD SMEARS, CYTO SMEARS, AND CELL PREPARATIONS. THIS SYSTEM HAS BEEN DEVELOPED BY DIRECTLY LABELING IMMUNOGLOBULIN'S WITH ENZYMES USING A PROPRIETARY TANDEM HYPER-LABELLING TECHNOLOGY. THIS ENSURES CONSISTENT AND REPRODUCIBLE IMMUNE-STAINING FOR ALL TYPES OF NUCLEAR, CYTOPLASMIC AND MEMBRANE ANTIGENS IN DIFFERENT TYPES OF TISSUES WITH SIGNIFICANTLY LOWER BACKGROUND THAN DETECTION SYSTEMS USING BIOTIN AND AVIDIN CONJUGATES. THE MOUSE/RABBIT POLYVUE PLUS™ HRP/DAB DETECTION SYSTEM CAN SIMULTANEOUSLY DETECT BOTH MOUSE AND RABBIT ANTIBODIES. THIS SYSTEM IS SUITABLE FOR USE WITH MOUSE IGG, IGM AND RABBIT PRIMARY ANTIBODIES, BOTH MONOCLONAL AND

	POLYCLONAL. THIS DETECTION SYSTEM CAN BE USED FOR MANUAL OR AUTOMATED STAINING. THE INCREASED SENSITIVITY OF THE MOUSE/RABBIT POLYVUE PLUS™ HRP/DAB DETECTION SYSTEM ENABLES FASTER STAINING PROCEDURES WITHOUT COMPROMISING RESULTS. THE USER MAY NEED TO FURTHER DILUTE PRIMARY ANTIBODY DUE TO THE SUPERIOR SENSITIVITY OF THE POLYVUE PLUS™ DETECTION SYSTEM.,RABBIT MONOCLONAL ANTIBODIES-PROGESTERONE RECEPTOR(PROGESTERONE RECEPTOR(PR))-THIS PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON (S) WHEN EVALUATING AND INTERPRETING RESULTS. THE PROGESTERONE RECEPTOR (PGR) IS AN ESTROGEN-REGULATED PROTEIN. IT HAS BEEN PROPOSED THAT EXPRESSION OF PGR INDICATES A RESPONSIVE ESTROGEN RECEPTOR (ER) PATHWAY, MONOCLONAL ANTIBODIES-EPSTEIN-BARR VIRUS(EPSTEIN-BARR VIRUS)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALINFIXED, PARAFFIN EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. THIS ANTIBODY IS SPECIFIC TO 60 KDA LATENT MEMBRANE PROTEIN (LMP-1) ENCODED BY THE BNLF1 GENE OF THE EBV. EACH CLONE REACTS WITH DIFFERENT EPITOPES ON THE HYDROPHILIC C-TERMINUS OF THE CYTOPLASMIC DOMAIN OF LMP- 1. THIS ANTIBODY STAINS STRONGLY WITH EBV POSITIVE LYMPHOBLASTOID CELL LINES AND EBV INFECTED B CELL IMMUNOBLASTS IN INFECTIOUS MONONUCLEOSIS.,MOUSE MONOCLONAL ANTIBODIES-ACTIN ALPHA SMOOTH MUSCLE(ACTIN, -SMOOTH MUSCLE)-THIS PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALIN-FIXED, PARAFFIN- EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING

	RESULTS. THIS ANTIBODY IS SPECIFIC TO ACTIN FROM SMOOTH MUSCLES,RABBIT MONOCLONAL ANTIBODIES-HER 2(HER 2)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON (S) WHEN EVALUATING AND INTERPRETING RESULTS. THIS ANTIBODY RECOGNIZES A C-ERBB-2 PROTEIN, WHICH IS A RECEPTOR TYROSINE KINASE OF THE C-ERBB FAMILY,MOUSE MONOCLONAL ANTIBODIES-CD56(CD56)-THIS PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALINFIXED, PARAFFIN EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. THIS ANTIBODY IS SPECIFIC TO TWO PROTEINS OF 185 KDA AND 145 KDA, IDENTIFIED AS TWO ISOFORMS OF NEURAL CELL ADHESION MOLECULES (NCAM/CD56). NCAM IS EXPRESSED ON MOST NEUROECTODERMAL DERIVED CELL LINES, TISSUES AND NEOPLASMS SUCH AS RETINOBLASTOMA, MEDULLOBLASTOMA, ASTROCYTOMA AND NEUROBLASTOMA,MOUSE MONOCLONAL ANTIBODIES-GALECTIN 3 (GALECTIN-3)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALINFIXED, PARAFFIN EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. GALECTINS ARE A FAMILY OF SOLUBLE -GALACTOSIDE-BINDING ANIMAL LECTINS THAT MODULATE CELL-TO-CELL ADHESION AND CELL-TO-EXTRACELLULAR MATRIX (ECM) INTERACTIONS AND PLAY A ROLE IN TUMOR PROGRESSION, PRE-MRNA SPLICING AND APOPTOSIS.,MOUSE MONOCLONAL ANTIBODIES-DESMIN(DESMIN)-THE PRODUCT IS INTENDED FOR QUALITATIVE IMMUNOHISTOCHEMISTRY WITH NORMAL AND NEOPLASTIC FORMALINFIXED, PARAFFIN EMBEDDED TISSUE SECTIONS, TO BE VIEWED BY LIGHT MICROSCOPY. CLINICAL

		INTERPRETATION OF STAINING RESULTS SHOULD BE ACCOMPANIED BY HISTOLOGICAL STUDIES WITH PROPER CONTROLS. PATIENTS' CLINICAL HISTORIES AND OTHER RELEVANT DIAGNOSTIC TESTS SHOULD BE UTILIZED BY A QUALIFIED PERSON(S) WHEN EVALUATING AND INTERPRETING RESULTS. THIS ANTIBODY REACTS WITH DESMIN PROTEIN OF 53 KDA.
911	IMP/IVD/2020/000911	1.License Holder Name: HEIDELCO MEDICORE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CARDIAC TROPONIN I (GETE IN)-AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY AND ACUTE MYOCARDIAL SYNDROME (ACS),T4(GETE IN)-THYROID FUNCTION MONITORING,HIGH SENSITIVITY C- REACTIVE PROTEIN (HS- CRP)(GETE IN)-AS AN AID IN THE EVALUATION OF MYOCARDIAL INJUR AMI;ACS,25-OH-VD(GETE IN)-BONE TURNOVER MARKER, MICROALBUMI NURIA (MALB)(GETE IN)-AS AN AID IN THE DIAGNOSIS OF KIDNEY DISEASES,TSH(GETE IN)-THYROID FUNCTION MONITORING,NEUTROPHILS GELATINASE ASSOCIATED LIPOCALIN (NGAL)-AS AN AID IN THE EARLY DIAGNOSIS OF ACUTE KIDNEY INJURY,HCG+(GETE IN)-PREGNANCY MONITORING,BETA 2 – MICROGLOBULI N (2-MG)(GETE IN)-AS AN AID THE DETECTION OF GLOMERULAR FILTRATION RATE,HBA1C(GETE IN)-DIABETES MONITORING.,CREATINE KINASE- MB/CARDIAC TROPONIN I/MYOGLOBIN(GETE IN)-AS AN AID IN THE EVALUATION OF MYOCARDIAL INJUR AMI;ACS,PROCALCITONIN (PCT)(GETE IN)-AS AN AID IN THE DETECTION AND EVALUATION OF INFECTION,N-TERMINAL PROHORMONE OF BRAIN NATRIURETIC PEPTIDE (NT-PROBNP)(GETE IN)-AS AN AID IN THE CLINICAL DIAGNOSIS, OF HEART FAILURE, CYSTATIN C (CYSC)(GETE IN)-AS AN AID THE ASSESSMENT AND EVALUATION OF INDEX OF GLOMERULAR FILTRATION RATE,T3(GETE IN)-THYROID FUNCTION MONITORING,D-DIMER(GETE IN)-RAPID SCREENING FOR DVT & PE
912	IMP/IVD/2020/000912	1.License Holder Name: DSS TAKARA BIO INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NUCLEOMAG® VIRUS (NUCLEOMAG® VIRUS)-NUCLEOMAG® VIRUS KIT COMPONENTS ARE INTENDED, DEVELOPED, DESIGNED, AND SOLD FOR RESEARCH PURPOSES ONLY,NUCLEOSPIN® VIRUS RNA -NUCLEOSPIN® VIRUS KIT IS A GENERIC SYSTEM FOR THE ISOLATION AND PURIFICATION OF VIRAL NUCLEIC ACIDS FROM HUMAN SERUM OR PLASMA SAMPLES FOR SUBSEQUENT IN-VITRO DIAGNOSTIC PURPOSES.

913	IMP/IVD/2020/000913	1.License Holder Name: KIN DIAGNOSTICS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROLS(EDAN)-CONTROLS ARE INTENDED FOR USE TO MONITOR TEST CARTRIDGE PERFORMANCE AT MULTIPLE POINTS.,TEST CARTRIDGE(EDAN)-THE TEST CARTRIDGE ARE INTENDED TO USE WITH EDAN I15 BLOOD GAS AND CHEMISTRY ANALYSIS SYSTEM. EACH DISPOSABLE CARTRIDGE ANALYZE BLOOD SAMPLE AND GIVE REPORT IN TERMS OF BLOOD ELECTROLYTES, BLOOD GASES AND BLOOD CHEMICALS, ETC, CALIBRANT FLUID PACK(EDAN)-CALIBRANT FLUID PACK CONTAIN CALIBRANT SOLUTION AND INTENDED TO BE USED TOGETHER WITH EDAN I15 BLOOD GAS AND CHEMISTRY ANALYSIS SYSTEM TO PERFORM SENSOR/CARTRIDGE CALIBRATION.
914	IMP/IVD/2020/000914	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CELL-DYN EMERALD 22 LYSE(CELL-DYN EMERALD 22 LYSE)-LYSING AGENT FOR THE CELL-DYN EMERALD 22 SYSTEM AND THE CELL-DYN EMERALD 22 AL (AUTOLOADER) SYSTEM.

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915	IMP/IVD/2020/000921	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTICHEM U LEVEL 1 (MULTICHEM U LEVEL 1)-MULTICHEM U IS INTENDED FOR USE AS A URINE QUALITY CONTROL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT. TWO LEVELS OF CONTROLS (LEVEL 1 AND LEVEL 2) ARE SUPPLIED IN LIQUID FORM.,MULTICHEM IA PLUS (MULTICHEM IA PLUS)-MULTICHEM IA PLUS IS INTENDED FOR USE AS A QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES: ALPHA FETOPROTEIN, BNP, CA 125 , CA 15-3 , CA 19-9 , CARBAMAZEPINE, CARCINOGENIC EMBRYONIC ANTIGEN, CK-MB, CORTISOL, C-PEPTIDE, DHEA SULFATE, DIGOXIN, ESTRADIOL, FERRITIN, FOLATE, FOLLICLE STIMULATING HORMONE, GENTAMICIN, HOMOCYSTEINE, HUMAN CHORIONIC GONADOTROPIN, INSULIN, LEUTINIZING HORMONE, MYOGLOBIN, PHENOBARBITAL, PHENYTOIN, PROGESTERONE, PROLACTIN, PROSTATE SPECIFIC ANTIGEN, TOTAL, PTH INTACT, TESTOSTERONE, THEOPHYLLINE, THYROID STIMULATING HORMONE, THYROXINE, FREE (FREE T4), TRIIODOTHYRONINE, FREE (FREE T3), TROPONIN I, VALPROIC ACID, VANCOMYCIN, VITAMIN B12, ANTI – TPO, ANTI-THYROGLOBULIN, SHBG, PSA (FREE), T UPTAKE, T3 (TOTAL), T4 (TOTAL), 25OH VITAMIN D, IGE, ACETOMINOPHEN, ACTH, ANDROSTENEDIONE, AMIKACIN, CALCITONIN, HUMAN GROWTH HORMONE, IGF-1, LITHIUM, SALICYLATE, THYROGLOBULIN, TOBRAMYCIN, ESTRIOL, FREE, EPO, NT PRO BNP, TROPONIN T, 17-OH PROGESTERONE, ALDOSTERONE, THYROXINE BINDING GLOBULIN CAFFEINE, CHLORAMPHENICOL, CYCLOSPORINE, DISOPYRAMIDE, ETHOSUXIMIDE, IBUPROFEN, LIDOCAINE, N-ACETYL PROCAINAMIDE, PRIMIDONE, PROCAINAMIDE, QUINIDINE, ANGIOTENSIN, OSTASE, PROCOLLAGEN NP TYPE 1, RENIN, CARBAMAZEPINE, FREE, ESTRIOL, TOTAL, ESTROGEN, TOTAL, PHENYTOIN, FREE, TESTOSTERONE, FREE, VALPROIC ACID, FREE, ULTRASENSITIVE CRP,MULTICHEM U LEVEL 2 (MULTICHEM U LEVEL 2)-MULTICHEM U IS INTENDED FOR USE AS A URINE QUALITY CONTROL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT. TWO LEVELS OF CONTROLS (LEVEL 1 AND LEVEL 2) ARE SUPPLIED IN LIQUID FORM.,MULTICHEM HSTN (MULTICHEM HSTN)-MULTICHEM HSTN IS INTENDED FOR USE AS A SINGLE LEVEL QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF HIGHLY SENSITIVE TROPONIN APPLICATIONS ON AUTOMATED ANALYSERS FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,MULTICHEM S PLUS LEVEL 1(MULTICHEM S PLUS LEVEL 1)-MULTICHEM S PLUS IS INTENDED FOR USE AS A QUALITY

		CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,MULTICHEM S PLUS LEVEL 3(MULTICHEM S PLUS LEVEL 3)-MULTICHEM S PLUS IS INTENDED FOR USE AS A QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT., MULTICHEM S PLUS LEVEL 2(MULTICHEM S PLUS LEVEL 2)-MULTICHEM S PLUS IS INTENDED FOR USE AS A QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.
916	IMP/IVD/2020/000922	1.License Holder Name: PHARMALEAF INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(GLUCOME™)-THE GLUCOME™ BLOOD GLUCOSE MONITORING SYSTEM IS DESIGNED FOR SELF-TESTING BLOOD GLUCOSE USING FRESH WHOLE CAPILLARY BLOOD. THIS SYSTEM IS INTENDED TO USE ONLY WITH GLUCOME™ BLOOD GLUCOSE TEST STRIPS AND OUTSIDE OF THE BODY (IN VITRO DIAGNOSTIC USE). THIS SYSTEM SHOULD NOT BE USED FOR DIAGNOSIS OF DIABETES.

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917	IMP/IVD/2020/000925	1.License Holder Name: WHEECON INSTRUMENTS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADP(CHRONO-PAR)-FOR MEASURING PLATELET AGGREGATION AND ATP SECRETION IN WHOLE BLOOD OR PLATELET RICH PLASMA,CHRONO-LUME (CHRONO-PAR)-FOR MEASURING PLATELET AGGREGATION AND ATP SECRETION IN WHOLE BLOOD OR PLATELET RICH PLASMA,ATP (CHRONO-PAR)-FOR MEASURING PLATELET AGGREGATION AND ATP SECRETION IN WHOLE BLOOD OR PLATELET RICH PLASMA, RISTOCETIN COFACTOR ASSAY(CHRONO-PAR)-FOR USE IN THE QUANTITATIVE DETERMINATION OF FACTOR VIII RISTOCETIN COFACTOR ACTIVITY IN CITRATED PLASMA,EPINEPHRINE(CHRONO-PAR)-FOR MEASURING PLATELET AGGREGATION AND ATP SECRETION IN WHOLE BLOOD OR PLATELET RICH PLASMA, ARACHIDONIC ACID(CHRONO-PAR)-FOR MEASURING PLATELET AGGREGATION AND ATP SECRETION IN WHOLE BLOOD OR PLATELET RICH PLASMA,COLLAGEN(CHRONO-PAR)-FOR MEASURING PLATELET AGGREGATION AND ATP SECRETION IN WHOLE BLOOD OR PLATELET RICH PLASMA,RISTOCETIN(CHRONO-PAR)-FOR MEASURING PLATELET AGGREGATION AND ATP SECRETION IN WHOLE BLOOD OR PLATELET RICH PLASMA,THROMBIN(CHRONO-PAR)-FOR MEASURING PLATELET AGGREGATION AND ATP SECRETION IN WHOLE BLOOD OR PLATELET RICH PLASMA

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918	IMP/IVD/2020/000926	1.License Holder Name: SD BIOSENSOR HEALTHCARE PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANIGEN RAPID CPV/CCV AG TEST KIT(NA)-THE ANIGEN RAPID CPV/CCV AG TEST KIT IS A CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF CANINE PARVOVIRUS ANTIGEN AND CORONAVIRUS ANTIGEN IN CANINE FECES.,ANIGEN RAPID CPV AG TEST KIT(NA)-THE ANIGEN RAPID CPV AG TEST KIT IS A CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF CANINE PARVOVIRUS ANTIGEN IN CANINE FECES.,ANIGEN RAPID CANIV-4 TEST KIT(NA)-THE ANIGEN RAPID CANIV-4 TEST KIT IS A CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF DIROFILARIA IMMITIS ANTIGEN, EHRLICHIA CANIS ANTIBODY, BORRELIA BURGDORFERI ANTIBODY AND ANAPLASMA PHAGOCYTOPHILUM/ANAPLASMA PLATYS ANTIBODY IN CANINE SERUM, PLASMA OR WHOLE BLOOD,ANIGEN RAPID CDV AG TEST KIT (NA)-THE ANIGEN RAPID CDV AG TEST KIT IS A CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF CANINE DISTEMPER VIRUS ANTIGEN IN CONJUNCTIVA, URINE, SERUM OR PLASMA.,ANIGEN RAPID E. CANIS AB TEST KIT(NA)-THE ANIGEN RAPID E. CANIS AB TEST KIT IS A CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF EHRLICHIA CANIS ANTIBODIES IN CANINE WHOLE BLOOD, SERUM OR PLASMA.,ANIGEN RAPID RABIES AG TEST KIT(NA)-ANIGEN RAPID RABIES AG TEST KIT IS A CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF RABIES VIRUS ANTIGEN IN FRESH BRAIN TISSUE OF CANINE, BOVINE OR RACCOON DOG.

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919	IMP/IVD/2020/000929	1.License Holder Name: EROTH TECHNOLOGIES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MASSCHECK® IMMUNOSUPPRESSANTS WHOLE BLOOD CONTROL LEVEL I (MASSCHECK® IMMUNOSUPPRESSANTS WHOLE BLOOD CONTROL LEVEL I)-QUALITY CONTROL SAMPLE FOR LC-MS/MS,MOBILE PHASE A MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD(MOBILE PHASE A MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-MOBILE PHASE FOR LC-MS/MS USED WITH THE 93000 & 93000/1200 KIT,MASSCHECK® IMMUNOSUPPRESSANTS WHOLE BLOOD CONTROL LEVEL II(MASSCHECK® IMMUNOSUPPRESSANTS WHOLE BLOOD CONTROL LEVEL II)-QUALITY CONTROL SAMPLE FOR LC-MS/MS, MASSCHECK® IMMUNOSUPPRESSANTS WHOLE BLOOD CONTROL FOUR-LEVEL (I+II+III+IV)(MASSCHECK® IMMUNOSUPPRESSANTS WHOLE BLOOD CONTROL FOUR-LEVEL (I+II+III+IV))-QUALITY CONTROL SAMPLE FOR LC-MS/MS,MASSCHECK® IMMUNOSUPPRESSANTS WHOLE BLOOD CONTROL LEVEL IV (MASSCHECK® IMMUNOSUPPRESSANTS WHOLE BLOOD CONTROL LEVEL IV)-QUALITY CONTROL SAMPLE FOR LC-MS/MS,LC-MS/MS REAGENT KIT INCLUDING STEROID 96 SPE WELL PLATE MASSCHROM STEROIDS IN SERUM/PLASMA(LC-MS/MS REAGENT KIT INCLUDING STEROID 96 SPE WELL PLATE MASSCHROM STEROIDS IN SERUM/PLASMA)-THIS REAGENT KIT IS USED FOR THE QUANTITATIVE DETECTION OF ALDOSTERONE, CORTISOL, CORTISONE, CORTI-COSTERONE, 11-DEOXYCORTISOL, ANDROSTENEDIONE, DEHYDROEPIANDROSTERONE (DHEA), DEHYDRO-EPIANDRO-STERONE SULFATE (DHEAS), DIHYDRO-TESTOSTERONE, ESTRADIOL, 17-HYDROXYPROGESTERONE, PROGESTERONE AND TESTOSTERONE IN PATIENT SERUM AND PLASMA SAMPLES VIA LC-MS/MS (LIQUID CHROMATOGRAPHY-MASS SPECTROMETRY). THE KIT IS INTENDED AS A TEST FOR PATIENTS REQUIRING MONITORING OF THE RELEVANT STEROID HORMONE LEVELS,TUNING MIX MASSTOX® IMMUNOSUPPRESSANTS ANALYTES AND INTERNAL STANDARDS(TUNING MIX MASSTOX® IMMUNOSUPPRESSANTS ANALYTES AND INTERNAL STANDARDS)-ACCESSORY FOR THE TUNING OF LC-MS/MS INSTRUMENTS FOR THE ANALYSIS OF IMMUNOSUPPRESSANTS,6PLUS1® MULTILEVEL WHOLE BLOOD CALIBRATOR SET MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD(6PLUS1® MULTILEVEL WHOLE BLOOD CALIBRATOR SET MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-USED FOR CALIBRATION OF THE INSTRUMENT (= LC-MS/MS),TRAP COLUMN MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD (TRAP COLUMN MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-USED FOR SEPARATION OF IMMUNOSUPPRESSANTS IN

	SAMPLES,TUNING MIX MASSCHROM® STEROID PANEL 1 ANALYTES AND INTERNAL STANDARDS(TUNING MIX MASSCHROM® STEROID PANEL 1 ANALYTES AND INTERNAL STANDARDS)-ACCESSORY FOR THE TUNING OF LC-MS/MS INSTRUMENT FOR THE ANALYSIS OF STEROIDS,RINSING SOLUTION MASSCHROM® STEROIDS IN SERUM/PLASMA(RINSING SOLUTION MASSCHROM® STEROIDS IN SERUM/PLASMA)-NEEDLE RINSING SOLUTION FOR THE INJECTOR, MASSCHECK® STEROID PANEL 2 SERUM CONTROL, LEVEL III (LYOPH.)(MASSCHECK® STEROID PANEL 2 SERUM CONTROL, LEVEL III (LYOPH.))-QUALITY CONTROL SAMPLE FOR LC-MS/MS FOR THE ANALYSIS OF STEROIDS,SYSTEM CHECK SOLUTION MASSCHROM® STEROID PANEL 2(SYSTEM CHECK SOLUTION MASSCHROM® STEROID PANEL 2)-STARTUP ACCESSORY FOR LC-MS/MS STATUS CHECK FOR THE ANALYSIS OF STEROIDS,RINSING SOLUTION MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD(RINSING SOLUTION MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-NEEDLE RINSING SOLUTION FOR THE INJECTOR,SYSTEM CHECK SOLUTION MASSCHROM® STEROID PANEL 1(SYSTEM CHECK SOLUTION MASSCHROM® STEROID PANEL 1)-STARTUP ACCESSORY FOR LC-MS/MS STATUS CHECK FOR THE ANALYSIS OF STEROIDS, ANALYTICAL COLUMN MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD(ANALYTICAL COLUMN MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-USED FOR SEPARATION OF IMMUNOSUPPRESSANTS IN SAMPLES,LC-MS/MS REAGENT KIT MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD(MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD REAGENT KIT FOR LC MS/MS, ANALYSIS OF CYLOSPORINE A, TACROLIMUS, SIROLIMUS & EVEROLIMUS IN WHOLE BLOOD)-THIS REAGENT KIT IS USED FOR THE QUANTITATIVE DETECTION OF CYCLOSPORIN A, EVEROLIMUS, SIROLIMUS (RAPAMYCIN) AND TACROLIMUS (FK-506) IN PATIENT EDTA WHOLE BLOOD SAMPLES VIA LC-MS/MS. IT IS INDICATED AS A MONITORING TEST FOR PATIENTS TREATED WITH IMMUNOSUPPRESSANTS AND AS AN AID TO ENSURE DRUG LEVELS WITHIN THE THERAPEUTIC RANGE,"INTERNAL STANDARD SET MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD "("INTERNAL STANDARD SET MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD ")-USED DURING SAMPLE PREPARATION FOR THE QUANTIFICATION OF IMMUNOSUPPRESSANTS,PRECIPITATION REAGENT MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD (PRECIPITATION REAGENT MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-USED DURING SAMPLE PREPARATION FOR PRECIPITATION OF IMMUNOSUPPRESSANTS,SAMPLE CLEAN UP COLUMNS MASSCHROM® STEROIDS IN SERUM/PLASMA(SAMPLE CLEAN UP COLUMNS MASSCHROM® STEROIDS IN SERUM/PLASMA)-

	USED FOR BINDING AND ELUTION OF STEROIDS,MASSCHECK® STEROID PANEL 1 SERUM CONTROL LEVEL III (LYOPH.)(MASSCHECK® STEROID PANEL 1 SERUM CONTROL LEVEL III (LYOPH.))-QUALITY CONTROL SAMPLE FOR LC-MS/MS FOR THE ANALYSIS OF STEROIDS, EQUILIBRATION REAGENT 1 MASSCHROM® STEROIDS IN SERUM/PLASMA(EQUILIBRATION REAGENT 1 MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED DURING SAMPLE PREPARATION FOR RECONSTITUTION OF STEROIDS TO MAXIMIZE THE RECOVERY AND ACTIVITY.,6PLUS1® MULTILEVEL SERUM CALIBRATOR SET MASSCHROM® STEROID PANEL 1 (LYOPH.)(6PLUS1® MULTILEVEL SERUM CALIBRATOR SET MASSCHROM® STEROID PANEL 1 (LYOPH.)) -USED FOR CALIBRATION OF THE INSTRUMENT (= LC-MS/MS), PIERCEABLE ADHESIVE SEALS MASSCHROM® STEROIDS IN SERUM/PLASMA FOR 96 SPE WELL PLATES(PIERCEABLE ADHESIVE SEALS MASSCHROM® STEROIDS IN SERUM/PLASMA FOR 96 SPE WELL PLATES)-COVERING SHEETS FOR WELL PLATES, RECONSTITUTION BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA(RECONSTITUTION BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED DURING SAMPLE PREPARATION FOR DETERMINATION OF STEROIDS,MASSCHECK® IMMUNOSUPPRESSANTS WHOLE BLOOD CONTROL LEVEL III (MASSCHECK® IMMUNOSUPPRESSANTS WHOLE BLOOD CONTROL LEVEL III)-QUALITY CONTROL SAMPLE FOR LC-MS/MS,ELUTION BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA(ELUTION BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED DURING SAMPLE PREPARATION FOR THE ELUTION OF STEROIDS,INTERNAL STANDARD MIX MASSCHROM® STEROIDS IN SERUM/PLASMA (INTERNAL STANDARD MIX MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED DURING SAMPLE PREPARATION FOR THE QUANTIFICATION OF STEROIDS,MOBILE PHASE B MASSCHROM® STEROIDS IN SERUM/PLASMA(MOBILE PHASE B MASSCHROM® STEROIDS IN SERUM/PLASMA)-MOBILE PHASE FOR LC-MS/MS USED WITH THE 72072/96, 72072/480 OR 72072/C KIT,MOBILE PHASE B MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD(MOBILE PHASE B MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-MOBILE PHASE FOR LC-MS/MS USED WITH THE 93000 & 93000/1200 KIT,MOBILE PHASE A MASSCHROM® STEROIDS IN SERUM/PLASMA (MOBILE PHASE A MASSCHROM® STEROIDS IN SERUM/PLASMA)-MOBILE PHASE FOR LC-MS/MS USED WITH THE 72072/96, 72072/480 OR 72072/C KIT,EXTRACTION BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA(EXTRACTION BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED DURING SAMPLE PREPARATION FOR THE EXTRACTION OF STEROIDS,EQUILIBRATION REAGENT 2 MASSCHROM® STEROIDS IN SERUM/PLASMA(EQUILIBRATION

	REAGENT 2 MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED DURING SAMPLE PREPARATION FOR RECONSTITUTION OF STEROIDS TO MAXIMIZE THE RECOVERY AND ACTIVITY,STEROID COLLECTION PLATES MASSCHROM® STEROIDS IN SERUM/PLASMA(STEROID COLLECTION PLATES MASSCHROM® STEROIDS IN SERUM/PLASMA)-MICROTITTER PLATES FOR COLLECTION OF STEROIDS,WASH BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA(WASH BUFFER MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED FOR WASHING OF STEROID SAMPLES DURING SAMPLE PREPARATION,MASSCHECK® STEROID PANEL 2 SERUM CONTROL LEVEL II (LYOPH.)(MASSCHECK® STEROID PANEL 2 SERUM CONTROL LEVEL II (LYOPH.))-QUALITY CONTROL SAMPLE FOR LC-MS/MS FOR THE ANALYSIS OF STEROIDS, TUNING MIX MASSCHROM® STEROID PANEL 2 ANALYTES AND INTERNAL STANDARDS(TUNING MIX MASSCHROM® STEROID PANEL 2 ANALYTES AND INTERNAL STANDARDS)-ACCESSORY FOR THE TUNING OF LC-MS/MS INSTRUMENTS,6PLUS1® MULTILEVEL SERUM CALIBRATOR SET STEROID PANEL 2 (LYOPH.)(6PLUS1® MULTILEVEL SERUM CALIBRATOR SET STEROID PANEL 2 (LYOPH.))-USED FOR CALIBRATION OF THE INSTRUMENT (= LC-MS/MS),ANALYTICAL COLUMN MASSCHROM® STEROIDS IN SERUM/PLASMA(ANALYTICAL COLUMN MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED FOR SEPARATION OF STEROIDS IN SAMPLES,STEROID 96 SPE WELL PLATE MASSCHROM® STEROIDS IN SERUM/PLASMA(STEROID 96 SPE WELL PLATE MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED FOR BINDING AND ELUTION OF STEROIDS,EXTRACTION BUFFER MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD(EXTRACTION BUFFER MASSTOX® IMMUNOSUPPRESSANTS IN WHOLE BLOOD)-USED DURING SAMPLE PREPARATION FOR EXTRACTION OF ANALYTES,MASSCHECK® STEROID PANEL 2 SERUM CONTROL LEVEL I (LYOPH.)(MASSCHECK® STEROID PANEL 2 SERUM CONTROL LEVEL I (LYOPH.))-QUALITY CONTROL SAMPLE FOR LC-MS/MS FOR THE ANALYSIS OF STEROIDS,WASTE PLATES MASSCHROM® STEROIDS IN SERUM/PLASMA(WASTE PLATES MASSCHROM® STEROIDS IN SERUM/PLASMA)-USED FOR COLLECTION OF WASTE SOLUTIONS DURING SAMPLE PREPARATION,MASSCHECK® STEROID PANEL 1 SERUM CONTROL LEVEL II (LYOPH.)(MASSCHECK® STEROID PANEL 1 SERUM CONTROL LEVEL II (LYOPH.))-QUALITY CONTROL SAMPLE FOR LC-MS/MS FOR THE ANALYSIS OF STEROIDS,MASSCHECK® STEROID PANEL 1 SERUM CONTROL LEVEL I (LYOPH.)(MASSCHECK® STEROID PANEL 1 SERUM CONTROL LEVEL I (LYOPH.))-QUALITY CONTROL SAMPLE FOR LC-MS/MS FOR THE ANALYSIS OF STEROIDS

920	IMP/IVD/2020/000934	1.License Holder Name: VORTEX MEDSOLUTIONS PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PIXO TEST LIPID TEST KIT (PIXO TEST LIPID TEST KIT)-THE PIXOTEST LIPID TEST KIT IS INTENDED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF INTENDED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF TOTAL CHOLESTEROL, TRIGLYCERIDES, AND HIGH-DENSITY LIPOPROTEIN (HDL) CHOLESTEROL IN WHOLE BLOOD. ESTIMATED VALUES FOR LOW-DENSITY LIPOPROTEIN (LDL) CHOLESTEROL IS CALCULATED. THE PIXOTEST LIPID TEST STRIP IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY (OUTSIDE OF THE BODY) AND FOR PROFESSIONAL USE.,PIXO TEST A1C TEST KIT(PIXO TEST A1C TEST KIT)-THE PIXOTEST A1C TEST KIT IS INTENDED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF GLYCATED HEMOGLOBIN (HBA1C) IN HUMAN CAPILLARY OR VENOUS WHOLE BLOOD ON PIXO TEST POCT ANALYZER. THE PIXO TEST A1C TEST KIT IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY (OUTSIDE OF THE BODY) AND FOR PROFESSIONAL USE TO MONITOR GLYCEMIC CONTROL IN PEOPLE WITH DIABETES.

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921	IMP/IVD/2020/000936	1.License Holder Name: ALPS DIAGNOSTICS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QUALITY CONTROL(EDAN (ED-50D HEMATOLOGY CONTROL))-CONTROLS ARE INTENDED TO MONITOR ANALYZER PERFORMANCE AT MULTIPLE POINTS,LYSE (HL310)(EDAN HL310)-THE PRODUCT IS USED FOR LYSING ERYTHROCYTES, COUNTING AND DIFFERENTIATING THE FIVE MAIN LEUKOCYTES SUBPOPULATIONS AND QUANTITATIVE DETERMINATION HEMOGLOBIN IN A BLOOD SAMPLE,CLEANER (HC 310)(EDAN HC310)-HC310 CLEANER APPLIES TO EDAN H30 PRO SERIES HEMATOLOGY ANALYZER. IT IS USED TO CLEAN THE FLUIDIC CHANNELS AND TUBING, AND GET RID OF BLOOD ALBUMIN AND SEDIMENT.,DILUENT (HD310)(EDAN HD310)-THE DILUENT IS INTENDED TO PERFORM ERYTHROCYTES AND PLATELETS MEASUREMENT IN A BLOOD SAMPLE,DILUENT(EDAN (HD300 DILUENT))-THE DILUENT IS INTENDED TO PERFORM ERYTHROCYTES AND PLATELETS MEASUREMENT IN A BLOOD SAMPLE,CALIBRATOR (EDAN (ED-CAL PLUS HEMATOLOGY CALIBRATOR))-CALIBRATORS ARE INTENDED TO CALIBRATE THE ANALYZER AT MULTIPLE POINTS, LYSE(EDAN (HL 300 LYSE))-THE PRODUCT IS USED FOR LYSING ERYTHROCYTES, COUNTING AND DIFFERENTIATING THE FIVE MAIN LEUKOCYTES SUBPOPULATIONS AND QUANTITATIVE DETERMINATION HEMOGLOBIN IN A BLOOD SAMPLE,CLEANER(EDAN (HC 300 CLEANER))-THE CLEANER IS INTENDED TO CLEAN AND RINSE THE FLUIDIC CHANNELS WITHIN ANALYZER TO ENSURE THE ANALYZER'S PERFORMANCE.,QUALITY CONTROL(EDAN (ED-30D HEMATOLOGY CONTROL))-CONTROLS ARE INTENDED TO MONITOR ANALYZER PERFORMANCE AT MULTIPLE POINTS

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922	IMP/IVD/2020/000940	1.License Holder Name: WEVIO GLOBAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: EXIPREP™ DX VIRAL DNA/RNA KIT(EXIPREP™ DX VIRAL DNA/RNA KIT)-EXIPREP™ DX VIRAL DNA/RNA KIT IS AN IN VITRO DIAGNOSTIC KIT DESIGNED FOR THE EXTRACTION OF VIRAL DNA AND VIRAL RNA FROM HUMAN CLINICAL SAMPLES THROUGH PARTICULAR NUCLEIC ACID DEVICE, EXIPREP™16 DX (A-5050), EXISTATION™ UNIVERSAL MOLECULAR DIAGNOSTIC SYSTEM (A-2200, A-2200-N, A-2200-F). THIS KIT IS A NUCLEIC ACID EXTRACTION FOR PROFESSIONAL USE ONLY., EXIPREP™ 96 VIRAL DNA/RNA KIT(EXIPREP™ 96 VIRAL DNA/RNA KIT)-EXIPREP ™ 96 VIRAL DNA/RNA KIT IS AN IN VITRO DIAGNOSTIC KIT DESIGNED FOR THE EXTRACTION OF VIRAL DNA/RNA FROM HUMAN CLINICAL SAMPLES (EX. NASAL SWAB, SPUTUM) THROUGH PARTICULAR NUCLEIC ACID DEVICE, EXIPREP ™ 96 LITE (A 5250). THIS KIT IS A NUCLEIC ACID EXTRACTION KIT FOR PROFESSIONAL USE ONLY.,ACCUPOWER® SARS-COV-2 REAL-TIME RT-PCR KIT(ACCUPOWER® SARS-COV-2 REAL-TIME RT-PCR KIT)-ACCUPOWER®SARS-COV-2 REAL-TIME RT-PCR KIT IS AN IN VITRO DIAGNOSTIC KIT THAT HELPS DIAGNOSE COVID-19 INFECTIONS (CORONAVIRUS DISEASE-19).THIS KIT IS DESIGNED FOR THE DETECTION OF SARS-COV-2 (E GENE AND RDRP GENE) RNA FROM A COVID-19(CORONAVIRUS DISEASE-19) SUSPECTED PATIENT'S SAMPLE SUCH AS SPUTUM, NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB THROUGH REAL-TIME POLYMERASE CHAIN REACTION (PCR).,ACCUPOWER® SARS-COV-2 MULTIPLEX REAL-TIME RT-PCR KIT(ACCUPOWER® SARS-COV-2 MULTIPLEX REAL-TIME RT-PCR KIT)-ACCUPOWER® SARS-COV-2 MULTIPLEX REAL-TIME RT-PCR KIT IS AN IN VITRO DIAGNOSTIC KIT THAT HELPS DIAGNOSE COVID-19 INFECTIONS. THIS KIT IS DESIGNED FOR THE DETECTION OF SARS-COV-2 NUCLEIC ACIDS (E GENE, RDRP GENE, AND N GENE) FROM A COVID-19 SUSPECTED INDIVIDUAL'S SPECIMEN (SUCH AS SPUTUM, NASOPHARYNGEAL SWAB AND OROPHARYNGEAL SWAB) THROUGH REAL-TIME POLYMERASE CHAIN REACTION (PCR),ACCUPREP® DX VIRAL RNA EXTRACTION KIT (ACCUPREP® DX VIRAL RNA EXTRACTION KIT)-ACCUPREP® DX VIRAL RNA EXTRACTION KIT IS AN IN VITRO DIAGNOSTIC KIT DESIGNED FOR THE EXTRACTION OF VIRAL RNA FROM VARIOUS HUMAN SAMPLES SUCH AS SERUM, PLASMA, CSF, SWAB AND SPUTUM. THIS PRODUCT CONSISTS OF SILICA-BASED RNA BINDING COLUMN, BINDING BUFFER, WASHING BUFFERS ELUTION BUFFER OPTIMIZED FOR VIRAL RNA EXTRACTION FROM THE VARIOUS SAMPLE. FURTHERMORE, POLY(A) POWDER IS INCLUDED IN THE PRODUCT FOR IMPROVED EFFICIENCY AND PREVENTING FOR RNA DEGRADATION. THIS KIT IS A NUCLEIC ACID

		EXTRACTION FOR PROFESSIONAL USE ONLY.,MAGLISTO ™ 5M VIRAL DNA / RNA EXTRACTION KIT(MAGLISTO ™ 5M VIRAL DNA / RNA EXTRACTION KIT)-MAGLISTO™ 5M VIRAL DNA/RNA EXTRACTION KIT IS AN IN VITRO DIAGNOSTIC KIT DESIGNED FOR THE EXTRACTION OF VIRAL DNA/RNA FROM VARIOUS HUMAN SAMPLES SUCH AS SERUM, PLASMA, CSF, SWAB AND SPUTUM. THIS PRODUCT CONSISTS OF MAGNETIC NANOBEADS, BINDING BUFFER, WASHING BUFFERS AND ELUTION BUFFER OPTIMIZED FOR VIRAL DNA/RNA EXTRACTION FROM VARIOUS SAMPLE. FURTHERMORE, POLY(A) POWDER IS INCLUDED IN THE PRODUCT FOR IMPROVED EFFICIENCY AND PREVENTING FOR RNA DEGRADATION. THIS KIT IS A NUCLEIC ACID EXTRACTION FOR PROFESSIONAL USE ONLY., EXIPREP™ 48 VIRAL DNA/RNA KIT(EXIPREP™ 48 VIRAL DNA/RNA KIT)-EXIPREP™ 48 VIRAL DNA/RNA KIT IS AN IN VITRO DIAGNOSTIC KIT DESIGNED FOR THE EXTRACTION OF VIRAL DNA OR VIRAL RNA FROM HUMAN CLINICAL SAMPLES THROUGH PARTICULAR NUCLEIC ACID DEVICE, EXIPREP™ 48 DX (A-5150), EXISTATION™ 48 AND EXISTATION™ 48 A UNIVERSAL MOLECULAR DIAGNOSTIC SYSTEM (A-2400, A-2410). THIS KIT IS A NUCLEIC ACID EXTRACTION FOR PROFESSIONAL USE ONLY.
923	IMP/IVD/2020/000944	1.License Holder Name: MYOVATEC SURGICAL SYSTEMS LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 PCR DIAGNOSTIC KIT(KAIRA 2019-NCOV DETECTION KIT)-THE KAIRA 2019-NCOV DETECTION KIT IS DESIGNED FOR QUALITATIVE DETECTION OF COVID-19 VIRUS (SARS-COV-2) RNA IN THE SPECIMENS OF SUSPECTED RESPIRATORY DISEASE PATIENTS (SPUTUM, ORAL SWAB, NASAL SWAB) IN IN-VITRO SETTINGS, BY REAL-TIME POLYMERASE CHAIN REACTION (RT-PCR), ASSISTING DIAGNOSIS OF COVID-19. FOR PROFESSIONAL USE ONLY.

924	IMP/IVD/2020/000945	1.License Holder Name: MEDICO SURGICAL CENTRE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS FOR QUANTITATIVELY MEASURE GLUCOSE IN CAPILLARY WHOLE BLOOD.(GLUCOSURE LIGHT)-TO QUANTITATIVELY MEASURE GLUCOSE IN CAPILLARY WHOLE BLOOD TAKEN FROM FINGERTIPS, PALM, OR FOREARM., FOR SELF-TESTING BY PERSONS WITH DIABETES AND BY HEALTH CARE PROFESSIONALS, BUT NOT INDICATED FOR THE DIAGNOSIS OR SCREENING OF DIABETES OR FOR NEONATAL USE.,HEMOGLOBIN TEST STRIP FOR QUANTITATIVE MEASUREMENT OF HEMOGLOBIN IN WHOLE BLOOD USING(HEMO SMART GOLD)-FOR THE QUANTITATIVE MEASUREMENT OF HEMOGLOBIN IN WHOLE BLOOD USING THE HEMO SMART GOLD HEMOGLOBIN METER IN THE RANGE OF 4 G/DL TO 24G/DL.,BLOOD URIC ACID TEST STRIPS FOR QUANTITATIVE MEASUREMENT OF URIC ACID IN WHOLE BLOOD(UA SURE)-UASURE® BLOOD URIC ACIDE TEST STRIP IS USED WITH UASURE® BLOOD URIC ACID METER, INTENDED FOR USE OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) IN A CLINICAL SETTING BY HEALTHCARE PROFESSIONALS AND AT HOME BY PERSON WITH HYPERURICEMIA AS AN AID TO MONITOR THE EFFECTIVENESS OF THE MEDICATION.

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925	IMP/IVD/2020/000948	1.License Holder Name: BIOSYSTEMS DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIACON 3 HEMATOLOGY CONTROL HIGH(DIACON 3 HEMATOLOGY CONTROL HIGH)-CONTROL MATERIAL USED ALONG WITH REAGENT PACK TO MEASURE THE BLOOD COMPONENTS IN HEMATOLOGY INSTRUMENT.,DIACON 3 HEMATOLOGY CONTROL NORMAL(DIACON 3 HEMATOLOGY CONTROL NORMAL)-CONTROL MATERIAL USED ALONG WITH REAGENT PACK TO MEASURE THE BLOOD COMPONENTS IN HEMATOLOGY INSTRUMENT.,DIATRO 3P REAGENT SMART PACK (SET OF 4×DRP07)(DIATRO 3P REAGENT SMART PACK (SET OF 4×DRP07))-REAGENTS USED TO MEASURE THE BLOOD COMPONENTS LEVEL IN HUMAN BLOOD USING AN HEMATOLOGY INSTRUMENT.,DIATRO. HYPOCLEAN CC(DIATRO. HYPOCLEAN CC)-REAGENT CLEANING SOLUTION USED TO CLEAN THE INNER PARTS OF THE HEMATOLOGY INSTRUMENT.,DIACON 3 HEMATOLOGY CONTROL SET (L-N-H) (DIACON 3 HEMATOLOGY CONTROL SET (L-N-H))-CONTROL MATERIAL USED ALONG WITH REAGENT PACK TO MEASURE THE BLOOD COMPONENTS IN HEMATOLOGY INSTRUMENT.,DIATROCAL HEMATOLOGY CALIBRATOR(DIATROCAL HEMATOLOGY CALIBRATOR)-CALIBRATOR REAGENT SOLUTION USED TO CALIBRATE THE HEMATOLOGY INSTRUMENT.,DIACON 3 HEMATOLOGY CONTROL LOW(DIACON 3 HEMATOLOGY CONTROL LOW)-CONTROL MATERIAL USED ALONG WITH REAGENT PACK TO MEASURE THE BLOOD COMPONENTS IN HEMATOLOGY INSTRUMENT.
926	IMP/IVD/2020/000949	1.License Holder Name: YPSOMED INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MYLIFE PURA BLOOD GLUCOSE TEST STRIPS(MYLIFE PURA X)-IT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN CORONARY WHOLE BLOOD FROM THE FINGERTIP , PALM OF FOREARM.,MYLIFE UNIO BLOOD GLUCOSE MONITORING METER(MYLIFE UNIO)-IT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN CORONARY WHOLE BLOOD FROM THE FINGERTIP , PALM OF FOREARM.,MYLIFE UNIO BLOOD GLUCOSE TEST STRIPS(MYLIFE UNIO)-IT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN CORONARY WHOLE BLOOD FROM THE FINGERTIP , PALM OF FOREARM.,MYLIFE PURA X BLOOD GLUCOSE MONITORING METER(MYLIFE PURA X)-IT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN CORONARY WHOLE BLOOD FROM THE FINGERTIP , PALM OF FOREARM.

927	IMP/IVD/2020/000950	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIFF LYSE-THIS PRODUCT IS USED TO DISSOLVED RBC AND MAINTAIN THE MORPHOLOGY OF THE CELLS NEEDED TO BE ANALYZED BEFORE BLOOD CELL ANALYSIS SO THAT FACILITATE CELL SORTING OR HBG QUANTIFICATION.,LH LYSE-THIS PRODUCT IS USED TO DISSOLVE RBC AND MAINTAIN THE MORPHOLOGY OF THE CELLS NEEDED TO BE ANALYZED BEFORE BLOOD CELL ANALYSE THEREBY FACILITATE CELL SORTING OR HGB QUANTIFICATION.,DILUENT-DILUTION OF BLOOD SAMPLES AND PREPARING CELL SUSPENSIONS PRIOR TO ANALYSIS OF THE CELLS.
928	IMP/IVD/2020/000951	1.License Holder Name: DSS IMAGETECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MONOCLONAL MOUSE ANTI-HUMAN PDL1, CLONE 22C3-FOR IVD USE. MONOCLONAL MOUSE ANTI-HUMAN PD-L1, CLONE 22C3, IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY. THIS ANTIBODY LABELS PD-L1 IN NORMAL AND NEOPLASTIC TISSUE. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOUDL EB COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A CERTIFIED PATHOLOGIST. THIS ANTIBODY IS INTENDED TO BE USED AFTER THE PRIMARY DIAGNOSIS OF TUMOR HAS BEEN MADE BY CONVENTIONAL HISTOPATHOLOGY USING NON-IMMUNOLOGIC HISTOCHEMICAL STAINS.
929	IMP/IVD/2020/000952	1.License Holder Name: SUN BIO SYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TANBEAD NUCLEIC ACID EXTRACTION KIT (TANBEAD)-TANBEAD® NUCLEIC ACID EXTRACTION KIT IS SUITABLE FOR ISOLATING NUCLEIC ACID FROM VARIOUS VIRUSES. AUTOMATED NUCLEIC ACID EXTRACTION CAN BE PERFORMED BY TANBEAD® NUCLEIC ACID EXTRACTOR (MAELSTROM SERIES). PURIFIED NUCLEIC ACIDS CAN BE ANALYZED BY DOWNSTREAM APPLICATIONS INCLUDING REAL-TIME PCR AND NEXT-GENERATION SEQUENCING.

930	IMP/IVD/2020/000959	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PCO CHECK ELISA-FOR IN VITRO DIAGNOSTIC USE, FOR THE QUANTITATIVE MEASUREMENT OF ANTI-MULLERIAN HORMONE(AMH) IN HUMAN SERUM, LI-HEPARIN AND K2 EDTA PLASMA. THIS ASSAY IS NOT IMPACTED BY AMH POST TRANSLATIONAL MODIFICATIONS. IT IS INTENDED TO BE USED AS AN AID IN THE DETERMINATION OF OVARIAN RESERVE, STRATIFICATION OF WOMEN WITH POLYCYSTIC OVARIAN MORPHOLOGY(PCOM), INHIBIN B ELISA-FOR IN VITRO DIAGNOSTIC USE, FOR THE QUANTITATIVE MEASUREMENT OF INHIBIN B IN HUMAN SERUM AND OTHER BIOLOGICAL FLUIDS,PICOAMH ELISA-FOR IN VITRO DIAGNOSTIC USE, FOR THE QUANTITATIVE MEASUREMENT OF ULTRA-LOW CONCENTRATIONS OF AMH IN HUMAN SERUM AND OTHER BIOLOGICAL FLUIDS,TOTAL IGF-I ELISA-FOR IN VITRO DIAGNOSTIC USE, FOR THE QUANTITATIVE MEASUREMENT OF IGF-I IN SERUM, PLASMA AND OTHER BIOLOGICAL FLUIDS,INHIBIN A ELISA-FOR IN VITRO DIAGNOSTIC USE, FOR THE QUANTITATIVE MEASUREMENT OF DIMERIC INHIBIN A IN HUMAN SERUM AND PLASMA. IT IS INTENDED AS AN AID IN THE DIAGNOSIS AND MONITORING OF VARIOUS HORMONAL REPRODUCTIVE DISORDERS. DOWN SYNDROME (TRISOMY 21) SCREENING IN THE 2ND TRIMESTER USING COMBINED BIOCHEMICAL AND ULTRASOUND MARKERS MAY BE ASSESSED WITH APPROPRIATE RISK CALCULATION SOFTWARE. IT IS STRONGLY RECOMMENDED TO USE VALIDATED SOFTWARE (CE MARKED) DESIGNATED SPECIFICALLY FOR EVALUATING THE RISK OF TRISOMY 21 USING INHIBIN A IN COMBINATION WITH HAFP, HCG, AND UE3 MEASUREMENTS.,ACTIVIN A ELISA-FOR IN VITRO DIAGNOSTIC USE, FOR THE QUANTITATIVE MEASUREMENT OF ACTIVIN A IN HUMAN SERUM AND OTHER BIOLOGICAL FLUIDS,ULTRASENSTITIVE AMH/MIS ELISA-FOR IN VITRO DIAGNOSTIC USE, FOR THE QUANTITATIVE MEASUREMENT OF AMH/MIS IN HUMAN SERUM, PLASMA AND OTHER BIOLOGICAL FLUIDS

931	IMP/IVD/2020/000960	1.License Holder Name: WELDON BIOTECH INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PAB KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN PAB,IGG KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN IGG,TRF KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN TRF,AAT KIT (NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN AAT,C4 KIT (NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN C4,AMG KIT (NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN AMG,RF KIT (NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN (RF),APO A1 KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN APO A1, USCRP KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN USCRP,BCRP KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN CRP,D-DIMER KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN D-DIMER,LIPOPROTEIN(A) KIT (NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN LIPOPROTEIN(A),SAA KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN SAA,LAM KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN LAM,1 MICROGLOBULIN KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN 1 MICROGLOBULIN,APO B KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN APO B,MALB KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN MALB,CYS C KIT (NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN CYS C,BMG KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN BMG, HBA1C KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN HBA1C,ASO KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN ASO,C1IN KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN C1IN,CRP KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN CRP,ALB KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN ALB,CER KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN CER,HPT KIT (NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN HPT,AAG KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN AAG, USCRP KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN USCRP,KAP KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN KAP,AT3 KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN AT3,RBP KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN RBP,CRP KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN CRP,IGA KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN IGA,IGM KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN IGM,C3 KIT(NEPHSTAR)-QUANTITATIVE DETERMINATION OF HUMAN C3,CYS C KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN CYS C ,IGM KIT(GPP-100)-QUANTITATIVE

		DETERMINATION OF HUMAN IGM ,DD KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN DD,IGA KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN IGA ,C3 KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN C3,ASO KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN ASO,RF KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN RF,HBA1C KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN HBA1C ,C4 KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN C4,FR-CRP KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN CRP,IGG KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN IGG,SAA KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN SAA,MALB KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN MALB ,A1M KIT(GPP-100)-QUANTITATIVE DETERMINATION OF HUMAN A1M
932	IMP/IVD/2020/000965	1.License Holder Name: MICROGENE DIAGNOSTIC SYSTEMS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIASPECT CONTROL PACK HBT4(DIASPECT)-DIASPECT CONTROL PACK IS USED WITH DIASPECT CUVETTES IN THE DIASPECT HEMOGLOBIN ANALYZER. IS INTENDED FOR USE AS QUALITY CONTROL WITH ASSIGNED VALUES., DIASPECT HEMOGLOBIN CUVETTES(DIASPECT)-DIASPECT HEMOGLOBIN CUVETTES ALONG WITH DIASPECT HEMOGLOBIN ANALYZER IS INTENDED FOR THE ESTIMATION OF TOTAL HEMOGLOBIN IN WHOLE BLOOD

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

933	IMP/IVD/2020/000967	1.License Holder Name: BIOTIME HEALTHCARE PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SAMPLING RELEASING REAGENT(ARDENT BIOMED)-THE PRODUCT CAN BE USED FOR PRE-PROCESSING OF VIRUS SAMPLES, RELEASING NUCLEIC ACID FROM THE SAMPLE BY LYSIS AND MAINTAINING THE INTEGRITY AND STABILITY OF THE NUCLEIC ACID. IT CAN ALSO BE DIRECTLY USED FOR SAMPLE PRETREATMENT OF COVID-19. IT CAN DIRECTLY LYSE THE COVID-19 VIRUS SAMPLE AND RELEASE NUCLEIC ACID DIRECTLY, SIMPLIFYING THE NUCLEIC ACID EXTRACTION STEP, SO THAT THE SAMPLE CAN BE DIRECTLY SUBJECTED TO NUCLEIC ACID DETECTION WITHOUT NUCLEIC ACID EXTRACTION.,DISPOSABLE SAMPLING KIT(ARDENT BIOMED)-THIS PRODUCT IS SUITABLE FOR THE COLLECTION, TRANSPORTATION AND STORAGE OF VIRUS SAMPLES. IT CAN ALSO BE DIRECTLY USED FOR COLLECTION, TRANSPORTATION AND STORAGE OF COVID-19 VIRUS SAMPLES. THE NUCLEIC ACIDS EXTRACTED FROM PRESERVED SAMPLES ARE SUITABLE FOR PCR AMPLIFICATION AND DETECTION.,NUCLEIC ACID EXTRACTION OR PURIFICATION KIT(ARDENT BIOMED)-THIS KIT IS USED FOR NUCLEIC ACID EXTRACTION, ENRICHMENT AND PURIFICATION. THIS KIT CAN ALSO BE DIRECTLY USED FOR NUCLEIC ACID EXTRACTION OF COVID-19 VIRUS SAMPLES, AND THE EXTRACTED PRODUCTS CAN BE DIRECTLY USED FOR DOWNSTREAM NUCLEIC ACID DETECTION.,NOVEL CORONAVIRUS (COVID-19) NUCLEIC ACID DETECTION KIT (PCR-FLUORESCENT PROBE)(ARDENT BIOMED)-THIS KIT IS AN IN VITRO DIAGNOSTIC TEST USED FOR THE DETECTION OF A NEW TYPE OF CORONAVIRUS (COVID-19).SAMPLES CAN BE OBTAINED FROM SWAB OR SPUTUM.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

934	IMP/IVD/2020/000974	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLINITEK MICROALBUMIN 2 REAGENT STRIPS(CLINITEK MICROALBUMIN 2 REAGENT STRIPS)-CLINITEK MICROALBUMIN 2 REAGENT STRIPS ARE FIRM PLASTIC STRIPS THAT CONTAIN TWO REAGENT PADS THAT TEST FOR ALBUMIN AND CREATININE IN URINE. AN ALBUMIN TO-CREATININE RATIO IS ALSO DETERMINED, WHICH ALLOWS FOR THE USE OF SINGLE-VOID SPECIMENS IN TESTING. THE RATIO IS GIVEN IN MILLIGRAMS ALBUMIN PER GRAM OR MILLIMOLE CREATININE (MG/G OR MG/MMOL). THIS PRODUCT PROVIDES SEMI-QUANTITATIVE RESULTS AND CAN BE USED FOR SCREENING SAMPLES FOR MICROALBUMINURIA; POSITIVE RESULTS SHOULD BE CONFIRMED WITH QUANTITATIVE METHODS FOR ALBUMIN. TEST RESULTS MAY AID CLINICIANS IN THE DETECTION OF PATIENTS AT RISK OF DEVELOPING KIDNEY DAMAGE,MICROALBUSTIX REAGENT STRIPS (MICROALBUSTIX REAGENT STRIPS)-MICROALBUSTIX REAGENT STRIPS ARE FIRM PLASTIC STRIPS THAT CONTAIN TWO REAGENT AREAS THAT TEST FOR ALBUMIN AND CREATININE IN URINE. AN ALBUMIN-TO-CREATININE RATIO CAN ALSO BE DETERMINED, WHICH ALLOWS FOR THE USE OF SINGLE-VOID SPECIMENS IN TESTING. THE RATIO IS GIVEN IN MILLIGRAMS ALBUMIN PER GRAM OR MILLIMOLE CREATININE (MG/G OR MG/MMOL). THIS PRODUCT PROVIDES SEMI-QUANTITATIVE RESULTS AND CAN BE USED FOR SCREENING SAMPLES FOR MICROALBUMINURIA; POSITIVE RESULTS SHOULD BE CONFIRMED WITH QUANTITATIVE METHODS FOR ALBUMIN. THE STRIPS ARE FOR PROFESSIONAL, IN VITRO DIAGNOSTIC USE. TEST RESULTS MAY AID CLINICIANS IN THE DETECTION OF PATIENTS AT RISK OF DEVELOPING KIDNEY DAMAGE. MICROALBUMINURIA HAS BEEN REPORTED TO BE AN EARLY PREDICTOR OF THE DEVELOPMENT OF GLOMERULAR DAMAGE IN THE ABSENCE OF OVERT NEPHROPATHY AND MICROALBUMINURIA HAS ALSO BEEN REPORTED AS AN EARLY PREDICTOR OF THE DEVELOPMENT OF PRE-ECLAMPSIA DURING PREGNANCY.,MULTISTIX 10SG REAGENT STRIPS (MULTISTIX 10SG REAGENT STRIPS)-SIEMENS HEALTHCARE DIAGNOSTICS ALBUSTIX, HEMASTIX, URISTIX, MULTISTIX, MULTISTIX 8 SG, MULTISTIX 10 SG REAGENT STRIPS FOR URINALYSIS INCLUDE TEST PADS FOR PROTEIN, BLOOD, LEUKOCYTES, NITRITE, GLUCOSE, KETONE (ACETOACETIC ACID), PH, SPECIFIC GRAVITY, BILIRUBIN AND UROBILINOGEN. PLEASE REFER TO THE CARTON OR BOTTLE LABEL TO SEE WHICH TESTS ARE INCLUDED ON THE PRODUCT YOU ARE USING. SIEMENS REAGENT STRIPS ARE FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE IN NEAR-PATIENT (POINT OF CARE) AND CENTRALIZED LABORATORY LOCATIONS. THE STRIPS ARE INTENDED

	FOR USE IN AT-RISK PATIENT GROUPS TO ASSIST DIAGNOSIS IN THE FOLLOWING AREAS: • KIDNEY FUNCTION • URINARY TRACT INFECTIONS • CARBOHYDRATE METABOLISM (E.G., DIABETES MELLITUS) • LIVER FUNCTION THE STRIPS ALSO MEASURE PHYSICAL CHARACTERISTICS, INCLUDING ACID-BASE BALANCE AND URINE CONCENTRATION. TEST RESULTS CAN BE USED ALONG WITH OTHER DIAGNOSTIC INFORMATION TO RULE OUT CERTAIN DISEASE STATES AND TO DETERMINE IF MICROSCOPIC ANALYSIS IS NEEDED., MULTISTIX 8SG REAGENT STRIPS(MULTISTIX 8SG REAGENT STRIPS)-SIEMENS HEALTHCARE DIAGNOSTICS ALBUSTIX, HEMASTIX, URISTIX, MULTISTIX, MULTISTIX 8 SG, MULTISTIX 10 SG REAGENT STRIPS FOR URINALYSIS INCLUDE TEST PADS FOR PROTEIN, BLOOD, LEUKOCYTES, NITRITE, GLUCOSE, KETONE (ACETOACETIC ACID), PH, SPECIFIC GRAVITY, BILIRUBIN AND UROBILINOGEN. PLEASE REFER TO THE CARTON OR BOTTLE LABEL TO SEE WHICH TESTS ARE INCLUDED ON THE PRODUCT YOU ARE USING. SIEMENS REAGENT STRIPS ARE FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE IN NEAR-PATIENT (POINT OF CARE) AND CENTRALIZED LABORATORY LOCATIONS. THE STRIPS ARE INTENDED FOR USE IN AT-RISK PATIENT GROUPS TO ASSIST DIAGNOSIS IN THE FOLLOWING AREAS: • KIDNEY FUNCTION • URINARY TRACT INFECTIONS • CARBOHYDRATE METABOLISM (E.G., DIABETES MELLITUS) • LIVER FUNCTION THE STRIPS ALSO MEASURE PHYSICAL CHARACTERISTICS, INCLUDING ACID-BASE BALANCE AND URINE CONCENTRATION. TEST RESULTS CAN BE USED ALONG WITH OTHER DIAGNOSTIC INFORMATION TO RULE OUT CERTAIN DISEASE STATES AND TO DETERMINE IF MICROSCOPIC ANALYSIS IS NEEDED.,MULTISTIX REAGENT STRIPS (MULTISTIX REAGENT STRIPS)-SIEMENS HEALTHCARE DIAGNOSTICS ALBUSTIX, HEMASTIX, URISTIX, MULTISTIX, MULTISTIX 8 SG, MULTISTIX 10 SG REAGENT STRIPS FOR URINALYSIS INCLUDE TEST PADS FOR PROTEIN, BLOOD, LEUKOCYTES, NITRITE, GLUCOSE, KETONE (ACETOACETIC ACID), PH, SPECIFIC GRAVITY, BILIRUBIN AND UROBILINOGEN. PLEASE REFER TO THE CARTON OR BOTTLE LABEL TO SEE WHICH TESTS ARE INCLUDED ON THE PRODUCT YOU ARE USING. SIEMENS REAGENT STRIPS ARE FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE IN NEAR-PATIENT (POINT OF CARE) AND CENTRALIZED LABORATORY LOCATIONS. THE STRIPS ARE INTENDED FOR USE IN AT-RISK PATIENT GROUPS TO ASSIST DIAGNOSIS IN THE FOLLOWING AREAS: • KIDNEY FUNCTION • URINARY TRACT INFECTIONS • CARBOHYDRATE METABOLISM (E.G., DIABETES MELLITUS) • LIVER FUNCTION THE STRIPS ALSO MEASURE PHYSICAL CHARACTERISTICS, INCLUDING ACID-BASE BALANCE AND URINE CONCENTRATION. TEST RESULTS CAN BE USED ALONG WITH OTHER DIAGNOSTIC INFORMATION TO RULE OUT CERTAIN DISEASE STATES

	AND TO DETERMINE IF MICROSCOPIC ANALYSIS IS NEEDED.,URISTIX REAGENT STRIPS(URISTIX REAGENT STRIPS)-SIEMENS HEALTHCARE DIAGNOSTICS ALBUSTIX, HEMASTIX, URISTIX, MULTISTIX, MULTISTIX 8 SG, MULTISTIX 10 SG REAGENT STRIPS FOR URINALYSIS INCLUDE TEST PADS FOR PROTEIN, BLOOD, LEUKOCYTES, NITRITE, GLUCOSE, KETONE (ACETOACETIC ACID), PH, SPECIFIC GRAVITY, BILIRUBIN AND UROBILINOGEN. PLEASE REFER TO THE CARTON OR BOTTLE LABEL TO SEE WHICH TESTS ARE INCLUDED ON THE PRODUCT YOU ARE USING. SIEMENS REAGENT STRIPS ARE FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE IN NEAR-PATIENT (POINT OF CARE) AND CENTRALIZED LABORATORY LOCATIONS. THE STRIPS ARE INTENDED FOR USE IN AT-RISK PATIENT GROUPS TO ASSIST DIAGNOSIS IN THE FOLLOWING AREAS: • KIDNEY FUNCTION • URINARY TRACT INFECTIONS • CARBOHYDRATE METABOLISM (E.G., DIABETES MELLITUS) • LIVER FUNCTION THE STRIPS ALSO MEASURE PHYSICAL CHARACTERISTICS, INCLUDING ACID-BASE BALANCE AND URINE CONCENTRATION. TEST RESULTS CAN BE USED ALONG WITH OTHER DIAGNOSTIC INFORMATION TO RULE OUT CERTAIN DISEASE STATES AND TO DETERMINE IF MICROSCOPIC ANALYSIS IS NEEDED.,HEMA-COMBISTIX REAGENT STRIPS(HEMA-COMBISTIX REAGENT STRIPS)-SIEMENS HEALTHCARE DIAGNOSTICS HEMA-COMBISTIX, LABSTIX & MULTISTIX SG REAGENT STRIPS REAGENT STRIPS FOR URINALYSIS INCLUDE TEST PADS FOR PROTEIN, BLOOD, LEUKOCYTES, NITRITE, GLUCOSE, KETONE (ACETOACETIC ACID), PH, SPECIFIC GRAVITY, BILIRUBIN, AND UROBILINOGEN. REFER TO THE CARTON OR BOTTLE LABEL FOR THE TESTS INCLUDED ON THE PRODUCT YOU ARE USING. THE REAGENT STRIPS ARE FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS. READ THE INSERT CAREFULLY BEFORE USING THE PRODUCT.,HEMASTIX REAGENT STRIP(HEMASTIX REAGENT STRIP)-SIEMENS HEALTHCARE DIAGNOSTICS ALBUSTIX, HEMASTIX, URISTIX, MULTISTIX, MULTISTIX 8 SG, MULTISTIX 10 SG REAGENT STRIPS FOR URINALYSIS INCLUDE TEST PADS FOR PROTEIN, BLOOD, LEUKOCYTES, NITRITE, GLUCOSE, KETONE (ACETOACETIC ACID), PH, SPECIFIC GRAVITY, BILIRUBIN AND UROBILINOGEN. PLEASE REFER TO THE CARTON OR BOTTLE LABEL TO SEE WHICH TESTS ARE INCLUDED ON THE PRODUCT YOU ARE USING. SIEMENS REAGENT STRIPS ARE FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE IN NEAR-PATIENT (POINT OF CARE) AND CENTRALIZED LABORATORY LOCATIONS. THE STRIPS ARE INTENDED FOR USE IN AT-RISK PATIENT GROUPS TO ASSIST DIAGNOSIS IN THE FOLLOWING AREAS: • KIDNEY FUNCTION • URINARY TRACT INFECTIONS • CARBOHYDRATE METABOLISM (E.G., DIABETES MELLITUS) • LIVER FUNCTION THE STRIPS ALSO MEASURE PHYSICAL CHARACTERISTICS, INCLUDING ACID-BASE BALANCE AND URINE

	CONCENTRATION. TEST RESULTS CAN BE USED ALONG WITH OTHER DIAGNOSTIC INFORMATION TO RULE OUT CERTAIN DISEASE STATES AND TO DETERMINE IF MICROSCOPIC ANALYSIS IS NEEDED., ALBUSTIX REAGENT STRIPS(ALBUSTIX REAGENT STRIPS)-SIEMENS HEALTHCARE DIAGNOSTICS ALBUSTIX, HEMASTIX, URISTIX, MULTISTIX, MULTISTIX 8 SG, MULTISTIX 10 SG REAGENT STRIPS FOR URINALYSIS INCLUDE TEST PADS FOR PROTEIN, BLOOD, LEUKOCYTES, NITRITE, GLUCOSE, KETONE (ACETOACETIC ACID), PH, SPECIFIC GRAVITY, BILIRUBIN AND UROBILINOGEN. PLEASE REFER TO THE CARTON OR BOTTLE LABEL TO SEE WHICH TESTS ARE INCLUDED ON THE PRODUCT YOU ARE USING. SIEMENS REAGENT STRIPS ARE FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE IN NEAR-PATIENT (POINT OF CARE) AND CENTRALIZED LABORATORY LOCATIONS. THE STRIPS ARE INTENDED FOR USE IN AT-RISK PATIENT GROUPS TO ASSIST DIAGNOSIS IN THE FOLLOWING AREAS: • KIDNEY FUNCTION • URINARY TRACT INFECTIONS • CARBOHYDRATE METABOLISM (E.G., DIABETES MELLITUS) • LIVER FUNCTION THE STRIPS ALSO MEASURE PHYSICAL CHARACTERISTICS, INCLUDING ACID-BASE BALANCE AND URINE CONCENTRATION. TEST RESULTS CAN BE USED ALONG WITH OTHER DIAGNOSTIC INFORMATION TO RULE OUT CERTAIN DISEASE STATES AND TO DETERMINE IF MICROSCOPIC ANALYSIS IS NEEDED.,MULTISTIX SG REAGENT STRIPS (MULTISTIX SG REAGENT STRIPS)-SIEMENS HEALTHCARE DIAGNOSTICS HEMA-COMBISTIX, LABSTIX & MULTISTIX SG REAGENT STRIPS REAGENT STRIPS FOR URINALYSIS INCLUDE TEST PADS FOR PROTEIN, BLOOD, LEUKOCYTES, NITRITE, GLUCOSE, KETONE (ACETOACETIC ACID), PH, SPECIFIC GRAVITY, BILIRUBIN, AND UROBILINOGEN. REFER TO THE CARTON OR BOTTLE LABEL FOR THE TESTS INCLUDED ON THE PRODUCT YOU ARE USING. THE REAGENT STRIPS ARE FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS. READ THE INSERT CAREFULLY BEFORE USING THE PRODUCT.,LABSTIX REAGENT STRIPS(LABSTIX REAGENT STRIPS)-SIEMENS HEALTHCARE DIAGNOSTICS HEMA-COMBISTIX, LABSTIX & MULTISTIX SG REAGENT STRIPS REAGENT STRIPS FOR URINALYSIS INCLUDE TEST PADS FOR PROTEIN, BLOOD, LEUKOCYTES, NITRITE, GLUCOSE, KETONE (ACETOACETIC ACID), PH, SPECIFIC GRAVITY, BILIRUBIN, AND UROBILINOGEN. REFER TO THE CARTON OR BOTTLE LABEL FOR THE TESTS INCLUDED ON THE PRODUCT YOU ARE USING. THE REAGENT STRIPS ARE FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS. READ THE INSERT CAREFULLY BEFORE USING THE PRODUCT.

935	IMP/IVD/2020/000975	1.License Holder Name: MD NEXT LIFE SCIENCES LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS COV 2 IGG/IGM RAPID TEST KIT(SARS COV 2 IGG/IGM RAPID TEST KIT)-THE TBG SARS-COV-2 IGG / IGM RAPID TEST KIT IS A LATERAL FLOW IMMUNOASSAY INTENDED FOR QUALITATIVE DETECTION AND DIFFERENTIATION OF IGG AND IGM ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM AND PLASMA [ACID CITRATE DEXTROSE (ACD)]. THE TBG SARS-COV-2 IGG / IGM RAPID TEST KIT IS INTENDED FOR USE AS AN AID IN IDENTIFYING INDIVIDUALS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS-COV-2, INDICATING RECENT OR PRIOR INFECTION. AT THIS TIME, IT IS UNKNOWN FOR HOW LONG ANTIBODIES PERSIST FOLLOWING INFECTION AND IF THE PRESENCE OF ANTIBODIES CONFERS PROTECTIVE IMMUNITY. THE TBG SARS-COV-2 IGG/IGM RAPID TEST KIT SHOULD NOT BE USED TO DIAGNOSE ACUTE SARS-COV-2 INFECTION. TESTING IS LIMITED TO LABORATORIES CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C 263A, THAT MEET REQUIREMENTS TO PERFORM MODERATE OR HIGH COMPLEXITY TESTS. RESULTS ARE FOR THE DETECTION OF SARS COV-2 ANTIBODIES. IGG AND/OR IGM ANTIBODIES TO SARS-COV-2 ARE GENERALLY DETECTABLE IN BLOOD SEVERAL DAYS AFTER INITIAL INFECTION, ALTHOUGH THE DURATION OF TIME ANTIBODIES ARE PRESENT POST-INFECTION IS NOT WELL CHARACTERIZED. INDIVIDUALS MAY HAVE DETECTABLE VIRUS PRESENT FOR SEVERAL WEEKS FOLLOWING SEROCONVERSION. LABORATORIES WITHIN THE UNITED STATES AND ITS TERRITORIES ARE REQUIRED TO REPORT ALL POSITIVE RESULTS TO THE APPROPRIATE PUBLIC HEALTH AUTHORITIES. THE SENSITIVITY OF TBG SARS-COV-2 IGG / IGM RAPID TEST KIT EARLY AFTER INFECTION IS UNKNOWN. NEGATIVE RESULTS DO NOT PRECLUDE ACUTE SARS-COV-2 INFECTION. IF ACUTE INFECTION IS SUSPECTED, DIRECT TESTING FOR SARS-COV-2 IS NECESSARY. FALSE POSITIVE RESULTS FOR TBG SARS-COV-2 IGG / IGM RAPID TEST KIT MAY OCCUR DUE TO CROSS-REACTIVITY FROM PRE-EXISTING ANTIBODIES OR OTHER POSSIBLE CAUSES. DUE TO THE RISK OF FALSE POSITIVE RESULTS, CONFIRMATION OF POSITIVE RESULTS SHOULD BE CONSIDERED USING SECOND, DIFFERENT IGG OR IGM ASSAY. THE TBG SARS-COV-2 IGG / IGM RAPID TEST KIT IS ONLY FOR USE UNDER THE FOOD AND DRUG ADMINISTRATION'S EMERGENCY USE AUTHORIZATION.,EXPROBETM SARS-COV-2 TESTING ASSAY(EXPROBETM SARS-COV-2 TESTING ASSAY)-EXPROBE™ SARS COV 2 TESTING KIT IS A REAL TIME RT PCR ASSAY INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS COV 2 IN OROPHARYNGEAL SWABS SPECIMEN FROM

		INDIVIDUALS SUSPECTED OF COVID 19 BY THEIR HEALTHCARE PROVIDER. THE TEST RESULTS OF THIS KIT CAN QUALITATIVELY DETERMINE WHETHER THE SUSPECTED PATIENT IS INFECTED WITH SARS COV 2 VIRUS
936	IMP/IVD/2020/000979	1.License Holder Name: SYNERGY MEDICAL SYSTEMS LLP. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEONATAL TOTAL GALACTOSE SCREENING ASSAY(ZENTECH)-ENZYMATIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL GALACTOSE LEVELS IN NEWBORN DRIED BLOOD SPOTS,NEONATAL MSUD SCREENING ASSAY(ZENTECH)-SCREENING ASSAY FOR QUANTITATIVE DETECTION OF MAPLE SYRUP URINE DISEASE IN NEWBORN.,ELIZEN PNEMOCOCCUS IGG(ZENTECH)-IMMUNOENZYME ASSAY FOR THE DETERMINATION OF ANTIBODIES ANTIPNEMOCOCCUS IN HUMAN SERUM AND IN PREPARATIONS OF THE IMMUNOGLOBULINS., NEONATAL IRT SCREENING ASSAY(ZENTECH)-ENZYME IMMUNOASSAY FOR THE TITRATION OF IMMUNOREACTIVE TRYPSIN IN DRIED BLOOD SPOT OF NEONATES,NEONATAL G-6-PD SCREENING ASSAY(ZENTECH)-ENZYMATIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE DEFICIENCY IN NEWBORNS DRIED BLOOD SPOTS.,NEONATAL BIOTINIDASE SCREENING ASSAY(ZENTECH)-SCREENING ASSAY FOR THE DETECTION OF BIOTINIDASE DEFICIENCY IN NEWBORNS., NEONATAL TSH SCREENING ELISA(ZENTECH)-ENZYME IMMUNOASSAY FOR THE TITRATION OF THYROID STIMULATING HARMONE IN DRIED BLOOD SPOTS OF NEONATES.,ELIZEN NEONATAL 17-OH-P SCREENING(ZENTECH)-ENZYME IMMUNOASSAY FOR THE TITRATION OF 17 ALPHA- HYDROXYPROGESTERONE IN DRIED BLOOD SPOTS OF NEONATES.,NEONATAL PKU SCREENING ASSAY(ZENTECH) -ENZYMATIC ASSAY FOR QUANTITATIVE DETERMINATION PHENYLALANINE LEVELS IN NEW BORN DRIED BLOOD SPOTS., NEONATAL PAP SCREENING ELISA(ZENTECH)-ENZYME IMMUNOASSAY FOR THE TITRATION OF PANCREATITIS-ASSOCIATED PROTEIN (PAP) FROM DRIED BLOOD SPOTS OF NEONATES,ELIZEN PROINSULIN(ZENTECH)-IMMUNOENZYMOMETRIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE PROINSULIN IN HUMAN SERUM AND PLASMA

937	IMP/IVD/2020/000983	1.License Holder Name: ASRITHA DIATECH INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALBUMIN (ALB) ASSAY KIT (BULK)(ALBUMIN ASSAY KIT (ALB) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ALBUMIN IN SERUM,ADENOSINE DEAMINASE (ADA) ASSAY KIT (BULK)(ADENOSINE DEAMINASE ASSAY KIT (ADA) (BULK))-ADENOSINE DEAMINASE (ADA) ASSAY KIT IS FOR DETERMINATION OF ADA ACTIVITY IN HUMAN SERUM OR PLASMA SAMPLES,POTASSIUM (K) ASSAY KIT (BULK)(POTASSIUM ASSAY KIT (K) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF POTASSIUM IN SERUM OR PLASMA,GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G-6-PD) ASSAY KIT (BULK) (GLUCOSE-6-PHOSPHATE DEHYDROGENASE ASSAY KIT (G-6-PD) (BULK))-FOR QUANTITATIVE DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD) IN HUMAN BLOOD ,DIRECT BILIRUBIN (D-BIL) ASSAY KIT (BULK)(DIRECT BILIRUBIN ASSAY KIT (D-BIL) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN SERUM. ,GLUTAMATE PYRUVATE TRANSAMINASE (GPT/ALT) ASSAY KIT (BULK)(ALANINE AMINOTRANSFERASE ASSAY KIT (GPT/ALT) (BULK))-FOR THE QUANTITATIVE IN VITRO OF ALANINE AMINOTRANSFERASE IN HUMAN SERUM. ,INORGANIC PHOSPHORUS (IP) ASSAY KIT (BULK) (INORGANIC PHOSPHORUS ASSAY KIT (IP) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHOROUS IN HUMAN SERUM,GAMMA-GLUTAMYL TRANSFERASE (GAMMA-GT/GGT) ASSAY KIT (BULK)(GAMMA-GLUTAMYL TRANSFERASE ASSAY KIT (GAMMA-GT/GGT) (BULK))-FOR THE IN VITRO QUANTI-TATIVE DETERMINATION OF GAMMA- GLUTAMYL TRANSFERASE IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS SUITABLE FOR MANUAL USE, AND IS ALSO SUITABLE FOR ALL AUTOMATIC ANALYZER.,ALKALINE PHOSPHATASE (ALP) ASSAY KIT (BULK)(ALKALINE PHOSPHATASE ASSAY KIT (ALP) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE (ALP) IN SERUM ., CREATINE KINASE - MB (CK-MB) ASSAY KIT (BULK)(CREATINE KINASE - MB ASSAY KIT (CK-MB) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CREATINE KINASE -MBCK-MBIN HUMAN SERUM, BICARBONATE (CO2) ASSAY KIT (BULK)(BICARBONATE ASSAY KIT (CO2) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CO2 IN SERUM OR PLASMA,TOTAL BILIRUBIN (T-BIL) ASSAY KIT (BULK)(TOTAL BILIRUBIN ASSAY KIT (T-BIL) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN SERUM. ,TRIGLYCERIDES (TG) ASSAY KIT (BULK)(TRIGLYCERIDES ASSAY KIT (TG) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN SERUM.,CEREBRO-SPINAL

	FLUID/URINE TOTAL PROTEIN (CSF/UP) (BULK)(TOTAL PROTEIN (URINE) ASSAY KIT (UP) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN URINE OR CEREBROSPINAL FLUID,SODIUM (NA) ASSAY KIT (BULK)(SODIUM ASSAY KIT (NA) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF SODIUM IN SERUM OR HEPARIN LITHIUM ANTICOAGULATIVE PLASMA,MICROALBUMIN (MALB) ASSAY KIT (BULK)(MICROALBUMIN ASSAY KIT (MALB) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF MICROALBUMIN IN URINE,CREATININE (CRE) ASSAY KIT (BULK)(CREATININE ASSAY KIT (CRE) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CREATININE IN SERUM, PLASMA OR URINE,LACTATE DEHYDROGENASE (LDH) ASSAY KIT (BULK)(LACTATE DEHYDROGENASE ASSAY KIT (LDH) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE ACTIVITY IN HUMAN SERUM,IRON (FE) ASSAY KIT (BULK)(IRON ASSAY KIT (FE) (BULK))-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF SERUM IRON IN SERUM OR PLASMA,UREA ASSAY KIT (BULK)(UREA ASSAY KIT (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF UREA IN SERUM,LIPASE (LPS) ASSAY KIT (BULK)(LIPASE ASSAY KIT (LPS) (BULK))-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF LIPASE IN HUMAN SERUM AND PLASMA,FERRITIN (FER) ASSAY KIT (BULK)(FERRITIN ASSAY KIT (FER) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FERRITIN IN SERUM AND PLASMA,CHLORIDE (CL) ASSAY KIT BULK)(CHLORIDE ASSAY KIT (CL) BULK))-FOR QUANTITATIVE DETERMINATION OF CHLORIDE IN HUMAN SERUM, GLYCATED ALBUMIN (GA) ASSAY KIT (BULK)(GLYCATED ALBUMIN ASSAY KIT (GA) (BULK))-FOR THE QUANTITATIVE RATIO DETERMINATION OF HUMAN GLYCATED ALBUMIN (GA) AND ALBUMIN (ALB) IN SERUM OR PLASMA. FOR IN VITRO DIAGNOSTIC USE ONLY, TOTAL PROTEIN (TP) ASSAY KIT (BULK)(TOTAL PROTEIN ASSAY KIT (TP) (BULK))-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM.,GLUTAMATE OXALOACETATE TRANSAMINASE (GOT/AST) ASSAY KIT (BULK)(ASPARATE AMINOTRANSFERASE ASSAY KIT (GOT/AST) (BULK))-THE ASPARTATE AMINOTRANSFERASE (AST) ASSAY IS USED FOR THE QUANTITATION OF ASPARTATE AMINOTRANSFERASE IN HUMAN SERUM. THIS PRODUCT IS SUITABLE FOR MANUAL USE.,ALPHA-AMYLASE (AMY) ASSAY KIT (BULK)(ALPHA-AMYLASE (AMY) ASSAY KIT (BULK))-FOR THE QUANTITATIVE DETERMINATION OF AMYLASE ACTIVITY, USING MANUAL OR AUTOMATED PROCEDURES, IN HUMAN SERUM SAMPLES,LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) ASSAY KIT (BULK)(LOW DENSITY LIPOPROTEIN CHOLESTEROL ASSAY KIT (LDL-C) (BULK))-FOR THE IN VITRO QUANTITATIVE

	DETERMINATION OF LDL IN SERUM.,HIGH DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) ASSAY KIT (BULK)(HIGH DENSITY LIPOPROTEIN CHOLESTEROL ASSAY KIT (HDL-C) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HDL-C IN SERUM., CHOLINESTERASE (CHE) ASSAY KIT (BULK)(CHOLINESTERASE ASSAY KIT (CHE) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CHOLINESTERASE (CHE) IN SERUM. ,URIC ACID (UA) ASSAY KIT (BULK)(URIC ACID ASSAY KIT (UA) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF URIC ACID IN SERUM,TOTAL CHOLESTEROL (CHO) ASSAY KIT (BULK)(TOTAL CHOLESTEROL ASSAY KIT (CHO) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CHOLESTEROL IN SERUM.,CREATINE KINASE (CK-NAC) ASSAY KIT (BULK)(CREATINE KINASE ASSAY KIT (CK-NAC) (BULK))-THIS REAGENT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CREATINE KINASE IN HUMAN SERUM,CALCIUM (CA) ASSAY KIT (BULK)(CALCIUM ASSAY KIT (CA) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM,HOMOCYSTEINE (HCY) ASSAY KIT (BULK) (HOMOCYSTEINE ASSAY KIT (HCY) (BULK))-ENZYMATIC HOMOCYSTEINE ASSAY IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TOTAL L-HOMOCYSTEINE IN SERUM OR PLASMA,PREALBUMIN (PALB) ASSAY KIT (BULK) (PREALBUMIN ASSAY KIT (PALB) (BULK))-FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PREALBUMIN(TRANSTHYRETIN) IN HUMAN SERUM,HEMOGLOBIN A1C (HBA1C) ASSAY KIT (BULK) (HEMOGLOBIN A1C ASSAY KIT (HBA1C) (BULK))-FOR QUANTITATIVE DETERMINATION OF THE HBA1C/TOTAL HEMOGLOBIN RATIO (%) IN HUMAN BLOOD,MAGNESIUM (MG) ASSAY KIT (BULK)(MAGNESIUM ASSAY KIT (MG) (BULK))-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF MAGNESIUM IN HUMAN SERUM,LIOPROTEIN (A) (LP(A)) ASSAY KIT (BULK)(LIOPROTEIN (A) ASSAY KIT (LP(A)) (BULK)) -FOR THE IN VITRO QUANTITATIVE DETERMINATION OF LIOPROTEIN (A) IN SERUM OR PLASMA.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

938	IMP/IVD/2020/000984	1.License Holder Name: SYSMEX INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROL PLASMA P (CONTROL PLASMA P)-CONTROL P IS AN ASSAYED CONTROL USED FOR THE ASSESSMENT OF PRECISION AND ANALYTICAL DEVIATION OF THE FOLLOWING ANALYTES IN THE PATHOLOGICAL RANGE: 1. PROTHROMBIN TIME (PT) 2. ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) 3. FIBRINOGEN (CLAUSS METHOD) 4. COAGULATION FACTORS II, V, VII, VIII, IX, X, XI, XII, XIII AND VWF 5. INHIBITORS: ANTITHROMBIN III, PROTEIN C, PROTEIN S, 2-ANTIPLASMIN, C1 INHIBITOR 6. PLASMINOGEN THE VALUES WERE DETERMINED USING SIEMENS HEALTHCARE DIAGNOSTICS REAGENTS ON MECHANICAL AND PHOTO-OPTICAL COAGULATION ANALYZERS. ,INNOVANCE D-DIMER CONTROLS(INNOVANCE D-DIMER CONTROLS)-INNOVANCE® D-DIMER CONTROL 1 AND INNOVANCE® D-DIMER CONTROL 2 ARE ASSAYED CONTROLS FOR THE ASSESSMENT OF PRECISION AND ANALYTICAL BIAS IN THE NORMAL AND PATHOLOGICAL RANGE FOR THE DETERMINATION OF D-DIMER ON SIEMENS AND SYSMEX SYSTEMS. ,COAGULATION FACTOR XI DEFICIENT PLASMA (COAGULATION FACTOR XI DEFICIENT PLASMA)-IN VITRO DIAGNOSTIC REAGENTS FOR THE DETERMINATION OF THE ACTIVITY OF COAGULATION FACTORS VIII, IX, XI AND XII IN HUMAN PLASMA BY COAGULOMETRIC METHODS. ,BATROXOBIN REAGENT(BATROXOBIN REAGENT)-REAGENT FOR THE DETERMINATION OF THE BATROXOBIN TIME,MULTIFIBREN U(MULTIFIBREN U)-QUANTITATIVE DETERMINATION OF FIBRINOGEN IN PLASMA. ,FIBRINOGEN CALIBRATOR KIT(FIBRINOGEN CALIBRATOR KIT)-FIBRINOGEN CALIBRATORS 1 TO 6 ARE USED TO PREPARE REFERENCE CURVES FOR THE ASSAY OF FIBRINOGEN BY THE METHOD OF CLAUSS1 USING SIEMENS HEALTHCARE DIAGNOSTICS MULTIFIBREN U.,BERICHROM PLASMINOGEN(BERICHROM PLASMINOGEN)-FOR THE QUANTITATIVE DETERMINATION OF BIOLOGICAL ACTIVITY OF PLASMINOGEN AS AN AID IN THE DIAGNOSIS AND MONITORING OF FIBRINOLYTIC DISORDERS. ,DADE FIBRINOGEN DETERMINATION REAGENTS(DADE FIBRINOGEN DETERMINATION REAGENTS)-FOR THE QUANTITATIVE DETERMINATION OF FIBRINOGEN IN HUMAN PLASMA. ,DADE THROMBIN REAGENTS(DADE THROMBIN REAGENTS)-FOR USE IN THE QUANTITATIVE DETERMINATION OF FIBRINOGEN IN PLASMA AND TO ACCELERATE COAGULATION OF ANTICOAGULATED SAMPLES FOR IMMUNOHEMATOLOGY STUDIES. ,BERICHROM FACTOR XIII (BERICHROM FACTOR XIII)-PHOTOMETRIC DETERMINATION OF FACTOR XIII ACTIVITY IN PLASMA SAMPLES MONITORING OF SUBSTITUTION THERAPY WITH FACTOR XIII CONCENTRATE ,PROC GLOBAL(PROC GLOBAL)-PROC GLOBAL IS A COAGULATION TEST

	FOR THE DETERMINATION OF THE ANTICOAGULATORY CAPACITY OF THE PROTEIN C SYSTEM IN HUMAN PLASMA AND IS USED TO DIAGNOSE HEREDITARY OR ACQUIRED DEFICIENCY STATES OF THE PROTEIN C SYSTEM. USED IN CONJUNCTION WITH SIEMENS HEALTHCARE DIAGNOSTICS COAGULATION FACTOR V DEFICIENT PLASMA, PROC® GLOBAL IS A SUITABLE TEST FOR THE DETERMINATION OF FACTOR V LEIDEN.,FACTOR VIII CHROMOGENIC ASSAY(FACTOR VIII CHROMOGENIC ASSAY)-FOR PHOTOMETRIC DETERMINATION OF FACTOR VIII (ANTIHEMOPHILIC FACTOR) ACTIVITY IN HUMAN PLASMA. ,INNOVANCE D-DIMER SAMPLE DILUENT(INNOVANCE D-DIMER SAMPLE DILUENT)-INNOVANCE® D-DIMER SAMPLE DILUENT IS AN IN-VITRO DIAGNOSTIC PRODUCT INTENDED TO BE USED IN CONJUNCTION WITH THE INNOVANCE® D-DIMER METHOD, FOR THE MEASUREMENT OF SAMPLES OUTSIDE THE INITIAL MEASURING RANGE.,DADE CI-TROL COAGULATION CONTROL LEVEL 2(DADE CI-TROL COAGULATION CONTROL LEVEL 2)-FOR USE IN CITRATED COAGULATION SYSTEMS ,INNOVANCE VWF AC (INNOVANCE VWF AC)-INNOVANCE® VWF AC IS A PARTICLE ENHANCED ASSAY FOR THE AUTOMATED DETERMINATION OF VON WILLEBRAND FACTOR ACTIVITY IN HUMAN CITRATED PLASMA., PATHROMTIN SL(PATHROMTIN SL)-REAGENT FOR THE DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) IN CITRATED HUMAN PLASMA.,INNOVANCE PFA P2Y (INNOVANCE PFA P2Y)-THE INNOVANCE® PFA P2Y IS A TEST CARTRIDGE FOR THE PFA-100® SYSTEM AND INNOVANCE® PFA-200 SYSTEM INTENDED FOR THE DETECTION OF PLATELET P2Y12-RECEPTOR BLOCKADE IN PATIENTS UNDERGOING THERAPY WITH A P2Y12-RECEPTOR ANTAGONIST. FOR USE IN THE CLINICAL LABORATORY WITH CITRATED HUMAN WHOLE BLOOD.,BC VON WILLEBRAND REAGENT(BC VON WILLEBRAND REAGENT)-IN-VITRO DIAGNOSTIC FOR THE DETERMINATION OF RISTOCETIN COFACTOR ACTIVITY OF VON WILLEBRAND FACTOR IN HUMAN PLASMA THROUGH PLATELET AGGLUTINATION.,TEST THROMBIN REAGENT (TEST THROMBIN REAGENT)-REAGENT FOR THE DETERMINATION OF THE THROMBIN TIME IN HUMAN PLASMA. ,PROTEIN S AC REAGENT (PROTEIN S AC REAGENT)-FOR THE DETERMINATION OF THE FUNCTIONAL ACTIVITY OF PROTEIN S IN HUMAN PLASMA. ,PT-MULTI CALIBRATOR(PT-MULTI CALIBRATOR)-CALIBRATOR SET FOR THE DIRECT CALIBRATION OF THE PROTHROMBIN TIME (PT) IN INR AND % OF NORM. FOR THE DETERMINATION OF A LOCAL ISI VALUE. ,DADE ACTIN ACTIVATED CEPHALOPLASTIN(DADE ACTIN ACTIVATED CEPHALOPLASTIN)-LIQUID RABBIT BRAIN CEPHALIN WITH PLASMA ACTIVATOR FOR USE IN THE DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) AND OTHER COAGULATION

	PROCEDURES REQUIRING AN ACTIVATED PARTIAL THROMBOPLASTIN REAGENT.,KAOLIN SUSPENSION(KAOLIN SUSPENSION)-KAOLIN SUSPENSION IS USED AS SUPPLEMENTARY REAGENT FOR THE FIBRINTIMER. ,BERICHROM C-1 INHIBITOR (BERICHROM C-1 INHIBITOR)-DETERMINATION OF THE FUNCTIONAL ACTIVITY OF C1-INHIBITOR IN PLASMA FOR THE DIAGNOSIS OF DIMINISHED C1-INHIBITOR SYNTHESIS, INCREASED CONSUMPTION AND FOR MONITORING SUBSTITUTION THERAPY AND ANDROGEN THERAPY.,BC THROMBIN REAGENT(BC THROMBIN REAGENT)-REAGENT FOR THE QUANTITATIVE DETERMINATION OF THE THROMBIN TIME IN CITRATED HUMAN PLASMA. ,COAGULATION FACTOR XII DEFICIENT PLASMA(COAGULATION FACTOR XII DEFICIENT PLASMA)-IN VITRO DIAGNOSTIC REAGENTS FOR THE DETERMINATION OF THE ACTIVITY OF COAGULATION FACTORS VIII, IX, XI AND XII IN HUMAN PLASMA BY COAGULOMETRIC METHODS, DADE CI-TROL HEPARIN CONTROL, HIGH(DADE CI-TROL HEPARIN CONTROL, HIGH)-FOR USE AS A CONTROL IN HEPARIN ASSAY PROCEDURES. ,INNOVANCE D-DIMER(INNOVANCE D-DIMER)-INNOVANCE® D-DIMER IS A PARTICLE-ENHANCED, IMMUNOTURBIDIMETRIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF CROSS-LINKED FIBRIN DEGRADATION PRODUCTS (D-DIMERS) IN HUMAN PLASMA FOR USE ON COAGULATION ANALYZERS. THE INNOVANCE® D-DIMER ASSAY IS INDICATED FOR USE IN CONJUNCTION WITH A CLINICAL PRETEST PROBABILITY (PTP) ASSESSMENT MODEL TO EXCLUDE DEEP VEIN THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE) DISEASE IN OUTPATIENTS SUSPECTED OF DVT OR PE. INNOVANCE® D-DIMER CAN BE USED FOR THE MONITORING OF THE RELATIVE CHANGE IN D-DIMER CONCENTRATION. ,INNOVANCE FREE PS AG(INNOVANCE FREE PS AG)-FOR THE QUANTITATIVE DETERMINATION OF FREE PROTEIN S IN HUMAN CITRATED PLASMA ON AUTOMATED COAGULATION ANALYZERS. FOR IN-VITRO DIAGNOSTIC USE.,COAGULATION FACTOR X DEFICIENT PLASMA(COAGULATION FACTOR X DEFICIENT PLASMA)-IN VITRO DIAGNOSTIC REAGENTS FOR THE DETERMINATION OF THE ACTIVITY OF COAGULATION FACTOR II (PROTHROMBIN), COAGULATION FACTOR VII AND COAGULATION FACTOR X IN HUMAN PLASMA BY COAGULOMETRIC METHODS,VON WILLEBRAND REAGENT (VON WILLEBRAND REAGENT)-IN-VITRO DIAGNOSTIC REAGENT FOR DETERMINATION OF THE RISTOCETIN COFACTOR ACTIVITY OF VON WILLEBRAND FACTOR IN HUMAN PLASMA USING THE PLATELET AGGLUTINATION METHOD.,DADE CI-TROL 1(DADE CI-TROL 1)-CI-TROL® 1 WAS SPECIALLY DEVELOPED AS A CONTROL FOR THE NORMAL RANGE IN COAGULATION TESTS WITH SODIUM CITRATE USED AS THE ANTICOAGULANT SOLUTION, AND IT IS USED AS A

	CONTROL OF PRECISION AND ACCURACY FOR VARIOUS REAGENT SYSTEMS IN THE FOLLOWING APPLICATIONS: 1. PROTHROMBIN TIME (PT) 2. ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) 3. THROMBIN TIME (TT) 4. FIBRINOGEN 5. ANTITHROMBIN III (ATIII) 6. BATROXOBIN/REPTILASE TIME ,BERICHROM PROTEIN C(BERICHROM PROTEIN C)-FOR THE QUANTITATIVE DETERMINATION OF FUNCTIONALLY ACTIVE PROTEIN C USING A CHROMOGENIC SUBSTRATE AS AN AID IN THE DIAGNOSIS OF INHERITED AND ACQUIRED DEFICIENCIES.,COAGULATION FACTOR II DEFICIENT PLASMA(COAGULATION FACTOR II DEFICIENT PLASMA)-IN VITRO DIAGNOSTIC REAGENTS FOR THE DETERMINATION OF THE ACTIVITY OF COAGULATION FACTOR II (PROTHROMBIN), COAGULATION FACTOR VII AND COAGULATION FACTOR X IN HUMAN PLASMA BY COAGULOMETRIC METHODS. ,THROMBOCLOTIN(THROMBOCLOTIN)-REAGENT FOR THE DETERMINATION OF THROMBIN TIME IN HUMAN CITRATED PLASMA,DADE HEPZYME(DADE HEPZYME)-FOR USE AS A HEPARIN NEUTRALIZER IN PLASMA TO RULE OUT HEPARIN CONTAMINATION IN COAGULATION TESTING,INNOVANCE ANTITHROMBIN(INNOVANCE ANTITHROMBIN)-INNOVANCE® ANTITHROMBIN IS A CHROMOGENIC ASSAY FOR THE AUTOMATIC QUANTIFICATION OF FUNCTIONALLY ACTIVE ANTITHROMBIN IN HUMAN CITRATED PLASMA. THE ASSAY IS SUITABLE FOR DIAGNOSIS OF CONGENITAL OR ACQUIRED ANTITHROMBIN DEFICIENCIES, WHICH ARE ASSOCIATED WITH A HIGH RISK OF THROMBOSIS. INNOVANCE® ANTITHROMBIN ASSAY CAN BE USED FOR MONITORING SUBSTITUTION THERAPY WITH ANTITHROMBIN CONCENTRATES. , THROMBOREL S(THROMBOREL S)-THROMBOREL® S REAGENT IS USED FOR THE DETERMINATION OF THE PROTHROMBIN TIME (PT) ACCORDING TO QUICK AND, IN CONJUNCTION WITH THE RELEVANT DEFICIENT PLASMAS, FOR THE DETERMINATION OF THE ACTIVITY OF COAGULATION FACTORS II, V, VII AND X. ,COAGULATION FACTOR IX DEFICIENT PLASMA(COAGULATION FACTOR IX DEFICIENT PLASMA)-IN VITRO DIAGNOSTIC REAGENTS FOR THE DETERMINATION OF THE ACTIVITY OF COAGULATION FACTORS VIII, IX, XI AND XII IN HUMAN PLASMA BY COAGULOMETRIC METHODS.,DADE CI-TROL COAGULATION CONTROL LEVEL 1(DADE CI-TROL COAGULATION CONTROL LEVEL 1)-FOR USE IN CITRATED COAGULATION SYSTEMS., DADE CI-TROL 2(DADE CI-TROL 2)-CI-TROL 2 IS USED FOR CONTROL OF COAGULATION TESTS IN THE MIDDLE TO UPPER THERAPEUTIC RANGE OF ORAL ANTICOAGULANT THERAPY. WITH ITS REDUCED ACTIVITIES OF FACTORS II, VII, IX AND X, THIS CONTROL IS EQUIVALENT TO PLASMA FROM A PATIENT RECEIVING ANTICOAGULANT TREATMENT. CI-TROL® 2 IS PREFERENTIALLY INCLUDED IN EACH RUN AS AN "ABNORMAL PLASMA" FOR THE

	CONTROL OF ACCURACY AND PRECISION. IN ADDITION TO CONTROL VALUES FOR THE PROTHROMBIN TIME (PT), CI-TROL® 2 ALSO PROVIDES ASSIGNED VALUES FOR THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) TO ENABLE MONITORING FOR REDUCED ACTIVITY OF THE INTRINSIC COAGULATION FACTORS AS WELL AS THE THERAPEUTIC RANGE IN HEPARIN THERAPY.,PROC CONTROL PLASMA(PROC CONTROL PLASMA)-PROC CONTROL PLASMA IS AN ASSAYED INTRALABORATORY CONTROL TO ESTIMATE PRECISION AND ANALYTICAL DEVIATION OF THE PROC® LINE TESTS IN THE PATHOLOGICAL RANGE. ,DADE CI TROL HEPARIN CONTROL, LOW(DADE CI TROL HEPARIN CONTROL, LOW)-FOR USE AS A CONTROL IN HEPARIN ASSAY PROCEDURES.,DADE PFA COLLAGEN/EPI TEST CARTIDGE(DADE PFA COLLAGEN/EPI TEST CARTIDGE)-TO AID IN THE DETECTION OF PLATELET DYSFUNCTION IN CITRATED HUMAN WHOLE BLOOD WITH THE PFA-100® SYSTEM AND INNOVANCE® PFA-200 SYSTEM.,COAGULATION FACTOR V DEFICIENT PLASMA(COAGULATION FACTOR V DEFICIENT PLASMA)-IN VITRO DIAGNOSTIC REAGENT FOR THE DETERMINATION OF THE ACTIVITY OF COAGULATION FACTOR V AND FOR THE DETECTION OF FACTOR V LEIDEN IN HUMAN PLASMA. ,STANDARD HUMAN PLASMA (STANDARD HUMAN PLASMA)-STANDARD HUMAN PLASMA IS USED FOR THE CALIBRATION OF THE FOLLOWING TESTS: 1. PROTHROMBIN TIME (PT) 2. FIBRINOGEN (CLAUSS METHOD) 3. COAGULATION FACTORS II, V, VII, VIII, IX, X, XI, XII, XIII AND VWF 4. INHIBITORS: ANTITHROMBIN III, PROTEIN C, PROTEIN S, 2-ANTIPLASMIN, C1 INHIBITOR 5. PLASMINOGEN IN ADDITION, THE STATED SENSITIVITY VALUES FOR PROC® REAGENTS ARE PROVIDED FOR CALCULATING THE NORMALIZED RATIO FOR PROC® GLOBAL AND PROC® GLOBAL/FV. ,CALCIUM CHLORIDE SOLUTION(CALCIUM CHLORIDE SOLUTION)-CALCIUM CHLORIDE SOLUTION IS USED AS SUPPLEMENTARY REAGENT FOR VARIOUS COAGULATION ASSAYS, COAGULATION FACTOR VII DEFICIENT PLASMA(COAGULATION FACTOR VII DEFICIENT PLASMA)-IN VITRO DIAGNOSTIC REAGENTS FOR THE DETERMINATION OF THE ACTIVITY OF COAGULATION FACTOR II (PROTHROMBIN), COAGULATION FACTOR VII AND COAGULATION FACTOR X IN HUMAN PLASMA BY COAGULOMETRIC METHODS. ,DADE PFA COLLAGEN/ADP TEST CARTRIDGE(DADE PFA COLLAGEN/ADP TEST CARTRIDGE)-TO AID IN THE DETECTION OF PLATELET DYSFUNCTION IN CITRATED HUMAN WHOLE BLOOD WITH THE PFA-100® SYSTEM AND INNOVANCE® PFA-200 SYSTEM.,DADE INNOVIN(DADE INNOVIN)-FOR USE IN PROTHROMBIN TIME (PT) DETERMINATIONS AND PROTHROMBIN TIME-BASED ASSAYS IN CITRATED HUMAN PLASMA,DADE DATA-FI ABNORMAL FIBRINOGEN CONTROL(DADE DATA-FI ABNORMAL FIBRINOGEN CONTROL)-

	DADE® DATA-FI® ABNORMAL FIBRINOGEN CONTROL PLASMA IS A CONTROL DERIVED FROM HUMAN PLASMA. IT IS USED TO ASSESS ACCURACY AND PRECISION OF DADE® FIBRINOGEN DETERMINATION REAGENTS IN THE LOW RANGE.,DADE PFA TRIGGER SOLUTION(DADE PFA TRIGGER SOLUTION)-TO AID IN THE DETECTION OF PLATELET DYSFUNCTIONS IN CITRATED HUMAN WHOLE BLOOD,BERICHROM ANTITHROMBIN III (A)(BERICHROM ANTITHROMBIN III (A))-FOR THE QUANTITATIVE DETERMINATION OF THE FUNCTIONAL ACTIVITY OF ANTITHROMBIN III (AT III) IN PLASMA USING AUTOMATED ANALYZERS FOR DIAGNOSING REDUCED AT III SYNTHESIS OR INCREASED CONSUMPTION AND FOR MONITORING SUBSTITUTION THERAPY. ,COAGULATION FACTOR VIII DEFICIENT PLASMA (COAGULATION FACTOR VIII DEFICIENT PLASMA)-IN VITRO DIAGNOSTIC REAGENTS FOR THE DETERMINATION OF THE ACTIVITY OF COAGULATION FACTORS VIII, IX, XI AND XII IN HUMAN PLASMA BY COAGULOMETRIC METHODS. ,CONTROL PLASMA N(CONTROL PLASMA N)-CONTROL N IS AN ASSAYED CONTROL USED FOR THE ASSESSMENT OF PRECISION AND ANALYTICAL DEVIATION OF THE FOLLOWING ANALYTES IN THE NORMAL RANGE: 1. PROTHROMBIN TIME (PT) 2. ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) 3. THROMBIN TIME (TT) 4. BATROXOBIN TIME 5. FIBRINOGEN 6. COAGULATION FACTORS II, V, VII, VIII, IX, X, XI, XII, XIII AND VWF 7. INHIBITORS: ANTITHROMBIN III, PROTEIN C, PROTEIN S, 2-ANTIPLASMIN, C1-INHIBITOR 8. PLASMINOGEN 9. PROC® LINE ANALYTES 10. LUPUS ANTICOAGULANTS THE ASSIGNED VALUES WERE DETERMINED AT SIEMENS HEALTHCARE DIAGNOSTICS USING SIEMENS REAGENTS ON MECHANICAL AND PHOTO-OPTICAL COAGULATION SYSTEMS. ,DADE ACTIN FSL ACTIVATED PTT REAGENT (DADE ACTIN FSL ACTIVATED PTT REAGENT)-LIQUID PURIFIED SOY AND RABBIT BRAIN PHOSPHATIDES WITH PLASMA ACTIVATOR. AN ACTIVATED PARTIAL THROMBOPLASTIN REAGENT WITH INCREASED SENSITIVITY TO LUPUS-LIKE INHIBITORS FOR USE IN THE DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) AND RELATED COAGULATION PROCEDURES. ,PROTEIN C REAGENTS(PROTEIN C REAGENTS)-PROTEIN C REAGENT IS A COAGULATION TEST FOR THE QUANTITATIVE DETERMINATION OF PROTEIN C ACTIVITY IN HUMAN PLASMA. ,DADE ACTIN FS ACTIVATED PTT REAGENT(DADE ACTIN FS ACTIVATED PTT REAGENT)-LIQUID PURIFIED SOY PHOSPHATIDES WITH PLASMA ACTIVATOR FOR USE IN THE DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) AND OTHER COAGULATION PROCEDURES REQUIRING AN ACTIVATED PARTIAL THROMBOPLASTIN REAGENT. ,BERICHROM 2-ANTIPLASMIN (BERICHROM 2-ANTIPLASMIN)-FOR THE QUANTITATIVE

	DETERMINATION OF BIOLOGICALLY ACTIVE 2-ANTIPLASMIN AS AN AID IN THE DIAGNOSIS OF INHERITED OR ACQUIRED DEFICIENCIES AND IN MANAGEMENT OF FIBRINOLYTIC THERAPY,IMIDAZOLE BUFFER SOLUTION(IMIDAZOLE BUFFER SOLUTION)-IMIDAZOLE BUFFER SOLUTION IS USED AS DILUENT FOR VARIOUS COAGULATION ASSAYS. ,DADE CI-TROL 3(DADE CI-TROL 3)-CI-TROL® 3 IS USED FOR CONTROL OF COAGULATION TESTS IN THE UPPER THERAPEUTIC RANGE OF ORAL ANTICOAGULANT THERAPY. WITH ITS REDUCED ACTIVITIES OF FACTORS II, VII, IX AND X, THIS CONTROL IS EQUIVALENT TO PLASMA FROM A PATIENT RECEIVING ANTICOAGULANT TREATMENT. CI-TROL® 3 IS PREFERENTIALLY INCLUDED IN EACH RUN AS AN „ABNORMAL PLASMA“ FOR THE CONTROL OF ACCURACY AND PRECISION. IN ADDITION TO CONTROL VALUES FOR THE PROTHROMBIN TIME (PT), CI-TROL® 3 ALSO PROVIDES ASSIGNED VALUES FOR THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) TO ENABLE MONITORING REDUCED ACTIVITY OF THE INTRINSIC COAGULATION FACTORS AS WELL AS THE THERAPEUTIC RANGE IN HEPARIN THERAPY.,DADE OWREN'S VERONAL BUFFER(DADE OWREN'S VERONAL BUFFER)-DILUTION BUFFER FOR COAGULATION TESTING.,BERICHROM PAI(BERICHROM PAI)-DETERMINATION OF PAI ACTIVITY IN HUMAN PLASMA. ,DADE CI-TROL COAGULATION CONTROL LEVEL 3(DADE CI-TROL COAGULATION CONTROL LEVEL 3)-FOR USE IN CITRATED COAGULATION SYSTEMS

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

939	IMP/IVD/2020/000987	1.License Holder Name: M/S. PEERLESS BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACE CAL(SPINREACT)-ANGIOTENSIN CONVERTING ENZYME (ACE) CALIBRATOR, APOLIPOPROTEIN AII(SPINREACT)-QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN A-II (APO A-II),CALCIUM OC(SPINREACT)-QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SAMPLES, APOLIPOPROTEIN E(SPINREACT)-QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN E (APO E),DIRECT HOMOCYSTEIN(SPINREACT)-QUANTITATIVE DETERMINATION OF HOMOCYSTEIN IN HUMAN SAMPLES,SPINTROL “H” PATOLOGICO.(SPINREACT)-MULTIPARAMETRIC CONTROL SERA INTENDED FOR ACCURACY CONTROL OF CLINICAL CHEMISTRY REAGENTS. THE CONCENTRATIONS AND ACTIVITIES ARE IN THE PATHOLOGICAL RANGE (HUMAN SOURCE),CYSTATIN C(SPINREACT)-QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SAMPLES,CREATININE –TR(SPINREACT)-QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SAMPLES,AMYLASE LQ(SPINREACT)-QUANTITATIVE DETERMINATION OF AMYLASE IN HUMAN SAMPLES,MAGNESIUM (SPINREACT)-QUALITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SAMPLES,ALBUMIN(SPINREACT)-QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SAMPLES,COMPLEMENT C4 (SPINREACT)-QUANTITATIVE DETERMINATION OF COMPLEMENT C4 IN HUMAN SAMPLES,GPT /ALT –LQ. IFCC(SPINREACT)-QUANTITATIVE DETERMINATION OF THE ALANINE AMINOTRANSFERASE (ALT) ACTIVITY IN HUMAN SAMPLES,CRP TURBI CAL(SPINREACT)-SERUM CONTROL CRP TURBIDIMETRY ASSAYS,HDLC –D. DIRECT. (SPINREACT)-QUANTITATIVE DETERMINATION OF CHOLESTEROL HDL IN HUMAN SAMPLES,INMUNOGLOBULINA E (IGE)(SPINREACT)-QUANTITATIVE DETERMINATION OF IGE IN HUMAN SAMPLES,TIBC (SPINREACT)-QUANTITATIVE DETERMINATION OF TIBC IN HUMAN SAMPLES,ASO/CRP/RF CONTROL LOW LEVEL.(SPINREACT)-SERUM CONTROL MUTICOMPONENT FOR ASO, CRP, RF TURBIDIMETRY ASSAYS WITH VALUES IN NORMAL RANGE,TOTAL LIPIDS(SPINREACT) -QUANTITATIVE DETERMINATION OF TOTAL LIPIDS IN HUMAN SAMPLES,SERUM PROTEINS CONTROL(SPINREACT)-SERUM CONTROL MULTIPARAMETRIC FOR IMMUNOTURBIDIMETRY ASSAYS, DIRECT HBA1C CAL(SPINREACT)-SERUM CALIBRATOR FOR DETERMINATION OF GLICATED HAEMOGLOBIN (HBA1C) ASSAY, LACTATE(SPINREACT)-QUANTITATIVE DETERMINATION OF THE LACTATE IN HUMAN SAMPLES S,MALB TURBI(SPINREACT)-QUANTITATIVE DETERMINATION OF MICROALBUMIN IN HUMAN URINE SAMPLES,PHOSPHOLIPIDS(SPINREACT)-QUANTITATIVE DETERMINATION OF PHOSPHOLIPIDS IN HUMAN SAMPLES,FERRITIN

	TURBI(SPINREACT)-QUANTITATIVE DETERMINATION OF FERITTIN IN HUMAN SAMPLES,RF TURBI CAL(SPINREACT)-SERUM CONTROL RF TURBIDIMETRY ASSAYS,BILIRUBIN T&D(SPINREACT)-QUANTITATIVE DETERMINATION OF TOTAL AND DIRECT BILIRUBIN IN HUMAN SAMPLES,TOTAL BILIRUBIN DMSO(SPINREACT)-QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SAMPLES, INMUNGOLOBULINA A (IGA)(SPINREACT)-QUANTITATIVE DETERMINATION OF IGA IN HUMAN SAMPLES,SPINTROL “H” NORMAL (SPINREACT)-MULTIPARAMETRIC CONTROL SERA INTENDED FOR ACCURACY CONTROL OF CLINICAL CHEMISTRY REAGENTS. THE CONCENTRATIONS AND ACTIVITIES ARE IN THE NORMAL RANGE (HUMAN SOURCE),TOTAL BILE ACIDS(SPINREACT)-QUANTITATIVE DETERMINATION OF TOTAL BILE ACIDS IN HUMAN SAMPLES,URIC ACID –LQ(SPINREACT)-QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SAMPLES,BETA 2 –MICROGLOBULIN TURBI CAL (SPINREACT)-QUANTITATIVE DETERMINATION OF BETA 2-MICROGLOBULIN (BETA 2-M),RF TURBI(SPINREACT)-QUANTITATIVE DETERMINATION OF RHEUMATIOD FACTOR IN HUMAN SAMPLES, AMMONIA(SPINREACT)-QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN SAMPLES,ALP LQ. AMP.IFCC(SPINREACT)-QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY IN HUMAN SAMPLES,IRON –FZ.(SPINREACT)-QUANTITATIVE DETERMINATION OF IRON IN HUMAN SAMPLES,CRP ULTRA CAL (SPINREACT)-SERUM CALIBRATOR FOR C-REATIVE PROTEIN ULTRASENSITIVE ASSAY,ASO/CRP/RF CONTROL HIGH LEVEL (SPINREACT)-SERUM CONTROL MUTICOMPONENT FOR ASO, CRP, RF TURBIDIMETRY ASSAYS WITH VALUES IN PATHOLOGICAL RANGE, CHLORIDE(SPINREACT)-QUANTITATIVE DETERMINATION OF CHLORIDE IN HUMAN SAMPLES,CYSTATIN C CONTROL(SPINREACT)-SERUM CONTROL FOR CYSTATIN C TURBIDIMETRY ASSAY, CHOLESTEROL LQ(SPINREACT)-QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SAMPLES,BILIRUBIN T&D –DMSO (SPINREACT)-QUANTITATIVE DETERMINATION OF TOTAL AND DIRECT BILIRUBIN IN HUMAN SAMPLES,GAMMA-GT –LQ(SPINREACT)-QUANTITATIVE DETERMINATION OF GAMMA-GT IN HUMAN SAMPLES, CK-MB –LQ(SPINREACT)-QUANTITATIVE DETERMINATION OF CREATINE KINASE-MB (CK-MB) ACTIVITY IN HUMAN SAMPLES, COPPER(SPINREACT)-QUANTITATIVE DETERMINATION OF COPPER IN HUMAN SAMPLES ,LDLC –D(SPINREACT)-QUANTITATIVE DETERMINATION OF CHOLESTEROL LDL IN HUMAN SAMPLES,CK-NAC –LQ(SPINREACT)-QUANTITATIVE DETERMINATION OF CK ACTIVITY IN HUMAN SAMPLES,LP(A) TURBI(SPINREACT)-QUANTITATIVE DETERMINATION OF LP (A) IN HUMAN SAMPLES,CYSTATIN C CAL (SPINREACT)-SERUM CALIBRATOR FOR CYSTATIN C TURBIDIMETRY

	ASSAY,CRP TURBI(SPINREACT)-QUANTITATIVE DETERMINATION OF C-REATIVE PROTEIN IN HUMAN SAMPLES,ACE(SPINREACT)-QUANTITATIVE DETERMINATION OF ANGIOTENSIN CONVERTING ENZYME (ACE) IN SERUM OR PLASMA,ADA CONTROL (ADENOSINE DEAMINASE)(SPINREACT)-SERUM CONTROL FOR ADA ASSAY,UREA – UV(SPINREACT)-QUANTITATIVE DETERMINATION OF UREA IN HUMAN SAMPLES,POTASSIUM – LQ(SPINREACT)-QUANTITATIVE DETERMINATION OF POTASSIUM IN HUMAN SAMPLES, CERULOPLASMIN(SPINREACT)-QUANTITATIVE DETERMINATION OF CERULOPLASMIN IN HUMAN SAMPLES,FERRITINE TURBI CONTROL (SPINREACT)-SERUM CONTROL FOR FERRITIN TURBIDIMETRY ASSAY, FRUCTOSAMINE(SPINREACT)-QUANTITATIVE DETERMINATION OF FRUCTOSAMINE IN HUMAN SAMPLES,DIRECT HBA1C(SPINREACT)-QUANTITATIVE DETERMINATION OF GLICATED HAEMOGLOBIN (HBA1C) IN HUMAN SAMPLES,FOB – TURBI(SPINREACT)-FECAL OCCULT BLOOD DETERMINATION BY TURBIDIMETRY,GOT/ AST. IFCC (SPINREACT)-QUANTITATIVE DETERMINATION OF THE ASPARTATE AMINOTRANSFERASE (AST) ACTIVITY IN HUMAN SAMPLES,GPT / ALT. IFCC(SPINREACT)-QUANTITATIVE DETERMINATION OF THE ALANINE AMINOTRANSFERASE (ALT) ACTIVITY IN HUMAN SAMPLES,CONTROL CK –NAC / CK -MB(SPINREACT)-CK-MB CONTROL SERUM,MALB TURBI CONTROL(SPINREACT)-SERUM CONTROL FOR MICROALBUMIN TURBIDIMETRY ASSAY,LDH –LQ IFCC(SPINREACT)-QUANTITATIVE DETERMINATION OF THE LACTATE DEHYDROGENASE (LDH) ACTIVITY IN HUMAN SAMPLES,DIRECT BIIRUBIN DPD(SPINREACT)-QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN,PHOSPHORUS (SPINREACT)-QUANTITATIVE DETERMINATION OF PHOSPHORUS IN HUMAN SAMPLES,SPINTROL “H” CAL.(SPINREACT)-MULTIPARAMETRIC CALIBRATOR SERA INTENDED FOR ACCURACY CONTROL OF CLINICAL CHEMISTRY REAGENTS. (HUMAN SOURCE). HDL/LDL CAL(SPINREACT)-SERUM CALIBRATOR FOR HDL/LDL ASSAY,SERUM PROTEINS CALIBRATOR.(SPINREACT)-SERUM CALIBRATOR MULTIPARAMETRIC FOR IMMUNOTURBIDIMETRY ASSAYS,INMUNOGLOBULINA E (IGE) CONTROL(SPINREACT)-SERUM CONTROL FOR IGE TURBIDIMETRY ASSAY,ADA CAL. (ADENOSINE DEAMINASE)(SPINREACT)-SERUM CALIBRATOR FOR ADA ASSAY,CRP ULTRA(SPINREACT)-QUANTITATIVE DETERMINATION OF C-REATIVE PROTEIN ULTRASENSITIVE IN HUMAN SAMPLES,CREATININE –J (SPINREACT)-QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SAMPLES,ADA (ADENOSINE DEAMINASE)(SPINREACT)-QUANTITATIVE DETERMINATION OF ADA IN HUMAN SAMPLES,LP(A) TURBI CONTROL(SPINREACT)-SERUM CONTROL FOR LP (A) TURBIDIMETRY ASSAY,ALP LQ(SPINREACT)-QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY IN HUMAN

	SAMPLES,LP(A) TURBI CAL(SPINREACT)-SERUM CALIBRATOR FOR LP (A) TURBIDIMETRY ASSAY,BILIRUBIN CAL(SPINREACT)-SERUM CALIBRATOR FOR BILIRRUBIN ASSAY,FERRITIN TURBI CAL (SPINREACT)-SERUM CALIBRATOR FOR FERRITIN TURBIDIMETRY ASSAY,APOLIPOPROTEIN A-I(SPINREACT)-QUANTITATIVE DETERMINATION OF HUMAN APOLIPOPROTEIN A-I,ASO TURBI CAL (SPINREACT)-SERUM CONTROL FOR ASO TURBIDIMETRY ASSAYS, APOLIPOPROTEIN CIII(SPINREACT)-QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN C-III (APO C-III),TOTAL PROTEINS(SPINREACT)-QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SAMPLES,ALPHA-1-GLYCOPROTEIN ACID(SPINREACT)-QUANTITATIVE DETERMINATION OF ALPHA-1-ACID GLYCOPROTEIN IN HUMAN SAMPLES,TOTAL BIIRUBIN DPD(SPINREACT)-QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN,DIRECT HOMOCYSTEIN CAL(SPINREACT)-SERUM CALIBRATOR FOR HOMOCYSTEIN ASSAY,UREA –LQ(SPINREACT)-QUANTITATIVE DETERMINATION OF UREA IN HUMAN SAMPLES,SODIUM – P (SPINREACT)-QUANTITATIVE DETERMINATION OF SODIUM IN HUMAN SAMPLES,ACE CONTROL(SPINREACT)-ANGIOTENSIN CONVERTING ENZYME (ACE) CONTROL SERUM,TRIGLYCERIDES –LQ(SPINREACT)-QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SAMPLES,U&CSF TOTAL PROTEINS(SPINREACT)-QUANTITATIVE DETERMINATION OF TOTAL URINARY & CSF PROTEIN IN HUMAN SAMPLES,ASO TURBI(SPINREACT)-QUANTITATIVE DETERMINATION OF ASO IN HUMAN SAMPLES,DIRECT HBA1C CONTROL(SPINREACT)-SERUM CONTROL FOR DETERMINATION OF GLICATED HAEMOGLOBIN (HBA1C) ASSAY,TRANSFERRIN(SPINREACT)-QUANTITATIVE DETERMINATION OF TRANSFERRIN IN HUMAN SAMPLES,CALCIUM AIII- ARSENAZO(SPINREACT)-QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SAMPLES,DIRECT HOMOCYSTEIN CONTROL (SPINREACT)-SERUM CONTROL FOR HOMOCYSTEIN ASSAY,CRP LATEX. SLIDE AGGLUTINATION(SPINREACT)-QUALITATIVE DETERMINATION OF CRP IN HUMAN SAMPLES,BILIRUBIN DIRECT. DMSO(SPINREACT)-QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SAMPLES,COMPLEMENT C3(SPINREACT)-QUANTITATIVE DETERMINATION OF COMPLEMENT C3 IN HUMAN SAMPLES,RF LATEX. SLIDE AGGLUTINATION(SPINREACT)-QUALITATIVE DETERMINATION OF RF IN HUMAN,INMUNGOLOBULINA M (IGM)(SPINREACT)-QUANTITATIVE DETERMINATION OF IGM IN HUMAN SAMPLES,INMUNGOLOBULINA G (IGG)(SPINREACT)-QUANTITATIVE DETERMINATION OF IGG IN HUMAN SAMPLES,LIPASE –LQ(SPINREACT)-QUANTITATIVE DETERMINATION OF THE LIPASE ACTIVITY IN HUMAN SAMPLES,APOLIPOPROTEIN CONTROL (SPINREACT)-SERUM CONTROL FOR APOLIPROTEIN TURBIDIMETRY

		ASSAY,UREA –B.(SPINREACT)-QUANTITATIVE DETERMINATION OF UREA IN HUMAN SAMPLES,HAPTOGLOBIN(SPINREACT)-QUANTITATIVE DETERMINATION OF HAPTOGLOBIN (HAPTO),ALPHA-1 ANTITRYPSIN(SPINREACT)-QUANTITATIVE DETERMINATION OF ALPHA 1-ANTITRYPSIN (ALPHA 1-ATRYP),ASO LATEX. SLIDE AGGLUTINATION(SPINREACT)-QUALITATIVE DETERMINATION OF ASO IN HUMAN SAMPLES,ANTITHROMBIN III(SPINREACT)-QUANTITATIVE DETERMINATION OF ANTITHROMBIN III (ATRHOMIII), PREALBUMIN(SPINREACT)-QUANTITATIVE DETERMINATION OF PREALBUMIN IN HUMAN SAMPLES,ACP. HILLMANN. KINETIC (SPINREACT)-QUANTITATIVE DETERMINATION OF ACID PHOSPHATASE (ACP) ACTIVITY IN HUMAN SAMPLES, APOLIPOPROTEIN CII(SPINREACT)-QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN C-II (APO C-II),LIPIDIC CONTROL(SPINREACT)-SERUM CONTROL FOR LIPID ASSAYS,GOT /AST –LQ. IFCC (SPINREACT)-QUANTITATIVE DETERMINATION OF THE ASPARTATE AMINOTRANSFERASE (AST) ACTIVITY IN HUMAN SAMPLES,BETA 2 – MICROGLOBULIN TURBI(SPINREACT)-QUANTITATIVE DETERMINATION OF BETA 2-MICROGLOBULIN (BETA 2-M), APOLIPOPROTEIN CAL(SPINREACT)-SERUM CALIBRATOR FOR APOLIPROTEIN TURBIDIMETRY ASSAY,INMUNOGLOBULINA E (IGE) CAL(SPINREACT)-SERUM CALIBRATOR FOR IGE TURBIDIMETRY ASSAY,APOLIPOPROTEIN B.(SPINREACT)-QUANTITATIVE DETERMINATION OF HUMAN APOLIPOPROTEIN B,CHOLINESTERASE LQ(SPINREACT)-QUANTITATIVE DETERMINATION OF CHOLINESTERASE (CHE) IN SERUM AND PLASMA,IM LATEX. SLIDE AGGLUTINATION(SPINREACT)-QUALITATIVE DETERMINATION OF HETROPHILE ANTIBODIES IN HUMAN SAMPLES
940	IMP/IVD/2020/000989	1.License Holder Name: ANJANAJYOTI SYSTEMS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:Q SENS NCOV 2019 DETECTION KIT-FOR IN VITRO DIAGNOSTIC USE

941	IMP/IVD/2020/000994	1.License Holder Name: SHREE VENKATESH MEDICAL AGENCIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REAL-TIME ONESTEP RT-PCR BASED ASSAY SYSTEM FOR DETECTION OF COVID19(DIAPLEXQ NOVEL CORONAVIRUS(2019-NCOV) DETECTION KIT CV-IVD)-THE DIAPLEXQ NOVEL CORONAVIRUS (2019-NCOV) DETECTION KIT IS A REAL-TIME REVERSE TRANSCRIPTASE (RT-PCR) TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN NASOPHARYNGEAL SWABS, OROPHARYNGEAL SWABS, SPUTUM FROM INDIVIDUALS SUSPECTED OF COVID-19.
942	IMP/IVD/2020/000995	1.License Holder Name: VOXTUR BIO LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TYPHOID IGG/IGM RAPID TEST UNCUT SHEET-RAW MATERIAL FOR FURTHER MANUFACTURING TYPHOID IGG/IGM RAPID TEST. A RAPID IMMUNO CHROMATOGRPHIC TEST FOR QUALITATIVE DETECTION OF ANTIBODIES(IGG AND IGM) TO SALMONELLA TYPHI IN HUMAN WHOLE BLOOD/SERUM /PLASMA., HCG PREGNANCY RAPID TEST -UNCUT SHEET-RAW MATERIALS FOR FURTHER MANUFACTURING HCG PREGNANCY RAPID TEST, A RAPID ONE STEP ASSAY DESIGNED FOR QUALITATIVE DETECTION OF HUMAN CHRONIC GONADOTROPIN(HCG) IN URINE FOR EARLY DETECTION OF PREGNANCY.

943	IMP/IVD/2020/000996	1.License Holder Name: SPECTRUM MEDICAL INDUSTRIES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIATRO LYSE-DIFF (DIATRON)-DIATRO•LYSE-DIFF LYSING REAGENT IS A STABILIZED AND MICROFILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE THREE-PART DIFFERENTIATION (LYM, MID, GRAN) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON DIATRON JUNIOR, ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 380, ABACUS 3CT HEMATOLOGY ANALYZERS.,DIATRO LYSE-EO(DIATRON)-DIATRO•LYSE-EO LYSING REAGENT IS A STABILIZED AND MICROFILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF EOSINOPHIL LEUKOCYTES (EOS) IN HUMAN BLOOD ON DIATRON ABACUS JUNIOR 5 HEMATOLOGY ANALYZERS.,DIATRO HYPOCLEAN (DIATRON)-DIATRO•HYPOCLEAN HYPOCHLORITE CLEANING REAGENT IS A STABILIZED AND MICRO-FILTERED HYPOCHLORITE SOLUTION FOR INTENSIVE OXIDATIVE CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON DIATRON ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 3CT, ABACUS 380 HEMATOLOGY ANALYZERS., DIATRO CLENZ(DIATRON)-DIATRO•CLENZ ENZYMATIC CLEANER REAGENT IS A STABILIZED AND MICRO-FILTERED PROTEOLYTIC ENZYME SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON DIATRON ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 3CT, ABACUS 380 HEMATOLOGY ANALYZERS., DIACON 3 HEMATOLOGY CONTROL KIT(DIATRON)-DIACON 3 HEMATOLOGY CONTROL IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS.,DIATRO LYSE-BASO(DIATRON)-DIATRO•LYSE-BASO LYSING REAGENT IS A STABILIZED AND MICROFILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF BASOPHIL LEUKOCYTES (BAS) IN HUMAN BLOOD ON DIATRON ABACUS JUNIOR 5 HEMATOLOGY ANALYZERS.,DIATROCAL HEMATOLOGY CALIBRATOR(DIATRON)-DIATROCAL HEMATOLOGY CALIBRATOR IS DESIGNED FOR USE IN THE CALIBRATION OF HEMATOLOGY ANALYZERS.,DIATRO LYSE-5P(DIATRON)-DIATRO•LYSE-5P LYSING REAGENT IS A STABILIZED AND MICROFILTERED LYSING AGENT FOR STROMATOLYSIS OF

	ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE 5-PART DIFFERENTIATION (LYM, MONO, NEU, EO, BA) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON DIATRON ABACUS 5 HEMATOLOGY ANALYZERS.,DIACON 5 HEMATOLOGY CONTROL KIT (DIATRON)-DIACON 5 HEMATOLOGY CONTROL IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI PARAMETER HEMATOLOGY CELL COUNTERS.,DIATRO DIL-5P (DIATRON)-DIATRO•DIL-5P DILUENT IS A BUFFERED, STABILIZED AND MICROFILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN ?HGB) CONCENTRATION ON DIATRON ABACUS 5 HEMATOLOGY ANALYZERS.,DIATRO DIL-DIFF(DIATRON)-DIATRO•DIL-DIFF DILUENT IS A BUFFERED, STABILIZED AND MICROFILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN (HGB) CONCENTRATION ON DIATRON JUNIOR, ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 380, ABACUS 3CT HEMATOLOGY ANALYZERS.,DIATRO DIFF-5P(DIATRON)-DIATRO•DIFF-5P WBC DIFFERENTIATION REAGENT IS A STABILIZED AND MICRO-FILTERED REAGENT FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC) AND LEUKOCYTE 5-PART DIFFERENTIATION (LYM, MONO, NEU, EO, BA) MEASUREMENT IN HUMAN BLOOD ON DIATRON ABACUS 5 HEMATOLOGY ANALYZERS., DIATRO CLEANER(DIATRON)-DIATRO•CLEANER CLEANING REAGENT IS A STABILIZED AND MICROFILTERED DETERGENT SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON DIATRON JUNIOR, ABACUS JUNIOR 30, ABACUS JUNIOR 5, ABACUS 3CT, ABACUS 380 HEMATOLOGY ANALYZERS., DIATRO CLENZ CC(DIATRON)-DIATRO•CLENZ CC ENZYMATIC CLEANER CONCENTRATE IS A STABILIZED AND MICRO-FILTERED CONCENTRATED PROTEOLYTIC ENZYME SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON ALL HEMATOLOGY ANALYZERS.,DIATRO HYPOCLEAN CC(DIATRON)-DIATRO•HYPOCLEAN CC HYPOCHLORITE CLEANING CONCENTRATE

		IS A STABILIZED AND MICRO-FILTERED CONCENTRATED HYPOCHLORITE SOLUTION FOR INTENSIVE OXIDATIVE CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON ALL HEMATOLOGY ANALYZERS.
944	IMP/IVD/2020/000998	1.License Holder Name: PREMAS LIFE SCIENCES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NUCLEIC ACID EXTRACTION KIT(TANBEAD NUCLEIC ACID EXTRACTION KIT)-NUCLEIC ACID EXTRACTION
945	IMP/IVD/2020/001010	1.License Holder Name: ACCUREX BIOMEDICALS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOGLOBIN TEST STRIPS(URIT)-H12 HEMOGLOBIN TEST STRIPS ARE APPLIED ON URIT-12 HEMOGLOBIN METER, FOR THE QUANTITATIVE MEASUREMENT OF TOTAL HEMOGLOBIN IN CAPILLARY AND VENOUS WHOLE BLOOD. THE TEST IS INTENDED FOR USE BY HEALTH CARE PROFESSIONALS ONLY, NOT TO BE USED FOR PATIENT SELF-TESTING.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

946	IMP/IVD/2020/001011	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARCHITECT ANTI-HBC II CALIBRATOR(ARCHITECT ANTI-HBC II CALIBRATOR)-THE ARCHITECT ANTI-HBC II CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM AND PLASMA.,ALINITY I ANTI-HCV CALIBRATOR(ALINITY I ANTI-HCV CALIBRATOR)-THE ALINITY I ANTI-HCV CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM AND PLASMA.,ALINITY I EBV EBNA1 IGG CONTROLS(ALINITY I EBV EBNA1 IGG CONTROLS)-THE ALINITY I EBV EBNA-1 IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR NUCLEAR ANTIGEN-1 (EBNA-1) IN HUMAN SERUM AND PLASMA. , ARCHITECT TOXO IGM CALIBRATOR(ARCHITECT TOXO IGM CALIBRATOR)-THE ARCHITECT TOXO IGM CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ALINITY I TOXO IGG CONTROLS(ALINITY I TOXO IGG CONTROLS)-THE ALINITY I TOXO IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ALINITY I EBV VCA IGM REAGENT KIT (ALINITY I EBV VCA IGM REAGENT KIT)-THE ALINITY I EBV VCA IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER. , ARCHITECT PEPSINOGEN I CONTROL(ARCHITECT PEPSINOGEN I CONTROL)-THE ARCHITECT PEPSINOGEN I CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN I IN HUMAN SERUM AND PLASMA.,ALINITY I ANTI-HCV CONTROLS(ALINITY I ANTI-HCV CONTROLS)-THE ALINITY I ANTI-HCV CONTROLS ARE FOR THE VERIFICATION OF THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV) IN

	HUMAN SERUM AND PLASMA.,ARCHITECT SYPHILIS TP CALIBRATOR (ARCHITECT SYPHILIS TP CALIBRATOR)-THE ARCHITECT SYPHILIS TP CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM AND PLASMA., ARCHITECT CHAGAS CALIBRATOR (ARCHITECT CHAGAS CALIBRATOR)-THE ARCHITECT CHAGAS CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TRYPANOSOMA CRUZI (T. CRUZI) IN HUMAN SERUM AND PLASMA. ,ARCHITECT I GENTAMICIN CALIBRATOR(ARCHITECT I GENTAMICIN CALIBRATOR)-THE ARCHITECT I GENTAMICIN CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF GENTAMICIN, AN ANTIBIOTIC DRUG, IN HUMAN SERUM OR PLASMA., ARCHITECT EBV VCA IGM REAGENT KIT(ARCHITECT EBV VCA IGM REAGENT KIT)-THE ARCHITECT EBV VCA IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA.,ALINITY I HAVAB IGG REAGENT KIT(ALINITY I HAVAB IGG REAGENT KIT)-THE ALINITY I HAVAB IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODY TO HEPATITIS A VIRUS (IGG ANTI-HAV) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER,ARCHITECT HIV AG/AB COMBO CALIBRATOR (ARCHITECT HIV AG/AB COMBO CALIBRATOR)-THE ARCHITECT HIV AG/AB COMBO CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND/OR TYPE 2 (HIV-1/HIV-2) IN HUMAN SERUM OR PLASMA.,ALINITY I HBEAG REAGENT KIT(ALINITY I HBEAG REAGENT KIT)-THE ALINITY I HBEAG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER AND IS TO BE USED AS AN AID IN THE DIAGNOSIS AND MONITORING OF HEPATITIS B VIRAL INFECTION.,ALINITY I HAVAB IGG CALIBRATOR(ALINITY I HAVAB IGG CALIBRATOR)-THE ALINITY I HAVAB IGG CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODY TO HEPATITIS A VIRUS (IGG ANTI-HAV) IN HUMAN SERUM AND PLASMA.,ALINITY I PEPSINOGEN I CALIBRATOR(ALINITY I PEPSINOGEN I CALIBRATOR)-THE ALINITY I PEPSINOGEN I

	CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN I IN HUMAN SERUM AND PLASMA,ALINITY I TOXO IGG REAGENT KIT(ALINITY I TOXO IGG REAGENT KIT)-THE ALINITY I TOXO IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ALINITY I PEPSINOGEN I REAGENT KIT(ALINITY I PEPSINOGEN I REAGENT KIT)-THE ALINITY I PEPSINOGEN I (PG I) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN I IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ALINITY I HIV AG/AB COMBO REAGENT KIT(ALINITY I HIV AG/AB COMBO REAGENT KIT)-THE ALINITY I HIV AG/AB COMBO ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND/OR TYPE 2 (HIV-1/HIV-2) IN HUMAN SERUM OR PLASMA INCLUDING SPECIMENS COLLECTED POST MORTEM (NONHEART- BEATING) ON THE ALINITY I ANALYZER.,ALINITY I RHTLV-I/II CALIBRATOR(ALINITY I RHTLV-I/II CALIBRATOR)-THE ALINITY I RHTLV-I/II CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HTLV-I AND HTLV-II IN HUMAN SERUM AND PLASMA.,ALINITY I PEPSINOGEN II CALIBRATOR(ALINITY I PEPSINOGEN II CALIBRATOR)-THE ALINITY I PEPSINOGEN II CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN II IN HUMAN SERUM AND PLASMA., ARCHITECT HBEAG QUANTITATIVE CALIBRATORS(ARCHITECT HBEAG QUANTITATIVE CALIBRATORS)-THE ARCHITECT HBEAG QUANTITATIVE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM AND ARE TO BE USED ONLY WITH THE ARCHITECT HBEAG REAGENT KIT. ,ALINITY I PEPSINOGEN II REAGENT KIT(ALINITY I PEPSINOGEN II REAGENT KIT)-THE ALINITY I PEPSINOGEN II (PG II) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN II IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT EBV EBNA-1 IGG REAGENT KIT(ARCHITECT EBV EBNA-1 IGG REAGENT KIT)-THE ARCHITECT EBV EBNA-1 IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR NUCLEAR ANTIGEN-1 (EBNA-1) IN HUMAN SERUM AND PLASMA. ,ALINITY I EBV

	VCA IGG REAGENT KIT(ALINITY I EBV VCA IGG REAGENT KIT)-THE ALINITY I EBV VCA IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER. ,ALINITY I HAVAB IGM CALIBRATOR (ALINITY I HAVAB IGM CALIBRATOR)-THE ALINITY I HAVAB IGM CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS A VIRUS (IGM ANTI-HAV) IN HUMAN SERUM AND PLASMA., ARCHITECT HIV AG/AB COMBO REAGENT KIT(ARCHITECT HIV AG/AB COMBO REAGENT KIT)-THE ARCHITECT HIV AG/AB COMBO ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND/OR TYPE 2 (HIV-1/HIV-2) IN HUMAN SERUM OR PLASMA INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING). ,ALINITY I TOXO IGM CALIBRATOR(ALINITY I TOXO IGM CALIBRATOR)-THE ALINITY I TOXO IGM CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ARCHITECT PEPSINOGEN II CALIBRATOR(ARCHITECT PEPSINOGEN II CALIBRATOR)-THE ARCHITECT PEPSINOGEN II CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN II IN HUMAN SERUM AND PLASMA.,ARCHITECT HBEAG QUANTITATIVE CONTROLS (ARCHITECT HBEAG QUANTITATIVE CONTROLS)-THE ARCHITECT HBEAG QUANTITATIVE CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA. ,ALINITY I TOXO IGM REAGENT KIT (ALINITY I TOXO IGM REAGENT KIT)-THE ALINITY I TOXO IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ALINITY I HBEAG QUANTITATIVE CONTROLS (ALINITY I HBEAG QUANTITATIVE CONTROLS)-THE ALINITY I HBEAG QUANTITATIVE CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA.,ALINITY I CHAGAS CONTROLS

	(ALINITY I CHAGAS CONTROLS)-THE ALINITY I CHAGAS CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TRYPANOSOMA CRUZI (T. CRUZI) IN HUMAN SERUM AND PLASMA.,ARCHITECT RHTLV I/II CONTROLS(ARCHITECT RHTLV I/II CONTROLS)-THE ARCHITECT RHTLV-I/II-I/II CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HTLV-I AND HTLV-II IN HUMAN SERUM AND PLASMA.,ALINITY I ANTI-HCV REAGENT KIT(ALINITY I ANTI-HCV REAGENT KIT)-THE ALINITY I ANTI-HCV ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM AND PLASMA, INCLUDING SPECIMENS COLLECTED POST MORTEM (NON-HEART BEATING) ON THE ALINITY I ANALYZER.,ARCHITECT EBV VCA IGG REAGENT KIT(ARCHITECT EBV VCA IGG REAGENT KIT)-THE ARCHITECT EBV VCA IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA., ALINITY I TOXO IGG CALIBRATORS(ALINITY I TOXO IGG CALIBRATORS)-THE ALINITY I TOXO IGG CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ARCHITECT ANTI-HCV REAGENT KIT (ARCHITECT ANTI-HCV REAGENT KIT)-THE ARCHITECT ANTI-HCV ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM AND PLASMA INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING). ,ALINITY I HIV AG/AB COMBO CONTROLS(ALINITY I HIV AG/AB COMBO CONTROLS)-THE ALINITY I HIV AG/AB COMBO CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND/OR TYPE 2 (HIV-1/HIV-2) IN HUMAN SERUM OR PLASMA.,ALINITY I HBEAG QUANTITATIVE CALIBRATORS(ALINITY I HBEAG QUANTITATIVE CALIBRATORS)-THE ALINITY I HBEAG QUANTITATIVE CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER AND ARE TO BE USED ONLY WITH THE ALINITY I HBEAG REAGENT KIT.,ALINITY

	I TOXO IGM CONTROLS(ALINITY I TOXO IGM CONTROLS)-THE ALINITY I TOXO IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ALINITY I ANTI-HBC II CALIBRATOR(ALINITY I ANTI-HBC II CALIBRATOR)-THE ALINITY I ANTI-HBC II CALIBRATOR 1 IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM AND PLASMA.,ARCHITECT PEPSINOGEN II REAGENT KIT (ARCHITECT PEPSINOGEN II REAGENT KIT)-THE ARCHITECT PEPSINOGEN II (PG II) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN II IN HUMAN SERUM AND PLASMA., ALINITY I SYPHILIS TP CALIBRATOR(ALINITY I SYPHILIS TP CALIBRATOR)-THE ALINITY I SYPHILIS TP CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM AND PLASMA. ,ALINITY I ANTI-HBE CONTROLS (ALINITY I ANTI-HBE CONTROLS)-THE ALINITY I ANTI-HBE CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B E ANTIGEN (ANTI-HBE) IN HUMAN SERUM AND PLASMA.,ALINITY I HAVAB IGM REAGENT KIT (ALINITY I HAVAB IGM REAGENT KIT)-THE ALINITY I HAVAB IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS A VIRUS (IGM ANTI-HAV) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT I CARBAMAZEPINE REAGENT KIT(ARCHITECT I CARBAMAZEPINE REAGENT KIT)-THE ARCHITECT I CARBAMAZEPINE ASSAY IS AN IN VITRO CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE MEASUREMENT OF CARBAMAZEPINE, AN ANTICONVULSANT DRUG, IN HUMAN SERUM OR PLASMA (COLLECTED IN LITHIUM HEPARIN, SODIUM HEPARIN, DIPOTASSIUM EDTA OR SODIUM EDTA TUBES) ON THE ARCHITECT I SYSTEM WITH STAT PROTOCOL CAPABILITY.,ARCHITECT EBV VCA IGM CALIBRATOR (ARCHITECT EBV VCA IGM CALIBRATOR)-THE ARCHITECT EBV VCA IGM CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA.,ALINITY I SYPHILIS TP REAGENT KIT(ALINITY I SYPHILIS TP REAGENT KIT)-THE ALINITY I

	SYPHILIS TP ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM AND PLASMA, INCLUDING SPECIMENS COLLECTED POSTMORTEM (NON-HEART-BEATING) ON THE ALINITY I ANALYZER. ,ARCHITECT TOXO IGG CALIBRATORS(ARCHITECT TOXO IGG CALIBRATORS)-THE ARCHITECT TOXO IGG CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ALINITY I EBV VCA IGG CONTROLS (ALINITY I EBV VCA IGG CONTROLS)-THE ALINITY I EBV VCA IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA. ,ALINITY I RHTLV-I/II REAGENT KIT(ALINITY I RHTLV-I/II REAGENT KIT)-THE ALINITY I RHTLV-I/II ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HTLV-I AND HTLV-II IN HUMAN SERUM AND PLASMA INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING) ON THE ALINITY I ANALYZER.,ALINITY I SYPHILIS TP CONTROLS(ALINITY I SYPHILIS TP CONTROLS)-THE ALINITY I SYPHILIS TP CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM AND PLASMA. ,ALINITY I CHAGAS REAGENT KIT(ALINITY I CHAGAS REAGENT KIT)-THE ALINITY I CHAGAS ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TRYPANOSOMA CRUZI (T. CRUZI) IN HUMAN SERUM AND PLASMA, INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING) ON THE ALINITY I ANALYZER.,ALINITY I ANTI-HBC IGM REAGENT KIT(ALINITY I ANTI-HBC IGM REAGENT KIT)-THE ALINITY I ANTI-HBC IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC IGM) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ALINITY I PEPSINOGEN II CONTROLS(ALINITY I PEPSINOGEN II CONTROLS)-THE ALINITY I PEPSINOGEN II CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN II IN HUMAN SERUM

	AND PLASMA.,ALINITY I ANTI-HBC IGM CONTROLS(ALINITY I ANTI-HBC IGM CONTROLS)-THE ALINITY I ANTI-HBC IGM CONTROLS ARE FOR THE VERIFICATION OF THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC IGM) IN HUMAN SERUM AND PLASMA.,ARCHITECT TOXO IGM CONTROLS(ARCHITECT TOXO IGM CONTROLS)-THE ARCHITECT TOXO IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA., ARCHITECT ANTI-HBC IGM CONTROLS(ARCHITECT ANTI-HBC IGM CONTROLS)-THE ARCHITECT ANTI-HBC IGM CONTROLS ARE FOR THE VERIFICATION OF THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC IGM) IN HUMAN SERUM AND PLASMA. ,ALINITY I HBEAG CONTROLS(ALINITY I HBEAG CONTROLS)-THE ALINITY I HBEAG CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA.,ALINITY I ANTI-HBE REAGENT KIT(ALINITY I ANTI-HBE REAGENT KIT)-THE ALINITY I ANTI-HBE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B E ANTIGEN (ANTI-HBE) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT PEPSINOGEN I REAGENT KIT(ARCHITECT PEPSINOGEN I REAGENT KIT)-THE ARCHITECT PEPSINOGEN I (PG I) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN I IN HUMAN SERUM AND PLASMA., ALINITY I ANTI-HBC II REAGENT KIT(ALINITY I ANTI-HBC II REAGENT KIT)-THE ALINITY I ANTI-HBC II ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM AND PLASMA, INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEARTBEATING) ON THE ALINITY I ANALYZER.,ARCHITECT EBV VCA IGG CONTROLS(ARCHITECT EBV VCA IGG CONTROLS)-THE ARCHITECT EBV VCA IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA.,ALINITY I CHAGAS CALIBRATOR (ALINITY I CHAGAS CALIBRATOR)-THE ALINITY I CHAGAS

	CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TRYPANOSOMA CRUZI (T. CRUZI) IN HUMAN SERUM AND PLASMA., ARCHITECT PEPSINOGEN II CONTROL(ARCHITECT PEPSINOGEN II CONTROL)-THE ARCHITECT PEPSINOGEN II CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN II IN HUMAN SERUM AND PLASMA.,ARCHITECT EBV EBNA-1 IGG CALIBRATOR(ARCHITECT EBV EBNA-1 IGG CALIBRATOR)-THE ARCHITECT EBV EBNA-1 IGG CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR NUCLEAR ANTIGEN-1 (EBNA-1) IN HUMAN SERUM AND PLASMA., ARCHITECT ANTI-HCV CALIBRATOR (ARCHITECT ANTI-HCV CALIBRATOR)-THE ARCHITECT ANTI-HCV CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM AND PLASMA.,ARCHITECT ANTI-HBC II REAGENT KIT(ARCHITECT ANTI-HBC II REAGENT KIT)-THE ARCHITECT ANTI-HBC II ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM AND PLASMA, INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEARTBEATING). ,ARCHITECT ANTI-HBE REAGENT KIT (ARCHITECT ANTI-HBE REAGENT KIT)-THE ARCHITECT ANTI-HBE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B E ANTIGEN (ANTI-HBE) IN HUMAN SERUM AND PLASMA., ARCHITECT HAVAB-IGG REAGENT KIT(ARCHITECT HAVAB-IGG REAGENT KIT)-THE ARCHITECT HAVAB-IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF IGG ANTIBODY TO HEPATITIS A VIRUS (IGG ANTI-HAV) IN HUMAN SERUM AND PLASMA. ,ARCHITECT PEPSINOGEN I CALIBRATOR(ARCHITECT PEPSINOGEN I CALIBRATOR) -THE ARCHITECT PEPSINOGEN I CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN I IN HUMAN SERUM AND PLASMA.,ARCHITECT EBV VCA IGM CONTROLS(ARCHITECT EBV VCA IGM CONTROLS)-THE ARCHITECT EBV VCA IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN

	HUMAN SERUM AND PLASMA.,ARCHITECT EBV VCA IGG CALIBRATOR (ARCHITECT EBV VCA IGG CALIBRATOR)-THE ARCHITECT EBV VCA IGG CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA.,ARCHITECT ANTI-HBE CONTROLS(ARCHITECT ANTI-HBE CONTROLS)-THE ARCHITECT ANTI-HBE CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B E ANTIGEN (ANTI- HBE) IN HUMAN SERUM AND PLASMA. ,ALINITY I HAVAB IGM CONTROLS(ALINITY I HAVAB IGM CONTROLS)-THE ALINITY I HAVAB IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS A VIRUS (IGM ANTI-HAV) IN HUMAN SERUM AND PLASMA.,ALINITY I TOXO IGG AVIDITY REAGENT KIT (ALINITY I TOXO IGG AVIDITY REAGENT KIT)-THE ALINITY I TOXO IGG AVIDITY ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE DETERMINATION OF THE AVIDITY OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT CHAGAS REAGENT KIT(ARCHITECT CHAGAS REAGENT KIT)-THE ARCHITECT CHAGAS ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TRYPANOSOMA CRUZI (T. CRUZI) IN HUMAN SERUM AND PLASMA INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING). ,ARCHITECT HBEAG REAGENT KIT (ARCHITECT HBEAG REAGENT KIT)-THE ARCHITECT HBEAG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA. , ALINITY I EBV VCA IGG CALIBRATOR(ALINITY I EBV VCA IGG CALIBRATOR)-THE ALINITY I EBV VCA IGG CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA. ,ARCHITECT HAVAB-IGM CALIBRATOR(ARCHITECT HAVAB-IGM CALIBRATOR)-THE ARCHITECT HAVAB-IGM CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS A VIRUS (IGM ANTI-HAV) IN HUMAN SERUM AND PLASMA. ,ALINITY I EBV VCA IGM CONTROLS(ALINITY I EBV VCA IGM CONTROLS)-THE ALINITY I EBV VCA IGM CONTROLS ARE FOR THE ESTIMATION OF TEST

	PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA. ,ARCHITECT RHTLV I/II REAGENT KIT (ARCHITECT RHTLV I/II REAGENT KIT)-THE ARCHITECT RHTLV-I/II-I/II ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HTLV-I AND HTLV-II IN HUMAN SERUM AND PLASMA INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING). ,ARCHITECT SYPHILIS TP REAGENT KIT(ARCHITECT SYPHILIS TP REAGENT KIT)-THE ARCHITECT SYPHILIS TP ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM AND PLASMA, INCLUDING SPECIMENS COLLECTED POST-MORTEM (NON-HEART-BEATING). ,ARCHITECT TOXO IGG AVIDITY CALIBRATOR & CONTROLS (ARCHITECT TOXO IGG AVIDITY CALIBRATOR & CONTROLS)-THE ARCHITECT TOXO IGG AVIDITY CALIBRATOR IS INTENDED FOR THE CREATION OF AN ACTIVE CALIBRATION FOR THE ASSAYS OF THE ARCHITECT TOXO IGG AVIDITY REAGENT KIT. THE ARCHITECT TOXO IGG AVIDITY CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM. ,ARCHITECT RHTLV I/II CALIBRATOR (ARCHITECT RHTLV I/II CALIBRATOR)-THE ARCHITECT RHTLV-I/II-I/II CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HTLV-I AND HTLV-II IN HUMAN SERUM AND PLASMA.,ARCHITECT TOXO IGG AVIDITY REAGENT KIT (ARCHITECT TOXO IGG AVIDITY REAGENT KIT)-THE ARCHITECT TOXO IGG AVIDITY ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE DETERMINATION OF THE AVIDITY OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA. ,ARCHITECT HBEAG CONTROLS (ARCHITECT HBEAG CONTROLS)-THE ARCHITECT HBEAG CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA.,ARCHITECT ANTI-HBC IGM CALIBRATORS(ARCHITECT ANTI-HBC IGM CALIBRATORS)-THE ARCHITECT ANTI-HBC IGM CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC IGM) IN HUMAN SERUM AND PLASMA.,ARCHITECT HBEAG CALIBRATORS(ARCHITECT HBEAG CALIBRATORS)-THE ARCHITECT

	HBEAG CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA., ARCHITECT HAVAB-IGM REAGENT KIT(ARCHITECT HAVAB-IGM REAGENT KIT)-THE ARCHITECT HAVAB-IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS A VIRUS (IGM ANTI-HAV) IN HUMAN SERUM AND PLASMA. ,ALINITY I RHTLV-I/II CONTROLS(ALINITY I RHTLV-I/II CONTROLS)-THE ALINITY I RHTLV-I/II CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HTLV-I AND HTLV-II IN HUMAN SERUM AND PLASMA.,ARCHITECT TOXO IGM REAGENT KIT (ARCHITECT TOXO IGM REAGENT KIT)-THE ARCHITECT TOXO IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA. ,ALINITY I EBV EBNA1 IGG REAGENT KIT(ALINITY I EBV EBNA1 IGG REAGENT KIT)-THE ALINITY I EBV EBNA-1 IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR NUCLEAR ANTIGEN-1 (EBNA-1) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER. ,ALINITY I PEPSINOGEN I CONTROLS(ALINITY I PEPSINOGEN I CONTROLS)-THE ALINITY I PEPSINOGEN I CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PEPSINOGEN I IN HUMAN SERUM AND PLASMA.,ARCHITECT HAVAB-IGM CONTROLS(ARCHITECT HAVAB-IGM CONTROLS)-THE ARCHITECT HAVAB-IGM CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS A VIRUS (IGM ANTI-HAV) IN HUMAN SERUM AND PLASMA. ,ARCHITECT CHAGAS CONTROLS(ARCHITECT CHAGAS CONTROLS)-THE ARCHITECT CHAGAS CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TRYPANOSOMA CRUZI (T. CRUZI) IN HUMAN SERUM AND PLASMA. ,ALINITY I EBV EBNA1 IGG CALIBRATOR(ALINITY I EBV EBNA1 IGG CALIBRATOR)-THE ALINITY I EBV EBNA-1 IGG CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION

	OF IGG ANTIBODIES TO EPSTEIN-BARR NUCLEAR ANTIGEN-1 (EBNA-1) IN HUMAN SERUM AND PLASMA. ,ARCHITECT TOXO IGG CONTROLS (ARCHITECT TOXO IGG CONTROLS)-THE ARCHITECT TOXO IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ALINITY I ANTI-HBC II CONTROLS (ALINITY I ANTI-HBC II CONTROLS)-THE ALINITY I ANTI-HBC II CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM AND PLASMA.,ALINITY I HIV AG/AB COMBO CALIBRATOR (ALINITY I HIV AG/AB COMBO CALIBRATOR)-THE ALINITY I HIV AG/AB COMBO CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 AND/OR TYPE 2 (HIV-1/HIV-2) IN HUMAN SERUM OR PLASMA.,ARCHITECT HAVAB-IGG CALIBRATOR(ARCHITECT HAVAB-IGG CALIBRATOR)-THE ARCHITECT HAVAB-IGG CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODY TO HEPATITIS A VIRUS (IGG ANTI-HAV) IN HUMAN SERUM AND PLASMA. ,ALINITY I EBV VCA IGM CALIBRATOR(ALINITY I EBV VCA IGM CALIBRATOR)-THE ALINITY I EBV VCA IGM CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO EPSTEIN-BARR VIRUS (EBV) VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM AND PLASMA. ,ARCHITECT HIV AG/AB COMBO CONTROLS (ARCHITECT HIV AG/AB COMBO CONTROLS)-THE ARCHITECT HIV AG/AB COMBO CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE SIMULTANEOUS QUALITATIVE DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS ,ALINITY I TOXO IGG AVIDITY CONTROLS(ALINITY I TOXO IGG AVIDITY CONTROLS)-THE ALINITY I TOXO IGG AVIDITY CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER., ARCHITECT SYPHILIS TP CONTROLS(ARCHITECT SYPHILIS TP CONTROLS)-THE ARCHITECT SYPHILIS TP CONTROLS ARE FOR THE VERIFICATION OF THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO

	TREPONEMA PALLIDUM (TP) IN HUMAN SERUM AND PLASMA. , ARCHITECT EBV EBNA-1 IGG CONTROLS(ARCHITECT EBV EBNA-1 IGG CONTROLS)-THE ARCHITECT EBV EBNA-1 IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO EPSTEIN-BARR NUCLEAR ANTIGEN-1 (EBNA-1) IN HUMAN SERUM AND PLASMA.,ARCHITECT ANTI-HCV CONTROLS (ARCHITECT ANTI-HCV CONTROLS)-THE ARCHITECT ANTI-HCV CONTROLS ARE FOR THE VERIFICATION OF THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV) IN HUMAN SERUM AND PLASMA. ,ARCHITECT I GENTAMICIN REAGENT KIT(ARCHITECT I GENTAMICIN REAGENT KIT)-THE ARCHITECT I GENTAMICIN ASSAY IS AN IN VITRO CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF GENTAMICIN, AN ANTIBIOTIC DRUG, IN HUMAN SERUM OR PLASMA ON THE ARCHITECT I SYSTEM WITH STAT PROTOCOL CAPABILITY.,ARCHITECT I CARBAMAZEPINE CALIBRATOR(ARCHITECT I CARBAMAZEPINE CALIBRATOR)-THE ARCHITECT I CARBAMAZEPINE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF CARBAMAZEPINE, AN ANTICONVULSANT DRUG, IN HUMAN SERUM OR PLASMA.,ALINITY I HAVAB IGG CONTROLS (ALINITY I HAVAB IGG CONTROLS)-THE ALINITY I HAVAB IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODY TO HEPATITIS A VIRUS (IGG ANTI-HAV) IN HUMAN SERUM AND PLASMA.,ARCHITECT ANTI-HBE CALIBRATOR (ARCHITECT ANTI-HBE CALIBRATOR)-THE ARCHITECT ANTI-HBE CALIBRATOR IS FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B E ANTIGEN (ANTI-HBE) IN HUMAN SERUM AND PLASMA. , ARCHITECT ANTI-HBC II CONTROLS(ARCHITECT ANTI-HBC II CONTROLS)-THE ARCHITECT ANTI-HBC II CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC) IN HUMAN SERUM AND PLASMA.,ARCHITECT HAVAB-IGG CONTROLS(ARCHITECT HAVAB-IGG CONTROLS)-THE ARCHITECT HAVAB-IGG CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM

	WHEN USED FOR THE QUALITATIVE DETECTION OF IGG ANTIBODY TO HEPATITIS A VIRUS (IGG ANTI-HAV) IN HUMAN SERUM AND PLASMA. , ALINITY I HBEAG CALIBRATORS(ALINITY I HBEAG CALIBRATORS)-THE ALINITY I HBEAG CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF HEPATITIS B E ANTIGEN (HBEAG) IN HUMAN SERUM AND PLASMA.,ALINITY I ANTI-HBE CALIBRATOR(ALINITY I ANTI-HBE CALIBRATOR)-THE ALINITY I ANTI-HBE CALIBRATOR IS FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF ANTIBODY TO HEPATITIS B E ANTIGEN (ANTI-HBE) IN HUMAN SERUM AND PLASMA.,ARCHITECT TOXO IGG REAGENT KIT (ARCHITECT TOXO IGG REAGENT KIT)-THE ARCHITECT TOXO IGG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM AND PLASMA.,ALINITY I ANTI-HBC IGM CALIBRATORS(ALINITY I ANTI-HBC IGM CALIBRATORS)-THE ALINITY I ANTI-HBC IGM CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC IGM) IN HUMAN SERUM AND PLASMA., ARCHITECT ANTI-HBC IGM REAGENT KIT (ARCHITECT ANTI-HBC IGM REAGENT KIT)-THE ARCHITECT ANTI-HBC IGM ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUALITATIVE DETECTION OF IGM ANTIBODY TO HEPATITIS B CORE ANTIGEN (ANTI-HBC IGM) IN HUMAN SERUM AND PLASMA.

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947	IMP/IVD/2020/001012	1.License Holder Name: PROMEGA BIOTECH INDIA PRIVATE LIMITED (PRIVATE LIMITED) 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLINICAL SAMPLE CONCENTRATOR (CSC)(MAXWELL CSC RNA BLOOD KIT)-THE MAXWELL CSC RNA BLOOD KIT IS INTENDED FOR USE, IN COMBINATION WITH THE MAXWELL CSC INSTRUMENT AND THE MAXWELL CSC RNA BLOOD PURIFICATION METHOD, AS AN IN VITRO DIAGNOSTIC (IVD) MEDICAL DEVICE TO PERFORM AUTOMATED ISOLATION OF RNA FROM 2.5ML OF WHOLE HUMAN BLOOD COLLECTED IN EDTA COLLECTION TUBES WITH A WHITE BLOOD CELL (WBC) COUNT IN THE RANGE OF 4 × 106 TO 10 × 106 WBC PER MILLILITER. THE PURIFIED RNA IS SUITABLE FOR USE IN AMPLIFICATION-BASED IN VITRO DIAGNOSTIC ASSAYS. THE MAXWELL CSC RNA BLOOD KIT IS INTENDED TO BE USED WITH 2.5ML OF WHOLE HUMAN BLOOD. THE MAXWELL CSC RNA BLOOD KIT IS INTENDED TO BE USED AT A TEMPERATURE BETWEEN 15°C AND 30°C. USE OUTSIDE OF THIS TEMPERATURE RANGE MAY RESULT IN SUBOPTIMAL RESULTS. THE MAXWELL CSC RNA BLOOD KIT IS NOT INTENDED FOR USE AS PART OF A SPECIFIC DIAGNOSTIC TEST. THE MAXWELL CSC RNA BLOOD KIT IS INTENDED FOR PROFESSIONAL USE ONLY. DIAGNOSTIC RESULTS OBTAINED USING THE RNA PURIFIED WITH THIS SYSTEM MUST BE INTERPRETED IN CONJUNCTION WITH OTHER CLINICAL OR LABORATORY DATA.,CLINICAL SAMPLE CONCENTRATOR (CSC)(MAXWELL CSC DNA FFPE KIT)-THE MAXWELL CSC DNA FFPE KIT IS INTENDED FOR USE, IN COMBINATION WITH THE MAXWELL CSC INSTRUMENT AND THE MAXWELL CSC FFPE DNA PURIFICATION METHOD, AS AN IN VITRO DIAGNOSTIC (IVD) MEDICAL DEVICE TO PERFORM AUTOMATED ISOLATION OF DNA FROM FFPE (FORMALIN-FIXED, PARAFFIN EMBEDDED) TISSUE SAMPLES. THE PURIFIED DNA IS SUITABLE FOR USE IN AMPLIFICATION-BASED IN VITRO DIAGNOSTIC ASSAYS. THE MAXWELL CSC DNA FFPE KIT IS INTENDED TO BE USED AT A TEMPERATURE BETWEEN 15°C AND 30°C. USE OUTSIDE OF THIS TEMPERATURE RANGE MAY RESULT IN SUBOPTIMAL RESULTS. FFPE SAMPLES PREPARED USING 10% NEUTRAL-BUFFERED FORMALIN CAN BE USED WITH THE MAXWELL CSC DNA FFPE KIT. THE MAXWELL CSC DNA FFPE KIT IS NOT INTENDED FOR USE AS PART OF A SPECIFIC DIAGNOSTIC TEST. THE MAXWELL CSC DNA FFPE KIT IS INTENDED FOR PROFESSIONAL USE ONLY. DIAGNOSTIC RESULTS OBTAINED USING THE DNA PURIFIED WITH THIS SYSTEM MUST BE INTERPRETED IN CONJUNCTION WITH OTHER CLINICAL OR LABORATORY DATA.,CLINICAL SAMPLE CONCENTRATOR (CSC)(MAXWELL CSC BLOOD DNA KIT)-THE MAXWELL CSC BLOOD DNA KIT IS INTENDED FOR USE, IN

	COMBINATION WITH THE MAXWELL CSC INSTRUMENT AND THE MAXWELL CSC BLOOD DNA PURIFICATION METHOD, AS AN IN VITRO DIAGNOSTIC (IVD) MEDICAL DEVICE TO PERFORM AUTOMATED ISOLATION OF GENOMIC DNA FROM HUMAN WHOLE BLOOD SAMPLES. THE PURIFIED DNA IS SUITABLE FOR USE IN AMPLIFICATION-BASED IN VITRO DIAGNOSTIC ASSAYS. THE MAXWELL CSC BLOOD DNA KIT IS INTENDED TO BE USED AT A TEMPERATURE BETWEEN 15°C AND 30°C. USE OUTSIDE OF THIS TEMPERATURE RANGE MAY RESULT IN SUBOPTIMAL RESULTS. WHOLE BLOOD SAMPLES COLLECTED IN BLOOD COLLECTION TUBES CONTAINING EDTA, HEPARIN OR SODIUM CITRATE ANTICOAGULANTS CAN BE USED WITH THE MAXWELL CSC BLOOD DNA KIT. THE TABLE BELOW SHOWS THE ACCEPTABLE TIME THAT SAMPLES CAN BE STORED UNDER DIFFERENT CONDITIONS PRIOR TO USE IN THE MAXWELL CSC BLOOD DNA KIT. THE MAXWELL CSC BLOOD DNA KIT IS NOT INTENDED FOR USE WITH SAMPLES THAT HAVE BEEN COLLECTED IN OTHER TYPES OF BLOOD COLLECTION TUBES OR STORED OUTSIDE OF THE CONDITIONS LISTED BELOW. SAMPLE STORAGE TEMPERATURE STORAGE TIME BEFORE PURIFICATION 15–30°C UP TO 72 HOURS 2–10°C UP TO 7 DAYS –80°C OR LOWER INDEFINITELY THE MAXWELL CSC BLOOD DNA KIT IS NOT INTENDED FOR USE AS PART OF A SPECIFIC DIAGNOSTIC TEST. THE MAXWELL CSC BLOOD DNA KIT IS INTENDED FOR PROFESSIONAL USE ONLY. DIAGNOSTIC RESULTS OBTAINED USING THE GENOMIC DNA PURIFIED WITH THIS SYSTEM MUST BE INTERPRETED IN CONJUNCTION WITH OTHER CLINICAL OR LABORATORY DATA.,CLINICAL SAMPLE CONCENTRATOR (CSC)(MAXWELL CSC RNA FFPE KIT)-THE MAXWELL CSC RNA FFPE KIT IS INTENDED FOR USE, IN COMBINATION WITH THE MAXWELL CSC INSTRUMENT AND THE MAXWELL CSC RNA FFPE PURIFICATION METHOD, AS AN IN VITRO DIAGNOSTIC (IVD) MEDICAL DEVICE TO PERFORM AUTOMATED ISOLATION OF RNA FROM HUMAN BREAST, LUNG AND COLON FFPE (FORMALIN-FIXED, PARAFFIN-EMBEDDED) TISSUE SAMPLES. THE PURIFIED RNA IS SUITABLE FOR USE IN AMPLIFICATION-BASED IN VITRO DIAGNOSTIC ASSAYS. THE MAXWELL CSC RNA FFPE KIT IS INTENDED TO BE USED AT A TEMPERATURE BETWEEN 15°C AND 30°C. USE OUTSIDE OF THIS TEMPERATURE RANGE MAY RESULT IN SUBOPTIMAL RESULTS. FFPE SAMPLES PREPARED USING 10% NEUTRAL-BUFFERED FORMALIN CAN BE USED WITH THE MAXWELL CSC RNA FFPE KIT. THE MAXWELL CSC RNA FFPE KIT IS NOT INTENDED FOR USE AS PART OF A SPECIFIC DIAGNOSTIC TEST. THE MAXWELL CSC RNA FFPE KIT IS INTENDED FOR PROFESSIONAL USE ONLY. DIAGNOSTIC RESULTS OBTAINED USING THE RNA PURIFIED WITH THIS SYSTEM MUST BE INTERPRETED IN CONJUNCTION WITH OTHER CLINICAL OR LABORATORY DATA

948	IMP/IVD/2020/001013	1.License Holder Name: ERIS LIFESCIENCES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE MONITORING SYSTEM(CIRCA VALIDIO)-BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED FOR SELF-TESTING OUTSIDE OF THE BODY (INVITRO DIAGNOSTIC USE) ONLY, FOR BOTH HOME USER AND PROFESSIONALS TO USE. THE SYSTEM IS USED FOR MONITORING OF BLOOD GLUCOSE LEVELS WITH FRESH CAPILLARY, VENOUS, ARTERIAL, AND NEONATAL WHOLE BLOOD SAMPLES. CAPILLARY SAMPLES MAY BE DRAWN FROM THE FINGERTIP,PALM AND FOREARM, AND IN THE CASE OF NEONATES, THE HEEL. THE TESTING RESULT IS CALIBRATED TO BE PLASMA EQUIVALENT., BLOOD GLUCOSE TEST CARTRIDGE(CIRCA VALIDIO)-CIRCA VALIDIO BLOOD GLUCOSE TEST CARTRIDGE ARE INTENDED FOR SELF-TESTING OUTSIDE OF THE BODY (IN VITRO DIAGNOSTIC USE) ONLY, FOR BOTH HOME USER AND PROFESSIONALS TO USE. BLOOD GLUCOSE TEST STRIPS ALONG WITH BLOOD GLUCOSE MONITORING SYSTEM IS USED FOR MONITORING OF BLOOD GLUCOSE LEVELS WITH FRESH CAPILLARY, VENOUS, ARTERIAL, AND NEONATAL WHOLE BLOOD SAMPLES. CAPILLARY SAMPLES MAY BE DRAWN FROM THE FINGERTIP, PALM AND FOREARM, AND IN THE CASE OF NEONATES, THE HEEL. THE TESTING RESULT IS CALIBRATED TO BE PLASMA EQUIVALENT.

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949	IMP/IVD/2020/001014	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FCAL CALIBRATOR SET (FCAL CALIBRATOR SET)-THE FCAL CALIBRATOR SET IS INTENDED FOR USE WITH THE FCAL TURBO FOR THE DETERMINATION OF FECAL CALPROTECTIN LEVELS IN EXTRACTED STOOL SAMPLES. EACH CALIBRATOR ESTABLISHES A POINT OF REFERENCE FOR THE WORKING CURVE THAT IS USED TO CALCULATE TEST RESULTS FROM PATIENT SAMPLES,FCAL(FCAL TURBO)-THE FCAL TURBO IS AN IN VITRO DIAGNOSTIC ASSAY INTENDED FOR THE QUANTITATIVE MEASUREMENT OF FECAL CALPROTECTIN, A NEUTROPHILIC PROTEIN THAT IS A MARKER OF INTESTINAL MUCOSAL INFLAMMATION, IN HUMAN STOOL. FCAL TURBO AIDS IN THE DIAGNOSIS OF INFLAMMATORY BOWEL DISEASE (IBD), SPECIFICALLY CROHN'S DISEASE (CD) AND ULCERATIVE COLITIS (UC) AND AIDS IN THE DIFFERENTIATION OF IBD FROM IRRITABLE BOWEL SYNDROME (IBS) IN CONJUNCTION WITH OTHER LABORATORY AND CLINICAL FINDINGS. THE FCAL TURBO IS INTENDED TO BE RUN ON COBAS C 501/502 SYSTEMS.,CALEX CAP(CALEX CAP)-THE CALEX® CAP IS A SINGLE USE TUBE INTENDED FOR THE PREPARATION OF HUMAN STOOL SAMPLES TO BE USED WITH THE FCAL TURBO.,FCAL CONTROL SET(FCAL CONTROL SET)-THE FCAL CONTROL SET IS INTENDED FOR USE WITH THE FCAL TURBO, FOR QUALITY CONTROL, IN THE DETERMINATION OF FECAL CALPROTECTIN LEVELS IN EXTRACTED STOOL SAMPLES.

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950	IMP/IVD/2020/001015	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:THE NGAL TEST(THE NGAL TEST)-THE NGAL TEST IS A PARTICLEENHANCED TURBIDIMETRIC IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF NEUTROPHIL GELATINASEASSOCIATED LIPOCALIN (NGAL) IN HUMAN URINE, EDTA PLASMA AND HEPARIN PLASMA ON COBAS C SYSTEMS. NGAL MEASUREMENTS ARE IMPORTANT IN THE DIAGNOSIS OF ACUTE KIDNEY INJURY WHICH MAY LEAD TO ACUTE RENAL FAILURE.,THE NGAL TEST CALIBRATOR SET(THE NGAL TEST CALIBRATOR SET)-THE NGAL TEST IS A PARTICLE-ENHANCED TURBIDIMETRIC IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF NEUTROPHIL GELATI NASE-ASSOCIATED LIPOCALIN (NGAL) IN HUMAN URINE, EDTA PLASMA AND HEPARIN PLASMA ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS. THE NGAL TEST CALIBRATOR SET CONTAINS CALIBRATOR SOLUTIONS FOR ESTABLISHING THE CALIBRATION CURVE. NGAL MEASUREMENTS ARE IMPORTANT IN THE,THE NGAL TEST CONTROL SET(THE NGAL TEST CONTROL SET)-THE NGAL TEST IS A PARTICLE-ENHANCED TURBIDIMETRIC IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF NEUTROPHIL GE LATINASE-ASSOCIATED LIPOCALIN (NGAL} IN HUMAN URINE, EDTA PLASMA AND HEPARIN PLASMA ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS. THE NGAL TEST CONTROL SET CONTAINS CONTROL SOLUTIONS FOR VALIDATING THE CALIBRATION CURVE. NGAL MEASUREMENTS ARE IMPORTANT IN THE DIAGNOSIS OF ACUTE KIDNEY INJURY WHICH MAY LEAD TO ACUTE RENAL FAILURE
951	IMP/IVD/2020/001020	1.License Holder Name: HAPTEN BIOSYSTEMS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALEX2 ALLERGY EXPLORER-THE ALLERGY EXPLORER2 (ALEX2) IS A QUANTITATIVE IN VITRO DIAGNOSTIC TEST FOR THE MEASUREMENT OF ALLERGEN SPECIFIC IGE (SIGE) AND A SEMI-QUANTITATIVE IN VITRO DIAGNOSTIC TEST FOR THE MEASUREMENT OF TOTAL IGE (TIGE) IN HUMAN SERUM OR PLASMA (EXCEPTION EDTA-PLASMA). IT IS TO BE USED BY CLINICAL CHEMISTRY LABORATORIES, TRAINED LABORATORY PERSONNEL AND MEDICAL PROFESSIONALS FOR THE PURPOSE OF SUPPORTING THE CLINICAL DIAGNOSIS OF IGE MEDIATED DISEASES, IN CONJUNCTION WITH OTHER CLINICAL FINDINGS OR DIAGNOSTIC TEST RESULTS.

952	IMP/IVD/2020/001022	1.License Holder Name: A & A ENTERPRISES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HCG+B(HCG+B FAST TEST KIT)-PREGNANCY MONITORING,25-OH-VD(25-OH-VD FAST TEST KIT)-BONE TURNOVER MARKER,MICROALBUMINURIA (MALB)(MALB FASTTEST KIT)-AS AN AID IN THE DIAGNOSIS OF KIDNEY DISEASES AND INCREASED CARDIOVASCULAR RISK IN DIABETIC NEPHROPATHY,T4(T4 FAST TEST KIT)-THYROID FUNCTION MONITORING,HBA1C(HBA1C FAST TEST KIT)-DIABETES MONITORING, TSH(TSH FAST TEST KIT)-THYROID FUNCTION MONITORING,N-TERMINAL B-TYPE NATRIURETIC PEPTIDE / CARDIAC TROPONIN I (NTPROBNP/CTNI)(NT-PROBNP/CTNI FAST TEST KIT)-AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF), ACUTE MYOCARDIAL INFARCTION (AMI) AND ACUTE MYOCARDIAL SUNDROME (ACS),NEUTROPHILS GELATINASE ASSOCIATED LIPOCALIN (NGAL)(NGAL FAST TEST KIT)-AS AN AID IN THE EARLY DIAGNOSIS OF ACUTE KIDNEY INJURY, RISK CLASSIFICATION AND TREATMENT MONITORING,D-DIMER(D-DIMER FAST TEST KIT)-RAPID SCREENING FOR DVT & PE,T3(T3 FAST TEST KIT)-THYROID FUNCTION MONITORING,CYSTATIN C (CYSC)(CYSC FAST TEST KIT)-AS AN AID IN THE ASSESSMENT AND EVALUATION OF INDEX OF GLOMERULAR FILTRATION RATE AND HAS IMPORTANT APPLICATION VALUE IN RENAL FUNCTION, KIDNEY DAMAGE AND RENAL TRANSPLANTATION,PROCALCITONIN (PCT)(PCT FAST TEST KIT)-AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF BACTERIAL INFECTION, TRAUMA OR SHOCK,HIGH SENSITIVITY C-REACTIVE PROTEIN (HS-CRP)(HS-CRP+CRP FAST TEST KIT)-AS AN AID IN THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY AND INFLAMATORY DISORDERS,N-TERMINAL B-TYPE NATRIURETIC PEPTIDE (NT-PROBNP)(NT-PROBNP FAST TEST KIT)-IS USED IN IN-VITRO QUANTITATIVE DETERMINATION OF N-TERMINAL B-TYPE NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM, WHOLE BLOOD, PLASMA AS AN AID IN THE CLINICAL, DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF), CARDIAC TROPONIN I(CARDIAC TROPONIN I FAST TEST KIT)-AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY AND ACUTE MYOCARDIAL SYNDROME (ACS),CREATININE KINASE-MB/CARDIAC TROPONIN I / MYOGLOBIN(CK-MB/CTNI/MYO FAST TEST KIT)-AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION AND ACUTE MYOCARDIAL SYNDROME

953	IMP/IVD/2020/001023	1.License Holder Name: BRAINROOTZ LABS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URCHECK 10 PARAMETERS(URICHECK)-REAGENT STRIPS FOR THE RAPID VISUAL DETERMINATION OF UROBILINOGEN, GLUCOSE, BILIRUBIN, KETONES (ACETO ACETIC ACID), SPECIFIC GRAVITY, BLOOD, PH, PROTEIN, NITRITE AND LEUKOCYTES IN URINE.,URICHECK 11 PARAMETERS (URICHECK)-REAGENT STRIPS FOR THE RAPID VISUAL DETERMINATION OF UROBILINOGEN, GLUCOSE, BILIRUBIN, KETONES (ACETO ACETIC ACID), SPECIFIC GRAVITY, BLOOD, PH, PROTEIN, NITRITE, LEUKOCYTES AND ASCORBIC ACID IN URINE.
954	IMP/IVD/2020/001024	1.License Holder Name: SPARKLABS DIAGNOSTICS LLP INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REAGENT STRIPS FOR URINALYSIS (URS-1K)(REAGENT STRIPS FOR URINALYSIS (URS-1K))-URINALYSIS REAGENT STRIPS ARE MADE FOR URINALYSIS OF BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. URINE REAGENT STRIPS ARE INTENDED FOR DETECTION OF KETONES IN THE URINE.,REAGENT STRIPS FOR URINALYSIS (URS-10T)(REAGENT STRIPS FOR URINALYSIS (URS-10T)) -URINALYSIS REAGENT STRIPS ARE MADE FOR URINALYSIS OF BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. URINE REAGENT STRIPS ARE INTENDED FOR DETECTION OFURINALYSIS (LEUKOCYTES, NITRITE, UROBILINOGEN, PROTEIN, PH, BLOOD, SPECIFIC GRAVITY, KETONE, BILIRUBIN, GLUCOSE) ,REAGENT STRIPS FOR URINALYSIS (PH TEST STRIPS 2-9)(REAGENT STRIPS FOR URINALYSIS (PH TEST STRIPS 2-9))-URINALYSIS REAGENT STRIPS ARE MADE FOR URINALYS IS OF BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. URINE REAGENT STRIPS ARE INTENDED FOR DETECTION OF PH IN THE URINE.,REAGENT STRIPS FOR URINALYSIS (URS-2K)(REAGENT STRIPS FOR URINALYSIS (URS-2K))-URINALYSIS REAGENT STRIPS ARE MADE FOR URINALYSIS OF BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. URINE REAGENT STRIPS ARE INTENDED FOR DETECTION OF KETONES AND PH IN URINE.,REAGENT STRIPS FOR URINALYSIS (URS-5K)(REAGENT STRIPS FOR URINALYSIS (URS-5K))-URINALYSIS REAGENT STRIPS ARE MADE FOR URINALYSIS OF BOTH QUALITATIVE AND SEMI-QUANTITATIVE, WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. URINE REAGENT STRIPS ARE INTENDED FOR DETECTION OF GLUCOSE, KETONE, BLOOD, PROTEIN, LEUKOCYTES PARAMETERS IN URINE.

955	IMP/IVD/2020/001025	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEV IGG-DETECTION ANTIBODIES IGG TO HEV IN HUMAN. SERA/PLASMA,HEV IGM-DETECTION ANTIBODIES IGM TO HEV IN HUMAN. SERA/PLASMA,HAV IGM-DETECTION TOTAL ANTIBODIES IGM TO HAV IN HUMAN. SERA/PLASMA,HAV AB-DETECTION TOTAL ANTIBODIES TO HAV IN HUMAN. SERA/PLASMA

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

956	IMP/IVD/2020/001026	1.License Holder Name: SYNDICATE DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STA® - LIATEST® D-DI PLUS(STA® - LIATEST® D-DI PLUS)-THE STA® - LIATEST® D-DI PLUS KIT IS AN IMMUNO-TURBIDIMETRIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN VENOUS PLASMA (IN 3.2 % SODIUM CITRATE) FOR USE ON STA-R®, STA COMPACT® AND STA SATELLITE® ANALYZERS BY PROFESSIONAL LABORATORY PERSONNEL. THE STA® - LIATEST® D-DI PLUS IS INTENDED FOR USE IN CONJUNCTION WITH A CLINICAL PRETEST PROBABILITY (PTP) ASSESSMENT MODEL TO EXCLUDE PULMONARY EMBOLISM (PE) AND DEEP VENOUS THROMBOSIS (DVT) IN OUTPATIENTS SUSPECTED OF PE OR DVT.,STA® - CEPHASCREEN 10(STA® - CEPHASCREEN 10)-THE STA® - CEPHASCREEN® KITS PROVIDE REAGENTS FOR THE DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) IN PLASMA ACCORDING TO LANGDELL R.D. ET AL. (1) AND LARRIEU M.J., WEILLAND C. (3) BY ANALYZERS OF THE STA® LINE SUITABLE WITH THIS REAGENT.,STA® - LIQUID FIB(STA® - LIQUID FIB)-THE STA® - LIQUID FIB KIT IS INTENDED FOR USE WITH STA-R®, STA COMPACT® AND STA SATELLITE® FOR THE QUANTITATIVE DETERMINATION OF FIBRINOGEN LEVELS IN PLASMA BY THE CLOTTING METHOD OF CLAUSS (1).,FACTEUR XIII REACTIFS (FACTEUR XIII REACTIFS)-SEMI-QUANTITATIVE ASSAY OF FACTOR XIII BASED ON THE DETERMINATION OF THE HIGHEST PLASMA DILUTION AT WHICH A CLOT, OBTAINED BY THE ACTION OF ADDED THROMBIN AND CALCIUM ON EXOGENOUS FACTOR XIII-FREE FIBRINOGEN, REMAINS INSOLUBLE IN THE PRESENCE OF CHLOROACETIC ACID (JOSSO ET AL.'S METHOD).,STA® - IMMUNODEF XI(STA® - IMMUNODEF XI)-STA® - IMMUNODEF XI IS AN IMMUNO-DEPLETED HUMAN PLASMA INTENDED FOR USE IN TESTS FOR THE DETERMINATION OF FACTOR XI ACTIVITY IN PLASMA ON STA-R® AND STA COMPACT®. THESE TESTS REQUIRE THE INCLUSION OF FACTOR XI DEFICIENT PLASMA.,STA-HEPANORM® H(STA-HEPANORM® H)-THE STA® - HEPANORM® H KIT IS A SET OF CALIBRATOR PLASMAS INTENDED FOR THE CALIBRATION OF UNFRACTIONATED HEPARIN (UFH) ACTIVITY ASSAY BY MEASURING THE ANTI-XA ACTIVITY,STA-FDP CALIBRATOR(STA-FDP CALIBRATOR)-THE STA® - FDP CALIBRATOR KIT PROVIDES A SET OF CALIBRATOR PLASMAS INTENDED FOR USE WITH STA-R® AND STA COMPACT® FOR THE ASSAY CALIBRATION OF FIBRIN/FIBRINOGEN DEGRADATION PRODUCTS (FDP) BY THE IMMUNOTURBIDIMETRIC METHOD (STA® - LIATEST® FDP, REF 00649).,STA-FONDAPARINUX CALIBRATOR(STA-FONDAPARINUX CALIBRATOR)-THE STA® - FONDAPARINUX CALIBRATOR KIT IS A SET OF CALIBRATOR

	PLASMAS INTENDED FOR USE WITH STA-R®, STA COMPACT® AND STA SATELLITE® FOR THE CALIBRATION OF FONDAPARINUX ACTIVITY ASSAY BY MEASURING THE ANTI-XA ACTIVITY,STA-QUALITY HNF/UFH(STA-QUALITY HNF/UFH)-THE STA® - QUALITY HNF/UFH KIT IS A SET OF TWO PLASMAS INTENDED FOR THE QUALITY CONTROL OF UNFRACTIONATED HEPARIN (UFH) ACTIVITY ASSAY BY MEASURING THE ANTI-XA ACTIVITY PERFORMED ON STA-R®, STA COMPACT® AND STA SATELLITE® ANALYZERS.,STA-APIXABAN CALIBRATOR(STA-APIXABAN CALIBRATOR)-THE STA® - APIXABAN CALIBRATOR KIT IS A SET OF CALIBRATOR PLASMAS INTENDED FOR USE WITH STA-R® AND STA COMPACT® FOR CALIBRATION OF THE MEASUREMENT OF APIXABAN ANTI-XA ACTIVITY USING THE STA® - LIQUID ANTI-XA (REF 00311, 00322) KITS.,ASSERACHROM FREE PROTEIN S(ASSERACHROM FREE PROTEIN S)-QUANTITATIVE DETERMINATION OF FREE PROTEIN S BY ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) ,CK PREST® 2, 5 (CK PREST® 2, 5)-DETERMINATION OF THE KAOLIN-ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),COAG CONTROL N+ P(COAG CONTROL N+ P)-THE COAG CONTROL + KIT PROVIDES TWO PLASMAS INTENDED FOR USE AS A NORMAL AND AN ABNORMAL CONTROLS FOR THE FOLLOWING TESTS: PROTHROMBIN TIME (PT), ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), FIBRINOGEN AND THROMBIN TIME (TT). THE TT CONTROL VALUE IS PROVIDED BY REAGENT 1 (NORMAL CONTROL) ONLY.,ASSERACHROM® VWF:CB (ASSERACHROM® VWF:CB)-THE ASSERACHROM® VWF:CB KIT IS AN ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE CAPACITY OF VON WILLEBRAND FACTOR TO BIND TO COLLAGEN (VWF:CB) BY ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA).,NÉOPLASTINE® CI PLUS 2, 5, 10(NÉOPLASTINE® CI PLUS 2, 5, 10)-THE NÉOPLASTINE® CI PLUS KITS PROVIDE REAGENTS FOR THE DETERMINATION OF THE PROTHROMBIN TIME (PT) IN PLASMA.,STA® - IMMUNODEF IX(STA® - IMMUNODEF IX)-STA® - IMMUNODEF IX IS AN IMMUNO-DEPLETED HUMAN PLASMA INTENDED FOR USE IN TESTS FOR THE DETERMINATION OF FACTOR IX (ANTIHEMOPHILIC B FACTOR) ACTIVITY IN PLASMA ON STA-R® AND STA COMPACT®. THESE TESTS REQUIRE THE INCLUSION OF FACTOR IX DEFICIENT PLASMA.,STA® - MULTI HEP CALIBRATOR(STA® - MULTI HEP CALIBRATOR)-THE STA® - MULTI HEP CALIBRATOR IS A SET OF CALIBRATOR PLASMAS INTENDED FOR USE WITH STA-R®, STA COMPACT® AND STA SATELLITE® ANALYZERS, FOR THE CALIBRATION OF HEPARIN (UFH AND LMWH) ACTIVITY ASSAY BY MEASURING THE ANTI-XA ACTIVITY., STA® - PTT A 5(STA® - PTT A 5)-THE STA® - PTT 5 KIT PROVIDES REAGENT FOR THE DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) ACCORDING TO LANGDELL R.D. ET

	AL. (1) AND LARRIEU M.J., WEILLAND C. (3) WITH STA-R®, STA COMPACT® AND STA SATELLITE®. (IN THE USA, THIS PROCEDURE HAS BEEN ASSIGNED TO THE MODERATE COMPLEXITY CATEGORY PER CLIA 1988 - CDC ANALYTE CODE 0409; CDC TEST SYSTEM CODE 04875).,UNICALIBRATOR(UNICALIBRATOR)-UNICALIBRATOR IS A PLASMA INTENDED FOR USE AS A CALIBRATION PLASMA FOR THE ASSAYS OF THE FOLLOWING COAGULATION PARAMETERS: PROTHROMBIN TIME (IF TO BE EXPRESSED AS %), FIBRINOGEN (CLAUSS' METHOD), FACTORS II, V, VII, VIII, IX, X, XI, XII, ANTITHROMBIN (AT), PROTEIN C AND PROTEIN S.,STA® - CONTROL LA 1+2(STA® - CONTROL LA 1+2)-THE STA® - CONTROL LA 1 + 2 KIT PROVIDES A LUPUS ANTICOAGULANT (LA) NEGATIVE PLASMA AND A LA POSITIVE PLASMA. THESE PLASMAS ARE INTENDED FOR THE QUALITY CONTROL OF THE TESTS FOR LA DETECTION CARRIED OUT WITH THE FOLLOWING TESTS: – STA® - STACLOT® DRVV SCREEN (REF 00339, 00333) – STA® - STACLOT® DRVV CONFIRM (REF 00334) – STACLOT® LA (REF 00600, 00594*).,STA® - LIATEST® FREE PROTEIN S 2(STA® - LIATEST® FREE PROTEIN S 2)-THE STA® - LIATEST® FREE PROTEIN S KITS ARE INTENDED FOR USE ON STA-R® AND STA COMPACT® FOR THE ANTIGENIC ASSAY OF FREE PROTEIN S IN PLASMA BY THE IMMUNO-TURBIDIMETRIC METHOD. (IN THE USA THIS PROCEDURE HAS BEEN ASSIGNED TO THE MODERATE COMPLEXITY CATEGORY PER CLIA 1988).,STA® - CK PREST 5(STA® - CK PREST 5)-THE STA® - C.K. PREST® 5 KIT PROVIDES REAGENTS FOR THE DETERMINATION OF THE KAOLIN-ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) IN PLASMA, ACCORDING TO LANGDELL R.D. ET AL. (1) AND LARRIEU M.J., WEILLAND C. (3) ON STA-R® AND STA COMPACT®. (IN THE USA THIS PROCEDURE HAS BEEN ASSIGNED TO THE MODERATE COMPLEXITY CATEGORY PER CLIA 1988 - CDC ANALYTE CODE 0409 ; CDC TEST SYSTEM CODES 4677 AND 4875).,STA® - LIQUID ANTI-XA 4, 8(STA® - LIQUID ANTI-XA 4, 8)-THE STA® - LIQUID ANTI-XA KITS ARE INTENDED FOR USE FOR THE QUANTITATIVE DETERMINATION IN THE PLASMA: – OF THE POTENTIATING EFFECT OF UNFRACTIONATED (UFH), LOW MOLECULAR WEIGHT HEPARINS (LMWH) AND FONDAPARINUX ON ANTITHROMBIN BY MEASURING THE ANTI-XA ACTIVITY IN A COMPETITIVE ASSAY USING A SYNTHETIC CHROMOGENIC SUBSTRATE ON STA-R®, STA COMPACT® AND STA SATELLITE®, – OF RIVAROXABAN, APIXABAN AND EDOXABAN BY MEASURING THEIR DIRECT ANTI-XA ACTIVITY IN A COMPETITIVE ASSAY USING A SYNTHETIC CHROMOGENIC SUBSTRATE ON STA-R® AND STA COMPACT®.,STA® - LIATEST® FM(STA® - LIATEST® FM)-THE STA® - LIATEST® FM KIT IS INTENDED FOR USE WITH STA-R® AND STA COMPACT® FOR THE QUANTITATIVE DETERMINATION IN PLASMA OF

	FIBRIN MONOMERS PRESENT OR NOT PRESENT IN SOLUBLE COMPLEXES AS AN AID IN THE DIAGNOSIS OF DISSEMINATED INTRAVASCULAR COAGULATION (DIC) BY THE IMMUNOTURBIDIMETRIC METHOD.,STA® - THROMBIN 2, 10(STA® - THROMBIN 2, 10)-THE STA® - THROMBIN KITS PROVIDE A REAGENT FOR THE DETERMINATION OF THE THROMBIN TIME (TT) ON STA-R® AND STA COMPACT®. (IN THE USA THIS PROCEDURE HAS BEEN ASSIGNED TO THE MODERATE COMPLEXITY CATEGORY PER CLIA 1988 - CDC ANALYTE CODE 6105; CDC TEST SYSTEM CODES 4677 AND 4875).,STA® - LIATEST® CONTROL N+P(STA® - LIATEST® CONTROL N+P)-THE STA® - LIATEST® CONTROL + KIT PROVIDES A NORMAL PLASMA AND AN ABNORMAL PLASMA INTENDED FOR THE QUALITY CONTROL OF THE FOLLOWING ANTIGENIC ASSAYS BY THE IMMUNO-TURBIDIMETRIC METHOD: – VON WILLEBRAND FACTOR (VWF) AND FREE PROTEIN S ASSAYS ON STA-R® AND STA COMPACT® WITH STA® - LIATEST® VWF:AG (REF 00518) AND STA® - LIATEST® FREE PROTEIN S (REF 00527, 00516) – D-DIMER ASSAY ON STA-R®, STA COMPACT® AND STA SATELLITE® WITH STA® - LIATEST® D-DI (REF 00515, 00968*) AND STA® - LIATEST® D-DI PLUS* (REF 00662)., STA® - DEFICIENT X(STA® - DEFICIENT X)-STA® - DEFICIENT X IS AN IMMUNO-DEPLETED HUMAN PLASMA INTENDED FOR USE IN TESTS FOR THE DETERMINATION OF FACTOR X ACTIVITY IN PLASMA WITH STA-R® AND STA COMPACT®. THESE TESTS REQUIRE THE INCLUSION OF FACTOR X DEFICIENT PLASMA. (IN THE USA, THIS PROCEDURE HAS BEEN ASSIGNED TO THE HIGH COMPLEXITY CATEGORY PER CLIA 1988 - CDC ANALYTE CODE 1044; CDC TEST SYSTEM CODES 4677 AND 4875).,STA® - DEFICIENT II(STA® - DEFICIENT II)-STA® - DEFICIENT II IS A SUBSTRATE PLASMA (HUMAN AND BOVINE) INTENDED FOR USE IN TESTS FOR THE DETERMINATION OF FACTOR II ACTIVITY IN PLASMA WITH STA-R® AND STA COMPACT®. THESE TESTS REQUIRE THE INCLUSION OF FACTOR II DEFICIENT PLASMA (1). (IN THE USA, THIS PROCEDURE HAS BEEN ASSIGNED TO THE HIGH COMPLEXITY CATEGORY PER CLIA 1988 - CDC ANALYTE CODE 1044; CDC TEST SYSTEM CODES 4677 AND 4875).,STA® - QUALITY HBPM/LMWH(STA® - QUALITY HBPM/LMWH) -THE STA® - QUALITY HBPM/LMWH KIT IS A SET OF TWO PLASMAS INTENDED FOR THE QUALITY CONTROL OF LOW MOLECULAR WEIGHT HEPARIN (LMWH) ACTIVITY ASSAY BY MEASURING THE ANTI-XA ACTIVITY PERFORMED ON STA-R®, STA COMPACT® AND STA SATELLITE® ANALYZERS.,STA® - STACLOT® DRVV SCREEN 2, 5 (STA® - STACLOT® DRVV SCREEN 2, 5)-THE STA® - STACLOT® DRVV SCREEN AND STA® - STACLOT® DRVV CONFIRM KITS ARE INTENDED FOR THE DETECTION OF THE LUPUS ANTICOAGULANTS (LA) IN PLASMA BY THE DILUTED RUSSELL'S VIPER VENOM TEST (1) ON STA-

	R® AND STA COMPACT®. (IN THE USA THIS PROCEDURE HAS BEEN ASSIGNED TO THE HIGH COMPLEXITY CATEGORY PER CLIA 1988)., SYSTEM CONTROL N+ P(SYSTEM CONTROL N+ P)-THE SYSTEM CONTROL + KIT PROVIDES TWO CITRATED PLASMAS INTENDED FOR USE AS NORMAL AND ABNORMAL CONTROL LEVELS FOR THE FOLLOWING TESTS: – REAGENT 1 (SYSTEM CONTROL) IS FOR PROTHROMBIN TIME (PT), ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), FIBRINOGEN (CLAUSS' METHOD), THROMBIN TIME (TT), REPTILASE® TIME, FACTORS II, V, VII, VIII, IX, X, XI AND XII, ANTITHROMBIN (AT), PROTEIN C AND PROTEIN S. – REAGENT 2 (SYSTEM CONTROL) IS FOR THE TESTS AS DESCRIBED ABOVE EXCEPT THROMBIN TIME (TT) AND REPTILASE® TIME.,STA® - RIVAROXABAN CONTROL(STA® - RIVAROXABAN CONTROL)-THE STA® - RIVAROXABAN CONTROL KIT IS A SET OF TWO PLASMAS INTENDED FOR USE WITH STA-R® AND STA COMPACT® FOR QUALITY CONTROL OF THE MEASUREMENT OF RIVAROXABAN ANTI-XA ACTIVITY USING THE STA® - LIQUID ANTI-XA (REF 00311, 00322) KITS.,STA® - STACLOT® DRVV CONFIRM(STA® - STACLOT® DRVV CONFIRM)-THE STA® - STACLOT® DRVV SCREEN AND STA® - STACLOT® DRVV CONFIRM KITS ARE INTENDED FOR THE DETECTION OF THE LUPUS ANTICOAGULANTS (LA) IN PLASMA BY THE DILUTED RUSSELL'S VIPER VENOM TEST (1) ON STA-R® AND STA COMPACT®. (IN THE USA THIS PROCEDURE HAS BEEN ASSIGNED TO THE HIGH COMPLEXITY CATEGORY PER CLIA 1988).,STA® - DESORB U(STA® - DESORB U)-THE STA® - DESORB U IS A DECONTAMINATING SOLUTION FOR USE WITH STA-R®, STA COMPACT® AND STA SATELLITE®. IT IS DESIGNED AS AN INTEGRAL PART OF THE STA® ANALYZER SYSTEM,STA® - DEFICIENT V(STA® - DEFICIENT V)-STA® - DEFICIENT V IS A HUMAN PLASMA INTENDED FOR USE IN TESTS FOR THE DETERMINATION OF FACTOR V ACTIVITY IN PLASMA BY STA-R® AND STA COMPACT®. THESE TESTS REQUIRE THE INCLUSION OF FACTOR V DEFICIENT PLASMA (1). (IN THE USA, THIS PROCEDURE HAS BEEN ASSIGNED TO THE HIGH COMPLEXITY CATEGORY PER CLIA 1988 - CDC ANALYTE CODE 1044; CDC TEST SYSTEM CODES 4677 AND 4875).,STA® - STACLOT® PROTEIN C 1(STA® - STACLOT® PROTEIN C 1)-THE STA® - STACLOT® PROTEIN C KITS ARE INTENDED FOR USE WITH STA COMPACT® AND STA-R®, FOR THE QUANTITATIVE MEASUREMENT OF THE FUNCTIONAL PROTEIN C LEVEL BASED ON THE PROLONGATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) (5). (IN THE USA, THIS PROCEDURE HAS BEEN ASSIGNED TO THE HIGH COMPLEXITY CATEGORY PER CLIA 1988 - CDC ANALYTE CODE 4929; CDC TEST SYSTEM CODES 4677 AND 4875).,STA® - CEPHASCREEN 4(STA® - CEPHASCREEN 4)-THE STA® - CEPHASCREEN® KITS PROVIDE REAGENTS FOR THE

	DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) IN PLASMA ACCORDING TO LANGDELL R.D. ET AL. (1) AND LARRIEU M.J., WEILLAND C. (3) BY ANALYZERS OF THE STA® LINE SUITABLE WITH THIS REAGENT.,STA® - NEOPLASTINE® R15 (STA® - NEOPLASTINE® R15)-THE STA® - NÉOPLASTINE® R KIT IS INTENDED FOR THE DETERMINATION OF THE PROTHROMBIN TIME (PT) IN PLASMA ON STA-R®, STA COMPACT® AND STA SATELLITE® , STA® - OWREN - KOLLER(STA® - OWREN - KOLLER)-THE STA® - OWREN-KOLLER IS A BUFFER SOLUTION INTENDED FOR USE AS A DILUENT FOR REAGENTS AND PATIENT SAMPLES IN COAGULATION TESTS.,STA® - STACLOT® PROTEIN S(STA® - STACLOT® PROTEIN S) -THE STA® - STACLOT® PROTEIN S KIT IS INTENDED FOR USE WITH ANALYZERS OF THE STA® LINE SUITABLE WITH THESE REAGENTS, FOR THE QUANTITATIVE MEASUREMENT OF THE FUNCTIONAL PROTEIN S LEVEL BASED ON THE PRINCIPLE OF FACTOR VA INHIBITION (7). (IN THE USA THIS PROCEDURE HAS BEEN ASSIGNED TO THE HIGH COMPLEXITY CATEGORY PER CLIA 1988 - CDC ANALYTE CODE 4930; CDC TEST SYSTEM CODES 04677 AND 04875).,STA® - CACL2 0.025 M(STA® - CACL2 0.025 M)-STA® - CACL2 0.025 M IS AN AQUEOUS SOLUTION OF CALCIUM CHLORIDE INTENDED FOR THE CLOTTING TESTS SUCH AS THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) OR FOR THE ASSAYS OF INTRINSIC PATHWAY FACTORS,STA® - STACLOT® APC-R(STA® - STACLOT® APC-R)-THE STA® - STACLOT® APC-R* KIT IS INTENDED FOR USE WITH STA-R® AND STA COMPACT® FOR THE ASSESSMENT OF THE ACTIVATED PROTEIN C RESISTANCE (APC-R) IN PLASMA.,STA® - STACHROM® PROTEIN C(STA® - STACHROM® PROTEIN C)-THE STA® - STACHROM® PROTEIN C KIT IS INTENDED FOR USE, WITH STA-R® AND STA COMPACT®, FOR THE QUANTITATIVE DETERMINATION OF THE FUNCTIONAL PROTEIN C LEVEL IN PLASMA BY THE SYNTHETIC CHROMOGENIC SUBSTRATE METHOD. (IN THE USA THIS PROCEDURE HAS BEEN ASSIGNED TO THE HIGH COMPLEXITY CATEGORY PER CLIA 1988 - CDC ANALYTE CODE 4929; CDC TEST SYSTEM CODES 4677 AND 4875).,STA® - DEFICIENT IX(STA® - DEFICIENT IX)-STA® - DEFICIENT IX IS AN IMMUNO-DEPLETED HUMAN PLASMA INTENDED FOR USE IN TESTS FOR THE DETERMINATION OF FACTOR IX ACTIVITY IN PLASMA BY STA-R® AND STA COMPACT®. THESE TESTS REQUIRE THE INCLUSION OF FACTOR IX DEFICIENT PLASMA (1). (IN THE USA, THIS PROCEDURE HAS BEEN ASSIGNED TO THE HIGH COMPLEXITY CATEGORY PER CLIA 1988 - CDC ANALYTE CODE 1044; CDC TEST SYSTEM CODES 4677 AND 4875).,STA® - DEFICIENT XI(STA® - DEFICIENT XI)-STA® - DEFICIENT XI IS A HUMAN PLASMA INTENDED FOR USE IN TESTS FOR THE DETERMINATION OF FACTOR XI ACTIVITY IN PLASMA WITH STA-R® AND STA COMPACT®. THESE TESTS

	REQUIRE THE INCLUSION OF FACTOR XI DEFICIENT PLASMA (1). (IN THE USA, THIS PROCEDURE HAS BEEN ASSIGNED TO THE HIGH COMPLEXITY CATEGORY PER CLIA 1988 - CDC ANALYTE CODE 1044; CDC TEST SYSTEM CODES 4677 AND 4875).,STA-DABIGATRAN CALIBRATOR(STA-DABIGATRAN CALIBRATOR)-THE STA® - DABIGATRAN CALIBRATOR KIT IS A SET OF CALIBRATOR PLASMAS INTENDED FOR USE WITH STA-R® AND STA COMPACT MAX® FOR CALIBRATION OF THE MEASUREMENT OF DABIGATRAN ANTI-IIA ACTIVITY USING THE STA® - ECA II KIT (REF 00992).,STA-ECA II(STA-ECA II)-STA® - ECA II IS INTENDED FOR USE WITH STA-R® AND STA COMPACT MAX® FOR MEASURING THE DIRECT ANTI-IIA ACTIVITY OF DABIGATRAN IN A COMPETITIVE ASSAY USING A SYNTHETIC CHROMOGENIC SUBSTRATE. THE KIT ALLOWS THE QUANTITATIVE DETERMINATION OF DABIGATRAN IN THE PLASMA OF PATIENTS TAKING THE DRUG. THE MEASUREMENT OF DABIGATRAN ANTI-IIA ACTIVITY IS CONVERTED INTO DABIGATRAN PLASMA CONCENTRATION. THIS CONCENTRATION IS HELPFUL FOR CLINICIANS TO ASSESS THE EXTENT OF ANTICOAGULATION IN SITUATIONS REQUIRING FURTHER CHARACTERIZATION OF THE CLINICAL PICTURE.,STA-DABIGATRAN CONTROL(STA-DABIGATRAN CONTROL)-THE STA® - DABIGATRAN CONTROL KIT IS A SET OF TWO PLASMAS INTENDED FOR USE WITH STA-R® AND STA COMPACT MAX® FOR QUALITY CONTROL OF THE MEASUREMENT OF DABIGATRAN ANTI-IIA ACTIVITY USING THE STA® - ECA II (REF 00992) KIT.,STA-APIXABAN CONTROL(STA-APIXABAN CONTROL)-THE STA® - APIXABAN CONTROL KIT IS A SET OF TWO PLASMAS INTENDED FOR USE WITH STA-R® AND STA COMPACT® FOR QUALITY CONTROL OF THE MEASUREMENT OF APIXABAN ANTI-XA ACTIVITY USING THE STA® - LIQUID ANTI-XA (REF 00311, 00322) KITS.,STA® - VWF:AG CALIBRATOR(STA® - VWF:AG CALIBRATOR)-STA® - VWF:AG CALIBRATOR IS A PLASMA INTENDED FOR THE CALIBRATION OF VON WILLEBRAND FACTOR (VWF) ANTIGENIC ASSAYS ON STA-R® AND STA COMPACT®, BY THE IMMUNO-TURBIDIMETRIC METHOD (STA® - LIATEST® VWF:AG, REF 00518).,STA® - DEFICIENT VIII(STA® - DEFICIENT VIII)-STA® - DEFICIENT VIII IS AN IMMUNO-DEPLETED HUMAN PLASMA INTENDED FOR USE IN TESTS FOR THE DETERMINATION OF FACTOR VIII ACTIVITY IN PLASMA ON STA-R® AND STA COMPACT®. THESE TESTS REQUIRE THE INCLUSION OF FACTOR VIII DEFICIENT PLASMA (1). (IN THE USA, THIS PROCEDURE HAS BEEN ASSIGNED TO THE HIGH COMPLEXITY CATEGORY PER CLIA 1988 - CDC ANALYTE CODE 1044; CDC TEST SYSTEM CODES 4677 AND 4875).,POOL NORM(POOL NORM)-THE POOL NORM IS A NORMAL HUMAN PLASMA POOL INTENDED FOR DIFFERENTIATING BETWEEN A COAGULATION FACTOR DEFICIENCY

	AND EXISTENCE OF CIRCULATING ANTICOAGULANTS.,STA® - UNICALIBRATOR(STA® - UNICALIBRATOR)-THE STA® - UNICALIBRATOR IS A PLASMA INTENDED FOR USE AS A CALIBRATION PLASMA FOR THE FUNCTIONAL ASSAYS OF THE FOLLOWING COAGULATION PARAMETERS ON STA-R®, STA COMPACT® AND STA SATELLITE®: – PROTHROMBIN TIME (IF TO BE EXPRESSED AS %), OWREN'S PT, FIBRINOGEN (CLAUSS' METHOD), FACTORS II, V, VII, VIII, IX, X, XI AND XII, PROTEIN C AND PROTEIN S BY THE CLOTTING METHOD; – ANTITHROMBIN (AT), PROTEIN C, PLASMINOGEN AND ANTIPLASMIN BY THE SYNTHETIC CHROMOGENIC SUBSTRATE METHOD.,STA® - COAG CONTROL N+P (STA® - COAG CONTROL N+P)-THE STA® - COAG CONTROL + KIT IS COMPOSED OF A NORMAL PLASMA AND AN ABNORMAL PLASMA INTENDED FOR THE QUALITY CONTROL OF THE FOLLOWING TESTS ON ANALYZERS OF THE STA® BRAND NAME SUITABLE WITH THESE REAGENTS: PROTHROMBIN TIME (PT), ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), FIBRINOGEN, THROMBIN TIME (TT) AND ANTITHROMBIN (AT). THE THROMBIN TIME IS DETERMINED ON THE REAGENT 1 ONLY.,STA® - LIATEST® FDP(STA® - LIATEST® FDP)-THE STA® - LIATEST® FDP KIT IS INTENDED FOR USE WITH STA-R® AND STA COMPACT® FOR THE QUANTITATIVE DETERMINATION OF FIBRIN/FIBRINOGEN DEGRADATION PRODUCTS (FDP) BY THE IMMUNO-TURBIDIMETRIC METHOD.,STA® - ROUTINE QC (P) PLUS (STA® - ROUTINE QC (P) PLUS)-STA® - ROUTINE QC PLUS IS AN ABNORMAL PLASMA KIT INTENDED FOR THE QUALITY CONTROL OF THE FOLLOWING TESTS ON STA-R® AND STA COMPACT®: PROTHROMBIN TIME (PT), ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), FIBRINOGEN, THROMBIN TIME (TT), AND ANTITHROMBIN (AT).,STA® - FM CONTROL(STA® - FM CONTROL)-THE STA® - FM CONTROL KIT PROVIDES TWO PLASMAS INTENDED FOR THE QUALITY CONTROL OF ASSAYS OF FIBRIN MONOMERS PRESENT OR NOT PRESENT IN SOLUBLE COMPLEXES ON STA-R® AND STA COMPACT® BY THE IMMUNO-TURBIDIMETRIC METHOD (STA® - LIATEST® FM, REF 00543).,STA® - STACLOT® HEPARIN 1(STA® - STACLOT® HEPARIN 1) -THE STA® - STACLOT® HEPARIN 1 KIT IS INTENDED, WITH STA-R® AND STA COMPACT®, FOR THE QUANTITATIVE DETERMINATION OF THE POTENTIATING EFFECT OF UNFRACTIONATED HEPARINS (UFH) AND OF LOW MOLECULAR WEIGHT HEPARINS (LMWH) ON ANTITHROMBIN BY MEASURING IN PLASMA THE ANTI-XA ACTIVITY AS APPLIED IN A CLOTTING METHOD (1, 2).,PTT AUTOMATE 5(PTT AUTOMATE 5)-THE PTT UTOMATE KIT IS INTENDED FOR THE DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) ACCORDING TO LANGDELL R.D. ET AL. (1) AND LARRIEU M.J., WEILLAND C. (3).,STA® - IMMUNODEF XII(STA® - IMMUNODEF

	XII)-STA® - IMMUNODEF XII IS AN IMMUNO-DEPLETED PLASMA INTENDED FOR USE IN THE DETERMINATION OF FACTOR XII ACTIVITY IN PLASMA WITH STA-R® AND STA COMPACT®. THESE TESTS REQUIRE THE INCLUSION OF FACTOR XII DEFICIENT PLASMA (3)., STA® - D-DI CONTROL(STA® - D-DI CONTROL)-THE STA® - D-DI CONTROL KIT INCLUDES TWO ASSAYED REAGENTS INTENDED FOR THE QUALITY CONTROL OF D-DIMER TESTS BY QUANTITATIVE IMMUNO-TURBIDIMETRIC METHOD PERFORMED WITH STA® - LIATEST® D-DI (REF 00515) AND STA® - LIATEST® D-DI PLUS (REF 00662) KITS ON STA-R® AND STA COMPACT®.,STA® - NEOPTIMAL® 5, 10, 20(STA® - NEOPTIMAL® 5, 10, 20)-THE STA® - NEOPTIMAL KITS PROVIDE THROMBOPLASTIN REAGENTS FROM RABBIT BRAIN EXTRACT, FOR THE QUANTITATIVE DETERMINATION, IN HUMAN CITRATED PLASMA (3.2 % SODIUM CITRATE), OF PROTHROMBIN TIME (PT) ON STA-R® FAMILY, STA COMPACT® FAMILY AND STA SATELLITE® FAMILY INSTRUMENTS. STA® - NEOPTIMAL IS A COAGULATION SCREENING TEST INTENDED TO BE USED BY PROFESSIONAL LABORATORY PERSONNEL FOR THE EVALUATION OF THE EXTRINSIC COAGULATION PATHWAY AND THE MONITORING OF ORAL VITAMIN K ANTAGONIST THERAPY USING THE INTERNATIONAL NORMALIZED RATIO (INR).,STA® - FDP CONTROL(STA® - FDP CONTROL)-THE STA® - FDP CONTROL KIT PROVIDES TWO PLASMAS INTENDED FOR THE QUALITY CONTROL OF ASSAYS OF FIBRIN/FIBRINOGEN DEGRADATION PRODUCTS (FDP) ON STA-R® AND STA COMPACT® BY THE IMMUNO-TURBIDIMETRIC METHOD (STA® - LIATEST® FDP, REF 00649).,FDP PLASMA(FDP PLASMA)-QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF FDP IN PLASMA BY LATEX AGGLUTINATION,STA® - LIATEST® FREE PROTEIN S 6(STA® - LIATEST® FREE PROTEIN S 6)-THE STA® - LIATEST® FREE PROTEIN S KITS ARE INTENDED FOR USE ON STA-R® AND STA COMPACT® FOR THE ANTIGENIC ASSAY OF FREE PROTEIN S IN PLASMA BY THE IMMUNO-TURBIDIMETRIC METHOD. (IN THE USA THIS PROCEDURE HAS BEEN ASSIGNED TO THE MODERATE COMPLEXITY CATEGORY PER CLIA 1988).,STA® - STACHROM® ATIII 3, 6(STA® - STACHROM® ATIII 3, 6)-THE STA® - STACHROM® AT III KITS ARE INTENDED FOR USE, WITH ANALYZERS OF THE STA® LINE SUITABLE WITH THESE REAGENTS, FOR THE QUANTITATIVE DETERMINATION OF THE ANTITHROMBIN (AT) ACTIVITY LEVEL IN PLASMA BY THE SYNTHETIC CHROMOGENIC SUBSTRATE METHOD (3). (IN THE USA, THIS PROCEDURE HAS BEEN ASSIGNED TO THE HIGH COMPLEXITY CATEGORY PER CLIA 1988 - CDC ANALYTE CODE 0456; CDC TEST SYSTEM CODES 4677 AND 4875).,STA® - SYSTEM CONTROL N+P(STA® - SYSTEM CONTROL N+P)-THE STA® - SYSTEM CONTROL + KIT PROVIDES A NORMAL PLASMA AND AN ABNORMAL PLASMA

	INTENDED FOR USE AS TWO CONTROL LEVELS FOR THE FOLLOWING ASSAYS PERFORMED ON ANALYZERS OF THE STA® LINE SUITABLE WITH THESE REAGENTS: – THE REAGENT 1 (STA® - SYSTEM CONTROL) IS FOR THE FOLLOWING TESTS: PROTHROMBIN TIME (PT), ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), FIBRINOGEN (CLAUSS' METHOD), THROMBIN TIME (TT), REPTILASE® TIME, FACTORS II, V, VII, VIII, IX, X, XI AND XII, ANTITHROMBIN (AT), PROTEIN C, PROTEIN S, PLASMINOGEN AND ANTIPLASMIN. – THE REAGENT 2 (STA® - SYSTEM CONTROL) IS FOR THE TESTS AS DESCRIBED ABOVE EXCEPT THROMBIN TIME (TT) AND REPTILASE® TIME.,STA® - FM CALIBRATOR(STA® - FM CALIBRATOR)-THE STA® - FM CALIBRATOR KIT PROVIDES A SET OF CALIBRATOR PLASMAS INTENDED FOR USE WITH STA-R® AND STA COMPACT® FOR THE ASSAY CALIBRATION OF FIBRIN MONOMERS PRESENT OR NOT PRESENT IN SOLUBLE COMPLEXES BY THE IMMUNO-TURBIDIMETRIC METHOD (STA® - LIATEST® FM, REF 00543).,D-DI TEST®(D-DI TEST®)-LATEX AGGLUTINATION SLIDE TEST FOR THE QUALITATIVE AND SEMI - QUANTITATIVE DETERMINATION OF D-DIMER,STA-FONDAPARINUX CONTROL(STA-FONDAPARINUX CONTROL)-THE STA® - FONDAPARINUX CONTROL KIT IS A SET OF TWO PLASMAS INTENDED FOR USE WITH STA-R®, STA COMPACT® AND STA SATELLITE® FOR THE QUALITY CONTROL OF FONDAPARINUX ACTIVITY ASSAY BY MEASURING THE ANTI-XA ACTIVITY,STA® - RIVAROXABAN CALIBRATOR(STA® - RIVAROXABAN CALIBRATOR)-THE STA® - RIVAROXABAN CALIBRATOR KIT IS A SET OF CALIBRATOR PLASMAS INTENDED FOR USE WITH STA-R® AND STA COMPACT® FOR CALIBRATION OF THE MEASUREMENT OF RIVAROXABAN ANTI-XA ACTIVITY USING THE STA® - LIQUID ANTI-XA (REF 00311, 00322) KITS.,STA® - IMMUNODEF VIII(STA® - IMMUNODEF VIII)-STA® - IMMUNODEF VIII IS AN IMMUNO-DEPLETED HUMAN PLASMA INTENDED FOR USE IN TESTS FOR THE DETERMINATION OF FACTOR VIII (ANTIHEMOPHILIC A FACTOR) ACTIVITY IN PLASMA ON STA-R® AND STA COMPACT®. THESE TESTS REQUIRE THE INCLUSION OF FACTOR VIII DEFICIENT PLASMA.,STA® - LIATEST® VWF: AG(STA® - LIATEST® VWF: AG)-THE STA® - LIATEST® VWF:AG KIT IS INTENDED FOR USE WITH STA-R® AND STA COMPACT®, FOR THE QUANTITATIVE DETERMINATION OF VON WILLEBRAND FACTOR ANTIGEN (VWF:AG) IN PLASMA BY THE IMMUNO-TURBIDIMETRIC METHOD,PTT-LA(PTT-LA)-THE PTT-LA KIT IS INTENDED FOR THE DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) ACCORDING TO LANGDELL ET AL. (1) AND LARRIEU M.J., WEILLAND C. (3). THE PTT-LA REAGENT HAS BEEN SENSITIZED TO AID THE DETECTION OF LUPUS ANTICOAGULANTS (LA) (7, 8).,STA® - DEFICIENT VII(STA® - DEFICIENT VII)-STA® - DEFICIENT VII IS A

		HUMAN PLASMA INTENDED FOR USE IN TESTS FOR THE DETERMINATION OF FACTOR VII ACTIVITY IN PLASMA BY STA-R® AND STA COMPACT®. THESE TESTS REQUIRE THE INCLUSION OF FACTOR VII DEFICIENT PLASMA (1). (IN THE USA, THIS PROCEDURE HAS BEEN ASSIGNED TO THE HIGH COMPLEXITY CATEGORY PER CLIA 1988 - CDC ANALYTE CODE 1044; CDC TEST SYSTEM CODES 4677 AND 4875).,LIATEST AT III(LIATEST AT III)-ANTIGENIC ASSAY OF ANTITHROMBIN (AT) CONCENTRATION BY THE IMMUNOTURBIDIMETRIC METHOD (8)
957	IMP/IVD/2020/001027	1.License Holder Name: PAMMVI EXPORTS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COTININE (COT) RAPID TEST DEVICE(URINE)-THE COTININE RAPID TEST DEVICE (URINE) IS A RAPID VISUAL IMMUNOASSAY FOR THE QUALITATIVE, PRESUMPTIVE DETECTION OF COTININE IN HUMAN URINE SPECIMENS.,MULTI PANEL DRUG TEST (URINE)-THE MULTI DRUG RAPID TEST DEVICE IS RAPID CHROMATOGRAPHIC IMMUNOASSAYS FOR THE QUALITATIVE AND SIMULTANEOUS DETECTION OF ONE OR MORE DRUGS IN A VARIETY OF COMBINATIONS IN HUMAN URINE.
958	IMP/IVD/2020/001028	1.License Holder Name: PREMAS LIFE SCIENCES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVANTA DX SARS-COV-2 RT-PCR ASSAY(NA)-ADVANTA™ DX SARS-COV-2 RT-PCR ASSAY IS A REAL-TIME REVERSE TRANSCRIPTION (RT) PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN SALIVA SPECIMENS COLLECTED WITHOUT PRESERVATIVES IN A STERILE CONTAINER FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER.

959	IMP/IVD/2020/001031	1.License Holder Name: M/S. PEERLESS BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LH FAST TEST KIT(LH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-LH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF LH IN SERUM, PLASMA. THIS TEST IS USED TO DETERMINE MENOPAUSE, PINPOINT OVULATION AND MONITOR ENDOCRINE THERAPY,CARDIAC TROPONIN I FAST TEST KIT(GETEIN)-CARDIAC TROPONIN I FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CTNL IN SERUM, PLASMA AND WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS AND CORONARY SYNDROME (ACS).,FERRITIN FAST TEST KIT(FERRITIN FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-FERRITIN FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA SAMPLES. IT CAN BE USED AS AN AID IN THE QUANTIFICATION OF HUMAN FERRITIN AND THE DIAGNOSIS OF IRON DEFICIENCY ANEMIA OR IRON OVERLOAD RELATED DISEASES., HCG+BETA FAST TEST KIT(GETEIN)-HCG+BETA FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN SERUM AND PLASMA. THIS TEST IS USED AS AID IN PREGNANCY TEST. ,FSH FAST TEST KIT(FSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-FSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM AND PLASMA. FSH TEST IS USED FOR WOMEN SUSPECTED OF HAVING POLYCYSTIC OVARY SYNDROME, AND IN INDIVIDUALS UNDERGOING EVALUATION FOR INFERTILITY, ALSO USED FOR EVALUATION OF INDIVIDUALS WITH SUSPECTED PITUITARY DISORDERS OR DISEASES OF THE OVARIES,MALB FAST TEST KIT(GETEIN)-MALB FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CYSC IN URINE. AN ELEVATED MALB CONCENTRATION BELOW THE PROTEINURIC LEVEL HAS LONG BEEN RECOGNIZED AS A MARKER OF KIDNEY DISEASE AND INCREASED CARDIOVASCULAR RISK IN DIABETIC NEPHROPATHY. , AMH FAST TEST KIT(AMH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-AMH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF AMH IN HUMAN SERUM AND PLASMA SAMPLES. THIS TEST CAN BE USED AS AN AID IN INDICATING OVARIAN FUNCTIONAL RESERVE, AND ALSO

	HELP TO DIAGNOSE MENSTRUAL DISORDERS OR TO MONITOR THE HEALTH OF WOMEN,PCT FAST TEST KIT(GETEIN)-PCT FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PCT IN SERUM, PLASMA AND WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF BACTERIAL INFECTION, TRAUMA OR SHOCK.,IL-6 FAST TEST KIT(IL-6 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-IL-6 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF INTERLEUKIN 6 (IL-6) IN HUMAN SERUM, PLASMA, WHOLE BLOOD AND PERIPHERAL BLOOD SAMPLES. IL-6 IS AN EARLY MARKER IN ACUTE INFLAMMATION AND THIS TEST CAN BE USED AS AN AID IN THE INFLAMMATORY DISEASES,SAA FAST TEST KIT(GETEIN)-SAA FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF SAA IN SERUM, PLASMA, WHOLE BLOOD AND FINGERTIP BLOOD. IT CAN BE USED AS A SENSITIVE INDEX IN THE DIAGNOSIS OF INFECTION AND INFLAMMATION.,PRL FAST TEST KIT(PRL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-PRL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN SERUM OR PLASMA SAMPLES. THIS TEST CAN BE USED AS AN AID IN THE DIAGNOSIS OF MALE AND FEMALE INFERTILITY AND PITUITARY DYSFUNCTION, MONITORING OF MALE AND FEMALE GONADAL DISORDERS AND MANAGEMENT OF AMENORRHEA AND GALACTORRHEA.,NGAL FAST TEST KIT(GETEIN)-NGAL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF NGAL IN URINE AND SERUM. THIS TEST IS USED AS AN AID IN THE EARLY DIAGNOSIS OF ACUTE KIDNEY INJURY (AKI) RISK CLASSIFICATION AND TREATMENT MONITORING.,HBA1C FAST TEST KIT(GETEIN)-HBA1C FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HBA1C IN WHOLE BLOOD. THIS TEST IS USED AS AN AID FOR MONITORING GLYCEMIC CONTROL IN DIABETICS. IN ADDITION IT CAN IDENTIFY PEOPLE AT RISK OF DEVELOPING THE DISEASES AND ONGOING MONITORING. ,D-DIMER FAST TEST KIT(GETEIN)-D-DIMER FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF D DIMER IN SERUM, PLASMA AND WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF DEEP VEIN THROMBOSIS OR PULMONARY EMBOLISM.,T3 FAST TEST KIT(GETEIN) -T3 (TRIIODOTHYRONINE) FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION

	OF T3 IN SERUM AND PLASMA. IT CAN BE USED IN THE MONITORING OF HYPERTHYROIDISM AND HYPOTHYROIDISM, AND ALSO USED AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA.,T4 FAST TEST KIT(GETEIN)-T4 (TRIIODOTHYRONINE) FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T4 IN SERUM AND PLASMA. IT CAN BE USED IN THE MONITORING OF HYPERTHYROIDISM AND HYPOTHYROIDISM, AND ALSO USED AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA.,NT-PROBNP FAST TEST KIT(GETEIN)-NT-PROBNP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T3 IN SERUM, PLASMA AND WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF).,CYSC FAST TEST KIT(GETEIN)-CYSC FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CYSC IN SERUM, PLASMA AND WHOLE BLOOD. THE TEST RESULT IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF INDEX OF GLOMERCULAR FILTRATION RATE, AND HAS IMPORTANT APPLICATION VALUE IN RENAL FUNCTION KIDNEY DAMAGE AND RENAL TRANSPLANTATION., CK-MB/CTNL/MYO FAST TEST KIT(GETEIN)-CK-MB/CTNL/MYO FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF 25-OH-VD IN SERUM, PLASMA AND WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS AND CORONARY SYNDROME (ACS),25-OH-VD FAST TEST KIT(GETEIN)-25-OH-VD FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF 25-OH-VD IN SERUM, PLASMA AND WHOLE BLOOD. THIS TEST MAY HELP UNDERSTAND THE METABOLIC CHANGES OF BONE.,HS-CRP+CRP FAST TEST KIT(GETEIN)-HS-CRP+CRP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T3 IN SERUM, PLASMA, WHOLE BLOOD AND FINGERTIP BLOOD. MEASUREMENT OF CRP IS USEFUL FOR THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY AND INFLAMMATORY DISORDERS. MEASUREMENT OF HIGH SENSITIVITY CRP (HS-CRP), WHEN USED IN CONJUNCTION WITH TRADITIONAL CLINICAL LABORATORY EVALUATION OF ACUTE CORONARY SYNDROMES (ACS), MAY BE USEFUL AS AN INDEPENDENT MAKER OF PROGNOSIS FOR RECURRENT EVENTS IN PATIENTS WITH STABLE CORONARY DISEASES OR ACS.,TSH FAST TEST KIT(GETEIN)-TSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION

		OF TSH IN SERUM AND PLASMA. THIS TEST IS USED IN THE SCREENING CLINICAL DIAGNOSIS PROGNOSIS AND THERAPEUTIC EFFECT EVALUATION OF THYROID DISEASES.
960	IMP/IVD/2020/001033	1.License Holder Name: SENTIER CONSULTING AND HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BSB 0082 MOUSE RABBIT IMMUNO DETECTOR AP WALK MAGENTA(BIO SB)-THE MOUSE/RABBIT IMMUNODETECTOR ALKALINE PHOSPHATASE/ ALK MAGENTA DETECTION SYSTEM IS A BIOTIN-STREPTAVIDIN-ALKALINE PHOSPHATASE DETECTION SYSTEM THAT ALLOWS FOR THE DEMONSTRATION OF ANTIGENS IN FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, CRYOSTAT SECTIONS, CYTOSMEARS, AND CELL PREPARATIONS. THE IMMUNODETECTOR AP BLOCKER IS USED TO BLOCK THE ENDOGENOUS ALKALINE PHOSPHATASE ENZYMES THAT NATURALLY OCCUR IN CELLS AND TISSUE SECTIONS WITHOUT AFFECTING ANTIGENS OR NUCLEIC ACIDS. THE MOUSE/RABBIT IMMUNODETECTOR ALKALINE PHOSPHATASE DETECTION SYSTEM IS SUITABLE FOR USE WITH MOUSE (IGG AND IGM) AND RABBIT PRIMARY MONOCLONAL AND POLYCLONAL ANTIBODIES.,BSB 0022 IMMUNO RETRIEVER WITH CITRATE 20X WITH CITRATE(BIO SB)-IMMUNODNA RETRIEVER CITRATE IS INTENDED TO BE USED WITH HEAT-INDUCED EPITOPE OR NUCLEIC ACID RETRIEVAL PROCEDURES FOR IMMUNOHISTOCHEMISTRY (IHC), IMMUNOCYTOCHEMISTRY (ICC), IMMUNOFLUORESCENCE (IF) AND IN SITU HYBRIDIZATION (ISH) OF NUCLEIC ACIDS (BOTH CISH OR FISH) ON FORMALIN FIXED, PARAFFIN EMBEDDED TISSUE SECTIONS. THIS PRODUCT CAN BE USED WITH ANY ANTIGEN OR NUCLEIC ACID.
961	IMP/IVD/2020/001036	1.License Holder Name: MERIL DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLYCATED HEMOGLOBIN (HBA1C) ASSAY KIT(--)-THE GLYCATED HEMOGLOBIN (HBA1C) ASSAY KIT IS INTENDED FOR THE PERCENT DETERMINATION OF HBA1C IN HUMAN WHOLE BLOOD USING ION-EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC).

962	IMP/IVD/2020/001037	1.License Holder Name: DSS IMAGETECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FLEX MONOCLONAL MOUSE ANTI-HUMAN MUTS PROTEIN HOMOLOG 2, CLONE FE11, READY-TO-USE (LINK)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN MUTS PROTEIN HOMOLOG 2, CLONE FE11, READY-TO-USE (LINK) IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY TOGETHER WITH AUTOSTAINER LINK INSTRUMENTS. THIS ANTIBODY DETECTS MUTS PROTEIN HOMOLOG 2 (MSH2) IN TISSUE BOTH NORMAL AND NEOPLASTIC TISSUE. RESULTS AID IN THE CLASSIFICATION OF TUMORS OF THE GASTROINTESTINAL TRACT.,FLEX MONOCLONAL RABBIT ANTI-HUMAN CYCLIN D1, CLONE EP12, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL RABBIT ANTI-HUMAN CYCLIN D1, CLONE EP12, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THE ANTIBODY LABELS CYCLIN D1-EXPRESSING CELLS IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS (1).,FLEX MONOCLONAL RABBIT ANTI-HUMAN ESTROGEN RECEPTOR , CLONE EP1, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL RABBIT ANTI-HUMAN ESTROGEN RECEPTOR , CLONE EP1, READY-TO-USE (DAKO AUTOSTAINER/ AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY TOGETHER WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS TO SEMI-QUANTITATIVELY DETECT HUMAN ESTROGEN RECEPTOR IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS OF HUMAN BREAST CANCER. THE ANTIBODY LABELS ESTROGEN RECEPTOR -POSITIVE CELLS AND IS USEFUL IN THE ASSESSMENT OF ESTROGEN RECEPTOR STATUS IN HUMAN BREAST CARCINOMAS., FLEX MONOCLONAL MOUSE ANTI-HUMAN OCTAMER-BINDING TRANSCRIPTION FACTOR 3/4, CLONE N1NK, READY-TO-USE (LINK)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN OCTAMER-BINDING TRANSCRIPTION FACTOR 3/4, CLONE N1NK, READY-TO-USE (LINK) IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC). THE ANTIBODY LABELS OCT 3/4-EXPRESSING CELLS AND MAY BE A USEFUL AID FOR CLASSIFICATION OF SPECIFIC SUBTYPES OF GERM CELL TUMORS INCLUDING SEMINOMA, EMBRYONAL CARCINOMA, AND INTRATUBULAR GERM CELL NEOPLASIA OF UNCLASSIFIED TYPE (IGCNU).,FLEX MONOCLONAL RABBIT ANTI-HUMAN POSTMEIOTIC SEGREGATION INCREASED 2, CLONE EP51, READY-TO-USE (LINK)-FOR IN VITRO

	DIAGNOSTIC USE. FLEX MONOCLONAL RABBIT ANTI-HUMAN POSTMEIOTIC SEGREGATION INCREASED 2, CLONE EP51, READY-TO-USE (LINK) IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY TOGETHER WITH AUTOSTAINER LINK INSTRUMENTS. THE ANTIBODY DETECTS POSTMEIOTIC SEGREGATION INCREASED 2 (PMS2) PROTEIN IN NORMAL AND NEOPLASTIC TISSUE. RESULTS AID IN THE CLASSIFICATION OF TUMORS OF THE INTESTINAL TRACT.,FLEX MONOCLONAL MOUSE ANTI-THYROID TRANSCRIPTION FACTOR, TTF-1, CLONE 8G7G3/1, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-THYROID TRANSCRIPTION FACTOR, CLONE 8G7G3/1, READY-TO-USE, (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THIS ANTIBODY IS A USEFUL AID FOR CLASSIFICATION OF TUMORS FROM LUNG AND THYROID.,FLEX MONOCLONAL MOUSE ANTI-HUMAN CD99, MIC2 GENE PRODUCT EWING'S SARCOMA MARKER, CLONE 12E7, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN CD99, MIC2 GENE PRODUCT, EWING'S SARCOMA MARKER, CLONE 12E7, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THIS ANTIBODY IS A USEFUL AID FOR CLASSIFICATION OF GLIOBLASTOMAS AND EPENDYMOMAS OF THE CNS, CERTAIN ISLET CELL TUMORS OF THE PANCREAS, PARTICULARLY EWING'S SARCOMA (ES), AND PRIMITIVE PERIPHERAL NEUROECTODERMAL TUMORS (PPNET).,FLEX MONOCLONAL MOUSE ANTI-HUMAN CD1A, CLONE 010, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN CD1A, CLONE 010, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THE ANTIBODY LABELS CD1A-EXPRESSING CELLS IN NORMAL AND NEOPLASTIC TISSUES. RESULTS AID IN THE CLASSIFICATION OF THYMOMAS AND MALIGNANCIES OF T-CELL PRECURSORS AND LANGERHANS' CELL HISTIOCYTOSIS.,FLEX MONOCLONAL MOUSE ANTI-HUMAN CYTOKERATIN HMW HIGH MOLECULAR WEIGHT, CLONE 34E12, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN CYTOKERATIN, HIGH MOLECULAR WEIGHT (HMW), CLONE 34E12, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS

	INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THIS ANTIBODY IS USEFUL FOR THE IDENTIFICATION OF BASAL CELLS AND SQUAMOUS EPITHELIUM IN VARIOUS TISSUES.,FLEX MONOCLONAL MOUSE ANTI-HUMAN E-CADHERIN, CLONE NCH-38, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN E-CADHERIN, CLONE NCH-38, READY-TO-USE, (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THIS ANTIBODY IS USEFUL FOR THE IDENTIFICATION OF E-CADHERIN-EXPRESSING CELLS IN NORMAL AND NEOPLASTIC TISSUES.,FLEX MONOCLONAL MOUSE ANTI-HUMAN CYTOKERATIN, CLONE AE1/AE3, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN CYTOKERATIN, CLONE AE1/AE3, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THIS ANTIBODY IS A USEFUL AID FOR THE CLASSIFICATION OF TUMORS OF EPITHELIAL ORIGIN.,FLEX MONOCLONAL MOUSE ANTI-HUMAN MUTL PROTEIN HOMOLOG 1, CLONE ES05, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN MUTL PROTEIN HOMOLOG 1, CLONE ES05 READY-TO-USE, (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY TOGETHER WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THE ANTIBODY DETECTS MUTL PROTEIN HOMOLOG 1 (MLH1) IN BOTH NORMAL AND NEOPLASTIC TISSUE.,FLEX MONOCLONAL RABBIT ANTI-HUMAN TERMINAL DEOXYNUCLEOTIDYL TRANSFERASE, CLONE EP266, READY-TO-USE (LINK)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL RABBIT ANTI-HUMAN TERMINAL DEOXYNUCLEOTIDYL TRANSFERASE, CLONE EP266, READY-TO-USE (LINK), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER WITH AUTOSTAINER LINK INSTRUMENTS. THE ANTIBODY LABELS TERMINAL DEOXYNUCLEOTIDYL TRANSFERASE (TDT) EXPRESSING CELLS IN NORMAL AND NEOPLASTIC TISSUES.,FLEX MONOCLONAL MOUSE ANTI-HUMAN PODOPLANIN, CLONE D2-40, READY-TO-USE DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN D2-40, CLONE D2-40, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER

	WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THIS ANTIBODY LABELS THE LYMPHATIC ENDOTHELIUM MARKER PODOPLANIN IN NORMAL AND NEOPLASTIC TISSUES. THE ANTIBODY IS A USEFUL AID FOR CLASSIFICATION OF A VARIETY OF CANCERS WITH LYMPHATIC INVASION.,FLEX MONOCLONAL MOUSE ANTI-HUMAN MELANOSOME, CLONE HMB45, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN MELANOSOME, CLONE HMB45, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THIS ANTIBODY IS USEFUL FOR THE IDENTIFICATION OF MELANOCYTES WITH IMMATURE MELANOSOME FORMATION IN NORMAL SKIN AND NEVUS.,FLEX MONOCLONAL MOUSE ANTI-HUMAN PROGESTERONE RECEPTOR, CLONE PGR 636, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN PROGESTERONE RECEPTOR, CLONE PGR 636, READY-TO-USE, (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY TOGETHER WITH ENVISION FLEX+, HIGH PH VISUALIZATION KIT TOGETHER WITH AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS TO SEMI-QUANTITATIVELY DETECT HUMAN PROGESTERONE RECEPTOR IN FORMALIN-FIXED, PARAFFIN-EMBEDDED HUMAN BREAST CARCINOMA. THIS ANTIBODY LABELS PROGESTERONE RECEPTOR-POSITIVE CELLS AND IS USEFUL IN THE ASSESSMENT OF PROGESTERONE RECEPTOR STATUS IN HUMAN BREAST CARCINOMAS.,FLEX MONOCLONAL RABBIT ANTI-HUMAN CYTOKERATIN 8/18, CLONE EP17/30, READY-TO-USE (LINK)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL RABBIT ANTI-HUMAN CYTOKERATIN 8/18, CLONE EP17/EP30, READY-TO-USE (LINK), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER WITH AUTOSTAINER LINK INSTRUMENTS. THIS ANTIBODY COCKTAIL LABELS CYTOKERATIN 8/18-EXPRESSING CELLS IN NORMAL AND NEOPLASTIC TISSUE.,FLEX MONOCLONAL MOUSE ANTI-HUMAN CALDESMON, CLONE H-CD, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN CALDESMON, CLONE H-CD, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THIS ANTIBODY LABELS SMOOTH MUSCLE CELLS AND IS A USEFUL AID FOR THE CLASSIFICATION OF TUMORS WITH SMOOTH MUSCLE CELL DIFFERENTIATION.,FLEX MONOCLONAL MOUSE ANTI-HUMAN WILMS'

	TUMOR 1 (WT1) PROTEIN, CLONE 6F-H2, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN WILMS' TUMOR (WT1), CLONE 6F-H2, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THIS ANTIBODY IS A USEFUL AID FOR CLASSIFICATION OF WILMS' TUMOR, ACUTE LEUKEMIAS, MALIGNANT MESOTHELIOMA, SEROUS OVARIAN ADENOCARCINOMA, GRANULOSA CELL TUMOR, AND OTHER TUMORS.,PD-L1 IHC 28-8 PHARMDX- FOR IN VITRO DIAGNOSTIC USE. PD-L1 IHC 28-8 PHARMDX IS A QUALITATIVE IMMUNOHISTOCHEMICAL ASSAY USING MONOCLONAL RABBIT ANTI-PD-L1, CLONE 28-8 INTENDED FOR USE IN THE DETECTION OF PD-L1 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) NON-SQUAMOUS NON-SMALL CELL LUNG CANCER (NSCLC) TISSUES USING ENVISION FLEX VISUALIZATION SYSTEM ON AUTOSTAINER LINK 48. PD-L1 PROTEIN EXPRESSION IS DEFINED AS THE PERCENTAGE OF TUMOR CELLS EXHIBITING POSITIVE MEMBRANE STAINING AT ANY INTENSITY. PD-L1 EXPRESSION AS DETECTED BY PD-L1 IHC 28-8 PHARMDX IN NON-SQUAMOUS NSCLC MAY BE ASSOCIATED WITH ENHANCED SURVIVAL FROM OPDIVO® (NIVOLUMAB). ,FLEX MONOCLONAL RABBIT ANTI-HUMAN AMACR, CLONE 13H4, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL RABBIT ANTI-HUMAN AMACR, CLONE 13H4, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. RESULTS AID IN THE CLASSIFICATION OF PROSTATE ADENOCARCINOMAS.,FLEX MONOCLONAL MOUSE ANTI-MYOGENIN, CLONE F5D, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-MYOGENIN, CLONE F5D, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THIS ANTIBODY LABELS MYOGENIN PROTEIN IN NORMAL AND NEOPLASTIC TISSUE. RESULTS AID IN THE CLASSIFICATION OF RHABDOMYOSARCOMA AND WILMS' TUMOR.,MONOCLONAL MOUSE ANTI-HUMAN PD-L1, CLONE 22C3-FOR IN VITRO DIAGNOSTIC USE. MONOCLONAL MOUSE ANTI-HUMAN PD-L1, CLONE 22C3, IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY. THIS ANTIBODY LABELS PD-L1 IN NORMAL AND NEOPLASTIC TISSUE.,FLEX MONOCLONAL MOUSE ANTI-HUMAN CDX2, CLONE DAK-CDX2, READY-TO-USE (DAKO

	AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN CDX2, CLONE DAK-CDX2, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THIS ANTIBODY IS A USEFUL AID FOR THE CLASSIFICATION OF ADENOCARCINOMAS AND CARCINOIDS OF THE GASTROINTESTINAL TRACT (1).,FLEX MONOCLONAL MOUSE ANTI-HUMAN CD15, CLONE CARB-3, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-IMMUNOHISTOCHEMISTRY (IHC),FLEX MONOCLONAL RABBIT ANTI-HUMAN MUTS PROTEIN HOMOLOG 6, CLONE EP49, READY-TO-USE (LINK)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL RABBIT ANTI-HUMAN MUTS PROTEIN HOMOLOG 6, CLONE EP49, READY-TO-USE (LINK) IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY TOGETHER WITH AUTOSTAINER LINK INSTRUMENTS. THE ANTIBODY DETECTS MUTS PROTEIN HOMOLOG 6 (MSH6) IN BOTH NORMAL AND NEOPLASTIC TISSUE. RESULTS AID IN THE CLASSIFICATION OF TUMORS OF THE INTESTINAL TRACT.,FLEX MONOCLONAL MOUSE ANTI-HUMAN CD5, CLONE 4C7, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS)-FOR IN VITRO DIAGNOSTIC USE. FLEX MONOCLONAL MOUSE ANTI-HUMAN CD5, CLONE 4C7, READY-TO-USE (DAKO AUTOSTAINER/AUTOSTAINER PLUS), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY (IHC) TOGETHER WITH DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS. THE ANTIBODY LABELS CD5-EXPRESSING CELLS IN NORMAL AND NEOPLASTIC TISSUE. RESULTS AID IN THE CLASSIFICATION OF B- AND T-CELL MALIGNANCIES INCLUDING B-CELL CHRONIC LYMPHOID LEUKEMIA (B-CLL), B-CELL SMALL LYMPHOCYTIC LYMPHOMA (B-SLL), MANTLE CELL LYMPHOMA (MCL) AND T-CELL LYMPHOMA AND LEUKEMIA.,PD-L1 IHC 22C3 PHARMDX-FOR IN VITRO DIAGNOSTIC USE. PD-L1 IHC 22C3 PHARMDX IS A QUALITATIVE IMMUNOHISTOCHEMICAL ASSAY USING MONOCLONAL MOUSE ANTI-PD-L1, CLONE 22C3 INTENDED FOR USE IN THE DETECTION OF PD-L1 PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) NON-SMALL CELL LUNG CANCER (NSCLC) TISSUE USING ENVISION FLEX VISUALIZATION SYSTEM ON AUTOSTAINER LINK 48. PD-L1 PROTEIN EXPRESSION IS DETERMINED BY USING TUMOR PROPORTION SCORE (TPS), WHICH IS THE PERCENTAGE OF VIABLE TUMOR CELLS SHOWING PARTIAL OR COMPLETE MEMBRANE STAINING AT ANY INTENSITY. THE SPECIMEN SHOULD BE CONSIDERED TO HAVE PD-L1 EXPRESSION IF TPS 1% AND HIGH PD-L1 EXPRESSION IF TPS 50%. PD-L1 IHC 22C3 PHARMDX IS INDICATED AS AN AID IN IDENTIFYING NSCLC PATIENTS FOR TREATMENT WITH KEYTRUDA® (PEMBROLIZUMAB). SEE THE KEYTRUDA® PRODUCT LABEL FOR EXPRESSION CUTOFF VALUES

		GUIDING THERAPY IN SPECIFIC CLINICAL CIRCUMSTANCES.
963	IMP/IVD/2020/001040	1.License Holder Name: THERMO FISHER SCIENTIFIC INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 TOTAL ANTIBODY ELISA TEST(OMNI PATH)-THE OMNIPATH COVID-19 TOTAL ANTIBODY ELISA TEST IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) INTENDED FOR QUALITATIVE DETECTION OF TOTAL ANTIBODIES (INCLUDING IGM, IGA AND IGG) TO SARS-COV-2 IN HUMAN SERUM. THE OMNIPATH COVID19 TOTAL ANTIBODY ELISA TEST IS INTENDED FOR USE AS AN AID IN IDENTIFYING INDIVIDUALS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS-COV-2, INDICATING RECENT OR PRIOR INFECTION. AT THIS TIME, IT IS UNKNOWN FOR HOW LONG ANTIBODIES PERSIST FOLLOWING INFECTION AND IF THE PRESENCE OF ANTIBODIES CONFERS PROTECTIVE IMMUNITY.
964	IMP/IVD/2020/001043	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARCHITECT STAT CK-MB CONTROLS(ARCHITECT STAT CK-MB CONTROLS)-THE ARCHITECT STAT CK-MB CONTROLS ARE FOR VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CK-MB IN HUMAN SERUM AND PLASMA.,ARCHITECT STAT MYOGLOBIN CONTROLS(ARCHITECT STAT MYOGLOBIN CONTROLS)-THE ARCHITECT STAT MYOGLOBIN CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM AND PLASMA.,IRON/MAGNESIUM CALIBRATOR (IRON/MAGNESIUM CALIBRATOR)-FOR USE IN THE CALIBRATION OF THE IRON AND MAGNESIUM ASSAYS.,ARCHITECT STAT TROPONIN-I CONTROLS(ARCHITECT STAT TROPONIN-I CONTROLS)-THE ARCHITECT STAT TROPONIN-I CONTROLS ARE FOR VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN-I (CTNI) IN HUMAN SERUM AND PLASMA.

965	IMP/IVD/2020/001044	1.License Holder Name: IASSIST HEALTH PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TIBC CALIBRATOR KIT (TOTAL IRON BINDING CAPACITY CALIBRATOR KIT)-USED TO CALIBRATE THE TIBC CHEMISTRY ON THE EASYRA ANALYZER,CK REAGENT KIT(CREATINE KINASE REAGENT KIT)-USED TO TEST CREATINE KINASE LEVELS IN PATIENT SAMPLESV,UALB CALIBRATOR KIT(CHEMISTRY UALB CALIBRATOR KIT)-USED TO CALIBRATE THE MICROALBUMIN CHEMISTRY ON THE EASYRA ANALYZER,HDL REAGENT KIT(HDL CHOLESTEROL REAGENT KIT)-USED TO TEST HDL CHOLESTEROL LEVELS IN PATIENT SAMPLES,BI-LEVEL HCT QC KIT (BI-LEVEL HCT QUALITY CONTROL KIT)-USED TO TEST THE PERFORMANCE OF HCT ON THE EASYSTAT ANALYZER,BUN REAGENT KIT(BLOOD UREA NITROGEN REAGENT KIT)-USED TO TEST BUN LEVELS IN PATIENT SAMPLES,ALB REAGENT KIT(ALBUMIN REAGENT KIT)-USED TO TEST ALBUMIN LEVELS IN PATIENT SAMPLES,WASH 1 CHEMISTRY KIT(WASH 1 CHEMISTRY KIT)-USED TO CLEAN THE PROBE ON THE EASYRA ANALYZER,CLEANER KIT - CHEMISTRY AND ISE (EASYRA CLEANER KIT - CHEMISTRY AND ISE)-USED TO CLEAN THE ANALYZER AFTER SAMPLE ANALYSIS,LDH REAGENT KIT(LACTATE DEHYDROGENASE REAGENT KIT)-USED TO TEST LDH LEVELS IN PATIENT SAMPLES,CA REAGENT KIT(CALCIUM REAGENT KIT)-USED TO TEST CALCIUM LEVELS IN PATIENT SAMPLES,AMY REAGENT KIT (AMYLASE REAGENT KIT)-USED TO TEST AMYLASE LEVELS IN PATIENT SAMPLES,CREA REAGENT KIT(CREATININE REAGENT KIT)-USED TO TEST CREATININE LEVELS IN PATIENT SAMPLES,GLU-H REAGENT KIT(GLUCOSE HEXOKINASE REAGENT KIT)-USED TO TEST GLUCOSE LEVELS IN PATIENT SAMPLES,MG REAGENT KIT (MAGNESIUM REAGENT KIT)-USED TO TEST MAGNESIUM LEVELS IN PATIENT SAMPLES,TBIL REAGENT KIT(TOTAL BILIRUBIN REAGENT KIT)-USED TO TEST BILIRUBIN LEVELS IN PATIENT SAMPLES,LIP REAGENT KIT(LIPASE REAGENT KIT)-USED TO MEASURE THE LEVEL OF LIPASE IN A PATIENT SAMPLE,URINE CREATININE CALIBRATOR KIT(EASYCAL URINE CREATININE CALIBRATOR KIT)-USED TO CALIBRATE THE URINE CREATININE CHEMISTRY ON THE EASYRA ANALYZER,CKMB REAGENT KIT(CREATINE KINASE-MB REAGENT KIT) -USED TO MEASURE THE LEVEL OF CKMB IN A PATIENT SAMPLE, CLEANER KIT - CHEMISTRY(EASYRA CLEANER KIT - CHEMISTRY)-USED TO CLEAN THE ANALYZER AFTER SAMPLE ANALYSIS, PRECISION DYE KIT(EASYRA PRECISION DYE KIT)-USED TO TEST THE PRECISION AND ACCURACY OF THE ANALYZER,DBIL REAGENT KIT (DIRECT BILIRUBIN REAGENT KIT)-USED TO TEST BILIRUBIN LEVELS IN PATIENT SAMPLES,ALP REAGENT KIT(ALKALINE PHOSPHATASE REAGENT KIT)-USED TO TEST ALKALINE PHSOPHATASE LEVELS IN

	PATIENT SAMPLES,LDL CALIBRATOR KIT(EASYCAL LDL CALIBRATOR KIT)-USED TO CALIBRATE THE LDL CHEMISTRY ON THE EASYRA ANALYZER,TIBC REAGENT KIT(TOTAL IRON BINDING CAPACITY REAGENT KIT)-USED TO MEASURE THE LEVEL OF TIBC IN A PATIENT SAMPLE,EASYQC QC KIT - LEVEL A(EASYQC QUALITY CONTROL KIT - LEVEL A)-USED TO TEST THE ACCURACY AND PRECISION OF THE EASYRA CHEMISTRIES,AST REAGENT KIT(ASPARTATE AMIONTRANSFERASE REAGENT KIT)-USED TO TEST ASPARTATE AMINOTRANSFERASE LEVELS IN PATIENT SAMPLES,TRI-LEVEL QC KIT(TRI-LEVEL QUALITY CONTROL KIT)-USED TO TEST THE PERFORMANCE OF THE ANALYZER,EASYQC QC KIT - LEVEL B (EASYQC QUALITY CONTROL KIT - LEVEL B)-USED TO TEST THE ACCURACY AND PRECISION OF THE EASYRA CHEMISTRIES,CREA-U REAGENT KIT(URINE CREATININE REAGENT KIT)-USED TO TEST URINE CREATININE IN PATIENT URINE SAMPLES,FE REAGENT KIT (IRON REAGENT KIT)-USED TO TEST IRON LEVELS IN PATIENT SAMPLES,URINE DILUENT(EASYELECTROLYTE URINE DILUENT)-USED TO DILUTE URINE SAMPLES PRIOR TO ANALYSIS,ES REAGENT MODULE(EASYSTAT REAGENT MODULE)-USED IN THE CALIBRATION AND SAMPLE ANALYSIS OF THE EASYSTAT ANALYZER,NA/K/LI REAGENT MODULE(EASYELECTROLYTE REAGENT MODULE, NA/K/LI) -USED IN THE CALIBRATION AND SAMPLE ANALYSIS OF THE EASYELECTROLYTE ANALYZER,CHEMISTRY CALIBRATOR KIT (EASYCAL CHEMISTRY CALIBRATOR KIT)-USED TO CALIBRATE THE CHEMISTRIES ON THE EASYRA ANALYZER,TRIG REAGENT KIT (TRIGLYCERIDES REAGENT KIT)-USED TO TEST TRIGLYCERIDES LEVELS IN PATIENT SAMPLES,PHOS REAGENT KIT(PHOSPHORUS REAGENT KIT)-USED TO TEST PHOSPHORUS LEVELS IN PATIENT SAMPLES,BLOOD GAS/ELECTROLYTE LEVEL 1 QC KIT(EASYQC LEVEL 1 BLOOD GAS AND ELECTROLYTE QUALITY CONTROL KIT)-USED TO TEST THE PERFORMANCE OF THE ANALYZER,LDL REAGENT KIT(LDL CHOLESTEROL REAGENT KIT)-USED TO TEST LDL CHOLESTEROL LEVELS IN PATIENT SAMPLES,UALB REAGENT KIT(MICROALBUMIN REAGENT KIT)-USED TO TEST MICROALBUMIN LEVELS IN PATIENT URINE SAMPLES,HDL CALIBRATOR KIT(EASYCAL HDL CHEMISTRY CALIBRATOR KIT)-USED TO CALIBRATE THE HDL CHEMISTRY ON THE EASYRA ANALYZER,NA/K/CL REAGENT MODULE(EASYELECTROLYTE REAGENT MODULE NA/K/CL)-USED IN THE CALIBRATION AND SAMPLE ANALYSIS OF THE EASYELECTROLYTE ANALYZER, SURFACTANT KIT(EASYRA SURFACTANT KIT)-USED AS AN ADDITIVE TO DIH2O TO BE USED WITH THE EASYRA DILUENT,EBG REAGENT MODULE(EASYBLOODGAS REAGENT MODULE)-USED IN THE CALIBRATION AND SAMPLE ANALYSIS OF THE EASYBLOODGAS ANALYZER,GGT REAGENT KIT(GAMMA-GLUTAMYL TRANSFERASE

		REAGENT KIT)-USED TO TEST GGT LEVELS IN PATIENT SAMPLES, DAILY CLEANING SOLUTION KIT(DAILY CLEANING SOLUTION KIT)-USED TO CLEAN THE ANALYZER AFTER SAMPLE ANALYSIS,URIC REAGENT KIT(URIC ACID REAGENT KIT)-USED TO TEST URIC ACID LEVELS IN PATIENT SAMPLES,NA/K/CL/LI REAGENT PACK(ISE 4 CHANNEL REAGENT PACK - NO WASTE)-USED IN THE CALIBRATION AND SAMPLE ANALYSIS OF THE ISE ELECTRODES,CO2 REAGENT KIT (CARBON DIOXIDE REAGENT KIT)-USED TO TEST CO2 LEVELS IN PATIENT SAMPLES,BLOOD GAS/ELECTROLYTE LEVEL 3 QC KIT (EASYQC LEVEL 3 BLOOD GAS AND ELECTROLYTE QUALITY CONTROL KIT)-USED TO TEST THE PERFORMANCE OF THE ANALYZER,CO2 CALIBRATOR KIT(EASYCAL CO2 CALIBRATOR KIT)-USED TO CALIBRATE THE CO2 CHEMISTRY ON THE EASYRA ANALYZER,RED TEST DYE SOLUTION(EASYELECTROLYTE RED TEST DYE SOLUTION)-USED TO TROUBLESHOOT THE ANALYZER,ALT REAGENT KIT(ALANINE AMINOTRANSFERASE REAGENT KIT)-USED TO TEST ALANINE AMINOTRANSFERASE LEVELS IN PATIENT SAMPLES,RED TEST DYE SOLUTION(EASYBLOODGAS RED TEST DYE SOLUTION)-USED TO TROUBLESHOOT THE ANALYZER,CHOL REAGENT KIT(CHOLESTEROL REAGENT KIT)-USED TO TEST CHOLESTEROL LEVELS IN PATIENT SAMPLES,BLOOD GAS/ELECTROLYTE LEVEL 2 QC KIT(EASYQC LEVEL 2 BLOOD GAS AND ELECTROLYTE QUALITY CONTROL KIT)-USED TO TEST THE PERFORMANCE OF THE ANALYZER,TP REAGENT KIT(TOTAL PROTEIN REAGENT KIT)-USED TO TEST TOTAL PROTEIN LEVELS IN PATIENT SAMPLES
966	IMP/IVD/2020/001045	1.License Holder Name: PERKINELMER INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHEMAGIC VIRAL DNA/RNA 300 KIT H96(CHEMAGIC VIRAL DNA/RNA 300 KIT H96)-THE CHEMAGIC™ VIRAL DNA/RNA 300 KIT H96 IS TO BE USED FOR THE EXTRACTION AND PURIFICATION OF DNA AND RNA FROM HUMAN PLASMA, SERUM, NASO- OR OROPHARYNGEAL SWABS, BRONCHOALVEOLAR LAVAGE (BAL) AND SPUTUM USING THE CHEMAGIC 360 INSTRUMENT.

967	IMP/IVD/2020/001046	1.License Holder Name: EDIF MEDICAL SYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CAL CATRIDGE GASTAT 700 MODEL (GASTAT 710, GASTAT 730 & GASTAT 735 GASTAT1800 & GASTAT 1802-FOR CALIBRATION OF BLOOD GAS SYSTEM GASTAT 700 MODEL (GASTAT 710, GASTAT 730 & GASTAT 735 GASTAT1800 & GASTAT 1802,FLUSH SOLUTION-FOR CLEANING OF BLOOD GAS SYSTEM GASTAT 1800 SERIERS AND 700 MODEL SAMPLE PATH AFTER CALIBRATION AND SAMPLE MEASUREMENT
968	IMP/IVD/2020/001052	1.License Holder Name: FITCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 ANTIGEN RAPID TEST(GENBODY COVID-19 AG)-GENBODY COVID-19 AG IS AN IMMUNOCHROMATOGRAPHIC ASSAY KIT FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIGEN IN NASOPHARYNGEAL AND OROPHARYNGEAL SWAB FROM HUMAN.
969	IMP/IVD/2020/001053	1.License Holder Name: DEEP MEDITECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PCL COVID19 AG RAPID FIA-PCL COVID19 AG RAPID FIA IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE BASED ON FLUORESCENT IMMUNOASSAY (FIA) FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIGEN IN HUMAN OROPHARYNGEAL AND NASOPHARYNGEAL SPECIMENS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

970	IMP/IVD/2020/001054	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EPOC BGEM TEST CARD (EPOC BGEM TEST CARD)-THE EPOC BLOOD ANALYSIS SYSTEM, IS INTENDED FOR USE BY TRAINED MEDICAL PROFESSIONALS AS AN IN VITRO DIAGNOSTIC DEVICE FOR THE QUANTITATIVE TESTING OF SAMPLES OF HEPARINIZED OR UN-ANTICOAGULATED ARTERIAL, VENOUS OR CAPILLARY WHOLE BLOOD IN THE LABORATORY OR AT THE POINT OF CARE IN HOSPITALS, NURSING HOMES OR OTHER CLINICAL CARE INSTITUTIONS. THE BLOOD GAS ELECTROLYTE AND METABOLITE (BGEM) TEST CARD PANEL CONFIGURATION INCLUDES SENSORS FOR SODIUM, POTASSIUM, IONIZED CALCIUM, PH, PCO2, PO2, HEMATOCRIT, GLUCOSE, LACTATE, CREATININE AND CHLORIDE. SOME BGEM TEST CARD CONFIGURATIONS MAY NOT CONTAIN ALL THESE TESTS.,EPOC BGEM TEST CARD(EPOC BGEM TEST CARD)-THE EPOC BLOOD ANALYSIS SYSTEM, IS INTENDED FOR USE BY TRAINED MEDICAL PROFESSIONALS AS AN IN VITRO DIAGNOSTIC DEVICE FOR THE QUANTITATIVE TESTING OF SAMPLES OF HEPARINIZED OR UN-ANTICOAGULATED ARTERIAL, VENOUS OR CAPILLARY WHOLE BLOOD IN THE LABORATORY OR AT THE POINT OF CARE IN HOSPITALS, NURSING HOMES OR OTHER CLINICAL CARE INSTITUTIONS. THE BLOOD GAS ELECTROLYTE AND METABOLITE (BGEM) TEST CARD PANEL CONFIGURATION INCLUDES SENSORS FOR SODIUM, POTASSIUM, IONIZED CALCIUM, PH, PCO2, PO2, HEMATOCRIT, GLUCOSE, LACTATE, CREATININE, BUN, TCO2 AND CHLORIDE. SOME BGEM TEST CARD CONFIGURATIONS MAY NOT CONTAIN ALL THESE TESTS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

971	IMP/IVD/2020/001055	1.License Holder Name: MINDRAY MEDICAL INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:M-6 LH LYSE(MINDRAY)-THE M-6LH LYSE FORMULATED TO MEASURE THE HEMOGLOBIN-RELATED PARAMETERS,M-6 FR DYE(MINDRAY)-THE M-6FR DYE PARTICIPATES IN THE MEASUREMENT OF RET-RELATED PARAMETERS TOGETHER WITH M-6DR DILUENT ,M-6 FD DYE (MINDRAY)-THE M-6FD DYE PARTICIPATES IN WBC DIFFERENTIATION IN THE DIFF CHANNEL TOGETHER WITH M-6LD LYSE.,M-10 CFL LYSE (MINDRAY)-FOR USE ON MINDRAY BC-10/BC-11 HAEMATOLOGY ANALYZER. FOR USE AS A CYANIDE-FREE LYTIC REAGENT FOR QUANTITATIVELY DETERMINING HAEMOGLOBIN AND FOR COUNTING AND SIZING LEUKOCYTES. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL. ,CARDIAC MARKER MULTI CONTROL (L) (MINDRAY)-MINDRAY CARDIAC MARKER MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF CARDIAC MARKER ANALYTES. ,RHEUMATOID FACTOR CALIBRATOR(MINDRAY) -RHEUMATOID FACTOR CALIBRATOR IS USED FOR CALIBRATION OF THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) ANALYTE ON THE MINDRAY BS MEASUREMENT SYSTEM. ,M-6 DR DILUENT (MINDRAY)-THE M-6DR DILUENT PARTICIPATES IN THE MEASUREMENT OF RET-RELATED PARAMETERS TOGETHER WITH M-6FR DYE,TBA CONTROL(MINDRAY)-TBA CONTROL IS USED IN TOTAL BILE ACIDS ANALYTE QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF THE MINDRAY BS MEASUREMENT SYSTEM AND TESTABILITY OF THE CLINICAL LABORATORY. ,TRF CALIBRATOR(MINDRAY)-TRF CALIBRATOR IS USED FOR THE CALIBRATION OF THE QUANTITATIVE DETERMINATION OF TRANSFERRIN ON THE MINDRAY BS MEASUREMENT SYSTEM.,ADA CONTROL(MINDRAY)-ADA CONTROL IS USED IN ADENOSINE DEAMINASE QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF THE MINDRAY BS MEASUREMENT SYSTEM AND TESTABILITY OF THE CLINICAL LABORATORY. ,HBA1C CALIBRATOR (MINDRAY)-HBA1C CALIBRATOR IS USED FOR CALIBRATION OF THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C ANALYTE ON THE MINDRAY BS MEASUREMENT SYSTEM.,MALB CALIBRATOR (MINDRAY)-MALB CALIBRATOR IS USED FOR THE CALIBRATION OF THE QUANTITATIVE DETERMINATION OF ALBUMIN IN URINE ON THE MINDRAY BS MEASUREMENT SYSTEM.,M-20 CFL LYSE(MINDRAY)-FOR USE ON MINDRAY BC-20/BC-21/BC-30/BC-31/BC-30EHEMATOLOGY ANALYZER. FOR USE AS A CYANIDE-FREE LYTIC

	REAGENT FOR QUANTITATIVELY DETERMINING HAEMOGLOBIN AND FOR COUNTING AND SIZING LEUKOCYTES. USE AS DIRECTED IN INSTRUMENT OPERATOR'S MANUAL. ,HS-CRP(MINDRAY)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF CRP CONCENTRATION IN SERUM ON PHOTOMETRIC SYSTEMS.,M-6 FN DYE (MINDRAY)-THE M-6FN DYE PARTICIPATES IN THE MEASUREMENT OF BASO-RELATED AND NRBC-RELATED PARAMETERS TOGETHER WITH M-6LN LYSE,IGE CALIBRATOR(MINDRAY)-IGE CALIBRATOR IS USED FOR THE CALIBRATION OF THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) ON THE MINDRAY BS MEASUREMENT SYSTEM.,FER CALIBRATOR(MINDRAY)-FER CALIBRATOR IS USED FOR THE CALIBRATION OF THE QUANTITATIVE DETERMINATION OF FERRITIN ON THE MINDRAY BS MEASUREMENT SYSTEM.,ADA CALIBRATOR(MINDRAY)-ADA CALIBRATOR IS USED FOR CALIBRATION OF THE QUANTITATIVE DETERMINATION OF ADENOSINE DEAMINASE ANALYTE ON THE MINDRAY BS MEASUREMENT SYSTEM.,CARDIAC MARKER MULTI CONTROL (H) (MINDRAY)-MINDRAY CARDIAC MARKER MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF MINDRAY CL-SERIES CHEMILUMINESCENCE IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF CARDIAC MARKER ANALYTES. ,DS DILUENT (MINDRAY)-THE DS DILUENT PARTICIPATES IN THE MEASUREMENT OF PARAMETERS RELATED TO RBC, PLT, WBC, RET AND NRBC,TOTAL HUMAN CHORIONIC GONADOTROPIN (CLIA)(MINDRAY)-THE CL-SERIES TOTAL HCG ASSAY IS A CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL HUMAN CHORIONIC GONADOTROPIN (TOTAL HCG) IN HUMAN SERUM AND PLASMA ,M-6 LD LYSE(MINDRAY)-THE M-6LD LYSE PARTICIPATES IN WBC DIFFERENTIATION IN THE DIFF CHANNEL TOGETHER WITH M-6FD DYE.,M-6 LN LYSE(MINDRAY)-THIS PRODUCT PARTICIPATES IN THE MEASUREMENT OF BASO-RELATED AND NRBC RELATED PARAMETERS TOGETHER WITH M-6FN DYE

972	IMP/IVD/2020/001062	1.License Holder Name: IMMUNOSHOP INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHORUS BETA 2-GLYCOPROTEIN-M(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE SEMIQUANTITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST 2-GLICOPROTEIN I IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,CHORUS A-TPO(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST THYROID PEROXIDASE (TPO) IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,CHORUS A-TG(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST THYROGLOBULIN (TG) IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,CHORUS HELICOBACTER PYLORI IGG(DIESSE)-SEMIQUANTITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO HELICOBACTER PYLORI IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS INSTRUMENTS ,CHORUS RESPIRATORY SYNCYTIAL VIRUS IGG(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST RESPIRATORY SYNCYTIAL VIRUS IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS.,CHORUS MUMPS IGG(DIESSE)-QUALITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO MUMPS VIRUS IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS INSTRUMENTS. POSITIVE RESULTS INDICATE THAT THE PATIENT IS IMMUNE. ,CHORUS WASHING BUFFER AUTOIMMUNITY (DIESSE)-FOR USE IN THE AUTOIMMUNITY TESTS IN THE CHORUS AUTOMATIC ANALYZER AS WASH SOLUTION FOR THE REACTION WELLS ,CHORUS ASCA-G(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE SEMIQUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST SACCHAROMYCES CEREVISIAE IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,CHORUS BETA 2-GLYCOPROTEIN-G(DIESSE)-SEMIQUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST - BETA 2-GLYCOPROTEIN IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS INSTRUMENTS ,CHORUS RF-M (DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUANTITATIVE DETERMINATION OF IGM RHEUMATOID FACTORS IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,CHORUS 25OH VITAMIN D TOTAL (DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUANTITATIVE

	DETERMINATION OF 25(OH) VITAMIN D IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,CHORUS COPROCOLLECT(DIESSE)-DISPOSABLE DEVICE FOR THE COLLECTION OF THE AMOUNT OF STOOLS REQUIRED TO PERFORM THE CHORUS CALPROTECTIN TEST (REF 86600-86600/36-86600/C03). ,CHORUS ADENOVIRUS IGA(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUALITATIVE DETERMINATION OF IGA-CLASS ANTIBODIES TO ADENOVIRUS IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,CHORUS NEGATIVE CONTROL/SAMPLE DILUENT (DIESSE)-FOR USE IN THE IMMUNOENZYMATIC KITS IN THE CHORUS ANALYZER AS NEGATIVE CONTROL OR SAMPLE DILUENT FOR THOSE WHICH GIVE A RESULT OVER RANGE ,CHORUS ADENOVIRUS IGG(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUALITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO ADENOVIRUS IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,CHORUS CLEANING SOLUTION 2000 (DIESSE)-FOR USE IN THE CHORUS/CHORUS TRIO AUTOMATIC ANALYZER AS WASH SOLUTION FOR THE TUBES AND AS RESUSPENDING SOLUTION FOR THE LYOPHILIZED PRODUCTS IN THE CFT LINE. ,ENZY-WELL/CHORUS WASHING BUFFER(DIESSE)-FOR USE IN THE IMMUNOENZYMATIC ENZY-WELL KITS AND IN THE CHORUS AUTOMATIC ANALYZER AS WASH SOLUTION FOR THE REACTION WELLS ,CHORUS CALPROTECTIN(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUANTITATIVE DETERMINATION OF CALPROTECTIN IN STOOLS SAMPLES, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. , CHORUS EPSTEIN BARR VCA IGG(DIESSE)-QUALITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO THE VIRAL CAPSID ANTIGEN OF EPSTEIN BARR VIRUS IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS INSTRUMENTS , CHORUS HELICOBACTER PYLORI IGA(DIESSE)-QUALITATIVE DETERMINATION OF IGA-CLASS ANTIBODIES ANTI HELICOBACTER PYLORI IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS INSTRUMENTS ,CHORUS EPSTEIN BARR EBNA IGG (DIESSE)-QUALITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO EPSTEIN BARR NUCLEAR ANTIGEN (EBNA) IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS INSTRUMENTS ,CHORUS VARICELLA IGG(DIESSE)-QUALITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO VARICELLA ZOSTER VIRUS IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS INSTRUMENTS ,CHORUS MEASLES IGM(DIESSE)-QUALITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO

	MEASLES VIRUS IN HUMAN SERUM USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS INSTRUMENTS. POSITIVE RESULTS INDICATE ACUTE INFECTIONS. ,CHORUS AMA-M2(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE SEMIQUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST ANTI-M2 IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,CHORUS PR3(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE SEMIQUANTITATIVE DETERMINATION OF ANTI-PROTEINASE 3 (PR3) ANTIBODIES IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,CHORUS SANITIZING SOLUTION (DIESSE)-FOR USE IN THE CHORUS/CHORUS TRIO AUTOMATIC ANALYZER AS SANITIZING SOLUTION FOR THE TUBES , CHORUS EPSTEIN BARR VCA IGM II(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST EPSTEIN-BARR VIRAL CAPSID ANTIGEN IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,CHORUS ANTI-CCP (DIESSE)-IMMUNOENZYMATIC METHOD FOR THE SEMIQUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CYCLIC CITRULLINATED PEPTIDE (ANTI-CCP) IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,CHORUS DSDNA-G(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUANTITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES AGAINST DSDNA IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,ENZY-WELL TOXOPLASMA IGM(DIESSE)-IMMUNOENZYMATIC CAPTURE METHOD FOR THE QUALITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF TOXOPLASMA INFECTION.,ENZY-WELL MUMPS IGM(DIESSE)-IMMUNOENZYMATIC CAPTURE METHOD FOR THE QUALITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO MUMPS VIRUS IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF MUMPS VIRUS INFECTION.,CHORUS MPO(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE SEMIQUANTITATIVE DETERMINATION OF ANTI-MYELOPEROXIDASE (MPO) ANTIBODIES IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,CHORUS EPSTEIN BARR EARLY ANTIGEN IGG(DIESSE) -QUALITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO EPSTEIN BARR EARLY ANTIGEN IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS INSTRUMENTS , CHORUS CARDIOLIPIN-G(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE SEMIQUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES

	AGAINST CARDIOLIPIN IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,CHORUS ANA-SCREEN(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST HEP2 CELLS IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,ENZY-WELL VARICELLA IGG(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUALITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO VARICELLA ZOSTER IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF VARICELLA VIRUS INFECTION.,ENZY-WELL MUMPS IGG (DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUALITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO MUMPS VIRUS IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF MUMPS VIRUS INFECTION.,CHORUS TTG-A(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE SEMIQUANTITATIVE DETERMINATION OF IGA CLASS ANTIBODIES AGAINST TISSUE TRANSGLUTAMINASE IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,ENZY-WELL MEASLES IGM(DIESSE)-IMMUNOENZYMATIC CAPTURE METHOD FOR THE QUALITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO MEASLES VIRUS IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF MEASLES VIRUS INFECTION.,CHORUS MYCOPLASMA PNEUMONIAE IGM(DIESSE)-QUALITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO MYCOPLASMA IN HUMAN SERUM USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS INSTRUMENTS ,CHORUS EPSTEIN BARR EARLY ANTIGEN IGM(DIESSE)-QUALITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO EPSTEIN BARR EARLY ANTIGEN IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS INSTRUMENTS ,ENZY-WELL HELICOBACTER PYLORI IGG(DIESSE)-IMMUNOENZYMATIC KIT FOR THE QUALITATIVE AND SEMIQUANTITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO HELICOBACTER PYLORI IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF H. PYLORI INFECTION.,ENZY-WELL TOXOPLASMA IGG (DIESSE)-IMMUNOENZYMATIC KIT FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF TOXOPLASMA INFECTION.,ENZY-WELL RUBELLA IGM (DIESSE)-IMMUNOENZYMATIC CAPTURE METHOD FOR THE QUALITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF RUBELLA VIRUS INFECTION.,ENZY-WELL VARICELLA IGM(DIESSE)-IMMUNOENZYMATIC CAPTURE METHOD FOR THE QUALITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO VARICELLA ZOSTER IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF VARICELLA

	VIRUS INFECTION.,ENZY-WELL HELICOBACTER PYLORI IGA(DIESSE)-IMMUNOENZYMATIC KIT FOR THE QUALITATIVE DETERMINATION OF IGA-CLASS ANTIBODIES TO HELICOBACTER PYLORI IN HUMAN SERUM,ENZY-WELL HERPES SIMPLEX 2 IGM(DIESSE)-IMMUNOENZYMATIC CAPTURE METHOD FOR THE QUALITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO HERPES SIMPLEX VIRUS (TYPE 2) IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF HERPES SIMPLEX VIRUS INFECTION.,ENZY-WELL HERPES SIMPLEX 1 IGM(DIESSE)-IMMUNOENZYMATIC CAPTURE METHOD FOR THE QUALITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO HERPES SIMPLEX VIRUS (TYPE 1) IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF HERPES SIMPLEX VIRUS INFECTION.,ENZY-WELL HERPES SIMPLEX 2 IGG RECOMBINANT(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUALITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO HERPES SIMPLEX VIRUS (TYPE 2) IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF HERPES SIMPLEX VIRUS INFECTION., ENZY-WELL MEASLES IGG(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUALITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO MEASLES VIRUS IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF MEASLES VIRUS INFECTION.,ENZY-WELL HERPES SIMPLEX 1+2 IGG(DIESSE)-IMMUNOENZYMATIC KIT FOR THE QUALITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO HERPES SIMPLEX VIRUS (TYPES 1 AND 2) IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF HERPES SIMPLEX VIRUS INFECTION.,CHORUS MEASLES IGG(DIESSE)-QUALITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO MEASLES VIRUS IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS INSTRUMENTS. POSITIVE RESULTS INDICATE THAT PATIENT IS IMMUNE. ,CHORUS CARDIOLIPIN-M(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE SEMIQUANTITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM, USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS AND CHORUS TRIO INSTRUMENTS. ,ENZY-WELL EPSTEIN-BARR VCA IGM(DIESSE)-IMMUNOENZYMATIC KIT FOR THE SEMIQUANTITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO THE VIRAL CAPSID ANTIGEN OF EPSTEIN BARR VIRUS IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF EPSTEIN BARR VIRUS INFECTION.,ENZY-WELL HERPES SIMPLEX 1+2 IGM (DIESSE)-IMMUNOENZYMATIC CAPTURE METHOD FOR THE QUALITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO HERPES SIMPLEX VIRUS (TYPES 1 AND 2) IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF HERPES SIMPLEX VIRUS INFECTION.,ENZY-WELL CYTOMEGALOVIRUS IGG(DIESSE)-IMMUNOENZYMATIC METHOD FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO CYTOMEGALOVIRUS

		IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF CYTOMEGALOVIRUS INFECTION.,ENZY-WELL CYTOMEGALOVIRUS IGM(DIESSE)-IMMUNOENZYMATIC CAPTURE METHOD FOR THE QUALITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF CYTOMEGALOVIRUS INFECTION.,ENZY-WELL RUBELLA IGG (DIESSE)-IMMUNOENZYMATIC KIT FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO RUBELLA IN HUMAN SERUM, AS AN AID IN THE DIAGNOSIS OF RUBELLA VIRUS INFECTION.,CHORUS MUMPS IGM(DIESSE)-QUALITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO MUMPS VIRUS IN HUMAN SERUM USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS INSTRUMENTS. POSITIVE RESULTS INDICATE ACUTE INFECTIONS. ,CHORUS VARICELLA IGM(DIESSE)-QUALITATIVE DETERMINATION OF IGM-CLASS ANTIBODIES TO VARICELLA ZOSTER VIRUS IN HUMAN SERUM USING A DISPOSABLE DEVICE APPLIED ON THE CHORUS INSTRUMENTS ,ENZY-WELL HERPES SIMPLEX 1 IGG RECOMBINANT(DIESSE)-IMMUNOENZYMATIC KIT FOR THE QUALITATIVE DETERMINATION OF IGG-CLASS ANTIBODIES TO HERPES SIMPLEX VIRUS (TYPE 1) IN HUMAN SERUM.
973	IMP/IVD/2020/001063	1.License Holder Name: M/S. CPC DIAGNOSTICS PVT, LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STANDARD SOLUTION 2 (NIL)-USED FOR MEASURING THE ACCURATE ELECTROLYTE CONCENTRATION OF THE SAMPLE BY EX-D/EX-DS,STANDARD SOLUTION 1 (NIL)-USED FOR MEASURING THE ACCURATE ELECTROLYTE CONCENTRATION OF THE SAMPLE BY EX-D/EX-DS, REFERENCE SOLUTION FOR EX- CA(NIL)-USED FOR MEASURING THE ACCURATE ELECTROLYTE CONCENTRATION OF THE SAMPLE BY EX-CA,ELECTROLYTE WASH SOLUTION(NIL)-USED FOR CLEANING THE FLOW PATH,STANDARD SOLUTION 2 EX-CA(NIL)-USED FOR MEASURING THE ACCURATE ELECTROLYTE CONCENTRATION OF THE SAMPLE BY EX-CA,STANDARD SOLUTION 1 FOR EX-CA(NIL)-USED FOR MEASURING THE ACCURATE ELECTROLYTE CONCENTRATION OF THE SAMPLE BY EX-CA

974	IMP/IVD/2020/001064	1.License Holder Name: ALTONA DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PARVOVIRUS B19 PCR KIT 1.5(ALTOSTAR®)-THE ALTOSTAR® PARVOVIRUS B19 PCR KIT 1.5 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE DETECTION AND QUANTIFICATION OF PARVOVIRUS B19 SPECIFIC DNA IN HUMAN PLASMA. THE ALTOSTAR® PARVOVIRUS B19 PCR KIT 1.5 IS CONFIGURED FOR USE WITH THE CFX96™ DEEP WELL DX SYSTEM (BIO-RAD) IN COMBINATION WITH THE ALTOSTAR® AUTOMATION SYSTEM AM16, THE ALTOSTAR® PURIFICATION KIT 1.5 AND THE ALTOSTAR® INTERNAL CONTROL 1.5. THE RESULTS GENERATED WITH THE ALTOSTAR® PARVOVIRUS B19 PCR KIT 1.5 HAVE TO BE INTERPRETED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS. THE ALTOSTAR® PARVOVIRUS B19 PCR KIT 1.5 IS INTENDED FOR USE BY PROFESSIONAL USERS TRAINED IN MOLECULAR BIOLOGICAL TECHNIQUES.,INFLUENZA SCREEN & TYPE RT - PCR KIT(REALSTAR®)-THE REALSTAR® INFLUENZA SCREEN & TYPE RT-PCR KIT 4.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE QUALITATIVE DETECTION AND DIFFERENTIATION OF INFLUENZA A VIRUS, INFLUENZA B VIRUS AND INFLUENZA A VIRUS HLNL SPECIFIC RNA.,HEV RT-PCR KIT 1.5 (ALTOSTAR®)-THE ALTOSTAR® HEV RT-PCR KIT 1.5 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL TIME PCR TECHNOLOGY, FOR THE DETECTION AND QUANTIFICATION OF HEPATITIS E VIRUS (HEV) SPECIFIC RNA IN HUMAN PLASMA. THE ALTOSTAR® HEV RT-PCR KIT 1.5 IS CONFIGURED FOR USE WITH THE CFX96™ DEEP WELL DX SYSTEM (BIO-RAD) IN COMBINATION WITH THE ALTOSTAR® AUTOMATION SYSTEM AM16, THE ALTOSTAR® PURIFICATION KIT 1.5 AND THE ALTOSTAR® INTERNAL CONTROL 1.5. THE RESULTS GENERATED WITH THE ALTOSTAR® HEV RT-PCR KIT 1.5 HAVE TO BE INTERPRETED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS. THE ALTOSTAR® HEV RT-PCR KIT 1.5 IS INTENDED FOR USE BY PROFESSIONAL USERS TRAINED IN MOLECULAR BIOLOGICAL TECHNIQUES.,BKV PCR KIT(REALSTAR®)-THE REALSTAR® BKV PCR KIT 1.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE DETECTION AND QUANTIFICATION OF BK VIRUS (BKV) SPECIFIC DNA.,JCV PCR KIT (REALSTAR®)-THE REALSTAR® JCV PCR KIT 1.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE DETECTION AND QUANTIFICATION OF JC VIRUS (JCV) SPECIFIC DNA.,VZV PCR KIT(REALSTAR®)-THE REALSTAR® VZV PCR KIT 1.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE DETECTION AND QUANTIFICATION OF

		VARICELLA-ZOSTER VIRUS (VZV) SPECIFIC DNA.,HSV PCR KIT (REALSTAR®)-THE REALSTAR® HSV PCR KIT 1.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE SIMULTANEOUS DETECTION AND QUANTIFICATION OF HERPES SIMPLEX VIRUS 1 (HSV-1) AND HERPES SIMPLEX VIRUS 2 (HSV- 2) SPECIFIC DNA.,EBV PCR KIT(REALSTAR®)-THE REALSTAR® EBV PCR KIT 2.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE DETECTION AND QUANTIFICATION OF EPSTEIN-BARR VIRUS (EBV) SPECIFIC DNA.,CMV PCR KIT (REALSTAR®)-THE REALSTAR® CMV PCR KIT 1.0 IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME PCR TECHNOLOGY, FOR THE DETECTION AND QUANTIFICATION OF CYTOMEGALOVIRUS (CMV) SPECIFIC DNA IN HUMAN EDTA PLASMA AND EDTA WHOLE BLOOD.
975	IMP/IVD/2020/001072	1.License Holder Name: SHREE SHYAM BIO-MEDICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COTININE RAPID TEST CASSETTE (URINE)(ACRO JUSCHEK)-THE QUALITATIVE DETECTION OF COTININE (NICOTINE METABOLITE) IN HUMAN URINE. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,ALCOHOL RAPID TEST DIPSTICK (URINE)(ACRO JUSCHEK)-A RAPID ONE STEP SCREENING TEST FOR THE SEMI-QUANTITATIVE DETECTION OF ALCOHOL IN URINE FOR FORENSIC USE ONLY.,CARDIAC TROPONIN I RAPID TEST CASSETTE (WHOLE BLOOD /SERUM/PLASMA)(ACRO JUSCHEK)-THE DIAGNOSIS OF MYOCARDIAL INFARCTION (MI) TO DETECT CARDIAC TROPONIN I(CTNI) QUALITATIVELY IN WHOLE BLOOD, SERUM OR PLASMA. FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY,SALIVA ALCOHOL RAPID TEST DIPSTICK (ACRO JUSCHEK)-A RAPID ONE STEP SCREENING TEST FOR THE SEMI QUANTITATIVE DETECTION OF ALCOHOL IN SALIVA FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.,URINE ALCOHOL RAPID TEST CASSETTE(ACRO JUSCHEK)-A RAPID ONE STEP SCREENING TEST FOR THE SEMI QUANTITATIVE DETECTION OF ALCOHOL IN URINE FOR FORENSIC USE ONLY.

976	IMP/IVD/2020/001073	1.License Holder Name: ANAND BROTHER'S 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMTEC-ANA SCREEN (CUT-OFF)(IMTEC-ANA SCREEN (CUT-OFF))-ELISA FOR THE QUALITATIVE DETERMINATION OF AUTOANTIBODIES AGAINST NUCLEAR ANTIGENS IN HUMAN SERUM.,IMTEC-AMA M2(IMTEC-AMA M2)-ELISA FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST MITOCHONDRIAL ANTIGENS IN HUMAN SERUM,IMTEC-ß2-GLYCOPROTEIN I-ANTIBODIES IGM(IMTEC-ß2-GLYCOPROTEIN I-ANTIBODIES IGM)-ELISA FOR THE QUANTITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST BETA-2-GLYCOPROTEIN I IN HUMAN SERUM AND PLASMA.,IMTEC-LKM1-ANTIBODIES(IMTEC-LKM1-ANTIBODIES)-ELISA FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST LKM1 IN HUMAN SERUM,IMTEC-RA33-ANTIBODIES(IMTEC-RA33-ANTIBODIES)-ELISA FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST RA33 (HNRNP A2) IN HUMAN SERUM,IMTEC-ANTI-C1Q-ANTIBODIES(IMTEC-ANTI-C1Q-ANTIBODIES)-ELISA FOR THE QUANTITATIVE MEASUREMENT OF ANTI C1 Q -ANTIBODIES IN HUMAN SERUM.,IMTEC-PR3-ANCA(IMTEC-PR3-ANCA)-ELISA FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST PROTEINASE 3 IN HUMAN SERUM.,IMTEC-CARDIOLIPIN-ANTIBODIES IGG(IMTEC-CARDIOLIPIN-ANTIBODIES IGG)-ELISA FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST CARDIO-LIPIN/BETA-2- GLYCOPROTEIN I IN HUMAN SERUM AND PLASMA,IMTEC-ß2-GLYCOPROTEIN I-ANTIBODIES IGG(IMTEC-ß2-GLYCOPROTEIN I-ANTIBODIES IGG)-ELISA FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA.,IMTEC-GBM-ANTIBODIES(IMTEC-GBM-ANTIBODIES)-ELISA FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST GLOMERULAR BASEMENT MEMBRANE ANTIEGEN(GBM, COLLAGEN IV) IN HUMAN SERUM.,IMTEC-ENA PROFILE(IMTEC-ENA PROFILE)-ELISA FOR THE QUALITATIVE DETERMINATION OF ENA PROFILE IN HUMAN SERUM,IMTEC-CARDIOLIPIN-ANTIBODIES COMBI (IMTEC-CARDIOLIPIN-ANTIBODIES COMBI)-ELISA FOR THE QUANTITATIVE MEASUREMENT OF IGG OR IGM CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN/BETA-2- GLYCOPROTEIN I IN HUMAN SERUM AN AND PLASMA.,IMTEC-ß2-GLYCOPROTEIN I-ANTIBODIES SCREEN(IMTEC-ß2-GLYCOPROTEIN I-ANTIBODIES SCREEN)-ELISA FOR THE QUANTITATIVE MEASUREMENT OF IGG, IGM AND IGA CLASS AUTOANTIBODIES AGAINST BETA-2- GLYCOPROTEIN I IN HUMAN SERUM AND PLASMA.,IMTEC-MPO-ANCA(IMTEC-MPO-ANCA)-ELISA FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS

	AUTOANTIBODIES AGAINST MYELOPEROXIDASE IN HUMAN SERUM., IMTEC-CARDIOLIPIN-ANTIBODIES SCREEN(IMTEC-CARDIOLIPIN-ANTIBODIES SCREEN)-ELISA FOR THE QUANTITATIVE MEASUREMENT OF IGG, IGM AND IGA CLASS AUTOANTI-BODIES AGAINST CARDIOLIPIN/BETA-2-GLYCOPROTEIN I IN HUMAN SERUM AND PLASMA,IMTEC-TPO-ANTIBODIES(IMTEC-TPO-ANTIBODIES)-ELISA FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST THYROID PEROXIDASE (TPO) IN HUMAN SERUM,IMTEC-ANA SCREEN(IMTEC-ANA SCREEN)-ELISA FOR THE QUANTITATIVE DETERMINATION OF AUTOANTIBODIES AGAINST NUCLEAR ANTIGENS IN HUMAN SERUM,IMTEC-CARDIOLIPIN-ANTIBODIES IGM(IMTEC-CARDIOLIPIN-ANTIBODIES IGM)-ELISA FOR THE QUANTITATIVE MEASUREMENT OF IGG & IGM CLASS AUTOANTIBODIES AGAINST CADIOLIPIN/BETA-2- GLYCOPROTEIN I IN HUMAN SERUM AND PLASMA.,IMTEC-DSDNA-ANTIBODIES(IMTEC-DSDNA-ANTIBODIES)-ELISA FOR THE QUANTITATIVE MEASUREMENT OF DSDNA IN HUMAN SERUM,IMTEC-RF-IGM(IMTEC-RF-IGM)-ELISA FOR THE QUANTITATIVE DETERMINATION OF IGM CLASS RHEUMATOID FACTORS (RF) IN HUMAN SERUM OR PLASMA

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977	IMP/IVD/2020/001078	1.License Holder Name: OSB AGENCIES PRIVATE LIMIATED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ECHINOCOCCUS IGG (NOVALISA®)-THE ECHINOCOCCUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST ECHINOCOCCUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)., ENTAMOEBA HISTOLYTICA IGG(NOVALISA®)-THE ENTAMOEBAHISTOLYTICAIGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST ENTAMOEBAHISTOLYTICAIN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,EPSTEIN-BARR VIRUS (VCA)IGG(NOVALISA®)-THE EPSTEIN-BARR VIRUS (VCA) IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST EPSTEIN-BARR VIRUS VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,DENGUE VIRUS IGG (NOVALISA®)-THE DENGUE VIRUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST DENGUE VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)., BRUCELLA IGM(NOVALISA®)-THE BRUCELLA IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST BRUCELLA IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,TRICHINELLA SPIRALIS IGG(NOVALISA®)-THE TRICHINELLASPIRALISIGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST TRICHINELLASPIRALISIN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,MUMPS VIRUS IGG(NOVALISA®)-THE MUMPS VIRUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST MUMPS VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,MEASLES VIRUS IGM(NOVALISA®)-THE MEASLES VIRUSIGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST MEASLES VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,MUMPS VIRUS IGM(NOVALISA®)-THE MUMPS VIRUSIGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST MUMPS VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,VARICELLA-ZOSTER VIRUS (VZV) IGM(NOVALISA®)-THE VARICELLA-ZOSTER VIRUS (VZV)IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST VARICELLA-ZOSTER VIRUS (VZV) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,CLOSTRIDIUM TETANI TOXIN IGG(NOVALISA®)-THE CLOSTRIDIUM TETANI TOXIN IGG ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CLOSTRIDIUM TETANI TOXIN IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,LEPTOSPIRA IGG(NOVALISA®)-THE

	LEPTOSPIRAIGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST LEPTOSPIRAIN HUMAN SERUM OR PLASMA (HEPARIN).,BORDETELLA PERTUSSIS IGM (NOVALISA®)-THE BORDETELLA PERTUSSIS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST BORDETELLA PERTUSSIS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,PARVOVIRUS B19 IGM(NOVALISA®)-THE PARVOVIRUS B19IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST PARVOVIRUS B19 IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)., CORYNEBACTERIUM DIPHTHERIAE TOXIN IGG(NOVALISA®)-THE CORYNEBACTERIUMDIPHTHERIAE TOXIN IGG ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CORYNEBACTERIUMDIPHTHERIAE TOXIN IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,BRUCELLA IGG(NOVALISA®)-THE BRUCELLA IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST BRUCELLA IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,EPSTEIN-BARR VIRUS (VCA) IGM(NOVALISA®)-THE EPSTEIN-BARR VIRUS (VCA) IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST EPSTEIN-BARR VIRUS VIRAL CAPSID ANTIGEN (VCA) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)., BORDETELLA PERTUSSIS IGG(NOVALISA®)-THE BORDETELLA PERTUSSIS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST BORDETELLA PERTUSSIS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN)., PARVOVIRUS B19 IGG(NOVALISA®)-THE PARVOVIRUS B19 IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST PARVOVIRUS B19 IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,VARICELLA-ZOSTER VIRUS (VZV) IGG (NOVALISA®)-THE VARICELLA-ZOSTER VIRUS (VZV) IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST VARICELLA-ZOSTER VIRUS (VZV) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,TOXOCARA CANIS IGG (NOVALISA®)-THE TOXOCARACANISIGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST TOXOCARACANISIN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,DENGUE VIRUS IGM(NOVALISA®)-THE DENGUE VIRUSIGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST DENGUE VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,MEASLES VIRUS IGG(NOVALISA®)-THE MEASLES VIRUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST MEASLES VIRUS IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,

	VARICELLA-ZOSTER VIRUS (VZV) IGA(NOVALISA®)-THE VARICELLA-ZOSTER VIRUS (VZV)IGA ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGA CLASS ANTIBODIES AGAINST VARICELLA-ZOSTER VIRUS (VZV) IN HUMAN SERUM OR PLASMA (CITRATE, HEPARIN).,LEPTOSPIRA IGM(NOVALISA®)-THE LEPTOSPIRA IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST LEPTOSPIRAIN HUMAN SERUM OR PLASMA (HEPARIN).

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978	IMP/IVD/2020/001079	1.License Holder Name: KIN DIAGNOSTICS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GENERAL BIOCHEMISTRY PANEL(SKYLA)-THE SKYLA GENERAL BIOCHEMISTRY PANEL USED WITH SKYLA CLINICAL CHEMISTRY ANALYZER, IS INTENDED TO BE USED FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN (ALB), ALKALINE PHOSPHATASE (ALP), ALANINE AMINOTRANSFERASE (ALT/GPT), ASPARTATE AMINOTRANSFERASE (AST/GOT), BLOOD UREA NITROGEN (BUN), CREATININE (CREA), GAMMA-GLUTAMYL TRANSPEPTIDACE (GGT), BLOOD GLUCOSE (GLU), TOTAL BILIRUBIN (TBIL), TOTAL CHOLESTEROL (TC), TOTAL PROTEIN (TP), URIC ACID (UA) IN HUMAN WHOLE BLOOD, PLASMA, OR SERUM. THE CALCULATED VALUES OF ALBUMIN/GLOBULIN RATIO (A/G RATIO), ESTIMATED GLOMERULAR FILTRATION RATE (EGFR) , AND GLOBULIN (GLOB) CAN THEN BE OBTAINED.,BASIC BIOCHEMISTRY PANEL (SKYLA)-THE SKYLA BASIC BIOCHEMISTRY PANEL USED WITH SKYLA CLINICAL CHEMISTRY ANALYZER, IS INTENDED TO BE USED FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN (ALB), ALANINE AMINOTRANSFERASE (ALT/GPT), BLOOD UREA NITROGEN (BUN), CREATININE (CREA), BLOOD GLUCOSE (GLU), TOTAL PROTEIN (TP), URIC ACID (UA) IN HUMAN WHOLE BLOOD, PLASMA, OR SERUM. THE CALCULATED VALUES OF ALBUMIN/GLOBULIN RATIO (A/G RATIO), ESTIMATED GLOMERULAR FILTRATION RATE (EGFR), AND C GLOBULIN (GLOB) CAN THEN BE OBTAINED,LIVER PANEL(SKYLA)-THE SKYLA LIVER PANEL USED WITH SKYLA CLINICAL CHEMISTRY ANALYZER, IS INTENDED TO BE USED FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN (ALB), ALKALINE PHOSPHATASE (ALP), ALANINE AMINOTRANSFERASE (ALT/GPT), ASPARTATE AMINOTRANSFERASE (AST/GOT), DIRECT BILIRUBIN (DBIL), GAMMA-GLUTAMYL TRANSPEPTIDACE (GGT), BLOOD GLUCOSE (GLU), TOTAL BILIRUBIN (TBIL), TOTAL PROTEIN (TP) IN HUMAN WHOLE BLOOD, PLASMA, OR SERUM. THE CALCULATED VALUES OF ALBUMIN/GLOBULIN RATIO (A/G RATIO), GLOBULIN (GLOB), AND INDIRECT BILIRUBIN (IBIL) CAN THEN BE OBTAINED.,ER PANEL (SKYLA)-THE SKYLA ER PANEL USED WITH SKYLA CLINICAL CHEMISTRY ANALYZER, IS INTENDED TO BE USED FOR THE QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE (ALT/GPT), AMYLASE (AMY), ASPARTATE AMINOTRANSFERASE (AST/GOT), BLOOD UREA NITROGEN (BUN), CALCIUM (CA), CHLORIDE (CL), CREATINE PHOSPHOKINASE (CPK), CREATININE (CREA), BLOOD GLUCOSE (GLU), LIPASE (LIPA), PHOSPHORUS (PHOS), POTASSIUM (K), SODIUM (NA) IN HUMAN WHOLE BLOOD, PLASMA, OR SERUM. THE CALCULATED VALUES OF ESTIMATED GLOMERULAR FILTRATION RATE (EGFR) CAN THEN BE OBTAINED,RENAL PANEL(SKYLA)-THE

	SKYLA RENAL PANEL USED WITH SKYLA CLINICAL CHEMISTRY ANALYZER, IS INTENDED TO BE USED FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN (ALB), BLOOD UREA NITROGEN (BUN), CALCIUM (CA), CHLORIDE (CL), CREATINE PHOSPHOKINASE (CPK), CREATININE (CREA), BLOOD GLUCOSE (GLU), PHOSPHORUS (PHOS), POTASSIUM (K), SODIUM (NA) IN HUMAN WHOLE BLOOD, PLASMA, OR SERUM. THE CALCULATED VALUES OF ESTIMATED GLOMERULAR FILTRATION RATE (EGFR) CAN THEN BE OBTAINED,LIPID PANEL (SKYLA)-THE SKYLA LIPID PANEL USED WITH SKYLA CLINICAL CHEMISTRY ANALYZER, IS INTENDED TO BE USED FOR THE QUANTITATIVE DETERMINATION OF BLOOD GLUCOSE (GLU), HIGH-DENSITY LIPOPROTEIN (HDL), TOTAL CHOLESTEROL (TC), TRIGLYCERIDE (TG) IN HUMAN WHOLE BLOOD, PLASMA, OR SERUM. THE CALCULATED VALUES OF LOW-DENSITY LIPOPROTEIN (LDL), AND VERY LOW-DENSITY LIPOPROTEIN (VLDL) CAN THEN BE OBTAINED.,METABOLIC PANEL(SKYLA)-THE SKYLA METABOLIC PANEL USED WITH SKYLA CLINICAL CHEMISTRY ANALYZER, IS INTENDED TO BE USED FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN (ALB), ALANINE AMINOTRANSFERASE (ALT/GPT), ASPARTATE AMINOTRANSFERASE (AST/GOT), BLOOD UREA NITROGEN (BUN), CALCIUM (CA), CHLORIDE (CL), CREATININE (CREA), BLOOD GLUCOSE (GLU), PHOSPHORUS (PHOS), POTASSIUM (K), SODIUM (NA), TOTAL PROTEIN (TP), URIC ACID (UA) IN HUMAN WHOLE BLOOD, PLASMA, OR SERUM. THE CALCULATED VALUES OF ALBUMIN/GLOBULIN RATIO (A/G RATIO), ESTIMATED GLOMERULAR FILTRATION RATE (EGFR), AND GLOBULIN (GLOB) CAN THEN BE OBTAINED

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979	IMP/IVD/2020/001080	1.License Holder Name: MERIL DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BF FBH LYSE-FOR THE DISSOLUTION OF RED BLOOD CELLS, CONTENT DETECTION OF WHITE BLOOD CELLS AND HEMOGLOBIN, THE QUANTITY AND RATIO OF BASOPHILIC GRANULOCYTE.,CONTROL FOR AUTOMATIC HEMATOLOGY ANALYZER (5-PART) (LEVEL 2)-IT IS USED FOR MONITORING OR EVALUATING TEST RESULT ACCURACY OF BF-SERIES AUTOMATIC HEMATOLOGY ANALYZER,PROBE CLEANSER I-IT IS USED FOR CLEANING THE DETECTION PART OF INSTRUMENT, ROTARY VALVE, WHOLE BLOOD SUCTION PIPE, HEMOGLOBIN CUVETTE, PREVENTION OF PROTEIN BUILD-UP.,CLEANSER-TO CLEAN AND WASH THE DETECTION PART AND FLUID SYSTEM OF THE HEMATOLOGY ANALYZERS,BF-FDOI LYSE-FOR THE DISSOLUTION OF RED BLOOD CELLS, DYE OF CELL, CONTENT DETECTION OF LYMPHOCYTES, MONOCYTES, EOSINOPHILS AND NEUTROPHILS., LYSE-IT IS USED FOR DISSOLVING RBC, DETECTING TOTAL NUMBER OF WBC, THREE-PART WBC COUNT AND THE CONTENT OF HEMOGLOBIN.,BF-FDT I LYSE-FOR THE DISSOLUTION OF RED BLOOD CELLS, DYE OF CELL, CONTENT DETECTION OF LYMPHOCYTES, MONOCYTES, EOSINOPHILS AND NEUTROPHILS.,CONTROL FOR AUTOMATIC HEMATOLOGY ANALYZER (5-PART) (LEVEL 1)-IT IS USED FOR MONITORING OR EVALUATING TEST RESULT ACCURACY OF BF-SERIES AUTOMATIC HEMATOLOGY ANALYZER,CONTROL FOR AUTOMATIC HEMATOLOGY ANALYZER (5-PART) (LEVEL 3)-IT IS USED FOR MONITORING OR EVALUATING TEST RESULT ACCURACY OF BF-SERIES AUTOMATIC HEMATOLOGY ANALYZER,BF-FDO LYSE-FOR THE DISSOLUTION OF RED BLOOD CELLS, DYE OF CELL, CONTENT DETECTION OF LYMPHOCYTE, MONOCYTE, EOSINOPHIL AND NEUTROPHIL,BF-FDT LYSE-FOR THE DISSOLUTION OF RED BLOOD CELLS, DYE OF CELL, CONTENT DETECTION OF LYMPHOCYTE, MONOCYTE, EOSINOPHIL AND NEUTROPHIL,DILUENT-DILUTE BLOOD SAMPLES

980	IMP/IVD/2020/001089	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROL SOLUTION (ALERE G1 CONTROL SOLUTION)-THE CONTROL SOLUTION IS FOR USE WITH THE BLOOD GLUCOSE MONITOR AND TEST STRIPS TO CHECK THAT THE MONITOR AND TEST STRIPS ARE WORKING TOGETHER PROPERLY,BLOOD GLUCOSE TEST STRIP(ALERE G1 BLOOD GLUCOSE TEST STRIP)-IT IS USED WITH AGM-4000, ALERE G1 BLOOD GLUCOSE TEST METER FOR QUANTITATIVELY MEASURING GLUCOSE IN FRESH CAPILLARY, VENOUS WHOLE BLOOD (IN VITRO DIAGNOSTIC USE)
981	IMP/IVD/2020/001090	1.License Holder Name: BIOSCREEN INSTRUMENT PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TANBEAD NUCLEIC ACID EXTRACTION KIT- OPTIPURE VIRAL AUTO PLATE (TAIWAN ADVANCED NANOTECH INC)-1) TANBEAD® NUCLEIC ACID EXTRACTION KIT (REF M665A46) IS SUITABLE FOR ISOLATE NUCLEIC ACID FROM VARIOUS VIRUSES. AUTOMATED NUCLEIC ACID EXTRACTION CAN BE PERFORMED BY MAELSTROM 8 AUTOSTAGE. EXTRACTED NUCLEIC ACIDS CAN BE ANALYZED BY DOWNSTREAM APPLICATION, SUCH AS REAL-TIME PCR, NEXT-GENERATION SEQUENCING. 2) TANBEAD® NUCLEIC ACID EXTRACTION KIT (REF W665A46) IS SUITABLE FOR ISOLATING NUCLEIC ACID FROM VARIOUS VIRUSES. AUTOMATED NUCLEIC ACID EXTRACTION CAN BE PERFORMED BY MAELSTROM 9600. EXTRACTED NUCLEIC ACIDS CAN BE ANALYZED BY DOWNSTREAM APPLICATION, SUCH AS REAL-TIME PCR, NEXT-GENERATION SEQUENCING. 3) TANBEAD NUCLEIC ACIDEXTRACTIONKIT (REF665A46) IS SUITABLE FOR EXTRACT A VARIETY OF VIRAL NUCLEIC ACIDS, THE MOST COMMON IS APPLIED WITH HEPATITIS C VIRUS, HEPATITIS B VIRUS, INFLUENZA VIRUS, ETC. TO USE THIS KITONLY NEED TO MIXSPECIMENS AND PROTEINASE K,THEN FOLLOWED BY TRANSFERRING TO THE AUTOPLATE/TUBE. THROUGH TANBEAD NUCLEIC ACID EXTRACTOR (SLA-16/32,SLA-E132SERIES) TO CONDUCT LYSIS, WASHING AND ELUTION STEPS. IT SPENDS ONLY 40 MINUTES; THE FINAL PRODUCT OF NUCLEIC ACID CAN BE DIRECTLY PROCESS TO ANALYSIS. FOR EXAMPLE: REAL-TIME PCR, RT-PCR WITH HIGH SENSITIVE, THIS REAGENT KIT IS SUITABLE FOR CLINICAL RESEARCH AND INSPECTION UNITS.

982	IMP/IVD/2020/001093	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ATELLICA IM MULTI-DILUENT 14(ATELLICA IM MULTI-DILUENT 14)-THE ATELLICA® IM MULTI-DILUENT 14 IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE RESPECTIVE ASSAY.,ATELLICA IM ANTI-THYROGLOBULIN II (ATGII)(ATELLICA IM ANTI-THYROGLOBULIN II (ATGII))-THE ATELLICA® IM ANTI-THYROGLOBULIN II (ATGII) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF AUTOANTIBODIES AGAINST THYROGLOBULIN IN HUMAN SERUM AND PLASMA (DIPOTASSIUM EDTA, LITHIUM HEPARIN, SODIUM HEPARIN) USING THE ATELLICA® IM ANALYZER. ANTI-THYROGLOBULIN (ATG, TGAB) MEASUREMENTS ARE USED AS AN AID IN THE DIAGNOSIS OF HASHIMOTO'S AND GRAVES' DISEASES, WHICH ARE AUTOIMMUNE DISEASES AFFECTING THE THYROID GLAND.,ATELLICA IM QUANTITATIVE HBSAG (QHBS) QUALITY CONTROL(ATELLICA IM QUANTITATIVE HBSAG (QHBS) QUALITY CONTROL)-THE ATELLICA® IM QUANTITATIVE HBSAG QUALITY CONTROL (QHBS QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PERFORMANCE OF THE ATELLICA IM QHBS ASSAY USING THE ATELLICA® IM ANALYZER., ADVIA CENTAUR QUANTITATIVE HBSAG (QHBS) QUALITY CONTROL (ADVIA CENTAUR QUANTITATIVE HBSAG (QHBS) QUALITY CONTROL) -THE ADVIA CENTAUR® QUANTITATIVE HBSAG (QHBS) QUALITY CONTROL IS FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PERFORMANCE OF THE ADVIA CENTAUR QUANTITATIVE HBSAG (QHBS) ASSAY.,ADVIA CENTAUR® ANTI-THYROGLOBULIN II (ATGII) (ADVIA CENTAUR® ANTI-THYROGLOBULIN II (ATGII))-THE ADVIA CENTAUR® ANTI-THYROGLOBULIN II (ATGII) ASSAY IS FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF AUTOANTIBODIES AGAINST THYROGLOBULIN IN HUMAN SERUM AND PLASMA (DIPOTASSIUM EDTA, LITHIUM HEPARIN, SODIUM HEPARIN) USING THE ADVIA CENTAUR SYSTEMS. ANTI-THYROGLOBULIN (ATG, TGAB) MEASUREMENTS ARE USED AS AN AID IN THE DIAGNOSIS OF HASHIMOTO'S AND GRAVES' DISEASES, WHICH ARE AUTOIMMUNE DISEASES AFFECTING THE THYROID GLAND.,ADVIA CENTAUR® ATGII MASTER CURVE MATERIAL (ATGII MCM)(ADVIA CENTAUR® ATGII MASTER CURVE MATERIAL (ATGII MCM))-THE ADVIA CENTAUR® ATGII MASTER CURVE MATERIAL (ATGII MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND MEASURING INTERVAL OF THE ADVIA CENTAUR ANTI-THYROGLOBULIN II (ATGII) ASSAY.,ADVIA CENTAUR® ATGII QUALITY CONTROL (ATGII QC)(ADVIA CENTAUR® ATGII QUALITY CONTROL (ATGII QC))-THE ADVIA CENTAUR® ATGII QUALITY CONTROL (ATGII

	QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND THE ACCURACY OF THE ADVIA CENTAUR ANTITHYROGLOBIN II (ATGII) ASSAY USING THE ADVIA CENTAUR SYSTEMS.,ATELLICA IM ATGII MASTER CURVE MATERIAL (ATGII MCM)(ATELLICA IM ATGII MASTER CURVE MATERIAL (ATGII MCM))-THE ATELLICA® IM ATGII MASTER CURVE MATERIAL (ATGII MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND MEASURING INTERVAL OF THE ATELLICA IM ANTITHYROGLOBULIN II (ATGII) ASSAY.,ATELLICA IM ATGII QUALITY CONTROL (ATGII QC)(ATELLICA IM ATGII QUALITY CONTROL (ATGII QC))-THE ATELLICA® IM ATGII QUALITY CONTROL (ATGII QC) IS FOR IN VITRO DIAGNOSTIC USE IN MONITORING THE PRECISION AND THE ACCURACY OF THE ATELLICA IM ANTITHYROGLOBIN II (ATGII) ASSAY USING THE ATELLICA® IM ANALYZER.,ATELLICA IM QUANTITATIVE HBSAG (QHBS) MASTER CURVE MATERIAL(ATELLICA IM QUANTITATIVE HBSAG (QHBS) MASTER CURVE MATERIAL)-THE ATELLICA® IM QUANTITATIVE HBSAG MASTER CURVE MATERIAL (QHBS MCM) IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ATELLICA® IM QHBS ASSAY.,ADVIA CENTAUR® QUANTITATIVE HBSAG (QHBS) MASTER CURVE MATERIAL(ADVIA CENTAUR® QUANTITATIVE HBSAG (QHBS) MASTER CURVE MATERIAL)-THE ADVIA CENTAUR® QUANTITATIVE HBSAG (QHBS) MASTER CURVE MATERIAL IS FOR IN VITRO DIAGNOSTIC USE IN THE VERIFICATION OF CALIBRATION AND REPORTABLE RANGE OF THE ADVIA CENTAUR QUANTITATIVE HBSAG (QHBS) ASSAY.,ADVIA CENTAUR MULTI-DILUENT 14(ADVIA CENTAUR MULTI-DILUENT 14)-ADVIA CENTAUR MULTI-DILUENT 14 IS FOR THE DILUTION OF PATIENT SAMPLES ABOVE THE LINEAR RANGE OF THE RESPECTIVE ASSAY.

CENTRAL DRUG STANDARD CONTROL ORGANIZATION
CDSCO
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

983	IMP/IVD/2020/001094	1.License Holder Name: PTS DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE METER-THE SAFE AQ ANGEL BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE (SUGAR) IN CAPILLARY WHOLE BLOOD SAMPLES OBTAINED FROM THE FINGERTIPS AND IN VENOUS WHOLE BLOOD SAMPLES AS AN AID IN MONITORING THE EFFECTIVENESS OF GLUCOSE CONTROL. THE SAFE AQ ANGEL BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO BE USED BY A SINGLE PERSON AND SHOULD NOT BE SHARED. THE SAFE AQ ANGEL BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED FOR IN VITRO DIAGNOSTIC USE (EXTERNAL USE ONLY) AS AN AID IN MONITORING THE EFFECTIVENESS OF GLUCOSE CONTROL. THE SAFE AQ ANGEL BLOOD GLUCOSE MONITORING SYSTEM SHOULD NOT BE USED FOR THE DIAGNOSIS OF OR SCREENING OF DIABETES.,BLOOD GLUCOSE METER-THE SAFE-ACCU 2 BLOOD GLUCOSE MONITORING SYSTEM IS DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD TAKEN FROM THE FINGERTIP OR IN VENOUS WHOLE BLOOD SAMPLES. THE BLOOD GLUCOSE MONITORING SYSTEM IS FOR USE OUTSIDE THE BODY ONLY (IN VITRO DIAGNOSTIC USE) FOR SELF-TESTING AND PROFESSIONAL USE AS AN AID IN THE MANAGEMENT OF DIABETES. THE SAFE-ACCU 2 BLOOD GLUCOSE MONITORING SYSTEM IS FOR IN VITRO DIAGNOSTIC USE ONLY AND SHOULD NOT BE USED FOR THE DIAGNOSIS OR SCREENING OF DIABETES.,BLOOD GLUCOSE METER-THE SAFE AQ SERIES BLOOD GLUCOSE MONITORING SYSTEM IS DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD TAKEN FROM THE FINGERTIP OR IN VENOUS WHOLE BLOOD SAMPLES. THE BLOOD GLUCOSE MONITORING SYSTEM IS FOR USE OUTSIDE THE BODY ONLY (IN VITRO DIAGNOSTIC USE) FOR SELF-TESTING AND PROFESSIONAL USE AS AN AID IN THE MANAGEMENT OF DIABETES. THE SAFE AQ SERIES BLOOD GLUCOSE MONITORING SYSTEM IS FOR IN VITRO DIAGNOSTIC USE ONLY AND SHOULD NOT BE USED FOR THE DIAGNOSIS OR SCREENING OF DIABETES,BLOOD GLUCOSE AND URIC ACID MONITORING SYSTEM-THE SAFE AQ UG BLOOD GLUCOSE AND URIC ACID MONITORING SYSTEM IS DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE AND URIC ACID IN FRESH CAPILLARY WHOLE BLOOD SAMPLES AND IN VENOUS WHOLE BLOOD SAMPLES. THE SAFE AQ UG BLOOD GLUCOSE AND URIC ACID MONITORING SYSTEM IS FOR USE OUTSIDE THE BODY ONLY (IN VITRO DIAGNOSTIC USE) FOR SELF-TESTING OR PROFESSIONAL USE AS AN AID IN THE MANAGEMENT OF DIABETES AND HYPERURICEMIA

	(HUA). THE SAFE AQ UG BLOOD GLUCOSE AND URIC ACID MONITORING SYSTEM IS INTENDED FOR IN VITRO DIAGNOSTIC USE AND SHOULD NOT BE USED FOR THE DIAGNOSIS OF OR SCREENING OF DIABETES AND HYPERURICEMIA (HUA).,BLOOD GLUCOSE METER-THE SAFE-ACCU BLOOD GLUCOSE MONITORING SYSTEM IS DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD TAKEN FROM THE FINGERTIP OR IN VENOUS WHOLE BLOOD SAMPLES. THE BLOOD GLUCOSE MONITORING SYSTEM IS FOR USE OUTSIDE THE BODY ONLY (IN VITRO DIAGNOSTIC USE) FOR SELF-TESTING AND PROFESSIONAL USE AS AN AID IN THE MANAGEMENT OF DIABETES. THE SAFE-ACCU BLOOD GLUCOSE MONITORING SYSTEM IS FOR IN VITRO DIAGNOSTIC USE ONLY AND SHOULD NOT BE USED FOR THE DIAGNOSIS OR SCREENING OF DIABETES.,BLOOD GLUCOSE METER-THE GOLD AQ PLUS BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED FOR USE IN THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN HUMAN WHOLE BLOOD TAKEN FROM THE FINGERTIP (CAPILLARY) OR FROM THE VEIN (VENOUS) OR FROM THE ARTERY (ARTERIAL). IT IS INTENDED TO BE USED BY PEOPLE WITH DIABETES AT HOME OR CLINICAL SITE AS AN AID IN MONITORING THE EFFECTIVENESS OF THEIR DIABETES CONTROL PROGRAMS. THE GOLD AQ PLUS BLOOD GLUCOSE MONITORING SYSTEM IS FOR IN VITRO DIAGNOSTIC USE ONLY.THE GOLD AQ PLUS BLOOD GLUCOSE MONITORING SYSTEM IS NOT INTENDED FOR THE DIAGNOSIS OF, OR SCREENING FOR DIABETES. IT IS NOT INTENDED FOR USE ON NEONATES.,BLOOD GLUCOSE METER-THE DNURSE SP1 BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED FOR USE IN THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN HUMAN WHOLE BLOOD TAKEN FROM THE FINGERTIP (CAPILLARY) OR FROM THE VEIN (VENOUS). IT IS INTENDED TO BE USED BY PEOPLE WITH DIABETES AT HOME OR CLINICAL SITE AS AN AID IN MONITORING THE EFFECTIVENESS OF THEIR DIABETES CONTROL PROGRAMS. IT IS FOR IN VITRO DIAGNOSTIC USE ONLY. IT IS NOT INTENDED FOR THE DIAGNOSIS OR SCREENING OF DIABETES. IT IS NOT INTENDED FOR USE ON NEONATES.,BLOOD GLUCOSE METER-THE SAFE AQ SERIES BLOOD GLUCOSE MONITORING SYSTEM IS DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD TAKEN FROM THE FINGERTIP OR IN VENOUS WHOLE BLOOD SAMPLES. THE BLOOD GLUCOSE MONITORING SYSTEM IS FOR USE OUTSIDE THE BODY ONLY (IN VITRO DIAGNOSTIC USE) FOR SELF-TESTING AND PROFESSIONAL USE AS AN AID IN THE MANAGEMENT OF DIABETES. THE SAFE AQ SERIES BLOOD GLUCOSE MONITORING SYSTEM IS FOR IN VITRO DIAGNOSTIC USE ONLY AND SHOULD NOT BE USED FOR THE DIAGNOSIS OR SCREENING OF DIABETES,URIC ACID TEST STRIP-THE

	SAFE AQ UG URIC ACID TEST STRIP IS USED ONLY WITH SAFE AQ UG BLOOD GLUCOSE AND URIC ACID METER TO QUANTITATIVE DETERMINE URIC ACID IN HUMAN CAPILLARY WHOLE BLOOD SAMPLES OR IN THE VENOUS SAMPLES. IT IS INTENDED FOR USE OUTSIDE THE BODY ONLY (IN VITRO DIAGNOSTIC USE) FOR SELF-TESTING OR PROFESSIONAL USE AS AN AID IN THE MANAGEMENT OF HYPEURICEMIA (HUA).,BLOOD GLUCOSE TEST STRIP-THE DNURSE SP1 BLOOD GLUCOSE TEST STRIP IS FOR USE OUTSIDE THE BODY (IN-VITRO DIAGNOSTIC USE). IT SHOULD NOT BE USED FOR THE DIAGNOSIS OR SCREENING OF DIABETES. THE DNURSE SP1 BLOOD GLUCOSE TEST STRIP IS TO BE USED WITH DNURSE SP1 BLOOD GLUCOSE METER TO QUANTITATIVELY MEASURE GLUCOSE IN HUMAN WHOLE BLOOD TAKEN FROM THE FINGERTIP(CAPILLARY) OR FROM THE VEIN (VENOUS).IT IS INTENDED FOR SELF-TESTING OR PROFESSIONAL USE AS AN AID IN THE MANAGEMENT OF DIABETES. THE TEST STRIPS REQUIRES NO CODING,BLOOD GLUCOSE TEST STRIP-THE SAFE AQ BLOOD GLUCOSE TEST STRIP IS USED ONLY WITH SAFE AQ SMART, SAFE AQ VOICE, SAFE AQ AIR METERS TO QUANTITATIVE DETERMINE GLUCOSE IN HUMAN WHOLE BLOOD TAKEN FROM THE FINGERTIP (CAPILLARY) OR FROM THE VEIN (VENOUS). IT IS INTENDED FOR USE OUTSIDE THE BODY ONLY (IN VITRO DIAGNOSTIC USE) FOR SELF-TESTING OR PROFESSIONAL USE AS AN AID IN THE MANAGEMENT OF DIABETES,BLOOD GLUCOSE TEST STRIP-THE SAFE-ACCU 2 BLOOD GLUCOSE TEST STRIP IS INTENDED TO BE USED WITH THE SAFE-ACCU 2 BLOOD GLUCOSE METER TO QUANTITATIVELY MEASURE GLUCOSE (SUGAR) IN CAPILLARY WHOLE BLOOD SAMPLES DRAWN FROM THE FINGERTIPS OR VENOUS WHOLE BLOOD SAMPLES. THE SAFE-ACCU 2 BLOOD GLUCOSE TEST STRIP IS INTENDED FOR USE BY PEOPLE WITH DIABETES MELLITUS IN THE HOME AND BY HEALTHCARE PROFESSIONALS IN CLINICAL SETTING AS AN AID IN MONITORING THE EFFECTIVENESS OF DIABETES CONTROL.,HBA1C REAGENT KIT-THE HBA1C REAGENT KIT IS DESIGNED TO BE USED WITH THE PCH-100 HBA1C ANALYZER TO QUANTITATIVELY DETERMINE HEMOGLOBIN A1C (HBA1C) IN CAPILLARY (FINGERPRICK) OR VENOUS WHOLE BLOOD. IT IS FOR IN VITRO DIAGNOSTIC USE ONLY. CLINICALLY, IT IS MAINLY USED FOR AUXILIARY DIAGNOSIS OF DIABETES AND MONITORING OF AVERAGE BLOOD GLUCOSE LEVEL.,BLOOD GLUCOSE TEST STRIP-THE SAFE-ACCU BLOOD GLUCOSE MONITORING SYSTEM IS FOR USE OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) AND SHOULD NOT BE USED FOR THE DIAGNOSIS OR SCREENING OF DIABETES. THE SAFE-ACCU BLOOD GLUCOSE TEST STRIP IS INTENDED TO BE USED WITH THE SAFE-ACCU BLOOD GLUCOSE METER TO QUANTITATIVELY MEASURE GLUCOSE (SUGAR) IN CAPILLARY WHOLE BLOOD SAMPLES DRAWN

	FROM THE FINGERTIPS OR VENOUS WHOLE BLOOD SAMPLES. THE SAFE-ACCU BLOOD GLUCOSE TEST STRIP IS INTENDED FOR USE BY PEOPLE WITH DIABETES MELLITUS IN THE HOME AND BY HEALTHCARE PROFESSIONALS IN CLINICAL SETTING AS AN AID IN MONITORING THE EFFECTIVENESS OF DIABETES CONTROL.,BLOOD GLUCOSE TEST STRIP-THE GOLD AQ PLUS BLOOD GLUCOSE TEST STRIP IS FOR USE OUTSIDE THE BODY (IN-VITRO DIAGNOSTIC USE). IT SHOULD NOT BE USED FOR THE DIAGNOSIS OR SCREENING OF DIABETES. THE GOLD AQ PLUS BLOOD GLUCOSE TEST STRIP IS TO BE USED WITH THE GOLD AQ PLUS BLOOD GLUCOSE METER TO QUANTITATIVELY MEASURE GLUCOSE IN HUMAN WHOLE BLOOD TAKEN FROM THE FINGERTIP (CAPILLARY) OR FROM THE VEIN (VENOUS) OR FROM THE ARTERY (ARTERIAL). IT IS INTENDED FOR SELF-TESTING OR PROFESSIONAL USE AS AN AID IN THE MANAGEMENT OF DIABETES. THE TEST STRIPS REQUIRES NO CODING.,BLOOD GLUCOSE TEST STRIP-THE SAFE AQ UG BLOOD GLUCOSE TEST STRIP IS INTENDED TO BE USED WITH THE SAFE AQ UG BLOOD GLUCOSE AND URIC ACID METER TO QUANTITATIVELY MEASURE GLUCOSE (SUGAR) IN CAPILLARY WHOLE BLOOD SAMPLES DRAWN FROM THE FINGERTIPS OR VENOUS WHOLE BLOOD SAMPLES. THE TEST STRIP IS REQUIRED NO CODING. THE SAFE AQ UG BLOOD GLUCOSE TEST STRIP, USED WITH SAFE AQ UG BLOOD GLUCOSE AND URIC ACID METER, IS INTENDED FOR USE BY PEOPLE WITH DIABETES MELLITUS IN THE HOME AND BY HEALTHCARE PROFESSIONALS IN CLINICAL SETTING AS AN AID IN MONITORING THE EFFECTIVENESS OF DIABETES CONTROL. THE SAFE AQ UG BLOOD GLUCOSE TEST STRIP IS INTENDED FOR USE OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) FOR SELF-TESTING OR PROFESSIONAL USE AS AN AID IN MONITORING THE EFFECTIVENESS OF DIABETES CONTROL. THE SAFE AQ UG BLOOD GLUCOSE TEST STRIP SHOULD NOT BE USED FOR THE DIAGNOSIS OF OR SCREENING OF DIABETES.,BLOOD GLUCOSE TEST STRIP-THE SAFE AQ ANGEL BLOOD GLUCOSE MONITORING SYSTEM IS FOR USE OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) AND SHOULD NOT BE USED FOR THE DIAGNOSIS OR SCREENING OF DIABETES. THE SAFE AQ ANGEL BLOOD GLUCOSE TEST STRIP IS INTENDED TO BE USED WITH THE SAFE AQ ANGEL BLOOD GLUCOSE METER TO QUANTITATIVELY MEASURE GLUCOSE (SUGAR) IN CAPILLARY WHOLE BLOOD SAMPLES DRAWN FROM THE FINGERTIPS OR VENOUS WHOLE BLOOD SAMPLES. THE SAFE AQ ANGEL BLOOD GLUCOSE TEST STRIP IS INTENDED FOR USE BY PEOPLE WITH DIABETES MELLITUS IN THE HOME AND BY HEALTHCARE PROFESSIONALS IN CLINICAL SETTING AS AN AID IN MONITORING THE EFFECTIVENESS OF DIABETES CONTROL.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

984	IMP/IVD/2020/001095	1.License Holder Name: WHEECON INSTRUMENTS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMBI 2 TEST STRIPS (MEDI-TEST COMBI 2)-SCREENING TEST FOR DETECTION AND MONITORING OF DIABETES AND DISEASES OF KIDNEY AND URINARY TRACT.,PROTEIN 2 TEST STRIPS(MEDI-TEST PROTEIN 2)-SCREENING TEST FOR DETECTION OF ILLNESSES IN THE AREA OF KIDNEY AND URINARY TRACT.,MICROALBUMIN TEST STRIPS(MEDI-TEST MICROALBUMIN)-SCREENING TEST FOR THE DETECTION OF MICROALBUMINURIA,KETONE TEST STRIPS(MEDI-TEST KETON)-SCREENING TEST FOR DETECTION OF METABOLIC ANOMALIES., COMBI 10 L TEST STRIPS(MEDI-TEST COMBI 10 L)-SCREENING TEST FOR DETECTION OF DIABETES, METABOLIC ABNORMALITIES, LIVER DISEASES, BILIARY AND HEPATIC OBSTRUCTIONS, HEMOLYTIC DISEASES AND DISEASES OF KIDNEY AND URINARY TRACT.,NITRITE TEST STRIPS(MEDI-TEST NITRIT)-SCREENING TEST FOR DETECTION OF ILLNESS IN THE AREA OF KIDNEY AND URINARY TRACT.,COMBI 6A TEST STRIPS(MEDI-TEST COMBI 6A)-SCREENING TEST FOR DETECTION OF DIABETES, METABOLIC ABNORMALITIES, LIVER DISEASES AND DISEASES OF KIDNEY AND URINARY TRACT,CONTROL (MEDI-TEST CONTROL)-CONTROL SOLUTION TO VERIFY THE CORRECT FUNCTIONING OF THE MEDI-TEST URINE TEST STRIPS AND THE URYXXON URINE ANALYSIS SYSTEM.,COMBI 5S TEST STRIPS (MEDI-TEST COMBI 5S)-SCREENING TEST FOR DETECTION OF DIABETES, METABOLIC ABNORMALITIES AND DISEASES OF KIDNEY AND URINARY TRACT,COMBI 8L TEST STRIPS(MEDI-TEST COMBI 8L)-SCREENING TEST FOR DETECTION OF DIABETES AND FOR DETECTING INFECTIONS AND DISEASE OF KIDNEY ANY URINARY TRACT.,COMBI 3A TEST STRIPS(MEDI-TEST COMBI 3A)-SCREENING TEST FOR DETECTION OF DIABETES AND DISEASE OF KIDNEY AND URINARY TRACT.,COMBI 10 SGL TEST STRIPS(MEDI-TEST COMBI 10 SGL)-SCREENING TEST FOR DETECTION OF DIABETES, METABOLIC ABNORMALITIES, LIVER DISEASES, BILIARY AND HEPATIC OBSTRUCTIONS, HEMOLYTIC DISEASES AND DISEASES OF KIDNEY AND URINARY TRACT.,COMBI 11 TEST STRIPS(MEDI-TEST COMBI 11)-SCREENING TEST FOR DETECTION OF DIABETES, METABOLIC ABNORMALITIES, LIVER DISEASES, BILIARY AND HEPATIC OBSTRUCTIONS, HEMOLYTIC DISEASES AND DISEASES OF KIDNEY AND URINARY TRACT.,COMBI 5 TEST STRIPS(MEDI-TEST COMBI 5)-SCREENING TEST FOR DETECTION OF DIABETES AND DISEASE OF KIDNEY AND URINARY TRACT.,URYXXON STICK 10 TEST STRIPS (MEDI-TEST URYXXON STICK 10)-SCREENING TEST FOR DETECTION OF DIABETES, METABOLIC ABNORMALITIES, LIVER DISEASES, BILIARY AND HEPATIC OBSTRUCTIONS, HEMOLYTIC DISEASES AND

		DISEASES OF KIDNEY AND URINARY TRACT.,COMBI 5N TEST STRIPS (MEDI-TEST COMBI 5N)-SCREENING TEST FOR EARLY DETECTION AND SUPERVISION OF DIABETES AND FOR DETECTING INFECTIONS AND DISEASE OF KIDNEY AND URINARY TRACT,COMBI 10 TEST STRIPS(MEDI-TEST COMBI 10)-SCREENING TEST FOR DETECTION OF DIABETES, METABOLIC ABNORMALITIES, LIVER DISEASES, BILIARY AND HEPATIC OBSTRUCTIONS, HEMOLYTIC DISEASES AND DISEASES OF KIDNEY AND URINARY TRACT.,GLUCOSE/ KETONE TEST STRIPS (MEDI-TEST GLUCOSE/ KETON)-SCREENING TEST FOR EARLY DETECTION AND MONITORING OF DIABETES AND METABOLIC ANOMALIES,GLUCOSE TEST STRIPS(MEDI-TEST)-SCREENING TEST FOR EARLY DETECTION AND MONITORING OF DIABETES AND METABOLIC ABNORMALITIES. THE TEST IS INTENDED FOR PROFESSIONAL USE AND FOR SELF-TESTING.,COMBI 7L TEST STRIPS (MEDI-TEST COMBI 7L)-SCREENING TEST FOR DETECTION OF DIABETES, METABOLIC ABNORMALITIES AND DISEASE OF KIDNEY ANY URINARY TRACT.,URBI TEST STRIPS(MEDI-TEST URBI)-SCREENING TEST FOR DETECTION OF LIVER DISEASES, BILIARY AND HEPATIC OBSTRUCTIONS AND HEMOLYTIC DISEASES.,COMBI 9 TEST STRIPS(MEDI-TEST COMBI 9)-SCREENING TEST FOR DETECTION OF DIABETES, METABOLIC ABNORMALITIES, LIVER DISEASES, BILIARY AND HEPATIC OBSTRUCTIONS, HEMOLYTIC DISEASES AND DISEASES OF KIDNEY AND URINARY TRACT.,COMBI 7 TEST STRIPS(MEDI-TEST COMBI 7)-SCREENING TEST FOR DETECTION OF DIABETES AND FOR DETECTING INFECTIONS AND DISEASE OF KIDNEY AND URINARY TRACT.
985	IMP/IVD/2020/001096	1.License Holder Name: SPARKLABS DIAGNOSTICS LLP INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QUANTITATIVE VITAMIN D TEST(SPARK D)-SPARK DIAGNOSTICS SPARK-D QUANTITATIVE VITAMIN D TESTIS AN IMMUNOCHROMATOGRAPHY-BASED ONE STEP IN VITRO TEST. IT IS DESIGNED FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25-HYDROXY VITAMIN D (25-OH VITAMIN D) IN HUMAN FINGER-PRICK BLOOD OR SERUM. THIS ASSAY PROVIDES A PRELIMINARY DIAGNOSTIC TEST RESULT AND CAN BE USED FOR SCREENING OF VITAMIN D DEFICIENCY.

986	IMP/IVD/2020/001100	1.License Holder Name: SYNDICATE DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STA-CLEANER SOLUTION (STA-CLEANER SOLUTION)-STA-CLEANER SOLUTION IS A READY FOR USE WASHING SOLUTION INTENDED TO BE USED WITH THE ANALYZERS OF THE STA LINE. WHEN THE BOTTLE IS EMPTY, IT IS USED FOR THE COLLECTION OF POTENTIALLY BIOHAZARDOUS WASTER LIQUIDS.
987	IMP/IVD/2020/001101	1.License Holder Name: THERMO FISHER SCIENTIFIC INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CRYOGENIC TUBE (NALGENE™)-THESE POLYPROPYLENE TUBES ARE INTENDED FOR USE IN CRYOGENIC STORAGE AND INTER-LABORATORY GROUND TRANSPORTATION OF SPECIMENS (INCLUDING BUT NOT LIMITED TO BLOOD /PLASMA/ SERUM, URINE, AND SALIVA) TAKEN FROM THE HUMAN BODY FOR IN VITRO DIAGNOSTIC (IVD) EXAMINATION. THEY CAN BE USED TO STORE SAMPLES DOWN TO VAPOR PHASE OF LIQUID NITROGEN TEMPERATURES. THE TUBES ARE MADE AS A DISPOSABLE AND ARE FOR SINGLE USE ONLY.

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988	IMP/IVD/2020/001102	1.License Holder Name: KHC HEALTHCARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FSH ELISA(FSH ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE IN HUMAN SERUM.,CRP HIGH SENSITIVE ELISA(CRP HIGH SENSITIVE ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE HIGH SENSITIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM AND PLASMA.,METANEPHRINE ELISA(METANEPHRINE ELISA)-ENZYME IMMUNOASSAY FOR THE IN-VITRO DIAGNOSTIC QUANTITATIVE DETERMINATION OF METANEPHRINE IN HUMAN URINE.,BETA-HCG, FREE ELISA(BETA-HCG, FREE ELISA)-ENZYME IMMUNOASSAYS FOR THE QUANTITATIVE DETERMINATION OF FREE BETA-HCG CHAIN IN HUMAN SERUM,LH ELISA(LH ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE IN HUMAN SERUM,MUMPS VIRUS (PAROTITIS) IGM ELISA(MUMPS VIRUS (PAROTITIS) IGM ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGM ANTIBODIES AGAINST MUMPS VIRUS IN HUMAN SERUM AND PLASMA.,PROLACTIN ELISA(PROLACTIN ELISA)-ENZYRNE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM.,ECHINOCOCCUS IGG ELISA (ECHINOCOCCUS IGG ELISA)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST ECHINOCOCCUS IN HUMAN SERUM AND PLASMA.,DHEA ELISA(DHEA ELISA)-ENZYME IMMUNOASSAY FOR THE IN-VITRO DIAGNOSTIC QUANTITATIVE DETERMINATION OF DHEA IN HUMAN SERUM.,MYCOPLASMA PNEUMONIAE IGG ELISA (MYCOPLASMA PNEUMONIAE IGG ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST MYCOPLASMA PNEUMONIAE IN HUMAN SERUM AND PLASMA.,MELATONIN ELISA (MELATONIN ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MELATONIN IN HUMAN SERUM AND PLASMA.,1,25-DIHYDROXY-VITAMIN D ELISA(1,25-DIHYDROXY-VITAMIN D ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 1,25-DIHYDROXY-VITAMIN D IN HUMAN SERUM., EPSTEIN-BARR VIRUS VCA IGM MICROCAPTURE ELISA(EPSTEIN-BARR VIRUS VCA IGM MICROCAPTURE ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGM ANTIBODIES AGAINST VIRAL CAPSID ANTIGEN (VCA) OF EPSTEIN-BARR VIRUS IN HUMAN SERUM AND PLASMA.,RF-ABSORBENT(RF-ABSORBENT)-TO BE USED WITH INFECTIOUS DISEASE IGM ELISAS, ESTRIOL, FREE ELISA(ESTRIOL, FREE ELISA)-ENZYME IMMUNOASSAY

	FOR THE QUANTITATIVE DETERMINATION OF UNCONJUGATED ESTRIOL IN HUMAN SERUM.,NORMETANEPHRINE ELISA (NORMETANEPHRINE ELISA)-ENZYME IMMUNOASSAY FOR THE IN-VITRO DIAGNOSTIC QUANTITATIVE DETERMINATION OF NORMETANEPHRINE IN HUMAN URINE.,METCOMBI PLASMA ELISA (METCOMBI PLASMA ELISA)-ENZYME IMMUNOASSAYS FOR THE QUANTITATIVE DETERMINATION OF FREE METANEPHRINE AND NORMETANEPHRINE IN HUMAN PLASMA,5-HIAA ELISA(5-HIAA ELISA) -ENZYME IMMUNOASSAY FOR THE IN-VITRO DIAGNOSTIC QUANTITATIVE DETERMINATION OF 5-HIAA IN HUMAN URINE., ERYTHROPOIETIN ELISA(ERYTHROPOIETIN ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ERYTHROPOIETIN (EPO) IN HUMAN SERUM.,ASPERGILLUS FUMIGATUS IGG ELISA(ASPERGILLUS FUMIGATUS IGG ELISA)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST ASPERGILLUS FUMIGATUS IN HUMAN SERUM AND PLASMA.,TETANUS IGG ELISA (TETANUS IGG ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST TETANUS IN HUMAN SERUM AND PLASMA.,ADENOVIRUS IGG ELISA(ADENOVIRUS IGG ELISA)-ENZYME IMMUNOASSAYS (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF LGG ANTIBODIES AGAINST THE ADENOVIRUS IN HUMAN SERUM AND PLASMA,FREE TESTOSTERONE ELISA(FREE TESTOSTERONE ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE IN HUMAN SERUM.,5ALPHA-DIHYDROTESTOSTERONE ELISA(5ALPHA-DIHYDROTESTOSTERONE ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 5ALPHA-DIHYDROTESTOSTERONE IN HUMAN SERUM.,17BETA-ESTRADIOL ELISA(17BETA-ESTRADIOL ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 17BETA-ESTRADIOL IN HUMAN SERUM AND PLASMA.,HISTAMINE ELISA(HISTAMINE ELISA)-ENZYME IMMUNOASSAYS FOR THE QUANTITATIVE DETERMINATION OF HISTAMINE IN HUMAN PLASMA. URINE AND EDTA WHOLE BLOOD FOR RESEARCH OF CELL CULTURE SUPERNATANTS.,HCG+BETA ELISA (HCG+BETA ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUANTITATIVE DETERMINATION OF HCG AND HCG-B IN HUMAN SERUM,POLIOVIRUS IGG ELISA(POLIOVIRUS IGG ELISA)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST POLIOVIRUS IN HUMAN SERUM AND PLASMA.,17-OH-PROGESTERONE ELISA(17-OH-PROGESTERONE ELISA)-ENZYME IMMUNOASSAY FOR THE IN-VITRO DIAGNOSTICS QUANTITATIVE DETERMINATION OF 17-

	OHPROGESTERONE IN HUMAN SERUM AND PLASMA., ANDROSTENEDIONE ELISA(ANDROSTENEDIONE ELISA)-ENZYME IMMUNOASSAY FOR THE DIRECT QUANTITATIVE DETERMINATION OF ANDROSTENEDIONE IN HUMAN SERUM.,MUMPS VIRUS (PAROTITIS) IGG ELISA(MUMPS VIRUS (PAROTITIS) IGG ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST MUMPS VIRUS IN HUMAN SERUM AND PLASMA.,ALDOSTERONE ELISA (ALDOSTERONE ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ALDOSTERONE IN HUMAN SERUM, PLASMA AND URINE.,INSULIN ELISA(INSULIN ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM AND PLASMA (HEPARIN- OR EDTA PLASMA).,CORTISOL ELISA(CORTISOL ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM AND PLASMA.,NORADRENALIN ELISA (NORADRENALIN ELISA)-MANUAL AND AUTOMATED ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF NORADRENALIN (NOREPINEPHRINE) IN HUMAN PLASMA AND URINE., EPSTEIN-BARR VIRUS EBNA-1 IGG ELISA(EPSTEIN-BARR VIRUS EBNA-1 IGG ELISA)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST THE EPSTEIN-BARR VIRUS NUCLEAR ANTIGEN (EBNA-1) IN HUMAN SERUM AND PLASMA.,ENTAMOEBA HISTOLYTICA IGG ELISA(ENTAMOEBA HISTOLYTICA IGG ELISA)-ENZYME IMMUNOASSAY FOR THE IN-VITRO DIAGNOSTIC QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST ENTAMOEBA HISTOLYTICA IN HUMAN SERUM AND PLASMA.,BORRELIA + VISE IGG ELISA(BORRELIA + VISE IGG ELISA)-ENZYME IMMUNOASSAY FOR THE IN-VITRO DIAGNOSTIC FOR THE QUALITATIVE OR QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST BORRELIA BURGDORFERI IN HUMAN SERUM, PLASMA AND CSF. INFECTIONS WITH ALL THREE B. BURGDORFERI SUBSPECIES (GARINIL, AFZELII AND SENSU STRICTU) ARE DETECTED.,PARATHYROID HORMONE INTACT ELISA(PARATHYROID HORMONE INTACT ELISA)-SPECIFIC QUANTITATIVE ASSAY FOR THE DETERMINATION OF INTACT PARATHYROID HORMONE IN HUMAN SERUM,RESPIRATORY SYNCYTIAL VIRUS IGG ELISA(RESPIRATORY SYNCYTIAL VIRUS IGG ELISA)-ENZYME IMMUNOASSAYS (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF LGG ANTIBODIES AGAINST THE RESPIRATORY SYNCYTIAL VIRUS (RSV) IN HUMAN SERUM AND PLASMA,EPSTEIN-BARR VIRUS VCA IGM ELISA(EPSTEIN-BARR VIRUS VCA IGM ELISA)-ENZYME IMMUNOASSAYS (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF LGM

	ANTIBODIES AGAINST THE VIRAL CAPSID ANTIGEN (VGA) OF EPSTEIN-BARR VIRUS IN HUMAN SERUM AND PLASMA, CORTICOSTERONE (HUMAN, RAT, MOUSE) ELISA(CORTICOSTERONE (HUMAN, RAT, MOUSE) ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CORTICOSTERONE IN HUMAN SERUM AND PLASMA.,EPSTEIN-BARR VIRUS VCA IGG ELISA(EPSTEIN-BARR VIRUS VCA IGG ELISA)-ENZYME IMMUNOASSAYS (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF LGG ANTIBODIES AGAINST THE VIRAL CAPSID ANTIGEN (VGA) OF EPSTEIN-BARR VIRUS IN HUMAN SERUM AND PLASMA,DIPHTHERIA IGG ELISA(DIPHTHERIA IGG ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST DIPHTHERIA IN HUMAN SERUM AND PLASMA.,BETA 2 MICROGLOBULIN ELISA(BETA 2 MICROGLOBULIN ELISA)-ENZYME IMMUNOASSAY FOR THE DIRECT QUANTITATIVE DETERMINATION OF BETA 2- MICROGLOBULIN IN HUMAN SERUM.,CORTISOL URINE ELISA (CORTISOL URINE ELISA)-ENZYME IMMUNOASSAYS FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN URINE., PROGESTERONE ELISA(PROGESTERONE ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM AND PLASMA.,EPSTEIN-BARR VIRUS VCA IGA ELISA(EPSTEIN-BARR VIRUS VCA IGA ELISA)-ENZYME IMMUNOASSAYS (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF LGA ANTIBODIES AGAINST THE VIRAL CAPSID ANTIGEN (VGA) OF EPSTEIN-BARR VIRUS IN HUMAN SERUM AND PLASMA,CHROMOGRANIN A ELISA(CHROMOGRANIN A ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHROMOGRANIN A IN HUMAN SERUM AND PLASMA (EDTA).,PARVOVIRUS B19 IGG ELISA(PARVOVIRUS B19 IGG ELISA)-ENZYME IMMUNOASSAY FOR THE IN-VITRO DIAGNOSTIC QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST PARVOVIRUS B19 IN HUMAN SERUM AND PLASMA.,BRUCELLA IGM ELISA(BRUCELLA IGM ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGM ANTIBODIES AGAINST BRUCELLA IN HUMAN SERUM AND PLASMA.,ADENOVIRUS IGM ELISA(ADENOVIRUS IGM ELISA)-ENZYME IMMUNOASSAYS (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF LGM ANTIBODIES AGAINST THE ADENOVIRUS IN HUMAN SERUM AND PLASMA,CANDIDA ALBICANS IGM ELISA(CANDIDA ALBICANS IGM ELISA)-ENZYME IMMUNOASSAYS FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF LGM ANTI -BODIES AGAINST CANDIDA ALBICANS IN HUMAN SERUM AND PLASMA.,ASPERGILLUS FUMIGATUS IGA ELISA(ASPERGILLUS FUMIGATUS IGA ELISA)-ENZYME IMMUNOASSAYS FOR THE

	QUALITATIVE AND QUANTITATIVE DETERMINATION OF LGA ANTI BODIES AGAINST ASPERGILLUS FUMIGATUS IN HUMAN SERUM AND PLASMA,SPERMATOZOA-AB ELISA(SPERMATOZOA-AB ELISA)-ENZYME IMMUNOASSAY FOR THE IN-VITRO DIAGNOSTIC QUANTITATIVE DETERMINATION OF AUTOANTIBODIES AGAINST SURFACE ANTIGENS OF SPERMATOZOA IN HUMAN SERUM.,MEASLES VIRUS IGG ELISA(MEASLES VIRUS IGG ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST MEASLES VIRUS IN HUMAN SERUM AND PLASMA.,MYCOPLASMA PNEUMONIAE IGM ELISA(MYCOPLASMA PNEUMONIAE IGM ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGM ANTIBODIES AGAINST MYCOPLASMA PNEUMONIAE IN HUMAN SERUM AND PLASMA.,MEASLES VIRUS IGM ELISA(MEASLES VIRUS IGM ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGM ANTIBODIES AGAINST MEASLES VIRUS IN HUMAN SERUM AND PLASMA.,EPSTEIN-BARR VIRUS EBNA-1 IGM ELISA(EPSTEIN-BARR VIRUS EBNA-1 IGM ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGM ANTIBODIES AGAINST THE EPSTEIN-BARR VIRUS NUCLEAR ANTIGEN (EBNA-1) IN HUMAN SERUM AND PLASMA.,CANDIDA ALBICANS IGG ELISA(CANDIDA ALBICANS IGG ELISA)-ENZYME IMMUNOASSAYS FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF LGG ANTIBODIES AGAINST CANDIDA ALBICANS IN HUMAN SERUM AND PLASMA.,HERPES SIMPLEX VIRUS 1/2 IGM ELISA(HERPES SIMPLEX VIRUS 1/2 IGM ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGM ANTIBODIES AGAINST HERPES SIMPLEX VIRUS 1 AND 2 IN HUMAN SERUM AND PLASMA., BRUCELLA IGG ELISA(BRUCELLA IGG ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST BRUCELLA IN HUMAN SERUM AND PLASMA.,TAENIA SOLIUM IGG ELISA(TAENIA SOLIUM IGG ELISA)-ENZYME IMMUNOASSAY FOR THE IN-VITRO DIAGNOSTIC QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST TAENIA SOLIUM IN HUMAN SERUM AND PLASMA.,HERPES SIMPLEX VIRUS 1/2 IGG ELISA(HERPES SIMPLEX VIRUS 1/2 IGG ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST HERPES SIMPLEX VIRUS 1 AND 2 IN HUMAN SERUM AND PLASMA., HELICOBACTER PYLORI IGA ELISA(HELICOBACTER PYLORI IGA ELISA)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND

	QUANTITATIVE DETERMINATION OF IGA ANTIBODIES AGAINST HELOCOBACTER PYLORI IN HUMAN SERUM AND PLASMA., PARVOVIRUS B19 IGM ELISA(PARVOVIRUS B19 IGM ELISA)-ENZYME IMMUNOASSAY FOR THE IN-VITRO DIAGNOSTIC QUANTITATIVE DETERMINATION OF IGM ANTIBODIES AGAINST PARVOVIRUS B19 IN HUMAN SERUM AND PLASMA.,PHOSPHOLIPID IGG/IGM SCREEN ELISA (PHOSPHOLIPID IGG/IGM SCREEN ELISA)-ENZYME IMMUNOASSAY FOR THE SEPRATE QUANTITATIVE AND QUALITATIVE DETECTION OF IGG AND/OR IGM ANTIBODIES AGAINST PHOSPHOLIPIDS IN HUMAN SERUM.,CATCOMBI ELISA(CATCOMBI ELISA)-MANUAL AND AUTOMATED ENZYME IMMUNOASSAY FOR THE IN-VITRO-DIAGNOSTICS QUANTITATIVE DETERMINATION OF ADRENALIN AND NORADRENALIN IN HUMAN PLASMA AND URINE.,ADRENALIN ELISA (ADRENALIN ELISA)-MANUAL AND AUTOMATED ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ADRENALIN IN HUMAN PLASMA AND URINE.,TRICAT TM ELISA (TRICAT TM ELISA)-MANUAL AND AUTOMATED ENZYME IMMUNOASSAY FOR THE IN-VIRO DIAGNOSTIC QUANTITATIVE DETERMINATION OF ADRENALIN, NORADRENALIN AND DOPAMINE IN HUMAN PLASMA AND URINE.,MUSK-AB ELISA(MUSK-AB ELISA)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF AUTOANTIBODIES AGAINST MUSCLE-SPECIFIC RECEPTOR TYROSINE KINASE (MUSK) IN HUMAN SERUM., MELATONIN-SULFATE URINE ELISA(MELATONIN-SULFATE URINE ELISA)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF MELATONIN-SULFATE (SYNONYMS: 6-HYDROXYMELATONIN SULFATE, 6-SULFATOXYMELATONIN) IN HUMAN URINE.,BORRELIA 14KDA + OSPC IGM ELISA(BORRELIA 14KDA + OSPC IGM ELISA)-ENZYME IMMUNOASSAY FOR THE IN-VITRO DIAGNOSTIC QUALITATIVE OR QUANTITATIVE DETERMINATION OF IGM ANTIBODIES AGAINST 14 KDA AND OSPC ANTIGENS OF BORRELIA BURGDORFERI IN HUMAN SERUM, PLASMA AND CSF. INFECTIONS WITH ALL THREE B. BURGDORFERI SUBSPECIES (GARINIL, AFZELII AND SENSU STRICTU) ARE DETECTED., BORDETELLA PERTUSSIS IGG ELISA(BORDETELLA PERTUSSIS IGG ELISA)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST BORDETELLA PERTUSSIS IN HUMAN SERUM AND PLASMA., HELICOBACTER PYLORI IGM ELISA(HELICOBACTER PYLORI IGM ELISA)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGM ANTIBODIES AGAINST HELOCOBACTER PYLORI IN HUMAN SERUM AND PLASMA., HELICOBACTER PYLORI IGG ELISA(HELICOBACTER PYLORI IGG ELISA)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND

	QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST HELOCOBACTER PYLORI IN HUMAN SERUM AND PLASMA.,DOPAMINE ELISA(DOPAMINE ELISA)-MANUAL AND AUTOMATED ENZYME IMMUNOASSAY FOR THE IN-VITRO DIAGNOSTIC QUANTITATIVE DETERMINATION OF DOPAMINE IN HUMAN PLASMA AND URINE., VARICELLA ZOSTER VIRUS IGM ELISA(VARICELLA ZOSTER VIRUS IGM ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGM ANTIBODIES AGAINST VARICELLA ZOSTER VIRUS IN HUMAN SERUM AND PLASMA.,EPSTEIN-BARR VIRUS EA IGG ELISA(EPSTEIN-BARR VIRUS EA IGG ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST THE "EARLY ANTIGEN" (EA) OF EPSTEIN-BARR VIRUS IN HUMAN SERUM AND PLASMA.,ASPERGILLUS FUMIGATUS IGM ELISA(ASPERGILLUS FUMIGATUS IGM ELISA)-ENZYME IMMUNOASSAY FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGM ANTIBODIES AGAINST ASPERGILLUS FUMIGATUS IN HUMAN SERUM AND PLASMA.,VARICELLA ZOSTER VIRUS IGG ELISA(VARICELLA ZOSTER VIRUS IGG ELISA)-ENZYME IMMUNOASSAY (MICROTITER STRIPS) FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST VARICELLA ZOSTER VIRUS IN HUMAN SERUM AND PLASMA.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

989	IMP/IVD/2020/001104	1.License Holder Name: DIASYS DIAGNOSTIC INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLINICAL CHEMISTRY - ELECTROLYTES(MAGNESIUM XL FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF MAGNESIUM IN SERUM, PLASMA, CEREBROSPINAL FLUID OR URINE ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF MAGNESIUM IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920,OTHER CLINICAL CHEMISTRY BUFFERS (UNASSIGNABLE), SUPPLEM. REAGENTS, ETC. (CC)(CLEANER A)-ACIDIC CLEANING SOLUTION,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY(TRUCAL D-DIMER)-CALIBRATOR FOR THE DIASYS TEST FOR QUANTITATIVE IN VITRO DETERMINATION OF D-DIMER ON PHOTOMETRIC SYSTEMS., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRULAB BICARBONATE)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY(ETHANOL STANDARD FS (2.0 MG/ML))-AQUEOUS STANDARD SOLUTIONS IN DIFFERENT CONCENTRATIONS, IMMUNOCHEMISTRY (IMMUNOLOGY) / SP. PROTEINS(PREALBUMIN FS)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PREALBUMIN IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PREALBUMIN IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,CLINICAL CHEMISTRY - ENZYMES(ASAT (GOT) FS (IFCC MOD.))-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ASAT (GOT) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ASAT (GOT) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS ®920. ,IMMUNOCHEMISTRY (IMMUNOLOGY) / SP. PROTEINS(CYSTATIN C FS) -REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CYSTATIN C IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CYSTATIN C IN SERUM AND PLASMA ON DIASYS RE-SPONS®910 AND DIASYS RE-SPONS®920.,CLINICAL CHEMISTRY - SUBSTRATES(UREA FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF UREA IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF UREA IN SERUM, PLASMA OR URINE ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,OTHER

	CLINICAL CHEMISTRY BUFFERS (UNASSIGNABLE), SUPPLEM. REAGENTS, ETC. (CC)(GLUCOSE HEMOLYZING SOLUTION)-DIAGNOSTIC REAGENT FOR IN VITRO DETERMINATION OF GLUCOSE WITH THE GLUCOSE DEHYDROGENASE METHOD (GLUC-DH) IN HEMOLYSATE ON PHOTOMETRIC SYSTEMS,CLINICAL CHEMISTRY - ENZYMES(ALPHA HBDH FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF -HBDH IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY(TRULAB CRP HS LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP).,CLINICAL CHEMISTRY - ENZYMES(GAMMA-GT FS (SZASZ MOD. /IFCC))-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GAMMA-GLUTAMYLTRANSFERASE (GAMMA-GT) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GAMMA-GLUTAMYLTRANSFERASE (GAMMA-GT) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920, IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL CRP 150)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF C REACTIVE PROTEIN (CRP) ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / ANEMIA(FERRITIN SR)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF FERRITIN IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRULAB HBA1C NET LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF HEMOGLOBIN A1C (HBA1C).,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRULAB ALBUMIN U/CSF LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN URINE., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRULAB PROTEIN LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS SERUM PROTEINS.,CLINICAL CHEMISTRY - SUBSTRATES(LDL-C SELECT FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE

	IN VITRO DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY(TRULAB PCT LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING THE ANALYTICAL PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF PROCALCITONIN.,CLINICAL CHEMISTRY - SUBSTRATES(HDL-C IMMUNO FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920. ,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (ETHANOL STANDARD FS (0.5MG/ML))-AQUEOUS STANDARD SOLUTIONS IN DIFFERENT CONCENTRATIONS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY(TRULAB CYSTATIN C LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF CYSTATIN C.,CLINICAL CHEMISTRY - SUBSTRATES(GLUCOSE GOD FS 10')-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,CLINICAL CHEMISTRY - SUBSTRATES(UREA CT FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF UREA IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS,IMMUNOCHEMISTRY (IMMUNOLOGY) / SP. PROTEINS(IMMUNOGLOBULIN M FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,IMMUNOCHEMISTRY (IMMUNOLOGY) / RHEUMATOID (CRP IS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN WHOLE BLOOD AND PLASMA ON INNOVASTAR®.,CLINICAL CHEMISTRY - SUBSTRATES(BILIRUBIN AUTO TOTAL FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILIRUBIN IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC

	REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILIRUBIN IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL CRP HIGH)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF C REACTIVE PROTEIN (CRP) ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY - SUBSTRATES(GLUCOSE/HEMOGLOBIN IS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE AND TOTAL HEMOGLOBIN IN WHOLE BLOOD ON INNOVASTAR®., IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL PCT)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF PROCALCITONIN (PCT) ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL LP(A) 21)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPOPROTEIN (A) [LP (A)] ON PHOTOMETRIC SYSTEMS.,OTHER CLINICAL CHEMISTRY BUFFERS (UNASSIGNABLE), SUPPLEM. REAGENTS, ETC. (CC) (CLEANER B)-ALKALINE CLEANING SOLUTION, CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (CREATININE STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS, CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (BICARBONATE STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE/TOTAL CO2 IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS., IMMUNOCHEMISTRY (IMMUNOLOGY) / SEPSIS(PROCALCITONIN FS)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PROCALCITONIN (PCT) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY - SUBSTRATES(ALBUMIN FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS ®920., IMMUNOCHEMISTRY (IMMUNOLOGY) / SP. PROTEINS(TRANSFERRIN FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TRANSFERRIN (TRF) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TRANSFERRIN (TRF) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,

	CLINICAL CHEMISTRY - ENZYMES(ALKALINE PHOSPHATASE FS IFCC 37°C)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALKALINE PHOSPHATASE (AP) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALKALINE PHOSPHATASE (AP) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS ®920., CONTROLS/STANDARDS/CALIBRATORS/ CLINICAL CHEMISTRY (TRUCAL CK-MB)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF CK-MB ACTIVITY ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY - ENZYMES(LDH FS IFCC)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LACTATE DEHYDROGENASE (LDH) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LACTATE DEHYDROGENASE (LDH) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,CLINICAL CHEMISTRY - SUBSTRATES(GLUCOSE HEXOKINASE FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE IN SERUM, PLASMA OR URINE ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL FERRITIN SR)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF FERRITIN ON AUTOMATED PHOTOMETRIC SYSTEMS,IMMUNOCHEMISTRY (IMMUNOLOGY) / SP. PROTEINS(D-DIMER FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF D-DIMER IN PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF D-DIMER IN PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TOTAL PROTEIN UC STANDARD FS)-STANDARD FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTEIN IN URINE OR CEREBROSPINAL FLUID ON PHOTOMETRIC SYSTEMS, IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL RF)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF RHEUMATOID FACTOR (RF) ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY - ENZYMES (CHOLINESTERASE FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHOLINESTERASE (CHE) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR

	QUANTITATIVE IN VITRO DETERMINATION OF CHOLINESTERASE (CHE) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY)(PHOSPHOLIPIDS FS STANDARD)-STANDARD FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF PHOSPHOLIPIDS ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / SP. PROTEINS(IMMUNOGLOBULIN G FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920 ,CALIBRATORS AND STANDARDS (CLINICAL CHEMISTRY)(TRUCAL LIPID)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPIDS AND LP-PLA2 ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL CRP U)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF C REACTIVE PROTEIN (CRP) ON PHOTOMETRIC SYSTEMS., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (NEFA STANDARD)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF NON-ESTERIFIED FATTY ACIDS (NEFA) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY - SUBSTRATES(UIBC FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF THE UNSATURATED IRON BINDING CAPACITY IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF THE UNSATURATED IRON BINDING CAPACITY IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,CLINICAL CHEMISTRY - ELECTROLYTES(PHOSPHATE FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PHOSPHORUS IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PHOSPHORUS IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920, IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL CRP HS)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF C REACTIVE PROTEIN (CRP) ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY - SUBSTRATES(URIC ACID FS TBHBA)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS.,

	CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRULAB URINE LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES,IMMUNOCHEMISTRY (IMMUNOLOGY) / SP. PROTEINS(IMMUNOGLOBULIN A FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,CLINICAL CHEMISTRY - SUBSTRATES(GLUCOSE GOD FS 5')-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL ASO)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF ANTISTREPTOLYSIN O (ASO) ON PHOTOMETRIC SYSTEMS,IMMUNOCHEMISTRY (IMMUNOLOGY) / RHEUMATOID(RHEUMATOID FACTOR FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF RHEUMATOID FACTOR (RF) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEM. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF RHEUMATOID FACTOR (RF) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920. ,CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY)(ALBUMIN STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRULAB N)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES.,CLINICAL CHEMISTRY - SUBSTRATES(TRIGLYCERIDES FS 5')-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDES IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY - ENZYMES(LP-PLA2 FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LP-PLA2 (LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2) IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LP-PLA2 (LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2) IN SERUM AND PLASMA ON DIASYS RESPONS®910,IMMUNOCHEMISTRY (IMMUNOLOGY) / SP. PROTEINS(APOLIPOPROTEIN A1 FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO

	DETERMINATION OF APOLIPOPROTEIN A1 (APO A1) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF APOLIPOPROTEIN A1 (APO A1) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRULAB D-DIMER LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING THE ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF D-DIMER.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY(TRUCAL CYSTATIN C)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF CYSTATIN C ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY – SUBSTRATES(GLUCOSE GLUC-DH FS)-DIAGNOSTIC REAGENT FOR IN VITRO DETERMINATION OF GLUCOSE WITH THE GLUCOSE DEHYDROGENASE METHOD (GLUC-DH) ON PHOTOMETRIC SYSTEMS. , CLINICAL CHEMISTRY - SUBSTRATES(TOTAL PROTEIN UC FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTEIN IN URINE OR CEREBROSPINAL FLUID ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTEIN IN URINE OR CEREBROSPINAL FLUID ON DIASYS RESPONS®910 ., CLINICAL CHEMISTRY - SUBSTRATES(NEFA FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF NON-ESTERIFIED FATTY ACIDS (NEFA) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF NON-ESTERIFIED FATTY ACIDS (NEFA) IN SERUM OR PLASMA ON DIASYS RESPONS®910, IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL ALBUMIN U/CSF HIGH)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN URINE AND CSF ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY(TRULAB ALBUMIN U/CSF LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN URINE.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL CRP)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF C REACTIVE PROTEIN (CRP) ON PHOTOMETRIC SYSTEMS.,OTHER CLINICAL CHEMISTRY BUFFERS (UNASSIGNABLE), SUPPLEM. REAGENTS, ETC. (CC)(ONE HBA1C HEMOLYZING SOLUTION)-HEMOLYZING SOLUTION FOR

	QUANTITATIVE IN VITRO DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN WHOLE BLOOD ON PHOTOMETRIC SYSTEMS, CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (CALCIUM STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / DIABETES ASSAYS(ONE HBA1C IS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HEMOGLOBIN A1C IN WHOLE BLOOD ON INNOVASTAR®, CONTROLS/STANDARDS/CALIBRATORS/ CLINICAL CHEMISTRY (TRUCAL G6PDH)-CALIBRATOR SET FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PDH) IN ERYTHROCYTES ON PHOTOMETRIC SYSTEMS., IMMUNOCHEMISTRY (IMMUNOLOGY) / RHEUMATOID(CRP U-HS FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRULAB CRP LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING THE ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP)., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (ATP STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ATP IN BLOOD AND ERYTHROCYTE CONCENTRATES WITH HEXOKINASE METHOD ON PHOTOMETRIC SYSTEMS.,CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY)(TRULAB URINE LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRUCAL TBA)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILE ACIDS ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY - SUBSTRATES(BILIRUBIN JENDRASSIK-GRÓF FS)-FOR IN VITRO DETERMINATION OF DIRECT AND TOTAL BILIRUBIN WITH THE JENDRASSIK-GRÓF METHOD ON PHOTOMETRIC SYSTEMS.,CALIBRATORS SINGLE COMPONENT (CC) (TRUCAL HBA1C NET)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF HEMOGLOBIN A1C (HBA1C) ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY ENZYMES(G6PDH)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GLU-COSE-6-PHOSPHATE

	DEHYDROGENASE (G6PDH) IN WHOLE BLOOD ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / SP. PROTEINS (APOLIPOPROTEIN B FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF APOLIPOPROTEIN B (APO B) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF APOLIPOPROTEIN B (APO B) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920,CLINICAL CHEMISTRY - SUBSTRATES (TRIGLYCERIDES FS 10')-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDES IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDES IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920,CLINICAL CHEMISTRY - SUBSTRATES (PHOSPHOLIPIDS FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF CHOLINE-CONTAINING PHOSPHOLIPIDS IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF CHOLINE-CONTAINING PHOSPHOLIPIDS IN SERUM OR PLASMA ON DIASYS RESPONS®910,CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY)(TRULAB L LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ANALYTICAL ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF LIPIDS,CLINICAL CHEMISTRY - ELECTROLYTES(CHLORIDE 21 FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHLORIDE IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHLORIDE IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920,CLINICAL CHEMISTRY - ENZYMES(ALAT (GPT) FS (IFCC MOD.))-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALAT (GPT) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALAT (GPT) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS ®920.,CLINICAL CHEMISTRY - SUBSTRATES(IRON FS FERENE)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IRON IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IRON IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TOTAL PROTEIN STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTEIN IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,OTHER CLINICAL

	CHEMISTRY BUFFERS (UNASSIGNABLE), SUPPLEM. REAGENTS, ETC. (CC)(HDL PRECIPITANT)-PRECIPITATION REAGENT FOR IN VITRO DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) ACCORDING TO THE CHOD-PAP-METHOD ON PHOTOMETRIC SYSTEMS,CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY)(CHOLESTEROL STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHOLESTEROL IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS, GLYCOSYLATED/GLYCATED HAEMOGLOBIN HBA1C(HBA1C NET FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN WHOLE BLOOD ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN WHOLE BLOOD ON DIASYS RESPONS®910., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRULAB ETHANOL)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF ETHANOL, CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRULAB HBA1C NET LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF HEMOGLOBIN A1C (HBA1C),CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY)(-HYDROXYBUTYRATE STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF -HYDROXYBUTYRATE IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL FERRITIN)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF FERRITIN ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / RHEUMATOID(ANTISTREPTOLYSIN O FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ANTISTREPTOLYSIN O (ASO) IN SERUM ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ANTISTREPTOLYSIN O (ASO) IN SERUM ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRULAB PCT LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING THE ANALYTICAL PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF PROCALCITONIN.,CLINICAL CHEMISTRY - ENZYMES(LDH FS DGKC)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LACTATE DEHYDROGENASE (LDH) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,

	CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (URIC ACID STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (MAGNESIUM STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF MAGNESIUM IN SERUM, PLASMA, CEREBROSPINAL FLUID OR URINE ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / ALLERGY (IMMUNOGLOBULIN E FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IMMUNOGLOBULIN E (IGE) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IMMUNOGLOBULIN E (IGE) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920. ,CONTROLS/STANDARDS/CALIBRATORS/ CLINICAL CHEMISTRY(TRUCAL E)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF SODIUM, POTASSIUM AND CHLORIDE ON PHOTOMETRIC SYSTEMS., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRULAB HOMOCYSTEINE LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF HOMOCYSTEINE., CLINICAL CHEMISTRY - SUBSTRATES(CHOLESTEROL FS 5')-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHOLESTEROL IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. ,CLINICAL CHEMISTRY - ELECTROLYTES (SODIUM FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF SODIUM IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF SODIUM IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,CLINICAL CHEMISTRY - ENZYMES(CK-NAC FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE KINASE IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE KINASE IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,CLINICAL CHEMISTRY - ENZYMES(CK-MB FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CK-MB IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CK-MB IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,CLINICAL CHEMISTRY - SUBSTRATES(LACTATE FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LACTATE IN PLASMA

	AND CSF ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LACTATE IN PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRULAB P)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY(TRUCAL APO A1/B)-CALIBRATOR FOR USE WITH DIASYS TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF APOLIPOPROTEIN A1 AND APOLIPOPROTEIN B ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRULAB HBA1C LIQUID LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF HEMOGLOBIN A1C (HBA1C).,OTHER CLINICAL CHEMISTRY BUFFERS (UNASSIGNABLE), SUPPLEM. REAGENTS, ETC. (CC)(PYRIDOXAL-5-PHOSPHATE FS)-SUPPLEMENTARY REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ASAT (GOT) AND ALAT (GPT) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ASAT (GOT) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALAT (GPT) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920, CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRIGLYCERIDES STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDES IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,CLINICAL CHEMISTRY - SUBSTRATES(CHOLESTEROL FS 10')-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHOLESTEROL IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHOLESTEROL IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920, IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRULAB D-DIMER LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF D-DIMER., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (UREA STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF UREA IN SERUM, PLASMA OR URINE ON

	PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY - SUBSTRATES(ATP HEXOKINASE FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ATP IN BLOOD AND ERYTHROCYTE CONCENTRATES WITH HEXOKINASE METHOD ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / ANEMIA(FERRITIN FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF FERRITIN IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL ALBUMIN U/CSF)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN URINE AND CSF ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY - ENZYMES (LIPASE DC FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPASE IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPASE IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,CLINICAL CHEMISTRY - SUBSTRATES(URIC ACID FS TOOS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRULAB CYSTATIN C LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING THE ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF CYSTATIN C.,CLINICAL CHEMISTRY - SUBSTRATES(HDL-C DIRECT FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HDL-C (HIGH DENSITY LIPOPROTEIN CHOLESTEROL) IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HDL-C (HIGH DENSITY LIPOPROTEIN CHOLESTEROL) IN SERUM AND PLASMA ON RESPONS®910 AND RESPONS®920,CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY)(TRULAB L LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ANALYTICAL ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF LIPIDS, IMMUNOCHEMISTRY (IMMUNOLOGY) / DIABETES ASSAYS(ONEHBA1C FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HEMOGLOBIN A1C IN WHOLE BLOOD ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN WHOLE BLOOD ON DIASYS RESPONS®910 AND DIASYS RESPONS®920., IMMUNOCHEMISTRY (IMMUNOLOGY) /

	CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRULAB HBA1C LIQUID LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF HEMOGLOBIN A1C (HBA1C),OTHER CLINICAL CHEMISTRY BUFFERS (UNASSIGNABLE), SUPPLEM. REAGENTS, ETC. (CC)(LDL PRECIPITANT)-PRECIPITATION REAGENT FOR IN VITRO DETERMINATION OF LDL-CHOLESTEROL WITH THE CHOD-PAP METHOD ON PHOTOMETRIC SYSTEMS, IMMUNOCHEMISTRY (IMMUNOLOGY) / SP. PROTEINS(COMPLEMENT C4 FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF COMPLEMENT COMPONENT C4 IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF COMPLEMENT COMPONENT C4 IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920, CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (GLUCOSE STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR IN VITRO DETERMINATION OF GLUCOSE WITH THE GLUCOSE DEHYDROGENASE METHOD (GLUC-DH) ON PHOTOMETRIC SYSTEMS. , IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL IGE)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF IMMUNOGLOBULIN E ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / TOXICOLOGY (ETHANOL FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ETHANOL IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ETHANOL IN SERUM OR PLASMA ON RESPONS®910.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL HOMOCYSTEINE)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF HOMOCYSTEINE ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL HBA1C LIQUID)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF HEMOGLOBIN A1C (HBA1C) ON PHOTOMETRIC SYSTEMS,CLINICAL CHEMISTRY - ELECTROLYTES(CALCIUM AS FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRULAB G6PDH)-CONTROLS FOR QUANTITATIVE IN-VITRO

	DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PDH) IN ERYTHROCYTES ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY - ENZYMES(PANCREATIC AMYLASE CC FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PANCREATIC AMYLASE IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PANCREATIC AMYLASE IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920., OTHER CLINICAL CHEMISTRY BUFFERS (UNASSIGNABLE), SUPPLEM. REAGENTS, ETC. (CC)(CLEANER FOR RESPONS 920)-CLEANING SOLUTIONS FOR USE ON DIASYS RESPONS®920,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY(ETHANOL STANDARD FS (3.0 MG/ML))-AQUEOUS STANDARD SOLUTIONS IN DIFFERENT CONCENTRATIONS, IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRUCAL MYOGLOBIN)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF MYOGLOBIN ON PHOTOMETRIC SYSTEMS,CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY)(IRON STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF IRON IN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY - ELECTROLYTES(CALCIUM-P FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920,IMMUNOCHEMISTRY (IMMUNOLOGY) / CARDIAC MARKERS(MYOGLOBIN FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF MYOGLOBIN IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF MYOGLOBIN IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920. , CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (PHOSPHATE STANDARD FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PHOSPHORUS IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS.,OTHER CLINICAL CHEMISTRY BUFFERS (UNASSIGNABLE), SUPPLEM. REAGENTS, ETC. (CC)(CK-MB DS)-SUPPLEMENTARY REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CK-MB IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRULAB HOMOCYSTEINE LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF

	QUANTITATIVE IN VITRO DETERMINATION OF HOMOCYSTEINE, CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRULAB PROTEIN LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS SERUM PROTEINS,CLINICAL CHEMISTRY - ENZYMES(GLDH FS DGKC)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUTAMATE DEHYDROGENASE (GLDH) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. ,IMMUNOCHEMISTRY (IMMUNOLOGY) / SP. PROTEINS(LP (A) 21 FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPOPROTEIN (A) [LP(A)] IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPOPROTEIN (A) [LP (A)] IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRULAB CRP HS LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP).,CLINICAL CHEMISTRY - SUBSTRATES(TOTAL PROTEIN FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTEIN IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTEIN IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920., IMMUNOCHEMISTRY (IMMUNOLOGY) / SP. PROTEINS(ALBUMIN IN URINE/CSF FS)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMINE IN URINE, CSF, SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMINE IN URINE AND CSF ON DIASYS RESPONS®910. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMINE IN URINE, CSF, SERUM OR PLSMA ON DIASYS RESPONS®920.,CLINICAL CHEMISTRY - SUBSTRATES(CREATININE PAP FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN SERUM, PLASMA OR URINE ON DIASYS RESPONS®910 AND DIASYS RESPONS®920., IMMUNOCHEMISTRY (IMMUNOLOGY) / SP. PROTEINS(COMPLEMENT C3C FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF COMPLEMENT COMPONENT C3C IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF COMPLEMENT

	COMPONENT C3C IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920,CLINICAL CHEMISTRY - SUBSTRATES(β-HYDROXYBUTYRATE 21 FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF -HYDROXYBUTYRATE IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF -HYDROXYBUTYRATE IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920,CLINICAL CHEMISTRY - SUBSTRATES(BILIRUBIN AUTO DIRECT FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF DIRECT BILIRUBIN IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF DIRECT BILIRUBIN IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS ®920.,CLINICAL CHEMISTRY - ENZYMES(ALKALINE PHOSPHATASE FS DGKC)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALKALINE PHOSPHATASE (ALP) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY - ELECTROLYTES(POTASSIUM FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF POTASSIUM IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF POTASSIUM IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS®920.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRULAB CRP LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING THE ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP)., IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY (TRULAB LP(A) LEVEL 2)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF LP(A).,CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY)(TRUCAL PROTEIN)-CALIBRATOR SET FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS SERUM PROTEINS ON PHOTOMETRIC SYSTEMS., CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY) (TRUCAL U)-MULTI-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / RHEUMATOID(CRP FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS

	RESPONS®920.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRYETHANOL STANDARD FS (1.0 MG/ML)(ETHANOL STANDARD FS (1.0 MG/ML))-AQUEOUS STANDARD SOLUTIONS IN DIFFERENT CONCENTRATIONS,OTHER CLINICAL CHEMISTRY BUFFERS (UNASSIGNABLE), SUPPLEM. REAGENTS, ETC. (CC)(G6PDH HEMOLYZING SOLUTION)-HEMOLYZING SOLUTION FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PDH) IN WHOLE BLOOD ON PHOTOMETRIC SYSTEMS.,OTHER CLINICAL CHEMISTRY BUFFERS (UNASSIGNABLE), SUPPLEM. REAGENTS, ETC. (CC)(HBA1C NET HEMOLYZING SOLUTION)-HEMOLYZING SOLUTION FOR QUANTITATIVE IN VITRO DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN WHOLE BLOOD ON PHOTOMETRIC SYSTEMS. HEMOLYZING SOLUTION FOR QUANTITATIVE IN VITRO DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN WHOLE BLOOD ON DIASYS RESPONS®910,CLINICAL CHEMISTRY SUBSTRATES(TOTAL BILE ACID 21 FS)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILE ACIDS IN SERUM ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILE ACIDS IN SERUM ON DIASYS RESPONS®910,CONTROLS/STANDARDS/CALIBRATORS/ (CLINICAL CHEMISTRY(TRUCAL PROTEIN HIGH)-CALIBRATOR FOR USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS SERUM PROTEINS ON PHOTOMETRIC SYSTEMS.,IMMUNOCHEMISTRY (IMMUNOLOGY) / CONTROLS/STANDARDS/CALIBRATORS IMMUNOCHEMISTRY(TRULAB LP(A) LEVEL 1)-ASSAYED QUALITY CONTROL MATERIAL FOR MONITORING ASSAY PERFORMANCE OF QUANTITATIVE IN VITRO DETERMINATION OF LP(A)., IMMUNOCHEMISTRY (IMMUNOLOGY) / CARDIAC MARKERS (HOMOCYSTEINE FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HOMOCYSTEINE IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,CLINICAL CHEMISTRY - ENZYMES (ALPHA-AMYLASE CC FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF -AMYLASE IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF -AMYLASE IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS RESPONS ®920., CLINICAL CHEMISTRY - ELECTROLYTES(BICARBONATE FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE/TOTAL CO2 IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE/TOTAL CO2 IN SERUM OR PLASMA ON DIASYS RESPONS®910 AND DIASYS

	RESPONS ®920.,CLINICAL CHEMISTRY - SUBSTRATES(CREATININE FS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS. DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN SERUM, PLASMA OR URINE ON DIASYS RESPONS®910 AND DIASYS RESPONS®920,OTHER CLINICAL CHEMISTRY BUFFERS (UNASSIGNABLE), SUPPLEM. REAGENTS, ETC. (CC)(CLEANER 14)-ALKALINE CLEANING SOLUTION

990	IMP/IVD/2020/001107	1.License Holder Name: IMPERIAL BIOTEK 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STA® - DEFICIENT VIII (STAGO)-IMMUNO-DEPLETED PLASMA FOR FACTOR VIII ASSAY,STA® - LIATEST® VWF: AG(STAGO)-IMMUNO-TURBIDIMETRIC ASSAY OF VON WILLEBRAND FACTOR,STA® - LIATEST® FDP(STAGO)-QUANTITATIVE DETERMINATION OF FIBRIN/FIBRINOGEN DEGRADATION PRODUCTS (FDP) BY THE IMMUNE-TURBIDIMETRIC METHOD,STA® - DESORB U(STAGO)-DESORBING SOLUTION FOR USE WITH ANALYZERS OF THE STA® - LINE,FDP PLASMA(STAGO)-QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF FDP IN PLASMA BY LATEX AGGLUTINATION,STA® - STACLOT® PROTEIN S (STAGO)-CLOTTING ASSAY OF PROTEIN S,STA® - LIATEST® FM (STAGO)-IMMUNO-TURBIDIMETRIC ASSAY OF FIBRIN MONOMERS, STA® - VWF:AG CALIBRATOR(STAGO)-CALIBRATION PLASMA FOR THE IMMUNO-TURBIDIMETRIC ASSAY OF VWF:AG,STA® - STACLOT® PROTEIN C 1(STAGO)-CLOTTING ASSAY OF PROTEIN C,STA® - FDP CONTROL(STAGO)-QUALITY CONTROL OF ASSAYS OF FIBRIN/FIBRINOGEN DEGRADATION PRODUCTS (FDP) BY THE IMMUNO-TURBIDIMETRIC METHOD,PTT AUTOMATE (STAGO)-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - LIQUID ANTI XA 4, 8(STAGO)-COLORIMETRIC ASSAY OF HEPARINS (UFH AND LMWH), FONDAPARINUX AND RIVAROXABAN,STA® - LIATEST® CONTROL N + P(STAGO)-CONTROL PLASMAS FOR IMMUNO-TURBIDIMETRIC ASSAYS,STA® -SYSTEM CONTROL N + P(STAGO)-CONTROL PLASMAS FOR ASSAYS OF COAGULATION PARAMETERS,POOL NORM(STAGO)-NORMAL HUMAN PLASMA POOL,STA® - LIATEST® FREE PROTEIN S 6(STAGO)-IMMUNO-TURBIDIMETRIC ASSAY OF FREE PROTEIN S,STA® - NEOPLASTINE® R 15(STAGO)-DETERMINATION OF PROTHROMBIN TIME (PT),STA® - DEFICIENT XI(STAGO)-DEFICIENT PLASMA FOR FACTOR XI ASSAY,STA® - CONTROL LA 1+2(STAGO)-CONTROL PLASMAS FOR LUPUS ANTICOAGULANT (LA) TESTS,STA® - D-DI CONTROL(STAGO)-QUALITY CONTROL FOR IMMUNO-TURBIDIMETRIC ASSAY OF D-DIMER,STA® - CACL2 0.025 M(STAGO)-CALCIUM CHLORIDE SOLUTION,STA® - IMMUNODEF XII(STAGO)-IMMUNO-DEPLETED PLASMA FOR FACTOR XII ASSAY,STA® - QUALITY HBPM/LMWH(STAGO)-CONTROL PLASMA FOR ASSAYS OF LOW MOLECULAR WEIGHT HEPARINS (LMWH) USING ANTI-XA METHOD, STA® - COAG CONTROL N + P(STAGO)-CONTROL PLASMAS FOR COAGULATION TESTS,C. K. PREST® ,(STAGO)-DETERMINATION OF THE KAOLIN-ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), STA® - STACLOT® APC-R(STAGO)-ASSESSMENT OF ACTIVATED PROTEIN C RESISTANCE,SYSTEM CONTROL N + P(STAGO)-CONTROL

	PLASMAS FOR ASSAYS OF COAGULATION PARAMETERS,STA® - DEFICIENT VII(STAGO)-IMMUNO-DEPLETED PLASMA FOR FACTOR VII ASSAY,STA® - STACLOT® DRVV CONFIRM(STAGO)-DETECTION OF LUPUS ANTICOAGULANTS,STA® - IMMUNODEF VIII(STAGO)-IMMUNO-DEPLETED PLASMA FOR FACTOR VIII ASSAY,STA® - OWREN-KOLLER (STAGO)-OWREN-KOLLER BUFFER SOLUTION FOR COAGULATION TESTS,STA® - NEOPTIMAL 5, 10, 20(STAGO)-DETERMINATION OF PROTHROMBIN TIME (PT),STA® - THROMBIN 2, 10(STAGO)-DETERMINATION OF THROMBIN TIME,D-DI TEST®(STAGO)-LATEX AGGLUTINATION SLIDE TEST FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETERMINATION OF D-DIMER,COAG CONTROL N + P (STAGO)-CONTROL PLASMAS FOR COAGULATION TESTS,STA® - UNICALIBRATOR(STAGO)-CALIBRATION PLASMA FOR FUNCTIONAL ASSAYS OF COAGULATION PARAMETERS,STA® - LIQUID FIB(STAGO)-QUANTITATIVE DETERMINATION OF FIBRINOGEN,STA® - HEPANORM® HBPM/LMWH(STAGO)-CALIBRATION PLASMAS FOR ASSAYS OF LOW MOLECULAR WEIGHT HEPARINS (LMWH) USING ANTI-XA METHOD,STA® - PTT A 5(STAGO)-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - QUALITY HNF/UFH(STAGO)-CONTROL PLASMA FOR ASSAYS OF UNFRACTIONATED HEPARINS (UFH) USING ANTI-XA METHOD,STA® - DEFICIENT II(STAGO)-SUBSTRATE PLASMA FOR FACTOR II ASSAY, STA® - FM CALIBRATOR(STAGO)-CALIBRATION PLASMAS FOR THE IMMUNO-TURBIDIMETRIC ASSAY OF FIBRIN MONOMERS,STA® - LIATEST® D-DI PLUS(STAGO)-IMMUNO-TURBIDIMETRIC ASSAY OF D-DIMER,STA® - CEPHASCREEN 10(STAGO)-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), NEOPLASTINE® CI PLUS 2, 5, 10(STAGO)-DETERMINATION OF PROTHROMBIN TIME (PT),STA® - STACLOT® DRVV SCREEN 2, 5 (STAGO)-DETECTION OF LUPUS ANTICOAGULANTS,STA® - CEPHASCREEN 4(STAGO)-DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - HBPM/LMWH CONTROL (STAGO)-CONTROL PLASMAS FOR ASSAYS OF LOW MOLECULAR WEIGHT HEPARINS (LMWH) USING ANTI-XA METHOD,STA® - IMMUNODEF IX(STAGO)-IMMUNO-DEPLETED PLASMA FOR FACTOR IX ASSAY,STA® - STACHROM® ATIII 3,6(STAGO)-COLORIMETRIC ASSAY OF ANTITHROMBIN,STA® - HEPANORM® H(STAGO)-CALIBRATION PLASMA FOR ASSAY OF UNFRACTIONATED HEPARIN (UFH) USING ANTI-XA METHOD,STA® - STACHROM® PROTEIN C(STAGO)-COLORIMETRIC ASSAY OF PROTEIN C,PTT-LA(STAGO)-LUPUS ANTICOAGULANT- SENSITIVE APTT REAGENT,STA® - DEFICIENT IX (STAGO)-IMMUNO-DEPLETED PLASMA FOR FACTOR IX ASSAY,STA® - LIATEST® FREE PROTEIN S 2(STAGO)-IMMUNO-TURBIDIMETRIC ASSAY OF FREE PROTEIN S,STA® - FM CONTROL(STAGO)-CONTROL

		PLASMAS FOR THE IMMUNO-TURBIDIMETRIC ASSAY OF FIBRIN MONOMERS,STA® - DEFICIENT X(STAGO)-IMMUNO-DEPLETED PLASMA FOR FACTOR X ASSAY,STA® - CK PREST® 5(STAGO)-DETERMINATION OF THE KAOLIN-ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT),STA® - DEFICIENT V(STAGO)-SUBSTRATE PLASMA FOR FACTOR V ASSAY,STA® - STACLOT® HEPARIN 1(STAGO)-CLOTTING ASSAY OF HEPARINS (UFH AND LMWH) BY ANTI-XA METHOD),STA® - HEPARIN CONTROL(STAGO)-CONTROL PLASMAS FOR ASSAYS OF UNFRACTIONED HEPARINS (UFH) USING ANTI-XA METHOD,UNICALIBRATOR(STAGO)-CALIBRATION PLASMA FOR FUNCTIONAL ASSAYS OF COAGULATION PARAMETERS
991	IMP/IVD/2020/001108	1.License Holder Name: M/S PICTOR DIAGNOSTICS INDIA PVT .LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TORCH ELISA KIT (PICTARRAY TORCH ELISA KIT)-PICTARRAY TORCH ELISA KIT IS INTENDED FOR DETECTION OF ANTIBODIES TO TOXOPLASMA GONDII, RUBELLA CMV AND HSV 1/2 IN HUMAN SERUM AS AN AID IN DETECTION OF INFECTION TO THESE AGENTS.
992	IMP/IVD/2020/001109	1.License Holder Name: NISHA SALES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TEST CARTRIDGE(EDAN)-THE TEST CARTRIDGE ARE INTENDED TO USE WITH EDAN I15 BLOOD GAS AND CHEMISTRY ANALYSIS SYSTEM. EACH DISPOSABLE CARTRIDGE ANALYZE BLOOD SAMPLE AND GIVE REPORT IN TERMS OF BLOOD ELECTROLYTES, BLOOD GASES AND BLOOD CHEMICALS, ETC.,CALIBRANT FLUID PACK(EDAN)-CALIBRANT FLUID PACK CONTAIN CALIBRANT SOLUTION AND INTENDED TO BE USED TOGETHER WITH EDAN I15 BLOOD GAS AND CHEMISTRY ANALYSIS SYSTEM TO PERFORM SENSOR/CARTRIDGE CALIBRATION , CONTROLS(EDAN)-CONTROLS ARE INTENDED FOR USE TO MONITOR TEST CARTRIDGE PERFORMANCE AT MULTIPLE POINTS.

993	IMP/IVD/2020/001116	1.License Holder Name: ADVY CHEMICAL PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENGUE NS1 AG TEST UNCUT SHEET-IT IS INTENDED TO BE USED BY THE PROFESSIONALS AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH DENGUE VIRUSES. IT IS A QUALITATIVE RAPID TEST FOR THE DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN SERUM/PLASMA/WHOLE BLOOD. THIS TEST IS FOR DIAGNOSTIC USE ONLY IN ACUTE DENGUE INFECTION,COVID -19 IGG/IGM ANTIBODY TEST UNCUT SHEET-EZDX COVID-19 ANTIBODY DETECTION RAPID KIT IS A RAPID AND QUALITATIVE IMMUNE-CHROMATOGRAPHIC IN VITRO ASSAY FOR THE DIFFERENTIAL DETECTION OF IGM & IGG ANTIBODIES TO COVID-19 VIRUS IN HUMAN SERUM, PLASMA/WHOLE BLOOD SAMPLES OBTAINED FROM PATIENT WITH SIGNS AND SYMPTOMS OF RESPIRATORY INFECTION. IT IS DESIGNED FOR QUALITATIVE DETECTION OF IMMUNOGLOBULIN G AND IMMUNOGLOBULIN M ANTIBODY OF NOVEL CORONAVIRUS (COVID-19) IN HUMAN BLOOD. THE TEST IS INTENDED FOR PROFESSIONAL AND LABORATORY USE.,COVID-19 AG TEST UNCUT SHEET-"COVID 19 RAPID ANTIGEN TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIGENS TO SARS-COV-2 PRESENT IN HUMAN NASOPHARYNGEAL SWAB SPECIMEN. THIS TEST IS FOR ADMINISTRATION BY HEALTHCARE WORKERS AND LABS ONLY, AS AN AID TO EARLY DIAGNOSIS OF SARS-COV-2 INFECTION IN PATIENT WITH CLINICAL SYMPTOMS WITH SARS-COV-2 INFECTION. IT PROVIDES ONLY AN INITIAL SCREENING TEST RESULT. THE RESULT OF THIS TEST SHOULD NOT BE THE SOLE BASIS FOR THE DIAGNOSIS; CONFIRMATORY TESTING IS REQUIRED."

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

994	IMP/IVD/2021/000007	1.License Holder Name: MICROLYN HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:C-REACTIVE PROTEIN HS (HIGH SENSITIVITY) (INFLAMMATION) CALIBRATOR HIGH(DIASPERTZ) -USED FOR CALIBRATION OF C-REACTIVE PROTEIN IN LOWER CONCENTRATION FOR INFLAMMATION IN HUMAN SERUM., COMPLEMENT C3 (5+1)(DIASPERTZ)-USED FOR ESTIMATION OF COMPLEMENT C3 IN HUMAN SERUM.,PROTEIN CONTROL(DIASPERTZ) -USED AS A CONTROL FOR ESTIMATION OF VARIOUS PROTEINS IN IMMUNOTURBIDIMETRIC ASSAYS.,CYSTATIN C CONTROL SET (DIASPERTZ)-USED AS CONTROLS FOR CYSTATIN C ASSAY,URIC ACID AOX, ENZYME COLOR(DIASPERTZ)-USED FOR QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN HUMAN SERUM & PLASMA., CO2 STANDARD(DIASPERTZ)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE (CO2) IN HUMAN SERUM OR PLASMA.,ALKALINE PHOSPHATASE, MOD. IFCC(DIASPERTZ)-USED FOR ESTIMATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR PLASMA.,DIACAL AUTO (ASSAY. CAL. SER.)(DIASPERTZ)-USED AS A CALIBRATOR FOR MULTIPLE ANALYTE ASSAYS.,LITHIUM ENZYMATIC(DIASPERTZ)-USED FOR ESTIMATION OF LITHIUM IN HUMAN SERUM.,MAGNESIUM, STANDARD (DIASPERTZ)-USED FOR CALIBRATION OF TEST OF MAGNESIUM IN HUMAN SERUM, PLASMA, CEREBROSPINAL FLUID OR URINE.,C-REACTIVE PROTEIN (INFLAMMATION) (5+1)(DIASPERTZ)-USED FOR ESTIMATION OF C-REACTIVE PROTEIN FOR INFLAMMATION IN HUMAN SERUM.,VIT D CONTROL SET (2 LEVELS)(DIASPERTZ)-USED AS A CONTROL FOR ESTIMATION OF VIT D IN HUMAN SERUM OR PLASMA.,CREATININE STANDARD(DIASPERTZ)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA & URINE SAMPLE.,BILIRUBIN TOTAL, JENDR. GROF(DIASPERTZ)-USED FOR ESTIMATION OF DIRECT BILIRUBIN IN HUMAN SERUM OR PLASMA., AMMONIA STANDARD(DIASPERTZ)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF AMMONIA IN HUMAN PLASMA.,BILIRUBIN AUTO TOTAL, DCA (DIASPERTZ)-USED FOR ESTIMATION OF DIRECT BILIRUBIN IN HUMAN SERUM OR PLASMA.,DIACAL CK-MB(DIASPERTZ)-USED AS A CALIBRATOR FOR CK-MB ASSAY.,HDL CHOLESTEROL CALIBRATOR (DIASPERTZ)-USED AS A CALIBRATOR FOR HDL CHOLESTEROL ASSAY.,DIACON URINE (LEVEL 1)(DIASPERTZ)-USED AS A CONTROL FOR ESTIMATION OF VARIOUS ANALYTES IN HUMAN URINE.,PROTEIN CONTROL LOW(DIASPERTZ)-USED AS A CONTROL FOR ESTIMATION OF VARIOUS PROTEINS IN IMMUNOTURBIDIMETRIC ASSAYS.,C-REACTIVE PROTEIN HS (HIGH SENSITIVITY) (INFLAMMATION)

	(DIASPERTZ)-USED FOR ESTIMATION OF C-REACTIVE PROTEIN IN LOWER CONCENTRATION FOR INFLAMMATION IN HUMAN SERUM., LACTATE ENZYMATIC UV(DIASPERTZ)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF LACTATE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,GOT (AST) MOD. IFCC(DIASPERTZ)-USED FOR ESTIMATION OF GOT(AST) IN HUMAN SERUM OR PLASMA.,HBA1C DIRECT CONTROL SET(DIASPERTZ)-USED AS CONTROLS FOR ESTIMATION OF GLYCOSYLATED HAEMOGLOBIN ASSAY,ALPHA-AMYLASE, MOD IFCC(DIASPERTZ)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF -AMYLASE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,LITHIUM CONTROL SET (2 LEVELS)(DIASPERTZ)-USED AS CONTROLS FOR LITHIUM ASSAY., UREA AUTO UREASE/GLDH(DIASPERTZ)-USED FOR QUANTITATIVE IN VITRO DETERMINATION OF PROTEIN TOTAL IN HUMAN SERUM, PLASMA & URINE.,PROTEIN TOTAL STANDARD(DIASPERTZ)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PROTEIN TOTAL IN HUMAN SERUM & PLASMA., CO2 CONTROL(DIASPERTZ)-USED AS A CONTROL FOR BICARBONATE (CO2) ASSAY.,GAMMA GT SZAZ STD TO IFCC(DIASPERTZ)-USED FOR ESTIMATION OF GAMMA GLUTAMYL TRANSFERASE IN HUMAN SERUM OR PLASMA.,GPT (ALT) MOD. IFCC(DIASPERTZ)-USED FOR ESTIMATION OF GPT(ALT) IN HUMAN SERUM OR PLASMA.,G6PDH LYSE REAGENT(DIASPERTZ)-USED FOR PREPARATION OF HUMAN BLOOD SAMPLES USED IN G6PDH IN HUMAN SERUM.,G6PDH (UV KINETIC)(DIASPERTZ)-USED FOR ESTIMATION OF G6PDH IN HUMAN SERUM.,FERRITIN AUTO(DIASPERTZ)-USED FOR ESTIMATION OF FERRITIN (IRON DEFICIENCY -ANAEMIA) IN HUMAN SERUM.,C-REACTIVE PROTEIN CALIBRATOR HIGH(DIASPERTZ)-USED FOR CALIBRATION OF C-REACTIVE PROTEIN IMMUNOTURBIDIMETRIC ASSAYS.,CHOLESTEROL LDL DIRECT, ENZYMATIC SELECTIVE PROTECTION METHOD(DIASPERTZ)-USED FOR ESTIMATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN HUMAN SERUM OR PLASMA.,ZINC, BR-PAPS(DIASPERTZ)-USED FOR ESTIMATION OF ZINC IN HUMAN SERUM, PLASMA OR URINE.,COPPER STANDARD (DIASPERTZ)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF COPPER IN SERUM OR PLASMA.,IGM (5+1)(DIASPERTZ)-USED FOR ESTIMATION OF IGM IN HUMAN SERUM.,ZINC STANDARD(DIASPERTZ)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ZINC IN SERUM, PLASMA OR URINE.,PROTEIN TOTAL, MONO BIURET(DIASPERTZ)-USED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PROTEIN TOTAL IN HUMAN SERUM & PLASMA,PROTEIN TOTAL, BIURET(DIASPERTZ)-USED FOR QUANTITATIVE IN VITRO DETERMINATION OF PROTEIN TOTAL IN

	HUMAN SERUM & PLASMA.,DIACON URINE (LEVEL 2)(DIASPERTZ)-USED AS A CONTROL FOR ESTIMATION OF VARIOUS ANALYTES IN HUMAN URINE.,ALPHA1 MICROGLOBULIN CONTROLS(DIASPERTZ)-USED AS CONTROLS FOR ALPHA1 MICROGLOBULIN ASSAY,ALKALINE PHOSPHATASE, OPT. DGKC(DIASPERTZ)-USED FOR ESTIMATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR PLASMA., MAGNESIUM, XYLIDYL BLUE(DIASPERTZ)-USED FOR ESTIMATION OF MAGNESIUM IN HUMAN SERUM, PLASMA, CEREBROSPINAL FLUID OR URINE.,CHOLINESTERASE OPT. DGKC(DIASPERTZ)-USED FOR QUANTITATIVE IN VITRO DETERMINATION OF CHOLINESTERASE IN HUMAN SERUM BY TURBIDIMETRIC ASSAY.,PHOSPHORUS INORGANIC, MOLYBD(DIASPERTZ)-USED REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF PHOSPHORUS IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS., COPPER, 3,5-DIBR-PAESA(DIASPERTZ)-USED FOR ESTIMATION OF COPPER IN HUMAN SERUM OR PLASMA.,MICROALBUMIN (5+1) (DIASPERTZ)-USED FOR ESTIMATION OF MICROALBUMIN IN HUMAN URINE.,HBA1C DIRECT CAL 5 SERIES(DIASPERTZ)-USED FOR CALIBRATION OF GLYCOSYLATED HAEMOGLOBIN ASSAY,HBA1C DIRECT(DIASPERTZ)-USED FOR ESTIMATION OF GLYCOSYLATED HEMOGLOBIN IN HUMAN BLOOD SAMPLES.,AMMONIA CONTROL SET (2 LEVELS)(DIASPERTZ)-USED AS A CONTROL FOR AMMONIA ASSAY., G6PDH CONTROLS SET(DIASPERTZ)-USED AS CONTROLS IN ESTIMATION OF G6PDH IN HUMAN SERUM.,DIACAL LIPIDS (DIASPERTZ)-USED AS A CALIBRATOR FOR MULTIPLE LIPID ASSAYS., IGA (5+1)(DIASPERTZ)-USED FOR ESTIMATION OF IGA IN HUMAN SERUM.,ALPHA1 MICROGLOBULIN(DIASPERTZ)-USED FOR ESTIMATION OF ALPHA1 MICROGLOBULIN IN HUMAN SERUM.,ADA CALIBRATOR(DIASPERTZ)-USED AS A CALIBRATOR FOR ADA ASSAY., CHOLESTEROL STANDARD(DIASPERTZ)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CHOLESTEROL IN HUMAN SERUM & PLASMA.,LDH-L, IFCC (DIASPERTZ)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF LDH-L IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,APO A1/A2/B CALIBRATOR HIGH(DIASPERTZ)-LYOPHILIZED HUMAN BASED CALIBRATOR FOR USE IN CALIBRATION OF IMMUNOTURBIDIMETRIC ASSAYS.,FERRITIN CONTROL LOW (DIASPERTZ)-USED AS CONTROLS FOR FERRITIN ASSAY., HOMOCYSTEINE, ENZYMATIC RECYCLING(DIASPERTZ)-USED FOR ESTIMATION OF HOMOCYSTEINE IN HUMAN SERUM.,LDL CHOLESTEROL CALIBRATOR(DIASPERTZ)-USED AS A CALIBRATOR FOR LDL CHOLESTEROL ASSAY.,RHEUMATOID FACTOR (5+1) (DIASPERTZ)-USED FOR ESTIMATION OF RHEUMATOID FACTOR IN HUMAN SERUM.,LIPOPROTEIN A CALIBRATOR HIGH(DIASPERTZ)-

	USED AS A CALIBRATOR FOR LIPOPROTEIN A ASSAY.,LIPOPROTEIN A (DIASPERTZ)-USED FOR ESTIMATION OF LIPOPROTEIN A IN HUMAN SERUM.,CALCIUM, ARSENAZO(DIASPERTZ)-USED FOR ESTIMATION OF CALCIUM IN HUMAN SERUM, PLASMA OR URINE.,HOMOCYSTEINE CALIBRATOR SET(DIASPERTZ)-USED AS A CALIBRATOR FOR HOMOCYSTEINE ASSAY.,ADENOSINE DEAMINASE ADA, ENZYMATIC (DIASPERTZ)-USED FOR ESTIMATION OF ADENOSINE DEAMINASE IN HUMAN SERUM, PLASMA, PLEURAL FLUID AND CEREBROSPINAL FLUID.,CALCIUM, CPC(DIASPERTZ)-USED FOR ESTIMATION OF CALCIUM IN HUMAN SERUM, PLASMA OR URINE.,HOMOCYSTEINE CONTROL SET(DIASPERTZ)-USED AS A CONTROL FOR HOMOCYSTEINE ASSAY.,AMMONIA(DIASPERTZ)-USED FOR ESTIMATION OF AMMONIA IN HUMAN PLASMA.,ANTI-STREPTOLYSIN O (5+1)(DIASPERTZ)-USED FOR ESTIMATION OF ANTI-STREPTOLYSIN O IN HUMAN SERUM.,IGE(DIASPERTZ)-USED FOR ESTIMATION OF IGE IN HUMAN SERUM.,ADA CONTROL(DIASPERTZ)-USED AS A CONTROL FOR ADA ASSAY.,FERRITIN CALIBRATOR (5 LEVEL SERIES) (DIASPERTZ)-USED FOR CALIBRATION OF FERRITIN (IRON DEFICIENCY -ANAEMIA) IN HUMAN SERUM.,BILE ACIDS, ENZYMATIC CYCLING(DIASPERTZ)-QUANTITATIVE IN VITRO DETERMINATION OF BILE ACIDS IN SERUM AND PLASMA.,TRIGLYCERIDES STANDARD (DIASPERTZ)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM & PLASMA.,ALBUMIN STANDARD(DIASPERTZ)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN HUMAN SERUM & PLASMA.,ALPHA-AMYLASE, CNP-G3(DIASPERTZ)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF -AMYLASE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,UIBC FERENE(DIASPERTZ)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF UIBC IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,C1 ESTERASE INHIBITOR (DIASPERTZ)-USED AS ESTIMATION OF C1 ESTERASE INHIBITOR IN HUMAN SERUM,CERULOPLASMIN (5+1)(DIASPERTZ)-USED FOR ESTIMATION OF CERULOPLASMIN IN HUMAN SERUM.,BETA HYDROXYBUTYRATE, STANDARD(DIASPERTZ)-USED FOR CALIBRATION OF BETA HYDROXYBUTYRATE IN HUMAN SERUM., PROTEIN CALIBRATOR HIGH(DIASPERTZ)-USED FOR CALIBRATION OF IMMUNOTURBIDIMETRIC ASSAYS.,C-REACTIVE PROTEIN HS (HIGH SENSITIVITY) (INFLAMMATION) CONTROL(DIASPERTZ)-USED FOR CONTROLS OF C-REACTIVE PROTEIN IN LOWER CONCENTRATION FOR INFLAMMATION IN HUMAN SERUM.,URIC ACID TBHBA, ENZYME COLOR(DIASPERTZ)-USED FOR QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN HUMAN SERUM & PLASMA., PROTEIN TOTAL URINE/CSF(DIASPERTZ)-USED FOR THE

	QUANTITATIVE IN VITRO DETERMINATION OF PROTEIN TOTAL IN URINE & CSF,RHEUMATOID FACTOR CALIBRATOR HIGH(DIASPERTZ)-USED AS A CALIBRATOR FOR RHEUMATOID FACTOR (RF) ASSAY,LDH-P, OPT. DGKC(DIASPERTZ)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF LDH-P IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,ETHANOL CALIBRATOR/CONTROL SET (DIASPERTZ)-USED FOR CALIBRATION AND RUNNING CONTROLS FOR ETHANOL ASSAY,LIPOPROTEIN A CONTROL (HIGH/LOW) (DIASPERTZ)-USED AS A CONTROL FOR LIPOPROTEIN A ASSAY., HAEMOLYSIS REAGENT FOR HBA1C(DIASPERTZ)-USED FOR PREPARATION OF HUMAN BLOOD SAMPLES USED IN GLYCOSYLATED HAEMOGLOBIN DIRECT ASSAY.,CK-MB, OPT. IFCC/DGKC(CK-MB, OPT. IFCC/DGKC)-USED FOR ESTIMATION OF CK-MB IN HUMAN SERUM OR PLASMA.,BETA HYDROXYBUTYRATE, ENZYMATIC UV(DIASPERTZ)-USED FOR ESTIMATION OF BETA HYDROXYBUTYRATE IN HUMAN SERUM.,ETHANOL ENZYMATIC UV(DIASPERTZ)-USED FOR ESTIMATION OF ETHANOL IN HUMAN SERUM.,FRUCTOSAMINE NBT (DIASPERTZ)-USED FOR ESTIMATION OF FRUCTOSAMINE IN HUMAN SERUM.,ANTI-STRPTOLYSIN O CALIBRATOR HIGH(DIASPERTZ)-USED AS A CALIBRATOR FOR ANTI-STREPTOLYSIN O ASSAY.,PROTEIN TOTAL URINE /CSF. STANDARD(DIASPERTZ)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PROTEIN TOTAL IN URINE & CSF.,CYSTATIN C(DIASPERTZ)-USED AS ESTIMATION OF CYSTATIN C IN HUMAN SERUM,BILE ACID STANDARD (DIASPERTZ)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF BILE ACID IN SERUM & PLASMA.,CARBON DIOXIDE (CO2) PEP-C(DIASPERTZ)-USED FOR ESTIMATION OF BICARBONATE (CO2) IN HUMAN SERUM OR PLASMA., DIACON P(DIASPERTZ)-USED AS A CONTROL FOR ESTIMATION OF VARIOUS ANALYTES IN HUMAN SERUM OR PLASMA.,IGG (5+1) (DIASPERTZ)-USED FOR ESTIMATION OF IGG IN HUMAN SERUM.,C-REACTIVE PROTEIN UHS - UNIVERSAL/HIGH SENSITIVITY (INFLAMMATION)(DIASPERTZ)-USED FOR ESTIMATION OF C-REACTIVE PROTEIN IN LOWER CONCENTRATION FOR INFLAMMATION IN HUMAN SERUM.,CREATININE MOD. JAFFE(DIASPERTZ)-USED FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA & URINE SAMPLE.,TRIGLYCERIDES GPO PAP (DIASPERTZ)-USED FOR QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM, & PLASMA.,IGE CALIBRATOR (DIASPERTZ)-USED FOR CALIBRATION OF IGE IN HUMAN SERUM., CHOLESTEROL HDL DIRECT, IMMUNOINHIBITION(DIASPERTZ)-USED FOR ESTIMATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) IN HUMAN SERUM OR PLASMA.,DIACON LIPIDS(DIASPERTZ)-USED AS A CONTROL FOR ESTIMATION OF VARIOUS LIPIDS IN HUMAN

	SERUM OR PLASMA.,IRON FERENE(DIASPERTZ)-USED FOR ESTIMATION OF IRON IN HUMAN SERUM OR PLASMA.,APO A1/A2/B CONTROLS(DIASPERTZ)-LYOPHILIZED HUMAN BASED CONTROLS FOR USE IN IMMUNO-TURBIDIMETRIC ASSAYS.,CYSTATIN C CALIBRATOR HIGH(DIASPERTZ)-USED AS CALIBRATION OF CYSTATIN C IN HUMAN SERUM,C-REACTIVE PROTEIN UHS - UNIVERSAL RANGE (INFLAMMATION) CONTROL SET(DIASPERTZ)-USED AS CONTROLS FOR C-REACTIVE PROTEIN IN UNIVERSAL RANGE FOR INFLAMMATION IN HUMAN SERUM.,C-REACTIVE PROTEIN UHS - CALIBRATION SET (INFLAMMATION)(DIASPERTZ)-USED AS CALIBRATORS FOR C-REACTIVE PROTEIN IN LOWER CONCENTRATION FOR INFLAMMATION IN HUMAN SERUM., CREATININE ENZYMATIC(DIASPERTZ)-USED FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA & URINE SAMPLE.,IRON STANDARD(DIASPERTZ)-USED FOR CALIBRATION OF IRON IN HUMAN SERUM OR PLASMA.,CK-NAC, OPT. DGKC/IFCC(DIASPERTZ)-USED FOR ESTIMATION OF CK-NAC IN HUMAN SERUM OR PLASMA.,BILIRUBIN DIRECT, JENDR. GROF (DIASPERTZ)-USED FOR ESTIMATION OF DIRECT BILIRUBIN IN HUMAN SERUM OR PLASMA.,C-REACTIVE PROTEIN CALIBRATOR (5 LEVEL SERIES)(DIASPERTZ)-USED FOR CALIBRATION OF C-REACTIVE PROTEIN IMMUNOTURBIDIMETRIC ASSAYS.,LIPASE ENZYMATIC COLORIMETRIC(DIASPERTZ)-USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF LIPASE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,URIC ACID STANDARD(DIASPERTZ)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN HUMAN SERUM & PLASMA., MICROALBUMIN CALIBRATOR(DIASPERTZ)-USED FOR CALIBRATION OF MICROALBUMIN ASSAY.,UREA STANDARD(DIASPERTZ)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF UREA IN HUMAN SERUM & PLASMA., APOLIPOPROTEIN A1 (5+1)(DIASPERTZ)-USED FOR ESTIMATION OF APOLIPOPROTEIN A1 IN HUMAN SERUM,TRIPLE CONTROL (ANTI-STREPTOLYSIN O, C-REACTIVE PROTEIN, RHEUMATOID FACTOR) (DIASPERTZ)-USED AS A CONTROL IN IMMUNOTURBIDIMETRIC ASSAYS FOR ANTI-STREPTOLYSIN O, C-REACTIVE PROTEIN & RHEUMATOID FACTOR.,DIACON N(DIASPERTZ)-USED AS A CONTROL FOR ESTIMATION OF VARIOUS ANALYTES IN HUMAN SERUM OR PLASMA.,BILIRUBIN AUTO DIRECT, DCA(DIASPERTZ)-USED FOR ESTIMATION OF DIRECT BILIRUBIN IN HUMAN SERUM OR PLASMA., APO B 5+1(DIASPERTZ)-USED FOR QUANTITATIVE IN VITRO DETERMINATION OF APOLIPOPROTEIN B IN HUMAN SERUM., MICROALBUMIN CONTROL(DIASPERTZ)-USED AS CONTROLS FOR MICROALBUMIN ASSAY.,CALCIUM STANDARD(DIASPERTZ)-USED FOR

	CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA & URINE., ALPHA1 MICROGLOBULIN CALIBRATORS(DIASPERTZ)-USED FOR CALIBRATION OF 1 MICROGLOBULIN IN HUMAN SERUM., CHOLESTEROL CHOD-PAP(DIASPERTZ)-USED FOR QUANTITATIVE IN VITRO DETERMINATION OF CHOLESTEROL IN HUMAN SERUM & PLASMA.,PHOSPHORUS STANDARD(DIASPERTZ)-USED FOR CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PHOSPHORUS IN HUMAN SERUM & PLASMA., COMPLEMENT C4 (5+1)(DIASPERTZ)-USED FOR ESTIMATION OF COMPLEMENT C4 IN HUMAN SERUM.,FERRITIN CONTROL HIGH (DIASPERTZ)-USED AS CONTROLS FOR FERRITIN ASSAY.,ALBUMIN BCG(DIASPERTZ)-USED FOR QUANTITATIVE IN VITRO OF DETERMINATION OF ALBUMIN IN HUMAN SERUM & PLASMA.,LITHIUM STANDARDS SET (3 LEVELS)(DIASPERTZ)-USED FOR CALIBRATION OF LITHIUM ASSAY.

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995	IMP/IVD/2021/000007	1.License Holder Name: M/S. MICROLYN HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 IGG-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES SPECIFIC FOR THE SARS-COV-2 SPIKE S1-RBD PROTEIN IN HUMAN SERUM OR PLASMA.,D-DIMER CALIBRATOR 5 LEVEL SERIES-LYOPHILIZED HUMAN BASED CALIBRATORS FOR USE AS CALIBRATORS IN IMMUNOTURBIDIMETRIC ASSAYS FOR D-DIMER., D-DIMER-QUANTITATIVE DETERMINATION OF FIBRINOGEN/FIBRIN DEGRADATION PRODUCTS (D-DIMER) IN HUMAN PLASMA.,D-DIMER CONTROL SET-LYOPHILIZED HUMAN BASED CONTROLS FOR USE AS CONTROLS IN IMMUNOTURBIDIMETRIC ASSAYS FOR D-DIMER.,APTT-EA LIQUID-DIAGNOSTIC REAGENT FOR QUANTITATIVE PARTIAL THROMBOPLASTIN TIME (APTT) DETERMINATION IN HUMAN PLASMA ON COAGULATION INSTRUMENTS (ELLAGIC ACID ACTIVATED)., ABNORMAL COAGULATION CONTROL PLASMA-IT IS INTENDED FOR QUALITY CONTROL FOR THE FOLLOWING HAEMOSTASIS SCREENING TESTS: PROTHROMBIN TIME (PT), ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), FIBRINOGEN AND THROMBIN TIME (TT).,NORMAL COAGULATION CONTROL PLASMA-INTENDED FOR NORMAL QUALITY CONTROL FOR THE FOLLOWING HAEMOSTASIS SCREENING TESTS: PROTHROMBIN TIME(PT), ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT), FIBRINOGEN AND THROMBIN TIME (TT).,THROMBOPLASTIN LIQUID-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PROTHROMBIN TIME (PT) IN HUMAN PLASMA.
996	IMP/IVD/2021/000008	1.License Holder Name: M/S. BHARTIVAISH HEALTHCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 IGM/IGG RAPID TEST(INDICAID OR ORAWELL)-QUALITATIVE DETERMINATION OF COVID-19 IGM AND IGG ANTIBODIES IN HUMAN WHOLE BLOOD (FINGERTIP), SERUM, OR PLASMA.

997	IMP/IVD/2021/000009	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:C-P(VIOONE)-FOR THE QUANTITATIVE DETERMINATION C-PEPTIDE (C-P) IN HUMAN SERUM, ESTRADIOL(VIOONE)-FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM,CTNL(VIOONE)-FOR THE QUANTITATIVE DETERMINATION OF TROPONIN I(CTNL) IN HUMAN SERUM,TG(VIOONE)-FOR THE QUANTITATIVE DETERMINATION THYROGLOBULIN (TG) IN HUMAN SERUM,TPOAB(VIOONE)-FOR THE QUANTITATIVE DETERMINATION ANTI HUMAN THYROID PEROXIDE ANTIBODY (TPO AB) IN HUMAN SERUM,FERRITIN(VIOONE)-FOR THE QUANTITATIVE DETERMINATION OF FERRITIN (FERRITIN) IN HUMAN SERUM,INS(VIOONE)-FOR THE QUANTITATIVE DETERMINATION INSULIN(INS) IN HUMAN SERUM,TGAB(VIOONE)-FOR THE QUANTITATIVE DETERMINATION ANTI HUMAN THYROGLOBULIN ANTIBODY (TG AB) IN HUMAN SERUM,TESTOSTERONE(VIOONE)-FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE(T) IN HUMAN SERUM,HA(VIOONE)-FOR THE QUANTITATIVE DETERMINATION HYALURONIC ACID(HA) IN HUMAN SERUM,FREE THYROXINE(FT4)(VIOONE)-FOR THE QUANTITATIVE DETERMINATION THYROGLOBULIN ANTIBODY IN HUMAN SERUM ,INTACT PARATHYROID (VIOONE)-FOR THE QUANTITATIVE DETERMINATION INTACT PARATHYROID HORMONE (IPTH) IN HUMAN SERUM,H-FABP (VIOONE)-FOR THE QUANTITATIVE DETERMINATION OF HEART-TYPE FATTY ACID BINDING PROTEIN (H-FABP) IN HUMAN ,FSH(VIOONE)-FOR THE QUANTITATIVE DETERMINATION OF FOLLICULAR STIMULATING HORMONE (FSH) IN HUMAN,NT-PROBNP(VIOONE)-FOR THE QUANTITATIVE DETERMINATION OF N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN ,LH-FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM,TOTAL 25-OH VITAMIN D(VIOONE)-FOR THE QUANTITATIVE DETERMINATION 25-OH VITAMIN D(25-OH-VIT-D IN HUMAN SERUM,BGP(VIOONE)-FOR THE QUANTITATIVE DETERMINATION OSTEOCALCIN/BONE GAMMA-CARBOXYGLUTAMIC-ACID-CONTAINING PROTEINS (BGP) IN HUMAN SERUM,D-DIMER (VIOONE)-FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN SERUM,HGH-FOR THE QUANTITATIVE DETERMINATION OF HUMAN GROWTH HORMONE(HGH) IN HUMAN SERUM,PRL-FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN(PRL) IN HUMAN SERUM,TOTAL TRIIODOTHYRONINE(TT3)(VIOONE)-FOR THE QUANTITATIVE DETERMINATION TOTAL TRIIODOTHYRONINE (TT3) IN HUMAN SERUM ,TOTAL THYROXINE(TT4)(VIOONE)-FOR THE QUANTITATIVE DETERMINATION FREE THYROXINE IN HUMAN SERUM ,FREE TRIIODOTHYRONINE(FT3)(VIOONE)-FOR THE QUANTITATIVE

		DETERMINATION FREE TRIIODOTHYRONINE IN HUMAN SERUM ,F-HCGB(VIOONE)-FOR THE QUANTITATIVE DETERMINATION OF FREE B SUBUNIT HUMAN CHORIONIC GONADOTROPIN(F-HCGB) IN HUMAN, PROGESTERONE(VIOONE)-FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE (P) IN HUMAN SERUM,TOTAL-HCGB(VIOONE)-FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN(TOTAL-HCGB) IN HUMAN SERUM,THYROID STIMULATING HORMONE(TSH)(VIOONE)-FOR THE QUANTITATIVE DETERMINATION THYROID STIMULATING HORMONE IN HUMAN SERUM ,LN(VIOONE)-FOR THE QUANTITATIVE DETERMINATION LAMININ(LN) IN HUMAN SERUM,COLLAGEN IV(VIOONE)-FOR THE QUANTITATIVE DETERMINATION COLLAGEN IV (CIV) IN HUMAN SERUM,TRAB(VIOONE)-FOR THE QUANTITATIVE DETERMINATION TSH RECEPTOR ANTIBODY(TRAB) IN HUMAN SERUM
998	IMP/IVD/2021/000011	1.License Holder Name: R.K.AGENCY 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SWELAB LUMI-L2 LYSE 500ML(SWELAB LUMI-L2 LYSE 500ML)-THE BOULE SWELAB LUMI-D DILUENT, SWELAB LUMI-L1 LYSE, SWELAB LUMI-L2 LYSE REAGENTS ARE INTENDED FOR USE WITH THE SWELAB LUMI HEMATOLOGY ANALYZER.,BOULE EASY CLEANER 50ML(BOULE EASY CLEANER 50ML)-THE BOULE EASY CLEANER 50 ML IS INTENDED FOR USE WITH THE MEDONIC M51 AND SWELAB LUMI HEMATOLOGY ANALYZERS, FOR CORRECTIVE AND PREVENTIVE CLEANING OF INLETS AND TUBING IN CONTACT WITH BLOOD (PROTEIN).,SWELAB LUMI-D DILUENT 20L(SWELAB LUMI-D DILUENT 20L)-THE BOULE SWELAB LUMI-D DILUENT, SWELAB LUMI-L1 LYSE, SWELAB LUMI-L2 LYSE REAGENTS ARE INTENDED FOR USE WITH THE SWELAB LUMI HEMATOLOGY ANALYZER.,SWELAB LUMI-L1 LYSE 200ML(SWELAB LUMI-L1 LYSE 200ML)-THE BOULE SWELAB LUMI-D DILUENT, SWELAB LUMI-L1 LYSE, SWELAB LUMI-L2 LYSE REAGENTS ARE INTENDED FOR USE WITH THE SWELAB LUMI HEMATOLOGY ANALYZER.

999	IMP/IVD/2021/000012	1.License Holder Name: MICROGENE DIAGNOSTIC SYSTEMS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOCREDIT DENGUE IGG IGM (RAPIGEN)-USED FOR THE RAPID QUALITATIVE DETECTION OF ANTIBODIES TO DENGUE VIRUS IN SERUM , PLASMA OR WHOLE BLOOD AS AN AID IN THE DIAGNOSIS OF DENGUE VIRUS INFECTION , BIOCREDIT DENGUE NS1 ANTIGEN TEST(RAPIGEN)-USED FOR THE RAPID QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN TO DENGUE VIRUS IN SERUM , PLASMA OR WHOLE BLOOD AS AN AID IN THE DIAGNOSIS OF DENGUE VIRUS INFECTION ,BIOCREDIT CHIKUNGUNYA IGM (RAPIGEN)-USED FOR THE RAPID QUALITATIVE DETECTION OF IGM ANTIBODIES TO CHIKUNGUNYA VIRUS IN SERUM , PLASMA OR WHOLE BLOOD AS AN AID IN THE DIAGNOSIS OF CHIKUNGUNYA VIRUS INFECTION ,BIOCREDIT DENGUE NS1 AG+AB DUO(RAPIGEN)-RAPID TEST USED FOR THE QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN AND OR ANTIBODIES TO DENGUE VIRUS IN SERUM , PLASMA OR WHOLE BLOOD AS AN AID IN THE DIAGNOSIS OF DENGUE VIRUS INFECTION

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1000	IMP/IVD/2021/000016	1.License Holder Name: AKSHAT BIO MEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IL 6(IL 6 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-IL 6 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF INTERLEUKIN 6 IN SERUM, PLASMA, WHOLE BLOOD AND PERIPHERAL BLOOD SAMPLES. IL 6 IS AN EARLY MARKER IN ACUTE INFLAMMATION AND THIS TEST CAN BE USED AS AN AID IN THE INFLAMMATORY DISEASES.,PROCALCITONIN (PCT)(PCT FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-PCT FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PCT IN SERUM, PLASMA AND WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF BACTERIAL INFECTION, TRAUMA OR SHOCK.,D-DIMER(D-DIMER FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-D-DIMER FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF D DIMER IN SERUM, PLASMA AND WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF DEEP VEIN THROMBOSIS OR PULMONARY EMBOLISM.,N-TERMINAL PROHORMONE OF BRAIN NATRIURETIC PEPTIDE (NT-PROBNP)(NT-PROBNP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-NT -PRO BNP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF N TERMINAL B-TYPE NATRIURETIC PEPTIDE PRECURSOR/CARDIAC TROPONIN I (NT -PRO BNP) IN SERUM, PLASMA AND WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF).,NEUTROPHILS GELATINASE ASSOCIATED LIPOCALIN (NGAL)(NGAL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-NGAL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF NGAL IN URINE AND SERUM. THIS TEST IS USED AS AN AID IN THE EARLY DIAGNOSIS OF ACUTE KIDNEY INJURY (AKI) RISK CLASSIFICATION AND TREATMENT MONITORING, T3(T3 FAST TEST KIT(IMMUNOFLUORESCENCE ASSAY))-T3 (TRIIODOTHYRONINE) FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T3 IN SERUM AND PLASMA. IT CAN BE USED IN THE MONITORING OF HYPERTHYROIDISM AND HYPOTHYROIDISM, AND ALSO USED AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA.,25-OH-VD (25-OH-VD FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-25-OH-VD FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF 25-OH-VD IN

	SERUM, PLASMA AND WHOLE BLOOD. THIS TEST MAY HELP UNDERSTAND THE METABOLIC CHANGES OF BONE.,T4(T4 FAST TEST KIT(IMMUNOFLUORESCENCE ASSAY))-T4 (TRIIODOTHYRONINE) FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T4 IN SERUM AND PLASMA. IT CAN BE USED IN THE MONITORING OF HYPERTHYROIDISM AND HYPOTHYROIDISM, AND ALSO USED AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA.,TSH(TSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-TSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF TSH IN SERUM AND PLASMA. THIS TEST IS USED IN THE SCREENING CLINICAL DIAGNOSIS PROGNOSIS AND THERAPEUTIC EFFECT EVALUATION OF THYROID DISEASES.,HCG+BETA(HCG+BETA FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-HCG+BETA FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN SERUM AND PLASMA. THIS TEST IS USED AS AID IN PREGNANCY TEST.,BETA 2 –MICROGLOBULIN (2-MG)(BETA2-MG FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-BETA 2 MG FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF BETA 2 MG IN SERUM, PLASMA AND WHOLE BLOOD. MEASUREMENT OF BETA 2 MG IS USEFUL FOR THE DETECTION AND EVALUATION OF GLOMERULAR FILTRATION RATE, RENAL TRANSPLANTATION AND RENAL FUNCTION,MICROALBUMINURIA (MALB)(MALB FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY)-MALB FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF MICROALBUMINURIA (MALB) IN URINE . AN ELEVATED MALB CONCENTRATION BELOW BELOW THE PROTEINURIC LEVEL HAS LONG BEEN RECOGNIZED AS A MARKER OF KIDNEY AND INCREASED CARDIOVASCULAR RISK IN DIABETIC NEPHROPATHY.,CYSTATIN C (CYSC)(CYSC FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-CYSC FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CYSC IN SERUM, PLASMA AND WHOLE BLOOD. THE TEST RESULT IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF INDEX OF GLOMERCULAR FILTRATION RATE, AND HAS IMPORTANT APPLICATION VALUE IN RENAL FUNCTION KIDNEY DAMAGE AND RENAL TRANSPLANTATION., HIGH SENSITIVITY C-REACTIVE PROTEIN (HS-CRP)(HS-CRP+CRP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-HS CRP+CRP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN

		(CRP) IN SERUM, PLASMA, WHOLE BLOOD OR FIGURE TIP BLOOD. MEASUREMENT OF CRP IS USEFUL FOR DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY AND INFLAMMATORY DISORDERS. MEASUREMENT OF HIGH SENSIVITY CRP (HS-CPR), WHEN USE IN CONJUNCTION WITH TRADITIONAL CLINICAL LABORATORY EVALUATION OF ACUTE CORONARY SYNDROME (ACS), MAY BE USEFUL AS AN INDEPENDENT MARKER OF PROGNOSIS FOR RECURRENT EVENTS IN PATIENTS WITH STABLE CORONARY DISEASE OR ACS.,CREATINE KINASE-MB/CARDIAC TROPONIN I/MYOGLOBIN (CK-MB/CTNI/MYO FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY)-CK-MB/CTNL/MYO FAST TEST KIT (IMUMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CK-MB/CTNL/MYO IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI). UNSTABLE ANGINA, ACUTE MYOCARDITIS, AND ACUTE CORONARY SYNDROME (ACS).,CARDIAC TROPONIN I(CARDIAC TROPONIN I FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-CARDIAC TROPONIN I FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CTNL IN SERUM, PLASMA AND WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS AND CORONARY SYNDROME (ACS).,HBA1C(HBA1C FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-HBA1C FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HBA1C IN WHOLE BLOOD. THIS TEST IS USED AS AN AID FOR MONITORING GLYCEMIC CONTROL IN DIABETICS. IN ADDITION IT CAN IDENTIFY PEOPLE AT RISK OF DEVELOPING THE DISEASES AND ONGOING MONITORING.
1001	IMP/IVD/2021/000020	1.License Holder Name: MOREPEN LABORATORIES LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE MONITOR(DR. MOREPEN GLUCOONE)-MEASUREMENT OF GLUCOSE IN CAPILLARY WHOLE BLOOD.

1002	IMP/IVD/2021/000021	1.License Holder Name: ABBOTT HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLUCOMETER(FREESTYLE OPTIUM NEO H BLOOD GLUCOSE & KETONE MONITORING SYSTEM)-THE FREESTYLE OPTIUM NEO H BLOOD GLUCOSE AND KETONE MONITORING SYSTEM IS FOR PROFESSIONAL USE TO MEASURE GLUCOSE AND KETONE (-HYDROXYBUTYRATE) IN FRESH WHOLE BLOOD OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE)., GLUCOMETER(FREESTYLE OPTIUM NEO BLOOD GLUCOSE & KETONE MONITORING SYSTEM 3. NOTIFIED)-THE FREESTYLE OPTIUM NEO BLOOD GLUCOSE AND KETONE MONITORING SYSTEM IS FOR USE OUTSIDE THE BODY ONLY (IN VITRO DIAGNOSTIC USE) FOR SELF -TESTING OR PROFESSIONAL USE AS AN AID IN THE MANAGEMENT OF DIABETES. USE FOR MEASURING GLUCOSE IN FRESH WHOLE BLOOD SAMPLES TAKEN FROM FINGERS, FOREARM, UPPER ARM OR THE BASE OF THE THUMB. USE FOR MEASURING KETONE (-HYDROXYBUTYRATE) IN FRESH WHOLE BLOOD SAMPLES FROM FINGERS ONLY. THE SYSTEM MAY ALSO AID IN THE MANAGEMENT OF DIABETES BY PROVIDING THE USER WITH SUGGESTED RECOMMENDATIONS TO INSULIN DOSE(S) BASED ON HEALTHCARE PROFESSIONAL ENTERED DATA.

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1003	IMP/IVD/2021/000022	1.License Holder Name: LIFESCAN MEDICAL DEVICES INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:METER (ONETOUCH SELECT®PLUS)(ONETOUCH SELECT®PLUS)-THE ONETOUCH SELECT® PLUS BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE (SUGAR) IN FRESH CAPILLARY WHOLE BLOOD SAMPLES DRAWN FROM THE FINGERTIP. THE SYSTEM IS INTENDED TO BE USED BY A SINGLE PATIENT AND SHOULD NOT BE SHARED. THE ONETOUCH SELECT® PLUS BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED FOR SELF-TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) BY PEOPLE WITH DIABETES AT HOME AND WITH THEIR HEALTHCARE PROFESSIONALS IN A CLINICAL SETTING AS AN AID TO MONITOR THE EFFECTIVENESS OF DIABETES CONTROL. THE ONETOUCH SELECT® PLUS BLOOD GLUCOSE MONITORING SYSTEM IS NOT TO BE USED FOR THE DIAGNOSIS OF OR SCREENING OF DIABETES OR FOR NEONATAL USE. THE SYSTEM IS INTENDED TO BE USED BY A SINGLE PATIENT AND SHOULD NOT BE SHARED.,METER (ONETOUCH VERIO FLEX™)(ONETOUCH VERIO FLEX™)-THE ONETOUCH VERIO FLEX™ BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE (SUGAR) IN FRESH CAPILLARY WHOLE BLOOD SAMPLES DRAWN FROM THE FINGERTIP. THE SYSTEM IS INTENDED TO BE USED BY A SINGLE PATIENT AND SHOULD NOT BE SHARED. THE ONETOUCH VERIO FLEX™ BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED FOR SELF-TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) BY PEOPLE WITH DIABETES AT HOME AND WITH THEIR HEALTHCARE PROFESSIONALS IN A CLINICAL SETTING AS AN AID TO MONITOR THE EFFECTIVENESS OF DIABETES CONTROL. THE ONETOUCH VERIO FLEX™ BLOOD GLUCOSE MONITORING SYSTEM IS NOT TO BE USED FOR THE DIAGNOSIS OF OR SCREENING OF DIABETES OR FOR NEONATAL USE.,METER (ONETOUCH SELECT PLUS SIMPLE™)(ONETOUCH SELECT PLUS SIMPLE™)-THE ONETOUCH SELECT PLUS SIMPLE™ BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE (SUGAR) IN FRESH CAPILLARY WHOLE BLOOD SAMPLES DRAWN FROM THE FINGERTIP. THE SYSTEM IS INTENDED TO BE USED BY A SINGLE PATIENT AND SHOULD NOT BE SHARED. THE ONETOUCH SELECT PLUS SIMPLE™ BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED FOR SELF-TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) BY PEOPLE WITH DIABETES AT HOME AND WITH THEIR HEALTHCARE PROFESSIONALS IN A CLINICAL SETTING AS AN AID TO MONITOR THE EFFECTIVENESS OF DIABETES CONTROL. THE ONETOUCH SELECT

	PLUS SIMPLE™ BLOOD GLUCOSE MONITORING SYSTEM IS NOT TO BE USED FOR THE DIAGNOSIS OF OR SCREENING OF DIABETES OR FOR NEONATAL USE. THE ONETOUCH SELECT PLUS SIMPLE™ BLOOD GLUCOSE MONITORING SYSTEM IS NOT FOR USE ON CRITICALLY ILL PATIENTS, PATIENTS IN SHOCK, DEHYDRATED PATIENTS OR HYPEROSMOLAR PATIENTS

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1004	IMP/IVD/2021/000023	1.License Holder Name: MATRIX LABS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SYSTEM TUBING CLEANING SOLUTION(MAGLUMI SYSTEM TUBING CLEANING SOLUTION)-THE MAGLUMI SYSTEM TUBING CLEANING SOLUTION IS USED TO CLEAN THE PIPETTOR AND THE WASHER NEEDLES. IT IS USEFUL TO MINIMIZE REAGENT CARRYOVER BY REDUCING PROTEIN PRECIPITATION IN THE TUBING, AND IMPROVE ROUTINE MAINTENANCE OF THE MAGLUMI SYSTEM. THE KIT CAN ONLY BE USED WITH MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8), WITH TUBING CLEANING PROGRAM.,STARTER 1+2 (MAGLUMI STARTER 1+2)-STARTER REAGENT KIT REQUIRED TO GENERATE THE CHEMILUMINOMETRIC LIGHT SIGNAL NECESSARY FOR THE IMPLEMENTATION OF MAGLUMI ASSAYS ON THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER.,T4 (CLIA)(MAGLUMI T4 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANTI-DSDNA IGG (CLIA)(MAGLUMI ANTI-DSDNA IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG AUTOANTIBODIES TO DOUBLE-STRANDED DNA (ANTI-DSDNA IGG) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,FSH (CLIA)(MAGLUMI FSH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,TGA (CLIA)(MAGLUMI TGA (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN AUTOANTIBODY (TGA) IN HUMAN SERUM USING MAGLUMI SERIES FULLY-AUTO

	CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,T3 (CLIA)(MAGLUMI T3 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ICA (CLIA)(MAGLUMI ICA (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO ISLET CELLS OF PANCREAS (ICA) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZERS (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,GAD 65 (CLIA)(MAGLUMI GAD 65 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GLUTAMIC ACID DECARBOXYLASE ANTIBODY (GAD65) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,VITAMIN B12 (CLIA)(MAGLUMI VITAMIN B12 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,IGF-I (CLIA)(MAGLUMI IGF-I (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN-LIKE GROWTH FACTOR-(IGF-) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,CRP (CLIA)(MAGLUMI CRP (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING

	MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,AMH (CLIA)(MAGLUMI AMH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-MULLERIAN HORMONE (AMH) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,PRG (CLIA)(MAGLUMI PRG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE (PRG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,LIGHT CHECK(MAGLUMI LIGHT CHECK)-LIGHT CHECK REAGENT REQUIRED TO CHECK THE VALIDITY OF STARTER 1+2 AS WELL AS THE FUNCTIONING OF THE MEASURING AND PIPETTING UNITS. A LIGHT CHECK HAS TO BE CARRIED OUT ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8) EITHER ONCE DAILY PRIOR TO STARTING THE FIRST MEASUREMENT OR WHENEVER A NEW LOT OF STARTER REAGENTS IS USED. THIS CONTROL PROGRAM CHECKS THE PROPER FUNCTIONING OF THE INSTRUMENT AND STARTER REAGENTS TO AVOID DATA ERROR DUE TO INSTRUMENT DEFECTS OR MISLOCATED OR EXPIRED STARTER REAGENTS.,ANTI-CCP (CLIA)(MAGLUMI ANTI-CCP (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG AUTOANTIBODIES TO CYCLIC CITRULLINATED PEPTIDES (ANTI-CCP) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,IGA (URINE ANALYSIS) (CLIA)(MAGLUMI IGA (URINE ANALYSIS) (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN URINE USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS,

	MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,SHBG (CLIA)(MAGLUMI SHBG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF SEX HORMONE-BINDING GLOBULIN (SHBG) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,PROINSULIN (CLIA)(MAGLUMI PROINSULIN (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROINSULIN IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANTI-HISTONES IGG (CLIA)(MAGLUMI ANTI-HISTONES IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO HISTONES (ANTI-HISTONES IGG) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,IGE (CLIA)(MAGLUMI IGE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,INSULIN (CLIA)(MAGLUMI INSULIN (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,WASH CONCENTRATE(MAGLUMI WASH CONCENTRATE)-MAGLUMI WASH CONCENTRATE IS INTENDED TO BE DILUTED FOR PREPARATION OF SYSTEM LIQUID WHICH IS REQUIRED FOR WASHING THE MAGNETIC MIRCOBEADS OF THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND

	MAGLUMI X8).,PRL (CLIA)(MAGLUMI PRL (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PRL IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,D-DIMER (CLIA)(MAGLUMI D-DIMER (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,TROPONIN I (CLIA)(MAGLUMI TROPONIN I (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TROPONIN I IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,HCG/BETA-HCG (CLIA)(MAGLUMI HCG/BETA-HCG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (-SUBUNIT) (HCG/BETA-HCG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ENA SCREEN (CLIA)(MAGLUMI ENA SCREEN (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES TO EXTRACTABLE NUCLEAR ANTIGENS (ENA) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,TSH (CLIA)(MAGLUMI TSH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000,

	MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANTI-TPO (CLIA)(MAGLUMI ANTI-TPO (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-TPO IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,IGA (SERUM ANALYSIS) (CLIA) (MAGLUMI IGA (SERUM ANALYSIS) (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A (IGA) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,TMA (CLIA)(MAGLUMI TMA (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID MICROSOMAL AUTOANTIBODY (TMA) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,IGFBP-3 (CLIA)(MAGLUMI IGFBP-3 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN 3 (IGFBP-3) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,GH (CLIA) (MAGLUMI GH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF GROWTH HORMONE (GH) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,FT3 (CLIA) (MAGLUMI FT3 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,FREE

	ESTRIOL (CLIA)(MAGLUMI FREE ESTRIOL (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE ESTRIOL IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 , MAGLUMI 4000 PLUS AND MAGLUMI X8).,HS-CTNI (CLIA)(MAGLUMI HS-CTNI (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,FA (CLIA)(MAGLUMI FA (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLIC ACID (FA) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,FT4 (CLIA)(MAGLUMI FT4 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,IGG (URINE ANALYSIS) (MAGLUMI IGG (URINE ANALYSIS))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN URINE USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,IAA (CLIA)(MAGLUMI IAA (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN AUTOANTIBODIES (IAA) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANTI-RIB-P IGG (CLIA)(MAGLUMI ANTI-RIB-P IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE

	IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO RIB-P (ANTI-RIB-P IGG) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANTI-M2-3E IGG (CLIA)(MAGLUMI ANTI-M2-3E IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO M2-3E (ANTI-M2-3E IGG) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANA SCREEN (CLIA)(MAGLUMI ANA SCREEN (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTINUCLEAR ANTIBODIES (ANA) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,25-OH VITAMIN D (CLIA)(MAGLUMI 25-OH VITAMIN D (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,C-PEPTIDE (CLIA)(MAGLUMI C-PEPTIDE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,NT-PROBNP (CLIA)(MAGLUMI NT-PROBNP (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF N-TERMINAL PROHORMONE B-TYPE NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI

	2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANTI-SS-B IGG (CLIA)(MAGLUMI ANTI-SS-B IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO SS-B (ANTI-SS-B IGG) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,17 OH-PROGESTERONE (CLIA)(MAGLUMI 17 OH-PROGESTERONE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 17-OH PROGESTERONE IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,PCT (CLIA)(MAGLUMI PCT (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PCT IN HUMAN SERUM AND PLASMA WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ACTH (CLIA)(MAGLUMI ACTH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ADRENOCORTICOTROPIC HORMONE (ACTH) IN HUMAN PLASMA WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,INTACT PTH (CLIA) (MAGLUMI INTACT PTH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INTACT PARATHYROID HORMONE (INTACT PTH) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,FK 506 (CLIA)(MAGLUMI FK 506 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FK 506 IN HUMAN WHOLE BLOOD USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS,

	MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,TG (CLIA)(MAGLUMI TG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANTI-NRNP/SM IGG (CLIA)(MAGLUMI ANTI-NRNP/SM IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO NRNP/SM (ANTI-NRNP/SM IGG) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,LH (CLIA)(MAGLUMI LH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,REV T3 (CLIA)(MAGLUMI REV T3 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF REVERSE TRIIODOTHYRONINE (REVT3) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,DHEA-S (CLIA)(MAGLUMI DHEA-S (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE (DHEA-S) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,CORTISOL (CLIA)(MAGLUMI CORTISOL (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM OR URINE USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS,

	MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,REACTION MODULE(MAGLUMI REACTION MODULE)-REACTION MODULES REQUIRED FOR THE IMPLEMENTATION OF THE MAGLUMI ASSAYS ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,TRAB (CLIA)(MAGLUMI TRAB (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TSH RECEPTOR ANTIBODIES (TRAB) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANTI-SM IGG (CLIA)(MAGLUMI ANTI-SM IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO SM (ANTI-SM IGG) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,TESTOSTERONE (CLIA)(MAGLUMI TESTOSTERONE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,IGG (SERUM ANALYSIS) (CLIA) (MAGLUMI IGG (SERUM ANALYSIS) (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANTI-IA2 (CLIA)(MAGLUMI ANTI-IA2 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TYROSINE PHOSPHATASE-LIKE PROTEINS ANTIBODY (ANTI-IA2) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZERS (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS,

	MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANTI-SCL-70 IGG (CLIA)(MAGLUMI ANTI-SCL-70 IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO SCL-70 (ANTI-SCL-70 IGG) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANTI-CENTROMERES IGG (CLIA)(MAGLUMI ANTI-CENTROMERES IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CENTROMERES (ANTI-CENTROMERES IGG) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,IL-6 (CLIA)(MAGLUMI IL-6 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IL-6 IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANTI-SS-A IGG (CLIA)(MAGLUMI ANTI-SS-A IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO SS-A (ANTI-SS-A IGG) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ESTRADIOL (CLIA)(MAGLUMI ESTRADIOL (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANTI-JO-1 IGG (CLIA)(MAGLUMI ANTI-JO-1 IGG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO JO-1 (ANTI-JO-1 IGG) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY

	ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,FREE TESTOSTERONE (CLIA)(MAGLUMI FREE TESTOSTERONE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,IGM (CLIA)(MAGLUMI IGM (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANDROSTENEDIONE (CLIA)(MAGLUMI ANDROSTENEDIONE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANDROSTENEDIONE IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

1005	IMP/IVD/2021/000024	1.License Holder Name: KOPRAN LABORATORIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HUMAN L TYPE FATTY ACID BINDING PROTEIN (L-FABP) KIT(NORUDIA L-FABP)-MEASUREMENT OF L-TYPE FATTY ACID-BINDING PROTEIN (L FABP) IN URINE,APOLIPOPROTEIN B KIT(APO B AUTON " DAIICHI")-MEASUREMENT OF APOLIPOPROTEIN B IN SERUM OR PLASMA, GAMMA -GLUTAMYL TRANSPEPTIDASE KIT FOR BLOOD TEST (PUREAUTO S GAMMA -GT)-FOR MEASUREMENT OF G-GLUTAMYL TRANSPEPTIDASE IN SERUM OR PLASMA,CARBAMAZEPINE KIT (NANOPIA TDM CARBAMAZEPINE)-MEASUREMENT OF CARBAMAZEPINE IN SERUM OR PLASMA,CREATININE KIT(CLINIMATE CRE)-MEASUREMENT OF CREATININE IN SERUM OR URINE, PHENYTOIN KIT(NANOPIA TDM PHENYTOIN)-MEASUREMENT OF PHENYTOIN IN SERUM OR PLASMA,LIPID HDL/LDL CONTROL 1 (CHOLESTEST CONTROL 1)-CHOLESTEST CONTROL IS USED FOR QUALITY CONTROL OF HDL-CHOLESTEROL OR LDL-CHOLESTEROL MEASUREMENT IN HUMAN SERUM OR PLASMA ANALYZED WITH CHOLESTEST N HDL OR CHOLESTEST LDL USING AUTOMATED ANALYZERS. IT CAN ALSO BE USED FOR MEASUREMENT OF TOTAL CHOLESTEROL AND TRIGLYCERIDE IN SERUM OR PLASMA.,LP(A) LATEX STANDARD SERUM M(LP(A) LATEX STANDARD SERUM M)-LP (A) LATEX STANDARD SERUM L, M, AND H ARE USED IN THE DETERMINATION OF LIPOPROTEIN (A) IN SERUM OR PLASMA USING LP (A) LATEX"DAIICHI" ON AN AUTOMATED ANALYZER.,ALKALINE PHOSPHATASE KIT FOR BLOOD(AUTOSERA S ALP)-MEASUREMENT OF ALKALINE PHOSPHATASE IN SERUM OR PLASMA.,IRON KIT (CLINIMATE FE)-MEASUREMENT OF IRON IN SERUM.,MG STANDARD (ANASERUM MG STANDARD SOLUTION)-ANASERUM MG STANDARD SOLUTION IS USED FOR CALIBRATION OF THE ASSAY USED FOR THE DETERMINATION OF MAGNESIUM IN SERUM USING CLINIMATE MG ON AN AUTOMATED ANALYZER,CYSTATIN C CALIBRATOR(CYSTATIN C CALIBRATOR N)-FOR MEASUREMENT OF CYSTATIN C IN SERUM OR PLASMA,L-FABP CALIBRATOR(L-FABP CALIBRATOR)-FOR MEASUREMENT OF L-FABP IN URINE.,FE/UIBC STANDARD (ANASERUM FEUIBC STANDARD SOLUTION)-ANASERUM FEUIBC STANDARD SOLUTION IS USED FOR CALIBRATION OF THE ASSAY USED FOR THE DETERMINATION OF DETERMINATION OF IRON (FE) AND UNSATURATED IRON BINDING CAPACITY (UIBC) IN SERUM USING CLINIMATE FE AND PUREAUTO S UIBC ON AN AUTOMATED ANALYZER.,LIPID HDL/LDL CALIBRATOR(CHOLESTEST N CALIBRATOR)-CHOLESTEST N CALIBRATOR IS USED IN THE DETERMINATION OF HDL-CHOLESTEROL (HDL-C) LDL-CHOLESTEROL(LDL-C) TRIGLYCERIDETGTOTAL CHOLESTEROL

	CHOFREE CHOLESTEROLF-CHOAND PHOSPHOLIPID.,CRP CALIBRATOR(CRP CALIBRATORNANOPIAD)-CRP CALIBRATOR NANOPIAD IS USED IN THE DETERMINATION OF C-REACTIVE PROTEIN IN SERUM OR PLASMA USING NANOPIA CRP KIT ON AN AUTOMATED ANALYZER.,PHENOBARBITAL KIT(NANOPIA TDM PHENOBARBITAL)-MEASUREMENT OF PHENOBARBITAL IN SERUM OR PLASMA,LDL CHOLESTEROL KIT(CHOLESTEST LDL)-MEASUREMENT OF LDL CHOLESTEROL IN SERUM OR PLASMA., VALPROIC ACID KIT(NANOPIA TDM VALPROIC ACID)-MEASUREMENT OF VALPROIC ACID IN SERUM OR PLASMA,CYSTATIN C KIT(NORUDIA CYSTATIN C)-MEASUREMENT OF CYSTATIN C IN SERUM OR PLASMA, UA-E STANDARD(ANASERUM UA-E STANDARD SOLUTION)-ANASERUM UA-E STANDARD SOLUTION IS USED FOR CALIBRATION OF THE ASSAY USED FOR THE DETERMINATION OF URIC ACID IN SERUM OR URINE USING PUREAUTO S UA, AUTOSERA S UA, AND CLINIMATE UA ON AN AUTOMATED ANALYZER.,TDM CALIBRATOR (CALIBRATOR FOR NANOPIA TDM)-THIS PRODUCT IS A MULTI-CALIBRATOR FOR THE CALIBRATION OF CARBAMAZEPINE, PHENOBARBITAL, PHENYTOIN, VALPROIC ACID AND THEOPHYLLINE ON AUTOMATED CLINICAL CHEMISTRY ANALYZER. IT IS TO BE USED IN CONJUNCTION WITH THE NANOPIA TDM CARBAMAZEPINE, THE NANOPIA TDM PHENOBARBITAL, THE NANOPIA TDM PHENYTOIN, THE NANOPIA TDM VALPROIC ACID AND THE NANOPIA TDM THEOPHYLLINE ASSAYS DURING THE MEASUREMENT OF THE SUBSTANCES MENTIONED ABOVE IN SERUM OR PLASMA.,CREATINE KINASE KIT(PUREAUTO S CK)-MEASUREMENT OF CREATINE KINASE IN SERUM OR PLASMA.,URIC ACID KIT(PUREAUTO S UA)-FOR MEASUREMENT OF URIC ACID IN SERUM,PLASMA OR URINE, MAGNESIUM KIT(CLINIMATE MG)-MEASUREMENT OF MAGNESIUM IN SERUM OR URINE,APOLIPOPROTEIN A 1 KIT(APO A-1 AUTO N " DAIICHI")-MEASUREMENT OF APOLIPOPROTEIN A 1 IN SERUM OR PLASMA,GLU STANDARD(ANASERUM GLU STANDARD SOLUTION)-ANASERUM GLU STANDARD SOLUTION IS USED FOR CALIBRATION OF THE ASSAY USED FOR THE DETERMINATION OF GLUCOSE IN SERUM, PLASMA, OR URINE USING PUREAUTO S GLU, AUTOSERA S GLU, PUREAUTO S GLU-R, AND CLINIMATE GLU ON AN AUTOMATED ANALYZER.,ALBTP STANDARD(ANASERUM ALBTP STANDARD SOLUTION)-ANASERUM ALBTP STANDARD SOLUTION IS USED FOR CALIBRATION OF THE ASSAY USED FOR THE DETERMINATION OF TOTAL PROTEIN AND ALBUMIN IN SERUM USING AUTOSERA TP AND CLINIMATE TP, AUTOSERA ALB, CLINIMATE ALB ON AN AUTOMATED ANALYZER.,LIPOPROTEIN (A) KIT(LP(A) LATEX "DAIICHI")-MEASUREMENT OF LIPOPROTEIN (A) IN SERUM OR PLASMA,CA STANDARD(ANASERUM CA STANDARD SOLUTION)-ANASERUM CA

	STANDARD SOLUTION IS USED FOR CALIBRATION OF THE ASSAY USED FOR THE DETERMINATION OF CALCIUM IN SERUM USING CLINIMATE CA, AUTOSERA CA, AND AUTOSERA CA (FOR PTS) ON AN AUTOMATED ANALYZER.,DIGOXIN KIT(NANOPIA TDM DIGOXIN)-MEASUREMENT OF DIGOXIN IN SERUM OR PLASMA,APO AUTON HIGH CALIB AB(APO AUTON HIGH CALIB AB)-APO AUTON HIGH CALIB AB IS A MULTI-POINT CALIBRATOR FOR THE MEASUREMENT OF APOLIPOPROTEIN A-I, A-II AND B IN SERUM OR PLASMA WITH APO A-1 AUTO N " DAIICHI", APO A-II AUTO N " DAIICHI", AND APO B AUTO N " DAIICHI" KITS ON AN AUTOMATED ANALYZER.,LP(A) CONTROL SERUM HIGH(LP(A) CONTROL SERUM "DAIICHI" HIGH)-LPACONTROL SERUM "DAIICHI" LOW AND HIGH ARE USED IN THE QUALITY CONTROL OF THE DETERMINATION OF LIPOPROTEINAIN SERUM OR PLASMA USING LPAAUTO"DAIICHI", AND LPALATEX "DAIICHI" KITS ON AN AUTOMATED ANALYZER.,IP STANDARD(ANASERUM IP STANDARD SOLUTION)-ANASERUM IP STANDARD SOLUTION IS USED FOR CALIBRATION OF THE ASSAY USED FOR THE DETERMINATION OF PHOSPHATE IN SERUM USING CLINIMATE IP AND CLINIMATE IP-2 ON AN AUTOMATED ANALYZER.,APO AUTON CALIBRATOR(APO AUTON "DAIICHI" CALIBRATOR)-FOR THE CALIBRATION IN THE FOLLOWING ASSAYS: APO A-AUTON"DAIICHI" APO A- AUTON"DAIICHI" APO B AUTON"DAIICHI" APO C- AUTON"DAIICHI" APO C - AUTON"DAIICHI" APO E AUTON"DAIICHI",LIPID HDL/LDL CONTROL 2(CHOLESTEST CONTROL 2)-CHOLESTEST CONTROL IS USED FOR QUALITY CONTROL OF HDL-CHOLESTEROL OR LDL-CHOLESTEROL MEASUREMENT IN HUMAN SERUM OR PLASMA ANALYZED WITH CHOLESTEST N HDL OR CHOLESTEST LDL USING AUTOMATED ANALYZERS. IT CAN ALSO BE USED FOR MEASUREMENT OF TOTAL CHOLESTEROL AND TRIGLYCERIDE IN SERUM OR PLASMA., APOLIPOPROTEIN CONTROL SERUM LOW(APOLIPOPROTEIN CONTROL SERUM "DAIICHI" LOW)-APOLIPOPROTEIN CONTROL SERUM "DAIICHI" LOW ARE USED AS CONTROLS IN THE DETERMINATION OF APOLIPOPROTEINS IN SERUM OR PLASMA USING APO AUTON "DAIICHI" KITS ON AUTOMATED ANALYZERS., CREATININE KIT(PUREAUTO S CRE N)-MEASUREMENT OF CREATININE IN SERUM, PLASMA, OR URINE.,LP(A) CONTROL SERUM LOW(LP(A) CONTROL SERUM "DAIICHI" LOW)-LPACONTROL SERUM "DAIICHI" LOW AND HIGH ARE USED IN THE QUALITY CONTROL OF THE DETERMINATION OF LIPOPROTEINAIN SERUM OR PLASMA USING LPAAUTO"DAIICHI", AND LPALATEX "DAIICHI" KITS ON AN AUTOMATED ANALYZER.,AMYLASE KIT(PUREAUTO S AMY-G2)-MEASUREMENT OF AMYLASE IN SERUM, PLASMA OR URINE.,C-REACTIVE PROTEIN KIT(NANOPIA CRP)-MEASUREMENT OF C REACTIVE PROTEIN IN SERUM OR PLASMA,LP(A) LATEX STANDARD

	SERUM H(LP(A) LATEX STANDARD SERUM H)-LP (A) LATEX STANDARD SERUM L, M, AND H ARE USED IN THE DETERMINATION OF LIPOPROTEIN (A) IN SERUM OR PLASMA USING LP (A) LATEX" DAIICHI" ON AN AUTOMATED ANALYZER.,UN STANDARD(ANASERUM UN STANDARD SOLUTION)-ANASERUM UN STANDARD SOLUTION IS USED FOR CALIBRATION OF THE ASSAY USED FOR THE DETERMINATION OF UREA NITROGEN IN SERUM, PLASMA, OR URINE USING PUREAUTO S UN AND CLINIMATE UN ON AN AUTOMATED ANALYZER.,UNSATURATED IRON-BINDING CAPACITY(PUREAUTO S UIBC)-FOR MEASUREMENT OF UIBC IN SERUM,CALCIUM KIT (AUTOSERA CA)-MEASUREMENT OF CALCIUM IN SERUM OR URINE. ALBUMIN KIT FOR BLOOD TESTS(AUTOSERA ALB)-MEASUREMENT OF ALBUMIN IN SERUM,INORGANIC PHOSPHORUS TEST KIT(CLINIMATE IP 2)-MEASUREMENT OF INORGANIC PHOSPHORUS IN SERUM PLASMA OR URINE,TOTAL PROTEIN KIT FOR BLOOD TESTS (CLINIMATE TP)-MEASUREMENT OF TOTAL PROTEIN IN SERUM OR PLASMA,LACTATE DEHYDROGENASE KIT(PUREAUTO S LD)-MEASUREMENT OF LACTATE DEHYDROGENASE IN SERUM OR PLASMA,ALBUMIN KIT FOR BLOOD TESTS(CLINIMATE ALB)-MEASUREMENT OF ALBUMIN IN SERUM,HBA1C CONTROL(HBA1C CONTROL FOR NORUDIA N HBA1C KIT)-THIS PRODUCT IS THE CONTROL FOR THE ASSAY TO DETERMINE LEVELS OF HEMOGLOBIN A1C IN WHOLE BLOOD USING NORUDIA N HBA1C ON AN AUTOMATED ANALYZER.,L-FABP CONTROL(L-FABP CONTROL)-FOR MEASUREMENT OF L-FABP IN URINE.,LP(A) LATEX STANDARD SERUM L(LP(A) LATEX STANDARD SERUM L)-LP (A) LATEX STANDARD SERUM L, M, AND H ARE USED IN THE DETERMINATION OF LIPOPROTEIN (A) IN SERUM OR PLASMA USING LP (A) LATEX" DAIICHI" ON AN AUTOMATED ANALYZER.,HBA1C CALIBRATOR(HBA1C CALIBRATOR FOR NORUDIA NHBA1C KIT)-THIS PRODUCT IS THE CALIBRATOR FOR THE ASSAY TO DETERMINE LEVELS OF HEMOGLOBIN A1C IN WHOLE BLOOD USING NORUDIA N HBA1C ON AN AUTOMATED ANALYZER.,CREATININE KIT(PUREAUTO S CRE L)-MEASUREMENT OF CREATININE CONCENTRATION IN SERUM, PLASMA, OR URINE,HBA1C PRETREATMENT SOLUTION(HBA1C PRETREATMENT SOLUTION FOR NORUDIA N HBA1C)-THE HBA1C PRETREATMENT SOLUTION IS TO BE USED FOR WITH NORUDIA N HBA1C AS A PRETREATMENT SOLUTION PRIOR TO THE DETERMINATION OF HBA1C IN HUMAN WHOLE BLOOD ON AUTOMATIC ANALYZERS.,APOLIPOPROTEIN CONTROL SERUM HIGH (APOLIPOPROTEIN CONTROL SERUM "DAIICHI" HIGH)-APOLIPOPROTEIN CONTROL SERUM "DAIICHI" HIGH ARE USED AS CONTROLS IN THE DETERMINATION OF APOLIPOPROTEINS IN SERUM OR PLASMA USING APO AUTON "DAIICHI" KITS ON AUTOMATED

	ANALYZERS.,ALKALINE PHOSPHATASE KIT FOR BLOOD TESTS (PUREAUTO S ALP)-MEASUREMENT OF ALKALINE PHOSPHATASE IN SERUM OR PLASMA.,DIGOXIN CALIBRATOR(CALIBRATOR FOR NANOPIA DIGOXIN)-DIGOXIN CALIBRATOR FOR NANOPIA IS USED FOR THE MEASUREMENT OF DIGOXIN IN SERUM OR PLASMA.,CRE STANDARD(ANASERUM CRE STANDARD SOLUTION)-ANASERUM CRE STANDARD IS USED FOR CALIBRATION OF THE ASSAY USED FOR THE DETERMINATION OF CREATININE IN SERUM, PLASMA, AND URINE USING PUREAUTO S CRE-N AND CLINIMATE CRE ON AN AUTOMATED ANALYZER.,THEOPHYLLINE KIT(NANOPIA TDM THEOPHYLLINE)-MEASUREMENT OF THEOPHYLLINE IN SERUM OR PLASMA,CYSTATIN C CONTROL N(CYSTATIN C CONTROL N)-THIS PRODUCT IS A QUALITY CONTROL MATERIAL FOR CYSTATIN C IN HUMAN SERUM OR PLASMA WHEN USING NORUDIA CYSTATIN C ON AUTOMATIC ANALYZERS., UREA NITROGEN KIT(PUREAUTO S UN)-FOR MEASUREMENT OF UN IN HUMAN SERUM, PLASMA, OR URINE.,CALCIUM KIT(CLINIMATE CA)-MEASUREMENT OF CALCIUM IN SERUM OR URINE,ALANINE AMINOTRANSFERASE KIT(PUREAUTO S ALT L)-MEASUREMENT OF ALANINE AMINOTRANSFERASE (ALT) IN SERUM OR PLASMA., ASPARTATE AMINOTRANSFERASE KIT(PUREAUTO S AST L)-MEASUREMENT OF ASPARTATE AMINOTRANSFERASE (AST) IN SERUM OR PLASMA,TRIGLYCERIDE KIT(CHOLESTEST® TG)-FOR MEASUREMENT OF TRIGLYCERIDE IN SERUM OR PLASMA,GLYCATED HEMOGLOBIN A1C TEST KIT(NORUDIA®N HBA1C)-FOR QUANTITATIVE MEASUREMENT OF HEMOGLOBIN A1C (HBA1C) IN WHOLE BLOOD., HDL-CHOLESTEROL KIT(CHOLESTEST®N HDL)-FOR MEASUREMENT OF HDL-CHOLESTEROL IN SERUM OR PLASMA,CHOLESTEROL KIT (CHOLESTEST® CHO)-FOR MEASUREMENT OF TOTAL CHOLESTEROL IN SERUM OR PLASMA,ALBUMIN KIT FOR BLOOD TESTS(AUTOSERA ALB)-MEASUREMENT OF ALBUMIN IN SERUM

1006	IMP/IVD/2021/000025	1.License Holder Name: SD BIOSENSOR HEALTHCARE PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:UNCUT SHEET OF BLOOD GLUCOSE TEST STRIP(UNCUT SHEET OF SD CHECK GOLD BLOOD GLUCOSE TEST STRIP)-IT IS AN IN VITRO DIAGNOSTIC USE TO MEASURE BLOOD GLUCOSE, DESIGNED FOR SELF-TESTING BLOOD GLUCOSE USING THE FRESH CAPILLARY WHOLE BLOOD FROM FINGERTIP.,STANDARD MENTOR BLOOD GLUCOSE METER(NA)-IT IS A DEVICE USED TO MEASURE THE CONCENTRATION OF GLUCOSE IN BLOOD.,UNCUT SHEET OF HBA1C (BULK)(UNCUT SHEET OF STANDARD F HBA1C (BULK))-IT IS AN IN VITRO DIAGNOSTIC SYSTEM FOR QUANTITATIVE MEASUREMENT OF HBA1C IN HUMAN CAPILLARY OR VENOUS WHOLE BLOOD.,UNCUT SHEET OF STANDARD GLUCONAVII GDH BLOOD GLUCOSE TEST STRIP (BULK))(NA)-IT IS DESIGNED FOR SELF-TESTING OF BLOOD GLUCOSE LEVEL USING FRESH CAPILLARY WHOLE BLOOD FROM FINGER PRICK, PALM, FOREARM OR UPPER ARM OR FRESH VENOUS BLOOD.,UNCUT SHEET OF BLOOD GLUCOSE TEST STRIP(UNCUT SHEET OF STANDARD MENTOR BLOOD GLUCOSE TEST STRIP)-IT IS AN IN VITRO DIAGNOSTIC USE TO MEASURE BLOOD GLUCOSE, DESIGNED FOR SELF-TESTING BLOOD GLUCOSE USING THE FRESH CAPILLARY WHOLE BLOOD FROM THE FINGER TIP.,SD CHECK GOLD BLOOD GLUCOSE METER(NA)-IT IS A DEVICE USED TO MEASURE THE CONCENTRATION OF GLUCOSE IN BLOOD.,SPOIT BLUE(NA)-IT INCLUDED THE BLUE DYED LATEX-MICRO PARTICLES CONJUGATED TO SPECIFIC ANTIBODIES,SD CODE FREE BLOOD GLUCOSE METER (NA)-IT IS A DEVICE USED TO MEASURE THE CONCENTRATION OF GLUCOSE IN BLOOD.,BUFFER SOLUTION(EXTRACTION BUFFER SOLUTION OF HBA1C)-IT IS INSTANTLY LYSED TO RELEASE THE GLYCATED HEMOGLOBIN.,UNCUT SHEET OF SD CODE FREE BLOOD GLUCOSE TEST STRIP (BULK)(NA)-IT IS DESIGNED FOR SELF-TESTING OF BLOOD GLUCOSE LEVEL USING FRESH CAPILLARY WHOLE BLOOD FROM FINGER PRICK, PALM, FOREARM OR UPPER ARM.,UNCUT SHEET OF TSH (BULK)(UNCUT SHEET OF STANDARD F TSH (BULK))-IT IS AN IN VITRO DIAGNOSTIC USE TO MEASURES THE TSH IN HUMAN SERUM.,STANDARD GLUCONAVII GDH BLOOD GLUCOSE METER(NA)-IT IS A DEVICE USED TO MEASURE THE CONCENTRATION OF GLUCOSE IN BLOOD.,BUFFER SOLUTION(EXTRACTION BUFFER SOLUTION OF TSH)-NA,STANDARD CODE FREE PLUS BLOOD GLUCOSE METER(NA)-IT IS A DEVICE USED TO MEASURE THE CONCENTRATION OF GLUCOSE IN BLOOD.

1007	IMP/IVD/2021/000026	1.License Holder Name: ASCENSIA DIABETES CARE INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE METER (CONTOUR PLUS ELITE)-THE CONTOUR PLUS ELITE BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO BE USED FOR THE MEASUREMENT OF BLOOD GLUCOSE IN BOTH INSULIN AND NON-INSULIN TREATED PATIENTS WITH DIABETES AS AN AID FOR PATIENTS AND THEIR HEALTH CARE PROFESSIONALS IN MONITORING THE EFFECTIVENESS OF THE PATIENT'S DIABETES CONTROL. THE CONTOUR PLUS ELITE BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED FOR SELF-TESTING BY PERSONS WITH DIABETES AND HEALTH CARE PROFESSIONALS IN VENOUS BLOOD AND IN FRESH CAPILLARY WHOLE BLOOD DRAWN FROM THE FINGERTIP OR PALM. THE CONTOUR PLUS ELITE BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED FOR SELF-TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE). THE CONTOUR PLUS ELITE BLOOD GLUCOSE MONITORING SYSTEM SHOULD NOT BE USED FOR THE DIAGNOSIS OF OR SCREENING FOR DIABETES OR FOR NEONATAL USE. ALTERNATIVE SITE TESTING (PALM) SHOULD BE DONE ONLY DURING STEADY STATE TIMES (WHEN GLUCOSE IS NOT CHANGING RAPIDLY). THE CONTOUR PLUS TEST STRIPS ARE FOR USE WITH THE CONTOUR PLUS ELITE BLOOD GLUCOSE METER TO QUANTITATIVELY MEASURE GLUCOSE IN VENOUS BLOOD AND FRESH CAPILLARY WHOLE BLOOD DRAWN FROM THE FINGERTIPS OR PALM. THE METER IS FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN WHOLE BLOOD FROM 0.6 MMOL/L–33.3 MMOL/L.,BLOOD GLUCOSE METER (CONTOUR PLUS)-THE CONTOUR PLUS BLOOD GLUCOSE MONITORING SYSTEM FROM ASCENSIA (METER, TEST STRIPS AND CONTROL SOLUTION) IS INTENDED FOR SELF-TESTING BY PERSONS WITH DIABETES AND BY HEALTH CARE PROFESSIONALS TO MONITOR GLUCOSE CONCENTRATIONS IN FRESH CAPILLARY WHOLE BLOOD DRAWN FROM THE FINGERTIP OR PALM, ARTERIAL AND VENOUS WHOLE BLOOD OR NEONATAL BLOOD. IT IS FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN WHOLE BLOOD FROM 0.6 MMOL/L TO 33.3 MMOL/L (10MG/DL TO 600MG/DL). IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY. THE CONTOUR PLUS BLOOD GLUCOSE MONITORING SYSTEM MAY BE USED AS AN AID TO MONITOR THE EFFECTIVENESS OF AN INDIVIDUAL'S PERSONAL BLOOD GLUCOSE CONTROL PROGRAM. THE CONTOUR PLUS BLOOD GLUCOSE MONITORING SYSTEM IS NOT INTENDED FOR THE DIAGNOSIS OF OR SCREENING FOR DIABETES MELLITUS.,BLOOD GLUCOSE METER (CONTOUR PLUS ONE)-THE CONTOUR PLUS ONE BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO BE USED FOR THE MEASUREMENT OF BLOOD GLUCOSE IN BOTH INSULIN AND NON-

	INSULIN TREATED PATIENTS WITH DIABETES AS AN AID FOR PATIENTS AND THEIR HCPS IN MONITORING THE EFFECTIVENESS OF THE PATIENT'S DIABETES CONTROL. THE CONTOUR PLUS ONE BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED FOR SELFTESTING BY PERSONS WITH DIABETES AND HEALTH CARE PROFESSIONALS IN VENOUS BLOOD AND IN FRESH CAPILLARY WHOLE BLOOD DRAWN FROM THE FINGERTIP OR PALM. THE CONTOUR PLUS ONE BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED FOR SELFTESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE). THE CONTOUR PLUS ONE BLOOD GLUCOSE MONITORING SYSTEM SHOULD NOT BE USED FOR THE DIAGNOSIS OF OR SCREENING FOR DIABETES OR FOR NEONATAL USE. ALTERNATIVE SITE TESTING (PALM) SHOULD BE DONE ONLY DURING STEADY STATE TIMES (WHEN GLUCOSE IS NOT CHANGING RAPIDLY). THE CONTOUR PLUS TEST STRIPS ARE FOR USE WITH THE CONTOUR PLUS ONE BLOOD GLUCOSE METER TO QUANTITATIVELYMEASURE GLUCOSE IN VENOUS BLOOD AND FRESH CAPILLARY WHOLE BLOOD DRAWN FROM THE FINGERTIPS OR PALM. THE METER IS FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN WHOLE BLOOD FROM 0.6 MMOL/L–33.3 MMOL/L(10MG/DL TO 600MG/DL). THE SYSTEM IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1008	IMP/IVD/2021/000027	1.License Holder Name: ASCENSIA DIABETES CARE INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE METER (CONTOUR)-THE CONTOUR BLOOD GLUCOSE MONITORING SYSTEM (METER, TEST STRIPS AND CONTROL SOLUTION) IS INTENDED FOR SELF-TESTING BY PEOPLE WITH DIABETES AND BY HEALTH CARE PROFESSIONALS TO MONITOR GLUCOSE CONCENTRATIONS IN FRESH CAPILLARY WHOLE BLOOD DRAWN FROM THE FINGERTIP. IN CLINICAL SETTINGS, THE CONTOUR SYSTEM MAY ALSO BE USED WITH FRESH VENOUS AND ARTERIAL WHOLE BLOOD. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY. THE TEST PROVIDES A QUANTITATIVE MEASUREMENT OF GLUCOSE IN BLOOD FROM 0.6 MMOL/L TO 33.3 MMOL/L. THE CONTOUR BLOOD GLUCOSE MONITORING SYSTEM IS NOT INTENDED FOR THE DIAGNOSIS OF OR SCREENING FOR DIABETES MELLITUS, AND IT IS NOT FOR USE IN NEONATAL CARE .,BLOOD GLUCOSE METER(CONTOUR TS)-THE CONTOUR TS BLOOD GLUCOSE MONITORING SYSTEM (METER, TEST STRIPS AND CONTROL SOLUTION IS INTENDED FOR SELF-TESTING BY PERSON WITH DIABETES AND BY HEALTHCARE PROFESSIONALS TO MONITOR GLUCOSE AND IN FRESH CAPILLARY WHOLE BLOOD DRAWN FROM THE FINGERTIP OR PALM. IT IS FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN WHOLE BLOOD FROM 0.6 MMOL/L TO 33.3 MMOL/L (10MG/DL TO 600MG/DL). THE CONTOUR TS BLOOD GLUCOSE MONITORING SYSTEM MAY BE USED AS AN AID TO MONITOR THE EFFECTIVENESS OF AN INDIVIDUAL'S PERSONAL BLOOD GLUCOSE CONTROL PROGRAM.THE CONTOUR TS BLOOD GLUCOSE MONITORING SYSTEM IS NOT INTENDED FOR THE DIAGNOSIS OF OR SCREENING FOR DIABETES MELLITUS AND IT IS NOT INTENDED FOR USE ON NEONATES. THE CONTOUR TS CONTROL SOLUTIONS ARE AQUEOUS GLUCOSE SOLUTIONS INTENDED FOR SELF-TESTING BY PERSONS WITH DIABETES AND BY HEALTH CARE PROFESSIONALS AS A QUALITY CONTROL CHECK.

1009	IMP/IVD/2021/000028	1.License Holder Name: VECTOR BIOTEK PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INSULIN (CLIA)(MAGLUMI) -THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,T3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,AMH (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-MULLERIAN HORMONE (AMH) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,PRL (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PRL IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,FT3 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,25-OH VITAMIN D (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,STARTER 1+2(MAGLUMI)-STARTER REAGENT KIT REQUIRED TO GENERATE THE CHEMILUMINOMETRIC LIGHT SIGNAL NECESSARY FOR THE IMPLEMENTATION OF MAGLUMI ASSAYS ON THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER., LIGHT CHECK(MAGLUMI)-LIGHT CHECK REAGENT REQUIRED TO CHECK THE VALIDITY OF STARTER 1+2 AS WELL AS THE FUNCTIONING OF THE MEASURING AND PIPETTING UNITS. A LIGHT CHECK HAS TO BE CARRIED OUT ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER EITHER ONCE DAILY PRIOR TO STARTING THE FIRST MEASUREMENT OR WHENEVER A NEW LOT OF STARTER REAGENTS IS USED. THIS CONTROL PROGRAM CHECKS THE PROPER FUNCTIONING OF THE INSTRUMENT AND STARTER REAGENTS TO AVOID DATA ERROR DUE TO INSTRUMENT DEFECTS OR MISLOCATED OR EXPIRED STARTER REAGENTS.,IGE (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE

	DETERMINATION OF IMMUNOGLOBULIN E (IGE) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,TSH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER., FERRITIN (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,FT4 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,T4 (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER., REACTION MODULE(MAGLUMI)-REACTION MODULES REQUIRED FOR THE IMPLEMENTATION OF THE MAGLUMI ASSAYS ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,ESTRADIOL (CLIA) (MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,IL-6 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF IL-6 IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,VITAMIN B12 (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,WASH CONCENTRATE(MAGLUMI)-MAGLUMI WASH CONCENTRATE IS INTENDED TO BE DILUTED FOR PREPARATION OF SYSTEM LIQUID WHICH IS REQUIRED FOR WASHING THE MAGNETIC MIRCOBEADS OF THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER.,LH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE

	IMMUNOASSAY ANALYZER.,FSH (CLIA)(MAGLUMI)-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER.,SYSTEM TUBING CLEANING SOLUTION (MAGLUMI)-THE MAGLUMI SYSTEM TUBING CLEANING SOLUTION IS USED TO CLEAN THE PIPETTOR AND THE WASHER NEEDLES. IT IS USEFUL TO MINIMIZE REAGENT CARRYOVER BY REDUCING PROTEIN PRECIPITATION IN THE TUBING, AND IMPROVE ROUTINE MAINTENANCE OF THE MAGLUMI SYSTEM. THE KIT CAN ONLY BE USED WITH MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER, WITH TUBING CLEANING PROGRAM.

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1010	IMP/IVD/2021/000030	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARCHITECT ACTIVE-B12 (HOLOTRANSCOBALAMIN) CONTROLS(ARCHITECT ACTIVE-B12 (HOLOTRANSCOBALAMIN) CONTROLS)-THE ARCHITECT ACTIVE-B12 (HOLOTRANSCOBALAMIN) CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM (REAGENTS, CALIBRATORS, AND INSTRUMENT) WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HOLOTRANSCOBALAMIN IN HUMAN SERUM., ALINITY I ACTIVE-B12 (HOLOTRANSCOBALAMIN) CALIBRATORS (ALINITY I ACTIVE-B12 (HOLOTRANSCOBALAMIN) CALIBRATORS)-THE ALINITY I ACTIVE-B12 (HOLOTRANSCOBALAMIN) CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HOLOTRANSCOBALAMIN IN HUMAN SERUM.,ARCHITECT ACTIVE-B12 (HOLOTRANSCOBALAMIN) CALIBRATORS(ARCHITECT ACTIVE-B12 (HOLOTRANSCOBALAMIN) CALIBRATORS)-THE ARCHITECT ACTIVE-B12 (HOLOTRANSCOBALAMIN) CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HOLOTRANSCOBALAMIN IN HUMAN SERUM.,ARCHITECT ACTIVE-B12 (HOLOTRANSCOBALAMIN) REAGENT KIT(ARCHITECT ACTIVE-B12 (HOLOTRANSCOBALAMIN))-THE ARCHITECT ACTIVE-B12 (HOLOTRANSCOBALAMIN) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF HOLOTRANSCOBALAMIN IN HUMAN SERUM ON THE ARCHITECT ISYSTEM. ACTIVE-B12 (HOLOTRANSCOBALAMIN) IS USED AS AN AID IN THE DIAGNOSIS AND TREATMENT OF VITAMIN B12 DEFICIENCY.,ALINITY I ACTIVE-B12 (HOLOTRANSCOBALAMIN) CONTROLS(ALINITY I ACTIVE-B12 (HOLOTRANSCOBALAMIN) CONTROLS)-THE ALINITY I ACTIVE-B12 (HOLOTRANSCOBALAMIN) CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER (REAGENTS, CALIBRATORS, AND INSTRUMENT) WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HOLOTRANSCOBALAMIN IN HUMAN SERUM.,ALINITY I ACTIVE-B12 (HOLOTRANSCOBALAMIN) REAGENT KIT(ALINITY I ACTIVE-B12 (HOLOTRANSCOBALAMIN) REAGENT KIT)-THE ARCHITECT ACTIVE-B12 (HOLOTRANSCOBALAMIN) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF HOLOTRANSCOBALAMIN IN HUMAN SERUM ON THE ARCHITECT ISYSTEM. ACTIVE-B12 (HOLOTRANSCOBALAMIN) IS USED AS AN AID IN THE DIAGNOSIS AND TREATMENT OF VITAMIN B12

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1011	IMP/IVD/2021/000031	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ROCHE CELL COLLECTION MEDIUM KIT(ROCHE CELL COLLECTION MEDIUM KIT)-ROCHE CELL COLLECTION MEDIUM IS DESIGNED FOR THE PRESERVATION AND TRANSPORT OF CELLS TO BE USED IN MOLECULAR TESTING AND/OR FOR THE PREPARATION OF CYTOLOGY SLIDES.
1012	IMP/IVD/2021/000032	1.License Holder Name: METROPOLIS HEALTHCARE LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARTTEST COVID-19 TEST KIT(ARTTEST)-THE ARTTEST COVID-19 TEST KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF SARS-COV-2 VIRUS RNA BY ONE-STEP RT-PCR ASSAY WITH REAL-TIME DETECTION.

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1013	IMP/IVD/2021/000034	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PANBIO™ COVID-19 AG RAPID TEST DEVICE (NASAL)(PANBIO™ COVID-19 AG RAPID TEST DEVICE (NASAL))-THE PANBIO COVID-19 AG RAPID TEST DEVICE IS AN IN VITRO DIAGNOSTIC RAPID TEST FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIGEN (AG) IN HUMAN NASAL, SWAB SPECIMENS FROM INDIVIDUALS WHO MEET COVID-19 CLINICAL AND/OR EPIDEMIOLOGICAL CRITERIA. PANBIO COVID-19 AG RAPID TEST DEVICE IS FOR PROFESSIONAL USE ONLY AND IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF SARS-COV-2 INFECTION. THE PRODUCT MAY BE USED IN ANY LABORATORY AND NON-LABORATORY ENVIRONMENT THAT MEETS THE REQUIREMENTS SPECIFIED IN THE INSTRUCTION FOR USE AND LOCAL REGULATION, PANBIO™ COVID-19 AG RAPID TEST DEVICE (NASOPHARYNGEAL) (PANBIO™ COVID-19 AG RAPID TEST DEVICE (NASOPHARYNGEAL))-PANBIO™ COVID-19 AG RAPID TEST DEVICE (NASOPHARYNGEAL) IS AN IN VITRO DIAGNOSTIC RAPID TEST FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIGEN (AG) IN HUMAN NASOPHARYNGEAL SWAB SPECIMENS FROM INDIVIDUALS WHO MEET COVID-19 CLINICAL AND / OR EPIDEMIOLOGICAL CRITERIA. PANBIO™ COVID-19 AG RAPID TEST DEVICE IS FOR PROFESSIONAL USE ONLY AND IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF SARS-COV-2 INFECTION. THE PRODUCT MAY BE USED IN ANY LABORATORY AND NONLABORATORY ENVIRONMENT THAT MEETS THE REQUIREMENTS SPECIFIED IN THE INSTRUCTIONS FOR USE AND LOCAL REGULATION.,PANBIO COVID-19 ANTIGEN SELF TEST (PANBIO COVID-19 ANTIGEN SELF TEST)-THE PANBIO™ COVID-19 ANTIGEN SELF-TEST IS A SINGLE-USE, IN VITRO (OUTSIDE THE BODY) VISUALLY READ RAPID IMMUNOASSAY THAT USES A HUMAN NASAL SWAB SPECIMEN FOR THE QUALITATIVE DETECTION OF NUCLEOCAPSID PROTEIN SARS-COV-2 ANTIGEN (AG). THE PANBIO™ COVID- 19 ANTIGEN SELF-TEST IS INTENDED TO BE USED MANUALLY BY UNTRAINED LAY USERS (SELF TESTING) IN A PRIVATE SETTING TO AID IN THE DIAGNOSIS OF AN ACTIVE SARS-COV-2 INFECTION. CHILDREN UNDER 14 YEARS SHOULD BE SUPPORTED BY AN ADULT.

1014	IMP/IVD/2021/000035	1.License Holder Name: INDELOX GLOBAL DISTRIBUTION PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TEST CARTRIDGE(EDAN)-THE TEST CARTRIDGE ARE INTENDED TO USE WITH EDAN I15 BLOOD GAS AND CHEMISTRY ANALYSIS SYSTEM. EACH DISPOSABLE CARTRIDGE ANALYZE BLOOD SAMPLE AND GIVE REPORT IN TERMS OF BLOOD ELECTROLYTES, BLOOD GASES AND BLOOD CHEMICALS, ETC.,CONTROLS(EDAN)-THE EDAN I15 BLOOD GAS AND ELECTROLYTE CONTROLS ARE EXTERNAL MULTI-ANALYTE QUALITY CONTROL MATERIAL INTENDED TO BE USED FOR THE VERIFICATION OF CORRECT OPERATION AND MEASUREMENT OF THE EDAN I15 BLOOD GAS AND ELECTROLYTE ANALYZER, TOGETHER WITH I15 CALIBRANT FLUID PACK AND I15 TEST CARTRIDGE FOR THE ANALYSIS OF PH, BLOOD GASES (PCO2, PO2), ELECTROLYTES (NA+ , K+ , CA++, AND CL-) AND METABOLITES (GLU AND LAC).,CALIBRANT FLUID PACK(EDAN)-THE EDAN I15 CALIBRANT FLUID PACK IS INTENDED FOR THE CALIBRATION OF PH, PO2 , PCO2 , NA+ , K+ , CA++, CL- , GLU, LAC AND HCT AS PART OF THE EDAN I15 BLOOD GAS AND CHEMISTRY ANALYSIS SYSTEM.

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1015	IMP/IVD/2021/000036	1.License Holder Name: R-2 HEMOSTASIS DIAGNOSTIC INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NOFACT IX(NOFACT IX)-NOFACT IX DEFICIENT PLASMA IS A HUMAN PLASMA IMMUNODEPLETED OF FACTOR IX AND INTENDED FOR THE QUANTITATIVE DETERMINATION OF FACTOR IX ACTIVITY IN CITRATED PLASMA FROM PATIENTS SUSPECTED OF FIX DEFICIENCY. FIX ACTIVITY IS BASED ON THE ACTIVATED PARTIAL THROMBOPLASTIN TIME. FOR IN VITRO DIAGNOSTIC USE.,PHOSPHOLIN ES APTT CHLORIDE(PHOSPHOLIN ES APTT CHLORIDE)-PHOSPHOLIN ES IS INTENDED FOR USE AS AN ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) REAGENT. THE APTT TEST IS A QUALITATIVE ASSAY USED IN ROUTINE COAGULATION SCREENING OF PATIENT PLASMA TO DETECT DEFICIENCIES IN THE INTRINSIC PATHWAY. IT IS ALSO USED TO MONITOR HEPARIN THERAPY AND IN THE DETECTION OF LUPUS ANTICOAGULANTS. PHOSPHOLIN ES IS TO BE USED BY QUALIFIED LABORATORY PERSONNEL.,PLASMACON L2 (PLASMACON L2)-PLASMACON L-2 IS A HUMAN LYOPHILIZED PLASMA CONTROL INTENDED FOR USE AS A HIGH LEVEL ABNORMAL CONTROL WITH CITRATED PLASMA TO MONITOR THE PERFORMANCE OF THE PROTHROMBIN TIME (PT) AND ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) TESTS.,PLASMACON N(PLASMACON N)-PLASMACON N IS A HUMAN LYOPHILIZED PLASMA CONTROL INTENDED FOR USE AS A NORMAL CONTROL WITH CITRATED PLASMA TO MONITOR THE PERFORMANCE OF THE PROTHROMBIN TIME (PT) AND ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) TESTS.,T-TEK THROMBIN TIME(T-TEK THROMBIN TIME)-THE T-TEK THROMBIN TIME REAGENT IS INTENDED FOR USE IN THE QUANTITATIVE DETERMINATION OF THROMBIN TIME (TT) IN CITRATED HUMAN PLASMA IN THE GENERAL PATIENT POPULATION. T-TEK SHOULD BE USED IN THE CLINICAL LABORATORY BY QUALIFIED LABORATORY PROFESSIONALS. THE TEST MAY BE PERFORMED USING MANUAL METHODS OR SEMI-AUTOMATED OR AUTOMATED COAGULATION ANALYZERS.,LUPOTEK DETECTIN VL (LUPOTEK DETECTIN VL)-LUPOTEK DETECTIN VL TEST KITS ARE QUALITATIVE TESTS INTENDED TO AID IN THE DETECTION OF LUPUS ANTICOAGULANTS (LA) IN CITRATED PLASMA BY THE DILUTE RUSSELL'S VIPER VENOM METHOD IN PROFESSIONAL CLINICAL LABORATORIES.,LUPOTEK KCT(LUPOTEK KCT)-THE LUPOTEK KAOLIN CLOTTING TIME (KCT) IS A KAOLIN ACTIVATED PARTIAL THROMBOPLASTIN REAGENT WITHOUT PHOSPHOLIPID. THE LUPOTEK KCT IS A QUALITATIVE IN VITRO COAGULATION SCREENING ASSAY FOR USE IN PROFESSIONAL LABORATORIES AS AN AID IN THE DETECTION OF CIRCULATING LUPUS-LIKE

	ANTICOAGULANTS IN CITRATED HUMAN PLASMA.,NOFACT VIII (NOFACT VIII)-NOFACT VIII DEFICIENT PLASMA IS A HUMAN PLASMA IMMUNODEPLETED OF FACTOR VIII AND INTENDED FOR THE QUANTITATIVE DETERMINATION OF FACTOR VIII ACTIVITY IN CITRATED PLASMA FROM PATIENTS SUSPECTED OF FVIII DEFICIENCY. FVIII ACTIVITY IS BASED ON THE ACTIVATED PARTIAL THROMBOPLASTIN TIME. FOR IN VITRO DIAGNOSTIC USE.,FIBROTEK FIBRINOGEN KIT(FIBROTEK FIBRINOGEN KIT)-THE FIBROTEK FIB FIBRINOGEN ASSAY KIT IS INTENDED FOR USE IN THE QUANTITATIVE DETERMINATION OF FIBRINOGEN IN CITRATED HUMAN PLASMA., PLASMACON L1(PLASMACON L1)-PLASMACON L-1 IS A HUMAN LYOPHILIZED PLASMA CONTROL INTENDED FOR USE AS A MID-LEVEL ABNORMAL CONTROL WITH CITRATED PLASMA TO MONITOR THE PERFORMANCE OF THE PROTHROMBIN TIME (PT) AND ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) TESTS., LUPOTEK CORECTIN VL(LUPOTEK CORECTIN VL)-LUPOTEK CORRECTIN VL TEST KITS ARE QUALITATIVE TESTS INTENDED TO AID IN THE DETECTION OF LUPUS ANTICOAGULANTS (LA) IN CITRATED PLASMA BY THE DILUTE RUSSELL'S VIPER VENOM METHOD IN PROFESSIONAL CLINICAL LABORATORIES.,PHOSPHOPLASTIN RL (PHOSPHOPLASTIN RL)-PHOSPHOPLASTIN RL IS INTENDED FOR USE IN THE ONE-STAGE PROTHROMBIN TIME (PT) TEST AND IN PT BASED HEMOSTASIS ASSAYS. THE PT CAN BE USED TO SCREEN FOR COAGULOPATHIES, FOR EXTRINSIC FACTOR ASSAYS, AND FOR THERAPEUTIC MONITORING OF WARFARIN AND RELATED DRUGS., PLASMACON LA(PLASMACON LA)-PLASMACON LA IS INTENDED FOR USE AS AN LA POSITIVE, ABNORMAL QUALITY CONTROL PLASMA TO MONITOR THE PERFORMANCE OF DIAGNOSTIC ASSAYS, PERFORMED IN PROFESSIONAL CLINICAL LABORATORIES, FOR THE PRESENCE OF LUPUS ANTICOAGULANTS IN CITRATED PLASMA.,THROMBOTEK PSE PROTEIN S KIT(THROMBOTEK PSE PROTEIN S KIT)-THROMBOTEK PSE IS A COMPLETE KIT FOR THE QUANTITATIVE DETERMINATION OF PROTEIN S ACTIVITY IN HUMAN PLASMA BY CLOTTING ASSAY.

1016	IMP/IVD/2021/000038	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARCHITECT CYFRA 21-1 REAGENT KIT(ARCHITECT CYFRA 21-1 REAGENT KIT)-THE ARCHITECT CYFRA 21-1 ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF HUMAN CYTOKERATIN 19 FRAGMENTS IN HUMAN SERUM AND PLASMA.,ALINITY I THYROGLOBULIN CONTROLS(ALINITY I THYROGLOBULIN CONTROLS)-THE ALINITY I THYROGLOBULIN CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) IN HUMAN SERUM AND PLASMA.,ARCHITECT CYFRA 21-1 CONTROLS(ARCHITECT CYFRA 21-1 CONTROLS)-THE ARCHITECT CYFRA 21-1 CONTROLS ARE USED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN CYTOKERATIN 19 FRAGMENTS IN HUMAN SERUM AND PLASMA.,ALINITY I THYROGLOBULIN REAGENT KIT(ALINITY I THYROGLOBULIN REAGENT KIT)-THE ALINITY I THYROGLOBULIN ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT CYFRA 21-1 CALIBRATORS(ARCHITECT CYFRA 21-1 CALIBRATORS)-THE ARCHITECT CYFRA 21-1 CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN CYTOKERATIN 19 FRAGMENTS IN HUMAN SERUM AND PLASMA.,ALINITY I THYROGLOBULIN CALIBRATORS(ALINITY I THYROGLOBULIN CALIBRATORS)-THE ALINITY I THYROGLOBULIN CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) IN HUMAN SERUM AND PLASMA.

1017	IMP/IVD/2021/000039	1.License Holder Name: THERMO FISHER SCIENTIFIC INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:UNIVERSAL™ TUBE (NUNC™)-THESE POLYPROPYLENE TUBES ARE INTENDED FOR USE IN CRYOGENIC STORAGE AND INTER-LABORATORY GROUND TRANSPORTATION OF SPECIMENS (INCLUDING BUT NOT LIMITED TO BLOOD /PLASMA/ SERUM, URINE, AND SALIVA) TAKEN FROM THE HUMAN BODY FOR IN VITRO DIAGNOSTIC (IVD) EXAMINATION. THEY CAN BE USED TO STORE SAMPLES DOWN TO VAPOR PHASE OF LIQUID NITROGEN TEMPERATURES. THE TUBES ARE MADE AS A DISPOSABLE AND ARE FOR SINGLE USE ONLY.,CRYOBANK™ VIAL (NUNC™)-THESE POLYPROPYLENE TUBES ARE INTENDED FOR USE IN CRYOGENIC STORAGE AND INTER-LABORATORY GROUND TRANSPORTATION OF SPECIMENS (INCLUDING BUT NOT LIMITED TO BLOOD /PLASMA/ SERUM, URINE, AND SALIVA) TAKEN FROM THE HUMAN BODY FOR IN VITRO DIAGNOSTIC (IVD) EXAMINATION. THEY CAN BE USED TO STORE SAMPLES DOWN TO VAPOR PHASE OF LIQUID NITROGEN TEMPERATURES. THE TUBES ARE MADE AS A DISPOSABLE AND ARE FOR SINGLE USE ONLY.,CRYOGENIC VIAL (NALGENE™)-THESE POLYPROPYLENE TUBES ARE INTENDED FOR USE IN CRYOGENIC STORAGE AND INTER-LABORATORY GROUND TRANSPORTATION OF SPECIMENS (INCLUDING BUT NOT LIMITED TO BLOOD /PLASMA/ SERUM, URINE, AND SALIVA) TAKEN FROM THE HUMAN BODY FOR IN VITRO DIAGNOSTIC (IVD) EXAMINATION. THEY CAN BE USED TO STORE SAMPLES DOWN TO VAPOR PHASE OF LIQUID NITROGEN TEMPERATURES. THE TUBES ARE MADE AS A DISPOSABLE AND ARE FOR SINGLE USE ONLY.

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1018	IMP/IVD/2021/000040	1.License Holder Name: CL MICROMED PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RINSING SOLUTION BGA-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,CAL PACK BGA+ISE+META-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,CAL PACK BGA+ISE-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,WASH 2+M-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,BGA 1-REAGENT FOR THE OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,QC LEVEL 3-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,RINSING SOLUTION BGA+ISE-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,QC LEVEL 2-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,BGA 2-REAGENT FOR THE OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,BGA 3-REAGENT FOR THE OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,PROTEIN REMOVER-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,CAL PACK BGA-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,QC LEVEL 1-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,RINSING SOLUTION BGA META-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,BGA 4-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,CAL 4+M-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,CAL 4-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,CAL 3-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,WASH 1-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS,WASH 2-REAGENT FOR OPERATION OF ESCHWEILER BLOOD GAS AND ELECTROLYTE ANALYZERS

1019	IMP/IVD/2021/000041	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIAZYME HUMAN KAPPA FREE LIGHT CHAIN ASSAY(DIAZYME HUMAN KAPPA FREE LIGHT CHAIN ASSAY)-THE DIAZYME HUMAN KAPPA FREE LIGHT CHAIN ASSAY IS INTENDED AS A LATEX PARTICLE-ENHANCED IMMUNOTURBIDIMETRIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF KAPPA FREE LIGHT CHAIN (FLC) CONCENTRATION IN SERUM.,DIAZYME HUMAN LAMBDA () FREE LIGHT CHAIN ASSAY(DIAZYME HUMAN LAMBDA () FREE LIGHT CHAIN ASSAY)-THE DIAZYME HUMAN LAMBDA () FREE LIGHT CHAIN ASSAY IS INTENDED AS A LATEX PARTICLE ENHANCED IMMUNOTURBIDIMETRIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF LAMBDA FREE LIGHT CHAIN (FLC) CONCENTRATION IN SERUM.,DIAZYME HUMAN KAPPA AND LAMBDA FLC CONTROL SET(DIAZYME HUMAN KAPPA AND LAMBDA FLC CONTROL SET)-INTENDED USE DIAZYME HUMAN KAPPA AND LAMBDA FLC CONTROL SET (DZ169A-CON) IS INTENDED FOR USE IN MONITORING THE QUALITY CONTROL OF RESULTS OBTAINED WITH THE DIAZYME HUMAN KAPPA AND LAMBDA FREE LIGHT CHAIN ASSAY.
1020	IMP/IVD/2021/000049	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCESS C-PEPTIDE (ACCESS C-PEPTIDE)-THE ACCESS C-PEPTIDE ASSAY IS A PARAMAGNETIC PARTICLE, CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE LEVELS IN HUMAN SERUM, PLASMA AND URINE USING THE ACCESS IMMUNOASSAY SYSTEMS AS AN AID IN THE DIAGNOSIS AND TREATMENT OF PATIENTS SUSPECTED OF HAVING DIABETES OR OTHER INSULIN SECRETION DISORDERS.,ACCESS C-PEPTIDE CALIBRATORS(ACCESS C-PEPTIDE CALIBRATORS)-THE ACCESS C-PEPTIDE CALIBRATORS ARE INTENDED TO CALIBRATE THE ACCESS C-PEPTIDE ASSAY FOR THE QUANTITATIVE DETERMINATION OF C-PEPTIDE LEVELS IN HUMAN SERUM, PLASMA AND URINE USING THE ACCESS IMMUNOASSAY SYSTEMS.

1021	IMP/IVD/2021/000050	1.License Holder Name: M/S. R-BIOPHARM NEUGEN PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHROMAGAR™ ORIENTATION(CHROMAGAR™ ORIENTATION)-FOR USE CLINICAL DIAGNOSTICS. FOR IN VITRO DIAGNOSTIC USE.,CHROMAGAR™ MSUPERCARBA(CHROMAGAR™ MSUPERCARBA)-USE FOR CLINICAL DIAGNOSTICS. FOR IN VITRO DIAGNOSTIC USE.,CHROMAGAR™ CANDIDA(CHROMAGAR™ CANDIDA)-USE FOR THE CLINICAL DIAGNOSTICS. FOR IN VITRO DIAGNOSTIC USE.
1022	IMP/IVD/2021/000051	1.License Holder Name: AMRTIT AG HEALTH & LIFECARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CARE SENS BLOOD TEST STRIPS(CARE SENS)-CARESENS BLOOD GLUCOSE TEST STRIPS WORK WITH THE CARESENS II PLUS BLOOD GLUCOSE METERS TO QUANTITATIVELY MEASURE GLUCOSE IN WHOLE BLOOD. CARESENS II PLUS BLOOD GLUCOSE MONITORING SYSTEM SHOULD BE USED ONLY FOR SELF-TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE). ,CARE SENS II PLUS BLOOD GLUCOSE MONITORING DEVICE (CARE SENS II PLUS)-CARESENS II PLUS BLOOD GLUCOSE MONITORING SYSTEM IS USED FOR THE QUANTITATIVE MEASUREMENT OF THE GLUCOSE LEVEL IN CAPILLARY WHOLE BLOOD AS AN AID IN MONITORING DIABETES MANAGEMENT EFFECTIVELY AT HOME OR IN CLINICAL SETTINGS. FRESH VENOUS WHOLE BLOOD DRAWN BY HEALTHCARE PROFESSIONALS MAY ALSO BE USED

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1023	IMP/IVD/2021/000052	1.License Holder Name: BIOTIME HEALTHCARE PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARSCOV-2) ANTIGEN DETECTION KIT (COLLOIDAL GOLD-BASED)(VAZYME)-THE TEST KIT IS APPLICABLE TO DETECT THE ANTIGEN OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2)ANTIGEN IN HUMAN THROAT SWAB, NASAL SWAB SAMPLES.,2019-NOVEL CORONAVIRUS (2019-NCOV) TRIPLEX RT-QPCR DETECTION KIT (VAZYME)-THIS PRODUCT IS INTENDED FOR THE DETECTION OF 2019-NOVEL CORONAVIRUS (2019-NCOV). THE DETECTION RESULT OF THIS PRODUCT IS ONLY FOR CLINICAL REFERENCE, AND IT SHOULD NOT BE USED AS THE ONLY EVIDENCE FOR CLINICAL DIAGNOSIS AND TREATMENT.,FASTPURE VIRAL DNA/RNA MINI KIT (VAZYME)-THIS PRODUCT IS USED FOR THE STEPS OF NUCLEIC ACID EXTRACTION, ENRICHMENT AND PURIFICATION. THIS KIT IS APPLICABLE FOR EXTRACTING HIGHLY PURE VIRAL NUCLEIC ACID (DNA/RNA) FROM SAMPLES SUCH AS HUMAN NASOPHARYNGEAL SWABS, SPUTUM, BRONCHO LAVAGE FLUID AND ALVEOLAR LAVAGE FLUID. THE OBTAINED NUCLEIC ACID CAN BE USED IN THE CLINICAL IN VITRO TESTING.
1024	IMP/IVD/2021/000061	1.License Holder Name: INVITROGEN BIOSERVICES INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TAQPATH 1 STEP MULTIPLEX MASTER MIX [NO ROX](APPLIED BIOSYSTEMS)-FOR LABORATORY USE.

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1025	IMP/IVD/2021/000063	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VITROS IMMUNODIAGNOSTIC PRODUCTS IL-6 CONTROLS-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR USE IN MONITORING THE PERFORMANCE OF THE AUTOMATED VITROS IMMUNODIAGNOSTIC SYSTEMS AND THE VITROS INTEGRATED SYSTEMS WHEN USED FOR THE DETERMINATION OF IL-6. ,VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN CONTROLS-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR USE IN MONITORING THE PERFORMANCE OF THE VITROS IMMUNODIAGNOSTIC SYSTEM AND THE VITROS INTEGRATED SYSTEMS FOR THE QUALITATIVE DETECTION OF THE SARS-COV-2 NUCLEOCAPSID ANTIGEN.,VITROS IMMUNODIAGNOSTIC PRODUCTS IL-6 CALIBRATORS-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR USE IN THE CALIBRATION OF THE AUTOMATED VITROS IMMUNODIAGNOSTIC SYSTEMS AND THE VITROS INTEGRATED SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF INTERLEUKIN-6 IN HUMAN SERUM AND PLASMA., VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN EXTRACTION BUFFER-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR USE TO EXTRACT THE VIRAL LOAD FROM SWAB SAMPLES PLACED IN APPROPRIATE TRANSPORT MEDIA FOR USE ON THE VITROS IMMUNODIAGNOSTIC SYSTEM AND THE VITROS INTEGRATED SYSTEMS.,VITROS IMMUNODIAGNOSTIC PRODUCTS IL-6 REAGENT PACK-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE VITROS IMMUNODIAGNOSTIC PRODUCTS IL-6 REAGENT PACK QUANTITATIVELY MEASURES INTERLEUKIN-6 IN HUMAN SERUM AND PLASMA USING THE AUTOMATED VITROS IMMUNODIAGNOSTIC SYSTEMS AND THE VITROS INTEGRATED SYSTEMS,VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN REAGENT PACK-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE THE VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN TEST IS A CHEMILUMINESCENT IMMUNOASSAY INTENDED FOR THE QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID ANTIGENS IN NASOPHARYNGEAL (NP) SPECIMENS FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 WITHIN ONE TO FIVE DAYS OF THE ONSET OF SYMPTOMS, OR MID-TURBINATE SPECIMENS COLLECTED FROM ASYMPTOMATIC INDIVIDUALS, USING THE VITROS IMMUNODIAGNOSTIC SYSTEM AND THE VITROS INTEGRATED SYSTEMS.,VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN CALIBRATOR-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR USE IN

	THE CALIBRATION OF THE VITROS IMMUNODIAGNOSTIC SYSTEM AND THE VITROS INTEGRATED SYSTEMS FOR THE QUALITATIVE DETECTION OF THE SARS-COV-2 NUCLEOCAPSID ANTIGEN.,VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN CALIBRATOR-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. THE VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN REAGENT PACK WHEN USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN CALIBRATOR IS A CHEMILUMINESCENT IMMUNOASSAY INTENDED FOR THE QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID PROTEIN ANTIGENS IN NASOPHARYNGEAL (NP) SPECIMENS COLLECTED IN CDC'S FORMULATION OF VTM, COPAN UNIVERSAL TRANSPORT MEDIA (UTM)®, REMEL M4RT® VTM, OR HARDY R99 VTM FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER WITHIN SEVEN DAYS OF THE ONSET OF SYMPTOMS USING THE VITROS IMMUNODIAGNOSTIC SYSTEM AND THE VITROS INTEGRATED SYSTEMS. ,VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN EXTRACTION BUFFER-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR USE TO EXTRACT THE VIRAL MATERIALS FROM NASOPHARYNGEAL SWAB SAMPLES PLACED IN CDC'S FORMULATION OF VTM, COPAN UNIVERSAL TRANSPORT MEDIA (UTM)®, REMEL M4RT® VTM, OR HARDY R99 VTM FOR USE ON THE VITROS IMMUNODIAGNOSTIC SYSTEM AND THE VITROS INTEGRATED SYSTEMS. ,VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN CONTROLS-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. FOR USE IN MONITORING THE PERFORMANCE OF THE VITROS IMMUNODIAGNOSTIC SYSTEM AND THE VITROS INTEGRATED SYSTEMS FOR THE QUALITATIVE DETECTION OF THE SARS-COV-2 NUCLEOCAPSID ANTIGEN. ,VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN REAGENT PACK-FOR IN VITRO DIAGNOSTIC AND LABORATORY PROFESSIONAL USE. THE VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN REAGENT PACK WHEN USED IN COMBINATION WITH THE VITROS IMMUNODIAGNOSTIC PRODUCTS SARS-COV-2 ANTIGEN CALIBRATOR IS A CHEMILUMINESCENT IMMUNOASSAY INTENDED FOR THE QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID PROTEIN ANTIGENS IN NASOPHARYNGEAL (NP) SPECIMENS COLLECTED IN CDC'S FORMULATION OF VTM, COPAN UNIVERSAL TRANSPORT MEDIA (UTM)®, REMEL M4RT® VTM, OR HARDY R99 VTM FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER WITHIN SEVEN DAYS OF THE ONSET OF SYMPTOMS USING THE VITROS IMMUNODIAGNOSTIC SYSTEM AND THE VITROS INTEGRATED SYSTEMS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1026	IMP/IVD/2021/000067	1.License Holder Name: M/S. SURGITECH INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAT PROFILE PHOX ULTRA/CCX BLOOD GAS CONTROLS AUTO- CARTRIDGE(NOVA BIOMEDICAL CORPORATION USA)-FOR IN VITRO DIAGNOSTIC USE FOR MONITORING THE PERFORMANCE OF NOVA BIOMEDICAL STAT PROFILE PHOX ULTRA/CRITICAL CARE XPRESS ANALYZERS,PRIME ES DILUENT SOLUTION(NOVA BIOMEDICAL CORPORATION USA)-URINE DILUENT PRIME ES IS INTENDED TO DILUTE THE URINE SAMPLES TO COVER THE ANALYTICAL MEASUREMENT RANGE FOR ALL ANALYTES.,NOVA LINEARITY CREATININE/BUN/HCT(NOVA BIOMEDICAL CORPORATION USA)-THIS IS INTENDED TO RECORD QUANTITATIVE DETERMINATION OF PH, PARTIAL PRESSURE OF CARBON DIOXIDE, PARTIAL PRESSURE OF OXYGEN, HEMATOCRIT, SODIUM, POTASSIUM, CHLO¬RIDE, IONIZED CALCIUM, IONIZED MAGNESIUM, GLUCOSE, LACTATE, CREATININE, BLOOD UREA NITROGEN, OXYGEN SATURATION, TOTAL HEMOGLOBIN, OXYHEMOGLOBIN, CARBOXYHEMOGLOBIN, METHEMOGLOBIN, DEOXYHEMOGLOBIN, FETAL HEMOGLOBIN, AND TOTAL BILIRUBIN (TBIL), IN HEPA¬RINIZED ARTERIAL, VENOUS, AND CAPILLARY WHOLE BLOOD.,STAT PROFILE PHOX ULTRA/CRITICAL CARE XPRESS CONTROL 1,2,3(NOVA BIOMEDICAL CORPORATION USA)-FOR IN VITRO DIAGNOSTIC USE FOR MONITORING THE PERFORMANCE OF PH, PCO2, PO2, SO2, HCT, AND HB ON STAT PROFILE PHOX ULTRA/CRITICAL CARE XPRESS (CCX) ANALYZERS.,STAT PROFILE PHOX /PHOX ULTRA/CRITICAL CARE XPRESS CCX SO2 CALIBRATORS 1,2(NOVA BIOMEDICAL CORPORATION USA)-FOR IN VITRO DIAGNOSTOC USE FOR MONITORING THE PERFORMANCE OF NOVA BIOMEDICAL STAT PROFILE PHOX/PLUS/L/C ANALYZERS AND STAT PROFILE CCX ANALYZERS,PRIME AMPULED CONTROL ABG/CCS (NOVA BIOMEDICAL CORPORATION USA)-THE STATPROFILE PRIME AMPULED CONTROL ABG/CCS IS A QUALITY CONTROL MATERIAL INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS FOR MONITORING THE PERFORMANCE OF THE STATPROFILE PRIME CCS ANALYZER.,STAT PROFILE PHOX PLUS M CALIBRATOR(NOVA BIOMEDICAL CORPORATION USA)-FOR THE QUANTITATIVE DETERMINATION OF NA+, K+, MG++, CA++ , GLUCOSE, LACTATE, PH, PCO2, PO2, AND HCT IN HUMAN BLOOD USING THE NOVA BIOMEDICAL STAT PROFILE PHOX PLUS M ANALYZER.,STAT PROFILE PHOX ULTRA/CCX CHEMISTRY CONTROLS AUTO-CARTRIDGE WITH CREATININE(NOVA BIOMEDICAL CORPORATION USA)-FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PERFORMANCE OF THE S TAT PROFILE PHOX ULTRA/CRITICAL CARE XPRESS ANALYZER AND TO INSURE OPTIMUM PERFORMANCE OF

	GLUCOSE AND CREAT ININE MEMBRANES. PERFORMANCE CHECK SOLUTION SHOULD BE ANALYZED BEFORE CONTROLS A RE RUN AND AFTER CHANGING GLUCOSE,NOVA GLU/LAC SENSOR SOAKING SOLUTION(NOVA BIOMEDICAL CORPORATION USA)-SOLUTION USED IN THE POLISHING OF THE ELECTRODE FOR IVD USE,PREHEATER DEPROTEINIZING SOLUTION(NOVA BIOMEDICAL CORPORATION USA) -NOVA RECOMMENDS THE USE OF DEPROTEINIZING SOLUTION (PN 12704) WHEN ROUTINE CLEANING IS REQUIRED. THE SOLUTION DISSOLVES PROTEIN BUILDUP,PRIME CALIBRATOR CARTRIDGE ES BASIC(NOVA BIOMEDICAL CORPORATION USA)-THE STAT PROFILE PRIME CALIBRATOR CARTRIDGE ES IS INTENDED FOR THE CALIBRATION OF HCT, NA+, K+, CL-, ICA, AND IMG USING THE STAT PROFILE PRIME ES ANALYZER.,STAT PROFILE PRIME PLUS® AUTO QC CARTRIDGE(NOVA BIOMEDICAL CORPORATION USA)-INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS FOR MONITORING THE PERFORMANCE OF THE STAT PROFILE PRIME PLUS ANALYZERS.,STAT PROFILE PRIME PLUS® CALIBRATOR CARTRIDGE(NOVA BIOMEDICAL CORPORATION USA)-FOR THE QUANTITATIVE DETERMINATION OF NA+, K+, CL-, ICA, IMG,BUN (UREA), GLUCOSE, LACTATE, PH, PCO2, PO2, SO2%, HCT,THB, HBF*, O2HB, COHB, METHB, HHB, AND TBIL* IN HUMAN BLOOD USING THE STAT PROFILE PRIME PLUS ANALYZER.,STAT PROFILE PRIME PLUS® AMPULED CONTROLS CHEMISTRY LEVELS 4,5(NOVA BIOMEDICAL CORPORATION USA)-INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS USE FOR MONITORING THE PERFORMANCE OF THE STAT PROFILE PRIME PLUS ANALYZERS., STAT PROFILE PHOX ULTRA/CCX CHEMISTRY CONTROLS AUTO-CARTRIDGE(NOVA BIOMEDICAL CORPORATION USA)-FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PERFORMANCE OF THE STAT PROFILE PHOX ULTRA/CRITICAL CARE XPRESS ANALYZER AND TO INSURE OPTIMUM PERFORMANCE OF GLUCOSE MEMBRANES. PERFORMANCE CHECK SOLUTION SHOULD BE ANALYZED BEFORE CONTROLS ARE RUN AND AFTER CHANGING GLUCOSE MEMBRANE., PRIME CALIBRATOR CARTRIDGE ES COMP(NOVA BIOMEDICAL CORPORATION USA)-THE STAT PROFILE PRIME CALIBRATOR CARTRIDGE ES IS INTENDED FOR THE CALIBRATION OF HCT, NA+, K+, CL-, ICA, AND IMG USING THE STAT PROFILE PRIME ES ANALYZER., PRIME AMPULED CONTROL ES(PRIME AMPULED CONTROL ES)-FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PERFORMANCE OF THE STATPROFILE PRIME ES ANALYZER.,STAT PROFILE PREHEATER CLEANING AGENT(NOVA BIOMEDICAL CORPORATION USA)-INTENDED TO BE USED AS AN AID IN THE CLEANING OF THE STAT PROFILE ANALYZERS,STAT PROFILE PRIME PLUS® CALIBRATOR CARTRIDGE WITH CREATININE(NOVA BIOMEDICAL CORPORATION

	USA)-FOR THE QUANTITATIVE DETERMINATION OF NA+, K+, CL-, ICA, IMG,BUN (UREA), GLUCOSE, LACTATE, CREATININE, PH, PCO2, PO2, SO2%, HCT, THB, HBF*, O2HB, COHB,MET HB, HHB, AND TBIL* IN HUMAN BLOOD USING THE STAT PROFILE PRIME PLUS ANALYZER.. STAT PROFILE PHOX ULTRA/CRITICAL CARE XPRESS CONTROL 7, 8, 9 (NOVA BIOMEDICAL CORPORATION USA)-FOR IVD BY HEALTHCARE PROFESSIONALS FOR MONITORING THE PERFORMANCE OF STAT PROFILE PHOX ULTRA/CCX ANALYZERS,STAT PROFILE PHOX PLUS L CONTROL 1,2,3(NOVA BIOMEDICAL CORPORATION USA)-FOR IN VITRO DIAGNOSTIC USE FOR MONITORING THE PERFORMANCE OF NOVA BIOMEDICAL STAT PROFILEPHOX PLUS L ANALYZERS,STAT PROFILE PHOX ULTRA/CRITICAL CARE XPRESS CONTROL 4,5(NOVA BIOMEDICAL CORPORATION USA)-FOR IN VITRO DIAGNOSTIC USE TO MONITOR THE PERFORMANCE OF THE STAT PROFILE PHOX ULTRA/CRITICAL CARE XPRESS ANALYZER,NOVA PERFORMANCE CHECK SOLN GLU/BUN/ CREAT(NOVA BIOMEDICAL CORPORATION USA)-TO CONFIRM THE OPERATIONAL RANGE OF THE GLU, BUN, AND CREAT MEMBRANES AND THE EFFECT OF INTERFERENCE FROM CREATINE ON THE CREATININE MEMBRANE.,STAT PROFILE PHOX ULTRA/CCX CALIBRATOR CARTRIDGE 1(NOVA BIOMEDICAL CORPORATION USA)-FOR THE QUANTITATIVE DETERMINATION OF NA+, K+, CL-, CA++, MG++, BUN (UREA), GLUCOSE, LACTATE, PH, CO2, PO2, SO2%, HB, AND HCT IN HUMAN BLOOD USING THE NOVA BIOMEDICAL STAT PROFILE PHOX ULTRA/CRITICAL CARE XPRESS (CCX) ANALYZER.,STAT PROFILE PHOX/BASIC CALIBRATOR(NOVA BIOMEDICAL CORPORATION USA)-FOR THE QUANTITATIVE DETERMINATION OF PH, PCO2, PO2, SO2%, HB, AND HCT IN HUMAN BLOOD USING THE NOVA BIOMEDICAL STAT PROFILE PHOX/BASIC ANALYZER.,STAT PROFILE PHOX CONDITIONING SOLUTION(NOVA BIOMEDICAL CORPORATION USA)-FOR IN VITRO DIAGNOSTIC USE, PRIME CALIBRATOR CARTRIDGE CCS(NOVA BIOMEDICAL CORPORATION USA)-THE STAT PROFILE PRIME CALIBRATOR CARTRIDGE CCS IS INTENDED FOR THE CALIBRATION OF PH, PCO2, PO2, HCT, NA+, K+, CL- ,ICA, GLUCOSE (GLU), AND LACTATE (LAC) USING THE STAT PROFILE PRIME CCS ANALYZER.,STAT PROFILE PRIME PLUS® AUTO QC CARTRIDGE(NOVA BIOMEDICAL CORPORATION USA)-INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS FOR MONITORING THE PERFORMANCE OF THE STAT PROFILE PRIME PLUS ANALYZERS, PRIME AUTO QC CARTRIDGE CCS(NOVA BIOMEDICAL CORPORATION USA)-THE STATPROFILE PRIME AUTO QC CARTRIDGE CCS IS A QUALITY CONTROL MATERIAL INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS FOR MONITORING THE PERFORMANCE OF THE STATPROFILE PRIME CCS ANALYZER.,STAT

	PROFILE PHOX ULTRA/CCX CO-OX CALIBRATOR CARTRIDGE WITH BILIRUBIN AND DEPROTEINIZING SOLUTION(NOVA BIOMEDICAL CORPORATION USA)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL HEMOGLOBIN, OXYHEMOGLOBIN, CARBOXYHEMOGLOBIN, METHEMOGLOBIN, DEOXYHEMOGLOBIN AND TOTAL BILIRUBIN IN HUMAN BLOOD USING THE STAT PROFILE PHOX ULTRA/CRITICAL CARE XPRESS CO-OXIMETER ANALYZER,STAT PROFILE PHOX ULTRA/CCX CALIBRATOR CARTRIDGE 1 WITH CREATININE(NOVA BIOMEDICAL CORPORATION USA)-FOR THE QUANTITATIVE DETERMINATION OF NA+, K+, CL-, CA++, MG++, BUN (UREA), GLUCOSE, LACTATE, CREATININE, PH, PCO2, PO2, SO2%, HB, AND HCT IN HUMAN BLOOD USING THE STAT PROFILE PHOX ULTRA/CRITICAL CARE XPRESS (CCX) ANALYZER.,STAT PROFILE PHOX PLUS C CALIBRATOR(NOVA BIOMEDICAL CORPORATION USA)-FOR THE QUANTITATIVE DETERMINATION OF NA+, K+, CL-, CA++, GLUCOSE, PH, PCO2, PO2, SO2%, HB, AND HCT IN HUMAN BLOOD USING THE NOVA BIOMEDICAL STAT PROFILE PHOX PLUS C ANALYZER.,STAT PROFILE PRIME PLUS® AMPULED CONTROLS BG, COOX LEVELS 1, 2, 3 (NOVA BIOMEDICAL CORPORATION USA)-INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS USE FOR MONITORING THE PERFORMANCE OF THE STAT PROFILE PRIME PLUS ANALYZERS.,STAT PROFILE PHOX/BASIC/PLUS/L/C/M PCO2 MEMBRANE CAP KIT(NOVA BIOMEDICAL CORPORATION USA)-FOR IN VITRO DIAGNOSTIC USE PCO2 WITH STAT PROFILE PHOX ANALYZER, STAT PROFILE PHOX PLUS/C CONTROL 1,2,3(NOVA BIOMEDICAL CORPORATION USA)-FOR IN VITRO DIAGNOSTIC USE FOR MONITORING THE PERFORMANCE OF NOVA BIOMEDICAL STAT PROFILE PHOX PLUS/C ANALYZERS.,STAT PROFILE PHOX ULTRA/CCX CO-OXIMETER CONTROLS AUTO- CARTRIDGE(NOVA BIOMEDICAL CORPORATION USA)-FOR IVD USE FOR MONITORING THE PERFORMANCE OF NOVA PHOX ULTRA AND CCX ANALYZERS, STAT PROFILE PHOX PLUS L CALIBRATOR(NOVA BIOMEDICAL CORPORATION USA)-FOR THE QUANTITATIVE DETERMINATION OF NA+, K+, CL-/CA++, GLUCOSE, LACTATE, PH, PCO2, PO2, SO2, HB, AND HCT IN HUMAN BLOOD USING THE NOVA BIOMEDICAL STAT PROFILE PHOX PLUS L ANALYZER.,PRIME CALIBRATOR CARTRIDGE CCS COMP(NOVA BIOMEDICAL CORPORATION USA)-THE STAT PROFILE PRIME CALIBRATOR CARTRIDGE CCS IS INTENDED FOR THE CALIBRATION OF PH, PCO2, PO2, HCT, NA+, K+, CL- ,ICA, GLUCOSE (GLU), AND LACTATE (LAC) USING THE STAT PROFILE PRIME CCS ANALYZER.,PRIME CALIBRATOR CARTRIDGE ABG(NOVA BIOMEDICAL CORPORATION USA)-FOR THE QUANTITATIVE DETERMINATION OF PH, PCO2, AND PO2 IN HUMAN BLOOD USING THE NOVA BIOMEDICAL PRIME ABG ANALYZER.,NOVA CLEANING SOLUTION(NOVA

		BIOMEDICAL CORPORATION USA)-FOR CLEANING SAMPLE PROBES, MIXERS, TUBING AND SENSORS IN NOVA ANALYZERS.,PRIME AUTO QC CARTRIDGE ABG(NOVA BIOMEDICAL CORPORATION USA)-THE STAT PROFILE PRIME AUTO QC CARTRIDGE ABG IS A QUALITY CONTROL MATERIAL INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS FOR MONITORING THE PERFORMANCE OF THE STAT PROFILE PRIME ABG ANALYZER.
1027	IMP/IVD/2021/000072	1.License Holder Name: BIO STATE INC. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MINI PARASEP SF (FAECAL PARASITE CONCENTRATOR)(PARASEP)-PARASEP FAECAL CONCENTRATOR KIT IS A PARASITE CONCENTRATION KIT RECOMMENDED FOR USE IN QUALITATIVE PROCEDURES FOR THE CONCENTRATION OF PROTOZOAN CYSTS, OOCYSTS AND HELMINTH EGGS AND LARVAE FROM FAECAL MATERIAL.
1028	IMP/IVD/2021/000078	1.License Holder Name: ELETE BIOTECH PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOTOXIN ACTIVITY ASSAY (EAA™)-THE EAA™ IS A RAPID IN VITRO DIAGNOSTIC TEST THAT UTILIZES A SPECIFIC MONOCLONAL ANTIBODY TO MEASURE THE ENDOTOXIN ACTIVITY IN EDTA WHOLE BLOOD SPECIMENS.

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1029	IMP/IVD/2021/000079	1.License Holder Name: GLOBAL MEDIAL SYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:1000 MOSM /KG H2O CALIBRATION STANDARD(MOSM/KG CALIBRATION STANDARD)-OSMOMETER STANDARDS ARE USED TO CALIBRATE AND/OR CHECK THE PERFORMANCE OF THE OSMOMETER. THESE STANDARDS SHOULD ONLY BE USED IN ACCORDANCE WITH THE OSMOMETER THAT IS BEING CALIBRATED. ,850 MOSM /KG H2O CALIBRATION STANDARD(MOSM/KG CALIBRATION STANDARD)-OSMOMETER STANDARDS ARE USED TO CALIBRATE AND/OR CHECK THE PERFORMANCE OF THE OSMOMETER. THESE STANDARDS SHOULD ONLY BE USED IN ACCORDANCE WITH THE OSMOMETER THAT IS BEING CALIBRATED. ,400 MOSM /KG H2O CALIBRATION STANDARD (MOSM/KG CALIBRATION STANDARD)-OSMOMETER STANDARDS ARE USED TO CALIBRATE AND/OR CHECK THE PERFORMANCE OF THE OSMOMETER. THESE STANDARDS SHOULD ONLY BE USED IN ACCORDANCE WITH THE OSMOMETER THAT IS BEING CALIBRATED. , OSMOLALITY LINEARITY SET 100-2000 MOSM/KG(OSMOLALITY LINEARITY SET)-"THE OSMOLALITY LINEARITY SET IS DESIGNED TO HELP CLINICAL LABORATORIES EASILY MONITOR OSMOMETER PERFORMANCE SPECIFICATIONS AND FULFILL CLIA REQUIREMENTS FOR VERIFYING THE REPORTABLE RANGE OF A LABOROATRY METHOD. # ASSESS AND DOCUMENT METHOD PERFORMANCE STANDARDS. # TEST LINEARITY SET AFTER PERFORMING CALIBRATION. VERIFY REPORTABLE RANGE OF PATIENT TEST RESULTS. # STRENGTHEN YOU LABORATORY'S QUALITY CONTROL PROGRAM BY USING PRODUCTS MADE SPECIFICALLY FOR YOUR OSMOMETER. " ,290 MOSM /KG H2O CLINITROL REFERENCE SOLUTION(CLINITROL REFERENCE SOLUTION)-CLINITROL 290 REFERENCE SOLUTION IS INTENDED FOR USE IN EVALUATING THE PERFORMANCE OF YOUR OSMOMETER. IT IS A TRUE REFERENCE DESIGNED TO VERIFY INSTRUMENT CALIBRATION. USE CLINITROL: • DAILY, PRIOR TO TESTING SAMPLES, TO VERIFY INSTRUMENT OPERATION AND CONFIRM CALIBRATION. • TO STRENGTHEN YOUR LABORATORY'S QUALITY CONTROL PROGRAM AND INCREASE CONFIDENCE. • TO MONITOR OPERATOR TECHNIQUE, PARTICULARLY IMPORTANT WHEN SEVERAL SHIFTS OR OPERATORS ARE INVOLVED. • AFTER PERFORMING A CALIBRATION.,RENOL 2 LEVEL OSMOMETER CONTROL 300 MOSM/KG H2O, 800 MOSM/KG H2O(RENOL URINE OSMOLALITY CONTROLS)-"RENOL URINE OSMOLALITY CONTROLS ARE INTENDED FOR USE IN EVALUATING PERFORMANCE OF OSMOEMTER. USE THESE CONTROLS DAILY TO MONITOR THE PRECISION OF THE TESTING PROCEDURE FOR OSMOLALITY, AND TO COMPLY WITH CLIA QUALITY CONTROL REQUIREMENTS. RENOL

	URINE OSMOLALITY CONTROLS ARE FORMULATED CLOSE TO MEDICAL DECISION LEVELS WHERE PERFORMANCE IS CRITICAL., 2000 MOSM /KG H2O CALIBRATION STANDARD(MOSM/KG CALIBRATION STANDARD)-OSMOMETER STANDARDS ARE USED TO CALIBRATE AND/OR CHECK THE PERFORMANCE OF THE OSMOMETER. THESE STANDARDS SHOULD ONLY BE USED IN ACCORDANCE WITH THE OSMOMETER THAT IS BEING CALIBRATED., 500 MOSM /KG H2O CALIBRATION STANDARD(MOSM/KG CALIBRATION STANDARD)-OSMOMETER STANDARDS ARE USED TO CALIBRATE AND/OR CHECK THE PERFORMANCE OF THE OSMOMETER. THESE STANDARDS SHOULD ONLY BE USED IN ACCORDANCE WITH THE OSMOMETER THAT IS BEING CALIBRATED. , 1500 MOSM /KG H2O CALIBRATION STANDARD(MOSM/KG CALIBRATION STANDARD)-OSMOMETER STANDARDS ARE USED TO CALIBRATE AND/OR CHECK THE PERFORMANCE OF THE OSMOMETER. THESE STANDARDS SHOULD ONLY BE USED IN ACCORDANCE WITH THE OSMOMETER THAT IS BEING CALIBRATED. , 100 MOSM /KG H2O, CALIBRATION STANDARD (MOSM/KG CALIBRATION STANDARD)-CALIBRATION STANDARDS ARE USED TO CALIBRATE AND/OR CHECK THE PERFORMANCE OF YOUR OSMOMETER. THESE STANDARDS SHOULD ONLY BE USED IN ACCORDANCE WITH THE OSMOMETER THAT IS BEING CALIBRATED., 50 MOSM /KG H2O, CALIBRATION STANDARD(MOSM/KG CALIBRATION STANDARD)-OSMOMETER STANDARDS ARE USED TO CALIBRATE AND/OR CHECK THE PERFORMANCE OF THE OSMOMETER. THESE STANDARDS SHOULD ONLY BE USED IN ACCORDANCE WITH THE OSMOMETER THAT IS BEING CALIBRATED., PROTINOL 3 LEVEL OSMOMETER CONTROL 240 MOSM/KG, 280MOSM/KG,320 MOSM/KG(PROTINOL PROTEIN-BASED CONTROLS)-PROTINOL PROTEIN-BASED OSMOLALITY CONTROLS ARE INTENDED FOR USE IN EVALUATING THE PERFORMANCE OF THE OSMOMETER. USE THESE CONTROLS TO MONITOR THE PRECISION OF THE TESTING PROCEDURE FOR OSMOLALITY, AND TO CONDUCT LABORATORY PROFICIENCY TESTING. PROTINOL PROTIEN-BASED CONTROLS ARE FORMULATED TO MIMIC REPORTABLE RANGES FOR HUMAN SERUM.,900 MOSM /KG H2O CALIBRATION STANDARD (MOSM/KG CALIBRATION STANDARD)-OSMOMETER STANDARDS ARE USED TO CALIBRATE AND/OR CHECK THE PERFORMANCE OF THE OSMOMETER. THESE STANDARDS SHOULD ONLY BE USED IN ACCORDANCE WITH THE OSMOMETER THAT IS BEING CALIBRATED. , 3000 MOSM /KG H2O CALIBRATION STANDARD(MOSM/KG CALIBRATION STANDARD)-OSMOMETER STANDARDS ARE USED TO CALIBRATE AND/OR CHECK THE PERFORMANCE OF THE OSMOMETER. THESE STANDARDS SHOULD ONLY BE USED IN

		ACCORDANCE WITH THE OSMOMETER THAT IS BEING CALIBRATED. , 200 MOSM /KG H2O CALIBRATION STANDARD(MOSM/KG CALIBRATION STANDARD)-OSMOMETER STANDARDS ARE USED TO CALIBRATE AND/OR CHECK THE PERFORMANCE OF THE OSMOMETER. THESE STANDARDS SHOULD ONLY BE USED IN ACCORDANCE WITH THE OSMOMETER THAT IS BEING CALIBRATED.
1030	IMP/IVD/2021/000081	1.License Holder Name: BIOLINE DIAGNOSTICS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DILUENT(EDAN)-THE DILUENT IS INTENDED TO PERFORM ERYTHROCYTES AND PLATELETS MEASUREMENT IN A BLOOD SAMPLE.,LYSE(EDAN)-LYSE IS USED TO REACT ON BLOOD SAMPLES FOR QUANTITATIVELY DETERMINING HEMOGLOBIN AND FOR DIFFERENTIATING AND COUNTING LEUKOCYTES.,CLEANER(EDAN)-THE CLEANER IS INTENDED TO CLEAN AND RINSE THE FLUIDIC CHANNELS WITHIN ANALYZER TO ENSURE THE ANALYZER'S PERFORMANCE.
1031	IMP/IVD/2021/000082	1.License Holder Name: INVITROGEN BIOSERVICES INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TAQPATH™ COVID-19 CE-IVD RT-PCR KIT(APPLIED BIOSYSTEMS)-TAQPATH™ COVID-19 CE-IVD RT-PCR KIT CONTAINS THE REAGENTS AND CONTROLS FOR A REAL-TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN NASOPHARYNGEAL SWAB, NASOPHARYNGEAL ASPIRATE, AND BRONCHOALVEOLAR LAVAGE (BAL) SPECIMENS FROM INDIVIDUALS SUSPECTED OF COVID-19.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1032	IMP/IVD/2021/000083	1.License Holder Name: HAPTEN BIOSYSTEMS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTI-THYROGLOBULIN (ANTI-TG) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) AUTOANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY ,D-DIMER CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF D-DIMER CONCENTRATION IN HUMAN PLASMA AND SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENSE,THYROTROPIN (TSH) CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF THYROTROPIN CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ,D-DIMER ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF D-DIMER CONCENTRATION IN HUMAN PLASMA AND SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, COLORIMETRIC,17-OH PROGESTERONE CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL 17 HYDROXY PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY , TOTAL THYROXINE (T4) CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ,FREE BETA HUMAN CHORIONIC GONADOTROPIN (F-BHCG) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE BETA CHORIONIC GONADOTROPIN SUBUNIT CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,CANCER ANTIGEN (CA 19-9) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 19-9 (CA 19-9) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE ASSAY ,CANCER ANTIGEN (CA 15-3) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 15-3 (CA 15-3) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE ASSAY , LUTEINIZING HORMONE (LH) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY ,FERTILITY VAST (LH+FSH+PRL+BHCG) CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF HCG, PRL, LH AND FSH CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ,CANCER ANTIGEN 125 (CA - 125) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 125 (CA-125) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE ASSAY ,THYROID

	VAST (T3+T4+TSH) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE, TOTAL TRIIODOTHYRONINE, THYROID STIMULATING HORMONE CONCENTRATION FOR A COMPREHENSIVE THYROID STATUS OF HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY , PROGESTERONE ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY ,CANCER ANTIGEN 125 (CA - 125) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 125 (CA-125) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY ,THYROID BINDING GLOBULIN (TBG) ELISA(ACCUBIND)-THE QUANTITATIVE DETERMINATION OF TBG THYROXINE BINDING GLOBULIN CONCENTRATION IN HUMAN SERUM, PLASMA OR WHOLE BLOOD BY A MICROPLATE ENZYME LABELED IMMUNOASSAY. ,ANTI-THYROGLOBULIN (ANTI-TG) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN AUTOANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ,INSULIN/C-PEPTIDE MAPS ELISA(ACCUBIND)-MONOBIND INSULIN/C-PEPTIDE MAPS ELISA TEST IS INTENDED TO BE USED FOR THE QUANTITATIVE DETERMINATION OF INSULIN OR C-PEPTIDE LEVELS IN HUMAN SERUM. ,UNCONJUGATED ESTRIOL (U-E3) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL ESTRIOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,ANTI-THYROPEROXIDASE (ANTI-TPO) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF THYROID PEROXIDASE (TPO) AUTOANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ,PROGESTERONE CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,CANCER PANEL VAST (AFP+CEA+PSA) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF AFP, CEA AND PSA CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE ASSAY ,THYROGLOBULIN (TG) CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN LEVELS IN HUMAN SERUM ,FREE TRIIODOTHYRONINE (FT3) CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA). ,ESTRADIOL CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL ESTRADIOL

	CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,VITAMIN B12 CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,DIGOXIN CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL DIGOXIN CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,TESTOSTERONE CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,FREE PROSTATE SPECIFIC ANTIGEN (FPSA) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (FPSA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY. ,CANCER ANTIGEN (CA 19-9) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 19-9 (CA 19-9) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY ,THYROID BINDING GLOBULIN (TBG) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TBG THYROXINE BINDING GLOBULIN CONCENTRATION IN HUMAN SERUM, PLASMA OR WHOLE BLOOD BY A MICROPLATE ENZYME LABELED CHEMILUMINESCENSE IMMUNOASSAY ,IMMUNOGLOBULIN E (IGE) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,HUMAN CHORIONIC GONADOTROPIN (BHCG) CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CHORIONIC GONADOTROPIN (HCG) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ,TOTAL TRIIODOTHYRONINE (T3) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE (TT3) CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,DIGOXIN ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL DIGOXIN CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY ,THYROID VAST (T3+T4+TSH) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE, TOTAL TRIIODOTHYRONINE, & THYROID STIMULATING HORMONE CONCENTRATION FOR A COMPREHENSIVE THYROID STATUS OF HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY ,FREE TRIIODOTHYRONINE (FT3) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) CONCENTRATION IN HUMAN SERUM BY A

	MICROPLATE ENZYME IMMUNOASSAY ,25-OH VITAMIN D TOTAL ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY. ,IMMUNOGLOBULIN E (IGE) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY ,FREE THYROXINE (FT4) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY ,FREE TESTOSTERONE CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,C-PEPTIDE ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING C-PEPTIDE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY ,C-PEPTIDE CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING C-PEPTIDE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY. ,FREE THYROID VAST (FT3+FT4+TSH) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE, FREE TRIIODOTHYRONINE, THYROID STIMULATING HORMONE CONCENTRATION FOR A COMPREHENSIVE THYROID STATUS OF HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,INSULIN ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF INSULIN LEVELS IN HUMAN SERUM ,TOTAL TRIIODOTHYRONINE (T3) UPTAKE CLIA(ACCULITE)-FOR THE MEASUREMENT OF TOTAL AMOUNT OF BINDING SITES AVAILABLE FOR THE THYROID HORMONES IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ,TUMOR MARKER QUALITY CONTROL MATERIAL(QSURE)-THE TUMOR MARKER PANEL CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE CONSISTENCY OF PERFORMANCE OF LABORATORY TEST PROCEDURES ASSOCIATED WITH DETERMINATION AND MONITORING OF THE TUMOR MARKER STATUS. ,FERRITIN ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING FERRITIN CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY , INSULIN/C-PEPTIDE MAPS CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF INSULIN OR C-PEPTIDE LEVELS IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY , TOTAL TRIIODOTHYRONINE (T3) CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE

	CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ,CORTISOL ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL CORTISOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY ,DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY ,PROLACTIN (PRL) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY ,MULTI LIGAND QUALITY CONTROL MATERIAL(QSURE)-THE MULTI LIGAND CONTROLS ARE INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE CONSISTENCY OF PERFORMANCE OF LABORATORY TEST PROCEDURES ASSOCIATED WITH DETERMINATION AND MONITORING OF THE CLINICAL STATUS. ,PROLACTIN (PRL) CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ,ANTI-MULLERIAN HORMONE (AMH) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF AMH CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, COLORIMETRIC, ANTI-MULLERIAN HORMONE (AMH) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF AMH CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,HUMAN GROWTH HORMONE (HGH) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF GROWTH HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY ,HIGH SENSITIVITY C-REACTIVE PROTEIN (HS CRP) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CRP C-REACTIVE PROTEIN CONCENTRATION IN HUMAN SERUM, PLASMA OR WHOLE BLOOD BY A MICROPLATE IMMUNOENZYMOMETRIC CHEMILUMINESCENCE ASSAY ,ESTRADIOL ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL ESTRADIOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY , ALPHA FETO PROTEIN (AFP) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF ALPHA FETOPROTEIN (AFP) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,UNCONJUGATED ESTRIOL (U-E3) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF ESTRIOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY ,PROSTATE SPECIFIC ANTIGEN (TPSA) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION

	OF TOTAL PROSTATE SPECIFIC ANTIGEN (TPSA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY , LUTEINIZING HORMONE (LH) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ,TOTAL THYROXINE (T4) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE (TT4) CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE CONCENTRATION (DHEA-$) IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,SOLUBLE TRANSFERRIN RECEPTOR CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF STFR CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE ASSAY (CLIA) ,H. PYLORI IGA CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF ANTI-H.PYLORI SPECIFIC ANTIBODIES OF THE IGA ANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,ANTI-THYROPEROXIDASE (ANTI-TPO) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF THYROID PEROXIDASE (TPO) AUTOANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY ,CREATINE KINASE (CK) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING CREATINE KINASE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,MYOGLOBIN CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING MYOGLOBIN CONCENTRATION IN HUMAN SERUM, PLASMA AND URINE BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,SOLUBLE TRANSFERRIN RECEPTOR ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF STFR CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY. ,CREATINE KINASE (CK) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING CREATINE KINASE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,25-OH VITAMIN D TOTAL CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,HIGH SENSITIVITY C-REACTIVE PROTEIN (HS CRP) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE

	IMMUNOENZYMOMETRIC ASSAY ,FERTILITY VAST (LH+FSH+PRL+BHCG) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF HCG, PRL, LH AND FSH CONCENTRATION IN HUMAN SERUM AND PLASMA BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY. ,FERRITIN CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING FERRITIN CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ,FOLLICLE STIMULATING HORMONE (FSH) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY ,THYROTROPIN (TSH) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF THYROTROPIN (TSH) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY ,H.PYLORI IGM CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF ANTI-H. PYLORI SPECIFIC ANTIBODIES OF THE IGM ANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,HUMAN GROWTH HORMONE (HGH) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF GROWTH HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,TOTAL TRIIODOTHYRONINE (T3) UPTAKE ELISA(ACCUBIND)-FOR THE MEASUREMENT OF TOTAL AMOUNT OF BINDING SITES AVAILABLE FOR THE THYROID HORMONES IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY ,CANCER PANEL VAST (AFP+CEA+PSA) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF AFP, CEA AND PSA CONCENTRATION IN HUMAN SERUM AND PLASMA BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY ,PROSTATE SPECIFIC ANTIGEN (TPSA) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROSTATE SPECIFIC ANTIGEN (TPSA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,INSULIN CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF INSULIN CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ,FREE PROSTATE SPECIFIC ANTIGEN (FPSA) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (FPSA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY , FOLATE ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FOLATE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY ,MYOGLOBIN ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING MYOGLOBIN CONCENTRATION IN HUMAN SERUM BY A MICROPLATE

	IMMUNOENZYMOMETRIC ASSAY ,H.PYLORI IGG CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF ANTI-H.PYLORI SPECIFIC ANTIBODIES OF THE IGG ANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,TROPONIN I CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING TROPONIN-I CONCENTRATIONS IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,CORTISOL CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL CORTISOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA) , CARCINOEMBRYONIC ANTIGEN (CEA) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY ,FREE BETA HUMAN CHORIONIC GONADOTROPIN (F-BHCG) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE BETA CHORIONIC GONADOTROPIN SUBUNIT CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY ,HUMAN CHORIONIC GONADOTROPIN (BHCG) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CHORIONIC GONADOTROPIN (HCG) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY ,TESTOSTERONE ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY ,FREE THYROXINE (FT4) CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ,17-OH PROGESTERONE ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF 17-OH PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY. ,FOLLICLE STIMULATING HORMONE (FSH) CLIA (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY ,ALPHA FETO PROTEIN (AFP) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF ALPHA FETOPROTEIN (AFP) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY ,H.PYLORI IGG ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF ANTI-H. PYLORI SPECIFIC ANTIBODIES OF THE IGG ANTIBODIES IN HUMAN SERUM OR PLASMA BY MICROPLATE ENZYME IMMUNOASSAY , CARCINOEMBRYONIC ANTIGEN (CEA) CLIA(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE

	CHEMILUMINESCENCE ASSAY (CLIA) ,TROPONIN I ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING TROPONIN I CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY. ,CANCER ANTIGEN (CA 15-3) ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 15-3 (CA 15-3) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY ,FREE TESTOSTERONE ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY ,THYROGLOBULIN (TG) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) LEVELS IN HUMAN SERUM,VITAMIN B12 ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY ,H.PYLORI IGA ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF ANTI-H.PYLORI SPECIFIC ANTIBODIES OF THE IGA ANTIBODIES IN HUMAN SERUM OR PLASMA BY MICROPLATE ENZYME IMMUNOASSAY ,FREE THYROID VAST (FT3+FT4+TSH) ELISA(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE, FREE TRIIODOTHYRONINE, & THYROID STIMULATING HORMONE CONCENTRATION FOR A COMPREHENSIVE THYROID STATUS OF HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY ,H.PYLORI IGM ELISA (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF ANTI-H. PYLORI SPECIFIC ANTIBODIES OF THE IGM ANTIBODIES IN HUMAN SERUM OR PLASMA BY MICROPLATE ENZYME IMMUNOASSAY

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1033	IMP/IVD/2021/000084	1.License Holder Name: ANAND BROTHER'S 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMMUGLOTM ANA HEP-2 SUBSTRATE(IMMUGLO HEP- 2 CELL IFA)-INDIRECT IMMUNOFLUORESCENCE (IF) ANTIBODY TEST FOR THE DETECTION OF ANA IN HUMAN SERUM.,IMMULISATM CELIAC (TTG) IGA ANTIBODY ENHANCED ELISA(ELISA CELIAC TTG IGA KIT)-DETECTION OF ANTI-HUMAN TISSUE TRANSGLUTAMINASE LGA AB IN HUMAN SERUM, IMMUGLOTM COMVI ANCA(IMMUGLO COMVI ANCA IFA)-AN INDIRECT IMMUNOFLUORESCENCE ANTIBODY TEST FOR THE DETECTION AND SEMI-QUANTITATION OF ANTI-NEUTROPHIL CYTOPLASMIC ANTIBODIES (ANCA) IN HUMAN SERUM.,NDNA ANTIBODY (CRITHIDIA LUCILIAE)(LMMUGLO ANTI NDNA IFA)-DETECTION OF ANTIBODIES TO NATIVE DNA (NDNA) IN HUMAN SERUM,COMVI-III KIT (MOUSE KIDNEY/STOMACH/LIVER SUBSTRATE)(IMMUGLO COMVI-III IFA)-INDIRECT IMMUNOFLUORESCENCE (IF) ANTIBODY TESTS FOR THE DETECTION AND QUANTITATION OF ANTI-NUCLEAR ANTIBODIES (ANA), ANTI-MITOCHONDRIAL ANTIBODIES (AMA), ANTI-SMOOTH MUSCLE ANTIBODIES (ASMA) AND ANTI-GASTRIC PARIETAL CELL ANTIBODIES (AGPA) IN HUMAN SERUM.,LMMUGLOTM COMVI IFA (IMMUGLO COMVI IFA)-INDIRECT IMMUNOFLUORESCENCE (IF) ANTIBODY TESTS FOR THE DETECTION AND QUANTITATION OF ANTI-NUCLEAR ANTIBODIES (ANA) ANTI-MITOCHONDRIAL ANTIBODIES (AMA), ANTI-SMOOTH MUSCLE ANTIBODIES (ASMA) AND ANTI-GASTRIC PARIETAL CELL ANTIBODIES (AGPA) IN HUMAN SERUM.,NTI-NEUTROPHIL CYTOPLASMIC ANTIBODY (ANCA) IFA KIT(IMMOGLO ANCA IFA)-DETECTION OF ANTI-NEUTROPHILL CYTOPLASMIC AB (ANCA) IN HUMAN SERUM.

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1034	IMP/IVD/2021/000085	1.License Holder Name: DIAGNOSTIC CARE AND TRADING PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 RT-PCR (MOLECISION SARS-COV-2 RT-PCR)-THE SARS-COV-2 RT-PCR ASSAY IS USED FOR QUALITATIVE DETECTION OF SARS-COV-2 FROM OROPHARYNGEAL SWABS, NASOPHARYNGEAL SWABS AND BALF (BRONCHOALVEOLAR LAVAGE FLUID) OF SUSPECTED CASES OF COVID-19.,SYSTEM TUBING CLEANING SOLUTION(MAGLUMI SYSTEM TUBING CLEANING SOLUTION)-THE MAGLUMI SYSTEM TUBING CLEANING SOLUTION IS USED TO CLEAN THE PIPETTOR AND THE WASHER NEEDLES. IT IS USEFUL TO MINIMIZE REAGENT CARRYOVER BY REDUCING PROTEIN PRECIPITATION IN THE TUBING, AND IMPROVE ROUTINE MAINTENANCE OF THE MAGLUMI SYSTEM. THE KIT CAN ONLY BE USED WITH MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8), WITH TUBING CLEANING PROGRAM, NUCLEIC ACID EXTRACTION KIT(MOLECISION NUCLEIC ACID EXTRACTION KIT)-THE NUCLEIC ACID EXTRACTION KIT IS INTENDED FOR ISOLATING NUCLEIC ACIDS (NA) FROM SAMPLE MATERIALS FOR AN IN VITRO TESTING,FT3 (CLIA)(MAGLUMI FT3 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENT IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,REACTION MODULE(MAGLUMI REACTION MODULE)-REACTION MODULES REQUIRED FOR THE IMPLEMENTATION OF THE MAGLUMI ASSAYS ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 AND MAGLUMI 4000 PLUS).,PRL (CLIA)(MAGLUMI PRL (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PRL IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,FREE TESTOSTERONE (CLIA) (MAGLUMI FREE TESTOSTERONE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE

	DETERMINATION OF FREE TESTOSTERONE IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,TG (CLIA)(MAGLUMI TG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,VITAMIN B12 (CLIA)(MAGLUMI VITAMIN B12 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8, SHBG (CLIA)(MAGLUMI SHBG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF SEX HORMONE-BINDING GLOBULIN (SHBG) IN HUMAN SERUM AND PLASMA USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,T4 (CLIA)(MAGLUMI T4 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ESTRADIOL (CLIA)(MAGLUMI ESTRADIOL (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,17 OH-PROGESTERONE (CLIA)(MAGLUMI 17 OH-PROGESTERONE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 17-OH PROGESTERONE IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO

	CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,WASH CONCENTRATE(MAGLUMI WASH CONCENTRATE)-MAGLUMI WASH CONCENTRATE IS INTENDED TO BE DILUTED FOR PREPARATION OF SYSTEM LIQUID WHICH IS REQUIRED FOR WASHING THE MAGNETIC MIRCOBEADS OF THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,ANTI-TPO (CLIA)(MAGLUMI ANTI-TPO (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-TPO IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,TSH (CLIA)(MAGLUMI TSH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,LH (CLIA)(MAGLUMI LH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,TESTOSTERONE (CLIA)(MAGLUMI TESTOSTERONE (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,25-OH VITAMIN D (CLIA)(MAGLUMI 25-OH VITAMIN D (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO

	CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,STARTER 1+2(MAGLUMI STARTER 1+2) -STARTER REAGENT KIT REQUIRED TO GENERATE THE CHEMILUMINOMETRIC LIGHT SIGNAL NECESSARY FOR THE IMPLEMENTATION OF MAGLUMI ASSAYS ON THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER.,PRG (CLIA)(MAGLUMI PRG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE (PRG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,LIGHT CHECK(MAGLUMI LIGHT CHECK)-LIGHT CHECK REAGENT REQUIRED TO CHECK THE VALIDITY OF STARTER 1+2 AS WELL AS THE FUNCTIONING OF THE MEASURING AND PIPETTING UNITS. A LIGHT CHECK HAS TO BE CARRIED OUT ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8) EITHER ONCE DAILY PRIOR TO STARTING THE FIRST MEASUREMENT OR WHENEVER A NEW LOT OF STARTER REAGENTS IS USED. THIS CONTROL PROGRAM CHECKS THE PROPER FUNCTIONING OF THE INSTRUMENT AND STARTER REAGENTS TO AVOID DATA ERROR DUE TO INSTRUMENT DEFECTS OR MISLOCATED OR EXPIRED STARTER REAGENTS.,HCG/BETA-HCG (CLIA)(MAGLUMI HCG/BETA-HCG (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (-SUBUNIT) (HCG/-HCG) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,AMH (CLIA)(MAGLUMI AMH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-MULLERIAN HORMONE (AMH) IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,T3 (CLIA)(MAGLUMI T3 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY

	FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,FSH (CLIA)(MAGLUMI FSH (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM WITH THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,FT4 (CLIA)(MAGLUMI FT4 (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000, MAGLUMI 4000 PLUS AND MAGLUMI X8).,FREE ESTRIOL (CLIA)(MAGLUMI FREE ESTRIOL (CLIA))-THE KIT IS AN IN VITRO CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE ESTRIOL IN HUMAN SERUM USING THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER (INCLUDING MAGLUMI 600, MAGLUMI 800, MAGLUMI 1000, MAGLUMI 1000 PLUS, MAGLUMI 2000, MAGLUMI 2000 PLUS, MAGLUMI 4000 , MAGLUMI 4000 PLUS AND MAGLUMI X8).

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1035	IMP/IVD/2021/000087	1.License Holder Name: M/S. GOLDEN HARVEST INDUSTRIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLEANING SOLUTION (CORNLEY)-THIS REAGENT IS INTENDED TO PROVIDE THOROUGH CLEANING OF THE REAGENT PATH.,BLOOD GAS CAL PACK IE (CORNLEY)-FOR USE IN BLOOD GAS ANALYZER; THIS CAL PACK IS INTENDED TO CALIBRATE AND FLUSH CORNLEY BLOOD GAS & ELECTROLYTE ANALYZER EMPLOYING ISE METHOD,REFILL SOLUTION(CORNLEY)-FILLING SOLUTION FOR USING ELECTROLYTE ANALYSER; REFILL SOLUTION FOR K+, NA+, CL-, CA2+, PH ELECTRODE IS INTENDED TO PROVIDE REFERENCE POTENTIAL FOR INTERNAL ELECTRODE OF K+, NA+, CL-, CA2+ AND PH ELECTRODE REFILL SOLUTION FOR REFERENCE ELECTRODE IS INTENDED TO PROVIDE REFERENCE POTENTIAL FOR INTERNAL ELECTRODE OF REF ELECTRODE,REFILL SOLUTION(CORNLEY)-FILLING SOLUTION FOR USE IN ELECTROLYTE ANALYZER ONLY WITH REFERENCE ELECTRODE. REFILL SOLUTION FOR K+, NA+, CL-, CA2+, PH ELECTRODE IS INTENDED TO PROVIDE REFERENCE POTENTIAL FOR INTERNAL ELECTRODE OF K+, NA+, CL-, CA2+ AND PH ELECTRODE REFILL SOLUTION FOR REFERENCE ELECTRODE IS INTENDED TO PROVIDE REFERENCE POTENTIAL FOR INTERNAL ELECTRODE OF REF ELECTRODE,CONDITIONING SOLUTION(CORNLEY)-CONDITIONING SOLUTION FOR USE IN BLOOD GAS ANALYZER FOR NA+ AND PH ELECTRODE FOR ROUTINE MAINTENANCE.,MULTI- ENZYME DE-PROTEINIZER(CORNLEY)-MULTI-ENZYME DE-PROTEINIZER FOR USE IN ELECTROLYTE ANALYZER FOR ROUTINE MAINTENANCE. THIS REAGENTS IS INTENDED TO MAINTAIN K+,CA2+, CL - ELECTRODES ON CORNLEY ELECTROLYTE ANALYZER.,ELECTROLYTES QUALITY CONTROL(CORNLEY)-FOR USE IN ELECTROLYTE ANALYZER , THIS REAGENT IS APPLICABLE FOR ASSAYED QUALITY CONTROL OF ION SELECTIVE INSTRUMENTATION. THIS REAGENT IS A SOLUTION WITH PREDETERMINED LEVELS OF K+, NA+, CL-, CA2+, PH, LI+. THREE LEVELS OF CONTROL ARE AVAILABLE TO ALLOW PERFORMANCE MONITORING WITHIN THE RANGE LEVEL 1, LEVEL 2, LEVEL 3., CALIBRATION STANDARD SOLUTION(CORNLEY)-FOR USE IN ELECTROLYTE ANALYZER AS DILUENT OF URINE SAMPLING,REFILL SOLUTION(CORNLEY)-FILLING SOLUTION FOR USE IN BLOOD GAS ANALYZER; REFILL SOLUTION FOR K+, NA+, CL-, CA2+ AND PH ELECTRODE. REFILL SOLUTION FOR REFERENCE ELECTRODE IS INTENDED TO PROVIDE REFERENCE POTENTIAL FOR INTERNAL ELECTRODE OF REF ELECTRODE.,CONDITIONING SOLUTION (CORNLEY)-CONDITIONING SOLUTION FOR USE IN ELECTROLYTE ANALYZER FOR NA AND PH ELECTRODE FOR ROUTINE MAINTENANCE.,BLOOD GAS ISE CONTROL / QUALITY CONTROL

	(CORNLEY)-FOR USE IN BLOOD GAS ANALYZER; THIS REAGENT IS APPLICABLE FOR ASSAYED QUALITY CONTROL OF ION SELECTIVE INSTRUMENTATION. THIS REAGENT IS A SOLUTION WITH PREDETERMINED LEVELS OF K+, NA+, CA++, PH, PCO2, PO2. THREE LEVELS OF CONTROL ARE AVAILABLE TO ALLOW PERFORMANCE MONITORING WITHIN THE RANGE: LEVEL 1, LEVEL 2, LEVEL 3, CALIBARATION STANDARD SOLUTION(CORNLEY)-IT IS USED FOR MULTI- PARAMETER MEASURING REAGENTS FOR ELECTROLYTE ANALYZER [TESTING ITEMS: K, NA, CL, CA, PH]; K, NA, CL, CA, PH ARE CALIBRATED, CORRECTED AND CLEANED BASED ON THE ION-SELECTIVE ELECTRODES PRINCIPLE.,MULTI-ENZYME DE-PROTEINIZER(CORNLEY)-DE- PROTEINIZER FOR USE IN BLOOD GAS ANALYSER FOR ROUTINE MAINTENANCE; THIS REAGENT IS INTENDED TO MAINTAIN K+, CA2+, CL- ELECTRODES ON CORNLEY ELECTROLYTE ANALYZER.,REFILL SOLUTION(CORNLEY)-FILLING SOLUTION FOR USE IN BLOOD GAS ANALYZER ONLY WITH REFERENCE ELECTRODE; REFILL SOLUTION FOR K+, NA+, CL-, CA2+, PH ELECTRODE IS INTENDED TO PROVIDE REFERENCE POTENTIAL FOR INTERNAL ELECTRODE OF K+, NA+, CL-, CA2+ AND PH ELECTRODE. REFILL SOLUTION FOR REFERENCE ELECTRODE IS INTENDED TO PROVIDE REFERENCE POTENTIAL FOR INTERNAL ELECTRODE OF REF ELECTRODE

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1036	IMP/IVD/2021/000088	1.License Holder Name: INSTRUMENTATION LABORATORY INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARA-TEM(ROTEM®)-ARA-TEM IS A ROTEM PLATELET SYSTEM REAGENT FOR THE ASSESSMENT OF PLATELET FUNCTION BY ACTIVATING THE ARACHIDONIC ACID PATHWAY (E.G. IN PATIENTS TREATED WITH CYCLOOXYGENASE INHIBITORS) IN ANTICOAGULATED WHOLE BLOOD.,SIGMA COMPLETE (ROTEM®)-ROTEM® SIGMA COMPLETE IS A ROTEM® SYSTEM CARTRIDGE CONTAINING REAGENTS FOR THE ASSESSMENT OF COAGULATION AND ITS INTERACTION WITH THROMBOCYTES IN CITRATED WHOLE BLOOD..,SIGMA COMPLETE + HEP(ROTEM®)-ROTEM SIGMA COMPLETE + HEP IS A ROTEM SYSTEM CARTRIDGE CONTAINING REAGENTS FOR THE ASSESSMENT OF COAGULATION AND ITS INTERACTION WITH THROMBOCYTES IN CITRATED WHOLE BLOOD.,R EX-TEM(ROTEM®)-R EX-TEM IS A ROTEM SYSTEM REAGENT FOR THE ASSESSMENT OF THE EXTRINSIC COAGULATION PATHWAY AND ITS INTERACTION WITH THROMBOCYTES IN CITRATED BLOOD. IT IS ALWAYS USED IN COMBINATION WITH STAR-TEM.,HEP-TEM (ROTEM®)-HEP-TEM IS A ROTEM SYSTEM REAGENT FOR A HEPARIN-INDEPENDENT ASSESSMENT OF THE INTRINSIC COAGULATION PATHWAY AND ITS INTERACTION WITH THROMBOCYTES IN CITRATED BLOOD. IT IS ALWAYS USED IN COMBINATION WITH IN-TEM.,ROTROL P(ROTEM®)-ROTROL P IS A QUALITY CONTROL MATERIAL FOR MONITORING ACCURACY AND PRECISION IN THE ABNORMAL RANGE ON THE ROTEM® WHOLE BLOOD HAEMOSTASIS SYSTEM.,STAR-TEM (ROTEM®)-STAR-TEM IS ROTEM SYSTEM REAGENT FOR RECALCIFYING CITRATED BLOOD. RECALCIFIED BLOOD CAN BE ANALYSED ON THE ROTEM ANALYSER USING THE NATEM TEST OR THE ACTIVATED TESTS INTEM AND EXTEM. THE NATEM TEST (WITHOUT ACCELERATING ACTIVATORS) IS RECOMMENDED FOR RESEARCH USE ONLY.,FIB-TEM(ROTEM®)-FIB-TEM IS A ROTEM SYSTEM REAGENT WHICH ALLOWS AN ISOLATED ASSESSMENT OF THE FIBRINOGEN LEVEL AND THE QUALITY OF THE FIBRIN POLYMERISATION IN CITRATED BLOOD. IT IS ALWAYS USED IN COMBINATION WITH R EX-TEM.,ADP-TEM(ROTEM®)-ADP-TEM® IS A ROTEM® PLATELET SYSTEM REAGENT FOR THE ASSESSMENT OF PLATELET FUNCTION BY ACTIVATING THE ADP RECEPTOR PATHWAY (E.G. IN PATIENTS TREATED WITH ADP RECEPTOR ANTAGONISTS) IN ANTICOAGULATED WHOLE BLOOD.,IN-TEM(ROTEM®)-IN-TEM IS A ROTEM SYSTEM REAGENT FOR THE ASSESSMENT OF THE INTRINSIC COAGULATION PATHWAY AND ITS INTERACTION WITH THROMBOCYTES IN CITRATED BLOOD. IT IS ALWAYS USED IN COMBINATION WITH STAR-TEM.,ROTEM® SIGMA ROTROL N(ROTEM®)

		-ROTEM® SIGMA ROTROL N IS A QUALITY CONTROL MATERIAL FOR MONITORING ACCURACY AND PRECISION OF TESTS CARRIED OUT ON THE ROTEM® SIGMA WHOLE BLOOD HEMOSTASIS SYSTEM. ROTEM® SIGMA ROTROL N IS A LEVEL 1 CONTROL.,AP-TEM(ROTEM®)-AP-TEM IS A ROTEM SYSTEM REAGENT FOR A FIBRINOLYSIS-INDEPENDENT ASSESSMENT OF THE EXTRINSIC COAGULATION PATHWAY AND ITS INTERACTION WITH THROMBOCYTES IN CITRATED BLOOD. IT IS ALWAYS USED IN COMBINATION WITH R EX-TEM.,ROTEM® SIGMA ROTROL P(ROTEM®)-ROTEM® SIGMA ROTROL P IS A QUALITY CONTROL MATERIAL FOR MONITORING ACCURACY AND PRECISION OF TESTS CARRIED OUT ON THE ROTEM® SIGMA WHOLE BLOOD HAEMOSTASIS SYSTEM. ROTEM® SIGMA ROTROL P IS A LEVEL 2 CONTROL.,TRAP-TEM(ROTEM®)-TRAP-TEM IS A ROTEM PLATELET SYSTEM REAGENT FOR THE ASSESSMENT OF PLATELET FUNCTION BY ACTIVATING THE THROMBIN RECEPTOR PATHWAY (E.G. IN PATIENTS TREATED WITH THROMBIN OR GPIIB/IIIA RECEPTOR ANTAGONISTS) IN ANTICOAGULATED WHOLE BLOOD.,ROTROL N (ROTEM®)-ROTROL N IS A QUALITY CONTROL MATERIAL FOR MONITORING ACCURACY AND PRECISION OF TESTS CARRIED OUT ON THE ROTEM® WHOLE BLOOD HAEMOSTASIS SYSTEM.
1037	IMP/IVD/2021/000093	1.License Holder Name: M/S. ASHISH INTERCHEM PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE METER-THE GLM-79 BLOOD GLUCOSE METER IS DESIGNED TO QUANTITATIVELY MEASURE THE CONCENTRATION OF GLUCOSE IN CAPILLARY WHOLE BLOOD BY PEOPLE WITH DIABETES OR BY HEALTHCARE PROFESSIONAL FOR MONITORING BLOOD GLUCOSE AT HOME OR IN HEALTHCARE FACILITIES.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1038	IMP/IVD/2021/000094	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONDITIONING SOLUTION-CONDITIONING SOLUTION IS USED FOR MAINTAINING THE ELECTRODES OF ELECTROLYTE ANALYZER,CLEANING SOLUTION-CLEANING SOLUTION IS USED FOR CLEANING OF THE REAGENT PATH OF ELECTROLYTE ANALYZER,ELECTROLYTES QUALITY CONTROL (MODEL NO. AFT-ISEQC)-THIS REAGENT IS APPLICABLE FOR ASSAYED QUALITY CONTROL OF ION SELECTIVE INSTRUMENTATION. ELECTROLYTES QUALITY CONTROL (ISE) IS USED FOR THE QUALITY CONTROL OF ELECTROLYTE ANALYZERS.,REFILL SOLUTION (MODEL NO. AFT-ISE)-REFILL SOLUTION (ISE) IS USED IN ELECTROLYTE ANALYZERS TO PROVIDE PROPER FUNCTIONING OF ELECTRODES USED FOR ESTIMATION OF SODIUM, POTASSIUM, CHLORIDE, CALCIUM PH & LITHIUM PARAMETERS IN SERUM/PLASMA/ OTHER BODY FLUIDS.,CALIBRATION STANDARD SOLUTION (MODEL NO. AFT-ISE IV) -IT'S USED FOR MULTI-PARAMETER MEASURING REAGENTS FOR ELECTROLYTE ANALYZER(TESTING ITEMS:K,NA,CL,CA LI PH,TCO2),K, NA,CL,CA LI PH ARE CALIBRATED,CORRECTED AND CLEANED BASED ON THE ION - SELECTIVE ELECTRODES PRINCIPLE,TCO2,MULTI-ENZYME DE-PROTEINIZER-MULTI-ENZYME DE-PROTEINIZER IS USED FOR MAINTAINING THE ELECTRODES OF ELECTROLYTE ANALYZER
1039	IMP/IVD/2021/000095	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CELL-FREE DNA COLLECTION TUBE(CELL-FREE DNA COLLECTION TUBE)-THE ROCHE CELL-FREE DNA COLLECTION TUBE IS A DIRECT DRAW WHOLE BLOOD COLLECTION TUBE INTENDED FOR COLLECTION, STABILIZATION, AND TRANSPORTATION OF WHOLE BLOOD SPECIMENS, AND FOR THE PRESERVATION OF NUCLEATED CELLS TO ENABLE ANALYSIS OF CELL-FREE DNA.

1040	IMP/IVD/2021/000096	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE MONITORING SYSTEM(CONTOUR PLUS LINK 2.4)-THE CONTOUR PLUS LINK 2.4 WIRELESS BLOOD GLUCOSE MONITORING SYSTEM FROM ASCENSIA IS INTENDED FOR SELF-TESTING BY PERSONS WITH DIABETES TO MONITOR GLUCOSE CONCENTRATIONS FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD DRAWN FROM THE FINGERTIP OR PALM. IT IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY. THE CLINICAL UTILITY OF THIS DEVICE IS THAT IT MAY BE USED AS AN AID TO MONITOR THE EFFECTIVENESS OF A DIABETES CONTROL PROGRAM. THE CONTOUR PLUS LINK 2.4 WIRELESS BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO BE USED TO TRANSMIT GLUCOSE VALUES AND SEND A REMOTE BOLUS TO MEDTRONIC DEVICES AND FACILITATE TRANSFER OF INFORMATION TO MEDTRONIC CARELINK® SOFTWARE THROUGH USE OF RADIO FREQUENCY COMMUNICATION. THE CONTOUR PLUS LINK 2.4 WIRELESS BLOOD GLUCOSE MONITORING SYSTEM FROM ASCENSIA IS NOT INTENDED FOR THE DIAGNOSIS OF OR SCREENING FOR DIABETES MELLITUS AND IT IS NOT INTENDED FOR USE ON NEONATES.
1041	IMP/IVD/2021/000100	1.License Holder Name: NIPRO MEDICAL (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST KITS(NIPRO PREMIER BLOOD GLUCOSE TEST STRIPS)-NIPRO PREMIER BLOOD GLUCOSE TEST STRIPS WORK WITH THE NIPRO PREMIER BRAND OF BLOOD GLUCOSE METERS TO QUANTITATIVELY MEASURE GLUCOSE IN WHOLE BLOOD. THE NIPRO PREMIER BRAND OF BLOOD GLUCOSE MONITORING SYSTEM ARE FOR SELF TESTING OUTSIDE THE BODY (IN VITRO DIAGNOTIC USE). IT SHOULD NOT BE USED FOR DIAGNOSIS OF DIABETES OR FOR TESTING NEWBORNS.

1042	IMP/IVD/2021/000101	1.License Holder Name: DIA SURE IMMUNODIAGNOSTIC LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HANTAVIRUS IGG ELISA (NOVALISA)-THE HANTAVIRUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST HANTAVIRUS IN HUMAN SERUM OR PLASMA,ECHINOCOCCUS IGG ELISA(NOVALISA)-THE ECHINOCOCCUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST ECHINOCOCCUS IN HUMAN SERUM OR PLASMA, ASPERGILLUS FUMIGATUS IGG ELISA(NOVALISA)-THE ASPERGILLUS FUMIGATUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST ASPERGILLUS FUMIGATUS IN HUMAN SERUM OR PLASMA,HANTAVIRUS IGM ELISA (NOVALISA)-THE HANTAVIRUS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM ANTIBODIES AGAINST HANTAVIRUS IN HUMAN SERUM OR PLASMA,BORDETELLA PERTUSSIS IGM ELISA(NOVALISA)-THE BORDETELLA PERTUSSIS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST BORDETELLA PERTUSSIS IN HUMAN SERUM OR PLASMA,BRUCELLA IGM ELISA(NOVALISA)-THE BRUCELLA IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST BRUCELLA IN HUMAN SERUM OR PLASMA,ENTAMOEBA HISTOLYTICA IGG ELISA-THE ENTAMOEBA HISTOLYTICA IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST ENTAMOEBA HISTOLYTICA IN HUMAN SERUM OR PLASMA, CORYNEBACTERIUM DIPHTHERIAE TOXIN IGG(NOVALISA)-THE CORYNEBACTERIUM DIPHTHERIAE TOXIN IGG ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST CORYNEBACTERIUM DIPHTHERIAE TOXIN IN HUMAN SERUM OR PLASMA,MEASLES VIRUS IGG ELISA(NOVALISA)-THE MEASLES VIRUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST MEASLES VIRUS IN HUMAN SERUM OR PLASMA,TOXOCARA CANIS IGG ELISA (NOVALISA)-THE TOXOCARA CANIS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST TOXOCARA CANIS IN HUMAN SERUM OR PLASMA,PARVOVIRUS B19 IGM ELISA(NOVALISA)-THE PARVOVIRUS B19 IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST PARVOVIRUS B19 IN HUMAN SERUM OR PLASMA, RESPIRATORY SYNCYTIAL VIRUS IGM ELISA(NOVALISA)-THE RESPIRATORY SYNCYTIAL VIRUS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST RESPIRATORY SYNCYTIAL VIRUS IN HUMAN SERUM OR PLASMA,

	MUMPS VIRUS IGG ELISA(NOVALISA)-THE MUMPS VIRUS IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST MUMPS VIRUS IN HUMAN SERUM OR PLASMA, PARVOVIRUS B19 IGG ELISA(NOVALISA)-THE PARVOVIRUS B19 IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST PARVOVIRUS B19 IN HUMAN SERUM OR PLASMA,MUMPS VIRUS IGM ELISA(NOVALISA)-THE MUMPS VIRUS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST MUMPS VIRUS IN HUMAN SERUM OR PLASMA,ASPERGILLUS FUMIGATUS IGM ELISA(NOVALISA)-THE ASPERGILLUS FUMIGATUS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST ASPERGILLUS FUMIGATUS IN HUMAN SERUM OR PLASMA,ANTI-TG ELISA(NOVALISA)-THE ANTI-TG ELISA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF AUTOANTIBODIES TO TG (THYROGLOBULIN) IN HUMAN SERUM OR PLASMA,BRUCELLA IGG ELISA(NOVALISA)-THE BRUCELLA IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST BRUCELLA IN HUMAN SERUM OR PLASMA,MEASLES VIRUS IGM ELISA (NOVALISA)-THE MEASLES VIRUS IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST MEASLES VIRUS IN HUMAN SERUM OR PLASMA,LEPTOSPIRA IGM ELISA(NOVALISA)-THE LEPTOSPIRA IGM ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGM CLASS ANTIBODIES AGAINST LEPTOSPIRA SPP. IN HUMAN SERUM OR PLASMA,TAENIA SOLIUM IGG ELISA(NOVALISA)-THE TAENIA SOLIUM IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST TAENIA SOLIUM IN HUMAN SERUM OR PLASMA, LEPTOSPIRA IGG ELISA(NOVALISA)-THE LEPTOSPIRA IGG ELISA IS INTENDED FOR THE QUALITATIVE DETERMINATION OF IGG CLASS ANTIBODIES AGAINST LEPTOSPIRA SPP. IN HUMAN SERUM OR PLASMA

1043	IMP/IVD/2021/000102	1.License Holder Name: HIPRA INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ELISA KIT FOR THE DETECTION AND QUANTIFICATION OF SPECIFIC ANTIBODIES AGAINST INFECTIOUS BRONCHITIS VIRUS(CIVTEST AVI IBV)-DETECTION AND QUANTIFICATION OF ANTIBODIES AGAINST BRONCHITIS VIRUS, BY INDIRECT ELISA.,ELISA KIT FOR THE DETECTION AND QUANTIFICATION OF SPECIFIC ANTIBODIES AGAINST NEWCASTLE DISEASE VIRUS(CIVTEST AVI NDV)-DETECTION AND QUANTIFICATION OF ANTIBODIES AGAINST NEWCASTLE VIRUS, BY INDIRECT ELISA.,ELISA KIT FOR THE DETECTION AND QUANTIFICATION OF SPECIFIC ANTIBODIES AGAINST PNEUMOVIRUS RESPONSIBLE FOR RHINOTRACHEITIS IN TURKEYS AND SWOLLEN HEAD SYNDROME IN CHICKENS(CIVTEST AVI TRT)-DETECTION AND QUANTIFICATION OF ANTIBODIES AGAINST PNEUMOVIRUS RESPONSIBLE OF RHINOTRACHEITIS, IN TURKEYS AND SWOLLEN HEAD SYNDROME IN CHICKENS, BY INDIRECT ELISA.,ELISA KIT FOR THE DETECTION AND QUANTIFICATION OF SPECIFIC ANTIBODIES AGAINST AVIAN ADENOVIRUS RESPONSIBLE FOR EGG DROP SYNDROME-76 (EDS)(CIVTEST AVI EDS)-DETECTION AND QUANTIFICATION OF SPECIFIC ANTIBODIES AGAINST AVIAN ADENOVIRUS RESPONSIBLE FOR EGG DROP SYNDROME-76(EDS) BY INDIRECT ELISA.,ELISA KIT FOR THE DETECTION AND QUANTIFICATION OF SPECIFIC ANTIBODIES AGAINST INFECTIOUS LARYNGOTRACHEITIS VIRUS(CIVTEST AVI ILT)-DETECTION AND QUANTIFICATION OF ANTIBODIES AGAINST LARYNGOTRACHEITIS VIRUS, BY INDIRECT ELISA.,ELISA KIT FOR THE DETECTION AND QUANTIFICATION OF ANTIBODIES AGAINST GUMBORO VIRUS (CIVTEST AVI IBD)-DETECTION AND QUANTIFICATION OF ANTIBODIES AGAINST GUMBORO VIRUS, BY INDIRECT ELISA.
1044	IMP/IVD/2021/000104	1.License Holder Name: THERMO FISHER SCIENTIFIC INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RAP/TAC/CSA CONTROL (NIL)-MORE DIAGNOSTICS' RAP/TAC/CSA CONTROL IS INTENDED TO BE USED AS A WHOLE BLOOD PRECISION CONTROL PRODUCT TO CHECK CALIBRATION IN CHEMISTRY ANALYZERS WHICH MEASURE RAPAMYCIN (SIROLIMUS), TACROLIMUS AND CYCLOSPORINE.

1045	IMP/IVD/2021/000105	1.License Holder Name: DHR HOLDING INDIA PVT. LTD, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SAFE CLINITUBES(SAFE CLINITUBES)-HEPARINIZED PLASTIC CAPILLARIES INTENDED FOR BLOOD SAMPLING,CLINITUBES(CLINITUBES)-HEPARINIZED GLASS CAPILLARIES INTENDED FOR BLOOD SAMPLING
1046	IMP/IVD/2021/000106	1.License Holder Name: ARKRAY HEALTHCARE PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IN-VITRO DIAGNOSTIC SYSTEM USED IN URINALYSIS(AUTION EYE CALIBRATOR)-AUTION EYE CALIBRATOR IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR FOCUSING AND CALIBRATING THE AUTION EYE AI-4510. DO NOT USE IT FOR ANY OTHER PURPOSE.,URINE TEST STRIPS(AUTION STICKS 10V)-AUTION STICKS 10V USED FOR THE DETERMINATION OF GLUCOSE, PROTEIN, BILIRUBIN, UROBILINOGEN, PH, SPECIFIC GRAVITY, BLOOD, KETONES, NITRITE, AND LEUKOCYTES IN URINE. AUTION STICKS 10V CAN BE READ VISUALLY USING THE COLOR CHART ON THE BOTTLE, OR WITH ARKRAY URINE ANALYZER *1 *1 AUTION MAX, AUTION ELEVEN, POCKETCHEM UA.,IN-VITRO DIAGNOSTIC SYSTEM USED IN URINALYSIS(AUTION EYE CONTROL SOLUTION)-AUTION EYE CONTROL SOLUTION IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR PERFORMING QUALITY CONTROL PROCEDURES WITH THE AUTION EYE AI-4510,. DO NOT USE IT FOR OTHER PURPOSE.
1047	IMP/IVD/2021/000107	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARCHITECT HCV AG CALIBRATORS(ARCHITECT HCV AG CALIBRATORS)-THE ARCHITECT HCV AG CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CORE ANTIGEN TO HEPATITIS C VIRUS IN HUMAN SERUM AND PLASMA.,ARCHITECT HCV AG CONTROLS(ARCHITECT HCV AG CONTROLS)-THE ARCHITECT HCV AG CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CORE ANTIGEN TO HEPATITIS C VIRUS IN HUMAN SERUM AND PLASMA.,ARCHITECT HCV AG REAGENT KIT(ARCHITECT HCV AG REAGENT KIT)-THE ARCHITECT HCV AG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF HEPATITIS C VIRUS CORE ANTIGEN IN HUMAN SERUM AND PLASMA.

1048	IMP/IVD/2021/000115	1.License Holder Name: DHR HOLDING INDIA PVT. LTD, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PICO50(PICO50)-ARTERIAL BLOOD SAMPLER FOR PH, BLOOD GAS, OXIMETRY, ELECTROLYTE AND METABOLITE ANALYSIS.,SAFEPICO ASPIRATOR (SAFEPICO ASPIRATOR)-ASPIRATING ARTERIAL BLOOD SAMPLER FOR COLLECTION OF ARTERIAL SAMPLES FOR PH, BLOOD GAS, OXIMETRY, ELECTROLYTE AND METABOLITE ANALYSES
1049	IMP/IVD/2021/000119	1.License Holder Name: INVITROGEN BIOSERVICES INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RPMI 1640 W/O PHENOL RED(GIBCO)-"RPMI 1640 CELL CULTURE MEDIA PRODUCTS ARE FOR PROFESSIONAL USE. THEY ARE USED IN MEDICAL LABORATORIES BY PERSONNEL WHO HAVE RECEIVED SPECIALIZED EDUCATION AND TRAINING WITH REGARD TO PROCEDURES UTILIZING IN VITRO DIAGNOSTIC PRODUCTS. IVD PRODUCTS OF THIS TYPE ARE NOT INTENDED AS SOLE DETERMINANT IN A DIAGNOSTIC SITUATION.", RPMI 1640 W/25MMHEPES W/OL-GLUT(GIBCO)-"RPMI 1640 CELL CULTURE MEDIA PRODUCTS ARE FOR PROFESSIONAL USE. THEY ARE USED IN MEDICAL LABORATORIES BY PERSONNEL WHO HAVE RECEIVED SPECIALIZED EDUCATION AND TRAINING WITH REGARD TO PROCEDURES UTILIZING IN VITRO DIAGNOSTIC PRODUCTS. IVD PRODUCTS OF THIS TYPE ARE NOT INTENDED AS SOLE DETERMINANT IN A DIAGNOSTIC SITUATION.",DMEM (HIGH GLUCOSE) W/O L-GLUT(GIBCO)-"DMEM CELL CULTURE MEDIA PRODUCTS ARE FOR PROFESSIONAL USE. THEY ARE USED IN MEDICAL LABORATORIES BY PERSONNEL WHO HAVE RECEIVED SPECIALIZED EDUCATION AND TRAINING WITH REGARD TO PROCEDURES UTILIZING IN VITRO DIAGNOSTIC PRODUCTS. IVDS OF THESE TYPES ARE NOT INTENDED AS SOLE DETERMINANT IN A DIAGNOSTIC SITUATION.",DMEM/F12 (1:1) W/O L-GLUT (CE)(GIBCO)-"DMEM CELL CULTURE MEDIA PRODUCTS ARE FOR PROFESSIONAL USE. THEY ARE USED IN MEDICAL LABORATORIES BY PERSONNEL WHO HAVE RECEIVED SPECIALIZED EDUCATION AND TRAINING WITH REGARD TO PROCEDURES UTILIZING IN VITRO DIAGNOSTIC PRODUCTS. IVDS OF THESE TYPES ARE NOT INTENDED AS SOLE DETERMINANT IN A DIAGNOSTIC SITUATION."

1050	IMP/IVD/2021/000122	1.License Holder Name: GENETIX BIOTECH ASIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 REAL TIME PCR KIT(SMARTCHEK® NOVEL CORONAVIRUS (SARS-COV-2) DETECTION KIT)-SMARTCHEK® NOVEL CORONAVIRUS (SARS-COV-2) DETECTION KIT IS BASED ON BIOCHIP SAMPLE FORMAT AND PROVIDES RELATIVELY SHORT TURN-AROUND-TIME WITH SIMPLE WORKFLOW WHILE IT OFFERS KEY BENEFITS OF REAL-TIME PCR TESTS. THIS KIT IS INTENDED FOR IN VITRO DIAGNOSTIC USE.
1051	IMP/IVD/2021/000128	1.License Holder Name: M/S. TRICELL BIOLOGICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 ANTIGEN RAPID TEST KIT(VSTRIP COVID-19 ANTIGEN RAPID TEST KIT)-VSTRIP COVID-19 ANTIGEN RAPID TEST IS A RAPID IN VITRO IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF SARS-COV-2 VIRUS FROM THE NASOPHARYNGEAL SWAB OF PATIENTS OR CONTACTS, IT CAN BE DETECTED AT AN EARLY STAGE OF INFECTION. THE TEST IS INTENDED FOR PROFESSIONAL AND LABORATORY USE AS AN AID IN THE RAPID DIAGNOSIS OF SARS-COV-2 VIRUS INFECTIONS. A NEGATIVE TEST IS PRESUMPTIVE AND IT IS RECOMMENDED THAT THESE RESULTS BE CONFIRMED BY MOLECULAR DIAGNOSTICS (PCR). NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 VIRUS INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISIONS.
1052	IMP/IVD/2021/000129	1.License Holder Name: JANA MED TECH PRIVATE LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:D NURSE SP1 BLOOD GLUCOSE TEST STRIP(D NURSE SP1)-THE DNURSE SP1 BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE (SUGAR) IN FRESH VENOUS AND CAPILLARY WHOLE BLOOD SAMPLES AS AN AID IN MONITORING THE EFFECTIVENESS OF GLUCOSE CONTROL.

1053	IMP/IVD/2021/000135	1.License Holder Name: GENWORKS HEALTH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REACTION MODULE (MAGLUMI)-REACTION MODULES REQUIRED FOR THE IMPLEMENTATION OF THE MAGLUMI ASSAYS ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER,LIGHT CHECK(MAGLUMI®)-LIGHT CHECK REAGENT REQUIRED TO CHECK THE VALIDITY OF STARTER 1+2 AS WELL AS THE FUNCTIONING OF THE MEASURING AND PIPETTING UNITS. A LIGHT CHECK HAS TO BE CARRIED OUT ON THE MAGLUMI SERIES FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY ANALYZER, WASH CONCENTRATE(MAGLUMI)-MAGLUMI WASH CONCENTRATE IS INTENDED TO BE DILUTED FOR PREPARATION OF SYSTEM LIQUID WHICH IS REQUIRED FOR WASHING THE MAGNETIC MIRCOBEADS OF THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER.,STARTER 1+2(MAGLUMI®)-STARTER REAGENT KIT REQUIRED TO GENERATE THE CHEMILUMINOMETRIC LIGHT SIGNAL NECESSARY FOR THE IMPLEMENTATION OF MAGLUMI ASSAYS ON THE MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER.,SYSTEM TUBING CLEANING SOLUTION (MAGLUMI®)-THE MAGLUMI SYSTEM TUBING CLEANING SOLUTION IS USED TO CLEAN THE PIPETTOR AND THE WASHER NEEDLES. IT IS USEFUL TO MINIMIZE REAGENT CARRYOVER BY REDUCING PROTEIN PRECIPITATION IN THE TUBING, AND IMPROVE ROUTINE MAINTENANCE OF THE MAGLUMI SYSTEM. THE KIT CAN ONLY BE USED WITH MAGLUMI FULLY-AUTO CHEMILUMINESCENCE IMMUNOASSAY (CLIA) ANALYZER
1054	IMP/IVD/2021/000137	1.License Holder Name: GENETIX BIOTECH ASIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENGUE ANTIGEN ANTIBODY KIT(CARESTART™ DENGUE COMBO NS1 & IGM/IGG)-CARESTART DENGUE COMBO NS1 & IGM/IGG IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN AND/OR IGM AND/OR IGG ANTIBODIES TO DENGUE VIRUS IN SERUM, PLASMA, OR WHOLE BLOOD AS AN AID IN THE DIAGNOSIS OF DENGUE VIRUS INFECTION.

1055	IMP/IVD/2021/000140	1.License Holder Name: GENWORKS HEALTH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FERRITIN FAST TEST KIT (GETEIN)-FERRITIN FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA SAMPLES. IT IS USED AS AN AID IN QUANTIFIES OF HUMAN FERRITIN AND USED IN THE DIAGNOSIS OF DISEASES AFFECTING IRON OVERLOAD AND IRON DEFICIENCY ANEMIA.,CARDIAC TROPONIN I FAST TEST KIT(GETEIN)-CARDIAC TROPONIN I FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNL) IN SERUM, PLASMA OR WHOLE BLOOD. THIS IS USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL SYNDROME(AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS AND ACUTE CORONARY SYNDROME (ACS).,IL-6 FAST TEST KIT (GETEIN)-IL-6 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF INTERLEUKIN 6 (IL-6) IN HUMAN SERUM, PLASMA, WHOLE BLOOD AND PERIPHERAL BLOOD SAMPLES. IL-6 IS AN EARLY MARKER IN ACUTE INFLAMMATION AND THIS TEST CAN BE USED AS AN AID IN THE INFLAMMATORY DISEASES.,NT-PROBNP FAST TEST KIT(GETEIN)-NT-PROBNP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF N-TERMINAL B-TYPE NATRIURETIC PEPTIDE PRECURSOR (NT-PROBNP) IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF).,LH FAST TEST KIT(GETEIN)-LH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF LH IN HUMAN SERUM AND PLASMA. THIS TEST IS USED TO DETERMINE MENOPAUSE, PINPOINT OVULATION AND MONITOR ENDOCRINE THERAPY.,AMH FAST TEST KIT(GETEIN)-AMH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF AMH IN HUMAN SERUM AND PLASMA SAMPLES. THIS TEST CAN BE USED AS AN AID IN INDICATING OVARIAN FUNCTIONAL RESERVE, AND ALSO HELP TO DIAGNOSE MENSTRUAL DISORDERS OR TO MONITOR THE HEALTH OF WOMEN.,MALB FAST TEST KIT(GETEIN)-MALB FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF MICROALBUMINURIA (MALB) IN URINE. AN ELEVATED MALB CONCENTRATION BELOW THE PROTEINURIC LEVEL HAS LONG BEEN RECOGNIZED AS A MARKER OF KIDNEY DISEASE AND INCREASED CARDIOVASCULAR RISK IN DIABETIC NEPHROPATHY.,HCG+ BETA FAST TEST KIT(GETEIN)-HCG+

	BETA FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN SERUM OR PLASMA. THIS TEST IS USED AS AN AID IN PREGNANCY TEST.,T3 FAST TEST KIT(GETEIN)-T3 (TRIIODOTHYRONINE) FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T3 IN SERUM AND PLASMA. IT CAN BE USED IN THE MONITORING OF HYPERTHYROIDISM AND HYPOTHYROIDISM, AND ALSO USED AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA.,HS-CRP+CRP FAST TEST KIT(GETEIN)-HS-CRP+CRP FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM, PLASMA WHOLE BLOOD, OR FINGERTIP BLOOD. MEASUREMENT OF CRP IS USEFUL FOR THE DETECTION AND EVALUATION OF INFECTION, TISSUE INJURY AND INFLAMMATORY DISORDERS. MEASUREMENT OF HIGH SENSITIVITY CRP (HS-CRP), WHEN USED IN CONJUNCTION WITH TRADITIONAL CLINICAL LABORATORY EVALUATION OF ACUTE CORONARY SYNDROMES (ACS), MAY BE USEFUL AS AN INDEPENDENT MARKER OF PROGNOSIS FOR RECURRENT EVENTS IN PATIENTS WITH STABLE CORONARY DISEASE OR ACS.,25-OH-VD FAST TEST KIT(GETEIN)-25-OH-VD FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF 25-OH-VD IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST MAY HELP UNDERSTAND THE METABOLIC CHANGES OF BONE.,FSH FAST TEST KIT(GETEIN)-FSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM AND PLASMA. FSH TESTING IS USED FOR WOMEN SUSPECTED OF HAVING POLYCYSTIC OVARY SYNDROME, AND IN INDIVIDUALS UNDERGOING EV¬ALUATION FOR INFERTILITY, ALSO USED FOR EVALUATION OF INDIVIDUALS WITH SUSPECTED PITUITARY DISORDERS OR DISEASES OF THE OVARIES.,PCT FAST TEST KIT (GETEIN)-PCT FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF BACTERIAL INFECTION, TRAUMA OR SHOCK.,D-DIMER FAST TEST KIT(GETEIN)-D-DIMER FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF D-DIMER IN PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF DEEP-VEIN THROMBOSIS OR PULMONARY EMBOLISM.,HBA1C FAST TEST KIT(GETEIN)-HBA1C FAST TEST KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT

	OF HBA1C IN WHOLE BLOOD. THIS TEST IS USED AS AN AID FOR MONITORING GLYCEMIC CONTROL IN DIABETICS. IN ADDITION, IT CAN IDENTIFY PEOPLE AT RISK OF DEVELOPING THE DISEASE AND ONGOING MONITORING,T4 FAST TEST KIT(GETEIN)-T4 (THYROXINE) FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T4 IN SERUM AND PLASMA. IT CAN BE USED IN THE MONITORING OF HYPERTHYROID¬ISM AND HYPOTHYROIDISM, AND ALSO USED AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA.,TSH FAST TEST KIT(GETEIN)-TSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN SERUM AND PLASMA. THIS TEST IS USED IN THE SCREENING, CLINICAL DIAGNOSIS, PROGNOSIS AND THERAPEUTIC EFFECT EVALUATION OF THYROID DISEASES.,PRL FAST TEST KIT(GETEIN)-PRL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN SERUM OR PLASMA SAMPLES. THIS TEST CAN BE USED AS AN AID IN THE DIAGNOSIS OF MALE AND FEMALE INFERTILITY AND PITUITARY DYSFUNCTION, MONITORING OF MALE AND FEMALE GONADAL DISORDERS AND MANAGEMENT OF AMENORRHEA AND GALACTORRHEA.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1056	IMP/IVD/2021/000142	1.License Holder Name: SHALOM HEALTHCARE LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HB TOTAL-CHECK-1(HB TOTAL-CHECK-1)-QUANTITATIVE DETERMINATION OF HAEMOGLOBIN IN WHOLE BLOOD SAMPLES,CYSTATIN C-CHECK-1(CYSTATIN C-CHECK-1)-QUANTITATIVE DETERMINATION OF CYSTATIN C IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES ,HBA1C-CHECK-1(HBA1C-CHECK-1)-QUANTITATIVE DETERMINATION OF GLYCATED HAEMOGLOBIN IN WHOLE BLOOD SAMPLES,FRT-CHECK-1(FRT-CHECK-1)-QUANTITATIVE DETERMINATION OF FERRITIN IN WHOLE BLOOD, SERUM OR PLASMA SAMPLES ,PROCAL-CHECK-1(PROCAL-CHECK-1)-QUANTITATIVE DETERMINATION OF PROCALCITONIN IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES,TRANSFERRIN-CHECK-1(TRANSFERRIN-CHECK-1)-QUANTITATIVE DETERMINATION OF TRANSFERRIN IN FAECES SAMPLES ,:CALPROTECTIN-CHECK-1(: CALPROTECTIN-CHECK-1)-QUANTITATIVE DETERMINATION OF CALPROTECTIN IN FAECES SAMPLES,CK-MB-CHECK-1(CK-MB-CHECK-1)-QUANTITATIVE DETERMINATION OF CREATINE KINASE (MB ISOENZYME) IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES ,C-PEPTIDE-CHECK-1(C-PEPTIDE-CHECK-1)-QUANTITATIVE DETERMINATION OF C-PEPTIDE IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES.,CRP-CHECK-1 LAB VERSION)(CRP-CHECK-1 LAB VERSION))-QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES. ,CORTISOL-CHECK-1 (CORTISOL-CHECK-1)-QUANTITATIVE DETERMINATION OF CORTISOL IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES,HCG-CHECK-1 (SERUM / URINE / WHOLE BLOOD)(HCG-CHECK-1 (SERUM / URINE / WHOLE BLOOD))-QUANTITATIVE DETERMINATION OF HCG IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES ,LH-CHECK-1(LH-CHECK-1)-IMMUNOCHROMATOGRAPHIC RAPID TEST FOR THE DETECTION OF LUTEINIZING HORMONE (LH) IN WHOLE BLOOD, PLASMA, OR SERUM SAMPLES,CRP-CHECK-1 (CRP-CHECK-1)-QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN WHOLE BLOOD ,M-ALBU-CHECK-1(M-ALBU-CHECK-1)-QUANTITATIVE DETERMINATION OF MICROALBUMIN IN URINE SAMPLES ,HCG-CHECK-1 (SERUM / URINE)(HCG-CHECK-1 (SERUM / URINE))-QUANTITATIVE DETERMINATION OF HCG IN PLASMA, SERUM OR URINE SAMPLES , PROLAC-CHECK-1(PROLAC-CHECK-1)-QUANTITATIVE DETERMINATION OF PROLACTIN IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES ,ULTRA TSH-CHECK-1(ULTRA TSH-CHECK-1)-ULTRA SENSITIVE QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE IN PLASMA OR SERUM SAMPLES ,TROPONIN I-CHECK-1(TROPONIN I-CHECK-1)-QUANTITATIVE DETERMINATION OF TROPONIN I IN WHOLE BLOOD, SERUM OR PLASMA SAMPLES ,MGL-

	CHECK-1(MGL-CHECK-1)-QUANTITATIVE DETERMINATION OF MYOGLOBIN IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES ,HS INSULIN-CHECK-1(HS INSULIN-CHECK-1)-HIGH SENSITIVE QUANTITATIVE DETERMINATION OF INSULIN IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES ,D-DIMER-CHECK-1(D-DIMER-CHECK-1)-QUANTITATIVE DETERMINATION OF D-DIMER IN WHOLE BLOOD AND CITRATED PLASMA SAMPLES ,INSULIN-CHECK-1(INSULIN-CHECK-1)-QUANTITATIVE DETERMINATION OF INSULIN IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES. ,HS-CRP-CHECK-1 (LAB VERSION)(HS-CRP-CHECK-1 (LAB VERSION))-HIGH SENSITIVE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES ,FSH-CHECK-1(FSH-CHECK-1)-QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE FSH) IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES , TOTAL T4-CHECK-1(TOTAL T4-CHECK-1)-QUANTITATIVE DETERMINATION OF THYROXIN (TOTAL T4) IN PLASMA OR SERUM SAMPLES FOR THE DETECTION OF HYPERTHYROID ,BHCG-CHECK-1 (BHCG-CHECK-1)-QUANTITATIVE DETERMINATION OF B-HCG IN PLASMA, SERUM OR URINE SAMPLES. ,IGE-CHECK-1(IGE-CHECK-1)-QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN-E IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES ,HS PRL-CHECK-1(HS PRL-CHECK-1)-HIGH SENSITIVE QUANTITATIVE DETERMINATION OF PROLACTIN IN PLASMA OR SERUM SAMPLES ,TOTAL T3-CHECK-1 (TOTAL T3-CHECK-1)-QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (TOTAL T3) IN PLASMA OR SERUM SAMPLES FOR THE DETECTION OF HYPERTHYROID ,HS TSH-CHECK-1(HS TSH-CHECK-1)-HIGH SENSITIVE QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE IN WHOLE BLOOD, PLASMA OR SERUM SAMPLES

1057	IMP/IVD/2021/000143	1.License Holder Name: DHR HOLDING INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPECTRIN (RECOMMENDED FOR HUMAN USE)(NOVOCASTRA)-NCL-SPEC1 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF SPECTRIN BY IMMUNOHISTOCHEMISTRY. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,CD33(BOND)-"CD33 (PWS44) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN CD33 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND SYSTEM (INCLUDES LEICA BONDMAX SYSTEM AND LEICA BOND-III SYSTEM). THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.", GRANZYME B(NOVOCASTRA)-NCL-L-GRAN-B IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF GRANZYME B MOLECULES IN PARAFFIN SECTIONS.,CD138 (SYNDECAN 1)(BOND)-"CD138 (MI15) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN CD138 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND SYSTEM (INCLUDES LEICA BONDMAX SYSTEM AND LEICA BOND-III SYSTEM). THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",SARCOGLYCAN, BETA (NOVOCASTRA)-NCL-L-B-SARC IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF BETA-SARCOGLYCAN BY IMMUNOHISTOCHEMISTRY. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,CD5(BOND)-"CD5 (4C7) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY

	LIGHT MICROSCOPY OF HUMAN CD5 MOLECULES IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND SYSTEM (INCLUDES LEICA BOND-MAX SYSTEM AND LEICA BOND-III SYSTEM). THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",PROGESTERONE RECEPTOR (NOVOCASTRA)-NCL-L-PGR-312 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF PROGESTERONE RECEPTOR MOLECULES IN PARAFFIN SECTIONS. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,E-CADHERIN(BOND)-"E-CADHERIN (36B5) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN E-CADHERIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING AN AUTOMATED BONDTM SYSTEM. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",SMA (ALPHA SMOOTH MUSCLE ACTIN)(BOND)-"SMOOTH MUSCLE ACTIN (ALPHA SM-1) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN ALPHA SMOOTH MUSCLE ACTIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND SYSTEM (INCLUDES LEICA BOND-MAX SYSTEM AND LEICA BOND-III SYSTEM). THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",DYSFERLIN(NOVOCASTRA)-NCL-HAMLET-2 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF DYSFERLIN BY IMMUNOHISTOCHEMISTRY., TERMINAL DEOXYNUCLEOTIDYL TRANSFERASE(BOND)-"TERMINAL DEOXYNUCLEOTIDYL TRANSFERASE (SEN28) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN TERMINAL

	DEOXYNUCLEOTIDYL TRANSFERASE IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND SYSTEM (INCLUDES LEICA BOND-MAX SYSTEM AND LEICA BOND-III SYSTEM). THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",GLIAL FIBRILLARY ACIDIC PROTEIN(BOND)-"GLIAL FIBRILLARY ACIDIC PROTEIN (GA5) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN GLIAL FIBRILLARY ACIDIC PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND SYSTEM (INCLUDES LEICA BOND-MAX SYSTEM AND LEICA BOND-III SYSTEM). THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.", THYROID TRANSCRIPTION FACTOR-1(BOND)-"THYROID TRANSCRIPTION FACTOR-1 (SPT24) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN THYROID TRANSCRIPTION FACTOR-1 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND SYSTEM. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.", PROGESTERONE RECEPTOR(BOND)-"PROGESTERONE RECEPTOR (16) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN PROGESTERONE RECEPTOR (PR) IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BONDTM SYSTEM. PROGESTERONE RECEPTOR CLONE (16) [PR (16)] SPECIFICALLY BINDS TO THE PR ANTIGEN LOCATED IN THE NUCLEUS OF PR POSITIVE NORMAL AND NEOPLASTIC CELLS. PR (16) IS INDICATED AS AN AID IN THE MANAGEMENT, PROGNOSIS AND PREDICTION OF THERAPY OUTCOME OF BREAST CANCER. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE

	CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",ESTROGEN RECEPTOR(BOND)-"ESTROGEN RECEPTOR CLONE 6F11 READY-TO-USE PRIMARY ANTIBODY FOR BOND MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN ESTROGEN RECEPTOR (ER) IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND SYSTEM (INCLUDES LEICA BOND-MAX SYSTEM AND LEICA BOND-III SYSTEM). ESTROGEN RECEPTOR CLONE 6F11 READY-TO-USE PRIMARY ANTIBODY FOR BOND SPECIFICALLY BINDS TO THE ER ANTIGEN LOCATED IN THE NUCLEUS OF ER POSITIVE NORMAL AND NEOPLASTIC CELLS. ER (6F11) IS INDICATED AS AN AID IN THE MANAGEMENT, PROGNOSIS AND PREDICTION OF THERAPY OUTCOME OF BREAST CANCER. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",EPITHELIAL MEMBRANE ANTIGEN(BOND)-"EPITHELIAL MEMBRANE ANTIGEN (GP1.4) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN EPITHELIAL MEMBRANE ANTIGEN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND-MAXTM SYSTEM. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",OCT-2 (BOND)-OCT-2 (OCT-207) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN OCT-2 IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND SYSTEM (INCLUDES LEICA BOND-MAX SYSTEM AND LEICA BOND-III SYSTEM).,NOVOCASTRA HMB45 (MELANOMA MARKER)(BOND)-"MELANOMA MARKER (HMB45) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN HMB45 ANTIGEN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING AN AUTOMATED BOND SYSTEM. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED

	WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.", DYSTROPHIN (C-TERMINUS)(NOVOCASTRA)-NCL-DYS2 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF DYSTROPHIN (C-TERMINUS) BY IMMUNOHISTOCHEMISTRY.,DESMIN (BOND)-"DESMIN (DE-R-11) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN DESMIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND SYSTEM (INCLUDES LEICA BOND-MAX SYSTEM AND LEICA BOND-III SYSTEM). THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",DYSTROPHIN (N-TERMINUS)(NOVOCASTRA)-NCL-DYS3 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF DYSTROPHIN (N-TERMINUS) BY IMMUNOHISTOCHEMISTRY.,CYTOKERATIN 20(NOVOCASTRA)-NCL-L-CK20-561 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF CYTOKERATIN 20 MOLECULES IN PARAFFIN SECTIONS.,CHROMOGRANIN A(BOND)-"CHROMOGRANIN A (5H7) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN CHROMOGRANIN A IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BONDTM SYSTEM. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",P63 PROTEIN(NOVOCASTRA)-NCL-L-P63 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN P63 IN PARAFFIN SECTIONS. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,OCT-3/4(BOND)-"OCT-3/4 (N1NK) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN OCT-3/4 IN FORMALIN-FIXED, PARAFFIN EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING AN AUTOMATED BONDTM SYSTEM. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS

	ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.", SYNAPTOPHYSIN(BOND)-"SYNAPTOPHYSIN (27G12) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN SYNAPTOPHYSIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BONDTM SYSTEM. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",KI67 ANTIGEN(BOND)-"KI67 (MM1) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN KI67 NUCLEAR ANTIGEN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND™ SYSTEM. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",BETA-DYSTROGLYCAN (NOVOCASTRA)-NCL-B-DG IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF BETA-DYSTROGLYCAN BY IMMUNOHISTOCHEMISTRY.,THYROID TRANSCRIPTION FACTOR-1 (NOVOCASTRA)-NCL-L-TTF-1 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF THYROID TRANSCRIPTION FACTOR-1 IN PARAFFIN SECTIONS. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,CYTOKERATIN (8/18)(BOND)-"CYTOKERATIN 8/18 (5D3) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN CYTOKERATIN 8 AND 18 INTERMEDIATE FILAMENTS IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND SYSTEM. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND

	OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.", SARCOGLYCAN, ALPHA (ADHALIN)(NOVOCASTRA)-NCL-L-A-SARC IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF ALPHA-SARCOGLYCAN (ADHALIN) MOLECULES IN FROZEN SECTIONS. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,CD11C(NOVOCASTRA)-NCL-L-CD11C-563 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN CD11C ANTIGEN IN PARAFFIN SECTIONS.,DYSTROPHIN (ROD DOMAIN)(NOVOCASTRA)-NCL-DYS1 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF DYSTROPHIN (ROD DOMAIN) BY IMMUNOHISTOCHEMISTRY., CYTOKERATIN, MULTI(NOVOCASTRA)-"MULTI-CYTOKERATIN (AE1/AE3) ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN CYTOKERATINS 56.5, 50, 50', 48 AND 40 KD OF THE ACIDIC SUBFAMILY AND 65 TO 67, 64, 59, 58, 56 AND 52 KD OF THE BASIC SUBFAMILY IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BONDTM SYSTEM. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",CD10 (BOND)-"CD10 (56C6) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF THE HUMAN CD10 MOLECULE IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND SYSTEM (INCLUDES LEICA BOND-MAX SYSTEM AND LEICA BOND-III SYSTEM). THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",EMERIN(NOVOCASTRA)-NCL-EMERIN IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF EMERIN BY IMMUNOHISTOCHEMISTRY.,DYSFERLIN(NOVOCASTRA)-NCL-HAMLET IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF DYSFERLIN BY IMMUNOHISTOCHEMISTRY. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING

	PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,MEROSIN LAMININ ALPHA 2 CHAIN(NOVOCASTRA)-NCL-MEROSIN IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF MEROSIN LAMININ ALPHA 2 CHAIN BY IMMUNOHISTOCHEMISTRY., CD31 (PECAM-1)(BOND)-"CD31 (1A10) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN CD31(PECAM-1) MOLECULE IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BONDTM SYSTEM. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",CD33 (NOVOCASTRA)-NCL-L-CD33 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN CD33 IN PARAFFIN SECTIONS.,SARCOGLYCAN, DELTA(NOVOCASTRA)-NCL-D-SARC IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF DELTA-SARCOGLYCAN BY IMMUNOHISTOCHEMISTRY. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,CD45(BOND)-"CD45 (X16/99) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN CD45 ANTIGEN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND SYSTEM (INCLUDES LEICA BOND-MAX SYSTEM AND LEICA BOND-III SYSTEM). THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",CD23 (BOND)-"CD23 (1B12) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN CD23 MOLECULES IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND SYSTEM (INCLUDES LEICA BOND-MAX SYSTEM AND LEICA BOND-III SYSTEM). THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY

	MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",CYTOKERATIN 7(BOND)-"CYTOKERATIN 7 (RN7) MONOCLONAL ANTIBODY IS INTENDED TO BE USED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN CYTOKERATIN 7 INTERMEDIATE FILAMENT PROTEIN IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE BY IMMUNOHISTOCHEMICAL STAINING USING THE AUTOMATED BOND™ SYSTEM. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES AND PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.",ESTROGEN RECEPTOR (NOVOCASTRA)-NCL-L-ER-6F11 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF ESTROGEN RECEPTOR MOLECULES IN PARAFFIN SECTIONS. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,SARCOGLYCAN, GAMMA(NOVOCASTRA)-NCL-G-SARC IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF GAMMA-SARCOGLYCAN BY IMMUNOHISTOCHEMISTRY. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,HER-2 (C-ERBB-2 ONCOPROTEIN) ANTIBODIES (NOVOCASTRA)-NCL-L-CB11 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF C-ERBB-2 ONCOPROTEIN MOLECULES IN PARAFFIN SECTIONS. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.

1058	IMP/IVD/2021/000143	1.License Holder Name: DHR HOLDING INDIA PVT.LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:POLYMER REFINE DETECTION(BOND POLYMER REFINE DETECTION)-DS9800 IS INTENDED FOR STAINING SECTIONS OF FORMALINFIXED, PARAFFIN-EMBEDDED TISSUE,CD3("BOND READY-TO-USE PRIMARY ANTIBODY CD3")-PA0553 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN CD3 MOLECULE IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE.,EPITOPE RETRIEVAL SOLUTION 2("BOND READY-TO-USE EPITOPE RETRIEVAL SOLUTION 2")-AR9640 IS INTENDED FOR THE HEAT-INDUCED EPITOPE RETRIEVAL (HIER) OF FORMALINFIXED, PARAFFINEMBEDDED TISSUE.,WASH SOLUTION 10X CONCENTRATE("BOND READY-TO-USE WASH SOLUTION 10X CONCENTRATE")-AR9590 IS INTENDED FOR WASHING SECTIONS OF FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE DURING IMMUNOSTAINING.,CD20("BOND READY-TO-USE PRIMARY ANTIBODY CD20")-PA0906 IS INTENDED FOR THE QUALITATIVE IDENTIFICATION BY LIGHT MICROSCOPY OF HUMAN CD20 MOLECULE IN FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. ,DEWAX SOLUTION(BOND READY-TO-USE DEWAX SOLUTION)-AR9222 IS INTENDED FOR REMOVAL OF PARAFFIN WAX FROM FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE. ,EPITOPE RETRIEVAL SOLUTION 1("BOND READY-TO-USE EPITOPE RETRIEVAL SOLUTION 1")-AR9961 IS INTENDED FOR THE HEAT-INDUCED EPITOPE RETRIEVAL (HIER) OF FORMALINFIXED, PARAFFINEMBEDDED TISSUE.

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1059	IMP/IVD/2021/000144	1.License Holder Name: LAB X 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRAP-6(STAGO)-"STUDY OF PLATELET AGGREGATION IN PLATELET-RICH PLASMA. IN THE CASE OF KNOWN DISORDER OR STRONG DIAGNOSIS SUSPICION, THE INVESTIGATION CAN BE LIMITED TO ONE OR SEVERAL AGONISTS.", EPINEPHRINE(STAGO)-"STUDY OF PLATELET AGGREGATION IN PLATELET-RICH PLASMA. IN THE CASE OF KNOWN DISORDER OR STRONG DIAGNOSIS SUSPICION, THE INVESTIGATION CAN BE LIMITED TO ONE OR SEVERAL AGONISTS.",COLLAGEN(STAGO)-"STUDY OF PLATELET AGGREGATION IN PLATELET-RICH PLASMA. IN THE CASE OF KNOWN DISORDER OR STRONG DIAGNOSIS SUSPICION, THE INVESTIGATION CAN BE LIMITED TO ONE OR SEVERAL AGONISTS.",ARACHIDONIC ACID(STAGO)-"STUDY OF PLATELET AGGREGATION IN PLATELET-RICH PLASMA. IN THE CASE OF KNOWN DISORDER OR STRONG DIAGNOSIS SUSPICION, THE INVESTIGATION CAN BE LIMITED TO ONE OR SEVERAL AGONISTS.",ADP(STAGO)-"STUDY OF PLATELET AGGREGATION IN PLATELET-RICH PLASMA. IN THE CASE OF KNOWN DISORDER OR STRONG DIAGNOSIS SUSPICION, THE INVESTIGATION CAN BE LIMITED TO ONE OR SEVERAL AGONISTS."

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1060	IMP/IVD/2021/000160	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HBA1C REAGENT KIT (HPLC)(NA)-APPLICABLE TO QUANTITATIVE EXAMINATION THE CONTENT OF HBA1C IN THE WHOLE BLOOD OF HUMAN BODY. IT ADOPTS HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) METHOD TO MEASURE THE LEVEL OF HBA1C.,ß-THALASSAEMIA & HBA1C REAGENT KIT (HPLC)(NA)-IT IS INTENDED FOR THE SEPARATION AND AREA PERCENT DETERMINATION OF HEMOGLOBIN HBA2, HBF AND HBA1C AND AS AN AID IN THE PRESUMPTIVE IDENTIFICATION OF ABNORMAL HUMAN HEMOGLOBINS IN WHOLE BLOOD USING ION-EXCHANGE HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC).THIS RESULT CAN BE USED FOR REFERENCE OF CLINICAL B-THALASSAEMIA DIAGNOSE.,ß-THALASSAEMIA & HBA1C CALIBRATOR(NA)-IT IS INTENDED FOR THE PERCENT DETERMINATION OF HBA2/HBF/ HBA1C IN HUMAN BLOOD USING HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)., HBA1C CONTROL MATERIAL(NA)-HBA1C CONTROL MATERIAL IS INTENDED FOR THE SYSTEM QUALITY CONTROL FOR ACCURACY AND REPEATABILITY.,HBA1C CALIBRATOR(NA)-HBA1C CALIBRATOR IS INTENDED FOR THE PERCENT DETERMINATION OF HBA1C IN HUMAN BLOOD USING HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC).,ß-THALASSAEMIA & HBA1C CONTROL MATERIAL(NA)-IT IS INTENDED TO COMPARE THE MEASURING RESULTS IN SAMPLE TEST PROGRAM WITH REFERENCE RANGE.

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1061	IMP/IVD/2021/000175	1.License Holder Name: M/S. PEERLESS BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTI-STREPTOLYSIN O (ASO)(ANTI-STREPTOLYSIN O (ASO) REAGENT FOR TURBIDIMETRY BIOLATEX)-QUANTITATIVE DETERMINATION OF ANTI-STREPTOLYSIN O (ASO) IN SERUM BY MEANS OF PARTICLE-ENHANCED TURBIDIMETRIC IMMUNOASSAY,CYSTATIN C(CYSTATIN C REAGENT FOR TURBIDIMETRY BIOLATEX)-FOR THE QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM BY IMMUNOTURBIDIMETRY.,MICROALBUMIN(MICROALBUMIN REAGENT FOR TURBIDIMETRY BIOLATEX)-IN VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN URINE (MAU) BY MEANS OF PARTICLE-ENHANCED TURBIDIMETRIC IMMUNOASSAY,RBP (RETINOL-BINDING PROTEIN)(RBP (RETINOL-BINDING PROTEIN) REAGENT FOR TURBIDIMETRY BIOLATEX)-FOR THE QUANTITATIVE DETERMINATION OF RETINOL-BINDING PROTEIN (RBP) IN HUMAN SERUM BY IMMUNOTURBIDIMETRY,FERRITIN (FERRITIN REAGENT FOR TURBIDIMETRY BIOLATEX)-IN VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF HUMAN FERRITIN IN SERUM BY MEANS OF PARTICLE-ENHANCED TURBIDIMETRIC IMMUNOASSAY.,LIPOPROTEIN (A) LP(A) (LIPOPROTEIN (A) LP(A) REAGENT FOR TURBIDIMETRY BIOLATEX)-IN VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN (A) [LP(A)] IN SERUM BY MEANS OF PARTICLE-ENHANCED TURBIDIMETRIC IMMUNOASSAY., LIPOPROTEIN (A) LP(A) CALIBRATOR(LIPOPROTEIN (A) LP(A) CALIBRATOR)-THE LP(A) CALIBRATOR IS USED FOR MAKING THE CALIBRATION CURVE.,IMMUNOGLOBULIN E (IGE)(IMMUNOGLOBULIN E (IGE) REAGENT FOR TURBIDIMETRY BIOLATEX)-IN VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF HUMAN IGE IN SERUM BY MEANS OF PARTICLE-ENHANCED TURBIDIMETRIC IMMUNOASSAY,C REACTIVE PROTEIN (CRP)(C REACTIVE PROTEIN (CRP) REAGENT FOR TURBIDIMETRY BIOLATEX)-QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM BY MEANS OF PARTICLE-ENHANCED TURBIDIMETRIC IMMUNOASSAY.,IMMUNOGLOBULIN E (IGE) CALIBRATOR (IMMUNOGLOBULIN E (IGE) CALIBRATOR)-IGE CALIBRATOR, FOR MAKING THE CALIBRATION CURVE,RHEUMATOID FACTOR (RF) (RHEUMATOID FACTOR (RF) REAGENT FOR TURBIDIMETRY BIOLATEX)-QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN SERUM BY MEANS OF PARTICLE-ENHANCED TURBIDIMETRIC IMMUNOASSAY

1062	IMP/IVD/2021/000176	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 RAPID ANTIGEN TEST NASAL(SARS-COV-2 RAPID ANTIGEN TEST NASAL)-THE SARSCOV2 RAPID ANTIGEN TEST NASAL IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SARSCOV2 NUCLEOCAPSID ANTIGEN PRESENT IN HUMAN NASAL SAMPLES. THIS TEST IS INTENDED TO DETECT ANTIGEN FROM SARSCOV2 IN INDIVIDUALS SUSPECTED OF COVID19 OR WITH KNOWN OR SUSPECTED EXPOSURE TO SARSCOV2. THIS PRODUCT IS INTENDED FOR PROFESSIONAL USE IN LABORATORY AND POINT OF CARE ENVIRONMENTS, OR SELF-COLLECTION UNDER THE SUPERVISION OF A HEALTHCARE WORKER, SARS-COV-2 RAPID ANTIGEN TEST(SARS-COV-2 RAPID ANTIGEN TEST)-THE SARSCOV2 RAPID ANTIGEN TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIGENS OF SARSCOV2 PRESENT IN NASOPHARYNGEAL OR COMBINED NASOPHARYNGEAL/OROPHARYNGEAL SAMPLES. THIS TEST IS INTENDED TO DETECT ANTIGEN FROM THE SARSCOV2 VIRUS IN INDIVIDUALS SUSPECTED OF COVID19. THIS PRODUCT IS STRICTLY INTENDED FOR PROFESSIONAL USE IN LABORATORY AND POINT OF CARE ENVIRONMENTS.
1063	IMP/IVD/2021/000189	1.License Holder Name: BIO STATE INC. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BTA STAT TEST(BTA STAT TEST)-THE BTA STAT TEST IS AN IN VITRO DIAGNOSTIC ASSAY INDICATED FOR THE QUALITATIVE DETECTION OF BLADDER TUMOR ANTIGEN IN HUMAN URINE. THIS TEST IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS AND MANAGEMENT OF BLADDER CANCER PATIENTS.
1064	IMP/IVD/2021/000192	1.License Holder Name: SEBIA DIAGNOSTICS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CAPIPROTECT (CAPIPROTECT)-RINSING SOLUTION FOR CAPILLARY ELECTROPHORESIS INSTRUMENTS

1065	IMP/IVD/2021/000193	1.License Holder Name: MP BIOMEDICALS INDIA PVT.LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASSURE H. PYLORI RAPID TEST(MP DIAGNOSTICS)-THE MP DIAGNOSTICS ASSURE H. PYLORI RAPID TEST IS AN IMMUNOCHROMATOGRAPHIC TEST DEVICE INTENDED FOR THE RAPID DETECTION OF IGG ANTIBODIES TO HELICOBACTER PYLORI IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED AS A CLINICAL DIAGNOSTIC TEST FOR DIAGNOSING INFECTION WITH H. PYLORI IN PATIENTS WITH GASTRIC DISORDERS. IN ADDITION, THE PRESENCE OF ANTIBODIES TO A RECOMBINANT CURRENT INFECTION MARKER (CIM) IS INDICATIVE OF CURRENT INFECTION.,HIV BLOT 2.2(MP DIAGNOSTICS)-THE MP DIAGNOSTICS HIV BLOT 2.2 IS A QUALITATIVE ENZYME IMMUNOASSAY FOR THE IN VITRO DETECTION OF ANTIBODIES TO HIV-1 AND HIV-2 IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR USE AS A MORE SPECIFIC SUPPLEMENTAL TEST ON HUMAN SERUM OR PLASMA SPECIMENS FOUND REPEATEDLY REACTIVE USING SCREENING PROCEDURES SUCH AS THE ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA).,HEV IGM ELISA 3.0(MP DIAGNOSTICS)-THE MP DIAGNOSTICS HEV IGM ELISA 3.0 IS AN ENZYME- LINKED IMMUNOSORBENT ASSAY INTENDED FOR THE DETECTION OF IGM ANTIBODIES TO HEPATITIS E VIRUS (HEV) IN HUMAN SERUM OR PLASMA.,HEV ELISA 4.0(MP DIAGNOSTICS)-THE MP DIAGNOSTICS HEV ELISA 4.0 IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY INTENDED FOR THE DETECTION OF TOTAL ANTIBODIES TO HEPATITIS E VIRUS IN HUMAN SERUM OR PLASMA. IT IS INTENDED AS A SCREENING TEST, REQUIRING REPEAT TESTING OF INITIALLY REACTIVE SPECIMENS.,ASSURE HEV IGM RAPID TEST(MP DIAGNOSTICS)-THE MP DIAGNOSTICS ASSURE HEV IGM RAPID TEST IS AN IMMUNOCHROMATOGRAPHIC TEST DEVICE INTENDED FOR THE RAPID DETECTION OF IGM ANTIBODIES TO HEPATITIS E VIRUS (HEV) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED AS A CLINICAL DIAGNOSTIC TEST FOR DIAGNOSING INFECTION WITH HEPATITIS E.,HELICO BLOT 2.1(MP DIAGNOSTICS)-THE MP DIAGNOSTICS HELICO BLOT 2.1 WESTERN BLOT KIT ASSAY IS A QUALITATIVE ASSAY FOR THE DETECTION OF IGG ANTIBODIES TO HELICOBACTER PYLORI (H. PYLORI) IN HUMAN SERUM OR PLASMA, WITH THE ADDED INDICATION OF CURRENT INFECTION STATUS. THE PRODUCT IS INTENDED FOR USE AS A SEROLOGICAL TEST FOR THE DETECTION OF BOTH CURRENT AND PAST INFECTION WITH H. PYLORI. UNLIKE AN ELISA, THE HELICO BLOT 2.1 ALLOWS FOR THE DETECTION OF ANTIBODIES TO SPECIFIC PROTEINS OF H. PYLORI, INCLUDING ANTIGENS ASSOCIATED WITH PATHOLOGY SUCH AS CAGA AND VACA.,HEV ELISA(MP DIAGNOSTICS)-THE MP

		DIAGNOSTICS HEV ELISA IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY INTENDED FOR THE DETECTION OF IGG ANTIBODIES TO HEPATITIS E VIRUS (HEV) IN HUMAN SERUM OR PLASMA
1066	IMP/IVD/2021/000194	1.License Holder Name: M/S. BRIDGEWAY MEDICAL SYSTEMS (A UNIT OF SKYLINE PEEVEES PROPERTIES (P) LTD) 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COOL BLOOD GLUCOSE TEST STRIP(COOL)-COOL GLUCOSE TEST STRIPS WORK WITH THE COOL BLOOD GLUCOSE METERS TO QUANTITATIVELY MEASURE GLUCOSE IN WHOLE BLOOD. THE COOL BLOOD GLUCOSE MONITORING SYSTEMS ARE FOR SELF-TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE).
1067	IMP/IVD/2021/000200	1.License Holder Name: ACCUREX BIOMEDICALS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLEANING SOLUTION (CORNLEY)-THIS REAGENT IS INTENDED TO PROVIDE THOROUGH CLEANING OF THE REAGENT PATH.,MULTI-ENZYME DE-PROTEINIZER (CORNLEY)-INTENDED TO MAINTAIN K+, CA2+, CL- ELECTRODES ON CORNLEY® ELECTROLYTE ANALYZER ,REFILL SOLUTION(CORNLEY)-REFILL SOLUTION FOR K+,NA+,CL-,CA2+,PH ELECTRODE IS INTENDED TO PROVIDE REFERENCE POTENTIAL FOR INTERNAL ELECTRODE OF K+,NA+,CL-,CA2+ AND PH ELECTRODE,CALIBRATION STANDARD SOLUTION(CORNLEY)-IT'S USED FOR MULTI-PARAMETER MEASURING REAGENTS FOR ELECTROLYTE ANALYZER(TESTING ITEMS:K,NA,CL,CA LI PH,TCO2),K,NA,CL,CA LI PH ARE CALIBRATED, CORRECTED AND CLEANED BASED ON THE ION - SELECTIVE ELECTRODES PRINCIPLE,TCO2,ELECTROLYTES QUALITY CONTROL (CORNLEY)-INTENDED FOR QUALITY CONTROL OF REAGENT KITS INTENDED FOR ESTIMATION OF SODIUM, POTASSIUM, CHLORIDE, CALCIUM AND PH PARAMETERS INSERUM/PLASMA / OTHER BODY FLUIDS.,CONDITIONING SOLUTION(CORNLEY)-THIS REAGENT IS INTENDED TO MAINTAIN NA+, PH ELECTRODES ON A CORNLEY® ELECTROLYTE ANALYZER

1068	IMP/IVD/2021/000201	1.License Holder Name: M/S. DIAGON VANGUARD DIAGNOSTICS INDIA (P) LIMITED. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIA-D-DIMER QUANTITATIVE D-DIMER TEST(DIAGON)-DIA-D-DIMER IS A DIAGNOSTIC TEST USED FOR QUANTITATIVE DETERMINATION OF D-DIMER INPLASMA ON PHOTOMETRIC SYSTEMS. (FOR IN- VITRO DIAGNOSTIC USE ONLY),DIA-CONT DDI I-II CONTROL PLASMAS FOR D-DIMER TEST(DIAGON)-DIA-CONT I-II TWO LEVELS CONTROL PLASMAS ARE INTENDED TO CONTROL OF THE FOLLOWING TEST D DIMER (DDI).
1069	IMP/IVD/2021/000208	1.License Holder Name: M/S AGAPPE DIAGNOSTICS LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD ELECTROLYTE REAGENT(I- SMART 30 PRO CARTRIDGE)-THE I-SMART 30 PRO CARTRIDGE IS INTENDED FOR USE IN THE QUANTITATIVE MEASUREMENTS OF SODIUM, POTASSIUM, AND CHLORIDE IN WHOLE BLOOD, SERUM, PLASMA, OR URINE. MEASUREMENTS OBTAINED BY THIS DEVICE ARE USED FOR THE DIAGNOSIS, MONITORING, AND TREATMENT OF DISEASES INVOLVING ELECTROLYTE IMBALANCE., BLOOD ELECTROLYTE REAGENT(I- SMART 30 CARTRIDGE)-THE I-SMART 30 CARTRIDGE IS INTENDED TO BE USED FOR THE MEASUREMENTS OF SODIUM, POTASSIUM, CHLORIDE AND HEMATOCRIT IN WHOLE BLOOD, PLASMA, OR SERUM. (HEMATOCRIT IS FOR WHOLE BLOOD ONLY) THE CARTRIDGE IS USED BY LABORATORY PROFESSIONALS FOR IN VITRO DIAGNOSTIC TESTING.

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1070	IMP/IVD/2021/000209	1.License Holder Name: LIFETECH BIOMEDICAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CAL CATRIDGE FOR GASTAT 1800, 700 SERIES/MODEL(TECHNO MEDICA)-CAL CATRIDGE IS USED FOR CALIBRATION OF BLOOD GAS SYSTEM GASTAT 1800, 700 SERIES/MODEL,GASTROL QC/ISE/A FOR GASTAT 600,700,1800 SERIES/MODEL(TECHNO MEDICA)-FOR QUALITY CONTROL MATERIAL INTENDED FOR PROCESSIONAL USE IN THE VERIFICATION OF THE PRECISION AND ACCURACY OF BLOOD GAS SYSTEM GASTAT- 600, 700, 1800 SERIES/MODEL. ,CAL CATRIDGE AQC FOR GASTAT 1800,700 SERIES/MODEL(TECHNO MEDICA)-CAL CATRIDGE AQC IS USED FOR CALIBRATION OF BLOOD GAS SYSTEM GASTAT 1800/700 SERIES/MODEL,PH REFILL SOLUTION (TECHNO MEDICA)-PH REFILL SOLUTION IS USED FOR MEASUREMENT OF PH ELECTRODE IN BLOOD GAS SYSTEM GASTAT 600, 700 AND 1800 SERIES,FLUSH SOLUTION (TECHNO MEDICA)-FLUSH SOLUTION / FLUSH IS USED FOR CLEANING OF BLOOD GAS SYSTEM GASTAT-1800SERIES AND 700MODEL SAMPLE PATH AFTER CALIBRATION AND SAMPLE MEASUREMENT.
1071	IMP/IVD/2021/000210	1.License Holder Name: RMD MEDIAIDS LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE MONITORING SYSTEM(GLUCOCARE ULTIMA)-GLUCOCARE ULTIMA-GLUCOMETER IS USED WITH BLOOD GLUCOSE TEST STRIPS AND INTENDED FOR SELF-TESTING BY PEOPLE WITH DIABETES AT HOME AND HEALTH CARE PROFESSIONALS IN A CLINICAL SETTING TO MONITOR GLUCOSE CONCENTRATIONS IN CAPILLARY WHOLE BLOOD. THEY ARE FOR TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE ONLY). DO NOT USE THEM FOR DIAGNOSIS OF DIABETES OR TESTING ON NEONATES.,BLOOD GLUCOSE MONITORING SYSTEM(GLUCOCARE SENSE, MAKESURE, OK METER MATCH)-GLUCOCARE SENSE, MAKESURE, OK METER MATCH: BLOOD GLUCOSE METER IS USED WITH BLOOD GLUCOSE TEST STRIPS AND INTENDED FOR SELF-TESTING BY PEOPLE WITH DIABETES AT HOME AND HEALTH CARE PROFESSIONALS IN A CLINICAL SETTING TO MONITOR GLUCOSE CONCENTRATIONS IN CAPILLARY WHOLE BLOOD. THEY ARE FOR TESTING OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE ONLY). DO NOT USE THEM FOR DIAGNOSIS OF DIABETES OR TESTING ON NEONATES.

1072	IMP/IVD/2021/000212	1.License Holder Name: A & A ENTERPRISES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALLERGY DIAGNOSTICS: MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (ATOPIC 30-II) FOR SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF ALLERGEN-SPECIFIC IGE IN SERUM(POLYCHECK)-THE POLYCHECK® , ATOPIC-30-II , SCANNER BASED ENZYME IMMUNOASSAY SCREENING IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGE IN SERUM, THE RELEVANT ALLERGENS ARE COATED SEPARATELY IN LINES AS WELL AS THE CALIBRATORS ON A CARRIER WHICH IS FIXED IN THE WELL OF THE POLYCHECK® FOR; F85 CELERY F14 SOYBEAN F13 PEANUT F12 PEA F96 AVOCADO F26 PORK MEAT F04 WHEAT FLOUR F24 SHRIMP F03 CODFISH F84 KIWI F02 COW'S MILK F01 EGG WHITE T03 BIRCH POLLEN T09 OLIVE POLLEN T07 WHITE OAK POLLEN T11 LONDON PLANE POLLEN T23 CYPRESS POLLEN G15 CULTIVATED WHEAT POLLEN G06 TIMOTHY GRASS POLLEN W01 RAGWEED POLLEN W21 WALL PELLITORY POLLEN W06 MUGWORT POLLEN E01 CAT EPITHELIA E02/E05 DOG EPITHELIA M03 ASPERGILLUS FUMIGATUS M06 ALTERNARIA ALTERNATA I06 COCKROACH (BLATELLA GERMANICA) D01 D. PTERONYSSINUS D02 D. FARINAE K202 CCD9,ALLERGY DIAGNOSTICS: MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (ATOPIC INDIA 30) FOR SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF ALLERGEN-SPECIFIC IGE IN SERUM(POLYCHECK)-THE POLYCHECK® , ATOPIC-30-II , SCANNER BASED ENZYME IMMUNOASSAY SCREENING IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGE IN SERUM, THE RELEVANT ALLERGENS ARE COATED SEPARATELY IN LINES AS WELL AS THE CALIBRATORS ON A CARRIER WHICH IS FIXED IN THE WELL OF THE POLYCHECK® FOR,ALLERGY DIAGNOSTICS: MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (INHALATION 30-I) FOR SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF ALLERGEN-SPECIFIC IGE IN SERUM(POLYCHECK)-THE POLYCHECK® , INHALATION 30-I , SCANNER BASED ENZYME IMMUNOASSAY (EIA) SCREENING IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGE IN SERUM, THE RELEVANT ALLERGENS ARE COATED SEPARATELY IN LINES AS WELL AS THE CALIBRATORS ON A CARRIER WHICH IS FIXED IN THE WELL OF THE POLYCHECK® FOR; T23 CYPRESS POLLEN T04 HAZEL POLLEN T15 WHITE ASH POLLEN T07 WHITE OAK POLLEN T09 OLIVE POLLEN T03 BIRCH POLLEN G12 RYE POLLEN G14 CULTIVATED OAT POLLEN G08 JUNE GRASS POLLEN G06 TIMOTHY GRASS POLLEN G15 CULTIVATED WHEAT POLLEN G03 COCKSFOOT POLLEN G02 BERMUDA GRASS POLLEN W09 PLANTAIN POLLEN W10 GOOSEFOOT POLLEN W21 WALL PELLITORY POLLEN

	W01 RAGWEED POLLEN W06 MUGWORT POLLEN E01 CAT EPITHELIA E02/E05 DOG EPITHELIA E03 HORSE EPITHELIA M06 ALTERNARIA ALTERNATA M03 ASPERGILLUS FUMIGATUS M05 CANDIDA ALBICANS D201 BLOMIA TROPICALIS D01 D. PTERONYSSINUS D02 D. FARINAE K82 LATEX I06 COCKROACH (BLATELLA GERMANICA) K202 CCD9,ALLERGY DIAGNOSTICS: MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (INHALATION 30-II) FOR SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF ALLERGEN-SPECIFIC IGE IN SERUM(POLYCHECK)-THE POLYCHECK® , INHALATION 30-II , SCANNER BASED ENZYME IMMUNOASSAY (EIA) SCREENING IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGE IN SERUM, THE RELEVANT ALLERGENS ARE COATED SEPARATELY IN LINES AS WELL AS THE CALIBRATORS ON A CARRIER WHICH IS FIXED IN THE WELL OF THE POLYCHECK® FOR; T01/T11 BOX ELDER/LONDON PLANE MIX T14 COTTONWOOD POLLEN T02 ALDER POLLEN T208 LIMETREE POLLEN T231 JUNIPER POLLEN T03 BIRCH POLLEN T04 HAZEL POLLEN T05 BEECH POLLEN T15 WHITE ASH POLLEN G06 TIMOTHY GRASS POLLEN GX7 6 GRASS MIX 1 W01/W03 RAGWEED/GIANT RAGWEED POLLEN W204 SUNFLOWER POLLEN W206 CAMOMILE POLLEN W21 WALL PELLITORY POLLEN W06 MUGWORT POLLEN W07 OXEYE DAISY POLLEN E01/E02/E05 CAT/DOG EPITHELIA MIX E03/E04 HORSE/COW EPITHELIA MIX EX10 RODENT EPITHELIA MIX 16 M02/M06 C. HERBARUM / A. ALTERNATA MIX M01/M03 P. NOTATUM / A. FUMIGATUS MIX D01 D. PTERONYSSINUS D02 D. FARINAE D70 ACARUS SIRO K82 LATEX I01 BEE VENOM I03 WASP VENOM I06 COCKROACH (BLATELLA GERMANICA) K202 CCD 9,ALLERGY DIAGNOSTICS: MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (IMF 10-1) FOR SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF ALLERGEN-SPECIFIC IGE IN SERUM(POLYCHECK)-THE POLYCHECK® , IMF-10-I , SCANNER BASED ENZYME IMMUNOASSAY (EIA) SCREENING IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGE IN SERUM, THE RELEVANT ALLERGENS ARE COATED SEPARATELY IN LINES AS WELL AS THE CALIBRATORS ON A CARRIER WHICH IS FIXED IN THE WELL OF THE POLYCHECK® FOR; CCD MITES BEE VENOM WASPVENOM HORNET VENOM MOSQUITO BLACK FRY CAGE BIRDS FEATHERS COCKROACH TOTAL IGE,AUTOIMMUNE DIAGNOSTICS MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (AI-STD-X) PANEL FOR AUTOIMMUNE SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF 18-ANTIGEN-SPECIFIC IGG OR IGA IN SERUM(POLYCHECK)-POLYCHECK® [AI-STD-X] PANEL AUTOIMMUNE SCREENING ASSAY IS AN ENZYME IMMUNOASSAY (EIA) FOR THE QUANTITATIVE MEASUREMENT OF ANTIGEN-SPECIFIC IGG OR IGA IN SERUM FOR; FOR SINGLE USE IN LABORATORY ONLY.

	01 RO/SS-A 52 02 LA/SS-B 03 CENP-B 04 SCL-70 05 DSDNA 06 JO-1 07 MPO 08 PR3 09 AMA M2 10 LC 1 11 LKM1 12 PM/SCL-100 13 SRP 54 14 SP 100 15 GP 210 16 KU 17 SM 18 U1-SNRNP,ALLERGY DIAGNOSTICS: MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (ECZEMA 10-I) FOR SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF ALLERGEN-SPECIFIC IGE IN SERUM(POLYCHECK)-THE POLYCHECK® , ECZEMA-10-I , SCANNER BASED ENZYME IMMUNOASSAY (EIA) SCREENING IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGE IN SERUM, THE RELEVANT ALLERGENS ARE COATED SEPARATELY IN LINES AS WELL AS THE CALIBRATORS ON A CARRIER WHICH IS FIXED IN THE WELL OF THE POLYCHECK® FOR; K202CCD D01D. PTERONYSSINUS E01 CAT EPITHELIA E02/E05 DOG EPITHELIA K82 LATEX F01 EGG WHITE F03 CODFISH F14 SOYBEAN F93 CACAO (CHOCOLATE) F17 HAZELNUT F13 PEANUT,AUTOIMMUNE DIAGNOSTICS : MULTIPARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (MYOSITIS) PANEL FOR AUTOIMMUNE SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF 10-ANTIGEN-SPECIFIC IGG OR IGA IN SERUM(POLYCHECK)-POLYCHECK® [MYOSITIS] AUTOIMMUNE SCREENING ASSAY IS AN ENZYME IMMUNOASSAY (EIA) FOR THE QUANTITATIVE MEASUREMENT OF ANTIGEN-SPECIFIC IGG OR IGA IN SERUM, FOR SINGLE USE, FOR LABORATORY USE FOR; 1.MI-2 2,PM/SCL-100 3.JO-1 4.SRP54 5.PL-7 6.PL-12 7.KU (P70/P80), AUTOIMMUNE DIAGNOSTICS : MULTIPARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (LIVER/KIDNEY) PANEL FOR AUTOIMMUNE SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF 3- ANTIGEN-SPECIFIC IGG OR IGA IN SERUM(POLYCHECK)-POLYCHECK® [LIVER/KIDNEY] AUTOIMMUNE SCREENING ASSAY IS AN ENZYME IMMUNOASSAY (EIA) FOR THE QUANTITATIVE MEASUREMENT OF ANTIGEN-SPECIFIC IGG OR IGA IN SERUM, FOR SINGLE USE, FOR LABORATORY USE FOR; 01AMA M2 02SP 100 03GP 210 04LKM 1 05LC 1 06CENP-B 07GBM 08PR3 09MPO 10SLA/LP,ALLERGY DIAGNOSTICS: MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (FOOD-30-II) FOR SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF ALLERGEN-SPECIFIC IGE IN SERUM FOOD 30-II(POLYCHECK)-THE POLYCHECK® , FOOD - 30-II , SCANNER BASED ENZYME IMMUNOASSAY SCREENING IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGE IN SERUM, THE RELEVANT ALLERGENS ARE COATED SEPARATELY IN LINES AS WELL AS THE CALIBRATORS ON A CARRIER WHICH IS FIXED IN THE WELL OF THE POLYCHECK® FOR; F02 COW'S MILK F76 ALPHA-LACTALBUMIN F77 BETA-LACTOGLOBULIN F78 CASEIN F01 EGG WHITE F75 EGG YOLK F114 SUNFLOWER SEED F14 SOYBEAN F17 HAZELNUT F13 PEANUT F12 PEA F260 TOFU F25 TOMATO F48 ONION FX69 HERB MIX 17 F281 CURRY FX4 FISH MIX 18 FX76 SEAFOOD MIX III

	19 F44 STRAWBERRY F92 BANANA F358 SOUR CHERRY F49 APPLE FX29 CITRUS MIX 3 F84 KIWI F259 GRAPES F95 PEACH F93 CACAO (CHOCOLATE) F07 OAT FLOUR F04 WHEAT FLOUR K202 CCD9, ALLERGY DIAGNOSTICS: MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (MILK PLUS GLUTEN 6) FOR SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF ALLERGEN-SPECIFIC IGE IN SERUM(POLYCHECK)-THE POLYCHECK® , MILK PLUS GLUTEN 6 , SCANNER BASED ENZYME IMMUNOASSAY SCREENING IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGE IN SERUM, THE RELEVANT ALLERGENS ARE COATED SEPARATELY IN LINES AS WELL AS THE CALIBRATORS ON A CARRIER WHICH IS FIXED IN THE WELL OF THE POLYCHECK® FOR; F02 COW'S MILK F76 ALPHA-LACTALBUMIN F77 BETA-LACTOGLOBULIN F78 CASEIN E204 BSA 20 F79 GLUTEN,AUTOIMMUNE DIAGNOSTICS : MULTIPARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (RHEUMA) PANEL FOR AUTOIMMUNE SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF 14 ANTIGEN-SPECIFIC IGG OR IGA IN SERUM(POLYCHECK)-POLYCHECK® [RHEUMA] AUTOIMMUNE SCREENING ASSAY IS AN ENZYME IMMUNOASSAY (EIA) FOR THE QUANTITATIVE MEASUREMENT OF ANTIGEN-SPECIFIC IGG OR IGA IN SERUM, FOR SINGLE USE, FOR LABORATORY USE FOR; 01RO/SS-A 52 02JO-1 03SM 04CENP-B 05LA/SS-B 06HISTONE 07PM/SCL 100 08RIB. PHOSPHOPR. PO 09DSDNA 10SCL-70 11U1-SNRNP 12RO/SS-A 60 13MI-2 14KU,ALLERGY DIAGNOSTICS: MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (PAEDIATRIC 30-I) FOR SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF ALLERGEN-SPECIFIC IGE IN SERUM(POLYCHECK)-THE POLYCHECK® , PAEDIATRIC- 30-I , SCANNER BASED ENZYME IMMUNOASSAY SCREENING IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGE IN SERUM, THE RELEVANT ALLERGENS ARE COATED SEPARATELY IN LINES AS WELL AS THE CALIBRATORS ON A CARRIER WHICH IS FIXED IN THE WELL OF THE POLYCHECK® FOR; GX7 6 GRASS MIX 1 T03 BIRCH POLLEN W06 MUGWORT POLLEN D01 D. PTERONYSSINUS D02 D. FARINAE E01 CAT EPITHELIA E02 DOG EPITHELIA E03 HORSE EPITHELIA M02 CLADOSPORIUM HERBARUM M03 ASPERGILLUS FUMIGATUS M06 ALTERNARIA ALTERNATA F01 EGG WHITE F75 EGG YOLK F02 COW'S MILK F76 ALPHA-LACTALBUMIN F77 BETA-LACTOGLOBULIN F78 CASEIN E204 BSA 20 F03 CODFISH FX10 FLOUR MIX 4 F09 RICE F14 SOYBEAN F13 PEANUT F17 HAZELNUT F31 CARROT F35 POTATO F49 APPLE F93 CACAO (CHOCOLATE) F83 CHICKEN MEAT K202 CCD9,ALLERGY DIAGNOSTICS: MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (PAEDIATRIC INDIA 30) FOR SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF ALLERGEN-SPECIFIC IGE IN

	SERUM(POLYCHECK)-THE POLYCHECK® , PAEDIATRIC INDIA 30 , SCANNER BASED ENZYME IMMUNOASSAY SCREENING IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGE IN SERUM, THE RELEVANT ALLERGENS ARE COATED SEPARATELY IN LINES AS WELL AS THE CALIBRATORS ON A CARRIER WHICH IS FIXED IN THE WELL OF THE POLYCHECK® FOR; F02 COW'S MILK F78 CASEIN F76 ALPHA-LACTALBUMIN F77 BETA-LACTOGLOBULIN GLUTEN BSA F01/ EGG WHITE F75/EGG YOLK F09 RICE F14 SOYBEAN F92 BANANA F83 CHICKEN D01/ D.PTERONYSSINUS D02 D FARINAE M02 CLADOSPORIUM HERBARUM M06ALTERNARIA ALTERNATA ASPERGILLUS FUMIGATUS T03 BIRCH POLLEN BERMUDA GRASS POLLEN MUGWORT POLLEN CAT EPITHELIA DOG EPITHELIA TUNA FISH HAZELNUT PEANUT CARROT POTATO APPLE CACAO CCD, AUTOIMMUNE DIAGNOSTICS: MULTIPARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (AI-STD) PANEL FOR AUTOIMMUNE SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF 14 ANTIGEN-SPECIFIC IGG OR IGA IN SERUM(POLYCHECK)-POLYCHECK® [AI-STD] AUTOIMMUNE SCREENING ASSAY IS AN ENZYME IMMUNOASSAY (EIA) FOR THE QUANTITATIVE MEASUREMENT OF ANTIGEN-SPECIFIC IGG OR IGA IN SERUM FOR, 01 RO/SS-A 60 02 LA/SS-B 03 SCL-70 04 PM/SCL 100 05 SM 06 PCNA 07 DSDNA 08 RIB. PHOSPHOPR. PO 09 CENP-B 10 AMA M2 11 PR3 12 MPO 13 TPO 14 THYROGLOBULIN (TG), ALLERGY DIAGNOSTICS: MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (EGG COMPONENTS) FOR SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF ALLERGEN-SPECIFIC IGE IN SERUM(POLYCHECK)-THE POLYCHECK® , (EGG COMPONENT) , SCANNER BASED ENZYME IMMUNOASSAY SCREENING IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGE IN SERUM, THE RELEVANT ALLERGENS ARE COATED SEPARATELY IN LINES AS WELL AS THE CALIBRATORS ON A CARRIER WHICH IS FIXED IN THE WELL OF THE POLYCHECK® FOR; F01 EGG WHITE F75 EGG YOLK F232 OVALBUMIN F233 OVOMUCOID F323 CONALBUMIN K208 LYSOZYME,ALLERGY DIAGNOSTICS: MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (FOOD 30 - I) FOR SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF ALLERGEN-SPECIFIC IGE IN SERUM(POLYCHECK)-THE POLYCHECK® , FOOD - 30-I , SCANNER BASED ENZYME IMMUNOASSAY SCREENING IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGE IN SERUM, THE RELEVANT ALLERGENS ARE COATED SEPARATELY IN LINES AS WELL AS THE CALIBRATORS ON A CARRIER WHICH IS FIXED IN THE WELL OF THE POLYCHECK® FOR; F25 TOMATO F96 AVOCADO F92 BANANA FX29 CITRUS MIX 3 F84 KIWI F13 PEANUT F17 HAZELNUT F12 PEA F14 SOYBEAN F85 CELERY F27 BEEF MEAT F83 CHICKEN MEAT F26 PORK MEAT F207 CLAM SHELL

	F24 SHRIMP F23 CRAB F40 TUNA, YELLOWFIN F03 CODFISH F47 GARLIC F48 ONION F45 BAKER'S YEAST F10 SESAME F09 RICE F08 CORN F04 WHEAT FLOUR F76 ALPHA-LACTALBUMIN F77 BETA-LACTOGLOBULIN F78 CASEIN F01 EGG WHITE K202 CCD9, AUTOIMMUNE DIAGNOSTICS : MULTIPARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (CELIAC-DUAL) PANEL FOR AUTOIMMUNE SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF 3-ANTIGEN-SPECIFIC IGG OR IGA IN SERUM(POLYCHECK)-POLYCHECK® [CELIAC-DUAL] AUTOIMMUNE SCREENING ASSAY IS AN ENZYME IMMUNOASSAY (EIA) FOR THE QUANTITATIVE MEASUREMENT OF ANTIGEN-SPECIFIC IGG OR IGA IN SERUM, FOR SINGLE USE, FOR LABORATORY USE FOR; 01 DEAM. GLIADIN IGA 02TTG IGA 03TOTAL IGA,ALLERGY DIAGNOSTICS: MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (DRUGS 10) FOR SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF ALLERGEN-SPECIFIC IGE IN SERUM(POLYCHECK)-THE POLYCHECK® , (DRUGS 10) , SCANNER BASED ENZYME IMMUNOASSAY SCREENING IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGE IN SERUM, THE RELEVANT ALLERGENS ARE COATED SEPARATELY IN LINES AS WELL AS THE CALIBRATORS ON A CARRIER WHICH IS FIXED IN THE WELL OF THE POLYCHECK® FOR; C01 PENICILLIN G C02 PENICILLIN V C05 AMPICILLIN C06 AMOXYCILLIN C223 SULFAMETHOXAZOL C201 CEPHALOSPORIN C436 OFLOXACIN C07 CEFACLOR C103 TETRACYCLIN C212 ERYTHROMYCIN,ALLERGY DIAGNOSTICS: MULTI-PARAMETER TECHNOLOGY, ENZYME IMMUNOASSAY (ATOPIC 30-I) FOR SCREENING ASSAY (QUANTITATIVE MEASUREMENT) OF ALLERGEN-SPECIFIC IGE IN SERUM ATOPIC 30 - I(POLYCHECK)-THE POLYCHECK® , ATOPIC-30-I , SCANNER BASED ENZYME IMMUNOASSAY SCREENING IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALLERGEN-SPECIFIC IGE IN SERUM, THE RELEVANT ALLERGENS ARE COATED SEPARATELY IN LINES AS WELL AS THE CALIBRATORS ON A CARRIER WHICH IS FIXED IN THE WELL OF THE POLYCHECK® FOR; F02 COW'S MILK F76 ALPHA-LACTALBUMIN F77 BETA-LACTOGLOBULIN F78 CASEIN F01 EGG WHITE F75 EGG YOLK F03 CODFISH F13 PEANUT F93 CACAO (CHOCOLATE) F14 SOYBEAN F49 APPLE F31 CARROT F25 TOMATO FX10 FLOUR MIX 4 F83 CHICKEN MEAT FX29 CITRUS MIX 3 F09 RICE GX7 6 GRASS MIX 1 G12 RYE POLLEN E02/E05 DOG EPITHELIA E01 CAT EPITHELIA M02 CLADOSPORIUM HERBARUM M06 ALTERNARIA ALTERNATA M03 ASPERGILLUS FUMIGATUS D01 D. PTERONYSSINUS D02 D. FARINAE T04 HAZEL POLLEN T03 BIRCH POLLEN W06 MUGWORT POLLEN K202 CCD9

1073	IMP/IVD/2021/000215	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREMIER BUFFER A REAGENT-THIS REAGENT IS INTENDED FOR USE WITH TRINITY BIOTECH PREMIER 9210TM ANALYZER ONLY. THE PREMIER HB9210TM SYSTEM IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HAEMOGLOBIN A1C (HBA1C) IN HUMAN CAPILLARY AND VENOUS WHOLE BLOOD. HBA1C IS USED FOR THE MONITORING OF LONG TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS.,PREMIER WASH REAGENT-THE PREMIER WASH REAGENT IS INTENDED FOR USE WITH TRINITY BIOTECH PREMIER 9210TM ANALYZER ONLY. THE PREMIER HB9210TM SYSTEM IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HAEMOGLOBIN A1C (HBA1C) IN HUMAN CAPILLARY AND VENOUS WHOLE BLOOD. HBA1C IS USED FOR THE MONITORING OF LONG TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS, HBA1C (GHB) CONTROL KIT-HBA1C (GHB) CONTROLS ARE INTENDED TO MONITOR THE PERFORMANCE OF GLYCATED HAEMOGLOBIN ASSAYS.,PREMIER DILUENT REAGENT-THE PREMIER DILUENT REAGENT IS INTENDED FOR USE WITH TRINITY BIOTECH PREMIER 9210TM ANALYZER ONLY. THE PREMIER HB9210TM SYSTEM IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HAEMOGLOBIN A1C (HBA1C) IN HUMAN CAPILLARY AND VENOUS WHOLE BLOOD. HBA1C IS USED FOR THE MONITORING OF LONG TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS, PREMIER AFFINITY A1C-THE PREMIER AFFINITY A1C SET IS INTENDED FOR USE WITH TRINITY BIOTECH PREMIER 9210TM ANALYZER ONLY. THE PREMIER AFFINITY A1C IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HAEMOGLOBIN A1C (HBA1C) IN HUMAN CAPILLARY AND VENOUS WHOLE BLOOD.,PREMIER BUFFER B REAGENT-THIS REAGENT IS INTENDED FOR USE WITH TRINITY BIOTECH PREMIER 9210TM ANALYZER ONLY. THE PREMIER HB9210TM SYSTEM IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HAEMOGLOBIN A1C (HBA1C) IN HUMAN CAPILLARY AND VENOUS WHOLE BLOOD. HBA1C IS USED FOR THE MONITORING OF LONG TERM GLYCEMIC CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS.,HBA1C (GHB) CALIBRATOR KIT-HBA1C (GHB) CALIBRATORS ARE INTENDED TO MONITOR THE PERFORMANCE OF GLYCATED HAEMOGLOBIN ASSAYS. CALIBRATORS ARE FOR THE CALIBRATION OF QUANTITATIVE HBA1C AFFINITY ASSAY SYSTEMS.

1074	IMP/IVD/2021/000216	1.License Holder Name: BIOMERIEUX INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COLOR GRAM 2(COLOR GRAM 2)-STAINING OF MICROORGANISMS.,PREVI COLOR GRAM IODINE SOLUTION-RB(PREVI COLOR GRAM IODINE SOLUTION-RB)-USED WITH THE PREVI® COLOR GRAM INSTRUMENT TO STAIN BACTERIAL AND FUNGAL MICROORGANISMS FOR DIRECT EXAMINATION, ACCORDING TO GRAM'S METHOD.,PREVI COLOR GRAM CRYSTAL VIOLET SOLUTION-RC(PREVI COLOR GRAM CRYSTAL VIOLET SOLUTION-RC)-USED WITH THE PREVI® COLOR GRAM INSTRUMENT TO STAIN BACTERIAL AND FUNGAL MICROORGANISMS FOR DIRECT EXAMINATION, ACCORDING TO GRAM'S METHOD.,PREVI COLOR GRAM ACETONE SAFRANIN SOLUTION-RA1(PREVI COLOR GRAM ACETONE SAFRANIN SOLUTION-RA1)-USED WITH THE PREVI® COLOR GRAM INSTRUMENT TO STAIN BACTERIAL AND FUNGAL MICROORGANISMS FOR DIRECT EXAMINATION, ACCORDING TO GRAM'S METHOD.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1075	IMP/IVD/2021/000217	1.License Holder Name: FUGEN BIOMED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMATOLOGY CALIBRATOR(CBC-CAL PLUS)-CBC-CAL PLUS IS AN INDEPENDENT CALIBRATOR MATERIAL FOR CALIBRATION OF HEMATOLOGY ANALYZERS. ,HEMATOLOGY QUALITY CONTROL(CBC-5DMR)-CBC-5DMR IS AN INDEPENDENT QUALITY CONTROL (QC) MATERIAL TO MONITOR VALUES ON FIVE PART DIFF MULTI PARAMETER HEMATOLOGY ANALYZERS. ,HEMATOLOGY QUALITY CONTROL(CBC-3D)-CBC-3D IS AN INDEPENDENT QUALITY CONTROL (QC) MATERIAL TO MONITOR VALUES ON THREE PART DIFF MULTI PARAMETER HEMATOLOGY ANALYZERS. ,HEMATOLOGY QUALITY CONTROL(CBC-ST PLUS)-CBC-ST PLUS IS AN INDEPENDENT QUALITY CONTROL (QC) MATERIAL TO MONITOR VALUES ON THREE PART DIFF MULTI PARAMETER HEMATOLOGY ANALYZERS. ,HEMATOLOGY QUALITY CONTROL(CBC-SYS)-CBC-SYS IS AN INDEPENDENT QUALITY CONTROL (QC) MATERIAL TO MONITOR VALUES ON FIVE PART DIFF MULTI PARAMETER HEMATOLOGY ANALYZERS. ,HEMATOLOGY QUALITY CONTROL(CBC-X)-CBC-X IS AN INDEPENDENT QUALITY CONTROL (QC) MATERIAL TO MONITOR VALUES ON FIVE PART DIFF MULTI PARAMETER HEMATOLOGY ANALYZERS. ,HEMATOLOGY QUALITY CONTROL(CBC-3K)-CBC-3K IS AN INDEPENDENT QUALITY CONTROL (QC) MATERIAL TO MONITOR VALUES ON FIVE PART DIFF MULTI PARAMETER HEMATOLOGY ANALYZERS. ,HEMATOLOGY QUALITY CONTROL(SEDRITE PLUS)-SEDRITE PLUS IS AN INDEPENDENT QUALITY CONTROL (QC) MATERIAL TO MONITOR ERYTHROCYTES SEDIMENTATION RATE (ESR) VALUES OBTAINED FROM MANUAL METHOD AND AUTOMATED ESR ANALYZERS. , HEMATOLOGY QUALITY CONTROL(CBC-DH)-CBC-DH IS AN INDEPENDENT QUALITY CONTROL (QC) MATERIAL TO MONITOR VALUES ON FIVE PART DIFF MULTI PARAMETER HEMATOLOGY ANALYZERS. ,HEMATOLOGY QUALITY CONTROL(CBC-TECH)-CBC-TECH IS AN INDEPENDENT QUALITY CONTROL (QC) MATERIAL TO MONITOR VALUES ON FIVE PART DIFF MULTI PARAMETER HEMATOLOGY ANALYZERS. ,HEMATOLOGY QUALITY CONTROL(CBC-5D)-CBC-5D IS AN INDEPENDENT QUALITY CONTROL (QC) MATERIAL TO MONITOR VALUES ON FIVE PART DIFF MULTI PARAMETER HEMATOLOGY ANALYZERS. ,HEMATOLOGY QUALITY CONTROL (ADVIA RETIC PLUS)-ADVIA RETIC PLUS IS AN INDEPENDENT QUALITY CONTROL (QC) MATERIAL TO MONITOR VALUES OBTAINED USING AUTOMATED RETICULOCYTES COUNTING HEMATOLOGY ANALYZERS

1076	IMP/IVD/2021/000220	1.License Holder Name: M/S AGAPPE DIAGNOSTICS LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ISE CLEANER(ISE CIEANER)-THIS IS A CLEANER TO BE USED TO WASH THE ION SELECTIVE ELECTRODE ATTACHED TO AN AUTOMATED BIOCHEMICAL ANALYZER,ISE CALIBRATOR S (FOR SERUM)(ISE CALIBRATOR S)-THIS IS A CALIBRATOR TO BE USED TO CALCULATE THE CALIBRATION CURVE IN THE MEASUREMENT OF SERUM ELECTROLYTE CONCENTRATIONS (NA ,,K+,CL) USING THE ION SELECTIVE ELECTRODE ATTACHED TO AN AUTOMATED BIOCHEMICAL ANALYZERS.,ISE BUFFER(ION CHARGE)-THIS PRODUCT IS A BUFFER THAT HAS BEEN DEVELOPED FOR THE ION SELECTIVE ELECTRODE ATTACHED TO AN AUTOMATED BIOCHEMICAL ANALYZER,ISE CALIBRATOR U (FOR URINE)(ISE CALIBRATOR U)-THIS IS A CALIBRATOR TO BE USED TO CALCULATE THE CALIBRATION CURVE IN THE MEASUREMENT OF URINE ELECTROLYTE CONCENTRATIONS (NA+,K+,C) USING THE ION SELECTIVE ELECTRODE ATTACHED TO AN AUTOMATED BIOCHEMICAL ANALYZER,ISE REFERENCE SOLUTION(ION CALIPER)-THIS PRODUCT IS REFERENCE SOLUTION THAT HAS BEEN DEVELOPED FOR THE ION SELECTIVE ELECTRODE ATTACHED TO AN AUTOMATED BIOCHEMICAL ANALYZER

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1077	IMP/IVD/2021/000221	1.License Holder Name: BIO STATE INC. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CANDIDA MANNAN IGG ANTIBODY DETECTION K-SET (LATERAL FLOW ASSAY)(CANDIDA MANNAN IGG ANTIBODY DETECTION K-SET (LATERAL FLOW ASSAY))-THE PRODUCT IS USED FOR IN VITRO QUALITATIVE DETECTION OF THE CANDIDA MANNAN IGG ANTIBODY IN SERUM. WITH THE WIDE APPLICATION OF ANTIBIOTICS, IMMUNOSUPPRESSANTS AND CORTICOSTEROIDS IN CLINICAL PRACTICE, THE INCIDENCE OF DEEP FUNGAL INFECTION IS INCREASING YEAR BY YEAR. CANDIDA IS THE MOST COMMON CONDITIONAL PATHOGEN IN INVASIVE FUNGAL INFECTIONS. MANNAN, THE MAIN COMPONENT OF CANDIDA CELL WALL, WHICH HAS GOOD IMMUNOGENICITY AND WILL BE RELEASED INTO THE BLOOD DURING CANDIDA INFECTION. MANNAN IS CURRENTLY RECOGNIZED AS ONE OF THE MAIN BIOMARKERS FOR THE DIAGNOSIS OF INVASIVE CANDIDA INFECTION. DURING SYSTEMIC FUNGAL INFECTION, MANNAN AND ITS METABOLIC COMPONENTS PERSIST IN THE BODY FLUIDS OF THE HOST, WHICH STIMULATES THE HUMORAL IMMUNE RESPONSE OF THE HOST AND PRODUCES SPECIFIC ANTIBODIES AGAINST MANNAN. SYSTEMIC FUNGAL INFECTION LACKS SPECIFIC CLINICAL SYMPTOMS AND EARLY RAPID DETECTION METHOD. THIS PRODUCT USES COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY TECHNOLOGY TO DETECT MANNAN-SPECIFIC IGG ANTIBODY IN HUMAN SERUM, PROVIDING A RAPID AND EFFECTIVE AUXILIARY METHOD FOR THE DIAGNOSIS OF SUSCEPTIBLE POPULATION.,CRYPTOCOCCAL CAPSULAR POLYSACCHARIDE DETECTION KIT (CLIA)(FUNGIXPERT CRYPTOCOCCAL CAPSULAR POLYACCHARIDE DETECTION KIT (CLIA))-THE PRODUCT IS USED FOR THE QUANTITATIVE DETECTION OF THE CRYPTOCOCCAL CAPSULAR POLYSACCHARIDE IN SERUM AND CEREBROSPINAL FLUID (CSF), THE ASSAY CAN AID IN THE DIAGNOSIS OF CRYPTOCOCCOSIS IN CLINICAL.,CANDIDA MANNAN IGM ANTIBODY DETECTION K-SET (LATERAL FLOW ASSAY)(CANDIDA MANNAN IGM ANTIBODY DETECTION K-SET (LATERAL FLOW ASSAY))-THE PRODUCT IS USED FOR IN VITRO QUALITATIVE DETECTION OF THE CANDIDA MANNAN IGM ANTIBODY IN SERUM. WITH THE WIDE APPLICATION OF ANTIBIOTICS, IMMUNOSUPPRESSANTS AND CORTICOSTEROIDS IN CLINICAL PRACTICE, THE INCIDENCE OF DEEP FUNGAL INFECTION IS INCREASING YEAR BY YEAR. CANDIDA IS THE MOST COMMON CONDITIONAL PATHOGEN IN INVASIVE FUNGAL INFECTIONS. MANNAN, THE MAIN COMPONENT OF CANDIDA CELL WALL, WHICH HAS GOOD IMMUNOGENICITY AND WILL BE RELEASED INTO THE BLOOD DURING CANDIDA INFECTION. MANNAN IS CURRENTLY RECOGNIZED AS ONE OF THE MAIN BIOMARKERS FOR

	THE DIAGNOSIS OF INVASIVE CANDIDA INFECTION. DURING SYSTEMIC FUNGAL INFECTION, MANNAN AND ITS METABOLIC COMPONENTS PERSIST IN THE BODY FLUIDS OF THE HOST, WHICH STIMULATES THE HUMORAL IMMUNE RESPONSE OF THE HOST AND PRODUCES SPECIFIC ANTIBODIES AGAINST MANNAN. SYSTEMIC FUNGAL INFECTION LACKS SPECIFIC CLINICAL SYMPTOMS AND EARLY RAPID DETECTION METHOD. THIS PRODUCT USES COLLOIDAL GOLD IMMUNOCHROMATOGRAPHY TECHNOLOGY TO DETECT MANNAN-SPECIFIC IGM ANTIBODY IN HUMAN SERUM, PROVIDING A RAPID AND EFFECTIVE AUXILIARY METHOD FOR THE DIAGNOSIS OF SUSCEPTIBLE POPULATION,ASPERGILLUS IGG ANTIBODY DETECTION K-SET (LATERAL FLOW ASSAY)(FUNGIXPERT® ASPERGILLUS IGG ANTIBODY DETECTION K-SET (LATERAL FLOW ASSAY))-THE PRODUCT IS USED FOR THE QUALITATIVE DETECTION OF THE ASPERGILLUS IGG ANTIBODY IN SERUM. THE PRODUCT IS MAINLY USED FOR THE AUXILIARY DIAGNOSIS OF SYSTEMIC FUNGAL INFECTION,CANDIDA MANNAN DETECTION K-SET (LATERAL FLOW ASSAY)(FUNGIXPERT® CANDIDA MANNAN DETECTION K-SET (LATERAL FLOW ASSAY))-IT IS USED FOR THE DETECTION OF CANDIDA MANNAN IN HUMAN SERUM AND BRONCHOALVEOLAR LAVAGE (BAL) FLUID AND IS USED TO ASSIST THE CLINICAL DIAGNOSIS OF CANDIDA INFECTION.,ASPERGILLUS GALACTOMANNAN DETECTION KIT (CLIA) (FUNGIXPERTASPERGILLUS GALACTOMANNAN DETECTION KIT (CLIA))-THE PRODUCT IS USED FOR THE QUANTITATIVE DETECTION OF THE ASPERGILLUS GALACTOMANNAN ANTIGEN IN SERUM AND BRONCHOALVEOLAR LAVAGE (BAL) FLUID.,ASPERGILLUS IGM ANTIBODY DETECTION K-SET (LATERAL FLOW ASSAY)(FUNGIXPERT ® ASPERGILLUS IGM ANTIBODY DETECTION K-SET (LATERAL FLOW ASSAY))-THE PRODUCT IS USED FOR THE QUALITATIVE DETECTION OF THE ASPERGILLUS IGM ANTIBODY IN SERUM. THE PRODUCT IS MAINLY USED FOR THE AUXILIARY DIAGNOSIS OF SYSTEMIC FUNGAL INFECTION.,ASPERGILLUS IGG ANTIBODY DETECTION KIT (CLIA) (FUNGIXPERT ASPERGILLUS IGG ANTIBODY DETECTION KIT (CLIA))-THE PRODUCT IS USED FOR THE QUALITATIVE DETECTION OF THE ASPERGILLUS IGG ANTIBODY IN SERUM.,ASPERGILLUS GALACTOMANNAN ELISA DETECTION KIT(FUNGIXPERT ASPERGILLUS GALACTOMANNAN ELISA DETECTION KIT)-THE FUNGIXPERT® ASPERGILLUS GALACTOMANNAN ELISA DETECTION KIT IS AN IMMUNOENZYMATIC SANDWICH MICROPLATE ASSAY FOR THE QUALITATIVE DETECTION OF ASPERGILLUS GALACTOMANNAN ANTIGEN IN ADULT AND PEDIATRIC SERUM SAMPLES AND BRONCHOALVEOLAR LAVAGE (BAL) FLUID SAMPLES OF PATIENTS WITH SYMPTOMS OF, OR MEDICAL CONDITIONS PREDISPOSING THE

	PATIENT TO, INVASIVE ASPERGILLUS INFECTION IN CLINICAL LABORATORIES.,FUNGUS (1-3)-BETA-D-GLUCAN DETECTION KIT (CHROMOGENIC METHOD)(FUNGIXPERT® FUNGUS (1-3)-BETA-D-GLUCAN DETECTION KIT (CHROMOGENIC METHOD))-BE USED TO PROVIDE RAPID DIAGNOSIS REFERENCE FOR CLINICAL INVASIVE FUNGAL INFECTION THROUGH QUANTITATIVE DETECTION OF (1-3)-BETA-D-GLUCAN IN THE SERUM AND BRONCHOALVEOLAR LAVAGE (BAL) FLUID. THE KIT SHOULD BE USED IN CONJUNCTION WITH OTHER DIAGNOSTIC PROCEDURES, SUCH AS MICROBIOLOGICAL CULTURE, HISTOLOGICAL EXAMINATION OF BIOPSY SAMPLES AND RADIOLOGICAL EXAMINATION.,ASPERGILLUS GALACTOMANNAN DETECTION K-SET (LATERAL FLOW ASSAY)(FUNGIXPERT ASPERGILLUS GALACTOMANNAN DETECTION K-SET (LATERAL FLOW ASSAY))-THE PRODUCT IS USED FOR THE QUALITATIVE DETECTION OF THE ASPERGILLUS GALACTOMANNAN ANTIGEN IN SERUM AND BRONCHOALVEOLAR LAVAGE (BAL) FLUID.,CRYPTOCOCCAL CAPSULAR POLYSACCHARIDE DETECTION K-SET (LATERAL FLOW ASSAY)(FUNGIXPERT® CRYPTOCOCCAL CAPSULAR POLYSACCHARIDE DETECTION K-SET (LATERAL FLOW ASSAY))-THE PRODUCT IS AN IMMUNOCHROMATOGRAPHIC TEST SYSTEM FOR THE QUALITATIVE, SEMI-QUANTITATIVE AND QUANTITATIVE (EQUIPPED WITH IMMUNOCHROMATOGRAPHY ANALYZER) DETECTION OF THE CAPSULAR POLYSACCHARIDE ANTIGENS OF CRYPTOCOCCUS SPECIES COMPLEX (CRYPTOCOCCUS NEOFORMANS AND CRYPTOCOCCUS GATTII) IN HUMAN SERUM AND CEREBRAL SPINAL FLUID (CSF), THE ASSAY IS A PRESCRIPTION-USE LABORATORY ASSAY WHICH CAN AID IN THE DIAGNOSIS OF CRYPTOCOCCOSIS., CANDIDA IGM ANTIBODY DETECTION KIT (CLIA)(FUNGIXPERT CANDIDA IGM ANTIBODY DETECTION KIT (CLIA))-THE PRODUCT IS USED FOR THE QUALITATIVE DETECTION OF THE CANDIDA MANNAN IGM ANTIBODY IN SERUM.,ASPERGILLUS IGM ANTIBODY DETECTION KIT (CLIA)(FUNGIXPERT ASPERGILLUS IGM ANTIBODY DETECTION KIT (CLIA))-THE PRODUCT IS USED FOR THE QUALITATIVE DETECTION OF THE ASPERGILLUS IGM ANTIBODY IN SERUM.,CANDIDA IGG ANTIBODY DETECTION KIT (CLIA)(FUNGIXPERT CANDIDA IGG ANTIBODY DETECTION KIT (CLIA))-THE PRODUCT IS USED FOR THE QUALITATIVE DETECTION OF THE CANDIDA MANNAN IGG ANTIBODY IN SERUM.,CANDIDA MANNAN DETECTION KIT (CLIA)(FUNGIXPERT CANDIDA MANNAN DETECTION KIT (CLIA))-THE PRODUCT IS USED FOR THE QUANTITATIVE DETECTION OF THE CANDIDA MANNAN ANTIGEN IN SERUM.

1078	IMP/IVD/2021/000222	1.License Holder Name: BIOHOUSE SOLUTIONS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MTBC DETECTION KIT (LOOPAMP)-THE LOOPAMP™ MTBC DETECTION KIT IS A QUALITATIVE IN VITRO DIAGNOSTIC TEST FOR THE DETECTION OF MYCOBACTERIUM TUBERCULOSIS COMPLEX (MTBC) DNA EXTRACTED FROM SPUTUM IN PATIENTS WITH ANY SYMPTOM INDICATIVE OF MTBC INFECTION. ,PURE DNA EXTRACTION KIT (LOOPAMP)-LOOPAMP PURE DNA EXTRACTION KIT PROVIDES A FAST AND SIMPLE METHOD FOR EXTRACTION AND PURIFICATION OF DNA FROM CLINICAL SAMPLES INCLUDING RAW OR NALC-NAOH TREATED SPUTUM. THE DNA SOLUTION OBTAINED USING THE LOOPAMP PURE DNA EXTRACTION KIT IS SUITABLE FOR LAMP-BASED AMPLIFICATION.
1079	IMP/IVD/2021/000224	1.License Holder Name: RAPID DIAGNOSTIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ERYTHROCYTE SEDIMENTATION RATE (ESR) QUALITY CONTROL(SEDITROL®)-SEDITROL® ESR QUALITY CONTROLS ARE INTENDED FOR USE AS A QC TOOL IN ORDER TO MONITOR THE PRECISION OF ESR LABORATORY TESTING PROCEDURES USING ESR ANALYZERS.
1080	IMP/IVD/2021/000227	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED HISARIA WAREHOUSE GROUND FLOOR 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RAP/TAC/CSA CONTROL LEVEL 1(RAP/TAC/CSA CONTROL LEVEL 1)-MORE DIAGNOSTICS' RAP/TAC/CSA CONTROL IS INTENDED TO BE USED AS A WHOLE BLOOD PRECISION CONTROL PRODUCT TO CHECK CALIBRATION IN CHEMISTRY ANALYZERS WHICH MEASURE RAPAMYCIN (SIROLIMUS), TACROLIMUS AND CYCLOSPORINE.,RAP/TAC/CSA CONTROL LEVEL 2 (RAP/TAC/CSA CONTROL LEVEL 2)-MORE DIAGNOSTICS' RAP/TAC/CSA CONTROL IS INTENDED TO BE USED AS A WHOLE BLOOD PRECISION CONTROL PRODUCT TO CHECK CALIBRATION IN CHEMISTRY ANALYZERS WHICH MEASURE RAPAMYCIN (SIROLIMUS), TACROLIMUS AND CYCLOSPORINE.,RAP/TAC/CSA CONTROL LEVEL 3 (RAP/TAC/CSA CONTROL LEVEL 3)-MORE DIAGNOSTICS' RAP/TAC/CSA CONTROL IS INTENDED TO BE USED AS A WHOLE BLOOD PRECISION CONTROL PRODUCT TO CHECK CALIBRATION IN CHEMISTRY ANALYZERS WHICH MEASURE RAPAMYCIN (SIROLIMUS), TACROLIMUS AND CYCLOSPORINE.

1081	IMP/IVD/2021/000228	1.License Holder Name: FUGEN BIOMED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URINALYSIS CONTROL (MEDI-TEST CONTROL)-MEDI-TEST CONTROL, SOLUTION TO CHECK MEDI-TEST URINE TEST STRIPS AND URYXXON INSTRUMENT. , URINALYSIS REAGENT STRIP FOR 10 PARAMETERS(MEDI-TEST COMBI 10 SGL)-IN VITRO TEST TO DETECT THE GLUCOSE, KETONES, DENSITY, PROTEIN, BLOOD, NITRITE, LEUKOCYTES, PH, BILIRUBIN AND UROBILINOGEN IN URINE. ,URINALYSIS REAGENT STRIP FOR 9 PARAMETERS(MEDI-TEST COMBI 9)-IN VITRO TEST TO DETECT THE GLUCOSE, KETONES, ASCORBIC ACID, PROTEIN, BLOOD, NITRITE, PH, BILIRUBIN AND UROBILINOGEN IN URINE. ,URINALYSIS REAGENT STRIP FOR 10 PARAMETERS(MEDI-TEST URYXXON STICK 10)-IN VITRO TEST TO DETECT THE GLUCOSE, KETONES, DENSITY, PROTEIN, BLOOD, NITRITE, LEUKOCYTES, PH, BILIRUBIN AND UROBILINOGEN IN URINE. ,URINALYSIS REAGENT STRIP FOR 2 PARAMETERS(MEDI-TEST MIKROALBUMIN)-IN VITRO TEST TO DETECT THE PROTEIN/ALBUMIN AND CREATININE IN URINE.,URINALYSIS REAGENT STRIP FOR 10 PARAMETERS(MEDI-TEST COMBI 10 SGL)-IN VITRO TEST TO DETECT THE GLUCOSE, KETONES, DENSITY, PROTEIN, BLOOD, NITRITE, LEUKOCYTES, PH, BILIRUBIN AND UROBILINOGEN IN URINE. , URINALYSIS REAGENT STRIP FOR 8 PARAMETERS(MEDI-TEST COMBI 8L)-IN VITRO TEST TO DETECT THE GLUCOSE, ASCORBIC ACID, PROTEIN, BLOOD LEUKOCYTES, NITRITE, PH AND DENSITY IN URINE.
1082	IMP/IVD/2021/000229	1.License Holder Name: RGB HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOGLOBIN TEST STRIP (DRY CHEMISTRY) (LYSUN)-THE HEMOGLOBIN TEST STRIPS (DRY CHEMISTRY) IS USED IN CONJUNCTION WITH HEMOGLOBIN ANALYSIS METER TO QUANTITATIVELY DETECT THE CONTENT OF HEMOGLOBIN (HB) IN HUMAN WHOLE BLOOD IN VITRO.

1083	IMP/IVD/2021/000232	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALPHA2-MACROGLOBULIN (MGTUR)-IN VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF ALPHA2-MACROGLOBULIN IN SAMPLES OF HUMAN ORIGIN BY IMMUNOTURBIDIMETRY ON PHOTOMETRIC SYSTEMS.,ALBUMIN (ALTUR)-IN VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN SAMPLES OF HUMAN ORIGIN BY IMMUNOTURBIDIMETRY ON PHOTOMETRIC SYSTEMS.,FIBRINOGEN CALIBRATOR (FIREM)-IN VITRO DIAGNOSTIC CALIBRATORS KIT TO BE USED WITH APPROPRIATE CONTROLS TO CALIBRATE PHOTOMETRIC SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF FIBRINOGEN.,BETA 2-MICROGLOBULIN MEDIUM CONTROL (B2CON)-IN VITRO DIAGNOSTIC ASSAYED CONTROL FOR BETA2-MICROGLOBULIN ASSAYS ON PHOTOMETRIC SYSTEMS.,BETA2-MICROGLOBULIN LOW CONTROL (B2COS)-IN VITRO DIAGNOSTIC ASSAYED LOW CONTROL FOR BETA2-MICROGLOBULIN ASSAYS ON PHOTOMETRIC SYSTEMS,FIBRINOGEN (FITUR)-IN VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF FIBRINOGEN IN SAMPLES OF HUMAN ORIGIN BY IMMUNOTURBIDIMETRY ON PHOTOMETRIC SYSTEMS,FIBRINOGEN CONTROL (FICON)-IN VITRO DIAGNOSTIC ASSAYED CONTROL FOR FIBRINOGEN ASSAYS ON PHOTOMETRIC SYSTEMS., MULTIPARAMETRIC LOW CONTROL (MPCOS)-IN VITRO DIAGNOSTIC ASSAYED MULTIPARAMETRIC LOW CONTROL FOR ALBUMIN, ALPHAL-ANTITRYPSIN, ALPHAL-ACID GLYCOPROTEIN, ALPHA2-MACROGLOBULIN, ANTITHROMBIN III, COMPLEMENT C3, COMPLEMENT C4,CERULOPLASMIN, HAPTOGLOBIN, LGA, LGG, LGM, PREALBUMIN AND TRANSFERRIN ASSAYS ON PHOTOMETRIC SYSTEMS,BETA2-MICROGLOBULIN HIGH CONTROL (B2COX)-IN VITRO DIAGNOSTIC ASSAYED HIGH CONTROL FOR BETA2-MICROGLOBULIN ASSAYS ON PHOTOMETRIC SYSTEMS,BETA2-MICROGOBULIN (B2DGX)-IN VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF BETA2-MICROGLOBULIN IN SAMPLES OF HUMAN ORIGIN BY IMMUNOTURBIDIMETRY ON PHOTOMETRIC SYSTEMS., CERULOPLASMIN (CETUR)-IN VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF CERULOPLASMIN IN SAMPLES OF HUMAN ORIGIN BY IMMUNOTURBIDIMETRY ON PHOTOMETRIC SYSTEMS.,ALPHA 1-GLYCOPROTEIN ACID (GPTUR)-IN VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF ALPHA1-GLYCOPROTEIN ACID IN SAMPLES OF HUMAN ORIGIN BY IMMUNOTURBIDIMETRY ON PHOTOMETRIC SYSTEMS., MULTIPARAMETRIC HIGH CONTROL (MPCOX)-IN VITRO DIAGNOSTIC

		ASSAYED MULTIPARAMETRIC HIGH CONTROL FOR ALBUMIN, ALPHAL-ANTITRYPSIN, ALPHAL-ACID GLYCOPROTEIN, ALPHA2-MACROGLOBULIN, ANTITHROMBIN ILL, COMPLEMENT C3, COMPLEMENT C4,CERULOPLASMIN, HAPTOGLOBIN, LGA, LGG, LGM, PREALBUMIN AND TRANSFERRIN ASSAYS ON PHOTOMETRIC SYSTEMS.,MULTIPARAMETRIC CALIBRATORS KIT (MPREK)-IN VITRO DIAGNOSTIC CALIBRATORS KIT TO BE USED WITH APPROPRIATE CONTROLS TO CALIBRATE PHOTOMETRIC SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF ALBUMIN, ALPHAL ANTITRYPSIN, ALPHA1-ACID GLYCOPROTEIN, ALPHA2- MACROGLOBULIN, ANTITHROMBIN ILL, COMPLEMENT C3, COMPLEMENT C4, CERULOPLASMIN, HAPTOGLOBIN, LGA, LGG, LGM, PREALBUMIN AND TRANSFERRIN.,ANTITHROMBIN III (A3TUR)-IN VITRO DIAGNOSTIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF ANTITHROMBIN III IN SAMPLES OF HUMAN ORIGIN BY IMMUNOTURBIDIMETRY ON PHOTOMETRIC SYSTEMS., MULTIPARAMETRIC CONTROL (MPCON)-IN VITRO DIAGNOSTIC ASSAYED MULTIPARAMETRIC CONTROL FOR ALBUMIN, ALPHAL-ANTITRYPSIN, ALPHAL-ACID GLYCOPROTEIN, ALPHA2-MACROGLOBULIN, ANTITHROMBIN III, COMPLEMENT C3, COMPLEMENT C4, CERULOPLASMIN, HAPTOGLOBIN, LGA, LGG, LGM, PREALBUMIN AND TRANSFERRIN ASSAYS ON PHOTOMETRIC SYSTEMS,BETA2-MICROGLOBULIN CALIBRATORS KIT (B2REK)-IN VITRO DIAGNOSTIC CALIBRATORS KIT TO BE USED WITH APPROPRIATE CONTROLS TO CALIBRATE PHOTOMETRIC SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF BETA2-MICROGLOBULIN.
1084	IMP/IVD/2021/000236	1.License Holder Name: KOPRAN LABORATORIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAT-NAT® COVID-19 HK (STAT-NAT® COVID-19 HK)-THE STAT-NAT® COVID-19 HK KIT IS A LYOPHILIZED REAL-TIME RT-PCR QUALITATIVE ASSAY BASED ON NUCLEIC ACID AMPLIFICATION FOR THE IDENTIFICATION OF THE NOVEL CORONAVIRUS SARS-COV-2 RNA IN HUMAN RESPIRATORY TRACT SPECIMENS1,2. THIS ASSAY IS AN AID IN THE DIAGNOSIS OF SARS-COV-2 INFECTION.

1085	IMP/IVD/2021/000237	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIAZYME D-DIMER CALIBRATOR SET-THE DIAZYME D-DIMER CALIBRATOR SET IS INTENDED FOR USE IN THE CALIBRATION OF THE D-DIMER ASSAY ONLY. FOR IN VITRO DIAGNOSTIC USE ONLY.,DIAZYME D- DIMER ASSAY-THE D-DIMER ASSAY IS FOR THE QUANTITATIVE DETERMINATION OF FIBRINOGEN/FIBRIN DEGRADATION PRODUCTS (D-DIMER) IN HUMAN PLASMA. MEASUREMENT OF D-DIMER IS USED AS AN AID IN DETECTING THE PRESENCE OF INTRAVASCULAR COAGULATION AND FIBRINOLYSIS. FOR IN VITRO DIAGNOSTIC USE ONLY.,DIAZYME D-DIMER CONTROL SET-THE DIAZYME D-DIMER CONTROL SET IS INTENDED FOR USE AS QUANTITATIVE QUALITY CONTROLS FOR THE DIAZYME D-DIMER ASSAY. FOR IN VITRO DIAGNOSTIC USE ONLY
1086	IMP/IVD/2021/000238	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 FLUORESCENT PCR-FOR IN VITRO QUALITATIVE DETECTION OF SARS-COV-2 (ALSO KNOWN AS 2019-NCOV) IN HUMAN OROPHARYNGEAL SWABS OR SPUTUM PECIMENS BY MULTIPLEX REAL-TIME REVERSE-TRANSCRIPTION PCR METHOD. IT IS MAINLY USED FOR SCREENING, DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS FOR SARS-COV-2 INFECTED CASES OR SUSPECTED CASES

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1087	IMP/IVD/2021/000239	1.License Holder Name: ARKRAY HEALTHCARE PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLUCOCARD VITAL TEST TRIPS (UNCUT SHEET)(GLUCOCARD VITAL TEST TRIPS (UNCUT SHEET))-GLUCOCARD VITAL TEST STRIPS ARE INTENDED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD SAMPLES DRAWN FROM THE FINGERTIPS OR PALM. GLUCOCARD VITAL TEST STRIPS MUST BE USED WITH THE GLUCOCARD VITAL BLOOD GLUCOSE METER. TESTING IS DONE OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE). THEY ARE INDICATED FOR USE AT HOME (OVER THE COUNTER [OTC]) BY PERSONS WITH DIABETES, OR IN CLINICAL SETTINGS BY HEALTHCARE PROFESSIONALS, AS AN AID TO MONITOR THE EFFECTIVENESS OF DIABETES CONTROL. IT IS NOT INTENDED FOR THE DIAGNOSIS OF OR SCREENING FOR DIABETES MELLITUS AND IS NOT INTENDED FOR NEONATES,GLUCOCARD G+ TEST STRIPS (UNCUT SHEET)(GLUCOCARD G+ TEST STRIPS (UNCUT SHEET))-GLUCOCARD G+ TEST STRIPS ARE FOR QUANTITATIVELY MEASURING THE GLUCOSE LEVEL IN FRESH CAPILLARY WHOLE BLOOD. THEY ARE INTENDED FOR USE OUTSIDE OF THE BODY (IN VITRO DIAGNOSTIC USE) AT HOME OR IN A CLINICAL SETTING AS AN AID TO MONITOR AND CONTROL BLOOD GLUCOSE LEVELS. ARE NOT USED TO DIAGNOSE DIABETES ALSO ALTER TREATMENT BASED ON THE TEST RESULTS OF THIS SYSTEM WITHOUT INSTRUCTIONS FROM YOUR DOCTOR OR HEALTHCARE PROFESSIONAL. THIS SYSTEM IS NOT INTENDED FOR NEONATES.,GLUCOCARD SIGMA TEST STRIPS (UNCUT SHEET)(GLUCOCARD SIGMA TEST STRIPS (UNCUT SHEET))-GLUCOCARD TEST STRIPS ARE FOR QUANTITATIVELY MEASURING THE GLUCOSE LEVEL IN FRESH CAPILLARY WHOLE BLOOD. THEY ARE INTENDED FOR USE OUTSIDE OF THE BODY (IN VITRO DIAGNOSTIC USE) AT HOME OR IN A CLINICAL SETTING AS AN AID TO MONITOR AND CONTROL BLOOD GLUCOSE LEVELS. DO NOT USE THEM TO DIAGNOSE DIABETES. ALSO, DO NOT ALTER TREATMENT BASED ON THE TEST RESULTS OF THIS SYSTEM WITHOUT INSTRUCTIONS FROM YOUR DOCTOR OR HEALTHCARE PROFESSIONAL. THIS SYSTEM IS NOT INTENDED FOR NEONATES.

1088	IMP/IVD/2021/000241	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAS® OMNI•IMMUNE™ LIQUID ASSAYED INTEGRATED IMMUNOASSAY CONTROL(MAS® OMNI•IMMUNE™ LIQUID ASSAYED INTEGRATED IMMUNOASSAY CONTROL)-THERMO SCIENTIFIC MAS® OMNI•IMMUNE™ IS INTENDED FOR USE AS AN ASSAYED CONTROL FOR MONITORING ASSAY CONDITIONS IN MANY CLINICAL LABORATORY DETERMINATIONS. INCLUDE OMNI•IMMUNE WITH PATIENT SERUM SPECIMENS WHEN ASSAYING FOR ANY OF THE LISTED CONSTITUENTS.,MAS® DIABETES LIQUID ASSAYED DIABETES CONTROL(MAS® DIABETES LIQUID ASSAYED DIABETES CONTROL)-MAS® DIABETES IS INTENDED FOR USE AS AN ASSAYED CONTROL MATERIAL FOR MONITORING GLYCOSYLATED HEMOGLOBIN (A1C) ASSAY PROCEDURES.,MAS® CARDIOIMMUNE® XL LIQUID ASSAYED CARDIAC MARKER CONTROL (MAS® CARDIOIMMUNE® XL LIQUID ASSAYED CARDIAC MARKER CONTROL)-MAS® CARDIOIMMUNE® · XL IS INTENDED FOR USE IN THE CLINICAL LABORATORY AS AN ASSAYED CONTROL SERUM FOR MONITORING ASSAY CONDITIONS IN SPECIFIC CARDIAC MARKER DETERMINATIONS.,MAS® CSF LIQUID ASSAYED CEREBROSPINAL FLUID CONTROL(MAS® CSF LIQUID ASSAYED CEREBROSPINAL FLUID CONTROL)-MAS® CSF IS INTENDED FOR USE IN THE CLINICAL LABORATORY AS A CONSISTENT TEST SAMPLE OF KNOWN CONCENTRATION FOR MONITORING ASSAY CONDITIONS IN MANY CEREBROSPINAL FLUID DETERMINATIONS. INCLUDE CSF WITH PATIENT CEREBROSPINAL FLUID SPECIMENS WHEN ASSAYING FOR ANY OF THE LISTED CONSTITUENTS.,MAS® OMNI• CORE™ LIQUID ASSAYED INTEGRATED CHEMISTRY CONTROL(MAS® OMNI• CORE™ LIQUID ASSAYED INTEGRATED CHEMISTRY CONTROL)-THERMO SCIENTIFIC MAS® OMNI•CORE™ IS INTENDED FOR USE AS AN ASSAYED CONTROL FOR MONITORING ASSAY CONDITIONS IN MANY CLINICAL LABORATORY DETERMINATIONS. INCLUDE OMNI•CORE WITH PATIENT SERUM SPECIMENS WHEN ASSAYING FOR ANY OF THE CONSTITUENTS.,MAS® ALCOHOL/ AMMONIA LIQUID ASSAYED ALCOHOL/AMMONIA CONTROL(MAS® ALCOHOL/ AMMONIA LIQUID ASSAYED ALCOHOL/AMMONIA CONTROL)-MAS® ALCOHOL/AMMONIA IS INTENDED FOR USE IN THE CLINICAL LABORATORY AS A QUANTITATIVE CONTROL FOR MONITORING TEST PROCEDURES USED TO ASSAY HUMAN SERUM AND/OR PLASMA SPECIMENS FOR ALCOHOL AND/OR AMMONIA. INCLUDE ALCOHOL/AMMONIA WITH PATIENT SERUM OR PLASMA SPECIMENS WHEN ASSAYING FOR ALCOHOL AND/OR AMMONIA,MAS® URICHEMTRAK LIQUID ASSAYED URINE CONTROL(MAS®

	URICHEMTRAK LIQUID ASSAYED URINE CONTROL)-MAS® URICHEMTRAK IS INTENDED FOR USE IN THE CLINICAL LABORATORY AS A CONSISTENT TEST SAMPLE OF KNOWN CONCENTRATION FOR MONITORING ASSAY CONDITIONS IN MANY URINE DETERMINATIONS. INCLUDE URICHEMTRAK WITH PATIENT URINE SPECIMENS WHEN ASSAYING FOR ANY OF THE LISTED CONSTITUENTS.

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1089	IMP/IVD/2021/000242	1.License Holder Name: SINDURI BIOTEC 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIGH SENSITIVE C-REACTIVE PROTEIN DETECTION KIT (NEPHELOMETRY)(HIGH SENSITIVE C-REACTIVE PROTEIN DETECTION KIT (NEPHELOMETRY))-FOR IN VITRO QUANTITATIVE DETERMINATION OF HIGH SENSITIVE C-REACTIVE PROTEIN (HS-CRP) CONTENT IN HUMAN SERUM OR WHOLE BLOOD.,HUMAN MICRO-ALBUMINURIA DETECTION KIT (NEPHELOMETRY)(HUMAN MICRO-ALBUMINURIA DETECTION KIT (NEPHELOMETRY))-FOR IN VITRO QUANTITATIVE DETERMINATION OF MICRO-ALBUMINURIA (MALB) IN HUMAN URINE.,KT03/KT03A DILUENT(KT03/KT03A DILUENT)-THIS PRODUCT IS USED FOR DILUTION OF BLOOD SAMPLES AND PREPARATION OF CELL SUSPENSIONS PRIOR TO CELL ANALYSIS.,IMMUNOGLOBULIN M (IGM) DETECTION KIT (NEPHELOMETRY)(IMMUNOGLOBULIN M (IGM) DETECTION KIT (NEPHELOMETRY))-FOR IN VITRO QUANTITATIVE DETERMINATION OF IGM CONTENT IN HUMAN SERUM OR PLASMA.,D-DIMER DETECTION KIT (NEPHELOMETRY)(D-DIMER DETECTION KIT (NEPHELOMETRY))-FOR IN VITRO QUANTITATIVE DETERMINATION OF D-DIMER CONTENT IN HUMAN PLASMA.,PROBE CLEANSER(PROBE CLEANSER)-THIS PRODUCT IS A HIGHLY EFFICIENT OXIDANT AND DISINFECTANT. RESIDUE AND BACTERIA CAN BE QUICKLY REMOVED FROM THE DETECTION SYSTEM,PVC ELECTRODE ACTIVATING SOLUTION(PVC ELECTRODE ACTIVATING SOLUTION)-USED FOR NEW ELECTRODE ACTIVATION,GLYCATED HEMOGLOBIN (HBA1C) DETECTION KIT (NEPHELOMETRY)(GLYCATED HEMOGLOBIN (HBA1C) DETECTION KIT (NEPHELOMETRY))-FOR IN VITRO QUANTITATIVE DETERMINATION OF THE PERCENTAGE CONTENT OF GLYCATED HEMOGLOBIN IN HUMAN BLOOD.,KT03/KT03A LYSE SOLUTION (KT03/KT03A LYSE SOLUTION)-DISSOLVING RED BLOOD CELLS TO RELEASE HEMOGLOBIN, MAINTAINING THE CELL STRUCTURE TO BE ANALYZED, FOR THE PURPOSE OF CELL COUNT AND QUANTITATIVE DETERMINATION OF HEMOGLOBIN.,RHEUMATOID FACTOR DETECTION KIT (NEPHELOMETRY)(RHEUMATOID FACTOR DETECTION KIT (NEPHELOMETRY))-FOR IN VITRO QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) CONTENT IN HUMAN SERUM OR PLASMA.,FIBRINOGEN DEGRADATION PRODUCT (FDP) DETECTION KIT (NEPHELOMETRY)(FIBRINOGEN DEGRADATION PRODUCT (FDP) DETECTION KIT (NEPHELOMETRY))-THE KIT IS USED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FDP IN HUMAN SERUM.,COMPLEMENT C4 (C4) DETECTION KIT (NEPHELOMETRY) (COMPLEMENT C4 (C4) DETECTION KIT (NEPHELOMETRY))-FOR IN VITRO QUANTITATIVE DETERMINATION OF COMPLEMENT C 4 (C4) CONTENT IN HUMAN SERUM OR PLASMA.,PROCALCITONIN (PCT)

	TEST KIT (IMMUNOFLUORESCENCE)(PROCALCITONIN (PCT) TEST KIT (IMMUNOFLUORESCENCE))-FOR IN VITRO QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) CONTENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD,C-REACTIVE PROTEIN DETECTION KIT (NEPHELOMETRY)(C-REACTIVE PROTEIN DETECTION KIT (NEPHELOMETRY))-FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) CONTENT IN HUMAN SERUM OR WHOLE BLOOD.,N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) TEST KIT (IMMUNOFLUORESCENCE)(N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) TEST KIT (IMMUNOFLUORESCENCE))-FOR IN VITRO QUANTITATIVE DETERMINATION OF N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) CONTENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD,QUALITY CONTROL SOLUTION(QUALITY CONTROL SOLUTION)-THIS 3-LEVEL QUALITY CONTROL IS USED TO MONITOR AND DETECT THE ELECTROLYTE ANALYZERS' PERFORMANCE, CTNI/CK-MB/MYO (CARDIAC PANEL) TEST KIT (IMMUNOFLUORESCENCE)(CTNI/CK-MB/MYO (CARDIAC PANEL) TEST KIT (IMMUNOFLUORESCENCE))-FOR IN VITRO QUANTITATIVE DETERMINATION OF CTNI/CK-MB/MYO CONTENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,URINE DILUENT(URINE DILUENT)-USED FOR DILUTION OF URINE SAMPLES AND MAKE IT CAN BE USED WITH ELECTROLYTE ANALYZERS BY PROFESSIONALS, FOR THE DETECTION OF POTASSIUM (K+), SODIUM (NA+), CHLORIDE (CL-), CALCIUM (CA2+) AND MAGNESIUM (MG2+) CONCENTRATION IN HUMAN URINE.,IMMUNOGLOBULIN G (IGG) DETECTION KIT (NEPHELOMETRY)(IMMUNOGLOBULIN G (IGG) DETECTION KIT (NEPHELOMETRY))-FOR IN VITRO QUANTITATIVE DETERMINATION OF IGG CONTENT IN HUMAN SERUM OR PLASMA.,CYSTATIN C DETECTION KIT (NEPHELOMETRY)(CYSTATIN C DETECTION KIT (NEPHELOMETRY))-FOR IN VITRO QUANTITATIVE DETERMINATION OF CYSTATIN C (CYS-C) CONTENT IN HUMAN SERUM OR PLASMA., KT05DIFF LYSE(KT05DIFF LYSE)-THIS PRODUCT IS USED TO DISSOLVE RBC AND MAINTAIN THE MORPHOLOGY OF THE CELLS NEEDED TO BE ANALYZED BEFORE BLOOD CELL ANALYSIS SO THAT FACILITATE CELL SORTING OR HGB QUANTIFICATION,PROBE CLEANSER(PROBE CLEANSER)-THIS PRODUCT CAN REGULARLY REMOVE THE CELL RESIDUES, BLOOD PROTEINS IN THE INSTRUMENT TO PREVENT PROTEIN PRECIPITATION IN THE SAMPLING NEEDLE, PIPE, COUNTING CHAMBER AND PROLONG THE LIFE OF THE MACHINE AND ASSURE THE ACCURACY OF THE TEST.,ANTI-CYCLIC CITRULLINATED PEPTIDE ANTIBODY DETECTION KIT (NEPHELOMETRY)(ANTI-CYCLIC CITRULLINATED PEPTIDE ANTIBODY DETECTION KIT (NEPHELOMETRY))-FOR IN VITRO QUANTITATIVE

	DETERMINATION OF ANTI-CYCLIC CITRULLINATED PEPTIDE ANTIBODY (ANTI-CCP) CONTENT IN HUMAN BLOOD SERUM., ELECTROLYTE REAGENTS (ISE, PRESSURE METHOD)(ELECTROLYTE REAGENTS (ISE, PRESSURE METHOD))-IT CAN BE USED WITH ELECTROLYTE ANALYZERS BY PROFESSIONALS, FOR THE DETECTION OF POTASSIUM (K+), SODIUM (NA+), CHLORIDE (CL-), CALCIUM (CA2+), MAGNESIUM (MG2+), LITHIUM (LI+), PH (PH VALUE) AND TCO2 CONCENTRATION IN HUMAN SERUM. IN ADDITION, GE-1 AND GE-2 ALSO CAN CONCENTRATION IN HUMAN BLOOD AND URINE.,ANTI-STREPTOLYSIN O DETECTION KIT (NEPHELOMETRY)(ANTI-STREPTOLYSIN O DETECTION KIT (NEPHELOMETRY))-FOR IN VITRO QUANTITATIVE DETERMINATION OF ANTI-STREPTOLYSIN O (ASO) CONTENT IN HUMAN SERUM OR PLASMA.,KT05LH LYSE (KT05LH LYSE)-THIS PRODUCT IS USED TO DISSOLVE RBC AND MAINTAIN THE MORPHOLOGY OF THE CELLS NEEDED TO BE ANALYZED BEFORE BLOOD CELL ANALYSIS THEREBY FACILITATES CELL SORTING OR HGB QUANTIFICATION.,IMMUNOGLOBULIN A (IGA) DETECTION KIT (NEPHELOMETRY)(IMMUNOGLOBULIN A (IGA) DETECTION KIT (NEPHELOMETRY))-FOR IN VITRO QUANTITATIVE DETERMINATION OF IGA CONTENT IN HUMAN SERUM OR PLASMA., MYOGLOBIN (MYO) TEST KIT (IMMUNOFLUORESCENCE)(MYOGLOBIN (MYO) TEST KIT (IMMUNOFLUORESCENCE))-FOR IN VITRO QUANTITATIVE DETERMINATION OF MYOGLOBIN (MYO) CONTENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD,HIGH SENSITIVE C-REACTIVE PROTEIN (HS-CRP) TEST KIT (IMMUNOFLUORESCENCE)(HIGH SENSITIVE C-REACTIVE PROTEIN (HS-CRP) TEST KIT (IMMUNOFLUORESCENCE))-FOR IN VITRO QUANTITATIVE DETERMINATION OF HIGH SENSITIVE C-REACTIVE PROTEIN CONTENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD,CARDIAC TROPONIN I (CTNI)TEST KIT (IMMUNOFLUORESCENCE)(CARDIAC TROPONIN I (CTNI)TEST KIT (IMMUNOFLUORESCENCE))-FOR IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) CONTENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD,CLEANING SOLUTION(CLEANING SOLUTION)-CLEANING THE TUBES OF ELECTROLYTE ANALYZER,KT05DIL DILUENT(KT05DIL DILUENT)-THIS PRODUCT IS USED FOR DILUTION OF BLOOD SAMPLES AND PREPARING CELL SUSPENSIONS PRIOR TO ANALYSIS OF THE CELLS., COMPLEMENTC3 (C3) DETECTION KIT (NEPHELOMETRY)(COMPLEMENTC3 (C3) DETECTION KIT (NEPHELOMETRY))-FOR IN VITRO QUANTITATIVE DETERMINATION OF COMPLEMENT C3 (C3) CONTENT IN HUMAN SERUM OR PLASMA.,DEPROTEINIZER (DEPROTEINIZER)-USED FOR CLEANING AND MAINTENANCE OF ELECTROLYTE ANALYZER TUBES AND ELECTRODES.

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1090	IMP/IVD/2021/000243	1.License Holder Name: SIRUS BIOCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CREATINKINASE(CK-NAC) -TEST REAGENT/KIT FOR THE ESTIMATION OF CREATINKINASE IN SERUM/PLASMA (HEPARINISED OR EDTA PLASMA),BILIRUBIN TOTAL (BILIRUBIN TOTAL)-TEST REAGENT/KIT FOR THE ESTIMATION OF BILIRUBIN TOTAL IN SERUM OR PLASMA (HEPARINISED OR EDTA PLASMA),TRIGLYCERIDES MONO(TRIGLYCERIDES MONO)-TEST REAGENT/KIT FOR THE ESTIMATION OF TRIGLYCERIDES IN SERUM/PLASMA (HEPARINISED OR EDTA PLASMA),CALCIUM MONO (CALCIUM MONO)-TEST REAGENT/KIT FOR THE ESTIMATION OF CALCIUM IN SERUM OR PLASMA (AVOID EDTA PLASMA),URIC ACID MONO(URIC ACID MONO)-TEST REAGENT/KIT FOR THE ESTIMATION OF URIC ACID IN SERUM/PLASMA (HEPARINISED OR EDTA PLASMA) AND URINE,UREA-UV (UREA-UV)-TEST REAGENT/KIT FOR THE ESTIMATION OF UREA IN SERUM/PLASMA (EDTA PLASMA) AND URINE,ALKALINE PHOSPHATASE(ALP)-TEST REAGENT/KT FOR THE ESTIMATION OF ALKALINE PHOSPHATASE IN SERUM/PLASMA (HEPARINISED OR EDTA PLASMA),CREATININE(CREATININE)-TEST REAGENT/KIT FOR THE ESTIMATION OF CREATININE IN SERUM/PLASMA (HEPARINISED OR EDTA PLASMA),BILIRUBIN DIRECT (BILIRUBIN DIRECT)-TEST REAGENT/KIT FOR THE ESTIMATION OF BILIRUBIN DIRECT IN SERUM/PLASMA (HEPARINISED OR EDTA PLASMA),PROTEIN TOTAL MONO(TOTAL PROTEIN)-TEST REAGENT/KIT FOR THE ESTIMATION OF PROTEIN IN SERUM/PLASMA (HEPARINISED OR EDTA PLASMA),C-REACTIVE PROTEIN(CRP)-TEST REAGENT/KIT FOR ESTIMATION OF C-REACTIVE PROTEIN IN SERUM/PLASMA (HEPARINISED OR EDTA PLASMA),LACTATE DEHYDROGENASE-L(LDH-L)-TEST REAGENT/KIT FOR THE ESTIMATION OF LACTATE DEHYDROGENASE-L IN SERUM/PLASMA (HEPARINISED OR EDTA PLASMA),ASPARTAT-AMINO TRANSFERASE (ASAT/GOT)(ASAT/GOT)-TEST REAGENT/KIT FOR THE ESTIMATION OF ASPARTAT-AMINO TRANSFERASE IN SERUM/PLASMA (HEPARINISED OR EDTA PLASMA),CREATINKINASE-MB(CK-MB)-TEST REAGENT/KIT FOR THE ESTIMATION OF CREATINKINASE-MB IN SERUM/PLASMA (HEPARINISED OR EDTA PLASMA),AMYLASE DIRECT (AMYLASE DIRECT)-TEST REAGENT/KIT FOR THE ESTIMATION OF AMYLASE DIRECT IN SERUM/PLASMA (HEPARINISED OR EDTA PLASMA),ALBUMIN MONO(ALBUMIN MONO)-TEST REAGENT/KIT FOR THE ESTIMATION OF ALBUMIN IN SERUM/PLASMA(HEPARINISED OR EDTA PLASMA),CHOLESTEROL MONO(CHOLESTEROL MONO)-TEST REAGENT/KIT FOR THE ESTIMATION OF CHOLESTEROL IN SERUM/PLASMA (HEPARINISED OR EDTA PLASMA),ALANIN-AMINO TRANSFERASE (ALAT/GPT)(ALAT/GPT)-TEST REAGENT/KIT FOR THE

		ESTIMATION OF ALANIN-AMINO TRANSFERASE IN SERUM/PLASMA (HEPARINISED OR EDTA)
1091	IMP/IVD/2021/000244	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CARBON DIOXIDE (CARBON DIOXIDE)-THE CARBON DIOXIDE ASSAY IS USED FOR THE QUANTITATION OF CARBON DIOXIDE IN HUMAN SERUM OR PLASMA., ALINITY C CARBON DIOXIDE REAGENT KIT(ALINITY C CARBON DIOXIDE REAGENT KIT)-THE ALINITY C CARBON DIOXIDE ASSAY IS USED FOR THE QUANTITATION OF CARBON DIOXIDE IN HUMAN SERUM OR PLASMA ON THE ALINITY C ANALYZER.
1092	IMP/IVD/2021/000246	1.License Holder Name: FINOVA HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SERUM AMYLOID A(SAA) TEST KIT(HEALES)-IT IS USED TO QUANTITATIVELY DETECT SERUM AMYLOID A (SAA) IN HUMAN SERUM IN VITRO.,CRP TEST KIT(HEALES) -IT IS USED FOR THE QUANTITATIVE DETERMINATION OF CRP IN WHOLE BLOOD/SERUM/PLASMA.,MALB TEST KIT(HEALES)-IT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF MALB IN URINE,FDP TEST KIT(HEALES)-IT IS USED FOR QUANTITATIVE DETERMINATION OF FDP IN HUMAN PLASMA,HBA1C TEST KIT (HEALES)-IT IS INTENDED FOR USE IN THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF GLYCATED HEMOGLOBIN A1C (HBA1C) IN HUMAN WHOLE BLOOD,D-DIMER TEST KIT(HEALES)-IT IS USED FOR QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA

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1093	IMP/IVD/2021/000248	1.License Holder Name: IMMUNOSHOP INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HC500 CLEANER(EDAN)-THE HC500 CLEANER IS INTENDED TO CLEAN AND RINSE THE FLUIDIC CHANNELS WITHIN ANALYZER TO ENSURE THE ANALYZER'S PERFORMANCE,HD500 DILUENT(EDAN)-THE HD500 DILUENT IS INTENDED TO PERFORM ERYTHROCYTES AND PLATELETS MEASUREMENT IN A BLOOD SAMPLE. WHEN USED WITH THE CORRESPONDING LYSE, THE DILUENTS FURTHER ENABLE TO HGB MEASUREMENT, RESISTIVELY COUNT LEUKOCYTES AND OPTICALLY DIFFERENTIATE THE FIVE MAIN LEUKOCYTES SUBPOPULATIONS., HL500 LYSE(EDAN)-THE PRODUCT IS USED FOR LYSING ERYTHROCYTES, COUNTING AND DIFFERENTIATING THE FIVE MAIN LEUKOCYTES SUBPOPULATIONS AND QUANTITATIVE DETERMINATION HEMOGLOBIN IN A BLOOD SAMPLE IN COMBINATION WITH DILUENTS ON H50 HEMATOLOGY ANALYZER,ED-50D - CONTROL(EDAN)-ED-50D HEMATOLOGY CONTROL IS DESIGNED TO MONITOR VALUES ON H50/H51HEMATOLOGY ANALYZER TO ENSURE THE ANALYZER'S PERFORMANCE BEFORE PATIENT'S SAMPLE TESTS.,ED-CAL PLUS - CALIBRATOR(EDAN)-HEMATOLOGY CALIBRATOR IS INTENDED FOR THE CALIBRATION OF EDAN HEMATOLOGY ANALYZER TO MAINTAIN THE ANALYZER'S ANALYTICAL PERFORMANCE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1094	IMP/IVD/2021/000249	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TPHA(CROMATEST)-MEASUREMENT OF TPHA ,BRUCELLA MELITENSIS(CROMATEST)-MEASUREMENT OF FEBRILE ANTIGENS ,TRANSFERRIN ID (CROMATEST)-MEASUREMENT OF TRANSFERRIN ,BRUCELLA POSITIVE CONTROL(CROMATEST)-MEASUREMENT OF FEBRILE ANTIGENS ,TRANSFERRIN AT(CROMATEST)-MEASUREMENT OF TRANSFERRIN,C3 ID(CROMATEST)-MEASUREMENT OF C3 ,ASLO LATEX 50 TESTS(CROMATEST)-MEASUREMENT OF ASLO ,A1-AC GLYCOPROTEIN AT(CROMATEST)-MEASUREMENT OF 1-ACID GLYCOPROTEIN,IGA ID(CROMATEST)-MEASUREMENT OF IGA ,ASLO TURBIDIMETRIC(CROMATEST)-MEASURMENTE OF ASLO ,PROTEUS OXK(CROMATEST)-MEASUREMENT OF FEBRILE ANTIGENS ,IGM ID (CROMATEST)-MEASUREMENT OF IGM ,FIBRINOGEN ID(CROMATEST)-MEASUREMENT OF FIBRINOGEN ,C4 AT(CROMATEST)-MEASUREMENT OF C4,C3 AT(CROMATEST)-MEASUREMENT OF C3,CRP TURBIDIMETRIC(CROMATEST)-MEASUREMENT OF CRP ,PLASMA PROTEIN CONTROL N-II(CROMATEST)-MEASUREMENT OF PLASMA PROTEINS ,IGG AT(CROMATEST)-MEASUREMENT OF IGG,IGM AT (CROMATEST)-MEASUREMENT OF IGM,PLASMA PROTEIN CONTROL N-I(CROMATEST)-MEASUREMENT OF PLASMA PROTEINS ,BRUCELLA ABORTUS(CROMATEST)-MEASUREMENT OF FEBRILE ANTIGENS ,CRP LATEX 50 TESTS(CROMATEST)-MEASUREMENT OF CRP ,C4 ID (CROMATEST)-MEASUREMENT OF C4 ,PROTEUS OX2(CROMATEST)-MEASUREMENT OF FEBRILE ANTIGENS ,IGA-IGG-IGM ID(CROMATEST)-MEASUREMENT OF IGA + IGG+ IGM ,RF TURBIDIMETRIC(CROMATEST)-MEASUREMENT OF RF ,VDRL ANTIGEN MR(CROMATEST)-MEASUREMENT OF VDRL ,MICROALBUMIN TURBIDIMETRIC (CROMATEST)-MEASUREMENT OF MICROALBUMIN ,SLE LATEX (CROMATEST)-MEASUREMENT OF SLE ,HBA1C TURBIDIMETRIC (CROMATEST)-MEASUREMENT OF HBA1C ,RF LATEX 50 TESTS (CROMATEST)-MEASUREMENT OF RF ,PROTEUS OX19(CROMATEST)-MEASUREMENT OF FEBRILE ANTIGENS ,ANTITHROMBIN III ID (CROMATEST)-MEASUREMENT OF ANTITHROMBIN ,FERRITIN TURBIDIMETRIC(CROMATEST)-MEASUREMENT OF FERRITIN , AGLUTININ NEGATIVE CONTROL(CROMATEST)-CONTROL NEGATIVE , US CRP TURBIDIMETRIC(CROMATEST)-MEASUREMENT OF CRP , PLASMA PROTEIN CALIBRATOR(CROMATEST)-MEASUREMENT OF PLASMA PROTEINS

1095	IMP/IVD/2021/000250	1.License Holder Name: BIO-RAD LABORATORIES (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIROCLEAR SARS-COV-2 (VIROCLEAR SARS-COV-2)-VIROCLEAR SARS-COV-2 IS INTENDED FOR USE AS AN UNASSAYED NON-REACTIVE QUALITY CONTROL WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF SARS-COV-2 TOTAL IGG/IGM AND SARS-COV-2 IGG IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES.,LYPHOCHEK ALLERGEN SIGE CONTROL, NEGATIVE (LYPHOCHEK ALLERGEN SIGE CONTROL, NEGATIVE)-LYPHOCHEK ALLERGEN SIGE CONTROL, NEGATIVE IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACAKAGE INSERT.,VIROTROL SARS-COV-2(VIROTROL SARS-COV-2)-VIROTROL SARS-COV-2 IS INTENDED FOR USE AS AN UNASSAYED REACTIVE QUALITY CONTROL WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF SARS- COV-2 TOTAL IGG/IGM AND SARS-COV-2 IGG IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES.,LYPHOCHEK ALLERGEN SIGE CONTROL, PANEL A(LYPHOCHEK ALLERGEN SIGE CONTROL, PANEL A)-LYPHOCHEK ALLERGEN SIGE CONTROL, PANEL A IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACAKAGE INSERT.,INTELIQ ETHANOL/AMMONIA CONTROL(INTELIQ ETHANOL/AMMONIA CONTROL)-INTELIQ ETHANOL/AMMONIA CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACAKAGE INSERT

1096	IMP/IVD/2021/000251	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONSOLIDATED CHEMISTRY CALIBRATOR(CONSOLIDATED CHEMISTRY CALIBRATOR) -THE CONSOLIDATED CHEMISTRY CALIBRATOR (CONCC) IS USED TO CALIBRATE CLINICAL CHEMISTRY ASSAYS FOR QUANTITATIVE MEASUREMENT ON THE ALINITY C SYSTEM.,CONSOLIDATED CHEMISTRY CALIBRATOR(CONSOLIDATED CHEMISTRY CALIBRATOR) -THE CONSOLIDATED CHEMISTRY CALIBRATOR (CONCC) IS USED TO CALIBRATE CLINICAL CHEMISTRY ASSAYS FOR QUANTITATIVE MEASUREMENT ON THE ARCHITECT C SYSTEMS.
1097	IMP/IVD/2021/000252	1.License Holder Name: MERIDIAN BIOTECH 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TANBEAD® NUCLEIC ACID EXTRACTION KIT(TANBEAD®)-TANBEAD® NUCLEIC ACID EXTRACTION KIT IS SUITABLE FOR ISOLATING NUCLEIC ACID FROM VARIOUS VIRUSES.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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1098	IMP/IVD/2021/000253	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD VERITOR SYSTEM FOR RAPID DETECTION OF SARS-COV-2(BD VERITOR SYSTEM FOR RAPID DETECTION OF SARS-COV-2)-THE BD VERITOR™ SYSTEM FOR RAPID DETECTION OF SARS-COV-2 IS A RAPID (APPROXIMATELY 15 MINUTES) CHROMATOGRAPHIC DIGITAL IMMUNOASSAY INTENDED FOR THE DIRECT AND QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID ANTIGENS IN NASAL SWABS FROM INDIVIDUALS WITH OR WITHOUT SYMPTOMS, WHO ARE SUSPECTED OF INFECTION WITH, OR EXPOSURE TO COVID-19, BY THEIR HEALTHCARE PROVIDER. RESULTS ARE FOR THE IDENTIFICATION OF SARS-COV-2 NUCLEOCAPSID ANTIGEN. THIS ANTIGEN IS GENERALLY DETECTABLE IN UPPER RESPIRATORY SAMPLES DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS INDICATE THE PRESENCE OF VIRAL ANTIGENS, BUT CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE INFECTION STATUS. THE BD VERITOR™ SYSTEM FOR RAPID DETECTION OF SARS-COV-2 IS INTENDED FOR USE IN POINT OF CARE SETTINGS BY LABORATORY PERSONNEL AND HEALTHCARE PROVIDERS APPROPRIATELY TRAINED IN THE USE OF THE BD VERITOR™ SYSTEM.,BD VERITOR SYSTEM FOR RAPID DETECTION OF SARS-COV-2(BD VERITOR SYSTEM FOR RAPID DETECTION OF SARS-COV-2)-THE BD VERITOR™ SYSTEM FOR RAPID DETECTION OF SARS-COV-2 IS A CHROMATOGRAPHIC DIGITAL IMMUNOASSAY INTENDED FOR THE DIRECT AND QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID ANTIGENS IN NASAL SWABS FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER WITHIN THE FIRST 5 DAYS OF THE ONSET OF SYMPTOMS. IN THE UNITED STATES, TESTING IS LIMITED TO LABORATORIES CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C. §263A, THAT MEET THE REQUIREMENTS TO PERFORM MODERATE, HIGH, OR WAIVED COMPLEXITY TESTS. THIS TEST IS AUTHORIZED FOR USE AT THE POINT OF CARE (POC), I.E., IN PATIENT CARE SETTINGS OPERATING UNDER A CLIA CERTIFICATE OF WAIVER, CERTIFICATE OF COMPLIANCE, OR CERTIFICATE OF ACCREDITATION. RESULTS ARE FOR THE IDENTIFICATION OF SARS-COV-2 NUCLEOCAPSID ANTIGEN. THIS ANTIGEN IS GENERALLY DETECTABLE IN UPPER RESPIRATORY SAMPLES DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS INDICATE THE PRESENCE OF VIRAL ANTIGENS, BUT CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL

	INFECTION OR CO-INFECTION WITH OTHER VIRUSES. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. LABORATORIES WITHIN THE UNITED STATES AND ITS TERRITORIES ARE REQUIRED TO REPORT ALL POSITIVE RESULTS TO THE APPROPRIATE PUBLIC HEALTH AUTHORITIES. NEGATIVE RESULTS SHOULD BE TREATED AS PRESUMPTIVE, DO NOT RULE OUT SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR PATIENT MANAGEMENT DECISIONS, INCLUDING INFECTION CONTROL DECISIONS. NEGATIVE RESULTS SHOULD BE CONSIDERED IN THE CONTEXT OF A PATIENT'S RECENT EXPOSURES, HISTORY AND THE PRESENCE OF CLINICAL SIGNS AND SYMPTOMS CONSISTENT WITH COVID-19, AND CONFIRMED WITH A MOLECULAR ASSAY, IF NECESSARY, FOR PATIENT MANAGEMENT. THE BD VERITOR™ SYSTEM FOR RAPID DETECTION OF SARS-COV-2 IS INTENDED FOR USE IN POINT OF CARE SETTINGS AND OPERATED BY HEALTHCARE PROFESSIONALS OR TRAINED USERS SPECIFICALLY INSTRUCTED IN THE USE OF THE BD VERITOR™ SYSTEM AND PROPER INFECTION CONTROL PROCEDURES.,BD KIT FOR RAPID DETECTION OF SARS-COV-2(BD KIT FOR RAPID DETECTION OF SARS-COV-2)-THE BD KIT FOR RAPID DETECTION OF SARSCOV2 IS A CHROMATOGRAPHIC IMMUNOASSAY INTENDED FOR THE DIRECT AND QUALITATIVE DETECTION OF SARSCOV2 NUCLEOCAPSID ANTIGENS IN NASAL SWABS FROM INDIVIDUALS WHO ARE WITHOUT SYMPTOMS, OR WITH SYMPTOMS, WHO ARE SUSPECTED OF SARSCOV2 INFECTION BY THEIR HEALTHCARE PROVIDER. VISUALLY READ RESULTS ARE FOR THE IDENTIFICATION OF SARSCOV2 NUCLEOCAPSID ANTIGEN. THIS ANTIGEN IS GENERALLY DETECTABLE IN UPPER RESPIRATORY SAMPLES DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS INDICATE THE PRESENCE OF VIRAL ANTIGENS, BUT CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE INFECTION STATUS. THE BD KIT FOR RAPID DETECTION OF SARSCOV2 IS INTENDED FOR USE IN POINT OF CARE SETTINGS BY HEALTHCARE PROFESSIONALS OR TRAINED USERS SPECIFICALLY INSTRUCTED IN THE USE OF THE BD KIT FOR RAPID DETECTION OF SARSCOV2 AND PROPER INFECTION CONTROL PROCEDURES

1099	IMP/IVD/2021/000254	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD VERITOR SYSTEM FOR RAPID DETECTION OF SARS-COV-2(BD VERITOR SYSTEM FOR RAPID DETECTION OF SARS-COV-2)-THE BD VERITOR™ SYSTEM FOR RAPID DETECTION OF SARS-COV-2 IS A CHROMATOGRAPHIC DIGITAL IMMUNOASSAY INTENDED FOR THE DIRECT AND QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID ANTIGENS IN NASAL SWABS FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER WITHIN THE FIRST 5 DAYS OF THE ONSET OF SYMPTOMS. IN THE UNITED STATES, TESTING IS LIMITED TO LABORATORIES CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C. §263A, THAT MEET THE REQUIREMENTS TO PERFORM MODERATE, HIGH, OR WAIVED COMPLEXITY TESTS. THIS TEST IS AUTHORIZED FOR USE AT THE POINT OF CARE (POC), I.E., IN PATIENT CARE SETTINGS OPERATING UNDER A CLIA CERTIFICATE OF WAIVER, CERTIFICATE OF COMPLIANCE, OR CERTIFICATE OF ACCREDITATION. RESULTS ARE FOR THE IDENTIFICATION OF SARS-COV-2 NUCLEOCAPSID ANTIGEN. THIS ANTIGEN IS GENERALLY DETECTABLE IN UPPER RESPIRATORY SAMPLES DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS INDICATE THE PRESENCE OF VIRAL ANTIGENS, BUT CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. LABORATORIES WITHIN THE UNITED STATES AND ITS TERRITORIES ARE REQUIRED TO REPORT ALL POSITIVE RESULTS TO THE APPROPRIATE PUBLIC HEALTH AUTHORITIES. NEGATIVE RESULTS SHOULD BE TREATED AS PRESUMPTIVE, DO NOT RULE OUT SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR PATIENT MANAGEMENT DECISIONS, INCLUDING INFECTION CONTROL DECISIONS. NEGATIVE RESULTS SHOULD BE CONSIDERED IN THE CONTEXT OF A PATIENT'S RECENT EXPOSURES, HISTORY AND THE PRESENCE OF CLINICAL SIGNS AND SYMPTOMS CONSISTENT WITH COVID-19, AND CONFIRMED WITH A MOLECULAR ASSAY, IF NECESSARY, FOR PATIENT MANAGEMENT. THE BD VERITOR™ SYSTEM FOR RAPID DETECTION OF SARS-COV-2 IS INTENDED FOR USE IN POINT OF CARE SETTINGS AND OPERATED BY HEALTHCARE PROFESSIONALS OR TRAINED USERS SPECIFICALLY INSTRUCTED IN THE USE OF THE BD VERITOR™ SYSTEM AND PROPER INFECTION CONTROL PROCEDURES.

1100	IMP/IVD/2021/000255	1.License Holder Name: QIAGEN INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MO-SCREEN CORONA ANTIGEN TEST(MO-SCREEN CORONA ANTIGEN TEST)-THE MÖ-SCREEN CORONA ANTIGEN TEST IS AN IN VITRO IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF NUCLEOCAPSID PROTEIN ANTIGEN FROM SARS-COV-2 IN DIRECT NASOPHARYNGEAL (NP) OR NASAL SWAB SPECIMENS DIRECTLY FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER WITHIN THE FIRST TEN DAYS OF SYMPTOM ONSET. IT IS INTENDED TO AID IN THE RAPID DIAGNOSIS OF SARS-COV-2 INFECTIONS. NEGATIVE RESULTS FROM PATIENTS WITH SYMPTOM ONSET BEYOND TEN DAYS, SHOULD BE TREATED AS PRESUMPTIVE AND CONFIRMATION WITH A MOLECULAR ASSAY, IF NECESSARY, FOR PATIENT MANAGEMENT, MAY BE PERFORMED. THE CORONAVIRUS AG RAPID TEST CASSETTE (SWAB) DOES NOT DIFFERENTIATE BETWEEN SARS-COV AND SARS-COV-2.
1101	IMP/IVD/2021/000256	1.License Holder Name: M/S. R-BIOPHARM NEUGEN PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIVALYTIC COV TEST (BOSCH)-THE BOSCH VIVALYTIC COV TEST IS A QUALITATIVE END POINT POLYMERASE CHAIN REACTION (PCR)-BASED ASSAY FOR THE DETECTION OF NUCLEIC ACIDS FROM SARS-COV-2 AND SARBECOVIRUSES FROM NASOPHARYNGEAL AND OROPHARYNGEAL SWABS TO AID IN THE DIAGNOSIS OF RESPIRATORY TRACT INFECTIONS. INTENDED FOR USE WIÎH A VIVALYTIC ANALYSER BY HEALTHCARE PROFESSIONALS. ,VIVALYTIC SARS-COV-2(BOSCH)-THE BOSCH VIVALYTIC SARS-COV-2 TEST IS A QUALITATIVE PCR-BASED ASSAY FOR THE DETECTION OF SARS-COV-2 FROM HUMAN NASOPHARYNGEAL AND OROPHARYNGEAL SWABS TO AID IN THE DIAGNOSIS OF A SARS-COV-2 INFECTION. POSITIVE AND NEGATIVE RESULTS MUST BE CLINICALLY CORRELATED WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. INTENDED FOR USE WITH A VIVALYTIC ANALYSER BY HEALTHCARE PROFESSIONALS.
1102	IMP/IVD/2021/000259	1.License Holder Name: IMPERIAL LIFE SCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOCREDIT COVID-19 AG (BIOCREDIT)-FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIGEN FROM HUMAN NASOPHARYNX

1103	IMP/IVD/2021/000261	1.License Holder Name: GENWORKS HEALTH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ISE BLOOD SAMPLE CALIBRATOR(ISE BLOOD SAMPLE CALIBRATOR)-THIS PRODUCT IS APPLICABLE TO THE ION-SELECTIVE ELECTRODE MODULE OF CS SERIES AUTO-CHEMISTRY ANALYZERS FOR MEASURING ELECTROLYTE IN ORDER TO ELIMINATE ERROR OF MEASURED RESULTS.,H12-800MA(H12-800MA)-FOR DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH, ASCORBIC ACID AND MICROALBUMIN IN URINE,ISE STANDARD SOLUTION(ISE STANDARD SOLUTION)-THIS PRODUCT IS APPLICABLE TO THE ION-SELECTIVE ELECTRODE MODULE OF CS SERIES AUTO-CHEMISTRY ANALYZERS FOR MEASURING ELECTROLYTE. THE SLOPE VALUE OF ICON-SELECTIVE ELECTRODE CAN BE OBTAINED BY TESTING THE COMBINATION OF ISE STANDARD SOLUTION LOW AND ISE STANDARD SOLUTION HIGH,H11-MA(N)(H11-MA(N))-FOR THE DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY AND PH IN URINE,NEGATIVE CONTROL(NEGATIVE CONTROL)-USED FOR QC DURING TEST , H13—CR(H13—CR)-FOR DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH, ASCORBIC ACID AND MICROALBUMIN IN URINE,H11-800(H11-800)-FOR DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH AND ASCORBIC ACID IN URINE,H SERIES URINE ANALYZER CALIBRATION LIQUID FOR TURBIDITY(H SERIES URINE ANALYZER CALIBRATION LIQUID FOR TURBIDITY)-USED FOR DIRUI'S H SERIES URINE ANALYZER TURBIDIMETER CALIBRATION. ,H SERIES URINE ANALYZER COLOR CONTROL(H SERIES URINE ANALYZER COLOR CONTROL)-USED FOR DIRUI'S H SERIES URINE ANALYZER COLOR QUALITY CONTROL,CS-ISE DETERGENT(CS-ISE DETERGENT)-FOR CLEANING ISE ELECTRODE OF CS SERIES AUTO-CHEMISTRY ANALYZER.,STANDARD SOLUTION (STANDARD SOLUTION)-THIS PRODUCT IS USED TO CALIBRATE URINE SEDIMENT ANALYZER TO GUARANTEE TO GET ACCURATE TEST RESULTS.,URINE SEDIMENT ANALYZER REAGENT SHEATH (URINE SEDIMENT ANALYZER REAGENT SHEATH)-USED TO WRAP THE SAMPLE TO FORM A SHEATH FLOW TO CONDUCT URINE PHYSICAL COMPONENT COUNTING,URINE SEDIMENT ANALYZER REAGENT DILUENT(URINE SEDIMENT ANALYZER REAGENT DILUENT)-USED TO DILUTE THE URINE SAMPLE,H SERIES URINE ANALYZER CALIBRATION LIQUID FOR SPECIFIC GRAVITY(H SERIES URINE ANALYZER CALIBRATION LIQUID FOR SPECIFIC GRAVITY)-USED FOR

	DIRUI'S H SERIES URINE ANALYZER'S REFRACTOMETER'S CALIBRATION,H SERIES URINE ANALYZER CLEANING LIQUID FOR REFRACTOMETER AND TURBIDIMETER(H SERIES URINE ANALYZER CLEANING LIQUID FOR REFRACTOMETER AND TURBIDIMETER)-TO CLEAN THE REFRACTOMETER AND TURBIDIMETER OF H SERIES URINE ANALYZER,ISE DILUENT(ISE DILUENT)-TO DILUTE THE SAMPLE AND STANDARD SOLUTION IN ISE MODULE.,ISE INTERNAL STANDARD SOLUTION(ISE INTERNAL STANDARD SOLUTION)-TO COMPENSATE FOR SYSTEM DRIFT AND RINSE THE MATCHING CUVETTES AND FLOW CELL.,CLEANSER(CLEANSER)-TO CLEAN AND WASH THE DETECTION PART AND FLUID SYSTEM OF THE HEMATOLOGY ANALYZERS.,H SERIES URINE ANALYZER CONTROL LIQUID FOR SPECIFIC GRAVITY(H SERIES URINE ANALYZER CONTROL LIQUID FOR SPECIFIC GRAVITY)-USED FOR DIRUI'S H SERIES URINE ANALYZER'S REFRACTOMETER'S QUALITY CONTROL.,FOCUS(FOCUS)-FOCUS IS USED FOR THE DETERMINE POSITION OF FOCAL PLANE OF MICROSCOPIC IMAGING SYSTEM ,ISE REFERENCE SOLUTION(ISE REFERENCE SOLUTION)-TO DETERMINE THE REFERENCE ELECTRODE POTENTIAL IN ISE MODULE. ,ISE BLOOD QC-HIGH/QC-LOW(ISE BLOOD QC-HIGH/QC-LOW)-THIS PRODUCT IS APPLICABLE TO THE ION-SELECTIVE ELECTRODE MODULE OF CS SERIES AUTO-CHEMISTRY ANALYZERS FOR MEASURING ELECTROLYTE. THE ACCURACY OF SERUM MEASUREMENT RESULT CAN BE CONFIRMED IN THE LINEAR RANGE OF INSTRUMENT MEASUREMENT BY MEASURING THIS PRODUCT,H11-MA(H11-MA)-FOR THE DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH AND MICROALBUMIN IN URINE,H SERIES URINE ANALYZER CONTROL LIQUID FOR TURBIDITY(H SERIES URINE ANALYZER CONTROL LIQUID FOR TURBIDITY)-USED FOR DIRUI'S H SERIES URINE ANALYZER'S REFRACTOMETER'S QUALITY CONTROL., URINE SEDIMENT ANALYZER DETERGENT(URINE SEDIMENT ANALYZER)-USE TO RINSE THE PIPELINE AND FLOW CELL,H10(H10)-FOR DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE (ACETOACETIC ACID), BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY AND PH,H14-CA(H14-CA)-FOR DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH, ASCORBIC ACID MICROALBUMIN, CREATININE AND CALCIUM IN URINE,DILUENT(DILUENT)-DILUTE BLOOD SAMPLES.,CS-ALKALINE DETERGENT(CS-ALKALINE DETERGENT)-FOR CLEANING SAMPLE PROBE AND REACTION CUVETTE OF CS SERIES AUTO-CHEMISTRY ANALYZER,CONTROL FOR HEMATOLOGY ANALYZER(CONTROL FOR HEMATOLOGY ANALYZER)-CONTROL FOR HEMATOLOGY ANALYZER IS USED FOR HEMATOLOGY ANALYZER QUALITY CONTROL IN

		HEMATOLOGICAL TESTS,POSITIVE CONTROL(POSITIVE CONTROL)-USED FOR QC DURING TEST ,H11(H11)-FOR THE DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE (ACETOACETIC ACID), BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH AND ASCORBIC ACID,URINALYSIS CONTROL (NEGATIVE)(URINALYSIS CONTROL (NEGATIVE))-USED FOR QUALITY CONTROL OF URINALYSIS STRIPS AND ANALYZERS,H10-800(H10-800)-FOR DETECTION OF UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH IN URINE,URINALYSIS CONTROL (POSITIVE)(URINALYSIS CONTROL (POSITIVE))-USED FOR QUALITY CONTROL OF URINALYSIS STRIPS AND ANALYZERS,LYSE(LYSE)-IT IS USED FOR DISSOLVING RBC, DETECTING TOTAL NUMBER OF WBC, THREE-PART WBC COUNT AND THE CONTENT OF HEMOGLOBIN,CS-ANTI-BACTERIAL PHOSPHOR-FREE DETERGENT(CS-ANTI-BACTERIAL PHOSPHOR-FREE DETERGENT)-FOR CLEANING REAGENT PROBE, REACTION CUVETTE AND SOAKING REACTION CUP OF THE CS SERIES AUTO-CHEMISTRY ANALYZER
1104	IMP/IVD/2021/000262	1.License Holder Name: FUJIFILM INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FUJI DRI-CHEM IMMUNO AU CARTRIDGE V-PRG(FUJI DRI-CHEM IMMUNO AU CARTRIDGE V-PRG)-QUANTITATIVE MEASUREMENT OF PROGENSTERONE (PRG) CONCENTRATION IN PLASMA OR SERUM FROM CANINE.FOR VETERINARY USE ONLY. ,FUJI DRI-CHEM IMMUNO AU CARTRIDGE VF-SAA(FUJI DRI-CHEM IMMUNO AU CARTRIDGE VF-SAA)-QUANTITATIVE MEASUREMENT OF SAA CONCENTRATION IN PLASMA OR SERUM FROM FELINE.FOR VETERINARY USE ONLY.

1105	IMP/IVD/2021/000263	1.License Holder Name: THERMO FISHER SCIENTIFIC INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS COV-2 TEST (ACCULA)-THE ACCULA™ SARS-COV-2 TEST PERFORMED ON THE ACCULA DOCK OR THE SILARIS™ DOCK IS A MOLECULAR IN VITRO DIAGNOSTIC TEST UTILIZING POLYMERASE CHAIN REACTION (PCR) AND LATERAL FLOW TECHNOLOGIES FOR THE QUALITATIVE, VISUAL DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN CLINICIAN-COLLECTED NASAL OR NASAL MID-TURBINATE SWAB SPECIMENS OR CLINICIAN-INSTRUCTED SELF-COLLECTED (COLLECTED ON SITE) NASAL SWAB SPECIMENS, COLLECTED FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. TESTING IS LIMITED TO LABORATORIES CERTIFIED UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 U.S.C. §263A, THAT MEET REQUIREMENTS TO PERFORM HIGH, MODERATE, OR WAIVED COMPLEXITY TESTS. THE ACCULA SARS-COV-2 TEST IS AUTHORIZED FOR USE AT THE POINT OF CARE (POC), I.E., IN PATIENT CARE SETTINGS OPERATING UNDER A CLIA CERTIFICATE OF WAIVER, CERTIFICATE OF COMPLIANCE, OR CERTIFICATE OF ACCREDITATION. ACCULA SARS-COV-2 TEST RESULTS ARE FOR THE IDENTIFICATION OF SARS-COV-2 RNA. THE SARS-COV-2 RNA IS GENERALLY DETECTABLE IN UPPER RESPIRATORY SPECIMENS DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS ARE INDICATIVE OF THE PRESENCE OF SARS-COV-2 RNA; CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. TESTING FACILITIES WITHIN THE UNITED STATES AND ITS TERRITORIES ARE REQUIRED TO REPORT ALL RESULTS TO THE APPROPRIATE PUBLIC HEALTH AUTHORITIES.,SARS COV-2 CONTROL KITS(ACCULA)-THE ACCULA™ SARS-COV-2 CONTROL KIT IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN QUALITY CONTROL TESTING WITH THE ACCULA™ SARS-COV-2 TEST.

1106	IMP/IVD/2021/000264	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIPASE-LQ(LABKIT)-QUANTITATIVE DETERMINATION OF LIPASE ACTIVITY IN HUMAN SAMPLES. ,AMMONIA LQ(LABKIT)-QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN SAMPLES. ,COOPER(LABKIT)-QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SAMPLES.,LGG(LABKIT)-QUANTITATIVE DETERMINATION OF HUMAN IMMNUOGLOBULIN G (LGG),LGA(LABKIT)-QUANTITATIVE DETERMINATION OF HUMAN IMMNUOGLOBULIN A (LGA),LGM(LABKIT)-QUANTITATIVE DETERMINATION OF HUMAN IMMNUOGLOBULIN M (LGM),CRP LATEX KIT(LABKIT)-QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SAMPLES. ,IRON FZ(LABKIT)-QUANTITATIVE DETERMINATION OF IRON IN HUMAN SAMPLES. ,CK-MB LQ(LABKIT)-QUANTITATIVE DETERMINATION OF CREATININE KINASE (MB) ACTIVITY IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY.,ASO LATEX KIT(LABKIT)-QUANTITATIVE DETERMINATION OF ASO IN HUMAN SAMPLES. ,CHOLESTEROL LS (LABKIT)-QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SAMPLES. ,PHOSPHORUS UV(LABKIT)-QUANTITATIVE DETERMINATION OF PHOSPHORUS IN HUMAN SAMPLES. , ASO/CRP/RF CONTROL H(LABKIT)-SERUM CONTROL MUTICOMPONET FOR ASO,CRP,RF TURBIDIMETRY ASSAYS WITH VALUS IN PATHOLOGICAL RANGE.,APO CONTROL(LABKIT)-SERUM CONTROL FOR APO A1/B TURBIDIMETRY ASSAY.,PHOSPHOLIPIDS (LABKIT)-QUANTITATIVE DETERMINATION OF PHOSPHOLIPIDS IN HUMAN SAMPLES. ,ALBUMIN(LABKIT)-QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SAMPLES.,OXALIC ACID (LABKIT)-QUANTITATIVE DETERMINATION OF OXALIC IN HUMAN SAMPLES. ,RF LATEX KIT (LABKIT)-QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR IN HUMAN SAMPLES. ,CK-MB CONTROL (LABKIT)-CONTROL SERA INTENDED FOR ACCURACY CONTROL OF CK-MB REAGENT.(HUMAN SOURCE),TOTAL PROTEIN(LABKIT)-QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SAMPLES. ,TRIGLYCERIDES LS(LABKIT)-QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SAMPLES. ,PROT CONTROL(LABKIT)-SERUM CONTROL FOR GENERAL TURBIDIMETRY ASSAY.,CALCIUM-AIII(LABKIT)-QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SAMPLES. ,LP(A) TURBI(LABKIT)-QUANTITATIVE DETERMINATION OF LP(A) IN HUMAN SAMPLES.,PROT CAL (LABKIT)-SERUM CALIBRATOR FOR GENERAL TURBIDIMETRY ASSAY., MICROALBUMIN TURBI(LABKIT)-QUANTITATIVE DETERMINATION OF MICROALBUMIN IN HUMAN SAMPLES. ,RF TURBI(LABKIT)-QUANTITATIVE DETERMINATION OF RHEUMATIOD FACTOR IN HUMAN

	SAMPLES. ,UREA UV-LQ(LABKIT)-QUANTITATIVE DETERMINATION OF URIC IN HUMAN SAMPLES. ,CITRIC ACID(LABKIT)-QUANTITATIVE DETERMINATION OF CITRIC IN HUMAN SAMPLES. ,CK-NAC LQ (LABKIT)-QUANTITATIVE DETERMINATION OF CREATININE KINASE (CK) ACTIVITY IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY.,HAPTO(LABKIT)-QUANTITATIVE DETERMINATION OF HAPTOGLOBIN IN HUMAN SAMPLES.,C3(LABKIT)-QUANTITATIVE DETERMINATION OF COMPLEMENT C3 IN HUMAN SAMPLES.,FERRITIN CTROL(LABKIT)-SERUM CONTROL FOR FERRITIN TURBIDIMETRY ASSAY..,BILIRUBIN T-DMSO(LABKIT)-QUANTITATIVE DETERMINATION OF BILIRUBIN IN HUMAN SAMPLES. ,ASO TURBI(LABKIT)-QUANTITATIVE DETERMINATION OF ASO IN HUMAN SAMPLES. ,TRF (LABKIT)-QUANTITATIVE DETERMINATION OF TRASFERRIN IN HUMAN SAMPLES.,BILIRUBIN D-DMSO(LABKIT)-QUANTITATIVE DETERMINATION OF BILIRUBIN IN HUMAN SAMPLES. ,C4(LABKIT)-QUANTITATIVE DETERMINATION OF COMPLEMENT C4 IN HUMAN SAMPLES.,ALP-LQ(LABKIT)-QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE (ALP) ACTIVITY IN HUMAN SAMPLES. ,ZINC LQ(LABKIT)-QUANTITATIVE DETERMINATION OF ZINC IN HUMAN SAMPLES. ,APO CAL(LABKIT)-SERUM CALIBRATOR FOR APO A1/B TURBIDIMETRY ASSAY.,CRP TURBI(LABKIT)-QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SAMPLES. , LDLC-D(LABKIT)-QUANTITATIVE DETERMINATION OF CHOLESTEROL LDL IN HUMAN SAMPLES. ,LACTATE(LABKIT)-QUANTITATIVE DETERMINATION OF LACTATE IN HUMAN SAMPLES. ,LDH-LQ(LABKIT) -QUANTITATIVE DETERMINATION OF LDH ACTIVITY IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY.,FRUCTOSAMINE(LABKIT) -QUANTITATIVE DETERMINATION OF FRUCTOSAMINE IN HUMAN SAMPLES. ,GPT/ALT-LQ(LABKIT)-QUANTITATIVE DETERMINATION OF GPT/ALT ACTIVITY IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY.,PROTEIN U&CSF(LABKIT)-QUANTITATIVE DETERMINATION OF TOTAL URINARY & CSF PROTEIN IN HUMAN SAMPLES. ,HDLC-D(LABKIT)-QUANTITATIVE DETERMINATION OF CHOLESTEROL HDL IN HUMAN SAMPLES. ,LABTROL H NORMAL (LABKIT)-MULTIPARAMETRIC CONTROL SERA INTENDED FOR ACCURACY CONTROL OF LABKIT CLINICAL CHEMISTRY REAGENTS. THE CONCENTRATIONS AND ACTIVITIES ARE IN THE NORMAL RANGE OR AT THE NORMAL THRESHOLD (HUMAN SOURCE) ,APO B(LABKIT)-QUANTITATIVE DETERMINATION OF HUMAN APOLIPOPROTEIN B(APO B),GAMMA GT LQ(LABKIT)-QUANTITATIVE DETERMINATION OF GAMMA-GT ACTIVITY IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY.,MAGNESIUM(LABKIT)-QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SAMPLES. ,PREALBUMIN(LABKIT)-QUANTITATIVE DETERMINATION OF PREALBUMIN IN HUMAN

		SAMPLES.,LABTROL H PATHOLOGICAL(LABKIT)-MULTIPARAMETRIC CONTROL SERA INTENDED FOR ACCURACY CONTROL OF LABKIT CLINICAL CHEMISTRY REAGENTS. THE CONCENTRATIONS AND ACTIVITIES ARE IN THE NORMAL RANGE OR AT THE NORMAL THRESHOLD (HUMAN SOURCE) ,URIC ACID LS(LABKIT)-QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SAMPLES. , CHLORIDE(LABKIT)-QUANTITATIVE DETERMINATION OF CHLORIDE IN HUMAN SAMPLES. ,CREATININE-J(LABKIT)-QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SAMPLES. ,AMYLASE-LQ (LABKIT)-QUANTITATIVE DETERMINATION OF THE ALPHA AMYLASE ACTIVITY IN HUMAN SAMPLES. ,GOT/AST-LQ(LABKIT)-QUANTITATIVE DETERMINATION OF GOT/AST ACTIVITY IN SERUM ONLY FOR IN VITRO USE IN CLINICAL CHEMISTRY.,ASO/CRP/RF CONTROL L (LABKIT)-SERUM CONTROL MUTICOMPONET FOR ASO,CRP,RF TURBIDIMETRY ASSAYS WITH VALUS IN NORMAL RANGE.,CITRIC AC. /OXALIC AC. CTROL 2 LEVELS(LABKIT)-MULTIPARAMETRIC CONTROL SERA INTENDED FOR ACCURACY CONTROL OF CITRIC ACID AND OXALIC CLINICAL CHEMISTRY REAGENTS. THE CONCENTRATIONS AND ACTIVITIES ARE IN THE NORMAL RANGE OR AT THE NORMAL THRESHOLD (HUMAN SOURCE) ,ACP(LABKIT)-QUANTITATIVE DETERMINATION OF ACID PHOSPHATASE (ACP) ACTIVITY IN HUMAN SAMPLES. ,TIBC(LABKIT)-QUANTITATIVE DETERMINATION OF IRON TIBC IN HUMAN SAMPLES. ,LABTROL H CAL(LABKIT)-MULTIPARAMETRIC CALIBRATOR INTENDED FOR THE CALIBRATION OF LABKIT REAGENTS.(HUMAN SOURCE) ,FERRITIN TURBI(LABKIT)-QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SAMPLES.
1107	IMP/IVD/2021/000268	1.License Holder Name: BIO STATE INC. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIRAL DNA/RNA NUCLEIC ACID EXTRACTION KIT (MAGNETIC BEAD METHOD)(VIRAL DNA/RNA NUCLEIC ACID EXTRACTION KIT (MAGNETIC BEAD METHOD))-THIS KIT CAN BE USED TO QUICKLY EXTRACT VIRAL DNA AND RNA FROM A VARIETY OF LIQUID SAMPLES SUCH AS SUCH AS SWAB, SPUTUM (SPUTUM SAMPLES NEED TO BE LIQUEFIED IN ADVANCE) AND STOOL SPECIMEN. THE PURIFIED VIRAL NUCLEIC ACID CAN BE DIRECTLY USED IN DOWNSTREAM ANALYSIS, SUCH AS PCR AMPLIFICATION, CLONING, AND SEQUENCE ANALYSIS. IT IS SUITABLE FOR THE DIAGNOSIS OF PATHOGEN, FORENSIC ANALYSIS AND GENETIC MUTATIONS DETECTION,SAMPLE PRESERVATION SOLUTION(SAMPLE PRESERVATION SOLUTION)-THIS KIT IS INTENDED FOR COLLECTION, TRANSPORT AND PRESERVATION OF CLINICAL SPECIMENS TO BE PROCESSED WITH MOLECULAR DIAGNOSTIC PLATFORMS

1108	IMP/IVD/2021/000269	1.License Holder Name: GENRUI BIOTECH INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:C-REACTIVE PROTEIN (CRP) TEST KIT (IMMUNOFLUORESCENCE)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF CRP IN HUMAN SERUM, PLASMA AND WHOLE BLOOD. CRP IS MAINLY USED AS AN INDICATOR OF NON-SPECIFIC INFLAMMATION.,HIGH SENSITIVE C-REACTIVE PROTEIN (HS-CRP) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF HIGH SENSITIVE C-REACTIVE PROTEIN (HS-CRP) CONTENT IN HUMAN SERUM OR WHOLE BLOOD., NUCLEIC ACID EXTRACTION KIT(GENRUI)-FOR NUCLEIC ACID EXTRACTION, ENRICHMENT, PURIFICATION AND OTHER STEPS. THE PROCESSED PRODUCT IS USED FOR CLINICAL IN VITRO TESTING,D-DIMER DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF D-DIMER CONTENT IN HUMAN PLASMA.,INTERLEUKIN 6 (IL-6) TEST KIT (IMMUNOFLUORESCENCE) (GENRUI)-USED FOR IN VITRO QUANTITATIVE DETECTION OF INTERLEUKIN-6 (IL-6) CONTENT IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD.,D-DIMER TEST KIT (IMMUNOFLUORESCENCE) (GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA AND WHOLE BLOOD. IT IS MAINLY USED CLINICALLY TO RULE OUT VENOUS THROMBOSIS, AS AN AID TO THE DIAGNOSIS OF DISSEMINATED INTRAVASCULAR COAGULATION AND TO MONITOR THROMBOLYTIC THERAPY.,C-REACTIVE PROTEIN DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) CONTENT IN HUMAN SERUM OR WHOLE BLOOD.

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1109	IMP/IVD/2021/000270	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALINITY C-SERIES DETERGENT A(ALINITY C-SERIES DETERGENT A)-THE ALINITY C-SERIES DETERGENT A IS AN ONBOARD SOLUTION USED IN DAILY MAINTENANCE, SELECTED DIAGNOSTIC PROCEDURES, AND IN CONJUNCTION WITH THE SMARTWASH FEATURE TO REDUCE CARRYOVER BETWEEN SPECIFIC ASSAY COMBINATIONS.,ALINITY C-SERIES DETERGENT B(ALINITY C-SERIES DETERGENT B)-THE ALINITY C-SERIES DETERGENT B IS AN ONBOARD SOLUTION USED WITH SELECTED DIAGNOSTIC PROCEDURES AND IN CONJUNCTION WITH THE SMARTWASH FEATURE TO REDUCE CARRYOVER BETWEEN SPECIFIC ASSAY COMBINATIONS.,ICT CLEANING FLUID(ICT CLEANING FLUID)-ICT CLEANING FLUID IS INTENDED FOR USE AS A CLEANING SOLUTION TO REMOVE PROTEIN FROM THE ICT UNIT AND CSYSTEMS PROBES.,ALINITY C-SERIES MAINTENANCE SOLUTIONS(ALINITY C-SERIES MAINTENANCE SOLUTIONS)-THE ALINITY C-SERIES MAINTENANCE SOLUTIONS ARE ONBOARD SOLUTIONS USED TO PERFORM THE AUTOMATED DAILY MAINTENANCE PROCEDURE AND SELECTED DIAGNOSTIC PROCEDURES ON THE ALINITY C ANALYZER.

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1110	IMP/IVD/2021/000271	1.License Holder Name: TCM LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 SPIKE PROTEIN TEST KIT (FLUORESCENCE IMMUNOASSAY)(FLUORECARE SARS-COV-2 SPIKE PROTEIN TEST KIT (FLUORESCENCE IMMUNOASSAY))-THE FLUORECARE® SARS-COV-2 SPIKE PROTEIN TEST KIT IS APPLICABLE TO THE QUALITATIVE DETECTION NOVEL CORONAVIRUS (SARS-COV-2) SPIKE PROTEIN IN POPULATION OROPHARYNGEAL SWABS OR NASOPHARYNGEAL SWABS SAMPLES IN VITRO.,SARS-COV-2 SPIKE PROTEIN TEST KIT (COLLOIDAL GOLD CHROMATOGRAPHIC IMMUNOASSAY)(FLUORECARE SARS-COV-2 SPIKE PROTEIN TEST KIT (COLLOIDAL GOLD CHROMATOGRAPHIC IMMUNOASSAY))-THE FLUORECARE® SARS-COV-2 SPIKE PROTEIN TEST KIT IS APPLICABLE TO THE QUALITATIVE DETECTION NOVEL CORONAVIRUS (SARS-COV-2) SPIKE PROTEIN IN POPULATION OROPHARYNGEAL SWABS OR NASOPHARYNGEAL SWABS SAMPLES IN VITRO ,SARS-COV-2 IGG AND IGM ANTIBODY COMBINED TEST KIT (COLLOIDAL GOLD CHROMATOGRAPHIC IMMUNOASSAY) (FLUORECARE SARS-COV-2 IGG AND IGM ANTIBODY COMBINED TEST KIT (COLLOIDAL GOLD CHROMATOGRAPHIC IMMUNOASSAY))-THE FLUORECARE® SARS-COV-2 IGG AND IGM ANTIBODY COMBINED TEST KIT IS APPLICABLE TO THE QUALITATIVE DETECTION OF SARS-COV-2 IGG AND IGM ANTIBODY IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,SARS-COV-2 IGG AND IGM ANTIBODY COMBINED TEST KIT (FLUORESCENCE IMMUNOASSAY)(FLUORECARE SARS-COV-2 IGG AND IGM ANTIBODY COMBINED TEST KIT (FLUORESCENCE IMMUNOASSAY))-THE FLUORECARE® SARS-COV-2 IGG AND IGM ANTIBODY COMBINED TEST KIT IS APPLICABLE TO THE QUALITATIVE DETECTION OF SARS-COV-2 IGG AND IGM ANTIBODY IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,SARS-COV-2 NEUTRALIZING ANTIBODY TEST KIT (FLUORESCENCE IMMUNOASSAY)(FLUORECARE SARS-COV-2 NEUTRALIZING ANTIBODY TEST KIT (FLUORESCENCE IMMUNOASSAY))-THE FLUORECARE® SARS-COV-2 NEUTRALIZING ANTIBODY TEST KIT IS APPLICABLE TO THE QUANTITATIVE TEST OF THE CONCENTRATION OF SARS-COV-2 NEUTRALIZING ANTIBODY TEST FOR HUMAN SERUM OR PLASMA.

1111	IMP/IVD/2021/000272	1.License Holder Name: OPERON BIOTECH & HEALTHCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PT-HS (QUIKCOAG)-THE QUIKCOAG PT-HS REAGENT IS AN IN VITRO DIAGNOSTIC ASSAY INTENDED FOR USE IN PERFORMING THE ONE STAGE PROTHROMBIN TIME (PT) TEST AND ASSAYS WHICH ARE BASED ON A MODIFIED PROTHROMBIN TIME.,APTT-EA (QUIKCOAG)-THE QUIKCOAG APTT-EA REAGENT IS AN IN VITRO DIAGNOSTIC ASSAY INTENDED FOR USE IN DETERMINING ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) AND COAGULATION FACTOR ASSAYS THAT ARE BASED ON A MODIFIED APTT.
1112	IMP/IVD/2021/000273	1.License Holder Name: FUGEN BIOMED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URINALYSIS REAGENT STRIP FOR 2 PARAMETERS(URS-2K)-IN VITRO TEST TO DETECT THE KETONES AND GLUCOSE IN URINE. ,URINALYSIS REAGENT STRIP FOR 10 PARAMETERS(URS-10H)-IN VITRO TEST TO DETECT THE UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY AND PH IN URINE. , URINALYSIS REAGENT STRIP FOR 1 PARAMETER(URS-1 KETONE)-IN VITRO TEST TO DETECT THE KETONES IN URINE. ,URINALYSIS REAGENT STRIP FOR 8 PARAMETERS(URS-8)-IN VITRO TEST TO DETECT THE UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, GLUCOSE, SPECIFIC GRAVITY AND PH IN URINE. ,URINALYSIS REAGENT STRIP FOR 4 PARAMETERS(URS-4SG)-IN VITRO TEST TO DETECT THE PROTEIN, SPECIFIC GRAVITY, PH AND GLUCOSE IN URINE. ,URINALYSIS REAGENT STRIP FOR 2 PARAMETERS(URS-2P)-IN VITRO TEST TO DETECT THE PROTEIN AND GLUCOSE IN URINE.

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1113	IMP/IVD/2021/000279	1.License Holder Name: BIO SCIENCE SALES CORPORATION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIPASE COLOUR(LIPASE COLOUR)-QUANTITATIVE DETERMINATION OF LIPASE IVD , CREATININE JAFFE COLOUR /KINETIC(CREATININE JAFFE COLOUR /KINETIC)-QUANTITATIVE DETERMINATION OF CREATININE ,URIC ACID URICASE(URIC ACID URICASE)-QUANTITATIVE DETERMINATION OF URIC ACID IVD ,HDL DIRECT COLOUR/ENZ(HDL DIRECT COLOUR/ENZ)-QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IVD ,BILIRUBIN TOTAL DPD(BILIRUBIN TOTAL DPD)-QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IVD ,ALP IFCC (ALP IFCC)-QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE (ALP) IVD ,HBA1C TURBILATEX(HBA1C TURBILATEX)-QUANTITATIVE DETERMINATION OF GLYCATED HEMOGLOBIN (HBA1BBC) IN HUMAN BLOOD IVD ,LDL DIRECT COLOUR/ENZ(LDL DIRECT COLOUR/ENZ)-QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IVD ,TOTAL PROTEIN BIURET(TOTAL PROTEIN BIURET)-QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IVD , BILIRUBIN DIRECT DPD(BILIRUBIN DIRECT DPD)-QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IVD ,CHOLESTEROL COLOUR /ENZ(CHOLESTEROL COLOUR /ENZ)-QUANTITATIVE DETERMINATION OF CHOLESTEROL IVD ,TRIGLYCERIDES GPD (TRIGLYCERIDES GPD)-QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IVD ,UREA KINETIC/UV(UREA KINETIC/UV)-QUANTITATIVE DETERMINATION OF UREA IVD ,ALT IFCC(ALT IFCC)-QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE ALT (GPT) IVD ,MULTICONTROL NORMAL(MULTICONTROL NORMAL)-SERUM CONTROL MULTICOMPONENT FOR CLINICAL CHEMISTRY ASSAYS IVD ,PHOSPHORUS UV(PHOSPHORUS UV)-QUANTITATIVE DETERMINATION OF PHOSPHORUS IVD ,ALBUMIN BCG(ALBUMIN BCG) -QUANTITATIVE DETERMINATION OF ALBUMIN IVD ,AST IFCC(AST IFCC)-QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE AST (GOT) IVD

1114	IMP/IVD/2021/000280	1.License Holder Name: ARKRAY HEALTHCARE PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST METER(GLUCOCARD SIGMA)-FOR QUANTITATIVELY MEASURING THE GLUCOSE LEVEL IN FRESH CAPILLARY WHOLE BLOOD,BLOOD GLUCOSE TEST METER(GLUCOCARD 01-MINI)-FOR QUANTITATIVELY MEASURING THE GLUCOSE LEVEL IN FRESH CAPILLARY WHOLE BLOOD ,BLOOD GLUCOSE TEST METER(GLUCOCARD 01-MINI PLUS)-FOR QUANTITATIVELY MEASURING THE GLUCOSE LEVEL IN FRESH CAPILLARY WHOLE BLOOD. ,BLOOD GLUCOSE TEST METER (GLUCOCARD VITAL)-FOR QUANTITATIVELY MEASURING THE GLUCOSE LEVEL IN FRESH CAPILLARY WHOLE BLOOD.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1115	IMP/IVD/2021/000282	1.License Holder Name: GENWORKS HEALTH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIGH SENSITIVE C REACTIVE PROTEIN (HS CRP) DETECTION KIT (NEPHELOMETRY) (GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF HIGH SENSITIVE C REACTIVE PROTEIN (HS CRP) CONTENT IN HUMAN SERUM OR WHOLE BLOOD., FIBRINOGEN DEGRADATION PRODUCT (FDP) DETECTION KIT (NEPHELOMETRY)(GENRUI)-THE KIT IS USED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FDP IN HUMAN SERUM.,D-DIMER DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF D DIMER CONTENT IN HUMAN PLASMA,CYSTATIN C (CYS C) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF CYSTATIN C (CYS C) CONTENT IN HUMAN SERUM OR PLASMA,ANTI CYCLIC CITRULLINATED PEPTIDE ANTIBODY ANTI CCP) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF ANTI CYCLIC CITRULLINATED PEPTIDE ANTIBODY (ANTI CCP) CONTENT IN HUMAN BLOOD,SERUM AMYLOID PROTEIN A (SAA) DETECTION KIT (NEPHELOMETRY) (GENRUI)-THE KIT IS USED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF SAA IN HUMAN SERUM, PLASMA AND WHOLE BLOOD.,COMPLEMENT C4 (C4) DETECTION KIT (NEPHELOMETRY) (GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF COMPLEMENT C 4 (C4) CONTENT IN HUMAN SERUM OR PLASMA, HUMAN MICRO ALBUMINURIA MALB DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF MICRO ALBUMINURIA (MALB) IN HUMAN URINE., IMMUNOGLOBULIN A (IGA) DETECTION KIT (NEPHELOMETRY) (GENRUI)- FOR IN VITRO QUANTITATIVE DETERMINATION OF IGA CONTENT IN HUMAN SERUM OR PLASMA. , RHEUMATOID FACTOR(RF) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) CONTENT IN HUMAN SERUM OR PLASMA,GLYCATED HEMOGLOBIN (HBA1C) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF THE PERCENTAGE CONTENT OF GLYCATEDHEMOGLOBIN IN HUMAN BLOOD.,C-REACTIVE PROTEIN (CRP) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF C REACTIVE PROTEIN (CRP) CONTENT IN HUMAN SERUM OR WHOLE BLOOD.,ANTI STREPTOLYSIN O (ASO) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF ANTI STREPTOLYSIN O (ASO) CONTENT IN HUMAN SERUM OR PLASMA.,IMMUNOGLOBULIN G (IGG) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF IGG CONTENT IN HUMAN SERUM

		OR PLASMA,COMPLEMENT C3 (C3) DETECTION KIT (NEPHELOMETRY) (GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF COMPLEMENT C3 (C3) CONTENT IN HUMAN SERUM OR PLASMA., IMMUNOGLOBULIN M (IGM) DETECTION KIT (NEPHELOMETRY) (GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF IGM CONTENT IN HUMAN SERUM OR PLASMA
1116	IMP/IVD/2021/000283	1.License Holder Name: NOVO HEALTHCARE LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIAZYME D-DIMER CONTROL SET, 2 X 1 ML(DIAZYME)-THE DIAZYME D-DIMER CONTROL SET IS INTENDED FOR USE AS QUANTITA-TIVE QUALITY CONTROLS FOR THE DIAZYME DDIMER ASSAY ONLY. FOR IN VITRO DIAGNOSTIC USE ONLY,DIAZYME D-DIMER ASSAY, KIT (LIQUID STABLE)(DIAZYME) -THE D-DIMER ASSAY IS FOR THE QUANTITATIVE DETERMINATION OF FIBRINOGEN/FIBRIN DEGRADATION PRODUCTS (D-DIMER) IN HUMAN PLASMA. MEASUREMENT OF D-DIMER IS USED AS AN AID IN DETECTING THE PRESENCE OF INTRAVASCU-LAR COAGULATION AND FIBRINOLYSIS. FOR IN VITRO DIAGNOSTIC USE ONLY,DIAZYME D-DIMER CALIBRATOR SET, 5 X 1 ML(DIAZYME)-THE DIAZYME D-DIMER CALIBRATOR SET IS INTENDED FOR USE IN THE CALIBRATION OF THE D-DIMER ASSAY ONLY. FOR IN VITRO DIAGNOSTIC USE ONLY.
1117	IMP/IVD/2021/000284	1.License Holder Name: M/S SAM LIFESTYLE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(WELLCHECK BLOOD GLUCOSE TEST STRIPS)-BLOOD GLUCOSE TEST STRIPS ARE USED WITH GLUCOMETER FOR QUANTITATIVE MEASURING OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD. THE GLUCOSE METER READS GLUCOSE LEVELS OF BLOOD SAMPLES ON A TEST STRIP. THE BLOOD GLUCOSE MONITORING SYSTEM IS PLASMA-CALIBRATED TO ALLOW COMPARISON OF RESULTS WITH LABORATORY METHODS. TEST STRIPS ARE FOR TESTING OUTSIDE THE BODY (IN-VITRO DIAGNOSTIC USE).

1118	IMP/IVD/2021/000286	1.License Holder Name: BIO-RAD LABORATORIES (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 POSITIVE RUN CONTROL(SARS-COV-2 POSITIVE RUN CONTROL)-EDX SARS-COV-2 POSITIVE RUN CONTROL IS AN EXTERNAL QUALITY CONTROL INTENDED TO BE USED WITH SARS-COV-2 ASSAYS TO MONITOR THE PERFORMANCE OF THAT GIVEN ASSAY. ROUTINE USE OF EDX SARS COV-2 POSITIVE RUN CONTROL ALLOWS LABORATORIES TO EVALUATE DAY-TODAY AND LOT-TO-LOT VARIATION OF THEIR MOLECULAR ASSAY AND TEST FOR OPERATOR PROFICIENCY.,SARS-COV-2 NEGATIVE RUN CONTROL(SARS-COV-2 NEGATIVE RUN CONTROL)-EDX SARS-COV-2 NEGATIVE RUN CONTROL IS AN EXTERNAL QUALITY CONTROL INTENDED TO BE USED WITH SARS-COV-2 ASSAYS TO MONITOR THE PERFORMANCE OF THAT GIVEN ASSAY. THE CONTROL IS USED TO MONITOR THE ABSENCE OF SARS-COV-2. ROUTINE USE OF EDX SARS-COV-2 NEGATIVE RUN CONTROL ALLOWS LABORATORIES TO EVALUATE DAY-TO-DAY AND LOT-TO-LOT VARIATION OF THEIR MOLECULAR ASSAY AND TEST FOR OPERATOR PROFICIENCY.
1119	IMP/IVD/2021/000287	1.License Holder Name: HUMOLE DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIRAL DNA/RNA EXTRACTION KIT (PLATE TYPE, SINGLE TUBE TYPE)(GENEFINDER™)-GENEFINDER™ VIRAL DNA/RNA EXTRACTION KIT IS DESIGNED TO EXTRACT AND ISOLATE VIRAL DNA/RNA FROM HUMAN SAMPLE USING AUTOMATED GENEFINDER™ EX-MATE 32 PLUS AND EX-MATE 32 SYSTEM.,GENOMIC DNA EXTRACTION KIT (PLATE TYPE, SINGLE TUBE TYPE)(GENEFINDER™)-GENEFINDER™ GENOMIC DNA EXTRACTION KIT IS DESIGNED TO EXTRACT AND ISOLATE GENOMIC DNA FROM HUMAN SAMPLE USING AUTOMATED GENEFINDER™ EX-MATE 32 PLUS AND EX-MATE 32 SYSTEM.,HLA-B 27 REALAMP KIT (GENEFINDER™)-GENEFINDER™ HLA-B*27 REALAMP KIT IS DESIGNED FOR DIRECT, QUALITATIVE DETECTION OF THE HLA-B*27 GENE IN THE HUMAN DNA SAMPLE. THE TEST IS INTENDED FOR USE AS AN AID IN DIAGNOSIS OF HLA-B*27 ASSOCIATED DISEASE IN PATIENTS., WHOLE BLOOD DNA EXTRACTION KIT (PLATE TYPE, SINGLE TUBE TYPE)(GENEFINDER™)-GENEFINDER™ WHOLE BLOOD DNA EXTRACTION KIT IS DESIGNED TO EXTRACT AND ISOLATE WHOLE BLOOD DNA FROM HUMAN SAMPLE USING AUTOMATED GENEFINDER™ EX-MATE 32 PLUS AND EXMATE 32 SYSTEM.

1120	IMP/IVD/2021/000288	1.License Holder Name: EPSILON DIAGNOSTICS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REAGENT PACK FOR 921E (CARETIUM)-FOR IN VITRO DIAGNOSTIC USE ONLY, USE FOR ONLY WITH XI-921 SERIES ELECTROLYTE ANALYZERS,K,NA,CL,PH FILLING SOLUTION(CARETIUM)-PASSING THE MEMBRANE POTENTIAL OF CALCIUM ELECTRODE TO THE AG/AGCL INTERNAL ELECTRODE AND CALIBRATING THE SODIUM, CHLORINIUM, PH ELECTRODE POTENTIAL. FILLING SOLUTION FOR PH,NA+ AND CL- ELECTRODE., REF, FILLING SOLUTION(CARETIUM)-PASSING THE REFERENCE MEMBRANE POTENTIAL TO THE AG/AGCL INTERNAL ELECTRODE, AND PROVING A CONSTANT REFERENCE POTENTIAL FOR THE MEASUREMENT OF REF ELECTRODE POTENTIAL. FILLING SOLUTION FOR THE REFERENCE ELECTRODE,NA CONDITIONER(CARETIUM)-ACTIVATING NATHIUM ELECTRODE AND IMPROVING THE SENSITIVITY AND STABILITY OF THE ELECTRODE. USE FOR ONLY WITH XL-921 SERIES ELECTROLYTE ANALYZERS,URINE SOLUTION(CARETIUM)-DILUTING THE URINE SAMPLE (1:1), USE FOR ONLY WITH XL-921 SERIES ELECTROLYTE ANALYZERS,REAGENT PACK FOR 921F (CARETIUM)-FOR IN-VITRO DIAGNOSTIC USE, USE FOR ONLY WITH XI-921 SERIES ELECTROLYTE ANALYZES,K FILLING SOLUTION (CARETIUM)-PASSING THE MEMBRANE POTENTIAL OF CALCIUM ELECTRODE TO THE AG/AGCL INTERNAL ELECTRODE AND CALIBRATING THE K ELECTRODE POTENTIAL. FILLING SOLUTION FOR K ELECTRODE.,C STANDARD(CARETIUM)-FOR CALIBRATING STABILITY OF THE LI ELECTRODE. USE FOR ONLY WITH XL-921 SERIES ELECTROLYTE ANALYZERS,LI FILLING SOLUTION(CARETIUM) -PASSING THE REFERENCE MEMBRANE POTENTIAL TO THE AG/AGCL INTERNAL ELECTRODE, AND PROVIDING A CONSTANT REFERENCE POTENTIAL FOR THE MEASUREMENT OF LI ELECTRODE POTENTIAL FILLING SOLUTION FOR LI ELECTRODE,WEEKLY CLEALING SOLUTION (CARETIUM)-REMOVING PROTEIN DEPOSIT INSIDE THE ELECTRODE MEMBRANE AND TUBE, TO IMPROVE THE SENSITIVITY AND STABILITY OF THE ELECTRODES. USE FOR ONLY WITH XL-921 SERIES ELECTROLYTE ANALYZERS
1121	IMP/IVD/2021/000290	1.License Holder Name: REGULATORY1 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIGEN TEST KIT (LFIA)(NA)-SARS-COV-2 ANTIGEN TEST KIT (LFIA) IS USED TO QUALITATIVELY DETECT SARS-COV-2 INHUMAN SAMPLES IN VITRO.

1122	IMP/IVD/2021/000292	1.License Holder Name: TCM LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FREE THYROXINE (FT4) DIAGNOSTIC KIT(FREE THYROXINE (FT4) DIAGNOSTIC KIT)-THE FLUORECARE ® FT4 IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF FT4 IN HUMAN SERUM OR PLASMA.,SERUM AMYLOID A (SAA) DIAGNOSTIC KIT(SERUM AMYLOID A (SAA) DIAGNOSTIC KIT)-THE FLUORECARE® SAA IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF SAA IN HUMAN SERUM AND PLASMA.,TESTOSTERONE (T) DIAGNOSTIC KIT (TESTOSTERONE (T) DIAGNOSTIC KIT)-THE FLUORECARE ® TESTOSTERONE IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF TESTOSTERONE IN HUMAN SERUM .,H. PYLORI ANTIGEN (HP-AG) DIAGNOSTIC KIT(COLLIDAL GOLD ASSAY) (H.PYLORI ANTIGEN (HP-AG) DIAGNOSTIC KIT(COLLIDAL GOLD ASSAY))-THE FLUORECARE ® HP AG DIAGNOSTIC KIT IS AN IN VITRO QUALITATIVE IMMUNO CHROMATOGRAPHIC ASSAY FOR THE RAPID DETECTION OF HELICOBACTER PYLORI ANTIGENS IN HUMAN FECAL SAMPLES. THE TEST MIGHT BE USED AS AN AID FOR DETECTING PATIENTS WITH ACUTE GASTROENTERITIS INFECTED WITH HELICOBACTER PYLORI. THE TEST IS FOR PROFESSIONAL USE ONLY., GLYCOSYLATED HEMOGLOBIN (HBA1C) DIAGNOSTIC KIT (GLYCOSYLATED HEMOGLOBIN (HBA1C) DIAGNOSTIC KIT)-THE FLUORECARE ® HBA1C IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF HBA1C IN HUMAN WHOLE BLOOD.,HEART-TYPE FATTY ACID-BINDING PROTEIN (H-FABP) DIAGNOSTIC KIT(HEART-TYPE FATTY ACID-BINDING PROTEIN (H-FABP) DIAGNOSTIC KIT)-THE FLUORECARE® H-FABP IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF H-FABP IN HUMAN SERUM AND PLASMA.,C-REACTIVE PROTEIN (CRP) DIAGNOSTIC KIT(C-REACTIVE PROTEIN (CRP) DIAGNOSTIC KIT)-THE FLUORECARE ® CRP IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF CRP IN HUMAN SERUM , PLASMA AND WHOLE BLOOD.,N-TERMINAL PRO BRAIN TYPE NATRIURETIC PEPTIDE (NT-PROBNP) DIAGNOSTIC KIT(N-TERMINAL PRO BRAIN TYPE NATRIURETIC PEPTIDE (NT-PROBNP) DIAGNOSTIC KIT)-THE FLUORECARE ® NT PROBNP IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF NT PROBNP IN HUMAN SE RUM AND PLASMA.,CYSTATIN C (CYS-C) DIAGNOSTIC KIT(CYSTATIN C (CYS-C) DIAGNOSTIC KIT)-THE FLUORECARE ® CYS C IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF CYS C IN HUMAN SERUM AND PLASMA., CARDIAC TROPONIN I (CTNI) DIAGNOSTIC KIT(CARDIAC TROPONIN I (CTNI) DIAGNOSTIC KIT)-THE FLUORECARE ® CTNI IS APPLICABLE TO

	THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF CTNI IN HUMAN SERUM AND PLASMA.,25-HYDROXYVITAMIN D (25-OH-D) DIAGNOSTIC KIT(25-HYDROXYVITAMIN D (25-OH-D) DIAGNOSTIC KIT) -THE FLUORECARE ® 25 OH D IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF 25 OH D IN HUMAN SERUM AND PLASMA.,TRIIODOTHYRONINE (T3) DIAGNOSTIC KIT (TRIIODOTHYRONINE (T3) DIAGNOSTIC KIT)-THE FLUORECARETM T3 DIAGNOSTIC KIT IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF T3 IN HUMAN SERUM AND PLASMA., FREE TRIIODOTHYRONINE (FT3) DIAGNOSTIC KIT(FREE TRIIODOTHYRONINE (FT3) DIAGNOSTIC KIT)-THE FLUORECARE ® FT3 IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF FT3 IN HUMAN SERUM OR PLASMA .,INSULIN (INS) DIAGNOSTIC KIT(INSULIN (INS) DIAGNOSTIC KIT)-THE FLUORECARE ® INSULIN IS AN IMMUNOASSAY SYSTEM FOR QUANTITATIVE DETECTION OF THE CONCENTRATION OF INSULIN IN HUMAN SERUM AND PLASMA WITH MF T1000 READER.,FOLLICLE STIMULATING HORMONE (FSH) DIAGNOSTIC KIT(FOLLICLE STIMULATING HORMONE (FSH) DIAGNOSTIC KIT)-THE FLUORECARE ® FSH IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF FSH IN HUMAN SERUM AND PLASM A.,C-PEPTIDE (C-P) DIAGNOSTIC KIT(C-PEPTIDE (C-P) DIAGNOSTIC KIT)-THE FLUORECARE TM FOLLICLE STIMULATING HORMONE (C-PEPTIDE) DIAGNOSTIC KIT IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF FOLLICLE STIMULATING HORMONE (C-PEPTIDE) IN HUMAN SERUM AND PLASMA.,FERRITIN (FERR) DIAGNOSTIC KIT(FERRITIN (FERR) DIAGNOSTIC KIT)-THE FLUORECARE® FERRITIN IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF FERRITIN IN HUMAN SERUM AND PLASMA.,ANTI-MULLERIAN HORMONE (AMH) DIAGNOSTIC KIT (ANTI-MULLERIAN HORMONE (AMH) DIAGNOSTIC KIT)-THE FLUORECARE ® AMH IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF AMH IN HUMAN SERUM AND PLASMA,URINARY MICROALBUMI (MAU) DIAGNOSTIC KIT(URINARY MICROALBUMI (MAU) DIAGNOSTIC KIT)-THE FLUORECARE ® MAU IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF MAU IN HUMAN URINE.,CREATINE KINASE ISOENZYME (CK-MB) DIAGNOSTIC KIT(CREATINE KINASE ISOENZYME (CK-MB) DIAGNOSTIC KIT)-THE FLUORECARE ® CK MB IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF CK MB IN HUMAN SERUM AND PLA SMA., THYROXINE (T4) DIAGNOSTIC KIT(THYROXINE (T4) DIAGNOSTIC KIT)-THE FLUORECARE ® T4 IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF T4 IN HUMAN SERUM OR

	PLASMA.,BETA SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN (-HCG) DIAGNOSTIC KIT(BETA SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN (-HCG) DIAGNOSTIC KIT)-THE FLUORECARE ® HCG IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF HCG IN HUMAN SERUM AND PLASMA., LUTEINIZING HORMONE (LH) DIAGNOSTIC KIT(LUTEINIZING HORMONE (LH) DIAGNOSTIC KIT)-THE FLUORECARE ® LH IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF LH IN HUMAN SERUM AND PLASMA.,THYROID STIMULATING HORMONE (TSH) DIAGNOSTIC KIT(THYROID STIMULATING HORMONE (TSH) DIAGNOSTIC KIT)-THE FLUORECARE ® TSH IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF TSH IN HUMAN SERUM AND PLASMA.,CORTISOL (COR) DIAGNOSTIC KIT(CORTISOL (COR) DIAGNOSTIC KIT)-THE FLUORECARE® CORTISOL IS AN IMMUNOASSAY SYSTEM FOR QUANTITATIVE DETECTION OF THE CONCENTRATION OF CORTISOL IN HUMAN SERUM AND PLASMA,D-DIMER DIAGNOSTIC KIT(D-DIMER DIAGNOSTIC KIT)-THE FLUORECARE ® D DIMER IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF D DIMER IN HUMAN PLASMA.,PROGESTERONE (P) DIAGNOSTIC KIT (PROGESTERONE (P) DIAGNOSTIC KIT)-THE FLUORECARE ® PROGESTERONE IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF PROGESTERONE IN HUMAN SERUM OR PLASMA.,MYOGLOBIN (MYO) DIAGNOSTIC KIT(MYOGLOBIN (MYO) DIAGNOSTIC KIT)-THE FLUORECARE ® MYO IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF MYO IN HUMAN SERUM AND PLASMA.,PROCALCITONIN (PCT) DIAGNOSTIC KIT(PROCALCITONIN (PCT) DIAGNOSTIC KIT)-THE FLUORECARE ® PCT IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF PCT IN HUMAN SERUM AND PLASM A., PROLACTIN (PRL) DIAGNOSTIC KIT(PROLACTIN (PRL) DIAGNOSTIC KIT)-THE FLUORECARE ® PRL IS APPLICABLE TO THE QUANTITATIVE DETECTION OF THE CONCENTRATION OF PRL IN HUMAN SERUM AND PLASMA.

1123	IMP/IVD/2021/000293	1.License Holder Name: PADMANABHA LABS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TSV KIT(IQ PLUS TM)-USES IIPCR TO DETECT THE RNA OF TAURA SYNDROME VIRUS (TSV)., WSSV KIT(IQ PLUS TM)-USES IIPCR TO DETECT THE DNA OF WHITE SPOT SYNDROME VIRUS.,IRIDO-M KIT(IQ PLUS TM)-USES IIPCR TO DETECT THE DNA OF MARINE FISH IRIDO-MEGALOCYTIVIRUSES.,IMNV KIT(IQ PLUS TM)-USES IIPCR TO DETECT RNA OF INFECTIOUS MYONECROSIS VIRUS.,AHPND /EMS TOXIN 1 KIT(IQ PLUS TM)-USES IIPCR TO DETECT AND SCREEN AHPND/EMS VIRULENCE PLASMID.,V. HARVEYI KIT(IQ PLUS TM)-USES IIPCR TO DETECT THE GENOME SEQUENCE OF VIBRIO HARVEYI.,TILV REAGENT SET(IQ PLUS TM)-USES IIPCR TO DETECT THE SPECIFIC NUCLEIC ACID(NA) SEQUENCE OF TILAPIA LAKE VIRUS.,VNN KIT(IQ PLUS TM)-USES IIPCR TO DETECT THE RNA OF NERVOUS NECROSIS VIRUS.,YHV KIT(IQ PLUS TM)-USES IIPCR TO DETECT THE RNA OF YELLOW HEAD VIRUS.,IRIDO-RG KIT(IQ PLUS TM)-USES IIPCR TO DETECT THE DNA OF MARINE FISH IRIDO-RANAVIRUSES. ,AHPND /EMS PLASMID KIT(IQ PLUS TM)-USES IIPCR TO DETECT AND SCREEN AHPND/ EMS PLASMIDS. ,PVNV KIT(IQ PLUS TM)-USES IIPCR TO DETECT THE RNA OF PENAEUS VANNAMEI NODAVIRUS.,EHP REAGENT SET(IQ PLUS TM)-USES IIPCR TO DETECT SPECIFIC NA SEQUENCE OF ENTEROCYTOZOON HEPATOPENAEI., CMNV REAGENT SET(IQ PLUS TM)-USES IIPCR TO DETECT SPECIFIC NA SEQUENCE OF COVERT MORTALITY NODAVIRUS.,NHPB KIT(IQ PLUS TM)-USES IIPCR TO DETECT DNA OF NECROTIZING HEPATOPANCREATITIS BACTERIUM. ,IHHNV KIT(IQ PLUS TM)-USES IIPCR TO DETECT DNA OF INFECTIOUS HYPODERMAL AND HEMATOPOIETIC NECROSIS VIRUS.

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1124	IMP/IVD/2021/000294	1.License Holder Name: SYNERGY MEDICAL SYSTEMS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DE-PROTEINIZER (CORNLEY)-INTENDED TO MAINTAIN K+, CA+,CL- ELECTRODE ON CORNELY ELECTROLYTE ANALYZER.,CLEANING SOLUTION (CORNLEY)-INTENDED TO PROVIDE THOROUGH CLEANING OF THE REAGENT PATH.,CONDITIONING SOLUTION(CORNLEY)-INTENDED TO MAINTAIN NA+, PH ELECTRODES ON CORNLEY ELECTROLYTE ANALYZER.,ELECTROLYTES QUALITY CONTROL(CORNLEY)-INTENDED FOR QUALITY CONTROL OF REAGENT KITS INTENDED FOR ESTIMATION OF SODIUM, POTASSIUM , CHLORIDE, CALCIUM AND PH PARAMETERS INSERUM /PLASMA / OTHER BODY FLUIDS.,REFILL SOLUTION FOR REFERENCE ELECTRODE(CORNLEY)-FILLING SOLUTION FOR USING ELECTROLYTE ANALYZER ; REFILL SOLUTION FOR REFERENCE ELECTRODE IS INTENDED TO PROVIDE REFERENCE POTENTIAL FOR INTERNAL ELECTRODE OF REF ELECTRODE., CALIBRATION STANDARD SOLUTION(CORNLEY)-REAGENT KIT INTENDED FOR THE ESTIMATION OF SODIUM ,POTASSIUM,CHLORIDE, CALCIUM AND PH PARAMETERS INSERUM/ PLASMA /OTHER BODY FLUIDS.,CALIBRATION STANDARD SOLUTION(CORNLEY)-INTENDED TO DILUTE THE URINE SAMPLE WHICH PLAN TO BE TESTED ON CORNLEY.,REFILL SOLUTION FOR K+/NA+/CL-/CA++/PH/LI ELECTRODES(CORNLEY)-INTENDED TO PROVIED PROPER FUNCTIONING OF ELECTRODE UESD FOR ESTIMATION OF SODIUM, POTASSIUM, CHLORIDE, CALCIUM AND PH PARAMETERS INSERUM/ PLASMA /OTHER BODY FLUIDS.

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1125	IMP/IVD/2021/000295	1.License Holder Name: RIVAARA LABS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACTIM® FECAL BLOOD (ACTIM® FECAL BLOOD)-THE ACTIM FECAL BLOOD TEST IS A VISUALLY INTERPRETED, QUALITATIVE IMMUNOCHROMATOGRAPHIC DIPSTICK TEST FOR DETECTING OCCULT BLOOD IN FECES. THE ACTIM FECAL BLOOD TEST DETECTS HUMAN HEMOGLOBIN IN A FECES SUSPENSION. THE TEST IS INTENDED FOR PROFESSIONAL USE TO HELP DIAGNOSE GASTROINTESTINAL BLEEDING.,ACTIM COMBI® HEMOGLOBIN. TRANSFERRIN.(ACTIM COMBI® HEMOGLOBIN. TRANSFERRIN.)-THE ACTIM COMBI HEMOGLOBIN TRANSFERRIN TEST IS A VISUALLY INTERPRETED, QUALITATIVE IMMUNOCHROMATOGRAPHIC DIPSTICK TEST FOR DETECTING OCCULT BLOOD IN FECES. THE ACTIM COMBI HEMOGLOBIN TRANSFERRIN TEST DETECTS HUMAN HEMOGLOBIN AND HUMAN TRANSFERRIN IN A FECES SUSPENSION. THE TEST IS INTENDED FOR PROFESSIONAL USE TO HELP DIAGNOSE GASTROINTESTINAL BLEEDING.,ACTIM® CALPROTECTIN(ACTIM® CALPROTECTIN)-THE ACTIM CALPROTECTIN TEST IS A VISUALLY INTERPRETED, SEMIQUANTITATIVE IMMUNOCHROMATOGRAPHIC DIPSTICK TEST, WHICH IS USED FOR DETERMINATION AND MONITORING OF CALPROTECTIN CONCENTRATIONS IN FECES. THE TEST IS INTENDED FOR PROFESSIONAL USE TO HELP DIAGNOSE INTESTINAL INFLAMMATION. ,ACTIM® PANCREATITIS(ACTIM® PANCREATITIS)-THE ACTIM PANCREATITIS TEST IS A VISUALLY INTERPRETED, QUALITATIVE IMMUNOCHROMATOGRAPHIC DIPSTICK TEST FOR USE WHEN ACUTE PANCREATITIS IS SUSPECTED. THE TEST IS BASED ON DETECTION OF ELEVATED LEVELS OF TRYPSINOGEN-2 IN URINE.
1126	IMP/IVD/2021/000296	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIGEN RAPID TEST(FLOWFLEX)-FOR QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID ANTIGENS IN NASAL NASOPHARYNGEAL SWAB SPECIMENS

1127	IMP/IVD/2021/000297	1.License Holder Name: INVEX HEALTH PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:2019- NCOV ANTIGEN TEST(WONDFO)-WONDFO 2019-NCOV ANTIGEN TEST (LATERAL FLOW METHOD) IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE DETECTION OF NOVEL CORONAVIRUS (2019-NCOV) ANTIGEN EXTRACTED FROM THE NASOPHARYNGEAL SWAB OR OROPHARYNGEAL SWAB SPECIMEN. THE TEST IS TO BE USED AS AN AID FOR THE DIAGNOSIS OF CORONAVIRUS INFECTION DISEASE (COVID-19), WHICH IS CAUSED BY 2019-NCOV. THE TEST MAY BE USED BY PROFESSIONALS IN LABORATORY AND NON-LABORATORY SETTINGS.THE TEST PROVIDES PRELIMINARY TEST RESULTS. NEGATIVE RESULTS CAN NOT EXCLUDE 2019-NCOV INFECTION AND THEY CANNOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISION. FOR IN VITRO DIAGNOSTIC USE ONLY.
1128	IMP/IVD/2021/000298	1.License Holder Name: PINKTECH DESIGN PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:96 SARS-COV-2 KIT-THE 96 SARS-COV-2 KIT IS INTENDED TO BE USED FOR THE QUALITATIVE DETECTION OF RNA FROM SARS-COV-2 IN UPPER RESPIRATORY SPECIMENS FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. RESULTS ARE FOR THE IDENTIFICATION OF SARS-COV-2 RNA. THE SARS-COV-2 RNA IS GENERALLY DETECTABLE IN UPPER RESPIRATORY SPECIMENS DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS ARE INDICATIVE OF THE PRESENCE OF SARS-COV-2 RNA; CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR PATIENT MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. THE 96 SARS-COV-2 KIT IS INTENDED TO BE USED BY A LABORATORY PROFESSIONAL PROFICIENT WITH MOLECULAR BIOLOGY TECHNIQUES. THE KIT IS INTENDED TO BE RUN ON THE FOLLOWING REAL-TIME THERMOCYCLER PLATFORMS: • ROCHE LIGHTCYCLER® 480 II • APPLIED BIOSYSTEMS® 7500 FAST REAL-TIME PCR INSTRUMENT • BIO-RAD CFX96 REAL-TIME PCR DETECTION SYSTEM

1129	IMP/IVD/2021/000299	1.License Holder Name: KOPRAN LABORATORIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:D-DIMER CONTROL SET (DIAZYME)-THE DIAZYME D-DIMER CONTROL SET IS INTENDED FOR USE AS QUANTITATIVE QUALITY CONTROLS FOR THE DIAZYME D-DIMER ASSAY ONLY. FOR IN VITRO DIAGNOSTIC USE ONLY., D-DIMER ASSAY(DIAZYME)-THE D-DIMER ASSAY IS FOR THE QUANTITATIVE DETERMINATION OF FIBRINOGEN/FIBRIN DEGRADATION PRODUCTS (D-DIMER) IN HUMAN PLASMA. MEASUREMENT OF D-DIMER IS USED AS AN AID IN DETECTING THE PRESENCE OF INTRAVASCULAR COAGULATION AND FIBRINOLYSIS. FOR IN VITRO DIAGNOSTIC USE ONLY.,D-DIMER CALIBRATOR SET(DIAZYME)-THE DIAZYME D-DIMER CALIBRATOR SET IS INTENDED FOR USE IN THE CALIBRATION OF THE D-DIMER ASSAY ONLY. FOR IN VITRO DIAGNOSTIC USE ONLY.

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1130	IMP/IVD/2021/000300	1.License Holder Name: GENWORKS HEALTH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIACON P(DIALAB)-LYOPHILIZED UNIVERSAL CONTROL SERUM FOR THE USE IN TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES IN HUMAN SAMPLES ON PHOTOMETRIC SYSTEMS.,ASO 5+1(DIALAB)-DIAGNOSTIC REAGENT FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ASO (ANTI-STREPTOLYSIN O) IN HUMAN SERUM BY TURBIDIMETRIC ASSAY,APO B 5+1(DIALAB)-DIAGNOSTIC REAGENT FOR THE QUANTITATIVE IN VITRO DETERMINATION OF APO B (APOLIPOPROTEIN B) INHUMAN SERUM BY TURBIDIMETRIC ASSAY, LP(A) CALIBRATOR HIGH(DIALAB)-AQUEOUS CALIBRATOR USED FOR CALIBRATION OF TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPOPROTEIN A IN HUMAN SERUM BY TURBIDIMETRIC ASSAY.,CK-MB OPT. DGKC / IFCC(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATINE KINASE (CK-MB) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,CHOLINESTERASE OPT. DGKC (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHOLINESTERASE (CHE) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,LIPASE ENZYMATIC, COLORIMETRIC(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF LIPASE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,APO A1/A2/B CALIBRATOR HIGH (DIALAB)-LYOPHILIZED HUMAN BASED CALIBRATOR FOR USE IN THE CALIBRATION OF IMMUNOTURBIDIMETRIC ASSAYS,CARBON DIOXIDE (CO2, BICARBONATE) PEP-C(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE (CO2) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,LP(A) (DIALAB)-DIAGNOSTIC REAGENT FOR THE QUANTITATIVE IN VITRO DETERMINATION OF LIPOPROTEIN (A) (LP(A)) IN HUMAN SERUM BY TURBIDIMETRIC ASSAY,COMPLEMENT C4 5+1(DIALAB)-DIAGNOSTIC REAGENT FOR THE QUANTITATIVE IN VITRO DETERMINATION OF COMPLEMENT C4 IN HUMAN SERUM BY TURBIDIMETRIC ASSAY, COMPLEMENT C3 5+1(DIALAB)-DIAGNOSTIC REAGENT FOR THE QUANTITATIVE IN VITRO DETERMINATION OF COMPLEMENT C3 IN HUMAN SERUM BY TURBIDIMETRIC ASSAY,CERULOPLASMIN 5+1 (DIALAB)-DIAGNOSTIC REAGENT FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CERULOPLASMIN IN HUMAN SERUM BY TURBIDIMETRIC ASSAY,UREA STANDARD(DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF UREA IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS.,APO A1 5+1 (DIALAB)-DIAGNOSTIC REAGENT FOR THE QUANTITATIVE IN VITRO

	DETERMINATION OF APO A1 (APOLIPOPROTEIN A1) IN HUMAN SERUM BY TURBIDIMETRIC ASSAY,PROTEIN CALIBRATOR HIGH(DIALAB)-LIQUID HUMAN BASED CALIBRATOR FOR USE AS A CALIBRATOR IN IMMUNOTURBIDIMETRIC ASSAYS,HEMOLYSIS REAGENT(DIALAB)-FOR THE PREPARATION OF SAMPLES USED IN THE DIALAB HBA1C DIRECT ASSAY,LACTATE ENZYMATIC, UV(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LACTATE IN HUMAN PLASMA OR CSF ON PHOTOMETRIC SYSTEMS, CO2 STANDARD(DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF BICARBONATE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,AMMONIA STANDARD(DIALAB)-STANDARD FOR THE USE IN TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF AMMONIA IN HUMAN PLASMA ON PHOTOMETRIC SYSTEMS,ZINC, STANDARD(DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR QUANTITATIVE IN-VITRO DETERMINATION OF ZINC IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS.,HOMOCYSTEINE CONTROL SET, 4 LEVELS (DIALAB)-HUMAN BASED SERUM FOR QUALITY CONTROL OF QUANTITATIVE IN VITRO DETERMINATION OF HOMO CYSTEINE IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS.,HOMOCYSTEINE CALIBRATOR SET, 5 LEVELS(DIALAB)-HUMAN BASED CALIBRATION SERUM FOR THE QUANTITATIVE IN VITRO DETERMINATION OF HOMOCYSTEINE IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS., IRON, FERENE(DIALAB)-DIAGNOSTIC REAGENT FOR THE QUANTITATIVE IN VITRO DETERMINATION OF IRON IN HUMAN SERUM AND PLASMA ON PHOTOMETRIC SYSTEMS,CALCIUM STANDARD (DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS., COPPER STANDARD(DIALAB)-STANDARD FOR THE CALIBRATION OF TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF COPPER INHUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,RF 5+1 (DIALAB)-DIAGNOSTIC REAGENT FOR THE QUANTITATIVE IN VITRO DETERMINATION OF RF (RHEUMATOID FACTOR) IN HUMAN SERUM BY TURBIDIMETRIC ASSAY,DIACAL CK-MB(DIALAB)-LYOPHILIZED CALIBRATION SERUM FOR THE USE IN TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CK-MB ACTIVITY ON PHOTOMETRIC SYSTEMS.,ALKALINE PHOSPHATASE MOD. IFCC(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALKALINE PHOSPHATASE (ALP) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,BILIRUBIN AUTO DIRECT, DCA(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM OR

	PLASMA ON PHOTOMETRIC SYSTEMS.,CREATININE STANDARD (DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS., BILE ACIDS ENZYMATIC CYCLING(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILE ACIDS IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,GLUCOSE STANDARD(DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS.,TRIPLE CONTROL (ASO, CRP, RF)(DIALAB)-LIQUID HUMAN BASED CONTROL SERUM FOR USE AS A CONTROL IN IMMUNOTURBIDIMETRIC ASSAYS FOR ASO, CRP AND RF,SODIUM, ENZYMATIC(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF SODIUM IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS.,ALBUMIN STANDARD(DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,ZINC, 5-BR-PAPS (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ZINC IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS,CHOLESTEROL HDL DIRECT, IMMUNOINHIBITION(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,LDH-L, IFCC(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF LACTATE DEHYDROGENASE(LDH-L) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,UIBC, FERENE(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF UNSATURATED IRON BINDING CAPACITY (UIBC) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,AMMONIA ENZYMATIC, UV (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF AMMONIA IN HUMAN PLASMA ON PHOTOMETRIC SYSTEMS.,RF CALIBRATOR HIGH(DIALAB)-LIQUID HUMAN BASED CALIBRATOR FOR USE AS A CALIBRATOR IN IMMUNOTURBIDIMETRIC ASSAYS FOR RF,PROTEIN TOTAL STANDARD(DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PROTEIN TOTAL IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,BETA-HYDROXYBUTYRATE ENZYMATIC, UV(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF BETA-HYDROXYBUTYRATE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,CO2 CONTROL(DIALAB)-CONTROL

	MATERIAL FOR QUALITY CONTROL OF THE QUANTITATIVE IN VITRO DETERMINATION OF CARBON DIOXIDE (CO2, BICARBONATE) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,COPPER 3,5-DIBR-PAESA(DIALAB)-QUANTITATIVE IN VITRO DETERMINATION OF COPPER IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,CHOLESTEROL STANDARD(DIALAB)-AQUEOUS STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,BETA-HYDROXYBUTYRATE STANDARD (DIALAB)-STANDARD FOR THE CALIBRATION OF TESTS FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF BETA-HYDROXYBUTYRATE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS,DIACON N(DIALAB)-LYOPHILIZED UNIVERSAL CONTROL SERUM FOR THE USE IN TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES IN HUMAN SAMPLES ON PHOTOMETRIC SYSTEMS.,BILE ACIDS STANDARD(DIALAB)-STANDARD FOR THE CALIBRATION OF TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL BILE ACIDS IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,CK-NAC OPT. DGKC / IFCC(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATINE KINASE (CK) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS, CHOLESTEROL LDL DIRECT, ENZYMATIC SELECTIVE PROTECTION (DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS, HOMOCYSTEINE, ENZYMATIC CYCLING(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF TOTAL HOMOCYSTEINE IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,POTASSIUM, ENZYMATIC(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF POTASSIUM IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS,ADA CALIBRATOR (DIALAB)-CALIBRATION SERUM FOR THE USE IN TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ADENOSINE DEAMINASE (ADA) IN HUMAN SERUM, PLASMA, PLEURAL FLUID OR CEREBROSPINAL FLUID ON PHOTOMETRIC SYSTEMS.,ASO CALIBRATOR HIGH(DIALAB)-LIQUID HUMAN BASED CALIBRATOR FOR USE AS A CALIBRATOR IN IMMUNOTURBIDIMETRIC ASSAYS FOR ASO,PHOSPHORUS INORGANIC, MOLYBDATE(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF PHOSPHORUS IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS.,ALPHA-AMYLASE, CNP-G3(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALPHA?-AMYLASE IN HUMAN SERUM OR

	PLASMA ON PHOTOMETRIC SYSTEMS,MAGNESIUM, XYLIDYL BLUE WITH ATCS*(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF MAGNESIUM IN HUMAN SERUM, PLASMA, CEREBROSPINAL FLUID OR URINE ON PHOTOMETRIC SYSTEMS, AMMONIA CONTROL SET, 2 LEVELS(DIALAB)-CONTROLS FOR THE USE IN TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF AMMONIA IN HUMAN PLASMA ON PHOTOMETRIC SYSTEMS,ADA CONTROL SET, 2 LEVELS(DIALAB)-CONTROL SERUM FOR THE USE IN TESTS FOR THE QUANTITATIVE IN VITRO DETERMINATION OF ADENOSINE DEAMINASE (ADA) IN HUMAN SERUM, PLASMA, PLEURAL FLUID OR CEREBROSPINAL FLUID ON PHOTOMETRIC SYSTEMS.,HDL CHOLESTEROL CALIBRATOR(DIALAB)-LYOPHILIZED HUMAN BASED CALIBRATOR FOR THE USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF HIGH DENSITY LIPOPROTEINS CHOLESTEROL (HDL-C) ON PHOTOMETRIC SYSTEMS.,CALCIUM ARSENAZO(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC SYSTEMS,LDL CHOLESTEROL CALIBRATOR (DIALAB)-LYOPHILIZED HUMAN BASED CALIBRATOR FOR THE USE IN TESTS FOR QUANTITATIVE IN VITRO DETERMINATION OF LOW DENSITY LIPOPROTEINS CHOLESTEROL (LDL-C) ON PHOTOMETRIC SYSTEMS.,ADENOSINE DEAMINASE (ADA), ENZYMATIC COLORIMETRIC(DIALAB)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF ADENOSINE DEAMINASE (ADA) IN HUMAN SERUM, PLASMA, PLEURAL FLUID AND CEREBROSPINAL FLUID ON PHOTOMETRIC SYSTEMS.

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1131	IMP/IVD/2021/000311	1.License Holder Name: CLINIEXPERTS SERVICES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CUE COVID-19 TEST-THE CUE COVID-19 TEST IS AN ISOTHERMAL NUCLEIC ACID AMPLIFICATION ASSAY INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN DIRECT ANTERIOR NASAL SWABS OR IN PREVIOUSLY COLLECTED ANTERIOR NASAL SWAB SPECIMENS IN VIRAL TRANSPORT MEDIA FROM INDIVIDUALS WITH OR WITHOUT SYMPTOMS OR OTHER EPIDEMIOLOGICAL REASONS TO SUSPECT COVID-19. THE TEST IS RUN USING THE CUE HEALTH MONITORING SYSTEM (CUE CARTRIDGE READER), THE CUE COVID-19 TEST CARTRIDGE, THE CUE SAMPLE WAND, AND THE CUE HEALTH APP ON THE COMPATIBLE MOBILE SMART DEVICES NAMED ON THE CUE HEALTH WEBSITE AT WWW.CUEHEALTH.COM.,CUE COVID- 19 EXTERNAL CONTROL SWABS PACK-CONTROL SWABS PACK CONTAINS THREE (3) CUE COVID-19 TEST POSITIVE CONTROL SWABS (REF C2111) AND THREE CUE TEST NEGATIVE CONTROL SWABS (REF C2112) AND ARE USED TO MONITOR THE ENTIRE ASSAY AND ENSURE THAT TEST REAGENTS ARE WORKING AND THAT THE TEST IS CORRECTLY PERFORMED .,CUE COVID-19 TEST CARTRIDGE PACK-THE CUE COVID-19 TEST IS AN ISOTHERMAL NUCLEIC ACID AMPLIFICATION ASSAY INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN DIRECT ANTERIOR NASAL SWABS OR IN PREVIOUSLY COLLECTED ANTERIOR NASAL SWAB SPECIMENS IN VIRAL TRANSPORT MEDIA FROM INDIVIDUALS WITH OR WITHOUT SYMPTOMS OR OTHER EPIDEMIOLOGICAL REASONS TO SUSPECT COVID-19.
1132	IMP/IVD/2021/000312	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAINING SOLUTION FOR HEMATOLOGY ANALYZER(NA)-THE STAINING SOLUTION IS USED TO STAIN THE RETICULOCYTE (RETIC) IN HUMAN BLOOD, SO AS TO OBSERVE THEIR MORPHOLOGY AND STRUCTURE, AND MAKES THE HEMATOLOGY ANALYZERS TO COUNT THE BLOOD CELLS.,SHEATH (NA)-IT IS USED ON 5-PART-DIFF AUTO HEMATOLOGY ANALYZER ALONG WITH DILUENT AND LYSE PRODUCED BY URIT, FOR TESTING THE CELL CONTENT IN HUMAN BLOOD.

1133	IMP/IVD/2021/000313	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALINITY C-SERIES ALKALINE WASH (ALINITY C-SERIES ALKALINE WASH)-ALINITY C-SERIES ALKALINE WASH- USED BY THE CUVETTE WASHER TO CLEAN THE CUVETTES AFTER SAMPLE ANALYSIS.,ALINITY C-SERIES ACID PROBE WASH(ALINITY C-SERIES ACID PROBE WASH)-THE ALINITY C-SERIES ACID PROBE WASH IS AN ONBOARD SOLUTION USED IN DAILY MAINTENANCE, SELECTED DIAGNOSTIC PROCEDURES, AND IN CONJUNCTION WITH THE SMARTWASH FEATURE TO REDUCE CARRYOVER BETWEEN SPECIFIC ASSAY COMBINATIONS.,ALINITY C-SERIES ACID WASH SOLUTION(ALINITY C-SERIES ACID WASH SOLUTION)-USED BY THE CUVETTE WASHER TO CLEAN THE CUVETTES AFTER SAMPLE ANALYSIS.

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1134	IMP/IVD/2021/000314	1.License Holder Name: M/S.ROCHE DIABETES CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE METER (ACCU-CHEK INSTANT S)-THE ACCU-CHEK INSTANT TEST STRIPS WITH THE ACCU-CHEK INSTANT S METER ARE INTENDED TO QUANTITATIVELY MEASURE GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD FROM THE FINGER, PALM, FOREARM, AND UPPER ARM AS AN AID IN MONITORING THE EFFECTIVENESS OF GLUCOSE CONTROL. THE ACCU-CHEK INSTANT TEST STRIPS WITH THE ACCU-CHEK INSTANT S METER ARE INTENDED FOR IN VITRO DIAGNOSTIC SELF-TESTING BY PEOPLE WITH DIABETES. THE ACCU-CHEK INSTANT TEST STRIPS WITH THE ACCU-CHEK INSTANT S METER ARE INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS IN CLINICAL SETTINGS. VENOUS, ARTERIAL, AND NEONATAL BLOOD TESTING IS LIMITED TO HEALTHCARE PROFESSIONAL USE. THIS SYSTEM IS NOT FOR USE IN THE DIAGNOSIS OF DIABETES MELLITUS, NOR FOR TESTING NEONATE CORD BLOOD SAMPLES. THIS SYSTEM IS NOT FOR USE IN DIAGNOSIS OF DIABETES MELLITUS, NOR FOR TESTING NEONATE CORD BLOOD SAMPLES,BLOOD GLUCOSE METER (ACCU-CHEK INSTANT)-THE ACCU-CHEK INSTANT TEST STRIPS WITH THE ACCU-CHEK INSTANT METER ARE INTENDED TO QUANTITATIVELY MEASURE GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD FROM THE FINGER, PALM, FOREARM, AND UPPER ARM AS AN AID IN MONITORING THE EFFECTIVENESS OF GLUCOSE CONTROL. THE ACCU-CHEK INSTANT TEST STRIPS WITH THE ACCU-CHEK INSTANT METER ARE INTENDED FOR IN VITRO DIAGNOSTIC SELF-TESTING BY PEOPLE WITH DIABETES. THE ACCU-CHEK INSTANT TEST STRIPS WITH THE ACCU-CHEK INSTANT METER ARE INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS IN CLINICAL SETTINGS. VENOUS, ARTERIAL, AND NEONATAL BLOOD TESTING IS LIMITED TO HEALTHCARE PROFESSIONAL USE. THIS SYSTEM IS NOT FOR USE IN THE DIAGNOSIS OF DIABETES MELLITUS, NOR FOR TESTING NEONATE CORD BLOOD SAMPLES.

1135	IMP/IVD/2021/000319	1.License Holder Name: EDIF MEDICAL SYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 FLUORESCENT PCR(MACCURA)-FOR IN VITRO QUALITATIVE DETECTION OF SARS-COV-2 (ALSO KNOWN AS 2019-NCOV) ORF1AB, E, AND N GENE IN OROPHARYNGEAL SWABS AND SPUTUM SPECIMENS OF SUSPECTED SARS-COV-2-INFECTED PNEUMONIA CASES, SUSPECTED CLUSTERED INFECTION CASES, AND OTHERS WHO NEED SARS-COV-2 INFECTION DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS.

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1136	IMP/IVD/2021/000330	1.License Holder Name: LAB X 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:K,NA,CL,PH FILLING SOLUTION(CARETIUM)-PASSING THE MEMBRANE POTENTIAL OF CALCIUM ELECTRODE TO THE AG/AGCL INTERNAL ELECTRODE AND CALIBRATING THE SODIUM , CHLORINUM , PH ELECTRODE POTENTIAL FILLING SOLLUTION FOR PH ,NA AND CL ELECTRODE, URINE SOLUTION(CARETIUM)-DILUTING THE URINE SAMPLE (1:1) , USE FOR ONLY WITH XI-931, SERIES ELECTROLYTE ANALYZERS,REAGENT PACK FOR 931DT(CARETIUM)-FOR IN VITRO DIAGNOSTIC USE ONLY , USE FOR ONLY WITH XI-931 SERIES ELECTROLYTE ANALYZERS, REAGENT PACK FOR 931AT/FT(CARETIUM)-FOR IN VITRO DIAGNOSTIC USE ONLY , USE FOR ONLY WITH XI-931 SERIES ELECTROLYTE ANALYZERS,REF FILLING SOLUTION(CARETIUM)-PASSING THE REFERENCE MEMBRANE POTENTIAL TO THE AG/AGCL INTERNAL ELECTRODE AND PROVIDING A CONSTANT REFERENCE POTENTIAL FOR THE MEASURMENT K+,NA+,CL,CA2+ PH ELECTRODE POTENTILAL FILLING SOLUTION FOR REFERENCE ELECTRODE, REAGENT PACK FOR 931CT(CARETIUM)-FOR IN VITRO DIAGNOSTIC USE ONLY , USE FOR ONLY WITH XI-931 SERIES ELECTROLYTE ANALYZERS,CA FILLING SOLUTION(CARETIUM)-PASSING THE MEMBRANE POTENTIAL OF CALCIUM ELECTRDE TO THE AG/ AGCL INTERNAL ELECTRODE AND CALIBRATING THE CALACIUM ELECTRODE POTENTIAL,REAGENT PACK FOR 931BT(CARETIUM)-FOR IN VITRO DIAGNOSTIC USE ONLY , USE FOR ONLY WITH XI-931 SERIES ELECTROLYTE ANALYZERS,QC SOLUTION (K, NA,CL,CA)(CARETIUM)-FOR CHECKING PERFORMANCE OF ELECTROLYTE ANALYZER ,USE FOR ONLY WITH XI-931 SERIES ELECTROLYTE ANALYZERS,AB STANDARD SOLUTION(CARETIUM)-FOR CALIBRATING STABILITY OF PRESSURE SENSOR. USE FOR ONLY WITH XI-931 SERIES ELECTROLYTE ANALYZERS,QC SOLUTION (K, NA,CL)(CARETIUM)-FOR CHECKING PERFORMANCE OF ELECTROLYTE ANALYZER ,USE FOR ONLY WITH XI-931 SERIES ELECTROLYTE ANALYZERS,NA CONDITIONER(CARETIUM)-ACTIVATING NATHIUM ELECTRODE AND IMPROVING THE SENSITIVITY AND STABILITY OF ELECTRODE,USE FOR ONLY WITH XI-931 SERIES ELECTROLYTE ANALYZERS,CLEANING SOLUTION(CARETIUM)-REMOVING PROTEIN DEPOSITE INSIDE THE ELECTRODE MEMBRANE AND TUBE , TO IMPROVE THE SENSITIVTY AND STABILITY OF THE ELECTRODE . USE FOR ONLY WITH XI-931 SERIES ELECTROLYTE ANALYZERS

1137	IMP/IVD/2021/000336	1.License Holder Name: WHEECON INSTRUMENTS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ESR-CHEX(ESR-CHEX)-INTENDED USE ESR-CHEX IS AN ASSAYED BI-LEVEL CONTROL FOR EVALUATING THE ACCURACY AND PRECISION OF AUTOMATED AND MANUAL ERYTHROCYTE SEDIMENTATION RATE (ESR) METHODS., CELL-CHEX ®(CELL-CHEX ®)-CELL-CHEX® IS AN ASSAYED CONTROL INTENDED FOR MONITORING TOTAL CELL COUNTS PERFORMED MANUALLY USING A HEMACYTOMETER TO VALIDATE QUANTITATION OF RED AND WHITE BLOOD CELLS IN PATIENT CEREBROSPINAL FLUID AND BODY FLUID SAMPLES INCLUDING PLEURAL, PERICARDIAL, PERITONEAL AND SYNOVIAL FLUID. LEVEL 1-UC CONTAINS MONOSODIUM URATE CRYSTALS, AND LEVEL 1-CC CONTAINS CALCIUM PYROPHOSPHATE DIHYDRATE (CPPD) CRYSTALS, WHICH CAN BE USED TO MONITOR THE PRESENCE OF CRYSTALS IN SYNOVIAL FLUID. CELL-CHEX IS ALSO INTENDED FOR MONITORING WHITE BLOOD CELL DIFFERENTIATION (MONONUCLEAR AND POLYMORPHONUCLEAR; NEUTROPHILS, EOSINOPHILS, BASOPHILS, LYMPHOCYTES AND MONOCYTES) IN BODY FLUID SAMPLES PERFORMED USING CYTOSPIN SMEARS.,CD-CHEX CD34® (CD-CHEX CD34®)-CD-CHEX CD34® IS A STABILIZED PREPARATION OF HUMAN BLOOD TO BE USED AS A COMPLETE PROCESS CONTROL WHEN EVALUATING CD34 POSITIVE CELLS. IT IS INTENDED TO BE USED WITH BD BIOSCIENCES PROCOUNT PROGENITOR CELL ENUMERATION KIT, BD STEM CELL ENUMERATION KIT, BECKMAN COULTER STEM-KIT, AND WITH SYSTEMS USING THE ISHAGE PROTOCOL FOR ENUMERATION OF CD34 CELLS.,UA-CELLULAR® COMPLETE(UA-CELLULAR® COMPLETE)-NTENDED USE UA-CELLULAR® COMPLETE IS AN ASSAYED CHEMISTRY AND CELLULAR URINE CONTROL FOR EVALUATING THE ACCURACY AND PRECISION OF THE PROCEDURES THAT MEASURE URINARY SEDIMENT AND CHEMISTRY PARAMETERS ON THE FOLLOWING INSTRUMENTS AND TESTING METHODS: SYSMEX UF-1000I AUTOMATED URINE PARTICLE ANALYZER; SIEMENS CLINITEK ATLAS AUTOMATED URINE CHEMISTRY ANALYZER UTILIZING THE CLINITEK ATLAS 10 REAGENT PAK; THE ARKRAY AUTION HYBRID AU-4050 FULLY-AUTOMATED INTEGRATED URINE ANALYZER, UTILIZING THE URIFLET S 9HA TEST STRIPS; SIEMENS CLINITEK STATUS LINE OF AUTOMATED CHEMISTRY STRIP READER ANALYZERS; MANUAL READING OF URINE REFRACTIVE INDEX; MANUAL READING OF THE SIEMENS MULTISTIX 10SG REAGENT STRIPS AND SIEMENS CLINITEST HCG PREGNANCY TEST.,PARA 12® PLUS(PARA 12® PLUS)-PARA 12® PLUS IS AN ASSAYED HEMATOLOGY CONTROL FOR EVALUATING THE ACCURACY AND PRECISION OF HEMATOLOGY INSTRUMENTS THAT

	PROVIDE A WHITE BLOOD CELL DIFFERENTIAL.,PARA 12® EXTEND (PARA 12® EXTEND)-INTENDED USE PARA 12® EXTEND IS AN ASSAYED HEMATOLOGY CONTROL FOR EVALUATING THE ACCURACY AND PRECISION OF HEMATOLOGY INSTRUMENTS THAT PROVIDE A WHITE BLOOD CELL DIFFERENTIA,A1C-CELLULAR® LINEARITY(A1C-CELLULAR® LINEARITY)-A1C-CELLULAR® LINEARITY IS A MULTI-LEVEL WHOLE-BLOOD BASED, ASSAYED CONTROL MATERIAL FOR EVALUATING THE ACCURACY AND PRECISION OF HBA1C PROCEDURES OVER THE INSTRUMENT REPORTABLE RANGE.,SICKLE-CHEX®(SICKLE-CHEX®)-SICKLE-CHEX IS A POSITIVE AND NEGATIVE WHOLE BLOOD CONTROL AVAILABLE FOR USE WITH SICKLE CELL SCREENING TESTS AND HEMOGLOBIN ELECTROPHORESIS. THE CONTROL DOES NOT REQUIRE RECONSTITUTION, WHICH ALLOWS IT TO BE USED LIKE A PATIENT SAMPLE. SICKLE-CHEX IS COMPATIBLE WITH THE FOLLOWING SICKLE CELL SCREENING KITS: STRECK SICKLEDEX®, SIEMENS DADE SICKLE-SOL TEST AND PACIFIC HEMOSTASIS SICKLESCREEN SICKLING HEMOGLOBIN SCREENING KIT,UA-CELLULAR® FOR IQ(UA-CELLULAR® FOR IQ)-INTENDED USE UA-CELLULAR® FOR IQ IS AN ASSAYED CELLULAR URINE CONTROL FOR EVALUATING THE ACCURACY AND PRECISION OF AUTOMATED PROCEDURES THAT MEASURE URINARY SEDIMENT PARAMETERS.,SICKLEDEX ® (SICKLEDEX ®)-INTENDED USE SICKLEDEX® 12-TEST IS A QUALITATIVE SOLUBILITY TEST FOR TESTING FOR THE PRESENCE OF SICKLING HEMOGLOBINS IN HUMAN BLOOD OR SICKLE CELL CONTROL MATERIAL.,PARA 4®(PARA 4®)-INTENDED USE PARA 4® IS AN ASSAYED HEMATOLOGY CONTROL FOR EVALUATING THE ACCURACY AND PRECISION OF AUTOMATED, SEMI-AUTOMATED AND MANUAL PROCEDURES THAT MEASURE BLOOD CELL PARAMETERS.

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1138	IMP/IVD/2021/000337	1.License Holder Name: EXCEL GLOBAL HEALTH 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID-19 RAPID ANTIGEN TEST KIT(V-STRIP COVID-19 RAPID ANTIGEN TEST KIT)-VSTRIP COVID-19 ANTIGEN RAPID TEST IS A RAPID IN VITRO IMMUNOCHROMATOGRAPHIC ASSAY INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEOCAPSID PROTEIN ANTIGEN FROM SARS-COV-2 IN NASOPHARYNGEAL SWAB FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER WITHIN THE FIRST FIVE DAYS OF THE ONSET OF SYMPTOMS. RESULTS ARE FOR THE IDENTIFICATION OF SARS-COV-2 NUCLEOCAPSID PROTEIN ANTIGEN. THIS ANTIGEN IS GENERALLY DETECTABLE IN UPPER RESPIRATORY SAMPLES DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS INDICATE THE PRESENCE OF VIRAL ANTIGENS, BUT CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. NEGATIVE RESULTS DO NOT RULE OUT SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR PATIENT MANAGEMENT DECISIONS, INCLUDING INFECTION CONTROL DECISIONS. NEGATIVE RESULTS SHOULD BE CONSIDERED IN THE CONTEXT OF A PATIENT'S RECENT EXPOSURES, HISTORY AND THE PRESENCE OF CLINICAL SIGNS AND SYMPTOMS CONSISTENT WITH COVID-19, AND CONFIRMED WITH A MOLECULAR ASSAY, IF NECESSARY FOR PATIENT MANAGEMENT. THE VSTRIP COVID-19 ANTIGEN RAPID TEST IS INTENDED FOR USE BY TRAINED CLINICAL LABORATORY PERSONNEL SPECIFICALLY INSTRUCTED AND TRAINED IN VITRO DIAGNOSTIC PROCEDURES
1139	IMP/IVD/2021/000338	1.License Holder Name: MEHAR HEALTHCARE CORPORATION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MH 007 MEHAR READY DIABTEK BLOOD GLUCOSE STRIPS(N/A)-MONITOR GLUCOSE CONCENTRATION IN WHOLE BLOOD SAMPLE.
1140	IMP/IVD/2021/000339	1.License Holder Name: ZOETIS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VETSCAN HM5 REAGENT PACK(HM5 REAGENT PACK)-THE VETSCAN HM 5 REAGENT PACK IS INTENDED FOR VETERINARY HEMATOLOGY USES

1141	IMP/IVD/2021/000343	1.License Holder Name: NURECA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIPS(DR TRUST)-BLOOD GLUCOSE TESTING,BLOOD GLUCOSE MONITORING SYSTEM(DR TRUST)-SYSTEM IS INTENDED FOR USE OUTSIDE THE BODY (IN- VITRO DIAGNOSTIC USE) BY PEOPLE WITH DIABETES AT HOME AND HEALTH CARE PROFESSIONAL IN CLINICAL SETTING AS AN AID TO MONITORING THE EFFECTIVENESS OF DIABETES CONTROL. IT IS INTENDED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE (SUGAR) IN FRESH WHOLE BLOOD SAMPLE (FROM THE FINGER, PALM, FOREARM AND UPPER ARM.

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1142	IMP/IVD/2021/000345	1.License Holder Name: OPERON BIOTECH & HEALTHCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DILUENT (KT05 DIL) (GENRUI)-THIS PRODUCT IS USED FOR DILUTION OF BLOOD SAMPLES AND PREPARING CELL SUSPENSIONS PRIOR TO ANALYSIS OF THE CELLS,ELECTROLYTE REAGENTS DS-I (NO.3) STANDARD A STANDARD B(GENRUI)-IT CAN BE USED WITH ELECTROLYTE ANALYZERS BY PROFESSIONALS, FOR THE DETECTION OF POTASSIUM (K+), SODIUM (NA+), CHLORIDE (CL-), CALCIUM (CA2+), MAGNESIUM (MG2+), LITHIUM (LI+), PH (PH VALUE) AND TCO2 CONCENTRATION IN HUMAN SERUM. IN ADDITION, GE-1 AND GE-2 ALSO CAN CONCENTRATION IN HUMAN BLOOD AND URINE.,LH LYSE (KT05LH)(GENRUI)-THIS PRODUCT IS USED TO DISSOLVE RBC AND MAINTAIN THE MORPHOLOGY OF THE CELLS NEEDED TO BE ANALYZED BEFORE BLOOD CELL ANALYSIS THEREBY FACILITATES CELL SORTING OR HGB QUANTIFICATION.,C-REACTIVE PROTEIN DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) CONTENT IN HUMAN SERUM OR WHOLE BLOOD.,DIFF LYSE (KT05DIFF)(GENRUI)-THIS PRODUCT IS USED TO DISSOLVE RBC AND MAINTAIN THE MORPHOLOGY OF THE CELLS NEEDED TO BE ANALYZED BEFORE BLOOD CELL ANALYSIS SO THAT FACILITATE CELL SORTING OR HGB QUANTIFICATION,KT03 LYSE(KT03 LYSE)-DISSOLVING RED BLOOD CELLS TO RELEASE HEMOGLOBIN, MAINTAINING THE CELL STRUCTURE TO BE ANALYZED, FOR THE PURPOSE OF CELL COUNT AND QUANTITATIVE DETERMINATION OF HEMOGLOBIN,DILUENT SOLUTIONS (KT03)(GENRUI)-THIS PRODUCT IS USED FOR DILUTION OF BLOOD SAMPLES AND PREPARATION OF CELL SUSPENSIONS PRIOR TO CELL ANALYSIS.,GLYCATED HEMOGLOBIN (HBA1C) DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF THE PERCENTAGE CONTENT OF GLYCATED HEMOGLOBIN IN HUMAN BLOOD.,D-DIMER DETECTION KIT (NEPHELOMETRY)(GENRUI)-FOR IN VITRO QUANTITATIVE DETERMINATION OF D-DIMER CONTENT IN HUMAN PLASMA.
1143	IMP/IVD/2021/000351	1.License Holder Name: SHALOM HEALTHCARE LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIPASE(LIPASE FL R1)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPASE IN BIOLOGICAL FLUIDS.,LIPASE(LIPASE FL R2)-REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPASE IN BIOLOGICAL FLUIDS.

1144	IMP/IVD/2021/000355	1.License Holder Name: M/S ONE ABOVE HEALTHCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE METER (ONE ABOVE)-FOR MONITOR GLUCOSE CONCENTRATIONS IN CAPILLARY WHOLE BLOOD.
1145	IMP/IVD/2021/000356	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMATOLOGY REAGENT-DILUENT (EUROCOUNT DILUENT)-DIATRO•DIL-DIFF DILUENT IS A BUFFERED, STABILIZED AND MICRO-FILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN (HGB) CONCENTRATION ON HEMATOLOGY ANALYZERS,HEMATOLOGY REAGENT - LYSE(EUROCOUNT LYSE)-LYSE-DIFF LYSING REAGENT IS A STABILIZED AND MICRO-FILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC), LEUKOCYTE THREE-PART DIFFERENTIATION (LYM, MID, GRAN) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON HEMATOLOGY ANALYZERS.,HEMATOLOGY REAGENT-CLEANER(EUROCOUNT CLEANER)-CLEANER CLEANING REAGENT IS A STABILIZED AND MICROFILTERED DETERGENT SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON HEMATOLOGY ANALYZERS.
1146	IMP/IVD/2021/000363	1.License Holder Name: ZOETIS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VETSCAN HM 5 CONTROLS (LOW, NORMAL, HIGH)(VETSCAN HM 5 CONTROLS)-THE CONTROLS ARE USED FOR VETERINARY HAEMATOLOGY TESTING FOR CALIBRATION

1147	IMP/IVD/2021/000364	1.License Holder Name: M/S. CPC DIAGNOSTICS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ELECTROLYTE WASH SOLUTION(NIL)-USED FOR CLEANING THE FLOW PATH,STANDARD SOLUTION 2(NIL)-USED FOR MEASURING THE ACCURATE ELECTROLYTE CONCENTRATION OF THE SAMPLE BY EX- D/EX-DS, REFERENCE SOLUTION FOR EX- CA(NIL)-USED FOR MEASURING THE ACCURATE ELECTROLYTE CONCENTRATION OF THE SAMPLE BY EX-CA,STANDARD SOLUTION 2 EX-CA(NIL)-USED FOR MEASURING THE ACCURATE ELECTROLYTE CONCENTRATION OF THE SAMPLE BY EX-CA,STANDARD SOLUTION 1(NIL)-USED FOR MEASURING THE ACCURATE ELECTROLYTE CONCENTRATION OF THE SAMPLE BY EX-D/EX-DS,STANDARD SOLUTION 1 FOR EX-CA(NIL)-USED FOR MEASURING THE ACCURATE ELECTROLYTE CONCENTRATION OF THE SAMPLE BY EX- CA

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1148	IMP/IVD/2021/000365	1.License Holder Name: BODITECH MED INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TSH(AFIAS TSH PLUS)-AFIAS TSH PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THYROID DISORDERS.,D-DIMER(AFIAS D-DIMER)-AFIAS D-DIMER IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN WHOLE BLOOD/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THERAPEUTIC EVALUATION OF THROMBOEMBOLIC DISEASE PATIENTS. FOR IN VITRO DIAGNOSTIC USE ONLY.,PCT (AFIAS PCT PLUS)-AFIAS PCT PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN WHOLE BLOOD / SERUM / PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF BACTERIAL INFECTION AND SEPSIS.,IL-6(AFIAS IL-6)-AFIAS IL-6 IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETECTION OF INTERLEUKIN-6 (IL-6) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF INFLAMMATORY DISEASE. FOR IN VITRO DIAGNOSTIC USE ONLY., TOTAL BETA HCG(AFIAS TOTAL BETA HCG)-AFIAS TOTAL BETA HCG IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPHIN (TOTAL BETA HCG) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF FERTILITY. , FERRITIN(AFIAS FERRITIN)-AFIAS FERRITIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID FOR QUANTIFYING HUMAN FERRITIN. FOR IN VITRO DIAGNOSTIC USE ONLY.,PRL(AFIAS PRL)-AFIAS PRL IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF HYPOTHALAMIC-PITUITARY DISORDERS.,LH (AFIAS LH)-AFIAS LH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF LH IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF EVALUATING FERTILITY ISSUES, FUNCTION OF REPRODUCTIVE ORGANS (OVARIES OR TESTICLES), OR DETECTION OF THE OVULATION.,NT-PROBNP (AFIAS NT-PROBNP)-AFIAS NT-PROBNP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF NT-PROBNP IN HUMAN WHOLE

		BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN DIAGNOSIS OF CONGESTIVE HEART FAILURE.,CRP(AFIAS CRP)-AFIAS CRP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF AUTOIMMUNE DISEASES AND INFECTIOUS PROCESSES, SUCH AS RHEUMATOID ARTHRITIS. FOR IN VITRO DIAGNOSTIC USE ONLY.,PCT (AFIAS PCT)-AFIAS PCT IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN WHOLE BLOOD / SERUM / PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF BACTERIAL INFECTION AND SEPSIS. ,AMH (AFIAS AMH)-AFIAS AMH IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF AMH (ANTI-MÜLLERIAN HORMONE) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF PREMATURE OVARIAN INSUFFICIENCY, MENOPAUSE, AND OVARIAN RESERVE.
1149	IMP/IVD/2021/000368	1.License Holder Name: VIW VACCINE WORLD PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 RT-PCR MULTIPLEX DIAGNOSTIC KIT(HA TECH)-THE HA TECH SARS-COV-2 RT-PCR MULTIPLEX DIAGNOSTIC KIT IS A REAL TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF RNA FROM THE SARS-COV-2 VIRUS IN UPPER RESPIRATORY SPECIMENS SUCH AS NASOPHARYNGEAL SWABS AND OROPHARYNGEAL SWABS. THE REAL-TIME RT-PCR TEST IS INTENDED FOR USE BY QUALIFIED CLINICAL LABORATORY PERSONNEL SPECIFICALLY TRAINED IN THE TECHNIQUES OF REAL-TIME PCR AND IN VITRO DIAGNOSTIC PROCEDURES. RESULTS ARE FOR THE IDENTIFICATION OF SARS-COV-2 RNA. SARS-COV-2 RNA IS GENERALLY DETECTABLE IN RESPIRATORY SPECIMENS DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS ARE INDICATIVE OF THE PRESENCE OF SARS-COV-2 RNA, CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR PATIENT MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION.

1150	IMP/IVD/2021/000376	1.License Holder Name: DIASYS DIAGNOSTIC INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMBISCREEN® MALB/CREA ROLL MATERIAL(COMBISCREEN®)-THE COMBISCREEN® MALB / CREA URINE TEST STRIP IS INTENDED TO BE USED FOR THE SEMI-QUANTITATIVE DETERMINATION OF ALBUMIN AND CREATININE IN HUMAN URINE. THIS PRODUCT CAN BE USED FOR SCREENING SAMPLES FOR MICROALBUMINURIA. THE MALB / CREA TEST STRIP IS DESIGNED AS IVD AND ONLY FOR PROFESSIONAL USE. IT SHOULD ONLY BE DONE BY MEDICALLY TRAINED PERSONNEL. THE COMBISCREEN® MALB / CREA URINE TEST STRIP MAY BE EVALUATED VISUALLY AS WELL AS INSTRUMENTALLY., COMBISCREEN® MALB/CREA(COMBISCREEN®)-THE COMBISCREEN® MALB / CREA URINE TEST STRIP IS INTENDED TO BE USED FOR THE SEMI-QUANTITATIVE DETERMINATION OF ALBUMIN AND CREATININE IN HUMAN URINE. THIS PRODUCT CAN BE USED FOR SCREENING SAMPLES FOR MICROALBUMINURIA. THE MALB / CREA TEST STRIP IS DESIGNED AS IVD AND ONLY FOR PROFESSIONAL USE. IT SHOULD ONLY BE DONE BY MEDICALLY TRAINED PERSONNEL. THE COMBISCREEN® MALB / CREA URINE TEST STRIP MAY BE EVALUATED VISUALLY AS WELL AS INSTRUMENTALLY., COMBISCREEN® 11 SYS PLUS(COMBISCREEN®)-FOR USE AS A PRELIMINARY SCREENING TEST FOR DIABETES, LIVER DISEASES, HEMOLYTIC DISEASES, UROGENITAL AND KIDNEY DISORDERS AND METABOLIC ABNORMALITIES. URINE TEST STRIPS FOR THE RAPID SEMI-QUANTITATIVE DETERMINATION OF ASCORBIC ACID, BILIRUBIN, BLOOD, GLUCOSE, KETONES, LEUCOCYTES, NITRITE, PH-VALUE, PROTEIN, SPECIFIC GRAVITY AND UROBILINOGEN IN HUMAN URINE. THE COMBISCREEN® URINE TEST STRIPS ARE ONLY FOR PROFESSIONAL USE.,COMBISCREEN® 11 SYS PLUS ROLL MATERIAL (COMBISCREEN®)-FOR USE AS A PRELIMINARY SCREENING TEST FOR DIABETES, LIVER DISEASES, HEMOLYTIC DISEASES, UROGENITAL AND KIDNEY DISORDERS AND METABOLIC ABNORMALITIES. URINE TEST STRIPS FOR THE RAPID SEMI-QUANTITATIVE DETERMINATION OF ASCORBIC ACID, BILIRUBIN, BLOOD, GLUCOSE, KETONES, LEUCOCYTES, NITRITE, PH-VALUE, PROTEIN, SPECIFIC GRAVITY AND UROBILINOGEN IN HUMAN URINE. THE COMBISCREEN® URINE TEST STRIPS ARE ONLY FOR PROFESSIONAL USE.

1151	IMP/IVD/2021/000379	1.License Holder Name: RIVAARA LABS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN(IB10 SPHINGOTEST BETA-HCG)-THE IB10 SPHINGOTEST® BETA-HCG IS A RAPID POINT-OF-CARE (POC) IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN LITHIUM HEPARIN WHOLE BLOOD AND PLASMA. THE IB10 SPHINGOTEST® BETA-HCG IS INTENDED FOR USE IN CONJUNCTION WITH THE NEXUS IB10 ANALYZER AND PROVIDES QUANTITATIVE RESULTS IN 20 MINUTES. THIS TEST DETECTS TOTAL HCG, MEASURING BOTH THE INTACT HCG MOLECULE AND ITS FREE BETA SUBUNIT. THE QUANTITATIVE MEASUREMENT OF HCG AIDS IN THE EARLY DETECTION OF PREGNANCY. THIS TEST IS DESIGNED FOR PROFESSIONAL USE ONLY AND MAY BE USED IN HOSPITAL CENTRAL LABORATORIES AND IN ALTERNATE CARE SETTINGS SUCH AS EMERGENCY DEPARTMENTS, CRITICAL CARE UNITS, AND OTHER SITES WHERE NEAR PATIENT TESTING IS PRACTICED,IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE(IB10 SPHINGOTEST TSH)-THE IB10 SPHINGOTEST® TSH IS A RAPID POINT-OF-CARE (POC) IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN LITHIUM HEPARIN WHOLE BLOOD AND PLASMA. THIS TSH TEST IS INTENDED FOR USE IN CONJUNCTION WITH THE NEXUS IB10 ANALYZER AND PROVIDES QUANTITATIVE RESULTS IN 20 MINUTES. THIS TEST IS DESIGNED FOR PROFESSIONAL USE ONLY AND MAY BE USED IN HOSPITAL CENTRAL LABORATORIES AND IN ALTERNATE CARE SETTINGS SUCH AS EMERGENCY DEPARTMENTS, CRITICAL CARE UNITS, AND OTHER POC SITES WHERE NEAR PATIENT TESTING IS PRACTICED.,IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE(IB10 SPHINGOTEST NT-PROBNP)-THE IB10 SPHINGOTEST® NT-PROBNP IS A RAPID TEST FOR THE IN VITRO QUANTITATIVE DETERMINATION OF N-TERMINAL PRO-BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN WHOLE BLOOD OR PLASMA USING EDTA OR LITHIUM HEPARIN AS THE ANTICOAGULANT. THE NT-PROBNP TEST IS INTENDED FOR USE IN CONJUNCTION WITH THE NEXUS IB10 ANALYZER AND PROVIDES QUANTITATIVE RESULTS IN 20 MINUTES. THIS TEST IS DESIGNED FOR PROFESSIONAL USE ONLY AND MAY BE USED IN HOSPITAL CENTRAL LABORATORIES AND IN ALTERNATE CARE SETTINGS SUCH AS EMERGENCY DEPARTMENTS, CRITICAL CARE UNITS, AND OTHER SITES WHERE NEAR PATIENT TESTING IS PRACTICED. NT-PROBNP DETERMINATIONS AID IN THE DIAGNOSIS

	AND MANAGEMENT OF CONGESTIVE HEART FAILURE (CHF)., IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN-99(CTNI)(IB10 SPHINGOTEST TROPONIN-99)-THE IB10 SPHINGOTEST® TROPONIN-99 IS A RAPID POINT-OF-CARE (POC) IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN-99 (CTNI) IN LITHIUM HEPARIN WHOLE BLOOD AND PLASMA. THE TROPONIN-99 TEST IS INTENDED FOR USE IN CONJUNCTION WITH THE NEXUS IB10 ANALYZER AND PROVIDES QUANTITATIVE RESULTS IN 20 MINUTES. THIS TEST IS DESIGNED FOR PROFESSIONAL USE ONLY AND MAY BE USED IN HOSPITAL CENTRAL LABORATORIES AND IN ALTERNATE CARE SETTINGS SUCH AS EMERGENCY DEPARTMENTS, CRITICAL CARE UNITS, AND OTHER SITES WHERE NEAR PATIENT TESTING IS PRACTICED. CTNI DETERMINATIONS AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION (MI) AND PATIENTS WITH NON-ST-SEGMENT ELEVATION (NSTEMI) ACUTE CORONARY SYNDROMES (ACS). ELEVATED CTNI LEVELS IN THE NSTEMI ACS SUBPOPULATION CORRELATE WITH THE RELATIVE RISK OF MORTALITY, MI OR INCREASED PROBABILITY OF ISCHEMIC EVENTS, REQUIRING URGENT REVASCULARIZATION PROCEDURES.,IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF PROCALCITONIN(IB10 SPHINGOTEST PCT)-THE IB10 SPHINGOTEST® PCT IS A RAPID POINT-OF-CARE (POC) IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN THE CONCENTRATION RANGE OF 0.3 G/L TO 10.00 G/L IN EDTA WHOLE BLOOD AND PLASMA. THIS PCT TEST IS INTENDED FOR USE IN CONJUNCTION WITH THE NEXUS IB10 ANALYZER AND PROVIDES QUANTITATIVE RESULTS IN 20 MINUTES. THE IB10 SPHINGOTEST® PCT IS INTENDED TO BE USED IN CONJUNCTION WITH CLINICAL EVALUATIONS AND OTHER LABORATORY FINDINGS TO DIAGNOSE SEPSIS, TO ASSESS THE DEGREE OF SEVERITY, AND TO MONITOR THE CHANGE OF SEPSIS SEVERITY. THIS ASSAY IS NEITHER SUITABLE NOR INTENDED FOR OTHER APPLICATIONS AND/OR USES. THE IB10 SPHINGOTEST® PCT IS DESIGNED FOR PROFESSIONAL USE ONLY AND MAY BE USED IN HOSPITAL CENTRAL LABORATORIES AND IN ALTERNATE CARE SETTINGS SUCH AS EMERGENCY DEPARTMENTS, CRITICAL CARE UNITS, AND OTHER POC SITES WHERE NEAR PATIENT TESTING IS PRACTICED.,IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF PROENKEPHALIN A 119-159(IB10 SPHINGOTEST PENKID)-THE IB10 SPHINGOTEST® PENKID® IS A RAPID POINT-OF-CARE (POC) IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PROENKEPHALIN A 119-159 IN HUMAN EDTA WHOLE BLOOD AND PLASMA. THIS TEST IS INTENDED FOR USE IN CONJUNCTION WITH THE NEXUS IB10 ANALYZER AND PROVIDES QUANTITATIVE RESULTS

	WITHIN 20 MINUTES. THE IB10 SPHINGOTEST® PENKID® IS DESIGNED FOR PROFESSIONAL USE ONLY AND MAY BE USED IN HOSPITAL CENTRAL LABORATORIES AND IN ALTERNATE CARE SETTINGS SUCH AS EMERGENCY DEPARTMENTS, CRITICAL CARE UNITS, AND OTHER SITES WHERE NEAR PATIENT TESTING IS PRACTICED.,IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF DIPEPTIDYL PEPTIDASE 3 (IB10 SPHINGOTEST DPP3)-THE IB10 SPHINGOTEST® DPP3 IS A RAPID POINT-OF-CARE (POC) IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF DIPEPTIDYL PEPTIDASE 3 (DPP3) IN HUMAN EDTA WHOLE BLOOD AND PLASMA. THIS TEST IS INTENDED FOR USE IN CONJUNCTION WITH THE NEXUS IB10 ANALYZER AND PROVIDES QUANTITATIVE RESULTS IN 20 MINUTES. THE IB10 SPHINGOTEST® DPP3 IS DESIGNED FOR PROFESSIONAL USE ONLY AND MAY BE USED IN HOSPITAL CENTRAL LABORATORIES AND IN ALTERNATE CARE SETTINGS SUCH AS EMERGENCY DEPARTMENTS, CRITICAL CARE UNITS, AND OTHER SITES WHERE NEAR PATIENT TESTING IS PRACTICED.,IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF HUMAN AMIDATED ADRENOMEDULLIN PEPTIDE(IB10 SPHINGOTEST BIO-ADM)-THE IB10 SPHINGOTEST® BIO-ADM® IS A RAPID POINT-OF-CARE (POC) IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HUMAN AMIDATED ADRENOMEDULLIN PEPTIDE (1-52), IN THE FOLLOWING REFERRED AS BIOACTIVE ADRENOMEDULLIN (BIO-ADM®), IN HUMAN EDTA WHOLE BLOOD AND PLASMA. THIS TEST IS INTENDED FOR USE IN CONJUNCTION WITH THE NEXUS IB10 ANALYZER AND PROVIDES QUANTITATIVE RESULTS WITHIN 20 MINUTES. THE IB10 SPHINGOTEST® BIO-ADM® IS DESIGNED FOR PROFESSIONAL USE ONLY AND MAY BE USED IN HOSPITAL CENTRAL LABORATORIES AND IN ALTERNATE CARE SETTINGS SUCH AS EMERGENCY DEPARTMENTS, CRITICAL CARE UNITS, AND OTHER SITES WHERE NEAR PATIENT TESTING IS PRACTICED

1152	IMP/IVD/2021/000380	1.License Holder Name: DSS IMAGETECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENVISION FLEX+ RABBIT (LINKER), (LINK)(DAKO ENVISION™)-USING ENVISION FLEX+ MOUSE (LINKER) OR ENVISION FLEX+ RABBIT (LINKER) SIGNAL AMPLIFICATION OF PRIMARY MOUSE ANTIBODIES OR PRIMARY RABBIT ANTIBODIES, RESPECTIVELY, CAN BE ACHIEVED. THE ENVISION FLEX+ REAGENTS ARE INTENDED FOR USE ON FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. ,ENVISION FLEX WASH BUFFER (20X)(DAKO ENVISION™)-ENVISION FLEX WASH BUFFER (20X) IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY. THE PRODUCT IS USED AS WASH BUFFER FOR IMMUNOHISTOCHEMICAL STAINING PROCEDURES USING AUTOSTAINER LINK INSTRUMENTS, DAKO AUTOSTAINER/AUTOSTAINER PLUS INSTRUMENTS OR PT LINK RINSE STATION. ,ENVISION™ FLEX ANTIBODY DILUENT(DAKO ENVISION™)-"ENVISION FLEX ANTIBODY DILUENT, IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY. IT IS A STABLE, READY-TO-USE REAGENT SPECIALLY DESIGNED FOR DILUTION OF DAKO CONCENTRATED PRIMARY ANTIBODIES USED ON DAKO AUTOSTAINER/AUTOSTAINER PLUS OR AUTOSTAINER LINK INSTRUMENTS." ,ENVISION FLEX TARGET RETRIEVAL SOLUTION, LOW PH (50X)(DAKO ENVISION™)-ENVISION FLEX TARGET RETRIEVAL SOLUTION, LOW PH (50X) IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY. THE REAGENT IS USED FOR HEAT-INDUCED EPITOPE RETRIEVAL ON FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS PRIOR TO IMMUNOHISTOCHEMICAL STAINING ON DAKO AUTOSTAINER/AUTOSTAINER PLUS OR AUTOSTAINER LINK INSTRUMENTS.,ENVISION FLEX+, MOUSE, HIGH PH, (LINK)(DAKO ENVISION™)-DAKO ENVISION™ FLEX+ DETECTION SYSTEM IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY TOGETHER WITH AUTOSTAINER LINK INSTRUMENTS. THE SYSTEM DETECTS PRIMARY MOUSE AND RABBIT ANTIBODIES AND THE REACTION IS VISUALIZED BY ENVISION™ FLEX DAB+ CHROMOGEN. IF USED WITH ENVISION™ FLEX+ MOUSE (LINKER) OR ENVISION™ FLEX+ RABBIT (LINKER) (CODE K8009) SIGNAL AMPLIFICATION OF PRIMARY MOUSE ANTIBODIES OR PRIMARY RABBIT ANTIBODIES, RESPECTIVELY, CAN BE ACHIEVED. THE ENVISION™ FLEX+ REAGENTS ARE INTENDED FOR USE ON FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. , ENVISION FLEX HEMATOXYLIN (LINK)(DAKO ENVISION™)-ENVISION FLEX HEMATOXYLIN (LINK) IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY TOGETHER WITH AUTOSTAINER LINK INSTRUMENTS. THE REAGENT IS USED FOR COUNTERSTAINING OF NUCLEI IN TISSUE SECTIONS. THE REAGENT IS INTENDED FOR USE ON

		FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. , ENVISION FLEX MINI KIT, HIGH PH (LINK)(DAKO ENVISION™)-DAKO ENVISION FLEX DETECTION SYSTEM IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY TOGETHER WITH AUTOSTAINER LINK INSTRUMENTS. THE SYSTEM DETECTS PRIMARY MOUSE AND RABBIT ANTIBODIES AND THE REACTION IS VISUALIZED BY ENVISION FLEX DAB+ CHROMOGEN. IF USED WITH ENVISION FLEX+ RABBIT (LINKER) (CODE K8009) OR ENVISION FLEX+ MOUSE (LINKER) (CODE K8021) SIGNAL AMPLIFICATION OF PRIMARY RABBIT ANTIBODIES OR PRIMARY MOUSE ANTIBODIES, RESPECTIVELY, CAN BE ACHIEVED. THE ENVISION FLEX REAGENTS ARE INTENDED FOR USE ON FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS. , ENVISION FLEX TARGET RETRIEVAL SOLUTION, HIGH PH (50X) (DAKO ENVISION™)-ENVISION FLEX TARGET RETRIEVAL SOLUTION, HIGH PH (50X), IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY. THE REAGENT IS USED FOR HEAT-INDUCED EPITOPE RETRIEVAL ON FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS PRIOR TO IMMUNOHISTOCHEMICAL STAINING ON DAKO AUTOSTAINER/AUTOSTAINER PLUS OR AUTOSTAINER LINK INSTRUMENTS. ,ENVISION FLEX+ MOUSE (LINKER) (LINK)(DAKO ENVISION™)-ENVISION FLEX+ MOUSE (LINKER) (LINK) IS INTENDED FOR USE IN IMMUNOHISTOCHEMISTRY TOGETHER WITH AUTOSTAINER LINK INSTRUMENTS. THE REAGENT IS USED FOR SIGNAL AMPLIFICATION OF PRIMARY MOUSE ANTIBODIES IN COMBINATION WITH THE ENVISION FLEX VISUALIZATION SYSTEM (CODES K8000/ K8002). THE REAGENT IS INTENDED FOR USE ON FORMALIN-FIXED, PARAFFIN-EMBEDDED TISSUE SECTIONS.
1153	IMP/IVD/2021/000381	1.License Holder Name: LIBRA DIAGNOSTICS PVT LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:C REACTIVE PROTEIN (CRP)(C REACTIVE PROTEIN (CRP) REAGENT FOR TURBIDIMETRY BIOLATEX)-IN VITRO DIAGNOSTIC PARTICLE-ENHANCED REAGENT FOR THE QUANTITATIVE DETERMINATION OF C REACTIVE PROTEIN (CRP) IN HUMAN SERUM BY TURBIDIMETRIC IMMUNOASSAY., FERRITIN(FERRITIN REAGENT FOR TURBIDIMETRY BIOLATEX)-IN VITRO DIAGNOSTIC PARTICLE-ENHANCED REAGENT FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM BY TURBIDIMETRIC IMMUNOASSAY.,RHEUMATOID FACTOR (RF) (RHEUMATOID FACTOR (RF) REAGENT FOR TURBIDIMETRY BIOLATEX)-IN VITRO DIAGNOSTIC PARTICLE-ENHANCED REAGENT FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN HUMAN SERUM BY TURBIDIMETRIC IMMUNOASSAY.

1154	IMP/IVD/2021/000382	1.License Holder Name: BIOMERIEUX INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KIT RAL STAINER FLUO-RAL METHYLENE BLUE(KIT RAL STAINER FLUO-RAL METHYLENE BLUE)-STAINING REAGENTS FOR RAL STAINER,KIT RAL STAINER COLD ZN(KIT RAL STAINER COLD ZN)-STAINING REAGENTS FOR RAL STAINER,KIT RAL STAINER FLUO-RAL(KIT RAL STAINER FLUO-RAL)-STAINING REAGENTS FOR RAL STAINER
1155	IMP/IVD/2021/000386	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GENTIAN CYSTATIN C REAGENT KIT(GENTIAN CYSTATIN C REAGENT KIT)-THE GENTIAN CYSTATIN C IMMUNOASSAY IS AN IMMUNOTURBIDIMETRIC ASSAY INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM AND PLASMA ON AUTOMATED CLINICAL ANALYSERS BY LABORATORY PROFESSIONAL USERS. THE MEASUREMENT OF CYSTATIN C IS USED IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASES. ,GENTIAN CYSTATIN C CONTROL KIT(GENTIAN CYSTATIN C CONTROL KIT)-THE GENTIAN CYSTATIN C CONTROLS ARE INTENDED TO MONITOR AND EVALUATE THE QUALITY OF THE CALIBRATION CURVE ESTABLISHED FROM THE GENTIAN CYSTATIN C CALIBRATOR WITH THE GENTIAN CYSTATIN C IMMUNOASSAY.,GENTIAN CYSTATIN C CALIBRATOR KIT(GENTIAN CYSTATIN C CALIBRATOR KIT)-THE GENTIAN CYSTATIN C CALIBRATOR KIT IS INTENDED TO BE USED TO ESTABLISH A CALIBRATION CURVE FOR MEASURING CYSTATIN C CONCENTRATION IN HUMAN LITHIUM HEPARIN PLASMA AND SERUM SAMPLES WITH THE GENTIAN CYSTATIN C IMMUNOASSAY.
1156	IMP/IVD/2021/000387	1.License Holder Name: M/S. I-SENS BIOSENSORS INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE & BLOOD BETA - KETONE METER(CARESENS DUAL)-CARESENS DUAL BLOOD GLUCOSE AND BETA KETONE MONITORING SYSTEM IS USED FOR THE QUANTITATIVE MEASUREMENT OF THE GLUCOSE LEVEL IN CAPILLARY WHOLE BLOOD AS AN AID IN MONITORING DIABETES MANAGEMENT EFFECTIVELY AT HOME OR IN CLINICAL SETTINGS.

1157	IMP/IVD/2021/000394	1.License Holder Name: FUJIFILM INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HRII SERIES P-HRII(HRII SERIES P-HRII COLOR A)-HRII SERIES P-HRII IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHORUS IN SERUM OR URINE. ,L-TYPE LDL-C M(L-TYPE LDL-C M PM-R2 (REACTING SOLUTION))-L-TYPE LDL-C M IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN SERUM OR PLASMA. ,HRII SERIES MAGNESIUM-HRII(HRII SERIES MAGNESIUM-HRII COLOR)-HRII SERIES MAGNESIUM-HRII IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN SERUM OR URINE. ,PROTEIN STANDARD SOLUTION(PROTEIN STANDARD SOLUTION)-THE WAKO PROTEIN STANDARD SOLUTION IS TO BE USED WITH WAKO'S ASSAY REAGENTS FOR THE DETERMINATION OF TOTAL PROTEIN IN URINE OR CEREBROSPINAL FLUID. ,L-TYPE UIBC (L-TYPE UIBC PM-R1 (BUFFER))-L-TYPE UIBC IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF UNSATURATED IRON BINDING CAPACITY (UIBC) IN SERUM OR PLASMA. ,BETA2M-LT (BETA2MLT LATEX REAGENT)-2M-LT IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF 2-MICROGLOBULIN (2-M) IN SERUM OR URINE. ,IGE-LT(IGE-LT LATEX REAGENT)-IGE-LT IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF NONSPECIFIC IGE IN SERUM OR PLASMA. ,L-TYPE TP(L-TYPE TP BUFFER (PM-R1))-L-TYPE TP IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN SERUM OR PLASMA. ,IMMUNO-CONTROL 1(IMMUNO-CONTROL 1)-IMMUNO-CONTROL 1 IS THE LIQUID TYPE CONTROL SERUM BASED ON HUMAN POOLED SERA AND DESIGNED FOR AN ACCURACY CONTROL FOR CRP, RF OR ASO. THE ASSIGNED VALUES ARE MEASURED BY USING WAKO'S REAGENTS FOR AUTOMATED ANALYZERS, STATED AS ASSAY VALUES. ,RF-LT(RF-LT PM-R1 (BUFFER))-RF-LT IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR ACTIVITY IN SERUM OR PLASMA. ,L-TYPE UA M(L-TYPE UA M PM-R2 (ENZYME COLOR B))-L-TYPE UA M IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN SERUM, PLASMA OR URINE. ,CALCIUM E-HA(CALCIUM E-HA PM-R2 (COLOR))-CALCIUM E-HA IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM, PLASMA OR URINE. ,DIRECT BILIRUBIN E-HA(DIRECT BILIRUBIN E-HA PM-R1 (BUFFER))-DIRECT BILIRUBIN E-HA IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN SERUM OR PLASMA. ,L-TYPE CREATININE M(L-TYPE CREATININE M PM-R2 (ENZYME COLOR B))-L-TYPE CREATININE M IS AN IN VITRO ASSAY FOR THE

	QUANTITATIVE DETERMINATION OF CREATININE IN SERUM, PLASMA OR URINE. ,CK-MB CALIBRATOR(CK-MB CALIBRATOR)-THE CK-MB CALIBRATOR IS INTENDED FOR USE AS CALIBRATOR OF CK-MB TESTING BASED ON THE IMMUNOINHIBITION METHOD REAGENTS, AND SHOULD BE USED WITH WAKO'S L-TYPE CK-MB(2). ,L-TYPE UIBC (L-TYPE UIBC PM-R2 (COLOR))-L-TYPE UIBC IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF UNSATURATED IRON BINDING CAPACITY (UIBC) IN SERUM OR PLASMA.,IGE CONTROL SET (IGE CONTROL SET)-THE IGE CONTROL SET IS DESIGNED TO BE USED WITH IGE-LT FOR THE QUALITY CONTROL OF IGE IN SERUM OR PLASMA. ,L-TYPE LDL-C M(L-TYPE LDL-C M PM-R1 (PRETREATMENT))-L-TYPE LDL-C M IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN SERUM OR PLASMA. ,PREALBUMIN CONTROL SET (PREALBUMIN CONTROL SET)-THE PREALBUMIN CONTROL SET IS DESIGNED TO BE USED WITH AUTOKIT PREALBUMIN FOR THE QUALITY CONTROL OF PREALBUMIN IN SERUM OR PLASMA . ,L-TYPE CK(L-TYPE CK PM-R2 (SUBSTRATE))-L-TYPE CK IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF CREATINE PHOSPHOKINASE (CPK) IN SERUM OR PLASMA. ,LP(A)-HA(LP(A)-HA BUFFER)-LP(A)-HA IS AN IN VITRO TURBIDIMETRIC IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN (A) IN SERUM OR PLASMA. ,ASO-LT(ASO-LT LATEX REAGENT)-ASO-LT IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN O (ASO) TITER IN SERUM. , LIPIDS CONTROL SET(LIPIDS CONTROL SET)-LIPIDS CONTROL SET IS LYOPHILIZED PRODUCT, WHICH IS HUMAN SERUM BASIS, AND DESIGNED TO BE USED AS A QUALITY CONTROL MATERIAL FOR TOTAL CHOLESTEROL, HDL-CHOLESTEROL, LDL-CHOLESTEROL AND TRIGLYCERIDE. ,AR SERIES MICRO TP-AR 2(AR SERIES MICRO TP-AR 2)-AR SERIES MICRO TP-AR 2 IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN URINE OR CEREBROSPINAL FLUID. ,FERRITIN CALIBRATOR SET(FERRITIN CALIBRATOR SET)-FERRITIN CALIBRATOR SET: THE FERRITIN CALIBRATOR SET IS DESIGNED TO BE USED WITH FERRITIN-LT FOR THE DETERMINATION OF FERRITIN IN SERUM OR PLASMA. ,BILIRUBIN CALIBRATOR(BILIRUBIN CALIBRATOR)-THE BILIRUBIN CALIBRATOR IS DESIGNED TO BE USED AS CALIBRATOR WITH WAKO'S TOTAL AND DIRECT BILIRUBIN REAGENTS BASED ON THE VANADATE OXIDATION METHOD. ,AUTOKIT PREALBUMIN(AUTOKIT PREALBUMIN ANTIBODY (PM-R2))-AUTOKIT PREALBUMIN IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF PREALBUMIN IN SERUM OR PLASMA. ,TOTAL BILIRUBIN E-HA(TOTAL BILIRUBIN E-HA PM-R1 (BUFFER))-TOTAL BILIRUBIN E-HA IS AN IN VITRO ASSAY FOR THE

	QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN SERUM OR PLASMA. ,CONTROL SERUM I WAKO/BR(CONTROL SERUM I WAKO/BR)-THE CONTROL SERUM I WAKO/BR IS DESIGNED TO BE USED AS A QUALITY CONTROL MATERIAL FOR GENERAL CHEMISTRY ASSAYS. USE THE CONTROL SERUM I WAKO/BR WITH EACH REAGENT OF FUJIFILM WAKO PURE CHEMICAL CORPORATION. ,L-TYPE LD IFCC (L-TYPE LD IFCC NAD (PM-R2))-L-TYPE LD IFCC IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF LACTATE DEHYDROGENASE (LD) IN SERUM OR PLASMA. ,LT CRP-HS CALIBRATOR SET HO(LT CRP-HS CALIBRATOR SET HO)-LT CRP-HS CALIBRATOR SET HO: THE LT CRP-HS CALIBRATOR SET HO IS DESIGNED TO BE USED WITH LT CRP-HSII FOR THE DETERMINATION OF CRP. ,DIRECT BILIRUBIN E-HA(DIRECT BILIRUBIN E-HA PM-R2 (VANADATE))-DIRECT BILIRUBIN E-HA IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN SERUM OR PLASMA. ,AUTOKIT PREALBUMIN(AUTOKIT PREALBUMIN BUFFER (PM-R1))-AUTOKIT PREALBUMIN IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF PREALBUMIN IN SERUM OR PLASMA. ,MULTI-CHEM CALIBRATOR A(MULTI-CHEM CALIBRATOR A)-THE WAKO MULTI-CHEM CALIBRATOR A IS TO BE USED WITH WAKO'S ASSAY REAGENTS FOR THE DETERMINATION OF CALCIUM (CA), IRON (FE) / UNSATURATED IRON BINDING CAPACITY (UIBC), MAGNESIUM (MG), INORGANIC PHOSPHOROUS (P) OR CREATININE (CRE) IN SPECIMEN. ,L-TYPE AMYLASE IFCC(L-TYPE AMYLASE IFCC ENZYME (PM-R1))-L-TYPE AMYLASE IFCC IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE AMYLASE ACTIVITY IN SERUM, PLASMA OR URINE. ,ENZYME CALIBRATOR(ENZYME CALIBRATOR)-THE ENZYME CALIBRATOR IS DESIGNED TO BE USED WITH FUJIFILM WAKO PURE CHEMICAL CORPORATION'S ASSAY REAGENTS FOR THE DETERMINATION OF AST, ALT, ALP, CK, LD, -GT, AMY AND CHE IN SPECIMEN. THIS CALIBRATOR IS TRACEABLE TO IFCC REFERENCE METHOD EXCEPT FOR CHE. ,IGE CALIBRATOR SET (IGE CALIBRATOR SET)-THE IGE CALIBRATOR SET IS DESIGNED TO BE USED WITH IGE-LT FOR THE DETERMINATION OF IGE IN SERUM OR PLASMA. ,L-TYPE AST.J2(L-TYPE AST.J2 PM-R1 (SUBSTRATE-ENZYME))-L-TYPE AST.J2 IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF ASPARTATE AMINOTRANSFERASE (AST) IN SERUM OR PLASMA. ,RF-LT(RF-LT PM-R2 (LATEX REAGENT))-RF-LT IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR ACTIVITY IN SERUM OR PLASMA. ,CONTROL SERUM II WAKO/BR(CONTROL SERUM II WAKO/BR)-THE CONTROL SERUM WAKO/BR IS DESIGNED TO BE USED AS A QUALITY CONTROL MATERIAL FOR GENERAL CHEMISTRY ASSAYS. USE THE CONTROL SERUM WAKO/BR WITH

	EACH REAGENT OF FUJIFILM WAKO PURE CHEMICAL CORPORATION. , L-TYPE UN(L-TYPE UN PM-R2 (SUBSTRATE-ENZYME))-L-TYPE UN IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF UREA NITROGEN IN SERUM, PLASMA OR URINE. ,BETA2M-LT BETA2M CALIBRATOR SET L (FOR URINE)(BETA2M-LT BETA2M CALIBRATOR SET L (FOR URINE))-2M-LT IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF 2-MICROGLOBULIN (2-M) IN SERUM OR URINE. ,RF-LT CALIBRATOR SET(RF-LT CALIBRATOR SET)-THE RF-LT CALIBRATOR SET IS DESIGNED TO BE USED WITH RF-LT FOR THE DETERMINATION OF RHEUMATOID FACTOR ACTIVITY IN SERUM OR PLASMA. ,ASO-LT(ASO-LT BUFFER)-ASO-LT IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN O (ASO) TITER IN SERUM. ,L-TYPE -GT.J(L-TYPE -GT.J PM-R1 (BUFFER))-L-TYPE -GT.J IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF -GLUTAMYL TRANSPEPTIDASE (-GT) IN SERUM OR PLASMA. ,L-TYPE CK-MB(2)(L-TYPE CK-MB(2) SUBSTRATE)-L-TYPE CK-MB(2) IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF CK-MB IN SERUM OR PLASMA. ,AUTOKIT MICRO ALBUMIN(AUTOKIT MICRO ALBUMIN ANTIBODY)-THE AUTOKIT MICRO ALBUMIN TEST IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN URINE. ,L-TYPE AST.J2(L-TYPE AST. J2 PM-R2 (-KG))-L-TYPE AST.J2 IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF ASPARTATE AMINOTRANSFERASE (AST) IN SERUM OR PLASMA. ,L-TYPE UN(L-TYPE UN PM-R1 (COENZYME))-L-TYPE UN IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF UREA NITROGEN IN SERUM, PLASMA OR URINE. ,IGE-LT(IGE-LT BUFFER)-IGE-LT IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF NONSPECIFIC IGE IN SERUM OR PLASMA. ,L-TYPE TRIGLYCERIDE M(L-TYPE TRIGLYCERIDE M PM-R2 (ENZYME COLOR B))-L-TYPE TRIGLYCERIDE M IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDE IN SERUM OR PLASMA. ,FERRITIN-LT(FERRITIN-LT BUFFER)-FERRITIN-LT IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN SERUM OR PLASMA. ,L-TYPE CK(L-TYPE CK PM-R1 (ENZYME))-L-TYPE CK IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF CREATINE PHOSPHOKINASE (CPK) IN SERUM OR PLASMA. ,L-TYPE FE N(L-TYPE FE N PM-R2 (COLOR))-L-TYPE FE N IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF IRON (FE) IN SERUM OR PLASMA. ,HA SERIES ALBUMIN II-HA(HA SERIES ALBUMIN II-HA PM-R1 (BCG))-HA SERIES ALBUMIN II-HA IS AN IN VITRO ASSAY FOR THE UANTITATIVE DETERMINATION OF ALBUMIN IN SERUM OR PLASMA. , LP(A) CALIBRATOR(LP(A) CALIBRATOR)-THE LP(A) CALIBRATORT IS

	DESIGNED TO BE USED WITH LP(A)-HA FOR THE DETERMINATION OF LIPOPROTEIN (A) IN SERUM OR PLASMA. ,BETA2M-LT BETA2M CALIBRATOR SET L (FOR SERUM)(BETA2M-LT BETA2M CALIBRATOR SET L (FOR SERUM))-2M-LT IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF 2-MICROGLOBULIN (2-M) IN SERUM OR URINE. ,L-TYPE CK-MB(2)(L-TYPE CK-MB(2) ENZYME)-L-TYPE CK-MB(2) IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF CK-MB IN SERUM OR PLASMA. , MICRO ALBUMIN CALIBRATOR SET(MICRO ALBUMIN CALIBRATOR SET)-THE MICRO ALBUMIN CALIBRATOR SET IS DESIGNED TO BE USED WITH AUTOKIT MICRO ALBUMIN FOR THE DETERMINATION OF ALBUMIN IN URINE. ,BETA2M-LT(BETA2MLT BUFFER)-2M-LT IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF 2-MICROGLOBULIN (2-M) IN SERUM OR URINE. ,L-TYPE AMYLASE IFCC (L-TYPE AMYLASE IFCC SUBSTRATE (PM-R2))-L-TYPE AMYLASE IFCC IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE AMYLASE ACTIVITY IN SERUM, PLASMA OR URINE. ,L-TYPE TRIGLYCERIDE M(L-TYPE TRIGLYCERIDE M PM-R1 (ENZYME COLOR A))-L-TYPE TRIGLYCERIDE M IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDE IN SERUM OR PLASMA. ,LP(A)-HA(LP(A)-HA ANTIBODY)-LP(A)-HA IS AN IN VITRO TURBIDIMETRIC IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LIPOPROTEIN (A) IN SERUM OR PLASMA. , PREALBUMIN CALIBRATOR SET(PREALBUMIN CALIBRATOR SET)-THE PREALBUMIN CALIBRATOR SET IS DESIGNED TO BE USED WITH AUTOKIT PREALBUMIN FOR THE DETERMINATION OF PREALBUMIN IN SERUM OR PLASMA . ,L-TYPE ALT.J2(L-TYPE ALT.J2 PM-R1 (SUBSTRATE-ENZYME))-L-TYPE ALT.J2 IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF ALANINE AMINOTRANSFERASE (ALT) IN SERUM OR PLASMA. ,MULTI-CHEM CALIBRATOR B(MULTI-CHEM CALIBRATOR B)-THE WAKO MULTI-CHEM CALIBRATOR B IS TO BE USED WITH WAKO'S ASSAY REAGENTS FOR THE DETERMINATION OF GLUCOSE, URIC ACID OR UREA NITROGEN IN SPECIMEN. ,L-TYPE CHE J(L-TYPE CHE J SUBSTRATE (PM-R2))-L-TYPE CHE J IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF CHOLINE ESTERASE (CHE) IN SERUM OR PLASMA. ,AUTOKIT MICRO ALBUMIN (AUTOKIT MICRO ALBUMIN BUFFER)-THE AUTOKIT MICRO ALBUMIN TEST IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN URINE. ,L-TYPE LD IFCC(L-TYPE LD IFCC SUBSTRATE BUFFER (PM-R1))-L-TYPE LD IFCC IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF LACTATE DEHYDROGENASE (LD) IN SERUM OR PLASMA. ,L-TYPE ALP IFCC(L-TYPE ALP IFCC SUBSTRATE)-L-TYPE ALP IFCC IS AN IN

	VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF ALKALINE PHOSPHATASE (ALP) IN SERUM OR PLASMA. , L-TYPE FE N(L-TYPE FE N PM-R1 (BUFFER))-L-TYPE FE N IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF IRON (FE) IN SERUM OR PLASMA. ,TOTAL BILIRUBIN E-HA(TOTAL BILIRUBIN E-HA PM-R2 (VANADATE))-TOTAL BILIRUBIN E-HA IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN SERUM OR PLASMA. ,L-TYPE CREATININE M(L-TYPE CREATININE M PM-R1 (ENZYME COLOR A))-L-TYPE CREATININE M IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN SERUM, PLASMA OR URINE. ,L-TYPE UA M(L-TYPE UA M PM-R1 (ENZYME COLOR A))-L-TYPE UA M IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN SERUM, PLASMA OR URINE. ,CK-MB CONTROL 1(CK-MB CONTROL 1)-THE CK-MB CONTROL 1 AND THE CK-MB CONTROL 2 ARE INTENDED FOR USE AS QUALITY CONTROL MATERIALS IN THE CLINICAL LABORATORY TO MONITOR THE ACCURACY AND PRECISION OF CK-MB TESTING BASED ON THE IMMUNOINHIBITION METHOD REAGENTS, AND SHOULD BE USED WITH WAKO'S L-TYPE CK-MB(2). ,L-TYPE TP(L-TYPE TP COLOR REAGENT (PM-R2))-L-TYPE TP IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN SERUM OR PLASMA. ,L-TYPE CHO M(L-TYPE CHO M PM-R1 (ENZYME COLOR A))-L-TYPE CHO M IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTALCHOLESTEROL IN SERUM OR PLASMA. ,L-TYPE HDL-C M (3)(L-TYPE HDL-C M (3) PM-R1 (PRETREATMENT))-L-TYPE HDL-C M (3) IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL IN SERUM OR PLASMA. ,L-TYPE -GT.J(L-TYPE -GT.J PM-R2 (SUBSTRATE))-L-TYPE -GT.J IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF -GLUTAMYL TRANSPEPTIDASE (-GT) IN SERUM OR PLASMA. ,CK-MB CONTROL 2 (CK-MB CONTROL 2)-THE CK-MB CONTROL 1 AND THE CK-MB CONTROL 2 ARE INTENDED FOR USE AS QUALITY CONTROL MATERIALS IN THE CLINICAL LABORATORY TO MONITOR THE ACCURACY AND PRECISION OF CK-MB TESTING BASED ON THE IMMUNOINHIBITION METHOD REAGENTS, AND SHOULD BE USED WITH WAKO'S L-TYPE CK-MB(2). ,L-TYPE ALT.J2(L-TYPE ALT.J2 PM-R2 (-KG))-L-TYPE ALT.J2 IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF ALANINE AMINOTRANSFERASE (ALT) IN SERUM OR PLASMA. ,FERRITIN CONTROL SET(FERRITIN CONTROL SET)-FERRITIN CONTROL SET: THE FERRITIN CONTROL SET IS DESIGNED TO BE USED WITH FERRITIN-LT FOR THE QUALITY CONTROL OF FERRITIN IN SERUM OR PLASMA. ,IMMUNO-CONTROL 2 (IMMUNO-CONTROL 2)-IMMUNO-CONTROL 2 IS THE LIQUID TYPE

	CONTROL SERUM BASED ON HUMAN POOLED SERA AND DESIGNED FOR AN ACCURACY CONTROL FOR CRP, RF OR ASO. THE ASSIGNED VALUES ARE MEASURED BY USING WAKO'S REAGENTS FOR AUTOMATED ANALYZERS, STATED AS ASSAY VALUES. ,HRII SERIES P-HRII(HRII SERIES P-HRII COLOR B)-HRII SERIES P-HRII IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHORUS IN SERUM OR URINE. ,LT CRP-HSII(LT CRP-HSII PM-R2 (LATEX REAGENT))-THE LT CRP-HSII IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM OR PLASMA. ,L-TYPE HDL-C M (3)(L-TYPE HDL-C M (3) PM-R2 (REACTING SOLUTION))-L-TYPE HDL-C M (3) IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL IN SERUM OR PLASMA. ,L-TYPE CHO M(L-TYPE CHO M PM-R2 (ENZYME COLOR B))-L-TYPE CHO M IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTALCHOLESTEROL IN SERUM OR PLASMA. ,MICRO ALBUMIN CONTROL SET(MICRO ALBUMIN CONTROL SET)-THE MICRO ALBUMIN CONTROL SET IS TO BE USED WITH AUTOKIT MICRO ALBUMIN FOR THE QUALITY CONTROL OF ALBUMIN IN URINE. ,CALCIUM E-HA (CALCIUM E-HA PM-R1 (BUFFER))-CALCIUM E-HA IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM, PLASMA OR URINE. ,L-TYPE ALP IFCC(L-TYPE ALP IFCC BUFFER)-L-TYPE ALP IFCC IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF ALKALINE PHOSPHATASE (ALP) IN SERUM OR PLASMA. ,TP/ALB CALIBRATOR (TP/ALB CALIBRATOR)-THE WAKO TP/ALB CALIBRATOR IS TO BE USED WITH WAKO'S ASSAY REAGENTS FOR THE DETERMINATION OF TOTAL PROTEIN (TP) AND ALBUMIN (ALB) IN SERUM OR PLASMA. , MULTI CALIBRATOR LIPIDS(MULTI CALIBRATOR LIPIDS)-THE WAKO MULTI CALIBRATOR LIPIDS IS TO BE USED WITH WAKO'S ASSAY REAGENTS FOR THE DETERMINATION OF TOTAL CHOLESTEROL (T-CHO), FREE CHOLESTEROL (F-CHO), HDL-CHOLESTEROL (HDL-C), LDL-CHOLESTEROL (LDL-C), TRIGLYCERIDE (TG) AND PHOSPHOLIPIDS (PL) IN SPECIMEN. ,ASO-LT ASO CALIBRATOR SET (ASO-LT ASO CALIBRATOR SET)-ASO-LT IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN O (ASO) TITER IN SERUM. ,L-TYPE CHE J(L-TYPE CHE J COENZYME (PM-R1))-L-TYPE CHE J IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF THE ACTIVITY OF CHOLINE ESTERASE (CHE) IN SERUM OR PLASMA. ,FERRITIN-LT(FERRITIN-LT LATEX REAGENT)-FERRITIN-LT IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN SERUM OR PLASMA. ,LT CRP-HSII(LT CRP-HSII PM-R1 (BUFFER))-THE LT CRP-HSII IS AN IN VITRO ASSAY FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN

	(CRP) IN SERUM OR PLASMA.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1158	IMP/IVD/2021/000395	1.License Holder Name: M/S VISHAT DIAGNOSTIC PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SAA RAPID QUANTITATIVE TEST(BIOTIME)-THE SAA RAPID QUANTITATIVE TEST IS INTENDED TO QUANTIFY THE CONCENTRATION OF SAA, IN HUMAN SERUM,PLASMA OR WHOLE BLOOD ON BIOTIME FIA ANALYZERS BY FLUORESCENT IMMUNOASAY. THE TEST IS USED AS AN AID DETECTION OF INFECTIOUS PROCESSES, SAA IS ALSO USED AS AN AID DETECTION OF INFLAMMATION.,FSH RAPID QUANTITATIVE TEST (BIOTIME)-THE FSH RAPID QUANTITATIVE TEST IS INTENDED TO QUANTIFY THE CONCENTRATION OF FSH IN HUMAN SERUM ON BIOTIME FIA ANALYZER BY FLUORESCENT IMMUNOASSAY. THE TEST IS USED AS AN AID DETECTION OF INFERTILITY.,CK-MB RAPID QUANTITATIVE TEST(BIOTIME)-THE BIOTIME CK-MB (CREATINE KINASE MB) RAPID QUANTITATIVE TEST IS INTENDED TO QUANTIFY THE CONCENTRATION OF CK-MB IN HUMAN SERUM OR PLASMA ON BIOTIME FIA ANALYZER BY FLUORESCENT IMMUNOASSAY. IT IS USED AS AN AID DETECTION OF ACUTE MYOCARDIAL INFARCTION.,TSH RAPID QUANTITATIVE TEST(BIOTIME)-THE BIOTIME TSH (THYROID-STIMULATING HORMONE) RAPID QUANTITATIVE TEST IS INTENDED TO QUANTIFY THE CONCENTRATION OF TSH IN HUMAN SERUM OR PLASMA ON BIOTIME FIA ANALYZERS BY FLUORESCENT IMMUNOASSAY. THE TEST IS USED AS AN AID DETECTION OF HYPERTHYROIDISM OR HYPOTHYROIDISM.,HBA1C RAPID QUANTITATIVE TEST(BIOTIME)-IT IS INTENDED TO QUANTIFY THE PERCENTAGE OF HBA1C IN HUMAN WHOLE BLOOD ON BIOTIME FIA ANALYZER BY FLUORESCENT IMMUNOASSAY.THE TEST IS USED AS AN AID IN MANAGEMENT AND MONITORING OF THE LONG-TERM GLYCEMIC STATUS IN PATIENTS WITH DIABETES MELLITUS.,PRL RAPID QUANTITATIVE TEST(BIOTIME)-THE BIOTIME PRL (PROLACTIN) RAPID QUANTITATIVE TEST IS INTENDED TO QUANTIFY THE CONCENTRATION OF PRL IN HUMAN SERUM ON BIOTIME FIA ANALYZER BY FLUORESCENT IMMUNOASSAY. THE TEST IS USED AS AN AID DETECTION OF INFERTILITY.,TT4 RAPID QUANTITATIVE TEST (BIOTIME)-THE BIOTIME TOTAL THYROXINE (TT4) RAPID QUANTITATIVE TEST IS INTENDED TO QUANTIFY THE CONCENTRATION OF TOTAL THYROXINE IN HUMAN SERUM OR PLASMA ON BIOTIME FIA ANALYZER BY FLUORESCENT IMMUNOASSAY. THE TEST IS USED AS AN AID DETECTION OF THYROID GLAND DISEASE.,FERRITIN RAPID QUANTITATIVE TEST (BIOTIME)-THE BIOTIME FERRITIN RAPID QUANTITATIVE TEST IS INTENDED TO QUANTIFY THE CONCENTRATION OF FERRITIN IN HUMAN SERUM ON BIOTIME FIA ANALYZERS BY FLUORESCENT IMMUNOASSAY. THE TEST IS USED AS AN AID DETECTION OF

	ANEMIA.,-HCG RAPID QUANTITATIVE TEST(BIOTIME)-THE BIOTIME -HCG (TOTAL HUMAN CHORIONIC GONADOTROPIN) RAPID QUANTITATIVE TEST IS INTENDED TO QUANTIFY THE CONCENTRATION OF TOTAL -HCG IN HUMAN SERUM OR PLASMA ON BIOTIME FIA ANALYZERS BY FLUORESCENT IMMUNOASSAY. THE TEST IS USED AS AN AID DETECTION OF EARLY PREGNANCY, EMBRYONIC DEVELOPMENT AND ECTOPIC PREGNANCY.,MYO RAPID QUANTITATIVE TEST(BIOTIME)-THE BIOTIME MYO (MYOGLOBIN) RAPID QUANTITATIVE TEST IS INTENDED TO QUANTIFY THE CONCENTRATION OF MYO IN HUMAN SERUM OR PLASMA ON BIOTIME FIA ANALYZERS BY FLUORESCENT IMMUNOASSAY. IT IS USED AS AN AID DETECTION OF ACUTE MYOCARDIAL INFARCTION.,25(OH)-D RAPID QUANTITATIVE TEST(BIOTIME)-THE BIOTIME 25(OH)-D RAPID QUANTITATIVE TEST IS INTENDED TO QUANTIFY THE CONCENTRATION OF 25(OH)-D IN WHOLE BLOOD ON BIOTIME FIA ANALYZER BY FLUORESCENT IMMUNOASSAY. THE TEST IS USED AS AN AID DETECTION TO VITAMIN D DEFICIENCY.,LH RAPID QUANTITATIVE TEST(BIOTIME)-THE BIOTIME LH RAPID QUANTITATIVE TEST IS INTENDED TO QUANTIFY THE CONCENTRATION OF LH IN HUMAN SERUM ON BIOTIME FIA ANALYZER BY FLUORESCENT IMMUNOASSAY. THE TEST IS USED AS AN AID DETECTION OF INFERTILITY.,TT3 RAPID QUANTITATIVE TEST (BIOTIME)-THE TOTAL TRIIODOTHYRONINE (TT3) RAPID QUANTITATIVE TEST IS INTENDED TO QUANTIFY THE CONCENTRATION OF TOTAL TRIIODOTHYRONINE IN HUMAN SERUM ON BIOTIME FIA ANALYZER BY FLUORESCENT IMMUNOASSAY. THE TEST IS USED AS AN AID DETECTION OF THYROID GLAND DISEASE.

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1159	IMP/IVD/2021/000396	1.License Holder Name: RIVAARA LABS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TICK-BORNE BACTERIA FLOW CHIP KIT (HS12 AND HS24)(MASTER DIAGNOSTICA)-TICK-BORNE BACTERIA FLOW CHIP IS AN IN VITRO DIAGNOSTIC KIT FOR THE IDENTIFICATION OF BACTERIAL ARTHROPOD-BORNE PATHOGENS. THE TICK-BORNE BACTERIA FLOW CHIP SYSTEM ALLOWS THE SIMULTANEOUS QUALITATIVE DETECTION OF THE MAIN BACTERIAL SPECIES BELONGING TO THE GENERA ANAPLASMA, EHRLICHIA, BORRELIA, BARTONELLA, COXIELLA, RICKETTSIA AND FRANCISELLA THROUGH THE BACTERIAL DNA AMPLIFICATION WITH TWO MULTIPLEX PCRS AND SUBSEQUENT REVERSE HYBRIDIZATION (“REVERSE DOT BLOT”) ON A MEMBRANE CONTAINING SPECIFIC PROBES FOR EACH GENUS TO BE DETECTED USING THE TECHNOLOGY BASED ON THE “DNA-FLOW” TECHNOLOGY, WHICH INCREASES THE SENSITIVITY OF THE TECHNIQUE AND SAVES TIME SIGNIFICANTLY.,AMR DIRECT FLOW CHIP KIT (MANUAL AND AUTO) (MASTER DIAGNOSTICA)-ANTIMICROBIAL RESISTANCE (AMR) DIRECT FLOW CHIP IS AN IN VITRO DIAGNOSTIC KIT THAT ALLOWS A QUICK DETECTION OF TWENTY ANTIBIOTIC RESISTANCE GENE FAMILIES (GES, SME, KPC, NMC/IMI, SIM, GIM, SPM, NDM, VIM, IMP, OXA23_LIKE, OXA24_LIKE, OXA48_LIKE, OXA51_LIKE, OXA58_LIKE, BLASHV, BLACTX-M, MECA, VANA AND VANB), WHICH ARE ASSOCIATED WITH MULTIDRUG-RESISTANT ORGANISMS (MRO) INCLUDING CARBAPENEM-RESISTANT GRAM-NEGATIVE BACTERIA AND EXTENDED-SPECTRUM BETA-LACTAMASE PRODUCERS (ESBL) ALONG WITH VANCOMYCIN-RESISTANT ENTEROCOCCUS (VRE) AND METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA). THE TEST IS PERFORMED DIRECTLY ON RECTAL EXUDATES, NASOPHARYNGEAL EXUDATES/ASPIRATES, BLOOD CULTURES AND/OR BACTERIAL COLONIES, IN INFECTED PATIENTS OR PATIENTS AT RISK FOR COLONIZATION, AS A MEASURE TO HELP IN THE CONTROL AND PREVENTION OF THIS TYPE OF INFECTIONS. THE METHOD IS BASED ON AMPLIFICATION OF DNA TARGETS THROUGH MULTIPLEX PCR REACTION, AND SUBSEQUENT REVERSE HYBRIDIZATION ON A MEMBRANE THAT CONTAINS SPECIFIC PROBES.,BACTERIAL CNS FLOW CHIP KIT (HS12 AND HS24)(MASTER DIAGNOSTICA)-BACTERIAL CNS FLOW CHIP IS AN IN VITRO DIAGNOSTIC KIT OF BACTERIA AND FUNGI THAT CAUSE MENINGITIS AND ENCEPHALITIS IN HUMANS. THE METHODS THAT ARE CURRENTLY USED FOR THEIR DIAGNOSIS ARE VERY LABORIOUS AND NOT ALWAYS SHOW A 100% SPECIFICITY. THE BACTERIAL CNS FLOW CHIP SYSTEM ALLOWS THE SIMULTANEOUS DETECTION OF NINE BACTERIAL SPECIES (NEISSERIA MENINGITIDIS, STREPTOCOCCUS

	PNEUMONIAE, STREPTOCOCCUS AGALACTIAE, LISTERIA MONOCYTOGENES, HAEMOPHILUS INFLUENZAE, MYCOBACTERIUM TUBERCULOSIS COMPLEX, TREPONEMA PALLIDUM, COXIELLA BURNETTI, AND BORRELIA BURGDORFERI) AND A FUNGUS (CRYPTOCOCCUS NEOFORMANS) THROUGH THE AMPLIFICATION OF THE BACTERIAL DNA BY MULTIPLEX PCR AND REVERSE HYBRIDIZATION ON A MEMBRANE THAT CONTAINS SPECIFIC DNA PROBES FOR EVERY SPECIES.,SEPSIS FLOW CHIP KIT (HS12 AND HS24)(MASTER DIAGNOSTICA)-SEPSIS FLOW CHIP IS AN IN VITRO DIAGNOSTIC KIT FOR HUMAN NOSOCOMIAL INFECTIONS BASED ON MULTIPLEX PCR AND REVERSE DOT BLOT HYBRIDIZATION FOR SIMULTANEOUS DETECTION OF BACTERIA, FUNGI, AND MAJOR ANTIBIOTIC RESISTANCE GENES IN A SINGLE ASSAY. SEPSIS FLOW CHIP SYSTEM ALLOWS SIMULTANEOUS DETECTION OF OVER 36 BACTERIA SPECIES (COAGULASE-NEGATIVE STAPHYLOCOCCI, STAPHYLOCOCCUS AUREUS, STREPTOCOCCUS SPP., STREPTOCOCCUS PNEUMONIAE, STREPTOCOCCUS AGALACTIAE, STREPTOCOCCUS PYOGENES, LISTERIA MONOCYTOGENES, ENTEROCOCCUS SPP., PSEUDOMONAS AERUGINOSA, ACINETOBACTER BAUMANNII, NEISSERIA MENINGITIDIS, STENOTROPHOMONAS MALTOPHILIA, ESCHERICHIA COLI, KLEBSIELLA PNEUMONIAE, SERRATIA MARCESCENS, ENTEROBACTERIACEAE SPECIES, AND PROTEUS/MORGANELLA SPP.), FUNGI SPECIES (CANDIDA ALBICANS AND CANDIDA SPP.) AND TWENTY ANTIBIOTIC RESISTANCE MARKERS. REGARDING THE ANTIBIOTIC RESISTANCE MARKERS, THE KIT DETECTS ONE GENE FOR METHICILLIN RESISTANCE (MECA), TWO GENES FOR VANCOMYCIN RESISTANCE (VANA AND VANB), TWO FOR -LACTAM ANTIBIOTIC RESISTANCE (BLASHV AND EXTENDED-SPECTRUM BLACTX- M), AND FIFTEEN GENES FOR CARBAPENEMS RESISTANCE (KPC ALLELE: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22 AND 23, SME ALLELE: 1, 2, 3, 4 AND 5, NMC/IMI ALLELE: 1, 2, 3, 4, 5, 6, 7, 8 AND 9, GES ALLELE: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 AND 26, VIM ALLELE: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45 AND 46, GIM ALLELE: 1 AND 2, SPM, NDM ALLELE: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15 AND 16, SIM, IMP3, 15, 19_LIKE ALLELE: 1, 2, 3, 5, 6, 8, 9, 10, 11, 15, 19, 20, 21, 24, 25, 28, 29, 30, 40, 41, 42 AND 47, OXA23_LIKE ALLELE: 23, 27, 49, 73, 133, 146, 165, 166, 167, 168, 169, 170, 171 AND 225, OXA24_LIKE ALLELE: 24, 25, 26, 40, 72, 139 AND 160, OXA48_LIKE ALLELE: 48, 162, 163 AND 181, OXA51_LIKE ALLELE: 51, 60, 65, 66, 67, 68, 69, 70, 75, 76, 77, 78, 79, 80, 82, 83, 84, 88, 89, 90, 91, 92, 93, 94, 95, 98, 99, 106, 107, 108, 109, 110, 111, 112, 113, 115, 116, 117, 128, 130, 131, 132, 138, 144, 148, 149, 150,

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	172, 173, 174, 175, 176, 177, 178, 179, 180, 195, 196, 197, 194, 200, 201, 202, 203, 206, 208 AND 223, OXA58_LIKE ALLELE: 58, 96, 97 AND 164). THE METHOD IS BASED ON AMPLIFYING THE TARGET DNAS WITH TWO MULTIPLEX PCR REACTIONS AND SUBSEQUENTLY HYBRIDIZING THE BIOTINYLATED AMPLICONS TO SPECIFIC DNA PROBES.,HPV DIRECT FLOW CHIP KIT (HS12 AND HS24)(MASTER DIAGNOSTICA)-HPV DIRECT FLOW CHIP IS AN IN VITRO DIAGNOSTIC KIT FOR THE HUMAN PAPILLOMAVIRUS (HPV). THE INFECTION WITH HPV IS AN ESSENTIAL FACTOR IN CERVICAL AND ANOGENITAL CARCINOGENESIS (ZUR HAUSEN ET AL, 1974; WALBOOMER ET AL, 1999; ZUR HAUSEN, 1996; ZUR HAUSEN 2002). BASED ON ITS ASSOCIATION WITH DIFFERENT DEGREES OF LESIONS, HPV HAS BEEN CLASSIFIED (MUÑOZ 2003) AS HIGH-RISK OR ONCOGENIC GENOTYPES, WHICH CAN INDUCE CARCINOGENESIS; AND LOW-RISK HPVS, WHICH CAUSE GENITAL WARTS AND COLLABORATE WITH HIGH-RISK HPVS. THE HPV DIRECT FLOW CHIP ALLOWS THE QUALITATIVE DETECTION OF THE HPV AND GENOTYPING OF 35 TYPES OF HPV (HIGH-RISK HPV 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73 AND 82, AND LOW-RISK HPV 6, 11, 40, 42, 43, 44, 54, 55, 61, 62, 67, 69, 70, 71, 72, 81 AND 84) BY PCR (POLYMERASE CHAIN REACTION), FOLLOWED BY REVERSE HYBRIDIZATION ON A MEMBRANE CONTAINING SPECIFIC PROBES. IN THIS PROTOCOL, THE CLINICAL SAMPLES CAN ALSO BE AMPLIFIED DIRECTLY WITHOUT THE NEED FOR DNA EXTRACTION PREVIOUSLY.,STD DIRECT FLOW CHIP KIT (MANUAL AND AUTO)(MASTER DIAGNOSTICA)-STD DIRECT FLOW CHIP IS AN IN VITRO DIAGNOSTIC KIT FOR THE DETECTION OF PATHOGENIC ORGANISMS CAUSING SEXUALLY TRANSMITTED DISEASES (STD) IN HUMANS. THE ORGANISMS CAUSING THESE INFECTIONS ARE OFTEN DIFFICULT TO DETECT AND INCLUDE VIRUSES, BACTERIA OR PARASITES, USUALLY OCCURRING CO-INFECTIONS. THE METHODS THAT ARE CURRENTLY USED FOR THEIR DIAGNOSIS ARE VERY LABORIOUS AND NOT ALWAYS SHOW A 100% SPECIFICITY. THE STD DIRECT FLOW CHIP ALLOWS THE SIMULTANEOUS DETECTION OF 11 PATHOGENS: CHLAMYDIA TRACHOMATIS1*, HAEMOPHILUSDUCREYI, HERPES SIMPLEX VIRUS 1 AND HERPES SIMPLEX VIRUS 2, MYCOPLASMA GENITALIUM, MYCOPLASMA HOMINIS, NEISSERIA GONORRHOEAE, TREPONEMA PALLIDUM, TRICHOMONAS VAGINALIS AND UREAPLASMA2 (UREALYTICUM/PARVUM). THE STD DIRECT FLOW CHIP KIT ALLOWS THE DIRECT DETECTION OF THESE INFECTIOUS AGENTS FROM DIFFERENT TYPES OF CLINICAL SAMPLES (URINE, SEMEN, LIQUID-BASED ENDOCERVICAL CYTOLOGIES; AND URETHRAL, ENDOCERVICAL, VAGINAL, ANAL AND PHARYNGEAL SWABS) WITHOUT PREVIOUS EXTRACTION OF DNA, AS WELL AS FROM

	PURIFIED DNA OF THESE TYPE OF CLINICAL SAMPLES.

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1160	IMP/IVD/2021/000397	1.License Holder Name: M/S. CPC DIAGNOSTICS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FCAL TURBO KIT (BUHLMANN (KK-CAL))-THE BÜHLMANN FCAL® TURBO IS AN AUTOMATED IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF CALPROTECTIN IN HUMAN STOOL SPECIMENS INTENDED AS AN AID IN THE ASSESSMENT OF INTESTINAL MUCOSAL INFLAMMATION. THE ASSAY RESULTS CAN BE USED AS AN AID TO DIAGNOSIS IN DISTINGUISHING ORGANIC, INFLAMMATORY DISEASE OF THE GASTROINTESTINAL TRACT (INFLAMMATORY BOWEL DISEASE, IBD, E.G. CROHN'S DISEASE OR ULCERATIVE COLITIS, UC) FROM FUNCTIONAL DISEASE (IRRITABLE BOWEL SYNDROME, IBS), IN PATIENTS WITH CHRONIC ABDOMINAL PAIN, ABOVE THE AGE OF FOUR, AND AS AN AID TO IBD DISEASE MONITORING,ACE KINETIC (BUHLMANN ACE KINETIC (KK-ACK,KK-ACK2, KK-ACK4, KK-ACKX))-THE BUHLMANN ACE KINETIC TEST IS INTENDED FOR THE DIRECT AND QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ANGIOTENSIN CONVERTING ENZYME (ACE) ACTIVITY IN SERUM BY AN ENZYMATIC ASSAY. ,GANGLIOCOMBI LIGHT ELISA KIT(BUHLMANN (EK-GCL-S))-BÜHLMANN GANGLIOCOMBITM LIGHT ELISA, IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO DETECT ANTIBODIES AGAINST DEFINED RELEVANT NEURAL ANTIGENS GM1, GD1B AND GQ1B (IGG AND IGM) IN SERUM SAMPLES FROM PATIENTS WITH SUSPECTED PERIPHERAL NEUROPATHIES WITH AN UNKNOWN ETIOLOGY. IT ALLOWS QUANTITATIVE CLASSIFICATION OF RESULTS INTO TITRE CATEGORIES AND SERVES AS AN AID TO DIAGNOSIS OF NEUROPATHIES.,FCAL ELISA CALPROTECTIN(BÜHLMANN (EK-CAL, EK-CAL2,EK-CAL2-WEX))-THE BÜHLMANN FCAL® ELISA IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUANTITATIVE DETERMINATION OF CALPROTECTIN IN HUMAN STOOL SPECIMENS INTENDED AS AN AID TO THE ASSESSMENT OF INTESTINAL MUCOSAL INFLAMMATION. THE ASSAY RESULTS CAN BE USED AS AN AID TO DIAGNOSIS IN DISTINGUISHING ORGANIC, INFLAMMATORY DISEASE OF THE GASTROINTESTINAL TRACT (INFLAMMATORY BOWEL DISEASE, IBD, E. G. CROHN'S DISEASE OR ULCERATIVE COLITIS, UC) FROM FUNCTIONAL DISEASE (IRRITABLE BOWEL SYNDROME, IBS), IN PATIENTS WITH CHRONIC ABDOMINAL PAIN, ABOVE THE AGE OF FOUR, AND AS AN AID TO IBD DISEASE MONITORING. ,GANGLIOCOMBI MAG ELISA KIT(BUHLMANN (EK-GCM))-BÜHLMANN GANGLIOCOMBITM MAG ELISA, IS AN IN VITRO DIAGNOSTIC TEST INTENDED TO DETECT AUTO-ANTIBODIES AGAINST DEFINED RELEVANT NEURAL ANTIGENS/EPITOPES IN SERUM SAMPLES FROM PATIENTS WITH SUSPECTED PERIPHERAL NEUROPATHIES WITH AN UNKNOWN ETIOLOGY. IT ALLOWS QUANTITATIVE CLASSIFICATION

		OF RESULTS INTO TITRE CATEGORIES AND SERVES AS AN AID TO DIAGNOSIS OF NEUROPATHIES
1161	IMP/IVD/2021/000401	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROALBUMIN CALIBRATORS(MICROALBUMIN CALIBRATORS)-FOR USE IN THE CALIBRATION OF THE MICROALBUMIN ASSAY ON THE ALINITY C SYSTEM.,MICROALBUMIN CONTROLS(MICROALBUMIN CONTROLS)-FOR USE IN THE QUALITY CONTROL OF THE MICROALBUMIN ASSAY ON THE ALINITY C SYSTEM.,MICROALBUMIN CONTROLS (MICROALBUMIN CONTROLS)-FOR USE IN THE QUALITY CONTROL OF THE MICROALBUMIN ASSAY ON THE ARCHITECT C SYSTEMS., MICROALBUMIN(MICROALBUMIN)-THE MICROALBUMIN ASSAY IS USED FOR THE QUANTITATIVE MEASUREMENT OF ALBUMIN IN HUMAN URINE ON THE ALINITY C SYSTEM,MICROALBUMIN (MICROALBUMIN)-THE MICROALBUMIN ASSAY IS USED FOR THE QUANTITATIVE MEASUREMENT OF ALBUMIN IN HUMAN URINE ON THE ARCHITECT C SYSTEMS.,MICROALBUMIN CALIBRATORS (MICROALBUMIN CALIBRATORS)-FOR USE IN THE CALIBRATION OF THE MICROALBUMIN ASSAY ON THE ARCHITECT C SYSTEMS.

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1162	IMP/IVD/2021/000407	1.License Holder Name: UNITRON BIO MEDICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:25-OH-VD(25-OH-VD FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-25-OH-VD FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF 25-OH-VD IN SERUM, PLASMA AND WHOLE BLOOD. THIS TEST MAY HELP UNDERSTAND THE METABOLIC CHANGES OF BONE.,CYSTATIN C (CYSC)(CYSC FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-CYSC FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CYSC IN SERUM, PLASMA AND WHOLE BLOOD. THE TEST RESULT IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF INDEX OF GLOMERCULAR FILTRATION RATE, AND HAS IMPORTANT APPLICATION VALUE IN RENAL FUNCTION KIDNEY DAMAGE AND RENAL TRANSPLANTATION., T4(T4 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-T4 (TRIIODOTHYRONINE) FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T4 IN SERUM AND PLASMA. IT CAN BE USED IN THE MONITORING OF HYPERTHYROIDISM AND HYPOTHYROIDISM, AND ALSO USED AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA., MICROALBUMINURIA (MALB)(MALB FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-MALB FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CYSC IN URINE. AN ELEVATED MALB CONCENTRATION BELOW THE PROTEINURIC LEVEL HAS LONG BEEN RECOGNIZED AS A MARKER OF KIDNEY DISEASE AND INCREASED CARDIOVASCULAR RISK IN DIABETIC NEPHROPATHY., HCG+BETA(HCG+BETA FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-HCG+BETA FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN SERUM AND PLASMA. THIS TEST IS USED AS AID IN PREGNANCY TEST.,T3(T3 FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-T3 (TRIIODOTHYRONINE) FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF T3 IN SERUM AND PLASMA. IT CAN BE USED IN THE MONITORING OF HYPERTHYROIDISM AND HYPOTHYROIDISM, AND ALSO USED AS AN AID IN THE FUNCTIONAL DIAGNOSIS OF THYROIDEA.,TSH(TSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-TSH FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF TSH IN SERUM AND PLASMA. THIS TEST IS USED IN THE SCREENING CLINICAL DIAGNOSIS PROGNOSIS AND THERAPEUTIC EFFECT EVALUATION OF THYROID

		DISEASES,HBA1C(HBA1C FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-HBA1C FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HBA1C IN WHOLE BLOOD. THIS TEST IS USED AS AN AID FOR MONITORING GLYCEMIC CONTROL IN DIABETICS. IN ADDITION IT CAN IDENTIFY PEOPLE AT RISK OF DEVELOPING THE DISEASES AND ONGOING MONITORING.,NEUTROPHILS GELATINASE ASSOCIATED LIPOCALIN (NGAL)(NGAL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY))-NGAL FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF NGAL IN URINE AND SERUM. THIS TEST IS USED AS AN AID IN THE EARLY DIAGNOSIS OF ACUTE KIDNEY INJURY (AKI) RISK CLASSIFICATION AND TREATMENT MONITORING.
1163	IMP/IVD/2021/000411	1.License Holder Name: FUGEN BIOMED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOGLOBIN TEST STRIPS(BIOAID HEMOGLOBIN TEST STRIPS)-THE TEST IS FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN (HB) AND CALCULATED HEMATOCRIT (HCT) IN CAPILLARY AND VENOUS WHOLE BLOOD.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1164	IMP/IVD/2021/000413	1.License Holder Name: STAR BIOMED PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BETA-HCG TEST (FINECARE BETA-HCG RAPID QUANTITATIVE TEST)-THE FINECARE™ -HCG RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF -HCG IN HUMAN WHOLE BLOOD, SERUM OR PLASMA, PROGESTERONE TEST(FINECARE PROGESTERONE RAPID QUANTITATIVE TEST)-THE FINECARETM PROGESTERONE RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,CK-MB TEST(FINECARE CK-MB RAPID QUANTITATIVE TEST)-THE FINECARE™ CK-MB RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF CREATINE KINASE-MB (CK-MB) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA,LH TEST (FINECARE LH RAPID QUANTITATIVE TEST)-THE FINECARE™ LH RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA., TESTOSTERONE(FINECARE TESTOSTERONE RAPID QUANTITATIVE TEST)-THE FINECARETM TESTOSTERONE RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARETM FIA METERS (MODEL NO.: FS-112, FS-113, FS-114 AND FS-205) FOR QUANTITATIVE MEASUREMENT OF TESTOSTERONE IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS TO BE USED AS AN AID IN THE DIAGNOSIS OF DISEASES RELATED TO ABNORMAL TESTOSTERONE LEVELS,T3 TEST(FINECARE T3 RAPID QUANTITATIVE TEST)-THE FINECARETM T3 RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (TOTAL T3) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,FSH TEST(FINECARE FSH RAPID QUANTITATIVE TEST)-THE FINECARE™ FSH RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112 / FS-113 / FS-205) FOR QUANTITATIVE MEASUREMENT OF FOLLICLE-STIMULATING HORMONE (FSH) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.,CTN I/CK-MB/MYO TEST(FINECARE CTN I/CK-MB/MYO RAPID QUANTITATIVE TEST)-THE FINECARE™ D-DIMER RAPID

	QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN WHOLE BLOOD AND PLASMA.,D-DIMER TEST(FINECARE D-DIMER RAPID QUANTITATIVE TEST)-THE FINECARE™ CTN I/CK-MB/MYO RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTN I), CREATINE KINASE-MB AND MYOGLOBIN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA,CRP TEST(FINECARE CRP RAPID QUANTITATIVE TEST)-THE FINECARE™ CRP RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.,HBA1C TEST (FINECARE HBA1C RAPID QUANTITATIVE TEST)-THE FINECARE™ HBA1C RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C IN HUMAN BLOOD.,T4 TEST(FINECARE T4 RAPID QUANTITATIVE TEST)-THE FINECARETM T4 RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF THYROXINE (TOTAL T4) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.,AMH TEST(FINECARE AMH RAPID QUANTITATIVE TEST)-THE FINECARETM AMH RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARETM FIA METERS (MODEL NO.: FS-113, FS-114 AND FS-205) FOR QUANTITATIVE MEASUREMENT OF AMH IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS MAINLY USED IN THE ASSESSMENT OF THE OVARIAN RESERVE AND AS AN AID IN THE DIAGNOSIS OF POLYCYSTIC OVARY SYNDROME (PCOS).,TSH TEST (FINECARE TSH RAPID QUANTITATIVE TEST)-THE FINECARE™ TSH RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.,CTN I TEST(FINECARE CTN I RAPID QUANTITATIVE TEST)-THE FINECARE™ CTN I RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTN I) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.,NT-PROBNP TEST(FINECARE NT-PROBNP RAPID QUANTITATIVE TEST)-THE FINECARE™ NT-PROBNP

		RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/ FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF N-TERMINAL PROHORMONE OF BRAIN NATRIURETIC PEPTIDE (NT-PROBNP) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.,MYO TEST(FINECARE MYO RAPID QUANTITATIVE TEST)-THE FINECARE™ MYO RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARE™ FIA SYSTEM (MODEL NO.: FS-112/FS-113/FS-205) FOR QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA,ESTRADIOL (E2)(FINECARE ESTRADIOL(E2) RAPID QUANTITATIVE TEST)-THE FINECARETM ESTRADIOL (E2) RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARETM FIA METERS (MODEL NO.:FS-112, FS-113, FS-114, FS-205) IS FOR QUANTITATIVE MEASUREMENT OF ESTRADIOL (E2) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE TEST IS USED AS AN AID TO THE EVALUATION OF OVARIAN DISEASES,PROLACTIN TEST(FINECARE PROLACTIN RAPID QUANTITATIVE TEST)-THE FINECARETM PROLACTIN RAPID QUANTITATIVE TEST IS A FLUORESCENCE IMMUNOASSAY USED ALONG WITH FINECARETM FIA METERS (MODEL NO.: FS-112, FS-113, FS-114, FS-205) FOR QUANTITATIVE MEASUREMENT OF PROLACTIN (PRL) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA
1165	IMP/IVD/2021/000414	1.License Holder Name: SD BIOSENSOR HEALTHCARE PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BAR DEVICE UNCUT SHEET (URINE) - BULK(NA)-IT IS USED FOR DETECTION OF BARBITURATE IN URINE.,AMP DEVICE UNCUT SHEET (URINE) - BULK (NA)-IT IS USED FOR THE DETECTION OF AMPHETAMINE IN URINE.

1166	IMP/IVD/2021/000418	1.License Holder Name: ADT INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TB/NTM PCR KIT [883003W/E](LYTESTAR TB/NTM PCR KIT 3.0)-THE LYTESTAR™ TB/NTM PCR KIT 3.0 IS INTENDED FOR SPECIFIC DETECTION OF MYCOBACTERIUM TUBERCULOSIS COMPLEX (MTBC) AND NON-TUBERCULOS MYCOBACTERIA (NTM) FROM HUMAN SPUTUM, BRONCHIAL WASHINGS, CEREBROSPINAL FLUID (CSF), URINE, BODY FLUIDS, TISSUE AND EDTA-WHOLE BLOOD.,TB/NTM PCR KIT [883003](LYTESTAR TB/NTM PCR KIT 3.0)-THE LYTESTAR™ TB/NTM PCR KIT 3.0 IS INTENDED FOR SPECIFIC DETECTION OF MYCOBACTERIUM TUBERCULOSIS COMPLEX (MTBC) AND NON-TUBERCULOS MYCOBACTERIA (NTM) FROM HUMAN SPUTUM, BRONCHIAL WASHINGS, CEREBROSPINAL FLUID (CSF), URINE, BODY FLUIDS, TISSUE AND EDTA-WHOLE BLOOD.
1167	IMP/IVD/2021/000419	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE MONITORING SYSTEM(ACCU-CHEK GUIDE LINK)-THE ACCUCHEK GUIDE TEST STRIPS WITH THE ACCUCHEK GUIDE LINK METER ARE INTENDED TO QUANTITATIVELY MEASURE GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD FROM THE FINGER, PALM, FOREARM, AND UPPER ARM AS AN AID IN MONITORING THE EFFECTIVENESS OF GLUCOSE CONTROL. THE ACCUCHEK GUIDE TEST STRIPS WITH THE ACCUCHEK GUIDE LINK METER ARE INTENDED FOR IN VITRO DIAGNOSTIC SELF-TESTING BY PEOPLE WITH DIABETES. THE ACCUCHEK GUIDE TEST STRIPS WITH THE ACCUCHEK GUIDE LINK METER ARE INTENDED FOR IN VITRO DIAGNOSTIC USE BY HEALTHCARE PROFESSIONALS IN CLINICAL SETTINGS. VENOUS, ARTERIAL, AND NEONATAL BLOOD TESTING ARE LIMITED TO HEALTHCARE PROFESSIONAL USE. THIS SYSTEM IS NOT FOR USE IN DIAGNOSIS OF DIABETES MELLITUS AND NOT FOR TESTING NEONATE CORD BLOOD SAMPLES. THE ACCUCHEK GUIDE LINK BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED TO BE USED TO WIRELESSLY TRANSMIT GLUCOSE VALUES TO A COMPATIBLE PUMP WITH BLUETOOTH® WIRELESS TECHNOLOGY THROUGH THE USE OF BLUETOOTH LOW ENERGY COMMUNICATION. SUITABLE FOR SELF-TESTING.

1168	IMP/IVD/2021/000420	1.License Holder Name: M/S AGAPPE DIAGNOSTICS LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL TRIIODOTHYRONINE KIT ELECTRO CHEMILUMINESCENCE IMMUNOASSAY-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE IN HUMAN SERUM AND PLASMA. ,TROPONIN I (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I IN HUMAN SERUM AND PLASMA. THIS ASSAY IS INTENDED TO AUXILIARY DIAGNOSIS OF MYOCARDIAL INFARCTION. ,MYOGLOBIN (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM AND PLASMA. THE RESULTS CAN BE USED IN ASSISTING DIAGNOSIS OF MYOCARDIAL INJURY.,VITAMIN B12 (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM AND PLASMA. ,LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 (ELECTRO CHEMINLUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF LP-PLA2 IN HUMAN SERUM AND PLASMA.,N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE(ELECTRO CHEMILUMINESCENCE-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE IN HUMAN PLASMA. ,ANTI-MULLERIAN HORMONE (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF ANTI-MULLERIAN HORMONE AMHIN HUMAN SERUM AND PLASMA. ,INTERLEUKIN-6 (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF INTERLEUKIN-6 (IL-6) IN HUMAN SERUM AND PLASMA. THIS ASSAY CAN BE USED TO AID IN THE MANAGEMENT OF CRITICALLY ILL PATIENTS AS AN EARLY INDICATOR FOR ACUTE INFLAMMATION. ,C-PEPTIDE (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM AND PLASMA. ,FREE TRIIODOTHYRONINE KIT ELECTRO CHEMILUMINESCENCE IMMUNOASSAY-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE IN HUMAN SERUM AND PLASMA. ,HEART-TYPE FATTY ACID BINDING PROTEIN (ELECTRO CHEMINLUMINESCENCE IMMUNOASS-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF H-FABP IN HUMAN SERUM AND PLASMA. CLINICALLY USED FOR THE AUXILIARY DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION.,25-OH VITAMIN D TOTAL (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-

	IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF TOTAL 25-HYDROXY VITAMIN D IN HUMAN SERUM AND PLASMA. THE RESULTS CAN BE USED IN ASSISTING DIAGNOSIS OF VITAMIN D SUFFICIENCY. ,D-DIMER (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA, WHICH IS MAINLY USED FOR THE ELIMINATION OF VENOUS THROMBOSIS, THE AUXILIARY DIAGNOSIS OF DISSEMINATED INTRAVASCULAR COAGULATION AND THE MONITORING OF THROMBOLYTIC THERAPY. ,PARATHYROID HORMONE (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IT'S USED FOR QUANTITATIVE DETERMINATION OF PARATHYROID HORMONE IN HUMAN SERUM OR PLASMA IN VITRO. , FERRITIN (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA. IT'S MAINLY USED FOR IRON-METABOLISM-RELATED DISEASES, SUCH AS HEMOCHROMATOSIS AND IRON-DEFICIENCY ANEMIA. ,ESTRADIOL (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF 17-ESTRADIOL (E2) IN HUMAN SERUM AND PLASMA, WHICH IS CLINICALLY USED FOR AUXILIARY DIAGNOSIS OF OVARIAN DISEASES. ,HIGH-SENSITIVITY C-REACTIVE PROTEIN (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM AND PLASMA.,THYROXINE-BINDING GLOBULIN (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF THYROXINE-BINDING GLOBULIN (TBG) IN HUMAN SERUM AND PLASMA. THE RESULTS CAN BE USED IN ASSISTING DIAGNOSIS OF THYROID DISEASES. ,LUTEINIZING HORMONE (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM AND PLASMA. THE RESULTS MAINLY USED TO EVALUATE PITUITARY ENDOCRINE FUNCTION. ,INSULIN (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM AND PLASMA. DETERMINATION OF INSULIN IS USED FOR EVALUATION OF PANCREATIC ISLET FUNCTION. ,THYROID PEROXIDASE ANTIBODY (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF ANTIBODY TO THYROID PEROXIDASE IN HUMAN SERUM AND PLASMA. CLINICALLY, IT'S MAINLY USED AS AN AID IN DIAGNOSIS OF HASHIMOTO'S THYROIDITIS AND EXOPHTHALMIC GOITER. ,TESTOSTERONE (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY

	FOR IN VITRO QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM AND PLASMA. CLINICALLY USED FOR THE AUXILIARY DIAGNOSIS OF DISEASES WITH ABNORMAL LEVEL OF TESTOSTERONE. ,TOTAL THYROXINE KIT ELECTRO CHEMILUMINESCENCE IMMUNOASSAY-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TOTAL THYROXINE IN HUMAN SERUM AND PLASMA ,PROLACTIN (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN HUMAN SERUM AND PLASMA. IT IS MAINLY USED TO EVALUATE THE ENDOCRINE FUNCTION OF PITUITARY IN CLINIC, AND CAN NOT BE USED FOR THE AUXILIARY DIAGNOSIS OF HYPOPHYSOMA. , PROGESTERONE (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM AND PLASMA. THE RESULTS CAN BE USED IN THE AUXILIARY DIAGNOSIS FOR PREMONITORY ABORTION. ,TOTAL BETA HUMAN CHORIONIC GONADOTROPIN (TOTAL -HCG) (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN IN HUMAN SERUM AND PLASMA. THIS ASSAY IS INTENDED FOR USE SPECIALLY IN ASSISTING DIAGNOSIS AND MONITORING OF PREGNANCY . ,FREE THYROXINE KIT ELECTRO CHEMILUMINESCENCE IMMUNOASSAY-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF FREE THYROXINE IN HUMAN SERUM AND PLASMA. ,FOLATE (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN SERUM. ,PROCALCITONIN (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR THE IN VITRO QUANTITATIVE DETERMINATION OF PCT (PROCALCITONIN) IN HUMAN SERUM AND PLASMA. THE RESULTS CAN BE USED TO AID IN THE EARLY DETECTION OF CLINICALLY RELEVANT BACTERIAL INFECTIONS. , FOLLICLE-STIMULATING HORMONE (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF FOLLICLE-STIMULATING HORMONE (FSH) IN HUMAN SERUM AND PLASMA. THE RESULTS MAINLY USED TO EVALUATE PITUITARY ENDOCRINE FUNCTION.,THYROID STIMULATING HORMONE (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF THYROTROPIN IN HUMAN SERUM AND PLASMA. THE RESULTS CAN BE USED IN THE PRELIMINARY SCREENING TEST OF THYROID FUNCTION. ,CREATINE KINASE MB (ELECTRO CHEMILUMINESCENCE IMMUNOASSAY)-IMMUNOASSAY FOR IN VITRO QUANTITATIVE DETERMINATION OF CREATINE KINASE MB IN HUMAN

		SERUM AND PLASMA. THE RESULTS CAN BE USED IN ASSISTING DIAGNOSIS OF MYOCARDIAL INJURY.
1169	IMP/MD/2018/000001	1.License Holder Name: CHITRARATH 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PRESSURE BANDAGE (SURESEAL PRESSURE BANDAGE)-USED AFTER COMPLETION OF DIALYSIS FOR THE CESSATION OF BLEEDING .
1170	IMP/MD/2018/000002	1.License Holder Name: SPARK PERIPHERAL TECHNOLOGIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AORTIC VALVE WITH INTRASUPRA-ANNULAR SEWING CUFF AND TISSUE ANNULUS (CARDIAMED)-IT IS INTENDED FOR REPLACEMENT OF DISEASED AORTIC NATIVE HUMAN HEART VALVE. ,MITRAL VALVE WITH INTRASUPRA-ANNULAR SEWING CUFF AND TISSUE ANNULUS (CARDIAMED)-IT IS INTENDED FOR REPLACEMENT OF DISEASED MITRAL NATIVE HUMAN HEART VALVE
1171	IMP/MD/2018/000003	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DYNAMIC COMPRESSION PLATES(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,LOCKING COMPRESSION PLATES(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.

1172	IMP/MD/2018/000003	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED ,A-1/50, ROOM NO. 2, 100 SHED AREA, G.L.D.C., VAPI, TAL PARDI (VALSAD) , VALSAD GUJARAT ,396195 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SCREW IMPLANTS FOR OR WITHOUT PLATES(NIL)-SCREW IMPLANTS FOR OR WITHOUT PLATES ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., SCREWS FOR INTERMEDULLARY NAIL(NIL)-SCREWS FOR INTERMEDULLARY NAIL ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN). OLECRANON OSTEOTOMY NAILS ARE INTENDED FOR FIXATION OF SIMPLE FRACTURES AND OSTEOTOMIES OF THE OLECRANON.,RECON FEMORAL NAILING IMPLANT(NIL)-RECON FEMORAL NAILING IMPLANT ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN). OLECRANON OSTEOTOMY NAILS ARE INTENDED FOR FIXATION OF SIMPLE FRACTURES AND OSTEOTOMIES OF THE OLECRANON.,TIBIAL NAILING IMPLANTS(NIL)-TIBIAL NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN). OLECRANON OSTEOTOMY NAILS ARE INTENDED FOR FIXATION OF SIMPLE FRACTURES AND OSTEOTOMIES OF THE OLECRANON.,SCREW IMPLANTS FOR PLATES(NIL)-SCREW IMPLANTS FOR PLATES ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.

1173	IMP/MD/2018/000005	1.License Holder Name: NOVO NORDISK INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC NEEDLES (NOVOFINE NEEDLES 31 G)(NOVOFINE NEEDLES 31G)-NOVOFINE® NEEDLES ARE INTENDED FOR USE WITH PREFILLED AND DURABLE DRUG DELIVERY SYSTEMS (PEN INJECTORS) FOR INJECTION NOVOFINE® NEEDLES ARE INTENDED FOR SUBCUTANEOUS DELIVERY OF DRUG PRODUCTS FOR DIABETES THERAPY, E.G. INSULIN AND GLP-1-ANALOGS. THE NEEDLES ARE ALSO INTENDED FOR SUBCUTANEOUSLY DELIVERY OF OTHER DRUG PRODUCTS SUCH AS SOMATROPIN.
1174	IMP/MD/2018/000006	1.License Holder Name: IOL ASIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYDROPHYLIC ACRYLIC INTRAOCULAR LENS(CIMFLEX)-IT IS INDICATED FOR IMPLANTATION IN ADULT AND PAEDIATRIC PATIENTS FOLLOWING CATARACT SURGERY DUE TO SENILE,CONGENITAL OR TRAUMATIC CATARACT.
1175	IMP/MD/2018/000008	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOLEY CATHETERS (BARDIA FOLEY CATHETERS)-THE FOLEY CATHETERS ARE INDICATED FOR THE DRAINAGE AND/OR COLLECTION AND/OR MEASUREMENT OF URINE.,FOLEY CATHETERS(BARDEX FOLEY CATHETERS)-THE FOLEY CATHETERS ARE INDICATED FOR THE DRAINAGE AND/OR COLLECTION AND/OR MEASUREMENT OF URINE., SUPRABUBIC CATHETER(BARD BIOCATH SUPRAPUBIC CATHETERISATION SET)-BARD BIOCATH SUPRAPUBIC CATHETERISATION SET IS INDICATED FOR URETHRAL STRICTURES OR FISTULA, OUTFLOW OBSTRUCTION, CHRONIC RETENTION, URETHRAL TRAUMA, PRE-, INTRA- AND POST OPERATIVE BLADDER DRAINAGE AS REQUESTED BY PHYSICIAN

1176	IMP/MD/2018/000009	1.License Holder Name: OLYMPUS MEDICAL SYSTEM INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ELECTRODE-ELECTROSURGICAL(NA)-THE ELECTRODES ARE PART OF AN INSTRUMENT COMBINATION FOR RESECTOSCOPY IN SALINE IRRIGATION FLUID. THEY ARE INTENDED TO BE USED WITH WORKING ELEMENTS, SHEATHS, HF-CABLE, IRRIGATION RINGS AND A TELESCOPE IN VARIOUS DIAGNOSTIC AND THERAPEUTICAL PROCEDURES INVOLVING THE ABLATION AND REMOVAL OF SOFT TISSUE AND HEMOSTASIS. UROLOGY: -- TRANSURETHRAL DIAGNOSIS AND TREATMENT (RESECTION, BIOPSY, VAPORIZATION, ABLATION, INCISION, CUTTING, ENUCLEATION) OF THE PROSTATE. -- TRANSURETHRAL DIAGNOSIS AND TREATMENT (RESECTION, BIOPSY, VAPORIZATION, ABLATION, INCISION, CUTTING, ENUCLEATION) OF BLADDER NECK AND BLADDER TUMORS. -- TREATMENT OF BLEEDINGS IN THE LOWER URINARY TRACT (COAGULATION). GYNECOLOGY: -- TRANSCERVICAL DIAGNOSIS AND TREATMENT (RESECTION, VAPORIZATION, ABLATION, BIOPSY, CUTTING AND COAGULATION) OF INTRAUTERINE MYOMAS, INTRAUTERINE POLYPS, SYNECHIAS AND ENDOMETRIUM (TCRIS). -- LYSIS OF INTRAUTERINE SEPTA. -- ENDOMETRIAL ABLATION.,ELECTRODE-ELECTROSURGICAL-FLEXIBLE HF ELECTRODES ARE INTENDED FOR ENDOSCOPIC DIAGNOSIS AND TREATMENT IN UROLOGIC APPLICATIONS.,ELECTRODE-ELECTROSURGICAL-HF-RESECTION ELECTRODE FOR TURIS ARE FOR ENDOSCOPIC TREATMENT IN UROLOGICAL AND GYNAECOLOGICAL APPLICATIONS. CUTTING, ABLATION, RESECTION AND COAGULATION WITH HF CURRENT. UROLOGY:- THE GENERAL UROLOGICAL INDICATIONS INCLUDE TRANSURETHRAL RESECTION, VAPORIZATION, ABLATION, INCISION, CUTTING AND COAGULATION OF PROSTATIC TISSUE AND TRANSURETHRAL RESECTION AND VAPORIZATION OF TUMORS IN THE URINARY BLADDER IN CONDUCTIVE IRRIGATION FLUID AS PART OF A RESECTOSCOPE SYSTEM. GYNECOLOGY:- THE GENERAL GYNECOLOGICAL INDICATIONS INCLUDE TRANSCERVICAL RESECTION, VAPORIZATION, ABLATION, CUTTING AND COAGULATION OF TISSUE IN THE UTERUS IN CONDUCTIVE IRRIGATION FLUID AS PART OF A RESECTOSCOPE SYSTEM., ELECTRODE-ELECTROSURGICAL-HF-RESECTION ELECTRODE FOR TURIS ARE FOR ENDOSCOPIC TREATMENT IN UROLOGICAL AND GYNAECOLOGICAL APPLICATIONS. CUTTING, ABLATION, RESECTION AND COAGULATION WITH HF CURRENT. UROLOGY:- THE GENERAL UROLOGICAL INDICATIONS INCLUDE TRANSURETHRAL RESECTION, VAPORIZATION, ABLATION, INCISION, CUTTING AND COAGULATION OF PROSTATIC TISSUE AND TRANSURETHRAL RESECTION AND

	VAPORIZATION OF TUMORS IN THE URINARY BLADDER IN CONDUCTIVE IRRIGATION FLUID AS PART OF A RESECTOSCOPE SYSTEM. GYNECOLOGY (EXCEPT FOR WA22558C):- THE GENERAL GYNECOLOGICAL INDICATIONS INCLUDE TRANSCERVICAL RESECTION, VAPORIZATION, ABLATION, CUTTING AND COAGULATION OF TISSUE IN THE UTERUS IN CONDUCTIVE IRRIGATION FLUID AS PART OF A RESECTOSCOPE SYSTEM., ELECTRODE-ELECTROSURGICAL-HF ELECTRODE FOR CUTTING AND COAGULATION WITH HF CURRENT IN THORACOSCOPIC AND LAPAROSCOPIC APPLICATIONS.,ELECTRODE-ELECTROSURGICAL-HF-RESECTION ELECTRODES ARE FOR ENDOSCOPIC TREATMENT IN UROLOGICAL AND GYNAECOLOGICAL APPLICATIONS. CUTTING, ABLATION, RESECTION AND COAGULATION WITH HF CURRENT. UROLOGY:- THE GENERAL UROLOGICAL INDICATIONS INCLUDE TRANSURETHRAL RESECTION, VAPORIZATION, ABLATION, INCISION, CUTTING AND COAGULATION OF PROSTATIC TISSUE AND TRANSURETHRAL RESECTION AND VAPORIZATION OF TUMORS IN THE URINARY BLADDER IN CONDUCTIVE IRRIGATION FLUID AS PART OF A RESECTOSCOPE SYSTEM. GYNECOLOGY: THE GENERAL GYNECOLOGICAL INDICATIONS INCLUDE TRANSCERVICAL RESECTION, VAPORIZATION, ABLATION, CUTTING AND COAGULATION OF TISSUE IN THE UTERUS IN CONDUCTIVE IRRIGATION FLUID AS PART OF A RESECTOSCOPE SYSTEM., ELECTRODE-ELECTROSURGICAL-HF-RESECTION ELECTRODE FOR USE IN TRANSURETHRAL RESECTION IN PEDIATRIC APPLICATIONS., ELECTRODE-ELECTROSURGICAL-HF-RESECTION ELECTRODES ARE FOR ENDOSCOPIC TREATMENT IN UROLOGICAL AND GYNAECOLOGICAL APPLICATIONS. CUTTING, ABLATION, RESECTION AND COAGULATION WITH HF CURRENT. UROLOGY:-THE GENERAL UROLOGICAL INDICATIONS INCLUDE TRANSURETHRAL RESECTION, VAPORIZATION, ABLATION, INCISION, CUTTING AND COAGULATION OF PROSTATIC TISSUE AND TRANSURETHRAL RESECTION AND VAPORIZATION OF TUMORS IN THE URINARY BLADDER IN CONDUCTIVE IRRIGATION FLUID AS PART OF A RESECTOSCOPE SYSTEM. GYNECOLOGY:-THE GENERAL GYNECOLOGICAL INDICATIONS INCLUDE TRANSCERVICAL RESECTION, VAPORIZATION, ABLATION, CUTTING AND COAGULATION OF TISSUE IN THE UTERUS IN CONDUCTIVE IRRIGATION FLUID AS PART OF A RESECTOSCOPE SYSTEM.

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1177	IMP/MD/2018/000009	1.License Holder Name: OLYMPUS MEDICAL SYSTEMS INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GENERATOR (ELECTROSURGICAL GENERATOR ESG-150)-THE ELECTROSURGICAL GENERATOR, IN CONJUNCTION WITH ELECTROSURGICAL ACCESSORIES AND ANCILLARY EQUIPMENT, IS INTENDED FOR CUTTING AND COAGULATING TISSUE IN ENDOSCOPIC SURGERY., GENERATOR(ELECTROSURGICAL GENERATOR ESG-400)-THE ESG-400 IS AN ELECTROSURGICAL GENERATOR INTENDED FOR TISSUE CUTTING AND COAGULATION IN OPEN, LAPAROSCOPIC AND ENDOSCOPIC SURGERY IN CONJUNCTION WITH ELECTROSURGICAL ACCESSORIES AND ANCILLARY EQUIPMENT.,GENERATOR (ELECTROSURGICAL GENERATOR ESG-300)-THE ELECTROSURGICAL GENERATOR, IN CONJUNCTION WITH ELECTROSURGICAL ACCESSORIES AND ANCILLARY EQUIPMENT, IS INTENDED FOR CUTTING AND COAGULATING TISSUE IN OPEN SURGERY, LAPAROSCOPIC SURGERY AND ENDOSCOPIC SURGERY.
1178	IMP/MD/2018/000011	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTA DILATATION CATHETER(ATLAS® GOLD PTA DILATATION CATHETER)-ATLAS® GOLD PTA DILATATION CATHETER IS INDICATED FOR USE IN PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF THE PERIPHERAL VASCULATURE, INCLUDING THE ILIAC ARTERIES AND ILIAC AND FEMORAL VEINS, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR POST-DILATATION OF STENTS AND STENT GRAFTS IN THE PERIPHERAL VASCULATURE. THIS CATHETER IS NOT FOR USE IN CORONARY ARTERIES.,PTV DILATATION CATHETER(VIDA® PTV DILATATION CATHETER)-THE VIDA™ PTV DILATATION CATHETER IS RECOMMENDED FOR PERCUTANEOUS TRANSLUMINAL VALVULOPLASTY OF THE PULMONARY AND AORTIC VALVES IN THE FOLLOWING: • A PATIENT WITH ISOLATED PULMONARY OR AORTIC VALVE STENOSIS • A PATIENT WITH VALVULAR PULMONARY OR AORTIC STENOSIS WITH OTHER MINOR CONGENITAL HEART DISEASE THAT DOES NOT REQUIRE SURGICAL INTERVENTION.

1179	IMP/MD/2018/000012	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLOSED MALE LUER (TEXIUM CLOSED MALE LUER WITH FEMALE CAP)-THE TEXIUM™ CLOSED MALE LUER IS THE KEY COMPONENT OF SAFE HANDLING PRODUCT FOR MIXING AND PREPARING HAZARDOUS DRUGS SUCH AS CHEMOTHERAPY. A SEALING MALE VALVE WILL ALLOW VARIOUS POTENTIALLY HAZARDOUS FLUIDS, SUCH AS THOSE CURRENTLY USED IN ONCOLOGY OR DURING BLOOD ADMINISTRATION
1180	IMP/MD/2018/000013	1.License Holder Name: ALCON LABORATORIES (INDIA) PVT. LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLAREON IOL ASPHERIC HYDROPHOIC ACRYLIC IOL WITH AUTONOME AUTOMATED PRE-LOADED DELIVERY SYSTEM(CLAREON IOL WITH AUTONOME)-CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) IS A FOLDABLE SINGLE-PIECE POSTERIOR CHAMBER INTRAOCULAR LENS (IOL) INTENDED AS AN OPTICAL IMPLANT FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER OF THE EYE.

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1181	IMP/MD/2018/000014	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VASCULAR STENT(VALEO VASCULAR STENT)-THE VALEO® VASCULAR STENT IS INTENDED FOR PRIMARY STENTING IN PATIENTS WITH ATHEROSCLEROTIC DISEASE OF THE PERIPHERAL ARTERIES.,RECANALIZATION CATHETER (CROSSER CTO RECANALIZATION CATHETER)-THE CROSSER CATHETER IS INDICATED TO FACILITATE THE INTRA-LUMINAL PLACEMENT OF CONVENTIONAL GUIDEWIRES BEYOND STENOTIC LESIONS, INCLUDING CHRONIC TOTAL INFRAINGUINAL OCCLUSIONS. THE CROSSER® CATHETER IS ONLY INTENDED FOR USE WITH THE CROSSER® GENERATOR.,PERIPHERAL BALLOON CATHETER (ATLAS PTA BALLOON DILATATION CATHETER)-ATLAS PTA BALLOON DILATATION CATHETERS ARE RECOMMENDED FOR USE IN PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF THE ILIAC ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS CATHETER IS NOT FOR USE IN CORONARY ARTERIES.,SUPPORT CATHETER(SIDEKICK SUPPORT CATHETER)-THE SIDEKICK® SUPPORT CATHETERS ARE SINGLE LUMEN CATHETERS INTENDED TO CREATE A PATHWAY FOR OTHER DEVICES IN THE PERIPHERAL VASCULATURE.,VENA CAVA FILTERS(DENALI FILTER SYSTEM)-THE DENALI FILTER IS INDICATED FOR USE IN THE PREVENTION OF RECURRENT PULMONARY EMBOLISM VIA PERMANENT PLACEMENT IN THE VENA CAVA IN THE FOLLOWING SITUATIONS: • PULMONARY THROMBOEMBOLISM WHEN ANTICOAGULANTS ARE CONTRAINDICATED • FAILURE OF ANTICOAGULANT THERAPY FOR THROMBOEMBOLIC DISEASE • EMERGENCY TREATMENT FOLLOWING MASSIVE PULMONARY EMBOLISM WHERE ANTICIPATED BENEFITS OF CONVENTIONAL THERAPY ARE REDUCED • CHRONIC, RECURRENT PULMONARY EMBOLISM WHERE ANTICOAGULANT THERAPY HAS FAILED OR IS CONTRAINDICATED ,PTA BALLOON(ULTRASCORE FOCUSED FORCE PTA BALLOON)-THE ULTRASCORE™ FOCUSED FORCE PTA BALLOON IS INTENDED TO DILATE STENOSES IN THE ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA-POPLITEAL AND RENAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO RECOMMENDED FOR POST DILATATION OF BALLOON EXPANDABLE STENTS, SELF-EXPANDING STENTS, AND STENT GRAFTS IN THE PERIPHERAL VASCULATURE., PERIPHERAL BALLOON CATHETER (RIVAL PTA DILATATION CATHETER)-THE RIVAL® PTA DILATATION CATHETER IS INTENDED TO DILATE STENOSES IN THE PERIPHERAL ARTERIES, TREAT OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC A-V FISTULAE,

		AND/OR RE-EXPAND ENDOLUMINAL STENT GRAFT ELEMENTS IN THE ILIAC ARTERIES. ,SUPPORT CATHETER(USHER SUPPORT CATHETER)-THE USHER SUPPORT CATHETERS ARE SINGLE LUMEN CATHETERS INTENDED TO CREATE A PATHWAY FOR OTHER DEVICES IN THE PERIPHERAL VASCULATURE.,VALVULOPLASTY PERFUSION CATHETER(TRUE FLOW)-THE TRUE FLOW VALVULOPLASTY PERFUSION CATHETER IS INDICATED FOR BALLOON AORTIC VALVULOPLASTY.
1182	IMP/MD/2018/000015	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CV CATHETER(BROVIAC)-BROVIAC CV CATHETERS ARE DESIGNED FOR LONG-TERM VASCULAR ACCESS AND FOR USE IN PATIENTS THAT LACK ADEQUATE PERIPHERAL VENOUS ACCESS. THEY ARE AVAILABLE IN SINGLE, DUAL AND TRIPLE LUMEN CATHETERS. THESE ARE DESIGNED FOR THE ADMINISTRATION OF I.V. FLUIDS, BLOOD PRODUCTS, DRUGS AND PARENTERAL NUTRITION SOLUTIONS, AS WELL AS BLOOD WITHDRAWAL. ,CV CATHETER(HICKMAN)-HICKMAN CV CATHETERS ARE DESIGNED FOR LONG-TERM VASCULAR ACCESS AND FOR USE IN PATIENTS THAT LACK ADEQUATE PERIPHERAL VENOUS ACCESS. THEY ARE AVAILABLE IN SINGLE, DUAL AND TRIPLE LUMEN CATHETERS. ALL HICKMAN CENTRAL VENOUS CATHETERS ARE DESIGNED FOR THE ADMINISTRATION OF I.V. FLUIDS, BLOOD PRODUCTS, DRUGS AND PARENTERAL NUTRITION SOLUTIONS, AS WELL AS BLOOD WITHDRAWAL.

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1183	IMP/MD/2018/000016	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDEWIRE(BARD NICORE NITINOL GUIDEWIRE)-BARD GUIDEWIRES ARE INDICATED TO PROVIDE TRANSURETHRAL AND/OR PERCUTANEOUS ACCESS INTO THE BLADDER, URETER OR RENAL PELVIS.,URETERAL STENT(BARD INLAY OPTIMA URETERAL STENT)-INDICATED TO RELIEVE OBSTRUCTION IN A VARIETY OF BENIGN, MALIGNANT AND POST-TRAUMATIC CONDITIONS IN THE URETER. THESE CONDITIONS INCLUDE STONES AND / OR STONE FRAGMENTS, OR OTHER URETERAL OBSTRUCTIONS SUCH AS THOSE ASSOCIATED WITH URETERAL STRICTURE, MALIGNANCY OF ABDOMINAL ORGANS, RETROPERITONEAL FIBROSIS OR URETERAL TRAUMA, OR IN ASSOCIATION WITH EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (ESWL). THE SENT MAY BE PLACED USING ENDOSCOPIC SURGICAL TECHNIQUES OR PERCUTANEOULY USING STANDARD RADIOGRAPHIC TECHNIQUE. IT IS RECOMMENDED THAT THE INDWELLING TIME NOT EXCEED 365 DAYS. THE STENT IS NOT INTENDED AS A PERMANENT INDWELLING DEVICE.,URETERAL STENTS(BARD INLAY VERSA FIT URETERAL STENT)-INDICATED TO RELIEVE OBSTRUCTION IN A VARIETY OF BENIGN, MALIGNANT AND POST-TRAUMATIC CONDITIONS IN THE URETER SUCH AS PRESENCE OF STONES AND / OR STONE FRAGMENTS, OR OTHER URETERAL OBSTRUCTIONS SUCH AS THOSE ASSOCIATED WITH URETERAL STRICTURE, CARCINOMA OF ABDOMINAL ORGANS, RETROPERITONEAL FIBROSIS OR URETERAL TRAUMA, OR IN ASSOCIATION WITH EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (ESWL). THE STENT MAY BE PLACED USING ENDOSCOPIC SURGICAL TECHNIQUES OR PERCUTANEOUSLY USING STANDARD RADIOGRAPHIC TECHNIQUE.,URETERAL STENTS(BARD INLAY URETERAL STENT)-INDICATED TO RELIEVE OBSTRUCTION IN A VARIETY OF BENIGN, MALIGNANT AND POST-TRAUMATIC CONDITIONS IN THE URETER SUCH AS PRESENCE OF STONES AND / OR STONE FRAGMENTS, OR OTHER URETERAL OBSTRUCTIONS SUCH AS THOSE ASSOCIATED WITH URETERAL STRICTURE, CARCINOMA OF ABDOMINAL ORGANS, RETROPERITONEAL FIBROSIS OR URETERAL TRAUMA, OR IN ASSOCIATION WITH EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (ESWL). THE STENT MAY BE PLACED USING ENDOSCOPIC SURGICAL TECHNIQUES OR PERCUTANEOUSLY USING STANDARD RADIOGRAPHIC TECHNIQUE.,SILICONE FOLEY CATHETERS(BARDEX ALL SILICONE FOLEY CATHETERS)-INDICATED FOR USE IN THE DRAINAGE AND / OR COLLECTION AND / OR MEASUREMENT OF URINE. GENERALLY, DRAINAGE IS ACCOMPLISHED BY INSERTING THE CATHETER THROUGH THE URETHRA AND INTO

		THE BLADDER. HOWEVER, DRAINAGE IS SOMETIMES ACCOMPLISHED BY SUPRAPUBIC OR OTHER PLACEMENT OF THE CATHETER SUCH AS NEPHROSTOMY TRACT.,SILICONE URETERAL STENT(BARD SILICONE URETERAL COIL STENT WITH FIGURE FOUR END, BARD FLUORO-4 SILICONE URETERAL STENT, BARD FLUORO-4 SILICONE URETERAL COIL STENT)-INDICATED TO RELIEVE OBSTRUCTION IN A VARIETY OF BENIGN, MALIGNANT AND POST-TRAUMATIC CONDITIONS IN THE URETER SUCH AS STONES AND / OR STONE FRAGMENTS, OR OTHER URETERAL OBSTRUCTIONS SUCH AS THOSE ASSOCIATED WITH URETERAL STRICTURE, CARCINOMA OF ABDOMINAL ORGANS, RETROPERITONEAL FIBROSIS OR URETERAL TRAUMA, OR IN ASSOCIATION WITH EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (ESWL). THE STENT MAY BE PLACED USING ENDOSCOPIC SURGICAL TECHNIQUES OR PERCUTANEOUSLY USING STANDARD RADIOGRAPHIC TECHNIQUE.
1184	IMP/MD/2018/000017	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HUBER NEEDLE SET (SAFESTEP)-SAFESTEP HUBER NEEDLE SET IS A DEVICE INTENDED FOR INSERTION INTO THE SEPTUM OF A SUBCUTANEOUSLY IMPLANTED PORT AND FOR THE INFUSION OF FLUIDS INTO THE PORT. THE SAFETY FEATURE IS MANUALLY ACTIVATED DURING NEEDLE REMOVAL AND IS DESIGNED TO AID IN THE PREVENTION OF ACCIDENTAL NEEDLE STICKS.,SAFETY INFUSION SET(POWERLOC)-POWERLOC SAFETY INFUSION SET IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS AND DRUGS, AS WELL AS BLOOD SAMPLING THROUGH SURGICALLY IMPLANTED VASCULAR PORTS. IT IS ALSO INDICATED FOR POWER INJECTION OF CONTRAST MEDIA INTO THE CENTRAL VENOUS SYSTEM ONLY WITH AN IMPLANTED PORT THAT IS ALSO INDICATED FOR POWER INJECTION. THE MAXIMUM RECOMMENDED INFUSION RATE AT 11.8 CPS IS 5ML/SECOND FOR 19 GA NEEDLES, 5ML/SECOND FOR 20 GA NEEDLES AND 2ML/SECOND FOR 22 GA NEEDLES.

1185	IMP/MD/2018/000018	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DRUG COATED BALLOON PTA CATHETER(LUTONIX 014 DRUG COATED BALLOON PTA CATHETER)-IT IS INTENDED FOR USE AS A PTA CATHETER TO DILATE STENOTIC OR OBSTRUCTIVE VASCULAR LESIONS IN THE LOWER EXTREMITIES FOR THE PURPOSE OF IMPROVING LIMB PERFUSION AND DECREASING THE INCIDENCE OF RESTENOSIS.,DRUG COATED BALLOON PTA CATHETER(LUTONIX 035 DRUG COATED BALLOON PTA CATHETER)-IT IS INTENDED FOR USE AS A PTA CATHETER TO DILATE STENOTIC OR OBSTRUCTIVE VASCULAR LESIONS IN THE LOWER EXTREMITIES, AND NATIVE OR SYNTHETIC ARTERIOVENOUS FISTULA, FOR THE PURPOSE OF IMPROVING LIMB PERFUSION AND DECREASING THE INCIDENCE OF RESTENOSIS.
1186	IMP/MD/2018/000019	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTA DILATATION CATHETER(ULTRAVERSE® 035 PTA DILATATION CATHETER)-INTENDED TO DILATE STENOSES IN THE PERIPHERAL ARTERIES, TO TREAT OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC AV FISTULAE AND/OR RE-EXPAND ENDOLUMINAL STENT GRAFT ELEMENTS IN THE ILIAC ARTERIES. THIS DEVICE IS ALSO RECOMMENDED FOR POST-DILATATION OF BALLOON EXPANDABLE AND SELF-EXPANDING STENTS IN THE PERIPHERAL VASCULATURE. THIS CATHETER IS NOT FOR USE IN CORONARY ARTERIES.,PTA BALLOON DILATATION CATHETER (ULTRAVERSE PTA BALLOON DILATATION CATHETER)-THE ULTRAVERSE 014 AND ULTRAVERSE 018 PTA DILATATION CATHETERS ARE RECOMMENDED FOR USE IN PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) OF THE RENAL, POPLITEAL, TIBIAL, FEMORAL, AND PERONEAL ARTERIES. THESE CATHETERS ARE NOT FOR USE IN CORONARY ARTERIES.
1187	IMP/MD/2018/000020	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FILTER RETRIEVAL KIT (BARD SNARE RETRIEVAL KIT)-THE BARD® SNARE RETRIEVAL KIT IS INTENDED FOR USE TO PERCUTANEOUSLY REMOVE ALL BARD® OPTIONAL VENA CAVA FILTERS WITH A RETRIEVAL HOOK

1188	IMP/MD/2018/000021	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STONE BASKET(BARD® DIMENSION STONE BASKET)-INTENDED FOR USE IN THE ENDOSCOPIC REMOVAL OF RENAL AND URETERAL STONES.
1189	IMP/MD/2018/000022	1.License Holder Name: M/S ZIMMER INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIP REPLACEMENT SYSTEM(G7 ACETABULAR SYSTEM - DUAL MOBILITY ACETABULAR LINER)-1. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE, INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. 2. RHEUMATOID ARTHRITIS. 3. CORRECTION OF FUNCTIONAL DEFORMITY. 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. 5. REVISION OF PREVIOUSLY FAILED TOTAL HIP ARTHROPLASTY. 6. DISLOCATION RISKS. THE G7 DUAL MOBILITY METAL LINERS ARE SINGLE-USE IMPLANTS, INTENDED FOR UNCEMENTED APPLICATIONS

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1190	IMP/MD/2018/000022	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED ,NO. 17, GROUND FLOOR AND MEZZANINE FLOOR, THIRUNEERMALAI ROAD, NAGALKENI, CHROMPET ,CHENNAI TAMIL NADU ,600044 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERSONA PARTIAL KNEE (PPK) SYSTEM(PERSONA PARTIAL KNEE (PPK) SYSTEM - FEMORAL)-O THE PERSONA PARTIAL KNEE SYSTEM IS LIMITED TO THE MEDIAL TIBIOFEMORAL COMPARTMENT OF THE KNEE INTENDED FOR PATIENTS WITH PAINFUL AND/OR DISABLING KNEE JOINTS DUE TO THE FOLLOWING INDICATIONS: NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., OSTEOARTHRITIS, AVASCULAR NECROSIS; TRAUMATIC ARTHRITIS; PREVIOUS TIBIAL CONDYLE OR PLATEAU FRACTURES WITH LOSS OF ANATOMY OR FUNCTION; VARUS DEFORMITIES; AND REVISION OF THE ARTICULAR SURFACE OF A PREVIOUSLY IMPLANTED PERSONA PARTIAL KNEE SYSTEM PROVIDING THAT THE TIBIAL PLATE LOCKING MECHANISM IS NOT COMPROMISED AND THE FEMORAL AND TIBIAL PLATE COMPONENTS REMAIN WELL FIXED AND UNDAMAGED. O THE PERSONA PARTIAL KNEE SYSTEM IS A SINGLE USE IMPLANT INTENDED FOR IMPLANTATION WITH BONE CEMENT. O INDICATIONS FOR COMBINED PERSONA PARTIAL KNEE SYSTEM AND ZIMMER GENDER SOLUTIONS PATELLO-FEMORAL JOINT (PFJ): OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, AND/OR SEVERE CHONDROCALCINOSIS OF THE PATELLOFEMORAL JOINT. THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS (E.G., ARTHROSCOPY, LATERAL RELEASE, CARTILAGE TRANSPLANTATION). HISTORY OF PATELLAR DISLOCATION OR PATELLA FRACTURE. DYSPLASIA-INDUCED DEGENERATION. O THESE INDICATIONS WILL BE USED FOR THE COMBINED MEDIAL UNICOMPARTMENTAL AND PATELLO-FEMORAL IMPLANT DEVICE, WHEREBY A SINGLE CONDYLE AND PATELLO-FEMORAL REGIONS HAVE BEEN AFFECTED BY ONE OR MORE OF THESE CONDITIONS. O COMBINED PERSONA PARTIAL KNEE SYSTEM AND ZIMMER GENDER SOLUTIONS PATELLO-FEMORAL JOINT (PFJ) IMPLANTS ARE INTENDED FOR IMPLANTATION WITH BONE CEMENT.,PERSONA PARTIAL KNEE (PPK) SYSTEM(PERSONA PARTIAL KNEE (PPK) SYSTEM - TIBIAL)-O THE PERSONA PARTIAL KNEE SYSTEM IS LIMITED TO THE MEDIAL TIBIOFEMORAL COMPARTMENT OF THE KNEE INTENDED FOR PATIENTS WITH PAINFUL AND/OR DISABLING KNEE JOINTS DUE TO THE FOLLOWING INDICATIONS: NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., OSTEOARTHRITIS, AVASCULAR NECROSIS; TRAUMATIC ARTHRITIS; PREVIOUS TIBIAL CONDYLE OR PLATEAU FRACTURES WITH LOSS OF ANATOMY OR FUNCTION; VARUS DEFORMITIES; AND REVISION OF

	THE ARTICULAR SURFACE OF A PREVIOUSLY IMPLANTED PERSONA PARTIAL KNEE SYSTEM PROVIDING THAT THE TIBIAL PLATE LOCKING MECHANISM IS NOT COMPROMISED AND THE FEMORAL AND TIBIAL PLATE COMPONENTS REMAIN WELL FIXED AND UNDAMAGED. O THE PERSONA PARTIAL KNEE SYSTEM IS A SINGLE USE IMPLANT INTENDED FOR IMPLANTATION WITH BONE CEMENT. O INDICATIONS FOR COMBINED PERSONA PARTIAL KNEE SYSTEM AND ZIMMER GENDER SOLUTIONS PATELLO-FEMORAL JOINT (PFJ): OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, AND/OR SEVERE CHONDROCALCINOSIS OF THE PATELLOFEMORAL JOINT. THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS (E.G., ARTHROSCOPY, LATERAL RELEASE, CARTILAGE TRANSPLANTATION). HISTORY OF PATELLAR DISLOCATION OR PATELLA FRACTURE. DYSPLASIA-INDUCED DEGENERATION. O THESE INDICATIONS WILL BE USED FOR THE COMBINED MEDIAL UNICOMPARTMENTAL AND PATELLO-FEMORAL IMPLANT DEVICE, WHEREBY A SINGLE CONDYLE AND PATELLO-FEMORAL REGIONS HAVE BEEN AFFECTED BY ONE OR MORE OF THESE CONDITIONS. O COMBINED PERSONA PARTIAL KNEE SYSTEM AND ZIMMER GENDER SOLUTIONS PATELLO-FEMORAL JOINT (PFJ) IMPLANTS ARE INTENDED FOR IMPLANTATION WITH BONE CEMENT.,PERSONA PARTIAL KNEE (PPK) SYSTEM(PERSONA PARTIAL KNEE (PPK) SYSTEM - ARTICULAR SURFACE)- O THE PERSONA PARTIAL KNEE SYSTEM IS LIMITED TO THE MEDIAL TIBIOFEMORAL COMPARTMENT OF THE KNEE INTENDED FOR PATIENTS WITH PAINFUL AND/OR DISABLING KNEE JOINTS DUE TO THE FOLLOWING INDICATIONS: NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., OSTEOARTHRITIS, AVASCULAR NECROSIS; TRAUMATIC ARTHRITIS; PREVIOUS TIBIAL CONDYLE OR PLATEAU FRACTURES WITH LOSS OF ANATOMY OR FUNCTION; VARUS DEFORMITIES; AND REVISION OF THE ARTICULAR SURFACE OF A PREVIOUSLY IMPLANTED PERSONA PARTIAL KNEE SYSTEM PROVIDING THAT THE TIBIAL PLATE LOCKING MECHANISM IS NOT COMPROMISED AND THE FEMORAL AND TIBIAL PLATE COMPONENTS REMAIN WELL FIXED AND UNDAMAGED. O THE PERSONA PARTIAL KNEE SYSTEM IS A SINGLE USE IMPLANT INTENDED FOR IMPLANTATION WITH BONE CEMENT. O INDICATIONS FOR COMBINED PERSONA PARTIAL KNEE SYSTEM AND ZIMMER GENDER SOLUTIONS PATELLO-FEMORAL JOINT (PFJ): OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, AND/OR SEVERE CHONDROCALCINOSIS OF THE PATELLOFEMORAL JOINT. THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS (E.G., ARTHROSCOPY, LATERAL RELEASE, CARTILAGE TRANSPLANTATION). HISTORY OF PATELLAR DISLOCATION OR PATELLA FRACTURE. DYSPLASIA-INDUCED DEGENERATION. O

	THESE INDICATIONS WILL BE USED FOR THE COMBINED MEDIAL UNICOMPARTMENTAL AND PATELLO-FEMORAL IMPLANT DEVICE, WHEREBY A SINGLE CONDYLE AND PATELLO-FEMORAL REGIONS HAVE BEEN AFFECTED BY ONE OR MORE OF THESE CONDITIONS. O COMBINED PERSONA PARTIAL KNEE SYSTEM AND ZIMMER GENDER SOLUTIONS PATELLO-FEMORAL JOINT (PFJ) IMPLANTS ARE INTENDED FOR IMPLANTATION WITH BONE CEMENT.

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1191	IMP/MD/2018/000023	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MESH(VENTRALIGHT ST MESH WITH ECHO PS POSITIONING SYSTEM)-VENTRALIGHT ST MESH IS INDICATED FOR USE IN THE RECONSTRUCTION OF SOFT TISSUE DEFICIENCIES, SUCH AS FOR THE REPAIR OF HERNIAS AND CHEST WALL DEFECTS. THE ECHO PS POSITIONING SYSTEM IS INTENDED TO BE USED TO FACILITATE THE DELIVERY OF SOFT TISSUE PROSTHESES DURING LAPAROSCOPIC HERNIA REPAIR.,HERNIA REPAIR DEVICE(BARD SOFT MESH AND BARD SOFT MESH PRESHAPED)-BARD SOFT MESH IS INDICATED TO REINFORCE SOFT TISSUE WHERE WEAKNESS EXISTS, E.G., REPAIR OF HERNIAS AND CHEST WALL DEFECTS. BARD SOFT MESH PRE-SHAPED IS INDICATED FOR THE REPAIR OF INGUINAL HERNIA DEFECTS,MESH(VENTRALIGHT ST MESH)-VENTRALIGHT ST MESH IS INDICATED FOR USE IN THE RECONSTRUCTION OF SOFT TISSUE DEFICIENCIES, SUCH AS REPAIR OF HERNIAS.,HERNIA PATCH(VENTRALEX ST HERNIA PATCH)-VENTRALEX ST HERNIA PATCH IS INDICATED FOR USE IN THE REINFORCEMENT OF SOFT TISSUE, WHERE WEAKNESS EXISTS, IN PROCEDURES INVOLVING SOFT TISSUE REPAIR, INCLUDING REPAIR OF HERNIAS AND DEFICIENCIES CAUSED BY TROCARS,MESH(PHASIX ST)-PHASIX ST MESH IS INDICATED FOR USE IN THE REINFORCEMENT OF SOFT TISSUE, WHERE WEAKNESS EXISTS, IN PROCEDURES INVOLVING SOFT TISSUE REPAIR, SUCH AS FOR THE REPAIR OF HERNIAS, INCLUDING HIATAL HERNIAS.,HERNIA REPAIR DEVICE (BARD COMPOSIX L/P MESH)-BARD COMPOSIX L/P MESH IS INDICATED FOR USE IN THE RECONSTRUCTION OF SOFT TISSUE DEFICIENCIES, SUCH AS FOR THE REPAIR OF HERNIAS AND CHEST WALL DEFECTS.,HERNIA REPAIR DEVICE(BARD 3D MAX MESH)-BARD 3DMAX MESH IS INDICATED TO REINFORCE SOFT TISSUE WHERE WEAKNESS EXISTS, E.G., FOR REPAIR OF HERNIA AND CHEST WALL DEFECTS.,HERNIA REPAIR DEVICE(BARD MESH AND BARD MESH PRE-SHAPED)-BARD MESH IS INDICATED TO REINFORCE SOFT TISSUE WHERE WEAKNESS EXISTS, I.E., REPAIR OF HERNIAS AND CHEST WALL DEFECTS. BARD PRE-SHAPED MESH IS INDICATED FOR THE REPAIR OF INGUINAL HERNIA DEFECTS.,MESH(BARD 3DMAX LIGHT MESH)-THE 3DMAX LIGHT MESH IS INDICATED FOR USE IN THE REINFORCEMENT OF SOFT TISSUE, WHERE WEAKNESS EXISTS, IN THE REPAIR OF INGUINAL HERNIAS,HERNIA PATCH(VENTRIO ST HERNIA PATCH)-VENTRIOTM ST HERNIA PATCH IS INDICATED FOR USE IN THE REINFORCEMENT OF SOFT TISSUE, WHERE WEAKNESS EXISTS, IN PROCEDURES INVOLVING SOFT TISSUE REPAIR, SUCH AS REPAIR OF HERNIAS.,FIXATION DEVICE(CAPSURETM PERMANENT FIXATION SYSTEM)-INDICATED FOR THE APPROXIMATION OF SOFT TISSUE &

		FIXATION OF SURGICAL MESH TO TISSUES DURING OPEN OR LAPAROSCOPIC SURGICAL PROCEDURES, SUCH AS HERNIA REPAIR, FIXATION DEVICE(PERMAFIX FIXATION SYSTEM)-THE PERMAFIX FIXATION SYSTEM IS INDICATED FOR THE APPROXIMATION OF SOFT TISSUE AND FIXATION OF SURGICAL MESH TO TISSUES DURING OPEN OR LAPAROSCOPIC SURGICAL PROCEDURES, SUCH AS HERNIA REPAIR.,MESH(PHASIX)-PHASIX MESH IS INDICATED TO REINFORCE SOFT TISSUE WHERE WEAKNESS EXISTS IN PATIENTS UNDERGOING PLASTIC AND RECONSTRUCTIVE SURGERY, OR FOR USE IN PROCEDURES INVOLVING SOFT TISSUE REPAIR, SUCH AS THE REPAIR OF HERNIA OR OTHER FASCIAL DEFECTS THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT.,HERNIA REPAIR DEVICE (SEPRAMESH IP BIORESORBABLE COATING/PERMANENT MESH)-SEPRAMESH IP BIORESORBABLE COATING/PERMANENT MESH IS INDICATED FOR USE IN THE RECONSTRUCTION OF SOFT TISSUE DEFICIENCIES, SUCH AS FOR THE REPAIR OF HERNIAS.,FIXATION DEVICE(SORBAFIX ABSORBABLE FIXATION SYSTEM)-THE SORBAFIX ABSORBABLE FIXATION SYSTEM IS INDICATED FOR THE APPROXIMATION OF SOFT TISSUE AND FIXATION OF SURGICAL MESH TO TISSUES DURING OPEN OR LAPAROSCOPIC SURGICAL PROCEDURES, SUCH AS HERNIA REPAIR.
1192	IMP/MD/2018/000024	1.License Holder Name: M/S. MANIK MEDICAIDS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT(INNO SLA SUBMERGED IMPLANT SYSTEM)-TO SUPPORT DENTAL PROSTHESIS AS A DENTAL DEVICE, WHICH IS IMPLANTED INTO ALVEOLAR BONE TO RECOVER MASTICATORY FUNCTION AND GIVE BETTER ESTHETICS IN PATIENTS WITH PARTIALLY OR FULL EDENTULOUS JAWS.

1193	IMP/MD/2018/000025	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDEWIRE(BARD HYDRO-GLIDE GUIDEWIRE)-BARD® GUIDEWIRES ARE INDICATED TO PROVIDE TRANSURETHRAL AND/OR PERCUTANEOUS ACCESS INTO THE BLADDER, URETER OR RENAL PELVIS.,CATHETER(UROFORCE BALLOON DILATION CATHETER)-RECOMMENDED FOR DILATION OF THE URINARY TRACT,TEMPORARY PACING ELECTRODE CATHETER (WITHOUT BALLOON)(SEMI-FLOATING)-BARD TEMPORARY PACING CATHETERS ARE DESIGNED TO TRANSMIT AN ELECTRICAL SIGNAL FROM AN EXTERNAL PULSE GENERATOR TO THE HEART OR FROM THE HEART TO A MONITORING DEVICE. WHEN AN INTERNAL LUMEN IS PRESENT (OTHER THAN THE ONE USED FOR BALLOON INFLATION), IT MAY BE USED FOR FLUID INFUSION, PRESSURE MONITORING, OR BLOOD SAMPLING.,TEMPORARY PACING ELECTRODE CATHETER (WITH BALLOON)(BALLOON BIPOLAR ELECTRODE CATHETER)-BARD TEMPORARY PACING CATHETERS ARE DESIGNED TO TRANSMIT AN ELECTRICAL SIGNAL FROM AN EXTERNAL PULSE GENERATOR TO THE HEART OR FROM THE HEART TO A MONITORING DEVICE. WHEN AN INTERNAL LUMEN IS PRESENT (OTHER THAN THE ONE USED FOR BALLOON INFLATION), IT MAY BE USED FOR FLUID INFUSION, PRESSURE MONITORING, OR BLOOD SAMPLING.,TEMPORARY PACING ELECTRODE CATHETER (WITHOUT BALLOON)(NBIH)-BARD TEMPORARY PACING CATHETERS ARE DESIGNED TO TRANSMIT AN ELECTRICAL SIGNAL FROM AN EXTERNAL PULSE GENERATOR TO THE HEART OR FROM THE HEART TO A MONITORING DEVICE. WHEN AN INTERNAL LUMEN IS PRESENT (OTHER THAN THE ONE USED FOR BALLOON INFLATION), IT MAY BE USED FOR FLUID INFUSION, PRESSURE MONITORING, OR BLOOD SAMPLING.

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1194	IMP/MD/2018/000026	1.License Holder Name: EDWARDS LIFESCIENCES (INDIA) PRIVATE LIMITED, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PRESSURE MONITORING SET(TRUWAVE /VAMP JR. PRESSURE MONITORING SET)-THE PRESSURE MONITORING KIT WITH TRUWAVE DISPOSABLE PRESSURE TRANSDUCER IS FOR USE ON PATIENTS REQUIRING INTRAVASCULAR, INTRACRANIAL, OR INTRAUTERINE PRESSURE MONITORING. THE VAMP JR.BLOOD SAMPLING SYSTEM IS INDICATED FOR USE ON NEONATAL OR PEDIATRIC PATIENTS REQUIRING PERIODIC WITHDRAWAL OF BLOOD SAMPLES FROM UMBILICAL, ARTERIAL AND CENTRAL LINE CATHETERS,AND FOR USE WITH DISPOSABLE AND REUSABLE PRESSURE TRANSDUCERS, IF DESIRED., CATHETER ACCESSORY(FLOW-THROUGH HOUSING)-WHEN USED IN CONJUNCTION WITH THE INJECTATE TEMPERATURE PROBE, THE FLOW-THROUGH HOUSING (MODEL 93505) ALLOWS DIRECT TEMPERATURE MEASUREMENT OF THE THERMAL INDICATOR AT THE PROXIMAL LUMEN INFUSION SITE,PRESSURE MONITORING SET (TRUWAVE PRESSURE MONITORING SET)-THE PRESSURE MONITORING KIT WITH TRUWAVE DISPOSABLE PRESSURE TRANSDUCER IS FOR USE ON PATIENTS REQUIRING INTRAVASCULAR, INTRACRANIAL, OR INTRAUTERINE PRESSURE MONITORING,PRESSURE MONITORING ACCESSORY(PRESSURE MONITORING ACCESSORY)-TO BE USED AS ACCESSORY WITH EDWARDS PRESSURE MONITORING OR BLOOD SAMPLING KITS. CONSULT PRESSURE MONITORING OR BLOOD SAMPLING KIT INSTRUCTIONS FOR USE PRIOR TO USING THIS DEVICE.,PRESSURE MONITORING SET(TRUWAVE/VAMP PLUS PRESSURE MONITORING SET)-THE PRESSURE MONITORING KIT WITH TRUWAVE DISPOSABLE PRESSURE TRANSDUCER IS FOR USE ON PATIENTS REQUIRING INTRAVASCULAR, INTRACRANIAL, OR INTRAUTERINE PRESSURE MONITORING. THE BLOOD SAMPLING SYSTEM IS INDICATED FOR USE ON PATIENTS REQUIRING PERIODIC WITHDRAWAL OF BLOOD SAMPLES FROM ARTERIAL AND CENTRAL LINE CATHETERS, INCLUDING PERIPHERALLY INSERTED CENTRAL CATHETERS AND CENTRAL VENOUS CATHETERS, WHICH ARE ATTACHED TO PRESSURE MONITORING LINES,BLOOD PRESSURE MONITORING DEVICE (CLEARSIGHT™ FINGER CUFF)-THE CLEARSIGHT FINGER CUFFS ARE INDICATED FOR PATIENTS OVER 18 YEARS OF AGE TO NONINVASIVELY MEASURE BLOOD PRESSURE AND ASSOCIATED HEMODYNAMIC PARAMETERS WHEN USED WITH THE EV1000 CLINICAL PLATFORM NI.,PRESSURE MONITORING SET(FLOTRAC SENSOR)-THE FLO TRAC SENSOR IS INDICATED FOR USE IN INTRAVASCULAR PRESSURE MONITORING. IT IS ALSO INDICATED

	FOR THE USE WITH THE EDWARDS ARTERIAL PRESSURE BASED CARDIAC OUTPUT MONITORING DEVICES OR HARDWARE TO MEASURE CARDIAC OUTPUT,BLOOD PRESSURE MONITORING DEVICE (CLEARSIGHT™ FINGER CUFF)-INTENDED USE: THE CLEARSIGHT™ FINGER CUFF IS INTENDED TO NON-INVASIVELY AND CONTINUOUSLY MEASURE BLOOD PRESSURE AND HEMODYNAMIC PARAMETERS IN ADULT PATIENTS. INDICATIONS - THE EV1000 CLINICAL PLATFORM NI AND CLEARSIGHT™ FINGER CUFFS ARE INDICATED FOR PATIENTS OVER 18 YEARS OF AGE IN WHICH THE BALANCE BETWEEN CARDIAC FUNCTION, FLUID STATUS AND VASCULAR RESISTANCE NEEDS CONTINUOUS ASSESSMENT. THE EV1000 CLINICAL PLATFORM MAYBE USED FOR THE MONITORING OF HEMODYNAMIC PARAMETERS IN CONJUNCTION WITH A PERIOPERATIVE GOAL DIRECTED THERAPY PROTOCOL. IN ADDITION, THE NONINVASIVE SYSTEM IS INDICATED FOR USE IN PATIENTS WITH CO-MORBIDITIES FOR WHICH HEMODYNAMIC OPTIMIZATION IS DESIRED AND INVASIVE MEASUREMENTS ARE DIFFICULT. THE EV1000 CLINICAL PLATFORM NI AND CLEARSIGHT™ FINGER CUFFS NONINVASIVELY MEASURES BLOOD PRESSURE AND ASSOCIATED HEMODYNAMIC PARAMETERS., PRESSURE MONITORING SENSOR(ACUMEN IQ SENSOR)-ACUMEN IQ SENSOR IS INDICATED FOR USE IN INTRAVASCULAR PRESSURE MONITORING. IT IS ALSO INDICATED FOR USE WITH THE EDWARDS ARTERIAL PRESSURE BASED CARDIAC OUTPUT MONITORING DEVICES OR HARDWARE TO MEASURE CARDIAC OUTPUT.

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1195	IMP/MD/2018/000029	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDEWIRE (PRESSUREWIRE X)-IT IS DESIGNED TO FIT INSIDE A PERCUTANEOUS CATHETER FOR THE PURPOSE OF DIRECTING THE CATHETER THROUGH A VESSEL. THE SIGNAL OUTPUT FROM THE SENSOR IS USED FOR CALCULATIONS AND PRESENTATION OF ANY PHYSIOLOGICAL PARAMETERS, FUNCTIONS OR INDICES BASED ON PRESSURE OR TEMPERATURE, E.G. FRACTIONAL FLOW RESERVE (FFR).,CATHETER(FLEXABILITY ABLATION CATHETER)-THE FLEXABILITY™ ABLATION CATHETER IS INTENDED FOR USE WITH THE COMPATIBLE IRRIGATION PUMP AND A COMPATIBLE RF CARDIAC ABLATION GENERATOR. THE CATHETER IS INTENDED FOR CREATING FOCAL LESIONS DURING CARDIAC ABLATION PROCEDURES (MAPPING, STIMULATION, AND ABLATION) FOR THE TREATMENT OF ARRHYTHMIAS. EPICARDIAL ABLATION SHOULD BE LIMITED TO APPROPRIATELY SELECTED PATIENTS WITH VENTRICULAR TACHYCARDIA. ,GUIDEWIRE(PRESSURE WIRE AERIES)-PRESSUREWIRE IS INDICATED TO DIRECT A CATHETER THROUGH A BLOOD VESSEL AND TO MEASURE PHYSIOLOGICAL PARAMETERS IN THE HEART AND IN THE CORONARY AND PERIPHERAL BLOOD VESSELS.,GUIDEWIRE(PRESSURE WIRE CERTUS)-PRESSUREWIRE IS INDICATED TO DIRECT A CATHETER THROUGH A BLOOD VESSEL AND TO MEASURE PHYSIOLOGICAL PARAMETERS IN THE HEART AND IN THE CORONARY AND PERIPHERAL BLOOD VESSELS.

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1196	IMP/MD/2018/000030	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VASCULAR GRAFT(IMPRA EPTFE VASCULAR GRAFTS)-IMPRA E PTFE GRAFTS ARE INDICATED FOR USE AS VASCULAR PROSTHESES.,CARDIOVASCULAR PATCH (IMPRA® EPTFE CARDIOVASCULAR PATCH)-INDICATED FOR USE IN REPAIR AND CLOSURE OF THE CARDIOVASCULAR SYSTEM., CROSSING SUPPORT CATHETER(SEEKER® CROSSING SUPPORT CATHETER)-THE SEEKER® CROSSING SUPPORT CATHETERS ARE RECOMMENDED FOR GUIDEWIRE EXCHANGE AND INFUSION DEVICES DESIGNED FOR USE IN THE PERIPHERAL VASCULAR SYSTEM. THE CATHETERS ARE INTENDED TO SUPPORT A GUIDEWIRE DURING ACCESS INTO THE VASCULATURE, ALLOW FOR GUIDEWIRE EXCHANGES, AND PROVIDE A PASSAGE FOR DELIVERY OF SALINE SOLUTIONS AND/OR DIAGNOSTIC CONTRAST AGENTS,VASCULAR GRAFT(DYNAFLO® BYPASS GRAFTS)-INTENDED FOR BYPASS OR RECONSTRUCTION OF PERIPHERAL ARTERIAL BLOOD VESSELS., VASCULAR GRAFT(IMPRA® CARBOFLO® EPTFE VASCULAR GRAFTS)-INDICATED FOR USE AS VASCULAR PROSTHESES.,VASCULAR GRAFT (DISTAFLO® BYPASS GRAFTS)-INTENDED FOR BYPASS OR RECONSTRUCTION OF PERIPHERAL ARTERIAL BLOOD VESSELS., VASCULAR GRAFT(VENAFLO® II EPTFE VASCULAR GRAFT)-INDICATED FOR USE AS SUBCUTANEOUS ARTERIOVENUOUS CONDUITS FOR BLOOD ACCESS ONLY.

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1197	IMP/MD/2018/000031	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EMBOLIZATION DEVICE (CATERPILLAR™/ CATERPILLAR™ MICRO ARTERIAL EMBOLIZATION DEVICE)-THE CATERPILLAR™ AND CATERPILLAR™ MICRO ARTERIAL EMBOLIZATION DEVICES ARE INDICATED FOR ARTERIAL EMBOLIZATION IN THE PERIPHERAL VASCULATURE. THE DEVICES ARE CONTRAINDICATED FOR USE IN VESSELS SUBJECT TO CYCLIC BENDING, SUCH AS LOCOMOTIVE JOINTS OR MUSCLE BEDS., BALLOON EXPANDABLE VASCULAR COVERED STENT SYSTEM (LIFESTREAM BALLOON EXPANDABLE VASCULAR COVERED STENT)-THE LIFESTREAM BALLOON EXPANDABLE VASCULAR COVERED STENT IS INDICATED FOR THE TREATMENT OF ATHEROSCLEROTIC LESIONS IN COMMON AND EXTERNAL ILIAC ARTERIES.,GUIDING SHEATH(HALO ONE THIN-WALLED GUIDING SHEATH)-THE HALO ONE™ THIN-WALLED GUIDING SHEATH IS INDICATED FOR USE IN PERIPHERAL ARTERIAL AND VENOUS PROCEDURES REQUIRING PERCUTANEOUS INTRODUCTION OF INTRAVASCULAR DEVICES. THE HALO ONE™ THIN-WALLED GUIDING SHEATH IS NOT INDICATED FOR USE IN THE NEUROVASCULATURE OR THE CORONARY VASCULATURE.,PTA BALLOON CATHETER(REEKROSS PTA BALLOON CATHETER, REEKROSS 14 PTA BALLOON CATHETER, REEKROSS 18 PTA BALLOON CATHETER)-THE REEKROSS PTA BALLOON CATHETERS ARE INTENDED FOR BALLOON DILATATION OF THE FEMORAL, POPLITEAL AND INFRA-POPLITEAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THESE CATHETERS ARE NOT DESIGNED TO BE USED IN THE CORONARY ARTERIES.

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1198	IMP/MD/2018/000032	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOPSY NEEDLE(BARD® BIOPTY-CUT® DISPOSABLE CORE BIOPSY NEEDLES)-INTENDED FOR USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS LIVER, KIDNEY, PROSTATE, SPLEEN, LYMPH NODES AND VARIOUS SOFT TISSUE TUMORS. IT IS NOT INTENDED FOR USE IN BONE.,PTA BALLOON DILATATION CATHETER (CONQUEST® PTA BALLOON DILATATION CATHETER)-RECOMMENDED FOR USE IN PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF THE FEMORAL, ILIAC AND RENAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO RECOMMENDED FOR POST-DILATATION OF STENT GRAFTS IN THE PERIPHERAL VASCULATURE. THIS CATHETER IS NOT FOR USE IN CORONARY ARTERIES.,BREAST LOCALIZATION WIRE(GHIATAS® BEADED BREAST LOCALIZATION WIRE)-INTENDED FOR USE DURING BREAST LESION SURGERY AS A GUIDE FOR THE SURGEON TO FOLLOW IN THE EXCISION OF THE LESION,BREAST LOCALIZATION WIRE(BARD® DUALOK® BREAST LESION LOCALIZATION WIRE)-INTENDED FOR USE AS A GUIDE FOR DIRECTING SURGICAL BIOPSIES,BIOPSY NEEDLE(BARD® TRUGUIDE® DISPOSABLE COAXIAL BIOPSY NEEDLE)-INTENDED FOR USE AS A GUIDING NEEDLE IN OBTAINING CORE BIOPSY SAMPLES FROM SOFT TISSUE SUCH AS LIVER, KIDNEY, SPLEEN, LYMPH NODES AND VARIOUS SOFT TISSUE LESIONS.,BIOPSY NEEDLE (BARD® MAGNUM® DISPOSABLE CORE TISSUE BIOPSY NEEDLE)-INTENDED FOR USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS LIVER, KIDNEY, PROSTATE, BREAST, SPLEEN, LYMPH NODES AND VARIOUS SOFT TISSUE TUMORS.,PTA BALLOON DILATATION CATHETER (CONQUEST® 40 PTA DILATATION CATHETER)-RECOMMENDED FOR USE IN PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF THE FEMORAL, ILIAC AND RENAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO RECOMMENDED FOR POST-DILATATION OF STENTS AND STENT GRAFTS IN THE PERIPHERAL VASCULATURE. THIS CATHETER IS NOT FOR USE IN CORONARY ARTERIES,BIOPSY NEEDLE(BARD® MONOPTY® DISPOSABLE CORE BIOPSY INSTRUMENT)-INTENDED FOR USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS LIVER, KIDNEY, PROSTATE, SPLEEN, LYMPH NODES AND VARIOUS SOFT TISSUE TUMORS. IT IS NOT INTENDED FOR USE IN BONE.,BIOPSY NEEDLE(BARD® MAX-CORE® DISPOSABLE CORE BIOPSY INSTRUMENT)-INTENDED FOR USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS LIVER, KIDNEY, PROSTATE, SPLEEN, LYMPH NODES AND VARIOUS SOFT TISSUE

	TUMORS. IT IS NOT INTENDED FOR USE IN BONE.

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1199	IMP/MD/2018/000033	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LONG-TERM HEMODIALYSIS CATHETER(GLIDEPATH)-THE GLIDEPATHTM LONG-TERM HEMODIALYSIS CATHETERS ARE INDICATED FOR USE IN ATTAINING SHORT-TERM OR LONG-TERM VASCULAR ACCESS FOR HEMODIALYSIS, HEMOPERFUSION OR APHERESIS THERAPY. ACCESS IS ATTAINED VIA THE INTERNAL JUGULAR VEIN, EXTRENAL JUGULAR VEIN, SUBCLAVIAN VEIN, OR FEMORAL VEIN. CATHETERS LONGER THAN 40 CM ARE INTENDED FOR FEMORAL VEIN INSERTION., CATHETER(POLY PER-Q-CATH CATHETER)-INDICATED FOR SHORT OR LONG TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY AND BLOOD SAMPLING. FOR BLOOD THERAPY, IT IS RECOMMENDED THAT A 4 FRENCH OR LARGER CATHETER BE USED.,CATHETER(POWER GROSHONG)-THE POWERGROSHONG CATHETER IS INDICATED FOR SHORT OR LONG TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY AND POWER INJECTION OF CONTRAST MEDIA. THE MAXIMUM RECOMMENDED INFUSION RATE IS 4ML/SEC FOR POWER INJECTION OF CONTRAST MEDIA.,CATHETER(GROSHONG NXT)-THE GROSHONG NXT PICC PROVIDES SHORT (LESS THAN 30 DAYS) OR LONG (GREATER THAN 30 DAYS) TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY OR BLOOD SAMPLING.,CATHETER WITH SHERLOCK TIP LOCATION SYSTEM STYLET(POWERPICC)-THE POWERPICC CATHETER IS INDICATED FOR SHORT OR LONG TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, POWER INJECTION OF CONTRAST MEDIA AND ALLOWS FOR CENTRAL VENOUS PRESSURE MONITORING. FOR BLOOD SAMPLING, INFUSION OR THERAPY, USE A 4 FRENCH OR LARGE CATHETER. THE MAXIMUM RECOMMENDED INFUSION RATE IS 5ML/SEC FOR POWER INJECTION OF CONTRAST MEDIA. FOR CENTRAL VENOUS PRESSURE MONITORING, IT IS RECOMMENDED THAT A CATHETER LUMEN OF 20 GAUGE OR LARGER BE USED., CATHETER WITH SHERLOCK TIP LOCATION SYSTEM STYLET(POWER GROSHONG)-THE POWERGROSHONG CATHETER IS INDICATED FOR SHORT OR LONG TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY AND POWER INJECTION OF CONTRAST MEDIA. THE MAXIMUM RECOMMENDED INFUSION RATE IS 4ML/SEC FOR POWER INJECTION OF CONTRAST MEDIA.,CATHETER WITH SHERLOCK TIP LOCATION SYSTEM STYLET (GROSHONG NXT)-THE GROSHONG NXT PICC PROVIDES SHORT (LESS THAN 30 DAYS) OR LONG (GREATER THAN 30 DAYS) TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR

	INTRAVENOUS THERAPY OR BLOOD SAMPLING.,INFUSION SETS (WINGED INFUSION SET)-THE BARD ACCESS SYSTEMS NON-CORING NEEDLE & NON-NEEDLE WINGED INFUSION SETS ARE INDICATED FOR THE ACCESSING OF SUBCUTANEOUSLY PLACED IMPLANTED PORTS WITH SILICONE SEPTUMS.,IMPLANTABLE PORT WITH SUTURE PLUGS (POWER PORT ISP MRI)-THE POWERPORT IMPLANTED PORT IS INDICATED FOR PATIENT THERAPIES REQUIRING REPEATED ACCESS TO THE VASCULAR SYSTEM. THE PORT SYSTEM CAN BE USED FOR INFUSION OF MEDICATION, I.V. FLUIDS, PARETRALS NUTRITION SOLUTIONS, BLOOD PRODUCTS AND FOR THE WITHDRAWAL OF BLOOD SAMPLES. WHEN USED WITH THE POWERLOC SAFETY INFUSION SET, THE POWERPORT DEVICE IS INDICATED FOR POWER INJECTION OF CONTRAST MEDIA. FOR POWER INJECTION OF CONTRAST MEDIA, THE MAXIMUM RECOMMENDED INFUSION RATE IS 5 ML/ SEC.,IMPLANTABLE PORT WITH ATTACHED 6F CHRONOFLEX OPEN-ENDED SINGLE-LUMEN VENOUS CATHETER(POWERPORT SLIM) -POWERPORT IMPLANTABLE PORTS ARE INDICATED FOR USE IN PATIENT THERAPIES REQUIRING REPEATED ACCESS TO THE VASCULAR SYSTEMS. THE PORT SYSTEM CAN BE USED FOR INFUSION OF MEDICATIONS, I.V. FLUIDS, PARENTRAL NUTRITION SOLUTIONS, BLOOD PRODUCTS, AND FOR THE WITHDRAWAL OF BLOOD SAMPLES. WHEN USED WITH THE POWERLOC SAFETY INFUSION SET, THE POWERPORT DEVICE IS INDICATED FOR POWER INJECTION OF CONTRAST MEDIA. FOR POWER INJECTION OF CONTRAST MEDIA, THE MAXIMUM RECOMMENDED INFUSION RATE IS 5 ML/ SEC.,CATHETER(POWERPICC)-THE POWERPICC CATHETER IS INDICATED FOR SHORT OR LONG TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, POWER INJECTION OF CONTRAST MEDIA, AND ALLOWS FOR CENTRAL VENOUS PRESSURE MONITORING. FOR BLOOD SAMPLING, INFUSION, OR THERAPY USE A 4 FRENCH OR LARGER CATHETER. THE MAXIMUM RECOMMENDED INFUSION RATE IS 5 ML/SEC FOR POWER INJECTION OF CONTRAST MEDIA. FOR CENTRAL VENOUS PRESSURE MONITORING, IT IS RECOMMENDED THAT A CATHETER LUMEN OF 20 GAUGE OR LARGER BE USED.,HEMODIALYSIS CATHETER WITH OR WITHOUT PRELOADED STYLET(EQUISTREAM AND EQUISTREAM XK)-THE EQUISTREAM AND EQUISTREAM XK LONG-TERM HEMODIALYSIS CATHETERS ARE INDICATED FOR USE IN ATTAINING SHORT-TERM OR LONG-TERM VASCULAR ACESS FOR HEMODIALYSIS, HEMOPERFUSION OR APHERESIS THERAPY. ACCESS IS ATTAINED VIA THE INTERNAL JUGULAR VEIN, EXTERNAL JUGULAR VEIN, SUBCLAVIAN VEIN, OR FEMORAL VEIN. CATHETERS LONGER THAN 40 CM ARE INTENDED FOR FEMORAL VEIN INSERTION.,HEMODIALYSIS CATHETER(HEMOSPLIT LONG-TERM HEMODIALYSIS CATHETER)-

	INDICATED FOR HEMODIALYSIS, HEMOPERFUSION OR APHERESIS THERAPY VIA THE JUGULAR, SUBCLAVIAN OR FEMORAL VEIN, PERIPHERALLY INSERTED CENTRAL VENOUS CATHETER(GROSHONG PICC CATHETER BASIC TRAY, GROSHONG NXT CLEARVUE BASIC TRAY S/L, PER Q CATH PLUS PICC X/ STIFFENING STYLET WIRE)- INDICATED FOR INFUSION OF MEDICATIONS, I.V FLUIDS, PARENTERAL NUTRITION SOLUTIONS, BLOOD PRODUCTS AND FOR THE WITHDRAWAL OF BLOOD SAMPLES,TITANIUM PORT(BARDPORT TITANIUM IMPLANTABLE PORT (TITANIUM PORT WITH ATTACHABLE OPEN ENDED CATHETER AND PEEL APART INTRODUCER KIT))- INDICATED FOR INFUSION OF MEDICATIONS, I.V FLUIDS, PARENTERAL NUTRITION SOLUTIONS, BLOOD PRODUCTS AND FOR THE WITHDRAWAL OF BLOOD SAMPLES.,IMPLANTED PORT(X-PORT IMPLANTABLE PORT (X PORT ISP MRI PLASTIC PORT WITH ATTACHABLE GROSHONG, X PORT DUO MRI PLASTIC PORT WITH ATTACHABLE GROSHONG CATHETER, X PORT ISP MRI PLASTIC IMPLANTED PORT WITH PRE-ATTACHABLE OPEN ENDED SILICONE CATHETER, X PORT ISP MRI PLASTIC IMPLANTABLE PORT WITH ATTACHABLE OPEN ENDED SILICONE CATHETER); BARDPORT M.R.I IMPLANTABLE PORT (MRI PLASTIC PORT WITH PREATTACHED OPEN ENDED CATHETER AND PEEL APART INTRODUCER KIT, MRI PLASTIC PORT WITH ATTACHED OPEN ENDED CATHETER AND PEEL APART INTRODUCER KIT, MRI HARD BASE IMPLANTED PORT WITH ATTACHABLE GROSHONG SINGLE LUMEN VENOUS CATHETER AND PEEL APART INRTODUCER KIT, MRI PLASTIC DUAL IMPLANTED PORT WITH ATTACHABLE GROSHONG DUAL LUMEN CATHETER AND PEELAPART INTRODUCER KIT); SLIMPORT IMPLANTABLE PORT (SLIMPORT MRI ULTRA LOW PROFILE IMPLANTED PORT WITH ATTACHABLE OPEN ENDED CHRONOFLEX CATHETER AND PEEL APART INTRODUCER KIT AND MICROINTODUCER KIT))-INDICATED FOR INFUSION OF MEDICATIONS, I.V. FLUIDS, PARENTERAL NUTRITION SOLUTIONS, BLOOD PRODUCTS AND FOR THE WITHDRAWAL OF BLOOD SAMPLES

1200	IMP/MD/2018/000034	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOSTASIS INTRODUCER(ULTIMUM EV)-IT IS INTENDED FOR THE INTRODUCTION OF ANGIOGRAPHIC CATHETERS, CLOSED END CATHETERS, BALLOON CATHETERS, AND ELECTRODES INTO A VESSEL WHERE MINIMIZING BLOOD LOSS IS ESSENTIAL.,INTRODUCER(FAST-CATH™ TRIO HEMOSTASIS INTRODUCER)-IT IS INTENDED FOR THE INTRODUCTION OF ANGIOGRAPHIC CATHETERS, CLOSED END CATHETERS, BALLOON CATHETERS, AND ELECTRODES INTO A VESSEL WHERE MINIMIZING BLOOD LOSS IS ESSENTIAL.,ABLATION CATHETER(TACTICATH QUARTZ)-IT IS INDICATED FOR USE IN CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATION AND RECORDING) AND WHEN USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION OF SUPRAVENTRICULAR ARRHYTHMIAS IN RIGHT AND LEFT ATRIUM, INCLUDING ATRIAL FIBRILLATION.,INTRODUCER(FAST-CATH™ DUO HEMOSTASIS INTRODUCER)-IT IS INTENDED FOR THE INTRODUCTION OF ANGIOGRAPHIC CATHETERS, CLOSED END CATHETERS, BALLOON CATHETERS, AND ELECTRODES INTO A VESSEL WHERE MINIMIZING BLOOD LOSS IS ESSENTIAL.,CIRCULAR MAPPING CATHETER (ADVISOR FL, SENSOR ENABLED)-THE ADVISOR FL CIRCULAR MAPPING CATHETER, SENSOR ENABLED IS A SENSOR ENABLED ELECTROPHYSIOLOGY CATHETER USED FOR RECORDING INTRA CARDIAC SIGNALS AND CARDIAC STIMULATION DURING DIAGNOSTIC ELECTROPHYSIOLOGY STUDIES. THE CATHETER CAN BE USED TO MAP ATRIAL REGIONS OF THE HEART. THE CATHETER IS COMPATIBLE WITH SJM VISUALIZATION AND NAVIGATION SYSTEMS TO ENABLE REAL-TIME POSITIONING AND NAVIGATION.,INTRODUCER (FAST-CATH™ GUIDING INTRODUCER)-FAST-CATH™ GUIDING INTRODUCER IS INDICATED FOR THE INTRODUCTION OF VARIOUS CARDIOVASCULAR CATHETERS OR BIOPSY DEVICES INTO THE HEART.,INTRODUCER(ENGAGE INTRODUCER)-ENGAGE INTRODUCER IS INTENDED FOR THE INTRODUCTION OF ANGIOGRAPHIC CATHETERS, CLOSED END CATHETERS, BALLOON CATHETERS AND ELECTRODES INTO A VESSEL (INCLUDING BUT NOT LIMITED TO FEMORAL, RADIAL, AND BRACHIAL ACCESS) WHERE MINIMIZING BLOOD IS ESSENTIAL.,HEMOSTASIS INTRODUCER(FAST-CATH)-FAST-CATH HEMOSTASIS INTRODUCERS ARE INTENDED FOR THE INTRODUCTION OF ANGIOGRAPHIC CATHETERS, CLOSED END CATHETERS, BALLOON CATHETERS, AND ELECTRODES INTO A VESSEL WHERE MINIMIZING BLOOD LOSS IS ESSENTIAL, HAEMOSTASIS VALVE ADAPTER, VESSEL DILATOR, REPOSITIONING SLEEVE, SHEATH OBTURATOR (INTRODUCER ACCESSORIES)-

	INTRODUCER ACCESSORIES ARE INTENDED FOR THE INTRODUCTION OF THE ANGIOGRAPHIC CATHETER, CLOSED END CATHETERS, BALLOON CATHETERS AND ELECTRODES INTO A VESSEL WHERE MINIMIZING BLOOD LOSS IS ESSENTIAL. HEMOSTASIS VALVE ADAPTER: THE INTRODUCTION OF ANGIOGRAPHIC CATHETERS, CLOSED END CATHETERS, BALLOON CATHETERS AND ELECTRODES INTO A VESSEL WHERE MINIMIZING BLOOD LOSS IS ESSENTIAL. VESSEL DILATOR: THE SJM™ VESSEL DILATOR IS INTENDED FOR USE IN ANGIOGRAPHIC PROCEDURES REQUIRING THE DILATION OF VESSELS PRIOR TO THE INTRODUCTION OF INTRODUCERS AND/OR CATHETERS. FOLLOW NORMALLY ACCEPTED PRACTICE FOR VESSEL PUNCTURE AND GUIDEWIRE INSERTION, VESSEL DILATOR, AND INTRODUCER USE. REPOSITIONING SLEEVE: SJM™ REPOSITIONING SLEEVES MAY BE USED WITH SJM™ INTRODUCERS TO PROVIDE AN ADDED MEASURE OF ENVIRONMENTAL PROTECTION TO THE EXPOSED PORTION OF LONG TERM VENOUS MONITORING CATHETERS REQUIRING FURTHER MANIPULATION. SHEATH OBTURATOR: A ST. JUDE MEDICAL™ SHEATH OBTURATOR MAY BE USED WITH A ST. JUDE MEDICAL™ HEMOSTASIS INTRODUCER TO SEAL THE HEMOSTASIS APERTURE AND AID IN MAINTAINING SHEATH PATENCY AND GENERAL MANAGEMENT OF THE INTRODUCTION SITE., INTRODUCER(SJM PEEL-AWAY INTRODUCER)-SJM PEEL-AWAY INTRODUCER IS INDICATED FOR THE INTRODUCTION OF CATHETERS INTO A VESSEL.,ABLATION CATHETER(FLEXABILITY)-THE FLEXABILITY ABLATION CATHETER IS INTENDED FOR USE WITH THE COMPATIBLE IRRIGATION PUMP AND A COMPATIBLE RF CARDAIC ABLATION GENERATOR. THE CATHETER IS INTENDED FOR CREATING FOCAL LESIONS DURING CARDIAC ABLATION PROCEDURES (MAPPING, STIMULATION AND ABLATION) FOR THE TREATMENT OF ARRHYTHMIAS. EPICARDIAL ABLATION SHOULD BE LIMITED TO APPROPRIATELY SELECTED PATIENTS WITH VENTRICULAR TACHYCARDIA.,BRAIDED TRANSSEPTAL GUIDING INTRODUCER (SWARTZ)-IT IS USED FOR INTRODUCING VARIOUS CARDIOVASCULAR CATHETERS INTO THE LEFT SIDE OF THE HEART THOUGH THE INTERATRIAL SEPTUM.,TRANSSEPTAL GUIDING INTRODUCER(FAST-CATH)-FAST-CATH TRANSSEPTAL GUIDING INTRODUCER SET IS INDICATED FOR INTRODUCING VARIOUS CARDIOVASCULAR CATHETERS INTO THE LEFT SIDE OF THE HEART THROUGH THE INTERATRIAL SEPTUM.,HEMOSTASIS INTRODUCER (ULTIMUM)-IT IS INTENDED FOR THE INTRODUCTION OF ANGIOGRAPHIC CATHETERS, CLOSED END CATHETERS, BALLOON CATHETERS, AND ELECTRODES INTO A VESSEL WHERE MINIMIZING BLOOD LOSS IS ESSENTIAL.,HIGH DENSITY MAPPING CATHETER (ADVISOR HD GRID, SENSOR ENABLED)-ADVISOR HD GRID, SENSOR

	ENABLED, IS INDICATED FOR MULTIPLE ELECTRODE ELECTROPHYSIOLOGICAL MAPPING OF CARDIAC STRUCTURES IN THE HEART, I.E., RECORDING OR STIMULATION ONLY. THIS CATHETER IS INTENDED TO OBTAIN ELECTROGRAMS IN THE ATRIAL AND VENTRICULAR REGIONS OF THE HEART

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1201	IMP/MD/2018/000037	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE CORE BIOPSY INSTRUMENT(BARD® MARQUEE® DISPOSABLE CORE BIOPSY INSTRUMENT)-THE BARD® MARQUEE® DISPOSABLE CORE BIOPSY INSTRUMENT ARE INTENDED FOR USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS LIVER, KIDNEY, PROSTATE, SPLEEN, LYMPH NODES AND VARIOUS SOFT TISSUE TUMORS. IT IS NOT INTENDED FOR USE IN BONE.,BREAST TISSUE MARKER (ULTRACLIP DUAL TRIGGER BREAST TISSUE MARKER)-THE ULTRACLIP® DUAL TRIGGER BREAST TISSUE MARKER IS INTENDED FOR USE TO ATTACH TO SOFT BREAST TISSUE AT THE SURGICAL SITE DURING AN OPEN SURGICAL BREAST BIOPSY OR A PERCUTANEOUS BREAST BIOPSY TO RADIOGRAPHICALLY MARK THE LOCATION OF THE BIOPSY PROCEDURE.,DISPOSABLE CORE BIOPSY INSTRUMENT KIT(BARD® MARQUEE® DISPOSABLE CORE BIOPSY INSTRUMENT KIT)-THE BARD® MARQUEE® DISPOSABLE CORE BIOPSY INSTRUMENT KIT ARE INTENDED FOR USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS LIVER, KIDNEY, PROSTATE, SPLEEN, LYMPH NODES AND VARIOUS SOFT TISSUE TUMORS. IT IS NOT INTENDED FOR USE IN BONE,BIOPSY NEEDLE(BARD® MISSION DISPOSABLE CORE BIOPSY INSTRUMENT KIT)-THE BARD® MISSION™ DISPOSABLE CORE BIOPSY INSTRUMENT IS INTENDED FOR USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS LUNG, LIVER, KIDNEY, PROSTATE, SPLEEN, LYMPH NODES, BREAST, THYROID AND VARIOUS SOFT TISSUE TUMORS. ,BIOPSY NEEDLE(BARD® MISSION DISPOSABLE CORE BIOPSY INSTRUMENT)-THE BARD® MISSION™ DISPOSABLE CORE BIOPSY INSTRUMENT IS INTENDED FOR USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS FROM THE LUNG, LIVER, KIDNEY, PROSTATE, SPLEEN, LYMPH NODES, BREAST, THYROID AND VARIOUS SOFT TISSUE TUMORS.,SURGICAL FELTS (BARD® PTFE FELTS)-BARD® PTFE SURGICAL FELTS ARE USED IN VARIOUS APPLICATIONS FOR GENERAL, VASCULAR AND CARDIAC SURGERY. THEY ARE MOST COMMONLY USED AS A PATCH, A BUTTRESS FOR SUTURES, AND AS A MATERIAL FOR REPLACEMENT OF SEGMENTS OF THE VENTRICULAR MYOCARDIUM AFTER RESECTION.,PLEDGETS(BARD® PTFE FELT PLEDGETS)-BARD® PTFE FELT PLEDGETS ARE USED AS BUTTRESSES UNDER SUTURES WHEN THERE IS A POSSIBILITY OF SUTURES TEARING THROUGH TISSUE. THESE PLEDGETS ARE USED IN VARIOUS SURGICAL SUTURING PROCEDURES, SUCH AS VASCULAR CLOSURE, SEPTAL REPAIR, MYOCARDIAL CLOSURE, HEPATIC REPAIR AND VALVULAR SUTURING.,CARDIOVASCULAR FABRICS(BARD® SAUVAGE® FILAMENTOUS FABRIC)-THE KNITTED AND WOVEN POLYESTER

		FABRICS ARE INDICATED FOR USE IN CARDIOVASCULAR SURGICAL PROCEDURES REQUIRING PATCH GRAFT ANGIOPLASTY SUCH AS CAROTID ENDARTERECTOMY. THESE FABRICS ARE ALSO INDICATED FOR REPAIR OF CERTAIN INTRACARDIAC ANOMALIES SUCH AS SEPTAL DEFECTS.
1202	IMP/MD/2018/000038	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER STABILIZATION DEVICES(STATLOCK STABILIZATION DEVICES)-THE STATLOCK STABILIZATION DEVICE IS FOR COMPATIBLE MEDICAL TUBES AND CATHETERS. MULTIPLE PAD AND RETAINER DESIGNS ARE AVAILABLE. CHOOSE THE STATLOCK STABILIZATION DEVICE INDICATED FOR THE TUBE OR CATHETER TO BE SECURED.

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1203	IMP/MD/2018/000039	1.License Holder Name: M/S DENTSPLY INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL SCREW (FRIADENT ATTACHMENT SCREW)-TO SCREW THE ATTACHMENT IN THE IMPLANT,XIVE® TG AUROBASE (XIVE®)-CUSTOM FABRICATION OF CROWNS AND BRIDGE ABUTMENTS,DENTAL SCREW(ANKYLOS RETAINING SCREW FOR TEMPORARY WELDING ABUTMENT)-FIXATION OF THE TEMPORARY WELDING ABUTMENTS ON IMPLANTS,XIVE® TG ABUTMENTS(XIVE®)-FABRICATION OF CEMENTABLE OR HORIZONTALLY SCREW-RETAINED SINGLE CROWNS OR BRIDGES, DENTAL INSERT HEAD(XIVE MP INSERT HEAD)-MP INSERT HEAD IS PROVIDING CONNECTION GEOMETRY FOR SUPRASTRUCTURES. THE INSERT HEAD IS SCREWED ONTO ANGLED MP ABUTMENT INSERTS., XIVE® TEMPORARY WELDING ABUTMENT(XIVE®)-FABRICATION OF AN INTRAORALLY OR EXTRAORALLY WELDED TITANIUM FRAMEWORK FOR IMMEDIATE TEMPORARY RESTORATIONS ON XIVE® IMPLANTS EXCLUSIVELY BY USE OF THE DENTSPLY IMPLANTS WELDONE™ WELDING UNIT AND THE TITANIUM WIRES DESIGNED FOR THAT PURPOSE,DENTAL SCREW(ANKYLOS C/X COVER SCREW)-TO CLOSE THE IMPLANT IN CASE OF SUBMERGED HEALING PROTOCOL., FRIADENT® AUROBASE ABUTMENT(FRIADENT®)-AUROBASE CAN BE USED TO CORRECT XIVE®, FRIALIT® OR FRIALIT®- 2 IMPLANT INCLINATION. INDIVIDUAL MODELLING ABOVE THE UPPER EDGE OF THE IMPLANT.,DENTAL ABUTMENT HEAD(ANKYLOS BALANCE BASE ABUTMENT HEAD)-BALANCE BASE ABUTMENT HEAD IS PROVIDING CONNECTION GEOMETRY FOR SUPRASTRUCTURES. THE ABUTMENT HEAD IS SCREWED ONTO ANGLED BALANCE BASE ABUTMENT., FRIADENT® TELESCOPIC ABUTMENT(FRIADENT®)-SUPPORT FOR TAPERED AND TELESCOPIC CROWNS TO RETAIN OVERDENTURES AND REMOVABLE BRIDGES. FABRICATION OF SINGLE TOOTH CROWNS,DENTAL SCREW(FRIADENT MP INSERT SCREW)-TO SCREW THE MP INSERT IN THE IMPLANT.,FRIADENT® GINGIVA FORMER (FRIADENT®)-AESTHETIC SHAPING OF SOFT TISSUE,DENTAL SCREW (ANKYLOS SCREW FOR SULCUS FORMER BALANCE ANTERIOR)-PROVISIONAL RESTORATION OF IMPLANTS IN COMBINATION WITH BALANCE ANTERIOR SULCUS FORMERS,XIVE® MP ABUTMENT (XIVE®)-PROSTHETIC RESTORATION OF SEVERAL XIVE® IMPLANTS WITH BRIDGES OR BAR CONSTRUCTIONS, TO BE USED AT LEAST IN PAIRS. WHEN USING FOUR OR MORE IMPLANTS, E.G. IN AN EDENTULOUS JAW, IMMEDIATE LOAD IS ALSO POSSIBLE.,DENTAL SCREW(ANKYLOS C/X MEMBRANE SCREW)-RETAINING MEMBRANES ON IMPLANTS,FRIADENT® MP ABUTMENT(FRIADENT®)-PROSTHETIC RESTORATION OF SEVERAL XIVE® OR FRIALIT® IMPLANTS WITH BRIDGES OR BAR CONSTRUCTIONS, TO BE USED AT LEAST IN PAIRS.

		WHEN USING FOUR OR MORE IMPLANTS, E.G. IN AN EDENTULOUS JAW, IMMEDIATE LOAD IS ALSO POSSIBLE.,DENTAL SCREW(ANKYLOS CENTRAL SCREW HEX FOR PERMADOR ABUTMENT)-RETAINING THE SULCUS FORMER IN THE IMPLANT,FRIADENT® ESTHETICBASE (FRIADENT®)-SUPPORT FOR SCREW-RETAINED OR CEMENTABLE CROWNS AND BRIDGES,DENTAL SCREW(FRIADENT STANDARD ABUTMENT SCREW/ FRIADENT SCREW FOR ESTHETICBASE)-TO ATTACH THE ABUTMENT TO THE IMPLANT.,FRIADENT® BALL AND SOCKET ATTACHMENT(FRIADENT®)-FABRICATION OF OVERDENTURES ON ATTACHMENTS IN THE INTERFORAMINAL AREA OF THE MANDIBLE ONLY (MIN. 2 SCREW IMPLANTS 13 MM)
1204	IMP/MD/2018/000040	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DRAINAGE CATHETER (NAVARRE PERCUTANEOUS BILIARY DRAINAGE CATHETER)-IT IS INTENDED TO BE USED FOR STANDARD PERCUTANEOUS TRANSHEPATIC BILIARY DRAINAGE PROCEDURES THAT REQUIRE INTERNAL RETENTION (EXAMPLES: OBSTRUCTIVE JAUNDICE, SEPSIS, HEPATIC DECOMPENSATION, AND PREOPERATIVE DECOMPRESSION), DRAINAGE CATHETER(NAVARRE OPTI-DRAIN MULTI-USE DRAINAGE CATHETER)-IT IS INTENDED TO BE USED FOR ABSCESS, CYST, AND OTHER GENERAL PURPOSE DRAINAGE APPLICATIONS.,DRAINAGE CATHETER(NAVARRE UNIVERSAL DRAINAGE CATHETER)-IT IS INTENDED TO BE USED FOR ABSCESS, CYST, AND OTHER GENERAL PURPOSE DRAINAGE APPLICATIONS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1205	IMP/MD/2018/000042	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHO™ SERA ANTI-JKB (ORTHO™ SERA ANTI-JKB)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR DIRECT AGGLUTINATION TEST BY COLUMN AGGLUTINATION TECHNOLOGY. THE ANTI-JKB REAGENT IS FOR THE QUALITATIVE IN VITRO DETECTION OF HUMAN JKB POSITIVE RED BLOOD CELLS BY THE DIRECT AGGLUTINATION TEST.,ORTHO CONFIDENCE WB(ORTHO CONFIDENCE™ WB)-FOR USE AS QUALITATIVE CONTROLS TO ASSURE THE RELIABILITY OF BASIC BLOOD BANK SEROLOGICAL REAGENTS AND AUTOMATED/MANUAL BLOOD GROUPING SYSTEMS USING COLUMN AGGLUTINATION TECHNIQUES.,ORTHO™ SERA ANTI-M(ORTHO™ SERA ANTI-M)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR DIRECT AGGLUTINATION TEST BY COLUMN AGGLUTINATION TECHNOLOGY. THE ANTI-M REAGENT IS FOR THE QUALITATIVE IN VITRO DETECTION OF HUMAN M POSITIVE RED BLOOD CELLS BY THE DIRECT AGGLUTINATION TEST.,ORTHO™ SERA ANTI-LEB(ORTHO™ SERA ANTI-LEB)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR DIRECT AGGLUTINATION TEST BY COLUMN AGGLUTINATION TECHNOLOGY. THE ANTI-LEB REAGENT IS FOR THE QUALITATIVE IN VITRO DETECTION OF HUMAN LEB POSITIVE RED BLOOD CELLS BY THE DIRECT AGGLUTINATION TEST.,ORTHO™ SERA ANTI-S(ORTHO™ SERA ANTI-S)-FOR IN VITRO DIAGNOSTIC USE ONLY FOR INDIRECT ANTIGLOBULIN TEST BY COLUMN AGGLUTINATION TECHNOLOGY. THE ANTI-S REAGENT IS FOR THE QUALITATIVE IN VITRO DETECTION OF HUMAN S POSITIVE RED BLOOD CELLS BY THE INDIRECT ANTIGLOBULIN TEST.,ORTHO™ SERA ANTI-P1(ORTHO™ SERA ANTI-P1)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR DIRECT AGGLUTINATION TEST BY COLUMN AGGLUTINATION TECHNOLOGY. THE ANTI-P1 REAGENT IS FOR THE QUALITATIVE IN VITRO DETECTION OF HUMAN P1 POSITIVE RED BLOOD CELLS BY THE DIRECT AGGLUTINATION TEST.,ORTHO™ SERA ANTI-S(ORTHO™ SERA ANTI-S)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR INDIRECT ANTIGLOBULIN TEST BY COLUMN AGGLUTINATION TECHNOLOGY. THE ANTI-S REAGENT IS FOR THE QUALITATIVE IN VITRO DETECTION OF HUMAN S POSITIVE RED BLOOD CELLS BY THE INDIRECT ANTIGLOBULIN TEST.,ORTHO™ SERA ANTI-FYB(ORTHO™ SERA ANTI-FYB)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR INDIRECT ANTIGLOBULIN TEST BY COLUMN AGGLUTINATION TECHNOLOGY. THE ANTI-FYB REAGENT IS FOR THE QUALITATIVE IN VITRO DETECTION OF HUMAN FYB POSITIVE RED BLOOD CELLS BY THE INDIRECT ANTIGLOBULIN TEST.,ORTHO™ SERA ANTI-D (DVI)(ORTHO™ SERA ANTI-D (DVI))-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR

	DIRECT AGGLUTINATION TEST BY COLUMN AGGLUTINATION TECHNOLOGY. THE ANTI-D (DVI) REAGENT IS FOR THE QUALITATIVE IN VITRO DETECTION OF HUMAN RHD POSITIVE RED BLOOD CELLS BY THE DIRECT AGGLUTINATION TEST. THIS ANTI-D REAGENT WILL DETECT D CATEGORY DVI CELLS.,ORTHO™ SERA ANTI-LEA(ORTHO™ SERA ANTI-LEA)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR DIRECT AGGLUTINATION TEST BY COLUMN AGGLUTINATION TECHNOLOGY. THE ANTI-LEA REAGENT IS FOR THE QUALITATIVE IN VITRO DETECTION OF HUMAN LEA POSITIVE RED BLOOD CELLS BY THE DIRECT AGGLUTINATION TEST.,ORTHO™ SERA ANTI-N(ORTHO™ SERA ANTI-N)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR DIRECT AGGLUTINATION TEST BY COLUMN AGGLUTINATION TECHNOLOGY. THE ANTI-N REAGENT IS FOR THE QUALITATIVE IN VITRO DETECTION OF HUMAN N POSITIVE RED BLOOD CELLS BY THE DIRECT AGGLUTINATION TEST.,ORTHO™ SERA ANTI-D (IAT)(ORTHO™ SERA ANTI-D (IAT))-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR INDIRECT ANTIGLOBULIN TEST (IAT) BY COLUMN AGGLUTINATION TECHNOLOGY. THE ANTI-D (IAT) REAGENT IS FOR THE QUALITATIVE IN VITRO DETECTION OF HUMAN RHD BLOOD GROUP STATUS BY THE INDIRECT ANTIGLOBULIN TEST.,ORTHO™ SERA ANTI-FYA(ORTHO™ SERA ANTI-FYA)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR INDIRECT ANTIGLOBULIN TEST BY COLUMN AGGLUTINATION TECHNOLOGY. THE ANTI-FYA REAGENT IS FOR THE QUALITATIVE IN VITRO DETECTION OF HUMAN FYA POSITIVE RED BLOOD CELLS BY THE INDIRECT ANTIGLOBULIN TEST.,ORTHO™ SERA ANTI-K(ORTHO™ SERA ANTI-K)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR DIRECT AGGLUTINATION TEST BY COLUMN AGGLUTINATION TECHNOLOGY. THE ANTI-K REAGENT IS FOR THE QUALITATIVE IN VITRO DETECTION OF HUMAN K POSITIVE RED BLOOD CELLS BY THE DIRECT AGGLUTINATION TEST,ORTHO™ SERA ANTI-JKA(ORTHO™ SERA ANTI-JKA)-FOR IN VITRO DIAGNOSTIC USE ONLY. FOR DIRECT AGGLUTINATION TEST BY COLUMN AGGLUTINATION TECHNOLOGY. THE ANTI-JKA REAGENT IS FOR THE QUALITATIVE IN VITRO DETECTION OF HUMAN JKA POSITIVE RED BLOOD CELLS BY THE DIRECT AGGLUTINATION TEST.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1206	IMP/MD/2018/000044	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERIPHERAL/CORONARY VASCULAR MICROCATHETER(MAMBA FLEX MICROCATHETER)-THE MAMBA AND MAMBA FLEX MICROCATHETER IS INTENDED TO PROVIDE SUPPORT TO FACILITATE THE PLACEMENT OF GUIDEWIRES IN THE CORONARY VASCULATURES, AND CAN BE USED TO EXCHANGE ONE GUIDEWIRE FOR ANOTHER. THE MICROCATHETER IS ALSO INTENDED TO ASSIST IN THE DELIVERY OF CONTRAST MEDIA INTO THE CORONARY VASCULATURES.,MECHANICAL ATHERECTOMY SYSTEM, CORONARY, BATTERY-POWERED(ROTAPRO PRE-CONNECTED EXCHANGEABLE BURR CATHETER AND BURR ADVANCING DEVICE)-PERCUTANEOUS ROTATIONAL CORONARY ATHERECTOMY WITH THE ROTAPRO ROTATIONAL ATHERECTOMY SYSTEM, AS A SOLE THERAPY OR WITH ADJUNCTIVE PERCUTANEOUS CORONARY INTERVENTION (PCI) IS INDICATED IN PATIENTS WITH CALCIFIC CORONARY ARTERY DISEASE WHO MEET ONE OF THE FOLLOWING SELECTION CRITERIA: • SINGLE VESSEL ATHEROSCLEROTIC CORONARY ARTERY DISEASE WITH A STENOSIS THAT CAN BE PASSED WITH A GUIDEWIRE; • MULTIPLE VESSEL CORONARY ARTERY DISEASE THAT IN THE PHYSICIAN'S JUDGMENT DOES NOT POSE UNDUE RISK TO THE PATIENT; • PATIENTS WHO HAVE HAD PRIOR PCI, AND WHO HAVE NATIVE CORONARY ARTERY POST-BALLOON ANGIOPLASTY RESTENOSIS; OR, • NATIVE VESSEL ATHEROSCLEROTIC CORONARY ARTERY DISEASE THAT IS LESS THAN 25 MM IN LENGTH.,PERIPHERAL/CORONARY VASCULAR MICROCATHETER(MAMBA MICROCATHETER)-THE MAMBA AND MAMBA FLEX MICROCATHETER IS INTENDED TO PROVIDE SUPPORT TO FACILITATE THE PLACEMENT OF GUIDEWIRES IN THE CORONARY VASCULATURES, AND CAN BE USED TO EXCHANGE ONE GUIDEWIRE FOR ANOTHER. THE MICROCATHETER IS ALSO INTENDED TO ASSIST IN THE DELIVERY OF CONTRAST MEDIA INTO THE CORONARY VASCULATURES.,GASTROINTESTINAL BALLOON CATHETER (HURRICANE RX BALLOON DILATATION CATHETER)-THE HURRICANE RX BILIARY BALLOON DILATATION CATHETER IS RECOMMENDED FOR ENDOSCOPIC DILATATION OF STRICTURES OF THE BILIARY TREE AND THE SPHINCTER OF ODDI. THE HURRICANE RX BILIARY BALLOON DILATATION CATHETER MAY BE USED FOR INJECTION OF CONTRAST MEDIUM FOR FLUOROSCOPIC VISUALIZATION OF THE BILE DUCTS.,GENERAL/MULTIPLE SURGICAL LASER SYSTEM BEAM GUIDE, REUSABLE(LIGHTTRAIL REUSABLE LASER FIBERS)-THE LIGHTTRAIL REUSABLE LASER FIBERS ARE COMPATIBLE WITH BOSTON SCIENTIFIC (STARMEDTEC) LASERS FOR INDICATIONS THAT ARE CLEARED FOR THESE LASER SYSTEMS. THIS MAY INCLUDE BUT

	IS NOT LIMITED TO SURGICAL PROCEDURES INVOLVING ENDOSCOPIC, LAPAROSCOPIC AND OPEN SURGICAL PROCEDURES INVOLVING VAPORIZATION, ABLATION, FRAGMENTATION OF CALCULI, COAGULATION, HEMOSTASIS, EXCISION, RESECTION AND INCISION OF SOFT TISSUES.,BRONCHIAL BALLOON CATHETER(CRE PULMONARY BALLOON DILATATION CATHETER)-THE CRE PULMONARY BALLOON DILATATION CATHETER IS INTENDED TO BE USED TO ENDOSCOPICALLY DILATE STRICTURES OF THE AIRWAY TREE,EMBOLIZATION PARTICLE, NON-BIOABSORBABLE(EMBOZENE COLOR-ADVANCED MICROSPHERE- MICROSPHERES FOR EMBOLIZATION)-EMBOZENE MICROSPHERES ARE INDICATED FOR EMBOLIZATION OF THE FOLLOWING CONDITIONS: * HYPERVASCULAR TUMORS * ARTERIOVENOUS MALFORMATIONS * UTERINE FIBROIDS (UFE) * HEPATOCELLULAR CARCINOMA * BENIGN PROSTATIC HYPERPLASIA (BPH) * TUMORS OF HEAD, NECK, TORSO, AND SKELETAL SYSTEM * BLEEDING AND TRAUMA * PRE-OPERATIVE REDUCTION OF BLEEDING OTHER THAN IN THE CENTRAL NERVOUS SYSTEM THIS DEVICE IS NOT INTENDED FOR NEUROVASCULAR USE., CATHETERS, ARTERIAL MICRO-FLOW CATHETER(RENEGADE HI FLO FATHOM SYSTEM PRELOADED MICROCATHETER SYSTEM WITH FATHOM 16 GUIDEWIRE)-THE RENEGADE HI-FLO FATHOM SYSTEM IS INTENDED FOR PERIPHERAL VASCULAR USE. THE FATHOM GUIDEWIRE CAN BE USED TO SELECTIVELY INTRODUCE AND POSITION THE RENEGADE HI-FLO MICROCATHETER IN THE PERIPHERAL VASCULATURE. THE MICROCATHETER CAN BE USED FOR CONTROLLED AND SELECTIVE INFUSION OF DIAGNOSTIC, EMBOLIC, OR THERAPEUTIC MATERIALS INTO VESSELS.,NON-NEUROVASCULAR EMBOLIZATION COIL(INTERLOCK FIBERED IDC OCCLUSION SYSTEM)-IT IS A MODIFIED INTERLOCKING DETACHABLE COIL INDICATED TO OBSTRUCT OR REDUCE RATE OF BLOOD FLOW IN THE PERIPHERAL VASCULATURE. THIS DEVICE IS NOT INTENDED FOR NEUROVASCULAR USE.,INTRAVASCULAR MICROFLOW CATHETER (RENEGADE STC 18 MICROCATHETER)-THE RENEGADE STC 18 MICROCATHETER IS INTENDED FOR PERIPHERAL VASCULAR USE. THE MICROCATHETER CAN BE COAXIALLY TRACKED OVER A STEERABLE GUIDEWIRE IN ORDER TO ACCESS DISTAL, TORTUOUS VASCULATURE. ONCE THE SUBSELECTIVE REGION HAS BEEN ACCESSED, THE MICROCATHETER CAN BE USED FOR THE CONTROLLED AND SELECTIVE INFUSION OF DIAGNOSTIC, EMBOLIC, OR THERAPEUTIC MATERIALS INTO VESSELS. DIAGNOSTIC, EMBOLIC, THERAPEUTIC AGENTS TO BE USED IN ACCORDANCE WITH SPECIFICATIONS OUTLINED BY THE MANUFACTURER., PERIPHERAL/CORONARY VASCULAR MICROCATHETER(DIREXION HI-FLO FATHOM-16 SYSTEM PRE-LOADED TORQUEABLE

	MICROCATHETER)-THE DIREXION AND DIREXION HI-FLO TORQUEABLE MICROCATHETERS ARE INTENDED FOR PERIPHERAL VASCULAR USE. THE PRE-LOADED FATHOM AND TRANSEND GUIDEWIRES CAN BE USED TO SELECTIVELY INTRODUCE AND POSITION THE MICROCATHETER IN THE PERIPHERAL VASCULATURE. THE MICROCATHETER CAN BE USED FOR CONTROLLED AND SELECTIVE INFUSION OF DIAGNOSTIC, EMBOLIC, OR THERAPEUTIC MATERIALS INTO THE VESSEL.,RADIO-FREQUENCY ABLATION SYSTEM(ALAIR BRONCHIAL THERMOPLASTY CATHETER)-THE ALAIR BRONCHIAL THERMOPLASTY SYSTEM IS INDICATED FOR THE TREATMENT OF SEVERE PERSISTENT ASTHMA IN PATIENTS 18 YEARS AND OLDER WHOSE ASTHMA IS NOT WELL CONTROLLED WITH INHALED CORTICOSTEROIDS AND LONG ACTING BETA AGONISTS., GASTROINTESTINAL DILATION BALLOON CATHETER(CRE WIREGUIDED BALLOON DILATATION CATHETER)-THE CRE WIREGUIDED BALLOON DILATATION CATHETERS ARE INTENDED FOR USE IN ADULT AND ADOLESCENT POPULATIONS TO ENDOSCOPICALLY DILATE STRICTURES OF THE ALIMENTARY TRACT. THE RECOMMENDED APPLICATION IS PRINTED ON THE PACKAGE LABEL.,CATHETER-BALLOON INFLATOR, SINGLE-USE(ALLIANCE II SINGLE-USE SYRINGE/ GAUGE ASSEMBLY)-THE ALLIANCE II SYSTEM (SYRINGE/GAUGE ASSEMBLY AND ALLIANCE II INFLATION HANDLE) IS INDICATED FOR INFLATION AND DEFLATION OF BALLOON DILATATION CATHETERS WHILE SIMULTANEOUSLY MONITORING BALLOON CATHETER PRESSURES.,MECHANICAL ATHERECTOMY SYSTEM, CORONARY, BATTERY-POWERED(ROTALINK PLUS PRE-CONNECTED EXCHANGEABLE BURR CATHETER AND BURR ADVANCING DEVICE)-PERCUTANEOUS ROTATIONAL CORONARY ANGIOPLASTY WITH THE ROTABLATOR ROTATIONAL ATHERECTOMY SYSTEM, AS A SOLE THERAPY OR WITH ADJUNCTIVE BALLOON ANGIOPLASTY, IS INDICATED IN PATIENTS WITH CORONARY ARTERY DISEASE WHO ARE ACCEPTABLE CANDIDATES FOR CORONARY ARTERY BYPASS GRAFT SURGERY AND WHO MEET ONE OF THE FOLLOWING SELECTION CRITERIA: • SINGLE VESSEL ATHEROSCLEROTIC CORONARY ARTERY DISEASE WITH A STENOSIS THAT CAN BE PASSED WITH A GUIDEWIRE; • MULTIPLE VESSEL CORONARY ARTERY DISEASE THAT IN THE PHYSICIAN'S JUDGMENT DOES NOT POSE UNDUE RISK TO THE PATIENT; • CERTAIN PATIENTS WHO HAVE HAD PRIOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA), AND WHO HAVE A RESTENOSIS OF THE NATIVE VESSEL; OR, • NATIVE VESSEL ATHEROSCLEROTIC CORONARY ARTERY DISEASE THAT IS LESS THAN 25 MM IN LENGTH., MECHANICAL ATHERECTOMY SYSTEM, CORONARY, BATTERY-POWERED(ROTALINK BURR EXCHANGEABLE BURR CATHETER)-

	PERCUTANEOUS ROTATIONAL CORONARY ANGIOPLASTY WITH THE ROTABLATOR ROTATIONAL ATHERECTOMY SYSTEM, AS A SOLE THERAPY OR WITH ADJUNCTIVE BALLOON ANGIOPLASTY, IS INDICATED IN PATIENTS WITH CORONARY ARTERY DISEASE WHO ARE ACCEPTABLE CANDIDATES FOR CORONARY ARTERY BYPASS GRAFT SURGERY AND WHO MEET ONE OF THE FOLLOWING SELECTION CRITERIA: • SINGLE VESSEL ATHEROSCLEROTIC CORONARY ARTERY DISEASE WITH A STENOSIS THAT CAN BE PASSED WITH A GUIDEWIRE; • MULTIPLE VESSEL CORONARY ARTERY DISEASE THAT IN THE PHYSICIAN'S JUDGMENT DOES NOT POSE UNDUE RISK TO THE PATIENT; • CERTAIN PATIENTS WHO HAVE HAD PRIOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA), AND WHO HAVE A RESTENOSIS OF THE NATIVE VESSEL; OR, • NATIVE VESSEL ATHEROSCLEROTIC CORONARY ARTERY DISEASE THAT IS LESS THAN 25 MM IN LENGTH.,NON-NEUROVASCULAR EMBOLIZATION COIL(VORTX DIAMOND -18 FIBERED PLATINUM COIL)-IT IS INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE,NON-NEUROVASCULAR EMBOLIZATION COIL(VORTX 35 FIBERED PLATINUM COIL)-IT IS INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE,INTRAVASCULAR OCCLUDING CATHETER(EQUALIZER OCCLUSION BALLOON CATHETER)-THE EQUALIZER OCCLUSION BALLOON CATHETER IS INDICATED FOR USE FOR TEMPORARY VESSEL OCCLUSION IN APPLICATIONS INCLUDING ARTERIOGRAPHY, PREOPERATIVE OCCLUSION, EMERGENCY CONTROL OF HEMORRHAGE, CHEMOTHERAPEUTIC DRUG INFUSION AND RENAL OPACIFICATION PROCEDURES. ANY USE FOR PROCEDURES OTHER THAN THOSE INDICATED IN THE INSTRUCTIONS IS NOT RECOMMENDED.,NON-NEUROVASCULAR EMBOLIZATION COIL (COMPLEX HELICAL -18 FIBERED PLATINUM COIL)-IT IS INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE,PERIPHERAL/CORONARY VASCULAR MICROCATHETER(DIREXION FATHOM-16 SYSTEM PRE-LOADED TORQUEABLE MICROCATHETER)-THE DIREXION AND DIREXION HI-FLO TORQUEABLE MICROCATHETERS ARE INTENDED FOR PERIPHERAL VASCULAR USE. THE PRE-LOADED FATHOM AND TRANSEND GUIDEWIRES CAN BE USED TO SELECTIVELY INTRODUCE AND POSITION THE MICROCATHETER IN THE PERIPHERAL VASCULATURE. THE MICROCATHETER CAN BE USED FOR CONTROLLED AND SELECTIVE INFUSION OF DIAGNOSTIC, EMBOLIC, OR THERAPEUTIC MATERIALS INTO THE VESSEL.,EMBOLIZATION PARTICLE, NON-BIOABSORBABLE(CONTOUR EMBOLIZATION PARTICLES)-IT IS USED FOR THE EMBOLIZATION OF PERIPHERAL HYPERVASCULAR TUMORS, INCLUDING LEIOMYOMA UTERI AND

	PERIPHERAL ARTERIOVENOUS MALFORMATIONS (AVMS). DO NOT USE PARTICLES SMALLER THAN 355 MICRONS FOR THE TREATMENT OF LEIOMYOMA UTERI.,NON-NEUROVASCULAR EMBOLIZATION COIL (FIGURE 8 -18 FIBERED PLATINUM COIL)-IT IS INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE,PERIPHERAL/CORONARY VASCULAR MICROCATHETER(DIREXION TRANSEND-14 SYSTEM PRE-LOADED TORQUEABLE MICROCATHETER)-THE DIREXION AND DIREXION HI-FLO TORQUEABLE MICROCATHETERS ARE INTENDED FOR PERIPHERAL VASCULAR USE. THE PRE-LOADED FATHOM AND TRANSEND GUIDEWIRES CAN BE USED TO SELECTIVELY INTRODUCE AND POSITION THE MICROCATHETER IN THE PERIPHERAL VASCULATURE. THE MICROCATHETER CAN BE USED FOR CONTROLLED AND SELECTIVE INFUSION OF DIAGNOSTIC, EMBOLIC, OR THERAPEUTIC MATERIALS INTO THE VESSEL.,NON-NEUROVASCULAR EMBOLIZATION COIL(VORTX- 18 FIBERED PLATINUM COIL)-IT IS INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE,CATHETERS, ARTERIAL MICRO-FLOW CATHETER(RENEGADE HI-FLO MICROCATHETER)-THE RENEGADE HI-FLO MICROCATHETER IS INTENDED FOR PERIPHERAL VASCULAR USE. THE MICROCATHETER CAN BE COAXIALLY TRACKED OVER A STEERABLE GUIDEWIRE IN ORDER TO ACCESS DISTAL, TORTUOUS VASCULATURE. ONCE THE SUBSELECTIVE REGION HAS BEEN ACCESSED, THE MICROCATHETER CAN BE USED FOR THE CONTROLLED AND SELECTIVE INFUSION OF DIAGNOSTIC, EMBOLIC, OR THERAPEUTIC MATERIALS INTO VESSELS. DIAGNOSTIC, EMBOLIC, OR THERAPEUTIC AGENTS TO BE USED IN ACCORDANCE WITH SPECIFICATIONS OUTLINED BY THE MANUFACTURER.,GASTROINTESTINAL DILATION BALLOON CATHETER(CRE FIXED WIRE BALLOON DILATATION CATHETER)-THE CRE FIXED WIRE BALLOON DILATATION CATHETER IS INTENDED FOR USE IN ADULT AND ADOLESCENT POPULATIONS TO ENDOSCOPICALLY DILATE STRICTURES OF THE ESOPHAGUS., INTRAVASCULAR OCCLUDING CATHETER, IMAGE-GUIDED (OCCLUSION BALLOON CATHETER)-BOSTON SCIENTIFIC OCCLUSION BALLOON CATHETERS ARE INDICATED FOR TEMPORARY VESSEL OCCLUSION IN APPLICATIONS INCLUDING ARTERIOGRAPHY, PREOPERATIVE OCCLUSION, EMERGENCY CONTROL OF HEMORRHAGE, CHEMOTHERAPEUTIC DRUG INFUSION AND RENAL OPACIFICATION PROCEDURES. THE OCCLUSION BALLOON CATHETER PRODUCT LINE CONSISTS OF TWO SPECIFIC DESIGNS–STANDARD AND BERENSTEIN OCCLUSION BALLOON CATHETERS. ONLY THE BERENSTEIN OCCLUSION BALLOON CATHETER HAS BEEN DESIGNED FOR COAXIAL DELIVERY OF SMALL CATHETERS OR EMBOLIC

	AGENTS.,BILIARY STONE RETRIEVAL BALLOON CATHETER (EXTRACTOR PRO XL RETRIEVAL BALLOON CATHETER)-THE EXTRACTOR PRO XL RETRIEVAL BALLOON CATHETER IS USED ENDOSCOPICALLY TO 1) REMOVE STONES FROM THE BILIARY SYSTEM; OR 2) TO FACILITATE INJECTION OF CONTRAST MEDIUM WHILE OCCLUDING THE DUCT WITH THE BALLOON.,NON-NEUROVASCULAR EMBOLIZATION COIL(MULTI-LOOP -18 FIBERED PLATINUM COIL)-IT IS INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE,NON-NEUROVASCULAR EMBOLIZATION COIL(STRAIGHT -18 FIBERED PLATINUM COIL)-IT IS INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE, PERIPHERAL/CORONARY VASCULAR MICROCATHETER(DIREXION TORQUEABLE MICROCATHETER)-THE DIREXION AND DIREXION HI-FLO TORQUEABLE MICROCATHETERS ARE INTENDED FOR PERIPHERAL VASCULAR USE. THE PRE-LOADED FATHOM AND TRANSEND GUIDEWIRES CAN BE USED TO SELECTIVELY INTRODUCE AND POSITION THE MICROCATHETER IN THE PERIPHERAL VASCULATURE. THE MICROCATHETER CAN BE USED FOR CONTROLLED AND SELECTIVE INFUSION OF DIAGNOSTIC, EMBOLIC, OR THERAPEUTIC MATERIALS INTO THE VESSEL.,NON-NEUROVASCULAR EMBOLIZATION COIL(2D-HELICAL-35 FIBERED PLATINUM COIL)-IT IS INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE,NON-NEUROVASCULAR EMBOLIZATION COIL(INTERLOCK-35 FIBERED IDC OCCLUSION SYSTEM)-IT IS INDICATED FOR OBSTRUCTING OR REDUCING BLOOD FLOW IN THE PERIPHERAL VASCULATURE DURING EMBOLIZATION PROCEDURES. THIS DEVICE IS NOT INTENDED FOR NEUROVASCULAR USE.,INTRAVASCULAR OCCLUDING CATHETER, IMAGE-GUIDED(OCCLUSION BALLOON CATHETER)-BOSTON SCIENTIFIC OCCLUSION BALLOON CATHETERS ARE INDICATED FOR TEMPORARY VESSEL OCCLUSION IN APPLICATIONS INCLUDING ARTERIOGRAPHY, PREOPERATIVE OCCLUSION, EMERGENCY CONTROL OF HEMORRHAGE, CHEMOTHERAPEUTIC DRUG INFUSION AND RENAL OPACIFICATION PROCEDURES. THE OCCLUSION BALLOON CATHETER PRODUCT LINE CONSISTS OF TWO SPECIFIC DESIGNS –STANDARD AND BERENSTEIN OCCLUSION BALLOON CATHETERS.

1207	IMP/MD/2018/000045	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CIRCULAR MAPPING CATHETER(ADVISOR FL, SENSOR ENABLED)-THE ADVISOR™ FL CIRCULAR MAPPING CATHETER, SENSOR ENABLED™ IS A SENSOR-ENABLED STEERABLE ELECTROPHYSIOLOGY CATHETER USED FOR RECORDING INTRACARDIAC SIGNALS AND CARDIAC STIMULATION DURING DIAGNOSTIC ELECTROPHYSIOLOGY STUDIES. THE CATHETER CAN BE USED TO MAP THE ATRIAL REGIONS OF THE HEART. THE CATHETER IS COMPATIBLE WITH SJM™ VISUALIZATION AND NAVIGATION SYSTEMS TO ENABLE REAL-TIME POSITIONING AND NAVIGATION.,CATHETER(FLEXABILITY SENSOR ENABLED ABLATION CATHETER)-FLEXABILITY SENSOR ENABLED CATHETER IS INTENDED FOR USE WITH THE COMPATIBLE IRRIGATION PUMP AND A COMPATIBLE RF CARDIAC ABLATION GENERATOR. THE CATHETER IS INTENDED FOR CREATING LESIONS DURING CARDIAC ABLATION PROCEDURES (MAPPING, STIMULATION, AND ABLATION) FOR THE TREATMENT OF ARRHYTHMIAS. SENSOR ENABLED ABLATION CATHETERS ARE USED WITH COMPATIBLE MAGNETIC TRACKING SYSTEMS TO ENABLE CATHETER POSITIONING AND NAVIGATION. EPICARDIAL ABLATION SHOULD BE LIMITED TO APPROPRIATELY SELECTED PATIENTS WITH VENTRICULAR TACHYCARDIA.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1208	IMP/MD/2018/000056	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOPICAL HEMOSTAT(ENT KIT WITH HEMADERM TOPICAL HEMOSTAT)-INTENDED FOR THE APPLICATION OF HEMADERM TOPICAL HEMOSTAT ONTO TOPICAL WOUNDS. HEMADERM TOPICAL HEMOSTAT IS INTENDED AS A TOPICAL DRESSING FOR THE TEMPORARY TREATMENT OF SEVERELY BLEEDING WOUNDS SUCH AS SURGICAL WOUNDS (E.G. POST-OPERATIVE, DONOR SITES, DERMATOLOGICAL), CUTS AND LACERATIONS, AND FOR THE TEMPORARY TREATMENT OF MILD BLEEDING FROM TOPICAL ENT SURGICAL WOUNDS AND NOSEBLEEDS.,APPLICATOR(ARISTA AH FLEXITIP APPLICATOR AND ARISTA AH FLEXITIP XL APPLICATOR)-INTENDED FOR APPLICATION OF ARISTA™ AH HEMOSTAT ONTO SURGICAL WOUND SURFACES CONSISTENT WITH THE PRODUCT LABELING.,ABSORBABLE HEMOSTAT PARTICLES(ARISTA AH ABSORBABLE HEMOSTAT PARTICLES)-INDICATED IN SURGICAL PROCEDURES (EXCEPT OPHTHALMIC) AS AN ADJUNCTIVE HEMOSTATIC DEVICE TO ASSIST WHEN CONTROL OF CAPILLARY, VENOUS AND ARTERIOLAR BLEEDING BY PRESSURE LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS INEFFECTIVE OR IMPRACTICAL.,MICROFIBRILLAR COLLAGEN HEMOSTAT(AVITENE)-IT IS USED IN SURGICAL PROCEDURES AS AN ADJUNCT TO HEMOSTASIS WHEN CONTROL OF BLEEDING BY LIGATURE OR CONVENTIONAL PROCEDURES IS INEFFECTIVE OR IMPRACTICAL.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1209	IMP/MD/2018/000057	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VASCULAR STENT (LIFESTAR VASCULAR STENT SYSTEM)-INDICATED FOR THE TREATMENT OF • ILIAC OCCLUSIVE DISEASE IN PATIENTS WITH SYMPTOMATIC VASCULAR DISEASE OF THE COMMON AND / OR EXTERNAL ILIAC ARTERIES • RESIDUES STENOSES WITH IMPAIRED PERFUSION (PRESSURE GRADIENT) FOLLOWING BALLOON DILATATION, ESPECIALLY IN STAGES III AND IV ACCORDING TO FONTAINE • DISSECTION • DETACHED ARTERIOSCLEROTIC PLAQUE MATERIAL AND LUMINAL OBSTRUCTION FOLLOWING BALLOON DILATATION •OCCLUSION AFTER THROMBOLYSIS OR AFTER ASPIRATION AND BEFORE DILATATION • RESTENOSIS OR REOCCLUSION,VASCULAR STENT GRAFT(FLUENCY PLUS VASCULAR STENT GRAFT)-RESIDUAL STENOSIS WITH IMPAIRED PERFUSION (PRESSURE GRADIENT) FOLLOWING BALLOON DILATATION, ESPECIALLY IN STAGES III AND IV ACCORDING TO FONTAINE •DISSECTION •DETACHED ARTERIOSCLEROTIC PLAGUE MATERIAL AND LUMINAL OBSTRUCTION FOLLOWING BALLOON DILATATION •OCCLUSION AFTER THROMBOLYSIS OR AFTER ASPIRATION AND BEFORE DILATATION,VASCULAR STENT(LIFESTENT VASCULAR STENT)-IT IS INTENDED FOR PRIMARY STENTING OF DENOVO OR RESTENOTIC LESIONS OF THE PERIPHERAL ARTERIES,VASCULAR STENT(E-LUMINEXX VASCULAR STENT)-• RESIDUAL STENOSIS WITH IMPAIRED PERFUSION (PRESSURE GRADIENT) FOLLOWING BALLOON DILATATION, ESPECIALLY IN STAGES III AND IV ACCORDING TO FONTAINE • DISSECTION • DETACHED ARTERIOSCLEROTIC PLAGUE MATERIAL AND LUMINAL OBSTRUCTION FOLLOWING BALLOON DILATATION • OCCLUSION AFTER THROMBOLYSIS OR AFTER ASPIRATION AND BEFORE DILATATION • RESTENOSIS OR REOCCLUSION,BIOPSY NEEDLE(INITIAL PUNCTURE NEEDLE)--PERCUTANEOUS PUNCTURES INTO ORGANS, TISSUES AND VESSELS TO OBTAIN SAMPLES FOR CYTOLOGY - PERCUTANEOUS PUNCTURES FOR THE INTRODUCTION OF GUIDE WIRES.,PTFE COATED GUIDE WIRE (GUIDE WIRE, PTFE COATED, GUIDE WIRE, PTFE COATED J-CURVED, GUIDE WIRE, PTFE COATED DOUBLE-ENDED J-CURVED, GUIDE WIRE, PTFE COATED MOVABLE CORE, GUIDE WIRE, PTFE COATED MOVABLE CORE J-CURVED, GUIDE WIRE, PTFE COATED BENSON, AMPLATZ GUIDE WIRE, PTFE COATED-MOVABLE CORE, AMPLATZ GUIDE WIRE, PTFE-COATED MOVABLE CORE, J-CURVED, GUIDE WIRE, PTFE COATED HEAVY DUTY, BARDSELECT GUIDE WIRE PTFE COATED)-THE DEVICE IS INDICATED FOR PERCUTANEOUS INTRODUCTION INTO VESSELS OR HOLLOW ORGANS (ARTERIES, VEINS, URETER, ETC.), USING THE SELDINGER TECHNIQUE AS WELL AS INTERVENTIONAL

	AND ENDOSCOPIC TECHNIQUES,VASCULAR COVERED STENT (COVERA VASCULAR COVERED STENT)-THE COVERA™ VASCULAR COVERED STENT IS INDICATED FOR THE TREATMENT OF STENOSES IN THE UPPER EXTREMITY VENOUS OUTFLOW OF PATIENTS DIALYZING WITH AN ARTERIO-VENOUS (AV) ACCESS GRAFT OR FISTULA.,VENOUS STENT SYSTEM(VENOVO VENOUS STENT SYSTEM)-THE VENOVO VENOUS STENT SYSTEM IS INDICATED FOR THE TREATMENT OF STENOSES AND OCCLUSIONS IN THE ILIAC AND FEMORAL VEINS,URETERAL SPLINT SET/REPLACEMENT URETER SPLINT(PUROFLEX URETERAL STENT SET (VIA CYSTOSCOPE, TIEMANN TIP, PERCUTANEOUS APPLICATION, AIK, PERCUTANEOUS APPLICATION, REPLACEMENT URETERAL STENT VIA CYSTOSCOPE, REPLACEMENT URETERAL STENT, PERCUTANEOUS APPLICATION)-•OBSTRUCTION OF THE URETER LUMEN BY STONES OR COAGULUM •URINE DRAINAGE AFTER STONE DISINTEGRATION BY ESWL •STRICTURES OR STENOSES OF THE URETERS •COMPRESSION OF THE URETERS (E.G. BY TUMOURS OR DURING PREGNANCY) •URINE DRAINAGE AFTER URETERAL SURGERY •URETER DILATATION BEFORE URETERORENOSCOPY •PREVENTION OF OEDEMA AND OBSTRUCTION AFTER ENDOSCOPIC INTERVENTION ON THE URETERS OR KIDNEYS,PERCUTANEOUS NEPHROSTOMY /ABSCESS DRAINAGE SET(NEPHROSTOMY DRAINAGE SET)-PERCUTANEOUS NEPHROSTOMY •DRAINAGE OBSTRUCTIONS IN THE UPPER URINARY TRACT •HYDRONEPHROSIS •DRAINAGE OF COLLECTIONS OF LIQUID SECRETION, E.G. ABSCESSES OR CYSTS,RENAL DILATATION SETS (RENAL DILATATION COMPLETE SET, RENAL DILATATION PARTIAL SET)-DILATION OF PERCUTANEOUS PUNCTURE ROUTES, E.G.: – PERCUTANEOUS ARTERIAL/ VENOUS ACCESSES –PERCUTANEOUS LITHOLAPAXY/ LITHOTRIPSY – PERCUTANEOUS DRAINAGES,BONE BIOPSY NEEDLES(OSTYCUT BONE BIOPSY NEEDLE)-BONE BIOPSY CANNULA FOR OBTAINING HISTOLOGICAL SPECIMENS.,VASCULAR COVERED STENT(COVERA PLUS VASCULAR COVERED STENT)-THE COVERA™ PLUS VASCULAR COVERED STENT IS INDICATED FOR THE TREATMENT OF STENOSES IN THE UPPER EXTREMITY VENOUS OUTFLOW OF PATIENTS DIALYZING WITH AN ARTERIO-VENOUS (AV) ACCESS GRAFT OR FISTULA AND FOR THE TREATMENT OF ATHEROSCLEROTIC LESIONS IN ILIAC AND FEMORAL ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 4.5 MM TO 9 MM.

1210	IMP/MD/2018/000058	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IV SETS(EXTENSION SET (ALARIS™ PRODUCTS, ASENA™CC SYRINGE PUMP, ALARIS™ CC SYRINGE PUMP, IVAC™ 701/711/770/P7000 SYRINGE PUMPS))-THE INTENDED USE OF ALARIS™ CC EXTENSION SETS IS TO CHANNEL LIQUIDS FOR INFUSION PURPOSES. EXTENSION SETS CAN BE CONNECTED TO SYRINGES AND BE USED AS ADD-ON PRODUCTS TO PRIMARY ADMINISTRATION SETS TO LENGTHEN ACCESS PORTS. CONNECTIONS ARE MADE THROUGH MALE AND FEMALE LUER LOCK CONNECTORS.,NEEDLE-FREE VALVES(SMARTSITE NEEDLE FREE VALVE)-THE SMARTSITE® NEEDLE-FREE VALVE IS INTENDED FOR A VARIETY OF NEEDLE-FREE INFUSION ACCESS APPLICATIONS INCLUDING MEDICATION FROM SYRINGES AND IV TUBING, AS WELL AS THE ABILITY TO WITHDRAW SOLUTIONS INCLUDING BLOOD FOR SAMPLING PURPOSES.,IV SETS(INFUSION SETS (ALARIS™ PRODUCTS, ALARIS™ GP VOLUMETRIC PUMP, ALARIS™ SAFETY CLAMP))-THE INTENDED USE OF ANY ALARIS™ GP INFUSION SET IS TO PROVIDE A CONDUIT FOR ADMINISTERING FLUIDS INTO THE BODY, ENABLING CONNECTION TO RESERVOIRS AND AN INVASIVE PUNCTURE DEVICE. THESE SETS ARE DESIGNED TO BE USED WITH THE ALARIS™ GP VOLUMETRIC PUMP.,ACCESS DEVICE(SMARTSITE ACCESS DEVICE)-USED FOR THE EXTRACTION AND TRANSFER OF IV FLUIDS., EXTENSION SETS(BD EXTENSION SET, ANTI-SIPHON VALVE)-THE EXTENSION SETS THAT ARE INTENDED FOR USE WITH THE ALARIS SYRINGE AND PCA MODULES, WHICH DO NOT INTERFACE WITH THE PUMP TO CO TROLL FLOW, PROVIDE A STERILE FLUID PATH FOR FLUIDS INFUSING WITH THE SYRINGE-BASED PUMP, ENABLING CONNECTION BETWEEN THE SYRINGE AND THE PATIENT'S VENOUS ACCESS DEVICE.,MAXZERO EXTENSION SETS(MAXZERO EXTENSION SETS)-TO PROVIDE A CONDUIT FOR ADMINISTERING FLUIDS INTO THE BODY ENABLING CONNECTION TO RESERVOIRS AND AN INVASIVE PUNCTURE DEVICE.,MAXZERO NEEDLELESS CONNECTOR (MAXZERO NEEDLELESS CONNECTOR)-AN ACCESSORY TO AN INTRAVASCULAR ADMINISTRATION SET USED AS A SECONDARY STERILE INJECTION SITE FOR DELIVERY OF FLUIDS TO A PATIENT'S VASCULAR SYSTEM THROUGH A CANNULA INSERTED IN A VEIN OR ARTER,MAXPLUS CLEAR NEEDLELESS CONNECTOR(MAXPLUS CLEAR NEEDLELESS CONNECTOR)-USED AS A STERILE INJECTION SITE FOR DELIVERY OF FLUIDS TO A PATIENTS VASCULAR SYSTEM THROUGH A CANNULA INSERTED INTO A VEIN OR ARTERY.,MAXPLUS EXTENSION SETS(MAXPLUS EXTENSION SETS)-TO BE USED FOR THE ADMINISTRATION OF LIQUID SUBSTANCES FROM A VESSEL (E.G. SYRINGE OR BAG VIA IV TUBING) TO A PATIENTS VASCULAR SYSTEM

	FOR INTRAVENOUS (IV) THERAPY,SMARTSITE EXTENSION SETS (SMARTSITE EXTENSION SETS)-THE SMARTSITE EXTENSION AND GRAVITY SET RANGE PROVIDES A STERILE FLUID PATH FOR CONDUCTING FLUIDS BETWEEN A RESERVOIR AND AN INDWELLING PATIENT LINE OR CANNULA

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1211	IMP/MD/2018/000059	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIGATION CLIP, METALLIC (RESOLUTION 360 CLIP)-THE RESOLUTION 360 CLIP IS INDICATED FOR CLIP PLACEMENT WITHIN THE GASTRO-INTESTINAL (GI) TRACT FOR THE PURPOSE OF: 1. ENDOSCOPIC MARKING, 2. HEMOSTASIS FOR: MUCOSAL/SUB-MUCOSAL DEFECTS LESS THAN 3 CM, BLEEDING ULCERS, ARTERIES LESS THAN 2 MM, POLYPS LESS THAN 1.5 CM IN DIAMETER, DIVERTICULA IN THE COLON, PROPHYLACTIC CLIPPING TO REDUCE THE RISK OF DELAYED BLEEDING POST LESION RESECTION, 3. ANCHORING TO AFFIX JEJUNAL FEEDING TUBES TO THE WALL OF THE SMALL BOWEL, 4. AS A SUPPLEMENTARY METHOD, CLOSURE OF GI TRACT LUMINAL PERFORATIONS LESS THAN 20 MM THAT CAN BE TREATED CONSERVATIVELY,NON-VASCULAR GUIDEWIRE(JAGWIRE REVOLUTION HIGH PERFORMANCE GUIDEWIRE) -THE JAGWIRE REVOLUTION HIGH PERFORMANCE GUIDEWIRE IS INDICATED FOR USE IN SELECTIVE CANNULATION OF THE BILIARY DUCTS INCLUDING THE COMMON BILE DUCT, PANCREATIC DUCT, CYSTIC DUCT, AND RIGHT AND LEFT HEPATIC DUCTS. THE ENDOSCOPIC GUIDEWIRE IS DESIGNED TO BE USED DURING ENDOSCOPIC PANCREATICO-BILIARY PROCEDURES FOR CATHETER INTRODUCTION, EXCHANGES OF CATHETERS, CANNULAS, AND SPHINCTEROTOMES, AND TO AID IN THE PLACEMENT OF DIAGNOSTIC AND THERAPEUTIC DEVICES.,LIGATION CLIP, METALLIC(RESOLUTION CLIP)-THE RESOLUTION CLIP IS INDICATED FOR CLIP PLACEMENT WITHIN THE GASTRO-INTESTINAL (GI) TRACT FOR THE PURPOSE OF: 1. ENDOSCOPIC MARKING, 2. HEMOSTASIS FOR: • MUCOSAL/SUB-MUCOSAL DEFECTS LESS THAN 3 CM, • BLEEDING ULCERS, • ARTERIES LESS THAN 2 MM, • POLYPS LESS THAN 1.5 CM IN DIAMETER, • DIVERTICULA IN THE COLON, • PROPHYLACTIC CLIPPING TO REDUCE THE RISK OF DELAYED BLEEDING POST LESION RESECTION, 3. ANCHORING TO AFFIX JEJUNAL FEEDING TUBES TO THE WALL OF THE SMALL BOWEL, 4. AS A SUPPLEMENTARY METHOD, CLOSURE OF GI TRACT LUMINAL PERFORATIONS LESS THAN 20 MM THAT CAN BE TREATED CONSERVATIVELY.,CATHETER(OPTICROSS 6 40 MHZ CORONARY IMAGING CATHETER)-THIS CATHETER IS INTENDED FOR ULTRASOUND EXAMINATION OF CORONARY INTRAVASCULAR PATHOLOGY ONLY. INTRAVASCULAR ULTRASOUND IMAGING IS INDICATED IN PATIENTS WHO ARE CANDIDATES FOR TRANSLUMINAL CORONARY INTERVENTIONAL PROCEDURES.,GASTRO-UROLOGICAL GUIDEWIRE, SINGLE-USE (SENSOR NITINOL WIRE WITH HYDROPHILLIC TIP)-UROLOGICAL GUIDEWIRES ARE INTENDED TO FACILITATE THE PLACEMENT OF ENDOUROLOGICAL INSTRUMENTS DURING DIAGNOSTIC OR

	INTERVENTIONAL PROCEDURES. THESE GUIDEWIRES ARE NOT INTENDED FOR CORONARY ARTERY, VASCULAR OR NEUROLOGICAL USE.,CATHETER(OPTICROSS 18 30 MHZ PERIPHERAL IMAGING CATHETER)-OPTICROSS 18 IS INTENDED FOR INTRAVASCULAR ULTRASOUND EXAMINATION OF PERIPHERAL VESSELS ONLY. INTRAVASCULAR ULTRASOUND IMAGING IS INDICATED IN PATIENTS WHO ARE CANDIDATES FOR TRANSLUMINAL INTERVENTIONAL PROCEDURES.,POLYMERIC URETERAL STENT(POLARIS ULTRA URETERAL STENT)-THE STENTS ARE INTENDED TO FACILITATE DRAINAGE FROM THE KIDNEY TO THE BLADDER VIA PLACEMENT ENDOSCOPICALLY OR FLUOROSCOPICALLY OR DURING AN OPEN SURGICAL PROCEDURE BY A TRAINED PHYSICIAN., SPHINCTEROTOMES(TRUETOME 44 CANNULATING SPHINCTEROTOME)-THE SPHINCTEROTOME IS INDICATED FOR USE IN THE SELECTIVE CANNULATION OF THE COMMON BILE DUCTS (CBD) AND THE TRANSENDOSCOPIC SPHINCTEROTOMY OF THE PAPILLA OF VATER AND/OR THE SPHINCTER OF ODDI. THE SPHINCTEROTOME CAN ALSO BE USED TO INJECT CONTRAST MEDIUM.,EMBOLIC PROTECTION SYSTEM; EMBOLI CAPTURE GUIDEWIRE(FILTERWIRE EZ EMBOLIC PROTECTION SYSTEM)-THE BOSTON SCIENTIFIC FILTERWIRE EZ EMBOLIC PROTECTION SYSTEM IS INDICATED FOR USE AS A GUIDEWIRE AND EMBOLIC PROTECTION SYSTEM TO CONTAIN AND REMOVE EMBOLIC MATERIAL (THROMBUS/DEBRIS) WHILE PERFORMING ANGIOPLASTY AND STENTING PROCEDURES IN THE PERIPHERAL VASCULAR SYSTEM, CAROTID ARTERIES, CORONARY ARTERIES AND SAPHENOUS VEIN GRAFTS. THE DIAMETER OF THE VESSEL AT THE SITE OF FILTER LOOP PLACEMENT SHOULD BE BETWEEN 3.5 MM AND 5.5 MM.,SPHINCTEROTOMES (TRUETOME 49 CANNULATING SPHINCTEROTOME)-THE SPHINCTEROTOME IS INDICATED FOR USE IN THE SELECTIVE CANNULATION OF THE COMMON BILE DUCTS (CBD) AND THE TRANSENDOSCOPIC SPHINCTEROTOMY OF THE PAPILLA OF VATER AND/OR THE SPHINCTER OF ODDI. THE SPHINCTEROTOME CAN ALSO BE USED TO INJECT CONTRAST MEDIUM.,ENDOSCOPIC ELECTROSURGICAL ELECTRODE, MONOPOLAR, SINGLE-USE (AUTOTOME RX 49 CANNULATING SPHINCTEROTOME)-THE SPHINCTEROTOME IS INDICATED FOR USE IN THE SELECTIVE CANNULATION OF THE COMMON BILE DUCTS (CBD) AND THE TRANSENDOSCOPIC SPHINCTEROTOMY OF THE PAPILLA OF VATER AND/OR THE SPHINCTER OF ODDI. THE SPHINCTEROTOME CAN ALSO BE USED TO INJECT CONTRAST MEDIUM. ,SPHINCTEROTOMES (TRUETOME 39 CANNULATING SPHINCTEROTOME)-THE SPHINCTEROTOME IS INDICATED FOR USE IN THE SELECTIVE CANNULATION OF THE COMMON BILE DUCTS (CBD) AND THE

	TRANSENDOSCOPIC SPHINCTEROTOMY OF THE PAPILLA OF VATER AND/OR THE SPHINCTER OF ODDI. THE SPHINCTEROTOME CAN ALSO BE USED TO INJECT CONTRAST MEDIUM.,MECHANICAL CUTTING ENDOSCOPIC POLYPECTOMY SNARE(CAPTIVATOR II SINGLE-USE POLYPECTOMY SNARE)-THE SINGLE-USE POLYPECTOMY SNARES ARE INDICATED FOR USE ENDOSCOPICALLY FOR THE REMOVAL AND OR CAUTERIZATION OF DIMINUTIVE POLYPS, SESSILE POLYPS, PEDUNCULATED POLYPS AND TISSUE FROM WITHIN THE GASTROINTESTINAL TRACT.,CATHETER(ULTRA ICE PLUS 9 MHZ INTRACARDIAC ECHO CATHETER)-THE ULTRA ICE PLUS ROUNDED TIP CATHETER IS INDICATED FOR ENHANCED ULTRASONIC VISUALIZATION OF INTRACARDIAC STRUCTURES.,FLEXIBLE ENDOSCOPIC BIOPSY FORCEPS, SINGLE USE(SPYBITE MAX SINGLE-USE BIOPSY FORCEPS)-THE SPYBITE MAX SINGLE-USE BIOPSY FORCEPS ARE DESIGNED TO COLLECT TISSUE SAMPLES ENDOSCOPICALLY FOR HISTOLOGIC EXAMINATION. THESE INSTRUMENTS SHOULD NOT BE USED FOR ANY PURPOSE OTHER THAN THE INTENDED FUNCTION. THE SPYBITE MAX SINGLE-USE BIOPSY FORCEPS ARE INDICATED FOR TISSUE ACQUISITION IN THE PANCREATICOBILIARY SYSTEM.,FLEXIBLE ENDOTHERAPY BIOPSY FORCEPS, SINGLE USE(SPYBITE SINGLE USE BIOPSY FORCEPS)-THE SPYBITE BIOPSY FORCEPS ARE DESIGNED TO COLLECT TISSUE SAMPLES ENDOSCOPICALLY FOR HISTOLOGIC EXAMINATION. THESE INSTRUMENTS SHOULD NOT BE USED FOR ANY PURPOSE OTHER THAN THE INTENDED FUNCTION. THE SPYBITE BIOPSY FORCEPS ARE INDICATED FOR TISSUE ACQUISITION IN THE PANCREATICOBILIARY SYSTEM.,POLYMERIC URETERAL STENT(POLARIS LOOP URETERAL STENT)-THE POLARIS LOOP URETERAL STENTS ARE INTENDED TO FACILITATE DRAINAGE FROM THE KIDNEY TO THE BLADDER VIA PLACEMENT ENDOSCOPICALLY, FLUOROSCOPICALLY, OR DURING AN OPEN SURGICAL PROCEDURE BY A TRAINED PHYSICIAN.,BIOPSY DEVICES(RADIAL JAW 4 SINGLE-USE BIOPSY FORCEPS)-THESE SINGLE-USE BIOPSY FORCEPS ARE SPECIFICALLY DESIGNED TO COLLECT TISSUE ENDOSCOPICALLY FOR HISTOLOGIC EXAMINATION. THESE FORCEPS SHOULD NOT BE USED FOR ANY PURPOSE OTHER THAN THEIR INTENDED FUNCTION.,MECHANICAL-CUTTING POLYPECTOMY SNARE, ENDOSCOPIC ELECTROSURGICAL HANDPIECE/ELECTRODE, MONOPOLAR, SINGLE-USE(ROTATABLE SNARE SINGLE-USE POLYPECTOMY SNARES)-THE ROTATABLE SNARE IS INDICATED FOR USE ENDOSCOPICALLY FOR THE REMOVAL AND OR CAUTERIZATION OF DIMINUTIVE POLYPS, SESSILE POLYPS, PEDUNCULATED POLYPS AND TISSUE FROM WITHIN THE GASTROINTESTINAL TRACT.,BIOPSY DEVICES(MULTIBITE SINGLE USE BIOPSY FORCEPS)-THE MULTIBITE MULTIPLE SAMPLE BIOPSY

	FORCEPS ARE DESIGNED SPECIFICALLY TO COLLECT TISSUE ENDOSCOPICALLY FOR HISTOLOGIC EXAMINATIONS. THESE INSTRUMENTS ARE INTENDED FOR ENDOSCOPIC GASTROINTESTINAL BIOPSY AND SHOULD NOT BE USED FOR ANY PURPOSE OTHER THAN THEIR INTENDED FUNCTION.,PERIPHERAL VASCULAR GUIDEWIRE (PLATINUM PLUS GUIDEWIRE)-THE PLATINUM PLUS GUIDEWIRE FACILITATES PLACEMENT OF A CATHETER DURING DIAGNOSTIC OR INTERVENTIONAL INTRAVASCULAR PROCEDURES. THE WIRE CAN BE TORQUED TO FACILITATE NAVIGATION THROUGH TORTUOUS ARTERIES AND/OR AVOID UNWANTED SIDE BRANCHES.,BIOPSY DEVICES, ENDOSCOPIC ELECTROSURGICAL HANDPIECE/ELECTRODE, MONOPOLAR, SINGLE-USE(RADIAL JAW 4 SINGLE-USE BIOPSY FORCEPS)-THESE SINGLE-USE HOT BIOPSY FORCEPS ARE INTENDED TO BE USED THROUGH AN ENDOSCOPE TO CAUTERIZE AND REMOVE POLYPS AND/OR TISSUE SPECIMENS THROUGHOUT THE ALIMENTARY TRACT. THE ALIMENTARY TRACT TO INCLUDE THE ESOPHAGUS, STOMACH, DUODENUM, JEJUNUM, ILEUM AND COLON., DRAINAGE BILIARY CATHETER (FLEXIMA BILIARY CATHETER SYSTEM)-TO PROVIDE EXTERNAL AND INTERNAL PERCUTANEOUS DRAINAGE OF THE BILIARY SYSTEM.,CORONARY IMAGING CATHETER (OPTICROSS HD 60 MHZ CORONARY IMAGING CATHETER)-THIS CATHETER IS INTENDED FOR ULTRASOUND EXAMINATION OF CORONARY INTRAVASCULAR PATHOLOGY ONLY. INTRAVASCULAR ULTRASOUND IMAGING IS INDICATED IN PATIENTS WHO ARE CANDIDATES FOR TRANSLUMINAL CORONARY INTERVENTIONAL PROCEDURES.,DRAINAGE BILIARY CATHETER (FLEXIMA BILIARY CATHETER SYSTEM WITH RADIOPAQUE MARKER)-TO PROVIDE EXTERNAL AND INTERNAL PERCUTANEOUS DRAINAGE OF THE BILIARY SYSTEM.,DRAINAGE BILIARY CATHETER (FLEXIMA BILIARY CATHETER SYSTEM KIT)-TO PROVIDE EXTERNAL AND INTERNAL PERCUTANEOUS DRAINAGE OF THE BILIARY SYSTEM.,ENDOSCOPIC NEEDLE, GENERAL PURPOSE, SINGLE-USE HEMOSTASIS DEVICES (INJECTION GOLD PROBE BIPOLAR ELECTROHEMOSTASIS CATHETER)-THE INJECTION GOLD PROBE CATHETER IS INDICATED FOR USE IN ENDOSCOPIC INJECTION THERAPY (TO DELIVER PHARMACOLOGICAL INJECTION AGENTS, SUCH AS VASOCONSTRICTORS) AND ENDOSCOPIC ELECTROHEMOSTASIS (CAUTERIZATION OF TISSUE AND COAGULATION OF BLOOD) OF ACTUAL OR POTENTIAL BLEEDING SITES IN THE GASTROINTESTINAL TRACT. THESE SITES INCLUDE THE FOLLOWING: • PEPTIC ULCERS • DIEULAFOY LESIONS • MALLORY-WEISS TEARS • BLEEDING POLYP STALKS • ARTERIOVENOUS MALFORMATIONS (AVMS) • ANGIOMATA THE INJECTION GOLD PROBE CATHETER ALSO HAS IRRIGATION CAPABILITY. ANY OTHER USE IS NOT RECOMMENDED.,DRAINAGE

	BILIARY CATHETER; NEPHROSTOMY CATHETER; MEDIASTINAL DRAIN; PLEURAL DRAIN(FLEXIMA APDL DRAINAGE CATHETER SYSTEM)-TO PROVIDE PERCUTANEOUS DRAINAGE OF ABSCESS FLUID, BILIARY, NEPHROSTOMY, URINARY, PLEURAL EMPYEMAS, LUNG ABSCESSES, AND MEDIASTINAL COLLECTION,INTRAVASCULAR ULTRASOUND IMAGING CATHETER, SINGLE-USE(OPTICROSS 40 MHZ CORONARY IMAGING CATHETER)-THIS CATHETER IS INTENDED FOR ULTRASOUND EXAMINATION OF CORONARY INTRAVASCULAR PATHOLOGY ONLY. INTRAVASCULAR ULTRASOUND IMAGING IS INDICATED IN PATIENTS WHO ARE CANDIDATES FOR TRANSLUMINAL CORONARY INTERVENTIONAL PROCEDURES.,PERIPHERAL VASCULAR GUIDEWIRE (PLATINUM PLUS GUIDEWIRES WITH GLIDEX HYDROPHILIC COATING)-THE PLATINUM PLUS GUIDEWIRE FACILITATES PLACEMENT OF A CATHETER DURING DIAGNOSTIC OR INTERVENTIONAL INTRAVASCULAR PROCEDURES. THE WIRE CAN BE TORQUED TO FACILITATE NAVIGATION THROUGH TORTUOUS ARTERIES AND/OR AVOID UNWANTED SIDE BRANCHES.,MECHANICAL CUTTING ENDOSCOPIC POLYPECTOMY SNARE(SENSATION SHORT THROW SINGLE-USE POLYPECTOMY SNARES)-THE SINGLE-USE POLYPECTOMY SNARES ARE INDICATED FOR USE ENDOSCOPICALLY FOR THE REMOVAL AND OR CAUTERIZATION OF DIMINUTIVE POLYPS, SESSILE POLYPS, PEDUNCULATED POLYPS AND TISSUE FROM WITHIN THE GASTROINTESTINAL TRACT.,DRAINAGE BILIARY CATHETER; NEPHROSTOMY CATHETER; MEDIASTINAL DRAIN; PLEURAL DRAIN(FLEXIMA APD DRAINAGE CATHETER SYSTEM)-TO PROVIDE PERCUTANEOUS DRAINAGE OF ABSCESS FLUID, BILIARY, NEPHROSTOMY, URINARY, PLEURAL EMPYEMAS, LUNG ABSCESSES, AND MEDIASTINAL COLLECTION,PERIPHERAL VASCULAR GUIDEWIRE (MAGIC TORQUE GLIDEX COATED HYDROPHILLIC GUIDEWIRE)-THE MAGIC TORQUE GUIDEWIRE FACILITATES PLACEMENT OF A CATHETER DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURES. THE WIRE CAN BE TORQUED TO FACILITATE NAVIGATION THROUGH TORTUOUS ARTERIES AND/OR AVOID UNWANTED SIDE BRANCHES. NOT INTENDED FOR USE IN CORONARY ARTERIES. ,NON-VASCULAR GUIDEWIRES(DREAMWIRE HIGH PERFORMANCE GUIDEWIRE)-DREAMWIRE HIGH PERFORMANCE GUIDEWIRE IS INDICATED FOR USE IN SELECTIVE CANNULATION OF THE BILIARY DUCTS INCLUDING THE COMMON BILE, PANCREATIC, CYSTIC, RIGHT AND LEFT HEPATIC DUCTS AND TO AID IN THE PLACEMENT OF DIAGNOSTIC AND THERAPEUTIC DEVICES DURING BRONCHOSCOPIC AND GASTROINTESTINAL PROCEDURES.,POLYMERIC URETERAL STENT (PERCUFLEX URETERAL STENT)-THE PERCUFLEX URETERAL STENT IS INTENDED TO FACILITATE DRAINAGE FROM THE KIDNEY TO THE BLADDER VIA PLACEMENT ENDOSCOPICALLY OR

	FLUOROSCOPICALLY BY A TRAINED PHYSICIAN.,NON- VASCULAR GUIDEWIRE(PULMONARY JAGWIRE GUIDEWIRE)-THE PULMONARY GUIDEWIRE IS INDICATED FOR USE TO PROVIDE ACCESS TO THE TRACHEOBRONCHIAL TREE.,GUIDEWIRE(HYDRA JAGWIRE HIGH PERFORMANCE GUIDEWIRE)-THE HYDRA JAGWIRE GUIDEWIRE IS INDICATED FOR USE IN SELECTIVE CANNULATION OF THE BILIARY DUCTS INCLUDING THE COMMON BILE, PANCREATIC, CYSTIC, RIGHT AND LEFT HEPATIC DUCTS AND TO AID IN THE PLACEMENT OF DIAGNOSTIC AND THERAPEUTIC DEVICES DURING BRONCHOSCOPIC PROCEDURES.,ENDOSCOPIC ELECTROSURGICAL ELECTRODE, MONOPOLAR, SINGLE-USE (MICROKNIFE XL TRIPLE LUMEN NEEDLE KNIFE)-THE SPHINCTEROTOME IS INDICATED FOR USE IN THE SELECTIVE CANNULATION OF THE COMMON BILE DUCTS (CBD) AND THE TRANSENDOSCOPIC SPHINCTEROTOMY OF THE PAPILLA OF VATER AND/OR THE SPHINCTER OF ODDI. THE SPHINCTEROTOME CAN ALSO BE USED TO INJECT CONTRAST MEDIUM. ,GASTRO-UROLOGICAL GUIDEWIRE, SINGLE-USE(ZEBRA GUIDEWIRES)-UROLOGICAL GUIDEWIRES ARE INTENDED TO FACILITATE THE PLACEMENT OF ENDOUROLOGICAL INSTRUMENTS DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURES. THESE GUIDE WIRES ARE NOT INTENDED FOR CORONARY ARTERY, VASCULAR OR NEUROLOGICAL USE.,ENDOSCOPIC NEEDLE, GENERAL PURPOSE, SINGLE-USE HEMOSTASIS DEVICES(GOLD PROBE BIPOLAR ELECTROHEMOSTASIS CATHETER)-THE GOLD PROBE CATHETER AND THE GOLD PROBE 350CM CATHETER ARE INDICATED FOR USE IN TRANSENDOSCOPIC ELECTROHEMOSTASIS OF VISIBLE BLEEDING AND NON-BLEEDING SITES IN THE GASTROINTESTINAL TRACT INCLUDING THE ESOPHAGUS, STOMACH, DUODENUM, AND COLON. THE INDICATIONS INCLUDE: • PEPTIC ULCERS • ANGIOMATA • MALLORY-WEISS TEARS • WATERMELON STOMACH • ARTERIOVENOUS MALFORMATIONS (AVMS) • BARRETT'S ESOPHAGUS • DIEULAFOY LESIONS • ANGIODYSPLASIA • BLEEDING POLYP STALKS • ESOPHAGEAL TUMORS ,ENDOSCOPIC ELECTROSURGICAL ELECTRODE, MONOPOLAR, SINGLE-USE (ULTRATOME XL TRIPLE LUMEN SPHINCTEROTOME)-THE SPHINCTEROTOME IS INDICATED FOR USE IN THE SELECTIVE CANNULATION OF THE COMMON BILE DUCTS (CBD) AND THE TRANSENDOSCOPIC SPHINCTEROTOMY OF THE PAPILLA OF VATER AND/OR THE SPHINCTER OF ODDI. THE SPHINCTEROTOME CAN ALSO BE USED TO INJECT CONTRAST MEDIUM. ,POLYMERIC URETERAL STENT(PERCUFLEX PLUS URETERAL STENT)-THE PERCUFLEX PLUS URETERAL STENT IS INTENDED TO FACILITATE DRAINAGE FROM THE KIDNEY TO THE BLADDER VIA PLACEMENT ENDOSCOPICALLY OR FLUOROSCOPICALLY BY A TRAINED PHYSICIAN.,NON-VASCULAR

		GUIDEWIRE(JAGWIRE HIGH PERFORMANCE GUIDEWIRE)-THE JAGWIRE HIGH PERFORMANCE GUIDEWIRE IS INDICATED FOR USE IN SELECTIVE CANNULATION OF THE BILIARY DUCTS INCLUDING, BUT NOT LIMITED TO THE COMMON BILE, CYSTIC, RIGHT AND LEFT HEPATIC DUCTS. THE JAGWIRE HIGH PERFORMANCE GUIDEWIRE IS DESIGNED TO BE USED DURING ENDOSCOPIC BILIARY PROCEDURE FOR CATHETER INTRODUCTION AND EXCHANGES.
1212	IMP/MD/2018/000060	1.License Holder Name: FRESENIUS MEDICAL CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TUBING SETS FOR HEMODIALYSIS-TUBING SETS FOR HEMODIALYSIS ARE INTENDED FOR SINGLE USE ONLY FOR EXTRACORPOREAL BLOOD PURIFICATIONS FOR HUMAN USE,DISPOSABLE A.V. FISTULA NEEDLE SETS-IT IS INTENDED IN VEIN PUNCTURE FOR HEMODIALYSIS TREATMENT.

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1213	IMP/MD/2018/000061	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER, CORONARY, GUIDE, SINGLE USE DEVICE (ACUITY PRO GUIDE CATHETER)-THE ACUITY PRO LEAD DELIVERY SYSTEM IS INTENDED TO ACCESS THE CORONARY VENOUS SYSTEM, AND MAY BE USED ALONE (9F) OR IN DUAL CATHETER DELIVERY (9F WITH 7F). THE CATHETER SERVES AS A CONDUIT FOR THE DELIVERY OF CONTRAST MEDIUM AND DEVICES, INCLUDING IMPLANTABLE CORONARY VENOUS LEADS, INTRODUCED INTO THE CORONARY VENOUS SYSTEM.,GUIDE CATHETER (GUIDEZILLA II LONG GUIDE EXTENSION CATHETER)-THE GUIDEZILLA II GUIDE EXTENSION CATHETER IS INTENDED TO BE USED IN CONJUNCTION WITH GUIDE CATHETERS TO ACCESS DISCRETE REGIONS OF THE CORONARY AND/OR PERIPHERAL VASCULATURE, AND TO FACILITATE PLACEMENT OF INTERVENTIONAL DEVICES., EMBOLECTOMY/THROMBECTOMY SUCTION CATHETER; SINGLE USE DEVICES(ANGIOJET SOLENT PROXI THROMBECTOMY SET)-THE ANGIOJET SOLENT PROXI THROMBECTOMY SETS ARE INTENDED FOR USE WITH THE ANGIOJET ULTRA CONSOLE TO BREAK APART AND REMOVE THROMBUS FROM: • UPPER AND LOWER EXTREMITY PERIPHERAL ARTERIES GREATER THAN OR EQUAL TO 3.0 MM IN DIAMETER, • UPPER EXTREMITY PERIPHERAL VEINS GREATER THAN OR EQUAL TO 3.0 MM IN DIAMETER, • ILEOFEMORAL AND LOWER EXTREMITY VEINS GREATER THAN OR EQUAL TO 3.0 MM IN DIAMETER, • A-V ACCESS CONDUITS GREATER THAN OR EQUAL TO 3.0 MM IN DIAMETER AND • FOR USE WITH THE ANGIOJET ULTRA POWER PULSE™ TECHNIQUE FOR THE CONTROL AND SELECTIVE INFUSION OF PHYSICIAN SPECIFIED FLUIDS, INCLUDING THROMBOLYTIC AGENTS, INTO THE PERIPHERAL VASCULAR SYSTEM.,GUIDE CATHETER(GUIDEZILLA II GUIDE EXTENSION CATHETER)-THE GUIDEZILLA II GUIDE EXTENSION CATHETER IS INTENDED TO BE USED IN CONJUNCTION WITH GUIDE CATHETERS TO ACCESS DISCRETE REGIONS OF THE CORONARY AND/OR PERIPHERAL VASCULATURE, AND TO FACILITATE PLACEMENT OF INTERVENTIONAL DEVICES.,INTRAVASCULAR HAEMODYNAMIC MONITORING SYSTEM GUIDEWIRE(COMET PRESSURE GUIDEWIRE)-THE COMET PRESSURE GUIDEWIRE MEASURES BLOOD PRESSURE GRADIENT ACROSS CORONARY LESIONS DURING ENDOVASCULAR PROCEDURES. COMET PRESSURE GUIDEWIRE MAY ALSO BE USED AS A CORONARY GUIDEWIRE FOR INTERVENTIONAL TREATMENTS. COMET PRESSURE GUIDEWIRE IS INDICATED TO DIRECT A CATHETER THROUGH A BLOOD VESSEL AND TO MEASURE PHYSIOLOGICAL PARAMETERS IN THE CORONARY BLOOD VESSELS., EMBOLECTOMY/THROMBECTOMY SUCTION CATHETER; SINGLE USE

	DEVICE(ANGIOJET SOLENT OMNI THROMBECTOMY SET)-THE ANGIOJET SOLENT OMNI THROMBECTOMY SETS ARE INTENDED FOR USE WITH THE ANGIOJET ULTRA CONSOLE TO BREAK APART AND REMOVE THROMBUS FROM: • UPPER AND LOWER EXTREMITY PERIPHERAL ARTERIES GREATER THAN OR EQUAL TO 3.0 MM IN DIAMETER, • UPPER EXTREMITY PERIPHERAL VEINS GREATER THAN OR EQUAL TO 3.0 MM IN DIAMETER, • ILEOFEMORAL AND LOWER EXTREMITY VEINS GREATER THAN OR EQUAL TO 3.0 MM IN DIAMETER, • A-V ACCESS CONDUITS GREATER THAN OR EQUAL TO 3.0 MM IN DIAMETER AND • FOR USE WITH THE ANGIOJET ULTRA POWER PULSE™ TECHNIQUE FOR THE CONTROL AND SELECTIVE INFUSION OF PHYSICIAN SPECIFIED FLUIDS, INCLUDING THROMBOLYTIC AGENTS, INTO THE PERIPHERAL VASCULAR SYSTEM.,PERIPHERAL ANGIOPLASTY BALLOON CATHETER, BASIC (STERLING SL OVER-THE WIRE PTA BALLOON DILATATION CATHETER)-THE STERLING SL OTW PTA BALLOON DILATATION CATHETER IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE PERIPHERAL VASCULATURE, INCLUDING ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA-POPLITEAL AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE.,INTRAVASCULAR GUIDING CATHETER, SINGLE USE DEVICE (RUBICON 18 SUPPORT CATHETER)-THE RUBICON SUPPORT CATHETER IS INTENDED TO FACILITATE PLACEMENT AND SUPPORT OF GUIDEWIRES AND OTHER INTERVENTIONAL DEVICES WITHIN THE PERIPHERAL VASCULATURE AND TO ALLOW FOR EXCHANGE OF GUIDEWIRES, AND PROVIDE A CONDUIT FOR THE DELIVERY OF SALINE OR CONTRAST SOLUTIONS.,BALLOON PERIPHERAL ANGIOPLASTY CATHETER, SINGLE USE DEVICE(COYOTE OVER-THE-WIRE PTA BALLOON DILATATION CATHETER)-THE COYOTE OTW PTA BALLOON DILATATION CATHETER IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE PERIPHERAL VASCULATURE, INCLUDING ILIAC, FEMORAL, POPLITEAL, INFRA-POPLITEAL AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE.,CATHETER, ANGIOPLASTY, BALLOON DILATATION, BASIC, SINGLE USE DEVICE(EMERGE MONORAIL PTCA DILATATION CATHETER)-THE EMERGE MONORAIL PTCA DILATION CATHETERS (BALLOON MODELS 1.20-4.00 MM) ARE INDICATED FOR THE BALLOON CATHETER DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. EMERGE MONORAIL PTCA DILATATION CATHETERS (BALLOON MODELS 2.00- 4.00 MM) ARE ALSO INDICATED FOR THE

	POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS (BARE METAL AND DRUG-ELUTING)., EMBOLECTOMY/THROMBECTOMY SUCTION CATHETER; SINGLE USE (ANGIOJET AVX THROMBECTOMY SET)-IT IS INTENDED FOR USE WITH THE ANGIOJET ULTRA SYSTEM IN BREAKING APART AND REMOVING THROMBUS FROM A-V ACCESS CONDUITS GREATER THAN OR EQUAL TO 3.0 MM IN DIAMETER.,INTRAVASCULAR GUIDING CATHETER, SINGLE USE DEVICE(RUBICON 14 SUPPORT CATHETER)-THE RUBICON SUPPORT CATHETER IS INTENDED TO FACILITATE PLACEMENT AND SUPPORT OF GUIDEWIRES AND OTHER INTERVENTIONAL DEVICES WITHIN THE PERIPHERAL VASCULATURE AND TO ALLOW FOR EXCHANGE OF GUIDEWIRES, AND PROVIDE A CONDUIT FOR THE DELIVERY OF SALINE OR CONTRAST SOLUTIONS.,INTRAVASCULAR GUIDING CATHETER, SINGLE USE DEVICE(RUBICON 35 SUPPORT CATHETER)-THE RUBICON SUPPORT CATHETER IS INTENDED TO FACILITATE PLACEMENT AND SUPPORT OF GUIDEWIRES AND OTHER INTERVENTIONAL DEVICES WITHIN THE PERIPHERAL VASCULATURE AND TO ALLOW FOR EXCHANGE OF GUIDEWIRES, AND PROVIDE A CONDUIT FOR THE DELIVERY OF SALINE OR CONTRAST SOLUTIONS., BALLOON PERIPHERAL ANGIOPLASTY CATHETER, SINGLE USE DEVICE(COYOTE MONORAIL PTA BALLOON DILATATION CATHETER)-THE COYOTE MONORAIL PTA BALLOON DILATATION CATHETER IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE PERIPHERAL VASCULATURE, INCLUDING ILIAC, FEMORAL, POPLITEAL, INFRA-POPLITEAL AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE.,MULTIPLE PERIPHERAL ARTERY STENT(EXPRESS VASCULAR SD PREMOUNTED STENT SYSTEM)-THE EXPRESS VASCULAR SD PREMOUNTED STENT SYSTEM IS INDICATED FOR USE IN THE TREATMENT OF PERIPHERAL VASCULAR LESIONS,MULTIPLE PERIPHERAL ARTERY STENT(INNOVA OTW SELF-EXPANDING STENT SYSTEM)-THE INNOVA SELF-EXPANDING STENT SYSTEM IS INDICATED FOR THE TREATMENT OF PERIPHERAL VASCULAR LESIONS.,EMBOLECTOMY/THROMBECTOMY SUCTION CATHETER; SINGLE USE DEVICE(ANGIOJET ZELANTE DVT THROMBECTOMY SET)-IT IS INTENDED FOR USE WITH THE ANGIOJET ULTRA CONSOLE TO BREAK APART AND REMOVE THROMBUS, INCLUDING DEEP VEIN THROMBUS (DVT), FROM: • ILIOFEMORAL AND LOWER EXTREMITY VEINS GREATER THAN OR EQUAL TO 6.0 MM IN DIAMETER AND • UPPER EXTREMITY PERIPHERAL VEINS GREATER THAN OR EQUAL TO 6.0 MM IN DIAMETER. IT IS ALSO INTENDED FOR USE WITH THE ANGIOJET ULTRA POWER PULSE™ TECHNIQUE FOR THE CONTROLLED AND SELECTIVE INFUSION OF PHYSICIAN SPECIFIED FLUIDS, INCLUDING THROMBOLYTIC AGENTS, INTO THE

	PERIPHERAL VASCULAR SYSTEM.,CATHETER, ANGIOPLASTY, BALLOON DILATATION, BASIC; SINGLE USE DEVICES(NC EMERGE MONORAIL PTCA DILATATION CATHETER)-THE NC EMERGE MR PTCA DILATATION CATHETER IS INDICATED FOR THE BALLOON CATHETER DILATATION OF THE STENOTIC PORTION OF A NATIVE CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION IN PATIENTS WITH ATHEROSCLEROSIS. THE NC EMERGE MR PTCA DILATATION CATHETER (BALLOON MODELS 2.00-5.00 MM) IS ALSO INDICATED FOR THE POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS (BARE METAL AND DRUG-ELUTING).,PERIPHERAL ANGIOPLASTY BALLOON CATHETER - BASIC(STERLING OVER-THE-WIRE PTA BALLOON DILATATION CATHETER)-THE STERLING OTW PTA BALLOON DILATATION CATHETER IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE PERIPHERAL VASCULATURE, INCLUDING ILIAC, FEMORAL, POPLITEAL, INFRA-POPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR POST-DILATATION OF BALLOON EXPANDABLE AND SELF-EXPANDING STENTS IN THE PERIPHERAL VASCULATURE., CATHETER, ANGIOPLASTY, BALLOON DILATATION, BASIC, SINGLE USE DEVICES(NC QUANTUM APEX MONORAIL PTCA DILATATION CATHETER)-THE NC QUANTUM APEX MONORAIL PTCA DILATION CATHETERS IS INDICATED FOR THE BALLOON CATHETER DILATATION OF THE STENOTIC PORTION OF A NATIVE CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.NC QUANTUM APEX MONORAIL PTCA DILATATION CATHETERS ARE ALSO INDICATED FOR THE POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS (BARE METAL AND DRUG-ELUTING).,INTRAVASCULAR GUIDING CATHETER, SINGLE USE DEVICE(CROSSBOSS CATHETER)-THE CROSSBOSS CATHETER IS INTENDED FOR USE WITH A GUIDEWIRE TO ACCESS DISCRETE REGIONS OF THE CORONARY VASCULATURE. WHEN USED AS PART OF THE SYSTEM CONSISTING OF THE CROSSBOSS CATHETER, STINGRAY™ LP CATHETER, AND STINGRAY GUIDEWIRE, THE CROSSBOSS CATHETER IS INDICATED FOR USE TO FACILITATE THE INTRALUMINAL PLACEMENT OF CONVENTIONAL GUIDEWIRES BEYOND STENOTIC CORONARY LESIONS (INCLUDING CHRONIC TOTAL OCCLUSIONS [CTOS]) PRIOR TO PTCA OR STENT INTERVENTION.,CORONARY ANGIOPLASTY BALLOON CATHETER, BASIC(MAVERICK2 MONORAIL PTCA DILATATION CATHETER)-THE MAVERICK2 MONORAIL PTCA DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF

	THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. THE MAVERICK2 MONORAIL PTCA DILATATION CATHETER (BALLOON MODELS 2.25 MM - 4.0 MM) IS ALSO INDICATED FOR THE POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS.,GENERAL-PURPOSE CATHETER CONNECTOR, STERILE; SINGLE USE DEVICE(ANGIOJET ULTRA POWER PULSE KIT)-THE ANGIOJET ULTRA POWER PULSE KIT IS INTENDED FOR USE ONLY WITH ANGIOJET ULTRA THROMBECTOMY SETS INDICATED FOR THE CONTROL AND SELECTIVE INFUSION OF PHYSICIAN SPECIFIED FLUIDS, INCLUDING THROMBOLYTIC AGENTS, INTO THE PERIPHERAL VASCULAR SYSTEM USING THE ANGIOJET ULTRA SYSTEM., EMBOLECTOMY/THROMBECTOMY SUCTION CATHETER; SINGLE USE DEVICE(ANGIOJET SOLENT DISTA THROMBECTOMY SET)-THE ANGIOJET SOLENT DISTA THROMBECTOMY SET IS INTENDED FOR USE WITH THE ANGIOJET ULTRA CONSOLE TO BREAK APART AND REMOVE THROMBUS FROM: • UPPER AND LOWER EXTREMITY PERIPHERAL ARTERIES AND • FOR USE WITH THE ANGIOJET ULTRA POWER PULSE™ TECHNIQUE FOR THE CONTROL AND SELECTIVE INFUSION OF PHYSICIAN SPECIFIED FLUIDS, INCLUDING THROMBOLYTIC AGENTS, INTO THE PERIPHERAL VASCULAR SYSTEM. THE MINIMUM VESSEL DIAMETER FOR THE THROMBECTOMY SET MODEL IS 1.5MM.,EMBOLECTOMY/THROMBECTOMY SUCTION CATHETER; SINGLE USE DEVICE(ANGIOJET PE CATHETER THROMBECTOMY SET)-IT IS INTENDED FOR USE WITH THE ANGIOJET SYSTEM IN BREAKING APART AND REMOVING THROMBUS FROM: • MAIN PULMONARY AND LOBAR ARTERIES GREATER THAN OR EQUAL TO 6 MM IN DIAMETER, • FOR USE WITH THE ANGIOJET POWER PULSE TECHNIQUE FOR THE CONTROL AND SELECTIVE INFUSION OF PHYSICIAN SPECIFIED FLUIDS, INCLUDING THROMBOLYTIC AGENTS, INTO THE PULMONARY VASCULARY SYSTEM.,CATHETER, BALLOON; SINGLE USE DEVICE(STERLING MONORAIL PTA BALLOON DILATATION CATHETER)-THE STERLING MONORAIL PTA BALLOON DILATATION CATHETER IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY IN THE PERIPHERAL VASCULATURE, INCLUDING ILIAC, FEMORAL, POPLITEAL, INFRA-POPLITEAL, RENAL, AND CAROTID ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR POST-DILATATION OF BALLOON EXPANDABLE AND SELF-EXPANDING STENTS IN THE PERIPHERAL VASCULATURE.,VASCULAR GUIDE-CATHETER, SINGLE-USE (STINGRAY LP CATHETER)-THE STINGRAY LP CATHETER IS INDICATED FOR DIRECTING, STEERING, CONTROLLING, AND SUPPORTING A GUIDEWIRE IN ORDER TO ACCESS DISCRETE

	REGIONS OF THE CORONARY VASCULATURE. WHEN USED AS PART OF THE SYSTEM CONSISTING OF THE CROSSBOSS™ CATHETER, STINGRAY LP CATHETER AND STINGRAY GUIDEWIRE, THE STINGRAY LP CATHETER IS INDICATED FOR USE TO FACILITATE THE INTRALUMINAL PLACEMENT OF CONVENTIONAL GUIDEWIRES BEYOND STENOTIC CORONARY LESIONS (INCLUDING CHRONIC TOTAL OCCLUSIONS [CTOS]) PRIOR TO PTCA OR STENT INTERVENTION.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1214	IMP/MD/2018/000062	1.License Holder Name: HORIBA INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:WHITEDIFF(WHITEDIFF)-LYSING SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) FOR LEUCOCYTES (WBC) COUNTING AND DIFFERENTIATION AND FOR HEMOGLOBIN DETERMINATION ON HORIBA MEDICAL BLOOD CELL COUNTERS. ,ABX PENTRA REFERENCE 280 ML(HORIBA MEDICAL)-ABX PENTRA REFERENCE 280 ML IS PART OF A CALIBRATOR SYSTEM INTENDED FOR THE QUANTITATIVE DETERMINATION OF SODIUM (NA+), POTASSIUM (K+) AND CHLORIDE (CL-) ON CLINICAL CHEMISTRY ANALYZER EQUIPPED WITH ISE MODULE OPTION. ,ABX ALPHALYSE (0.4L)(ABX ALPHALYSE (0.4L))-"ABX ALPHALYSE IS LYSING SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) AND FOR HEMOGLOBIN DETERMINATION ON HORIBA MEDICAL BLOOD CELL COUNTERS " , ABX PENTRA DEPROTEINIZER CP(HORIBA MEDICAL)-ABX PENTRA DEPROTEINIZER CP IS A CLEANING SOLUTION USED ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYSERS. ,ABX FLUOCYTE (0.5L)(ABX FLUOCYTE (0.5L))-"ABX FLUOCYTE IS A STAINING SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR ERYTHROCYTES (RBC) COUNTING AND DIFFERENTIATION ON HORIBA MEDICAL BLOOD CELL COUNTERS " ,ABX PENTRA CLEAN-CHEM 99 CP(HORIBA MEDICAL)-ABX PENTRA CLEAN-CHEM 99 CP IS A CLEANING SOLUTION USED ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS. ,ABX ALPHALYSE (360 ML)(ABX ALPHALYSE (360 ML))-"ABX ALPHALYSE IS LYSING SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) AND FOR HEMOGLOBIN DETERMINATION ON HORIBA MEDICAL BLOOD CELL COUNTERS " , ABX PENTRA LDH IFCC CP(HORIBA MEDICAL)-"ABX PENTRA LDH IFCC CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF LACTATE DEHYDROGENASE (LDH) IN SERUM OR PLASMA. LACTATE DEHYDROGENASE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIVER DISEASES SUCH AS ACUTE VIRAL HEPATITIS, CIRRHOSIS, AND METASTATIC CARCINOMA OF THE LIVER, CARDIAC DISEASES SUCH AS MYOCARDIAL INFARCTION, AND TUMORS OF THE LUNG OR KIDNEYS. " ,ABX VET PACK(ABX VET PACK)-IT IS CONSTITUTED OF REAGENTS (R1, R2, R3) AND A WASTE CONTAINER INTENDED FOR USE ON BLOOD CELL COUNTERS. ,ABX PENTRA STANDARD 1(HORIBA MEDICAL)-ABX PENTRA STANDARD 1 IS PART OF A CALIBRATOR SYSTEM INTENDED FOR THE QUANTITATIVE DETERMINATION OF SODIUM (NA+), POTASSIUM (K+) AND CHLORIDE (CL-) ON CLINICAL CHEMISTRY

	ANALYZER EQUIPPED WITH ISE MODULE OPTION. ,ABX RETIX (0.5L)(ABX RETIX (0.5L))-"ABX RETIX IS A STAINING SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR ERYTHROCYTES (RBC) COUNTING AND DIFFERENTIATION ON HORIBA MEDICAL BLOOD CELL COUNTERS " ,ABX PENTRA REFERENCE(HORIBA MEDICAL)-ABX PENTRA REFERENCE IS PART OF A CALIBRATOR SYSTEM INTENDED FOR THE QUANTITATIVE DETERMINATION OF SODIUM (NA+), POTASSIUM (K+) AND CHLORIDE (CL-) ON PENTRA C200 INSTRUMENT EQUIPPED WITH ISE MODULE OPTION. , MINILYSEBIO (0.4L)(MINILYSEBIO (0.4L))-MINILYSEBIO IS INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) FOR LEUCOCYTES (WBC) COUNTING AND DIFFERENTIATION AND FOR HEMOGLOBIN DETERMINATION ON HORIBA MEDICAL BLOOD CELL COUNTERS. ,ABX PENTRA CLEAN-CHEM CP(HORIBA MEDICAL)-ABX PENTRA CLEAN-CHEM CP IS A CLEANING SOLUTION USED ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS. ,ABX EOSINOFIX (1L)(ABX EOSINOFIX (1L))-"ABX EOSINOFIX IS LYSING SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) FOR LEUCOCYTES (WBC) COUNTING AND DIFFERENTIATION ON HORIBA MEDICAL BLOOD CELL COUNTERS " ,ABX PENTRA ISE CLEANER CP (HORIBA MEDICAL)-ABX PENTRA ISE CLEANER CP IS A SOLUTION USED TO CLEAN THE ELECTRODES OF THE ISE MODULE OF THE HORIBA MEDICAL PENTRA C200 CLINICAL CHEMISTRY ANALYSER. ,ABX BASOLYSE (5L)(ABX BASOLYSE (5L))-"ABX BASOLYSE IS LYSING SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) FOR LEUCOCYTES (WBC) COUNTING AND DIFFERENTIATION ON HORIBA MEDICAL BLOOD CELL COUNTERS " ,ABX PENTRA PRECITEST SOLUTION(HORIBA MEDICAL)-ABX PENTRA PRECITEST SOLUTION IS A CONTROL SOLUTION USED ON HORIBA MEDICAL CLINICAL CHEMISTRY ANALYZERS TO CHECK THE PIPETTING PRECISION OF THE INSTRUMENT. ,ABX BASOLYSE II (1L)(ABX BASOLYSE II (1L))-"ABX BASOLYSE II IS LYSING SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) FOR LEUCOCYTES (WBC) COUNTING AND DIFFERENTIATION ON HORIBA MEDICAL BLOOD CELL COUNTERS " ,ABX PENTRA TOTAL PROTEIN 100 CP(HORIBA MEDICAL)-"ABX PENTRA TOTAL PROTEIN 100 CP REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF TOTAL PROTEIN IN SERUM AND PLASMA BY COLORIMETRY. MEASUREMENTS OBTAINED BY THIS DEVICE ARE USED IN THE DIAGNOSIS AND TREATMENT OF A VARIETY OF DISEASES INVOLVING THE LIVER, KIDNEY, OR BONE MARROW AS WELL AS OTHER METABOLIC OR NUTRITIONAL DISORDERS. " ,

	MINIPACK AD60 (X4)(MINIPACK AD60 (X4))-MINIPACK AD 60 IS COMPRISED OF 4 IDENTICAL REAGENTS PACKS, EACH PACK IS CONSTITUTED OF 3 REAGENTS (R1, R2, R3) AND A WASTE CONTAINER INTENDED FOR IN VITRO DIAGNOSTICS USE ON HORIBA MEDICAL BLOOD CELL COUNTERS. ,ABX PENTRA STANDARD 2(HORIBA MEDICAL)-ABX PENTRA STANDARD 2 IS PART OF A CALIBRATOR SYSTEM INTENDED FOR THE QUANTITATIVE DETERMINATION OF SODIUM (NA+), POTASSIUM (K+) AND CHLORIDE (CL-) ON CLINICAL CHEMISTRY ANALYZER EQUIPPED WITH ISE MODULE OPTION. ,ABX MINILYSE (1L)(ABX MINILYSE (1L))-ERYTHROCYTE LYSING REAGENT FOR WHITE BLOOD CELL COUNTING AND HEMOGLOBIN DETERMINATION ON HORIBA ABX BLOOD CELL COUNTERS. ,ABX PENTRA ETCHING CP(HORIBA MEDICAL)-ABX PENTRA ETCHING CP IS A SOLUTION USED TO CLEAN THE SODIUM ELECTRODE OF THE ISE MODULE OF THE HORIBA MEDICAL CLINICAL CHEMISTRY ANALYSERS. ,ABX DILUENT (10L)(ABX DILUENT (10L))-ABX DILUENT IS BUFFERED ISOTONIC SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR SHEATING AND DILUTING LEUCOCYTES (WBC), AND FOR THE DETERMINATION AND DIFFERENTIATION OF BLOOD CELLS AND THE MEASUREMENT OF HEMATOCRIT ON HORIBA MEDICAL BLOOD CELL COUNTERS. ,ABX PENTRA CREATININE 120 CP(HORIBA MEDICAL)-"ABX PENTRA CREATININE 120 CP REAGENT IS A DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE BASED ON A KINETIC METHOD USING ALKALINE PICRATE (JAFFÉ METHOD). CREATININE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASES, IN MONITORING RENAL DIALYSIS, AND AS A CALCULATION BASIS FOR MEASURING OTHER URINE ANALYTES. " ,ABX DILUENT (20L)(ABX DILUENT (20L))-"ABX DILUENT IS BUFFERED ISOTONIC SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR SHEATING AND DILUTING LEUCOCYTES (WBC), AND FOR THE DETERMINATION AND DIFFERENTIATION OF BLOOD CELLS AND THE MEASUREMENT OF HEMATOCRIT ON HORIBA MED1CAL BLOOD CELL COUNTERS. " ,ABX MINIDIL LMG (20L)(ABX MINIDIL LMG (20L))-"ABX MINIDIL LMG IS A BUFFERED ISOTONIC SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR THE DETERMINATION OF BLOOD CELLS COUNTING, AND THE MEASUREMENT OF HEMATOCRIT ON HORIBA MEDICAL BLOOD CELL COUNTRIES " ,ABX MINIDIL LMG (10L)(ABX MINIDIL LMG (10L))-"ABX MINIDIL LMG IS A BUFFERED ISOTONIC SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR THE DETERMINATION OF BLOOD CELLS COUNTING, AND THE MEASUREMENT OF HEMATOCRIT ON HORIBA MEDICAL BLOOD CELL COUNTRIES " ,NUCEDIFF (1L)(NUCEDIFF (1L))-NUCEDIFF

	1L IS A LYSING SOLUTION INTENDED FOR IN VITRODIAGNOSTIC USE AND DESIGNED FOR DIFFERENTIATION OFNUCLEATED SUBPOPULATIONS ON HORIBA MEDICAL BLOOD CELLCOUNTERS. , ABX MINIPACK LMG(ABX MINIPACK LMG)-ABX MINIPACK IS CONSTITUTED OF 3 REAGENTS (R1, R2, R3) INTENDED FOR IN VITRO DIAGNOSTICS USE ON HORIBA MEDICAL BLOOD CELL COUNTERS. , ABX MINOCLAIR (0.5L)(ABX MINOCLAIR (0.5L))-"ABX MINOCLAIR IS A CHEMICAL SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR CLEANING OF HORIBA MEDICAL BLOOD CELL COUNTERS " ,ABX MINICLEAN (1L)(ABX MINICLEAN (1L))-"ABX MINOCLAIR IS AN ENZYMATIC SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE WITH PROTEOLYTIC ACTION FOR THE CLEANING OF HORIBA MEDICAL BLOOD CELL COUNTERS " ,ABX CLEANER (1L)(ABX CLEANER (1L))-"ABX CLEANER IS AN ENZYMATIC SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE WITH PROTEOLYTIC ACTION FOR THE CLEANING OF HORIBA MEDICAL BLOOD CELL COUNTERS " ,MINILYSEBIO 1L(MINILYSEBIO 1L)-MINILYSEBIO 1L IS A LYSING SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR LYSING ERYTHROCYTES (RBC)FOR LEUCOCYTES (WBC) COUNTING AND DIFFERENTIATION AND FOR HEMOGLOBIN DETERMINATION ON HORIBA MEDICAL BLOOD CELL COUNTERS. ,ABX LYSEBIO (1L)(ABX LYSEBIO (1L))-"ABX LYSEBIO IS LYSING SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) AND FOR HEMOGLOBIN DETERMINATION ON HORIBA MEDICAL BLOOD CELL COUNTERS " , ABX LEUCODIFF (1L)(ABX LEUCODIFF (1L))-"ABX LEUCODIFF IS LYSING SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) FOR LEUCOCYTES (WBC) COUNTING AND DIFFERENTIATION ON HORIBA MEDICAL BLOOD CELL COUNTERS " ,ABX MINILYSE LMG (1L)(ABX MINILYSE LMG (1L))-"ABX MIOILYSE LMG IS A LYSING SOLUTION INTENDED FOR INVITRO DIAGNOSTIC USE AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) FOR LEUCOCYTES (WBC) COUNTING AND DIFFERENTIATION AND FOR HEMOGLOBIN DETERMINATION ON HORIBA MEDICAL BLOOD CELL COUNTERS. " ,ABX LYSEBIO (0.4L) (ABX LYSEBIO (0.4L))-"ABX LYSEBIO IS LYSING SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) AND FOR HEMOGLOBIN DETERMINATION ON HORIBA MEDICAL BLOOD CELL COUNTERS " ,ABX CLEANER (0.5L) (ABX CLEANER (0.5L))-"ABX CLEANER IS AN ENZYMATIC SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE WITH PROTEOLYTIC ACTION FOR THE CLEANING OF HORIBA MEDICAL BLOOD CELL COUNTERS "

1215	IMP/MD/2018/000063	1.License Holder Name: TRANSLUMINA THERAPEUTICS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA BALLOON CATHETERS(NIC NANO)-THE CLINICAL DATA PRESENTLY AVAILABLE INDICATES THAT THE LUMINAL DIAMETER OF A CORONARY ARTERY AT THE SITE OF CERTAIN TYPES OF STENOTIC LESIONS CAN BE INCREASED BY BALLOON DILATATION AND THAT PTCA IS A SAFE AND EFFICIENT PROCEDURE FOR REDUCTION OF SOME FORMS OF ATHEROSCLEROTIC CORONARY ARTERY DISEASE,PTCA BALLOON CATHETERS(OPN NC)-THE CLINICAL DATA PRESENTLY AVAILABLE INDICATES THAT THE LUMINAL DIAMETER OF A CORONARY ARTERY AT THE SITE OF CERTAIN TYPES OF STENOTIC LESIONS CAN BE INCREASED BY BALLOON DILATATION AND THAT PTCA IS A SAFE AND EFFICIENT PROCEDURE FOR REDUCTION OF SOME FORMS OF ATHEROSCLEROTIC CORONARY ARTERY DISEASE

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1216	IMP/MD/2018/000064	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLINICAL SCREWS - TITANIUM AND ITS ALLOYS(ABUTMENT SCREW)-THE CLINICAL SCREW, ABUTMENT SCREW AND PROSTHETIC SCREW ARE INTENDED TO SECURE A DENTAL ABUTMENT OR FRAMEWORK TO A DENTAL IMPLANT OR ABUTMENT IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION.,DENTAL SCREW - TITANIUM (STERILE)(ON1 CLINICAL/PROSTHETIC SCREW)-THE ON1 CLINICAL/PROSTHETIC SCREW IS INTENDED TO BE USED AS SCREW FOR TIGHTENING THE SUPPORTING SUBSTRUCTURE / FRAMEWORK ONTO THE NOBEL BIOCARE CONICAL CONNECTION DENTAL IMPLANTS AND ON1 ABUTMENTS.,ABUTMENTS - TITANIUM AND ITS ALLOYS(ESTHETIC ABUTMENT, TEMPORARY ABUTMENT, TEMPORARY COPING)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH TWO-STAGE ENDOSSEOUS IMPLANTS ARE USED AS THE FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. RESTORATIONS RANGE FROM REPLACING ONE SINGLE TOOTH TO FIXED PARTIAL DENTURES USING CEMENT-RETAINED SUPRA-CONSTRUCTIONS.,DENTAL IMPLANT ABUTMENT - ZIRCONIA (NON-STERILE)(ON1)-ON1 ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION AND ESTHETICS.,ABUTMENTS - PLASTIC(TEMPORARY COPING)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH TWO- STAGE ENDOSSEOUS IMPLANTS ARE USED AS THE FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. RESTORATIONS RANGE FROM REPLACING ONE SINGLE TOOTH TO FIXED PARTIAL DENTURES USING CEMENT-RETAINED SUPRA- CONSTRUCTIONS., DENTAL IMPLANT ABUTMENT - TITANIUM (NON-STERILE)(ON1)-ON1 ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION AND ESTHETICS.,DENTAL IMPLANT ABUTMENT - TITANIUM (STERILE)(ON1)-ON1 ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION AND ESTHETICS., DENTAL IMPLANT - TITANIUM(TREFOIL)-DENTAL IMPLANTS ARE TO BE INTEGRATED IN THE JAW BONE (OSSEOINTEGRATION) AND USED FOR ANCHORING OR SUPPORTING TOOTH REPLACEMENTS IN EITHER

		JAW. RESTORATIONS RANGE FROM A SINGLE TOOTH TO A FIXED FULL DENTAL ARCH OR OVERDENTURE APPLICATIONS TO RESTORE CHEWING FUNCTION.
1217	IMP/MD/2018/000066	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MALE EXTERNAL CATHETER(ULTRAFLEX)-THE SELF-ADHERING MALE EXTERNAL CATHETER IS DESIGNED FOR THE MANAGEMENT OF MALE URINARY INCONTINENCE.,INTERMITTENT CATHETER(PERSONAL CATHETER ANTIBACTERIAL)-THE CATHETER IS INTENDED FOR URINARY BLADDER DRAINAGE IN ADULT MALES AND FEMALES REQUIRING CATHETERIZATION FOR MANAGEMENT OF INCONTINENCE, VOIDING DYSFUNCTION, AND SURGICAL PROCEDURES. EFFICACY OF THE CATHETER IN PREVENTING URINARY TRACT INFECTION DURING INTERMITTENT USE HAS NOT BEEN ESTABLISHED. THE DEVICE IS NOT INTENDED TO BE USED AS A TREATMENT FOR ACTIVE URINARY TRACT INFECTION.,INTERMITTENT CATHETER(PERSONAL CATHETER) -URINARY CATHETERS ARE INTENDED FOR USE FOR BLADDER MANAGEMENT INCLUDING URINE DRAINAGE, COLLECTION AND MEASUREMENT.
1218	IMP/MD/2018/000068	1.License Holder Name: KATARA DENTAL PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL ABUTMENT AND SCREWS(BIOHORIZONS)-BIOHORIZONS PROSTHETIC COMPONENTS ARE INTENDED FOR THE RESTORATION OF DENTAL IMPLANT WITHIN THE SPECIFIC INDICATIONS OF EACH IMPLANT SYSTEM,DENTAL IMPLANT SYSTEM(BIOHORIZONS)-BIOHORIZONS IMPLANTS ARE INTENDED FOR USE IN THE MANDIBLE OR MAXILLA FOR USE AS AN ARTIFICIAL ROOT STRUCTURE FOR SINGLE TOOTH REPLACEMENT OR FOR FIXED BRIDGEWORK AND DENTAL RETENTION.

1219	IMP/MD/2018/000069	1.License Holder Name: M/S. INSIGHTRA MEDICAL INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INGUINAL HERNIA REPAIR SYSTEM(FREEDOM™)-THE FREEDOM™ INGUINAL HERNIA IMPLANT IS INTENDED FOR USE IN SURGICAL PROCEDURES WHERE REPAIR OF INGUINAL HERNIA.,INTRA AORTIC BALLOON CATHETER KIT(ULTRA IABP 7FR CATHETER KIT)-THE INSIGHTRA INTRA AORTIC BALLOON CATHETER KIT HAS THE FOLLOWING INDICATIONS FOR USE: A. REFRACTORY UNSTABLE ANGINA. B. IMPENDING INFARCTION. C. POST INFARCTION ANGINA. D. REFRACTORY LEFT VENTRICULAR FAILURE. E. COMPLICATIONS OF ACUTE MI (IE. ACUTE MR ORVSD OR PAPILLARY MUSCLE RUPTURE). F. CARDIOGENIC SHOCK. G. SUPPORT FOR DIAGNOSTIC, PERCUTANEOUS REVASCULARIZATION AND INTERVENTIONAL PROCEDURES. H. ISCHEMIC RELATED INTRACTABLE VENTRICULAR ARRYTHMIAS. I. SEPTIC SHOCK. J. INTRAOPERATIVE PULSATILE FLOW GENERATION. K. WEANING FROM CARDIOPULMONARY BYPASS. L. CARDIAC SUPPORT FOR NON-CARDIAC SURGERY. M. PROPHYLACTIC SUPPORT IN PREPARATION FOR CARDIAC SURGERY. N. POST-SURGICAL MYOCARDIAL DYSFUNCTION/LOW CARDIAC OUTPUT SYNDROME. O. CARDIAC CONTUSION. P. MECHANICAL BRIDGE TO OTHER ASSIST DEVICES. Q. CARDIAC SUPPORT FOLLOWING CORRECTION OF ANATOMICAL DEFECTS.,VENTRAL HERNIA REPAIR SYSTEM(FREEDOM™)-THE FREEDOM VENTRAL HERNIA REPAIR SYSTEM IS INTENDED FOR USE IN THE OPEN REPAIR OF VENTRAL HERNIAS.
1220	IMP/MD/2018/000070	1.License Holder Name: CLINIEXPERTS SERVICES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CAST/ SPLINT (EKONOCAST SOFT)-EKONOCAST PRODUCTS ARE DEVICES FOR MAINTENANCE OF IMMOBILIZATION OF EXTREMITIES AND FOR SUPPORTING SOFT AND HARD TISSUES E.G. IN ORTHOPAEDIC TREATMENTS.,CAST/ SPLINT(EKONOCAST)-EKONOCAST PRODUCTS ARE DEVICES FOR MAINTENANCE OF IMMOBILIZATION OF EXTREMITIES AND FOR SUPPORTING SOFT AND HARD TISSUES E.G. IN ORTHOPAEDIC TREATMENTS.

1221	IMP/MD/2018/000071	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDEWIRES(STINGRAY GUIDEWIRE WITH HYDROPHILIC COATING)-THE STINGRAY GUIDEWIRES ARE INTENDED TO FACILITATE PLACEMENT OF BALLOON DILATATION CATHETERS OR OTHER INTRAVASCULAR DEVICES DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) . STINGRAY GUIDEWIRES ARE NOT TO BE USED IN CEREBRAL BLOOD VESSELS. WHEN USED AS PART OF THE SYSTEM CONSISTING OF THE CROSSBOSS™ CATHETER, STINGRAY LP CATHETER, AND STINGRAY GUIDEWIRE, THE STINGRAY GUIDEWIRE IS INDICATED FOR USE TO FACILITATE THE INTRALUMINAL PLACEMENT OF CONVENTIONAL GUIDEWIRES BEYOND STENOTIC CORONARY LESIONS (INCLUDING CHRONIC TOTAL OCCLUSIONS [CTOS]) PRIOR TO PTCA OR STENT INTERVENTION.,EXTENSION WIRE(STINGRAY EXTENSION WIRE)-THE ATTACHMENT OF THE STINGRAY EXTENSION WIRE TO THE EXTENDABLE GUIDEWIRE CREATES A GUIDEWIRE THAT CAN BE USED TO EXCHANGE A CATHETER WITHOUT REMOVING THE GUIDEWIRE FROM THE VESSEL. WHEN THE EXCHANGE IS COMPLETE, THE GUIDEWIRE EXTENSION CAN BE DETACHED AND THE ORIGINAL GUIDEWIRE CAN AGAIN BE USED IN A CONVENTIONAL MANNER.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1222	IMP/MD/2018/000072	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IV SETS(BD GRAVITY IV SET WITH ANTI-RUN DRY (ARD) TECHNOLOGY AND AUTO PRIME. SMARTSITE™ NEEDLE-FREE SYSTEM. FLOW CONTROLLER. INFUSION SET. VENTED.)-THE INTENDED USE OF THE GRAVITY ADMINISTRATION SET RANGE IS TO PROVIDE A CONDUIT FOR FLUIDS INTENDED FOR INFUSION ENABLING CONNECTION TO A FLUID RESERVOIR AND A VENOUS-PUNCTURE DEVICE. GRAVITY ALONE PROVIDES THE SOURCE OF ENERGY FOR INFUSION.,GRAVITY IV SET (BD GRAVITY IV SET WITH ANTI RUN DRY (ARD) TECHNOLOGY AND AUTO PRIME. BACK CHECK VALVE.)-INTENDED USE OF GRAVITY IV SET RANGE IS TO PROVIDE A CONDUIT FOR FLUIDS INTENDED FOR INFUSION ENABLING CONNECTION TO A FLUID RESERVOIR AND A VENOUS-PUNCTURE DEVICE. GRAVITY ALONE PROVIDES THE SOURCE OF ENERGY FOR INFUSION,IV SETS(ALARIS PRODUCTS. SMARTSITE NEEDLE-FREE SYSTEM. INFUSION SET. VENTED. 15 MICROMETER FILTER.)-THE INTENDED USE OF THE GRAVITY ADMINISTRATION SET RANGE IS TO PROVIDE A CONDUIT FOR FLUIDS INTENDED FOR INFUSION ENABLING CONNECTION TO A FLUID RESERVOIR AND A VENOUS-PUNCTURE DEVICE. GRAVITY ALONE PROVIDES THE SOURCE OF ENERGY FOR INFUSION.,GRAVITY IV SET (BD GRAVITY IV SET WITH ANTI RUN DRY (ARD) TECHNOLOGY AND AUTO PRIME)-INTENDED USE OF GRAVITY IV SET RANGE IS TO PROVIDE A CONDUIT FOR FLUIDS INTENDED FOR INFUSION ENABLING CONNECTION TO A FLUID RESERVOIR AND A VENOUS-PUNCTURE DEVICE. GRAVITY ALONE PROVIDES THE SOURCE OF ENERGY FOR INFUSION.,IV SETS(ALARIS PRODUCTS, TRANSFUSION/BLOOD SET. VENTED. 200 MICROMETER FILTER)-BLOOD TRANSFUSION SETS ARE STERILE, INTRAVASCULAR ADMINISTRATION SETS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,GRAVITY IV SET(BD GRAVITY IV SET WITH ANTI RUN DRY (ARD) TECHNOLOGY AND AUTO PRIME. SMARTSITE™ NEEDLE-FREE SYSTEM. FLOW CONTROLLER.)-INTENDED USE OF GRAVITY IV SET RANGE IS TO PROVIDE A CONDUIT FOR FLUIDS INTENDED FOR INFUSION ENABLING CONNECTION TO A FLUID RESERVOIR AND A VENOUS-PUNCTURE DEVICE. GRAVITY ALONE PROVIDES THE SOURCE OF ENERGY FOR INFUSION, TRANSFUSION/BLOOD SET (TRANSFUSION/ BLOOD SET (ALARIS™ PRODUCTS, ALARIS™ GW VOLUMETRIC PUMP , ASENA™ GW VOLUMETRIC PUMP, SMARTSITE™ NEEDLE FREE SYSTEM, ALARIS™ GW 800 VOLUMETRIC PUMP))-THE INTENDED USE OF THE ALARIS™ GW INFUSION SET RANGE IS TO PROVIDE A CONDUIT FOR FLUIDS

	INTENDED FOR INTRA-VENOUS INFUSION ENABLING CONNECTION TO A FLUID RESERVOIR AND A VENOUS-PUNCTURE DEVICE. THESE SETS ARE DESIGNED TO BE USED WITH THE ALARIS™ GW VOLUMETRIC PUMP.,GRAVITY IV SET(BD GRAVITY IV SET WITH ANTI RUN DRY (ARD) TECHNOLOGY AND AUTO PRIME. SMARTSITE™ NEEDLE-FREE SYSTEM)-INTENDED USE OF GRAVITY IV SET RANGE IS TO PROVIDE A CONDUIT FOR FLUIDS INTENDED FOR INFUSION ENABLING CONNECTION TO A FLUID RESERVOIR AND A VENOUS-PUNCTURE DEVICE. GRAVITY ALONE PROVIDES THE SOURCE OF ENERGY FOR INFUSION.,IV SETS(INFUSION SET (ALARIS™ PRODUCTS, ALARIS™ GP VOLUMETRIC PUMP, ALARIS™ SAFETY CLAMP))-THE INTENDED USE OF ANY ALARIS™ GP INFUSION SET RANGE IS TO PROVIDE A CONDUIT FOR ADMINISTERING FLUIDS INTO THE BODY, ENABLING CONNECTION TO RESERVOIRS AND AN INVASIVE PUNCTURE DEVICE. THESE SETS ARE DESIGNED TO BE USED WITH THE ALARIS™ GP VOLUMETRIC PUMP.,IV SETS(MULTI INFUSION SET (ALARIS™ PRODUCTS, ALARIS™ GW VOLUMETRIC PUMP , ASENA™ GW VOLUMETRIC PUMP, SMARTSITE™ NEEDLE FREE SYSTEM, ALARIS™ GW 800 VOLUMETRIC PUMP))-THE INTENDED USE OF THE ALARIS™ GW INFUSION SET RANGE IS TO PROVIDE A CONDUIT FOR FLUIDS INTENDED FOR INTRA-VENOUS INFUSION ENABLING CONNECTION TO A FLUID RESERVOIR AND A VENOUS-PUNCTURE DEVICE. THESE SETS ARE DESIGNED TO BE USED WITH THE ALARIS™ GW VOLUMETRIC PUMP.,IV SETS(MULTI-INFUSION SET (ALARIS™ PRODUCTS , ALARIS™ GP VOLUMETRIC PUMP, ALARIS™ SAFETY CLAMP, SMARTSITE™ NEEDLE FREE SYSTEM))-THE INTENDED USE OF ANY ALARIS™ GP INFUSION SET RANGE IS TO PROVIDE A CONDUIT FOR ADMINISTERING FLUIDS INTO THE BODY, ENABLING CONNECTION TO RESERVOIRS AND AN INVASIVE PUNCTURE DEVICE. THESE SETS ARE DESIGNED TO BE USED WITH THE ALARIS™ GP VOLUMETRIC PUMP.,IV SETS(INFUSION SET (ALARIS™ PRODUCTS, ALARIS™ GW VOLUMETRIC PUMP, ASENA™ GW VOLUMETRIC PUMPS, ALARIS™ GW 800 VOLUMETRIC PUMP))-THE INTENDED USE OF THE ALARIS™ GW INFUSION SET RANGE IS TO PROVIDE A CONDUIT FOR FLUIDS INTENDED FOR INTRA-VENOUS INFUSION ENABLING CONNECTION TO A FLUID RESERVOIR AND A VENOUS-PUNCTURE DEVICE. THESE SETS ARE DESIGNED TO BE USED WITH THE ALARIS™ GW VOLUMETRIC PUMP.,TRANSFUSION/ BLOOD SET(TRANSFUSION/ BLOOD SET (ALARIS™ PRODUCTS, ALARIS™ GP VOLUMETRIC PUMP , ALARIS™ SAFETY CLAMP))-THE INTENDED USE OF ANY ALARIS™ GP INFUSION SET RANGE IS TO PROVIDE A CONDUIT FOR ADMINISTERING FLUIDS INTO THE BODY, ENABLING CONNECTION TO RESERVOIRS AND AN INVASIVE PUNCTURE DEVICE. THESE SETS ARE DESIGNED TO BE USED WITH THE ALARIS™ GP VOLUMETRIC PUMP.

1223	IMP/MD/2018/000073	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PEN NEEDLES(PEN NEEDLES)-THE BD PEN NEEDLE IS INTENDED FOR USE WITH PEN INJECTOR DEVICES FOR THE SUBCUTANEOUS INJECTION OF DRUGS, PEN NEEDLES(BD ULTRA-FINE PEN NEEDLES EASYFLOW TECHNOLOGY PENTA POINT COMFORT)-THE BD PEN NEEDLE IS INTENDED FOR USE WITH PEN INJECTOR DEVICES FOR THE SUBCUTANEOUS INJECTION OF DRUGS,PEN NEEDLES(BD ULTRA-FINE MICRO PEN NEEDLES)-THE BD PEN NEEDLE IS INTENDED FOR USE WITH PEN INJECTOR DEVICES FOR THE SUBCUTANEOUS INJECTION OF DRUGS

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1224	IMP/MD/2018/000076	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL HIP SYSTEM(R3)-HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTUREDISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY.,UNICOMPARTMENTAL KNEE SYSTEM (JOURNEY II UNI TIBIAL INSERT)-UNICOMPARTMENTAL KNEE IMPLANTS ARE INDICATED FOR RESTORING EITHER COMPARTMENT OF A KNEE THAT HAS BEEN AFFECTED BY THE FOLLOWING: • NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OR AVASCULAR NECROSIS; • CORRECTION OF FUNCTIONAL DEFORMITY; • REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED; AND • TREATMENT OF FRACTURES THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES.,KNEE SYSTEM (GENESIS II)-"1. RHEUMATOID ARTHRITIS. 2. POST TRAUMATIC ARTHRITIS, OSTEOARTHRITIS, OR DEGENERATIVE ARTHRITIS. 3. FAILED OSTEOTOMIES, UNICOMPARTMENTAL REPLACEMENT, OR TOTAL KNEE REPLACEMENT. 4. POSTERIOR STABILIZED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE INCOMPETENT AND THE COLLATERAL LIGAMENTS REMAIN INTACT. 5. CONSTRAINED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE INCOMPETENT. 6. HINGE KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL

	LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE ABSENT OR INCOMPETENT.", EXTERNAL FIXATION SYSTEM-PINS (NON-STERILE)(NA)-THE WIRES AND PINS ARE THE IMPLANTABLE COMPONENTS USED IN EXTERNAL FIXATION DEVICES WHOSE INDICATIONS FOR USE ARE: 1. POST-TRAUMATIC JOINT CONTRACTURE WHICH HAS RESULTED IN LOSS OF RANGE OF MOTION (NOT APPLICABLE FOR SMITH & NEPHEW RAIL SYSTEM) 2. FRACTURES AND DISEASE WHICH GENERALLY MAY RESULT IN JOINT CONTRACTURES OR LOSS OF RANGE OF MOTION AND FRACTURES REQUIRING DISTRACTION 3. OPEN AND CLOSED FRACTURE FIXATION 4. PSEUDOARTHROSIS OF LONG BONES 5. LIMB LENGTHENING BY EPIPHYSEAL OR METAPHYSEAL DISTRACTION (NOT APPLICABLE FOR COMPASS UNIVERSAL HINGE OR JET-X™ FIXATOR) 6. CORRECTION OF BONY OR SOFT TISSUE DEFORMITIES (NOT APPLICABLE FOR COMPASS UNIVERSAL HINGE) 7. CORRECTION OF SEGMENTAL BONY OR SOFT TISSUE DEFECTS 8. JOINT ARTHRODESIS (NOT APPLICABLE FOR SMITH & NEPHEW RAIL SYSTEM) 9. INFECTED FRACTURES OR NONUNIONS 10. MINI EXTERNAL FIXATOR SYSTEMS ARE INDICATED FOR THE MANAGEMENT OF COMMINUTED INTRAARTICULAR FRACTURES OF THE DISTAL RADIUS (NOT APPLICABLE FOR SMITH & NEPHEW RAIL SYSTEM) 11. CALANDRUCCIO DEVICES ARE INDICATED FOR ARTHRODESIS OF THE ANKLE OR SUBTALAR JOINTS, AS WELL AS SOME SELECT FRACTURES, NONUNION, OR OSTEOTOMY OF THE DISTAL TIBIA; AND ACUTE TRANSVERSE FRACTURES OR NONUNION OF THE DISTAL TIBIA (NOT APPLICABLE FOR SMITH & NEPHEW RAIL SYSTEM),FEMORAL HEADS(NA)-"HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTURE-DISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY.",EXTERNAL FIXATION SYSTEM-WIRES(NA)-THE

	WIRES AND PINS ARE THE IMPLANTABLE COMPONENTS USED IN EXTERNAL FIXATION DEVICES WHOSE INDICATIONS FOR USE ARE: 1. POST-TRAUMATIC JOINT CONTRACTURE WHICH HAS RESULTED IN LOSS OF RANGE OF MOTION (NOT APPLICABLE FOR SMITH & NEPHEW RAIL SYSTEM) 2. FRACTURES AND DISEASE WHICH GENERALLY MAY RESULT IN JOINT CONTRACTURES OR LOSS OF RANGE OF MOTION AND FRACTURES REQUIRING DISTRACTION 3. OPEN AND CLOSED FRACTURE FIXATION 4. PSEUDOARTHROSIS OF LONG BONES 5. LIMB LENGTHENING BY EPIPHYSEAL OR METAPHYSEAL DISTRACTION (NOT APPLICABLE FOR COMPASS UNIVERSAL HINGE OR JET-X™ FIXATOR) 6. CORRECTION OF BONY OR SOFT TISSUE DEFORMITIES (NOT APPLICABLE FOR COMPASS UNIVERSAL HINGE) 7. CORRECTION OF SEGMENTAL BONY OR SOFT TISSUE DEFECTS 8. JOINT ARTHRODESIS (NOT APPLICABLE FOR SMITH & NEPHEW RAIL SYSTEM) 9. INFECTED FRACTURES OR NONUNIONS 10. MINI EXTERNAL FIXATOR SYSTEMS ARE INDICATED FOR THE MANAGEMENT OF COMMINUTED INTRAARTICULAR FRACTURES OF THE DISTAL RADIUS (NOT APPLICABLE FOR SMITH & NEPHEW RAIL SYSTEM) 11. CALANDRUCCIO DEVICES ARE INDICATED FOR ARTHRODESIS OF THE ANKLE OR SUBTALAR JOINTS, AS WELL AS SOME SELECT FRACTURES, NONUNION, OR OSTEOTOMY OF THE DISTAL TIBIA; AND ACUTE TRANSVERSE FRACTURES OR NONUNION OF THE DISTAL TIBIA (NOT APPLICABLE FOR SMITH & NEPHEW RAIL SYSTEM),INTRAMEDULLARY NAIL SYSTEM(TRIGEN)-"INDICATIONS FOR INTERLOCKING INTRAMEDULLARY NAILS INCLUDE SIMPLE LONG BONE FRACTURES; SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNIONS AND MALUNIONS; POLYTRAUMA AND MULTIPLE FRACTURES; PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES; RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; SUPRACONDYLAR FRACTURES; BONE LENGTHENING AND SHORTENING. INTERLOCKING INTRAMEDULLARY NAILS ARE INDICATED FOR FIXATION OF FRACTURES THAT OCCUR IN AND BETWEEN THE PROXIMAL AND DISTAL THIRD OF THE LONG BONES BEING TREATED.",HIP SYSTEM(ECHELON)-HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS,

	ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTURE-DISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY.,KNEE SYSTEM(LEGION)-"1. RHEUMATOID ARTHRITIS. 2. POST TRAUMATIC ARTHRITIS, OSTEOARTHRITIS, OR DEGENERATIVE ARTHRITIS. 3. FAILED OSTEOTOMIES, UNICOMPARTMENTAL REPLACEMENT, OR TOTAL KNEE REPLACEMENT. 4. POSTERIOR STABILIZED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE INCOMPETENT AND THE COLLATERAL LIGAMENTS REMAIN INTACT. 5. CONSTRAINED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE INCOMPETENT. 6. HINGE KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE ABSENT OR INCOMPETENT.",EXTERNAL FIXATION SYSTEM-PINS (STERILE)(NA)-THE WIRES AND PINS ARE THE IMPLANTABLE COMPONENTS USED IN EXTERNAL FIXATION DEVICES WHOSE INDICATIONS FOR USE ARE: 1. POST-TRAUMATIC JOINT CONTRACTURE WHICH HAS RESULTED IN LOSS OF RANGE OF MOTION (NOT APPLICABLE FOR SMITH & NEPHEW RAIL SYSTEM) 2. FRACTURES AND DISEASE WHICH GENERALLY MAY RESULT IN JOINT CONTRACTURES OR LOSS OF RANGE OF MOTION AND FRACTURES REQUIRING DISTRACTION 3. OPEN AND CLOSED FRACTURE FIXATION 4. PSEUDOARTHROSIS OF LONG BONES 5. LIMB LENGTHENING BY EPIPHYSEAL OR METAPHYSEAL DISTRACTION (NOT APPLICABLE FOR COMPASS UNIVERSAL HINGE OR JET-X™ FIXATOR) 6. CORRECTION OF BONY OR SOFT TISSUE DEFORMITIES (NOT APPLICABLE FOR COMPASS UNIVERSAL HINGE) 7. CORRECTION OF SEGMENTAL BONY OR SOFT TISSUE DEFECTS 8. JOINT ARTHRODESIS (NOT APPLICABLE FOR SMITH & NEPHEW RAIL SYSTEM) 9. INFECTED FRACTURES OR NONUNIONS 10. MINI EXTERNAL FIXATOR SYSTEMS ARE INDICATED FOR THE MANAGEMENT OF COMMINUTED INTRAARTICULAR FRACTURES OF THE DISTAL RADIUS (NOT APPLICABLE FOR SMITH & NEPHEW RAIL SYSTEM) 11. CALANDRUCCIO

	DEVICES ARE INDICATED FOR ARTHRODESIS OF THE ANKLE OR SUBTALAR JOINTS, AS WELL AS SOME SELECT FRACTURES, NONUNION, OR OSTEOTOMY OF THE DISTAL TIBIA; AND ACUTE TRANSVERSE FRACTURES OR NONUNION OF THE DISTAL TIBIA (NOT APPLICABLE FOR SMITH & NEPHEW RAIL SYSTEM),BONE PLATE SYSTEM(PERI-LOC)-"THE PERI-LOC PLATE AND SCREW SYSTEM CAN BE USED FOR ADULT AND PEDIATRIC PATIENTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. PERI-LOC BONE PLATES AND BONE SCREWS ARE INDICATED FOR FIXATION OF PELVIC, SMALL, AND LONG BONE FRACTURES, INCLUDING THOSE OF THE TIBIA, FIBULA, FEMUR, PELVIS, ACETABULUM, METACARPALS, METATARSALS, HUMERUS, ULNA, RADIUS, CALCANEUS, AND CLAVICLE. THE PERI-LOC ANKLE FUSION PLATING SYSTEM CAN BE USED IN ADOLESCENT (12-18 YEARS) AND TRANSITIONAL ADOLESCENT (18-21 YEARS) SUBPOPULATIONS AND ADULTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. THE PERILOC ANKLE FUSION PLATING SYSTEM IS INDICATED FOR ANKLE ARTHRODESIS AND FRACTURES, INCLUDING THE DISTAL TIBIA, TALUS, AND CALCANEUS. PERI-LOC PERIARTICULAR LOCKED PLATING SYSTEM PROXIMAL FEMUR BONE PLATES, BONE SCREWS, AND CABLE ACCESSORIES CAN BE USED FOR ADULT PATIENTS AS WELL AS PATIENTS WITH OSTEOPENIC BONE. PERI-LOC PROXIMAL FEMUR BONE PLATES, BONE SCREWS, AND CABLE ACCESSORIES ARE INDICATED FOR FRACTURES OF THE TROCHANTERIC REGION INCLUDING SIMPLE INTERTROCHANTERIC, REVERSE OBLIQUE TROCHANTERIC, TRANSVERSE TROCHANTERIC, COMPLEX MULTI-FRAGMENTARY, AND FRACTURES WITH MEDIAL CORTEX INSTABILITY; PROXIMAL FEMUR FRACTURES COMBINED WITH IPSILATERAL SHAFT FRACTURES; PATHOLOGICAL FRACTURES OF THE PROXIMAL FEMUR INCLUDING METASTATIC FRACTURES; PROXIMAL FEMUR OSTEOTOMIES; FIXATION OF FRACTURES IN OSTEOPENIC BONE; FIXATION OF NONUNIONS AND MALUNIONS; BASI/TRANSCERVICAL FEMORAL NECK FRACTURES; SUBCAPITAL FEMORAL NECK FRACTURES; AND SUBTROCHANTERIC FEMUR FRACTURES. PERI-LOC PERIARTICULAR LOCKED PLATING SYSTEM VLP PLATES AND SCREWS CAN BE USED FOR ADULT AND PEDIATRIC PATIENTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. PERI-LOC CONTOURED VLP PLATES AND SCREWS ARE INDICATED FOR PARTIAL ARTICULAR FRACTURES (AO/OTA FRACTURE CLASSIFICATION TYPE B) OF THE DISTAL AND PROXIMAL TIBIA, AND FOR FRACTURE FIXATION OF THE FIBULA. PERI-LOC VLP [3.5MM1] ONE-THIRD TUBULAR LOCKING PLATES ARE INDICATED FOR, BUT NOT LIMITED TO, FIXATION OF FRACTURES, NON-UNIONS, AND OSTEOTOMIES OF THE MEDIAL MALLEOLUS, FIBULA, DISTAL ULNA,

	OLECRANON, CALCANEUS, AND METATARSALS.", UNICOMPARTMENTAL KNEE SYSTEM(JOURNEY II UNI TIBIA BASEPLATE)-UNICOMPARTMENTAL KNEE IMPLANTS ARE INDICATED FOR RESTORING EITHER COMPARTMENT OF A KNEE THAT HAS BEEN AFFECTED BY THE FOLLOWING: • NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OR AVASCULAR NECROSIS; • CORRECTION OF FUNCTIONAL DEFORMITY; • REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED; AND • TREATMENT OF FRACTURES THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES.,TOTAL HIP SYSTEM(SYNERGY)-"HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTURE-DISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY." ,SCREWS-THE SMITH & NEPHEW PARTIALLY-THREADED SCREWS ARE INTENDED FOR USE FOR INTERNAL BONE FIXATION INCLUDING FRACTURES OF THE TIBIA, FIBULA, CLAVICLE, SCAPULA, OLECRANON, METACARPALS, METATARSALS, HUMERUS, ULNA, MIDDLE HAND BONES, MIDDLE FOOT BONES, AND CALCANEOUS. SCREWS ARE ADDITIONALLY INTENDED FOR ARTHRODESES AND OSTEOTOMIES OF SMALL BONES AND SMALL JOINTS INCLUDING SCAPHOID AND OTHER CARPAL BONES, METACARPALS, TARSALS, METATARSALS, CLAVICLE, SCAPULA, OLECRANON, ULNAR STYLOID, RADIAL HEAD, AND RADIAL STYLOID., TOTAL KNEE SYSTEM(ANTHEM)-"• RHEUMATOID ARTHRITIS. • POST-TRAUMATIC ARTHRITIS, OSTEOARTHRITIS, OR DEGENERATIVE ARTHRITIS. • FAILED OSTEOTOMIES, UNICOMPARTMENTAL REPLACEMENT, OR TOTAL KNEE REPLACEMENT. • POSTERIOR STABILIZED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE INCOMPETENT AND THE

	COLLATERAL LIGAMENTS REMAIN INTACT.",REVISION ACETABULAR SYSTEM(REDAPT)-HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGES AS A RESULT OF TRAUMA OR NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTURE-DISLOCATION OF THE HIP AND CORRECTION OF DEFORMITY.,DISTAL RADIUS FRACTURE IMPLANTS(D-RAD)-THE D-RAD SMART PACK SYSTEM IS INTENDED FOR THE FIXATION OF FRACTURES INVOLVING THE DISTAL RADIUS.,KNEE SYSTEM (JOURNEY PFJ)-"* DEGENERATIVE ARTHRITIS IN THE DISTAL FEMUR AND PATELLA; * A HISTORY OF PATELLAR DISLOCATION OR PATELLAR FRACTURE; AND * FAILED PREVIOUS SURGERY (ARTHROPLASTY, TIBIAL TUBERCLE ELEVATION, LATERAL RELEASE) WHERE PAIN, DEFORMITY OR DYSFUNCTION PERSISTS.",TOTAL HIP SYSTEM(SMF STIKTITE COATED)-" HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTURE-DISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY",KNEE SYSTEM(JOURNEY)-"* RHEUMATOID

	ARTHRITIS * POSTTRAUMATIC ARTHRITIS, OSTEOARTHRITIS, OR DEGENERATIVE ARTHRITIS * FAILED OSTEOTOMIES, UNICOMPARTMENTAL REPLACEMENT, OR TOTAL KNEE REPLACEMENT. * POSTERIOR STABILIZED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE INCOMPETENT AND THE COLLATERAL LIGAMENTS REMAIN INTACT. * CONSTRAINED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE INCOMPETENT. * HINGE KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE ABSENT OR INCOMPETENT.",TOTAL HIP SYSTEM(REFLECTION)-"HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTURE-DISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY.",KNEE SYSTEM(JOURNEY UNI)-"UNICOMPARTMENTAL KNEE IMPLANTS ARE INDICATED FOR RESTORING EITHER COMPARTMENT OF A KNEE THAT HAS BEEN AFFECTED BY THE FOLLOWING: * NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OR AVASCULAR NECROSIS; * CORRECTION OF FUNCTIONAL DEFORMITY; * REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED; AND * TREATMENT OF FRACTURES THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES.",ENDOPROSTHESES SYSTEMS(TANDEM)-"1. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING

	OSTEOARTHRITIS, OSTEONECROSIS, AVASCULAR NECROSIS AND POST TRAUMATIC ARTHRITIS; 2. RHEUMATOID ARTHRITIS; 3. ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES AND CORRECTION OF FUNCTIONAL DEFORMITY SUCH AS CONGENITAL HIP DYSPLASIA OR ANKYLOSING SPONDYLITIS; 4. REVISION PROCEDURES WHERE OTHER TREATMENTS HAVE FAILED; 5. TREATMENT OF PROXIMAL FEMORAL NON&UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT." ,KNEE SYSTEM(JOURNEY II)-"* RHEUMATOID ARTHRITIS * POSTTRAUMATIC ARTHRITIS, OSTEOARTHRITIS, OR DEGENERATIVE ARTHRITIS * FAILED OSTEOTOMIES, UNICOMPARTMENTAL REPLACEMENT, OR TOTAL KNEE REPLACEMENT. * POSTERIOR STABILIZED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE INCOMPETENT AND THE COLLATERAL LIGAMENTS REMAIN INTACT. * CONSTRAINED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE INCOMPETENT. * HINGE KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE ABSENT OR INCOMPETENT.",FEMORAL HEAD(NA)-"HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTURE-DISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY.",ACETABULAR AUGMENTS (REDAPT)-HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS

	UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT.HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTURE-DISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY. REDAPT AUGMENTS ARE INTENDED FOR SINGLE USE ONLY AND ARE TO BE IMPLANTED WITH BONE CEMENT TO THE MATING ACETABULAR SHELL AND WITHOUT BONE CEMENT TO THE BONE INTERFACE. ACETABULAR AUGMENTS ARE INTENDED TO BE USED IN PRIMARY AND REVISION SURGERIES WHERE THE ACETABULUM HAS THE DEFICIENCIES OF THE ACETABULAR ROOF, ANTERIOR OR POSTERIOR PILLAR, MEDIAL WALL DEFICIENCY, AND / OR PROTRUSION AS A RESULT OF THE INDICATIONS LISTED PREVIOUSLY.,FRACTURE FIXATION DEVICES(CANNULATED SCREWS)-"BONE PLATES AND SCREWS FROM THE SMITH & NEPHEW BONE PLATE SYSTEM ARE USED FOR ADULT AND PEDIATRIC PATIENTS AS INDICATED FOR PELVIC, SMALL, AND LONG BONE FRACTURE FIXATION. INDICATIONS FOR USE INCLUDE FRACTURES OF THE TIBIA, FIBULA, FEMORAL CONDYLE, PELVIS, ACETABULUM, METACARPALS, METATARSALS, HUMERUS, ULNA, MIDDLE HAND AND MIDDLE FOOT BONES; TREATMENT OF THE CALCANEUS; HIP ARTHRODESIS, AND PROVISIONAL HOLE FIXATION. THE 4.0MM CANNULATED SCREWS AND ASSOCIATED WASHERS ARE ADDITIONALLY INTENDED FOR ARTHRODESIS AND OSTEOTOMIES OF SMALL BONES AND SMALL JOINTS, INCLUDING SCAPHOID AND OTHER CARPAL BONES, METACARPALS, TARSALS, METATARSALS, PATELLA, ULNAR STYLOID, CAPITELLUM, RADIAL HEAD AND RADIAL STYLOID. THE 5.5 MM, 6.5MM, 7.0MM, AND 8.0MM CANNULATED SCREWS AND ASSOCIATED WASHERS ARE ADDITIONALLY INTENDED FOR RECONSTRUCTION, OSTEOTOMY, AND ARTHRODESIS OF VARIOUS BONES AND BONE FRAGMENTS APPROPRIATE FOR THE SIZE OF THE DEVICE INCLUDING ",HIP SYSTEM(ANTHOLOGY)-HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND

	REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; OLD, REMOTE OSTEOMYELITIS WITH AN EXTENDED DRAINAGE-FREE PERIOD, IN WHICH CASE, THE PATIENT SHOULD BE WARNED OF AN ABOVE NORMAL DANGER OF INFECTION POSTOPERATIVELY; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTURE-DISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY.,FRACTURE FIXATION DEVICES (CHS (COMPRESSION HIP SCREW))-"COMPRESSION HIP SCREWS • INTRACAPSULAR FRACTURES OF THE FEMORAL NECK. (FOR HIGH SUBCAPSULAR FRACTURES IT MAY BE MORE PRUDENT TO SELECT A PROSTHESIS IN LIEU OF INTERNAL FIXATION TO REDUCE THE RISK OF A NONUNION OR AVASCULAR NECROSIS OF THE FEMORAL HEAD.) • TROCHANTERIC OR SUBTROCHANTERIC FRACTURES WITH APPROPRIATE ADDITIONAL POSTOPERATIVE PRECAUTIONS ABOUT WEIGHT BEARING AND MORE THAN SEDENTARY ACTIVITY. • OSTEOTOMIES FOR PATIENTS WITH DISEASES OR DEFORMITIES OF THE HIP. • HIP ARTHRODESIS. • SUPRACONDYLAR FRACTURES AND DISTAL FEMORAL FRACTURES USING A SUPRACONDYLAR PLATE. • IPSILATERAL FEMORAL SHAFT/NECK FRACTURES. PEDIATRIC AND INTERMEDIATE COMPRESSION HIP SCREWS • CONGENITAL COXA VARA. • CONGENITAL DISLOCATION OF THE HIP. • SUBLUXATION OR DISLOCATION SECONDARY TO NEUROLOGIC DISORDERS SUCH AS CEREBRAL PALSY, MYELOMENIGOCELE, POLIOMYELITIS, ETC. USUALLY VALGUS-ANTEVERSION DEFORMITIES. • COXA PLANA (LEGG-CALVE-PERTHES DISEASE) FOR CONTAINMENT OF THE HEAD COMPLETELY WITHIN THE ACETABULUM. ",REVISION FEMORAL SYSTEM(REDAPT)-HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR

	NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; OLD, REMOTE OSTEOMYELITIS WITH AN EXTENDED DRAINAGE-FREE PERIOD, IN WHICH CASE, THE PATIENT SHOULD BE WARNED OF AN ABOVE NORMAL DANGER OF INFECTION POSTOPERATIVELY; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTURE-DISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY.,TOTAL HIP SYSTEM(CPCS (COLLARLESS POLISHED CEMENTED STEM))-HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTUREDISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY.

1225	IMP/MD/2018/000076	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SMALL FRAGMENT PLATING SYSTEM - PLATES(EVOS)-THE EVOS SMALL FRAGMENT PLATING SYSTEM IS INDICATED FOR ADULT AND PEDIATRIC PATIENTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. IT IS INDICATED FOR FIXATION OF SMALL AND LONG BONE FRACTURES, INCLUDING BUT NOT LIMITED TO, THOSE OF THE TIBIA, FIBULA, FEMUR, HUMERUS, ULNA, RADIUS, PELVIS, ACETABULUM, METACARPALS, METATARSALS, AND CLAVICLE. THE EVOS PARTIAL ARTICULAR AND ANTI-GLIDE PLATES ARE INDICATED FOR THE TREATMENT OF PARTIAL ARTICULAR FRACTURES OF THE DISTAL AND PROXIMAL TIBIA (AO/OTA FRACTURE CLASSIFICATION TYPE B), AND FOR FRACTURE FIXATION OF THE FIBULA.,SMALL FRAGMENT PLATING SYSTEM - PLATES(EVOS)-THE EVOS SMALL FRAGMENT PLATING SYSTEM IS INDICATED FOR ADULT AND PEDIATRIC PATIENTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. IT IS INDICATED FOR FIXATION OF SMALL AND LONG BONE FRACTURES, INCLUDING BUT NOT LIMITED TO, THOSE OF THE TIBIA, FIBULA, FEMUR, HUMERUS, ULNA, RADIUS, PELVIS, ACETABULUM, METACARPALS, METATARSALS, AND CLAVICLE. THE EVOS PARTIAL ARTICULAR AND ANTI-GLIDE PLATES ARE INDICATED FOR THE TREATMENT OF PARTIAL ARTICULAR FRACTURES OF THE DISTAL AND PROXIMAL TIBIA (AO/OTA FRACTURE CLASSIFICATION TYPE B), AND FOR FRACTURE FIXATION OF THE FIBULA.,SMALL FRAGMENT PLATING SYSTEM - SCREWS(EVOS)-THE EVOS SMALL FRAGMENT PLATING SYSTEM IS INDICATED FOR ADULT AND PEDIATRIC PATIENTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. IT IS INDICATED FOR FIXATION OF SMALL AND LONG BONE FRACTURES, INCLUDING BUT NOT LIMITED TO, THOSE OF THE TIBIA, FIBULA, FEMUR, HUMERUS, ULNA, RADIUS, PELVIS, ACETABULUM, METACARPALS, METATARSALS, AND CLAVICLE. THE EVOS PARTIAL ARTICULAR AND ANTI-GLIDE PLATES ARE INDICATED FOR THE TREATMENT OF PARTIAL ARTICULAR FRACTURES OF THE DISTAL AND PROXIMAL TIBIA (AO/OTA FRACTURE CLASSIFICATION TYPE B), AND FOR FRACTURE FIXATION OF THE FIBULA.,SMALL FRAGMENT PLATING SYSTEM - WASHERS(EVOS)-THE EVOS SMALL FRAGMENT PLATING SYSTEM IS INDICATED FOR ADULT AND PEDIATRIC PATIENTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. IT IS INDICATED FOR FIXATION OF SMALL AND LONG BONE FRACTURES, INCLUDING BUT NOT LIMITED TO, THOSE OF THE TIBIA, FIBULA,

	FEMUR, HUMERUS, ULNA, RADIUS, PELVIS, ACETABULUM, METACARPALS, METATARSALS, AND CLAVICLE. THE EVOS PARTIAL ARTICULAR AND ANTI-GLIDE PLATES ARE INDICATED FOR THE TREATMENT OF PARTIAL ARTICULAR FRACTURES OF THE DISTAL AND PROXIMAL TIBIA (AO/OTA FRACTURE CLASSIFICATION TYPE B), AND FOR FRACTURE FIXATION OF THE FIBULA.,SMALL FRAGMENT PLATING SYSTEM - SCREWS(EVOS)-THE EVOS SMALL FRAGMENT PLATING SYSTEM IS INDICATED FOR ADULT AND PEDIATRIC PATIENTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. IT IS INDICATED FOR FIXATION OF SMALL AND LONG BONE FRACTURES, INCLUDING BUT NOT LIMITED TO, THOSE OF THE TIBIA, FIBULA, FEMUR, HUMERUS, ULNA, RADIUS, PELVIS, ACETABULUM, METACARPALS, METATARSALS, AND CLAVICLE. THE EVOS PARTIAL ARTICULAR AND ANTI-GLIDE PLATES ARE INDICATED FOR THE TREATMENT OF PARTIAL ARTICULAR FRACTURES OF THE DISTAL AND PROXIMAL TIBIA (AO/OTA FRACTURE CLASSIFICATION TYPE B), AND FOR FRACTURE FIXATION OF THE FIBULA.,SMALL FRAGMENT PLATING SYSTEM - PEGS(EVOS)-THE EVOS SMALL FRAGMENT PLATING SYSTEM IS INDICATED FOR ADULT AND PEDIATRIC PATIENTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. IT IS INDICATED FOR FIXATION OF SMALL AND LONG BONE FRACTURES, INCLUDING BUT NOT LIMITED TO, THOSE OF THE TIBIA, FIBULA, FEMUR, HUMERUS, ULNA, RADIUS, PELVIS, ACETABULUM, METACARPALS, METATARSALS, AND CLAVICLE. THE EVOS PARTIAL ARTICULAR AND ANTI-GLIDE PLATES ARE INDICATED FOR THE TREATMENT OF PARTIAL ARTICULAR FRACTURES OF THE DISTAL AND PROXIMAL TIBIA (AO/OTA FRACTURE CLASSIFICATION TYPE B), AND FOR FRACTURE FIXATION OF THE FIBULA.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1226	IMP/MD/2018/000077	1.License Holder Name: MACO PHARMA INDIA TRANSFUSION SOLUTIONS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SINGLE OR MULTIPLE BLOOD BAGS, LEUKODEPLETION FILTERS, SINGLE OR MULTIPLE BAGS WITH LEUKODEPLETION FILTERS(SINGLE OR MULTIPLE BLOOD BAGS, LEUKODEPLETION FILTERS, SINGLE OR MULTIPLE BAGS WITH LEUKODEPLETION FILTERS)-INTENDED FOR THE COLLECTION OF HUMAN BLOOD AND THE PRESERVATION OF BLOOD COMPONENTS., SINGLE OR MULTIPLE BLOOD BAGS, LEUKODEPLETION FILTERS, SINGLE OR MULTIPLE BAGS WITH LEUKODEPLETION FILTERS(SINGLE OR MULTIPLE BLOOD BAGS, LEUKODEPLETION FILTERS, SINGLE OR MULTIPLE BAGS WITH LEUKODEPLETION FILTERS)-INTENDED FOR THE COLLECTION OF HUMAN BLOOD AND THE PRESERVATION OF BLOOD COMPONENTS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1227	IMP/MD/2018/000078	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GENERAL SPINE SYSTEM (ECO POSTERIOR THORACOLUMBAR FIXATION SYSTEM (DEGEN))-THE ECO POSTERIOR THORACOLUMBAR FIXATION SYSTEM (DEGEN) CAN BE USED FOR NON-NECK FIXATION THROUGH THE POSTERIOR APPROACH, AS AN AUXILIARY DEVICE FOR THE TREATMENT OF THE FOLLOWING DISEASES: DEGENERATIVE DISEASES OF INTERVERTEBRAL DISK(BACK PAIN CAUSED BY INTERVERTEBRAL DISC DISEASE AND CONFIRMED BY PATIENT'S MEDICAL HISTORY AND IMAGING EXAMINATION), SPONDYLOLISTHESIS, TRAUMA (NAMELY: FRACTURE OR DISLOCATION), SPINAL STENOSIS, DEFORMITIES (SCOLIOTIC DEFORMITY, KYPHOTIC DEFORMITY AND/OR LORDOTIC DEFORMITY), TUMORS, PSEUDARTHROSIS AND OR FAILURE OF FUSION IN PREVIOUS SURGERIES.,BONE PLATES (NON – STERILE)(VARILOC LOCKING COMPRESSION PLATE SYSTEM)-IT IS SUITABLE FOR LIMBS FACTURE INTERNAL FIXATION WHILE IN ORTHOPEDIC SURGERY. WITH THE DEVELOPMENT OF SCIENCE AND THE EXPANSION OF SURGICAL TREATMENT FOR DISEASES, IN ORDER TO MEET THE CLINICAL NEEDS, MEDICAL EQUIPMENT HAS A GREAT IMPROVEMENT AND DEVELOPMENT, METAL LOCKING PLATE SCREW SYSTEM IS ONE OF INTERNAL FIXATION IMPLANTS.,GENERAL SPINE SYSTEM (NON STERILE)(CERVINE ANTERIOR CERVICAL PLATES SYSTEM)-CERVINE ANTERIOR CERVICAL PLATES SYSTEM IS INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR SPINE DURING THE DEVELOPMENT OF CERVICAL SPINAL FUSIONS IN PATIENTS WITH: 1) DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), 2) TRAUMA (INCLUDING FRACTURES), 3) TUMORS, 4) DEFORMITY (DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS), 5) PSEUDARTHROSIS, AND/OR 6) FAILED PREVIOUS FUSIONS. THIS DEVICE SYSTEM IS INTENDED FOR ANTERIOR CERVICAL INTERVERTEBRAL BODY FUSIONS. ONLY.,GENERAL SPINE SYSTEM (NON – STERILE)(G5 SPINE SYSTEM)-THE G5 SPINE SYSTEM IN THIS SERIES IS SUITABLE FOR TEMPORARY OR PERMANENT INTERNAL FIXATION OF ANTERIOR CERVICAL SPINE AND POSTERIOR VERTEBRA FOR SPINAL CORRECTION FROM CERVICAL SPINE TO LUMBOSACRAL SPINE IN A BID TO HELP BONE FUSION. THE G5 SPINE SYSTEM IN THIS SERIES IS SUITABLE FOR DEGENERATIVE DISEASES OF INTERVERTEBRAL DISK, SPONDYLOLISTHESIS, TRAUMA, STENOSIS, DEFORMITIES (SCOLIOTIC DEFORMITY, KYPHOTIC DEFORMITY AND LORDOTIC DEFORMITY), TUMORS, PSEUDARTHROSIS AND FAILURE OF FUSION IN PREVIOUS

	SURGERIES. ,BONE PLATES (NON-STERILE) TITANIUM ALLOY (DHS/DCS SYSTEM)-IT IS INTENDED TO FIX THE FRACTURED BONES OF PATIENT. IN SURGERY, THEY ARE FASTENED ONTO BONE BY SCREWS OR CERCLAGES.,LOCKABLE INTRAMEDULLARY NAILS (NON – STERILE)(NEOGEN II NAILS SYSTEM)-NEOGEN II NAILS SYSTEM INCLUDE SIMPLE SHAFT FRACTURES OF FEMUR AND TIBIA; SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES, NONUNIONS AND MALUNIONS; POLYTRAUMA AND MULTIPLE FRACTURES; PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES; RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; SUPRACONDYLAR FRACTURES; BONE LENGTHENING AND SHORTENING. INTERLOCKING INTRAMEDULLARY NAILS ARE INDICATED FOR FIXATION OF FRACTURES THAT OCCUR IN AND BETWEEN THE PROXIMAL AND DISTAL THIRD OF THE LING BINES BEING TREATED. NAILS THAT CONTAIN HOLES PROXIMALLY TO ACCEPT SCREWS THAT THREAD INTO THE FEMORAL HEAD FOR COMPRESSION AND ROTATIONAL STABILITY ARE INDICATED FOR THE FOLLOWING: SUBTROCHANTERIC FACTURES, INTERTROCHANTERIC FRACTURES, AND IPSILATERAL FEMORAL SHAFT/NECK FRACTURES.,BONE SCREW (NON-STERILE)(KCS CANNULATED SCREW SYSTEM)-IT IS INTENDED TO FIX THE FRACTURED BONES OF PATIENTS. IN SURGERY, THEY ARE USED EITHER TO FASTEN BONE PLATES OR SIMILAR DEVICES ONTO BONE, OR, AS COMPRESSION SCREWS, TO HOLD TOGETHER FRAGMENTS OF BONE,GENERAL SPINE SYSTEM (NON – STERILE)(COBRA II POSTERIOR CERVICAL SYSTEM)-THE COBRA II POSTERIOR CERVICAL SYSTEM IN THIS SERIES IS SUITABLE FOR TEMPORARY OR PERMANENT INTERNAL FIXATION OF ANTERIOR CERVICAL SPINE AND POSTERIOR VERTEBRA FOR SPINAL CORRECTION FROM CERVICAL SPINE TO LUMBOSACRAL SPINE IN A BID TO HELP BONE FUSION. THE COBRA II POSTERIOR CERVICAL SYSTEM IN THIS SERIES IS SUITABLE FOR DEGENERATIVE DISEASES OF INTERVERTEBRAL DISK, SPONDYLOLISTHESIS, TRAUMA, STENOSIS, DEFORMITIES (SCOLIOTIC DEFORMITY, KYPHOTIC DEFORMITY AND LORDOTIC DEFORMITY), TUMORS, PSEUDARTHROSIS AND FAILURE OF FUSION IN PREVIOUS SURGERIES. ,INTRAMEDULLARY NAILS (NON STERILE)-TITANIUM ALLOY(NEOGEN NAILS SYSTEM)-IT IS INTENDED TO FIX THE FRAGMENTS OF LONG TUBULAR BONE. IN CLINICAL APPLICATION, FOLLOWING EXTENSION AND REDUCTION OF THE FRACTURED SITES OF THE PATIENT, INTRAMEDULLARY NAIL IS IMPLANTED IN TO THE MEDULLA OF A PATIENT AND BOTH ENDS OF THE NAIL ARE LOCKED (INCLUDING STATIC LOCKING AND DYNAMIC LOCKING)SO AS TO EFFECTIVELY MAINTAIN THE LENGTH OF BONE STRUCTURE, CONTROL SHORTENING AND PROMOTE NORMAL BONY

	HEALING. THE INTRAMEDULLARY NAIL CAN BE USED FOR BONE PATHOLOGICAL STATE OR KNEE JOINT FUSION.,BONE PLATES (NON – STERILE)(CRANIAL MAXILLOFACIAL PLATES SYSTEM)-IT IS SUITABLE FOR LIMBS FACTURE INTERNAL FIXATION WHILE IN ORTHOPEDIC SURGERY. WITH THE DEVELOPMENT OF SCIENCE AND THE EXPANSION OF SURGICAL TREATMENT FOR DISEASES, IN ORDER TO MEET THE CLINICAL NEEDS, MEDICAL EQUIPMENT HAS A GREAT IMPROVEMENT AND DEVELOPMENT. CRANIAL MAXILLOFACIAL PLATES SYSTEM IS ONE OF MICRO PLATE DESIGNED ON THE PHYSIOLOGICAL SHAPE AND BIOMECHANICAL OF HUMAN SKULL, FACIAL AND OTHER PARTS. IT GIVES THE SURGEON A WAY TO MAKE RECONSTRUCTION FRACTURE FIXATION ON BRAIN SECTION, MAXILLOFACIAL. IT IS HELPFUL FOR FRACTURE TREATMENT AND RECONSTRUCTIVE SURGERY. ,BONE PLATES (NON-STERILE) TITANIUM(MONOLOC LOCKING COMPRESSION PLATES 2.7 MM SYSTEM)-IT IS INTENDED TO FIX THE FRACTURED BONES OF PATIENT. IN SURGERY, THEY ARE FASTENED ONTO BONE BY SCREWS OR CERCLAGES.,EXTERNAL FIXATOR (NON STERILE)(EXTERNAL FIXATOR SYSTEM)-IT IS INTENDED TO FIX THE FRACTURED BONES OF PATIENTS DURING THE ORTHOPEDIC SURGERY.,BONE SCREW (NON-STERILE)(SCREWS AND WASHERS)-IT IS INTENDED TO FIX THE FRACTURED BONES OF PATIENTS. IN SURGERY, THEY ARE USED EITHER TO FASTEN BONE PLATES OR SIMILAR DEVICES ONTO BONE, OR, AS COMPRESSION SCREWS, TO HOLD TOGETHER FRAGMENTS OF BONE.,GENERAL SPINE SYSTEM (NON STERILE)(CERES ANTERIOR CERVICAL PLATES SYSTEM)-IT IS INTENDED FOR THE TREATMENT OF PATIENTS' ILLNESSES (FRACTURES, TUMORS, DEGENERATIVE DISEASES, SPONDYLOLISTHESIS AND DEFORMITIES) WHEN INDICATIONS ARE IDENTIFIED THROUGH DIAGNOSIS ON THE PATIENT'S SPINAL DISEASES BY SPINAL SURGEONS .THE SPINAL IMPLANTS CAN PROVIDE AN APPROPRIATE STABILITY UNTIL THE FUSION OF SPINAL SURGICAL SITES,WHICH NOT ONLY MAINTAIN THE INTEGRATION AND FUSION OF A MOTION SEGMENT, BUT ALSO MAINTAIN THE THREE-DIMENSIONAL FORMATION AND BALANCE OF THE SPINAL COLUMN PHYSIOLOGICALLY.,GENERAL SPINE SYSTEM (NON STERILE)(POLYNICES II SPINE SYSTEM)-IT IS INTENDED FOR THE TREATMENT OF PATIENTS' ILLNESSES (FRACTURES, TUMORS, DEGENERATIVE DISEASES, SPONDYLOLISTHESIS AND DEFORMITIES) WHEN INDICATIONS ARE IDENTIFIED THROUGH DIAGNOSIS ON THE PATIENT'S SPINAL DISEASES BY SPINAL SURGEONS .THE SPINAL IMPLANTS CAN PROVIDE AN APPROPRIATE STABILITY UNTIL THE FUSION OF SPINAL SURGICAL SITES,WHICH NOT ONLY MAINTAIN THE INTEGRATION AND FUSION OF A MOTION SEGMENT, BUT ALSO MAINTAIN THE THREE-DIMENSIONAL FORMATION AND BALANCE OF

	THE SPINAL COLUMN PHYSIOLOGICALLY.,BONE PLATES (NON-STERILE) TITANIUM(SYNPLATE SMALL FRAGMENT SYSTEM)-IT IS INTENDED TO FIX THE FRACTURED BONES OF PATIENT. IN SURGERY, THEY ARE FASTENED ONTO BONE BY SCREWS OR CERCLAGES., INTRAMEDULLARY NAILS (NON STERILE)- TITANIUM ALLOY(NEOGEN AR NAILS SYSTEM)-IT IS INTENDED TO FIX THE FRAGMENTS OF LONG TUBULAR BONE. IN CLINICAL APPLICATION, FOLLOWING EXTENSION AND REDUCTION OF THE FRACTURED SITES OF THE PATIENT, INTRAMEDULLARY NAIL IS IMPLANTED IN TO THE MEDULLA OF A PATIENT AND BOTH ENDS OF THE NAIL ARE LOCKED (INCLUDING STATIC LOCKING AND DYNAMIC LOCKING)SO AS TO EFFECTIVELY MAINTAIN THE LENGTH OF BONE STRUCTURE, CONTROL SHORTENING AND PROMOTE NORMAL BONY HEALING. THE INTRAMEDULLARY NAIL CAN BE USED FOR BONE PATHOLOGICAL STATE OR KNEE JOINT FUSION.,BONE PLATES (NON-STERILE) TITANIUM(MONOLOC LOCKING COMPRESSION PLATES 4.5/5.0 MM SYSTEM)-IT IS INTENDED TO FIX THE FRACTURED BONES OF PATIENT. IN SURGERY, THEY ARE FASTENED ONTO BONE BY SCREWS OR CERCLAGES.,BONE PLATES (NON-STERILE) TITANIUM(MONOLOC LOCKING COMPRESSION PLATES 3.5 MM SYSTEM)-IT IS INTENDED TO FIX THE FRACTURED BONES OF PATIENT. IN SURGERY, THEY ARE FASTENED ONTO BONE BY SCREWS OR CERCLAGES.,BONE PINS(NON STERILE)(WIRES AND PINS)-IT IS USED FOR HUMAN BONE FRACTURES, BONE GRAFTING, OSTEOTOMY, ARTHRODESIS FIXED., BONE SCREW (NON-STERILE)(2.4/3.0 HEADLESS COMPRESSION SCREWS)-IT IS INTENDED TO FIX THE FRACTURED BONES OF PATIENTS. IN SURGERY, THEY ARE USED EITHER TO FASTEN BONE PLATES OR SIMILAR DEVICES ONTO BONE, OR, AS COMPRESSION SCREWS, TO HOLD TOGETHER FRAGMENTS OF BONE.,BONE PLATES (NON-STERILE) TITANIUM(SYNPLATE LARGE FRAGMENT SYSTEM)-IT IS INTENDED TO FIX THE FRACTURED BONES OF PATIENT. IN SURGERY, THEY ARE FASTENED ONTO BONE BY SCREWS OR CERCLAGES.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO UNDER MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1228	IMP/MD/2018/000079	1.License Holder Name: HALYARD HEALTH INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLOSED SUCTION SYSTEM FOR ADULTS, DOUBLE SWIVEL ELBOW(HALYARD*)-FOR AIRWAY MANAGEMENT (SUCTIONING) OF PATEINTS WITH ARTIFICIAL AIRWAYS ALLOWING FOR A PATENT AIRWAY.,CLOSED SUCTION SYSTEM FOR ADULTS, DOUBLE SWIVEL ELBOW, DUAL LUMEN (HALYARD*)-FOR AIRWAY MANAGEMENT (SUCTIONING) OF PATEINTS WITH ARTIFICIAL AIRWAYS ALLOWING FOR A PATENT AIRWAY.,MULTI-ACCESS CATHETER(HALYARD*)-FOR SURFACTANT DELIVERY TO THE DISTAL AIRWAY,MINI-BAL SAMPLING CATHETER (HALYARD*)-HALYARD* MINI-BAL SAMPLING CATHETER IS USED IN THE DIAGNOSIS OF LUNG DISEASE BY ALLOWING COLLECTION OF BRONCHOALVEOLAR LAVAGE (BAL) SPECIMENS FROM DEEP WITHIN THE LUNG.,SEAL CASSETTE(HALYARD*)-ACCESSSORY OF HALYARD* MULTI ACCESS PORT CLOSED SUCTION SYSTEM FOR ADULTS.THE SEAL CASETTE IS DESIGNATED AS SINGLE PROCEDURE USE DESIGNED TO BE THE SEALING INTERFACE BETWEEN THE MAP CATHETER AND ALTERNATIVE THERAPY DEVICES TO INCLUDE, BUT NOT LIMITED TO, BRONCHOSCOPES AND BRONCHIAL ASPIRATE SAMPLING CATHETERS.,MULTI-ACCESS PORT REPLACEMENT CATHETER(HALYARD*)-ACCESSSORY OF HALYARD* MULTI ACCESS PORT CLOSED SUCTION SYSTEM FOR ADULTS. THE REPLACEABLE CATHETER IS INTENDED TO BE USED FOR UPTO 72 HOURS.,MULTI-ACCESS PORT CLOSED SUCTION SYSTEM FOR ADULTS, WET PAK* (HALYARD*)-FOR THE INTERMITTENT REMOVAL OF PULMONARY EXUDATES AND SECRETIONS FROM THE ADULT PATEINT'S ARTIFICIAL AIRWAY WITHOUT REQUIRING DISCONNECTION FROM THE MECHANICAL VENTILATOR OR OTHER SUPPORT DEVICES., MULTI-ACCESS PORT CLOSED SUCTION SYSTEM FOR ADULTS, DOUBLE SWIVEL ELBOW(HALYARD*)-FOR THE INTERMITTENT REMOVAL OF PULMONARY EXUDATES AND SECRETIONS FROM THE ADULT PATEINT'S ARTIFICIAL AIRWAY WITHOUT REQUIRING DISCONNECTION FROM THE MECHANICAL VENTILATOR OR OTHER SUPPORT DEVICES.,CLOSED SUCTION SYSTEM FOR NEONATES / PEDIATRICS(HALYARD*)-FOR AIRWAY MANAGEMENT (SUCTIONING) OF PATEINTS WITH ARTIFICIAL AIRWAYS ALLOWING FOR A PATENT AIRWAY.,TURBO-CLEANING CLOSED SUCTION SYSTEM FOR ADULTS, T-PIECE(HALYARD*)-FOR AIRWAY MANAGEMENT (SUCTIONING) OF PATEINTS WITH ARTIFICIAL AIRWAYS ALLOWING FOR A PATENT AIRWAY.,TURBO-CLEANING CLOSED SUCTION SYSTEM FOR ADULTS, DOUBLE SWIVEL ELBOW, WET PAK*(HALYARD*)-FOR AIRWAY MANAGEMENT (SUCTIONING) OF PATEINTS WITH ARTIFICIAL AIRWAYS ALLOWING FOR A PATENT AIRWAY.,TURBO-CLEANING

		CLOSED SUCTION SYSTEM FOR ADULTS, DOUBLE SWIVEL ELBOW (HALYARD*)-FOR AIRWAY MANAGEMENT (SUCTIONING) OF PATEINTS WITH ARTIFICIAL AIRWAYS ALLOWING FOR A PATENT AIRWAY.
1229	IMP/MD/2018/000080	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE GRAFTING MATERIAL(OSSIX™ BONE)-OSSIX BONE IS A STERILE, BIOCOMPATIBLE BONE GRAFTING MATERIAL INTENDED TO FILL, AUGUMENT, OR RECONSTRUCT PERIODONTAL AND BONY DEFECTS OF THE MAXILLO-FACIAL COMPLEX.,RESORBABLE COLLAGEN MEMBRANE(OSSIX® PLUS AND OSSIX® VOLUMAX)-OSSIX® PLUS AND OSSIX® VOLUMAX IS A RESORBABLE COLLAGEN MEMBRANE INTENDED FOR USE DURING THE PROCESS OF GUIDED BONE REGENERATION (GBR) AND GUIDED TISSUE REGENERATION (GTR) AS A BIODEGRADABLE BARRIER

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1230	IMP/MD/2018/000081	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BREAST TISSUE MARKER (SENOMARK ULTRACOR MRI BREAST TISSUE MARKER)-THE SENOMARK ULTRACOR MRI IS INTENDED TO RADIOGRAPHICALLY AND SONOGRAPHICALLY MARK BREAST TISSUE PRIOR TO OR DURING A BREAST BIOPSY PROCEDURE.,BIOPSY NEEDLES (ENCOR ULTRA® BREAST BIOPSY SYSTEM ENCOR ENSPIRE® BREAST BIOPSY SYSTEM)-THE ENCOR BREAST BIOPSY SYSTEM IS INDICATED TO PROVIDE BREAST TISSUE SAMPLES FOR DIAGNOSTIC SAMPLING OF BREAST ABNORMALITIES. • IT IS INTENDED TO PROVIDE BREAST TISSUE FOR HISTOLOGIC EXAMINATION WITH PARTIAL OR COMPLETE REMOVAL OF THE IMAGED ABNORMALITY. • IT IS INTENDED TO PROVIDE BREAST TISSUE FOR HISTOLOGIC EXAMINATION WITH PARTIAL REMOVAL OF A PALPABLE ABNORMALITY. THE EXTENT OF A HISTOLOGIC ABNORMALITY CANNOT ALWAYS BE READILY DETERMINED FROM PALPATION OR IMAGED APPEARANCE. THEREFORE, THE EXTENT OF REMOVAL OF THE PALPATED OR IMAGED EVIDENCE OF AN ABNORMALITY DOES NOT PREDICT THE EXTENT OF REMOVAL OF A HISTOLOGIC ABNORMALITY, E.G., MALIGNANCY. WHEN THE SAMPLED ABNORMALITY IS NOT HISTOLOGICALLY BENIGN, IT IS ESSENTIAL THAT THE TISSUE MARGINS BE EXAMINED FOR COMPLETENESS OF REMOVAL USING STANDARD SURGICAL PROCEDURES. IN INSTANCES WHEN A PATIENT PRESENTS WITH A PALPABLE ABNORMALITY THAT HAS BEEN CLASSIFIED AS BENIGN THROUGH CLINICAL AND/OR RADIOLOGICAL CRITERIA (E.G. FIBROADENOMA, FIBROCYSTIC LESION), THE ENCOR BREAST BIOPSY SYSTEM MAY ALSO BE USED TO PARTIALLY REMOVE SUCH PALPABLE LESIONS. WHENEVER BREAST TISSUE IS REMOVED, HISTOLOGICAL EVALUATION OF THE TISSUE IS THE STANDARD OF CARE. WHEN THE SAMPLED ABNORMALITY IS NOT HISTOLOGICALLY BENIGN, IT IS ESSENTIAL THAT THE TISSUE MARGINS BE EXAMINED FOR COMPLETENESS OF REMOVAL USING STANDARD SURGICAL PROCEDURES. ,BREAST TISSUE MARKER(GEL MARK ULTRACOR BREAST TISSUE MARKER)-THE GEL MARK ULTRACOR IS INTENDED TO RADIOGRAPHICALLY MARK BREAST TISSUE DURING A PERCUTANEOUS BIOPSY PROCEDURE

1231	IMP/MD/2018/000084	1.License Holder Name: OLYMPUS MEDICAL SYSTEM INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BALLOON CATHETER (STONEMASTERV)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE FOR PAPILLOTOMY AND FOR DILATING THE MAJOR PAPILLA TO RETRIEVE BILIARY STONES., BIOPSY FORCEPS -THE BIOPSY FORCEPS HAS BEEN DESIGNED SPECIFICALLY TO COLLECT TISSUE ENDOSCOPICALLY FOR EXAMINATION IN CONJUNCTION WITH A FLEXIBLE OLYMPUS URETERO-RENO SCOPE TRANSURETHRALLY AND A FLEXIBLE OLYMPUS BRONCHOSCOPE.,ASPIRATION NEEDLE(VIZISHOT2)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH ULTRASOUND ENDOSCOPES FOR ULTRASOUND GUIDED FINE NEEDLE ASPIRATION (FNA) OF SUBMUCOSAL AND EXTRAMURAL LESIONS OF THE TRACHEOBRONCHIAL TREE AND THE GASTROINTESTINAL TRACT., LIGATING DEVICE -THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE TO DELIVER A NYLON LOOP SNARE DESIGNED TO PREVENT OR CONTROL BLEEDING FOLLOWING POLYPECTOMY OF PEDUNCULATED POLYPS. ,COAGULATION ELECTRODE-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES TO ELECTROSURGICALLY CAUTERIZE OR TO PERFORM ELECTROSURGICAL HEMOSTASIS WITHIN THE UPPER AIRWAYS, TRACHEOBRONCHIAL TREE AND URINARY ORGANS.,GRASPING FORCEPS-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE TO RETRIEVE FOREIGN BODIES OR RESECTED TISSUE FROM THE URINARY ORGANS TRANSURETHRALLY.,BIOPSY FORCEPS-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE TO ELECTROSURGICALLY COLLECT TISSUE WITHIN THE UPPER AIRWAYS, TRACHEOBRONCHIAL TREE AND URINARY ORGANS., RETRIEVAL BASKET -THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES TO RETRIEVE FOREIGN BODIES, CALCULI OR TISSUE SPECIMENS FROM THE DIGESTIVE TRACT. , HEMOSTASIS FORCEPS(COAGRASPER)-THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES TO CAUTERIZE AND COAGULATE OR TO PERFORM HEMOSTASIS USING HIGH-FREQUENCY CURRENT WITHIN THE DIGESTIVE TRACT., CYTOLOGY BRUSH (BRUSHMASTER V)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES TO COLLECT TISSUE SPECIMENS IN THE PANCREATIC DUCT AND COMMON BILE DUCT. ,ELECTROSURGICAL SNARE(SNAREMASTER)-THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE TO ELECTROSURGICALLY RESECT TISSUE WITHIN THE DIGESTIVE TRACT.,CYTOLOGY BRUSH(NA)-THIS INSTRUMENT HAS

	BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES TO COLLECT TISSUE SPECIMENS IN THE TRACHEOBRONCHIAL TREE., ELECTROSURGICAL SNARE-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPES TO ELECTROSURGICALLY RESECT TISSUE WITHIN THE UPPER AIRWAYS, TRACHEOBRONCHIAL TREE AND URINARY ORGANS., ELECTROSURGICAL KNIFE-SINGLE USE ELECTROSURGICAL KNIFE - IT KNIFE2: THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES AND ELECTROSURGICAL UNITS TO CUT TISSUE USING HIGH-FREQUENCY CURRENT WITHIN THE UPPER DIGESTIVE TRACT. SINGLE USE ELECTROSURGICAL KNIFE - HOOK KNIFE: THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES AND ELECTROSURGICAL UNITS TO CUT TISSUE USING HIGH-FREQUENCY CURRENT WITHIN THE DIGESTIVE TRACT. SINGLE USE ELECTROSURGICAL KNIFE - HOOK KNIFE J & TRIANGLE TIP KNIFE: THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES, ELECTROSURGICAL UNITS TO CUT TISSUE AND COAGULATE OR TO PERFORM HEMOSTASIS USING HIGH-FREQUENCY CURRENT AND FLUSHING DEVICES FOR SUBMUCOSAL INJECTION IN THE DIGESTIVE TRACT. SINGLE USE ELECTROSURGICAL KNIFE – TRIANGLETIP KNIFE J: THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES, ELECTROSURGICAL UNITS TO CUT AND COAGULATE TISSUE USING HIGH-FREQUENCY CURRENT AND FLUSHING DEVICES FOR SUBMUCOSAL INJECTION WITHIN THE DIGESTIVE TRACT. SINGLE USE ELECTROSURGICAL KNIFE - DUALKNIFE: THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES AND ELECTROSURGICAL UNITS TO CUT TISSUE USING HIGH-FREQUENCY CURRENT WITHIN THE DIGESTIVE TRACT. SINGLE USE ELECTROSURGICAL KNIFE - DUALKNIFE J: THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES, ELECTROSURGICAL UNITS TO CUT TISSUE AND COAGULATE OR TO PERFORM HEMOSTASIS USING HIGH-FREQUENCY CURRENT AND FLUSHING DEVICES FOR SUBMUCOSAL INJECTION IN THE DIGESTIVE TRACT.,SPHINCTEROTOME(NEEDLECUT 3V)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE AND ELECTROSURGICAL UNIT FOR PAPILLOTOMY.,SPHINCTEROTOME (FLOWCUT)-THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE FOR PAPILLOTOMY USING HIGH-FREQUENCY CURRENT.,SPHINCTEROTOME(CLEVERCUT3V)-SINGLE USE 3-LUMEN SPHINCTEROTOME V - THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE AND GUIDEWIRE FOR PAPILLOTOMY USING HIGH-FREQUENCY CURRENT. SINGLE USE SPHINCTEROTOME V (DISTAL WIRE GUIDED) - THESE

	INSTRUMENTS (SPHINCTEROTOMES AND GUIDEWIRES) HAVE BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE FOR PAPILLOTOMY USING HIGH-FREQUENCY CURRENT. THE PRELOADED GUIDEWIRE IS USED FOR GUIDING AND EXCHANGING ENDOSCOPIC ACCESSORIES FOR BILIARY DUCT, INCLUDING BUT NOT LIMITED TO THE COMMON BILE, CYSTIC, PANCREATIC AND RIGHT AND LEFT HEPATIC DUCTS.

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1232	IMP/MD/2018/000084	1.License Holder Name: OLYMPUS MEDICAL SYSTEMS INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOPSY FORCEPS(NA)-FB-19C-1 & FB-19K-1: THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE TO COLLECT TISSUE WITHIN THE DIGESTIVE TRACT, UPPER AIRWAYS, TRACHEOBRONCHIAL TREE, FEMALE REPRODUCTIVE ORGANS AND URINARY ORGANS. FB-56D-1: THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE TO COLLECT TISSUE WITHIN THE DIGESTIVE TRACT, RESPIRATORY ORGANS, FEMALE REPRODUCTIVE TRACT AND URINARY ORGANS. FB-20C-1 & FB-24U-1: THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE TO COLLECT TISSUE WITHIN THE DIGESTIVE TRACT AND RESPIRATORY ORGANS. FB-25K-1: THIS INSTRUMENT HAVE BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE TO COLLECT TISSUE WITHIN THE DIGESTIVE TRACT.,ELECTROSURGICAL CUTTING & COAGULATION DEVICE(THUNDER BEAT)-THE THUNDERBEAT HAND INSTRUMENT IS INTENDED TO BE USED WITH THE ULTRASONIC GENERATOR (USG-400), THE ELECTROSURGICAL GENERATOR (ESG-400), AND THE THUNDERBEAT TRANSDUCER, (TD TB400). SEAL & CUT MODE: THE THUNDERBEAT HAND INSTRUMENT WHEN USED IN COMBINATION WITH THE SEAL & CUT MODE IS INDICATED FOR OPEN GENERAL SURGERY AND GYNECOLOGICAL SURGERY (INCLUDING UROLOGIC, THORACIC, PLASTIC AND RECONSTRUCTIVE, BOWEL RESECTIONS, CHOLECYSTECTOMIES, NISSEN FUNDOPLICATION, ADHESIOLYSIS, OOPHORECTOMY, HYSTERECTOMIES (BOTH VAGINAL ASSISTED AND ABDOMINAL) ETC) OR IN ANY PROCEDURE IN WHICH CUTTING, VESSEL LIGATION (SEALING AND CUTTING), COAGULATION, GRASPING, AND DISSECTION IS PERFORMED. THE DEVICE HAS BEEN DESIGNED TO SEAL AND CUT VESSELS (UP TO AND INCLUDING 7 MM IN DIAMETER), TISSUE BUNDLES, AND LYMPHATICS. SEAL MODE: THE THUNDERBEAT HAND INSTRUMENT WHEN USED IN COMBINATION WITH THE SEAL MODE IS INDICATED FOR OPEN GENERAL SURGERY AND GYNECOLOGICAL SURGERY (INCLUDING UROLOGIC, THORACIC, PLASTIC AND RECONSTRUCTIVE, BOWEL RESECTIONS, CHOLECYSTECTOMIES, NISSEN FUNDOPLICATION, ADHESIOLYSIS, OOPHORECTOMY, HYSTERECTOMIES (BOTH VAGINAL ASSISTED AND ABDOMINAL) ETC) OR IN ANY PROCEDURE IN WHICH VESSEL SEALING, COAGULATION, GRASPING IS PERFORMED. THE DEVICE HAS BEEN DESIGNED TO SEAL VESSELS (UP TO AND INCLUDING 7 MM IN DIAMETER), TISSUE BUNDLES, AND LYMPHATICS. THE THUNDERBEAT HAND INSTRUMENT HAS NOT BEEN SHOWN TO BE EFFECTIVE FOR TUBAL STERILIZATION OR TUBAL COAGULATION FOR STERILIZATION PROCEDURES, AND SHOULD NOT BE USED FOR

	THESE PROCEDURES.,LIGATING DEVICE(EZ CLIP)-THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE FOR ENDOSCOPIC CLIP PLACEMENT WITHIN THE GASTROINTESTINAL (GI) TRACT FOR THE PURPOSE OF; (1) ENDOSCOPIC MARKING, (2) HEMOSTASIS FOR (A) MUCOSAL/SUB-MUCOSAL DEFECTS 3 CM, (B) BLEEDING ULCERS, (C) ARTERIES 2 MM, (D) POLYPS 1.5 CM IN DIAMETER, (E) DIVERTICULA IN THE COLON, (3) AS A SUPPLEMENTARY METHOD, CLOSURE OF GI TRACT LUMINAL PERFORATIONS 20 MM THAT CAN BE TREATED CONSERVATIVELY., ELECTROSURGICAL SNARE(SNAREMASTER PLUS)-THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE FOR THE REMOVAL AND/OR CAUTERIZATION OF DIMINUTIVE POLYPS, SESSILE POLYPS, PEDUNCULATED POLYPS AND TISSUE FROM WITHIN THE GI TRACT.,DISPOSABLE BIOPSY FORCEPS (ENDOJAW)-THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE TO COLLECT TISSUE WITHIN THE DIGESTIVE TRACT.,ELECTROSURGICAL CUTTING & COAGULATION DEVICE(THUNDER BEAT)-THE THUNDERBEAT OPEN FINE JAW HAND INSTRUMENT IS INTENDED TO BE USED WITH THE ULTRASONIC GENERATOR (USG-400), THE ELECTROSURGICAL GENERATOR (ESG-400), AND THE THUNDERBEAT TRANSDUCER (TD-TB400). SEAL & CUT MODE: THE THUNDERBEAT OPEN FINE JAW HAND INSTRUMENT WHEN USED IN COMBINATION WITH THE SEAL & CUT MODE IS INDICATED FOR OPEN, GENERAL SURGERY (INCLUDING PLASTIC AND RECONSTRUCTIVE, ETC) OR IN ANY PROCEDURE IN WHICH CUTTING, VESSEL LIGATION (SEALING AND CUTTING), COAGULATION, GRASPING, AND DISSECTION IS PERFORMED. THE DEVICE HAS BEEN DESIGNED TO SEAL AND CUT VESSELS (UP TO AND INCLUDING 7 MM IN DIAMETER), TISSUE BUNDLES, AND LYMPHATICS. THIS MODE IS ALSO INDICATED FOR OPEN ENT PROCEDURE IN ADULTS (THYROIDECTOMY, PARATHYROIDECTOMY, PAROTIDECTOMY, AND TONSILLECTOMY) FOR ONLY LIGATION (SEALING AND CUTTING) OF VESSELS, LYMPHATICS AND TISSUE BUNDLES 2-3 MM *1 AWAY FROM UNINTENDED THERMALLY SENSITIVE STRUCTURES SUCH AS NERVES AND PARATHYROID GLANDS. SEAL MODE: THE THUNDERBEAT OPEN FINE JAW HAND INSTRUMENT WHEN USED IN COMBINATION WITH THE SEAL MODE IS INDICATED FOR OPEN, GENERAL SURGERY (INCLUDING PLASTIC AND RECONSTRUCTIVE, ETC) OR IN ANY PROCEDURE IN WHICH VESSEL SEALING, COAGULATION, GRASPING IS PERFORMED. THE DEVICE HAS BEEN DESIGNED TO SEAL VESSELS (UP TO AND INCLUDING 7 MM IN DIAMETER), TISSUE BUNDLES, AND LYMPHATICS. THIS MODE IS ALSO INDICATED FOR OPEN ENT PROCEDURE IN ADULTS (THYROIDECTOMY, PARATHYROIDECTOMY, PAROTIDECTOMY, AND TONSILLECTOMY) FOR SEALING OF VESSELS,

	LYMPHATICS AND TISSUE BUNDLES 2-3 MM *1 AWAY FROM UNINTENDED THERMALLY SENSITIVE STRUCTURES SUCH AS NERVES AND PARATHYROID GLANDS. THE THUNDERBEAT OPEN FINE JAW HAND INSTRUMENT HAS NOT BEEN SHOWN TO BE EFFECTIVE FOR TUBAL STERILIZATION OR TUBAL COAGULATION FOR STERILIZATION PROCEDURES, AND SHOULD NOT BE USED FOR THESE PROCEDURES.,LIGATING CLIP(EZ CLIP)-THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE FOR ENDOSCOPIC CLIP PLACEMENT WITHIN THE GASTROINTESTINAL (GI) TRACT FOR THE PURPOSE OF; (1) ENDOSCOPIC MARKING, (2) HEMOSTASIS FOR (A) MUCOSAL/SUB-MUCOSAL DEFECTS 3 CM, (B) BLEEDING ULCERS, (C) ARTERIES 2 MM, (D) POLYPS 1.5 CM IN DIAMETER, (E) DIVERTICULA IN THE COLON, (3) AS A SUPPLEMENTARY METHOD, CLOSURE OF GI TRACT LUMINAL PERFORATIONS 20 MM THAT CAN BE TREATED CONSERVATIVELY., CATHETER(MULTI-3 V PLUS)-THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES TO ENDOSCOPICALLY REMOVE STONES SUCH AS CALCULI, PANCREATIC AND COMMON BILE DUCT STONES, TO REMOVE BILE SLUDGE FROM THE BILIARY SYSTEM AND TO FACILITATE INJECTION OF CONTRAST MEDIUM INTO THE BILIARY SYSTEM.,BIOPSY FORCEPS(SWINGJAW)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE TO COLLECT TISSUE WITHIN THE DIGESTIVE TRACT, RESPIRATORY ORGANS.,ASPIRATION NEEDLE(VIZISHOT 2)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH ULTRASOUND ENDOSCOPES FOR ULTRASOUND GUIDED FINE NEEDLE ASPIRATION (FNA) OF SUB MUCOSAL AND EXTRAMURAL LESIONS OF THE TRACHEOBRONCHIAL TREE AND THE GASTROINTESTINAL TRACT.,LIGATING DEVICE(NA)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE TO DELIVER A NYLON LOOP SNARE DESIGNED TO PREVENT OR CONTROL BLEEDING FOLLOWING POLYPECTOMY OF PEDUNCULATED POLYPS., ASPIRATION NEEDLE(EZ SHOT 3 PLUS)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ULTRASOUND ENDOSCOPE FOR ULTRASONICALLY GUIDED FINE NEEDLE ASPIRATION FNA AND FINE NEEDLE BIOPSY FNB OF SUBMUCOSAL AND EXTRAMURAL LESIONS WITHIN THE GASTROINTESTINAL TRACT I.E. PANCREATIC MASSES & MEDIASTINAL MASSES & PERIRECTAL MASSES AND LYMPH NODES.,BASKET GRASPER(TETRACATCH V)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES TO RETRIEVE FOREIGN BODIES, CALCULI OR TISSUE SPECIMENS FROM THE DIGESTIVE TRACT.,GUIDE SHEATH KIT (GUIDESHEATH KIT 2)-THESE INSTRUMENTS HAVE BEEN DESIGNED TO BE USED WITH OLYMPUS BRONCHOSCOPES, ENDOTHERAPY

	ACCESSORIES, AND/OR ULTRASONIC PROBES TO GUIDE THE ENDOTHERAPY ACCESSORIES AND/OR THE ULTRASONIC PROBES TO THE TARGET AREA WITHIN THE RESPIRATORY ORGANS AND COLLECT TISSUE, SPECIMENS, OR CELLS ENDOSCOPICALLY.,GUIDING FORCEPS(NA)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE AND GUIDE SHEATH TO GUIDE THE GUIDE SHEATH TO RESPIRATORY ORGANS AND TO COLLECT SPECIMENS WITHIN THE RESPIRATORY ORGANS.,ASPIRATION NEEDLE(VIZISHOT)-NA-201SX-4021- THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH ULTRASOUND ENDOSCOPES FOR ULTRASOUND GUIDED FINE NEEDLE ASPIRATION (FNA) OF SUBMUCOSAL AND EXTRAMURAL LESIONS OF THE TRACHEOBRONCHIAL TREE AND THE ESOPHAGUS. DO NOT USE THIS INSTRUMENT FOR ANY PURPOSE OTHER THAN ITS INTENDED USE. NA-201SX-4022- THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH ULTRASOUND ENDOSCOPES FOR ULTRASOUND GUIDED FINE NEEDLE ASPIRATION (FNA) OF SUBMUCOSAL AND EXTRAMURAL LESIONS OF THE TRACHEOBRONCHIAL TREE. DO NOT USE THIS INSTRUMENT FOR ANY PURPOSE OTHER THAN ITS INTENDED USE.,LOOP(NA)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE TO DELIVER A NYLON LOOP SNARE DESIGNED TO PREVENT OR CONTROL BLEEDING FOLLOWING POLYPECTOMY OF PEDUNCULATED POLYPS., DISPOSABLE NEEDLE(NEEDLEMASTER)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE TO PERFORM ENDOSCOPIC VASCULAR OR SUBMUCOSAL INJECTION IN THE GI TRACT.,GRASPING FORCEPS(NA)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES IN RETRIEVING FOREIGN BODIES OR TISSUE SPECIMENS FROM WITHIN THE DIGESTIVE TRACT, UPPER AIRWAYS, TRACHEOBRONCHIAL TREE, FEMALE REPRODUCTIVE AND URINARY ORGANS.,GRASPING FORCEPS(NA)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES IN RETRIEVING DRAINAGE TUBE OR FOREIGN BODIES FROM THE DIGESTIVE TRACT.,BIOPSY FORCEPS (ENDOJAW)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE TO COLLECT TISSUE WITHIN THE UPPER AIRWAYS AND TRACHEOBRONCHIAL TREE.,GRASPING FORCEPS(NA)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES TO RETRIEVE FOREIGN BODIES, CALCULI OR TISSUE SPECIMENS FROM THE DIGESTIVE TRACT, URINARY TRACT, FEMALE REPRODUCTIVE TRACT AND RESPIRATORY ORGANS.,LITHOTRIPTOR(LITHOCRUSHV)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ENDOSCOPE FOR CRUSHING CALCULI INSIDE THE BILE DUCT.,SURGICAL TISSUE

	MANAGEMENT SYSTEM(ULTRASONIC GENERATOR)-THE ULTRASONIC GENERATOR (USG-400) IS INTENDED TO BE USED WITH THE ELECTROSURGICAL GENERATOR (ESG-400), THE THUNDERBEAT TRANSDUCER (TDTB400), THE SONICBEAT TRANSDUCER (TD-SB400), THE THUNDERBEAT, AND/ OR THE SONICBEAT FOR OPEN, LAPAROSCOPIC (INCLUDING SINGLE-SITE SURGERY), AND ENDOSCOPIC SURGERY TO CUT (DISSECT) OR COAGULATE SOFT TISSUE OR TO LIGATE (SEAL AND CUT) VESSELS.,BASKET GRASPER (NA)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES TO RETRIEVE FOREIGN BODIES, CALCULI OR RESECTED TISSUE FROM WITHIN THE DIGESTIVE TRACT AND RESPIRATORY ORGANS.,BASKET GRASPER(NA)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOSCOPES TO RETRIEVE FOREIGN BODIES, CALCULUS OR TISSUE SPECIMENS FROM THE DIGESTIVE TRACT.,TROCAR(NA)-THIS PRODUCT HAS BEEN DESIGNED TO BE USED WITH LTF-160, LTF-240 OR LTF-260 TO DO THORACOSCOPIC EXAMINATION.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1233	IMP/MD/2018/000086	1.License Holder Name: 3M INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISINFECTING CAP(3M CUROS STOPPER DISINFECTING CAP STRIP (RED) FOR OPEN FEMALE LUERS)-INTENDED TO USE FOR ONLY ON OPEN FEMALE LUERS SUCH AS CATHETER HUBS AND STOPCOCKS. AFTER APPLICATION, IT ACTS AS AN EXTERNAL DISINFECTING CLEANER PRIOR TO IV ACCESS AND AS A COVER BETWEEN LINE ACCESS. IN 1 MINUTE AFTER APPLICATION THE CAP WILL DISINFECT THE CONNECTION AND PROTECT FROM CONTAMINATION BETWEEN ACCESSES FOR UPTO 7 DAYS IF NOT REMOVED. THIS CAP MAY BE USED IN THE HOME OR HEALTHCARE FACILITY.,DISINFECTING CAP FOR NEEDLELESS CONNECTORS(3M CUROS DISINFECTING CAP FOR TEGO® HEMODIALYSIS CONNECTORS)-THE CUROS™ DISINFECTING CAP IS INTENDED FOR USE ON NEEDLELESS CONNECTORS ONLY AS A DISINFECTING CLEANER PRIOR TO I.V. ACCESS AND TO ACT AS A COVER BETWEEN LINE ACCESSES. THE CAP WILL DISINFECT THE NEEDLELESS CONNECTOR ONE (1) MINUTE AFTER APPLICATION AND PROTECT FROM CONTAMINATION BETWEEN ACCESSES FOR UP TO SEVEN (7) DAYS IF NOT REMOVED. THE CAP MAY BE USED IN THE HOME OR HEALTHCARE FACILITY.,DISINFECTING CAP FOR NEEDLELESS CONNECTORS(3M CUROS DISINFECTING CAP STRIP FOR NEEDLELESS CONNECTORS)-THE CUROS™ DISINFECTING CAP IS INTENDED FOR USE ON NEEDLELESS CONNECTORS ONLY AS A DISINFECTING CLEANER PRIOR TO I.V. ACCESS AND TO ACT AS A COVER BETWEEN LINE ACCESSES. THE CAP WILL DISINFECT THE NEEDLELESS CONNECTOR ONE (1) MINUTE AFTER APPLICATION AND PROTECT FROM CONTAMINATION BETWEEN ACCESSES FOR UP TO SEVEN (7) DAYS IF NOT REMOVED. THE CAP MAY BE USED IN THE HOME OR HEALTHCARE FACILITY.,DISINFECTING CAP FOR NEEDLELESS CONNECTORS(3M CUROS TIPS DISINFECTING CAP STRIP FOR MALE LUERS)-THE CUROS TIPS™ DISINFECTING CAP IS INTENDED FOR USE AS A DISINFECTING CLEANER ON MALE LUER CONNECTIONS ONLY AND TO ACT AS A COVER BETWEEN LINE ACCESSES. THE CUROS TIPS DISINFECTING CAP WILL DISINFECT THE MALE LUER ONE (1) MINUTE AFTER APPLICATION AND PROTECT FROM CONTAMINATION BETWEEN ACCESSES FOR UP TO SEVEN (7) DAYS IF NOT REMOVED. THE CUROS TIP DISINFECTING CAP MAY BE USED IN THE HOME OR HEALTHCARE FACILITY.,DISINFECTING CAP FOR NEEDLELESS CONNECTORS(3M CUROS DISINFECTING CAP FOR NEEDLELESS CONNECTORS)-THE CUROS™ DISINFECTING CAP IS INTENDED FOR USE ON NEEDLELESS CONNECTORS ONLY AS A DISINFECTING CLEANER PRIOR TO I.V. ACCESS AND TO ACT AS A COVER BETWEEN LINE ACCESSES. THE CAP WILL DISINFECT THE

	NEEDLELESS CONNECTOR ONE (1) MINUTE AFTER APPLICATION AND PROTECT FROM CONTAMINATION BETWEEN ACCESSES FOR UP TO SEVEN (7) DAYS IF NOT REMOVED. THE CAP MAY BE USED IN THE HOME OR HEALTHCARE FACILITY.,DISINFECTING CAP FOR NEEDLELESS CONNECTORS(3M CUROS JET DISINFECTING CAP STRIP FOR NEEDLELESS CONNECTORS)-THE CUROS™ JET™ DISINFECTING CAP IS INTENDED FOR USE ON NEEDLELESS CONNECTORS ONLY AS A DISINFECTING CLEANER PRIOR TO I.V. ACCESS AND TO ACT AS A COVER BETWEEN LINE ACCESSES. THE CAP WILL DISINFECT THE NEEDLELESS CONNECTOR ONE (1) MINUTE AFTER APPLICATION AND PROTECT FROM CONTAMINATION BETWEEN ACCESSES FOR UP TO SEVEN (7) DAYS IF NOT REMOVED. THE CAP MAY BE USED IN THE HOME OR HEALTHCARE FACILITY.,DISINFECTING CAP FOR NEEDLELESS CONNECTORS(3M CUROS JET DISINFECTING CAP FOR NEEDLELESS CONNECTORS)-THE CUROS™ JET™ DISINFECTING CAP IS INTENDED FOR USE ON NEEDLELESS CONNECTORS ONLY AS A DISINFECTING CLEANER PRIOR TO I.V. ACCESS AND TO ACT AS A COVER BETWEEN LINE ACCESSES. THE CAP WILL DISINFECT THE NEEDLELESS CONNECTOR ONE (1) MINUTE AFTER APPLICATION AND PROTECT FROM CONTAMINATION BETWEEN ACCESSES FOR UP TO SEVEN (7) DAYS IF NOT REMOVED. THE CAP MAY BE USED IN THE HOME OR HEALTHCARE FACILITY.,DISINFECTING CAP(3M CUROS STOPPER DISINFECTING CAP STRIP (TEAL) FOR OPEN FEMALE LUERS)-INTENDED TO USE FOR ONLY ON OPEN FEMALE LUERS SUCH AS CATHETER HUBS AND STOPCOCKS. AFTER APPLICATION, IT ACTS AS AN EXTERNAL DISINFECTING CLEANER PRIOR TO IV ACCESS AND AS A COVER BETWEEN LINE ACCESS. IN 1 MINUTE AFTER APPLICATION THE CAP WILL DISINFECT THE CONNECTION AND PROTECT FROM CONTAMINATION BETWEEN ACCESSES FOR UPTO 7 DAYS IF NOT REMOVED. THIS CAP MAY BE USED IN THE HOME OR HEALTHCARE FACILITY.,DISINFECTING CAP(3M CUROS STOPPER DISINFECTING CAP (TEAL) FOR OPEN FEMALE LUERS)-INTENDED TO USE FOR ONLY ON OPEN FEMALE LUERS SUCH AS CATHETER HUBS AND STOPCOCKS. AFTER APPLICATION, IT ACTS AS AN EXTERNAL DISINFECTING CLEANER PRIOR TO IV ACCESS AND AS A COVER BETWEEN LINE ACCESS. IN 1 MINUTE AFTER APPLICATION THE CAP WILL DISINFECT THE CONNECTION AND PROTECT FROM CONTAMINATION BETWEEN ACCESSES FOR UPTO 7 DAYS IF NOT REMOVED. THIS CAP MAY BE USED IN THE HOME OR HEALTHCARE FACILITY.,DISINFECTING CAP(3M CUROS STOPPER DISINFECTING CAP (RED) FOR OPEN FEMALE LUERS)-INTENDED TO USE FOR ONLY ON OPEN FEMALE LUERS SUCH AS CATHETER HUBS AND STOPCOCKS. AFTER APPLICATION, IT ACTS AS AN EXTERNAL DISINFECTING CLEANER PRIOR TO IV ACCESS AND AS A COVER BETWEEN LINE

		ACCESS. IN 1 MINUTE AFTER APPLICATION THE CAP WILL DISINFECT THE CONNECTION AND PROTECT FROM CONTAMINATION BETWEEN ACCESSES FOR UPTO 7 DAYS IF NOT REMOVED. THIS CAP MAY BE USED IN THE HOME OR HEALTHCARE FACILITY.
1234	IMP/MD/2018/000088	1.License Holder Name: MACO PHARMA INDIA TRANSFUSION SOLUTIONS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STORAGE SOLUTION FOR PLATELETS - SSP+(STORAGE SOLUTION FOR PLATELETS - SSP+)-THE PLATELET ADDITIVE SOLUTIONS SSP AND SSP+ ARE DESIGNED TO PARTIALLY REPLACE PLASMA IN THE PREPARATION AND STORAGE OF BUFFY-COAT DERIVED PLATELET CONCENTRATES OR APHERESIS PLATELET UNITS
1235	IMP/MD/2018/000089	1.License Holder Name: COOK INDIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BILIARY STENT (ZILVER 635® BILIARY STENT)-THE ZILVER 635® BILIARY STENT IS USED IN PALLIATION OF MALIGNANT NEOPLASMS IN THE BILIARV TREE.
1236	IMP/MD/2018/000089	1.License Holder Name: M/S COOK INDIA MEDICAL DEVICES PVT. LTD. , PLOT NO 22(SP), THIRD AND FOURTH FLOOR, KOCHAR JADE, THIRU VI KA INDUSTRIAL ESTATE, GUINDY TALUK ,CHENNAI TAMIL NADU , 600032 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIGH DEFINITION ENDOBRONCHIAL ULTRASOUND NEEDLE(ECHOTIP PROCORE ENDOBRONCHIAL HIGH DEFINITION ULTRASOUND BIOPSY NEEDLE)-IT IS USED WITH AN ULTRASOUND ENDOSCOPE FOR FINE NEEDLE BIOPSY (FNB), OF SUBMUCOSAL AND EXTRAMURAL LESIONS WITHIN OR ADJACENT TO THE TRACHEOBRONCHIAL TREE OR GASTROINTESTINAL TRACT.

1237	IMP/MD/2018/000090	1.License Holder Name: DIAGAST 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAG-PLATES(MAG-PLATES)-EMPTY MICROPLATES FOR DILUTION OF RED BLOOD CELLS, USED WITH AN AUTOMATED TECHNIQUE QWALYS IN E.M.T. THESE MICROPLATES ARE USED FOR DILUTION OF TESTS FOR IMMUNO-HEMATOLOGY TESTS.,D-PLATES(D-PLATES)-EMPTY MICROPLATES FOR DILUTION OF RED BLOOD CELLS, USED WITH AN AUTOMATED TECHNIQUE QWALYS IN E.M.T. THESE MICROPLATES ARE USED FOR DILUTION OF TESTS FOR IMMUNO-HEMATOLOGY TESTS.,HEMA CQI (HEMA CQI)-HEMA CQI IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE (IVDMD) OF HUMAN ORIGIN FOR PROFESSIONAL USE. HEMA CQI IS AN INTERNAL QUALITY CONTROL. IT IS ADDED TO THE GROUPING SERIES (ERYTHROCYTE TEST AND PLASMA TEST) ABO-RH1 OR PHENOTYPING SERIES RH-K. ITS USE ENABLES DETECTION OF ANOMALIES (HANDLING, REAGENTS, APPARATUS AND ENVIRONMENT) AND IMPLEMENTATION OF CORRECTIVE ACTIONS, GROUPA DVI LYS(GROUPA DVI LYS)-THESE REAGENTS KITS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THEY ARE USED FOR ABO-RH1 GROUPING OF HUMAN RED BLOOD CELLS. - GROUPA DVI LYS ENABLES DETERMINATION OF THE PRESENCE OF ERYTHROCYTIC ANTIGENS A, B AND D. IT CAN ENABLE THE IDENTIFICATION OF PHENOTYPE PARTIAL D OF TYPE DVI, A VARIANT CATEGORY OF ANTIGEN D. THESE DEVICES, INTENDED FOR ABO GROUPING, MUST BE USED WITH HEMALYS OR RED BLOOD CELLS MAGNETIZED ACCORDING TO THE RECOMMENDATIONS OF DIAGAST FOR THE REALIZATION OF THE PLASMA TEST (REVERSE GROUP). THESE DEVICES ARE FOR USE ON THE AUTOMATED MACHINES QWALYS® AND/OR ON MANUAL WORKSTATIONS FREELYS® NANO AND FREELYS® IN THE EM® TECHNOLOGY METHOD.,HEMALYS 1 A1,B(HEMALYS 1 A1,B)-THESE REAGENT KITS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THEY ARE INTENDED FOR THE ANALYSIS OF HUMAN BIOLOGICAL SPECIMENS. HEMALYS IS USED IN THE PLASMA TEST FOR ABO BLOOD GROUPING. AFTER HAVING TESTED FOR ERYTHROCYTIC ANTIGENS IN THE ERYTHROCYTE TEST, HEMALYS ENABLES VERIFICATION OF THE PRESENCE OF THE CORRESPONDING ANTIBODIES IN THE TEST PLASMA. THESE DEVICES ARE READY TO USE AND CAN BE USED DIRECTLY ON EM® TECHNOLOGY (ERYTHROCYTES MAGNETIZED TECHNOLOGY) ON THE AUTOMATED MACHINES QWALYS® OR ON MANUAL WORKSTATIONS FREELYS®NANO AND FREELYS®.,HEMA-IDENT(HEMA-IDENT)-HEMA-IDENT IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE (IVDMD) FOR PROFESSIONAL USE. HEMA-IDENT IS A KIT OF RED BLOOD CELLS FOR

	IDENTIFICATION OF IRREGULAR ANTIERYTHROCYTIC ANTIBODIES IN HUMAN SERUM OR PLASMA. HEMA-IDENT IS USED IN EM® TECHNOLOGY (ERYTHROCYTES MAGNETIZED TECHNOLOGY) ON THE FULLY AUTOMATED QWALYS® MACHINES.,IRON MAG(IRON MAG)-IRONMAG IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE (IVDMD) FOR PROFESSIONAL USE. IT IS DESIGNED FOR ANALYSES OF HUMAN BIOLOGICAL SAMPLES. IT IS USED FOR THE MAGNETIZATION OF RED BLOOD CELLS IN EM® TECHNOLOGY (ERYTHROCYTES MAGNETIZED® TECHNOLOGY) AND MUST ONLY BE USED ON QWALYS® AUTOMATED SYSTEM AND WITH ITS ASSOCIATED REAGENTS,LISS(LISS)-THIS REAGENT IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE (IVDMD) FOR PROFESSIONAL USE. LISS (LOW-IONIC-STRENGTH SOLUTION) IS A BUFFERED SALINE SOLUTION USED TO PREPARE HUMAN RED BLOOD CELL SUSPENSIONS. IT IS A COMPLEMENTARY REAGENT FOR VARIOUS IMMUNOHAEMATOLOGICAL METHODS.,MAGLYS(MAGLYS)-MAGLYS IS A MAGNETIZING SOLUTION FOR BLOOD CELL PREPARATIONS. RED BLOOD CELLS PUT IN SUSPENSION IN MAGLYS BECOME SENSITIVE TO MAGNETIC FIELD VARIATIONS, AS FOR EXAMPLE IN A MICROPLATE DEPOSITED ON BATTERY-POWERED MAGNETS. THE RED BLOOD CELLS THUS TREATED MIGRATE TO THE BOTTOM OF THE WELLS OF THE MICROPLATE.,HEMASCREEN(HEMASCREEN)-HEMASCREEN IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE (IVDMD) FOR PROFESSIONAL USE. HEMASCREEN IS USED FOR SCREENING OF IRREGULAR ANTIERYTHROCYTIC ANTIBODY IN HUMAN SERUM OR PLASMA. THIS KIT IS USED IN ONLY EM® TECHNOLOGY (ERYTHROCYTE MAGNETISED TECHNOLOGY) ON THE FREELYS® NANO WORKSTATIONS WITH SCREENLYS AND ON THE FULLY AUTOMATED QWALYS®MACHINES WITH SCREENLYS, SCREENLYS 2 OR CROSSLYS.,AGH MAESTRIA IGG + C3D(AGH MAESTRIA IGG + C3D)-THE REAGENTS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THEY ARE INTENDED FOR THE ANALYSIS OF HUMAN BIOLOGICAL SPECIMENS. AGH MAESTRIA IGG+C3D IS USED FOR ERYTHROCYTE PHENOTYPING WITH BLOOD PHENOTYPING REAGENTS, IN TESTING FOR IMMUNE ANTIBODIES REQUIRING AN INDIRECT ANTIGLOBULIN TEST METHOD. AGH MAESTRIA IGG+C3D, AGH MAESTRIA IGG AND AGH MAESTRIA C3D ARE USED IN THE DIRECT ANTIGLOBULIN TEST (DIRECT COOMBS' TEST) ON HUMAN RED BLOOD CELLS. - AGH MAESTRIA IGG+C3D: IN ADDITION TO RECOGNIZING IGG ANTIBODIES, IS ABLE TO RECOGNIZE (LIKE AGH MAESTRIA C3D) IGM ANTIBODIES ON THE SURFACE OF RED BLOOD CELLS SINCE IGM ANTIBODIES ALWAYS FIX COMPLEMENT IN VIVO (AND IN VITRO IF THE REACTION OCCURS IN THE PRESENCE OF COMPLEMENT: I.E. WHEN USING A FRESH SAMPLE).,MAGNELYS

	(MAGNELYS)-MAGNELYS IS AN IN VITRO MEDICAL DIAGNOSTIC DEVICE (IVDMD) FOR PROFESSIONAL USE. IT IS DESIGNED FOR ANALYSES OF HUMAN BIOLOGICAL SAMPLES. IT IS USED FOR THE MAGNETIZATION OF RED BLOOD CELLS.,PAD BUFFER(PAD BUFFER)-PAD BUFFER AND PAD BUFFER 500 ARE IN-VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THEY ARE USED IN COMBINATION WITH THE PAD® DEVICES AS A REAGENT ACTIVATION AND REVELATION BUFFER FOR THE RESULTS. THEY ARE BASED ON M-TRAP® TECHNOLOGY, WHICH DETECTS A REACTION BETWEEN AN ERYTHROCYTE ANTIGEN AND AN ANTIBODY FROM A WHOLE BLOOD SAMPLE OR AN ERYTHROCYTE CONCENTRATE / PELLET DIRECTED SPECIFICALLY AGAINST THIS ANTIGEN. THIS TECHNIQUE IS BASED ON AN IMMUNOBLOTTING TEST USING SPOTS. THE TESTED RED BLOOD CELLS, CARRYING AN ANTIGEN, INTERACT WITH THE CORRESPONDING ANTIBODIES, REVEALING A RED COLORED SPOT. THE ERYTHROCYTES WHICH DO NOT CARRY THE ANTIGEN, DO NOT INTERACT WITH THE ANTIBODIES AND CROSS THE MEMBRANE. THE SPOT WILL APPEAR LIGHT GREEN OR WHITE, SCREENLYS(SCREENLYS)-SCREENLYS IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE (IVDMD) FOR PROFESSIONAL USE. SCREENLYS IS USED WITH HEMASCREEN FOR SCREENING, WITH HEMA-IDENTEXT OR HEMA-IDENT FOR IDENTIFICATION OF IRREGULAR ANTIERYTHROCYTIC ANTIBODIES WITH HEMASCREEN POOL FOR SCREENING OF ANTIERYTHROCYTIC ANTIBODIES IN HUMAN SERUM OR PLASMA. THIS KIT IS ONLY USED IN EM® TECHNOLOGY (ERYTHROCYTE MAGNETISED TECHNOLOGY). THE ANTIBODY SCREENING CAN BE CARRIED OUT ON AUTOMATED MACHINES QWALYS® AND/OR ON MANUAL WORKSTATIONS FREELYS® NANO. THE ANTIBODY IDENTIFICATION CAN ONLY BE CARRIED OUT ON THE AUTOMATED MACHINES QWALYS®.,DC-LYS(DC-LYS)-DC-LYS IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE (IVDMD) FOR PROFESSIONAL USE TO PERFORM THE DIRECT ANTIGLOBULIN TEST. DC-LYS SHOULD BE ONLY USED IN E.M.® TECHNOLOGY (ERYTHROCYTES MAGNETIZED TECHNOLOGY) ON FULLY AUTOMATED MACHINE QWALYS® IN COMBINAISON WITH ASSOCIATED DEVICES. THIS TEST SHOWS THE IN VIVO SENSITIZATION OF THE HUMAN RED BLOOD CELLS BY SOME IGG ANTI-ERYTHROCYTES ANTIBODIES AND/OR BY COMPONENT C3D OF THE COMPLEMENT SYSTEM.,AGH MAESTRIA IGG (AGH MAESTRIA IGG)-THE REAGENTS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THEY ARE INTENDED FOR THE ANALYSIS OF HUMAN BIOLOGICAL SPECIMENS. AGH MAESTRIA IGG ARE USED FOR ERYTHROCYTE PHENOTYPING WITH BLOOD PHENOTYPING REAGENTS, IN TESTING FOR IMMUNE ANTIBODIES REQUIRING AN INDIRECT ANTIGLOBULIN TEST METHOD.

	AGH MAESTRIA IGG IS USED IN THE DIRECT ANTIGLOBULIN TEST (DIRECT COOMBS' TEST) ON HUMAN RED BLOOD CELLS. - AGH MAESTRIA IGG RECOGNIZES IGG ANTIBODIES.,NEG CONTROL(NEG CONTROL)-THE NEG CONTROL IS USED IN BLOOD ABO GROUPING. IT IS DEVOID OF ANTIBODY ACTIVITY. TESTED UNDER THE SAME CONDITIONS AS THE REAGENT USED, THE CONTROL ENABLES INTERPRETATION OF THE RESULT OBTAINED.,HEMALYS 1 A1,A2,B,O (HEMALYS 1 A1,A2,B,O)-THESE REAGENT KITS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THEY ARE INTENDED FOR THE ANALYSIS OF HUMAN BIOLOGICAL SPECIMENS. HEMALYS IS USED IN THE PLASMA TEST FOR ABO BLOOD GROUPING. AFTER HAVING TESTED FOR ERYTHROCYTIC ANTIGENS IN THE ERYTHROCYTE TEST, HEMALYS ENABLES VERIFICATION OF THE PRESENCE OF THE CORRESPONDING ANTIBODIES IN THE TEST PLASMA. THESE DEVICES ARE READY TO USE AND CAN BE USED DIRECTLY ON EM® TECHNOLOGY (ERYTHROCYTES MAGNETIZED TECHNOLOGY) ON THE AUTOMATED MACHINES QWALYS® OR ON MANUAL WORKSTATIONS FREELYS®NANO AND FREELYS®.,HEMASCREEN POOL(HEMASCREEN POOL)-HEMASCREEN POOL IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE (IVDMD) FOR PROFESSIONAL USE. HEMASCREEN POOL IS USED FOR SCREENING OF ANTIERYTHROCYTIC ANTIBODY IN HUMAN SERUM OR PLASMA. THIS KIT IS USED IN ONLY EM® TECHNOLOGY (ERYTHROCYTE MAGNETISED TECHNOLOGY) ON THE FREELYS® NANO WORKSTATIONS WITH SCREENLYS AND ON THE FULLY AUTOMATED QWALYS®MACHINES WITH SCREENLYS, SCREENLYS 2 OR CROSSLYS.,SERA CQI(SERA CQI)-SERA CQI IS INTERNAL QUALITY CONTROL REAGENTS. THEY ARE ADDED TO THE TEST SERIES FOR TESTING FOR IRREGULAR ANTIBODIES (TIA). THEY ARE USED ON E.M. ® TECHNOLOGY (ERYTHROCYTE MAGNETIZED TECHNOLOGY) ON THE FULLY AUTOMATED MACHINE QWALYS® AND ON THE FREELYS® NANO WORKSTATION. THEIR USE ENABLES THE DETECTION OF ANOMALIES (HANDLING, REAGENTS, APPARATUS AND ENVIRONMENT) AND IMPLEMENTATION FOR CORRECTIVE ACTIONS.,ABD PAD(ABD PAD)-ABD PAD® ALLOWS THE CONTROL OF THE ABO/RH BLOOD GROUP (CONFIRMATION OR PRE-DONATION CONTROL), BY DETERMINING THE PRESENCE OF THE A, B AND D ERYTHROCYTE ANTIGENS ON THE SURFACE OF HUMAN RED BLOOD CELLS.THIS TECHNIQUE IS BASED ON AN IMMUNOBLOTTING TEST, USING SPOTS. THE TESTED RED BLOOD CELLS, CARRYING AN ANTIGEN, INTERACT WITH THE CORRESPONDING ANTIBODIES, REVEALING A RED COLOR SPOT. THE RED BLOOD CELLS WHICH DO NOT CARRY THE ANTIGEN, DO NOT INTERACT WITH THE ANTIBODIES AND CROSS THE MEMBRANE. THE SPOT WILL APPEAR LIGHT GREEN

	OR WHITE.,PHENOLYS(PHENOLYS)-THESE REAGENTS KITS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THEY ARE USED FOR RH-K PHENOTYPING OF HUMAN RED BLOOD CELLS. T - PHENOLYS ENABLE DETERMINATION OF THE PRESENCE OF ERYTHROCYTIC ANTIGENS C, E, C, E AND K. THESE DEVICES ARE FOR USE ON THE AUTOMATED MACHINES QWALYS® AND/OR ON MANUAL WORKSTATIONS FREELYS® NANO AND FREELYS® IN THE EM® TECHNOLOGY METHOD.,QR NEG CONTROL (QR NEG CONTROL)-NEG CONTROL IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE (IVDMD) FOR PROFESSIONAL USE. IT IS DESIGNED FOR THE ANALYSIS OF BIOLOGICAL HUMAN SAMPLES. IT IS ADDED TO THE SERIES OF ANTIGEN SCREENING AND MUST BE USED EXCLUSIVELY IN EM® TECHNOLOGY (ERYTHROCYTES MAGNETIZED® TECHNOLOGY) ON QWALYS® AND WITH ITS ASSOCIATED REAGENTS.,CROSSLYS(CROSSLYS)-CROSSLYS IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE (IVDMD) FOR PROFESSIONAL USE, DESIGNED FOR COMPATIBILITY TESTS OR FOR THE SCREENING OF IRREGULAR ANTIBODIES OR FOR THE SCREENING OF IRREGULAR ANTIERYTHROCYTIC ANTIBODIES OR FOR THE DETERMINATION OF RED BLOOD CELLS PHENOTYPE, RECOMMENDING AN INDIRECT ANTIGLOBULIN TEST TECHNIQUE. CROSSLYS MUST BE EXCLUSIVELY USED IN E.M.® TECHNOLOGY (ERYTHROCYTES MAGNETIZED® TECHNOLOGY) WITH ITS ASSOCIATED REAGENTS.,DILUENTLYS (DILUENTLYS)-DILUENTLYS IS AN IN VITRO MEDICAL DIAGNOSTIC DEVICE (IVDMD) FOR PROFESSIONAL USE. IT IS DESIGNED FOR ANALYSES OF HUMAN BIOLOGICAL SAMPLES. IT IS USED AS A DILUTION MEDIUM FOR THE RED BLOOD CELLS BEFORE THEIR MAGNETIZATION IN EM® TECHNOLOGY (ERYTHROCYTES MAGNETIZED TECHNOLOGY).,BROMELINE(BROMELINE)-BROMELINE, A PROTEOLYTIC ENZYME, INDUCES A MARKED DECREASE IN THE ELECTRONEGATIVE CHARGE ON THE RED BLOOD CELL SURFACE, ENABLING ERYTHROCYTE AGGLUTINATION BY NORMALLY 'NON-AGGLUTINATING' ANTIBODIES IN A SALINE MEDIUM. THE RED BLOOD CELL SUSPENSION WITH BROMELINE IS THEN USED IN THE MICROPLATE METHOD. THE MICROPLATE METHOD IS BASED ON THE PRINCIPLE OF HAEMAGGLUTINATION. RED BLOOD CELLS BEARING AN ANTIGEN, PRE-TREATED WITH BROMELINE, AGGLUTINATE IN THE PRESENCE OF THE REAGENT CONTAINING THE CORRESPONDING ANTIBODY.,PALERM(PALERM)-PAPAIN, A PROTEOLYTIC ENZYME DERIVED FROM PAPAYA (CARICA PAPAYA), INDUCES A MARKED DECREASE IN THE ELECTRONEGATIVE CHARGE ON THE SURFACE OF RED BLOOD CELLS ENABLING THEIR AGGLUTINATION BY NORMALLY 'NON-AGGLUTINATING' ANTIBODIES IN SALINE MEDIUM. THE METHOD USED IS BASED ON THE PRINCIPLE OF HAEMAGGLUTINATION. RED

	BLOOD CELLS BEARING AN ANTIGEN, PRETREATED WITH PAPAIN, AGGLUTINATE IN THE PRESENCE OF THE CORRESPONDING ANTIBODIES.,CLEANLYS(CLEANLYS)-CLEANLYS IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE (IVDMD) FOR PROFESSIONAL USE. CLEANLYS IS A DECONTAMINATION SOLUTION USED ON THE AUTOMATED MACHINES QWALYS®.,NANOLYS(NANOLYS)-THIS KIT IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE (IVDMD) FOR PROFESSIONAL USE. IT IS DESIGNED FOR ANALYSES OF HUMAN BIOLOGICALS SAMPLES IN E.M.® TECHNOLOGY (ERYTHROCYTES MAGNETIZED TECHNOLOGY) USING FULLY AUTOMATED MACHINE QWALYS® AND / OR MANUAL WORKSTATION FREELYS® NANO. NANOLYS IS A HIGH-DENSITY SUSPENSION. IT IS INTENDED TO PROTECT MONOCLONAL ANTIGLOBULIN PRESENT IN THE WELLS OF THE MICROPLATES DIAGAST AND TO BLOCK THE NON-SPECIFIC ANTIBODIES.,SCREENDILUENT(SCREENDILUENT)-SCREENDILUENT IS AN IN VITRO MEDICAL DIAGNOSTIC DEVICE (IVDMD) FOR PROFESSIONAL USE. IT IS DESIGNED FOR ANALYSES OF HUMAN BIOLOGICAL SAMPLES IN EM® TECHNOLOGY (ERYTHROCYTES MAGNETIZED TECHNOLOGY). IT IS A SPECIFIC BUFFER TO COVER NANOLYS. THIS BUFFER ALLOWS A PERFECT INTERFACE BETWEEN RED CELLS AND NANOLYS.,AGH MAESTRIA C3D(AGH MAESTRIA C3D) -THE REAGENTS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THEY ARE INTENDED FOR THE ANALYSIS OF HUMAN BIOLOGICAL SPECIMENS. IN TESTING FOR IMMUNE ANTIBODIES REQUIRING AN INDIRECT ANTIGLOBULIN TEST METHOD. AGH MAESTRIA C3D ARE USED IN THE DIRECT ANTIGLOBULIN TEST (DIRECT COOMBS' TEST) ON HUMAN RED BLOOD CELLS. - AGH MAESTRIA C3D ONLY RECOGNIZES THE COMPLEMENT FRAGMENT C3D AND, CONSEQUENTLY, CANNOT REACT WITH COMPONENT C4.,PAD BUFFER 500(PAD BUFFER 500)-PAD BUFFER 500 ARE IN-VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THEY ARE USED IN COMBINATION WITH THE PAD® DEVICES AS A REAGENT ACTIVATION AND REVELATION BUFFER FOR THE RESULTS. THEY ARE BASED ON M-TRAP® TECHNOLOGY, WHICH DETECTS A REACTION BETWEEN AN ERYTHROCYTE ANTIGEN AND AN ANTIBODY FROM A WHOLE BLOOD SAMPLE OR AN ERYTHROCYTE CONCENTRATE / PELLET DIRECTED SPECIFICALLY AGAINST THIS ANTIGEN. THIS TECHNIQUE IS BASED ON AN IMMUNOBLOTTING TEST USING SPOTS. THE TESTED RED BLOOD CELLS, CARRYING AN ANTIGEN, INTERACT WITH THE CORRESPONDING ANTIBODIES, REVEALING A RED COLORED SPOT. THE ERYTHROCYTES WHICH DO NOT CARRY THE ANTIGEN, DO NOT INTERACT WITH THE ANTIBODIES AND CROSS THE MEMBRANE. THE SPOT WILL APPEAR LIGHT GREEN OR WHITE.,ANTI-B CONCENTRATE

	BULK(ANTI-B CONCENTRATE BULK)-THIS REAGENT IS IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THE ANTI-B CONCENTRATE BULK BULK (ABO2) IS USED IN THE RED BLOOD CELL DETERMINATION OF BLOOD ABO GROUP. IT ENABLES DETERMINATION OF THE PRESENCE OF ERYTHROCYTIC ANTIGEN$ B ON THE SURFACE OF HUMAN RED BLOOD CELLS." THESE PRODUCTS ARE RAW MATERIALS FOR IN VITRO DIAGNOSTIC MEDICAL DEVICE PRODUCTION,ANTI-A CONCENTRATE BULK(ANTI-A CONCENTRATE BULK)-THIS REAGENT IS IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THE ANTI-A CONCENTRATE BULK (ABO1) IS USED IN THE RED BLOOD CELL DETERMINATION OF BLOOD ABO GROUP. IT ENABLES DETERMINATION OF THE PRESENCE OF ERYTHROCYTIC ANTIGENS B ON THE SURFACE OF HUMAN RED BLOOD CELLS." THESE PRODUCTS ARE RAW MATERIALS FOR IN VITRO DIAGNOSTIC MEDICAL DEVICE PRODUCTION,ANTI-B DIAGAST BULK(ANTI-B DIAGAST BULK)-"THIS REAGENT IS IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THE ANTI-B DIAGAST BULK (ABO2) IS USED IN THE RED BLOOD CELL DETERMINATION OF BLOOD ABO GROUP. IT ENABLES DETERMINATION OF THE PRESENCE OF ERYTHROCYTIC ANTIGEN$ B ON THE SURFACE OF HUMAN RED BLOOD CELLS." THESE PRODUCTS ARE RAW MATERIALS FOR IN VITRO DIAGNOSTIC MEDICAL DEVICE PRODUCTION.,ANTI-A DIAGAST BULK(ANTI-A DIAGAST BULK)-"THIS REAGENT IS IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THE ANTI-A (ABO1) IS USED IN THE RED BLOOD CELL DETERMINATION OF BLOOD ABO GROUP. IT ENABLES DETERMINATION OF THE PRESENCE OF ERYTHROCYTIC ANTIGEN$ A AND/OR B ON THE SURFACE OF HUMAN RED BLOOD CELLS." THESE PRODUCTS ARE RAW MATERIALS FOR IN VITRO DIAGNOSTIC MEDICAL DEVICE PRODUCTION.,ANTI-D (RH1) TOTEM(ANTI-D (RH1) TOTEM)-"THIS REAGENT IS IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THE ANTI-D (RH1) TOTEM IS USED FOR BLOOD GROUPING. THEY ENABLE THE DETERMINATION OF THE PRESENCE OF ANTIGEN D (RH1) ON THE SURFACE OF HUMAN RED BLOOD CELLS." - OR IN THE INDIRECT HEMAGGLUTINATION METHOD: ANTIGLOBULIN TEST IN THE EVENT OF USE OF AN IGG ANTIBODY. THE REACTION OCCURS IN TWO STAGES: THE TEST RED BLOOD CELLS ARE EXPOSED TO THE IGG ANTIBODY. THE ANTIBODIES BIND TO THE RED BLOOD CELLS CARRYING THE CORRESPONDING ANTIGEN. AFTER WASHING, ADDITION OF ANTIGLOBULIN “AGH MAESTRIA IGG” INDUCES AGGLUTINATION OF THE SENSITIZED RED BLOOD CELLS CARRYING THE CORRESPONDING ANTIGEN. ,ANTI-D (RH1) IGM(ANTI-D (RH1) IGM)-"THIS REAGENT IS IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THE ANTI-D

	(RH1) IGM I IS USED FOR BLOOD GROUPING. IT ENABLE THE DETERMINATION OF THE PRESENCE OF ANTIGEN D (RH1) ON THE SURFACE OF HUMAN RED BLOOD CELLS." THE MANUAL TECHNIQUE EMPLOYED, ON A PLATE OR IN A TUBE, UTILIZES THE PRINCIPLE OF HEMAGGLUTINATION. TEST RED BLOOD CELLS BEARING AN ANTIGEN AGGLUTINATE IN THE PRESENCE OF THE REAGENT CONTAINING THE CORRESPONDING ANTIBODY: - EITHER IN THE DIRECT HEMAGGLUTINATION METHOD, WHEN THEY COME INTO CONTACT WITH THE REAGENT CONTAINING THE ANTIBODY (TYPE: IGM),ANTI-B (ABO2)(ANTI-B (ABO2))-"THIS REAGENT IS IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THE ANTI-B (ABO2) IS USED IN THE RED BLOOD CELL DETERMINATION OF BLOOD ABO GROUP. IT ENABLES DETERMINATION OF THE PRESENCE OF ERYTHROCYTIC ANTIGENS B ON THE SURFACE OF HUMAN RED BLOOD CELLS."THE MANUAL TECHNIQUE EMPLOYED, ON A PLATE OR IN A TUBE, UTILIZES THE PRINCIPLE OF HEMAGGLUTINATION. TEST RED BLOOD CELLS BEARING AN ANTIGEN AGGLUTINATE IN THE PRESENCE OF THE REAGENT CONTAINING THE CORRESPONDING ANTIBODY: - EITHER IN THE DIRECT HEMAGGLUTINATION METHOD, WHEN THEY COME INTO CONTACT WITH THE REAGENT CONTAINING THE ANTIBODY (TYPE: IGM) ; - OR IN THE INDIRECT HEMAGGLUTINATION METHOD: ANTIGLOBULIN TEST IN THE EVENT OF USE OF AN IGG ANTIBODY. THE REACTION OCCURS IN TWO STAGES: THE TEST RED BLOOD CELLS ARE EXPOSED TO THE IGG ANTIBODY. THE ANTIBODIES BIND TO THE RED BLOOD CELLS CARRYING THE CORRESPONDING ANTIGEN. AFTER WASHING, ADDITION OF ANTIGLOBULIN “AGH MAESTRIA IGG” INDUCES AGGLUTINATION OF THE SENSITIZED RED BLOOD CELLS CARRYING THE CORRESPONDING ANTIGEN,ANTI- A (ABO1)(ANTI- A (ABO1))-"THIS REAGENT IS IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THE ANTI-A (ABO1) IS USED IN THE RED BLOOD CELL DETERMINATION OF BLOOD ABO GROUP. IT ENABLES DETERMINATION OF THE PRESENCE OF ERYTHROCYTIC ANTIGENS A AND/OR B ON THE SURFACE OF HUMAN RED BLOOD CELLS." THE MANUAL TECHNIQUE EMPLOYED, ON A PLATE OR IN A TUBE, UTILIZES THE PRINCIPLE OF HEMAGGLUTINATION. TEST RED BLOOD CELLS BEARING AN ANTIGEN AGGLUTINATE IN THE PRESENCE OF THE REAGENT CONTAINING THE CORRESPONDING ANTIBODY: - EITHER IN THE DIRECT HEMAGGLUTINATION METHOD, WHEN THEY COME INTO CONTACT WITH THE REAGENT CONTAINING THE ANTIBODY (TYPE: IGM) ; - OR IN THE INDIRECT HEMAGGLUTINATION METHOD: ANTIGLOBULIN TEST IN THE EVENT OF USE OF AN IGG ANTIBODY. THE REACTION OCCURS IN TWO STAGES: THE TEST RED BLOOD CELLS ARE EXPOSED TO THE IGG ANTIBODY. THE

	ANTIBODIES BIND TO THE RED BLOOD CELLS CARRYING THE CORRESPONDING ANTIGEN. AFTER WASHING, ADDITION OF ANTIGLOBULIN “AGH MAESTRIA IGG” INDUCES AGGLUTINATION OF THE SENSITIZED RED BLOOD CELLS CARRYING THE CORRESPONDING ANTIGEN. ABO GROUP DETERMINATION IS DEFINED BY BOTH THE DEMONSTRATION OF ANTIGENS A AND/OR B ON THE SURFACE OF HUMAN RED BLOOD CELLS AND BY THE PRESENCE OR ABSENCE OR ANTI-A AND/OR ANTI-B ANTIBODIES IN THE PLASMA. IT IS THEREFORE APPROPRIATE TO IDENTIFY THE ERYTHROCYTIC ANTIGENS USING KNOWN ANTI-A, ANTI-B AND ANTI-A,B REAGENTS (RED BLOOD CELL TEST), THEN TO CONFIRM THE PRECEDING RESULTS BY VERIFYING THE PRESENCE OF THE CORRESPONDING ANTIBODIES IN THE PLASMA FROM THE TEST BLOOD USING KNOWN RED BLOOD CELLS A1, B AND, POSSIBLY, A2 AND O (PLASMA TES,QR ANTI-K (KEL2)(QR ANTI-K (KEL2))-"THESE REAGENTS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE, DESIGNED FOR THE ANALYSIS OF HUMAN BIOLOGICAL SAMPLES. THEY ARE USED TO PHENOTYPE HUMAN RED BLOOD CELLS. THEY ALLOW DETERMINING THE PRESENCE OF ANTIGENS K (KEL2) ON THE RED BLOOD CELLS SURFACE. THEY MUST BE EXCLUSIVELY USED IN E.M.® TECHNOLOGY (ERYTHROCYTES MAGNETIZED® TECHNOLOGY) ON QWALYS® AUTOMATED SYSTEM AND WITH THEIR ASSOCIATED REAGENTS." ,QR ANTI-D WEAK(QR ANTI-D WEAK)-ANTI-D WEAK IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE (IVDMD) FOR PROFESSIONAL USE, DESIGNED FOR THE SCREENING OF WEAK D AND/OR PARTIAL D ANTIGEN (RH1) IN E.M.® TECHNOLOGY (ERYTHROCYTES MAGNETIZED® TECHNOLOGY). ANTI-D WEAK MUST BE EXCLUSIVELY USED IN E.M.® TECHNOLOGY ON QWALYS® AUTOMATED SYSTEM AND WITH ITS ASSOCIATED REAGENTS. THE PRINCIPLE OF THIS METHOD IS BASED ON THE MAGNETIZATION OF RED BLOOD CELLS: E. M.® TECHNOLOGY. THIS PRINCIPLE USES THE INDIRECT ANTIGLOBULIN TEST (IAT) IN SOLID PHASE COMBINED TO MAGNETIC FIELD. - THE RED BLOOD CELLS OF DONOR OR PATIENT ARE MAGNETIZED WITH A SOLUTION CONTAINING MAGNETIC BEADS. THESE MAGNETIZED RED BLOOD CELLS ARE PUT IN CONTACT WITH THE ANTI-D WEAK REAGENT. - WHEN SUBJECTED TO A MAGNETIC FIELD, THE MAGNETIZED RED BLOOD CELLS MIGRATE TO THE BOTTOM OF THE WELL. - THE MONOCLONAL ANTIGLOBULINS PRESENT IN THE WELLS SHOW THE PRESENCE OF ANTIBODIES FIXED ON PATIENT OR DONOR RED BLOOD CELLS. THIS IS SHOWN BY A POSITIVE REACTION AS A CARPET LAYER OF RED BLOOD CELLS FORMS AT THE BOTTOM OF THE WELL. A NEGATIVE REACTION IS SHOWN BY THE FORMATION OF A COMPACT PELLET OF RED BLOOD CELLS AT THE BOTTOM OF THE WELL AND INDICATES THE ABSENCE

	OF ANTIGEN D (RH1) IN THE PATIENT OR DONOR ,QR ANTI-FYB(QR ANTI-FYB)-"THESE REAGENTS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE, DESIGNED FOR THE ANALYSIS OF HUMAN BIOLOGICAL SAMPLES. THEY ARE USED TO PHENOTYPE HUMAN RED BLOOD CELLS. THEY ALLOW DETERMINING THE PRESENCE OF ANTIGENS FYB (FY2) ON THE RED BLOOD CELLS SURFACE. THEY MUST BE EXCLUSIVELY USED IN E.M.® TECHNOLOGY (ERYTHROCYTES MAGNETIZED® TECHNOLOGY) ON QWALYS® AUTOMATED SYSTEM AND WITH THEIR ASSOCIATED REAGENTS.",QR ANTI-FYA(QR ANTI-FYA)-"THESE REAGENTS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE, DESIGNED FOR THE ANALYSIS OF HUMAN BIOLOGICAL SAMPLES. THEY ARE USED TO PHENOTYPE HUMAN RED BLOOD CELLS. THEY ALLOW DETERMINING THE PRESENCE OF ANTIGENS FYA (FY1) ON THE RED BLOOD CELLS SURFACE. THEY MUST BE EXCLUSIVELY USED IN E.M.® TECHNOLOGY (ERYTHROCYTES MAGNETIZED® TECHNOLOGY) ON QWALYS® AUTOMATED SYSTEM AND WITH THEIR ASSOCIATED REAGENTS.",QR ANTI-JKB(QR ANTI-JKB)-"THESE REAGENTS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE, DESIGNED FOR THE ANALYSIS OF HUMAN BIOLOGICAL SAMPLES. THEY ARE USED TO PHENOTYPE HUMAN RED BLOOD CELLS. THEY ALLOW DETERMINING THE PRESENCE OF ANTIGENS JKB (JK2) ON THE RED BLOOD CELLS SURFACE. THEY MUST BE EXCLUSIVELY USED IN E.M.® TECHNOLOGY (ERYTHROCYTES MAGNETIZED® TECHNOLOGY) ON QWALYS® AUTOMATED SYSTEM AND WITH THEIR ASSOCIATED REAGENTS.",QR ANTI-JKA(QR ANTI-JKA)-"THESE REAGENTS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE, DESIGNED FOR THE ANALYSIS OF HUMAN BIOLOGICAL SAMPLES. THEY ARE USED TO PHENOTYPE HUMAN RED BLOOD CELLS. THEY ALLOW DETERMINING THE PRESENCE OF ANTIGENS JKA (JK1) ON THE RED BLOOD CELLS SURFACE. THEY MUST BE EXCLUSIVELY USED IN E.M.® TECHNOLOGY (ERYTHROCYTES MAGNETIZED® TECHNOLOGY) ON QWALYS® AUTOMATED SYSTEM AND WITH THEIR ASSOCIATED REAGENTS.",QR ANTI-S(QR ANTI-S)-"THESE REAGENTS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE, DESIGNED FOR THE ANALYSIS OF HUMAN BIOLOGICAL SAMPLES. THEY ARE USED TO PHENOTYPE HUMAN RED BLOOD CELLS. THEY ALLOW DETERMINING THE PRESENCE OF ANTIGENS S (MNS4) ON THE RED BLOOD CELLS SURFACE. THEY MUST BE EXCLUSIVELY USED IN E.M.® TECHNOLOGY (ERYTHROCYTES MAGNETIZED® TECHNOLOGY) ON QWALYS® AUTOMATED SYSTEM AND WITH THEIR ASSOCIATED REAGENTS.",QR ANTI-S(QR ANTI-S)-"THESE REAGENTS ARE IN VITRO DIAGNOSTIC

	MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE, DESIGNED FOR THE ANALYSIS OF HUMAN BIOLOGICAL SAMPLES. THEY ARE USED TO PHENOTYPE HUMAN RED BLOOD CELLS. THEY ALLOW DETERMINING THE PRESENCE OF ANTIGENS S (MNS3) ON THE RED BLOOD CELLS SURFACE. THEY MUST BE EXCLUSIVELY USED IN E.M.® TECHNOLOGY (ERYTHROCYTES MAGNETIZED® TECHNOLOGY) ON QWALYS® AUTOMATED SYSTEM AND WITH THEIR ASSOCIATED REAGENTS.", GROUPA 2 LYS(GROUPA 2 LYS)-"THESE REAGENTS KITS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THEY ARE USED FOR ABO-RH1 GROUPING AND/OR RH-K PHENOTYPING OF HUMAN RED BLOOD CELLS. THEY ARE NOT INTENDED FOR SCREENING FOR WEAK ANTIGEN D. - GROUPA 2 LYS ENABLE DETERMINATION OF THE PRESENCE OF ERYTHROCYTIC ANTIGENS A, B AND D. THESE DEVICES, INTENDED FOR ABO GROUPING, MUST BE USED WITH HEMALYS OR RED BLOOD CELLS MAGNETIZED ACCORDING TO THE RECOMMENDATIONS OF DIAGAST FOR THE REALIZATION OF THE PLASMA TEST (REVERSE GROUP). THESE DEVICES ARE FOR USE ON THE AUTOMATED MACHINES QWALYS® AND/OR ON MANUAL WORKSTATIONS FREELYS® NANO AND FREELYS® IN THE EM® TECHNOLOGY METHOD. ,DUOLYS (DUOLYS)-"THESE REAGENTS KITS ARE IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THEY ARE USED FOR ABO-RH1 GROUPING AND/OR RH-K PHENOTYPING OF HUMAN RED BLOOD CELLS. THEY ARE NOT INTENDED FOR SCREENING FOR WEAK ANTIGEN D. - DUOLYS ENABLES DETERMINATION OF THE PRESENCE OF ERYTHROCYTIC ANTIGENS A, B, D, C, E, C, E AND K. THESE DEVICES, INTENDED FOR ABO GROUPING, MUST BE USED WITH HEMALYS OR RED BLOOD CELLS MAGNETIZED ACCORDING TO THE RECOMMENDATIONS OF DIAGAST FOR THE REALIZATION OF THE PLASMA TEST (REVERSE GROUP). THESE DEVICES ARE FOR USE ON THE AUTOMATED MACHINES QWALYS® AND/OR ON MANUAL WORKSTATIONS FREELYS® NANO AND FREELYS® IN THE EM® TECHNOLOGY METHOD.,ABD-LYS(ABD-LYS)-"THIS KIT OF REAGENTS IS IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. IT IS USED FOR ABO-RH1 GROUPING OF HUMAN RED BLOOD CELLS. IT ENABLES DETERMINATION OF THE PRESENCE OF ERYTHROCYTIC ANTIGENS A (ABO1), B (ABO2) AND D (RH1), ON THE SURFACE OF HUMAN RED BLOOD CELLS. THE ANTI-D (RH1) IS NOT INTENDED FOR SCREENING FOR WEAK ANTIGEN D (RH1). ABD-LYS MUST BE USED WITH HEMALYS OR RED BLOOD CELLS MAGNETIZED ACCORDING TO THE RECOMMENDATIONS OF DIAGAST FOR THE REALIZATION OF THE PLASMA TEST (REVERSE GROUP). THIS DEVICE IS FOR USE ON THE AUTOMATED MACHINE QWALYS® OR ON MANUAL WORKSTATIONS FREELYS® NANO AND FREELYS® IN

		THE METHOD NAMED EM® TECHNOLOGY. " ,ANTI-D TOTEM DIAGAST BULK(ANTI-D TOTEM DIAGAST BULK)-"THESE PRODUCTS ARE RAW MATERIALS FOR IN VITRO DIAGNOSTIC MEDICAL DEVICE PRODUCTION. "THIS REAGENT IS IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THE ANTI-D (RH1) IGM I IS USED FOR BLOOD GROUPING. IT ENABLE THE DETERMINATION OF THE PRESENCE OF ANTIGEN D (RH1) ON THE SURFACE OF HUMAN RED BLOOD CELLS." ,ANTI-D IGM CONCENTRATE BULK(ANTI-D IGM CONCENTRATE BULK)-"THESE PRODUCTS ARE RAW MATERIALS FOR IN VITRO DIAGNOSTIC MEDICAL DEVICE PRODUCTION. "THIS REAGENT IS IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THE ANTI-D (RH1) IGM I IS USED FOR BLOOD GROUPING. IT ENABLE THE DETERMINATION OF THE PRESENCE OF ANTIGEN D (RH1) ON THE SURFACE OF HUMAN RED BLOOD CELLS.", ANTI-D IGM DIAGAST BULK(ANTI-D IGM DIAGAST BULK)-"THESE PRODUCTS ARE RAW MATERIALS FOR IN VITRO DIAGNOSTIC MEDICAL DEVICE PRODUCTION. "THIS REAGENT IS IN VITRO DIAGNOSTIC MEDICAL DEVICES (IVDMD) FOR PROFESSIONAL USE. THE ANTI-D (RH1) IGM I IS USED FOR BLOOD GROUPING. IT ENABLE THE DETERMINATION OF THE PRESENCE OF ANTIGEN D (RH1) ON THE SURFACE OF HUMAN RED BLOOD CELLS."
1238	IMP/MD/2018/000104	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TUMOR MARKER CONTROL(TUMOR MARKER CONTROL)-FOR IN VITRO DIAGNOSTICS USE ONLY. FUJERIBIO DIAGNOSTICS TUMOR MARKER CONTROL IS INTENDED FOR USE AS AN ASSAYED CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE LOT SPECIFIC ASSIGNED VALUE SHEETS.

1239	IMP/MD/2018/000110	1.License Holder Name: BRS BIO SOLUTIONS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT(NA)-DENTALIS BIO SOLUTIONS IMPLANT SYSTEM IS INTENDED TO REPLACE MISSING TOOTH/ TEETH IN EITHER JAW FOR SUPPORTING PROSTHETIC DEVICES THAT MAY AID IN RESTORING THE PATIENT'S CHEWING FUNCTION. THE PROCEDURE CAN BE ACCOMPLISHED IN A ONE-STAGE WHEN GOOD PRIMARY STABILITY IS ACHIEVED AND THE FUNCTIONAL LOAD IS APPROPRIATE OR TWO-STAGE SURGICAL OPERATION. THE SYSTEM CONSISTS OF ONE AND TWO STAGE ENDOSSEOUS FORM DENTAL IMPLANTS, INTERNAL HEXAGONAL AND ONE PIECE IMPLANTS SYSTEM.,ABUTMENTS & PROSTHETIC PRODUCTS & LOCATORS & MULTI UNIT SYSTEM(NA)-DENTALIS BIO SOLUTIONS IMPLANT SYSTEM IS INTENDED TO REPLACE MISSING TOOTH/ TEETH IN EITHER JAW FOR SUPPORTING PROSTHETIC DEVICES THAT MAY AID IN RESTORING THE PATIENT'S CHEWING FUNCTION. THE PROCEDURE CAN BE ACCOMPLISHED IN A ONE-STAGE WHEN GOOD PRIMARY STABILITY IS ACHIEVED AND THE FUNCTIONAL LOAD IS APPROPRIATE OR TWO-STAGE SURGICAL OPERATION. THE SYSTEM CONSISTS OF ONE AND TWO STAGE ENDOSSEOUS FORM DENTAL IMPLANTS, INTERNAL HEXAGONAL AND ONE PIECE IMPLANTS SYSTEM.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1240	IMP/MD/2018/000111	1.License Holder Name: EDWARDS LIFESCIENCES (INDIA) PRIVATE LIMITED, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERCUTANEOUS INSERTION KIT(PERCUTANEOUS INSERTION KIT - ARTERIAL)-THE EDWARDS LIFESCIENCES GUIDEWIRE IS INTENDED FOR USE IN SITUATIONS WHICH REQUIRE A GUIDEWIRE. THE EDWARDS LIFESCIENCES DILATOR SHOULD BE USED IN SITUATIONS WHICH REQUIRE DILATOR.,INTRA-VASCULAR BALLOON CATHETER (RETROGRADE CARDIOPLEGIA CATHETER)-RETROGRADE CORONARY SINUS CARDIOPLEGIA CATHETERS WITH AND WITHOUT DURAFLO TREATMENT ARE INTENDED FOR DELIVERY OF BLOOD OR CARDIOPLEGIA SOLUTION INTRAOPERATIVELY TO AVOID CARDIAC DAMAGE AND AID IN MYOCARDIAL PROTECTION. EXTRACORPOREAL CIRCUIT COMPONENTS WITH A DURAFLO TREATMENT ARE INTENDED FOR USE IN CARDIOPULMONARY BYPASS WHEN A HEPARIN TREATED CATHETER IS DESIRED UPON INITIAL PLACEMENT.,ANNULOPLASTY RING(CARPENTIER – EDWARDS PHYSIO II)-THE CARPENTIER – EDWARDS PHYSIO II RING, IS INTENDED FOR THE CORRECTION OF MITRAL VALVE INSUFFICIENCY, OR MIXED MITRAL INSUFFICIENCY AND STENOSIS, WHERE TREATMENT DOES NOT NECESSITATE A REPLACEMENT OF THE NATURAL MITRAL VALVE.,ANNULOPLASTY RING(CARPENTIER – EDWARDS PHYSIO TRICUSPID)-THE CARPENTIER – EDWARDS PHYSIO TRICUSPID ANNULOPLASTY RING, IS INTENDED FOR USE IN PATIENTS WITH TRICUSPID INSUFFICIENCY, TO CORRECT ANNULAR DILATATION, INCREASE LEAFLET COAPTATION, REINFORCE ANNULAR SUTURE LINES, AND PREVENT FURTHER DILATATION OF THE ANNULUS.,FEMORAL VENOUS CANNULA (FEMORAL VENOUS CANNULA)-EDWARDS LIFESCIENCES FEMORAL VENOUS ACCESS CANNULAE ARE INTENDED FOR USE IN SITUATIONS WHICH REQUIRE RAPID FEMORAL VENOUS ACCESS FOR SHORT-TERM (LESS THAN OR EQUAL TO 6 HOURS) CARDIOPULMONARY BYPASS. FEMORAL VESSEL ACCESS IS LEFT TO THE DISCRETION OF THE PHYSICIAN. FEMORAL ACCESS CANNULAE MAY BE USED IN PEDIATRIC POPULATIONS OR ADULT POPULATIONS BASED ON FLOW RATE REQUIREMENTS AND INDIVIDUAL PATIENT ANATOMY. PLEASE CONSULT LABELING TO DETERMINE PRESSURE DROP RELATED TO FLOW RATES. EXTRACORPOREAL CIRCUIT COMPONENTS WITH A DURAFLO TREATMENT ARE INTENDED FOR USE IN CARDIOPULMONARY BYPASS WHEN A HEPARIN TREATED CANNULA IS DESIRED UPON INITIAL PLACEMENT.,FEMORAL ARTERIAL CANNULA(FEM-FLEX II FEMORAL ARTERIAL CANNULA)-EDWARDS LIFESCIENCES FEMORAL ARTERIAL ACCESS CANNULAE ARE INTENDED FOR USE IN SITUATIONS WHICH REQUIRE RAPID FEMORAL

	ARTERIAL ACCESS FOR SHORT-TERM (LESS THAN OR EQUAL TO 6 HOURS) CARDIOPULMONARY BYPASS. FEMORAL VESSEL ACCESS IS LEFT TO THE DISCRETION OF THE PHYSICIAN. FEMORAL ACCESS CANNULAE MAY BE USED IN PEDIATRIC POPULATIONS OR ADULT POPULATIONS BASED ON FLOW RATE REQUIREMENTS AND INDIVIDUAL PATIENT ANATOMY. PLEASE CONSULT LABELING TO DETERMINE PRESSURE DROP RELATED TO FLOW RATES. EXTRACORPOREAL CIRCUIT COMPONENTS WITH A DURAFLO TREATMENT ARE INTENDED FOR USE IN CARDIOPULMONARY BYPASS WHEN A HEPARIN TREATED CANNULA IS DESIRED UPON INITIAL PLACEMENT.,ANNULOPLASTY RING(EDWARDS MC3 TRICUSPID)-THE EDWARDS MC3 TRICUSPID ANNULOPLASTY RING IS INTENDED FOR USE IN PATIENTS TO CORRECT ANNULAR DILATATION, INCREASE LEAFLET COAPTATION, REINFORCE ANNULAR SUTURE LINES AND PREVENT FURTHER DILATATION OF THE ANNULUS.,ARTERIAL PERFUSION CANNULA(OPTISITE ARTERIAL PERFUSION CANNULA)-THE EDWARDS LIFESCIENCES ARTERIAL PERFUSION CANNULAE ARE INDICATED FOR ARTERIAL PERFUSION IN THE EXTRACORPOREAL CIRCUIT FOR LESS THAN 6 HOURS. CANNULATION SITE SELECTION IS LEFT TO THE DISCRETION OF THE SURGEON AND MAY INCLUDE THE FEMORAL ARTERY OR THE AORTIC ARCH. EXTRACORPOREAL CIRCUIT COMPONENTS WITH A DURAFLO TREATMENT ARE INTENDED FOR USE IN CARDIOPULMONARY BYPASS WHEN A HEPARIN TREATED CANNULA IS DESIRED UPON INITIAL PLACEMENT.,ANNULOPLASTY RING WITH HOLDER - MITRAL (CARPENTIER – EDWARDS PHYSIO)-THE CARPENTIER – EDWARDS PHYSIO ANNULOPLASTY RING IS INTENDED FOR THE CORRECTION OF MITRAL VALVE INSUFFICIENCY OR MIXED MITRAL INSUFFICIENCY AND STENOSIS, WHERE TREATMENT DOES NOT NECESSITATE A REPLACEMENT OF THE NATURAL MITRAL VALVE.

1241	IMP/MD/2018/000112	1.License Holder Name: BIO-TECH VISION CARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MONOFOCAL HYDROPHILIC ASPHERIC INTRAOCULAR LENS(OPTIFLEX GENE)-IT IS INTENDED TO USE IN: SENILE CATARACT, CONGENIAL CATARACT, JUVENILE CATARACT, TRAUMATIC CATARACT ,MONOFOCAL HYDROPHILIC SPHERICAL INTRAOCULAR LENS(OPTIFLEX)-IT IS INTENDED TO USE IN: SENILE CATARACT, CONGENIAL CATARACT, JUVENILE CATARACT, TRAUMATIC CATARACT,PRELOADED MONOFOCAL HYDROPHOBIC ASPHERIC NATURAL YELLOW INTRAOCULAR LENS(OPTIFLEX GENESIS COMFORT NY)-THE OPTIFLEX GENESIS COMFORT NY PRE-LOADED IOL SYSTEM WITH ASPHERIC NATURAL YELLOW HYDROPHOBIC LENSES ARE INDICATED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS IN CAPSULAR BAG TO ACHIEVE CORRECTION OF APHAKIA IN PATIENTS AND IN ORDER TO GUARANTEE AND EXCELLENT VISUAL CORRECTION FURTHER TO EXTRACTION OF THE CRYSTALLINE LENS , PRELOADED MONOFOCAL HYDROPHOBIC ASPHERIC INTRAOCULAR LENS(OPTIFLEX GENESIS COMFORT)-THE OPTIFLEX GENESIS COMFORT PRE-LOADED IOL SYSTEM WITH ASPHERIC HYDROPHOBIC LENSES ARE INDICATED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS IN CAPSULAR BAG TO ACHIEVE CORRECTION OF APHAKIA IN PATIENTS AND IN ORDER TO GUARANTEE AND EXCELLENT VISUAL CORRECTION FURTHER TO EXTRACTION OF THE CRYSTALLINE LENS,TRIFOCAL HYDROPHOBIC ASPHERIC INTRAOCULAR LENS(OPTIFLEX TRIO)-THE OPTIFLEX TRIO REFRACTIVE - DIFFRACTIVE TRIFOCAL IOL IS INTENDED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA SECONDARY TO REMOVAL OF A CATARACTOUS LENS IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA, WHO WISH NEAR, INTERMEDIATE AND DISTANCE VISION WITH DECREASED DEPENDENCY ON SPECTACLES. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,PHAKIC MONOFOCAL HYDROPHILIC ASPHERIC INTRAOCULAR LENS(OPTIFLEX GLAZE)-THE OPTIFLEX GLAZE PHAKIC IOLS ARE INDICATED IN PHAKIC ADULTS FOR THE TREATMENT OF MODERATE TO HIGH MYOPIA. THE AVAILABLE POWERS ARE RANGING FROM -3.0D TO -23.0D.,TORIC DIFFRACTIVE HYDROPHOBIC ASPHERIC INTRAOCULAR LENS(OPTIFLEX OPUS AXIS)-THE OPTIFLEX OPUS AXIS IOLS ARE INTENDED TO IMPLANT IN CAPSULAR BAG OF EYE AS REPLACEMENT OF CATARACTOUS NATURAL CRYSTALLINE LENS FOR VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENT WITH OR WITHOUT PRESBYOPIA, WHO DESIRE IMPROVED UNCORRECTED DISTANCE, INTERMEDIATE AND NEAR VISION,

	REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCY.,REFRACTIVE-DIFFRACTIVE MULTIFOCAL (+3) HYDROPHOBIC ASPHERIC INTRAOCULAR LENS (OPTIFLEX OPUS)-OPTIFLEX OPUS REFRACTIVE - DIFFRACTIVE MULTIFOCAL IOLS ARE INTENDED FOR PRIMARY IMPLEMENTATION FOR THE VISUAL CORRECTION OF APHAKIA, SECONDARY TO REMOVAL OF A CATARACTOUS NATURAL HUMAN CRYTALLINE LENS IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA, WHO WITH NEAR, INTERMEDIATE AND DISTANCE VISION WITH DECREASED DEPENDENCY ON SPECTACLES. THE DIFFRACTIVE SURFACE PROFILE OF IOL GIVES PRECISE AND ACCURATE ENERGY DISTRIBUTION IN ALL VISION DISTANCE . THE IOL IS INTENDED TO BE PLACED IN THE CAPSULAR BAG. ,TORIC MONOFOCAL HYDROPHOBIC ASPHERIC INTRAOCULAR LENS(OPTIFLEX AXIS)-THE OPTIFLEX AXIS TORIC IOLS ARE INTENDED TO IMPLANT IN CAPSULAR BAG OF EYE FOR VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENT WITH OR WITHOUT PRESBYOPIA, WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCY FOR DISTANCE VISION.,ASPHERIC HYDROPHOBIC MONOFOCAL NATURAL YELLOW INTRAOCULAR LENS (OPTIFLEX GENESIS)-OPTIFLEX GENESIS NATURAL YELLOW HYDROPHOBIC ASPHERIC INTRAOCULAR LENES ARE INTENDED FOR THE REPLACEMENT OF THE HUMAN LENS / TO ACHIEVE CORRECTION OF APHAKIA IN ADULT PATIENTS THESE LENSES ARE INTENDED FOR REPLACEMENT IN THE CAPSULAR BAG.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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1242	IMP/MD/2018/000113	1.License Holder Name: CARDINAL HEALTH MEDICAL PRODUCTS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STEERABLE GUIDEWIRES (STABILIZER)-CORDIS GUIDEWIRES ARE INTENDED FOR USE IN ANGIOGRAPHIC PROCEDURES TO INTRODUCE AND POSITION CATHETERS AND INTERVENTIONAL DEVICES WITHIN THE CORONARY AND PERIPHERAL VASCULATURE,STEERABLE GUIDEWIRES(ATW)-CORDIS GUIDEWIRES ARE INTENDED FOR USE IN ANGIOGRAPHIC PROCEDURES TO INTRODUCE AND POSITION CATHETERS AND INTERVENTIONAL DEVICES WITHIN CORONARY AND PERIPHERAL VASCULATURE. IN ADDITION, THE GUIDEWIRES ARE INTENDED TO FACILITATE THE ALIGNMENT OF INTERVENTIONAL DEVICES AND FUNCTION AS A MEASUREMENT TOOL.,STEERABLE GUIDEWIRES(SV)-CORDIS GUIDEWIRES ARE INTENDED FOR USE IN ANGIOGRAPHIC PROCEDURES TO INTRODUCE AND POSITION CATHETERS AND INTERVENTIONAL DEVICES WITHIN THE PERIPHERAL VASCULATURE., STEERABLE GUIDEWIRES(SHINOBI)-CORDIS GUIDEWIRES ARE INTENDED FOR USE IN ANGIOGRAPHIC PROCEDURES TO INTRODUCE AND POSITION CATHETERS AND INTERVENTIONAL DEVICES WITHIN THE CORONARY AND PERIPHERAL VASCULATURE,GUIDEWIRE (EMERALD)-CORDIS GUIDEWIRES ARE INTENDED FOR USE IN THE PERCUTANEOUS INTRODUCTION OF CATHETERS
1243	IMP/MD/2018/000114	1.License Holder Name: SHREYAAS HEALTH CARE PRODUCTS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VOICE PROSTHESIS(BLOM SINGER)-TRACHEOESOPHAGEAL VOICE RESTORATION FOLLOWING LARYNGECTOMY

1244	IMP/MD/2018/000116	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED ,NO. 17, GROUND FLOOR AND MEZZANINE FLOOR, THIRUNEERMALAI ROAD, NAGALKENI, CHROMPET ,CHENNAI TAMIL NADU ,600044 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL KNEE REPLACEMENT(PERSONA THE PERSONALIZED KNEE SYSTEM - FEMORAL COMPONENT)-THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: A) RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS; B) COLLAGEN DISORDERS AND/ OR AVASCULAR NECROSIS OF FEMORAL CONDYLE; C) POST TRAUMATIC LOSS OF JOINT CONFIGURATION PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY; D) MODERATE VALGUS, VARUS OR FLEXON DEFORMITIES; E) SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR KNEE IN WHICH SATISFACTORY STABILITY IN FLEXON CANNOT BE OBTAINED AT TIME OF SURGERY. THE DEVICE IS INTENDED FOR CEMENTED USE ONLY.,TOTAL KNEE REPLACEMENT (NEXGEN COMPLETE KNEE SOLUTION -FEMORAL COMPONENT)-THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: A) RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS; B) COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE; C) POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY; D) MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES; E) THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY
1245	IMP/MD/2018/000117	1.License Holder Name: MERIL LIFE SCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER (NON STERILE)(TAMARIN BLUE)-NON STERILE DEVICE IS FOR FURTHER MANUFACTURING USE. STERILE DEVICE IS INTENDED FOR USE IN PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES AND WHO ARE REGARDED AS BEING CANDIDATES FOR MYOCARDIAL REVASCULARIZATION.

1246	IMP/MD/2018/000118	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REVASCULARIZATION DEVICE(SOLITAIRE X REVASCULARIZATION DEVICE)-THE SOLITAIRE™ X REVASCULARIZATION DEVICE IS DESIGNED FOR USE IN THE FLOW RESTORATION OF PATIENTS WITH ISCHEMIC STROKE DUE TO LARGE INTRACRANIAL VESSEL OCCLUSION. PATIENTS WHO ARE INELIGIBLE FOR INTRAVENOUS TISSUE PLASMINOGEN ACTIVATOR (IV T-PA) OR WHO FAIL IV T-PA THERAPY ARE CANDIDATES FOR TREATMENT. THE SOLITAIRE™ X REVASCULARIZATION DEVICE SHOULD ONLY BE USED BY PHYSICIANS TRAINED IN INTERVENTIONAL NEURORADIOLOGY AND TREATMENT OF ISCHEMIC STROKE.,DELIVERY CATHETER (MARKSMAN)(DELIVERY CATHETER)-MARKSMAN MICROCATHETER IS INTENDED FOR THE INTRODUCTION OF INTERVENTIONAL DEVICES AND INFUSION OF DIAGNOSTIC OR THERAPEUTIC AGENTS INTO THE NEURO, PERIPHERAL, AND CORONARY VASCULATURE.,CATHETER (REACT)-THE REACT CATHETERS ARE INTENDED FOR THE INTRODUCTION OF INTERVENTIONAL/DIAGNOSTIC DEVICES INTO THE PERIPHERAL AND NEUROVASCULATURE. THE REACT CATHETERS ARE ALSO INTENDED FOR THE REMOVAL /ASPIRATION OF EMBOLI AND THROMBI FROM SELECTED BLOOD VESSELS IN THE ARTERIAL SYSTEM, INCLUDING THE NEUROVASCULATURE., THREADED SYRINGE (CADENCE)(CADENCE THREADED SYRINGE)-THE CADENCE PRECISION INJECTOR IS INTENDED FOR THE CONTROLLED DELIVERY OF FLUIDS IN THE INFLATION AND DEFLATION OF TEMPORARY OCCLUSION BALLOONS,EMBOLIZATION DEVICE (PIPELINE VANTAGE EMBOLIZATION DEVICE WITH SHIELD TECHNOLOGY)-THE PIPELINE™ VANTAGE EMBOLIZATION DEVICE WITH SHIELD TECHNOLOGY™ IS INTENDED FOR ENDOVASCULAR EMBOLIZATION OF CEREBRAL ANEURYSMS.,NEUROVASCULAR REMODELING DEVICE (SOLITAIRE AB)(SOLITAIRE AB NEUROVASCULAR REMODELING DEVICE)-THE SOLITAIRE™ AB NEUROVASCULAR REMODELING DEVICE IS DESIGNED FOR USE AS AN ADJUNCTIVE DEVICE IN THE TREATMENT OF INTRACRANIAL ANEURYSMS.,DETACHABLE COIL SYSTEM -PGLA (AXIUM)(AXIUM DETACHABLE COIL SYSTEM -PGLA)-THE AXIUM™ DETACHABLE COILS ARE INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS. THE AXIUM DETACHABLE COILS ARE ALSO INTENDED FOR THE EMBOLIZATION OF OTHER NEUROVASCULAR ABNORMALITIES, SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE,GUIDEWIRE (X-PEDION)(X-PEDION GUIDEWIRE)-X-PEDION GUIDEWIRE IS INDICATED FOR GENERAL INTRAVASCULAR USE TO AID IN THE SELECTIVE

	PLACEMENT OF CATHETERS IN THE PERIPHERAL, VISCERAL AND CEREBRAL VASCULATURE DURING DIAGNOSTIC AND/OR THERAPEUTIC PROCEDURES,MICROCATHETER (REBAR)(REBAR MICROCATHETER)-THE REBAR MICRO CATHETER IS INTENDED FOR THE CONTROLLED SELECTIVE INFUSION OF PHYSICIAN-SPECIFIED THERAPEUTIC AGENTS OR CONTRAST MEDIA INTO THE VASCULATURE OF THE PERIPHERAL AND NEUROANATOMY., GUIDEWIRE (MIRAGE)(MIRAGE GUIDEWIRE)-MIRAGE GUIDEWIRE IS INDICATED FOR GENERAL INTRAVASCULAR USE TO AID IN THE SELECTIVE PLACEMENT OF CATHETERS IN THE PERIPHERAL, VISCERAL AND CEREBRAL VASCULATURE DURING DIAGNOSTIC AND/OR THERAPEUTIC PROCEDURES.,DETACHABLE COIL (AXIUM PRIME)(AXIUM PRIME DETACHABLE COIL)-THE AXIUM PRIME DETACHABLE COILS ARE INTENDED FOR THE ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS. IT IS ALSO INTENDED FOR THE EMBOLIZATION OF OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE,REVASCULARIZATION DEVICE (SOLITAIRE 2)(SOLITAIRE 2 REVASCULARIZATION DEVICE)-IT IS INTENDED TO RESTORE BLOOD FLOW BY REMOVING THROMBUS FROM A LARGE INTRACRANIAL VESSEL IN PATIENTS EXPERIENCING ISCHEMIC STROKE WITHIN 8 HOURS OF SYMPTOM ONSET. PATIENTS WHO ARE INELIGIBLE FOR INTRAVENOUS TISSUE PLASMINOGEN ACTIVATOR (IV T-PA) OR WHO FAIL IV T-PA THERAPY ARE CANDIDATES FOR TREATMENT.,HYDROPHILIC GUIDEWIRE (AVIGO)(AVIGO HYDROPHILIC GUIDEWIRE)-THE AVIGO HYDROPHILIC GUIDEWIRE IS INDICATED FOR GENERAL INTRAVASCULAR USE TO AID IN THE SELECTIVE PLACEMENT OF CATHETERS IN THE PERIPHERAL AND CEREBRAL VASCULATURE DURING DIAGNOSTIC AND/OR THERAPEUTIC PROCEDURES. THE DEVICE IS NOT INTENDED FOR USE IN THE CORONARY ARTERIES. THE GUIDEWIRE TORQUE DEVICE IS INTENDED TO FACILITATE GUIDEWIRE MANIPULATION DURING INTERVENTIONAL PROCEDURES. THE GUIDEWIRE INTRODUCER IS INTENDED TO FACILITATE GUIDEWIRE INSERTION INTO A CATHETER HUB OR THROUGH A HEMOSTASIS VALVE , EMBOLIZATION DEVICE (DIAMETER 2.50MMX5.0MM)(PIPELINE FLEX EMBOLIZATION DEVICE)-THE PIPELINE FLEX EMBOLIZATION DEVICE IS INDICATED FOR THE ENDOVASCULAR TREATMENT OF ADULTS (22 YEARS OF AGE OR OLDER) WITH LARGE OR GIANT WIDE NECKED ARTERY FROM THE PETROUS TO THE SUPERIOR HYPOPHYSEAL SEGMENTS,INTRACRANIAL SUPPORT CATHETER (ARC AND ARC MINI)(ARC INTRACRANIAL SUPPORT CATHETER AND ARC MINI INTRACRANIAL SUPPORT CATHETER)-THE ARC AND ARC MINI INTRACRANIAL SUPPORT CATHETER IS INDICATED FOR THE

	INTRODUCTION OF INTERVENTIONAL/DIAGNOSTIC DEVICES INTO THE PERIPHERAL, CORONARY, AND NEURO VASCULATURE. THE ARC AND ARC MINI INTRACRANIAL SUPPORT CATHETER IS ALSO INDICATED FOR THE REMOVAL/ASPIRATION OF FRESH, SOFT EMBOLI AND THROMBI FROM SELECTED BLOOD VESSELS IN THE ARTERIAL SYSTEM, INCLUDING NEUROVASCULATURE.,DETACHABLE COIL SYSTEM (CONCERTO PGLA)(CONCERTO DETACHABLE COIL SYSTEM-PGLA FIBRE)-INDICATED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE,DETACHABLE COIL SYSTEM (CONCERTO NYLON)(CONCERTO DETACHABLE COIL SYSTEM- NYLON FIBRE)-INDICATED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE,INTRACRANIAL SUPPORT CATHETER (NAVIEN)(NAVIEN INTRACRANIAL SUPPORT CATHETER)-THE NAVIEN INTRACRANIAL SUPPORT CATHETER IS INDICATED FOR THE INTRODUCTION OF INTERVENTIONAL DEVICES INTO THE PERIPHERAL AND NEURO VASCULATURE.,GUIDEWIRE (SILVERSPEED)(SILVERSPEED GUIDEWIRE)-SILVERSPEED GUIDEWIRE IS INDICATED FOR GENERAL INTRAVASCULAR USE TO AID IN THE SELECTIVE PLACEMENT OF CATHETERS IN THE PERIPHERAL, VISCERAL AND CEREBRAL VASCULATURE DURING DIAGNOSTIC AND/OR THERAPEUTIC PROCEDURES.,DETACHABLE COIL SYSTEM - NYLON (AXIUM)(DETACHABLE COIL SYSTEM - NYLON)-THE AXIUM™ DETACHABLE COILS ARE INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS. THE AXIUM DETACHABLE COILS ARE ALSO INTENDED FOR THE EMBOLIZATION OF OTHER NEUROVASCULAR ABNORMALITIES, SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE.,DELIVERY MICROCATHETER (APOLLO ONYX)(APOLLO ONYX DELIVERY MICROCATHETER)-THE APOLLO ONYX DELIVERY MICRO CATHETER IS INTENDED TO ACCESS THE NEURO VASCULATURE FOR CONTROLLED SELECTIVE INFUSION OF PHYSICIAN-SPECIFIED THERAPEUTIC AGENTS SUCH AS EMBOLIZATION MATERIALS AND OF DIAGNOSTIC MATERIALS SUCH AS CONTRAST MEDIA,MULTIPLE SIDEHOLE INFUSION WIRE (PROSTREAM)(PROSTREAM MULTIPLE SIDEHOLE INFUSION WIRE)-THE PROSTREAM™ MULTIPLE SIDEHOLE INFUSION WIRE IS INTENDED FOR THE CONTROLLED SELECTIVE INFUSION OF PHYSICIAN-SPECIFIED PHARMACOLOGICAL AGENTS OR RADIOPAQUE CONTRAST MEDIA INTO THE GENERAL VASCULATURE. ALL PHARMACOLOGIC AGENTS UTILIZED WITH THE INFUSION WIRE SHOULD BE FULLY PREPARED AND USED ACCORDING TO INSTRUCTIONS FOR USE OF THE SPECIFIC PHARMACOLOGIC AGENT. THE PROSTREAM MULTIPLE INFUSION WIRE IS NOT INTENDED FOR CORONARY OR NEUROVASCULAR USE. ,MULTIPLE SIDEHOLE

	INFUSION CATHETER (MICROMEWI)(MICROMEWI MULTIPLE SIDEHOLE INFUSION CATHETER)-THE MICROMEWI™ MULTIPLE SIDEHOLE INFUSION CATHETER IS INTENDED FOR THE CONTROLLED SELECTIVE INFUSION OF PHYSICIAN-SPECIFIED PHARMACOLOGICAL AGENTS OR RADIOPAQUE CONTRAST MEDIA INTO THE GENERAL VASCULATURE. ALL PHARMACOLOGIC AGENTS UTILIZED WITH THE INFUSION CATHETER SHOULD BE FULLY PREPARED AND USED ACCORDING TO INSTRUCTIONS FOR USE OF THE SPECIFIC PHARMACOLOGIC AGENT. THE INFUSION CATHETER IS NOT INTENDED FOR CORONARY, PEDIATRIC OR NEONATAL USE. ,VALVED INFUSION CATHETER (CRAGG-MCNAMARA)(CRAGG-MCNAMARA VALVED INFUSION CATHETER)-THE CRAGG-MCNAMARA™ VALVED INFUSION CATHETER IS INTENDED FOR THE CONTROLLED SELECTIVE INFUSION OF PHYSICIAN-SPECIFIED PHARMACOLOGICAL AGENTS OR RADIOPAQUE CONTRAST MEDIA INTO THE GENERAL VASCULATURE. ALL PHARMACOLOGIC AGENTS UTILIZED WITH THE INFUSION CATHETER SHOULD BE FULLY PREPARED AND USED ACCORDING TO INSTRUCTIONS FOR USE OF THE SPECIFIC PHARMACOLOGIC AGENT. THE INFUSION CATHETER IS NOT INTENDED FOR CORONARY, PEDIATRIC OR NEONATAL USE ,DETACHABLE COIL SYSTEM (AXIUM)(AXIUM DETACHABLE COIL SYSTEM)-THE AXIUM DETACHABLE COILS ARE INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS. THE AXIUM DETACHABLE COILS ARE ALSO INTENDED FOR THE EMBOLIZATION OF OTHER NEUROVASCULAR ABNORMALITIES, SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE.,BALLOON MICROCATHETER (HYPERFORM)(HYPERFORM BALLOON MICROCATHETER)-THE HYPERFORM BALLOON CATHETER IS INDICATED FOR USE IN BLOOD VESSELS OF THE PERIPHERAL AND NEURO VASCULATURE WHERE TEMPORARY OCCLUSION IS DESIRED. THIS CATHETER OFFER A VESSEL SELECTIVE TECHNIQUE OF TEMPORARY VASCULAR OCCLUSION, WHICH IS USEFUL IN SELECTIVELY STOPPING OR CONTROLLING BLOOD FLOW; THIS MAY ALSO BE USED IN BALLOON-ASSISTED EMBOLIZATION OF INTRACRANIAL ANEURYSMS AND TREATMENT OF VASOSPASMS., LIQUID EMBOLIC SYSTEM (ONYX)(ONYX LIQUID EMBOLIC SYSTEM)-PRESURGICAL EMBOLIZATION OF BRAIN ARTERIOVENOUS MALFORMATIONS (BAVMS).,MICROCATHETER (ECHELON)(ECHELON MICROCATHETER)-THE ECHELON MICRO CATHETER IS INTENDED TO ACCESS PERIPHERAL AND NEURO-VASCULATURE FOR THE CONTROLLED SELECTIVE INFUSION OF PHYSICIAN-SPECIFIED THERAPEUTIC AGENTS SUCH AS EMBOLIZATION MATERIALS AND OF DIAGNOSTIC MATERIALS SUCH AS CONTRAST MEDIA, MICROCATHETER (MARATHON)(MARATHON MICROCATHETER)-THE

	MARATHON FLOW DIRECTED MICRO CATHETER IS INTENDED TO ACCESS THE PERIPHERAL AND NEURO-VASCULATURE FOR THE CONTROLLED SELECTIVE INFUSION OF PHYSICIAN-SPECIFIED THERAPEUTIC AGENTS SUCH AS EMBOLIZATION MATERIALS AND OF DIAGNOSTIC MATERIALS SUCH AS CONTRAST MEDIA,BALLOON MICROCATHETER (HYPERGLIDE)(HYPERGLIDE BALLOON MICROCATHETER)-THE HYPERGLIDE BALLOON CATHETER IS INDICATED FOR USE IN BLOOD VESSELS OF THE PERIPHERAL AND NEURO VASCULATURE WHERE TEMPORARY OCCLUSION IS DESIRED. THIS CATHETER OFFER A VESSEL SELECTIVE TECHNIQUE OF TEMPORARY VASCULAR OCCLUSION, WHICH IS USEFUL IN SELECTIVELY STOPPING OR CONTROLLING BLOOD FLOW; THIS MAY ALSO BE USED IN BALLOON-ASSISTED EMBOLIZATION OF INTRACRANIAL ANEURYSMS AND TREATMENT OF VASOSPASMS., EMBOLIZATION DEVICE (PIPELINE)(PIPELINE EMBOLIZATION DEVICE) -THE PIPELINE™ EMBOLIZATION DEVICE IS INTENDED TO BE USED FOR ENDOVASCULAR EMBOLIZATION OF CEREBRAL ANEURYSMS, GUIDEWIRE (X-CELERATOR)(X-CELERATOR GUIDEWIRE)-X-CELERATOR IS INDICATED FOR GENERAL INTRAVASCULAR USE TO AID IN THE SELECTIVE PLACEMENT OF CATHETERS IN THE PERIPHERAL, VISCERAL AND CEREBRAL VASCULATURE DURING DIAGNOSTIC AND/OR THERAPEUTIC PROCEDURES.,HPC FLOW DIRECTED MICROCATHETER (ULTRAFLOW)(ULTRAFLOW HPC FLOW DIRECTED MICROCATHETER)-THE ULTRAFLOW HPC FLOW DIRECTED MICROCATHETER IS INTENDED TO ACCESS THE PERIPHERAL AND NEURO-VASCULATURE FOR THE CONTROLLED SELECTIVE INFUSION OF PHYSICIAN SPECIFIED THERAPEUTIC AGENTS SUCH AS EMBOLIZATION MATERIALS AND OF DIAGNOSTIC MATERIALS SUCH AS CONTRAST MEDIA. NOT INTENDED FOR USE IN CORONARY VASCULATURE.,EMBOLIZATION DEVICE(PIPELINE™ FLEX EMBOLIZATION DEVICE WITH SHIELD TECHNOLOGY™)-THE PIPELINE™ FLEX EMBOLIZATION DEVICE WITH SHIELD TECHNOLOGY™ IS INTENDED FOR ENDOVASCULAR EMBOLIZATION OF CEREBRAL ANEURYSMS.,REVASCULARIZATION DEVICE (SOLITAIRE™ PLATINUM REVASCULARIZATION DEVICE)-THE SOLITAIRE™ PLATINUM REVASCULARIZATION DEVICE IS INTENDED TO RESTORE BLOOD FLOW BY REMOVING THROMBUS FROM A LARGE INTRACRANIAL VESSEL IN PATIENTS EXPERIENCING ISCHEMIC STROKE WITHIN 8 HOURS OF SYMPTOM ONSET. PATIENTS WHO ARE INELIGIBLE FOR INTRAVENOUS TISSUE PLASMINOGEN ACTIVATOR (IV T-PA) OR WHO FAIL IV T-PA THERAPY ARE CANDIDATES FOR TREATMENT.,DETACHABLE COIL(AXIUM™ PRIME DETACHABLE COIL SYSTEM- FRAME COMPLEX COILS)-THE AXIUM™ PRIME DETACHABLE COILS ARE INTENDED FOR THE ENDOVASCULAR EMBOLIZATION OF

		INTRACRANIAL ANEURYSMS. THE AXIUM™ PRIME DETACHABLE COILS ARE ALSO INTENDED FOR THE EMBOLIZATION OF OTHER NEURO VASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE.
1247	IMP/MD/2018/000119	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROWAVE ABLATION ANTENNA(EMPRINT™ SHORT PERCUTANEOUS ANTENNA WITH THERMOSPHERE™ TECHNOLOGY)-EMPRINT™ ABLATION SYSTEM IS INTENDED FOR USE IN PERCUTANEOUS, LAPAROSCOPIC, AND INTRAOPERATIVE COAGULATION (ABLATION) OF SOFT TISSUE, INCLUDING PARTIAL OR COMPLETE ABLATION OF NON-RESECTABLE LIVER TUMORS. THE EMPRINT™ ABLATION SYSTEM IS NOT INTENDED FOR USE IN CARDIAC PROCEDURES.,SINGLE USE CIRCULAR STAPLER (PREMIUM PLUS CEEA AUTOSUTURE)-PREMIUM PLUS CEEA STAPLER IS USED THROUGHOUT THE ALIMENTARY TRACT FOR THE CREATION OF END-TO-END, END-TO-SIDE AND SIDE-TO-SIDE ANASTOMOSES IN BOTH OPEN AND LAPAROSCOPIC SURGERIES.,MICROWAVE ABLATION ANTENNA(EMPRINT™ STANDARD PERCUTANEOUS ANTENNA WITH THERMOSPHERE™ TECHNOLOGY)-EMPRINT™ ABLATION SYSTEM IS INTENDED FOR USE IN PERCUTANEOUS, LAPAROSCOPIC, AND INTRAOPERATIVE COAGULATION (ABLATION) OF SOFT TISSUE, INCLUDING PARTIAL OR COMPLETE ABLATION OF NON-RESECTABLE LIVER TUMORS. THE EMPRINT™ ABLATION SYSTEM IS NOT INTENDED FOR USE IN CARDIAC PROCEDURES., MICROWAVE ABLATION ANTENNA(EMPRINT™ LONG PERCUTANEOUS ANTENNA WITH THERMOSPHERE™ TECHNOLOGY)-EMPRINT™ ABLATION SYSTEM IS INTENDED FOR USE IN PERCUTANEOUS, LAPAROSCOPIC, AND INTRAOPERATIVE COAGULATION (ABLATION) OF SOFT TISSUE, INCLUDING PARTIAL OR COMPLETE ABLATION OF NON-RESECTABLE LIVER TUMORS. THE EMPRINT™ ABLATION SYSTEM IS NOT INTENDED FOR USE IN CARDIAC PROCEDURES.
1248	IMP/MD/2018/000123	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLOSED SUCTION SYSTEM(DAR)-CLOSED SUCTION SYSTEM IS INDICATED FOR ENDOTRACHEAL/ TRACHEOSTOMY SUCTION OF ADULT PAEDIATRIC AND NEONATAL INTUBATED PATIENTS. THE DEVICE IS INTENDED FOR SINGLE USE

1249	IMP/MD/2018/000124	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEONATAL TRACHEOSTOMY TUBE WITH TAPERGUARD™ CUFF(SHILEY)-THIS DEVICE IS INTENDED FOR USE IN PROVIDING TRACHEAL ACCESS FOR AIRWAY MANAGEMENT.,TAPERGUARD ORAL/ NASAL TRACHEAL TUBE(SHILEY)-THE TAPERGUARD TRACHEAL TUBES ARE INDICATED FOR ORAL/ NASAL INTUBATION OF THE TRACHEA FOR ANESTHESIA AND FOR GENERAL AIRWAY MANAGEMENT.,PEDIATRIC TRACHEOSTOMY TUBE WITH TAPERGUARD™ CUFF(SHILEY)-THIS DEVICE IS INTENDED FOR USE IN PROVIDING TRACHEAL ACCESS FOR AIRWAY MANAGEMENT.,TRACHEOSTOMY TUBE(SHILEY)-THE DEVICES ARE INTENDED FOR USE IN PROVIDING TRACHEAL ACCESS FOR AIRWAY MANAGEMENT. THE FENESTRATED DEVICES (FEN, CFN) ARE ALSO INDICATED WHEN THE USE OF FENESTRATIONS IS DESIRABLE IN ORDER TO SAFELY AND EFFECTIVELY WEAN A TRACHEOSTOMY PATIENT. WHEN USED IN CONJUNCTION WITH THE DECANULATION PLUG (DCP), THE FENESTRATED TRACHEOSTOMY TUBE CAN PROVIDE A MEANS OF WEANING AND/OR PHONATION FOR THE PATIENT. USE OF THE DECANNULATION PLUG (DCP) WITH THE FENESTRATED TRACHEOSTOMY TUBES FORCES AIR THROUGH THE FENESTRATIONS AND AROUND THE TUBE, AND INTO THE UPPER AIRWAY AND VOCAL CORDS,NASOPHARYNGEAL AIRWAY(SHILEY)-THE SHILEY NASOPHARYNGEAL AIRWAY IS INTENDED FOR THE PROVISION OF OXYGEN TO THE PATIENT.,TAPERGUARD EVAC ORAL TRACHEAL TUBE(SHILEY)-THE TAPERGUARD EVAC ORAL TRACHEAL TUBES ARE INDICATED FOR ORAL INTUBATION OF THE TRACHEA FOR AIRWAY MANAGEMENT WHEN DURATION OF INTUBATION IS EXPECTED TO BE MORE THAN 24 HOURS. WHERE PROFUSE SECRETIONS BUILD UP ABOVE THE CUFF OR TRACHEAL INFECTION NEEDS TO BE MINIMIZED, THE EVAC LUMEN IS INDICATED.,TAPERGUARD EVAC ORAL TRACHEAL TUBE WITH STYLET(SHILEY)-THE TAPERGUARD EVAC ORAL TRACHEAL TUBE WITH STYLET IS INDICATED FOR ORAL INTUBATION OF THE TRACHEA FOR ANESTHESIA AND FOR AIRWAY MANAGEMENT WHEN DURATION OF INTUBATION IS EXPECTED TO BE MORE THAN 24 HOURS. WHERE PROFUSE SECRETIONS BUILD UP ABOVE THE CUFF OR TRACHEAL INFECTION NEEDS TO BE MINIMIZED, THE EVAC LUMEN IS INDICATED

1250	IMP/MD/2018/000125	1.License Holder Name: CARDINAL HEALTH MEDICAL PRODUCTS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA DILATATION CATHETER(EMPIRA NC RX)-THE CORDIS EMPIRA NC RX PTCA DILATATION CATHETERS ARE INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. THE CORDIS EMPIRA NC RX PTCA DILATATION CATHETER IS ALSO INDICATED FOR POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS.,PTCA DILATATION CATHETER (EMPIRA RX)-THE CORDIS EMPIRA RX PTCA DILATATION CATHETER ARE INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.

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1251	IMP/MD/2018/000126	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SYNCHRO SELECT GUIDEWIRES(SYNCHRO SELECT GUIDEWIRES)-THE SYNCHRO SELECT GUIDEWIRE SERIES IS INTENDED FOR GENERAL INTRAVASCULAR USE, INCLUDING NEUROVASCULAR AND PERIPHERAL VASCULATURES. IT CAN BE USED TO SELECTIVELY INTRODUCE AND POSITION CATHETERS AND OTHER INTERVENTIONAL DEVICES WITHIN THE PERIPHERAL AND NEUROVASCULATURE. THIS DEVICE SHOULD BE USED ONLY BY PHYSICIANS TRAINED IN PERCUTANEOUS, INTRAVASCULAR TECHNIQUES AND PROCEDURES., SYNCHRO GUIDE WIRES(SYNCHRO® -10 & SYNCHRO® -14 GUIDE WIRES)-"THE SYNCHRO NEURO GUIDEWIRE SERIES IS INTENDED FOR NEUROVASCULAR USE. IT CAN BE USED TO SELECTIVELY INTRODUCE AND POSITION CATHETERS AND OTHER INTERVENTIONAL DEVICES WITHIN THE NEUROVASCULATURE. THIS DEVICE SHOULD BE USED ONLY BY PHYSICIANS TRAINED IN PERCUTANEOUS, INTRAVASCULAR TECHNIQUES AND PROCEDURES.",TREVO NXT PROVUE RETRIEVER (TREVO NXT PROVUE RETRIEVER)-THE TREVO RETRIEVER IS INDICATED FOR USE TO RESTORE BLOOD FLOW IN THE NEUROVASCULATURE BY REMOVING THROMBUS FOR THE TREATMENT OF ACUTE ISCHEMIC STROKE TO REDUCE DISABILITY IN PATIENTS WITH A PERSISTENT, PROXIMAL ANTERIOR CIRCULATION, LARGE VESSEL OCCLUSION, AND SMALLER CORE INFARCTS WHO HAVE FIRST RECEIVED INTRAVENOUS TISSUE PLASMINOGEN ACTIVATOR (IV T-PA). ENDOVASCULAR THERAPY WITH THE DEVICE SHOULD START WITHIN 6 HOURS OF SYMPTOM ONSET. THE TREVO RETRIEVER IS INTENDED TO RESTORE BLOOD FLOW IN THE NEUROVASCULATURE BY REMOVING THROMBUS IN PATIENTS EXPERIENCING ISCHEMIC STROKE WITHIN 8 HOURS OF SYMPTOM ONSET. PATIENTS WHO ARE INELIGIBLE FOR INTRAVENOUS TISSUE PLASMINOGEN ACTIVATOR (IV T-PA) OR WHO FAIL IV T-PA THERAPY ARE CANDIDATES FOR TREATMENT. THE TREVO RETRIEVER IS INDICATED FOR USE TO RESTORE BLOOD FLOW IN THE NEUROVASCULATURE BY REMOVING THROMBUS FOR THE TREATMENT OF ACUTE ISCHEMIC STROKE TO REDUCE DISABILITY IN PATIENTS WITH A PERSISTENT, PROXIMAL ANTERIOR CIRCULATION, LARGE VESSEL OCCLUSION OF THE INTERNAL CAROTID ARTERY (ICA) OR MIDDLE CEREBRAL ARTERY (MCA)-M1 SEGMENTS WITH SMALLER CORE INFARCTS (0-50CC FOR AGE 80 YEARS, 0-20CC FOR AGE 80 YEARS). ENDOVASCULAR THERAPY WITH THE DEVICE SHOULD START WITHIN 6-24 HOURS OF TIME LAST SEEN WELL IN PATIENTS WHO ARE INELIGIBLE FOR INTRAVENOUS TISSUE PLASMINOGEN ACTIVATOR (IV T-PA) OR WHO FAIL IV T-PA THERAPY.,

	MICROCATHETERS(TREVO PRO 18 MICROCATHETER)-"THE MICROCATHETER IS INDICATED FOR USE IN THE SELECTIVE PLACEMENT OF FLUIDS AND/OR OTHER DEVICES OR AGENTS INTO THE PERIPHERAL, CORONARY, AND NEURO VASCULATURE DURING DIAGNOSTIC AND/OR THERAPEUTIC PROCEDURES.",TREVO TRAK 21 MICROCATHETER(TREVO TRAK 21 MICROCATHETER)-THE MICROCATHETER IS INDICATED FOR USE IN THE SELECTIVE PLACEMENT OF DEVICES AND/OR FLUIDS, SUCH AS CONTRAST MEDIA, INTO THE PERIPHERAL, CORONARY, AND NEUROVASCULATURE DURING DIAGNOSTIC AND/OR THERAPEUTIC PROCEDURES.,RETRIEVERS(TREVO XP PROVUE RETRIEVERS)-"THE TREVO RETRIEVER IS INTENDED TO RESTORE BLOOD FLOW IN THE NEUROVASCULATURE BY REMOVING THROMBUS IN PATIENTS EXPERIENCING ISCHEMIC STROKE WITHIN 8 HOURS OF SYMPTOM ONSET. PATIENTS WHO ARE INELIGIBLE FOR INTRAVENOUS TISSUE PLASMINOGEN ACTIVATOR (IV T-PA) OR WHO FAIL IV T-PA THERAPY ARE CANDIDATES FOR TREATMENT.",DISTAL ACCESS CATHETERS (DISTAL ACCESS CATHETERS (DAC))-"• THE DISTAL ACCESS CATHETER IS INDICATED FOR USE IN FACILITATING THE INSERTION AND GUIDANCE OF AN OCCLUSION CATHETER, INFUSION CATHETER OR OTHER APPROPRIATE MICROCATHETER INTO A SELECTED BLOOD VESSEL IN THE PERIPHERAL, CORONARY AND NEURO VASCULAR SYSTEMS. IT MAY ALSO BE USED AS A DIAGNOSTIC ANGIOGRAPHIC CATHETER. • IT IS ALSO INDICATED FOR THE REMOVAL/ASPIRATION OF FRESH, SOFT EMBOLI AND THROMBI FROM VESSELS IN THE ARTERIAL SYSTEM, INCLUDING THE NEUROVASCULATURE.", BALLOON GUIDE CATHETERS(FLOW GATE 2 8F BALLON GUIDE CATHETER)-"FLOWGATE BALLOON GUIDE CATHETERS ARE INDICATED FOR USE IN FACILITATING THE INSERTION AND GUIDANCE OF AN INTRAVASCULAR CATHETER INTO A SELECTED BLOOD VESSEL IN THE PERIPHERAL AND NEURO VASCULAR SYSTEMS. THE BALLOON PROVIDES TEMPORARY VASCULAR OCCLUSION DURING THESE AND OTHER ANGIOGRAPHIC PROCEDURES. THE BALLOON GUIDE CATHETER IS ALSO INDICATED FOR USE AS A CONDUIT FOR RETRIEVAL DEVICES.",SYNCHRO2GUIDE WIRES(SYNCHRO2GUIDE WIRES)-"THE SYNCHRO2 GUIDEWIRE SERIES IS INTENDED FOR GENERAL INTRAVASCULAR USE, INCLUDING NEUROVASCULAR AND PERIPHERAL VASCULATURES. IT CAN BE USED TO SELECTIVELY INTRODUCE AND POSITION CATHETERS AND OTHER INTERVENTIONAL DEVICES WITHIN THE PERIPHERAL AND NEUROVASCULATURE. THIS DEVICE SHOULD BE USED ONLY BY PHYSICIANS TRAINED IN PERCUTANEOUS, INTRAVASCULAR TECHNIQUES AND PROCEDURES",BALLOON GUIDE CATHETERS (MERCI BALLOON GUIDE CATHETER)-"CONCENTRIC AND MERCI

	BALLOON GUIDE CATHETERS ARE INDICATED FOR USE IN FACILITATING THE INSERTION AND GUIDANCE OF AN INTRAVASCULAR CATHETER INTO A SELECTED BLOOD VESSEL IN THE PERIPHERAL AND NEURO VASCULAR SYSTEMS. THE BALLOON PROVIDES TEMPORARY VASCULAR OCCLUSION DURING THESE AND OTHER ANGIOGRAPHIC PROCEDURES. THE BALLOON GUIDE CATHETER IS ALSO INDICATED FOR USE AS A CONDUIT FOR RETRIEVAL DEVICES.",BALLOON GUIDE CATHETERS(CONCENTRIC 7F BALLOON GUIDE CATHETER)-"CONCENTRIC AND MERCI BALLOON GUIDE CATHETERS ARE INDICATED FOR USE IN FACILITATING THE INSERTION AND GUIDANCE OF AN INTRAVASCULAR CATHETER INTO A SELECTED BLOOD VESSEL IN THE PERIPHERAL AND NEURO VASCULAR SYSTEMS. THE BALLOON PROVIDES TEMPORARY VASCULAR OCCLUSION DURING THESE AND OTHER ANGIOGRAPHIC PROCEDURES. THE BALLOON GUIDE CATHETER IS ALSO INDICATED FOR USE AS A CONDUIT FOR RETRIEVAL DEVICES."

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1252	IMP/MD/2018/000127	1.License Holder Name: M/S LINVATEC INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALL SUTURE ANCHOR SYSTEM(TRUSHOT)-THE DEVICE MAY BE USED IN EITHER ARTHROSCOPIC OR OPEN SURGICAL PROCEDURES. AFTER THE SUTURE IS ANCHORED TO THE BONE, IT MAY BE USED TO REATTACH SOFT TISSUE, SUCH AS LIGAMENTS, TENDONS, OR JOINT CAPSULES TO THE BONE. THE SUTURE ANCHOR SYSTEMSTHEREBY STABILIZE THE DAMAGED SOFT TISSUE, IN CONJUNCTION WITHAPPROPRIATE POSTOPERATIVE IMMOBILIZATION, THROUGHOUT THE HEALING PERIOD.,TENODESIS ANCHORS (CONMED TENOLOK TENODESIS ANCHORS)-CONMED TENOLOK TENODESIS ANCHORS THE CONMED TENOLOK TENODESIS ANCHORS ARE INTENDED TO REATTACH SOFT TISSUE TO BONE IN EITHER ARTHROSCOPIC OR OPEN ORTHOPEDIC SURGICAL PROCEDURES. (SOURCE IFU W55-000-965),CANNULAS (CONMED DISPOSABLE CANNULA)-THE DISPOSABLE CANNULA LINE OF PRODUCTS ARE INTENDED TO CREATE A SURGICAL PORTAL IN WHICH VARIOUS SURGICAL INSTRUMENTS MAY BE PASSED THROUGH DURING ARTHROSCOPIC PROCEDURES.,NON-ABSORBABLE IMPLANTS(CROSSFT SUTURE ANCHORS)-THE NON-ABSORBABLE SUTURE ANCHOR IS INTENDED TO REATTACH SOFT TISSUE TO BONE IN ORTHOPEDIC SURGICAL PROCEDURES. (SOURCE IFU W55-000-814, W55-000-954),MENISCAL REPAIR SYSTEM(ZONE SPECIFIC II MENISCAL REPAIR SYSTEM)-THE MENISCAL REPAIR NEEDLES ARE INTENDED FOR USE DURING ARTHROSCOPIC SURGICAL PROCEDURES TO REPAIR MENISCAL TEARS; SPECIFICALLY, THE NEEDLES ARE INTENDED FOR USE IN SUTURING MENISCAL TEARS.,SUSPENSORY FIXATION DEVICE(XO BUTTON CORTICAL FIXATION DEVICE)-THE XO BUTTON IS INDICATED FOR FIXATION OF SOFT TISSUE TO BONE IN ORTHOPAEDIC PROCEDURES SUCH AS ACL REPAIR, PCL REPAIR, MCL REPAIR, AND LCL REPAIR. (SOURCE IFU W55-000-816) ,FIXATION SYSTEM(INFINITY FIXATION SYSTEM)-THE INFINITY FIXATION SYSTEM IS INTENDED TO PROVIDE SUSPENSION FIXATION FOR SOFT TISSUE TO BONE IN THE REPAIR OF THE NATURAL LIGAMENT OR TENDON DISRUPTION OR RECONSTRUCTION OF A LIGAMENT USING SOFT TISSUE GRAFTS. EXAMPLES OF SUCH PROCEDURES INCLUDE ANTERIOR CRUCIATE LIGAMENT, POSTERIOR CRUCIATE LIGAMENT, MEDIAL COLLATERAL LIGAMENT AND LATERAL COLLATERAL LIGAMENT.,BIOABSORBABLE IMPLANTS(BIOABSORBABLE INTERFERENCE SCREWS)-BIOSCREW® BIOABSORBABLE INTERFERENCE SCREWS: THE BIOSCREW IS USED TO PROVIDE INTERFERENCE FIXATION IN ANTERIOR AND POSTERIOR CRUCIATE LIGAMENT RECONSTRUCTION USING BONE-TENDON-BONE GRAFTS AND FOR FEMORAL AND/OR TIBIAL FIXATION IN

	ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION USING A SOFT TISSUE GRAFT. IMPLANTATION OF THE INTERFERENCE SCREW IS ACCOMPLISHED THROUGH ARTHROSCOPY OR ARTHOTOMY. (SOURCE IFU W55-000-894) BIOSCREW® BIOABSORBABLE FEMORAL INTERFERENCE SCREWS (GUARDSMAN INTERFERENCE SCREWS): THE BIOSCREW FEMORAL INTERFERENCE SCREW IS USED TO PROVIDE FEMORAL INTERFERENCE FIXATION IN ANTERIOR AND POSTERIOR CRUCIATE LIGAMENT RECONSTRUCTION USING BONE-TENDON-BONE GRAFTS AND FOR FEMORAL FIXATION IN ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION USING A SOFT TISSUE GRAFT. IMPLANTATION OF THE INTERFERENCE SCREW IS ACCOMPLISHED THROUGH ARTHROSCOPY OR ARTHROTOMY. (SOURCE IFU W55-000-894) BIOSCREW® XTRALOK® BIOABSORBABLE INTERFERENCE SCREWS: THE BIOSCREWXTRALOK SCREW PROVIDES TIBIAL INTERFERENCE FIXATION OF A SOFT TISSUE GRAFT FOR ACL AND PCL RECONSTRUCTION. (SOURCE IFU W55-000-834),CANNULAS(CONMED LINVATEC HEX FLEX CANNULAS AND CONMED LINVATEC DRY DOC CANNULAS)-THE DRYDOC AND HEX FLEX CANNULAS ARE INTENDED TO MAINTAIN A PORTAL INTO THE JOINT AND PROVIDE A MEANS OF PASSING INSTRUMENTATION, IMPLANTS AND/ OR FLUID INTO AND OUT OF THE JOINT.,SOFT TISSUE ANCHOR(REVO AND SUPER REVO SUTURE ANCHORS/ THREVO SUTURE ANCHORS)-INTENDED USE: CF6140H, CF6160H, CF6140H, CF6160H, CF6140HN, CF6160HN, CF6140HB, CF6160HB, CF6140HNB, CF6160HNB) EACH NON-ABSORBABLE SUTURE ANCHOR IS INTENDED TO REATTACH SOFT TISSUE TO BONE IN ORTHOPEDIC SURGICAL PROCEDURES. (SOURCE IFU: W55-000-807 FOR CF6140H, CF6160H W55-000-853 FOR CF6140H, CF6160H, CF6140H, CF6160H, CF6140HN, CF6160HN W55-000-958 FOR CF6140HB, CF6160HB, CF6140HNB, CF6160HNB) C6160, C6160H, C6161H, C6160HB THE CONMED LINVATECTHREVO SOFT TISSUE ANCHOR IS INTENDED TO BE USED FOR ROTATOR CUFF REPAIRS IN THE SHOULDER, EITHER ARTHROSCOPICALLY OR IN A MINI-OPEN TECHNIQUE. (SOURCE IFU: W55-000-812 FOR C6160, C6160H, C6161H W55-000-957 FOR C6160HB) C6101A, C6101H, C6102H, C6109A, C6109H THE CONMED LINVATEC PRELOADED REVO/MINI-REVO SOFT TISSUE ANCHOR IS INTENDED TO BE USED TO ATTACH SOFT TISSUE TO BONE. THE FOLLOWING ARE INDICATIONS FOR USE: SHOULDER: 1. BANKART LESION REPAIRS 2. SLAP LESION REPAIRS 3. ROTATOR CUFF TEAR REPAIRS (REVO ONLY) 4. CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTIONS 5. BICEPS TENODESIS BLADDER NECK SUSPENSION: 1. FEMALE URINARY INCONTINENCE DUE TO URETHRAL HYPEMOBILITY. (SOURCE IFU: W55-000-813) C6140, C6141, C6140H, C6141H, C6140HB THE CONMED LINVATECH SUPER REVO SOFT

	TISSUE ANCHOR IS INTENDED TO BE USED FOR ROTATOR CUFF REPAIRS IN THE SHOULDER, EITHER ARTHROSCOPICALLY OR IN A MINI-OPEN TECHNIQUE. (SOURCE IFU: W55-000-837 FOR C6140, C6141, C6140H, C6141H W55-000-956 FOR C6140HB),NON-ABSORBABLE IMPLANTS(POPLOK SUTURE ANCHORS)-THE NON-ABSORBABLE SUTURE ANCHOR IS INTENDED TO REATTACH SOFT TISSUE TO BONE IN ORTHOPEDIC SURGICAL PROCEDURES., NONABSORBABLE IMPLANT KITS(CONMED TENOLOK KITS)-CONMED TENOLOK KITS THE TENOLOKKITS ARE INTENDED TO REATTACH SOFT TISSUE TO BONE IN EITHER ARTHROSCOPIC OR OPEN ORTHOPEDIC SURGICAL PROCEDURES. (SOURCE IFU W55-000-968) , MENISCAL REPAIR DEVICE(SEQUENT MENISCAL REPAIR DEVICE)-THE SEQUENT MENISCAL REPAIR DEVICE IS AN IMPLANTABLE SUTURE RETENTION DEVICE WHICH FACILITATES PERCUTANEOUS OR ENDOSCOPIC SOFT TISSUE REPAIRS, INCLUDING THE REPAIR OF MENISCAL TEARS.,ALL SUTURE ANCHOR(Y-KNOT RC ALL-SUTURE ANCHOR/ Y-KNOT RC WITH NEEDLES ALL-SUTURE ANCHOR/ Y-KNOT RC WITH TAPE ALL-SUTURE ANCHOR /Y-KNOT FLEX ALL-SUTURE ANCHOR)-THE NON-ABSORBABLE SUTURE ANCHORS ARE INTENDED TO REATTACH SOFT TISSUE TO BONE IN ORTHOPEDIC SURGICAL PROCEDURES.,BIOCOMPOSITE ANCHOR FOR RC(GENESYS CROSS FT) -THE CONMED LINVATEC GENESYS CROSSFT SUTURE ANCHORS ARE INTENDED TO REATTACH SOFT TISSUE TO BONE IN ORTHOPEDIC SURGICAL PROCEDURES.,PEEK ANCHOR(PRESS FT)-THE CONMED LINVATEC PRESSFT AND GENESYS PRESSFT SUTURE ANCHORS ARE INTENDED TO REATTACH SOFT TISSUE TO BONE IN ORTHOPEDIC SURGICAL PROCEDURES.,ADJUSTABLE LOOP BUTTON(GRAFT MAX BUTTON)-THE GRAFTMAX BUTTON ALB AND GRAFTMAX BUTTON BTB ARE INTENDED TO PROVIDE SUSPENSION FIXATION FOR SOFT TISSUE TO BONE IN THE REPAIR OF THE NATURAL LIGAMENT OR TENDON DISRUPTION OR RECONSTRUCTION OF A LIGAMENT USING SOFT TISSUE GRAFTS OR BONE TENDON GRAFTS. EXAMPLES OF SUCH PROCEDURES INCLUDE ANTERIOR CRUCIATE LIGAMENT, POSTERIOR CRUCIATE LIGAMENT, MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, DISTAL BICEPS TENDON RUPTURE, AND SEPARATIONS DUE TO CORACOVASCULAR LIGAMENT DISRUPTIONS. THE GRAFTMAX BUTTON CRADLE MUST BE USED WITH THE GRAFTMAX BUTTON ALB, GRAFTMAX BUTTON BTB OR XO BUTTON IMPLANTS AND IS INTENDED TO PROVIDE SUSPENSION FIXATION FOR SOFT TISSUE TO BONE IN THE REPAIR OF THE NATURAL LIGAMENT OR TENDON DISRUPTION OR RECONSTRUCTION OF A LIGAMENT USING SOFT TISSUE GRAFTS OR BONE TENDON GRAFTS. EXAMPLES OF SUCH PROCEDURES INCLUDE ANTERIOR CRUCIATED LIGAMENT, POSTERIOR CRUCIATED LIGAMENT, MEDIAL

		COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGMENT, DISTAL BICEPS TENDON RUPTURE, AND SEPARATIONS DUE TO CORACOOVASCULAR LIGAMENT DISRUPTIONS.,BIOCOMPOSITE ANCHOR FOR INSTABILITY(GENESYS PRESS FT)-THE CONMED LINVATECPRESSFT AND GENSYS PRESSFT SUTURE ANCHORS ARE INTENDED TO REATTACH SOFT TISSUE TO BONE IN ORTHOPEDIC SURGICAL PROCEDURES.
1253	IMP/MD/2018/000128	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE (NON-STERILE)(BD HYPAK™)-COMPONENT OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS,PREFILLABLE GLASS BARREL WITH NEEDLE (STERILE)(BD HYPAK SCF™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1254	IMP/MD/2018/000129	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BALLOON PERIPHERAL ANGIOPLASTY CATHETER(XXL VASCULAR BALLOON DILATATION CATHETER)-XXL BALLOON DILATATION CATHETERS ARE INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF NARROWED SEGMENTS IN THE ILIAC ARTERIES IN THE PERIPHERAL VASCULATURE. XXL BALLOON DILATATION CATHETERS ARE NOT INDICATED FOR USE IN CORONARY ARTERIES NOR IN THE NEUROVASCULATURE.,STENT SYSTEM(HOT AXIOS STENT AND ELECTROCAUTERY-ENHANCED DELIVERY SYSTEM)-THE HOT AXIOS STENT AND ELECTROCAUTERY- ENHANCED DELIVERY SYSTEM IS INDICATED FOR USE TO FACILITATE TRANSGASTRIC OR TRANSDUODENAL ENDOSCOPIC DRAINAGE OF A PANCREATIC PSEUDOCYST OR A WALLED-OFF NECROSIS WITH 70% FLUID CONTENT OR THE BILIARY TRACT.,ILIAC ARTERY STENT; MULTIPLE PERIPHERAL ARTERY STENT, BARE METAL; TRACHEA PROSTHESIS; BARE METAL BILIARY STENT; BARE METAL BRONCHIAL STENT (WALLSTENT UNI ENDOPROSTHESIS SELF EXPANDING STENT)-ILIAC ARTERY THE WALLSTENT-UNI ENDOPROSTHESIS IS INDICATED FOR USE FOLLOWING SUBOPTIMAL PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) OF COMMON AND/OR EXTERNAL ILIAC ARTERY STENOTIC LESIONS, WHICH ARE LESS THAN OR EQUALS TO 10 CM IN LENGTH. A SUBOPTIMAL PTA IS DEFINED AS A TECHNICALLY SUCCESSFUL DILATION, JUDGED BY THE PHYSICIAN TO BE SUBOPTIMAL DUE TO THE PRESENCE OF UNFAVORABLE LESION MORPHOLOGY SUCH AS: * AN INADEQUATE ANGIOGRAPHIC AND/OR HEMODYNAMIC RESULT AS DEFINED BY A 30 PERCENTAGE OR GREATER RESIDUAL STENOSIS AFTER PTA, LESION RECOIL, OR INTIMAL FLAPS. * FLOW LIMITING DISSECTIONS POST PTA LONGER THAN THE INITIAL LESION LENGTH. * A 5 MM HG OR GREATER MEAN TRANSTENOTIC PRESSURE GRADIENT POST PTA. SUPERFICIAL FEMORAL ARTERY THE WALLSTENT-UNI ENDOPROSTHESIS IS INTENDED FOR USE IN THE TREATMENT OF SUPERFICIAL FEMORAL ARTERY (SFA) STENOSES OR OCCLUSIONS. TRANSJUGULAR INTRAHEPATIC PORTOSYSTEMIC SHUNT (TIPS) THE WALLSTENT-UNI ENDOPROSTHESIS IS INDICATED FOR CREATION OF TRANSJUGULAR INTRAHEPATIC SHUNT CONNECTIONS BETWEEN THE PORTAL VENOUS SYSTEM AND THE HEPATIC VEIN FOR PROPHYLAXIS OF VARICEAL BLEEDING OR INTRACTABLE ASCITES IN THE TREATMENT OF PORTAL HYPERTENSION AND ITS COMPLICATIONS IN PATIENTS WHO HAVE PREVIOUSLY FAILED CONVENTIONAL TREATMENT TECHNIQUES. BILIARY THE WALLSTENT-UNI ENDOPROSTHESIS IS INDICATED FOR USE IN THE TREATMENT OF BILIARY STRICTURES

	PRODUCED BY MALIGNANT NEOPLASMS. TRACHEOBRONCHIAL THE WALLSTENT-UNI ENDOPROSTHESIS IS INDICATED FOR USE IN THE TREATMENT OF TRACHEOBRONCHIAL STRICTURES PRODUCED BY MALIGNANT NEOPLASMS. CENTRAL VENOUS THE WALLSTENT-UNI ENDOPROSTHESIS IS INDICATED FOR THE TREATMENT OF CENTRAL VENOUS OBSTRUCTION AND FOR IMPROVING CENTRAL VENOUS LUMINAL DIAMETER FOLLOWING UNSUCCESSFUL ANGIOPLASTY IN PATIENTS ON CHRONIC HEMODIALYSIS WITH STENOSIS OF THE VENOUS OUTFLOW TRACT. UNSUCCESSFUL ANGIOPLASTY IS DEFINED AS RESIDUAL STENOSIS GREATER THAN OR EQUALS TO 30 PERCENTAGE FOR A VEIN LESS THAN OR EQUALS TO 10 MM IN DIAMETER OR GREATER THAN OR EQUALS TO 50 PERCENTAGE FOR A VEIN GREATER THAN 10 MM IN DIAMETER, A TEAR WHICH INTERRUPTS THE INTEGRITY OF THE INTIMA LUMEN, ABRUPT LESION SITE OCCLUSION, OR REFRACTORY SPASM. THE VESSELS THAT CAN BE TREATED WITH THE WALLSTENT-UNI ENDOPROSTHESIS ARE THE INNOMINATE AND SUBCLAVIAN VEINS, RANGING FROM 8 MM TO 15 MM IN DIAMETER. SUPERIOR VENA CAVA (SVC) THE WALLSTENT-UNI ENDOPROSTHESIS IS INTENDED FOR USE IN THE PALLIATIVE TREATMENT OF STENOSIS OF THE SUPERIOR VENA CAVA DUE TO A MALIGNANT PROCESS. ILIAC VEIN THE WALLSTENT-UNI ENDOPROSTHESIS IS INTENDED FOR USE IN THE ILIAC VEINS FOR THE TREATMENT OF SYMPTOMATIC VENOUS OBSTRUCTION.,STENT SYSTEM(HOT AXIOS STENT AND ELECTROCAUTERY-ENHANCED DELIVERY SYSTEM)-THE HOT AXIOS STENT AND ELECTROCAUTERY-ENHANCED DELIVERY SYSTEM IS INDICATED FOR USE TO FACILITATE TRANSGASTRIC OR TRANSDUODENAL ENDOSCOPIC DRAINAGE OF A PANCREATIC PSEUDOCYST OR A WALLED-OFF NECROSIS WITH 70% FLUID CONTENT OR THE BILIARY TRACT.,PERIPHERAL ANGIOPLASTY BALLOON CATHETER, BASIC(MUSTANG PTA BALLOON DILATATION CATHETER)-THE MUSTANG BALLOON DILATATION CATHETER IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE PERIPHERAL VASCULATURE, INCLUDING ILIAC, FEMORAL, POPLITEAL, TIBIAL, PERONEAL, SUBCLAVIAN, AND RENAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THE MUSTANG BALLOON DILATATION CATHETER IS ALSO INDICATED FOR POST-DILATATION OF BALLOON EXPANDABLE AND SELF-EXPANDING STENTS IN THE PERIPHERAL VASCULATURE. MUSTANG BALLOON DILATATION CATHETERS WITH BALLOONS UP TO 120 MM IN LENGTH ARE INDICATED FOR THE TREATMENT OF BILIARY STRICTURES.,STENT SYSTEM(AXIOS STENT AND DELIVERY SYSTEM)-THE AXIOS STENT AND DELIVERY SYSTEM IS INDICATED FOR USE TO FACILITATE TRANSGASTRIC OR TRANSDUODENAL ENDOSCOPIC

	DRAINAGE OF A PANCREATIC PSEUDOCYST OR A WALLED-OFF NECROSIS WITH 70% FLUID CONTENT OR THE BILIARY TRACT., URETHRAL DILATATION CATHETER, NON-MEDICATED(UROMAX ULTRA BALLOON DILATATION CATHETER)-BALLOON DILATATION CATHETERS ARE RECOMMENDED FOR DILATATION OF THE URINARY TRACT.,STENT SYSTEM(HOT AXIOS STENT AND ELECTROCAUTERY-ENHANCED DELIVERY SYSTEM)-THE HOT AXIOS STENT AND ELECTROCAUTERY- ENHANCED DELIVERY SYSTEM IS INDICATED FOR USE TO FACILITATE TRANSGASTRIC OR TRANSDUODENAL ENDOSCOPIC DRAINAGE OF A PANCREATIC PSEUDOCYST OR A WALLED-OFF NECROSIS WITH 70% FLUID CONTENT OR THE BILIARY TRACT.,OESOPHAGEAL BALLOON CATHETER(XXL ESOPHAGEAL BALLOON DILATATION CATHETER)-THE XXL BALLOON DILATATION CATHETER IS INTENDED FOR USE IN ADULT AND ADOLESCENT POPULATIONS TO DILATE STRICTURES OF THE ESOPHAGUS.,BARE-METAL BILIARY STENT(EPIC BILIARY ENDOSCOPIC STENT SYSTEM)-THE EPIC BILIARY ENDOSCOPIC STENT SYSTEM IS INDICATED FOR PALLIATION OF MALIGNANT NEOPLASMS IN THE BILIARY TREE.,POLYMER-METAL OESOPHAGEAL STENT, NON-STERILE(WALLFLEX ESOPHAGEAL PARTIALLY COVERED STENT SYSTEM)-THE WALLFLEX ESOPHAGEAL PARTIALLY COVERED STENT SYSTEM IS INTENDED FOR MAINTAINING ESOPHAGEAL LUMINAL PATENCY IN ESOPHAGEAL STRICTURES CAUSED BY INTRINSIC AND/OR EXTRINSIC MALIGNANT TUMORS, AND OCCLUSION OF CONCURRENT ESOPHAGEAL FISTULAS.,STENT: DRUG-ELUTING CORONARY ARTERY STENT, NON-BIOABSORBABLE-POLYMER-COATED; CATHETER: CORONARY ANGIOPLASTY BALLOON CATHETER BASIC(PROMUS ELITE EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM)-THE PROMUS ELITE EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE, INCLUDING PATIENTS WITH ACUTE MYOCARDIAL INFARCTION AND PATIENTS WITH CONCOMITANT DIABETES MELLITUS DUE TO DISCRETE DE NOVO NATIVE CORONARY ARTERY LESIONS. THE PROMUS ELITE EVEROLIMUS- ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM IS ALSO INDICATED FOR TREATMENT OF PATIENTS PRESENTING WITH: • CORONARY BIFURCATION LESIONS • CORONARY ARTERY OSTIAL LESIONS • UNPROTECTED LEFT MAIN CORONARY ARTERY LESIONS • CORONARY ARTERY TOTAL OCCLUSION LESIONS • IN-STENT RESTENOSIS IN CORONARY ARTERY LESIONS THE TREATED LESION LENGTH SHOULD BE LESS THAN THE NOMINAL STENT LENGTH (8 MM, 12 MM, 16 MM, 20 MM, 24 MM, 28 MM, 32 MM AND 38 MM) WITH A

	REFERENCE VESSEL DIAMETER OF 2.25 MM - 4.00 MM.,MULTIPLE PERIPHERAL ARTERY STENT(EPIC SELF-EXPANDING NITINOL STENT WITH DELIVERY SYSTEM)-THE EPIC NITINOL VASCULAR STENT SYSTEM IS INDICATED FOR THE TREATMENT OF PERIPHERAL VASCULAR LESIONS AND OBSTRUCTIONS.,STENT: DRUG-ELUTING CORONARY ARTERY STENT, BIOABSORBABLE-POLYMER-COATED CATHETER: BALLOON CORONARY ANGIOPLASTY CATHETER, BASIC (SYNERGY MONORAIL EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM)-THE SYNERGY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE, INCLUDING PATIENTS WITH ACUTE MYOCARDIAL INFARCTION AND PATIENTS WITH CONCOMITANT DIABETES MELLITUS DUE TO DISCRETE DE NOVO NATIVE CORONARY ARTERY LESIONS. THE SYNERGY STENT SYSTEM IS ALSO INDICATED FOR THE TREATMENT OF PATIENTS PRESENTING WITH: • ACUTE CORONARY SYNDROME • UNSTABLE ANGINA • RENAL FAILURE • CORONARY BIFURCATION LESIONS • CORONARY MULTI-VESSEL DISEASE • CORONARY SAPHENOUS VEIN GRAFT LESIONS • CORONARY ARTERY OSTIAL LESIONS • UNPROTECTED LEFT MAIN CORONARY ARTERY LESIONS • CORONARY ARTERY TOTAL OCCLUSION LESIONS • IN-STENT RESTENOSIS IN CORONARY ARTERY LESIONS FOR 8MM TO 38MM NOMINAL UNEXPANDED STENT LENGTH: THE TREATED LESION LENGTH SHOULD BE LESS THAN THE NOMINAL STENT LENGTH (8 MM, 12 MM, 16 MM, 20 MM, 24 MM, 28 MM, 32 MM AND 38 MM) WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM - 4.00 MM. FOR 48MM NOMINAL UNEXPANDED STENT LENGTH: THE TREATED LESION LENGTH SHOULD BE LESS THAN THE NOMINAL STENT LENGTH (8 MM, 12 MM, 16 MM, 20 MM, 24 MM, 28 MM, 32 MM, 38 MM AND 48 MM*) WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM - 4.00 MM. * THE 48 MM LENGTH IS NOT AVAILABLE IN 2.25 MM DIAMETER. FOR 4.5MM AND 5MM NOMINAL EXPANDED INNER DIAMETER: THE TREATED LESION LENGTH SHOULD BE LESS THAN THE NOMINAL STENT LENGTH (8 MM, 12 MM, 16 MM, 20 MM, 24 MM, 28 MM, 32 MM AND 38 MM) WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM - 5.00 MM. POLYMER-METAL OESOPHAGEAL STENT, NON STERILE(ULTRAFLEX ESOPHAGEAL NG COVERED PROXIMAL RELEASE STENT SYSTEM)-THE ULTRAFLEX ESOPHAGEAL NG STENT SYSTEM IS INTENDED FOR MAINTAINING ESOPHAGEAL LUMINAL PATENCY IN ESOPHAGEAL STRICTURES CAUSED BY INTRINSIC AND/OR EXTRINSIC MALIGNANT TUMORS ONLY. THE ULTRAFLEX ESOPHAGEAL NG COVERED STENT SYSTEM IS ALSO INDICATED FOR OCCLUSION OF CONCURRENT ESOPHAGEAL FISTULA.,STENT: DRUG-ELUTING CORONARY ARTERY STENT, NON-BIOABSORBABLE-POLYMER-COATED; CATHETER:

	CORONARY ANGIOPLASTY BALLOON CATHETER BASIC(PROMUS PREMIER SELECT MONORAIL EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM)-THE PROMUS PREMIER SELECT EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE, INCLUDING PATIENTS WITH ACUTE MYOCARDIAL INFARCTION AND PATIENTS WITH CONCOMITANT DIABETES MELLITUS DUE TO DISCRETE DE NOVO NATIVE CORONARY ARTERY LESIONS. THE PROMUS PREMIER SELECT EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM IS ALSO INDICATED FOR TREATMENT OF PATIENTS PRESENTING WITH: • CORONARY BIFURCATION LESIONS • CORONARY ARTERY OSTIAL LESIONS • UNPROTECTED LEFT MAIN CORONARY ARTERY LESIONS • CORONARY ARTERY TOTAL OCCLUSION LESIONS • IN-STENT RESTENOSIS IN CORONARY ARTERY LESIONS THE TREATED LESION LENGTH SHOULD BE LESS THAN THE NOMINAL STENT LENGTH (8 MM, 12 MM, 16 MM, 20 MM, 24 MM, 28 MM, 32 MM AND 38 MM) WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM - 4.00 MM.,CORONARY ANGIOPLASTY BALLOON CATHETER, CUTTING/SCORING(WOLVERINE CORONARY CUTTING BALLOON MONORAIL MICROSURGICAL DILATATION DEVICE)-THE WOLVERINE CUTTING BALLOON DEVICE IS INDICATED FOR USE IN PATIENTS WITH CORONARY VESSEL DISEASE WHO ARE ACCEPTABLE CANDIDATES FOR CORONARY ARTERY BYPASS GRAFT SURGERY, SHOULD IT BE URGENTLY NEEDED, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. IN ADDITION, THE TARGET LESION SHOULD POSSESS THE FOLLOWING CHARACTERISTICS: *DISCRETE LESS THAN/EQUAL TO 15 MM IN LENGTH), OR TUBULAR (10 MM TO 20 MM IN LENGTH) *REFERENCE VESSEL DIAMETER (RVD) OF 2.00 MM TO 4.00 MM * READILY ACCESSIBLE TO THE DEVICE * LIGHT TO MODERATE TORTUOSITY OF PROXIMAL VESSEL SEGMENT * NONANGULATED LESION SEGMENT (LESS THAN 45°) * SMOOTH ANGIOGRAPHIC CONTOUR * ABSENCE OF ANGIOGRAPHICALLY VISIBLE THROMBUS,CARDIAC OCCLUDER (WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE DEVICE WITH DELIVERY SYSTEM)-THE WATCHMAN LAA CLOSURE TECHNOLOGY IS INTENDED TO PREVENT THROMBUS EMBOLIZATION FROM THE LEFT ATRIAL APPENDAGE AND REDUCE THE RISK OF LIFE-THREATENING BLEEDING EVENTS IN PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION WHO ARE ELIGIBLE FOR ANTICOAGULATION THERAPY OR WHO HAVE A CONTRAINDICATION TO ANTICOAGULATION THERAPY.,CATHETER, ANGIOPLASTY, BALLOON DILATATION(2CM PERIPHERAL CUTTING BALLOON MICROSURGICAL DILATATION DEVICE)-THE PERIPHERAL CUTTING BALLOON DEVICE IS INDICATED

	FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) OF OBSTRUCTIVE LESIONS IN PERIPHERAL VESSELS. THE TARGET LESION SHOULD POSSESS THE FOLLOWING CHARACTERISTICS: MINIMAL TORTUOSITY OF PROXIMAL VESSEL SEGMENT, AND BE A NON-ANGULATED LESION SEGMENT (LESS THAN OR EQUAL TO 45 DEGREE).,POLYMER-METAL OESOPHAGEAL STENT, NON-STERILE (WALLFLEX ESOPHAGEAL FULLY COVERED STENT SYSTEM)-THE WALLFLEX ESOPHAGEAL FULLY COVERED STENT SYSTEM IS INTENDED FOR MAINTAINING ESOPHAGEAL LUMINAL PATENCY IN ESOPHAGEAL STRICTURES CAUSED BY INTRINSIC AND/OR EXTRINSIC MALIGNANT TUMORS, AND OCCLUSION OF CONCURRENT ESOPHAGEAL FISTULAS.,BARE-METAL BILIARY STENT(WALLSTENT BILIARY ENDOSCOPIC BILIARY ENDOPROSTHESIS UNCOVERED)-THE WALLSTENT BILIARY ENDOSCOPIC BILIARY ENDOPROSTHESIS UNCOVERED IS INDICATED FOR USE IN THE TREATMENT OF BILIARY STRICTURES PRODUCED BY MALIGNANT NEOPLASMS.,BARE-METAL COLONIC STENT(WALLFLEX COLONIC STENT SYSTEM WITH ANCHOR LOCK DELIVERY SYSTEM)-THE DEVICE IS INDICATED FOR THE PALLIATIVE TREATMENT OF COLONIC STRICTURES PRODUCED BY MALIGNANT NEOPLASM AND TO RELIEVE LARGE BOWEL OBSTRUCTION PRIOR TO COLECTOMY IN PATIENTS WITH MALIGNANT STRICTURES.,BARE-METAL TRACHEAL/BRONCHIAL STENT, STERILE (ULTRAFLEX TRACHEOBRONCHIAL PROXIMAL RELEASE STENT SYSTEM UNCOVERED)-THE ULTRAFLEX TRACHEOBRONCHIAL STENT SYSTEM IS INDICATED FOR USE IN THE TREATMENT OF TRACHEOBRONCHIAL STRICTURES PRODUCED BY MALIGNANT NEOPLASMS.,POLYMER-METAL BILIARY STENT(WALLFLEX BILIARY RX PARTIALLY COVERED STENT SYSTEM)-THE WALLFLEX BILIARY RX PARTIALLY COVERED STENT SYSTEM IS INDICATED FOR USE IN THE PALLIATIVE TREATMENT OF BILIARY STRICTURES PRODUCED BY MALIGNANT NEOPLASMS AND RELIEF OF MALIGNANT BILIARY OBSTRUCTION PRIOR TO SURGERY.,POLYMER-METAL BILIARY STENT (WALLSTENT BILIARY ENDOSCOPIC BILIARY ENDOPROSTHESIS PARTIALLY COVERED)-THE WALLSTENT BILIARY ENDOSCOPIC BILIARY ENDOPROSTHESIS PARTIALLY COVERED IS INDICATED FOR USE IN THE TREATMENT OF BILIARY STRICTURES PRODUCED BY MALIGNANT NEOPLASMS.,DRUG-ELUTING CORONARY ARTERY STENT, NON-BIOABSORBABLE - POLYMER-COATED(PROMUS ELEMENT PLUS MONORAIL EVEROLIMUS ELUTING CORONARY STENT SYSTEM)-THE PROMUS ELEMENT PLUS EVEROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE, INCLUDING PATIENTS WITH ACUTE MYOCARDIAL INFARCTION AND PATIENTS WITH CONCOMITANT

	DIABETES MELLITUS, DUE TO DISCRETE DE NOVO NATIVE CORONARY ARTERY LESIONS. THE PROMUS ELEMENT PLUS EVEROLIMUS ELUTING CORONARY STENT SYSTEM IS ALSO INDICATED FOR TREATMENT OF PATIENTS PRESENTING WITH: • CORONARY BIFURCATION LESIONS • CORONARY ARTERY OSTIAL LESIONS • UNPROTECTED LEFT MAIN CORONARY ARTERY LESIONS • CORONARY ARTERY TOTAL OCCLUSION LESIONS • IN-STENT RESTENOSIS IN CORONARY ARTERY LESIONS THE TREATED LESION LENGTH SHOULD BE LESS THAN THE NOMINAL STENT LENGTH (8 MM, 12 MM, 16 MM, 20 MM, 24 MM, 28 MM, 32 MM AND 38 MM) WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM - 4.0 MM.,CARDIAC OCCLUDER DELIVERY KIT(WATCHMAN ACCESS SYSTEM)-THE WATCHMAN ACCESS SYSTEM IS INTENDED TO PROVIDE VASCULAR AND TRANSSEPTAL ACCESS FOR THE WATCHMAN LEFT ATRIAL APPENDAGE CLOSURE DEVICE WITH DELIVERY SYSTEM., NEPHROSTOMY CATHETER(NEPHROMAX HIGH PRESSURE NEPHROSTOMY BALLOON CATHETER)-THE NEPHROMAX BALLOON CATHETERS ARE RECOMMENDED FOR DILATATION OF THE NEPHROSTOMY TRACT.,MULTIPLE PERIPHERAL ARTERY STENT, BARE METAL(EXPRESS LD VASCULAR PRE-MOUNTED STENT SYSTEM)-THE EXPRESS LD VASCULAR PREMOUNTED STENT SYSTEM IS INDICATED FOR USE IN THE TREATMENT OF PERIPHERAL VASCULAR LESIONS.,BARE-METAL DUODENAL STENT(WALLFLEX DUODENAL STENT SYSTEM WITH ANCHOR LOCK DELIVERY SYSTEM)-THE DEVICE IS INDICATED FOR THE PALLIATIVE TREATMENT OF GASTRODUODENAL OBSTRUCTIONS PRODUCED BY MALIGNANT NEOPLASMS.,STENT: DRUG-ELUTING FEMORAL ARTERY STENT; CATHETER: PERIPHERAL VASCULAR CATHETER(ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM)-THE ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM IS INTENDED TO IMPROVE LUMINAL DIAMETER IN THE TREATMENT OF SYMPTOMATIC DE-NOVO OR RESTENOTIC LESIONS IN THE NATIVE SUPERFICIAL FEMORAL ARTERY (SFA) AND/OR PROXIMAL POPLITEAL ARTERY WITH REFERENCE VESSEL DIAMETERS (RVD) RANGING FROM 4.0 MM - 6.0 MM.,PROSTHESIS, INTERNAL STENT, NONVASCULAR; POLYMER-METAL BILIARY STENT(WALLFLEX BILIARY TRANSHEPATIC FULLY COVERED STENT SYSTEM RMV)-THE FULLY COVERED WALLFLEX BILIARY TRANSHEPATIC STENT SYSTEM RMV IS INDICATED FOR USE IN THE PALLIATIVE TREATMENT OF BILIARY STRICTURES PRODUCED BY MALIGNANT NEOPLASMS, AND FOR TREATMENT OF BENIGN BILIARY STRICTURES.,BARE-METAL BILIARY STENT(WALLSTENT RX BILIARY ENDOPROSTHESIS STENT SYSTEM UNCOVERED)-THE WALLSTENT RX BILIARY, WITH OR WITHOUT PERMALUME COVERING, IS INDICATED FOR USE IN THE TREATMENT OF BILIARY STRICTURES

	PRODUCED BY MALIGNANT NEOPLASMS.,CATHETER, ANGIOPLASTY, BALLOON DILATATION(SMALL PERIPHERAL CUTTING BALLOON MICROSURGICAL DILATATION DEVICE)-THE PERIPHERAL CUTTING BALLOON DEVICE IS INDICATED FOR PTA OF OBSTRUCTIVE LESIONS IN PERIPHERAL VESSELS WITH A REFERENCE DIAMETER RANGING FROM 2 MM - 4 MM. THE TARGET LESION SHOULD POSSESS THE FOLLOWING CHARACTERISTICS: MINIMAL TORTUOSITY OF PROXIMAL VESSEL SEGMENT, AND BE A NONANGULATED LESION SEGMENT (LESS THAN OR EQUAL TO 45 DEGREE).,PROSTHESIS, INTERNAL STENT, NONVASCULAR; POLYMER-METAL BILIARY STENT(WALLFLEX BILIARY TRANSHEPATIC FULLY COVERED STENT SYSTEM)-THE FULLY COVERED WALLFLEX BILIARY TRANSHEPATIC STENT SYSTEM IS INDICATED FOR USE IN THE PALLIATIVE TREATMENT OF BILIARY STRICTURES PRODUCED BY MALIGNANT NEOPLASMS.,CAROTID ARTERY STENT(CAROTID WALLSTENT MONORAIL ENDOPROSTHESIS CLOSED CELL SELF-EXPANDING STENT)-TREATMENT OF STENOSES OF THE COMMON CAROTID ARTERY (CCA), INTERNAL CAROTID ARTERY (ICA) AND CAROTID BIFURCATION.,POLYMER-METAL TRACHEAL/BRONCHIAL STENT, STERILE(ULTRAFLEX TRACHEOBRONCHIAL DISTAL RELEASE STENT SYSTEM COVERED)-THE ULTRAFLEX TRACHEOBRONCHIAL STENT SYSTEM IS INDICATED FOR USE IN THE TREATMENT OF TRACHEOBRONCHIAL STRICTURES PRODUCED BY MALIGNANT NEOPLASMS.,POLYMER-METAL BILIARY STENT(WALLFLEX BILIARY RX FULLY COVERED STENT SYSTEM RMV)-THE WALLFLEX BILIARY RX FULLY COVERED STENT SYSTEM IS INDICATED FOR USE IN THE PALLIATIVE TREATMENT OF BILIARY STRICTURES PRODUCED BY MALIGNANT NEOPLASMS, RELIEF OF MALIGNANT BILIARY OBSTRUCTION PRIOR TO SURGERY AND FOR TREATMENT OF BENIGN BILIARY STRICTURES.,PROSTHESIS, INTERNAL STENT, NONVASCULAR ; POLYMER METAL BILIARY STENT (WALLFLEX BILIARY TRANSHEPATIC PARTIALLY COVERED STENT SYSTEM)-THE PARTIALLY COVERED WALLFLEX BILIARY TRANSHEPATIC STENT SYSTEM IS INDICATED FOR USE IN THE PALLIATIVE TREATMENT OF BILIARY STRICTURES PRODUCED BY MALIGNANT NEOPLASMS.,BARE-METAL BILIARY STENT(WALLFLEX BILIARY RX UNCOVERED STENT SYSTEM)-THE WALLFLEX BILIARY RX UNCOVERED STENT SYSTEM IS INDICATED FOR USE IN THE PALLIATIVE TREATMENT OF BILIARY STRICTURES PRODUCED BY MALIGNANT NEOPLASMS AND RELIEF OF MALIGNANT BILIARY OBSTRUCTION PRIOR TO SURGERY.,POLYMER-METAL OESOPHAGEAL STENT, NON-STERILE(ULTRAFLEX ESOPHAGEAL NG COVERED DISTAL RELEASE STENT SYSTEM)-THE ULTRAFLEX ESOPHAGEAL NG STENT SYSTEM IS INTENDED FOR MAINTAINING ESOPHAGEAL LUMINAL PATENCY IN ESOPHAGEAL STRICTURES

		CAUSED BY INTRINSIC AND/OR EXTRINSIC MALIGNANT TUMORS ONLY. THE ULTRAFLEX ESOPHAGEAL NG COVERED STENT SYSTEM IS ALSO INDICATED FOR OCCLUSION OF CONCURRENT ESOPHAGEAL FISTULA.,PROSTHESIS, INTERNAL STENT, NONVASCULAR ; BARE-METAL BILIARY STENT(WALLFLEX BILIARY TRANSHEPATIC UNCOVERED STENT SYSTEM)-THE UNCOVERED WALLFLEX BILIARY TRANSHEPATIC STENT SYSTEM IS INDICATED FOR USE IN THE PALLIATIVE TREATMENT OF BILIARY STRICTURES PRODUCED BY MALIGNANT NEOPLASMS.
1255	IMP/MD/2018/000130	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER(VIEWFLEX XTRA ICE CATHETER)-THE VIEWFLEX XTRA ICE CATHETER IS INDICATED FOR USE IN ADULT AND ADOLESCENT PEDIATRIC PATIENTS TO VISUALIZE CARDIAC STRUCTURES, BLOOD FLOW AND OTHER DEVICES WITHIN THE HEART.,CATHETER(INQUIRY STEERABLE DIAGNOSTIC CATHETER)-THE INQUIRY DIAGNOSTIC CATHETER IS USED FOR ELECTROGRAM RECORDING AND CARDIAC STIMULATION DURING DIAGNOSTIC ELECTROPHYSIOLOGY STUDIES. THE CATHETERS ARE COMMONLY PLACED AT THE HIGH RIGHT ATRIUM, RIGHT VENTRICULAR APEX, AND HIS BUNDLE.
1256	IMP/MD/2018/000131	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CARDIAC MARKER CONTROL(LIQUID QC® CARDIAC MARKER CONTROL VS)-CLINIQA® LIQUID QC® CARDIAC MARKER CONTROL VS IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL FOR CK-MB, MYOGLOBIN, TROPONIN I, AND NT-PROBNP. CLINIQA LIQUID QC CARDIAC MARKER CONTROL VS IS NOT INTENDED FOR USE AS A STANDARD.

1257	IMP/MD/2018/000132	1.License Holder Name: FRESENIUS KABI INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FREKA FEEDING TUBE (FREKA (7750911AP))-GASTRIC DECOMPRESSION UNDER SIMULTANEOUS AERATION AND JEJUNAL ENTERAL FEEDING OF INTENSIVE CARE PATIENTS WITH IMPAIRED GASTRIC MOTILITY., FREKA FEEDING TUBE(FREKA (7755031AP))-NASOINTESTINAL TUBE INTESTINAL FEEDING,FREKA FEEDING TUBE(FREKA (7980111AP))-TRANSNASAL FEEDING TUBE,FREKA FEEDING TUBES(FREKA (7981821AP))-TRANSNASAL FEEDING TUBE,FREKA FEEDING TUBE (FREKA (7980961AP))-TRANSNASAL FEEDING TUBE,FREKA FEEDING TUBE(FREKA (7751531AP))-LONG-TERM INTRAGASTRIC FEEDING IN PATIENTS WITH INADEQUATE ORAL NUTRITIONAL INTAKE (60% OF THE CALCULATED ENERGY SUPPLY) AND THE NEED FOR NUTRITIONAL FEEDING FOR A PERIOD EXCEEDING 2-3 WEEKS. PALLIATIVE GASTRIC DECOMPRESSION/DRAINAGE BY GRAVITY IT CAN BE USED FOR APPLICATION OF AN INTESTINAL TUBE AS A GUIDE TUBE. USE OF A WIDE-LUMEN GASTRIC PEG IS PARTICU LARLY RECOMMENDED FOR BOLUS/GRAVITY FEED ADMINISTRATION, DECOMPRESSION AND DRAINAGE OF VISCOUS FLUID, FREQUENT DRUG ADMINISTRATION, USE OF THE GASTRIC PORT FOR INSTRUMENT INSERTION FOR THERAPEUTIC/DIAGNOSTIC PURPOSES AND POSITIONING OF AN INTESTINAL TUBE FOR GASTRIC DECOMPRESSION AND INTESTINAL FEEDING.,FREKA FEEDING TUBE (FREKA (7840051AP))-TRANSNASAL FEEDING TUBE,FREKA FEEDING TUBE(FREKA (7981101AP))-TRANSNASAL FEEDING TUBE

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1258	IMP/MD/2018/000133	1.License Holder Name: EDWARDS LIFESCIENCES (INDIA) PRIVATE LIMITED, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERICARDIAL BIOPROSTHESIS (AORTIC)(CARPENTIER- EDWARDS PERIMOUNT MAGNA EASE)-THE MAGNA EASE AORTIC BIOPROSTHESIS IS INTENDED FOR USE IN PATIENTS WHOSE AORTIC VALVULAR DISEASE IS SUFFICIENTLY ADVANCED TO WARRANT REPLACEMENT OF THEIR NATURAL VALVE WITH A PROSTHETIC ONE. IT IS ALSO INTENDED FOR USE IN PATIENTS WITH A PREVIOUSLY IMPLANTED AORTIC VALVE PROSTHESIS THAT IS NO LONGER FUNCTIONING ADEQUATELY AND REQUIRES REPLACEMENT. IN THE LATTER CASE, THE PREVIOUSLY IMPLANTED PROSTHESIS IS SURGICALLY EXCISED AND REPLACED BY THE REPLACEMENT PROSTHESIS. THE BIOPROSTHESIS CAN BE IMPLANTED IN EITHER THE SUPER-ANNULAR OR INTRA-ANNULAR POSITION.,PERICARDIAL BIOPROSTHESIS (MITRAL)(CARPENTIER- EDWARDS PERIMOUNT MAGNA MITRAL EASE)-THE CARPENTIER-EDWARDS PERIMOUNT MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS IS INDICATED FOR PATIENTS WHO REQUIRE REPLACEMENT OF THEIR NATIVE OR PROSTHETIC MITRAL VALVE.,TRANSCATHETER HEART VALVE (EDWARDS SAPIEN 3 - EDWARDS COMMANDER KIT)-THE EDWARDS SAPIEN 3 VALVE, EDWARDS COMMANDER DELIVERY SYSTEM AND ACCESSORIES ARE INDICATED FOR USE IN PATIENTS WITH SEVERE, SYMPTOMATIC, CALCIFIC AORTIC VALVE STENOSIS WITH AN STS-PROM SCORE OF MORE THAN OR EQUAL TO 8 OR LOGISTIC EUROSCORE MORE THAN OR EQUAL TO 15.,AORTIC VALVE(INSPIRIS RESILIA AORTIC VALVE)-THE INSPIRIS RESILIA AORTIC VALVE IS INTENDED FOR USE AS A HEART VALVE REPLACEMENT. IT IS INDICATED FOR PATIENTS WHO REQUIRE REPLACEMENT OF THEIR NATIVE OR PROSTHETIC AORTIC VALVE.,VALVE SYSTEM (AORTIC) (EDWARDS INTUITY ELITE)-INDICATED FOR PATIENTS WHOSE AORTIC VALVULAR DISEASE IS SUFFICIENTLY ADVANCED TO WARRANT REPLACEMENT OF THEIR NATIVE VALVE WITH A PROSTHETIC VALVE. THESE DEVICES ARE ALSO INTENDED FOR USE IN PATIENTS WITH A PREVIOUSLY IMPLANTED AORTIC VALVE THAT REQUIRES REPLACEMENT. IN THE LATTER CASE, THE PREVIOUSLY IMPLANTED PROSTHESIS IS SURGICALLY EXCISED AND REPLACED WITH THE MODEL 8300AB VALVE

1259	IMP/MD/2018/000137	1.License Holder Name: CARL ZEISS INDIA (BANGALORE) PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:POSTERIOR CHAMBER INTRAOCULAR LENS (PSEUDOPHAKIC)(CT LUCIA 201P, CT LUCIA 601P, CT LUCIA 601PY)-IT IS INTENDED TO BE USED FOR SENILE CATARACTS AND OTHER FORMS OF CATARACT AND THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,POSTERIOR CHAMBER INTRAOCULAR LENSES (PSEUDOPHAKIC)(CT LUCIA 202)-THE THREE-PIECE LUCIA IOL IS INTENDED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG IN PATIENTS WHERE A CATARACTROUS LENS HAS BEEN REMOVED BY CATARACT EXTRACTION,POSTERIOR CHAMBER INTRAOCULAR LENSES (PSEUDOPHAKIC)(CT LUCIA 611 P AND CT LUCIA 611 PY)-SENILE CATARACTS AND OTHER FORMS CATARACT. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.

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1260	IMP/MD/2018/000138	1.License Holder Name: M/S SARK HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT ABUTMENT -PEEK(STRAIGHT TEMPORARY PEEK ABUTMENT, TEMPORARY PEEK ABUTMENT, SCAN BODY/ABUTMENT - PEEK)-THE DENTAL IMPLANT AND ITS ABUTMENTS ARE INTENDED TO BE USED AS AN IMPLANT IN FULLY OR PARTIALLY EDENTULOUS PATIENTS FOR PROSTHETIC REHABILITATION. THE PRODUCT IS INTENDED TO SUPPORT PROSTHETIC DEVICES AND TO RESTORE THE PATIENTS CHEWING FUNCTION,DENTAL IMPLANT ABUTMENT – COBALT CHROME(COBALT CHROME CASTING ABUTMENT)-THE DENTAL IMPLANT AND ITS ABUTMENTS ARE INTENDED TO BE USED AS AN IMPLANT IN FULLY OR PARTIALLY EDENTULOUS PATIENTS FOR PROSTHETIC REHABILITATION. THE PRODUCT IS INTENDED TO SUPPORT PROSTHETIC DEVICES AND TO RESTORE THE PATIENTS CHEWING FUNCTION,DENTAL IMPLANT – TITANIUM(ARRC - ARROW CHANGEABLE IMPLANT, ATID - ALPHA-TEC DUAL IMPLANT, ARB-ARROW BALL IMPLANT, ARR- ARROW IMPLANT, ARRP - ARROW PRESS IMPLANT, DFI - DUAL FIT IMPLANT, ICE-IMPLANT CLASSICAL ESTHETIC IMPLANT, NEO/ MULTINEO IMPLANT, NICE IMPLANT, SPI/SPIRAL - SPIRAL IMPLANT)-THE DENTAL IMPLANTS ARE INTENDED TO BE USED AS AN IMPLANT IN FULLY OR PARTIALLY EDENTULOUS PATIENTS FOR PROSTHETIC REHABILITATION. THE PRODUCT IS INTENDED TO SUPPORT PROSTHETIC DEVICES AND TO RESTORE THE PATIENTS CHEWING FUNCTION,DENTAL IMPLANT ABUTMENT -TITANIUM(ALPHA UNIBASE, ALPHA UNIVERSE, ALPHA UNIVERSE UNISCREW, ALPHALOC ABUTMENT, ANGLED TITANIUM ABUTMENT, BLANK ABUTMENT, CAD/CAM TITANIUM BASE, CONICAL HEALING ABUTMENT, ESTHETIC ANATOMIC ABUTMENT, ESTHETIC ANGLED TITANIUM ABUTMENT, ESTHETIC OMNI ABUTMENT, ESTHETIC STANDARD ABUTMENT, ESTHETIC STRAIGHT TITANIUM ABUTMENT, HEALING ABUTMENT, HEX BASE CONNECTION, MENTOR ABUTMENT, OMNI TITANIUM ABUTMENT, PREFACE COMPATIBLE BLANK ABUTMENT, PRO HEALING ABUTMENT, PRO STRAIGHT TITANIUM ABUTMENT, PRO TAPERED CONNECTION ABUTMENT, PRO TEMPORARY TITANIUM ABUTMENT, PRO UNICOVER, INTRAORAL SCAN BODY, SIMPLY ESTHETIC STRAIGHT TITANIUM ABUTMENT, SIMPLY STRAIGHT TITANIUM ABUTMENT, STANDARD ABUTMENT, STRAIGHT TITANIUM ABUTMENT, TAPERED CONNECTION ABUTMENT, TITANIUM BALL ABUTMENT, TITANIUM CASTING ABUTMENT, TITANIUM LOCK ABUTMENT, UNICOVER, UNICOVER BALL)-THE DENTAL IMPLANT AND ITS ABUTMENTS ARE INTENDED TO BE USED AS AN IMPLANT IN FULLY OR PARTIALLY EDENTULOUS PATIENTS FOR PROSTHETIC REHABILITATION. THE PRODUCT IS INTENDED TO

		SUPPORT PROSTHETIC DEVICES AND TO RESTORE THE PATIENTS CHEWING FUNCTION,DENTAL IMPLANT ABUTMENT – ZIRCONIUM (ANGLED ZIRCONIUM ABUTMENT 15°, STRAIGHT ZIRCONIUM ABUTMENT)-THE DENTAL IMPLANT AND ITS ABUTMENTS ARE INTENDED TO BE USED AS AN IMPLANT IN FULLY OR PARTIALLY EDENTULOUS PATIENTS FOR PROSTHETIC REHABILITATION. THE PRODUCT IS INTENDED TO SUPPORT PROSTHETIC DEVICES AND TO RESTORE THE PATIENTS CHEWING FUNCTION,DENTAL IMPLANT ABUTMENT – PLASTIC(ANGLED PLASTIC ABUTMENT, PRO SNAP PLASTIC HEALING ABUTMENT, STRAIGHT PLASTIC ABUTMENT)-THE DENTAL IMPLANT AND ITS ABUTMENTS ARE INTENDED TO BE USED AS AN IMPLANT IN FULLY OR PARTIALLY EDENTULOUS PATIENTS FOR PROSTHETIC REHABILITATION. THE PRODUCT IS INTENDED TO SUPPORT PROSTHETIC DEVICES AND TO RESTORE THE PATIENTS CHEWING FUNCTION
1261	IMP/MD/2018/000139	1.License Holder Name: MEDCENTRAL GLOBAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STOPSBLEEDING™ HAEMOSTAT FOAM PAD(STOPSBLEEDING HEMOSTAT FOAM PAD)-• MINOR BLEEDING WOUNDS SUCH AS CUTS, LACERATIONS AND ABRASIONS AND FOR MINOR NOSE BLEEDS. • TEMPORARY TREATMENT OF MODERATE TO SEVERELY BLEEDING WOUNDS SUCH AS SURGICAL WOUNDS (POST-OPERATIVE, DONOR SITES, DERMATOLOGICAL), CUTS AND LACERATIONS AND ARE ALSO INDICATED FOR CONTROL OF BLEEDING FROM THE SKIN AT PERCUTANEOUS NEEDLE ACCESS, VASCULAR ACCESS AND PERCUTANEOUS CATHETER ACCESS SITES.,STOPSBLEEDING TOPICAL HAEMOSTAT POWDER(STOPSBLEEDING HEMOSTAT POWDER)-1. MINOR BLEEDING WOUNDS SUCH AS CUTS, LACERATIONS AND ABRASIONS AND FOR MINOR NOSE BLEEDS. 2. TEMPORARY TREATMENT OF MODERATE TO SEVERELY BLEEDING WOUNDS SUCH AS SURGICAL WOUNDS (POST-OPERATIVE, DONOR SITES, DERMATOLOGICAL), CUTS AND LACERATIONS AND ARE ALSO INDICATED FOR CONTROL OF BLEEDING FROM THE SKIN AT PERCUTANEOUS NEEDLE ACCESS, VASCULAR ACCESS AND PERCUTANEOUS CATHETER ACCESS SITES.

1262	IMP/MD/2018/000140	1.License Holder Name: BIODENTA INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT SYSTEM(BIODENTA DENTAL ABUTMENTS)-THE BIODENTA ABUTMENT AND ABUTMENT SCREW IS A PRE MANUFACTURED PROSTHETIC COMPONENT DIRECTLY CONNECTED TO THE BIODENTA ENDOSSEOUS DENTAL IMPLANT AND IS INTENDED FOR USE AS AN AID IN PROSTHETIC REHABILITATION,DENTAL IMPLANT SYSTEM (BIODENTA DENTAL IMPLANTS)-BIODENTA DENTAL IMPLANTS ARE INTENDED FOR SURGICAL PLACEMENT IN MANDIBLESOR MAXILLAE TO SUPPORT SINGLE OR MULTIPLE TOOTH RESTORATIONS, TERMINAL OR INTERMEDIATE ABUTMENT SUPPORT FOR FIXED OR REMOVABLE BRIDGEWORK AND OVERDENTURES

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1263	IMP/MD/2018/000141	1.License Holder Name: ALCON LABORATORIES (INDIA) PVT. LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TORIC PRESBYOPIA CORRECTING IOL(ACRYSOF IQ PANOPTIX TORIC PRESBYOPIA CORRECTING IOL)-THE ACRYSOF IQ PANOPTIX TORIC PRESBYOPIA CORRECTING INTRAOCULAR LENS IS INTENDED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER OF THE HUMAN EYE FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM SECONDARY TO REMOVAL OF A CATARACTOUS LENS OR CLEAR LENS IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA, WHO DESIRE NEAR, INTERMEDIATE AND DISTANCE VISION WITH INCREASED SPECTACLE INDEPENDENCE., MULTIFOCAL TORIC INTRAOCULAR LENS(ACRYSOF IQ RESTOR MULTIFOCAL TORIC IOL)-THE ACRYSOF IQ RESTOR MULTIFOCAL TORIC IOL IS INTENDED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM SECONDARY TO REMOVAL OF A CATARACTOUS LENS IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA, WHO DESIRE NEAR, INTERMEDIATE AND DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER, AND INCREASED SPECTACLE INDEPENDENCE. THE ACRYSOF IQ RESTOR MULTIFOCAL TORIC IOL IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS IN REFRACTIVE LENS EXCHANGE (RLE) IN ADULT PATIENTS WHO MAY BENEFIT FROM NEAR VISION WITHOUT A READING AID, AND FROM INCREASED SPECTACLE INDEPENDENCE. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,PRE-LOADED DELIVERY SYSTEM (ACRYSOF IQ ASPHERIC IOL WITH THE ULTRASERT PRE-LOADED DELIVERY SYSTEM)-ACRYSOF IQ POSTERIOR CHAMBER INTRAOCULAR LENSES ARE INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,ASPHERIC SINGLE PIECE NATURAL INTRAOCULAR LENS(ACRYSOF IQ ASPHERIC NATURAL IOL)-THE ACRYSOF IQ POSTERIOR CHAMBER INTRAOCULAR LENS IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY. THIS LENS IS INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,TORIC ASTIGMATISM INTRAOCULAR LENS(ACRYSOF IQ TORIC ASTIGMATISM IOL)-IT IS INTENDED FOR THE PRIMARY IMPLANTATION IN THE CAPSULAR BAG OF THE EYE FOR THE VISUAL CORRECTION OF THE APHAKIA AND PREEXISTING CORNEAL ASTIGMATISM SECONDARY TO REMOVAL OF CATARACTOUS LENS IN ADULT PATIENTS WITH OR WITHOUT PRESBYOPIA, WHO DESIRE

	IMPROVED UNCORRECTED DISTANCE VISION. REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE VISION.,FOLDABLE SINGLE-PIECE/MULTI-PIECE INTRAOCULAR LENS(ACRYSOF ACRYLIC FOLDABLE IOL)-ACRYSOF POSTERIOR CHAMBER INTRAOCULAR LENSES ARE INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY WHEN EXTRACAPSULAR CATARACT EXTRACTION OR PHACOEMULSIFICATION ARE PERFORMED. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,MULTIFOCAL INTRAOCULAR LENS(ACRYSOF IQ RESTOR MULTIFOCAL IOL)-THE ACRYSOF IQ RESTOR POSTERIOR CHAMBER LNTRAOCULAR LENS (IOL) IS INTENDED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA SECONDARY TO REMOVAL OF A CATARACTOUS LENS IN ADULT PATIENTS, WITH AND WITHOUT PRESBYOPIA, WHO DESIRE NEAR, INTERMEDIATE AND DISTANCE VISION WITH INCREASED SPECTACLE INDEPENDENCE. THE ACRYSOF IQ RESTOR POSTERIOR CHAMBER IOL IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS IN REFRACTIVE LENS EXCHANGE (RLE) IN ADULT PATIENTS WHO MAY BENEFIT FROM NEAR VISION WITHOUT A READING AID AND FROM INCREASED SPECTACLE INDEPENDENCE. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,ACRYSOF EXPAND SERIES MULTI-PIECE IOL(ALCON EXPAND SERIES)-ACRYSOF POSTERIOR CHAMBER INTRAOCULAR LENSES ARE INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY WHEN EXTRACAPSULAR CATARACT EXTRACTION OR PHACOEMULSIFICATION ARE PERFORMED. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,IOL PRE-LOADED DELIVERY SYSTEM(ACRYSOF IQ ASPHERIC UV ABSORBING IOL WITH THE ULTRASERT PRE-LOADED DELIVERY SYSTEM)-THE ACRYSOF IQ ASPHERIC UV ABSORBING IOL IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY. THIS LENS IS INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,PRESBYOPIA CORRECTING IOL (ACRYSOF IQ PANOPTIX PRESBYOPIA- CORRECTING IOL)-THE ACRYSOF IQ PANOPTIX PRESBYOPIA CORRECTING, INTRAOCULAR LENS IS INTENDED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER FOR THE VISUAL CORRECTION OF APHAKIA SECONDARY TO REMOVAL OF A CATARACTOUS LENS OR CLEAR LENS IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA, WHO DESIRE NEAR, INTERMEDIATE AND DISTANCE VISION WITH

		INCREASED SPECTACLE INDEPENDENCE.
1264	IMP/MD/2018/000142	1.License Holder Name: SD BIOSENSOR HEALTHCARE PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PEN NEEDLE(STANDARD NANOFINE PEN NEEDLE)-IT IS INTENDED FOR USE WITH PEN INJECTOR DEVICE FOR THE SUBCUTANEOUS INJECTION OF INSULIN.
1265	IMP/MD/2018/000144	1.License Holder Name: ALLERGAN HEALTHCARE INDIA PRIVATE LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYALURONIC ACID 12MG + LIDOCAINE HYDROCHLORIDE 3MG(JUVEDERM VOLITE)-JUVÉDERM® VOLITE™ IS AN INJECTABLE IMPLANT USED FOR THE TREATMENT, BY FILLING, OF SUPERFICIAL CUTANEOUS DEPRESSIONS SUCH AS FINE LINES AND FOR ADDITIONAL IMPROVEMENT OF SKIN QUALITY ATTRIBUTES SUCH AS HYDRATION AND ELASTICITY. JUVÉDERM® VOLITE™ SHOULD ONLY BE ADMINISTERED AS SUPERFICIAL INTRA-DERMAL INJECTION BY SPECIALLY TRAINED MEDICAL PRACTITIONER. THE PRESENCE OF LIDOCAINE IS MEANT TO REDUCE THE PATIENT'S PAIN DURING TREATMENT.,HYALURONIC ACID 15MG + LIDOCAINE HYDROCHLORIDE 3MG(JUVEDERM VOLBELLA WITH LIDOCAINE)-JUVÉDERM® VOLBELLA™ WITH LIDOCAINE CAN BE USED FOR THE TREATMENT OF FINE LINES AND MEDIUM SIZED SKIN DEPRESSIONS SUCH AS PERI-ORAL, PERI ORBITAL, GLABELLAR, NECK AND FOREHEAD LINES BY INJECTION IN THE SUPERFICIAL/MID-DERMIS. JUVÉDERM® VOLBELLA™ WITH LIDOCAINE CAN BE USED TO CORRECT INFRAORBITAL SKIN DEPRESSIONS (TEAR TROUGH) VIA DEEP (SUBMUSCULAR / PRE PERIOSTEAL) INJECTION. JUVÉDERM® VOLBELLA™ WITH LIDOCAINE SHOULD BE INJECTED BY A TRAINED AND REGISTERED MEDICAL PRACTITIONER. THE PRESENCE OF LIDOCAINE IS MEANT TO REDUCE THE PATIENT'S PAIN DURING TREATMENT.,HYALURONIC ACID 25MG + LIDOCAINE HYDROCHLORIDE 3 MG(JUVEDERM® VOLUX™)-JUVÉDERM® VOLUX™ IS AN INJECTABLE IMPLANT INTENDED TO RESTORE AND CREATE VOLUME OF THE FACE.THE PRESENCE OF LIDOCAINE IS MEANT TO REDUCE THE PATIENT'S PAIN DURING TREATMENT.

1266	IMP/MD/2018/000145	1.License Holder Name: EVENT MEDI SYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICRO CATHETER(M-CATH)-INDICATED FOR SUPPORTING THE GUIDE WIRE IN CROSSING STENOTIC LESIONS WHILE PERFORMING PCI (PERCUTANEOUS CORONARY INTERVENTION) AND TO FACILITATE THE EXCHANGE OF GUIDE WIRES WHILE MAINTAINING ACCESS TO DISTAL VASCULATURE.,PTCA BALLOON CATHETER(GRIP)-INDICATED FOR BALLOON DILATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,PTCA BALLOON CATHETER (ACROSS HP)-INDICATED FOR BALLOON DILATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,PTCA BALLOON CATHETER(ACROSS CTO)-INDICATED FOR BALLOON DILATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.

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1267	IMP/MD/2018/000146	1.License Holder Name: MICROPORT SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL HIP SYSTEM (PROFEMUR, PROFEMUR GLADIATOR CLASSIC, PROFEMUR TL CLASSIC, PROCOTYL L, DYNASTY, CANCELLOUS BONE SCREW, RIM-LOCK "A-CLASS®" ACETABULAR POLY LINER, FEMORAL HEAD BIOLOX DELTA CERAMIC/ RIM-LOCK BIOLOX DELTA CERAMIC LINER, COCR FEMORAL HEAD)-MICROPORT TOTAL HIP SYSTEMS ARE INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED HIP FUNCTION IN SKELETALLY MATURE PATIENTS. INDICATIONS FOR USE: 1) NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE SUCH AS OSTEOARTHRITIS, AVASCULAR NECROSIS, ANKYLOSIS, PROTRUSIOACETABULI, AND PAINFUL HIP DYSPLASIA; 2) INFLAMMATORY DEGENERATIVE JOINT DISEASE SUCH AS RHEUMATOID ARTHRITIS; CORRECTION OF FUNCTIONAL DEFORMITY; AND, REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED. ROUGH GRIT BLAST SURFACES AND THE HYDROXYAPATITE AND TITANIUM PLASMA SPRAYCOATINGS APPLIED TO IMPLANT SURFACES ARE INTENDED FOR UNCEMENTED ARTHROPLASTY.,TOTAL KNEE SYSTEM(ADVANCE® AND ADVANCE STATURE®)-IT IS INTENDED FOR USE IN TOTAL KNEE ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED KNEE FUNCTION IN SKELETALLY MATURE PATIENTS. MICROPORT KNEE SYSTEMS ARE INDICATED FOR USE IN KNEE ARTHROPLASTY IN SKELETALLY MATURE PATIENTS WITH THE FOLLOWING CONDITIONS: 1) NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OR AVASCULAR NECROSIS; 2) INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS; 3) CORRECTION OF FUNCTIONAL DEFORMITY; 4) REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED; AND TREATMENT OF FRACTURES THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES.

1268	IMP/MD/2018/000148	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRACHEOSTOMY TUBES (SHILEY)-THE SHILEY RANGE OF TRACHEOSTOMY TUBES ARE INDICATED FOR USE IN AIRWAY MANAGEMENT IN CONJUNCTION WITH A MEDICAL NEED TO PERFORM A TRACHEOTOMY.CERTAIN CIRCUMSTANCES WILL SOMETIMES REQUIRE SPECIAL FEATURES WHICH ARE DESCRIBED BELOW. ONE PRODUCT COULD HAVE MORE THAN ONE SPECIAL FEATURE. INDICATIONS LANZ: WHERE INTRA-CUFF PRESSURE IS CRITICAL, OVER PROLONGED PERIODS OF PLACEMENT, THE LANZ PRESSURE REGULATING VALVE IS INDICATED. INDICATIONS EVAC: WHERE PROFUSE SECRETIONS BUILD UP ABOVE THE CUFF OR TRACHEAL INFECTION NEEDS TO BE MINIMIZED, THE EVAC LUMEN VERSIONS ARE INDICATED. INDICATIONS PITT : WHERE IT IS DESIRED THAT THE PATIENT HAS A DEGREE OF SPEECH, THE PITT SPEAKING TUBE IS INDICATED., ENDOBRONCHIAL TUBES(SHILEY)-THE ENDOBRONCHIAL TUBE IS INTENDED FOR USE IN THORACIC SURGERY, BRONCHOSPIROMETRY, FOR THE ADMINISTRATION OF ENDOBRONCHIAL ANAESTHESIA AND OTHER USES COMMONLY ASSOCIATED WITH ENDOBRONCHIAL TUBES. THE TUBE ALLOWS ISOLATION AND SELECTIVE INFLATION OR DEFLATION OF EITHER LUNG. THE ENDOBRONCHIAL TUBE LEFT (WITH AND WITHOUT CARINAL HOOK) IS INDICATED FOR INTUBATION OF THE LEFT MAIN BRONCHUS WHILE THE ENDOBRONCHIAL TUBE RIGHT IS INDICATED FOR RIGHT MAIN BRONCHUS INTUBATION. THE RIGHT ANGLE SWIVEL AIRWAY CONNECTOR CAPS ALLOW INTRODUCTION OF SUCTIONING AND FIBREOPTIC BRONCHOSCOPY INSTRUMENT INTO THE PATIENT'S AIRWAY THROUGH THE CHOICE OF A LARGE PORT OR A 12 FRENCH MEMBRANE PORT.,TRACHEAL TUBE (SHILEY)-STERILE SINGLE USE MEDICAL DEVICE TO ALLOW THE PASSAGE OF GAS MIXTURES DIRECTLY INTO THE LUNGS VIA THE MOUTH OR NOSE AND THE TRACHEA,TRACHEAL TUBE(SHILEY)-IT IS INTENDED FOR AIRWAY MANAGEMENT DURING SURGICAL PROCEDURES INVOLVING THE USE OF ONLY CO2 OR KTP LASERS IN SURGERY OF THE LARYNX OF OTHER AREAS IN CLOSE PROXIMITY TO TRACHEAL TUBE.

1269	IMP/MD/2018/000149	1.License Holder Name: SHREYAAS HEALTH CARE PRODUCTS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NASAL PACKING (CENEFOM)-THE DEVICE IS DESIGNED FOR PLACING INSIDE THE NASAL CAVITIES OR EAR CANAL FOR USE AS A TEMPONADE OR HEMOSTASIS DEVICE TO CONTROL BLOOD OOZING OR PERSISTENT BLEEDING.

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1270	IMP/MD/2018/000152	1.License Holder Name: SPAN HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD FILTER SYSTEMS (STERILE)(RC LEUCOCYTE FILTER FOR BLOOD)-RC1VAE: IT IS INDICATED FOR THE REMOVAL OF LEUCOCYTES, PLATELETS AND MICRO AGGREGATES FROM A SINGLE UNIT OF RED CELLS OR WHOLE BLOOD.RC2VAE : IT IS INDICATED FOR THE REMOVAL OF LEUCOCYTES, PLATELETS AND MICRO AGGREGATES FROM UP TO TWO UNITS OF BUFFY COAT DEPLETED RED CELLS.,BLOOD FILTER SYSTEMS (STERILE)(PL LEUCOCYTE FILTER FOR PLATELETS)-IT IS INDICATED FOR THE REMOVAL OF LEUCOCYTES, MICRO AGGREGATES AND THE REDUCTION OF ANAPHYLATOXIN C3A (A PRODUCT OF COMPLEMENT ACTIVATION) FROM 3 TO 6 UNITS OF PLATELET CONCENTRATE OR AN EQUIVALENT SINGLE DONOR PLATELET COLLECTION.,BLOOD FILTER SYSTEMS (STERILE)(POST-PROCESS FILTER SYSTEM FOR PLATELETS.)-IT IS INDICATED FOR THE REMOVAL OF LEUCOCYTES AND MICROAGGREGATES AND THE REDUCTION OF ANAPHYLATOXIN C3A FROM PLATELETS PREPARED FROM POOLED PLATELET CONCENTRATES OR APHERESIS PLATELETS IN AN OPEN OR CLOSED SYSTEM.,BLOOD FILTER SYSTEMS (STERILE)(LEUKOTRAP RCPL)-IT IS INDICATED FOR COLLECTION OF 450ML OF BLOOD AND PREPARATION OF RED CELLS, PLATELETS AND PLASMA WITH PRE-STORAGE LEUCOCYTE REMOVAL.,BLOOD FILTER SYSTEMS (STERILE)(LEUKOTRAP RC)-IT IS INDICATED FOR COLLECTION OF 450ML OF BLOOD AND PREPARATION OF PLATELETS, PLASMA AND PRE-STORAGE LEUCOCYTE REMOVAL FROM RED CELLS.,BLOOD FILTER SYSTEMS (STERILE)(HIGH EFFICIENCY POST-PROCESS FILTER SYSTEM FOR LEUCOCYTE REMOVAL FROM RED CELLS.)-IT IS INDICATED FOR THE REMOVAL OF LEUCOCYTES, PLATELETS AND MICRO AGGREGATES FROM A SINGLE UNIT OF RED CELLS OR WHOLE BLOOD.,BLOOD FILTER SYSTEMS (STERILE)(LEUKOTRAP RC T & B)-RCB DEVICES ARE INDICATED FOR THE COLLECTION OF 450ML OF BLOOD AND PREPARATION OF BUFFY COAT, PLASMA AND PRE-STORAGE LEUCOCYTE REMOVAL FROM RED CELLS (COLLECTION OF WHOLE BLOOD AND FILTRATION OF SUBSEQUENT RED CELL UNIT AND PLASMA UNIT DERIVED FROM THIS COLLECTION).

1271	IMP/MD/2018/000153	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER (CELLO) (CELLO BALLOON GUIDE CATHETER, INTRAVASCULAR CATHETER WITH CUFF)-THE CATHETER IS INTENDED TO TEMPORARILY BLOCK BLOOD FLOW BY EXPANDING A BALLOON INSIDE BLOOD VESSELS DURING OPERATIONS, SUCH AS: URGENT HEMOSTASIS, HEMOSTASIS FOR SURGERY, PERFUSION OF BLOOD TO PERIPHERAL VESSEL, AND ARTERIAL INJECTION FOR CHEMOTHERAPY

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1272	IMP/MD/2018/000154	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHRONIC CATHETER ACCESSORY PULL APART INTRODUCER SET, ROUND AND OVAL: (ARGYLE™ PULL APART INTRODUCER SET FOR INSERTING CATHETERS AND PACING LEADS 16 FR/CH (5.3 MM))-THE PULL-APART INTRODUCER SET IS USED TO AID PERCUTANEOUS INSERTION OF PERITONEAL, RIGHT ATRIAL, AND MAHURKAR™* 13.5 FR/CH CUFFED CATHETERS MANUFACTURED BY COVIDIEN AND CARDIAC PACING LEADS. THE OVAL PULL-APART INTRODUCER SET IS DESIGNED TO AID PERCUTANEOUS INSERTION OF ADULT PERMCATH™ CATHETERS MANUFACTURED BY COVIDIEN., PALINDROME PRECISION CHRONIC CATHETER KIT(PALINDROME)-THE PALINDROME PRECISION 14.5 FR/CH CHRONIC CATHETER IS INTENDED FOR ACUTE AND CHRONIC HEMODIALYSIS. APHERESIS. AND INFUSION. IT MAY BE INSERTED EITHER PERCUTANEOUSLY OR BY CUT DOWN.,PALINDROME PRECISION HSI CHRONIC CATHETER KIT (PALINDROME)-PALINDROME HSI 14.5 FR/CH CHRONIC CATHETER WITH HEPARIN COATING AND SLIVER ION SUBCUTANEOUS SLEEVE IS INTENDED FOR HEMODIALYSIS. APHERESIS. AND INFUSION. IT MAY BE INSERTED EITHER PERCUTANEOUSLY OR BY CUT DOWN., PALINDROME PRECISION RT CHRONIC CATHETER KIT(PALINDROME)-PALINDROME PRECISION RT (REVERSE TUNNELED) 15 FR/CH CUFFED CATHETER IS INTENDED FOR ACUTE AND CHRONIC HEMODIALYSIS. APHERESIS. AND INFUSION. IT MAY BE INSERTED EITHER PERCUTANEOUSLY OR BY CUT DOWN.,PALINDROME PRECISION SI CHRONIC CATHETER KIT(PALINDROME)-PALINDROME SI CHRONIC CATHETER WITH SLIVER ION SUBCUTANEOUS SLEEVE IS INTENDED FOR ACUTE AND CHRONIC HEMODIALYSIS. APHERESIS. AND INFUSION. IT MAY BE INSERTED EITHER PERCUTANEOUSLY OR BY CUT DOWN.,MAHURKAR CHRONIC SILICONE CATHETERS AND KITS (MAHURKAR)-IT IS INTENDED FOR ACUTE AND CHRONIC HEMODIALYSIS. APHERESIS AND INFUSION.IT MAY BE INSERTED EITHER PERCUTANEOUSLY OR BY CUT DOWN.,MAHURKAR ACUTE HIGH PRESSURE TRIPLE LUMEN CATHETER AND KITS(MAHURKAR)-IT IS INDICATED FOR SHIRT TERM CENTRAL VENOUS ACCESS FOR HEMODIALYSIS, APHERESIS AND INFUSION,PERMCATH CHRONIC SILICONE OVAL CATHETERS AND KITS(PERMCATH)-IT IS INTENDED FOR ACUTE AND CHRONIC HEMODIALYSIS. APHERESIS AND INFUSION.IT MAY BE INSERTED EITHER PERCUTANEOUSLY OR BY CUTDOWN.,ARGYLE ACUTE SINGLE LUMEN CATHETER(ARGYLE)-ARGYLE ACUTE SINGLE LUMEN CATHETER 8FR/CH PROVIDES SWIFT, TEMPORARY ACCESS FOR ACUTE HEMODIALYSIS. THE FLEXIBLE TUBING PERMITS PER CUTANEOUS INSERTION INTO SUBCLAVIAN,

	JUGULAR, AND FEMORAL.,PALINDROME CHRONIC CATHETER KIT (PALINDROME)-THE PALINDROME 14.5 FR/CH CHRONIC CATHETER IS INTENDED FOR ACUTE AND CHRONIC HEMODIALYSIS. APHERESIS AND INFUSION. IT MAY BE INSERTED EITHER PERCUTANEOUSLY OR BY CUT DOWN,MAHURKAR ELITE ACUTE DUAL LUMEN CATHETER AND KITS(MAHURKAR)-IT IS INTENDED FOR SHORT-TERM CENTRAL VENOUS ACCESS FOR HEMODIALYSIS, APHERESIS, AND INFUSION, MAHURKAR ACUTE DUAL LUMEN HIGH FLOW CATHETER & KITS (MAHURKAR)-IT IS INDICATED AS SHORT TERM CENTRAL VENOUS ACCESS DEVICES FOR HEMODIALYSIS, APHERESIS AND INFUSION., MAHURKAR ACUTE DUAL LUMEN CATHETERS AND KITS(MAHURKAR) -IT IS INDICATED AS SHORT TERM CENTRAL VENOUS ACCESS DEVICES FOR HEMODIALYSIS. APHERESIS AND INFUSION.,ARGYLE PERITONEAL DIALYSIS CATHETER AND KITS:(ARGYLE)-IT IS INDICATED FOR ACUTE AND CHRONIC PERITONEAL DIALYSIS AND INTRAPERITONEAL CHEMOTHERAPY.,PALINDROME RT CHRONIC CATHETER KIT(PALINDROME)-PALINDROME RT (REVERSE TUNNELED) 15 FR/CH CUFFED IS INTENDED FOR ACUTE AND CHRONIC HEMODIALYSIS. APHERESIS AND INFUSION. IT MAY BE INSERTED EITHER PERCUTANEOUSLY OR BY CUT DOWN.,MAHURKAR CHRONIC CARBOTHANE CATHETER KIT(MAHURKAR)-MAHURKAR CARBOTHANE CATHETER IS INTENDED FOR ACUTE AND CHRONIC HEMODIALYSIS. APHERESIS. AND INFUSION. IT MAY BE INSERTED EITHER PERCUTANEOUSLY OR BY CUT DOWN.,PALINDROME HSI CHRONIC CATHETER KIT(PALINDROME)-THE PALINDROME HIS 14.5 FR/ CH CHRONIC CATHETER WITH HEPARIN COATING AND SLIVER ION SUBCUTANEOUS SLEEVE IS INTENDED FOR HEMODIALYSIS. APHERESIS AND INFUSION. IT MAY BE INSERTED EITHER PERCUTANEOUSLY OR BY CUT DOWN.,PALINDROME SI CHRONIC CATHETER KIT(PALINDROME)-THE PALINDROME SI CHRONIC CATHETER WITH SILVER ION SUBCUTANEOUS SLEEVE IS INTENDED FOR ACUTE AND CHRONIC HEMODIALYSIS. APHERESIS. AND INFUSION. IT MAY BE INSERTED EITHER PERCUTANEOUSLY OR BY CUT DOWN.,PALINDROME H CHRONIC CATHETER KIT(PALINDROME)-THE PALINDROME H 14.5 FR/CH CHRONIC CATHETER WITH HEPARIN COATING IS INTENDED FOR HEMODIALYSIS. APHERESIS AND INFUSION.,PALINDROME PRECISION H CHRONIC CATHETER KIT (PALINDROME)-PALINDROME PRECISION H 14.5 FR/ CH CHRONIC CATHETER WITH HEPARIN COATING IS INTENDED FOR HEMODIALYSIS. APHERESIS AND INFUSION. IT MAY BE INSERTED EITHER PERCUTANEOUSLY OR BY CUT DOWN.,MAHURKAR ACUTE TRIPLE LUMEN CATHETERS AND KITS(MAHURKAR)-IT IS INDICATED FOR ACUTE AND CHRONIC HEMODIALYSIS. APHERESIS. INFUSION. CENTRAL VENOUS PRESSURE . MONITORING AND PRESSURE

		INJECTION OF CONTRAST MEDIA . THE MAXIMUM RECOMMENDED RATE IS 5ML/SEC FOR POWER INJECTION OF CONTRAST.,MAHURKAR ELITE ACUTE TRIPLE LUMEN CATHETERS AND KITS(MAHURKAR)-IT IS INTENDED FOR SHORT-TERM CENTRAL VENOUS ACCESS FOR HEMODIALYSIS, APHERESIS, INFUSION, CENTRAL VENOUS PRESSURE MONITORING, AND PRESSURE INJECTION OF CONTRAST MEDIA. THE MAXIMUM RECOMMENDED INFUSION RATE IS 5 ML/SEC FOR POWER INJECTION OF CONTRAST MEDIA.
1273	IMP/MD/2018/000155	1.License Holder Name: TOTIPOTENTRX CELL THERAPY PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CORD BLOOD PROCESSING BAGS(AUTOXPRESS® (AXP®) SYSTEM PROCESSING BAG SET)-THE AXP AUTOXPRESS PLATFORM IS A CORD BLOOD PROCESSING SYSTEM INTENDED FOR LABORATORY USE IN COMBINATION WITH A SPECIFIC AND COMPATIBLE SINGLE-USE SEPARATION KIT SUPPLIED BY THERMOGENESIS CORP. THE AXP SYSTEM ALLOWS THE FAST, AUTOMATED AND REPRODUCIBLE SEPARATION OF CORD BLOOD IN A CLOSED AND STERILE ENVIRONMENT

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1274	IMP/MD/2018/000156	1.License Holder Name: ALERE MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SD BIOLINE INFLUENZA ANTIGEN(SD BIOLINE INFLUENZA ANTIGEN)-SD BIOLINE INFLUENZA ANTIGEN TEST IS A CHROMATOGRAPHIC IMMUNOASSAY FOR THE DIFFERENTIAL AND QUALITATIVE DETECTION OF INFLUENZA VIRUS TYPE A AND TYPE B ANTIGENS DIRECTLY FROM NASAL / THROAT / NASOPHARYNGEAL SWAB OR NASAL/NASOPHARYNGEAL ASPIRATE SPECIMENS.,SD BIOLINE ROTAVIRUS(SD BIOLINE ROTAVIRUS)-THE SD BIOLINE ROTAVIRUS KIT IS A RAPID, QUALITATIVE TEST FOR THE DETECTION OF GROUP A ROTAVIRUS IN HUMAN FAECAL SPECIMENS, SD CHIKUNGUNYA IGM ELISA(SD CHIKUNGUNYA IGM ELISA)-THE SD CHIKUNGUNYA IGM ELISA IS INDIRECT SANDWICH ELISA FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES AGAINST CHIKUNGUNYA VIRUS,SD DENGUE IGM CAPTURE ELISA(SD DENGUE IGM CAPTURE ELISA)-THE SD DENGUE IGM CAPTURE ELISA KIT IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES SPECIFIC TO DENGUE VIRUS IN HUMAN SERUM,SD BIOLINE H.PYLORI AG(SD BIOLINE H.PYLORI AG)-THE SD BIOLINE H.PYLORI AG TEST IT IS A RAPID TEST FOR THE QUALITATIVE DETECTION OF H. PYLORI ANTIGEN IN HUMAN FECAL SPECIMENS.,SD BIOLINE HAV IGG/IGM(SD BIOLINE HAV IGG/IGM)-SD BIOLINE HAV IGG/IGM RAPID TEST IS A SOLID PHASE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE RAPID, QUALITATIVE AND DIFFERENTIAL DETECTION OF IGG AND IGM ANTIBODIES TO HEPATITIS A VIRUS IN HUMAN SERUM OR PLASMA,SD DENGUE NS1 AG ELISA(SD DENGUE NS1 AG ELISA)-THE SD DENGUE NS1 AG ELISA KIT IS AN ENZYME–LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF DENGUE NS1 ANTIGENS IN HUMAN SERUM.,SD DENGUE IGG CAPTURE ELISA(SD DENGUE IGG CAPTURE ELISA)-THE SD DENGUE IGG CAPTURE ELISA KIT IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES SPECIFIC TO DENGUE VIRUS IN HUMAN SERUM, SD BIOLINE MALARIA AG P.F/PAN(SD BIOLINE MALARIA AG P.F/PAN)-THE SD BIOLINE MALARIA AG P.F/PAN TEST IS A ONE STEP, RAPID, QUALITATIVE AND DIFFERENTIAL TEST FOR THE DETECTION OF HRP-II (HISTIDINE-RICH PROTEIN II) SPECIFIC TO PLASMODIUM FALCIPARUM AND PLDH (PLASMODIUM LACTATE DEHYDROGENASE) PAN SPECIFIC TO PLASMODIUM SPECIES IN HUMAN BLOOD SAMPLE, SD BIOLINE H.PYLORI(SD BIOLINE H.PYLORI)-THE SD BIOLINE H. PYLORI KIT IS A RAPID, QUALITATIVE TEST FOR THE DETECTION OF ANTIBODIES TO HELICOBACTER PYLORI IN HUMAN SERUM AND PLASMA. THE SD BIOLINE H. PYLORI KIT IS INTENDED ONLY FOR AN INITIAL SCREENING TEST AND REACTIVE SAMPLES SHOULD BE

	CONFIRMED BY A SUPPLEMENTAL ASSAY SUCH AS ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY).,SD BIOLINE DENGUE DUO(SD BIOLINE DENGUE DUO)-THE SD BIOLINE DENGUE DUO RAPID TEST IS AN IN VITRO IMMUNOCHROMATOGRAPHIC, ONE STEP ASSAY DESIGNED TO DETECT DENGUE VIRUS NS1 ANTIGEN, IGG AND IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM, PLASMA OR WHOLE BLOOD,SD BIOLINE DENGUE NS1 AG(SD BIOLINE DENGUE NS1 AG)-THE SD BIOLINE DENGUE NS1 AG RAPID TEST IS AN IN VITRO IMMUNOCHROMATOGRAPHIC, ONE STEP ASSAY DESIGNED TO DETECT DENGUE VIRUS NS1 ANTIGEN IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,SD BIOLINE CHIKUNGUNYA IGM(SD BIOLINE CHIKUNGUNYA IGM)-SD BIOLINE CHIKUNGUNYA IGM TEST IS SOLID PHASE IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE DETECTION OF IGM ANTIBODIES TO CHIKUNGUNYA IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,SD BIOLINE CEA(SD BIOLINE CEA)-SD BIOLINE CEA KIT IS A RAPID, QUALITATIVE TEST FOR THE DETECTION OF CEA (CARCINOEMBRYONIC ANTIGEN) IN HUMAN SERUM OR PLASMA,SD BIOLINE AFP(SD BIOLINE AFP)-THE SD BIOLINE AFP TEST IS AN IMMUNOCHROMATOGRAPHIC, ONE-STEP ASSAY DESIGNED FOR THE QUALITATIVE DETERMINATION OF AFP IN HUMAN SERUM OR PLASMA.,SD BIOLINE HCV(SD BIOLINE HCV)-SD BIOLINE HCV IS AN IN VITRO IMMUNOCHROMATOGRAPHIC, RAPID ASSAY DESIGNED FOR THE QUALITATIVE DETECTION OF ANTIBODIES SPECIFIC TO HCV, IN HUMAN SERUM, PLASMA (HEPARIN, EDTA AND SODIUM CITRATE) OR VENOUS WHOLE BLOOD (HEPARIN, EDTA AND SODIUM CITRATE).,SD BIOLINE MALARIA AG P.F/P.V(SD BIOLINE MALARIA AG P.F/P.V)-THE SD BIOLINE MALARIA AG P.F/P.V IS A ONE STEP, RAPID, QUALITATIVE TEST FOR THE DETECTION OF HRP II (HISTIDINE RICH PROTEIN II) SPECIFIC TO PLASMODIUM FALCIPARUM AND PLDH (PLASMODIUM LACTATE DEHYDROGENASE) SPECIFIC TO PLASMODIUM VIVAX IN HUMAN BLOOD SAMPLE,SD BIOLINE SYPHILIS FAST 3.0(SD BIOLINE SYPHILIS FAST 3.0)-SD BIOLINE SYPHILIS FAST 3.0 TEST IS A SOLID PHASE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES OF ALL ISOTYPES(IGG, IGM, IGA) AGAINST TREPONEMA PALLIDUM (TP). THIS TEST IS INTENDED FOR PROFESSIONAL USE AS AN AID ON THE DIAGNOSIS OF SYPHILIS.,SD BIOLINE DENGUE IGG/IGM WB(SD BIOLINE DENGUE IGG/IGM WB)-SD BIOLINE DENGUE IGG/IGM WB TEST DEVICE IS A SOLID PHASE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE RAPID, QUALITATIVE AND DIFFERENTIAL DETECTION OF IGG AND IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM, PLASMA OR WHOLE BLOOD,SD BIOLINE TROPONIN I(SD BIOLINE TROPONIN I)-THE SD BIOLINE TROPONIN I IS AN IN-VITRO IMMUNOCHROMATOGRAPHIC, ONE STEP ASSAY DESIGNED FOR

	QUALITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. SD BIOLINE TROPONIN I IS INTENDED FOR PROFESSIONAL USE, ONLY FOR L AND POSITIVE SAMPLES SHOULD BE CONFIRMED BY A SUPPLEMENTAL ASSAY SUCH AS ELECTROCARDIOGRAM OR CORONARY ANGIOGRAM. THIS KIT IS FOR IN VITRO DIAGNOSTIC USE ONLY.,SD BIOLINE LEPTOSPIRA (SD BIOLINE LEPTOSPIRA)-THE SD BIOLINE LEPTOSPIRA KIT IS A RAPID, QUALITATIVE TEST FOR THE DETECTION OF ANTIBODIES OF IGG SPECIFIC TO LEPTOSPIRA INTERROGANS IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE SD BIOLINE LEPTOSPIRA KIT IS INTENDED ONLY FOR AN INITIAL SCREENING TEST AND REACTIVE SAMPLES SHOULD BE CONFIRMED BY A SUPPLEMENTAL ASSAY SUCH AS PHA OR MAT(MICROSCOPIC AGGLUTINATION) REFERENCE TEST,SD BIOLINE TSUTSUGAMUSHI(SD BIOLINE TSUTSUGAMUSHI)-THE SD BIOLINE TSUTSUGAMUSHI IS A RAPID, QUALITATIVE TEST FOR THE DETECTION OF ANTIBODIES OF IGG, IGM AND IGA SPECIFIC TO ORIENTIA TSUTSUGAMUSHI IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE SD BIOLINE TSUTSUGAMUSHI IS INTENDED ONLY FOR AN INITIAL SCREENING TEST AND REACTIVE SAMPLES SHOULD BE CONFIRMED BY A SUPPLEMENTAL ASSAY SUCH AS ELISA, PHA OR IFA (INDIRECT IMMUNOFLUORESCENCE ASSAY) REFERENCE TEST

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1275	IMP/MD/2018/000157	1.License Holder Name: EURASIA HEALTHCARE LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE PRESSURE TRANSDUCER(NA)-DISPOSABLE PRESSURE TRANSDUCER IS INTENDED TO CONVERT THE HEMODYNAMIC WAVE FROM THE PATIENT'S CATHETER, THROUGH INTEGRATED PRESSURE SENSOR, INTO ELECTRICAL SIGNALS WHICH CAN BE DISPLAYED USING SEPARATE MONITORING EQUIPMENT.,INTRODUCER SETS(NA)-INTRODUCTION SET IS SINGLE USE DEVICE ALLOWING FOR INTRODUCTION, MANIPULATION, AND REMOVAL SIMULATION LED AFTER PERCUTANEOUS ENTRY IS GAINED WITH A NEEDLE,BALLOON INFLATION DEVICE(NA)-BALLOON INFLATION DEVICES ARE MAINLY USED IN PTCA OPERATION, THE BALLOON DILATATION CATHETER IS PRESSURIZED IN ORDER TO ACHIEVE THE EXPANSION OF BLOOD VESSELS OR STAY IN THE PURPOSE OF INTRAVASCULAR STENT, GUIDEWIRE(NA)-GUIDE WIRE IS APPLICABLE AS AN INVASIVE MEDICAL DEVICE. IT IS INDICATED FOR GUIDING AND ASSISTING INSERTION OF A PERCUTANEOUS CATHETER,CONNECTING TUBE(NA)-CONNECTING TUBE IS INTENDED TO PROVIDE CHANNEL FOR INFUSION AND PRESSURE MONITORING,HEMODIALYSIS CATHETER KIT(NA)-THE HEMODIALYSIS CATHETER KITS ARE PROVIDED TEMPORARY VASCULAR ACCESS FOR HEMODIALYSIS UNIT A PERMANENT ACCESS IS AVAILABLE OR UNTIL ANOTHER TYPE OF DIALYSIS THERAPY IS SUBSTITUTED

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1276	IMP/MD/2018/000158	1.License Holder Name: M/S ZIMMER INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NON-ABSORBABLE INTERNAL FIXATION DEVICE(APERFIX® TIBIAL IMPLANT)-THE CAYENNE MEDICAL APERFIX® TIBIAL IMPLANT WITH INSERTER IS INTENDED FOR USE IN TENODESIS PROCEDURES WITH SOFT TISSUE GRAFTS, UTILIZING EITHER ARTHROSCOPIC OR OPEN TECHNIQUES DURING ANTERIOR CRUCIATE LIGAMENT (ACL), POSTERIOR CRUCIATE LIGAMENT (PCL), MEDIAL COLLATERAL LIGAMENT (MCL), LATERAL COLLATERAL LIGAMENT (LCL), AND MEDIAL PATELLOFEMORAL LIGAMENT (MPFL) RECONSTRUCTION.,NON-ABSORBABLE INTERNAL FIXATION DEVICE(QUATTRO® BOLT TENODESIS SCREW)-THE CAYENNE MEDICAL, INC. QUATTRO® BOLT TENODESIS SCREWS ARE INTENDED TO BE USED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: SHOULDER ACROMIOCLAVICULAR SEPARATION REPAIRS DELTOID REPAIRS ROTATOR CUFF REPAIRS BICEPS TENODESIS ELBOW, WRIST, AND HAND BICEPS TENDON REATTACHMENT ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION LATERAL EPICONDYLITIS REPAIR KNEE EXTRA-CAPSULAR REPAIRS MEDIAL COLLATERAL LIGAMENT LATERAL COLLATERAL LIGAMENT POSTERIOR OBLIQUE LIGAMENT PATELLAR REALIGNMENT AND TENDON REPAIRS ILLIOTIBIAL BAND TENODESIS FOOT AND ANKLE HALLUX VALGUS REPAIRS MEDIAL OR LATERAL INSTABILITY REPAIRS/ RECONSTRUCTIONS ACHILLES TENDON REPAIRS/RECONSTRUCTIONS MIDFOOT RECONSTRUCTIONS METATARSAL LIGAMENT/TENDON REPAIRS/ RECONSTRUCTIONS BUNIONECTOMY,NON-ABSORBABLE INTERNAL FIXATION DEVICE(SURELOCK® ALL-SUTURE ANCHOR)-THE CAYENNE MEDICAL, INC. SURELOCK ALL-SUTURE ANCHORS ARE INTENDED TO BE USED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: SHOULDER CAPSULAR STABILIZATION O BANKART REPAIR O ANTERIOR SHOULDER INSTABILITY O SLAP LESION REPAIRS O CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTIONS ACROMIOCLAVICULAR SEPARATION REPAIRS DELTOID REPAIRS ROTATOR CUFF REPAIRS BICEPS TENODESIS FOOT AND ANKLE HALLUX VALGUS REPAIRS MEDIAL OR LATERAL INSTABILITY REPAIRS/RECONSTRUCTIONS ACHILLES TENDON REPAIRS/RECONSTRUCTIONS MID AND FOREFOOT RECONSTRUCTIONS METATARSAL LIGAMENT/TENDON REPAIRS/RECONSTRUCTIONS BUNIONECTOMY ELBOW ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION LATERAL EPICONDYLITIS REPAIR BICEPS TENDON REPAIR HAND AND WRIST

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		COLLATERAL LIGAMENT REPAIR SCAPHOLUNATE LIGAMENT RECONSTRUCTION VOLAR PLATE RECONSTRUCTION TENDON TRANSFERS IN PHALANX HIP ACETABULAR LABRAL REPAIR KNEE EXTRA-CAPSULAR REPAIRS O MEDIAL COLLATERAL LIGAMENT O LATERAL COLLATERAL LIGAMENT O POSTERIOR OBLIQUE LIGAMENT PATELLAR REALIGNMENT AND TENDON REPAIRS ILLIOTIBIAL BAND TENODESIS VMO ADVANCEMENT JOINT CAPSULE CLOSURE,NON-ABSORBABLE INTERNAL FIXATION DEVICE(APERFIX® FEMORAL IMPLANT)-THE APERFIX® FEMORAL IMPLANT IS INTENDED FOR USE IN TENODESIS PROCEDURES WITH SOFT TISSUE GRAFTS, UTILIZING EITHER ARTHROSCOPIC OR OPEN TECHNIQUES DURING ANTERIOR CRUCIATE LIGAMENT (ACL), POSTERIOR CRUCIATE LIGAMENT (PCL), MEDIAL COLLATERAL LIGAMENT (MCL), LATERAL COLLATERAL LIGAMENT (LCL), AND MEDIAL PATELLOFEMORAL LIGAMENT (MPFL) RECONSTRUCTION.
1277	IMP/MD/2018/000158	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED ,NO. 17, GROUND FLOOR AND MEZZANINE FLOOR, THIRUNEERMALAI ROAD, NAGALKENI, CHROMPET ,CHENNAI TAMIL NADU ,600044 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SCREWS(IFIX® INTERFERENCE SCREW)-THE IFIX® INTERFERENCE SCREW IS INTENDED FOR USE WITH BPTB GRAFTS TO PROVIDE BONE TO BONE FIXATION DURING ARTHROSCOPIC OR OPEN ACL RECONSTRUCTION PROCEDURES,NON-ABSORBABLE KNOTLESS ANCHOR(QUATTRO™ LINK KNOTLESS ANCHOR W/WO SELF-PUNCHING (SP) TITANIUM TIP)-THE CAYENNE MEDICAL, INC. QUATTRO® LINK KNOTLESS ANCHORS ARE INTENDED TO BE USED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR SHOULDER PROCEDURES SUCH AS ROTATOR CUFF REPAIRS,MENISCAL REPAIR DEVICE(CROSSFIX® II STERILE DEVICE PRELOADED WITH SUTURE)-THE CROSSFIX® II MENISCAL REPAIR DEVICE IS INTENDED FOR APPROXIMATION OF SOFT TISSUE IN MENISCAL REPAIR PROCEDURES,NON-ABSORBABLE SUTURE ANCHOR(QUATTRO® GL SUTURE ANCHOR)-THE CAYENNE MEDICAL, INC. QUATTRO GL SUTURE ANCHOR IS INTENDED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR BANKART REPAIR AND SLAP LESION REPAIR,NON-ABSORBABLE SUTURE ANCHOR (QUATTRO® X/X3 SUTURE ANCHOR)-THE CAYENNE MEDICAL, INC. QUATTRO® X AND X3 SUTURE ANCHORS ARE INTENDED FOR USE FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR ROTATOR CUFF REPAIRS.

1278	IMP/MD/2018/000159	1.License Holder Name: BSN MEDICAL PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CAST PADDING(DELTA DRY)-DELTA DRY CAST PADDING CONSISTS OF WATER RESISTANT MATERIAL WITH SYNTHETIC ADHESIVE ON ONE SIDE DESIGNED TO ALLOW WATER TO PASS THROUGH THE MATERIAL.,POLYESTER CAST TAPE(DELTA CAST)-DELTA CAST IS A POLYESTER CAST TAPE SYSTEM THAT PROVIDES RIGID EXTERNAL IMMOBILIZATION AND IS USED IN CONJUNCTION WITH CAST PADDING TO IMMOBILIZATION A LIMB THAT REQUIRES SUPPORT AND PROTECTION DUE TO A BONE INJURY.,FIBERGLASS CAST TAPE(DYNACAST)-THIS PRODUCT IS INTENDED FOR PATIENTS REQUIRING IMMOBILIZATION OF FRACTURES AND SPRAINS, SUPPORT OF SOFT TISSUE INJURIES, CHRONIC AND REHABILITATIVE ORTHOPEDIC CONDITIONS.
1279	IMP/MD/2018/000160	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CALCIUM LINE FOR PRISMAFLEX - CA 250-THE CALCIUM LINE FOR PRISMAFLEX– CA250 IS A MEDICAL DEVICE TO BE USED ONLY WITH THE PRISMAX CONTROL UNIT (IN COUNTRIES WHERE PRISMAX IS CLEARED OR REGISTERED) OR WITH THE PRISMAFLEX CONTROL UNIT SOFTWARE VERSION 5.0 OR LATER FOR PERFORMING THE “CITRATE-CALCIUM VIA INTERNAL SYRINGE PUMP” ANTICOAGULATION METHOD. CAREFULLY READ THE PRISMAFLEX OPERATOR’S MANUAL AND ON-LINE SCREEN INSTRUCTIONS. ALL TREATMENTS ADMINISTERED VIA THE CALCIUM LINE FOR PRISMAFLEX - CA250 MUST BE PRESCRIBED BY A PHYSICIAN.

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1280	IMP/MD/2018/000161	1.License Holder Name: EVOLUTIS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PLLA POLYMER INTERFERENCE SCREWS - FIXION-THE INTERFERENCE SCREWS ARE INDICATED FOR THE FIXATION OF THE TENDINOUS TRANSPLANT IN THE SURGICAL REPAIR OF THE RUPTURE OF THE ACL (ANTERIOR CRUCIATE LIGAMENT) OR THE PCL (POSTERIOR CRUCIATE LIGAMENT) OF THE KNEE.,CUP LINER - FREELINER-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEM OF THE HIP IN PATIENTS. WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLERS AND CONSERVATIVE TREATMENT USED CORRECTLY HAVE FAILED. THE ANATOMY AND STRUCTURE OF THE PATIENTS ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S).,FEMORAL STEM - STEMSYS-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEM OF THE HIP IN PATIENTS. WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLERS AND CONSERVATIVE TREATMENT USED CORRECTLY HAVE FAILED. THE ANATOMY AND STRUCTURE OF THE PATIENTS ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S).,FEMORAL STEM - AMETHIST-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEM OF THE HIP IN PATIENTS. WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLERS AND CONSERVATIVE TREATMENT USED CORRECTLY HAVE FAILED. THE ANATOMY AND STRUCTURE OF THE PATIENTS ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S).,BIOGLASS INTERFERENCE SCREW - FIXION-THE INTERFERENCE SCREWS ARE INDICATED FOR THE FIXATION OF THE TENDINOUS TRANSPLANT IN THE SURGICAL REPAIR OF THE RUPTURE OF THE ACL (ANTERIOR CRUCIATE LIGAMENT) OR THE PCL (POSTERIOR CRUCIATE LIGAMENT) OF THE KNEE.,FEMORAL CONDYLES - ROLFLEX TONIC-HEMI AND TOTAL KNEE ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEMS OF THE KNEE IN PATIENTS WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLERS AND CONSERVATIVE TREATMENT USED CORRECTLY HAVE FAILED. THE ANATOMY AND STRUCTURE OF THE PATIENT'S ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S).,ACETABULAR CUP - FREELINER-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEM OF THE HIP IN PATIENTS. WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN

	KILLERS AND CONSERVATIVE TREATMENT USED CORRECTLY HAVE FAILED. THE ANATOMY AND STRUCTURE OF THE PATIENTS ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S).,FEMORAL HEAD-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEM OF THE HIP IN PATIENTS. WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLERS AND CONSERVATIVE TREATMENT USED CORRECTLY HAVE FAILED. THE ANATOMY AND STRUCTURE OF THE PATIENTS ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S).,TIBIAL INSERT - ROLFLEX TONIC-HEMI AND TOTAL KNEE ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEMS OF THE KNEE IN PATIENTS WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLERS AND CONSERVATIVE TREATMENT USED CORRECTLY HAVE FAILED. THE ANATOMY AND STRUCTURE OF THE PATIENT'S ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S).,TIBIAL BASEPLATES - ROLFLEX TONIC-HEMI AND TOTAL KNEE ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEMS OF THE KNEE IN PATIENTS WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLERS AND CONSERVATIVE TREATMENT USED CORRECTLY HAVE FAILED. THE ANATOMY AND STRUCTURE OF THE PATIENT'S ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S).,SCREWS - FREELINER-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEM OF THE HIP IN PATIENTS. WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLERS AND CONSERVATIVE TREATMENT USED CORRECTLY HAVE FAILED. THE ANATOMY AND STRUCTURE OF THE PATIENTS ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S).

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1281	IMP/MD/2018/000162	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SMALL FRAGMENT PLATING SYSTEM - SCREWS(EVOS)-THE EVOS SMALL FRAGMENT PLATING SYSTEM IS INDICATED FOR ADULT AND PEDIATRIC PATIENTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. IT IS INDICATED FOR FIXATION OF SMALL AND LONG BONE FRACTURES, INCLUDING BUT NOT LIMITED TO, THOSE OF THE TIBIA, FIBULA, FEMUR, HUMERUS, ULNA, RADIUS, PELVIS, ACETABULUM, METACARPALS, METATARSALS, AND CLAVICLE. THE EVOS PARTIAL ARTICULAR AND ANTI-GLIDE PLATES ARE INDICATED FOR THE TREATMENT OF PARTIAL ARTICULAR FRACTURES OF THE DISTAL AND PROXIMAL TIBIA (AO/OTA FRACTURE CLASSIFICATION TYPE B), AND FOR FRACTURE FIXATION OF THE FIBULA.,TOTAL KNEE SYSTEM (GENESIS II)-1. RHEUMATOID ARTHRITIS. 2. POST-TRAUMATIC ARTHRITIS, OSTEOARTHRITIS, OR DEGENERATIVE ARTHRITIS. 3. FAILED OSTEOTOMIES, UNICOMPARTMENTAL REPLACEMENT, OR TOTAL KNEE REPLACEMENT. 4. POSTERIOR STABILIZED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE INCOMPETENT AND THE COLLATERAL LIGAMENTS REMAIN INTACT. 5. CONSTRAINED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE INCOMPETENT. 6. HINGE KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE ABSENT OR INCOMPETENT.,TOTAL KNEE SYSTEM(ANTHEM)-• RHEUMATOID ARTHRITIS. • POST-TRAUMATIC ARTHRITIS, OSTEOARTHRITIS, OR DEGENERATIVE ARTHRITIS. • FAILED OSTEOTOMIES, UNICOMPARTMENTAL REPLACEMENT, OR TOTAL KNEE REPLACEMENT. • POSTERIOR STABILIZED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE INCOMPETENT AND THE COLLATERAL LIGAMENTS REMAIN INTACT.

1282	IMP/MD/2018/000162	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SCREWS(NA)-SCREWS ARE INTENDED TO BE USED WITH NAILS AND PLATES FOR FRACTURE FIXATION IN TRAUMA SURGERIES.
1283	IMP/MD/2018/000163	1.License Holder Name: M/S NOVO NORDISK INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE PERFUSION SETS TRANSFUSION OR PERFUSION SETS FOR SINGLE USE (ADMINISTRATION SET)-THE ADMINISTRATION SET IS TO BE USED FOR INJECTION (ADMINISTRATION) OF NOVO NORDISK FACTOR PRODUCTS.
1284	IMP/MD/2018/000164	1.License Holder Name: DACE LABORATORIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PRP KIT(T-LAB PRP KIT)-THE SYSTEM IS DESIGNED TO BE USED FOR THE SAFE AND RAPID PREPARATION OF AUTOLOGOUS PLATELET-RICH-PLASMA (PRP) FROM A SMALL SAMPLE OF BLOOD AT THE PATIENT'S POINT OF CARE. THE PRP IS PREPARED PRIOR TO APPLICATION TO A LOCAL AREA OF SOFT TISSUE OR HARD TISSUE (INCLUDING BONE) SITE AS DEEMED NECESSARY BY THE CLINICAL USE REQUIREMENTS. AND ITS INTENDED USE IS FOR THE APPLICATION OF PRP IN ORDER TO ACHIEVE THE STIMULATION OF SOFT TISSUE AND HARD TISSUE (INCLUDING BONE) AND ACCELERATION OF SOFT TISSUE AND HARD TISSUE (INCLUDING BONE) HEALING
1285	IMP/MD/2018/000165	1.License Holder Name: SHREYAAS HEALTH CARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TALC POWDER (STERITALC)-IT IS INDICATED FOR CHRONIC PLEURISY, PRINCIPALLY MALIGNANT SPONTANEOUS PNEUMOTHORAX OTHER CASES IN WHICH A PLEURODESIS IS INDICATED.

1286	IMP/MD/2018/000166	1.License Holder Name: M/S DENTSPLY INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EXTRAORAL X-RAY DEVICE(ORTHOPHOS E (ORTHOPHOS E PAN, ORTHOPHOS E CEPH, ORTHOPHOS E INDIVID.))-THE ORTHOPHOS E / CEPH IS DESIGNED FOR PRODUCING DIFFERENT TOMOGRAPHIC EXPOSURES OF THE MAXILLOFACIAL AREA OR OF PARTS OF THIS. PROJECTIONS OF THE SKULL AND CARPUS EXPOSURES FOR ORTHODONTICS ARE ALSO POSSIBLE WITH THE CEPHALOMETRIC ARM.,TITANIUM BASE ABUTMENT(TIBASE)-TITANIUM ABUTMENT FOR THE MANUFACTURE OF A TWO-PIECE ABUTMENT CONSISTING OF THE TIBASE AND THE INCORIS ZI MESO-STRUCTURE,INTRAORAL X-RAY DEVICE (HELIODENT PLUS)-THE HELIODENT PLUS IS AN X-RAY DEVICE FOR ESTABLISHED DENTAL SURGERIES AND CLINICS INTENDED TO BE USED FOR INTRAORAL RADIOGRAPHY FOR EXAMINATION AND DIAGNOSIS OF DISEASES OF THE TEETH, JAW, AND ORAL STRUCTURES,EXTRAORAL X-RAY DEVICE(AXEOS)-THE X-RAY SYSTEM CREATES DATA FOR DIGITAL EXPOSURES IN THE MAXILLOFACIAL REGION AND SUBREGIONS FOR DENTISTRY AND PEDIATRIC DENTISTRY, FOR HARD-TISSUE DIAGNOSTICS WITHIN ENT MEDICINE, AND FOR CARPAL EXPOSURES.,EXTRAORAL X-RAY DEVICE(ORTHOPHOS SL 3D / ORTHOPHOS SL 3D CEPH)-THE X-RAY SYSTEM CREATES DATA FOR DIGITAL EXPOSURES IN THE MAXILLOFACIAL AREA AND IN SUBAREAS FOR DENTISTRY AND PEDIATRIC DENTISTRY, FOR HARD-TISSUE DIAGNOSTICS WITHIN ENT MEDICINE, AND CARPUS EXPOSURES. PROJECTIONS OF THE SKULL AND CARPUS EXPOSURES FOR ORTHODONTICS ARE ALSO POSSIBLE WITH THE CEPHALOMETRIC ARM.,EXTRAORAL X-RAY DEVICE (ORTHOPHOS S (ORTHOPHOS S 2D/ORTHOPHOS S 2D CEPH, ORTHOPHOS S 3D/ORTHOPHOS S 3D CEPH))-THE X-RAY SYSTEM CREATES DATA FOR DIGITAL EXPOSURES IN THE MAXILLOFACIAL AREA AND IN SUBAREAS FOR DENTISTRY AND PEDIATRIC DENTISTRY, FOR HARD-TISSUE DIAGNOSTICS WITHIN ENT MEDICINE, AND CARPUS EXPOSURES. THE OPERATING AND MAINTENANCE INSTRUCTIONS MUST BE OBSERVED.

1287	IMP/MD/2018/000167	1.License Holder Name: M/S JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINE SYSTEM- WASHER (EXPEDIUM)-THE EXPEDIUM SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE THE EXPEDIUM SPINE SYSTEM ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SPINE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SPINE SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH., SPINAL SYSTEM - WASHER(MOSS MIAMI)-THE MOSS MIAMI SPINE SYSTEMS ARE PEDICLE SCREW SYSTEMS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE: DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, FRACTURE, DISLOCATION, SCOLIOSIS, KYPHOSIS, SPINAL TUMOR, AND FAILED PREVIOUS FUSION (PSEUDARTHROSIS). THE MOSS MIAMI SPINE SYSTEMS ARE ALSO INDICATED FOR PEDICLE SCREW FIXATION FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADES 3 AND 4) OF THE L5–S1 VERTEBRA IN SKELETALLY MATURE PATIENTS RECEIVING FUSION BY AUTOGENOUS BONE GRAFT HAVING IMPLANTS ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 TO SACRUM) WITH REMOVAL OF THE IMPLANTS AFTER THE ATTAINMENT OF A SOLID FUSION. THE MOSS MIAMI SPINE SYSTEMS ARE ALSO A HOOK AND SACRAL/ILIAC SCREW FIXATION SYSTEM OF THE NONCERVICAL SPINE INDICATED FOR DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES),

	SPONDYLOLISTHESIS, TRAUMA (FRACTURE AND/OR DISLOCATION), SPINAL STENOSIS, DEFORMITIES (SCOLIOSIS, LORDOSIS AND/OR KYPHOSIS), TUMOR, AND PREVIOUS FAILED FUSION (PSEUDARTHROSIS). THE MOSS MIAMI SPINE SYSTEMS WHEN USED AS ANTERIOR THORACIC/LUMBAR SCREW FIXATION SYSTEMS, ARE INDICATED FOR DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (FRACTURE AND/OR DISLOCATION), SPINAL STENOSIS, DEFORMITIES (SCOLIOSIS, LORDOSIS AND/OR KYPHOSIS), TUMOR, AND PREVIOUS FAILED FUSION (PSEUDARTHROSIS).,SPINE SYSTEM- ROD(EXPEDIUM)-THE EXPEDIUM SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM SPINE SYSTEM ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SPINE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SPINE SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH.,SPINAL SYSTEM - CONNECTOR(MOSS MIAMI)-THE MOSS MIAMI SPINE SYSTEMS ARE PEDICLE SCREW SYSTEMS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE: DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, FRACTURE, DISLOCATION, SCOLIOSIS, KYPHOSIS, SPINAL TUMOR, AND FAILED PREVIOUS FUSION (PSEUDARTHROSIS). THE MOSS MIAMI SPINE SYSTEMS ARE ALSO INDICATED FOR PEDICLE SCREW FIXATION FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADES 3 AND 4) OF THE L5–S1

	VERTEBRA IN SKELETALLY MATURE PATIENTS RECEIVING FUSION BY AUTOGENOUS BONE GRAFT HAVING IMPLANTS ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 TO SACRUM) WITH REMOVAL OF THE IMPLANTS AFTER THE ATTAINMENT OF A SOLID FUSION. THE MOSS MIAMI SPINE SYSTEMS ARE ALSO A HOOK AND SACRAL/ILIAC SCREW FIXATION SYSTEM OF THE NONCERVICAL SPINE INDICATED FOR DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (FRACTURE AND/OR DISLOCATION), SPINAL STENOSIS, DEFORMITIES (SCOLIOSIS, LORDOSIS AND/OR KYPHOSIS), TUMOR, AND PREVIOUS FAILED FUSION (PSEUDARTHROSIS). THE MOSS MIAMI SPINE SYSTEMS WHEN USED AS ANTERIOR THORACIC/LUMBAR SCREW FIXATION SYSTEMS, ARE INDICATED FOR DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (FRACTURE AND/OR DISLOCATION), SPINAL STENOSIS, DEFORMITIES (SCOLIOSIS, LORDOSIS AND/OR KYPHOSIS), TUMOR, AND PREVIOUS FAILED FUSION (PSEUDARTHROSIS).,SPINE SYSTEM- ROD(VIPER2)-THE VIPER2 SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE VIPER2 SPINE SYSTEM ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SPINE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SPINE SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH,SPINE SYSTEM-HOOK(EXPEDIUM)-THE EXPEDIUM SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES

	OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM SPINE SYSTEM ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SPINE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SPINE SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH., SPINE SYSTEM- CONNECTOR(EXPEDIUM)-THE EXPEDIUM SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM SPINE SYSTEM ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SPINE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SPINE SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH.,SPINE SYSTEM-SCREW(EXPEDIUM)-THE EXPEDIUM SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM SPINE SYSTEM ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING

	INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SPINE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SPINE SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1288	IMP/MD/2018/000170	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETERIZATION SET(ARROW®)-1. THE ARROW® SINGLE-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION. 2. THE MULTIPLE-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION OF PEDIATRIC PATIENTS., HEMODIALYSIS CATHETERS(ARROW®)-THE LARGE-BORE TWO-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION FOR RAPID FLUID ADMINISTRATION, TEMPORARY OR ACUTE HEMODIALYSIS, APHERESIS AND HEMOFILTRATION. IT MAY BE INSERTED INTO THE JUGULAR, SUBCLAVIAN, OR FEMORAL VEINS. THE ARROWG+ARD BLUE ANTIMICROBIAL SURFACE CATHETER HELPS PROVIDE PROTECTION AGAINST CATHETER-RELATED INFECTIONS RESULTING FROM MICROORGANISMS MIGRATING THE SUBCUTANEOUS TRACT ALONG THE EXTERIOR SURFACE OF THE CATHETER WHEN USED FOR INFUSION. CLINICAL DATA HAVE NOT BEEN COLLECTED THAT DEMONSTRATE THE USE OF THE ARROWG+ARD BLUE ANTIMICROBIAL SURFACE IN DECREASING CATHETER RELATED INFECTIONS IN HEMODIALYSIS PATIENTS. THE CATHETER IS NOT INTENDED TO BE USED AS A TREATMENT FOR EXISTING INFECTIONS, NOR IS IT INDICATED FOR LONG-TERM USE., ARTERIAL CATHETERIZATION SET(ARROW®)-THE ARROW® SELDINGER ARTERIAL CATHETERIZATION DEVICES PERMIT ACCESS TO THE PERIPHERAL ARTERIAL CIRCULATION OR TO OTHER SMALL VESSELS.,ARTERIAL CATHETERIZATION SET(ARROW®)-THE ARROW® ARTERIAL CATHETERIZATION DEVICE PERMITS ACCESS TO THE PERIPHERAL ARTERIAL CIRCULATION.,CENTRAL VENOUS CATHETERIZATION SET(ARROW®)-THE LARGE-BORE MULTIPLE-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION FOR RAPID FLUID ADMINISTRATION. IT MAY BE INSERTED INTO THE JUGULAR, SUBCLAVIAN, OR FEMORAL VEINS., CENTRAL VENOUS CATHETERIZATION SET(ARROW®)-THE ARROWG+ARD BLUE PLUS® MULTIPLE-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION BY WAY OF THE FEMORAL, JUGULAR, OR SUBCLAVIAN VEINS. THE ARROWG+ARD® TECHNOLOGY IS INTENDED TO PROVIDE PROTECTION AGAINST CATHETER-RELATED BLOODSTREAM INFECTIONS. IT IS NOT INTENDED TO BE USED AS A TREATMENT FOR EXISTING INFECTIONS NOR IS IT INDICATED FOR LONG-TERM USE (> 30 DAYS). CLINICAL EFFECTIVENESS OF THE ARROWG+ARD BLUE PLUS® CATHETER IN PREVENTING CRBSI'S COMPARED TO THE ORIGINAL ARROWG+ARD BLUE® CATHETER HAS NOT BEEN STUDIED.

1289	IMP/MD/2018/000171	1.License Holder Name: GETINGE MEDICAL INDIA PVT. LTD ,203-204, B-WING,FULCRUM,SAHAR ROAD ,MUMBAI SUBURBAN MAHARASHTRA ,400099 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HLS CANNULAE-HLS CANNULA IS INDICATED FOR CANNULATION OF ALL SUITABLE VESSELS (FEMORAL VESSELS) AND FORMS THE CONNECTION WITH THE EXTRACORPOREAL CIRCULATION WITH BIOLINE COATING IN COMBINATION WITH A PLS SET,PLS SET PLUS OR HLS SET ADVANCED FROM MAQUET IS 30 DAYS .IN THE EVENT THAT THE COATED HLS CANNULAE ARE NOT USED IN COMBINATION WITH THE SETS MENTIONED ABOVE ,THE MAXIMUM DURATION OF USE FOR THE HLS CANNULAE IS 6HOURS.,PERCUTANEOUS INSERTION KIT-THE INSERTION KIT IS USED FOR PREPARING THE CANNULATION OF VESSELS FOR EXTRACORPOREAL CIRCULATION. SURGICAL PROCEDURES CAN BE PERFORMED UNDER VISUAL CONTROL OR WITH PERCUTANEOUS CANNULATION USING THE SELDINGER TECHNIQUE.,HEMOCONCENTRATORS-THE BC-20 PLUS, BC -60 PLUS, AND BC 140 PLUS HEMOCONCETRATORS ARE USED TO REMOVE PLASMA FLUID AND THE LO-MOLECULAR SUBSTANCES DISSOLVED IN IT FROM THE BLOOD OR TO CONCENTRATE HIGHLY DILUTED BLOOD SOLUTIONS.THEY ARE INTENDED FOR USE IN EXTRA CORPOREAL CIRCULATION DURING AND IMMEDIATELY AFTER A CARDIAC SURGERY PROCEDURE. THE MAXIMUM DURATION OF USE IS 6 HOURS. THE PHYSICIAN IN CHARGE OF TREATMENT HAS SOLE RESPONSIBILITY FOR DECISIONS CONCERNING USE OF THE HEMOCONCENTRATOR.

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1290	IMP/MD/2018/000172	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BALLOON DILATATION CATHETER(NANOCROSS ELITE 0.014" OVER-THE-WIRE PTA BALLOON DILATATION CATHETER)-IT IS INTENDED TO DILATE STENOSES IN THE ILIAC, FEMORAL ILIO-FEMORAL POPLITEAL, INFRA-POPLITEAL AND RENAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR STENT POST-DILATATION IN THE PERIPHERAL VASCULATURE.,0.14 OTW PTA DILATATION CATHETER(NANOCROSS)-THE NANOCROSS 0.14 OTW PTA DILATATION CATHETER IS INTENDED TO DILATE STENOSIS IN THE ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA-POPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULA.,BALLOON EXPANDABLE BILIARY STENT SYSTEM(VISI-PRO)-THIS STENT SYSTEM IS INTENDED AS A PALLIATIVE TREATMENT FOR MALIGNANT NEOPLASMS IN THE BILIARY TREE,0.18 OTW PT A DILATATION CATHETER(POWERCROSS)-THE POWERCROSS 0.18 OTW PTA DILATATION CATHETER IS INTENDED TO DILATE STENOSIS IN THE ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA-POPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR STENT POST-DILATATION IN THE PERIPHERAL VASCULATURE.,PTA RAPID EXCHANGE BALLOON DILATION CATHETER(RAPID CROSS™)-IT IS INTENDED TO DILATE STENOSES IN THE ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INTRA-POPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR STENT POST-DILATION IN THE PERIPHERAL VASCULATURE,0.035 OTW PTA DILATATION CATHETER(EVERCROSS) -THE EVERCROSS 0.035 OTW PTA DILATATION CATHETER IS INTENDED TO DILATE STENOSIS IN THE ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA-POPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR STENT POST-DILATATION IN THE PERIPHERAL VASCULATURE.,STENT SYSTEM(EVERFLEX SELF EXPANDING PERIPHERAL STENT WITH ENTRUST DELIVERY SYSTEM)-INDICATED FOR USE IN OCCLUSIONS, LESIONS AT HIGH RISK FOR ABRUPT CLOSURE OR THREATENED CLOSURE FOLLOWING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA); OR LESIONS BELIEVED TO BE AT HIGH RISK FOR RESTENOSIS FOLLOWING PTA IN THE COMMON

	ILIAC, EXTERNAL ILIAC, SUPERFICIAL FEMORAL, PROXIMAL POPLITEAL OR SUBCLAVIAN ARTERIES. STENTING IS INTENDED TO IMPROVE AND MAINTAIN ARTERY LUMINAL DIAMETER.,GUIDEWIRE (NITREX)-THE 0.014 IN. (0.36 MM) AND 0.018 IN. (0.46 MM) DIAMETER NITREX NITINOL GUIDEWIRES ARE INTENDED FOR USE IN THE PERIPHERAL AND CORONARY VASCULATURE. THE 0.025 IN. (0.64 MM) AND 0.035 IN.(0.89 MM) DIAMETER NITREX NITINOL GUIDEWIRES ARE INDICATED FOR USE IN THE PERIPHERAL VASCULATURE., BALLOON EXPANDABLE PERIPHERAL STENT SYSTEM(VISI-PRO)-PERIPHERAL - THE VISI-PRO STENT IS INDICATED FOR USE IN OCCLUSIONS, LESIONS AT HIGH RISK FOR ABRUPT CLOSURE OR THREATENED CLOSURE FOLLOWING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA), OR LESIONS BELIEVED TO BE AT HIGH RISK OF STENOSIS FOLLOWING PTA IN THE FOLLOWING ARTERIES: • COMMON AND EXTERNAL ILIAC, SUBCLAVIAN • RENAL STENTING IS INTENDED TO IMPROVE AND MAINTAIN ARTERY LUMINAL DIAMETER. BILIARY – THE VISI-PRO STENT IS INTENDED AS A PALLIATIVE TREATMENT OF MALIGNANT NEOPLASMS IN THE BILIARY TREE.,SUPPORT CATHETER(TRAIL BLAZER)-TRAIL BLAZER SUPPORT CATHETERS ARE PERCUTANEOUS, SINGLE LUMEN CATHETERS DESIGNED FOR USE IN THE PERIPHERAL VASCULAR SYSTEM. TRAIL BLAZER SUPPORT CATHETERS ARE INTENDED TO GUIDE AND SUPPORT A GUIDE WIRE DURING ACCESS OF THE VASCULATURE, ALLOW FOR WIRE EXCHANGE, AND PROVIDE A CONDUIT FOR THE DELIVERY OF SALINE SOLUTIONS OR DIAGNOSTIC CONTRAST AGENTS.,MICROSNARE KIT(AMPLATZ GOOSENECK)-IT IS INTENDED FOR USE IN THE RETRIEVAL AND MANIPULATION OF ATRAUMATIC FOREIGN BODIES LOCATED IN THE CORONARY AND PERIPHERAL CARDIOVASCULAR SYSTEM AND THE EXTRA-CRANIAL NEUROVASCULAR ANATOMY.,SNARE KIT(AMPLATZ GOOSENECK)-AMPLATZ GOOSE NECK SNARE, ONE AMPLATZ GOOSE NECK SNARE CATHETER, SNARE INTRODUCER AND TORQUE DEVICE. INDICATION AND/OR INTENDED USE - THE AMPLATZ GOOSE NECK® SNARE IS INTENDED FOR USE IN THE CARDIOVASCULAR SYSTEM OR HOLLOW VISCUS TO RETRIEVE AND MANIPULATE FOREIGN OBJECTS. MANIPULATION PROCEDURES INCLUDE INDWELLING VENOUS CATHETER FIBRIN SHEATH STRIPPING, AND CENTRAL VENOUS ACCESS VENIPUNCTURE PROCEDURE ASSISTANCE.,EMBOLIC PROTECTION DEVICE(SPIDER FX)-THE SPIDERFX EMBOLIC PROTECTION DEVICES PROVIDE DISTAL EMBOLIZATION PROTECTION DURING GENERAL VASCULAR USE, INCLUDING PERIPHERAL, CORONARY, AND CAROTID INTERVENTIONS.,BALLOON-EXPANDABLE PERIPHERAL STENT SYSTEM(PARAMOUNT MINI GPS)-PARAMOUNT MINI GPS STENT AND DELIVERY SYSTEM IS INDICATED FOR USE IN

	OCCLUSIONS, LESIONS AT HIGH RISK FOR ABRUPT CLOSURE OR THREATENED CLOSURE FOLLOWING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) OR LESIONS BELIEVED TO BE AT HIGH RISK OF RESTENOSIS FOLLOWING PTA IN THE RENAL ARTERIES. STENTING IS INTENDED TO IMPROVE AND MAINTAIN ARTERY LUMINAL DIAMETER. IT IS ALSO INTENDED AS A PALLIATIVE TREATMENT OF MALIGNANT NEOPLASMS IN THE BILIARY TREE., SELF-EXPANDING PERIPHERAL STENT SYSTEM(PROTÉGÉ RX)-THE STENT IS INDICATED FOR USE IN OCCLUSIONS, LESIONS AT HIGH RISK FOR ABRUPT CLOSURE OR THREATENED CLOSURE FOLLOWING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA); OR LESIONS BELIEVED TO BE AT HIGH RISK FOR RESTENOSIS, FOLLOWING PTA IN THE COMMON ILIAC, EXTERNAL ILIAC, OR SUBCLAVIAN ARTERIES. STENTING IS INTENDED TO IMPROVE AND MAINTAIN ARTERY LUMINAL DIAMETER. CAROTID: THE PROTÉGÉ RX IS INTENDED FOR THE TREATMENT OF STENOSIS OF THE COMMON CAROTID ARTERY (CCA), INTERNAL CAROTID ARTERY (ICA) AND CAROTID BIFURCATION,SELF-EXPANDING PERIPHERAL STENT SYSTEM (PROTÉGÉ EVERFLEX)-PERIPHERAL THE STENT IS INDICATED FOR USE IN THE FOLLOWING TYPES OF OCCLUSIONS OR LESIONS: • OCCLUSIONS OR LESIONS AT HIGH RISK FOR ABRUPT CLOSURE OR THREATENED CLOSURE FOLLOWING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) • LESIONS THAT APPEAR TO BE AT HIGH RISK FOR RESTENOSIS FOLLOWING PTA IN THE COMMON ILIAC, EXTERNAL ILIAC, SUPERFICIAL FEMORAL, PROXIMAL POPLITEAL, OR SUBCLAVIAN ARTERIES STENTING IS INTENDED TO IMPROVE AND MAINTAIN THE ARTERY LUMINAL DIAMETER. BILIARY THE STENT IS INDICATED AS A PALLIATIVE TREATMENT OF MALIGNANT NEOPLASMS IN THE BILIARY TREE. .,SELF-EXPANDING PERIPHERAL STENT SYSTEM(PROTÉGÉ GPS)-PERIPHERAL THE STENT IS INDICATED FOR USE IN THE FOLLOWING TYPES OF OCCLUSIONS OR LESIONS: • OCCLUSIONS OR LESIONS AT HIGH RISK FOR ABRUPT CLOSURE OR THREATENED CLOSURE FOLLOWING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) • LESIONS THAT APPEAR TO BE AT HIGH RISK FOR RESTENOSIS FOLLOWING PTA IN THE COMMON ILIAC, EXTERNAL ILIAC, OR SUBCLAVIAN ARTERIES STENTING IS INTENDED TO IMPROVE AND MAINTAIN THE ARTERY LUMINAL DIAMETER. BILIARY THE STENT IS INTENDED AS A PALLIATIVE TREATMENT OF MALIGNANT NEOPLASMS IN THE BILIARY TREE.

1291	IMP/MD/2018/000173	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BRAIDED FAST ABSORBABLE SUTURE(VELOSORB FAST)-VELOSORB FAST ABSORBABLE SUTURES ARE INDICATED FOR USE IN SOFT TISSUE APPROXIMATION OF THE SKIN AND MUCOSA, WHERE ONLY 7-10 DAYS OF WOUND SUPPORT IS REQUIRED,BUT NOT FOR USE IN LIGATION,OPHTHALMIC,CARDIOVASCULAR OR NEUROLOGICAL PROCEDURES.
1292	IMP/MD/2018/000174	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERIPHERAL PLAQUE EXCISION SYSTEM(TURBOHAWK)-IT IS INTENDED FOR USE IN ATHERECTOMY OF THE PERIPHERAL VASCULATURE. IT IS NOT INTENDED FOR USE IN THE CORONARY, CAROTID, ILIAC, OR RENAL VASCULATURE

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1293	IMP/MD/2018/000175	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VITROS XT ALTV-AST SLIDES(VITROS XT CHEMISTRY PRODUCTS ALTV-AST SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. THE ALTV TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS ALTV AST SLIDES QUANTITATIVELY MEASURES ALANINE AMINOTRANSFERASE (ALT) ACTIVITY IN SERUM AND PLASMA USING APPLICABLE VITROS SYSTEMS. ALANINE AMINOTRANSFERASE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CERTAIN LIVER DISEASES (E.G., VIRAL HEPATITIS AND CIRRHOSIS) AND HEART DISEASES. THE AST TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS ALTV AST SLIDES QUANTITATIVELY MEASURES ASPARTATE AMINOTRANSFERASE (AST) ACTIVITY IN SERUM AND PLASMA USING APPLICABLE VITROS SYSTEMS. ASPARTATE AMINO TRANSFERASE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CERTAIN TYPES OF LIVER AND HEART DISEASE.,ALANINE AMINOTRANSFERASE ASSAY (VITROS CHEMISTRY PRODUCTS ALTV SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS ALTV SLIDES QUANTITATIVELY MEASURE ALANINE AMINOTRANSFERASE (ALT) ACTIVITY IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM. ALANINE AMINOTRANSFERASE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CERTAIN LIVER DISEASES (E.G. VIRAL HEPATITIS AND CIRRHOSIS) AND HEART DISEASES.,VITROS XT ALB-TP SLIDES (VITROS XT CHEMISTRY PRODUCTS ALB-TP SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. THE ALB TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS ALB-TP SLIDES QUANTITATIVELY MEASURES ALBUMIN (ALB) CONCENTRATION IN SERUM AND PLASMA USING APPLICABLE VITROS SYSTEMS. ALBUMIN MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF NUMEROUS DISEASES INVOLVING PRIMARILY THE LIVER OR KIDNEYS. THE TP TEST WITHIN VITROS XT CHEMISTRY PRODUCTS ALB-TP SLIDES QUANTITATIVELY MEASURES TOTAL PROTEIN (TP) CONCENTRATION IN SERUM AND PLASMA USING APPLICABLE VITROS SYSTEMS. MEASUREMENTS OBTAINED BY THIS DEVICE ARE USED IN THE DIAGNOSIS AND TREATMENT OF A VARIETY OF DISEASES INVOLVING THE LIVER, KIDNEY, OR BONE MARROW AS WELL AS OTHER METABOLIC OR NUTRITIONAL DISORDERS. ,VITROS CHEMISTRY PRODUCTS CL-SLIDES(VITROS CHEMISTRY PRODUCTS CL- SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CL- SLIDES QUANTITATIVELY MEASURE CHLORIDE (CL-) CONCENTRATION IN SERUM, PLASMA AND URINE USING VITROS CHEMISTRY SYSTEMS

	AND THE VITROS INTEGRATED SYSTEM. CHLORIDE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF ELECTROLYTE AND METABOLIC DISORDERS SUCH AS CYSTIC FIBROSIS AND DIABETIC ACIDOSIS,VITROS XT TBIL-ALKP SLIDES(VITROS XT CHEMISTRY PRODUCTS TBIL-ALKP SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. THE TBIL TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS TBIL-ALKP SLIDES QUANTITATIVELY MEASURE TOTAL BILIRUBIN (TBIL) CONCENTRATION IN SERUM AND PLASMA USING APPLICABLE VITROS SYSTEMS. MEASUREMENTS OF THE LEVELS OF BILIRUBIN, AN ORGANIC COMPOUND FORMED DURING THE NORMAL AND ABNORMAL DESTRUCTION OF RED BLOOD CELLS, ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIVER, HEMOLYTIC HEMATOLOGICAL AND METABOLIC DISORDERS, INCLUDING HEPATITIS AND GALL BLADDER BLOCK. THE ALKP TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS TBIL-ALKP SLIDES QUANTITATIVELY MEASURE ALKALINE PHOSPHATASE (ALKP) ACTIVITY IN SERUM AND PLASMA USING APPLICABLE VITROS SYSTEMS. MEASUREMENTS OF ALKALINE PHOSPHATASE OR ITS ISOENZYMES ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIVER, BONE, PARATHYROID, AND INTESTINAL DISEASES.,VITROS CHEMISTRY PRODUCTS LDHI SLIDES(VITROS CHEMISTRY PRODUCTS LDHI SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS LDHI SLIDES QUANTITATIVELY MEASURE LACTATE DEHYDROGENASE (LDH) ACTIVITY IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,VITROS XT UREA-CREA SLIDES(VITROS XT CHEMISTRY PRODUCTS UREA-CREA SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. THE UREA TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS UREA-CREA SLIDES QUANTITATIVELY MEASURES UREA CONCENTRATION, REPORTED EITHER AS UREA NITROGEN OR AS UREA (UREA), IN SERUM, PLASMA, AND URINE USING APPLICABLE VITROS SYSTEMS. MEASUREMENTS OBTAINED BY THIS DEVICE ARE USED IN THE DIAGNOSIS AND TREATMENT OF CERTAIN RENAL AND METABOLIC DISEASES. THE CREA TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS UREA-CREA SLIDES QUANTITATIVELY MEASURES CREATININE (CREA) CONCENTRATION IN SERUM, PLASMA, AND URINE USING APPLICABLE VITROS SYSTEMS. CREATININE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF RENAL DISEASES, IN MONITORING RENAL DIALYSIS, AND AS A CALCULATION BASIS FOR MEASURING OTHER URINE ANALYTES,GLUCOSE ASSAY(VITROS CHEMISTRY PRODUCTS GLU SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS GLU SLIDES QUANTITATIVELY MEASURE GLUCOSE (GLU) CONCENTRATION IN SERUM, PLASMA, URINE, AND CEREBROSPINAL

	FLUID USING CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,VITROS XT TRIG-CHOL SLIDES(VITROS XT CHEMISTRY PRODUCTS TRIG-CHOL SLIDES)-FOR IN-VITRO DIAGNOSTIC USE ONLY. THE TRIG TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS TRIG-CHOL SLIDES QUANTITATIVELY MEASURE TRIGLYCERIDE (TRIG) CONCENTRATION IN SERUM AND PLASMA USING APPLICABLE VITROS SYSTEMS. TRIGLYCERIDE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH DIABETES MELLITUS, NEPHROSIS, LIVER OBSTRUCTION, OTHER DISEASES INVOLVING LIPID METABOLISM, OR VARIOUS ENDOCRINE DISORDERS. THE CHOL TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS TRIG-CHOL SLIDES QUANTITATIVELY MEASURE CHOLESTEROL (CHOL) CONCENTRATION IN SERUM AND PLASMA USING APPLICABLE VITROS SYSTEMS. LIPOPROTEIN MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF LIPID DISORDERS (SUCH AS DIABETES MELLITUS), ATHEROSCLEROSIS, AND VARIOUS LIVER AND RENAL DISEASES., URIC ACID ASSAY(VITROS CHEMISTRY PRODUCTS URIC SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS URIC SLIDES QUANTITATIVELY MEASURE URIC ACID (URIC) CONCENTRATION IN SERUM, PLASMA, AND URINE USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM., VITROS XT GLU-CA SLIDES(VITROS XT CHEMISTRY PRODUCTS GLU-CA SLIDES)-FOR IN-VITRO DIAGNOSTIC USE ONLY. THE GLU TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS GLU-CA SLIDES QUANTITATIVELY MEASURES GLUCOSE {GLU) CONCENTRATION IN SERUM, PLASMA, URINE, AND CEREBROSPINAL FLUID (CSF) USING APPLICABLE VITROS SYSTEMS. GLUCOSE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF CARBOHYDRATE METABOLISM DISORDERS INCLUDING DIABETES MELLITUS, NEONATAL HYPOGLYCEMIA, IDIOPATHIC HYPOGLYCEMIA, AND OF PANCREATIC ISLET CELL CARCINOMA. THE CA TEST WITHIN THE VITROS XT CHEMISTRY PRODUCTS GLU-CA SLIDES QUANTITATIVELY MEASURES· CALCIUM (CA) CONCENTRATION IN SERUM, PLASMA, AND URINE USING APPLICABLE VITROS SYSTEMS. CALCIUM MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PARATHYROID DISEASE, A VARIETY OF BONE DISEASES, CHRONIC RENAL DISEASE AND TETANY (INTERMITTENT MUSCULAR CONTRACTIONS OR SPASMS).,URINE PROTEIN ASSAY(VITROS CHEMISTRY PRODUCTS UPRO SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS UPRO SLIDES QUANTITATIVELY MEASURE PROTEIN (UPRO) CONCENTRATION IN URINE USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,TRIGLYCERIDE ASSAY(VITROS CHEMISTRY

	PRODUCTS TRIG SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS TRIG SLIDES QUANTITATIVELY MEASURE TRIGLYCERIDE (TRIG) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM. TRIGLYCERIDE MEASUREMENTS ARE USED IN THE DIAGNOSIS AND TREATMENT OF PATIENTS WITH DIABETES MELLITUS, NEPHROSIS, LIVER OBSTRUCTION, OTHER DISEASES INVOLVING LIPID METABOLISM, OR VARIOUS ENDOCRINE DISORDERS.,TOTAL PROTEIN ASSAY(VITROS CHEMISTRY PRODUCTS TP SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS TP SLIDES QUANTITATIVELY MEASURE TOTAL PROTEIN (TP) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,THEOPHYLLINE ASSAY(VITROS CHEMISTRY PRODUCTS THEO SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS THEO SLIDES QUANTITATIVELY MEASURE THEOPHYLLINE (THEO) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,TOTAL BILIRUBIN ASSAY(VITROS CHEMISTRY PRODUCTS TBIL SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS TBIL SLIDES QUANTITATIVELY MEASURE TOTAL BILIRUBIN (TBIL) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,SALICYLATE ASSAY(VITROS CHEMISTRY PRODUCTS SALI SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS SALI SLIDES QUANTITATIVELY MEASURE SALICYLATE (SALI) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,CEREBROSPINAL FLUID PROTEIN ASSAY (VITROS CHEMISTRY PRODUCTS PROT SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS PROT SLIDES QUANTITATIVELY MEASURE PROTEIN (PROT) CONCENTRATION IN CEREBROSPINAL FLUID USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,PHENYTOIN ASSAY(VITROS CHEMISTRY PRODUCTS PHYT SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS PHYT SLIDES QUANTITATIVELY MEASURE PHENYTOIN (PHYT) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,PHOSPHORUS ASSAY(VITROS CHEMISTRY PRODUCTS PHOS SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS PHOS SLIDES QUANTITATIVELY MEASURE PHOSPHORUS (PHOS) CONCENTRATION IN SERUM, PLASMA, AND URINE USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,SODIUM ASSAY(VITROS CHEMISTRY PRODUCTS NA+ SLIDES)-FOR IN VITRO DIAGNOSTIC USE

	ONLY. VITROS NA+ SLIDES QUANTITATIVELY MEASURE SODIUM (NA+) CONCENTRATION IN SERUM, PLASMA, AND URINE USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,MAGNESIUM ASSAY(VITROS CHEMISTRY PRODUCTS MG SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS MG SLIDES QUANTITATIVELY MEASURE MAGNESIUM (MG) CONCENTRATION IN SERUM, PLASMA, AND URINE USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,LIPASE ASSAY(VITROS CHEMISTRY PRODUCTS LIPA SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS LIPA SLIDES QUANTITATIVELY MEASURE LIPASE (LIPA) ACTIVITY IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,LITHIUM ASSAY(VITROS CHEMISTRY PRODUCTS LI SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS LI SLIDES QUANTITATIVELY MEASURE LITHIUM (LI) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,LACTATE DEHYDROGENASE ASSAY(VITROS CHEMISTRY PRODUCTS LDH SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS LDH SLIDES QUANTITATIVELY MEASURE LACTATE DEHYDROGENASE (LDH) ACTIVITY IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,LACTATE ASSAY (VITROS CHEMISTRY PRODUCTS LAC SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS LAC SLIDES QUANTITATIVELY MEASURE LACTATE (LAC) CONCENTRATION IN PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,POTASSIUM ASSAY(VITROS CHEMISTRY PRODUCTS K+ SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS K+ SLIDES QUANTITATIVELY MEASURE POTASSIUM (K+) CONCENTRATION IN SERUM, PLASMA, AND URINE USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,GAMMA GLUTAMYLTRANSFERASE ASSAY(VITROS CHEMISTRY PRODUCTS GGT SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS GGT SLIDES QUANTITATIVELY MEASURE GAMMA GLUTAMYLTRANSFERASE (GGT) ACTIVITY IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,IRON ASSAY(VITROS CHEMISTRY PRODUCTS FE SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS FE SLIDES QUANTITATIVELY MEASURE IRON (FE) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM., CARBON DIOXIDE ASSAY(VITROS CHEMISTRY PRODUCTS ECO2 SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS ECO2 SLIDES QUANTITATIVELY MEASURE TOTAL

	CARBON DIOXIDE (CO2) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,DIRECT HDL CHOLESTEROL ASSAY(VITROS CHEMISTRY PRODUCTS DHDL SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS DHDL SLIDES ARE USED TO QUANTITATIVELY MEASURE HDL CHOLESTEROL (HDLC) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM. HIGH DENSITY LIPOPROTEIN (HDL) CHOLESTEROL IS USED TO EVALUATE THE RISK OF DEVELOPING CORONARY HEART DISEASE (CHD). THE RISK OF CHD INCREASES WITH LOWER HDL CHOLESTEROL CONCENTRATIONS.,DIGOXIN ASSAY(VITROS CHEMISTRY PRODUCTS DGXN SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS DGXN SLIDES QUANTITATIVELY MEASURE DIGOXIN (DGXN) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,C-REACTIVE PROTEIN ASSAY(VITROS CHEMISTRY PRODUCTS CRP SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CRP SLIDES QUANTITATIVELY MEASURE C-REACTIVE PROTEIN (CRP) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,CREATININE ASSAY(VITROS CHEMISTRY PRODUCTS CREA SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CREA SLIDES QUANTITATIVELY MEASURE CREATININE (CREA) CONCENTRATION IN SERUM, PLASMA, AND URINE USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,CARBAMAZEPINE ASSAY(VITROS CHEMISTRY PRODUCTS CRBM SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CRBM SLIDES QUANTITATIVELY MEASURE CARBAMAZEPINE (CRBM) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,CHLORIDE ASSAY(VITROS CHEMISTRY PRODUCTS CL- SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CL- SLIDES QUANTITATIVELY MEASURE CHLORIDE (CL-) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,CREATINE KINASE MB ASSAY(VITROS CHEMISTRY PRODUCTS CKMB SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS SLIDES QUANTITATIVELY MEASURE CREATINE KINASE MB (CK-MB) ACTIVITY IN SERUM USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM., CREATINE KINASE ASSAY(VITROS CHEMISTRY PRODUCTS CK SLIDES) -FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CK SLIDES QUANTITATIVELY MEASURE CREATINE KINASE (CK) ACTIVITY IN

	SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,CHOLESTEROL ASSAY(VITROS CHEMISTRY PRODUCTS CHOL SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CHOL SLIDES QUANTITATIVELY MEASURE CHOLESTEROL (CHOL) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,CHOLINESTERASE ASSAY(VITROS CHEMISTRY PRODUCTS CHE SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CHE SLIDES QUANTITATIVELY MEASURE CHOLINESTERASE (CHE) ACTIVITY IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,CALCIUM ASSAY(VITROS CHEMISTRY PRODUCTS CA SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CA SLIDES QUANTITATIVELY MEASURE CALCIUM (CA) CONCENTRATION IN SERUM, PLASMA, AND URINE USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,BLOOD UREA NITROGEN ASSAY(VITROS CHEMISTRY PRODUCTS BUN/UREA SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS BUN/UREA SLIDES QUANTITATIVELY MEASURE UREA CONCENTRATION, REPORTED EITHER AS UREA NITROGEN (BUN) OR AS UREA (UREA), IN SERUM, PLASMA, AND URINE USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM., BILIRUBIN, UNCONJUGATED AND CONJUGATED, ASSAY(VITROS CHEMISTRY PRODUCTS BUBC SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS BUBC SLIDES QUANTITATIVELY MEASURE UNCONJUGATED BILLIRUBIN (BU) AND CONJUGATED BILIRUBIN (BC) CONCENTRATIONS IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,ASPARTATE AMINOTRANSFERASE ASSAY (VITROS CHEMISTRY PRODUCTS AST SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS AST SLIDES QUANTITATIVELY MEASURE ASPARTATE AMINOTRANSFERASE (AST) ACTIVITY IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,AMYLASE ASSAY (VITROS CHEMISTRY PRODUCTS AMYL SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS AMYL SLIDES QUANTITATIVELY MEASURE AMYLASE (AMYL) ACTIVITY IN SERUM, PLASMA, AND URINE USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM,AMMONIA ASSAY(VITROS CHEMISTRY PRODUCTS AMON SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS AMON SLIDES QUANTITATIVELY MEASURE AMMONIA CONCENTRATION IN PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM,ALANINE AMINOTRANSFERASE ASSAY(VITROS CHEMISTRY

		PRODUCTS ALT SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS ALT SLIDES QUANTITATIVELY MEASURE ALANINE AMINOTRANSFERASE (ALT) ACTIVITY IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM,ALKALINE PHOSPHATASE ASSAY(VITROS CHEMISTRY PRODUCTS ALKP SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS ALKP SLIDES QUANTITATIVELY MEASURE ALKALINE PHOSPHATASE (ALKP) ACTIVITY IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,ALCOHOL ASSAY (VITROS CHEMISTRY PRODUCTS ALC SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS ALC SLIDES QUANTITATIVELY MEASURE ETHANOL (ALC) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,ALBUMIN ASSAY(VITROS CHEMISTRY PRODUCTS ALB SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS ALB SLIDES QUANTITATIVELY MEASURE ALBUMIN (ALB) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,ACETAMINOPHEN ASSAY(VITROS CHEMISTRY PRODUCTS ACET SLIDES)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS ACET SLIDES QUANTITATIVELY MEASURE ACETAMINOPHEN (ACET) CONCENTRATION IN SERUM AND PLASMA USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.
1294	IMP/MD/2018/000177	1.License Holder Name: HORIBA INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CRP UNIT 50(CRP UNIT 50)-CRP UNIT 50 IS QUANTITATIVE IN-VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP) ON HORIBA MEDICAL HEMATOLOGY ANALYZER WITH CRP MEASUREMENT.
1295	IMP/MD/2018/000185	1.License Holder Name: GRI-ALLESET INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VERESS NEEDLE (ALLESET)-VERESS NEEDLE IS A SINGLE-USE DEVICE USED IN MINIMALLY INVASIVE ABDOMINAL PROCEDURES FOR THE ESTABLISHMENT OF PNEUMOPERITONENT

1296	IMP/MD/2018/000186	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:20 X WASH BUFFER CONCENTRATE-IN VITRO DIAGNOSTICS USE ONLY. WASH BUFFER IS AN ACCESSORY REAGENT FOR USE WITH ALL ORTHO ENZYME LINKED LMMUNOSORBENT ASSAY (ELISA) TEST SYSTEM ASSAYS. WASH BUFFER IS INTENDED FOR PROFESSIONAL USE ONLY.,ANTI-HUMAN GLOBULIN ANTI -C3B,-C3D (MURINE MONOCLONAL) BIOCLONE®(ANTI-HUMAN GLOBULIN ANTI -C3B,-C3D (MURINE MONOCLONAL) BIOCLONE®)-QUALITATIVE PROCEDURE FOR THE DETECTION OF COMPONENTS OF COMPLEMENT BOUND TO RED BLOOD CELLS,ANTI-HUMAN GLOBULIN ANTI-IGG (RABBIT) (GREEN) (ANTI-HUMAN GLOBULIN ANTI-IGG (RABBIT) (GREEN))-QUALITATIVE PROCEDURE FOR THE DETECTION OF IGG BOUND TO RED BLOOD CELLS,ORTHO® BOVINE SERUM ALBUMIN SOLUTION, 22% PROTEIN CONCENTRATION , PH7.2(ORTHO® BOVINE SERUM ALBUMIN SOLUTION, 22% PROTEIN CONCENTRATION , PH7.2)-FOR QUALITATIVE USE IN ANTIBODY DETECTION, IDENTIFICATION AND TITRATION,REAGENT RED BLOOD CELLS RESOLVE® PANEL B (REAGENT RED BLOOD CELLS RESOLVE® PANEL B)-A QUALITATIVE TEST FOR THE RESOLUTION OF COMPLEX MIXTURES OF BLOOD GROUP ANTIBODIES,REAGENT RED BLOOD CELLS RESOLVE® PANEL A(REAGENT RED BLOOD CELLS RESOLVE® PANEL A)-A QUALITATIVE TEST FOR THE IDENTIFICATION OF UNEXPECTED BLOOD GROUP ANTIBODIES,REAGENT RED BLOOD CELLS ORTHO® POOLED SCREENING CELLS(REAGENT RED BLOOD CELLS ORTHO® POOLED SCREENING CELLS)-A QUALITATIVE TEST FOR THE DETECTION OF UNEXPECTED BLOOD GROUP ANTIBODIES,REAGENT RED BLOOD CELLS SURGISCREEN®(REAGENT RED BLOOD CELLS SURGISCREEN®)-A QUALITATIVE TEST FOR THE DETECTION OF UNEXPECTED BLOOD GROUP ANTIBODIES

1297	IMP/MD/2018/000187	1.License Holder Name: M/S. ORTHO CLINICAL DIAGNOSTICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 32(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 32)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 32 IS USED TO CALIBRATE APPLICABLE VITROS SYSTEMS FOR THE QUANTITATIVE MEASUREMENT OF SODIUM, CHLORIDE, POTASSIUM AND ECO2 ., CALIBRATOR FOR CHEMISTRY ANALYZER(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 99)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 99 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF PROTEINS IN BODY FLUIDS.,MULTIPLE CHEMISTRY CONSTITUENT CONTROL(VITROS CHEMISTRY PRODUCTS AAT/HPT PERFORMANCE VERIFIER III)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS AAT/HPT PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM TO MONITOR PERFORMANCE OF PROTEIN MEASUREMENTS IN BODY FLUIDS.,MULTIPLE CHEMISTRY CONSTITUENT CONTROL(VITROS CHEMISTRY PRODUCTS AAT/HPT PERFORMANCE VERIFIER II)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS AAT/HPT PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM TO MONITOR PERFORMANCE OF PROTEIN MEASUREMENTS IN BODY FLUIDS., SPECIFIC PROTEIN IVD (1-ANTITRYPSIN)(VITROS CHEMISTRY PRODUCTS AAT REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS AAT REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE 1-ANTITRYPSIN CONCENTRATION IN HUMAN SERUM. THE MEASUREMENT OF 1-ANTITRYPSIN (AAT) CONCENTRATION IN SERUM AIDS IN THE DIAGNOSIS OF CIRRHOSIS OF THE LIVER AND PULMONARY EMPHYSEMA.,MULTIPLE CHEMISTRY CONSTITUENT CONTROL(VITROS CHEMISTRY PRODUCTS AAT/HPT PERFORMANCE VERIFIER I)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS AAT/HPT PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM TO MONITOR PERFORMANCE OF PROTEIN MEASUREMENTS IN BODY FLUIDS., SPECIFIC PROTEIN IVD (HAPTOGLOBIN)(VITROS CHEMISTRY PRODUCTS HPT REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS HPT REAGENT IS USED ON THE

	VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE HAPTOGLOBIN (HPT) CONCENTRATION IN HUMAN SERUM AND PLASMA. THE MEASUREMENT OF HAPTOGLOBIN (HPT) IN SERUM AND PLASMA IS USED TO AID IN THE DETECTION OF INTRAVASCULAR RED CELL DESTRUCTION.,DILUENT (VITROS CHEMISTRY PRODUCTS FS DILUENT PACK 4(DAT DILUENT/DAT DILUENT 2))-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS FS DILUENT PACK 4 IS USED TO DILUTE CALIBRATORS AND SAMPLES ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM.,DILUENT(VITROS CHEMISTRY PRODUCTS FS DILUENT PACK 3(SPECIALTY DILUENT/WATER))-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS FS DILUENT PACK 3 IS USED TO DILUTE SAMPLES TO BE ASSAYED ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM.,DILUENT(VITROS CHEMISTRY PRODUCTS FS DILUENT PACK 2 (BSA/SALINE))-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS FS DILUENT PACK 2 IS USED TO DILUTE SAMPLES TO BE ASSAYED ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM., DILUENT(VITROS CHEMISTRY PRODUCTS FS DILUENT PACK 1(APO DILUENT/UED))-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS FS DILUENT PACK 1 IS USED TO DILUTE SAMPLES TO BE ASSAYED ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM.,DILUENT(VITROS CHEMISTRY PRODUCTS FS RECONSTITUTION DILUENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS FS RECONSTITUTION DILUENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM TO RECONSTITUTE VITROS CHEMISTRY PRODUCTS CALIBRATOR KITS 18, 19, 29 AND 31, VITROS CHEMISTRY PRODUCTS ASO/RF PERFORMANCE VERIFIERS, AND VITROS CHEMISTRY PRODUCTS %A1C PERFORMANCE VERIFIERS,PROTEIN (TRANSFERRIN, C3, C4, IGA, IGG, IGM) CONTROL LEVELS III(VITROS CHEMISTRY PRODUCTS PROTEIN PERFORMANCE VERIFIER III)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS PROTEIN PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED TO MONITOR THE PERFORMANCE OF VITROS TRFRN, C3, C4, IGA, IGG AND IGM REAGENTS ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM,PROTEIN (TRANSFERRIN, C3, C4, IGA, IGG, IGM) CONTROL LEVELS II(VITROS CHEMISTRY PRODUCTS PROTEIN PERFORMANCE VERIFIER II)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS PROTEIN PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED TO MONITOR THE PERFORMANCE OF VITROS TRFRN, C3, C4, IGA, IGG AND IGM REAGENTS ON THE VITROS CHEMISTRY SYSTEMS AND

	VITROS INTEGRATED SYSTEM,PROTEIN (TRANSFERRIN, C3, C4, IGA, IGG, IGM) CONTROL LEVELS I(VITROS CHEMISTRY PRODUCTS PROTEIN PERFORMANCE VERIFIER I)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS PROTEIN PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED TO MONITOR THE PERFORMANCE OF VITROS TRFRN, C3, C4, IGA, IGG AND IGM REAGENTS ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM,PREALBUMIN CONTROL, LEVELS II(VITROS CHEMISTRY PRODUCTS PALB PERFORMANCE VERIFIER II)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS VITROS PALB PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED TO MONITOR THE PERFORMANCE OF VITROS PALB REAGENT ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM,PREALBUMIN CONTROL, LEVELS I(VITROS CHEMISTRY PRODUCTS PALB PERFORMANCE VERIFIER I)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS VITROS PALB PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED TO MONITOR THE PERFORMANCE OF VITROS PALB REAGENT ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM, MICROALBUMIN CONTROL LEVELS II(VITROS CHEMISTRY PRODUCTS MALB PERFORMANCE VERIFIER II)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS MALB PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED TO MONITOR THE PERFORMANCE OF VITROS MALB REAGENT ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM., MICROALBUMIN CONTROL LEVELS I(VITROS CHEMISTRY PRODUCTS MALB PERFORMANCE VERIFIER I)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS MALB PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED TO MONITOR THE PERFORMANCE OF VITROS MALB REAGENT ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM.,HIGH SENSITIVITY C-REACTIVE PROTEIN CONTROL LEVELS III(VITROS CHEMISTRY PRODUCTS HSCRP PERFORMANCE VERIFIER III)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS HSCRP PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED TO MONITOR PERFORMANCE OF VITROS HSCRP REAGENT ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM. HIGH SENSITIVITY C-REACTIVE PROTEIN CONTROL LEVELS II(VITROS CHEMISTRY PRODUCTS HSCRP PERFORMANCE VERIFIER II)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS HSCRP PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED TO MONITOR PERFORMANCE OF VITROS HSCRP REAGENT ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM. HIGH SENSITIVITY C-REACTIVE PROTEIN CONTROL LEVELS I(VITROS

	CHEMISTRY PRODUCTS HSCRP PERFORMANCE VERIFIER I)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS HSCRP PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED TO MONITOR PERFORMANCE OF VITROS HSCRP REAGENT ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM. HOMOCYSTEINE CONTROL LEVELS I, II & III(VITROS CHEMISTRY PRODUCTS HCY 2 PERFORMANCE VERIFIERS I, II AND III)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS HCY 2 PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED TO MONITOR PERFORMANCE OF VITROS CHEMISTRY PRODUCTS HCY 2 REAGENT ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM.,DIRECT TOTAL IRON BINDING CAPACITY CONTROL LEVELS II(VITROS CHEMISTRY PRODUCTS DTIBC PERFORMANCE VERIFIER II)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS DTIBC PERFORMANCE VERIFIER IS AN ASSAYED CONTROL USED TO MONITOR PERFORMANCE OF VITROS DTIBC REAGENTS ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM.,DIRECT TOTAL IRON BINDING CAPACITY CONTROL LEVELS I(VITROS CHEMISTRY PRODUCTS DTIBC PERFORMANCE VERIFIER I)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS DTIBC PERFORMANCE VERIFIER IS AN ASSAYED CONTROL USED TO MONITOR PERFORMANCE OF VITROS DTIBC REAGENTS ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM.,DRUGS OF ABUSE CONTROL LEVELS (VITROS CHEMISTRY PRODUCTS DAT PERFORMANCE VERIFIER I, II, III, IV AND V)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS DAT PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED TO MONITOR PERFORMANCE OF URINE DRUGS OF ABUSE SCREENING ASSAYS ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM.,ANTISTREPTOLYSIN O AND RHEUMATOID FACTOR CONTROL LEVELS II(VITROS CHEMISTRY PRODUCTS ASO/RF PERFORMANCE VERIFIER II)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS ASO/RF PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED TO MONITOR PERFORMANCE OF VITROS ASO AND RF REAGENTS ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM, ANTISTREPTOLYSIN O AND RHEUMATOID FACTOR CONTROL LEVELS I(VITROS CHEMISTRY PRODUCTS ASO/RF PERFORMANCE VERIFIER I) -FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS ASO/RF PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED TO MONITOR PERFORMANCE OF VITROS ASO AND RF REAGENTS ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM,APOLIPOPROTEIN B CONTROL LEVEL I(VITROS CHEMISTRY PRODUCTS APOB PERFORMANCE VERIFIER I)-FOR IN

	VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS APOB PERFORMANCE VERIFIER I IS AN ASSAYED CONTROL USED TO MONITOR THE PERFORMANCE OF VITROS APOB REAGENT ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM.,APOLIPOPROTEIN A1 CONTROL LEVEL I(VITROS CHEMISTRY PRODUCTS APOA1 PERFORMANCE VERIFIER I)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS APOA1 PERFORMANCE VERIFIER I IS AN ASSAYED CONTROL USED TO MONITOR THE PERFORMANCE OF VITROS APOA1 REAGENT ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM.,%A1C CONTROL LEVELS II(VITROS CHEMISTRY PRODUCTS % A1C PERFORMANCE VERIFIER II)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS %A1C PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED ON VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO MONITOR PERFORMANCE OF THE VITROS D%A1C AND VITROS HBA1C REAGENT KITS,%A1C CONTROL LEVELS I(VITROS CHEMISTRY PRODUCTS %A1C PERFORMANCE VERIFIER I)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS %A1C PERFORMANCE VERIFIERS ARE ASSAYED CONTROLS USED ON VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO MONITOR PERFORMANCE OF THE VITROS D%A1C AND VITROS HBA1C REAGENT KITS,DIRECT % GLYCATED HEMOGLOBIN CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 31)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CALIBRATOR KIT 31 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE DETERMINATION OF PERCENT GLYCATED HEMOGLOBIN (HBA1C) IN HUMAN WHOLE BLOOD.,CANNABINOIDS CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 30)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 30 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUALITATIVE OR SEMI-QUANTITATIVE MEASUREMENT OF CANNABINOIDS (THC).,TOTAL IRON BINDING CAPACITY CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 29)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 29 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF TOTAL IRON-BINDING CAPACITY (TIBC) USING VITROS CHEMISTRY PRODUCTS DTIBC REAGENT.,ANTISTREPTOLYSIN O CALIBRATOR (VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 28)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 28 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE

	MEASUREMENT OF ANTISTREPTOLYSIN O (ASO).,HOMOCYSTEINE CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 27)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 27 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF HOMOCYSTEINE.,DRUGS OF ABUSE CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 26)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 26 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUALITATIVE OR SEMI-QUANTITATIVE MEASUREMENT OF DRUGS OF ABUSE.,MICROALBUMIN CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 24)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 24 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALBUMIN IN URINE (MALB).,PREALBUMIN CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 23)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 23 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF PREALBUMIN (PALB).,APOLIPOPROTEIN B CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 22)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 22 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF APOLIPOPROTEIN B (APOB)., APOLIPOPROTEIN A1 CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 21)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 21 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF APOLIPOPROTEIN A1 (APOA1).,C3, C4, IGA, IGG, & IGM CALIBRATOR (VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 20)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 20 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF TRANSFERRIN, C3, C4, IGA, IGG AND IGM.,DIRECT LDL CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 19)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 19 IS USED IN CONJUNCTION WITH VITROS FS CALIBRATOR 1 TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF LDL CHOLESTEROL USING VITROS DLDL

	REAGENTS.,C-REACTIVE PROTEIN CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 17)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 17 IS USED IN CONJUNCTION WITH VITROS CHEMISTRY PRODUCTS FS CALIBRATOR 1 TO CALIBRATE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF C-REACTIVE PROTEIN (CRP) USING VITROS HSCRP REAGENT., RHEUMATOID FACTOR CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 16)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 16 IS USED IN CONJUNCTION WITH VITROS CHEMISTRY PRODUCTS FS CALIBRATOR 1 TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF RHEUMATOID FACTOR (RF).,TOBRAMYCIN CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 14)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 14 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF TOBRAMYCIN (TOBRA).,GENTAMYCIN CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 13)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 13 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF GENTAMICIN (GENT).,VALPROIC ACID CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 12)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 12 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF VALPROIC ACID (VALP)., VANCOMYCIN CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 11)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 11 IS USED TO CALIBRATE THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF VANCOMYCIN (VANC).,FS CALIBRATOR LEVEL 1(VITROS CHEMISTRY PRODUCTS FS CALIBRATOR 1)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS FS CALIBRATOR 1 IS USED IN CONJUNCTION WITH VITROS CHEMISTRY PRODUCTS CALIBRATOR KITS TO CALIBRATE THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM.,DIRECT % GLYCATED HEMOGLOBIN REAGENT (VITROS CHEMISTRY PRODUCTS HBA1C REAGENT KIT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS HBA1C REAGENT IS USED ON VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE DETERMINATION OF

	PERCENT GLYCATED HEMOGLOBIN A1C (DCCT/NGSP) AND MMOL/MOL HEMOGLOBIN A1C (IFCC) IN HUMAN WHOLE BLOOD. THE TEST IS TO BE USED AS AN AID IN DIAGNOSIS OF DIABETES, AS AN AID IN IDENTIFYING PATIENTS WHO MAY BE AT RISK FOR DEVELOPING DIABETES MELLITUS, AND FOR THE MONITORING OF LONG-TERM BLOOD GLUCOSE CONTROL IN INDIVIDUALS WITH DIABETES MELLITUS.,CAFFEINE REAGENT(VITROS CHEMISTRY PRODUCTS CAFFN REAGENT KIT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CAFFN REAGENT KIT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE CAFFEINE (CAFFN) CONCENTRATION IN HUMAN SERUM AND PLASMA OF SUBJECTS UNDERGOING THERAPY WITH CAFFEINE, ESPECIALLY FOR CASES OF NEONATAL APNEA.,VANCOMYCIN REAGENT(VITROS CHEMISTRY PRODUCTS VANC REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS VANC REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE VANCOMYCIN (VANC) CONCENTRATION IN HUMAN SERUM AND PLASMA,VALPROIC ACID REAGENT(VITROS CHEMISTRY PRODUCTS VALP REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS VALP REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE VALPROIC ACID (VALP) CONCENTRATION IN HUMAN SERUM AND PLASMA.,TRANSFERRIN REAGENT(VITROS CHEMISTRY PRODUCTS TRFRN REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS TRFRN REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE TRANSFERRIN (TRFRN) CONCENTRATION IN HUMAN SERUM AND PLASMA.,TOBRAMYCIN REAGENT(VITROS CHEMISTRY PRODUCTS TOBRA REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS TOBRA REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE TOBRAMYCIN (TOBRA) CONCENTRATION IN HUMAN SERUM AND PLASMA.,CANNABINOIDS REAGENT(VITROS CHEMISTRY PRODUCTS THC REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS THC REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE SEMI-QUANTITATIVE OR QUALITATIVE DETERMINATION OF CANNABINOIDS (THC) IN HUMAN URINE USING A CUTOFF OF EITHER 20 NG/ML OR 50 NG/ML. MEASUREMENTS OBTAINED WITH THE VITROS THC METHOD ARE USED IN THE DIAGNOSIS AND TREATMENT OF CANNABINOID USE OR OVERDOSE.,RHEUMATOID FACTOR REAGENT(VITROS CHEMISTRY

	PRODUCTS RF REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS RF REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE RHEUMATOID FACTOR (RF) CONCENTRATION IN HUMAN SERUM AND PLASMA.,PHENCYCLIDINE REAGENT(VITROS CHEMISTRY PRODUCTS PCP REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS PCP REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE SEMI-QUANTITATIVE OR QUALITATIVE DETERMINATION OF PHENCYCLIDINE (PCP) IN HUMAN URINE USING A CUTOFF OF 25 NG/ML. MEASUREMENTS OBTAINED WITH THE VITROS PCP METHOD ARE USED IN THE DIAGNOSIS AND TREATMENT OF PHENCYCLIDINE USE OR OVERDOSE.,PREALBUMIN REAGENT(VITROS CHEMISTRY PRODUCTS PALB REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS PALB REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE PREALBUMIN (PALB) CONCENTRATION IN HUMAN SERUM AND PLASMA.,OPIATES REAGENT(VITROS CHEMISTRY PRODUCTS OP REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS OP REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE SEMI-QUANTITATIVE OR QUALITATIVE DETERMINATION OF OPIATES (OP) IN HUMAN URINE USING A CUTOFF OF EITHER 300 NG/ML OR 2000 NG/ML. MEASUREMENTS OBTAINED WITH THE VITROS OP ASSAY ARE USED IN THE DIAGNOSIS AND TREATMENT OF OPIATE USE OR OVERDOSE.,METHADONE REAGENT(VITROS CHEMISTRY PRODUCTS METD REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS METD REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE SEMI-QUANTITATIVE OR QUALITATIVE DETERMINATION OF METHADONE (METD) IN HUMAN URINE USING A CUTOFF OF EITHER 150 NG/ML OR 300 NG/ML. MEASUREMENTS OBTAINED WITH THE VITROS METD METHOD ARE USED IN THE DIAGNOSIS AND TREATMENT OF METHADONE USE OR OVERDOSE.,MICROALBUMIN REAGENT(VITROS CHEMISTRY PRODUCTS MALB REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS MALB REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE ALBUMIN CONCENTRATION IN HUMAN URINE (MALB). MEASUREMENT OF URINARY ALBUMIN AIDS IN THE DIAGNOSIS OF DIABETIC NEPHROPATHY, HYPERTENSION AND CARDIOVASCULAR DISEASE., IMMUNOGLOBULIN M REAGENT(VITROS CHEMISTRY PRODUCTS IGM REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY

	PRODUCTS IGM REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE IMMUNOGLOBULIN M (IGM) CONCENTRATION IN HUMAN SERUM AND PLASMA.,IMMUNOGLOBULIN G REAGENT(VITROS CHEMISTRY PRODUCTS IGG REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS IGG REAGENT IS USED ON THE CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE IMMUNOGLOBULIN G (IGG) CONCENTRATION IN HUMAN SERUM AND PLASMA., IMMUNOGLOBULIN A REAGENT(VITROS CHEMISTRY PRODUCTS IGA REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS IGA REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE IMMUNOGLOBULIN A (IGA) CONCENTRATION IN HUMAN SERUM AND PLASMA.,HIGH SENSITIVITY C-REACTIVE PROTEIN REAGENT(VITROS CHEMISTRY PRODUCTS HSCRP REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS HSCRP REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM AND PLASMA. CRP IS USED TO EVALUATE CONDITIONS THOUGHT TO BE ASSOCIATED WITH INFLAMMATION IN OTHERWISE HEALTHY INDIVIDUALS., HOMOCYSTEINE REAGENT(VITROS CHEMISTRY PRODUCTS HCY 2 REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY VITROS CHEMISTRY PRODUCTS HCY 2 REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE TOTAL HOMOCYSTEINE CONCENTRATION IN HUMAN SERUM AND PLASMA. SERUM AND PLASMA HOMOCYSTEINE LEVELS CAN ASSIST IN THE DIAGNOSIS AND TREATMENT OF PATIENTS SUSPECTED OF HAVING HYPERHOMOCYSTEINEMIA AND HOMOCYSTINURIA.,GENTAMYCIN REAGENT(VITROS CHEMISTRY PRODUCTS GENT REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY VITROS CHEMISTRY PRODUCTS GENT REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE GENTAMICIN (GENT) CONCENTRATION IN HUMAN SERUM AND PLASMA.,DIRECT TOTAL IRON BINDING CAPACITY REAGENT(VITROS CHEMISTRY PRODUCTS DTIBC REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY VITROS CHEMISTRY PRODUCTS DTIBC REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE TOTAL IRON-BINDING CAPACITY (TIBC) IN HUMAN SERUM. THE IRON-BINDING CAPACITY IS USEFUL IN THE DIFFERENTIAL DIAGNOSIS OF ANEMIA, IRON DEFICIENCY ANEMIA, THALASSEMIA, SIDEROBLASTIC ANEMIA, AND IRON POISONING.,

	DIRECT LDL REAGENT(VITROS CHEMISTRY PRODUCTS DLDL REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY VITROS CHEMISTRY PRODUCTS DLDL REAGENT IS USED ON VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE LDL CHOLESTEROL (LDLC) CONCENTRATION IN SERUM AND PLASMA. LOW DENSITY LIPOPROTEIN (LDL) CHOLESTEROL IS USED TO EVALUATE THE RISK OF DEVELOPING CORONARY HEART DISEASE (CHD). THE RISK OF CHD INCREASES WITH HIGHER LDL CHOLESTEROL CONCENTRATIONS.,COMPLEMENT C4(VITROS CHEMISTRY PRODUCTS C4 REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY VITROS CHEMISTRY PRODUCTS C4 REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE COMPLEMENT C4 (C4) CONCENTRATION IN HUMAN SERUM AND PLASMA. MEASUREMENTS OF THESE PROTEINS AIDS IN THE DIAGNOSIS OF IMMUNOLOGIC DISORDERS, ESPECIALLY THOSE ASSOCIATED WITH DEFICIENCIES OF COMPLEMENT COMPONENTS.,COMPLEMENT C3(VITROS CHEMISTRY PRODUCTS C3 REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS C3 REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE COMPLEMENT C3 (C3) CONCENTRATION IN HUMAN SERUM AND PLASMA. MEASUREMENTS OF THESE PROTEINS AIDS IN THE DIAGNOSIS OF IMMUNOLOGIC DISORDERS, ESPECIALLY THOSE ASSOCIATED WITH DEFICIENCIES OF COMPLEMENT COMPONENTS.,COCAINE METABOLITE REAGENT (VITROS CHEMISTRY PRODUCTS COCM REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS COCM REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE SEMI-QUANTITATIVE OR QUALITATIVE DETERMINATION OF BENZOYLECGONINE (COCAINE METABOLITE) IN HUMAN URINE USING A CUTOFF OF EITHER 150 NG/ML OR 300 NG/ML. MEASUREMENTS OBTAINED WITH THE VITROS COCM METHOD ARE USED IN THE DIAGNOSIS AND TREATMENT OF COCAINE USE OR OVERDOSE.,BENZODIAZEPINS REAGENT(VITROS CHEMISTRY PRODUCTS BENZ REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS BENZ REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE SEMI-QUANTITATIVE OR QUALITATIVE DETERMINATION OF BENZODIAZEPINES (BENZ) IN HUMAN URINE USING A CUTOFF OF EITHER 200 NG/ML OR 300 NG/ML. MEASUREMENTS OBTAINED WITH THE VITROS BENZ METHOD ARE USED IN THE DIAGNOSIS AND TREATMENT OF BENZODIAZEPINES USE OR OVERDOSE.,BARBITURATES REAGENT(VITROS CHEMISTRY PRODUCTS BARB REAGENT)-VITROS CHEMISTRY PRODUCTS BARB

	REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM FOR THE SEMI-QUANTITATIVE OR QUALITATIVE DETERMINATION OF BARBITURATES (BARB) IN HUMAN URINE USING A CUTOFF OF EITHER 200 NG/ML OR 300 NG/ML. MEASUREMENTS OBTAINED WITH THE VITROS BARB ASSAY ARE USED IN THE DIAGNOSIS AND TREATMENT OF BARBITURATES USE OR OVERDOSE.,ANTISTREPTOLYSIN O REAGENT(VITROS CHEMISTRY PRODUCTS ASO REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS ASO REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE DETERMINATION OF ANTIBODIES TO STREPTOLYSIN O IN HUMAN SERUM AND PLASMA. DETERMINATION OF ANTIBODIES TO STREPTOLYSIN O CAN AID IN THE DIAGNOSIS OF INDIVIDUALS INFECTED WITH GROUP A STREPTOCOCCUS BACTERIA., APOLIPOPROTEIN B REAGENT(VITROS CHEMISTRY PRODUCTS APOB REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS APOB REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM TO QUANTITATIVELY MEASURE APOLIPOPROTEIN B (APOB) CONCENTRATION IN HUMAN SERUM AND PLASMA.,APOLIPOPROTEIN A1 REAGENT(VITROS CHEMISTRY PRODUCTS APOA1 REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS APOA1 REAGENT IS USED TO QUANTITATIVELY MEASURE APOLIPOPROTEIN A1 (APOA1) CONCENTRATION IN HUMAN SERUM AND PLASMA ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM., AMPHETAMINE REAGENT(VITROS CHEMISTRY PRODUCTS AMPH REAGENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS AMPH REAGENT IS USED ON THE VITROS CHEMISTRY SYSTEM AND VITROS INTEGRATED SYSTEM FOR THE SEMI-QUANTITATIVE OR QUALITATIVE DETERMINATION OF AMPHETAMINES (AMPH) IN HUMAN URINE USING A CUTOFF OF EITHER 500 NG/ML OR 1000 NG/ML. MEASUREMENTS OBTAINED WITH THE VITROS AMPH METHOD ARE USED IN THE DIAGNOSIS AND TREATMENT OF AMPHETAMINES USE OR OVERDOSE.,VITROS CHEMISTRY PRODUCTS ELECTROLYTE REFERENCE FLUID (ERF) 300 (VITROS CHEMISTRY PRODUCTS ELECTROLYTE REFERENCE FLUID (ERF) 300)-FOR IN-VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCT ELECTROLYTE REFERENCE FLUID (ERF) 300 IS USED ON THE VITROS CHEMISTRY SYSTEM IN THE POTENTIOMETRIC MEASUREMENT OF SODIUM (NA+), POTASSIUM (K+), AND CHLORIDE (CL-).,VITROS CHEMISTRY PRODUCTS ELECTROLYTE REFERENCE FLUID (ERF) 800(VITROS CHEMISTRY PRODUCTS ELECTROLYTE REFERENCE FLUID (ERF) 800)-FOR IN-VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCT ELECTROLYTE REFERENCE FLUID

	(ERF) 800 IS USED ON THE VITROS CHEMISTRY SYSTEM AND THE VITROS INTEGRATED SYSTEM IN THE POTENTIOMETRIC MEASUREMENT OF SODIUM (NA+), POTASSIUM (K+), AND CHLORIDE (CL-).,WASH FLUID(VITROS CHEMISTRY PRODUCTS IMMUNO-WASH FLUID)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS IMMUNO-WASH FLUID IS USED AS A WASH FLUID FOR IMMUNO-RATE ASSAYS ON VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,REFERENCE FLUID(VITROS CHEMISTRY PRODUCTS 950/FS REFERENCE FLUID)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS 950/FS REFERENCE FLUID IS USED ON THE VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM IN THE POTENTIOMETRIC MEASUREMENT OF SODIUM (NA+), POTASSIUM (K+), AND CHLORIDE (CL-).,REFERENCE FLUID(VITROS CHEMISTRY PRODUCTS 250/350 REFERENCE FLUID)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS 250/350 REFERENCE FLUID IS USED IN THE POTENTIOMETRIC MEASUREMENT OF SODIUM (NA+), POTASSIUM (K+), AND CHLORIDE (CL-) ON VITROS CHEMISTRY SYSTEMS,DILUENT(VITROS CHEMISTRY PRODUCTS URINE ELECTROLYTE DILUENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS URINE ELECTROLYTE DILUENT IS USED TO DILUTE URINE SPECIMENS FOR ANALYSIS OF SODIUM (NA+) AND POTASSIUM (K+) ON VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,DILUENT(VITROS CHEMISTRY PRODUCTS SPECIALTY DILUENT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS SPECIALTY DILUENT IS USED TO DILUTE SAMPLES WHEN ASSAY VALUES EXCEED THE MEASURING (REPORTABLE OR DYNAMIC) RANGE USING VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,7% BOVINE SERUM ALBUMIN(VITROS CHEMISTRY PRODUCTS 7% BSA)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS 7% BSA IS USED TO DILUTE SAMPLES WHEN ASSAY VALUES EXCEED THE REPORTABLE (DYNAMIC) RANGE USING THE VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM.,7% BOVINE SERUM ALBUMIN(ORTHO 7% BSA)-ORTHO 7% BSA IS A GENERAL PURPOSE REAGENT.,TOTAL IRON-BINDING CAPACITY ASSAY(VITROS CHEMISTRY PRODUCTS TIBC KIT)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS TIBC KIT WITH VITROS CHEMISTRY PRODUCTS FE SLIDES QUANTITATIVELY MEASURE TOTAL IRON-BINDING CAPACITY (TIBC) IN SERUM.,THERAPEUTIC DRUG MONITORING CONTROL LEVEL (VITROS CHEMISTRY PRODUCTS TDM PERFORMANCE VERIFIER I, II AND III)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS TDM PERFORMANCE VERIFIERS IS AN ASSAYED CONTROLS USED TO MONITOR PERFORMANCE ON VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM.,URINE

	PROTEIN CONTROL LEVEL I(VITROS CHEMISTRY PRODUCTS UPRO PERFORMANCE VERIFIER I)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS UPRO PERFORMANCE VERIFIERS IS AN ASSAYED CONTROLS USED TO MONITOR PERFORMANCE ON VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM.,URINE PROTEIN CONTROL LEVEL II(VITROS CHEMISTRY PRODUCTS UPRO PERFORMANCE VERIFIER II)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS UPRO PERFORMANCE VERIFIERS IS AN ASSAYED CONTROLS USED TO MONITOR PERFORMANCE ON VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM.,C-REACTIVE PROTEIN CONTROL LEVEL II (VITROS CHEMISTRY PRODUCTS CRP PERFORMANCE VERIFIER II)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CRP PERFORMANCE VERIFIERS IS AN ASSAYED CONTROLS USED TO MONITOR PERFORMANCE ON VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM.,C-REACTIVE PROTEIN CONTROL LEVEL I(VITROS CHEMISTRY PRODUCTS CRP PERFORMANCE VERIFIER I)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CRP PERFORMANCE VERIFIERS IS AN ASSAYED CONTROLS USED TO MONITOR PERFORMANCE ON VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM.,ISOENZYME CONTROL LEVEL II (VITROS CHEMISTRY PRODUCTS ISOENZYME PERFORMANCE VERIFIER II)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS ISOENZYME PERFORMANCE VERIFIER IS AN ASSAYED CONTROL USED TO MONITOR PERFORMANCE ON VITROS CHEMISTRY SYSTEMS AND VITROS 5600 INTEGRATED SYSTEM., ISOENZYME CONTROL LEVEL I(VITROS CHEMISTRY PRODUCTS ISOENZYME PERFORMANCE VERIFIER I)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS ISOENZYME PERFORMANCE VERIFIER IS AN ASSAYED CONTROL USED TO MONITOR PERFORMANCE ON VITROS CHEMISTRY SYSTEMS AND VITROS 5600 INTEGRATED SYSTEM.,CLINICAL CHEMISTRY CONTROL LEVEL II(VITROS CHEMISTRY PRODUCTS PERFORMANCE VERIFIER II)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS PERFORMANCE VERIFIERS IS AN ASSAYED CONTROLS USED TO MONITOR PERFORMANCE ON VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM.,CLINICAL CHEMISTRY CONTROL LEVEL I(VITROS CHEMISTRY PRODUCTS PERFORMANCE VERIFIER I)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS PERFORMANCE VERIFIERS IS AN ASSAYED CONTROLS USED TO MONITOR PERFORMANCE ON VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM.,CLINICAL CHEMISTRY CONTROL LEVEL II(VITROS CHEMISTRY PRODUCTS LIQUID PERFORMANCE

	VERIFIER II)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS LIQUID PERFORMANCE VERIFIER IS AN ASSAYED CONTROL USED TO MONITOR PERFORMANCE ON VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM.,CLINICAL CHEMISTRY CONTROL LEVEL I(VITROS CHEMISTRY PRODUCTS LIQUID PERFORMANCE VERIFIER I)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS LIQUID PERFORMANCE VERIFIER IS AN ASSAYED CONTROL USED TO MONITOR PERFORMANCE ON VITROS CHEMISTRY SYSTEMS AND VITROS INTEGRATED SYSTEM.,CLINICAL CHEMISTRY CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 25)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 25 IS USED TO CALIBRATE VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF HDL CHOLESTEROL USING VITROS CHEMISTRY PRODUCTS DHDL SLIDES.,CLINICAL CHEMISTRY CALIBRATOR (VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 10)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 10 IS USED TO CALIBRATE VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF UPRO.,CLINICAL CHEMISTRY CALIBRATOR (VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 9)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 9 IS USED TO CALIBRATE VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ACET, CRBM, DGXN, PHBR, AND PHYT.,CLINICAL CHEMISTRY CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 8)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 8 IS USED TO CALIBRATE VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALC.,CLINICAL CHEMISTRY CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 7)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 7 IS USED TO CALIBRATE VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF CRP.,CLINICAL CHEMISTRY CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 6)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 6 IS USED TO CALIBRATE VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF CHE AND CKMB., CLINICAL CHEMISTRY CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 5)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 5 IS USED TO CALIBRATE

	VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF AMON AND PROT, CLINICAL CHEMISTRY CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 4)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 4 IS USED TO CALIBRATE VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALB, BUBC, FE, TBIL, TIBC, AND TP.,CLINICAL CHEMISTRY CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 3)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 3 IS USED TO CALIBRATE VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF ALT, ALKP, AMYL, AST, CK, GGT, LDH AND LIPA., CLINICAL CHEMISTRY CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 2)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 2 IS USED TO CALIBRATE VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF CHOL, CL-, ECO2, K+, NA+, AND TRIG.,CLINICAL CHEMISTRY CALIBRATOR(VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 1)-FOR IN VITRO DIAGNOSTIC USE ONLY. VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 1 IS USED TO CALIBRATE VITROS CHEMISTRY SYSTEMS AND THE VITROS INTEGRATED SYSTEM FOR THE QUANTITATIVE MEASUREMENT OF BUN/UREA, CA, CREA, GLU, LAC, LI, MG, PHOS, SALI, THEO, AND URIC.

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1298	IMP/MD/2018/000188	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL MESH (DEXTILE™ ANATOMICAL MESH)-DEXTILE™ ANATOMICAL MESH IS INTENDED TO BE USED FOR THE REINFORCEMENT OF SOFT TISSUES WHERE WEAKNESS EXISTS DURING REPAIR OF INGUINAL HERNIAS BY LAPAROSCOPIC APPROACH.,MESH(PARIETENE DS COMPOSITE MESH)-PARIETENE DS COMPOSITE MESH IS INTENDED FOR THE REINFORCEMENT OF ABDOMINAL WALL SOFT TISSUE WHERE A WEAKNESS EXISTS AND IS INDICATED FOR THE REPAIR OF VENTRAL HERNIAS,POLYESTER MESH(PROGRIPTM SELF-GRIPPING POLYESTER MESH)-INGUINAL AND INCISIONAL HERNIAS REPAIR, POLYPROPYLENE MESH(PROGRIPTM SELF-GRIPPING POLYPROPYLENE MESH)-INGUINAL HERNIA REPAIR VIA ANTERIOR TENSION-FREE APPROACH.,POLYPROPYLENE MESH(PARIETENE COMPOSITE MESH)-PARIETENETM COMPOSITE MESH IS USED FOR THE REINFORCEMENT OF TISSUES DURING SURGICAL REPAIR. IT IS INDICATED FOR THE TREATMENT OF INCISIONAL HERNIAS, ABDOMINAL WALL REPAIR AND PARIETAL (I.E. PERTAINING TO THE WALLS) REINFORCEMENT OF TISSUES. THE NON- ABSORBABLE THREE-DIMENSIONAL POLYPROPYLENE MESH PROVIDES LONG TERM REINFORCEMENT OF SOFT TISSUES. ON THE OPPOSITE SIDE, THE ABSORBABLE HYDROPHILIC FILM MINIMIZES TISSUE ATTACHMENT TO THE MESH IN CASE OF DIRECT CONTACT WITH THE VISCERA.,MESH(PROGRIPTM LAPAROSCOPIC SELF -FIXATING MESH)-PROGRIPTM LAPAROSCOPIC SELF-FIXATING MESH IS INDICATED FOR THE REINFORCEMENT OF SOFT TISSUES DURING REPAIR OF INGUINAL HERNIA DEFECTS BY LAPAROSCOPIC APPROACH.,MESH (PARIETEX OPTIMISED COMPOSITE MESH)-THE PARIETEX OPTIMIZED COMPOSITE MESH IS USED FOR THE REINFORCEMENT OF TISSUES DURING SURGICAL REPAIR. IT IS INDICATED FOR THE TREATMENT OF INCISIONAL HERNIAS, ABDOMINAL WALL REPAIR, AND PARIETAL (I.E. PERTAINING TO THE WALLS) REINFORCEMENT OF TISSUES. THE NON-ABSORBABLE THREE-DIMENSIONAL POLYESTER MESH PROVIDES LONG TERM REINFORCEMENT OF SOFT TISSUES. ON THE OPPOSITE SIDE, THE ABSORBABLE HYDROPHILIC FILM MINIMIZES TISSUE ATTACHMENT TO THE MESH IN CASE OF DIRECT CONTACT WITH THE VISCERA.,HERNIA MESH KIT(PARIETEX PLUG AND PATCH SYSTEM)-PARIETEX PLUG AND PATCH SYSTEM IS INDICATED FOR THE REINFORCEMENT OF SOFT TISSUES DURING REPAIR OF GROIN HERNIA DEFECTS BY OPEN APPROACH,MESH(PARIETEX LIGHTWEIGHT MESH)-PARIETEX LIGHTWEIGHT MESH IS INDICATED FOR INGUINAL AND VENTRAL HERNIA REPAIR .,MESH(PARIETEX COMPOSITE VENTRAL PATCH)-THE PARIETEX COMPOSITE CENTRAL

	PATCH IS USED FOR THE REINFORCEMENT OF SOFT TISSUES DURING SURGICAL REPAIR. IT IS INDICATED FOR THE TREATMENT OF VENTRAL DEFECTS (PRIMARY AND INCISIONAL HERNIAS). THE THREE-DIMENSIONAL NON-ABSORBABLE MONOFILAMENT POLYESTER MESH PROVIDES LONG TERM REINFORCEMENT OF SOFT TISSUES. THE ABSORBABLE HYDROPHILIC FILM MINIMIZES TISSUE ATTACHMENT TO THE MESH IN CASE OF DIRECT CONTACT WITH THE VISCERA.,MESH(PARIETEX COMPOSITE MESH)-PARIETEX COMPOSITE MESH IS USED FOR THE REINFORCEMENT OF TISSUES DURING SURGICAL REPAIR.IT IS INDICATED FOR THE TREATMENT OF INCISIONAL HERNIAS,ABDOMINAL WALL REPAIR AND PARIETAL (I.E. PERTAINING TO THE WALLS) REINFORCEMENT OF TISSUES. THE NON-ABSORBABLE THREE-DIMENSIONAL POLY ESTER MESH PROVIDES LONG TERM REINFORCEMENT OF SOFT TISSUES. ON THE OPPOSITE SIDE, THE ABSORBABLE HYDROPHILIC FILM MINIMIZES TISSUE ATTACHMENT TO THE MESH IN CASE OF DIRECT CONTACT WITH THE VISCERA.,MESH(PARIETEX HYDROPHILLIC ANATOMICAL MESH, PARIETEX HYDROPHILLIC TWO DIMENSIONAL MESH,PARIETEX HYDROPHILLIC THREE DIMENSIONAL MESH)-PARIETEX HYDROPHILIC 2-DIMENSIONAL MESH, HYDROPHILLIC 3-DIMENSIONAL MESH AND HYDROPHILIC ANATOMICAL MESH HAS BEEN ADAPTED FOR VARIOUS TECHNIQUE OF ABDOMINAL REPAIR. THE RECTANGULAR MESH IS DESIGNED FOR THE REPAIR OF INGUINAL AND INCISIONAL HERNIAS IN A PRE-PERITONEAL OR PRE-MUSCULAR APPROACH. THE PRE-CUT AND CLIT MESH (WITH OR WITHOUT A SELF GRIPPING FLAP) IS SUITABLE FOR THE REPAIR OF INGUINAL HERNIAS VIA ANTERIOR APPROACH USING THE TENSION FREE TECHNIQUE THE MESH WITH A SELF-GRIPPING ,FOLDING FLAP IS AVAILABLE FOR THE LEFT AND/OR RIGHT SIDE. THE FOLDING MESH (IN TWO - DIMENSIONAL TEXTILE) IS DESIGNED FOR THE REPAIR OF DIRECT OR INDIRECT INGUINAL HERNIAS THROUGH A LAPAROSCOPIC APPROACH (TRANS-ABDOMINAL OR PRE-PERITONEAL OR TOTALLY EXTRA¬ PERITONEAL). SOME CODES HAVE A SLIT FOR THE PASSAGE OF THE CORD. THE ANATOMICAL MESH IS MAINLY DESIGNED FOR THE REPAIR OF INGUINAL HERNIAS VIA LAPAROSCOPIC OR POSTERIOR OPEN PROCEDURES AND IS AVAILABLE FOR THE LEFT AND/OR RIGHT SIDE. PARIETEX HYDROPHILLIC -2-DIMENSIONAL MESH: TREATMENT OF INGUINAL HERNIAS,THROUGH SURGICAL PROCEDURE,ACCORDING TO THE "PLUG AND MESH"TECHNIQUE., MESH(PARIETENE FLAT SHEET MESH,PARIETENE LIGHTWEIGHT MESH)-PARIETENE FLAT MESH AND LIGHT WEIGHT MESH IS A POLYPROPYLENE MESH INTENDED FOR THE REINFORCEMENT OF TISSUE DURING SURGICAL REPAIR.IT IS INDICATED FOR INGUINAL HERNIAS,PARIETAL REINFORCEMENT OF TISSUES AND ABDOMINAL

		WALL HERNIA REPAIR.,MESH(PARIETENETM MACROPOROUS MESH)-PARIETENE MACROPOROUS MESH IS INTENDED FOR THE REPAIR OF HERNIAS OR OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING MATERIAL.,POLYESTER MESH WITH PORCINE COLLAGEN AND GLYCEROL HYDROPHILIC FILM(SYMBOTEX TM COMPOSITE MESH)-SYMBOTEX COMPOSITE MESH IS INTENDED FOR THE REINFORCEMENT OF SOFT TISSUE WHERE A WEAKNESS EXISTS IN PROCEDURES INVOLVING PRIMARY ABDOMINAL WALL AND INCISIONAL HERNIA SURGERIES. THE NON-ABSORBABLE THREE DIMENSIONAL POLYESTER MESH PROVIDES LONG TERM REINFORCEMENT OF SOFT TISSUES.ON THE OPPOSITE SIDE,THE ABSORBABLE HYDROPHILIC FILM MINIMIZES TISSUE ATTACHMENT TO THE MESH IN CASE OF DIRECT CONTACT WITH THE VISCERA ., PERMACOL SURGICAL IMPLANT(PERMACOL)-PERMACOL™ SURGICAL IMPLANT IS INTENDED FOR PERMANENT IMPLANTATION IN HUMANS AND IS INDICATED FOR THE RECONSTRUCTION, RECONTOURING AND REFORMATION OF HUMAN SOFT CONNECTIVE TISSUE, PARTICULARLY WHERE LOSS OF DERMIS HAS OCCURRED, AND AS A SUPPORTING TISSUE IN SURGICAL PROCEDURES SUCH AS ABDOMINAL WALL HERNIAS AND DEFECTS.
1299	IMP/MD/2018/000189	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRANSSEPTAL NEEDLES (BRK TRANSSEPTAL NEEDLES)-THE BRK™ TRANSSEPTAL NEEDLE IS USED TO PUNCTURE THE INTERATRIAL SEPTUM DURING A TRANSSEPTAL CATHETERIZATION. PROCEDURE TO GAIN LEFT HEART ACCESS.,STEERABLE INTRODUCER(AGILIS NXT)-THE AGILIS NXT STEERABLE INTRODUCER IS INDICATED WHEN INTRODUCING VARIOUS CARDIOVASCULAR CATHETERS INTO THE HEART, INCLUDING THE LEFT SIDE OF THE HEART THROUGH THE INTERATRIAL SEPTUM,TRANSSEPTAL NEEDLES(BRK-1 TRANSSEPTAL NEEDLES)-THE BRK™ TRANSSEPTAL NEEDLE IS USED TO PUNCTURE THE INTERATRIAL SEPTUM DURING A TRANSSEPTAL CATHETERIZATION. PROCEDURE TO GAIN LEFT HEART ACCESS., CATHETER(RESPONSE ELECTROPHYSIOLOGY CATHETER)-RESPONSE ELECTROPHYSIOLOGY CATHETERS CAN BE USED IN THE EVALUATION OF A VARIETY OF CARDIAC ARRHYTHMIAS FROM ENDOCARDIAL AND INTRAVASCULAR SITES.,CATHETER(SUPREME ELECTROPHYSIOLOGY CATHETER)-SUPREME ELECTROPHYSIOLOGY CATHETERS CAN BE USED IN THE EVALUATION OF A VARIETY OF CARDIAC ARRHYTHMIAS FROM ENDOCARDIAL AND INTRAVASCULAR SITES.

1300	IMP/MD/2018/000190	1.License Holder Name: SMITHS MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INNER CANNULA(BIVONA) -A PACK OF SINGLE PATIENT USE INNER CANNULA ONLY FOR USE WITH BIVONA ADULT TRACHEOSTOMY TUBES. THE INNER CANNULA HAS BEEN DETERMINED TO MR-SAFE HOWEVER USERS SHOULD REFER TO THE RELEVANT BIVONA ADULT TRACHEOSTOMY TUBE, TRACHEOSTOMY TUBES(BIVONA)-THE BIVONA TRACHEOSTOMY TUBE IS INTENDED TO PROVIDE DIRECT AIRWAY ACCESS FOR A TRACHEOTOMIZED PATIENT FOR UPTO 29 DAYS. IT MAY BE REPROCESSED FOR SINGLE-PATIENT USE UPTO 5 TIMES

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1301	IMP/MD/2018/000191	1.License Holder Name: COOK INDIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BILIARY DILATION BALLOON(FUSION TITAN BILIARY DILATION BALLOON)-THE FUSION™ BILIARY DILATION BALLOON IS INTENDED TO DILATE STRICTURES OF THE BILIARY TREE.,PERCUTANEOUS ABSCESS DRAINAGE CATHETERS AND SETS(THAL-QUICK ABSCESS DRAINAGE SET AND THAL-QUICK ABSCESS DRAINAGE CATHETER)-INTENDED FOR ABSCESS DRAINAGE.,DIAGNOSTIC VISCERAL CATHETER (TORCON NB® ADVANTAGE CATHETER & ROYAL FLUSH® PLUS HIGH FLOW CATHETER)-INTENDED FOR USE IN ANGIOGRAPHIC PROCEDURES BY PHYSICIANS TRAINED AND EXPERIENCED IN ANGIOGRAPHIC PROCEDURES,VASCULAR BALLOON CATHETERS (ADVANCE 14 LP LOW PROFILE PTA BALLOON DILATATION CATHETER)-THE ADVANCE 14 LP LOW PROFILE PTA BALLOON DILATATION CATHETER IS INTENDED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) OF LESIONS IN PERIPHERAL ARTERIES INCLUDING ILIAC, RENAL, POPLITEAL, INFRAPOPLITEAL, FEMORAL AND ILIOFEMORAL AS WELL AS OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE, INTRODUCER SETS(MICROPUNCTURE® INTRODUCER SET SILHOUETTE TRANSITIONLESS PUSH-PLUS DESIGN – STIFFENED CANNULA WITH NITINOL WIRE GUIDE)-THE MICROPUNCTURE INTRODUCER SET IS INTENDED FOR THE PLACEMENT OF WIRE GUIDES UPTO 0.038 INCH DIAMETER INTO THE PERIPHERAL VASCULAR SYSTEM WHEN A SMALL 21 GAGE NEEDLE STICK IS DESIRED.,VASCULAR EMBOLIZATION DEVICES(MREYE EMBOLIZATION COIL)-MREYE® EMBOLIZATION COILS ARE INTENDED FOR USE IN PERIPHERAL ARTERIAL AND VENOUS VESSEL EMBOLIZATION PROCEDURES.,SELECTIVE INFUSION SETS(MULTI-SIDEPORT CATHETER INFUSION SET DUAL CHECK VALVE)-THE MULTI-SIDEPORT CATHETER INFUSION SET IS INTENDED FOR DELIVERING CONTROLLED INFUSIONS OF INTRAVASCULAR THERAPEUTIC SOLUTIONS,VASCULAR EMBOLIZATION DEVICES (HILAL EMBOLIZATION MICROCOIL, MICRONESTER AND NESTER EMBOLIZATION COILS)-HILAL EMBOLIZATION MICROCOILS ARE INTENDED FOR EMBOLIZATION OF SELECTIVE VESSEL SUPPLY TO ARTERIOVENOUS MALFORMATIONS AND OTHER VASCULAR LESIONS OF THE BRAIN, SPINAL CORD, AND SPINE MICRONESTER AND NESTER EMBOLIZATION COILS ARE INTENDED FOR ARTERIAL AND VENOUS VESSEL EMBOLIZATION PROCEDURES.,TRANSJUGULAR SETS(LIVER ACCESS AND BIOPSY NEEDLE SET , RENAL ACCESS AND BIOPSY SET & TRANSJUGULAR CHOLANGIOGRAPHY/ LIVER BIOPSY SETS)-1. LIVER ACCESS AND BIOPSY NEEDLE SET: INTENDED FOR USE IN

	OBTAINING LIVER HISTOLOGY SAMPLES VIA A JUGULAR VEIN APPROACH. 2. RENAL ACCESS AND BIOPSY SET: INTENDED FOR USE FOR TRANSJUGULAR RENAL BIOPSY PROCEDURES. DESIGNED FOR USE IN OBTAINING RENAL HISTOLOGY SAMPLES VIA A JUGULAR VEIN ANOROACH. 3. TRANSJUGULAR CHOLANGIOGRAPHY/ LIVER BIOPSY SETS- INTENDED FOR USE FOR PERCUTANEOUS TRANSJUGULAR APPROACH FOR CHOLANGIOGRAPHY AND LIVER BIOPSY PROCEDURES.,VASCULAR BALLOON CATHETERS(ADVANCE MICRO 14 ULTRA LOW-PROFILE PTA BALLOON CATHETER, ATB ADVANCE PTA DILATATION CATHETER, ADVANCE 18 LP LOW PROFILE PTA BALLOON DILATATION CATHETER, ADVANCE 35 LP LOW PROFILE PTA BALLOON DILATATION CATHETER)-1. ADVANCE MICRO 14 ULTRA LOW-PROFILE PTA BALLOON CATHETER- INTENDED FOR USE IN PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) OF LESIONS IN PERIPHERAL ARTERIES INCLUDING INTERNAL PUDENDAL, ILIAC, RENAL, POPLITEAL, FEMORAL, ILIOFEMORAL, ANTERIOR TIBIAL, POSTERIOR TIBIAL, PERONEAL, PEDAL, RADIAL, BRACHIAL, AND ULNAR, AS WELL AS OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. NOT FOR USE IN CORONARY ARTERIES 2. ATB ADVANCE PTA DILATATION CATHETER- DESIGNED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) OF LESIONS IN PERIPHERAL ARTERIES INCLUDING ILIAC, RENAL, POPLITEAL, INFRAPOPLITEAL, FEMORAL AND ILIOFEMORAL AS WELL AS OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. IT IS ALSO INTENDED FOR POST DILATATION OF BALLOON-EXPANDABLE PERIPHERAL VASCULAR STENTS 3. ADVANCE 18 LP LOW PROFILE PTA BALLOON DILATATION CATHETER- THE ADVANCE 18LP LOW PROFILE PTA BALLOON DILATATION CATHETER HAVE BEEN DESIGNED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) OF LESIONS IN PERIPHERAL ARTERIES INCLUDING ILIAC, RENAL, POPLITEAL, INFRAPOPLITEAL, FEMORAL AND ILIOFEMORAL AS WELL AS OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE 4. ADVANCE 35 LP LOW PROFILE PTA BALLOON DILATATION CATHETER- THE ADVANCE 35LP LOW PROFILE PTA BALLOON DILATATION CATHETER IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) OF LESIONS IN PERIPHERAL ARTERIES INCLUDING ILIAC, RENAL, POPLITEAL, INFRAPOPLITEAL, FEMORAL AND ILIOFEMORAL AS WELL AS OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE.,INTRAOSSEOUS ACCESS NEEDLES(INTRAOSSEOUS INFUSION NEEDLE [35 DEGREE LANCET, 45 DEGREE TROCAR & PENCIL POINT - PEDIATRIC USE (LESS THAN 24 MONTHS))-INTRAOSSEOUS INFUSION NEEDLES ARE STERILE,

	DISPOSABLE DEVICES USED PRIMARILY DURING PEDIATRIC EMERGENCIES AS AN ALTERNATIVE TO UNSUCCESSFUL INTRAVENOUS ACCESS TO ALLOW FOR EFFECTIVE INFUSION OR RESUSCITATIVE DRUGS OR FLUIDS.,DIAGNOSTIC CATHETER(CXI SUPPORT CATHETER)-INTENDED FOR USE IN SMALL VESSELS OR SUPER SELECTIVE ANATOMY FOR DIAGNOSTIC AND INTERVENTIONAL PROCEDURES, INCLUDING PERIPHERAL USE., INTRODUCER SETS(MICROPUNCTURE® PEDAL ACCESS SET SILHOUETTE TRANSITIONLESS – WITH NITINOL WIRE GUIDE AND HEMOSTATIC VALVE)-THE DEVICE IS INTENDED TO INTRODUCE UPTO AN 0.038" WIRE GUIDE INTO PERIPHERAL VASCULATURE. IT IS ALSO USED TO INTRODUCE DIGNOSTIC AND / OR INTERVENTIONAL DEVICES ABLE TO PASS THROUGH THE ID OF THE INTRODUCER., EMBOLIZATION DEVICE(POLYVINYL ALCOHOL FOAM EMBOLIZATION PARTICLES 1CC)-POLYVINYL ALCOHOL FOAM EMBOLIZATION PARTICLES ARE INTENDED FOR EMBOLIZATION OF THE BLOOD SUPPLY TO HYPERVASCULAR TUMORS AND ARTERIOVENOUS MALFORMATIONS, INCLUDING USE IN INTRACRANIAL EMBOLIZATION.,INTRODUCER SETS(MICROPUNCTURE® INTRODUCER SET SILHOUETTE TANSITIONLESS WITH STAINLESS STEEL WIRE GUIDE)-THE MICROPUNCTURE INTRODUCER SET IS INTENDED FOR THE PLACEMENT OF WIRE GUIDES UPTO 0.038 INCH DIAMETER INTO THE PERIPHERAL VASCULAR SYSTEM WHEN A SMALL 21 GAGE NEEDLE STICK IS DESIRED.,CRICOTHYROTOMY CATHETER SET(ARNDT EMERGENCY CRICOTHYROTOMY CATHETER SET, EMERGENCY CRICOTHYROTOMY CATHETER SET, COOK CRICOTHYROTOMY CATHETER SET, MELKER CUFFED EMERGENCY CRICOTHYROTOMY CATHETER SET, CUFFED EMERGENCY CRICOTHYROTOMY CATHETER SET, MELKER UNIVERSAL CUFFED EMERGENCY CRICOTHYROTOMY CATHETER SET)-THE CRICOTHYROTOMY CATHETER SETS ARE USED TO ESTABLISH EMERGENCY AIRWAY ACCESS WHEN ENDOTRACHEAL INTUBATION CANNOT BE PERFORMED.,FLEXOR® CHECK-FLO® INTRODUCER (FLEXOR® CHECK-FLO® INTRODUCER RAABE MODIFICATION, FLEXOR® CHECK-FLO® INTRODUCER ANSEL MODIFICATION, FLEXOR® CHECK-FLO® INTRODUCER ANSEL MODIFICATION WITH HIGH-FLEX DILATOR AND HYDROPHILIC COATING, FLEXOR® CHECK-FLO® INTRODUCER BALKIN UP & OVER® CONTRALATERAL DESIGN, FLEXOR® CHECK-FLO® II INTRODUCER SET, FLEXOR® CHECK-FLO® INTRODUCER SET, FLEXOR® TUOHY-BORST SIDE-ARM INTRODUCER & FLEXOR® TUOHY-BORST SIDE-ARM INTRODUCER ANSEL MODIFICATION)-INTENDED TO INTRODUCE THERAPEUTIC OR DIAGNOSTIC DEVICES INTO THE VASCULATURE, EXCLUDING CORONARY AND NEURO VASCULATURE.,ENDOVASCULAR STENT-

	GRAFTS(ZENITH RENU AAA ANCILLARY GRAFT CONVERTER)-IT IS INDICATED FOR USE WITH THE ZENITH AAA ENDOVASCULAR GRAFT FAMILY OF PRODUCTS, INCLUDING THE ZENITH FLEX AAA ENDOVASCULAR GRAFT, ZENITH ALPHA ABDOMINAL ENDOVASCULAR GRAFT, ZENITH LOW PROFILE AAA ENDOVASCULAR GRAFT, ZENITH RENU ANCILLARY GRAFT, ZENITH FENESTRATED AAA ENDOVASCULAR GRAFT, ZENITH UNIVERSAL DISTAL BODY ENDOVASCULAR GRAFT, ZENITH FLEX AUI, OR ZENITH BRANCH, DURING EITHER A PRIMARY OR A SECONDARY PROCEDURE IN PATIENTS WHO HAVE ADEQUATE ILIAC/FEMORAL ACCESS COMPATIBLE WITH THE REQUIRED INTRODUCTION SYSTEMS. THE GRAFT IS USED IN COMBINATION WITH THESE PRODUCTS FOR THE ENDOVASCULAR TREATMENT OF ABDOMINAL AORTIC AND AORTO-ILIAC ANEURYSMS.,INTRODUCER SETS(MICROPUNCTURE® INTRODUCER SET SILHOUETTE TRANSITIONLESS WITH NITINOL WIRE GUIDE)-THE MICROPUNCTURE INTRODUCER SET IS INTENDED FOR THE PLACEMENT OF WIRE GUIDES UPTO 0.038 INCH DIAMETER INTO THE PERIPHERAL VASCULAR SYSTEM WHEN A SMALL 21 GAGE NEEDLE STICK IS DESIRED.,ENDOVASCULAR STENT GRAFTS(ZENITH FLEX AAA ENDO VASCULAR GRAFT MAIN BODY)-THE ZENITH FLEX AAA ENDOVASCULAR GRAFT WITH THE Z-TRAK INTRODUCTION SYSTEM IS INDICATED FOR THE ENDOVASCULAR TREATMENT OF PATIENTS WITH ABDOMINAL AORTIC OR AORTOILIAC ANEURYSMS HAVING MORPHOLOGY SUITABLE FOR ENDOVASCULAR REPAIR, INCLUDING: • ADEQUATE ILIAC/FEMORAL ACCESS COMPATIBLE WITH THE REQUIRED INTRODUCTION SYSTEMS, • NON-ANEURYSMAL INFRARENAL AORTIC SEGMENT (NECK) PROXIMAL TO THE ANEURYSM: • WITH A LENGTH OF AT LEAST 15 MM, • WITH A DIAMETER MEASURED OUTER WALL TO OUTER WALL OF NO GREATER THAN 32 MM AND NO LESS THAN 18 MM, • WITH AN ANGLE LESS THAN 60 DEGREES RELATIVE TO THE LONG AXIS OF THE ANEURYSM, AND • WITH AN ANGLE LESS THAN 45 DEGREES RELATIVE TO THE AXIS OF THE SUPRARENAL AORTA. • ILIAC ARTERY DISTAL FIXATION SITE GREATER THAN 10 MM IN LENGTH AND 7.5-20 MM IN DIAMETER (MEASURED OUTER WALL TO OUTER WALL)., ENDOVASCULAR STENT GRAFTS(ZENITH AAA ENDOVASCULAR GRAFT CONVERTER)-THE ZENITH AAA ANCILLARY COMPONENTS WITH THE Z-TRAK INTRODUCTION SYSTEM ARE INDICATED FOR USE WITH THE ZENITH AAA GRAFT DURING EITHER A PRIMARY OR A SECONDARY PROCEDURE IN PATIENTS WHO HAVE ADEQUATE ILIAC/FEMORAL ACCESS COMPATIBLE WITH THE REQUIRED INTRODUCTION SYSTEMS.,ENDOVASCULAR STENT GRAFTS(ZENITH FLEX AAA ENDOVASCULAR GRAFT ILIAC LEG)-THE ZENITH FLEX AAA ENDOVASCULAR GRAFT WITH THE Z-TRAK INTRODUCTION SYSTEM

	IS INDICATED FOR THE ENDOVASCULAR TREATMENT OF PATIENTS WITH ABDOMINAL AORTIC OR AORTOILIAC ANEURYSMS HAVING MORPHOLOGY SUITABLE FOR ENDOVASCULAR REPAIR, INCLUDING: • ADEQUATE ILIAC/FEMORAL ACCESS COMPATIBLE WITH THE REQUIRED INTRODUCTION SYSTEMS, • NON-ANEURYSMAL INFRARENAL AORTIC SEGMENT (NECK) PROXIMAL TO THE ANEURYSM: • WITH A LENGTH OF AT LEAST 15 MM, • WITH A DIAMETER MEASURED OUTER WALL TO OUTER WALL OF NO GREATER THAN 32 MM AND NO LESS THAN 18 MM, • WITH AN ANGLE LESS THAN 60 DEGREES RELATIVE TO THE LONG AXIS OF THE ANEURYSM, AND • WITH AN ANGLE LESS THAN 45 DEGREES RELATIVE TO THE AXIS OF THE SUPRARENAL AORTA. • ILIAC ARTERY DISTAL FIXATION SITE GREATER THAN 10 MM IN LENGTH AND 7.5-20 MM IN DIAMETER (MEASURED OUTER WALL TO OUTER WALL)., ENDOVASCULAR STENT GRAFTS(ZENITH FLEX AAA ENDOVASCULAR GRAFT MAIN BODY EXTENSION)-THE ZENITH AAA ANCILLARY COMPONENTS WITH THE Z-TRAK INTRODUCTION SYSTEM ARE INDICATED FOR USE WITH THE ZENITH AAA GRAFT DURING EITHER A PRIMARY OR A SECONDARY PROCEDURE IN PATIENTS WHO HAVE ADEQUATE ILIAC/FEMORAL ACCESS COMPATIBLE WITH THE REQUIRED INTRODUCTION SYSTEMS.,PERCUTANEOUS DRAINAGE CATHETERS AND SETS(RING DRAINAGE CATHETER NEEDLE SET)-INTENDED TO BE USED AS AN INITIAL ACCESS DEVICE FOR DIAGNOSTIC AND DRAINAGE PROCEDURES.,PERCUTANEOUS DRAINAGE CATHETERS(PERCUTANEOUS NEPHROSTOMY SETS)-INTENDED TO BE USED FOR EXTERNAL URINE DRAINAGE FROM THE RENAL PELVIS,OCCLUSION BALLOON CATHETER(CODA BALLOON CATHETER & CODA LP BALLOON CATHETER)-INTENDED FOR TEMPORARY OCCLUSION OF LARGE VESSELS, OR TO EXPAND VASCULAR PROSTHESES,BIOPSY ACCESS NEEDLE(CHIBA BIOPSY NEEDLE)-INTENDED FOR ASPIRATION BIOPSY,BIOPSY /ACCESS NEEDLE(QUICK-CORE® BIOPSY NEEDLE & SETS)-INTENDED FOR SOFT TISSUE BIOPSY. THE PRODUCT IS INTENDED FOR USE BY PHYSICIANS TRAINED AND EXPERIENCED IN DIAGNOSTIC AND INTERVENTIONAL TECHNIQUES. STANDARD TECHNIQUES FOR SOFT TISSUE BIOPSY SHOULD BE EMPLOYED,RESPIRATORY MANAGEMENT SETS(COOK RETROGRADE INTUBATION SET)-INTENDED TO ASSIST IN THE PLACEMENT OF AN ENDOTRACHEAL TUBE DURING DIFFICULT OR EMERGENCY AIRWAY ACCESS PROCEDURES WHERE VISUALIZATION OF THE VOCAL CORDS IN NOT POSSIBLE SECONDARY TO SECRETIONS, BLOOD AND-OR ANATOMIC ANOMALIES.,VASCULAR WIRE GUIDES(AMPLATZ ULTRA STIFF WIRE GUIDE, FIXED CORE WIRE GUIDE SAFE T-J CURVED, FIXED CORE WIRE GUIDE STRAIGHT, ROSEN CURVED WIRE GUIDE, AMPLATZ EXTRA STIFF WIRE GUIDE &

	AMPLATZ EXTRA STIFF WHISKER WIRE GUIDE)-THE VASCULAR WIRE GUIDES ARE INTENDED TO ASSIST IN INSERTING CATHETERS, INTRODUCER SHEATHS AND OTHER MEDICAL DEVICES IN VASCULAR APPLICATIONS.,RESPIRATORY MANAGEMENT SET(COOK AIRWAY EXCHANGE CATHETER, SOFT-TIPPED EXTRA-FIRM EXCHANGE CATHETER FOR DOUBLE LUMEN ENDOTRACHEAL TUBES, ARNDT AIRWAY EXCHANGE CATHETER, AINTREE INTUBATION CATHETER, FROVA INTUBATING INTRODUCER WITH STIFFENING CANNULA)-COOK AIRWAY EXCHANGE CATHETER & SOFT-TIPPED EXTRA-FIRM EXCHANGE CATHETER FOR DOUBLE LUMEN ENDOTRACHEAL TUBES [INTENDED FOR UNCOMPLICATED, ATRAUMATIC ENDOTRACHEAL TUBE EXCHANGE.] ARNDT AIRWAY EXCHANGE CATHETER [THE ARNDT AIRWAY EXCHANGE CATHETER SET IS INTENDED FOR THE EXCHANGE OF LARYNGEAL MASK AIRWAYS (LMA) AND ENDOTRACHEAL TUBES USING A FIBEROPTIC BRONCHOSCOPE, BRONCHOSCOPIC PORT, WIRE GUIDE AND EXCHANGE CATHETER. THE PRODUCT MAY BE USED FOR EMERGENCY, URGENT AND ELECTIVE AIRWAY MANAGEMENT. THE REMOVABLE RAPI-FIT ADAPTER PERMITS USE OF VENTILATOR DEVICE, IF NECESSARY, DURING EXCHANGE PROCEDURE.] AINTREE INTUBATION CATHETER [THE AINTREE INTUBATION CATHETER HAS BEEN DESIGNED FOR ASSISTED FIBEROPTIC INTUBATION AND FOR UNCOMPLICATED, ATRAUMATIC ENDOTRACHEAL TUBE EXCHANGE] FROVA INTUBATING INTRODUCER WITH STIFFENING CANNULA [INTENDED TO FACILITATE ENDOTRACHEAL INTUBATION IN PATIENTS WHERE VISUALIZATION OF THE GLOTTIS IS INADEQUATE.],PEEL-AWAY® INTRODUCER SETS(PEEL-AWAY® INTRODUCER, PEEL-AWAY® INTRODUCER SETS & SUBCLAVIAN HEMODIALYSIS CATHETER INTRODUCER SET)-INTENDED FOR PERCUTANEOUS INTRODUCTION OF BALLOON, ELECTRODE AND CLOSED OR NON-TAPERED END CATHETERS FOR VASCULAR AND NON-VASCULAR USE., RESPIRATORY MANAGEMENT SET(EMERGENCY TRANSTRACHEAL AIRWAY CATHETER)-THE TRANSTRACHEAL CATHETER IS USED FOR EMERGENCY AIRWAY ACCESS WHEN CONVENTIONAL ENDOTRACHEAL INTUBATION CANNOT BE PERFORMED., TRANSSEPTAL NEEDLES(TRANSSEPTAL NEEDLE)-INTENDED FOR LEFT HEART ACCESS IN BOTH DIAGNOSTIC AND INTERVENTIONAL PROCEDURES,DIAGNOSTIC HEART AND CEREBRAL CATHETERS (TORCON NB® ADVANTAGE CATHETER, ROYAL FLUSH® PLUS HIGH FLOW CATHETER & TORCON NB® ADVANTAGE CATHETER)-THE CATHETERS ARE INTENDED FOR USE IN ANGIOGRAPHIC PROCEDURES BY PHYSICIANS TRAINED AND EXPERIENCED IN ANGIOGRAPHIC TECHNIQUES. STANDARD TECHNIQUES FOR PLACEMENT OF VASCULAR ACCESS SHEATHS, ANGIOGRAPHIC

	CATHETERS AND WIRE GUIDES SHOULD BE EMPLOYED, ENDOBRONCHIAL BLOCKER SET(ARNDT PEDIATRIC ENDOBRONCHIAL BLOCKER SET WITH SPHERICAL BALLOON, ARNDT ENDOBRONCHIAL BLOCKER SET WITH SPHERICAL BALLOON & COHEN ENDOBRONCHIAL BLOCKER SET)-THE ENDOBRONCHIAL BLOCKER SET IS USED TO DIFFERENTIALLY INTUBATE A PATIENT'S BRONCHUS IN ORDER TO ISOLATE THE LEFT OR RIGHT LUNG FOR PROCEDURES THAT REQUIRE ONE-LUNG VENTILATION. THE 5.0 FR ARNDT ENDOBRONCHIAL BLOCKER IS INDICATED FOR PEDIATRIC POPULATIONS, IN CHILDREN I YEAR AND OLDER. ALL OTHER SIZES ARE FOR ADULT USE ONLY.,PERCUTANEOUS ACCESS SET(NEFF PERCUTANEOUS ACCESS SET, NEFF PERCUTANEOUS ACCESS SET WITH NITINOL WIRE GUIDE, NEFF PERCUTANEOUS ACCESS SET WITH HYDROPHILIC COATING, NEFF PERCUTANEOUS ACCESS SET WITH HYDROPHILIC COATING AND NITINOL WIRE GUIDE & NEFF PERCUTANEOUS ACCESS SET D'AGOSTINO MODIFICATION)-INTENDED FOR SINGLE PUNCTURE PERCUTANEOUS ACCESS TO FACILITATE PLACEMENT OF A 0.038 INCH DIAMETER WORKING WIRE GUIDE FOR INTERVENTIONAL RADIOLOGY PROCEDURES.,PRESSURE MONITORING ARTERIAL SETS(RADIAL ARTERY CATHETER SET AND FEMORAL ARTERY CATHETER SET)-THE PRESSURE MONITORING ARTERIAL SETS ARE INTENDED FOR ARTERIAL PRESSURE MONITORING AND BLOOD SAMPLING.,INTRODUCER SETS(EXTRA LARGE CHECK-FLO® INTRODUCER)-INTENDED TO BE USED FOR THE INTRODUCTION OF BALLOONS, CLOSED AND NON-TAPERED END CATHETERS OR OTHER DIAGNOSTIC OR INTERVENTIONAL DEVICES., PERCUTANEOUS DRAINAGE CATHETERS AND SETS(BILIARY DRAINAGE CATHETER ULTRATHANE® AND RING BILIARY DUCT DRAINAGE CATHETER ULTRATHANE®)-THEY ARE INTENDED FOR TRANSHEPATIC ANTEGRADE BILIARY DRAINAGE IN PATIENTS WITH BILIARY OBSTRUCTION,PERCUTANEOUS DRAINAGE CATHETERS AND SETS(MULTIPURPOSE DRAINAGE CATHETER SET ULTRATHANE® NEFF ACCESS SET WITH NITINOL WIRE GUIDE, DAWSON-MUELLER DRAINAGE CATHETER ULTRATHANE® (WITH/WITHOUT HYDROPHILIC COATING), MULTIPURPOSE DRAINAGE CATHETER ULTRATHANE®)-1. MULTIPURPOSE DRAINAGE CATHETER SET ULTRATHANE® NEFF ACCESS SET WITH NITINOL WIRE GUIDE, DAWSON-MUELLER DRAINAGE CATHETER ULTRATHANE® (WITH/WITHOUT HYDROPHILIC COATING), MULTIPURPOSE DRAINAGE CATHETER ULTRATHANE®, - INTENDED FOR PERCUTANEOUS DRAINAGE IN A VARIETY OF DRAINAGE APPLICATIONS (E.G., NEPHROSTOMY, BILIARY AND ABSCESS), EITHER BY DIRECT STICK OR SELDINGER ACCESS TECHNIQUE. 2. RING DRAINAGE CATHETER NEEDLE SET- INTENDED TO BE USED AS AN INITIAL ACCESS DEVICE FOR DIAGNOSTIC AND

		DRAINAGE PROCEDURES.,CHECK-FLO PERFORMER® INTRODUCERS AND SETS(CHECK-FLO PERFORMER INTRODUCER SET, CHECK-FLO INTRODUCER SET, MICROPUNCTURE CHECK-FLO PERFORMER INTRODUCER SET, CHECK- FLO PERFORMER INTRODUCER SET, CHECK-FLO PERFORMER INTRODUCER SET MICROPUNCTURE RADIAL ARTERY ACCESS, CHECK-FLO PERFORMER INTRODUCER AND PERFORMER BALKIN GUIDING SHEATH)-INTRODUCERS ARE INTENDED FOR INTRODUCTION OF BALLOONS, CLOSED AND NON-TAPERED END CATHETERS OR OTHER DIAGNOSTIC AND INTERVENTIONAL DEVICES. ,TRACHEOSTOMY INTRODUCER SET (CIAGLIA BLUE RHINO G2 ADVANCED PERCUTANEOUS TRACHEOSTOMY INTRODUCER SET, CIAGLIA BLUE RHINO PERCUTANEOUS TRACHEOSTOMY INTRODUCER SET)-USED FOR PERCUTANEOUS DILATIONAL TRACHEOSTOMY FOR MANAGEMENT OF THE AIRWAY IN ADULTS ONLY.
1302	IMP/MD/2018/000191	1.License Holder Name: M/S COOK INDIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DILATORS(DILATOR)-THE DILATORS ARE INTENDED TO BE USED FOR DILATING PUNCTURE SITES OR CATHETER TRACTS FOR PERCUTANEOUS PLACEMENT OF DEVICES FOR VASCULAR AND NON-VASCULAR APPLICATIONS SUCH AS IN THE VENOUS, ARTERIAL, BILIARY AND RENAL SYSTEMS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1303	IMP/MD/2018/000191	1.License Holder Name: M/S COOK INDIA MEDICAL DEVICES PVT. LTD. , PLOT NO 22(SP), THIRD AND FOURTH FLOOR, KOCHAR JADE, THIRU VI KA INDUSTRIAL ESTATE, GUINDY TALUK ,CHENNAI TAMIL NADU , 600032 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYDROPHILLIC WIRE GUIDES(ROADRUNNER® PC WIRE GUIDE NIMBLE & ROADRUNNER® PC WIRE GUIDE THE FIRM™,)-ROADRUNNER PC WIRE GUIDES ARE INTENDED FOR COMPLEX DIAGNOSTIC AND INTERVENTIONAL PROCEDURES. THE PRODUCT IS INTENDED FOR USE BY PHYSICIANS TRAINED AND EXPERIENCED IN DIAGNOSTIC AND INTERVENTIONAL TECHNIQUES. STANDARD TECHNIQUES FOR PLACEMENT OF VASCULAR ACCESS SHEATHS, ANGIOGRAPHIC CATHETERS AND WIRE GUIDES SHOULD BE EMPLOYED.,HYDROPHILLIC WIRE GUIDES (ROADRUNNER® EXTRA SUPPORT WIRE GUIDE)-THE ROADRUNNER EXTRA SUPPORT WIRE GUIDE IS INTENDED FOR USE IN FACILITATING DELIVERY OF PERCUTANEOUS CATHETERS INTO THE CARDIOVASCULAR SYSTEM.,HYDROPHILLIC WIRE GUIDES (ROADRUNNER® UNIGLIDE™ HYDROPHILIC WIRE GUIDE)-THE ROADRUNNER UNIGLIDE HYDROPHILIC WIRE GUIDE IS INTENDED FOR USE IN FACILITATING THE DELIVERY OF PERCUTANEOUS CATHETERS INTO THE PERIPHERAL VASCULATURE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1304	IMP/MD/2018/000192	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER(LIVEWIRE STEERABLE ELECTROPHYSIOLOGY CATHETERS)-THE LIVEWIRE™ STEERABLE ELECTROPHYSIOLOGY CATHETER CAN BE USED IN THE EVALUATION OF A VARIETY OF CARDIAC ARRHYTHMIAS FROM ENDOCARDIAL AND INTRAVASCULAR SITES.,STEERABLE INTRODUCER(AGILIS EPI)-AGILIS EPI STEERABLE INTRODUCER IS INTENDED FOR INTRODUCING VARIOUS DIAGNOSTIC CATHETERS TO THE EPICARDIAL SURFACE OF THE HEART.,CATHETER(SUPREME ELECTROPHYSIOLOGY CATHETER)-SUPREME ELECTROPHYSIOLOGY CATHETERS CAN BE USED IN THE EVALUATION OF A VARIETY OF CARDIAC ARRHYTHMIAS FROM ENDOCARDIAL AND INTRAVASCULAR SITES.,CATHETER(PACEL FLOW DIRECTED PACING CATHETER)-IT INDICATED FOR USE IN TEMPORARY, TRANSVENOUS, RIGHT VENTRICULAR PACING. ,INTRODUCER(AGILIS NXT STEERABLE INTRODUCER)-THE AGILIS NXT STEERABLE INTRODUCER IS INDICATED WHEN INTRODUCING VARIOUS CARDIOVASCULAR CATHETERS INTO THE HEART, INCLUDING THE LEFT SIDE OF THE HEART THROUGH THE INTERATRIAL SEPTUM. ,CATHETER(LIVEWIRE TC ABLATION CATHETER)-• THE 4MM LIVEWIRE™ TC CATHETER IS INDICATED FOR CARDIAC ELECTROPHYSIOLOGICAL MAPPING AND FOR USE WITH A COMPATIBLE RF GENERATOR SET TO DELIVER UP TO 50 WATTS FOR CREATING ENDOCARDIAL FOCAL OR LINEAR LESIONS DURING CARDIAC ABLATION PROCEDURES TO TREAT ARRHYTHMIAS. • THE 8MM LIVEWIRE™ TC CATHETER IS INDICATED FOR CARDIAC ELECTROPHYSIOLOGICAL MAPPING AND FOR USE WITH A COMPATIBLE RF GENERATOR SET TO DELIVER UP TO 100 WATTS FOR TREATMENT OF TYPE I ATRIAL FLUTTER.,CATHETER (PACEL BIPOLAR PACING CATHETER)-PACEL™ BIPOLAR PACING CATHETERS ARE INDICATED FOR INTRACARDIAC PACING AND/OR ECG RECORDING.,CATHETER(REFLEXION SPIRAL VARIABLE RADIUS CATHETER)-THE REFLEXION SPIRAL CATHETER CAN BE USED FOR RECORDING INTRACARDIAC SIGNALS AND FOR CARDIAC STIMULATION DURING ELECTROPHYSIOLOGY STUDIES. THE REFLEXION SPIRAL CATHETER IS TO BE USED TO MAP THE ATRIAL REGIONS OF THE HEART.,CATHETER(SAFIRE ABLATION CATHETERS)-THE 4MM SAFIRE BIDIRECTIONAL AND THERAPY COMFORTGRIP BIDIRECTIONAL ABLATION CATHETER IS INDICATED FOR CARDIAC ELECTROPHYSIOLOGY MAPPING AND FOR USE WITH A COMPATIBLE RF GENERATOR SET TO DELIVER UP TO 50 WATTS FOR CREATING ENDOCARDIAL FOCAL OR LINEAR LESIONS DURING CARDIAC ABLATION PROCEDURES TO TREAT ARRHYTHMIAS. THE 8MM SAFIRE BIDIRECTIONAL AND THERAPY COMFORTGRIP BIDIRECTIONAL

		ABLATION CATHETER IS INDICATED FOR ELECTROPHYSIOLOGY MAPPING AND FOR USE WITH A COMPATIBLE RF GENERATOR SET TO DELIVER UP TO 100 WATTS FOR TREATMENT OF TYPE 1 ATRIAL FLUTTER.
1305	IMP/MD/2018/000194	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMMULITE 2000 CHEMILUMINESCENT SUBSTRATE MODULE-FOR USE IN THE ROUTINE OPERATION OF THE IMMULITE SERIES OF ANALYZERS,IMMULITE CHEMILUMINESCENT SUBSTRATE MODULE-FOR USE IN THE ROUTINE OPERATION OF THE IMMULITE SERIES OF ANALYZERS
1306	IMP/MD/2018/000195	1.License Holder Name: M/S G.S MEDILINKS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHOPEDIC CASTING TAPE(ALTOCAST)-ALTOCAST IS INTENDED FOR USE IN THE CONSTRUCTION OF MOST COMMON ORTHOPEDIC CAST APPLICATION, AS WELL AS SPECIALIZED AND PROSTHETICS DEVICES
1307	IMP/MD/2018/000199	1.License Holder Name: STAR AEROSPACE INDUSTRIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SOLUBLE HEMOSTAT (WOUNDCLOT SURGICAL)-SURGICAL GAUZE: THE WOUNDCLOT BIO ABSORBABLE SURGICAL GAUZE IS INTENDED FOR BLEEDING CONTROL DURING SURGICAL PROCEDURES.,SOLUBLE HEMOSTAT (WOUNDCLOT TRAUMA)-PRESCRIPTION USE: TRAUMA GAUZE: THE WOUNDCLOT TRAUMA GAUZE IS INTENDED FOR BLEEDING CONTROL OF TRAUMATIC WOUNDS, INCLUDING MODERATE TO SEVERE BLEEDING APPLICATIONS.,SOLUBLE HEMOSTAT(WOUNDCLOT)-OVER THE COUNTER USE: WOUNDCLOT: THE WOUNDCLOT GAUZE IS INTENDED FOR EXTERNAL BLEEDING CONTROL OF SUPERFICIAL WOUNDS, MINOR CUTS, AND ABRASIONS.

1308	IMP/MD/2018/000203	1.License Holder Name: DIASYS DIAGNOSTIC INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:D-DIMER(QDX INSTACHECK™ D-DIMER)-QDX INSTACHECK™ D-DIMER IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN WHOLE BLOOD / PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF POST THERAPEUTIC EVALUATION OF THROMBOEMBOLIC DISEASE PATIENTS. FOR IN VITRO DIAGNOSTIC USE ONLY.,TEST FOR THYROID STIMULATING HORMONE(QDX INSTACHECK™ TSH)-QDX INSTACHECK™ TSH IN CONJUNCTION WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY FOR QUANTITATIVE MEASUREMENT OF THYROID STIMULATING HORMONE (TSH) CONCENTRATION IN HUMAN SERUM/PLASMA AS AN AID IN THE DIAGNOSIS OF THYROID AND/OR PITUITARY DISORDERS.,TN-I PLUS (QDX INSTACHECK™ TN-I PLUS)-QDX INSTACHECK™ TN-I PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN-I (TN-I) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION (AMI). FOR IN VITRO DIAGNOSTIC USE ONLY.,TEST FOR FERRITIN(QDX INSTACHECK™ FERRITIN)-QDX INSTACHECK™ FERRITIN ALONG WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY THAT QUANTIFIES CONCENTRATION OF FERRITIN IN HUMAN SERUM AND PLASMA.,RF IGM(QDX INSTACHECK™ RF IGM)-QDX INSTACHECK™ RF IGM IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF RF IGM IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF RHEUMATOID ARTHRITIS. FOR IN VITRO DIAGNOSTIC USE ONLY.,TEST FOR TOTAL 25 (OH) D2/D3(QDX INSTACHECK™ VITAMIN D)-QDX INSTACHECK™ VITAMIN D ALONG WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25(OH)D2/D3 LEVEL IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF REGULATING THE CONCENTRATION OF CALCIUM AND PHOSPHATE IN THE BLOODSTREAM AND PROMOTING THE HEALTHY GROWTH AND REMODELING OF BONE.,IL-6(QDX INSTACHECK™ IL-6)-QDX INSTACHECK™ IL-6 IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF IL-6 IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGING AND MONITORING OF INFLAMMATORY DISEASE. FOR IN VITRO DIAGNOSTIC USE ONLY.,TEST FOR TESTOSTERONE(QDX INSTACHECK™ TESTOSTERONE)-QDX INSTACHECK™ TESTOSTERONE

	ALONG WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ANDROGEN LEVEL.,DENGUE NS1 AG(QDX INSTACHECK™ DENGUE NS1 AG)-QDX INSTACHECK™ DENGUE NS1 AG IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE DETERMINATION OF NS1 AG IN HUMAN WHOLE BLOOD/SERUM/PLASMA DURING DENGUE VIRUS INFECTION. IT IS USEFUL AS AN AID IN SCREENING OF EARLY DENGUE VIRUS INFECTION. FOR IN VITRO DIAGNOSTIC USE ONLY.,TEST FOR PROGESTERONE(QDX INSTACHECK™ PROGESTERONE)-QDX INSTACHECK™ PROGESTERONE ALONG WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THE CAUSE OF INFERTILITY, TRACK OVULATION, DIAGNOSE AN ECTOPIC OR FAILING PREGNANCY, MONITOR THE HEALTH OF A PREGNANCY.,DENGUE IGG/IGM(QDX INSTACHECK™ DENGUE IGG/IGM)-QDX INSTACHECK™ DENGUE IGG/IGM IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE DETERMINATION OF IGG/IGM ANTIBODIES AGAINST DENGUE VIRUS IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN SCREENING OF DENGUE VIRUS INFECTION. FOR IN VITRO DIAGNOSTIC USE ONLY.,TEST FOR MYOGLOBIN(QDX INSTACHECK™ MYOGLOBIN)-QDX INSTACHECK™ MYOGLOBIN ALONG WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN WHOLE BLOOD/ SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAL INFARCTION (AMI).,IFOB NEO(QDX INSTACHECK™ IFOB NEO)-QDX INSTACHECK™ IFOB NEO IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN IN HUMAN FECES. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF COLORECTAL CANCER. FOR IN VITRO DIAGNOSTIC USE ONLY.,TEST FOR MICROALBUMINURIA(QDX INSTACHECK™ MICROALBUMIN)-QDX INSTACHECK™ MICROALBUMIN ALONG WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN URINE. THE TEST IS USED FOR ASSESSING MICROALBUMINURIA FOR EARLY DETECTION OF KIDNEY DAMAGE MOST COMMONLY ASSOCIATED WITH DIABETES.,NT-PROBNP(QDX INSTACHECK™ NT-PROBNP)-QDX INSTACHECK™ NT-PROBNP IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF NT-PROBNP IN HUMAN WHOLE BLOOD/ SERUM/PLASMA. IT IS USEFUL AS AN AID IN

	THE DIAGNOSIS OF PERSONS SUSPECTED OF HAVING CONGESTIVE HEART FAILURE. FOR IN VITRO DIAGNOSTIC USE ONLY.,TEST FOR CYSTATIN C(QDX INSTACHECK™ CYSTATIN C)-QDX INSTACHECK™ CYSTATIN C ALONG WITH QDX INSTACHECK™ READER IS FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF OF CYSTATIN C IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF RENAL DISEASE.,PCT PLUS(QDX INSTACHECK™ PCT PLUS)-QDX INSTACHECK™ PCT PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF BACTERIAL INFECTION AND SEPSIS. FOR IN VITRO DIAGNOSTIC USE ONLY.,TEST FOR CORTISOL (QDX INSTACHECK™ CORTISOL)-QDX INSTACHECK™ CORTISOL ALONG WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN WHOLE BLOOD/SERUM/ PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF CONCENTRATION OF CORTISOL,ANTI-CCP PLUS(QDX INSTACHECK™ ANTI-CCP PLUS)-QDX INSTACHECK™ ANTI-CCP PLUS IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUALITATIVE OR SEMI-QUANTITATIVE DETERMINATION OF HUMAN IGG AUTOANTIBODIES TO CYCLIC CITRULLINATED PEPTIDES (CCP) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN THE DIAGNOSIS OF RHEUMATOID ARTHRITIS (RA) IN COMBINATION WITH OTHER CLINICAL AND LABORATORY FINDINGS. FOR IN VITRO DIAGNOSTIC USE ONLY.,TEST FOR CREATINE KINASE ISOENZYME-MB(QDX INSTACHECK™ CK-MB)-QDX INSTACHECK™ CK-MB ALONG WITH QDX INSTACHECK™ READER IS FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE ISOENZYME-MB (CK-MB) IN HUMAN WHOLE BLOOD/SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF ACUTE MYOCARDIAC INFARCTION (AMI) AND ACUTE CORONARY SYNDROME (ACS).,CALPROTECTIN(QDX INSTACHECK™ CALPROTECTIN)-QDX INSTACHECK™ CALPROTECTIN IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR QUANTITATIVE DETERMINATION OF CALPROTECTIN (MRP8/14; S100A8/S100A9) IN HUMAN FECES. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THE REFLEX GASTROINTESTINAL INFLAMMATION CAUSED BY SEVERAL PATHOLOGIES (INFLAMMATORY BOWEL DISEASE, COLORECTAL CANCER AND SOME ENTEROPATHIES). FOR IN VITRO DIAGNOSTIC USE ONLY.,TEST FOR T3(QDX INSTACHECK™ T3)-QDX INSTACHECK™ T3 ALONG WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE

	DETERMINATION OF TRIIODOTHYRONINE (TOTAL T3) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF THYROID DISORDERS.,TEST FOR TOTAL BETA HUMAN CHORIONIC GONADOTROPIN(QDX INSTACHECK™ -HCG)-QDX INSTACHECK™-HCG IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL BETA HUMAN CHORIONIC GONADOTROPIN (TOTAL -HCG) LEVEL IN HUMAN WHOLE BLOOD OR SERUM OR PLASMA.,TEST FOR PROLACTIN(QDX INSTACHECK™ PRL)-QDX INSTACHECK™ PRL IN CONJUNCTION WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY FOR QUANTITATIVE MEASUREMENT OFPROLACTIN (PRL) CONCENTRATION IN HUMAN SERUM OR PLASMA.,TEST FOR LUTEINIZING HORMONE(QDX INSTACHECK™ LH)-QDX INSTACHECK™ LH ALONG WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY THAT QUANTIFIES CONCENTRATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF DETERMINATION OF EVALUATING FERTILITY ISSUES, FUNCTION OF REPRODUCTIVE ORGANS (OVARIES OR TESTICLES), OR DETECTION OF THE OVULATION.,TEST FOR T4(QDX INSTACHECK™ T4)-QDX INSTACHECK™ T4 ALONG WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY THAT QUANTIFIES CONCENTRATION OF T4 IN HUMAN SERUM AND PLASMA.,TEST FOR HBA1C(QDX INSTACHECK™ HBA1C)-QDX INSTACHECK™ HBA1C ALONG WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY (FIA) FOR THE QUANTITATIVE DETERMINATION OF HBA1C (HEMOGLOBIN A1C) IN HUMAN WHOLE BLOOD. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF THE LONG-TERM GLYCEMIC STATUS IN PATIENTS WITH DIABETES MELLITUS.,TEST FOR FOLLICLE STIMULATING HORMONE(QDX INSTACHECK™ FSH)-QDX INSTACHECK™ FSH IN CONJUNCTION WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY FOR QUANTITATIVE MEASUREMENT OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN SERUM/PLASMA. IT IS USEFUL AS AN AID IN MANAGEMENT AND MONITORING OF CONCENTRATION OF FSH., TEST FOR THYROID STIMULATING HORMONE(QDX INSTACHECK™ TSH WB)-QDX INSTACHECK™ TSH WB IN CONJUNCTION WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY FOR QUANTITATIVE MEASUREMENT OF THYROID STIMULATING HORMONE (TSH) CONCENTRATION IN HUMAN WHOLE BLOOD AS AN AID IN THE DIAGNOSIS OF THYROID AND/OR PITUITARY DISORDERS.,TEST FOR C- REACTIVE PROTEIN (QDX INSTACHECK™ HSCRP-ALL IN ONE)-QDX INSTACHECK™ HSCRP - ALL IN ONE ALONG WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY FOR QUANTITATIVE

		DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM, PLASMA, OR WHOLE BLOOD. THE TEST IS USED AS AN AID TO PREDICT FUTURE CARDIOVASCULAR DISEASES (CDC) AS WELL AS TO SEE INFECTION INFLAMMATION ,TEST FOR PROCALCITONIN(QDX INSTACHECK™ PCT)-QDX INSTACHECK™ PCT IN CONJUNCTION WITH THE QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY FOR QUANTITATIVE MEASUREMENT OF PROCALCITONIN (PCT) CONCENTRATION IN HUMAN WHOLE BLOOD/SERUM/PLASMA FOR DIAGNOSIS OF BACTERIAL INFECTION AND SEPSIS.,TEST FOR CARDIAC TROPONIN-I(QDX INSTACHECK™ TN-I)-QDX INSTACHECK™ TN-I ALONG WITH QDX INSTACHECK™ READER IS A FLUORESCENCE IMMUNOASSAY THAT MEASURES CARDIAC TROPONIN-I (TN-I) CONCENTRATION IN HUMAN SERUM/PLASMA.
1309	IMP/MD/2018/000205	1.License Holder Name: HERZ HEALTHCARE SYSTEMS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRA-AORTIC BALLOON CATHETER WITH INSERTION KIT(XEMEX IABP BALLOON PLUS)-XEMEX IABP BALLOON PLUS IS A BALLOON CATHETER SET USED FOR BALLOON PUMPING IN THE AORTA TO ASSIST HEART FUNCTION IN CARDIOGENIC SHOCK OR LOW CARDIAC OUTPUT SYNDROME CASES

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1310	IMP/MD/2018/000206	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NON-ABSORBABLE RELOAD(V-LOC™ PBT)-THE V-LOC™ PBT NON-ABSORBABLE RELOADS ARE INTENDED FOR USE WITH THE ENDO STITCH™ SUTURING DEVICE AND SILS™ STITCH SUTURING DEVICE. THE ENDO STITCH™ SUTURING DEVICE AND SILS™ STITCH SUTURING DEVICE, WHEN USED WITH THE RELOADS, HAVE APPLICATION IN ENDOSCOPIC SURGERY FOR THE PLACEMENT OF RUNNING STITCHES IN SOFT TISSUE. THE V-LOC™ PBT NON-ABSORBABLE RELOADS ARE INDICATED FOR SOFT TISSUE APPROXIMATION. ,STAPLES LOADING UNIT(TRI-STAPLE™ 2.0)-THE TRI-STAPLE™ 2.0 RELOADS HAVE APPLICATION IN ABDOMINAL, GYNAECOLOGIC, PAEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES, AND FOR TRANSECTION AND RESECTION OF PANCREAS. THE TRI-STAPLE™ 2.0 CURVED TIP RELOADS CAN BE USED TO BLUNT DISSECT OR SEPARATE TARGET TISSUE FROM OTHER TISSUE. ,ABSORBABLE RELOAD(V-LOC™ 180)-THE V-LOC™ 180 ABSORBABLE RELOADS ARE INTENDED FOR USE WITH THE ENDO STITCH™ SUTURING DEVICE AND SILS™ STITCH SUTURING DEVICE. THE ENDO STITCH™ SUTURING DEVICE AND SILS™ STITCH SUTURING DEVICE, WHEN USED WITH THE RELOADS, HAVE APPLICATION IN ENDOSCOPIC SURGERY FOR THE PLACEMENT OF RUNNING STITCHES IN SOFT TISSUE. THE V-LOC™ 180 ABSORBABLE RELOADS ARE INDICATED FOR SOFT TISSUE APPROXIMATION WHERE USE OF AN ABSORBABLE SUTURE IS APPROPRIATE.,STAPLES LOADING UNIT (SIGNIA™ LOADING UNIT- ARTICULATING)-THE SIGNIA™ LOADING UNITS HAVE THE SAME INTENDED US AS OF THE TRI-STAPLE™ 2.0 RELOADS. THEY HAVE APPLICATION IN ABDOMINAL, GYNAECOLOGIC, PAEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES, AND FOR TRANSECTION AND RESECTION OF PANCREAS. ,STAPLER/ LOADING UNIT(GIA™ STAPLER/CARTRIDGE WITH TRI-STAPLE™ TECHNOLOGY)-THE GIA™ STAPLER WITH TRISTAPLE™ TECHNOLOGY HAS APPLICATIONS IN ABDOMINAL AND THORACIC SURGICAL PROCEDURES FOR RESECTION, TRANSECTION AND CREATION OF ANASTOMOSIS.,STAPLES LOADING UNIT(TRI-STAPLE™ 2.0 INTELLIGENT RELOAD)-THE TRI-STAPLE™ 2.0 RELOADS HAVE APPLICATION IN ABDOMINAL, GYNAECOLOGIC, PAEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION OF TISSUE

	AND CREATION OF ANASTOMOSIS. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES, AND FOR TRANSECTION AND RESECTION OF PANCREAS. THE TRI-STAPLE™ 2.0 CURVED TIP RELOADS CAN BE USED TO BLUNT DISSECT OR SEPARATE TARGET TISSUE FROM OTHER TISSUE.,CANNULA (REUSABLE POSITIONING TROCAR SYSTEM)(VERSAONE™)-THE VERSAONE™ REUSABLE POSITIONING TROCAR SYSTEM IS INTENDED FOR USE IN A VARIETY OF GYNECOLOGIC, GENERAL, THORACIC AND UROLOGIC ENDOSCOPIC PROCEDURES TO CREATE AND MAINTAIN A PORT OF ENTRY. THE 11 MM AND 12 MM TROCAR MAY BE USED WITH OR WITHOUT VISUALIZATION FOR PRIMARY AND SECONDARY INSERTIONS,STAPLES LOADING UNIT(TRI-STAPLE 2.0 BLACK/RADIAL INTELLIGENT RELOAD)-THE TRI-STAPLE™ 2.0 RADIAL RELOADS HAVE APPLICATION IN ABDOMINAL, GYNAECOLOGIC, PAEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS, AS WELL AS APPLICATIONS DEEP IN THE PELVIS E.G. LOWER ANTERIOR RESECTION. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES, AND FOR TRANSECTION AND RESECTION OF PANCREAS.,BLADELESS/OPTICAL OBTURATOR (REUSABLE POSITIONING TROCAR SYSTEM) (VERSAONE™)-THE VERSAONE™ REUSABLE POSITIONING TROCAR SYSTEM IS INTENDED FOR USE IN A VARIETY OF GYNECOLOGIC, GENERAL, THORACIC AND UROLOGIC ENDOSCOPIC PROCEDURES TO CREATE AND MAINTAIN A PORT OF ENTRY. THE 11 MM AND 12 MM TROCAR MAY BE USED WITH OR WITHOUT VISUALIZATION FOR PRIMARY AND SECONDARY INSERTIONS. ,STAPLES LOADING UNIT (TRI-STAPLE™ 2.0 BLACK /GRAY INTELLIGENT RELOAD)-THE TRI-STAPLE™ 2.0 RELOADS HAVE APPLICATIONS IN ABDOMINAL, GYNAECOLOGIC, PAEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES, AND FOR TRANSECTION AND RESECTION OF PANCREAS. ,STAPLES LOADING UNIT(TRI-STAPLE™ 2.0 BLACK/REINFORCED INTELLIGENT RELOAD)-THE REINFORCED TRI-STAPLE™ 2.0 RELOADS HAVE APPLICATION IN ABDOMINAL, GYNAECOLOGIC, PAEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES, AND FOR TRANSECTION AND RESECTION OF PANCREAS. ,STAPLES LOADING UNIT(TRI-STAPLE™ 2.0

	GRAY/CURVED TIP INTELLIGENT RELOAD AND INTRODUCER)-THE TRI-STAPLE™ 2.0 RELOADS HAVE APPLICATIONS IN ABDOMINAL, GYNAECOLOGIC, PAEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES, AND FOR TRANSECTION AND RESECTION OF PANCREAS. THE TRI-STAPLE™ 2.0 CURVED TIP RELOADS CAN BE USED TO BLUNT DISSECT OR SEPARATE TARGET TISSUE FROM OTHER TISSUE. ,HEMOSTATIC PATCH(VERISET)-VERISET™ HEMOSTATIC PATCH IS INTENDED FOR USE IN SURGICAL PROCEDURES (EXCEPT NEUROLOGICAL, ORTHOPEDIC, OPHTHALMIC, AND RESPIRATORY) AS AN ADJUNCT TO HEMOSTASIS WHEN THE CONTROL OF CAPILLARY, VENOUS, AND ARTERIOLAR BLEEDING BY PRESSURE, LIGATURE OR OTHER CONVENTIONAL METHODS IS INEECTIVE OR IMPRACTICAL.,COATED BRAIDED SYNTHETIC ABSORBABLE SUTURE(POLYSORB™)-POLYSORB™ SUTURES ARE INDICATED FOR USE IN SOFT TISSUE APPROXIMATION OR LIGATION AND OPHTHALMIC SURGERY, BUT NOT IN CARDIOVASCULAR OR NEURAL TISSUE,MONOFILAMENT POLYBUTESTER NONABSORBABLE SUTURE(VASCUFIL™)-VASCUFILTM SUTURES ARE INDICATED FOR USE AS NON-ABSORBABLE SUTURES IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR AND OPHTHALMIC SURGERY, BUT NOT IN MICROSURGERY AND NEURAL TISSUE.,ABSORBABLE WOUND CLOSURE DEVICE(V-LOC™ 180)-V-LOC™ 180 ABSORBABLE WOUND CLOSURE DEVICES ARE INDICATED FOR SOFT TISSUE APPROXIMATION WHERE USE OF AN ABSORBABLE SUTURE IS APPROPRIATE.,NON-ABSORBABLE WOUND CLOSURE DEVICE(V-LOC™ PBT)-V-LOC™ PBT NONABSORBABLE WOUND CLOSURE DEVICES ARE INDICATED FOR SOFT TISSUE APPROXIMATION WHERE USE OF AN ABSORBABLE SUTURE IS APPROPRIATE.,MONOFILAMENT POLYGLUCONATE SYNTHETIC ABSORBABLE SUTURE(MAXON™)-MAXON™ INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,INCLUDING USE IN PEDIATRIC CARDIOVASCULAR TISSUE, WHERE GROWTH IS EXPECTED TO OCCUR, AND IN PERIPHERAL VASCULAR SURGERY.,ABSORBABLE WOUND CLOSURE DEVICE(V-LOC™ 90)-V-LOC™ 90 ABSORBABLE WOUND CLOSURE DEVICES ARE INDICATED FOR SOFT TISSUE APPROXIMATION WHERE USE OF AN ABSORBABLE SUTURE IS APPROPRIATE.,FIXATION DEVICE WITH ABSORBABLE TACKS (RELIATACK™ ARTICULATING RELOADABLE FIXATION DEVICE)-THE DEVICE IS INTENDED FOR FIXATION OF PROSTHETIC MATERIAL TO SOFT TISSUE IN VARIOUS MINIMALLY INVASIVE AND OPEN SURGICAL

	PROCEDURES SUCH AS HERNIA REPAIR.,STAPLE(ENDO GIA™ REINFORCED RELOAD WITH TRI-STAPLE™ TECHNOLOGY)-ENDO GIA™ REINFORCED RELOAD WITH TRI-STAPLETM TECHNOLOGY PRELOADED WITH POLYGLYCOLIC ACID STAPLE LINE REINFORCEMENT BAS APPLICATIONS IN ABDOMINAL, GYNECOLOGIC, PEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES, AND FOR TRANSECTION AND RESECTION OF PANCREAS.,LIGATING CLIP(LAPRO-CLIP™ AUTO SUTURE™ ABSORBABLE LIGATING CLIP CARTRIDGE)-LAPRO-CLIPTM AUTO SUTURE TM ABSORBABLE LIGATING CLIP CARTRIDGE ARE INTENDED FOR USE AS ABSORBABLE LIGATURES. LAPRO- CLIPTM AUTO SUTURETM ABSORBABLE LIGATING CLIP CARTRIDGE ARE RADIO TRANSPARENT AND WILL NOT INTERFERE WITH INTERPRETATIONS OF POSTOPERATIVE X-RAY, CT, OR MRI SCANS. THE LAPRO-CLIPTM AUTO SUTURETM ABSORBABLE LIGATING CLIP CARTRIDGE MAY BE USED FOR LIGATION OF THE CYSTIC ARTERY AND CYSTIC DUCT AND OTHER GENERAL LIGATION.,LOADING UNIT (RELIAMAX™ SINGLE USE GASTROINTESTINAL ANASTOMOSIS RELOAD)-THE RELIAMAX™ SINGLE USE GASTROINTESTINAL ANASTOMOSIS RELOAD WHEN USED WITH RELIAMAX™ REUSABLE GASTROINTESTINAL ANASTOMOSIS STAPLER HAVE APPLICATIONS IN ABDOMINAL, GYNAECOLOGICAL, PAEDIATRIC AND THORACIC SURGICAL PROCEDURES FOR RESECTION, TRANSECTION AND CREATION OF ANASTOMOSIS. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF THE PANCREAS,LIGATING LOOP WITH DELIVERY SYSTEM(SURGITIE™ AUTOSUTURE™)-THE SURGITIE™ LIGATING LOOP IS INDICATED FOR USE IN GYNECOLOGIC LAPAROSCOPY AND OTHER ABDOMINAL AND THORACIC ENDOSCOPIC PROCEDURES. IT IS APPROPRIATE FOR THE ENDOSCOPIC LIGATION OF BLOOD VESSELS AND OTHER SMALL TUBULAR STRUCTURES.,STAPLER WITH LOADING UNIT(EEA™ AUTO SUTURE™ HEMORRHOID AND PROLAPSE STAPLER WITH DST SERIES TECHNOLOGY)-THE EEA™ HEMORRHOID AND PROLAPSE STAPLER SET WITH DST SERIES™ TECHNOLOGY HAS APPLICATION THROUGHOUT THE ANAL CANAL TO PERFORM SURGICAL TREATMENT OF HEMORRHOIDAL DISEASE. THE EEA™ HEMORRHOID AND PROLAPSE STAPLER ALSO HAS APPLICATION IN THE DISTAL ALIMENTARY TRACT FOR THE CREATION OF END-TO-END AND END-TO-SIDE ANASTOMOSES. THE DST SERIES™ EEA™ STAPLER IS USED THROUGHOUT THE ALIMENTARY TRACT FOR THE CREATION OF END-TO END, END-TO SIDE, AND SIDE-TO-SIDE ANASTOMOSES IN BOTH OPEN AND LAPAROSCOPIC SURGERIES., STAPLER WITH LOADING UNIT(EEA™ ORVIL™ AUTO SUTURE™

	TRANSORAL)-THE EEA™ ORVIL™ TRANSORAL CIRCULAR STAPLER ANVIL HAS APPLICATIONS THROUGHOUT THE ALIMENTARY TRACT FOR THE CREATION OF END-TO-END, END-TO-SIDE AND SIDE-TO-SIDE ANASTOMOSES IN BOTH OPEN AND LAPAROSCOPIC SURGERIES, INCLUDING BARIATRIC SURGERY.,LOADING UNIT(ENDO GIA™ RELOAD WITH TRI-STAPLE TECHNOLOGY (ARTICULATING, CURVED TIP ARTICULATING))-THE ENDO GIA™ RADIAL RELOAD WITH TRI-STAPLE TECHNOLOGY HAS APPLICATION IN OPEN OR MINIMALLY INVASIVE GENERAL ABDOMINAL, GYNECOLOGIC AND THORACIC SURGERY FOR RESECTION AND TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS, AS WELL AS APPLICATION DEEP IN THE PELVIS, E.G. LOW ANTERIOR RESECTION. IT MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES AND FOR TRANSECTION AND RESECTION OF THE PANCREAS.,LOADING UNIT(ENDO GIA™ AUTO SUTURE™ (SINGLE USE UNIVERSAL STRAIGHT LOADING UNIT, ULTRA UNIVERSAL STAPLER AND SINGLE USE UNIVERSAL ARTICULATING LOADING UNIT))-ENDO GIA™ AUTO SUTURE UNIVERSAL STAPLER HAVE AN APPLICATION IN ABDOMINAL, GYNECOLOGIC AND THORACIC SURGERY FOR RESECTION AND TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS, LOADING UNIT(GIA PREMIUM™ AUTO SUTURE™)-THE GIA PREMIUM™ SINGLE USE LOADING UNITS (SULUS) HAVE APPLICATION IN ABDOMINAL, GYNECOLOGICAL, PEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION, AND CREATION OF ANASTOMOSIS., POLYPROPYLENE MESH(SURGIPRO™ (MONOFILAMENT AND MULTIFILAMENT))-SURGIPRO™ MESH IS INTENDED TO ASSIST IN THE REPAIR AND/OR REINFORCEMENT OF HERNIA AND OTHER FASCIAL DEFECTS REQUIRING THE ADDITIONAL SUPPORT OF A NON-ABSORBABLE MESH DURING AND AFTER WOUND HEALING.,FIXATION DEVICE WITH ABSORBABLE TACKS(ABSORBATACK™)-THE ABSORBATACK™ FIXATION DEVICE IS INTENDED FOR FIXATION OF PROSTHETIC MATERIAL TO SOFT TISSUE IN VARIOUS MINIMALLY INVASIVE AND OPEN GENERAL SURGICAL PROCEDURES LIKE AS HERNIA REPAIR,MONOFILAMENT POLYPROPYLENE NON-ABSORBABLE SUTURE(SURGIPRO™II)-SURGIPRO™II POLYPROPYLENE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC, AND NEUROLOGICAL SURGERY, SYNTHETIC MONOFILAMENT ABSORBABLE SUTURE(BIOSYN™)-BIOSYN™ SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION USE IN OPHTHALMIC SURGERY, BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL SURGERY,MONOFILAMENT

		SYNTHETIC ABSORBABLE SUTURE(CAPROSYN™)-CAPROSYN™ SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL SURGERY, MICROSURGERY, OR OPHTHALMIC SURGERY
1311	IMP/MD/2018/000207	1.License Holder Name: ESSITY INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHOPEDIC CASTING TAPE (NON-STERILE)(ARTICAST)-ARTICAST PROVIDES RIGID EXTERNAL IMMOBILIZATION FOR FRACTURES AND OTHER ORTHOPEDIC INDICATION. THE PRODUCT CAN BE USED FOR ALL CASTING REQUIREMENTS EXCEPT WHEN OEDEMA IS PRESENT, OR LIKELY TO OCCUR. VALVING THE CAST MAY BE NECESSARY ACCOMMODATE SWOLLEN TISSUE.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1312	IMP/MD/2018/000208	1.License Holder Name: M/S ZIMMER INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL KNEE REPLACEMENT(PERSONA THE PERSONALIZED KNEE SYSTEM-TIBIAL COMPONENT)-THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. THIS DEVICE IS INTENDED FOR CEMENT USE ONLY.,TOTAL KNEE REPLACEMENT(PERSONA THE PERSONALIZED KNEE SYSTEM-ARTICULAR SURFACE COMPONENT)-THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: -> RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS -> COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE -> POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. -> MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. -> THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. THIS DEVICE IS INTENDED FOR CEMENT USE ONLY.

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1313	IMP/MD/2018/000208	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED ,NO. 17, GROUND FLOOR AND MEZZANINE FLOOR, THIRUNEERMALAI ROAD, NAGALKENI, CHROMPET ,CHENNAI TAMIL NADU ,600044 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KNEE SYSTEM (PERSONA® THE PERSONALIZED KNEE SYSTEM - ARTICULAR SURFACE - MEDIAL CONGRUENT (MC))-WHEN A MECHANICAL ALIGNMENT APPROACH IS UTILIZED, THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: – RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. – COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. – POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. – MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. – THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. WHEN A KINEMATIC ALIGNMENT* APPROACH IS UTILIZED, THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: – RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. – COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. – MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. THE KINEMATIC ALIGNMENT (KA) SURGICAL TECHNIQUE MAY ONLY BE USED WITH PERSONA CR FEMORAL COMPONENTS, PERSONA CR OR UC ARTICULAR SURFACE COMPONENTS, AND CEMENTED NONPOROUS PERSONA TIBIAL COMPONENTS WITHOUT A STEM EXTENSION. POROUS COATED COMPONENTS MAY BE USED CEMENTED OR UNCEMENTED (BIOLOGICAL FIXATION). ALL OTHER FEMORAL, TIBIAL BASEPLATE, AND ALL-POLYETHYLENE (UHMWPE AND VEHXPE) PATELLA COMPONENTS ARE INDICATED FOR CEMENTED USE ONLY.

1314	IMP/MD/2018/000209	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD NEOPAK)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS,PREFILLABLE GLASS BARREL WITH NEEDLE(BD NEOPAK XSI)-COMPONENT OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS,PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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1315	IMP/MD/2018/000210	1.License Holder Name: ROCHE DIAGNOSTICS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COBAS® HBV/HCV/HIV-1 CONTROL KIT(COBAS® HBV/HCV/HIV-1 CONTROL KIT (HXV))-COBAS® HBV/HCV/HIV-1 CONTROL KIT WILL BE USED WITH THE MAIN KITS ON THE COBAS 6800/8800 SYSTEM,COBAS® 4800 HBV/HCV/HIV-1 CONTROL KIT(COBAS® 4800 HBV/HCV/HIV-1 CONTROL KIT)-COBAS® 4800 HBV/HCV/HIV-1 CONTROL KIT CONTAINS PLASMA DERIVED FROM HUMAN BLOOD. THE SOURCE MATERIAL HAS BEEN TESTED BY A LICENSED ANTIBODY TEST AND FOUND TO BE NON-REACTIVE FOR THE PRESENCE OF ANTIBODY TO HCV, ANTIBODY TO HIV-1/2, ANTIBODY TO HBSAG AND ANTIBODY TO HBC. TESTING BY PCR METHODS SHOWED NO DETECTABLE HIV-1 RNA, HIV-2 RNA, HCV RNA, AND HBV DNA. NO KNOWN TEST METHOD CAN OFFER COMPLETE ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.,COBAS® 4800 SYSTEM SPECIMEN DILUENT 2(COBAS® 4800 SYSTEM SPECIMEN DILUENT 2)-SAMPLE PREPARATION REAGENT TO DILUTE SPECIMENS (SAMPLES) PRIOR TO SAMPLE PREPARATION AND LYSIS, COBAS® AMPLIPREP/COBAS® TAQMAN® HIV-1 QUALITATIVE TEST, VERSION 2.0(COBAS® AMPLIPREP/COBAS® TAQMAN® HIV-1 QUALITATIVE TEST, VERSION 2.0)-THE COBAS® AMPLIPREP/COBAS® TAQMAN® HIV-1 QUALITATIVE TEST, VERSION 2.0 IS AN IN VITRO DIAGNOSTIC, TOTAL NUCLEIC ACID AMPLIFICATION TEST FOR THE QUALITATIVE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) DNA AND RNA (OR TOTAL NUCLEIC ACID, TNA) IN HUMAN PLASMA OR DRIED BLOOD SPOTS USING THE COBAS® AMPLIPREP INSTRUMENT FOR AUTOMATED SPECIMEN PROCESSING AND THE COBAS® TAQMAN® ANALYZER OR COBAS® TAQMAN® 48 ANALYZER FOR AUTOMATED AMPLIFICATION AND DETECTION. THE TEST IS A DIAGNOSTIC TEST, INDICATED FOR INDIVIDUALS WHO ARE SUSPECTED TO BE ACTIVELY INFECTED WITH HIV-1. DETECTION OF HIV-1 TNA IS INDICATIVE OF ACTIVE HIV INFECTION. INFANTS BORN TO MOTHERS INFECTED WITH HIV-1 MAY HAVE MATERNAL ANTIBODIES TO HIV-1, AND THE PRESENCE OF HIV-1 NUCLEIC ACID IN THE INFANT INDICATES ACTIVE HIV-1 INFECTION. IN ADULTS, THE TEST MAY BE USED AS AN AID IN THE DIAGNOSIS OF HIV-1 INFECTION.,COBAS® EGFR MUTATION TEST V2(COBAS® EGFR MUTATION TEST V2)-"THE COBAS® EGFR MUTATION TEST V2 IS A REAL-TIME PCR TEST FOR THE QUALITATIVE DETECTION OF DEFINED MUTATIONS OF THE EPIDERMAL GROWTH FACTOR RECEPTOR (EGFR) GENE IN NON-SMALL CELL LUNG CANCER (NSCLC) PATIENTS. DEFINED EGFR MUTATIONS ARE DETECTED USING DNA ISOLATED FROM FORMALIN-FIXED PARAFFIN-EMBEDDED TUMOR TISSUE

	(FFPET) OR CIRCULATING-FREE TUMOR DNA (CFDNA) FROM PLASMA DERIVED FROM EDTA ANTI-COAGULATED PERIPHERAL WHOLE BLOOD. THE TEST IS INDICATED AS A COMPANION DIAGNOSTIC TO AID IN SELECTING NSCLC PATIENTS FOR TREATMENT WITH EGFR TYROSINE KINASE INHIBITORS (INCLUDING THE TARGETED THERAPIES LISTED IN TABLE 1 BELOW) IN ACCORDANCE WITH THE APPROVED THERAPEUTIC PRODUCT LABELING: TABLE 1: DRUG: TARCEVA® (ERLOTINIB) FFPET EXON 19 DELETIONS AND L858R PLASMA EXON 19 DELETIONS AND L858R. DRUG:TAGRISSO® (OSIMERTINIB): FFPET EXON 19 DELETIONS, L858R AND T790M PLASMA:EXON 19 DELETIONS, L858R AND T790M. DRUG:IRESSA® (GEFITINIB) FFPET EXON 19 DELETIONS AND L858R PLASMA EXON 19 DELETIONS AND L858R TESTING OF PLASMA SPECIMENS IS MOST APPROPRIATE FOR CONSIDERATION IN PATIENTS FROM WHOM A TUMOR BIOPSY CANNOT BE OBTAINED. PATIENTS WHO ARE NEGATIVE FOR THESE MUTATIONS BY THIS TEST USING PLASMA SPECIMENS SHOULD BE REFLEXED TO ROUTINE TISSUE BIOPSY AND TESTING FOR EGFR MUTATIONS WITH THE FFPET SAMPLE TYPE, IF AVAILABLE. DRUG SAFETY AND EFFICACY HAVE NOT BEEN ESTABLISHED FOR THE FOLLOWING EGFR MUTATIONS ALSO DETECTED BY THE COBAS® EGFR MUTATION TEST V2: TARCEVA® (ERLOTINIB):G719X, EXON 20 INSERTIONS, T790M, S768I AND L861Q G719X, EXON 20 INSERTIONS, T790M, S768I AND L861Q TAGRISSO® (OSIMERTINIB) G719X, EXON 20 INSERTIONS, S768I, AND L861Q G719X, EXON 20 INSERTIONS, S768I, AND L861Q IRESSA® (GEFITINIB) G719X, EXON 20 INSERTIONS, T790M, S768I AND L861Q G719X, EXON 20 INSERTIONS, T790M, S768I AND L861Q THE COBAS® EGFR MUTATION TEST V2 FOR USE WITH PLASMA INCLUDES A SEMI-QUANTITATIVE MEASUREMENT OF MUTATIONS IN EXONS 18, 19, 20, AND 21 OF THE EGFR GENE. THIS MEASUREMENT, REPORTED AS A SEMI-QUANTITATIVE INDEX (SQI), CORRELATES TO THE AMOUNT OF TARGET MUTANT CFDNA IN PLASMA AND CAN BE USED TO DETERMINE CHANGES IN TARGET MUTANT CFDNA LOAD OVER TIME FOR A GIVEN PATIENT. FOR MANUAL SAMPLE PREPARATION, FFPET SPECIMENS ARE PROCESSED USING THE COBAS® DNA SAMPLE PREPARATION KIT AND PLASMA SPECIMENS ARE PROCESSED USING THE COBAS® CFDNA SAMPLE PREPARATION KIT. THE COBAS Z 480 ANALYZER IS USED FOR AUTOMATED AMPLIFICATION AND DETECTION" ,COBAS® 4800 HCV GT CONTROL KIT(COBAS® 4800 HCV GT CONTROL KIT)-COBAS® HCV GT CONTROL KIT CONTAINS PLASMA DERIVED FROM HUMAN BLOOD. THE SOURCE MATERIAL HAS BEEN TESTED BY LICENSED SEROLOGY TESTS AND FOUND TO BE NON-REACTIVE FOR ANTIBODY TO HCV, ANTIBODY TO HIV- 1/2, HBSAG AND ANTIBODY TO HBC. TESTING BY PCR METHODS SHOWED

	NO DETECTABLE HIV-1, HIV-2 RNA, HCV RNA, AND HBV DNA. NO KNOWN TEST METHOD CAN OFFER COMPLETE ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.,COBAS® CMV(COBAS® CMV)-COBAS® CMV IS AN IN-VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATIVE MEASUREMENT OF CYTOMEGALOVIRUS (CMV) DNA IN HUMAN EDTA PLASMA. COBAS® CMV IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS AND MANAGEMENT OF CMV IN SOLID ORGAN TRANSPLANT PATIENTS AND IN HEMATOPOIETIC STEM CELL TRANSPLANT PATIENTS. THE TEST CAN BE USED IN THESE POPULATIONS TO ASSESS THE NEED TO INITIATE ANTIVIRAL TREATMENT. IN PATIENTS RECEIVING ANTI-CMV THERAPY, SERIAL DNA MEASUREMENTS CAN BE USED TO ASSESS VIRAL RESPONSE TO TREATMENT. THE RESULTS FROM COBAS® CMV MUST BE INTERPRETED WITHIN THE CONTEXT OF ALL RELEVANT CLINICAL AND LABORATORY FINDINGS.,COBAS® HCV GT(COBAS® HCV GT)-COBAS® HCV GT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUALITATIVE IDENTIFICATION OF HEPATITIS C VIRUS (HCV) GENOTYPES 1 TO 6 AND GENOTYPE 1 SUBTYPES A AND B IN HUMAN EDTA PLASMA OR SERUM FROM INDIVIDUALS WITH CHRONIC HCV INFECTION, USING THE COBAS® 4800 SYSTEM: THE COBAS X 480 INSTRUMENT FOR AUTOMATED SAMPLE PROCESSING AND THE COBAS Z 480 ANALYZER FOR AUTOMATED AMPLIFICATION AND DETECTION. COBAS® HCV GT IS INTENDED FOR USE IN SELECTING INDIVIDUALS WITH CHRONIC HCV INFECTION FOR ANTIVIRAL THERAPY AND IN DETERMINING THE DURATION OF THERAPY REGIMENS ACCORDING TO THE ANTIVIRAL THERAPY PRESCRIBING INFORMATION,COBAS® DPX CONTROL KIT(COBAS® DPX CONTROL KIT)-"THE COBAS® DPX TEST IS AN IN VITRO TEST FOR THE DIRECT QUANTITATION OF PARVOVIRUS B19 GENOTYPES 1, 2, AND 3 DNA AND THE DIRECT QUALITATIVE DETECTION OF HEPATITIS A VIRUS (HAV) GENOTYPES I, II, AND III RNA IN HUMAN PLASMA. THIS TEST IS INTENDED FOR USE AS AN IN-PROCESS TEST TO QUANTIFY PARVOVIRUS B19 DNA ALONE OR TO SIMULTANEOUSLY QUANTIFY PARVOVIRUS B19 DNA AND DETECT HAV RNA IN PLASMA INTENDED FOR FURTHER MANUFACTURE COLLECTED FROM DONORS OF WHOLE BLOOD, BLOOD COMPONENTS, OR PLASMA. PLASMA FROM ALL DONORS OR MANUFACTURING POOLS MAY BE TESTED AS INDIVIDUAL SAMPLES OR IN POOLS COMPRISED OF ALIQUOTS OF INDIVIDUAL SAMPLES. THIS TEST IS NOT INTENDED FOR USE ON SAMPLES OF CORD BLOOD. THIS TEST IS NOT INTENDED FOR USE AS AN AID IN DIAGNOSIS FOR PARVOVIRUS B19 OR HAV.",COBAS® HBV (COBAS® HBV)-COBAS® HBV IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF HEPATITIS B

	VIRUS (HBV) DNA IN HUMAN EDTA PLASMA OR SERUM OF HBV-INFECTED INDIVIDUALS. THIS TEST IS INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF PATIENTS WITH CHRONIC HBV INFECTION UNDERGOING ANTI-VIRAL THERAPY. THE TEST CAN BE USED TO MEASURE HBV DNA LEVELS AT BASELINE AND DURING TREATMENT TO AID IN ASSESSING RESPONSE TO TREATMENT. THE RESULTS FROM COBAS® HBV MUST BE INTERPRETED WITHIN THE CONTEXT OF ALL RELEVANT CLINICAL AND LABORATORY FINDINGS.,COBAS® WNV CONTROL KIT(COBAS® WNV CONTROL KIT)-COBAS® WNV CONTROL KIT WILL BE USED WITH THE MAIN KITS COBAS WNV TEST , COBAS® HCV(COBAS® HCV)-COBAS® HCV IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR BOTH THE DETECTION AND QUANTITATION OF HEPATITIS C VIRUS (HCV) RNA, IN HUMAN EDTA PLASMA OR SERUM, OF HCV-INFECTED INDIVIDUALS. SAMPLES CONTAINING HCV GENOTYPE 1 TO 6 ARE VALIDATED FOR DETECTION AND QUANTITATION IN THE ASSAY. THE TEST IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF HCV INFECTION IN THE FOLLOWING POPULATIONS: INDIVIDUALS WITH ANTIBODY EVIDENCE OF HCV WITH EVIDENCE OF LIVER DISEASE, INDIVIDUALS SUSPECTED TO BE ACTIVELY INFECTED WITH HCV ANTIBODY EVIDENCE, AND INDIVIDUALS AT RISK FOR HCV INFECTION WITH ANTIBODIES TO HCV. DETECTION OF HCV RNA INDICATES THAT THE VIRUS IS REPLICATING AND THEREFORE IS EVIDENCE OF ACTIVE INFECTION. THE TEST IS INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF HCV-INFECTED PATIENTS UNDERGOING ANTI-VIRAL THERAPY. THE ASSAY MEASURES HCV RNA LEVELS AT BASELINE AND DURING TREATMENT AND CAN BE UTILIZED TO PREDICT SUSTAINED AND NON-SUSTAINED VIROLOGICAL RESPONSE TO HCV THERAPY. THE RESULTS MUST BE INTERPRETED WITHIN THE CONTEXT OF ALL RELEVANT CLINICAL AND LABORATORY FINDING.,COBAS® CFDNA SAMPLE PREPARATION KIT(COBAS® CFDNA SAMPLE PREPARATION KIT)-THE COBAS® CFDNA SAMPLE PREPARATION KIT IS USED FOR MANUAL SAMPLE PREPARATION TO ISOLATE CIRCULATING CELL-FREE DNA (CFDNA) FROM PLASMA SAMPLES.,COBAS® HIV-1(COBAS® HIV-1)-COBAS®HIV-1 IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) IN EDTA PLASMA OR FROM A COBAS® PLASMA SEPARATION CARD (PSC) DRIED PLASMA SPOT AND FOR THE QUALITATIVE DETECTION OF HIV-1 IN DRIED BLOOD SPOTS OF HIV-1-INFECTED INDIVIDUALS INCLUDING INFANTS BORN TO MOTHERS INFECTED WITH HIV-1. THE TEST IS TO BE USED WITH COBAS® 4800 SYSTEM.THIS TEST IS INTENDED FOR USE IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS OF DISEASE PROGRESSION FOR THE CLINICAL MANAGEMENT OF HIV-1-

	INFECTED PATIENTS. WHEN USED AS A QUANTITATIVE TEST, THIS TEST CAN BE USED AS AN AID IN DIAGNOSIS FOR CONFIRMATION OF HIV-1 INFECTION IN ANTIBODY REACTIVE INDIVIDUALS AND TO ASSESS PATIENT PROGNOSIS BY MEASURING THE BASELINE HIV-1 RNA LEVEL OR TO MONITOR THE EFFECTS OF ANTIRETROVIRAL THERAPY BY MEASURING CHANGES IN HIV-1 RNA LEVELS DURING THE COURSE OF ANTIRETROVIRAL TREATMENT. WHEN USED AS A QUALITATIVE TEST WITH DRIED BLOOD SPOTS, DETECTION OF HIV-1 NUCLEIC ACIDS IS INDICATIVE OF ACTIVE HIV-1 INFECTION IN INFANTS BORN TO HIV-INFECTED MOTHERS WHO HAVE MATERNAL ANTIBODIES TO HIV-1. THIS TEST CAN ALSO BE USED FOR CONFIRMATION OF HIV-1 INFECTION IN INDIVIDUALS REACTIVE FOR HIV-1 ANTIBODIES OR ANTIGENS. ,COBAS® KRAS MUTATION TEST (COBAS® KRAS MUTATION TEST)-"THE COBAS® KRAS MUTATION TEST, FOR USE WITH THE COBAS® 4800 SYSTEM, IS A REAL-TIME PCR TEST FOR THE DETECTION OF SOMATIC MUTATIONS IN CODONS 12, 13 AND 61 OF THE KRAS GENE IN DNA DERIVED FROM FORMALIN-FIXED PARAFFIN-EMBEDDED HUMAN COLORECTAL CANCER (CRC) TUMOR TISSUE. THE TEST IS INTENDED TO BE USED AS AN AID IN THE IDENTIFICATION OF CRC PATIENTS WHO SHOULD NOT BE TREATED WITH ERBITUX® (CETUXIMAB) OR WITH VECTIBIX® (PANITUMUMAB) WHEN KRAS CODON 12 OR 13 MUTATION IS DETECTED. SAFETY AND EFFICACY OF ERBITUX® (CETUXIMAB) OR VECTIBIX® (PANITUMUMAB) HAVE NOT BEEN ESTABLISHED IN PATIENTS WHOSE TUMORS HAVE CODON 61 MUTATION. SPECIMENS ARE PROCESSED USING THE COBAS® DNA SAMPLE PREPARATION KIT FOR MANUAL SAMPLE PREPARATION AND THE COBAS Z 480 ANALYZER FOR AUTOMATED AMPLIFICATION AND DETECTION.",COBAS® CMV - 96 (COBAS® CMV - 96)-"COBAS® CMV IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF CYTOMEGALOVIRUS (CMV) DNA IN HUMAN EDTA PLASMA. COBAS® CMV IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS AND MANAGEMENT OF CMV IN SOLID ORGAN TRANSPLANT PATIENTS AND IN HEMATOPOIETIC STEM CELL TRANSPLANT PATIENTS. THE TEST CAN BE USED IN THESE POPULATIONS TO ASSESS THE NEED TO INITIATE ANTIVIRAL TREATMENT. IN PATIENTS RECEIVING ANTI-CMV THERAPY, SERIAL DNA MEASUREMENTS CAN BE USED TO ASSESS VIRAL RESPONSE TO TREATMENT. THE RESULTS FROM COBAS® CMV MUST BE INTERPRETED WITHIN THE CONTEXT OF ALL RELEVANT CLINICAL AND LABORATORY FINDINGS." ,COBAS® DPX(COBAS® DPX)-THE COBAS DPX TEST IS AN IN VITRO TEST FOR THE DIRECT QUANTITATION OF PARVOVIRUS B19 GENOTYPES 1, 2, AND 3 DNA AND THE DIRECT QUALITATIVE DETECTION OF HEPATITIS A VIRUS (HAV) GENOTYPES I, II, AND III RNA IN HUMAN PLASMA. THIS TEST IS

	INTENDED FOR USE AS AN IN-PROCESS TEST TO QUANTIFY PARVOVIRUS B19 DNA ALONE OR TO SIMULTANEOUSLY QUANTIFY PARVOVIRUS B19 DNA AND DETECT HAV RNA IN PLASMA INTENDED FOR FURTHER MANUFACTURE COLLECTED FROM DONORS OF WHOLE BLOOD, BLOOD COMPONENTS, OR PLASMA. PLASMA FROM ALL DONORS OR MANUFACTURING POOLS MAY BE TESTED AS INDIVIDUAL SAMPLES OR IN POOLS COMPRISED OF ALIQUOTS OF INDIVIDUAL SAMPLES. THIS TEST IS NOT INTENDED FOR USE ON SAMPLES OF CORD BLOOD. THIS TEST IS NOT INTENDED FOR USE AS AN AID IN DIAGNOSIS FOR PARVOVIRUS B19 OR HAV.,COBAS® CMV CONTROL KIT(COBAS® CMV CONTROL KIT)-THE COBAS® CMV CONTROL KIT IS TO BE USED IN CONJUNCTION WITH THE COBAS® CMV QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEMS COBAS® CMV QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 4800 SYSTEM ,COBAS® WNV - 96 (COBAS® WNV - 96)-"COBAS® WNV FOR USE ON COBAS® 6800 AND COBAS® 8800 SYSTEMS IS A QUALITATIVE IN VITRO NUCLEIC ACID SCREENING TEST FOR THE DIRECT DETECTION OF WEST NILE VIRUS (WNV) RNA IN HUMAN PLASMA. THIS TEST IS INTENDED FOR USE TO SCREEN DONOR SAMPLES FOR WNV RNA IN PLASMA SAMPLES FROM INDIVIDUAL HUMAN DONORS, INCLUDING DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS, AS WELL AS OTHER LIVING DONORS. THIS TEST IS ALSO INTENDED FOR USE TO SCREEN ORGAN AND TISSUE DONORS WHEN DONOR SAMPLES ARE OBTAINED WHILE THE DONOR'S HEART IS STILL BEATING OR FROM CADAVERIC (NON-HEART BEATING) DONORS. PLASMA FROM ALL DONORS MAY BE SCREENED AS INDIVIDUAL SAMPLES. FOR DONATIONS OF WHOLE BLOOD AND BLOOD COMPONENTS, PLASMA SAMPLES MAY BE TESTED INDIVIDUALLY OR IN POOLS COMPRISED OF NOT MORE THAN SIX INDIVIDUAL SAMPLES. FOR ALL OTHER DONORS, SAMPLES MAY ONLY BE SCREENED AS INDIVIDUAL SAMPLES. THIS TEST IS NOT INTENDED FOR USE AS AN AID IN DIAGNOSIS OF WNV INFECTION. THIS TEST IS NOT INTENDED FOR USE ON SAMPLES OF CORD BLOOD." ,COBAS OMNI SPECIMEN DILUENT(COBAS OMNI SPECIMEN DILUENT)-SAMPLE PREPARATION REAGENT TO DILUTE SPECIMENS (SAMPLES) PRIOR TO SAMPLE PREPARATION AND LYSIS.,COBAS® MTB POSITIVE CONTROL KIT(COBAS® MTB POSITIVE CONTROL KIT)-COBAS® MTB POSITIVE CONTROL KIT IS TO BE USED IN CONJUNCTION WITH THE COBAS® MTB TEST ON COBAS 6800 AND COBAS 8800 SYSTEM, COBAS® MICROBIAL INACTIVATION SOLUTION (MIS)(COBAS® MICROBIAL INACTIVATION SOLUTION (MIS))-COBAS® MICROBIAL INACTIVATION SOLUTION (MIS) IS TO USED IN CONJUCTION WITH COBAS MTB/MAI/MTB RIF NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEMS,COBAS OMNI WASH REAGENT(COBAS

	OMNI WASH REAGENT)-SAMPLE PREPARATION REAGENT THAT REMOVES UNBOUND SUBSTANCES AND IMPURITIES AND REDUCES THE SALT CONCENTRATION BEFORE PCR IS INITIATED,COBAS® HBV QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEMS(COBAS® HBV QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEMS)-COBAS® HBV IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF HEPATITIS B VIRUS (HBV) DNA IN HUMAN EDTA PLASMA OR SERUM OF HBV-INFECTED INDIVIDUALS. THIS TEST IS INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF PATIENTS WITH CHRONIC HBV INFECTION UNDERGOING ANTI-VIRAL THERAPY. THE TEST CAN BE USED TO MEASURE HBV DNA LEVELS AT BASELINE AND DURING TREATMENT TO AID IN ASSESSING RESPONSE TO TREATMENT. THE RESULTS FROM COBAS® HBV MUST BE INTERPRETED WITHIN THE CONTEXT OF ALL RELEVANT CLINICAL AND LABORATORY FINDINGS.,COBAS® MTB-RIF/INH(COBAS® MTB-RIF/INH)-COBAS® MTB-RIF/INH FOR USE ON THE COBAS® 6800/8800 SYSTEMS IS AN AUTOMATED, QUALITATIVE IN VITRO DIAGNOSTIC TEST, THAT UTILIZES REAL-TIME POLYMERASE CHAIN REACTION (PCR), FOR THE DIRECT DETECTION OF RIFAMPICIN-RESISTANCE ASSOCIATED MUTATIONS OF THE RPOB GENE, AND ISONIAZID-RESISTANCE ASSOCIATED MUTATIONS IN THE KATG AND INHA GENES, OF MYCOBACTERIUM TUBERCULOSIS, FROM HUMAN RESPIRATORY SPECIMENS. THE TEST IS INTENDED FOR USE ON EITHER ACID-FAST BACILLI (AFB) SMEAR-POSITIVE OR SMEAR-NEGATIVE, RAW SPUTUM, AND DIGESTED AND DECONTAMINATED (N-ACETYL-L-CYSTEINE/ NAOH TREATED) SPUTUM AND BRONCHIAL ALVEOLAR LAVAGE (BAL) SAMPLES, THAT TESTED POSITIVE FOR MYCOBACTERIUM TUBERCULOSIS COMPLEX (MTBC) BY COBAS® MTB. THIS TEST IS INTENDED FOR USE IN CONJUNCTION WITH CULTURE AND DRUG SUSCEPTIBILITY TESTING, AND AS A REFLEX TEST TOGETHER WITH COBAS® MTB, AS AN AID IN THE DIAGNOSIS OF INFECTION WITH A MULTIDRUG RESISTANT M. TUBERCULOSIS (MDR-TB).,COBAS® HCV QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEMS (COBAS® HCV QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEMS)-COBAS® HCV IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR BOTH THE DETECTION AND QUANTITATION OF HEPATITIS C (HCV) RNA, GENOTYPES 1 TO 6, IN HUMAN EDTA PLASMA OR SERUM OF HCV-INFECTED INDIVIDUALS. COBAS® HCV IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF HCV INFECTION IN THE FOLLOWING POPULATIONS: INDIVIDUALS WITH ANTIBODY EVIDENCE OF HCV WITH EVIDENCE OF LIVER DISEASE, INDIVIDUALS SUSPECTED TO BE ACTIVELY INFECTED WITH HCV ANTIBODY EVIDENCE, AND

	INDIVIDUALS AT RISK FOR HCV INFECTION WITH ANTIBODIES TO HCV. DETECTION OF HCV RNA INDICATES THAT THE VIRUS IS REPLICATING AND THEREFORE IS EVIDENCE OF ACTIVE INFECTION. THE TEST IS INTENDED FOR USE IN THE MANAGEMENT OF PATIENTS WITH CHRONIC HCV IN CONJUNCTION WITH CLINICAL AND LABORATORY MARKERS OF INFECTION. THE TEST CAN BE USED TO PREDICT THE PROBABILITY OF SUSTAINED VIROLOGIC RESPONSE (SVR) EARLY DURING A COURSE OF ANTIVIRAL THERAPY, AND TO ASSESS VIRAL RESPONSE TO ANTIVIRAL TREATMENT (RESPONSE GUIDED THERAPY) AS MEASURED BY CHANGES OF HCV RNA LEVELS IN SERUM OR EDTA PLASMA. THE RESULTS MUST BE INTERPRETED WITHIN THE CONTEXT OF ALL RELEVANT CLINICAL AND LABORATORY FINDING.,COBAS® MPX CONTROL KIT(COBAS® MPX CONTROL KIT)-THE COBAS MPX CONTROL KIT IS TO BE USED IN CONJUNCTION WITH THE COBAS® MPX TEST ON COBAS® 6800 AND COBAS® 8800 SYSTEMS,COBAS® MPX(COBAS® MPX)-THE COBAS® MPX TEST, FOR USE ON COBAS® 6800 AND COBAS® 8800 SYSTEMS IS A QUALITATIVE IN VITRO TEST FOR THE DIRECT DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV1) GROUP M RNA, HIV-1 GROUP O RNA, HUMAN IMMUNODEFICIENCY VIRUS TYPE 2 (HIV-2) RNA, HEPATITIS C VIRUS (HCV) RNA, AND HEPATITIS B VIRUS (HBV) DNA IN HUMAN PLASMA AND SERUM. THIS TEST IS INTENDED FOR USE TO SCREEN DONOR SAMPLES FOR HIV-1 GROUP M RNA, HIV-1 GROUP O RNA, HIV-2 RNA, HCV RNA, AND HBV DNA IN PLASMA AND SERUM SAMPLES FROM INDIVIDUAL HUMAN DONORS, INCLUDING DONORS OF WHOLE BLOOD, BLOOD COMPONENTS, AND OTHER LIVING DONORS. THIS TEST IS ALSO INTENDED FOR USE TO SCREEN ORGAN AND TISSUE DONORS WHEN DONOR SAMPLES ARE OBTAINED WHILE THE DONOR'S HEART IS STILL BEATING AND IN TESTING OF CADAVERIC (NON-HEART BEATING) DONORS. PLASMA AND SERUM FROM ALL DONORS MAY BE SCREENED AS INDIVIDUAL SAMPLES. FOR DONATIONS OF WHOLE BLOOD AND BLOOD COMPONENTS, PLASMA AND SERUM SAMPLES MAY BE TESTED INDIVIDUALLY OR PLASMA MAY BE TESTED IN POOLS COMPRISED OF ALIQUOTS OF INDIVIDUAL SAMPLES. FOR DONATIONS FROM CADAVERIC (NON-HEART BEATING) ORGAN AND TISSUE DONORS, SAMPLES MAY ONLY BE SCREENED AS INDIVIDUAL SAMPLE. FOR AN INDIVIDUAL SAMPLE, RESULTS ARE SIMULTANEOUSLY DETECTED AND DISCRIMINATED FOR HIV, HCV, AND HBV. THE COBAS® MPX TEST CAN BE CONSIDERED A SUPPLEMENTAL TEST THAT CONFIRMS HIV INFECTION FOR SAMPLES THAT ARE REPEATEDLY REACTIVE ON A CE-IVD TEST FOR ANTIBODIES TO HIV AND REACTIVE ON THE COBAS® MPX TEST. THE COBAS® MPX TEST CAN BE CONSIDERED A SUPPLEMENTAL TEST THAT CONFIRMS HCV INFECTION FOR

	SAMPLES THAT ARE REPEATEDLY REACTIVE ON A CE-IVD TEST FOR ANTIBODIES TO HCV AND REACTIVE ON THE COBAS® MPX TEST. THE COBAS® MPX TEST CAN BE CONSIDERED A SUPPLEMENTAL TEST THAT CONFIRMS HBV INFECTION FOR SAMPLES THAT ARE REPEATEDLY REACTIVE ON A CE-IVD TEST FOR HEPATITIS B SURFACE ANTIGEN AND REACTIVE ON THE COBAS® MPX TEST. THIS TEST IS NOT INTENDED FOR USE AS AN AID IN DIAGNOSIS OF INFECTION WITH HIV, HCV, OR HBV.,COBAS® HIV-1 QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEMS (COBAS® HIV-1 QUANTITATIVE NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEMS)-COBAS® HIV-1 IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUANTITATION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) IN EDTA PLASMA OR FROM A COBAS® PLASMA SEPARATION CARD (PSC) DRIED PLASMA SPOT OF HIV-1-INFECTED INDIVIDUALS. THIS TEST IS INTENDED FOR USE IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS FOR THE CLINICAL MANAGEMENT OF HIV-1-INFECTED PATIENTS. THIS TEST CAN BE USED FOR CONFIRMATION OF HIV-1 INFECTION IN ANTIBODY REACTIVE INDIVIDUALS AND TO ASSESS PATIENT PROGNOSIS BY MEASURING THE BASELINE HIV-1 LEVEL OR TO MONITOR THE EFFECTS OF ANTIRETROVIRAL THERAPY BY MEASURING CHANGES IN HIV-1 RNA LEVELS DURING THE COURSE OF ANTIRETROVIRAL TREATMENT.,COBAS OMNI LYSIS REAGENT(COBAS OMNI LYSIS REAGENT)-SAMPLE PREPARATION PROCESS TO LYSE VIRUSES, DENATURE PROTEINS AND INACTIVE NUCLEASES.,COBAS® BUFFER NEGATIVE CONTROL KIT(COBAS® BUFFER NEGATIVE CONTROL KIT)-NEGATIVE CONTROL KIT FOR COBAS DPX TEST,COBAS® HEV CONTROL KIT(COBAS® HEV CONTROL KIT)-COBAS® HEV CONTROL KIT WILL BE USED WITH THE MAIN KITS COBAS® HEV - 96 ,COBAS® MAI(COBAS® MAI)-COBAS® MAI FOR USE ON THE COBAS® 6800/8800 SYSTEMS IS AN AUTOMATED, QUALITATIVE IN VITRO DIAGNOSTIC TEST, THAT UTILIZES REAL-TIME POLYMERASE CHAIN REACTION (PCR), FOR THE DIRECT DETECTION AND DIFFERENTIATION OF MYCOBACTERIUM AVIUM AND MYCOBACTERIUM INTRACELLULARE DNA IN HUMAN RESPIRATORY SPECIMENS INCLUDING INACTIVATED RAW SPUTUM, AND INACTIVATED DIGESTED AND DECONTAMINATED (N-ACETYL-L-CYSTEINE/NAOH [NALC-NAOH]-TREATED) SPUTUM INACTIVATED, DIGESTED AND DECONTAMINATED (NALC-NAOH-TREATED) BRONCHOALVEOLAR LAVAGE (BAL) SAMPLES. THIS TEST IS INTENDED FOR USE IN CONJUNCTION WITH CULTURE AS AN AID IN THE DIAGNOSIS OF M. AVIUM-INTRACELLULARE COMPLEX (MAC) INFECTION.,COBAS® MAI POSITIVE CONTROL KIT(COBAS® MAI

	POSITIVE CONTROL KIT)-COBAS® MAI POSITIVE CONTROL KIT IS TO BE USED IN CONJUNCTION WITH THE COBAS® MAI NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEMS,COBAS OMNI MGP REAGENT(COBAS OMNI MGP REAGENT)-THE MAGNETIC GLASS PARTICLES (MGP) REAGENT IS A SAMPLE PREPARATION REAGENT USED TO BIND THE RELEASED NUCLEIC ACIDS RELEASED BY THE ADDITION OF OROTEINASE AND LYSIS REAGENT TO THE SAMPLE., COBAS® MTB(COBAS® MTB)-COBAS® MTB FOR USE ON THE COBAS® 6800/8800 SYSTEMS IS AN AUTOMATED, QUALITATIVE IN VITRO DIAGNOSTIC TEST, THAT UTILIZES REAL-TIME POLYMERASE CHAIN REACTION (PCR), FOR THE DIRECT DETECTION OF MYCOBACTERIUM TUBERCULOSIS COMPLEX (MTBC) DNA IN EITHER ACID-FAST BACILLI (AFB) SMEAR-POSITIVE OR SMEAR-NEGATIVE, HUMAN RESPIRATORY SPECIMENS; INCLUDING RAW SPUTUM, AND DIGESTED AND DECONTAMINATED (N-ACETYL-L-CYSTEINE/NAOH [NALC-NAOH]-TREATED) SPUTUM AND BRONCHOALVEOLAR LAVAGE (BAL) SAMPLES. THIS TEST IS FOR USE WITH SPECIMENS FROM PATIENTS WHO ARE SUSPECTED OF MYCOBACTERIUM TUBERCULOSIS INFECTION, AND WHO ARE NOT TAKING ANTITUBERCULOSIS THERAPY. THIS TEST IS INTENDED FOR THE AID OF PULMONARY TUBERCULOSIS DIAGNOSIS, AND IN CONJUNCTION WITH CULTURE AND OTHER LABORATORY FINDINGS, AS WELL AS CLINICAL SIGNS AND SYMPTOMS.,COBAS® MTB-RIF/INH POSITIVE CONTROL KIT(COBAS® MTB-RIF/INH POSITIVE CONTROL KIT)-COBAS® MTB-RIF/INH POSITIVE CONTROL KIT IS TO BE USED IN CONJUNCTION WITH COBAS® MTB-RIF/INH NUCLEIC ACID TEST FOR USE ON THE COBAS® 6800/8800 SYSTEMS,COBAS® DNA SAMPLE PREPARATION KIT(COBAS® DNA SAMPLE PREPARATION KIT)-THE COBAS® DNA SAMPLE PREPARATION KIT IS USED FOR MANUAL SAMPLE PREPARATION TO ISOLATE GENOMIC DNA FROM FORMALIN-FIXED PARAFFIN-EMBEDDED TUMOR TISSUE (FFPET) SAMPLES., COBAS® HEV - 96(COBAS® HEV - 96)-"THE COBAS® HEV TEST FOR USE ON COBAS® 6800 AND COBAS® 8800 SYSTEMS IS A QUALITATIVE IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE DIRECT DETECTION OF HEPATITIS E VIRUS (HEV) RNA (GENOTYPES 1-4) IN HUMAN PLASMA. THIS TEST IS INTENDED FOR USE TO SCREEN DONOR SAMPLES FOR HEV RNA IN PLASMA SAMPLES FROM INDIVIDUAL HUMAN DONORS, INCLUDING DONORS OF WHOLE BLOOD, BLOOD COMPONENTS (RED CELLS, PLATELETS, AND PLASMA), AND OTHER LIVING DONORS. PLASMA FROM ALL DONORS MAY BE SCREENED AS INDIVIDUAL SAMPLES. FOR DONATIONS OF WHOLE BLOOD AND BLOOD COMPONENTS, PLASMA SAMPLES MAY BE TESTED INDIVIDUALLY OR PLASMA MAY BE TESTED IN POOLS COMPRISED OF ALIQUOTS OF INDIVIDUAL SAMPLES. THIS TEST IS

	NOT INTENDED FOR USE ON SAMPLES OF CORD BLOOD. THIS TEST IS NOT INTENDED FOR USE AS AN AID IN DIAGNOSIS FOR HEV." , COBAS® 4800 BRAF V600 MUTATION TEST(COBAS® 4800 BRAF V600 MUTATION TEST)-THE PRIMARY USE OF THE COBAS® 4800 BRAF V600 MUTATION TEST IS THE DETECTION OF THE BRAF V600 MUTATIONS IN DNA EXTRACTED FROM FORMALIN-FIXED, PARAFFIN-EMBEDDED HUMAN MELANOMA AND PAPILLARY THYROID CARCINOMA (PTC) TISSUE. IN MELANOMA, IT IS INTENDED TO BE USED AS AN AID IN SELECTING PATIENTS WHOSE TUMORS CARRY BRAF V600 MUTATIONS FOR TREATMENT WITH ZELBORAF (VEMURAFENIB).

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1316	IMP/MD/2018/000213	1.License Holder Name: INSTRUMENTATION LABORATORY INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD GAS CARTRIDGE (GEM 3/3.5K BG/ISE 150/300/450 TEST IQM PAK)(GEM PREMIER 3500 IQM BG/LYTES 150/300/450)-SENSOR AND REAGENT CARTRIDGE FOR IL GEM PREMIER 3500/3000.THE GEM PREMIER 3500 SYSTEM WITH INTELLIGENT QUALITY MANAGEMENT (IQM) SIMPLIFIES AND STANDARDIZES WHOLE BLOOD TESTING WHILE DELIVERING RAPID, QUALITY RESULTS IN THE LABORATORY OR AT THE POINT-OF-CARE,BLOOD GAS QUALITY CONTROL (CONTRILL 9 MULTI-PAK)(CONTRILL 9 MULTI-PAK)-QUALITY CONTROL MATERIAL AVAILABLE IN THREE FORMULATIONS TO SIMULATE CLINICALLY SIGNIFICANT CONDITIONS OF ACID BASE, ELECTROLYTES, GLUCOSE AND LACTATE BALANCE.,BLOOD GAS QUALITY CONTROL (CRIT CHECK MULTILVL GEM)(CRIT CHECK MULTILEVEL (15 X 2 X 3ML))-QUALITY CONTROL MATERIAL AVAILABLE IN TWO FORMULATIONS INTENDED TO VERIFY THAT THE INSTRUMENT AND CARTRIDGE ARE OPERATING ACCORDING TO THEIR PERFORMANCE SPECIFICATIONS., BLOOD GAS CARTRIDGE (GEM 3K BG/ISE/GL 150/300/450/600 TEST CARTRIDGE)(GEM PREMIER 3000 PAK FOR BLOOD GAS/ HCT/LYTES/GLUCOSE/LACTATE 150/300/450/600 SAMPLE SIZE)-SENSOR AND REAGENT CARTRIDGE FOR IL GEM PREMIER 3000 IN - THE GEM PREMIER 3000 SYSTEM WITH INTELLIGENT QUALITY MANAGEMENT (IQM) SIMPLIFIES AND STANDARDIZES WHOLE BLOOD TESTING WHILE DELIVERING RAPID, QUALITY RESULTS IN THE LABORATORY OR AT THE POINT-OF-CARE,BLOOD GAS CARTRIDGE (GEM 3K BG/ISE 075/150/300/450/600 TEST CARTRIDGE)(GEM PREMIER 3000 PAK FOR BLOOD GAS/HCT/LYTES 75/150/300/450/600 SAMPLE SIZE)-SENSOR AND REAGENT CARTRIDGE FOR IL GEM PREMIER 3000 IN - THE GEM PREMIER 3000 SYSTEM WITH INTELLIGENT QUALITY MANAGEMENT (IQM) SIMPLIFIES AND STANDARDIZES WHOLE BLOOD TESTING WHILE DELIVERING RAPID, QUALITY RESULTS IN THE LABORATORY OR AT THE POINT-OF-CARE,CLINICAL CHEMISTRY SYSTEM (NA/K/CL SOLNS PACK)(SOLUTION PACK-ILYTE NA/K/CL - ME002112)-SOLUTION PACK FOR USE WITH THE ILYTE ANALYZER NA+/K+/CL,CLINICAL CHEMISTRY SYSTEM (NA/K/LI SOLN PACK ILYTE)(SOLUTION PACK-ILYTE NA/K/LI - ME002115)-SOLUTION PACK FOR USE WITH THE ILYTE ANALYZER NA+/K+/LI,CLINICAL CHEMISTRY SYSTEM (NA/K/CA/PH SOLNS PACK ILYTE 800ML)(SOLUTION PACK-ILYTE NA/K/CA/PH - ME002123)-SOLUTION PACK FOR USE WITH THE ILYTE ANALYZER NA+/K+/CA++/PH,CLINICAL CHEMISTRY CONTROL (TRI-LEVEL CONTROL KIT)(QUALITY CONTROL KIT - ME002816)-QUALITY

	CONTROLS FOR USE AS AN AID IN THE EVALUATION OF PERFORMANCE OF THE ILYTE ANALYZERS,BUFFERED WASH SOLUTION IVD (FLUSH SOLUTION)(FLUSH SOLUTION)-FLUSH SOLUTION FOR USE ON ALL MODELS OF ILYTE ANALYZERS,CLINICAL CHEMISTRY SYSTEM (SOLUTION PACK-ILYTE NA/K)(SOLUTIONS PACK - ILYTE NA/K)-SOLUTION PACK FOR USE WITH THE ILYTE ANALYZER NA+/K+,BUFFERED SAMPLE DILUENT IVD (CALCIUM RINSE SOLUTION KIT)(CALCIUM RINSE SOLUTION KIT)-RINSE SOLUTION FOR USE WITH ILYTE ANALYZER NA/K/CA/PH,BUFFERED WASH SOLUTION IVD (INTERNAL FILLING SOLUTION)(INTERNAL FILLING SOLUTION)-SOLUTIONS FOR ELECTRODES FOR USE WITH ILYTE ANALYZER,BUFFERED SAMPLE DILUENT IVD (URINE DILUENT) (URINE DILUENT)-DILUENT FOR URINE SPECIMENS FOR USE WITH ILYTE ANALYZER,BUFFERED WASH SOLUTION IVD (DAILY CLEANING SOLUTION)(DAILY CLEANING SOLUTION)-SOLUTION TO REMOVE THE PROTEINS DEPOSITED ON FLUID PATH,CLINICAL CHEMISTRY SYSTEM (QUALITY CONTROL KIT)(QUALITY CONTROL KIT (BI-LEVEL) ME002814)-QUALITY CONTROL MATERIAL TO VERIFY THE ACCURACY AND PRECISION FOR USE WITH ILYTE ANALYZER . ILYTETM SYSTEMS MEASURE ELECTROLYTES IN ONLY ONE MINUTE FROM A SINGLE WHOLE BLOOD, PLASMA OR SERUM SAMPLE. URINE SAMPLES IN JUST 90 SECONDS.,HEMOSIL CLEANING AGENT (CLEAN B)(CRITICAL CARE/HEMOSIL CLEANING AGENT)-TO DECONTAMINATE ANALYZERS WHEN SUSPECTED INFECTED SAMPLES HAVE BEEN ANALYZED,BLOOD GAS QUALITY CONTROL (GEM CVP 3/4HCT GEM 4K 10 X 1.8 ML)(GEM CVP (CALIBRATION VALUATION PRODUCT) 3/4 HEMATOCRIT)-EXTERNAL CALIBRATION VALUATION PRODUCT USED TO COMPLETE THE CALIBRATION PROCESS OF THE GEM PREMIER 3500/3000 AND GEM PREMIER 4000 ANALYZERS PRIOR TO USE WITH PATIENT SAMPLES.,BLOOD GAS QUALITY CONTROL (GEM CVP 2 WITH CO-OX GEM 4K 10 X 1.8 ML)(GEM CVP (CALIBRATION VALUATION PRODUCT) 2 WITH CO-OX)-EXTERNAL CALIBRATION VALUATION PRODUCT USED TO COMPLETE THE CALIBRATION PROCESS OF THE GEM PREMIER 3500/3000 AND GEM PREMIER 4000 ANALYZERS PRIOR TO USE WITH PATIENT SAMPLES.,BLOOD GAS QUALITY CONTROL (GEM CVP 1 WITH CO-OX)(GEM CVP 1 WITH CO-OX GEM CVP (CALIBRATION VALUATION PRODUCT) 1 WITH CO-OX)-EXTERNAL CALIBRATION VALUATION PRODUCT USED TO COMPLETE THE CALIBRATION PROCESS OF THE GEM PREMIER 3500/3000 AND GEM PREMIER 4000 ANALYZERS PRIOR TO USE WITH PATIENT SAMPLES,BLOOD GAS CARTRIDGE GEM PREMIER 4000-150/300/450/600-30DAY(PH, PCO2, PO2, NA+, K+, CA++, CL-, GLU, LAC, HCT, THB, O2HB, COHB, HHB, METHB, SO2 CARTRIDGE - 30 DAYS 150/300/450/600 SAMPLE SIZE)-SENSOR AND REAGENT

		CARTRIDGE FOR USE WITH THE IL GEM PREMIER 4000 ANALYZER. THE GEM PREMIER 4000 SYSTEM WITH INTELLIGENT QUALITY MANAGEMENT (IQM) SIMPLIFIES AND STANDARDIZES WHOLE BLOOD TESTING WHILE DELIVERING RAPID, QUALITY RESULTS IN THE LABORATORY OR AT THE POINT-OF-CARE,BLOOD GAS QUALITY CONTROL (GEM CVP GEM 4X5X2.5ML MULTIPAK)(GEM CVP MULTIPAK (4 X 5 X 2.5ML))-FOR VERIFICATION OF GEM PREMIER 3500 AND 3000 IQM® CARTRIDGES PRIOR TO USE WITH PATIENT SAMPLES., BLOOD GAS CARTRIDGE (GEM 3/3.5K BG/ISE/GL 150/300/450/600 TEST IQM PAK)(GEM PREMIER 3500 IQM BG/LYTES/GL 150/300/450/600)-SENSOR AND REAGENT CARTRIDGE FOR IL GEM PREMIER 3500/3000.THE GEM PREMIER 3500 SYSTEM WITH INTELLIGENT QUALITY MANAGEMENT (IQM) SIMPLIFIES AND STANDARDIZES WHOLE BLOOD TESTING WHILE DELIVERING RAPID, QUALITY RESULTS IN THE LABORATORY OR AT THE POINT-OF-CARE
1317	IMP/MD/2018/000214	1.License Holder Name: BHARAT SERUMS AND VACCINES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QUALITATIVE IMMUNOCHROMATOGRAPHIC DIPSTICK TEST FOR DETECTING THE PRESENCE OF PHOSPHORYLATED IGFBP-1 (INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN-1) IN CERVICAL SECRETIONS DURING PREGNANCY.(ACTIM PARTUS KIT)-ACTIM® PARTUS TEST IS A VISUALLY INTERPRETED, QUALITATIVE IMMUNOCHROMATOGRAPHIC DIPSTICK TEST FOR DETECTING THE PRESENCE OF PHOSPHORYLATED IGFBP-1 (INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN-1) IN CERVICAL SECRETIONS DURING PREGNANCY. THE TEST IS INTENDED FOR PROFESSIONAL USE TO HELP PREDICT THE RISK OF PRETERM OR IMMINENT DELIVERY WHEN FETAL MEMBRANES ARE INTACT.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1318	IMP/MD/2018/000215	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUCTION AND IRRIGATION DEVICE(SURGIWAND II AUTO SUTURE SUCTION AND IRRIGATION DEVICE)-THE SURGIWAND™ DEVICE IS DESIGNED FOR INTRODUCTION AND USE THROUGH ALL APPROPRIATELY SIZED COVIDIEN™ TROCAR SLEEVES OR LARGER SIZED TROCAR SLEEVES WITH THE USE OF A CONVERTER. THE DEVICE IS INTENDED FOR USE IN LAPAROSCOPIC PROCEDURES AS A MULTI-PURPOSE OPERATING TOOL WITH IRRIGATION AND SUCTION CAPABILITIES.,STAPLER/ LOADING UNIT(TA AUTO SUTURE STAPLER/ LOADING UNIT WITH DST SERIES TECHNOLOGY)-TA™ SINGLE USE LOADING UNIT WITH DST SERIES™ TECHNOLOGY HAS APPLICATIONS IN ABDOMINAL, GYNECOLOGICAL, PEDIATRIC AND THORACIC SURGICAL PROCEDURES FOR RESECTION OR TRANSECTION OF TISSUE., LOADING UNIT(ENDO GIA™ RELOAD WITH TRI-STAPLE TECHNOLOGY (ARTICULATING,GRAY/ CURVED TIP ARTICULATING))-THE ENDO GIA™ ULTRA UNIVERSAL SHORT, ENDO GIA™ ULTRA UNIVERSAL AND ENDO GIA™ ULTRA UNIVERSAL XL STAPLERS HAVE APPLICATIONS IN ABDOMINAL, GYNECOLOGIC, PEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION AND CREATION OF ANASTOMOSIS. IT MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES. THE ENDO GIA™ ULTRA UNIVERSAL SHORT, ENDO GIA™ ULTRA UNIVERSAL AND ENDO GIA™ ULTRA UNIVERSAL XL STAPLERS WHEN USED WITH THE ENDO GIA™ CURVED TIP SINGLE USE RELOADS CAN BE USED TO BLUNT DISSECT OR SEPARATE TARGET TISSUE FROM OTHER TISSUE. ,LOADING UNIT(TA PREMIUM AUTO SUTURE VASCULAR LOADING UNIT)-TA PREMIUM™ SINGLE USE VASCULAR LOADING UNIT FOR USE WITH TA PREMIUM™ REUSABLE STAPLER (30MM) HAS APPLICATION IN ABDOMINAL, GYNECOLOGICAL, PEDIATRIC AND THORACIC SURGERY FOR RESECTION AND TRANSACTION OF TISSUE,STAPLER/LOADING UNIT(TRI-STAPLE™ 2.0 GRAY INTELLIGENT RELOAD)-THE TRI-STAPLE™ 2.0 INTELLIGENT RELOADS HAVE APPLICATION IN ABDOMINAL, GYNAECOLOGIC, PAEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES, AND FOR TRANSECTION AND RESECTION OF PANCREAS. THE TRI-STAPLE™ 2.0 CURVED TIP INTELLIGENT RELOADS CAN BE USED TO BLUNT DISSECT OR SEPARATE TARGET TISSUE FROM OTHER TISSUE., FIXATION DEVICE(PROTACK AUTOSUTURE FIXATION DEVICES)-THE AUTOSUTURE™ PROTACK™ 5 MM INSTRUMENT HAS APPLICATION IN

	ENDOSCOPIC SURGERY PROCEDURES FOR FIXATION OF PROSTHETIC MATERIAL AND APPROXIMATION OF TISSUE IN VARIOUS SURGICAL SPECIALTIES, SUCH AS THE REPAIR OF HERNIAL DEFECTS.,ACCESS AND DISSECTOR SYSTEM(SPACEMAKER PRO)-THE SPACEMAKER PRO DISSECTION BALLOON IS PRIMARILY INDICATED FOR PATIENTS UNDERGOING LAPAROSCOPIC SURGERY REQUIRING TISSUE SEPARATION OF THE EXTRAPERITONEAL SPACE. THE SPACEMAKER PRO BLUNT TIP TROCAR IS INTENDED FOR USE IN ESTABLISHING A PORT OF ACCESS FOR INSERTION OF ENDOSCOPIC INSTRUMENTS INTO THE ABDOMINAL CAVITY OR EXTRAPERITONEAL SPACE IN ABDOMINAL AND EXTRAPERITONEAL SURGERY. THE SPACEMAKER™ PRO STRUCTURAL BALLOON TROCAR IS PRIMARILY INDICATED FOR PATIENTS UNDERGOING LAPAROSCOPIC SURGICAL PROCEDURES REQUIRING A SEALED PORT OF ACCESS AND/OR TISSUE RETRACTION. THIS IS ALSO INDICATED IN PATIENTS UNDERGOING LAPAROSCOPIC SURGERY REQUIRING A SEALED PORT OF ACCESS AND/OR TISSUE SEPARATION IN EXTRAPERITONEAL PROCEDURES, SUCH AS IN HERNIA REPAIR, LYMPHADENECTOMY OR BLADDER NECK SUSPENSION PROCEDURES. ,STAPLER/ LOADING UNIT(GIA AUTOSUTURE STAPLER/ LOADING UNIT WITH DST SERIES TECHNOLOGY)-THE AUTO SUTURE™ GIA™ RELOADABLE STAPLERS HAVE APPLICATIONS IN ABDOMINAL, GYNECOLOGICAL, PEDIATRIC AND THORACIC SURGICAL PROCEDURES FOR RESECTION, TRANSECTION AND CREATION OF ANASTOMOSIS., STAPLER/LOADING UNIT(TRI-STAPLE™ 2.0 CURVED TIP INTELLIGENT RELOAD)-THE TRI-STAPLE™ 2.0 INTELLIGENT RELOADS HAVE APPLICATION IN ABDOMINAL, GYNAECOLOGIC, PAEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES, AND FOR TRANSECTION AND RESECTION OF PANCREAS. THE TRI-STAPLE™ 2.0 CURVED TIP INTELLIGENT RELOADS CAN BE USED TO BLUNT DISSECT OR SEPARATE TARGET TISSUE FROM OTHER TISSUE.,STAPLER/ LOADING UNIT(MULTIFIRE ENDO GIA AUTOSUTURE LOADING UNIT/ STAPLER)-THE STAPLERS WITH LOADING UNITS HAVE APPLICATIONS IN ABDOMINAL, GYNECOLOGIC, PEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION AND CREATION OF ANASTOMOSIS., STAPLER/LOADING UNIT(MULTIFIRE ENDO TA AUTO SUTURE STAPLER/LOADING UNIT)-MULTIFIRE ENDO TA™ STAPLER HAS APPLICATION IN ABDOMINAL, GYNECOLOGIC, PEDIATRIC AND THORACIC ENDOSCOPIC SURGERY FOR RESECTION AND TRANSECTION,STAPLER/ LOADING UNIT(TA PREMIUM AUTO SUTURE LOADING UNIT/ REUSABLE STAPLER)-THE TA PREMIUM™ STAPLERS

	AND SULUS HAVE APPLICATION IN ABDOMINAL, GYNECOLOGICAL, PEDIATRIC AND THORACIC SURGERY FOR RESECTION AND TRANSACTION OF TISSUE.,STAPLER/LOADING UNIT(TRI-STAPLE™ 2.0 CURVED TIP INTELLIGENT RELOAD AND INTRODUCER)-THE TRI-STAPLE™ 2.0 INTELLIGENT RELOADS HAVE APPLICATION IN ABDOMINAL, GYNAECOLOGIC, PAEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES, AND FOR TRANSECTION AND RESECTION OF PANCREAS. THE TRI-STAPLE™ 2.0 CURVED TIP INTELLIGENT RELOADS CAN BE USED TO BLUNT DISSECT OR SEPARATE TARGET TISSUE FROM OTHER TISSUE.,STAPLER/ LOADING UNIT(TA 90 B AUTO SUTURE BARIATRIC LOADING UNIT/ STAPLER)-THE TA 90 B™ AND TA 90 BN™ SURGICAL STAPLER INSTRUMENTS HAVE APPLICATION IN BARIATRIC SURGERY FOR RESECTION OF TISSUE ONLY.,STAPLES LOADING UNIT(TRI-STAPLE™ 2.0 INTELLIGENT RELOAD)-THE TRI-STAPLE™ 2.0 INTELLIGENT RELOADS HAVE APPLICATION IN ABDOMINAL, GYNAECOLOGIC, PAEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES, AND FOR TRANSECTION AND RESECTION OF PANCREAS. THE TRI-STAPLE™ 2.0 CURVED TIP INTELLIGENT RELOADS CAN BE USED TO BLUNT DISSECT OR SEPARATE TARGET TISSUE FROM OTHER TISSUE. ,STAPLER/ LOADING UNIT(TA AUTO SUTURE VASCULAR STAPLER/ LOADING UNIT WITH DST SERIES TECHNOLOGY)-TA™ AUTOSUTURE™ SINGLE USE VASCULAR LOADING UNIT WITH DST SERIES™ TECHNOLOGY (30MM - V3) HAS APPLICATION IN ABDOMINAL, GYNECOLOGICAL, PEDIATRIC AND THORACIC SURGICAL PROCEDURES FOR RESECTION OR TRANSECTION OF TISSUE.,STAPLER WITH LOADING UNIT(EEA CIRCULAR STAPLER WITH TRI-STAPLE TECHNOLOGY)-THE EEA™ CIRCULAR STAPLER WITH TRI-STAPLE™ TECHNOLOGY HAS APPLICATION THROUGHOUT THE ALIMENTARY TRACT FOR THE CREATION OF END-TO-END, END-TO-SIDE AND SIDE-TO-SIDE ANASTOMOSES IN BOTH OPEN AND LAPAROSCOPIC SURGERIES., CLIP APPLIERS AND CLIPS(PREMIUM SURGICLIP™ AUTO SUTURE™ CLIP APPLIER)-THE PREMIUM SURGICLIP ™AUTO SUTURE™ CLIP APPLIER HAS APPLICATION IN MANY TYPES OF SURGICAL PROCEDURES TO OCCLUDE VESSELS AND OTHER TUBULAR STRUCTURES AND FOR VAGOTOMY, SYMPATHECTOMY AND RADIOGRAPHIC MARKINGS.,STAPLER/LOADING UNIT(TRI-STAPLE™ 2.0 GRAY CURVED TIP INTELLIGENT RELOAD AND INTRODUCER)-THE

	TRI-STAPLE™ 2.0 INTELLIGENT RELOADS HAVE APPLICATION IN ABDOMINAL, GYNAECOLOGIC, PAEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF LIVER SUBSTANCE, HEPATIC VASCULATURE AND BILIARY STRUCTURES, AND FOR TRANSECTION AND RESECTION OF PANCREAS. THE TRI-STAPLE™ 2.0 CURVED TIP INTELLIGENT RELOADS CAN BE USED TO BLUNT DISSECT OR SEPARATE TARGET TISSUE FROM OTHER TISSUE.,PURSE STRING DEVICE(PURSTRING AUTO SUTURE PURSE STRING DEVICE)-PURSTRING™ SINGLE USE AUTOMATIC PURSE STRING DEVICE HAS APPLICATION IN INTESTINAL, COLORECTAL, ESOPHAGEAL, GASTRIC AND CARDIAC SURGERY FOR TEMPORARY AND PERMANENT PURSE-STRING PLACEMENT. SUTURES AND IS INTENDED FOR USE WITH VALTRAC™ AND EEA™ INSTRUMENTS.,CLIP APPLIERS AND CLIPS(PREMIUM SURGICLIP™ II AUTO SUTURE™ CLIP APPLIER)-THE PREMIUM SURGICLIP™ AUTO SUTURE™ II CLIP APPLIER HAS APPLICATION IN MANY TYPES OF SURGICAL PROCEDURES TO OCCLUDE VESSELS AND OTHER TUBULAR STRUCTURES AND FOR VAGOTOMY, SYMPATHECTOMY AND RADIOGRAPHIC MARKINGS.,CLIP APPLIERS AND CLIPS(PREMIUM SURGICLIP™ III CLIP APPLIER)-THE PREMIUM SURGICLIP™ III CLIP APPLIER HAS APPLICATION IN MANY TYPES OF SURGICAL PROCEDURES TO OCCLUDE VESSELS AND OTHER TUBULAR STRUCTURES AND FOR VAGOTOMY, SYMPATHECTOMY AND RADIOGRAPHIC MARKINGS.,STAPLE(EEA AUTO SUTURE CIRCULAR STAPLER/ LOADING UNIT WITH DST SERIES TECHNOLOGY) -THE DST SERIES™ EEA™ STAPLER IS USED THROUGHOUT THE ALIMENTARY TRACT FOR THE CREATION OF END-TO END, END-TO SIDE, AND SIDE-TO-SIDE ANASTOMOSES IN BOTH OPEN AND LAPAROSCOPIC SURGERIES.,LOADING UNIT(ENDO GIA™ AUTO SUTURE™ UNIVERSAL LOADING UNIT)-ENDO GIA™ AUTO SUTURE UNIVERSAL STAPLER HAVE AN APPLICATION IN ABDOMINAL, GYNECOLOGIC AND THORACIC SURGERY FOR RESECTION AND TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS

1319	IMP/MD/2018/000217	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NON-WOVEN ADHESIVE WOUND DRESSING(PRIMAPORE)-IT IS INDICATED FOR POST-OPERATIVE WOUNDS AND CUTS, ABRASIONS, LACERATION AND SUTURED WOUNDS.

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1320	IMP/MD/2018/000218	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CORONARY ARTERY GUIDEWIRE EXTENSION(STRETCH EXTENSION WIRE)-ATTACHMENT OF THE STRETCH EXTENSION WIRE TO A BOSTON SCIENTIFIC EXTENDABLE GUIDEWIRE CREATES AN EXTENDED GUIDEWIRE THAT CAN BE USED TO EXCHANGE OUT A PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) OR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) CATHETER WITHOUT REMOVING THE ORIGINAL GUIDEWIRE FROM THE ARTERY. WHEN THE EXCHANGE IS COMPLETE, THE STRETCH EXTENSION WIRE CAN BE DETACHED AND THE ORIGINAL GUIDEWIRE CAN BE USED IN A CONVENTIONAL MANNER.,CATHETER GUIDEWIRE(MARVEL GUIDEWIRE)-IT IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS OR OTHER INTERVENTIONAL THERAPEUTIC DEVICES DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) OR OTHER INTRAVASCULAR INTERVENTIONAL PROCEDURES. THESE GUIDEWIRES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE.,CATHETER GUIDEWIRE(SAMURAI GUIDEWIRE)-IT IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS OR OTHER INTERVENTIONAL THERAPEUTIC DEVICES DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) OR OTHER INTRAVASCULAR INTERVENTIONAL PROCEDURES. THESE GUIDEWIRES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE.,CATHETER GUIDEWIRE(SAMURAI RC GUIDEWIRE)-IT IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS OR OTHER INTERVENTIONAL THERAPEUTIC DEVICES DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) OR OTHER INTRAVASCULAR INTERVENTIONAL PROCEDURES. THESE GUIDEWIRES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE.,CATHETER GUIDEWIRE(HORNET GUIDEWIRE)-IT IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS OR OTHER INTERVENTIONAL THERAPEUTIC DEVICES DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) OR OTHER INTRAVASCULAR INTERVENTIONAL PROCEDURES. THESE GUIDEWIRES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE.,CATHETER GUIDEWIRE(HORNET 14 GUIDEWIRE)-IT IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS OR OTHER INTERVENTIONAL THERAPEUTIC DEVICES DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) OR OTHER INTRAVASCULAR INTERVENTIONAL PROCEDURES. THESE GUIDEWIRES ARE NOT INTENDED FOR USE IN THE CEREBRAL

		VASCULATURE.,CATHETER GUIDEWIRE(HORNET 10 GUIDEWIRE)-IT IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS OR OTHER INTERVENTIONAL THERAPEUTIC DEVICES DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) OR OTHER INTRAVASCULAR INTERVENTIONAL PROCEDURES. THESE GUIDEWIRES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE.,CATHETER GUIDEWIRE(FIGHTER GUIDEWIRE)-IT IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS OR OTHER INTERVENTIONAL THERAPEUTIC DEVICES DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) OR OTHER INTRAVASCULAR INTERVENTIONAL PROCEDURES. THESE GUIDEWIRES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE.
1321	IMP/MD/2018/000219	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IV CATHETER(BD NEOFLON™ PRO SAFETY IV CATHETER)-BD NEOFLON™ PRO SAFETY IV CATHETERS ARE INTENDED TO BE INSERTED INTO A PATIENT'S PERIPHERAL VASCULAR SYSTEM FOR SHORT TERM USE TO SAMPLE BLOOD, MONITOR BLOOD PRESSURE, OR ADMINISTER FLUIDS.,IV CANNULA(BD ARTERIAL CANNULA)-ARTERIAL CANNULA IS INDICATED FOR PATIENTS REQUIRING CONTINUOUS DIRECT BLOOD PRESSURE MONITORING & ARTERIAL BLOOD GAS SAMPLING.,IV CATHETER(BD INSYTE-W)-THIS IV CATHETER IS INSERTED INTO PATIENT'S VASCULAR SYSTEM TO ADMINISTER FLUIDS, MEDICATIONS OR BLOOD PRODUCTS TO OBTAIN BLOOD SAMPLE AND TO MONITOR BLOOD PRESSURE
1322	IMP/MD/2018/000220	1.License Holder Name: RUPASHREE HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHOPEDIC CASTING TAPE (SPLINT)(OPTTY CAST)-CASTING TAPE IS INTENDED FOR USE IN THE CONSTRUCTION OF MOST COMMON ORTHOPEDIC CASTS, AS WELL AS SPECIALIZED PROSTHETIC AND ORTHOTIC DEVICES AND SPLINT IS USE IN THE CONSTRUCTION OF COMMON ORTHOPEDIC SPLINTS AND EXTERNAL IMMOBILIZATION.

1323	IMP/MD/2018/000221	1.License Holder Name: FRESENIUS KABI INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AMICORE APHERESIS KIT - SINGLE NEEDLE WITH TWO PLATELET CONTAINERS AND PAS CONNECTOR (AMICORE)-THE KIT IS DESIGNED FOR USE WITH THE AMICORE APHRESIS SYSTEM FOR THE COLLECTION OF PLATELETS, LEUKOCYTES REDUCED AND PLASMA.,AMICUS APHERESIS KIT-SINGLE NEEDLE WITH PLATELET ADDITIVE SOLUTION CONNECTOR U6R2301(AMICUS)-DESIGNED FOR USE WITH THE AMICUS SEPARATOR FOR THE COLLECTION OF LEUCKOREDUCED PLATELET CONCENTRATE, PLASMA AND RED CELLS.,PLASMACELL-C DISPOSABLE SET(NA)-FOR COLLECTION OF PLASMA BY MEMBRANE FILTRATION. FOR USE WITH THE AURORA INSTRUMENT OR THE AUTOPHERESIS-C INSTRUMENT,AMICUS APHERESIS KIT - SINGLE NEEDLE U6R2312 (AMICUS)-DESIGNED FOR USE WITH AMICUS SEPARATOR FOR THE COLLECTION OF PLASMA, RED BLOOD CELLS AND LEUKOREDUCED PLATELETS.,AMICUS APHERESIS KIT - DOUBLE NEEDLE WITH PLATELET ADDITIVE SOLUTION CONNECTOR X6R2302 (AMICUS)-DESIGNED FOR USE WITH THE AMICUS SEPARATOR FOR THE COLLECTION OF LEUKOREDUCED PLATELET CONCENTRATE AND PLASMA.,PLASMALINK TRANSFER PACK- CONTAINER WITH LUER ADAPTER AND NO OUTLET PORTS - 1000 ML 6R2088(PLASMALINK)-USE FOR PROCESSING AND/ OR STORAGE OF BLOOD OR BLOOD COMPONENTS.,AMICUS EXCHANGE KIT X6R2339(AMICUS)-DESIGNED FOR USE WITH THE AMICUS SEPARATOR FOR THE THERAPEUTIC PLASMA EXCHANGE PROCEDURE.,AMICUS APHERESIS KIT- DOUBLE NEEDLE X6R2326(AMICUS MNC)-DESIGNED FOR USE WITH AMICUS SEPARATOR FOR THE COLLECTION OF MNC'S (MONONUCLEAR CELLS) AND PLASMA.,AMI CORE APHERESIS KIT - SINGLE NEEDLE WITH TWO PLATELET CONTAINERS P6R8882 (AMICORE)-THE AMICORE APHERESIS SYSTEM IS AN AUTOMATED BLOOD CELL SEPARATOR INDICATED FOR USE IN THE COLLECTION OF BLOOD COMPONENTS.,AMICORE APHERESIS KIT - SINGLE NEEDLE WITH TWO PLATELET CONTAINERS X6R8882(AMICORE)-THE AMICORE APHERESIS SYSTEM IS AN AUTOMATED BLOOD CELL SEPARATOR INDICATED FOR USE IN THE COLLECTION OF BLOOD COMPONENTS., AMICORE APHERESIS KIT - SINGLE NEEDLE P6R8880 (AMICORE)-THE AMICORE APHERESIS SYSTEM IS AN AUTOMATED BLOOD CELL SEPARATOR INDICATED FOR USE IN THE COLLECTION OF BLOOD COMPONENTS.,AMICORE APHERESIS KIT - SINGLE NEEDLE X6R8880 (AMICORE)-THE AMICORE APHERESIS SYSTEM IS AN AUTOMATED BLOOD CELL SEPARATOR INDICATED FOR USE IN THE COLLECTION OF BLOOD COMPONENTS.

1324	IMP/MD/2018/000222	1.License Holder Name: BHARAT SERUMS AND VACCINES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QUALITATIVE TEST FOR DETECTION OF AMNIOTIC FLUID IN VAGINAL SECRETION(ACTIM PROM KIT)-ACTIM PROM TEST IS A VISUALLY INTERPRETED, QUALITATIVE IMMUNOCHROMATOGRAPHIC DIPSTICK TEST FOR DETECTION OF AMNIOTIC FLUID IN VAGINAL SECRETIONS DURING PREGNANCY. ACTIM PROM DETECTS IGFBP-1, WHICH IS A MAJOR PROTEIN IN AMNIOTIC FLUID AND A MARKER OF THE AMNIOTIC FLUID IN A VAGINAL SAMPLE. THE TEST IS INTENDED FOR PROFESSIONAL USE TO HELP DIAGNOSE THE RUPTURE OF FETAL MEMBRANES (ROM) IN PREGNANT WOMEN.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1325	IMP/MD/2018/000223	1.License Holder Name: ABBOTT HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREALBUMIN (PREALBUMIN)-THE PREALBUMIN ASSAY IS USED FOR THE QUANTITATION OF PREALBUMIN IN HUMAN SERUM ON THE ARCHITECT C SYSTEMS.,ALINITY I LH REAGENT KIT-USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN LUTEINIZING HORMONE (LH) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER., ALBUMIN BCP2(ALBUMIN BCP2)-THE ALBUMIN BCP2 ASSAY IS USED FOR THE QUANTITATION OF ALBUMIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM.,ALINITY I URINE NGAL CONTROLS (ALINITY I URINE NGAL CONTROLS)-THE ALINITY I URINE NGAL CONTROLS ARE USED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN (NGAL) IN HUMAN URINE.,COMPLEMENT C4 (COMPLEMENT C4)-THE COMPLEMENT C4 ASSAY IS USED FOR THE QUANTITATION OF C4 IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM.,ALINITY I URINE NGAL REAGENT KIT(ALINITY I URINE NGAL REAGENT KIT)-THE ALINITY I URINE NGAL ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN (NGAL) IN HUMAN URINE ON THE ALINITY I ANALYZER. THE ALINITY I URINE NGAL ASSAY IS TO BE USED FOR THE IN VITRO DETERMINATION OF HUMAN NGAL IN URINE AS AN INDICATION OF KIDNEY INJURY.,COMPLEMENT C3 (COMPLEMENT C3)-THE COMPLEMENT C3 ASSAY IS USED FOR THE QUANTITATION OF C3 IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY I FOLATE MANUAL DILUENT(ALINITY I FOLATE MANUAL DILUENT)-THE ALINITY I FOLATE MANUAL DILUENT IS USED FOR MANUALLY DILUTING SPECIMENS FOR TESTING BY THE ALINITY I FOLATE ASSAY ON THE ALINITY I ANALYZER.,IMMUNOGLOBULIN A(IMMUNOGLOBULIN A)-THE IMMUNOGLOBULIN A ASSAY IS USED FOR THE QUANTITATION OF IGA IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS., ALINITY I B12 CONTROLS(ALINITY I B12 CONTROLS)-THE ALINITY I B12 CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM AND/OR PLASMA WHEN USING THE ALINITY I B12 REAGENT KIT., IMMUNOGLOBULIN M(IMMUNOGLOBULIN M)-THE IMMUNOGLOBULIN M ASSAY IS USED FOR THE QUANTITATION OF IGM IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY I PROGESTERONE MANUAL DILUENT-USED FOR MANUALLY DILUTING

	SPECIMENS FOR TESTING USING THE ALINITY I PROGESTERONE REAGENT KIT ON THE ALINITY I ANALYZER. ,COMPLEMENT C4 (COMPLEMENT C4)-THE COMPLEMENT C4 ASSAY IS USED FOR THE QUANTITATION OF C4 IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY I PROGESTERONE CONTROLS-USED FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER (REAGENTS, CALIBRATORS AND INSTRUMENT) WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF PROGESTERONE IN HUMAN SERUM AND PLASMA. ,APOLIPOPROTEIN B(APOLIPOPROTEIN B)-THE APOLIPOPROTEIN B ASSAY IS USED FOR THE QUANTITATION OF APOB IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS., ALINITY I PROGESTERONE CALIBRATORS-USED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM AND PLASMA.,URIC ACID2(URIC ACID2)-THE URIC ACID2 ASSAY IS USED FOR THE QUANTITATION OF URIC ACID IN HUMAN SERUM, PLASMA, OR URINE ON THE ARCHITECT C SYSTEMS.,ALINITY I PROGESTERONE REAGENT KIT-USED FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER,HAPTOGLOBIN(HAPTOGLOBIN)-THE HAPTOGLOBIN ASSAY IS USED FOR THE QUANTITATION OF HAPTOGLOBIN IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY I LH CALIBRATORS-USED FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN LUTEINIZING HORMONE (LH) IN HUMAN SERUM AND PLASMA.,CREATININE2(CREATININE2)-THE CREATININE2 ASSAY IS USED FOR THE QUANTITATION OF CREATININE IN HUMAN SERUM, PLASMA, OR URINE ON THE ARCHITECT C SYSTEMS.,ALINITY I FSH CONTROLS-USED FOR THE ESTIMATION OF TEST PRECISION AND DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF ALINITY I ANALYSER (REAGENTS, CALIBRATORS AND INSTRUMENT) WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM AND PLASMA.,MAGNESIUM(MAGNESIUM)-THE MAGNESIUM ASSAY IS USED FOR THE QUANTITATION OF MAGNESIUM IN HUMAN SERUM, PLASMA, OR URINE ON THE ARCHITECT C SYSTEMS.,ALINITY I FSH CALIBRATORS-USED FOR THE CALIBRATION OF ALINITY I ANALYSER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN SERUM AND PLASMA. , RHEUMATOID FACTOR(RHEUMATOID FACTOR)-THE RHEUMATOID FACTOR ASSAY IS USED FOR THE QUANTITATION OF RHEUMATOID FACTOR IN HUMAN SERUM ON THE ARCHITECT C SYSTEMS.,ALINITY I FSH REAGENT KIT-USED FOR THE QUANTITATIVE DETERMINATION

	OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER,TRANSFERRIN(TRANSFERRIN)-THE TRANSFERRIN ASSAY IS USED FOR THE QUANTITATION OF TRANSFERRIN IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY I B12 REAGENT KIT(ALINITY I B12 REAGENT KIT)-THE ALINITY I B12 ASSAY IS A CHEMILUMINESCENT MICROPARTICLE INTRINSIC FACTOR ASSAY USED FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,TRANSFERRIN(TRANSFERRIN)-THE TRANSFERRIN ASSAY IS USED FOR THE QUANTITATION OF TRANSFERRIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM.,ALINITY I B12 CALIBRATORS(ALINITY I B12 CALIBRATORS)-THE ALINITY I B12 CALIBRATORS ARE USED TO CALIBRATE THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM AND PLASMA USING THE ALINITY I B12 REAGENT KIT.,IMMUNOGLOBULIN G (IMMUNOGLOBULIN G)-THE IMMUNOGLOBULIN G ASSAY IS USED FOR THE QUANTITATION OF IGG IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY I FOLATE LYSIS REAGENT(ALINITY I FOLATE LYSIS REAGENT)-THE ALINITY I FOLATE LYSIS REAGENT IS FOR USE WITH THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN RED BLOOD CELLS.,ACTIVATED ASPARTATE AMINOTRANSFERASE(ACTIVATED ASPARTATE AMINOTRANSFERASE)-THE ACTIVATED ASPARTATE AMINOTRANSFERASE ASSAY IS USED FOR THE QUANTITATION OF ASPARTATE AMINOTRANSFERASE IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY I FOLATE CALIBRATORS (ALINITY I FOLATE CALIBRATORS)-THE ALINITY I FOLATE CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN SERUM, PLASMA, AND RED BLOOD CELLS., APOLIPOPROTEIN A1(APOLIPOPROTEIN A1)-THE APOLIPOPROTEIN A1 ASSAY IS USED FOR THE QUANTITATION OF APOLIPOPROTEIN A-I IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS., ALINITY I FOLATE CONTROLS(ALINITY I FOLATE CONTROLS)-THE ALINITY I FOLATE CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN SERUM, PLASMA, AND RED BLOOD CELLS.,TOTAL PROTEIN2(TOTAL PROTEIN2)-THE TOTAL PROTEIN2 ASSAY IS USED FOR THE QUANTITATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM.,ALINITY I FOLATE RBC LYSIS DILUENT (ALINITY I FOLATE RBC LYSIS DILUENT)-THE ALINITY I FOLATE RBC LYSIS DILUENT IS USED IN THE PREPARATION OF RED BLOOD CELL

	HEMOLYSATE FOR TESTING USING THE ALINITY I FOLATE REAGENT KIT ON THE ALINITY I ANALYZER.,URIC ACID2(URIC ACID2)-THE URIC ACID2 ASSAY IS USED FOR THE QUANTITATION OF URIC ACID IN HUMAN SERUM, PLASMA, OR URINE ON THE ALINITY C SYSTEM., ALINITY I FOLATE REAGENT KIT(ALINITY I FOLATE REAGENT KIT)-THE ALINITY I FOLATE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN SERUM, PLASMA, AND RED BLOOD CELLS ON THE ALINITY I ANALYZER.,IMMUNOGLOBULIN M (IMMUNOGLOBULIN M)-THE IMMUNOGLOBULIN M ASSAY IS USED FOR THE QUANTITATION OF IGM IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM.,ALINITY I URINE NGAL CALIBRATORS (ALINITY I URINE NGAL CALIBRATORS)-THE ALINITY I URINE NGAL CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN (NGAL) IN HUMAN URINE.,ALBUMIN BCG2(ALBUMIN BCG2)-THE ALBUMIN BCG2 ASSAY IS USED FOR THE QUANTITATION OF ALBUMIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM.,ALINITY I ESTRADIOL CALIBRATORS(ALINITY I ESTRADIOL CALIBRATORS)-INTENDED FOR THE CALIBRATION OF THE ALIINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM AND PLASMA.,ALBUMIN BCP2(ALBUMIN BCP2)-THE ALBUMIN BCP2 ASSAY IS USED FOR THE QUANTITATION OF ALBUMIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM.,ALINITY I ESTRADIOL REAGENT KIT(ALINITY I ESTRADIOL REAGENT KIT)-INTENDED FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,COMPLEMENT C3(COMPLEMENT C3)-THE COMPLEMENT C3 ASSAY IS USED FOR THE QUANTITATION OF C3 IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM.,ALINITY I ESTRADIOL MANUAL DILUENT KIT(ALINITY I ESTRADIOL MANUAL DILUENT KIT)-INTENDED FOR MANUALLY DILUTING SPECIMENS FOR TESTING USING THE ALINITY I ESTRADIOL REAGENT KIT ON THE ALINITY I ANALYZER.,AMYLASE2(AMYLASE2)-THE AMYLASE2 ASSAY IS USED FOR THE QUANTITATION OF AMYLASE IN HUMAN SERUM, PLASMA, OR URINE ON THE ALINITY C SYSTEM.,ALINITY I ESTRADIOL CONTROLS(ALINITY I ESTRADIOL CONTROLS)-INTENDED FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF ESTRADIOL IN HUMAN SERUM AND PLASMA., UREA NITROGEN2(UREA NITROGEN2)-THE UREA NITROGEN2 ASSAY IS USED FOR THE QUANTITATION OF UREA NITROGEN IN HUMAN SERUM, PLASMA, OR URINE ON THE ARCHITECT C SYSTEMS.,

	ARCHITECT 25-OH VITAMIN D CALIBRATORS(ARCHITECT 25-OH VITAMIN D CALIBRATORS)-ARCHITECT 25-OH VITAMIN D CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF 25-HYDROXYVITAMIN D (25-OH VITAMIN D) IN HUMAN SERUM AND PLASMA. ,AMYLASE2(AMYLASE2)-THE AMYLASE2 ASSAY IS USED FOR THE QUANTITATION OF AMYLASE IN HUMAN SERUM, PLASMA, OR URINE ON THE ARCHITECT C SYSTEMS.,ARCHITECT 25-OH VITAMIN D REAGENT KIT(ARCHITECT 25-OH VITAMIN D)-THE ARCHITECT 25-OH VITAMIN D ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF 25-HYDROXYVITAMIN D (25-OH VITAMIN D) IN HUMAN SERUM AND PLASMA.,HAPTOGLOBIN(HAPTOGLOBIN)-THE HAPTOGLOBIN ASSAY IS USED FOR THE QUANTITATION OF HAPTOGLOBIN IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM., ARCHITECT 25-OH VITAMIN D CONTROLS (ARCHITECT 25-OH VITAMIN D CONTROLS)-THE ARCHITECT 25-OH VITAMIN D CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF 25-HYDROXYVITAMIN D (25-OH VITAMIN D) IN HUMAN SERUM AND PLASMA. ,IMMUNOGLOBULIN A (IMMUNOGLOBULIN A)-THE IMMUNOGLOBULIN A ASSAY IS USED FOR THE QUANTITATION OF IGA IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM.,ACTIVATED ASPARTATE AMINOTRANSFERASE (ACTIVATED ASPARTATE AMINOTRANSFERASE)-THE ACTIVATED ASPARTATE AMINOTRANSFERASE ASSAY IS USED FOR THE QUANTITATION OF ASPARTATE AMINOTRANSFERASE IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM.,MAGNESIUM (MAGNESIUM)-THE MAGNESIUM ASSAY IS USED FOR THE QUANTITATION OF MAGNESIUM IN HUMAN SERUM, PLASMA, OR URINE ON THE ALINITY C SYSTEM.,APOLIPOPROTEIN A1 (APOLIPOPROTEIN A1)-THE APOLIPOPROTEIN A1 ASSAY IS USED FOR THE QUANTITATION OF APOLIPOPROTEIN A-I IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM.,CHOLESTEROL2 (CHOLESTEROL2)-THE CHOLESTEROL2 ASSAY IS USED FOR THE QUANTITATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM.,UREA NITROGEN2(UREA NITROGEN2)-THE UREA NITROGEN2 ASSAY IS USED FOR THE QUANTITATION OF UREA NITROGEN IN HUMAN SERUM, PLASMA, OR URINE ON THE ALINITY C SYSTEM.,TOTAL PROTEIN2(TOTAL PROTEIN2)-THE TOTAL PROTEIN2 ASSAY IS USED FOR THE QUANTITATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS., APOLIPOPROTEIN B(APOLIPOPROTEIN B)-THE APOLIPOPROTEIN B

	ASSAY IS USED FOR THE QUANTITATION OF APOLIPOPROTEIN B (APOB) IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM., ALBUMIN BCG2(ALBUMIN BCG2)-THE ALBUMIN BCG2 ASSAY IS USED FOR THE QUANTITATION OF ALBUMIN IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,PREALBUMIN(PREALBUMIN)-THE PREALBUMIN ASSAY IS USED FOR THE QUANTITATION OF PREALBUMIN IN HUMAN SERUM ON THE ALINITY C SYSTEM., IMMUNOGLOBULIN G(IMMUNOGLOBULIN G)-THE IMMUNOGLOBULIN G ASSAY IS USED FOR THE QUANTITATION OF IGG IN HUMAN SERUM OR PLASMA ON THE ALINITY C SYSTEM.,ALINITY I STAT HIGH SENSITIVE TROPONIN-I CALIBRATORS(ALINITY I STAT HIGH SENSITIVE TROPONIN-I CALIBRATORS)-THE ALINITY I STAT HIGH SENSITIVE TROPONIN-I CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN HUMAN SERUM AND PLASMA.,CHOLESTEROL2(CHOLESTEROL2)-THE CHOLESTEROL2 ASSAY IS USED FOR THE QUANTITATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA ON THE ARCHITECT C SYSTEMS.,ALINITY I TOTAL ß-HCG REAGENT KIT(ALINITY I TOTAL ß-HCG REAGENT KIT)-THE ALINITY I TOTAL -HCG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE AND QUALITATIVE DETERMINATION OF BETA-HUMAN CHORIONIC GONADOTROPIN (-HCG) IN HUMAN SERUM AND PLASMA FOR THE EARLY DETECTION OF PREGNANCY ON THE ALINITY I ANALYZER.,ALINITY I TSH CONTROLS(ALINITY I TSH CONTROLS)-THE ALINITY I TSH CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM AND PLASMA.,ALINITY I TOTAL T3 REAGENT KIT(ALINITY I TOTAL T3 REAGENT KIT)-THE ALINITY I TOTAL T3 (TT3) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE (TOTAL T3) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT FREE T4 CALIBRATORS (ARCHITECT FREE T4 CALIBRATORS)-THE ARCHITECT FREE T4 CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FREE T4) IN HUMAN SERUM AND PLASMA., ARCHITECT FSH CALIBRATOR(ARCHITECT FSH CALIBRATOR)-THE ARCHITECT FSH CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN SERUM AND PLASMA.,ARCHITECT TSH CALIBRATOR

	(ARCHITECT TSH CALIBRATOR)-THE ARCHITECT TSH CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM AND PLASMA., ARCHITECT TSH CONTROL(ARCHITECT TSH CONTROL)-THE ARCHITECT TSH CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM AND PLASMA. , ALINITY I PROLACTIN CALIBRATORS(ALINITY I PROLACTIN CALIBRATORS)-THE ALINITY I PROLACTIN CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM AND PLASMA.,ALINITY I FERRITIN CONTROL(ALINITY I FERRITIN CONTROL)-THE ALINITY I FERRITIN CONTROLS ARE ASSAYED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA., ARCHITECT FERRITIN REAGENT KIT(ARCHITECT FERRITIN REAGENT KIT)-THE ARCHITECT FERRITIN ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA., ARCHITECT TOTAL -HCG CALIBRATORS(ARCHITECT TOTAL -HCG CALIBRATORS)-THE ARCHITECT TOTAL -HCG CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE AND QUALITATIVE DETERMINATION OF BETA HUMAN CHORIONIC GONADOTROPIN (-HCG) IN HUMAN SERUM AND PLASMA.,ALINITY I 25-OH VITAMIN D REAGENT KIT(ALINITY I 25-OH VITAMIN D REAGENT KIT)-THE ALINITY I 25-OH VITAMIN D ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF 25 HYDROXYVITAMIN D (25-OH VITAMIN D) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER. THE ALINITY I 25-OH VITAMIN D ASSAY IS TO BE USED AS AN AID IN THE ASSESSMENT OF VITAMIN D SUFFICIENCY.,ARCHITECT PROLACTIN CONTROLS(ARCHITECT PROLACTIN CONTROLS)-THE ARCHITECT PROLACTIN CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM (REAGENTS, CALIBRATORS, AND INSTRUMENTS) WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM AND PLASMA., ALINITY I STAT HIGH SENSITIVE TROPONIN-I CONTROLS(ALINITY I STAT HIGH SENSITIVE TROPONIN-I CONTROLS)-THE ALINITY I STAT HIGH SENSITIVE TROPONIN-I CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC

	ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNL) IN HUMAN SERUM AND PLASMA.,ARCHITECT STAT HIGH SENSITIVE TROPONIN-I CONTROL(ARCHITECT STAT HIGH SENSITIVE TROPONIN-I CONTROL)-THE ARCHITECT STAT HIGH SENSITIVE TROPONIN-I CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT I SYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN HUMAN SERUM AND PLASMA WITH THE ARCHITECT STAT HIGH SENSITIVE TROPONIN-I REAGENT KIT., ARCHITECT B12 REAGENT KIT(ARCHITECT B12 REAGENT KIT)-THE ARCHITECT B12 ASSAY IS A CHEMILUMINESCENT MICROPARTICLE INTRINSIC FACTOR ASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM AND PLASMA ON THE ARCHITECT ISYSTEM.,ALINITY I TSH REAGENT KIT(ALINITY I TSH REAGENT KIT)-THE ALINITY I TSH ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER., ARCHITECT TOTAL T3 REAGENT KIT(ARCHITECT TOTAL T3 REAGENT KIT)-THE ARCHITECT TOTAL T3 (TT3) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE (TOTAL T3) IN HUMAN SERUM AND PLASMA.,ALINITY I FREE T4 CALIBRATORS(ALINITY I FREE T4 CALIBRATORS)-THE ALINITY I FREE T4 CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FREE T4) IN HUMAN SERUM AND PLASMA., ARCHITECT TOTAL -HCG REAGENT KIT(ARCHITECT TOTAL -HCG REAGENT KIT)-THE ARCHITECT TOTAL -HCG ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE AND QUALITATIVE DETERMINATION OF BETA HUMAN CHORIONIC GONADOTROPIN (-HCG) IN HUMAN SERUM AND PLASMA FOR THE EARLY DETECTION OF PREGNANCY.,ARCHITECT FREE T3 CONTROL(ARCHITECT FREE T3 CONTROL)-THE ARCHITECT FREE T3 CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM (REAGENTS, CALIBRATORS AND INSTRUMENT), WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF FREE TRIIODOTHYRONINE (FREE T3) IN HUMAN SERUM AND PLASMA.,ALINITY I TOTAL T3 MANUAL DILUENT(ALINITY I TOTAL T3 MANUAL DILUENT)-THE ALINITY I TOTAL T3 MANUAL DILUENT IS USED FOR MANUALLY DILUTING SPECIMENS FOR TESTING USING THE

	ALINITY I TOTAL T3 REAGENT KIT ON THE ALINITY I ANALYZER., ARCHITECT TOTAL T3 CALIBRATOR(ARCHITECT TOTAL T3 CALIBRATOR)-THE ARCHITECT TOTAL T3 CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE (TOTAL T3) IN HUMAN SERUM AND PLASMA.,ARCHITECT TOTAL T3 MANUAL DILUENT(ARCHITECT TOTAL T3 MANUAL DILUENT)-THE ARCHITECT TOTAL T3 MANUAL DILUENT IS USED FOR MANUALLY DILUTING SPECIMENS FOR TESTING BY THE ARCHITECT TOTAL T3 ASSAY ON THE ARCHITECT ISYSTEM.,ARCHITECT B12 CALIBRATOR (ARCHITECT B12 CALIBRATOR)-THE ARCHITECT B12 CALIBRATORS ARE USED TO CALIBRATE THE ARCHITECT ISYSTEM WHEN THE SYSTEM IS USED FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM AND PLASMA USING THE ARCHITECT B12 REAGENT KIT.,ALINITY I TOTAL ß-HCG CALIBRATORS(ALINITY I TOTAL ß-HCG CALIBRATORS)-THE ALINITY I TOTAL -HCG CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE AND QUALITATIVE DETERMINATION OF BETA HUMAN CHORIONIC GONADOTROPIN (-HCG) IN HUMAN SERUM AND PLASMA.,ALINITY I FREE T3 REAGENT KIT(ALINITY I FREE T3 REAGENT KIT)-THE ALINITY I FREE T3 (FT3) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FREE T3) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ALINITY I FERRITIN CALIBRATOR(ALINITY I FERRITIN CALIBRATOR)-THE ALINITY I FERRITIN CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA.,ARCHITECT LH CALIBRATOR(ARCHITECT LH CALIBRATOR)-THE ARCHITECT LH CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN LUTEINIZING HORMONE (LH) IN HUMAN SERUM AND PLASMA.,ARCHITECT LH REAGENT (ARCHITECT LH REAGENT)-THE ARCHITECT LH ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF HUMAN LUTEINIZING HORMONE (LH) IN HUMAN SERUM AND PLASMA.,ARCHITECT FSH REAGENT KIT(ARCHITECT FSH REAGENT KIT)-THE ARCHITECT FSH ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN SERUM AND PLASMA., ARCHITECT FERRITIN CALIBRATOR(ARCHITECT FERRITIN CALIBRATOR)-THE ARCHITECT FERRITIN CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE

	QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA.,ARCHITECT FOLATE REAGENT KIT(ARCHITECT FOLATE REAGENT KIT)-THE ARCHITECT FOLATE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE FOLATE BINDING PROTEIN ASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN SERUM, PLASMA, AND RED BLOOD CELLS ON THE ARCHITECT ISYSTEM.,ARCHTECT TOTAL T4 CONTROLS(ARCHTECT TOTAL T4 CONTROLS)-THE ARCHITECT TOTAL T4 CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (TOTAL T4) IN HUMAN SERUM AND PLASMA.,ALINITY I TSH CALIBRATORS(ALINITY I TSH CALIBRATORS)-THE ALINITY I TSH CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM AND PLASMA.,ARCHITECT B12 CONTROL (ARCHITECT B12 CONTROL)-THE ARCHITECT B12 CONTROLS ARE USED FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM AND PLASMA WHEN USING THE ARCHITECT B12 REAGENT KIT.,ARCHITECT ESTRADIOL REAGENT KIT (ARCHITECT ESTRADIOL REAGENT KIT)-THE ARCHITECT ESTRADIOL ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM AND PLASMA.,FOLATE LYSIS REAGENT(FOLATE LYSIS REAGENT)-THE FOLATE LYSIS REAGENT IS FOR USE WITH THE ARCHITECT ISYSTEMS WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN RED BLOOD CELLS., ARCHITECT URINE NGAL CONTROLS(ARCHITECT URINE NGAL CONTROLS)-THE ARCHITECT URINE NGAL CONTROLS ARE USED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN (NGAL) IN HUMAN URINE.,ALINITY I TOTAL ß-HCG CONTROLS(ALINITY I TOTAL ß-HCG CONTROLS)-THE ALINITY I TOTAL -HCG CONTROLS ARE FOR THE USE IN QUALITY CONTROL TO MONITOR THE ACCURACY AND PRECISION OF THE ALINITY I TOTAL -HCG ASSAY SYSTEM IN HUMAN SERUM OR PLASMA.,ARCHTECT TOTAL T4 REAGENT KIT(ARCHTECT TOTAL T4 REAGENT KIT)-THE ARCHITECT TOTAL T4 (TT4) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (TOTAL T4) IN HUMAN SERUM AND PLASMA.,ARCHTECT TOTAL T4 CALIBRATORS(ARCHTECT TOTAL T4

	CALIBRATORS)-THE ARCHITECT TOTAL T4 CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (TOTAL T4) IN HUMAN SERUM AND PLASMA.,ARCHITECT FSH CONTROLS (ARCHITECT FSH CONTROLS)-THE ARCHITECT FSH CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM (REAGENTS, CALIBRATORS, AND INSTRUMENT) WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FSH IN HUMAN SERUM AND PLASMA.,ARCHITECT PROGESTERONE MANUAL DILUENT(ARCHITECT PROGESTERONE MANUAL DILUENT)-THE ARCHITECT PROGESTERONE MANUAL DILUENT IS USED FOR MANUALLY DILUTING SPECIMENS FOR TESTING BY THE ARCHITECT PROGESTERONE ASSAY ON THE ARCHITECT ISYSTEM.,ARCHITECT PROLACTIN CALIBRATOR(ARCHITECT PROLACTIN CALIBRATOR)-THE ARCHITECT PROLACTIN CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM AND PLASMA., ARCHITECT ESTRADIOL CALIBRATORS(ARCHITECT ESTRADIOL CALIBRATORS)-THE ARCHITECT ESTRADIOL CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM AND PLASMA.,ARCHITECT PROGESTERONE CALIBRATORS (ARCHITECT PROGESTERONE CALIBRATORS)-THE ARCHITECT PROGESTERONE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM AND PLASMA.,ARCHITECT URINE NGAL CALIBRATORS(ARCHITECT URINE NGAL CALIBRATORS)-THE ARCHITECT URINE NGAL CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN (NGAL) IN HUMAN URINE., ARCHITECT TOTAL -HCG CONTROLS(ARCHITECT TOTAL -HCG CONTROLS)-THE ARCHITECT TOTAL -HCG CONTROLS ARE FOR THE USE IN QUALITY CONTROL TO MONITOR THE ACCURACY AND PRECISION OF THE ARCHITECT TOTAL -HCG ASSAY SYSTEM IN HUMAN SERUM OR PLASMA.,ARCHITECT PROGESTERONE REAGENT KIT(ARCHITECT PROGESTERONE REAGENT KIT)-THE ARCHITECT PROGESTERONE ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM AND PLASMA.,ARCHITECT FREE T4 REAGENT KIT(ARCHITECT FREE T4 REAGENT KIT)-THE ARCHITECT FREE T4 (FT4) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF

	FREE THYROXINE (FREE T4) IN HUMAN SERUM AND PLASMA., ARCHITECT PROLACTIN REAGENT KIT(ARCHITECT PROLACTIN REAGENT KIT)-THE ARCHITECT PROLACTIN ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM AND PLASMA.,ARCHITECT FREE T4 CONTROLS(ARCHITECT FREE T4 CONTROLS)-THE ARCHITECT FREE T4 CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FREE T4) IN HUMAN SERUM AND PLASMA.,ARCHITECT URINE NGAL REAGENT KIT(ARCHITECT URINE NGAL REAGENT KIT)-THE ARCHITECT URINE NGAL ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN (NGAL) IN HUMAN URINE. NGAL QUANTITATION MAY BE USED FOR THE IN VITRO DETERMINATION OF HUMAN NGAL IN URINE AS AN INDICATION OF KIDNEY INJURY., ARCHITECT ESTRADIOL MANUAL DILUENT(ARCHITECT ESTRADIOL MANUAL DILUENT)-THE ARCHITECT ESTRADIOL MANUAL DILUENT IS USED FOR MANUALLY DILUTING SPECIMENS FOR TESTING USING THE ARCHITECT ESTRADIOL ASSAY ON THE ARCHITECT ISYSTEM, ARCHITECT PROGESTERONE CONTROLS(ARCHITECT PROGESTERONE CONTROLS)-THE ARCHITECT PROGESTERONE CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM (REAGENTS, CALIBRATORS AND INSTRUMENT) WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF PROGESTERONE IN HUMAN SERUM AND PLASMA.,ALINITY I FREE T3 CALIBRATORS(ALINITY I FREE T3 CALIBRATORS)-THE ALINITY I FREE T3 CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FREE T3) IN HUMAN SERUM AND PLASMA., ARCHITECT ESTRADIOL CONTROLS(ARCHITECT ESTRADIOL CONTROLS)-THE ARCHITECT ESTRADIOL CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMIC ANALYTICAL DEVIATIONS OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF ESTRADIOL IN HUMAN SERUM AND PLASMA.,ALINITY I TOTAL T3 CALIBRATORS(ALINITY I TOTAL T3 CALIBRATORS)-THE ALINITY I TOTAL T3 CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE (TOTAL T3) IN HUMAN SERUM AND PLASMA., ALINITY I TOTAL T4 REAGENT KIT(ALINITY I TOTAL T4 REAGENT KIT)-THE ALINITY I TOTAL T4 (TT4) ASSAY IS A CHEMILUMINESCENT

	MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (TOTAL T4) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER., ARCHITECT FOLATE CALIBRATORS(ARCHITECT FOLATE CALIBRATORS)-THE ARCHITECT FOLATE CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN SERUM, PLASMA, AND RED BLOOD CELLS.,ARCHITECT TSH REAGENT KIT (ARCHITECT TSH REAGENT KIT)-THE ARCHITECT TSH ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM AND PLASMA. , ALINITY I FERRITIN REAGENT KIT(ALINITY I FERRITIN REAGENT KIT)-THE ALINITY I FERRITIN ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT FOLATE CONTROLS(ARCHITECT FOLATE CONTROLS)-THE ARCHITECT FOLATE CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN SERUM, PLASMA, AND RED BLOOD CELLS.,ARCHITECT STAT HIGH SENSITIVE TROPONIN-I REAGENT KIT(ARCHITECT STAT HIGH SENSITIVE TROPONIN-I REAGENT KIT)-THE ARCHITECT STAT HIGH SENSITIVE TROPONIN-I ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN HUMAN PLASMA AND SERUM ON THE ARCHITECT ISYSTEM WITH STAT PROTOCOL CAPABILITY.,ARCHITECT FOLATE MANUAL DILUENT(ARCHITECT FOLATE MANUAL DILUENT)-THE ARCHITECT FOLATE MANUAL DILUENT IS USED FOR MANUALLY DILUTING SPECIMENS FOR TESTING BY THE ARCHITECT FOLATE ASSAY ON THE ARCHITECT ISYSTEM.,ALINITY I PROLACTIN REAGENT KIT(ALINITY I PROLACTIN REAGENT KIT)-THE ALINITY I PROLACTIN ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.,ARCHITECT FOLATE RBC LYSIS DILUENT(ARCHITECT FOLATE RBC LYSIS DILUENT)-THE FOLATE RBC LYSIS DILUENT IS USED FOR MANUALLY DILUTING SPECIMENS AS A PART OF INITIAL MANUAL PRE-TREATMENT STEP TOWARDS PREPARATION OF RBC HEMOLYSATE BEFORE TESTING BY THE ARCHITECT FOLATE REAGENT KIT,ALINITY I PROLACTIN CONTROLS(ALINITY I PROLACTIN CONTROLS)-THE ALINITY I PROLACTIN CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF

	SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER (REAGENTS, CALIBRATORS, AND INSTRUMENTS), WHEN USED FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN IN HUMAN SERUM AND PLASMA.,ALINITY I FREE T3 CONTROLS(ALINITY I FREE T3 CONTROLS)-THE ALINITY I FREE T3 CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER (REAGENTS, CALIBRATORS AND INSTRUMENT), WHEN USED FOR THE QUANTITATIVE MEASUREMENT OF FREE TRIIODOTHYRONINE (FREE T3) IN HUMAN SERUM AND PLASMA.,ALINITY I FREE T4 REAGENT KIT (ALINITY I FREE T4 REAGENT KIT)-THE ALINITY I FREE T4 ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FREE T4) IN HUMAN SERUM AND PLASMA ON THE ALINITY I ANALYZER.THE ALINITY I FREE T4 ASSAY IS TO BE USED AS AN AID IN THE ASSESSMENT OF THYROID STATUS.,ALINITY I STAT HIGH SENSITIVE TROPONIN-I REAGENT KIT(ALINITY I STAT HIGH SENSITIVE TROPONIN-I REAGENT KIT)-THE ALINITY I STAT HIGH SENSITIVE TROPONIN-I ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) USED FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN HUMAN PLASMA AND SERUM ON THE ALINITY I ANALYZER.,ALINITY I 25-OH VITAMIN D CONTROLS(ALINITY I 25-OH VITAMIN D CONTROLS)-THE ALINITY I 25-OH VITAMIN D CONTROLS ARE FOR THE ESTIMATION OF TEST PRECISION AND THE DETECTION OF SYSTEMATIC ANALYTICAL DEVIATIONS OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF 25-HYDROXYVITAMIN D (25-OH VITAMIN D) IN HUMAN SERUM AND PLASMA.,ALINITY I TOTAL T4 CALIBRATORS(ALINITY I TOTAL T4 CALIBRATORS)-THE ALINITY I TOTAL T4 CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (TOTAL T4) IN HUMAN SERUM AND PLASMA.,ALINITY I FREE T4 CONTROLS(ALINITY I FREE T4 CONTROLS)-THE ALINITY I FREE T4 CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FREE T4) IN HUMAN SERUM AND PLASMA.,ALINITY I TOTAL T4 CONTROLS (ALINITY I TOTAL T4 CONTROLS)-THE ALINITY I TOTAL T4 CONTROLS ARE FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (TOTAL T4) IN HUMAN SERUM AND PLASMA.,ARCHITECT STAT HIGH SENSITIVE TROPONIN-I CALIBRATOR(ARCHITECT STAT HIGH SENSITIVE TROPONIN-I CALIBRATOR)-THE ARCHITECT STAT HIGH SENSITIVE TROPONIN-I

	CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT I SYSTEM WITH STAT PROTOCOL CAPABILITY WHEN USED FOR THE QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN HUMAN SERUM AND PLASMA WITH THE ARCHITECT STAT HIGH SENSITIVE TROPONIN-I REAGENT KIT.,ARCHITECT FREE T3 REAGENT KIT(ARCHITECT FREE T3 REAGENT KIT)-THE ARCHITECT FREE T3 (FT3) ASSAY IS A CHEMILUMINESCENT MICROPARTICLE IMMUNOASSAY (CMIA) FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FREE T3) IN HUMAN SERUM AND PLASMA., ALINITY I 25-OH VITAMIN D CALIBRATORS(ALINITY I 25-OH VITAMIN D CALIBRATORS)-THE ALINITY I 25-OH VITAMIN D CALIBRATORS ARE FOR THE CALIBRATION OF THE ALINITY I ANALYZER WHEN USED FOR THE QUANTITATIVE DETERMINATION OF 25-HYDROXYVITAMIN D (25-OH VITAMIN D) IN HUMAN SERUM AND PLASMA.,ARCHITECT FERRITIN CONTROL(ARCHITECT FERRITIN CONTROL)-THE ARCHITECT FERRITIN CONTROLS ARE ASSAYED FOR THE VERIFICATION OF THE ACCURACY AND PRECISION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM AND PLASMA.,ARCHITECT FREE T3 CALIBRATOR(ARCHITECT FREE T3 CALIBRATOR)-THE ARCHITECT FREE T3 CALIBRATORS ARE FOR THE CALIBRATION OF THE ARCHITECT ISYSTEM WHEN USED FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FREE T3) IN HUMAN SERUM AND PLASMA.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1326	IMP/MD/2018/000224	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINE IMPLANT(XIA)-THE XIA SPINAL SYSTEM IS INTENDED FOR ANTERIOR ANTEROLATERAL AND POSTERIOR NONCERVICAL PEDICLE AND NON PEDICLE FIXATION OF THE SPINE TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E.,SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS), TUMOR, PSEUDOARTHROSIS AND FAILED PREVIOUS FUSION. THE 6 MM DIAMETER RODS FROM THE DIAPASONTM SPINAL SYSTEM AND OPUSTM SPINAL SYSTEM ARE INTENDED TO BE USED WITH THE OTHER COMPONENTS OF THE XIAR TITANIUM SPINAL SYSTEM. THE TITANIUM MULTI-AXIS CROSS-CONNECTORS ARE INTENDED TO BE USED WITH THE OTHER COMPONENTS OF THE XIAR TITANIUM SPINAL SYSTEM,VERTEBRAL SPACER(AVS ANCHOR-L CAGE SYSTEM)-THE STRYKER SPINE AVS ANCHOR-L IS AN INTERVERTEBRAL BODY FUSION DEVICE INDICATED FOR USE WITH AUTOGENOUS BONE GRAFT IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE LEVEL OR TWO CONTIGUOUS LEVELS FROM L2 TO S1. DDD IS DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. DDD PATIENTS MAY ALSO HAVE UP TO GRADE I SPONDYLOLISTHESIS AT THE INVOLVED LEVEL(S). THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE SIX MONTHS OF NONOPERATIVE THERAPY. THE AVSR ANCHOR-L LUMBAR CAGE SYSTEM IS TO BE IMPLANTED VIA AN OPEN, ANTERIOR APPROACH. THE AVSR ANCHOR-L LUMBAR CAGE SYSTEM MAY BE USED AS A STAND-ALONE DEVICE OR IN CONJUNCTION WITH SUPPLEMENTAL FIXATION. WHEN USED AS A STAND-ALONE DEVICE, THE AVSR ANCHOR-L LUMBAR CAGE MUST BE USED WITH THE INTERNAL SCREW AND PLATE FIXATION PROVIDED BY AVSR ANCHOR-L FIXATION SCREWS AND LOCKING PLATE. IF AVSR ANCHOR-L IS USED WITH LESS THAN THREE OR NONE OF THE PROVIDED SCREWS, THEN ADDITIONAL SUPPLEMENTAL FIXATION THAT HAS BEEN CLEARED BY THE FDA FOR USE IN THE LUMBAR SPINE MUST BE USED TO AUGMENT STABILITY. THE ACCOMPANYING LOCKING PLATE MUST BE USED ANYTIME THE DEVICE IS USED WITH ANY NUMBER OF SCREWS, SPINE IMPLANT - SCREW(XIA PRECISION)-THE XIA SPINAL SYSTEM IS INTENDED FOR ANTERIOR/ANTEROLATERAL AND POSTERIOR,

	NONCERVICAL PEDICLE AND NON-PEDICLE FIXATION OF THE SPINE TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS), TUMOR, PSEUDOARTHROSIS AND FAILED PREVIOUS FUSION. THE 6 MM DIAMETER RODS FROM THE DIAPASONTM SPINAL SYSTEM AND OPUSTM SPINAL SYSTEM ARE INTENDED TO BE USED WITH THE OTHER COMPONENTS OF THE XIAR TITANIUM SPINAL SYSTEM. THE TITANIUM MULTI-AXIS CROSS-CONNECTORS ARE INTENDED TO BE USED WITH THE OTHER COMPONENTS OF THE XIAR TITANIUM SPINAL SYSTEM,CERVICAL CAGE SYSTEM(AVS ANCHOR-C CAGE SYSTEM)-THE AVS ANCHOR C CERVICAL CAGE SYSTEM IS INDICATED FOR THE TREATMENT OF SPONDYLOLISTHESIS DEGENERATIVE SPINE DISORDERS DISCAL AND VERTEBRAL INSTABILITY AS WELL AS IN CASES OF SPINE REVISION SURGERY. IT IS RECOMMENDED TO PACK BONE GRAFT MATERIAL INSIDE THE IMPLANT. THE AVS ANCHOR C CERVICAL CAGES ARE TO BE IMPLANTED VIA AN OPEN, ANTERIOR APPROACH. THE AVS ANCHOR C CERVICAL CAGE MUST BE USED WITH THE INTERNAL SCREW FIXATION PROVIDED BY AVS ANCHOR C FIXATION SCREWS.,SPINE IMPLANT(XIA 3 SYSTEM - SERRATO)-THE XIA 3 SPINAL SYSTEM IS INTENDED FOR USE IN THE NON CERVICAL SPINE. WHEN USED AS AN ANTERIOR ANTEROLATERAL AND POSTERIOR NONCERVICAL PEDICLE AND NONPEDICLE FIXATION SYSTEM, THE XIA® 3 SPINAL SYSTEM IS INTENDED TO PROVIDE ADDITIONAL SUPPORT DURING FUSION USING AUTOGRAFT OR ALLOGRAFT IN SKELETALLY MATURE PATIENTS IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES: • DEGENERATIVE DISC DISEASE (AS DE$NED BY BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CON$RMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES) • SPONDYLOLISTHESIS • TRAUMA (I.E. FRACTURE OF DISLOCATION) • SPINAL STENOSIS • CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS) • TUMOR • PSEUDARTHROSIS • FAILED PREVIOUS FUSION THE 5.5 MM RODS FROM THE STRYKER SPINE RADIUS™ SPINAL SYSTEM AND 6.0 MM VITALLIUM RODS FROM THE XIA® SPINAL SYSTEM ARE INTENDED TO BE USED WITH THE OTHER COMPONENTS OF THE XIA® 3 SPINAL SYSTEM. WHEN USED FOR POSTERIOR, NON-CERVICAL, PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE XIA® 3 SPINAL SYSTEM IMPLANTS ARE INDICATED AS

	AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE SPINAL DEFORMITIES (I.E., SCOLIOSIS, KYPHOSIS, OR LORDOSIS) INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS, AND CONGENITAL SCOLIOSIS. ADDITIONALLY, THE XIA® 3 SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS DIAGNOSED WITH: SPONDYLOLISTHESIS/SPONDYLOLYSIS, FRACTURE CAUSED BY TUMOR AND/OR TRAUMA, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. THIS SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH.,SPINE IMPLANT (XIA 3)-THE XIA 3 SPINAL SYSTEM IS INTENDED FOR USE IN THE NONCERVICAL SPINE. WHEN USED AS AN ANTERIOR ANTEROLATERAL AND POSTERIOR NON CERVICAL PEDICLE AND NONPEDICLE FIXATION SYSTEM, THE XIA® 3 SPINAL SYSTEM IS INTENDED TO PROVIDE ADDITIONAL SUPPORT DURING FUSION USING AUTOGRAFT OR ALLOGRAFT IN SKELETALLY MATURE PATIENTS IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES: • DEGENERATIVE DISC DISEASE (AS DE$NED BY BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CON$RMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES) • SPONDYLOLISTHESIS • TRAUMA (I.E. FRACTURE OF DISLOCATION) • SPINAL STENOSIS • CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS) • TUMOR • PSEUDARTHROSIS • FAILED PREVIOUS FUSION THE 5.5 MM RODS FROM THE STRYKER SPINE RADIUS™ SPINAL SYSTEM AND 6.0 MM VITALLIUM RODS FROM THE XIA® SPINAL SYSTEM ARE INTENDED TO BE USED WITH THE OTHER COMPONENTS OF THE XIA® 3 SPINAL SYSTEM. WHEN USED FOR POSTERIOR, NON-CERVICAL, PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE XIA® 3 SPINAL SYSTEM IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE SPINAL DEFORMITIES (I.E., SCOLIOSIS, KYPHOSIS, OR LORDOSIS) INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS, AND CONGENITAL SCOLIOSIS. ADDITIONALLY, THE XIA® 3 SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS DIAGNOSED WITH: SPONDYLOLISTHESIS/SPONDYLOLYSIS, FRACTURE CAUSED BY TUMOR AND/OR TRAUMA, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. THIS SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH,SPINE IMPLANT (XIA II)-THE XIA SPINAL SYSTEM IS INTENDED FOR ANTERIOR ANTEROLATERAL AND POSTERIOR NONCERVICAL PEDICLE AND NON PEDICLE FIXATION OF THE SPINE TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE

		PATIENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E.,SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS), TUMOR, PSEUDOARTHROSIS AND FAILED PREVIOUS FUSION. THE 6 MM DIAMETER RODS FROM THE DIAPASONTM SPINAL SYSTEM AND OPUSTM SPINAL SYSTEM ARE INTENDED TO BE USED WITH THE OTHER COMPONENTS OF THE XIAR TITANIUM SPINAL SYSTEM. THE TITANIUM MULTI-AXIS CROSS-CONNECTORS ARE INTENDED TO BE USED WITH THE OTHER COMPONENTS OF THE XIAR TITANIUM SPINAL SYSTEM.
1327	IMP/MD/2018/000225	1.License Holder Name: M/S MOLNLYCKE HEALTHCARE INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SELF-ADHERENT SOFT SILICONE SURGICAL DRESSING(MEPILEX BORDER POST-OP)-MEPILEX BORDER POST-OP IS A SELF-ADHESIVE ABSORBENT SURGICAL DRESSING DESIGNED FOR EXUDING WOUNDS. IT IS INTENDED FOR ACUTE WOUNDS, SUCH AS SURGICAL WOUNDS, CUTS AND ABRASIONS.
1328	IMP/MD/2018/000226	1.License Holder Name: OLYMPUS MEDICAL SYSTEMS INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDE WIRE FOR ENDOSCOPY(VISIGLIDE2)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOTHERAPY ACCESSORIES. THE INSTRUMENT IS USED FOR GUIDING AND EXCHANGING ENDOSCOPIC ACCESSORIES FOR BILIARY DUCT, INCLUDING BUT NOT LIMITED TO THE COMMON BILE, CYSTIC, PANCREATIC AND RIGHT AND LEFT HEPATIC DUCTS.,GUIDE WIRE FOR ENDOSCOPY(VISIGLIDE)-THIS INSTRUMENT HAS BEEN DESIGNED TO BE USED WITH OLYMPUS ENDOTHERAPY ACCESSORIES. THE INSTRUMENT IS USED FOR GUIDING AND EXCHANGING ENDOSCOPIC ACCESSORIES FOR BILIARY DUCT, INCLUDING BUT NOT LIMITED TO THE COMMON BILE, CYSTIC, PANCREATIC AND RIGHT AND LEFT HEPATIC DUCTS.

1329	IMP/MD/2018/000227	1.License Holder Name: SMITHS MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRACHEAL INTUBATION STYLET(PORTEX)-THE STYLET IS INTENDED FOR FACILITATING ORAL INTUBATION OF THE TRACHEA. ,NASOPHARYNGEAL AIRWAY (PORTEX)-A STERILE USE OF NASOPHARYNGEAL AIRWAY MANUFACTURED FROM IVORY PVC MATERIAL ,ORATOR-TRACHEOSTOMY SPEAKING VALVE(PORTEX)-A ONE WAY SPEAKING VALVE INTENDED FOR SINGLE PATIENT USE WHICH CAN BE USED WITH FENESTRATED, CUFFED OR UNCUFFED TRACHEOSTOMY TUBES.
1330	IMP/MD/2018/000228	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT ABUTMENT - GOLD(GOLDADAPT ABUTMENT)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER AND LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION.
1331	IMP/MD/2018/000232	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDEWIRE(CPS COURIER GUIDEWIRE)-IT IS INTENDED FOR USE IN THE CORONARY AND PERIPHERAL VASCULATURE.
1332	IMP/MD/2018/000233	1.License Holder Name: SHAH EYE CARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRAOCULAR LENS (ORIZON)-IT IS INTENDED FOR THE REPLACEMENT OF HUMAN CRYSTALLINE LENS.,INTRAOCULAR LENS(SIDA-LENS)-IT IS INTENDED FOR THE REPLACEMENT OF HUMAN CRYSTALLINE LENS.

1333	IMP/MD/2018/000233	1.License Holder Name: SHAH EYE CARE PRIVATE LIMITED ,PLOT NO. 8 &9, KARUR INDUSTRIAL AREA, P B ROAD, DAVANGERE-577006, KARNATAKA, INDIA ,DAVANGERE KARNATAKA ,577006 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PMMA INTRAOCULAR LENS(SIDA-LENS)-SIDA-LENS PMMA INTRAOCULAR LENSES (IOLS) ARE INTENDED FOR IMPLANTATION IN THE POSTERIOR CHAMBER (FOR SDHS, SDALP) AND ANTERIOR CHAMBER (FOR SDANT) IN PATIENTS WHERE A CATARACTOUS LENS HAS BEEN REMOVED, HYDROPHILIC ONE-PIECE ACRYLIC FOLDABLE INTRAOCULAR LENS (SIDA-LENS)-SIDA-LENS HYDROPHILIC INTRAOCULAR LENSES (IOLS) ARE INTENDED FOR IMPLANTATION IN THE POSTERIOR CHAMBER IN PATIENTS WHERE A CATARACTOUS LENS HAS BEEN REMOVED.
1334	IMP/MD/2018/000235	1.License Holder Name: CARDINAL HEALTH MEDICAL PRODUCTS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EMBOLI CAPTURE GUIDEWIRE SYSTEM(ANGIOGUARD)-ANGIOGUARD GUIDEWIRE IS INTENDED FOR CORONARY, CAROTID AND PERIPHERAL USES TO FACILITATE THE PLACEMENT OF DIAGNOSTIC AND INTERVENTIONAL DEVICES AND CAPTURE EMBOLI, THEREBY REDUCING THE RISK OF EMBOLIZATION, DURING PROCEDURES.

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1335	IMP/MD/2018/000236	1.License Holder Name: BIO-RAD LABORATORIES (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIROTROL III(VIROTROL III)-VIROTROL III IS INTENDED FOR USE AS AN UNASSAYED REACTIVE CONTROL WITH IN VITRO ASSAY PROCEDURES FOR THE QUALITATIVE DETERMINATION OF IMMUNOGLOBULIN M ANTIBODIES TO HEPATITIS A VIRUS (HAV-IGM), IMMUNOGLOBULIN M ANTIBODIES TO HEPATITIS B CORE ANTIGEN (HBC-IGM), AND TOTAL ANTIBODY TO HEPATITIS A VIRUS (ANTI-HAV). SPECIFIC REACTIVITY FOR IMMUNOGLOBULIN G ANTIBODIES TO HEPATITIS A VIRUS HAS NOT BEEN ESTABLISHED. THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES.,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL C1(LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL C1)-LIQUICHEK URINE TOXICOLOGY CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY CONFIRMATORY PROCEDURES.,AMPLICLEAR(AMPLICLEAR)-AMPLICLEAR IS INTENDED FOR USE AS AN UNASSAYED NON-REACTIVE QUALITY CONTROL REAGENT WITH IN VITRO DIAGNOSTIC PROCEDURES FOR DETECTION OF CHLAMYDIA TRACHOMATIS (CT) AND NEISSERIA GONORRHOEAE (GC). THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES. USE OF THIS PRODUCT WILL MONITOR ASSAY FUNCTIONALITY AND NOT SENSITIVITY OF THE ASSAY DETECTION LIMITS.,LIQUICHEK MICROALBUMIN CONTROL(LIQUICHEK MICROALBUMIN CONTROL)-LIQUICHEK MICROALBUMIN CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,VIROCLEAR (VIROCLEAR)-VIROCLEAR IS INTENDED FOR USE AS AN UNASSAYED NON-REACTIVE QUALITY ASSURANCE REAGENT WITH IN VITRO ASSAYS DETECTING ANTIBODY TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (ANTI-HIV-1), ANTIBODY TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 2 (ANTI-HIV-2), ANTIBODY TO HUMAN T-LYMPHOTROPIC VIRUS TYPE I (ANTI-HTLV-I), HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 ANTIGEN (HIV-1 AG), ANTIBODY TO HUMAN T-LYMPHOTROPIC VIRUS TYPE II (ANTI-HTLV-II), ANTIBODY TO HEPATITIS C VIRUS (ANTI-HCV), IMMUNOGLOBULIN M AND TOTAL ANTIBODIES TO HEPATITIS B CORE ANTIGEN (HBC-IGM AND ANTI-HBC TOTAL), HEPATITIS B SURFACE ANTIGEN (HBSAG), ANTIBODY TO

	HEPATITIS B SURFACE ANTIGEN (ANTI-HBS), IMMUNOGLOBULIN M AND TOTAL ANTIBODY TO HEPATITIS A VIRUS (HAV-IGM AND ANTI-HAV TOTAL), HEPATITIS B E ANTIGEN (HBEAG), ANTIBODY TO HEPATITIS B E ANTIGEN (ANTI-HBE), ANTIBODY TO HEPATITIS DELTA VIRUS (ANTI-HDV), ANTIBODY TO CYTOMEGALOVIRUS (ANTI-CMV), IMMUNOGLOBULIN G (IGG) AND IMMUNOGLOBULIN M (IGM) ANTIBODIES TO TREPONEMA PALLIDUM AND NON-TREPONEMAL ANTIBODIES (REAGIN). THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES,LIQUICHEK ANTI-SS-B CONTROL, POSITIVE (LIQUICHEK ANTI-SS-B CONTROL, POSITIVE)-LIQUICHEK ANTI-SS-B CONTROL, POSITIVE, IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL TO MONITOR INDIRECT IMMUNOFLUORESCENT TESTING FOR THE DETECTION OF SS-B AUTOANTIBODIES., LYPHOCHEK HEMOGLOBIN A1C LINEARITY SET(LYPHOCHEK HEMOGLOBIN A1C LINEARITY SET)-LYPHOCHEK HEMOGLOBIN A1C LINEARITY SET IS INTENDED TO VERIFY THE LINEARITY THROUGHOUT THE PATIENT REPORTABLE RANGE OF HEMOGLOBIN A1C ASSAYS USING PROTOCOLS ESTABLISHED IN INDIVIDUAL LABORATORIES.,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S1E LOW OPIATE(LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S1E LOW OPIATE)-LIQUICHEK URINE TOXICOLOGY CONTROL LEVEL S1E LOW OPIATE IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY ENZYME IMMUNOASSAY (EIA) SCREENING PROCEDURES,LIQUICHEK RETICULOCYTE CONTROL (S)(LIQUICHEK RETICULOCYTE CONTROL (S))-LIQUICHEK RETICULOCYTE CONTROL (S) IS A CONTROL DESIGNED TO MONITOR VALUES OBTAINED USING AUTOMATIC RETICULOCYTE COUNTING METHODS.,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL C2(LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL C2)-LIQUICHEK URINE TOXICOLOGY CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY CONFIRMATORY PROCEDURES,VIROCLEAR TORCH(VIROCLEAR TORCH)-VIROCLEAR TORCH IS INTENDED FOR USE AS AN UNASSAYED NON-REACTIVE CONTROL REAGENT WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF IMMUNOGLOBULIN G (IGG) AND IMMUNOGLOBULIN M (IGM) ANTIBODIES TO TOXOPLASMA GONDII (TOXO), IGG AND IGM ANTIBODIES TO RUBELLA VIRUS, IGG AND IGM ANTIBODIES TO CYTOMEGALOVIRUS (CMV), AND IGG AND IGM ANTIBODIES TO HERPES SIMPLEX VIRUS (HSV) TYPES 1 AND 2. THIS PRODUCT IS NOT INTENDED FOR USE IN TESTING DONATED BLOOD OR PLASMA. THIS PRODUCT IS INTENDED TO PROVIDE A

	MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES,LYPHOCHEK IMMUNOLOGY PLUS CONTROL (LYPHOCHEK IMMUNOLOGY PLUS CONTROL)-LYPHOCHEK IMMUNOLOGY PLUS CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT. ,VIROTROL HIV 1 GO(VIROTROL HIV 1 GO)-VIROTROL HIV-1 GO IS INTENDED FOR USE AS AN UNASSAYED REACTIVE QUALITY CONTROL WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1 GROUP O) IN HUMAN SERUM OR PLASMA. THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES. SPECIFIC REACTIVITY FOR OTHER HIV-1 SUBTYPES (M OR N), AND HIV-2 HAS NOT BEEN ESTABLISHED. THIS PRODUCT IS NOT INTENDED FOR USE WITH BLOOD SCREENING ASSAYS.,LIQUICHEK DIABETES CONTROL(LIQUICHEK DIABETES CONTROL)-LIQUICHEK DIABETES CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT.,LIQUICHEK IMMUNOASSAY PREMIUM CONTROL(LIQUICHEK IMMUNOASSAY PREMIUM CONTROL)-LIQUICHEK IMMUNOASSAY PREMIUM CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT.,LYPHOCHEK TUMOR MARKER PLUS CONTROL(LYPHOCHEK TUMOR MARKER PLUS CONTROL)-LYPHOCHEK TUMOR MARKER PLUS CONTROL IS INTENDED FOR USE QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,AMPLICHEK STI LEVELS POSITIVE AND NEGATIVE(AMPLICHEK STI LEVELS POSITIVE AND NEGATIVE)-AMPLICHEK STI IS INTENDED FOR USE AS AN EXTERNAL UNASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PERFORMANCE OF IN VITRO LABORATORY NUCLEIC ACID TESTING PROCEDURES FOR THE QUALITATIVE DETECTION OF CHLAMYDIA TRACHOMATIS (CT), NEISSERIA GONORRHOEAE (NG OR GC) AND HIGH-RISK HUMAN PAPILLOMAVIRUS (HPV). THIS PRODUCT IS NOT INTENDED TO REPLACE MANUFACTURER CONTROLS PROVIDED WITH THE DEVICE.,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S2E (LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S2E)-LIQUICHEK URINE TOXICOLOGY CONTROL LEVEL S2E IS INTENDED FOR USE AS A

	QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY ENZYME IMMUNOASSAY (EIA) SCREENING PROCEDURES.,VIROTROL EBV(VIROTROL EBV)-VIROTROL EBV IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL REAGENT WITH IN VITRO DIAGNOSTIC ASSAY PROCEDURES FOR DETERMINATION OF IMMUNOGLOBULIN G (IGG) AND IMMUNOGLOBULIN M (IGM) ANTIBODIES TO THE VIRAL CAPSID ANTIGEN (VCA) OF EPSTEIN-BARR VIRUS (EBV) AND IMMUNOGLOBULIN G (IGG) ANTIBODIES TO THE VIRAL POLYPEPTIDE NUCLEAR ANTIGEN OF EPSTEIN-BARR VIRUS (EBNA). THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES,ASSAYED VIROTROL II-B(ASSAYED VIROTROL II-B)-ASSAYED VIROTROL II-B IS AN ASSAYED CONTROL PREPARED FROM PROCESSED HUMAN PLASMA OR SERUM AND IS INTENDED FOR USE WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF ANTIBODIES TO HEPATITIS B SURFACE ANTIGEN (ANTI-HBS) AND QUALITATIVE ASSAY PROCEDURES FOR DETERMINATION OF ANTIBODIES TO HEPATITIS A VIRUS (ANTI-HAV),VIROTROL LYME(VIROTROL LYME)-VIROTROL LYME IS INTENDED FOR USE AS A REACTIVE UNASSAYED QUALITY CONTROL REAGENT WITH IN VITRO ENZYME IMMUNOASSAY PROCEDURES FOR DETERMINATION OF IMMUNOGLOBULIN G (IGG) ANTIBODY TO BORRELIA BURGDORFERI. THIS PRODUCT IS INTENDED AS A MEANS OF MONITORING PRECISION AND HAS THE POTENTIAL TO DETECT SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES.,ASSAYED VIROTROL I-C(ASSAYED VIROTROL I-C)-ASSAYED VIROTROL I-C IS INTENDED FOR USE WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1), ANTIBODIES TO HUMAN T-LYMPHOTROPIC VIRUS TYPE I (HTLV-I), ANTIBODIES TO HEPATITIS C VIRUS (HCV), HEPATITIS B SURFACE ANTIGEN (HBSAG), ANTIBODIES TO HEPATITIS B CORE ANTIGEN (HBC) AND ANTIBODIES TO CYTOMEGALOVIRUS (CMV).,VIROTROL I(VIROTROL I)-VIROTROL I IS INTENDED FOR USE WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1), ANTIBODIES TO HUMAN T-LYMPHOTROPIC VIRUS TYPE I (HTLV-I), ANTIBODIES TO HEPATITIS C VIRUS (HCV), HEPATITIS B SURFACE ANTIGEN (HBSAG), ANTIBODIES TO HEPATITIS B CORE ANTIGEN (HBC) AND ANTIBODIES TO CYTOMEGALOVIRUS, LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S1E (LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S1E)-LIQUICHEK URINE TOXICOLOGY CONTROL LEVEL S1E IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF

	LABORATORY URINE TOXICOLOGY ENZYME IMMUNOASSAY (EIA) SCREENING PROCEDURES.,VIROTROL EBV(VIROTROL EBV)-VIROTROL EBV IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL REAGENT WITH IN VITRO DIAGNOSTIC ASSAY PROCEDURES FOR DETERMINATION OF IMMUNOGLOBULIN G (IGG) AND IMMUNOGLOBULIN M (IGM) ANTIBODIES TO THE VIRAL CAPSID ANTIGEN (VCA) OF EPSTEIN-BARR VIRUS (EBV) AND IMMUNOGLOBULIN G (IGG) ANTIBODIES TO THE VIRAL POLYPEPTIDE NUCLEAR ANTIGEN OF EPSTEIN-BARR VIRUS (EBNA). THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES.,ASSAYED VIROTROL I-F(ASSAYED VIROTROL I-F)-ASSAYED VIROTROL I-F IS INTENDED FOR USE WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1), ANTIBODIES TO HUMAN T-LYMPHOTROPIC VIRUS TYPE I (HTLV-I), ANTIBODIES TO HEPATITIS C VIRUS (HCV), HEPATITIS B SURFACE ANTIGEN (HBSAG), ANTIBODIES TO HEPATITIS B CORE ANTIGEN (HBC) AND ANTIBODIES TO CYTOMEGALOVIRUS (CMV).,VIROCLEAR EBV(VIROCLEAR EBV)-VIROCLEAR EBV IS INTENDED FOR USE AS AN UNASSAYED NON-REACTIVE CONTROL REAGENT WITH IN VITRO DIAGNOSTIC ASSAY PROCEDURES FOR DETERMINATION OF IMMUNOGLOBULIN G (IGG) AND IMMUNOGLOBULIN M (IGM) ANTIBODIES TO THE VIRAL CAPSID ANTIGEN (VCA) OF EPSTEIN-BARR VIRUS (EBV), IGG ANTIBODIES TO EARLY ANTIGEN (EA) AND IGG ANTIBODIES TO THE NUCLEAR ANTIGEN OF EPSTEIN-BARR VIRUS (EBNA). THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES,LYPHOCHEK WHOLE BLOOD METALS CONTROL(LYPHOCHEK WHOLE BLOOD METALS CONTROL)-LYPHOCHEK WHOLE BLOOD METALS CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT., VIROTROL MUMZ(VIROTROL MUMZ)-VIROTROL MUMZ IS INTENDED FOR USE AS AN UNASSAYED REACTIVE CONTROL REAGENT WITH IN VITRO DIAGNOSTIC ENZYME IMMUNOASSAY PROCEDURES FOR DETERMINATION OF IMMUNOGLOBULIN G (IGG) ANTIBODY TO MUMPS VIRUS, IMMUNOGLOBULIN G (IGG) ANTIBODY TO MEASLES (RUBEOLA) VIRUS AND IMMUNOGLOBULIN G (IGG) ANTIBODY TO VARICELLA-ZOSTER VIRUS (VZV). THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM

	SPECIFIC LABORATORY TESTING PROCEDURES.,LIQUICHEK ETHANOL/AMMONIA CONTROL(LIQUICHEK ETHANOL/AMMONIA CONTROL)-LIQUICHEK ETHANOL/AMMONIA CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK HOMOCYSTEINE CONTROL(LIQUICHEK HOMOCYSTEINE CONTROL)-LIQUICHEK HOMOCYSTEINE CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURE FOR HOMOCYSTEINE, LIQUICHEK ANTI-RNP CONTROL, POSITIVE(LIQUICHEK ANTI-RNP CONTROL, POSITIVE)-LIQUICHEK ANTI-RNP CONTROL, POSITIVE, IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL TO MONITOR INDIRECT IMMUNOFLUORESCENT TESTING FOR THE DETECTION OF RIBONUCLEOPROTEIN (RNP) AUTOANTIBODIES., AMPLICHEK II LEVELS NEGATIVE, 1, 2, AND 3(AMPLICHEK II LEVELS NEGATIVE, 1, 2, AND 3)-AMPLICHEK II IS INTENDED FOR USE AS AN EXTERNAL ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PERFORMANCE OF IN VITRO LABORATORY NUCLEIC ACID TESTING PROCEDURES FOR THE QUALITATIVE DETECTION OF METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS, METHICILLIN SENSITIVE STAPHYLOCOCCUS AUREUS, CLOSTRIDIUM DIFFICILE AND VANCOMYCIN-RESISTANT ENTEROCOCCI PERFORMED ON CEPHEID GENEXPERT SYSTEMS. THIS PRODUCT IS NOT INTENDED TO REPLACE MANUFACTURER CONTROLS PROVIDED WITH THE DEVICE. THIS PRODUCT IS ONLY FOR USE WITH ASSAYS AND INSTRUMENTS LISTED IN THE REPRESENTATIVE RESULTS CHART IN THIS LABELING, LYPHOCHEK HEMOGLOBIN A1C LINEARITY SET(LYPHOCHEK HEMOGLOBIN A1C LINEARITY SET)-LYPHOCHEK HEMOGLOBIN A1C LINEARITY SET IS INTENDED TO VERIFY THE LINEARITY THROUGHOUT THE PATIENT REPORTABLE RANGE OF HEMOGLOBIN A1C ASSAYS USING PROTOCOLS ESTABLISHED IN INDIVIDUAL LABORATORIES.,VIROTROL WNV(VIROTROL WNV)-VIROTROL WNV IS INTENDED FOR USE AS AN UNASSAYED PRECISION CONTROL REAGENT WITH IN VITRO IMMUNOASSAY PROCEDURES FOR DETECTION OF IMMUNOGLOBULIN G (IGG) AND IMMUNOGLOBULIN M (IGM) ANTIBODIES TO WEST NILE VIRUS (WNV) IN HUMAN SERUM. THIS PRODUCT IS DESIGNED FOR ROUTINE USE TO PROVIDE A MEANS OF ESTIMATING PRECISION AND MONITORING TEST SYSTEM PERFORMANCE.,LIQUICHEK ANA CONTROL, HOMOGENEOUS PATTERN, POSITIVE (LIQUICHEK ANA CONTROL, HOMOGENEOUS PATTERN, POSITIVE)-LIQUICHEK ANA CONTROL, HOMOGENEOUS PATTERN, POSITIVE IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL TO MONITOR INDIRECT IMMUNOFLUORESCENT

	TESTING OF ANTINUCLEAR ANTIBODIES (ANA).,VIROTROL RPR PANEL(VIROTROL RPR PANEL)-VIROTROL RPR PANEL IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL PANEL WITH IN VITRO ASSAY PROCEDURES FOR THE QUALITATIVE DETERMINATION OF NON-TREPONEMAL ANTIBODIES (SYPHILITIC REAGIN). THIS PRODUCT IS DESIGNED FOR ROUTINE USE TO PROVIDE A MEANS OF ESTIMATING REPRODUCIBILITY AND MONITORING TEST SYSTEM PERFORMANCE.,LIQUICHEK THERAPEUTIC DRUG MONITORING CONTROL (TDM)(LIQUICHEK THERAPEUTIC DRUG MONITORING CONTROL (TDM))-LIQUICHEK THERAPEUTIC DRUG MONITORING CONTROL (TDM) IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK RETICULOCYTE CONTROL (A)(LIQUICHEK RETICULOCYTE CONTROL (A))-LIQUICHEK RETICULOCYTE CONTROL (A) IS A BILEVEL CONTROL FOR USE IN MONITORING THE PERFORMANCE OF CELL-DYN® HEMATOLOGY INSTRUMENTS., LYPHOCHEK ENDOCRINE CONTROL(LYPHOCHEK ENDOCRINE CONTROL)-LYPHOCHEK ENDOCRINE CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,INTELIQ ASSAYED MULTIQUAL CONTROL(INTELIQ ASSAYED MULTIQUAL CONTROL)-INTELIQ ASSAYED MULTIQUAL CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF THE LABORATORY TESTING PROCEDURES FOR THE ANAYTES LISTED IN THIS PACKAGE INSERT.,LIQUICHEK URINE CHEMISTRY CONTROL(LIQUICHEK URINE CHEMISTRY CONTROL)-LIQUICHEK URINE CHEMISTRY CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL URINE TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,AMPLITROL CT/GC(AMPLITROL CT/GC)-AMPLITROL CT/GC IS INTENDED FOR USE AS AN UNASSAYED CONTROL REAGENT WITH IN VITRO ASSAY PROCEDURES FOR DETECTION OF CHLAMYDIA TRACHOMATIS (CT) OR NEISSERIA GONORRHOEAE (GC) IN NUCLEIC ACID BASED METHODS OF DETECTION. THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES. USE OF THIS PRODUCT WILL MONITOR ASSAY FUNCTIONALITY AND NOT SENSITIVITY OF THE ASSAY DETECTION LIMITS.,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S2S (LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S2S)-LIQUICHEK URINE TOXICOLOGY CONTROL IS INTENDED FOR USE AS A QUALITY

	CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY ENZYME IMMUNOASSAY (EIA) SCREENING PROCEDURES.,VIROTROL HIV 1 AG(VIROTROL HIV 1 AG)-VIROTROL HIV-1 AG IS INTENDED FOR USE AS AN UNASSAYED REACTIVE QUALITY CONTROL WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF ANTIGENS TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1). THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES.,LIQUICHEK ANTI-SS-A CONTROL, POSITIVE (LIQUICHEK ANTI-SS-A CONTROL, POSITIVE)-LIQUICHEK ANTI-SS-A CONTROL, POSITIVE, IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL TO MONITOR INDIRECT IMMUNOFLUORESCENT TESTING FOR THE DETECTION OF SS-A AUTOANTIBODIES., VIROCLEAR MUMZ(VIROCLEAR MUMZ)-VIROCLEAR MUMZ IS INTENDED FOR USE AS AN UNASSAYED NON-REACTIVE PRECISION QUALITY CONTROL WITH IN VITRO ASSAY PROCEDURES FOR DETECTION OF IMMUNOGLOBULIN G (IGG) ANTIBODIES TO MUMPS, MEASLES (RUBEOLA) AND VARICELLA-ZOSTER VIRUS (VZV). THIS PRODUCT IS DESIGNED FOR ROUTINE USE TO PROVIDE A MEANS OF ESTIMATING PRECISION AND MONITORING TEST SYSTEM PERFORMANCE.,LIQUICHEK AUTOIMMUNE NEGATIVE CONTROL (LIQUICHEK AUTOIMMUNE NEGATIVE CONTROL)-LIQUICHEK AUTOIMMUNE NEGATIVE CONTROL IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL TO MONITOR INDIRECT IMMUNOFLUORESCENT TESTING FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,AMPLIPROBE CT/GC(AMPLIPROBE CT/GC)-AMPLIPROBE CT/GC IS INTENDED FOR USE AS AN UNASSAYED CONTROL REAGENT WITH IN VITRO ASSAY PROCEDURES FOR THE MOLECULAR (NUCLEIC ACID) DETECTION OF CHLAMYDIA TRACHOMATIS (CT) AND NEISSERIA GONORRHOEAE (GC). THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF MONITORING PERFORMANCE OF LABORATORY PROCEDURES ON A ROUTINE BASIS, AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES. USE OF THIS PRODUCT WILL MONITOR ASSAY FUNCTIONALITY AND NOT ANALYTICAL SENSITIVITY OF THE ASSAY DETECTION LIMITS., LIQUICHEK TORCH PLUS CONTROL, POSITIVE(LIQUICHEK TORCH PLUS CONTROL, POSITIVE)-LIQUICHEK TORCH PLUS CONTROL, POSITIVE IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT.,INTELIQ SPECIALTY IMMUNOASSAY CONTROL(INTELIQ SPECIALTY IMMUNOASSAY CONTROL)-INTELIQ SPECIALTY

	IMMUNOASSAY CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT. ,LYPHOCHEK HEMOSTASIS CONTROL (LYPHOCHEK HEMOSTASIS CONTROL)-LYPHOCHEK HEMOSTASIS CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL PLASMA TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT, LIQUICHEK CARDIAC MARKERS PLUS CONTROL LT(LIQUICHEK CARDIAC MARKERS PLUS CONTROL LT)-LIQUICHEK CARDIAC MARKERS PLUS CONTROL LT IS INTENDED FOR USE AS A QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK SEDIMENTATION RATE CONTROL(LIQUICHEK SEDIMENTATION RATE CONTROL)-LIQUICHEK SEDIMENTATION RATE CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL TO MONITOR THE PRECISION OF ERYTHROCYTE SEDIMENTATION RATE (ESR) LABORATORY TESTING PROCEDURES,VIROTROL IV(VIROTROL IV)-VIROTROL IV IS INTENDED FOR USE AS AN UNASSAYED REACTIVE CONTROL WITH IN VITRO ENZYME IMMUNOASSAY (EIA) PROCEDURES FOR DETERMINATION OF ANTIBODIES TO HEPATITIS B E ANTIGEN (ANTI-HBE). THIS PRODUCT IS DESIGNED FOR ROUTINE USE TO PROVIDE A MEANS OF ESTIMATING PRECISION AND MONITORING TEST SYSTEM PERFORMANCE,LYPHOCHEK MATERNAL SERUM CONTROL(LYPHOCHEK MATERNAL SERUM CONTROL)-LYPHOCHEK MATERNAL SERUM CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,VIROTROL TORCH-M (VIROTROL TORCH-M)-VIROTROL TORCH-M IS INTENDED FOR USE AS AN UNASSAYED REACTIVE QUALITY CONTROL, WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF IMMUNOGLOBULIN G (IGG) AND IMMUNOGLOBULIN M (IGM) ANTIBODIES TO TOXOPLASMA GONDII (TOXO), IGG AND IGM ANTIBODIES TO RUBELLA VIRUS (RUBELLA), IGG AND IGM ANTIBODIES TO CYTOMEGALOVIRUS (CMV), AND IGG ANTIBODIES TO HERPES SIMPLEX VIRUS (HSV) TYPES 1 AND 2. THIS PRODUCT IS NOT INTENDED FOR USE IN TESTING OF DONATED BLOOD OR PLASMA. THIS PRODUCT IS DESIGNED FOR ROUTINE USE TO PROVIDE A MEANS OF ESTIMATING PRECISION AND MONITORING TEST SYSTEM PERFORMANCE,LIQUICHEK ELEVATED CRP CONTROL(LIQUICHEK ELEVATED CRP CONTROL)-LIQUICHEK ELEVATED CRP CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR C-REACTIVE PROTEIN (CRP).,LIQUICHEK

	HEMATOLOGY CONTROL (A)(LIQUICHEK HEMATOLOGY CONTROL (A)) -LIQUICHEK HEMATOLOGY CONTROL (A) IS AN ASSAYED WHOLE BLOOD CONTROL DESIGNED TO MONITOR VALUES ON MULTI-PARAMETER HEMATOLOGY CELL COUNTERS.,LIQUICHEK D-DIMER CONTROL(LIQUICHEK D-DIMER CONTROL)-LIQUICHEK D-DIMER CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR D-DIMER.,INTELIQ TUMOR MARKER CONTROL (INTELIQ TUMOR MARKER CONTROL)-INTELIQ TUMOR MARKER CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT., LYPHOCHEK HYPERTENSION MARKERS CONTROL(LYPHOCHEK HYPERTENSION MARKERS CONTROL)-LYPHOCHEK HYPERTENSION MARKERS CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT., QUANTIFY ADVANCE CONTROL(QUANTIFY ADVANCE CONTROL)-QUANTIFY ADVANCE IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL TO MONITOR THE PRECISION OF URINALYSIS TEST PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT, LIQUICHEK ANTI-SM CONTROL, POSITIVE(LIQUICHEK ANTI-SM CONTROL, POSITIVE)-LIQUICHEK ANTI-SM CONTROL, POSITIVE, IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL TO MONITOR INDIRECT IMMUNOFLUORESCENT TESTING FOR THE DETECTION OF SMITH (SM) AUTOANTIBODIES,VIROTROL CHAGAS (VIROTROL CHAGAS)-VIROTROL CHAGAS IS INTENDED FOR USE AS AN UNASSAYED REACTIVE EXTERNAL QUALITY CONTROL REAGENT WITH IN VITRO DIAGNOSTIC QUALITATIVE ASSAY PROCEDURES FOR DETERMINATION OF ANTIBODIES TO TRYPANOSOMA CRUZI (T. CRUZI) IN HUMAN SERUM OR PLASMA, CHARACTERISTICALLY ASSOCIATED WITH CHAGAS DISEASE. THIS PRODUCT IS INTENDED AS A MEANS OF MONITORING PRECISION AND HAS THE POTENTIAL TO DETECT SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES.,LIQUICHEK CARDIAC MARKERS PLUS CONTROL(LIQUICHEK CARDIAC MARKERS PLUS CONTROL)-LIQUICHEK CARDIAC MARKERS PLUS CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK HEMATOLOGY 16T CONTROL(LIQUICHEK HEMATOLOGY 16T CONTROL)-LIQUICHEK HEMATOLOGY-16T CONTROL IS A CONTROL DESIGNED TO MONITOR VALUES ON AUTOMATED AND SEMI-AUTOMATED IMPEDANCE TYPE HEMATOLOGY ANALYZERS. IT CAN

	ALSO BE USED FOR MANUAL METHODS.,LIQUICHEK BLOOD GAS PLUS EGL CONTROL(LIQUICHEK BLOOD GAS PLUS EGL CONTROL)-LIQUICHEK BLOOD GAS PLUS EGL CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR USE IN MONITORING THE PRECISION OF AN INDIVIDUAL LABORATORY'S MEASUREMENT OF PH, PCO2, PO2, ELECTROLYTES, GLUCOSE, LACTATE (LACTIC ACID) AND MAGNESIUM BY BLOOD GAS, ION SELECTIVE ELECTRODE (ISE) AND BIOSENSOR INSTRUMENTATION.,LIQUICHEK CARDIAC TROPONINS CONTROL(LIQUICHEK CARDIAC TROPONINS CONTROL)-LIQUICHECK CARDIAC TROPONINS CONTROL IS INTENDED FOR THE USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE.,LIQUICHEK BLOOD GAS CONTROL(LIQUICHEK BLOOD GAS CONTROL)-LIQUICHEK BLOOD GAS CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR USE IN MONITORING THE PRECISION OF AN INDIVIDUAL LABORATORY'S MEASUREMENT OF PH, PCO2 AND PO2 BY BLOOD GAS INSTRUMENTATION.,LYPHOCHEK SPECIALTY IMMUNOASSAY CONTROL(LYPHOCHEK SPECIALTY IMMUNOASSAY CONTROL)-LYPHOCHEK SPECIALTY IMMUNOASSAY CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT.,LYPHOCHEK COAGULATION CONTROL(LYPHOCHEK COAGULATION CONTROL)-LYPHOCHEK COAGULATION CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL PLASMA TO MONITOR THE PRECISION OF CITRATED COAGULATION SYSTEMS,LIQUICHEK CARDIAC MARKERS PLUS CONTROL LT(LIQUICHEK CARDIAC MARKERS PLUS CONTROL LT)-LIQUICHEK CARDIAC MARKERS PLUS CONTROL LT IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK BLOOD GAS PLUS E CONTROL(LIQUICHEK BLOOD GAS PLUS E CONTROL)-LIQUICHEK BLOOD GAS PLUS E CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR USE IN MONITORING THE PRECISION OF AN INDIVIDUAL LABORATORY'S MEASUREMENT OF PH, PCO2, PO2, AND ELECTROLYTES BY BLOOD GAS AND ION SELECTIVE ELECTRODE (ISE) INSTRUMENTATION.,VIROTROL II(VIROTROL II)-VIROTROL II IS AN UNASSAYED POSITIVE CONTROL PREPARED FROM PROCESSED HUMAN PLASMA OR SERUM AND IS INTENDED FOR USE WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF ANTIBODIES TO HEPATITIS B SURFACE ANTIGEN (ANTI-HBS) AND QUALITATIVE ASSAY PROCEDURES FOR DETERMINATION OF ANTIBODIES TO HEPATITIS A VIRUS (ANTI-HAV). THIS PRODUCT IS INTENDED TO

	PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES,LYPHOCHEK BENZO/TCA CONTROL -SET B(LYPHOCHEK BENZO/TCA CONTROL -SET B)-LYPHOCHEK BENZO/TCA CONTROL-SET B IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,VIROTROL HBC IGM (VIROTROL HBC IGM)-VIROTROL HBC-IGM IS INTENDED FOR USE AS AN UNASSAYED REACTIVE CONTROL WITH IN VITRO ASSAY PROCEDURES FOR THE QUALITATIVE DETERMINATION OF IMMUNOGLOBULIN M ANTIBODIES TO HEPATITIS B CORE ANTIGEN (HBC-IGM). THIS PRODUCT IS DESIGNED FOR ROUTINE USE TO PROVIDE A MEANS OF ESTIMATING PRECISION AND MONITORING TEST SYSTEM PERFORMANCE. THIS PRODUCT IS NOT INTENDED FOR USE IN CONJUNCTION WITH BLOOD DONOR SCREENING TESTS, LYPHOCHEK DIABETES CONTROL(LYPHOCHEK DIABETES CONTROL)-LYPHOCHEK DIABETES CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT.,VIROTROL HBEAG (VIROTROL HBEAG)-VIROTROL HBEAG IS INTENDED FOR USE AS AN UNASSAYED REACTIVE CONTROL WITH IN VITRO ASSAY PROCEDURES FOR THE QUALITATIVE DETERMINATION OF HEPATITIS B E ANTIGEN (HBEAG). THIS PRODUCT IS DESIGNED FOR ROUTINE USE TO PROVIDE A MEANS OF ESTIMATING PRECISION AND MONITORING TEST SYSTEM PERFORMANCE. THIS PRODUCT IS NOT INTENDED FOR USE IN CONJUNCTION WITH BLOOD DONOR SCREENING TESTS,LYPHOCHEK DRUG FREE SERUM(LYPHOCHEK DRUG FREE SERUM)-LYPHOCHEK DRUG FREE SERUM IS INTENDED FOR USE AS A NEGATIVE QUALITY CONTROL SERUM FOR THE DRUGS LISTED IN THE INSERT.,INTELIQ HOMOCYSTEINE CONTROL(INTELIQ HOMOCYSTEINE CONTROL)-INTELIQ HOMOCYSTEINE CONTROL IS INTENDED FOR A USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR HOMOCYSTEINE.,LIQUICHEK™ ANA CONTROLS SET, POSITIVE: HOMOGENOUS, SPECKLED, CENTROMERE AND NUCLEOLAR PATTERNS(LIQUICHEK™ ANA CONTROLS SET, POSITIVE: HOMOGENOUS, SPECKLED, CENTROMERE AND NUCLEOLAR PATTERNS)-LIQUICHEK ANA CONTROLS SET, POSITIVE: HOMOGENOUS, SPECKLED, CENTROMERE AND NUCLEOLAR PATTERNS, IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL SET TO MONITOR INDIRECT IMMUNOFLUORESCENT TESTING OF ANTINUCLEAR ANTIBODIES (ANA).,VIROTROL HIV 2

	(VIROTROL HIV 2)-VIROTROL HIV-2 IS INTENDED FOR USE AS AN UNASSAYED REACTIVE CONTROL WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 2 (HIV-2). THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES,LIQUICHEK SPINAL FLUID CONTROL(LIQUICHEK SPINAL FLUID CONTROL)-LIQUICHEK SPINAL FLUID CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEKTM AMH CONTROL(LIQUICHEKTM AMH CONTROL)-LIQUICHECK AMH CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF THE LABORATORY TESTING PROCEDURES FOR ANTI MULERIAN HORMONE,LIQUICHEK ANTI-NDNA CONTROL, POSITIVE(LIQUICHEK ANTI-NDNA CONTROL, POSITIVE)-LIQUICHEK ANTI-NDNA CONTROL, POSITIVE, IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL TO MONITOR INDIRECT IMMUNOFLUORESCENT TESTING FOR THE DETECTION OF NDNA AUTOANTIBODIES.,LIQUICHEK WHOLE BLOOD IMMUNOSUPPRESANT CONTROL(LIQUICHEK WHOLE BLOOD IMMUNOSUPPRESANT CONTROL)-LIQUICHEK WHOLE BLOOD IMMUNOSUPPRESSANT CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT.,LIQUICHEK ANTI-SCL-70 CONTROL, POSITIVE(LIQUICHEK ANTI-SCL-70 CONTROL, POSITIVE)-LIQUICHEK ANTI-SCL-70 CONTROL, POSITIVE, IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL TO MONITOR INDIRECT IMMUNOFLUORESCENT TESTING FOR THE DETECTION OF SCL-70 AUTOANTIBODIES.,VIROTROL SYPHILLIS LR-A (VIROTROL SYPHILLIS LR-A)-VIROTROL SYPHILIS LR-A IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS AN UNASSAYED PRECISION CONTROL REAGENT FOR THE QUALITATIVE DETERMINATION OF TOTAL ANTIBODIES TO TREPONEMA PALLIDUM. THIS PRODUCT IS INTENDED TO PROVIDE A MEANS OF ESTIMATING PRECISION AND HAS THE POTENTIAL FOR DETECTING SYSTEMATIC DEVIATIONS FROM SPECIFIC LABORATORY TESTING PROCEDURES.,LIQUICHEK QUALITATIVE URINE TOXICOLOGY CONTROL(LIQUICHEK QUALITATIVE URINE TOXICOLOGY CONTROL)-LIQUICHEK QUALITATIVE URINE TOXICOLOGY CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY PROCEDURES FOR QUALITATIVE

	URINE TOXICOLOGY.,LIQUICHEK RETICULOCYTE CONTROL (C) (LIQUICHEK RETICULOCYTE CONTROL (C))-LIQUICHEK RETICULOCYTE CONTROL (C) IS A TRILEVEL, ASSAYED HEMATOLOGY CONTROL DESIGNED TO MONITOR VALUES OBTAINED FROM AUTOMATED RETICULOCYTE COUNTING METHODS.,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL C4(LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL C4)-LIQUICHEK URINE TOXICOLOGY CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY CONFIRMATORY PROCEDURES,LIQUICHEK MATERNAL SERUM II CONTROL(LIQUICHEK MATERNAL SERUM II CONTROL)-LIQUICHEK MATERNAL SERUM II CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT.,LIQUICHEK IMMUNOLOGY CONTROL (1 ML) (LIQUICHEK IMMUNOLOGY CONTROL (1 ML))-LIQUICHEK IMMUNOLOGY CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK HEMATOLOGY CONTROL (X) (LIQUICHEK HEMATOLOGY CONTROL (X))-LIQUICHEK HEMATOLOGY CONTROL (X) IS A TRI-LEVEL CONTROL DESIGNED TO MONITOR VALUES OBTAINED ON SYSMEX HEMATOLOGY ANALYZERS, LIQUICHEK ANA CONTROL, SPECKLED PATTERN, POSITIVE (LIQUICHEK ANA CONTROL, SPECKLED PATTERN, POSITIVE)-LIQUICHEK ANA CONTROL, SPECKLED PATTERN, POSITIVE IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL TO MONITOR INDIRECT IMMUNOFLUORESCENT TESTING OF ANTINUCLEAR ANTIBODIES (ANA).,LIQUICHEK RETICULOCYTE CONTROL (X)(LIQUICHEK RETICULOCYTE CONTROL (X))-LIQUICHEK RETICULOCYTE CONTROL (X) IS A TRI-LEVEL ASSAYED HEMATOLOGY CONTROL DESIGNED FOR USE IN MONITORING THE PRECISION OF SYSMEX HEMATOLOGY ANALYZERS,LYPHOCHEK HEMOGLOBIN A2 CONTROL(LYPHOCHEK HEMOGLOBIN A2 CONTROL) -LYPHOCHEK HEMOGLOBIN A2 CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,VIROTROL HAV IGM (VIROTROL HAV IGM)-VIROTROL HAV-IGM IS INTENDED FOR USE AS AN UNASSAYED REACTIVE CONTROL WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF IMMUNOGLOBULIN M ANTIBODIES TO HEPATITIS A VIRUS (HAV-IGM). THIS PRODUCT IS DESIGNED FOR ROUTINE USE TO PROVIDE A MEANS OF ESTIMATING PRECISION AND MONITORING TEST SYSTEM PERFORMANCE. THIS

	PRODUCT IS NOT INTENDED FOR USE IN CONJUNCTION WITH BLOOD DONOR SCREENING TESTS,LIQUICHEK URINE TOXICOLOGY NEGATIVE CONTROL(LIQUICHEK URINE TOXICOLOGY NEGATIVE CONTROL)-LIQUICHEK URINE TOXICOLOGY NEGATIVE CONTROL IS INTENDED FOR USE AS NEGATIVE QUALITY CONTROL URINE FOR THE ANALYTES LISTED IN THE PACKAGE INSERT. THE CONCENTRATION OF EACH ANALYTE WILL BE BELOW ITS LISTED GAS CHROMATOGRAPHY (GC) DETECTION LIMIT.,LIQUICHEK MATERNAL SERUM 1ST TRIMESTER CONTROL(LIQUICHEK MATERNAL SERUM 1ST TRIMESTER CONTROL)-LIQUICHEK MATERNAL SERUM 1ST TRIMESTER CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK ANA CONTROL, NUCLEOLAR PATTERN, POSITIVE (LIQUICHEK ANA CONTROL, NUCLEOLAR PATTERN, POSITIVE)-LIQUICHEK ANA CONTROL, NUCLEOLAR PATTERN, POSITIVE, IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL TO MONITOR INDIRECT IMMUNOFLUORESCENT TESTING OF ANTINUCLEAR ANTIBODIES (ANA).,PNEUMOTROL (PNEUMOTROL)-PNEUMOTROL IS INTENDED FOR USE AS AN UNASSAYED PRECISION CONTROL REAGENT WITH IN VITRO IMMUNOASSAY PROCEDURES FOR DETERMINATION OF IMMUNOGLOBULIN G (IGG) ANTIBODIES TO MYCOPLASMA PNEUMONIAE, IMMUNOGLOBULIN M (IGM) ANTIBODIES TO MYCOPLASMA PNEUMONIAE AND IGG ANTIBODIES TO CHLAMYDIA STRAINS IN HUMAN SERUM. THIS PRODUCT IS DESIGNED FOR ROUTINE USE TO PROVIDE A MEANS OF ESTIMATING PRECISION AND MONITORING TEST SYSTEM PERFORMANCE,LIQUICHEK ANA CONTROL, CENTROMERE PATTERN, POSITIVE(LIQUICHEK ANA CONTROL, CENTROMERE PATTERN, POSITIVE)-LIQUICHEK ANA CONTROL, CENTROMERE PATTERN, POSITIVE IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL TO MONITOR INDIRECT IMMUNOFLUORESCENT TESTING OF ANTINUCLEAR ANTIBODIES (ANA).,LIQUICHEK SPECIALITY IMMUNOASSAY CONTROL(LIQUICHEK SPECIALITY IMMUNOASSAY CONTROL)-LIQUICHEK SPECIALITY IMMUNOASSAY CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S1(LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S1)-LIQUICHEK URINE TOXICOLOGY CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY SCREENING PROCEDURES., AMPLICHEK I LEVELS NEGATIVE, 1, 2 AND 3(AMPLICHEK I LEVELS

	NEGATIVE, 1, 2 AND 3)-AMPLICHEK I IS INTENDED FOR USE AS AN EXTERNAL ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PERFORMANCE OF IN VITRO LABORATORY NUCLEIC ACID TESTING PROCEDURES FOR THE QUANTITATIVE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1), HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) FOR MOLECULAR DIAGNOSTIC PLATFORMS LISTED IN THE PACKAGE INSERT. THIS PRODUCT IS NOT INTENDED TO REPLACE MANUFACTURER CONTROLS PROVIDED WITH THE DEVICE. THIS PRODUCT IS NOT INTENDED FOR USE WITH BLOOD DONOR SCREENING ASSAYS IN U.S. OR CANADA.,LIQUICHEK ANTI-SMOOTH MUSCLE CONTROL, POSITIVE (LIQUICHEK ANTI-SMOOTH MUSCLE CONTROL, POSITIVE)-LIQUICHEK ANTI-SMOOTH MUSCLE CONTROL, POSITIVE, IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL TO MONITOR INDIRECT IMMUNOFLUORESCENT TESTING FOR THE DETECTION OF SMOOTH MUSCLE AUTOANTIBODIES,VIROTROL TORCH(VIROTROL TORCH)-VIROTROL TORCH IS INTENDED FOR USE AS AN UNASSAYED PRECISION CONTROL REAGENT WITH IN VITRO DIAGNOSTIC ASSAY PROCEDURES FOR DETERMINATION OF IMMUNOGLOBULIN G (IGG) ANTIBODIES TO TOXOPLASMA GONDII (TOXO), IGG ANTIBODIES TO RUBELLA VIRUS, IGG ANTIBODIES TO CYTOMEGALOVIRUS (CMV), AND IGG ANTIBODIES TO HERPES SIMPLEX VIRUS (HSV) TYPES 1 AND 2 IN HUMAN SERUM. THIS PRODUCT IS NOT INTENDED FOR USE IN TESTING OF DONATED BLOOD OR PLASMA. THIS PRODUCT IS DESIGNED FOR ROUTINE USE TO PROVIDE A MEANS OF ESTIMATING PRECISION AND MONITORING TEST SYSTEM PERFORMANCE, LIQUICHEK ANTI-MITOCHONDRIAL CONTROL, POSITIVE(LIQUICHEK ANTI-MITOCHONDRIAL CONTROL, POSITIVE)-LIQUICHEK ANTI-MITOCHONDRIAL CONTROL, POSITIVE, IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL TO MONITOR INDIRECT IMMUNOFLUORESCENT TESTING FOR THE DETECTION OF MITOCHONDRIAL AUTOANTIBODIES,PYLORITROL(PYLORITROL)-PYLORITROL IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL WITH IN VITRO ENZYME IMMUNOASSAY PROCEDURES FOR THE QUALITATIVE DETERMINATION OF IMMUNOGLOBULIN G (IGG) ANTIBODIES TO HELICOBACTER PYLORI. THIS PRODUCT IS DESIGNED FOR ROUTINE USE TO PROVIDE A MEANS OF ESTIMATING PRECISION AND MONITORING TEST SYSTEM PERFORMANCE.,QUANTIFY CONTROL (QUANTIFY CONTROL)-QUANTIFY® CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL TO MONITOR THE PRECISION OF URINALYSIS TEST PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK RETICULOCYTE CONTROL (A-I)(LIQUICHEK RETICULOCYTE CONTROL (A-I))-LIQUICHEK RETICULOCYTE CONTROL (A-I) IS A CONTROL

	DESIGNED TO MONITOR VALUES OBTAINED BY RETICULOCYTE COUNTING METHODS.,LIQUICHEK TUMOR MARKER CONTROL (LIQUICHEK TUMOR MARKER CONTROL)-LIQUICHEK TUMOR MARKER CONTROL IS INTENDED FOR USE QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK HEMATOLOGY CONTROL (S)(LIQUICHEK HEMATOLOGY CONTROL (S)) -LIQUICHEK HEMATOLOGY CONTROL (S) IS A CONTROL DESIGNED TO MONITOR VALUES OBTAINED ON SIEMENS HEMATOLOGY ANALYZERS.,LIQUICHEK IMMUNOLOGY CONTROL (3 ML)(LIQUICHEK IMMUNOLOGY CONTROL (3 ML))-LIQUICHEK IMMUNOLOGY CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,VIROTROL TORCH M(VIROTROL TORCH M)-VIROTROL TORCH-M IS INTENDED FOR USE AS AN UNASSAYED REACTIVE CONTROL REAGENT, WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF IMMUNOGLOBULIN G (IGG) AND IMMUNOGLOBULIN M (IGM) ANTIBODIES TO TOXOPLASMA GONDII (TOXO), IGG AND IGM ANTIBODIES TO RUBELLA VIRUS, IGG AND IGM ANTIBODIES TO CYTOMEGALOVIRUS (CMV), AND IGG ANTIBODIES TO HERPES SIMPLEX VIRUS (HSV) TYPES 1 AND 2. THIS PRODUCT IS NOT INTENDED FOR USE IN TESTING OF DONATED BLOOD OR PLASMA. THIS PRODUCT IS DESIGNED FOR ROUTINE USE TO PROVIDE A MEANS OF ESTIMATING PRECISION AND MONITORING TEST SYSTEM PERFORMANCE,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL C3 (LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL C3)-LIQUICHEK URINE TOXICOLOGY CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY CONFIRMATORY PROCEDURES.,METER TRAX CONTROL(METER TRAX CONTROL)-METER TRAX CONTROL IS AN ASSAYED WHOLE BLOOD CONTROL USED IN MONITORING THE PRECISION OF LABORATORY PROCEDURES FOR GLUCOSE, HEMOGLOBIN AND HEMATOCRIT TESTING.,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S1S(LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S1S)-LIQUICHEK URINE TOXICOLOGY CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY ENZYME IMMUNOASSAY (EIA) SCREENING PROCEDURES.,LIQUICHEK URINALYSIS CONTROL(LIQUICHEK URINALYSIS CONTROL)-LIQUICHEK URINALYSIS CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL URINE TO MONITOR THE PRECISION OF URINALYSIS TEST PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LYPHOCHEK ASSAYED CHEMISTRY CONTROL

	(LYPHOCHEK ASSAYED CHEMISTRY CONTROL)-LYPHOCHEK ASSAYED CHEMISTRY CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT,LIQUID UNASSAYED MULTIQUAL(LIQUID UNASSAYED MULTIQUAL)-LIQUID UNASSAYED MULTIQUAL IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT., LYPHOCHEK WHOLE BLOOD CONTROL(LYPHOCHEK WHOLE BLOOD CONTROL)-LYPHOCHEK WHOLE BLOOD CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT,LYPHOCHEK UNASSAYED CHEMISTRY CONTROL (HUMAN), 5 ML(LYPHOCHEK UNASSAYED CHEMISTRY CONTROL (HUMAN), 5 ML)-LYPHOCHEK UNASSAYED CHEMISTRY CONTROL IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,QUANTIFY PLUS CONTROL(QUANTIFY PLUS CONTROL)-QUANTIFY® PLUS CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL TO MONITOR THE PRECISION OF URINALYSIS TEST PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LYPHOCHEK IMMUNOASSAY PLUS CONTROL (LYPHOCHEK IMMUNOASSAY PLUS CONTROL)-LYPHOCHEK IMMUNOASSAY PLUS CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S2E LOW OPIATE(LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S2E LOW OPIATE)-LIQUICHEK URINE TOXICOLOGY CONTROL LEVEL S2E LOW OPIATE IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY ENZYME IMMUNOASSAY (EIA) SCREENING PROCEDURES.,LIQUICHEK RHEUMATOID FACTOR CONTROL (LIQUICHEK RHEUMATOID FACTOR CONTROL)-LIQUICHEK RHEUMATOID FACTOR CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY PROCEDURES FOR RHEUMATOID FACTOR TESTING., LYPHOCHEK URINE METALS CONTROL(LYPHOCHEK URINE METALS CONTROL)-LYPHOCHEK URINE METALS CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL URINE TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT,LIQUICHEK SERUM

	VOLATILES CONTROL(LIQUICHEK SERUM VOLATILES CONTROL)-LIQUICHEK SERUM VOLATILES CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LYPHOCHEK QUANTITATIVE URINE CONTROL(LYPHOCHEK QUANTITATIVE URINE CONTROL)-LYPHOCHEK QUANTITATIVE URINE CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL URINE TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT,LIQUICHEK SPECIALTY IMMUNOASSAY CONTROL(LIQUICHEK SPECIALTY IMMUNOASSAY CONTROL)-LIQUICHEK SPECIALTY IMMUNOASSAY CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK TORCH PLUS IGM CONTROL(LIQUICHEK TORCH PLUS IGM CONTROL)-LIQUICHEK TORCH PLUS IGM CONTROL IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL SERUM TO MONITOR PRECISION OF IGM LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT. THIS PRODUCT IS NOT INTENDED FOR USE IN BLOOD DONOR SCREENING ASSAYS.,LYPHOCHEK URINE BONE MARKERS CONTROL(LYPHOCHEK URINE BONE MARKERS CONTROL)-LYPHOCHEK URINE BONE MARKERS CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT., LYPHOCHEK WHOLE BLOOD IMMUNOSUPPRESSANT CONTROL (LYPHOCHEK WHOLE BLOOD IMMUNOSUPPRESSANT CONTROL)-LYPHOCHEK WHOLE BLOOD IMMUNOSUPPRESSANT CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL MATERIAL TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT., LIQUICHEK PEDIATRIC CONTROL(LIQUICHEK PEDIATRIC CONTROL)-LIQUICHEK PEDIATRIC CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK CK/LD ISOENZYME CONTROL (LIQUICHEK CK/LD ISOENZYME CONTROL)-LIQUICHEK CK/LD ISOENZYME CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S2(LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S2)-LIQUICHEK URINE TOXICOLOGY CONTROL IS INTENDED FOR USE AS

	A QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY SCREENING PROCEDURES., LIQUICHEK CARDIAC MARKERS CONTROL LT(LIQUICHEK CARDIAC MARKERS CONTROL LT)-LIQUICHEK CARDIAC MARKERS CONTROL LT IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT,LIQUICHEK CARDIAC MARKERS PLUS CONTROL LT LOW(LIQUICHEK CARDIAC MARKERS PLUS CONTROL LT LOW)-LIQUICHEK CARDIAC MARKERS PLUS CONTROL LT LOW IS INTENDED FOR USE AS QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES LISTED IN THE PACKAGE INSERT.,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S2 LOW OPIATE(LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S2 LOW OPIATE)-LIQUICHEK URINE TOXICOLOGY CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY SCREENING PROCEDURES.,LYPHOCHEK ANEMIA CONTROL(LYPHOCHEK ANEMIA CONTROL)-LYPHOCHEK ANEMIA CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT., LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S1 LOW OPIATE (LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S1 LOW OPIATE)-LIQUICHEK URINE TOXICOLOGY CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY SCREENING PROCEDURES., LYPHOCHEK FERTILITY CONTROL (LYPHOCHEK FERTILITY CONTROL)-LYPHOCHEK FERTILITY CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL C2 LOW OPIATE(LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL C2 LOW OPIATE)-LIQUICHEK URINE TOXICOLOGY CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY CONFIRMATORY PROCEDURES,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL C3 LOW OPIATE(LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL C3 LOW OPIATE)-LIQUICHEK URINE TOXICOLOGY CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE PERFORMANCE OF LABORATORY URINE TOXICOLOGY CONFIRMATORY PROCEDURES.,LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S3(LIQUICHEK URINE TOXICOLOGY CONTROL, LEVEL S3)-LIQUICHEK URINE TOXICOLOGY CONTROL IS INTENDED FOR USE AS A QUALITY CONTROL URINE TO MONITOR THE

	PERFORMANCE OF LABORATORY URINE TOXICOLOGY SCREENING PROCEDURES,LIQUICHEK TORCH PLUS CONTROL, NEGATIVE (LIQUICHEK TORCH PLUS CONTROL, NEGATIVE)-LIQUICHEK TORCH PLUS CONTROL, NEGATIVE IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT.,LIQUICHEK UNASSAYED CHEMISTRY CONTROL (HUMAN)(LIQUICHEK UNASSAYED CHEMISTRY CONTROL (HUMAN))-LIQUICHEK UNASSAYED CHEMISTRY CONTROL IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT., LIQUICHEK ANA CONTROL, MITOTIC SPINDLE PATTERN, POSITIVE (LIQUICHEK ANA CONTROL, MITOTIC SPINDLE PATTERN, POSITIVE)-LIQUICHEK ANA CONTROL, MITOTIC SPINDLE PATTERN, POSITIVE IS INTENDED FOR USE AS AN UNASSAYED QUALITY CONTROL TO MONITOR INDIRECT IMMUNOFLUORESCENT TESTING OF ANTINUCLEAR ANTIBODIES (ANA).,LIQUICHEK TORCH PLUS CONTROL, POSITIVE(LIQUICHEK TORCH PLUS CONTROL, POSITIVE)-LIQUICHEK TORCH PLUS CONTROL, POSITIVE IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT.,LIQUICHEK LIPIDS CONTROL(LIQUICHEK LIPIDS CONTROL)-LIQUICHEK LIPIDS CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUID ASSAYED MULTIQUAL(LIQUID ASSAYED MULTIQUAL)-LIQUID ASSAYED MULTIQUAL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK IMMUNOASSAY PLUS CONTROL (LIQUICHEK IMMUNOASSAY PLUS CONTROL)-LIQUICHEK IMMUNOASSAY PLUS CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LYPHOCHEK THERAPEUTIC DRUG MONITORING CONTROL(LYPHOCHEK THERAPEUTIC DRUG MONITORING CONTROL)-LYPHOCHEK THERAPEUTIC DRUG MONITORING CONTROL IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THE PACKAGE INSERT.,LIQUICHEK HEMATOLOGY CONTROL (C) (LIQUICHEK HEMATOLOGY CONTROL (C))-LIQUICHEK HEMATOLOGY

	CONTROL (C) IS A CONTROL DESIGNED TO MONITOR VALUES ON COULTER® HEMATOLOGY ANALYZERS.,LIQUICHEK HEMATOLOGY-16 CONTROL(LIQUICHEK HEMATOLOGY-16 CONTROL)-LIQUICHEK HEMATOLOGY-16 CONTROL IS A HEMATOLOGY REFERENCE CONTROL USED IN MONITORING DETERMINATIONS OF BLOOD CELL VALUES ON ALL IMPEDANCE CELL COUNTERS.,ASSAYED VIROTROL I-E(ASSAYED VIROTROL I-E)-ASSAYED VIROTROL I-E IS INTENDED FOR USE WITH IN VITRO ASSAY PROCEDURES FOR DETERMINATION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1), ANTIBODIES TO HUMAN T-LYMPHOTROPIC VIRUS TYPE I (HTLV-I), ANTIBODIES TO HEPATITIS C VIRUS (HCV), HEPATITIS B SURFACE ANTIGEN (HBSAG), ANTIBODIES TO HEPATITIS B CORE ANTIGEN (HBC) AND ANTIBODIES TO CYTOMEGALOVIRUS (CMV)

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1336	IMP/MD/2018/000237	1.License Holder Name: NOVOMED INCORPORATION PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VASCULAR GRAFTS (GORE® PROPATEN VASCULAR GRAFT)-GORE® PROPATEN VASCULAR GRAFT IS INDICATED FOR USE AS VASCULAR PROSTHESES FOR REPLACEMENT OR BYPASS OF DISEASED VESSELS IN PATIENTS SUFFERING OCCLUSIVE OR ANEURISMAL DISEASES, IN TRAUMA PATIENTS REQUIRING VASCULAR REPLACEMENT OR FOR OTHER VASCULAR PROCEDURES.,CARDIOVASCULAR PATCH(GORE® PRECLUDE® PERICARDIAL MEMBRANE)-GORE® PRECLUDE® PERICARDIAL MEMBRANE IS INDICATED FOR USE IN RECONSTRUCTION OR REPAIR OF THE PERICARDIUM, CARDIOVASCULAR PATCH(GORE® ACUSEAL CARDIOVASCULAR PATCH)-GORE® ACUSEAL CARDIOVASCULAR PATCH IS INDICATED FOR USE IN CARDIOVASCULAR PATCHING.,VASCULAR GRAFTS(GORE TEX® VASCULAR GRAFTS)-GORE TEX® VASCULAR GRAFTS ARE INTENDED FOR USE AS VASCULAR PROSTHESES FOR REPLACEMENT OR BYPASS OF DISEASED VESSELS IN PATIENTS SUFFERING OCCLUSIVE OR ANEURYSMAL DISEASES, IN TRAUMA PATIENTS REQUIRING VASCULAR REPLACEMENT, FOR DIALYSIS ACCESS, OR FOR OTHER VASCULAR PROCEDURES.,VASCULAR GRAFT(GORE TEX® VASCULAR GRAFT)-GORE TEX® VASCULAR GRAFTS ARE INTENDED FOR USE AS VASCULAR PROSTHESES FOR REPLACEMENT OR BYPASS OF DISEASED VESSELS IN PATIENTS SUFFERING OCCLUSIVE OR ANEURYSMAL DISEASES, IN TRAUMA PATIENTS REQUIRING VASCULAR REPLACEMENT, FOR DIALYSIS ACCESS, OR FOR OTHER VASCULAR PROCEDURES.,CARDIOVASCULAR PATCH (GORE-TEX® CARDIOVASCULAR PATCH)-GORE-TEX® CARDIOVASCULAR PATCH IS INDICATED FOR USE IN CARDIOVASCULAR PATCHING.

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1337	IMP/MD/2018/000238	1.License Holder Name: BAUSCH & LOMB INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTI-PURPOSE SOLUTION(RENU ADVANCED FORMULA)-RENU ADVANCED FORMULA MULTI-PURPOSE SOLUTION IS INDICATED FOR USE IN THE DAILY CONDITIONING, CLEANING, REMOVAL OF PROTEIN DEPOSITS, RINSING, CHEMICAL (NOT HEAT) DISINFECTION, AND STORAGE OF SOFT (HYDROPHILIC) CONTACT LENSES, INCLUDING SILICONE HYDROGEL CONTACT LENSES, AS RECOMMENDED BY YOUR EYE CARE PRACTITIONER.,MULTI PURPOSE SOLUTION(RENU FRESH)-RENU FRESH MULTI-PURPOSE SOLUTION IS INDICATED FOR USE IN THE DAILY CLEANING, REMOVING PROTEIN DEPOSITS, RINSING, CHEMICAL (NOT HEAT) DISINFECTION AND STORAGE OF SOFT (HYDROPHILIC) CONTACT LENSES AS RECOMMENDED BY AN EYE CARE PROFESSIONAL.,MULTI ACTION SOLUTION(BOSTON SIMPLUS)-FOR CLEANING, REMOVING PROTEINS, RINSING, DISINFECTING, CONDITIONING, STORING AND CUSHIONING FLUORO SILICONE ACRYLATE RIGID GAS PERMEABLE CONTACT LENSES.,MULTI PURPOSE SOLUTION(BIOTRUE)-BIOTRUE MULTI-PURPOSE SOLUTION IS INDICATED FOR USE IN THE DAILY CONDITIONING, CLEANING, REMOVAL OF PROTEIN DEPOSITS, RINSING, CHEMICAL (NOT HEAT) DISINFECTION AND STORAGE OF SOFT (HYDROPHILIC) CONTACT LENSES, INCLUDING SILICONE HYDROGEL CONTACT LENSES AS RECOMMENDED BY AN EYE CARE PRACTITIONER.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1338	IMP/MD/2018/000239	1.License Holder Name: BIO-RAD LABORATORIES (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ID- DIACELL ABO A1, B(ID-DIACELL ABO A1, B)-USED FOR THE DETECTION OF SERUM ANTIBODIES AGAINST A 1, B,ID-DIACELL ABO A1, A2 , B, 0(ID-DIACELL ABO A1, A2 , B, 0)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM AGAINST A 1, A2 , B AND H,ID-DIACELL ABO A1, B, 0(ID-DIACELL ABO A1, B, 0)-USED FOR THE SCREENING SERUM ANTIBODIES ON THE ID SYSTEM AGAINST A 1, B AND H,ID- PAPAIN(ID- PAPAIN)-"ID-PAPAIN" IS A STANDARDISÉE) LIQUID PAPAIN SOLUTION AND MAY BE USED FOR PRE-TREATING RED CELLS BY LABORATORIES THAT PRÉPARE THEIR OWN RED CELL REAGENTS, OR MAY BE USED AS AN ENZYME ADDITIVE REAGENT IN A ONE STAGE TECHNIQUE. "ID-PAPAIN" SHOULD ALSO BE USED FOR THE AUTOCONTROL IN ANTIBODY SCREENING/IDENTIFICATION PROCÉDURES USING PAPAINIZED TEST CELLS "IDDIACELL IP-IIP-IIIP", "ID-DIASCREEN" AND/OR "ID-DIAPANEL P".,DIACELL ABO O(DIACELL ABO O)-USED FOR THE DETECTION OF SERUM ANTIBODIES AGAINST O,DIACELL I+II+III(DIACELL I+II+III)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES FOR ANTIBODY SCREENING,DIACELL ABO B (DIACELL ABO B)-USED FOR THE DETECTION OF SERUM ANTIBODIES AGAINST B,DIACELL ABO A1(DIACELL ABO A1)-USED FOR THE DETECTION OF SERUM ANTIBODIES AGAINST A 1,COOMBS-CONTROL LGG(COOMBS-CONTROL LGG)-USED FOR THE DETECTION OF CELL BOUND BLOOD GROUP LGG ANTIBODIES,DIAMED BASIC Q.C.(DIAMED BASIC Q.C.)-"DIAMED BASIC Q.C." IS INTENDED TO BE USED AS A CONTROL FOR BLOOD GROUP TYPING , REVERSE GROUPING AND ANTIBODY SCREENING/IDENTIFICATION BY PROVIDING BLOOD OF KNOWN BLOOD GROUPS AND WITH KNOWN ANTIBODIES, FOR THE USE OF MANUAL TECHNIQUES AND INSTRUMENTS WITH THE ID-SYSTEM.,DIAMED Q.C. SYSTEM(DIAMED Q.C. SYSTEM)-"DIAMED Q.C. SYSTEM" IS DESIGNED NOT ONLY FOR CHECKING OF THE REAGENTS AND WORKING PROCEDURES, BUT ALSO TO CONTROL THE INSTRUMENTS USED FOR BLOOD GROUPING AND ANTIBODY ASSAYS. THE "DIAMED Q.C. SYSTEM" IS SUITABLE FOR PERFORMING CHECKS WITH THE ID-SYSTEM. ,ID-I NEGATIVE CELLS(ID-I NEGATIVE CELLS)-TEST CELL REAGENTS FOR ANTIBODY SCREENING : ID-DIACELL 1-11, ID- DIACELL 1-11-111 , ID-DIACELL IP-LLP-LLLP (PAPAINIZED) , ID-DIACELL 1-11-111 ASIA, ID-DIACELL POOL; FOR ANTIBODY IDENTIFICATION : ID-PANEL, ID-PANEL-P; SPECIAL ANTIGENS: ID-DIA (DIEGO) POSITIVE, ID-I NEGATIVE CELL,ID- INTERNAL QUALITY CONTROL(ID- INTERNAL QUALITY CONTROL)-"ID-INTERNAL QUALITY CONTROL" IS DESIGNED TO ALLOW CONTROL OF THE REAGENTS IN

	USE AND THE WORKING PROCEDURES WITH ID-SYSTEM. THE CONTROL SHOULD BE USED REGULARLY AND BY EACH MEMBER OF THE LABORATORY STAFF.,ID-DIASCREEN PROPHYLAX(ID-DIASCREEN PROPHYLAX)-THE "ID-DIASCREEN PROPHYLAX" CAN BE USED AS AN ADJUNCT TO "ID- DIACELL I-II-III,ID- DIAPANEL PLUS 6(ID- DIAPANEL PLUS 6)-THE PRODUCT "ID-DIAPANEL PLUS 6" IS FOR USE IN ANTIBODY SCREENING AND IDENTIFICATION, AS AN ADDITION TO THE "ID-DIAPANEL".,ID-DIAPANEL- P(ID-DIAPANEL- P)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM FOR ANTIBODY IDENTIFICATION IN ENZYME TECHNIQUE,ID- DIAPANEL (ID- DIAPANEL)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM FOR ANTIBODY IDENTIFICATION,ID-DIACELL I-II-II ASIA(ID- DIACELL I-II-II ASIA)-USED FOR THE DETECTION OF SERUM ANTIBODIES ON THE ID SYSTEM FOR ANTIBODY SCREENING,ID- DIACELL I-II(ID- DIACELL I-II)-USED FOR THE DETECTION OF SERUM ANTIBODIES ON THE ID SYSTEM FOR ANTIBODY SCREENING,ID- DIACELL IP-IIP-IIIP (ID- DIACELL IP-IIP-IIIP)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM FOR ANTIBODY SCREENING IN ENZYME TECHNIQUE,ID-DIACELL I-II-III(ID- DIACELL I-II-III)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM FOR ANTIBODY SCREENING, ID-DIACELL POOL(ID-DIACELL POOL)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM FOR ANTIBODIES SCREENING FOR DONOR,ID-DIACELL ABO O(ID-DIACELL ABO O)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM AGAINST H,ID-DIACELL ABO B(ID-DIACELL ABO B)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM AGAINST B,ID-DIACELL ABO A2(ID-DIACELL ABO A2)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM AGAINST A2,ID-DIACELL ABO A1(ID-DIACELL ABO A1)-USED FOR THE DETECTION OF THE SERUM ANTIBODIES ON THE ID SYSTEM AGAINST A1

1339	IMP/MD/2018/000250	1.License Holder Name: CEPHEID INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:XPERT HCV VL FINGERSTICK(XPERT HCV VL FINGERSTICK)-THE XPERT HCV VL FINGERSTICK (FS) ASSAY IS AN IN VITRO REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) ASSAY FOR THE DETECTION AND QUANTIFICATION OF HEPATITIS C VIRUS (HCV) RNA IN HUMAN CAPILLARY FINGERSTICK EDTA WHOLE BLOOD AND VENOUS EDTA WHOLE BLOOD FROM HCV-INFECTED INDIVIDUALS USING THE AUTOMATED GENEXPERT® INSTRUMENT SYSTEMS. THE XPERT HCV VL FS ASSAY IS INTENDED FOR USE AS AN AID IN THE INITIAL DIAGNOSIS IN INDIVIDUALS AT HIGH RISK OF HCV INFECTION OR IN ANTI-HCV POSITIVE INDIVIDUALS. DETECTION OF HCV RNA INDICATES THAT THE VIRUS IS REPLICATING AND THEREFORE IS EVIDENCE OF ACTIVE INFECTION. THE XPERT HCV VL FS ASSAY IS INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF HCV INFECTED PATIENTS UNDERGOING ANTIVIRAL THERAPY. THE TEST MEASURES HCV RNA LEVELS AT ANY TIME DURING VIREMIA AND DURING TREATMENT; AND CAN BE UTILIZED TO PREDICT SUSTAINED AND NONSUSTAINED VIROLOGICAL RESPONSES TO HCV THERAPY. THE XPERT HCV VL FS ASSAY IS INTENDED TO BE USED BY LABORATORY PROFESSIONALS OR SPECIFICALLY-TRAINED HEALTHCARE WORKERS. THE ASSAY IS NOT INTENDED TO BE USED AS A BLOOD DONOR SCREENING TEST FOR HCV,XPERT VANA/VANB (XPERT VANA/VANB)-THE CEPHEID XPERT VANA/VANB ASSAY, PERFORMED ON GENEXPERT® INSTRUMENT SYSTEMS, IS A QUALITATIVE IN VITRO DIAGNOSTIC TEST DESIGNED FOR RAPID DETECTION OF VANCOMYCIN-RESISTANCE (VANA/VANB) GENES FROM RECTAL AND PERIANAL SWAB SPECIMENS IN PATIENTS AT RISK FOR INTESTINAL COLONIZATION OF VANCOMYCIN-RESISTANT BACTERIA. THE TEST UTILIZES AUTOMATED REAL-TIME POLYMERASE CHAIN REACTION (PCR) TO DETECT THE VANA AND VANB GENES THAT CAN BE ASSOCIATED WITH VANCOMYCIN-RESISTANT ENTEROCOCCI (VRE). THE XPERT VANA/VANB ASSAY IS INTENDED TO AID IN THE RECOGNITION, PREVENTION AND CONTROL OF VANCOMYCIN-RESISTANT ORGANISM COLONIZATION IN HEALTHCARE SETTINGS. THE XPERT VANA/VANB ASSAY IS NOT INTENDED TO DIAGNOSE VRE NOR TO GUIDE OR MONITOR TREATMENT FOR VRE INFECTIONS. CONCOMITANT CULTURES ARE NECESSARY ONLY TO RECOVER ORGANISMS FOR EPIDEMIOLOGICAL TYPING, SUSCEPTIBILITY TESTING AND FOR FURTHER CONFIRMATORY IDENTIFICATION OF VRE.,XPERT HBV VIRAL LOAD (XPERT HBV VIRAL LOAD)-THE CEPHEID XPERT® HBV VIRAL LOAD (VL) ASSAY IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST

	DESIGNED FOR THE QUANTITATION OF HEPATITIS B VIRUS (HBV) DNA IN HUMAN SERUM OR PLASMA (EDTA) FROM CHRONICALLY HBV-INFECTED INDIVIDUALS USING THE AUTOMATED GENEXPERT® SYSTEMS. THE ASSAY IS INTENDED FOR USE IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS AS AN INDICATOR OF DISEASE PROGNOSIS AND FOR USE AS AN AID IN ASSESSING VIRAL RESPONSE TO ANTIVIRAL TREATMENT AS MEASURED BY CHANGES IN PLASMA OR SERUM HBV DNA LEVELS. THE TEST IS NOT INTENDED TO BE USED AS A DONOR SCREENING TEST FOR HBV, OR TO BE USED AS A DIAGNOSTIC TEST TO CONFIRM THE PRESENCE OF HBV INFECTION.,XPERT MRSA/SA SSTI(XPERT MRSA/SA SSTI)-THE CEPHEID XPERT MRSA/SA SKIN AND SOFT TISSUE INFECTION ASSAY (XPERT MRSA/SA SSTI ASSAY) PERFORMED IN THE GENEXPERT DX SYSTEM IS A QUALITATIVE IN VITRO DIAGNOSTIC TEST INTENDED FOR THE DETECTION OF STAPHYLOCOCCUS AUREUS (SA) AND METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) FROM SKIN AND SOFT TISSUE INFECTION SWABS. THE TEST UTILIZES AUTOMATED REAL-TIME POLYMERASE CHAIN REACTION (PCR) TO DETECT MRSA/SA DNA. THE XPERT MRSA/SA SSTI ASSAY IS INDICATED FOR USE IN CONJUNCTION WITH OTHER LABORATORY TESTS SUCH AS MICROBIOLOGY CULTURE, AND CLINICAL DATA AVAILABLE TO THE CLINICIAN AS AN AID IN THE DETECTION OF MRSA/SA FROM SKIN AND SOFT TISSUE INFECTIONS. THE XPERT MRSA/SA SSTI ASSAY IS NOT INTENDED TO MONITOR TREATMENT FOR MRSA/SA INFECTIONS. CONCOMITANT CULTURES FOR SA AND MRSA ARE NECESSARY TO RECOVER ORGANISMS FOR SUSCEPTIBILITY TESTING OR EPIDEMIOLOGICAL TYPING.,XPERT HPV(XPERT HPV)-THE XPERT HPV ASSAY IS A QUALITATIVE IN VITRO TEST FOR THE DETECTION OF THE E6/E7 REGION OF THE VIRAL DNA GENOME FROM HIGH RISK HUMAN PAPILLOMAVIRUS (HPV) IN PATIENT SPECIMENS. THE TEST CARRIES OUT MULTIPLEXED AMPLIFICATION OF TARGET DNA BY REAL-TIME POLYMERASE CHAIN REACTION (PCR) OF 14 HIGH RISK HPV TYPES IN A SINGLE ANALYSIS. XPERT HPV SPECIFICALLY IDENTIFIES TYPES HPV 16 AND HPV 18/45 IN TWO DISTINCT DETECTION CHANNELS, AND REPORTS 11 OTHER HIGH RISK TYPES (31, 33, 35, 39, 51, 52, 56, 58, 59, 66 AND 68) IN A POOLED RESULT. SPECIMENS ARE LIMITED TO CERVICAL CELLS COLLECTED IN PRESERVCYT® SOLUTION (HOLOGIC CORP.). CERVICAL SPECIMENS COLLECTED IN PRESERVCYT SOLUTION THAT HAVE BEEN PRETREATED WITH GLACIAL ACETIC ACID (GAA) TO LYSE EXCESS RED BLOOD CELLS FOR CYTOLOGY REVIEW HAVE ALSO BEEN VALIDATED FOR USE WITH THE XPERT HPV ASSAY. INDICATIONS FOR THE XPERT HPV ASSAY: • THE XPERT HPV ASSAY CAN BE USED WITH A PAP SPECIMEN TO ASSESS THE

	PRESENCE OR ABSENCE OF HIGH RISK HPV TYPES. THIS INFORMATION, TOGETHER WITH THE PHYSICIAN'S ASSESSMENT OF THE PATIENT'S MEDICAL HISTORY, OTHER RISK FACTORS, AND PROFESSIONAL GUIDELINES, MAY BE USED TO GUIDE PATIENT MANAGEMENT. • THE XPERT HPV ASSAY CAN BE USED WITH A PAP SPECIMEN TO ASSESS THE PRESENCE OR ABSENCE OF HPV GENOTYPES 16 AND 18/45. THIS INFORMATION, TOGETHER WITH THE PHYSICIAN' S ASSESSMENT OF THE PATIENT'S MEDICAL HISTORY, OTHER RISK FACTORS, AND PROFESSIONAL GUIDELINES, MAY BE USED TO GUIDE PATIENT MANAGEMENT.,XPERT MRSA/SA BC(XPERT MRSA/SA BC)-THE CEPHEID XPERT MRSA/SA ASSAY PERFORMED IN THE GENEXPERT DX SYSTEM IS A QUALITATIVE IN VITRO DIAGNOSTIC TEST DESIGNED FOR RAPID AND SIMULTANEOUS DETECTION OF STAPHYLOCOCCUS AUREUS (SA) AND METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) FROM PATIENTS WITH POSITIVE BLOOD CULTURES. THE TEST UTILIZES AUTOMATED REAL-TIME POLYMERASE CHAIN REACTION (PCR) TO DETECT MRSA/SA DNA. THE XPERT MRSA/SA ASSAY IS INTENDED TO AID IN THE DETECTION AND IDENTIFICATION OF MRSA/SA FROM POSITIVE BLOOD CULTURE BOTTLES. THE XPERT MRSA/SA BLOOD CULTURE ASSAY IS INDICATED FOR USE IN CONJUNCTION WITH OTHER LABORATORY TESTS, SUCH AS CULTURE, AND CLINICAL DATA AVAILABLE TO THE CLINICIAN AS AN AID IN THE DETECTION OF MRSA/SA FROM PATIENT POSITIVE BLOOD CULTURES. SUBCULTURING OF POSITIVE BLOOD CULTURES IS NECESSARY TO RECOVER ORGANISMS FOR SUSCEPTIBILITY TESTING OR FOR EPIDEMIOLOGICAL TYPING. THE CEPHEID XPERT MRSA/SA BLOOD CULTURE ASSAY IS NOT INTENDED TO MONITOR TREATMENT FOR MRSA/SA INFECTIONS.,XPERT MTB/RIF ULTRA(XPERT MTB/RIF ULTRA)-THE XPERT MTB/RIF ULTRA ASSAY, PERFORMED ON THE GENEXPERT INSTRUMENT SYSTEMS, IS A SEMI-QUANTITATIVE, NESTED REAL-TIME POLYMERASE CHAIN REACTION (PCR) IN VITRO DIAGNOSTIC TEST FOR THE DETECTION OF MYCOBACTERIUM TUBERCULOSIS (MTB) COMPLEX DNA IN UNPROCESSED SPUTUM SAMPLES OR CONCENTRATED SEDIMENTS PREPARED FROM INDUCED OR EXPECTORATED SPUTUM. IN SPECIMENS WHERE MYCOBACTERIUM TUBERCULOSIS COMPLEX IS DETECTED, THE XPERT MTB/RIF ULTRA ASSAY CAN ALSO DETECT RIFAMPIN-RESISTANCE ASSOCIATED MUTATIONS OF THE RPOB GENE. THE XPERT MTB/RIF ULTRA ASSAY IS INTENDED FOR USE WITH SPECIMENS FROM PATIENTS FOR WHOM THERE IS CLINICAL SUSPICION OF TUBERCULOSIS (TB) AND WHO HAVE RECEIVED NO ANTITUBERCULOSIS THERAPY, OR LESS THAN 3 DAYS OF THERAPY IN THE LAST 6 MONTHS. THIS TEST IS INTENDED AS AN AID IN THE DIAGNOSIS OF PULMONARY TUBERCULOSIS WHEN USED IN

	CONJUNCTION WITH CLINICAL AND OTHER LABORATORY FINDINGS., XPERT C. DIFFICILE ASSAY(XPERT C. DIFFICILE)-THE XPERT C. DIFFICILE ASSAY, PERFORMED ON THE CEPHEID GENEXPERT® INSTRUMENT SYSTEMS, IS A QUALITATIVE IN-VITRO DIAGNOSTIC TEST FOR THE RAPID IDENTIFICATION AND DIFFERENTIATION OF TOXIN B, AND BINARY TOXIN FROM APPROPRIATE STOOL SPECIMENS COLLECTED FROM PATIENTS SUSPECTED OF HAVING CLOSTRIDIUM DIFFICILE INFECTION (CDI). THE TEST UTILIZES AUTOMATED REAL-TIME POLYMERASE CHAIN REACTION (PCR) TO DETECT TOXIN PRODUCING C. DIFFICILE, WHICH IS ASSOCIATED WITH CDI. THE XPERT C. DIFFICILE ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF CDI. CONCOMITANT TESTING IS NECESSARY ONLY IF FURTHER TYPING IS REQUIRED.,XPERT CT/NG ASSAY(XPERT CT/NG)-THE XPERT CT/NG ASSAY, PERFORMED ON THE GENEXPERT® INSTRUMENT SYSTEMS, IS A QUALITATIVE IN VITRO REAL-TIME PCR TEST FOR THE AUTOMATED DETECTION AND DIFFERENTIATION OF GENOMIC DNA FROM CHLAMYDIA TRACHOMATIS (CT) AND/OR NEISSERIA GONORRHOEAE (NG) TO AID IN THE DIAGNOSIS OF CHLAMYDIAL AND GONORRHEAL UROGENITAL DISEASE. THE ASSAY MAY BE USED TO TEST THE FOLLOWING SPECIMENS FROM ASYMPTOMATIC AND SYMPTOMATIC INDIVIDUALS: FEMALE AND MALE URINE, ENDOCERVICAL SWAB, AND PATIENT-COLLECTED VAGINAL SWAB (COLLECTED IN A CLINICAL SETTING).,XPERT FLU (XPERT FLU)-THE CEPHEID® XPERT FLU ASSAY, PERFORMED ON THE GENEXPERT® INSTRUMENT SYSTEMS, IS AN AUTOMATED, MULTIPLEX REAL-TIME RTPCR ASSAY INTENDED FOR THE IN VITRO QUALITATIVE DETECTION AND DIFFERENTIATION OF INFLUENZA A, INFLUENZA B AND 2009 H1N1 INFLUENZA VIRAL RNA. THE XPERT FLU ASSAY USES NASAL ASPIRATES/WASHES AND NASOPHARYNGEAL SWAB SPECIMENS COLLECTED FROM PATIENTS WITH SIGNS AND SYMPTOMS OF RESPIRATORY INFECTION IN CONJUNCTION WITH CLINICAL AND EPIDEMIOLOGICAL RISK FACTORS. THE XPERT FLU ASSAY IS INTENDED AS AN AID IN THE DIAGNOSIS OF INFLUENZA. NEGATIVE RESULTS DO NOT PRECLUDE INFLUENZA VIRUS INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER PATIENT MANAGEMENT DECISIONS. PERFORMANCE CHARACTERISTICS FOR INFLUENZA A WERE ESTABLISHED DURING THE 2012-2013 INFLUENZA SEASON. WHEN OTHER INFLUENZA A VIRUSES ARE EMERGING, PERFORMANCE CHARACTERISTICS MAY VARY. IF INFECTION WITH A NOVEL INFLUENZA A VIRUS IS SUSPECTED BASED ON CURRENT CLINICAL AND EPIDEMIOLOGICAL SCREENING CRITERIA RECOMMENDED BY PUBLIC HEALTH AUTHORITIES, SPECIMENS SHOULD BE COLLECTED WITH APPROPRIATE INFECTION CONTROL PRECAUTIONS FOR NOVEL

	VIRULENT INFLUENZA VIRUSES AND SENT TO STATE OR LOCAL HEALTH DEPARTMENT FOR TESTING. VIRAL CULTURE SHOULD NOT BE ATTEMPTED IN THESE CASES UNLESS A BSL 3+ FACILITY IS AVAILABLE TO RECEIVE AND CULTURE SPECIMENS.,XPERT MTB/RIF (XPERT MTB/RIF)-THE XPERT MTB/RIF ASSAY FOR USE WITH THE CEPHEID GENEXPERT® SYSTEM IS A SEMI-QUANTITATIVE, NESTED REAL-TIME PCR IN-VITRO DIAGNOSTIC TEST FOR THE DETECTION OF: • MYCOBACTERIUM TUBERCULOSIS COMPLEX DNA IN SPUTUM SAMPLES OR CONCENTRATED SEDIMENTS PREPARED FROM INDUCED OR EXPECTORATED SPUTA THAT ARE EITHER ACID-FAST BACILLI (AFB) SMEAR POSITIVE OR NEGATIVE • RIFAMPIN-RESISTANCE ASSOCIATED MUTATIONS OF THE RPOB GENE IN SAMPLES FROM PATIENTS AT RISK FOR RIFAMPIN RESISTANCE THE XPERT MTB/RIF ASSAY IS INTENDED FOR USE WITH SPECIMENS FROM UNTREATED PATIENTS FOR WHOM THERE IS CLINICAL SUSPICION OF TUBERCULOSIS (TB). USE OF THE XPERT MTB/RIF ASSAY FOR THE DETECTION OF M. TUBERCULOSIS (MTB) OR DETERMINATION OF RIFAMPIN SUSCEPTIBILITY HAS NOT BEEN VALIDATED FOR PATIENTS WHO ARE RECEIVING TREATMENT FOR TUBERCULOSIS.,XPERT HIV-1 VIRAL LOAD(XPERT HIV-1 VIRAL LOAD)-THE XPERT HIV-1 VL ASSAY IS AN IN VITRO REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION (RT-PCR) ASSAY FOR THE DETECTION AND QUANTIFICATION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) RNA IN HUMAN PLASMA FROM HIV-1 INFECTED INDIVIDUALS, USING THE AUTOMATED GENEXPERT INSTRUMENT SYSTEMS. THE ASSAY CAN QUANTIFY HIV-1 RNA OVER THE RANGE OF 40 TO 10,000,000 COPIES/ML. THE XPERT HIV-1 VL ASSAY IS VALIDATED FOR QUANTIFICATION OF RNA FROM HIV-1 GROUP M (SUBTYPES A, B, C, D, F, G, H, J, K, CRF01_AE, CRF02_AG, AND CRF03_AB), GROUP N, AND GROUP O. THE XPERT HIV-1 VL ASSAY IS INTENDED FOR USE IN CONJUNCTION WITH CLINICAL PRESENTATION AND OTHER LABORATORY MARKERS FOR DISEASE PROGNOSIS AND FOR USE AS AN AID IN ASSESSING VIRAL RESPONSE TO ANTIRETROVIRAL TREATMENT AS MEASURED BY CHANGES IN PLASMA HIV-1 RNA LEVELS. THE ASSAY IS INTENDED TO BE USED BY LABORATORY PROFESSIONALS OR SPECIFICALLY-TRAINED HEALTHCARE WORKERS. THE XPERT HIV-1 VL ASSAY IS NOT INTENDED TO BE USED AS A DONOR SCREENING TEST FOR HIV-1 OR AS A DIAGNOSTIC TEST TO CONFIRM THE PRESENCE OF HIV-1 INFECTION.,XPERT HCV VIRAL LOAD(XPERT HCV VIRAL LOAD)-THE HCV VL ASSAY, PERFORMED ON GENEXPERT® INSTRUMENT SYSTEMS, IS DESIGNED FOR THE RAPID QUANTITATION OF HEPATITIS C VIRUS (HCV) RNA IN HUMAN SERUM OR PLASMA (EDTA) FROM HCV-INFECTED INDIVIDUALS. THE TEST UTILIZES AUTOMATED REVERSE

	TRANSCRIPTASE POLYMERASE CHAIN REACTION (RT-PCR) USING FLUORESCENCE TO DETECT THE RNA OF INTEREST FOR THE QUANTITATION OF HCV. THE HCV VL ASSAY QUANTIFIES HCV GENOTYPES 1-6 OVER THE RANGE OF 10 TO 100,000,000 FU/ML. THE HCV VL ASSAY IS INTENDED FOR USE AS AN AID IN THE MANAGEMENT OF HCV INFECTED PATIENTS UNDERGOING ANTIVIRAL THERAPY. THE TEST MEASURES HCV RNA LEVELS AT BASELINE AND DURING TREATMENT AND CAN BE UTILIZED TO PREDICT SUSTAINED AND NONSUSTAINED VIROLOGICAL RESPONSES TO HCV THERAPY. RESULTS FROM THE HCV VL ASSAY MAY ALSO BE USED TO CONFIRM HCV INFECTION IN ANTI-HCV POSITIVE INDIVIDUALS. IN ANTI-HCV POSITIVE INDIVIDUALS WHO TEST NEGATIVE FOR HCV RNA, USE OF ANOTHER HCV ANTIBODY ASSAY MAY BE CONSIDERED FOR DISTINCTION BETWEEN TRUE HCV EXPOSURE AND BIOLOGIC FALSE POSITIVITY. REPEAT HCV RNA TESTING MAY BE INDICATED IN CASES THAT HAVE HAD HCV EXPOSURE IN THE LAST 6 MONTHS OR HAVE CLINICAL EVIDENCE OF HCV DISEASE. THE ASSAY IS NOT INTENDED TO BE USED AS A BLOOD DONOR SCREENING TEST FOR HCV,XPERT SA NASAL COMPLETE(XPERT SA NASAL COMPLETE)-THE CEPHEID XPERT SA NASAL COMPLETE ASSAY PERFORMED IN THE GENEXPERT® DX SYSTEM IS A QUALITATIVE IN VITRO DIAGNOSTIC TEST DESIGNED FOR RAPID AND SIMULTANEOUS DETECTION OF STAPHYLOCOCCUS AUREUS (SA) AND METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) FROM NASAL SWABS IN PATIENTS AT RISK FOR NASAL COLONIZATION, INCLUDING PRE-SURGICAL PATIENTS. THE TEST UTILIZES AUTOMATED REAL-TIME POLYMERASE CHAIN REACTION (PCR) TO DETECT MRSA/SA DNA. THE XPERT SA NASAL COMPLETE ASSAY IS INTENDED TO AID IN THE PREVENTION AND CONTROL OF MRSA/SA INFECTIONS IN HEALTHCARE SETTINGS. THE XPERT SA NASAL COMPLETE ASSAY IS NOT INTENDED TO GUIDE OR MONITOR TREATMENT FOR MRSA/SA INFECTIONS. CONCOMITANT CULTURES ARE NECESSARY ONLY TO RECOVER ORGANISMS FOR EPIDEMIOLOGICAL TYPING OR FOR FURTHER SUSCEPTIBILITY TESTING.

1340	IMP/MD/2018/000252	1.License Holder Name: NOVABONE PRODUCTS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANORGENIC BONE MINERALS-MATRIXOSS™ GRANULES IS INDICATED FOR: - AUGMENTATION OR RECONSTRUCTIVE TREATMENT OF THE ALVEOLAR RIDGE. - FILLING OF INFRABONY PERIODONTAL DEFECTS. - FILLING OF DEFECTS AFTER ROOT RESECTION, APICOECTOMY, AND CYSTECTOMY. - FILLING OF EXTRACTION SOCKETS TO ENHANCE PRESERVATION OF THE ALVEOLAR RIDGE. - ELEVATION OF THE MAXILLARY SINUS FLOOR. - FILLING OF PERIODONTAL DEFECTS IN CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED TISSUE REGENERATION (GTR) AND GUIDED BONE REGENERATION (GBR). - FILLING OF PERI-IMPLANT DEFECTS IN CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED BONE REGENERATION (GBR)., REGENERATION COLLAGEN DENTAL MEMBRANE-MATRIXDERM® REGENERATIVE COLLAGEN DENTAL MEMBRANE IS INTENDED FOR USE IN ORAL SURGICAL PROCEDURES AS A RESORBABLE MATERIAL FOR USE IN AUGMENTATION AROUND IMPLANTS PLACED IN IMMEDIATE EXTRACTION SOCKETS, DELAYED EXTRACTION SOCKETS; LOCALIZED RIDGE AUGMENTATION FOR LATER IMPLANTATION; ALVEOLAR RIDGE RECONSTRUCTION FOR PROSTHETIC TREATMENT; FILLING OF BONE DEFECTS; GUIDED BONE REGENERATION IN DEHISCENCE DEFECTS AND GUIDED TISSUE REGENERATION PROCEDURES IN PERIODONTAL DEFECTS.,RESORBABLE COLLAGEN MEMBRANE-MATRIXFLEX™ IS A BIORESORBABLE, IMPLANTABLE COLLAGEN MATERIAL THAT IS INTENDED FOR USE IN ORAL SURGICAL PROCEDURES AS A RESORBABLE MEMBRANE MATERIAL FOR USE IN – SIMULTANEOUS USE OF GUIDED BONE REGENERATION (GBR)-MEMBRANE AND IMPLANTS; – AUGMENTATION AROUND IMPLANTS PLACED IN IMMEDIATE EXTRACTION SOCKETS; – AUGMENTATION AROUND IMPLANTS PLACED IN DELAYED EXTRACTION SOCKETS; – LOCALIZED RIDGE AUGMENTATION FOR LATER IMPLANTATION; – ALVEOLAR RIDGE RECONSTRUCTION FOR PROSTHETIC TREATMENT; – FILLING OF BONE DEFECTS AFTER ROOT RESECTION, CYSTECTOMY OR REMOVAL OF RETAINED TEETH; – GUIDED BONE REGENERATION IN DEHISCENCE DEFECTS; AND – GUIDED TISSUE REGENERATION PROCEDURES IN PERIODONTAL DEFECTS.

1341	IMP/MD/2018/000253	1.License Holder Name: M/S PRIME MEDICA PROMOTION PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPLINT(PRIME POP SPLINT)-SPLINTING AND/OR CASTING IN CASE OF FRACTURE, POLIO FOR IMMOBILIZATION OF THE LIMB.

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1342	IMP/MD/2018/000254	1.License Holder Name: CARDINAL HEALTH MEDICAL PRODUCTS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRODUCER(LONG SHEATH SETS)-IT IS INDICATED FOR USE IN ARTERIAL AND VENOUS PROCEDURES REQUIRING PERCUTANEOUS INTRODUCTION OF CORDIS BIOPSY FORCEPS AND CATHETERS.,NITINOL STENT SYSTEM (SMART CONTROL)-THE CORDIS S.M.A.R.T. CONTROL NITINOL STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH ATHEROSCLEROTIC DISEASE OF PERIPHERAL ARTERIES, INCLUDING ILIAC AND SUPERFICIAL FEMORAL, FOR TIPSS (TRANSJUGULAR INTRAHEPATIC PORTOSYSTEMIC SHUNT) PROCEDURES AND FOR PALLIATION OF MALIGNANT NEOPLASMS IN THE BILIARY TREE, SHEATHLESS ACCESS SYSTEM(RAILWAY)-IT IS INDICATED FOR USE IN RADIAL ARTERIAL PROCEDURES REQUIRING PERCUTANEOUS INTRODUCTION OF INTRAVASCULAR DEVICES.,NITINOL STENT SYSTEM(PRECISE PRO RX)-THE CORDIS PRECISE PRO RX NITINOL STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH STENOTIC LESIONS OF THE CAROTID ARTERY(IES).,VASCULAR CLOSURE DEVICE (EXOSEAL)-THE EXOSEAL VASCULAR CLOSURE DEVICE IS INDICATED FOR FEMORAL ARTERY PUNCTURE SITE CLOSURE, REDUCING TIME TO HEMOSTASIS AND AMBULATION IN PATIENTS WHO HAVE UNDERGONE DIAGNOSTIC OR INTERVENTIONAL PROCEDURES USING A STANDARD CORRESPONDING FRENCH SIZE VASCULAR SHEATH INTRODUCER WITH UP TO A 12 CM WORKING LENGTH.,GUIDING CATHETER(VISTA BRITE TIP)-THE GUIDING CATHETER IS INTENDED FOR USE FOR INTRAVASCULAR INTRODUCTION OF INTERVENTIONAL/ DIAGNOSTIC DEVICES INTO THE CORONARY OR PERIPHERAL VASCULAR SYSTEMS,DIAGNOSTIC ANGIOGRAPHIC CATHETER(HIGH FLOW)-CORDIS CATHETERS ARE DESIGNED TO DELIVER RADIOPAQUE CONTRAST MEDIUM TO SELECTED SITES IN THE VASCULAR SYSTEM,DIAGNOSTIC ANGIOGRAPHIC CATHETER (TEMPO AQUA)-CORDIS CATHETERS ARE DESIGNED TO DELIVER RADIOPAQUE CONTRAST MEDIUM TO SELECTED SITES IN THE VASCULAR SYSTEM,DIAGNOSTIC ANGIOGRAPHIC CATHETER (INFINITI)-CORDIS CATHETERS ARE DESIGNED TO DELIVER RADIOPAQUE CONTRAST MEDIUM TO SELECTED SITES IN THE VASCULAR SYSTEM.,CATHETER SHEATH INTRODUCER(BRITE TIP)-THE CSI IS INDICATED FOR USE IN ARTERIAL AND VENOUS PROCEDURES REQUIRING PERCUTANEOUS INTRODUCTION OF INTRAVASCULAR DEVICES.,CATHETER SHEATH INTRODUCER(AVANTI +)-THE CSI IS INDICATED FOR USE IN ARTERIAL AND VENOUS PROCEDURES REQUIRING PERCUTANEOUS INTRODUCTION OF INTRAVASCULAR DEVICES,DIAGNOSTIC ANGIOGRAPHIC CATHETER

	(TEMPO)-CORDIS CATHETERS ARE DESIGNED TO DELIVER RADIOPAQUE CONTRAST MEDIUM TO SELECTED SITES IN THE VASCULAR SYSTEM,RETRIEVAL CATHETER(OPTEASE)-THE OPTEASE RETRIEVAL CATHETER IS INDICATED FOR THE RETRIEVAL OF THE OPTEASE RETRIEVABLE FILTER FROM THE INFERIOR VENA CAVA., GUIDING CATHETER(VISTA BRITE TIP)-THE GUIDING CATHETER IS INTENDED FOR USE FOR INTRAVASCULAR INTRODUCTION OF INTERVENTIONAL/ DIAGNOSTIC DEVICES INTO THE CORONARY OR PERIPHERAL VASCULAR SYSTEMS,INTRODUCER GUIDE(VISTA BRITE TIP IG)-THE INTRODUCER GUIDE IS INTENDED FOR USE FOR INTRAVASCULAR INTRODUCTION OF INTERVENTIONAL AND/OR DIAGNOSTIC DEVICES INTO THE PERIPHERAL VASCULATURE., GUIDING CATHETER(ADROIT)-THE GUIDING CATHETER IS INTENDED FOR USE FOR INTRAVASCULAR INTRODUCTION OF INTERVENTIONAL /DIAGNOSTIC DEVICES INTO THE CORONARY OR PERIPHERAL VASCULAR SYSTEMS,DIAGNOSTIC ANGIOGRAPHIC CATHETER(SUPER TORQUE PLUS)-CORDIS CATHETERS ARE DESIGNED TO DELIVER RADIOPAQUE CONTRAST MEDIUM TO SELECTED SITES IN THE VASCULAR SYSTEM

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1343	IMP/MD/2018/000255	1.License Holder Name: MEDICON SURGICAL TECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMPLANTS FOR OSTEOSYNTHESIS (PLATES, SCREWS)(MANDIBLE SYSTEM-TI MANDIBRECO, TIMANDIB FRACTURE)-FIXATION OF MANDIBULAR BONE AFTER FRACTURES AND OSTEOTOMIES. REPLACEMENT OF MANDIBULAR BONE FOR FUNCTIONALLY STABLE BRIDGING OF MANDIBULAR DEFECTS AFTER TUMOR SURGERY OR TRAUMA. FIXATION OF BONE GRAFTS.,IMPLANTS FOR OSTEOSYNTHESIS (PLATES, SCREWS)(MICRO SYSTEM-TI MICRO)-FIXATION OF BONES IN CASES OF ALL KIND OF FRACTURES OF THE MAXILLA, MIDFACE AND CRANIAL SKELETON. FIXATION OF BONES IN THE MAXILLA, MIDFACE AND CRANIAL BONE FOR RECONSTRUCTION OF BONY DEFECTS AND ANOMALIES. FIXATION OF BONES IN THE MAXILLA, MIDFACE AND CRANIAL BONE AFTER OSTEOTOMIES. FIXATION OF BONE GRAFTS., IMPLANTS FOR OSTEOSYNTHESIS (PLATES, SCREWS)(MINI SYSTEM-TI MINI)-FIXATION OF BONES IN CASE OF ALL KIND OF FRACTURES OF THE MANDIBLE, THE MAXILLA, THE MIDFACE AND CRANIAL SKELETON. FIXATION OF BONES IN THE MANDIBLE, MIDFACE AND CRANIAL BONE FOR RECONSTRUCTION OF BONY DEFECTS AND ANOMALIES. FIXATION OF BONES IN THE MANDIBLE AND CRANIAL BONE AFTER OSTEOTOMIES. FIXATION OF BONE GRAFTS,IMPLANTS FOR OSTEOSYNTHESIS (PLATES, SCREWS)(CMS SYSTEM-TI CMS)-FIXATION OF THE THIN BONES OF SKULL AND MIDFACE AFTER FRACTURES AND FOR RECONSTRUCTION OF CONGENITAL ANOMALIES ON CHILDREN AND FIXATION OF BONES OF SKULL AND FACE AFTER OSTEOMOIES. FIXATION OF BONE GRAFTS.

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1344	IMP/MD/2018/000256	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BRONCHIAL TUBE (RUSCH)-ALL AREAS OF THORACIC OR PULMONARY SURGERY, ENDOBRONCHIAL ANAESTHESIA, BRONCHOSPIROMETRY AND VENTILATION REQUIRING UNILATERAL PULMONARY RESPIRATION., INNER CANNULA(RUSCH CRYSTAL CLEAR PLUS)-CANNULATION OF TRACHEOSTOMY PATIENTS WITH AN EXISTING TRACHEOSTOMA. INDICATION TO BE DETERMINED BY PHYSICIAN ONLY!, PERCUTANEOUS DILATIVE TRACHEOSTOMY SET(RUSCH CRYSTAL CLEAR PLUS)-CANNULATION OF TRACHEOSTOMISED PATIENTS, IN WHOM THE STOMA WAS CREATED BY PERCUTANEOUS DILATIVE TRACHEOSTOMY.,TRACHEOSTOMY TUBE SET(RUSCH CRYSTAL CLEAR PLUS & CRYSTAL CLEAR PLUS C)-CANNULATION OF TRACHEOSTOMY PATIENTS WITH AN EXISTING TRACHEOSTOMA. INDICATION TO BE DETERMINED BY PHYSICIAN ONLY!
1345	IMP/MD/2018/000257	1.License Holder Name: SMITHS MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRACHEOSTOMY TUBES (BIVONA)-IT IS INTENDED TO PROVIDE DIRECT AIRWAY ACCESS FOR A TRACHEOSTOMIZED PATIENT FOR UPTO 29 DAYS. IT MAY BE REPROCESSED UPTO 10 TIMES FOR SINGLE PATIENT USE
1346	IMP/MD/2018/000263	1.License Holder Name: SMITHS MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOTRACHEAL TUBE (PORTEX)-IT IS INTENDED FOR ORAL AND/OR NASAL INTUBATION FOR AIRWAY MANAGEMENT. EXPERT CLINICAL JUDGEMENT SHOULD BE EXERCISED IN THE SELECTION OF THE APPROPRIATE TRACHEAL TUBE AND STYLE FOR AN INDIVIDUAL PATIENT.

1347	IMP/MD/2018/000264	1.License Holder Name: TRANSLUMINA THERAPEUTICS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CORONARY STENT SYSTEM (NON-STERILE)(NIL)-INTENDED FOR USE IN THE PATIENT ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DE NOVO LESIONS OF LENGTH 40 MM IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.25 TO 4.50 MM AND THOSE WHO ARE ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA).,PTCA CATHETER (NON STERILE)(TAMARIN BLUE)-IT IS INDICATED FOR: • BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. • BALLOON DILATATION OF A STENT AFTER IMPLANTATION (BALLOON MODELS 2.00MM - 4.50MM),PTCA CATHETER (NON STERILE)(FILAO NC)-IT IS INDICATED FOR: • BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. • BALLOON DILATATION OF A STENT AFTER IMPLANTATION (BALLOON MODELS 2.00MM - 4.50MM)
1348	IMP/MD/2018/000268	1.License Holder Name: SMITHS MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:I.V. CATHETER RADIOPAQUE(JELCO)-THE JELCO CATHETERS ARE DESIGNED FOR SINGLE USE VASCULAR ACCESS BY QUALIFIED OPERATORS. A PROPERLY PLACED I.V. CATHETER PROVIDES ACCESS TO THE VEIN OR ARTERY FOR THE ADMINISTRATION OF SOLUTIONS AND MEDICATIONS

1349	IMP/MD/2018/000270	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED ,NO. 17, GROUND FLOOR AND MEZZANINE FLOOR, THIRUNEERMALAI ROAD, NAGALKENI, CHROMPET ,CHENNAI TAMIL NADU ,600044 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTERBODY IMPLANT (FIDJI CERVICAL)-FIDJI CERVICAL IMPLANTS ARE INDICATED FOR OBTAINING SINGLE-LEVEL OR MULTI-LEVEL SEGMENTAL FUSION IN THE FOLLOWING CASES: A) FORAMINAL STENOSIS, B) INTERBODY FUSION AFTER ANTERIOR DECOMPRESSION FOR MYELOPATHY, C) SPONDYLOLISTHESIS OR RETROLISTHESIS, D) POST-TRAUMATIC INSTABILITY, E) REVISION SURGERY,SPINAL OSTEOSYNTHESIS IMPLANTS (NON -STERILE)(INSTINCT JAVA SYSTEM)-THE INSTINCT JAVA SPINAL FIXATION SYSTEM IS DESIGNED FOR SPINAL FIXATION PROCEDURES IN SKELETALLY MATURE PATIENTS PERFORMED THROUGH A POSTERIOR APPROACH. THE INSTINCT JAVA SPINAL FIXATION SYSTEM IS INDICATED FOR THE TEMPORARY REALIGNMENT AND STABILIZATION OF ONE OR MORE INTERVERTEBRAL SEGMENTS FROM THE THORACIC SPINE TO THE SACRUM UNTIL BONY FUSION IS OBTAINED. THE INSTINCT JAVA SPINAL FIXATION SYSTEM IS INDICATED TO ACHIEVE BONY FUSION VIA OSTEOSYNTHESIS AT THORACIC, LUMBAR AND/OR LUMBOSACRAL LEVELS OF THE SPINE IN DOCUMENTED CASES OF DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, FRACTURE, SPINAL STENOSIS, KYPHOTIC OR LORDOTIC SPINAL DEFORMITIES, SCOLIOSIS, TUMOR AND PSEUDOARTHROSIS, OR FOR REVISION OF A FAILED PREVIOUS FUSION.,NON- FUSION IMPLANTS(UNIWALLIS)-IT IS USED TO STABILIZE THE SPINAL COLUMN IN THE FOLLOWING CASES: A) LARGE DISK HERNIATION IN YOUNG ADULTS OR RECURRENCE OF DISK HERNIATION OR DISK HERNIATION AT L4-5 IN PATIENTS WITH A TRANSITIONAL ANOMALY BY SACRALIZATION OF L5, TREATED BY DISCECTOMY; B) DEGENERATIVE DISCOPATHY AT A LEVEL ADJACENT TO FUSED LUMBAR OR LUMBOSACRAL SEGMENTS; C) DEGENERATIVE LESIONS WITH OR WITHOUT MODIC TYPE 1 CHANGES; D) NARROW LUMBAR CANAL TREATED BY LAMINOTOMY (WITHOUT COMPLETE LAMINECTOMY).,SPINAL OSTEOSYNTHESIS IMPLANTS(UNIVERSAL CLAMP)-IT IS A SPINAL ANCHORING COMPONENT WHICH, COMBINED WITH A COMPATIBLE SYSTEM OF OSTEOSYNTHESIS, PROVIDES THE STABILITY REQUIRED FOR SOLID BONE FUSION AND HELPS REDUCE SPINAL DEFORMITIES AND FRACTURES. THE UNIVERSAL CLAMP IMPLANT IS INDICATED FOR THE FOLLOWING APPLICATIONS: A) SPINAL TRAUMA SURGERY AS A COMPONENT OF SPINAL FUSION; B) RECONSTRUCTIVE SPINAL

	SURGERY AS AN IMPLANT COMBINED WITH CONSTRUCTS INTENDED TO CORRECT SPINAL DEFORMITIES SUCH AS SCOLIOSIS, HYPERKYPHOSIS OR SPONDYLOLISTHESIS; C) DEGENERATIVE SPINAL SURGERY AS A COMPONENT OF SPINAL FUSION.,INTERBODY IMPLANT(FIDJI LOMBAIRE (LUMBAR))-FIDJI LOMBAIRE (LUMBAR) IMPLANTS ARE INDICATED FOR OBTAINING SINGLE-LEVEL OR MULTI-LEVEL SEGMENTAL FUSION IN THE FOLLOWING CASES: A) DEGENERATIVE INSTABILITY, B) POST-DISCECTOMY SYNDROMES, C) SPONDYLOLISTHESIS, D) POST-TRAUMATIC INSTABILITY, E) REVISION SURGERY

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1350	IMP/MD/2018/000272	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAPLER AND CARTRIDGE(ENDO LINEAR CUTTER STAPLER)-THE ENDO LINEAR CUTTER STAPLER TOGETHER WITH ENDO LINEAR CUTTER STAPLER CARTRIDGE CAN BE APPLIED TO DIGESTIVE TRACT RECONSTRUCTION AND CONSTRUCTION OF ANASTOMOTIC STOMA IN OTHER VISCERAL RESECTION SURGERY AND CLOSURE OF STUMP OR NOTCH.,STAPLER AND CARTRIDGE(STAPLER EXTRACTOR)-STAPLE EXTRACTOR IS USED FOR REMOVING STAPLES SUTURED ON THE HEALED WOUND OR INCISION SUPERFICIAL SKIN.,STAPLER AND CARTRIDGE(ENDO LINEAR CUTTER STAPLER CARTRIDGE)-THE ENDO LINEAR CUTTER STAPLER TOGETHER WITH ENDO LINEAR CUTTER STAPLER CARTRIDGE CAN BE APPLIED TO DIGESTIVE TRACT RECONSTRUCTION AND CONSTRUCTION OF ANASTOMOTIC STOMA IN OTHER VISCERAL RESECTION SURGERY AND CLOSURE OF STUMP OR NOTCH. ,STAPLER AND CARTRIDGE(DISPOSABLE SKIN STAPLER)-THE DISPOSABLE SKIN STAPLER IS MAINLY USED FOR SURGICAL STAPLING OF SUPERFICIAL SKIN IN HUMAN BODY WOUND AND OPERATIVE INCISION.,STAPLER AND CARTRIDGE(THE CARTRIDGE FOR DISPOSABLE LINEAR CUTTER)-DISPOSABLE LINEAR CUTTER AND CARTRIDGE FOR DISPOSABLE LINEAR CUTTER HAVE APPLICATION IN ABDOMINAL SURGERY, GYNECOLOGICAL SURGERY AND THORACIC SURGERY FOR RESECTION, TRANSECTION AND CREATION OF ANASTOMOSES OF TISSUE.,STAPLER AND CARTRIDGE (DISPOSABLE LINEAR CUTTER)-DISPOSABLE LINEAR CUTTER AND CARTRIDGE FOR DISPOSABLE LINEAR CUTTER HAVE APPLICATION IN ABDOMINAL SURGERY, GYNECOLOGICAL SURGERY AND THORACIC SURGERY FOR RESECTION, TRANSECTION AND CREATION OF ANASTOMOSES OF TISSUE.,STAPLER AND CARTRIDGE(STERILE DISPOSABLE LINEAR STAPLER CARTRIDGE)-STERILE DISPOSABLE LINEAR STAPLER CARTRIDGE (TYPE KFDZ) TOGETHER WITH TYPE KFD STAPLER CAN BE USED IN ABDOMINAL, THORACIC, GYNECOLOGICAL AND PEDIATRIC SURGICAL PROCEDURES, MAINLY FOR CLOSURE OF ORGAN OR TISSUE STUMPS OR INCISIONS., STAPLER AND CARTRIDGE(DISPOSABLE CIRCULAR STAPLER FOR HEMORRHOIDS)-THE DISPOSABLE CIRCULAR STAPLER FOR HEMORRHOIDS IS MAINLY USED IN THE PROCEDURE FOR PROLAPSE HEMORRHOIDS PERFORMED FOR IIL-IVHEMORRHOIDS AND RECTAL MUCOSA INTUSSUSCEPTION,STAPLER AND CARTRIDGE(STERILE DISPOSABLE LINEAR STAPLER)-THE MAJOR APPLICATION OF DISPOSABLE LINEAR STAPLER HAS APPLICATIONS IN ABDOMINAL, THORACIC, GYNECOLOGICAL AND PEDIATRIC SURGICAL PROCEDURES, MAINLY FOR CLOSURE OF ORGAN OR TISSUE STUMPS

	OR INCISIONS.,STAPLER AND CARTRIDGE(STERILE DISPOSABLE CIRCULAR STAPLER)-THE DISPOSABLE CIRCULAR STAPLER IS MAINLY USED FOR CREATION OF END-TO-END, END-TO-SIDE AND SIDE-TO- SIDE ANASTOMOSIS IS SURGERY OF THE ALIMENTARY TRACT INCLUDING ESOPHAGUS, STOMACH AND INTESTINES. THE KYGW IS ONLY SUITABLE FOR OPEN SURGERY AND TYPE KYWC IS SUITABLE FOR ENDOSCOPE AND OPEN SURGERY.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1351	IMP/MD/2018/000273	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACL INTERFERENCE SCREW(ACL INTERFERENCE SCREW)-STRYKER'S ACL INTERFERENCE SCREWS ARE INTENDED FOR USE IN THE SURGICAL RECONSTRUCTION OF THE ANTERIOR CRUCIATE LIGAMENT (ACL) DEFICIENT KNEE TO PROVIDE INTERFERENCE FIXATION OF THE FEMORAL AND TIBIAL BONY ATTACHMENTS OF THE PATELLA BONE-PATELLAR TENDON-TIBIAL BONE GRAFT COMPLEX, THE SEMI-MEMBRANOSUS TENDON GRAFTS, AND THE SEMI-TENDINOSUS TENDON GRAFTS, OR FIXATION OF THE ALLOGRAFT TECHNIQUES SUCH AS ACL ALLOGRAFTS AND ACHILLES TENDON ALLOGRAFTS. KNEE: ANTERIOR CRUCIATE LIGAMENT REPAIR,SOFT TISSUE FIXATION SYSTEM (SUTURE ANCHOR)(ICONIX TT)-THE STRYKER ICONIX ANCHORS ARE INTENDED TO BE USED FOR SOFT-TISSUE TO BONE FIXATION IN THE FOOT, ANKLE KNEE HIP, HAND WRIST ELBOW AND SHOULDER. SPECIFIC INDICATIONS ARE LISTED BELOW. ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION. SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL REPAIR. HAND/WRIST: SCAPHULOLUNATE LIGAMENT RECONSTRUCTION, CARPAL LIGAMENT RECONSTRUCTION, REPAIR/RECONSTRUCTION OF COLLATERAL LIGAMENTS, REPAIR OF FLEXOR AND EXTENSOR TENDONS AT THE PIP, DIP, AND MCP JOINTS FOR ALL DIGITS, DIGITAL TENDON REPAIR. FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR, METATARSAL LIGAMENT REPAIR, HALLUX VALGUS RECONSTRUCTION, DIGITAL TENDON TRANSFERS, MID-FOOT RECONSTRUCTION. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, PATELLAR TENDON REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILLIOTIBIAL BAND TENODESIS. HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR, GLUTEAL TENDON REPAIR., SUTURE ANCHOR (SOFT TISSUE FIXATION SYSTEM)(WEDGE ANCHOR , WEDGE ANCHOR II)-THE STRYKER WEDGE ANCHOR IS INTENDED FOR THE FIXATION OF SUTURE TO BONE. THE NON-NEEDLE VERSION IS USED PRIMARILY IN ARTHROSCOPIC PROCEDURES, BUT IS SUITABLE IN OPEN PROCEDURES AS WELL. THE NEEDLE VERSION IS USED ONLY IN OPEN PROCEDURES. THE STRYKER WEDGE ANCHOR IS CLEARED FOR USE IN THE FOLLOWING PROCEDURES: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR FOOT/ANKLE: ACHILLES TENDON REPAIR ELBOW/HAND/WRIST: BICEPS TENDON REATTACHMENT,

	SCAPHOLUNATE LIGAMENT RECONSTRUCTION PELVIS: BLADDER NECK SUSPENSION PROCEDURE,ORTHOPEDIC INTERNAL FIXATION SYSTEMS AND ACCESSORIES(CINCHLOCK SS KNOTLESS ANCHOR)-THE PIVOT CINCHLOCK SS KNOTLESS ANCHOR IS INTENDED FOR FIXATION OF SOFT TISSUE TO BONE IN THE HIP, SHOULDER FOOT ANKLE HAND WRIST ELBOW AND KNEE, IN THE FOLLOWING PROCEDURES: HIP: CAPSULAR REPAIR, ACETABULAR LABRUM REATTACHMENT SHOULDER: CAPSULAR STABILIZATION (BANKART REPAIR, ANTERIOR SHOULDER INSTABILITY, SLAP LESION REPAIRS, AND CAPSULAR SHIFT OR CAPSULOLARBAL RECONSTRUCTION), ACROMIOLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, ROTATOR CUFF REPAIR, BICEPS TENODESIS FOOT AND ANKLE: HALLUX VALGUS REPAIR, MEDIAL OR LATERAL INSTABILITY REPAIR/RECONSTRUCTION, ACHILLES TENDON REPAIR/RECONSTRUCTION, MIDFOOT RECONSTRUCTION, METATARSAL LIGAMENT/TENDON REPAIR/ RECONSTRUCTION, BUNIONECTOMY ELBOW, WRIST, AND HAND: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION, LATERAL EPICONDYLITIS REPAIR KNEE: EXTRA-CAPSULAR REPAIR, MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT, PATELLAR REALIGNMENT AND TENDON REPAIR, VASTUS MEDIALIS OBLIQUOUS ADVANCEMENT, ILIOTIBIAL BAND TENODESIS,ORTHOPEDIC INTERNAL FIXATION SYSTEMS AND ACCESSORIES(PROCINCH)-THE STRYKER PROCINCH ADJUSTABLE LOOP FIXATION DEVICE IS INTENDED FOR THE FIXATION OF BONE-TO-BONE OR SOFT TISSUE-TO-BONE AS FIXATION POSTS, A DISTRIBUTION BRIDGE, OR FOR DISTRIBUTING SUTURE TENSION DURING ANTERIOR CRUCIATE LIGAMENT (ACL) AND POSTERIOR CRUCIATE LIGAMENT (PCL) REPAIR AND RECONSTRUCTION,ORTHOPEDIC INTERNAL FIXATION SYSTEMS AND ACCESSORIES(NANOTACK SUTURE ANCHOR)-THE NANOTACK SUTURE ANCHOR IS INTENDED FOR FIXATION OF SOFT TISSUE TO BONE IN THE HIP, SHOULDER, FOOT ANKLE HAND WRIST ELBOW AND KNEE, IN THE FOLLOWING PROCEDURES: HIP: CAPSULAR REPAIR, ACETABULAR LABRUM REATTACHMENT SHOULDER: CAPSULAR STABILIZATION, BANKART REPAIR, ANTERIOR SHOULDER INSTABILITY, SLAP LESION REPAIR, CAPSULAR SHIFTS OR CAPSULOLABRAL RECONSTRUCTIONS, ACROMILAVICULAR SEPARATION REPAIR, DELTOID REPAIR, ROTATOR CUFF TEAR REPAIR, BICEPS TENODESIS FOOT AND ANKLE: HALLUX VALGUS REPAIR, MEDIAL OR LATERAL INSTABILITY REPAIR/RECONSTRUCTION, ACHILLES TENDON REPAIR/RECONSTRUCTION, MIDFOOT RECONSTRUCTION, METATARSAL LIGAMENT/TENDON REPAIR/RECONSTRUCTION,

	BUNIONECTOMY ELBOW, WRIST, AND HAND: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION, LATERAL EPICONDYLITIS REPAIR KNEE: EXTRA-CAPSULAR REPAIR, MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT, PATELLAR REALIGNMENT AND TENDON REPAIR, VASTUS MEDIALIS OBLIQUOUS ADVANCEMENT, ILIOTIBIAL BAND TENODESIS,SOFT TISSUE FIXATION SYSTEM(CINCH LOCK FLEX ANCHOR WITH INSERTER)-THE CINCHLOCK FLEX KNOTLESS ANCHOR IS A NON-DEGRADABLE IMPLANT DEVICE INTENDED FOR THE FIXATION OF SOFT TISSUE TO BONE. THE DEVICE CONSISTS OF A PEEK ANCHOR PREASSEMBLED ON A FLEXIBLE INSERTION DEVICE AND A NON-ABSORBABLE SIZE #1 SUTURE.,SOFT TISSUE FIXATION SYSTEM (SUTURE ANCHOR)(X BRAID TT)-XBRAID TT IS INTENDED TO APPROXIMATE AND OR LIGATE SOFT TISSUES INCLUDING THE USE OF ALLOGRAFT TISSUE FOR ORTHOPAEDIC SURGERIES.,ANCHOR SYSTEM(OMEGA PEEK KNOTLESS ANCHOR SYSTEM)-THE STRYKER OMEGA PEEK KNOTLESS ANCHOR SYSTEM IS INTENDED TO BE USED FOR SOFT-TISSUE TO BONE FIXATION IN THE SHOULDER, FOOT/ ANKLE, KNEE, HAND/WRIST, ELBOW, AND HIP. IT IS INDICATED FOR USE IN THE FOLLOWING PROCEDURES: •SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION •FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR, HALLUX VALGUS RECONSTRUCTION, MID-FOOT RECONSTRUCTION, METATARSAL LIGAMENT REPAIR/ TENDON REPAIR AND BUNIONECTOMY •KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, PATELLAR TENDON REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS, SECONDARY FIXATION FOR ACL/PCL RECONSTRUCTION OR REPAIR •HAND/WRIST: SCAPHOLUNATE LIGAMENT RECONSTRUCTION, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION •ELBOW: BICEPS TENDON REATTACHMENT, TENNIS ELBOW REPAIR, ULNAR OR RADIAL COLLATERAL RECONSTRUCTION, LATERAL EPICONDYLITIS REPAIR •HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR, ORTHOPEDIC INTERNAL FIXATION SYSTEMS AND ACCESSORIES (PEEK INTRALINE ANCHOR)-THE STRYKER PEEK INTRALINE ANCHOR IS A SOFT TISSUE ANCHOR WHICH WILL BE USED FOR TISSUE FIXATION TO BONE IN THE SHOULDER, FOOT/ANKLE, KNEE, HAND/WRIST, ELBOW, AND PELVIS. THE ANCHOR IS INTENDED FOR USE IN THE FOLLOWING PROCEDURES: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS

	TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT/CAPSULOLABRAL RECONSTRUCTION. FOOT AND ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR, HALLUX VALGUS RECONSTRUCTION, MIDFOOT RECONSTRUCTION, METATARSAL LIGAMENT REPAIR. KNEE: ANTERIOR CRUCIATE LIGAMENT REPAIR, MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, PATELLAR TENDON REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILLIOTIBIAL BAND TENODESIS. HAND AND WRIST: SCAPHOLUNATE LIGAMENT RECONSTRUCTION, ULNAR COLLATERAL LIGAMENT RECONSTRUCTION, RADIAL COLLATERAL LIGAMENT RECONSTRUCTION. ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION. PELVIS: BLADDER NECK SUSPENSION PROCEDURES,SOFT-TISSUE ANCHORS(ICONIX SPEED)-THE ICONIX SPEED ANCHORS ARE SOFT-TISSUE FIXATION DEVICES WITH A SELF-PUNCHING DESIGN, PROVIDED PRELOADED ON A DISPOSABLE INSERTER. THEY ARE COMPOSED OF A SHEATH STRUCTURE THAT CONTAINS WORKING SUTURES. THE SHEATH BUNCHES AS THE ANCHOR IS DEPLOYED TO FIXATE IN BONE.,SUTURE ANCHOR SYSTEM(PEEK TWIN LOOP ANCHORS)-IS INTENDED TO USE FOR SUTURE OR TISSUES FIXATION IN THE FOOT, ANKLE,KNEE,HIP,HAND, WRIST,ELBOW,PELVIS AND SHOULDER,(SUTURE ANCHOR) SOFT-TISSUE FIXATION DEVICES(ICONIX)-THE STRYKER ICONIX ANCHORS ARE INDICATED FOR SUTURE OR TISSUE FIXATION IN THE FOOT, ANKLE, KNEE, HIP, HAND, WRIST, ELBOW AND SHOULDER. SPECIFIC INDICATIONS ARE LISTED BELOW AND ARE SIZE-APPROPRIATE PER PATIENT NEEDS: ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION. SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION. HAND/WRIST: SCAPHULOLUNATE LIGAMENT RECONSTRUCTION, CARPAL LIGAMENT RECONSTRUCTION, REPAIR/RECONSTRUCTION OF COLLATERAL LIGAMENTS, REPAIR OF FLEXOR AND EXTENSOR TENDONS AT THE PIP, DIP, AND MCP JOINTS FOR ALL DIGITS, DIGITAL TENDON TRANSFERS. FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR, METATARSAL LIGAMENT REPAIR, HALLUX VALGUS RECONSTRUCTION, DIGITAL TENDON TRANSFERS, MID-FOOT RECONSTRUCTION. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, PATELLAR TENDON REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILLIOTIBIAL BAND TENODESIS. HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR,

	ORTHOPEDIC INTERNAL FIXATION SYSTEMS AND ACCESSORIES (NANOTACK TT SUTURE ANCHOR WITH XBRAID TT)-THE NANOTACK TT SUTURE ANCHOR IS A NON-DEGRADABLE IMPLANT DEVICE INTENDED FOR THE FIXATION OF SOFT TISSUE TO BONE. THE DEVICE CONSISTS OF A SUTURE ANCHOR WITH ATTACHED NON-DEGRADABLE SUTURE PREASSEMBLED ON AN INSERTION DEVICE., ORTHOPEDIC INTERNAL FIXATION SYSTEMS AND ACCESSORIES (TITANIUM INTRALINE ANCHORS)-THE STRYKER TITANIUM INTRALINE ANCHOR IS A SOFT TISSUE ANCHOR WHICH WILL BE USED FOR TISSUE FIXATION TO BONE IN THE SHOULDER, FOOT/ANKLE, KNEE, HAND/WRIST, ELBOW, AND PELVIS. THE ANCHOR IS INTENDED FOR USE IN THE FOLLOWING PROCEDURES: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT/CAPSULOLABRAL RECONSTRUCTION. FOOT AND ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDONREPAIR, HALLUX VALGUS RECONSTRUCTION, MIDFOOT RECONSTRUCTION, METATARSAL LIGAMENT REPAIR. KNEE: ANTERIOR CRUCIATE LIGAMENT REPAIR, MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, PATELLAR TENDON REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILLIOTIBIAL BAND TENODESIS. HAND AND WRIST: SCAPHOLUNATE LIGAMENT RECONSTRUCTION, ULNAR COLLATERAL LIGAMENT RECONSTRUCTION, RADIAL COLLATERAL LIGAMENT RECONSTRUCTION. ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION. PELVIS: BLADDER NECK SUSPENSION PROCEDURES.,ORTHOPEDIC INTERNAL FIXATION SYSTEMS AND ACCESSORIES(PEEK TWINLOOP FLEX)-THE STRYKER PEEK TWINLOOP FLEX ANCHORS ARE INTENDED TO BE USED FOR SUTURE OR TISSUE FIXATION IN THE FOOT, ANKLE, KNEE, HIP, HAND, WRIST, ELBOW AND SHOULDER. SPECIFIC INDICATIONS ARE LISTED BELOW AND ARE SIZE-APPROPRIATE PER PATIENT NEEDS: ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION. SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION. HAND/WRIST: SCAPHULOLUNATE LIGAMENT RECONSTRUCTION, CARPAL LIGAMENT RECONSTRUCTION, REPAIR/RECONSTRUCTION OF COLLATERAL LIGAMENTS, REPAIR OF FLEXOR AND EXTENSOR TENDONS AT THE PIP, DIP, AND MCP JOINTS FOR ALL DIGITS, DIGITAL TENDON TRANSFERS. FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR, METATARSAL

	LIGAMENT REPAIR, HALLUX VALGUS RECONSTRUCTION, DIGITAL TENDON TRANSFERS, MID-FOOT RECONSTRUCTION. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, PATELLAR TENDON REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILLIOTIBIAL BAND TENODESIS. PELVIS: BLADDER NECK SUSPENSION FOR FEMALE URINARY INCONTINENCE DUE TO URETHRAL HYPERMOBILITY OR INTRINSIC SPHINCTER DEFICIENCY. HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR.,(SUTURE ANCHOR) SOFT-TISSUE FIXATION DEVICES(REELX STT)-THE REELX STT SUTURE ANCHOR SYSTEM IS INDICATED FOR SUTURE OR TISSUE FIXATION TO BONE IN THE SHOULDER, FOOT AND ANKLE, KNEE, AND ELBOW. THE ANCHOR IS INDICATED FOR USE IN THE FOLLOWING PROCEDURE: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT/ CAPSULOLABRAL RECONSTRUCTION. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, PATELLAR TENDON REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILLIOTIBIAL BAND TENODESIS. FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR, METATARSAL LIGAMENT REPAIR, HALLUX VALGUS RECONSTRUCTION, MID-FOOT RECONSTRUCTION, METATARSAL LIGAMENT REPAIR. ELBOW: BICEPS TENDON REATTACHMENT, ORTHOPEDIC INTERNAL FIXATION SYSTEMS AND ACCESSORIES (PEEK ZIP SUTURE ANCHOR)-THE STRYKER PEEK ZIP SUTURE ANCHOR IS INTENDED TO PROVIDE AN ANCHOR SITE IN BONE FOR THE FIXATION OF SUTURE, WHICH CAN THEN BE USED TO SECURE SOFT TISSUE TO BONE. THE ANCHOR IS INDICATED FOR USE IN THE ANATOMICAL LOCATIONS AND PROCEDURES LISTED BELOW: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, ACROMIO-CLAVICULAR SEPARATION REPAIR, CAPSULAR SHIFT/CAPSULOLABRAL RECONSTRUCTION, BICEPS TENODESIS, DELTOID REPAIR. KNEE: EXTRA CAPSULAR REPAIRS (MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT), ILLIOTIBIAL BAND TENODESIS, PATELLAR TENDON REPAIR. ELBOW, WRIST, HAND: SCAPHOLUNATE LIGAMENT RECONSTRUCTION, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION, BICEPS TENDON REATTACHMENT. FOOT AND ANKLE: MEDIAL INSTABILITY REPAIR/RECONSTRUCTION, LATERAL INSTABILITY REPAIR/RECONSTRUCTION, HALLUX VALGUS RECONSTRUCTION. PELVIS: BLADDER NECK SUSPENSION PROCEDURE.

1352	IMP/MD/2018/000274	1.License Holder Name: BIO-RAD LABORATORIES (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIACLON ABO/D + REVERSE GROUPING FOR DONORS(DIACLON ABO/D + REVERSE GROUPING FOR DONORS)-THIS ANTI SERA IS FOR THE DETECTION OF THE AB (ABO3) ANTIGEN ON HUMAN RED BLOOD CELLS,DIACLON ANTI-E(DIACLON ANTI-E)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES, ID-ANTIGEN PROFILE III(ID-ANTIGEN PROFILE III)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,ID-ANTIGEN PROFILE II(ID-ANTIGEN PROFILE II)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,DIACLON ANTI-JKB (DIACLON ANTI-JKB)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,ANTI-KPA(ANTI-KPA)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,ID-CARD S(ID-CARD S)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,DIACLON ABD-CONFIRMATION FOR PATIENTS(DIACLON ABD-CONFIRMATION FOR PATIENTS)-THIS ANTI SERA IS FOR THE DETECTION OF THE AB (ABO3) ANTIGEN ON HUMAN RED BLOOD CELLS,DIACLON ABO/D + REVERSE GROUPING(DIACLON ABO/D + REVERSE GROUPING)-THIS ANTI SERA IS FOR THE DETECTION OF THE AB (ABO3) ANTIGEN ON HUMAN RED BLOOD CELLS,DIACLON ABD - CONFIRMATION FOR DONORS(DIACLON ABD - CONFIRMATION FOR DONORS)-THIS ANTI SERA IS FOR THE DETECTION OF THE AB (ABO3) ANTIGEN ON HUMAN RED BLOOD CELLS,DIACLON ABO/RH FOR NEWBORNS DVI+(DIACLON ABO/RH FOR NEWBORNS DVI+)-THIS ANTI SERA IS FOR THE DETECTION OF THE AB (ABO3) ANTIGEN ON HUMAN RED BLOOD CELLS,DIACLON ABO/RH FOR NEWBORNS DVI-(DIACLON ABO/RH FOR NEWBORNS DVI-)-THIS ANTI SERA IS FOR THE DETECTION OF THE AB (ABO3) ANTIGEN ON HUMAN RED BLOOD CELLS,ANTI-JKA (ANTI-JKA)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,ANTI-A1 LECTIN(ANTI-A1 LECTIN)-TYPING OF A1 AND A2 SUBGROUPS WITH

	THE HELP OF ANTISERA IN TUBE AND SLIDE AND BY CARD PREFILLED WITH ANTISERA.,ID-ANTIGEN PROFILE I(ID-ANTIGEN PROFILE I)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,ANTI-K(ANTI-K)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,DIACLON ANTI-LEA(DIACLON ANTI-LEA)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,DIACLON ANTI-N (DIACLON ANTI-N)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,DIACLON TYPE + SCREEN(DIACLON TYPE + SCREEN)-THIS ANTI SERA IS FOR THE DETECTION OF THE AB (ABO3) ANTIGEN ON HUMAN RED BLOOD CELLS,DIACLON RH-SUBGROUPS + K(DIACLON RH-SUBGROUPS + K)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,DIACLON ANTI-K (DIACLON ANTI-K)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,ANTI-CW (ANTI-CW)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES.,ID-CARD S(ID-CARD S)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,DIACLON ANTI- A(DIACLON ANTI- A)-THIS ANTI SERA IS FOR THE DETECTION OF THE A (ABO1) ANTIGEN ON HUMAN RED BLOOD CELLS,DIACLON ANTI-DVI NEG. FOR DONORS(DIACLON ANTI-DVI NEG. FOR DONORS)-THESE CARDS OR ANTISERA ARE USED FOR THE TYPING OF D ANTIGENS ON RED CELLS,ANTI-D(ANTI-D)-THESE CARDS OR ANTISERA ARE USED FOR THE TYPING OF D ANTIGENS ON RED CELLS,ANTI-LUB(ANTI-LUB)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES, ANTI-LUA(ANTI-LUA)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,DIACLON ANTI-JKA(DIACLON ANTI-JKA)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED

		MICROPLATES,ANTI-KPB(ANTI-KPB)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,ID-CARD FYA(ID-CARD FYA)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,DIACLON ANTI-LEB(DIACLON ANTI-LEB)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES,RH-SUBGROUPS + CW + K (RH-SUBGROUPS + CW + K)-TYPING OF OTHER ANTIGENS (KNOWN AS RARE ANTIGENS) ON RED CELLS WITH THE HELP OF ANTISERA OR CARDS PREFILLED WITH ANTISERA OR PRE-COATED MICROPLATES, ANTI A1 ABSORBED(ANTI A1 ABSORBED)-TYPING OF A1 AND A2 SUBGROUPS WITH THE HELP OF ANTISERA IN TUBE AND SLIDE AND BY CARD PREFILLED WITH ANTISERA.,DIACLON ABO/D(DIACLON ABO/D)-THIS ANTI SERA IS FOR THE DETECTION OF THE AB (ABO3) ANTIGEN ON HUMAN RED BLOOD CELLS
1353	IMP/MD/2018/000275	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VASCULAR RECONSTRUCTION DEVICE AND DELIVERY SYSTEM(ENTERPRISE 2)-THE ENTERPRISE 2 VASCULAR RECONSTRUCTION DEVICE IS INTENDED FOR USE WITH OCCLUSIVE DEVICES IN THE TREATMENT OF INTRACRANIAL ANEURYSMS.
1354	IMP/MD/2018/000276	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE (BD HYPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS
1355	IMP/MD/2018/000277	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDEWIRE (GUIDERIGHT™ GUIDEWIRES)-GUIDERIGHT GUIDEWIRES ARE INTENDED FOR USE IN THE PERCUTANEOUS INTRODUCTION OF CATHETERS,GUIDEWIRE(AMPLATZER GUIDEWIRE)-IT IS INTENDED FOR PERCUTANEOUS VESSEL ENTRY TYPICALLY USING THE SELDINGER TECHNIQUE TO FACILITATE SUBSEQUENT INTRODUCTION OF AN INTRAVASCULAR DEVICE.

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1356	IMP/MD/2018/000278	1.License Holder Name: HERAEUS TECHNOLOGIES INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE CEMENT WITH GENTAMYCIN AND VANCOMYCIN(COPAL G+V)-IT IS INDICATED FOR FILLING, STABILIZING OR PERMANENTLY FIXING REVISION JOINT ENDOPROTHESES IN SURGICALLY CLEANED BONE CAVITIES WHICH WERE PREVIOUSLY INFECTED BY PATHOGEN SENSITIVE TO VANCOMYCIN AND WHEN SOLELY GENTAMICIN CONTAINING CEMENT IS CONSIDERED INADEQUATE OR UNDESIRABLE DURING SINGLE STAGE AND TWO STAGE REPLACEMENT PROCEDURE.,BONE CEMENT WITH GENTAMYCIN AND CLINDAMYCIN.(COPAL G+C)-IT IS USED FOR THE STABLE ANCHORING OF ALL SUITABLE JOINT PROSTHESES IN PRIMARY ARTHROPLASTY OPERATIONS, WITH ADDED PROTECTION AGAINST INFECTION. IT IS ALSO USED IN REVISION OPERATIONS RESULTING FROM THE ASEPTIC LOOSENING OF THE PROSTHESES AND INFECTION OF THE PROSTHESES BY ORGANISMS SENSITIVE TO GENTAMICIN AND/OR CLINDAMYCIN.,LOW VISCOSITY, RADIOPAQUE, POLYMETHYLMETHACRYLATE (PMMA) BONE CEMENT CONTAINING GENTAMICIN(PALACOS LV+G)-STABLE ATTACHMENT OF TOTAL OR PARTIAL JOINT ENDOPROSTHESES IN BONE. FILLING AND STABILISING BONE DEFECTS WITHIN THE SCOPE OF INTERNAL FIXATION TREATMENT OF FOR ENDOPROSTHESES REVISION SURGERY. ,MEDIUM VISCOSITY, RADIOPAQUE, POLYMETHYLMETHACRYLATE (PMMA) BONE CEMENT CONTAINING GENTAMICIN.(PALACOS MV+G)-STABLE ATTACHMENT OF TOTAL OR PARTIAL JOINT ENDOPROSTHESES IN BONE. FILLING AND STABILISING BONE DEFECTS WITHIN THE SCOPE OF INTERNAL FIXATION TREATMENT OF FOR ENDOPROSTHESES REVISION SURGERY. PRIMARY AND SECONDARY COVERAGE OF SKULL BONE DEFECTS.,HIGH VISCOSITY, RADIOPAQUE, POLYMETHYLMETHACRYLATE (PMMA) BONE CEMENT CONTAINING GENTAMICIN.(PALACOS R+G)-STABLE ATTACHMENT OF TOTAL OR PARTIAL JOINT ENDOPROSTHESES IN BONE. FILLING AND STABILISING BONE DEFECTS WITHIN THE SCOPE OF INTERNAL FIXATION TREATMENT OF FOR ENDOPROSTHESES REVISION SURGERY. PRIMARY AND SECONDARY COVERAGE OF SKULL BONE DEFECTS. ,POLYMETHYLMETHACRYLATE (PMMA) BONE CEMENT (OSTEOPAL V)-OSTEOPAL V IS OBTAINED BY MIXING THE POLYMER POWDER COMPONENT WITH THE CORRESPONDING LIQUID MONOMER COMPONENT. AFTER MIXING, LOW-VISCOSITY DOUGH IS OBTAINED WHICH IS FILLED INTO THE VERTEBRAL BODIES AS A STABILIZATION MEDIUM AND ALLOWED TO HARDEN. INDICATIONS OSTEOPAL V IS USED FOR AUGMENTATION OF VERTEBRAL BODIES • FOR PAINFUL COMPRESSION FRACTURES OF THE VERTEBRAL BODY • FOR

		PAINFUL TUMORS IN THE VERTEBRAL BODY (METASTATIC CARCINOMAS OR MYELOMAS) • FOR SYMPTOMATIC VERTEBRAL HEMANGIOMAS ,LOW VISCOSITY, RADIOPAQUE, POLYMETHYLMETHACRYLATE (PMMA) BONE CEMENT.(PALACOS LV)-STABLE ATTACHMENT OF TOTAL OR PARTIAL JOINT ENDOPROSTHESES IN BONE. FILLING AND STABILISING BONE DEFECTS WITHIN THE SCOPE OF INTERNAL FIXATION TREATMENT OF FOR ENDOPROSTHESES REVISION SURGERY. ,MEDIUM VISCOSITY/HIGH VISCOSITY, RADIOPAQUE, POLYMETHYLMETHACRYLATE (PMMA) BONE CEMENT(PALACOS MV/PALACOS R)-STABLE ATTACHMENT OF TOTAL OR PARTIAL JOINT ENDOPROSTHESES IN BONE. FILLING AND STABILISING BONE DEFECTS WITHIN THE SCOPE OF INTERNAL FIXATION TREATMENT OF FOR ENDOPROSTHESES REVISION SURGERY. PRIMARY AND SECONDARY COVERAGE OF SKULL BONE DEFECTS.
1357	IMP/MD/2018/000279	1.License Holder Name: VK DENTAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT (MONOIMPLANT)-MONO IMPLANT IS AN END - OSSEOUS DENTAL IMPLANT THAT IS INDICATED TO USE FOR SURGICAL PLACEMENT IN THE UPPER AND LOWER JAW ARCHES (JAW BONES), TO PROVIDE A ROOT FORM MEANS TO RESTORE A PATIENT'S CHEWING FUNCTION. MONO IMPLANT CAN BE PLACED IN A SINGLE STAGE SURGICAL PROCESS FOR IMMEDIATE LOADING.
1358	IMP/MD/2018/000280	1.License Holder Name: SREE BHAGAVATHY AGENCIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERITONEAL DIALYSIS INTRODUCER KIT(PERITONEAL DIALYSIS INTRODUCER SET)-TO INSERT CAPD CATHETERS INTO PERITONEAL CAVITY.,PERITONEAL DIALYSIS INTRODUCER SET(PERITONEAL DIALYSIS INTRODUCER SET)-TO INSERT CAPD CATHETERS INTO PERITONEAL CAVITY., PERITONEAL DIALYSIS CATHETER(PERITONEAL DIALYSIS CATHETER)-PERITONEAL DIALYSIS CATHETER IS USED IN THE ABDOMEN FOR HEMO- DIALYSIS

1359	IMP/MD/2018/000281	1.License Holder Name: CONVATEC INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALL SILICONE FOLEY CATHETER(UNOMEDICAL 2 WAY PEDIATRIC CATHETER)-THE 100% SILICONE FOLEY CATHETER ARE INDICATED FOR TRANSURETHRAL DRAINAGE OF URINE FROM THE BLADDER AND/OR CONTINUOUS IRRIGATION OF FLUIDS. THE STANDARD 2-WAY CATHETERS (SIZE 12 TO 18) CAN ALSO BE USED FOR REPLACEMENT OF SUPRAPUBIC CATHETERS FOR DRAINAGE OF THE BLADDER (EXCHANGE ONLY). PEDIATRIC SIZED (CH/FR 6, 8, 10) CAN BE RETAINED FOR UP TO 30 DAYS.,ENDOTRACHEAL TUBE(UNOMEDICAL ORAL/ NASAL TRACHEAL TUBES WITH MURPHY- EYE (HVLP), UNOMEDICAL ORAL/NASAL TRACHEAL TUBE WITH HVLP-CUFF, UNOMEDICAL ORAL/NASAL TRACHEAL TUBES WITH MURPHY- EYE (UNCUFFED), UNOMEDICAL PLAIN ORAL/NASAL TRACHEAL TUBE (UNCUFFED))-TRACHEAL TUBES ARE USED IN GENERAL ANESTHESIA, INTENSIVE CARE AND EMERGENCY MEDICINE FOR AIRWAY MANAGEMENT AND MECHANICAL VENTILATION. THE TUBE IS INSERTED INTO THE PATIENT'S TRACHEA THROUH THE NOSE OR MOUTH IN ORDER TO MAINTAIN THE AIRWAY.,FOLEY CATHETER KITS(UNOMEDICAL CARELINE 2 WAY CATHETER WITH SYRINGE (1 EMPTY SYRINGE AND 1 PREFILLED SYRINGE WITH 10% GLYCERIN WATER))-THE 100% SILICONE FOLEY CATHETER ARE INDICATED FOR TRANSURETHRAL DRAINAGE OF URINE FROM THE BLADDER AND/OR CONTINUOUS IRRIGATION OF FLUIDS. THE STANDARD 2-WAY CATHETERS (SIZE 12 TO 18) CAN ALSO BE USED FOR REPLACEMENT OF SUPRAPUBIC CATHETERS FOR DRAINAGE OF THE BLADDER (EXCHANGE ONLY). THE ADULT 2-WAY CATHETER CAN BE USED RETAINED IN THE HUMAN BODY FOR UP TO 90 DAYS.,ENDOTRACHEAL TUBE (UNOMEDICAL UNOFLEXTM REINFORCED ORAL/NASAL TRACHEAL TUBE – HVLP, UNOMEDICAL UNOFLEXTM REINFORCED TRACHEAL TUBE WITH MURPHY EYE – ORAL/NASAL - HVLP)-TRACHEAL TUBES ARE USED IN GENERAL ANESTHESIA, INTENSIVE CARE AND EMERGENCY MEDICINE FOR AIRWAY MANAGEMENT AND MECHANICAL VENTILATION. THE TUBE IS INSERTED INTO THE PATIENT'S TRACHEA THROUH THE NOSE OR MOUTH IN ORDER TO MAINTAIN THE AIRWAY.,ALL SILICONE FOLEY CATHETER (UNOMEDICAL 2 WAY CATHETER)-THE 100% SILICONE FOLEY CATHETER ARE INDICATED FOR TRANSURETHRAL DRAINAGE OF URINE FROM THE BLADDER AND/OR CONTINUOUS IRRIGATION OF FLUIDS. THE STANDARD 2-WAY CATHETERS (SIZE 12 TO 18) CAN ALSO BE USED FOR REPLACEMENT OF SUPRAPUBIC CATHETERS FOR DRAINAGE OF THE BLADDER (EXCHANGE ONLY). THE ADULT 2-WAY CATHETER CAN BE USED RETAINED IN THE HUMAN BODY FOR UP TO

	90 DAYS.,ALL SILICONE FOLEY CATHETER(UNOMEDICAL 3 WAY CATHETER)-THE 100% SILICONE FOLEY CATHETER ARE INDICATED FOR TRANSURETHRAL DRAINAGE OF URINE FROM THE BLADDER AND/OR CONTINUOUS IRRIGATION OF FLUIDS. THE STANDARD 2-WAY CATHETERS (SIZE 12 TO 18) CAN ALSO BE USED FOR REPLACEMENT OF SUPRAPUBIC CATHETERS FOR DRAINAGE OF THE BLADDER (EXCHANGE ONLY). THE 3-WAY CATHETER CAN BE USED RETAINED IN THE HUMAN BODY FOR UP TO 30 DAYS.

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1360	IMP/MD/2018/000282	1.License Holder Name: JOHNSON & JOHNSON SURGICAL VISION INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOLDABLE 1-PIECE TORIC IOL WITH TECNIS SIMPLICITY PRELOADED DELIVERY SYSTEM(TECNIS EYHANCE TORIC II IOL WITH TECNIS SIMPLICITY DELIVERY SYSTEM)-THE TECNIS SIMPLICITY DELIVERY SYSTEM IS USED TO FOLD AND ASSIST IN INSERTING THE TECNIS EYHANCE TORIC II IOL WHICH IS INDICATED FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS REDUCES THE RESIDUAL REFRACTIVE CYLINDER AND EXTENDS THE DEPTH OF FOCUS, WHICH IMPROVES VISION FOR INTERMEDIATE TASKS, AND PROVIDES SIMILAR DISTANCE VISION AS COMPARED TO A STANDARD ASPHERIC MONOFOCAL IOL. THE LENS IS INDICATED FOR PLACEMENT IN THE CAPSULAR BAG ONLY,FOLDABLE 1-PIECE EXTENDED RANGE OF VISION TRIFOCAL INTRAOCULAR LENS(TECNIS SYNERGY IOL)-THE LENS MODEL ZFR00 IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF: [1] APHAKIA IN ADULTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED, AND [2] APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO MAY BENEFIT FROM USEFUL NEAR VISION AND REDUCED SPECTACLE DEPENDENCE ACROSS A RANGE OF DISTANCES. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE 1-PIECE TORIC INTRAOCULAR LENS(TECNIS EYHANCE TORIC II IOL)-THE TECNIS EYHANCE TORIC II IOL, MODEL ICU, IS INDICATED FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS REDUCES THE RESIDUAL REFRACTIVE CYLINDER AND EXTENDS THE DEPTH OF FOCUS, WHICH IMPROVES VISION FOR INTERMEDIATE TASKS, AND PROVIDES SIMILAR DISTANCE VISION AS COMPARED TO A STANDARD ASPHERIC MONOFOCAL IOL. THE LENS IS INDICATED FOR PLACEMENT IN THE CAPSULAR BAG ONLY.,FOLDABLE 1-PIECE EXTENDED RANGE OF VISION TRIFOCAL INTRAOCULAR LENS(TECNIS SYNERGY OPTIBLUE IOL)-THE LENS MODEL ZFR00V IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED, AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO MAY BENEFIT FROM USEFUL NEAR VISION AND REDUCED SPECTACLE DEPENDENCE ACROSS A RANGE OF DISTANCES. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR

	BAG.,FOLDABLE CONTINUOUS RANGE OF VISION TORIC 1-PIECE INTRAOCULAR LENS WITH TECNIS SIMPLICITY PRELOADED DELIVERY SYSTEM(TECNIS SYNERGY TORIC II OPTIBLUE IOL WITH TECNIS SIMPLICITY DELIVERY SYSTEM)-THE TECNIS SIMPLICITY™ DELIVERY SYSTEM IS USED TO FOLD AND ASSIST IN INSERTING THE TECNIS SYNERGY™ TORIC II OPTIBLUE™ IOL WHICH IS INDICATED FOR THE PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN [1] ASTIGMATIC ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION AND [2] APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN ASTIGMATIC PRESBYOPIC ADULTS, WHO DESIRE IMPROVED UNCORRECTED VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER, USEFUL NEAR VISION AND REDUCED SPECTACLE DEPENDENCE ACROSS A RANGE OF DISTANCES. THE INTRAOCULAR LENSES ARE INTENDED TO MAINTAIN ROTATIONAL STABILITY AFTER IMPLANTATION IN THE CAPSULAR BAG.,FOLDABLE MONOFOCAL TORIC 1-PIECE INTRAOCULAR LENS(TECNIS TORIC II 1-PIECE INTRAOCULAR LENS)-THE TECNIS TORIC (II) 1-PIECE POSTERIOR CHAMBER INTRAOCULAR LENSES ARE INTENDED FOR PRIMARY IMPLANTATION FOR VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION, WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE VISION. THIS DEVICE IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE CONTINUOUS RANGE OF VISION 1-PIECE INTRAOCULAR LENS WITH TECNIS SIMPLICITY PRELOADED DELIVERY SYSTEM(TECNIS SYNERGY OPTIBLUE IOL WITH TECNIS SIMPLICITY DELIVERY SYSTEM)-THE TECNIS SIMPLICITY™ DELIVERY SYSTEM IS USED TO FOLD AND ASSIST IN INSERTING THE TECNIS SYNERGY™ OPTIBLUE™ IOL WHICH IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF: [1] APHAKIA IN ADULTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED, AND [2] APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO MAY BENEFIT FROM USEFUL NEAR VISION AND REDUCED SPECTACLE DEPENDENCE ACROSS A RANGE OF DISTANCES. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE MONOFOCAL TORIC 1-PIECE INTRAOCULAR LENS(TECNIS TORIC 1-PIECE IOL)-THE TECNIS TORIC POSTERIOR CHAMBER LENSES ARE INDICATED FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM OF ONE DIOPTER OR GREATER IN

	ADULT PATIENT WITH OR WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION AND WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION IN RESIDUAL REFRACTIVE CYLINDER, AND INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE VISION. THE DEVICE IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE MONOFOCAL TORIC 1-1 PIECE INTRAOCULAR(TECNIS TORIC 1-PIECE IOL)-THE TECNIS® TORIC 1-PIECE LENS IS INDICATED FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENTS WITH OR WITHOUT PRESBYOPIA, IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION AND WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE VISION. THIS DEVICE IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE MULTIFOCAL 3-PIECE INTRAOCULAR LENS(TECNIS MULTIFOCAL 3-PIECE INTRAOCULAR LENS)-TECNIS MULTIFOCAL INTRAOCULAR LENSES ARE INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH OR WITHOUT IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO MAY BENEFIT FROM USEFUL NEAR VISION AND REDUCED SPECTACLE DEPENDENCE ACROSS A RANGE OF DISTANCES. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG. ,FOLDABLE EXTENDED RANGE OF VISION 1-PIECE IOL(TECNIS SYMFONY EXTENDED RANGE OF VISION 1-PIECE IOL)-THE TECNIS® SYMFONY IOL, MODEL ZXR00, IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION, AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS, WHO DESIRE USEFUL VISION OVER A CONTINUOUS RANGE OF DISTANCES INCLUDING FAR, INTERMEDIATE AND NEAR, AND INCREASED SPECTACLE INDEPENDENCE. THIS DEVICE IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE EXTENDED RANGE OF VISION TORIC 1-PIECE IOL(TECNIS SYMFONY EXTENDED RANGE OF VISION TORIC 1-PIECE IOL)-THE TECNIS® SYMFONY IOLS, MODELS ZXT100, ZXT150, ZXT225, ZXT300, ZXT375, ZXT450, ZXT525, ZXT600 ARE INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA AND PREEXISTING CORNEAL ASTIGMATISM IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY

	EXTRACAPSULAR CATARACT EXTRACTION, AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS, WHO DESIRE USEFUL VISION OVER A CONTINUOUS RANGE OF DISTANCES INCLUDING FAR, INTERMEDIATE AND NEAR, A REDUCTION OF RESIDUAL REFRACTIVE CYLINDER, AND INCREASED SPECTACLE INDEPENDENCE. THESE DEVICES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE MULTIFOCAL 1-PIECE INTRAOCULAR LENS(TECNIS MULTIFOCAL 1-PIECE INTRAOCULAR LENS)-MODEL ZMB00, TECNIS MULTIFOCAL FOLDABLE ACRYLIC 1-PIECE INTRAOCULAR LENSES ARE INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO MAY BENEFIT FROM USEFUL NEAR VISION AND REDUCED SPECTACLE DEPENDENCE ACROSS A RANGE OF DISTANCES. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG. MODEL ZKB00, ZLB00, TECNIS MULTIFOCAL FOLDABLE ACRYLIC 1-PIECE INTRAOCULAR LENSES ARE INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH OR WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO DESIRE IMPROVED UNCORRECTED NEAR, INTERMEDIATE, AND DISTANCE VISION AND INCREASED SPECTACLE INDEPENDENCE ACROSS A RANGE OF DISTANCES. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG. ,FOLDABLE EXTENDED RANGE OF VISION 1-PIECE IOL(TECNIS SYMFONY PLUS EXTENDED RANGE OF VISION IOL)-THE LENS MODEL ZHR00 IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION, AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS, WHO DESIRE USEFUL VISION OVER A CONTINUOUS RANGE OF DISTANCES INCLUDING FAR, INTERMEDIATE AND NEAR, AND INCREASED SPECTACLE INDEPENDENCE. THIS DEVICE IS INTENDED TO BE PLACED IN THE CAPSULAR BAG ONLY.,FOLDABLE EXTENDED RANGE OF VISION TORIC 1-PIECE IOL(TECNIS SYMFONY PLUS EXTENDED RANGE OF VISION TORIC IOL)-THE LENS MODELS ZHT100, ZHT150, ZHT225, ZHT300, ZHT375, ZHT450, ZHT525, AND ZHT600, ARE INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY

	EXTRACAPSULAR CATARACT EXTRACTION, AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO DESIRE USEFUL VISION OVER A CONTINUOUS RANGE OF DISTANCES, INCLUDING FAR, INTERMEDIATE AND NEAR, A REDUCTION OF RESIDUAL REFRACTIVE CYLINDER, AND INCREASED SPECTACLE INDEPENDENCE. THESE DEVICES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG. ,FOLDABLE MULTIFOCAL 1-PIECE INTRAOCULAR LENS(TECNIS MULTIFOCAL TORIC 1-PIECE INTRAOCULAR LENS)-THE TECNIS MULTIFOCAL TORIC 1-PIECE LENS IS INDICATED FOR THE PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM ASTIGMATIC ADULT PATIENTS WITH OR WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION AND AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN ASTIGMATIC PRESBYOPIC ADULTS WHO DESIRE IMPROVED, INTENDED TO MAINTAIN ROTATIONAL STABILITY AFTER IMPLANTATION IN THE CAPSULAR BAG.,FOLDABLE 1-PIECE ACRYLIC IOL WITH TECNIS SIMPLICITY PRELOADED DELIVERY SYSTEM(TECNIS 1-PIECE IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM)-THE TECNIS SIMPLICITY™ DELIVERY SYSTEM IS USED TO FOLD AND ASSIST IN INSERTING THE TECNIS® 1-PIECE INTRAOCULAR LENS FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THESE DEVICES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG., FOLDABLE 1-PIECE ACRYLIC POSTERIOR CHAMBER INTRAOCULAR LENS WITH TECNIS SIMPLICITY PRELOADED DELIVERY SYSTEM (TECNIS EYHANCE IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM) -THE TECNIS SIMPLICITY™ DELIVERY SYSTEM IS USED TO FOLD AND ASSIST IN INSERTING THE TECNIS EYHANCE IOL WHICH IS INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS EXTENDS THE DEPTH OF FOCUS, WHICH IMPROVES VISION FOR INTERMEDIATE TASKS, AND PROVIDE SIMILAR DISTANCE VISION AS COMPARED TO A STANDARD ASPHERIC MONOFOCAL IOL. THE LENS IS INDICATED FOR PLACEMENT IN THE CAPSULAR BAG ONLY.,FOLDABLE 1-PIECE OPTIBLUE ACRYLIC IOL WITH TECNIS SIMPLICITY PRELOADED DELIVERY SYSTEM(TECNIS OPTIBLUE 1-PIECE IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM)-THE TECNIS SIMPLICITY™ DELIVERY SYSTEM IS USED TO FOLD AND ASSIST IN INSERTING THE TECNIS® OPTIBLUE 1-PIECE INTRAOCULAR LENSES WHICH ARE INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY

	EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE 1-PIECE ACRYLIC POSTERIOR CHAMBER INTRAOCULAR LENS(TECNIS EYHANCE IOL)- THE TECNIS EYHANCE IOL, MODEL ICB00, IS INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED TO EXTEND DEPTH OF FOCUS, WHICH IMPROVES VISION FOR INTERMEDIATE TASKS, AND PROVIDE SIMILAR DISTANCE VISION AS COMPARED TO A STANDARD MONOFOCAL IOL. THE LENS IS INDICATED FOR PLACEMENT IN THE CAPSULAR BAG ONLY.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1361	IMP/MD/2018/000284	1.License Holder Name: PERKINELMER INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PKAMP™ RESPIRATORY SARS-COV-2 RT-PCR PANEL KIT(PKAMP™ RESPIRATORY SARS-COV-2 RT-PCR PANEL KIT)-THE PERKINELMER PKAMP™ RESPIRATORY SARS-COV-2 RT-PCR PANEL KIT IS INTENDED FOR USE FOR THE SIMULTANEOUS QUALITATIVE DETECTION AND DIFFERENTIATION OF SARS-COV-2, INFLUENZA A, INFLUENZA B, AND RESPIRATORY SYNCYTIAL VIRUS (RSV) NUCLEIC ACIDS IN RNA EXTRACTED FROM THE HEALTHCARE PROVIDER-COLLECTED HUMAN NASOPHARYNGEAL SWAB SPECIMENS FROM INDIVIDUALS SUSPECTED OF RESPIRATORY VIRAL INFECTION CONSISTENT WITH COVID-19.,DELFIA® WASH CONCENTRATE(DELFIA® WASH CONCENTRATE)-THE DELFIA® WASH CONCENTRATE IS INTENDED FOR IN VITRO USE WITH THE DELFIA XPRESS CLINICAL SCREENING RANDOM ACCESS PLATFORM OR WITH THE DELFIA PLATEWASH., DELFIA® DILUENT 3(DELFIA® DILUENT 3)-THE DELFIA® DILUENT 3 IS INTENDED TO BE USED WITH AUTODELFIA® AND DELFIA KITS FOR SAMPLE DILUTION,DELFIA® DILUENT I(DELFIA® DILUENT I)-THE DELFIA® DILUENT I IS INTENDED TO BE USED WITH AUTODELFIA® AND DELFIA KITS FOR SAMPLE DILUTION. THE USE OF DILUENT I IN SAMPLE DILUTION OR OTHER PURPOSES IS DESCRIBED IN THE KIT INSERTS.,GSP® WASH CONCENTRATE(GSP® WASH CONCENTRATE)-WASH CONCENTRATE IS INTENDED FOR IN VITRO DIAGNOSTIC USE ESPECIALLY WITH THE GSP INSTRUMENT. IT CAN ALSO BE USED WITH DELFIA® AND AUTODELFIA® INSTRUMENTS.,NEOBASE™ NON-DERIVATIZED MSMS KIT(NEOBASE™ NON-DERIVATIZED MSMS KIT)-THIS TANDEM MASS SPECTROMETRY (MSMS) REAGENT KIT IS INTENDED FOR THE MEASUREMENT AND EVALUATION OF AMINO ACIDS, SUCCINYLACETONE, FREE CARNITINE, AND ACYLCARNITINE CONCENTRATIONS FROM NEWBORN HEEL PRICK BLOOD SAMPLES DRIED ON FILTER PAPER. QUANTITATIVE ANALYSIS OF THESE ANALYTES (TABLE 1) AND THEIR RELATIONSHIP WITH EACH OTHER IS INTENDED TO PROVIDE ANALYTE CONCENTRATION PROFILES THAT MAY AID IN SCREENING NEWBORNS FOR METABOLIC DISORDERS ,CHS™ MSMS STEROIDS TOOL BOX(CHS™ MSMS STEROIDS TOOL BOX) -THE CHS™ MSMS STEROIDS TOOL BOX IS INTENDED FOR IN VITRO DIAGNOSTIC USE WITH THE CHS MSMS STEROIDS KIT (3070-0020)., DELFIA® INDUCER(DELFIA® INDUCER)-THE DELFIA INDUCER IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF EUROPIUM (EU3+) IN DISSOCIATION-ENHANCED TIME-RESOLVED FLUORO-IMMUNOASSAYS WHEN USING THE GSP INSTRUMENT,GSP® NEONATAL PHENYLALANINE KIT(GSP® NEONATAL PHENYLALANINE KIT)-THIS KIT IS INTENDED FOR THE

	QUANTITATIVE DETERMINATION OF PHENYLALANINE CONCENTRATIONS IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR PHENYLKETONURIA BY USING THE GSP® INSTRUMENT.,RESOLVE®HB ELUTION SOLUTION (RESOLVE®HB ELUTION SOLUTION)-THE RESOLVE HB ELUTION SOLUTION IS INTENDED FOR IN VITRO USE WITH THE RESOLVE HEMOGLOBIN KITS 9FR-9120, FR-9400, FR-9360) FOR ISOELECTRIC FOCUSING),GSP® NEONATAL 17-OH-PROGESTERONE KIT(GSP® NEONATAL 17-OH-PROGESTERONE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN 17-OH-PROGESTERONE IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL ADRENAL HYPERPLASIA (CAH) USING THE GSP® INSTRUMENT.,DELFIA® WASH CONCENTRATE(DELFIA® WASH CONCENTRATE)-THE WASH CONCENTRATE IS INTENDED FOR IN VITRO USE WITH THE DELFIA® PLATEWASH OR THE AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM AFTER DILUTION WITH DEIONIZED WATER.,CHS™ MSMS STEROIDS KIT(CHS™ MSMS STEROIDS KIT)-THIS IN VITRO DIAGNOSTIC HIGH PERFORMANCE LIQUID CHROMATOGRAPHY TANDEM MASS SPECTROMETRY (HPLC-MSMS) REAGENT KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF 10 STEROIDS IN HUMAN SERUM SAMPLES. DETERMINATION OF CONCENTRATION PROFILES OF THESE ANALYTES MAY AID IN THE CLINICAL RECOGNITION, DIAGNOSIS AND TREATMENT OF DISEASES AFFECTING THE ADRENAL GLANDS, OVARIES, TESTES, AND PLACENTA.,NEOBASE 2 NON-DERIVATIZED MSMS KIT(NEOBASE 2 NON-DERIVATIZED MSMS KIT)-THE NEOBASE™ 2 NON-DERIVATIZED MSMS KIT IS INTENDED FOR THE MEASUREMENT AND EVALUATION OF AMINO ACID, SUCCINYLACETONE, FREE CARNITINE, ACYLCARNITINE, NUCLEOSIDE AND LYSOPHOSPHOLIPID CONCENTRATIONS (TABLE 1) WITH A TANDEM MASS SPECTROMETER FROM NEWBORN HEEL PRICK BLOOD SPECIMENS DRIED ON FILTER PAPER. QUANTITATIVE ANALYSIS OF THESE ANALYTES AND THEIR RELATIONSHIP WITH EACH OTHER IS INTENDED TO PROVIDE ANALYTE CONCENTRATION PROFILES THAT MAY AID IN SCREENING NEWBORNS FOR METABOLIC DISORDERS.,GSP® NEONATAL GALT KIT(GSP® NEONATAL GALT KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROXINE (T4) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL (NEONATAL) HYPOTHYROIDISM USING THE GSP® INSTRUMENT.,NEOBASE 2 SUCCINYLACETONE ASSAY SOLUTION(NEOBASE 2 SUCCINYLACETONE ASSAY SOLUTION)-THE NEOBASE™ 2 SUCCINYLACETONE ASSAY SOLUTION IS INTENDED FOR IN VITRO DIAGNOSTIC USE WITH THE NEOBASE™ 2 NON-DERIVATIZED MSMS

	KIT (3044-0010, 3044-001U) AND THE NEOBASE™ 2 NON-DERIVATIZED ASSAY SOLUTIONS (3045-0010) TO EXTRACT SUCCINYLACETONE FROM BLOOD SAMPLES DRIED ON FILTER PAPER. MEASUREMENT OF ARGININOSUCCINIC ACID REQUIRES USE OF NEOBASE 2 SUCCINYLACETONE ASSAY SOLUTION.,GSP® NEONATAL G6PD KIT(GSP® NEONATAL G6PD KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD) ACTIVITY IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR G6PD DEFICIENCY USING THE GSP® INSTRUMENT,AUTODELFIA®INHIBIN A KIT(AUTODELFIA®INHIBIN A KIT)-THE KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF DIMERIC HUMAN INHIBIN A IN MATERNAL SERUM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM. THE KIT IS INTENDED FOR SCREENING FOR RISK OF DOWN'S SYNDROME (TRISOMY 21) IN THE SECOND TRIMESTER OF PREGNANCY AND USED TOGETHER WITH RISK CALCULATION SOFTWARE, E.G. LIFECYCLE™ FOR PRENATAL SCREENING. THE KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: INHIBIN A + FREE HCG / HCG + HAFP + UE3 INHIBIN A + FREE HCG / HCG + HAFP. ,JB-2 STAINING SYSTEM(JB-2 STAINING SYSTEM)-THE JB-2 STAINING SYSTEM IS DESIGNED TO STAIN HEMOGLOBIN ON RESOLVE HEMOGLOBIN ELECTROPHORESIS GELS (FR-9120, FR-9400, FR-9360).,DELFIA®/AUTODELFIA®PLGF 1-2-3 (DELFIA®/AUTODELFIA®PLGF 1-2-3)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF PLACENTAL GROWTH FACTOR (PLGF) IN MATERNAL SERUM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM OR THE MODULAR DELFIA® SYSTEM. THE KIT IS USED AS AN AID IN SCREENING PREGNANT WOMEN FOR PRE-ECLAMPSIA IN ALL TRIMESTERS OF PREGNANCY AND FOR SCREENING FOR RISK OF DOWN'S SYNDROME IN THE FIRST TRIMESTER OF PREGNANCY.,DELFIA® INDUCER(DELFIA® INDUCER)-THE DELFIA® INDUCER IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE DETERMINATION OF EUROPIUM (EU3+) IN DISSOCIATION-ENHANCED TIME-RESOLVED FLUOROIMMUNOASSAYS WHEN USING THE GSP® INSTRUMENT ,DELFIA / AUTODELFIA UNCONJUGATED ESTRIOL (UE3) KIT(DELFIA / AUTODELFIA UNCONJUGATED ESTRIOL (UE3) KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF UNCONJUGATED ESTRIOL (UE3) IN MATERNAL SERUM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM OR THE MODULAR DELFIA® SYSTEM. THIS KIT IS INTENDED FOR SCREENING FOR DOWN'S SYNDROME (TRISOMY 21) IN THE SECOND TRIMESTER OF PREGNANCY. THIS KIT IS INTENDED FOR USE IN E.G. ONE OF THE COMBINATIONS DESCRIBED

	BELOW: UE3 + HAFP + FREE HCG/HCG UE3 + HAFP + FREE HCG/HCG + INHIBIN A,GSP® NEONATAL BIOTINIDASE KIT(GSP® NEONATAL BIOTINIDASE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF HUMAN BIOTINIDASE ACTIVITY IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR BIOTINIDASE DEFICIENCY USING THE GSP® INSTRUMENT,DELFIA® DILUENT II(DELFIA® DILUENT II)-THE DELFIA® DILUENT II IS INTENDED TO BE USED WITH AUTODELFIA® AND DELFIA KITS FOR SAMPLE DILUTION. THE USE OF DILUENT II IN SAMPLE DILUTION OR OTHER PURPOSES IS DESCRIBED IN THE KIT INSERTS.,GSP® NEONATAL THYROXINE (T4) KIT(GSP® NEONATAL THYROXINE (T4) KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROXINE (T4) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL (NEONATAL) HYPOTHYROIDISM USING THE GSP® INSTRUMENT.,DELFIA® XPRESS PLGF 1-2-3(DELFIA® XPRESS PLGF 1-2-3)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF PLACENTAL GROWTH FACTOR (PLGF) IN MATERNAL SERUM USING THE 6000 DELFIA® XPRESS CLINICAL RANDOM ACCESS SCREENING PLATFORM. THE KIT IS USED AS AN AID IN SCREENING PREGNANT WOMEN FOR PRE-ECLAMPSIA IN ALL TRIMESTERS OF PREGNANCY AND FOR SCREENING FOR RISK OF DOWN'S SYNDROME IN THE FIRST TRIMESTER OF PREGNANCY.,GSP® NEONATAL TOTAL GALACTOSE KIT(GSP® NEONATAL TOTAL GALACTOSE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL GALACTOSE (GALACTOSE AND GALACTOSE-1-PHOSPHATE) CONCENTRATIONS IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR GALACTOSEMIA USING THE GSP® INSTRUMENT,NEOBASE™ NON-DERIVATIZED ASSAY SOLUTIONS(NEOBASE™ NON-DERIVATIZED ASSAY SOLUTIONS)-INTENDED FOR IN VITRO DIAGNOSTIC USE WITH THE NEOBASE NON-DERIVATIZED MSMS KIT AND NEOBASE SUCCINYLACETONE ASSAY SOLUTION,GSP® NEONATAL HTSH KIT(GSP® NEONATAL HTSH KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID STIMULATING HORMONE (HTSH) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL (NEONATAL) HYPOTHYROIDISM USING THE GSP® INSTRUMENT.,DELFIA® XPRESS FREE HCGß KIT(DELFIA® XPRESS FREE HCGß KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE FREE ß SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN (FREE HCGß) IN MATERNAL SERUM USING THE 6000 DELFIA® XPRESS CLINICAL RANDOM ACCESS SCREENING PLATFORM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: IN THE FIRST TRIMESTER OF

	PREGNANCY: FREE HCGß + PAPP-A FREE HCGß + PAPP-A + NT (NUCHAL TRANSLUCENCY) IN THE SECOND TRIMESTER OF PREGNANCY: FREE HCGß + HAFP FREE HCGß + HAFP + UE3 ,GSP® NEONATAL IRT KIT(GSP® NEONATAL IRT KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN IMMUNOREACTIVE TRYPSIN(OGEN) (IRT) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CYSTIC FIBROSIS USING THE GSP® INSTRUMENT.,NEONATAL BIOTINIDASE KIT(NEONATAL BIOTINIDASE KIT)-THIS KIT IS INTENDED FOR THE SEMI-QUANTITATIVE DETERMINATION OF BIOTINIDASE ACTIVITY IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR BIOTINIDASE DEFICIENCY.,DELFIA® NEONATAL THYROXINE (T4) KIT(DELFIA® NEONATAL THYROXINE (T4) KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROXINE (T4) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL (NEONATAL) HYPOTHYROIDISM.,DELFIA® XPRESS UE3 KIT(DELFIA® XPRESS UE3 KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN UNCONJUGATED ESTRIOL (UE3) IN MATERNAL SERUM USING THE 6000 DELFIA® XPRESS CLINICAL RANDOM ACCESS SCREENING PLATFORM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW IN SECOND TRIMESTER SCREENING: HAFP + FREE HCGß + UE3 FREE HCGß + UE3 ,SARS-COV-2 RT-QPCR REAGENT KIT(SARS-COV-2 RT-QPCR REAGENT KIT)-THE KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF SARS-COV-2 (SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2) NUCLEIC ACIDS IN RNA EXTRACTED FROM THE HUMAN OROPHARYNGEAL SWAB, NASOPHARYNGEAL SWAB AND SALIVA AS AN AID IN DIAGNOSING PATIENTS SUSPECTED OF COVID-19 (CORONAVIRUS DISEASE) BY THEIR HEALTHCARE PROVIDER.,NEOBASE™ SUCCINYLACETONE ASSAY SOLUTION (NEOBASE™ SUCCINYLACETONE ASSAY SOLUTION)-THE NEOBASE™ SUCCINYLACETONE ASSAY SOLUTION IS INTENDED FOR IN VITRO DIAGNOSTIC USE WITH THE NEOBASE NON-DERIVATIZED MSMS KIT (3040-0010/3040-001U) AND THE NEOBASE NONDERIVATIZED ASSAY SOLUTIONS (3041-0020).,AUTODELFIA® HCG KIT (AUTODELFIA® HCG KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN MATERNAL SERUM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: HAFP + INTACT HCG HAFP + INTACT HCG + UE3 INTACT HCG + UE3 ,PLGF CONTROLS(PLGF CONTROLS)-PLGF CONTROL IS A LYOPHILIZED HUMAN CONTROL SERUM. IT IS INTENDED FOR USE AS

	AN ASSAYED QUALITY CONTROL SERUM TO MONITOR PRECISION OF LABORATORY MEASUREMENT PROCEDURES FOR THE DELFIA®PLGF ASSAYS. TWO LEVELS OF CONTROLS ARE AVAILABLE TO ALLOW PERFORMANCE MONITORING WITHIN THE CLINICAL RANGE. THE VALUE ASSIGNMENT HAS BEEN ESTABLISHED IN ACCORDANCE WITH THE ESSENTIAL REQUIREMENTS – ANNEX 1 – OF THE IVD DIRECTIVE 98/79/EC. THIS PRODUCT IS NOT INTENDED TO BE USED AS A CALIBRATOR. ,NEONATAL GALT KIT(NEONATAL GALT KIT)-THIS KIT IS INTENDED FOR THE (SEMI-QUANTITATIVE) DETERMINATION OF GALACTOSE-1-PHOSPHATE URIDYL TRANSFERASE (GALT) CONCENTRATIONS IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CLASSICAL GALACTOSEMIA CAUSED BY GALT DEFICIENCY.,RESOLVE® HEMOGLOBIN KIT(RESOLVE® HEMOGLOBIN KIT)-THE RESOLVE SYSTEMS HEMOGLOBIN KIT IS DESIGNED TO SEPARATE WHOLE BLOOD, CORD BLOOD OR DRIED BLOOD SPOT SPECIMEN FOR DETECTION OF NORMAL AND VARIANT HEMOGLOBIN BY ISOELECTRONIC FOCUSING. THE KIT IS DESIGNED TO BE RUN ON A FLAT-BED ELECTROFOCUSING UNIT. THE ASSAY IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF NEONATAL AND ADULT HEMOGLOBINOPATHIES.,AUTODELFIA® NEONATAL THYROXINE (T4) KIT(AUTODELFIA® NEONATAL THYROXINE (T4) KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROXINE (T4) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL (NEONATAL) HYPOTHYROIDISM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM.,FRAGILEASE™ FRAGILE X PCR KIT (FRAGILEASE™ FRAGILE X PCR KIT)-THE FRAGILEASE KIT IS INTENDED TO AMPLIFY AND DETECT THE CYTOSINE-GUANINE-GUANINE (CGG) TRINUCLEOTIDE REPEAT SEQUENCE IN THE 5'-UNTRANSLATED REGION OF THE FRAGILE X MENTAL RETARDATION-1 (FMR-1) GENE. THE TEST CONSISTS OF A DNA AMPLIFICATION STEP, FOLLOWED BY FRAGMENT SIZING ON A MICROFLUIDIC CAPILLARY ELECTROPHORESIS INSTRUMENT AND SUBSEQUENT DETECTION OF THE NUMBER OF CGG REPEATS TO AID THE DIAGNOSIS OF FRAGILE X SYNDROME AND FRAGILE X ASSOCIATED DISORDERS E.G. TREMOR AND ATAXIA SYNDROME (FX-TAS) AND PRIMARY OVARIAN INSUFFICIENCY (FX-POI).,DELFIA® WASH CONCENTRATE(DELFIA® WASH CONCENTRATE)-WASH CONCENTRATE IS INTENDED FOR IN VITRO DIAGNOSTIC USE. WASH CONCENTRATE CAN BE USED WITH THE DELFIA® PLATEWASH AFTER DILUTION WITH DEIONIZED WATER. IT CAN ALSO BE USED WITH OTHER DELFIA INSTRUMENTS., NEONATAL TOTAL GALACTOSE KIT(NEONATAL TOTAL GALACTOSE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION

	OF TOTAL GALACTOSE (GALACTOSE AND GALACTOSE-1-PHOSPHATE) CONCENTRATIONS IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR GALACTOSEMIA. ,NEOBASE 2 NON-DERIVATIZED ASSAY SOLUTIONS (NEOBASE 2 NON-DERIVATIZED ASSAY SOLUTIONS)-THE NEOBASE™ 2 NON-DERIVATIZED ASSAY SOLUTIONS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE WITH THE NEOBASE™ 2 NON-DERIVATIZED MSMS KIT (3044-0010, 3044-001U) TO EXTRACT TARGET ANALYTES FROM BLOOD SAMPLES DRIED ON FILTER PAPER AND TO CARRY TARGET ANALYTES TO THE MSMS SYSTEM.,DELFIA® / AUTODELFIA® PAPP-A/ FREE HCGß DUAL DBS KIT(DELFIA® / AUTODELFIA® PAPP-A/ FREE HCGß DUAL DBS KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN PAPP-A (PREGNANCY ASSOCIATED PLASMA PROTEIN A) AND FREE ß SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN (FREE HCGß) IN MATERNAL BLOOD DRIED ON FILTER PAPER USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM OR THE MODULAR DELFIA® SYSTEM. , AUTODELFIA® NEONATAL IRT KIT(AUTODELFIA® NEONATAL IRT KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN IMMUNOREACTIVE TRYPSIN(OGEN) (IRT) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CYSTIC FIBROSIS USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM.,NEOLSD MSMS KIT(NEOLSD MSMS KIT)-THE NEOLSD™ MSMS KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF THE ACTIVITY OF THE ENZYMES ACID--GLUCOCEREBROSIDASE (ABG), ACID-SPHINGOMYELINASE (ASM), ACID--GLUCOSIDASE (GAA), -GALACTOCEREBROSIDASE (GALC), -GALACTOSIDASE A (GLA) AND -L-IDURONIDASE (IDUA) IN DRIED BLOOD SPOTS (DBS) FROM NEWBORN BABIES. THE ANALYSIS OF THE ENZYMATIC ACTIVITY IS INTENDED AS AN AID IN SCREENING NEWBORNS FOR THE FOLLOWING LYSOSOMAL STORAGE DISORDERS (LSD) RESPECTIVELY; GAUCHER DISEASE, NIEMANN-PICK A/B DISEASE, POMPE DISEASE, KRABBE DISEASE, FABRY DISEASE, AND MPS I DISEASE ,DELFIA®HAFP/FREE HCGß DUAL KIT (DELFIA®HAFP/FREE HCGß DUAL KIT)-THIS KIT IS INTENDED FOR THE SIMULTANEOUS QUANTITATIVE DETERMINATION OF HUMAN ALPHAFETOPROTEIN (HAFP) AND THE FREE SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN (FREE HCG) IN MATERNAL SERUM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: IN THE FIRST TRIMESTER OF PREGNANCY: HAFP / FREE HCG + PAPP-A HAFP / FREE HCG + PAPP-A + NT (NUCHAL TRANSLUCENCY) IN THE SECOND TRIMESTER OF PREGNANCY: HAFP / FREE HCG HAFP / FREE HCG + UE3 ,AUTODELFIA®NEONATAL 17-OH-PROGESTERONE KIT(AUTODELFIA®NEONATAL 17-OH-

	PROGESTERONE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN 17 -OH-PROGESTERONE IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL ADRENAL HYPERPLASIA (CAH) USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM. , AUTODELFIA® NEONATAL HTSH KIT(AUTODELFIA® NEONATAL HTSH KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID STIMULATING HORMONE (HTSH) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL (NEONATAL) HYPOTHYROIDISM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM. , DELFIA® NEONATAL IRT KIT(DELFIA® NEONATAL IRT KIT)-THIS KITS IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN IMMUNOREACTIVE TRYPSIN (OGEN) (IRT) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CYSTIC FIBROSIS,CHEMAGIC™ DNA CS200 KIT(CHEMAGIC™ DNA CS200 KIT)-THE CHEMAGIC™ DNA CS200 KIT IS INTENDED FOR THE EXTRACTION AND PURIFICATION OF DNA FROM HUMAN WHOLE BLOOD OR PLASMA FOR ANALYSIS BY IN VITRO DIAGNOSTIC TEST SYSTEMS. THE PRODUCT IS INTENDED FOR PROFESSIONAL USERS SUCH AS TECHNICIANS AND PHYSICIANS TRAINED IN MOLECULAR BIOLOGY TECHNIQUES.,NEONATAL G6PD KIT(NEONATAL G6PD KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD) CONCENTRATIONS IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR G6PD DEFICIENCY. , NEONATAL PHENYLALANINE KIT(NEONATAL PHENYLALANINE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF PHENYLALANINE IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR ELEVATED LEVELS OF PHENYLALANINE IN THE BLOOD. ,AUTODELFIA® PAPP-A KIT (AUTODELFIA® PAPP-A KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN PAPP-A (PREGNANCY ASSOCIATED PLASMA PROTEIN A) IN MATERNAL SERUM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM. , AUTODELFIA®HAFP/FREE HCGß DUAL KIT(AUTODELFIA®HAFP/FREE HCGß DUAL KIT)-THIS KIT IS INTENDED FOR THE SIMULTANEOUS QUANTITATIVE DETERMINATION OF HUMAN ALPHAFETOPROTEIN (HAFP) AND THE FREE SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN (FREE HCG) IN MATERNAL SERUM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: IN THE FIRST TRIMESTER OF PREGNANCY: HAFP / FREE HCG + PAPP-A HAFP / FREE HCG + PAPP-A + NT (NUCHAL

	TRANSLUCENCY) IN THE SECOND TRIMESTER OF PREGNANCY: HAFP / FREE HCG HAFP / FREE HCG + UE3 ,DELFIA® FREE HCGß KIT (DELFIA® FREE HCGß KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE FREE ß SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN (FREE HCGß) IN MATERNAL SERUM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: IN THE FIRST TRIMESTER OF PREGNANCY: FREE HCGß + PAPP-A FREE HCGß + PAPP-A + NT (NUCHAL TRANSLUCENCY) IN THE SECOND TRIMESTER OF PREGNANCY: FREE HCGß + HAFP FREE HCGß + HAFP + UE3 ,DELFIA® PAPP-A KIT(DELFIA® PAPP-A KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF PAPP-A (PREGNANCY ASSOCIATED PLASMA PROTEIN A) IN MATERNAL SERUM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: PAPP-A + FREE HCGß PAPP-A + FREE HCGß + NT (NUCHAL TRANSLUCENCY) ,AUTODELFIA® FREE HCGß KIT(AUTODELFIA® FREE HCGß KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE FREE ß SUBUNIT OF HUMAN CHORIONIC GONADOTROPIN (FREE HCGß) IN MATERNAL SERUM USING THE 1235 AUTODELFIA® AUTOMATIC IMMUNOASSAY SYSTEM.,DELFIA® NEONATAL HTSH KIT(DELFIA® NEONATAL HTSH KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID STIMULATING HORMONE (HTSH) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL (NEONATAL) HYPOTHYROIDISM. , DELFIA® ENHANCEMENT SOLUTION(DELFIA® ENHANCEMENT SOLUTION)-THE ENHANCEMENT SOLUTION IS INTENDED FOR IN VITRO USE IN THE QUANTITATIVE DETERMINATION OF EUROPIUM (EU3+) AND SAMARIUM (SM3+) IN DISSOCIATION-ENHANCED TIME-RESOLVED FLUOROIMMUNOASSAYS.,DELFIA® NEONATAL 17-OH-PROGESTERONE KIT(DELFIA® NEONATAL 17-OH-PROGESTERONE KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN 17-OH-PROGESTERONE IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING NEWBORNS FOR CONGENITAL ADRENAL HYPERPLASIA (CAH).,PRENATAL BOBS™ (PRENATAL BOBS™)-THIS BACS-ON-BEADS™ ASSAY IS INTENDED FOR THE DETECTION OF GAINS AND LOSSES OF DNA IN CHROMOSOMAL REGIONS ASSOCIATED WITH 9 MICRODELETION SYNDROMES AND CHROMOSOMES 13, 18, 21, X, AND Y IN HUMAN DNA USING THE LUMINEX® 100/200™ INSTRUMENT SYSTEM . THE PRENATAL BOBS™ KIT CAN BE USED AS AN AID IN DIAGNOSIS OF ANEUPLOIDIES OF CHROMOSOMES 13, 18, 21, X AND Y, AND OF COPY NUMBER ABNORMALITIES IN THE MICRODELETION SYNDROME REGIONS COVERED BY THE PRODUCT.,DELFIA® XPRESS HAFP KIT (DELFIA® XPRESS HAFP KIT)-THIS KIT IS INTENDED FOR THE

	QUANTITATIVE DETERMINATION OF HUMAN ALPHA-FETOPROTEIN (HAFP) IN MATERNAL SERUM (DURING THE FIRST AND SECOND TRIMESTERS OF PREGNANCY) AND AMNIOTIC FLUID (DURING THE SECOND TRIMESTER OF PREGNANCY) USING THE 6000 DELFIA® XPRESS CLINICAL RANDOM ACCESS SCREENING PLATFORM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW: IN THE FIRST TRIMESTER OF PREGNANCY: HAFP (IN SERUM ONLY) + FREE HCG + PAPP-A HAFP (IN SERUM ONLY) + FREE HCG + PAPP-A + NT (NUCHAL TRANSLUCENCY) IN THE SECOND TRIMESTER OF PREGNANCY: HAFP (IN SERUM ONLY) + FREE HCG HAFP (IN SERUM ONLY) + FREE HCG + UE3 ,DELFIA® XPRESS PAPP-A KIT(DELFIA® XPRESS PAPP-A KIT)-THIS KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF PAPP-A (PREGNANCY ASSOCIATED PLASMA PROTEIN A) IN MATERNAL SERUM USING THE 6000 DELFIA® XPRESS CLINICAL RANDOM ACCESS SCREENING PLATFORM. THIS KIT IS INTENDED FOR USE IN ONE OF THE COMBINATIONS DESCRIBED BELOW IN THE FIRST TRIMESTER SCREENING: PAPP-A + FREE HCGß PAPP-A + FREE HCGß + NT (NUCHAL TRANSLUCENCY)

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1362	IMP/MD/2018/000285	1.License Holder Name: OMEGA DX (ASIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COVID -19 IGG ELISA KIT (COVID -19 IGG ELISA KIT)-COVID - 19 IGG ELISA KIT IS A SEMI QUANTATIVE ELISA KIT FOR DETECTION OF IGG ANTIBODIES TO SARS -COV-2 IN HUMAN SERUM OR PLASMA AS AN AID TO DIAGNOSIS OF ACTIVE COVID 19 INFECTION IN SYMPTOMATIC AMD ASYMPTOMATIC INDIVIDUALS. THE TEST SHOULD BE CONSIDERED IN CONJUNCATION WITH OTHER TEST RESULTS & CLINICAL INFORMATION. DETECTION OF ANTIBODIES MAY INDICATE IMMUNITY OR ATTENUATION TO SUBSEQUENT RE - INFECTION.,MPO ANTIBODIES ELISA KIT(MPO ANTIBODIES ELISA KIT)-THE MPO KIT IS A RAPID ELISA METHOD FOR THE DETECTION OF IGG ANTIBODIES TO MYELOPEROXIDASE, AN ENZYME FOUND IN THE CYTOPLASM OF NEUTROPHILS. IT IS INTENDED FOR USE IN CLINICAL LABORATORIES AS AN AID TO DIAGNOSIS OF SYSTEMIC VASCULITIS &AUTOIMMUNE GLOMERULONEPHRITIS.,PR3 ANTIBODIES ELISA KIT(PR3 ANTIBODIES ELISA KIT)-THE ANTI-PR3 KIT IS A RAPID ELISA TEST FOR THE DETECTION OF IGG ANTIBODIES TO SERINE PROTEASE - 3 (PR3). IT IS INTENDED FOR USE IN CLINICAL LABORATORIES AS AN AID TO THE DIAGNOSIS OF WEGENER'S GRANULOMATOSIS AND ASSOCIATED DISEASES.,DSDNA IGG ANTIBODIES ELISA KIT(DSDNA IGG ANTIBODIES ELISA KIT)-THE DS-DNA IGG ANTIBODIES KIT IS A RAPID ELISA METHOD FOR THE DETECTION OF IGG ANTIBODIES TO DOUBLE-STRANDED (DS) DNA. IT IS INTENDED AS AN AID TO DIAGNOSIS OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE).,THYROGLOBULIN IGG ELISA KIT(THYROGLOBULIN IGG ELISA KIT)-THE THYROGLOBULIN IGG ELISA KIT IS A RAPID ELISA METHOD FOR THE DETECTION OF IGG ANTIBODIES TO HUMAN THYROGLOBULIN. IT IS INTENDED AS AN AID TO DIAGNOSIS OF AUTOIMMUNE THYROID DISEASE,ANA EASE ELISA KIT(ANA EASE ELISA KIT)-THE ANAEASE ELISA KIT IS A RAPID ELISA METHOD FOR THE DETECTION OF ANTI-NUCLEAR ANTIBODIES (ANAS) OF THE IGG ISOTYPE,THYROID PEROXIDASE IGG ELISA KIT (THYROID PEROXIDASE IGG ELISA KIT)-THE THYROID PEROXIDASE IGG ELISA KIT IS A RAPID ELISA METHOD FOR THE DETECTION OF IGG ANTIBODIES TO HUMAN THYROID PEROXIDASE. IT IS INTENDED AS AN AID TO DIAGNOSIS OF AUTOIMMUNE THYROID DISEASE, CITRULLINATED PROTEIN ANTIBODIES IGG ELISA KIT (CITRULLINATED PROTEIN ANTIBODIES IGG ELISA KIT)-THE CITRULLINATED PROTEIN ANTIBODIES ELISA KIT IS A RAPID ELISA METHOD FOR THE DETECTION OF RHEUMATOID ARTHRITIS SPECIFIC IGG ANTIBODIES TO CITRULLINATED PROTEIN,GENARRAYT MICROARRAY 200+ FOOD IGG(GENARRAYT MICROARRAY 200+ FOOD IGG)-THE GENARRAYT MICROARRAY 200+ FOOD IGG KIT IS A

		RAPID QUANTITATIVE ELISA METHOD FOR THE DETECTION OF IGG ANTIBODIES TO 221 DIFFERENT FOOD ANTIGENS, IN HUMAN SERA OR PLASMA OR WHOLE BLOOD.,TOTAL IGE ELISA KIT(TOTAL IGE ELISA KIT)-THE TOTAL IGE KIT IS A SENSITIVE ELISA METHOD FOR THE DETECTION OF IGE CLASS ANTIBODIES. IT IS INTENDED AS AN AID TO DIAGNOSIS OF ATOPY IN CHILDREN AND ADULTS, TRANSGLUTAMINASE IGA ELISA KIT (RECOMBINANT)(T-TG-IGA (RECOMBINANT))-T-TG TGA KIT IS A RAPID ELISA METHOD FOR DETECTION OF CIRCULATING IGA ANTIBODIES TO TISSUE TRANSGLUTAMINASE (T-TG)
1363	IMP/MD/2018/000288	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRODUCER KIT (RADIFOCUS INTRODUCER II)-IT IS USED FOR SINGLE USE AND STERILE, IS INTENDED TO BE INSERTED PERCUTANEOUS LY INTO A VESSEL TO FACILITATE THE INSERTION OF ANGIOGRAPHIC, ELECTRODE, BALLOON, OR SIMILAR CATHETERS.,ANGIOGRAPHIC CATHETER(RADIFOCUS OPTITORQUE)-THE RADIFOCUS OPTITORQUE IS INTENDED FOR USE IN ANGIOGRAPHIC PROCEDURES. IT DELIVERS RADIOPAQUE MEDIA AND THERAPEUTIC AGENTS TO SELECTED SITES IN THE VASCULAR SYSTEM. IT IS ALSO USED TO LEAD A GUIDE WIRE OR A CATHETER INTO THE TARGET SITE.,RADIFOCUS GUIDE WIREM (RADIFOCUS GUIDE WIREM)-IT IS DESIGNED TO DIRECT A CATHETER TO THE DESIRED ANATOMICAL LOCATION IN THE VASCULATORY SYSTEM DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURES.

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1364	IMP/MD/2018/000289	1.License Holder Name: NIPRO MEDICAL (INDIA) PRIVATE LIMITED , 2ND FLOOR, GMR AERO TOWER, NEAR RAJIV GANDHI AIRPORT, MAMIDIPALLY VILLAGE, BALAPUR MANDAL, RANGA REDDY DIST, MAMIDPALLY(V), BALAPUR(M), RANGA REDDY(DIST.) ,RANGA REDDY TELANGANA ,501218 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYDROPHILIC NI-TI ALLOY GUIDEWIRE(AQUALINER)-THIS DEVICE IS DESIGNED FOR USE IN ANGIOGRAPHIC PROCEDURES TO INTRODUCE/POSITION CATHETERS AND INTERVENTIONAL DEVICES WITHIN THE VASCULATURE.,SPINAL NEEDLE-SPINAL NEEDLE IS A PUNCTURE USED FOR THE ADMINISTRATION OF ANESTHETICS INTO SPINAL SUBARACHNOID PACE, AND FOR THE COLLECTION OF CEREBROSPINAL FLUID (LIQUOR CEREBROSPINAL),BLOOD COLLECTION NEEDLE(N.A.)-THE BLOOD COLLECTION NEEDLE IS INTENDED FOR USE IN COMBINATION WITH SPECIFIC NEEDLE HOLDER AND BLOOD COLLECTION TUBES TO COLLECT BLOOD SPECIMENS FOR DIAGNOSTIC ANALYSIS. ,DENTAL NEEDLE-THE DENTAL NEEDLE IS A DEVICE FOR INJECTING LIQUID ANESTHETICS AND IS USED FOR CONDUCTION ANESTHESIA IN DENTAL TREATMENT.
1365	IMP/MD/2018/000290	1.License Holder Name: ADAPTIVE OCCULAR SCIENCES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASQELIO™ SOFT HYDROPHOBIC INTRAOCULAR LENSES(ASQELIO™ SOFT HYDROPHOBIC INTRAOCULAR LENSES)-ASQELIO™ SOFT HYDROPHOBIC INTRAOCULAR LENSES (HEREINAFTER CALLED ASQELIO™ IOLS) ARE ONE PIECE FOLDABLE POSTERIOR CHAMBER, UV ABSORBING OPTICAL IMPLANT LENSES. ITS INTENDED USE IS TO BE PLACED IN THE CAPSULAR BAG OR SULCUS FOR REPLACING THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING SUCCESSFUL CATARACTOUS LENS EXTRACTION WITH A VERIFIED ABSENCE OF RADIAL TEARS PERFORMED BY AN OPHTHALMOLOGIST DURING CAPSULOTOMY. ASQELIO™ IOLS ARE INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN PERSONS 55 YEARS OF AGE OR OLDER IN WHOM THE CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION CATARACT EXTRACTION. WHEN IMPLANTED, ASQELIO™ IOLS REPLACE THE NATURAL LENS OF THE EYE AND FUNCTION AS A REFRACTING MEDIUM IN THE CORRECTION OF APHAKIA.

1366	IMP/MD/2018/000291	1.License Holder Name: FRESENIUS MEDICAL CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOODLINES-EXTRACORPOREAL CIRCUIT FOR HAEMODIALYSIS,BLOODLINES-EXTRACORPOREAL CIRCUIT FOR HAEMODIALYSIS
1367	IMP/MD/2018/000292	1.License Holder Name: SMITHS MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARTERIAL BLOOD SAMPLING(PRO-VENT ABS, LINE DRAW)-THE ARTERIAL BLOOD SAMPLING SYRINGE FOR CALCIUM NEUTRALIZED DRY LITHIUM HEPARIN SYRINGES IS INTENDED FOR SAMPLING OF ARTERIAL BLOOD FOR THE MEASUREMENT OF PO2, PCO2, PH, CO-OXIMETRY, ELECTROLYTES (CA++, NA+, K+, CL-, AND MG++), TOTAL MAGNESIUM, AND THE METABOLITES (GLUCOSE AND LACTATE). DRY LITHIUM HEPARIN IS NEUTRALIZED FOR IONIC CALCIUM. THE SYRINGE IS HEPARINIZED FOR ANTICOAGULANT EFFECT.
1368	IMP/MD/2018/000293	1.License Holder Name: DKNSB MEDICAL DEVICE CONSULTANTS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE GRAFTING MATERIAL (THE GRAFT)-THE GRAFT IS INTENDED FOR USE AS A BONE GRAFTING MATERIAL IN DENTAL SURGERY SUCH AS: - AUGMENTATION OR RECONSTRUCTIVE TREATMENT OF ALVEOLAR RIDGE - FILLING OF INFRA-BONY PERIODONTAL DEFECTS - FILLING OF DEFECTS AFTER ROOT RESECTION, APICOECTOMY, AND CYSTECTOMY - FILLING OF EXTRACTION SOCKETS TO ENHANCE PRESERVATION OF THE ALVEOLAR RIDGE - ELEVATION OF MAXILLARY SINUS FLOOR - FILLING OF PERIODONTAL DEFECTS IN CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED TISSUE REGENERATION (GTR) AND GUIDED BONE REGENERATION (GBR) - FILLING OF PERI-IMPLANT DEFECTS IN CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED BONE REGENERATION

1369	IMP/MD/2018/000299	1.License Holder Name: COLOPLAST INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOAM DRESSING (BIATAIN)-BIATAIN FOAM DRESSINGS ARE INDICATED FOR A WIDE RANGE OF EXUDING WOUNDS INCLUDING LEG ULCERS AND PRESSURE ULCERS. BIATAIN FOAM DRESSINGS MAY BE USED FOR SECOND-DEGREE BURNS, POSTOPERATIVE WOUNDS AND SKIN ABRASIONS. BIATAIN NON-ADHESIVE FOAM DRESSINGS ARE ALSO INDICATED FOR NON-INFECTED DIABETIC FOOT ULCERS. BIATAIN NON-ADHESIVE AND ADHESIVE FOAM DRESSINGS ARE ALSO INDICATED FOR DONOR SITES. BIATAIN FOAM DRESSINGS MAY BE USED ON PATIENTS WHO ARE IN TREATMENT FOR A LOCAL OR SYSTEMIC INFECTION AT THE DISCRETION OF A PHYSICIAN. BIATAIN FOAM DRESSINGS MAY BE USED THROUGHOUT THE HEALING PROCESS TO PROVIDE PROTECTION FOR THE TYPES OF WOUNDS INDICATED. BIATAIN FOAM DRESSINGS ARE SUITABLE FOR USE IN COMBINATION WITH COMPRESSION THERAPY. BIATAIN FOAM DRESSINGS AND BIATAIN FOAM FILLER/CAVITY MAY BE USED TOGETHER WITH PURILON GEL FOR EFFECTIVE AUTOLYTIC DEBRIDEMENT OF NECROTIC TISSUE. BIATAIN FOAM FILLER/CAVITY IS INDICATED FOR DEEP EXUDING WOUNDS, INCLUDING LEG ULCERS, PRESSURE ULCERS, NON-INFECTED DIABETIC FOOT ULCERS AND ACUTE WOUNDS.,HYDROCOLLOID DRESSING(COMFEEL PLUS)-THE PRODUCT IS INTENDED FOR MOIST WOUND HEALING AND EXUDATE MANAGEMENT. COMFEEL PLUS TRANSPARENT IS INDICATED FOR A WIDE RANGE OF NON- TO LOW-EXUDING WOUNDS. THE PRODUCT: - IS INDICATED FOR CHRONIC WOUNDS SUCH AS LEG ULCERS AND PRESSURE ULCERS; AND ACUTE WOUNDS, SUCH AS SUPERFICIAL BURNS, SUPERFICIAL PARTIAL-THICKNESS BURNS, DONOR SITES, POSTOPERATIVE WOUNDS AND SKIN ABRASIONS - MAY BE USED ON PATIENTS WHO ARE IN TREATMENT FOR A LOCAL OR SYSTEMIC INFECTION AT THE DISCRETION OF A HEALTH CARE PROFESSIONAL, FOAM DRESSING WITH SILVER(BIATAIN AG)-BIATAIN AG NON-ADHESIVE - THE PRODUCT IS INTENDED FOR MOIST WOUND HEALING AND EXUDATE MANAGEMENT OF WOUNDS WITH DELAYED HEALING DUE TO BACTERIA OR WOUNDS AT RISK OF INFECTION. THE PRODUCT: - IS INDICATED FOR A WIDE RANGE OF LOW TO HIGHLY EXUDING WOUNDS. THIS INCLUDES ACUTE WOUNDS SUCH AS SECOND DEGREE BURNS, DONOR SITES, POSTOPERATIVE WOUNDS AND TRAUMATIC WOUNDS; AND CHRONIC WOUNDS SUCH AS LEG ULCERS, PRESSURE ULCERS AND DIABETIC FOOT ULCERS. BIATAIN AG ADHESIVE, BIATAIN AG ADHESIVE, HEEL & BIATAIN AG ADHESIVE, SACRAL - THE PRODUCT IS INTENDED FOR MOIST WOUND HEALING AND EXUDATE MANAGEMENT OF WOUNDS WITH DELAYED HEALING

	DUE TO BACTERIA OR WOUNDS AT RISK OF INFECTION. THE PRODUCT: - IS INDICATED FOR A WIDE RANGE OF LOW TO HIGHLY EXUDING WOUNDS. THIS INCLUDES ACUTE WOUNDS SUCH AS SECOND DEGREE BURNS, DONOR SITES, POSTOPERATIVE WOUNDS AND TRAUMATIC WOUNDS; AND CHRONIC WOUNDS SUCH AS LEG ULCERS AND PRESSURE ULCERS. BIATAIN AG FILLER/CAVITY - THE PRODUCT IS INTENDED FOR MOIST WOUND HEALING AND EXUDATE MANAGEMENT OF WOUNDS WITH DELAYED HEALING DUE TO BACTERIA OR WOUNDS AT RISK OF INFECTION. THE PRODUCT: - IS INDICATED FOR A WIDE RANGE OF LOW TO HIGHLY EXUDING WOUNDS. THIS INCLUDES CHRONIC WOUNDS SUCH AS LEG ULCERS, PRESSURE ULCERS AND DIABETIC FOOT ULCERS; AND ACUTE WOUNDS.,HYDROCOLLOID DRESSING(COMFEEL PLUS)-THE PRODUCT IS INTENDED FOR MOIST WOUND HEALING AND EXUDATE MANAGEMENT. THE PRODUCT: - IS INDICATED FOR A WIDE RANGE OF NON- TO MODERATE-EXUDING WOUNDS - IS INDICATED FOR PRESSURE ULCERS - MAY REDUCE THE RISK FROM PRESSURE,FOAM DRESSING WITH SILVER(BIATAIN SILICONE AG)-THE PRODUCT IS INTENDED FOR MOIST WOUND HEALING AND EXUDATE MANAGEMENT OF WOUNDS WITH DELAYED HEALING DUE TO BACTERIA OR WOUNDS AT RISK OF INFECTION. BIATAIN SILICONE AG - IS INDICATED FOR A WIDE RANGE OF LOW TO HIGHLY EXUDING WOUNDS WITH DELAYED HEALING DUE TO BACTERIA OR WOUNDS AT RISK OF INFECTION. THIS INCLUDES ACUTE WOUNDS SUCH AS SECOND DEGREE BURNS, DONOR SITES, POSTOPERATIVE WOUNDS AND TRAUMATIC WOUNDS; AND CHRONIC WOUNDS SUCH AS LEG ULCERS, PRESSURE ULCERS AND DIABETIC FOOT ULCERS., HYDROCOLLOID DRESSING(COMFEEL PLUS)-THE PRODUCT IS INTENDED FOR MOIST WOUND HEALING AND EXUDATE MANAGEMENT. THE PRODUCT: - IS INDICATED FOR A WIDE RANGE OF NON- TO MODERATE-EXUDING WOUNDS. THIS INCLUDES CHRONIC WOUNDS SUCH AS LEG ULCERS AND PRESSURE ULCERS; AND ACUTE WOUNDS, SUCH AS SUPERFICIAL BURNS, SUPERFICIAL PARTIAL-THICKNESS BURNS, DONOR SITES, POSTOPERATIVE WOUNDS AND SKIN ABRASIONS - MAY BE USED ON PATIENTS WHO ARE IN TREATMENT FOR A LOCAL OR SYSTEMIC INFECTION AT THE DISCRETION OF A HEALTH CARE PROFESSIONAL,FOAM DRESSING (BIATAIN SILICONE LITE)-THE PRODUCT IS INTENDED FOR MOIST WOUND HEALING AND EXUDATE MANAGEMENT. THE PRODUCT: - IS INDICATED FOR A WIDE RANGE OF NON - TO LOW EXUDING WOUNDS. THIS INCLUDES ACUTE WOUNDS SUCH AS DONOR SITES, POST OPERATIVE WOUNDS AND TRAUMATIC WOUNDS; AND CHRONIC WOUNDS SUCH AS LEG ULCERS, PRESSURE ULCERS AND NON-INFECTED DIABETIC FOOT ULCERS,FOAM DRESSING(BIATAIN

		SILICONE)-THE PRODUCT IS INTENDED FOR MOIST WOUND HEALING AND EXUDATE MANAGEMENT. BIATAIN SILICONE - IS INDICATED FOR A WIDE RANGE OF LOW- TO HIGHLY EXUDING WOUNDS. THIS INCLUDES ACUTE WOUNDS SUCH AS DONOR SITES, POST OPERATIVE WOUNDS AND TRAUMATIC WOUNDS; AND CHRONIC WOUNDS SUCH AS LEG ULCERS, PRESSURE ULCERS AND NON-INFECTED DIABETIC FOOT ULCERS - MAY BE USED TO PREVENT POST OPERATIVE BLISTERING,PROTECTIVE SHEET(BRAVA)-INTENDED FOR PROTECTION OF INTACT SKIN AGAINST STOMA OUTPUT, AND FOR SKIN PROTECTION WHERE BODY SECRETION MAY DAMAGE THE SKIN.
1370	IMP/MD/2018/000300	1.License Holder Name: JOHNSON & JOHNSON SURGICAL VISION INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OPHTHALMIC VISCOSURGICAL DEVICE(HEALON GV)-VISCOELASTIC SOLUTION FOR INTRAOCULAR USE DURING EYE SURGERY,OPHTHALMIC VISCOISURGICAL DEVICE(HEALON GV PRO)-VISCOELASTIC SOLUTION FOR INTRAOCULAR USE DURING EYE SURGERY, OPHTHALMIC VISCOSURGICAL DEVICE(HEALON® 5 PRO)-VISCOELASITIC SOLUTION FOR INTRAOCULAR USE DURING EYE SURGERY,OPHTHALMIC VISCOSURGICAL DEVICE(HEALON® PRO)-VISCOELASTIC SOLUTION FOR INTRAOCULAR USE DURING EYE SURGERY

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1371	IMP/MD/2018/000302	1.License Holder Name: SHAH EYE CARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SODIUM HYALURONATE (CROWN VISC)-IT IS INDICATED FOR USE AS A SURGICAL AID IN THE ANTERIOR SEGMENT DURING CATARACT EXTRACTION, INTRAOCULAR LENS IMPLANTATION AND GLAUCOMA SURGERY. IT MAINTAINS THE ANATOMICAL SPACE OF THE ANTERIOR SEGMENT WITH REDUCED TRAUMA TO THE CORNEAL ENDOTHELIUM DURING SURGERY. IT IS INTENDED FOR INTRAOCULAR USE ONLY, PERFLUOROCARBON FLUID(OCUDEKA DECALINE)-AS AN AGENT 1) RETINAL DETACHMENT 2) PROLIFERATIVE DIABETIC RETINOPATHY 3) MACULAR HOLES WITH PERIPHERAL RD 4) RETRIEVAL OF FOREIGN BODIES FROM VITREOUS 5) REFLOATING LUXATED LENSES, SILICONE OIL(OCUSIL)-THE OCUSIL SILICONE OIL IS INDICATED IN PROLONGED TAMPONADE AFTER SURGICAL TREATMENT FOR SEVERE RETINAL DETACHMENT, ESPECIALLY: 1) RETINAL DETACHMENT WITH PROLIFERATIVE VITREORETINOPATHY. 2) RETINAL DETACHMENT THAT COMPLICATE A DIABETIC RETINOPATHY. 3) RETINAL DETACHMENT WITH GIANT TEARS. 4) TRAUMATIC RETINAL DETACHMENT. 5) SECONDARY RETINAL DETACHMENT TO A VIRAL RETINIST.

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1372	IMP/MD/2018/000303	1.License Holder Name: VSY OPHTHALMIC INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OPHTALMIC VISCOSURGICAL DEVICE(PROTECTALON)-VISCOELASTIC SURGICAL DEVICES INTENDED FOR INTRAOCULAR SURGERY OF THE ANTERIOR SEGMENT, INCLUDING CATARACT EXTRACTION.,ACRIVAUDREVIOL TRI-ED TORIC INTRAOCULAR LENS [SINGLE PIECE- HYDROPHOBIC SURFACE- ACRYLIC-VIOLET/BLUE LIGHT FILTERING- ASPHERIC- FOLDABLE- MULTIFOCAL-TORIC- 360 ALL SQUARE EDGE] (ACRIVAUDREVIOL TRI-ED TORIC)-CATARACT DUE TO AGE AS WELL AS OTHER CATARACT,ACRIVAUDTRINOVA ULTRA DEFINITION, VIOLET/BLUE LIGHT FILTERING, MULTIFOCAL INTRAOCULAR LENS [SINGLE PIECE -HYDROPHOBIC SURFACE – ACRYLIC – ASPHERIC - FOLDABLE – 360 ALL SQUARE EDGE](ACRIVA TRINOVA)-CATARACT DUE TO AGE AS WELL AS OTHER CATARACT.,ACRIVAUDREVIOL TRI-ED INTRAOCULAR LENS [SINGLE PIECE-HYDROPHOBIC SURFACE-ACRYLIC-VIOLET/BLUE LIGHT FILTERING- ASPHERIC- FOLDABLE-MULTIFOCAL 360 ALL SQUARE EDGE](ACRIVAUDREVIOL TRI-ED)-CATARACT DUE TO AGE AS WELL AS OTHER CATARACT,ENOVA ULTRA DEFINITION INTRAOCULAR LENS [SINGLE PIECE-HYDROPHOBIC-ACRYLIC-ASPHERIC-FOLDABLE-360 ALL SQUARE EDGE-GLISTENING FREE-THERMOSTABLE](ENOVA)-CATARACT DUE TO AGE AS WELL AS OTHER CATARACT.,ACRIVAUDREVIOL MULTIFOCAL INTRAOCULAR LENS [SINGLE PIECE -HYDROPHOBIC SURFACE –ACRYLIC – ASPHERIC FOLDABLE -360 ALL SQUARE EDGE] (ACRIVAUDREVIOL)-CATARACT DUE TO AGE AS WELL AS OTHER CATARACT,ACRIVAUDTRINOVA ULTRA DEFINITION, VIOLET/BLUE LIGHT FILTERING TORIC MULTIFOCAL INTRAOCULAR LENS [SINGLE PIECE -HYDROPHOBIC SURFACE – ACRYLIC – ASPHERIC - FOLDABLE – 360 ALL SQUARE EDGE](ACRIVA TRINOVA TORIC)-CATARACT DUE TO AGE AS WELL AS OTHER CATARACT,ACRIVAUD ULTRA DEFINITION INTRA OCULAR LENS [SINGLE PIECE -HYDROPHOBIC SURFACE – ACRYLIC – ASPHERIC - FOLDABLE – 360 ALL SQUARE EDGE](ACRIVAUD)-CATARACT DUE TO AGE AS WELL AS OTHER CATARACT,INTRAARTICULAR VISCOSUPPLEMENTATION DEVICE (REVISCON)-INTENDED FOR INTRA-ARTICULAR USE TO TREAT PAIN ASSOCIATED WITH OSTEOARTHRITIS OF THE KNEE., ACRIVAUDREVIOL BB TORIC BLUE LIGHT FILTERING ULTRA DEFINITION MULTIFOCAL TORIC INTRAOCULAR LENS. [SINGLE PIECE -HYDROPHOBIC SURFACE- ACRYLIC-BLUE LIGHT FILTERING ASPHERIC-FOLDABLE TORIC- 360(ACRIVAUDREVIOL BB TORIC)-CATARACT DUE TO AGE AS WELL AS OTHER CATARACT,OPHTALMIC VISCOSURGICAL DEVICE(PROTECTACEL)-VISCOELASTIC SURGICAL DEVICES INTENDED FOR INTRAOCULAR SURGERY OF THE ANTERIOR

	SEGMENT, INCLUDING CATARACT EXTRACTION.,ACRIVAUD BB TORIC BLUE LIGHT FILTERING ULTRA DEFINITION TORIC INTRAOCULAR LENS [SINGLE PIECE -HYDROPHOBIC SURFACE- ACRYLIC-BLUE LIGHT FILTERING- ASPHERIC-FOLDABLE-TORIC 360 ALL SQUARE EDGE](ACRIVAUD BB TORIC)-CATARACT DUE TO AGE AS WELL AS OTHER CATARACT,INTRAARTICULAR VISCOSUPPLEMENTATION DEVICE(REVISCON MONO 2.0%)-INTENDED FOR INTRA-ARTICULAR USE TO TREAT PAIN ASSOCIATED WITH OSTEOARTHRITIS OF THE KNEE.,ACRIVAUDREVIOL BB, BLUE LIGHT FILTERING ULTRA DEFINITION MULTIFOCAL INTRAOCULAR LENS [SINGLE PIECE - HYDROPHOBIC SURFACE- ACRYLIC-BLUE LIGHT FILTERING- ASPHERIC- FOLDABLE- 360 ALL SQUARE EDGE](ACRIVAUD REVIOL BB)-CATARACT DUE TO AGE AS WELL AS OTHER CATARACT, ACRIVAUD BB, BLUE LIGHT FILTERING ULTRA DEFINITION INTRAOCULAR LENS [SINGLE PIECE -HYDROPHOBIC SURFACE- ACRYLIC-BLUE LIGHT FILTERING- ASPHERIC-FOLDABLE- 360 ALL SQUARE EDGE](ACRIVAUD BB)-CATARACT DUE TO AGE AS WELL AS OTHER CATARACT,OCUVA ASPHERIC FOLDABLE INTRAOCULAR LENS (OCUVA)-CATARACT DUE TO AGE AS WELL AS OTHER CATARACT

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1373	IMP/MD/2018/000304	1.License Holder Name: COCHLEAR MEDICAL DEVICE COMPANY INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COCHLEAR IMPLANT WITH SLIM MODIOLAR ELECTRODE(COCHLEAR™ NUCLEUS®)-A COCHLEAR IMPLANT PROVIDES AUDITORY SENSATION AND SOUND PERCEPTION BY ELECTRICALLY STIMULATING THE AUDITORY NERVE OF A HEARING-IMPAIRED EAR. COCHLEAR NUCLEUS COCHLEAR IMPLANTS ARE INTENDED FOR THE FOLLOWING INDIVIDUALS: GROUP A INDIVIDUALS AGED UP TO 17 YEARS WHO HAVE CLINICALLY ESTABLISHED BILATERAL OR UNILATERAL SENSORINEURAL HEARING LOSS, AND WHO HAVE COMPROMISED FUNCTIONAL HEARING WITH HEARING AIDS OR WOULD RECEIVE NO BENEFIT WITH HEARING AIDS. TYPICAL PREOPERATIVE THRESHOLD LEVELS IN THE IMPAIRED EARS DEMONSTRATE A PURE-TONE AVERAGE LOSS OF MODERATELY SEVERE TO PROFOUND DEGREE. GROUP B INDIVIDUALS AGED 18 YEARS AND OLDER WHO HAVE CLINICALLY ESTABLISHED POSTLINGUISTIC BILATERAL OR UNILATERAL SENSORINEURAL HEARING LOSS, AND WHO HAVE COMPROMISED FUNCTIONAL HEARING WITH HEARING AIDS OR WOULD RECEIVE NO BENEFIT WITH HEARING AIDS. TYPICAL PREOPERATIVE THRESHOLD LEVELS IN THE IMPAIRED EARS DEMONSTRATE A PURE-TONE AVERAGE LOSS OF MODERATELY SEVERE TO PROFOUND DEGREE. GROUP C PRELINGUISTICALLY OR PERILINGUISTICALLY DEAFENED INDIVIDUALS AGED 18 YEARS AND OLDER WHO HAVE PROFOUND BILATERAL SENSORINEURAL HEARING LOSS AND WHO HAVE COMPROMISED HEARING WITH HEARING AIDS.,COCHLEAR IMPLANT WITH SLIM STRAIGHT ELECTRODE(COCHLEAR™ NUCLEUS®)-A COCHLEAR IMPLANT PROVIDES AUDITORY SENSATION AND SOUND PERCEPTION BY ELECTRICALLY STIMULATING THE AUDITORY NERVE OF A HEARING-IMPAIRED EAR. COCHLEAR NUCLEUS COCHLEAR IMPLANTS ARE INTENDED FOR THE FOLLOWING INDIVIDUALS: GROUP A INDIVIDUALS AGED UP TO 17 YEARS WHO HAVE CLINICALLY ESTABLISHED BILATERAL OR UNILATERAL SENSORINEURAL HEARING LOSS, AND WHO HAVE COMPROMISED FUNCTIONAL HEARING WITH HEARING AIDS OR WOULD RECEIVE NO BENEFIT WITH HEARING AIDS. TYPICAL PREOPERATIVE THRESHOLD LEVELS IN THE IMPAIRED EARS DEMONSTRATE A PURE-TONE AVERAGE LOSS OF MODERATELY SEVERE TO PROFOUND DEGREE. GROUP B INDIVIDUALS AGED 18 YEARS AND OLDER WHO HAVE CLINICALLY ESTABLISHED POSTLINGUISTIC BILATERAL OR UNILATERAL SENSORINEURAL HEARING LOSS, AND WHO HAVE COMPROMISED FUNCTIONAL HEARING WITH HEARING AIDS OR WOULD RECEIVE NO BENEFIT WITH HEARING AIDS. TYPICAL PREOPERATIVE THRESHOLD

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1374	IMP/MD/2018/000304	1.License Holder Name: COCHLEAR MEDICAL DEVICE COMPANY INDIA PVT. LTD. ,GALA NO. 6A, GROUND FLOOR, WAREHOUSE NO. 6, BGR LOGISTIC PARK, C/O PAREKH INTEGRATED SERVICES PVT LTD, VAHULI, TAL BHIWANDI-16 ,THANE MAHARASHTRA ,421302 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE CONDUCTION HEARING IMPLANT(COCHLEAR™ OSIA®)-THE COCHLEAR OSIA SYSTEM USES BONE CONDUCTION TO TRANSMIT SOUNDS TO THE COCHLEA (INNER EAR) WITH THE PURPOSE OF ENHANCING HEARING. OSIA IMPLANTS ARE SINGLE USE DEVICES INTENDED FOR LONG TERM IMPLANTATION UNDER THE SKIN IN THE MASTOID REGION OF EITHER SIDE OF THE HEAD. INDICATION: • PATIENTS 5 YEARS OF AGE OR OLDER. • PATIENTS WHO HAVE A CONDUCTIVE OR MIXED HEARING LOSS AND STILL CAN BENEFIT FROM SOUND AMPLIFICATION. THE PURE TONE AVERAGE (PTA) BONE CONDUCTION (BC) THRESHOLD (MEASURED AT 0.5, 1, 2, AND 3 KHZ) SHOULD BE BETTER THAN OR EQUAL TO 55 DB HL. • BILATERAL FITTING OF THE OSIA 2 SYSTEM IS INTENDED FOR PATIENTS HAVING A SYMMETRICALLY CONDUCTIVE OR MIXED HEARING LOSS. THE DIFFERENCE BETWEEN THE LEFT AND RIGHT SIDES' BC THRESHOLDS SHOULD BE LESS THAN 10 DB ON AVERAGE MEASURED AT 0.5, 1, 2, AND 3 KHZ, OR LESS THAN 15 DB AT INDIVIDUAL FREQUENCIES. • PATIENTS WHO HAVE PROFOUND SENSORINEURAL HEARING LOSS IN ONE EAR AND NORMAL HEARING IN THE OPPOSITE EAR (I.E., SINGLE-SIDED DEAFNESS OR "SSD"). THE PURE TONE AVERAGE AIR CONDUCTION HEARING THRESHOLDS OF THE HEARING EAR SHOULD BE BETTER THAN OR EQUAL TO 20 DB HL (MEASURED AT 0.5, 1, 2, AND 3 KHZ). • THE OSIA 2 SYSTEM FOR SSD IS ALSO INDICATED FOR ANY PATIENT WHO IS INDICATED FOR AN AIR-CONDUCTION CONTRALATERAL ROUTING OF SIGNALS (AC CROS) HEARING AID, BUT WHO FOR SOME REASON CANNOT OR WILL NOT USE AN AC CROS. • PRIOR TO RECEIVING THE DEVICE, IT IS RECOMMENDED THAT AN INDIVIDUAL HAVE EXPERIENCE WITH APPROPRIATELY FITTED AIR CONDUCTION OR BONE CONDUCTION HEARING AIDS.

1375	IMP/MD/2018/000305	1.License Holder Name: GENETIX BIOTECH ASIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ELECTROLYSED SOLUTION WITH HYPOCHLOROUS ACID NEUTRAL PH FOR CLEANING SURFACE AREAS AND OBJECTS IN GENERAL(ECOSAFE)-ECOSAFE IS AN ELECTROLYZED SOLUTION INTENDED FOR THE DISINFECTION OF MEDICAL DEVICES AS WELL AS INANIMATE SURFACES, ELECTROLYSED SOLUTION WITH HYPOCHLOROUS ACID-ANTISEPTIC WOUND CARE SOLUTION(PETVET WOUND & SKIN CARE)-BROAD SPECTRUM ANTI-MICROBIAL SOLUTION FOR CLEANING OF TRAUMATIC WOUNDS, CUTS, ABRASIONS, SKIN IRRITATIONS, SKIN ULCERS, POST-SURGICAL INCISION SITES HOT SPOTS, BURNS, SCRATCHES, RASHES, CRACKED TEATS, CLEANING THE UMBILICAL, NAVEL AND WOUND ODORS. SAFE FOR USE ON ALL ANIMAL SPECIES. ,SOLUTION FOR SKIN CLEANING ELECTROLYZED SOLUTION WITH HYPOCHLOROUS ACID AND NEUTRAL PH FOR WOUND CARE (MICRODACYN 60 WOUND CARE)-MICRODACYN 60 WOUND CARE IS INTENDED FOR USE IN THE DEBRIDEMENT, IRRIGATION AND MOISTENING OF ACUTE AND CHRONIC WOUNDS, ULCERS, CUTS, ABRASIONS AND BURNS. THROUGH REDUCING THE AMOUNT OF MICROORGANISMS AND CONTRIBUTING TO A MOIST ENVIRONMENT, IT ENABLES THE BODY TO PERFORM ITS OWN HEALING PROCESS. THE SOLUTION CAN BE BROADLY APPLIED WITHIN A COMPREHENSIVE WOUND TREATMENT. ,ELECTROLYSED HYDROGEL WITH HYPOCHLOROUS ACID-ANTISEPTIC WOUND CARE HYDROGEL (PETVET WOUND & SKIN CARE HYDROGEL)-BROAD SPECTRUM ANTI-MICROBIAL HYDROGEL FOR CARE OF TRAUMATIC WOUNDS, CUTS, ABRASIONS, SKIN IRRITATIONS, SKIN ULCERS, POST-SURGICAL INCISION SITES, HOT SPOTS, BURNS, SCRATCHES, RASHES, CRACKED TEATS AND WOUND ODORS. SAFE FOR USE ON ALL ANIMAL SPECIES., HYDROGEL FOR SKIN CLEANING ELECTROLYZED HYDROGEL WITH HYPOCHLOROUS ACID AND NEUTRAL PH FOR WOUND CARE (MICRODACYN 60 HYDROGEL)-MICRODACYN 60 HYDROGEL IS INTENDED FOR USE AS SKIN MOISTURIZER, CARE OF SKIN ABRASIONS, LACERATIONS AND IRRITATION AND AN ANTISEPTIC FOR INTACT SKIN. IT IS ALSO INTENDED FOR THE MANAGEMENT OF EXUDING WOUNDS SUCH AS LEG ULCERS, PRESSURE ULCERS, DIABETIC ULCERS AND FOR THE MANAGEMENT OF MECHANICALLY OR SURGICALLY DEBRIDED WOUNDS.,ELECTROLYSED SOLUTION WITH HYPOCHLOROUS ACID-ANTISEPTIC WOUND CARE SOLUTION (PETVET EYE & EAR RINSE)- BROAD SPECTRUM ANTI-MICROBIAL SOLUTION FOR FLUSHING AND CLEANING, WOUNDS AND IRRITATIONS TO THE OUTER EAR & EYE. USE TO CLEAN AND RELIEVE OUTER EARS & EYES AFFECTED BY BURNING, STINGING, ITCHING,

		POLLUTANTS AND CONTAMINANTS. SAFE FOR USE ON ALL ANIMAL SPECIES. ,ELECTROLYSED HYDROGEL WITH HYPOCHLOROUS ACID-ANTISEPTIC WOUND CARE HYDROGEL(PETVET OPTHALMIC GEL)-BROAD SPECTRUM ANTI-MICROBIAL HYDROGEL USE TO CLEAN AND RELIEVE EYES AFFECTED BY BURNING, STINGING, ITCHING, POLLUTANTS, CONTAMINANTS AND IRRITATIONS. ALLEVIATES SYMPTOMS COMMONLY ASSOCIATED WITH BACTERIAL, FUNGAL & VIRAL INFECTIONS. SAFE FOR USE ON ALL ANIMALS SPECIES. , ELECTROLYSED HYDROGEL WITH HYPOCHLOROUS ACID-ANTISEPTIC WOUND CARE HYDROGEL(PETVET ANTI-ITCH SPRAY GEL)-BROAD SPECTRUM ANTI-MICROBIAL HYDROGEL FOR THE MANAGEMENT OF BURNING, ITCHING, AND PAIN EXPERIENCED WITH VARIOUS TYPE OF SKIN IRRITATIONS. MAY ALSO BE USED TO RELIEVE THE PAIN OF FIRST-AND SECOND-DEGREE BURNS. HELPS MAINTAIN A MOIST WOUND AND SKIN ENVIRONMENT. CAN BE USE IN ALL ANIMAL SPECIES.
1376	IMP/MD/2018/000311	1.License Holder Name: BOSTON IVY SOLUTIONS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BTM WOUND DRESSING (NOVOSORB)-THE NOVOSORB™ BTM WOUND DRESSING IS INDICATED FOR USE IN THE MANAGEMENT OF WOUNDS INCLUDING: PARTIAL AND FULL THICKNESS WOUNDS, PRESSURE ULCERS, VENOUS ULCERS, DIABETIC ULCERS, CHRONIC AND VASCULAR ULCERS, SURGICAL WOUNDS (DONOR SITES/GRAFTS, POST-MOH'S SURGERY, POST-LASER SURGERY, PODIATRIC, WOUND DEHISCENCE), TRAUMA WOUNDS (ABRASIONS, LACERATIONS, SECOND-DEGREE BURNS, AND SKIN TEARS) AND DRAINING WOUNDS. THE DEVICE IS FOR SINGLE USE ONLY.
1377	IMP/MD/2018/000312	1.License Holder Name: SCHOTT KAISHA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: GLASS PREFILLABLE SYRINGE WITH FIXED NEEDLE(SYRIQ)-INTENDED FOR AUTOMATIC SELF ADMINISTRATION OD DRUG AND BIOLOGICS FROM STANDARD GLASS BARRELS

1378	IMP/MD/2018/000320	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CARDIOVASCULAR FABRIC PATCHES(PATCH)-VASCULAR OR CARDIOVASCULAR REPAIR. THE SOFT HANDLING OF THE GELSOFT PATCH MAKES IT IDEAL FOR PERIPHERAL USE. DUE TO ITS PARTICULARLY HIGH STRENGTH GELSEAL PATCHES ARE ESPECIALLY SUITABLE FOR THORACIC USE. THE THIN WALL FABRIC IS DESIGNED FOR PATCH CLOSURE AFTER ENDARTERECTOMY, PARTICULARLY OF THE CAROTID ARTERIES. , ANACONDA STENT GRAFT SYSTEM(ANACONDA)-THE VASCUTEK ANACONDATM STENT GRAFT SYSTEM IS INTENDED FOR; “INFRA-RENAL ABDOMINAL AORTIC ANEURYSM REPAIR”,POLYESTER VASCULAR PROSTHESIS(GELWEAVE™)-SYSTEMIC VASCULAR REPAIR I.E. REPLACEMENT OR BYPASS PROCEDURES IN ANEURYSMAL & OCCLUSIVE DISEASE OF THE ARTERIES. ANTE-FLOTM IS ALSO INDICATED FOR REPLACEMENT OF THE THORACIC AORTA DUE TO ANEURYSMAL AND/OR ATHEROSCLEROTIC ARTERIAL DISEASE. PLEXUS VASCULAR PROSTHESES ARE ALSO INDICATED FOR THE REPLACEMENT OF THE AORTIC ARCH & ITS MAJOR BRANCHES I.E. THE BRACIOCEPHALIC TRUNK, COMMON CAROTID ARTERY AND SUBCLAVIAN ARTERY. GELWEAVETM BRANCHED VASCULAR PROSTHESES, INCLUDING SIENA VASCULAR PROSTHESES CAN ALSO BE USED FOR DEBRANCHING, I.E. RECONSTRUCTION OF THE AORTIC VESSELS & ASSOCIATED HYBRID PROCEDURES. HYBRID PROCEDURES ARE DEFINED AS A TREATMENT COMBINATION EMPLOYING OPEN SURGICAL DEBRANCHING WITH ENDOVASULAR AORTIC REPAIR. GELWEAVETM VALSALVA IS INDICATED FOR REPAIR OR REPLACEMENT OF DAMAGED & DISEASED THORACIC AORTA IN CASES OF ANEURYSM, DISSECTION OR COARCTATION. ,THORAFLEX HYBRID DEVICES(THORAFLEX HYBRID DEVICES)-THE THORAFLEX HYBRID DEVICES ARE INTENDED FOR USE THE OPEN SURGICAL REPAIR OR REPLACEMENT OF DAMAGED OR DISEASED VESSELS OF THE AORTIC ARCH AND DESCENDING AORTA WITH OR WITHOUT INVOLVEMENT OF THE ASCENDING AORTA IN CASES OF ANEURYSM AND/OR DISSECTION,POLYESTER VASCULAR PROSTHESIS(GELSOFT PLUS)-SYSTEMIC VASCULAR REPAIR I.E. REPLACEMENT OR BYPASS PROCEDURES IN ANEURYSMAL & OCCLUSIVE DISEASE OF THE ARTERIES. SYSTEMIC VASCULAR REPAIR I.E.PRIMARILY FOR AXILLO-FEMORAL CM BYPASS PROCEDURES & FEMORAL-POPLITEAL RECONSTRUCTION IN ANEURYSMAL & OCCLUSIVE DISEASE OF THE ARTERIES. SYSTEMIC VASCULAR REPAIR I.E. PRIMARILY FOR AXILLO-BI-FEMORAL BYPASS PROCEDURES IN ANEURYSMAL & OCCLUSIVE DISEASE OF THE ARTERIES. SYSTEMIC VASCULAR REPAIR I.E. PRIMARILY FOR AXILLO-FEMORAL BYPASS PROCEDURES &

	FEMORAL POPLITEAL RECONSTRUCTION IN ANEURYSMAL & OCCLUSIVE DISEASE OF THE ARTERIES. INDICATED FOR SYSTEMIC VASCULAR REPAIR I.E. PRIMARILY FOR FEMORO-FEMORAL BYPASS PROCEDURES IN ANEURYSMAL & OCCLUSIVE DISEASE OF THE ARTERIES. SYSTEMIC VASCULAR REPAIR I.E. PRIMARILY FOR AXILO-BI-FEMORAL BYPASS PROCEDURES IN ANEURYSMAL & OCCLUSIVE DISEASE OF THE ARTERIES. ,ANACONDA STENT GRAFT SYSTEM (ANACONDA)-THE VASCUTEK ANACONDA AAA STENT GRAFT SYSTEM IS INTENDED FOR INFRA-RENAL AAA REPAIR. SPECIFICALLY, THE SYSTEM IS INTENDED TO BE USED IN A MINIMALLY INVASIVE ENDOVASCULAR PROCEDURE (EVAR), WITHOUT THE NEED FOR CONVENTIONAL OPEN, INVASIVE ABDOMINAL SURGERY.,ANACONDA STENT GRAFT SYSTEM(ANACONDA)-THE VASCUTEK ANACONDA AAA STENT GRAFT SYSTEM IS INTENDED FOR INFRA-RENAL AAA REPAIR. SPECIFICALLY, THE SYSTEM IS INTENDED TO BE USED IN A MINIMALLY INVASIVE ENDOVASCULAR PROCEDURE (EVAR), WITHOUT THE NEED FOR CONVENTIONAL OPEN, INVASIVE ABDOMINAL SURGERY. AORTIC CUFF IS USED AS AN INFRARENAL EXTENSION CUFF WHERE THE ANCHORED BIFURCATE BODY HAS BEEN DEPLOYED TOO LOW IN THE AORTIC NECK. AORTIC CUFF ALSO PROVIDE ADDITIONAL SEALING SHOULD A PROXIMAL ENDOLEAK BE OBSERVED.,ANACONDA STENT GRAFT SYSTEM(ANACONDA)-ACCESSORIES TO ANACONDA STENT GRAFT SYSTEM,ANACONDA STENT GRAFT SYSTEM(ANACONDA)-THE ANACONDA ILIAC STENT GRAFT SYSTEM IS USED TO COMPLETE THE EVAR PROCEDURE BUT IS ALSO INDICATED FOR ISOLATED ILIAC ARTERY ANEURYSM REPAIR.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1379	IMP/MD/2018/000321	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KNEE REPLACEMENT SYSTEM - FEMORAL(SIGMA CR-150)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1380	IMP/MD/2018/000322	1.License Holder Name: COOK INDIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VASCULAR WIRE GUIDES (CONIC-16 TORQUE WIRE GUIDE)-THE MICRO WIRE GUIDE IS INTENDED FOR DIAGNOSTIC AND INTERVENTIONAL PROCEDURES., VASCULAR WIRE GUIDES(AMPLATZ ULTRA STIFF, CIRRUS-14, LUNDERQUIST EXTRA STIFF)-1. AMPLATZ ULTRA STIFF & CIRRUS-14 VASCULAR WIRE GUIDES- THE WIRE GUIDE IS INTENDED FOR DIAGNOSTIC AND INTERVENTIONAL PROCEDURES 2. LUNDERQUIST EXTRA STIFF VASCULAR WIRE GUIDES- THE DEVICE IS INTENDED FOR COMPLEX DIAGNOSTIC AND INTERVENTIONAL PROCEDURES WHERE INCREASED BODY, FLEXIBILITY, AND LOW SURFACE FRICTION OF THE WIRE GUIDE IS NEEDED. THE PRODUCT IS INTENDED FOR USE BY PHYSICIANS TRAINED AND EXPERIENCED IN DIAGNOSTIC AND INTERVENTIONAL TECHNIQUES. STANDARD TECHNIQUES FOR PLACEMENT OF VASCULAR ACCESS SHEATHS, ANGIOGRAPHIC CATHETERS AND WIRE GUIDES SHOULD BE EMPLOYED. ,VASCULAR WIRE GUIDES(WIRE GUIDE AQ HYDROPHILIC COATING)-THE MICRO WIRE GUIDE IS INTENDED FOR DIAGNOSTIC AND INTERVENTIONAL PROCEDURES.,ENDOVASCULAR STENT GRAFT(ZENITH ALPHA THORACIC ENDOVASCULAR GRAFT)-THE ZENITH ALPHA THORACIC ENDOVASCULAR GRAFT IS INDICATED FOR THE ENDOVASCULAR TREATMENT OF PATIENTS WITH ANEURYSMS OR ULCERS OF THE DESCENDING THORACIC AORTA HAVING VASCULAR MORPHOLOGY SUITABLE FOR ENDOVASCULAR REPAIR, INCLUDING: • ILIAC/FEMORAL ANATOMY THAT IS SUITABLE FOR ACCESS WITH THE REQUIRED INTRODUCTION SYSTEMS • NONANEURYSMAL AORTIC SEGMENTS (FIXATION SITES) PROXIMAL AND DISTAL TO THE THORACIC ANEURYSM OR ULCER: • WITH A LENGTH OF AT LEAST 20 MM, AND • WITH A DIAMETER MEASURED OUTER-WALL-TO-OUTER-WALL OF NO GREATER THAN 42 MM AND NO LESS THAN 20 MM, INTRAVASCULAR RETRIEVAL DEVICES AND SETS(GÜNTHER TULIP® VENA CAVA FILTER RETRIEVAL SET)-THE PRODUCT HAS BEEN DESIGNED FOR RETRIEVAL OF IMPLANTED GÜNTHER TULIP AND COOK CELECT VENA CAVA FILTERS IN PATIENTS WHO NO LONGER REQUIRE A FILTER. RETRIEVAL OF THE FILTER CAN BE PERFORMED ONLY BY JUGULAR APPROACH.,RESPIRATORY MANAGEMENT CATHETER(FROVA INTUBATING INTRODUCER)-IT IS INTENDED TO FACILITATE ENDOTRACHEAL INTUBATION IN PATIENTS WHERE VISUALISATION OF THE GLOTTIS IS INADEQUATE. THE 14 FR CATHETER INTRODUCER HAS BEEN DESIGNED FOR PLACEMENT OF A SINGLE LUMEN ENDOTRACHEAL TUBE WHOSE INNER DIAMETER IS 6MM OR LARGER.,VENA CAVA FILTER SETS(COOK CELECT® PLATINUM VENA CAVA FILTER)-THE COOK CELECT® PLATINUM

	FILTER IMPLANT IS INTENDED FOR THE PREVENTION OF RECURRENT PULMONARY EMBOLISM (PE) VIA PLACEMENT IN THE VENA CAVA IN THE FOLLOWING SITUATIONS: • PULMONARY THROMBOEMBOLISM WHEN ANTICOAGULANT THERAPY IS CONTRAINDICATED; • FAILURE OF ANTICOAGULANT THERAPY IN THROMBOEMBOLIC DISEASES; • EMERGENCY TREATMENT FOLLOWING MASSIVE PE WHERE ANTICIPATED BENEFITS OF CONVENTIONAL THERAPY ARE REDUCED; AND • CHRONIC, RECURRENT PE WHERE ANTICOAGULANT THERAPY HAS FAILED OR IS CONTRAINDICATED. THE COOK CELECT PLATINUM FILTER IMPLANT MAY BE RETRIEVED IF CLINICALLY INDICATED; PLEASE REFER TO THE “OPTIONAL FILTER RETRIEVAL” SECTION OF THE INSTRUCTIONS FOR USE FOR MORE INFORMATION. THE PRODUCT IS INTENDED FOR PERCUTANEOUS PLACEMENT VIA A FEMORAL OR JUGULAR VEIN FOR FILTRATION OF INFERIOR VENA CAVA (IVC) BLOOD TO PREVENT PE.,RESPIRATORY MANAGEMENT CATHETER(FROVA INTUBATING CATHETER)-IT IS INTENDED TO FACILITATE ENDOTRACHEAL INTUBATION IN PATIENTS WHERE THE VISUALISATION OF THE GLOTTIS IS INADEQUATE. THE 14 FRENCH CATHETER INTRODUCER HAS BEEN DESIGNED FOR PLACEMENT OF A SINGLE LUMEN ENDOTRACHEAL TUBE WHOSE INNER DIAMETER IS 6 MM OR LARGER.

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1381	IMP/MD/2018/000322	1.License Holder Name: M/S COOK INDIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOVASCULAR STENT GRAFT(ZENITH DISSECTION ENDOVASCULAR STENT WITH THE Z-TRAK PLUS INTRODUCTION SYSTEM)-THE ZENITH DISSECTION ENDOVASCULAR STENT WITH THE Z-TRAK PLUS INTRODUCTION SYSTEM IS INDICATED FOR THE ENDOVASCULAR TREATMENT OF PATIENTS WITH SYMPTOMATIC AORTIC DISSECTION DISTAL TO THE LEFT SUBCLAVIAN ARTERY (CAN BE USED TO PROVIDE SUPPORT TO DELAMINATED SEGMENTS OF THE AORTA TYPICAL IN DISSECTION) HAVING VASCULAR MORPHOLOGY SUITABLE FOR ENDOVASCULAR REPAIR, INCLUDING: • ADEQUATE ILIAC/FEMORAL ACCESS COMPATIBLE WITH THE REQUIRED INTRODUCTION SYSTEMS; WHEN USED TOGETHER WITH THE ZENITH TX2 DISSECTION ENDOVASCULAR GRAFT WITH PRO-FORM. • RADIUS OF CURVATURE GREATER THAN 35 MM ALONG THE ENTIRE LENGTH OF AORTA INTENDED TO BE TREATED BY THE ZENITH DISSECTION ENDOVASCULAR STENT, • LOCALIZED ANGULATION LESS THAN 45 DEGREES, AND • DIAMETER AT INTENDED IMPLANT SITE (MEASURED OUTER WALL TO OUTER WALL) OF NO GREATER THAN 38 MM (TRUE LUMEN) AND NO LESS THAN 20 MM (TOTAL AORTIC DIAMETER). THE ZENITH DISSECTION ENDOVASCULAR STENT IS INTENDED TO BE USED AS A DISTAL COMPONENT TO A ZENITH TX2 DISSECTION ENDOVASCULAR GRAFT WITH PRO-FORM STRAIGHT COMPONENT OR TAPERED COMPONENT, TO PROVIDE SUPPORT TO DELAMINATED SEGMENTS OF AORTIC DISSECTION DISTAL TO THE LEFT SUBCLAVIAN ARTERY.,ENDOVASCULAR STENT GRAFT(ZENITH TX2 DISSECTION ENDOVASCULAR GRAFT WITH PRO-FORM AND THE Z-TRAK PLUS INTRODUCTION SYSTEM)-THE ZENITH TX2 DISSECTION ENDOVASCULAR GRAFT WITH PRO-FORM AND THE Z-TRAK PLUS INTRODUCTION SYSTEM IS INDICATED FOR THE ENDOVASCULAR TREATMENT OF PATIENTS WITH SYMPTOMATIC DISSECTION OF THE DESCENDING THORACIC AORTA HAVING VASCULAR MORPHOLOGY SUITABLE FOR ENDOVASCULAR REPAIR, INCLUDING: • ADEQUATE ILIAC/FEMORAL ACCESS COMPATIBLE WITH THE REQUIRED INTRODUCTION SYSTEMS, • RADIUS OF CURVATURE GREATER THAN 35 MM ALONG THE LENGTH OF AORTA INTENDED TO BE TREATED BY STRAIGHT OR TAPERED COMPONENT, • NON-DISSECTED/ANEURYSMAL AORTIC SEGMENTS (FIXATION SITES) PROXIMAL TO THE ENTRY TEAR: • WITH A LENGTH OF AT LEAST 20 MM, • WITH A DIAMETER MEASURED OUTER WALL TO OUTER WALL OF NO GREATER THAN 38 MM AND NO LESS THAN 20 MM, AND • WITH LOCALIZED ANGULATION LESS THAN 45 DEGREES.,ENDOVASCULAR STENT GRAFT(ZENITH TX2 TAA ENDOVASCULAR GRAFT WITH PRO-

		FORM)-THE ZENITH TX2 TAA ENDOVASCULAR GRAFT WITH PRO-FORM WITH THE Z-TRAK PLUS INTRODUCTION SYSTEM IS INTENDED FOR TREATMENT OF PATIENTS WITH ATHEROSCLEROTIC ANEURYSMS, SYMPTOMATIC ACUTE OR CHRONIC DISSECTIONS, CONTAINED RUPTURES, GROWING ANEURYSMS AND/OR RESULTING IN DISTAL ISCHEMIA, IN THE DESCENDING THORACIC AORTA. THE DEVICE IS INTENDED FOR USE IN AORTAS HAVING VASCULAR MORPHOLOGY SUITABLE FOR ENDOVASCULAR REPAIR, INCLUDING: • ADEQUATE ILIAC/FEMORAL ACCESS COMPATIBLE WITH THE REQUIRED INTRODUCTION SYSTEMS. • RADIUS OF CURVATURE GREATER THAN 35 MM ALONG THE ENTIRE LENGTH OF AORTA INTENDED TO BE TREATED. • NONANEURYSMAL AORTIC SEGMENTS (FIXATION SITES) PROXIMAL AND DISTAL TO THE ANEURYSM: • WITH A LENGTH OF AT LEAST 20 MM, AND • WITH A DIAMETER MEASURED OUTER-WALL-TO-OUTER-WALL OF NO GREATER THAN 38 MM AND NO LESS THAN 20 MM, AND • WITH AN ANGLE LESS THAN 45 DEGREES.
1382	IMP/MD/2018/000322	1.License Holder Name: M/S COOK INDIA MEDICAL DEVICES PVT. LTD. , PLOT NO 22(SP), THIRD AND FOURTH FLOOR, KOCHAR JADE, THIRU VI KA INDUSTRIAL ESTATE, GUINDY TALUK ,CHENNAI TAMIL NADU , 600032 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EMBOLIZATION DEVICES (HILAL EMBOLIZATION MICROCOILS)-THE PRODUCT HAS BEEN DESIGNED TO BE USED FOR ARTERIAL AND VENOUS EMBOLIZATION, EMBOLIZATION DEVICES(MREYE FLIPPER PDA CLOSURE DETACHABLE COIL)-THE PRODUCT IS INTENDED FOR PATENT DUCTUS ARTERIOSUS (PDA) CLOSURE. THE DETACHABLE COIL DELIVERY SYSTEM PROVIDES SAFE DELIVERY OF EMBOLIZATION COILS WHEN CORRECT POSITIONING IS ESPECIALLY CRITICAL., EMBOLIZATION IMPLANT INSERTER(FLIPPER 35 PDA CLOSURE DETACHABLE COIL DELIVERY SYSTEM)-THE PRODUCT IS INTENDED FOR PATENT DUCTUS ARTERIOSUS (PDA) CLOSURE. THE DETACHABLE COIL DELIVERY SYSTEM PROVIDES SAFE DELIVERY OF EMBOLIZATION COILS WHEN CORRECT POSITIONING IS ESPECIALLY CRITICAL.

1383	IMP/MD/2018/000323	1.License Holder Name: CARDINAL HEALTH MEDICAL PRODUCTS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RETRIEVABLE VENA CAVA FILTER AND INTRODUCTION KIT(OPTEASE)-THE OPTEASE RETRIEVABLE FILTER IS INDICATED FOR THE PREVENTION OF PULMONARY EMBOLISM (PE) VIA PERCUTANEOUS PLACEMENT IN THE IVC IN PATIENTS CONSIDERED AT HIGH RISK OF PE. THE ANGIOGRAPHIC VESSEL DILATOR IS DESIGNED TO PROVIDE ANGIOGRAPHIC VISUALIZATION AND LINEAR MEASUREMENT OF THE VASCULATURE WHEN COMBINED WITH THE DELIVERY OF RADIOPAQUE CONTRAST MEDIA TO THE VENA CAVA.,PERMANENT VENA CAVA FILTER AND INTRODUCTION KIT(TRAPEASE)-TRAPEASE FILTER IS INDICATED FOR THE PREVENTION OF RECURRENT PULMONARY EMBOLISM VIA PERCUTANEOUS PLACEMENT IN THE INFERIOR VENA CAVA IN THE FOLLOWING SITUATIONS: • PULMONARY THROMBOEMBOLISM WHEN ANTICOAGULANTS ARE CONTRAINDICATED. • FAILURE OF ANTICOAGULANT THERAPY IN THROMBOEMBOLIC DISEASES. • EMERGENCY TREATMENT FOLLOWING MASSIVE PULMONARY EMBOLISM WHERE ANTICIPATED BENEFITS OF CONVENTIONAL THERAPY ARE REDUCED. • CHRONIC, RECURRENT PULMONARY EMBOLISM WHERE ANTICOAGULANT THERAPY HAS FAILED OR IS CONTRAINDICATED,AAA STENT GRAFT SYSTEM(INCRAFT)-THE INCRAFT® STENT GRAFT SYSTEM IS INTENDED FOR THE ENDOVASCULAR TREATMENT OF PATIENTS WITH INFRARENAL ABDOMINAL AORTIC ANEURYSMS WITH THE FOLLOWING CHARACTERISTICS: • FEMORAL ACCESS VESSELS SHOULD BE ADEQUATE TO FIT THE SELECTED DELIVERY SYSTEM • PROXIMAL NECK LENGTH 10MM • AORTIC NECK DIAMETERS 17MM AND 31MM • AORTIC NECK SUITABLE FOR SUPRARENAL FIXATION • INFRARENAL AND SUPRARENAL NECK ANGULATION 60° • ILIAC FIXATION LENGTH 15MM • ILIAC DIAMETERS 7MM AND 22MM • MINIMUM OVERALL AAA TREATMENT LENGTH (PROXIMAL LANDING LOCATION TO DISTAL LANDING LOCATION) 128MM • MORPHOLOGY SUITABLE FOR ANEURYSM REPAIR

1384	IMP/MD/2018/000324	1.License Holder Name: KCI MEDICAL INDIA PRIVATE LIMITED ,K. NO. 2606/115 (P. NO. 60/16) GROUND FLOOR, HUSKUR ROAD ELECTRONIC POST ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560100 , INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TIELLE® SACRUM HYDROPOLYMER ADHESIVE DRESSING(TIELLE® SACRUM)-TIELLE® DRESSING IS INDICATED FOR THE MANAGEMENT OF LOW TO MODERATELY EXUDING WOUNDS. TIELLE® DRESSING SHOULD BE USED UNDER HEALTH CARE PROFESSIONAL DIRECTION FOR THE FOLLOWING INDICATIONS: • PRESSURE ULCERS • LOWER EXTREM TY ULCERS • VENOUS • ARTERIAL • MIXED AETIOLOGY • DIABETIC ULCERS • DONOR SITES TIELLE® DRESSING IS SUITABLE FOR USE UNDER COMPRESSION BANDAGING.
1385	IMP/MD/2018/000329	1.License Holder Name: SMITHS MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRACHEOSTOMY TUBES (PORTEX)-A RANGE OF STERILE SINGLE-USE TRACHEOSTOMY TUBES WITH AN ADJUSTABLE FLANGE FOR USE ON PATIENTS WITH ABNORMAL SKIN TO TRACHEA DEPTH AND/OR TO FACILITATE STOMA CARE ,SUCTIONPRO 72 CLOSED SUCTION CATHETER (PORTEX)-IT IS INTENDED FOR SINGLE PATIENT USE SUCTIONING DEVICE FOR THE REMOVAL OF SECRETIONS FROM THE TRACHEA-BRONCHIAL TREE OF VENTILATOR DEPENDENT ADULT PATIENTS. INTENDED OF 72 HRS OF MAXIMUM USE. ,ENDOBRONCHIAL TUBES (PORTEX)-IT IS INTENDED FOR USE IN THORACIC SURGERY, BRONCHO-SPIROMETRY, FOR THE ADMINISTRATION OF ENDOBRONCHIAL INTUBATION. ENDOBRONCHIAL TUBES ARE INDICATED FOR MAIN STEM BRONCHUS INTUBATION AND ALLOW FOR SELECTIVE INFLATION AND/OR DEFLATION, SUCTIONING, INDEPENDENT LUNG VENTILATION AND BRONCHOSCOPIC VIEWING OF EITHER LUNG. ENDOBRONCHIAL TUBES SHOULD ALWAYS BE USED IN ACCORDANCE WITH CURRENTLY ACCEPTED MEDICAL TECHNIQUES. SWIVEL ADAPTERS ARE INDICATED WHERE IT IS DESIRABLE TO DECREASE THE TRANSMISSION OF UNDESIRABLE TORQUE AND MOTION BETWEEN CIRCUITS AND TRACHEAL OR TRACHEOSTOMY TUBES. THE DUAL-AXIS SWIVEL ADAPTER CAN BE USED FOR SUCTION ACCESS. ,ENDOTRACHEAL TUBE(PORTEX)-IT IS INTENDED FOR ORAL AND/OR NASAL INTUBATION FOR AIRWAY MANAGEMENT. EXPERT CLINICAL JUDGEMENT SHOULD BE EXERCISED IN THE SELECTION OF THE APPROPRIATE TRACHEAL TUBE SIZE AND STYLE FOR AND INDIVIDUAL PATIENT

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1386	IMP/MD/2018/000341	1.License Holder Name: M/S MERIT MEDICAL SYSTEMS INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIAGNOSTIC GUIDE WIRE (INQWIRE DIAGNOSTIC GUIDE WIRE)-MERIT MEDICAL GUIDE WIRES ARE USED TO FACILITATE THE PLACEMENT OF DEVICES DURING DIAGNOSTIC AND INTERVENTIONAL PROCEDURES.,ENDOVASCULAR SNARE SYSTEM(ONE SNARE ENDOVASCULAR SNARE SYSTEM)-THE ONE SNARE™ ENDOVASCULAR SNARE SYSTEM IS INTENDED FOR USE IN THE CORONARY AND PERIPHERAL VASCULAR SYSTEM OR HOLLOW VISCOUS TO RETRIEVE AND MANIPULATE FOREIGN OBJECTS. RETRIEVAL AND MANIPULATION PROCEDURES INCLUDE INDWELLING VENOUS CATHETER REPOSITIONING, INDWELLING VENOUS CATHETER FIBRIN SHEATH STRIPPING, AND CENTRAL VENOUS ACCESS VENIPUNCTURE PROCEDURE ASSISTANCE., ENDOVASCULAR SNARE SYSTEM(EN SNARE ENDOVASCULAR SNARE SYSTEM)-THE EN SNARE® ENDOVASCULAR SNARE SYSTEM IS INTENDED FOR USE IN THE CORONARY AND PERIPHERAL VASCULAR SYSTEM OR HOLLOW VISCOUS TO RETRIEVE AND MANIPULATE FOREIGN OBJECTS. RETRIEVAL AND MANIPULATION PROCEDURES INCLUDE, INDWELLING VENOUS CATHETER REPOSITIONING, INDWELLING VENOUS CATHETER FIBRIN SHEATH STRIPPING, AND CENTRAL VENOUS ACCESS VENIPUNCTURE PROCEDURE ASSISTANCE.,ANGIOPLASTY KIT(MERIT ANGIOPLASTY PACK KIT (MAP - HEMOSTASIS VALVE: HONOR, ACCESS-9, ACCESS PLUS, PASSAGE, DOUBLEPLAY, MBA, MBA PLUS WITH SPRING, PHD, PHD WITH SIDEARM TUBING))-THE MERIT HEMOSTASIS VALVES ARE INTENDED FOR MAINTAINING HEMOSTASIS / FLUID TIGHT SEAL DURING THE INTRODUCTION, USE AND WITHDRAWAL OF INTERVENTIONAL AND DIAGNOSTIC DEVICES DURING USE. MERIT ANGIOPLASTY PACK (MAP KITS) TYPICALLY CONSIST OF A HEMOSTASIS VALVE, A GUIDE WIRE INSERTION TOOL, AND A PIN VISE TORQUE DEVICE.,HEMOSTASIS VALVES AND ACCESSORIES (HEMOSTASIS VALVES AND ACCESSORIES (HONOR, FLO30, FLO40XR, ACCESS PLUS, DOUBLEPLAY, MBA, MBA PLUS WITH SPRING, PHD, PHD WITH SIDE ARM TUBING))-THE MERIT HEMOSTASIS VALVES ARE INTENDED FOR MAINTAINING HEMOSTASIS / FLUID TIGHT SEAL DURING THE INTRODUCTION, USE AND WITHDRAWAL OF INTERVENTIONAL AND DIAGNOSTIC DEVICES DURING USE., HYDROPHILIC COATED GUIDE WIRE(LAUREATE HYDROPHILIC GUIDE WIRE)-THE MERIT HYDROPHILIC GUIDE WIRE IS INTENDED TO BE USED IN THE PERIPHERAL VASCULAR SYSTEM TO FACILITATE THE PLACEMENT OF DEVICES DURING DIAGNOSTIC AND INTERVENTIONAL PROCEDURES.

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1387	IMP/MD/2018/000342	1.License Holder Name: M/S DENTSPLY INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANKYLOS® REGULAR C/X ABUTMENT(ANKYLOS®)-PROSTHETIC RESTORATION OF ANKYLOS C/X IMPLANTS,ANKYLOS® BALANCE POSTERIOR C/ ABUTMENT (ANKYLOS®)-PROSTHETIC RESTORATION OF ANKYLOS IMPLANTS, ANKYLOS® TEMPORARY ABUTMENT BALANCE(ANKYLOS®)-ANATOMICAL ABUTMENT FOR SUPPORTING PROVISIONAL CROWNS OR BRIDGES OVER MAX. 2 BRIDGE PONTICS SHORT-TERM PROVISIONAL FOR ESTHETIC SOFT-TISSUE CONTOURING,ANKYLOS® SULCUS FORMER(ANKYLOS®)-SHAPE THE GINGIVA AFTER IMPLANT UNCOVERY, USED FOR TRANSGINGIVAL HEALING,ANKYLOS® CERCON BALANCE(ANKYLOS®)-SUPPORT FOR HIGHLY ESTHETIC SINGLE TOOTH CROWNS IN THE ANTERIOR REGION OF THE MAXILLA AND MANDIBLE 13-23 AND 33-43 (ACC. TO US SCHEME: 6-11 AND 22-27) - INCLUDING WHERE THE MUCOSA IS VERY THIN - IN COMBINATION WITH IMPLANTS OF THE ANKYLOS® IMPLANT SYSTEM. THE CERCON® BALANCE CAN BE USED WITH A STRAIGHT IMPLANT ALIGNMENT AND AN ANGLED ALIGNMENT.,ANKYLOS® ANGLED BALANCE BASE ABUTMENT(ANKYLOS®)-PROSTHETIC RESTORATION OF SEVERAL ANKYLOS IMPLANTS WITH BRIDGES OR BAR CONSTRUCTIONS, TO BE USED AT LEAST IN PAIRS. WHEN USING FOUR OR MORE IMPLANTS, E.G. IN AN EDENTULOUS JAW, IMMEDIATE LOAD ALSO POSSIBLE,ANKYLOS® TEMPORARY WELDING ABUTMENT (ANKYLOS®)-FABRICATION OF AN INTRAORALLY OR EXTRAORALLY WELDED TITANIUM FRAMEWORK FOR IMMEDIATE TEMPORARY RESTORATION ON ANKYLOS IMPLANTS EXCLUSIVELY BY USE OF THE DENTSPLY IMPLANTS WELDONE WELDING UNIT AND THE TITANIUM WIRES DESIGNED FOR THAT PURPOSE,XIVE® TITANIUMBASE(XIVE®)-FABRICATION OF COMPLETE SUPERSTRUCTURES ON XIVE® IMPLANTS,ANKYLOS® BALANCE BASE ABUTMENT(ANKYLOS®)-PROSTHETIC RESTORATION OF SEVERAL ANKYLOS IMPLANTS WITH BRIDGES OR BAR CONSTRUCTIONS, TO BE USED AT LEAST IN PAIRS. WHEN USING FOUR OR MORE IMPLANTS, E.G. IN AN EDENTULOUS JAW, IMMEDIATE LOAD ALSO POSSIBLE,ANKYLOS® TITANIUMBASE (ANKYLOS®)-USE THE XIVE OR ANKYLOS TITANIUMBASE FOR CEMENTING TO MESOSTRUCTURES OF ZIRCONIUM DIOXIDE., ANKYLOS® STANDARD C/ ABUTMENT(ANKYLOS®)-STRAIGHT AND ANGLED ABUTMENTS: PROSTHETIC RESTORATIONS OF ANKYLOS® IMPLANTS ,ANKYLOS® BALANCE ANTERIOR C/X ABUTMENT (ANKYLOS®)-PROSTHETIC RESTORATION OF ANKYLOS® IMPLANTS, ANKYLOS® SYNCONE® ABUTMENTS(ANKYLOS®)-IMMEDIATE LOADING OF AN IMPLANT SUPPORTED PROSTHESIS IN AN EDENTULOUS MANDIBLE SUPPORTED BY 4 ANKYLOS® IMPLANTS OF

		AT LEAST 11 MM PREFERABLY 14 MM IN LENGTH AND PLACED INTERFORAMINALLY ,ANKYLOS® ABUTMENT WITH SNAP ATTACHMENT(ANKYLOS®)-RETAIN IMPLANT-SUPPORTED RESTORATIONS IN THE EDENTULOUS MANDIBLE. THE RESTORATION IS RETAINED ON TWO INTERFORAMINAL, OSSEOINTEGRATED ANKYLOS® IMPLANTS.,ANKYLOS® GINGIVA FORMER(ANKYLOS®)-CONTOURING THE GINGIVA AFTER UNCOVERY, USE WITH TRANSGINGIVAL HEALING.
1388	IMP/MD/2018/000343	1.License Holder Name: CLINICARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYPODERMIC NEEDLES (UNIFINE)-IT IS ATTACHED TO A INSULIN DELIVERY PENS AND THE INTENDED USE IS TO INJECT THE INSULIN .

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1389	IMP/MD/2018/000344	1.License Holder Name: EDWARDS LIFESCIENCES (INDIA) PRIVATE LIMITED, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERCUTANEOUS SHEATH INTRODUCER SET(INTRO-FLEX)-INTRO-FLEX POLYURETHANE PERCUTANEOUS SHEATH INTRODUCERS ARE INDICATED FOR USE IN PATIENTS REQUIRING ACCESS OF THE VENOUS SYSTEM OR TO FACILITATE CATHETER INSERTION.,THROMBECTOMY CATHETER (FOGARTY GRAFT THROMBECTOMY CATHETERS)-INTENDED USE - THE FOGARTY GRAFT THROMBECTOMY CATHETER IS DESIGNED TO REMOVE ORGANIZED THROMBUS AND ADHERENT THROMBOTIC MATERIAL FROM SYNTHETIC BYPASS GRAFTS, SPECIFICALLY AV FISTULAS FOR DIALYSIS ACCESS AND GRAFTS FOR ILIOFEMORAL BYPASS. THE FOGARTY GRAFT THROMBECTOMY CATHETERS ARE INDICATED FOR THE FOLLOWING: 1. GENERAL INDICATIONS FOR ARTERIAL RECONSTRUCTION OF AN OBSTRUCTED GRAFT INCLUDE DISABLING CLAUDICATION, ISCHEMIC PAIN AT REST, ISCHEMIC SKIN LESIONS, OR GANGRENE. 2. GENERAL INDICATIONS FOR RECONSTRUCTION OF A SYNTHETIC AV FISTULA INTERNAL BRIDGE GRAFT INCLUDE THE INABILITY TO PROPERLY DIALYZE THE PATIENT.,EMBOLECTOMY CATHETERS(FOGARTY ARTERIAL EMBOLECTOMY CATHETERS)-THE FOGARTY ARTERIAL EMBOLECTOMY CATHETER IS INDICATED FOR THE REMOVAL OF FRESH, SOFT EMBOLI AND THROMBI FROM VESSELS IN THE ARTERIAL SYSTEM OF THE NON- CENTRAL CIRCULATORY SYSTEM.,NON-THERMODILUTION CATHETER(SWAN-GANZ TRUE SIZE MONITORING CATHETER (TRIPLE LUMEN & DOUBLE LUMEN))-SWAN-GANZ FLOW-DIRECTED MONITORING CATHETERS ARE INDICATED FOR THE ASSESSMENT OF A PATIENT'S HEMODYNAMIC CONDITION THROUGH DIRECT INTRACARDIAC AND PULMONARY ARTERY PRESSURE MONITORING. SECONDARY INDICATIONS ARE FOR SAMPLING BLOOD AND INFUSING SOLUTIONS.,CATHETER(FOGARTY CORKSCREW CATHETER)-THE FOGARTY CORKSCREW CATHETER IS INDICATED FOR THE REMOVAL OF EMBOLI AND THROMBI FROM EITHER NATIVE VESSELS OR SYNTHETIC GRAFTS IN THE ARTERIAL OF THE NON- CENTRAL CIRCULATORY SYSTEM.,THERMODILUTION CATHETERS(SWAN-GANZ CCO, SWAN-GANZ CCO V, SWAN-GANZ CCOMBO, SWAN-GANZ CCOMBO V THERMODILUTION CATHETERS)-THE CCO/CEDV THERMODILUTION CATHETER SERIES IS FOR USE IN PATIENTS WHO REQUIRE HEMODYNAMIC MONITORING. THEY ARE INTENDED TO BE USED IN COMBINATION WITH CLINICAL PRESSURE MONITORING EQUIPMENT TO MEASURE RIGHT HEART AND PULMONARY ARTERY PRESSURES, AND WITH A COMPATIBLE CARDIAC OUTPUT COMPUTER TO CONTINUOUSLY MEASURE

	CARDIAC OUTPUT. MODELS 744F75, 746F8, 774F75, AND 777F8 ALSO MEASURE MIXED VENOUS OXYGEN SATURATION. WHEN USED WITH THE COMPATIBLE CARDIAC OUTPUT COMPUTER, MODELS 177F75N, 774F75, AND 777F8 ALSO MEASURE VOLUMETRIC PARAMETERS, INCLUDING RIGHT VENTRICULAR EJECTION FRACTION AND END DIASTOLIC VOLUME.,CATHETER(EDWARDS OXIMETRY CENTRAL VENOUS CATHETER SET)-EDWARDS OXIMETRY CENTRAL VENOUS CATHETERS ARE INDICATED FOR HEMODYNAMIC MONITORING THROUGH BLOOD SAMPLING, PRESSURE MONITORING, AND OXYGEN SATURATION MEASUREMENT.,CATHETER(VOLUME VIEW COMBO KIT)-VOLUME VIEW SET/KIT IS INDICATED FOR USE IN CRITICAL CARE PATIENTS IN WHICH THE BALANCE BETWEEN CARDIAC FUNCTION, FLUID STATUS AND VASCULAR RESISTANCE NEEDS CONTINUOUS OR INTERMITTENT ASSESSMENT. THE VOLUMEVIEW CATHETER IS INDICATED FOR FEMORAL ARTERY INSERTION.,CATHETER(PEDIASAT OXIMETRY CATHETER SET)-PEDIASAT CATHETERS ARE INDICATED FOR HEMODYNAMIC MONITORING THROUGH BLOOD SAMPLING, PRESSURE MONITORING, AND OXYGEN SATURATION MEASUREMENTS IN ADULTS AND/OR PEDIATRIC PATIENTS., EMBOLECTOMY CATHETER(FOGARTY THRU-LUMEN EMBOLECTOMY CATHETER)-THE FOGARTY THRU-LUMEN EMBOLECTOMY CATHETER IS INDICATED FOR THE REMOVAL OF FRESH, SOFT EMBOLI AND THROMBI FROM VESSELS IN THE ARTERIAL SYSTEM OF THE NON-CENTRAL CIRCULATORY SYSTEM. ADDITIONALLY, IT MAY ALSO BE USED FOR TEMPORARY OCCLUSION OF BLOOD VESSELS, INFUSION OF FLUIDS, AND BLOOD SAMPLING.,THERMODILUTION CATHETERS (SWAN-GANZ TRUE SIZE THERMODILUTION CATHETER, SWAN-GANZ THERMODILUTION VENOUS INFUSION PORT (VIP) CATHETER)-SWAN GANZ THERMODILUTION CATHETERS ARE INDICATED FOR THE ASSESSMENT OF A PATIENT'S HEMODYNAMIC CONDITION THROUGH DIRECT INTRACARDIAC AND PULMONARY ARTERY PRESSURE MONITORING, CARDIAC OUTPUT DETERMINATION, AND FOR INFUSING SOLUTIONS. THE DISTAL (PULMONARY ARTERY) PORT ALSO ALLOWS SAMPLING OF MIXED VENOUS BLOOD FOR THE ASSESSMENT OF OXYGEN TRANSPORT BALANCE AND THE CALCULATION OF DERIVED PARAMETERS SUCH AS OXYGEN CONSUMPTION, OXYGEN UTILIZATION COEFFICIENT, AND INTRAPULMONARY SHUNT FRACTION.

1390	IMP/MD/2018/000345	1.License Holder Name: HOYA MEDICAL INDIA PRIVATE LIMITED (GODOWN) 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HOYA VIVINEX ISERT (HOYA VIVINEX ISERT)-THE HOYA VIVINEX ISERT IOL IS INTENDED TO BE PLACED INTO THE CAPSULAR BAG OF THE EYE AFTER EXTRACAPSULAR CATARACT REMOVAL, FUNCTIONING AS A REFRACTIVE MEDIUM TO REPLACE THE NATURAL CRYSTALLINE LENS.,HOYA VIVINEX TORIC(HOYA VIVINEX TORIC)-THE HOYA VIVINEX TORIC IOL IS INTENDED TO BE PLACED INTO THE CAPSULAR BAG OF THE EYE AFTER EXTRACAPSULAR CATARACT REMOVAL, FUNCTIONING AS A REFRACTIVE MEDIUM TO REPLACE THE NATURAL CRYSTALLINE LENS.,HOYA VIVINEX MULTISERT(HOYA VIVINEX MULTISERT)-HOYA VIVINEX MULTISERT IOL IS INTENDED TO BE PLACED INTO THE CAPSULAR BAG OF THE EYE AFTER EXTRACAPSULAR CATARACT REMOVAL, FUNCTIONING AS A REFRACTIVE MEDIUM TO REPLACE THE NATURAL CRYSTALLINE LENS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1391	IMP/MD/2018/000346	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KNEE SYSTEM - TIBIAL BASE(ATTUNE REVISION)-TOTAL KNEE ARTHROPLASTY IS A TOTAL JOINT REPLACEMENT SURGERY DESIGNED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY DISABLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. TOTAL KNEE ARTHROPLASTY MAY INCLUDE SUPPLEMENTAL FIXATION THROUGH STEMS, SLEEVES, AND/OR MODULAR AUGMENTS WHERE BONE LOSS REQUIRES SAID FIXATION IN THE OPINION OF THE SURGEON. TOTAL KNEE ARTHROPLASTY MAY ALSO INCLUDE MORE CONSTRAINED BEARING SURFACES WHERE NECESSARY TO PROVIDE STABILITY WHERE MUSCULOLIGAMENTOUS SUPPORTING STRUCTURES ARE INSUFFICIENT.,HIP SYSTEM- STEM(CORAIL)-CORAIL AMT HA COATED STEMS ARE INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY. THE STEMS ARE INTENDED ONLY FOR UNCEMENTED USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS.,SHOULDER REPLACEMENT SYSTEM - EPIPHYSIS (GLOBAL UNITE PLATFORM)-THE GLOBAL UNITE PLATFORM SHOULDER SYSTEM IS INTENDED FOR CEMENTED OR UNCEMENTED TOTAL OR HEMISHOULDER ARTHROPLASTY IN TREATMENT OF THE FOLLOWING: • A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS • FRACTURE OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY • IRREDUCIBLE 3- AND 4-PART FRACTURES OF THE PROXIMAL HUMERUS • UNUNITED HUMERAL HEAD FRACTURES • AVASCULAR NECROSIS OF THE HUMERAL HEAD • OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER

	ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT) HEMI-SHOULDER ARTHROPLASTY IS ALSO INDICATED FOR: • DEFORMITY AND/OR LIMITED MOTION THE GLOBAL UNITE REVERSE FRACTURE EPIPHYSEAL COMPONENT, IN CONJUNCTION WITH COMPONENTS FROM THE EXISTING DELTA XTEND™ REVERSE SHOULDER SYSTEM AND GLOBAL UNITE PLATFORM SHOULDER SYSTEM, IS INDICATED FOR USE IN A GROSSLY ROTATOR CUFF DEFICIENT GLENOHUMERAL JOINT WITH SEVERE ARTHROPATHY OR A PREVIOUSLY FAILED JOINT REPLACEMENT WITH A GROSS ROTATOR CUFF DEFICIENCY. THE PATIENT'S JOINT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE SELECTED IMPLANT(S), AND A FUNCTIONAL DELTOID MUSCLE IS NECESSARY TO USE THE DEVICE. IT IS INTENDED FOR CEMENTED OR UNCEMENTED REVERSE SHOULDER ARTHROPLASTY IN TREATMENT OF THE FOLLOWING: • FRACTURE OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY • IRREDUCIBLE 3- AND 4-PART FRACTURES OF THE PROXIMAL HUMERUS • UNUNITED HUMERAL HEAD FRACTURES THE GLOBAL UNITE REVERSE FRACTURE EPIPHYSEAL COMPONENT IS ONLY INTENDED FOR USE IN THE TREATMENT OF PROXIMAL HUMERAL FRACTURES. BONE PREPARATION INSTRUMENTATION HAS NOT BEEN DEVELOPED TO ACCOMMODATE ITS USE IN A NON-FRACTURE PRESS-FIT APPLICATION. GLOBAL UNITE HUMERAL STEMS, IN CONJUNCTION WITH EXISTING DELTA XTEND™ EPIPHYSEAL COMPONENTS, ARE INDICATED FOR USE IN REVERSE SHOULDER ARTHROPLASTY IN TREATMENT OF A GROSSLY DEFICIENT ROTATOR CUFF JOINT WITH SEVERE ARTHROPATHY OR A PREVIOUSLY FAILED JOINT REPLACEMENT WITH A GROSSLY DEFICIENT ROTATOR CUFF JOINT. THE PATIENT'S JOINT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE SELECTED IMPLANT(S), AND A FUNCTIONAL DELTOID MUSCLE IS NECESSARY TO USE THE DEVICE. WHEN USED IN A TOTAL SHOULDER ARTHROPLASTY, THE GLOBAL UNITE IMPLANTS ARE TO BE USED WITH DEPUY GLENOID COMPONENTS. THE GLENOID COMPONENTS ARE FOR CEMENTED USE ONLY. GLOBAL UNITE HUMERAL IMPLANTS ARE FOR CEMENTED OR UNCEMENTED USE. WHEN USED IN A REVERSE SHOULDER ARTHROPLASTY, THE GLOBAL UNITE AND DELTA XTEND HUMERAL IMPLANTS ARE TO BE USED WITH THE HA-COATED DELTA XTEND METAGLENE DEVICES. THE METAGLENE IMPLANTS ARE INTENDED FOR UNCEMENTED USE ONLY WITH ADDITIONAL SCREW FIXATION. THE HA-COATED DELTA XTEND

	HUMERAL IMPLANTS ARE INTENDED FOR UNCEMENTED USE ONLY. GLOBAL UNITE HUMERAL IMPLANTS ARE FOR CEMENTED OR UNCEMENTED USE.,KNEE REPLACEMENT SYSTEM- FEMORAL(SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE SYSTEM - ADAPTOR(ATTUNE REVISION)-TOTAL KNEE ARTHROPLASTY IS A TOTAL JOINT REPLACEMENT SURGERY DESIGNED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY DISABLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. TOTAL KNEE ARTHROPLASTY MAY INCLUDE SUPPLEMENTAL FIXATION THROUGH STEMS, SLEEVES, AND/OR MODULAR AUGMENTS WHERE BONE LOSS REQUIRES SAID FIXATION IN THE OPINION OF THE SURGEON. TOTAL KNEE ARTHROPLASTY MAY ALSO INCLUDE MORE CONSTRAINED BEARING SURFACES WHERE NECESSARY TO PROVIDE STABILITY WHERE MUSCULOLIGAMENTOUS SUPPORTING STRUCTURES ARE INSUFFICIENT.,SHOULDER SYSTEM- EPIPHYSEAL COMPONENT (GLOBAL UNITE)-THE GLOBAL UNITE PLATFORM SHOULDER SYSTEM IS INTENDED FOR CEMENTED OR UNCEMENTED TOTAL OR HEMISHOULDER ARTHROPLASTY IN TREATMENT OF THE FOLLOWING: • A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR

	RHEUMATOID ARTHRITIS • FRACTURE OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY • IRREDUCIBLE 3- AND 4-PART FRACTURES OF THE PROXIMAL HUMERUS • UNUNITED HUMERAL HEAD FRACTURES • AVASCULAR NECROSIS OF THE HUMERAL HEAD • OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT) HEMI-SHOULDER ARTHROPLASTY IS ALSO INDICATED FOR: • DEFORMITY AND/OR LIMITED MOTION GLOBAL UNITE HUMERAL STEMS, IN CONJUNCTION WITH EXISTING DELTA XTEND™ EPIPHYSEAL COMPONENTS, ARE INDICATED FOR USE IN REVERSE SHOULDER ARTHROPLASTY IN TREATMENT OF A GROSSLY DEFICIENT ROTATOR CUFF JOINT WITH SEVERE ARTHROPATHY OR A PREVIOUSLY FAILED JOINT REPLACEMENT WITH A GROSSLY DEFICIENT ROTATOR CUFF JOINT. THE PATIENT'S JOINT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE SELECTED IMPLANT(S), AND A FUNCTIONAL DELTOID MUSCLE IS NECESSARY TO USE THE DEVICE. WHEN USED IN A TOTAL SHOULDER ARTHROPLASTY, THE GLOBAL UNITE IMPLANTS ARE TO BE USED WITH DEPUY GLENOID COMPONENTS. THE GLENOID COMPONENTS ARE FOR CEMENTED USE ONLY. GLOBAL UNITE HUMERAL IMPLANTS ARE FOR CEMENTED OR UNCEMENTED USE.,SHOULDER SYSTEM (ANATOMIC BODY)(GLOBAL UNITE)-"THE GLOBAL UNITE PLATFORM SHOULDER SYSTEM IS INTENDED FOR CEMENTED OR UNCEMENTED TOTAL OR HEMISHOULDER ARTHROPLASTY IN TREATMENT OF THE FOLLOWING: • A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS • FRACTURE OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY • IRREDUCIBLE 3- AND 4-PART FRACTURES OF THE PROXIMAL HUMERUS • UNUNITED HUMERAL HEAD FRACTURES • AVASCULAR NECROSIS OF THE HUMERAL HEAD • OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT) HEMI-SHOULDER ARTHROPLASTY IS ALSO INDICATED FOR: • DEFORMITY AND/OR LIMITED MOTION GLOBAL UNITE HUMERAL STEMS, IN CONJUNCTION WITH EXISTING DELTA XTEND™ EPIPHYSEAL COMPONENTS, ARE INDICATED FOR USE IN REVERSE

	SHOULDER ARTHROPLASTY IN TREATMENT OF A GROSSLY DEFICIENT ROTATOR CUFF JOINT WITH SEVERE ARTHROPATHY OR A PREVIOUSLY FAILED JOINT REPLACEMENT WITH A GROSSLY DEFICIENT ROTATOR CUFF JOINT. THE PATIENT'S JOINT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE SELECTED IMPLANT(S), AND A FUNCTIONAL DELTOID MUSCLE IS NECESSARY TO USE THE DEVICE. WHEN USED IN A TOTAL SHOULDER ARTHROPLASTY, THE GLOBAL UNITE IMPLANTS ARE TO BE USED WITH DEPUY GLENOID COMPONENTS. THE GLENOID COMPONENTS ARE FOR CEMENTED USE ONLY. GLOBAL UNITE HUMERAL IMPLANTS ARE FOR CEMENTED OR UNCEMENTED USE. WHEN USED IN A REVERSE SHOULDER ARTHROPLASTY, THE GLOBAL UNITE AND DELTA XTEND HUMERAL IMPLANTS ARE TO BE USED WITH THE HA-COATED DELTA XTEND METAGLENE DEVICES. THE METAGLENE IMPLANTS ARE INTENDED FOR UNCEMENTED USE ONLY WITH ADDITIONAL SCREW FIXATION. THE HA-COATED DELTA XTEND HUMERAL IMPLANTS ARE INTENDED FOR UNCEMENTED USE ONLY. GLOBAL UNITE HUMERAL IMPLANTS ARE FOR CEMENTED OR UNCEMENTED USE." ,ORTHOPAEDIC IMPLANT- HEADS(PINNACLE HIP SYSTEM)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3. ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK. 4. FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5. CERTAIN CASES OF ANKYLOSIS.,KNEE SYSTEM-TIBIAL BASE (ATTUNE)-THE ROTATING PLATFORM (RP) TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE ROTATING PLATFORM PROSTHESIS IS INDICATED FOR PRIMARY TOTAL KNEE ARTHROPLASTY OR THE REVISION OF FAILED KNEE PROSTHESES. THE CR RP DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE POSTERIOR CRUCIATE LIGAMENT IS INTACT, ABSENT, OR IN SUCH CONDITION AS TO JUSTIFY ITS SACRIFICE.,KNEE SYSTEM- TIBIAL BASE (FB)(ATTUNE)-TOTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS

	WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,HIP SYSTEM (CORAIL (SHORT NECK))-CORAIL AMT HA COATED STEMS ARE INTENDED FOR USE IN TOTAL AND PARTIAL HIP ARTHROPLASTY. THE STEMS ARE INTENDED ONLY FOR UNCEMENTED USE.TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. PARTIAL HIP ARTHROPLASTY (HIP HEMIARTHROPLASTY) IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM , SHOULDER SYSTEM- STEM(GLOBAL UNITE)-THE GLOBAL UNITE PLATFORM SHOULDER SYSTEM IS INTENDED FOR CEMENTED OR UNCEMENTED TOTAL OR HEMISHOULDER ARTHROPLASTY IN TREATMENT OF THE FOLLOWING: • A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS • FRACTURE OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY • IRREDUCIBLE 3- AND 4-PART FRACTURES OF THE PROXIMAL HUMERUS • UNUNITED HUMERAL HEAD FRACTURES • AVASCULAR NECROSIS OF THE HUMERAL HEAD • OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT) HEMI-SHOULDER ARTHROPLASTY IS ALSO INDICATED FOR: • DEFORMITY AND/OR LIMITED MOTION GLOBAL UNITE HUMERAL STEMS, IN CONJUNCTION WITH EXISTING DELTA XTEND™ EPIPHYSEAL COMPONENTS, ARE INDICATED FOR USE IN REVERSE SHOULDER ARTHROPLASTY IN TREATMENT OF A GROSSLY DEFICIENT ROTATOR CUFF JOINT WITH SEVERE ARTHROPATHY OR A

	PREVIOUSLY FAILED JOINT REPLACEMENT WITH A GROSSLY DEFICIENT ROTATOR CUFF JOINT. THE PATIENT'S JOINT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE SELECTED IMPLANT(S), AND A FUNCTIONAL DELTOID MUSCLE IS NECESSARY TO USE THE DEVICE. WHEN USED IN A TOTAL SHOULDER ARTHROPLASTY, THE GLOBAL UNITE IMPLANTS ARE TO BE USED WITH DEPUY GLENOID COMPONENTS. THE GLENOID COMPONENTS ARE FOR CEMENTED USE ONLY. GLOBAL UNITE HUMERAL IMPLANTS ARE FOR CEMENTED OR UNCEMENTED USE.,SHOULDER SYSTEM-COLLAR(GLOBAL UNITE)-THE GLOBAL UNITE PLATFORM SHOULDER SYSTEM IS INTENDED FOR CEMENTED OR UNCEMENTED TOTAL OR HEMISHOULDER ARTHROPLASTY IN TREATMENT OF THE FOLLOWING: • A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS • FRACTURE OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY • IRREDUCIBLE 3- AND 4-PART FRACTURES OF THE PROXIMAL HUMERUS • UNUNITED HUMERAL HEAD FRACTURES • AVASCULAR NECROSIS OF THE HUMERAL HEAD • OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT) HEMI-SHOULDER ARTHROPLASTY IS ALSO INDICATED FOR: • DEFORMITY AND/OR LIMITED MOTION GLOBAL UNITE HUMERAL STEMS, IN CONJUNCTION WITH EXISTING DELTA XTEND™ EPIPHYSEAL COMPONENTS, ARE INDICATED FOR USE IN REVERSE SHOULDER ARTHROPLASTY IN TREATMENT OF A GROSSLY DEFICIENT ROTATOR CUFF JOINT WITH SEVERE ARTHROPATHY OR A PREVIOUSLY FAILED JOINT REPLACEMENT WITH A GROSSLY DEFICIENT ROTATOR CUFF JOINT. THE PATIENT'S JOINT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE SELECTED IMPLANT(S), AND A FUNCTIONAL DELTOID MUSCLE IS NECESSARY TO USE THE DEVICE. WHEN USED IN A TOTAL SHOULDER ARTHROPLASTY, THE GLOBAL UNITE IMPLANTS ARE TO BE USED WITH DEPUY GLENOID COMPONENTS. THE GLENOID COMPONENTS ARE FOR CEMENTED USE ONLY. GLOBAL UNITE HUMERAL IMPLANTS ARE FOR CEMENTED OR UNCEMENTED USE.,KNEE SYSTEM- INSERTS (FB)(ATTUNE)-TOTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL KNEE REPLACEMENT MAY

	BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE SYSTEM- TIBIAL BASE (RP)(ATTUNE)-THE ROTATING PLATFORM (RP) TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE ROTATING PLATFORM PROSTHESIS IS INDICATED FOR PRIMARY TOTAL KNEE ARTHROPLASTY OR THE REVISION OF FAILED KNEE PROSTHESES. THE CR RP DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE POSTERIOR CRUCIATE LIGAMENT IS INTACT, ABSENT, OR IN SUCH CONDITION AS TO JUSTIFY ITS SACRIFICE.,KNEE SYSTEM- INSERTS (RP)(ATTUNE)-THE ROTATING PLATFORM (RP) TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE ROTATING PLATFORM PROSTHESIS IS INDICATED FOR PRIMARY TOTAL KNEE ARTHROPLASTY OR THE REVISION OF FAILED KNEE PROSTHESES. THE CR RP DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE POSTERIOR CRUCIATE LIGAMENT IS INTACT, ABSENT, OR IN SUCH CONDITION AS TO JUSTIFY ITS SACRIFICE.,KNEE SYSTEM- PATELLA(ATTUNE)-TOTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE SYSTEM- FEMORAL(ATTUNE)-TOTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE

	SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.

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1392	IMP/MD/2018/000347	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MODULAR FEMORAL HEADS(ARTICUL/EZE)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM., MODULAR FEMORAL HEADS(S-ROM)-THE FEMORAL HEAD IS INDICATED FOR USE IN TOTAL OR PARTIAL HIP REPLACEMENT PROCEDURES FOR PATIENTS SUFFERING SEVERE PAIN AND DISABILITY DUE TO STRUCTURAL DAMAGE IN THE HIP JOINT FROM RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, POST TRAUMATIC ARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS AND NONUNION OF FEMORAL FRACTURES. USE OF THE PROSTHESIS IS ALSO INDICATED FOR PATIENTS WITH CONGENITAL HIP DYSPLASIA, PROTRUSIO ACETABULI, SLIPPED CAPITAL FEMORAL EPIPHYSIS AND DISABILITY DUE TO PREVIOUS FUSION, WHERE BONE STOCK IS INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES.,HIP PROSTHESIS(C-STEM)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.,HIP SYSTEM - CUPS(ELITE PLUS)-IT IS INDICATED FOR SEVERE ARTHROPATHY DUE TO ADVANCED RHEUMATOID OR OSTEO-ARTHRITIS WHERE CONSERVATIVE THERAPY OR ALTERNATIVE TREATMENTS HAVE FAILED OR ARE CONSIDERED UNSUITABLE, ARTHROPATHY DUE TO DEGENERATIVE DISEASE, ACUTE TRAUMA, AND A PREVIOUS FAILED JOINT REPLACEMENT. THE PATIENT'S JOINT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE SELECTED IMPLANT(S).,KNEE REPLACEMENT SYSTEM - FEMORAL(LCS)-WITH CEMENT: THE LCS® COMPLETE – PFC RP MOBILE BEARING TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION

	COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES. WITHOUT CEMENT: THE POROUS COATED COMPONENTS WITHIN THE LCS TOTAL KNEE SYSTEM ARE INDICATED FOR NONCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR RECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE ROTATING PLATFORM DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE ABSENT OR ARE IN SUCH CONDITION AS TO JUSTIFY THEIR SACRIFICE. THE PFC RP CURVED BEARINGS WHEN USED WITH THE PFC CRUCIATE RETAINING FEMORAL COMPONENT CAN BE USED IN POSTERIOR CRUCIATE LIGAMENT RETAINING PROCEDURES. IN ADDITION, TITANIUM ALLOY COMPONENTS, COATED WITH TITANIUM-NITRIDE ARE AVAILABLE AND MAY BE SELECTED WHERE PATIENT METAL SENSITIVITY TO CO-CR IS SUSPECTED.,KNEE REPLACEMENT SYSTEM- TIBIAL TRAY(LCS)-WITH CEMENT: THE LCS® COMPLETE – PFC RP MOBILE BEARING TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES. WITHOUT CEMENT: THE POROUS COATED COMPONENTS WITHIN THE LCS TOTAL KNEE SYSTEM ARE INDICATED FOR NONCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR RECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE ROTATING PLATFORM DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE ABSENT OR ARE IN SUCH CONDITION AS TO JUSTIFY THEIR SACRIFICE. THE PFC RP CURVED BEARINGS WHEN USED WITH THE PFC CRUCIATE RETAINING FEMORAL COMPONENT CAN BE USED IN POSTERIOR CRUCIATE LIGAMENT RETAINING PROCEDURES. IN ADDITION, TITANIUM ALLOY COMPONENTS, COATED WITH TITANIUM-NITRIDE ARE AVAILABLE AND MAY BE SELECTED WHERE PATIENT METAL SENSITIVITY TO CO-CR IS SUSPECTED.,HIP SYSTEM - HEADS (ELITE PLUS)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-

		HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.
1393	IMP/MD/2018/000348	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:UROLOGICAL RETRIEVAL COIL(STONECONE NITINOL UROLOGICAL RETRIEVAL COIL)-THE STONE CONE COIL IS INTENDED TO BE USED ENDOSCOPICALLY TO ENTRAP AND REMOVE CALCULI AND OTHER FOREIGN OBJECTS FROM THE URINARY TRACT.
1394	IMP/MD/2018/000349	1.License Holder Name: NK HEALTHCARE PVT.LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COLLAGEN MEMBRANE (CREOS XENOPROTECT)-THE CREOS XENOPROTECT IS A BIODEGRADABLE BARRIER MEMBRANE FOR USE IN GUIDED TISSUE REGENERATION (GTR) AND GUIDED BONE REGENERATION (GBR) PROCEDURES. IN THESE PROCEDURES, CREOS XENOPROTECT CAN BE USED AS A RESORBABLE MEMBRANE FOR THE CONTAINMENT OF BONE GRAFT IN BONE REPAIR PROCEDURES DURING TREATMENT OF PERIODONTAL BONE DEFECT (GTR) AND FOR BONE AUGMENTATION PROCEDURE (GBR).

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1395	IMP/MD/2018/000350	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIP REPLACEMENT SYSTEM-ACETABULAR SHELL/ CUPS(PINNACLE)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM. POROUS-COATED FEMORAL HIP STEMS AND METAL BACKED ACETABULAR CUP TOTAL HIP COMPONENTS ARE INDICATED FOR CEMENTLESS USE WITH FIXATION PROVIDED BY BIOLOGICAL TISSUE INGROWTH INTO THE POROUS COATING.,KNEE REPLACEMENT SYSTEM-FEMORAL(LCS COMPLETE)-WITH CEMENT: IT IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE RPF AND RPS INSERTS AND FEMORAL COMPONENTS ARE INDICATED WHERE A HIGHER THAN NORMAL DEGREE OF POST-OPERATIVE FLEXION IS REQUIRED. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES. WITHOUT CEMENT: THE POROUS COATED KEELED AND NON KEELED M.B.T.™ (MOBILE BEARING TIBIAL) TRAY CONFIGURATIONS OF THE LCS TOTAL KNEE SYSTEM ARE INDICATED FOR NONCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR ECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE ROTATING PLATFORM DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE ABSENT OR ARE IN SUCH CONDITION AS TO JUSTIFY THEIR SACRIFICE. THE P.F.C. SIGMA RP CURVED BEARINGS WHEN USED WITH THE P.F.C. SIGMA CRUCIATE RETAINING FEMORAL COMPONENT CAN BE USED IN POSTERIOR CRUCIATE LIGAMENT RETAINING PROCEDURES.,HIP REPLACEMENT SYSTEM-STEM(S-ROM)-IT IS INDICATED FOR USE IN TOTAL HIP REPLACEMENT PROCEDURES FOR PATIENTS SUFFERING SEVERE PAIN AND DISABILITY DUE TO STRUCTURAL DAMAGE IN THE HIP JOINT FROM RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS, AND NONUNION OF FEMORAL FRACTURES. USE OF THE PROSTHESIS IS

	ALSO INDICATED FOR REVISION OF PREVIOUS HIP ARTHROPLASTY AND FOR PATIENTS WITH CONGENITAL HIP DYSPLASIA, PROTRUSIO ACETABULI, SLIPPED CAPITAL FEMORAL EPIPHYSIS, AND DISABILITY DUE TO PREVIOUS FUSION. ZTT POROUS COATED PROXIMAL SLEEVES AND SPA POROUS COATED PROXIMAL SLEEVES ARE INTENDED FOR CEMENTLESS USE ONLY.,KNEE REPLACEMENT SYSTEM-TIBIAL INSERT (RP)(PFC SIGMA)-WITH CEMENT: IT IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE RPF AND RPS INSERTS AND FEMORAL COMPONENTS ARE INDICATED WHERE A HIGHER THAN NORMAL DEGREE OF POST-OPERATIVE FLEXION IS REQUIRED. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES. WITHOUT CEMENT: THE POROUS COATED KEELED AND NON KEELED M.B.T.™ (MOBILE BEARING TIBIAL) TRAY CONFIGURATIONS OF THE LCS TOTAL KNEE SYSTEM ARE INDICATED FOR NONCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR ECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE ROTATING PLATFORM DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE ABSENT OR ARE IN SUCH CONDITION AS TO JUSTIFY THEIR SACRIFICE. THE P.F.C. SIGMA RP CURVED BEARINGS WHEN USED WITH THE P.F.C. SIGMA CRUCIATE RETAINING FEMORAL COMPONENT CAN BE USED IN POSTERIOR CRUCIATE LIGAMENT RETAINING PROCEDURES.,KNEE REPLACEMENT SYSTEM-FEMORAL (10 YEARS) (SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-PATELLA(SIGMA)-THE P.F.C. AND P.F.C.

	MODULAR KNEE SYSTEM— PATELLA COMPONENTS ARE INDICATED FOR USE IN KNEE REPLACEMENTS FOR PATIENTS SUFFERING FROM SEVERE PAIN AND DISABILITY DUE TO PERMANENT STRUCTURAL DAMAGE IN THE KNEE JOINT FROM RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, COLLAGEN DISORDERS, OR PSEUDOGOUT. THIS DAMAGE MAY ALSO BE THE RESULT OF TRAUMA OR FAILED PRIOR SURGICAL INTERVENTION. THE P.F.C. AND P.F.C. MODULAR KNEE SYSTEM— PATELLA COMPONENTS ARE INDICATED FOR USE ONLY WITH PMMA BONE CEMENT.",KNEE REPLACEMENT SYSTEM-FEMORAL(PFC SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,HIP REPLACEMENT SYSTEM-SLEEVE(S-ROM)-IT IS INDICATED FOR USE IN TOTAL HIP REPLACEMENT PROCEDURES FOR PATIENTS SUFFERING SEVERE PAIN AND DISABILITY DUE TO STRUCTURAL DAMAGE IN THE HIP JOINT FROM RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS, AND NONUNION OF FEMORAL FRACTURES. USE OF THE PROSTHESIS IS ALSO INDICATED FOR REVISION OF PREVIOUS HIP ARTHROPLASTY AND FOR PATIENTS WITH CONGENITAL HIP DYSPLASIA, PROTRUSIO ACETABULI, SLIPPED CAPITAL FEMORAL EPIPHYSIS, AND DISABILITY DUE TO PREVIOUS FUSION. ZTT POROUS COATED PROXIMAL SLEEVES AND SPA POROUS COATED PROXIMAL SLEEVES ARE INTENDED FOR CEMENTLESS USE ONLY.,KNEE REPLACEMENT SYSTEM-PATELLA(PFC SIGMA)-THE P.F.C. AND P.F.C. MODULAR KNEE SYSTEM— PATELLA COMPONENTS ARE INDICATED FOR USE IN KNEE REPLACEMENTS FOR PATIENTS SUFFERING FROM SEVERE PAIN AND DISABILITY DUE TO PERMANENT STRUCTURAL DAMAGE IN THE KNEE JOINT FROM RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, COLLAGEN DISORDERS, OR PSEUDOGOUT. THIS DAMAGE MAY ALSO BE THE RESULT OF TRAUMA OR FAILED PRIOR SURGICAL INTERVENTION.

	THE P.F.C. AND P.F.C. MODULAR KNEE SYSTEM— PATELLA COMPONENTS ARE INDICATED FOR USE ONLY WITH PMMA BONE CEMENT.,KNEE REPLACEMENT SYSTEM-FEMORAL (5 YEARS)(SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-TIBIAL INSERT(PFC SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-TIBIAL TRAY(PFC SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED

	PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-TIBIAL TRAY(LCS COMPLETE)-WITH CEMENT: IT IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE RPF AND RPS INSERTS AND FEMORAL COMPONENTS ARE INDICATED WHERE A HIGHER THAN NORMAL DEGREE OF POST-OPERATIVE FLEXION IS REQUIRED. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES. WITHOUT CEMENT: THE POROUS COATED KEELED AND NON KEELED M.B.T.™ (MOBILE BEARING TIBIAL) TRAY CONFIGURATIONS OF THE LCS TOTAL KNEE SYSTEM ARE INDICATED FOR NONCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR ECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE ROTATING PLATFORM DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE ABSENT OR ARE IN SUCH CONDITION AS TO JUSTIFY THEIR SACRIFICE. THE P.F.C. SIGMA RP CURVED BEARINGS WHEN USED WITH THE P.F.C. SIGMA CRUCIATE RETAINING FEMORAL COMPONENT CAN BE USED IN POSTERIOR CRUCIATE LIGAMENT RETAINING PROCEDURES.,KNEE REPLACEMENT SYSTEM - TIBIAL TRAY (COCR)(PFC SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.

1396	IMP/MD/2018/000356	1.License Holder Name: SMITHS MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PRESSURE MONITORING KITS(LOGICAL PRESSURE TRANSDUCERS)-THE SMITHS MEDICAL LOGICAL® PRESSURE TRANSDUCER IS A HEMODYNAMIC PRESSURE MONITORING SYSTEM THAT IS INTENDED FOR BLOOD PRESSURE MONITORING AND BLOOD SAMPLING.,EPIDURAL CATHETERS (PORTEX)-A RANGE OF STERILE, SINGLE USE PACKS CONTAINING A VARIETY OF COMPONENTS FOR THE PLACEMENT OF AN EPIDURAL CATHETER INTO THE EPIDURAL SPACE TO ALLOW BOLUS INJECTIONS OR CONTINUOUS INFUSION OF LOCAL ANAESTHETIC OR OTHER DRUGS FOR PAIN RELIEF. THE RANGE IS AVAILABLE WITH A CHOICE OF COLOUR CODED 16G AND 18G EPIDURAL NEEDLES, CLEAR OR RADIOOPAQUE, CLOSED END, 3-LATERAL EYE AND CLOSER THREE EYE (CTE) OR OPEN END FORMED NYLON EPIDURAL CATHETERS. CONSULT PRODUCT LITERATURE FOR DETAILS/CODE NUMBERS. THE PAEDIATRIC 18G MINIPACK SYSTEM 1 (100/391/180) CONTAINS A PAEDIATRIC LENGTH (50MM) GRADUATED EPIDURAL TUOHY NEEDLE AND 18G EPIDURAL CATHETER (650MM). THE MINIPACK SYSTEM 1 (100/391/516-518) CONTAINS AN EXTRA LENGTH EPIDURAL TUOHY NEEDLE (110MM). THE 16G AND 18G EPIDURAL CATHETERS IN SYSTEM 3 PACKS ARE INTENDED FOR INTRODUCTION THROUGH 16G AND 18G EPIDURAL TUOHY NEEDLES RESPECTIVELY, PERCUTANEOUS TRACHEOSTOMY KIT(PORTEX BLUELINE ULTRA TRACHEOSTOMY KIT)-THE PERCUTANEOUS TRACHEOSTOMY TECHNIQUE IS A NEW, MINIMALLY INVASIVE PROCEDURE WHICH OFFERS AN EASIER, MORE RAPID METHOD OF INSERTION OF A TRACHEOSTOMY TUBE THAN CONVENTIONAL OPEN SURGICAL TECHNIQUES. IT ALSO HAS THE ADVANTAGE IN THAT IT CAN BE PERFORMED AT THE BEDSIDE.,TRACHEOSTOMY TUBES(BLUE LINE ULTRA)-A STERILE RANGE OF SINGLE USE TRACHEOSTOMY TUBES MANUFACTURED FROM CLEAR BIOCOMPATIBLE POLYVINYL CHLORIDE (PVC) INCORPORATING THE FOLLOWING FEATURES: SMOOTH ARC SHAPED DESIGN WITH TAPERED TIP TO ASSIST PLACEMENT AND REMOVAL OF BOTH TRACHEOSTOMY TUBE AND SMOOTH INNER CANNULA WITH MINIMAL DISRUPTION TO PATIENT'S ANATOMY. THERMOSENSITIVE MATERIAL WITH SUFFICIENT INITIAL RIGIDITY FOR INSERTION WHICH THEN CONFORMS TO THE INDIVIDUAL PATIENT'S UPPER RESPIRATORY TRACT AT BODY TEMPERATURE ENSURING MINIMUM TRAUMA. 15MM CONNECTOR FOR CONNECTION TO ANAESTHETIC OR VENTILATOR BREATHING CIRCUIT IS LOCATED ON THE TUBE NOT THE INNER CANNULA. ANATOMICALLY SHAPED FLEXIBLE FLANGE FOR IMPROVED PATIENT COMFORT AND IMPROVED SECURITY OF THE TRACHEOSTOMY TUBE.

		NEW PROFILE® SOFT-SEAL® CUFF DESIGN WITH REDUCED BULK AND SMOOTH TRANSITION TO TRACHEOSTOMY TUBE TO IMPROVE EASE OF INSERTION. A HOLLOW OBTURATOR WITH ATRAUMATIC TIP FOR USE WITH OR WITHOUT GUIDE WIRE FOR IMPROVED EASE OF INSERTION. THE OBTURATOR RETAINING CLIPS PREVENT OBTURATOR MOVEMENT DURING INSERTION. THE REUSABLE FENESTRATED AND NON FENESTRATED INNER CANNULAE ARE COLOUR CODED FOR EASE OF IDENTIFICATION. FENESTRATED INNER CANNULAE ARE COLOURED RED. NON FENESTRATED INNER CANNULAE ARE CLEAR. THEY CAN BE EASILY INSERTED AND REMOVED FROM THE OUTER TUBE WITH A “RING PULL”. SELF-ADHESIVE ‘PATIENT NOTES LABEL’ PROVIDING TRACHEOSTOMY TUBE SIZE AND MANUFACTURING BATCH DETAILS. TRACHEOSTOMY FLANGE TAG’ PROVIDES TRACHEOSTOMY TUBE SIZE DETAILS AND INDICATING IF THE TUBE IS FENESTRATED.
1397	IMP/MD/2018/000357	1.License Holder Name: KCI MEDICAL INDIA PRIVATE LIMITED ,K. NO. 2606/115 (P. NO. 60/16) GROUND FLOOR, HUSKUR ROAD ELECTRONIC POST ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560100 , INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NON-ADHERENT ANTIMICROBIAL DRESSING WITH SILVER(SILVERCEL® NON-ADHERENT HYDRO-ALGINATE ANTIMICROBIAL DRESSING / PACKING WITH SILVER)-SILVERCEL® NON-ADHERENT HYDRO-ALGINATE ANTIMICROBIAL DRESSING / PACKING WITH SILVER IS INTENDED FOR USE IN THE MANAGEMENT OF ALL MODERATE TO HEAVILY EXUDING PARTIAL AND FULL-THICKNESS CHRONIC AND ACUTE WOUNDS INCLUDING: DECUBITUS (PRESSURE) ULCERS,VENOUS ULCERS, DIABETIC ULCERS, DONOR SITES, TRAUMATIC AND SURGICAL WOUNDS.,ANTIMICROBIAL WOUND DRESSING WITH SILVER (SILVERCEL® HYDRO-ALGINATE ANTIMICROBIAL DRESSING / PACKING WITH SILVER)-SILVERCEL® HYDRO-ALGINATE ANTIMICROBIAL DRESSING / PACKING WITH SILVER IS INTENDED FOR USE IN THE MANAGEMENT OF ALL MODERATE TO HEAVILY EXUDING PARTIAL AND FULL-THICKNESS CHRONIC WOUNDS INCLUDING: DECUBITUS (PRESSURE) ULCERS, VENOUS ULCERS, DIABETIC ULCERS, DONOR SITES, TRAUMATIC AND SURGICAL WOUNDS

1398	IMP/MD/2018/000358	1.License Holder Name: ZYDUS HEALTHCARE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:20.0 MG/ML STERILE VISCOELASTIC SODIUM HYALURONATE GEL FOR INTRA-ARTICULAR INJECTION(HYLASTO-S)-THE VISCOELASTIC SOLUTION IS DESIGNED TO BE INJECTED INTRA-ARTICULARLY (KNEE, HIP AND SMALLER JOINTS SUCH AS FINGERS, TOES, ANKLE, SHOULDER, ELBOW, TEMPORO-MANDIBULAR, ETC.) AS VISCOSUPPLEMENTATION IN THE TREATMENT OF OSTEOARTHRITIS. IT IS INDICATED TO REDUCE PAIN AND RESTRICTED MOBILITY DUE TO DEGENERATIVE AND TRAUMATIC CHANGES IN SYNOVIAL JOINTS.
1399	IMP/MD/2018/000359	1.License Holder Name: HALYARD HEALTH INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROCUFF* ENDOTRACHEAL TUBE FOR PEDIATRICS, ORAL/NASAL MAGILL (HALYARD*)-HALYARD* MICROCUFF* ENDOTRACHEAL TUBES ARE INDICATED FOR AIRWAY MANAGEMENT BY NASAL OR ORAL INTUBATION OF THE TRACHEA IN PEDIATRIC AND ADULT PATIENTS., MICROCUFF* ENDOTRACHEAL TUBE FOR PEDIATRICS, ORAL CURVED (HALYARD*)-HALYARD* MICROCUFF* ENDOTRACHEAL TUBES ARE INCICATED FOR AIRWAY MANAGEMENT BY NASAL OR ORAL INTUBATION OF THE TRACHEA IN PEDIATRIC AND ADULT PATIENTS., MICROCUFF* ENDOTRACHEAL TUBE FOR ADULTS, ORAL/NASAL MAGILL(HALYARD*)-HALYARD* MICROCUFF* ENDOTRACHEAL TUBES ARE INCICATED FOR AIRWAY MANAGEMENT BY NASAL OR ORAL INTUBATION OF THE TRACHEA IN PEDIATRIC AND ADULT PATIENTS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1400	IMP/MD/2018/000360	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOTRACHEAL TUBE (RUSCH LASERTUBE (RUBBER))-TRACHEAL INTUBATION DURING LASER SURGERY IN THE LARYNGEAL AREA. THE TUBE IS RESISTANT TO THE FOLLOWING KINDS OF LASER: AR+LASER, ND/YAG LASER, CO2 LASERS (CONTINUOUS-WAVE OR PULSED) WITH A WAVE LENGTH RANGING FROM 0.488 M TO 10.6 M.,EMERGENCY CONIOTOMY SET CUFFED(RUSCH TRACHEOQUICK PLUS)-RISK OF SUFFOCATION. EMERGENCY CONIOTOMY SET TO SECURE THE RESPIRATORY TRACT IN EMERGENCY SITUATIONS, WHERE THE UPPER RESPIRATORY TRACT IS OBSTRUCTED AND AN INTUBATION HAS BEEN UNSUCCESSFULLY ATTEMPTED OR A TRACHEOTOMY CANNOT BE PERFORMED SAFELY AND QUICKLY ENOUGH. ,BLADDER CATHETER(RUSCH PVC CATHETER TIEMANN PATTERN)-THESE CATHETERS ARE INDICATED FOR THE ROUTINE DRAINAGE OF URINE FROM THE BLADDER. THESE CATHETERS ARE NOT INTENDED OR DESIGNED FOR INDWELLING USE.,EMERGENCY CONIOTOMY SET (RUSCH TRACHEOQUICK)-DANGER OF ASPHYXIATION. OBSTRUCTION OF UPPER AIRWAYS IN EMERGENCY SITUATIONS WHERE AN INTUBATION ATTEMPT WAS UNSUCCESSFUL OR TRACHEOTOMY CANNOT BE PERFORMED SAFELY OR QUICKLY ENOUGH. , REPLACEMENT DILATOR(RUSCH POLYURETHANE)-THESE DILATORS ARE INDICATED FOR THE ROUTINE DILATION OF THE URETER OR URETERIC ORIFICES.,URETER DILATOR SET(RUSCH POLYURETHANE)-THESE DILATORS ARE INDICATED FOR THE ROUTINE DILATION OF THE URETER OR URETERIC ORIFICES.,INTUBATION AID/TUBE EXCHANGER(RUSCH ENDOGUIDE T PVC)-FOR TRACHEAL INTUBATION AND FOR CHANGING TRACHEAL TUBES AND TRACHEOSTOMY TUBES.,INTUBATION AID(RUSCH PVC)-INTUBATION AID,NASOPHARYNGEAL AIRWAY(RUSCH RUBBER)-IT IS INTENDED AS A TYPE OF AIRWAY ADJUNCT THAT IS DESIGNED TO BE INSERTED INTO THE NASAL PASSAGEWAY - TO SECURE A PATENT AIRWAY; - TRUMPET AS AN ALTERNATIVE TO ORAL AIRWAYS (GUEDEL) - AS A SUCTION AID - TO MINIMIZE THE TRAUMA FOR TRANSNASAL FIBEROPTIC BRONCHOSCOPY - AS AN ADJUNCT TO SURGERY IN THE THROAT.

1401	IMP/MD/2018/000361	1.License Holder Name: NIPRO MEDICAL (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDE EXTENSION CATHETER(GUIDEPLUS II)-THIS DEVICE IS INSERTED INTO CORONARY ARTERIES AND USED TO GUIDE INTERVENTIONAL DEVICES, ETC. TO AFFECTED AREAS IN CORONARY ARTERIES DURING PROCEDURES SUCH AS PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY. NOTABLY, THIS PRODUCT IS PLACED IN FRONT OF AFFECTED AREAS THAT ARE DIFFICULT FOR INTERVENTIONAL DEVICES TO REACH, AND THEN USED TO SUPPORT AN INTERVENTIONAL DEVICE,
1402	IMP/MD/2018/000361	1.License Holder Name: NIPRO MEDICAL (INDIA) PRIVATE LIMITED , 2ND FLOOR, GMR AERO TOWER, NEAR RAJIV GANDHI AIRPORT, MAMIDIPALLY VILLAGE, BALAPUR MANDAL, RANGA REDDY DIST, MAMIDPALLY(V), BALAPUR(M), RANGA REDDY(DIST.) ,RANGA REDDY TELANGANA ,501218 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BUTTONHOLE DEVICE (BIOHOLE)-IT IS USED TO FORM A "BUTTON HOLE" (A FIXED POSITION PUNCTURE TUNNEL) FOR CONNECTION TO HEMODIALYSIS EQUIPMENT.,THROMBUS VACUUM ASPIRATION CATHETER(TVAC II)-IT IS INTENDED FOR THE REMOVAL OF A THROMBUS IN AN ARTERY (PARTICULARLY THE CORONARY ARTERY BYPASS SURGERY VESSEL) BY ASPIRATION ON PATIENTS WITH THROMBOSIS UNSTABLE ANGINA OR ACUTE MYOCARDIAL INFARCTION AND REVASCULARIZATION.,THROMBUS VACUUM ASPIRATION CATHETER (TVAC)-IT IS INTENDED FOR THE REMOVAL OF A THROMBUS IN AN ARTERY (PARTICULARLY THE CORONARY ARTERY BYPASS SURGERY VESSEL) BY ASPIRATION ON PATIENTS WITH THROMBOSIS UNSTABLE ANGINA OR ACUTE MYOCARDIAL INFARCTION AND REVASCULARIZATION.
1403	IMP/MD/2018/000362	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EMBRYO TRANSFER CATHETER(LABOTECT)-THE EMBRYO TRANSFER CATHETER SET IS USED FOR TRANSVAGINAL TRANSFER OF EMBRYOS INTO THE UTERUS DURING IVF-PROCEDURES

1404	IMP/MD/2018/000363	1.License Holder Name: L&K BIOMED INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINAL FIXATION SYSTEM (LNK, OPENLOC-L)-LNK SPINAL FIXATION SYSTEM/ OPENLOC-L SPINAL FIXATION SYSTEM IS NON-CERVICAL SPINAL FIXATION DEVICES INTENDED FOR USE AS POSTERIOR PEDICLE SCREW FIXATION SYSTEMS (T1-S2/ILIUM), OR AS AN ANTEROLATERAL FIXATION SYSTEM (T8-L5). ALL COMPONENTS IN THE SYSTEM ARE LIMITED TO SKELETALLY MATURE PATIENTS. THESE DEVICES ARE INDICATED AS AN ADJUNCT TO FUSION FOR ALL OF THE FOLLOWING INDICATIONS REGARDLESS OF THE INTENDED USE: • DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); • SPONDYLOLISTHESIS; • TRAUMA (I.E. FRACTURE OR DISLOCATION); • DEFORMITIES OR CURVATURES (I.E. SCOLIOSIS, KYPHOSIS AND/OR LORDOSIS); • TUMOR; • STENOSOS AND • FAILEDPREVIOUS FUSION (PSEUDOARTHROSIS) THE LNK SPINAL FIXATION SYSTEM/ OPENLOC-L SPINAL FIXATION SYSTEM IS A PEDICLE SCREW SYSTEM INDICATED FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADE 3 AND 4) OF THE L5-S1 VERTEBRA IN SKELETALLY MATURE PATIENTS RECEIVING FUSION BY AUTOGENOUS BONE GRAFT HAVING IMPLANTS ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 TO SACRUM) WITH REMOVAL OF THE IMPLANTS AFTER THE ATTAINMENT OF A SOLID FUSION. IN ADDITION, THE LNK SPINAL FIXATION SYSTEM/ OPENLOC-L SPINAL FIXATION SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE: DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, FRACTURE, DISLOCATION, SCOLIOSIS, KYPHOSIS, SPINAL TUMOR AND FAILED PREVIOUS FUSION (PSEUDARTHROSIS).,POSTERIOR CERVICAL FIXATION SYSTEM(LNK, CASTLELOCS)-THE LNK/CASTLELOCS POSTERIOR CERVICAL FIXATION SYSTEM IS INDICATED FOR THE FOLLOWING: DDD (NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC AS CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES) SPONDYLOLISTHESIS SPINAL STENOSIS FRACTURE/DISLOCATION FAILED PREVIOUS FUSION TUMORS THE IMPLANTS ARE INTENDED TO PROVIDE STABILIZATION AS AN ADJUNCT TO FUSION WHEN USED WITH AUTOGENOUS BONE GRAFT OR ALLOGRAFT FOLLOWING THE REDUCTION OF FRACTURES/DISLOCATIONS OR TRAUMA IN THE SPINE. HOOKS AND RODS ARE ALSO INTENDED TO PROVIDE

	STABILIZATION TO PROMOTE FUSION FOLLOWING REDUCTION OF FRACTURE/DISLOCATION OR TRAUMA IN THE CERVICAL/UPPER THORACIC (C1 –T3) SPINE.,MIS SPINAL FIXATION SYSTEM(LNK, PATHLOC-L)-LNK/ PATHLOCL MIS SPINAL SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. LNK MIS SPINAL SYSTEM CAN BE USED IN AN OPEN APPROACH AND A PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION. LNK/ PATHLOCL MIS SPINAL SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND FOR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION, THE LNK/ PATHLOCL MIS SPINAL SYSTEM ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND FOR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS.,LUMBER INTERBODY FUSION CAGE SYSTEM(LNK)-LNK LUMBAR INTERBODY FUSION CAGE SYSTEM IS INDICATED FOR INTERVERTEBRAL BODY FUSION PROCEDURES IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTIGUOUS LEVELS FROM L2S1. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES. THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVEL(S). THIS DEVICE IS TO BE USED WITH AUTOGENOUS BONE GRAFT. LNK LUMBAR INTERBODY FUSION CAGE SYSTEM IS TO BE USED WITH SUPPLEMENTAL FIXATION. PATIENTS SHOULD HAVE AT LEAST SIX (6) MONTHS OF NONOPERATIVE TREATMENT PRIOR TO TREATMENT WITH AN INTERVERTEBRAL CAGE.,CERVICAL INTERBODY FUSION CAGE SYSTEM(LNK, CASTLELOCC)-LNK/CASTLELOCC CERVICAL INTERBODY FUSION

	CAGE SYSTEM IS INDICATED FOR USE IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) OF THE CERVICAL SPINE WITH ACCOMPANYING RADICULAR SYMPTOMS AT ONE DISC LEVEL. DDD IS DEFINED AS DISOGENIC PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES. LNK/CASTLELOCC CERVICAL INTERBODY FUSION CAGE SYSTEM IS USED TO FACILITATE INTERBODY FUSION IN THE CERVICAL SPINE AT THE C3 TO C7 DISC LEVELS USING AUTOGRAFT BONE. LNK/CASTLELOCC CERVICAL INTERBODY FUSION CAGE SYSTEM IS TO BE USED WITH SUPPLEMENTAL FIXATION. PATIENTS SHOULD HAVE AT LEAST SIX (6) WEEKS OF NON OPERATIVE TREATMENT PRIOR TO TREATMENT WITH AN INTERVERTEBRAL CAGE.,ANTERIOR CERVICAL PLATE SYSTEM (CASTLELOC-P, LNK)-INTENDED FOR ANTERIOR SCREW FIXATION TO THE CERVICAL SPINE (C2 C7). THE SYSTEM IS INDICATED FOR USE IN THE IMMOBILIZATION AND STABILIZATION OF THE SPINE AS AN ADJUNCT TO FUSIONS IN PATIENTS WITH: DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), • SPONDYLOLISTHESIS, • TRAUMA (I.E. FRACTURES OR DISLOCATIONS), • TUMORS, • DEFORMITY (DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS), • PSEUDOARTHROSIS, • FAILED PREVIOUS FUSION, • SPINAL STENOSIS.

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1405	IMP/MD/2018/000365	1.License Holder Name: CARL ZEISS INDIA (BANGALORE) PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:POSTERIOR CHAMBER INTRAOCULAR LENSES (PSEUDOPHAKIC)(AT LISA 809 M, AT LISA TORIC 909 M, AT LISA 801, AT LISA 809 MP, AT LISA TRI 839 MP, AT LISA TORIC 909 MP, AT LARA 829 MP)-THE LENS IS INTENDED TO CORRECT APHAKIA. THE LENS IS INTENDED FOR SENILE CATARACTS AND OTHER FORMS OF CATARACT AND TO BE PLACED IN CAPSULAR BAG. TORIC LENSES ARE INTENDED FOR THE CORRECTION OF REGULAR CORNEAL ASTIGMATISM. EXTENDED RANGE OF INDICATIONS FOR MULTIFOCAL IOLS (TYPE LISA): PRESBYOPIA CORRECTION IN PATIENTS WITH OR WITHOUT CATARACT (PRELEX OR CLEAR LENS EXCHANGE).TYPE LARA THE LENS IS INDICATED FOR IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN PATIENTS WITH OR WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC PATIENTS.,POSTERIOR CHAMBER INTRAOCULAR LENS (PSEUDOPHAKIC)(CT SPHERIS 204, CT SPHERIS 209 M, CT ASPHINA 409 M, CT ASPHINA 509 M, CT ASPHINA 404, AT TORBI 709 M, CT ASPHINA 409 MP, CT ASPHINA 509 MP, AT TORBI 709MP)-THE LENS IS INTENDED TO CORRECT APHAKIA. THE LENS IS INTENDED FOR SENILE CATARACTS AND OTHER FORMS OF CATARACT AND TO BE PLACED IN THE CAPSULAR BAG. EXTENDED RANGE OF INDICATIONS FOR MULTIFOCAL IOLS (TYPE LISA): PRESBYOPIA CORRECTION IN PATIENTS WITH OR WITHOUR CATARACT (PRELEX OR CLEAR LENS EXCHANGE). TORIC LENSES ARE INTENDED FOR THE CORRECTION OF REGULAR CORNEAL ASTIGMATISM.

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1406	IMP/MD/2018/000366	1.License Holder Name: MICROPORT SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA BALLOON CATHETER(FIREFIGHTER NC)-BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION; BALLOON DILATATION OF A STENT AFTER IMPLANTATION.,RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM(FIREHAWK LIBERTY)-THE FIREHAWK LIBERTYTM RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM (FIREHAWK LIBERTY RTECSS) IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO DE NOVO NATIVE CORONARY ARTERY LESIONS LENGTH 60 MM WITH REFERENCE VESSEL DIAMETERS OF 2.25 TO 4.0 MM.

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1407	IMP/MD/2018/000366	1.License Holder Name: MICROPORT SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA BALLOON CATHETER(FOXTROT PRO PTCA BALLOON CATHETER)-FOXTROT PRO IS INDICATED FOR BALLOON PRE-DILATATION OF THE STENOTIC ATHEROSCLEROTIC LESIONS IN PATIENTS WITH FOLLOWING CORONARY ARTERY DISEASES: ANGINA PECTORIS (STABLE OR UNSTABLE); MYOCARDIAL INFARCTION (ACUTE OR CHRONIC); ONE OR MORE STENOSIS IN ONE VESSEL; MULTI-VESSEL STENOSIS AND DISTAL VESSEL STENOSIS; CORONARY ARTERY RE-STENOSIS AFTER CORONARY ARTERY BYPASS GRAFT (CABG); CORONARY ARTERY RE-STENOSIS AFTER PTCA; PROTECTED LEFT MAIN CORONARY ARTERY STENOSIS.,PTCA BALLOON CATHETER(FOXTROT NC PTCA BALLOON CATHETER)-BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION; BALLOON DILATATION OF A STENT AFTER IMPLANTATION.,PTCA BALLOON CATHETER(FIREFIGHTER PTCA BALLOON CATHETER)-FIREFIGHTER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION IN PATIENTS WITH FOLLOWING CORONARY ARTERY DISEASES: ANGINA PECTORIS (STABLE OR UNSTABLE); MYOCARDIAL INFARCTION (ACUTE OR CHRONIC); ONE OR MORE STENOSIS IN ONE VESSEL; MULTI-VESSEL STENOSIS AND DISTAL VESSEL STENOSIS; CORONARY ARTERY RE-STENOSIS AFTER CORONARY ARTERY BYPASS GRAFT (CABG); CORONARY ARTERY RE-STENOSIS AFTER PTCA; CORONARY ARTERY RE-STENOSIS AFTER PTCA.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

1408	IMP/MD/2018/000366	1.License Holder Name: MICROPORT SCIENTIFIC INDIA PVT. LTD., , SHOP NO. 9, KAMLA PALACE, CIVIL LINE, BARFKHANA ,GURGAON HARYANA ,122001 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TARGET ELUTING CORONARY STENT SYSTEM(FIREHAWKTM RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM)-THE FIREHAWKTM RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO DE NOVO NATIVE CORONARY ARTERY LESIONS LENGTH 60 MM WITH REFERENCE VESSEL DIAMETERS OF 2.25 TO 4.0 MM.,RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM(FIREHAWK LIBERTY)-THE FIREHAWK LIBERTYTM RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM (FIREHAWK LIBERTY RTECSS) IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO DE NOVO NATIVE CORONARY ARTERY LESIONS LENGTH 60 MM WITH REFERENCE VESSEL DIAMETERS OF 2.25 TO 4.0 MM.
1409	IMP/MD/2018/000367	1.License Holder Name: M/S MERIT MEDICAL SYSTEMS INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EMBOLIZATION MICROSPHERES(EMBOSPHERE MICROSPHERES IN VIAL)-EMBOSPHERE MICROSPHERES ARE INDICATED FOR USE IN THE EMBOLIZATION OF ARTERIOVENOUS MALFORMATIONS, HYPERVASCULAR TUMORS AND SYMPTOMATIC UTERINE FIBROIDS., EMBOLIZATION MICROSPHERES(HEPASPHERE EMBOLIZATION MICROSPHERES)-HEPASPHERE MICROSPHERES ARE INDICATED FOR USE IN THE EMBOLIZATION OF BLOOD VESSELS WITH OR WITHOUT DELIVERY OF DOXORUBICIN HCI FOR THERAPEUTIC OR PRE-OPERATIVE PURPOSES IN THE FOLLOWING PROCEDURES: • EMBOLIZATION OF HEPATOCELLULAR CARCINOMA • EMBOLIZATION OF METASTASES TO THE LIVER

1410	IMP/MD/2018/000368	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRANSURETHRAL CATHETERS(RUSCH)-THESE CATHETERS ARE INDICATED FOR ROUTINE TRANSURETHRAL DRAINAGE OF THE BLADDER OR FOR ROUTINE POST-OPERATIVE TRANSURETHRAL DRAINAGE AND IRRIGATION OF THE BLADDER.,TRANSURETHRAL CATHETERS (RUSCH)-THESE CATHETERS ARE INDICATED FOR ROUTINE TRANSURETHRAL DRAINAGE OF THE BLADDER OR FOR ROUTINE POST-OPERATIVE TRANSURETHRAL DRAINAGE AND IRRIGATION OF THE BLADDER.,ENDOTRACHEAL TUBES AND ACCESSORIES(RUSCH RUSCHFLEX)-RUSCH TRACHEAL TUBES ARE INDICATED FOR ORAL OR NASAL INTUBATION FOR AIRWAY MANAGEMENT. REINFORCED TRACHEAL TUBES MAY BE USED TO REDUCE THE POTENTIAL FOR KINKING WHEREVER UNUSUAL POSITIONING OF THE HEAD AND NECK IS REQUIRED FOLLOWING INTUBATION.,ENDOTRACHEAL TUBES AND ACCESSORIES(RUSCH RUSCHELIT)-RUSCH TRACHEAL TUBES ARE INDICATED FOR ORAL OR NASAL INTUBATION FOR AIRWAY MANAGEMENT. REINFORCED TRACHEAL TUBES MAY BE USED TO REDUCE THE POTENTIAL FOR KINKING WHEREVER UNUSUAL POSITIONING OF THE HEAD AND NECK IS REQUIRED FOLLOWING INTUBATION.,HEAT AND MOISTURE EXCHANGER(GIBECK)-HUMID-VENT FILTER PEDI IS A COMBINED HEAT AND MOISTURE EXCHANGER (HME) AND BACTERIAL/VIRAL FILTER FOR HUMIDIFICATION AND BACTERIAL/VIRAL FILTRATION DURING ANESTHESIA AND INTENSIVE CARE. IT REDUCES HYPOTHERMIA AND POST-OPERATIVE SHIVERING AS WELL AS THE RISK OF BACTERIAL/VIRAL CONTAMINATION.,HEAT AND MOISTURE EXCHANGER(GIBECK)-HUMID-VENT ARE HEAT AND MOISTURE EXCHANGER (HME) FOR HUMIDIFICATION DURING ANAESTHESIA AND VENTILATOR CARE. IT REDUCES HYPOTHERMIA AND POSTOPERATIVE SHIVERING. EXPERT CLINICAL JUDGEMENT MUST BE USED IN ASSESSING THE PATIENT'S HUMIDIFICATION REQUIREMENTS.,TRANSURETHRAL CATHETERS(NA)-THIS CATHETER PLUS URINE BAG SYSTEM IS INDICATED FOR ROUTINE CONTINUOUS DRAINAGE OF THE BLADDER.,HEAT AND MOISTURE EXCHANGER (GIBECK)-HUMID-VENT MICRO+ IS A HEAT AND MOISTURE EXCHANGER (HME) FOR HUMIDIFICATION DURING ANAESTHESIA AND INTENSIVE CARE. HUMID-VENT MICRO+ IS DESIGNED FOR EASY SUCTIONING OF THE PATIENT.,TRANSURETHRAL CATHETERS(NA)-INTERMITTENT CATHETERISATION (E.G. NEUROGENIC BLADDER DYSFUNCTION). THIS PRODUCT IS USED FOR INTERMITTENT CATHETERIZATION. THE PRODUCT IS A FLEXIBLE TUBULAR DEVICE THAT IS INSERTED INTO THE URETHRA TO PASS FLUIDS TO AND FROM THE URINARY TRACT.,TRANSURETHRAL CATHETERS(NA)-

	INTERMITTENT CATHETERISATION (E.G. NEUROGENIC BLADDER DYSFUNCTION). THIS PRODUCT IS USED FOR INTERMITTENT CATHETERIZATION. THE PRODUCT IS A FLEXIBLE TUBULAR DEVICE THAT IS INSERTED INTO THE URETHRA TO PASS FLUIDS TO AND FROM THE URINARY TRACT.,BREATHING CIRCUITS(GIBECK)-HUMID-VENT FILTERS (HMEF) ARE COMBINED HEAT AND MOISTURE EXCHANGER (HME) AND BACTERIAL/VIRAL FILTER FOR HUMIDIFICATION AND BACTERIAL/VIRAL FILTRATION DURING ANAESTHESIA AND VENTILATOR CARE. EXPERT CLINICAL JUDGEMENT MUST BE USED IN ASSESSING THE PATIENT'S HUMIDIFICATION REQUIREMENTS.,INTERMITTENT CATHETERS (RUSCH)-THIS PRODUCT IS USED FOR INTERMITTENT CATHETERIZATION.,ENDOTRACHEAL TUBE(RUSCH)-THE INTUBATING STYLET IS INTENDED FOR USE IN FACILITATING INTUBATION OF TRACHEAL TUBES. APPLICABILITY OF STYLET SIZE TO TRACHEAL TUBE.,TRANSURETHRAL CATHETERS(NA)-INTERMITTENT CATHETERISATION (E.G. NEUROGENIC BLADDER DYSFUNCTION). THIS PRODUCT IS USED FOR INTERMITTENT CATHETERIZATION. THE PRODUCT IS A FLEXIBLE TUBULAR DEVICE THAT IS INSERTED INTO THE URETHRA TO PASS FLUIDS TO AND FROM THE URINARY TRACT., TRANSURETHRAL CATHETERS(RUSCH)-THIS CATHETER PLUS URINE BAG SYSTEM IS INDICATED FOR ROUTINE CONTINUOUS DRAINAGE OF THE BLADDER.,TRANSURETHRAL CATHETERS(RUSCH)-THESE CATHETERS ARE INDICATED FOR ROUTINE TRANSURETHRAL DRAINAGE OF THE BLADDER OR FOR ROUTINE POST-OPERATIVE TRANSURETHRAL DRAINAGE AND IRRIGATION OF THE BLADDER., TRANSURETHRAL CATHETERS(RUSCH)-THESE CATHETERS ARE INDICATED FOR ROUTINE TRANSURETHRAL DRAINAGE OF THE BLADDER OR FOR ROUTINE POST-OPERATIVE TRANSURETHRAL DRAINAGE AND IRRIGATION OF THE BLADDER.,HEAT AND MOISTURE EXCHANGER(GIBECK)-THE HUMIDIFICATION SYSTEM, WITH OR WITHOUT OXYGEN SUPPLY, FOR TRACHEOSTOMIZED OR INTUBATED SPONTANEOUSLY BREATHING PATIENTS,BREATHING CIRCUITS (GIBECK)-BACTERIAL/VIRAL FILTERS FOR USE IN BREATHING SYSTEMS FOR THE PROTECTION OF THE PATIENT AND EQUIPMENT., TRANSURETHRAL CATHETERS(NA)-INTERMITTENT CATHETERISATION (E.G. NEUROGENIC BLADDER DYSFUNCTION). THIS PRODUCT IS USED FOR INTERMITTENT CATHETERIZATION. THE PRODUCT IS A FLEXIBLE TUBULAR DEVICE THAT IS INSERTED INTO THE URETHRA TO PASS FLUIDS TO AND FROM THE URINARY TRACT., TRANSURETHRAL CATHETERS(NA)-INTERMITTENT CATHETERISATION (E.G. NEUROGENIC BLADDER DYSFUNCTION). THIS PRODUCT IS USED FOR INTERMITTENT CATHETERIZATION. THE PRODUCT IS A FLEXIBLE TUBULAR DEVICE THAT IS INSERTED INTO

	THE URETHRA TO PASS FLUIDS TO AND FROM THE URINARY TRACT., TRACHEOSTOMY TUBE(RUSCH)-FOR AIRWAY MANAGEMENT OF TRACHEOSTOMIZED PATIENTS.,NASOPHARYNGEAL AIRWAY(RUSCH GOLD®)-TO PROVIDE A PATENT AIRWAY FOR A PATIENT WITH A BLOCKAGE OR POTENTIAL BLOCKAGE OF THE NASAL CAVITY OR NASOPHARYNX.,NASOPHARYNGEAL AIRWAY(RUSCH)-TO PROVIDE A PATENT AIRWAY FOR A PATIENT WITH A BLOCKAGE OR POTENTIAL BLOCKAGE OF THE NASAL CAVITY OR NASOPHARYNX., TRANSURETHRAL CATHETERS(RUSCH)-THESE CATHETERS ARE USED TO PASS FLUID TO AND FROM THE URINARY TRACT.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1411	IMP/MD/2018/000369	1.License Holder Name: M/S ZIMMER INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VERSANAIL NAILING SYSTEM(VERSANAIL - SCREWS)-IT IS INTENDED FOR BONE FIXATION IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERIES,SHOULDER FIXATION SYSTEM: SHOULDER NAIL PLATING SYSTEM(S3 SHOULDER NAIL PLATING SYSTEM - PEGS)-IT IS INTENDED FOR FRACTURES AND FRACTURE DISLOCATIONS, OSTEOTOMIES AND NON-UNIONS OF THE PROXIMAL HUMERUS., DISTAL RADIUS SYSTEM: DISTAL VOLAR RADIUS ANATOMICAL SYSTEM(DVR - PEGS)-IT IS INTENDED FOR THE FIXATION OF FRACTURES AND OSTEOTOMIES INVOLVING THE DISTAL RADIUS, FRACTURE REPAIR SYSTEM: PLATING(POLYAX - SCREWS)-IT IS INTENDED FOR USE IN CASES REQUIRING STABILIZATION OF MALUNIONS, NON-UNIONS, AND OSTEOTOMIES OF THE DISTAL FEMUR AND PROXIMAL TIBIA AND OPEN REDUCTION INTERNAL FIXATION (ORIF) REPAIR OF CLOSED AND OPEN FRACTURES OF THE DISTAL FEMUR AND PROXIMAL TIBIA,FRACTURE REPAIR SYSTEM: PLATING(POLYAX - PLATES)-IT IS INTENDED FOR USE IN CASES REQUIRING STABILIZATION OF MALUNIONS, NON-UNIONS, AND OSTEOTOMIES OF THE DISTAL FEMUR AND PROXIMAL TIBIA AND OPEN REDUCTION INTERNAL FIXATION (ORIF) REPAIR OF CLOSED AND OPEN FRACTURES OF THE DISTAL FEMUR AND PROXIMAL TIBIA, VERSANAIL NAILING SYSTEM(VERSANAIL - SCREWS)-IT IS INTENDED FOR BONE FIXATION IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERIES.,SHOULDER FIXATION SYSTEM: SHOULDER NAIL PLATING SYSTEM(S3 SHOULDER NAIL PLATING SYSTEM -PLATES)-IT IS INTENDED FOR FRACTURES AND FRACTURE DISLOCATIONS, OSTEOTOMIES AND NON-UNIONS OF THE PROXIMAL HUMERUS.,SHOULDER FIXATION SYSTEM: SHOULDER NAIL PLATING SYSTEM(S3 SHOULDER NAIL PLATING SYSTEM - SCREWS)-IT IS INTENDED FOR FRACTURES AND FRACTURE DISLOCATIONS, OSTEOTOMIES AND NON-UNIONS OF THE PROXIMAL HUMERUS., DISTAL RADIUS SYSTEM: FRAGMENT PLATE SYSTEM(F3 - PEGS)-IT IS INTENDED FOR ESSENTIALLY FOR NON-LOAD BEARING STABILIZATION AND FIXATION OF SMALL BONE FRAGMENTS IN FRESH FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF SMALL BONES OF THE HAND , FOOT, WRIST, ANKLE, HUMERUS, SCAPULA, FINGER, TOE, PELVIS AND CRANIOMAXILLOFACIAL SKELETON.,DISTAL RADIUS SYSTEM: DORSAL NAIL PLATING SYSTEM(DNP - PLATES)-IT IS INTENDED FOR THE FIXATION OF FRACTURES AND OSTEOTOMIES INVOLVING THE DISTAL RADIUS,DISTAL RADIUS SYSTEM: DORSAL NAIL PLATING SYSTEM(DNP - SCREWS)-IT IS INTENDED FOR THE FIXATION OF

	FRACTURES AND OSTEOTOMIES INVOLVING THE DISTAL RADIUS, DISTAL RADIUS SYSTEM: FRAGMENT PLATE SYSTEM (F3 - PLATES)-IT IS INTENDED FOR ESSENTIALLY FOR NON-LOAD BEARING STABILIZATION AND FIXATION OF SMALL BONE FRAGMENTS IN FRESH FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF SMALL BONES OF THE HAND , FOOT, WRIST, ANKLE, HUMERUS, SCAPULA, FINGER, TOE, PELVIS AND CRANIOMAXILLOFACIAL SKELETON.,DISTAL RADIUS SYSTEM: DORSAL NAIL PLATING SYSTEM(DNP - PEGS)-IT IS INTENDED FOR THE FIXATION OF FRACTURES AND OSTEOTOMIES INVOLVING THE DISTAL RADIUS,VERSANAIL NAILING SYSTEM(VERSANAIL - END CAPS)-IT IS INTENDED FOR BONE FIXATION IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERIES.,VERSANAIL NAILING SYSTEM(VERSANAIL - NAILS)-IT IS INTENDED FOR BONE FIXATION IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERIES.,FRACTURE REPAIR SYSTEM(AFFIXUS HIP FRACTURE NAIL SYSTEM - SCREWS)-IT IS INTENDED FOR BONE FIXATION IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERIES, FRACTURE REPAIR SYSTEM (AFFIXUS HIP FRACTURE NAIL SYSTEM - NAILS)-IT IS INTENDED FOR BONE FIXATION IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERIES,FRACTURE REPAIR SYSTEM(AFFIXUS HIP FRACTURE NAIL SYSTEM - END CAPS)-IT IS INTENDED FOR BONE FIXATION IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERIES,DISTAL RADIUS SYSTEM: DISTAL VOLAR RADIUS ANATOMICAL SYSTEM(DVR - SCREWS)-IT IS INTENDED FOR THE FIXATION OF FRACTURES AND OSTEOTOMIES INVOLVING THE DISTAL RADIUS,DISTAL RADIUS SYSTEM: DISTAL VOLAR RADIUS ANATOMICAL SYSTEM(DVR - PLATES)-IT IS INTENDED FOR THE FIXATION OF FRACTURES AND OSTEOTOMIES INVOLVING THE DISTAL RADIUS,TRAUMA FIXATION DEVICES(A.L.P.S. LARGE FRAGMENT PLATING SYSTEM – WASHERS)-THE SYSTEM IS INTENDED FOR FIXATION OF VARIOUS LONG BONES, SUCH AS THE HUMERUS, FEMUR AND TIBIA. IT IS ALSO FOR USE IN FIXATION OF OSTEOPENIC BONE AND FIXATION AND STABILIZATION OF NON-UNIONS, MALUNIONS AND OSTEOTOMIES.,TRAUMA FIXATION DEVICES(A.L.P.S. LARGE FRAGMENT PLATING SYSTEM – SCREWS)-THE SYSTEM IS INTENDED FOR FIXATION OF VARIOUS LONG BONES, SUCH AS THE HUMERUS, FEMUR AND TIBIA. IT IS ALSO FOR USE IN FIXATION OF OSTEOPENIC BONE AND FIXATION AND STABILIZATION OF NON-UNIONS, MALUNIONS AND OSTEOTOMIES.,TRAUMA FIXATION DEVICES(A.L.P.S. LARGE FRAGMENT PLATING SYSTEM – PLATES)-THE SYSTEM IS INTENDED FOR FIXATION OF VARIOUS LONG BONES, SUCH AS THE HUMERUS, FEMUR AND TIBIA. IT IS ALSO FOR USE IN FIXATION OF OSTEOPENIC BONE AND FIXATION AND STABILIZATION

	OF NON-UNIONS, MALUNIONS AND OSTEOTOMIES.,TRAUMA FIXATION DEVICES(DVR CROSSLOCK DISTAL RADIUS PLATING SYSTEM – PEGS)-THE SYSTEM IS INTENDED FOR FIXATION OF FRACTURES, MALUNIONS AND OSTEOTOMIES INVOLVING THE DISTAL RADIUS,TRAUMA FIXATION DEVICES(DVR CROSSLOCK DISTAL RADIUS PLATING SYSTEM – SCREWS)-THE SYSTEM IS INTENDED FOR FIXATION OF FRACTURES, MALUNIONS AND OSTEOTOMIES INVOLVING THE DISTAL RADIUS,TRAUMA FIXATION DEVICES(DVR CROSSLOCK DISTAL RADIUS PLATING SYSTEM – SCREWS,)-THE SYSTEM IS INTENDED FOR FIXATION OF FRACTURES, MALUNIONS AND OSTEOTOMIES INVOLVING THE DISTAL RADIUS,TRAUMA FIXATION DEVICES(DVR CROSSLOCK DISTAL RADIUS PLATING SYSTEM – PLATES)-THE SYSTEM IS INTENDED FOR FIXATION OF FRACTURES, MALUNIONS AND OSTEOTOMIES INVOLVING THE DISTAL RADIUS

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	TALUS 2. FAILED TOTAL ANKLE ARTHROPLASTY 3. TRAUMA (MALUNITED TIBIAL PILON FRACTURE) 4. SEVERE DEFORMITY OR INSTABILITY AS A RESULT OF TALIPES EQUINOVARUS, CEREBRAL VASCULAR ACCIDENT, PARALYSIS OR OTHER NEUROMUSCULAR DISEASE 5. REVISION ANKLE ARTHRODESIS 6. NEUROARTHROPATHY 7. RHEUMATOID ARTHRITIS 8. OSTEOARTHRITIS 9. PSEUDOARTHROSIS 10. POST-TRAUMATIC ARTHROSIS 11. PREVIOUSLY INFECTED ARTHROSIS 12. CHARCOT FOOT 13. SEVERE ENDSTAGE DEGENERATIVE ARTHRITIS 14. SEVERE DEFECTS AFTER TUMOR RESECTION 15. PANTALAR ARTHRODESIS,INTRAMEDULLARY FIXATION DEVICES(PHOENIX ANKLE NAIL SYSTEM- NAIL)-THE PHOENIX ANKLE ARTHRODESIS NAIL SYSTEM IS INDICATED FOR TIBIOTALOCALCANEAL ARTHRODESIS (FUSION). SPECIFIC INDICATIONS INCLUDE: 1. AVASCULAR NECROSIS OF THE TALUS 2. FAILED TOTAL ANKLE ARTHROPLASTY 3. TRAUMA (MALUNITED TIBIAL PILON FRACTURE) 4. SEVERE DEFORMITY OR INSTABILITY AS A RESULT OF TALIPES EQUINOVARUS, CEREBRAL VASCULAR ACCIDENT, PARALYSIS OR OTHER NEUROMUSCULAR DISEASE 5. REVISION ANKLE ARTHRODESIS 6. NEUROARTHROPATHY 7. RHEUMATOID ARTHRITIS 8. OSTEOARTHRITIS 9. PSEUDOARTHROSIS 10. POST-TRAUMATIC ARTHROSIS 11. PREVIOUSLY INFECTED ARTHROSIS 12. CHARCOT FOOT 13. SEVERE ENDSTAGE DEGENERATIVE ARTHRITIS 14. SEVERE DEFECTS AFTER TUMOR RESECTION 15. PANTALAR ARTHRODESIS,TRAUMA FIXATION DEVICES(ALPS PROXIMAL HUMERUS PLATING SYSTEM- PEGS)-THE BIOMET PROXIMAL HUMERAL PLATING SYSTEM IS INDICATED FOR FIXATION OF FRACTURES AND FRACTURE DISLOCATIONS, FUSIONS, OSTEOTOMIES AND NON-UNIONS OF THE HUMERUS, PARTICULARLY IN OSTEOPENIC BONE. PATIENT SELECTION FACTORS TO BE CONSIDERED INCLUDE: 1. NEED FOR ALIGNMENT AND STABILIZATION OF BONE FRACTURES 2. ABILITY AND WILLINGNESS OF THE PATIENT TO FOLLOW POSTOPERATIVE CARE INSTRUCTIONS UNTIL HEALING IS COMPLETE 3. A GOOD NUTRITIONAL STATE OF THE PATIENT., INTRAMEDULLARY FIXATION DEVICES(PHOENIX ANKLE NAIL SYSTEM- END CAPS)-THE PHOENIX ANKLE ARTHRODESIS NAIL SYSTEM IS INDICATED FOR TIBIOTALOCALCANEAL ARTHRODESIS (FUSION). SPECIFIC INDICATIONS INCLUDE: 1. AVASCULAR NECROSIS OF THE TALUS 2. FAILED TOTAL ANKLE ARTHROPLASTY 3. TRAUMA (MALUNITED TIBIAL PILON FRACTURE) 4. SEVERE DEFORMITY OR INSTABILITY AS A RESULT OF TALIPES EQUINOVARUS, CEREBRAL VASCULAR ACCIDENT, PARALYSIS OR OTHER NEUROMUSCULAR DISEASE 5. REVISION ANKLE ARTHRODESIS 6. NEUROARTHROPATHY 7. RHEUMATOID ARTHRITIS 8. OSTEOARTHRITIS 9. PSEUDOARTHROSIS 10. POST-TRAUMATIC ARTHROSIS 11.

	PREVIOUSLY INFECTED ARTHROSIS 12. CHARCOT FOOT 13. SEVERE ENDSTAGE DEGENERATIVE ARTHRITIS 14. SEVERE DEFECTS AFTER TUMOR RESECTION 15. PANTALAR ARTHRODESIS,TRAUMA FIXATION DEVICES(ALPS SMALL FRAGMENT PLATING SYSTEM- WIRE & PIN)- THE SMALL FRAGMENT LOCKING PLATING SYSTEM IS INTENDED FOR FIXATION OF FRACTURES, OSTEOTOMIES AND NON-UNIONS OF THE CLAVICLE, SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, DISTAL TIBIA, FIBULA, PARTICULARLY IN OSTEOPENIC BONE., TRAUMA FIXATION DEVICES(ALPS PROXIMAL TIBIA PLATING SYSTEM- PLATES)-INTENDED FOR TREATMENT OF NONUIONS, OSTEOTOMIES, MALUNIONS, OSTEOPENIC BONE AND FRACTURES OF THE PROXIMAL TIBIA, INCLUDING SIMPLE, COMMINUTED, LATERAL WEDGE, DEPRESSION, MEDIAL WEDGE, BICONDYLAR COMBINATION OF LATERAL WEDGE AND DEPRESSION, PERIPROSTHETIC AND FRACTURES WITH ASSOCIATED SHAFT FRACTURES.,TRAUMA FIXATION DEVICES(TITANIUM SCREWS-STERILE)-THE USE OF METALLIC SURGICAL APPLIANCES PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF BONE FIXATION AND HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERIES. THESE IMPLANTS ARE INTENDED AS A GUIDE TO NORMAL HEALING, AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURE OR BEAR THE WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING. DELAYED UNIONS OR NONUNIONS IN THE PRESENCE OF LOAD BEARING OR WEIGHT BEARING MIGHT EVENTUALLY CAUSE THE IMPLANT TO BREAK DUE TO METAL FATIGUE. ALL METAL SURGICAL IMPLANTS ARE SUBJECTED TO REPEATED STRESS IN USE WHICH CAN RESULT IN METAL FATIGUE.,TRAUMA FIXATION DEVICES(ALPS PROXIMAL HUMERUS PLATING SYSTEM- PLATES)-THE BIOMET PROXIMAL HUMERAL PLATING SYSTEM IS INDICATED FOR FIXATION OF FRACTURES AND FRACTURE DISLOCATIONS, FUSIONS, OSTEOTOMIES AND NON-UNIONS OF THE HUMERUS, PARTICULARLY IN OSTEOPENIC BONE. PATIENT SELECTION FACTORS TO BE CONSIDERED INCLUDE: 1. NEED FOR ALIGNMENT AND STABILIZATION OF BONE FRACTURES 2. ABILITY AND WILLINGNESS OF THE PATIENT TO FOLLOW POSTOPERATIVE CARE INSTRUCTIONS UNTIL HEALING IS COMPLETE 3. A GOOD NUTRITIONAL STATE OF THE PATIENT.,TRAUMA FIXATION DEVICES(ALPS TOTAL FOOT SYSTEM- PLATES)-THE A.L.P.S TOTAL FOOT SYSTEM INTENDED FOR USE IN STABILIZATION AND FIXATION OF FRACTURES, REVISION PROCEDURES, FUSIONS, RECONSTRUCTIONS (OSTEOTOMY) AND NON-UNIONS OF THE BONES OF THE HAND, FOOT, WRIST, ANKLE, FINGER, TOE, HUMERUS, OLECRANON, CLAVICLE, SCAPULA AND PELVIS, PARTICULARLY IN OSTEOPENIC BONE. THE SYSTEM CAN BE USED IN BOTH ADULT AND

	PEDIATRIC PATIENTS (ADOLESCENTS [>12-21 YEARS OF AGE]), WHERE THE IMPLANT WOULD NOT CROSS OPEN EPIPHYSEAL PLATES IN SKELETALLY IMMATURE PATIENTS.,TRAUMA FIXATION DEVICES (ALPS SMALL FRAGMENT PLATING SYSTEM- WASHER)-THE SMALL FRAGMENT LOCKING PLATING SYSTEM IS INTENDED FOR FIXATION OF FRACTURES, OSTEOTOMIES AND NON-UNIONS OF THE CLAVICLE, SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, DISTAL TIBIA, FIBULA, PARTICULARLY IN OSTEOPENIC BONE.,TRAUMA FIXATION DEVICES(ALPS TOTAL FOOT SYSTEM- WASHER)-THE A.L.P. S TOTAL FOOT SYSTEM INTENDED FOR USE IN STABILIZATION AND FIXATION OF FRACTURES, REVISION PROCEDURES, FUSIONS, RECONSTRUCTIONS (OSTEOTOMY) AND NON-UNIONS OF THE BONES OF THE HAND, FOOT, WRIST, ANKLE, FINGER, TOE, HUMERUS, OLECRANON, CLAVICLE, SCAPULA AND PELVIS, PARTICULARLY IN OSTEOPENIC BONE. THE SYSTEM CAN BE USED IN BOTH ADULT AND PEDIATRIC PATIENTS (ADOLESCENTS [>12-21 YEARS OF AGE]), WHERE THE IMPLANT WOULD NOT CROSS OPEN EPIPHYSEAL PLATES IN SKELETALLY IMMATURE PATIENTS.,TRAUMA FIXATION DEVICES (TITANIUM SCREWS- NON-STERILE)-THE USE OF METALLIC SURGICAL APPLIANCES PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF BONE FIXATION AND HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERIES. THESE IMPLANTS ARE INTENDED AS A GUIDE TO NORMAL HEALING, AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURE OR BEAR THE WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING. DELAYED UNIONS OR NONUNIONS IN THE PRESENCE OF LOAD BEARING OR WEIGHT BEARING MIGHT EVENTUALLY CAUSE THE IMPLANT TO BREAK DUE TO METAL FATIGUE. ALL METAL SURGICAL IMPLANTS ARE SUBJECTED TO REPEATED STRESS IN USE WHICH CAN RESULT IN METAL FATIGUE.,TRAUMA FIXATION DEVICES (COCR SCREWS (MULTIDIRECTIONAL)- STERILE)-THE USE OF METALLIC SURGICAL APPLIANCES PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF BONE FIXATION AND HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERIES. THESE IMPLANTS ARE INTENDED AS A GUIDE TO NORMAL HEALING, AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURE OR BEAR THE WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING. DELAYED UNIONS OR NONUNIONS IN THE PRESENCE OF LOAD BEARING OR WEIGHT BEARING MIGHT EVENTUALLY CAUSE THE IMPLANT TO BREAK DUE TO METAL FATIGUE. ALL METAL SURGICAL IMPLANTS ARE SUBJECTED TO REPEATED STRESS IN USE WHICH CAN RESULT IN METAL FATIGUE.,TRAUMA FIXATION DEVICES(ALPS SMALL FRAGMENT PLATING SYSTEM- PLATE)-THE SMALL FRAGMENT

	LOCKING PLATING SYSTEM IS INTENDED FOR FIXATION OF FRACTURES, OSTEOTOMIES AND NON-UNIONS OF THE CLAVICLE, SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, DISTAL TIBIA, FIBULA, PARTICULARLY IN OSTEOPENIC BONE. THE TUBLAR PLATES ARE INDICATED FOR FRACTURE FIXATION OF THE FIBULA, LATERAL MALLEOLUS, METATARSALS, METACARPALS, OLECRANON, DISTAL HUMERUS, HUMERAL HEAD, RADIUS, ULNA AND INTRA-ARTICULAR DISTAL TIBIA. THE SPIDER PLATES ARE INDICATED FOR FIXATION OF METAPHYSEAL FRACTURES OF THE DISTAL TIBIA, PROXIMAL METAPHYSEAL TIBIA FRACTURES AND PROXIMAL HUMERAL HEAD/SHAFT FRACTURES.,TRAUMA FIXATION DEVICES (BIOMET CANNULATED SCREW SYSTEM- SCREWS)-SMALL CANNULATED SCREWS (4.0MM AND SMALLER DIAMETER) ARE INTENDED FOR USE IN: 1. FIXATION OF SMALL BONES, INCLUDING THOSE IN THE FOOT, PATELLA, ANKLE, WRIST AND ELBOW. 2. ARTHRODESIS OF THE FOOT, WRIST AND ELBOW. 3. SMALL AND LONG BONE OSTEOTOMIES. 4. FRACTURE FIXATION OF SMALL BONES, SMALL BONE FRAGMENTS AND LONG BONES. LARGE CANNULATED SCREWS (5MM AND LARGER IN DIAMETER) ARE INTENDED FOR USE IN: 1. FIXATION OF FRACTURES IN LONG BONES AND LONG BONE FRAGMENTS. 2. LONG BONE OSTEOTOMIES (FEMUR, TIBIA, FOOT, ANKLE, OLECRANON). 3. ARTHRODESIS AND FRACTURE FIXATION OF THE FOOT AND ANKLE, SUCH AS JONES FRACTURES OF THE FIFTH METATARSAL, AND CALCANEAL FRACTURES. LARGE CANNULATED SCREWS (6.5MM AND LARGER IN DIAMETER) ARE INTENDED FOR USE IN: 1. SLIPPED CAPITAL FEMORAL EPIPHYSIS 2. PEDIATRIC FEMORAL NECK FRACTURES 3. TIBIAL PLATEAU FRACTURES 4. SI JOINT DISRUPTIONS 5. INTERCONDYLAR FEMUR FRACTURES 6. SUBTALAR ARTHRODESIS 7. FIXATION OF PELVIS AND ILIOSACRAL JOINT., TRAUMA FIXATION DEVICES(ALPS DISTAL TIBIA PLATING SYSTEM-PLATES (STERILE))-THE MEDIAL LOCKING PLATE IS INDICATED FOR: • PILON FRACTURES, DISTAL INTRA- ARTICULAR FRACTURES • HIGH MEDIAL MALLEOLAR FRACTURES • LOW BOOT TYPES ROTATIONAL DISTAL EXTRA-ARTICULAR SHAFT FRACTURES WHILE THE ANTEROLATERAL LOCKING PLATE IS INDICATED FOR: • DISTAL INTRA-ARTICULAR TIBIA FRACTURES • PROXIMAL TIBIA FRACTURES • PROXIMAL AND DISTAL HUMERUS FRACTURES,TRAUMA FIXATION DEVICES(ALPS DISTAL TIBIA PLATING SYSTEM- PLATES)-THE MEDIAL LOCKING PLATE IS INDICATED FOR: • PILON FRACTURES, DISTAL INTRA- ARTICULAR FRACTURES • HIGH MEDIAL MALLEOLAR FRACTURES • LOW BOOT TYPES ROTATIONAL DISTAL EXTRA-ARTICULAR SHAFT FRACTURES WHILE THE ANTEROLATERAL LOCKING PLATE IS INDICATED FOR: • DISTAL INTRA-ARTICULAR TIBIA FRACTURES • PROXIMAL TIBIA FRACTURES • PROXIMAL AND

		DISTAL HUMERUS FRACTURES
1413	IMP/MD/2018/000370	1.License Holder Name: BLUE NEEM MEDICAL DEVICES PRIVATE LIMITED ,PLOT NOS 270 & 271, ROAD NO 5, HAROHALLI INDUSTRIAL AREA, II PHASE, KANAKAPURA TALUK ,RAMANAGARA KARNATAKA , 562112 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URETERAL STENT SYSTEM(ANTEGRADE URETERAL STENT SYSTEM (URS) WITH ANCHOR AND RETROGRADE URETERAL STENT (URS) SYSTEM WITH AND WITHOUT ANCHOR)-ALLIUM URETERAL STENTS ARE INDICATED FOR USE IN MALIGNANT OR BENIGN URETERAL OCCLUSIONS NECESSITATING LONG-TERM OR CHRONIC URETERAL STENTING (I.E. PATIENTS INDICATED FOR INSERTING DOUBLE J STENTS FOR 6 MONTHS OR LONGER): - PELVIC MALIGNANCIES COMPRESSING THE URETER - NON-OPERABLE, OCCLUDING, PRIMARY OR INFILTRATIVE URETERAL MALIGNANCIES - URETERO-INTESTINAL ANASTOMOTIC OF THE URETER.,URETHRAL STENT SYSTEM(TRIANGULAR PROSTATIC URETHRAL STENT (TPS) SYSTEM)-MANAGEMENT OF BLADDER OUTLET OBSTRUCTIONS (BOO) IN THE FOLLOWING CASES: - PROSTATIC ENLARGEMENT (BENIGN OR MALIGNANT) - AFTER MINIMALLY INVASIVE TREATMENTS (MIT) BASED ON THERMAL TISSUE DAMAGE. - AFTER INTERSTITIAL IRRADIATION (MIT) FOR PROSTATE CANCER, THIS MAY CAUSE POST-PROCEDURAL TEMPORARY EDEMA AND SEVERE VOIDING DIFFICULTIES OR URINE RETENTION.,URETHRAL STENT SYSTEM(ROUND POSTERIOR URETHRAL STENT (RPS) SYSTEM)-MANAGEMENT OF BLADDER OUTLET OBSTRUCTIONS (BOO) CAUSED BY:- - PROSTRATE SURGERY - RADICAL PROSTATECTOMY AND CYSTO-PROSTATECTOMY - POSTERIOR URETERAL STRICTURES,URETHRAL STENT SYSTEM (BULBAR URETHRAL STENT (BUS) SYSTEM)-MANAGEMENT OF BLADDER OUTLET OBSTRUCTIONS (BOO) CAUSED BY BULBAR URETHRAL STRICTURES

1414	IMP/MD/2018/000371	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTICOLOR ANTIBODY REAGENT(BD FACS COUNT CD4 REAGENT KIT)-BD FACS COUNT CD4 REAGENT KIT (CAT#339010) IS USED TO ENUMERATE THE ABSOLUTE COUNTS OF CD4 T LYMPHOCYTES AND DETERMINE THE PERCENTAGE OF LYMPHOCYTES THAT ARE CD4 T LYMPHOCYTES IN UNLYSED WHOLE BLOOD (CD4 COUNTS AND CD4 PERCENTAGES). THE REAGENTS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE ON A BD FACSCOUNT™ INSTRUMENT.,MULTICOLOR ANTIBODIES REAGENT (1. BD TRITEST CD3/CD4/CD45; 2. BD TRITEST CD3 FITC/CD4 PE/CD45 PERCP REAGENT 50 TESTS; 3. BD TRITEST CD3 FITC/CD4 PE/CD45 PERCP REAGENT 50 TESTS + TRUCOUNT TUBES)-BD TRITEST CD3/CD4/CD45 (CAT#340383) IS A THREE COLOR DIRECT IMMUNOFLUORESCENCE REAGENT FOR USE WITH A SUITABLY EQUIPPED FLOW CYTOMETER TO IDENTIFY AND DETERMINE THE PERCENTAGES AND ABSOLUTE COUNTS OF MATURE HUMAN T LYMPHOCYTES (CD3+) AND HELPER/INDUCER(CD3+CD4+) T LYMPHOCYTE SUBSETS IN ERYTHROCYTE-LYSED WHOLE BLOOD. WHEN USED WITH BD TRUCOUNT™ TUBES, ABSOLUTE COUNTS OF THESE POPULATIONS CAN BE ENUMERATED FROM A SINGLE TUBE. THIS BD TRITEST REAGENT AND BD TRUCOUNT TUBES CAN BE USED WITH THE BD FACS™ LOADER. THE REAGENT CAN BE USED WITH OR WITHOUT AN ISOTYPE CONTROL. BD TRITEST CD3 FITC/CD4 PE/CD45 PERCP REAGENT 50 TESTS (CAT#342413) IS USED TO IDENTIFY AND DETERMINE THE PERCENTAGES AND ABSOLUTE COUNTS OF MATURE HUMAN T LYMPHOCYTES (CD3+) AND HELPER/INDUCER (CD3+CD4+) T-LYMPHOCYTE SUBSETS IN ERYTHROCYTE-LYSED WHOLE BLOOD BD TRITEST CD3 FITC/CD4 PE/CD45 PERCP REAGENT 50 TESTS + TRUCOUNT TUBES (CAT#342444) IS USED TO IDENTIFY AND DETERMINE THE PERCENTAGES AND ABSOLUTE COUNTS OF MATURE HUMAN T LYMPHOCYTES (CD3+) AND HELPER/INDUCER (CD3+CD4+) T-LYMPHOCYTE SUBSETS IN ERYTHROCYTE-LYSED WHOLE BLOOD.,MULTICOLOR ANTIBODIES REAGENT(BD TRITEST CD3/CD16+CD56/CD45)-BD TRITEST CD3/CD16+CD56/CD45 (CAT#340300) IS A THREE-COLOR DIRECT IMMUNOFLUORESCENCE REAGENT FOR USE WITH A SUITABLY EQUIPPED FLOW CYTOMETER TO IDENTIFY AND DETERMINE THE PERCENTAGES AND ABSOLUTE COUNTS OF MATURE HUMAN T LYMPHOCYTES (CD3+) AND NATURAL KILLER (NK) (CD3–CD16+CD56+) LYMPHOCYTE SUBSETS IN ERYTHROCYTE-LYSED WHOLE BLOOD. WHEN USED WITH TRUCOUNT™ TUBES, ABSOLUTE COUNTS OF THESE POPULATIONS CAN BE ENUMERATED FROM A SINGLE TUBE. BD TRITEST REAGENT AND TRUCOUNT TUBES CAN BE USED WITH THE FACS LOADER.

	REAGENT CAN BE USED WITH OR WITHOUT AN ISOTYPE CONTROL., MULTICOLOR ANTIBODY REAGENT(BD FACSCOUNT REAGENT KIT)-BD FACSCOUNT REAGENT KIT (CAT#340167) IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN ENUMERATING THE ABSOLUTE COUNTS OF CD4, CD8, AND CD3 T LYMPHOCYTES IN UNLYSED WHOLE BLOOD, USING THE BD FACSCOUNT™ INSTRUMENT.,MULTICOLOR ANTIBODIES REAGENT(BD FACSCOUNT CONTROL KIT)-BD FACSCOUNT CONTROL KIT (CAT#340166) IS NTENDED FOR IN VITRO DIAGNOSTIC USE IN SETTING UP THE BD FACSCOUNT™ INSTRUMENT AND FOR CHECKING LINEARITY,MULTICOLOR ANTIBODY REAGENT (BD LEUCOCOUNT™ KIT)-THE BD LEUCOCOUNT™ KIT (CAT#340523) IS DESIGNED FOR COUNTING RESIDUAL WHITE BLOOD CELLS (RWBCS) IN LEUCOREDUCED BLOOD PRODUCTS.,MULTICOLOR ANTIBODIES REAGENT(1. BD MULTITEST 6-COLOR TBNK REAGENT ; 2. BD MULTITEST 6-COLOR TBNK REAGENT WITH BD TRUCOUNT TUBES)-BD MULTITEST 6-COLOR TBNK REAGENT (CAT#644611) IS USED TO IDENTIFY AND DETERMINE THE PERCENTAGES AND ABSOLUTE COUNTS OF T, B, AND NATURAL KILLER (NK) CELLS AS WELL AS THE CD4 AND CD8 SUBPOPULATIONS OF T CELLS IN PERIPHERAL BLOOD. BD MULTITEST 6-COLOR TBNK REAGENT WITH BD TRUCOUNT TUBES (CAT#337166) IS USED TO IDENTIFY AND DETERMINE THE PERCENTAGES AND ABSOLUTE COUNTS OF T, B, AND NATURAL KILLER (NK) CELLS AS WELL AS THE CD4 AND CD8 SUBPOPULATIONS OF T CELLS IN PERIPHERAL BLOOD. BD MULTITEST 6-COLOR TBNK REAGENT AND BD TRUCOUNT TUBES CAN BE USED WITH THE BD FACS™ LOADER INSTRUMENT.,MULTICOLOR ANTIBODIES REAGENT(1. BD MULTITEST CD3/CD16+56/CD45/CD19; 2. BD MULTITEST CD3 FITC/CD16 + CD56 PE/CD45 PERCP/CD19 APC REAGENT 50 TESTS)-BD MULTITEST CD3/CD16+56/CD45/CD19 (CAT#340500) IS USED FOR DETERMINING PERCENTAGES AND ABSOLUTE COUNTS OF HUMAN T, NATURAL KILLER, AND B LYMPHOCYTES IN ERYTHROCYTE- LYSED WHOLE BLOOD. BD MULTITEST CD3 FITC/CD16 + CD56 PE/CD45 PERCP/CD19 APC REAGENT 50 TESTS (CAT#342416) IS USED TO IDENTIFY AND DETERMINE THE PERCENTAGES AND ABSOLUTE COUNTS OF MATURE HUMAN T (CD3+), NATURAL KILLER (NK) (CD3–CD16+CD56+), AND B (CD3–CD19+) LYMPHOCYTES IN ERYTHROCYTELYSED WHOLE BLOOD., MULTICOLOR ANTIBODIES REAGENT(1. BD MULTITEST CD3/CD8/CD45/CD4 ; 2. BD MULTITEST CD3 FITC/CD8 PE/CD45 PERCP/CD4 APC REAGENT 50 TESTS)-BD MULTITEST CD3/CD8/CD45/CD4 (340499) IS USED FOR DETERMINING PERCENTAGES AND ABSOLUTE COUNTS OF HUMAN HELPER/INDUCER AND SUPPRESSOR/CYTOTOXIC T LYMPHOCYTES IN ERYTHROCYTE-LYSED WHOLE BLOOD BD MULTITEST CD3

		FITC/CD8 PE/CD45 PERCP/CD4 APC REAGENT 50 TESTS (342417) IS USED TO IDENTIFY AND DETERMINE THE PERCENTAGES AND ABSOLUTE COUNTS OF MATURE HUMAN T LYMPHOCYTES (CD3+), SUPPRESSOR/CYTOTOXIC (CD3+CD8+) T-LYMPHOCYTE SUBSETS, AND HELPER/INDUCER (CD3+CD4+) T-LYMPHOCYTE SUBSETS IN ERYTHROCYTE-LYSED WHOLE BLOOD.,BD TRUCOUNT TUBES(BD TRUCOUNT TUBES)-BD TRUCOUNT™ TUBES ARE USED FOR DETERMINING ABSOLUTE COUNTS OF LEUCOCYTES IN BLOOD., MULTICOLOR ANTIBODIES REAGENTS(1. BD TRITEST CD4/CD8/CD3; 2. BD TRITEST CD4 FITC/CD8 PE/CD3 PERCP REAGENT 50 TESTS)-BD TRITEST CD4/CD8/CD3 (340298) A THREECOLOR DIRECT IMMUNOFLUORESCENCE REAGENT USED WITH BD TRUCOUNT™ ABSOLUTE COUNT TUBES FOR IDENTIFYING AND DETERMINING ABSOLUTE COUNTS IN CELLS/L OF MATURE HUMAN T LYMPHOCYTES (CD3+), HELPER/INDUCER (CD3+CD4+) T LYMPHOCYTES, AND SUPPRESSOR/CYTOTOXIC (CD3+CD8+) T LYMPHOCYTES IN ERYTHROCYTELYSED WHOLE BLOOD. BD TRITEST CD4 FITC/CD8 PE/CD3 PERCP REAGENT 50 TESTS (342414) USED TO IDENTIFY AND DETERMINE THE ABSOLUTE COUNTS OF MATURE HUMAN T LYMPHOCYTES (CD3+), HELPER/INDUCER (CD3+CD4+) T LYMPHOCYTES, AND SUPPRESSOR/CYTOTOXIC (CD3+CD8+) T LYMPHOCYTES IN ERYTHROCYTELYSED WHOLE BLOOD.
1415	IMP/MD/2018/000372	1.License Holder Name: ROMSONS SCIENTIFIC & SURGICAL INDUSTRIES PVT LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PRESSURE TRANSDUCER NON STERILE BULK(NIL)-APPLY TO CLINICAL FOR TRAUMATIC ARTERIOVENOUS PRESSURE MONITORING.,CENTRAL VENOUS CATHETER & ACCESSORIES (NON STERILE BULK)(NIL)-THE PRODUCTS ARE APPLICABLE FOR MONITORING THE CENTRAL VENOUS PRESSURE, COLLECTING THE BLOOD SAMPLE AND INJECTING THE DRUG OR SOLUTION. THE DESIGN OF MULTICAVITY CAN GO ON THE PROCESS ABOVE AT THE SAME TIME. THE TIME OF USE IS LESS THAN 30 DAYS

1416	IMP/MD/2018/000373	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SIROLIMUS ELUTING CORONARY STENT SYSTEM(ULTIMASTER)-THE ULTIMASTER SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING MYOCARDIAL BLOOD FLOW IN PATIENTS WITH STENOTIC LESIONS IN CORONARY ARTERIES, INCLUDING BUT NOT LIMITED TO PATIENTS WITH STEMI, NSTEMI, ACUTE CORONARY SYNDROME, DIABETES MELLITUS, MULTIVESSEL DISEASE, BIFURCATION LESIONS, PATIENTS OLDER THAN 65 YEARS, MALE AND FEMALE PATIENTS, PATIENTS WITH TOTALLY OCCLUDED LESIONS, LONG LESIONS, LESIONS RESIDING IN SMALL CORONARY VESSELS, RESTENOTIC LESIONS INCLUDING IN-STENT RESTENOSIS, OSTIAL LESIONS, LESIONS IN LEFT MAIN CORONARY ARTERY. THE ULTIMASTER STENT SYSTEM IS SUITABLE FOR BOTH FEMORAL AND RADIAL APPROACH., SIROLIMUS ELUTING CORONARY STENT SYSTEM(ULTIMASTER TANSEI)-ULTIMASTER TANSEI SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING MYOCARDIAL BLOOD FLOW IN PATIENTS WITH STENOTIC LESIONS IN CORONARY ARTERIES, INCLUDING BUT NOT LIMITED TO PATIENTS WITH STEMI, NSTEMI, ACUTE CORONARY SYNDROME, DIABETES MELLITUS, MULTIVESSEL DISEASE, BIFURCATION LESIONS, PATIENTS OLDER THAN 65 YEARS, MALE AND FEMALE PATIENTS, PATIENTS WITH TOTALLY OCCLUDED LESIONS, LONG LESIONS, LESIONS RESIDING IN SMALL CORONARY VESSELS, RESTENOTIC LESIONS INCLUDING IN-STENT RESTENOSIS, OSTIAL LESIONS, LESIONS IN LEFT MAIN CORONARY ARTERY. THE ULTIMASTER TANSEI STENT SYSTEM IS SUITABLE FOR BOTH FEMORAL AND RADIAL APPROACH.

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1417	IMP/MD/2018/000374	1.License Holder Name: BL LIFESCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL ADHESIVE WITH SYRINGE DELIVERY SYSTEM(BIOGLUE)-BIOGLUE SURGICAL ADHESIVE IS INDICATED FOR USE AS AN ADJUNCT TO STANDARD METHODS OF SURGICAL REPAIR (SUCH AS SUTURES, STAPLES, ELECTROCAUTERY, AND/OR PATCHES) TO BOND, SEAL, AND/OR REINFORCE SOFT TISSUE. BIOGLUE MAY ALSO BE APPLIED ALONE TO SEAL AND/OR REINFORCE DAMAGED PARENCHYMA WHEN OTHER LIGATURE OR CONVENTIONAL PROCEDURES ARE INEFFECTIVE OR IMPRACTICAL. INDICATED SOFT TISSUES ARE CARDIAC, VASCULAR, PULMONARY, GENITOURINARY, DURAL, ALIMENTARY (ESOPHAGEAL, GASTROINTESTINAL, AND COLORECTAL), AND OTHER ABDOMINAL (PANCREATIC, SPLENIC, HEPATIC, BILIARY). ADDITIONALLY, BIOGLUE IS USED IN THE FIXATION OF SURGICAL MESHES IN HERNIA REPAIR., SURGICAL ADHESIVE WITH SYRINGE DELIVERY SYSTEM(BIOGLUE-BG3502-5-G)-BIOGLUE SURGICAL ADHESIVE IS INDICATED FOR USE AS AN ADJUNCT TO STANDARD METHODS OF SURGICAL REPAIR (SUCH AS SUTURES, STAPLES, ELECTROCAUTERY, AND/OR PATCHES) TO BOND, SEAL, AND/OR REINFORCE SOFT TISSUE. BIOGLUE MAY ALSO BE APPLIED ALONE TO SEAL AND/OR REINFORCE DAMAGED PARENCHYMA WHEN OTHER LIGATURE OR CONVENTIONAL PROCEDURES ARE INEFFECTIVE OR IMPRACTICAL. INDICATED SOFT TISSUES ARE CARDIAC, VASCULAR, PULMONARY, GENITOURINARY, DURAL, ALIMENTARY (ESOPHAGEAL, GASTROINTESTINAL, AND COLORECTAL), AND OTHER ABDOMINAL (PANCREATIC, SPLENIC, HEPATIC, BILIARY). ADDITIONALLY, BIOGLUE IS USED IN THE FIXATION OF SURGICAL MESHES IN HERNIA REPAIR.

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1418	IMP/MD/2018/000375	1.License Holder Name: COOK INDIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URETERAL STENT SETS (BLACK SILICONE FILIFORM DOUBLE PIGTAIL URETERAL STENT SET)-USED FOR TEMPORARY INTERNAL DRAINAGE FROM THE URETEROPELVIC JUNCTION TO THE BLADDER. THE WIRE GUIDE IS USED TO GAIN URETERAL ACCESS, TO ESTABLISH A TRACT, AND TO ASSIST IN THE PLACEMENT, REPLACEMENT, AND EXCHANGE OF MEDICAL DEVICES DURING UROLOGICAL AND GYNECOLOGIC PROCEDURES. ,URETERAL STENT SETS(SOF-FLEX PEDIATRIC DOUBLE PIGTAIL URETERAL STENT SET)-THE DOUBLE PIGTAIL STENT IS USED FOR TEMPORARY INTERNAL DRAINAGE FROM THE URETEROPELVIC JUNCTION TO THE BLADDER. DOUBLE PIGTAIL URETERAL STENTS HAVE BEEN EMPLOYED TO RELIEVE OBSTRUCTION IN A VARIETY OF BENIGN, MALIGNANT, AND POST-TRAUMATIC CONDITIONS. THESE STENTS MAY BE PLACED USING ENDOSCOPIC, PERCUTANEOUS, OR OPEN SURGICAL TECHNIQUES. THE WIRE GUIDE IS USED TO GAIN URETERAL ACCESS, TO ESTABLISH A TRACT, AND TO ASSIST IN THE PLACEMENT, REPLACEMENT, AND EXCHANGE OF MEDICAL DEVICES DURING UROLOGICAL AND GYNECOLOGIC PROCEDURES. ,URETERAL STENT SETS (KOYLE DIAPER STENT)-USED FOR STENTING THE URETHRA FOLLOWING HYPOSPADIAS OR EPISPADIAS REPAIR TO PROVIDE POSTOPERATIVE DRAINAGE OF THE BLADDER. THE EXTERNALIZED PORTION OF THE STENT IS OF SUFFICIENT LENGTH TO ALLOW DRAINAGE INTO A SECOND OR OUTSIDE DIAPER, KEEPING THE INSIDE DIAPER DRY DURING THE HEALING PROCESS. INTENDED FOR ONE-TIME USE., STONE EXTRACTORS(PERC NCIRCLE NITINOL TIPLESS, PERC NCOMPASS NITINOL, PERC NGAGE NITINOL)-USED FOR THE EXTRACTION OF STONES AND FOREIGN OBJECTS IN THE KIDNEY OR BLADDER.,AMNIOCENTESIS NEEDLE (ECHOTIP DISPOSABLE AMNIOCENTESIS NEEDLE)-USED FOR ASPIRATION OF FLUID FROM THE AMNIOTIC SAC.
1419	IMP/MD/2018/000375	1.License Holder Name: M/S COOK INDIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRODUCER/ACCESS DEVICES(FLEXOR URETERAL ACCESS SHEATHS)-INTENDED TO ESTABLISH A CONDUIT DURING ENDOSCOPIC UROLOGICAL PROCEDURES FACILITATING THE PASSAGE OF ENDOSCOPES AND OTHER INSTRUMENTS INTO THE URINARY TRACT.

1420	IMP/MD/2018/000375	1.License Holder Name: M/S COOK INDIA MEDICAL DEVICES PVT. LTD. , PLOT NO 22(SP), THIRD AND FOURTH FLOOR, KOCHAR JADE, THIRU VI KA INDUSTRIAL ESTATE, GUINDY TALUK ,CHENNAI TAMIL NADU , 600032 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EMBRYO TRANSFER CATHETER (GUARDIA ACCESS EMBRYO TRANSFER CATHETER, GUARDIA ACCESSET EMBRYO TRANSFER CATHETER, GUARDIA ACCESS NANO EMBRYO TRANSFER CATHETER)-USED TO PLACE IN VITRO FERTILIZED (IVF) EMBRYOS INTO THE UTERINE CAVITY
1421	IMP/MD/2018/000376	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED ,A-1/ 50, ROOM NO. 2, 100 SHED AREA, G.L.D.C., VAPI, TAL PARDI (VALSAD) , VALSAD GUJARAT ,396195 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOSCOPIC CLIP APPLIER(LIGACLIP)-THE LIGACLIP ENDOSCOPIC CLIP APPLIER HAS APPLICATION FOR USE ON TUBULAR STRUCTURES OR VESSELS WHEREVER METAL LIGATING CLIPS ARE INDICATED. THE TISSUE BEING LIGATED SHOULD BE CONSISTENT WITH THE SIZE OF THE CLIP.,CLIP APPLIER(LIGACLIP)-THE LIGACLIP CLIP APPLIER HAS APPLICATION FOR USE ON TUBULAR STRUCTURES OR VESSELS WHEREVER METAL LIGATING CLIPS ARE INDICATED. THE TISSUE BEING LIGATED SHOULD BE CONSISTENT WITH THE SIZE OF THE CLIP.

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1422	IMP/MD/2018/000377	1.License Holder Name: YOGI KRIPA MEDI-CHEM PVT. LTD. ,UNIT NO 206, 2ND FLOOR, UJAGAR CHAMBERS SUNDAR BAUG, PLOT NO. 2E, NEAR DEONAR BUS DEPOT, MUMBAI ,MUMBAI CITY MAHARASHTRA , 400088 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LUMBAR CAGE SYSTEM (KILI)-KILI IMPLANTS ARE INDICATED FOR INTERVERTEBRAL BODY FUSION PROCEDURES IN SKELETALLY MATURE PATIENTS WITH:- DEGENERATIVE DISC DISEASE (DDD) OF THE LUMBAR SPINE AT ONE OR MORE CONTIGUOUS LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES, -FAILED PRIOR SURGERY. KILI IMPLANTS ARE TO BE USED WITH EITHER AUTOGENOUS BONE GRAFT, OR BONE SUBSTITUTE. PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE EXPERIENCED AT LEAST SIX MONTHS OF NON--OPERATIVE TREATMENT.,OSTEOSYNTHESIS SYSTEM [STERILE](MONT BLANC MIS)-THE MONT BLANC MIS SPINAL SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE AND SACRAL/ILIAC SCREW FIXATION.,LUMBAR CAGE [STERILE](TWIN PEAKS)-THE TWIN PEAKS LUMBAR INTERBODY FUSION SYSTEM IS INDICATED FOR INTERVERTEBRAL BODY FUSION PROCEDURES IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) OF THE LUMBAR SPINE AT ONE OR TWO CONTIGUOUS LEVELS FROM L2-S1. DEGENERATIVE DISC DISEASE IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. THESE DDD PATIENTS MAY HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVEL(S).,CERVICAL CAGE [STERILE](AYERS ROCK)-THE AYERS ROCK CERVICAL INTERBODY FUSION SYSTEM IS INDICATED FOR INTERVERTEBRAL BODY FUSION PROCEDURES IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTIGUOUS LEVELS OF THE CERVICAL SPINE WITH/WITHOUT RADICULAR SYMPTOMS FROM C2 TO T1. DDD IS DEFINED AS DISCOGENIC PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES., OSTEOSYNTHESIS SYSTEM PEDIATRIC [STERILE](MONT BLANC BABY)-THE MONT BLANC BABY SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY IMMATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR

	DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE MONT BLANC BABY SYSTEM IS INDICATED FOR POSTERIOR, NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR SKELETALLY IMMATURE PATIENTS WITH POTENTIAL FOR ADDITIONAL SPINAL GROWTH FROM 2 TO 11 YEARS OF AGE WHO REQUIRE SURGICAL TREATMENT WITH A GROWING ROD CONSTRUCT TO OBTAIN AND MAINTAIN CORRECTION OF SEVERE, PROGRESSIVE, LIFE--THREATENING, EARLY-ONSET SPINAL DEFORMITIES ASSOCIATED WITH THORACIC INSUFFICIENCY, INCLUDING EARLY--ONSET SCOLIOSIS (EOS).THE MONT BLANC BABY SYSTEM MAY BE USED WITH COMPONENTS OF MONT BLANC SYSTEM. THE MONT BLANC BABY SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. ,CERVICAL PLATE SYSTEM [NON-STERILE] (BLUE MOUNTAIN)-THE BLUE MOUNTAIN SYSTEM IS USED IN ARTHRODESIS ON THE CERVICAL SPINE, INCLUDING DEGENERATIVE DISEASE OF THE INTERVERTEBRAL DISKS ONE OR MORE LEVELS, INJURY, VERTEBRAL DEFORMATION SUCH AS EXCESSIVE KYPHOSIS OR LORDOSIS, SCOLIOSIS, PSEUDARTHROSIS FOLLOWING FAILED SURGERY ON THE VERTEBRAL COLUMN, SURGERY TO REMOVE A PRIMARY OR METASTATIC TUMOUR ON THE VERTEBRAL COLUMN., OSTEOSYNTHESIS SYSTEM PEDIATRIC [NON-STERILE](MONT BLANC BABY)-THE MONT BLANC BABY SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY IMMATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE MONT BLANC BABY SYSTEM IS INDICATED FOR POSTERIOR, NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR SKELETALLY IMMATURE PATIENTS WITH POTENTIAL FOR ADDITIONAL SPINAL GROWTH FROM 2 TO 11 YEARS OF AGE WHO REQUIRE SURGICAL TREATMENT WITH A GROWING ROD CONSTRUCT TO OBTAIN AND MAINTAIN CORRECTION OF SEVERE, PROGRESSIVE, LIFE--THREATENING, EARLY-ONSET SPINAL DEFORMITIES ASSOCIATED WITH THORACIC INSUFFICIENCY, INCLUDING EARLY--ONSET SCOLIOSIS (EOS).THE MONT BLANC BABY SYSTEM MAY BE USED WITH COMPONENTS OF MONT BLANC SYSTEM. THE MONT BLANC BABY SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. ,OSTEOSYNTHESIS SYSTEM [NON-STERILE] (MONT BLANC)-THE MONT BLANC SPINAL SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE AND SACRAL/ILIAC SCREW FIXATION.

1423	IMP/MD/2018/000388	1.License Holder Name: M/S MERIT MEDICAL SYSTEMS INDIA PRIVATE LIMITED, ,UNIT NO. 404-405, H. M. GENEVA HOUSE, 4TH FLOOR, NO. 14/84 & 85, CUNNINGHAM ROAD ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560052 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MINI ACCESS KIT – CONTAINS ONE CO-AXIAL INTRODUCER / DILATOR PAIR, ONE INTRODUCER NEEDLE AND ONE GUIDE WIRE(MERIT MAK AND MERIT S-MAK)-MINI ACCESS KIT IS INTENDED FOR PERCUTANEOUS PLACEMENT OF A 0.035” 0.89MM) OR 0.038” (0.97MM) GUIDE WIRE INTO THE VASCULAR SYSTEM.

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1424	IMP/MD/2018/000388	1.License Holder Name: M/S MERIT MEDICAL SYSTEMS INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TUBING(HIGH PRESSURE TUBING, PRESSURE MONITORING TUBING)-MERIT MEDICAL TUBING IS INTENDED TO BE USED DURING AN ANGIOGRAPHIC PROCEDURE AS A CONDUIT TO SUPPLY A BOLUS OF CONTRAST MEDIA WHICH IS USUALLY INJECTED MECHANICALLY TO VIEW HEART FUNCTION UNDER FLUOROSCOPY ,BIOPSY SYSTEM(ACHIVE PROGRAMMABLE AUTOMATIC BIOPSY SYSTEM)-INTENDED FOR USE IN OBTAINING CORE BIOPSY SAMPLES FROM SOFT TISSUE SUCH AS KIDNEY, LIVER, PROSTRATE, SPLEEN, LYMPH NODES, AND VARIOUS SOFT TISSUE MASSES. THIS DEVICE IS ALSO INDICATED TO PROVIDE BREAST TISSUE SAMPLES FOR DIAGNOSTIC SAMPLING OF BREAST ABNORMALITIES. ,MULTIPACK PLUS CATHETERS(MULTI PACK PLUS CATHETERS/RADIAL MULTIPACK PLUS (INCLUDES THREE DEVICES – (I) PERFORMA ANGIOGRAPHIC CATHETER (II) PRELUDE SHEATH INTRODUCER (III) INQWIRE DIAGNOSTIC GUIDE WIRE))-THE MULTIPACK PLUS CATHETER CONFIGURATION CONSISTS OF BUNDLING INDIVIDUALLY STERILIZED, POUCHED AND LABELED STANDALONE DEVICES 1. PERFORMA ANGIOGRAPHIC CATHETERS - ANGIOGRAPHIC CATHETERS ARE DESIGNED TO BE USED FOR DELIVERING RADIOPAQUE MEDIA TO SELECTED SITES IN THE VASCULAR SYSTEM IN CONJUNCTION WITH ROUTINE DIAGNOSTIC PROCEDURES. ANGIOGRAPHIC CATHETERS WITH MARKER BANDS MAY ALSO BE USED FOR ANATOMICAL MEASUREMENTS. 2. PRELUDE SHEATH INTRODUCER - THE MERIT PRELUDE SHEATH INTRODUCER IS INTENDED TO PROVIDE ACCESS AND FACILITATE THE PER CUTANEOUS INTRODUCTION OF VARIOUS DEVICES INTO VEINS AND/OR ARTERIES WHILE MAINTAINING HEMOSTASIS FOR A VARIETY OF DIAGNOSTIC AND THERAPEUTIC PROCEDURES. 3. INQWIRE DIAGNOSTIC GUIDE WIRE - MERIT MEDICAL GUIDE WIRES ARE USED TO FACILITATE THE PLACEMENT OF DEVICES DURING DIAGNOSTIC AND INTERVENTIONAL PROCEDURES.,BIOPSY NEEDLES / SYSTEMS(TEMNO DEVICES (1. TEMNO BIOPSY DEVICE, 2. TEMNO EVOLUTION BIOPSY DEVICE, 3. TEMNO ACT BIOPSY DEVICE))-INTENDED FOR USE IN OBTAINING CORE BIOPSY SAMPLES FROM SOFT TISSUE SUCH AS BREAST, KIDNEY, LIVER, LUNG, THYROID, AND VARIOUS SOFT TISSUE MASSES. NOT INTENDED FOR USE IN BONE. , ANGIOGRAPHIC CATHETER(PERFORMA ANGIOGRAPHIC CATHETER)-ANGIOGRAPHIC CATHETERS ARE DESIGNED TO BE USED FOR DELIVERING RADIOPAQUE MEDIA TO SELECTED SITES IN THE VASCULAR SYSTEM IN CONJUNCTION WITH ROUTINE DIAGNOSTIC PROCEDURES. ANGIOGRAPHIC CATHETERS WITH MARKER BANDS

	MAY ALSO BE USED FOR ANATOMICAL MEASUREMENTS.

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1425	IMP/MD/2018/000389	1.License Holder Name: JOHNSON & JOHNSON SURGICAL VISION INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOLDABLE MULTIFOCAL 3-PIECE INTRAOCULAR LENS(TECNIS MULTIFOCAL 3-PIECE)-TECNIS MULTIFOCAL INTRAOCULAR LENSES ARE INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF: APHAKIA IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO MAY BENEFIT FROM USEFUL NEAR VISION AND REDUCED SPECTACLE DEPENDENCE ACROSS A RANGE OF DISTANCES. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG. ,FOLDABLE SOFT ACRYLIC POSTERIOR CHAMBER INTRAOCULAR LENS(SENSAR 3- PIECE)-SENSAR FOLDABLE IOLS WITH OPTIEDGE DESIGN ARE INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THIS LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG,FOLDABLE 1-PIECE ACRYLIC POSTERIOR CHAMBER INTRAOCULAR LENS(TECNIS EYHANCE IOL)--THE TECNIS EYHANCE IOL, MODEL ICB00, IS INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED TO EXTEND DEPTH OF FOCUS, WHICH IMPROVES VISION FOR INTERMEDIATE TASKS, AND PROVIDE SIMILAR DISTANCE VISION AS COMPARED TO A STANDARD MONOFOCAL IOL. THE LENS IS INDICATED FOR PLACEMENT IN THE CAPSULAR BAG ONLY.,FOLDABLE 1-PIECE ACRYLIC POSTERIOR CHAMBER INTRAOCULAR LENS(SENSAR 1-PIECE)-SENSAR 1-PIECE LENSES ARE INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THESE DEVICES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG., FOLDABLE MULTIFOCAL 1-PIECE INTRAOCULAR LENS(TECNIS MULTIFOCAL 1-PIECE IOL)-THE TECNIS MULTIFOCAL FOLDABLE ACRYLIC 1-PIECE INTRAOCULAR LENS IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO MAY BENEFIT FROM USEFUL NEAR VISION AND REDUCED SPECTACLE DEPENDENCE ACROSS A RANGE OF DISTANCE. THE INTRAOCULAR LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE ACRYLIC MONOFOCAL INTRAOCULAR

	LENS 3 PIECE(TECNIS 3- PIECE)-TECNIS FOLDABLE ACRYLIC IOLS WITH OPTIEDGE DESIGN ARE INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THIS LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE MONOFOCAL TORIC 1-PIECE INTRAOCULAR LENS(TECNIS TORIC II 1-PIECE INTRAOCULAR LENS)-THE TECNIS TORIC (II) 1-PIECE POSTERIOR CHAMBER INTRAOCULAR LENSES ARE INTENDED FOR PRIMARY IMPLANTATION FOR VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION, WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE VISION. THIS DEVICE IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE 1-PIECE ACRYLIC POSTERIOR CHAMBER INTRAOCULAR LENS(TECNIS 1- PIECE)-AMO TECNIS 1-PIECE LENSES ARE INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THESE DEVICES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE 1-PIECE ACRYLIC PRELOADED IOL FOR THE UNFOLDER VITAN™ INSERTER(TECNIS EYHANCE IOL WITH SMARTLOAD DELIVERY TECHNOLOGY)-THE SMARTLOAD™ DELIVERY TECHNOLOGY IS USED IN COMBINATION WITH THE UNFOLDER VITAN™ INSERTER, MODEL DK9000 TO FOLD AND ASSIST IN INSERTING THE TECNIS EYHANCE IOL WHICH IS INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS EXTENDS THE DEPTH OF FOCUS, WHICH IMPROVES VISION FOR INTERMEDIATE TASKS, AND PROVIDES SIMILAR DISTANCE VISION AS COMPARED TO A STANDARD ASPHERIC MONOFOCAL IOL. THE LENS IS INDICATED FOR PLACEMENT IN THE CAPSULAR BAG ONLY.,FOLDABLE MULTIFOCAL 1-PIECE INTRAOCULAR LENS(TECNIS MULTIFOCAL TORIC 1-PIECE IOL)-THE TECNIS MULTIFOCAL TORIC 1-PIECE LENS IS INDICATED FOR THE PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN [1] ASTIGMATIC ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION AND [2] APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN ASTIGMATIC PRESBYOPIC ADULTS, WHO DESIRE IMPROVED UNCORRECTED VISION, REDUCTION OF RESIDUAL

	REFRACTIVE CYLINDER, USEFUL NEAR VISION AND REDUCED SPECTACLE DEPENDENCE ACROSS A RANGE OF DISTANCES. THE INTRAOCULAR LENSES ARE INTENDED TO MAINTAIN ROTATIONAL STABILITY AFTER IMPLANTATION IN THE CAPSULAR BAG.,FOLDABLE MULTIFOCAL 1-PIECE INTRAOCULAR LENS WITH TECNIS SIMPLICITY PRELOADED DELIVERY SYSTEM(TECNIS MULTIFOCAL 1-PIECE IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM)-THE TECNIS SIMPLICITY™ DELIVERY SYSTEM IS USED TO FOLD AND ASSIST IN INSERTING THE TECNIS® MULTIFOCAL IOL WHICH IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF [1] APHAKIA IN ADULTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED, AND [2] APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO MAY BENEFIT FROM USEFUL NEAR VISION AND REDUCED SPECTACLE DEPENDENCE ACROSS A RANGE OF DISTANCES. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE MONOFOCAL TORIC 1-PIECE INTRAOCULAR LENS(TECNIS TORIC 1-PIECE IOL)- THE TECNIS TORIC 1-PIECE LENS IS INDICATED FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENTS WITH OR WITHOUT PRESBYOPIA, IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION AND WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE VISION. THIS DEVICE IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE 1-PIECE OPTIBLUE ACRYLIC IOL WITH TECNIS SIMPLICITY PRELOADED DELIVERY SYSTEM(TECNIS OPTIBLUE 1-PIECE IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM) -THE TECNIS SIMPLICITY™ DELIVERY SYSTEM IS USED TO FOLD AND ASSIST IN INSERTING THE TECNIS® OPTIBLUE 1-PIECE INTRAOCULAR LENSES WHICH ARE INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE MONOFOCAL TORIC 1-PIECE INTRAOCULAR LENS(TECNIS TORIC 1-PIECE IOL)-THE TECNIS TORIC 1-PIECE LENS IS INDICATED FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENTS WITH OR WITHOUT PRESBYOPIA, IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION AND WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE VISION. THIS DEVICE IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE MULTIFOCAL 1-PIECE

	INTRAOCULAR LENS WITH TECNIS SIMPLICITY PRELOADED DELIVERY SYSTEM(TECNIS MULTIFOCAL 1-PIECE IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM)-THE TECNIS SIMPLICITY™ DELIVERY SYSTEM IS USED TO FOLD AND ASSIST IN INSERTING THE TECNIS® MULTIFOCAL IOL WHICH IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF [1] APHAKIA IN ADULTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION, AND [2] APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO DESIRE IMPROVED UNCORRECTED NEAR, INTERMEDIATE, AND DISTANCE VISION AND INCREASED SPECTACLE INDEPENDENCE ACROSS A RANGE OF DISTANCES. THE INTRAOCULAR LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE EXTENDED RANGE OF VISION TORIC 1-PIECE INTRAOCULAR LENS(TECNIS SYMFONY EXTENDED RANGE OF VISION TORIC 1-PIECE IOL)-THE TECNIS SYMFONY IOLS ARE INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION, AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS, WHO DESIRE USEFUL VISION OVER A CONTINUOUS RANGE OF DISTANCES INCLUDING FAR, INTERMEDIATE AND NEAR, A REDUCTION OF RESIDUAL REFRACTIVE CYLINDER, AND INCREASED SPECTACLE INDEPENDENCE. THESE DEVICES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE MULTIFOCAL 1-PIECE INTRAOCULAR LENS WITH TECNIS SIMPLICITY PRELOADED DELIVERY SYSTEM(TECNIS MULTIFOCAL 1-PIECE IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM)-THE TECNIS SIMPLICITY™ DELIVERY SYSTEM IS USED TO FOLD AND ASSIST IN INSERTING THE TECNIS® MULTIFOCAL IOL WHICH IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF [1] APHAKIA IN ADULTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION, AND [2] APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO DESIRE IMPROVED UNCORRECTED NEAR, INTERMEDIATE, AND DISTANCE VISION AND INCREASED SPECTACLE INDEPENDENCE ACROSS A RANGE OF DISTANCES. THE INTRAOCULAR LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE EXTENDED RANGE OF VISION 1-PIECE INTRAOCULAR LENS(TECNIS SYMFONY EXTENDED RANGE OF VISION 1-PIECE IOL)-THE TECNIS SYMFONY IOL, MODEL ZXR00, IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED

	BY EXTRACAPSULAR CATARACT EXTRACTION, AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS, WHO DESIRE USEFUL VISION OVER A CONTINUOUS RANGE OF DISTANCES INCLUDING FAR, INTERMEDIATE AND NEAR, AND INCREASED SPECTACLE INDEPENDENCE. THIS DEVICE IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE EXTENDED RANGE OF VISION 1-PIECE IOL WITH TECNIS SIMPLICITY PRELOADED DELIVERY SYSTEM(TECNIS SYMFONY EXTENDED RANGE OF VISION IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM)-THE TECNIS SIMPLICITY™ DELIVERY SYSTEM, MODEL DXR00 IS USED TO FOLD AND ASSIST IN INSERTING THE TECNIS SYMFONY® IOL WHICH IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION, AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS, WHO DESIRE USEFUL VISION OVER A CONTINUOUS RANGE OF DISTANCE INCLUDING FAR, INTERMEDIATE AND NEAR, AND INCREASED SPECTACLE INDEPENDENCE. THIS DEVICE IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE MULTIFOCAL 1-PIECE INTRAOCULAR LENS(TECNIS MULTIFOCAL 1-PIECE IOL)-THE TECNIS MULTIFOCAL FOLDABLE ACRYLIC 1-PIECE INTRAOCULAR LENS IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF [1] APHAKIA IN ADULTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION AND [2] APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO DESIRE IMPROVED UNCORRECTED NEAR, INTERMEDIATE, AND DISTANCE VISION AND INCREASED SPECTACLE INDEPENDENCE ACROSS A RANGE OF DISTANCES. THE INTRAOCULAR LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG. ,FOLDABLE 1-PIECE ACRYLIC POSTERIOR CHAMBER INTRAOCULAR LENS WITH TECNIS SIMPLICITY PRELOADED DELIVERY SYSTEM(TECNIS EYHANCE IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM)-THE TECNIS SIMPLICITY™ DELIVERY SYSTEM IS USED TO FOLD AND ASSIST IN INSERTING THE TECNIS EYHANCE IOL WHICH IS INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS EXTENDS THE DEPTH OF FOCUS, WHICH IMPROVES VISION FOR INTERMEDIATE TASKS, AND PROVIDE SIMILAR DISTANCE VISION AS COMPARED TO A STANDARD ASPHERIC MONOFOCAL IOL. THE LENS IS INDICATED FOR PLACEMENT IN THE CAPSULAR BAG ONLY.,FOLDABLE 1-PIECE ACRYLIC IOL WITH TECNIS ITEC PRELOADED DELIVERY SYSTEM

	(TECNIS® 1-PIECE IOL WITH TECNIS ITEC PRELOADED DELIVERY SYSTEM)-AMO TECNIS 1-PIECE LENSES ARE INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THESE DEVICES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE 1-PIECE ACRYLIC PRELOADED IOL FOR THE UNFOLDER VITAN™ INSERTER(SENSAR 1-PIECE IOL WITH SMARTLOAD DELIVERY TECHNOLOGY)-THE SMARTLOAD™ DELIVERY TECHNOLOGY IS USED IN COMBINATION WITH THE UNFOLDER VITAN INSERTER, MODEL DK9000 TO FOLD AND ASSIST IN INSERTING THE SENSAR 1-PIECE LENS FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE SENSAR 1-PIECE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE 1-PIECE ACRYLIC IOL WITH TECNIS SIMPLICITY PRELOADED DELIVERY SYSTEM(TECNIS 1-PIECE IOL WITH TECNIS SIMPLICITY™ DELIVERY SYSTEM)-THE TECNIS SIMPLICITY™ DELIVERY SYSTEM IS USED TO FOLD AND ASSIST IN INSERTING THE TECNIS® 1-PIECE INTRAOCULAR LENS FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THESE DEVICES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE 1-PIECE, STERILE UV AND VIOLET LIGHT-FILTERING ACRYLIC PRELOADED IOL FOR THE UNFOLDER VITAN™ INSERTER(TECNIS OPTIBLUE 1-PIECE IOL WITH SMARTLOAD DELIVERY TECHNOLOGY)-THE SMARTLOAD DELIVERY TECHNOLOGY SYSTEM, IS USED IN COMBINATION WITH THE UNFOLDER VITAN INSERTER, MODEL DK9000 TO FOLD AND ASSIST IN INSERTING THE TECNIS OPTIBLUE 1-PIECE INTRAOCULAR LENSES FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,FOLDABLE 1-PIECE ACRYLIC PRELOADED IOL FOR THE UNFOLDER VITAN™ INSERTER(TECNIS 1-PIECE IOL WITH SMARTLOAD DELIVERY TECHNOLOGY)-THE SMARTLOAD DELIVERY TECHNOLOGY IS USED IN COMBINATION WITH THE UNFOLDER VITAN INSERTER, MODEL DK9000, TO FOLD AND ASSIST IN INSERTING THE TECNIS 1-PIECE LENS FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THESE TECNIS 1-PIECE LENSES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG.

1426	IMP/MD/2018/000390	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE SYNTHETIC BONE SUBSTITUTE(ADBONE®BCP)-INTENDED FOR THE FILLING OF BONE VOIDS OR DEFECTS OF THE SKELETAL SYSTEM THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE.,STERILE SYNTHETIC BONE SUBSTITUTE(ADBONE®TCP)-INTENDED FOR THE FILLING OF BONE VOIDS OR DEFECTS OF THE SKELETAL SYSTEM THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE
1427	IMP/MD/2018/000391	1.License Holder Name: 3M INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: INTRAVENOUS CATHETER HOLDER AND ANTIMICROBIAL SYNTHETIC POLYMER SEMI-PERMEABLE FILM DRESSING ADHESIVE.(3M PICC/CVC SECUREMENT DEVICE + CHG IV SECUREMENT DRESSING)-3M™ TEGADERM™ CHG CHLORHEXIDINE GLUCONATE IV SECUREMENT DRESSING CAN BE USED TO COVER AND PROTECT CATHETER SITES AND TO SECURE DEVICES TO SKIN. COMMON APPLICATIONS INCLUDE CENTRAL VENOUS AND ARTERIAL CATHETERS, OTHER INTRAVASCULAR CATHETERS AND PERCUTANEOUS DEVICES. TEGADERM CHG DRESSING IS INTENDED TO REDUCE SKIN COLONIZATION AND CATHETER COLONIZATION AND TO SUPPRESS REGROWTH OF MICROORGANISMS COMMONLY RELATED TO BLOOD STREAM INFECTIONS. TEGADERM CHG IS INTENDED TO REDUCE CATHETER-RELATED BLOODSTREAM INFECTIONS (CRBSI) IN PATIENTS WITH CENTRAL VENOUS OR ARTERIAL CATHETERS., ANTIMICROBIAL DRESSING(3M TEGADERM CHG CHLORHEXIDINE GLUCONATE IV PORT DRESSING)-3M™ TEGADERM™ CHG CHLORHEXIDINE GLUCONATE I.V. PORT DRESSING CAN BE USED TO COVER AND PROTECT VASCULAR ACCESS SITES AND TO SECURE DEVICES TO SKIN.,INTRAVENOUS CATHETER HOLDER AND SYNTHETIC POLYMER SEMIPERMEABLE FILM DRESSING ADHESIVE, STERILE(3M PICC/CVC SECUREMENT DEVICE + TEGADERM IV ADVANCED SECUREMENT DRESSING)-3M™ PICC/CVC SECUREMENT DEVICE + TEGADERM™ I. V. ADVANCED SECUREMENT DRESSING (“SECUREMENT SYSTEM”) IS USED TO SECURE PERIPHERALLY INSERTED CENTRAL VENOUS CATHETERS (PICCS) AND SHORT TERM CENTRAL VENOUS CATHETERS (CVCS) TO THE SKIN AND TO COVER AND PROTECT CATHETER INSERTION SITES. THE DEVICE WILL ACCOMMODATE THE MAJORITY OF SINGLE, DOUBLE AND TRIPLE LUMEN CVC CATHETERS UP TO AND INCLUDING 12 FRENCH.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1428	IMP/MD/2018/000392	1.License Holder Name: LIVANOVA INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AORTOVALVULAR PROSTHESIS(CARBOMEDICS CARBOSEAL VALSALVA)-THE CARBOMEDICS CARBO-SEAL VALSALVA ASCENDING AORTIC PROSTHESES ARE INTENDED FOR USE IN OPEN HEART SURGERY FOR SIMULTANEOUS REPLACEMENT OF THE ASCENDING AORTA AND THE AORTIC VALVE IN CASES OF ANEURYSM, DISSECTION, OR OTHER DISEASE CONDITIONS OF THE AORTA COMBINED WITH DISEASE OR DEGENERATION OF THE AORTIC VALVE.,BIOLOGICAL HEART VALVE (PERICARBON MORE MITRAL)-THE PERICARBON MORE VALVE IS A LOW PROFILE BIOPROSTHETIC HEART VALVE INDICATED FOR THE REPLACEMENT OF DAMAGED OR MALFUNCTIONING HEART VALVE OR PROSTHESES IN HUMANS. IT CONSISTS OF THREE LEAFLETS OF BOVINE PERICARDIUM STABILIZED IN BUFFERED GLUTARALDEHYDE SOLUTIONS.,ANNULOPLASTY DEVICE(MEMO 3D RECHORD SEMIRIGID ANNULOPLASTY RING)-THE MEMO 3D RECHORD IS INDICATED FOR CORRECTION OF CONGENITAL OR ACQUIRED MITRAL INSUFFICIENCIES WITH DILATATION AND DEFORMATION OF MITRAL ANNULUS.,BIOLOGICAL HEART VALVE(PERCEVAL S)-PERCEVAL S HEART VALVE IS A BIOPROSTHETIC VALVE DESIGNED TO REPLACE A DISEASED NATIVE OR A MALFUNCTIONING PROSTHETIC AORTIC VALVE VIA OPEN HEART SURGERY.,ASCENDING AORTIC PROSTHESIS (CARBOMEDICS CARBOSEAL)-CARBOMEDICS CARBOSEAL ASCENDING AORTIC PROSTHESIS ARE INTENDED FOR USE IN OPEN HEART SURGERY FOR SIMULTANEOUS REPLACEMENT OF THE ASCENDING AORTA AND THE AORTIC VALVE IN CASES OF ANEURYSM, DISSECTION, OR OTHER DISEASE CONDITIONS OF THE AORTA COMBINED WITH DISEASE OR DEGENERATION OF THE AORTIC VALVE.,MECHANICAL VALVE(BICARBON MECHANICAL BILEAFLET HEART VALVE)-BICARBON PROSTHESIS ARE INDICATED FOR THE REPLACEMENT OF DAMAGED NATURAL HEART VALVES OR MALFUNCTIONING PROSTHESIS DEVICES IN PARTICULAR THE BICARBON OVERLINE PROSTHESIS ARE INDICATED FOR IMPLANTATION IN A COMPLETELY SUPRAANNULAR POSITION AND THE BICARBON SLIMLINE PROSTHESIS ARE INDICATED IN CASES IN WHICH THE EXTERNAL VALVE DIMENSION NEEDS TO BE REDUCED IN RELATION TO AVAILABLE FLOW AREA ,ANNULOPLASTY DEVICE (MEMO 3D)-IT IS USED FOR CORRECTION OF CONGENITAL OR ACQUIRED MITRAL INSUFFICIENCIES WITH DILATION AND DEFORMATION OF THE MITRAL ANNULUS.,MECHANICAL VALVE (CARBOMEDICS PROSTHETIC HEART VALVES)-THE CARBOMEDICS PROSTHETIC HEART VALVES (CPHV) ARE INDICATED AS A REPLACEMENT FOR HUMAN CARDIAC VALVES THAT ARE

		MALFUNCTIONING AS A RESULT OF ACQUIRED OR CONGENITAL DISEASE, OR AS A REPLACEMENT FOR A PREVIOUSLY IMPLANTED PROSTHESIS. THE PROSTHESIS CONSISTS OF AN ORIFICE HOUSING TWO IDENTICAL LEAFLETS, WHICH ARTICULATE ALMOST ENTIRELY WITHIN THE ORIFICE.,ANNULOPLASTY DEVICE(SOVERING ANNULOPLASTY DEVICE)-IT IS INDICATED FOR THE CORRECTION OF ARTERIOVENTRICULAR VALVE INSUFFICIENCY OR STENO-INSUFFICIENCIES,ANNULOPLASTY DEVICE(CARBOMEDICS ANNULOPLASTY RINGS)-IT IS INDICATED AS REINFORCEMENT FOR REPAIR OF THE HUMAN CARDIAC TRICUSPID VALVE DAMAGED BY ACQUIRED OR CONGENITAL DISEASE, OR AS A REPLACEMENT FOR A PREVIOUSLY IMPLANTED ANNULOPLASTY RING
1429	IMP/MD/2018/000393	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER(TACTICATH SENSOR ENABLED)-THE TACTICATH CONTACT FORCE ABLATION CATHETER, SENSOR ENABLED IS INDICATED FOR USE IN CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATION AND RECORDING), AND, WHEN USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION OF SUPRAVENTRICULAR ARRHYTHMIAS IN RIGHT AND LEFT ATRIUM, INCLUDING ATRIAL FIBRILLATION.

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1430	IMP/MD/2018/000394	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KNEE REPLACEMENT SYSTEM - TIBIAL INSERT(PFC SIGMA RPF)-WITH CEMENT: THE P.F.C. SIGMA RP MOBILE BEARING TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE RPF AND RPS INSERTS AND FEMORAL COMPONENTS ARE INDICATED WHERE A HIGHER THAN NORMAL DEGREE OF POST-OPERATIVE FLEXION IS REQUIRED. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES. WITHOUT CEMENT: THE POROUS COATED KEELED AND NON KEELED M.B.T. (MOBILE BEARING TIBIAL) TRAY CONFIGURATIONS OF THE LCS TOTAL KNEE SYSTEM ARE INDICATED FOR NONCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR RECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE ROTATING PLATFORM DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE ABSENT OR ARE IN SUCH CONDITION AS TO JUSTIFY THEIR SACRIFICE. THE P.F.C. SIGMA RP CURVED BEARINGS WHEN USED WITH THE P.F.C. SIGMA CRUCIATE RETAINING FEMORAL COMPONENT CAN BE USED IN POSTERIOR CRUCIATE LIGAMENT RETAINING PROCEDURES.THE P.F.C.® SIGMA® RP MOBILE BEARING TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE RPF AND RPS INSERTS AND FEMORAL COMPONENTS ARE INDICATED WHERE A HIGHER THAN NORMAL DEGREE OF POST-OPERATIVE FLEXION IS REQUIRED. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES.,KNEE REPLACEMENT SYSTEM - FEMORAL(PFC SIGMA RPF)-THE P.F.C. SIGMA RP MOBILE BEARING TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE RPF AND RPS INSERTS AND FEMORAL COMPONENTS ARE INDICATED WHERE A HIGHER THAN NORMAL DEGREE OF POST-OPERATIVE FLEXION IS REQUIRED. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES. THE POROUS COATED KEELED AND NON KEELED M.B.T. (MOBILE BEARING TIBIAL) TRAY CONFIGURATIONS OF THE LCS TOTAL KNEE SYSTEM ARE INDICATED FOR NONCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY

		SURGERY FOR RECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE ROTATING PLATFORM DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE ABSENT OR ARE IN SUCH CONDITION AS TO JUSTIFY THEIR SACRIFICE. THE P.F.C. SIGMA RP CURVED BEARINGS WHEN USED WITH THE P.F.C. SIGMA CRUCIATE RETAINING FEMORAL COMPONENT CAN BE USED IN POSTERIOR CRUCIATE LIGAMENT RETAINING PROCEDURES.
1431	IMP/MD/2018/000395	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYPODERMIC NEEDLES (BD MICROLANCE 3)-IT IS INTENDED FOR THE HYPODERMIC ADMINISTRATION OF PHARMACEUTICALS AND FOR 30G X ½" NEEDLES HAS THE ADDITIONAL INTENDED USE OF INTRA OCULAR ADMINISTRATION OF LUCENTIS.

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1432	IMP/MD/2018/000396	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KNOTLESS FIXATION IMPLANT(SPEEDLOCK)-"THE SPEEDLOCK KNOTLESS FIXATION DEVICE IS INDICATED FOR USE IN THE FIXATION OF SOFT TISSUE TO BONE. EXAMPLES OF SUCH PROCEDURES INCLUDE: SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ACROMIOCLAVICULAR SEPARATION, ROTATOR CUFF REPAIR, CAPSULE SHIFT/CAPSULE-LABRAL RECONSTRUCTION, BICEPS TENODESIS AND DELTOID REPAIR. ANKLE: LATERAL INSTABILITY, MEDIAL INSTABILITY, ACHILLES TENDON REPAIR/RECONSTRUCTION AND MIDFOOT RECONSTRUCTION. FOOT: HALLUX VALGUS RECONSTRUCTION. ELBOW: TENNIS ELBOW REPAIR, BICEPS TENDON REATTACHMENT. KNEE: EXTRA-CAPSULAR REPAIRS; REATTACHMENT OF MEDIAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT OR JOINT CAPSULE CLOSURE TO ANTERIOR PROXIMAL TIBIA; EXTRA CAPSULAR RECONSTRUCTION, ITB TENODESIS; PATELLAR LIGAMENT AND TENDON AVULSIONS",KNOTLESS FIXATION IMPLANT(MAGNUM 2)-"THE MAGNUM2 IS INDICATED FOR USE IN FIXATION OF SOFT TISSUE TO BONE. EXAMPLES OF SUCH PROCEDURES INCLUDE: SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ACROMIOCLAVICULAR SEPARATION, ROTATOR CUFF REPAIR, CAPSULE SHIFT/CAPSULE-LABRAL RECONSTRUCTION, BICEPS TENODESIS, AND DELTOID REPAIR ANKLE: LATERAL INSTABILITY, MEDIAL INSTABILITY, ACHILLES TENDON REPAIR/RECONSTRUCTION, AND MIDFOOT RECONSTRUCTION FOOT: HALLUX VALGUS RECONSTRUCTION ELBOW: TENNIS ELBOW REPAIR, BICEPS TENDON REATTACHMENT KNEE: EXTRA-CAPSULAR REPAIRS; REATTACHMENT OF: MEDIAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT OR JOINT CAPSULE CLOSURE TO ANTERIOR PROXIMAL TIBIA; EXTRA CAPSULAR RECONSTRUCTION, ITB TENODESIS; PATELLAR LIGAMENT AND TENDON AVULSIONS.",EPISTAXIS BALLOON(RAPID RHINO)-AN EPISTAXIS BALLOON IS A DEVICE CONSISTING OF AN INFLATABLE BALLOON INTENDED TO CONTROL INTERNAL NASAL BLEEDING BY EXERTING PRESSURE AGAINST THE SPHENOPALATINE ARTERY.,KNOTLESS FIXATION IMPLANT (MULTIFIX)-"IT IS INDICATED FOR USE IN THE FIXATION OF SOFT TISSUE TO BONE. EXAMPLES OF SUCH PROCEDURES INCLUDE: SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ACROMIO-CLAVICULAR SEPARATION, ROTATOR CUFF REPAIR, CAPSULE SHIFT/CAPSULE-LABRAL RECONSTRUCTION, BICEPS TENODESIS AND DELTOID REPAIR. ANKLE: LATERAL INSTABILITY, MEDIAL INSTABILITY, ACHILLES TENDON REPAIR/RECONSTRUCTION AND MIDFOOT RECONSTRUCTION FOOT: HALLUX VALGUS

		RECONSTRUCTION ELBOW: TENNIS ELBOW REPAIR, BICEPS TENDON REATTACHMENT KNEE: EXTRA-CAPSULAR REPAIRS; REATTACHMENT OF MEDIAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT OR JOINT CAPSULE CLOSURE TO ANTERIOR PROXIMAL TIBIA; EXTRA CAPSULAR RECONSTRUCTION, ITB TENODESIS; PATELLAR LIGAMENT AND TENDON AVULSIONS.",SUTURE(MAGNUMWIRE)-MAGNUMWIRE SUTURE IS INDICATED FOR USE IN APPROXIMATION AND/OR LIGATION OF SOFT TISSUE INCLUDING THE USE OF ALLOGRAFT TISSUE FOR ORTHOPEDIC SURGERIES.,NASAL DRESSING(RAPID RHINO SINU-KNIT)-AN INTRANASAL SPLINT IS INTENDED TO MINIMIZE BLEEDING AND EDEMA AND TO PREVENT ADHESIONS BETWEEN THE SEPTUM AND THE NASAL CAVITY. IT IS PLACED IN THE NASAL CAVITY AFTER SURGERY OR TRAUMA.,NASAL DRESSING (RAPID RHINO SINU-FOAM)-AN INTRANASAL SPLINT IS INTENDED TO MINIMIZE BLEEDING AND EDEMA AND TO PREVENT ADHESIONS BETWEEN THE SEPTUM AND THE NASAL CAVITY. IT IS PLACED IN THE NASAL CAVITY AFTER SURGERY OR TRAUMA.,ADJUSTABLE FIXATION DEVICE(ULTRABUTTON)-"THE ULTRABUTTON ADJUSTABLE FIXATION DEVICE IS INDICATED FOR SOFT TISSUE TO BONE FIXATION FOR: ACL/PCL REPAIR / RECONSTRUCTION, ACL/PCL PATELLAR BONE-TENDONBONE GRAFTS, DOUBLE-TUNNEL ACL RECONSTRUCTION, EXTRACAPSULAR REPAIR: MCL, LCL, AND POSTERIOR OBLIQUE LIGAMENT."
1433	IMP/MD/2018/000396	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUTURE ANCHOR(Q-FIX)-Q-FIX SUTURE ANCHOR ARE INTENDED TO BE USED FOR SOFT TISSUE TO BONE FIXATION FOR SHOULDER, FOOT & ANKLE, ELBOW, KNEE AND HIP.

1434	IMP/MD/2018/000397	1.License Holder Name: ALCON LABORATORIES (INDIA) PVT. LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OPHTHALMIC VISCOSURGICAL DEVICE(VISCOAT)-VISCOAT (OVD) IS INDICATED FOR USE AS A SURGICAL AID IN ANTERIOR SEGMENT PROCEDURES INCLUDING CATARACT EXTRACTION AND INTRAOCULAR LENS IMPLANTATION. VISCOAT (OVD) MAINTAINS A DEEP CHAMBER DURING ANTERIOR SEGMENT SURGERY, ENHANCES VISUALIZATION DURING THE SURGICAL PROCEDURE, AND PROTECTS THE CORNEAL ENDOTHELIUM AND OTHER OCULAR TISSUES. THE VISCOELASTICITY OF THE SOLUTION MAINTAINS THE NORMAL POSITION OF THE VITREOUS FACE AND PREVENTS FORMATION OF A FLAT CHAMBER DURING SURGERY.,OPHTHALMIC VISCOSURGICAL DEVICE(PROVISC)-PROVISC OPHTHALMIC VISCOSURGICAL DEVICE IS INDICATED FOR USE AS AN OPHTHALMIC SURGICAL AID IN THE ANTERIOR SEGMENT DURING CATARACT EXTRACTION AND INTRAOCULAR LENS (IOL) IMPLANTATION. OPHTHALMIC VISCOELASTICS SERVES TO MAINTAIN A DEEP ANTERIOR CHAMBER DURING ANTERIOR SEGMENT SURGERY ALLOWING REDUCED TRAUMA TO THE CORNEAL ENDOTHELIUM AND SURROUNDING OCULAR TISSUES. THEY HELP TO PUSH BACK THE VITREOUS FACE AND PREVENT FORMATION OF A FLAT CHAMBER DURING SURGERY.,OPHTHALMIC VISCOSURGICAL DEVICE (DISCOVISC)-DISCOVISC OVD IS INDICATED FOR USE DURING SURGERY IN THE ANTERIOR SEGMENT OF THE EYE. IT IS DESIGNED TO CREATE AND MAINTAIN SPACE, TO PROTECT THE CORNEAL ENDOTHELIUM AND OTHER INTRAOCULAR TISSUES AND TO MANIPULATE TISSUES DURING SURGERY. IT MAY ALSO BE USED TO COAT INTRAOCULAR LENSES AND INSTRUMENTS DURING CATARACT EXTRACTION AND IOL INSERTION.
1435	IMP/MD/2018/000398	1.License Holder Name: KCI MEDICAL INDIA PRIVATE LIMITED ,K. NO. 2606/115 (P. NO. 60/16) GROUND FLOOR, HUSKUR ROAD ELECTRONIC POST ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560100 , INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TIELLE® HYDROPOLYMER ADHESIVE DRESSING(TIELLE®)-TIELLE® HYDROPOLYMER ADHESIVE DRESSING IS INDICATED FOR THE MANAGEMENT OF LOW TO MODERATELY EXUDING WOUNDS THAT CAN ONLY HEAL BY SECONDARY INTENT.

1436	IMP/MD/2018/000399	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHODONTIC WIRE (COPPER NICKEL TITANIUM)(BROAD ARCHWIRE, DAMON ARCHWIRE, COPPER NI-TI ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH., ORTHODONTIC TUBE (STAINLESS STEEL)(ACCENT BUCCAL TUBES, MICRO TUBES, PEERLESS BUCCAL TUBES, TERMINAL TUBE)-INTENDED TO BE APPLIED TO A PATIENT'S 1ST AND 2ND MOLARS IN ORDER TO CORRECT MALOCCLUSION.,ORTHODONTIC WIRE (BETA TITANIUM)(TMA ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH., ORTHODONTIC WIRE (NICKEL TITANIUM)(NI-TI ARCHWIRE, TRU-ARCH ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH.,ORTHODONTIC WIRE (STAINLESS STEEL)(BROAD ARCHWIRE, BURSTONE ARCHWIRE, D-RECT ARCHWIRE, LINGUAL ARCHWIRE, ORTHOS ARCHWIRE, RESPOND ARCHWIRE, STAINLESS STEEL ARCHWIRE, STB STRAIGHTWIRE, VARI- SIMPLEX ARCHWIRE, LIGATURE WIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH.
1437	IMP/MD/2018/000400	1.License Holder Name: BECTON DICKINSON INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC NEEDLE(BD MICROLANCE 3 (NON STERILE BULK NEEDLES))-USED AS A COMPONENT FOR THE PRODUCTION OF OTHER MEDICAL DEVICES AND AFTER STERILIZATION INTENDED FOR INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS (CORPORAL FLUIDS BLOOD, ETC) AND DRUGS,DISPOSABLE HYPODERMIC SYRINGES(BD DISCARDIT II (NON STERILE BULK SYRINGES))-IT IS INTENDED FOR INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS (CORPORAL FLUIDS BLOOD, ETC) AND DRUGS,DISPOSABLE HYPODERMIC SYRINGES(BD SOLOMED (NON STERILE BULK SYRINGES))-IT IS INTENDED FOR INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS (CORPORAL FLUIDS BLOOD, ETC) AND DRUGS

1438	IMP/MD/2018/000401	1.License Holder Name: HEALTHIUM MEDTECH PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SYNTHETIC ABSORBABLE PDO (POLYDIAXANONE) SELF-RETAINING SYSTEM BARBED NEEDLED SUTURE QUILL KNOTLESS TISSUE-CLOSURE DEVICE(QUILL PDO)-QUILL KNOTLESS TISSUE-CLOSURE DEVICE COMPRISED OF DYED PDO IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE USE OF ABSORBABLE SUTURES IS APPROPRIATE.,NON ABSORBABLE POLYPROPYLENE SELF-RETAINING SYSTEM BARBED NEEDLED SUTURE KNOTLESS TISSUE-CLOSURE DEVICE(QUILL POLYPROPYLENE)-QUILL KNOTLESS TISSUE-CLOSURE DEVICE COMPRISED OF POLYPROPYLENE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION EXCLUDING CLOSURE OF THE EPIDERMIS. , SYNTHETIC ABSORBABLE MONOFILAMENT (PGA-PCL) SELF RETAINING SYSTEM BARBED NEEDLED SUTURE KNOTLESS TISSUE CLOSURE DEVICE(QUILL MONODERM)-QUILL MONODERM DEVICE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE THE USE OF ABSORBABLE SUTURES IS APPROPRIATE

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1439	IMP/MD/2018/000402	1.License Holder Name: CARL ZEISS INDIA (BANGALORE) PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:POSTERIOR CHAMBER INTRAOCULAR LENSES (PSEUDOPHAKIC)(AT LARA 829 MP)-THE LENS IS INTENDED FOR SENILE CATARACTS AND OTHER FORMS OF CATARACT AND TO BE PLACED IN THE CAPSULAR BAG. TORIC LENSES ARE INTENDED FOR THE CORRECTION OF REGULAR CORNEAL ASTIGMATISM. EXTENDED RANGE OF INDICATIONS FOR MULTIFOCAL IOLS (TYPE LISA): PRESBYOPIA CORRECTION IN PATIENTS WITH OR WITHOUT CATARACT (PRELEX OR CLEAR LENS EXCHANGE). TYPE LARA: THE LENS IS INDICATED FOR IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION, AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC PATIENTS.,POSTERIOR CHAMBER INTRAOCULAR LENSES (PSEUDOPHAKIC)(AT LISA TRI 839 MP, AT LISA TRI TORIC 939 M, AT LISA TORIC 939 MP)-THE LENS IS INTENDED FOR SENILE CATARACTS AND OTHER FORMS OF CATARACT AND TO BE PLACED IN THE CAPSULAR BAG. TORIC LENSES ARE INTENDED FOR THE CORRECTION OF REGULAR CORNEAL ASTIGMATISM. EXTENDED RANGE OF INDICATIONS FOR MULTIFOCAL IOLS (TYPE LISA): PRESBYOPIA CORRECTION IN PATIENTS WITH OR WITHOUT CATARACT (PRELEX OR CLEAR LENS EXCHANGE). TYPE LARA: THE LENS IS INDICATED FOR IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION, AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC PATIENTS., POSTERIOR CHAMBER INTRAOCULAR LENSES (PSEUDOPHAKIC)(AT TORBI 709 M AND AT TORBI 709 MP)-THE LENS IS INTENDED FOR SENILE CATARACTS AND OTHER FORMS OF CATARACT AND TO BE PLACED IN THE CAPSULAR BAG. TORIC LENSES ARE INTENDED FOR THE CORRECTION OF REGULAR CORNEAL ASTIGMATISM. EXTENDED RANGE OF INDICATIONS FOR MULTIFOCAL IOLS (TYPE LISA): PRESBYOPIA CORRECTION IN PATIENTS WITH OR WITHOUT CATARACT (PRELEX OR CLEAR LENS EXCHANGE). TYPE LARA: THE LENS IS INDICATED FOR IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION, AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC PATIENTS., POSTERIOR CHAMBER INTRAOCULAR LENS (PSEUDOPHAKIC)(AT LISA 809M, AT LISA 809MP, AT LISA TORIC 909M, AT LISA TORIC

	909MP)-THE LENS IS INTENDED FOR SENILE CATARACTS AND OTHER FORMS OF CATARACT AND TO BE PLACED IN THE CAPSULAR BAG. TORIC LENSES ARE INTENDED FOR THE CORRECTION OF REGULAR CORNEAL ASTIGMATISM. EXTENDED RANGE OF INDICATIONS FOR MULTIFOCAL IOLS (TYPE LISA): PRESBYOPIA CORRECTION IN PATIENTS WITH OR WITHOUT CATARACT (PRELEX OR CLEAR LENS EXCHANGE). TYPE LARA: THE LENS IS INDICATED FOR IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION, AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC PATIENTS.,POSTERIOR CHAMBER INTRAOCULAR LENS (PSEUDOPHAKIC)(CT SPHERIS 204, CT ASPHINA 404, CT ASPHINA 509M, CT ASPHINA 509 MP, CT ASPHINA 409MP)-THE LENS IS INTENDED FOR SENILE CATARACTS AND OTHER FORMS OF CATARACT AND TO BE PLACED IN THE CAPSULAR BAG. TORIC LENSES ARE INTENDED FOR THE CORRECTION OF REGULAR CORNEAL ASTIGMATISM. EXTENDED RANGE OF INDICATIONS FOR MULTIFOCAL IOLS (TYPE LISA): PRESBYOPIA CORRECTION IN PATIENTS WITH OR WITHOUT CATARACT (PRELEX OR CLEAR LENS EXCHANGE). TYPE LARA: THE LENS IS INDICATED FOR IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION, AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC PATIENTS.,POSTERIOR CHAMBER INTRAOCULAR LENSES (PSEUDOPHAKIC)(AT LARA TORIC 929 M AND AT LARA TORIC 929 MP)-THE LENS IS INTENDED TO CORRECT APHAKIA. THE LENS IS INTENDED FOR SENILE CATARACTS AND OTHER FORMS OF CATARACT AND TO BE PLACED IN CAPSULAR BAGS. TORIC LENSES ARE INTENDED FOR THE CORRECTION OF REGULAR CORNEAL ASTIGMATISM. TYPE LARA: THE LENS IS INDICATED FOR IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION, AND APHAKIA FOLLOWING REFRACTIVE LENSECTOMY IN PRESBYOPIC PATIENTS.

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1440	IMP/MD/2018/000403	1.License Holder Name: DR. BLOODO 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTING NEEDLES FOR SINGLE USE- TYPE- A (MULTI- SAMPLE NEEDLE) (NEEDLE- O-MAN)-BLOOD COLLECTING NEEDLE IS USED WITH A VACUUM BLOOD COLLECTING TUBE AND VACUUM BLOOD COLLECTION TUBE HOLDER. THIS SYSTEM OF VACUUM BLOOD COLLECTION IS USED FOR A SAMPLE OF VENOUS BLOOD TO PERFORM AND ANALYSIS OF MEDICAL BIOLOGY.,BLOOD COLLECTING NEEDLES FOR SINGLE USE- TYPE- C (MULTI SAMPLE NEEDLE WITH FLASH BACK)(NEEDLE- O-MAN)-BLOOD COLLECTING NEEDLE IS USED WITH A VACUUM BLOOD COLLECTING TUBE AND VACUUM BLOOD COLLECTION TUBE HOLDER. THIS SYSTEM OF VACUUM BLOOD COLLECTION IS USED FOR A SAMPLE OF VENOUS BLOOD TO PERFORM AND ANALYSIS OF MEDICAL BIOLOGY.

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1441	IMP/MD/2018/000404	1.License Holder Name: LIFETECH SCIENTIFIC INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ATRIAL SEPTAL DEFECT (ASD) OCCLUDER(CERATM)-THE CERATM ASD OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER, ATRIAL SEPTAL DEFECT CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF ATRIAL SEPTAL DEFECT (ASD) IN SECUNDUM POSITION OR PATIENTS WHO HAVE UNDERGONE A FENESTRATED FONTAN PROCEDURE AND WHO NOW REQUIRE CLOSURE OF THE FENESTRATION. PATIENTS INDICATED FOR ASD CLOSURE HAVE ECHOCARDIOGRAGHIC EVIDENCE OF (FENESTRATED) OSTIUM SECUNDEM ATRIAL SEPTAL DEFECT AND CLINICAL EVIDENCE OF RIGHT VENTRICULAR VOLUME OVERLOAD., ASD [ATRIAL SEPTAL DEFECT] OCCLUDER(HEARTRTM)-THE HEARTRTM ASD OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER, ATRIAL SEPTAL DEFECT CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF ATRIAL SEPTAL DEFECT (ASD) IN SECUNDUM POSITION OR PATIENTS WHO HAVE UNDERGONE A FENESTRATED FONTAN PROCEDURE AND WHO NOW REQUIRE CLOSURE OF THE FENESTRATION.,VENA CAVA FILTER(AEGISYTM)-AEGISYTM VENA CAVA FILTER IS INDICATED FOR FILTRATING THROMBUS AFTER PERCUTANEOUS PLACEMENT IN THE INFERIOR VENA CAVA IN THE FOLLOWING SITUATIONS: PULMONARY EMBOLISM, WHEN ANTICOAGULANTS ARE CONTRAINDICATED FAILURE OF ANTICOAGULANT THERAPY IN THROMBO-EMBOLIC DISEASES EMERGENCY TREATMENT FOLLOWING MASSIVE PULMONARY EMBOLISM WHEN ANTICIPATED BENEFITS OF CONVENTIONAL THERAPY ARE REDUCED CHRONIC, RECURRENT PULMONARY EMBOLISM WHEN ANTICOAGULANT THERAPY HAS FAILED OR IS CONTRAINDICATED.,PDA [PATENT DUCTUS ARTERIOSUS] OCCLUDER (CERATM)-THE CERATM PDA OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER DEVICE, INTENDED FOR THE NON-SURGICAL CLOSURE OF PATENT DUCTUS ARTERIOSUS (PDA).,SIZING BALLOON (ACUMARKTM)-ACUMARKTM SIZING BALLOON IS INTENDED FOR USE IN THOSE PATIENTS WITH CARDIOVASCULAR DEFECTS WHEREIN ACCURATE MEASUREMENT OF THE DEFECT IS IMPORTANT TO SELECT AN APPROPRIATELY SIZED OCCLUSION DEVICE. MEASURING CAN BE ACCOMPLISHED IN TWO WAYS: RADIOGRAPHICALLY OR ECHOCARDIOGRAPHICALLY.,STENT GRAFT SYSTEM(ANKURATM)-THE ANKURATM STENT GRAFT SYSTEMS ARE INDICATED FOR THE ENDOVASCULAR REPAIR OF PATIENTS WITH AORTIC AND AORTO-ILIAC DISEASES HAVING MORPHOLOGY SUITABLE FOR ENDOVASCULAR REPAIR. THE ANKURATM TAA STENT GRAFT SYSTEM IS INDICATED FOR ENDOVASCULAR REPAIR OF PATIENTS WITH THORACIC AORTIC ANEURYSMS OR THORACIC AORTIC

	DISSECTION, REQUIRING: 1) ADEQUATE ILIAC/FEMORAL ACCESS VESSEL THAT IS COMPATIBLE WITH THE REQUIRED DELIVERY SYSTEM. 2) AORTIC INNER DIAMETER IN THE RANGE OF 18-42MM. 3) 15MM NON-ANEURYSMAL AORTA PROXIMAL AND DISTAL TO THE LESION. 4) MORPHOLOGY SUITABLE FOR ENDOVASCULAR REPAIR. TYPE B DISSECTIONS IN PATIENTS WHO HAVE APPROPRIATE ANATOMY,INDUDING; 1) ADEQUATE ILIAC/FEMORAL ACCESS VESSEL THAT IS COMPATIBLE WITH THE REQUIRED DELIVERY SYSTEM. 2 15MM LANDING ZONE PROXIMAL TO THE PRIMARY ENTRY TEAR; PROXIMAL EXTENT OF THE LANDING ZONE MUST NOT BE DISSECTED. DIAMETER AT PROXIMAL EXTENT OF PROXIMAL LANDING ZONE IN THE RANGE OF 16-44MM. 315MM LANDING ZONE DISTAL TO THE PRIMARY ENTRY TEAR; DISTAL EXTENT OF THE LANDING ZONE MUST NOT BE DISSECTED. DIAMETER AT DISTAL EXTENT OF DISTAL LANDING ZONE IN THE RANGE OF 16-44MM. 4MORPHOLOGY SUITABLE FOR ENDOVASCULAR REPAIR. THE ANKURATM AAA STENT GRAFT AND CUFF STENT GRAFT CONSISTED OF A MODULAR SYSTEM, WHICH IS INDICATED FOR ENDOVASCULAR REPAIR OF PATIENTS WITH ABDOMINAL AORTIC ANEURYSMS, REQUIRING: 1ADEQUATE ILIAC/FEMORAL ACCESS COMPATIBLE WITH THE REQUIRED DELIVERY SYSTEM; 2NON-ANEURYSMAL PROXIMAL AORTIC NECK LENGTH 15MM; 3PROXIMAL AORTIC NECK ANGULATION 60°; 4 DISTAL ILIAC ARTERY ANCHORAGE ZONE 15MM; 5DISTAL ILIAC ARTERY DIAMETER OF 8-22MM; 6MORPHOLOGY SUITABLE FOR ENDOVASCULAR REPAIR. THE ANKURATM AUI STENT GRAFT SYSTEM IS INDICATED FOR ENDOVASCULAR REPAIR OF PATIENTS WITH ABDOMINAL AORTIC ANEURYSMS, REQUIRING: 1ADEQUATE ILIAC/FEMORAL ACCESS COMPATIBLE WITH THE REQUIRED DELIVERY SYSTEM; 2NON-ANEURYSMAL PROXIMAL AORTIC NECK LENGTH 15MM; 3NON-ANEURYSMAL PROXIMAL AORTIC NECK DIAMETER OF 18-32MM; 4PROXIMAL AORTIC NECK ANGULATION 60°; 5DISTAL ILIAC ARTERY ANCHORAGE ZONE 15MM; 6DISTAL ILIAC ARTERY DIAMETER OF 10-16 MM; 7MORPHOLOGY SUITABLE FOR ENDOVASCULAR REPAIR.,MULTI-FENESTRATED (MF) ASD OCCLUDER(CERATM)-THE CERATM MULTI-FENESTRATED ASD OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER, ATRIAL SEPTAL DEFECT CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF MULTI-FENESTRATED ATRIAL SEPTAL DEFECTS (ASD).,VSD [VENTRICULAR SEPTAL DEFECT] OCCLUDER(CERATM)-THE CERATM VSD OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER, VENTRICULAR SEPTAL DEFECT CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF VENTRICULAR SEPTAL DEFECT (VSD).,PDA [PATENT DUCTUS ARTERIOSUS] OCCLUDER(HEARTRTM)-THE HEARTRTM PDA OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER DEVICE,

		INTENDED FOR THE NON-SURGICAL CLOSURE OF PATENT DUCTUS ARTERIOSUS (PDA).,SNARE SYSTEM(SEQURETM)-SEQURETM SNARE SYSTEM IS INTENDED FOR USE IN THE CARDIOVASCULAR SYSTEM AS A TOOL TO RETRIEVE FOREIGN OBJECTS.,INTRODUCER (STEEREASETM)-THE STEEREASETM INTRODUCER IS INTENDED TO REACH THE CARDIOVASCULAR SYSTEM OR THE PERIPHERAL VASCULATURE AND WOULD PROVIDE A PATHWAY TO PERFORM THE DELIVERY OF THE DEVICES,VSD [VENTRICULAR SEPTAL DEFECT] OCCLUDER(HEARTRTM)-THE HEARTRTM VSD OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER, INTENDED FOR THE OCCLUSION OF VENTRICULAR SEPTAL DEFECT (VSD).,STEERABLE INTRODUCER (FUSTARTM)-THE FUSTARTM STEERABLE INTRODUCER IS INDICATED TO PROVIDE A PATHWAY THROUGH WHICH DEVICES ARE INTRODUCED WITHIN THE CHAMBERS AND CORONARY VASCULATURE OF THE HEART OR IN THE PERIPHERAL VASCULATURE.,VASCULAR PLUG SYSTEM(CERATM)-THE CERATM VASCULAR PLUG SYSTEM IS INDICATED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE.
1442	IMP/MD/2018/000404	1.License Holder Name: LIFETECH SCIENTIFIC INDIA PVT. LTD. ,NO. 521, I FLOOR, 4TH CROSS, 9TH MAIN, HAL IIND STAGE, INDIRANAGAR, BENGALURU ,BENGALURU (BANGALORE) URBAN KARNATAKA , 560038 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VSD OCCLUDER(KONAR-MF)-THE KONAR-MF VSD OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF VSDS.,LEFT ATRIAL APPENDAGE (LAA) CLOSURE SYSTEMS (LAMBRE DELIVERY SYSTEM)-THE LAMBRE LEFT ATRIAL APPENDAGE CLOSURE SYSTEM IS A PERCUTANEOUS TRANSCATHETER DEVICE INTENDED TO PREVENT THROMBUS EMBOLIZATION FROM THE LEFT ATRIAL APPENDAGE (LAA) IN PATIENTS WHO HAVE NONVALVULAR ATRIAL FIBRILLATION.,LEFT ATRIAL APPENDAGE (LAA) CLOSURE SYSTEMS(LAMBRE LEFT ATRIAL APPENDAGE OCCLUDER)-THE LAMBRE LEFT ATRIAL APPENDAGE CLOSURE SYSTEM IS A PERCUTANEOUS TRANSCATHETER DEVICE INTENDED TO PREVENT THROMBUS EMBOLIZATION FROM THE LEFT ATRIAL APPENDAGE (LAA) IN PATIENTS WHO HAVE NONVALVULAR ATRIAL FIBRILLATION.

1443	IMP/MD/2018/000405	1.License Holder Name: ARK DIAGNOSTICS BANGALORE PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LYSE FOR BLOOD CELL ANALYSIS(DIFF LYSE-(KT05DIFF))-THISPRODUCTIS USEDTODISSOLVERBC ANDMAINTAIN THEMORPHOLOGYOFTHECELLS NEEDEDTOBEANALYZEDBEFOREBLOOD CELLANALYSIS SOTHAT FACILITATECELLSORTINGORHGB QUANTIFICATION,LYSE FOR BLOOD CELL ANALYSIS(LH LYSE- (KT05LH))-THIS PRODUCT IS USED TO DISSOLVE RBC AND MAINTAIN THE MORPHOLOGY OF THE CELLS NEEDED TO BE ANALYZED BEFORE BLOOD CELL ANALYSIS THEREBY FACILITATE CELL SORTING OR HGB QUANTIFICATION.,DILUENT FOR BLOOD CELL ANALYSIS(DILUENT-(KT05 DIL))-THIS PRODUCT IS USED FOR DILUTION OF BLOOD SAMPLES AND PREPARE CELL SUSPENSIONS PRIOR TO ANALYSIS OF THE CELLS.,LYSE FOR HEMOCYTE ANALYSIS(LYSE SOLUTION (KT03))-THIS PRODUCT CAN DISSOLVE RBC AND CREATE COMPLEX SUBSTANCE WITH HEMOGLOBIN TO COUNT HUMAN'S WBC,SUBPOPULATE WBC AND MEASURE HEMOGLOBIN,DILUENT FOR HEMOCYTE ANALYSIS (DILUENT SOLUTION(KT03))-THIS PRODUCT IS ISOTONIC SOLUTION WITH A SPECIFIC CONDUCTIVITY AND ASSURE STABLE ENVIRONMENT TO COUNT BLOOD CELL.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1444	IMP/MD/2018/000406	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TIERED-THERAPY CARDIOVERTER/DEFIBRILLATOR(ELLIPSE DR)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,SLITTABLE OUTER GUIDE CATHETER(CPS DIRECT SL II)-THE ST. JUDE MEDICAL CPS DIRECT SL II SLITTABLE OUTER GUIDE CATHETER IS DESIGNED FOR INTRACARDIAC ACCESS OF THE VENOUS SYSTEM OF THE HEART AND TO SERVE AS A CONDUIT DURING IMPLANTATION FOR THE DELIVERY OF CONTRAST MEDIUM AND ST. JUDE MEDICAL DEVICES (INCLUDING IMPLANTABLE LEFT HEART LEADS AND DELIVERY TOOLS), AND SUPPORT OF FLUIDS WHERE MINIMIZING BLOOD LOSS IS ESSENTIAL. IN ADDITION, CPS DIRECT SL II SLITTABLE OUTER GUIDE CATHETERS CAN WORK WITH INNER CATHETERS AS A SYSTEM.,CARDIAC RESYNCHRONIZATION THERAPY- CARDIOVERTER/DEFIBRILLATOR(QUADRA ASSURA MP)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRTDS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,PEELABLE OUTER GUIDE CATHETER (CPS DIRECT™ PL)-THE ST. JUDE MEDICAL CPS DIRECT PL PEELABLE OUTER GUIDE CATHETER IS DESIGNED FOR INTRACARDIAC ACCESS OF THE VENOUS SYSTEM OF THE HEART AND TO SERVE AS A CONDUIT DURING IMPLANTATION FOR THE DELIVERY OF CONTRAST MEDIUM AND ST. JUDE MEDICAL DEVICES (INCLUDING IMPLANTABLE LEFT HEART LEADS AND DELIVERY TOOLS), AND SUPPORT OF FLUIDS WHERE MINIMIZING BLOOD LOSS IS ESSENTIAL. IN ADDITION, CPS DIRECT PL PEELABLE OUTER GUIDE CATHETERS CAN WORK

	WITH INNER CATHETERS AS A SYSTEM.,TIERED-THERAPY CARDIOVERTER/DEFIBRILLATOR(ELLIPSE VR)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,SLITTABLE OUTER GUIDE CATHETERS(CPS DIRECT UNIVERSAL)-IT IS DESIGNED FOR INTRACARDIAC ACCESS OF THE VENOUS SYSTEM OF THE HEART AND TO SERVE AS A CONDUIT DURING IMPLANTATION FOR THE DELIVERY OF CONTRAST MEDIUM AND ST. JUDE MEDICAL DEVICES (INCLUDING IMPLANTABLE LEFT HEART LEADS AND DELIVERY TOOLS), SUPPORT OF FLUIDS WHERE MINIMIZING BLOOD LOSS IS ESSENTIAL. IT CAN WORK WITH INNER CATHETERS AS A SYSTEM.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR(GALLANT DR)-THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) AND CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D) DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR CARDIOVERSION/ DEFIBRILLATION. CRT-D DEVICES ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES., SLITTABLE INNER CATHETERS(CPS AIM™ UNIVERSAL)-IT IS DESIGNED FOR INTRACARDIAC ACCESS OF THE CORONARY SINUS AND SUBSELECTION OF THE VENOUS SYSTEM OF THE HEART, AND TO SERVE AS A CONDUIT DURING IMPLANTATION FOR THE DELIVERY OF CONTRAST MEDIUM AND ST. JUDE MEDICAL™ DEVICES, (SUCH AS GUIDEWIRES AND IMPLANTABLE LEFT HEART LEADS). IT CAN WORK WITH OUTER GUIDE CATHETERS AS A SYSTEM.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR(GALLANT VR)-THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) AND CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D) DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR CARDIOVERSION/ DEFIBRILLATION. CRT-D DEVICES ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES.,SLITTABLE INNER CATHETER(CPS AIM™ SL)-THE ST. JUDE MEDICAL CPS AIM™ SL SLITTABLE INNER CATHETER IS DESIGNED FOR INTRACARDIAC ACCESS OF THE CORONARY SINUS AND SUBSELECTION OF THE VENOUS SYSTEM OF THE HEART, AND TO SERVE AS A CONDUIT DURING IMPLANTATION OF ACTIVE

	IMPLANT MEDICAL DEVICES FOR DELIVERY OF CONTRAST MEDIUM AND ST. JUDE MEDICAL DEVICES, INCLUDING GUIDEWIRES. IN ADDITION, CPS AIM SL SLITTABLE INNER CATHETERS CAN WORK WITH OUTER GUIDE CATHETERS AS A SYSTEM.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR(ENTRANT VR)-THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) AND CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D) DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR CARDIOVERSION/ DEFIBRILLATION. CRT-D DEVICES ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES.,PACING LEAD(TENDRIL STS)-THE TENDRIL™ STS MODEL 2088TC LEAD IS DESIGNED FOR PERMANENT SENSING AND PACING IN EITHER THE RIGHT ATRIUM OR THE RIGHT VENTRICLE, IN COMBINATION WITH A COMPATIBLE DEVICE. ACTIVE LEADS SUCH AS TENDRIL STS MODEL 2088TC LEADS MAY BE INDICATED FOR PATIENTS WHERE PERMANENT FIXATION OF PASSIVE LEADS IS SUSPECTED TO BE UNSTABLE. IN ATRIAL APPLICATIONS, THE USE OF A SCREW-IN LEAD SUCH AS TENDRIL STS MODEL 2088TC LEADS MAY BE INDICATED IN THE PRESENCE OF AN ABNORMAL, SURGICALLY ALTERED OR EXCISED ATRIAL APPENDAGE.,CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR(ENTRANT HF)-THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) AND CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D) DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR CARDIOVERSION/ DEFIBRILLATION. CRT-D DEVICES ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES.,DEFIBRILLATION LEADS(DURATA)-THE DURATA TRANSVENOUS LEADS ARE INDICATED FOR USE WITH COMPATIBLE PULSE GENERATOR (REFER TO THE APPLICABLE DEFIBRILLATOR MANUAL FOR SYSTEM INDICATIONS). THEY PROVIDE PACING AND SENSING AND DELIVER CARDIOVERSION/DEFIBRILLATION THERAPY TO THE HEART. A TRANSVENOUS LEAD SYSTEM MAY OFFER THE PATIENT THE BENEFIT OF AVOIDING A THORACOTOMY FOR LEAD IMPLANTATION. IF THE INITIAL LEAD CONFIGURATION IS NOT EFFECTIVE, REPOSITIONING OF THE LEAD OR OTHER LEAD CONFIGURATION SHOULD BE ATTEMPTED. IN SOME PATIENTS, A NONTHORACOTOMY LEAD CONFIGURATION MAY NOT PROVIDE RELIABLE CONVERSION OF ARRHYTHMIAS, AND THE USE OF SUBCUTANEOUS OR EPICARDIAL PATCH DEFIBRILLATION LEADS SHOULD BE CONSIDERED.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR(AVANT DR)-THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) AND CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D) DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR

	CARDIOVERSION/ DEFIBRILLATION. CRT-D DEVICES ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES., LEFT HEART LEAD(QUARTET)-THE QUARTET LEADS ARE DESIGNED FOR USE IN COMBINATION WITH A COMPATIBLE PULSE GENERATOR TO PROVIDE LONG-TERM STIMULATION AND SENSING OF THE LEFT VENTRICLE VIA THE GREAT CARDIAC VEIN OR ONE OF ITS TRIBUTARIES,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ENTRANT DR)-THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) AND CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D) DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR CARDIOVERSION/ DEFIBRILLATION. CRT-D DEVICES ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES., DEFIBRILLATION LEADS(DURATA)-THE DURATA TRANSVENOUS LEADS ARE INDICATED FOR USE WITH COMPATIBLE PULSE GENERATOR (REFER TO THE APPLICABLE DEFIBRILLATOR MANUAL FOR SYSTEM INDICATIONS). THEY PROVIDE PACING AND SENSING AND DELIVER CARDIOVERSION/DEFIBRILLATION THERAPY TO THE HEART. A TRANSVENOUS LEAD SYSTEM MAY OFFER THE PATIENT THE BENEFIT OF AVOIDING A THORACOTOMY FOR LEAD IMPLANTATION. IF THE INITIAL LEAD CONFIGURATION IS NOT EFFECTIVE, REPOSITIONING OF THE LEAD OR OTHER LEAD CONFIGURATION SHOULD BE ATTEMPTED. IN SOME PATIENTS, A NONTHORACOTOMY LEAD CONFIGURATION MAY NOT PROVIDE RELIABLE CONVERSION OF ARRHYTHMIAS, AND THE USE OF SUBCUTANEOUS OR EPICARDIAL PATCH DEFIBRILLATION LEADS SHOULD BE CONSIDERED.,CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR(AVANT HF)-THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) AND CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D) DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR CARDIOVERSION/ DEFIBRILLATION. CRT-D DEVICES ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES., DEFIBRILLATION LEADS(DURATA)-THE DURATA TRANSVENOUS LEADS ARE INDICATED FOR USE WITH COMPATIBLE PULSE GENERATOR (REFER TO THE APPLICABLE DEFIBRILLATOR MANUAL FOR SYSTEM INDICATIONS). THEY PROVIDE PACING AND SENSING AND DELIVER CARDIOVERSION/DEFIBRILLATION THERAPY TO THE HEART. A TRANSVENOUS LEAD SYSTEM MAY OFFER THE PATIENT THE BENEFIT OF AVOIDING A THORACOTOMY FOR LEAD IMPLANTATION. IF THE INITIAL LEAD CONFIGURATION IS NOT EFFECTIVE, REPOSITIONING OF THE LEAD OR OTHER LEAD CONFIGURATION SHOULD BE ATTEMPTED. IN SOME PATIENTS, A NONTHORACOTOMY LEAD CONFIGURATION MAY NOT PROVIDE

	RELIABLE CONVERSION OF ARRHYTHMIAS, AND THE USE OF SUBCUTANEOUS OR EPICARDIAL PATCH DEFIBRILLATION LEADS SHOULD BE CONSIDERED.,STEERABLE CATHETER WITH ELECTRODES (AGILIS HISPRO™)-THE AGILIS HISPRO™ STEERABLE CATHETER WITH ELECTRODES IS INTENDED FOR TRANSVENOUS INTRODUCTION OF CARDIAC CATHETERS OR LEADS INTO THE HEART AND MAY BE USED FOR FLUID INFUSION AND ASPIRATION. THE AGILIS HISPRO™ STEERABLE CATHETER WITH ELECTRODES IS USED IN PATIENTS UNDERGOING AN ELECTROPHYSIOLOGY PROCEDURE AND CAN BE USED TO RECORD ELECTROGRAMS, DELIVER PACING, AND IMPLANT A LEAD.,LEFT HEART LEAD(QUARTET)-THE QUARTET LEADS ARE DESIGNED FOR USE IN COMBINATION WITH A COMPATIBLE PULSE GENERATOR TO PROVIDE LONG-TERM STIMULATION AND SENSING OF THE LEFT VENTRICLE VIA THE GREAT CARDIAC VEIN OR ONE OF ITS TRIBUTARIES,CARDIAC RESYNCHRONIZATION THERAPY-CARDIOVERTER/DEFIBRILLATOR(UNIFY)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,DEFIBRILLATION LEADS(DURATA)-THE DURATA TRANSVENOUS LEADS ARE INDICATED FOR USE WITH COMPATIBLE PULSE GENERATOR (REFER TO THE APPLICABLE DEFIBRILLATOR MANUAL FOR SYSTEM INDICATIONS). THEY PROVIDE PACING AND SENSING AND DELIVER CARDIOVERSION/DEFIBRILLATION THERAPY TO THE HEART. A TRANSVENOUS LEAD SYSTEM MAY OFFER THE PATIENT THE BENEFIT OF AVOIDING A THORACOTOMY FOR LEAD IMPLANTATION. IF THE INITIAL LEAD CONFIGURATION IS NOT EFFECTIVE, REPOSITIONING OF THE LEAD OR OTHER LEAD CONFIGURATION SHOULD BE ATTEMPTED. IN SOME PATIENTS, A NONTHORACOTOMY LEAD CONFIGURATION MAY NOT PROVIDE RELIABLE CONVERSION OF ARRHYTHMIAS, AND THE USE OF SUBCUTANEOUS OR EPICARDIAL PATCH DEFIBRILLATION LEADS SHOULD BE CONSIDERED.,CARDIAC RESYNCHRONIZATION THERAPY- CARDIOVERTER/DEFIBRILLATOR(UNIFY)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS.

	CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,PULSE GENERATOR(ASSURITY MRI) -IMPLANTATION OF A SINGLE-CHAMBER PULSE GENERATOR, DUAL-CHAMBER PULSE GENERATOR, OR CRT-P (CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER) IS INDICATED IN ONE OR MORE OF THE FOLLOWING PERMANENT CONDITIONS OR ANY COMBINATIONS OF THESE SYMPTOMS: • SYNCOPE • PRESYNCOPE • FATIGUE • DISORIENTATION DUE TO ARRHYTHMIA OR BRADYCARDIA. IMPLANTATION OF A CRT-P IS INDICATED FOR PATIENTS WHO: • WOULD BENEFIT FROM RESYNCHRONIZATION OF THE RIGHT AND LEFT VENTRICLES. • HAVE ONE OR MORE CONVENTIONAL INDICATIONS FOR THE IMPLANTATION OF A PACEMAKER. MR CONDITIONAL PULSE GENERATOR IS CONDITIONALLY SAFE FOR USE IN THE MRI ENVIRONMENT WHEN USED IN A COMPLETE MR CONDITIONAL PACING SYSTEM AND ACCORDING TO THE INSTRUCTIONS IN THE MRI-READY SYSTEM MANUAL FOR THE ST. JUDE MEDICAL MR CONDITIONAL PACING SYSTEM. RATE-MODULATED PACING IS INDICATED FOR PATIENTS WITH CHRONOTROPIC INCOMPETENCE, AND FOR THOSE WHO WOULD BENEFIT FROM INCREASED STIMULATION RATES CONCURRENT WITH PHYSICAL ACTIVITY. DUAL-CHAMBER PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR THOSE PATIENTS EXHIBITING: • SICK SINUS SYNDROME • CHRONIC, SYMPTOMATIC SECOND- AND THIRD-DEGREE AV BLOCK • RECURRENT ADAMS-STOKES SYNDROME • SYMPTOMATIC BILATERAL BUNDLE BRANCH BLOCK WHEN TACHYARRHYTHMIA AND OTHER CAUSES HAVE BEEN RULED OUT. ATRIAL PACING IS INDICATED FOR PATIENTS WITH SINUS NODE DYSFUNCTION AND NORMAL AV AND INTRAVENTRICULAR CONDUCTION SYSTEMS. VENTRICULAR PACING IS INDICATED FOR PATIENTS WITH SIGNIFICANT BRADYCARDIA AND: • NORMAL SINUS RHYTHM WITH ONLY RARE EPISODES OF AV BLOCK OR SINUS ARREST • CHRONIC ATRIAL FIBRILLATION (AF) • SEVERE PHYSICAL DISABILITY. AF SUPPRESSION PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR SUPPRESSION OF PAROXYSMAL OR PERSISTENT ATRIAL FIBRILLATION EPISODES IN PATIENTS WITH ONE OR MORE OF THE ABOVE PACING INDICATIONS. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH

	HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF. FOR SPECIFIC INDICATIONS ASSOCIATED WITH INDIVIDUAL MODES, REFER TO THE PROGRAMMER'S ON-SCREEN HELP.,TIERED-THERAPY CARDIOVERTER/DEFIBRILLATOR(ELLIPSE DR)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,CARDIAC RESYNCHRONIZATION THERAPY-CARDIOVERTER/DEFIBRILLATOR(QUADRA ASSURA MP)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRTDS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR(AVANT VR)-THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) AND CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D) DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR CARDIOVERSION/ DEFIBRILLATION. CRT-D DEVICES ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES., INSERTABLE CARDIAC MONITOR(CONFIRM RX)-THE CONFIRM RX™ ICM IS INDICATED FOR THE MONITORING AND DIAGNOSTIC EVALUATION OF PATIENTS WHO EXPERIENCE UNEXPLAINED SYMPTOMS SUCH AS: DIZZINESS, PALPITATIONS, CHEST PAIN, SYNCOPE, AND SHORTNESS OF BREATH, AS WELL AS PATIENTS WHO ARE AT RISK FOR CARDIAC ARRHYTHMIAS. IT IS ALSO INDICATED FOR PATIENTS WHO HAVE BEEN PREVIOUSLY DIAGNOSED WITH ATRIAL FIBRILLATION OR WHO ARE SUSCEPTIBLE TO DEVELOPING ATRIAL FIBRILLATION.,TIERED-THERAPY

	CARDIOVERTER/DEFIBRILLATOR(ELLIPSE VR)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,PULSE GENERATOR(ASSURITY MRI)-IMPLANTATION OF A SINGLE-CHAMBER PULSE GENERATOR, DUAL-CHAMBER PULSE GENERATOR, OR CRT-P (CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER) IS INDICATED IN ONE OR MORE OF THE FOLLOWING PERMANENT CONDITIONS OR ANY COMBINATIONS OF THESE SYMPTOMS: • SYNCOPE • PRESYNCOPE • FATIGUE • DISORIENTATION DUE TO ARRHYTHMIA OR BRADYCARDIA. IMPLANTATION OF A CRT-P IS INDICATED FOR PATIENTS WHO: • WOULD BENEFIT FROM RESYNCHRONIZATION OF THE RIGHT AND LEFT VENTRICLES. • HAVE ONE OR MORE CONVENTIONAL INDICATIONS FOR THE IMPLANTATION OF A PACEMAKER. MR CONDITIONAL PULSE GENERATOR IS CONDITIONALLY SAFE FOR USE IN THE MRI ENVIRONMENT WHEN USED IN A COMPLETE MR CONDITIONAL PACING SYSTEM AND ACCORDING TO THE INSTRUCTIONS IN THE MRI-READY SYSTEM MANUAL FOR THE ST. JUDE MEDICAL MR CONDITIONAL PACING SYSTEM. RATE-MODULATED PACING IS INDICATED FOR PATIENTS WITH CHRONOTROPIC INCOMPETENCE, AND FOR THOSE WHO WOULD BENEFIT FROM INCREASED STIMULATION RATES CONCURRENT WITH PHYSICAL ACTIVITY. DUAL-CHAMBER PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR THOSE PATIENTS EXHIBITING: • SICK SINUS SYNDROME • CHRONIC, SYMPTOMATIC SECOND- AND THIRD-DEGREE AV BLOCK • RECURRENT ADAMS-STOKES SYNDROME • SYMPTOMATIC BILATERAL BUNDLE BRANCH BLOCK WHEN TACHYARRHYTHMIA AND OTHER CAUSES HAVE BEEN RULED OUT. ATRIAL PACING IS INDICATED FOR PATIENTS WITH SINUS NODE DYSFUNCTION AND NORMAL AV AND INTRAVENTRICULAR CONDUCTION SYSTEMS. VENTRICULAR PACING IS INDICATED FOR PATIENTS WITH SIGNIFICANT BRADYCARDIA AND: • NORMAL SINUS RHYTHM WITH ONLY RARE EPISODES OF AV BLOCK OR SINUS ARREST • CHRONIC ATRIAL FIBRILLATION (AF) • SEVERE PHYSICAL DISABILITY. AF SUPPRESSION PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR SUPPRESSION OF

	PAROXYSMAL OR PERSISTENT ATRIAL FIBRILLATION EPISODES IN PATIENTS WITH ONE OR MORE OF THE ABOVE PACING INDICATIONS. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF. FOR SPECIFIC INDICATIONS ASSOCIATED WITH INDIVIDUAL MODES, REFER TO THE PROGRAMMER'S ON-SCREEN HELP.,CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR(GALLANT HF)-THE IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) AND CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (CRT-D) DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR CARDIOVERSION/ DEFIBRILLATION. CRT-D DEVICES ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1445	IMP/MD/2018/000407	1.License Holder Name: FRESENIUS KABI INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLES FOR APHERESIS AND CELL SEPARATION (PL1 PLASMA EXCHANGE SET)-THERAPEUTIC PLASMA EXCHANGE, RED BLOOD CELL EXCHANGE., DISPOSABLE FOR AUTOTRANSFUSION(ATR 120 RESERVOIR)-ATR 120 RESERVOIR IS A 3 LITER COLLECTION RESERVOIR, CONTAINING A 120 M FILTER, DESIGNATED TO COLLECT, DEFOAM, FILTER AND STORE BLOOD PRIOR TO PROCESSING.,DISPOSABLE FOR AUTOTRANSFUSION(AT1 AUTO TRANSFUSION SET)-AT1 AUTOTRANSFUSION SET IS A DISPOSABLE FOR CATS CONTAINING A WASHING CHAMBER, TUBING, WASTE BAG AND REINFUSION BAG., DISPOSABLES FOR APHERESIS AND CELL SEPARATION (C5L PLATELET SET)-COLLECTION OF PLATELETS PERMITS 5-DAY STORAGE PERIOD, PERMITS SIMULTANEOUS COLLECTION OF PLASMA WITH PLASMA TRANSFER BAG AND PRE-DONATION SAMPLING BAG FOR USE WITH COM.TEC,DISPOSABLES FOR APHERESIS AND CELL SEPARATION (P1YA WHITE BLOOD CELL SET)-GRANULOCYTE DONATION, BONE MARROW STEM CELL PROCESSING, MONOCYTE /PERIPHERAL BLOOD STEM CELL DONATION/DEPLETION, FOR USE WITH COM.TEC.,AUTOTRANSFUSION SET(AT3 AUTOTRANSFUSION SET (9005177))-AT3 AUTOTRANSFUSION SET IS A DISPOSABLE FOR CONTINUOUS AUTOTRANSFUSION SYSTEM CONTAINING A WASHING CHAMBER, TUBING WASTE BAG AND REINFUSION BAG.,DISPOSABLE FOR AUTOTRANSFUSION(ATS SUCTION LINE)-ATS SUCTION LINE IS A SUCTION LINE TO ASPIRATE AND ANTICOAGULATE BLOOD FROM SURGICAL FIELD INTO AN AUTOTRANSFUSION RESERVOIR WITH A ¼" SUCTION PORT TO BE CONNECTED TO A VACUUM SOURCE., DISPOSABLES FOR APHERESIS AND CELL SEPARATION (S5L PLATELET SET)-COLLECTION OF PLATELETS PERMITS 5-DAY STORAGE PERIOD, PERMITS SIMULTANEOUS COLLECTION OF PLASMA WITH PLASMA TRANSFER BAG AND PRE-DONATION SAMPLING BAG FOR USE WITH COM.TEC, BUT DESIGNED FOR SINGLE NEEDLE OPERATION, FOR USE WITH COM.TEC.,DISPOSABLES FOR APHERESIS AND CELL SEPARATION (P1R PLASMA TREATMENT SET)-THERAPEUTIC PLASMA TREATMENT (E.G. LDL-APHERESIS)

1446	IMP/MD/2018/000408	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENT PLASMA WAND SURGICAL DEVICES-INDICATED FOR ABLATION, RESECTION, AND COAGULATION OF SOFT TISSUE AND HEMOSTASIS OF BLOOD VESSELS IN OTORHINOLARYNGOLOGY (ENT) SURGERY,NASAL DRESSING-DISSOLVABLE(NASASTENT)-NASASTENT™ DRESSING IS INTENDED TO MINIMIZE BLEEDING AND EDEMA AND TO PREVENT ADHESIONS BETWEEN THE SEPTUM AND THE NASAL CAVITY. IT IS PLACED IN THE NASAL CAVITY AFTER SURGERY OR TRAUMA., ARTHROWAND SURGICAL DEVICES-INDICATED FOR RESECTION, ABLATION, AND COAGULATION OF SOFT TISSUE, AND HEMOSTASIS OF BLOOD VESSELS IN ARTHROSCOPIC AND ORTHOPEDIC PROCEDURES.
1447	IMP/MD/2018/000410	1.License Holder Name: ALCON LABORATORIES (INDIA) PVT. LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTI PURPOSE DISINFECTANT SOLUTION(OPTI FREE PUREMOIST)-FOR USE IN THE DAILY CLEANING, RECONDITIONING, RINSING, REMOVING PROTEIN DEPOSITS, REDUCING LIPID DEPOSITION, CHEMICAL (NOT HEAT) DISINFECTION, AND STORAGE OF SILICONE HYDROGEL AND SOFT (HYDROPHILIC) CONTACT LENSES AS RECOMMENDED BY YOUR EYE CARE PRACTITIONER.,MULTI-PURPOSE DISINFECTANT SOLUTION (OPTI-FREE REPLENISH)-FOR USE IN THE DAILY CLEANING, CONDITIONING, RINSING, REMOVING PROTEIN DEPOSITS, CHEMICAL (NOT HEAT) DISINFECTION, AND STORAGE OF SILICONE HYDROGEL AND SOFT (HYDROPHILIC) CONTACT LENSES AS RECOMMENDED BY YOUR EYE CARE PRACTITIONER.

1448	IMP/MD/2018/000411	1.License Holder Name: ADVANCED BIONICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIRESOLUTION BIONIC EAR SYSTEM(HIRES 90K ADVANTAGE CI HIFOCUS MS ELECTRODE (CI-1500-04))-IT IS A COCHLEAR IMPLANT SYSTEM INTENDED TO RESTORE A LEVEL OF AUDITORY SENSATION TO INDIVIDUALS WITH SEVERE-TO-PROFOUND SENSORINEURAL HEARING LOSS VIA ELECTRICAL STIMULATION OF THE AUDITORY NERVE,HIRESOLUTION BIONIC EAR SYSTEM(HIRES ULTRA 3D CI HIFOCUS MS ELECTRODE (CI-1601-04))-IT IS A COCHLEAR IMPLANT SYSTEM INTENDED TO RESTORE A LEVEL OF AUDITORY SENSATION TO INDIVIDUALS WITH SEVERE-TO-PROFOUND SENSORINEURAL HEARING LOSS VIA ELECTRICAL STIMULATION OF THE AUDITORY NERVE,HIRESOLUTION BIONIC EAR SYSTEM(HIRES ULTRA CI HIFOCUS MS ELECTRODE (CI-1600-04))-IT IS A COCHLEAR IMPLANT SYSTEM INTENDED TO RESTORE A LEVEL OF AUDITORY SENSATION TO INDIVIDUALS WITH SEVERE-TO-PROFOUND SENSORINEURAL HEARING LOSS VIA ELECTRICAL STIMULATION OF THE AUDITORY NERVE,HIRESOLUTION BIONIC EAR SYSTEM(HIRES ULTRA 3D CI HIFOCUS SLIMJ ELECTRODE (CI-1601-05))-IT IS A COCHLEAR IMPLANT SYSTEM INTENDED TO RESTORE A LEVEL OF AUDITORY SENSATION TO INDIVIDUALS WITH SEVERE-TO-PROFOUND SENSORINEURAL HEARING LOSS VIA ELECTRICAL STIMULATION OF THE AUDITORY NERVE,HIRESOLUTION BIONIC EAR SYSTEM(HIRES 90K ADVANTAGE CI HIFOCUS 1J ELECTRODE (CI-1500-01))-IT IS A COCHLEAR IMPLANT SYSTEM INTENDED TO RESTORE A LEVEL OF AUDITORY SENSATION TO INDIVIDUALS WITH SEVERE-TO-PROFOUND SENSORINEURAL HEARING LOSS VIA ELECTRICAL STIMULATION OF THE AUDITORY NERVE,HIRESOLUTION BIONIC EAR SYSTEM(HIRES ULTRA CI HIFOCUS SLIMJ ELECTRODE (CI-1600-05))-IT IS A COCHLEAR IMPLANT SYSTEM INTENDED TO RESTORE A LEVEL OF AUDITORY SENSATION TO INDIVIDUALS WITH SEVERE-TO-PROFOUND SENSORINEURAL HEARING LOSS VIA ELECTRICAL STIMULATION OF THE AUDITORY NERVE

1449	IMP/MD/2018/000412	1.License Holder Name: BL LIFESCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VENOUS CATHETERS (BULK NON-STERILE)(NA)-VENOUS DRAINAGE DURING CARDIOPLUMONARY BYPASS PROCEDURES,VENOUS CANNULA (BULK NON-STERILE)(NA)-VENOUS DRAINAGE DURING CARDIOPLUMONARY BYPASS PROCEDURES,AORTIC CANNULA (BULK NON-STERILE)(NA)-PERFUSION DURING CARDIOPLUMONARY BYPASS PROCEDURES,AORTIC CATHETERS (BULK NON-STERILE)(NA) -PERFUSION DURING CARDIOPLUMONARY BYPASS PROCEDURES
1450	IMP/MD/2018/000415	1.License Holder Name: BL LIFESCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER & ACCESSORIES (NON STERILE BULK)(NA)-THE PRODUCT IS APPLICABLE FOR MONITORING THE CENTRAL VENOUS PRESSURE, COLLECTING THE BLOOD SAMPLE AND INJECTING THE DRUG OR SOLUTION. THE DESIGN OF MULTICAVITY CAN GO ON THE PROCESS ABOVE AT THE SAME TIME. THE TIME OF USE IS LESS THAN 30 DAYS.
1451	IMP/MD/2018/000416	1.License Holder Name: SMITHS MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMBINED SPINAL EPIDURAL MINIPACK(RAPID PORTEX, PORTEX)-IT IS SINGLE AND EPIDURAL NEEDLES TO PERFORM A SPINAL (SUBARACHNOID) INJECTION THROUGH AN EPIDURAL TUOHY NEEDLE PLACED IN THE EPIDURAL SPACE FOLLOWED BY THE PLACEMENT OF AN EPIDURAL CATHETER TO ALLOW MODIFICATION OF THE SPINAL ANALGESIA IF NECESSARY OR BOLUS INJECTIONS OR CONTINUOUS INFUSION OF LOCAL ANESTHETICS OR OTHER DRUGS INTO THE EPIDURAL SPACE FOR SUBSEQUENT PAIN RELIEF IF REQUIRED.

1452	IMP/MD/2018/000418	1.License Holder Name: HALYARD HEALTH INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GASTROSTOMY FEEDING TUBE(HALYARD*)-THE HALYARD* MIC* GASTROSTOMY / BOLUS FEEDING TUBE ARE INDICATED FOR USE IN PATIENTS WHO REQUIRE LONG TERM FEEDING, ARE UNABLE TO TOLERATE ORAL FEEDING, WHO ARE AT LOW RISK FOR ASPIRATION, REQUIRE GASTRIC DECOMPRESSION AND / OR MEDICATION DELIVERY DIRECTLY INTO THE STOMACH.,MIC* JEJUNOSTOMY FEEDING TUBE(HALYARD*)-THE MIC* JEJUNOSTOMY TUBE CAN BE USED IN CANCER PATIENTS, SUFFERING FROM HEAD AND NECK PATHOLOGIES. THESE PATIENTS ARE FREQUENTLY ON RIGOROUS PROGRAMS OF CHEMOTHERAPY AND/OR RADIATION THERAPY AND OFTEN DEVELOP ANOREXIA, NAUSEA, PHARYNGITIS, ESOPHAGITIS, ETC., THUS PRECLUDING AN ALREADY COMPROMISED ABILITY TO EAT.,MIC* PEG REPLACEMENT FEEDING ADAPTER(HALYARD*)-MIC* PEG REPLACEMENT FEEDING ADAPTER IS AN ACCESSORY INCLUDED IN THE PEG TUBE KIT ALLOW FOR INITIAL PLACEMENT OF THE PEG TUBE.,ENTERAL ACCESS DILATION SYSTEM(HALYARD*)-THE HALYARD* ENTERAL ACCESS DILATION SYSTEM IS INTENDED TO FACILITATE STOMA TRACT DILATION PRIOR TO PLACEMENT OF THE HALYARD* MIC*AND MIC-KEY* BRAND ENTERAL FEEDING TUBES.,MIC-KEY* CONTINUOUS FEED EXTENSION SET(HALYARD*)-THE ACCESSORY EXTENSIONS ARE USED TO CONNECT THE ENTERAL FEEDING TUBE TO ENTERAL FEEDING EQUIPMENT OR A SYRINGE FOR THE DELIVERY OF ENTERAL NUTRITION, MEDICATION, OR GASTRIC DECOMPRESSION TO THE STOMACH.,MIC-KEY* BOLUS EXTENSION SET(HALYARD*)-THE ACCESSORY EXTENSIONS ARE USED TO CONNECT THE ENTERAL FEEDING TUBE TO ENTERAL FEEDING EQUIPMENT OR A SYRINGE FOR THE DELIVERY OF ENTERAL NUTRITION, MEDICATION, OR GASTRIC DECOMPRESSION TO THE STOMACH.,MIC-KEY* OVER-THE-WIRE STOMA MEASURING DEVICE(HALYARD*)-MIC-KEY* OVER-THE-WIRE STOMA MEASURING DEVICE ALLOWS MEASUREMENT OF THE STOMA SITE FOR CORRECT TUBE LENGTH.,MICROCUFF* SUBGLOTTIC SUCTIONING ENDOTRACHEAL TUBE(HALYARD*)-HALYARD* MICROCUFF* SUBGLOTTIC SUCTIONING ENDOTRACHEAL TUBES ARE INDICATED FOR AIRWAY MANAGEMENT BY ORAL INTUBATION OF THE TRACHEA AND FOR THE REMOVAL OF SECRETIONS THAT ACCUMULATE IN THE SUBGLOTTIC SPACE.,MIC-KEY* GASTROSTOMY FEEDING TUBE, LOW PROFILE(HALYARD*)-THE HALYARD* MIC-KEY* LOW-PROFILE GASTROSTOMY FEEDING TUBE IS INDICATED FOR USE IN PATIENTS WHO REQUIRE LONG-TERM FEEDING, ARE UNABLE TO TOLERATE ORAL FEEDING, WHO ARE AT LOW RISK FOR ASPIRATION, REQUIRE GASTRIC DECOMPRESSION AND/OR MEDICATION DELIVERY

	DIRECTLY INTO THE STOMACH.,GASTROINTESTINAL ANCHOR SET (HALYARD*)-THE HALYARD* GASTROINTESTINAL ANCHOR SET WITH SAF-T-PEXY* T-FASTENERS IS INTENDED TO AFFIX THE STOMACH TO THE ANTERIOR ABDOMINAL WALL FACILITATING PRIMARY PLACEMENT OF THE HALYARD* MIC* AND MIC-KEY* BRAND ENTERAL FEEDING TUBES.,MIC* GASTRIC-JEJUNAL FEEDING TUBE KIT(HALYARD*)-THE HALYARD* MIC* GASTRIC-JEJUNAL FEEDING TUBE IS INDICATED FOR USE IN PATIENTS WHO CANNOT ABSORB ADEQUATE NUTRITION THROUGH THE STOMACH, WHO HAVE INTESTINAL MOTILITY PROBLEMS, GASTRIC OUTLET OBSTRUCTION, SEVERE GASTROESOPHAGEAL REFLUX, ARE AT RISK OF ASPIRATION, OR IN THOSE WHO HAVE HAD PREVIOUS ESOPHAGECTOMY OR GASTRECTOMY.,INTRODUCER KIT FOR GASTROSTOMY FEEDING TUBE (HALYARD*)-THE HALYARD* INTRODUCER KIT FOR GASTROSTOMY FEEDING TUBES IS INTENDED TO FACILITATE THE PRIMARY PLACEMENT OF THE HALYARD* MIC* AND MIC-KEY* BRAND OF GASTROSTOMY FEEDING TUBES.,MIC-KEY* GASTRIC-JEJUNAL FEEDING TUBE KIT LOW PROFILE(HALYARD*)-THE HALYARD* MIC-KEY* GASTRIC-JEJUNAL FEEDING TUBE IS INDICATED FOR USE IN PATIENTS WHO CANNOT ABSORB ADEQUATE NUTRITION THROUGH THE STOMACH, WHO HAVE INTESTINAL MOTILITY PROBLEMS, GASTRIC OUTLET OBSTRUCTION, SEVERE GASTROESOPHAGEAL REFLUX, ARE AT RISK OF ASPIRATION, OR IN THOSE WHO HAVE HAD PREVIOUS ESOPHAGECTOMY OR GASTRECTOMY.,MIC* PERCUTANEOUS ENDOSCOPIC GASTROSTOMY (PEG) KIT(HALYARD*) -MIC* PERCUTANEOUS ENDOSCOPIC GASTROSTOMY (PEG) KIT IS INTENDED AS AN INITIAL PLACEMENT OF A PERCUTANEOUS ENDOSCOPIC GASTROSTOMY TUBE FOR ENTERAL NUTRITION AND MEDICATION DELIVERY AS WELL AS DECOMPRESSION.,MIC-KEY* BOLUS FEED EXTENSION SET(HALYARD*)-THE ACCESSORY EXTENSIONS ARE USED TO CONNECT THE ENTERAL FEEDING TUBE TO ENTERAL FEEDING EQUIPMENT OR A SYRINGE FOR THE DELIVERY OF ENTERAL NUTRITION, MEDICATION, OR GASTRIC DECOMPRESSION TO THE STOMACH.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1453	IMP/MD/2018/000420	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use: GASTROINTESTINAL/AIRWAY FOREIGN BODY RETRIEVAL BASKET (SPYGLASS RETRIEVAL SNARE)-THE SPYGLASS RETRIEVAL SNARE IS INDICATED FOR THE ENDOSCOPIC RETRIEVAL OF FOREIGN BODIES IN THE PANCREATICOBILIARY SYSTEM. THIS DEVICE SHOULD NOT BE USED FOR ANY PURPOSE OTHER THAN ITS INTENDED APPLICATION., URINARY STONE RETRIEVAL BASKET, SINGLE USE(ZEROTIP NITINOL STONE RETRIEVAL)-THE STONE RETRIEVAL BASKET IS INTENDED TO BE USED DURING UROLOGICAL PROCEDURES TO ENDOSCOPICALLY GRASP, MANIPULATE AND REMOVE CALCULI AND OTHER FOREIGN OBJECTS.,RADIO-FREQUENCY ABLATION SYSTEM PROBE CANNULA, SINGLE-USE(LEVEEN SUPERSLIM NEEDLE ELECTRODES SYSTEM)-THE LEVEEN NEEDLE ELECTRODE FAMILY IS INTENDED TO BE USED IN CONJUNCTION WITH THE RF 3000 GENERATOR FOR THE THERMAL COAGULATION NECROSIS OF SOFT TISSUES, INCLUDING PARTIAL OR COMPLETE ABLATION OF NONRESECTABLE LIVER LESIONS. THESE PROCEDURES SHOULD ONLY BE PERFORMED BY PHYSICIANS AND STAFF FAMILIAR WITH THE EQUIPMENT AND TECHNIQUES INVOLVED.,BILIARY STONE RETRIEVAL BASKET(SPYGLASS RETRIEVAL BASKET)-THE SPYGLASS RETRIEVAL BASKET IS INDICATED FOR ENDOSCOPIC REMOVAL OF STONES, STONE FRAGMENTS, OR FOREIGN BODIES IN THE PANCREATICOBILIARY SYSTEM. THE RETRIEVAL BASKET SHOULD NOT BE USED FOR ANY PURPOSE OTHER THAN ITS INTENDED APPLICATION. THIS BASKET IS NOT INDICATED FOR LITHOTRIPSY.,MULTI-PURPOSE PERCUTANEOUS DRAINAGE CATHETER(AMPLATZ TYPE RENAL DILATOR /SHEATH SET)-THE AMPLATZ TYPE RENAL DILATOR/SHEATH SET IS RECOMMENDED FOR DILATATION OF THE NEPHROSTOMY TRACT AND SHEATH PLACEMENT.,FLEXIBLE VIDEO CHOLEDOCHOSCOPE (SPYSCOPE DS II ACCESS AND DELIVERY CATHETER)-THIS IS INTENDED TO PROVIDE DIRECT VISUALIZATION AND TO GUIDE BOTH OPTICAL AND ACCESSORY DEVICES FOR DIAGNOSTIC AND THERAPEUTIC APPLICATIONS DURING ENDOSCOPIC PROCEDURES IN THE PANCREATICO-BILIARY SYSTEM INCLUDING THE HEPATIC DUCTS.,RADIO-FREQUENCY ABLATION SYSTEM PROBE CANNULA, SINGLE-USE(LEVEEN COACCESS NEEDLE ELECTRODES SYSTEM)-THE LEVEEN NEEDLE ELECTRODE FAMILY IS INTENDED TO BE USED IN CONJUNCTION WITH THE RF 3000 GENERATOR FOR THE THERMAL COAGULATION NECROSIS OF SOFT TISSUES, INCLUDING PARTIAL OR COMPLETE ABLATION OF NONRESECTABLE LIVER LESIONS. THESE PROCEDURES SHOULD ONLY BE PERFORMED BY PHYSICIANS AND STAFF FAMILIAR WITH THE EQUIPMENT AND TECHNIQUES

	INVOLVED.,URINARY STONE RETRIEVAL BASKET(DAKOTA NITINOL STONE RETRIEVAL DEVICE WITH OPENSURE HANDLE)-THE STONE RETRIEVAL DEVICE IS INTENDED TO BE USED DURING UROLOGICAL PROCEDURES TO ENDOSCOPICALLY GRASP, MANIPULATE, RELEASE AND REMOVE CALCULI AND OTHER FOREIGN OBJECTS FROM THE UPPER URINARY TRACT (URETER, RENAL PELVIS AND CALYCES)., FLEXIBLE VIDEO CHOLEDOCHOSCOPE, SINGLE-USE(SPYGLASS DISCOVER DIGITAL CATHETER)-THE SPYGLASS DISCOVER DIGITAL SYSTEM IS INDICATED FOR USE IN DIAGNOSTIC AND THERAPEUTIC APPLICATIONS DURING ENDOSCOPIC PROCEDURES IN THE PANCREATICOBILIARY SYSTEM INCLUDING THE HEPATIC DUCTS. THE SPYGLASS DISCOVER DIGITAL SYSTEM COMPRISES TWO COMPONENTS: THE SPYGLASS DISCOVER DIGITAL CATHETER AND THE SPYGLASS DISCOVER DIGITAL CONTROLLER. THE SPYGLASS DISCOVER DIGITAL CATHETER IS INTENDED TO PROVIDE DIRECT VISUALIZATION AND TO GUIDE BOTH OPTICAL AND ACCESSORY DEVICES FOR DIAGNOSTIC AND THERAPEUTIC APPLICATIONS DURING ENDOSCOPIC PROCEDURES IN THE PANCREATICO-BILIARY SYSTEM INCLUDING THE HEPATIC DUCTS. THE SPYGLASS DISCOVER DIGITAL CONTROLLER IS INTENDED TO PROVIDE ILLUMINATION AND RECEIVE, PROCESS, AND OUTPUT IMAGES FROM THE SPYGLASS DISCOVER DIGITAL CATHETER FOR DIAGNOSTIC AND THERAPEUTIC APPLICATIONS DURING ENDOSCOPIC PROCEDURES IN THE PANCREATICOBILIARY SYSTEM INCLUDING THE HEPATIC DUCTS., MALE STRESS URINARY INCONTINENCE SURGICAL MESH(ADVANCE XP MALE SLING SYSTEM)-THE ADVANCE XP MALE SLING SYSTEM IS INTENDED FOR THE TREATMENT OF MALE STRESS URINARY INCONTINENCE (SUI) BY THE PLACEMENT OF A SUBURETHRAL SLING.,URINARY STONE RETRIEVAL BASKET, SINGLE USE(ZEROTIP NITINOL STONE RETRIEVAL BASKET)-THE STONE RETRIEVAL BASKET IS INTENDED TO BE USED DURING UROLOGICAL PROCEDURES TO ENDOSCOPICALLY GRASP, MANIPULATE AND REMOVE CALCULI AND OTHER FOREIGN OBJECTS.,NEEDLE(ACQUIRE FLEXIBLE ENDOSCOPIC ULTRASOUND FINE NEEDLE BIOPSY (FNB) DEVICE)-THE ACQUIRE FINE NEEDLE BIOPSY DEVICE IS DESIGNED TO SAMPLE TARGETED SUBMUCOSAL AND EXTRAMURAL GASTROINTESTINAL LESIONS THROUGH THE ACCESSORY CHANNEL OF A CURVILINEAR ECHOENDOSCOPE.,RADIO-FREQUENCY ABLATION SYSTEM PROBE CANNULA, SINGLE-USE(LEVEEN STANDARD NEEDLE ELECTRODE SYSTEM)-THE LEVEEN NEEDLE ELECTRODE FAMILY IS INTENDED TO BE USED IN CONJUNCTION WITH THE RF 3000 GENERATOR FOR THE THERMAL COAGULATION NECROSIS OF SOFT TISSUES, INCLUDING PARTIAL OR COMPLETE ABLATION OF NONRESECTABLE LIVER LESIONS. THESE PROCEDURES SHOULD ONLY BE PERFORMED BY

	PHYSICIANS AND STAFF FAMILIAR WITH THE EQUIPMENT AND TECHNIQUES INVOLVED.,NEEDLE(ACQUIRE ENDOSCOPIC ULTRASOUND FINE NEEDLE BIOPSY (FNB) DEVICE)-THE ACQUIRE FINE NEEDLE BIOPSY DEVICE IS DESIGNED TO SAMPLE TARGETED SUBMUCOSAL AND EXTRAMURAL GASTROINTESTINAL LESIONS THROUGH THE ACCESSORY CHANNEL OF A CURVILINEAR ECHOENDOSCOPE.,OESOPHAGEAL ENDOSCOPIC LIGATOR, SINGLE-USE/ HAEMORRHOID LIGATOR(SPEEDBAND SUPERVIEW SUPER 7 MULTIPLE BAND LIGATOR)-THE SPEEDBAND SUPERVIEW SUPER 7 BAND LIGATOR IS USED FOR ENDOSCOPIC LIGATION OF ESOPHAGEAL VARICES AND ANORECTAL HEMORRHOIDS.,BODY ASPIRATION NEEDLE, SINGLE USE(ACQUIRE PULMONARY ENDOBRONCHIAL ULTRASOUND FINE NEEDLE BIOPSY DEVICE)-THE ACQUIRE PULMONARY ENDOBRONCHIAL ULTRASOUND FINE NEEDLE BIOPSY (FNB) DEVICE IS DESIGNED TO BE USED WITH ENDOBRONCHIAL ULTRASOUND ENDOSCOPES FOR ULTRASOUND GUIDED FINE NEEDLE ASPIRATION (FNA) OF THE SUBMUCOSAL AND EXTRAMURAL LESIONS OF THE TRACHEOBRONCHIAL TREE AND THE GASTROINTESTINAL TRACT. DO NOT USE THIS INSTRUMENT FOR ANY PURPOSE OTHER THAN ITS INTENDED USE.,ENDOSCOPIC STENT-PLACEMENT SYSTEM(NAVIFLEX LONG WIRE PUSHER)-THE ADVANIX PANCREATIC STENT USED WITH THE NAVIFLEX PUSHER IS INTENDED FOR DELIVERY OF THE STENT TO THE PANCREATIC DUCT (PD): • USED TO DRAIN PANCREATIC DUCTS ,ENDOSCOPIC-ACCESS DILATOR, SINGLE-USE(NAVIGATOR HD URETERAL ACCESS SHEATH SET)-THE NAVIGATOR HD URETERAL ACCESS SHEATH IS INDICATED FOR USE IN ENDOSCOPIC PROCEDURES TO FACILITATE THE PASSAGE OF ENDOSCOPES, UROLOGICAL INSTRUMENTS AND FOR THE INJECTION OF FLUIDS INTO THE URINARY TRACT.,URINARY STONE RETRIEVAL BASKET, SINGLE-USE(ESCAPE NITINOL STONE RETRIEVAL BASKET)-THIS BASKET IS INTENDED TO BE USED ENDOSCOPICALLY TO GRASP, MANIPULATE AND REMOVE CALCULI FROM THE URINARY TRACT., POLYMERIC PANCREATIC STENT, NON-BIOABSORBABLE(ADVANIX PANCREATIC STENT)-IT IS INTENDED FOR DELIVERY OF THE STENT TO THE PANCREATIC DUCT (PD): • USED TO DRAIN PANCREATIC DUCT,BODY ASPIRATION NEEDLE SINGLE USE(EXPECT PULMONARY ENDOBRONCHIAL ULTRASOUND TRANSBRONCHIAL ASPIRATION NEEDLE)-THE EXPECT PULMONARY ENDOBRONCHIAL ULTRASOUND TRANSBRONCHIAL ASPIRATION NEEDLE IS DESIGNED TO BE USED WITH ENDOBRONCHIAL ULTRASOUND ENDOSCOPES FOR ULTRASOUND GUIDED FINE NEEDLE ASPIRATION (FNA) OF THE SUBMUCOSAL AND EXTRAMURAL LESIONS OF THE TRACHEOBRONCHIAL TREE AND THE GASTROINTESTINAL TRACT. DO NOT USE THIS INSTRUMENT FOR ANY PURPOSE OTHER THAN ITS

	INTENDED USE.,ENDOSCOPIC STENT-PLACEMENT SYSTEM(NAVIFLEX RX DELIVERY SYSTEM)-THE ADVANIX BILIARY STENT WITH NAVIFLEX RX DELIVERY SYSTEM IS INTENDED FOR DELIVERY OF THE STENT TO THE BILIARY TRACT FOR DRAINAGE OF THE BILE DUCT, FOR SPLINTING OF A BILE DUCT DURING HEALING, OR FOR PROVIDING BILE DUCT PATENCY IN A STRICTURE OR PAST A STONE., GASTROSTOMY TUBE(ENDOVIVE LOW PROFILE REPLACEMENT BUTTON/GASTROSTOMY TUBE)-THE ENDOVIVE LOW PROFILE REPLACEMENT BUTTON GASTROSTOMY DEVICE IS INTENDED TO PROVIDE NUTRITION TO A PATIENT DIRECTLY INTO THE STOMACH THROUGH A STOMA. IT IS INDICATED FOR USE ON PATIENTS WHO ARE UNABLE TO CONSUME NUTRITION BY CONVENTIONAL MEANS., GASTROSTOMY TUBE KIT, NON-MEDICATED(ENDOVIVE STANDARD PEG KIT)-THE INITIAL PLACEMENT PEG IS INDICATED FOR ENTERAL NUTRITION DIRECTLY INTO THE STOMACH IN BOTH PEDIATRIC AND ADULT PATIENTS WHO ARE UNABLE TO CONSUME NUTRITION BY CONVENTIONAL MEANS.,NEEDLES(EXPECT SLIMLINE (SL) ENDOSCOPIC ULTRASOUND ASPIRATION NEEDLE)-THE EXPECT SLIMLINE (SL) NEEDLE IS DESIGNED TO SAMPLE TARGETED SUBMUCOSAL AND EXTRAMURAL GASTROINTESTINAL LESIONS THROUGH THE ACCESSORY CHANNEL OF A CURVILINEAR ECHOENDOSCOPE. IT CAN ALSO BE USED FOR DELIVERY OF INJECTABLE MATERIALS (FLUIDS) OR FIDUCIALS INTO TISSUE OR FOR PASSAGE OF ACCESSORY DEVICES.,FLEXIBLE ENDOTHERAPY CYTOLOGY BRUSH, SINGLE-USE(RX WIREGUIDED CYTOLOGY BRUSH) -IT IS USED ENDOSCOPICALLY TO COLLECT CELLS OR TO OBTAIN A CHOLANGIOGRAM IN THE BILIARY SYSTEM., GASTROINTESTINAL/AIRWAY FOREIGN BODY RETRIEVAL BASKETS (ZERO TIP AIRWAY RETRIEVAL BASKET)-THE ZERO TIP AIRWAY RETRIEVAL BASKET IS INTENDED TO BE USED TO ENDOSCOPICALLY REMOVE FOREIGN BODIES IN THE AIRWAY.,BILIARY STONE RETRIEVAL BASKET(TRAPEZOID RX WIREGUIDED RETRIEVAL BASKET)-THE TRAPEZOID RX WIREGUIDED RETRIEVAL BASKET IS INDICATED FOR ENDOSCOPIC CRUSHING AND REMOVAL OF BILIARY CALCULI. THE LITHOTRIPTER COMPATIBLE BASKET SHOULD NOT BE USED FOR ANY OTHER PURPOSE OTHER THAN ITS INTENDED APPLICATION.,ENDOSCOPIC NEEDLE, GENERAL-PURPOSE, SINGLE-USE(INTERJECT CONTRAST INJECTION THERAPY NEEDLE CATHETER) -THE INTERJECT INJECTION THERAPY NEEDLE CATHETER IS USED FOR ENDOSCOPIC INJECTION INTO GASTROINTESTINAL MUCOSA AND SUBMUCOSA TO: • INTRODUCE A SCLEROSING AGENT VASOCONSTRICTOR OR OTHER SOLUTIONS INTO SELECTED SITES TO CONTROL ACTUAL OR POTENTIAL BLEEDING LESIONS IN THE DIGESTIVE SYSTEM • AID IN ENDOSCOPIC MUCOSAL RESECTION

	(EMR), ENDOSCOPIC SUBMUCOSAL DISSECTION (ESD) OR POLYPECTOMY PROCEDURES • CONTROL NON-VARICEAL HEMORRHAGE ,RADIO-FREQUENCY ABLATION SYSTEM PROBE CANNULA, SINGLE-USE(SOLOIST SINGLE NEEDLE ELECTRODE)-THE SOLOIST SINGLE NEEDLE ELECTRODE IS INTENDED TO BE USED IN CONJUNCTION WITH THE RF 3000 GENERATOR FOR THE THERMAL COAGULATION NECROSIS OF SOFT TISSUES, INCLUDING PARTIAL OR COMPLETE ABLATION OF NONRESECTABLE LIVER LESIONS.,NEEDLES (EXPECT ENDOSCOPIC ULTRASOUND ASPIRATION NEEDLE)-THE EXPECT NEEDLE IS DESIGNED TO SAMPLE TARGETED SUBMUCOSAL AND EXTRAMURAL GASTROINTESTINAL LESIONS THROUGH THE ACCESSORY CHANNEL OF A CURVILINEAR ECHOENDOSCOPE.,MULTI-PURPOSE PERCUTANEOUS DRAINAGE CATHETER(AMPLATZ TYPE RENAL DILATOR)-*IT IS USED TO GRADUALLY ENLARGE THE SIZE OF THE NEPHROSTOMY DURING PERCUTANEOUS NEPHROSTOMY PROCEDURES. *THE AMPLATZ TYPE RENAL DILATORS ARE NOT SUPPLIED WITH A DFU AND THEREFORE HAVE NO LABELED INDICATIONS FOR USE/INTENDED USE. THE USER'S KNOWLEDGE AND TRAINING ARE ASSUMED TO HAVE ADDRESSED THE COMMON INDICATIONS AND CONTRAINDICATIONS OF THE DEVICE. ,NEEDLES (EXPECT FLEXIBLE ENDOSCOPIC ULTRASOUND ASPIRATION NEEDLE) -THE EXPECT NEEDLE IS DESIGNED TO SAMPLE TARGETED SUBMUCOSAL AND EXTRAMURAL GASTROINTESTINAL LESIONS THROUGH THE ACCESSORY CHANNEL OF A CURVILINEAR ECHOENDOSCOPE.,BODY ASPIRATION NEEDLE, SINGLE-USE (EXCELON TRANSBRONCHIAL ASPIRATION NEEDLE)-THE EXCELON TRANSBRONCHIAL ASPIRATION NEEDLE IS INDICATED FOR USE IN ASPIRATION IN CARINAL, PARATRACHEAL, AND HILAR LESIONS OF THE BRONCHIAL TREE WHERE BIOPSY FORCEPS CANNOT OBTAIN A SUBMUCOSAL SAMPLE.,MULTI-PURPOSE PERCUTANEOUS DRAINAGE CATHETER(8/10 DILATOR/SHEATH SET)-*IS USED TO HELP ESTABLISH INITIAL PERCUTANEOUS ACCESS DURING A NEPHROSTOMY PROCEDURE. *THE 8/10 DILATOR/SHEATH SET IS NOT SUPPLIED WITH A DFU AND THEREFORE HAS NO LABELED INDICATIONS FOR USE/INTENDED USE. THE USER'S KNOWLEDGE AND TRAINING ARE ASSUMED TO HAVE ADDRESSED THE COMMON INDICATIONS AND CONTRAINDICATIONS OF THE DEVICE. ,VASCULAR CATHETER INTRODUCTION SET(ACCUSTICK II INTRODUCER SYSTEM)-THE ACCUSTICK II INTRODUCER SYSTEM WITH RADIOPAQUE MARKER FACILITATES INTRODUCTION AND PLACEMENT OF A GUIDEWIRE., ENDOSCOPIC STENT-PLACEMENT SYSTEM(NAVIFLEX RX PANCREATIC STENT DELIVERY SYSTEM)-THE ADVANIX PANCREATIC STENT USED WITH THE NAVIFLEX RX DELIVERY SYSTEM IS INTENDED FOR DELIVERY OF THE STENT TO THE PANCREATIC DUCT (PD): • USED

	TO DRAIN PANCREATIC DUCTS ,RADIO-FREQUENCY ABLATION SYSTEM PROBE CANNULA, SINGLE-USE(COACCESS INTRODUCER SET)-THE LEVEEN NEEDLE ELECTRODE FAMILY IS INTENDED TO BE USED IN CONJUNCTION WITH THE RF 3000 GENERATOR FOR THE THERMAL COAGULATION NECROSIS OF SOFT TISSUES, INCLUDING PARTIAL OR COMPLETE ABLATION OF NONRESECTABLE LIVER LESIONS. THESE PROCEDURES SHOULD ONLY BE PERFORMED BY PHYSICIANS AND STAFF FAMILIAR WITH THE EQUIPMENT AND TECHNIQUES INVOLVED. ,MULTI-PURPOSE PERCUTANEOUS DRAINAGE CATHETER(AMPLATZ TYPE RENAL SHEATH)-IT IS RECOMMENDED FOR THE ESTABLISHMENT OF PERCUTANEOUS ACCESS.,URINARY STONE RETRIEVAL BASKET, SINGLE USE(OPTIFLEX NITINOL STONE RETRIEVAL BASKET)-THE OPTIFLEX NITINOL STONE RETRIEVAL BASKET IS INTENDED TO BE USED ENDOSCOPICALLY TO GRASP, MANIPULATE AND REMOVE CALCULI AND OTHER FOREIGN OBJECTS FROM THE URINARY TRACT.,CANNULAS(TANDEM XL TRIPLE-LUMEN ERCP CANNULA)-THE TANDEM XL TRIPLE-LUMEN ERCP CANNULA IS USED TO INJECT CONTRAST MEDIUM TO OBTAIN A CHOLANGIOGRAM OF THE BILIARY DUCT SYSTEM. THE CONTRAST MEDIA IS INJECTED THROUGH THE CANNULA AND FLUOROSCOPY OR X-RAY IS PERFORMED TO OBTAIN THE CHOLANGIOGRAM.,FLEXIBLE ENDOTHERAPY CYTOLOGY BRUSH, SINGLE-USE(CELLEBRITY ENDOSCOPIC CYTOLOGY BRUSH)-*THE CYTOLOGY BRUSHES ARE INDICATED FOR ACQUIRING TISSUE SAMPLES USED FOR THE DIAGNOSIS OF SUSPECTED PATHOLOGY IN THE AIRWAY TREE. *THIS PRODUCT IS NOT SUPPLIED WITH INSTRUCTIONS FOR USE

CENTRAL DRUG STANDARD CONTROL ORGANIZATION CDSCO HQ NIC CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1454	IMP/MD/2018/000421	1.License Holder Name: ABBOTT HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDEWIRE(HI-TORQUE TURNTRAC GUIDEWIRE, HI-TORQUE TURNTRAC FLEX GUIDEWIRE)-INTENDED TO FACILITATE THE DELIVERY OF CATHETER-BASED INTERVENTIONAL DEVICES DURING THE FOLLOWING PROCEDURES: • PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) • PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) THIS GUIDE WIRE MAY ALSO BE USED WITH COMPATIBLE STENT DEVICES. THIS DEVICE IS DESIGNED AND INTENDED FOR ONE-TIME USE ONLY. DO NOT RE-STERILIZE AND / OR REUSE.,GUIDE WIRE(HI-TORQUE BALANCE MIDDLEWEIGHT GUIDE WIRE)-THE HI-TORQUE GUIDE WIRE IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA).,GUIDE WIRE(HI -TORQUE EXTRA S'PPORT GUIDE WIRE , HI -TORQUE WIGGLE GUIDE WIRE , HI -TORQUE IRON MAN GUIDE WIRE, HI -TORQUE FLOPPY II GUIDE WIRE , HI -TORQUE FLOPPY II EXTRA SUPPORT GUIDE WIRE ,HI -TORQUE ALL STAR GUIDE WIRE, HI -TORQUE CROSS-IT 100XT GUIDE WIRE ,HI -TORQUE CROSS-IT 200XT GUIDE WIRE,HI -TORQUE CROSS-IT 300XT GUIDE WIRE,HI -TORQUE CROSS-IT 400XT GUIDE WIRE, HI -TORQUE WHISPER EXTRA SUPPORT GUIDE WIRE, HI -TORQUE WHISPER LS GUIDE WIRE, HI -TORQUE WHISPER MS GUIDE WIRE,HI -TORQUE POWERTURN ULTRAFLEX GUIDE WIRE, POWERTURN FLEX GUIDE WIRE ,HI-TORQUE POWERTURN GUIDE WIRE)-THE HI-TORQUE GUIDE WIRE IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). HI-TORQUE POWER TURN GUIDE WIRE MAY ALSO BE USED WITH COMPATIBLE STENT DEVICES DURING THERAPEUTIC PROCEDURES. • HI -TORQUE-WIGGLE THE HI-TORQUE WIGGLE GUIDE WIRE IS INTENDED TO FACILITATE THE PLACEMENT OF THE CATHETER BY ORIENTING THE CATHETER TIP DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA), PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) AND OTHER INTERVENTIONAL DIAGNOSTIC OR THERAPEUTIC PROCEDURES., GUIDE WIRE(DOC GUIDEWIRE EXTENSION)-THE DOC GUIDE WIRE EXTENSION IS INTENDED TO PROVIDE THE NECESSARY LENGTH TO ALLOW THE EXCHANGE OF ONE DILATATION CATHETER FOR ANOTHER WHILE MAINTAINING THE POSITION OF THE GUIDE WIRE IN THE CORONARY ARTERY. AFTER THE DILATATION CATHETER EXCHANGE HAS BEEN COMPLETED, THE DOC GUIDE WIRE EXTENSION CAN BE DETACHED AND THE INITIAL WIRE CAN BE USED AS A CONVENTIONAL GUIDE WIRE.,CAROTID STENT SYSTEM(RX ACCULINK CAROTID STENT SYSTEM)-THE RX ACCULINK CAROTID STENT

	SYSTEM IS INDICATED FOR USE IN PATIENTS WITH ATHEROSCLEROTIC DISEASE OF THE CAROTID ARTERIES.,EMBOLIC PROTECTION SYSTEM(EMBOSHIELD NAV6 EMBOLIC PROTECTION SYSTEM)-THE SYSTEM IS DESIGNED TO REDUCE DISTAL EMBOLIZATION WHILE MAINTAINING BLOOD FLOW DURING INTERVENTIONAL PROCEDURES. THE SYSTEM IS INDICATED FOR USE DURING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY, AND STENTING PROCEDURES IN SAPHENOUS VEIN GRAFTS AND CAROTID ARTERIES AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY, ATHERECTOMY AND STENTING PROCEDURES IN THE LOWER EXTREMITY ARTERIES.,GUIDE WIRE(BAREWIRE DISTAL ACCESS , BAREWIRE WORKHORSE , BAREWIRE SUPPORT)-THE SYSTEM IS DESIGNED TO REDUCE DISTAL EMBOLIZATION WHILE MAINTAINING BLOOD FLOW DURING INTERVENTIONAL PROCEDURES. THE SYSTEM IS INDICATED FOR USE DURING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY, AND STENTING PROCEDURES IN SAPHENOUS VEIN GRAFTS AND CAROTID ARTERIES AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY, ATHERECTOMY AND STENTING PROCEDURES IN THE LOWER EXTREMITY ARTERIES.,PERIPHERAL DILATATION CATHETER(VIATRAC 14 PLUS PERIPHERAL DILATATION CATHETER)-THE VIATRAC 14 PLUS PERIPHERAL DILATATION CATHETER IS INTENDED: • TO DILATE STENOSIS IN THE PERIPHERAL ARTERIES (ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA POPLITEAL, RENAL ARTERIES). • FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE.,PERIPHERAL STENT SYSTEM(RX HERCULINK ELITE PERIPHERAL STENT SYSTEM)-THE RX HERCULINK ELITE PERIPHERAL STENT SYSTEM IS INTENDED TO OPEN LUMEN RESTRICTIONS IN THE BILIARY TREE, RENAL ARTERIES, AND PROTECTED PERIPHERAL ARTERIES.,PERIPHERAL STENT SYSTEM (ABSOLUTE PRO PERIPHERAL SELF-EXPANDING STENT SYSTEM , ABSOLUTE PRO LL PERIPHERAL SELF-EXPANDING STENT SYSTEM)-THE ABSOLUTE PRO PERIPHERAL SELF-EXPANDING STENT SYSTEM AND ABSOLUTE PRO LL PERIPHERAL SELF-EXPANDING STENT SYSTEM IS INTENDED FOR THE STENTING OF PERIPHERAL ARTERIES AS AN ADJUNCT TO PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) AND FOR THE PALLIATION OF MALIGNANT STRICTURES IN THE BILIARY TREE.,GUIDE WIRE(HI-TORQUE SPARTACORE 14 , HI-TORQUE STEELCORE 18 , HI-TORQUE STEELCORE 18 LT)-ALL HI-TORQUE GUIDE WIRES ARE INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA).,GUIDE WIRE (HI-TORQUE VERSATURN)-IT IS INTENDED TO FACILITATE THE

	DELIVERY OF CATHETER BASED INTERVENTIONAL DEVICES DURING THE FOLLOWING PROCEDURES: PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). THIS GUIDE WIRE MAY ALSO BE USED WITH COMPATIBLE STENT DEVICES. THIS DEVICE IS DESIGNED AND INTENDED FOR ONE-TIME USE ONLY. DO NOT RESTERILIZE AND/OR REUSE.,GUIDE WIRE(HI-TORQUE COMMAND 18 ST GUIDE WIRE , HI-TORQUE COMMAND 18 LT GUIDE WIRE)-THIS HI-TORQUE GUIDE WIRE IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN ARTERIES SUCH AS THE FEMORAL, POPLITEAL, AND INFRA-POPLITEAL ARTERIES. THIS GUIDE WIRE MAY ALSO BE USED WITH COMPATIBLE STENT DEVICES DURING THERAPEUTIC PROCEDURES. THE GUIDE WIRE MAY ALSO BE USED TO REACH AND CROSS A TARGET LESION, PROVIDE A PATHWAY WITHIN THE VESSEL STRUCTURE, FACILITATE THE SUBSTITUTION OF ONE DIAGNOSTIC OR INTERVENTIONAL DEVICE FOR ANOTHER, AND TO DISTINGUISH THE VASCULATURE.,CAROTID STENT SYSTEM(X.ACT CAROTID STENT SYSTEM)-THE X.ACT CAROTID STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH ATHEROSCLEROTIC DISEASE OF THE CAROTID ARTERIES. THE X.ACT CAROTID STENT SYSTEM IS INDICATED FOR USE IN CONJUNCTION WITH ABBOTT VASCULAR'S ACCUNET OR EMBOSHIELD FAMILY OF EMBOLIC PROTECTION SYSTEMS (EPS).,GUIDE WIRE(HI-TORQUE SUPRA CORE 35)-HI-TORQUE SUPRA CORE 35 GUIDE WIRES ARE INTENDED TO FACILITATE THE PLACEMENT AND EXCHANGE OF INTERVENTIONAL DEVICES DURING DIAGNOSTIC OR THERAPEUTIC INTERVENTIONAL PROCEDURES.,PERIPHERAL STENT SYSTEM(SUPERA PERIPHERAL STENT SYSTEM)-THE SUPERA PERIPHERAL STENT SYSTEM IS INDICATED FOR PERIPHERAL VASCULAR USE FOLLOWING FAILED PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) AND PALLIATIVE TREATMENT OF BILIARY STRICTURES PRODUCED BY MALIGNANT NEOPLASMS

1455	IMP/MD/2018/000422	1.License Holder Name: INMITO MEDITECH PVT. LTD. ,UNIT NO. 501, FIFTH FLOOR, TOWER HIGH RISE, PARAS TRADE CENTRE, SECTOR-2, GWAL PAHARI ,GURGAON HARYANA ,122003 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INFUSION DEVICE [STERILE](REFILL SET DUO)-THE REFILL SET DUO (REF 292V0000010WA) IS INTENDED TO BE USED FOR THE EMPTYING AND REFILLING OF IMPLANTABLE INFUSION PUMPS IP2000V, IP1000V, SIROMEDES,SPINAL CATHETER [STERILE](SPINAL KATHETERSET 4000)-THE SPINAL CATHETER SET 4000 ARE USED WITH PATIENTS WHEN TREATMENT REQUIRES REPEATED ACCESS TO THE INTRASPINAL SPACE.THE SPINAL CATHETER 4000 CAN BE USED FOR CONTINUOUS INFUSION OF MEDICATION.THE CATHETER ARE DETERMINED FOR SINGLE USE.THE CATHETER COULD BE USED AS AN IMPLANT LONGER THAN 30 DAYS
1456	IMP/MD/2018/000424	1.License Holder Name: KCI MEDICAL INDIA PRIVATE LIMITED ,K. NO. 2606/115 (P. NO. 60/16) GROUND FLOOR, HUSKUR ROAD ELECTRONIC POST ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560100 , INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NON ADHERENT PRIMARY WOUND CONTACT DRESSING(ADAPTIC® NON-ADHERING DRESSING)-ADAPTIC DRESSING IS INDICATED FOR DRY TO HEAVILY EXUDING WOUNDS WHERE ADHERENCE OF DRESSING AND EXUDATE IS TO BE PREVENTED INCLUDING: 1ST & 2ND DEGREE BURNS, ABRASIONS, GRAFTS, VENOUS ULCERS, PRESSURE ULCERS,NAIL EXTRATIONS, ECZEMA, STAPLES, SURGICAL INCISIONS, LACERATIONS, RECONSTRUCTIVE PROCEDURES, SUTURE LINES.

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1457	IMP/MD/2018/000425	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PUNCTURE SET FOR PERCUTANEOUS NEPHROSTOMY(RUSCH)-PUNCTURE SETS FOR PERCUTANEOUS NEPHROSTOMY, 2-STEP TECHNIQUE, ARE INDICATED FOR ROUTINE PERCUTANEOUS PUNCTURE AND DRAINAGE OF THE UPPER URINARY TRACT.,ECO URETERAL STENT SET, OPEN TIP, WITHOUT GUIDE WIRE.(RUSCH ECO URETERAL STENT SET POLYURETHANE)-RUSCH URETER STENTS ARE INTENDED FOR USE AS ROUTINE URETER STENTS AS RECOMMENDED BY A PHYSICIAN OR OTHER SUITABLY QUALIFIED MEDICAL PERSONNEL., URETER STENT SET(RUSCH)- RUSCH URETER STENTS ARE INTENDED FOR USE AS ROUTINE URETER STENTS AS RECOMMENDED BY A PHYSICIAN OR SUITABLY QUALIFIED MEDICAL PERSONNEL. EXAMPLES OF INDICATIONS FOR PLACEMENT INCLUDE FOLLOWING URETERIC SURGERY OR LITHOTRIPSY FOR URETER STONE TREATMENT.,ECO URETERAL STENT SET, CYLINDRICAL CLOSED (RUSCH ECO URETERAL STENT SET POLYURETHANE)-RUSCH URETER STENTS ARE INTENDED FOR USE AS ROUTINE URETER STENTS AS RECOMMENDED BY A PHYSICIAN OR OTHER SUITABLY QUALIFIED MEDICAL PERSONNEL.,URETER CATHETER(RUSCH)-THESE URETER CATHETERS ARE INDICATED FOR THE FOLLOWING PROCEDURES: DRAINAGE OF THE URETER, REMOVAL OF URINE SAMPLES, PASSAGE OF SHORT STRETCHES OF STENOSIS AND ACCESS TO THE RENAL PELVIS, INJECTION OF CONTRAST MEDIA INTO THE URETER FOR RADIOGRAPHIC IMAGING OF THE UPPER URINARY TRACT AND FOR OTHER DIAGNOSTIC OR THERAPEUTIC PROCEDURES COMMON IN UROLOGY.,BRONCHIAL BLOCKER(RUSCH® EZ- BLOCKER KIT)-THE EZ-BLOCKER IS INDICATED FOR USE TO INTUBATE THE PATIENT'S BRONCHI IN ORDER TO DIFFERENTIALLY ISOLATE THE LEFT OR RIGHT LUNG FOR PROCEDURES WHICH REQUIRE ONE-LUNG VENTILATION, LUNG SEPARATION. PATIENT POPULATION: PATIENTS REQUIRING ONE LUNG ISOLATION. ENVIRONMENT OF USE: HOSPITALS - OR OPERATING ROOM AND ICU INTENSIVE CARE UNIT., URETER CATHETER(RUSCH)-RUSCH URETER CATHETERS ARE AMONG OTHERS INDICATED FOR THE FOLLOWING PROCEDURES: DRAINAGE OF THE URETER, TAKING OF URINE SPECIMEN, CROSSING OF SMALL STENOSIS AND ACCESS OF THE RENAL PELVIS. ALSO FOR OTHER USUAL DIAGNOSTIC AND THERAPEUTIC MEASURES IN UROLOGY. THE CHEVASSU TIP CATHETER IS SPECIFICALLY INDICATED FOR ROUTINE INJECTION OF CONTRAST MEDIA INTO THE URETER FOR RADIOGRAPHIC VISUALIZATION OF THE UPPER URINARY TRACT.

1458	IMP/MD/2018/000433	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHODONTIC TUBE (STAINLESS STEEL)(ACCENT MINI BUCCAL TUBE, PEERLESS BUCCAL TUBES, SL BUCCAL TUBE, SNAPLINK, TERMINAL TUBES)-INTENDED TO BE APPLIED TO A PATIENT'S 1ST AND 2ND MOLARS IN ORDER TO CORRECT MALOCCLUSION.,ORTHODONTIC TUBE (TITANIUM) (TITANIUM BUCCAL TUBE)-INTENDED TO BE APPLIED TO A PATIENT'S 1ST AND 2ND MOLARS IN ORDER TO CORRECT MALOCCLUSION., ORTHODONTIC WIRE (COPPER NICKEL TITANIUM)(STB SOCIAL 6, STB STRAIGHTWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH.
1459	IMP/MD/2018/000434	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTION NEEDLES(BD VACUTAINER ECLIPSE SIGNAL)-THE BD VACUTAINER® ECLIPSE™ SIGNAL™ BLOOD COLLECTION NEEDLE IS A STERILE, SINGLE USE, MEDICAL DEVICE SPECIFICALLY INTENDED TO BE USED BY TRAINED HEALTHCARE PROFESSIONALS IN ACCORDANCE WITH THE INSTRUCTIONS FOR USE FOR THE COLLECTION OF MULTIPLE BLOOD SAMPLES INTO EVACUATED BLOOD COLLECTION TUBES, FOR THE PURPOSE OF IN VITRO DIAGNOSTIC TESTING. THE DEVICE INCORPORATES A FLASH TECHNOLOGY TO INDICATE VENOUS ACCESS AND A HINGED SAFETY SHIELD. IN THE ACTIVATED POSITION, THE SAFETY SHIELD PROTECTS AGAINST AN ACCIDENTAL NEEDLE STICK INJURY DURING NORMAL HANDLING AND DISPOSAL., DISPOSABLE HYPODERMIC SYRINGES(BD PRESET ARTERIAL BLOOD COLLECTION SYRINGES (WITH OR WITHOUT NEEDLE))-INTENDED TO COLLECT WHOLE BLOOD SPECIMENS FOR DIAGNOSTIC TESTING WHICH MAY INCLUDE: PH, BLOOD GASES, ELECTROLYTES (INCLUDING IONIZED CALCIUM), METABOLITES, CO-OXIMETRY AND OTHER TESTS.,DISPOSABLE HYPODERMIC SYRINGES(BD A-LINE ARTERIAL BLOOD COLLECTION SYRINGES (WITHOUT NEEDLE))-INTENDED TO COLLECT WHOLE BLOOD SPECIMENS FOR DIAGNOSTIC TESTING WHICH MAY INCLUDE: PH, BLOOD GASES, ELECTROLYTES (INCLUDING IONIZED CALCIUM), METABOLITES, CO-OXIMETRY AND OTHER TESTS.,DISPOSABLE HYPODERMIC NEEDLES(BD VACUTAINER® PRECISION GLIDE MULTI-SAMPLE NEEDLE)-INTENDED TO BE USED FOR SAMPLING OF VENOUS BLOOD DERIVED FROM THE HUMAN BODY FOR THE PURPOSE OF IN-VITRO DIAGNOSTIC EXAMINATION

1460	IMP/MD/2018/000439	1.License Holder Name: LIVANOVA INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AUTOTRANSFUSION SYSTEM DISPOSABLES(1. XTRA PROCEDURE SET)-XTRA DISPOSABLE DEVICES ARE INTENDED TO BE USED IN ASSOCIATION WITH XTRA BLOOD PROCESSING EQUIPMENT FOR AUTOLOGOUS BLOOD RECOVERY, WITH COLLECTION OF BLOOD AS WELL AS CONCENTRATION AND WASHING OF RED BLOOD CELLS. PROCEDURE SETS DESIGNED TO BE USED IN SITUATIONS WHERE THE RISK OF SIGNIFICANT BLOOD LOSS IS EXPECTED PREOPERATIVELY. THE OPERATOR FACING A HIGH BLEEDING SITUATION IS PROVIDED WITH ALL NECESSARY COMPONENTS FOR BLOOD SALVAGE IN ONE KIT., HAEMOCONCENTRATORS(DHF- HAEMOCONCENTRATOR)-DHF HAEMOCONCENTRATORS ARE INTENDED FOR USE IN CARDIOPULMONARY BY-PASS CIRCUITS FOR HEMOCONCENTRATION AND CONSEQUENT RESTORING OF PATIENT'S PHYSIOLOGICAL HAEMATOCRIT. THE BLOOD TO BE TREATED SHOULD CONTAIN ANTICOAGULANT. ,VENOUS CANNULAE(1. VENOUS TWO STAGE CANNULAE 2. VENOUS HIGH FLOW CANNULAE 3. VENOUS OPTIFLOW CANNULAE)-THE VENOUS CANNULAE ARE INTENDED TO BE USED TO CANNULAE THE MAJOR VENOUS VESSELS DURING CARDIOPULMONARY SURGERY FOR PERIODS OF UP TO SIX HOURS. , CANNULAE(1. BI-FLOW ARTERIAL CANNULAE)-BI-FLOW IS A SINGLE USE STERILE DEVICE INTENDED AS A FEMORAL PERFUSION CANNULA TO RETURN ARTERIAL BLOOD FROM THE EXTRACORPOREAL CIRCUIT TO THE PATIENT'S SYSTEMIC CIRCULATION AND LOWER LIMB DURING CARDIOPULMONARY SURGERY FOR PERIODS UP TO SIX HOURS.,CORONARY PERFUSION CANNULAE (1. CORONARY PERFUSION CARDIOPLEGIA CANNULAE; 2. CARDIOPLEGIA PERFUSION 3D CARDIOPLEGIA CANNULAE)-THE CORONARY PERFUSION CANNULAE ARE INTENDED TO BE USED TO CANNULATE THE CORONARY OSTIUM AND TO DELIVER CARDIOPLEGIC SOLUTION DURING THE CARDIOPULMONARY SURGERY FOR PERIOD UP TO SIX HOURS. ,CATHETER(1. LEFT VENTRICLE VENT CATHETER)-THE VENT CATHETERS ARE INTENDED TO BE USED TO VENT BLOOD OF THE LEFT HEART ATRIUM OR THE LEFT VENTRICLE OR THE PULMONARY AORTA DURING CARDIOPULMONARY SURGERY FOR PERIODS OF UP TO SIX HOURS., PEDIATRIC CANNULAE(1. PEDIATRIC ARTERIAL CANNULAE 2. PEDIATRIC VENOUS CANNULAE)-THE PEDIATRIC CANNULAE ARE INTENDED TO BE USED IN BOTH THE VENOUS AND THE ARTERIAL LINE OF THE EXTRACORPORTAL CIRCUIT DURING CARDIOPULMONARY SURGERY FOR PERIODS OF UP TO SIX HOURS. , CORONARY AORTIC ROOT CANNULAE(1. CARDIOPLEGIA AORTIC

	ROOT CANNULAE)-THE AORTIC ROOT CANNULAE ARE INTENDED FOR VENTING THE AORTIC ROOT FOR DELIVERY OF CARDIOPLEGIC SOLUTION AND FOR RAPID AND SECURE PERFUSION INTO THE CORONARY ARTERIES DURING CARDIOPULMONARY SURGERY FOR PERIODS UP TO SIX HOURS. THE AORTIC ROOT CANNULAE WITH PRESSURE MEASUREMENT LINE ARE INTENDED FOR VENTING THE AORTIC ROOT FOR DELIVERY OF CARDIOPLEGIC SOLUTION AND FOR RAPID AND SECURE PERFUSION INTO CORONARY ARTERIES DURING CARDIOPULMONARY SURGERY FOR THE PERIODS OF UP TO SIX HOURS. THE PRESSURE MEASUREMENT LINE ENABLES PERFORMING PRESSURE MEASUREMENTS IN THE AORTIC ROOT.,CANNULAE(1. PUREFLEX® ARTERIAL CANNULAE)-THE ARTERIAL CANNULAE ARE INTENDED TO BE USED AS PERFUSION CANNULAE TO RETURN THE ARTERIAL BLOOD FROM THE EXTRACORPOREAL CIRCUIT TO THE PATIENT DURING THE CARDIOPULMONARY SURGERY FOR THE PERIOD OF UP TO SIX HOURS.,ARTERIAL CANNULAE(1. ARTERIAL BENT TIP CANNULAE 2. ARTERIAL STRAIGHT TIP CANNULAE 3. ARTERIAL OPTIFLOW BENT TIP CANNULAE 4. ARTERIAL OPTIFLOW STRAIGHT TIP CANNULAE)-THE ARTERIAL CANNULAE ARE INTENDED TO BE USED AS PERFUSION CANNULAE TO RETURN ARTERIAL BLOOD FROM THE EXTRACORPORTAL CIRCUIT TO THE PATIENT DURING CARDIOPULMONARY SURGERY FOR PERIOD OF UP TO SIX HOURS

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1461	IMP/MD/2018/000440	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER GUIDE WIRE (RADIFOCUS GUIDEWIRE M)-IT IS DESIGNED TO DIRECT A CATHETER TO THE DESIRED ANATOMICAL LOCATION IN THE VASCULAR SYSTEM DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURES.,CARDIAC CATHETER GUIDE WIRE(RUNTHROUGH NS)-IT IS INDICATED TO BE USED TO GUIDE DILATATION CATHETERS TO A LESION FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIPLASTY (PTCA) FOR THE PURPOSE OF IMPROVING MYOCARDIAL BLOOD FLOW IN A STENOTIC LESION IN CORONARY VESSELS. DO NOT US FOR ANY OTHER PURPOSE.,CATHETER GUIDE WIRE(RADIFOCUS GLIDEWIRE ADVANTAGE)-IT IS DESIGNED TO DIRECT A CATHETER TO THE DESIRED ANATOMICAL LOCATION DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURES, EXCEPT FOR CENTRAL CIRCULATORY SYSTEM.,BALLOON DILATATION CATHETER(RYUREI)-IT IS INTENDED TO BE USED FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) FOR THE PURPOSE OF IMPROVING MYOCARDIAL BLOOD FLOW IN THE LOCALIZED STENOTIC LESION OF THE CORONARY ARTERIES.,CATHETER INTRODUCER(GLIDESHEATH SLENDER)-IT IS USED TO FACILITATE PLACING A CATHETER THROUGH THE SKIN INTO THE RADIAL ARTERY.,BALLOON DILATATION CATHETER(ACCUFORCE)-IT IS INTENDED TO BE USED FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) FOR THE PURPOSE OF IMPROVING MYOCARDIAL BLOOD FLOW IN THE LOCALIZED STENOTIC LESION OF THE CORONARY ARTERIES.,BALLOON DILATATION CATHETER(TAZUNA)-IT IS INTENDED TO BE USED FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) FOR THE PURPOSE OF IMPROVING MYOCARDIAL BLOOD FLOW IN THE LOCALIZED STENOTIC LESION OF THE CORONARY ARTERIES.,INTRAVASCULAR GUIDING CATHETER (FINECROSS MG)-IT IS INTENDED TO BE PERCUTANEOUSLY INTRODUCED INTO BLOOD VESSLES AND SUPPORT A GUIDE WIRE IN CROSSING THE LOCALIZED STENOTIC LESION OF THE CORONARY ARTERY WHILE PERFORMING PCI (PERCUTANEOUS CORONARY INTERVENTION) IN CASE THE GUIDE WIRE CAN HARDLY CROSS THE LESION, THE PRODUCT IS ALSO INTENDED FOR INJECTION OF RADIOPAQUE CONTRAST MEDIA FOR THE PURPOSE OF ANGIOGRAPHY.,ANGIOGRAPHIC CATHETER(PROGREAT)-THIS MICRO CATHETER IS INTENDED FOR THE INFUSION OF CONTRAST MEDIA INTO ALL BLOOD VESSELS. THE CATHETER IS ALSO INTENDED FOR DRUG INFUSION IN INTRA-ARTERIAL THERAPY AND FOR THE INFUSION OF EMBOLIC MATERIALS FOR HAEMOSTASIS. DO NOT USE THIS PRODUCT IN CORONARY BLOOD VESSELS. DO NOT USE THIS

	PRODUCT IN CEREBRAL BLOOD VESSELS, EXCEPT 2.0 FR., ANGIOGRAPHIC CATHETER(RADIFOCUS GLIDECATH)-IT IS INTENDED FOR USE IN ANGIOGRAPHIC PROCEDURES. IT DELIVERS RADIOPAQUE MEDIA AND THERAPEUTIC AGENTS TO SELECTED SITES IN THE VASCULAR SYSTEM. IT IS ALSO USED TO LEAD A GUIDE WIRE OR A CATHETER INTO THE TARGET SITE.,ANGIOGRAPHIC CATHETER (RADIFOCUS OPTITORQUE)-IT IS INTENDED FOR USE IN ANGIOGRAPHIC PROCEDURES. IT DELIVERS RADIOPAQUE MEDIA AND THERAPEUTIC AGENTS TO SELECTED SITES IN THE VASCULAR SYSTEM. IT IS ALSO USED TO LEAD A GUIDE WIRE OR A CATHETER INTO THE TARGET SITE.,INTRAVASCULAR GUIDING CATHETER (HEARTRAIL II)-IT IS DESIGNED FOR THE INTRODUCTION OF INTERVENTIONAL DEVICES AND/OR GUIDE WIRES FOR THE DELIVERY OF RADIOPAQUE MEDIA INTO THE CORONARY OR PERIPHERAL VASCULAR SYSTEMS.,BALLOON DILATATION CATHETER(RYUJIN PLUS)-IT IS INTENDED TO BE USED FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIPLASTY (PTCA) FOR THE PURPOSE OF IMPROVING MYOCARDIAL BLOOD FLOW IN THE LOCALIZED STENOTIC LESION OF THE CORONARY ARTERIES.,PRESSURE BANDAGE(TR BAND)-THIS IS A COMPRESSION DEVICE TO ASSIST HEMOSTASIS OF THE RADIAL ARTERY AFTER A TRANSRADIAL PROCEDURE.,SYRINGE INFUSION PUMP(TERUFUSION SYRINGE PUMP TYPE SS3)-IT IS INTENDED FOR THE INFUSION OF GENERAL AND LOCAL ANESTHETICS, VASODILATORS, CARDIOTONICS, PARENTERAL FEEDING, ANTI-CANCER DRUGS, LABOR-INDUCING DRUGS AND BLOOD TRANSFUSION AT ICU, CCU, NICU, OPERATING ROOMS OR GENERAL WARDS.,INFUSION PUMP(TERUFUSION INFUSION PUMP TYPE LM3)-IT IS INTENDED FOR THE INFUSION OF GENERAL AND LOCAL ANESTHETICS, VASODILATORS, CARDIOTONICS, PARENTERAL FEEDING, CHEMOTHERAPY MEDICATIONS, ANTI-CANCER DRUGS, LABOR-INDUCING DRUGS, ANTI-COAGLANTS AND BLOOD TRANSFUSION AT ICU, CCU, NICU, OPERATING ROOMS OR GENERAL WARDS.,INFUSION PUMP(TERUFUSION INFUSION PUMP TYPE LF)-IT IS INTENDED FOR THE INFUSION OF GENERAL AND LOCAL ANESTHETICS, VASODILATORS, CARDIOTONICS, PARENTERAL FEEDING, CHEMOTHERAPY MEDICATIONS, ANTI-CANCER DRUGS, LABOR-INDUCING DRUGS AND ANTI-COAGLANTS AT ICU, CCU, NICU, OPERATING ROOMS OR GENERAL WARDS.,CATHETER INTRODUCER (RADIFOCUS INTRODUCER II)-THE RADIFOCUS INTRODUCER II, WHICH IS FOR SINGLE USE AND STERILE, IS INTENDED TO BE INSERTED PERCUTANEOUSLY INTO A VESSEL TO FACILITATE THE INSERTION OF ANGIOGRAPHIC, ELECTRODE, BALLOON, OR SIMILAR CATHETERS., BALLOON DILATATION CATHETER(HIRYU)-IT IS INTENDED TO BE USED FOR PERCUTANEOUS TRANSLUMINAL CORONARY

	ANGIOPLASTY (PTCA) FOR THE PURPOSE OF IMPROVING MYOCARDIAL BLOOD FLOW IN THE LOCALIZED STENOTIC LESION OF THE CORONARY ARTERIES.,CATHETER GUIDE WIRE(RADIFOCUS GUIDE WIRE GT WITH GOLD COIL)-IT IS DESIGNED TO DIRECT A CATHETER TO THE DESIRED ANATOMICAL LOCATION IN THE VASCULAR SYSTEM DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURES.,INFUSION PUMP(TERUFUSION INFUSION PUMP TYPE LM)-IT IS INTENDED FOR THE INFUSION OF GENERAL AND LOCAL ANESTHETICS, VASODILATORS, CARDIOTONICS, PARENTERAL FEEDING, CHEMOTHERAPY MEDICATIONS, ANTI-CANCER DRUGS, LABOR-INDUCING DRUGS, ANTI-COAGLANTS AND BLOOD TRANSFUSION AT ICU, CCU, NICU, OPERATING ROOMS OR GENERAL WARDS.,INFUSION PUMP(TERUFUSION INFUSION PUMP TYPE LF3)-IT IS INTENDED FOR THE INFUSION OF GENERAL AND LOCAL ANESTHETICS, VASODILATORS, CARDIOTONICS, PARENTERAL FEEDING, CHEMOTHERAPY MEDICATIONS, ANTI-CANCER DRUGS, LABOR-INDUCING DRUGS AND ANTI-COAGLANTS AT ICU, CCU, NICU, OPERATING ROOMS OR GENERAL WARDS.,SYRINGE INFUSION PUMP (TERUFUSION SYRINGE PUMP TYPE SS)-IT IS INTENDED FOR THE INFUSION OF GENERAL AND LOCAL ANESTHETICS, VASODILATORS, CARDIOTONICS, PARENTERAL FEEDING, ANTI-CANCER DRUGS, LABOR-INDUCING DRUGS AND BLOOD TRANSFUSIONS AT ICU, CCU, NICU, OPERATING ROOMS OR GENERAL WARDS., HEMOCONCENTRATOR(CAPIOX HEMOCONCENTRATOR)-IT IS INTENDED TO BE USED DURING AND AFTER SURGICAL PROCEDURES REQUIRING CARDIOPULMONARY BYPASS (UP TO 6 HOURS) WHEN THE REMOVAL OF EXCESS FLUID FROM BLOOD IS REQUIRED. IT SHOULD NOT BE USED AS A DIALYZER, HEMOFILTER OR OTHER DEVICE.,INTRAVASCULAR GUIDING CATHETER(NAVICROSS)-IT IS INTEDED TO GUIDE AND SUPPORT A GUIDE WIRE DURING ACCESS OF THE VASCULATURE EXCEPT CENTRAL CIRCULATORY SYSTEM TO ALLOW WIRE EXCHANGES AND PROVIDE A CONDUIT FOR THE DELIVERY OF PHYSIOLOGICAL HEPARINIZED SALINE SOLUTION OR RADIOPAQUE MEDIA.

1462	IMP/MD/2018/000441	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RADIOPAQUE BONE CEMENT(VERTAPLEX / VERTAPLEX HIGH VISCOSITY (HV))-VERTAPLEX / VERTAPLEX HV RADIOPAQUE BONE CEMENT IS INDICATED FOR THE FIXATION OF PATHOLOGICAL FRACTURES OF THE VERTEBRAL BODY USING VERTEBROPLASTY OR KYPHOPLASTY PROCEDURES. PAINFUL VERTEBRAL COMPRESSION FRACTURES MAY RESULT FROM OSTEOPOROSIS, BENIGN LESIONS (HEMANGIOMA), AND MALIGNANT LESIONS (METASTATIC CANCERS, MYELOMA)., RADIOPAQUE BONE CEMENT(SPINEPLEX)-SPINEPLEX RADIOPAQUE BONE CEMENT IS INDICATED FOR THE FIXATION OF PATHOLOGICAL FRACTURES OF THE VERTEBRAL BODY USING VERTEBROPLASTY OR KYPHOPLASTY PROCEDURES. PAINFUL VERTEBRAL COMPRESSION FRACTURES MAY RESULT FROM OSTEOPOROSIS, BENIGN LESIONS (HEMANGIOMA), AND MALIGNANT LESIONS (METASTATIC CANCERS, MYELOMA)
1463	IMP/MD/2018/000442	1.License Holder Name: SMITHS MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERCUTANEOUS TRACHEOSTOMY KIT(ULTRAPERC)-CONTROLLED, ELECTIVE SUBCRICIOD PERCUTANEOUS INSERTION OF A TRACHEOSTOMY TUBE FOR AIRWAY MANAGEMENT USING A SELDINGER GUIDEWIRE DILATION TECHNIQUE
1464	IMP/MD/2018/000443	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHODONTIC WIRE (NICKEL TITANIUM)(NITI ARCHWIRE, DAMON ARCHWIRE, TRU-ARCH ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH.,ORTHODONTIC WIRE (STAINLESS STEEL)(DAMON ARCHWIRE, RESPOND ARCHWIRE, STAINLESS STEEL ARCHWIRE, TRIPLEFLEX ARCHWIRE, TRU-ARCH ARCHWIRE, TEFLON COATED LIGATURE WIRES)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH. ,ORTHODONTIC WIRE (BETA TITANIUM)(TMA ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH.,ORTHODONTIC WIRE (COPPER NICKEL TITANIUM)(COPPER NI-TI ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH.

1465	IMP/MD/2018/000444	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE DEVICES FOR THE INTERSPINOUS SPACE WITH LAMINA SUPPORT(INTRASPINE®)- THE INTRASPINE PROTHESIS IS RECOMMENTED IN LOMBAR SURGERY IN THE FOLLOWING CASES: - ARTHROPATHIC FACET-SYNDROME - FORAMINAL STENOSIS - DEGENERATIVE DISCOPATHY - INTERVERTEBRAL LIGAMENT INSUFFICIENCY

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1466	IMP/MD/2018/000445	1.License Holder Name: M/S ZIMMER INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL ELBOW PROSTHESIS(ZIMMER NEXEL TOTAL ELBOW-HUMERAL COMPONENT) -ELBOW JOINT DESTRUCTION WHICH SIGNIFICANTLY COMPROMISES THE ACTIVITIES OF DAILY LIVING • POST-TRAUMATIC LESIONS OR BONE LOSS CONTRIBUTING TO ELBOW INSTABILITY • ANKYLOSED JOINTS, ESPECIALLY IN CASES OF BILATERAL ANKYLOSIS FROM CAUSES OTHER THAN ACTIVE SEPSIS • ADVANCED RHEUMATOID, POST-TRAUMATIC, OR DEGENERATIVE ARTHRITIS WITH INCAPACITATING PAIN • INSTABILITY OR LOSS OF MOTION WHEN THE DEGREE OF JOINT OR SOFT TISSUE DAMAGE PRECLUDES RELIABLE OSTEOSYNTHESIS • ACUTE COMMINUTED ARTICULAR FRACTURE OF THE ELBOW JOINT SURFACES THAT PRECLUDES LESS RADICAL PROCEDURES, INCLUDING 13-C3 FRACTURES OF THE DISTAL HUMERUS • REVISION ARTHROPLASTY CAUTION: THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY.,KNEE REPLACEMENT (PERSONA THE PERSONALIZED KNEE SYSTEM - ARTICULAR SURFACE (CRUCIATE RETAINING (CR); ULTRA CONGRUENT (UC) AND POSTERIOR STABILIZED (PS))-THE DEVICE INDICATIONS ARE THE FOLLOWING: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • COLLAGEN DISORDERS AND/ OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. • POST- TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS OR FLEXION DEFORMITIES. THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY ,TOTAL ELBOW PROSTHESIS(ZIMMER NEXEL TOTAL ELBOW-AXLE PIN)-• ELBOW JOINT DESTRUCTION WHICH SIGNIFICANTLY COMPROMISES THE ACTIVITIES OF DAILY LIVING • POST-TRAUMATIC LESIONS OR BONE LOSS CONTRIBUTING TO ELBOW INSTABILITY • ANKYLOSED JOINTS, ESPECIALLY IN CASES OF BILATERAL ANKYLOSIS FROM CAUSES OTHER THAN ACTIVE SEPSIS • ADVANCED RHEUMATOID, POST-TRAUMATIC, OR DEGENERATIVE ARTHRITIS WITH INCAPACITATING PAIN • INSTABILITY OR LOSS OF MOTION WHEN THE DEGREE OF JOINT OR SOFT TISSUE DAMAGE PRECLUDES RELIABLE OSTEOSYNTHESIS • ACUTE COMMINUTED ARTICULAR FRACTURE OF THE ELBOW JOINT SURFACES THAT PRECLUDES LESS RADICAL PROCEDURES, INCLUDING 13-C3 FRACTURES OF THE DISTAL HUMERUS • REVISION ARTHROPLASTY CAUTION: THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY.,KNEE SYSTEM(NATURAL KNEE II SYSTEM - PATELLA)-THE DEVICE INDICATIONS ARE THE

	FOLLOWING: • NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY DEGENERATIVE JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS; • CORRECTABLE VALGUS-VARUS DEFORMITY AND MODERATE FLEXION CONTRACTURE; • THOSE PATIENTS WITH FAILED PREVIOUS SURGERY WHERE PAIN, DEFORMITY, OR DYSFUNCTION PERSISTS; AND REVISION OF PREVIOUSLY FAILED KNEE ARTHROPLASTY. ,TOTAL ELBOW PROSTHESIS(ZIMMER NEXEL TOTAL ELBOW-HUMERAL SCREWS)- ELBOW JOINT DESTRUCTION WHICH SIGNIFICANTLY COMPROMISES THE ACTIVITIES OF DAILY LIVING • POST-TRAUMATIC LESIONS OR BONE LOSS CONTRIBUTING TO ELBOW INSTABILITY • ANKYLOSED JOINTS, ESPECIALLY IN CASES OF BILATERAL ANKYLOSIS FROM CAUSES OTHER THAN ACTIVE SEPSIS • ADVANCED RHEUMATOID, POST-TRAUMATIC, OR DEGENERATIVE ARTHRITIS WITH INCAPACITATING PAIN • INSTABILITY OR LOSS OF MOTION WHEN THE DEGREE OF JOINT OR SOFT TISSUE DAMAGE PRECLUDES RELIABLE OSTEOSYNTHESIS • ACUTE COMMINUTED ARTICULAR FRACTURE OF THE ELBOW JOINT SURFACES THAT PRECLUDES LESS RADICAL PROCEDURES, INCLUDING 13-C3 FRACTURES OF THE DISTAL HUMERUS • REVISION ARTHROPLASTY CAUTION: THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY.,KNEE SYSTEM(NATURAL KNEE II SYSTEM - FEMORAL COMPONENT)-THE DEVICE INDICATIONS ARE THE FOLLOWING: • NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY DEGENERATIVE JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS; • CORRECTABLE VALGUS-VARUS DEFORMITY AND MODERATE FLEXION CONTRACTURE; • THOSE PATIENTS WITH FAILED PREVIOUS SURGERY WHERE PAIN, DEFORMITY, OR DYSFUNCTION PERSISTS; AND REVISION OF PREVIOUSLY FAILED KNEE ARTHROPLASTY. ,TOTAL ELBOW PROSTHESIS(ZIMMER NEXEL TOTAL ELBOW-ULNAR BEARING-B)-• ELBOW JOINT DESTRUCTION WHICH SIGNIFICANTLY COMPROMISES THE ACTIVITIES OF DAILY LIVING • POST-TRAUMATIC LESIONS OR BONE LOSS CONTRIBUTING TO ELBOW INSTABILITY • ANKYLOSED JOINTS, ESPECIALLY IN CASES OF BILATERAL ANKYLOSIS FROM CAUSES OTHER THAN ACTIVE SEPSIS • ADVANCED RHEUMATOID, POST-TRAUMATIC, OR DEGENERATIVE ARTHRITIS WITH INCAPACITATING PAIN • INSTABILITY OR LOSS OF MOTION WHEN THE DEGREE OF JOINT OR SOFT TISSUE DAMAGE PRECLUDES RELIABLE OSTEOSYNTHESIS • ACUTE COMMINUTED ARTICULAR FRACTURE OF THE ELBOW JOINT SURFACES THAT PRECLUDES LESS RADICAL PROCEDURES, INCLUDING 13-C3 FRACTURES OF THE DISTAL HUMERUS • REVISION ARTHROPLASTY CAUTION: THIS DEVICE IS

	INTENDED FOR CEMENTED USE ONLY.,KNEE REPLACEMENT (PERSONA THE PERSONALIZED KNEE SYSTEM STEM EXTENSION)- THE DEVICE INDICATIONS ARE THE FOLLOWING: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • COLLAGEN DISORDERS, AND/ OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. • POST- TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS OR FLEXION DEFORMITIES. THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY ,TOTAL ELBOW PROSTHESIS(ZIMMER NEXEL TOTAL ELBOW-HUMERAL BEARING-A)-ELBOW JOINT DESTRUCTION WHICH SIGNIFICANTLY COMPROMISES THE ACTIVITIES OF DAILY LIVING • POST-TRAUMATIC LESIONS OR BONE LOSS CONTRIBUTING TO ELBOW INSTABILITY • ANKYLOSED JOINTS, ESPECIALLY IN CASES OF BILATERAL ANKYLOSIS FROM CAUSES OTHER THAN ACTIVE SEPSIS • ADVANCED RHEUMATOID, POST-TRAUMATIC, OR DEGENERATIVE ARTHRITIS WITH INCAPACITATING PAIN • INSTABILITY OR LOSS OF MOTION WHEN THE DEGREE OF JOINT OR SOFT TISSUE DAMAGE PRECLUDES RELIABLE OSTEOSYNTHESIS • ACUTE COMMINUTED ARTICULAR FRACTURE OF THE ELBOW JOINT SURFACES THAT PRECLUDES LESS RADICAL PROCEDURES, INCLUDING 13-C3 FRACTURES OF THE DISTAL HUMERUS • REVISION ARTHROPLASTY CAUTION: THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY.,ACETABULAR SYSTEM(LONGEVITY CROSS-LINKED POLYETHYLENE LINERS – CONSTRAINED LINERS)-THE TRILOGY LONGEVITY CONSTRAINED LINER IS INDICATED AS A COMPONENT OF A TOTAL HIP PROSTHESIS IN PRIMARY OR REVISION TOTAL HIP ARTHROPLASTIES WHERE THERE IS A HIGH RISK OF HIP DISLOCATION DUE TO A HISTORY OF INSTABILITY, BONE LOSS, JOINT, MUSCLE OR TISSUE LAXITY, OR DISEASE CONDITION. THIS DEVICE IS INTENDED FOR PATIENTS FOR WHOM ALL OTHER OPTIONS TO CONSTRAINED ACETABULAR COMPONENTS HAVE BEEN CONSIDERED.,TOTAL ELBOW PROSTHESIS (ZIMMER NEXEL TOTAL ELBOW-ULNAR COMPONENT)-• ELBOW JOINT DESTRUCTION WHICH SIGNIFICANTLY COMPROMISES THE ACTIVITIES OF DAILY LIVING • POST-TRAUMATIC LESIONS OR BONE LOSS CONTRIBUTING TO ELBOW INSTABILITY • ANKYLOSED JOINTS, ESPECIALLY IN CASES OF BILATERAL ANKYLOSIS FROM CAUSES OTHER THAN ACTIVE SEPSIS • ADVANCED RHEUMATOID, POST-TRAUMATIC, OR DEGENERATIVE ARTHRITIS WITH INCAPACITATING PAIN • INSTABILITY OR LOSS OF MOTION WHEN THE DEGREE OF JOINT OR SOFT TISSUE DAMAGE PRECLUDES RELIABLE

	OSTEOSYNTHESIS • ACUTE COMMINUTED ARTICULAR FRACTURE OF THE ELBOW JOINT SURFACES THAT PRECLUDES LESS RADICAL PROCEDURES, INCLUDING 13-C3 FRACTURES OF THE DISTAL HUMERUS • REVISION ARTHROPLASTY CAUTION: THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY.,KNEE REPLACEMENT (PERSONA THE PERSONALIZED KNEE SYSTEM - ALL POLY PATELLA)- THE DEVICE INDICATIONS ARE THE FOLLOWING: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • COLLAGEN DISORDERS, AND/ OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. • POST- TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS OR FLEXION DEFORMITIES. THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY , ACETABULAR SYSTEM(TRABECULAR METAL ACETABULAR REVISION CAGE)-THIS DEVICE IS INDICATED FOR PATIENTS WITH CONDITIONS OF, BUT NOT LIMITED TO: • ACETABULAR DYSPLASIA, OSTEOPOROSIS, PROTRUSIO ACETABULI, CYSTIC ACETABULAR ROOF, RECONSTRUCTION IN CASES OF DEFECTS AFTER FRACTURE, ACETABULAR LOOSENING, TUMORS OR REVISION SURGERY. • ADVANCED JOINT DESTRUCTION RESULTING FROM DEGENERATIVE, POST-TRAUMATIC, OR RHEUMATOID ARTHRITIS. • FAILED PREVIOUS SURGERY, E.G., OSTEOSYNTHESIS, JOINT RECONSTRUCTION, ARTHRODESIS, HEMIARTHROPLASTY, OR TOTAL HIP REPLACEMENT, ACETABULAR SYSTEM(TRABECULAR METAL ACETABULAR REVISION SHELL LINER)-THE ACETABULAR CUP IS INDICATED FOR: • CEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY OR REVISION SURGERY FOR REHABILITATING HIPS DAMAGES AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. • THE TRABECULAR METAL REVISION SHELL LINER IS INDICATED FOR CEMENTED USE IN THE TRABECULAR METAL REVISION SHELL FOR INITIAL PLACEMENT OR AS AN IN SITU REPLACEMENT POLYETHYLENE BEARING SURFACE FOR JOINT INSTABILITY, WEAR AND/OR DAMAGE,CUP-LINER AND SHELL WITH PLASTIC BARRIER(ZIMMER MAXERA CUP)-THE ZIMMER MAXERA CUP IS INDICATED FOR NONCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR REHABILITATING HIPS DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD)

	INCLUDING BUT NOT LIMITED TO OSTEOARTHRITIS, AVASCULAR NECROSIS, POST-TRAUMATIC ARTHRITIS, CONGENITAL HIP DYSPLASIA, AND INFLAMMATORY JOINT DISEASE (IJD),E.G. RHEUMATOID ARTHRITIS IF BONE QUALITY IS ADEQUATE,HIP SYSTEM(ZIMMER M/L TAPER HIP FEMORAL STEM WITH KINECTIV TECHNOLOGY - FEMORAL STEM AND NECK)-• TOTAL HIP REPLACEMENT FOR PATIENTS WITH: SEVERE HIP PAIN AND DISABILITY DUE TO RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS OF THE FEMORAL HEAD, NONUNION OF PREVIOUS FRACTURES OF THE FEMUR; CONGENITAL HIP DYSPLASIA, PROTRUSIO ACETABULI, PREVIOUSLY FAILED ENDOPROSTHESES, AND/OR TOTAL HIP COMPONENTS IN THE AFFECTED EXTREMITY AND ACUTE FEMORAL NECK FRACTURES. • HEMI-HIP REPLACEMENT FOR PATIENTS WITH: FRACTURE DISLOCATION OF THE HIP; ELDERLY, DEBILITATED PATIENTS WHEN A TOTAL HIP REPLACEMENT IS CONTRAINDICATED; IRREDUCIBLE FRACTURES IN WHICH ADEQUATE FIXATION CANNOT BE OBTAINED; CERTAIN HIGH SUBCAPITAL FRACTURES AND COMMINUTED FEMORAL NECK FRACTURES IN THE AGED; NONUNION OF FEMORAL NECK FRACTURES; SECONDARY AVASCULAR NECROSIS OF THE FEMORAL HEAD; PATHOLOGICAL FRACTURES OF THE FEMORAL NECK; AND OSTEOARTHRITIS IN WHICH THE FEMORAL HEAD IS PRIMARILY AFFECTED. • THE FEMORAL STEM IS FOR CEMENTLESS USE ONLY.,ACETABULAR SYSTEM(ZCA ALL-POLY ACETABULAR CUP WITH SPACER)-• THE ACETABULAR CUP IS INDICATED FOR:CEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY OR REVISION SURGERY FOR REHABILITATING HIPS DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. • THE TRABECULAR METAL™ REVISION SHELL LINER IS INDICATED FOR CEMENTED USE IN THE TRABECULAR METAL REVISION SHELL FOR INITIAL PLACEMENT OR AS AN IN SITU REPLACEMENT POLYETHYLENE BEARING SURFACE FOR JOINT INSTABILITY, WEAR AND/OR DAMAGE,HIP SYSTEM(ZIMMER M/L TAPER FEMORAL STEM HIP PROSTHESIS - FEMORAL STEM)-• TOTAL HIP REPLACEMENT FOR THE FOLLOWING: SEVERE HIP PAIN AND DISABILITY DUE TO RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS OF THE FEMORAL HEAD, NONUNION OF PREVIOUS FRACTURES OF THE FEMUR; CONGENITAL HIP DYSPLASIA, PROTRUSIO ACETABULI, SLIPPED CAPITAL FEMORAL EPIPHYSIS; DISABILITY DUE TO

	PREVIOUS FUSION; PREVIOUSLY FAILED ENDOPROSTHESES, AND/OR TOTAL HIP COMPONENTS IN THE AFFECTED EXTREMITY AND ACUTE FEMORAL NECK FRACTURES. • HEMI-HIP REPLACEMENT FOR THE FOLLOWING: FRACTURE DISLOCATION OF THE HIP; ELDERLY, DEBILITATED PATIENTS WHEN A TOTAL HIP REPLACEMENT IS CONTRAINDICATED; IRREDUCIBLE FRACTURES IN WHICH ADEQUATE FIXATION CANNOT BE OBTAINED; CERTAIN HIGH SUBCAPITAL FRACTURES AND COMMINUTED FEMORAL NECK FRACTURES IN THE AGED; NONUNION OF FEMORAL NECK FRACTURES; SECONDARY AVASCULAR NECROSIS OF THE FEMORAL HEAD; PATHOLOGICAL FRACTURES OF THE FEMORAL NECK; AND OSTEOARTHRITIS IN WHICH THE FEMORAL HEAD IS PRIMARILY AFFECTED.,ACETABULAR SYSTEM(TRILOGY IT ACETABULAR SYSTEM - SHELL AND SCREW HOLE PLUG)-THE SYSTEM IS INDICATED FOR: • PRIMARY OR REVISION SURGERY IN SKELETALLY MATURE INDIVIDUALS FOR REHABILITATING HIPS DAMAGED AS RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ITS COMPOSITE DIAGNOSIS OF OSTEOARTHRITIS, AVASCULAR NECROSIS, PROTRUSIO ACETABULI, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. • THE SYSTEM IS INTENDED FOR USE WITH OR WITHOUT BONE CEMENT IN TOTAL HIP ARTHROPLASTY,ACETABULAR SYSTEM (LONGEVITY HIGHLY CROSS-LINKED POLYETHYLENE LINERS (CONSTRAINED LINERS))-THE LONGEVITY IT CONSTRAINED LINER IS INDICATED AS A COMPONENT OF A TOTAL HIP PROSTHESIS IN PRIMARY OR REVISION TOTAL HIP ARTHROPLASTIES WHERE THERE IS A HIGH RISK OF HIP DISLOCATION DUE TO A HISTORY OF INSTABILITY, BONE LOSS, JOINT, MUSCLE OR TISSUE LAXITY, OR DISEASE CONDITION. THIS DEVICE IS INTENDED FOR PATIENTS FOR WHOM ALL OTHER OPTIONS TO CONSTRAINED ACETABULAR COMPONENTS HAVE BEEN CONSIDERED.,ACETABULAR SYSTEM (LONGEVITY HIGHLY CROSS-LINKED POLYETHYLENE LINERS)-THE SYSTEM IS INDICATED FOR: • PRIMARY OR REVISION SURGERY IN SKELETALLY MATURE INDIVIDUALS FOR REHABILITATING HIPS DAMAGED AS RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, PROTRUSIO ACETABULI, AND TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. THE SYSTEM IS INTENDED FOR USE WITH OR WITHOUT BONE CEMENT IN TOTAL HIP ARTHROPLASTY,ACETABULAR SYSTEM(CONTINUUM ACETABULAR SYSTEM - SHELL, SCREW HOLE PLUG AND DOME HOLE PLUG)-THE SYSTEM IS INDICATED FOR: • PRIMARY OR REVISION SURGERY IN SKELETALLY MATURE INDIVIDUALS FOR

	REHABILITATING HIPS DAMAGED AS RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, PROTRUSIO ACETABULI, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. THE SYSTEM IS INTENDED FOR USE WITH OR WITHOUT BONE CEMENT IN TOTAL HIP ARTHROPLASTY,HIP SYSTEM(ALLEN MEDULLARY PLUG)-INTRAMEDULLARY CEMENT PLUGS ARE INDICATED FOR • USE IN TOTAL JOINT ARTHROPLASTY TO CONTROL, RESTRICT, OR IMPEDE THE FLOW OF CEMENT. LARGER INTRAMEDULLARY CEMENT PLUGS ARE USEFUL IN REVISION SURGERY WHERE A WIDE, SMOOTH INTRAMEDULLARY CANAL MUST BE PLUGGED,HIP SYSTEM(CPT HIP SYSTEM - FEMORAL STEM AND CENTRALIZER)-THE CPT HIP SYSTEM IS INDICATED FOR CEMENTED USE IN: • PATIENTS SUFFERING FROM SEVERE HIP PAIN AND DISABILITY DUE TO RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS OF FEMORAL HEAD, AND NONUNION OF PREVIOUS FRACTURES OF FEMUR. • PATIENTS WITH CONGENITAL HIP DYSPLASIA, PROTRUSIO ACETABULI, OR SLIPPED CAPITAL FEMORAL EPIPHYSIS. • PATIENTS SUFFERING FROM DISABILITY DUE TO PREVIOUS FUSION. • PATIENTS WITH PREVIOUSLY FAILED ENDOPROSTHESES AND/OR TOTAL HIP COMPONENTS IN THE AFFECTED EXTREMITY. PATIENTS WITH ACUTE FEMORAL NECK FRACTURES,KNEE SYSTEM(GENDER SOLUTIONS PATELLO FEMORAL JOINT – FEMORAL COMPONENT)-THE DEVICE INDICATIONS ARE THE FOLLOWING: • OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, AND/OR SEVERE CHONDROCALCINOSIS OF THE PATELLOFEMORAL JOINT. • THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS (E.G., ARTHROSCOPY, LATERAL RELEASE, CARTILAGE TRANSPLANTATION). • HISTORY OF PATELLAR DISLOCATION OR PATELLA FRACTURE. • DYSPLASIA-INDUCED DEGENERATION. • THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY. ,PLATES FOR TRAUMA FIXATION(ZIMMER RECONSTRUCTION SYSTEM (NON-STERILE) - PLATES)-TEMPORARY INTERNAL FIXATION DEVICES ARE DESIGNED TO STABILIZE FRACTURES DURING THE NORMAL HEALING PROCESS,PLATES AND SCREWS FOR TRAUMA FIXATION(ZIMMER® PERIARTICULAR LOCKING PLATE SYSTEM - PLATES - SCREWS)-THE PERIARTICULAR LOCKING PLATE SYSTEM IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF OSTEOTOMIES AND FRACTURES: • COMMINUTED FRACTURES, • SUPRACONDYLAR FRACTURES, • INTRA – ARTICULAR AND EXTRA – ARTICULAR CONDYLAR FRACTURES, • FRACTURES IN OSTEOPENIC BONE • NON-UNIONS, • MALUNIONS,TRAUMA PLATING

	SYSTEM(ZIMMER UNIVERSAL LOCKING SYSTEM (TITANIUM) - PLATES - SCREWS)-THE UNIVERSAL LOCKING SYSTEM IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF OSTEOTOMIES AND FRACTURES, INCLUDING: COMMINUTED FRACTURES, SUPRACONDYLAR FRACTURES, EXTRA- ARTICULAR FRACTURES, FRACTURES IN OSTEOPENIC BONE, NON-UNION AND MALUNIONS.,HIP SYSTEM(VERSYS HIP SYSTEM FEMORAL STEM BEADED - STEM)-A. THIS DEVICE IS INDICATED FOR TOTAL HIP REPLACEMENT FOR THE FOLLOWING: SEVERE HIP PAIN AND DISABILITY DUE TO RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS OF THE FEMORAL HEAD, NON-UNION OF PREVIOUS FRACTURES OF THE FEMUR; CONGENITAL HIP DYSPLASIA, PROTRUSIO ACETABULI, SLIPPED CAPITAL FEMORAL EPIPHYSIS; DISABILITY DUE TO PREVIOUS FUSION; PREVIOUSLY FAILED ENDOPROSTHESES, AND/OR TOTAL HIP COMPONENTS IN THE AFFECTED EXTREMITY AND ACUTE FEMORAL NECK FRACTURES. HEMI-HIP REPLACEMENT FOR THE FOLLOWING: FRACTURE DISLOCATION OF THE HIP; ELDERLY, DEBILITATED PATIENTS WHEN A TOTAL HIP REPLACEMENT IS CONTRAINDICATED; IRREDUCIBLE FRACTURES IN WHICH ADEQUATE FIXATION CANNOT BE OBTAINED; CERTAIN HIGH SUB CAPITAL FRACTURES AND COMMINUTED FEMORAL NECK FRACTURES IN THE AGED; NON-UNION OF FEMORAL NECK FRACTURES; SECONDARY AVASCULAR NECROSIS OF THE FEMORAL HEAD; PATHOLOGICAL FRACTURES OF THE FEMORAL NECK; AND OSTEOARTHRITIS IN WHICH THE FEMORAL HEAD IS PRIMARILY AFFECTED.,SHOULDER SYSTEM(BIGLIANI/ FLATOW THE COMPLETE SHOULDER SOLUTION - HUMERAL STEM)-PROSTHETIC REPLACEMENT WITH THIS DEVICE MAY BE INDICATED FOR THE TREATMENT OF SEVERE PAIN OR SIGNIFICANT DISABILITY IN DEGENERATIVE, RHEUMATOID, OR TRAUMATIC DISEASE OF THE GLENOHUMERAL JOINT; UN-UNITED HUMERAL HEAD FRACTURES OF LONG DURATION; IRREDUCIBLE 3- AND 4-PART PROXIMAL HUMERAL FRACTURES; AVASCULAR NECROSIS OF THE HUMERAL HEAD; OR OTHER DIFFICULT CLINICAL MANAGEMENT PROBLEMS WHERE ARTHRODESIS OR RESECTIONAL ARTHROPLASTY IS NOT ACCEPTABLE. THE ASSEMBLED HUMERAL COMPONENT MAY BE USED ALONE FOR HEMIARTHROPLASTY OR COMBINED WITH THE GLENOID COMPONENT FOR TOTAL SHOULDER ARTHROPLASTY. HUMERAL HEADS WITH HEIGHTS OF 27MM OR GREATER MAY BE USED FOR DIFFICULT CLINICAL MANAGEMENT PROBLEMS INVOLVING ROTATOR CUFF DEFICIENCY WHERE ARTHRODESIS OR CONVENTIONAL NON-CONSTRAINED ARTHROPLASTY IS NOT ACCEPTABLE,ELBOW SYSTEM(COONRAD/ MORREY TOTAL ELBOW

	CEMENT RESTRICTOR)-THIS DEVICE IS INDICATED FOR POST-TRAUMATIC LESIONS OR BONE LOSS CONTRIBUTING TO ELBOW INSTABILITY; ANKYLOSED JOINTS, ESPECIALLY IN CASES OF BILATERAL ANKYLOSIS FROM CAUSES OTHER THAN SEPSIS; ADVANCED RHEUMATOID OR DEGENERATIVE ARTHRITIS WITH INCAPACITATING PAIN; REVISION ARTHROPLASTY; AND INSTABILITY OR LOSS OF MOTION WHEN THE DEGREE OF JOINT DAMAGE PRECLUDES LESS RADICAL PROCEDURES. THE CANDIDATE FOR TOTAL ELBOW ARTHROPLASTY SHOULD EXHIBIT JOINT DESTRUCTION WHICH SIGNIFICANTLY COMPROMISES THE ACTIVITIES OF DAILY LIVING. PATIENTS WITH SINGLE JOINT INVOLVEMENT (GENERALLY THOSE WITH TRAUMATIC OR DEGENERATIVE ARTHRITIS) OR SIGNIFICANT LOWER EXTREMITY DISABILITY WHICH REQUIRE WALKING AIDS ARE LESS AMENABLE TO TREATMENT THAN PATIENTS WITH ADVANCED AND PREDOMINATELY UPPER EXTREMITY INVOLVEMENT. IF POSSIBLE, ELBOW REPLACEMENT SHOULD BE DONE AFTER HIP OR KNEE SURGERY TO AVOID EXCESSIVE STRESS TO THE PROSTHESIS REQUIRED BY CRUTCH WALKING DURING TOTAL HIP OR KNEE REHABILITATION,ELBOW SYSTEM(COONRAD/ MORREY TOTAL ELBOW - PIN/BUSHING)-THIS DEVICE IS INDICATED FOR POST-TRAUMATIC LESIONS OR BONE LOSS CONTRIBUTING TO ELBOW INSTABILITY; ANKYLOSED JOINTS, ESPECIALLY IN CASES OF BILATERAL ANKYLOSIS FROM CAUSES OTHER THAN SEPSIS; ADVANCED RHEUMATOID OR DEGENERATIVE ARTHRITIS WITH INCAPACITATING PAIN; REVISION ARTHROPLASTY; AND INSTABILITY OR LOSS OF MOTION WHEN THE DEGREE OF JOINT DAMAGE PRECLUDES LESS RADICAL PROCEDURES. THE CANDIDATE FOR TOTAL ELBOW ARTHROPLASTY SHOULD EXHIBIT JOINT DESTRUCTION WHICH SIGNIFICANTLY COMPROMISES THE ACTIVITIES OF DAILY LIVING. PATIENTS WITH SINGLE JOINT INVOLVEMENT (GENERALLY THOSE WITH TRAUMATIC OR DEGENERATIVE ARTHRITIS) OR SIGNIFICANT LOWER EXTREMITY DISABILITY WHICH REQUIRE WALKING AIDS ARE LESS AMENABLE TO TREATMENT THAN PATIENTS WITH ADVANCED AND PREDOMINATELY UPPER EXTREMITY INVOLVEMENT. IF POSSIBLE, ELBOW REPLACEMENT SHOULD BE DONE AFTER HIP OR KNEE SURGERY TO AVOID EXCESSIVE STRESS TO THE PROSTHESIS REQUIRED BY CRUTCH WALKING DURING TOTAL HIP OR KNEE REHABILITATION,ELBOW SYSTEM(COONRAD/ MORREY TOTAL ELBOW - ULNAR COMPONENT)-THIS DEVICE IS INDICATED FOR POST-TRAUMATIC LESIONS OR BONE LOSS CONTRIBUTING TO ELBOW INSTABILITY; ANKYLOSED JOINTS, ESPECIALLY IN CASES OF BILATERAL ANKYLOSIS FROM CAUSES OTHER THAN SEPSIS; ADVANCED RHEUMATOID OR DEGENERATIVE ARTHRITIS WITH INCAPACITATING PAIN; REVISION ARTHROPLASTY;

	AND INSTABILITY OR LOSS OF MOTION WHEN THE DEGREE OF JOINT DAMAGE PRECLUDES LESS RADICAL PROCEDURES. THE CANDIDATE FOR TOTAL ELBOW ARTHROPLASTY SHOULD EXHIBIT JOINT DESTRUCTION WHICH SIGNIFICANTLY COMPROMISES THE ACTIVITIES OF DAILY LIVING. PATIENTS WITH SINGLE JOINT INVOLVEMENT (GENERALLY THOSE WITH TRAUMATIC OR DEGENERATIVE ARTHRITIS) OR SIGNIFICANT LOWER EXTREMITY DISABILITY WHICH REQUIRE WALKING AIDS ARE LESS AMENABLE TO TREATMENT THAN PATIENTS WITH ADVANCED AND PREDOMINATELY UPPER EXTREMITY INVOLVEMENT. IF POSSIBLE, ELBOW REPLACEMENT SHOULD BE DONE AFTER HIP OR KNEE SURGERY TO AVOID EXCESSIVE STRESS TO THE PROSTHESIS REQUIRED BY CRUTCH WALKING DURING TOTAL HIP OR KNEE REHABILITATION,SHOULDER SYSTEM(TRABECULAR METAL REVERSE SHOULDER SYSTEM - TRABECULAR METAL REVERSE SHOULDER HUMERAL STEM AND SPACER)-THIS DEVICE IS INDICATED FOR REVERSE APPLICATION: • TREATMENT OF SEVERE PAIN OR SIGNIFICANT DISABILITY IN DEGENERATIVE, RHEUMATOID, TRAUMATIC DISEASE OF THE GLENOHUMERAL JOINT; • UN-UNITED HUMERAL HEAD FRACTURES OF LONG DURATION; • IRREDUCIBLE 3-AND 4-PART PROXIMAL HUMERAL FRACTURES; AVASCULAR NECROSIS OF THE HUMERAL HEAD OR OTHER DIFFICULT CLINICAL MANAGEMENT PROBLEMS (SUCH AS A FAILED TOTAL SHOULDER ARTHROPLASTY OR GROSSLY ROTATOR CUFF DEFICIENT JOINT) WHERE ARTHRODESIS OR RE-SECTIONAL ARTHROPLASTY IS NOT ACCEPTABLE ,ELBOW SYSTEM (COONRAD/ MORREY TOTAL ELBOW - HUMERAL COMPONENT)-THIS DEVICE IS INDICATED FOR POST-TRAUMATIC LESIONS OR BONE LOSS CONTRIBUTING TO ELBOW INSTABILITY; ANKYLOSED JOINTS, ESPECIALLY IN CASES OF BILATERAL ANKYLOSIS FROM CAUSES OTHER THAN SEPSIS; ADVANCED RHEUMATOID OR DEGENERATIVE ARTHRITIS WITH INCAPACITATING PAIN; REVISION ARTHROPLASTY; AND INSTABILITY OR LOSS OF MOTION WHEN THE DEGREE OF JOINT DAMAGE PRECLUDES LESS RADICAL PROCEDURES. THE CANDIDATE FOR TOTAL ELBOW ARTHROPLASTY SHOULD EXHIBIT JOINT DESTRUCTION WHICH SIGNIFICANTLY COMPROMISES THE ACTIVITIES OF DAILY LIVING. PATIENTS WITH SINGLE JOINT INVOLVEMENT (GENERALLY THOSE WITH TRAUMATIC OR DEGENERATIVE ARTHRITIS) OR SIGNIFICANT LOWER EXTREMITY DISABILITY WHICH REQUIRE WALKING AIDS ARE LESS AMENABLE TO TREATMENT THAN PATIENTS WITH ADVANCED AND PREDOMINATELY UPPER EXTREMITY INVOLVEMENT. IF POSSIBLE, ELBOW REPLACEMENT SHOULD BE DONE AFTER HIP OR KNEE SURGERY TO AVOID EXCESSIVE STRESS TO THE PROSTHESIS REQUIRED BY CRUTCH WALKING DURING TOTAL HIP OR KNEE REHABILITATION,SHOULDER

	SYSTEM(TRABECULAR METAL REVERSE SHOULDER SYSTEM - TRABECULAR METAL GLENOID HEAD)-THIS DEVICE IS INDICATED FOR REVERSE APPLICATION: • TREATMENT OF SEVERE PAIN OR SIGNIFICANT DISABILITY IN DEGENERATIVE, RHEUMATOID, TRAUMATIC DISEASE OF THE GLENOHUMERAL JOINT; • UN-UNITED HUMERAL HEAD FRACTURES OF LONG DURATION; • IRREDUCIBLE 3- AND 4-PART PROXIMAL HUMERAL FRACTURES; AVASCULAR NECROSIS OF THE HUMERAL HEAD OR OTHER DIFFICULT CLINICAL MANAGEMENT PROBLEMS (SUCH AS A FAILED TOTAL SHOULDER ARTHROPLASTY OR GROSSLY ROTATOR CUFF DEFICIENT JOINT) WHERE ARTHRODESIS OR RE-SECTIONAL ARTHROPLASTY IS NOT ACCEPTABLE ,SHOULDER SYSTEM(TRABECULAR METAL REVERSE SHOULDER SYSTEM - TRABECULAR METAL REVERSE BASEPLATE)-THIS DEVICE IS INDICATED FOR REVERSE APPLICATION: • TREATMENT OF SEVERE PAIN OR SIGNIFICANT DISABILITY IN DEGENERATIVE, RHEUMATOID, TRAUMATIC DISEASE OF THE GLENOHUMERAL JOINT; • UN-UNITED HUMERAL HEAD FRACTURES OF LONG DURATION; • IRREDUCIBLE 3-AND 4-PART PROXIMAL HUMERAL FRACTURES; AVASCULAR NECROSIS OF THE HUMERAL HEAD OR OTHER DIFFICULT CLINICAL MANAGEMENT PROBLEMS (SUCH AS A FAILED TOTAL SHOULDER ARTHROPLASTY OR GROSSLY ROTATOR CUFF DEFICIENT JOINT) WHERE ARTHRODESIS OR RE-SECTIONAL ARTHROPLASTY IS NOT ACCEPTABLE ,SHOULDER SYSTEM(TRABECULAR METAL REVERSE SHOULDER SYSTEM - TRABECULAR METAL REVERSE HUMERAL STEM)-THIS DEVICE IS INDICATED FOR REVERSE APPLICATION: • TREATMENT OF SEVERE PAIN OR SIGNIFICANT DISABILITY IN DEGENERATIVE, RHEUMATOID, TRAUMATIC DISEASE OF THE GLENOHUMERAL JOINT; • UN-UNITED HUMERAL HEAD FRACTURES OF LONG DURATION; • IRREDUCIBLE 3- AND 4-PART PROXIMAL HUMERAL FRACTURES; AVASCULAR NECROSIS OF THE HUMERAL HEAD OR OTHER DIFFICULT CLINICAL MANAGEMENT PROBLEMS (SUCH AS A FAILED TOTAL SHOULDER ARTHROPLASTY OR GROSSLY ROTATOR CUFF DEFICIENT JOINT) WHERE ARTHRODESIS OR RE-SECTIONAL ARTHROPLASTY IS NOT ACCEPTABLE ,SHOULDER SYSTEM(TRABECULAR METAL REVERSE SHOULDER SYSTEM - DUAL TAPER INSERT)-THIS DEVICE IS INDICATED FOR REVERSE APPLICATION: • TREATMENT OF SEVERE PAIN OR SIGNIFICANT DISABILITY IN DEGENERATIVE, RHEUMATOID, TRAUMATIC DISEASE OF THE GLENOHUMERAL JOINT; • UN-UNITED HUMERAL HEAD FRACTURES OF LONG DURATION; • IRREDUCIBLE 3- AND 4-PART PROXIMAL HUMERAL FRACTURES; AVASCULAR NECROSIS OF THE HUMERAL HEAD OR OTHER DIFFICULT CLINICAL MANAGEMENT PROBLEMS (SUCH AS A FAILED TOTAL SHOULDER ARTHROPLASTY OR GROSSLY ROTATOR CUFF DEFICIENT JOINT)

	WHERE ARTHRODESIS OR RE-SECTIONAL ARTHROPLASTY IS NOT ACCEPTABLE ,HIP SYSTEM(MULTIPOLAR BIPOLAR CUP LINER)-USE OF THE MULTIPOLAR BIPOLAR CUP IS INDICATED IN: • FRACTURE DISLOCATION OF THE HIP. • ELDERLY, DEBILITATED PATIENTS WHEN A TOTAL HIP REPLACEMENT IS CONTRAINDICATED. • IRREDUCIBLE FRACTURES IN WHICH ADEQUATE FIXATION CANNOT BE OBTAINED. • CERTAIN HIGH SUBCAPITAL FRACTURES AND COMMINUTED FEMORAL NECK FRACTURES IN THE AGED. • NONUNION OF FEMORAL NECK FRACTURES. • SECONDARY AVASCULAR NECROSIS OF THE FEMORAL HEAD. • PATHOLOGICAL FRACTURES OF THE FEMORAL NECK. • OSTEOARTHRITIS IN WHICH THE FEMORAL HEAD IS PRIMARILY AFFECTED ,KNEE SYSTEM(NATURAL KNEE II SYSTEM TIBIAL COMPONENT)-THE DEVICE INDICATIONS ARE THE FOLLOWING: • NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY DEGENERATIVE JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS; • CORRECTABLE VALGUS-VARUS DEFORMITY AND MODERATE FLEXION CONTRACTURE; • THOSE PATIENTS WITH FAILED PREVIOUS SURGERY WHERE PAIN, DEFORMITY, OR DYSFUNCTION PERSISTS; AND REVISION OF PREVIOUSLY FAILED KNEE ARTHROPLASTY. ,PLATES AND SCREWS FOR TRAUMA FIXATION(ZIMMER® PERIARTICULAR LOCKING PLATE SYSTEM - PLATES - SCREWS)-THE PERIARTICULAR LOCKING PLATE SYSTEM IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF OSTEOTOMIES AND FRACTURES: • COMMINUTED FRACTURES, • SUPRACONDYLAR FRACTURES, • INTRA – ARTICULAR AND EXTRA – ARTICULAR CONDYLAR FRACTURES, • FRACTURES IN OSTEOPENIC BONE • NON-UNIONS, • MALUNIONS,HIP SYSTEM (MULTIPOLAR BIPOLAR CUP - SHELL)-USE OF THE MULTIPOLAR BIPOLAR CUP IS INDICATED IN: • FRACTURE DISLOCATION OF THE HIP. • ELDERLY, DEBILITATED PATIENTS WHEN A TOTAL HIP REPLACEMENT IS CONTRAINDICATED. • IRREDUCIBLE FRACTURES IN WHICH ADEQUATE FIXATION CANNOT BE OBTAINED. • CERTAIN HIGH SUBCAPITAL FRACTURES AND COMMINUTED FEMORAL NECK FRACTURES IN THE AGED. • NONUNION OF FEMORAL NECK FRACTURES. • SECONDARY AVASCULAR NECROSIS OF THE FEMORAL HEAD. • PATHOLOGICAL FRACTURES OF THE FEMORAL NECK. • OSTEOARTHRITIS IN WHICH THE FEMORAL HEAD IS PRIMARILY AFFECTED ,ACETABULAR SYSTEM(TRILOGY ACETABULAR SYSTEM LINERS)-THIS DEVICE IS INDICATED FOR: • EITHER CEMENTED OR UNCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY OR REVISION SURGERY FOR REHABILITATING HIPS DAMAGED AS A RESULT OF NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ITS

	COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, PROTRUSIO ACETABULI, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. ,ACETABULAR SYSTEM(TRILOGY ACETABULAR SYSTEM - SCREWS)-THIS DEVICE IS INDICATED FOR: • EITHER CEMENTED OR UNCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY OR REVISION SURGERY FOR REHABILITATING HIPS DAMAGED AS A RESULT OF NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, PROTRUSIO ACETABULI, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT.,ACETABULAR SYSTEM(TRILOGY ACETABULAR SYSTEM - SHELLS)-THIS DEVICE IS INDICATED FOR: • EITHER CEMENTED OR UNCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY OR REVISION SURGERY FOR REHABILITATING HIPS DAMAGED AS A RESULT OF NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, PROTRUSIO ACETABULI, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. ,KNEE SYSTEM(ZIMMER UNICOMPARTMENTAL KNEE TIBIAL COMPONENT)-THE DEVICE INDICATIONS ARE THE FOLLOWING: • THESE DEVICES ARE INDICATED FOR PATIENTS WITH: - PAINFUL AND/OR DISABLING KNEE JOINTS DUE TO OSTEOARTHRITIS OR TRAUMATIC ARTHRITIS. - PREVIOUS TIBIAL CONDYLE OR PLATEAU FRACTURES WITH LOSS OF ANATOMY OR FUNCTION. - VARUS OR VALGUS DEFORMITIES. - REVISION OF PREVIOUS ARTHROPLASTY PROCEDURES. • THESE DEVICES ARE INDICATED FOR CEMENTED USE ONLY. THE ZIMMER UNICOMPARTMENTAL KNEE SYSTEM IS DESIGNED FOR USE WHEN LOAD BEARING ROM IS EXPECTED TO BE LESS THAN OR EQUAL TO 155 DEGREES ,KNEE SYSTEM(ZIMMER UNICOMPARTMENTAL KNEE ARTICULAR SURFACE)-THE DEVICE INDICATIONS ARE THE FOLLOWING: • THESE DEVICES ARE INDICATED FOR PATIENTS WITH: - PAINFUL AND/OR DISABLING KNEE JOINTS DUE TO OSTEOARTHRITIS OR TRAUMATIC ARTHRITIS. - PREVIOUS TIBIAL CONDYLE OR PLATEAU FRACTURES WITH LOSS OF ANATOMY OR FUNCTION. - VARUS OR VALGUS DEFORMITIES. - REVISION OF PREVIOUS ARTHROPLASTY PROCEDURES. • THESE DEVICES ARE INDICATED FOR CEMENTED USE ONLY. THE ZIMMER UNICOMPARTMENTAL KNEE SYSTEM IS DESIGNED FOR USE WHEN LOAD BEARING ROM IS EXPECTED TO BE LESS THAN OR EQUAL TO 155 DEGREES ,KNEE SYSTEM(ZIMMER UNICOMPARTMENTAL KNEE - FEMORAL

	COMPONENT)-THE DEVICE INDICATIONS ARE THE FOLLOWING: • THESE DEVICES ARE INDICATED FOR PATIENTS WITH: - PAINFUL AND/OR DISABLING KNEE JOINTS DUE TO OSTEOARTHRITIS OR TRAUMATIC ARTHRITIS. - PREVIOUS TIBIAL CONDYLE OR PLATEAU FRACTURES WITH LOSS OF ANATOMY OR FUNCTION. - VARUS OR VALGUS DEFORMITIES. - REVISION OF PREVIOUS ARTHROPLASTY PROCEDURES. • THESE DEVICES ARE INDICATED FOR CEMENTED USE ONLY. THE ZIMMER UNICOMPARTMENTAL KNEE SYSTEM IS DESIGNED FOR USE WHEN LOAD BEARING ROM IS EXPECTED TO BE LESS THAN OR EQUAL TO 155 DEGREES ,KNEE SYSTEM(NEXGEN COMPLETE KNEE SOLUTION STEM EXTENSIONS)-THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, • COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE, • POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. • THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. ,KNEE SYSTEM(NEXGEN COMPLETE KNEE SOLUTION TIBIAL COMPONENT)-THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, • COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE, • POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. • THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY.,HIP SYSTEM(VERSYS HIP SYSTEM FEMORAL HEADS)-FEMORAL HEADS ARE INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY; THE UNIPOLAR ENDOPROSTHESIS FEMORAL HEADS ARE INTENDED FOR USE IN HEMI-HIP ARTHROPLASTY. REFER TO THE FEMORAL STEM PACKAGE INSERT FOR THE FULL DESCRIPTION OF INDICATIONS FOR THE CONSTRUCT.,TRAUMA PLATING SYSTEM(ZIMMER UNIVERSAL LOCKING SYSTEM (STAINLESS STEEL) - PLATES - SCREWS)-THE UNIVERSAL LOCKING SYSTEM IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF OSTEOTOMIES AND FRACTURES, INCLUDING: COMMINUTED FRACTURES, SUPRACONDYLAR FRACTURES, EXTRA-ARTICULAR FRACTURES, FRACTURES IN OSTEOPENIC BONE, NON-

	UNION AND MALUNIONS,NAILS AND SCREWS FOR TRAUMA FIXATION (M/DN® INTRAMEDULLARY FIXATION SYSTEM - NAIL CAP AND CORTICAL NUT)-TEMPORARY FIXATION AND STABILIZATION OF LONG BONE FRACTURES,HIP SYSTEM(VERSYS HIP SYSTEM FEMORAL STEM FIBER METAL MIDCOAT - FEMORAL STEM)-• TOTAL HIP REPLACEMENT FOR THE FOLLOWING: SEVERE HIP PAIN AND DISABILITY DUE TO RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS OF THE FEMORAL HEAD, NONUNION OF PREVIOUS FRACTURES OF THE FEMUR; CONGENITAL HIP DYSPLASIA, PROTRUSIO ACETABULI, SLIPPED CAPITAL FEMORAL EPIPHYSIS; DISABILITY DUE TO PREVIOUS FUSION; PREVIOUSLY FAILED ENDOPROSTHESES, AND/OR TOTAL HIP COMPONENTS IN THE AFFECTED EXTREMITY AND ACUTE FEMORAL NECK FRACTURES. • HEMI-HIP REPLACEMENT FOR THE FOLLOWING: FRACTURE DISLOCATION OF THE HIP; ELDERLY, DEBILITATED PATIENTS WHEN A TOTAL HIP REPLACEMENT IS CONTRAINDICATED; IRREDUCIBLE FRACTURES IN WHICH ADEQUATE FIXATION CANNOT BE OBTAINED; CERTAIN HIGH SUBCAPITAL FRACTURES AND COMMINUTED FEMORAL NECK FRACTURES IN THE AGED; NONUNION OF FEMORAL NECK FRACTURES; SECONDARY AVASCULAR NECROSIS OF THE FEMORAL HEAD; PATHOLOGICAL FRACTURES OF THE FEMORAL NECK; AND OSTEOARTHRITIS IN WHICH THE FEMORAL HEAD IS PRIMARILY AFFECTED.,SHOULDER SYSTEM(BIGLIANI/ FLATOW THE COMPLETE SHOULDER SOLUTION - GLENOID)-PROSTHETIC REPLACEMENT WITH THIS DEVICE MAY BE INDICATED FOR THE TREATMENT OF SEVERE PAIN OR SIGNIFICANT DISABILITY IN DEGENERATIVE, RHEUMATOID, OR TRAUMATIC DISEASE OF THE GLENOHUMERAL JOINT; UN-UNITED HUMERAL HEAD FRACTURES OF LONG DURATION; IRREDUCIBLE 3- AND 4-PART PROXIMAL HUMERAL FRACTURES; AVASCULAR NECROSIS OF THE HUMERAL HEAD; OR OTHER DIFFICULT CLINICAL MANAGEMENT PROBLEMS WHERE ARTHRODESIS OR RESECTIONAL ARTHROPLASTY IS NOT ACCEPTABLE. THE ASSEMBLED HUMERAL COMPONENT MAY BE USED ALONE FOR HEMIARTHROPLASTY OR COMBINED WITH THE GLENOID COMPONENT FOR TOTAL SHOULDER ARTHROPLASTY. HUMERAL HEADS WITH HEIGHTS OF 27MM OR GREATER MAY BE USED FOR DIFFICULT CLINICAL MANAGEMENT PROBLEMS INVOLVING ROTATOR CUFF DEFICIENCY WHERE ARTHRODESIS OR CONVENTIONAL NON-CONSTRAINED ARTHROPLASTY IS NOT ACCEPTABLE,HIP SYSTEM(ZIMTRON MODULAR HEAD (HEAD))-FEMORAL HEADS ARE INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY; THE UNIPOLAR ENDOPROSTHESIS FEMORAL HEADS ARE INTENDED FOR USE IN HEMI-HIP ARTHROPLASTY. REFER

	TO THE FEMORAL STEM PACKAGE INSERT FOR THE FULL DESCRIPTION OF INDICATIONS FOR THE CONSTRUCT.,SCREWS FOR TRAUMA FIXATION(VERSA-FX® FEMORAL FIXATION SYSTEM - SCREWS)-THIS DEVICE IS INDICATED FOR: • INTERNAL FIXATION OF PROXIMAL FEMUR FRACTURES WITH APPLICATION TO INTRACAPSULAR AND INTERTROCHANTERIC FRACTURES, OSTEOTOMIES, AND ARTHRODESES. THE SYSTEM MAY ALSO BE USED FOR SUBTROCHANTERIC FRACTURES WITH EXTENSION INTO THE PIRIFORMIS FOSSA. • INTERNAL FIXATION OF SUPRACONDYLAR FRACTURES WITH DISPLACED INTRA-ARTICULAR FRAGMENTS, WITH VERTICAL INTRA-ARTICULAR EXTENSION, AND IN THE PATIENT WITH MULTIPLE LOWER EXTREMITY FRACTURES ,KNEE SYSTEM(NEXGEN COMPLETE KNEE SOLUTION ARTICULAR SURFACE)-INTENDED USE THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, • COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE, • POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. • THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. ,KNEE SYSTEM(NEXGEN COMPLETE KNEE SOLUTION - FEMORAL COMPONENT)-THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, • COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE, • POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. • THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. ,SCREWS FOR TRAUMA FIXATION(MOTIONLOC SCREW FOR NCB POLYAXIAL LOCKING PLATE SYSTEM - SCREW)-THIS DEVICE IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF FRACTURES AND OSTEOTOMIES OF LONG BONES,KNEE SYSTEM (NATURAL KNEE II SYSTEM - ARTICULAR SURFACE)-THE DEVICE INDICATIONS ARE THE FOLLOWING: • NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY DEGENERATIVE JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS; • CORRECTABLE

	VALGUS-VARUS DEFORMITY AND MODERATE FLEXION CONTRACTURE; • THOSE PATIENTS WITH FAILED PREVIOUS SURGERY WHERE PAIN, DEFORMITY, OR DYSFUNCTION PERSISTS; AND REVISION OF PREVIOUSLY FAILED KNEE ARTHROPLASTY. , SHOULDER SYSTEM(TRABECULAR METAL REVERSE SHOULDER SYSTEM - TRABECULAR METAL REVERSE UHMWPE LINER)-THIS DEVICE IS INDICATED FOR REVERSE APPLICATION: • TREATMENT OF SEVERE PAIN OR SIGNIFICANT DISABILITY IN DEGENERATIVE, RHEUMATOID, TRAUMATIC DISEASE OF THE GLENOHUMERAL JOINT; • UN-UNITED HUMERAL HEAD FRACTURES OF LONG DURATION; • IRREDUCIBLE 3-AND 4-PART PROXIMAL HUMERAL FRACTURES; AVASCULAR NECROSIS OF THE HUMERAL HEAD OR OTHER DIFFICULT CLINICAL MANAGEMENT PROBLEMS (SUCH AS A FAILED TOTAL SHOULDER ARTHROPLASTY OR GROSSLY ROTATOR CUFF DEFICIENT JOINT) WHERE ARTHRODESIS OR RE-SECTIONAL ARTHROPLASTY IS NOT ACCEPTABLE ,HIP SYSTEM(VERSYS HIP SYSTEM FEMORAL STEM CEMENTED REVISION/ CALCAR - FEMORAL STEM & BUILD UP BLOCKS)-THE VERSYS CRC HIP SYSTEM IS INDICATED FOR: • TOTAL HIP ARTHROPLASTY IN PATIENTS WHOSE BONE STOCK IS OF POOR QUALITY OR INADEQUATE FOR OTHER RECONSTRUCTION TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE FEMORAL HEAD, NECK, OR PORTIONS OF THE PROXIMAL FEMUR. ARTHROPLASTY SHOULD BE PERFORMED ONLY WHEN MORE CONSERVATIVE METHODS OF TREATMENT HAVE FAILED TO PROVIDE SYMPTOMATIC RELIEF AND WHEN THERE IS PROGRESSIVE DISABILITY.,HIP SYSTEM(VERSYS HIP SYSTEM VERSYS HERITAGE HIP PROSTHESIS - FEMORAL STEM - CENTRALIZER)-TOTAL HIP ARTHROPLASTY IS INDICATED FOR PATIENTS WITH: • SEVERE HIP PAIN AND DISABILITY DUE TO RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS OF THE FEMORAL HEAD, AND NONUNION OF PREVIOUS FRACTURES OF THE FEMUR. • CONGENITAL HIP DYSPLASIA, PROTRUSIO ACETABULI, OR SLIPPED CAPITAL FEMORAL EPIPHYSIS. • DISABILITY DUE TO PREVIOUS FUSION. • PREVIOUSLY FAILED ENDOPROSTHESES AND/OR TOTAL HIP COMPONENTS IN THE AFFECTED EXTREMITY. • ACUTE FEMORAL NECK FRACTURES. HEMI-HIP ARTHROPLASTY IS INDICATED FOR: • FRACTURE DISLOCATION OF THE HIP. • ELDERLY, DEBILITATED PATIENTS WHEN A TOTAL HIP REPLACEMENT IS CONTRAINDICATED. • IRREDUCIBLE FRACTURES IN WHICH ADEQUATE FIXATION CANNOT BE OBTAINED. • CERTAIN HIGH SUBCAPITAL FRACTURES AND COMMINUTED FEMORAL FRACTURES IN THE AGED. • NON-UNION OF FEMORAL NECK FRACTURES. • SECONDARY AVASCULAR NECROSIS OF THE FEMORAL HEAD. • PATHOLOGICAL FRACTURES OF THE

	FEMORAL NECK. • OSTEOARTHRITIS IN WHICH THE FEMORAL HEAD IS PRIMARILY AFFECTED,KNEE SYSTEM(NEXGEN COMPLETE KNEE SOLUTION PATELLA COMPONENT)-THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, • COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE, • POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. • THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. ,SCREW FOR TRAUMA FIXATION(ZIMMER MOTIONLOC SCREW FOR PERIARTICULAR LOCKING PLATE SYSTEM - SCREW)-ZIMMER MOTIONLOC SCREWS, WHEN USED WITH THE PERIARTICULAR LOCKING PLATE SYSTEM ARE INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF OSTEOTOMIES AND FRACTURES OF LONG BONES, INCLUDING: • COMMINUTED FRACTURES • SUPRACONDYLAR FRACTURES • INTRA-ARTICULAR AND EXTRA-ARTICULAR CONDYLAR FRACTURES • FRACTURES IN OSTEOPENIC BONE • NON-UNIONS • MALUNIONS,SCREW FOR TRAUMA FIXATION(ZIMMER MOTIONLOC SCREW FOR PERIARTICULAR LOCKING PLATE SYSTEM - SCREW)-ZIMMER MOTIONLOC SCREWS, WHEN USED WITH THE PERIARTICULAR LOCKING PLATE SYSTEM ARE INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF OSTEOTOMIES AND FRACTURES OF LONG BONES, INCLUDING: • COMMINUTED FRACTURES • SUPRACONDYLAR FRACTURES • INTRA-ARTICULAR AND EXTRA-ARTICULAR CONDYLAR FRACTURES • FRACTURES IN OSTEOPENIC BONE • NON-UNIONS • MALUNIONS,SHOULDER SYSTEM (BIGLIANI/ FLATOW THE COMPLETE SHOULDER SOLUTION - HUMERAL HEAD)-PROSTHETIC REPLACEMENT WITH THIS DEVICE MAY BE INDICATED FOR THE TREATMENT OF SEVERE PAIN OR SIGNIFICANT DISABILITY IN DEGENERATIVE, RHEUMATOID, OR TRAUMATIC DISEASE OF THE GLENOHUMERAL JOINT; UN-UNITED HUMERAL HEAD FRACTURES OF LONG DURATION; IRREDUCIBLE 3- AND 4-PART PROXIMAL HUMERAL FRACTURES; AVASCULAR NECROSIS OF THE HUMERAL HEAD; OR OTHER DIFFICULT CLINICAL MANAGEMENT PROBLEMS WHERE ARTHRODESIS OR RESECTIONAL ARTHROPLASTY IS NOT ACCEPTABLE. THE ASSEMBLED HUMERAL COMPONENT MAY BE USED ALONE FOR HEMIARTHROPLASTY OR COMBINED WITH THE GLENOID COMPONENT FOR TOTAL SHOULDER ARTHROPLASTY. HUMERAL HEADS WITH HEIGHTS OF 27MM OR

	GREATER MAY BE USED FOR DIFFICULT CLINICAL MANAGEMENT PROBLEMS INVOLVING ROTATOR CUFF DEFICIENCY WHERE ARTHRODESIS OR CONVENTIONAL NON-CONSTRAINED ARTHROPLASTY IS NOT ACCEPTABLE,PLATES AND SCREW FOR TRAUMA FIXATION(ZIMMER PLATES AND SCREWS)-TEMPORARY INTERNAL FIXATION DEVICES ARE DESIGNED TO STABILIZE FRACTURES DURING THE NORMAL HEALING PROCESS,PLATES AND SCREWS FOR TRAUMA FIXATION(ZIMMER® PERIARTICULAR PLATE SYSTEM - PLATES AND SCREWS)-TEMPORARY INTERNAL FIXATION DEVICES DESIGNED TO STABILIZE FRACTURES DURING THE NORMAL HEALING PROCESS ,KNEE REPLACEMENT(PERSONA THE PERSONALIZED KNEE SYSTEM FEMORAL COMPONENT (POSTERIOR STABILIZED (PS), CRUCIATE RETAINING (CR), NARROW AND STANDARD)-THE DEVICE INDICATIONS ARE THE FOLLOWING: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • COLLAGEN DISORDERS, AND/ OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. • POST- TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS OR FLEXION DEFORMITIES. THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY ,KNEE REPLACEMENT(PERSONA THE PERSONALIZED KNEE SYSTEM - TIBIAL BASEPLATE AND PLUG)-THE DEVICE INDICATIONS ARE THE FOLLOWING: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • COLLAGEN DISORDERS AND/ OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. • POST- TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS OR FLEXION DEFORMITIES. THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY ,PINS AND WIRES FOR TRAUMA FIXATION(STEINMANN PINS, KIRSCHNER WIRES - PINS AND WIRES)-KIRSCHNER WIRES AND STEINMANN PINS ARE UTILIZED IN SKELETAL TRACTION FOR ALIGNMENT AND REDUCTION OF LONG BONE FRACTURES, AS GUIDE WIRES IN HIP PINNING, AND FOR FRACTURE ALIGNMENT IN CERTAIN OTHER TYPES OF FRACTURES. PARTICULAR INDICATIONS FOR SKELETAL TRACTION INCLUDE: FEMORAL SHAFT FRACTURES, HIP FRACTURES WITH PROXIMAL MIGRATION OF THE DISTAL FEMORAL FRAGMENT; TIBIAL PLATEAU FRACTURES; FRACTURES OF THE HUMERUS; RADIAL AND ULNAR FRACTURES; AND, ALTHOUGH RARE, CALCANEAL

	FRACTURES WITH LOSS OF BOHLER'S TUBER-JOINT ANGLE. , STAPLES FOR TRAUMA FIXATION(FRACTURE STAPLES - STAPLES)- FOR FRACTURE FRAGMENT FIXATION, PARTICULARLY IN SMALL FRAGMENTS AND WHERE INTRA-FRAGMENT FIXATION IS NOT POSSIBLE,NAIL FIXATION SYSTEM(ZIMMER NATURAL NAIL SYSTEM (TITANIUM) - NAIL - SCREW)- TEMPORARY FRACTURE FIXATION AND STABILIZATION OF THE BONE.,PINS FOR TRAUMA FIXATION (KNOWLES PINS)-FOR PERCUTANEOUS PINNING OF REDUCIBLE INTRACAPSULAR FRACTURES OF THE FEMORAL NECK AND TO TREAT MILD TO MODERATE SLIPPED UPPER FEMORAL EPIPHYSES ,HIP SYSTEM(VERSYS HIP SYSTEM FEMORAL STEM FIBER METAL TAPER - FEMORAL STEM)-• TOTAL HIP REPLACEMENT FOR THE FOLLOWING: SEVERE HIP PAIN AND DISABILITY DUE TO RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS OF THE FEMORAL HEAD, NONUNION OF PREVIOUS FRACTURES OF THE FEMUR; CONGENITAL HIP DYSPLASIA, PROTRUSIO ACETABULI, SLIPPED CAPITAL FEMORAL EPIPHYSIS; DISABILITY DUE TO PREVIOUS FUSION; PREVIOUSLY FAILED ENDOPROSTHESES, AND/OR TOTAL HIP COMPONENTS IN THE AFFECTED EXTREMITY AND ACUTE FEMORAL NECK FRACTURES. • HEMI-HIP REPLACEMENT FOR THE FOLLOWING: FRACTURE DISLOCATION OF THE HIP; ELDERLY, DEBILITATED PATIENTS WHEN A TOTAL HIP REPLACEMENT IS CONTRAINDICATED; IRREDUCIBLE FRACTURES IN WHICH ADEQUATE FIXATION CANNOT BE OBTAINED; CERTAIN HIGH SUBCAPITAL FRACTURES AND COMMINUTED FEMORAL NECK FRACTURES IN THE AGED; NONUNION OF FEMORAL NECK FRACTURES; SECONDARY AVASCULAR NECROSIS OF THE FEMORAL HEAD; PATHOLOGICAL FRACTURES OF THE FEMORAL NECK; AND OSTEOARTHRITIS IN WHICH THE FEMORAL HEAD IS PRIMARILY AFFECTED.,SCREWS FOR TRAUMA FIXATION(NCB PERIPROSTHETIC PLATE SYSTEM - SCREW)- THIS DEVICE IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF FRACTURES AND OSTEOTOMIES OF LONG BONES INCLUDING PERIPROSTHETIC FRACTURES, COMMINUTED FRACTURES, SUPRACONDYLAR FRACTURES, FRACTURES IN OSTEOPENIC BONE, NON-UNIONS AND MALUNIONS,SCREWS FOR TRAUMA FIXATION(NCB PERIPROSTHETIC PLATE SYSTEM - SCREW)- THIS DEVICE IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF FRACTURES AND OSTEOTOMIES OF LONG BONES INCLUDING PERIPROSTHETIC FRACTURES, COMMINUTED FRACTURES, SUPRACONDYLAR FRACTURES, FRACTURES IN OSTEOPENIC BONE, NON-UNIONS AND MALUNIONS,SCREWS FOR TRAUMA FIXATION(MOTIONLOC SCREW FOR NCB POLYAXIAL LOCKING PLATE SYSTEM - SCREW)-THIS DEVICE IS INDICATED FOR

	TEMPORARY INTERNAL FIXATION AND STABILIZATION OF FRACTURES AND OSTEOTOMIES OF LONG BONES,TRAUMA PLATING SYSTEM(ZIMMER UNIVERSAL LOCKING SYSTEM (STAINLESS STEEL) - PLATES - SCREWS)-THE UNIVERSAL LOCKING SYSTEM IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF OSTEOTOMIES AND FRACTURES, INCLUDING: COMMINUTED FRACTURES, SUPRACONDYLAR FRACTURES, EXTRA- ARTICULAR FRACTURES, FRACTURES IN OSTEOPENIC BONE, NON-UNION AND MALUNIONS,PINS AND WIRES FOR TRAUMA FIXATION(STEINMANN PINS, KIRSCHNER WIRES, SUTURE WIRES AND WIRE LOOPS - PINS AND WIRES)-KIRSCHNER WIRES AND STEINMANN PINS ARE UTILIZED IN SKELETAL TRACTION FOR ALIGNMENT AND REDUCTION OF LONG BONE FRACTURES, AS GUIDE WIRES IN HIP PINNING, AND FOR FRACTURE ALIGNMENT IN CERTAIN OTHER TYPES OF FRACTURES. PARTICULAR INDICATIONS FOR SKELETAL TRACTION INCLUDE: FEMORAL SHAFT FRACTURES, HIP FRACTURES WITH PROXIMAL MIGRATION OF THE DISTAL FEMORAL FRAGMENT; TIBIAL PLATEAU FRACTURES; FRACTURES OF THE HUMERUS; RADIAL AND ULNAR FRACTURES; AND, ALTHOUGH RARE, CALCANEAL FRACTURES WITH LOSS OF BOHLER'S TUBER-JOINT ANGLE. THE SUTURE WIRES AND WIRE LOOPS HAVE INDICATIONS AS FOLLOWS: SUTURE WIRES ARE INDICATED FOR USE FOR BONE FRACTURE FIXATION, OSTEOTOMY, ARTHRODESIS, CORRECTION OF DEFORMITY, REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE BEEN UNSUCCESSFUL, AND BONE RECONSTRUCTION PROCEDURES , TRAUMA PLATING SYSTEM(ZIMMER UNIVERSAL LOCKING SYSTEM (TITANIUM) - PLATES - SCREWS)-THE UNIVERSAL LOCKING SYSTEM IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF OSTEOTOMIES AND FRACTURES, INCLUDING: COMMINUTED FRACTURES, SUPRACONDYLAR FRACTURES, EXTRA-ARTICULAR FRACTURES, FRACTURES IN OSTEOPENIC BONE, NON-UNION AND MALUNIONS

1467	IMP/MD/2018/000445	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED ,NO. 17, GROUND FLOOR AND MEZZANINE FLOOR, THIRUNEERMALAI ROAD, NAGALKENI, CHROMPET ,CHENNAI TAMIL NADU ,600044 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRAUMA FIXATION DEVICES(CABLE-READY CABLE GRIP SYSTEM-CABLE BUTTONS)-THE CABLE BUTTON IS INTENDED FOR USE IN COMBINATION WITH THE ZIMMER LOCKING BONE PLATING SYSTEMS AND CERCLAGE CABLES, TO STABILIZE MULTIPLE FRACTURES OR BUTTERFLY FRAGMENTS IN LONG BONES.,TRAUMA FIXATION DEVICES(CABLE-READY CABLE GRIP SYSTEM-CERCLAGE CABLE)-THE 1.8 MM CERCLAGE CABLE CAN BE USED TO SECURE FRACTURES OF THE OLECRANON, PATELLA, FEMUR, HUMERUS, AND ANKLE, AS WELL AS TO REDUCE AND SECURE ACROMIOCLAVICULAR DISLOCATIONS. THE 1.8 MM CABLES CAN ALSO BE USED TO REATTACH THE GREATER TROCHANTER AFTER TROCHANTERIC OSTEOTOMY DURING TOTAL HIP ARTHROPLASTY., TRAUMA FIXATION DEVICES(CABLE-READY CABLE GRIP SYSTEM-BONE PLATE)-THE CABLEREADY BONE PLATE WITH CERCLAGE CABLE IS INDICATED FOR USE WHERE WIRE, CABLE, OR BAND CERCLAGE IS USED IN COMBINATION WITH BONE PLATES TO PROVIDE FIXATION AND/OR STABILIZATION OF LONG BONES - FEMUR, TIBIA AND HUMERUS. EXAMPLES INCLUDE PERIPROSTHETIC FRACTURES OR BONE LOSS, COMMINUTED SHAFT FRACTURES, AND NONUNIONS OF PREVIOUS FRACTURES WITH OR WITHOUT FAILED HARDWARE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1468	IMP/MD/2018/000446	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTERVERTEBRAL FUSION DEVICE WITH BONE GRAFT, CERVICAL(CORNERSTONE® PSR CERVICAL FUSION SYSTEM)-THE CORNERSTONE® PSR DEVICE IS INDICATED FOR CERVICAL INTERBODY FUSION PROCEDURES IN SKELETALLY MATURE PATIENTS WITH CERVICAL DISC DISEASE AT ONE LEVEL FROM THE C2-C3 DISC TO THE C7-T1 DISC. CERVICAL DISC DISEASE IS DEFINED AS INTRACTABLE RADICULOPATHY AND/OR MYELOPATHY WITH HERNIATED DISC AND/OR OSTEOPHYTE FORMATION ON POSTERIOR VERTEBRAL ENDPLATES PRODUCING SYMPTOMATIC NERVE ROOT AND/OR SPINAL CORD COMPRESSION CONFIRMED BY RADIOGRAPHIC STUDIES. THIS DEVICE IS TO BE USED IN PATIENTS WHO HAVE HAD SIX WEEKS OF NON-OPERATIVE TREATMENT. THE CORNERSTONE® PSR DEVICE IS TO BE USED WITH SUPPLEMENTAL FIXATION. THE CORNERSTONE® PSR DEVICE IS ALSO REQUIRED TO BE USED WITH AUTOGRAFT.,ORTHOSIS CERVICAL PEDICLE SCREW SPINAL FIXATION(INFINITY™ OCCIPITO CERVICAL-UPPER THORACIC SYSTEM (OCT SYSTEM))-THE INFINITY™ OCT SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OF THE CRANIOCERVICAL JUNCTION, THE CERVICAL SPINE (C1 TO C7), AND THE THORACIC SPINE FROM T1-T3: TRAUMATIC SPINAL FRACTURES AND/OR TRAUMATIC DISLOCATIONS. INSTABILITY OR DEFORMITY. FAILED PREVIOUS FUSIONS (E.G. PSEUDARTHROSIS). TUMORS INVOLVING THE CERVICAL SPINE. DEGENERATIVE DISEASE, INCLUDING INTRACTABLE RADICULOPATHY AND/OR MYELOPATHY NECK AND/OR ARM PAIN OF DISCOGENIC ORIGIN AS CONFIRMED BY RADIOGRAPHIC STUDIES, AND DEGENERATIVE DISEASE OF THE FACETS WITH INSTABILITY. THE INFINITY™ OCT SYSTEM IS ALSO INTENDED TO RESTORE THE INTEGRITY OF THE SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A LIMITED TIME IN PATIENTS WITH ADVANCED STAGE TUMORS INVOLVING THE CERVICAL SPINE IN WHOM LIFE EXPECTANCY IS OF INSUFFICIENT DURATION TO PERMIT ACHIEVEMENT OF FUSION. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE INFINITY™ OCT SYSTEM MAY BE CONNECTED TO THE CD HORIZON™ SPINAL SYSTEM AND VERTEX™ RECONSTRUCTION SYSTEM RODS WITH THE INFINITY™ OCT SYSTEM ROD CONNECTORS. TRANSITION RODS WITH DIFFERING DIAMETERS MAY ALSO BE USED TO CONNECT THE INFINITY™ OCT SYSTEM TO THE CD HORIZON™ SPINAL SYSTEM. REFER TO THE CD HORIZON™ SPINAL SYSTEM PACKAGE INSERT AND VERTEX™ RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE INDICATIONS OF USE.

	NOTE: THE 3.0MM MULTI AXIAL SCREW (MAS) REQUIRES THE USE OF MAS CROSSLINK™ AT EACH LEVEL IN WHICH THE 3.0MM SCREW IS INTENDED TO BE USED. THE LATERAL OFFSET CONNECTORS AND MAS EXTENSION CONNECTORS ARE INTENDED TO BE USED WITH 3.5 MM AND LARGER DIAMETER MULTI AXIAL SCREWS. THE LATERAL OFFSET CONNECTORS AND MAS EXTENSION CONNECTORS ARE NOT INTENDED TO BE USED WITH 3.0MM SCREWS. NOTE: SEGMENTAL FIXATION IS RECOMMENDED FOR THESE CONSTRUCTS., INTERVERTEBRAL BODY FUSION DEVICE (CLYDESDALE® SPINAL SYSTEM)-THE CLYDESDALE® SPINAL SYSTEM IS DESIGNED TO BE USED WITH AUTOGENOUS BONE GRAFT TO FACILITATE INTERBODY FUSION AND IS INTENDED FOR USE WITH SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBAR SPINE. THE CLYDESDALE® SPINAL SYSTEM IS USED FOR PATIENTS DIAGNOSED WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTIGUOUS LEVELS FROM L2 TO S1. THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THESE IMPLANTS MAY BE IMPLANTED VIA A MINIMALLY INVASIVE LATERAL APPROACH. , FENESTRATED SCREW SPINAL SYSTEM(CD HORIZON FENESTRATED SCREW SET)-WHEN USED WITHOUT CEMENT, CD HORIZON™ FENESTRATED SCREWS (WITH OR WITHOUT SEXTANT™ OR LONGITUDE™ INSTRUMENTATION) ARE INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDDDEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TUMOR AND/OR TRAUMA (I.E. FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E. SCOLIOSIS, KYPHOSIS, OR LORDOSIS), PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. ADDITIONALLY, CD HORIZON™ FENESTRATED SCREWS MAY BE USED FOR IMMOBILIZATION AND STABILIZATION WHEN USED FOR TRAUMA (E.G., FRACTURE OR DISLOCATION) WITH THE USAGE OF BONE GRAFT MATERIAL LEFT TO THE SURGEON'S DISCRETION. WHEN USED IN CONJUNCTION WITH MEDTRONIC HV-R™ FENESTRATED SCREW CEMENT OR KYPHON™ XPEDE™ BONE CEMENT, CD HORIZON™ FENESTRATED SCREWS ARE INTENDED TO RESTORE THE INTEGRITY OF THE SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A LIMITED TIME IN PATIENTS WITH ADVANCED STAGE TUMORS

	INVOLVING THE THORACIC, LUMBAR, OR SACRAL SPINE IN WHOM LIFE EXPECTANCY IS OF INSUFFICIENT DURATION TO PERMIT ACHIEVEMENT OF FUSION. CD HORIZON™ FENESTRATED SCREWS AUGMENTED WITH MEDTRONIC HV-R™ FENESTRATED SCREW CEMENT OR KYPHON™ XPEDE™ BONE CEMENT ARE FOR USE AT SPINAL LEVELS WHERE THE STRUCTURAL INTEGRITY OF THE SPINE IS NOT SEVERELY COMPROMISED.,INTERVERTEBRAL BODY FUSION DEVICE(DIVERGENCE -L ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM)-THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY CAGE IS INTENDED FOR INTERBODY FUSION IN SKELETALLY MATURE PATIENTS AND IS TO BE USED WITH SUPPLEMENTAL FIXATION INSTRUMENTATION CLEARED FOR USE IN THE LUMBAR SPINE. THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY DEVICE IS INDICATED FOR USE IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTAGIOUS LEVELS FROM L2 TO S1 (EXCEPT AS DEFINED FOR USE WITH INFUSE BONE GRAFT ABOVE). THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. ADDITIONALLY, THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM DEVICE IS INDICATED FOR USE IN PATIENTS DIAGNOSED WITH DEFORMITY CONDITIONS AS AN ADJUNCT TO FUSION. THESE PATIENTS SHOULD HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY DEVICE IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGENIC BONE GRAFT COMPRISED OF CANCELLOUS AND/OR CORTICOCANCELLOUS BONE GRAFT. THESE IMPLANTS MAY BE IMPLANTED VIA A VARIETY OF OPEN OR MINIMALLY INVASIVE APPROACHES. THESE APPROACHES INCLUDE ANTERIOR AND OBLIQUE. THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM PLATE AND BONE SCREW COMPONENTS ARE INDICATED AS A SUPPLEMENTAL FIXATION DEVICE FOR THE LUMBOSACRAL LEVEL, ANTERIOR BELOW THE BIFURCATION(L5-S1) OF THE VASCULAR STRUCTURES OR ANTERIOR OBLIQUE ABOVE THE BIFURCATION(L1-S5) OF THE VASCULAR STRUCTURES. THE INDICATIONS AND CONTRAINDICATIONS OF SPINAL INSTRUMENTATION SYSTEMS SHOULD BE WELL UNDERSTOOD BY THE SURGEON. THE PLATE AND BONE SCREW COMPONENTS ARE INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR LUMBAR SPINE DURING THE DEVELOPMENT OF SPINAL FUSIONS IN PATIENTS WITH: 1) DEGENERATIVE DISC DISEASE (DDD) DEFINED BY BACK PAIN OF

	DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES; 2) TRAUMA (INCLUDING FRACTURES); 3) TUMORS; 4) DEFORMITY DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS; 5) PSEUDOARTHROSIS; AND/OR 6) FAILED PREVIOUS FUSIONS. CERTAIN SIZES OF THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY DEVICE MAY ALSO BE USED WITH INFUSE BONE GRAFT FOR PATIENTS DIAGNOSED WITH DDD,AS DEFINED ABOVE. THE DEVICE MAY BE IMPLANTED AT A SINGLE LEVEL USING AN ANTERIOR LUMBAR INTERBODY FUSION(ALIF) APPROACH FROM L2-S1. THE DEVICE MAY ALSO BE IMPLANTED AT A SINGLE LEVEL USING AN OBLIQUE LATERAL INTERBODY INFUSION(OLIF) APPROACH FROM L5-S1. THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY DEVICE IS INTENDED FOR USE WITH SUPPLEMENTAL FIXATION INSTRUMENTATION, WHICH HAS BEEN CLEARED FOR USE IN THE LUMBAR SPINE WHEN USED TO TREAT DDD. CONSULT THE LABELING FOR THE INFUSE BONE GRAFT/MEDTRONIC INTERBODY FUSION DEVICE FOR ADDITIONAL INFORMATION ON THE SPECIFIC SIZES OF THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY DEVICE APPROVED FOR USE WITH INFUSE BONE GRAFT, AS WELL AS SPECIFIC INFORMATION REGARDING CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS ASSOCIATED WITH INFUSE BONE GRAFT. THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY DEVICE MAY ALSO BE USED WITH INFUSE BONE GRAFT.,ORTHOSIS CERVICAL PEDICLE SCREW SPINAL FIXATION(INFINITY™ OCCIPITO CERVICAL-UPPER THORACIC SYSTEM (OCT SYSTEM))-THE INFINITY™ OCT SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OF THE CRANIOCERVICAL JUNCTION, THE CERVICAL SPINE (C1 TO C7), AND THE THORACIC SPINE FROM T1-T3: TRAUMATIC SPINAL FRACTURES AND/OR TRAUMATIC DISLOCATIONS. INSTABILITY OR DEFORMITY. FAILED PREVIOUS FUSIONS (E.G. PSEUDARTHROSIS). TUMORS INVOLVING THE CERVICAL SPINE. DEGENERATIVE DISEASE, INCLUDING INTRACTABLE RADICULOPATHY AND/OR MYELOPATHY, NECK AND/OR ARM PAIN OF DISCOGENIC ORIGIN AS CONFIRMED BY RADIOGRAPHIC STUDIES, AND DEGENERATIVE DISEASE OF THE FACETS WITH INSTABILITY. THE INFINITY™ OCT SYSTEM IS ALSO INTENDED TO RESTORE THE INTEGRITY OF THE SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A LIMITED TIME IN PATIENTS WITH ADVANCED STAGE TUMORS INVOLVING THE CERVICAL SPINE IN WHOM LIFE EXPECTANCY IS OF INSUFFICIENT DURATION TO PERMIT

	ACHIEVEMENT OF FUSION. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE INFINITY™ OCT SYSTEM MAY BE CONNECTED TO THE CD HORIZON™ SPINAL SYSTEM AND VERTEX™ RECONSTRUCTION SYSTEM RODS WITH THE INFINITY™ OCT SYSTEM ROD CONNECTORS. TRANSITION RODS WITH DIFFERING DIAMETERS MAY ALSO BE USED TO CONNECT THE INFINITY™ OCT SYSTEM TO THE CD HORIZON™ SPINAL SYSTEM. REFER TO THE CD HORIZON™ SPINAL SYSTEM PACKAGE INSERT AND VERTEX™ RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE INDICATIONS OF USE. NOTE: THE 3.0MM MULTI AXIAL SCREW (MAS) REQUIRES THE USE OF MAS CROSSLINK™ AT EACH LEVEL IN WHICH THE 3.0MM SCREW IS INTENDED TO BE USED. THE LATERAL OFFSET CONNECTORS AND MAS EXTENSION CONNECTORS ARE INTENDED TO BE USED WITH 3.5 MM AND LARGER DIAMETER MULTI AXIAL SCREWS. THE LATERAL OFFSET CONNECTORS AND MAS EXTENSION CONNECTORS ARE NOT INTENDED TO BE USED WITH 3.0MM SCREWS. NOTE: SEGMENTAL FIXATION IS RECOMMENDED FOR THESE CONSTRUCTS.,SPINAL INTERVERTEBRAL BODY FIXATION ORTHOSIS (ZEVO ANTERIOR CERVICAL PLATE SYSTEM)-THE DISTRACTABLE WAVE CAGE IS INDICATED FOR INTERBODY FUSION WITH AUTOGENOUS BONE GRAFT IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTIGUOUS LEVELS FROM L2 TO S1. THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THESE IMPLANTS MAY BE IMPLANTED VIA AN OPEN OR A MINIMALLY INVASIVE POSTERIOR APPROACH. THESE IMPLANTS ARE TO BE USED WITH AUTOGENOUS BONE GRAFT. THESE DEVICES ARE INTENDED TO BE USED WITH SUPPLEMENTAL FIXATION INSTRUMENTATION, WHICH HAS BEEN CLEARED BY THE FDA FOR USE IN THE LUMBAR SPINE., INTERVERTEBRAL BODY FIXATION ORTHOSIS (ZEPHIR ANTERIOR CERVICAL SYSTEM)-PROPERLY USED, THIS SYSTEM IS INTENDED FOR ANTERIOR INTERBODY SCREW/PLATE FIXATION OF THE CERVICAL SPINE. THE INDICATIONS AND CONTRAINDICATIONS OF SPINAL INSTRUMENTATION SYSTEMS SHOULD BE WELL UNDERSTOOD BY THE SURGEON. THE SYSTEM IS INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR SPINE DURING THE DEVELOPMENT OF CERVICAL SPINAL FUSIONS IN PATIENTS WITH: 1) DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC

	STUDIES), 2) TRAUMA (INCLUDING FRACTURES), 3) TUMORS, 4) DEFORMITY (DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS), 5) PSEUDARTHROSIS, AND/OR 6) FAILED PREVIOUS FUSIONS.,SPINAL VERTEBRAL BODY REPLACEMENT DEVICE(VERTE-STACK SPINAL SYSTEM (CORNERSTONE PSR))-THE CORNERSTONE® PSR DEVICE IS INDICATED FOR CERVICAL INTERBODY FUSION PROCEDURES IN SKELETALLY MATURE PATIENTS WITH CERVICAL DISC DISEASE AT ONE LEVEL FROM THE C2-C3 DISC TO THE C7-T1 DISC. CERVICAL DISC DISEASE IS DEFINED AS INTRACTABLE RADICULOPATHY AND/OR MYELOPATHY WITH HERNIATED DISC AND/OR OSTEOPHYTE FORMATION ON POSTERIOR VERTEBRAL ENDPLATES PRODUCING SYMPTOMATIC NERVE ROOT AND/OR SPINAL CORD COMPRESSION CONFIRMED BY RADIOGRAPHIC STUDIES. THIS DEVICE IS TO BE USED IN PATIENTS WHO HAVE HAD SIX WEEKS OF NON-OPERATIVE TREATMENT. THE CORNERSTONE® PSR DEVICE IS TO BE USED WITH SUPPLEMENTAL FIXATION. THE CORNERSTONE® PSR DEVICE IS ALSO REQUIRED TO BE USED WITH AUTOGRAFT.,ORTHOPAEDIC IMPLANTS(CD HORIZON SPINAL SYSTEM (PEEK HYDROXYAPATITE))-THE CD HORIZON® SPINAL SYSTEM WITH OR WITHOUT SEXTANT® INSTRUMENTATION IS INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, OR LORDOSIS), TUMOR, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. EXCEPT FOR HOOKS, WHEN USED AS AN ANTEROLATERAL THORACIC/LUMBAR SYSTEM, THE CD HORIZON® SPINAL SYSTEM MAY ALSO BE USED FOR THE SAME INDICATIONS AS AN ADJUNCT TO FUSION. WITH THE EXCEPTION OF DEGENERATIVE DISC DISEASE, THE CD HORIZON® LEGACY™ 3.5MM RODS AND THE CD HORIZON® SPINAL SYSTEM PEEK RODS AND ASSOCIATED COMPONENTS MAY BE USED FOR THE AFOREMENTIONED INDICATIONS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION. THE 3.5MM RODS MAY BE USED FOR THE SPECIFIC PEDIATRIC INDICATIONS NOTED BELOW. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE CD HORIZON® SPINAL SYSTEM IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE SPINAL DEFORMITIES(I.E., SCOLIOSIS, KYPHOSIS OR LORDOSIS) INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS, AND CONGENITAL SCOLIOSIS. ADDITIONALLY, THE CD HORIZON® SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS DIAGNOSED WITH THE

	FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS AND FRACTURE CAUSED BY TUMOR AND/OR TRAUMA. THESE DEVICES ARE TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE CD HORIZON® SPIRE™ PLATE IS A POSTERIOR, SINGLE-LEVEL, NON-PEDICLE SUPPLEMENTAL FIXATION DEVICE INTENDED FOR USE IN THE NON-CERVICAL SPINE (T1-S1) AS AN ADJUNCT TO FUSION IN SKELETALLY MATURE PATIENTS. IT IS INTENDED FOR PLATE FIXATION/ATTACHMENT TO SPINOUS PROCESSES FOR THE PURPOSE OF ACHIEVING SUPPLEMENTAL FIXATION IN THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (AS PREVIOUSLY DEFINED), SPONDYLOLISTHESIS, TRAUMA, AND/OR TUMOR. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE CD HORIZON® SPINAL SYSTEM RODS MAY BE CONNECTED TO THE VERTEX® RECONSTRUCTION SYSTEM WITH THE VERTEX® ROD CONNECTOR. REFER TO THE VERTEX® RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE VERTEX® INDICATIONS OF USE.,FENESTRATED SCREW SPINAL SYSTEM (CD HORIZON® FENESTRATED SCREW SPINAL SYSTEM)-IN COMBINATION WITH OTHER COMPONENTS OF THE CD HORIZON® SPINAL SYSTEM, THE CD HORIZON® FENESTRATED SCREWS ARE INTENDED FOR POSTERIOR, NON-CERVICAL SPINAL FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); ANKYLOSING SPONDYLITIS, SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE AND/OR DISLOCATION); SPINAL STENOSIS, FAILED PREVIOUS FUSION (PSEUDOARTHROSIS), DEFORMITY (E.G. ADULT DEGENERATIVE DEFORMITY, SCOLIOSIS, KYPHOSIS, LORDOSIS), REVISION SURGERY, AND/OR TUMOR. WHEN USED IN CONJUNCTION WITH FENESTRATED SCREW CEMENT, THE CD HORIZON® FENESTRATED SCREWS ARE INTENDED TO PROVIDE ENHANCED PEDICULAR FIXATION IN PATIENTS WITH POOR/COMPROMISED BONE QUALITY DUE TO PATHOLOGIES SUCH AS OSTEOPOROSIS.,INTERVERTEBRAL BODY FUSION DEVICE(PIVOX OBLIQUE LATERAL SPINAL SYSTEM)-THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM INTERBODY CAGE IS DESIGNED TO BE USED WITH AUTOGRAFT AND/OR ALLOGENIC BONE GRAFT COMPRISED OF CANCELLOUS AND/OR CORTICOCANCELLOUS BONE GRAFT TO FACILITATE INTERBODY FUSION AND IS INTENDED FOR USE WITH SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBAR SPINE. THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM INTERBODY CAGE IS USED FOR PATIENTS DIAGNOSED WITH DDD AT ONE OR TWO CONTIGUOUS LEVELS FROM L2 TO S1. DDD

	PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. ADDITIONALLY, THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM CAN BE USED TO PROVIDE ANTERIOR COLUMN SUPPORT IN PATIENTS DIAGNOSED WITH DEGENERATIVE SCOLIOSIS AS AN ADJUNCT TO PEDICLE SCREW FIXATION. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THESE IMPLANTS MAY BE IMPLANTED VIA A MINIMALLY INVASIVE OR OPEN LATERAL OR OBLIQUE APPROACH. CERTAIN SIZES OF THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM INTERBODY CAGE MAY ALSO BE USED WITH INFUSE BONE GRAFT FOR PATIENTS DIAGNOSED WITH DDD, AS DEFINED ABOVE, WHO ARE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THE DEVICE MAY BE IMPLANTED AT A SINGLE LEVEL USING AN OBLIQUE LATERAL INTERBODY FUSION (OLIF) APPROACH FROM L2-L5 AND IS INTENDED FOR USE WITH SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBAR SPINE. CONSULT THE LABELING FOR THE INFUSE BONE GRAFT/ MEDTRONIC INTERBODY FUSION DEVICE FOR INFORMATION ON THE SPECIFIC SIZES OF THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM INTERBODY CAGE APPROVED FOR USE WITH INFUSE BONE GRAFT, AS WELL AS SPECIFIC INFORMATION REGARDING CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS ASSOCIATED WITH INFUSE BONE GRAFT. INFUSE BONE GRAFT IS NOT INDICATED FOR USE IN A DIRECT LATERAL INTERBODY FUSION(DLIF) SURGICAL APPROACH. ADDITIONALLY, PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM CAN BE USED TO PROVIDE ANTERIOR COLUMN SUPPORT IN PATIENTS DIAGNOSED WITH DEGENERATIVE SCOLIOSIS AS AN ADJUNCT TO PEDICLE SCREW FIXATION. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THESE IMPLANTS MAY BE IMPLANTED VIA A MINIMALLY INVASIVE OR OPEN LATERAL OR OBLIQUE APPROACH. INFUSE BONE GRAFT IS NOT INDICATED FOR USE IN PATIENTS WITH THIS CONDITION. THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM PLATE AND BONE SCREW COMPONENTS ARE INDICATED AS A SUPPLEMENTAL FIXATION DEVICE FOR THE LUMBOSACRAL LEVELS, ANTERIOR BELOW THE BIFURCATION (L5-S1) OF THE VASCULAR STRUCTURES, AND OBLIQUE OR LATERAL ABOVE THE BIFURCATION (L1-L5) OF THE VASCULAR STRUCTURES. THE INDICATIONS AND CONTRAINDICATIONS OF SPINAL INSTRUMENTATION SYSTEMS SHOULD BE UNDERSTOOD BY THE SURGEON. THE PLATE AND BONE SCREW COMPONENTS ARE INDICATED AS A SUPPLEMENTAL

	FIXATION DEVICE FOR THE LUMBOSACRAL LEVELS, ANTERIOR BELOW THE BIFURCATION (L5-S1) OF THE VASCULAR STRUCTURES, AND OBLIQUE OR LATERAL ABOVE THE BIFURCATION (L1-L5) OF THE VASCULAR STRUCTURES. THE INDICATIONS AND CONTRAINDICATIONS OF SPINAL INSTRUMENTATION SYSTEMS SHOULD BE UNDERSTOOD BY THE SURGEON. THE PLATE AND BONE SCREW COMPONENTS ARE INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR LUMBAR SPINE DURING THE DEVELOPMENT OF SPINAL FUSIONS IN PATIENTS WITH: 1) DEGENERATIVE DISC DISEASE (DDD) DEFINED BY BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES; 2) TRAUMA (INCLUDING FRACTURES); 3) TUMORS; 4) DEFORMITY DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS; 5) PSEUDARTHROSIS; AND/OR 6) FAILED PREVIOUS FUSIONS. WHEN USED TOGETHER, THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM COMPONENTS CAN BE USED TO TREAT PATIENTS WITH DDD AT ONE OR TWO CONTIGUOUS LEVELS FROM L2 TO S1(EXCEPT AS DEFINED FOR USE WITH INFUSE BONE GRAFT ABOVE). THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS.,SPINAL INTERVERTEBRAL BODY FIXATION ORTHOSIS (DIVERGENCE ANTERIOR CERVICAL FUSION SYSTEM)-THE DIVERGENCE™ ANTERIOR CERVICAL FUSION SYSTEM CONSISTS OF A STAND-ALONE INTERBODY DEVICE INDICATED FOR USE IN ANTERIOR CERVICAL INTERBODY FUSION PROCEDURES IN SKELETALLY MATURE PATIENTS WITH CERVICAL DISC DISEASE AT ONE LEVEL FROM THE C2-C3 DISC TO THE C7-T1 DISC. CERVICAL DISC DISEASE IS DEFINED AS INTRACTABLE RADICULOPATHY AND/OR MYELOPATHY WITH HERNIATED DISC AND/OR OSTEOPHYTE FORMATION ON POSTERIOR VERTEBRAL ENDPLATES PRODUCING SYMPTOMATIC NERVE ROOT AND/OR SPINAL CORD COMPRESSION CONFIRMED BY RADIOGRAPHIC STUDIES. THE DIVERGENCE™ STAND-ALONE CERVICAL INTERBODY DEVICE MUST BE USED WITH INTERNAL SCREW FIXATION. THE DIVERGENCE™ STAND-ALONE CERVICAL INTERBODY DEVICE IS ALSO REQUIRED TO BE USED WITH AUTOGENOUS BONE GRAFT AND IS TO BE IMPLANTED VIA AN OPEN, ANTERIOR APPROACH. THIS CERVICAL DEVICE IS TO BE USED IN PATIENTS WHO HAVE HAD SIX WEEKS OF NON-OPERATIVE TREATMENT. PATIENTS WITH PREVIOUS NON-FUSION SPINAL SURGERY AT INVOLVED LEVEL MAY BE TREATED WITH THE DEVICE. , SPINAL INTERLAMINAL FIXATION ORTHOSIS(VERTEX RECONSTRUCTION SYSTEM)-WHEN INTENDED AS AN ADJUNCT TO FUSION OF THE OCCIPITOCERVICAL SPINE, CERVICAL SPINE, AND THE THORACIC SPINE (OCCIPUT-T3), THE VERTEX®

	RECONSTRUCTION SYSTEM IS INDICATED FOR SKELETALLY MATURE PATIENTS USING ALLOGRAFT AND/OR AUTOGRAFT FOR THE FOLLOWING: DDD (NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, SPINAL STENOSIS, FRACTURE, DISLOCATION, FAILED PREVIOUS FUSION, AND/OR TUMORS. OCCIPITOCERVICAL COMPONENTS: PLATE ROD/PLATES/RODS/OCCIPITAL SCREWS/HOOKS THE OCCIPITOCERVICAL PLATE RODS, PLATES, RODS, OCCIPITAL SCREWS, AND HOOKS ARE INTENDED TO PROVIDE STABILIZATION TO PROMOTE FUSION FOLLOWING REDUCTION OF FRACTURE/DISLOCATION OR TRAUMA IN THE OCCIPITOCERVICAL JUNCTION AND THE CERVICAL SPINE. WHEN USED TO TREAT THESE OCCIPITOCERVICAL AND CERVICAL CONDITIONS, THESE SCREWS ARE LIMITED TO OCCIPITAL FIXATION ONLY. THE SCREWS ARE NOT INTENDED TO BE PLACED IN THE CERVICAL SPINE. OCCIPITOCERVICAL CONSTRUCTS REQUIRE BILATERAL FIXATION TO C2 AND BELOW. NOTE: SEGMENTAL FIXATION IS RECOMMENDED FOR THESE CONSTRUCTS. HOOKS AND RODS THE HOOKS AND RODS ARE ALSO INTENDED TO PROVIDE STABILIZATION TO PROMOTE FUSION FOLLOWING REDUCTION OF FRACTURE/DISLOCATION OR TRAUMA IN THE CERVICAL/UPPER THORACIC (C1-T3) SPINE. MULTI-AXIAL SCREWS THE USE OF MULTI-AXIAL SCREWS IS LIMITED TO PLACEMENT IN T1-T3. THE SCREWS ARE NOT INTENDED TO BE PLACED IN THE CERVICAL SPINE. TITANIUM ATLAS® CABLE SYSTEM TO BE USED WITH THE VERTEX® RECONSTRUCTION SYSTEM ALLOWS FOR CABLE ATTACHMENT TO THE POSTERIOR CERVICAL OR THORACIC SPINE. CONNECTORS IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE VERTEX® RECONSTRUCTION SYSTEM MAY BE CONNECTED TO THE CD HORIZON® SPINAL SYSTEM RODS WITH THE VERTEX® ROD CONNECTORS. TRANSITION RODS WITH DIFFERING DIAMETERS MAY ALSO BE USED TO CONNECT THE VERTEX® RECONSTRUCTION SYSTEM TO THE CD HORIZON® SPINAL SYSTEM SCREWS, HOOKS, AND CONNECTORS. REFER TO THE CD HORIZON® SPINAL SYSTEM PACKAGE INSERT FOR A LIST OF THE CD HORIZON® SPINAL SYSTEM INDICATIONS OF USE. ,INTERVERTEBRAL BODY FUSION DEVICE(CAPSTONE PTC SPINAL SYSTEM)-THE CAPSTONE PTC™ SPINAL SYSTEM IS INDICATED FOR INTERBODY FUSION WITH AUTOGENOUS BONE GRAFT IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO LEVELS FROM L2 TO S1. THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND

	RADIOGRAPHIC STUDIES. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. ADDITIONALLY, THE CAPSTONE PTC™ SPINAL SYSTEM IS INDICATED TO ASSIST IN THE SETTING OF SPINAL DEFORMITY AS A SUPPLEMENT TO PEDICLE SCREW FIXATION IN PATIENTS DIAGNOSED WITH DEGENERATIVE SCOLIOSIS. THESE IMPLANTS MAY BE IMPLANTED VIA AN OPEN OR A MINIMALLY INVASIVE POSTERIOR APPROACH. ALTERNATIVELY, THESE IMPLANTS MAY ALSO BE IMPLANTED VIA AN ANTERIOR AND/OR TRANSFORAMINAL APPROACH. THESE IMPLANTS ARE TO BE USED WITH AUTOGENOUS BONE GRAFT. THESE DEVICES ARE INTENDED TO BE USED WITH SUPPLEMENTAL FIXATION INSTRUMENTATION, WHICH HAS BEEN CLEARED BY THE FOOD AND DRUG ADMINISTRATION (FDA) FOR USE IN THE LUMBAR SPINE.,ORTHOSIS, SPINAL PEDICLE FIXATION, FOR DEGENERATIVE DISC DISEASE(CD HORIZON SPINAL SYSTEM)-THE CD HORIZON® SPINAL SYSTEM WITH OR WITHOUT SEXTANT® INSTRUMENTATION IS INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, OR LORDOSIS), TUMOR, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. EXCEPT FOR HOOKS, WHEN USED AS AN ANTEROLATERAL THORACIC/LUMBAR SYSTEM, THE CD HORIZON® SPINAL SYSTEM MAY ALSO BE USED FOR THE SAME INDICATIONS AS AN ADJUNCT TO FUSION. WITH THE EXCEPTION OF DEGENERATIVE DISC DISEASE, THE CD HORIZON® LEGACY™ 3.5MM RODS AND THE CD HORIZON® SPINAL SYSTEM PEEK RODS AND ASSOCIATED COMPONENTS MAY BE USED FOR THE AFOREMENTIONED INDICATIONS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION. THE 3.5MM RODS MAY BE USED FOR THE SPECIFIC PEDIATRIC INDICATIONS NOTED BELOW. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE CD HORIZON® SPINAL SYSTEM IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE SPINAL DEFORMITIES(I.E., SCOLIOSIS, KYPHOSIS OR LORDOSIS) INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS, AND CONGENITAL SCOLIOSIS. ADDITIONALLY, THE CD HORIZON® SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS DIAGNOSED WITH THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS AND FRACTURE CAUSED BY TUMOR AND/OR TRAUMA. THESE DEVICES ARE TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT.

	PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE CD HORIZON® SPIRE™ PLATE IS A POSTERIOR, SINGLE-LEVEL, NON-PEDICLE SUPPLEMENTAL FIXATION DEVICE INTENDED FOR USE IN THE NON-CERVICAL SPINE (T1-S1) AS AN ADJUNCT TO FUSION IN SKELETALLY MATURE PATIENTS. IT IS INTENDED FOR PLATE FIXATION/ATTACHMENT TO SPINOUS PROCESSES FOR THE PURPOSE OF ACHIEVING SUPPLEMENTAL FIXATION IN THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (AS PREVIOUSLY DEFINED), SPONDYLOLISTHESIS, TRAUMA, AND/OR TUMOR. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE CD HORIZON® SPINAL SYSTEM RODS MAY BE CONNECTED TO THE VERTEX® RECONSTRUCTION SYSTEM WITH THE VERTEX® ROD CONNECTOR. REFER TO THE VERTEX® RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE VERTEX® INDICATIONS OF USE.,ORTHOSIS, SPINAL PEDICLE FIXATION, FOR DEGENERATIVE DISC DISEASE(CD HORIZON SPINAL SYSTEM (COBALT CHROMIUM MOLYBDENUM ALLOY))-THE CD HORIZON® SPINAL SYSTEM WITH OR WITHOUT SEXTANT® INSTRUMENTATION IS INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, OR LORDOSIS), TUMOR, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. EXCEPT FOR HOOKS, WHEN USED AS AN ANTEROLATERAL THORACIC/LUMBAR SYSTEM, THE CD HORIZON® SPINAL SYSTEM MAY ALSO BE USED FOR THE SAME INDICATIONS AS AN ADJUNCT TO FUSION. WITH THE EXCEPTION OF DEGENERATIVE DISC DISEASE, THE CD HORIZON® LEGACY™ 3.5MM RODS AND THE CD HORIZON® SPINAL SYSTEM PEEK RODS AND ASSOCIATED COMPONENTS MAY BE USED FOR THE AFOREMENTIONED INDICATIONS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION. THE 3.5MM RODS MAY BE USED FOR THE SPECIFIC PEDIATRIC INDICATIONS NOTED BELOW. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE CD HORIZON® SPINAL SYSTEM IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE SPINAL DEFORMITIES(I.E., SCOLIOSIS, KYPHOSIS OR LORDOSIS) INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS, AND CONGENITAL SCOLIOSIS. ADDITIONALLY, THE CD HORIZON® SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS DIAGNOSED WITH THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS

	AND FRACTURE CAUSED BY TUMOR AND/OR TRAUMA. THESE DEVICES ARE TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE CD HORIZON® SPIRE™ PLATE IS A POSTERIOR, SINGLE-LEVEL, NON-PEDICLE SUPPLEMENTAL FIXATION DEVICE INTENDED FOR USE IN THE NON-CERVICAL SPINE (T1-S1) AS AN ADJUNCT TO FUSION IN SKELETALLY MATURE PATIENTS. IT IS INTENDED FOR PLATE FIXATION/ATTACHMENT TO SPINOUS PROCESSES FOR THE PURPOSE OF ACHIEVING SUPPLEMENTAL FIXATION IN THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (AS PREVIOUSLY DEFINED), SPONDYLOLISTHESIS, TRAUMA, AND/OR TUMOR. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE CD HORIZON® SPINAL SYSTEM RODS MAY BE CONNECTED TO THE VERTEX® RECONSTRUCTION SYSTEM WITH THE VERTEX® ROD CONNECTOR. REFER TO THE VERTEX® RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE VERTEX® INDICATIONS OF USE.,ORTHOSIS, SPINAL PEDICLE FIXATION, FOR DEGENERATIVE DISC DISEASE(CD HORIZON SPINAL SYSTEM (PEEK OPTIMA LT1))-THE CD HORIZON® SPINAL SYSTEM WITH OR WITHOUT SEXTANT® INSTRUMENTATION IS INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, OR LORDOSIS), TUMOR, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. EXCEPT FOR HOOKS, WHEN USED AS AN ANTEROLATERAL THORACIC/LUMBAR SYSTEM, THE CD HORIZON® SPINAL SYSTEM MAY ALSO BE USED FOR THE SAME INDICATIONS AS AN ADJUNCT TO FUSION. WITH THE EXCEPTION OF DEGENERATIVE DISC DISEASE, THE CD HORIZON® LEGACY™ 3.5MM RODS AND THE CD HORIZON® SPINAL SYSTEM PEEK RODS AND ASSOCIATED COMPONENTS MAY BE USED FOR THE AFOREMENTIONED INDICATIONS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION. THE 3.5MM RODS MAY BE USED FOR THE SPECIFIC PEDIATRIC INDICATIONS NOTED BELOW. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE CD HORIZON® SPINAL SYSTEM IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE SPINAL DEFORMITIES(I.E., SCOLIOSIS, KYPHOSIS OR LORDOSIS) INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS, AND CONGENITAL SCOLIOSIS. ADDITIONALLY, THE CD HORIZON® SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS

	DIAGNOSED WITH THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS AND FRACTURE CAUSED BY TUMOR AND/OR TRAUMA. THESE DEVICES ARE TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE CD HORIZON® SPIRE™ PLATE IS A POSTERIOR, SINGLE-LEVEL, NON-PEDICLE SUPPLEMENTAL FIXATION DEVICE INTENDED FOR USE IN THE NON-CERVICAL SPINE (T1-S1) AS AN ADJUNCT TO FUSION IN SKELETALLY MATURE PATIENTS. IT IS INTENDED FOR PLATE FIXATION/ATTACHMENT TO SPINOUS PROCESSES FOR THE PURPOSE OF ACHIEVING SUPPLEMENTAL FIXATION IN THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (AS PREVIOUSLY DEFINED), SPONDYLOLISTHESIS, TRAUMA, AND/OR TUMOR. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE CD HORIZON® SPINAL SYSTEM RODS MAY BE CONNECTED TO THE VERTEX® RECONSTRUCTION SYSTEM WITH THE VERTEX® ROD CONNECTOR. REFER TO THE VERTEX® RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE VERTEX® INDICATIONS OF USE.,ORTHOSIS, SPINAL PEDICLE FIXATION, FOR DEGENERATIVE DISC DISEASE(CD HORIZON SPINAL SYSTEM (TITANIUM ALLOY))-THE CD HORIZON® SPINAL SYSTEM WITH OR WITHOUT SEXTANT® INSTRUMENTATION IS INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, OR LORDOSIS), TUMOR, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. EXCEPT FOR HOOKS, WHEN USED AS AN ANTEROLATERAL THORACIC/LUMBAR SYSTEM, THE CD HORIZON® SPINAL SYSTEM MAY ALSO BE USED FOR THE SAME INDICATIONS AS AN ADJUNCT TO FUSION. WITH THE EXCEPTION OF DEGENERATIVE DISC DISEASE, THE CD HORIZON® LEGACY™ 3.5MM RODS AND THE CD HORIZON® SPINAL SYSTEM PEEK RODS AND ASSOCIATED COMPONENTS MAY BE USED FOR THE AFOREMENTIONED INDICATIONS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION. THE 3.5MM RODS MAY BE USED FOR THE SPECIFIC PEDIATRIC INDICATIONS NOTED BELOW. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE CD HORIZON® SPINAL SYSTEM IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE SPINAL DEFORMITIES(I.E., SCOLIOSIS, KYPHOSIS OR LORDOSIS) INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS, AND CONGENITAL

	SCOLIOSIS. ADDITIONALLY, THE CD HORIZON® SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS DIAGNOSED WITH THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS AND FRACTURE CAUSED BY TUMOR AND/OR TRAUMA. THESE DEVICES ARE TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE CD HORIZON® SPIRE™ PLATE IS A POSTERIOR, SINGLE-LEVEL, NON-PEDICLE SUPPLEMENTAL FIXATION DEVICE INTENDED FOR USE IN THE NON-CERVICAL SPINE (T1-S1) AS AN ADJUNCT TO FUSION IN SKELETALLY MATURE PATIENTS. IT IS INTENDED FOR PLATE FIXATION/ATTACHMENT TO SPINOUS PROCESSES FOR THE PURPOSE OF ACHIEVING SUPPLEMENTAL FIXATION IN THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (AS PREVIOUSLY DEFINED), SPONDYLOLISTHESIS, TRAUMA, AND/OR TUMOR. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE CD HORIZON® SPINAL SYSTEM RODS MAY BE CONNECTED TO THE VERTEX® RECONSTRUCTION SYSTEM WITH THE VERTEX® ROD CONNECTOR. REFER TO THE VERTEX® RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE VERTEX® INDICATIONS OF USE.,ORTHOSIS, SPINAL PEDICLE FIXATION, FOR DEGENERATIVE DISC DISEASE(CD HORIZON SPINAL SYSTEM (TITANIUM))-THE CD HORIZON® SPINAL SYSTEM WITH OR WITHOUT SEXTANT® INSTRUMENTATION IS INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, OR LORDOSIS), TUMOR, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. EXCEPT FOR HOOKS, WHEN USED AS AN ANTEROLATERAL THORACIC/LUMBAR SYSTEM, THE CD HORIZON® SPINAL SYSTEM MAY ALSO BE USED FOR THE SAME INDICATIONS AS AN ADJUNCT TO FUSION. WITH THE EXCEPTION OF DEGENERATIVE DISC DISEASE, THE CD HORIZON® LEGACY™ 3.5MM RODS AND THE CD HORIZON® SPINAL SYSTEM PEEK RODS AND ASSOCIATED COMPONENTS MAY BE USED FOR THE AFOREMENTIONED INDICATIONS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION. THE 3.5MM RODS MAY BE USED FOR THE SPECIFIC PEDIATRIC INDICATIONS NOTED BELOW. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE CD HORIZON® SPINAL SYSTEM IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE SPINAL DEFORMITIES(I.E., SCOLIOSIS, KYPHOSIS OR LORDOSIS)

	INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS, AND CONGENITAL SCOLIOSIS. ADDITIONALLY, THE CD HORIZON® SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS DIAGNOSED WITH THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS AND FRACTURE CAUSED BY TUMOR AND/OR TRAUMA. THESE DEVICES ARE TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE CD HORIZON® SPIRE™ PLATE IS A POSTERIOR, SINGLE-LEVEL, NON-PEDICLE SUPPLEMENTAL FIXATION DEVICE INTENDED FOR USE IN THE NON-CERVICAL SPINE (T1-S1) AS AN ADJUNCT TO FUSION IN SKELETALLY MATURE PATIENTS. IT IS INTENDED FOR PLATE FIXATION/ATTACHMENT TO SPINOUS PROCESSES FOR THE PURPOSE OF ACHIEVING SUPPLEMENTAL FIXATION IN THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (AS PREVIOUSLY DEFINED), SPONDYLOLISTHESIS, TRAUMA, AND/OR TUMOR. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE CD HORIZON® SPINAL SYSTEM RODS MAY BE CONNECTED TO THE VERTEX® RECONSTRUCTION SYSTEM WITH THE VERTEX® ROD CONNECTOR. REFER TO THE VERTEX® RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE VERTEX® INDICATIONS OF USE.,ORTHOSIS, SPINAL PEDICLE FIXATION FOR DEGENERATIVE DISC DISEASE(CD HORIZON ESSENCE SPINAL SYSTEM)-THE CD HORIZON® SPINAL SYSTEM WITH OR WITHOUT SEXTANT® INSTRUMENTATION IS INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, OR LORDOSIS), TUMOR, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. EXCEPT FOR HOOKS, WHEN USED AS AN ANTEROLATERAL THORACIC/LUMBAR SYSTEM, THE CD HORIZON® SPINAL SYSTEM MAY ALSO BE USED FOR THE SAME INDICATIONS AS AN ADJUNCT TO FUSION. WITH THE EXCEPTION OF DEGENERATIVE DISC DISEASE, THE CD HORIZON® LEGACY™ 3.5MM RODS AND THE CD HORIZON® SPINAL SYSTEM PEEK RODS AND ASSOCIATED COMPONENTS MAY BE USED FOR THE AFOREMENTIONED INDICATIONS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION. THE 3.5MM RODS MAY BE USED FOR THE SPECIFIC PEDIATRIC INDICATIONS NOTED BELOW. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE CD HORIZON® SPINAL SYSTEM IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE

	SPINAL DEFORMITIES(I.E., SCOLIOSIS, KYPHOSIS OR LORDOSIS) INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS, AND CONGENITAL SCOLIOSIS. ADDITIONALLY, THE CD HORIZON® SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS DIAGNOSED WITH THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS AND FRACTURE CAUSED BY TUMOR AND/OR TRAUMA. THESE DEVICES ARE TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE CD HORIZON® SPIRE™ PLATE IS A POSTERIOR, SINGLE-LEVEL, NON-PEDICLE SUPPLEMENTAL FIXATION DEVICE INTENDED FOR USE IN THE NON-CERVICAL SPINE (T1-S1) AS AN ADJUNCT TO FUSION IN SKELETALLY MATURE PATIENTS. IT IS INTENDED FOR PLATE FIXATION/ATTACHMENT TO SPINOUS PROCESSES FOR THE PURPOSE OF ACHIEVING SUPPLEMENTAL FIXATION IN THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (AS PREVIOUSLY DEFINED), SPONDYLOLISTHESIS, TRAUMA, AND/OR TUMOR. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE CD HORIZON® SPINAL SYSTEM RODS MAY BE CONNECTED TO THE VERTEX® RECONSTRUCTION SYSTEM WITH THE VERTEX® ROD CONNECTOR. REFER TO THE VERTEX® RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE VERTEX® INDICATIONS OF USE.,SPINAL INTERVERTEBRAL BODY FIXATION ORTHOSIS (ATLANTIS ANTERIOR CERVICAL PLATE SYSTEM)-PROPERLY USED, THIS SYSTEM IS INTENDED FOR ANTERIOR INTERBODY SCREW FIXATION FROM C2 TO T1. THE INDICATIONS AND CONTRAINDICATIONS OF SPINAL INSTRUMENTATION SYSTEMS SHOULD BE WELL UNDERSTOOD BY THE SURGEON. THE SYSTEM IS INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR SPINE DURING THE DEVELOPMENT OF CERVICAL SPINAL FUSIONS IN PATIENTS WITH: 1) DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), 2) TRAUMA (INCLUDING FRACTURES), 3) TUMORS, 4) DEFORMITY (DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS), 5) PSEUDARTHROSIS, AND/OR 6) FAILED PREVIOUS FUSIONS.,INTERVERTEBRAL BODY FUSION DEVICE(CAPSTONE SPINAL SYSTEM)-THE CAPSTONE® SPINAL SYSTEM IS INDICATED FOR INTERBODY FUSION WITH AUTOGENOUS BONE GRAFT IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO LEVELS FROM L2 TO S1. THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND

		RADIOGRAPHIC STUDIES. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THESE IMPLANTS MAY BE IMPLANTED VIA AN OPEN OR A MINIMALLY INVASIVE POSTERIOR APPROACH. ALTERNATIVELY, THESE IMPLANTS MAY ALSO BE IMPLANTED VIA AN ANTERIOR AND/OR TRANSFORAMINAL APPROACH. THESE IMPLANTS ARE TO BE USED WITH AUTOGENOUS BONE GRAFT. THESE DEVICES ARE INTENDED TO BE USED WITH SUPPLEMENTAL FIXATION INSTRUMENTATION, WHICH HAS BEEN CLEARED BY THE FDA FOR USE IN THE LUMBAR SPINE.
1469	IMP/MD/2018/000447	1.License Holder Name: COSMOS ENTERPRISES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA DILATATION CATHETER(COSMOS NC)-THE COSMOS NC PTCA DILATATION CATHETERS ARE INDICATED FOR: 1. BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. 2. BALLOON DILATATION OF A STENT AFTER IMPLANTATION (BALLOON MODELS 2.00MM - 4.50MM).,PTCA DILATATION CATHETER(COSMOS RX)-THE COSMOS RX PTCA DILATATION CATHETERS ARE INDICATED FOR: 1. BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. 2. BALLOON DILATATION OF A STENT AFTER IMPLANTATION(BALLOON MODELS 2.00MM - 4.50MM).

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1470	IMP/MD/2018/000449	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:THROMBECTOMY DEVICE (REVIVE SE)-IT IS INTENDED TO RESTORE BLOOD FLOW IN PATIENTS WITH ACUTE ISCHEMIC STROKE SECONDARY TO INTRACRANIAL OCCLUSIVE VESSEL DISEASE BY PROVIDING TEMPORARY BYPASS ACROSS THE OCCLUSION AND/OR BY THE NONSURGICAL REMOVAL OF EMBOLI AND THROMBI. IT MAY BE USED WITH ASPIRATION AND WITH THE INJECTION OR INFUSION OF CONTRAST MEDIA AND OTHER FLUIDS.,MICROCOIL(ORBIT GALAXY G2)-THE ORBIT GALAXY G2 MICROCOIL DELIVERY SYSTEM IS INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS, OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE, AND IS ALSO INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE.,MICROCOIL(PRESIDIO)-THE PRESIDIO MICROCOIL DELIVERY SYSTEM IS INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS.,MICROCOIL (MICRUSPHERE)-THE MICRUSPHERE MICROCOIL DELIVERY SYSTEM IS INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS.,MICROCOIL(HELIPAQ)-THE HELIPAQ MICROCOIL DELIVERY SYSTEM IS INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS.,MICROCOIL (DELTAPLUSH)-THE DELTAPLUSH MICROCOIL DELIVERY SYSTEM IS INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS.,MICROCOIL SYSTEM(MICRUSFRAME)-MICRUSFRAME, DELTAFILL, AND DELTAXSFT MICROCOIL DELIVERY SYSTEMS ARE INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS, OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE, AND ARE ALSO INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE.

1471	IMP/MD/2018/000449	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED ,A-1/50, ROOM NO. 2, 100 SHED AREA, G.L.D.C., VAPI, TAL PARDI (VALSAD) , VALSAD GUJARAT ,396195 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROCOIL SYSTEM (DELTA XSFT)-MICRUSFRAME, DELTAFILL, AND DELTAXSFT MICROCOIL DELIVERY SYSTEMS ARE INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS, OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE, AND ARE ALSO INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE.,MICROCOIL SYSTEM(GALAXY G3 XSFT)-THE GALAXY G3 XSFT 12 STRETCH RESISTANT COIL MICROCOIL DELIVERY SYSTEM IS INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS.,MICROCOIL SYSTEM (MICRUSFRAME)-MICRUSFRAME, DELTAFILL, AND DELTAXSFT MICROCOIL DELIVERY SYSTEMS ARE INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS, OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE, AND ARE ALSO INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE.,MICROCOIL SYSTEM(GALAXY G3 MINI)-THE GALAXY G3 MINI MICROCOIL DELIVERY SYSTEM IS INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS, OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE, AND IS ALSO INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE.,MICROCOIL SYSTEM(DELTAFILL)-MICRUSFRAME, DELTAFILL, AND DELTAXSFT MICROCOIL DELIVERY SYSTEMS ARE INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS, OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE, AND ARE ALSO INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE.,MICROCOIL SYSTEM(GALAXY G3)-THE GALAXY G3 MICROCOIL DELIVERY SYSTEM IS INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS, OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE, AND IS ALSO INTENDED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE

1472	IMP/MD/2019/000001	1.License Holder Name: DELVIN SURGICALS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RESIN ADSORPTION COLUMN(HA130 / HA230 / HA330 / HA330 II / BS330)-THE PRODUCT IS USED AS A DISPOSABLE CARTRIDGE, USED AS A DISPOSABLE DEVICE IN DIALYSIS MACHINE, CRRT ETC. FOR REMOVAL OF ENDOGENOUS AND EXOGENOUS METABOLITES, TOXINS AND RESIDUAL DRUGS BY EXTRACORPOREAL CIRCULATION.
1473	IMP/MD/2019/000002	1.License Holder Name: FUSION MEDICAL & DENTAL TECHNOLOGY, CO. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT (DENTIN)-DENTIN IMPLANTS IS INDICATED FOR USE IN SURGICAL AND RESTORATIVE APPLICATIONS FOR PLACEMENT IN THE BONE OF THE UPPER OR LOWER JAW TO PROVIDE SUPPORT FOR PROSTHETIC DEVICES, SUCH AS ARTIFICIAL TEETH, IN ORDER TO RESTORE THE PATIENT'S CHEWING FUNCTION.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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1474	IMP/MD/2019/000003	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANCHOR(HEALIX ADVANCE KNOTLESS PEEK ANCHOR)-THE HEALIX ADVANCE KNOTLESS ANCHORS ARE INDICATED FOR USE IN THE FOLLOWING PROCEDURES FOR REATTACHMENT OF SOFT TISSUE TO BONE: BR: ROTOR CUFF, BICEPS TENODESIS PEEK: ROTOR CUFF, BICEPS TENODESIS,SHEATH AND SCREW SYSTEM (PEEK SCREW)(INTRAFIX ADVANCE)-THE DEPUY MITEK INTRAFIX ADVANCE TIBIAL SHEATH AND SCREW SYSTEM IS INDICATED FOR FIXATION OF TISSUE INCLUDING LIGAMENT, OR TENDON TO BONE DURING CRUCIATE LIGAMENT RECONSTRUCTION.,ANCHOR WITH SUTURE(GRYPHON BR ANCHOR WITH PERMACORD)-THE GRYPHON BR ANCHOR IS INDICATED FOR: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION, FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS, ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR,SHEATH AND SCREW SYSTEM (POLYPROPYLENE SHEATH)(INTRAFIX ADVANCE)-THE DEPUY MITEK INTRAFIX ADVANCE TIBIAL SHEATH AND SCREW SYSTEM IS INDICATED FOR FIXATION OF TISSUE INCLUDING LIGAMENT, OR TENDON TO BONE DURING CRUCIATE LIGAMENT RECONSTRUCTION.,SCREW(INTRAFIX SCREW)-THE DEPUY MITEK TIBIAL TAPERED SCREW AND TIBIAL SHEATH ARE INDICATED FOR FIXATION OF SOFT TISSUE GRAFTS DURING CRUCIATE LIGAMENT RECONSTRUCTION.,GRAFT PREPARATION SYSTEM (SUTURE)(SPEEDTRAP)-THE SPEEDTRAP SUTURE CONSTRUCT IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION IN ORTHOPEDIC PROCEDURES.,ANCHOR WITH SUTURE(MINI QUICK ANCHOR PLUS WITH ETHIBOND)-THE DEPUY MITEK MINI QUICKANCHOR PLUS IS INTENDED FOR FIXATION OF USP SIZE #0 THROUGH 2/0 SUTURE TO BONE FOR THE INDICATIONS LISTED BELOW. SHOULDER: BANKART REPAIR. ANKLE: MID-FOOT RECONSTRUCTION. FOOT: HALLUX VALGUS RECONSTRUCTION. HAND: ULNAR OR LATERAL COLLATERAL LIGAMENT RECONSTRUCTION. WRIST: SCAPHOLUNATE LIGAMENT RECONSTRUCTION. MAXILLOFACIAL: FOR THE REPAIR, REPOSITIONING OR REATTACHMENT OF SOFT TISSUES, LIGAMENT AND TENDONS TO THE MANDIBLE FOR SURGICAL STABILIZATION OF

	THE TMJ ARTICULAR DISC.,SHEATH AND SCREW SYSTEM (BR SCREW AND SHEATH)(INTRAFIX ADVANCE)-THE DEPUY MITEK INTRAFIX ADVANCE TIBIAL SHEATH AND SCREW SYSTEM IS INDICATED FOR FIXATION OF TISSUE INCLUDING LIGAMENT, OR TENDON TO BONE DURING CRUCIATE LIGAMENT RECONSTRUCTION.,ANCHOR WITH SUTURE(MINI QUICK ANCHOR PLUS WITH ORTHOCORD)-THE DEPUY MITEK MINI QUICKANCHOR PLUS IS INTENDED FOR FIXATION OF USP SIZE #0 THROUGH 2/0 SUTURE TO BONE FOR THE INDICATIONS LISTED BELOW. SHOULDER: BANKART REPAIR. ANKLE: MID-FOOT RECONSTRUCTION. FOOT: HALLUX VALGUS RECONSTRUCTION. HAND: ULNAR OR LATERAL COLLATERAL LIGAMENT RECONSTRUCTION. WRIST: SCAPHOLUNATE LIGAMENT RECONSTRUCTION,MENISCAL REPAIR SYSTEM(TRUESPAN)-THE TRUESPAN MENISCAL REPAIR SYSTEM IS INTENDED FOR USE IN MENISCAL REPAIRS AND MENISCAL ALLOGRAFT TRANSPLANT PROCEDURES. THE TRUESPAN MENISCAL REPAIR SYSTEM IS INTENDED TO BE USED FOR ANCHORING THE ALLOGRAFT TO THE MENISCAL RIM DURING ALLOGRAFT TRANSPLANT PROCEDURES., ANCHOR WITH SUTURE(MICRO QUICK ANCHOR PLUS WITH ORTHOCORD)-"THE DEPUY MITEK 1.3MM MICRO QUICKANCHOR PLUS IS USED FOR THE FIXATION OF NON-ABSORBABLE BRAIDED POLYESTER OR PARTIALLY ABSORBABLE BRAIDED COMPOSITE SURGICAL SUTURE TO BONE. THIS PRODUCT IS INTENDED FOR THE INDICATIONS LISTED BELOW: HAND: REPAIR/RECONSTRUCTION OF COLLATERAL LIGAMENTS, FLEXOR AND EXTENSOR TENDON AT THE PIP (PROXIMAL INTERPHALANGEAL), DIP (DISTAL INTERPHALANGEAL), AND MCP (METACARPAL INTERPHALANGEAL) JOINTS FOR ALL DIGITS. SKULL: LATERAL CANTHOPLASTY,SUTURE (PERMATAPE)-PERMATAPE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, AND/OR LIGATION, INCLUDING USE WITH ALLOGRAFT TISSUE FOR ORTHOPEDIC PROCEDURES.,ANCHOR(GII ANCHOR)-SHOULDER: ACROMIO-CLAVICULAR; BANKART REPAIR; BICEPS TENODESIS; CAPSULE SHIFT/CAPSULOLABRAL RECONSTRUCTION; DELTOID REPAIR; ROTATOR CUFF REPAIR; SLAP LESION REPAIR; ANKLE: ACHILLES TENDON REPAIR/RECONSTRUCTION; LATERAL INSTABILITY; MEDIAL INSTABILITY; MIDFOOT RECONSTRUCTIONS.; FOOT: HALLUX VALGUS RECONSTRUCTION; WRIST: SCAPHOLUNATE LIGAMENT RECONSTRUCTION; HAND: ULNAR OR LATERAL COLLATERAL LIGAMENT RECONSTRUCTION; ELBOW: BICEPS TENDON REATTACHMENT; TENNIS ELBOW REPAIR; KNEE: EXTRA CAPSULAR RECONSTRUCTION, ITB TENODESIS; LATERAL COLLATERAL LIGAMENT; PATELLAR LIGAMENT AND TENDON AVULSION REPAIRS; POSTERIOR OBLIQUE LIGAMENT OR JOINT CAPSULE TO TIBIA; JOINT

	CAPSULE CLOSURE TO ANTERIOR PROXIMAL TIBIA; MEDIAL COLLATERAL LIGAMENT. BNS: FIXATION IN PUBIC BONE FOR BLADDER NECK SUSPENSION USING USP CLASS I NONABSORBABLE SYNTHETIC SUTURE (E.G. POLYPROPYLENE). A MINIMUM OF 2 ANCHORS SHOULD BE USED IN THIS PROCEDURE.,SHOULDER REPLACEMENT SYSTEM (SCREW)(LATARJET EXPERIENCE)-THE LATARJET EXPERIENCE CORTICAL SCREW SET IS INTENDED TO PROVIDE THE ORTHOPEDIC SURGEON WITH A MEANS OF BONE FIXATION AND TO ASSIST IN THE MANAGEMENT OF RECONSTRUCTIVE SURGERIES.,SCREW(ABSOLUTE ABSORABLE INTERFERENCE SCREW SYSTEM)-THE DEPUY MITEK ABSOLUTE ABSORBABLE INTERFERENCE SCREW INTENDED FOR ATTACHMENT OF SOFT TISSUE GRAFTS OR BONE-TENDON GRAFTS TO THE TIBIA AND/OR FEMUR DURING CRUCIATE LIGAMENT RECONSTRUCTION SURGERIES.,SHOULDER REPLACEMENT SYSTEM (TOP HAT) (LATARJET EXPERIENCE)-THE LATARJET EXPERIENCE CORTICAL SCREW SET IS INTENDED TO PROVIDE THE ORTHOPEDIC SURGEON WITH A MEANS OF BONE FIXATION AND TO ASSIST IN THE MANAGEMENT OF RECONSTRUCTIVE SURGERIES.,SCREW(MILAGRO INTERFERENCE SCREW)-THE DEPUY MITEK MILAGRO INTERFERENCE SCREW IS INDICATED AS FOLLOWS - KNEE: ATTACHMENT OF A BONE-TENDON-BONE (BTB) GRAFT TO THE TIBIA AND/OR FEMUR DURING CRUCIATE LIGAMENT RECONSTRUCTION PROCEDURES, ATTACHMENT OF A SOFT TISSUE (ST) GRAFT TO THE TIBIA AND/OR FEMUR DURING CRUCIATE LIGAMENT RECONSTRUCTION PROCEDURES, MEDIAL AND LATERAL COLLATERAL LIGAMENT REPAIR. SHOULDER: PROXIMAL BICEP TENODESIS. ELBOW: DISTAL BICEP TENODESIS.,SUTURE(ORTHOCORD)-ORTHOCORD SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, AND/OR LIGATION, INCLUDING ORTHOPEDIC PROCEDURES. IT IS NOT INDICATED FOR CARDIOVASCULAR OR NEUROLOGICAL PROCEDURES.,ANCHOR WITH SUTURE(MICRO QUICK ANCHOR PLUS WITH ETHIBOND)-THE DEPUY MITEK 1.3 MM MICRO QUICKANCHOR PLUS IS USED FOR THE FIXATION OF NON-ABSORBABLE BRAIDED POLYESTER SURGICAL SUTURE TO BONE. THIS PRODUCT IS INTENDED FOR THE INDICATIONS LISTED BELOW: HAND: REPAIR/RECONSTRUCTION OF COLLATERAL LIGAMENTS, FLEXOR AND EXTENSOR TENDON AT THE PIP (PROXIMAL INTERPHALANGEAL), DIP (DISTAL INTERPHALANGEAL), AND MCP (METACARPAL INTERPHALANGEAL) JOINTS FOR ALL DIGITS. SKULL: LATERAL CANTHOPLASTY,PEEK ANCHOR WITH SUTURE(HEALIX ADVANCE PEEK ANCHOR WITH PERMATAPE SUTURE)-THE HEALIX ADVANCE ANCHOR IS INDICATED IN SOFT-TISSUE TO BONE FIXATION IN ASSOCIATION WITH POST-OPERATIVE IMMOBILIZATION AS

	FOLLOWS: SHOULDER- ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIOCLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION; FOOT/ANKLE- LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE- MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE, LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS; ELBOW- BICEPS TENDON REATTACHMENT, ULNAR COLLATERAL LIGAMENT RECONSTRUCTION, RADIAL COLLATERAL LIGAMENT RECONSTRUCTION.,ANCHOR WITH SUTURE(GRYPHON PEEK ANCHOR WITH PROKNOT TECHNOLOGY)-THE GRYPHON ANCHOR WITH PROKNOT TECHNOLOGY IS INTENDED FOR: SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR.,SUTURE(DYNACORD)-DYNACORD SUTURE IS INDICATED FOR ORTHOPEDIC PROCEDURAL USE IN SOFT-TISSUE APPROXIMATION, AND OR LIGATION, INCLUDING USE WITH ALLOGRAFT TISSUE.,ANCHOR WITH SUTURE(BIOKNOTLESS BR ANCHOR WITH ORTHOCORD)-THE DEPUY MITEK BIOKNOTLESS BR ANCHOR IS INDICATED FOR USE IN SOFT TISSUE TO BONE FIXATION IN ASSOCIATION WITH ADEQUATE POSTOPERATIVE IMMOBILIZATION AS FOLLOWS: SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ACROMIOCLAVICULAR SEPARATION, ROTATOR CUFF REPAIR, CAPSULE SHIFT/ CAPSULO-LABRAL RECONSTRUCTION, BICEPS TENODESIS, AND DELTOID REPAIR. ANKLE: LATERAL INSTABILITY, MEDIAL INSTABILITY, ACHILLES TENDON REPAIR/RECONSTRUCTION, AND MIDFOOT RECONSTRUCTION. FOOT: HALLUX VALGUS RECONSTRUCTION ELBOW: TENNIS ELBOW REPAIR, BICEPS TENDON REATTACHMENT. KNEE: EXTRA-CAPSULAR REPAIRS; REATTACHMENT OF: MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT OR JOINT CAPSULE TO TIBIA AND JOINT CAPSULE CLOSURE TO ANTERIOR PROXIMAL TIBIA; EXTRA CAPSULAR RECONSTRUCTION, ITB TENODESIS; PATELLAR LIGAMENT AND TENDON AVULSIONS.,PEEK ANCHOR WITH SUTURE(HEALIX ADVANCE PEEK ANCHOR WITH DYNACORD SUTURE)-THE HEALIX ADVANCE ANCHOR IS INDICATED IN SOFT-TISSUE TO BONE FIXATION IN ASSOCIATION WITH POST-OPERATIVE IMMOBILIZATION AS FOLLOWS: SHOULDER- ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIOCLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION; FOOT/ANKLE- LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE- MEDIAL COLLATERAL LIGAMENT

	REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE, LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS; ELBOW- BICEPS TENDON REATTACHMENT, ULNAR COLLATERAL LIGAMENT RECONSTRUCTION, RADIAL COLLATERAL LIGAMENT RECONSTRUCTION; HIP- CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR.,ANCHOR WITH SUTURE(GRYPHON BR ANCHOR WITH PROKNOT TECHNOLOGY)-THE GRYPHON ANCHOR WITH PROKNOT TECHNOLOGY IS INTENDED FOR: SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR.,BR ANCHOR WITH SUTURE(HEALIX ADVANCE BR ANCHOR WITH PERMATAPE SUTURE)-THE HEALIX ADVANCE ANCHOR IS INDICATED IN SOFT-TISSUE TO BONE FIXATION IN ASSOCIATION WITH POST-OPERATIVE IMMOBILIZATION AS FOLLOWS: SHOULDER- ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIOCLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION; FOOT/ANKLE- LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE- MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE, LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS; ELBOW- BICEPS TENDON REATTACHMENT, ULNAR COLLATERAL LIGAMENT RECONSTRUCTION, RADIAL COLLATERAL LIGAMENT RECONSTRUCTION.,ANCHOR WITH SUTURE(LUPINE LOOP PLUS ANCHOR WITH ORTHOCORD)-"THE LUPINE ANCHOR SYSTEM IS INDICATED FOR USE IN SOFT TISSUE TO BONE FIXATION IN ASSOCIATION WITH ADEQUATE POSTOPERATIVE IMMOBILIZATION AS FOLLOWS: OPEN PROCEDURES- SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ROTATOR CUFF REPAIR, CAPSULE SHIFT/CAPSULO-LABRAL RECONSTRUCTION, AT THE ANTERIOR GLENOID AT RIM SITE, CAPSULE SHIFT/CAPSULO-LABRAL RECONSTRUCTION AT THE LESSER TUBEROSITY OF THE HUMERUS, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION, DELTOID REPAIR ELBOW: BICEPS TENDON REATTACHMENT, TENNIS ELBOW REPAIR. ANKLE: ACHILLES TENDON REPAIR/RECONSTRUCTION, LATERAL STABILIZATION, MEDIAL STABILIZATION AT THE MEDIAL TALUS SITE; FOOT: HALLUX VALGUS RECONSTRUCTION, MIDFOOT RECONSTRUCTION. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, JOINT CAPSULE CLOSURE TO ANTERIOR PROXIMAL TIBIA, POSTERIOR OBLIQUE LIGAMENT OR JOINT CAPSULE TO TIBIA REPAIR, EXTRA CAPSULAR RECONSTRUCTION/ITB TENODESIS, PATELLAR LIGAMENT AND TENDON AVULSION REPAIRS. ARTHROSCOPIC PROCEDURES SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ROTATOR CUFF

	REPAIR, CAPSULE SHIFT REPAIR (GLENOID RIM)" ,BR ANCHOR WITH SUTURE(HEALIX ADVANCE BR ANCHOR WITH DYNACORD SUTURE)- THE HEALIX ADVANCE ANCHOR IS INDICATED IN SOFT-TISSUE TO BONE FIXATION IN ASSOCIATION WITH POST-OPERATIVE IMMOBILIZATION AS FOLLOWS: SHOULDER- ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIOCLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION; FOOT/ANKLE- LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE- MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE, LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS; ELBOW- BICEPS TENDON REATTACHMENT, ULNAR COLLATERAL LIGAMENT RECONSTRUCTION, RADIAL COLLATERAL LIGAMENT RECONSTRUCTION; HIP- CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR,SCREW(PROFILE INTERFERENCE SCREW)-"THE ADVANTAGE, PROFILE, BIG ADVANTAGE AND M. KUROSAKA INTERFERENCE SCREWS AND THE XACT SET SCREW ARE INTENDED TO BE USED TO PROVIDE INTERFERENCE FIXATION OF BONE-PATELLAR TENDON-BONE GRAFTS IN ACL RECONSTRUCTION. THE PROFILE INTERFERENCE SCREW, 20 MM AND LONGER, IS ALSO INTENDED TO PROVIDE INTERFERENCE FIXATION OF BONE-PATELLAR TENDON-BONE GRAFTS IN PCL RECONSTRUCTION AND TO PROVIDE FIXATION OF SOFT TISSUE GRAFTS IN ACL RECONSTRUCTION. THE XACT CROSS PIN IS INTENDED TO BE USED TO PROVIDE FIXATION OF SOFT TISSUE GRAFTS IN ACL RECONSTRUCTION.,SHEATH AND SCREW SYSTEM(INTRAFIX SHEATH AND SCREW SYSTEM- FEMORAL)-THE FEMORAL INTRAFIX SYSTEM IS INDICATED FOR FIXATION OF SOFT TISSUE GRAFTS DURING CRUCIATE LIGAMENT RECONSTRUCTION., ANCHOR WITH SUTURE(HEALIX ADVANCE BR ANCHOR WITH PERMACORD)-THE HEALIX ADVANCE ANCHOR IS INDICATED FOR USE IN SOFT TISSUE TO BONE FIXATION IN ASSOCIATION WITH POST-OPERATIVE IMMOBILIZATION AS FOLLOWS: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION, FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS, ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR ,SCREW(MILAGRO ADVANCE INTERFERENCE SCREW) -KNEE: ATTACHMENT OF A BONE-TENDONBONE (BTB) GRAFT TO THE

	TIBIA AND/OR FEMUR DURING CRUCIATE LIGAMENT RECONSTRUCTION PROCEDURES, ATTACHMENT OF A SOFT TISSUE (ST) GRAFT TO THE TIBIA AND/OR FEMUR DURING CRUCIATE LIGAMENT RECONSTRUCTION PROCEDURES, MEDIAL AND LATERAL COLLATERAL LIGAMENT REPAIR, MEDIAL AND LATERAL COLLATERAL LIGAMENT REPAIR; SHOULDER: PROXIMAL BICEP TENODESIS, ELBOW: DISTAL BICEP TENODESIS.,ANCHOR(HEALIX ADVANCE KNOTLESS BR ANCHOR)-THE HEALIX ADVANCE KNOTLESS ANCHORS ARE INDICATED FOR USE IN THE FOLLOWING PROCEDURES FOR REATTACHMENT OF SOFT TISSUE TO BONE: BR: ROTOR CUFF, BICEPS TENODESIS PEEK: ROTOR CUFF, BICEPS TENODESIS,ANCHOR WITH SUTURE(HEALIX PEEK ANCHOR WITH ORTHOCORD)-THE HEALIX DUAL THREADED SUTURE ANCHOR IS INTENDED FOR: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO- CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION. FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS. ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION. HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR.,ANCHOR WITH SUTURE (LUPINE ANCHOR WITH ORTHOCORD)-THE LUPINE ANCHOR SYSTEM IS INDICATED FOR USE IN SOFT TISSUE TO BONE FIXATION IN ASSOCIATION WITH ADEQUATE POSTOPERATIVE IMMOBILIZATION AS FOLLOWS: OPEN PROCEDURES- SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ROTATOR CUFF REPAIR, CAPSULE SHIFT/CAPSULO-LABRAL RECONSTRUCTION, AT THE ANTERIOR GLENOID AT RIM SITE, CAPSULE SHIFT/CAPSULOLABRAL RECONSTRUCTION AT THE LESSER TUBEROSITY OF THE HUMERUS, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION, DELTOID REPAIR ELBOW: BICEPS TENDON REATTACHMENT, TENNIS ELBOW REPAIR. ANKLE: ACHILLES TENDON REPAIR/RECONSTRUCTION, LATERAL STABILIZATION, MEDIAL STABILIZATION AT THE MEDIAL TALUS SITE; FOOT: HALLUX VALGUS RECONSTRUCTION, MIDFOOT RECONSTRUCTION. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, JOINT CAPSULE CLOSURE TO ANTERIOR PROXIMAL TIBIA, POSTERIOR OBLIQUE LIGAMENT OR JOINT CAPSULE TO TIBIA REPAIR, EXTRA CAPSULAR RECONSTRUCTION/ITB TENODESIS, PATELLAR LIGAMENT AND TENDON AVULSION REPAIRS. ARTHROSCOPIC PROCEDURES SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ROTATOR CUFF REPAIR, CAPSULE SHIFT REPAIR (GLENOID RIM),MENISCAL REPAIR

	SYSTEM - SUTURE(OMNISPAN MENISCAL REPAIR SYSTEM)-THE OMNISPAN SYSTEM IS INTENDED FOR USE IN THE ARTHROSCOPIC FIXATION OF SOFT TISSUE PROCEDURES SUCH AS MENISCAL REPAIR, ANCHOR WITH SUTURE(MICROFIX QUICK ANCHOR PLUS WITH ETHIBOND)-THE DEPUY MITEK MICROFIX QUICKANCHOR PLUS IS INTENDED FOR FIXATION OF SOFT TISSUE TO BONE, USING SUTURE, FOR THE INDICATIONS LISTED BELOW. HAND: REPAIR/RECONSTRUCTION OF COLLATERAL LIGAMENTS, FLEXOR AND EXTENSOR TENDON AT THE PIP (PROXIMAL INTERPHALANGEAL), DIP (DISTAL INTERPHALANGEAL), AND MCP (METACARPAL INTERPHALANGEAL) JOINTS FOR ALL DIGITS. SKULL: SOFT TISSUE ATTACHMENT TO THE PARIETAL, TEMPORAL RIDGE, FRONTAL, MANDIBLE, MAXILLA, ZYGOMA, AND PERIORBITAL BONES OF THE SKULL.,SHEATH(INTRAFIX SHEATH - TIBIAL)-THE DEPUY MITEK TIBIAL TAPERED SCREW AND TIBIAL SHEATH ARE INDICATED FOR FIXATION OF SOFT TISSUE GRAFTS DURING CRUCIATE LIGAMENT RECONSTRUCTION. , CORTICAL FIXATION ADJUSTABALE IMPLANT(RIGIDLOOP ADJUSTABLE CORTICAL FIXATION IMPLANT)-THE RIGIDLOOP ADJUSTABLE CORTICAL FIXATION SYSTEM IS INDICATED FOR FIXATION OF SOFT TISSUE TO BONE IN FEMORAL CRUCIATE LIGAMENT RECONSTRUCTION., CORTICAL FIXATION IMPLANT(RIGIDLOOP CORTICAL FIXATION IMPLANT)-THE RIGIDLOOP CORTICAL FIXATION SYSTEM IS INTENDED FOR FIXATION OF SOFT TISSUE TO BONE IN ORTHOPEDIC PROCEDURES SUCH AS ACL REPAIRS. ,ANCHOR WITH SUTURE(HEALIX BR ANCHOR WITH ORTHOCORD)-THE HEALIX BR ANCHOR IS INTENDED FOR: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION. FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS. ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION.,ANCHOR (VERSALOK PEEK ANCHOR)-THE VERSALOK PEEK ANCHOR IS INDICATED FOR USE IN THE FOLLOWING PROCEDURES FOR REATTACHMENT OF SOFT TISSUE TO BONE: SHOULDER: REPAIR OF ROTATOR CUFF TEARS AND BICEPS TENODESIS. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS, JOINT CAPSULE CLOSURE. ELBOW: BICEPS TENDON REATTACHMENT,ANCHOR WITH SUTURE(HEALIX ADVANCE PEEK ANCHOR WITH PERMACORD)-THE HEALIX ADVANCE ANCHOR IS

	INDICATED FOR USE IN SOFT TISSUE TO BONE FIXATION IN ASSOCIATION WITH POST-OPERATIVE IMMOBILIZATION AS FOLLOWS: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION, FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS, ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR,SCREW(MILAGRO INTERFERENCE SCREW)-THE MITEK MILAGRO INTERFERENCE SCREW IS INTENDED FOR ATTACHMENT OF SOFT TISSUE GRAFTS OR BONE-TENDON-BONE GRAFTS TO THE TIBIA AND/OR FEMUR DURING CRUCIATE LIGAMENT RECONSTRUCTION PROCEDURES. ADDITIONALLY, THE 7, 8 AND 9 MM X 23 MM SCREWS WILL BE INDICATED FOR: MEDIAL AND LATERAL COLLATERAL LIGAMENT REPAIR OF THE KNEE, PROXIMAL BICEP TENODESIS IN THE SHOULDER AND DISTAL BICEP TENODESIS IN THE ELBOW.,ANCHOR WITH SUTURE(GRYPHON BR ANCHOR WITH ORTHOCORD)-THE GRYPHON BR ANCHOR IS INTENDED FOR: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION; FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS; ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION; HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR.,ANCHOR WITH SUTURE(VERSALOK PEEK ANCHOR WITH ORTHOCORD)-THE VERSALOK PEEK ANCHOR IS INDICATED FOR USE IN THE FOLLOWING PROCEDURES FOR REATTACHMENT OF SOFT TISSUE TO BONE: SHOULDER: REPAIR OF ROTATOR CUFF TEARS AND BICEPS TENODESIS. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS, JOINT CAPSULE CLOSURE. ELBOW: BICEPS TENDON REATTACHMENT,ANCHOR WITH SUTURE(GII QUICK ANCHOR PLUS WITH ORTHOCORD)-THE DEPUY MITEK GII ANCHOR (QUICKANCHOR) IS INTENDED FOR FIXATION OF USP SIZE #2 SUTURE TO BONE FOR THE INDICATIONS LISTED BELOW. SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ACROMIO-CLAVICULAR SEPARATION,

	ROTATOR CUFF REPAIR, CAPSULE SHIFT/CAPSULO-LABRAL RECONSTRUCTION, BICEPS TENODESIS, DELTOID REPAIR. ANKLE: LATERAL INSTABILITY, MEDIAL INSTABILITY, ACHILLES TENDON REPAIR/RECONSTRUCTION, MIDFOOT RECONSTRUCTION. FOOT: HALLUX VALGUS RECONSTRUCTION. WRIST: SCAPHOLUNATE LIGAMENT. HAND: ULNAR OR LATERAL COLLATERAL LIGAMENT RECONSTRUCTION. ELBOW: TENNIS ELBOW REPAIR, BICEPS TENDON REATTACHMENT. KNEE: EXTRA CAPSULAR REPAIRS; REATTACHMENT OF: MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT OR JOINT CAPSULE TO TIBIA AND JOINT CAPSULE CLOSURE TO ANTERIOR PROXIMAL TIBIA; EXTRA CAPSULAR RECONSTRUCTION, ITB TENODESIS; PATELLAR LIGAMENT AND TENDON AVULSIONS. ,ANCHOR WITH SUTURE(FASTIN RC ANCHOR WITH ORTHOCORD)-SHOULDER: BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, ROTATOR CUFF REPAIR, SLAP REPAIR; FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS ELBOW: BICEPS TENDON REATTACHMENT, TENNIS ELBOW ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION,ANCHOR WITH SUTURE(GRYPHON PEEK ANCHOR WITH PERMACORD)-THE GRYPHON PEEK ANCHOR IS INDICATED FOR: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION, FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS, ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR,SCREW(MILAGRO INTERFERENCE SCREW)-THE DEPUY MITEK MILAGRO BR INTERFERENCE SCREWS ARE DESIGNED TO ATTACH SOFT TISSUES TO BONE IN ORTHOPEDIC SURGICAL PROCEDURES FOR THE FOLLOWING INDICATIONS: SHOULDER: PROXIMAL BICEPS TENODESIS, ACROMIO-CLAVICULAR REPAIR ELBOW: DISTAL BICEPS TENODESIS, ULNAR COLLATERAL LIGAMENT REPAIR KNEE: COLLATERAL LIGAMENT REPAIR,ANCHOR(MINI ANCHOR)-SHOULDER: BANKART REPAIR; ANKLE: MIDFOOT RECONSTRUCTIONS; FOOT: HALLUX VALGUS RECONSTRUCTION; WRIST: SCAPHOLUNATE LIGAMENT RECONSTRUCTION; HAND: ULNAR OR LATERAL COLLATERAL LIGAMENT RECONSTRUCTION; PUBIS: FIXATION IN THE

		PUBIS FOR THE PURPOSE OF BLADDER NECK SUSPENSION FOR STRESS URINARY INCONTINENCE DUE TO URETHRAL OR BLADDER NECK HYPERMOBILITY, WITH MINIMAL OR NO CYSTOCELE. A MINIMUM OF 6 DEPUY MITEK ANCHORS SHOULD BE USED IN THE MODIFIED MMK PROCEDURE.
1475	IMP/MD/2019/000004	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER(CODMAN MICROSENSOR)-USE OF THE VENTRICULAR CATHETER KIT IS INDICATED WHEN DIRECT INTRAVENTRICULAR PRESSURE MONITORING IS REQUIRED. THE KIT IS INDICATED FOR USE IN ICP MONITORING AND CEREBROSPINAL FLUID (CSF) DRAINAGE APPLICATIONS.,LUMBAR DRAINAGE CATHETER KIT II(CODMAN)-IT IS INDICATED FOR TEMPORARY ACCESS TO THE LUMBAR SUBARACHNOID REGION. IT IS DESIGNED FOR USE WITH DIMENSIONALLY COMPATIBLE DEVICES FOR DRAINING CEREBROSPINAL FLUID (CSF) AND OTHER FLUIDS OF SIMILAR PHYSICAL CHARACTERISTICS AS A MEANS OF REDUCING INTRACRANIAL PRESSURE AND CSF VOLUME.,DURAL GRAFT IMPLANT(DURAFORM)-THE DURAFORM DURAL GRAFT IMPLANT IS INTENDED FOR USE IN PROCEDURES WHERE THE REPAIR OR SUBSTITUTION OF THE PATIENT'S DURA MATER IS NEEDED.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1476	IMP/MD/2019/000005	1.License Holder Name: M/S GLOBUS MEDICAL INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STABILIZATION SYSTEM (H-LINK)-INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE.,CORPECTOMY SPACER(FORTIFY)-INTENDED TO REPLACE A COLLAPSED, DAMAGED OR UNSTABLE VERTEBRAL BODY DUE TO TUMOR OR TRAUMA IN THE CERVICAL, THORACIC, OR LUMBAR SPINE,STABILIZATION SYSTEM(REVERE STABILIZATION SYSTEM)-INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE: DEGENERATIVE DISC DISEASE, DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGIC,LUMBAR SPACER(SUSTAIN)-INTENDED FOR TREATMENT OF DEGENERATIVE DISORDERS OF THE LUMBOSACRAL SPINE,EXPANDABLE LUMBAR SPACER(LATIS)-INTENDED FOR USE IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR MORE CONTIGUOUS LEVELS OF THE LUMBOSACRAL SPINE (L2-S1).,BONE VOID FILLER(SIGNIFY BIOACTIVE)-INTENDED FOR USE AS A BONE VOID FILLER AND AUTOGRAFT EXTENDER FOR VOIDS OR GAPS THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE., EXPANDABLE LUMBAR SPACER(RISE)-INTENDED FOR USE IN PATIENTS WITH DEGENERATIVE DISC DISEASE(DDD) AT ONE OR MORE CONTIGUOUS LEVELS OF THE LUMBOSACRAL SPINE (L2-S1)., CERVICAL PLATE SYSTEM(XTEND)-INTENDED FOR ANTERIOR SCREW FIXATION TO THE CERVICAL SPINE FOR ACUTE OR CHRONIC SPINAL STABILIZATION OR DEFORMITIES,CERVICAL ARTIFICIAL DISC (SECURE-C ARTIFICIAL DISC)-INTENDED FOR THE TREATMENT OF CERVICAL DISC DISEASE,SPINAL STABILIZATION SYSTEM(REFLECT)-INTENDED TO PROVIDE SPINAL ALIGNMENT AND DYNAMIC STABILIZATION SYSTEM FOR TREATMENT OF DEFORMITIES OR CURVATURES OF THE THORACOLUMBAR SPINE,FENESTRATED SCREW SYSTEM(REVLOK (STERILE))-INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE., CERVICAL SPACER(PATRIOT COLONIAL TPS)-INTENDED FOR USE IN PATIENTS WITH DEGENERATIVE DISC DISEASE OF THE CERVICAL

	SPINE,FACET FIXATION SYSTEM(CORRIDOR FIXATION SYSTEM)-INTENDED TO STABILIZE THE SPINE AS AN AID TO FUSION THROUGH BILATERAL IMMOBILIZATION OF THE FACET JOINTS, WITH OR WITHOUT BONE GRAFT, AT SINGLE OR MULTIPLE LEVELS, FROM T1 TO S1 AND TO STABILIZE TYPE II ODONTOID FRACTURES.,CERVICAL ARTIFICIAL DISK(SECURE C3)-INTENDED FOR TREATMENT OF SYMPTOMATIC CERVICAL DISK DISEASE,ANTERIOR CERVICAL PLATE (VIP ANTERIOR CERVICAL PLATE SYSTEM)-INTENDED FOR ANTERIOR SCREW FIXATION TO THE CERVICAL SPINE C2-C7 FOR DEGENERATIVE DISC DISEASE (DDD), TRAUMA, TUMORS, DEFORMITY, PSEUDOARTHROSIS, FAILED PREVIOUS FUSION, SPONDYLOLISTHESIS, AND SPINAL STENOSIS.,LUMBAR DISC(ORBIT R)-USED FOR SPINAL ARTHROPLASTY IN PATIENTS WITH ACUTE OR CHRONIC INSTABILITIES OF THE LUMBOSACRAL SPINE,ANTERIOR LUMBAR PLATE SYSTEM(CITADEL)-INTENDED FOR USE BY AN ANTERIOR OR ANTEROLATERAL APPROACH IN THE TREATMENT OF LUMBAR AND LUMBOSACRAL (L1-S1) SPINE INSTABILITY.,SPINAL STABILIZATION SYSTEM(CREO)-INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE.,STABILIZATION SYSTEM(REVERE STABILIZATION SYSTEM (NON-STERILE))-INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE: DEGENERATIVE DISC DISEASE, DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGIC,CERVICAL PLATE SYSTEM(PROVIDENCE)-INTENDED FOR ANTERIOR SCREW FIXATION TO THE CERVICAL SPINE FOR ACUTE OR CHRONIC SPINAL INSTABILITIES OR DEFORMITIES,LUMBAR SPACER(SUSTAIN)-INTENDED FOR TREATMENT OF DEGENERATIVE DISORDERS OF THE LUMBOSACRAL SPINE,BONE VOID FILLER(KINEX BIOACTIVE)-INTENDED FOR USE AS A BONE VOID FILLER AND AUTOGRAFT EXTENDER FOR VOIDS OR GAPS THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE,LUMBAR SPACER (INDEPENDENCE (STERILE))-INTENDED FOR USE IN PATIENTS WITH DEGENERATIVE DISC DISEASE AT ONE OR MORE CONTIGUOUS LEVELS OF THE LUMBOSACRAL SPINE (L2-S1).,CERVICAL ARTIFICIAL DISK(SECURE CR)-INTENDED FOR TREATMENT OF SYMPTOMATIC CERVICAL DISK DISEASE,LUMBAR SPACER(MONUMENT)-INTENDED FOR USE IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR MORE CONTIGUOUS LEVELS OF THE LUMBOSACRAL SPINE

	(L2-S1).,SPINAL STABILIZATION SYSTEM(CREO)-INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THORACIC, LUMBAR AND SACRAL SPINE,LAMINOPLASTY FIXATION SYSTEM (RELIEVE LAMINOPLASTY SYSTEM)-INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE., CORPECTOMY SPACERS(FORTIFY)-INTENDED TO REPLACE A COLLAPSED, DAMAGED OR UNSTABLE VERTEBRAL BODY DUE TO TUMOR OR TRAUMA IN THE CERVICAL, THORACIC OR LUMBAR SPINE, BONE CEMENT(FORTRESS)-INDICATED FOR THE FIXATION OF PATHOLOGICAL FRACTURES OF THE VERTEBRAL BODY USING VERTEBROPLASTY OR KYPHOPLASTY PROCEDURES.,SPINAL STABILIZATION SYSTEM(CREO)-INTENDED TO PROVIDE IMMOBILIZATION, AND STABILIZATION OF SPINAL SEGMENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THORACIC, LUMBAR AND SACRAL SPINE,LUMBAR SPACER(PATRIOT TRANSCONTINENTAL SPACER)-: INTENDED FOR USE IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE OF THE LUMBOSACRAL SPINE (L2-S1),CORPECTOMY SPACER(NIKO CORPECTOMY SPACER)-INTENDED FOR USE IN THE THORACOLUMBAR SPINE (T1-L5) TO REPLACE A COLLAPSED, DAMAGED, OR UNSTABLE VERTEBRAL BODY DUE TO TUMOR OR TRAUMA (I.E., FRACTURE).,LUMBAR SPACER (PATRIOT SIGNATURE TLIF SPACER)-INTENDED FOR USE IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR MORE LEVELS OF THE LUMBOSACRAL SPINE (L2-S1).,EXPANDABLE LUMBAR SPACERS(ALTERA)-INTENDED FOR USE IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR MORE CONTIGUOUS LEVELS OF THE LUMBOSACRAL SPINE (L2-S1)., CERVICAL INTERBODY FUSION DEVICE(COALITION SPACER SYSTEM)-INTENDED FOR USE IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) OF THE CERVICAL SPINE (C2-T1) AT ONE OR MORE CONTIGUOUS LEVELS.,CERVICAL SPACER(PATRIOT COLONIAL ACDF SPACER)-INTENDED FOR USE IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE OF THE CERVICAL SPINE (C2-T1) AT ONE OR MORE LEVELS.,OCCIPITO-CERVICO-THORACIC SPINAL SYSTEM(PROTEX CT)-INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OF THE CRANIOCERVICAL JUNCTION

	THE CERVICAL SPINE (C1-C7) AND THE THORACIC SPINE (T1-T3), TRAUMATIC SPINAL FRACTURES AND/OR TRAUMATIC DISLOCATIONS; INSTABILITY OR DEFORMITY; FAILED PREVIOUS FUSIONS (E.G. PSEUDOARTHROSIS); TUMORS INVOLVING THE CERVICAL/THORACIC SPINE; AND DEGENERATIVE DISEASE INCLUDING INTRACTABLE RADIOCULOPATHY AND/OR MYELOPATHY, NECK AND/OR ARM PAIN OF DISCOGENIC ORIGIN AS CONFIRMED BY RADIOGRAPHIC STUDIES, AND DEGENERATIVE DISEASE OF THE FACETS WITH INSTABILITY.,STABILIZATION SYSTEM (TRANSITION STABILIZATION SYSTEM)-INTENDED TO PROVIDE SPINAL ALIGNMENT AND DYNAMIC STABILIZATION IN SKELETALLY MATURE PATIENTS IN THE THORACIC, LUMBAR, AND SACRAL SPINE., CORPECTOMY SPACERS(XPAND RADIOLUCENT SPACER)-INTENDED FOR USE IN THE THORACOLUMBAR SPINE (T1-L5) TO REPLACE A COLLAPSED, DAMAGED, OR UNSTABLE VERTEBRAL BODY DUE TO TUMOR OR TRAUMA (I.E., FRACTURE).,CORPECTOMY SPACERS (XPAND)-INTENDED FOR USE IN THE THORACOLUMBAR SPINE (T1-L5) TO REPLACE A COLLAPSED, DAMAGED, OR UNSTABLE VERTEBRAL BODY DUE TO TUMOR OR TRAUMA (I.E., FRACTURE).,LUMBAR PLATE-SPACER SYSTEM(INTERCONTINENTAL (NON STERILE))-INTENDED FOR USE IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR MORE CONTIGUOUS LEVELS OF THE LUMBOSACRAL SPINE (L2-S1),LUMBAR SPACER(SUSTAIN RADIOLUCENT SPACER)-INTENDED FOR TREATMENT OF DEGENERATIVE DISORDERS OF THE LUMBOSACRAL SPINE,SPINAL STABILIZATION SYSTEM(PROTEX STABILIZATION SYSTEM)-INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE.,EXPANDABLE LUMBAR SPACERS (CALIBER)-INTENDED FOR USE IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR MORE CONTIGUOUS LEVELS OF THE LUMBOSACRAL SPINE (L2-S1).,CERVICAL PLATE SYSTEM(ASSURE ANTERIOR CERVICAL PLATE SYSTEM)-THE ASSURE ANTERIOR CERVICAL PLATE SYSTEM IS INTENDED FOR ANTERIOR SCREW FIXATION TO THE CERVICAL SPINE (C2-C7) FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), TRAUMA (INCLUDING FRACTURES), TUMORS, DEFORMITY (KYPHOSIS, LORDOSIS OR SCOLIOSIS), PSEUDARTHROSIS, FAILED PREVIOUS FUSIONS, SPONDYLOLISTHESIS, AND SPINAL STENOSIS.,VERTEBRAL COMPRESSION FRACTURE SYSTEM(AFFIRM)-INTENDED TO BE USED FOR THE REDUCTION AND FIXATION OF FRACTURES AND/OR

	CREATION OF A VOID IN CANCELLOUS BONE IN THE SPINE, HAND, TIBIA, RADIUS, AND CALCANEUS.,FIXATION SYSTEM(SILC (STERILE))-INTENDED TO PROVIDE TEMPORARY STABILIZATION AS A BONE ANCHOR DURING THE DEVELOPMENT OF SOLID BONY FUSION AND AID IN THE REPAIR OF BONE FRACTURES.,LUMBAR SPACER (INDEPENDENCE (NON STERILE))-INTENDED FOR USE IN PATIENTS WITH DEGENERATIVE DISC DISEASE AT ONE OR MORE CONTIGUOUS LEVELS OF THE LUMBOSACRAL SPINE (L2-S1).,FIXATION SYSTEM (SILC (NON STERILE))-INTENDED TO PROVIDE TEMPORARY STABILIZATION AS A BONE ANCHOR DURING THE DEVELOPMENT OF SOLID BONY FUSION AND AID IN THE REPAIR OF BONE FRACTURES., LUMBAR PLATE-SPACER SYSTEM(INTERCONTINENTAL (STERILE))-INTENDED FOR USE IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR MORE CONTIGUOUS LEVELS OF THE LUMBOSACRAL SPINE (L2-S1),FENESTRATED SCREW SYSTEM (REVLOK (NON STERILE))-INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE.,SACROILIAC FIXATION(SI-LOK (STERILE))-INTENDED FOR SACROILIAC JOINT FUSION FOR CONDITIONS INCLUDING SACROILIAC JOINT DISRUPTIONS AND DEGENERATIVE SACROILIITIS.,OCCIPITO-CERVICO-THORACIC STABILIZATION SYSTEM(ELLIPSE)-INTENDED TO BE USED IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION USING AUTOGRAFT OR ALLOGRAFT, FOR STABILIZATION OF THE CERVICAL SPINE AND OCCIPITO-CERVICO-THORACIC JUNCTION (OCCIPUT-T3), STABILIZATION SYSTEM(REVOLVE STABILIZATION SYSTEM)-INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE.,VERTEBRAL COMPRESSION FRACTURE SYSTEM (SHIELD)-INTENDED FOR USE IN THE TREATMENT OF OSTEOPOROTIC VERTEBRAL BODY COMPRESSION FRACTURES IN THE ADULT SPINE, LEVELS T4-L5.

1477	IMP/MD/2019/000006	1.License Holder Name: DR REDDYS LABORATORIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DERMAL REGENERATION TEMPLATE(INTEGRA DERMAL REGENERATION TEMPLATE)-IT IS INDICATED FOR THE POSTEXCISIONAL TREATMENT OF FULL-THICKNESS AND PARTIAL-THICKNESS INJURIES WHERE SUFFICIENT AUTOGRAFT IS NOT AVAILABLE AT THE TIME OF EXCISION DUE TO THE PHYSIOLOGICAL CONDITION OF THE PATIENT. IT IS ALSO INDICATED FOR USE IN RECONSTRUCTION OF POSTEXCISIONAL, FULL-THICKNESS DEFECTS OF THE INTEGUMENT WHERE THERE IS, IN THE OPINION OF THE TREATING SURGEON, A POTENTIAL BENEFIT TO THE PATIENT BY IMPROVING THE RECONSTRUCTIVE OUTCOME OF DECREASING THEIR MORTALITY/MORBIDITY.,DERMAL REGENERATION TEMPLATE - SINGLE LAYER(INTEGRA DERMAL REGENERATION TEMPLATE - SINGLE LAYER)-IT IS INDICATED FOR THE POSTEXCISIONAL TREATMENT OF FULL-THICKNESS AND PARTIAL-THICKNESS INJURIES WHERE SUFFICIENT AUTOGRAFT IS NOT AVAILABLE AT THE TIME OF EXCISION DUE TO THE PHYSIOLOGICAL CONDITION OF THE PATIENT. IT IS ALSO INDICATED FOR USE IN RECONSTRUCTION OF POSTEXCISIONAL, FULL-THICKNESS DEFECTS OF THE INTEGUMENT WHERE THERE IS, IN THE OPINION OF THE TREATING SURGEON, A POTENTIAL BENEFIT TO THE PATIENT BY IMPROVING THE RECONSTRUCTIVE OUTCOME OF DECREASING THEIR MORTALITY/MORBIDITY.,MESHED DERMAL REGENERATION TEMPLATE(INTEGRA MESHED DERMAL REGENERATION TEMPLATE)-IT IS INDICATED FOR THE POSTEXCISIONAL TREATMENT OF LIFE THREATENING FULL-THICKNESS OR DEEP PARTIAL-THICKNESS THERMAL INJURY WHERE SUFFICIENT AUTOGRAFT IS NOT AVAILABLE AT THE TIME OF EXCISION OR NOT DESIRABLE DUE TO THE PHYSIOLOGICAL CONDITION OF THE PATIENT AND. IT IS ALSO INDICATED FOR THE REPAIR OF SCAR CONTRACTURES WHEN OTHER THERAPIES HAVE FAILED OR WHEN DONOR SITES FOR REPAIR ARE NOT SUFFICIENT OR DESIRABLE DUE TO THE PHYSIOLOGICAL CONDITION OF THE PATIENT,WOUND MATRIX THIN(INTEGRA WOUND MATRIX THIN)-INDICATED FOR THE MANAGEMENT OF WOUNDS INCLUDING: PARTIAL AND FULL-THICKNESS WOUNDS, PRESSURE ULCERS, VENOUS ULCERS, DIABETIC ULCERS, CHRONIC VASCULAR ULCERS, TUNNELLED/UNDERMINED WOUNDS, SURGICAL WOUNDS (DONOR SITES/GRAFTS, POST-MOH'S SURGERY, POST-LASER SURGERY, PODIATRIC, WOUND DEHISCENCE), TRAUMA WOUNDS (ABRASIONS, LACERATIONS, SECOND-DEGREE BURNS, SKIN TEARS) AND DRAINING WOUNDS. THE DEVICE INTENDED FOR ONE TIME USE.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1478	IMP/MD/2019/000006	1.License Holder Name: DR. REDDYS LABORATORIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADHESION BARRIER MATRIX(DURAGEN PLUS)-DURAGEN PLUS® ADHESION BARRIER MATRIX IS INDICATED AS AN ONLAY GRAFT FOR THE REPAIR AND RESTORATION OF DURAL DEFECTS IN CRANIAL AND SPINAL SURGICAL PROCEDURES. DURAGEN PLUS MATRIX IS ALSO INDICATED AS AN ADHESION BARRIER FOR THE INHIBITION OF POST-SURGICAL PERIDURAL FIBROSIS. DURAGEN PLUS MATRIX READILY CONFORMS TO THE SURFACE OF THE BRAIN, SPINAL CORD AND OVERLYING TISSUES. DURAGEN PLUS MATRIX MAY BE USED TO CLOSE DURAL DEFECTS FOLLOWING TRAUMATIC INJURY, EXCISION, RETRACTION OR SHRINKAGE. DURAGEN PLUS MATRIX MAY BE USED TO SUPPLEMENT PRIMARY CLOSURE. IN CLINICAL EVALUATIONS, DURAGEN PLUS MATRIX HAS BEEN DEMONSTRATED TO BE AN EFFECTIVE DURAL GRAFT MATRIX FOR THE FOLLOWING PROCEDURES: • CRANIAL CONVEXITY: MAY BE USED TO COVER LARGE DEFECTS FOLLOWING SURGERY, ESPECIALLY FOR DURAL LOSS FROM EXCISION, CONTRACTION, RETRACTION AND/OR SHRINKAGE; • BRAIN SWELLING: INTRA-OPERATIVE BRAIN SWELLING OR ANTICIPATED POSTOPERATIVE SWELLING; • POSTERIOR FOSSA SURGERY: 1) GENERAL USE AS A DURAL GRAFT, 2) DECOMPRESSION CRANIECTOMY AND DURAL RELEASE FOR INFARCTS, I.E., POSTERIOR INFERIOR CEREBELLAR ARTERY (PICA) INFARCTS, 3) ANTICIPATED SWELLING AFTER TRAUMA, AND 4) MAY BE USED IN CHIARI DECOMPRESSION PROCEDURES; • SPINAL SURGERY: 1) GENERAL USE AS A SPINAL ONLAY DURAL GRAFT, ESPECIALLY USEFUL FOR DEFECTS ARISING FROM PINHOLE TEARS, DISC SURGERY, AND SPINAL STENOSIS DECOMPRESSION, 2) AFTER RESECTION OF INTRADURAL TUMORS, 3) ONLAY GRAFT AFTER DURAL APPROXIMATION WITH SUTURES, 4) AS A SEPARATION LAYER BETWEEN THE DURA AND OVERLYING TISSUES; • ADHESION BARRIER: TO INHIBIT POST-SURGICAL PERIDURAL FIBROSIS IN LAMINECTOMY, LAMINOTOMY OR DISCECTOMY PROCEDURES WHERE NERVE ROOTS ARE EXPOSED.,DURAL REGENERATION MATRIX (SUTURABLE DURAGEN)-SUTURABLE DURAGEN IS INDICATED AS A DURAL SUBSTITUTE FOR THE REPAIR AND RESTORATION OF DURAL DEFECTS IN CRANIAL AND SPINAL SURGICAL PROCEDURES. SUTURABLE DURAGEN READILY CONFORMS TO THE SURFACE OF THE BRAIN AND OVERLYING TISSUES. SUTURABLE DURAGEN MAY BE USED TO CLOSE DURAL DEFECTS FOLLOWING TRAUMATIC INJURY, EXCISION, RETRACTION OR SHRINKAGE. SUTURABLE DURAGEN MAY BE USED TO SUPPLEMENT PRIMARY CLOSURE. SUTURABLE DURAGEN MAY BE USED IN THE FOLLOWING PROCEDURES: •

		CRANIAL CONVEXITY: MAY BE USED TO COVER LARGE DEFECTS FOLLOWING SURGERY, ESPECIALLY FOR DURAL LOSS FROM EXCISION, CONTRACTION, RETRACTION AND/OR SHRINKAGE; • BRAIN SWELLING: INTRA-OPERATIVE BRAIN SWELLING OR ANTICIPATED POSTOPERATIVE SWELLING; • POSTERIOR FOSSA SURGERY: 1) GENERAL USE AS A DURAL GRAFT, 2) DECOMPRESSION CRANIECTOMY AND DURAL RELEASE FOR INFARCTS, I.E., POSTERIOR INFERIOR CEREBELLAR ARTERY (PICA) INFARCTS, 3)ANTICIPATED SWELLING AFTER TRAUMA, AND 4) MAY BE USED IN CHIARI DECOMPRESSION PROCEDURES; • SPINAL SURGERY: 1) GENERAL USE AS A SPINAL DURAL GRAFT, ESPECIALLY USEFUL FOR DEFECTS ARISING FROM PINHOLE TEARS, DISC SURGERY, AND SPINAL STENOSIS DECOMPRESSION, 2) AFTER RESECTION OF INTRADURAL TUMORS,3) ONLAY GRAFT AFTER DURAL APPROXIMATION WITH SUTURES, AND 4) AS A SEPARATION LAYER BETWEEN THE DURA AND OVERLYING TISSUES.
1479	IMP/MD/2019/000007	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALCOHOL PADS(SOFTA® SWABS)-FOR CLEANSING PRIOR TO INJECTION, FOR PREPARATION OF SKIN, INSTRUMENTS OR UTENSILS, FOR PROFESSIONAL AND HOSPITAL USE.
1480	IMP/MD/2019/000008	1.License Holder Name: INFOMED IMPEX INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CASTING TAPE (SPLINT) (CASTING TAPE (SPLINT))-CASTING TAPE IS INTENDED FOR EXTERNAL IMMOBILIZATION OF FRACTURE AND SPRAINS OF LIMBS.
1481	IMP/MD/2019/000009	1.License Holder Name: HANSTRONICS MEDICAL EQUIPMENTS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTIBACTERIAL FOAM DRESSING(HYDROFERA BLUE CLASSIC)-THE ANTIBACTERIAL FOAM DRESSINGS ARE INTENDED AS EXTERNAL DRESSING FOR USE IN LOCAL MANAGEMENT OF WOUNDS SUCH AS PRESSURE ULCERS, DONOR SITES, VENOUS STASIS ULCERS, ARTERIAL ULCERS, DIABETIC ULCERS, ABRASIONS, LACERATIONS, SUPERFICIAL BURNS, POST-SURGICAL INCISIONS AND OTHER EXTERNAL WOUNDS INFECTED BY TRAUMA.

1482	IMP/MD/2019/000012	1.License Holder Name: PRIME MEDICA PROMOTION PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CASTING TAPE(PRIME CAST)-PRIME CAST IS INTENDED FOR EXTERNAL IMMOBILIZATION OF FRACTURES AND SPRAINS OF LIMBS.
1483	IMP/MD/2019/000013	1.License Holder Name: ENDOVASCULAR CORPORATION PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEUROVASCULAR EMBOLIZATION DEVICE(BARRICADE EMBOLIZATION COIL SYSTEM)-THE BARRICADE COIL SYSTEM (BCS) IS INTENDED FOR THE ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS AND OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE. THE BCS IS ALSO INTENDED FOR VASCULAR OCCLUSION OF BLOOD VESSELS WITHIN THE NEUROVASCULAR SYSTEM TO PERMANENTLY OBSTRUCT BLOOD FLOW TO AN ANEURYSM OR OTHER VASCULAR MALFORMATION AND FOR ARTERIAL AND VENOUS EMBOLIZATION IN THE PERIPHERAL VASCULATURE.
1484	IMP/MD/2019/000014	1.License Holder Name: CONFIDENT SALES INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PROSTHETIC COMPONENTS(PALTOP PROSTHETIC COMPONENTS)-PALTOP DENTAL PROSTHETIC COMPONENT IS A PRE-MANUFACTURED COMPONENT DIRECTLY CONNECTED TO THE ENDOSSOUS DENTAL IMPLANT AND IS INTENDED FOR USE AS AN AID IN PROSTHETIC REHABILITATION. PALTOP DENTAL PROSTHETIC COMPONENT ARE INTENDED FOR SINGLE USE. RAUSE OF THE DEVICE MAY CAUSE MICROBIAL CONTAMINATION AND LOSS OF PERFORMANCE,DENTAL IMPLANTS (PALTOP DENTAL IMPLANTS)-THE PALTOP DENTAL IMPLANT SYSTEM IS INDICATED FOR USE IN SURGICAL AND RESTORATIVE APPLICATIONS FOR PLACEMENT IN THE BONE OF THE UPPER OR LOWER JAW TO PROVIDE SUPPORT FOR PROSTHETIC DEVICES, SUCH AS ARTIFICIAL TEETH, IN ORDER TO RESTORE THE PATIENT'S CHEWING FUNCTION. THE PALTOP DENTAL IMPLANT SYSTEM IS INDICATED ALSO FOR IMMEDIATE LOADING WHEN GOOD PRIMARY STABILITY IS ACHIEVED AND WITH APPROPRIATE OCCLUSAL LOADING

1485	IMP/MD/2019/000015	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABDOMINAL STENT GRAFT SYSTEM(TREO ABDOMINAL STENT GRAFT SYSTEM)-FOR THE ENDOVASCULAR TREATMENT OF INFRARENAL ABDOMINAL AORTIC AND AORTO-ILIAC ANEURYSMS IN PATIENTS WHO HAVE APPROPRIATE ANATOMY (AS DEFINED BY LOCAL STATUTES)., THORACIC STENT GRAFT SYSTEM(RELAY PLUS)-INTENDED FOR THE TREATMENT OF THORACIC AORTIC PATHOLOGIES SUCH AS ANEURYSMS, PSEUDOANEURYSMS, DISSECTIONS, PENETRATING ULCERS AND INTRAMURAL HEMATOMA, IN ADULT PATIENTS (AS DEFINED BY LOCAL STATUTES).,ABDOMINAL STENT GRAFT SYSTEM (TREO ABDOMINAL STENT GRAFT SYSTEM)-FOR THE ENDOVASCULAR TREATMENT OF INFRARENAL ABDOMINAL AORTIC AND AORTO-ILIAC ANEURYSMS IN PATIENTS WHO HAVE APPROPRIATE ANATOMY (AS DEFINED BY LOCAL STATUTES), THORACIC STENT GRAFT SYSTEM(RELAY NBS PLUS)-INTENDED FOR THE TREATMENT OF THORACIC AORTIC PATHOLOGIES SUCH AS ANEURYSMS, PSEUDOANEURYSMS, DISSECTIONS, PENETRATING ULCERS AND INTRAMURAL HEMATOMA, IN ADULT PATIENTS (AS DEFINED BY LOCAL STATUTES).,THORACIC STENT GRAFT SYSTEM (RELAY PRO THORACIC STENT-GRAFT SYSTEM (NBS CONFIGURATION))-FOR THE TREATMENT OF THORACIC AORTIC PATHOLOGIES SUCH AS ANEURYSMS, PSEUDOANEURYSMS, DISSECTIONS, PENETRATING ULCERS, AND INTRAMURAL HEMATOMA IN ADULT PATIENTS (AS DEFINED BY LOCAL STATUTES).,THORACIC STENT GRAFT SYSTEM(RELAY PRO THORACIC STENT-GRAFT SYSTEM (BARE STENT CONFIGURATION))-THE RELAYPRO THORACIC STENT-GRAFT SYSTEM (BARE STENT CONFIGURATION) IS INTENDED FOR THE TREATMENT OF THORACIC AORTIC PATHOLOGIES SUCH AS ANEURYSMS, PSEUDOANEURYSMS, DISSECTIONS, PENETRATING ULCERS, AND INTRAMURAL HEMATOMA IN ADULT PATIENTS (AS DEFINED BY LOCAL STATUTES).

1486	IMP/MD/2019/000016	1.License Holder Name: KCI MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:V.A.C. DRESSING(V.A.C. DRESSING)-THE V.A.C.ULTA™ NEGATIVE PRESSURE WOUND THERAPY SYSTEM IS AN INTEGRATED WOUND MANAGEMENT SYSTEM THAT PROVIDES NEGATIVE PRESSURE WOUND THERAPY WITH AN INSTILLATION OPTION. NEGATIVE PRESSURE WOUND THERAPY IN THE ABSENCE OF INSTILLATION IS INTENDED TO CREATE AN ENVIRONMENT THAT PROMOTES WOUND HEALING BY SECONDARY OR TERTIARY (DELAYED PRIMARY) INTENTION BY PREPARING THE WOUND BED FOR CLOSURE, REDUCING EDEMA, PROMOTING GRANULATION TISSUE FORMATION AND PERFUSION, AND BY REMOVING EXUDATES AND INFECTIOUS MATERIAL. THE INSTILLATION OPTION IS INDICATED FOR PATIENTS WHO WOULD BENEFIT FROM VACUUM ASSISTED DRAINAGE AND CONTROLLED DELIVERY OF TOPICAL WOUND TREATMENT SOLUTIONS AND SUSPENSIONS OVER THE WOUND BED. THE V.A.C.ULTA™ NEGATIVE PRESSURE WOUND THERAPY SYSTEM WITH AND WITHOUT INSTILLATION IS INDICATED FOR PATIENTS WITH CHRONIC, ACUTE, TRAUMATIC, SUB-ACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC, PRESSURE AND VENOUS INSUFFICIENCY), FLAPS AND GRAFTS.

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1487	IMP/MD/2019/000016	1.License Holder Name: KCI MEDICAL INDIA PRIVATE LIMITED ,K. NO. 2606/115 (P. NO. 60/16) GROUND FLOOR, HUSKUR ROAD ELECTRONIC POST ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560100 , INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:V.A.C. DRESSING(V.A.C. VERAFLO DRESSING SYSTEM SMALL , MEDIUM, LARGE)-THE V.A.C. ULTA NEGATIVE PRESSURE WOUND THERAPY SYSTEM IS AN INTEGRATED WOUND MANAGEMENT SYSTEM THAT PROVIDES NEGATIVE PRESSURE WOUND THERAPY WITH AN INSTILLATION OPTION. NEGATIVE PRESSURE WOUND THERAPY IN THE ABSENCE OF INSTILLATION IS INTENDED TO CREATE AN ENVIRONMENT THAT PROMOTES WOUND HEALING BY SECONDARY OR TERTIARY (DELAYED PRIMARY) INTENTION BY PREPARING THE WOUND BED FOR CLOSURE, REDUCING EDEMA, PROMOTING GRANULATION TISSUE FORMATION AND PERFUSION, AND BY REMOVING EXUDATES AND INFECTIOUS MATERIAL. THE INSTILLATION OPTION IS INDICATED FOR PATIENTS WHO WOULD BENEFIT FROM VACUUM ASSISTED DRAINAGE AND CONTROLLED DELIVERY OF TOPICAL WOUND TREATMENT SOLUTIONS AND SUSPENSIONS OVER THE WOUND BED. THE V.A.C. ULTA NEGATIVE PRESSURE WOUND THERAPY SYSTEM WITH & WITHOUT INSTILLATION IS INDICATED FOR PATIENTS WITH CHRONIC, ACUTE, TRAUMATIC, SUB-ACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC, PRESSURE AND VENOUS INSUFFICIENCY), FLAPS AND GRAFTS.,V.A.C. DRESSING(V.A.C. VERAFLO CLEANSE DRESSING SYSTEM)-THE V.A.C. ULTA NEGATIVE PRESSURE WOUND THERAPY SYSTEM IS AN INTEGRATED WOUND MANAGEMENT SYSTEM THAT PROVIDES NEGATIVE PRESSURE WOUND THERAPY WITH AN INSTILLATION OPTION. NEGATIVE PRESSURE WOUND THERAPY IN THE ABSENCE OF INSTILLATION IS INTENDED TO CREATE AN ENVIRONMENT THAT PROMOTES WOUND HEALING BY SECONDARY OR TERTIARY (DELAYED PRIMARY) INTENTION BY PREPARING THE WOUND BED FOR CLOSURE, REDUCING EDEMA, PROMOTING GRANULATION TISSUE FORMATION AND PERFUSION, AND BY REMOVING EXUDATES AND INFECTIOUS MATERIAL. THE INSTILLATION OPTION IS INDICATED FOR PATIENTS WHO WOULD BENEFIT FROM VACUUM ASSISTED DRAINAGE AND CONTROLLED DELIVERY OF TOPICAL WOUND TREATMENT SOLUTIONS AND SUSPENSIONS OVER THE WOUND BED. THE V.A.C. ULTA NEGATIVE PRESSURE WOUND THERAPY SYSTEM WITH & WITHOUT INSTILLATION IS INDICATED FOR PATIENTS WITH CHRONIC, ACUTE, TRAUMATIC, SUB-ACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC, PRESSURE AND

	VENOUS INSUFFICIENCY), FLAPS AND GRAFTS.,V.A.C. TUBE SET(V.A.C. VERA T.R.A.C. DUO TUBE SET)-THE V.A.C. ULTA NEGATIVE PRESSURE WOUND THERAPY SYSTEM IS AN INTEGRATED WOUND MANAGEMENT SYSTEM THAT PROVIDES NEGATIVE PRESSURE WOUND THERAPY WITH AN INSTILLATION OPTION. NEGATIVE PRESSURE WOUND THERAPY IN THE ABSENCE OF INSTILLATION IS INTENDED TO CREATE AN ENVIRONMENT THAT PROMOTES WOUND HEALING BY SECONDARY OR TERTIARY (DELAYED PRIMARY) INTENTION BY PREPARING THE WOUND BED FOR CLOSURE, REDUCING EDEMA, PROMOTING GRANULATION TISSUE FORMATION AND PERFUSION, AND BY REMOVING EXUDATES AND INFECTIOUS MATERIAL. THE INSTILLATION OPTION IS INDICATED FOR PATIENTS WHO WOULD BENEFIT FROM VACUUM ASSISTED DRAINAGE AND CONTROLLED DELIVERY OF TOPICAL WOUND TREATMENT SOLUTIONS AND SUSPENSIONS OVER THE WOUND BED. THE V.A.C. ULTA NEGATIVE PRESSURE WOUND THERAPY SYSTEM WITH & WITHOUT INSTILLATION IS INDICATED FOR PATIENTS WITH CHRONIC, ACUTE, TRAUMATIC, SUB-ACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC, PRESSURE AND VENOUS INSUFFICIENCY), FLAPS AND GRAFTS.

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1488	IMP/MD/2019/000017	1.License Holder Name: EDWARDS LIFESCIENCES (INDIA) PRIVATE LIMITED, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DUAL STAGE VENOUS DRAINAGE/ RETURN CANNULA(THIN-FLEX DUAL STAGE VENOUS DRAINAGE CANNULA, DUAL STAGE VENOUS DRAINAGE CANNULA, TRIM-FLEX DUAL STAGE VENOUS DRAINAGE CANNULA)-DUAL DRAINAGE VENOUS RETURN CANNULAE ARE INDICATED FOR VENOUS CANNULATION SO THAT EXTRACORPOREAL CIRCULATION OF THE VENOUS BLOOD TO A HEART-LUNG MACHINE MAY BE ACHIEVED, FOR A DURATION OF (LESS THAN 6 HOURS). THEY ARE ALSO INDICATED FOR CORONARY BYPASS PROCEDURES WHERE SINGLE TUBE VENOUS DRAINAGE FROM THE RIGHT ATRIUM ONLY IS ORDINARILY CONTRAINDICATED BECAUSE OF DIMINISHED CAVAL RETURN DUE TO INTRA-OPERATIVE MANIPULATION OF THE HEART. VENOUS RETURN CANNULAE IN SIZES 6 FR. (2 MM) TO 18 FR. (6 MM) CAN BE USED IN PEDIATRIC PATIENTS. EXTRACORPOREAL CIRCUIT COMPONENTS WITH A DURAFLO TREATMENT ARE INTENDED FOR USE IN CARDIOPULMONARY BYPASS WHEN A HEPARIN TREATED CANNULA IS DESIRED UPON INITIAL PLACEMENT.,AORTIC PERFUSION CANNULA(EZ GLIDE AORTIC CANNULA)-AORTIC PERFUSION CANNULAE ARE INTENDED FOR PERFUSION OF THE ASCENDING AORTA DURING SHORT-TERM (LESS THAN 6 HOURS) CARDIOPULMONARY BYPASS PROCEDURES. AORTIC CANNULAE IN SIZES 6 FR. (2 MM) TO 18 FR. (6 MM) CAN BE USED IN PEDIATRIC PATIENT POPULATIONS. EXTRACORPOREAL CIRCUIT COMPONENTS WITH A DURAFLO TREATMENT ARE INTENDED FOR USE IN CARDIOPULMONARY BYPASS WHEN A HEPARIN TREATED CANNULA IS DESIRED UPON INITIAL PLACEMENT.,SINGLE STAGE VENOUS DRAINAGE/RETURN CANNULA(THIN-FLEX SINGLE STAGE VENOUS DRAINAGE CANNULA)-VENOUS RETURN CANNULAE ARE INTENDED FOR CANNULA DRAINAGE FROM THE SUPERIOR AND INFERIOR VENA CAVA DURING EXTRACORPOREAL CIRCULATION FOR A DURATION OF (LESS THAN 6 HOURS). VENOUS RETURN CANNUALE IN SIZES 6 FR. (2 MM) TO 18 FR. (6 MM) CAN BE USED IN PEDIATRIC PATIENTS. THE 40 FR. (13.3 MM) WIRE REINFORCED VENOUS RETURN CANNULA IS ALSO INDICATED FOR SINGLE TUBE VENOUS DRAINAGE FROM THE RIGHT ATRIUM. EXTRACORPOREAL CIRCUIT COMPONENTS WITH DURAFLO TREATMENT ARE INTENDED FOR USE IN CARDIOPULMONARY BYPASS WHEN A HEPARIN TREATED CANNULA IS DESIRED UPON INITIAL PLACEMENT.

1489	IMP/MD/2019/000018	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURPASS EVOLVE ™ FLOW DIVERTER SYSTEM(SURPASS EVOLVE ™ FLOW DIVERTER SYSTEM)-THE SURPASS EVOLVE FLOW DIVERTER SYSTEM IS INDICATED FOR USE FOR THE TREATMENT OF SACCULAR OR FUSIFORM INTRACRANIAL ANEURYSMS ARISING FROM A PARENT VESSEL WITH A DIAMETER 2.0MM AND 5.0MM.,AXS INFINITY LS (AXS INFINITY LS)-THE AXS INFINITY LS LONG SHEATH IS INDICATED FOR THE INTRODUCTION OF INTERVENTIONAL DEVICES INTO THE PERIPHERAL, CORONARY, AND NEURO VASCULATURE.,EXCELSIOR® SL-10® MICROCATHETERS(EXCELSIOR® SL-10® MICROCATHETERS)-STRYKER NEUROVASCULAR EXCELSIOR SL-10 MICROCATHETER IS INTENDED TO ASSIST IN THE DELIVERY OF DIAGNOSTIC AGENTS, SUCH AS CONTRAST MEDIA, AND THERAPEUTIC AGENTS, SUCH AS OCCLUSION COILS, INTO THE PERIPHERAL, CORONARY, AND NEUROVASCULATURE,AXS OFFSET™ DELIVERY ASSIST CATHETER (AXS OFFSET™ DELIVERY ASSIST CATHETER)-THE AXS OFFSET DELIVERY ASSIST CATHETER IS INTENDED TO ASSIST IN THE DELIVERY OF INTERVENTIONAL DEVICES IN THE NEUROVASCULATURE,EXCELSIOR® 1018® REINFORCED MICROCATHETER(EXCELSIOR® 1018® REINFORCED MICROCATHETER)-STRYKER NEUROVASCULAR'S REINFORCED MICROCATHETERS ARE INTENDED TO ASSIST IN THE DELIVERY OF DIAGNOSTIC AGENTS, SUCH AS CONTRAST MEDIA, AND THERAPEUTIC AGENTS, SUCH AS OCCLUSION COILS, INTO THE PERIPHERAL, CORONARY, AND NEUROVASCULATURE.,SURPASS STREAMLINE™ FLOW DIVERTER(SURPASS STREAMLINE™ FLOW DIVERTER)-THE SURPASS STREAMLINE FLOW DIVERTER IS INDICATED FOR USE FOR THE TREATMENT OF SACCULAR OR FUSIFORM INTRACRANIAL ANEURYSMS ARISING FROM A PARENT VESSEL WITH A DIAMETER OF 2.5 MM AND 5.3 MM.,TARGET™ DETACHABLE COIL(TARGET™ 360 NANO DETACHABLE COILS, TARGET™ 360 SOFT DETACHABLE COILS,TARGET™ 360 STANDARD DETACHABLE COILS,TARGET™ 360 ULTRA DETACHABLE COILS, TARGET™ 3D DETACHABLE COILS,TARGET™ HELICAL NANO DETACHABLE COILS,TARGET™ HELICAL ULTRA DETACHABLE COILS, TARGET™ XL 360 SOFT DETACHABLE COILS,TARGET™ XL 360 STANDARD DETACHABLE COILS,TARGET™ XL HELICAL DETACHABLE COILS,TARGET™ XXL 360 DETACHABLE COILS)-TARGET DETACHABLE COILS ARE INTENDED TO ENDOVASCULARLY OBSTRUCT OR OCCLUDE BLOOD FLOW IN VASCULAR ABNORMALITIES OF THE NEUROVASCULAR AND PERIPHERAL VESSELS. TARGET DETACHABLE COILS ARE INDICATED FOR

	ENDOVASCULAR EMBOLIZATION OF: • INTRACRANIAL ANEURYSMS • OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE • ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE,NEUROFORM ATLAS™ STENT SYSTEM(NEUROFORM ATLAS™ STENT SYSTEM)-THE NEUROFORM ATLAS STENT SYSTEM IS INTENDED TO BE USED WITH OCCLUSIVE DEVICES IN THE TREATMENT OF INTRACRANIAL ANEURYSMS.,EXCELSIOR® 1018® PRE-SHAPED MICROCATHETERS(EXCELSIOR® 1018® PRE-SHAPED MICROCATHETERS)-STRYKER NEUROVASCULAR EXCELSIOR 1018 PRE-SHAPED MICROCATHETERS ARE INTENDED TO ASSIST IN THE DELIVERY OF DIAGNOSTIC AGENTS, SUCH AS CONTRAST MEDIA, AND THERAPEUTIC AGENTS, SUCH AS OCCLUSION COILS TO THE PERIPHERAL, CORONARY, AND NEURO VASCULATURE,WINGSPAN STENT SYSTEM(WINGSPAN STENT SYSTEM)-THE WINGSPAN STENT SYSTEM WITH GATEWAY PTA BALLOON CATHETER IS INDICATED FOR USE IN IMPROVING CEREBRAL ARTERY LUMEN DIAMETER IN PATIENTS 22 TO 80 YEARS OLD WITH RECURRENT (2 OR MORE) STROKES REFRACTORY TO A COMPREHENSIVE REGIMEN OF MEDICAL THERAPY AND DUE TO ATHEROSCLEROTIC DISEASE OF INTRACRANIAL VESSELS WITH 70-99% STENOSIS THAT ARE ACCESSIBLE TO THE SYSTEM. THE MOST RECENT STROKE MUST HAVE OCCURRED MORE THAN 7 DAYS PRIOR TO TREATMENT WITH THE WINGSPAN STENT SYSTEM. PATIENTS ARE ELIGIBLE FOR TREATMENT WITH THE WINGSPAN STENT SYSTEM IF THEIR MODIFIED RANKIN SCORE (MRS) IS 3 OR LESS AT THE TIME OF TREATMENT., EXCELSIOR® SL-10® PRE-SHAPED MICROCATHETER(EXCELSIOR® SL-10® PRE-SHAPED MICROCATHETER)-STRYKER NEUROVASCULAR EXCELSIOR SL-10 PRE-SHAPED MICROCATHETERS ARE INTENDED TO ASSIST IN THE DELIVERY OF DIAGNOSTIC AGENTS, SUCH AS CONTRAST MEDIA, AND THERAPEUTIC AGENTS, SUCH AS OCCLUSION COILS TO THE PERIPHERAL, CORONARY, AND NEUROVASCULATURE., TRANSFORM™ OCCLUSION BALLOON CATHETER(TRANSFORM™ OCCLUSION BALLOON CATHETER)-THE STRYKER NEUROVASCULAR TRANSFORM OCCLUSION BALLOON CATHETER IS INDICATED FOR USE IN THE NEUROVASCULATURE TO TEMPORARILY STOP OR CONTROL BLOOD FLOW, FOR BALLOON-ASSISTED COIL EMBOLIZATION OF INTRACRANIAL ANEURYSMS, AND AS AN ADJUNCT TO THE MEDICAL MANAGEMENT OF VASOSPASMS OR THE TREATMENT OF REFRACTORY SYMPTOMATIC CEREBRAL VASOSPASMS.THE STRYKER NEUROVASCULAR TRANSFORM OCCLUSION BALLOON CATHETER IS INDICATED FOR USE IN THE PERIPHERAL VASCULATURE TO TEMPORARILY STOP OR CONTROL BLOOD FLOW, AND FOR BALLOON-ASSISTED COIL EMBOLIZATION OF

	ANEURYSMS.,EXCELSIOR® XT-17™ MICROCATHETER(EXCELSIOR® XT-17™ MICROCATHETER)-STRYKER NEUROVASCULAR'S EXCELSIOR XT-17 MICROCATHETERS ARE INTENDED TO ASSIST IN THE DELIVERY OF DIAGNOSTIC AGENTS, SUCH AS CONTRAST MEDIA, AND THERAPEUTIC AGENTS, SUCH AS OCCLUSION COILS, INTO THE PERIPHERAL, CORONARY AND NEURO VASCULATURE.,AXS CATALYST™ DISTAL ACCESS CATHETER(AXS CATALYST™ 5 DISTAL ACCESS CATHETER,AXS CATALYST™ 6 DISTAL ACCESS CATHETER, AXS CATALYST™ 7 DISTAL ACCESS CATHETER)-THE AXS CATALYST DISTAL ACCESS CATHETER IS INDICATED FOR USE IN FACILITATING THE INSERTION AND GUIDANCE OF APPROPRIATELY SIZED INTERVENTIONAL DEVICES INTO A SELECTED BLOOD VESSEL IN THE PERIPHERAL AND NEUROVASCULAR SYSTEMS. IT IS ALSO INDICATED FOR THE REMOVAL / ASPIRATION OF SOFT EMBOLI AND THROMBI FROM VESSELS IN THE PERIPHERAL AND NEUROVASCULATURE. , EXCELSIOR® XT-27® MICROCATHETERS(EXCELSIOR® XT-27® MICROCATHETERS)-STRYKER NEUROVASCULAR EXCELSIOR XT-27 MICROCATHETER IS INTENDED TO ASSIST IN THE DELIVERY OF DIAGNOSTIC AGENTS (SUCH AS CONTRAST MEDIA), THERAPEUTIC AGENTS, AND NON-LIQUID INTERVENTIONAL DEVICES (SUCH AS STENTS) THAT ARE INDICATED FOR USE IN THE NEUROVASCULATURE AND WITH A CATHETER OF 0.027 INCHES IN INNER DIAMETER.

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1490	IMP/MD/2019/000019	1.License Holder Name: BLUE NEEM MEDICAL DEVICES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIVER BIOPSY SYSTEM (TLAB TRANSJUGULAR)-FOR TRANSJUGULAR LIVER ACCESS BIOPSY.,RETRIEVABLE VENA CAVA FILTER(OPTION ELITE)-THE OPTION™ ELITE FILTER IS INDICATED FOR THE PREVENTION OF RECURRENT PULMONARY EMBOLISM (PE) VIA PERCUTANEOUS PLACEMENT IN THE INFERIOR VENA CAVA (IVC) IN THE FOLLOWING CONDITIONS: - PULMONARY THROMBOEMBOLISM WHEN ANTICOAGULANTS ARE CONTRAINDICATED - FAILURE OF ANTICOAGULANT THERAPY IN THROMBOEMBOLIC DISEASE - EMERGENCY TREATMENT FOLLOWING MASSIVE PULMONARY EMBOLISM WHERE ANTICIPATED BENEFITS OF CONVENTIONAL THERAPY ARE REDUCED - CHRONIC, RECURRENT PULMONARY EMBOLISM WHERE ANTICOAGULANT THERAPY HAS FAILED OR IS CONTRAINDICATED ,VASCULAR SNARE KIT(ATRIEVE)-THE ATRIEVE™ VASCULAR SNARE KIT IS INTENDED FOR USE IN THE CARDIOVASCULAR SYSTEM OR HOLLOW VISCOUS TO RETRIEVE AND MANIPULATE FOREIGN OBJECTS. MANIPULATION PROCEDURES INCLUDE INDWELLING VENOUS CATHETER REPOSITIONING, INDWELLING VENOUS CATHETER FIBRIN SHEATH STRIPPING, AND CENTRAL VENOUS ACCESS VENI-PUNCTURE PROCEDURE ASSISTANCE.,BIOPSY INSTRUMENT(SUPER CORE)-DISPOSABLE GUILLOTINE SOFT TISSUE INSTRUMENT FOR OBTAINING PERCUTANEOUS OR SURGICAL HISTOLOGICAL SAMPLES, (E.G. LUNG, LIVER, SPLEEN, KIDNEY, PROSTATE, LYMPH NODES, BREAST, THYROID, AND PANCREAS).,FULL CORE BIOPSY INSTRUMENTS(BIO PINCE)-THE DISPOSABLE, AUTOMATIC BIO PINCE FULL CORE BIOPSY INSTRUMENT IS USED TO OBTAIN MULTIPLE CORE SAMPLES FROM SOFT TISSUE SUCH AS LIVER, KIDNEY, ABDOMINAL MASSES, ETC., THROMBECTOMY SYSTEM(CLEANER ROTATIONAL)-THE OPTION™ ELITE FILTER IS INDICATED FOR THE PREVENTION OF RECURRENT PULMONARY EMBOLISM (PE) VIA PERCUTANEOUS PLACEMENT IN THE INFERIOR VENA CAVA (IVC) IN THE FOLLOWING CONDITIONS: - PULMONARY THROMBOEMBOLISM WHEN ANTICOAGULANTS ARE CONTRAINDICATED - FAILURE OF ANTICOAGULANT THERAPY IN THROMBOEMBOLIC DISEASE - EMERGENCY TREATMENT FOLLOWING MASSIVE PULMONARY EMBOLISM WHERE ANTICIPATED BENEFITS OF CONVENTIONAL THERAPY ARE REDUCED - CHRONIC, RECURRENT PULMONARY EMBOLISM WHERE ANTICOAGULANT THERAPY HAS FAILED OR IS CONTRAINDICATED ,BIOPSY INSTRUMENT(TRU-CORE II) -THE TRU-CORE II AUTOMATIC BIOPSY INSTRUMENT IS USED TO OBTAIN MULTIPLE CORE SAMPLES FROM SOFT TISSUE SUCH AS LIVER, KIDNEY, PROSTATE, BREAST, ETC. AND NOT INTENDED FOR

	BONE.,CHRONIC DIALYSIS CATHETER (ULTRASTREAM)-THE ULTRASTREAM CHRONIC HAEMODIALYSIS CATHETER IS DESIGNED FOR CHRONIC HAEMODIALYSIS AND APHERESIS

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1491	IMP/MD/2019/000024	1.License Holder Name: M/S LEPUCARE (INDIA) VASCULAR SOLUTIONS PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PLUG(MEMOPART PLUG)-THE MEMOPARTTM VASCULAR PLUG CAN BE USED FOR A WIDE VARIETY OF OCCLUSIONS OF VEINS OR ARTERIES. REDUCING OR ELIMINATING BLOOD FLOW TO AN AREA OF THE BODY BY BLOCKING. PLUG CAN BE USED FOR PATIENTS WITH CLINICAL SYMPTOMS OF ABNORMAL BLOOD VESSELS, SUCH AS: -- AORTOPULMONARY COLLATERALS -- ARTERIOVENOUS MALFORMATION -- SURGICAL AORTOPULMONARY SHUNTS -- ANOMALOUS VENOVENOUS CONNECTIONS -- ARTERIOVENOUS FISTULAS -- PERIPHERAL VESSELS,PFO OCCLUDER(MEMOPART PFO OCCLUDER)-THE MEMOPARTTM PFO OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER OCCLUSION DEVICE INTENDED TO CLOSE ALL TYPES PFOS (I.E. CLASSICAL AS WELL AS THOSE WITH ANEURYSM OF THE SEPTUM) IN PATIENTS WITH A HISTORY OF STROKE OR TRANSIENT ISCHEMIC ATTACKS (TIAS) DIAGNOSED BY ECHOCARDIOGRAPHY WITH RIGHT – TO - LEFT SHUNTING DURING THE VALSALVA MANOEUVRE.,OCCLUDER DELIVERY SYSTEM (MEMOPART OCCLUDER DELIVERY SYSTEM)-MEMOPARTTM OCCLUDER DELIVERY SYSTEM IS INTENDED TO PROVIDE A PATHWAY THROUGH WHICH DEVICES ARE INTRODUCED WITHIN THE CHAMBERS AND CORONARY VASCULATURE OF THE HEART OR IN THE PERIPHERAL VASCULATURE.,SNARE(MEMOPART SNARE)-THE MEMOPART SNARE IS USED IN THE RETRIEVAL AND MANIPULATION OF ATRAUMATIC FOREIGN BODIES LOCATED IN THE CORONARY AND PERIPHERAL CARDIOVASCULAR SYSTEM.,PDA OCCLUDER (MEMOPART PDA CCLUDER)-THE MEMOPARTTM PDA OCCLUDER CAN BE USED FOR THE NONSURGICAL CLOSURE OF A PATENT DUCTUS ARTERIOSUS (PDA) IN THE PERCUTANEOUS, TRANSCATHETER THERAPY.,VSD OCCLUDER(MEMOPART VSD OCCLUDER)-1. THE MEMOPARTTM MUSCULAR VSD OCCLUDER IS USED FOR PATIENTS WHO HAVE LARGE VENTRICULAR SEPTAL DEFECTS. 2. THE MEMOPARTTM MUSCULAR VSD OCCLUDER IS USED FOR OCCLUSION OF MEMBRANOUS VENTRICULAR SEPTAL DEFECT WITH A DIAMETER BETWEEN 4-16 MM AND THE DISTANCE FROM THE EDGE OF THE DEFECT TO THE AORTA AND TO THE TRICUSPID VALVE BEING MORE THAN 3 MM AT THE PRESENCE OF LEFT-TO-RIGHT SHUNT ACCOMPANIED BY RIGHT VENTRICULAR OVERLOADING.,ASD OCCLUDER(MEMOPART ASD OCCLUDER)-THE MEMOPARTTM ASD OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER, ATRIAL SEPTAL DEFECT CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF ATRIAL SEPTAL DEFECTS (ASD) IN SECUNDUM POSITION OR PATIENTS WHO

		HAVE UNDERGONE A FENESTRATED FONTAN PROCEDURE AND WHO REQUIRE CLOSURE OF THE FENESTRATION. PATIENTS INDICATED FOR ASD CLOSURE HAVE ECHOCARDIOGRAPHIC EVIDENCE OF OSTIUM SECUNDUM ATRIAL SEPTAL DEFECT AND CLINICAL EVIDENCE OF RIGHT VENTRICULAR VOLUME OVERLOADI.E.,1.5:1 DEGREE OF LEFT-TO-RIGHT SHUNT OR RV ENLARGEMENT).
1492	IMP/MD/2019/000025	1.License Holder Name: SMITHS MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FLUID WARMING SET (WARMER HOTLINE)-THE HOTLINE WARMING SET IS A SINGLE USE DEVICE, DESIGNED TO WARM BLOOD, AND INTRAVENOUS FLUIDS AND DELIVER THEM TO THE PATIENTS INTRAVENOUS ACCESS SITE AT NORMOTHERMIC TEMPERATURES UNDER GRAVITY FLOW CONDITIONS,NORMOTHERMIC I.V. FLUID ADMINISTRATION SET (LEVEL 1)-THE DI-100, DI-300 AND DI-60HL DISPOSABLE SETS IS A SINGLE PATIENT USE DISPOSABLE I.V. FLUID ADMINISTRATION SET, DESIGNED FOR USE BY TRAINED MEDICAL PROFESSIONALS FOR WARMING BLOOD AND I.V. SOLUTIONS. IT IS INTENDED FOR USE WITH LEVEL 1 H-1200 FAST FLOW WARMERS ONLY.,AMBULATORY PUMP DISPOSABLES(CADD)-CADD DISPOSABLES PUMPS ARE DESIGNED TO BE USED IN VARIETY OF CADD PUMPS FOR MEDICATION DELIVERY

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1493	IMP/MD/2019/000026	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TISSUE HEART VALVE (TRIFECTA VALVE AORTIC)-THE TRIFECTA VALVE IS INTENDED AS A REPLACEMENT FOR A DISEASED, DAMAGED, OR MALFUNCTIONING AORTIC HEART VALVE. THE TRIFECTA VALVE MAY ALSO BE USED AS REPLACEMENT FOR PREVIOUSLY IMPLANTED AORTIC PROSTHETIC HEART VALVES,TISSUE HEART VALVE(TRIFECTA VALVE WITH GLIDE TECHNOLOGY AORTIC)-THE VALVE IS INTENDED AS A REPLACEMENT FOR A DISEASED, DAMAGED, OR MALFUNCTIONING AORTIC HEART VALVE. THE VALVE MAY ALSO BE USED AS A REPLACEMENT FOR A PREVIOUSLY IMPLANTED AORTIC PROSTHETIC HEART VALVE. , HEART VALVE(EPIC SUPRA VALVE AORTIC)-THE EPIC SUPRA VALVE IS INDICATED FOR PATIENTS REQUIRING REPLACEMENT OF A DISEASED, DAMAGED, OR MALFUNCTIONING NATIVE AORTIC HEART VALVE. THE EPIC SUPRA VALVE MAY ALSO BE USED AS REPLACEMENT FOR PREVIOUSLY IMPLANTED AORTIC PROSTHETIC HEART VALVES.,HEART VALVE(EPIC VALVE AORTIC AND MITRAL)-EPIC VALVES ARE INDICATED FOR PATIENTS REQUIRING REPLACEMENT OF A DISEASED, DAMAGED, OR MALFUNCTIONING NATIVE AORTIC AND/OR MITRAL HEART VALVE. EPIC VALVES MAY ALSO BE USED AS REPLACEMENTS FOR PREVIOUSLY IMPLANTED AORTIC AND/OR MITRAL PROSTHETIC HEART VALVES.,HEART VALVE (BIOCOR VALVE AORTIC AND MITRAL)-BIOCOR VALVES ARE INDICATED FOR PATIENTS REQUIRING REPLACEMENT OF A DISEASED, DAMAGED, OR MALFUNCTIONING NATIVE AORTIC AND/OR MITRAL HEART VALVE. BIOCOR VALVES MAY ALSO BE USED AS REPLACEMENTS FOR PREVIOUSLY IMPLANTED AORTIC AND/OR MITRAL PROSTHETIC HEART VALVES

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1494	IMP/MD/2019/000027	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LARYNGEAL MASK AIRWAY(LMA PROTECTOR CUFF PILOT)-THE LMA PROTECTOR™ CUFF PILOT™ ARE INDICATED FOR USE IN ACHIEVING, AND MAINTAINING CONTROL OF, THE PATIENT'S AIRWAY DURING ROUTINE ANAESTHETICPROCEDURES, IN FASTED PATIENTS, USING EITHER SPONTANEOUS OR POSITIVE PRESSURE VENTILATION. IT IS ALSO INDICATED FOR USE AS A RESCUE AIRWAY DEVICE IN CPR PROCEDURES, IN WHICH LMA PROSEAL™, LMA CLASSIC™ OR THE LMA UNIQUE™ HAVE TRADITIONALLY BEEN USED. THIS DEVICE IS ALSO INDICATED AS A "RESCUE AIRWAY DEVICE" IN KNOWN, OR UNEXPECTED DIFFICULT AIRWAY SITUATIONS. THIS DEVICE MAY BE USED TO ESTABLISH AN IMMEDIATE, CLEAR AIRWAY DURING RESUSCITATION IN THE PROFOUNDLY UNCONSCIOUS PATIENT WITH ABSENT GLOSSOPHARYNGEAL AND LARYNGEAL REFLEXES WHO MAY NEED ARTIFICIAL VENTILATION. IT MAY ALSO BE USED TO SECURE AN IMMEDIATE AIRWAY WHEN TRACHEAL INTUBATION IS PRECLUDED DUE TO LACK OF AVAILABLE EXPERTISE OR EQUIPMENT, OR WHEN ATTEMPTS AT TRACHEAL INTUBATION HAVE FAILED.,LARYNGEAL MASK AIRWAY(LMA® SUPREME™)-THE LMA SUPREME IS INDICATED FOR USE IN ACHIEVING AND MAINTAINING CONTROL OF AIRWAY DURING ROUTINE AND EMERGENCY ANAESTHETIC PROCEDURES IN FASTED PATIENTS USING EITHER SPONTANEOUS OR POSITIVE PRESSURE VENTILATION. IT IS ALSO INDICATED FOR USE AS THE RESCUE AIRWAY DEVICE IN CPR PROCEDURES, IN WHICH THE LMA PROSEAL, LMA CLASSIC OR THE LMA UNIQUE HAVE TRADITIONALLY BEEN USED. THE LMA SUPREME IS ALSO INDICATED AS A "RESCUE AIRWAY DEVICE" IN KNOWN OR UNEXPECTED DIFFICULT AIRWAY SITUATIONS. THE LMA SUPREME MAY BE USED TO ESTABLISH AN IMMEDIATE CLEAR AIRWAY DURING RESUSCITATION IN THE PROFOUNDLY UNCONSCIOUS PATIENT WITH ABSENT GLOSSOPHARYNGEAL AND LARYNGEAL REFLEXES WHO MAY NEED ARTIFICIAL VENTILATION. IT MAY ALSO BE USED TO SECURE AN IMMEDIATE AIRWAY WHEN TRACHEAL INTUBATION IS PRECLUDED BY LACK OF AVAILABLE EXPERTISE OR EQUIPMENT, OR WHEN ATTEMPTS AT TRACHEAL INTUBATION HAVE FAILED., LARYNGEAL MASK AIRWAY(LMA® GASTRO™ CUFF PILOT™)-LMA® GASTRO™ CUFF PILOT™ IS INDICATED FOR USE IN ACHIEVING AND MAINTAINING CONTROL OF THE PATIENT'S AIRWAY WHILE PROVIDING DIRECT ACCESS TO THE OESOPHAGUS AND UPPER GASTROINTESTINAL TRACT IN ADULT PATIENTS UNDERGOING ENDOSCOPIC PROCEDURES. IT CAN BE USED FOR EITHER SPONTANEOUS RESPIRATION OR POSITIVE PRESSURE VENTILATION.,

		LARYNGEAL MASK AIRWAY(LMA PROTECTOR)-THE LMA PROTECTOR™ IS INDICATED FOR USE IN ACHIEVING, AND MAINTAINING CONTROL OF, THE PATIENT'S AIRWAY DURING ROUTINE ANAESTHETIC PROCEDURES, IN FASTED PATIENTS, USING EITHER SPONTANEOUS OR POSITIVE PRESSURE VENTILATION. IT IS ALSO INDICATED FOR USE AS A RESCUE AIRWAY DEVICE IN CPR PROCEDURES, IN WHICH LMA PROSEAL™, LMA CLASSIC™ OR THE LMA UNIQUE™ HAVE TRADITIONALLY BEEN USED. THIS DEVICE IS ALSO INDICATED AS A "RESCUE AIRWAY DEVICE" IN KNOWN, OR UNEXPECTED DIFFICULT AIRWAY SITUATIONS. THIS DEVICE MAY BE USED TO ESTABLISH AN IMMEDIATE, CLEAR AIRWAY DURING RESUSCITATION IN THE PROFOUNDLY UNCONSCIOUS PATIENT WITH ABSENT GLOSSOPHARYNGEAL AND LARYNGEAL REFLEXES WHO MAY NEED ARTIFICIAL VENTILATION. IT MAY ALSO BE USED TO SECURE AN IMMEDIATE AIRWAY WHEN TRACHEAL INTUBATION IS PRECLUDED DUE TO LACK OF AVAILABLE EXPERTISE OR EQUIPMENT, OR WHEN ATTEMPTS AT TRACHEAL INTUBATION HAVE FAILED.
1495	IMP/MD/2019/000028	1.License Holder Name: FRESENIUS KABI INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PLATELET ADDITIVE SOLUTION(INTERSOL)-PLASMA REPLACEMENT FLUID FOR THE PREPARATION AND STORAGE OF PLATELET CONCENTRATES IN ROUTINE BLOOD BANKING CONDITIONS UNTIL THE PLATELETS ARE TRANSFUSED TO PATIENTS REQUIRING SUCH TRANSFUSIONS.

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1496	IMP/MD/2019/000029	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SHOULDER REPLACEMENT SYSTEM (HEAD)(GLOBAL AP CTA)-THE DEPUY GLOBAL ADVANTAGE AND GLOBAL AP SHOULDER SYSTEMS ARE INDICATED FOR USE IN TOTAL OR HEMISHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS; 2. FRACTURE-DISLOCATIONS OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY; 3. OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT). THE DEPUY GLOBAL ADVANTAGE, AND GLOBAL AP SHOULDER SYSTEMS ARE ALSO INDICATED FOR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. UNUNITED HUMERAL HEAD FRACTURES; 2. AVASCULAR NECROSIS OF THE HUMERAL HEAD. THE DEPUY GLOBAL ADVANTAGE AND GLOBAL AP CTA HUMERAL HEADS ARE INDICATED ONLY FOR HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE DEPUY GLOBAL ADVANTAGE CTA HUMERAL HEADS CAN BE USED WITH THE GLOBAL FX AND GLOBAL ADVANTAGE HUMERAL STEMS AND THE GLOBAL AP CTA HUMERAL HEAD CAN BE USED WITH THE GLOBAL AP HUMERAL STEM IN HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE DEPUY GLOBAL FX, GLOBAL ADVANTAGE AND GLOBAL AP SHOULDER SYSTEMS ARE INDICATED FOR THE FOLLOWING FIXATION METHODS: • POROCOAT™ POROUS-COATED COMPONENTS - POROCOAT POROUS-COATED HUMERAL STEM PROSTHESES ARE INDICATED FOR CEMENTED OR UNCEMENTED USE WITH FIXATION PROVIDED BY BIOLOGICAL TISSUE INGROWTH INTO THE POROUS COATING. • CEMENTED COMPONENTS - HUMERAL STEM AND GLENOID COMPONENTS LABELED "FOR CEMENTED USE ONLY" ARE INDICATED ONLY FOR USE WITH BONE CEMENT. • PRESS-FIT OR CEMENTED COMPONENTS - HUMERAL STEM PROSTHESES WITHOUT POROUS COATING AND LABELED "FOR PRESS-FIT OR CEMENTED USE ONLY" ARE INDICATED FOR PRESS-FIT UNCEMENTED USE OR FOR USE WITH BONE CEMENT.,KNEE REPLACEMENT SYSTEM-SLEEVE (UNIVERSAL FEMORAL SLEEVE)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS

	EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. ,SHOULDER REPLACEMENT SYSTEM (HEAD)(GLOBAL AP)-THE DEPUY GLOBAL ADVANTAGE AND GLOBAL AP SHOULDER SYSTEMS ARE INDICATED FOR USE IN TOTAL OR HEMISHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS; 2. FRACTURE-DISLOCATIONS OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY; 3. OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT). THE DEPUY GLOBAL ADVANTAGE, AND GLOBAL AP SHOULDER SYSTEMS ARE ALSO INDICATED FOR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. UNUNITED HUMERAL HEAD FRACTURES; 2. AVASCULAR NECROSIS OF THE HUMERAL HEAD. THE DEPUY GLOBAL ADVANTAGE AND GLOBAL AP CTA HUMERAL HEADS ARE INDICATED ONLY FOR HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE DEPUY GLOBAL ADVANTAGE CTA HUMERAL HEADS CAN BE USED WITH THE GLOBAL FX AND GLOBAL ADVANTAGE HUMERAL STEMS AND THE GLOBAL AP CTA HUMERAL HEAD CAN BE USED WITH THE GLOBAL AP HUMERAL STEM IN HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE DEPUY GLOBAL FX, GLOBAL ADVANTAGE AND GLOBAL AP SHOULDER SYSTEMS ARE INDICATED FOR THE FOLLOWING FIXATION METHODS: • POROCOAT™ POROUS-COATED COMPONENTS - POROCOAT POROUS-COATED HUMERAL STEM PROSTHESES ARE INDICATED FOR CEMENTED OR UNCEMENTED USE WITH FIXATION PROVIDED BY BIOLOGICAL TISSUE INGROWTH INTO THE POROUS COATING. • CEMENTED COMPONENTS - HUMERAL STEM AND GLENOID COMPONENTS LABELED "FOR CEMENTED USE ONLY" ARE INDICATED ONLY FOR USE WITH BONE CEMENT. • PRESS-FIT OR

	CEMENTED COMPONENTS - HUMERAL STEM PROSTHESES WITHOUT POROUS COATING AND LABELED “FOR PRESS-FIT OR CEMENTED USE ONLY” ARE INDICATED FOR PRESS-FIT UNCEMENTED USE OR FOR USE WITH BONE CEMENT.,HIP REPLACEMENT SYSTEM-STEM(TRI-LOCK BONE PRESERVATION SYSTEM (BPS))-IT IS INTENDED FOR TOTAL HIP PROSTHESIS, HEMI-HIP PROSTHESIS, AND SELF-CENTERING HIP PROSTHESIS. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESIS AND HEMI-HIP PROSTHESIS ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.,SHOULDER REPLACEMENT SYSTEM (STEM)(GLOBAL AP)-THE DEPUY GLOBAL ADVANTAGE AND GLOBAL AP SHOULDER SYSTEMS ARE INDICATED FOR USE IN TOTAL OR HEMISHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS; 2. FRACTURE-DISLOCATIONS OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON’S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY; 3. OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT). THE DEPUY GLOBAL ADVANTAGE, AND GLOBAL AP SHOULDER SYSTEMS ARE ALSO INDICATED FOR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. UNUNITED HUMERAL HEAD FRACTURES; 2. AVASCULAR NECROSIS OF THE HUMERAL HEAD. THE DEPUY GLOBAL ADVANTAGE AND GLOBAL AP CTA HUMERAL HEADS ARE INDICATED ONLY FOR HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE DEPUY GLOBAL ADVANTAGE CTA HUMERAL HEADS CAN BE USED WITH THE GLOBAL FX AND GLOBAL ADVANTAGE HUMERAL STEMS AND THE GLOBAL AP CTA HUMERAL HEAD CAN BE USED WITH THE GLOBAL AP HUMERAL STEM IN HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE DEPUY GLOBAL FX, GLOBAL ADVANTAGE AND GLOBAL AP SHOULDER SYSTEMS ARE INDICATED FOR THE FOLLOWING FIXATION METHODS: • POROCOAT™ POROUS-COATED COMPONENTS - POROCOAT POROUS-COATED HUMERAL STEM PROSTHESES ARE INDICATED FOR CEMENTED OR UNCEMENTED USE WITH FIXATION

	PROVIDED BY BIOLOGICAL TISSUE INGROWTH INTO THE POROUS COATING. • CEMENTED COMPONENTS - HUMERAL STEM AND GLENOID COMPONENTS LABELED “FOR CEMENTED USE ONLY” ARE INDICATED ONLY FOR USE WITH BONE CEMENT. • PRESS-FIT OR CEMENTED COMPONENTS - HUMERAL STEM PROSTHESES WITHOUT POROUS COATING AND LABELED “FOR PRESS-FIT OR CEMENTED USE ONLY” ARE INDICATED FOR PRESS-FIT UNCEMENTED USE OR FOR USE WITH BONE CEMENT.,KNEE REPLACEMENT SYSTEM-TIBIAL TRAY (M.B.T. REVISION)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,SHOULDER REPLACEMENT SYSTEM (GLENOID)(GLOBAL AP)-THE DEPUY GLOBAL ADVANTAGE AND GLOBAL AP SHOULDER SYSTEMS ARE INDICATED FOR USE IN TOTAL OR HEMISHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS; 2. FRACTURE-DISLOCATIONS OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON’S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY; 3. OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT). THE DEPUY GLOBAL ADVANTAGE, AND GLOBAL AP SHOULDER SYSTEMS ARE ALSO INDICATED FOR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. UNUNITED HUMERAL HEAD FRACTURES; 2. AVASCULAR NECROSIS OF THE HUMERAL HEAD. THE DEPUY GLOBAL ADVANTAGE AND GLOBAL AP CTA HUMERAL HEADS ARE INDICATED ONLY FOR HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE DEPUY GLOBAL ADVANTAGE CTA HUMERAL HEADS CAN BE USED WITH THE GLOBAL FX AND GLOBAL

	ADVANTAGE HUMERAL STEMS AND THE GLOBAL AP CTA HUMERAL HEAD CAN BE USED WITH THE GLOBAL AP HUMERAL STEM IN HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE DEPUY GLOBAL FX, GLOBAL ADVANTAGE AND GLOBAL AP SHOULDER SYSTEMS ARE INDICATED FOR THE FOLLOWING FIXATION METHODS: • POROCOAT™ POROUS-COATED COMPONENTS - POROCOAT POROUS-COATED HUMERAL STEM PROSTHESES ARE INDICATED FOR CEMENTED OR UNCEMENTED USE WITH FIXATION PROVIDED BY BIOLOGICAL TISSUE INGROWTH INTO THE POROUS COATING. • CEMENTED COMPONENTS - HUMERAL STEM AND GLENOID COMPONENTS LABELED “FOR CEMENTED USE ONLY” ARE INDICATED ONLY FOR USE WITH BONE CEMENT. • PRESS-FIT OR CEMENTED COMPONENTS - HUMERAL STEM PROSTHESES WITHOUT POROUS COATING AND LABELED “FOR PRESS-FIT OR CEMENTED USE ONLY” ARE INDICATED FOR PRESS-FIT UNCEMENTED USE OR FOR USE WITH BONE CEMENT.,KNEE REPLACEMENT SYSTEM-SLEEVE(M.B.T. REVISION)-THE MOBILE BEARING TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE RPF AND RPS INSERTS AND FEMORAL COMPONENTS ARE INDICATED WHERE A HIGHER THAN NORMAL DEGREE OF POST-OPERATIVE FLEXION IS REQUIRED. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES. THE POROUS COATED KEELED AND NON KEELED M.B.T (MOBILE BEARING TIBIAL) TRAY CONFIGURATIONS OF THE LCS TOTAL KNEE SYSTEM ARE INDICATED FOR NONCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR RECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE ROTATING PLATFORM DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE ABSENT OR ARE IN SUCH CONDITION AS TO JUSTIFY THEIR SACRIFICE. ,HIP/KNEE REPLACEMENT SYSTEM-INTERCALARY SEGMENT(LIMB PRESERVATION SYSTEM (LPS))-THE LPS SYSTEM IS INTENDED FOR USE IN REPLACEMENT OF THE MID-SHAFT PORTION OF THE FEMUR, PROXIMAL, DISTAL AND/OR TOTAL FEMUR, AND PROXIMAL TIBIA, ESPECIALLY IN CASES THAT REQUIRE EXTENSIVE RESECTION AND REPLACEMENT. SPECIFIC DIAGNOSTIC INDICATIONS FOR USE INCLUDE: 1. MALIGNANT TUMORS (E.G., OSTEOSARCOMAS, CHONDROSARCOMAS, GIANT CELL TUMORS, BONE TUMORS) REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 2. PATIENT CONDITIONS OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE

	(NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS, REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 3. REVISION CASES FOR A FAILED PREVIOUS PROSTHESIS REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 4. SEVERE TRAUMA REQUIRING EXTENSIVE RESECTION AND REPLACEMENT. THE LPS SYSTEM IS ALSO INTENDED FOR USE IN BONE LOSS POST-INFECTION, WHERE THE SURGEON HAS ELECTED TO EXCISE THE BONE AND REPLACEMENT IS REQUIRED.,HIP/KNEE REPLACEMENT SYSTEM-FEMORAL SEGMENT COMPONENT(LIMB PRESERVATION SYSTEM (LPS))-THE LPS SYSTEM IS INTENDED FOR USE IN REPLACEMENT OF THE MID-SHAFT PORTION OF THE FEMUR, PROXIMAL, DISTAL AND/OR TOTAL FEMUR, AND PROXIMAL TIBIA, ESPECIALLY IN CASES THAT REQUIRE EXTENSIVE RESECTION AND REPLACEMENT. SPECIFIC DIAGNOSTIC INDICATIONS FOR USE INCLUDE: 1. MALIGNANT TUMORS (E.G., OSTEOSARCOMAS, CHONDROSARCOMAS, GIANT CELL TUMORS, BONE TUMORS) REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 2. PATIENT CONDITIONS OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS, REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 3. REVISION CASES FOR A FAILED PREVIOUS PROSTHESIS REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 4. SEVERE TRAUMA REQUIRING EXTENSIVE RESECTION AND REPLACEMENT. THE LPS SYSTEM IS ALSO INTENDED FOR USE IN BONE LOSS POST-INFECTION, WHERE THE SURGEON HAS ELECTED TO EXCISE THE BONE AND REPLACEMENT IS REQUIRED.,HIP/KNEE REPLACEMENT SYSTEM-PROXIMAL FEMORAL BODY(LIMB PRESERVATION SYSTEM (LPS))-THE LPS SYSTEM IS INTENDED FOR USE IN REPLACEMENT OF THE MID-SHAFT PORTION OF THE FEMUR, PROXIMAL, DISTAL AND/OR TOTAL FEMUR, AND PROXIMAL TIBIA, ESPECIALLY IN CASES THAT REQUIRE EXTENSIVE RESECTION AND REPLACEMENT. SPECIFIC DIAGNOSTIC INDICATIONS FOR USE INCLUDE: 1. MALIGNANT TUMORS (E.G., OSTEOSARCOMAS, CHONDROSARCOMAS, GIANT CELL TUMORS, BONE TUMORS) REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 2. PATIENT CONDITIONS OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS, REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 3. REVISION CASES FOR A FAILED PREVIOUS PROSTHESIS REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 4. SEVERE TRAUMA REQUIRING EXTENSIVE RESECTION AND REPLACEMENT. THE LPS SYSTEM IS ALSO INTENDED FOR USE IN BONE LOSS POST-INFECTION, WHERE

	THE SURGEON HAS ELECTED TO EXCISE THE BONE AND REPLACEMENT IS REQUIRED.,HIP/KNEE REPLACEMENT SYSTEM-SEGMENTAL COMPONENT(LIMB PRESERVATION SYSTEM (LPS))-THE LPS SYSTEM IS INTENDED FOR USE IN REPLACEMENT OF THE MID-SHAFT PORTION OF THE FEMUR, PROXIMAL, DISTAL AND/OR TOTAL FEMUR, AND PROXIMAL TIBIA, ESPECIALLY IN CASES THAT REQUIRE EXTENSIVE RESECTION AND REPLACEMENT. SPECIFIC DIAGNOSTIC INDICATIONS FOR USE INCLUDE: 1. MALIGNANT TUMORS (E.G., OSTEOSARCOMAS, HONDROSARCOMAS, GIANT CELL TUMORS, BONE TUMORS) REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 2. PATIENT CONDITIONS OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS, REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 3. REVISION CASES FOR A FAILED PREVIOUS PROSTHESIS REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 4. SEVERE TRAUMA REQUIRING EXTENSIVE RESECTION AND REPLACEMENT. THE LPS SYSTEM IS ALSO INTENDED FOR USE IN BONE LOSS POST-INFECTION, WHERE THE SURGEON HAS ELECTED TO EXCISE THE BONE AND REPLACEMENT IS REQUIRED.,SHOULDER REPLACEMENT SYSTEM-GLENOID PEG(GLOBAL)-THE GLOBAL SHOULDER SYSTEM IS INDICATED FOR USE IN TOTAL OR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF:1. A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS; 2. FRACTURE-DISLOCATIONS OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY; 3. OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT). THE GLOBAL SHOULDER SYSTEM IS ALSO INDICATED FOR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. UNUNITED HUMERAL HEAD FRACTURES; 2. AVASCULAR NECROSIS OF THE HUMERAL HEAD. THE HUMERAL STEMS WHEN USED WITH A GLOBAL HUMERAL HEAD AND THE GLOBAL HUMERAL STEM WHEN USED WITH A GLOBAL HUMERAL HEAD ARE INDICATED FOR HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE GLOBAL SHOULDER SYSTEM IS INDICATED FOR THE FOLLOWING FIXATION METHODS: 1) POROCOAT POROUS-COATED COMPONENTS - POROCOAT POROUS-COATED HUMERAL STEM PROSTHESES ARE INDICATED FOR CEMENTED OR UNCEMENTED USE WITH FIXATION PROVIDED BY BIOLOGICAL TISSUE INGROWTH INTO THE POROUS COATING. 2)

	CEMENTED COMPONENTS - HUMERAL STEM AND GLENOID COMPONENTS LABELED “FOR CEMENTED USE ONLY” ARE INDICATED ONLY FOR USE WITH BONE CEMENT. 3) PRESS-FIT OR CEMENTED COMPONENTS - HUMERAL STEM PROSTHESIS WITHOUT POROUS COATING AND LABELED “FOR PRESS-FIT OR CEMENTED USE ONLY” ARE INDICATED FOR PRESS-FIT UNCEMENTED USE OR FOR USE WITH BONE CEMENT. THE GLOBAL RESURFACING SHOULDER HUMERAL HEADS ARE INTENDED AS A TOTAL OR HEMI-SHOULDER REPLACEMENT IN PATIENTS WHERE THE HUMERAL HEAD AND NECK ARE OF SUFFICIENT BONE STOCK AND THE ROTATOR CUFF IS INTACT OR RECONSTRUCTABLE. THIS DEVICE IS DESIGNED TO INCREASE SHOULDER MOBILITY BY: REDUCING PAIN; RESTORING ALIGNMENT; RESTORING FLEXION AND EXTENSION MOVEMENT; AND RESISTING DISLOCATION. THE GLOBAL RESURFACING SHOULDER HUMERAL HEADS ARE INDICATED FOR USE AS A REPLACEMENT OF SHOULDER JOINTS DISABLED BY RHEUMATOID ARTHRITIS WITH PAIN, NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (I.E. OSTEOARTHRITIS AND AVASCULAR NECROSIS), DEFORMITY AND/OR LIMITED MOTION, FRACTURES OF THE HUMERAL HEAD AND TRAUMATIC ARTHRITIS. THE GLOBAL RESURFACING SHOULDER HUMERAL HEADS ARE INTENDED FOR UNCEMENTED USE ONLY. , HIP/KNEE REPLACEMENT SYSTEM-DISTAL FEMORAL COMPONENT (LIMB PRESERVATION SYSTEM (LPS))-THE LPS SYSTEM IS INTENDED FOR USE IN REPLACEMENT OF THE MID-SHAFT PORTION OF THE FEMUR, PROXIMAL, DISTAL AND/OR TOTAL FEMUR, AND PROXIMAL TIBIA, ESPECIALLY IN CASES THAT REQUIRE EXTENSIVE RESECTION AND REPLACEMENT. SPECIFIC DIAGNOSTIC INDICATIONS FOR USE INCLUDE: 1. MALIGNANT TUMORS (E.G., OSTEOSARCOMAS, CHONDROSARCOMAS, GIANT CELL TUMORS, BONE TUMORS) REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 2. PATIENT CONDITIONS OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS, REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 3. REVISION CASES FOR A FAILED PREVIOUS PROSTHESIS REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 4. SEVERE TRAUMA REQUIRING EXTENSIVE RESECTION AND REPLACEMENT. THE LPS SYSTEM IS ALSO INTENDED FOR USE IN BONE LOSS POST-INFECTION, WHERE THE SURGEON HAS ELECTED TO EXCISE THE BONE AND REPLACEMENT IS REQUIRED. ,HIP/KNEE REPLACEMENT SYSTEM-PROXIMAL TIBIAL(LIMB PRESERVATION SYSTEM (LPS))-THE LPS SYSTEM IS INTENDED FOR USE IN REPLACEMENT OF THE MID-SHAFT PORTION OF THE FEMUR, PROXIMAL, DISTAL AND/OR TOTAL FEMUR, AND PROXIMAL TIBIA, ESPECIALLY IN CASES THAT REQUIRE

	EXTENSIVE RESECTION AND REPLACEMENT. SPECIFIC DIAGNOSTIC INDICATIONS FOR USE INCLUDE: 1. MALIGNANT TUMORS (E.G., OSTEOSARCOMAS, CHONDROSARCOMAS, GIANT CELL TUMORS, BONE TUMORS) REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 2. PATIENT CONDITIONS OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS, REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 3. REVISION CASES FOR A FAILED PREVIOUS PROSTHESIS REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 4. SEVERE TRAUMA REQUIRING EXTENSIVE RESECTION AND REPLACEMENT. THE LPS SYSTEM IS ALSO INTENDED FOR USE IN BONE LOSS POST-INFECTION, WHERE THE SURGEON HAS ELECTED TO EXCISE THE BONE AND REPLACEMENT IS REQUIRED.,HIP/KNEE REPLACEMENT SYSTEM-STEMS(LIMB PRESERVATION SYSTEM (LPS))-THE LPS SYSTEM IS INTENDED FOR USE IN REPLACEMENT OF THE MID-SHAFT PORTION OF THE FEMUR, PROXIMAL, DISTAL AND/OR TOTAL FEMUR, AND PROXIMAL TIBIA, ESPECIALLY IN CASES THAT REQUIRE EXTENSIVE RESECTION AND REPLACEMENT. SPECIFIC DIAGNOSTIC INDICATIONS FOR USE INCLUDE: 1. MALIGNANT TUMORS (E.G., OSTEOSARCOMAS, CHONDROSARCOMAS, GIANT CELL TUMORS, BONE TUMORS) REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 2. PATIENT CONDITIONS OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS, REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 3. REVISION CASES FOR A FAILED PREVIOUS PROSTHESIS REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; 4. SEVERE TRAUMA REQUIRING EXTENSIVE RESECTION AND REPLACEMENT. THE LPS SYSTEM IS ALSO INTENDED FOR USE IN BONE LOSS POST-INFECTION, WHERE THE SURGEON HAS ELECTED TO EXCISE THE BONE AND REPLACEMENT IS REQUIRED.,FINGER REPLACEMENT SYSTEM(NEUFLEX)-THE NEUFLEX FINGER JOINT PROSTHESES ARE INDICATED FOR CEMENTLESS REPLACEMENT OF THE METACARPOPHALANGEAL (MCP) AND INTERPHALANGEAL (PIP) JOINTS, RESPECTIVELY, WHERE DISABLED BY RHEUMATOID, DEGENERATIVE OR TRAUMATIC ARTHRITIS. ,SHOULDER REPLACEMENT SYSTEM-HEAD(GLOBAL CAP)-THE GLOBAL SHOULDER SYSTEM IS INDICATED FOR USE IN TOTAL OR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF:1. A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS; 2. FRACTURE-DISLOCATIONS OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY

	COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY; 3. OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT). THE GLOBAL SHOULDER SYSTEM IS ALSO INDICATED FOR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. UNUNITED HUMERAL HEAD FRACTURES; 2. AVASCULAR NECROSIS OF THE HUMERAL HEAD. THE HUMERAL STEMS WHEN USED WITH A GLOBAL HUMERAL HEAD AND THE GLOBAL HUMERAL STEM WHEN USED WITH A GLOBAL HUMERAL HEAD ARE INDICATED FOR HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE GLOBAL SHOULDER SYSTEM IS INDICATED FOR THE FOLLOWING FIXATION METHODS: 1) POROCOAT POROUS-COATED COMPONENTS - POROCOAT POROUS-COATED HUMERAL STEM PROSTHESES ARE INDICATED FOR CEMENTED OR UNCEMENTED USE WITH FIXATION PROVIDED BY BIOLOGICAL TISSUE INGROWTH INTO THE POROUS COATING. 2) CEMENTED COMPONENTS - HUMERAL STEM AND GLENOID COMPONENTS LABELED "FOR CEMENTED USE ONLY" ARE INDICATED ONLY FOR USE WITH BONE CEMENT. 3) PRESS-FIT OR CEMENTED COMPONENTS - HUMERAL STEM PROSTHESIS WITHOUT POROUS COATING AND LABELED "FOR PRESS-FIT OR CEMENTED USE ONLY" ARE INDICATED FOR PRESS-FIT UNCEMENTED USE OR FOR USE WITH BONE CEMENT. THE GLOBAL RESURFACING SHOULDER HUMERAL HEADS ARE INTENDED AS A TOTAL OR HEMI-SHOULDER REPLACEMENT IN PATIENTS WHERE THE HUMERAL HEAD AND NECK ARE OF SUFFICIENT BONE STOCK AND THE ROTATOR CUFF IS INTACT OR RECONSTRUCTABLE. THIS DEVICE IS DESIGNED TO INCREASE SHOULDER MOBILITY BY: REDUCING PAIN; RESTORING ALIGNMENT; RESTORING FLEXION AND EXTENSION MOVEMENT; AND RESISTING DISLOCATION. THE GLOBAL RESURFACING SHOULDER HUMERAL HEADS ARE INDICATED FOR USE AS A REPLACEMENT OF SHOULDER JOINTS DISABLED BY RHEUMATOID ARTHRITIS WITH PAIN, NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (I.E. OSTEOARTHRITIS AND AVASCULAR NECROSIS), DEFORMITY AND/OR LIMITED MOTION, FRACTURES OF THE HUMERAL HEAD AND TRAUMATIC ARTHRITIS. THE GLOBAL RESURFACING SHOULDER HUMERAL HEADS ARE INTENDED FOR UNCEMENTED USE ONLY. , SHOULDER REPLACEMENT SYSTEM-HEAD(GLOBAL ADVANTAGE)- THE GLOBAL SHOULDER SYSTEM IS INDICATED FOR USE IN TOTAL OR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF:1. A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID

	ARTHRITIS; 2. FRACTURE-DISLOCATIONS OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY; 3. OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT). THE GLOBAL SHOULDER SYSTEM IS ALSO INDICATED FOR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. UNUNITED HUMERAL HEAD FRACTURES; 2. AVASCULAR NECROSIS OF THE HUMERAL HEAD. THE HUMERAL STEMS WHEN USED WITH A GLOBAL HUMERAL HEAD AND THE GLOBAL HUMERAL STEM WHEN USED WITH A GLOBAL HUMERAL HEAD ARE INDICATED FOR HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE GLOBAL SHOULDER SYSTEM IS INDICATED FOR THE FOLLOWING FIXATION METHODS: 1) POROCOAT POROUS-COATED COMPONENTS - POROCOAT POROUS-COATED HUMERAL STEM PROSTHESES ARE INDICATED FOR CEMENTED OR UNCEMENTED USE WITH FIXATION PROVIDED BY BIOLOGICAL TISSUE INGROWTH INTO THE POROUS COATING. 2) CEMENTED COMPONENTS - HUMERAL STEM AND GLENOID COMPONENTS LABELED "FOR CEMENTED USE ONLY" ARE INDICATED ONLY FOR USE WITH BONE CEMENT. 3) PRESS-FIT OR CEMENTED COMPONENTS - HUMERAL STEM PROSTHESIS WITHOUT POROUS COATING AND LABELED "FOR PRESS-FIT OR CEMENTED USE ONLY" ARE INDICATED FOR PRESS-FIT UNCEMENTED USE OR FOR USE WITH BONE CEMENT. THE GLOBAL RESURFACING SHOULDER HUMERAL HEADS ARE INTENDED AS A TOTAL OR HEMI-SHOULDER REPLACEMENT IN PATIENTS WHERE THE HUMERAL HEAD AND NECK ARE OF SUFFICIENT BONE STOCK AND THE ROTATOR CUFF IS INTACT OR RECONSTRUCTABLE. THIS DEVICE IS DESIGNED TO INCREASE SHOULDER MOBILITY BY: REDUCING PAIN; RESTORING ALIGNMENT; RESTORING FLEXION AND EXTENSION MOVEMENT; AND RESISTING DISLOCATION. THE GLOBAL RESURFACING SHOULDER HUMERAL HEADS ARE INDICATED FOR USE AS A REPLACEMENT OF SHOULDER JOINTS DISABLED BY RHEUMATOID ARTHRITIS WITH PAIN, NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (I.E. OSTEOARTHRITIS AND AVASCULAR NECROSIS), DEFORMITY AND/OR LIMITED MOTION, FRACTURES OF THE HUMERAL HEAD AND TRAUMATIC ARTHRITIS. THE GLOBAL RESURFACING SHOULDER HUMERAL HEADS ARE INTENDED FOR UNCEMENTED USE ONLY. , SHOULDER REPLACEMENT SYSTEM-HUMERAL STEM(GLOBAL ADVANTAGE)-THE GLOBAL SHOULDER SYSTEM IS INDICATED FOR USE IN TOTAL OR HEMI-SHOULDER REPLACEMENT FOR THE

	TREATMENT OF:1. A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS; 2. FRACTURE-DISLOCATIONS OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY; 3. OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT). THE GLOBAL SHOULDER SYSTEM IS ALSO INDICATED FOR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. UNUNITED HUMERAL HEAD FRACTURES; 2. AVASCULAR NECROSIS OF THE HUMERAL HEAD. THE HUMERAL STEMS WHEN USED WITH A GLOBAL HUMERAL HEAD AND THE GLOBAL HUMERAL STEM WHEN USED WITH A GLOBAL HUMERAL HEAD ARE INDICATED FOR HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE GLOBAL SHOULDER SYSTEM IS INDICATED FOR THE FOLLOWING FIXATION METHODS: 1) POROCOAT POROUS-COATED COMPONENTS - POROCOAT POROUS-COATED HUMERAL STEM PROSTHESES ARE INDICATED FOR CEMENTED OR UNCEMENTED USE WITH FIXATION PROVIDED BY BIOLOGICAL TISSUE INGROWTH INTO THE POROUS COATING. 2) CEMENTED COMPONENTS - HUMERAL STEM AND GLENOID COMPONENTS LABELED "FOR CEMENTED USE ONLY" ARE INDICATED ONLY FOR USE WITH BONE CEMENT. 3) PRESS-FIT OR CEMENTED COMPONENTS - HUMERAL STEM PROSTHESIS WITHOUT POROUS COATING AND LABELED "FOR PRESS-FIT OR CEMENTED USE ONLY" ARE INDICATED FOR PRESS-FIT UNCEMENTED USE OR FOR USE WITH BONE CEMENT. THE GLOBAL RESURFACING SHOULDER HUMERAL HEADS ARE INTENDED AS A TOTAL OR HEMI-SHOULDER REPLACEMENT IN PATIENTS WHERE THE HUMERAL HEAD AND NECK ARE OF SUFFICIENT BONE STOCK AND THE ROTATOR CUFF IS INTACT OR RECONSTRUCTABLE. THIS DEVICE IS DESIGNED TO INCREASE SHOULDER MOBILITY BY: REDUCING PAIN; RESTORING ALIGNMENT; RESTORING FLEXION AND EXTENSION MOVEMENT; AND RESISTING DISLOCATION. THE GLOBAL RESURFACING SHOULDER HUMERAL HEADS ARE INDICATED FOR USE AS A REPLACEMENT OF SHOULDER JOINTS DISABLED BY RHEUMATOID ARTHRITIS WITH PAIN, NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (I.E. OSTEOARTHRITIS AND AVASCULAR NECROSIS), DEFORMITY AND/OR LIMITED MOTION, FRACTURES OF THE HUMERAL HEAD AND TRAUMATIC ARTHRITIS. THE GLOBAL RESURFACING SHOULDER HUMERAL HEADS ARE INTENDED FOR UNCEMENTED USE ONLY., SHOULDER REPLACEMENT SYSTEM-HUMERAL STEM(GLOBAL FX)-

	THE GLOBAL FX SHOULDER SYSTEM IS INDICATED ONLY FOR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF:1. A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS; 2. FRACTURE-DISLOCATIONS OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY; 3. OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT). 4. UNUNITED HUMERAL HEAD FRACTURES; 5. AVASCULAR NECROSIS OF THE HUMERAL HEAD. THE DEPUY GLOBAL ADVANTAGE CTA HUMERAL STEMS CAN BE USED WITH THE GLOBAL FX HUMERAL STEMS IN HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE DEPUY GLOBAL FX SHOULDER SYSTEM IS INDICATED FOR THE FOLLOWING FIXATION METHODS: 1) POROCOAT POROUS-COATED COMPONENTS - POROCOAT POROUS-COATED HUMERAL STEM PROSTHESES ARE INDICATED FOR CEMENTED OR UNCEMENTED USE WITH FIXATION PROVIDED BY BIOLOGICAL TISSUE INGROWTH INTO THE POROUS COATING. 2) CEMENTED COMPONENTS - HUMERAL STEM AND GLENOID COMPONENTS LABELED "FOR CEMENTED USE ONLY" ARE INDICATED ONLY FOR USE WITH BONE CEMENT. 3) PRESS-FIT OR CEMENTED COMPONENTS - HUMERAL STEM PROSTHESIS WITHOUT POROUS COATING AND LABELED "FOR PRESS-FIT OR CEMENTED USE ONLY" ARE INDICATED FOR PRESS-FIT UNCEMENTED USE OR FOR USE WITH BONE CEMENT. ,KNEE REPLACEMENT SYSTEM-FEMORAL ADAPTER BOLT(SIGMA)-SIGMA KNEE SYSTEM INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINTLOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. ,KNEE REPLACEMENT SYSTEM-FEMORAL ADAPTER(SIGMA)-SIGMA KNEE

	SYSTEM INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINTLOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-FEMORAL(SIGMA)-SIGMA KNEE SYSTEM INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINTLOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-TIBIAL INSERT(SIGMA)-SIGMA KNEE SYSTEM INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINTLOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,HIP REPLACEMENT

	SYSTEM-CAGE(PROTRUSIO CAGE SYSTEM)-THE DEPUY PROTRUSIO CAGE IS INTENDED TO BE USED TO REINFORCE A DEFICIENT OR WEAKENED MEDIAL ACETABULAR WALL TO PREVENT THE PROTRUSION OF AN ACETABULAR CUP PROSTHESIS INTO THE ABDOMINAL CAVITY. IT MAY BE INDICATED FOR USE IN CASES INVOLVING: ACETABULAR REVISION PROCEDURES; SEVERE STEOPOROSIS; PROTRUSIO ACETABULI; AND/OR A SHALLOW ACETABULAR ROOT.,HIP REPLACEMENT SYSTEM- LINERS(PINNACLE) -IT IS INTENDED FOR TOTAL HIP PROSTHESES, HEMI-HIP PROSTHESES, AND SELF-CENTERING HIP PROSTHESES. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM. THE PINNACLE CONSTRAINED ACETABULAR LINER IS INDICATED FOR USE AS A COMPONENT OF A TOTAL HIP PROSTHESIS IN PRIMARY OR REVISION PATIENTS AT HIGH RISK OF HIP DISLOCATION DUE TO A HISTORY OF PRIOR DISLOCATION, BONE LOSS, JOINT OR SOFT TISSUE LAXITY, NEUROMUSCULAR DISEASE OR INTRAOPERATIVE INSTABILITY. THE PINNACLE® CONSTRAINED ACETABULAR LINER IS INDICATED FOR USE WITH THE PINNACLE® ACETABULAR CUP IN CEMENTLESS APPLICATION.,HIP REPLACEMENT SYSTEM- CUPS(PINNACLE)-IT IS INTENDED FOR TOTAL HIP PROSTHESES, HEMI-HIP PROSTHESES, AND SELF-CENTERING HIP PROSTHESES. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM. THE PINNACLE CONSTRAINED ACETABULAR LINER IS INDICATED FOR USE AS A COMPONENT OF A TOTAL HIP PROSTHESIS IN PRIMARY OR REVISION PATIENTS AT HIGH RISK OF HIP DISLOCATION DUE TO A HISTORY OF PRIOR DISLOCATION, BONE LOSS, JOINT OR SOFT TISSUE LAXITY, NEUROMUSCULAR DISEASE OR INTRAOPERATIVE INSTABILITY. THE PINNACLE® CONSTRAINED ACETABULAR LINER IS INDICATED FOR

	USE WITH THE PINNACLE® ACETABULAR CUP IN CEMENTLESS APPLICATION.,HIP REPLACEMENT SYSTEM- SLEEVE(CONTROL CABLE SYSTEM)-THE CONTROL CABLE SYSTEM IS INDICATED FOR USE AS A CERCLAGE FIXATION DEVICE IN GENERAL ORTHOPAEDIC REPAIRS. THESE INCLUDE PROCEDURES SUCH AS: REINFORCEMENT OF BONE; REATTACHMENT OF THE GREATER TROCHANTER; FIXATION OF LONG BONE FRACTURES WITH GRAFTING ; FIXATION OF PATELLAR FRACTURES ; AND CLOSURE OF THE STERNUM FOLLOWING OPEN HEART SURGERY.,HIP REPLACEMENT SYSTEM- STEMS(SOLUTION)-IT IS INTENDED FOR TOTAL HIP PROSTHESES, HEMI-HIP PROSTHESES, AND SELF-CENTERING HIP PROSTHESES. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUOOORT THE FEMORAL STEM.,HIP REPLACEMENT SYSTEM-STEM(SUMMIT)-IT IS INTENDED FOR TOTAL HIP PROSTHESES, HEMI-HIP PROSTHESES, AND SELF-CENTERING HIP PROSTHESES. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORV NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.,HIP REPLACEMENT SYSTEM-HEADS(SELF-CENTERING)-SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.,HIP REPLACEMENT SYSTEM-LINERS(DURALOC)-THE DURALOC CONSTRAINED ACETABULAR LINERS ARE INDICATED FOR USE AS COMPONENTS OF TOTAL HIP PROSTHESIS IN PRIMARY OR REVISION PATIENTS AT HIGH RISK OF HIP DISLOCATION DUE TO A HISTORY OF PRIOR DISLOCATION, BONE LOSS, JOINT OR SOFT TISSUE LAXITY, NEUROMUSCULAR DISEASE OR INTRAOPERATIVE INSTABILITY.

1497	IMP/MD/2019/000034	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEALING SCREWS (WINSIX)-WINSIX IMPLANT SYSTEM IS INDICATED FOR SINGLE OR MULTIPLE TOOTH REPLACEMENT, OR FOR USE IN TERMINAL INTERMEDIATE EDENTULOUS SITES IN THE MANDIBLE AND/OR THE MAXILLA, AND FOR TOTALLY EDENTULOUS ARCHES. THE SYSTEM IS DESIGNED TO BE SURGICALLY INSERTED IN THE BONE STRUCTURE OF THE MOUTH IN ORDER TO REPLACE MISSING TEETH. IT IS INTENDED FOR IMMEDIATE LOADING WHEN GOOD PRIMARY STABILITY IS ACHIEVED AND WITH APPROPRIATE OCCLUSAL LOADING.,DENTAL ABUTMENTS(WINSIX)-WINSIX IMPLANT SYSTEM IS INDICATED FOR SINGLE OR MULTIPLE TOOTH REPLACEMENT, OR FOR USE IN TERMINAL INTERMEDIATE EDENTULOUS SITES IN THE MANDIBLE AND/OR THE MAXILLA, AND FOR TOTALLY EDENTULOUS ARCHES. THE SYSTEM IS DESIGNED TO BE SURGICALLY INSERTED IN THE BONE STRUCTURE OF THE MOUTH IN ORDER TO REPLACE MISSING TEETH. IT IS INTENDED FOR IMMEDIATE LOADING WHEN GOOD PRIMARY STABILITY IS ACHIEVED AND WITH APPROPRIATE OCCLUSAL LOADING.,DENTAL IMPLANTS(WINSIX)-WINSIX IMPLANT SYSTEM IS INDICATED FOR SINGLE OR MULTIPLE TOOTH REPLACEMENT, OR FOR USE IN TERMINAL INTERMEDIATE EDENTULOUS SITES IN THE MANDIBLE AND/OR THE MAXILLA, AND FOR TOTALLY EDENTULOUS ARCHES. THE SYSTEM IS DESIGNED TO BE SURGICALLY INSERTED IN THE BONE STRUCTURE OF THE MOUTH IN ORDER TO REPLACE MISSING TEETH.
1498	IMP/MD/2019/000035	1.License Holder Name: SURGIMEDIK HEALTHCARE INDIA PVT LTD. , PLOT NO. 5138/1, FIRST FLOOR G.I.D.C., SACHIN, SURAT ,SURAT GUJARAT ,394230 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INJECTABLE IMPLANT FOR THE TREATMENT OF VESICOURETRAL REFLUX(DEXELL VUR)-DEXELL VUR IS INDICATED FOR TEMPORARY VOLUME SUBSTITUTION BY WAY OF INJECTION INTO THE SUBMUCOSA FOR TREATMENT OF VESICOURETERAL REFLUX

1499	IMP/MD/2019/000036	1.License Holder Name: NANO THERAPEUTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASPIRATION CATHETER (PEGASE)-IT IS INTENDED FOR USE IN THE CENTRAL & PERIPHERAL CIRCULATORY SYSTEM INCLUDING SAPHENOUS VEIN GRAFTS, TO CONTAIN AND ASPIRATE EMBOLIC MATERIAL (THROMBUS/ DEBRIS) WHILE PERFORMING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) OR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) AND/OR STENTING PROCEDURES.,PTCA-PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER(MAYA)-IT IS INTENDED FOR USE IN TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. IT IS THEREFOR INDICATED TO DILATE THE DISEASE SEGMENT(S) IN A CORONARY ARTERY OR CORONARY BYPASS TO IMPROVE MYOCARDIAL PERFUSION.,PTCA-PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER(FILAO NC)-IT IS INTENDED FOR USE IN PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA-RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES AND WHO ARE REGARDED AS BEING CANDIDATES FOR REVASCULARIZATION.,PTA-PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY CATHETER(LYNX)-IT IS INDICATED FOR IMPROVING PERIPHERAL LUMINAL DIAMETER IN PATIENTS WITH STENOSIS OF THE CAROTID, VERTEBRAL, SUB-CLAVIAN, VISCERAL, RENAL, ARTERIES OF THE LOWER LIMBS, USING EITHER DILATATION OR STENTING/POST-STENTING TECHNIQUE,PTCA-PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER(VEGA)-IT IS INTENDED FOR USE IN TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. IT IS THEREFOR INDICATED TO DILATE THE DISEASE SEGMENT(S) IN A CORONARY ARTERY OR CORONARY BYPASS TO IMPROVE MYOCARDIAL PERFUSION.,PTCA-PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER(FILAO RX)-IT IS INTENDED FOR USE IN PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA-RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES AND WHO ARE REGARDED AS BEING CANDIDATES FOR REVASCULARIZATION.,PTA-PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY CATHETER(EBONY 0.035” OTW)-IT IS INTENDED FOR DILATATION OF LESIONS IN THE FEMORAL, RENAL, ILIAC, & POPLITEAL ARTERIES.,PTA-PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY CATHETER(EBONY 0.014” RX)-IT IS INTENDED FOR DILATATION OF LESIONS IN THE FEMORAL, RENAL, ILIAC, &

	POPLITEAL ARTERIES.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1500	IMP/MD/2019/000037	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHOSIS, SPINAL PEDICLE FIXATION, FOR DEGENERATIVE DISC DISEASE(TSRH SPINAL SYSTEM)-WHEN USED AS A PEDICLE SCREW FIXATION SYSTEM OF THE NON-CERVICAL POSTERIOR SPINE IN SKELETALLY MATURE PATIENTS USING BONE GRAFT, THE TSRH® SPINAL SYSTEM IS INDICATED AS AN ADJUNCT TO FUSION FOR ONE OR MORE OF THE FOLLOWING: (1) DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), (2) DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGIC IMPAIRMENT, (3) FRACTURE, (4) DISLOCATION, (5) SCOLIOSIS, (6) KYPHOSIS, (7) SPINAL TUMOR, AND/OR (8) FAILED PREVIOUS FUSION (PSEUDARTHROSIS). IN ADDITION, WHEN USED AS A PEDICLE SCREW FIXATION SYSTEM, THE TSRH® SPINAL SYSTEM IS INDICATED AS AN ADJUNCT TO FUSION FOR SKELETALLY MATURE PATIENTS USING BONE GRAFT: (1) HAVING SEVERE SPONDYLOLISTHESIS (GRADES 3 AND 4) OF THE FIFTH LUMBAR-FIRST SACRAL (L5-S1) VERTEBRAL JOINT: (2) WHO ARE RECEIVING FUSIONS USING AUTOGENOUS BONE GRAFT ONLY: (3) WHO ARE HAVING THE DEVICE FIXED OR ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 AND BELOW); AND (4) WHO ARE HAVING THE DEVICE REMOVED AFTER THE DEVELOPMENT OF A SOLID FUSION MASS. WHEN USED AS A POSTERIOR, NON-CERVICAL, NON-PEDICLE SCREW FIXATION SYSTEM, THE TSRH® SPINAL SYSTEM IS INTENDED FOR THE FOLLOWING INDICATIONS: (1) DEGENERATIVE DISC DISEASE (AS DEFINED BY BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), (2) SPONDYLOLISTHESIS, (3) FRACTURE, (4) SPINAL DEFORMITIES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS), (5) SPINAL STENOSIS, (6) PSEUDARTHROSIS, (7) TUMOR RESECTION, AND/OR (8) UNSUCCESSFUL PREVIOUS ATTEMPTS AT SPINAL FUSION. WHEN USED AS A UNILATERAL SUPPLEMENTAL FIXATION DEVICE IN THE ANTERO-LATERAL THORACIC/LUMBAR REGION, THE TSRH® L-PLATE AND VANTAGE™ SCREWS ARE INTENDED FOR THE FOLLOWING INDICATIONS: SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS AND/OR LORDOSIS); TUMOR; PSEUDARTHROSIS; AND/OR FAILED PREVIOUS FUSION.FOR ANTERIOR USE ONLY THE TSRH® SPINAL SYSTEM HAS THE ADDITIONAL INDICATION OF: SPONDYLOLYSIS.,INTERVERTEBRAL BODY FUSION DEVICE(PIVOX OBLIQUE LATERAL SPINAL SYSTEM)-THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM INTERBODY CAGE IS

	DESIGNED TO BE USED WITH AUTOGRAFT AND/OR ALLOGENIC BONE GRAFT COMPRISED OF CANCELLOUS AND/OR CORTICOCANCELLOUS BONE GRAFT TO FACILITATE INTERBODY FUSION AND IS INTENDED FOR USE WITH SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBAR SPINE. THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM INTERBODY CAGE IS USED FOR PATIENTS DIAGNOSED WITH DDD AT ONE OR TWO CONTIGUOUS LEVELS FROM L2 TO S1. DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. ADDITIONALLY, THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM CAN BE USED TO PROVIDE ANTERIOR COLUMN SUPPORT IN PATIENTS DIAGNOSED WITH DEGENERATIVE SCOLIOSIS AS AN ADJUNCT TO PEDICLE SCREW FIXATION. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THESE IMPLANTS MAY BE IMPLANTED VIA A MINIMALLY INVASIVE OR OPEN LATERAL OR OBLIQUE APPROACH. CERTAIN SIZES OF THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM INTERBODY CAGE MAY ALSO BE USED WITH INFUSE BONE GRAFT FOR PATIENTS DIAGNOSED WITH DDD, AS DEFINED ABOVE, WHO ARE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THE DEVICE MAY BE IMPLANTED AT A SINGLE LEVEL USING AN OBLIQUE LATERAL INTERBODY FUSION (OLIF) APPROACH FROM L2-L5 AND IS INTENDED FOR USE WITH SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBAR SPINE. CONSULT THE LABELING FOR THE INFUSE BONE GRAFT/ MEDTRONIC INTERBODY FUSION DEVICE FOR INFORMATION ON THE SPECIFIC SIZES OF THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM INTERBODY CAGE APPROVED FOR USE WITH INFUSE BONE GRAFT, AS WELL AS SPECIFIC INFORMATION REGARDING CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS ASSOCIATED WITH INFUSE BONE GRAFT. INFUSE BONE GRAFT IS NOT INDICATED FOR USE IN A DIRECT LATERAL INTERBODY FUSION(DLIF) SURGICAL APPROACH. ADDITIONALLY, PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM CAN BE USED TO PROVIDE ANTERIOR COLUMN SUPPORT IN PATIENTS DIAGNOSED WITH DEGENERATIVE SCOLIOSIS AS AN ADJUNCT TO PEDICLE SCREW FIXATION. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THESE IMPLANTS MAY BE IMPLANTED VIA A MINIMALLY INVASIVE OR OPEN LATERAL OR OBLIQUE APPROACH. INFUSE BONE GRAFT IS NOT INDICATED FOR USE IN PATIENTS WITH THIS CONDITION. THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM PLATE AND BONE SCREW COMPONENTS ARE INDICATED AS A

	SUPPLEMENTAL FIXATION DEVICE FOR THE LUMBOSACRAL LEVELS, ANTERIOR BELOW THE BIFURCATION (L5-S1) OF THE VASCULAR STRUCTURES, AND OBLIQUE OR LATERAL ABOVE THE BIFURCATION (L1-L5) OF THE VASCULAR STRUCTURES. THE INDICATIONS AND CONTRAINDICATIONS OF SPINAL INSTRUMENTATION SYSTEMS SHOULD BE UNDERSTOOD BY THE SURGEON. THE PLATE AND BONE SCREW COMPONENTS ARE INDICATED AS A SUPPLEMENTAL FIXATION DEVICE FOR THE LUMBOSACRAL LEVELS, ANTERIOR BELOW THE BIFURCATION (L5-S1) OF THE VASCULAR STRUCTURES, AND OBLIQUE OR LATERAL ABOVE THE BIFURCATION (L1-L5) OF THE VASCULAR STRUCTURES. THE INDICATIONS AND CONTRAINDICATIONS OF SPINAL INSTRUMENTATION SYSTEMS SHOULD BE UNDERSTOOD BY THE SURGEON. THE PLATE AND BONE SCREW COMPONENTS ARE INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR LUMBAR SPINE DURING THE DEVELOPMENT OF SPINAL FUSIONS IN PATIENTS WITH: 1) DEGENERATIVE DISC DISEASE (DDD) DEFINED BY BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES; 2) TRAUMA (INCLUDING FRACTURES); 3) TUMORS; 4) DEFORMITY DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS; 5) PSEUDARTHROSIS; AND/OR 6) FAILED PREVIOUS FUSIONS. WHEN USED TOGETHER, THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM COMPONENTS CAN BE USED TO TREAT PATIENTS WITH DDD AT ONE OR TWO CONTIGUOUS LEVELS FROM L2 TO S1(EXCEPT AS DEFINED FOR USE WITH INFUSE BONE GRAFT ABOVE). THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS.,ORTHOSIS, SPINAL PEDICLE FIXATION, FOR DEGENERATIVE DISC DISEASE(CD HORIZON SOLERA SPINAL SYSTEM)-THE CD HORIZON™ SPINAL SYSTEM WITH OR WITHOUT SEXTANT™ INSTRUMENTATION IS INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD - DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E. FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E. SCOLIOSIS, KYPHOSIS, OR LORDOSIS), TUMOR, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. EXCEPT FOR HOOKS, WHEN USED AS AN ANTEROLATERAL THORACIC/LUMBAR SYSTEM, THE CD HORIZON™ SPINAL SYSTEM MAY ALSO BE USED FOR THE SAME INDICATIONS AS AN ADJUNCT TO FUSION. WITH THE EXCEPTION OF DDD, THE CD HORIZON™ LEGACY™ 3.5MM RODS AND THE CD HORIZON™ SPINAL SYSTEM PEEK RODS AND ASSOCIATED COMPONENTS MAY BE USED FOR THE

	AFOREMENTIONED INDICATIONS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION. THE 3.5MM RODS MAY BE USED FOR THE SPECIFIC PEDIATRIC INDICATIONS NOTED BELOW. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE CD HORIZON™ SPINAL SYSTEM IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE SPINAL DEFORMITIES (I.E. SCOLIOSIS, KYPHOSIS, OR LORDOSIS) INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS, AND CONGENITAL SCOLIOSIS. ADDITIONALLY, THE CD HORIZON™ SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS DIAGNOSED WITH THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS, FRACTURE CAUSED BY TUMOR AND/OR TRAUMA, PSEUDARTHOSIS, AND/OR FAILED PREVIOUS FUSION. THESE DEVICES ARE TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE CD HORIZON™ SPIRE™ PLATE IS A POSTERIOR, SINGLE-LEVEL, NON-PEDICLE SUPPLEMENTAL FIXATION DEVICE INTENDED FOR USE IN THE NON-CERVICAL SPINE (T1-S1) AS AN ADJUNCT TO FUSION IN SKELETALLY MATURE PATIENTS. IT IS INTENDED FOR PLATE FIXATION/ATTACHMENT TO SPINOUS PROCESSES FOR THE PURPOSE OF ACHIEVING SUPPLEMENTAL FIXATION IN THE FOLLOWING CONDITIONS: DDD (AS PREVIOUSLY DEFINED), SPONDYLOLISTHESIS, TRAUMA, AND/OR TUMOR. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE CD HORIZON™ SPINAL SYSTEM RODS MAY BE CONNECTED TO THE VERTEX™ RECONSTRUCTION SYSTEM WITH THE VERTEX™ ROD CONNECTOR. REFER TO THE VERTEX™ RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE VERTEX™ INDICATIONS OF USE.,INTERVERTEBRAL BODY FUSION DEVICE (WAVE D SPINAL SYSTEM)-THE DISTRACTABLE WAVE CAGE IS INDICATED FOR INTERBODY FUSION WITH AUTOGENOUS BONE GRAFT IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTIGUOUS LEVELS FROM L2 TO S1. THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THESE IMPLANTS MAY BE IMPLANTED VIA AN OPEN OR A MINIMALLY INVASIVE POSTERIOR APPROACH. THESE IMPLANTS ARE TO BE USED WITH AUTOGENOUS BONE GRAFT. THESE DEVICES ARE INTENDED TO BE USED WITH SUPPLEMENTAL FIXATION INSTRUMENTATION, WHICH HAS BEEN CLEARED BY THE FDA FOR USE IN THE LUMBAR SPINE.,ORTHOSIS,

	SPINAL PEDICLE FIXATION, FOR DEGENERATIVE DISC DISEASE(GDLH POSTERIOR SPINAL SYSTEM)-THE GDLH POSTERIOR SPINAL SYSTEM, WHEN USING TSRH VARIABLE ANGLE SCREWS OR DYNA-LOK BOLTS AS PEDICLE SCREWS, IS INTENDED ONLY FOR PATIENTS (A) HAVING SEVERE SPONDYLOLISTHESIS (GRADES 3 AND 4) OF THE FIFTH LUMBAR FIRST SACRAL (L5-S1) VERTEBRAL JOINT; (B) WHO ARE RECEIVING FUSIONS USING AUTOGENOUS BONE GRAFT ONLY; (C) WHO ARE HAVING THE DEVICE FIXED OR ATTACHED TO THE LUMBAR AND SACRAL SPINE: AND (D) WHO ARE HAVING THE DEVICE REMOVED AFTER THE DEVELOPMENT OF A SOLID FUSION MASS. PROPERLY USED, THIS SYSTEM IS INTENDED TO ASSIST STABILIZATION UNTIL A SOLID SPINAL FUSION DEVELOPS. EXCEPT FOR SITUATIONS WHERE SCREWS ARE ATTACHED TO THE PEDICLES OF THE LUMBAR AND SACRAL SPINE VIA A POSTERIOR SURGICAL APPROACH IN A GDLH CONSTRUCT FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADE 3 AND GRADE 4) AT THE L5-S1 VERTEBRAL JOINT, THE SPECIFIC INDICATIONS FOR THE GDLH POSTERIOR SPINAL SYSTEM ARE THE FOLLOWING: 1. DEGENERATIVE DISC DISEASE (AS DEFINED BY INSTABILITY IN THE PRESENCE OF ONE OR MORE OF THE FOLLOWING: OSTEOPHYTE FORMATION, DECREASE IN DISC SPACE HEIGHT, ENDPLATE SCLEROSIS, DISC HERNIATIONS, FACET JOINT CHANGES, AND SCARRING AND/OR THICKENING OF THE ANNULUS FIBROSIS, LIGAMENTUM FLAVUM, OR FACET JOINT CAPSULE). 2. PSEUDOARTHROSIS. 3. STENOSIS. 4. SPONDYLOLISTHESIS. 5. SPINAL DEFORMITIES SUCH AS SCOLIOSIS, KYPHOSIS, AND LORDOSIS. 6. FRACTURE. 7. UNSUCCESSFUL PREVIOUS ATTEMPTS AT SPINAL FUSION. 8. TUMOR RESECTION., SPINAL INTERVERTEBRAL BODY FIXATION ORTHOSIS(ZEVO ANTERIOR CERVICAL PLATE SYSTEM)-THE ZEVO™ ANTERIOR CERVICAL PLATE SYSTEM IS INTENDED FOR ANTERIOR INTERBODY SCREW FIXATION FROM C2 TO T1. THE SYSTEM IS INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR SPINE DURING THE DEVELOPMENT OF CERVICAL SPINAL FUSIONS IN PATIENTS WITH: 1) DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), 2) TRAUMA (INCLUDING FRACTURES), 3) TUMORS, 4) DEFORMITY (DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS), 5) PSEUDARTHROSIS, AND/OR 6) FAILED PREVIOUS FUSIONS., ORTHOSIS CERVICAL PEDICLE SCREW SPINAL FIXATION(THE INFINITY OCCIPITO CERVICAL-UPPER THORACIC SYSTEM (OCT SYSTEM))-THE INFINITY™ OCT SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING ACUTE AND CHRONIC

	INSTABILITIES OF THE CRANIOCERVICAL JUNCTION, THE CERVICAL SPINE (C1 TO C7), AND THE THORACIC SPINE FROM T1-T3: TRAUMATIC SPINAL FRACTURES AND/OR TRAUMATIC DISLOCATIONS. INSTABILITY OR DEFORMITY. FAILED PREVIOUS FUSIONS (E.G. PSEUDARTHROSIS). TUMORS INVOLVING THE CERVICAL SPINE. DEGENERATIVE DISEASE, INCLUDING INTRACTABLE RADICULOPATHY AND/OR MYELOPATHY, NECK AND/OR ARM PAIN OF DISCOGENIC ORIGIN AS CONFIRMED BY RADIOGRAPHIC STUDIES, AND DEGENERATIVE DISEASE OF THE FACETS WITH INSTABILITY. THE INFINITY™ OCT SYSTEM IS ALSO INTENDED TO RESTORE THE INTEGRITY OF THE SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A LIMITED TIME IN PATIENTS WITH ADVANCED STAGE TUMORS INVOLVING THE CERVICAL SPINE IN WHOM LIFE EXPECTANCY IS OF INSUFFICIENT DURATION TO PERMIT ACHIEVEMENT OF FUSION. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE INFINITY™ OCT SYSTEM MAY BE CONNECTED TO THE CD HORIZON™ SPINAL SYSTEM AND VERTEX™ RECONSTRUCTION SYSTEM RODS WITH THE INFINITY™ OCT SYSTEM ROD CONNECTORS. TRANSITION RODS WITH DIFFERING DIAMETERS MAY ALSO BE USED TO CONNECT THE INFINITY™ OCT SYSTEM TO THE CD HORIZON™ SPINAL SYSTEM. REFER TO THE CD HORIZON™ SPINAL SYSTEM PACKAGE INSERT AND VERTEX™ RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE INDICATIONS OF USE. NOTE: THE 3.0MM MULTI AXIAL SCREW (MAS) REQUIRES THE USE OF MAS CROSSLINK™ AT EACH LEVEL IN WHICH THE 3.0MM SCREW IS INTENDED TO BE USED. THE LATERAL OFFSET CONNECTORS AND MAS EXTENSION CONNECTORS ARE INTENDED TO BE USED WITH 3.5 MM AND LARGER DIAMETER MULTI AXIAL SCREWS. THE LATERAL OFFSET CONNECTORS AND MAS EXTENSION CONNECTORS ARE NOT INTENDED TO BE USED WITH 3.0MM SCREWS. NOTE: SEGMENTAL FIXATION IS RECOMMENDED FOR THESE CONSTRUCTS., INTERVERTEBRAL BODY FUSION DEVICE(DIVERGENCE -L ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM)-THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY CAGE IS INTENDED FOR INTERBODY FUSION IN SKELETALLY MATURE PATIENTS AND IS TO BE USED WITH SUPPLEMENTAL FIXATION INSTRUMENTATION CLEARED FOR USE IN THE LUMBAR SPINE. THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY DEVICE IS INDICATED FOR USE IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTAGIOUS LEVELS FROM L2 TO S1 (EXCEPT AS DEFINED FOR USE WITH INFUSE BONE GRAFT ABOVE). THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH

	DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. ADDITIONALLY, THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM DEVICE IS INDICATED FOR USE IN PATIENTS DIAGNOSED WITH DEFORMITY CONDITIONS AS AN ADJUNCT TO FUSION. THESE PATIENTS SHOULD HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY DEVICE IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGENIC BONE GRAFT COMPRISED OF CANCELLOUS AND/OR CORTICOCANCELLOUS BONE GRAFT. THESE IMPLANTS MAY BE IMPLANTED VIA A VARIETY OF OPEN OR MINIMALLY INVASIVE APPROACHES. THESE APPROACHES INCLUDE ANTERIOR AND OBLIQUE. THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM PLATE AND BONE SCREW COMPONENTS ARE INDICATED AS A SUPPLEMENTAL FIXATION DEVICE FOR THE LUMBOSACRAL LEVEL, ANTERIOR BELOW THE BIFURCATION(L5-S1) OF THE VASCULAR STRUCTURES OR ANTERIOR OBLIQUE ABOVE THE BIFURCATION(L1-S5) OF THE VASCULAR STRUCTURES. THE INDICATIONS AND CONTRAINDICATIONS OF SPINAL INSTRUMENTATION SYSTEMS SHOULD BE WELL UNDERSTOOD BY THE SURGEON. THE PLATE AND BONE SCREW COMPONENTS ARE INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR LUMBAR SPINE DURING THE DEVELOPMENT OF SPINAL FUSIONS IN PATIENTS WITH: 1) DEGENERATIVE DISC DISEASE (DDD) DEFINED BY BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES; 2) TRAUMA (INCLUDING FRACTURES); 3) TUMORS; 4) DEFORMITY DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS; 5) PSEUDOARTHROSIS; AND/OR 6) FAILED PREVIOUS FUSIONS. CERTAIN SIZES OF THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY DEVICE MAY ALSO BE USED WITH INFUSE BONE GRAFT FOR PATIENTS DIAGNOSED WITH DDD,AS DEFINED ABOVE. THE DEVICE MAY BE IMPLANTED AT A SINGLE LEVEL USING AN ANTERIOR LUMBAR INTERBODY FUSION(ALIF) APPROACH FROM L2-S1. THE DEVICE MAY ALSO BE IMPLANTED AT A SINGLE LEVEL USING AN OBLIQUE LATERAL INTERBODY INFUSION(OLIF) APPROACH FROM L5-S1. THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY DEVICE IS INTENDED FOR USE WITH SUPPLEMENTAL FIXATION INSTRUMENTATION, WHICH HAS BEEN CLEARED FOR USE IN THE LUMBAR SPINE WHEN USED TO TREAT DDD. CONSULT THE LABELING FOR THE INFUSE BONE GRAFT/MEDTRONIC INTERBODY FUSION DEVICE FOR ADDITIONAL INFORMATION ON THE SPECIFIC SIZES OF THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY DEVICE

	APPROVED FOR USE WITH INFUSE BONE GRAFT, AS WELL AS SPECIFIC INFORMATION REGARDING CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS ASSOCIATED WITH INFUSE BONE GRAFT. THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY DEVICE MAY ALSO BE USED WITH INFUSE BONE GRAFT.,ORTHOSIS CERVICAL PEDICLE SCREW SPINAL FIXATION(THE INFINITY OCCIPITO CERVICAL-UPPER THORACIC SYSTEM (OCT SYSTEM))- THE INFINITY™ OCT SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OF THE CRANIOCERVICAL JUNCTION, THE CERVICAL SPINE (C1 TO C7), AND THE THORACIC SPINE FROM T1-T3: TRAUMATIC SPINAL FRACTURES AND/OR TRAUMATIC DISLOCATIONS. INSTABILITY OR DEFORMITY. FAILED PREVIOUS FUSIONS (E.G. PSEUDARTHROSIS). TUMORS INVOLVING THE CERVICAL SPINE. DEGENERATIVE DISEASE, INCLUDING INTRACTABLE RADICULOPATHY AND/OR MYELOPATHY, NECK AND/OR ARM PAIN OF DISCOGENIC ORIGIN AS CONFIRMED BY RADIOGRAPHIC STUDIES, AND DEGENERATIVE DISEASE OF THE FACETS WITH INSTABILITY. THE INFINITY™ OCT SYSTEM IS ALSO INTENDED TO RESTORE THE INTEGRITY OF THE SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A LIMITED TIME IN PATIENTS WITH ADVANCED STAGE TUMORS INVOLVING THE CERVICAL SPINE IN WHOM LIFE EXPECTANCY IS OF INSUFFICIENT DURATION TO PERMIT ACHIEVEMENT OF FUSION. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE INFINITY™ OCT SYSTEM MAY BE CONNECTED TO THE CD HORIZON™ SPINAL SYSTEM AND VERTEX™ RECONSTRUCTION SYSTEM RODS WITH THE INFINITY™ OCT SYSTEM ROD CONNECTORS. TRANSITION RODS WITH DIFFERING DIAMETERS MAY ALSO BE USED TO CONNECT THE INFINITY™ OCT SYSTEM TO THE CD HORIZON™ SPINAL SYSTEM. REFER TO THE CD HORIZON™ SPINAL SYSTEM PACKAGE INSERT AND VERTEX™ RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE INDICATIONS OF USE. NOTE: THE 3.0MM MULTI AXIAL SCREW (MAS) REQUIRES THE USE OF MAS CROSSLINK™ AT EACH LEVEL IN WHICH THE 3.0MM SCREW IS INTENDED TO BE USED. THE LATERAL OFFSET CONNECTORS AND MAS EXTENSION CONNECTORS ARE INTENDED TO BE USED WITH 3.5 MM AND LARGER DIAMETER MULTI AXIAL SCREWS. THE LATERAL OFFSET CONNECTORS AND MAS EXTENSION CONNECTORS ARE NOT INTENDED TO BE USED WITH 3.0MM SCREWS. NOTE: SEGMENTAL FIXATION IS RECOMMENDED FOR THESE CONSTRUCTS,SPINAL INTERVERTEBRAL BODY FIXATION ORTHOSIS (ZEPHIR ANTERIOR CERVICAL SYSTEM)-PROPERLY USED, THIS SYSTEM IS INTENDED FOR ANTERIOR INTERBODY SCREW/PLATE FIXATION OF THE

	CERVICAL SPINE. THE INDICATIONS AND CONTRAINDICATIONS OF SPINAL INSTRUMENTATION SYSTEMS SHOULD BE WELL UNDERSTOOD BY THE SURGEON. THE SYSTEM IS INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR SPINE DURING THE DEVELOPMENT OF CERVICAL SPINAL FUSIONS IN PATIENTS WITH: 1) DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), 2) TRAUMA (INCLUDING FRACTURES), 3) TUMORS, 4) DEFORMITY (DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS), 5) PSEUDARTHROSIS, AND/OR 6) FAILED PREVIOUS FUSIONS.,SPINAL INTERLAMINAL FIXATION ORTHOSIS(VERTEX RECONSTRUCTION SYSTEM)-WHEN INTENDED AS AN ADJUNCT TO FUSION OF THE OCCIPITOCERVICAL SPINE, CERVICAL SPINE, AND THE THORACIC SPINE (OCCIPUT-T3), THE VERTEX® RECONSTRUCTION SYSTEM IS INDICATED FOR SKELETALLY MATURE PATIENTS USING ALLOGRAFT AND/OR AUTOGRAFT FOR THE FOLLOWING: DDD (NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, SPINAL STENOSIS, FRACTURE, DISLOCATION, FAILED PREVIOUS FUSION, AND/OR TUMORS. OCCIPITOCERVICAL COMPONENTS: PLATE ROD/PLATES/RODS/OCCIPITAL SCREWS/HOOKS THE OCCIPITOCERVICAL PLATE RODS, PLATES, RODS, OCCIPITAL SCREWS, AND HOOKS ARE INTENDED TO PROVIDE STABILIZATION TO PROMOTE FUSION FOLLOWING REDUCTION OF FRACTURE/DISLOCATION OR TRAUMA IN THE OCCIPITOCERVICAL JUNCTION AND THE CERVICAL SPINE. WHEN USED TO TREAT THESE OCCIPITOCERVICAL AND CERVICAL CONDITIONS, THESE SCREWS ARE LIMITED TO OCCIPITAL FIXATION ONLY. THE SCREWS ARE NOT INTENDED TO BE PLACED IN THE CERVICAL SPINE. OCCIPITOCERVICAL CONSTRUCTS REQUIRE BILATERAL FIXATION TO C2 AND BELOW. NOTE: SEGMENTAL FIXATION IS RECOMMENDED FOR THESE CONSTRUCTS. HOOKS AND RODS THE HOOKS AND RODS ARE ALSO INTENDED TO PROVIDE STABILIZATION TO PROMOTE FUSION FOLLOWING REDUCTION OF FRACTURE/DISLOCATION OR TRAUMA IN THE CERVICAL/UPPER THORACIC (C1-T3) SPINE. MULTI-AXIAL SCREWS THE USE OF MULTI-AXIAL SCREWS IS LIMITED TO PLACEMENT IN T1-T3. THE SCREWS ARE NOT INTENDED TO BE PLACED IN THE CERVICAL SPINE. TITANIUM ATLAS® CABLE SYSTEM TO BE USED WITH THE VERTEX® RECONSTRUCTION SYSTEM ALLOWS FOR CABLE ATTACHMENT TO THE POSTERIOR CERVICAL OR THORACIC SPINE. CONNECTORS IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE VERTEX® RECONSTRUCTION SYSTEM MAY BE CONNECTED TO THE CD HORIZON® SPINAL SYSTEM RODS WITH

	THE VERTEX® ROD CONNECTORS. TRANSITION RODS WITH DIFFERING DIAMETERS MAY ALSO BE USED TO CONNECT THE VERTEX® RECONSTRUCTION SYSTEM TO THE CD HORIZON® SPINAL SYSTEM SCREWS, HOOKS, AND CONNECTORS. REFER TO THE CD HORIZON® SPINAL SYSTEM PACKAGE INSERT FOR A LIST OF THE CD HORIZON® SPINAL SYSTEM INDICATIONS OF USE.,SYSTEM, FACET SCREW SPINAL DEVICE (UCSS SCREW SET)-THE UCSS™ SCREW SET IS INTENDED TO STABILIZE THE SPINE AS AN AID TO FUSION BY TWO DIFFERENT FIXATION METHODS. THE FIRST FIXATION METHOD USES THE UCSS™ SCREW SET SCREWS AS JUST FACET FIXATION SCREWS, WHERE THE SCREWS ARE INSERTED BILATERALLY THROUGH THE SUPERIOR SIDE OF THE FACET, ACROSS THE FACET JOINT AT (USUALLY) A SINGLE LEVEL, AND INTO THE PEDICLE. IN THE SECOND FIXATION METHOD, THE UCSS™ SCREW SET SCREWS ARE INSERTED BILATERALLY THROUGH THE SUPERIOR SIDE OF THE FACET, ACROSS THE FACET JOINT, AND INTO THE PEDICLE AT MULTIPLE LEVELS AT THE SAME TIME THAT A DYNA-LOK® PLATE IS ATTACHED TO THE BASE OF THE SPINOUS PROCESSES AT THE CORRESPONDING LEVELS WITH UCSS™ SCREW SET SCREWS. THE SECOND FIXATION METHOD SHOULD BE USED WHEN THE SPINE HAS INCREASED INSTABILITY OR MULTIPLE LEVELS NEED TO BE FUSED. BONE GRAFT MUST BE USED FOR BOTH FIXATION METHODS. FOR BOTH METHODS, THIS SYSTEM IS INDICATED FOR THE POSTERIOR SURGICAL TREATMENT OF ANY OR ALL OF THE FOLLOWING AT THE C2 TO S1 (INCLUSIVE) SPINAL LEVELS: 1) TRAUMA, INCLUDING SPINAL FRACTURES AND/OR DISLOCATIONS; 2) SPONDYLOLISTHESIS. ; 3) SPONDYLOLYSIS; 4) PSEUDARTHROSIS OR FAILED PREVIOUS FUSIONS WHICH ARE SYMPTOMATIC OR WHICH MAY CAUSE SECONDARY INSTABILITY OR DEFORMITY;) DEGENERATIVE DISEASES WHICH INCLUDE: (A) DEGENERATIVE DISC DISEASE (DDD) AS DEFINED BY NECK AND/OR BACK PAIN OF DISCOGENIC ORIGIN AS CONFIRMED BY PATIENT HISTORY WITH DEGENERATION OF THE DISC AS CONFIRMED BY RADIOGRAPHIC STUDIES AND/OR; (B) DEGENERATIVE DISEASE OF THE FACETS WITH INSTABILITY. ,SPINAL VERTEBRAL BODY REPLACEMENT DEVICE(PYRAMESH C TITANIUM MESH)-THE PYRAMESH® C TITANIUM MESH IS FOR USE IN THE THORACOLUMBAR SPINE (T1 TO L5) TO REPLACE AND RESTORE THE HEIGHT OF A DISEASED OR DAMAGED VERTEBRAL BODY CAUSED BY TUMOR AND/OR FRACTURE. PYRAMESH® C TITANIUM MESH DEVICE IS INTENDED TO BE USED WITH SUPPLEMENTAL FIXATION. ALLOGRAFT OR AUTOGRAFT MATERIAL MAY BE USED AT THE SURGEON'S DISCRETION.,MESH SURGICAL, METAL(PYRAMESH IMPLANT SYSTEM)-PYRAMESH® IMPLANTS ARE INTENDED FOR USE IN REINFORCING WEAK BONY TISSUES IN ORTHOPEDIC SURGICAL

	PROCEDURES AND IN MAXILLO-FACIAL RECONSTRUCTIVE SURGICAL PROCEDURES,ARTIFICIAL CERVICAL DISC(PRESTIGE LP CERVICAL DISC SYSTEM)-THE PRESTIGE® CERVICAL DISC IS GENERALLY INDICATED FOR USE AT ANY LEVEL FROM C2/C3 TO C7/T1: - FOR CERVICAL DEGENERATIVE DISCOPATHY AND INSTABILITY • IN PATIENTS WITH ADJACENT LEVELS EITHER CONGENITALLY OR SURGICALLY FUSED • FOR PRIMARY SURGERY FOR DEGENERATIVE DISCOPATHIES OR EXTENSIVE ANTERIOR DECOMPRESSION • REVISION SURGERY FOR FAILED DISC OPERATION, STENOSIS, POST-OPERATIVE INSTABILITY - PSEUDARTHROSIS OR FAILED ARTHRODESIS.,ORTHOSIS, SPINAL PEDICLE FIXATION, FOR DEGENERATIVE DISC DISEASE(CD HORIZON SPINAL SYSTEM (TITANIUM ALLOY/HYDROXYAPATITE))-THE CD HORIZON™ SPINAL SYSTEM WITH OR WITHOUT SEXTANT™ INSTRUMENTATION IS INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD - DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E. FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E. SCOLIOSIS, KYPHOSIS, OR LORDOSIS), TUMOR, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. EXCEPT FOR HOOKS, WHEN USED AS AN ANTEROLATERAL THORACIC/LUMBAR SYSTEM, THE CD HORIZON™ SPINAL SYSTEM MAY ALSO BE USED FOR THE SAME INDICATIONS AS AN ADJUNCT TO FUSION. WITH THE EXCEPTION OF DDD, THE CD HORIZON™ LEGACY™ 3.5MM RODS AND THE CD HORIZON™ SPINAL SYSTEM PEEK RODS AND ASSOCIATED COMPONENTS MAY BE USED FOR THE AFOREMENTIONED INDICATIONS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION. THE 3.5MM RODS MAY BE USED FOR THE SPECIFIC PEDIATRIC INDICATIONS NOTED BELOW. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE CD HORIZON™ SPINAL SYSTEM IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE SPINAL DEFORMITIES (I.E. SCOLIOSIS, KYPHOSIS, OR LORDOSIS) INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS, AND CONGENITAL SCOLIOSIS. ADDITIONALLY, THE CD HORIZON™ SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS DIAGNOSED WITH THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS, FRACTURE CAUSED BY TUMOR AND/OR TRAUMA, PSEUDARTHOSIS, AND/OR FAILED PREVIOUS FUSION. THESE DEVICES ARE TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE CD

	HORIZON™ SPIRE™ PLATE IS A POSTERIOR, SINGLE-LEVEL, NON-PEDICLE SUPPLEMENTAL FIXATION DEVICE INTENDED FOR USE IN THE NON-CERVICAL SPINE (T1-S1) AS AN ADJUNCT TO FUSION IN SKELETALLY MATURE PATIENTS. IT IS INTENDED FOR PLATE FIXATION/ATTACHMENT TO SPINOUS PROCESSES FOR THE PURPOSE OF ACHIEVING SUPPLEMENTAL FIXATION IN THE FOLLOWING CONDITIONS: DDD (AS PREVIOUSLY DEFINED), SPONDYLOLISTHESIS, TRAUMA, AND/OR TUMOR. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE CD HORIZON™ SPINAL SYSTEM RODS MAY BE CONNECTED TO THE VERTEX™ RECONSTRUCTION SYSTEM WITH THE VERTEX™ ROD CONNECTOR. REFER TO THE VERTEX™ RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE VERTEX™ INDICATIONS OF USE.,ORTHOSIS, SPINAL PEDICLE FIXATION, FOR DEGENERATIVE DISC DISEASE(CD HORIZON SPINAL SYSTEM)-THE CD HORIZON™ SPINAL SYSTEM WITH OR WITHOUT SEXTANT™ INSTRUMENTATION IS INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD - DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E. FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E. SCOLIOSIS, KYPHOSIS, OR LORDOSIS), TUMOR, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. EXCEPT FOR HOOKS, WHEN USED AS AN ANTEROLATERAL THORACIC/LUMBAR SYSTEM, THE CD HORIZON™ SPINAL SYSTEM MAY ALSO BE USED FOR THE SAME INDICATIONS AS AN ADJUNCT TO FUSION. WITH THE EXCEPTION OF DDD, THE CD HORIZON™ LEGACY™ 3.5MM RODS AND THE CD HORIZON™ SPINAL SYSTEM PEEK RODS AND ASSOCIATED COMPONENTS MAY BE USED FOR THE AFOREMENTIONED INDICATIONS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION. THE 3.5MM RODS MAY BE USED FOR THE SPECIFIC PEDIATRIC INDICATIONS NOTED BELOW. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE CD HORIZON™ SPINAL SYSTEM IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE SPINAL DEFORMITIES (I.E. SCOLIOSIS, KYPHOSIS, OR LORDOSIS) INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS, AND CONGENITAL SCOLIOSIS. ADDITIONALLY, THE CD HORIZON™ SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS DIAGNOSED WITH THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS, FRACTURE CAUSED BY TUMOR AND/OR TRAUMA, PSEUDARTHOSIS, AND/OR FAILED PREVIOUS FUSION. THESE DEVICES ARE TO BE USED WITH

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	TUMOR AND/OR TRAUMA, PSEUDARTHOSIS, AND/OR FAILED PREVIOUS FUSION. THESE DEVICES ARE TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE CD HORIZON™ SPIRE™ PLATE IS A POSTERIOR, SINGLE-LEVEL, NON-PEDICLE SUPPLEMENTAL FIXATION DEVICE INTENDED FOR USE IN THE NON-CERVICAL SPINE (T1-S1) AS AN ADJUNCT TO FUSION IN SKELETALLY MATURE PATIENTS. IT IS INTENDED FOR PLATE FIXATION/ATTACHMENT TO SPINOUS PROCESSES FOR THE PURPOSE OF ACHIEVING SUPPLEMENTAL FIXATION IN THE FOLLOWING CONDITIONS: DDD (AS PREVIOUSLY DEFINED), SPONDYLOLISTHESIS, TRAUMA, AND/OR TUMOR. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE CD HORIZON™ SPINAL SYSTEM RODS MAY BE CONNECTED TO THE VERTEX™ RECONSTRUCTION SYSTEM WITH THE VERTEX™ ROD CONNECTOR. REFER TO THE VERTEX™ RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE VERTEX™ INDICATIONS OF USE.,ORTHOSIS, SPINAL PEDICLE FIXATION, FOR DEGENERATIVE DISC DISEASE(CD HORIZON SPINAL SYSTEM (PEEK OPTIMA LT1))-THE CD HORIZON™ SPINAL SYSTEM WITH OR WITHOUT SEXTANT™ INSTRUMENTATION IS INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD - DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E. FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E. SCOLIOSIS, KYPHOSIS, OR LORDOSIS), TUMOR, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. EXCEPT FOR HOOKS, WHEN USED AS AN ANTEROLATERAL THORACIC/LUMBAR SYSTEM, THE CD HORIZON™ SPINAL SYSTEM MAY ALSO BE USED FOR THE SAME INDICATIONS AS AN ADJUNCT TO FUSION. WITH THE EXCEPTION OF DDD, THE CD HORIZON™ LEGACY™ 3.5MM RODS AND THE CD HORIZON™ SPINAL SYSTEM PEEK RODS AND ASSOCIATED COMPONENTS MAY BE USED FOR THE AFOREMENTIONED INDICATIONS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION. THE 3.5MM RODS MAY BE USED FOR THE SPECIFIC PEDIATRIC INDICATIONS NOTED BELOW. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE CD HORIZON™ SPINAL SYSTEM IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE SPINAL DEFORMITIES (I.E. SCOLIOSIS, KYPHOSIS, OR LORDOSIS) INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS, AND CONGENITAL SCOLIOSIS. ADDITIONALLY, THE CD HORIZON™ SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS

	DIAGNOSED WITH THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS, FRACTURE CAUSED BY TUMOR AND/OR TRAUMA, PSEUDARTHOSIS, AND/OR FAILED PREVIOUS FUSION. THESE DEVICES ARE TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE CD HORIZON™ SPIRE™ PLATE IS A POSTERIOR, SINGLE-LEVEL, NON-PEDICLE SUPPLEMENTAL FIXATION DEVICE INTENDED FOR USE IN THE NON-CERVICAL SPINE (T1-S1) AS AN ADJUNCT TO FUSION IN SKELETALLY MATURE PATIENTS. IT IS INTENDED FOR PLATE FIXATION/ATTACHMENT TO SPINOUS PROCESSES FOR THE PURPOSE OF ACHIEVING SUPPLEMENTAL FIXATION IN THE FOLLOWING CONDITIONS: DDD (AS PREVIOUSLY DEFINED), SPONDYLOLISTHESIS, TRAUMA, AND/OR TUMOR. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE CD HORIZON™ SPINAL SYSTEM RODS MAY BE CONNECTED TO THE VERTEX™ RECONSTRUCTION SYSTEM WITH THE VERTEX™ ROD CONNECTOR. REFER TO THE VERTEX™ RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE VERTEX™ INDICATIONS OF USE.,ORTHOSIS, SPINAL PEDICLE FIXATION, FOR DEGENERATIVE DISC DISEASE(CD HORIZON SPINAL SYSTEM (TITANIUM ALLOY))-THE CD HORIZON™ SPINAL SYSTEM WITH OR WITHOUT SEXTANT™ INSTRUMENTATION IS INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD - DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E. FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E. SCOLIOSIS, KYPHOSIS, OR LORDOSIS), TUMOR, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. EXCEPT FOR HOOKS, WHEN USED AS AN ANTEROLATERAL THORACIC/LUMBAR SYSTEM, THE CD HORIZON™ SPINAL SYSTEM MAY ALSO BE USED FOR THE SAME INDICATIONS AS AN ADJUNCT TO FUSION. WITH THE EXCEPTION OF DDD, THE CD HORIZON™ LEGACY™ 3.5MM RODS AND THE CD HORIZON™ SPINAL SYSTEM PEEK RODS AND ASSOCIATED COMPONENTS MAY BE USED FOR THE AFOREMENTIONED INDICATIONS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION. THE 3.5MM RODS MAY BE USED FOR THE SPECIFIC PEDIATRIC INDICATIONS NOTED BELOW. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE CD HORIZON™ SPINAL SYSTEM IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE SPINAL DEFORMITIES (I.E. SCOLIOSIS, KYPHOSIS, OR LORDOSIS) INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS,

	AND CONGENITAL SCOLIOSIS. ADDITIONALLY, THE CD HORIZON™ SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS DIAGNOSED WITH THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS, FRACTURE CAUSED BY TUMOR AND/OR TRAUMA, PSEUDARTHOSIS, AND/OR FAILED PREVIOUS FUSION. THESE DEVICES ARE TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE CD HORIZON™ SPIRE™ PLATE IS A POSTERIOR, SINGLE-LEVEL, NON-PEDICLE SUPPLEMENTAL FIXATION DEVICE INTENDED FOR USE IN THE NON-CERVICAL SPINE (T1-S1) AS AN ADJUNCT TO FUSION IN SKELETALLY MATURE PATIENTS. IT IS INTENDED FOR PLATE FIXATION/ATTACHMENT TO SPINOUS PROCESSES FOR THE PURPOSE OF ACHIEVING SUPPLEMENTAL FIXATION IN THE FOLLOWING CONDITIONS: DDD (AS PREVIOUSLY DEFINED), SPONDYLOLISTHESIS, TRAUMA, AND/OR TUMOR. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE CD HORIZON™ SPINAL SYSTEM RODS MAY BE CONNECTED TO THE VERTEX™ RECONSTRUCTION SYSTEM WITH THE VERTEX™ ROD CONNECTOR. REFER TO THE VERTEX™ RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE VERTEX™ INDICATIONS OF USE.,ORTHOSIS, SPINAL PEDICLE FIXATION, FOR DEGENERATIVE DISC DISEASE(CD HORIZON SPINAL SYSTEM (TITANIUM))-THE CD HORIZON™ SPINAL SYSTEM WITH OR WITHOUT SEXTANT™ INSTRUMENTATION IS INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD - DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E. FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E. SCOLIOSIS, KYPHOSIS, OR LORDOSIS), TUMOR, PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. EXCEPT FOR HOOKS, WHEN USED AS AN ANTEROLATERAL THORACIC/LUMBAR SYSTEM, THE CD HORIZON™ SPINAL SYSTEM MAY ALSO BE USED FOR THE SAME INDICATIONS AS AN ADJUNCT TO FUSION. WITH THE EXCEPTION OF DDD, THE CD HORIZON™ LEGACY™ 3.5MM RODS AND THE CD HORIZON™ SPINAL SYSTEM PEEK RODS AND ASSOCIATED COMPONENTS MAY BE USED FOR THE AFOREMENTIONED INDICATIONS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION. THE 3.5MM RODS MAY BE USED FOR THE SPECIFIC PEDIATRIC INDICATIONS NOTED BELOW. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE CD HORIZON™ SPINAL SYSTEM IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT PROGRESSIVE

	SPINAL DEFORMITIES (I.E. SCOLIOSIS, KYPHOSIS, OR LORDOSIS) INCLUDING IDIOPATHIC SCOLIOSIS, NEUROMUSCULAR SCOLIOSIS, AND CONGENITAL SCOLIOSIS. ADDITIONALLY, THE CD HORIZON™ SPINAL SYSTEM IS INTENDED TO TREAT PEDIATRIC PATIENTS DIAGNOSED WITH THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS, FRACTURE CAUSED BY TUMOR AND/OR TRAUMA, PSEUDARTHOSIS, AND/OR FAILED PREVIOUS FUSION. THESE DEVICES ARE TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE CD HORIZON™ SPIRE™ PLATE IS A POSTERIOR, SINGLE-LEVEL, NON-PEDICLE SUPPLEMENTAL FIXATION DEVICE INTENDED FOR USE IN THE NON-CERVICAL SPINE (T1-S1) AS AN ADJUNCT TO FUSION IN SKELETALLY MATURE PATIENTS. IT IS INTENDED FOR PLATE FIXATION/ATTACHMENT TO SPINOUS PROCESSES FOR THE PURPOSE OF ACHIEVING SUPPLEMENTAL FIXATION IN THE FOLLOWING CONDITIONS: DDD (AS PREVIOUSLY DEFINED), SPONDYLOLISTHESIS, TRAUMA, AND/OR TUMOR. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE CD HORIZON™ SPINAL SYSTEM RODS MAY BE CONNECTED TO THE VERTEX™ RECONSTRUCTION SYSTEM WITH THE VERTEX™ ROD CONNECTOR. REFER TO THE VERTEX™ RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE VERTEX™ INDICATIONS OF USE.,INTERVERTEBRAL BODY FUSION DEVICE(CRESCENT SPINAL SYSTEM TITANIUM)-THE CRESCENT® SPINAL SYSTEM TITANIUM IS INDICATED FOR INTERBODY FUSION WITH AUTOGENOUS BONE GRAFT IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTIGUOUS LEVELS FROM L2 TO S1. THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THESE IMPLANTS ARE TO BE USED WITH AUTOGENOUS BONE GRAFT. THESE DEVICES ARE INTENDED TO BE USED WITH MEDTRONIC SUPPLEMENTAL FIXATION INSTRUMENTATION WHICH HAS BEEN CLEARED BY THE FDA FOR USE IN THE LUMBAR SPINE., WIRE, SURGICAL(ATLAS CABLE SYSTEM (TITANIUM ALLOY))-PROPERLY USED, THIS DEVICE WILL AID IN THE REPAIR OR ATTACHMENT OF BONY STRUCTURES. THE INDICATIONS AND CONTRAINDICATIONS OF THIS SYSTEM SHOULD BE WELL UNDERSTOOD BY THE SURGEON. THE SYSTEM IS INDICATED FOR USE WHENEVER A CONSERVATIVE OR A NON-IMPLANT SURGERY IS DEEMED INSUFCIENT TO IMPROVE THE MEDICAL CONDITION OF THE

	PATIENT. THE ATLASTM CABLE SYSTEM CAN BE UTILIZED ANYWHERE MONOLAMENT WIRE HAS BEEN PREVIOUSLY FOUND TO BE INDICATED. THE INDICATIONS ARE: 1. SPINAL APPLICATIONS WOULD INCLUDE SUBLAMINAR AND INTRASPINOUS PROCESS WIRING FOR TRAUMA APPLICATIONS. ANOTHER APPLICATION WOULD BE THE USE OF THE ATLASTM CABLE SYSTEM FOR INSTRUMENTATION INVOLVED IN THE CORRECTION OF SCOLIOTIC, KYPHOTIC, AND LORDOTIC DEFORMITIES. THE STAINLESS STEEL SYSTEM MAY ALSO BE USED WITH OTHER STAINLESS STEEL SPINAL IMPLANTS SUCH AS THE UNIT ROD OR LUQUE ROD OR WHEREVER “WIRING” MAY HELP SECURE THE ATTACHMENT OF OTHER IMPLANTS. THE TITANIUM SYSTEM MAY ALSO BE USED WITH OTHER TITANIUM IMPLANTS. 2. TROCHANTERIC REATTACHMENT AFTER TROCHANTERIC OSTEOTOMY FOLLOWING TOTAL HIP ARTHROPLASTY. 3. STERNOTOMY INDICATIONS WOULD INCLUDE THE “RE-WIRING” OF OSTEOMIZING STERNUMS. 4. TRAUMA SURGERY INDICATIONS WOULD INCLUDE OLECRANON, ANKLE, PATELLA, AND SOME SHOULDER FRACTURE REWIRING.,SPINAL INTERVERTEBRAL BODY FIXATION ORTHOSIS (ATLANTIS ANTERIOR CERVICAL PLATE SYSTEM (NON-STERILE))-PROPERLY USED, THIS SYSTEM IS INTENDED FOR ANTERIOR INTERBODY SCREW FIXATION FROM C2 TO T1. THE INDICATIONS AND CONTRAINDICATIONS OF SPINAL INSTRUMENTATION SYSTEMS SHOULD BE WELL UNDERSTOOD BY THE SURGEON. THE SYSTEM IS INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR SPINE DURING THE DEVELOPMENT OF CERVICAL SPINAL FUSIONS IN PATIENTS WITH: 1) DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), 2) TRAUMA (INCLUDING FRACTURES), 3) TUMORS, 4) DEFORMITY (DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS), 5) PSEUDARTHROSIS, AND/OR 6) FAILED PREVIOUS FUSIONS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1501	IMP/MD/2019/000039	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DRUG COATED BALLOON CATHETER(RANGER OVER-THE-WIRE PACLITAXEL-COATED PTA BALLOON CATHETER)-THE RANGER AND RANGER SL BALLOON CATHETERS ARE INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE PERIPHERAL VASCULATURE, INCLUDING ILIAC AND INFRAINGUINAL ARTERIES.,DRUG COATED BALLOON CATHETER(AGENT MONORAIL PACLITAXEL-COATED PTCA BALLOON CATHETER)-THE AGENT BALLOON CATHETER IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) IN THE CORONARY ARTERIES TO TREAT IN-STENT RESTENOSIS (ISR) AND DE NOVO/ SMALL VESSEL DISEASE.,DRUG COATED BALLOON CATHETER(RANGER SL OVER-THE-WIRE PACLITAXEL-COATED PTA BALLOON CATHETER)-THE RANGER AND RANGER SL BALLOON CATHETERS ARE INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE PERIPHERAL VASCULATURE, INCLUDING ILIAC AND INFRAINGUINAL ARTERIES.,DRUG COATED BALLOON CATHETER(RANGER OVER-THE-WIRE PACLITAXEL-COATED PTA BALLOON CATHETER)-THE RANGER AND RANGER SL BALLOON CATHETERS ARE INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE PERIPHERAL VASCULATURE, INCLUDING ILIAC AND INFRAINGUINAL ARTERIES.

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1502	IMP/MD/2019/000040	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRATHECAL CATHETER (INTRATHECAL CATHETER WITH SUTURELESS CONNECTOR)-IT IS DESIGNED FOR CHRONIC INFUSION OF DRUG OR FLUID TESTED AS COMPATIBLE,INTRATHECAL CATHETER PUMP SEGMENT REVISION KIT(ASCENDA)-IT IS INTENDED TO DELIVER PARENTERAL DRUGS TO THE INTRATHECAL SPACE,CONNECTOR PLUG (ACCESSORY KIT)-THE MEDTRONIC MODEL B31060 CONNECTOR PLUG IS A COMPONENT OF A NEUROSTIMULATION SYSTEM. THE CONNECTOR PLUG FITS INTO AN UNUSED SOCKET OF A DUAL CHANNEL NEUROSTIMULATOR ., INTRATHECAL CATHETER(ASCENDA)-IT IS INTENDED TO DELIVER PARENTERAL DRUGS TO THE INTRATHECAL SPACE., NEUROSTIMULATOR(PERCEPT PC BRAINSENSE)-MEDTRONIC DBS THERAPY FOR MOVEMENT DISORDERS IS INDICATED FOR STIMULATION OF THE VENTRAL INTERMEDIATE NUCLEUS (VIM) FOR PATIENTS WITH DISABLING ESSENTIAL TREMOR OR PARKINSONIAN TREMOR, OR STIMULATION OF THE INTERNAL GLOBUS PALLIDUS (GPI) OR THE SUBTHALAMIC NUCLEUS (STN) FOR PATIENTS WITH SYMPTOMS OF PARKINSON'S DISEASE. STUDIES HAVE SHOWN THAT DEEP BRAIN STIMULATION WITH THE MEDTRONIC DBS THERAPY SYSTEM IS EFFECTIVE IN CONTROLLING ESSENTIAL TREMOR AND SYMPTOMS OF PARKINSON'S DISEASE THAT ARE NOT ADEQUATELY CONTROLLED WITH MEDICATIONS. ADDITIONALLY, DEEP BRAIN STIMULATION IS EFFECTIVE IN CONTROLLING DYSKINESIAS AND FLUCTUATIONS ASSOCIATED WITH MEDICAL THERAPY FOR PARKINSON'S DISEASE. MEDTRONIC DBS THERAPY FOR MOVEMENT DISORDERS IS ALSO INDICATED FOR STIMULATION OF THE INTERNAL GLOBUS PALLIDUS (GPI) OR THE SUBTHALAMIC NUCLEUS (STN) AS AN AID IN THE MANAGEMENT OF CHRONIC, INTRACTABLE (DRUG REFRACTORY) PRIMARY DYSTONIA, INCLUDING GENERALIZED AND SEGMENTAL DYSTONIA, HEMIDYSTONIA, AND CERVICAL DYSTONIA (TORTICOLLIS) FOR INDIVIDUALS 7 YEARS OF AGE AND OLDER. MEDTRONIC® DBS THERAPY FOR EPILEPSY BILATERAL ANTERIOR THALAMIC NUCLEUS (ANT) STIMULATION USING THE MEDTRONIC DBS SYSTEM FOR EPILEPSY IS INDICATED AS ADJUNCTIVE THERAPY FOR REDUCING THE FREQUENCY OF SEIZURES IN ADULTS DIAGNOSED WITH EPILEPSY CHARACTERIZED BY PARTIAL-ONSET SEIZURES, WITH OR WITHOUT SECONDARY GENERALIZATION, THAT ARE REFRACTORY TO ANTIEPILEPTIC MEDICATIONS.,INTRATHECAL CATHETER SPINAL SEGMENT REVISION KIT(ASCENDA)-IT IS INTENDED TO DELIVER PARENTERAL DRUGS TO THE INTRATHECAL SPACE.,CATHETER PASSER (CATHETER PASSER)-THE MEDTRONIC® MODEL 8583, 38 CM (15.0 IN.), CATHETER PASSERS ARE DESIGNED TO

		FACILITATE THE SUBCUTANEOUS PLACEMENT OF CATHETERS WITH AN OUTSIDE DIAMETER UP TO 4.0 MM (0.16 IN.) ,TUNNELING TOOL (DBS TUNNELING TOOL ACCESSORY KIT FOR USE WITH DBS EXTENSIONS)-THE MEDTRONIC MODEL 3755 DBS TUNNELING TOOL ACCESSORY KIT IS USED TO ASSIST IN THE TUNNELING AND PASSAGE OF EXTENSIONS.
1503	IMP/MD/2019/000041	1.License Holder Name: RECKITT BENCKISER (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NATURAL RUBBER LATEX CONDOMS(DUREX, KOHINOOR)-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION.
1504	IMP/MD/2019/000042	1.License Holder Name: DELTA BIOSCIENCE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL ABUTMENTS WITH SCREW(BIOLINE™ SIGDENT™ SDI™)-THE DENTAL SYSTEM IS INTENDED FOR SURGICAL PLACEMENT IN THE MAXILLARY AND/OR MANDIBULAR ARCH TO SUPPORT CROWNS, BRIDGES, OR OVER DENTURES IN EDENTULOUS OR PARTIALLY EDENTULOUS PATIENTS., DENTAL IMPLANT(BIOLINE™ SIGDENT™ SDI™)-THE DENTAL SYSTEM IS INTENDED FOR SURGICAL PLACEMENT IN THE MAXILLARY AND/OR MANDIBULAR ARCH TO SUPPORT CROWNS, BRIDGES, OR OVER DENTURES IN EDENTULOUS OR PARTIALLY EDENTULOUS PATIENTS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1505	IMP/MD/2019/000043	1.License Holder Name: M/S. BENQ INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANSCARE CHITOCLOT GAUZE(ANSCARE CHITOCLOT GAUZE)-FOR THE RAPID CONTROL OF MODERATE TO SEVERE BLEEDING AND MANAGEMENT OF ABRASIONS, LACERATIONS, CONTUSIONS, PUNCTURE WOUND AND BURNS.,ANSCARE CHITOCLOT BANDAGE(ANSCARE CHITOCLOT BANDAGE)-1. ANSCARE CHITOCLOT BANDAGE IS INTENDED FOR BLEEDING CONTROL OF WOUND. IT PROMOTES RAPID CONTROL OF WOUND BLEEDING AND EXUDATES ABSORPTION. 2. ACTS AS A PROTECTIVE BARRIER TO AVOID ABRASION, FRICTION AND CONTAMINATION. 3. USED FOR ABRA SIONS, LACERATION, OPEN CONTUSIONS, PUNCTURE WOUNDS ANDBURN/SCALD.,ANSCARE ENT SURGICAL SPONGE (STERILE)(ANSCARE ENT SURGICAL SPONGE)-THE DEVICE IS DESIGNED FOR PLACING INSIDE THE NASAL CAVITIES OR EAR CANAL FOR USE AS A TAMPONADE OR HEMOSTASIS DEVICE TO CONTROL BLOOD OOZING OR PERSISTENT BLEEDING.,ANSCARE HYDROCOLLOID DRESSING (NON-STERILE)(ANSCARE HYDROCOLLOID DRESSING)-WOUNDS CAUSED BY LASER OPERATIONS/ACNES/SUPERFICIAL WOUNDS.,DERMA ANGEL ACNE PATCHES (NON-STERILE)(ANSCARE DERMA ANGEL ACNE PATCHES)-DERMA ANGEL ACNE PATCH ENHANCES PUS ABSORBANCE AND HEALING FROM ACNES WOUNDS.,ANSCARE OPHTHALMIC SPONGE (ANSCARE OPHTHALMIC SPONGE)-THE PVA SPEAR IS INDICATED FOR USE IN OPHTHALMIC OR MICROSCOPIC SURGICAL PROCEDURES FOR ABSORBING EXCESS FLUIDS FROM THE OPERATIVE FIELD., ANSCARE SCAR REDUCTION SILICONE GEL (NON-STERILE)(ANSCARE SCAR REDUCTION SILICONE GEL)-SCAR REDUCTION SILICONE GEL HELPS PREVENT AND TREAT BOTH EXISTING AND NEW SCARS LIKE KELOIDS AND HYPERTROPHIC SCARS RESULTING FROM SURGERY, TRAUMA, BURNS ETC. (EXTERNAL USE ONLY),ANSCARE SCAR REDUCTION SILICONE GEL C+ (NON-STERILE)(ANSCARE SCAR REDUCTION SILICONE GEL C+)-SCAR REDUCTION SILICONE GEL C+ HELPS PREVENT AND TREAT BOTH EXISTING AND NEW SCARS LIKE KELOIDS AND HYPERTROPHIC SCARS RESULTING FROM SURGERY, TRAUMA, BURNS ETC. (EXTERNAL USE ONLY),ANSCARE CHITOCLOT PAD(ANSCARE CHITOCLOT PAD)-1. ANSCARE CHITOCLOT PAD IS INDICATED FOR OF BLEEDING WOUND MANAGEMENT. IT PROMOTES RAPID CONTROL OF WOUND BLEEDING AND EXUDATES ABSORPTION. IN ADDITION, IT ACTS AS A PROTECTIVE BARRIER TO PREVENT WOUND FROM CONTAMINATION. 2. IT IS INDICATED FOR THE FOLLOWING WOUND, INCLUDING LACERATIONS, ABSORPTION, HEMODIALYSIS WOUND AND PUNCTURE SITES FOR VASCULAR PROCEDURES.

1506	IMP/MD/2019/000044	1.License Holder Name: MERCK SPECIALITIES PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PEN NEEDLES (PENCYLCAP)-INTENDED USE NEEDLE USED WITH NEEDLE-BASED INJECTION SYSTEMS (NIS) FOR SUBCUTANEOUS INJECTION OF FLUID DRUG PRODUCTS
1507	IMP/MD/2019/000044	1.License Holder Name: MERCK SPECIALITIES PVT LTD ,GALA NO. 1 TO 10, BLDG NO. C-9, SHREE ARIHANT COMPOUND, GROUND FLOOR, RETIBUNDER ROAD, , KALHER , TAL -BHIWANDI - 15 (THANE Z5) , THANE MAHARASHTRA ,421302 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PEN NEEDLES(SEROFINE)-INTENDED FOR USE WITH NEEDLE- BASED INJECTION SYSTEM (NIS) FOR SUBCUTANEOUS INJECTION OF FLUID DRUG PRODUCTS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1508	IMP/MD/2019/000045	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DELIVERY SHEATH (AMPLATZER AMULET DELIVERY SHEATH)-THE AMPLATZER AMULET DELIVERY SHEATH IS INTENDED TO PROVIDE A PATHWAY THROUGH WHICH DEVICES ARE INTRODUCED WITHIN THE CHAMBERS OF THE HEART.,CARDIAC OCCLUDER DELIVERY SYSTEM(AMPLATZER TREVISIO INTRAVASCULAR DELIVERY SYSTEM)-THE AMPLATZER™ TREVISIO™ INTRAVASCULAR DELIVERY SYSTEM IS INTENDED TO FACILITATE THE ATTACHMENT, LOADING, DELIVERY AND DEPLOYMENT OF THE AMPLATZER™ OCCLUDER DEVICES.,CARDIAC OCCLUDER DELIVERY SYSTEM(AMPLATZER TORQVUE 45X45 DELIVERY SHEATH)-THE AMPLATZER TORQVUE 45X45 DELIVERY SHEATH IS INTENDED TO PROVIDE A PATHWAY THROUGH WHICH DEVICES ARE INTRODUCED WITHIN THE CHAMBERS OF THE HEART., DUCT OCCLUDER(AMPLATZER PICCOLO OCCLUDER)-THE AMPLATZER PICCOLO OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER OCCLUSION DEVICE INTENDED FOR THE NONSURGICAL CLOSURE OF A PATENT DUCTUS ARTERIOSUS (PDA)., CARDIAC OCCLUDERS(AMPLATZER PFO OCCLUDER)-THE AMPLATZER PFO OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER OCCLUSION DEVICE INTENDED TO CLOSE ALL TYPES OF PFOS (I.E. CLASSICAL AS WELL AS THOSE ANEURYSM OF THE SEPTUM) IN PATIENTS WITH HISTORY OF STROKE OR TRANSIENT ISCHEMIC ATTACKS (TIAS) DIAGNOSED BY ECHOCRADIOGRAPHY WITH RIGHT-TO-LEFT SHUNTING DURING THE VALSALVA MANEUVER.,CARDIAC OCCLUDER(AMPLATZER VALVULAR PLUG III)-THE AMPLATZER™ VALVULAR PLUG III (AVPIII) IS INTENDED FOR PERCUTANEOUS, TRANSCATHETER CLOSURE OF A PARAVALVULAR LEAK THAT HAS DEVELOPED AFTER AN AORTIC OR MITRAL MECHANICAL SURGICAL VALVE IMPLANT PROCEDURE. THE DEVICE IS INDICATED FOR PATIENTS WITH A CLINICALLY SIGNIFICANT PARAVALVULAR LEAK SHOWING SIGNS OF HEART FAILURE AND/OR PARAVALVULAR LEAK-ASSOCIATED HEMOLYSIS, NECESSITATING RECURRING BLOOD TRANSFUSIONS.,CARDIAC OCCLUDERS(AMPLATZER CARDIAC PLUG)-THE AMPLATZER CARDIAC PLUG IS A PERCUTANEOUS TRANSCATHETER DEVICE INTENDED TO PREVENT THROMBUS EMBOLIZATION FROM THE LEFT ATRIAL APPENDAGE (LAA) IN PATIENTS WHO HAVE NONVALVULAR ATRIAL FIBRILLATION., CARDIAC OCCLUDERS(AMPLATZER VASCULAR PLUG 4)-THE AMPLATZER VASCULAR PLUG 4 IS INDICATED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE., CARDIAC OCCLUDERS(AMPLATZER POST INFARCT MUSCULAR VSD OCCLUDER)-THE AMPLATZER P.I. MUSCULAR VSD OCCLUDER IS

	PERCUTANEOUS, TRANSCATHETER, VENTRICULAR SEPTAL DEFECT CLOSURE DEVICE DESIGNED FOR THE OCCLUSION OF MUSCULAR VENTRICULAR SEPTAL DEFECTS.,CARDIAC OCCLUDERS(AMPLATZER VASCULAR PLUG III)-THE AMPLATZER VASCULAR PLUG III IS INDICATED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE.,CARDIAC OCCLUDERS(AMPLATZER MUSCULAR VSD OCCLUDER)-THE AMPLATZER MUSCULAR VSD OCCLUDER IS PERCUTANEOUS, TRANSCATHETER, VENTRICULAR SEPTAL DEFECT CLOSURE DEVICE DESIGNED FOR THE OCCLUSION OF MUSCULAR VENTRICULAR SEPTAL DEFECTS.,CARDIAC OCCLUDERS(AMPLATZER DUCT OCCLUDER II)-THE AMPLATZER DUCT OCCLUDER II IS A PERCUTANEOUS TRANSCATHETER OCCLUSION DEVICE INTENDED FOR THE NON-SURGICAL CLOSURE OF PATENT DUCTUS ARTERIOSUS (PDA).,CARDIAC OCCLUDERS (AMPLATZER DUCT OCCLUDER)-THE AMPLATZER DUCT OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER OCCLUSION DEVICE INTENDED FOR THE NONSURGICAL CLOSURE OF A PATENT DUCTUS ARTERIOSUS (PDA).,CARDIAC OCCLUDER DELIVERY SYSTEM (AMPLATZER TORQVUE LP DELIVERY SYSTEM)-THE AMPLATZER TORQVUE LP DELIVERY SYSTEM IS INTENDED TO FACILITATE THE ATTACHMENT, LOADING, DELIVERY, AND DEPLOYMENT OF THE AMPLATZER DEVICES.,CARDIAC OCCLUDER DELIVERY SYSTEM (AMPLATZER TORQVUE EXCHANGE SYSTEM)-THE AMPLATZER TORQVUE EXCHANGE SYSTEM IS INTENDED FOR REMOVAL OF AN AMPLATZER DELIVERY SHEATH AND SUBSEQUENT EXCHANGE FOR AN AMPLATZER DELIVERY SHEATH OF EQUAL OR LARGER DIAMETER.,CARDIAC OCCLUDERS(AMPLATZER SEPTAL OCCLUDER)-THE AMPLATZER SEPTAL OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER ATRIAL SEPTAL DEFECT CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF ATRIAL SEPTAL DEFECTS (ASD'S) IN SECUNDUM POSITION OR PATIENTS WHO HAVE UNDERGONE A FENESTRATED FONTAN PROCEDURE AND WHO NOW REQUIRE CLOSURE OF THE FENESTRATION,CARDIAC OCCLUDERS(AMPLATZER VASCULAR PLUG II)-THE AMPLATZER VASCULAR PLUG II (AVP II) IS INDICATED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE.,CARDIAC OCCLUDERS(AMPLATZER VASCULAR PLUG)-THE AMPLATZER VASCULAR PLUG IS INDICATED FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE.,CARDIAC OCCLUDERS(AMPLATZER MEMBRANOUS VSD OCCLUDER)-THE AMPLATZER MEMBRANOUS VSD OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER OCCLUSION DEVICE INTENDED FOR OCCLUSION OF HEMODYNAMICALLY SIGNIFICANT PERIMEMBRANOUS VSDS IN THE MEMBRANOUS VENTRICULAR SEPTUM.,CARDIAC OCCLUDER DELIVERY SYSTEM(AMPLATZER

		TORQVUE DELIVERY SYSTEM WITH PUSHER CATHETER)-THE AMPLATZER TORQVUE DELIVERY SYSTEM WITH PUSHER CATHETER IS INTENDED TO FACILITATE THE ATTACHMENT, LOADING, DELIVERY AND DEPLOYMENT OF THE AMPLATZER MEMBRANOUS VSD OCCLUDER DEVICE.,CARDIAC OCCLUDER DELIVERY SYSTEM (AMPLATZER TORQVUE DELIVERY SYSTEM)-THE AMPLATZER TORQVUE DELIVERY SYSTEM IS INDICATED FOR USE BY INTERVENTIONAL CARDIOLOGIST TO PLACE AN AMPLATZER OCCLUDER DEVICE.,CARDIAC OCCLUDERS(AMPLATZER DUCT OCCLUDER II ADDITIONAL SIZES)-THE AMPLATZER DUCT OCCLUDER II ADDITIONAL SIZES IS A PERCUTANEOUS TRANSCATHETER OCCLUSION DEVICE INTENDED FOR THE NON-SURGICAL CLOSURE OF PATENT DUCTUS ARTERIOSUS (PDA).,CARDIAC OCCLUDERS (AMPLATZER MULTI-FENESTRATED SEPTAL OCCLUDER-“CRIBRIFORM”)-THE AMPLATZER CRIBRIFORM OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER, ATRIAL SEPTAL DEFECT CLOSURE DEVICE INTENDED FOR THE CLOSURE OF MULTI-FENESTRATED (CRIBRIFORM) ATRIAL SEPTAL DEFECTS.,CARDIAC OCCLUDER DELIVERY SYSTEM(AMPLATZER SIZING BALLOON II)-THE AMPLATZER SIZING BALLOON II IS INDICATED FOR USE IN THOSE PATIENTS WITH CARDIOVASCULAR DEFECTS WHEREIN ACCURATE MEASUREMENT OF THE DEFECT IS IMPORTANT IN SELECTING THE APPROPRIATELY SIZED OCCLUDER DEVICE.,CARDIAC OCCLUDER DELIVERY SYSTEM(AMPLATZER TORQVUE LP CATHETER)-THE AMPLATZER TORQVUE LP CATHETER IS INTENDED TO FACILITATE THE LOADING, DELIVERY AND DEPLOYMENT OF AMPLATZER DEVICES.
1509	IMP/MD/2019/000046	1.License Holder Name: CADILA HEALTHCARE LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK SCF)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS
1510	IMP/MD/2019/000047	1.License Holder Name: SUN PHARMACEUTICAL INDUSTRIES LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS

1511	IMP/MD/2019/000048	1.License Holder Name: DR. REDDYS LABORATORIES LIMITED, C/O M/S GLAND PHARMA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE (STERILE)(BD HYPAK SCF)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS.
1512	IMP/MD/2019/000049	1.License Holder Name: CADILA HEALTHCARE LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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1513	IMP/MD/2019/000050	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STENT GRAFT BALLOON CATHETER(RELIANT)-THE RELIANT STENT GRAFT BALLOON CATHETER IS INTENDED TO TEMPORARILY OCCLUDE LARGE VESSELS OR TO EXPAND VASCULAR PROSTHESES.THE DEVICE IS INTENDED TO ASSIST IN THE EXPANSION OF SELF-EXPANDING STENT GRAFTS., VENASEAL™ CLOSURE SYSTEM(VENASEAL™ CLOSURE SYSTEM)-THE VENASEAL CLOSURE SYSTEM IS INTENDED FOR PERMANENT, COMPLETE, ENDOVASCULAR ADHESIVE CLOSURE OF THE GREAT SAPHENOUS VEIN (GSV) AND ASSOCIATED VARICOSITIES IN THE TREATMENT OF VENOUS REFLUX DISEASE,TRANSCATHETER LEADLESS PACEMAKER(MICRA AV)-MICRA AV MODEL MC1AVR1 IS INDICATED FOR VDD PACING IN PATIENTS WHEN A DUAL CHAMBER TRANSVENOUS PACING SYSTEM IS CONSIDERED A POOR OPTION OR NOT DEEMED NECESSARY FOR EFFECTIVE THERAPY, AND WHEN A RIGHT VENTRICULAR TRANSCATHETER PACING SYSTEM PROMOTING AV SYNCHRONY AT REST IS ACCEPTABLE. CONDITIONS WHEN A PATIENT IS CONSIDERED A POOR CANDIDATE FOR TRANSVENOUS PACING MAY INCLUDE, BUT ARE NOT LIMITED TO, TORTUOUS ANATOMY, A NEED TO PRESERVE VENOUS ACCESS, OR INCREASED RISK OF INFECTION. THE DEVICE PROVIDES AV SYNCHRONY AT REST AND RATE RESPONSIVE (VVIR) PACING DURING PERIODS OF HIGH PATIENT ACTIVITY. DEVICE-MEDIATED AV SYNCHRONY CAN VARY DEPENDING ON PATIENT CONDITION AND ACTIVITY LEVELS, AND IT CAN BE LIMITED AT HIGH SINUS RATES. DURING PERIODS OF INTERMITTENT AV SYNCHRONY, THE DEVICE WILL PROVIDE VENTRICULAR PACING SUPPORT WITH AN INCREASED POTENTIAL FOR PACING RATE VARIABILITY. MICRA AV MODEL MC1AVR1 IS INDICATED FOR USE IN PATIENTS WHO HAVE EXPERIENCED ONE OF THE FOLLOWING: • PAROXYSMAL OR PERMANENT HIGH-GRADE AV BLOCK IN THE ABSENCE OF AF • PAROXYSMAL OR PERMANENT HIGH-GRADE AV BLOCK IN THE PRESENCE OF PAROXYSMAL AF • PAROXYSMAL OR PERMANENT HIGH-GRADE AV BLOCK IN THE PRESENCE OF PERSISTENT AF WHEN ATTEMPTS AT RESTORING SINUS RHYTHM ARE STILL PLANNED THE DEVICE IS DESIGNED TO BE USED ONLY IN THE RIGHT VENTRICLE.,DIRECTIONAL ATHERECTOMY SYSTEM (HAWKONE DIRECTIONAL ATHERECTOMY SYSTEM)-THE HAWKONE DIRECTIONAL ATHERECTOMY SYSTEM IS INDICATED FOR USE IN ATHERECTOMY OF THE PERIPHERAL VASCULATURE. THE HAWKONE CATHETER IS NOT INTENDED FOR USE IN THE CORONARY, CAROTID, ILIAC, OR RENAL VASCULATURE.,ENDOVASCULAR GRAFT (VALIANT THORACIC STENT GRAFT WITH THE CAPTIVIA DELIVERY SYSTEM)-THE VALIANT THORACIC STENT GRAFT WITH THE CAPTIVIA

	DELIVERY SYSTEM IS INDICATED FOR TREATMENT OF DISEASES OF THE DESCENDING THORACIC AORTA INCLUDING BUT NOT LIMITED TO ANEURYSMS AND DISSECTIONS. THE VALIANT THORACIC STENT GRAFT IS INDICATED FOR EXCLUSION OF THE ANEURYSM, THE FALSE LUMEN OR SITE OF RUPTURE AND RESTORATION OF BLOOD FLOW THROUGH THE STENT GRAFT LUMEN. THE DEVICE IS INTENDED FOR USE IN PATIENTS WHO ARE CANDIDATES FOR CONVENTIONAL SURGICAL REPAIR, AND IN PATIENTS WHO ARE NOT CANDIDATES FOR CONVENTIONAL SURGICAL REPAIR DUE TO PRE-EXISTING RISK FACTORS ,GUIDE EXTENSION CATHETER(TELESCOPE GUIDE EXTENSION CATHETER)-TELESCOPE GUIDE EXTENSION CATHETER IS INTENDED TO BE USED IN CONJUNCTION WITH GUIDE CATHETERS TO ACCESS DISCRETE REGIONS OF THE CORONARY AND/OR PERIPHERAL VASCULATURE, AND TO FACILITATE PLACEMENT OF INTERVENTIONAL DEVICES.,ENDOVASCULAR GRAFT(ENDURANT II STENT GRAFT SYSTEM)-THE ENDURANT II/ENDURANT IIS STENT GRAFT SYSTEM IS INDICATED FOR THE ENDOVASCULAR TREATMENT OF INFRARENAL ABDOMINAL AORTIC OR AORTOILIAC ANEURYSMS IN PATIENTS WITH THE FOLLOWING CHARACTERISTICS: • ADEQUATE ILIAC OR FEMORAL ACCESS VESSEL MORPHOLOGY THAT IS COMPATIBLE WITH • VASCULAR ACCESS TECHNIQUES, DEVICES OR ACCESSORIES • PROXIMAL NECK LENGTH OF 10 MM WITH INSIGNIFICANT CALCIFICATION, OR INSIGNIFICANT • THROMBUS WITH 60° INFRARENAL AND 45° SUPRARENAL ANGULATION AND A VESSEL • DIAMETER APPROXIMATELY 10% TO 20% SMALLER THAN THE LABELED • ENDURANT II/ENDURANT IIS STENT GRAFT DIAMETER. • PROXIMAL NECK LENGTH OF 15 MM WITH INSIGNIFICANT CALCIFICATION, OR INSIGNIFICANT • THROMBUS WITH 75° INFRARENAL AND 60° SUPRARENAL ANGULATION AND A VESSEL • DIAMETER APPROXIMATELY 10% TO 20% SMALLER THAN THE LABELED ENDURANT II/ENDURANT IIS STENT GRAFT DIAMETER. • DISTAL FIXATION LENGTH OF 15 MM • AORTIC NECK DIAMETERS WITH A RANGE OF 19 TO 32 MM • ILIAC DIAMETERS WITH A RANGE OF 8 TO 25 MM • MORPHOLOGY SUITABLE FOR ANEURYSM REPAIR • ONE OF THE FOLLOWING: O ANEURYSM DIAMETER >5 CM O ANEURYSM DIAMETER OF 4 TO 5 CM, WHICH HAS ALSO INCREASED IN SIZE BY 0.5 CM O IN THE LAST 6 MONTHS O ANEURYSM THAT IS AT LEAST 1.5 TIMES THE DIAMETER OF THE NORMAL INFRARENAL O AORTA , THORACIC STENT GRAFT SYSTEM(VALIANT NAVION THORACIC STENT GRAFT SYSTEM)-THE VALIANT NAVION THORACIC STENT GRAFT SYSTEM IS INDICATED FOR TREATMENT OF DISEASES OF THE DESCENDING THORACIC AORTA, INCLUDING, BUT NOT LIMITED TO, ANEURYSMS, DISSECTIONS, AND BLUNT TRAUMATIC AORTIC INJURIES (BTAIS). THE VALIANT NAVION THORACIC STENT GRAFT IS

	INDICATED FOR EXCLUSION OF THE ANEURYSM, THE FALSE LUMEN, OR SITE OF RUPTURE, AND THE RESTORATION OF BLOOD FLOW THROUGH THE STENT GRAFT LUMEN. THE DEVICE IS INTENDED FOR USE IN PATIENTS WHO ARE CANDIDATES FOR CONVENTIONAL SURGICAL REPAIR, AND IN PATIENTS WHO ARE NOT CANDIDATES FOR CONVENTIONAL SURGICAL REPAIR DUE TO PRE-EXISTING RISK FACTORS.,DELIVERY CATHETER(MICRA TRANSCATHETER LEADLESS PACEMAKER)-MICRA MODEL MC1VR01 IS INDICATED FOR USE IN PATIENTS WHO HAVE EXPERIENCED ONE OR MORE OF THE FOLLOWING CONDITIONS: · PAROXYSMAL OR PERMANENT HIGH-GRADE AV BLOCK IN THE PRESENCE OF AF · PAROXYSMAL OR PERMANENT HIGH-GRADE AV BLOCK IN THE ABSENCE OF AF, AS AN ALTERNATIVE TO DUAL CHAMBER PACING, WHEN A DUAL CHAMBER TRANSVENOUS PACING SYSTEM IS CONSIDERED DIFFICULT, HIGH RISK, OR NOT DEEMED NECESSARY FOR EFFECTIVE THERAPY · SYMPTOMATIC BRADYCARDIA-TACHYCARDIA SYNDROME OR SINUS NODE DYSFUNCTION (SINUS BRADYCARDIA OR SINUS PAUSES), AS AN ALTERNATIVE TO ATRIAL OR DUAL CHAMBER PACING, WHEN A DUAL-CHAMBER TRANSVENOUS PACING SYSTEM IS CONSIDERED DIFFICULT, HIGH RISK, OR NOT DEEMED NECESSARY FOR EFFECTIVE THERAPY RATE-RESPONSIVE PACING IS INDICATED TO PROVIDE INCREASED HEART RATE APPROPRIATE TO INCREASING LEVELS OF ACTIVITY. THE DEVICE IS DESIGNED TO BE USED ONLY IN THE RIGHT VENTRICLE,DELIVERY CATHETER(C315 DELIVERY CATHETER)-THE C315 DELIVERY CATHETER IS INDICATED FOR THE INTRODUCTION OF VARIOUS TYPES OF PACING OR DEFIBRILLATOR LEADS AND CATHETERS.,PACLITAXEL ELUTING PTCA BALLOON CATHETER(IN. PACT FALCON)-THE IN. PACT FALCON IS INTENDED TO BE USED IN THE NATIVE CORONARY ARTERIES. IT IS INDICATED FOR THE DILATATION OF THE STENOSIS PORTIONS, INCLUDING TOTAL OCCLUSIONS AND ACUTE MYOCARDIAL INFARCTION. IT IS ALSO INDICATED FOR THE POST DILATATION OF STENTS.,DRUG ELUTING STENT(RESOLUTE ONYX ZOTAROLIMUS ELUTING CORONARY STENT SYSTEM)-THE RESOLUTE ONYX STENT SYSTEM IS INTENDED FOR USE IN PATIENT ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) WITH A REFERENCE VESSEL DIAMETER OF 2.0 MM TO TO 5.0MM. THE RESOLUTE ONYX STENT IS INDICATED FOR THE TREATMENT OF THE FOLLOWING PATIENTS AND LESION SUNSETS. • DIABETES MELLITUS • MULTI VESSEL DISEASE • ACUTE CORONARY SYNDROME (ACS) • ACUTE MYOCARDIAL INFRACTION (AMI) • UNSTABLE ANGINA (UA) • BIFURACTION LESIONS • IN-STENT RESTENOSIS (ISR) • CHRONIC TOTAL OCCLUSION (CTO) • TOTAL OCCLUSION (TO) • LEFT MAIN (LM) • SMALL VESSEL (SV) THE RESOLUTE ONYX STENT IS INTENDED TO IMPROVE CORONARY

	LUMINAL DIAMETER OF EITHER SINGLE OR MULTIPLE VESSEL AS AN ADJUNCT TO CORONARY INTERVENTION AND REDUCE STENOSIS. THE STENT IS INTENDED AS A PERMANENT IMPLANTED DEVICE., DELIVERY CATHETER SYSTEM(ATTAIN SELECT II + SURE VALVE)-THE ATTAIN SELECT II + SUREVALVE DELIVERY CATHETER SYSTEM IS INDICATED FOR THE DELIVERY OF CONTRAST MEDIUM AND TRANSVENOUS DEVICES TO THE CORONARY SINUS AND LEFT-HEART VENOUS ANATOMY. THE DELIVERY CATHETER SYSTEM IS INDICATED FOR USE WITH OUTER GUIDE CATHETERS.,GUIDE CATHETER FOR LEFT HEART DELIVERY (ATTAIN COMMAND + SUREVALVE)-THE LEFT-HEART DELIVERY SYSTEM IS INTENDED FOR INTRODUCING TRANSVENOUS DEVICES AND LEADS INTO VESSELS OF THE LEFT HEART VIA THE CORONARY SINUS.,DRUG ELUTING STENT(ENDEAVOR RESOLUTE ZOTAROLIMUS ELUTING CORONARY STENT SYSTEM)-THE ENDEAVOR RESOLUTE ZOTAROLIMUS ELUTING CORONARY STENT SYSTEM IS INTENDED FOR USE IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM TO 4.0 MM. ENDEAVOR RESOLUTE STENT IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETERS AS AN ADJUNCT TO CORONARY INTERVENTIONS AND REDUCE RESTENOSIS. THE STENTS ARE INTENDED AS PERMANENTLY IMPLANTED DEVICES.,DRUG ELUTING STENT(RESOLUTE INTEGRITY ZOTAROLIMUS ELUTING CORONARY STENT SYSTEM)-THE RESOLUTE INTEGRITY STENT SYSTEM IS INTENDED FOR USE IN PATIENTS, INCLUDING THOSE WITH DIABETES MELLITUS, ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM TO 4.0 MM. THE RESOLUTE INTEGRITY STENT IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER OF EITHER SINGLE OR MULTIPLE VESSEL AS AN ADJUNCT TO CORONARY INTERVENTIONS AND TO REDUCE RESTENOSIS. THE STENT IS INTENDED AS A PERMANENTLY IMPLANTED DEVICE., COATED PTA BALLOON CATHETER(IN.PACT ADMIRAL)-THE IN.PACT ADMIRAL IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN PATIENTS WITH OBSTRUCTIVE DISEASE OF PERIPHERAL ARTERIES, INCLUDING INSTENT RESTENOSIS (ISR), AND WITH OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE.

1514	IMP/MD/2019/000051	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACETABULAR SHELLS(R3) -HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTUREDISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY

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1515	IMP/MD/2019/000052	1.License Holder Name: DISPO SURGICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EXTENSION SET (OPTISTAR™ MR SYRINGE 60/60/90 MULTIPACK)-THESE DISPOSABLES ARE DESIGNED TO BE USED AS PART OF THE CONTRAST INJECTION SYSTEM TO OBTAIN DIAGNOSTIC IMAGES WHEN USED WITH COMPUTED TOMOGRAPHY (CT), MR OR ANGIOGRAPHIC EQUIPMENT,EXTENSION SET(EXTENSION TUBING, HIGH PRESSURE – MALE LUER ADAPTER)-THESE DISPOSABLES ARE DESIGNED TO BE USED AS PART OF THE CONTRAST INJECTION SYSTEM TO OBTAIN DIAGNOSTIC IMAGES WHEN USED WITH COMPUTED TOMOGRAPHY (CT), MR OR ANGIOGRAPHIC EQUIPMENT, SYRINGE FOR INJECTOR(ANGIOMAT™ SYRINGE WITH HANDI-FIL™ STRAW)-THESE DISPOSABLE ARE DESIGNED TO BE USED AS PART OF THE CONTRAST INJECTION SYSTEM TO OBTAIN DIAGNOSTIC IMAGES WHEN USED WITH COMPUTED TOMOGRAPHY (CT), MR OR ANGIOGRAPHIC EQUIPMENT,EXTENSION SET(EXTENSION TUBING, Y-TUBING ADAPTER – DUAL CHECK VALVES)-THESE DISPOSABLES ARE DESIGNED TO BE USED AS PART OF THE CONTRAST INJECTION SYSTEM TO OBTAIN DIAGNOSTIC IMAGES WHEN USED WITH COMPUTED TOMOGRAPHY (CT), MR OR ANGIOGRAPHIC EQUIPMENT, SYRINGE FOR INJECTOR(CT9000™ FRONT LOAD SYRINGE WITH HANDI-FIL™ STRAW)-THESE DISPOSABLES ARE DESIGNED TO BE USED AS PART OF THE CONTRAST INJECTION SYSTEM TO OBTAIN DIAGNOSTIC IMAGES WHEN USED WITH COMPUTED TOMOGRAPHY (CT), MR OR ANGIOGRAPHIC EQUIPMENT ,EXTENSION SET(CT9000™ ADV-CT MULTIPACK)-THESE DISPOSABLES ARE DESIGNED TO BE USED AS PART OF THE CONTRAST INJECTION SYSTEM TO OBTAIN DIAGNOSTIC IMAGES WHEN USED WITH COMPUTED TOMOGRAPHY (CT), MR OR ANGIOGRAPHIC EQUIPMENT,EXTENSION SET (OPTIVANTAGE™ SYRINGE-DUAL PACK)-THESE DISPOSABLES ARE DESIGNED TO BE USED AS PART OF THE CONTRAST INJECTION SYSTEM TO OBTAIN DIAGNOSTIC IMAGES WHEN USED WITH COMPUTED TOMOGRAPHY (CT), MR OR ANGIOGRAPHIC EQUIPMENT, SYRINGE FOR INJECTOR(OPTISTAR™ MR SYRINGE – LATERAL FLOW NEEDLE)-THESE DISPOSABLES ARE DESIGNED TO BE USED AS PART OF THE CONTRAST INJECTION SYSTEM TO OBTAIN DIAGNOSTIC IMAGES WHEN USED WITH COMPUTED TOMOGRAPHY (CT), MR OR ANGIOGRAPHIC EQUIPMENT,SYRINGE FOR INJECTOR(ILLUMENA™ LINDEN-LUER SYRINGE WITH HANDI-FIL STRAW)-THESE DISPOSABLES ARE DESIGNED TO BE USED AS PART OF THE CONTRAST INJECTION SYSTEM TO OBTAIN DIAGNOSTIC IMAGES WHEN USED WITH COMPUTED TOMOGRAPHY (CT), MR OR ANGIOGRAPHIC EQUIPMENT,EXTENSION SET(OPTIVANTAGE™ -CT Y-

		TUBING)-THESE DISPOSABLES ARE DESIGNED TO BE USED AS PART OF THE CONTRAST INJECTION SYSTEM TO OBTAIN DIAGNOSTIC IMAGES WHEN USED WITH COMPUTED TOMOGRAPHY (CT), MR OR ANGIOGRAPHIC EQUIPMENT,EXTENSION SET(OPTIVANTAGE™ SYRINGE-DUAL PACK)-THESE DISPOSABLES ARE DESIGNED TO BE USED AS PART OF THE CONTRAST INJECTION SYSTEM TO OBTAIN DIAGNOSTIC IMAGES WHEN USED WITH COMPUTED TOMOGRAPHY (CT), MR OR ANGIOGRAPHIC EQUIPMENT,EXTENSION SET (OPTISTAR™- Y-TUBING – SINGLE CHECK VALVE.)-THESE DISPOSABLES ARE DESIGNED TO BE USED AS PART OF THE CONTRAST INJECTION SYSTEM TO OBTAIN DIAGNOSTIC IMAGES WHEN USED WITH COMPUTED TOMOGRAPHY (CT), MR OR ANGIOGRAPHIC EQUIPMENT.
1516	IMP/MD/2019/000053	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEEDLE FREE SYRINGE (TEXIUM NEEDLE-FREE SYRINGE)-TO PROVIDE LEAK-FREE HANDLING OF POTENTIALLY HAZARDOUS FLUIDS DURING ALL THREE PHASES OF DRUG HANDLING WHEN THE CML IS USED IN CONJUNCTION WITH THE SMARTSITE NEEDLE-FREE VALVE: THE PREPARATION OF THE DRUG, THE ADMINISTRATION OF THE DRUG TO THE PATIENT AND WASTE HANDLING

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1517	IMP/MD/2019/000054	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER(DRAGONFLY OPSTAR IMAGING CATHETER)-THE DRAGONFLY OPSTAR™ IMAGING CATHETER WITH THE OCT IMAGING SYSTEM IS INTENDED FOR THE IMAGING OF CORONARY ARTERIES AND IS INDICATED IN PATIENTS WHO ARE CANDIDATES FOR TRANSLUMINAL INTERVENTIONAL PROCEDURES. THE DRAGONFLY OPSTAR IMAGING CATHETER IS INTENDED FOR USE IN VESSELS 2.0 TO 3.5 MM IN DIAMETER. THE DRAGONFLY OPSTAR IMAGING CATHETER IS NOT INTENDED FOR USE IN THE LEFT MAIN CORONARY ARTERY OR IN A TARGET VESSEL WHICH HAS UNDERGONE A PREVIOUS BYPASS PROCEDURE.,IMAGING CATHETER(DRAGONFLY OPTIS)-THE DRAGONFLY OPTIS IMAGING CATHETER AND OCT IMAGING SYSTEM ARE INTENDED: 1.FOR QUALITATIVE AND QUANTITATIVE EVALUATION OF VASCULAR MORPHOLOGY IN THE CORONARY ARTERIES 2. AS AN ADJUNCT TO CONVENTIONAL ANGIOGRAPHIC PROCEDURE TO PROVIDE AN IMAGE OF VESSEL LUMEN AND WALL STRUCTURES 3. FOR THE IMAGING OF CORONARY ARTERIES AND IS INDICATED IN PATIENTS WHO ARE CANDIDATES FOR TRANSLUMINAL INTERVENTIONAL PROCEDURE.. IMAGING CATHETER KIT(DRAGONFLY OPTIS KIT)-THE DRAGONFLY OPTIS IMAGING CATHETER AND OCT IMAGING SYSTEM ARE INTENDED: 1.FOR QUALITATIVE AND QUANTITATIVE EVALUATION OF VASCULAR MORPHOLOGY IN THE CORONARY ARTERIES 2. AS AN ADJUNCT TO CONVENTIONAL ANGIOGRAPHIC PROCEDURE TO PROVIDE AN IMAGE OF VESSEL LUMEN AND WALL STRUCTURES 3. FOR THE IMAGING OF CORONARY ARTERIES AND IS INDICATED IN PATIENTS WHO ARE CANDIDATES FOR TRANSLUMINAL INTERVENTIONAL PROCEDURE.
1518	IMP/MD/2019/000055	1.License Holder Name: M/S NIPRO MEDICAL (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD TUBING SET (NIPRO SET, BLOOD TUBING SET)-IT IS INDICATED FOR USE DURING THE HEMODIALYSIS TO PROVIDE ACCESS TO PATIENT BLOOD. WHEN USED IN HEMODIALYSIS IT IS PART OF AN ARTIFICIAL KIDNEY SYSTEM FOR TREATMENT OF PATIENTS WITH RENAL FAILURE OR TOXEMIC CONDITION

1519	IMP/MD/2019/000056	1.License Holder Name: CARDINAL HEALTH MEDICAL PRODUCTS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYDROPHILIC GUIDEWIRE (AQUATRACK)-AQUATRACK HYDROPHILIC NITINOL GUIDEWIRES ARE INTENDED FOR USE IN ANGIOGRAPHIC PROCEDURES TO INTRODUCE AND POSITION CATHETERS AND INTERVENTIONAL DEVICES WITHIN THE PERIPHERAL VASCULATURE.
1520	IMP/MD/2019/000059	1.License Holder Name: 3M INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHODONTIC WIRE-ORTHODONTIC WIRES ARE INTENDED FOR USE WITH BRACKETS, BUCCAL TUBES, AND MOLAR BANDS IN ORDER TO EFFECT THE MOVEMENT OF THE TEETH INTO DESIRED POSITION DURING ORTHODONTIC TREATMENT. ARCHWIRES MOVE THE TEETH TO PRESCRIBED POSITION BY EXERTING FORCE AGAINST ORTHODONTIC BRACKETS, AND THEREBY TO THE TEETH. THE RESILIENCY OF THE WIRE IS AN ELASTIC FORCE CAUSED BY THE DEFLECTION OF THE ORTHODONTIC WIRE TO THE MALOCCLUSION. THE AMOUNT OF FORCE EXERTED BY THE DEFLECTION IS A FUNCTION OF THE ORTHODONTIC WIRE SIZE AND THE ALLOY'S ELASTIC MODULUS., ORTHODONTIC BUCCAL TUBE-3M UNITEK PRODUCTS ARE INTENDED FOR USE DURING ORTHODONTIC TREATMENT OF MALOCCLUSIONS (IMPERFECT POSITIONING OF THE TEETH WHEN THE JAWS ARE CLOSED).

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1521	IMP/MD/2019/000060	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIP REPLACEMENT SYSTEM - STEM(C-STEM AMT)-TOTAL HIP PROSTHESIS TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3. ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK. 4. FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5. CERTAIN CASES OF ANKYLOSIS. HEMI-HIP PROSTHESIS HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM. HEMI-HIP ARTHROPLASTY IS INDICATED IN THE FOLLOWING CONDITIONS: 1. ACUTE FRACTURE OF THE FEMORAL HEAD OR NECK THAT CANNOT BE APPROPRIATELY REDUCED AND TREATED WITH INTERNAL FIXATION. 2. FRACTURE DISLOCATION OF THE HIP THAT CANNOT BE APPROPRIATELY REDUCED AND TREATED WITH INTERNAL FIXATION. 3. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 4. NON-UNION OF FEMORAL NECK FRACTURES. 5. CERTAIN HIGH SUBCAPITAL AND FEMORAL NECK FRACTURES IN THE ELDERLY. 6. DEGENERATIVE ARTHRITIS INVOLVING ONLY THE FEMORAL HEAD IN WHICH THE ACETABULUM DOES NOT REQUIRE REPLACEMENT. 7. PATHOLOGY INVOLVING ONLY THE FEMORAL HEAD/NECK AND/OR PROXIMAL FEMUR THAT CAN BE ADEQUATELY TREATED BY HEMI-HIP ARTHROPLASTY. 8. WHERE THE ACETABULUM BECOMES SYMPTOMATIC FOLLOWING HEMI-HIP ARTHROPLASTY, CONVERSION TO A TOTAL HIP ARTHROPLASTY WITH RETENTION OF THE MODULAR HEMI ARTHROPLASTY STEM, WITH A NEW ACETABULAR CUP AND COMPATIBLE FEMORAL HEAD MAY BE PREFERABLE TO REVISION OF THE HEMI-HIP PROSTHESIS., HIP REPLACEMENT SYSTEM - SIZE CDH(C-STEM AMT)-TOTAL HIP PROSTHESIS TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT

	THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3. ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK. 4. FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5. CERTAIN CASES OF ANKYLOSIS. HEMI-HIP PROSTHESIS HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM. HEMI-HIP ARTHROPLASTY IS INDICATED IN THE FOLLOWING CONDITIONS: 1. ACUTE FRACTURE OF THE FEMORAL HEAD OR NECK THAT CANNOT BE APPROPRIATELY REDUCED AND TREATED WITH INTERNAL FIXATION. 2. FRACTURE DISLOCATION OF THE HIP THAT CANNOT BE APPROPRIATELY REDUCED AND TREATED WITH INTERNAL FIXATION. 3. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 4. NON-UNION OF FEMORAL NECK FRACTURES. 5. CERTAIN HIGH SUBCAPITAL AND FEMORAL NECK FRACTURES IN THE ELDERLY. 6. DEGENERATIVE ARTHRITIS INVOLVING ONLY THE FEMORAL HEAD IN WHICH THE ACETABULUM DOES NOT REQUIRE REPLACEMENT. 7. PATHOLOGY INVOLVING ONLY THE FEMORAL HEAD/NECK AND/OR PROXIMAL FEMUR THAT CAN BE ADEQUATELY TREATED BY HEMI-HIP ARTHROPLASTY. 8. WHERE THE ACETABULUM BECOMES SYMPTOMATIC FOLLOWING HEMI-HIP ARTHROPLASTY, CONVERSION TO A TOTAL HIP ARTHROPLASTY WITH RETENTION OF THE MODULAR HEMI ARTHROPLASTY STEM, WITH A NEW ACETABULAR CUP AND COMPATIBLE FEMORAL HEAD MAY BE PREFERABLE TO REVISION OF THE HEMI-HIP PROSTHESIS., HIP REPLACEMENT SYSTEM - STEM(C-STEM REVISION)-TOTAL HIP PROSTHESIS TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3. ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK. 4. FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE

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	REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5. CERTAIN CASES OF ANKYLOSIS. HEMI-HIP PROSTHESIS HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM. HEMI-HIP ARTHROPLASTY IS INDICATED IN THE FOLLOWING CONDITIONS: 1. ACUTE FRACTURE OF THE FEMORAL HEAD OR NECK THAT CANNOT BE APPROPRIATELY REDUCED AND TREATED WITH INTERNAL FIXATION. 2. FRACTURE DISLOCATION OF THE HIP THAT CANNOT BE APPROPRIATELY REDUCED AND TREATED WITH INTERNAL FIXATION. 3. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 4. NON-UNION OF FEMORAL NECK FRACTURES. 5. CERTAIN HIGH SUBCAPITAL AND FEMORAL NECK FRACTURES IN THE ELDERLY. 6. DEGENERATIVE ARTHRITIS INVOLVING ONLY THE FEMORAL HEAD IN WHICH THE ACETABULUM DOES NOT REQUIRE REPLACEMENT. 7. PATHOLOGY INVOLVING ONLY THE FEMORAL HEAD/NECK AND/OR PROXIMAL FEMUR THAT CAN BE ADEQUATELY TREATED BY HEMI-HIP ARTHROPLASTY. 8. WHERE THE ACETABULUM BECOMES SYMPTOMATIC FOLLOWING HEMI-HIP ARTHROPLASTY, CONVERSION TO A TOTAL HIP ARTHROPLASTY WITH RETENTION OF THE MODULAR HEMI ARTHROPLASTY STEM, WITH A NEW ACETABULAR CUP AND COMPATIBLE FEMORAL HEAD MAY BE PREFERABLE TO REVISION OF THE HEMI-HIP PROSTHESIS., HIP REPLACEMENT SYSTEM- FEMORAL HEAD(ARTICUL/EZE)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.,HIP REPLACEMENT SYSTEM - STEM(C-STEM)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.

1522	IMP/MD/2019/000061	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER (TRANSDUCERS)(CODMAN MICROSENSOR-PLASTIC SKULL BOLT KIT) -IT IS INDICATED WHEN DIRECT INTRACRANIAL PRESSURE (ICP) MONITORING IS REQUIRED. THE KIT IS INDICATED FOR USE IN BOTH SUBDURAL AND INTRAPARENCHYMAL PRESSURE MONITORING APPLICATIONS.,RESERVOIR(CODMAN ACCU FLO)-THE ACCU-FLO CSF RESERVOIR, WHEN ATTACHED TO A VENTRICULAR CATHETER, IS DESIGNED TO PROVIDE DIRECT ACCESS TO THE LATERAL CEREBRAL VENTRICLES FOR ASPIRATION AND THE INJECTION OF MEDICATION, AND TO CYSTIC TUMORS FOR CHRONIC DRAINAGE OR THE INJECTION OF HEMOTHERAPEUTIC AGENTS AND/OR RADIOISOTOPES VIA A SYRINGE FITTED WITH A 25-GAUGE, OR SMALLER, HUBERPOINT NEEDLE THROUGH THE RESERVOIR DOME., CATHETER (TRANSDUCERS)(CODMAN MICROSENSOR-BASIC KIT)-IT IS INDICATED WHEN DIRECT ICP MONITORING IS REQUIRED. THE KIT IS INDICATED FOR USE IN BOTH SUBDURAL AND INTRAPARENCHYMAL PRESSURE MONITORING APPLICATIONS ONLY.,CATHETERS(CODMAN MEDOS)-IT IS INTENDED FOR USE IN THE TREATMENT OF HYDROCEPHALUS AS A COMPONENT OF A SHUNT SYSTEM WHEN DRAINING OR SHUNTING OF CEREBROSPINAL FLUID (CSF) IS INDICATED.,CATHETER (TRANSDUCERS)(CODMAN MICROSENSOR-METAL SKULL BOLT KIT)-IT IS INDICATED WHEN DIRECT INTRACRANIAL PRESSURE (ICP) MONITORING IS REQUIRED. THE KIT IS INDICATED FOR USE IN BOTH SUBDURAL AND INTRAPARENCHYMAL PRESSURE MONITORING APPLICATIONS., CATHETERS(CODMAN ACCU FLO)-IT IS INTENDED FOR USE IN THE TREATMENT OF HYDROCEPHALUS AS A COMPONENT OF A SHUNT SYSTEM WHEN DRAINING OR SHUNTING OF CEREBROSPINAL FLUID (CSF) IS INDICATED.,PROGRAMMABLE & PRECISION VALVES(CODMAN HAKIM)-THESE ARE IMPLANTABLE DEVICES THAT PROVIDE CONSTANT INTRAVENTRICULAR PRESSURE AND DRAINAGE OF CSF FOR THE MANAGEMENT OF HYDROCEPHALUS.,JAMES LUMBAR PERITONEAL SHUNT(CODMAN ACCU-FLO)-IT IS INTENDED FOR TREATMENT OF THE FOLLOWING CONDITIONS: COMMUNICATING HYDROCEPHALUS, CSF INTRACRANIAL FISTULA, SUBCUTANEOUS AND CUTANEOUS CSF, SPINAL FISTULA, PSEUDOTUMOR CEREBRI, SUBARACHNOID AND SUBDURAL CSF, INTRACRANIAL EXTRADURAL COLLECTIONS FOLLOWING SURGERY.,VENTRICULAR STRAIGHT CATHETER(CODMAN EXTERNAL DRAINAGE SYSTEM 3 (EDS 3))-EDS 3 CSF EXTERNAL DRAINAGE SYSTEM IS INDICATED FOR DRAINING CEREBROSPINAL FLUID (CSF) AND OTHER FLUIDS OF SIMILAR PHYSICAL CHARACTERISTICS AS A MEANS OF REDUCING

		INTRACRANIAL PRESSURE AND CSF VOLUME WHEN THE INSERTION OF A PERMANENT, INTERNAL SHUNT IS NOT INDICATED.,CATHETERS (CODMAN EXTERNAL DRAINAGE SYSTEM 3 (EDS 3))-EDS 3 CSF EXTERNAL DRAINAGE SYSTEM IS INDICATED FOR DRAINING CEREBROSPINAL FLUID (CSF) AND OTHER FLUIDS OF SIMILAR PHYSICAL CHARACTERISTICS AS A MEANS OF REDUCING INTRACRANIAL PRESSURE AND CSF VOLUME WHEN THE INSERTION OF A PERMANENT, INTERNAL SHUNT IS NOT INDICATED.,LUMBAR EXTERNAL DRAINAGE CATHETER WITH TUOHY NEEDLE(CODMAN)-THE CODMAN LUMBAR EXTERNAL DRAINAGE CATHETER WITH TUOHY NEEDLE IS INDICATED FOR TEMPORARY ACCESS TO THE LUMBAR SUBARACHNOID REGION AND, WHEN USED WITH OTHER CODMAN DEVICES, IS DESIGNED TO DRAIN CEREBROSPINAL FLUID (CSF) AND OTHER FLUIDS OF SIMILAR PHYSICAL CHARACTERISTICS AS A MEANS OF REDUCING INCREASED INTRACRANIAL VOLUME AND PRESSURE.
1523	IMP/MD/2019/000062	1.License Holder Name: ADVANCE MEDI-SURG PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GASTROINTESTINAL STENTS(EGIS COLORECTAL STENTS)-MAINTAINING LUMINAL PATENCY IN COLORECTAL STRICTURES CAUSED BY MALIGNANT NEOPLASM AND TO RELIEVE LARGE BOWEL OBSTRUCTION ., GASTROINTESTINAL STENTS(EGIS BILIARY STENT)-THE EGIS BILIARY STENT IS INTENDED FOR MAINTAINING BILIARY LUMINAL PATENCY IN BILIARY TRACK CAUSED BY INTRINSIC AND/OR EXTRINSIC MALIGNANT AND/OR BENIGN STRICTURES.,GASTROINTESTINAL STENTS(EGIS ESOPHAGEAL STENT)-MAINTAINING ESOPHAGEAL LUMINAL PATENCY CAUSED BY INTRINSIC AND/OR EXTRINSIC MALIGNANT AND/OR BENIGN STRICTURE.,GASTROINTESTINAL STENTS(EGIS PYLORIC / DUODENAL STENT)-THE DEVICE IS INDICATED FOR THE PALLIATIVE TREATMENT INTRINSIC AND/OR EXTRINSIC MALIGNANT AND/OR BENIGN STRICTURE, PARTICULARLY IN OF GASTRODUODENAL OBSTRUCTIONS IN PYLORIC AND /OR DUODENUM.

1524	IMP/MD/2019/000063	1.License Holder Name: CIMA INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OPHTHALMIC VISCOSURGICAL DEVICE (PRE FILLED SYRINGE)(OCUVIS)-FOR USE DURING SURGICAL PROCEDURES IN THE ANTERIOR SEGMENT OF THE EYE TO CREATE/ MAINTAIN SPACE, PROTECT INTRAOCULAR TISSUES, AND MANIPULATE TISSUE.,PMMA (POLYMETHYLMETHACRYLATE) INTRAOCULAR LENS-PMMA INTRAOCULAR LENSES ARE GENERALLY INDICATED FOR IMPLANTATION IN ADULTS WHO HAVE HAD A CATARACTOUS LENS REMOVED. THE OUTER BOX LABEL INDICATES WHETHER HE LENS IS INTENDED FOR ANTERIOR OR POSTERIOR CHAMBER PLACEMENT., HYDROPHILIC ACRYLIC INTRAOCULAR LENS(CIMFLEX)-CIMFLEX INTRAOCULAR LENSES ARE USUALLY INDICATED FOR IMPLANTATION IN ADULT PATIENTS FOLLOWING CATARACT SURGERY DUE TO: SENILE, CONGENITAL OR TRAUMATIC CATARACTS. ,OPHTHALMIC VISCOSURGICAL DEVICE(BIVISC)-BIVISC IS TO BE USED AS AN OPHTHALMIC SURGICAL AID DURING ANTERIOR SEGMENT SURGERY DURING CATARACT EXTRACTION AND INTRAOCULAR LENS IMPLANTATION. THE OVD HELPS CREATE AND MAINTAIN SPACE, PROTECT CORNEAL ENDOTHELIUM AND MINIMIZE DAMAGE TO SURROUNDING OCULAR TISSUES. OVDS MAY ALSO BE USED TO COAT SURGICAL INSTRUMENTS, THE IOL PRIOR TO INSERTION AND FOR LENS CARTRIDGE LUBRICATION.,HYDROPHOBIC ACRYLIC INTRAOCULAR LENS(ASTERI)-ASTERI 56 INTRAOCULAR LENSES ARE INTENDED FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM THE CATARACTOUS LENS HAS BEEN REMOVED.

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1525	IMP/MD/2019/000064	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BALLOON DILATATION CATHETER(NC SOLARICE RAPID EXCHANGE BALLOON DILATATION CATHETER)-THE BALLOON DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. THE BALLOON DILATATION CATHETER IS ALSO INDICATED FOR POST-DEPLOYMENT EXPANSION OF BALLOON EXPANDABLE STENTS.,BALLOON DILATATION CATHETER(SPRINTER OVER-THE-WIRE BALLOON DILATATION CATHETER)-THE SPRINTER BALLOON DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. THE BALLOON DILATATION CATHETER (BALLOON MODELS 2.5MM - 4.0MM) IS ALSO INDICATED FOR POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS.,ADULT CANNULAE KIT (VENOUS AND ARTERIAL)(BIO-MEDICUS)-THESE DEVICES ARE TO BE USED BY A TRAINED PHYSICIAN ONLY. CANNULAE ARE USED TO CANNULATE VESSELS, PERFUSE VESSELS OR ORGANS, AND/OR CONNECT WITH ACCESSORY EXTRACORPOREAL EQUIPMENT. THE CANNULA INTRODUCER IS INTENDED TO FACILITATE PROPER INSERTION AND PLACEMENT OF THE APPROPRIATELY-SIZED CANNULA WITHIN THE VESSEL FOR CARDIOPULMONARY BYPASS. THE BIO-MEDICUS CANNULA (18 CM [7.09 IN] TIP-LENGTH MODELS) MAY BE USED IN EITHER THE FEMORAL POSITION AS AN ARTERIAL DELIVERY CANNULA OR IN THE JUGULAR POSITION AS A VENOUS RETURN CANNULA. THIS PRODUCT IS INTENDED FOR USE UP TO 6 HOURS.,BALLOON DILATATION CATHETER(SPRINTER LEGEND OVER-THE-WIRE BALLOON DILATATION CATHETER)-THE BALLOON DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,PEDIATRIC CANNULA AND INTRODUCER(BIOMEDICUS)-THESE DEVICES ARE TO BE USED BY A TRAINED PHYSICIAN ONLY. CANNULAE ARE USED TO CANNULATE VESSELS, PERFUSE VESSELS OR ORGANS, AND/OR CONNECT WITH ACCESSORY EXTRACORPOREAL EQUIPMENT. THE CANNULA INTRODUCER IS INTENDED TO FACILITATE PROPER INSERTION AND PLACEMENT OF THE APPROPRIATELY-SIZED CANNULA WITHIN THE VESSEL FOR CARDIOPULMONARY BYPASS. THESE PRODUCTS ARE INTENDED FOR USE UP TO 6 HOURS. ,BALLOON DILATATION CATHETER(SPRINTER LEGEND RAPID EXCHANGE BALLOON DILATATION CATHETER)-THE

	BALLOON DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. THE BALLOON DILATATION CATHETER (BALLOON MODELS 2.25 MM - 4.0 MM) IS ALSO INDICATED FOR POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS.,AUTO TRANSFUSION SYSTEM & DISPOSABLE(AUTOLOG ONE SOURCE PACK)-ONE SOURCE PACK IS INTENDED FOR USE IN THE COLLECTION, CONCENTRATION, WASHING AND REINFUSION OF AUTOLOGOUS BLOOD. AREAS OF APPLICATION MAY INCLUDE, BUT ARE NOT LIMITED TO, THE FOLLOWING: • SURGERIES INCLUDING GENERAL, CARDIOVASCULAR, ORTHOPEDIC, VASCULAR, PLASTIC/RECONSTRUCTIVE, OBSTETRIC/GYNECOLOGIC AND NEUROLOGICAL • POSTOPERATIVE TREATMENT AREAS ,BALLOON DILATATION CATHETER(SOLARICE RAPID EXCHANGE BALLOON DILATATION CATHETER)-THE SOLARICE DEVICE IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION,RAPID EXCHANGE BALLOON DILATATION CATHETER(NC SPRINTER RAPID EXCHANGE BALLOON DILATATION CATHETER)-THE BALLOON DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOSIS PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. THE BALLOON DILATATION CATHETER (BALLOON MODEL 2.25MM-5.0MM) IS ALSO INDICATED FOR POSTDELIVERY EXPANSION OF BALLOON EXPANDABLE STENT.,RAPID EXCHANGE BALLOON DILATATION CATHETER(EUPHORA RAPID EXCHANGE BALLOON DILATATION CATHETER)-THE BALLOON DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOSIS PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. THE BALLOON DILATATION CATHETER (BALLOON MODEL 2.0MM-4.00MM) IS ALSO INDICATED FOR POSTDEPLOYMENT EXPANSION OF BALLOON EXPANDABLE STENT.,RAPID EXCHANGE BALLOON DILATATION CATHETER(NC EUPHORA RAPID EXCHANGE BALLOON DILATATION CATHETER)-THE BALLOON DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOSIS PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. THE BALLOON DILATATION CATHETER IS ALSO INDICATED FOR POST-DEPLOYMENT EXPANSION OF BALLOON EXPANDABLE STENT,GUIDING CATHETER (LAUNCHER)-THE MEDTRONIC GUIDING CATHETER IS DESIGNED TO PROVIDE A PATHWAY THROUGH WHICH THE THERAPEUTIC DEVICES

		ARE INTRODUCED. THE GUIDING CATHETER IS INTENDED TO BE USED IN THE CORONARY OR PERIPHERAL VASCULAR SYSTEM.,PEDIATRIC INSERTION KIT(BIOMEDICUS)-THIS KIT IS INTENDED FOR USE BY A TRAINED PHYSICIAN ONLY, TO ASSIST IN VESSEL CANNULATION FOR CARDIOPULMONARY BYPASS CIRCULATION. STANDARD SURGICAL OR PERCUTANEOUS INSERTION TECHNIQUES CAN BE EMPLOYED. THIS KIT IS INTENDED FOR USE FOR UP TO 6 HOURS,INSERTION KIT (BIOMEDICUS)-THIS KIT IS INTENDED FOR USE BY A TRAINED PHYSICIAN ONLY, TO ASSIST IN VESSEL CANNULATION FOR CARDIOPULMONARY BYPASS CIRCULATION. STANDARD SURGICAL OR PERCUTANEOUS INSERTION TECHNIQUES CAN BE EMPLOYED. THIS KIT IS INTENDED FOR USE FOR UP TO 6 HOURS,VENOUS INSERTION KIT(BIOMEDICUS)-THIS KIT IS INTENDED FOR USE BY A TRAINED PHYSICIAN ONLY, TO ASSIST IN VESSEL CANNULATION FOR CARDIOPULMONARY BYPASS CIRCULATION. STANDARD SURGICAL OR PERCUTANEOUS INSERTION TECHNIQUES CAN BE EMPLOYED. THIS KIT IS INTENDED FOR USE FOR UP TO 6 HOURS,CANNULA AND INTRODUCER (ADULT VENOUS AND ARTERIAL)(BIOMEDICUS)-THESE DEVICES ARE TO BE USED BY A TRAINED PHYSICIAN ONLY. CANNULAE ARE USED TO CANNULATE VESSELS, PERFUSE VESSELS OR ORGANS, AND/OR CONNECT WITH ACCESSORY EXTRACORPOREAL EQUIPMENT. THE CANNULA INTRODUCER IS INTENDED TO FACILITATE PROPER INSERTION AND PLACEMENT OF THE APPROPRIATELY-SIZED CANNULA WITHIN THE VESSEL FOR CARDIOPULMONARY BYPASS. THE BIO-MEDICUS CANNULA (18 CM [7.09 IN] TIP-LENGTH MODELS) MAY BE USED IN EITHER THE FEMORAL POSITION AS AN ARTERIAL DELIVERY CANNULA OR IN THE JUGULAR POSITION AS A VENOUS RETURN CANNULA. THIS PRODUCT IS INTENDED FOR USE UP TO 6 HOURS.
1526	IMP/MD/2019/000065	1.License Holder Name: NIPRO PHARMAPACKAGING INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILEPRE-FILLABLE GLASS SYRINGE(D2F)-IT IS INTENDED FOR THE PRIMARY PACKAGING MATERIAL FOR MEDICAL PRODUCT TO BE INJECTED

1527	IMP/MD/2019/000066	1.License Holder Name: LALJI HEALTHCARE PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT(S-CLEAN PLASTIC ABUTMENT)-THE UPPER STRUCTURE OF THE IMPLANT IS INSERTED TO SUPPORT PROSTHETIC APPLIANCES SUCH AS ARTIFICIAL TEETH USED TO RECOVER THE MASTICATORY FUNCTION OF THE PATIENT.,DENTAL IMPLANT(S-CLEAN STAINLESS ABUTMENT)-THE UPPER STRUCTURE OF THE IMPLANT IS INSERTED TO SUPPORT PROSTHETIC APPLIANCES SUCH AS ARTIFICIAL TEETH USED TO RECOVER THE MASTICATORY FUNCTION OF THE PATIENT., DENTAL IMPLANT(S-CLEAN ONEQ-SL FIXTRE,NARROW,REGULAR, WIDE SIZE)-THE ONEQ-SL S-CLEAN IMPLANT SYSTEM IS INDICATED FOR USE IN PARTIALLY OR FULLY EDENTULOUS MANDIBLES AND MAXILLAE,IN SUPPORT OF SINGLE OR MULTIPLE UNIT RESTORATIONS INCLUDING:CEMENTED RETAINED,SCREW RETAINED , OR OVERDENTURE RESTORATIONS AND TERMINALLY OR INTERMEDIATE ABUTMENT SUPPORT FOR FIXED BRIDGEWORK., DENTAL IMPLANT(S-CLEAN HEALING ABUTMENT)-A SUPERSTRUCTURE MOUNTED TEMPORARILY TO FORM GINGIVAL SOFT TISSUE AFTER HEALING TIME FOR OSSEOINTEGRATION,DENTAL IMPLANT(S-CLEAN TITANIUMABUTMENT)-THE UPPER STRUCTURE OF THE IMPLANT IS INSERTED TO SUPPORT PROSTHETIC APPLIANCES SUCH AS ARTIFICIAL TEETH USED TO RECOVER THE MASTICATORY FUNCTION OF THE PATIENT.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1528	IMP/MD/2019/000067	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VERTEBRAL BODY REPLACEMENT SYSTEM(VLIFT)-THE VLIFT SYSTEM IS A DEVICE INTENDED TO REPLACE A VERTEBRAL BODY OR AN ENTIRE VERTEBRA. IT IS FOR USE IN THE THORACOLUMBAR SPINE (T1 L5) TO REPLACE A COLLAPSED, DAMAGED, OR UNSTABLE VERTEBRAL BODY OR VERTEBRA RESECTED OR EXCISED DURING TOTAL AND PARTIAL CORPECTOMY AND VERTEBRECTOMY PROCEDURES DUE TO TUMOR OR TRAUMA (I.E., FRACTURE). FOR BOTH, CORPECTOMY AND VERTEBRECTOMY PROCEDURES, VLIFT SYSTEM IS INTENDED TO BE USED WITH SUPPLEMENTAL INTERNAL FIXATION SYSTEMS. THE SUPPLEMENTAL INTERNAL FIXATION SYSTEMS THAT MAY BE USED WITH VLIFT SYSTEM INCLUDE, BUT ARE NOT LIMITED TO, STRYKER SPINE PLATE OR ROD SYSTEMS (XIA SPINAL SYSTEM). THE USE OF BONE GRAFT WITH THE VLIFT SYSTEM IS OPTIONAL,PLATE SYSTEM (LITE® PLATE SYSTEM)-THE LITE® PLATE SYSTEM UNIVERSAL, SACRAL, 2 SCREW AND 4 SCREW PLATES ARE INDICATED FOR USE VIA A LATERAL OR ANTEROLATERAL SURGICAL APPROACH ABOVE THE BIFURCATION OF THE GREAT VESSELS IN THE TREATMENT OF THE THORACIC AND THORACOLUMBAR (T1-L5) SPINE OR VIA AN ANTERIOR APPROACH BELOW THE BIFURCATION OF THE GREAT VESSELS IN THE TREATMENT OF LUMBAR AND LUMBOSACRAL (L1-S1) SPINE. THE SYSTEM IS INTENDED TO PROVIDE ADDITIONAL SUPPORT DURING FUSION IN SKELETALLY MATURE PATIENTS IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES: ? DEGENERATIVE DISC DISEASE (DEFI NED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFI RMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES); ? PSEUDOARTHROSIS; ? SPONDYLOLYSIS; ? SPONDYLOLISTHESIS; ? SPINAL STENOSIS; ? TUMORS; ? TRAUMA (I. E. FRACTURES OR DISLOCATION); ? DEFORMITIES (I.E. SCOLIOSIS, KYPHOSIS OR LORDOSIS); ? FAILED PREVIOUS FUSION. INDICATIONS FOR LITE® PLATE SYSTEM BUTTRESS PLATE THE LITE® PLATE SYSTEM BUTTRESS PLATE IS INTENDED TO STABILIZE THE ALLOGRAFT OR AUTOGRAFT AT ONE LEVEL (T1-S1) AS AN AID TO SPINAL FUSION AND TO PROVIDE TEMPORARY STABILIZATION AND AUGMENT DEVELOPMENT OF A SOLID SPINAL FUSION. IT MAY BE USED ALONE OR WITH OTHER ANTERIOR, ANTEROLATERAL, OR POSTERIOR SPINAL SYSTEMS MADE OF COMPATIBLE MATERIALS. THIS DEVICE IS NOT INTENDED FOR LOAD BEARING APPLICATIONS., SPINAL SYSTEM(ES2)-THE ES2TM SPINAL SYSTEM IS INTENDED FOR PERCUTANEOUS, POSTERIOR, NON-CERVICAL PEDICLE AND NON-PEDICLE FIXATION OF THE SPINE TO PROVIDE IMMOBILIZATION AND

		STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLITHESIS; TRAUMA (I.E. FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E. SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PERVIOUS FUSION. THE TITANIUM AND VITALLIUMR RODS FROM THE STRYKER SPINE RADIUSR, MANTISR AND MANTISR REDUX SPINAL SYSTEMS ARE INTENDED TO BE USED WITH THE OTHER COMPONENTS OF THE ES2TM SPINAL SYSTEM.
1529	IMP/MD/2019/000068	1.License Holder Name: M/S MERIT MEDICAL SYSTEMS INDIA PRIVATE LIMITED, ,UNIT NO. 404-405, H. M. GENEVA HOUSE, 4TH FLOOR, NO. 14/84 & 85, CUNNINGHAM ROAD ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560052 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANGIOGRAPHIC CATHETER(PERFORMA ANGIOGRAPHIC CATHETERS)-ANGIOGRAPHIC CATHETERS ARE DESIGNED TO BE USED FOR DELIVERING RADIOPAQUE MEDIA TO SELECTED SITES IN THE VASCULAR SYSTEM IN CONJUNCTION WITH ROUTINE DIAGNOSTIC PROCEDURES. ANGIOGRAPHIC CATHETERS WITH MAKER BANDS MAY ALSO BE USED FOR ANATOMICAL MEASUREMENTS.,GUIDING CATHETER (CONCIERGE GUIDING CATHETERS)-THESE GUIDING CATHETERS ARE INTENDED FOR USE FOR INTRAVASCULAR INTRODUCTION OF INTERVENTIONAL/DIAGNOSTIC DEVICES INTO CORONARY OR PERIPHERAL VASCULAR SYSTEMS.,ANGIOGRAPHIC CATHETER (IMPRESS ANGIOGRAPHIC CATHETERS/IMPRESS ANGIOGRAPHIC CATHETERS WITH LEGATO HYDROPHILIC COATING)-ANGIOGRAPHIC CATHETERS ARE DESIGNED TO BE USED FOR DELIVERING RADIOPAQUE MEDIA TO SELECTED SITES IN THE VASCULAR SYSTEM IN CONJUNCTION WITH ROUTINE DIAGNOSTIC PROCEDURES. ANGIOGRAPHIC CATHETERS WITH MARKER BANDS MAY ALSO BE USED FOR ANATOMICAL MEASUREMENTS.,ANGIOGRAPHIC CATHETER(FEP PIGTAIL ANGIOGRAPHIC CATHETERS (ADULT AND PEDIATRIC))-ANGIOGRAPHIC CATHETERS ARE DESIGNED TO BE USED FOR DELIVERING RADIOPAQUE MEDIA TO SELECTED SITES IN THE VASCULAR SYSTEM IN CONJUNCTION WITH ROUTINE DIAGNOSTIC PROCEDURES. ANGIOGRAPHIC CATHETERS WITH MARKER BANDS MAY ALSO BE USED FOR ANATOMICAL MEASUREMENTS

1530	IMP/MD/2019/000069	1.License Holder Name: M/S GEISTLICH PHARMA INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RESORBABLE BILAYER MEMBRANE(BIO-GIDE)-GEISTLICH BIO-GIDE IS INTENDED TO BE USED AS A BARRIER MEMBRANE IN THE REGENERATION OF BONE DEFECTS. GEISTLICH BIO-GIDE® IS USED AFTER BONE GRAFTING PROCEDURES AND TO ENHANCE SOFT TISSUE FORMATION, E.G. IN •GBR (GUIDED BONE REGENERATION) PROCEDURES •IMMEDIATE OR DELAYED AUGMENTATION AROUND IMPLANTS PLACED IN EXTRACTION SOCKETS •RECONSTRUCTION OF THE ALVEOLAR RIDGE •FILLING OF BONE DEFECTS IN THE MAXILLOFACIAL AREA •CLEFT CLOSURE SURGERIES ,SPONGIOUS BONE SUBSTITUTE(GEISTLICH BIO-OSS COLLAGEN (100MG))-GEISTLICH BIO-OSS® COLLAGEN IS INTENDED TO BE USED IN THE TREATMENT OF HARD TISSUE DEFECTS IN ORAL-MAXILLOFACIAL SURGERY.,SPONGIOUS BONE SUBSTITUTE (GEISTLICH BIO OSS)-GEISTLICH BIO-OSS® IS INTENDED TO BE USED IN THE TREATMENT OF HARD TISSUE DEFECTS IN ORAL-MAXILLOFACIAL SURGERY,SPONGIOUS BONE SUBSTITUTE (GEISTLICH BIO-OSS COLLAGEN 250MG)-GEISTLICH BIO-OSS® COLLAGEN IS INTENDED TO BE USED IN THE TREATMENT OF HARD TISSUE DEFECTS IN ORAL-MAXILLOFACIAL SURGERY.,SPONGIOUS BONE SUBSTITUTE(GEISTLICH BIO OSS PEN)-GEISTLICH BIO-OSS® / GEISTLICH BIO-OSS PEN® IS INTENDED TO BE USED IN THE TREATMENT OF HARD TISSUE DEFECTS IN ORAL-MAXILLOFACIAL SURGERY,RESORBABLE BILAYER MEMBRANE(GEISTLICH BIO-GIDE)-GEISTLICH BIO-GIDE PERIO, GEISTLICH BIO-GIDE COMPRESSED ARE INTENDED TO BE USED AS BARRIER MEMBRANES IN THE REGENERATION OF BONE DEFECTS. GEISTLICH BIO-GIDE PERIO, GEISTLICH BIO-GIDE COMPRESSED ARE USED AFTER BONE GRAFTING PROCEDURES AND TO ENHANCE SOFT TISSUE FORMATION: A) GBR (GUIDED BONE REGENERATION) PROCEDURES B) IMMEDIATE OR DELAYED AUGMENTATION AROUND IMPLANTS PLACED IN EXTRACTION SOCKETS C) RECONSTRUCTION OF THE ALVEOLAR RIDGE D) FILLING OF BONE DEFECTS IN THE MAXILLOFACIAL AREA E) CLEFT CLOSURE SURGERIES GEISTLICH BIO-GIDE PERIO IS ESPECIALLY INDICATED FOR PERIODONTAL BONE DEFECTS. GEISTLICH BIO-GIDE SHAPE IS INTENDED TO BE USED AS A BARRIER MEMBRANE IN THE REGENERATION OF ALVEOLAR BONE DEFECTS. GEISTLICH BIO-GIDE SHAPE IS USED FOR ALVEOLAR BONE DEFECTS IN EXTRACTION SOCKETS.,COLLAGEN MATRIX(GEISTLICH FIBRO-GIDE)-GEISTLICH FIBRO-GIDE® IS INTENDED TO BE USED FOR SOFT-TISSUE REGENERATION AT THE ALVEOLAR RIDGE. INDICATIONS OF GEISTLICH FIBRO-GIDE® ARE: • INSUFFICIENT SOFT TISSUE VOLUME • RECESSION DEFECTS,SPONGIOUS BONE SUBSTITUTE(GEISTLICH BIO-

	OSS COLLAGEN 500MG)-GEISTLICH BIO-OSS® COLLAGEN IS INTENDED TO BE USED IN THE TREATMENT OF HARD TISSUE DEFECTS IN ORAL-MAXILLOFACIAL SURGERY.,COLLAGEN MATRIX(GEISTLICH COMBI-KIT COLLAGEN)-GEISTLICH BIO-OSS® COLLAGEN IS INTENDED FOR RECONSTRUCTION OF BONE DEFECTS IN MAXILLOFACIAL SURGERY AND IN DENTAL SURGERY, E.G.: • AUGMENTATION/RECONSTRUCTION OF ALVEOLAR RIDGES • FILLING OF EXTRACTION SOCKETS • IMPLANTOLOGY: PREPARATION OF IMPLANT SITES, FILLING OF BONE DEHISCENCES, AND SINUS FLOOR AUGMENTATIONS • PERIODONTOLOGY: FILLING OF BONE DEFECTS, SUPPORT OF THE MEMBRANE DURING GUIDED BONE REGENERATION (GBR) AND GUIDED TISSUE REGENERATION (GTR) GEISTLICH BIO-GIDE IS INTENDED TO BE USED AS A BARRIER MEMBRANE IN THE REGENERATION OF BONE DEFECTS. GEISTLICH BIO-GIDE® IS USED AFTER BONE GRAFTING PROCEDURES AND TO ENHANCE SOFT TISSUE FORMATION, E.G. IN • GBR (GUIDED BONE REGENERATION) PROCEDURES • IMMEDIATE OR DELAYED AUGMENTATION AROUND IMPLANTS PLACED IN EXTRACTION SOCKETS • RECONSTRUCTION OF THE ALVEOLAR RIDGE • FILLING OF BONE DEFECTS IN THE MAXILLOFACIAL AREA • CLEFT CLOSURE SURGERIES,COLLAGEN MATRIX(GEISTLICH MUCOGRAFT)-GEISTLICH MUCOGRAFT® / GEISTLICH MUCOGRAFT® SEAL IS INTENDED TO BE USED IN CLOSED AND OPEN HEALING SITUATIONS TO:-CLOSE WOUNDS OF ORAL MUCOSA-SUPPORT WOUND HEALING AND REGENERATION PROCESSES IN CASE OF ORAL MUCOSA DEFECTS AND DEFICIENCIES. THE CONCERNED ORAL MUCOSA DEFECTS AND DEFICIENCIES MAY BE SURGICALLY CREATED OR RESULT FROM TRAUMATIC INJURIES, PATHOLOGICAL CONDITIONS, MEDICAL TREATMENTS AND THERAPIES, OR HISTORY OF PERSONAL LIFESTYLE HABITS., COLLAGEN MATRIX(GEISTLICH PERIO SYSTEM COMBI PACK)-GEISTLICH BIO-OSS® COLLAGEN IS INTENDED FOR RECONSTRUCTION OF BONE DEFECTS IN MAXILLOFACIAL SURGERY AND IN DENTAL SURGERY, E.G.: • AUGMENTATION/RECONSTRUCTION OF ALVEOLAR RIDGES • FILLING OF EXTRACTION SOCKETS • IMPLANTOLOGY: PREPARATION OF IMPLANT SITES, FILLING OF BONE DEHISCENCES, AND SINUS FLOOR AUGMENTATIONS • PERIODONTOLOGY: FILLING OF BONE DEFECTS, SUPPORT OF THE MEMBRANE DURING GUIDED BONE REGENERATION (GBR) AND GUIDED TISSUE REGENERATION (GTR) GEISTLICH BIO-GIDE PERIO IS INTENDED TO BE USED AS A BARRIER MEMBRANE IN THE REGENERATION OF BONE DEFECTS. GEISTLICH BIO-GIDE PERIO IS USED AFTER BONE GRAFTING PROCEDURES AND TO ENHANCE SOFT TISSUE FORMATION, E.G. IN • GBR (GUIDED BONE REGENERATION) PROCEDURES • IMMEDIATE OR DELAYED AUGMENTATION AROUND

	IMPLANTS PLACED IN EXTRACTION SOCKETS • RECONSTRUCTION OF THE ALVEOLAR RIDGE • FILLING OF BONE DEFECTS IN THE MAXILLOFACIAL AREA • CLEFT CLOSURE SURGERIES GEISTLICH BIO-GIDE PERIO® PERIO IS ESPECIALLY INDICATED FOR PERIODONTAL BONE DEFECTS

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1531	IMP/MD/2019/000070	1.License Holder Name: HALYARD HEALTH INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ON-Q* PAIN RELIEF SYSTEM(HALYARD*)-THE ON-Q* PUMP IS INTENDED TO PROVIDE CONTINUOUS DELIVERY OF MEDICATION (SUCH AS LOCAL ANESTHETICS) TO OR AROUND SURGICAL WOUND SITES AND/OR CLOSE PROXIMITY TO NERVES FOR PREOPERATIVE, PERIOPERATIVE AND POSTOPERATIVE REGIONAL ANESTHESIA AND/OR PAIN MANAGEMENT.,ON-Q* PAIN RELIEF SYSTEM(HALYARD*)-THE ON-Q* PUMP IS INTENDED TO PROVIDE CONTINUOUS DELIVERY OF MEDICATION (SUCH AS LOCAL ANESTHETICS) TO OR AROUND SURGICAL WOUND SITES AND/OR CLOSE PROXIMITY TO NERVES FOR PREOPERATIVE, PERIOPERATIVE AND POSTOPERATIVE REGIONAL ANESTHESIA AND/OR PAIN MANAGEMENT.,ON-Q* EXPANSION KITS (HALYARD*)-ON-Q* CATHETERS ARE INDICATED FOR THE DELIVERY OF MEDICATION (SUCH AS LOCAL ANESTHETICS) TO OR AROUND SURGICAL WOUND SITES FOR PREOPERATIVE, PERIOPERATIVE AND POSTOPERATIVE PAIN MANAGEMENT. ON-Q* INTRODUCERS ARE INTENDED FOR THE PERCUTANEOUS INTRODUCTION AND PLACEMENT OF ON-Q* CATHETERS.,PROLONG* CONTINUOUS NERVE BLOCK SET(HALYARD*)-THE PROLONG* CONTINUOUS NERVE BLOCK SET IS FOR PROLONGED REGIONAL ANESTHESIA AND ANALGESIA VIA BLOCKADE OF PERIPHERAL NERVES.,PROBLOC* II INSULATED REGIONAL BLOCK NEEDLE(HALYARD*)-PROBLOC IS USED IN PERFORMANCE OF REGIONAL ANESTHESIA BLOCK.,ON-Q PAIN RELIEF SYSTEM QUIKBLOC* OVER-THE-NEEDLE CATHETER SET (HALYARD*)-THE ON-Q* QUIKBLOC* OVER-THE-NEEDLE CATHETER SET IS INDICATED FOR DELIVERY OF MEDICATION FOR REGIONAL ANESTHESIA AND PAIN MANAGEMENT.,ECHOLONG* CONTINUOUS NERVE BLOCK SET(HALYARD*)-THE ECHOLONG* CONTINUOUS NERVE BLOCK SET IS FOR PROLONGED REGIONAL ANESTHESIA AND ANALGESIA VIA BLOCKADE OF PERIPHERAL NERVES.,ON-Q* TUNNELERS & SHEATHS(HALYARD*)-"THE ON-Q INTRODUCERS ARE INTENDED FOR THE PERCUTANEOUS INTRODUCTION AND PLACEMENT OF CATHETERS INTO OR AROUND SURGICAL WOUND SITES AND/OR CLOSE PROXIMITY TO NERVES. INTRODUCERS WITH A LUER HUB MAY BE USED TO ASPIRATE OR INJECT A BOLUS OF FLUID OR MEDICATION PRIOR TO PLACING THE CATHETERS. ",ON-Q* ELASTOMERIC PUMP(HALYARD*)-THE ON-Q* PUMP IS INTENDED TO PROVIDE CONTINUOUS DELIVERY OF MEDICATION (SUCH AS LOCAL ANESTHETICS) TO OR AROUND SURGICAL WOUND SITES AND/OR CLOSE PROXIMITY TO NERVES FOR PREOPERATIVE, PERIOPERATIVE AND POSTOPERATIVE REGIONAL ANESTHESIA AND/OR PAIN MANAGEMENT.,ON-Q* TUNNELERS & SHEATHS(HALYARD*)-"THE ON-

		Q INTRODUCERS ARE INTENDED FOR THE PERCUTANEOUS INTRODUCTION AND PLACEMENT OF CATHETERS INTO OR AROUND SURGICAL WOUND SITES AND/OR CLOSE PROXIMITY TO NERVES. INTRODUCERS WITH A LUER HUB MAY BE USED TO ASPIRATE OR INJECT A BOLUS OF FLUID OR MEDICATION PRIOR TO PLACING THE CATHETERS. ",ECHOBRIGHT* ECHOGENIC REGIONAL BLOCK NEEDLE WITH INJECTION SET(HALYARD*)-ECHOBRIGHT ECHOGENIC REGIONAL BLOCK NEEDLE IS FOR PROLONGED REGIONAL ANESTHESIA AND ANALGESIA VIA BLOCKADE OF PERIPHERAL NERVES.,ON-Q* INTRODUCER NEEDLES AND SHEATHS(HALYARD*)-THE ON-Q INTRODUCERS ARE INTENDED FOR THE PERCUTANEOUS INTRODUCTION AND PLACEMENT OF CATHETERS INTO OR AROUND SURGICAL WOUND SITES AND/OR CLOSE PROXIMITY TO NERVES. INTRODUCERS WITH A LUER HUB MAY BE USED TO ASPIRATE OR INJECT A BOLUS OF FLUID OR MEDICATION PRIOR TO PLACING THE CATHETERS.
1532	IMP/MD/2019/000071	1.License Holder Name: CARDINAL HEALTH MEDICAL PRODUCTS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) BALLOON DILATATION CATHETER(POWERFLEX® PRO)-THE POWERFLEX® PRO PTA CATHETER IS INTENDED TO DILATE STENOSES IN ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA POPLITEAL AND RENAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THE DEVICE IS ALSO INDICATED FOR POST-DILATION OF BALLOON EXPANDABLE AND SELF-EXPANDING STENTS IN THE PERIPHERAL VASCULATURE.

1533	IMP/MD/2019/000072	1.License Holder Name: KLB INSTRUMENTS CO. PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:POSTERIOR CHAMBER INTRAOCULAR LENS, PSEUDOPHAKIC(NEX-ACRI 1P)-THIS LENS IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION OR EXTRACAPSULAR EXTRACTION. THIS LENS IS INTENDED TO BE PLACED IN CAPSULAR BAG.,POSTERIOR CHAMBER INTRAOCULAR LENS, PSEUDOPHAKIC(NEX-LOAD SYSTEM SP)-THIS LENS IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION OR EXTRACAPSULAR EXTRACTION. THIS LENS IS INTENDED TO BE PLACED IN CAPSULAR BAG.,POSTERIOR CHAMBER INTRAOCULAR LENS, PSEUDOPHAKIC(NEX-ACRI AA1P)-THIS LENS IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION OR EXTRACAPSULAR EXTRACTION. THIS LENS IS INTENDED TO BE PLACED IN CAPSULAR BAG.,POSTERIOR CHAMBER INTRAOCULAR LENS, PSEUDOPHAKIC(NEX-LOAD SYSTEM SP CLEAR)-THIS LENS IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION OR EXTRACAPSULAR EXTRACTION. THIS LENS IS INTENDED TO BE PLACED IN CAPSULAR BAG.
1534	IMP/MD/2019/000073	1.License Holder Name: M/S. IMPLANTIUM INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT SYSTEM(DENTIUM IMPLANT SYSTEM)-THE DENTAL IMPLANT SYSTEM IS AVAILABLE TO RECOVER DEFICIENT TEETH IN DENTISTRY. THE IMPLANTATION SYSTEM RELIEVES OCCLUDE- LOAD AND RECOVER THE BUCCAL MASTICATION FUNCTION WITH A BIOLOGICAL MECHANISM. PROSTHETIC APPLIANCE COEXISTS WITH DENTATE AND PERMANENTLY BE BALANCED. THE PRODUCT IS IMPLANTED TO MAXILLARY AND MANDIBLE.

1535	IMP/MD/2019/000074	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SOFT TISSUE FIXATION (AIR™ ALL-INSIDE MENISCAL REPAIR DEVICE)-THE AIR™ ALL-INSIDE MENISCAL REPAIR DEVICE IS INTENDED FOR USE AS A SUTURE RETENTION DEVICE TO FACILITATE PERCUTANEOUS OR ENDOSCOPIC SOFT TISSUE PROCEDURES. THE AIR™ ALL-INSIDE MENISCAL REPAIR DEVICE IS INDICATED FOR USE IN MENISCAL REPAIRS AND ALLOGRAFT TRANSPLANT PROCEDURES. THE AIR™ ALL-INSIDE MENISCAL REPAIR DEVICE IS INTENDED TO BE USED FOR ANCHORING THE ALLOGRAFT TO THE MENISCAL RIM DURING ALLOGRAFT TRANSPLANT PROCEDURES.
1536	IMP/MD/2019/000075	1.License Holder Name: GLAND PHARMA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE (STERILE)(BD HYPAK SCF)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKING AND ADMINISTRATION OF PARENTERAL DRUGS
1537	IMP/MD/2019/000076	1.License Holder Name: SUN PHARMACEUTICAL INDUSTRIES LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYPODERMIC NEEDLE (SURGUARD®2 SAFETY HYPODERMIC NEEDLE)-USED IN ASPIRATION AND INJECTION OF FLUID FOR MEDICAL PURPOSES.
1538	IMP/MD/2019/000077	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRICUSPID BAND(TRI-AD 2.0 ADAMS)-THE TRI-AD 2.0 ADAMS TRICUSPID BAND IS INDICATED FOR THE RECONSTRUCTION OR REMODELING OF PATHOLOGICAL TRICUSPID VALVES. THE BAND PROVIDES SUPPORT AND RESTRICTS EXPANSION OF THE TRICUSPID ANNULUS. ,HEART VALVE - AORTIC (AVALUS BIOPROSTHESIS)-THE AVALUS BIOPROSTHESIS IS INDICATED FOR THE REPLACEMENT OF A DISEASED, DAMAGED, OR MALFUNCTIONING NATIVE OR PROSTHETIC AORTIC VALVE.

1539	IMP/MD/2019/000078	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RADIO-FREQUENCY ABLATION SYSTEM(ALAIR BRONCHIAL THERMOPLASTY RF CONTROLLER)-THE ALAIR BRONCHIAL THERMOPLASTY SYSTEM IS INDICATED FOR THE TREATMENT OF SEVERE PERSISTENT ASTHMA IN PATIENTS 18 YEARS AND OLDER WHOSE ASTHMA IS NOT WELL CONTROLLED WITH INHALED CORTICOSTEROIDS AND LONG ACTING BETA AGONISTS.,ELECTROSURGICAL SYSTEM GENERATOR(RF 3000 RADIOFREQUENCY GENERATOR)-THE RF 3000 RADIOFREQUENCY GENERATOR IS INTENDED FOR USE WITH SEPARATELY CLEARED ELECTRODES FOR THERMAL COAGULATION OF SOFT TISSUES.

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1540	IMP/MD/2019/000082	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIP SYSTEM(TANDEM BIPOLAR)-1. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, OSTEONECROSIS, AVASCULAR NECROSIS AND POST TRAUMATIC ARTHRITIS; 2. RHEUMATOID ARTHRITIS; 3. ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES AND CORRECTION OF FUNCTIONAL DEFORMITY SUCH AS CONGENITAL HIP DYSPLASIA OR ANKYLOSING SPONDYLITIS; 4. REVISION PROCEDURES WHERE OTHER TREATMENTS HAVE FAILED; AND 5. TREATMENT OF PROXIMAL FEMORAL NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT.,KNEE SYSTEM(GENESIS II)-1. RHEUMATOID ARTHRITIS. 2. POST-TRAUMATIC ARTHRITIS, OSTEOARTHRITIS, OR DEGENERATIVE ARTHRITIS. 3. FAILED OSTEOTOMIES, UNICOMPARTMENTAL REPLACEMENT, OR TOTAL KNEE REPLACEMENT. 4. POSTERIOR STABILIZED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE INCOMPETENT AND THE COLLATERAL LIGAMENTS REMAIN INTACT. 5. CONSTRAINED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE INCOMPETENT. 6. HINGE KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE ABSENT OR INCOMPETENT.
1541	IMP/MD/2019/000083	1.License Holder Name: SUN PHARMACEUTICAL INDUSTRIES LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS,PREFILLABLE GLASS BARREL WITH NEEDLE(BD NEOPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS

1542	IMP/MD/2019/000084	1.License Holder Name: BICON DENTAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE GRAFT MATERIAL (SYNTHOGRAFT)-SYNTHOGRAFT IS USED BY COMBINING THE SYNTHOGRAFT BETA-TRICALCIUM PHOSPHATE PARTICLES WITH THE PATIENTS BLOOD. AS SOON AS THE SYNTHOGRAFT IS MIXED WITH THE PATIENTS BLOOD, OR "WETTED" , IT MAY BE PLACED IN THE SURGICAL SITE. THE IMPLANTATION SITE IS SUTURED TO ACHIEVE PRIMARY CLOSURE.,DENTAL IMPLANT(BICON DENTAL IMPLANT SYSTEM - INTEGRA TI, INTEGRA - CP)-BICON DENTAL IMPLANTS ARE INTENDED TO BE SURGICALLY PLACED IN THE MAXILLA OR MANDIBLE TO PROVIDE SUPPORT FOR PROSTHETIC DEVICES TO RESTORE A PATIENT'S CHEWING FUNCTION.,DENTAL IMPLANT ABUTMENT(BICON DENTAL IMPLANT ABUTMENT SYSTEM - BREVIS, LOCATOR)-BICON DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE SURGICALLY PLACED IN THE MAXILLA OR MANDIBLE TO PROVIDE SUPPORT FOR PROSTHETIC DEVICES TO RESTORE A PATIENT' CHEWING FUNCTION.

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1543	IMP/MD/2019/000085	1.License Holder Name: STRAUMANN DENTAL INDIA LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NATIVE COLLAGEN MEMBRANE(COLLPROTECT MEMBRANE)-INTENDED FOR IMMEDIATE OR DELAYED CONTROLLED REGENERATION OF TISSUE AND BONE IN DENTAL SURGERY.,NATURAL BOVINE BONE GRAFTING MATERIAL (CERABONE)-CERABONE IS INDICATED FOR PERMANENT FILLING OR RECONSTRUCTION OF ASEPTIC BONE DEFECT. IN TRAUMA AND ORTHOPEDIC SURGERY FOR: - FILLING OF BONE DEFECTS IN JUXTA-ARTICULAR DEPRESSED FRACTURES - FILLING OF BONE CYSTS, TISSUE DEFECTS, DEFECTS FOLLOWING APICECTOMY, DENTAL EXTRACTION - FILLING OF BONE DEFECTS AT DONOR SITES FOLLOWING HARVEST OF AUTOGENOUS CANCELLOUS BONE - FILLING OF DEFECTS CAUSED BY THE EXCISION OF BENIGN BONE TUMORS OR BONE CYSTS - FILLING OF DEFECTS FOLLOWING OSTEOTOMY OF THE JAW,COLLAGEN TISSUE MATRIX(MUCODERM)-IS INDICATED FOR DENTAL REGENERATION OF SOFT TISSUE DEFECTS AND REGENERATION OF SOFT TISSUES AROUND TEETH OR IMPLANTS.,NATIVE COLLAGEN MEMBRANE(JASON MEMBRANE)-JASON MEMBRANE ALONE OR IN COMBINATION WITH SUTIABLE AUGMENTATION MATERIALS (LIKE AUTOGENOUS BONE, ALLOGENEIC, XENOGENEIC OR ALLOPLASTIC BONE REPLACEMENT MATERIALS) IS INDICATED FOR IMMEDIATE OR DELAYED GUIDED TISSUE AND BONE REGENERATION IN CASE OF SURGICAL BONE DEFECTS AND BONE WALL DEFECTS IN THE CONTEXT OF SINUS FLOOR AUGMENTATION AND SUPPORT OF THE SCHNEIDERIAN MEMBRANE IN THE CONTEXT OF MAXILLARY RIDGE AUGMENTATION IN THE CONTEXT OF MAXILLARY RIDGE RECONSTRUCTION FOR PROSTHETIC TREATMENT IN THE CONTEXT OF A TREATMENT OF FENESTRATION DEFECTS IN CASE OF PERIODONTAL BONE DEFECTS (ONE TO THREE-WALL DEFECTS, CLASS I AND CLASS II FURCATION DEFECTS) IN CASE OF DEHISCENCE DEFECTS AFTER APICOECTOMY, CYSTECTOMY, RESECTION OF RETAINED TETH AND RESECTION OF OTHER BONE LESIONS IN EXTRACTION SOCKETS AFTER TOOTH EXTRACTIONS IN CASE OF IMMEDIATE OR DELAYED AUGMENTATION AROUND IMPLANTS IN EXTRACTION SOCKETS

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1544	IMP/MD/2019/000086	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTION SETS (BD VACUTAINER® ULTRATOUCH™ PUSH BUTTON BLOOD COLLECTION SET)-THE BD VACUTAINER® ULTRATOUCH™ PUSH BUTTON BLOOD COLLECTION SET IS A STERILE, MULTIPLE SAMPLE, SINGLE-USE FIXED WINGED BLOOD COLLECTION SET INTENDED FOR VENIPUNCTURE TO OBTAIN BLOOD SPECIMENS FROM PATIENTS. WHEN USED WITHOUT THE MALE ADAPTER, THE DEVICE ALLOWS THE CLINICIAN TO OBTAIN BLOOD SAMPLING TO THE FEMALE HUB WITH A SYRINGE, IF NECESSARY, OR CAN BE USED FOR SHORT-TERM, SINGLE INFUSIONS WITH CONSIDERATION GIVEN TO PATIENT SIZE AND APPROPRIATENESS FOR THE SOLUTION BEING INFUSED. THE DEVICE IS NOT TO BE LEFT IN PLACE AND REMAIN UNDER THE DIRECT SUPERVISION OF A CLINICIAN. THE RECOMMENDED USE OF THE DEVICE IS TO ACTIVATE THE NEEDLE SAFETY FEATURE PRIOR TO REMOVAL FROM THE VENIPUNCTURE SITE. THE RETRACTION OF THE INTRAVENOUS (IV) END OF THE NEEDLE AIDS IN THE PREVENTION OF ACCIDENTAL NEEDLESTICK INJURY.,HYPODERMIC NEEDLES(BD VACUTAINER® ECLIPSE™ BLOOD COLLECTION NEEDLE (WITH OR WITHOUT HOLDER))-THE BD VACUTAINER® ECLIPSE™ BLOOD COLLECTION NEEDLE IS A STERILE, DISPOSABLE, SINGLE-USE COLLECTION DEVICE FOR VENIPUNCTURE TO COLLECT BLOOD SPECIMENS FROM PATIENTS.,BLOOD COLLECTION SETS(BD VACUTAINER® ULTRATOUCH™ PUSH BUTTON BLOOD COLLECTION SET WITH PRE-ATTACHED HOLDER)-THE BD VACUTAINER® ULTRATOUCH™ PUSH BUTTON BLOOD COLLECTION SET WITH PRE-ATTACHED HOLDER IS A STERILE, MULTIPLE SAMPLE, SINGLE-USE FIXED WINGED BLOOD COLLECTION SET INTENDED FOR VENIPUNCTURE TO OBTAIN BLOOD SPECIMENS FROM PATIENTS. WHEN USED WITHOUT THE MALE ADAPTER, THE DEVICE ALLOWS THE CLINICIAN TO OBTAIN BLOOD SAMPLING TO THE FEMALE HUB WITH A SYRINGE, IF NECESSARY, OR CAN BE USED FOR SHORT-TERM, SINGLE INFUSIONS WITH CONSIDERATION GIVEN TO PATIENT SIZE AND APPROPRIATENESS FOR THE SOLUTION BEING INFUSED. THE DEVICE IS NOT TO BE LEFT IN PLACE AND REMAIN UNDER THE DIRECT SUPERVISION OF A CLINICIAN. THE RECOMMENDED USE OF THE DEVICE IS TO ACTIVATE THE NEEDLE SAFETY FEATURE PRIOR TO REMOVAL FROM THE VENIPUNCTURE SITE. THE RETRACTION OF THE INTRAVENOUS (IV) END OF THE NEEDLE AIDS IN THE PREVENTION OF ACCIDENTAL NEEDLESTICK INJURY.,LUER ADAPTER(BD VACUTAINER® MULTIPLE SAMPLE LUER ADAPTER)-THE VACUTAINER® LUER ADAPTER IS A STERILE, NON-INVASIVE DEVICE USED TO CONNECT VENOUS ACCESS DEVICES SUCH AS NEEDLES,

		BLOOD COLLECTION SETS, AND INFUSION SETS TO BLOOD COLLECTION TUBES.,BLOOD COLLECTION SETS(BD VACUTAINER® PUSH BUTTON BLOOD COLLECTION SET (WITH OR WITHOUT HOLDER))-IT IS A STERILE, MULTIPLE-SAMPLE, SINGLE-USE WINGED BLOOD COLLECTION SET INTENDED FOR VENIPUNCTURE TO OBTAIN BLOOD SPECIMENS FROM PATIENTS AND FOR THE INTRAVENOUS ADMINISTRATION OF FLUIDS.,BLOOD COLLECTION SETS(BD VACUTAINER® SAFETY LOK™ BLOOD COLLECTION SET)-THE BD VACUTAINER® BRAND BLOOD COLLECTION SET/SAFETY-LOK BLOOD COLLECTION SET IS A STERILE, DISPOSABLE, SINGLE-USE COLLECTION DEVICE FOR VENIPUNCTURE TO COLLECT BLOOD SPECIMENS FROM PATIENTS AND FOR THE INTRAVENOUS ADMINISTRATION OF FLUIDS.
1545	IMP/MD/2019/000087	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DETACHABLE COIL SYSTEM (AXIUM)(AXIUM DETACHABLE COIL SYSTEM)-AXIUM™ DETACHABLE COILS ARE INTENDED FOR THE ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS. AXIUM™ DETACHABLE COILS ARE ALSO INTENDED FOR THE EMBOLIZATION OF OTHER NEURO VASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE.,CATHETER(MARKSMAN™ CATHETER)-THE MARKSMAN™ CATHETER IS INTENDED FOR THE INTRODUCTION OF INTERVENTIONAL DEVICES AND INFUSION OF DIAGNOSTIC OR THERAPEUTIC AGENTS INTO THE NEURO, PERIPHERAL AND CORONARY VASCULATURE.,DETACHABLE COIL SYSTEM (AXIUM PRIME)(AXIUM PRIME DETACHABLE COIL SYSTEM)-THE AXIUM™ PRIME DETACHABLE COILS ARE INTENDED FOR THE ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS. THE AXIUM™ PRIME DETACHABLE COILS ARE ALSO INTENDED FOR THE EMBOLIZATION OF OTHER NEURO VASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE.

1546	IMP/MD/2019/000088	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL HIP REPLACEMENT SYSTEM-SLEEVES(SLEEVES)-PAINFUL, DISABLING JOINT DISEASE OF THE HIP RESULTING FROM: DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS, POSTTRAUMATIC ARTHRITIS OR LATE STAGE AVASCULAR NECROSIS. • REVISION OF PREVIOUS UNSUCCESSFUL FEMORAL HEAD REPLACEMENT, CUP ARTHROPLASTY OR OTHER PROCEDURE. • CLINICAL MANAGEMENT PROBLEMS WHERE ARTHRODESIS OR ALTERNATIVE RECONSTRUCTIVE TECHNIQUES ARE LESS LIKELY TO ACHIEVE SATISFACTORY RESULTS. • WHERE BONE STOCK IS OF POOR QUALITY OR IS INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE ACETABULUM ,TOTAL HIP REPLACEMENT SYSTEM(TRIDENT II ACETABULAR COMPONENT SYSTEM)-• PAINFUL DISABLING JOINT DISEASE OF THE HIP RESULTING FROM DEGENERATIVE ARTHRITIS RHEUMATOID ARTHRITIS POSTTRAUMATIC ARTHRITIS OR LATE STAGE AVASCULAR NECROSIS. • REVISION OF PREVIOUS UNSUCCESSFUL FEMORAL HEAD REPLACEMENT, CUP ARTHROPLASTY OR OTHER PROCEDURE. • CLINICAL MANAGEMENT PROBLEMS WHERE ARTHRODESIS OR ALTERNATIVE RECONSTRUCTIVE TECHNIQUES ARE LESS LIKELY TO ACHIEVE SATISFACTORY RESULTS. • WHERE BONE STOCK IS OF POOR QUALITY OR IS INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE ACETABULUM WHEN USED WITH MDM LINERS • TREATMENT OF NONUNION, FEMORAL NECK AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES. • DISLOCATION RISKS WHEN USED WITH CONSTRAINED LINERS • THE TRIDENT CONSTRAINED ACETABULAR INSERT IS INDICATED FOR USE IN PRIMARY AND REVISION PATIENTS AT HIGH RISK OF HIP DISLOCATION DUE TO A HISTORY OF PRIOR DISLOCATION, BONE LOSS, JOINT OR SOFT TISSUE LAXITY, NEUROMUSCULAR DISEASE, OR INTRAOPERATIVE INSTABILITY. THE TRIDENT II ACETABULAR SHELLS ARE INDICATED FOR CEMENTLESS USE ONLY.,TOTAL HIP REPLACEMENT SYSTEM(OMNIFIT)- PAINFUL, DISABLING JOINT DISEASE OF THE HIP RESULTING FROM: DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS, POSTTRAUMATIC ARTHRITIS OR LATE STAGE AVASCULAR NECROSIS. • REVISION OF PREVIOUS UNSUCCESSFUL FEMORAL HEAD REPLACEMENT, CUP ARTHROPLASTY OR OTHER PROCEDURE. • CLINICAL MANAGEMENT PROBLEMS WHERE ARTHRODESIS OR ALTERNATIVE RECONSTRUCTIVE TECHNIQUES ARE LESS LIKELY TO ACHIEVE SATISFACTORY RESULTS. WHERE BONE STOCK IS OF POOR

	QUALITY OR INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE ACETABULUM , RECON AND TRAUMA CABLE SYSTEM(DALL MILES)-THE DALL-MILES SYSTEM IS INDICATED FOR REATTACHMENT OF THE TROCHANTER IN ANY HIP PROCEDURE USING THE TROCHANTERIC OSTEOTOMY (TOTAL OR PARTIAL) APPROACH. THE DALL-MILES MINI CLEAT IS INDICATED FOR VERTICAL REATTACHMENT OR REINFORCEMENT OF THE TROCHANTER IN ANY SITUATION WHERE THE SURGEON FEELS THAT THE TROCHANTER IS AT RISK FOR DETACHMENT. THE MINI CLEAT AND TENSION BAND IMPLANT ARE INTENDED FOR USE WITH THE DALL-MILES SYSTEM FOR TROCHANTERIC REATTACHMENT ONLY. THE DALL-MILES GROOVED BUTTON IS INTENDED TO BE USED IN CONJUNCTION WITH THE HOWMEDICA ALTA FEMORAL CHANNEL PLATE AND THE DALL-MILES SYSTEM FOR FEMORAL FRACTURE FIXATION. THE DALL-MILES CABLES AND CABLE SLEEVES ARE INDICATED FOR SPINAL WIRING, TROCHANTERIC REATTACHMENT AND STERNOTOMY APPLICATIONS; TRAUMA SURGERY OF THE SHOULDER, ELBOW, KNEE, HIP AND ANKLE; TO STABILIZE BONE GRAFT MATERIAL; AND FOR SUPPLEMENTARY CERCLAGE FIXATION WITH PLATES AND SCREWS FOR FRACTURE FIXATION. THE DALL-MILES STAINLESS STEEL COMPRESSION PLATE IS INDICATED FOR FRACTURE FIXATION OF LONG BONES WHEN SCREW AND PLATE FIXATION ALONE IS INADEQUATE DUE TO POOR BONE QUALITY OR WHEN SCREWS CANNOT BE PLACED BECAUSE OF INTERNAL FIXATION DEVICES. THE DALL-MILES TROCHANTERIC GRIPS AND GRIP PLATES ARE INDICATED FOR USE IN THE FIXATION OF THE GREATER TROCHANTER DUE TO TROCHANTERIC FRACTURE OR OSTEOTOMY WITH INTRAMEDULLARY FIXATION AS THE PRIMARY DEVICE THE DALL-MILES TROCHANTERIC GRIP PLATE IS ADDITIONALLY INDICATED FOR USE IN THE FIXATION OF THE GREATER TROCHANTER DUE TO EXTENDED TROCHANTERIC OSTEOTOMIES. THE CERCLAGE WIRE IS INDICATED FOR BONE FRACTURE FIXATION, OSTEOTOMY, ARTHRODESIS, CORRECTION OF DEFORMITY, REVISION PROCEDURES, AND BONE RECONSTRUCTION PROCEDURES,HIP REPLACEMENT IMPLANT COMPONENT-LINER (MODULAR DUAL MOBILITY INSERT (MDM COCRLINER))-THE INDICATIONS FOR USE FOR TOTAL HIP ARTHROPLASTY INCLUDE: 3. NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS; 4. RHEUMATOID ARTHRITIS; 5. CORRECTION OF FUNCTIONAL DEFORMITY; 6. REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED; AND, 7. TREATMENT OF ON-UNION, FEMORAL NECK AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD 8. INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER

	TECHNIQUES. 9. DISLOCATION RISKS,HIP REPLACEMENT RESTORATION INSERTS(RESTORATION ADM SYSTEM)-THE INDICATIONS FOR USE FOR TOTAL HIP ARTHROPLASTY INCLUDE: • NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS; • RHEUMATOID ARTHRITIS; • CORRECTION OF FUNCTIONAL DEFORMITY; • REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED; AND, • TREATMENT OF ON-UNION, FEMORAL NECK AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD • INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES. • DISLOCATION RISKS ,TOTAL HIP REPLACEMENT SYSTEM(RESTORATION MODULAR HIP SYSTEM)-NONINFLAMMATORY DEGENERATIVE JOINT DISEASE, INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS; • RHEUMATOID ARTHRITIS; • CORRECTION OF FUNCTIONAL DEFORMITY; • REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED; AND, • NONUNIONS, FEMORAL NECK FRACTURES, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES. ADDITIONAL INDICATIONS SPECIFIC TO THE RESTORATION MODULAR HIP SYSTEM: • THE RESTORATION MODULAR HIP SYSTEM IS INTENDED FOR PRIMARY AND REVISION TOTAL HIP ARTHROPLASTY AS WELL AS IN THE PRESENCE OF SEVERE PROXIMAL BONE LOSS. THESE FEMORAL STEMS ARE DESIGNED TO BE PRESS FIT INTO THE PROXIMAL FEMUR ,TOTAL HIP REPLACEMENT SYSTEM(ACCOLADE)-NONINFLAMMATORY DEGENERATIVE JOINT DISEASE, INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS; • RHEUMATOID ARTHRITIS; • CORRECTION OF FUNCTIONAL DEFORMITY; • REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED; AND, NONUNIONS, FEMORAL NECK FRACTURES, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES. ADDITIONAL INDICATION SPECIFIC TO USE OF ANATO HIP STEM WITH COMPATIBLE HOWMEDICA OSTEONICS CONSTRAINED LINERS: • WHEN THE STEM IS TO BE USED WITH COMPATIBLE HOWMEDICA OSTEONICS CONSTRAINED LINERS, THE DEVICE IS INTENDED FOR USE IN PRIMARY OR REVISION PATIENTS AT HIGH RISK OF HIP DISLOCATION DUE TO A HISTORY OF PRIOR DISLOCATION, BONE LOSS, SOFT TISSUE LAXITY, NEUROMUSCULAR DISEASE, OR INTRA-OPERATIVE INSTABILITY. THE ANATO HIP STEM IS INTENDED FOR CEMENTLESS USE ONLY AND IS INTENDED FOR TOTAL AND HEMI-ARTHROPLASTY PROCEDURES.,TOTAL HIP REPLACEMENT SYSTEM-SCREWS(SCREWS)-PAINFUL, DISABLING JOINT DISEASE OF THE HIP

	RESULTING FROM: DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS, POSTTRAUMATIC ARTHRITIS OR LATE STAGE AVASCULAR NECROSIS. REVISION OF PREVIOUS UNSUCCESSFUL FEMORAL HEAD REPLACEMENT, CUP ARTHROPLASTY OR OTHER PROCEDURE. CLINICAL MANAGEMENT PROBLEMS WHERE ARTHRODESIS OR ALTERNATIVE RECONSTRUCTIVE TECHNIQUES ARE LESS LIKELY TO ACHIEVE SATISFACTORY RESULTS. WHERE BONE STOCK IS OF POOR QUALITY OR IS INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE ACETABULUM.,TOTAL KNEE REPLACEMENT SYSTEM(SCORPIO)- PAINFUL, DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM: DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS. • POST-TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION. • MODERATE VARUS, VALGUS, OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY. • REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURE. ADDITIONAL INDICATIONS FOR POSTERIOR STABILIZED COMPONENTS: • LIGAMENTOUS INSTABILITY REQUIRING IMPLANT BEARING SURFACE GEOMETRIES WITH INCREASED CONSTRAINT. • ABSENT OR NON-FUNCTIONING POSTERIOR CRUCIATE LIGAMENT. FOR TS COMPONENTS ONLY: SEVERE ANTEROPOSTERIOR AND MEDIAL/LATERAL INSTABILITY OF THE KNEE JOINT. INDICATIONS FOR BONE AUGMENTATION: • PAINFUL, DISABLING JOINT DISEASE OF THE KNEE SECONDARY TO: DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS, OR POST-TRAUMATIC ARTHRITIS, COMPLICATED BY THE PRESENCE OF BONE LOSS. • SALVAGE OF PREVIOUS UNSUCCESSFUL TOTAL KNEE REPLACEMENT OR OTHER SURGICAL PROCEDURE, ACCOMPANIED BY BONE LOSS.,TOTAL KNEE REPLACEMENT SYSTEM(TRIATHLON)- GENERAL TOTAL KNEE ARTHROPLASTY (TKR) INDICATIONS: • PAINFUL, DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM: NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OR AVASCULAR NECROSIS), RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS. • POSTTRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION. • MODERATE VARUS, VALGUS, OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY. • REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURE. • FRACTURE OF THE DISTAL FEMUR AND/OR PROXIMAL TIBIA THAT CANNOT BE STABILIZED BY STANDARD FRACTURE -MANAGEMENT TECHNIQUES. THE TRIATHLON TRITANIUM TIBIAL BASEPLATE AND TRITANIUM METAL- BACKED PATELLA

	COMPONENTS ARE INDICATED FOR BOTH UNCEMENTED AND CEMENTED USE. THE TRIATHLON TOTAL KNEE SYSTEM BEADED AND BEADED WITH PERI-APATITE COMPONENTS ARE INTENDED FOR UNCEMENTED USE ONLY. THE TRIATHLON ALL POLYETHYLENE TIBIAL COMPONENTS ARE INDICATED FOR CEMENTED USE ONLY. ADDITIONAL INDICATIONS FOR POSTERIOR STABILIZED (PS) AND TOTAL STABILIZER (TS) COMPONENTS: • LIGAMENTOUS INSTABILITY REQUIRING IMPLANT BEARING SURFACE GEOMETRIES WITH INCREASED CONSTRAINT. • ABSENT OR NON-FUNCTIONING POSTERIOR CRUCIATE LIGAMENT. • SEVERE ANTEROPOSTERIOR INSTABILITY OF THE KNEE JOINT. ADDITIONAL INDICATIONS FOR TOTAL STABILIZER (TS) COMPONENTS: • SEVERE INSTABILITY OF THE KNEE SECONDARY TO COMPROMISED COLLATERAL LIGAMENT INTEGRITY OR FUNCTION. INDICATIONS FOR BONE AUGMENTS: • PAINFUL, DISABLING JOINT DISEASE OF THE KNEE SECONDARY TO: DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS, OR POST-TRAUMATIC ARTHRITIS, COMPLICATED BY THE PRESENCE OF BONE LOSS. • SALVAGE OF PREVIOUS UNSUCCESSFUL TOTAL KNEE REPLACEMENT OR OTHER SURGICAL PROCEDURE, ACCOMPANIED BY BONE LOSS. ADDITIONAL INDICATIONS FOR CONE AUGMENTS • SEVERE DEGENERATION OR TRAUMA REQUIRING EXTENSIVE RESECTION AND REPLACEMENT • FEMORAL AND TIBIAL BONE VOIDS • METAPHYSEAL RECONSTRUCTION THE TRIATHLON TRITANIUM® CONE AUGMENT COMPONENTS ARE INTENDED FOR CEMENTED OR CEMENTLESS USE ,TOTAL HIP REPLACEMENT SYSTEM(FEMORAL HEADS)-PAINFUL, DISABLING JOINT DISEASE OF THE HIP RESULTING FROM: DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS, POSTTRAUMATIC ARTHRITIS OR LATE STAGE AVASCULAR NECROSIS. • REVISION OF PREVIOUS UNSUCCESSFUL FEMORAL HEAD REPLACEMENT, CUP ARTHROPLASTY OR OTHER PROCEDURE. • CLINICAL MANAGEMENT PROBLEMS WHERE ARTHRODESIS OR ALTERNATIVE RECONSTRUCTIVE TECHNIQUES ARE LESS LIKELY TO ACHIEVE SATISFACTORY RESULTS. • WHERE BONE STOCK IS OF POOR QUALITY OR IS INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE ACETABULUM., TOTAL HIP REPLACEMENT SYSTEM-CUPS AND SHELLS(TRIDENT)-PAINFUL, DISABLING JOINT DISEASE OF THE HIP RESULTING FROM: DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS, POSTTRAUMATIC ARTHRITIS OR LATE STAGE AVASCULAR NECROSIS. REVISION OF PREVIOUS UNSUCCESSFUL FEMORAL HEAD REPLACEMENT, CUP ARTHROPLASTY OR OTHER PROCEDURE. CLINICAL MANAGEMENT PROBLEMS WHERE ARTHRODESIS OR ALTERNATIVE RECONSTRUCTIVE TECHNIQUES ARE LESS LIKELY TO ACHIEVE SATISFACTORY RESULTS. WHERE BONE STOCK IS OF POOR

	QUALITY OR IS INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE ACETABULUM., TOTAL HIP REPLACEMENT SYSTEM(ACCOLADE II HIP STEM)-THE INDICATIONS FOR USE OF THE TOTAL HIP REPLACEMENT PROSTHESES INCLUDE: 1. NONINFLAMMATORY DEGENERATIVE JOINT DISEASE, INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS; 2. RHEUMATOID ARTHRITIS; 3. CORRECTION OF FUNCTIONAL DEFORMITY; 4. REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED; AND, 5. NONUNIONS, FEMORAL NECK FRACTURES, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES. ADDITIONAL INDICATION SPECIFIC TO USE OF ACCOLADE II FEMORAL STEMS WITH COMPATIBLE HOWMEDICA OSTEONICS CONSTRAINED LINERS: 1. WHEN THE STEM IS TO BE USED WITH COMPATIBLE HOWMEDICA OSTEONICS CONSTRAINED LINERS, THE DEVICE IS INTENDED FOR USE IN PRIMARY OR REVISION PATIENTS AT HIGH RISK OF HIP DISLOCATION DUE TO A HISTORY OF PRIOR DISLOCATION, BONE LOSS, SOFT TISSUE LAXITY, NEUROMUSCULAR DISEASE, OR INTRA-OPERATIVE INSTABILITY. ACCOLADE II FEMORAL STEMS ARE INTENDED FOR CEMENTLESS USE ONLY AND ARE INTENDED FOR TOTAL AND HEMIARTHROPLASTY PROCEDURES. ,TOTAL HIP REPLACEMENT SYSTEM-INSERTS(TRIDENT INSERTS)-PAINFUL, DISABLING JOINT DISEASE OF THE HIP RESULTING FROM: DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS, POSTTRAUMATIC ARTHRITIS OR LATE STAGE AVASCULAR NECROSIS. • REVISION OF PREVIOUS UNSUCCESSFUL FEMORAL HEAD REPLACEMENT, CUP ARTHROPLASTY OR OTHER PROCEDURE. • CLINICAL MANAGEMENT PROBLEMS WHERE ARTHRODESIS OR ALTERNATIVE RECONSTRUCTIVE TECHNIQUES ARE LESS LIKELY TO ACHIEVE SATISFACTORY RESULTS. • WHERE BONE STOCK IS OF POOR QUALITY OR IS INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE ACETABULUM.,TOTAL KNEE REPLACEMENT SYSTEM (TRIATHLON)-GENERAL TOTAL KNEE ARTHROPLASTY (TKR) INDICATIONS: • PAINFUL, DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM: NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OR AVASCULAR NECROSIS), RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS. • POSTTRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION. • MODERATE VARUS, VALGUS, OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY. • REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURE. • FRACTURE OF THE DISTAL FEMUR AND/OR

	PROXIMAL TIBIA THAT CANNOT BE STABILIZED BY STANDARD FRACTURE-MANAGEMENT TECHNIQUES. ADDITIONAL INDICATIONS FOR CONE AUGMENTS • SEVERE DEGENERATION OR TRAUMA REQUIRING EXTENSIVE RESECTION AND REPLACEMENT • FEMORAL AND TIBIAL BONE VOIDS • METAPHYSEAL RECONSTRUCTION THE TRIATHLON TRITANIUM® CONE AUGMENT COMPONENTS ARE INTENDED FOR CEMENTED OR CEMENTLESS USE

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1547	IMP/MD/2019/000089	1.License Holder Name: M/S. ASAHI INTECC CO., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROCATHETER(ASAHI CARAVEL)-THIS MICROCATHETER IS INTENDED TO PROVIDE SUPPORT TO FACILITATE THE PLACEMENT OF GUIDE WIRES IN THE CORONARY AND PERIPHERAL VASCULATURES, AND CAN BE USED TO EXCHANGE ONE GUIDE WIRE FOR ANOTHER. THIS MICROCATHETER IS ALSO INTENDED TO ASSIST IN THE DELIVERY OF CONTRAST MEDIA INTO THE CORONARY AND PERIPHERAL VASCULATURES. DO NOT USE THIS MICROCATHETER OTHER THAN FOR USE IN THE CORONARY AND PERIPHERAL VASCULATURES., ASAHI PERIPHERAL VASCULAR GUIDE WIRE(ASAHI MEISTER 16)-ASAHI PERIPHERAL VASCULAR GUIDE WIRE IS INTENDED FOR USE IN THE PERIPHERAL VASCULATURE, TO FACILITATE THE EXCHANGE AND PLACEMENT OF DIAGNOSTIC AND THERAPEUTIC DEVICES SUCH AS VASCULAR CATHETERS DURING PERIPHERAL INTERVENTIONAL PROCEDURES. THIS GUIDE WIRE IS NOT INTENDED FOR USE IN CORONARY ARTERIES, LOWER LIMB BLOOD VESSELS, NEUROVASCULATURE AND CAROTID ARTERIES.,EXTENSION WIRE (ASAHI)-THE EXTENSION WIRE ACCESSORY IS INTENDED FOR EXTENSION OF THE WORKING LENGTH OF AN ALREADY INTRODUCED GUIDE WIRE WHEN EXCHANGING OVER-THE-WIRE INTERVENTIONAL DEVICES DURING AN ANGIOPLASTY PROCEDURE.,NEUROVASCULAR GUIDE WIRE(ASAHI)-THIS GUIDE WIRE IS INTENDED TO BE USED IN THE NEURO VASCULATURE TO FACILITATE THE PLACEMENT AND EXCHANGE OF THERAPEUTIC DEVICES SUCH AS CEREBRAL CATHETERS DURING NEURORADIOLOGY. THIS GUIDE WIRE IS INTENDED FOR USE ONLY IN THE NEURO VASCULATURE.,PTCA GUIDE WIRE(ASAHI)-ASAHI PTCA GUIDE WIRES ARE INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). THE ASAHI PTCA GUIDE WIRES ARE NOT INTENDED FOR USE IN THE NEUROVASCULATURE,HYDROPHILIC COATED SPRING COIL GUIDE WIRE(ASAHI SILVERWAY)-THIS PRODUCT IS INTENDED TO BE USED FOR THE ADJUSTMENT OF THE POSITION OF THE CATHETER OR THE LIKE IN A BLOOD VESSEL AND AS AN AID IN MOVING THE CATHETER. IT IS NOT FOR USE IN CORONARY ARTERIES OR INTRACRANIAL VESSELS.

1548	IMP/MD/2019/000090	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYPROCURE® SINUS TARSI(HYPROCURE® SINUS TARSI STENT)-HYPROCURE IS A TALOTARSAL STABILIZATION DEVICE USED IN THE TREATMENT OF TALOTARSAL DISLOCATION AND RESULTING SEQUELA. THE IMPLANT IS DESIGNED TO STABILIZE THE TALUS ON THE TARSAL MECHANISM TO PREVENT EXCESSIVE ANTERIOR, AND/OR MEDIAL, AND/OR PLANTAR FLEXION OF THE TALUS ON THE TARSAL MECHANISM, WHILE ALLOWING NORMAL TALOTARSAL JOINT MOTION.
1549	IMP/MD/2019/000091	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANGIOGRAPHY CATHETERS(WOVEN ANGIOGRAPHY CATHETERS)-THESE DEVICES ARE USED TO RECORD INTRACARDIAC PRESSURES, TO SAMPLE BLOOD, AND TO INTRODUCE SUBSTANCES INTO THE HEART AND VESSELS.,CARDIOVASCULAR ANGIOGRAPHY GUIDEWIRES(NIL)-FOR PERCUTANEOUS ENTRY INTO VESSEL USING THE SELDINGER TECHNIQUE.,BALLOON SEPTOSTOMY CATHETERS(RASHKIND BALLOON SEPTOSTOMY CATHETERS)-THESE DEVICES ARE DESIGNED FOR CREATING AN ATRIAL SEPTAL DEFECT OR ENLARGING AN EXISTING ATRIAL SEPTAL DEFECT.
1550	IMP/MD/2019/000092	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NON-STICK BIPOLAR ELECTROSURGICAL FORCEPS(SILVERGLIDE® PROSERIES)-STRYKER SILVERGLIDE PROSERIES NON-STICK BIPOLAR ELECTROSURGICAL FORCEPS ARE INTENDED TO FACILITATE GRASPING AND MANIPULATION OF SOFT TISSUE AND PROVIDE ELECTROCAUTERY IN SURGICAL PROCEDURES

1551	IMP/MD/2019/000093	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE INFLATION DEVICE(EVEREST)-THE EVEREST INFLATION DEVICE/SURVIVAL KIT ARE TO BE USED TO FACILITATE THE USE OF CATHETERS AND GUIDEWIRES DURING INTERVENTIONAL PROCEDURES. THE EVEREST INFLATION DEVICE IS DESIGNED TO BE USED TO INFLATE/DEFLATE BALLOON CATHETERS AS WELL AS TO MONITOR PRESSURE WITHIN THE BALLOON. THE Y-ADAPTER WITH HEMOSTASIS VALVE IS DESIGNED TO BE USED ON A GUIDING CATHETER OR DILATATION CATHETER TO CONTROL BACK-BLEEDING AND TO PROVIDE A PORT FOR INTRODUCTION OF FLUIDS INTO THE INTERVENTIONAL SYSTEM. THE GUIDE WIRE INSERTION TOOL IS DESIGNED TO FACILITATE PLACEMENT OF A GUIDE WIRE TIP THROUGH THE Y-ADAPTER AND INTO THE WIRE LUMEN OF AN INTERVENTIONAL CATHETER. THE STEERING HANDLE IS DESIGNED TO HOLD A SMALL DIAMETER GUIDE WIRE AND PROVIDE A HANDLE FOR MANIPULATING THE WIRE., CORONARY CATHETERS(DXTERITY™)-THE DXTERITY DIAGNOSTIC CATHETERS ARE INDICATED FOR CARDIAC AND VASCULAR PROCEDURES. IT IS DESIGNED TO DELIVER RADIOPAQUE MEDIA, GUIDEWIRES, AND THERAPEUTIC AGENTS TO SELECTED SITES IN THE VASCULAR SYSTEM. THE DIFFERENT CONFIGURATIONS OF THE DIAGNOSTIC CATHETER ARE DESIGNED TO BE USED IN ARTERIES FROM ACCESS SITES SUCH AS THE RADIAL, BRACHIAL, AND FEMORAL ARTERIES.

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1552	IMP/MD/2019/000094	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER SETS (ESPOCAN)-IT IS USED FOR COMBINED AND EPIDURAL ANESTHESIA , CATHETER SETS AND CATHETERS(PERIFIX CATHETER/ PERIFIX)-IT IS USED AS AN ASSET FOR CONTINUOUS EPIDURAL ANESTHESIA, CLOSED IV CATHETER(INTROCAN SAFETY 3)-INTROCAN SAFETY 3 CLOSED INTRAVASCULAR CATHETER IS INSERTED INTO A PATIENT'S VASCULAR SYSTEM FOR SHORT TERM USE (LESS THAN 30 DAYS) TO SAMPLE BLOOD, MONITOR BLOOD PRESSURE, OR ADMINISTER FLUIDS AND BLOOD INTRAVASCULARLY,I.V. INDWELLING CANNULA (VASOFIX SAFETY/ VASOFIX BRAUNÜLE/ VASOFIX CERTO)-IT IS INTENDED FOR BLOOD TRANSFUSION OR INFUSION OF I.V. SOLUTIONS SUITABLE ADMINISTRATION VIA PERIPHERAL VEINS. INTERMITTENT INTRAVENOUS DRUG ADMINISTRATION. PROPHYLACTIC CREATION OF A SECURE VENOUS ACCESS IN PATIENTS WHO MAY REQUIRE URGENT INTRAVENOUS DRUG ADMINISTRATION, IN PARTICULAR PRIOR TO DIAGNOSTIC OR THERAPEUTIC PROCEDURES.,I.V. INDWELLING CANNULA(INTROCAN SAFETY/ INTROCAN SAFETY-W/ INTROCAN/ INTROCAN-W CERTO/ INTROCAN-W)-IT IS INTENDED FOR BLOOD TRANSFUSION OR INFUSION OF I.V. SOLUTIONS SUITABLE ADMINISTRATION VIA PERIPHERAL VEINS. INTERMITTENT INTRAVENOUS DRUG ADMINISTRATION. PROPHYLACTIC CREATION OF A SECURE VENOUS ACCESS IN PATIENTS WHO MAY REQUIRE URGENT INTRAVENOUS DRUG ADMINISTRATION, IN PARTICULAR PRIOR TO DIAGNOSTIC OR THERAPEUTIC PROCEDURES. ,I.V. ADMINISTRATION SET WITH DOSING CONTAINER(DOSIFIX)-IT IS INTENDED FOR PRECISE DOSAGE OF SMALL VOLUMES IN INFUSION THERAPY. THE DEVICE IS FITTED WITH A MICRODROPPER, 60 DROPS BEING EQUIVALENT TO APPROXIMATELY 1ML OF DISTILLED WATER,NEEDLE FOR SPINAL ANESTHESIA(PENCAN/ PENCAN PAED)-LUMBAR PUNCTURE (DIAGNOSIS), SPINAL ANESTHESIA (INJECTION OF LOCAL ANESTHETICS INTO SUBARACHNOID SPACE FOR DIAGNOSIS OPERATIVE PROCEDURES AND PAIN MANAGEMENT),NEEDLE FOR SPINAL ANESTHESIA(SPINOCAN)-LUMBAR PUNCTURE(DIAGNOSIS), SPINAL ANESTHESIA (INJECTION OF LOCAL ANESTHETICS INTO SUBARACHNOID SPACE FOR DIAGNOSIS OPERATIVE PROCEDURES AND PAIN MANAGEMENT),NEEDLES FOR EPIDURAL ANESTHESIA (PERICAN/ PERICAN PAED)-EPIDURAL ANESTHESIA (LUMBAR, THORACAL, CERVICAL) AND CAUDAL BLOCK FOR FAST AND RELIABLE ANESTHESIA DURING SURGERY,DISPOSABLE ELASTOMERIC INFUSION PUMP SYSTEM(EASYPUMP II LT/ST)-ELASTOMERIC PUMP DEVICES ARE INTENDED TO INFUSE

		MEDICATION FOR EITHER CONTINUOUS INTRAVENOUS, SUBCUTANEOUS OR EPIDURAL INFUSION (ACCORDING TO PUMP MODEL). CHEMOTHERAPY, ANTIBIOTICS, ANESTHESIA AND PAIN MANAGEMENT ARE THE MOST COMMON THERAPIES WHERE ELASTOMERIC PUMPS CAN BE USED, EITHER IN ADULT OR PEDIATRIC PATIENTS.
1553	IMP/MD/2019/000095	1.License Holder Name: CADILA HEALTHCARE LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK)-COMPONENT OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS,PREFILLABLE GLASS BARREL WITH NEEDLE(BD NEOPAK)-COMPONENT OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS

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1554	IMP/MD/2019/000096	1.License Holder Name: COOK INDIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYDROPHILLIC COATED WIRE GUIDE(APPROACH® CTO MICRO WIRE GUIDE)-THE APPROACH® CTO MICRO WIRE GUIDES ARE INTENDED FOR USE IN FACILITATING DELIVERY OF PERCUTANEOUS CATHETERS INTO THE PERIPHERAL VASCULATURE.,INFUSION CATHETER(CANTATA MICROCATHETER (CANTATA 2.5, CANTATA 2.8, CANTATA 2.5 DUO, CANTATA 2.8 DUO, CANTATA 2.9))-THE CANTATA® MICROCATHETER, AND CANTATA® DUO MICROCATHETER ARE DESIGNED FOR USE IN SMALL VESSEL OR SUPERSELECTIVE ANATOMY FOR DIAGNOSTIC AND INTERVENTIONAL PROCEDURES INCLUDING PERIPHERAL OR CORONARY USE.,INTRODUCTION/ DRAINAGE CATHETER AND ACCESSORIES(FUHRMAN PLEURAL/ PNEUMOPERICARDIAL DRAINAGE SET)-IT IS INTENDED FOR EVACUATION OF AIR FORM THE PERICARDIAL SAC OR DRAINAGE OF AIR OR FLUID FROM THE PLEURAL SPACE. THE PRODUCT IS INTENDED FOR USE BY PHYSICIANS TRAINED AND EXPERIENCED IN DIAGNOSTIC AND INTERVENTIONAL TECHNIQUES. STANDARD SELDINGER TECHNIQUE FOR PLACEMENT OF NEEDLES, WIRE GUIDES, DILATORS AND CATHETERS SHOULD BE EMPLOYED,ENDOVASCULAR STENT-GRAFTS (ZENITH SPIRAL-Z AAA ILIAC LEG)-IT IS INDICATED FOR USE WITH THE ZENITH AAA ENDOVASCULAR GRAFT FAMILY OF PRODUCTS, INCLUDING THE ZENITH FLEX AAA ENDOVASCULAR GRAFT, ZENITH ALPHA ABDOMINAL ENDOVASCULAR GRAFT, ZENITH LOW PROFILE AAA ENDOVASCULAR GRAFT, ZENITH RENU ANCILLARY GRAFT, ZENITH FENESTRATED AAA ENDOVASCULAR GRAFT, ZENITH UNIVERSAL DISTAL BODY ENDOVASCULAR GRAFT, ZENITH FLEX AUI, OR ZENITH BRANCH, DURING EITHER A PRIMARY OR A SECONDARY PROCEDURE IN PATIENTS WHO HAVE ADEQUATE ILIAC/FEMORAL ACCESS COMPATIBLE WITH THE REQUIRED INTRODUCTION SYSTEMS. THE GRAFT IS USED IN COMBINATION WITH THESE PRODUCTS FOR THE ENDOVASCULAR TREATMENT OF ABDOMINAL AORTIC AND AORTO-ILIAC ANEURYSMS,INTRODUCTION/ DRAINAGE CATHETER AND ACCESSORIES(LOCK PERICARDIOCENTESIS SET)-1. LOCK PERICARDIOCENTESIS SET ARE INTENDED TO REMOVE FLUID FROM THE PERICARDIAL SAC ,BALLOON EXPANDABLE STENT(FORMULA VASCULAR BALLOON-EXPANDABLE STENT)-INTENDED FOR STENTING OF PERIPHERAL ARTERIES.,TRANSJUGULAR SETS(ROSCH-UCHIDA TRANSJUGULAR LIVER ACCESS SET & STYLET CATHETER COMBINATION)-INTENDED FOR TRANSJUGULAR LIVER ACCESS IN DIAGNOSTIC AND INTERVENTIONAL PROCEDURES,TRANSJUGULAR SETS(RING TRANSJUGULAR INTRAHEPATIC ACCESS SET)-INTENDED FOR TRANSJUGULAR LIVER ACCESS IN DIAGNOSTIC AND

		INTERVENTIONAL PROCEDURES
1555	IMP/MD/2019/000096	1.License Holder Name: M/S COOK INDIA MEDICAL DEVICES PVT. LTD. , PLOT NO 22(SP), THIRD AND FOURTH FLOOR, KOCHAR JADE, THIRU VI KA INDUSTRIAL ESTATE, GUINDY TALUK ,CHENNAI TAMIL NADU , 600032 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER(SPECTRUM CENTRAL VENOUS CATHETER SET MINOCYCLINE/ RIFAMPIN ANTIBIOTIC IMPREGNATED)-THE CENTRAL VENOUS CATHETER IS DESIGNED FOR TREATMENT OF CRITICALLY ILL PATIENTS AND IS DESIGNED FOR: 1.CONTINUOUS OR INTERMITTENT DRUG INFUSIONS 2. CENTRAL VENOUS BLOOD PRESSURE MONITORING (CVP) 3. ACUTE HYPERALIMENTATION 4. BLOOD SAMPLING 5. DELIVERY OF WHOLE BLOOD OR BLOOD PRODUCTS 6. SIMULTANEOUS, SEPARATE INFUSION OF DRUGS THE ACTIVITY OF THE ANTIMICROBIAL AGENTS, MINOCYCLINE, AND RIFAMPIN, IS LOCALIZED AT THE INTERNAL AND EXTERNAL CATHETER SURFACE AND IS NOT INTENDED FOR TREATMENT OF SYSTEMIC INFECTIONS. THE DEVICE IS A SHORT-TERM USE CATHETER.
1556	IMP/MD/2019/000097	1.License Holder Name: ALTO MEDICAL SYSTEMS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DUAL LUMEN CATHETER (CRUSADE)-CRUSADE IS INTENDED TO BE USED FOR; - GUIDE WIRE SUPPORT FOR CROSSING SIDE BRANCH - EXCHANGE OF GUIDE WIRES, DURING PERCUTANEOUS CORONARY INTERVENTION (PCI) , ASPIRATION CATHETER SET(THROMBUSTER II)-THROMBUSTER IS INTENDED FOR USE TO REMOVE THROMBUS AND DEBRIS IN THE CORONARY OR PERIPHERAL ARTERIES BY PERCUTANEOUS SUCTION.

1557	IMP/MD/2019/000098	1.License Holder Name: FLEXICARE MEDICAL (INDIA) PRIVATE LIMITED. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BREATHING FILTER (FLEXICARE)-THIS DEVICE PROVIDES A MEDIUM THROUGH WHICH GASES MAY PASS BETWEEN A PATIENT AND EQUIPMENT USED IN ANAESTHESIA AND CRITICAL CARE. THIS DISPOSABLE, SINGLE PATIENT USE DEVICE IS INTENDED TO BE REPLACED WITH EACH PATIENT WHEN USED AT THE PATIENT / BREATHING SYSTEM INTERFACE. IT IS TO BE USED BY MEDICALLY TRAINED PROFESSIONALS ONLY,HIGH FLOW NASAL CANNULA(FLEXICARE)-INTENDED FOR USE WITH A BREATHING SYSTEM DURING HIGH FLOW OXYGEN THERAPY TO DELIVER HEATED AND HUMIDIFIED GAS, PROVIDING RESPIRATORY SUPPORT TO SPONTANEOUSLY BREATHING PATIENTS,ENDOTRACHEAL TUBE(FLEXICARE)-AN ENDOTRACHEAL TUBE IS INSERTED THROUGH THE MOUTH OR NOSE INTO THE TRACHEA TO MAINTAIN AN UNOBSTRUCTED AIRWAY, TO VENTILATE THE PATIENT, TO PERMIT THE SUCTIONING OF MUCUS OR TO PREVENT ASPIRATION OF THE STOMACH CONTENTS, AND DELIVER AIR, OXYGEN ENRICHED AIR, OR ANAESTHETIC GASES TO THE LUNGS IN ANAESTHESIA, CRITICAL CARE, EMERGENCY CARE AND/OR PRE-HOSPITAL SETTINGS.,NEBULISER(FLEXICARE)-WHEN USED WITH A SUITABLE AIR SUPPLY, THE NEBULISER IS INTENDED TO AEROSOLISE LIQUIDS THAT ARE DELIVERED DIRECTLY TO A PATIENT BY THE GAS FLOW. IT IS INTENDED FOR ADULT AND PAEDIATRIC PATIENTS, AND MAY BE USED IN PREHOSPITAL, HOSPITAL, AND HOME CARE ENVIRONMENTS.,DUAL NASAL CANNULA (FLEXICARE)-DUAL NASAL CANNULA ARE USED TO DELIVER SUPPLEMENTARY OXYGEN WHEN RESPIRATORY SUPPORT IS REQUIRED & PROVIDE THE OPTION FOR ACCURATE ETCO2 MONITORING.,NASOPHARYNGEAL AIRWAY(FLEXICARE)-IT IS INTENDED TO BE INSERTED THROUGH A NOSTRIL TO PROVIDE AN OPENING TO MAINTAIN THE PATENCY OF A PATIENT'S AIRWAY WHEN ACCESS VIA THE MOUTH IS NOT POSSIBLE OR DESIRABLE. IT CAN ALSO BE USED AS A CONDUIT FOR OTHER MEDICAL DEVICES, SUCH AS SUCTION CATHETERS.,NASAL CPAP(FLEXICARE)-FOR ADMINISTERING CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) TO INFANTS

1558	IMP/MD/2019/000098	1.License Holder Name: FLEXICARE MEDICAL(INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LARYNGEAL MASK AIRWAYS(LARYSEAL PRO LARYNGEAL MASK AIRWAYS)-A SUPRAGLOTTIC MEDICAL DEVICE THAT KEEPS A PATIENT'S AIRWAY OPEN DURING ANAESTHESIA AND ARTIFICIAL RESPIRATION AND OTHER TYPES OF ASSISTED RESPIRATION.,LARYNGEAL MASK AIRWAYS(LARYSEAL MRI LARYNGEAL MASK AIRWAY)-A SUPRAGLOTTIC MEDICAL DEVICE THAT KEEPS A PATIENT'S AIRWAY OPEN DURING ANAESTHESIA AND ARTIFICIAL RESPIRATION AND OTHER TYPES OF ASSISTED RESPIRATION.,LARYNGEAL MASK AIRWAYS(LARYSEAL FLEXI LARYNGEAL MASK AIRWAY)-DESIGNED FOR USE IN OPHTHALMIC, ENT, DENTAL AND OTHER HEAD/NECK SURGERIES. THE REINFORCED CONSTRUCTION OF THE MAIN TUBE ALLOWS IT TO BE POSITIONED WELL AWAY FROM THE SURGICAL FIELD, IMPROVING SURGICAL ACCESS WITHOUT COMPROMISING THE SEAL.,LARYNGEAL MASK AIRWAYS(LARYSEAL CLEAR LARYNGEAL MASK AIRWAYS)-A SUPRAGLOTTIC MEDICAL DEVICE THAT KEEPS A PATIENT'S AIRWAY OPEN DURING ANAESTHESIA AND ARTIFICIAL RESPIRATION AND OTHER TYPES OF ASSISTED RESPIRATION, LARYNGEAL MASK AIRWAYS(LARYSEAL MULTIPLE LARYNGEAL MASK AIRWAY)-A SUPRAGLOTTIC MEDICAL DEVICE THAT KEEPS A PATIENT'S AIRWAY OPEN DURING ANAESTHESIA AND ARTIFICIAL RESPIRATION AND OTHER TYPES OF ASSISTED RESPIRATION., LARYNGEAL MASK AIRWAYS(LARYSEAL BLUE LARYNGEAL MASK AIRWAY)-A SUPRAGLOTTIC MEDICAL DEVICE THAT KEEPS A PATIENT'S AIRWAY OPEN DURING ANAESTHESIA AND ARTIFICIAL RESPIRATION AND OTHER TYPES OF ASSISTED RESPIRATION.
1559	IMP/MD/2019/000101	1.License Holder Name: SPAN HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD TRANSFUSION FILTER SET(HAEMONETICS)-THE FILTER IS INDICATED FOR THE REMOVAL OF POTENTIALLY HARMFUL MICRO-AGGREGATES FROM STORED BLOOD, RED CELLS, PLATELET AND GRANULOCYTE CONCENTRATES, CRYOPRECIPITATES, PLASMA FRACTIONS AND FOR THE FILTRATION OF VIASPAN (COLD STORAGE SOLUTIONS).

1560	IMP/MD/2019/000102	1.License Holder Name: STRAUMANN DENTAL INDIA LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INJECTABLE SYNTHETIC RESORBABLE BONE GRAFT(MAXRESORB INJECT)-MAXRESORB INJECT IS A SYNTHETIC, OSTEOCONDUCTIVE BONE PASTE FOR THE FILLING AND SUPPORTING OF ADJACENT, VIABLE BONE MATERIAL IN CASES OF BONE DEFECTS THAT ARE NOT CRITICAL TO THE STABILITY OF THE BONE STRUCTURE.,SYNTHETIC, RESORBABLE BONE GRAFT SUBSTITUTE(MAXRESORB)-INTENDED FOR FILLING OF INTRAOSSEOUS, PERIODONTAL AND ROOT RESECTION DEFECTS, EXTRACTION ALVEOLAE, ELEVATION OF THE MAXILLARY SINUS FLOOR, AUGMENTATION OR RECONSTRUCTIVE TREATMENT OF ALVEOLAR RIDGE. ALSO FOR PRODUCTS INTENDED FOR (GBR) GUIDED BONE REGENERATION
1561	IMP/MD/2019/000103	1.License Holder Name: VIECARE ELECTRONICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANTS (IMPLANT-ONE DENTAL IMPLANT SYSTEM)-TO REPLACE MISSING TOOTH OR TEETH
1562	IMP/MD/2019/000104	1.License Holder Name: 3M INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CASTING TAPE(3M SOFT CAST)-INTENDED FOR USE IN THE CONSTRUCTION OF MOST COMMON ORTHOPAEDIC/TRAUMA CAST APPLICATIONS IN A SO CALLED “CLOSED FUNCTIONAL STABILISATION” IN FRACTURE MANAGEMENT, AS WELL AS FOR SPECIALIZED PAEDIATRIC INDICATIONS, FOR SERIAL CASTING IN NEUROSPASTIC PATIENTS, PROSTHETICS AND ORTHOTIC DEVICES AS WELL AS IN THE SO CALLED “TOTAL CONTACT CAST” APPLICATIONS IN DIABETIC FOOT ULCER TREATMENT. SPECIFIC APPLICATION SUITABILITY SHOULD BE THE RESPONSIBILITY OF A QUALIFIED, ON-SITE MEDICAL PROFESSIONAL,CASTING TAPE(3M SCOTCHCAST PLUS)-INTENDED FOR USE IN THE CONSTRUCTION OF MOST COMMON ORTHOPAEDIC/TRAUMA CAST APPLICATIONS AS WELL AS FOR SPECIALIZED PROSTHETICS AND ORTHOTIC DEVICES. SPECIFIC APPLICATION SUITABILITY SHOULD BE THE RESPONSIBILITY OF A QUALIFIED, ON-SITE MEDICAL PROFESSIONAL.

1563	IMP/MD/2019/000105	1.License Holder Name: B.J.ZH.F PANTHER MEDICAL EQUIPMENT INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CUTTER STAPLER (PANTHER)-CUTTER STAPLER IS APPLICABLE TO THE RECONSTRUCTION OF THE DIGESTIVE TRACT WITH THE DIFFICULTIES OF EXPOSING THE OPERATIVE EYE, THE RECONSTRUCTION OF ANASTOMOTIC STOMA AFTER THE VISCERAL RESECTIONS AND THE CLOSURE OF AN INCISION OR STUMP.,HEMORRHOIDAL STAPLER (PANTHER)-THE HEMORRHOIDAL STAPLER AND ACCESSORIES HAVE APPLICATION THROUGHOUT THE ANAL CANAL TO PERFORM SURGICAL TREATMENT OF HEMORRHOIDAL DISEASE.,LINEAR CUTTER STAPLER(PANTHER)-THE LINEAR CUTTER STAPLERS CAN BE APPLIED IN ABDOMINAL, GYNECOLOGICAL PEDIATRIC AND THORACIC SURGICAL PROCEDURES FOR RESECTION, TRANSECTION AND CREATION OF ANASTOMOSIS.,ENDO LINEAR CUTTER STAPLER (PANTHER)-THE ENDO LINEAR CUTTER STAPLER HAS APPLICATIONS IN ABDOMINAL, GYNECOLOGIC PEDIATRIC AND THORACIC SURGERY PROCEDURES FOR RESECTION, TRANSECTION AND CREATION OF ANASTOMOSIS.,LINEAR STAPLER(PANTHER)-THE LINEAR SURGICAL STAPLER CAN BE APPLIED IN ABDOMINAL, THORACIC AND PEDIATRIC SURGICAL PROCEDURE FOR TRANSECTION OR RESECTION OF TISSUE.,CIRCULAR STAPLER(PANTHER)-THE CIRCULAR STAPLER CAN BE APPLIED THROUGHOUT THE ALIMENTARY TRACT TO CREATE END TO END, END TO SIDE AND SIDE TO SIDE ANASTOMOSIS
1564	IMP/MD/2019/000106	1.License Holder Name: RELIANCE LIFE SCIENCES PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE (STERILE)(BD HYPAK SCF)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS.

1565	IMP/MD/2019/000107	1.License Holder Name: M/S SOLLUNA SURGICAL PRIVATE LIMITED, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:METAL LOCKING BONE PLATE SYSTEM(DOUBLE MEDICAL)-METAL LOCKING BONE PLATE SYSTEM IS PROVIDED AS NON-STERILE. IT IS IMPLANTED AROUND THE FRACTURE END TO CORRECT, FIX AND STABILIZE FRACTURES CAUSED BY TRAUMA OR DISEASE.,METAL CANNULATED SCREW (DOUBLE MEDICAL)-METAL CANNULATED SCREW CONSISTS OF HEADLESS COMPRESSION SCREW, CANNULATED SCREW, WASHER AND SUBTALAR SCREW. METAL CANNULATED SCREW IS PROVIDED IN NON-STERILE STATE. HEADLESS COMPRESSION SCREW AND CANNULATED SCREW ARE APPLICABLE FOR THE TREATMENT OF VARIOUS LIMB AND METAPHYSEAL FRACTURES, HAND, FOOT AND IRREGULAR BONE FRACTURES, INTERNAL FIXATION AND ORTHOPAEDIC FIXATION, ETC. SUBTALAR SCREW IS USED FOR THE TREATMENT OF FLAT FOOT ORTHOPEDIC SURGERY .,METAL BONE PIN(DOUBLE MEDICAL)-METAL BONE PIN IS INTENDED FOR THE TREATMENT OF LIMB BONE FRACTURE.

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1566	IMP/MD/2019/000107	1.License Holder Name: M/S SOLLUNA SURGICAL PRIVATE LIMITED, , PROPERTY NO 535. IST FLOOR, FRONT PORTION, FUNCTIONAL INDUSTRIAL ESTATE, PATPARGANJ INDUSTRIAL AREA, ,EAST DELHI DELHI ,110092 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:METAL SPINAL BONE PLATE SYSTEM(DOUBLE MEDICAL)-THE ANTERIOR CERVICAL PLATE SYSTEM IS INDICATED FOR STABILIZATION OF THE CERVICAL SPINE FROM C2 TO C7 EMPLOYING UNICORTICAL SCREW FIXATION AT THE ANTERIOR FACE OF THE VERTEBRAL BODIES. SPECIFIC CLINICAL INDICATIONS FOR ANTERIOR PLATING INCLUDE: INSTABILITY CAUSED BY TRAUMA; INSTABILITY ASSOCIATED WITH ORRECTION OF CERVICAL LORDOSIS AND KYPHOSIS DEFORMITY; INSTABILITY ASSOCIATED WITH PSEUDOARTHROSIS AS A RESULT OF PREVIOUSLY FAILED CERVICAL SPINE SURGERY; INSTABILITY ASSOCIATED WITH MAJOR RECONSTRUCTIVE SURGERY FOR PRIMARY TUMORS OR METATSTATIC MALIGNANT TUMORS OF THE CERVICAL SPINE; INSTABILITY ASSOCIATED WITH SINGLE OR MULTIPLE LEVEL CORPECTOMY IN ADVANCED DEGENERATIVE DISC DISEASE, SPINAL CANAL STENOSIS AND CERVICAL MYELOPATHY. IT IS PROVIDED AS NON-STERILE. ANTERIOR THORACIC-LUMBAR SPINE SYSTEM IS PROVIDED AS NON-STERILE. IT CAN BE USED TO TREAT VARIOUS FRACTURES OF THORACIC-LUMBAR SPINE.,ORTHOPEDIC CABLE SYSTEM(DOUBLE MEDICAL)-ORTHOPEDIC CABLE SYSTEM IS PROVIDED AS NON-STERILE. IT IS INTENDED FOR THE INTERNAL FIXATION OF LIMB AND PERIPROSTHETIC FRACTURES.,METAL LOCKING BONE PLATE SYSTEM(DOUBLE MEDICAL)-METAL LOCKING BONE PLATE SYSTEM IS PROVIDED AS NONSTERILE. PLATES AND SCREWS CAN BE COMBINED TO TREAT VARIOUS BONE FRACTURES, INCLUDING LARGE BONE (CLAVICLE, SCAPULA, PELVIS, HUMERUS, ULNA, RADIUS, FEMUR, TIBIA, AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, AND PHALANGES) FRACTURE., METAL SPINAL SYSTEM(DOUBLE MEDICAL)-METAL SPINAL SYSTEM IS PROVIDED AS NON-STERILE. IT IS USED FOR THE INTERNAL FIXATION OF POSTERIOR CERVICAL AND THORACIC-LUMBAR SPINE FRACTURE. METAL SPINAL SYSTEM IS DESIGNED AND MANUFACTURED IN ACCORDANCE WITH THE ANATOMIC FEATURE OF HUMAN SPINE. IT IS COMPOSED OF CORTEX SCREWS AND PLATES, WHICH ARE APPLICABLE FOR DIFFERENT SEGMENTS OF POSTERIOR SPINE FIXATION.,SPINAL CAGE/MESH(DOUBLE MEDICAL)-SPINAL CAGE/MESH IS INTENDED FOR INTERVERTEBRAL FUSION FIXATION OF SPINAL FRACTURE, SPONDYLOLISTHESIS INSTABILITY, DISC PROTRUSION. IT IS PROVIDED AS BOTH NON-STERILE AND STERILE., METAL INTRAMEDULLARY NAIL SYSTEM(DOUBLE MEDICAL)-METAL

		INTRAMEDULLARY NAIL SYSTEM IS PROVIDED AS NONSTERILE; IT IS INTENDED TO BE IMPLANTED INTO THE MEDULLARY CANAL OF LIMBS FOR ALIGNMENT, STABILIZATION, FIXATION OF FRACTURES CAUSED BY TRAUMA OR DISEASES.
1567	IMP/MD/2019/000108	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ULTRASONIC ABLATION DEVICE AND ASPIRATOR(SONOPET SYSTEM)-THE STRYKER SONOPET UNIVERSAL SURGICAL SYSTEM IS INTENDED FOR USE IN SURGICAL PROCEDURES WHERE FRAGMENTATION, EMULSIFICATION AND ASPIRATION OF SOFT AND HARD TISSUE IS DESIRABLE, INCLUDING NEUROSURGERY, GASTROINTESTINAL AND AFFILIATED ORGAN SURGERY, UROLOGICAL SURGERY, PLASTIC AND RECONSTRUCTIVE SURGERY, GENERAL SURGERY, ORTHOPAEDIC SURGERY, GYAENACOLOGICAL SURGERY, LAPAROSCOPIC SURGERY, AND THROCOSCOPIC SURGERY.
1568	IMP/MD/2019/000109	1.License Holder Name: RADDMED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE MICROWAVE THERAPEUTIC ANTENNAS(HIGH POWER MICROWAVE ABLATION ANTENNA, MICROWAVE ABLATION ANTENNA, MICROWAVE ABLATION ANTENNA FOR THYROID NODULES, MICROWAVE ABLATION ANTENNA INTELLIGENT VERSION)-THE DEVICE IS A STERILE, HAND-HELD SURGICAL INSTRUMENT DESIGNED TO CONNECT TO THE MICROWAVE THERAPEUTIC SYSTEM TO DELIVER MICROWAVES TO A TARGETED OPERATIVE SITE FOR LOCALIZED SOFT-TISSUE ABLATION, TYPICALLY TO TREAT TUMOURS AND/OR HYDATID CYSTS. THE PROBE INCLUDES A HANDLE AND COOLING MECHANISM. THE DEVICE IS INTENDED TO BE USED IN PERCUTANEOUS, LAPAROSCOPIC, OR OPEN SURGERY PROCEDURES TO ABLATE TISSUE TYPICALLY IN THE LIVER, LUNG, AND KIDNEY. THIS IS A SINGLE-USE DEVICE.

1569	IMP/MD/2019/000110	1.License Holder Name: M/S ZIMMER INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIP SYSTEM(CERAMIC FEMORAL HEAD)-THE DEVICE IS INDICATE FOR FOLLOWING:• ADVANCED WEAR OF THE JOINT DUE TO DEGENERATIVE, POST-TRAUMATIC OR RHEUMATIC DISEASES. • FRACTURES OR AVASCULAR NECROSIS.• STATUS FOLLOWING EARLIER OPERATIONS, SUCH AS JOINT RECONSTRUCTION (OSTEOTOMY), ARTHRODESIS, HEMIARTHROPLASTY OR TOTAL HIP PROSTHESIS (THP), TOTAL KNEE PROSTHESIS AND STATUS FOLLOWING OTHER OPERATIONS WITH PROSTHESES, E.G., ON SHOULDER OR ELBOW JOINTS, OR FOLLOWING SPINAL SURGERY.,PLATES MINI/ SMALL/ LARGE FRAGMENTS - STAINLESS STEEL/ TITANIUM (NON- STERILE)(NIL)-THE PLATES MINI-SMALL- LARGE FRAGMENTS HAVE DIFFERENT SHAPES AND ARE INTENDED TO BE USED IN COMBINATION WITH CANCELLOUS OR CORTICAL SCREWS, WHEN NEEDED WITH WASHERS OR NUTS, FOR TEMPORARY FIXATION OF THE BONE FRACTURES.,HIP SYSTEM (ORIGINAL M.E. MULLER REINFORCEMENT RING)-THIS DEVICE IS INDICATED FOR CASES WITH INSUFFICIENT BONE SUBSTANCE OR PARTIAL ACETABULAR DEFECTS AND HAS A VERY BROAD RANGE OF INDICATIONS. TYPICAL CASES WHERE THIS PRODUCT IS USED ARE: • SEVERE OSTEOPOROSIS• RHEUMATOID ARTHRITIS• ACETABULAR ROOF CYST• SMALL DYSPLASTIC HIPS• AFTER ARTHRODESIS• PROTRUSION• FEMORAL HEAD NECROSIS• DYSPLASTIC OR SMALL ACETABULA• SIMPLE REVISION CASES,NAIL SYSTEM - TITANIUM (ZIMMER NATURAL NAIL SYSTEM)-THE ZIMMER NATURAL NAIL SYSTEM IS INTENDED FOR TEMPORARY FRACTURE FIXATION AND STABILIZATION OF THE BONE.,HIP SYSTEM(MS-30 STEM WITH CENTRALIZER)-THE DEVICE IS INDICATE FOR:• NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS. • FAILED PREVIOUS SURGERY WHERE PAIN, DEFORMITY, OR DYSFUNCTION PERSISTS. • REVISION OF PREVIOUSLY FAILED HIP ARTHROPLASTY. • TOTAL HIP REPLACEMENTS MAY BE CONSIDERED FOR YOUNGER PATIENTS IF ANY UNEQUIVOCAL INDICATION OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT AND MODIFIED DEMANDS REGARDING ACTIVITY AND HIP JOINT LOADING ARE ASSURED. THIS INCLUDES SEVERELY HANDICAPPED PATIENTS WITH MULTIPLE JOINT INVOLVEMENTS, FOR WHOM AN IMMEDIATE NEED OF HIP MOBILITY LEADS TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,HIP SYSTEM(BIOLOX DELTA TAPER LINER)-THE DEVICE IS INDICATE FOR FOLLOWING:• NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G.,

	AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS. • FAILED PREVIOUS SURGERY WHERE PAIN, DEFORMITY, OR DYSFUNCTION PERSISTS. • REVISION OF PREVIOUSLY FAILED HIP ARTHROPLASTY. • TOTAL HIP REPLACEMENTS MAY BE CONSIDERED FOR YOUNGER PATIENTS IF ANY UNEQUIVOCAL INDICATION OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT AND MODIFIED DEMANDS REGARDING ACTIVITY AND HIP JOINT LOADING ARE ASSURED. THIS INCLUDES SEVERELY HANDICAPPED PATIENTS WITH MULTIPLE JOINT INVOLVEMENTS, FOR WHOM AN IMMEDIATE NEED OF HIP MOBILITY LEADS TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,PLATES FOR TRAUMA FIXATION- TITANIUM ALLOY (STERILE)(NCB STRAIGHT NARROW SHAFT PLATE)-THE NCB STRAIGHT NARROW SHAFT PLATE IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF HUMERAL AND TIBIAL SHAFT FRACTURES AND OSTEOTOMIES, INCLUDING:• PERIPROSTHETIC FRACTURES• COMMINUTED FRACTURES• FRACTURES IN OSTEOPENIC BONE• NON-UNIONS• MALUNIONS,HIP SYSTEM(BURCH- SCHNEIDER REINFORCEMENT CAGE)-THIS DEVICE IS INDICATED:• NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS. • FAILED PREVIOUS SURGERY WHERE PAIN, DEFORMITY, OR DYSFUNCTION PERSISTS. • REVISION OF PREVIOUSLY FAILED HIP ARTHROPLASTY. • TOTAL HIP REPLACEMENTS MAY BE CONSIDERED FOR YOUNGER PATIENTS IF ANY UNEQUIVOCAL INDICATION OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT AND MODIFIED DEMANDS REGARDING ACTIVITY AND HIP JOINT LOADING ARE ASSURED. THIS INCLUDES SEVERELY HANDICAPPED PATIENTS WITH MULTIPLE JOINT INVOLVEMENTS, FOR WHOM AN IMMEDIATE NEED OF HIP MOBILITY LEADS TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,PLATES FOR TRAUMA FIXATION- TITANIUM ALLOY (STERILE)(NCB PERIPROSTHETIC FEMUR PLATES)-THE NCB PERIPROSTHETIC FEMUR POLYAXIAL LOCKING PLATE SYSTEM IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF FRACTURES AND OSTEOTOMIES OF LONG BONES, INCLUDING:• PERIPROSTHETIC FRACTURES• COMMINUTED FRACTURES• NON-UNIONS• MALUNIONS, PLATES FOR TRAUMA FIXATION- TITANIUM ALLOY (NON-STERILE) (NCB STRAIGHT NARROW SHAFT PLATE)-THE NCB STRAIGHT NARROW SHAFT PLATE IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF HUMERAL AND TIBIAL SHAFT FRACTURES AND OSTEOTOMIES, INCLUDING:• PERIPROSTHETIC

	FRACTURES• COMMINUTED FRACTURES• FRACTURES IN OSTEOPENIC BONE• NON-UNIONS• MALUNIONS,PLATES FOR TRAUMA FIXATION- TITANIUM ALLOY (NON-STERILE)(NCB PERIPROSTHETIC FEMUR PLATES)-THE NCB PERIPROSTHETIC FEMUR POLYAXIAL LOCKING PLATE SYSTEM IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF FRACTURES AND OSTEOTOMIES OF LONG BONES, INCLUDING:• PERIPROSTHETIC FRACTURES• COMMINUTED FRACTURES• NON-UNIONS• MALUNIONS, HIP SYSTEM(CLS SPOTORNO HIP STEMS)-THIS DEVICE IS INDICATED FOR:• NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS. • FAILED PREVIOUS SURGERY WHERE PAIN, DEFORMITY, OR DYSFUNCTION PERSISTS. • REVISION OF PREVIOUSLY FAILED HIP ARTHROPLASTY• TOTAL HIP REPLACEMENTS MAY BE CONSIDERED FOR YOUNGER PATIENTS IF ANY UNEQUIVOCAL INDICATION OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT AND MODIFIED DEMANDS REGARDING ACTIVITY AND HIP JOINT LOADING ARE ASSURED. THIS INCLUDES SEVERELY HANDICAPPED PATIENTS WITH MULTIPLE JOINT INVOLVEMENTS, FOR WHOM AN IMMEDIATE NEED OF HIP MOBILITY LEADS TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,CANCELLOUS SCREW - TITANIUM (NON-STERILE)(NIL)-CANCELLOUS SCREWS ARE INTENDED FOR USE WITH VARIOUS TRAUMA SYSTEMS SUCH AS TROFIX TROCHANTERIC FIXATION PLATES AND SMALL AND LARGE FRAGMENTS PLATES.,SPINAL FIXATION SYSTEM(DYNESYS@ TOP-LOADING SPINAL SYSTEM)-THE DYNESYS TOP-LOADING SPINAL SYSTEM IS INDICATED TO PROVIDE SPINAL ALIGNMENT AND DYNAMIC RE-STABILIZATION IN SKELETALLY MATURE PATIENTS UP TO 5 CONTIGUOUS LEVELS FROM L1-S1 (DYNAMIC NEUTRALIZATION™). THE SYSTEM IS INTENDED TO BE USED WITHOUT BONE GRAFT FOR THE FOLLOWING INDICATIONS- PRIMARY DISCOPATHY (SPONDYLOSIS) AND SPONDYLARTHROSIS IN COMBINATION WITH:• HYPOMOBILE DISCOPATHY; DEGENERATIVE RETROLISTHESIS (UP TO GRADE I)• HYPERMOBILE DISCOPATHY; DEGENERATIVE ANTELISTHESIS (UP TO GRADE I)• DEGENERATIVE SPONDYLOLISTHESIS (UP TO GRADE I)• MONO- OR MULTISEGMENTAL LUMBAR STENOSIS WITH OR WITHOUT DEGENERATIVE SPONDYLOLISTHESIS,SPINAL FIXATION SYSTEM (DYNESYS DYNAMIC STABILIZATION SYSTEM)-THE DYNESYS DYNAMIC STABILIZATION SYSTEM IS INDICATED TO PROVIDE SPINAL ALIGNMENT AND DYNAMIC RE-STABILIZATION IN SKELETALLY MATURE PATIENTS UP TO 5 CONTIGUOUS LEVELS FROM L1-S1 (DYNAMIC NEUTRALIZATION™). THE SYSTEM IS INTENDED TO BE

	USED WITHOUT BONE GRAFT FOR THE FOLLOWING INDICATIONS- PRIMARY DISCOPATHY (SPONDYLOSIS) AND SPONDYLARTHROSIS IN COMBINATION WITH:• HYPOMOBILE DISCOPATHY; DEGENERATIVE RETROLISTHESIS (UP TO GRADE I)• HYPERMOBILE DISCOPATHY; DEGENERATIVE ANTELISTHESIS (UP TO GRADE I)• DEGENERATIVE SPONDYLOLISTHESIS (UP TO GRADE I)• MONO- OR MULTISEGMENTAL LUMBAR STENOSIS WITH OR WITHOUT DEGENERATIVE SPONDYLOLISTHESIS,STEINMANN PINS - STAINLESS STEEL/ TITANIUM (NON- STERILE)(NIL)-STEINMANN PINS ARE INTENDED FOR TEMPORARY INTERNAL FIXATION OF FRACTURES AND OSTEOTOMIES OF VARIOUS LONG BONES, WHICH INCLUDE BUT NOT LIMITED TO THE HUMERUS, THE RADIS, THE FEMUR AND THE TIBIA. THE STEINMANN PINS ARE USED TO BRIDGE THE FRACTURE GAP BY FIXING THE FRACTURED PARTS TOGETHER UNTIL THE BONE HEALING OCCURS.,CABLE BUTTON FOR PLATES FOR TRAUMA FIXATION – TITANIUM ALLOY(NCB CABLE BUTTON FOR NCB POLYAXIAL LOCKING PLATE)-THE CABLE BUTTON IS INTENDED FOR USE IN COMBINATION WITH THE ZIMMER LOCKING BONE PLATING SYSTEMS AND CERCLAGE CABLES, TO STABILIZE MULTIPLE FRACTURES OR BUTTERFLY FRAGMENTS IN LONG BONES.,PLATE AND SCREW FOR TRAUMA FIXATION(TROFIX TROCHANTERIC FIXATION PLATING SYSTEM)-THE DEVICE IS INTENDED FOR THE FIXATION OF TROCHANTERIC FRACTURES AND OSTEOTOMIES.,NAIL AND SCREWS FOR TRAUMA FIXATION(SIRUS INTRAMEDULLARY NAIL SYSTEM)-THE SIRUS INTRAMEDULLARY NAIL SYSTEM IS INTENDED FOR TEMPORARY INTERNAL FIXATION OF FRACTURES OF THE FEMUR AND THE TIBIA UNTIL BONE CONSOLIDATION HAS BEEN ACHIEVED. THEY ARE SINGLE USE ONLY,HIP SYSTEM(MEDULLARY PLUG)-THE DEVICE IS INDICATED FOR : • ADVANCED WEAR OF THE JOINT DUE TO DEGENERATIVE, POST-TRAUMATIC OR RHEUMATIC DISEASES.• FRACTURES OR AVASCULAR NECROSIS.• STATUS FOLLOWING EARLIER OPERATIONS, SUCH AS JOINT RECONSTRUCTION (OSTEOTOMY), ARTHRODESIS, HEMIARTHROPLASTY OR TOTAL HIP PROSTHESIS (THP), TOTAL KNEE PROSTHESIS AND STATUS FOLLOWING OTHER OPERATIONS WITH PROSTHESES, E.G., ON THE SHOULDER OR ELBOW JOINTS, OR FOLLOWING SPINAL SURGERY. HIP SYSTEM(WAGNER CONE PROSTHESIS)-THE DEVICE IS INDICATED FOR:• NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS. • FAILED PREVIOUS SURGERY WHERE PAIN, DEFORMITY, OR DYSFUNCTION PERSISTS• REVISION OF PREVIOUSLY FAILED HIP ARTHROPLASTY • TOTAL HIP REPLACEMENTS MAY BE CONSIDERED FOR YOUNGER PATIENTS IF ANY UNEQUIVOCAL INDICATION OUTWEIGHS THE RISKS

	ASSOCIATED WITH THE AGE OF THE PATIENT AND MODIFIED DEMANDS REGARDING ACTIVITY AND HIP JOINT LOADING ARE ASSURED. THIS INCLUDES SEVERELY HANDICAPPED PATIENTS WITH MULTIPLE JOINT INVOLVEMENTS, FOR WHOM AN IMMEDIATE NEED OF HIP MOBILITY LEADS TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE SYSTEM (ALLEGRETTO KNEE REPLACEMENT SYSTEM)-THIS DEVICE IS INDICATED FOR: • UNICOMPARTMENTAL NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND ARTHRITIS SECONDARY TO A VARIETY OF DISEASES, AND ANOMALIES. • FAILED PREVIOUS SURGERY WHERE PAIN, DEFORMITY, OR DYSFUNCTION PERSISTS. • PASSIVELY CORRECTABLE VALGUS-VARUS DEFORMITY AND MODERATE FLEXION CONTRACTURE. • THESE DEVICES ARE INDICATED FOR CEMENTED USE ONLY.,PLATING FOR TRAUMA FIXATION(NCB POLYAXIAL LOCKING PLATE SYSTEM)-THE NCB POLYAXIAL LOCKING PLATE SYSTEM IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF FRACTURES AND OSTEOTOMIES OF LONG BONES.,SHOULDER SYSTEM(ANATOMICAL SHOULDER SYSTEM)-THIS DEVICE IS INDICATED FOR REVERSE APPLICATION:• ADVANCED WEAR AND TEAR OF THE SHOULDER JOINT RESULTING FROM DEGENERATIVE, POSTTRAUMATIC OR RHEUMATOID ARTHRITIS.• FRACTURES OR AVASCULAR NECROSIS.• CONDITIONS CONSEQUENT TO EARLIER OPERATIONS.• OMARTHROSIS.• RHEUMATOID ARTHRITIS.• REVISION OF SHOULDER PROSTHESIS.• TRAUMATOLOGY: THE ONLY CONE TO BE USED IN TRAUMATOLOGICAL INDICATIONS IS THE FRACTURE CONE., CORTICAL SCREW - TITANIUM (NON-STERILE)(NIL)-CORTICAL SCREW IS INTENDED FOR USE WITH VARIOUS TRAUMA SYSTEMS SUCH AS MINI, SMALL, LARGE FRAGMENTS SYSTEMS, TROFIX TROCHANTERIC FIXATION PLATES.,PLATING FOR TRAUMA FIXATION(NCB POLYAXIAL LOCKING PLATE SYSTEM)-THE NCB POLYAXIAL LOCKING PLATE SYSTEM IS INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF FRACTURES AND OSTEOTOMIES OF LONG BONES., HIP SYSTEM(WAGNER SL REVISION STEM)-THE DEVICE IS INDICATED FOR:• NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS. • FAILED PREVIOUS SURGERY WHERE PAIN, DEFORMITY, OR DYSFUNCTION PERSISTS. • REVISION OF PREVIOUSLY FAILED HIP ARTHROPLASTY. • TOTAL HIP REPLACEMENTS MAY BE CONSIDERED FOR YOUNGER PATIENTS IF ANY UNEQUIVOCAL INDICATION OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT AND MODIFIED DEMANDS REGARDING ACTIVITY AND HIP JOINT LOADING ARE

	ASSURED. THIS INCLUDES SEVERELY HANDICAPPED PATIENTS WITH MULTIPLE JOINT INVOLVEMENTS, FOR WHOM AN IMMEDIATE NEED OF HIP MOBILITY LEADS TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,SHOULDER SYSTEM (ANATOMICAL SHOULDER BIGLIANI/ FLATOW ADAPTOR)-ADVANCED DESTRUCTION OF THE SHOULDER JOINT RESULTING FROM:• OMARTHROSIS.• RHEUMATOID ARTHRITIS• POST-TRAUMATIC ARTHRITIS• AVASCULAR NECROSIS OF THE HUMERAL HEAD• CUFF-TEAR ARTHROPATHY (BIGLIANI/FLATOW HEADS WITH HEIGHTS OF 27MM OR GREATER)• CONDITIONS FOLLOWING EARLIER OPERATIONS (INCLUDING REVISION SHOULDER ARTHROPLASTY)., SHOULDER SYSTEM(ANATOMICAL SHOULDER INVERSE/ REVERSE SYSTEM)-THIS DEVICE IS INDICATED FOR HEMIARTHROPLASTY/ TOTAL APPLICATION: • THE ANATOMICAL SHOULDER INVERSE/REVERSE SYSTEM IS INDICATED FOR PRIMARY, FRACTURE OR REVISION TOTAL SHOULDER REPLACEMENT FOR THE RELIEF OF PAIN AND SIGNIFICANT DISABILITY DUE TO GROSS ROTATOR CUFF DEFICIENCY.• THE PATIENT'S JOINT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE SELECTED IMPLANTS AND A FUNCTIONAL DELTOID MUSCLE IS NECESSARY TO USE THE DEVICE., HIP SYSTEM(BIPOLAR SHELL AND INSERT)-THIS DEVICE IS INDICATED FOR:• ADVANCED WEAR OF THE JOINT DUE TO DEGENERATIVE, POST-TRAUMATIC OR RHEUMATIC DISEASES. • FRACTURES OR AVASCULAR NECROSIS. • STATUS FOLLOWING EARLIER OPERATIONS, SUCH AS JOINT RECONSTRUCTION (OSTEOTOMY), ARTHRODESIS, HEMIARTHROPLASTY OR TOTAL HIP PROSTHESIS (THP), TOTAL KNEE PROSTHESIS AND STATUS FOLLOWING OTHER OPERATIONS WITH PROSTHESES, E.G., ON THE SHOULDER OR ELBOW JOINTS, OR FOLLOWING SPINAL SURGERY. SCREWS FOR TRAUMA FIXATION (NON-STERILE)(COUNTERSUNK CANCELLOUS BONE SCREWS)-THE COUNTERSUNK CANCELLOUS BONE SCREWS ARE INTENDED TO ENABLE ADEQUATE FIXATION AT SPECIFIED ACETABULAR IMPLANTS IN THE COURSE OF TOTAL HIP ARTHROPLASTY, THEREBY HELPING TO REDUCE PAIN AND INCREASE HIP MOBILITY THROUGH CEMENTLESS FIXATION IN THE ACETABULUM AND ILIUM OF PATIENTS WITH ADEQUATE BONE STOCK TO SUPPORT THE COMPONENT.,HIP SYSTEM (REINFORCEMENT RING WITH HOOK)-THE FORM OF THE RING AND ITS ANCHORING WITH CANCELLOUS BONE SCREWS ENABLES A COMPREHENSIVE SCOPE OF INDICATIONS: • ACETABULAR DYSPLASIA,• OSTEOPOROSIS,• PROTRUSIO ACETABULI• CYSTIC ACETABULAR ROOF • RECONSTRUCTION OF DEFECTS AFTER TRAUMA• ACETABULAR LOOSENING AND TUMOURS• AUTO-GENEOUS AND ALLO-GENEOUS BONE TRANSPLANTS CAN BE FIRMLY

	ANCHORED WITH THE RING.,SHOULDER SYSTEM(ANATOMICAL SHOULDER FRACTURE SYSTEM)-THE ANATOMICAL SHOULDER FRACTURE SYSTEM IS INTENDED FOR USE IN PROSTHETIC REPLACEMENT OF THE PROXIMAL HUMERUS AND THE GLENOID ARTICULAR SURFACE OF THE SCAPULA DURING TOTAL-, HEMI AND FRACTURE SHOULDER ARTHROPLASTY IN TREATMENT OF THE FOLLOWING:• COMPLEX 3- AND 4-PART FRACTURES OF THE PROXIMAL HUMERUS WITH SUBLUXATION OF THE HEAD FRAGMENT.• COMPLEX 3- AND 4-PART FRACTURES OF THE PROXIMAL HUMERUS WITH LOOSENING OF THE SPONGIOSA IN THE HEAD FRAGMENT• COMPLEX 3- AND 4-PART FRACTURES OF THE PROXIMAL HUMERUS WITH ADDITIONAL CROSS SPLIT OF THE HEAD FRAGMENT• FRACTURE INSTABILITY AFTER OSTEOSYNTHESIS OF 3- AND 4-PART FRACTURE FRAGMENTS OF THE PROXIMAL HUMERUS• POSTTRAUMATIC NECROSIS OF THE HUMERAL HEAD• POSTTRAUMATIC ARTHROSIS AFTER HUMERAL HEAD FRACTURE

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1570	IMP/MD/2019/000110	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED ,NO. 17, GROUND FLOOR AND MEZZANINE FLOOR, THIRUNEERMALAI ROAD, NAGALKENI, CHROMPET ,CHENNAI TAMIL NADU ,600044 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIP SCREW AND BLADE & PLATE- STAINLESS STEEL (NON- STERILE)(DYNAMIC-BLADE PLATE)-THE DYNAMIC HIP SCREW AND BLADE PLATE SYSTEM ARE INTENDED FOR TEMPORARY FIXATION OF FRACTURE OR OSTEOTOMIES IN THE PROXIMAL OR DISTAL FEMUR.,HIP SCREW AND BLADE & PLATE-STAINLESS STEEL (NON- STERILE)(DYNAMIC-SCREW PLATE)-THE DYNAMIC HIP SCREW AND BLADE PLATE SYSTEM ARE INTENDED FOR TEMPORARY FIXATION OF FRACTURE OR OSTEOTOMIES IN THE PROXIMAL OR DISTAL FEMUR.,CANNULATED SCREW - TITANIUM (NON-STERILE)(CANNULATED SCREW)-CANNULATED SCREW IS INTENDED FOR FRACTURE FIXATION, ARTHRODESES AND OSTEOTOMIES OF SMALL AND LARGE BONES, AS WELL AS SMALL AND LARGE BONE FRAGMENTS AND PELVIS.,KRISCHNER WIRE - STAINLESS STEEL/TITANIUM (NON STERILE)(KRISCHNER WIRE)-KRISCHNER WIRE ARE INTENDED FOR TEMPORARY INTERNAL FIXATION OF FRACTURES AND OSTEOTOMIES OF VARIOUS LONG BONES, WHICH INCLUDE BUT NOT LIMITED TO THE HUMERUS, THE RADIUS, THE FEMUR AND THE TIBIA. KRISCHNER WIRE ARE INDICATED FOR TEMPORARY INTERNAL FIXATION OF FRACTURES OF VARIOUS BONES, SUCH AS BUT NOT LIMITED TO THE OLECRANON AND THE PATELLA.,CERCLAGE WIRE (NON-STERILE)(CERCLAGE WIRE)-CERCLAGE WIRES ARE INDICATED FOR TEMPORARY INTERNAL FIXATION OF FRACTURES OF VARIOUS BONES, SUCH AS THE OLECRANON, THE PATELLA ETC.,HIP SCREW AND BLADE & PLATE-STAINLESS STEEL (NON- STERILE)(DYNAMIC-SCREWS)-THE DYNAMIC HIP SCREW AND BLADE PLATE SYSTEM ARE INTENDED FOR TEMPORARY FIXATION OF FRACTURE OR OSTEOTOMIES IN THE PROXIMAL OR DISTAL FEMUR.

1571	IMP/MD/2019/000111	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRAVENOUS ADMINISTRATION SETS(INTRAFIX® SAFESET - IV ADMINISTRATION SETS WITH AIR VENT FOR PRESSURE AND GRAVITY INFUSIONS)-IT IS USED AS INFUSION SET FOR FLUID VOLUME MAINTENANCE, REPLACEMENT AND DELIVERY OF CHEMOTHERAPEUTIC AGENTS, NUTRITIONAL SUPPLEMENTS, ANTIBIOTICS, ETC.,CATHETER SETS (PERIFIX ONE/ PERIFIX ONE PAED)-IT IS USED AS AN ASSET FOR CONTINUOUS EPIDURAL ANESTHESIA,CENTRAL VENOUS CATHETER (CERTOFIX MONO/CERTOFIX DUO/CERTOFIX TRIO/CERTOFIX MONO PAED/CERTOFIX DUO PAED/CERTOFIX TRIO PAED/ CERTOFIX DUO HF/CERTOFIX TRIO HF/CERTOFIX QUINTO/CERTOFIX QUATTRO/CERTOFIX PROTECT MONO/CERTOFIX PROTECT DUO/CERTOFIX PROTECT TRIO/CERTOFIX PROTECT QUINTO/CERTOFIX PROTECT QUATTRO/CERTOFIX PROTECT DUO HF/CERTOFIX PROTECT TRIO HF)-IT IS USED IN CATHETERIZATION FOR SUPERIOR VENA CAVA USING THE SELDINGER TECHNIQUE FOR LONG TERM INFUSION THERAPY OR PARENTERAL NUTRITION FOR ADMINISTRATION OF HIGHLY OSMOLAR OR VERY VEIN IRRITATING SOLUTION FOR CONTINUOUS OR INTERMITTENT MONITORING OF THE CENTRAL VENOUS PRESSURE, FOR BLOOD SAMPLING, OR WHEN PERIPHERAL VENOUS PUNCTURE IS NOT POSSIBLE IN STATE OF SHOCK, IN PATIENTS WITH INJURED EXTREMITIES OR NO DETECTABLE PERIPHERAL VEINS,CENTRAL VENOUS CATHETER (CAVAFIX® DUO / CAVAFIX® CERTODYN® / CAVAFIX® MT)-IT IS USED IN CATHERIZATION OF VENA CAVA FOR SHORT TERM INFUSION THERAPY OR PARENTERAL NUTRITION FOR ADMINISTRATION OF HIGHLY OSMOLAR OR VERY VEIN IRRITATING SOLUTION, CONTINUOUS PLEXUS SET(CONTIPLEX S ULTRA 360/ CONTIPLEX TUOHY ULTRA 360)-CONTINUOUS PERIPHERAL NERVE BLOCK CATHETER SET WITH ULTRASOUND-VISIBLE STIMULATION NEEDLES, CENTRAL VENOUS CATHETER(CAVAFIX® CERTO® / CAVAFIX® CERTO® WITH SPLITTOCAN®)-IT IS USED IN CATHERIZATION OF VENA CAVA FOR SHORT TERM INFUSION THERAPY OR PARENTERAL NUTRITION FOR ADMINISTRATION OF HIGHLY OSMOLAR OR VERY VEIN IRRITATING SOLUTION,WITHDRAWAL AND INJECTION SPIKES FOR MULTIDOSE VIALS(MINI-SPIKE V)-WITHDRAWAL AND INJECTION SPIKES FOR MULTIDOSE VIALS,TRANSFER SET FOR STERILE FLUIDS (TRANSOFIX)-TRANSFER SET FOR STERILE FLUIDS

1572	IMP/MD/2019/000112	1.License Holder Name: CARL ZEISS INDIA (BANGALORE) PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SILICONE OIL(PURIFIED SILICONE OIL)-THE PURIFIED SILICONE OIL IS INDICATED IN PROLONGED TAMPONADE AFTER SURGICAL TREATMENT FOR SEVERE RETINAL DETACHMENT, ESPECIALLY: - RETINAL DETACHMENT WITH PROLIFERATIVE VITREORETINOPATHY, - RETINAL DETACHMENT THAT COMPLICATE A DIABETIC RETINOPATHY - RETINAL DETACHMENT WITH GIANT TEARS, - TRAUMATIC RETINAL DETACHMENT, - SECONDARY RETINAL DETACHMENT TO A VIRAL RETINITIS

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1573	IMP/MD/2019/000113	1.License Holder Name: CARDINAL HEALTH MEDICAL PRODUCTS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) BALLOON DILATATION CATHETER(AVIATOR™ PLUS)-THE CORDIS AVIATOR™ PLUS PTA BALLOON DILATATION CATHETER IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY IN THE PERIPHERAL VASCULATURE, INCLUDING ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA POPLITEAL, RENAL, AND CAROTID ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR POST-DILATATION OF BALLOON-EXPANDABLE AND SELF-EXPANDING STENTS IN THE PERIPHERAL VASCULATURE., PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) DILATATION CATHETER(SABER)-THE SABER PTA CATHETER IS INTENDED TO DILATE STENOSES IN ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA POPLITEAL AND RENAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THE DEVICE IS ALSO INDICATED FOR POST-DILATION OF BALLOON-EXPANDABLE AND SELF-EXPANDING STENTS IN THE PERIPHERAL VASCULATURE. , PERIPHERAL STENT SYSTEM (SLALOM)(PALMAZ® BLUE .018)-THE CORDIS PALMAZ® BLUE™ .018 PERIPHERAL STENT SYSTEM (SLALOM) IS INTENDED FOR USE IN THE TREATMENT OF ATHEROSCLEROTIC DISEASE OF PERIPHERAL ARTERIES BELOW THE AORTIC ARCH AND FOR PALLIATION OF MALIGNANT NEOPLASMS IN THE BILIARY TREE.,LARGE DIAMETER BALLOON PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) DILATATION CATHETER(MAXI LD)-THE MAXI LD LARGE DIAMETER BALLOON PTA CATHETER IS INTENDED TO DILATE STENOSES IN PERIPHERAL ARTERIES., PERIPHERAL STENT ON OPTA® PRO .035" DELIVERY SYSTEM (PALMAZ GENESIS®)-THE CORDIS PALMAZ GENESIS® PERIPHERAL STENT ON OPTA® PRO .035" DELIVERY SYSTEM IS INTENDED FOR USE IN THE TREATMENT OF ATHEROSCLEROTIC DISEASE OF PERIPHERAL ARTERIES BELOW THE AORTIC ARCH AND FOR PALLIATION OF MALIGNANT NEOPLASMS IN THE BILIARY TREE., PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) DILATATION CATHETER(SABERX)-THE SABERX PTA CATHETER IS INTENDED TO DILATE STENOSES IN ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA POPLITEAL AND RENAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THE DEVICE IS ALSO INDICATED FOR POST-DILATION OF BALLOON-EXPANDABLE AND

	SELF-EXPANDING STENTS IN THE PERIPHERAL VASCULATURE.

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1574	IMP/MD/2019/000114	1.License Holder Name: M/S MERIT MEDICAL SYSTEMS INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RADIAL COMPRESSION DEVICE(PRELUDESYNC / PRELUDESYNC DISTAL)-USED TO ASSIST IN GAINING HEMOSTASIS OF ARTERIAL PERCUTANEOUS ACCESS SITES., CUSTOMIZED KITS - 1(MERIT CUSTOMS KIT - 1 (INCLUDES EIGHT DEVICES - I. HEMOSTASIS VALVES AND ACCESSORIES II. MANIFOLDS III. STOPCOCKS IV. SYRINGES, V. NEEDLES, VI. INFLATION DEVICES VII. TUBING - HIGH PRESSURE TUBING & PRESSURE MONITORING TUBING, VIII. SCALPELS))-THE CUSTOMIZED KIT CONFIGURATION CONSISTS OF BUNDLING INDIVIDUALLY STERILIZED, POUCHED AND LABELED STANDALONE DEVICES. HEMOSTASIS VALVES - THE MERIT HEMOSTASIS VALVES ARE INTENDED FOR MAINTAINING HEMOSTASIS / FLUID TIGHT SEAL DURING THE INTRODUCTION, USE AND WITHDRAWAL OF INTERVENTIONAL AND DIAGNOSTIC DEVICES DURING USE. MANIFOLD - MERIT MANIFOLDS ARE INDICATED FOR USE IN DIAGNOSTIC AND INTERVENTIONAL APPLICATIONS TO CONTROL OR DIRECT FLUID FLOW BETWEEN TUBING, CATHETERS, OR OTHER DEVICES. STOPCOCK – ARE INDICATED FOR USE IN CARDIOVASCULAR, RADIOLOGIC, SURGICAL, AND THERAPEUTIC APPLICATIONS TO CONTROL OR DIRECT FLUID FLOW BETWEEN TUBING, CATHETERS OR OTHER DEVICES. SYRINGES - THE MERIT SYRINGE IS USED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, THE BODY. THE MERIT CORONARY CONTROL SYRINGE IS INTENDED TO BE USED FOR THE INTRA-ARTERIAL OR INTRAVENOUS ADMINISTRATION OF RADIOGRAPHIC CONTRAST MEDIA. THE SYRINGE CAN ALSO BE USED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, THE BODY. NEEDLES - THE MERIT MAJESTIK SERIES ANGIOGRAPHY NEEDLES ARE DISPOSABLE NON-PYROGENIC, SINGLE USE, FOR PROVIDING A PUNCTURE SITE IN VESSELS FOR THE INTRODUCTION OF VASCULAR ACCESS DEVICES. THE MERIT ADVANCE ANGIOGRAPHIC SAFETY NEEDLE IS USED FOR PROVIDING A PUNCTURE SITE IN BLOOD VESSELS FOR THE INTRODUCTION OF VASCULAR ACCESS DEVICES. IT ALSO INCORPORATES A SAFETY MECHANISM TO MINIMIZE NEEDLESTICK INJURIES. THE MERIT ADVANCE SERIES ANGIOGRAPHIC NEEDLES ARE USED FOR PROVIDING A PUNCTURE SITE IN BLOOD VESSELS FOR THE INTRODUCTION OF VASCULAR ACCESS DEVICES. INFLATION DEVICE - INFLATION DEVICES ARE USED TO INFLATE AND DEFLATE AN ANGIOPLASTY BALLOON OR OTHER INTERVENTIONAL DEVICE, AND TO MEASURE THE PRESSURE WITHIN THE BALLOON. TUBING - MERIT MEDICAL TUBING IS INTENDED TO BE USED DURING AN ANGIOGRAPHIC PROCEDURE AS A CONDUIT TO SUPPLY A BOLUS OF

	CONTRAST MEDIA WHICH IS USUALLY INJECTED MECHANICALLY TO VIEW HEART FUNCTION UNDER FLUOROSCOPY SCALPEL - A MANUAL SURGICAL INSTRUMENT FOR GENERAL USE, HAND-HELD, DISPOSABLE, INTENDED TO BE USED IN VARIOUS GENERAL SURGICAL PROCEDURES.,INFLATION DEVICES AND KITS(BASIX TOUCH, BASIX COMPAK (INFLATION DEVICES EITHER WITH STOPCOCKS / HEMOSTASIS VALVES OR WITH BOTH))-INFLATION DEVICE - INFLATION DEVICES ARE USED TO INFLATE AND DEFLATE AN ANGIOPLASTY BALLOON OR OTHER INTERVENTIONAL DEVICE, AND TO MEASURE THE PRESSURE WITHIN THE BALLOON. STOPCOCK – ARE INDICATED FOR USE IN CARDIOVASCULAR, RADIOLOGIC, SURGICAL, AND THERAPEUTIC APPLICATIONS TO CONTROL OR DIRECT FLUID FLOW BETWEEN TUBING, CATHETERS OR OTHER DEVICES. HEMOSTASIS VALVES - THE MERIT HEMOSTASIS VALVES ARE INTENDED FOR MAINTAINING HEMOSTASIS / FLUID TIGHT SEAL DURING THE INTRODUCTION, USE AND WITHDRAWAL OF INTERVENTIONAL AND DIAGNOSTIC DEVICES DURING USE., CUSTOMIZED KITS - 3(MERIT CUSTOMS KIT - 3 (INCLUDES FOUR DEVICES - I. HEMOSTASIS VALVES AND ACCESSORIES II. MANIFOLDS III. STOPCOCKS, IV. INFLATION DEVICES))-THE CUSTOMIZED KIT CONFIGURATION CONSISTS OF BUNDLING INDIVIDUALLY STERILIZED, POUCHED AND LABELED STANDALONE DEVICES. HEMOSTASIS VALVES - THE MERIT HEMOSTASIS VALVES ARE INTENDED FOR MAINTAINING HEMOSTASIS / FLUID TIGHT SEAL DURING THE INTRODUCTION, USE AND WITHDRAWAL OF INTERVENTIONAL AND DIAGNOSTIC DEVICES DURING USE. MANIFOLD - MERIT MANIFOLDS ARE INDICATED FOR USE IN DIAGNOSTIC AND INTERVENTIONAL APPLICATIONS TO CONTROL OR DIRECT FLUID FLOW BETWEEN TUBING, CATHETERS, OR OTHER DEVICES. STOPCOCK – ARE INDICATED FOR USE IN CARDIOVASCULAR, RADIOLOGIC, SURGICAL, AND THERAPEUTIC APPLICATIONS TO CONTROL OR DIRECT FLUID FLOW BETWEEN TUBING, CATHETERS OR OTHER DEVICES. INFLATION DEVICE - INFLATION DEVICES ARE USED TO INFLATE AND DEFLATE AN ANGIOPLASTY BALLOON OR OTHER INTERVENTIONAL DEVICE, AND TO MEASURE THE PRESSURE WITHIN THE BALLOON.,CUSTOMIZED KITS - 2(MERIT CUSTOMS KIT - 2 (INCLUDES SEVEN DEVICES - I. HEMOSTASIS VALVES AND ACCESSORIES II. MANIFOLDS III. STOPCOCKS IV. SYRINGES, V. NEEDLES, VI. INFLATION DEVICES VII. SCALPELS)-THE CUSTOMIZED KIT CONFIGURATION CONSISTS OF BUNDLING INDIVIDUALLY STERILIZED, POUCHED AND LABELED STANDALONE DEVICES. HEMOSTASIS VALVES - THE MERIT HEMOSTASIS VALVES ARE INTENDED FOR MAINTAINING HEMOSTASIS / FLUID TIGHT SEAL DURING THE INTRODUCTION, USE

	AND WITHDRAWAL OF INTERVENTIONAL AND DIAGNOSTIC DEVICES DURING USE. MANIFOLD - MERIT MANIFOLDS ARE INDICATED FOR USE IN DIAGNOSTIC AND INTERVENTIONAL APPLICATIONS TO CONTROL OR DIRECT FLUID FLOW BETWEEN TUBING, CATHETERS, OR OTHER DEVICES. STOPCOCK – ARE INDICATED FOR USE IN CARDIOVASCULAR, RADIOLOGIC, SURGICAL, AND THERAPEUTIC APPLICATIONS TO CONTROL OR DIRECT FLUID FLOW BETWEEN TUBING, CATHETERS OR OTHER DEVICES. SYRINGES - THE MERIT SYRINGE IS USED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, THE BODY. THE MERIT CORONARY CONTROL SYRINGE IS INTENDED TO BE USED FOR THE INTRA-ARTERIAL OR INTRAVENOUS ADMINISTRATION OF RADIOGRAPHIC CONTRAST MEDIA. THE SYRINGE CAN ALSO BE USED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, THE BODY. NEEDLES - THE MERIT MAJESTIK SERIES ANGIOGRAPHY NEEDLES ARE DISPOSABLE NON-PYROGENIC, SINGLE USE, FOR PROVIDING A PUNCTURE SITE IN VESSELS FOR THE INTRODUCTION OF VASCULAR ACCESS DEVICES. THE MERIT ADVANCE ANGIOGRAPHIC SAFETY NEEDLE IS USED FOR PROVIDING A PUNCTURE SITE IN BLOOD VESSELS FOR THE INTRODUCTION OF VASCULAR ACCESS DEVICES. IT ALSO INCORPORATES A SAFETY MECHANISM TO MINIMIZE NEEDLESTICK INJURIES. THE MERIT ADVANCE SERIES ANGIOGRAPHIC NEEDLES ARE USED FOR PROVIDING A PUNCTURE SITE IN BLOOD VESSELS FOR THE INTRODUCTION OF VASCULAR ACCESS DEVICES. INFLATION DEVICE - INFLATION DEVICES ARE USED TO INFLATE AND DEFLATE AN ANGIOPLASTY BALLOON OR OTHER INTERVENTIONAL DEVICE, AND TO MEASURE THE PRESSURE WITHIN THE BALLOON. SCALPEL - A MANUAL SURGICAL INSTRUMENT FOR GENERAL USE, HAND-HELD, DISPOSABLE, INTENDED TO BE USED IN VARIOUS GENERAL SURGICAL PROCEDURES.,NEEDLES(MERIT ADVANCE NEEDLE, MERIT ADVANCE ANGIOGRAPHIC SAFETY NEEDLE AND MERIT MAJESTIK NEEDLE)-THE MERIT MAJESTIK SERIES ANGIOGRAPHY NEEDLES ARE DISPOSABLE NON-PYROGENIC, SINGLE USE, FOR PROVIDING A PUNCTURE SITE IN VESSELS FOR THE INTRODUCTION OF VASCULAR ACCESS DEVICES. THE MERIT ADVANCE ANGIOGRAPHIC SAFETY NEEDLE IS USED FOR PROVIDING A PUNCTURE SITE IN BLOOD VESSELS FOR THE INTRODUCTION OF VASCULAR ACCESS DEVICES. IT ALSO INCORPORATES A SAFETY MECHANISM TO MINIMIZE NEEDLESTICK INJURIES. THE MERIT ADVANCE SERIES ANGIOGRAPHIC NEEDLES ARE USED FOR PROVIDING A PUNCTURE SITE IN BLOOD VESSELS FOR THE INTRODUCTION OF VASCULAR ACCESS DEVICES. ,MICROCATHETER(MERIT MAESTRO MICROCATHETER)-THE MICROCATHETER IS INTENDED FOR GENERAL INTRAVASCULAR USE, INCLUDING PERIPHERAL AND CORONARY

	VASCULATURE. ONCE THE SUBSELECTIVE REGION HAS BEEN ACCESSED, THE MICROCATHETER CAN BE USED FOR THE CONTROLLED AND SELECTIVE INFUSION OF DIAGNOSTIC, EMBOLIC, OR THERAPEUTIC MATERIALS INTO VESSELS. THE CATHETER SHOULD NOT BE USED IN THE CEREBRAL VESSELS.,SYRINGES (VACLOK SYRINGES)-THE VACLOK SYRINGE IS INTENDED TO BE USED BY A CARDIOLOGIST OR RADIOLOGIST DURING ANGIOGRAPHIC OR RADIOLOGIC PROCEDURES.,SYRINGES(MEDALLION SYRINGE AND CORONARY CONTROL SYRINGES)-THE MERIT SYRINGE IS USED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, THE BODY. THE MERIT CORONARY CONTROL SYRINGE IS INTENDED TO BE USED FOR THE INTRA-ARTERIAL OR INTRAVENOUS ADMINISTRATION OF RADIOGRAPHIC CONTRAST MEDIA. THE SYRINGE CAN ALSO BE USED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, THE BODY. , ASPIRATION CATHETERS(ASAP ASPIRATION CATHETER KIT AND ASAPLP LOW PROFILE ASPIRATION CATHETER KIT)-THE MERIT ASAP AND ASAPLP ASPIRATION CATHETERS ARE INTENDED FOR THE REMOVAL OF FRESH, SOFT EMBOLI AND THROMBI FROM VESSELS OF THE ARTERIAL SYSTEM. ,MANIFOLDS(MERIT MANIFOLDS AND MERIT MANIFOLD-DEVOS)-MERIT MANIFOLDS ARE INDICATED FOR USE IN DIAGNOSTIC AND INTERVENTIONAL APPLICATIONS TO CONTROL OR DIRECT FLUID FLOW BETWEEN TUBING, CATHETERS, OR OTHER DEVICES. ,SHEATH INTRODUCER(PRELUDE SHEATH INTRODUCER CONSISTING OF PRODUCT FAMILIES: 1. PRELUDE SHEATH INTRODUCER 2. PRELUDE SHORT SHEATH INTRODUCER 3. PRELUDE EASE HYDROPHILIC SHEATH INTRODUCER 4. PRELUDE IDEAL HYDROPHILIC SHEATH INTRODUCER)-MERIT PRELUDE SHEATH INTRODUCER IS INTENDED TO PROVIDE ACCESS AND FACILITATE THE PERCUTANEOUS INTRODUCTION OF VARIOUS DEVICES INTO VEINS AND/OR ARTERIES WHILE MAINTAINING HEMOSTASIS FOR A VARIETY OF DIAGNOSTIC AND THERAPEUTIC PROCEDURES. THE MERIT PRELUDE SHORT SHEATH INTRODUCER IS INTENDED TO PROVIDE ACCESS AND FACILITATE THE PERCUTANEOUS INTRODUCTION OF VARIOUS DEVICES INTO VEINS AND/OR ARTERIES WHILE MAINTAINING HEMOSTASIS FOR A VARIETY OF DIAGNOSTIC AND THERAPEUTIC PROCEDURES. THIS DEVICE CAN ALSO PROVIDE ACCESS TO A NATIVE OR SYNTHETIC GRAFT USED FOR HEMODIALYSIS. THE SIDE PORT OF THE SHEATH ALLOWS ADEQUATE FLOW TO PERFORM TEMPORARY HEMODIALYSIS. THIS DEVICE IS NOT INDICATED FOR LONG TERM VASCULAR OR HEMODIALYSIS ACCESS. THE MERIT PRELUDE EASE HYDROPHILIC SHEATH INTRODUCER IS INTENDED TO PROVIDE ACCESS AND FACILITATE THE PERCUTANEOUS INTRODUCTION OF VARIOUS DEVICES INTO VEINS AND/OR ARTERIES, INCLUDING BUT NOT LIMITED TO THE RADIAL

		ARTERY, WHILE MAINTAINING HEMOSTASIS FOR A VARIETY OF DIAGNOSTIC AND THERAPEUTIC PROCEDURES. THE ACCESS NEEDLE WITH INNER METAL NEEDLE AND OUTER PLASTIC CANNULA IS USED TO GAIN ACCESS TO THE VEIN OR ARTERY FOR PLACEMENT OF GUIDE WIRES. THE MERIT PRELUDE IDEAL HYDROPHILIC SHEATH INTRODUCER IS INTENDED TO PROVIDE ACCESS AND FACILITATE THE PERCUTANEOUS INTRODUCTION OF VARIOUS DEVICES INTO VEINS AND/OR ARTERIES, INCLUDING BUT NOT LIMITED TO THE RADIAL ARTERY, WHILE MAINTAINING HEMOSTASIS FOR A VARIETY OF DIAGNOSTIC AND THERAPEUTIC PROCEDURES. THE ACCESS NEEDLE WITH INNER METAL NEEDLE AND OUTER PLASTIC CANNULA IS USED TO GAIN ACCESS TO THE VEIN OR ARTERY FOR PLACEMENT OF GUIDE WIRES
1575	IMP/MD/2019/000115	1.License Holder Name: TUOREN MEDICAL DEVICE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRACHEOTOMY TUBE (TUOREN)-THROAT BLOCKING , LOWER RESPIRATORY TRACT SECRETION BLOCKING DUE TO ANY REASON, ORAL CAVITY, NASOPHARYNX, PHARYNX AND THROAT OPERATIONS, RESPIRATORY TRACT DEGRADATION DUE TO ANY REASON, MECHANICAL VENTILATION, FOREIGN MATTERS FOUND IN THE LOWER RESPIRATORY TRACT,ANESTHESIA KIT(TUOREN)-AS-E: USED IN THE CLINIC EPIDURAL BLOCK AND ANESTHESIA TO HUMAN BODY FOR PUNCTURE AND INJECTION. AS-SIT IS USED FOR PUNCTURE AND DRUG INJECTION IN SUBARACHNOID BLOCK ANESTHESIA. AS-E/S II:IT IS USED FOR PUNCTURE AND DRUG INJECTION IN COMBINED SPINAL AND EPIDURAL ANESTHESIA. AS-N: IT IS USED FOR PUNCTURE AND DRUG INJECTION IN NERVE BLOCK ANESTHESIA., DISPOSABLE CENTRAL VENOUS CATHETER KIT(TUOREN)-IT IS MAINLY USED IN INTRAVENOUS INFUSION, DETERMINATION OF VENOUS PRESSURE, PARENTERAL HYPERALIMENTATION,INFUSION PUMP(TUOREN)-IT IS CLINICALLY USED FOR INJECTING ANALGESIC AND ATIBIOTICS AFTER OPERATION.

1576	IMP/MD/2019/000115	1.License Holder Name: TUOREN MEDICAL DEVICE INDIA PRIVATE LIMITED ,A-62, BASEMENT, SUITE NO. B05, DDA SHED, OKHLA INDUSTRIAL AREA, PHASE II ,SOUTH DELHI DELHI ,110020 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LARYNGEAL MASK AIRWAY(TUOREN)-THE LARYNGEAL MASK AIRWAY IS MAINLY USED FOR OPENING AND SEALING THE UPPER LARYNX, PROVIDING A GAS PASSAGE IN THE PATIENT'S BODY DURING AUTONOMIC, AUXILIARY OR CONTROLLED VENTILATION.,ENDOTRACHEAL TUBE(TUOREN)-THE ENDOTRACHEAL TUBE IS USED FOR PATIENTS FOR ENDOTRACHEAL INTUBATION DURING GENERAL ANESTHESIA OPERATION TO ENSURE AIRWAY PATENCY, OXYGEN SUPPLY, RESPIRATORY TRACT SUCTION AND ASPIRATION.,ENDOBRONCHIAL TUBE(TUOREN)-THE ENDOBRONCHIAL TUBE IS USED TO ISOLATE THE LEFT OR THE RIGHT LUNG OF A PATIENT FOR SURGERY, ONE LUNG VENTILATION OR ONE LUNG ANESTHESIA.
1577	IMP/MD/2019/000116	1.License Holder Name: EMCURE PHARMACEUTICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE (STERILE) (BD HYPAK SCF™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS
1578	IMP/MD/2019/000117	1.License Holder Name: INTAS PHARMACEUTICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD NEOPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS,PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS
1579	IMP/MD/2019/000120	1.License Holder Name: BIOLOGICAL E. LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE (STERILE)(BD HYPAK SCF™)-COMPONENT OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS

1580	IMP/MD/2019/000121	1.License Holder Name: CADILA HEALTHCARE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PROGRESSIVE IOL(MINI)-MINI WELL PROXA INTRAOCULAR LENSES ARE INTENDED FOR PRIMARY IMPLANTATION FOR VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH OR WITHOUT PRESBYOPIA AFTER REMOVAL OF A CATARACTOUS LENS AND OF APHAKIA AFTER REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO DESIRE INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE AND NEAR VISION. THESE IMPLANTS MUST BE POSITIONED WITHIN THE CAPSULAR BAG., PROGRESSIVE IOL(MINI)-MINI WELL TORIC READY INTRAOCULAR LENS IS INTENDED FOR PRIMARY IMPLANTATION FOR VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULTS WITH OR WITHOUT PRESBYOPIA AFTER REMOVAL OF A CATARACTOUS LENS AND OF APHAKIA AFTER REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO DESIRE INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE AND NEAR VISION. THESE IMPLANTS MUST BE POSITIONED WITHIN THE CAPSULAR BAG.,PROGRESSIVE IOL(MINI)-MINI WELL READY INTRAOCULAR LENS IS INTENDED FOR PRIMARY IMPLANTATION FOR VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH OR WITHOUT PRESBYOPIA AFTER REMOVAL OF A CATARACTOUS LENS AND OF APHAKIA AFTER REFRACTIVE LENSECTOMY IN PRESBYOPIC ADULTS WHO DESIRE INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE AND NEAR VISION. THESE IMPLANTS MUST BE POSITIONED WITHIN THE CAPSULAR BAG.,INTRAOCULAR LENS(MINI)-MINI TORIC READY INTRAOCULAR LENS IS INDICATED FOR THE CORRECTION OF SURGICAL APHAKIA IN THE PRESENCE OF PRE-SURGICAL CORNEAL ASTIGMATISM AFTER REMOVAL OF THE CRYSTALLINE LENS AFFECTED BY CATARACTS IN ADULT PATIENTS WHO WANT TO IMPROVE THEIR FAR VISION WITHOUT ANY ADDITIONAL CORRECTION. THIS LENS MUST BE POSITIONED IN THE REAR CHAMBER OF THE EYE, WITHIN THE CAPSULAR SAC; ITS PLACEMENT IN THIS NATURAL SLOT MAKES IT POSSIBLE FOR IT TO FUNCTION AS A REFRACTIVE MEDIUM.,INTRAOCULAR LENS(MINI)-THE ASPHERICAL INTRAOCULAR LENSES MINI 2 READY AND MINI 4 READY ARE INDICATED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS IN ORDER TO GUARANTEE A GOOD VISUAL CORRECTION FURTHER TO EXTRACTION OF THE CRYSTALLINE LENS. THE INTENDED USE OF THESE LENSES IS THEIR POSITIONING IN THE POSTERIOR CHAMBER OF THE EYE WITHIN THE CAPSULAR BAG; THE POSITION ENABLES THE LENS TO ACT AS A REFRACTIVE MEDIUM IN THE CORRECTION OF APHAKIA.,INTRAOCULAR LENS(MINI)-MINI 2 AND MINI 4 LENSES ARE INDICATED FOR THE REPLACEMENT OF THE

		HUMAN CRYSTALLINE LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA AFTER EXTRACTION OF THE CATARACTOUS NATURAL LENS. THE INTENDED USE OF THESE LENSES IS FOR PLACEMENT IN THE POSTERIOR CHAMBER OF THE EYE WITHIN THE CAPSULAR BAG; THIS POSITION ENABLES THE LENS TO ACT AS A REFRACTIVE MEANS TO CORRECT APHAKIA.
1581	IMP/MD/2019/000124	1.License Holder Name: INTAS PHARMACEUTICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS
1582	IMP/MD/2019/000125	1.License Holder Name: SYNERGYPHARMA FORMULATIONS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FIT(FIT)-FOR RELIEVING SITUATIONS OF MUSCULAR-SKELETAL DISCOMFORT BY THE EXCESSIVE BUILDUP OF TISSUE FROM OVERLOADING THE MUSCULAR FIBERS THROUGH QUICKER DISPOSAL OF LACTIC ACID. -IN FUNCTIONAL RECOVERY PROCESS OF THE MUSCLE TISSUE AFFECTED BY CONTRACTION, DUE TO OVERLOAD, ANTALGIC CONTRACTION AND STRENGTH DEFICIT FROM OVER-STRESS SYNDROME. AS THEY PROMOTE RELIEF OF THE PAINFUL SYMPTOMS AND BRING ABOUT A MYO-RELAXING ACTION ON THE MUSCLE AREA IN QUESTION.
1583	IMP/MD/2019/000126	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GENERAL/MULTIPLE SURGICAL LASER SYSTEM BEAM GUIDE, SINGLE-USE(FLEXIVA HIGH POWER SINGLE-USE LASER FIBERS)-THE FLEXIVA LASER FIBER IS DESIGNED FOR USE WITH HO:YAG AND ND:YAG LASERS FOR INDICATIONS THAT ARE CLEARED FOR THESE LASER SYSTEMS, INCLUDING, BUT NOT LIMITED TO ENDOSCOPIC, LAPAROSCOPIC, AND OPEN SURGICAL PROCEDURES INVOLVING VAPORIZATION, ABLATION, COAGULATION, HEMOSTASIS, EXCISION, RESECTION, INCISION OF SOFT AND CARTILAGINOUS TISSUE, AND FRAGMENTATION OF URINARY AND BILIARY CALCULI (HO:YAG WAVELENGTH ONLY). THE FIBER IS DESIGNED FOR USE WITH A STANDARD SMA-905 CONNECTOR THAT HAVE BEEN CLEARED FOR SURGICAL USE.

1584	IMP/MD/2019/000128	1.License Holder Name: BOSTON IVY HEALTHCARE SOLUTIONS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FEMALE INCONTINENCE SLING(I-STOP)-PUBO URETHERAL SLING FOR THE TREATMENT OF FEMALE URINARY INCONTINENCE
1585	IMP/MD/2019/000129	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CARDIAC OCCLUDERS (AMPLATZER AMULET LEFT ATRIAL APPENDAGE OCCLUDER)-THE AMPLATZER AMULET LEFT ATRIAL APPENDAGE OCCLUDER IS A PERCUTANEOUS TRANSCATHETER DEVICE INTENDED TO PREVENT THROMBUS EMBOLIZATION FROM THE LEFT ATRIAL APPENDAGE (LAA) IN PATIENTS WHO HAVE NONVALVULAR ATRIAL FIBRILLATION.,CARDIAC OCCLUDERS(AMPLATZER SEPTAL OCCLUDER)-THE AMPLATZER SEPTAL OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER ATRIAL SEPTAL DEFECT CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF ATRIAL SEPTAL DEFECTS (ASDS) IN SECUNDUM POSITION OR PATIENTS WHO HAVE UNDERGONE A FENESTRATED FONTAN PROCEDURE AND WHO NOW REQUIRE CLOSURE OF THE FENESTRATION.

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1586	IMP/MD/2019/000130	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:UROGENITAL SURGICAL LASER SYSTEM BEAM GUIDE, SINGLE-USE(MOXY LIQUID COOLED LASER FIBER)-THE MOXY LASER FIBER FEATURES A SIDE FIRING MECHANISM DELIVERING UP TO 180 W OF 532 NM LIGHT TO TISSUE. THE FIBER CAN BE USED FOR THE SURGICAL INCISION/EXCISION, VAPORIZATION, ABLATION, HEMOSTASIS, AND COAGULATION OF SOFT TISSUE. ALL SOFT TISSUE IS INCLUDED, SUCH AS SKIN, CUTANEOUS TISSUE, SUBCUTANEOUS TISSUE, STRIATED AND SMOOTH TISSUE, MUSCLE, CARTILAGE, MENISCUS, MUCOUS MEMBRANE, LYMPH VESSELS AND NODES, ORGANS, AND GLANDS. THE MOXY LASER FIBER WILL DELIVER 532 NM LASER ENERGY FROM A COMPATIBLE LASER CONSOLE (GREENLIGHT XPS LASER SYSTEM) TO TISSUE DURING SURGICAL PROCEDURES, INCLUDING PHOTO-SELECTIVE VAPORIZATION OF THE PROSTATE FOR BENIGN PROSTATIC HYPERPLASIA (BPH).,FORCEPS, ENDOSCOPIC(RADIAL JAW 4 SINGLE-USE BIOPSY FORCEPS)-THESE SINGLE-USE BIOPSY FORCEPS ARE SPECIFICALLY DESIGNED TO COLLECT TISSUE ENDOSCOPICALLY FOR HISTOLOGIC EXAMINATION. THESE FORCEPS SHOULD NOT BE USED FOR ANY PURPOSE OTHER THAN THEIR INTENDED FUNCTION.,CORONARY ANGIOPLASTY BALLOON CATHETER, BASIC(MAVERICK2 MONORAIL PTCA DILATATION CATHETER)-THE MAVERICK2 MONORAIL PTCA DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. THE MAVERICK2 MONORAIL PTCA DILATATION CATHETER (BALLOON MODELS 2.25 MM- 4.0 MM) IS ALSO INDICATED FOR THE POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS.,PERIPHERAL ANGIOPLASTY BALLOON CATHETER, BASIC (MUSTANG PTA BALLOON DILATATION CATHETER)-THE MUSTANG BALLOON DILATATION CATHETER IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE PERIPHERAL VASCULATURE, INCLUDING ILIAC, FEMORAL, POPLITEAL, TIBIAL, PERONEAL, SUBCLAVIAN, AND RENAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THE MUSTANG BALLOON DILATATION CATHETER IS ALSO INDICATED FOR POST-DILATATION OF BALLOON EXPANDABLE AND SELF-EXPANDING STENTS IN THE PERIPHERAL VASCULATURE. MUSTANG BALLOON DILATATION CATHETERS WITH BALLOONS UP TO 120 MM IN LENGTH ARE INDICATED FOR THE TREATMENT OF BILIARY STRICTURES.

1587	IMP/MD/2019/000131	1.License Holder Name: SMITHS MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRACHEOSTOMY TUBES (PORTEX BLUE LINE ULTRA PEDIATRIC TRACHEOSTOMY TUBE)-BLUE LINE ULTRA® PAEDIATRIC TRACHEOSTOMY TUBE IS INTENDED FOR PAEDIATRIC PATIENTS THAT REQUIRE AN ARTIFICIAL AIRWAY DUE TO TRAUMA OR MEDICAL CONDITION AND IS USED IN PATIENTS THAT ARE EITHER SPONTANEOUSLY BREATHING OR REQUIRE MECHANICAL VENTILATION; ALLOWING ACCESS TO THE TRACHEA FOR SUCTIONING. MAXIMUM RECOMMENDED PERIOD OF USE IS 29 DAYS. THIS DEVICE IS INTENDED FOR USE IN THE PAEDIATRIC PATIENT POPULATION BORN AT GESTATIONAL AGE GREATER THAN 37 WEEKS AND NOT IN THE NEONATAL DEVELOPMENTAL STAGE. THIS DEVICE IS NOT INTENDED FOR PRETERM AND NEONATAL POPULATION. THE NEONATAL DEVELOPMENTAL STAGE IS THE 28 DAYS FOLLOWING BIRTH.
1588	IMP/MD/2019/000132	1.License Holder Name: TERUMO PENPOL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD ADMINISTRATION SET(TERUFUSION)-THIS IS USED FOR INTRAVENOUS DRIP INJECTION OF A LARGE VOLUME OF FLUID INFUSION AND BLOOD PRODUCTS, ETC., WITHOUT USING AN INJECTION SYRINGE.

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1589	IMP/MD/2019/000133	1.License Holder Name: ROMSONS SCIENTIFIC & SURGICAL INDUSTRIES PVT LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EPIDURAL NEEDLE STERILE AND NON STERILE BULK(NIL)-THE EPIDURAL NEEDLES IS APPLIED TO PUNCTURE THE HUMAN BODY EPIDURAL, ANESTHESIA CATHETER INSERTION, INJECTION OF DRUGS. THE PATIENT IS ASKED TO SLOUCH AND BEND FORWARD SLIGHTLY FROM THE WAIST TO INCREASE THE CURVATURE OF THE SPINE, A EPIDURAL NEEDLE IS INSERTED INTO A SUITABLE ANATOMICAL GAP (DEPENDING ON THE AREA THAT SHALL BE ANESTHETIZED), ADVANCES SLOWLY, WITH THE NEEDLE SLOPE PARALLELED TO THE LONGITUDINAL AXIS OF BODY AT THE FIRST 2~3CM PATH, WHEN THE NEEDLE REACHES THE LIGAMENTUM FLAVUM, ROTATE IT BY 90 DEGREE, AND THEN ADVANCE IT WITH THE NEEDLE ASLOPE VERTICAL TO THE LONGITUDINAL AXIS OF BODY UNTIL A SENSATION OF "LOSS OF RESISTANCE" IS FELT, WHICH MEANS THAT THE EPIDURAL SPACE IS IDENTIFIED. THEN REMOVES THE NEEDLE CORE OF TROCAR, INJECTS EXPERIMENTAL DOSE OF SALINE, AND IN TURN ROTATES THE,SPINAL NEEDLE STERILE / NON STERILE BULK (NIL)-THE SPINAL NEEDLES IS APPLIED TO PUNCTURE, DRUG INJECTION, CEREBROSPINAL FLUID COLLECTION THROUGH LUMBAR VERTEBRA. THE PATIENT IS ASKED TO OBTAIN THE MOST APPROPRIATE POSITION, A SPINAL NEEDLE IS INSERTED IN THE MIDLINE BETWEEN THE ILIAC CRESTS (CORRESPONDING TO THE POSITION BETWEEN LUMBAR VERTEBRAE L3/L4), AND YOU CAN ALSO CHOOSE THE POSITION BETWEEN L2/L3 AND L4/L5. FIX THE SKIN WITH YOUR LEFT HAND, AND ADVANCE THE NEEDLE SLOWLY IN A VERTICAL DIRECTION TO THE BACK, AND THE NEEDLE POINT CAN SLIGHT INCLINATION TO THE HEAD. PUSH THE NEEDLE IN UNTIL TWO BREAK THROUGH ARE FELT, CORE NEEDLE CAN BE WITHDRAWN SLOWLY, YOU CAN SEE THE CEREBROSPINAL FLUID FLOW OUT, COLLECT ENOUGH CSF AS SPECIFIED, AFTER INSERTING THE NEEDLE PULLED OUT THE NEEDLE CORE.

1590	IMP/MD/2019/000134	1.License Holder Name: RUKMAN MEDICAL DEVICES AND EQUIPMENTS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CORONARY SCORING SEMI-COMPLIANT BALLOON DILATATION CATHETER(WEDGE SCORING BALLOON DILATATION CATHETER)-WEDGE BALLOON DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY, INCLUDING IN-STENT RESTENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,ACCESSORY(CONNECTING TUBING)-THE PRODUCT IS INTENDED TO CONNECT PIPELINES AND DEVICES WHICH PROVIDES PATHWAY OF THE LIQUID-INJECTION OR/AND INVASIVE BLOOD PRESSURE MONITORING IN INTERVENTIONAL OPERATION.,NON-COMPLIANT PTA BALLOON DILATATION CATHETER(ACHILLES NC PTA BALLOON CATHETER)-THE PTA BALLOON DILATATION CATHETER IS INTENDED TO DILATE STENOSES IN THE ILIAC, FEMORAL, ILIOFEMORAL, POPLITEAL, INFRAPOPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR STENT DILATATION POST-DEPLOYMENT IN THE PERIPHERAL VASCULATURE.,NON-COMPLIANT PTA BALLOON DILATATION CATHETER(TRI-WEDGE PTA SCORING BALLOON DILATATION CATHETER)-TRI-WEDGE PTA IS INDICATED TO DILATE STENOSIS IN THE ILIAC, FEMORAL, ILIOFEMORAL, PEPLITEAL, INFRAPOPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYIS FISTULAE.,NON-COMPLIANT PTA BALLOON DILATATION CATHETER(CASTOR NC PTA BALLOON CATHETER)-THE PTA BALLOON DILATATION CATHETER IS INTENDED TO DILATE STENOSES IN THE ILIAC, FEMORAL, ILIOFEMORAL, POPLITEAL, INFRAPOPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR STENT DILATATION POST-DEPLOYMENT IN THE PERIPHERAL VASCULATURE.,NON-COMPLIANT CORONARY BALLOON DILATATION CATHETER(ALVEO HP BALLOON DILATATION CATHETER)-ALEO HP IS INTENDED FOR BALLOON DILATATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION,SEMI-COMPLIANT PTA BALLOON DILATATION CATHETER (MINERVA SC PTA BALLOON CATHETER)-THE PTA BALLOON DILATATION CATHETER IS INTENDED TO DILATE STENOSES IN THE ILIAC, FEMORAL, ILIOFEMORAL, POPLITEAL, INFRAPOPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE

	LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR STENT DILATATION POST-DEPLOYMENT IN THE PERIPHERAL VASCULATURE., ACCESSORY(DOES-CONTROL SYRINGE)-THE PRODUCT IS MAINLY USED OR INJECTING SOLUTION OR CONTRAST MEDIUM BY MANUAL CONTROL IN MINIMALLY INVASIVE INTERVENTIONAL THERAPY OR DIAGNOSTIC SURGERY.,SEMI-COMPLIANT PTA BALLOON DILATATION CATHETER(ATROPOS SC PTA BALLOON CATHETER)-THE PTA BALLOON DILATATION CATHETER IS INTENDED TO DILATE STENOSES IN THE ILIAC, FEMORAL, ILIOFEMORAL, POPLITEAL, INFRAPOPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR STENT DILATATION POST-DEPLOYMENT IN THE PERIPHERAL VASCULATURE.,ACCESSORY(AGIOGRAPHIC SYRINGES AND ACCESSORIES)-THE PRODUCT IS INTENDED TO INJECT CONTRAST MEDIA, SUPPORTING THE USE OF HIGH-PRESSURE INJECTION PUMP OF CT, MRI OR DSA.,SEMI-COMPLIANT PTA BALLOON DILATATION CATHETER(POLUX SC PTA BALLOON CATHETER)-THE PTA BALLOON DILATATION CATHETER IS INTENDED TO DILATE STENOSES IN THE ILIAC, FEMORAL, ILIOFEMORAL, POPLITEAL, INFRAPOPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR STENT DILATATION POST-DEPLOYMENT IN THE PERIPHERAL VASCULATURE.,NON-COMPLIANT CORONARY SCORING BALLOON DILATATION CATHETER(WEDGE NC SCORING BALLOON DILATATION CATHETER)-WEDGE NC IS INDICATED FOR BALLOON DILATATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY, INCLUDING IN-STENT RESTENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION,NON-COMPLIANT PTA BALLOON DILATATION CATHETER(HERMES NC PTA BALLOON CATHETER)-THE PTA BALLOON DILATATION CATHETER IS INTENDED TO DILATE STENOSES IN THE ILIAC, FEMORAL, ILIOFEMORAL, POPLITEAL, INFRAPOPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR STENT DILATATION POST-DEPLOYMENT IN THE PERIPHERAL VASCULATURE.,ACCESSORY(INTRODUCER NEEDLE)-THE PRODUCT IS INTENDED FOR BODY PUNCTURE TO COLLECT HUMAN SAMPLES, INJECT LIQUID AND GAS, ETC. OR BE A PATH FOR OTHER DEVICES ENTERING THE BODY.,ACCESSORY(Y CONNECTOR SET)-THE PRODUCT IS AN ANXILIARY INSTRUMENT IN PERCUTANEOUS ANGIOPLASTY.,ACCESSORY(INTRODUCER SHEATH

		SET)-THE PRODUCT IS INTENDED TO ENLARGE THE INCISION OF PERCUTANEOUS INTERVENTION, WHICH ASSISTS CATHETER INTO BLOOD VESSEL.,CATHETER GUIDE WIRE(CONGER HYDROPHILIC GUIDEWIRE)-CONGER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY, INCLUDING IN-STENT RESTENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION
1591	IMP/MD/2019/000135	1.License Holder Name: SPAN HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASPIRATION / ANTICOAGULATION SETS(HAEMONETICS)- IT IS INTENDED TO BE USED TO ASPIRATE AND ANTI-COAGULATE WOUND BLOOD TO PASS IT THROUGH THE TUBING INTO A COLLECTION RESERVOIR.
1592	IMP/MD/2019/000136	1.License Holder Name: FUSION MEDICAL & DENTAL TECHNOLOGY, CO. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT SYSTEM(ANKER)-ANKER DENTAL IMPLANT SYSTEM IS INTENDED TO BE SURGICALLY PLACED IN THE BONE OF THE UPPER OR LOWER JAW ARCHES TO PROVIDE SUPPORT FOR PROSTHETIC DEVICES, SUCH AS ARTIFICIAL TEETH, AND TO RESTORE THE PATIENT'S CHEWING FUNCTION. IT IS INTENDED FOR DELAYED LOADING.
1593	IMP/MD/2019/000137	1.License Holder Name: KAMAL ENCON INDUSTRIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA CATHETER (TAMARIN BLUE)-IT IS INDICATED FOR: BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. BALLOON DILATATION OF A STENT AFTER IMPLANTATION.

1594	IMP/MD/2019/000138	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENLITE GLUCOSE SENSOR (ENLITE)-THE ENLITE GLUCOSE SENSOR (SENSOR) IS INTENDED FOR USE WITH MEDTRONIC DIABETES (MEDTRONIC) GLUCOSE SENSING SYSTEMS TO CONTINUOUSLY MONITOR GLUCOSE LEVELS IN PERSONS WITH DIABETES.,GLUCOSE SENSOR(GUARDIAN SENSOR (3))-THE SENSOR IS INTENDED FOR USE WITH GUARDIAN LINK (3) AND GUARDIAN CONNECT TRANSMITTERS TO CONTINUOUSLY MONITOR GLUCOSE LEVELS IN PERSONS WITH DIABETES.

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1595	IMP/MD/2019/000139	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SOFT TISSUE FIXATION DEVICE(JUGGERSTITCH MENISCAL REPAIR DEVICE STRAIGHT AND CURVED)-THE JUGGERSTITCH MENISCAL REPAIR DEVICE IS INDICATED FOR THE REPAIR OF VERTICAL LONGITUDINAL FULL THICKNESS TEARS (I.E. BUCKET-HANDLE) IN THE RED-RED AND RED-WHITE ZONES. THESE DEVICES ARE NOT TO BE USED FOR MENISCAL TEARS IN THE AVASCULAR ZONE OF THE MENISCUS.,INTERFERENCE SCREWS(GENTLE THREADS INTERFERENCE SCREWS)-INDICATIONS FOR THE GENTLE THREADS INTERFERENCE SCREW INCLUDE USE IN SOFT TISSUE REATTACHMENT PROCEDURES IN THE KNEE. SPECIFIC INDICATIONS INCLUDE THE FOLLOWING: KNEE: MEDIAL COLLATERAL LIGAMENT (MCL) REPAIR, LATERAL COLLATERAL LIGAMENT (LCL) REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, AND PATELLAR LIGAMENT/TENDON REPAIR. IN ADDITION TO THE ABOVE INDICATIONS, 7.0MM, 8.0 MM, 9.0 MM, 10.0 MM, 11.0 MM AND 12.0 MM SCREWS ARE INDICATED FOR THE FOLLOWING USES: 1. TO PROVIDE INTERFERENCE FIXATION OF PATELLAR BONE-TENDON-BONE GRAFTS IN ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION. 2. TO PROVIDE INTERFERENCE FIXATION DURING FEMORAL AND/OR TIBIAL FIXATION IN ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION USING A SOFT TISSUE GRAFT (SEMITENDINOSUS, GRACILIS). 3. TO PROVIDE INTERFERENCE FIXATION DURING POSTERIOR CRUCIATE LIGAMENT (PCL) RECONSTRUCTION., CANNULA FOR ARTHROSCOPIC PROCEDURE(HYDRODAM CANNULA SYSTEM)-THE HYDRODAM CANNULA SYSTEM IS INTENDED FOR USE IN ARTHROSCOPIC PROCEDURES TO ESTABLISH AND MAINTAIN A PORTAL FOR PASSAGE OF IMPLANTS AND SURGICAL INSTRUMENTS INTO THE JOINT SPACE.,TITANIUM INTERFERENCE SCREW(NA)-THE TITANIUM INTERFERENCE SCREWS ARE INTENDED FOR BONE TO BONE FIXATION DURING ARTHROSCOPY AND ARTHROTOMY, SPECIFICALLY IN ANTERIOR CRUCIATE LIGAMENT (ACL) REPAIR. TITANIUM INTERFERENCE SCREWS ARE INTENDED FOR USE IN FIXATION OF PATELLAR TENDON-BONE GRAFTS IN ACL RECONSTRUCTION.

1596	IMP/MD/2019/000140	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIP REPLACEMENT SYSTEM- LINERS(DURALOC)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.,HIP REPLACEMENT SYSTEM- HEADS(S-ROM)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.,HIP REPLACEMENT SYSTEM- HEADS(ARTICUL/EZE)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.,HIP REPLACEMENT SYSTEM- CUPS(DURALOC)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.

1597	IMP/MD/2019/000142	1.License Holder Name: MACO PHARMA INDIA TRANSFUSION SOLUTIONS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SINGLE OR MULTIPLE EMPTY BLOOD BAGS, WITHOUT LEUKODEPLETION FILTER, TRANSFER BAGS(EMPTY TRANSFER BAG)-INTENDED FOR THE TRANSFER OF BLOOD PRODUCTS (WHOLE BLOOD, PLATELETS, PLASMA, SERUM, CRYOPRECIPITATE),SINGLE OR MULTIPLE BLOOD BAGS, LEUKODEPLETION FILTERS, SINGLE OR MULTIPLE BAGS WITH LEUKODEPLETION FILTERS(SINGLE OR MULTIPLE BLOOD BAGS, LEUKODEPLETION FILTERS, SINGLE OR MULTIPLE BAGS WITH LEUKODEPLETION FILTERS)-INTENDED FOR THE COLLECTION OF HUMAN BLOOD AND THE PRESERVATION OF BLOOD COMPONENTS., SINGLE OR MULTIPLE EMPTY BLOOD BAGS, WITHOUT LEUKODEPLETION FILTER, TRANSFER BAGS(PLATELETS STORAGE BAG (1800 ML))-INTENDED FOR THE TRANSFER OF BLOOD PRODUCTS (WHOLE BLOOD, PLATELETS, PLASMA, SERUM, CRYOPRECIPITATE), SINGLE OR MULTIPLE BLOOD BAGS, LEUKODEPLETION FILTERS, SINGLE OR MULTIPLE BAGS WITH LEUKODEPLETION FILTERS(SINGLE OR MULTIPLE BLOOD BAGS, LEUKODEPLETION FILTERS, SINGLE OR MULTIPLE BAGS WITH LEUKODEPLETION FILTERS)-INTENDED FOR THE COLLECTION OF HUMAN BLOOD AND THE PRESERVATION OF BLOOD COMPONENTS.,SINGLE OR MULTIPLE BLOOD BAGS, WITH LCG2B FILTER(LAB SIDE FILTER WITH EMPTY BAG (LEUCOLAB LCG2B))-INTENDED FOR THE REMOVAL OF LEUKOCYTES AND MICRO-AGREGATES FROM A SINGLE UNIT OF RED CELLS (PREPARED FROM APPROXIMATELY 450 TO 500 ML OF BLOOD), AT EITHER 1 TO 6 DEGREE CELCIUS OR AT ROOM TEMPERATURE (20-24 DEGREE CELCIUS).
1598	IMP/MD/2019/000143	1.License Holder Name: M/S NIPRO MEDICAL (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE HYPODERMIC SYRINGES FOR SINGLE USE-IT IS APPLIED TO SUCTION FLUID OR INJECT IMMEDIATELY AFTER INJECTION

1599	IMP/MD/2019/000144	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED ,NO. 17, GROUND FLOOR AND MEZZANINE FLOOR, THIRUNEERMALAI ROAD, NAGALKENI, CHROMPET ,CHENNAI TAMIL NADU ,600044 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RESORBABLE INTERFERENCE SCREW(COMPOSITCP 30 INTERFERENCE SCREW)-THE COMPOSITCP® 30 INTERFERENCE SCREW IS DESIGNED FOR INTERFERENCE FIXATION IN ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION.,RESORBABLE INTERFERENCE SCREW (COMPOSITCP 60 INTERFERENCE SCREW)-THE COMPOSITCP® 60 INTERFERENCE SCREW IS EXCLUSIVELY USED FOR INTERFERENCE FIXATION OF A SOFT TISSUE TRANSPLANT, FOR INSTANCE FROM THE HAMSTRING TENDON, WHEN RECONSTRUCTING THE ANTERIOR CRUCIATE LIGAMENT.
1600	IMP/MD/2019/000145	1.License Holder Name: MIV THERAPEUTICS (INDIA) PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RX PTA CATHETER (EBONY 0.014)-IT IS INTENDED FOR DILATATION OF LESIONS IN THE FEMORAL, RENAL, ILIAC AND POPLITEAL ARTERIES,PTCA CATHETER (FILAO RX)-IT IS INTENDED FOR USE IN PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES AND WHO ARE REGARDED AS BEING CANDIDATES FOR MYOCARDIAL REVASCULARIZATION,PTCA CATHETER(FILAO NC)-IT IS INTENDED FOR USE IN PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES AND WHO ARE REGARDED AS BEING CANDIDATES FOR MYOCARDIAL REVASCULARIZATION,PTCA CATHETER(TAMARIN BLUE)-IT IS INTENDED FOR USE IN PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES AND WHO ARE REGARDED AS BEING CANDIDATES FOR MYOCARDIAL REVASCULARIZATION
1601	IMP/MD/2019/000146	1.License Holder Name: GENNOVA BIOPHARMACEUTICALS LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE (STERILE)(BD HYPAK SCF™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS

1602	IMP/MD/2019/000147	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EXTRA-CORPOREAL BLOOD CIRCUIT PRE-CONNECTED TO A HEMOCONCENTRATOR (TUBING SET WITH X-COATING (OPTIONAL) PRE-CONNECTED TO HEMOCONCENTRATOR)-THIS SET IS INTENDED FOR USE UNDER THE ORDER OF A PHYSICIAN BY AN APPROPRIATELY TRAINED AND QUALIFIED PERFUSIONIST FOR EXTRACORPOREAL CIRCULATION DURING CARDIOPULMONARY BYPASS. THE CAPIOX HEMOCONCENTRATOR IS INTENDED TO BE USED DURING AND AFTER SURGICAL PROCEDURES REQUIRING CARDIOPULMONARY BYPASS (UP TO 6 HOUR) WHEN THE REMOVAL OF EXCESS FLUID FROM THE BLOOD IS REQUIRED. IT COULD NOT BE USED AS A DIALYZER, HEMOFILTER OR OTHER DEVICE.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1603	IMP/MD/2019/000148	1.License Holder Name: VYGON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURFACTANT ADMINISTRATION CATHETER(SURFCATH)-SURFACTANT ADMINISTRATION CATHETER FOR THE TREATMENT OF PREMATURE OR FULL-TERM HIGH-RISK NEONATES OR WITH RESPIRATORY DISTRESS SYNDROMECAUSED BY PULMONARY SURFACTANT DEFICIENCY.,SURGICAL DRESSINGS & INCISE DRAPES(DERMAFILM & DERMINCISE)-TRANSPARENT POLYURETHANE DRESSING FILM FOR PROTECTING CATHETER INTRODUCTION SITES.,FEEDING TUBES(NS2 FEEDING TUBES)-ENTERAL NUTRITION OF NEONATES, INFANTS AND CHILDREN IN NICU, PICU, NEONATOLOGY AND PAEDIATRICS.,SPINAL NEEDLE(SPINAL NEEDLE)-THESE NEEDLES ARE INTENDED TO BE INSERTED IN THE SUBARACHNOID SPACE TO INJECT ANAESTHETIC AGENTS FOR SPINAL ANAESTHESIA. ,NUTRISAFE 2 CONNECTORS (NUTRISAFE 2 SAMPLING DEVICE, NUTRISAFE2 BOTTLE CAP, VIAL ACCESS CAP WITH NUTRISAFE 2 CONNECTION, NUTRISAFE 2 GASTRIC ASPIRATOR)--ENTERAL NUTRITION OF NEWBORNS, BABIES AND INFANTS IN NICU, PICU, NEONATALOGY AND PAEDIATRIC UNITS. LOCKABLE CAP FOR DRUG SAMPLINGS WITH A NUTRISAFE 2 SYRINGE. THE DRUG IS THEN ADMINISTERED EITHER ORALLY OR THROUGH A NUTRISAFE 2 FEEDING TUBE. ENTERAL NUTRITION OF NEONATES, INFANTS AND CHILDREN IN NICU, PICU, NEONATALOGY AND PAEDIATRICS. GASTRIC ASPIRATION FOR LABORATORY SPECIMEN SAMPLING.,NUTRICATH(NUTRICATH S)-NUTRICATH "S" IS RECOMMENDED FOR : - PROLONGUED PARENTERAL NUTRITION - CHEMOTHERAPY - TRANSFUSION OF BLOOD OR BLOOD PRODUCTS - REPEATED BLOOD SAMPLINGS - DRUGS ADMINISTRATION LIKE ANTIVIRALS, ANTIBIOTICS IN CASE OF AIDS, CYSTIC FIBROSIS ETC. , NUTRISAFE 2 ADAPTOR FOR FEEDING TUBES(NUTRISAFE 2 ADAPTER TO FEEDING PUMPS TUBING, TAPER CONNECTOR WITH NUTRISAFE 2 MALE CONNECTION, NUTRISAFE 2 FEEDING TUBE OBTURATOR, NUTRISAFE 2 THREE-WAY STOPCOCK)-ENTERAL NUTRITION OF INFANTS AND CHILDREN IN PICU AND PAEDIATRICS.,HUBER NEEDLE (PERFUSAFE 2)-PERFUSAFE IS A SAFETY INFUSION DEVICE WITH HUBER BEVEL FOR IMPLANTABLE PORTS WHICH CAN BE USED FOR INTERMITTENT INJECTIONS, CONTINUOUS INFUSIONS OF DRUGS OR SOLUTIONS, BLOOD SAMPLING,EXCHANGE TRANSFUSION SET (EXCHANGE TRANSFUSION SET)-EXCHANGE TRANSFUSION IN NEONATES. ,EPIDURAL CATHETER(EPIDURAL CATHETER)-EPIDURAL ANAESTHESIA / ANALGESIA. ,STOPCOCK(OCTOPUS, VYCLIC, VEDSITE)-- EXTENSION TUBE FOR I.V. CATHETERS . OCTOPUS 1 AND OCTOPUS 2 ARE MORE PARTICULARLY RECOMMENDED FOR PERIPHERAL SHORT I.V. CANNULAE, FOR CENTRAL VENOUS

	CATHETERS. ,THORACIC TROCAR DRAIN(THORACIC TROCAR AND DRAIN)-THORACIC / PLEURAL DRAINAGE (PNEUMOTHORAX, HEMOTHORAX, CHYLOTHORAX, PYOTHORAX). ,ASPISAFE(ASPISAFE 2)-CATHETER FOR PROTECTED DISTAL BRONCHIAL SAMPLING FOR DIAGNOSIS OF VENTILATOR-ASSOCIATED PNEUMONIA IN INTENSIVE CARE OF PATIENTS MECHANICALLY VENTILATED.,ENTERAL FEEDING TUBES(ENTERAL FEEDING TUBE)-PVC NASO-GASTRIC FEEDING TUBE FOR SHORT-TERM ENTERAL NUTRITION.,HUBER NEEDLE(PERFUSAFE 2 AUTOFLUSH WITH BIONECTOR)-PERFUSAFE IS A SAFETY INFUSION DEVICE WITH HUBER BEVEL FOR IMPLANTABLE PORTS WHICH CAN BE USED FOR INTERMITTENT INJECTIONS, CONTINUOUS INFUSIONS OF DRUGS OR SOLUTIONS, BLOOD SAMPLING,QIMONO (QIMOHARPOON)-QIMOHARPOON IS A MEDICATION RECONSTITUTION AND WITHDRAWAL DEVICE FOR HIGH-RISK MEDICATION. ,NERVE STIMULATION NEEDLES(ECHOPLEX + SILVERSTIM)-ECHOPLEX IS A NEEDLE FOR PLEXUS BLOCKS AND PERIPHERAL NERVE BLOCKS ALLOWING TO LOCATE THE PLEXUS OR NERVE EITHER UNDER ULTRASOUND OR WITH ELECTRO-NEURO STIMULATION. SILVERSTIM IS A CATHETER FOR CONTINUOUS PLEXUS AND PERIPHERAL NERVE BLOCKS.,IMPLANTABLE PORTS (SITIMPLANT)-IMPLANTABLE PORT FOR LONG-TERM IV THERAPY - INTERMITTENT AND PROLONGED CHEMOTHERAPY IN ONCOLOGY AND IN HAEMATOLOGY, - TREATMENTS ASSOCIATING ANTIBIOTICS, ANTIVIRAL AGENTS AND PARENTERAL NUTRITION IN PATIENTS SUFFERING FROM AIDS AND OTHER INFECTIOUS DISEASES, - PARENTERAL NUTRITION WITH PATIENT SUFFERING FROM CHRONIC GASTRO-INTESTINAL/METABOLIC PROBLEMS, - CYSTIC FIBROSIS WITH REPEATED INTRAVENOUS ADMINISTRATIONS OF ANTIBIOTICS AND OTHER DRUGS, - PATIENTS PRESENTING WITH VARIOUS DISORDERS AFFECTING THE CIRCULATORY SYSTEM AND REQUIRING A LONG-TERM TRANSFUSION PROGRAMME. ,MUCUS EXTRACTOR (MUCUS EXTRACTOR)-MUCUS EXTRACTOR CONNECTED TO A FIBROSCOPE FOR MUCUS SAMPLING DURING FIBROSCOPY / BRONCHOSCOPY. ,UMBILICAL CATHETER(UMBILICAL CATHETER)-CATHETER INSERTED IN THE UMBILICAL VEIN OR IN THE UMBILICAL ARTERY OF THE NEWBORN. UMBILICAL VENOUS CATHETER ARE USED IN CASE OF NEONATAL EMERGENCY, FOR A SHORT PERIOD OF TIME (FEW DAYS). IT ALLOWS: THE INFUSION OF PARENTERAL NUTRITION, THE ADMINISTRATION OF DRUGS, EXCHANGE - TRANSFUSION...) THE UMBILICAL ARTERIAL CATHETER IS USED IN CASE OF NEONATAL EMERGENCY FOR BLOOD GAS MONITORING, BLOOD PRESSURE MEASUREMENT,REGIONAL ANAESTHESIA (LOCOPLEX, INFUPLEX, TECHNIPLEX)-CATHETER FOR CONTINUOUS PLEXUS BLOCKS AND PERIPHERAL NERVE BLOCKS MAINLY USED

	FOR POST-OPERATIVE ANALGESIA AFTER JOINT SURGERY.,I.V. CANNULA(INTRANULE)-THIS CATHETER IS MAINLY USED FOR INSERTION IN THE PERIPHERAL VEINS OF THE FOREARM IN ORDER TO: - INFUSE HYDRIC, ELECTROLYTIC AND NUTRIENT SOLUTIONS . . . - ADMINISTER MEDICATION, - TRANSFUSE BLOOD OR BLOOD DERIVATIVES, - CARRY OUT BLOOD SAMPLING. ,ENDOTRACHEAL TUBE(ENDOTRACHEAL TUBE)-ENDOTRACHEAL INTUBATION OF NEONATES, BABIES AND INFANTS.,CENTRAL VENOUS CATHETER (CENTRACATH)-CENTRACATH IS USED FOR: - PARENTERAL NUTRITION - FLUID LOADING - DRUG ADMINISTRATIONS - TRANSFUSION OF BLOOD OR BLOOD PRODUCTS - BLOOD SAMPLING - CENTRAL VENOUS PRESSURE MEASUREMENT ,PERITONEAL DIALYSIS CATHETER(PERITONEUM DIALYSIS SET/ TRAY)-THIS DEVICE IS EITHER USED FOR EMERGENCY PERITONEAL DIALYSIS OR FOR ABDOMINAL LAVAGE AFTER CAR ACCIDENT FOR EXAMPLE TO CHECK THE POSSIBLE RUPTURE OF AN ABDOMINAL ORGAN OR AN INTRA-PERITONEAL HAEMORRHAGE. ,QIMONO(QIMOPRIME, QIMOFEMALE, QIMOMALE, QIMOSPIKE, QIMOCAP, QIMOTRANSFER, QIMOCONNECT, QIMOPUMP, QIMO IV SET, QIMOOCTOPUS, QIMOPERFUSAFE)- -NEEDLELESS, CLOSED I.V. SYSTEM, ALLOWS BLOOD SAMPLINGS, INTERMITTENT INJECTIONS AND CONTINUOUS INFUSIONS. ,ARTERIAL CATHETER(ARTERIOSEL, LEADERCATH 2, LEADER-FLEX)-ARTERIAL LEADER-CATH IS USED: - FOR BLOOD GAS MEASUREMENTS (PAO2, PACO2...) - INVASIVE ARTERIAL PRESSURE MONITORING ,STOPCOCK(BIONECTOR- OCTOPUS)- BIONECTOR IS CONNECTED DIRECTLY TO IV CATHETERS OR TO IV EXTENSION TUBES, STOPCOCKS, RAMPS OF STOCOCKS ETC. IT ALLOWS BLOOD SAMPLINGS, INTERMITTENT INJECTIONS OR CONTINUOUS INFUSIONS OF FLUIDS OR DRUGS MAINTAINING CONSTANTLY A CLOSED IV SYSTEM. -OCTOPUS: INTRAVENOUS CATHETER EXTENSION TUBE , EXTENSION TUBES(EXTENSION LINES)--THE MEMBRANE CAP ON THE LATERAL PORT ALLOWS INTERMITTENT DRUG INJECTIONS (REF 141 ONLY). -THIS CAP MAY BE REMOVED ; IN THIS CASE, IT IS POSSIBLE TO USE THIS LATERAL PORT TO CONNECT A 2ND PERFUSION. -THESE EXTENSION TUBES ALLOW HOSPITAL PERSONNEL TO AVOID DIRECT MANIPULATION OF THE CATHETER HUB WHICH INCREASES THE RISK OF PHLEBITIS (DUE TO THE MOVEMENTS OF THE CATHETER IN THE VEIN) , SINCE THE VESSEL IS ALREADY IRRITATED BY THE PRESENCE OF A FOREIGN BODY. -THEY REDUCE AIR EMBOLISM RISK (IT IS POSSIBLE TO CLAMP THE EXTENSION TUBE WHEREAS IT IS NOT POSSIBLE TO CLAMP A SHORT CANNULA OR SOME CENTRAL VENOUS CATHETERS WHICH MAY BE PINCHED AND WEAKENED) OR LOSS OF BLOOD. -THEY ALSO ALLOW THE MAKING OF A SECURITY LOOP WHICH IMPROVES THE FIXATION OF THE I.V. CATHETER AND

		PREVENTS IT FROM BEING ACCIDENTALLY PULLED OUT OF THE VEIN. ,TRACHEAL SUCTION CATHETER(SUCTION CATHETER)-SUCTION CATHETER FOR TRACHEAL OR BRONCHIAL SUCTIONING. , HYPODERMIC NEEDLE(HUBSITE)-HUBSITE IS A DEVICE FOR PUNCTURING THE SEPTUM OF IMPLANTABLE PORTS SUCH AS SITIMPLANT, MINI-SITIMPLANT, MICRO-SITIMPLANT AND OTHER IMPLANTABLE PORTS, ALLOWING INFUSIONS, INJECTIONS AND BLOOD SAMPLES.
1604	IMP/MD/2019/000149	1.License Holder Name: SMITHS MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETERS-THE CATHETERS ARE INTENDED AS CATHETERIZATION OF THE SUPERIOR VENA CAVA USING THE SELDINGER TECHNIQUE TO GET A CENTRAL VENOUS ACCESS

1605	IMP/MD/2019/000150	1.License Holder Name: MED-EL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIBRATING OSSICULAR PROSTHESIS (VORP)(VIBRANT SOUNDBRIDGE)-THE VIBRANT SOUNDBRIDGE IS INDICATED FOR USE IN PATIENTS WHO HAVE MILD TO SEVERE HEARING IMPAIRMENT AND CANNOT ACHIEVE SUCCESS OR ADEQUATE BENEFIT FROM TRADITIONAL THERAPY.,AUDITORY BRAINSTEM IMPLANT SYSTEM(MI 1000 CONCERTO)-INTENDED TO EVOKE AUDITORY SENSATION BY STIMULATION OF THE COCHLEAR NUCLEUS (CN) IN PATIENTS WITH NON-FUNCTIONAL COCHLEAR NERVES AND RESTORE SOME DEGREE OF HEARING IN INDIVIDUALS WHO SUFFER FROM PROFOUND HEARING IMPAIRMENT.,COCHLEAR IMPLANT SYSTEM(SONATA TI100)-COCHLEAR IMPLANT IS INTENDED TO EVOKE AUDITORY SENSATIONS VIA ELECTRICAL STIMULATION OF THE AUDITORY PATHWAYS FOR SEVERELY TO PROFOUNDLY HEARING IMPAIRED INDIVIDUALS WHO OBTAIN LITTLE OR NO BENEFIT FROM ACOUSTIC AMPLIFICATION IN THE BEST AIDED CONDITION.,COCHLEAR IMPLANT SYSTEM(MI 1000 CONCERTO)-IT IS INTENDED TO EVOKE AUDITORY SENSATIONS VIA ELECTRICAL STIMULATION OF THE AUDITORY PATHWAYS FOR SEVERELY TO PROFOUNDLY HEARING IMPAIRED INDIVIDUALS WHO OBTAIN LITTLE OR NO BENEFIT FROM ACOUSTIC AMPLIFICATION IN THE BEST AIDED CONDITION.,AUDITORY BRAINSTEM IMPLANT SYSTEM(MI 1200 SYNCHRONY)-INTENDED TO EVOKE AUDITORY SENSATION BY STIMULATION OF THE COCHLEAR NUCLEUS (CN) IN PATIENTS WITH NON-FUNCTIONAL COCHLEAR NERVES AND RESTORE SOME DEGREE OF HEARING IN INDIVIDUALS WHO SUFFER FROM PROFOUND HEARING IMPAIRMENT.,COCHLEAR IMPLANT SYSTEM(MI 1200 SYNCHRONY)-INTENDED TO EVOKE AUDITORY SENSATIONS VIA ELECTRICAL STIMULATION OF THE AUDITORY PATHWAYS FOR SEVERELY TO PROFOUNDLY HEARING IMPAIRED INDIVIDUALS WHO OBTAIN LITTLE OR NO BENEFIT FROM ACOUSTIC AMPLIFICATION IN THE BEST AIDED CONDITION.,BONE CONDUCTION IMPLANT (BCI) (BONEBRIDGE)-THE BONEBRIDGE IS INTENDED TO TREAT PATIENTS WITH EITHER CONDUCTIVE OR MIXED HEARING LOSS OR PATIENTS SUFFERING FROM SINGLE-SIDED SENSORINEURAL DEAFNESS. THE BONEBRIDGE AUGMENTS HEARING BY PROVIDING ACOUSTIC INFORMATION TO THE INNER EAR VIA BONE CONDUCTION.

1606	IMP/MD/2019/000151	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SINGLE USE NEGATIVE PRESSURE WOUND THERAPY SYSTEM(PICO 7)-IT IS INDICATED FOR PATIENTS WHO WOULD BENEFIT FROM A SUCTION DEVICE (NPWT) AS IT MAY PROMOTE WOUND HEALING VIA REMOVAL OF LOW TO MODERATE LEVELS OF EXUDATE AND INFECTIOUS MATERIALS. APPROPRIATE WOUND TYPES INCLUDE: CHRONIC, ACUTE, TRAUMATIC, SUBACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC OR PRESSURE), FLAPS AND GRAFTS, SURGICALLY CLOSED INCISION SITES. PICO 7 SINGLE USE NEGATIVE PRESSURE SYSTEMS ARE SUITABLE FOR USE BOTH IN A HOSPITAL AND HOMECARE SETTING. ,HYDROCELLULAR ADHESIVE DRESSING(ALLEVYN ADHESIVE)-WOUND MANAGEMENT BY SECONDARY INTENTION ON SHALLOW, GRANULATING WOUNDS CHRONIC AND ACUTE EXUDATIVE WOUNDS, FULL AND PARTIAL THICKNESS WOUNDS SUCH AS PRESSURE ULCERS, LEG ULCERS, DIABETIC FOOT ULCERS, MALIGNANT WOUNDS, SURGICAL WOUNDS, FIRST AND SECOND DEGREE BURNS, DONOR SITES AND FUNGATING ULCERS. ALLEVYN ADHESIVE CAN BE USED IN CONJUNCTION WITH INTRASITE™ GEL FOR NECROTIC OR SLOUGHY WOUNDS. ALLEVYN ADHESIVE MAY BE USED ON INFECTED WOUNDS. WHERE THE PRODUCT IS USED ON INFECTED WOUNDS THE WOUNDS SHOULD BE TREATED AS PER LOCAL CLINICAL PROTOCOL.,SILICONE GEL ADHESIVE COMPOSITE HYDROCELLULAR FOAM DRESSING(ALLEVYN LIFE)-1. WOUND MANAGEMENT BY SECONDARY INTENTION ON SHALLOW, GRANULATING WOUNDS, CHRONIC AND ACUTE EXUDATIVE WOUNDS, FULL AND PARTIAL THICKNESS WOUNDS INCLUDING: • PRESSURE ULCERS • LEG ULCERS • DIABETIC FOOT ULCERS • SURGICAL WOUNDS • FIRST AND SECOND DEGREE BURNS • DONOR SITES • SKIN TEARS • FUNGATING ULCERS CAN BE USED IN CONJUNCTION WITH INTRASITE™ GEL FOR NECROTIC OR SLOUGHY WOUNDS. 2. PRESSURE ULCER PREVENTION ON INTACT SKIN AS PART OF A PRESSURE ULCER PREVENTION PROTOCOL.,SILICONE GEL ADHESIVE ANTIMICROBIAL HYDROCELLULAR FOAM DRESSING (ALLEVYN AG GENTLE BORDER)-ALLEVYN AG GENTLE BORDER IS AN ABSORBENT ANTIMICROBIAL DRESSING FOR THE MANAGEMENT, BY SECONDARY INTENTION OF CHRONIC AND ACUTE FULL THICKNESS, PARTIAL THICKNESS OR SHALLOW GRANULATING, EXUDING WOUNDS SUCH AS: PRESSURE ULCERS, VENOUS ULCERS, DIABETIC ULCERS, BURNS, DONOR SITES, FUNGATING / MALIGNANT WOUNDS AND SURGICALLY DEHISCED WOUNDS. ALLEVYN AG GENTLE BORDER MAY BE USED ON INFECTED WOUNDS. WHERE THE PRODUCT IS USED ON INFECTED WOUNDS THE WOUNDS SHOULD BE TREATED AS PER

	LOCAL PROTOCOL. ALLEVYN AG GENTLE BORDER CAN BE USED IN CONJUNCTION WITH INTRASITE™ GEL FOR NECROTIC OR SLOUGHY WOUNDS. ALLEVYN AG GENTLE BORDER IS SUITABLE FOR USE ON FRAGILE SKIN.,SINGLE USE NEGATIVE PRESSURE WOUND THERAPY SYSTEM(PICO)-"PICO IS INDICATED FOR PATIENTS WHO WOULD BENEFIT FROM A SUCTION DEVICE (NEGATIVE PRESSURE WOUND THERAPY) AS IT MAY PROMOTE WOUND HEALING VIA REMOVAL OF LOW TO MODERATE LEVELS OF EXUDATE AND INFECTIOUS MATERIALS. EXAMPLES OF APPROPRIATE WOUND TYPES INCLUDE - CHRONIC, ACUTE, TRAUMATIC, SUBACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC OR PRESSURE), FLAPS AND GRAFTS, SURGICALLY CLOSED INCISION SITES. PICO SINGLE USE NEGATIVE PRESSURE WOUND THERAPY SYSTEM IS SUITABLE FOR USE BOTH IN A HOSPITAL AND HOMECARE SETTING.,NON-ADHESIVE HYDROCELLULAR ANTIMICROBIAL DRESSING(ALLEVYN AG NON-ADHESIVE)-ALLEVYN AG NON-ADHESIVE IS AN ANTIMICROBIAL ABSORBENT DRESSING FOR THE MANAGEMENT, BY SECONDARY INTENTION OF CHRONIC AND ACUTE FULL THICKNESS, PARTIAL THICKNESS OR SHALLOW GRANULATING, EXUDING WOUNDS SUCH AS: PRESSURE ULCERS, VENOUS ULCERS, DIABETIC ULCERS, BURNS, DONOR SITES, FUNGATING/MALIGNANT WOUNDS AND SURGICALLY DEHISCED WOUNDS. ALLEVYN AG NON-ADHESIVE MAY BE USED ON INFECTED WOUNDS. WHERE THE PRODUCT IS USED ON INFECTED WOUNDS THE WOUNDS SHOULD BE TREATED AS PER LOCAL PROTOCOL.,ADHESIVE HYDROCELLULAR ANTIMICROBIAL DRESSING(ALLEVYN AG ADHESIVE)-ALLEVYN AG ADHESIVE IS AN ANTIMICROBIAL ABSORBENT DRESSING FOR THE MANAGEMENT, BY SECONDARY INTENTION OF CHRONIC AND ACUTE FULL THICKNESS, PARTIAL THICKNESS OR SHALLOW GRANULATING, EXUDING WOUNDS SUCH AS: PRESSURE ULCERS, VENOUS ULCERS, DIABETIC ULCERS, BURNS, DONOR SITES, FUNGATING / MALIGNANT WOUNDS AND SURGICALLY DEHISCED WOUNDS. ALLEVYN AG ADHESIVE MAY BE USED ON INFECTED WOUNDS. WHERE THE PRODUCT IS USED ON INFECTED WOUNDS THE WOUNDS SHOULD BE TREATED AS PER LOCAL PROTOCOL.,SILICONE GEL ADHESIVE HYDROCELLULAR FOAM DRESSING(ALLEVYN GENTLE BORDER)-1. WOUND MANAGEMENT ON SHALLOW, GRANULATING WOUNDS, CHRONIC AND ACUTE EXUDATIVE WOUNDS, FULL AND PARTIAL THICKNESS WOUNDS INCLUDING PRESSURE ULCERS, LEG ULCERS, DIABETIC FOOT ULCERS, SURGICAL WOUNDS, FIRST AND SECOND DEGREE BURNS, DONOR SITES, SKIN TEARS, FUNGATING ULCERS. CAN BE USED IN CONJUNCTION WITH INTRASITE™ GEL FOR NECROTIC OR SLOUGHY WOUNDS. 2. PRESSURE ULCER PREVENTION ON INTACT SKIN, INCLUDING PRESSURE ULCERS CAUSED BY

	MEDICAL DEVICES, AS PART OF A PRESSURE ULCER PREVENTION PROTOCOL.,HYDROPHILIC POLYURETHANE WOUND DRESSING (ALLEVYN NON-ADHESIVE)-WOUND MANAGEMENT, BY SECONDARY INTENTION OF CHRONIC AND ACUTE FULL THICKNESS, PARTIAL THICKNESS OR SHALLOW GRANULATING EXUDING WOUNDS, SUCH AS PRESSURE ULCERS, LEG ULCERS, DIABETIC FOOT ULCERS, MALIGNANT WOUNDS, SURGICAL WOUNDS, FIRST AND SECOND DEGREE BURNS, DONOR SITES AND FUNGATING ULCERS. ALLEVYN NON-ADHESIVE MAY BE USED ON INFECTED WOUNDS. WHERE THE PRODUCT IS USED ON INFECTED WOUNDS THE WOUNDS SHOULD BE TREATED AS PER LOCAL CLINICAL PROTOCOL. ALLEVYN NON ADHESIVE CAN BE USED UNDER COMPRESSION. ALLEVYN NON-ADHESIVE CAN BE USED IN CONJUNCTION WITH INTRASITE™ GEL FOR NECROTIC OR SLOUGHY WOUNDS. ALLEVYN HEEL IS SUITABLE FOR DRESSING HEELS AND OTHER AWKWARD AREAS AND CONTRIBUTES TO A PRESSURE RELIEVING PROTOCOL WHEN USED IN CONJUNCTION WITH PRESSURE RELIEVING DEVICES. FOR PRESSURE AND LEG ULCERS WITH MODERATE TO HEAVY EXUDATE. ALLEVYN NON-ADHESIVE CAN EVEN BE USED UNDER COMPRESSION. ALLEVYN HEEL IS SUITABLE FOR DRESSING HEELS AND OTHER AWKWARD AREAS.,TRANSPARENT ADHESIVE FILM DRESSING(OPSITE)-OPSITE IS INDICATED FOR: •THE MANAGEMENT OF SUPERFICIAL WOUNDS (E.G. MINORBURNS, SCALDS, ABRASIONS, AND LACERATIONS) •SPLIT-THICKNESS SKIN GRAFT DONOR SITES •FOR USE AS AN INCISION DRAPE IN ALL TYPES OF SURGERY •TO DRESS CLOSED SURGICAL WOUNDS •IV FIXATION (CENTRAL, PERIPHERAL OR VENOUSCATHETERS).,SILICONE GEL SHEET(CICA-CARE)-CICA-CARE IS DESIGNED FOR TEMPORARY USE: FOR THE MANAGEMENT OF BOTH EXISTING AND NEW HYPERTROPHIC SCARS AND KELOIDS. AS A PROPHYLACTIC THERAPY ON HEALED WOUNDS TO HELP TO PREVENT HYPERTROPHIC SCARRING AND KELOIDS. ,TRANSPARENT DRESSING(OPSITE FLEXIGRID)-OPSITE FLEXIGRID IS INDICATED FOR: • THE MANAGEMENT OF SUPERFICIAL WOUNDS (E.G. MINOR BURNS, SCALDS, ABRASIONS, LACERATIONS AND LEG ULCERS IN THE FINAL STAGE OF HEALING). • THE PROTECTION OF SKIN FROM FRICTION AND EXTERNAL CONTAMINATION. FOR PROPHYLAXIS AGAINST PRESSURE SORES. • THE RETENTION OF PRIMARY DRESSINGS E.G. INTRASITE™ GEL, ALLEVYN™ CAVITY, ALLEVYN NON-ADHESIVE. • THE FIXATION OF CATHETERS. • THE PROTECTION OF SKIN AROUND STOMA AND UNDER LEG BAGS. • THE DRESSING OF POST-OPERATIVE WOUNDS, SKIN GRAFTS AND DONOR SITES.,ABSORBENT, WATERPROOF AND BACTERIA PROOF FILM DRESSING(OPSITE POST-OP)-TO DRESS ACUTE WOUNDS SUCH AS LACERATIONS, CUTS, ABRASIONS, POST-OPERATIVE WOUNDS, MINOR BURNS WHERE

		LEVELS OF EXUDATE ARE LOW TO MODERATE.,HYDROGEL WOUND DRESSING(INTRASITE GEL)-INTRASITE GEL IS INDICATED FOR THE REMOVAL OF NON-VIABLE TISSUE FROM SHALLOW, UNDERMINED AND DEEP WOUNDS (E.G. PRESSURE SORES, LEG ULCERS, DIABETIC FOOT ULCERS, MALIGNANT WOUNDS, BURNS, SURGICAL WOUNDS, SCALDS, LACERATIONS, GRAZES, AMPUTATIONS AND FUNGATING ULCERS). ALSO, FOR THE TREATMENT OF GRANULATING CAVITY WOUNDS, EXCORIATED SKIN AND RADIATION BURNS.
1607	IMP/MD/2019/000152	1.License Holder Name: M/S LINVATEC INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOABSORBABLE IMPLANTS(CROSS FT KNOTLESS BIOCOMPOSITE SUTURE ANCHOR)-THE BIOCOMPOSITE SUTURE ANCHOR IS INTENDED TO REATTACH SOFT TISSUE TO BONE IN ORTHOPEDIC SURGICAL PROCEDURES., BIOCOMPOSITE SCREW(GENESYSMATRYX INTERFERENCE SCREW)-GENESYS MATRYX SCREWS ARE INTENDED FOR USE IN INTERFERENCE FIXATION OF BONE - PATELLAR TENDON - BONE AND SOFT TISSUE GRAFTS IN ANTERIOR AND POSTERIOR CRUCIATE LIGAMENT RECONSTRUCTIONS. GENESYS MATRYX SCREWS SHOULD BE USED IN COMBINATION WITH APPROPRIATE IMMOBILIZATION/CONTROLLED MOBILIZATION. GENESYS MATRYX SCREWS ARE FOR ATTACHING SOFT TISSUE TO BONE IN ORTHOPEDIC SURGICAL PROCEDURES. GENESYS MATRYX SCREWS ARE INTENDED TO BE USED FOR INTERFERENCE FIXATION OF SOFT TISSUE (INCLUDING LIGAMENTS OR TENDONS) TO BONE, WHERE THE IMPLANT SIZES OFFERED ARE PATIENT APPROPRIATE. THE IMPLANT OPERATES IN CONJUNCTION WITH APPROPRIATE POSTOPERATIVE IMMOBILIZATION, THROUGHOUT THE HEALING PERIOD, TO ATTACH SOFT TISSUE TO BONE.
1608	IMP/MD/2019/000153	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC NEEDLE(BD ULTRA-FINE PEN NEEDLES)-PARENTERAL ADMINISTRATION OF A DRUG (INSULIN) FROM A CARTRIDGE CONTAINED IN A DRUG (INSULIN) PEN INJECTOR.

1609	IMP/MD/2019/000154	1.License Holder Name: DR. REDDYS LABORATORIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE (STERILE)(BD HYPAK SCF™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS
1610	IMP/MD/2019/000155	1.License Holder Name: MEDITEK SYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRACHEAL PROSTHESIS (BONASTENT)-IT IS USED TO BE IMPLANTED TO RESTORE THE STRUCTURE AND/OR FUNCTION OF THE TRACHEA OR TRACHEALBRONCHIAL TREE.,COLONIC STENT(BONASTENT)-A COLONIC STENT IS A FLEXIBLE HOLLOW TUBE DESIGNED TO KEEP A SEGMENT OF THE COLON(LARGE BOWEL) OPEN WHEN IT HAS BECOME BLOCKED. THIS BLOCKAGE IS COMMONLY CAUSED BY A TUMOUR INSIDE THE BOWEL OR OUTSIDE PRESSURE ON THE BOWEL WALL.,DUODENAL STENTS(BONASTENT)-DUODENAL STENT IS INDICATED FOR THE PALLIATIVE TREATMENT OF GASTRODUODENAL OBSTRUCTIONS.,ESOPHAGEAL STENTS(BONASTENT)-AN ESOPHAGEAL STENT IS A STENT PLACED IN THE OESOPHAGUS TO KEEP A BLOCKED AREA OPEN SO THAT THE PATIENT CAN SWALLOW SOFT FOOD AND LIQUIDS.,BILIARY STENTS(BONASTENT)-BILIARY STENTS PROVIDE BILE DRAINAGE FROM THE GALLBLADDER, PANCREAS AND BILE DUCTS TO THE DUODENUM IN CONDITONS SUCH AS ASCENDING CHOLANGITIS DUE TO OBSTRUCTING GALLSTONES.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1611	IMP/MD/2019/000157	1.License Holder Name: KLS MARTIN INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEADLESS BONE SCREWS- TITANIUM (HBS2)(N/A)-OSTEOSYNTHESIS IN HAND SURGERY AND ORTHOPAEDICS. THE HBS2 HEADLESS BONE SCREW IS USED IN THE FIELD OF HAND SURGERY, ACCIDENT SURGERY AND RECONSTRUCTIVE SURGERY, AND IN OTHORPEDICS FOR THE TREATMENT OF INTRA ARTICULAR AND EXTRA ACTICULAR FRACTURES AND PSEUDOARTHOSES OF SMALL BONES AND BONE FRAGMENTS AND FOR ARTHRODESES ON SMALL JOINTS.,RADIUS PLATING SYSTEM- TITANIUM (IXOS)(N/A)-OSTEOSYNTHESIS IN HAND SURGERY AND ORTHOPAEDICS. THE IXOS RADIUS PLATING SYSTEM IS USED IN THE FIELD OF HAND, ACCIDENT AND RECONSTRUCTIVE SURGERY AND ORTHOPEDICS ESPECIALLY FOR THE FIXATION OF ACUTE DISTAL INTRA AND EXTRA- ARTICULAR FRACTURES OF THE RADIUS.
1612	IMP/MD/2019/000159	1.License Holder Name: ABBOTT HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FLASH GLUCOSE MONITORING SYSTEM(FREESTYLE LIBRE)-THE FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM IS INDICATED FOR MEASURING INTERSTITIAL FLUID GLUCOSE LEVELS IN PEOPLE (AGE 4 AND OLDER) WITH DIABETES MELLITUS, INCLUDING PREGNANT WOMEN. IT IS INTENDED TO PROVIDE PATIENTS WITH DIABETES A MORE CONVENIENT AND INFORMATIVE WAY TO EFFECTIVELY MANAGE DIABETES.,FLASH GLUCOSE MONITORING SYSTEM (FREESTYLE LIBRE PRO)-THE FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM IS A GLUCOSE MONITORING DEVICE INDICATED FOR DETECTING TRENDS AND TRACKING PATTERNS IN PERSONS (AGE 4 AND OLDER) WITH DIABETES. IT IS INTENDED TO PROVIDE A HEALTHCARE PROVIDER (HCP) AND PATIENTS WITH A MORE CONVENIENT AND INFORMATIVE WAY TO EFFECTIVELY MANAGE DIABETES.

1613	IMP/MD/2019/000160	1.License Holder Name: CARDINAL HEALTH MEDICAL PRODUCTS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENTERAL FEEDING SETS (KANGAROO)-THE KANGAROO CONNECT, E-PUMP, JOEY PUMPS, FEEDING SETS AND ACCESSORIES, ARE INTENDED TO BE USED ON PATIENTS (BOTH AMBULATORY AND NON-AMBULATORY) WOTH CONDITIONS REQUIRING ENTERAL FEEDING AND/OR HYDRATION; THIS IS ACCOMPLISHED BY DELIVERING ENTERAL NUTRITION AT A CONTROLLED RATE TO A PATIENT'S GASTROINTESTINAL SYSTEM, ENTERAL FEEDING SETS(KANGAROO)-THE KANGAROO CONNECT, E-PUMP, JOEY PUMPS, FEEDING SETS AND ACCESSORIES, ARE INTENDED TO BE USED ON PATIENTS (BOTH AMBULATORY AND NON-AMBULATORY) WOTH CONDITIONS REQUIRING ENTERAL FEEDING AND/OR HYDRATION; THIS IS ACCOMPLISHED BY DELIVERING ENTERAL NUTRITION AT A CONTROLLED RATE TO A PATIENT'S GASTROINTESTINAL SYSTEM,ENTERAL FEEDING SETS(KANGAROO)-THE KANGAROO CONNECT, E-PUMP, JOEY PUMPS, FEEDING SETS AND ACCESSORIES, ARE INTENDED TO BE USED ON PATIENTS (BOTH AMBULATORY AND NON-AMBULATORY) WOTH CONDITIONS REQUIRING ENTERAL FEEDING AND/OR HYDRATION; THIS IS ACCOMPLISHED BY DELIVERING ENTERAL NUTRITION AT A CONTROLLED RATE TO A PATIENT'S GASTROINTESTINAL SYSTEM, ENTERAL FEEDING GRAVITY SETS(KANGAROO)-THIS SET IS INTENDED FOR ENTERAL FEEDING ONLY. NOTE: IT IS RECOMMENDED THAT THIS DEVICE BE REPLACED EVERY 24 HOURS. SINGLE PATIENT USE,ENTERAL FEEDING GRAVITY SETS(KANGAROO)-THIS SET IS INTENDED FOR ENTERAL FEEDING ONLY. NOTE: IT IS RECOMMENDED THAT THIS DEVICE BE REPLACED EVERY 24 HOURS. SINGLE PATIENT USE

1614	IMP/MD/2019/000161	1.License Holder Name: FRESENIUS KABI INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COMPONENT FILTER(BIOR)-MEDICAL DEVICE FOR LEUKOCYTE REDUCTION OF RED CELL CONCENTRATES,BLOOD COMPONENT FILTER (BIOR)-MEDICAL DEIVCE FOR THE LEUKOCYTE REDUCTION FROM RED CELL ONCENTRATES AT PATIENT'S BED SIDE WITHOUT COLLECTING BAG., BLOOD COMPONENT FILTER(BIOP)-MEDICAL DEVICE FOR LEUKOCYTE REDUCTION OF PLATELET CONCENTRATES,BLOOD COMPONENT FILTER (BIOR)-MEDICAL DEIVCE FOR THE LEUKOCYTE REDUCTION FROM RED CELL CONCENTRATE FOR LABORATORY USE WITH COLLECTING BAG.,BLOOD COMPONENT FILTER(BIOP)-MEDICAL DEVICE FOR LEUKOCYTE REDUCTION OF PLATELET CONCENTRATES
1615	IMP/MD/2019/000162	1.License Holder Name: HEALTHIUM MEDTECH PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE SKIN STAPLER(TRUPLER)-SKIN STAPLER MAY BE USED 1.FOR SKIN CLOSURE IN GENERAL SURGERY IN A VARIETY OF SURGICAL PROCEDURES. 2. FOR CLOSURE OF UNINFECTED POST TRAUMATIC WOUNDS. 3. FOR PRIMARY, DELAYED PRIMARY AND SECONDARY CLOSURE OF SURGICAL INCISION AND WOUNDS.
1616	IMP/MD/2019/000163	1.License Holder Name: INTAS PHARMACEUTICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK SCF™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS

1617	IMP/MD/2019/000165	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SCALP LIGATION CLIPS (WECK RANEY CLIPS)-WECK RANEY CLIPS ARE INTENDED FOR USE IN PROCEDURES FOR WHICH THE SURGEON DETERMINES SCALP CLIPS ARE THE BEST CHOICE. SURGEONS SHOULD MAKE THE DECISION BASED UPON THEIR EXPERIENCE, JUDGEMENT, AND NEEDS., DISPOSABLE SKIN STAPLER(WECK VISISTAT)-THE VISISTAT® SKIN STAPLER MAY BE USED FOR EXTERNAL SKIN CLOSURE IN A WIDE RANGE OF GENERAL, THORACIC, OBSTETRIC, GYNECOLOGICAL, ORTHOPEDIC, CARDIOVASCULAR, UROLOGICAL, AND PLASTIC SURGERY PROCEDURES.,POLYMER LIGATING CLIPS(WECK HEM-O-LOK LIGATING CLIPS)-HEM-O-LOK LIGATING CLIPS ARE INTENDED FOR USE IN PROCEDURES INVOLVING LIGATION OF VESSELS OR TISSUE STRUCTURES. SURGEONS SHOULD APPLY THE APPROPRIATE SIZE CLIP FOR THE SIZE OF THE VESSEL OR TISSUE STRUCTURE TO BE LIGATED SUCH THAT THE CLIP COMPLETELY ENCOMPASSES THE VESSEL OR TISSUE STRUCTURE.,METAL LIGATING CLIPS(WECK HEMOCLIP TRADITIONAL LIGATING CLIPS)-WECK® LIGATING CLIPS ARE INTENDED FOR USE IN PROCEDURES INVOLVING VESSELS OR ANATOMIC STRUCTURES FOR WHICH THE SURGEON DETERMINES LIGATING CLIPS ARE THE BEST CHOICE. SURGEONS SHOULD SELECT THE SIZE, TYPE, AND MATERIAL OF THE CLIP BASED UPON THEIR EXPERIENCE, JUDGMENT, AND NEEDS.,METAL LIGATING CLIPS(WECK HORIZON LIGATING CLIPS)-WECK® LIGATING CLIPS ARE INTENDED FOR USE IN PROCEDURES INVOLVING VESSELS OR ANATOMIC STRUCTURES FOR WHICH THE SURGEON DETERMINES LIGATING CLIPS ARE THE BEST CHOICE. SURGEONS SHOULD SELECT THE SIZE, TYPE, AND MATERIAL OF THE CLIP BASED UPON THEIR EXPERIENCE, JUDGMENT, AND NEEDS.
1618	IMP/MD/2019/000166	1.License Holder Name: M/S. IMPLANTIUM INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RESORBABLE DENTAL BARRIER MEMBRANE, ANIMAL SOURCE(GENOSS COLLAGEN MEMBRANE)-TISSUE RECONSTRUCTIVE MATERIALS
1619	IMP/MD/2019/000167	1.License Holder Name: SUN PHARMACEUTICAL INDUSTRIES LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK SCF™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS

1620	IMP/MD/2019/000168	1.License Holder Name: ADLER MEDIEQUIP PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHOPAEDIC NAILS-RAW MATERIAL FOR FURTHER PROCESSING WHICH IS USED FOR INTERNAL FIXATION.,ORTHOPAEDIC SCREWS-RAW MATERIAL FOR FURTHER PROCESSING WHICH IS USED FOR INTERNAL FIXATION.
1621	IMP/MD/2019/000169	1.License Holder Name: TRANSLUMINA THERAPEUTICS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDING CATHETER (NON STERILE)(NIL)-THE GUIDING CATHETER IS DESIGNED TO PROVIDE A PATHWAY THROUGH WHICH THERAPEUTIC AND DIAGNOSTIC DEVICES ARE INTRODUCED. THE GUIDING CATHETER IS INTENDED TO BE USED IN THE CORONARY OR PERIPHERAL VASCULAR SYSTEM
1622	IMP/MD/2019/000170	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NON-VASCULAR GUIDEWIRES(ZIPWIRE HYDROPHILLIC GUIDEWIRE)-THE ZIPWIRE HYDROPHILIC GUIDEWIRE IS INTENDED TO FACILITATE THE PLACEMENT OF ENDOUROLOGICAL INSTRUMENTS DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURES. THE ZIPWIRE HYDROPHILIC GUIDEWIRE IS NOT INTENDED FOR CORONARY ARTERY, VASCULAR OR NEUROLOGICAL USE.,CARDIAC CATHETER GUIDEWIRE(SAFARI 2 GUIDEWIRE)- THE SAFARI 2 GUIDEWIRE IS INTENDED TO FACILITATE THE INTRODUCTION AND PLACEMENT OF INTERVENTIONAL DEVICES WITHIN THE CHAMBERS OF THE HEART INCLUDING THOSE USED WITHIN TRANSCATHETER AORTIC VALVE PROCEDURES.

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1623	IMP/MD/2019/000171	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC SYRINGES(BD LUER LOK TIP)-THESE PRODUCTS ARE USED FOR GENERAL PURPOSE INJECTION AND ASPIRATION OF FLUIDS FROM VIALS, AMPOULES AND PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.,DISPOSABLE HYPODERMIC SYRINGE(BD LUER-LOK SYRINGE)-THESE PRODUCTS ARE USED FOR GENERAL PURPOSE INJECTION AND ASPIRATION OF FLUIDS FROM VIALS, AMPOULES AND PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.,DISPOSABLE HYPODERMIC SYRINGES(BD PLASTIPAK)-THESE PRODUCTS ARE USED FOR GENERAL PURPOSE INJECTION AND ASPIRATION OF FLUIDS FROM VIALS, AMPOULES AND PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.,DISPOSABLE HYPODERMIC SYRINGES(BD SAFETYGLIDE INJECTION NEEDLE WITH LUER-LOK SYRINGE)-INTENDED FOR GENERAL PURPOSE INJECTION AND ASPIRATION OF FLUIDS FROM VIALS, AMPOULES AND PARTS OF BODY BELOW THE SURFACE OF SKIN,DISPOSABLE HYPODERMIC NEEDLE(BD SAFETYGLIDE NEEDLE)-INTENDED FOR GENERAL PURPOSE INJECTION AND ASPIRATION OF FLUIDS FROM VIALS, AMPOULES AND PARTS OF BODY BELOW THE SURFACE OF SKIN

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1624	IMP/MD/2019/000172	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIP SYSTEM - HEAD(ELITE PLUS)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS: 1.A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMA?C ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3.A CUTE TRAUMA?C FRACTURE OF THE FEMORAL HEAD OR NECK. 4.F AILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5.CERTAIN CASES OF ANKYLOSIS.,HIP SYSTEM- STEM(CORAIL)-THIS STEM IS INDICATED ONLY FOR USE WITH BONE CEMENT. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3. ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK. 4. FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5.CERTAIN CASES OF ANKYLOSIS.,HIP SYSTEM - CUPS(DURALOC)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS: 1.A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMA?C ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3.A CUTE TRAUMA?C FRACTURE OF THE FEMORAL HEAD OR NECK. 4.F AILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5.

	CERTAIN CASES OF ANKYLOSIS.,HIP SYSTEM- STEM(C-STEM AMT)- TOTAL HIP PROSTHESIS TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3. ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK. 4. FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5. CERTAIN CASES OF ANKYLOSIS. HEMI-HIP PROSTHESIS HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM. HEMI-HIP ARTHROPLASTY IS INDICATED IN THE FOLLOWING CONDITIONS: 1. ACUTE FRACTURE OF THE FEMORAL HEAD OR NECK THAT CANNOT BE APPROPRIATELY REDUCED AND TREATED WITH INTERNAL FIXATION. 2. FRACTURE DISLOCATION OF THE HIP THAT CANNOT BE APPROPRIATELY REDUCED AND TREATED WITH INTERNAL FIXATION. 3.AVASCULAR NECROSIS OF THE FEMORAL HEAD. 4. NON-UNION OF FEMORAL NECK FRACTURES. 5. CERTAIN HIGH SUBCAPITAL AND FEMORAL NECK FRACTURES IN THE ELDERLY. 6. DEGENERATIVE ARTHRITIS INVOLVING ONLY THE FEMORAL HEAD IN WHICH THE ACETABULUM DOES NOT REQUIRE REPLACEMENT. 7. PATHOLOGY INVOLVING ONLY THE FEMORAL HEAD/NECK AND/OR PROXIMAL FEMUR THAT CAN BE ADEQUATELY TREATED BY HEMI-HIP ARTHROPLASTY. 8. WHERE THE ACETABULUM BECOMES SYMPTOMATIC FOLLOWING HEMI-HIP ARTHROPLASTY, CONVERSION TO A TOTAL HIP ARTHROPLASTY WITH RETENTION OF THE MODULAR HEMI ARTHROPLASTY STEM, WITH A NEW ACETABULAR CUP AND COMPATIBLE FEMORAL HEAD, MAY BE PREFERABLE TO REVISION OF THE HEMI-HIP PROSTHESIS. TOTAL OR HEMI HIP ARTHROPLASTY MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR HIP REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT AND IF LIMITED DEMANDS REGARDING ACTIVITY AND HIP JOINT LOADING CAN BE ASSURED (SEE WARNINGS AND PRECAUTIONS SECTION). THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN

	IN HIP MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,HIP SYSTEM - LINERS(DURALOC)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS: 1.A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMA?C ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3.A CUTE TRAUMA?C FRACTURE OF THE FEMORAL HEAD OR NECK. 4.F AILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5. CERTAIN CASES OF ANKYLOSIS.,HIP REPLACEMENT SYSTEM- HEAD (ARTICUL/EZE)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM., POLYETHYLENE ACETABULUM PROSTHESIS - CUPS(MARATHON XLPE)-IT IS INDICATED FOR SEVERE ARTHROPATHY DUE TO ADVANCED RHEUMATOID OR OSTEOARTHRITIS WHERE CONSERVATIVE THERAPY OR ALTERNATIVE TREATMENTS HAVE FAILED OR ARE CONSIDERED UNSUITABLE, ARTHROPATHY DUE TO DEGENERATIVE DISEASE, ACUTE TRAUMA, AND A PREVIOUS FAILED JOINT REPLACEMENT. THE PATIENT'S JOINT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE SELECTED IMPLANT(S).,HIP REPLACEMENT SYSTEM- STEM(C-STEM)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS HERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.,HIP SYSTEM - CUPS(ELITE PLUS)-IT IS INDICATED FOR SEVERE ARTHROPATHY DUE TO ADVANCED

	RHEUMATOID OR OSTEOARTHRITIS WHERE CONSERVATIVE THERAPY OR ALTERNATIVE TREATMENTS HAVE FAILED OR ARE CONSIDERED UNSUITABLE, ARTHROPATHY DUE TO DEGENERATIVE DISEASE, ACUTE TRAUMA, AND A PREVIOUS FAILED JOINT REPLACEMENT. THE PATIENT'S JOINT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE SELECTED IMPLANT(S).,HIP REPLACEMENT SYSTEM- REVISION STEM(C-STEM)-TOTAL HIP PROSTHESIS TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3. ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK. 4. FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HERNIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5. CERTAIN CASES OF ANKYLOSIS. HEMI-HIP PROSTHESIS HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM. HEMI-HIP ARTHROPLASTY IS INDICATED IN THE FOLLOWING CONDITIONS: 1. ACUTE FRACTURE OF THE FEMORAL HEAD OR NECK THAT CANNOT BE APPROPRIATELY REDUCED AND TREATED WITH INTERNAL FIXATION. 2. FRACTURE DISLOCATION OF THE HIP THAT CANNOT BE APPROPRIATELY REDUCED AND TREATED WITH INTERNAL FIXATION. 3. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 4. NON-UNION OF FEMORAL NECK FRACTURES. 5. CERTAIN HIGH SUBCAPITAL AND FEMORAL NECK FRACTURES IN THE ELDERLY. 6. DEGENERATIVE ARTHRITIS INVOLVING ONLY THE FEMORAL HEAD IN WHICH THE ACETABULUM DOES NOT REQUIRE REPLACEMENT. 7. PATHOLOGY INVOLVING ONLY THE FEMORAL HEAD/NECK AND/OR PROXIMAL FEMUR THAT CAN BE ADEQUATELY TREATED BY HEMI-HIP ARTHROPLASTY. 8. WHERE THE ACETABULUM BECOMES SYMPTOMATIC FOLLOWING HEMI-HIP ARTHROPLASTY, CONVERSION TO A TOTAL HIP ARTHROPLASTY WITH RETENTION OF THE MODULAR HEMI ARTHROPLASTY STEM, WITH A NEW ACETABULAR CUP AND COMPATIBLE FEMORAL HEAD, MAY BE PREFERABLE TO REVISION OF THE HEMI-HIP PROSTHESIS. TOTAL OR HEMI HIP ARTHROPLASTY MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF

	THE SURGEON, AN UNEQUIVOCAL INDICATION FOR HIP REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT AND IF LIMITED DEMANDS REGARDING ACTIVITY AND HIP JOINT LOADING CAN BE ASSURED (SEE WARNINGS AND PRECAUTIONS SECTION). THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN HIP MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,CEMENT RESTRICTOR(HARDINGE CEMENT RESTRICTOR)-HARDINGE CEMENT RESTRICTOR IS INDICATED FOR USE WITH CEMENTED FEMORAL STEMS TO OCCLUDE THE MEDULLARY CANAL TO ENABLE CEMENT CONTAINMENT, TO FACILITATE CEMENT PRESSURISATION TO ACHIEVE CEMENTBONE INTERDIGITATION AND PREVENT EXCESSIVE BONE CEMENT USAGE. IT CAN BE USED WITH ANY CEMENTED FEMORAL STEM UP TO A MAXIMUM OF 220MM IN LENGTH.

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1625	IMP/MD/2019/000173	1.License Holder Name: TERUMO PENPOL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTION SET (PLATELET POOLING SET 41910)-THE PLATELET POOLING SET IS INTENDED FOR USE WITH WHOLE BLOOD DERIVED PLATELETS, INCLUDING POOLING AND FILTRATION, RESULTING IN A PLATELET PRODUCT FOR TRANSFUSION.,ADIPREP PROCEDURE PACK (HARVEST)-THE ADIPREP® ADIPOSE TRANSFER SYSTEM IS USED IN MEDICAL PROCEDURES INVOLVING THE HARVESTING AND TRANSFERRING OF AUTOLOGOUS TISSUE. THE ADIPREP SYSTEM IS USED FOR CONCENTRATING ADIPOSE TISSUE HARVESTED WITH A LEGALLY MARKETED LIPOPLASTY SYSTEM. THE ADIPREP ADIPOSE TRANSFER SYSTEM IS INTENDED FOR USE IN THE FOLLOWING SURGICAL SPECIALTIES WHEN THE CONCENTRATION OF HARVESTED ADIPOSE TISSUE IS DESIRED: ARTHROSCOPIC SURGERY, GASTROINTESTINAL SURGERY, GENERAL SURGERY, GYNECOLOGICAL SURGERY, LAPAROSCOPIC SURGERY, NEUROSURGERY, PLASTIC AND RECONSTRUCTIVE SURGERY, THORACIC SURGERY, AND UROLOGICAL SURGERY.,BLOOD COLLECTION SET(SPECTRA OPTIA BMP ACCESSORY SET 11300)-THE SPECTRA OPTIA BMP ACCESSORY SET IS INTENDED FOR USE WITH THE SPECTRA OPTIA APHERESIS SYSTEM.,DUAL LIQUID APPLICATOR KIT(HARVEST)-THE SMARTJET® BONE LIQUID APPLICATOR IS DESIGNED TO FACILITATE PRE-MIXING OF ALLOGRAFT, AUTOGRAFT, OR SYNTHETIC BONE GRAFT MATERIALS FOR APPLICATION TO AN ORTHOPEDIC SURGICAL SITE, WITH I.V. FLUIDS, AUTOLOGOUS BLOOD, PLASMA, PLATELETRICH PLASMA, OR OTHER SPECIFIC BLOOD COMPONENTS AS DEEMED NECESSARY BY THE CLINICAL USE REQUIREMENTS.,BLOOD COLLECTION SET(SPECTRA OPTIA EXCHANGE SET 10220)-THE SPECTRA OPTIA APHERESIS SYSTEM IS INTENDED FOR USE IN THERAPEUTIC APHERESIS APPLICATIONS. THE SPECTRA OPTIA EXCHANGE SET IS INTENDED FOR USE WITH THE SPECTRA OPTIA APHERESIS SYSTEM.,CLEAR PRP KIT(HARVEST)-THE HARVEST® PRP SEPARATION SYSTEM IS DESIGNED TO BE USED FOR THE SAFE AND RAPID PREPARATION OF AUTOLOGOUS PLATELETRICH PLASMA FROM A SMALL SAMPLE OF BLOOD AT THE PATIENT'S POINT OF CARE. THE PRP IS MIXED WITH AUTOGRAFT AND/OR ALLOGRAFT BONE PRIOR TO APPLICATION TO A BONY DEFECT FOR IMPROVING HANDLING CHARACTERISTICS.,BLOOD COLLECTION SET(SPECTRA OPTIA IDL SET 10300)-THE SPECTRA OPTIA APHERESIS SYSTEM IS INTENDED FOR USE IN THERAPEUTIC APHERESIS APPLICATIONS. THE SPECTRA OPTIA IDL SET IS INTENDED FOR USE WITH THE SPECTRA OPTIA APHERESIS SYSTEM., SPRAY APPLICATOR KIT(HARVEST)-THE SMARTJET GRAFTING

	LIQUID APPLICATOR IS INTENDED FOR THE APPLICATION OF FLUIDS, AS DEEMED NECESSARY, BY THE SURGEON'S DETERMINATION OF THE CLINICAL USE REQUIREMENTS, TO FACILITATE THE PREPARATION OF SOFT TISSUE AUTOGRAFT MATERIAL PRIOR TO THE APPLICATION OF THE GRAFT MATERIAL TO A REPAIR SITE., BLOOD COLLECTION SET(SPECTRA OPTIA COLLECTION SET 10120)-THE SPECTRA OPTIA APHERESIS SYSTEM IS INTENDED FOR USE IN THERAPEUTIC APHERESIS APPLICATIONS. THE SPECTRA OPTIA COLLECTION SET IS INTENDED FOR USE WITH THE SPECTRA OPTIA APHERESIS SYSTEM.,AUTOLOGOUS PLATELET CONCENTRATE PROCEDURE PACK(HARVEST)-THE HARVEST® PRP SEPARATION SYSTEM IS DESIGNED TO BE USED FOR THE SAFE AND RAPID PREPARATION OF AUTOLOGOUS PLATELETRICH PLASMA FROM A SMALL SAMPLE OF BLOOD AT THE PATIENT'S POINT OF CARE. THE PRP CAN BE MIXED WITH AUTOGRAFT AND ALLOGRAFT BONE MATERIALS PRIOR TO APPLICATION TO AN ORTHOPEDIC SURGICAL SITE AS DEEMED NECESSARY BY THE CLINICAL USE REQUIREMENTS., BLOOD COLLECTION SET(SPECTRA OPTIA IDL SET 10310)-THE SPECTRA OPTIA APHERESIS SYSTEM IS INTENDED FOR USE IN THERAPEUTIC APHERESIS AND CELL COLLECTIONS. THE SPECTRA OPTIA IDL SET IS INTENDED FOR USE WITH THE SPECTRA OPTIA APHERESIS SYSTEM.,GRAFT DELIVERY PACK(HARVEST)-THE HARVEST GRAFT DELIVERY SYSTEM IS INDICATED FOR THE DELIVERY OF ALLOGRAFT, AUTOGRAFT, OR SYNTHETIC BONE GRAFT MATERIALS TO AN ORTHOPEDIC SURGICAL SITE. IN ADDITION, IT IS DESIGNED TO FACILITATE PRE-MIXING OF BONE GRAFT MATERIALS WITH INTRAVENOUS FLUIDS, BLOOD, PLASMA, PLATELETRICH PLASMA, BONE MARROW, OR OTHER SPECIFIC BLOOD COMPONENT (S) AS DEEMED NECESSARY BY THE CLINICAL USE REQUIREMENTS., BLOOD COLLECTION SET(SPECTRA OPTIA PLATELET, PLASMA SET 10400)-THE SPECTRA OPTIA PLATELET, PLASMA SET IS INTENDED FOR USE WITH THE SPECTRA OPTIA APHERESIS SYSTEM TO COLLECT PLATELETS AND PLASMA.,BONE MARROW ASPIRATE CONCENTRATE PROCEDURE PACK(HARVEST)-THE SMARTPREP BONE MARROW PROCEDURE PACK USED IN CONJUNCTION WITH THE SMARTPREP® CENTRIFUGE SYSTEM IS INTENDED TO BE USED IN THE CLINICAL LABORATORY OR INTRA-OPERATIVELY AT THE POINT OF CARE FOR THE SAFE AND RAPID PREPARATION OF A CELL CONCENTRATE FROM BONE MARROW.,BLOOD COLLECTION SET(MIRASOL® 10090)-THE MIRASOL SYSTEM IS INTENDED TO REDUCE THE PATHOGEN LOAD AND INACTIVATE RESIDUAL WHITE BLOOD CELLS IN DONOR PLATELET CONCENTRATES FOR TRANSFUSION.,BLOOD COLLECTION SET(COBE® SPECTRA 70500)-COBE SPECTRA TUBING SETS ARE INTENDED FOR USE WITH THE COBE SPECTRA APHERESIS SYSTEM.,

	BLOOD COLLECTION SET(MIRASOL® 10590)-THE MIRASOL SYSTEM IS INTENDED TO REDUCE THE PATHOGEN LOAD AND INACTIVATE RESIDUAL WHITE BLOOD CELLS IN DONOR PLATELET CONCENTRATES FOR TRANSFUSION.,BLOOD COLLECTION SET (COBE® SPECTRA 70300)-COBE SPECTRA TUBING SETS ARE INTENDED FOR USE WITH THE COBE SPECTRA APHERESIS SYSTEM., BLOOD COLLECTION SET(MIRASOL® 10790)-THE MIRASOL SYSTEM IS INTENDED TO REDUCE THE PATHOGEN LOAD AND INACTIVATE RESIDUAL WHITE BLOOD CELLS IN DONOR PLATELET CONCENTRATES FOR TRANSFUSION.,BLOOD COLLECTION SET (COBE® SPECTRA 70600)-COBE SPECTRA TUBING SETS ARE INTENDED FOR USE WITH THE COBE SPECTRA APHERESIS SYSTEM., BLOOD COLLECTION SET(MIRASOL® 10690)-THE MIRASOL SYSTEM IS INTENDED TO REDUCE THE PATHOGEN LOAD AND INACTIVATE RESIDUAL WHITE BLOOD CELLS IN DONOR PLATELET CONCENTRATES FOR TRANSFUSION.,BLOOD COLLECTION SET (COBE® SPECTRA 70700)-COBE SPECTRA TUBING SETS ARE INTENDED FOR USE WITH THE COBE SPECTRA APHERESIS SYSTEM., BLOOD COLLECTION SET(TRIMA ACCEL 80300, 82300)-TRIMA ACCEL DISPOSABLE TUBING SETS ARE INTENDED FOR USE WITH THE TRIMA ACCEL AUTOMATED BLOOD COLLECTION SYSTEM.,BONE MARROW CELL SEPARATOR(HARVEST SMARTPREP 3)-THE SMARTPREP 3 SYSTEM IS DESIGNED TO BE USED FOR THE SAFE AND RAPID PREPARATION OF AUTOLOGOUS PLATELETRICH PLASMA (PRP) FROM A SMALL SAMPLE OF BLOOD AT THE PATIENT'S POINT OF CARE. THE PRP CAN BE MIXED WITH AUTOGRAFT OR ALLOGRAFT BONE GRAFTING MATERIALS PRIOR TO APPLICATION TO AN ORTHOPEDIC SURGICAL SITE AS DEEMED NECESSARY BY THE CLINICAL USE REQUIREMENTS. THE SMARTPREP 3 SYSTEM IS INTENDED TO BE USED IN THE CLINICAL LABORATORY OR INTRAOPERATIVELY AT THE POINT OF CARE FOR THE SAFE AND RAPID PREPARATION OF PLATELETPOOR PLASMA AND PLATELET CONCENTRATE FROM A SMALL SAMPLE OF BLOOD AND FOR PREPARATION OF A CELL CONCENTRATE FROM BONE MARROW. THE ADIPREP® ADIPOSE TRANSFER SYSTEM IS USED IN MEDICAL PROCEDURES INVOLVING THE HARVESTING AND TRANSPLANTING OF AUTOLOGOUS TISSUE. THE ADIPREP SYSTEM IS USED FOR CONCENTRATING ADIPOSE TISSUE HARVESTED WITH A LEGALLY MARKETED LIPOPLASTY SYSTEM. THE ADIPREP ADIPOSE TRANSFER SYSTEM IS INTENDED FOR USEIN THEFOLLOWING SURGICAL SPECIALTIES WHEN THE CONCENTRATION OF HARVESTED ADIPOSETISSUEIS DESIRED: ARTHROSCOPIC SURGERY, GASTROINTESTINAL SURGERY, GENERAL SURGERY, GYNECOLOGICAL SURGERY, LAPAROSCOPIC SURGERY,

	NEUROSURGERY, PLASTIC AND RECONSTRUCTIVE SURGERY, THORACIC SURGERY, AND UROLOGICAL SURGERY.,BLOOD COLLECTION SET(TRIMA ACCEL 80410, 82410)-TRIMA ACCEL DISPOSABLE TUBING SETS ARE INTENDED FOR USE WITH THE TRIMA ACCEL AUTOMATED BLOOD COLLECTION SYSTEM.,BONE MARROW CELL SEPARATOR(HARVEST SMARTPREP 2)-THE SMARTPREP 2 SYSTEM IS DESIGNED TO BE USED FOR THE SAFE AND RAPID PREPARATION OF AUTOLOGOUS PLATELETRICH PLASMA (PRP) FROM A SMALL SAMPLE OF BLOOD AT THE PATIENT'S POINT OF CARE. THE PRP CAN BE MIXED WITH AUTOGRAFT OR ALLOGRAFT BONE GRAFTING MATERIALS PRIOR TO APPLICATION TO AN ORTHOPEDIC SURGICAL SITE AS DEEMED NECESSARY BY THE CLINICAL USE REQUIREMENTS. THE SMARTPREP 2 SYSTEM IS INTENDED TO BE USED IN THE CLINICAL LABORATORY OR INTRAOPERATIVELY AT THE POINT OF CARE FOR THE SAFE AND RAPID PREPARATION OF PLATELETPOOR PLASMA AND PLATELET CONCENTRATE FROM A SMALL SAMPLE OF BLOOD AND FOR PREPARATION OF A CELL CONCENTRATE FROM BONE MARROW. THE ADIPREP® ADIPOSE TRANSFER SYSTEM IS USED IN MEDICAL PROCEDURES INVOLVING THE HARVESTING AND TRANSPLANTING OF AUTOLOGOUS TISSUE. THE ADIPREP SYSTEM IS USED FOR CONCENTRATING ADIPOSE TISSUE HARVESTED WITH A LEGALLY MARKETED LIPOPLASTY SYSTEM. THE ADIPREP ADIPOSE TRANSFER SYSTEM IS INTENDED FOR USEIN THEFOLLOWING SURGICAL SPECIALTIES WHEN THE CONCENTRATION OF HARVESTED ADIPOSETISSUEIS DESIRED: ARTHROSCOPIC SURGERY, GASTROINTESTINAL SURGERY, GENERAL SURGERY, GYNECOLOGICAL SURGERY, LAPAROSCOPIC SURGERY, NEUROSURGERY, PLASTIC AND RECONSTRUCTIVE SURGERY, THORACIC SURGERY, AND UROLOGICAL SURGERY.,BLOOD COLLECTION SET(TRIMA ACCEL 80406, 82406)-TRIMA ACCEL DISPOSABLE TUBING SETS ARE INTENDED FOR USE WITH THE TRIMA ACCEL AUTOMATED BLOOD COLLECTION SYSTEM.,BLOOD COLLECTION SET(MIRASOL® 10390)-THE MIRASOL PRT SYSTEM IS INTENDED TO REDUCE THE PATHOGEN LOAD AND INACTIVATE RESIDUAL WHITE BLOOD CELLS IN DONOR PLASMA FOR TRANSFUSION.,BLOOD COLLECTION SET(TRIMA ACCEL 80500, 82500)-TRIMA ACCEL DISPOSABLE TUBING SETS ARE INTENDED FOR USE WITH THE TRIMA ACCEL AUTOMATED BLOOD COLLECTION SYSTEM.,BLOOD COLLECTION SET(TRIMA ACCEL 80400, 82400)-TRIMA ACCEL DISPOSABLE TUBING SETS ARE INTENDED FOR USE WITH THE TRIMA ACCEL AUTOMATED BLOOD COLLECTION SYSTEM., BLOOD COLLECTION SET(TRIMA ACCEL 80310, 82310)-TRIMA ACCEL DISPOSABLE TUBING SETS ARE INTENDED FOR USE WITH THE TRIMA

		ACCEL AUTOMATED BLOOD COLLECTION SYSTEM.
1626	IMP/MD/2019/000174	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYPODERMIC NEEDLE (SURGUARD®2 SAFETY HYPODERMIC NEEDLE)-INTENDED FOR USE IN THE ASPIRATION AND INJECTION OF FLUIDS FORMEDICAL PURPOSES SUCH AS INJECTING MEDICATION SOLUTION INTO TISSUES SUCH AS AN INTRACUTANEOUS TISSUE, A SUBCUTANEOUS TISSUE, A MUSCLE,ETC.OR BODY CAVITIES, ORCOLLECTING BLOOD OR BODY FLUID.,SYRINGE(TERUMO SYRINGE WITH AND WITHOUT NEEDLE)-INTENDED FOR USE IN THE ASPIRATION AND/OR INJECTION OF FLUIDS FOR MEDICAL PURPOSES SUCH AS INJECTING MEDICATION SOLUTION INTO TISSUES SUCH AS AN INTRACUTANEOUS TISSUE, A SUBCUTANEOUS TISSUE, A MUSCLE, ETC. OR BODY CAVITIES, OR COLLECTING BLOOD OR BODY FLUID., HYPODERMIC NEEDLE(SURGUARD®3 SAFETY HYPODERMIC NEEDLE) -INTENDED FOR USE IN THE ASPIRATION AND INJECTION OF FLUIDS FORMEDICAL PURPOSES SUCH AS INJECTING MEDICATION SOLUTION INTO TISSUES SUCH AS AN INTRACUTANEOUS TISSUE, A SUBCUTANEOUS TISSUE, A MUSCLE,ETC.OR BODY CAVITIES, ORCOLLECTING BLOOD OR BODY FLUID.,HYPODERMIC SYRINGES WITH SAFETY NEEDLE(TERUMO SURGUARD3 HYPODERMIC SYRINGE WITH SAFETY NEEDLE)-INTENDED FOR USE IN THE ASPIRATION AND/OR INJECTION OF FLUIDS FOR MEDICAL PURPOSES; SUCH AS INJECTING MEDICATION SOLUTION INTO TISSUES AND BODY CAVITIES, OR COLLECTING BLOOD AND BODY FLUID.,NEEDLE (TERUMO NEEDLE)-INTENDED FOR USE IN THE ASPIRATION AND/OR INJECTION OF FLUIDS FOR MEDICAL PURPOSES.

1627	IMP/MD/2019/000178	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISINFECTING CAP(BD PUREHUB™ DISINFECTING CAP)-BD PUREHUB™ DISINFECTING CAPS ARE INTENDED TO BE USED AS A DISINFECTING DEVICE FOR SWABBABLE NEEDLE-FREE LUER CONNECTORS PRIOR TO ACCESS AND TO ACT AS A PHYSICAL BARRIER BETWEEN LINE ACCESSES., DISPOSABLE HYPODERMIC NEEDLE(BD BLUNT FILL NEEDLE)-INTENDED FOR ASPIRATION OF FLUIDS FROM VIALS AND AMPOULES. NOT FOR SKIN INJECTION,HEPARIN LOCK FLUSH SYRINGE(BD POSIFLUSH HEPARIN LOCK FLUSH SYRINGE)-FOR USE IN MAINTAINING PATENCY OF VASCULAR ACCESS DEVICES (FOR FLUSHING ONLY),FLUSH SYRINGE(BD POSIFLUSH SP)-FOR USE IN MAINTAINING PATENCY OF VASCULAR ACCESS DEVICES (FOR FLUSHING ONLY) ,DISPOSABLE HYPODERMIC NEEDLE(BD BLUNT FILL NEEDLE WITH FILTER)-INTENDED FOR ASPIRATION OF FLUIDS FROM VIALS AND AMPOULES. NOT FOR SKIN INJECTION
1628	IMP/MD/2019/000179	1.License Holder Name: OLYMPUS MEDICAL SYSTEMS INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASPIRATION NEEDLE (VIZISHOT 2 FLEX)-THE VIZISHOT 2 FLEX HAS BEEN DESIGNED TO BE USED WITH ULTRASOUND ENDOSCOPES FOR ULTRASOUND GUIDED FINE NEEDLE ASPIRATION (FNA) OF SUBMUCOSAL AND EXTRAMURAL LESIONS OF THE TRACHEOBRONCHIAL TREE.

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1629	IMP/MD/2019/000180	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEART VALVE-AORTIC (MEDTRONIC OPEN PIVOT)-THE MEDTRONIC OPEN PIVOT HEART VALVE IS INTENDED FOR USE AS A REPLACEMENT VALVE IN PATIENTS WITH DISEASED, DAMAGED, OR MALFUNCTIONING HEART VALVES. THIS DEVICE MAY ALSO BE USED TO REPLACE A PREVIOUSLY IMPLANTED PROSTHETIC HEART VALVE.,AORTIC VALVE GRAFT(MEDTRONIC OPEN PIVOT)-THE AVG IS INTENDED FOR USE SECONDARY TO A DISEASED, DAMAGED, OR MALFUNCTIONING AORTIC VALVE WITH AORTIC ANEURYSMAL OR OCCLUSIVE DISEASE WHERE A REPLACEMENT OR REPAIR OF THE AORTA IS REQUIRED. THIS DEVICE MAY BE USED TO REPLACE A PREVIOUSLY IMPLANTED PROSTHETIC HEART VALVE AND CONDUIT.,HEART VALVE-MITRAL (MEDTRONIC OPEN PIVOT)-THE MEDTRONIC OPEN PIVOT HEART VALVE IS INTENDED FOR USE AS A REPLACEMENT VALVE IN PATIENTS WITH DISEASED, DAMAGED, OR MALFUNCTIONING HEART VALVES. THIS DEVICE MAY ALSO BE USED TO REPLACE A PREVIOUSLY IMPLANTED PROSTHETIC HEART VALVE.
1630	IMP/MD/2019/000181	1.License Holder Name: M/S MATSON SURGICALS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOLEY CATHETERS (BARDIA FOLEY CATHETERS)-THE FOLEY CATHETERS ARE INDICATED FOR THE DRAINAGE AND/OR COLLECTION AND/OR MEASUREMENT OF URINE.,FOLEY CATHETERS(BARDEX FOLEY CATHETERS)-THE FOLEY CATHETER ARE INDICATED FOR THE DRAINAGE AND/OR COLLECTION AND/OR MEASUREMENT OF URINE.

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1631	IMP/MD/2019/000182	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SKIN CLOSURE SYSTEM (DERMABOND PRINEO SKIN CLOSURE SYSTEM)-DERMABOND™ PRINEO™ SYSTEM IS INTENDED FOR TOPICAL APPLICATION ONLY TO HOLD CLOSED EASILY APPROXIMATED SKIN EDGES OF WOUNDS FROM SURGICAL INCISIONS INCLUDING PUNCTURES FROM MINIMALLY INVASIVE SURGERY AND SIMPLE THOROUGHLY CLEANSED TRAUMA-INDUCED LACERATIONS. DERMABOND™ PRINEO™ SYSTEM SHOULD BE USED IN CONJUNCTION WITH BUT NOT IN PLACE OF DEEP DERMAL STITCHES. ADDITIONALLY, THE ADJUNCT WOUND CLOSURE DEVICE COMPONENT MAINTAINS TEMPORARY SKIN EDGE ALIGNMENT ALONG THE LENGTH OF THE WOUND DURING APPLICATION OF THE LIQUID ADHESIVE.,ENDOSCOPIC APPLICATOR (SURGICEL ENDOSCOPIC APPLICATOR)-THE SURGICEL ENDOSCOPIC APPLICATOR IS INTENDED FOR USE IN DELIVERING SURGICEL POWDER ABSORBABLE HEMOSTAT TO BLEEDING SURGICAL SITES THROUGH A 5 MM OR LARGER TROCAR.,HAEMOSTAT(SURGICEL POWDER)-SURGICEL POWDER (OXIDIZED REGENERATED CELLULOSE) IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS, AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE. SURGICEL POWDER CAN ALSO BE APPLIED IN LAPAROSCOPIC OR OTHER ENDOSCOPIC PROCEDURES WHEN USED WITH THE SURGICEL ENDOSCOPIC APPLICATOR.

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1632	IMP/MD/2019/000182	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED ,A-1/50, ROOM NO. 2, 100 SHED AREA, G.L.D.C., VAPI, TAL PARDI (VALSAD) , VALSAD GUJARAT ,396195 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUTURES(MERSILENE TAPE SUTURE)-"MERSILENE™ TAPE IS INDICATED FOR CIRCULAR SUTURE OF THE CERVIX. NON-NEEDLED TAPES ARE USED AS RETRACTION AND/OR FIXING TAPE DURING SURGERY.",SUTURES (PROLENE(NON-CE))-"PROLENE™ SUTURES ARE FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN CARDIOVASCULAR OPHTHALMIC AND NEUROSURGICAL PROCEDURES.",SUTURES(PROLENE(CE))-PROLENE™ SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN CARDIOVASCULAR OPHTHALMIC AND NEUROSURGICAL PROCEDURES.,ADHESION BARRIER(GYNECARE INTERCEED)-GYNECARE INTERCEED™ ABSORBABLE ADHESION BARRIER IS INDICATED AS AN ADJUVANT IN OPEN (LAPAROTOMY) GYNECOLOGIC PELVIC SURGERY FOR REDUCING THE INCIDENCE OF POSTOPERATIVE PELVIC ADHESIONS AFTER METICULOUS HEMOSTASIS IS ACHIEVED CONSISTENT WITH MICROSURGICAL PRINCIPLES.,SKIN CLOSURE SYSTEM(DERMABOND PRINEO)-"DERMABOND™ PRINEO™ SYSTEM IS INTENDED FOR TOPICAL APPLICATION ONLY TO HOLD CLOSED EASILY APPROXIMATED SKIN EDGES OF WOUNDS FROM SURGICAL INCISIONS INCLUDING PUNCTURES FROM MINIMALLY INVASIVE SURGERY AND SIMPLE THOROUGHLY CLEANSED TRAUMA-INDUCED LACERATIONS. DERMABOND™ PRINEO™ SYSTEM SHOULD BE USED IN CONJUNCTION WITH BUT NOT IN PLACE OF DEEP DERMAL STITCHES. ADDITIONALLY THE ADJUNCT WOUND CLOSURE DEVICE COMPONENT MAINTAINS TEMPORARY SKIN EDGE ALIGNMENT ALONG THE LENGTH OF THE WOUND DURING APPLICATION OF THE LIQUID ADHESIVE.",SUTURES(VIRGIN SILK)-"SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN CARDIOVASCULAR OPHTHALMIC AND NEUROSURGICAL PROCEDURES.",TOPICAL SKIN ADHESIVE(DERMABOND TOPICAL SKIN ADHESIVES)-"DERMABOND TOPICAL SKIN ADHESIVE IS INTENDED FOR TOPICAL APPLICATION ONLY TO HOLD CLOSED EASILY APPROXIMATED SKIN EDGES OF WOUNDS FROM SURGICAL INCISIONS INCLUDING INCISIONS FROM MINIMALLY INVASIVE SURGERY AND SIMPLE THOROUGHLY CLEANSED TRAUMA-INDUCED LACERATIONS. DERMABOND ADHESIVE MAY BE USED IN CONJUNCTION WITH BUT NOT IN PLACE OF DEEP DERMAL STITCHES.",SUTURES(ETHIBOND EXCEL (CE))-

	ETHIBOND EXCEL SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN CARDIOVASCULAR OPTHALMIC AND NEUROLOGICAL PROCEDURES, MESH(PROLENE POLYPROPYLENE SOFT MESH(CE))-"THIS MESH MAY BE USED FOR THE REPAIR OF HERNIA OR OTHER FASCIAL DEFECTS THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT.",SUTURES (SURGICAL STAINLESS STEEL SUTURE(CE))-"STAINLESS STEEL SUTURES ARE FOR USE IN ABDOMINAL WOUND CLOSURE HERNIA REPAIR STERNAL CLOSURE AND ORTHOPEDIC PROCEDURES INCLUDING CERCLAGE AND TENDON REPAIR.",HEMOSTAT(SURGICEL FIBRILLAR ABSORBABLE HEMOSTAT)-"SURGICEL® ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS INDICATED FOR ADJUNCTIVE USE TO ASSIST IN THE CONTROL OF BLEEDING IN EXODONTIA AND ORAL SURGERY. IT MAY ALSO BE USED TO HELP ACHIEVE HEMOSTASIS AFTER SINGLE OR MULTIPLE TOOTH EXTRACTIONS ALVEOLOPLASTY GINGIVAL HEMORRHAGE IMPACTIONS BIOPSIES AND OTHER PROCEDURES IN THE ORAL CAVITY.",HEMOSTAT(SURGICEL SNOW ABSORBABLE HEMOSTAT)-SURGICEL® ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY VENOUS AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE. SURGICEL® SNOW™ ABSORBABLE HEMOSTAT CAN BE CUT TO SIZE FOR USE IN ENDOSCOPIC PROCEDURES.,HEMOSTAT (SURGICEL ORIGINAL ABSORBABLE HEMOSTAT)-"SURGICEL® ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS INDICATED FOR ADJUNCTIVE USE TO ASSIST IN THE CONTROL OF BLEEDING IN EXODONTIA AND ORAL SURGERY. IT MAY ALSO BE USED TO HELP ACHIEVE HEMOSTASIS AFTER SINGLE OR MULTIPLE TOOTH EXTRACTIONS ALVEOLOPLASTY GINGIVAL HEMORRHAGE IMPACTIONS BIOPSIES AND OTHER PROCEDURES IN THE ORAL CAVITY.",MESH(PROLENE POLYPROPYLENE SOFT MESH(NON-CE))-"THIS MESH MAY BE USED FOR THE REPAIR OF HERNIA OR OTHER FASCIAL DEFECTS THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT.",SUTURES(SURGICAL STAINLESS STEEL SUTURE(NON-CE))-SURGICAL STAINLESS STEEL SUTURE IS INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE HERNIA REPAIR STERNAL CLOSURE AND ORTHOPAEDIC PROCEDURES INCLUDING CERCLAGE AND TENDON REPAIR.,SUTURES(ETHILON(CE))-ETHILON™ BLACK/UNDYED SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APROXIMATION AND/OR LIGATION INCLUDING

		CARDIOVASCULAR SURGERY NEUROSURGERY AND OPHTHALMIC PROCEDURES INCLUDING MICROSURGERY.,SUTURES(ETHIBOND EXCEL(NON-CE))-ETHIBOND EXCEL SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN CARDIOVASCULAR OPTHALMIC AND NEUROLOGICAL PROCEDURES,HEMOSTAT(SURGICEL NU-KNIT ABSORBABLE HEMOSTAT)-SURGICEL® ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS INDICATED FOR ADJUNCTIVE USE TO ASSIST IN THE CONTROL OF BLEEDING IN EXODONTIA AND ORAL SURGERY. IT MAY ALSO BE USED TO HELP ACHIEVE HEMOSTASIS AFTER SINGLE OR MULTIPLE TOOTH EXTRACTIONS ALVEOLOPLASTY GINGIVAL HEMORRHAGE IMPACTIONS BIOPSIES AND OTHER PROCEDURES IN THE ORAL CAVITY.,SUTURES(PRONOVA)-PRONOVA™ SUTURES ARE FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN CARDIOVASCULAR OPHTHALMIC AND NEUROSURGICAL PROCEDURES.,SUTURES(ETHILON(NON-CE))-ETHILON SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APROXIMATION AND/OR LIGATION INCLUDING USE IN CARDIOVASCULAR OPHTHALMIC AND NEUROLOGICAL PROCEDURES.
1633	IMP/MD/2019/000183	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SINGLE USE NEGATIVE PRESSURE WOUND THERAPY SYSTEM(PICO)-IT IS INDICATED FOR PATIENTS WHO WOULD BENEFIT FROM A SUCTION DEVICE (NPWT) AS IT MAY PROMOTE WOUND HEALING VIA REMOVAL OF LOW TO MODERATE LEVELS OF EXUDATE AND INFECTIOUS MATERIALS. APPROPRIATE WOUND TYPES INCLUDE CHRONIC, ACUTE, TRAUMATIC, SUBACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC OR PRESSURE), FLAPS AND GRAFTS, SURGICALLY CLOSED INCISION SITES. PICO SINGLE USE NEGATIVE PRESSURE SYSTEMS ARE SUITABLE FOR USE BOTH IN A HOSPITAL AND HOMECARE SETTING.

1634	IMP/MD/2019/000183	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SILICONE GEL ADHESIVE COMPOSITE HYDROCELLULAR FOAM DRESSING(ALLEVYN LIFE)-1. WOUND MANAGEMENT BY SECONDARY INTENTION ON SHALLOW, GRANULATING WOUNDS, CHRONIC AND ACUTE EXUDATIVE WOUNDS, FULL AND PARTIAL THICKNESS WOUNDS INCLUDING: • PRESSURE ULCERS • LEG ULCERS • DIABETIC FOOT ULCERS • SURGICAL WOUNDS • FIRST AND SECOND DEGREE BURNS • DONOR SITES • SKIN TEARS • FUNGATING ULCERS CAN BE USED IN CONJUNCTION WITH INTRASITE™ GEL FOR NECROTIC OR SLOUGHY WOUNDS. 2. PRESSURE ULCER PREVENTION ON INTACT SKIN AS PART OF A PRESSURE ULCER PREVENTION PROTOCOL.
1635	IMP/MD/2019/000184	1.License Holder Name: CELON LABORATORIES PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARRELS WITH NEEDLE (STERILE)(BD HYPAK SCF)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL
1636	IMP/MD/2019/000185	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLED SYRINGE WITH SODIUM CHLORIDE 0.9% (STERILE SOLUTION)(BD POSIFLUSH™ SP SYRINGE)-THE BD POSIFLUSH™ SP SYRINGE IS INTENDED FOR IMMEDIATE USE IN MAINTAINING PATENCY OF VASCULAR ACCESS DEVICES. THE SYRINGE CONSISTS OF A READY TO USE SYRINGE, WHICH IS PRE-FILLED WITH AN INJECTABLE STERILE, NON-PYROGENIC AND ISOTONIC 0.9% SODIUM CHLORIDE SOLUTION. THE SYRINGE IS NOT TO BE RE-STERILIZED OR RE-USED.

1637	IMP/MD/2019/000186	1.License Holder Name: FAITH BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANEURYSM EMBOLIZATION SYSTEM(WEB ANEURYSM EMBOLIZATION SYSTEM)-THE WEB ANEURYSM EMBOLIZATION SYSTEM IS INTENDED FOR THE ENDOVASCULAR EMBOLIZATION OF RUPTURED AND UNRUPTURED INTRACRANIAL ANEURYSMS AND OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS FISTULAE (AVF). THE WEB ANEURYSM EMBOLIZATION SYSTEM IS ALSO INTENDED FOR VASCULAR OCCLUSION OF BLOOD VESSELS WITHIN THE NEUROVASCULAR SYSTEM TO PERMANENTLY OBSTRUCT BLOOD FLOW TO AN ANEURYSM OR OTHER VASCULAR MALFORMATION.
1638	IMP/MD/2019/000187	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IV CANNULAE(BD VENFLON PRO SAFETY IV CANNULA (BD INSTAFLASH NEEDLE TECHNOLOGY))-THE PRODUCT IS DESIGNED TO ACCESS THE PERIPHERAL VEINS OF THE PATIENT'S BLOOD SYSTEM FOR REHYDRATION, PARENTERAL NUTRITION, MEDICATION DELIVERY, BLOOD TRANSFUSION AND MONITORING PURPOSES. A SPECIAL PRODUCT FEATURE IS THE NEEDLE TIP PROTECTION DEVICE, WHICH IS ACTIVATED WHEN THE STEEL NEEDLE IS WITHDRAWN. IT COVERS THE STEEL NEEDLE TIP AND PROTECT AGAINST ACCIDENTAL NEEDLE STICK.,IV CANNULAE(BD NEOFLON PRO IV CANNULA)-DESIGNED TO GAIN ACCESS TO PERIPHERAL VEINS OF THE PATIENT'S BLOOD SYSTEM FOR REHYDRATION, PARENTERAL NUTRITION, MEDICATION DELIVERY BLOOD TRANSFUSION, AND MONITORING PURPOSES,IV CANNULA(BD VENFLON PRO SAFETY NEEDLE PROTECTED I.V CANNULA)-FOR INFUSION THERAPY,IV CANNULA(BD NEOFLON™ IV CANNULA)-FOR INFUSION THERAPY

1639	IMP/MD/2019/000188	1.License Holder Name: EVENT MEDI SYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SIROLIMUS ELUTING CORONARY STENT SYSTEM(IHTDESTINY)-IHTDESTINY SIROLIMUS ELUTING CORONARY STENT SYSTEM, IS INDICATED FOR USE IN PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) FOR PERMANENT DILATION OF THE STENOTIC PART OF A NATIVE CORONARY ARTERY, THROUGH THE PLACEMENT OF A CORONARY STENT IN ORDER TO IMPROVE MYOCARDIAL PERFUSION.,THROMBUS EXTRACTION CATHETER(HUNTER)-INTENDED FOR VISUALIZING THE STATE OF ARTERY AND THE POSSIBLE EXISTENCE OF THROMBI BEYOND ACUTE TOTAL OCCLUSION , ADMINISTERING MEDICINAL PRODUCTS TO PREPARE MICROCIRCULATION, EXTRACTING EMBOLI AND SOFT THROMBI RECENTLY FORMED ON CORONARY ARTERIAL SYSTEM.,DILATATION AND PERFUSION CORONARY CATHETER (AMICATH II)-AMICATH II IS A CATHETER FOR DILATATION AND PERFUSION OF CORONARY LESIONS, PARTICULARLY INDICATED IN PATIENTS WITH ACUTE MYOCARDIAL INFRACTION WITH ACUTE TOTAL OCCLUSION , SUITABLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND WHICH ALLOW DILATING THE STENOSED PART OF THE ACUTE TOTAL OCCLUSION UP TO A CHARACTERISTIC DIAMETER OF 1.30MM, VIEWING OF THE STATE OF THE ARTERY ANY THROMBUS DISTAL TO THE ACUTE TOTAL OCCLUSION, ADMINISTRATION OF PHARMACOLOGICAL SUBSTANCES FOR LOCAL TREATMENT, LOCATING THE LESION IN-SITU AND ENABLING THE ESTIMATION OF ITS LENGTH IF AND WHEN IT IS LESS THAN 40MM.
1640	IMP/MD/2019/000190	1.License Holder Name: VEENA CARDIO SYSTEM 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SIROLIMUS ELUTING CORONARY STENT SYSTEM WITH COCR STENT AND PERMANENT POLYMER(IVASCULAR ANGIOLITE SIROLIMUS ELUTING CORONARY STENT SYSTEM)-THE DEVICE IS INDICATED FOR INCREASING THE INTERNAL DIAMETER OF AN ARTERY WITH THE AIM OF IMPROVING BLOOD FLOW IN THE FOLLOWING CASES: - PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO “DE NOVO” STENOTIC AND RE-STENOTIC LESIONS LOCATED IN ARTERIES WITH DIAMETERS FROM 2MM TO 4.5MM.

1641	IMP/MD/2019/000191	1.License Holder Name: CUROSIL LIFECARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHOPEDIC CASTING TAPE(TRIANGO CAST)-TRIANGO CAST IS INTENDED FOR USE IN CONSTRUCTION OF MOST COMMON ORTHOPEDIC CAST APPLICATION, AS WELL AS SPECIALIZED AND PROSTHETICS DEVICES
1642	IMP/MD/2019/000195	1.License Holder Name: LA MED HEALTHCARE PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER & ACCESSORIES (NON STERILE BULK)(NIL)-THE CENTRAL VENOUS CATHETERS MAY BE APPLICABLE TO THE ONE OF FOLLOWING THERAPY: - MONITOR OF CENTRAL VENOUS PRESSURE; - CONTINUOUS OR DISCONTINUOUS VENOUS TRANSFUSION; - BLOOD SAMPLING. THE CATHETER IS SURGICALLY PENETRATED INTO THREE OPTIONAL PUNCTURE POINTS DEPENDED ON THE CLINICAL REQUIREMENT WITH SELDINGER TECHNIQUE. THE INSERTION SITES ARE : 1. INTERNAL JUGULAR VEIN; 2. SUBCLAVIAN VEIN; 3. FEMORAL VEIN. IT IS POSSIBLE TO BE INSERTED INSIDE THE BODY FOR LESS THAN 30DAYS. IF DURATION EXCEEDS 30 DAYS, IT MAY OCCURE THE RISK OF COMBINING THE CATHETER AND INSIDE TISSUE, WHICH RESULT IN SERIOUS INCIDENT.

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1643	IMP/MD/2019/000196	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINAL SYSTEM-SPACER (SYNFIX EVOLUTION)-SYNFIX EVOLUTION SECURED SPACER SYSTEM IS AN IMPLANT AND INSTRUMENT SYSTEM FOR STAND-ALONE ANTERIOR LUMBAR INTERBODY FUSION (ALIF) FOR SKELETALLY MATURE PATIENTS. IT IS INTENDED TO REPLACE LUMBAR INTERBODY DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES AT VERTEBRAL LEVELS L1-S1 FOLLOWING ANTERIOR LUMBAR DISCECTOMY FOR STABILIZATION OF THE LUMBAR SPINE., POSTERIOR CONNECTORS- CONNECTOR(NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.",TROCAR(NA)-"TROCARS ARE INTENDED FOR PUNCTURING A BODILY ENTRY POINT AND/OR FOR PARTITION OF SURROUNDING SOFT TISSUE.",TRANSFORAMINAL POSTERIOR ATRAUMATIC LUMBAR (T-PAL) CAGES- CAGE(NA)-THE T-PAL IMPLANT IS INTENDED TO REPLACE LUMBAR INTERVERTEBRAL DISCS AND TO FUSE THE ADJACENT VERTEBRAL BODIES TOGETHER AT VERTEBRAL LEVELS L1–S1. THE T-PAL IMPLANT IS DESIGNED FOR A TRANSFORAMINAL APPROACH.,POSTERIOR RODS- ROD(NA)-"THE AXON SYSTEM IS A COMPREHENSIVE SET OF INSTRUMENTS AND IMPLANTS, INCLUDING — TOP-LOADING VARIABLE AXIS SCREWS, — HOOKS, — TRANSVERSE BARS AND — RODS. IT IS DESIGNED FOR POSTERIOR STABILISATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY

		REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY. THE AXON SYSTEM USES THE EXISTING CERVIFIX RODS, ALLOWING COMPONENTS FROM AXON AND CERVIFIX TO BE COMBINED. THIS ALLOWS A CONSTRUCT TO EXTEND FROM THE OCCIPUT TO THE LOWER SPINE USING THE UNIVERSAL SPINE SYSTEM (USS).", UNIVERSAL SPINE SYSTEM (USS)- CONNECTOR(NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.",CABLE IMPLANTS -COIL WITH CERCLAGE WIRE(NA)-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE.,CABLE IMPLANTS- CERCLAGE WIRE(NA)-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE.
1644	IMP/MD/2019/000197	1.License Holder Name: NEON LABORATORIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER & ACCESSORIES (NIL)-THE PRODUCTS ARE APPLICABLE FOR MONITORING THE CENTRAL VENOUS PRESSURE,COLLECTING THE BLOOD SAMPLE AND INJECTING THE DRUG OR SOLUTION. THE DESIGN OF MULTICAVITY CAN GO ONTHE PROCESS ABOVE AT THE SAME TIME. THE TIME OF USE IS LESS THAN 30 DAYS

1645	IMP/MD/2019/000198	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:I.V. ADMINISTRATION SETS WITH AIR VENT FOR PRESSURE AND GRAVITY INFUSIONS SET (INTRAFIX SAFESET)-IT IS INTENDED FOR INTRAVENOUS ADMINISTRATION OF FLUIDS FOR VOLUME MAINTENANCE, VOLUME REPLACEMENT AND DELIVERY OF CHEMOTHERAPEUTIC AGENTS, NUTRITIONAL SUPPORT, ANTIBIOTICS AND OTHER MEDICATIONS, BLOOD ADMINISTRATION SETS VENTED AND NON VENTED (SANGOFIX)-TRANSFUSIONS SYSTEM FOR THE PURPOSE OF TRANSFUSION OF BLOOD AND BLOOD COMPONENT
1646	IMP/MD/2019/000199	1.License Holder Name: M/S ASIA ACTUAL INDIA (OPC) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COLD STERILANT (RENALIN 100 COLD STERILANT)-RENALIN 100 COLD STERILANT IS INDICATED FOR THE IN VITRO CLEANING AND STERILIZING OF HOLLOW FIBER DIALYZERS WITH THE RENATRON PA 100 SERIES AND RENATRON II 100 SERIES DIALYZER REPROCESSING SYSTEM LABELED FOR USE WITH RENALIN 100. RENALIN 100 COLD STERILANT ALSO MAY BE USED FOR DISINFECTING DIALYSIS EQUIPMENT (E.G. KIDNEY MACHINES) AND SUPPLIES (E.G. PORT CAPS).
1647	IMP/MD/2019/000202	1.License Holder Name: MEDI AID INC 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRA OCULAR LENSES (OCULENTIS)-INTRA OCULAR LENSES (IOL) ARE LENS IMPLANTED IN THE EYE USED TO TREAT CATARACT OR MYOPIA
1648	IMP/MD/2019/000204	1.License Holder Name: DR. REDDYS LABORATORIES LIMITED, C/O M/S GLAND PHARMA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS.

1649	IMP/MD/2019/000205	1.License Holder Name: FAITH BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROCATHETER(VIA)-VIA 17 - THE VIA MICROCATHETER IS INTENDED FOR THE INTRODUCTION OF NON-LIQUID INTERVENTIONAL DEVICES (SUCH AS ANEURYSM EMBOLIZATION DEVICES (E.G WEB DEVICE, COILS) / STENTS / FLOW DIVERTERS) AND INFUSION OF DIAGNOSTIC (SUCH AS CONTRAST MEDIA) OR NON-LIQUID THERAPEUTIC AGENTS INTO THE NEURO, PERIPHERAL, AND CORONARY VASCULATURE. VIA 21 27, 33 - THE VIA MICROCATHETER IS INTENDED FOR THE INTRODUCTION OF NON-LIQUID INTERVENTIONAL DEVICES (SUCH AS ANEURYSM EMBOLIZATION DEVICES (E.G. WEB DEVICE) / STENTS / FLOW DIVERTERS) AND INFUSION OF DIAGNOSTIC (SUCH AS CONTRAST MEDIA) OR NON-LIQUID THERAPEUTIC AGENTS INTO THE NEURO, PERIPHERAL, AND CORONARY VASCULATURE.

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1650	IMP/MD/2019/000207	1.License Holder Name: ACCESS DEVICES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROWAVE TISSUE ABLATION SYSTEM(MTA GENERATOR)(SOLERO)-THE SOLERO MICROWAVE TISSUE ABLATION (MTA) SYSTEM AND ACCESSORIES ARE INDICATED FOR THE ABLATION OF SOFT TISSUE DURING OPEN PROCEDURES. THE SOLERO MTA SYSTEM IS NOT INTENDED FOR CARDIAC USE.,RADIOFREQUENCY ABALATION (RFA) DISPOSABLE ELECTRODES(STARBURST TALON ELECTROSURGICAL DEVICE)-TO BE USED IN CONJUNCTION WITH THE RITA RF GENERATOR AND INTELLIFLOW INFUSION PUMP FOR THE ABLATION OF SOFT TISSUE., MICROWAVE TISSUE ABLATION SYSTEM(MTA APPLICATORS) (SOLERO)-THE SOLERO MICROWAVE TISSUE ABLATION (MTA) SYSTEM AND ACCESSORIES ARE INDICATED FOR THE ABLATION OF SOFT TISSUE DURING OPEN PROCEDURES. THE SOLERO MTA SYSTEM IS NOT INTENDED FOR CARDIAC USE.,RADIOFREQUENCY ABALATION (RFA) DISPOSABLE ELECTRODES(1.STARBURST ELECTROSURGICAL DEVICE, 2.STARBURST MRI ELECTROSURGICAL DEVICE, 3. STARBURST SEMI FLEX, 4.STARBURST SDE ELECTROSURGICAL DEVICE, 5.STARBURST XL ELECTROSURGICAL DEVICE, 6.STARBURST XLI ENHANCED ELECTROSURGICAL DEVICE)-A TOOL TO TRANSMIT ENERGY (PROVIDED BY THE RITA 1500X RF GENERATOR) FOR USE IN ELECTROSURGERY (ABLATION) IN SOFT TISSUE, LIVER, AND BONE METASTASES.,RADIOFREQUENCY ABALATION (RFA) SYSTEM INTRODUCER SETS(STARBURST ACCESS SYSTEM)-TO PROVIDE ACCESS FOR DELIVERY OF THE STARBURST DEVICES, FLUIDS, AND MATERIAL (SUCH AS SALINE) TO INTERSTITIAL TISSUE., RADIOFREQUENCY ABALATION (RFA) DISPOSABLE ELECTRODES (UNIBLATE ELECTROSURGICAL DEVICE)-TO BE USED IN CONJUNCTION WITH THE RITA RF GENERATOR AND INTELLIFLOW INFUSION PUMP FOR THE ABLATION OF SOFT TISSUE.
1651	IMP/MD/2019/000208	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL MESH (NON-ABSORBABLE)(OMYRA MESH)-IT IS INTENDED TO ASSIST IN THE REPAIR AND /OR REINFORCEMENT OF HERNIA AND OTHER FASCIAL DEFECTS REQUIRING THE ADDITIONAL SUPPORT OF A NONABSORBABLE IMPLANT DURING AND AFTER WOUND HEALING.

1652	IMP/MD/2019/000209	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABSORBABLE COLLAGEN MEMBRANE(OSSGUIDE® T-GEN®)-THE PRODUCT IS INDICATED FOR GUIDED TISSUE REGENERATION PROCEDURES IN PERIODONTAL DEFECTS
1653	IMP/MD/2019/000210	1.License Holder Name: HOYA MEDICAL INDIA PRIVATE LIMITED (GODOWN) 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HOYA-PS AF-1(UV)(HOYA-PS AF-1(UV))-THE HOYA-PS AF-1 IOL IS INTENDED TO BE PLACED INTO THE CAPSULAR BAG OF THE EYE AFTER EXTRACAPSULAR CATARACT REMOVAL, FUNCTIONING AS A REFRACTIVE MEDIUM TO REPLACE THE NATURAL CYRSTALLINE LENS.,HOYA NANEX MULTISERT+(HOYA NANEX MULTISERT+)-HOYA NANEX MULTISERT+ IOL IS INTENDED TO BE PLACED INTO THE CAPSULAR BAG OF THE EYE AFTER EXTRACAPSULAR CATARACT REMOVAL, FUNCTIONING AS A REFRACTIVE MEDIUM TO REPLACE THE NATURAL CRYSTALLINE LENS.,HOYA ISERT®(HOYA ISERT®)-THE HOYA ISERT® IOL IS INTENDED TO BE PLACED INTO THE CAPSULAR BAG OF THE EYE AFTER EXTRACAPSULAR CATARACT REMOVAL, FUNCTIONING AS A REFRACTIVE MEDIUM TO REPLACE THE NATURAL CRYSTALLINE LENS.
1654	IMP/MD/2019/000211	1.License Holder Name: BHARAT SERUMS AND VACCINES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK SCF™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS

1655	IMP/MD/2019/000212	1.License Holder Name: BSN MEDICAL PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:WOUND DRESSING (CUTIMED SILTEC SACRUM)-THE CUTIMED® SILTEC® SACRUM ASSORTMENT IS INDICATED FOR EXUDING WOUNDS SUCH AS: VENOUS AND ARTERIAL ULCERS, PRESSURE ULCERS, DIABETIC GANGRENES, SURGICAL INCISIONS, SKIN GRAFTS AND DONOR SITES, LACERATIONS OR ABRASIONS. CUTIMED® SILTEC® SACRUM IS RECOMMENDED FOR WOUNDS WITH LOW TO HIGH EXUDATE LEVELS., WOUND DRESSING(CUTIMED SILTEC PLUS HEEL)-THE CUTIMED® SILTEC® PLUS HEEL ASSORTMENT IS INDICATED FOR EXUDING WOUNDS SUCH AS: VENOUS AND ARTERIAL ULCERS, PRESSURE ULCERS, DIABETIC GANGRENES, SURGICAL INCISIONS, SKIN GRAFTS AND DONOR SITES, LACERATIONS OR ABRASIONS. CUTIMED® SILTEC® PLUS HEEL IS RECOMMENDED FOR WOUNDS WITH LOW TO HIGH EXUDATE LEVELS.,WOUND DRESSING(CUTIMED SILTEC)-THE CUTIMED® SILTEC® ASSORTMENT IS INDICATED FOR EXUDING WOUNDS SUCH AS: VENOUS AND ARTERIAL ULCERS, PRESSURE ULCERS, DIABETIC GANGRENES, SURGICAL INCISIONS, SKIN GRAFTS AND DONOR SITES, LACERATIONS OR ABRASIONS. CUTIMED® SILTEC® IS RECOMMENDED FOR WOUNDS WITH LOW TO HIGH EXUDATE LEVELS.

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1656	IMP/MD/2019/000212	1.License Holder Name: ESSITY INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IV CANNULA FIXATOR (LEUKOMED I.V. (NON WOVEN))-INTENDED FOR FIXATION OF INTRA VENOUS CATHETERS AND FOR COVERING AND PROTECTION OF THE PUNCTURE SITES ,ADHESIVE FIXATION(LEUKOSILK®)-INTENDED FOR SHORT TIME USE ON INTACT SKIN FOR FIXATION OF DRESSINGS OF ALL TYPES AND SIZES AND FOR FIXATION AND SECURING OF TUBES, CATHETERS, PROBES AND CANNULAE.,STERILE WOUND DRESSING (LEUKOMED T)-THE PRODUCT IS INTENDED TO COVER SUPERFICIAL WOUNDS AND WOUNDS AFTER SURGERY, AND FOR STERILE FIXATION OF WOUND DRESSINGS AND CATHETERS. THE FILM DRESSING CAN STAY IN PLACE FOR ONE DAY TO SEVERAL DAYS DEPENDING ON THE STATUS OF THE WOUND AND ON THE SKIN CONDITION.,ADHESIVE FIXATION(FIXOMULL® SKIN SENSITIVE)-INTENDED FOR FIXATION OF PRIMARY WOUND DRESSINGS AND ADDITIONAL SECUREMENT OF DEVICES, SUCH AS CATHETERS, TUBES, PROBES OR DRAINAGES.,ADHESIVE FIXATION(LEUKOPLAST® SKIN SENSITIVE)-INTENDED FOR FIXATION OF WOUND DRESSINGS AND SECUREMENT OF DEVICES, SUCH AS CATHETERS, TUBES, PROBES OR DRAINAGES. IT IS PARTICULARLY SUITABLE FOR HIGHLY SENSITIVE, DELICATE, CRACKED, FRAGILE, ELDERLY, INFANT, CORTISONE/MEDICATION-DAMAGED, DIABETIC SKIN AND FOR USE ON ALL BODY PARTS, INCLUDING FREQUENTLY MOVED OR HIGHLY CONTOURED PARTS OF THE BODY.,IV CANNULA FIXATOR (LEUKOMED I.V. FILM)-INTENDED FOR FIXATION OF INTRA VENOUS CATHETERS AND FOR COVERING AND PROTECTION OF THE PUNCTURE SITES,STERILE WOUND DRESSING(LEUKOMED)-THE PRODUCT IS A STERILE POST-OP DRESSING AND IS INTENDED FOR SHORT TIME USE ON SKIN TO COVER MINOR TO MEDIUM SIZE WOUNDS LIKE WOUNDS AFTER SURGERY OR MINIMAL INVASIVE SURGERY.,STERILE WOUND DRESSING(LEUKOMED T PLUS)-THE PRODUCT IS INTENDED TO COVER MINOR TO MEDIUM SIZE WOUNDS LIKE WOUNDS AFTER SURGERY OR MINIMAL INVASIVE SURGERY. THE FILM DRESSING CAN STAY IN PLACE FOR ONE DAY TO SEVERAL DAYS DEPENDING ON THE STATUS OF THE WOUND AND ON THE SKIN CONDITION,ADHESIVE FIXATION(FIXOMULL STRETCH)-INTENDED FOR WIDE-AREA FIXATION OF WOUND DRESSINGS, PARTICULARLY ON JOINTS AS WELL AS ON FREQUENTLY MOVED AND CONTOURED PARTS OF THE BODY.,ADHESIVE FIXATION(FIXOMULL TRANSPARENT)-WIDE AREA FIXATION OF DRESSINGS, TUBES, CATHETERS, MEASURING DEVICES AND OTHER INSTRUMENTS

1657	IMP/MD/2019/000213	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DELIVERY CATHETER SYSTEM(ENVEO PRO)-THE COREVALVE EVOLUT PRO SYSTEM IS INDICATED FOR PATIENTS WITH SYMPTOMATIC NATIVE AORTIC VALVE STENOSIS OR A STENOSED, INSUFFICIENT, OR COMBINED SURGICAL BIOPROSTHETIC VALVE FAILURE NECESSITATING VALVE REPLACEMENT. THE SYSTEM IS INDICATED FOR PATIENTS WHO ARE AT HIGH RISK OR GREATER RISK FOR SURGICAL AORTIC VALVE REPLACEMENT OR ARE (GREATER THAN OR EQUAL TO) 75 YEARS OF AGE AND AT INTERMEDIATE RISK FOR SURGICAL AVR (SOCIETY OF THORACIC SURGEONS OPERATIVE RISK SCORE (GREATER THAN OR EQUAL TO) 4% OR WITH AN ESTIMATED HOSPITAL MORTALITY (GREATER THAN OR EQUAL TO) 4%AS ASSESSED BY THE HEART TEAM

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1658	IMP/MD/2019/000214	1.License Holder Name: FRESENIUS KABI INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:QUADRUPLE BLOOD BAG SYSTEM(COMPOFLEX (T431169))-BLOOD BAG SYSTEMS ARE DESIGNED FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD AND BLOOD COMPONENTS.,QUADRUPLE BLOOD BAG SYSTEM (COMPOFLEX (T431142))-BLOOD BAG SYSTEMS ARE DESIGNED FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD AND BLOOD COMPONENTS.,QUADRUPLE BLOOD BAG SYSTEM (COMPOFLOW (CQC2820))-BLOOD BAG SYSTEMS ARE DESIGNED FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD AND BLOOD COMPONENTS.,QUADRUPLE BLOOD BAG SYSTEM (COMPOSELECT (PQT4920))-BLOOD BAG SYSTEMS ARE DESIGNED FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD AND BLOOD COMPONENTS.,QUADRUPLE BLOOD BAG SYSTEM (COMPOFLEX (T432163))-BLOOD BAG SYSTEMS ARE DESIGNED FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD AND BLOOD COMPONENTS.,QUINTUPLE BLOOD BAG SYSTEM (COMPOSELECT (T4922))-BLOOD BAG SYSTEMS ARE DESIGNED FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD AND BLOOD COMPONENTS.,TRIPLE BLOOD BAG SYSTEM(COMPOFLEX (T331142))-BLOOD BAG SYSTEMS ARE DESIGNED FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD AND BLOOD COMPONENTS.,TRIPLE BLOOD BAG SYSTEM(COMPOFLEX (T331162))-BLOOD BAG SYSTEMS ARE DESIGNED FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD AND BLOOD COMPONENTS., TRIPLE BLOOD BAG SYSTEM(COMPOFLEX (T331161))-BLOOD BAG SYSTEMS ARE DESIGNED FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD AND BLOOD COMPONENTS.,QUINTUPLE BLOOD BAG SYSTEM(COMPOFLOW (C4922))-BLOOD BAG SYSTEMS ARE DESIGNED FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD AND BLOOD COMPONENTS.,QUADRUPLE BLOOD BAG SYSTEM (COMPOFLEX (T432153))-BLOOD BAG SYSTEMS ARE DESIGNED FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD AND BLOOD COMPONENTS.

1659	IMP/MD/2019/000215	1.License Holder Name: INVENT BIOMED PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA CATHETER (TAMARIN BLUE)-THE TAMARIN BLUE PTCA RX DILATATION CATHETERS ARE INDICATED FOR: BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. BALLOON DILATATION OF THE STENT AFTER IMPLANTATION (BALLOON MODELS 2.00 MM - 4.50 MM) ,PTCA CATHETER(FILAO RX)-THE FILAO RX PTCA RX DILATATION CATHETERS ARE INDICATED FOR: BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. BALLOON DILATATION OF THE STENT AFTER IMPLANTATION (BALLOON MODELS 2.00 MM - 4.50 MM),PTCA CATHETER(FILAO NC)-THE FILAO NC PTCA RX DILATATION CATHETERS ARE INDICATED FOR: BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. BALLOON DILATATION OF THE STENT AFTER IMPLANTATION (BALLOON MODELS 2.00 MM - 4.50 MM)

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1660	IMP/MD/2019/000216	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CALCANEAL PLATES - PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,ELASTIC NAILING IMPLANTS (NOT APPLICABLE)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN). OLECRANON OSTEOTOMY NAILS ARE INTENDED FOR FIXATION OF SIMPLE FRACTURES AND OSTEOTOMIES OF THE OLECRANON.,HAND PLATES -PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., TITANIUM STERNAL FIXATION SYSTEM - PLATE (STERILE- 5 YEARS) (TICP)(NA)-FIXATION OF STERNAL HALVES,TITANIUM STERNAL FIXATION SYSTEM - PIN_STERILE 10 YEARS (TAN)(NA)-FIXATION OF STERNAL HALVES,DISTAL TIBIAL PLATES - PLATE (SS)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,COMPACT MANDIBLE -PLATE (TICP)(NA)-THE SYNTHES COMPACT 2.0 AND COMPACT 2.4 TRAUMA PLATES AND SCREWS SYSTEM MANDIBLE IS INTENDED FOR ORAL, MAXILLOFACIAL SURGERY, TRAUMA, RECONSTRUCTIVE SURGERY, AND ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES).,TITANIUM STERNAL FIXATION SYSTEM - PLATE (NON-STERILE) (TAN / TICP)(NA)-FIXATION OF STERNAL HALVES,FEMORAL SHAFT NAILING IMPLANTS - BLADE (TAN)(NA)-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",MATRIXNEURO- BURR HOLE COVER (TICP)(NA)-DEPUY SYNTHES MATRIXNEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION.,WRIST FUSION PLATES -PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS

	ANATOMICAL REGIONS.,MATRIXMANDIBLE- PLATE (TICP)(NA)-"THE DEPUY SYNTHES MATRIXMANDIBLE PLATING SYSTEM IS INTENDED FOR ORAL, MAXILLOFACIAL SURGERY. THE DEPUY SYNTHES MATRIXMANDIBLE RECONSTRUCTION PLATES IS INTENDED FOR RECONSTRUCTIVE SURGERY. THE DEPUY SYNTHES MATRIXMANDIBLE SUBCONDYLAR PLATES ARE INTENDED FOR THE TRAUMA OF THE MANDIBLE.",SYNMESH-SYNMESH CORPECTOMY DEVICE(NA)-SYNMESH IS A VERTEBRAL BODY REPLACEMENT DEVICE FOR THE CERVICAL, THORACIC AND LUMBAR SPINE. TITANIUM IMPLANTS IN VARIOUS FOOTPRINTS AND HEIGHTS ENABLE THE SURGEON TO CHOOSE THE CONFIGURATION THAT IS BEST SUITED TO THE PATIENT'S INDIVIDUAL PATHOLOGY AND ANATOMY. THE MESH MAY ALSO BE TRIMMED FOR A CUSTOM FIT. THE IMPLANTS CAN BE INSERTED ANTERIORLY, LATERALLY OR ANTEROLATERALLY., TROCHANTERIC FEMORAL NAIL IMPLANTS (TFNA)- SCREW (STERILE- 10 YEARS) (TAN)(NA)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,RADIUS PLATES -PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., TROCHANTERIC FEMORAL NAIL IMPLANTS (TFNA) - SCREW (NON-STERILE) (TAN)(NA)-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",TITANIUM STERNAL FIXATION SYSTEM - PLATE (NON-STERILE) (TICP)(NA)-FIXATION OF STERNAL HALVES,TITANIUM STERNAL FIXATION SYSTEM - PIN_NON STERILE (TAN)(NA)-FIXATION OF STERNAL HALVES,PROXIMAL TIBIAL PLATES - PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,TITANIUM STERNAL FIXATION SYSTEM - PLATE (STERILE- 5 YEARS) (TAN /TICP)(NA)-FIXATION OF STERNAL HALVES,WIRES (POWER DRIVEN)(NA)-THE WIRE INSTRUMENTS ARE INTENDED FOR PROVISIONAL FRACTURE FIXATION AND SHORT TERM INSERTION INTO BONE IN ORDER TO FACILITATE AND GUIDE

	IMPLANT OR INSTRUMENT APPLICATION DURING ORTHOPEDIC SURGERY.,PELVIC IMPLANTS - PLATE (STERILE 10 YEARS) (SS)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,FIBULA PLATES- PLATE (SS)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,LOW PROFILE NEURO -PLATE (TICP)(NA)-DEPUY SYNTHES LOW PROFILE NEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION., CLAVICLE PLATES -PLATE (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., OLECRANON PLATES-PLATE (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., LOW PROFILE NEURO- BURR HOLE COVER (TICP)(NA)-DEPUY SYNTHES LOW PROFILE NEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION.,FOOT PLATES - PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., TITANIUM STERNAL FIXATION SYSTEM - PLATE (STERILE- 10 YEARS) (TAN /TICP)(NA)-FIXATION OF STERNAL HALVES,FOOT PLATES - PLATE (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,TROCHANTERIC FEMORAL NAIL IMPLANTS (TFNA)- BLADE (STERILE-10 YEARS) (TAN)(NA)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,TROCHANTERIC FEMORAL NAIL IMPLANTS (TFNA) -BLADE (NON-STERILE) (TAN)(NA)-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",TITANIUM STERNAL FIXATION SYSTEM - PLATE (STERILE-10 YEARS) (TICP)(NA)-FIXATION

		OF STERNAL HALVES,MATRIXNEURO -PLATE (TICP)(NA)-DEPUY SYNTHES MATRIXNEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION.,MATRIXMIDFACE - PLATE (TICP)(NA)-MATRIXMIDFACE PLATE AND SCREW SYSTEM IS INTENDED FOR USE AS TRAUMA REPAIR AND RECONSTRUCTION OF THE CRANIO-MAXILLOFACIAL SKELETON.,DISTAL TIBIAL PLATES - PLATE (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DISTAL HUMERUS PLATES - PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,PROXIMAL HUMERUS PLATES- PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DISTAL HUMERUS PLATES - PLATE (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,PROXIMAL TIBIAL PLATES - PLATE (SS)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SYNMESH- END RING (TICP)(NA)- SYNMESH IS A VERTEBRAL BODY REPLACEMENT DEVICE FOR THE CERVICAL, THORACIC AND LUMBAR SPINE. TITANIUM IMPLANTS IN VARIOUS FOOTPRINTS AND HEIGHTS ENABLE THE SURGEON TO CHOOSE THE CONFIGURATION THAT IS BEST SUITED TO THE PATIENT'S INDIVIDUAL PATHOLOGY AND ANATOMY. THE MESH MAY ALSO BE TRIMMED FOR A CUSTOM FIT. THE IMPLANTS CAN BE INSERTED ANTERIORLY, LATERALLY OR ANTEROLATERALLY.,GUIDE WIRES FOR SPINE -KIRSCHNER WIRE (SS)(NA)-WIRE IMPLANTS ARE INTENDED FOR FIXATION OF BONE FRAGMENTS.,PELVIC IMPLANTS- PLATE (NON-STERILE) (SS)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., WIRES (POWER DRIVEN) - GUIDE WIRE(NA)-WIRE IMPLANTS ARE INTENDED FOR FIXATION OF BONE FRAGMENTS.
1661	IMP/MD/2019/000217	1.License Holder Name: BSN MEDICAL PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMPRESSION SYSTEMS (JOBST COMPRI 2, JOBST COMPRI 2 SIX-PACK, JOBST COMPRI 2 LITE, JOBST COMPRI 2 LITE SIX-PACK)-COMPRESSION TREATMENT OF VENOUS LEG ULCERS AND ANY ACCOMPANYING OEDEMAS AND THE COMPRESSION TREATMENT OF LYMPHATIC OEDEMAS

1662	IMP/MD/2019/000218	1.License Holder Name: FAITH BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FLOW RE-DIRECTION ENDOLUMINAL DEVICE(FRED)-THE FRED SYSTEM IS INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL NEUROVASCULAR ANEURYSMS. THE FRED SYSTEM MAY ALSO BE USED WITH EMBOLIC COILS FOR THE TREATMENT OF INTRACRANIAL NEUROVASCULAR LESIONS.
1663	IMP/MD/2019/000219	1.License Holder Name: DR. REDDYS LABORATORIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS.
1664	IMP/MD/2019/000220	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL SUTURE (ULTRABRAID)-ULTRABRAID SUTURE IS INDICATED FOR USE IN APPROXIMATION AND/OR LIGATION OF SOFT TISSUES, INCLUDING ALLOGRAFT TISSUE FOR ORTHOPEDIC SURGERIES.

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1665	IMP/MD/2019/000221	1.License Holder Name: VEIVA SCIENTIFIC INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOSTATIC DRESSING (QUIKCLOT)-IS APPLIED TOPICALLY AS AN ADJUNCT TO MANUAL COMPRESSION AND IS INDICATED FOR THE LOCAL MANAGEMENT AND CONTROL OF SURFACE BLEEDING FROM VASCULAR ACCESS SITES, PERCUTANEOUS CATHETERS OR TUBES UTILIZING INTRODUCER SHEATHS UP TO 12 FR OR 7 FR FOR PATIENTS ON DRUG/INDUCED ANTI-COAGULATION TREATMENT.,HEMOSTATIC DRESSING(QUIKCLOT)-INTENDED FOR USE AS A TOPICAL DRESSING FOR LOCAL MANAGEMENT OF BLEEDING WOUNDS SUCH AS CUTS, LACERATIONS, AND ABRASIONS. IT MAY ALSO BE USED FOR TEMPORARY TREATMENT OF SEVERELY BLEEDING WOUNDS SUCH AS SURGICAL WOUNDS (OPERATIVE, POSTOPERATIVE, DERMATOLOGICAL, ETC.) AND TRAUMATIC INJURIES.,HEMOSTATIC DRESSING(QUIKCLOT)-IS APPLIED TOPICALLY AS AN ADJUNCT TO MANUAL COMPRESSION AND IS INDICATED FOR THE LOCAL MANAGEMENT AND CONTROL OF SURFACE BLEEDING FROM VASCULAR ACCESS SITES, PERCUTANEOUS CATHETERS OR TUBES UTILIZING INTRODUCER SHEATHS UP TO 12 FR OR 7 FR FOR PATIENTS ON DRUG/INDUCED ANTI-COAGULATION TREATMENT.

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1666	IMP/MD/2019/000222	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED ,A-1/50, ROOM NO. 2, 100 SHED AREA, G.L.D.C., VAPI, TAL PARDI (VALSAD) , VALSAD GUJARAT ,396195 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISTAL ACCESS GUIDING CATHETER(ENVOY DA)-THE ENVOY DISTAL ACCESS GUIDING CATHETER IS INDICATED FOR USE IN THE PERIPHERAL, CORONARY, AND NEUROVASCULATURE FOR THE INTRAVASCULAR INTRODUCTION OF INTERVENTIONAL/DIAGNOSTIC DEVICES., INTERMEDIATE CATHETER(REVIVE IC)-THE REVIVE INTERMEDIATE CATHETER IS INTENDED FOR USE IN THE PERIPHERAL, CORONARY AND NEUROVASCULATUREFOR THE INTRAVASCULAR INTRODUCTION OF INTERVENTIONAL/DIAGNOSTIC DEVICES., OCCLUSION BALLOON CATHETER(ASCENT)-ASCENT OCCLUSION BALLOON CATHETER IS INTENDED FOR USE IN THE BLOOD VESSELS OF THE PERIPHERAL AND THE NEUROVASCULATURE WHERE TEMPORARY OCCLUSSION IS DESIRED AND OFFERS A VESSEL SELECTIVE TECHNIQUE OF TEMPORARY VASCULAR OCCLUSION WHICH IS USEFUL IN SELECTIVELY STOPPING OR CONTROLLING BLOOD FLOW. ASCENT OCCLUSION BALLON CATHETER IS ALSO INTENDED TO ASSIST IN THE DELIVERY OF DIAGNOSTIC AGENTS SUCH AS CONTRAST MEDIA, AND THERAPEUTIC AGENTS SUCH AS OCCLUSION COILS, INTO THE PERIPHERAL AND NEUROVASCULATURE.,MICROCATHETER(PROWLER 27)-PROWLER 27 MICROCATHETERS ARE INTENDED TO AID IN THE DELIVERY OF DIAGNOSTIC AGENTS, SUCH AS CONTRAST MEDIA, AS WELL AS THERAPEUTIC AGENTS, SUCH AS OCCLUSION COILS, INTO THE PERIPHERAL, CORONARY AND NEUROVASCULATURE.
1667	IMP/MD/2019/000223	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COLLAGEN DURA SUBSTITUTE MEMBRANE(DURAMATRIX)-DURAMATRIX® COLLAGEN DURA SUBSTITUTE MEMBRANE IS INDICATED AS A DURA SUBSTITUTE FOR THE REPAIR OF DURA MATER.,COLLAGEN DURA SUBSTITUTE MEMBRANE(DURAMATRIX-ONLAY)-DURAMATRIX-ONLAY® COLLAGEN DURA SUBSTITUTE MEMBRANE IS INDICATED AS A DURA SUBSTITUTE FOR THE REPAIR OF DURA MATER

1668	IMP/MD/2019/000224	1.License Holder Name: M/S HESTER DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA BALLOON DILATATION CATHETER(IKAZUCHI ZERO, RAIDEN 3)-THIS PRODUCT IS INTENDED TO BE USED FOR DILATING THE STENOSIS LESION IN THE CORONARY ARTERY WHEN PERFORMING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA).
1669	IMP/MD/2019/000225	1.License Holder Name: EDWARDS LIFESCIENCES (INDIA) PRIVATE LIMITED, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERICARDIAL BIOPROSTHESIS (MITRAL)(CARPENTIER- EDWARDS PERIMOUNT MAGNA MITRAL EASE)-THE CARPENTIER-EDWARDS PERIMOUNT MAGNA MITRAL EASE PERICARDIAL BIOPROSTHESIS IS INDICATED FOR PATIENTS WHO REQUIRE REPLACEMENT OF THEIR NATIVE OR PROSTHETIC MITRAL VALVE.,TRANSCATHETER HEART VALVE (EDWARDS SAPIEN 3 - EDWARDS COMMANDER KIT)-THE EDWARDS SAPIEN 3 VALVE, EDWARDS COMMANDER DELIVERY SYSTEM AND ACCESSORIES ARE INDICATED FOR USE IN PATIENTS WITH HEART DISEASE DUE TO NATIVE CALCIFIC AORTIC STENOSIS AT ANY OR ALL LEVELS OF SURGICAL RISK FOR OPEN HEART SURGERY WITH AGE 65 OF YEARS OR ABOVE" AND "FOR USE IN PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO A FAILING AORTIC BIOPROSTHETIC VALVE OR A FAILING MITRAL SURGICAL BIOPROTHETIC VALVE WHO ARE JUDGED BY A HEART TEAM TO BE AT HIGH OR GREATER RISK FOR OPEN SURGICAL THERAPY I.E. A PREDICTED RISK OF SURGICAL MORTALITY 8% AT 30 DAYS BASED ON THE STS RISK SCORE AND OTHER CLINICAL CO-MORBIDITIES UNMEASURED BY THE STS RISK CALCULATOR,PERICARDIAL BIOPROSTHESIS (AORTIC)(CARPENTIER- EDWARDS PERIMOUNT MAGNA EASE)-THE CARPENTIER-EDWARDS PERIMOUNT MAGNA EASE PERICARDIAL BIOPROSTHESIS IS INDICATED FOR PATIENTS WHO REQUIRE REPLACEMENT OF THEIR NATIVE OR PROSTHETIC AORTIC VALVE.

1670	IMP/MD/2019/000226	1.License Holder Name: EVOLUTIS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE CEMENT(CEMFIX)-IT IS INDICATED FOR FIXATION OF PROSTHESES TO LIVING BONE IN ORTHOPEDIC MUSCULOSKELETAL SURGICAL PROCEDURES FOR RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OSTEOPOROSIS, AVASCULAR NECROSIS, COLLAGEN DISEASE, SEVERE JOINT DESTRUCTION SECONDARY TO TRAUMA OR OTHER CONDITIONS, AND REVISION OF PREVIOUS ARTHROPLASTY.,BONE CEMENT WITH GENTAMICIN(GENTAFIX)-IT IS INDICATED USE AS BONE CEMENT IN ARTHROPLASTY PROCEDURE OF THE HIP, KNEE AND OTHER JOINTS TO FIX PLASTIC AND METAL PROSTHETIC PARTS TO LIVING BONE WHEN RECONSTRUCTION IS NECESSARY BECAUSE OF REVISION OF PREVIOUS ARTHROPLASTY PROCEDURES DUE TO JOINT INFECTION.THE CEMENTS ARE INTENDED FOR USE TO AFFIX A NEW PROSTHESIS IN THE SECOND PHASE OF A TWO STAGE REVISION AFTER THE INITIAL INFECTION HAS BEEN CLEARED.
1671	IMP/MD/2019/000227	1.License Holder Name: CBC CORPORATION (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADHESIVE BANDAGE (STEPTY)-STEPTY IS USED FOR COVERING AND PROTECTION OF WOUND, CLOSING OPEN SKIN WOUNDS, SUPPORT OF WOUND SITES., ADHESIVE BANDAGE(INJECTION PAD)-INJECTION PAD IS INTENDED FOR COVERING AND PROTECTING WOUNDS, CLOSING OPEN SKIN WOUNDS, AND SUPPORTING WOUND SITES.

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1672	IMP/MD/2019/000228	1.License Holder Name: BSN MEDICAL PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:WOUND DRESSING (CUTIMED SORBACT DRESSING PAD)-CUTIMED® SORBACT® CAN BE USED FOR ALL TYPES OF CONTAMINATED, COLONISED OR INFECTED EXUDING WOUNDS, REGARDLESS OF THEIR AETIOLOGY, SUCH AS: - CHRONIC WOUNDS, E.G. VENOUS, ARTERIAL, OR DIABETIC ULCERS AND PRESSURE ULCERS - WOUNDS AFTER EXCISION OF FISTULAS AND ABSCESS´ - POSTOPERATIVE DEHISCED WOUNDS - TRAUMATIC WOUNDS,WOUND DRESSING(CUTIMED SORBACT SWABS)-CUTIMED® SORBACT® CAN BE USED FOR ALL TYPES OF CONTAMINATED, COLONISED OR INFECTED EXUDING WOUNDS, REGARDLESS OF THEIR AETIOLOGY, SUCH AS: - CHRONIC WOUNDS, E.G. VENOUS, ARTERIAL, OR DIABETIC ULCERS AND PRESSURE ULCERS - WOUNDS AFTER EXCISION OF FISTULAS AND ABSCESS´ - POSTOPERATIVE DEHISCED WOUNDS - TRAUMATIC WOUNDS,WOUND DRESSING(CUTIMED SORBACT NPWT WOUND FILLER)-CUTIMED® SORBACT® NPWT WOUND FILLER IS INTENDED TO BE USED IN CONJUNCTION WITH NEGATIVE PRESSURE WOUND THERAPY SYSTEMS TO PROVIDE NEGATIVE PRESSURE DISTRIBUTION AND A PATHWAY FOR WOUND EXUDATE TO EXIT.
1673	IMP/MD/2019/000229	1.License Holder Name: BL LIFESCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ON-X AORTIC PROSTHETIC HEART VALVE WITH STANDARD AND CONFORM-X SEWING RING(ON-X®)-THE ON-X PROSTHETIC HEART VALVE IS INDICATED FOR THE REPLACEMENT OF DISEASED, DAMAGED, OR MALFUNCTIONING NATIVE OR PROSTHETIC HEART VALVE IN THE AORTIC POSITIONS.,ON-X MITRAL PROSTHETIC HEART VALVE WITH STANDARD AND CONFORM-X SEWING RING(ON-X®)-THE ON-X PROSTHETIC HEART VALVE IS INDICATED FOR THE REPLACEMENT OF DISEASED, DAMAGED, OR MALFUNCTIONING NATIVE OR PROSTHETIC HEART VALVE IN THE MITRAL POSITIONS.

1674	IMP/MD/2019/000230	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIP SYSTEM - STEM (POLARSTEM)-"• ADVANCED DEGENERATION OF THE HIP JOINT AS A RESULT OF DEGENERATIVE, POST-TRAUMATIC OR RHEUMATOID ARTHRITIS. • FRACTURE OR AVASCULAR NECROSIS OF THE FEMORAL HEAD • CONDITIONS RESULTING FROM PREVIOUS OPERATIONS, SUCH AS STEOSYNTHESIS, JOINT RECONSTRUCTION, ARTHRODESIS, HEMIARTHROPLASTY OR HIP TOTAL PROSTHESIS.",HIP SYSTEM - ACETABULAR CUP(POLARCUP)-"• ADVANCED DEGENERATION OF THE HIP JOINT AS A RESULT OF DEGENERATIVE, POST-TRAUMATIC OR RHEUMATOID ARTHRITIS. • FRACTURE OR AVASCULAR NECROSIS OF THE FEMORAL HEAD • CONDITIONS RESULTING FROM PREVIOUS OPERATIONS, SUCH AS OSTEOSYNTHESIS, JOINT RECONSTRUCTION, ARTHRODESIS, HEMIARTHROPLASTY OR HIP TOTAL PROSTHESIS."
1675	IMP/MD/2019/000231	1.License Holder Name: ADVANCED BIONICS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIRESOLUTION BIONIC EAR SYSTEM(HIRES 90K ADVANTAGE CI HIFOCUS MS ELECTRODE (CI-1500-04))-IT IS A COCHLEAR IMPLANT SYSTEM INTENDED TO RESTORE A LEVEL OF AUDITORY SENSATION TO INDIVIDUALS WITH SEVERE-TO-PROFOUND SENSORINEURAL HEARING LOSS VIA ELECTRICAL STIMULATION OF THE AUDITORY NERVE,HIRESOLUTION BIONIC EAR SYSTEM(HIRES 90K ADVANTAGE CI HIFOCUS 1J ELECTRODE (CI-1500-01))-IT IS A COCHLEAR IMPLANT SYSTEM INTENDED TO RESTORE A LEVEL OF AUDITORY SENSATION TO INDIVIDUALS WITH SEVERE-TO-PROFOUND SENSORINEURAL HEARING LOSS VIA ELECTRICAL STIMULATION OF THE AUDITORY NERVE

1676	IMP/MD/2019/000232	1.License Holder Name: NIPRO MEDICAL (INDIA) PRIVATE LIMITED , 2ND FLOOR, GMR AERO TOWER, NEAR RAJIV GANDHI AIRPORT, MAMIDIPALLY VILLAGE, BALAPUR MANDAL, RANGA REDDY DIST, MAMIDPALLY(V), BALAPUR(M), RANGA REDDY(DIST.) ,RANGA REDDY TELANGANA ,501218 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE SYRINGE - DEVICE IS THE DISPOSABLE SYRINGE WITH AND WITHOUT NEEDLES WHICH IS INTENDED FOR THE ASPIRATION OF FLUIDS OR FOR THE INJECTION OF FLUIDS IMMEDIATELY AFTER FILLING,INSULIN SYRINGE -DEVICE IS THE DISPOSABLE INSULIN SYRINGE IS INTENDED FOR THE INJECTION OF INSULIN FLUIDS IMMEDIATELY AFTER FILLING.
1677	IMP/MD/2019/000233	1.License Holder Name: RECKITT BENCKISER (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NATURAL RUBBER LATEX CONDOMS - (LUBRICATED FINISHED)(NA)-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION.,NATURAL RUBBER LATEX CONDOMS - (LUBRICATED BULK FOILED).(NA)-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION., SYNTHETIC RUBBER/ POLYISOPRENE CONDOMS - (LUBRICATED)(NA) -CONDOMS MANUFACTURED FROM POLYISOPRENE SYNTHETIC RUBBER ARE BARRIER CONTRACEPTIVE FOR THE PREVENTION OF PREGNANCY AND PREVENTION OF THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX CONDOMS WITH BENZOCAINE - (LUBRICATED FINISHED)(NA)-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION.

1678	IMP/MD/2019/000235	1.License Holder Name: EURASIA HEALTHCARE LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DRUG ELUTING CORONARY STENT SYSTEM(BIOMATRIX NEOFLEX)-THE BIOMATRIX NEOFLEX DES IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER RANGING BETWEEN 2.25 MM AND 4.0 MM. STENTS WITH LENGTH 33 MM AND 36 MM ARE ONLY AVAILABLE FOR ARTERY DIAMETERS RANGING BETWEEN 2.5 MM AND 3.5 MM. THE BIOMATRIX NEOFLEX DES WITH STENT LENGTH UP TO 28 MM IS ALSO INDICATED FOR USE IN PATIENTS WITH: • ST ELEVATED MYOCARDIAL INFARCTION (STEMI) • ACUTE CORONARY SYNDROMES (ACS) INCLUDING ACS-STEMI, ACS-NSTEMI AND UNSTABLE ANGINA • DIABETES MELLITUS,DRUG COATED CORONARY STENT SYSTEM(BIOFREEDOM)-THE BIOFREEDOM DCS IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER FOR THE TREATMENT OF DE-NOVO LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER RANGING FROM 2.25 MM TO 4.0 MM. STENTS WITH LENGTHS OF 33 MM AND 36 MM ARE ONLY AVAILABLE FOR ARTERY DIAMETERS RANGING FROM 2.5 MM TO 3.5 MM.,DRUG ELUTING CORONARY STENT SYSTEM(BIOMATRIX ALPHA)-THE BIOMATRIX ALPHA STENT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER RANGING BETWEEN 2.25 MM AND 4.0 MM. STENTS WITH LENGTHS 33 AND 36 MM ARE ONLY AVAILABLE FOR ARTERY DIAMETERS RANGING BETWEEN 2.5 MM AND 3.5 MM.,DRUG ELUTING CORONARY STENT SYSTEM(BIOMATRIX FLEX)-THE BIOMATRIX FLEX DES IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER RANGING BETWEEN 2.25 MM AND 4.0 MM. STENTS WITH LENGTH 33MM AND 36MM ARE ONLY AVAILABLE FOR ARTERY DIAMETERS RANGING BETWEEN 2.5MM AND 3.5MM. THE BIOMATRIX FLEX DES WITH STENT LENGTH UP TO 28 MM IS ALSO INDICATED FOR USE IN PATIENTS WITH: • ST ELEVATED MYOCARDIAL INFARCTION (STEMI) • ACUTE CORONARY SYNDROMES (ACS) INCLUDING ACS-STEMI, ACS-NSTEMI AND UNSTABLE ANGINA • DIABETES MELLITUS

1679	IMP/MD/2019/000236	1.License Holder Name: SEPTODONT HEALTHCARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RESORBABLE BONE SUBSTITUTE -BETA-TCP(R.T.R. SYRINGE)-R.T.R. IS DESIGNED FOR THE FILLING AND THE RECONSTRUCTION OF BONE DEFECTS IN MAXILLOFACIAL AND DENTAL SURGERY.
1680	IMP/MD/2019/000237	1.License Holder Name: DR. REDDYS LABORATORIES LIMITED, C/O M/S GLAND PHARMA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD NEOPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS.,PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS.

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1681	IMP/MD/2019/000238	1.License Holder Name: MERZ INDIA HEALTH CARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SODIUM HYALURONATE LIDOCAINE HYDROCHLORIDE IN PREFILLED SYRINGES(BELOTERO® VOLUME LIDOCAINE)-BELOTERO® VOLUME LIDOCAINE IS AN INJECTABLE RESORBABLE IMPLANT TO RESTORE FACIAL VOLUMES, AS FOR EXAMPLE TO ENHANCE THE CHEEKS OR THE CHIN.,SODIUM HYALURONATE LIDOCAINE HYDROCHLORIDE IN PREFILLED SYRINGES(BELOTERO® SOFT LIDOCAINE)-• BELOTERO® SOFT LIDOCAINE IS AN INJECTABLE BIODEGRADABLE IMPLANT INTENDED FOR FILLING OF PERIORAL FINE LINES. • THE PRESENCE OF LIDOCAINE AIMS TO REDUCE LOCAL PAIN ASSOCIATED WITH THE INJECTION OF THE GEL AND TO IMPROVE PATIENT COMFORT., SODIUM HYALURONATE LIDOCAINE HYDROCHLORIDE IN PREFILLED SYRINGES(BELOTERO® BALANCE LIDOCAINE)-•BELOTERO® BALANCE LIDOCAINE IS AN INJECTABLE BIODEGRADABLE IMPLANT INTENDEDFOR FILLING OF MODERATE FACIAL WRINKLES AND FOLDS AS WELL AS FOR LIP ENHANCEMENT. •THE PRESENCE OF LIDOCAINE AIMS TO REDUCE LOCAL PAIN ASSOCIATED WITH THE INJECTION OF THE GEL AND TO IMPROVE PATIENT COMFORT. ,SODIUM HYALURONATE LIDOCAINE HYDROCHLORIDE IN PREFILLED SYRINGES(BELOTERO® INTENSE LIDOCAINE)-•BELOTERO® INTENSE LIDOCAINE IS AN INJECTABLE BIODEGRADABLE IMPLANT INTENDED FOR FILLING OF DEEP FACIAL WRINKLES AND FOLDS AS WELL AS TO RESTORE AND ENHANCE SOFT TISSUE VOLUME •THE PRESENCE OF LIDOCAINE AIMS TO REDUCE LOCAL PAIN ASSOCIATED WITH THE INJECTION OF THE GEL AND TO IMPROVE PATIENT COMFORT.

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1682	IMP/MD/2019/000239	1.License Holder Name: BAIHE MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE SILICONE FOLEY CATHETER(ABLE - DISPOSABLE SILICONE FOLEY CATHETER)-THE PRODUCT IS INTENDED USE FOR DISPOSABLE CATHETERIZATION FOR PATIENTS FOR MEDICAL THERAPY UNITS., DISPOSABLE INJECTION SITE ADAPTOR(ABLE - DISPOSABLE INJECTION SITE ADAPTOR)-THE PRODUCT IS USED TO CLOSE THE TRANSFUSION PORT, SUPPLY LIQUID MEDICINE WHEN THE ADAPTOR IS CLOSED AND PREVENT THE TRANSFUSION SYSTEM FROM POLLUTING DURING INTRAVENOUS INFUSION THERAPY., DISPOSABLE FISTULA NEEDLE(ABLE - DISPOSABLE FISTULA NEEDLE) -THE PRODUCT IS INTENDED TO PUNCTURE THE MATURE FISTULA, AND CONNECT WITH THE BLOOD LINES TO ESTABLISH BLOOD CIRCULATING PATH OUTSIDE HUMAN BODY IN THE PROCESS OF HEMODIALYSIS.,DISPOSABLE BLOOD LINE(ABLE - DISPOSABLE BLOOD LINE)-THE PRODUCT IS INTENDED TO ESTABLISH BLOOD CIRCULATION PATH OUTSIDE HUMAN BODY. I CAN MATCH ALL DIALYSIS MACHINES.,DISPOSABLE BLOOD PRESSURE TRANSDUCER & ACCESSORIES(ABLE - DISPOSABLE BLOOD PRESSURE TRANSDUCER & ACCESSORIES)-THE PRODUCT APPLY TO CLINICAL FOR TRAUMATIC ARTERIOVENOUS PRESSURE MONITORING., HAEMODIALYSIS CATHETER KIT/SET(ABLECATH - DISPOSABLE HAEMODIALYSIS CATHETER KIT/SET & ACCESSORIES)-THE PRODUCT IS APPLICABLE FOR HEMODIALYSIS, VENOUS TRANSFUSION, CONTINUOUS MONITORING THE VENOUS PRESSURE. THE TIME OF USE IS LESS THAN 30 DAYS.,CENTRAL VENOUS CATHETER KIT/SET (ABLECATH - DISPOSABLE CENTRAL VENOUS CATHETER & ACCESSORIES)-THE PRODUCT IS USED TO INFUSE HIGHLY OSMOLAR OR GREATLY VEIN-IRRITATING SOLUTIONS, FOR INTERMITTENT OR CONTINUOUS MONITORING OF CENTRAL VENOUS PRESSURE, FOR BLOOD SAMPLING. IT IS POSSIBLE TO BE INSERTED INSIDE THE BODY FOR MORE THAN 30 DAYS.

1683	IMP/MD/2019/000240	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MINIMALLY INVASIVE PEDICLE SCREW SYSTEM(PATHFINDER NXT SYSTEM-POLYAXIAL CANNULATED SCREWS)-WHEN INTENDED FOR PEDICLE SCREW FIXATION FROM T1 – S1, THE INDICATIONS INCLUDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE: DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGIC IMPAIRMENT, FRACTURE, DISLOCATION, DEFORMITIES OR CURVATURES (I.E. SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS), TUMOR AND FAILED PREVIOUS FUSION. AS A PEDICLE SCREW SYSTEM PLACED BETWEEN L3 AND S1, THE INDICATIONS INCLUDE GRADE 3 OR GRADE 4 SPONDYLOLISTHESIS, WHEN UTILIZING AUTOGRAFT OR ALLOGRAFT, WHEN AFFIXED TO THE POSTERIOR LUMBOSACRAL SPINE, AND INTENDED TO BE REMOVED AFTER THE SOLID FUSION IS ESTABLISHED.,SPINAL FIXATION SYSTEM(ZYSTON CURVE INTERBODY SPACER SYSTEM - SPACER)-THE ZYSTON CURVE INTERBODY SPACER SYSTEM IS INDICATED FOR INTERVERTEBRAL BODY FUSION AT ONE LEVEL OR TWO CONTIGUOUS LEVELS IN THE LUMBAR SPINE FROM L2 TO S1 IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) WITH UP TO GRADE 1 SPONDYLOLISTHESIS AT THE INVOLVED LEVEL(S). DDD IS DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THE ZYSTON CURVE INTERBODY SPACER SYSTEM IS DESIGNED FOR USE WITH AUTOGRAFT TO FACILITATE FUSION AND IS INTENDED FOR USE WITH SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBAR SPINE. THE ZYSTON CURVE INTERBODY SPACER SYSTEM MAY ALSO BE IMPLANTED USING THE ACCUVISION SYSTEM TO PROVIDE THE SURGEON WITH A MINIMALLY INVASIVE APPROACH FOR POSTERIOR OR POSTEROLATERAL SPINAL SURGERY. , MINIMALLY INVASIVE PEDICLE SCREW SYSTEM(PATHFINDER NXT SYSTEM-RODS)-WHEN INTENDED FOR PEDICLE SCREW FIXATION FROM T1 – S1, THE INDICATIONS INCLUDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE

	FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE: DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGIC IMPAIRMENT, FRACTURE, DISLOCATION, DEFORMITIES OR CURVATURES (I.E. SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS), TUMOR AND FAILED PREVIOUS FUSION. AS A PEDICLE SCREW SYSTEM PLACED BETWEEN L3 AND S1, THE INDICATIONS INCLUDE GRADE 3 OR GRADE 4 SPONDYLOLISTHESIS, WHEN UTILIZING AUTOGRAFT OR ALLOGRAFT, WHEN AFFIXED TO THE POSTERIOR LUMBOSACRAL SPINE, AND INTENDED TO BE REMOVED AFTER THE SOLID FUSION IS ESTABLISHED.,SPINAL FIXATION SYSTEM(POLARIS 5.5 SPINAL SYSTEM - DOMINO)-THE POLARIS SPINAL SYSTEM IS A NON-CERVICAL SPINAL FIXATION DEVICE INTENDED FOR IMMOBILIZATION AND STABILIZATION AS AN ADJUNCT TO FUSION AS A PEDICLE SCREW FIXATION SYSTEM, A POSTERIOR HOOK AND SACRAL/ILIAC SCREW FIXATION SYS¬TEM, OR AS AN ANTERIOR OR ANTEROLATERAL FIXATION SYSTEM FOR USE WITH AUTOGRAFT AND/OR ALLOGRAFT. THE POLARIS SPINAL SYSTEM IS INDICATED FOR ALL THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUD¬IES), SPONDYLOLISTHESIS, TRAUMA, (I.E., FRACTURE OR DISLOCATION), DEFORMITY OR CURVATURE (I.E., SCOLIOSIS, KYPHOSIS, SCHEUERMANN'S DISEASE, AND/OR LORDO¬SIS), TUMOR, STENOSIS, PSEUDOARTHROSIS, OR FAILED PREVIOUS FUSION. THE BALLISTA INSTRUMENTS ARE INTENDED TO BE USED WITH THE BALLISTA/POLARIS 5.5 IMPLANTS. CANNULATED SCREWS AND PERCUTANEOUS RODS, MAY BE USED WITH THE BALLISTA INSTRUMENTS TO PROVIDE THE SURGEON WITH A PERCUTANEOUS APPROACH FOR POSTERIOR SPINAL SURGERY FOR THE FOLLOWING ABOVE INDICATIONS. FOR PEDIATRIC PATIENTS, THE POLARIS SPINAL SYSTEM MAY BE USED FOR POSTERIOR, NON-CERVICAL PEDICLE SCREW FIXATION AS AN ADJUNCT TO FUSION TO TREAT ADOLES¬CENT IDIOPATHIC SCOLIOSIS AND IS ALSO INDICATED FOR TREATMENT OF THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS AND FRACTURES CAUSED BY TUMOR AND/OR TRAUMA. PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE POLARIS SPINAL SYSTEM MAY BE USED WITH THE INSTRUMENTS IN ACCUVISION MINIMALLY INVASIVE SPINAL EXPOSURE SYSTEM TO PROVIDE THE SURGEON WITH A MINIMALLY INVASIVE APPROACH FOR POSTERIOR SPINAL SURGERY.

	THE DOMINOS IN THE POLARIS SPINAL SYSTEM CAN BE USED TO CONNECT THE PO¬LARIS SPINAL SYSTEM TO THE ALTIUS SPINAL SYSTEM, THE LINEUM OCT SPINE SYSTEM, THE ARRAY SPINAL SYSTEM, THE BIOMET® OMEGA21 SPINAL SYSTEM, OR THE SYNERGY SPINAL SYSTEM TO ACHIEVE ADDITIONAL LEVELS OF FIXATION. PLEASE REFER TO THE INDIVIDUAL SYSTEM'S PACKAGE INSERT FOR A LIST OF THE INDI¬CATIONS FOR USE FOR EACH SYSTEM. , ANTERIOR CERVICAL PLATE SYSTEM(TRINICA - PLATES)-THE TRINICA AND TRINICA SELECT ANTERIOR CERVICAL PLATE SYSTEM IS INTENDED FOR ANTERIOR INTERBODY SCREW FIXATION OF THE CERVICAL SPINE AT LEVEL C2–T1. THE SYSTEM IS INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR SPINE DURING THE DEVELOPMENT OF CERVICAL SPINAL FUSIONS IN PATIENTS WITH DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF DISCOGENIC ORIGIN CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), TRAUMA (INCLUDING FRACTURES), TUMORS, DEFORMITY (DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS), PSEUDOARTHROSIS, AND/OR FAILED PREVIOUS FUSIONS.,SPINAL FIXATION SYSTEM(POLARIS 5.5 SPINAL SYSTEM - HOOKS)-THE POLARIS SPINAL SYSTEM IS A NON-CERVICAL SPINAL FIXATION DEVICE INTENDED FOR IMMOBILIZATION AND STABILIZATION AS AN ADJUNCT TO FUSION AS A PEDICLE SCREW FIXATION SYSTEM, A POSTERIOR HOOK AND SACRAL/ILIAC SCREW FIXATION SYS¬TEM, OR AS AN ANTERIOR OR ANTEROLATERAL FIXATION SYSTEM FOR USE WITH AUTOGRAFT AND/OR ALLOGRAFT. THE POLARIS SPINAL SYSTEM IS INDICATED FOR ALL THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUD¬IES), SPONDYLOLISTHESIS, TRAUMA, (I.E., FRACTURE OR DISLOCATION), DEFORMITY OR CURVATURE (I.E., SCOLIOSIS, KYPHOSIS, SCHEUERMANN'S DISEASE, AND/OR LORDO¬SIS), TUMOR, STENOSIS, PSEUDOARTHROSIS, OR FAILED PREVIOUS FUSION. THE BALLISTA INSTRUMENTS ARE INTENDED TO BE USED WITH THE BALLISTA/POLARIS 5.5 IMPLANTS. CANNULATED SCREWS AND PERCUTANEOUS RODS, MAY BE USED WITH THE BALLISTA INSTRUMENTS TO PROVIDE THE SURGEON WITH A PERCUTANEOUS APPROACH FOR POSTERIOR SPINAL SURGERY FOR THE FOLLOWING ABOVE INDICATIONS. FOR PEDIATRIC PATIENTS, THE POLARIS SPINAL SYSTEM MAY BE USED FOR POSTERIOR, NON-CERVICAL PEDICLE SCREW FIXATION AS AN ADJUNCT TO FUSION TO TREAT ADOLES¬CENT IDIOPATHIC SCOLIOSIS AND IS ALSO INDICATED FOR TREATMENT OF THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS AND FRACTURES CAUSED BY

	TUMOR AND/OR TRAUMA. PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE POLARIS SPINAL SYSTEM MAY BE USED WITH THE INSTRUMENTS IN ACCUVISION MINIMALLY INVASIVE SPINAL EXPOSURE SYSTEM TO PROVIDE THE SURGEON WITH A MINIMALLY INVASIVE APPROACH FOR POSTERIOR SPINAL SURGERY. THE DOMINOS IN THE POLARIS SPINAL SYSTEM CAN BE USED TO CONNECT THE PO¬LARIS SPINAL SYSTEM TO THE ALTIUS SPINAL SYSTEM, THE LINEUM OCT SPINE SYSTEM, THE ARRAY SPINAL SYSTEM, THE BIOMET® OMEGA21 SPINAL SYSTEM, OR THE SYNERGY SPINAL SYSTEM TO ACHIEVE ADDITIONAL LEVELS OF FIXATION. PLEASE REFER TO THE INDIVIDUAL SYSTEM'S PACKAGE INSERT FOR A LIST OF THE INDI¬CATIONS FOR USE FOR EACH SYSTEM. , ANTERIOR CERVICAL PLATE SYSTEM(TRINICA AND TRINICA SELECT-SCREWS)-THE TRINICA AND TRINICA SELECT ANTERIOR CERVICAL PLATE SYSTEM IS INTENDED FOR ANTERIOR INTERBODY SCREW FIXATION OF THE CERVICAL SPINE AT LEVEL C2–T1. THE SYSTEM IS INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR SPINE DURING THE DEVELOPMENT OF CERVICAL SPINAL FUSIONS IN PATIENTS WITH DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF DISCOGENIC ORIGIN CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), TRAUMA (INCLUDING FRACTURES), TUMORS, DEFORMITY (DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS), PSEUDOARTHROSIS, AND/OR FAILED PREVIOUS FUSIONS.,NON-CERVICAL SPINAL SPACER (ZYSTON STRAIGHT SPACER SYSTEM - SPACER)-THE ZYSTON STRAIGHT SPACER SYSTEM IS INDICATED FOR VERTEBRAL BODY REPLACEMENT AND INTERVERTEBRAL BODY FUSION. WHEN USED FOR VERTEBRAL BODY REPLACEMENT, THE ZYSTON STRAIGHT SPACER SYSTEM IS INDICATED FOR USE IN THE THORACOLUMBAR SPINE (I.E., T1- L5) FOR PARTIAL REPLACEMENT OF A DISEASED VERTEBRAL BODY RESECTED OR EXCISED FOR THE TREATMENT OF TUMORS IN ORDER TO ACHIEVE ANTERIOR DECOMPRESSION OF THE SPINAL CORD AND NEURAL TISSUES, AND TO RESTORE THE HEIGHT OF A COLLAPSED VERTEBRAL BODY. THE ZYSTON STRAIGHT SPACER SYSTEM IS ALSO INDICATED FOR TREATING FRACTURES OF THE THORACIC AND LUMBAR SPINE. THE ZYSTON STRAIGHT SPACER SYSTEM IS DESIGNED TO RESTORE THE BIOMECHANICAL INTEGRITY OF THE ANTERIOR, MIDDLE, AND POSTERIOR SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A PROLONGED PERIOD OF TIME. WHEN USED FOR VERTEBRAL BODY REPLACEMENT, THE ZYSTON STRAIGHT SPACER SYSTEM IS DESIGNED FOR USE WITH BONE GRAFT AND IS INTENDED FOR USE WITH SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE THORACOLUMBAR SPINE. AS AN INTERVERTEBRAL BODY FUSION DEVICE, THE ZYSTON STRAIGHT

	SPACER SYSTEM IS INDICATED FOR INTERVERTEBRAL BODY FUSION AT ONE LEVEL OR TWO CONTIGUOUS LEVELS IN THE LUMBAR SPINE FROM L2 TO S1 IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) WITH UP TO GRADE 1 SPONDYLOLISTHESIS AT THE INVOLVED LEVEL(S). DDD IS DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. WHEN USED AS AN INTERVERTEBRAL BODY FUSION DEVICE, THE ZYSTON STRAIGHT SPACER SYSTEM IS DESIGNED FOR USE WITH AUTOGRAFT TO FACILITATE FUSION AND IS INTENDED FOR USE WITH SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBAR SPINE. THE ZYSTON STRAIGHT SPACER SYSTEM MAY ALSO BE IMPLANTED USING THE ACCUVISION SYSTEM TO PROVIDE THE SURGEON WITH A MINIMALLY INVASIVE APPROACH FOR POSTERIOR OR POSTEROLATERAL SPINAL SURGERY,ANTERIOR CERVICAL PLATE SYSTEM(TRINICA SELECT-PLATES)-THE TRINICA AND TRINICA SELECT ANTERIOR CERVICAL PLATE SYSTEM IS INTENDED FOR ANTERIOR INTERBODY SCREW FIXATION OF THE CERVICAL SPINE AT LEVEL C2–T1. THE SYSTEM IS INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR SPINE DURING THE DEVELOPMENT OF CERVICAL SPINAL FUSIONS IN PATIENTS WITH DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF DISCOGENIC ORIGIN CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), TRAUMA (INCLUDING FRACTURES), TUMORS, DEFORMITY (DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS), PSEUDOARTHROSIS, AND/OR FAILED PREVIOUS FUSIONS.,SPINAL FIXATION SYSTEM(POLARIS 5.5 SPINAL SYSTEM - RODS)-THE POLARIS SPINAL SYSTEM IS A NON-CERVICAL SPINAL FIXATION DEVICE INTENDED FOR IMMOBILIZATION AND STABILIZATION AS AN ADJUNCT TO FUSION AS A PEDICLE SCREW FIXATION SYSTEM, A POSTERIOR HOOK AND SACRAL/ILIAC SCREW FIXATION SYS¬TEM, OR AS AN ANTERIOR OR ANTEROLATERAL FIXATION SYSTEM FOR USE WITH AUTOGRAFT AND/OR ALLOGRAFT. THE POLARIS SPINAL SYSTEM IS INDICATED FOR ALL THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUD¬IES), SPONDYLOLISTHESIS, TRAUMA, (I.E., FRACTURE OR DISLOCATION), DEFORMITY OR CURVATURE (I.E., SCOLIOSIS, KYPHOSIS, SCHEUERMANN'S DISEASE, AND/OR LORDO¬SIS), TUMOR, STENOSIS, PSEUDOARTHROSIS, OR FAILED PREVIOUS FUSION. THE BALLISTA INSTRUMENTS ARE INTENDED TO BE USED WITH THE BALLISTA/POLARIS 5.5 IMPLANTS. CANNULATED SCREWS AND

	PERCUTANEOUS RODS, MAY BE USED WITH THE BALLISTA INSTRUMENTS TO PROVIDE THE SURGEON WITH A PERCUTANEOUS APPROACH FOR POSTERIOR SPINAL SURGERY FOR THE FOLLOWING ABOVE INDICATIONS. FOR PEDIATRIC PATIENTS, THE POLARIS SPINAL SYSTEM MAY BE USED FOR POSTERIOR, NON-CERVICAL PEDICLE SCREW FIXATION AS AN ADJUNCT TO FUSION TO TREAT ADOLES¬CENT IDIOPATHIC SCOLIOSIS AND IS ALSO INDICATED FOR TREATMENT OF THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS AND FRACTURES CAUSED BY TUMOR AND/OR TRAUMA. PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE POLARIS SPINAL SYSTEM MAY BE USED WITH THE INSTRUMENTS IN ACCUVISION MINIMALLY INVASIVE SPINAL EXPOSURE SYSTEM TO PROVIDE THE SURGEON WITH A MINIMALLY INVASIVE APPROACH FOR POSTERIOR SPINAL SURGERY. THE DOMINOS IN THE POLARIS SPINAL SYSTEM CAN BE USED TO CONNECT THE PO¬LARIS SPINAL SYSTEM TO THE ALTIUS SPINAL SYSTEM, THE LINEUM OCT SPINE SYSTEM, THE ARRAY SPINAL SYSTEM, THE BIOMET® OMEGA21 SPINAL SYSTEM, OR THE SYNERGY SPINAL SYSTEM TO ACHIEVE ADDITIONAL LEVELS OF FIXATION. PLEASE REFER TO THE INDIVIDUAL SYSTEM'S PACKAGE INSERT FOR A LIST OF THE INDI¬CATIONS FOR USE FOR EACH SYSTEM. ,SPINAL FIXATION SYSTEM(POLARIS 5.5 SPINAL SYSTEM - SCREWS)-THE POLARIS SPINAL SYSTEM IS A NON-CERVICAL SPINAL FIXATION DEVICE INTENDED FOR IMMOBILIZATION AND STABILIZATION AS AN ADJUNCT TO FUSION AS A PEDICLE SCREW FIXATION SYSTEM, A POSTERIOR HOOK AND SACRAL/ILIAC SCREW FIXATION SYS¬TEM, OR AS AN ANTERIOR OR ANTEROLATERAL FIXATION SYSTEM FOR USE WITH AUTOGRAFT AND/OR ALLOGRAFT. THE POLARIS SPINAL SYSTEM IS INDICATED FOR ALL THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUD¬IES), SPONDYLOLISTHESIS, TRAUMA, (I.E., FRACTURE OR DISLOCATION), DEFORMITY OR CURVATURE (I.E., SCOLIOSIS, KYPHOSIS, SCHEUERMANN'S DISEASE, AND/OR LORDO¬SIS), TUMOR, STENOSIS, PSEUDOARTHROSIS, OR FAILED PREVIOUS FUSION. THE BALLISTA INSTRUMENTS ARE INTENDED TO BE USED WITH THE BALLISTA/POLARIS 5.5 IMPLANTS. CANNULATED SCREWS AND PERCUTANEOUS RODS, MAY BE USED WITH THE BALLISTA INSTRUMENTS TO PROVIDE THE SURGEON WITH A PERCUTANEOUS APPROACH FOR POSTERIOR SPINAL SURGERY FOR THE FOLLOWING ABOVE INDICATIONS. FOR PEDIATRIC PATIENTS, THE POLARIS SPINAL SYSTEM MAY BE USED FOR POSTERIOR, NON-CERVICAL PEDICLE SCREW FIXATION AS AN ADJUNCT TO FUSION TO TREAT ADOLES¬CENT IDIOPATHIC SCOLIOSIS AND IS ALSO

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	THE DOMINOS IN THE POLARIS SPINAL SYSTEM CAN BE USED TO CONNECT THE PO¬LARIS SPINAL SYSTEM TO THE ALTIUS SPINAL SYSTEM, THE LINEUM OCT SPINE SYSTEM, THE ARRAY SPINAL SYSTEM, THE BIOMET® OMEGA21 SPINAL SYSTEM, OR THE SYNERGY SPINAL SYSTEM TO ACHIEVE ADDITIONAL LEVELS OF FIXATION. PLEASE REFER TO THE INDIVIDUAL SYSTEM'S PACKAGE INSERT FOR A LIST OF THE INDI¬CATIONS FOR USE FOR EACH SYSTEM. ,SPINAL FIXATION SYSTEM(POLARIS 5.5 SPINAL SYSTEM - CONNECTOR)-THE POLARIS SPINAL SYSTEM IS A NON-CERVICAL SPINAL FIXATION DEVICE INTENDED FOR IMMOBILIZATION AND STABILIZATION AS AN ADJUNCT TO FUSION AS A PEDICLE SCREW FIXATION SYSTEM, A POSTERIOR HOOK AND SACRAL/ILIAC SCREW FIXATION SYS¬TEM, OR AS AN ANTERIOR OR ANTEROLATERAL FIXATION SYSTEM FOR USE WITH AUTOGRAFT AND/OR ALLOGRAFT. THE POLARIS SPINAL SYSTEM IS INDICATED FOR ALL THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUD¬IES), SPONDYLOLISTHESIS, TRAUMA, (I.E., FRACTURE OR DISLOCATION), DEFORMITY OR CURVATURE (I.E., SCOLIOSIS, KYPHOSIS, SCHEUERMANN'S DISEASE, AND/OR LORDO¬SIS), TUMOR, STENOSIS, PSEUDOARTHROSIS, OR FAILED PREVIOUS FUSION. THE BALLISTA INSTRUMENTS ARE INTENDED TO BE USED WITH THE BALLISTA/POLARIS 5.5 IMPLANTS. CANNULATED SCREWS AND PERCUTANEOUS RODS, MAY BE USED WITH THE BALLISTA INSTRUMENTS TO PROVIDE THE SURGEON WITH A PERCUTANEOUS APPROACH FOR POSTERIOR SPINAL SURGERY FOR THE FOLLOWING ABOVE INDICATIONS. FOR PEDIATRIC PATIENTS, THE POLARIS SPINAL SYSTEM MAY BE USED FOR POSTERIOR, NON-CERVICAL PEDICLE SCREW FIXATION AS AN ADJUNCT TO FUSION TO TREAT ADOLES¬CENT IDIOPATHIC SCOLIOSIS AND IS ALSO INDICATED FOR TREATMENT OF THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS AND FRACTURES CAUSED BY TUMOR AND/OR TRAUMA. PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE POLARIS SPINAL SYSTEM MAY BE USED WITH THE INSTRUMENTS IN ACCUVISION MINIMALLY INVASIVE SPINAL EXPOSURE SYSTEM TO PROVIDE THE SURGEON WITH A MINIMALLY INVASIVE APPROACH FOR POSTERIOR SPINAL SURGERY. THE DOMINOS IN THE POLARIS SPINAL SYSTEM CAN BE USED TO CONNECT THE PO¬LARIS SPINAL SYSTEM TO THE ALTIUS SPINAL SYSTEM, THE LINEUM OCT SPINE SYSTEM, THE ARRAY SPINAL SYSTEM, THE BIOMET® OMEGA21 SPINAL SYSTEM, OR THE SYNERGY SPINAL SYSTEM TO ACHIEVE ADDITIONAL LEVELS OF FIXATION. PLEASE REFER TO THE INDIVIDUAL SYSTEM'S PACKAGE INSERT FOR A LIST OF THE INDI¬CATIONS FOR USE FOR EACH SYSTEM. ,SPINAL

	FIXATION SYSTEM(POLARIS 5.5 SPINAL SYSTEM - PLUG)-THE POLARIS SPINAL SYSTEM IS A NON-CERVICAL SPINAL FIXATION DEVICE INTENDED FOR IMMOBILIZATION AND STABILIZATION AS AN ADJUNCT TO FUSION AS A PEDICLE SCREW FIXATION SYSTEM, A POSTERIOR HOOK AND SACRAL/ILIAC SCREW FIXATION SYS¬TEM, OR AS AN ANTERIOR OR ANTEROLATERAL FIXATION SYSTEM FOR USE WITH AUTOGRAFT AND/OR ALLOGRAFT. THE POLARIS SPINAL SYSTEM IS INDICATED FOR ALL THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUD¬IES), SPONDYLOLISTHESIS, TRAUMA, (I.E., FRACTURE OR DISLOCATION), DEFORMITY OR CURVATURE (I.E., SCOLIOSIS, KYPHOSIS, SCHEUERMANN'S DISEASE, AND/OR LORDO¬SIS), TUMOR, STENOSIS, PSEUDOARTHROSIS, OR FAILED PREVIOUS FUSION. THE BALLISTA INSTRUMENTS ARE INTENDED TO BE USED WITH THE BALLISTA/POLARIS 5.5 IMPLANTS. CANNULATED SCREWS AND PERCUTANEOUS RODS, MAY BE USED WITH THE BALLISTA INSTRUMENTS TO PROVIDE THE SURGEON WITH A PERCUTANEOUS APPROACH FOR POSTERIOR SPINAL SURGERY FOR THE FOLLOWING ABOVE INDICATIONS. FOR PEDIATRIC PATIENTS, THE POLARIS SPINAL SYSTEM MAY BE USED FOR POSTERIOR, NON-CERVICAL PEDICLE SCREW FIXATION AS AN ADJUNCT TO FUSION TO TREAT ADOLES¬CENT IDIOPATHIC SCOLIOSIS AND IS ALSO INDICATED FOR TREATMENT OF THE FOLLOWING CONDITIONS: SPONDYLOLISTHESIS/SPONDYLOLYSIS AND FRACTURES CAUSED BY TUMOR AND/OR TRAUMA. PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH. THE POLARIS SPINAL SYSTEM MAY BE USED WITH THE INSTRUMENTS IN ACCUVISION MINIMALLY INVASIVE SPINAL EXPOSURE SYSTEM TO PROVIDE THE SURGEON WITH A MINIMALLY INVASIVE APPROACH FOR POSTERIOR SPINAL SURGERY. THE DOMINOS IN THE POLARIS SPINAL SYSTEM CAN BE USED TO CONNECT THE PO¬LARIS SPINAL SYSTEM TO THE ALTIUS SPINAL SYSTEM, THE LINEUM OCT SPINE SYSTEM, THE ARRAY SPINAL SYSTEM, THE BIOMET® OMEGA21 SPINAL SYSTEM, OR THE SYNERGY SPINAL SYSTEM TO ACHIEVE ADDITIONAL LEVELS OF FIXATION. PLEASE REFER TO THE INDIVIDUAL SYSTEM'S PACKAGE INSERT FOR A LIST OF THE INDI¬CATIONS FOR USE FOR EACH SYSTEM.

1684	IMP/MD/2019/000241	1.License Holder Name: SURGIPLUS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC SYRINGES WITH NEEDLE(TOP)-USED TO ADMINISTER INJECTION, INSERT INTRAVENOUS DRUGS INTO THE BLOODSTREAM, TO INJECT LIQUID OR GASES INTO BODY TISSUES, OR TO REMOVE FROM THE BODY,DISPOSABLE HYPODERMIC SYRINGES WITH OUT NEEDLE(TOP)-USED TO ADMINISTER INJECTION, INSERT INTRAVENOUS DRUGS INTO THE BLOODSTREAM, TO INJECT LIQUID OR GASES INTO BODY TISSUES, OR TO REMOVE FROM THE BODY
1685	IMP/MD/2019/000242	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRAMEDULLARY NAIL SYSTEM(TRIGEN)-INDICATIONS FOR INTERLOCKING INTRAMEDULLARY NAILS INCLUDE SIMPLE LONG BONE FRACTURES; SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNIONS AND MALUNIONS; POLYTRAUMA AND MULTIPLE FRACTURES; PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES; RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; SUPRACONDYLAR FRACTURES; BONE LENGTHENING AND SHORTENING. INTERLOCKING INTRAMEDULLARY NAILS ARE INDICATED FOR FIXATION OF FRACTURES THAT OCCUR IN AND BETWEEN THE PROXIMAL AND DISTAL THIRD OF THE LONG BONES BEING TREATED.
1686	IMP/MD/2019/000243	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEEDLES AND CATHETER KITS FOR PLEXUS ANAESTHESIA(STIMUPLEX A)-IT IS USED FOR PLEXUS AND PERIPHERAL NERVE BLOCKS USING ELECTRICAL NERVE STIMULATION AS BLOCK ANESTHESIA FOR SURGICAL PROCEDURES INVOLVING THE UPPER AND LOWER EXTREMITIES WITH VARIOUS BLOCK TECHNIQUES.

1687	IMP/MD/2019/000244	1.License Holder Name: M/S. IMPLANTIUM INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INJECTABLE DERMAL FILLER(MONALISA FILLER)-MONALISA FILLER IS INTENDED TO BE USED FOR CORRECTION OF THE FACIAL WRINKLES AND FOLDS., SYNTHETIC BONE GRAFT MATERIAL(OSTEON II (SINUS/LIFTING))-THE USE OF OSTEON-II MAY BE CONSIDERED WHEN AUTOGENOUS BONE IS NOT INDICATED, OR INSUFFICIENT IN QUANTITY TO FULLFILL THE NEEDS OF THE PROPOSED SURGICAL PROCEDURE. CASE SELECTION AND USE OF APPROPRIATE SURGICAL PROCEDURE IS AT THE DISCRETION OF THE PHYSICIAN.
1688	IMP/MD/2019/000245	1.License Holder Name: VERITAZ TRADING & EXIM PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOSTATIC DRESSING (QUIKCLOT EMS)-FOR TEMPORARY EXTERNAL USE TO CONTROL TRAUMATIC BLEEDING.,HEMOSTATIC DRESSING(QUIKCLOT COMBAT GAUZE)-FOR TEMPORARY EXTERNAL USE TO CONTROL TRAUMATIC BLEEDING.
1689	IMP/MD/2019/000246	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUSPENSION FIXATION DEVICE(G-LOK)-IT IS INTENDED TO PROVIDE SUSPENSION FIXATION FOR SOFT TISSUE TO BONE IN THE REPAIR OF THE NATURAL LIGAMENT OR TENDON DISRUPTION OR ASSIST IN RECONSTRUCTION SURGERIES AND TO ASSIST IN THE MANAGEMENT OF RECONSTRUCTIVE SURGERIES,ANCHOR SYSTEM(KNOTILUS™ ANCHOR SYSTEM)-THE KNOTILUS™ ANCHOR SYSTEM IS INTENDED FOR USE IN SOFT TISSUE TO BONE FIXATION IN THE REPAIR OF THE NATURAL LIGAMENT OR TENDON DISRUPTION OR TO ASSIST IN RECONSTRUCTION SURGERIES. THE KNOTILUS™ ANCHOR SYSTEM IS INDICATED FOR USE IN THE: FOOT, ANKLE, KNEE, HIP, HAND, WRIST, ELBOW AND SHOULDER.

1690	IMP/MD/2019/000247	1.License Holder Name: SMITHS MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE PERFUSION SETS(NEOFUSER, NEOFUSER PLUS, NEOFUSER BOLUS, NEOFUSER VARIO, NEOFUSER VARIO PLUS, NEOFUSER ONCO)-NEOFUSER IS INTENDED FOR THE INFUSION OF CHEMOTHERAPY ANTIBIOTIC THERAPY, ANALGESIC THERAPY AND OTHER GENERAL INTRAVENOUS, INTRA-ARTERIAL, SUBCUTANEOUS, EPIDURAL, PERINEURAL AND INTRA-LESIONAL (IN OPERATIVE WOUNDS) INFUSIONS

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1691	IMP/MD/2019/000248	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUTURE ANCHOR (HEALICOIL KNOTLESS PK)-SMITH & NEPHEW HEALICOIL KNOTLESS PK SUTURE ANCHOR IS INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: SHOULDER (BICEPS TENODESIS, ROTATOR CUFF TEAR REPAIR).,SUTURE ANCHOR(SUTUREFIX CURVED)-THE SMITH & NEPHEW SUTUREFIX CURVED SUTURE ANCHORS ARE INTENDED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE.,SUTURE ANCHOR (HEALICOIL KNOTLESS REGENESORB)-SMITH & NEPHEW HEALICOIL KNOTLESS REGENESORB SUTURE ANCHOR IS INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: SHOULDER (BICEPS TENODESIS, ROTATOR CUFF TEAR REPAIR).,SUTURE ANCHOR(HEALICOIL REGENESORB)-HEALICOIL REGENESORB SUTURE ANCHORS ARE INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: SHOULDER - BANKART LESION REPAIRS, SLAP LESION REPAIRS, ACROMIOCLAVICULAR SEPARATION REPAIRS, ROTATOR CUFF TEAR REPAIRS, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTIONS, BICEPS TENODESIS, DELTOID REPAIRS; FOOT AND ANKLE - HALLUX VALGUS REPAIRS, MEDIAL OR LATERAL INSTABILITY REPAIRS/RECONSTRUCTIONS, ACHILLES TENDON REPAIRS/RECONSTRUCTIONS, MIDFOOT RECONSTRUCTIONS, METATARSAL LIGAMENT/TENDON REPAIRS/RECONSTRUCTIONS; ELBOW - ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTIONS, LATERAL EPICONDYLITIS REPAIR, BICEPS TENDON REATTACHMENT; KNEE - EXTRA-CAPSULAR REPAIRS (MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT), ILIOTIBIAL BAND TENODESIS, PATELLAR REALIGNMENT AND TENDON REPAIRS (VASTUS MEDIALIS OBLIQUUS ADVANCEMENT)., INTERFERENCE SCREWS(BICEPTOR KIT)-THE PK INTERFERENCE SCREW IS INTENDED FOR THE REATTACHMENT OF LIGAMENT, TENDON, OR SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: • SHOULDER - ACROMIOCLAVICULAR SEPARATION REPAIRS, BICEPS TENODESIS • KNEE - EXTRA-CAPSULAR REPAIRS (MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT); PATELLAR REALIGNMENT AND TENDON REPAIRS (VASTUS MEDIALIS OBLIQUUS ADVANCEMENT); ILIOTIBIAL BAND TENODESIS; ACL REPAIRS; PATELLAR TENDON REPAIR (APPLICABLE ONLY FOR 15MM LENGTH SCREWS); POSTERIOR OBLIQUE LIGAMENT REPAIR (APPLICABLE ONLY FOR 15MM LENGTH SCREWS); PCL REPAIRS (APPLICABLE ONLY FOR THE 25MM LENGTH

	SCREWS). THE SINGLE USE SURGICAL INSTRUMENTS IN THE KIT ARE INTENDED FOR USE IN ORTHOPAEDIC SURGICAL PROCEDURES., INTERFERENCE SCREWS(BIOSURE PK)-"THE BIOSURE PK SCREW IS INDICATED FOR THE REATTACHMENT OF LIGAMENT, TENDON, SOFT TISSUE, OR BONE TO BONE DURING CRUCIATE LIGAMENT RECONSTRUCTION SURGERIES OF THE KNEE. ALL SCREWS WITH A DIAMETER OF 9 MM OR LESS AND A LENGTH OF 25 MM OR LESS ARE ALSO INTENDED FOR USE IN THE FOLLOWING PROCEDURES: KNEE - ACL REPAIRS, PCL REPAIRS, EXTRA-CAPSULAR REPAIRS (MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT), PATELLAR REALIGNMENT AND TENDON REPAIRS (VASTUS MEDIALIS OBLIQUUS ADVANCEMENT), ILIOTIBIAL BAND TENODESIS; SHOULDER - ACROMIOCLAVICULAR SEPARATION REPAIRS, BICEPS TENODESIS; FOOT AND ANKLE - MEDIAL OR LATERAL INSTABILITY REPAIRS/RECONSTRUCTIONS, ACHILLES TENDON REPAIRS/RECONSTRUCTIONS, METATARSAL LIGAMENT/TENDON REPAIRS/RECONSTRUCTIONS, FLEXOR HULLUCIS LONGUS (FHL), TENDON TRANSFERS; ELBOW, WRIST, AND HAND - BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTIONS, LATERAL EPICONDYLITIS REPAIR, SCAPHOLUNATE LIGAMENT RECONSTRUCTION, TENDON TRANSFERS, CARPOMEDICARPAL JOINT ARTHROPLASTY",WRIST REPAIR KIT(TFCC FAST-FIX KIT)-THE SMITH & NEPHEW TFCC FAST-FIX KIT IS INTENDED FOR USE AS A SUTURE RETENTION DEVICE TO FACILITATE TRIANGULAR FIBROCARTILAGE COMPLEX (TFCC) REPAIR PROCEDURES.,MENISCAL REPAIR SYSTEM (FAST-FIX 360)-THE SMITH & NEPHEW FAST-FIX 360 MENISCAL REPAIR SYSTEM IS INTENDED FOR USE AS A SUTURE RETENTION DEVICE TO FACILITATE PERCUTANEOUS OR ENDOSCOPIC SOFT TISSUE PROCEDURES. IT IS INDICATED FOR USE IN MENISCAL REPAIRS AND ALLOGRAFT TRANSPLANT PROCEDURES. THE FAST-FIX 360 SYSTEM IS INTENDED TO BE USED FOR ANCHORING THE ALLOGRAFT TO THE MENISCAL RIM DURING ALLOGRAFT TRANSPLANT PROCEDURES.,SUTURE(ULTRATAPE)-ULTRATAPE SUTURE IS INDICATED FOR USE IN APPROXIMATION AND/OR LIGATION OF SOFT TISSUES, INCLUDING ALLOGRAFT TISSUE FOR ORTHOPEDIC SURGERIES.,FIXATION BUTTON(ENDOBUTTON)-THE ENDOBUTTON FIXATION DEVICE IS INDICATED FOR USE IN SUTURE FIXATION OF LIGAMENTS AND TENDONS IN PATIENTS REQUIRING LIGAMENT OR TENDON REPAIR. THE ENDOBUTTON CL BTB FIXATION DEVICE IS USED FOR FIXATION OF A BONE-TENDON-BONE GRAFT DURING ORTHOPEDIC RECONSTRUCTION PROCEDURES SUCH AS ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION.,SUTURE ANCHOR(TWINFIX ULTRA HA)-TWINFIX ULTRA HA PRELOADED

	SUTURE ANCHORS ARE INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: SHOULDER - BANKART LESION REPAIRS, SLAP LESION REPAIRS, ACROMIOCLAVICULAR SEPARATION REPAIRS, ROTATOR CUFF TEAR REPAIRS, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTIONS, BICEPS TENODESIS, DELTOID REPAIRS, INTERFERENCE SCREWS (ABSORBABLE)(BIOSURE HA)-"THE BIOSURE HA INTERFERENCE SCREW IS INDICATED FOR FIXATION OF BONE-TENDON-BONE OR SOFT TISSUE GRAFTS DURING ANTERIOR/POSTERIOR CRUCIATE LIGAMENT (ACL/PCL) RECONSTRUCTION PROCEDURES.",SUTURE ANCHOR(FOOTPRINT ULTRA)-SMITH & NEPHEW FOOTPRINT ULTRA PK SUTURE ANCHORS ARE INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: SHOULDER - ROTATOR CUFF TEAR REPAIRS, BICEPS TENODESIS, DELTOID REPAIRS; KNEE - EXTRA-CAPSULAR REPAIRS (MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT).,SUTURE ANCHOR(MINI TAC)-AS PER IFU 1061170-G 10600149-E,SUTURE ANCHOR(SUTUREFIX ULTRA)-THE SMITH & NEPHEW SUTUREFIX ULTRA SUTURE ANCHOR IS INTENDED FOR THE SECURE FIXATION OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: HIP - HIP CAPSULE REPAIR (ACETABULAR LABRUM REPAIR/RECONSTRUCTION); SHOULDER - CAPSULAR STABILIZATION (BANKART REPAIR, ANTERIOR SHOULDER INSTABILITY, SLAP LESION REPAIRS, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTIONS), ACROMIOCLAVICULAR SEPARATION REPAIRS, DELTOID REPAIRS, ROTATOR CUFF TEAR REPAIRS, BICEPS TENODESIS; FOOT AND ANKLE - HALLUX VALGUS REPAIRS, MEDIAL OR LATERAL INSTABILITY REPAIRS/RECONSTRUCTIONS, ACHILLES TENDON REPAIRS/RECONSTRUCTIONS, MIDFOOT RECONSTRUCTIONS, METATARSAL LIGAMENT/TENDON REPAIRS/RECONSTRUCTIONS, BUNIONECTOMY; ELBOW, WRIST, AND HAND - BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTIONS, LATERAL EPICONDYLITIS REPAIR; KNEE - EXTRA-CAPSULAR REPAIRS (MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT), PATELLAR REALIGNMENT AND TENDON REPAIRS (VASTUS MEDIALIS OBLIQUUS ADVANCEMENT), ILIOTIBIAL BAND TENODESIS,SUTURE ANCHOR(MICRORAPTOR REGENESORB)-MICRORAPTOR REGENESORB SUTURE ANCHOR IS INTENDED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: HIP - ACETABULAR LABRUM REPAIR/RECONSTRUCTION; SHOULDER - CAPSULAR STABILIZATION (BANKART REPAIR, ANTERIOR SHOULDER INSTABILITY, SLAP LESION

	REPAIRS, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTIONS), BICEPS TENODESIS,SUTURE ANCHOR (MICRORAPTOR KNOTLESS-PEEK)-"SMITH & NEPHEW MICRORAPTOR KNOTLESS SUTURE ANCHOR IS INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: HIP ACETABULAR LABRUM REPAIR/RECONSTRUCTION SHOULDER • CAPSULAR STABILIZATION — BANKART REPAIR — ANTERIOR SHOULDER INSTABILITY — SLAP LESION REPAIRS — CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTIONS • BICEPS TENODESIS • ROTATOR CUFF TEAR REPAIRS",SUTURE ANCHOR (MICRORAPTOR KNOTLESS-REGENESORB)-"SMITH & NEPHEW MICRORAPTOR KNOTLESS SUTURE ANCHOR IS INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: HIP ACETABULAR LABRUM REPAIR/RECONSTRUCTION SHOULDER • CAPSULAR STABILIZATION — BANKART REPAIR — ANTERIOR SHOULDER INSTABILITY — SLAP LESION REPAIRS — CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTIONS • BICEPS TENODESIS • ROTATOR CUFF TEAR REPAIRS",SUTURE(MINITAPE)-MINITAPE SUTURE IS INDICATED FOR USE IN APPROXIMATION AND/OR LIGATION OF SOFT TISSUES, INCLUDING ALLOGRAFT TISSUE FOR ORTHOPEDIC SURGERIES., SUTURE ANCHOR(HEALICOIL)-HEALICOIL PK PRELOADED SUTURE ANCHORS ARE INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: SHOULDER - ROTATOR CUFF TEAR REPAIRS, BICEPS TENODESIS, DELTOID REPAIRS.,INTERFERENCE SCREW (ABSORBABLE)(BIOSURE REGENESORB)-THE BIOSURE REGENESORB INTERFERENCE SCREW IS INDICATED FOR THE REATTACHMENT OF LIGAMENT, TENDON, SOFT TISSUE, OR BONE-TENDON-BONE FOR THE FOLLOWING INDICATIONS: KNEE - ACL REPAIRS, PCL REPAIRS, EXTRA-CAPSULAR REPAIRS (MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT), PATELLAR REALIGNMENT AND TENDON REPAIRS (VASTUS MEDIALIS OBLIQUUS ADVANCEMENT), ILIOTIBIAL BAND TENODESIS.,SUTURE ANCHOR(TWINFIX ULTRA TI)-AS PER IFU 10600538-E,SUTURE ANCHOR(TWINFIX TI)-TWINFIX TI PRELOADED SUTURE ANCHORS ARE INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: SHOULDER• BANKART LESION REPAIRS• SLAP LESION REPAIRS• ROTATOR CUFF TEAR REPAIRS• CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTIONS• BICEPS TENODESIS• DELTOID REPAIRS FOOT AND ANKLE• MIDFOOT RECONSTRUCTIONS• METATARSAL LIGAMENT/TENDON REPAIRS/RECONSTRUCTIONS ELBOW, WRIST, AND HAND• ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTIONS(ONLY TWINFIX TI PRELOADED

	SUTURE ANCHORS IS INDICATED FOR THIS INDICATION)• BICEPS TENDON REATTACHMENTSCAPHOLUNATE LIGAMENT RECONSTRUCTION(ONLY TWINFIX TI PRELOADED SUTURE ANCHORS IS INDICATED FOR THIS INDICATION)KNEE -EXTRA-CAPSULAR REPAIRS (MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT), ILIOTIBIAL BAND TENODESIS, PATELLAR REALIGNMENT AND TENDON REPAIRS, INCLUDING VASTUS MEDIALIS OBLIQUOUS ADVANCEMENT,SUTURE ANCHOR(TWINFIX ULTRA PK)-"TWINFIX ULTRA PK PRELOADED SUTURE ANCHORS ARE INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: SHOULDER - ROTATOR CUFF TEAR REPAIRS, BICEPS TENODESIS, DELTOID REPAIRS; FOOT AND ANKLE - HALLUX VALGUS REPAIRS, MEDIAL OR LATERAL INSTABILITY REPAIRS/RECONSTRUCTIONS, ACHILLES TENDON REPAIRS/RECONSTRUCTIONS, MIDFOOT RECONSTRUCTIONS, METATARSAL LIGAMENT/TENDON REPAIRS/RECONSTRUCTIONS; ELBOW - ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTIONS, LATERAL EPICONDYLITIS REPAIR, BICEPS TENDON REATTACHMENT.",FIXATION SCREW(SOFTSILK)-THE SMITH & NEPHEW SOFTSILK SCREWS ARE USED FOR INTERFERENCE FIXATION OF BONE-TENDON-BONE OR SOFT TISSUE GRAFTS IN ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION.,ACL/PCL FIXATION SYSTEMS(GTS TAPERED SCREW)-"THE GTS TAPERED SCREW IS INDICATED FOR FIXATION OF SOFT TISSUE GRAFTS DURING CRUCIATE LIGAMENT RECONSTRUCTION.",FIXATION SCREW(BIORCI SCREWS)-THEY ARE INDICATED FOR FIXATION OF BONE-TENDON-BONE OR SOFT TISSUE GRAFTS IN ANTERIOR/POSTERIOR CRUCIATE LIGAMENT (ACL/PCL) RECONSTRUCTION PROCEDURES.,SUTURE ANCHOR(OSTEORAPTOR)-THE SMITH & NEPHEW OSTEORAPTOR SUTURE ANCHOR IS INTENDED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: HIP - HIP CAPSULE REPAIR (ACETABULAR LABRUM REATTACHMENT); SHOULDER - CAPSULAR STABILIZATION (BANKART REPAIR, ANTERIOR SHOULDER INSTABILITY, SLAP LESION REPAIRS, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTIONS), ACROMIOCLAVICULAR SEPARATION REPAIRS, DELTOID REPAIRS, ROTATOR CUFF TEAR REPAIRS, BICEPS TENODESIS.,FIXATION BUTTON(SUTURE WASHER)-THE SMITH & NEPHEW SUTURE WASHERS ARE INDICATED FOR USE AS A FIXATION POINT FOR SUTURES USED IN ORTHOPEDIC LIGAMENT REPAIR.,SUTURE ANCHOR(BIORAPTOR)-"THE BIORAPTOR SUTURE ANCHOR IS INTENDED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: HIP - ACETABULAR LABRUM REATTACHMENT;

	SHOULDER - CAPSULAR STABILIZATION (BANKART REPAIR, ANTERIOR SHOULDER INSTABILITY, SLAP LESION REPAIRS, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTIONS); FOOT AND ANKLE - HALLUX VALGUS REPAIRS, MEDIAL OR LATERAL INSTABILITY REPAIRS/RECONSTRUCTIONS, ACHILLES TENDON REPAIRS/RECONSTRUCTIONS, MIDFOOT RECONSTRUCTIONS, METATARSAL LIGAMENT/TENDON REPAIRS/RECONSTRUCTIONS, BUNIONECTOMY; ELBOW, WRIST, AND HAND - BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTIONS, LATERAL EPICONDYLITIS REPAIR. BIORAPTOR SUTURE ANCHOR WITH NEEDLES AND BIORAPTOR™ KNOTLESS ARE ONLY INDICATED FOR HIP AND SHOULDER; WHILE THE BIORAPTOR™ CURVED IS INDICATED FOR SHOULDER ONLY. ",SUTURE ANCHOR (ULTRA FAST-FIX)-THE ULTRA FAST-FIX MENISCAL REPAIR SYSTEM IS INTENDED FOR USE AS A SUTURE RETENTION DEVICE TO FACILITATE PERCUTANEOUS OR ENDOSCOPIC SOFT TISSUE PROCEDURES. IT IS INDICATED FOR USE IN KNEE MENISCAL REPAIR AND ALLOGRAFT TRANSPLANTATION PROCEDURES. IT IS INTENDED TO BE USED FOR ANCHORING THE ALLOGRAFT TO THE MENISCAL RIM DURING MENISCAL ALLOGRAFT TRANSPLANTATION PROCEDURES.,SUTURE ANCHOR(SPYROMITE)-"THE SMITH & NEPHEW SPYROMITE 2.0 PK SUTURE ANCHOR IS INTENDED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: ELBOW, WRIST, AND HAND - BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTIONS, LATERAL EPICONDYLITIS REPAIR, SCAPHOLUNATE LIGAMENT RECONSTRUCTION.",FIXATION SCREW (RCI SCREWS)-SMITH & NEPHEW RCI FIXATION SCREWS ARE USED FOR INTERFERENCE FIXATION OF BONE-TENDON-BONE OR SOFT TISSUE GRAFTS IN ANTERIOR OR POSTERIOR CRUCIATE LIGAMENT RECONSTRUCTION.,SUTURE ANCHOR(DYNOMITE)-"THE SMITH & NEPHEW DYNOMITE 2.0 PK SUTURE ANCHOR IS INTENDED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: FOOT AND ANKLE - MEDIAL OR LATERAL INSTABILITY REPAIRS/RECONSTRUCTIONS, ACHILLES TENDON REPAIRS/RECONSTRUCTIONS, BUNIONECTOMY; ELBOW, WRIST, AND HAND - BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTIONS, LATERAL EPICONDYLITIS REPAIR "

1692	IMP/MD/2019/000249	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FENESTRATED SCREW SYSTEM(VIPER)-THE VIPER® FENESTRATED SCREW SYSTEM IS INTENDED TO BE USED WITH THE CONFIDENCE SPINAL CEMENT SYSTEM® OR THE V-MAX® MIXING AND DELIVERY SYSTEM AND THE VERTEBROPLASTIC® RADIOPAQUE RESINOUS MATERIAL OR THE VERTECEM V+ CEMENT KIT TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC LUMBAR AND SACRAL SPINE IN PATIENTS WITH DIMINISHED BONE QUALITY (E.G. OSTEOPOROSIS OSTEOPENIA METASTATIC DISEASE). IT IS INTENDED TO PROVIDE TEMPORARY INTERNAL SUPPORT AND FIXATION WHILE FUSION MASS IS CONSOLIDATING OR FRACTURE IS HEALING OR FOR THE PALLIATIVE RECONSTRUCTION OF THE TUMOR PATIENTS. ,SPINE SYSTEM - WASHER(MOSS MIAMI SPINE SYSTEM)-THE MOSS MIAMI SPINE SYSTEMS WHEN USED AS ANTERIOR THORACIC/LUMBAR SCREW FIXATION SYSTEMS, ARE INDICATED FOR DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (FRACTURE AND/OR DISLOCATION), SPINAL STENOSIS, DEFORMITIES (SCOLIOSIS, LORDOSIS AND/OR KYPHOSIS), TUMOR, AND PREVIOUS FAILED FUSION (PSEUDARTHROSIS),SPINE SYSTEM-SCREW (EXPEDIUM VERSE)-THE EXPEDIUM VERSE SPINE SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM VERSE SPINE SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR, PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A POSTERIOR PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION, THE EXPEDIUM VERSE SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED

	BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR, PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM VERSE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM VERSE SYSTEMS ARE INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH.,SPINAL SYSTEM (TITANIUM ALLOY CONNECTOR)(MONARCH)-THE ISOLA, VSP, MOSS MIAMI, TIMX AND MONARCH SPINE SYSTEMS ARE PEDICLE SCREW SYSTEMS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE: DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, FRACTURE, DISLOCATION, SCOLIOSIS, KYPHOSIS, SPINALTUMOR, AND FAILED PREVIOUS FUSION (PSEUDARTHROSIS).THE ISOLA, VSP, MOSS MIAMI, TIMX AND MONARCH SPINE SYSTEMS ARE ALSO INDICATED FOR PEDICLE SCREW FIXATION FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADES 3 AND 4) OF THE L5–S1 VERTEBRA IN SKELETALLY MATURE PATIENTS RECEIVING FUSION BY AUTOGENOUS BONE GRAFT HAVING IMPLANTS ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 TO SACRUM) WITH REMOVAL OF THE IMPLANTS AFTER THE ATTAINMENT OF A SOLID FUSION.THE ISOLA, MOSS MIAMI, TIMX AND MONARCH SPINE SYSTEMS ARE ALSO A HOOK AND SACRAL/ILIAC SCREW FIXATION SYSTEM OF THE NONCERVICAL SPINE INDICATED FOR DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (FRACTURE AND/OR DISLOCATION), SPINAL STENOSIS, DEFORMITIES (SCOLIOSIS, LORDOSIS AND/OR KYPHOSIS),TUMOR, AND PREVIOUS FAILED FUSION (PSEUDARTHROSIS).THE ISOLA, VSP, AND MONARCH SPINE SYSTEMS WHEN USED WITH PEDICLE SCREWS ARE INDICATED FOR DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES).LEVELS OF FIXATION ARE FOR THE THORACIC, LUMBAR AND SACRAL SPINE. THE MONARCH SPINE SYSTEM DUAL ROD CONNECTORS CAN BE USED TO CONNECT

	MONARCH SPINE SYSTEM RODS TO RODS OF OTHER DEPUY SPINE 4.75MM, 5.5MM, AND 6.35MM DIAMETER ROD SYSTEMS.,SPINE SYSTEM - SCREW(MOSS MIAMI SPINE SYSTEM)-THE MOSS MIAMI SPINE SYSTEMS ARE PEDICLE SCREW SYSTEMS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE: DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, FRACTURE, DISLOCATION, SCOLIOSIS, KYPHOSIS, SPINAL TUMOR, AND FAILED PREVIOUS FUSION (PSEUDARTHROSIS). THE MOSS MIAMI SPINE SYSTEMS ARE ALSO INDICATED FOR PEDICLE SCREW FIXATION FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADES 3 AND 4) OF THE L5–S1 VERTEBRA IN SKELETALLY MATURE PATIENTS RECEIVING FUSION BY AUTOGENOUS BONE GRAFT HAVING IMPLANTS ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 TO ACRUM) WITH REMOVAL OF THE IMPLANTS AFTER THE ATTAINMENT OF A SOLID FUSION.,SPINE SYSTEM - RODS(EXPEDIUM SPINE SYSTEM)-EXPEDIUM SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM SPINE SYSTEMS ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SYSTEMS ARE INTENDED TO BE USED WITH AUTOGRAFT AND/ OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH, SPINE SYSTEM - HOOK(EXPEDIUM SPINE SYSTEM)-THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR

	DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES) SPONDYLOLISTHESIS TRAUMA (I.E., FRACTURE OR DISLOCATION) SPINAL STENOSIS CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS) TUMOR PSEUDOARTHROSIS AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS.,SPINE SYSTEM - SCREW(VIPER SPINE SYSTEM)-THE VIPER SPINE SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. IT IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES) SPONDYLOLISTHESIS TRAUMA (I.E., FRACTURE OR DISLOCATION) SPINAL STENOSIS CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS) TUMOR PSEUDOARTHROSIS AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A PERCUTANEOUS, POSTERIOR APPROACH WITH MIS INSTRUMENTATION, THE VIPER SYSTEMS ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES) SPONDYLOLISTHESIS TRAUMA (I.E., FRACTURE OR ISLOCATION) SPINAL STENOSIS CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS) TUMOR PSEUDOARTHROSIS AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS,SPINAL SYSTEM (TITANIUM ALLOY ROD)(MOUNTAINEER OCT)-THE SUMMIT SI OCT SPINAL SYSTEM AND MOUNTAINEER OCT SPINAL SYSTEM ARE INTENDED TO PROMOTE FUSION OF THE CERVICAL SPINE AND OCCIPITO-CERVICO-THORACIC JUNCTION (OCCIPUT-T3), AND ARE INDICATED FOR THE FOLLOWING: • DDD (NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC AS CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES) • SPONDYLOLISTHESIS • SPINAL STENOSIS • FRACTURE/DISLOCATION • ATLANTO/AXIAL FRACTURE WITH INSTABILITY • OCCIPITOCERVICAL DISLOCATION • REVISION OF PREVIOUS

	CERVICAL SPINE SURGERY • TUMORS THE OCCIPITAL BONE SCREWS ARE LIMITED TO OCCIPITAL FIXATION ONLY.THE USE OF THE MONOAXIAL AND POLYAXIAL SCREWS IS LIMITED TO PLACEMENT IN THE UPPER THORACIC SPINE (T1-T3) IN TREATING THORACIC CONDITIONS ONLY. THEY ARE NOT INTENDED TO BE PLACED IN THE CERVICAL SPINE.THE SONGER WIRE/CABLE SYSTEM TO BE USED WITH THE SUMMIT SI OCT SPINAL SYSTEM AND MOUNTAINEER OCT SPINAL SYSTEM ALLOWS FOR WIRE/CABLE ATTACHMENT TO THE POSTERIOR CERVICAL SPINE.THE SUMMIT SI OCT SYSTEM AND MOUNTAINEER OCT SPINAL SYSTEM CAN ALSO BE LINKED TO THE ISOLA, MONARCH, MOSS MIAMI, VIPER AND EXPEDIUM SYSTEMS USING THE DUAL WEDDING BAND AND AXIAL CONNECTORS, AND VIA DUAL DIAMETER RODS.,SPINE SYSTEM - CONNECTOR(EXPEDIUM SPINE SYSTEM)-EXPEDIUM SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM SPINE SYSTEMS ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SYSTEMS ARE INTENDED TO BE USED WITH AUTOGRAFT AND/ OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH, SPINAL SYSTEM (TITANIUM ALLOY ROD)(MONARCH)-THE ISOLA, VSP, MOSS MIAMI, TIMX AND MONARCH SPINE SYSTEMS ARE PEDICLE SCREW SYSTEMS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE: DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, FRACTURE, DISLOCATION, SCOLIOSIS, KYPHOSIS, SPINALTUMOR, AND FAILED PREVIOUS FUSION (PSEUDARTHROSIS).THE ISOLA, VSP, MOSS MIAMI, TIMX AND

	MONARCH SPINE SYSTEMS ARE ALSO INDICATED FOR PEDICLE SCREW FIXATION FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADES 3 AND 4) OF THE L5–S1 VERTEBRA IN SKELETALLY MATURE PATIENTS RECEIVING FUSION BY AUTOGENOUS BONE GRAFT HAVING IMPLANTS ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 TO SACRUM) WITH REMOVAL OF THE IMPLANTS AFTER THE ATTAINMENT OF A SOLID FUSION.THE ISOLA, MOSS MIAMI, TIMX AND MONARCH SPINE SYSTEMS ARE ALSO A HOOK AND SACRAL/ILIAC SCREW FIXATION SYSTEM OF THE NONCERVICAL SPINE INDICATED FOR DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (FRACTURE AND/OR DISLOCATION), SPINAL STENOSIS, DEFORMITIES (SCOLIOSIS, LORDOSIS AND/OR KYPHOSIS),TUMOR, AND PREVIOUS FAILED FUSION (PSEUDARTHROSIS).THE ISOLA, VSP, AND MONARCH SPINE SYSTEMS WHEN USED WITH PEDICLE SCREWS ARE INDICATED FOR DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES).LEVELS OF FIXATION ARE FOR THE THORACIC, LUMBAR AND SACRAL SPINE.THE MONARCH SPINE SYSTEM DUAL ROD CONNECTORS CAN BE USED TO CONNECT MONARCH SPINE SYSTEM RODS TO RODS OF OTHER DEPUY SPINE 4.75MM, 5.5MM, AND 6.35MM DIAMETER ROD SYSTEMS.,SPINE SYSTEM - SCREW(EXPEDIUM SPINE SYSTEM)-"EXPEDIUM SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM SPINE SYSTEMS ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SYSTEMS ARE INTENDED TO BE USED WITH AUTOGRAFT AND/ OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS

	LIMITED TO A POSTERIOR APPROACH "

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1693	IMP/MD/2019/000250	1.License Holder Name: TERUMO PENPOL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTION SET (TERUFLEX BP-KIT)-TERUFLEX BP-KIT IS A STERILE NON-INVASIVE MEDICAL DEVICE FOR SINGLE USE ONLY, AND USED FOR COLLECTING AND STORING THE LEUKOCYTE-POOR PLATELETS IN THE PREPARATION OF PLATELETS.,LEUKOCYTE REMOVAL FILTER SET (IMUGARD III-RC - TF*IR1002ND)-IMUGARD III-RC IS A STERILE NON INVASIVE MEDICAL DEVICE FOR SINGLE USE ONLY, AND USED FOR REMOVING LEUKOCYTES FROM BLOOD OR RED CELLS COMPONENT TO COLLECT OR TRANSFUSE LEUKOCYTE-POOR RED CELLS IN THE PREPARATION OR TRANSFUSION OF RED BLOOD CELLS.,BLOOD COLLECTION SET(TERUFLEX BP-KIT WITH IMUGARDIII-S PL)-TERUFLEX BP-KIT WITH IMUGARD III-S PL IS A STERILE NON-INVASIVE MEDICAL DEVICE FOR SINGLE USE ONLY, AND USED FOR REMOVING LEUKOCYTES FROM THE PLATELETS COMPONENT TO COLLECT AND STORE THE LEUKOCYTE-POOR PLATELETS IN THE PREPARATION OF PLATELETS COMPONENT.,LEUKOCYTE REMOVAL FILTER SET(IMUGARD III-RC - TF*IR1602ES)-IMUGARD III-RC IS A STERILE NON INVASIVE MEDICAL DEVICE FOR SINGLE USE ONLY, AND USED FOR REMOVING LEUKOCYTES FROM BLOOD OR RED CELLS COMPONENT TO COLLECT OR TRANSFUSE LEUKOCYTE-POOR RED CELLS IN THE PREPARATION OR TRANSFUSION OF RED BLOOD CELLS.,LEUKOCYTE REMOVAL FILTER SET(IMUGARD III-RC - TF*IR2002NC)-IMUGARD III-RC IS A STERILE NON INVASIVE MEDICAL DEVICE FOR SINGLE USE ONLY, AND USED FOR REMOVING LEUKOCYTES FROM BLOOD OR RED CELLS COMPONENT TO COLLECT OR TRANSFUSE LEUKOCYTE-POOR RED CELLS IN THE PREPARATION OR TRANSFUSION OF RED BLOOD CELLS.,LEUKOCYTE REMOVAL FILTER SET(IMUGARD III-PL - TF*IP2002N)-IMUGARD III-PL IS A STERILE NON INVASIVE MEDICAL DEVICE FOR SINGLE USE ONLY, AND USED FOR REMOVING LEUKOCYTES FROM PLATELETS COMPONENT TO COLLECT OR TRANSFUSE LEUKOCYTE POOR PLATELETS IN THE PREPARATION OR TRANSFUSION OF PLATELETS.,LEUKOCYTE REMOVAL FILTER SET(IMUGARD III-PL - TF*IP1AS2DS)-IMUGARD III-PL IS A STERILE NON INVASIVE MEDICAL DEVICE FOR SINGLE USE ONLY, AND USED FOR REMOVING LEUKOCYTES FROM PLATELETS COMPONENT TO COLLECT OR TRANSFUSE LEUKOCYTE POOR PLATELETS IN THE PREPARATION OR TRANSFUSION OF PLATELETS., LEUKOCYTE REMOVAL FILTER SET(IMUGARD III-PL - TF*IP1002N)-IMUGARD III-PL IS A STERILE NON INVASIVE MEDICAL DEVICE FOR SINGLE USE ONLY, AND USED FOR REMOVING LEUKOCYTES FROM PLATELETS COMPONENT TO COLLECT OR TRANSFUSE LEUKOCYTE POOR PLATELETS IN THE PREPARATION OR TRANSFUSION OF

		PLATELETS.
1694	IMP/MD/2019/000251	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPIKED WSHER SCREWS (WASHERLOC TIBIAL FIXATION DEVICE)-SOFT TISSUE FIXATION TO BONE FIXATION SPECIFICALLY DURING LIGAMENT RECONSTRUCTIVE PROCEDURES.,ORTHOPAEDIC IMPLANT-INTERNAL FIXATION(ALL THREAD L-15 SUTURE ANCHOR, ALL THREAD L-15 LACTOSORB ANCHOR)-SOFT TISSUE REATTACHMENT PROCEDURES IN THE SHOULDER, WRIST/HAND, ANKLE/FOOT, ELBOW, AND KNEE., ORTHOPAEDIC IMPLANT-INTERNAL FIXATION(PEEK ALL THREAD KNOTLESS ANCHOR IMPLANT)-SOFT TISSUE REATTACHMENT PROCEDURES IN THE SHOULDER, WRIST/HAND, ANKLE/FOOT, ELBOW, AND KNEE.,ARTIFICIAL LIGAMENT FIXATION DEVICE (TOGGLELOC-ARTIFICIAL LIGAMENT FIXATION DEVICE)-IT IS INTENDED FOR SOFT TISSUE TO BONE FIXATION FOR SHOULDER, FOOT, ANKLE, HAND, AND WRIST.,SOFT ANCHOR(JUGGERKNOT LONG-SOFT ANCHOR)-IT IS INTENDED FOR SOFT TISSUE TO BONE FIXATION FOR SHOULDER, FOOT, ANKLE, ELBOW, KNEE, HAND, WRIST, AND HIP.,SOFT ANCHOR(JUGGERKNOT MINI-SOFT ANCHOR)-IT IS INTENDED FOR SOFT TISSUE TO BONE FIXATION FOR SHOULDER, FOOT, ANKLE, HAND, AND WRIST.,ORTHOPAEDIC IMPLANT-INTERNAL FIXATION(ALL THREAD-TI ANCHOR, ALL THREAD TI III ANCHOR)-SOFT TISSUE REATTACHMENT PROCEDURES IN THE SHOULDER, WRIST/HAND, ANKLE/FOOT, ELBOW, AND KNEE.,SOFT ANCHOR (JUGGERKNOT-SOFT ANCHOR)-IT IS INTENDED FOR SOFT TISSUE TO BONE FIXATION FOR SHOULDER, FOOT, ANKLE, ELBOW, KNEE, HAND, WRIST, AND HIP.

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1695	IMP/MD/2019/000252	1.License Holder Name: ORIGIO INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OOCYTE RECOVERY NEEDLE(WALLACE)-ULTRASOUND-GUIDED TRANSVAGINAL COLLECTION OF OOCYTES.,OOCYTE RECOVERY SET(WALLACE)-ULTRASOUND-GUIDED TRANSVAGINAL COLLECTION OF OOCYTES., EMBRYO REPLACEMENT CATHETER(WALLACE SURE-PRO ULTRA)-IT IS INTENDED TO BE USED FOR INTRODUCTION OF EMBRYOS INTO THE UTERINE CAVITY.,MALLEABLE STYLET(WALLACE)-IT IS INTENDED TO BE USED FOR PROVIDING RIGIDITY WHEN USING A WALLACE EMBRYO REPLACEMENT CATHETER AND A PASSAGE THROUGH THE CERVIX IS IMPEDED OR DIFFICULT.,TRIAL TRANSFER CATHETER(WALLACE SURE VIEW)-IT IS INTENDED TO DETERMINE WHETHER THE CERVIX IS PASSABLE FOR WALLACE EMBRYO REPLACEMENT CATHETER., EMBRYO REPLACEMENT CATHETER(WALLACE SURE-PRO)-IT IS INTENDED TO BE USED FOR INTRODUCTION OF EMBRYOS INTO THE UTERINE CAVITY.,TRIAL TRANSFER CATHETER(WALLACE)-IT IS INTENDED TO DETERMINE WHETHER THE CERVIX IS PASSABLE FOR WALLACE EMBRYO REPLACEMENT CATHETER.,EMBRYO REPLACEMENT CATHETER(WALLACE)-IT IS INTENDED TO BE USED FOR INTRODUCTION OF EMBRYOS INTO THE UTERINE CAVITY., EMBRYO REPLACEMENT CATHETER(WALLACE SURE VIEW)-IT IS INTENDED TO BE USED FOR INTRODUCTION OF EMBRYOS INTO THE UTERINE CAVITY.,OOCYTE RECOVERY SET(WALLACE)-ULTRASOUND-GUIDED TRANSVAGINAL COLLECTION OF OOCYTES.,EMBRYO REPLACEMENT CATHETER(WALLACE)-IT IS INTENDED TO BE USED FOR INTRODUCTION OF EMBRYOS INTO THE UTERINE CAVITY.

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1696	IMP/MD/2019/000253	1.License Holder Name: 365 MEDICAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ELECTROLYSED SOLUTION WITH HYPOCHLOROUS ACID WITH NEUTRAL PH FOR WOUND CARE(AQUACYN WOUND CARE SOLUTION)-AQUACYN WOUND CARE IS INTENDED FOR USE IN CLEANING THE SKIN, EYELID AND EYELASHES, IRRIGATION OF BODY CAVITIES LIKE NASAL AND ORAL AND DEBRIDEMENT AND MOISTENING OF ALL ACUTE AND CHRONIC WOUNDS, ULCERS, ACNE, CUTS , RASHES, ABRASIONS AND BURNS BY REDUCING THE AMOUNT OF MICRO ORGANISMS AND CONTRIBUTING TO MOIST WOUND ENVIRONMENT. IT ENABLES BODY TO PERFORM IT OWN HEALING PROCESS. THIS SOLUTION CAN BE BROADLY APPLIED TO A COMPREHENSIVE WOUND TREATMENT., ELECTROLYSED HYDROGEL WITH HYPOCHLOROUS ACID NEUTRAL PH FOR WOUND CARE(AQUACYN WOUND CARE HYDROGEL)-AQUACYN HYDROGEL IS INTENDED FOR USE AS SKIN MOISTURISER, CARE OF SKIN ULCERS, ACNE, ABRASIONS, MICRODERM ABRASIONS, POST LASER TREATMENT, POST CHEMICAL PEELS, BURNS, LACERATIONS AND IRRITATIONS AND ANTISEPTIC FOR INTACT SKIN FOR DISINFECTION AND SANITIZATION. IT IS ALSO INTENDED FOR MANAGEMENT OF EXUDING WOUNDS SUCH AS LEG ULCER, PRESSURE ULCER, DIABETIC ULCER, SKIN INFECTION AND FOR THE MANAGEMENT OF MECHANICALLY OR SURGICALLY DEBRIDED WOUNDS.

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1697	IMP/MD/2019/000254	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLADELESS POSITIONING TROCAR SYSTEM- BLADELESS TROCAR WITH FIXATION CANNULA (VERSAONE™)-THE DEVICE IS INTENDED FOR USE IN A VARIETY OF GYNECOLOGIC, AND/OR GENERAL, THORACIC AND UROLOGIC ENDOSCOPIC PROCEDURES TO CREATE AND MAINTAIN A PORT OF ENTRY. ,POLYESTER TRIPLE STITCH RELOAD(SURGIDAC™)-THE SURGIDAC™ RELOADS ARE INTENDED FOR USE WITH THE ENDO STITCH™ AND SILS™ STITCH SUTURING DEVICES. THE ENDO STITCH™ AND SILS™ STITCH SUTURING DEVICES HAVE APPLICATION IN ENDOSCOPIC SURGERY FOR THE PLACEMENT OF INTERRUPTED OR RUNNING STITCHED IN SOFT TISSUE.,OPTICAL TROCAR WITH FIXATION CANNULA(VERSAONE™)-THE DEVICE IS INTENDED FOR USE IN A VARIETY OF GYNECOLOGIC, AND/OR GENERAL, THORACIC AND UROLOGIC ENDOSCOPIC PROCEDURES TO CREATE AND MAINTAIN A PORT OF ENTRY. THE TROCAR MAY BE USED WITH OR WITHOUT VISUALIZATION FOR PRIMARY AND SECONDARY INSERTIONS., MONOFILAMENT NYLON NON-ABSORBABLE SUTURE(MONOSOF)-MONOSOF MONOFILAMENT NYLON SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC, AND NEUROLOGICAL SURGERY. ALSO INDICATED FOR MICROSURGERY, BLADED TROCAR WITH FIXATION CANNULA- BLADED TROCAR WITH SMOOTH CANNULA(VERSAONE™)-THE DEVICE IS INTENDED FOR USE IN A VARIETY OF GYNECOLOGIC, GENERAL, THORACIC, AND UROLOGIC ENDOSCOPIC PROCEDURES TO CREATE AND MAINTAIN A PORT OF ENTRY.,ABSORBABLE SINGLE STITCH RELOAD (POLYSORB™)-THE POLYSORB™ RELOADS ARE INTENDED FOR USE WITH THE ENDO STITCH™ AND SILS™ STITCH SUTURING DEVICES. THE ENDO STITCH™ AND SILS™ STITCH SUTURING DEVICES HAVE APPLICATION IN ENDOSCOPIC SURGERY FOR THE PLACEMENT OF INTERRUPTED OR RUNNING STITCHED IN SOFT TISSUE.,FACIAL CLOSURE SYSTEM BLADED/OPTICAL TROCAR(VERSAONE™)-THE VERSAONE™ FASCIAL CLOSURE SYSTEM IS INTENDED FOR USE IN A VARIETY OF MINIMALLY INVASIVE GYNECOLOGIC, GENERAL, AND UROLOGIC PROCEDURES TO CREATE AND MAINTAIN A PORT OF ENTRY FOR LAPAROSCOPIC INSTRUMENTS.,MONOFILAMENT POLYPROPYLENE NON-ABSORBABLE SUTURE(SURGIPRO)-SURGIPRO™ POLYPROPYLENE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC TISSUES.,AUTO SUTURE™ SINGLE USE SLIM BODY SKIN STAPLER(APPOSE™ ULC)-THE AUTO SUTURE™ APPOSE™ ULC SINGLE USE SKIN STAPLER CAN

	BE USED FOR CLOSURE OF SKIN IN A WIDE VARIETY OF SURGICAL PROCEDURES.,NOVAFIL NONABSORBABLE SUTURE(NOVAFIL MONOFILAMENT POLYBUTESTER)-NOVAFIL POLYBUTESTER SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR AND OPHTHALMIC SURGERY, BUT NOT IN MICROSURGERY AND NEURAL TISSUE.,BLADELESS TROCAR WITH FIXATION CANNULA- BLADELESS TROCAR WITH SMOOTH CANNULA- BLUNT TROCAR WITH THREADED ANCHOR- BLADELESS POSITIONING TROCAR(VERSAONE™)-THE DEVICE IS INTENDED FOR USE IN A VARIETY OF GYNECOLOGIC, GENERAL, THORACIC AND UROLOGIC ENDOSCOPIC PROCEDURES TO CREATE AND MAINTAIN A PORT OF ENTRY.,MONOFILAMENT POLYGLYCONATE SYNTHETIC ABSORBABLE SUTURES(MAXON & MAXON CV)-MAXON AND MAXON CV SUTURES ARE INDICATED FOR USE AS ABSORBABLE SUTURES IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, IN PEDIATRIC CARDIOVASCULAR TISSUE, WHERE GROWTH IS EXPECTED TO OCCUR, AND IN PERIPHERAL VASCULAR TISSUE. MAXON AND MAXON CV SUTURES ARE NOT INDICATED FOR USE IN ADULT CARDIOVASCULAR TISSUE, OPHTHALMIC SURGERY, MICROSURGERY, AND NEURAL TISSUE.,UNIVERSAL FIXATION CANNULA-UNIVERSAL CANNULA POSITIONING TROCAR SYSTEM- UNIVERSAL SMOOTH CANNULA (VERSAONE™)-THE DEVICE IS INTENDED FOR USE IN A VARIETY OF GYNECOLOGIC, GENERAL, THORACIC AND UROLOGIC ENDOSCOPIC PROCEDURES TO CREATE AND MAINTAIN A PORT OF ENTRY. , COATED BRAIDED POLYESTER NON-ABSORBABLE SUTURE(TICRON)- TICRON™ POLYESTER SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL SURGERY.,CLIP APPLIER WITH CLIP LOGIC TECHNOLOGY(ENDO CLIP™ III AUTO SUTURE™ CLIP APPLIER WITH CLIP LOGIC™ TECHNOLOGY)-THE ENDO CLIP III AUTO SUTURE™ CLIP APPLIER IS PRIMARILY INDICATED FOR PATIENTS UNDERGOING LAPAROSCOPIC SURGICAL PROCEDURES INVOLVING DISSECTION AND OCCLUSION OF BLOOD VESSELS, DUCTS AND OTHER TUBULAR STRUCTURES, AND FOR RADIOGRAPHIC MARKINGS.,MONOFILAMENT POLYPROPYLENE NON-ABSORBABLE SUTURE(SURGIPRO II)- SURGIPRO™ II POLYPROPYLENE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC TISSUES., UMBILICAL TAPE(SYNETURE UMBILICAL TAPE)-UMBILICAL TAPE IS INDICATED FOR USE IN TYING THE UMBILICAL CORD OF NEW BORN INFANTS,SYNTHETIC MONOFILAMENT ABSORBABLE SUTURE (BIOSYN)-BIOSYN SYNTHETIC ABSORBABLE SUTURES ARE

	INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION USE IN OPHTHALMIC SURGERY, BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL SURGERY.,CLIP APPLIER (ENDO CLIP™ II AUTO SUTURE™ CLIP APPLIER)-THE ENDO CLIP™ II AUTO SUTURE™ CLIP APPLIERS HAS APPLICATION IN MANY TYPES OF ENDOSCOPIC PROCEDURES TO ACHIEVE OCCLUSION OF VESSELS AND OTHER TUBULAR STRUCTURES AND FOR RADIO GRAPHIC MARKINGS.,COATED BRAIDED NYLON NON-ABSORBABLE SUTURE (SURGILON)-SURGILON BRAIDED NYLON SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC, AND NEUROLOGICAL SURGERY.,SINGLE STITCH RELOAD(SURGIDAC™)-SURGIDAC™ RELOADS ARE INTENDED FOR USE WITH THE ENDO STITCH™ AND SILS™ STITCH SUTURING DEVICES. THE ENDO STITCH™ AND SILS™ STITCH SUTURING DEVICES HAVE APPLICATION IN ENDOSCOPIC SURGERY FOR THE PLACEMENT OF INTERRUPTED OR RUNNING STITCHES IN SOFT TISSUE. ,MONOFILAMENT STAINLESS STEEL NON-ABSORBABLE SUTURE(STEEL-MONFILAMENT STAINLESS STEEL)-STEEL SUTURES ARE INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, INTESTINAL ANASTOMOSIS, HERNIA REPAIR AND STERNAL CLOSURE.,OPTICAL TROCAR WITH FIXATION CANNULA-OPTICAL POSITIONING TROCAR SYSTEM- OPTICAL TROCAR WITH SMOOTH CANNULA(VERSAONE™)-THE DEVICE IS INTENDED FOR USE IN A VARIETY OF GYNECOLOGIC, GENERAL, THORACIC AND UROLOGIC ENDOSCOPIC PROCEDURES TO CREATE AND MAINTAIN A PORT OF ENTRY. THE TROCAR MAY BE USED WITH OR WITHOUT VISUALIZATION FOR PRIMARY AND SECONDARY INSERTIONS., MULTIFILAMENT TEMPORARY CARDIAC PACING LEAD(FLEXON)-FLEXON™ TEMPORARY CARDIAC PACING LEAD IS INDICATED FOR USE IN TEMPORARY (NO MORE THAN 7 DAYS) ATRIAL AND VENTRICULAR PACING AND SENSING DURING AND AFTER CARDIAC SURGERY.,CLIP APPLIER(ENDO CLIP™ AUTO SUTURE™ CLIP APPLIER) -ENDO CLIP™ CLIP APPLIER HAS APPLICATION IN ENDOSCOPIC PROCEDURES TO ACHIEVE OCCLUSION OF VESSELS AND OTHER SMALL TISSUE STRUCTURES AND FOR RADIOGRAPHIC MARKINGS., COATED BRAIDED SYNTHETIC ABSORBABLE SUTURE(POLYSORB)-POLYSORB SUTURES ARE INDICATED FOR USE IN SOFT TISSUE APPROXIMATION OR LIGATION AND OPHTHALMIC SURGERY, BUT NOT IN CARDIOVASCULAR OR NEURAL TISSUE.,MONOFILAMENT NYLON NON-ABSORBABLE SUTURE(DERMALON)-DERMALON MONOFILAMENT NYLON SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC, AND NEUROLOGICAL SURGERY.,MONOFILAMENT SYNTHETIC

		ABSORBABLE SUTURE(CAPROSYN)-CAPROSYN SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL SURGERY, MICROSURGERY, OR OPHTHALMIC SURGERY.,COATED BRAIDED SILK NON-ABSORBABLE SUTURE(SOFSILK)-SOFSILK SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC, MICROSURGERY, AND NEUROLOGICAL SURGERY.,PLEDGETS(PTFE POLYMER PLEDGETS)-PTFE PLEDGETS ARE INDICATED FOR USE AS NON ABSORBABLE SUTURE BUTTRESSES WHEN THERE IS A POSSIBILITY OF SUTURE TEARING THROUGH TISSUE. THESE PLEDGETS ARE USED IN VARIOUS SURGICAL PROCEDURES SUCH AS VASCULAR CLOSURE, SEPTAL REPAIR, MYOCARDIAL CLOSURE, VALVULAR SUTURING AND HEPATIC REPAIR.
1698	IMP/MD/2019/000255	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLED SYRINGE WITH SODIUM CHLORIDE 0.9% (STERILE SOLUTION)(BD POSIFLUSH™ XS SYRINGE)-INTENDED TO BE USED ONLY FOR FLUSHING OF VASCULAR ACCESS DEVICES (FOR FLUSHING ONLY)
1699	IMP/MD/2019/000256	1.License Holder Name: DR. REDDYS LABORATORIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS.,PREFILLABLE GLASS BARREL WITH NEEDLE(BD NEOPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS.
1700	IMP/MD/2019/000257	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASPIRATION CATHETER (ELIMINATE)-THE ELIMINATE ASPIRATION CATHETER IS INTENDED FOR THE REMOVAL OF FRESH, SOFT EMBOLI AND THROMBI FROM VESSELS IN THE CORONARY AND PERIPHERAL VASCULATURE.

1701	IMP/MD/2019/000258	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA BALLOON CATHETER(SEQUENT NEO)-IT IS INTENDED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,DRUG ELUTING CORONARY STENT SYSTEM(COROFLEX ISAR NEO)-IT IS INTENDED FOR IMPROVING INTRALUMINAL DIAMETER IN CORONARY VESSELS AND TO REDUCE THE POSSIBLE EVENT OF RESTENOSIS. IT CAN BE USED FOR THE TREATMENT OF DE-NOVO LESIONS AND RE-STENOTIC LESIONS UPTO A LENGTH OF 38MM WITH A REFERENCE VESSEL DIAMETER OF 2.0 TO 4.0 MM,DRUG COATED PTCA BALLOON(SEQUENT PLEASE NEO)-DE-NOVO LESIONS (PRIMARY USE IN THE CASE OF STENOSIS OR OCCLUSIONS) INCLUDING SMALL VESSELS (SMALL VESSEL DISEASE (SVD)) ;RESTENOSIS AFTER BALLOON- OR STENT-PTCA (ISR) • PRE- AND POST-DILATATION DURING CORONARY STENT IMPLANTATION ; ACUTE OR IMPENDING VASCULAR OCCLUSION,DRUG ELUTING CORONARY STENT SYSTEM(COROFLEX ISAR)-IT IS INTENDED FOR IMPROVING INTRALUMINAL DIAMETER IN CORONARY VESSELS AND TO REDUCE THE POSSIBLE EVENT OF RE-STENOSIS. IT CAN BE USED FOR THE TREATMENT OF DE-NOVO LESIONS AND RE-STENOTIC LESIONS UP TO A LENGTH OF ~ 32MM WITH A REFERENCE VESSEL DIAMETER OF 2.0 TO 4.0 MM.
1702	IMP/MD/2019/000259	1.License Holder Name: NOVOMED INCORPORATION PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EVRF(EVRF)-THERMOCOGULATOR USING RADIOFREQUENCY ABLATION INTENDED FOR TREATMENT OF VARICOSE VEIN, SPIDER VEINS AND HEMORRHOIDS, INCLUDING TREATMENT OF THE GREAT SAPHENOUS VEIN (VENA SAPHENA MAGNA) AND SMALL SAPHENOUS VEIN (VENA SAPHENA PARVA).,HPR45I(HPR45I)-STERILE INVASIVE RADIOFREQUENCY THERMOCOAGULATION PROBES AS ACCESSORY FOR THERMOCOAGULATOR EVRF FOR TREATMENT OF HEMORRHOIDS.,CR CATHETERS(CR12I, CR12KAB, CR30I, CR30KAB CR40I, CR45I)-STERILE INVASIVE RADIOFREQUENCY THERMOCOAGULATION PROBES AS ACCESSORIES FOR THERMOCOAGULATOR EVRF FOR TREATMENT OF VARICOSE VEINS INCLUDING THE GREA SAPHENOUS VEIN (VENA SAPHENA MAGNA) AND SMALL SAPHENOUS VEIN (VENA SAPHENA PARVA).

1703	IMP/MD/2019/000260	1.License Holder Name: ENVISION SCIENTIFIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASPIRATION CATHETER (TRANSPORT AC)-THE TRANSPORT AC CATHETER IS INDICATED FOR USE IN THE CENTRAL AND PERIPHERAL CIRCULATORY SYSTEM, INCLUDING SAPHENOUS VEIN GRAFTS TO: CONTAIN AND ASPIRATE EMBOLIC MATERIAL (THROMBUS/DEBRIS) WHILE PERFORMING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY AND/OR STENTING PROCEDURES. ,PTCA CATHETER(MAYA)-THE MAYA CATHETER IS INTENDED FOR DILATATION OF DISEASED SEGMENT(S) IN A CORONARY ARTERY OR A CORONARY BYPASS. THE MAYA CATHETER IS INDICATED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. THE MAYA PTCA CATHETER IS THEREFORE INDICATED TO DILATE THE DISEASED SEGMENT(S) IN A CORONARY ARTERY OR A CORONARY BYPASS, TO IMPROVE MYOCARDIAL PERFUSION. IT ALLOWS ALSO FOR RESTORING CORONARY FLOW IN PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION. THE PATIENTS SHOULD FULFIL ONE OR MORE OF THE FOLLOWING CRITERIA: • PATIENTS MUST BE JUDGED TO BE ACCEPTABLE CANDIDATES FOR CORONARY BYPASS SURGERY. • PATIENTS WITH SINGLE VESSEL ATHEROSCLEROTIC LESION(S), SUBTOTAL AND ACCESSIBLE TO DILATATION WITH GUIDEWIRE AND CATHETER. • CERTAIN MULTI-VESSEL DISEASED PATIENTS MAY ALSO BE CANDIDATES FOR THIS PROCEDURE. • CERTAIN PATIENTS, WHO HAVE UNDERGONE PREVIOUS CORONARY BYPASS SURGERY WITH RECURRENCE OF SYMPTOMS AND PROGRESSION OF THE DISEASE IN THE CORONARY ARTERY, OR STENOSIS AND CLOSURE OF THE GRAFTS, MAY ALSO BE CANDIDATES. ,PTA CATHETER(LYNX 14 OTW)-THE LYNX 14 OTW ANGIOPLASTY CATHETER IS DESIGNED FOR USE IN PATIENTS WITH STENOSIS OF THE PERIPHERAL ARTERIES, INCLUDING RENAL, ILIAC, FEMORAL, POPLITEAL, INFRA-POPLITEAL, PEDAL, PLANTAR AND OTHER BELOW THE KNEE ARTERIES. THE CATHETER CAN BE USED AS STENT DELIVERY SYSTEM, SUBJECT TO THE COMPATIBILITY OF THE STENT WITH THE CATHETER. THE LYNX 14 OTW IS ALSO DESIGNED FOR TREATMENT OF OCCLUSIVE LESION OF NATIVE OR SYNTHETHIC ARTERIO-VENOUS DIALYSIS FISTULA. ,Y CONNECTORS (Y CONNECTORS)-Y CONNECTORS ARE DESIGNED TO PROVIDE HAEMOSTATIC DURING ENDOVASCULAR PROCEDURES. THE Y CONNECTORS 00 OR 20 OR 50, INCLUDE A STRAIGHT AND A SIDE ACCESS LUMEN. THE HAEMOSTATIC VALVE, LOCATED AT THE PROXIMAL END OF THE STRAIGHT LUMEN, CAN BE OPENED AND

	CLOSED BY OPERATION OF THE "PUSH/PULL" BUTTON VALVE. THE DISTAL END HAS A ROTATING MALE LUER LOCK. THE SIDE ACCESS LUMEN ALLOWS PRESSURE MONITORING AND PERFUSION. THE SIDE ACCESS LUMEN OF THE Y CONNECTOR 00 ENDS WITH A FEMALE LUER LOCK. THE SIDE ACCESS LUMEN OF THE Y CONNECTOR 20 OR 50 WITH A SIDE ARM TUBING ENDING BY A STANDARD THREE WAY STOPCOCK.,COBALT CHROMIUM CORONARY STENT SYSTEM(CYGNUS III)-THE STENT COCR IS INTENDED FOR USE IN THE TREATMENT OF PATIENT WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. RECOGNIZED USE OF INTRACORONARY STENTS CURRENTLY INCLUDES BUT IS NOT LIMITED TO THE TREATMENT OF DE NOVO OR RESTENOSTIC LESIONS IN NATIVE CORONARY ARTERIES AND IN DE NOVO LESION OF SAPHENOUS VEIN GRAFTS. THE STENT COCR IS AVAILABLE FOR INTRACORONARY IMPLANTATION FOR INNER DIAMETERS OF 2.25 TO 5.0 MM THE STENT IS VALIDATED TO BE DELIVERED BY ARTHESYS DELIVERY SYSTEM.,COBALT CHROMIUM CORONARY STENT SYSTEM(CYGNUS II) -THE CYGNUS II COCR® INTRACORONARY STENT SYSTEM IS INTENDED FOR USE IN THE TREATMENT OF PATIENT WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. RECOGNIZED USE OF INTRACORONARY STENTS CURRENTLY INCLUDES BUT IS NOT LIMITED TO THE TREATMENT OF DE NOVO OR RESTENOSTIC LESIONS IN NATIVE CORONARY ARTERIES AND IN DE NOVO LESION OF SAPHENOUS VEIN GRAFTS. THE CYGNUS II COCR® IS AVAILABLE FOR INTRACORONARY IMPLANTATION FOR INNER DIAMETERS OF 2.25 TO 5.00 MM.,PTA CATHETER(LYNX RX)-THE LYNX ANGIOPLASTY CATHETER IS INTENDED TO IMPROVE PERIPHERAL LUMINAL DIAMETER IN PATIENTS WITH STENOSIS. THE LYNX ANGIOPLASTY CATHETER IS INDICATED FOR THE TREATMENT OF PATIENTS WITH STENOSIS OF THE FOLLOWING VESSELS: • RENAL ARTERIES • ARTERIES OF THE LOWER LIMBS,PTCA CATHETER(MAYA) -MAYA CATHETER IS INTENDED FOR DILATATION OF DISEASED SEGMENT(S) IN A CORONARY ARTERY OR A CORONARY BYPASS. THE MAYA CATHETER IS INDICATED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. THE MAYA PTCA CATHETER IS THEREFORE INDICATED TO DILATE THE DISEASED SEGMENT(S) IN A CORONARY ARTERY OR A CORONARY BYPASS, TO IMPROVE MYOCARDIAL PERFUSION. IT ALLOWS ALSO FOR RESTORING CORONARY FLOW IN PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION. THE PATIENTS SHOULD FULFIL ONE OR MORE OF THE FOLLOWING

		CRITERIA: • PATIENTS MUST BE JUDGED TO BE ACCEPTABLE CANDIDATES FOR CORONARY BYPASS SURGERY. • PATIENTS WITH SINGLE VESSEL ATHEROSCLEROTIC LESION(S), SUBTOTAL AND ACCESSIBLE TO DILATATION WITH GUIDEWIRE AND CATHETER. • CERTAIN MULTI-VESSEL DISEASED PATIENTS MAY ALSO BE CANDIDATES FOR THIS PROCEDURE. • CERTAIN PATIENTS, WHO HAVE UNDERGONE PREVIOUS CORONARY BYPASS SURGERY WITH RECURRENCE OF SYMPTOMS AND PROGRESSION OF THE DISEASE IN THE CORONARY ARTERY, OR STENOSIS AND CLOSURE OF THE GRAFTS, MAY ALSO BE CANDIDATES.,PTA CATHETER(LYNX 18 OTW)-THE LYNX 18 OTW ANGIOPLASTY CATHETER IS DESIGNED FOR USE IN PATIENTS WITH STENOSIS OF THE PERIPHERAL ARTERIES, INCLUDING RENAL, ILIAC, FEMORAL, POPLITEAL AND INFRA-POPLITEAL ARTERIES AND FOR TREATMENT OF OCCLUSIVE LESION OF NATIVE OR SYNTHETHIC ARTERIO-VENOUS DIALYSIS FISTULA. THE LYNX 18 OTW IS ALSO DESIGNED FOR POST-DILATATION OF BALLOON EXPANDABLE AND SELF-EXPANDABLE STENTS IN THE PERIPHERAL VASCULATURE.,PTA CATHETER(LYNX 35 OTW)-THE LYNX 35 OTW ANGIOPLASTY CATHETER IS DESIGNED FOR DILATING STENOSES OF PERIPHERAL ARTERIES, INCLUDING RENAL, ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA-POPLITEAL, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIO-VENOUS DIALYSIS FISTULA. THE LYNX 35 OTW IS ALSO INDICATED FOR POST-DILATATION OF BALLOON-EXPANDABLE AND SELF-EXPENDABLE STENTS IN THE PERIPHERAL VASCULATURE.
1704	IMP/MD/2019/000261	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERITONEAL DIALYSIS CATHETER(I SERIES PD CATHETERS, V SERIES PD CATHETHERS)-THE PERITONEAL CATHETER IS INDICATED FOR ACUTE AND CHRONIC PERITONEAL DIALYSIS.

1705	IMP/MD/2019/000262	1.License Holder Name: M/S. INNOVATIVE THERAPEUTICS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BILIARY STENT (COVERED) - SILICONE, PTFE(NITI-S)-THE NITI-S BILIARY STENT IS INTENDED FOR MAINTAINING BILIARY LUMINAL PATENCY IN MALIGNANT/BENIGN STRICTURES.,PANCREATIC PSEUDOCYST STENT (NITI-S HOT NAGI STENT)-NITI-S HOT NAGITM STENT IS SELF-EXPANDING ENDOPROSTHESIS COMPOSED OF NICKEL TITANIUM ALLOY (NITINOL), X-RAY MARKERS (PT/IR), CONNECTOR (STAINLESS STEEL), COVER MEMBRANE (SILICONE) AND SUTURES (NYLON AND PE). NITI-S HOT NAGI STENT AND ELECTROCAUTERY STENT DELIVERY SYSTEM IS INTENDED FOR THE DRAINAGE OF A PANCREATIC PSEUDOCYST THROUGH A TRANSGASTRIC OR TRANSDUODENAL APPROACH.,PYLORIC/DUODENAL STENT - PTFE (COMVI)-THE COMVI PYLORIC/DUODENAL STENT IS INTENDED FOR MAINTAINING PYLORIC/DUODENUM LUMINAL PATENCY IN PYLORIC/DUODENUM STRICTURES CAUSED BY INTRINSIC AND/EXTRINSIC MALIGNANT OR BENIGN STRICTURE,PANCREATIC PSEUDOCYSTS/GALLBLADDER DRAINAGE STENT(NITI-S SPAXUS STENT)-THE NITI-S SPAXUS STENT IS INTENDED FOR DRAINAGE OF PANCREATIC PSEUDOCYST OR GALLBLADDER THROUGH TRANSGASTRIC OR TRANSDUODENAL APPROACH,PANCREATIC PSEUDOCYSTS/ GALLBLADDER DRAINAGE STENT(NITI-S HOT SPAXUS STENT)-THE NITI-S HOT SPAXUS STENT IS INTENDED FOR DRAINAGE OF PANCREATIC PSEUDOCYST OR GALLBLADDER THROUGH TRANSGASTRIC OR TRANSDUODENAL APPROACH, PYLORIC/DUODENAL STENT (COVERED) SILICONE(NITI-S)-THE NITI-S PYLORIC/DUODENAL STENT IS INTENDED FOR MAINTAINING PYLORIC/DUODENUM LUMINAL PATENCY IN PYLORIC/DUODENUM STRICTURES CAUSED BY INTRINSIC AND/EXTRINSIC MALIGNANT OR BENIGN STRICTURE,BILIARY STENT - PTFE(COMVI)-THE COMVI BILIARY STENT IS INTENDED FOR MAINTAINING BILIARY LUMINAL PATENCY IN MALIGNANT/BENIGN STRICTURES.,TRACHEAL STENT (UNCOVERED)(NITI-S)-IT IS INTENDED FOR MAINTAINING TRACHEAL OR BRONCHIAL LUMINAL PATENCY IN TRACHEOBRONCHIAL STRICTURE CAUSED BY INTRINSIC AND/OR EXTRINSIC MALIGNANT AND/OR BENIGN STRICTURE.,URETERAL STENT(UVENTA TM)-UVENTATM URETERAL STENT IS SELF-EXPANDING ENDOPROSTHESIS COMPOSED OF NICKEL TITANIUM ALLOY (NITINOL). IT IS INTENDED FOR MAINTAINING URETERAL LUMINAL PATENCY IN URETERAL STRICTURE CAUSED BY INTRINSIC AND/OR EXTRINSIC MALIGNANT STRICTURE.,BILIARY STENT (UNCOVERED)(NITI-S)-THE NITI-S BILIARY STENT IS INTENDED FOR MAINTAINING BILIARY LUMINAL PATENCY IN MALIGNANT STRICTURES.,BRONCHIAL STENT

	(COVERED)(NITI-S)-IT IS INTENDED FOR MAINTAINING TRACHEAL OR BRONCHIAL LUMINAL PATENCY IN TRACHEOBRONCHIAL STRICTURE CAUSED BY INTRINSIC AND/OR EXTRINSIC MALIGNANT AND/OR BENIGN STRICTURE.,TRACHEAL STENT (COVERED)(NITI-S)-IT IS INTENDED FOR MAINTAINING TRACHEAL OR BRONCHIAL LUMINAL PATENCY IN TRACHEOBRONCHIAL STRICTURE CAUSED BY INTRINSIC AND/OR EXTRINSIC MALIGNANT AND/OR BENIGN STRICTURE., ENTERAL COLONIC STENT (UNCOVERED)(NITI-S)-THE NITI-S ENTERAL COLONIC STENT IS INTENDED FOR MAINTAINING COLORECTAL LUMINAL PATENCY IN COLONIC STRICTURES CAUSED BY INTRINSIC AND/EXTRINSIC MALIGNANT OR BENIGN STRICTURE, PYLORIC/DUODENAL STENT (UNCOVERED)(NITI-S)-THE NITI-S PYLORIC/DUODENAL STENT IS INTENDED FOR MAINTAINING PYLORIC/DUODENUM LUMINAL PATENCY IN PYLORIC/DUODENUM STRICTURES CAUSED BY INTRINSIC AND/EXTRINSIC MALIGNANT OR BENIGN STRICTURE,BRONCHIAL STENT (UNCOVERED)(NITI-S)-IT IS INTENDED FOR MAINTAINING TRACHEAL OR BRONCHIAL LUMINAL PATENCY IN TRACHEOBRONCHIAL STRICTURE CAUSED BY INTRINSIC AND/OR EXTRINSIC MALIGNANT AND/OR BENIGN STRICTURE., ENTERAL COLONIC STENT - PTFE(COMVI)-THE COMVI ENTERAL COLONIC STENT IS INTENDED FOR MAINTAINING COLORECTAL LUMINAL PATENCY IN COLONIC STRICTURES CAUSED BY INTRINSIC AND/EXTRINSIC MALIGNANT OR BENIGN STRICTURE,ESOPHAGEAL STENT (COVERED) - SILICONE(NITI-S)-NITI-S & COMVI ESOPHAGEAL STENT IS SELF-EXPANDING ENDOPROSTHESIS COMPOSED OF NICKEL TITANIUM ALLOY (NITINOL). THE NITI-S & COMVI ESOPHAGEAL STENT IS INTENDED FOR MAINTAINING ESOPHAGEAL LUMINAL PATENCY IN MALIGNANT STRICTURES. THE NITI-S FULLY COVERED ESOPHAGEAL STENT IS INTENDED FOR THE USE IN MALIGNANT AND/OR BENIGN STRICTURE AND TRACHEOESOPHAGEAL FISTULA, ESOPHAGEAL STENT (COVERED) - SILICONE, PTFE(NITI-S)-NITI-S & COMVI ESOPHAGEAL STENT IS SELF-EXPANDING ENDOPROSTHESIS COMPOSED OF NICKEL TITANIUM ALLOY (NITINOL). THE NITI-S & COMVI ESOPHAGEAL STENT IS INTENDED FOR MAINTAINING ESOPHAGEAL LUMINAL PATENCY IN MALIGNANT STRICTURES. THE NITI-S FULLY COVERED ESOPHAGEAL STENT IS INTENDED FOR THE USE IN MALIGNANT AND/OR BENIGN STRICTURE AND TRACHEOESOPHAGEAL FISTULA.,ENTERAL COLONIC STENT (COVERED) SILICONE(NITI-S)-THE NITI-S ENTERAL COLONIC STENT IS INTENDED FOR MAINTAINING COLORECTAL LUMINAL PATENCY IN COLONIC STRICTURES CAUSED BY INTRINSIC AND/EXTRINSIC MALIGNANT OR BENIGN STRICTURE,ESOPHAGEAL STENT (UNCOVERED)(NITI-S)-THE NITI-S ESOPHAGEAL STENT IS INTENDED FOR MAINTAINING ESOPHAGEAL LUMINAL PATENCY IN MALIGNANT

		STRICTURES.,BILIARY STENT (COVERED) - SILICONE(NITI-S)-THE NITI-S BILIARY STENT IS INTENDED FOR MAINTAINING BILIARY LUMINAL PATENCY IN MALIGNANT/BENIGN STRICTURES.
1706	IMP/MD/2019/000263	1.License Holder Name: VIRCHOW BIOTECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE (STERILE)(BD HYPAK SCF)-THIS ARE THE COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS.
1707	IMP/MD/2019/000264	1.License Holder Name: SURGICON HEALHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RAYNER PRELOADED HYDROPHOBIC ACRYLIC INTRAOCULAR LENS INJECTION SYSTEM (RAYONE)-RAYNER IOLS ARE INDICATED FOR VISUAL CORRECTION OF APHAKIA IN PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION OR EXTRACAPSULAR CATARACT EXTRACTION. THESE DEVICES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG.,RAYNER PRELOADED HYDROPHILIC ACRYLIC INTRAOCULAR LENS INJECTION SYSTEM(RAYONE)-RAYNER IOLS ARE INDICATED FOR VISUAL CORRECTION OF APHAKIA IN PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION OR EXTRACAPSULAR CATARACT EXTRACTION. THESE DEVICES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG.,RAYNER HYDROPHILIC ACRYLIC INJECTABLE PSEUDOPHAKIC SUPPLEMENTARY IOL FOR PLACEMENT IN THE CILIARY SULCUS(SULCOFLEX TRIFOCAL)-PSEUDOPHAKIC PATIENTS WITH A PRIMARY CAPSULAR BAG FIXATED INTRAOCULAR LENS, REQUIRING A REFRACTION ADJUSTMENT BY A SECONDARY LENS IMPLANTATION INTO THE CILIARY SULCUS
1708	IMP/MD/2019/000265	1.License Holder Name: ALTO MEDICAL SYSTEMS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA BALLOON DILATATION CATHETER(IKAZUCHI ZERO, RAIDEN 3)-THIS PRODUCT IS INTENDED TO BE USED FOR DILATING THE STENOSIS LESION IN THE CORONARY ARTERY WHEN PERFORMING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA).

1709	IMP/MD/2019/000266	1.License Holder Name: ADVANCED LIFESCIENCES PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETERS & ACCESSORIES-THE CENTRAL VENOUS CATHETERS MAY BE APPLICABLE TO THE ONE OF FOLLOWING THERAPY (ONLY AFTER STERILIZATION) - MONITOR OF CENTRAL VENOUS PRESSURE; - CONTINUOUS OR DISCONTINUOUS VENOUS TRANSFUSION; - BLOOD SAMPLING. THE CATHETER IS SURGICALLY PENETRATED INTO THREE OPTIONAL PUNCTURE POINTS DEPENDED ON THE CLINICAL REQUIREMENT WITH SELDINGER TECHNIQUE. THE INSERTION SITES ARE : 1. INTERNAL JUGULAR VEIN; 2. SUBCLAVIAN VEIN; 3. FEMORAL VEIN. IT IS POSSIBLE TO BE INSERTED INSIDE THE BODY FOR LESS THAN 30DAYS. IF DURATION EXCEEDS 30 DAYS, IT MAY OCCURE THE RISK OF COMBINING THE CATHETER AND INSIDE TISSUE, WHICH RESULT IN SERIOUS INCIDENT.
1710	IMP/MD/2019/000267	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HAEMOCER™ PATCH - HAEMOSTATIC PATCH(HAEMOCER™ PATCH)-HAEMOCER™ PATCH IS AN ADJUNCT HAEMO-STATIC AGENT FOR USE IN SURGICAL PROCEDURES AND TRAUMATIC INJURIES WHEN CONTROL OF BLEEDING FROM CAPILLARY, VENOUS, OR ARTERIOLAR VESSELS BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS EITHER INEFFECTIVE OR IMPRAC-TICAL.,HAEMOSTATIC POWDER (HAEMOCER™ PLUS HAEMOSTATIC POWDER)-HAEMOCER™ PLUS IS AN ADJUNCT HEMOSTATIC AGENT FOR USE IN SURGICAL PROCEDURES, WHEN CONTROL OF BLEEDING FROM CAPILLARY, VENOUS, OR ARTERIOLAR VESSELS BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS EITHER INEFFECTIVE OR IMPRACTICAL.,SURGICAL MESH IMPLANT(TIO2MESH™/TIO2MESH™ LIGHT- SURGICAL MESH IMPLANT)-TIO2MESH™ IS A SURGICAL MESH IMPLANT SPECIFICALLY INDICATED FOR REPAIR OF TISSUE DEFECTS OF THE ABDOMINAL WALL, WHERE A NON-REABSORBABLE SUPPORT MATERIAL IS REQUIRED. RELEVANT APPLICATIONS INCLUDE THE REPAIR OF INGUINAL AND INCISIONAL HERNIA IN ALL COMMON SURGICAL METHODS. TIOMESH™ CAN BE USED FOR BOTH LAPAROSCOPIC AND OTHER OPEN PROCEDURES.

1711	IMP/MD/2019/000268	1.License Holder Name: TRANSLUMINA THERAPEUTICS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA BALLOON DILATATION CATHETER(IKAZUCHI ZERO)-KANEKA PTCA BALLOON DILATATION CATHETER IS INTENDED TO BE USED FOR DILATING THE STENOSIS LESION IN THE CORONARY ARTERY WHEN PERFORMING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY.,PTCA BALLOON DILATATION CATHETER(RAIDEN 3)-KANEKA PTCA BALLOON DILATATION CATHETER IS INTENDED TO BE USED FOR DILATING THE STENOSIS LESION IN THE CORONARY ARTERY WHEN PERFORMING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY.

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1712	IMP/MD/2019/000269	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GENERAL/MULTIPLE SURGICAL SOLID-STATE LASER SYSTEM(AURIGA 30 LASER SYSTEM)-THE AURIGA 30 HOLMIUM LASER IS DESIGNED FOR USE FOR INVASIVE AND NON-INVASIVE UROLOGIC PROCEDURES. DUE TO ITS APPLICATION ADAPTED PARAMETERS, THE AURIGA 30 LASER CONSOLE IS QUALIFIED FOR: • LITHOTRIPSY • ABLATION (DISSECTION, ABLATION) OF SOFT TISSUE • COAGULATION OF SOFT TISSUE • VAPORIZATION OF LIQUID,GENERAL/MULTIPLE SURGICAL FREQUENCY-DOUBLED SOLID-STATE LASER SYSTEM(GREENLIGHT XPS LASER SYSTEM)-THE GREENLIGHT XPS LASER SYSTEM IS INTENDED FOR THE SURGICAL INCISION, EXCISION, VAPORIZATION, ABLATION, HEMOSTASIS, AND COAGULATION OF SOFT TISSUE. ALL SOFT TISSUE IS INCLUDED, SUCH AS SKIN, CUTANEOUS TISSUE, SUBCUTANEOUS TISSUE, STRIATED AND SMOOTH TISSUE, MUSCLE, CARTILAGE MENISCUS, MUCOUS MEMBRANE, LYMPH VESSELS AND NODES, ORGANS, AND GLANDS. SUGGESTED APPLICATIONS INCLUDE: • GENERAL SURGERY: VAPORIZING, COAGULATING, INCISING, EXCISING, DEBULKING, AND ABLATING OF SOFT TISSUE AS WELL AS IN ENDOSCOPIC (FOR EXAMPLE, LAPAROSCOPIC) OR OPEN SURGERIES. • GASTROENTEROLOGY: TISSUE ABLATION AND HEMOSTASIS IN THE GASTROINTESTINAL TRACT; ESOPHAGEAL NEOPLASTIC OBSTRUCTIONS, INCLUDING SQUAMOUS CELL CARCINOMA AND ADENOCARCINOMA; GASTROINTESTINAL HEMOSTASIS (INCLUDING VARICES, ESOPHAGITIS, ESOPHAGEAL ULCER, MALLORY-WEISS TEAR, GASTRIC ULCER, ANGIODYSPLASIA, STOMAL ULCERS, NON-BLEEDING ULCERS, GASTRIC EROSIONS); GASTROINTESTINAL TISSUE ABLATION (BENIGN AND MALIGNANT NEOPLASM, ANGIODYSPLASIA, POLYPS, ULCERS, COLITIS, HEMORRHOIDS). • GYNECOLOGY: VAPORIZING, INCISING, OR COAGULATING TISSUE ASSOCIATED WITH TREATMENTS OF CONDITIONS SUCH AS ENDOMETRIOSIS; CERVICAL, VULVAR, AND VAGINAL INTRAEPITHELIAL NEOPLASIA; CONDYLOMA ACUMINATA; UTERINE SEPTUM; INTRAUTERINE ADHESIONS; SUBMUCOSAL FIBROIDS. • HEAD AND NECK/OTORHINOLARYNGOLOGY (ENT): TISSUE INCISION, EXCISION, ABLATION, AND VESSEL HEMOSTASIS. • NEUROSURGERY: INCISING, EXCISING, COAGULATING, AND VAPORIZING NEUROLOGICAL TUMORS OF THE FIRM TEXTURED TYPE. • OPHTHALMOLOGY: POST-VITRECTOMY ENDOPHOTOCOAGULATION OF THE RETINA. • PLASTIC SURGERY: VAPORIZING, COAGULATING INCISING, EXCISING, DEBULKING, AND ABLATING OF SOFT TISSUE IN ENDOSCOPIC AND OPEN PROCEDURES. • SPINAL SURGERY: PERCUTANEOUS LUMBAR DISCECTOMY. • THORACIC SURGERY:

		VAPORIZING, COAGULATING, INCISING, EXCISING, DEBULKING, AND ABLATING OF SOFT TISSUE, INCLUDING LUNG TISSUE IN THORACOSCOPIC OR OPEN PROCEDURES. • UROLOGY: CUTTING, COAGULATING, OR VAPORIZING UROLOGIC SOFT TISSUES. OPEN ENDOSCOPIC MINIMALLY INVASIVE UROLOGICAL SURGERY (ABLATION, VAPORIZATION, INCISION, EXCISION, AND COAGULATION OF SOFT TISSUE) INCLUDING TREATMENT OF BLADDER, URETHRAL AND URETERAL TUMORS; CONDYLOMATA; LESIONS OF EXTERNAL GENITALIA; URETHRAL AND PENILE HEMANGIOMA; URETHRAL STRICTURES; BLADDER NECK OBSTRUCTIONS; AND VAPORIZATION OF PROSTATE TISSUE FOR MEN SUFFERING FROM BENIGN PROSTATIC HYPERPLASIA (BPH). THE GREENLIGHT XPS LASER SYSTEM IS INTENDED FOR THE HOSPITAL, OFFICE, AND OUTPATIENT SURGERY CENTER MARKETS.,GENERAL/MULTIPLE SURGICAL SOLID-STATE LASER SYSTEM(AURIGA XL 4007 LASER SYSTEM)-THE AURIGA XL HOLMIUM LASER IS DESIGNED FOR USE FOR ALL INVASIVE AND NON-INVASIVE UROLOGIC PROCEDURES. DUE TO ITS APPLICATION ADAPTED PARAMETERS, THE AURIGA XL LASER CONSOLE IS QUALIFIED FOR: • LITHOTRIPSY • ABLATION (DISSECTION, ABLATION) OF SOFT TISSUE • COAGULATION OF SOFT TISSUE • VAPORIZATION OF LIQUID
1713	IMP/MD/2019/000273	1.License Holder Name: CLINIEXPERTS SERVICES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABMC KIT (ASIA)(ABMC KIT (ASIA))-ABMC KIT (ASIA) IS ONE STEP PROCEDURE PACK FOR COLLECTING AND CONCENTRATING BONE MARROW FROM PATIENT AND EXTRACTION OF DESIRED BONE MARROW MATERIAL BEFORE USE.
1714	IMP/MD/2019/000274	1.License Holder Name: TERUMO PENPOL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTION SET (REVEOS NLR 4NG456S0)-THE REVEOS NLR SET IS INTENDED TO COLLECT A UNIT OF WHOLE BLOOD AND TO PROCESS THE WHOLE BLOOD UNIT ON THE REVEOS AUTOMATED BLOOD PROCESSING SYSTEM, PRODUCING BLOOD COMPONENTS,BLOOD COLLECTION SET (REVEOS LR 4FG456S0)-THE REVEOS LR SET IS INTENDED TO COLLECT A UNIT OF WHOLE BLOOD AND TO PROCESS THE WHOLE BLOOD UNIT ON THE REVEOS AUTOMATED BLOOD PROCESSING SYSTEM, PRODUCING BLOOD COMPONENTS.

1715	IMP/MD/2019/000275	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC NEEDLES(NANOPASS 32.5, NANOPASS 34)-THIS PRODUCT IS INTENDED FOR USE WITH PEN INJECTOR FOR THE SUBCUTANEOUS INJECTION OF DRUGS INCLUDING INSULIN & HUMAN GROWTH HORMONE.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1716	IMP/MD/2019/000276	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEURO IMPLANTS (CRANIOFIX ABSORBABLE)-THE IMPLANTS ARE USED FOR FIXATING BONE FLAPS AFTER A CRANIOTOMY.,TROCAR(TROCAR)-IT IS USED IN LAPAROSCOPIC GENERAL SURGERY, GYNECOLOGY AND UROLOGY TO CREATE AND MAINTAIN ACCESS TO THE OPERATING FIELD FOR INSTRUMENTS AND ENDOSCOPES IN LAPAROSCOPIC OPERATIONS., KNEE RECONSTRUCTION SYSTEM(UNIVATION XF TIBIA/ UNIVATION XM TIBIA , AS UNIVATION XF TIBIA /UNIVATION XM TIBIA)-THE IMPLANT IS USED AS A COMPONENT PART OF A HUMAN KNEE ENDOPROSTHESIS,TROCAR(TROCAR BODY / SHAFT / OBTURATOR/ PIN / TIP, TROCAR CANNULA / TUBE / SLEEVE, TROCAR SEALING UNIT / CAP, MINOP TROCAR/ MINOP INVENT TROCAR, SINUSCOPY TROCAR, UNIVERSAL TROCAR, TILLEY LICHTWITZ ANTRUM TROCAR, MIASPAS TL TROCAR, CANNULA COMPLETE W/O TROCAR, FLEXIBLE TROCAR)-• IT IS USED IN ENDOSCOPIC OPERATION IN WHICH TISSUE NEEDS TO BE SEPARATED IN THE EXTRAPERITONEAL SPACE. • IT IS USED FOR ENDOSCOPIC AND ENDOSCOPE-ASSISTED SURGERY ON THE CENTRAL NERVOUS SYSTEM, PARTICULARLY FOR THE TREATMENT OF INTRAVENTRICULAR AND PARAVENTRICULAR PATHOLOGICAL STRUCTURES. • IT IS USED FOR ENDOSCOPIC EXAMINATIONS AND THERAPIES IN THE CENTRAL NERVOUS SYSTEM. • IT IS USED TO PREVENT LEAKS WHEN INSERTING 3 - 5 MM INSTRUMENTS IN 5 MM TROCARS AND TO INSERT E.G. NEEDLES OR SWABS SAFELY THROUGH THE TROCAR VALVE UNIT. • IT IS USED IN LAPAROSCOPIC GENERAL SURGERY, GYNECOLOGY AND UROLOGY TO RETRIEVE LARGER PORTIONS OF RESECTED TISSUE. • IT IS USED IN ENDOSCOPIC OPERATION TO INTRODUCE INSTRUMENTS AND ENDOSCOPES INTO THE OPERATING FIELD. • IT IS USED IN LAPAROSCOPIC GENERAL SURGERY, GYNECOLOGY AND UROLOGY. IT SERVES, WITH HASSON TECHNOLOGY, TO CREATE AND MAINTAIN AN APPROACH TO THE OPERATING FIELD FOR INSTRUMENTS AND ENDOSCOPES IN LAPAROSCOPIC SURGERY. • IT IS USED IN LAPAROSCOPIC GENERAL SURGERY, GYNECOLOGY AND UROLOGY TO CREATE AND MAINTAIN AN APPROACH TO THE OPERATING FIELD FOR INSTRUMENTS AND ENDOSCOPES IN LAPAROSCOPIC OPERATIONS. • IT IS USED IN LAPAROSCOPIC GENERAL SURGERY, GYNECOLOGY AND UROLOGY TO CREATE AND MAINTAIN AN APPROACH TO THE OPERATING FIELD FOR INSTRUMENTS AND ENDOSCOPES IN LAPAROSCOPIC SURGERY HASSON. • THESE INSTRUCTIONS FOR USE DESCRIBES AN INSTRUMENT FOR UNIVERSAL SURGICAL USE IN ALL SPECIALIST AREAS. • IT IS USED TO CREATE AN ACCESS POINT INTO THE BODY CAVITY FOR MINIMALLY

	INVASIVE SURGICAL INSTRUMENTS. • IT IS USED IN LAPAROSCOPIC OPERATIONS FOR INTRODUCING INSTRUMENTS AND ENDOSCOPES INTO THE OPERATING FIELD.,KNEE RECONSTRUCTION SYSTEM (UNIVATION F MENISCAL COMPONENT/ UNIVATION M MENISCAL COMPONENT)-THE IMPLANT IS USED AS A COMPONENT PART OF A HUMAN KNEE ENDOPROSTHESIS,SUCTION / IRRIGATION INSTRUMENT(SUCTION CANNULA / SUCTION TUBE / SUCTION TIP, MINOP SUCTION CANNULA / TREND, TUBULAR STAINLESS STEEL INSTRUMENTS, SUCTION CONTROL VALVE CERULLO, ASPIRATION AND IRRIGATION INSTRUMENTS, MONOPOLAR ASPIRATOR FOR MINIMALLY INVASIVE THORACIC SURGERY, REUSABLE SUCTION/IRRIGATION TUBE)-• REUSABLE SUCTION/IRRIGATION INSTRUMENTS ARE USED IN LAPAROSCOPIC SURGERY FOR THE ASPIRATION/IRRIGATION OF FLUIDS FROM/ INTO THE ABDOMEN. • THE SUCTION CANNULAS ARE SPECIALLY SUITED FOR MICROSURGICAL INTERVENTIONS IN NEUROSURGERY AND ENT SURGERY. IT CAN ALSO BE USED IN MANY OTHER DISCIPLINES SUCH AS ORAL AND MAXILLOFACIAL SURGERY, SPINE SURGERY OR CARDIOTHORACIC SURGERY. • THE MINOP TREND (TRANSNASAL ENDOSCOPY SYSTEM) IS USED FOR OPERATING SITES THAT CAN BE REACHED THROUGH A TRANSNASAL APPROACH. THE MINOP TREND (TRANSNASAL ENDOSCOPY SYSTEM KEEPS THE FIELD OF VIEW OF THE ADAPTED MINOP TREND ENDOSCOPE CLEAR FROM ANY BLOOD AND SECRETION, AND OPTIMUM VIEWING CONDITIONS ARE GUARANTEED DURING TRANSNASAL ACCESS IN THE OPERATIONAL AREA. THE MINOP TREND (TRANSNASAL ENDOSCOPY SYSTEM) CAN BE OPERATED FREEHAND OR VIA THE ADAPTER FOR HOLDING ARMRT099R ON THE CORRESPONDING HOLDING ARM, AND USED WITH A RINSING LIQUID CONTAINER, SUCTION PUMP AS WELL AS THE INSTRUMENT SET FOR TRANSNASAL ACCESS. • THESE INSTRUMENTS ARE INTENDED FOR UNIVERSAL SURGICAL USE IN ALL SPECIALIST AREAS. • THESE ARE USED TO REGULATE SUCTION POWER AND IS INTENDED FOR UNIVERSAL SURGICAL USE IN ALL DISCIPLINES. • SUCTION AND IRRIGATION TUBES ARE USED TO SUCTION BODILY FLUIDS, BLOOD, TISSUES OR SECRETIONS AND FOR IRRIGATION USING IRRIGATING SOLUTIONS. THE ASPIRATION AND IRRIGATION INSTRUMENTS ARE SPECIALLY SUITED FOR MICROSURGICAL INTERVENTIONS IN NEUROSURGERY AND ENT SURGERY. • THE MONOPOLAR ASPIRATOR IS USED FOR ASPIRATING LIQUIDS AND COAGULATING TISSUE IN MINIMALLY INVASIVE THORACIC SURGERY. • REUSABLE SUCTION/IRRIGATION TUBES ARE USED IN LAPAROSCOPIC SURGERY FOR THE ASPIRATION/IRRIGATION OF FLUIDS FROM/INTO THE ABDOMEN.,TOTAL KNEE REPLACEMENT (VEGA SYSTEM PS FEMORAL COMPONENT)-THE IMPLANT IS USED AS

	A COMPONENT PART OF A HUMAN KNEE ENDOPROSTHESIS,TOTAL HIP REPLACEMENT SYSTEM(EXCIA T, EXCIA TL)-COMPONENT OF A HUMAN HIP ENDOPROSTHESIS: HIP ENDOPROSTHESIS STEM • COMBINATION WITH AESCULAP HIP ENDOPROSTHESIS COMPONENTS SEVERE HIP CONDITIONS THAT CANNOT BE TREATED WITH OTHER THERAPIES: • DEGENERATIVE OSTEOARTHRITIS • RHEUMATIC ARTHRITIS • FRACTURES OF THE JOINT • FEMORAL HEAD NECROSIS, NEURO IMPLANT(YASARGIL ANEURYSM CLIPS)-"THE PERMANENT ANEURYSM CLIPS ARE INTENDED FOR PERMANENT OCCLUSION OF CEREBRAL ANEURYSMS. THE TEMPORARY ANEURYSM CLIPS ARE INTENDED FOR THE TEMPORARY LIGATION OF ANEURYSMS OR BLOOD VESSELS. ",NEURO IMPLANTS(CRANIOFIX 2)-THE CLAMP SYSTEM IS USED FOR THE FIXATION OF CRANIOTOMIZED BONE FLAPS AND FRACTURES TO THE NEUROCRANIUM.,KNEE RECONSTRUCTION SYSTEM(UNIVATION XF FEMUR/ UNIVATION XM FEMUR/ AS UNIVATION XF FEMUR/ UNIVATION XM FEMUR)-THE IMPLANT IS USED AS A COMPONENT PART OF A HUMAN KNEE ENDOPROSTHESIS,TOTAL KNEE REPLACEMENT(COLUMBUS UCR TIBIAL PLATEAU/ COLUMBUS TIB HEMI-SPACER/ AS COLUMBUS TIB HEMI-SPACER/ TIBIAL OBTURATOR/ AS TIBIAL OBTURATOR, TIBIA EXTENTION STEM/ AS TIBIA EXTENTION STEM/ TIBIA OFFSET STEM/ AS TIBIA OFFSET STEM)-THE IMPLANT IS USED AS A COMPONENT PART OF A HUMAN KNEE ENDOPROSTHESIS,TOTAL KNEE REPLACEMENT(COLUMBUS CR DD GLIDING SURFACE/ COLUMBUS UC GLIDING SURFACE/ COLUMBUS UCR GLIDING SURFACE/ COLUMBUS PS GLIDING SURFACE/ COLUMBUS REV F MC GLIDING SURFACE/ COLUMBUS REV F HC GLIDING SURFACE)-THE IMPLANT IS USED AS A COMPONENT PART OF A HUMAN KNEE ENDOPROSTHESIS,TOTAL KNEE REPLACEMENT(COLUMBUS CR FEMORAL/ AS COLUMBUS CR FEMORAL/ COLUMBUS PS FEMORAL/ AS COLUMBUS PS FEMORAL/ COLUMBUS CR NARROW FEMUR/ AS COLUMBUS NARROW FEMUR/ COLUMBUS PS NARROW FEMUR/ COLUMBUS REV F FEMUR/ AS COLUMBUS REV F FEMUR/ COLUMBUS REV FEMUR SPACER/ AS COLUMBUS REV FEMUR SPACER/ FEMUR EXTENSION STEM/ AS FEMUR EXTENSION STEM; NUT F/FEMUR EXTENSION STEM)-THE IMPLANT IS USED AS A COMPONENT PART OF A HUMAN KNEE ENDOPROSTHESIS,TOTAL HIP REPLACEMENT SYSTEM(METHA HIP STEM)-THE IMPLANT IS USED AS A COMPONENT OF A HUMAN HIP ENDOPROSTHESIS,TOTAL HIP REPLACEMENT SYSTEM(IMSET RESORB.INTRAMEDULLARY PLUG)-"THE BIODEGRADABLE IMSET MEDULLARY CAVITY PLUG FOR ORTHOPEDIC PURPOSES IS USED TO SEAL THE MEDULLARY CAVITY OF A LONG BONE PRIOR TO INJECTION OF BONE CEMENT WITH THE FOLLOWING AIMS: - TO PREVENT THE BONE CEMENT FROM PENETRATING DEEP IN THE

	DIAPHYSIS. - TO ENABLE THE COMPRESSION AND PENETRATION OF THE BONE CEMENT IN THE CANCELLOUS BONE",TOTAL HIP REPLACEMENT SYSTEM(BIOLOX DELTA INSERT)-THE IMPLANT IS USED AS A COMPONENT OF A HUMAN HIP ENDOPROSTHESIS,TOTAL HIP REPLACEMENT SYSTEM(BICONTACT REV)-THE IMPLANT IS USED AS A COMPONENT OF A HUMAN HIP ENDOPROSTHESIS,TOTAL HIP REPLACEMENT SYSTEM(BICONTACT N/ BICONTACT H/ BICONTACT S/ BICONTACT SD)-THE IMPLANT IS USED AS A COMPONENT OF A HUMAN HIP ENDOPROSTHESIS,TOTAL HIP REPLACEMENT SYSTEM (CENTRALIZER)-THE CENTRALIZER SERVES AS AN ADDITIONAL GUIDE ELEMENT WHEN USING AESCULAP HIP ENDOPROSTHESES SYSTEM.,TOTAL HIP REPLACEMENT SYSTEM(PLASMACUP SC/ PLASMACUP DELTA/ PLASMAFIT POLY/ PLASMAFIT PLUS)-THE IMPLANT IS USED AS A COMPONENT OF A HUMAN HIP ENDOPROSTHESIS,TOTAL HIP REPLACEMENT SYSTEM(LOCKING SCREW (HIP REVISION)/PLASMACUP FIXATION SCREW/ FIXATION SCREW)-THE IMPLANT IS USED AS A COMPONENT OF A HUMAN HIP ENDOPROSTHESIS,TOTAL KNEE REPLACEMENT(VEGA SYSTEM PS ALL POLY TIBIA/ PATELLA IMPLANT)-THE IMPLANT IS USED AS A COMPONENT PART OF A HUMAN KNEE ENDOPROSTHESIS,TOTAL KNEE REPLACEMENT(VEGA SYSTEM PS GLIDING SURFACE / VEGA SYSTEM PS+ GLIDING SURFACE)-THE IMPLANT IS USED AS A COMPONENT PART OF A HUMAN KNEE ENDOPROSTHESIS,TOTAL HIP REPLACEMENT SYSTEM(SYSTEM SC/MSC PE-INSERT/ VITELENE INSERT)-THE IMPLANT IS USED AS A COMPONENT OF A HUMAN HIP ENDOPROSTHESIS,TOTAL HIP REPLACEMENT SYSTEM(PE- CUP/ RECON RING/ BIPOLAR CUP)-THE IMPLANT IS USED AS A COMPONENT OF A HUMAN HIP ENDOPROSTHESIS,TOTAL KNEE REPLACEMENT(COLUMBUS REV F TIBIA OFFSET/ AS COLUMBUS REV F TIBIA OFFSET/ COLUMBUS CR/PS TIB. PLATEAU/ AS COLUMBUS CR/PS TIB. PLATEAU)-THE IMPLANT IS USED AS A COMPONENT PART OF A HUMAN KNEE ENDOPROSTHESIS,TOTAL HIP REPLACEMENT SYSTEM(ISODUR PROSTHESIS HEAD/ BIOLOX PROSTHESIS HEAD/ BIOLOX DELTA PROSTH. HEAD)-THE IMPLANT IS USED AS A COMPONENT OF A HUMAN HIP ENDOPROSTHESIS,TOTAL KNEE REPLACEMENT(VEGA SYSTEM PS TIBIAL)-THE IMPLANT IS USED AS A COMPONENT PART OF A HUMAN KNEE ENDOPROSTHESIS

1717	IMP/MD/2019/000278	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE CEMENTS-SMARTSET GHV GENTAMICIN(SMARTSET GHV GENTAMICIN BONE CEMENTS)-SMARTSET GHV GENTAMICIN IS INDICATED FOR THE FIXATION OF PROSTHESES TO LIVING BONE IN ARTHROPLASTY PROCEDURES OF JOINTS IN WHICH INFECTION BY GENTAMICIN SENSITIVE ORGANISMS IS A POTTENTIAL RISK. THE BONE CEMENTS ARE INDICATED FOR USE IN CHILDREN ONLY IN THE CASE OF LIMB PRESERVATION WHERE NO OTHER PROCEDURE IS LIKELY TO GIVE A GOOD CHANCE OF SUCCESSFUL TREATMENT. THE BONE CEMENT SHOULD BE USED WITH AN APPROPRIATE PROSTHESIS.,BONE CEMENTS- DEPUY CMW 1 GENTAMICIN(DEPUY CMW 1 GENTAMICIN BONE CEMENTS)-DEPUY CMW 1 GENTAMICIN BONE CEMENTS ARE INDICATED FOR THE FIXATION OF PROSTHESES TO LIVING BONE IN ARTHROPLASTY PROCEDURES OF JOINTS IN WHICH INFECTION BY GENTAMICIN SENSITIVE ORGANISMS IS A POTENTIAL RISK. THEY ARE INDICATED FOR USE IN CHILDREN ONLY IN CASE OF LIMB PRESERVATION WHERE NO OTHER PROCEDURE IS LIKELY TO GIVE A GOOD CHANCE OF SUCCESSFUL TREATMENT. THE CEMENTS SHOULD BE USED WITH AN APPROPRIATE PROSTHESIS.,BONE CEMENTS-DEPUY CMW 3 GENTAMICIN(DEPUY CMW 3 GENTAMICIN BONE CEMENTS)-DEPUY CMW 3 GENTAMICIN BONE CEMENTS ARE INDICATED FOR THE FIXATION OF PROSTHESES TO LIVING BONE IN ARTHROPLASTY PROCEDURES OF JOINTS IN WHICH INFECTION BY GENTAMICIN SENSITIVE ORGANISMS IS A POTENTIAL RISK. THEY ARE INDICATED FOR USE IN CHILDREN ONLY IN CASE OF LIMB PRESERVATION WHERE NO OTHER PROCEDURE IS LIKELY TO GIVE A GOOD CHANCE OF SUCCESSFUL TREATMENT. THE CEMENTS SHOULD BE USED WITH AN APPROPRIATE PROSTHESIS.,BONE CEMENTS-DEPUY CMW 3(DEPUY CMW 3 BONE CEMENTS)-DEPUY CMW BONE CEMENTS ARE INDICATED FOR THE FIXATION OF PROSTHESES TO LIVING BONE IN ORTHOPEDIC MUSCULOSKELETAL SURGICAL PROCEDURES FOR RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OSTEOPOROSIS, AVASCULAR NECROSIS, COLLAGEN DISEASE, SEVERE JOINT DESTRUCTION SECONDARY TO TRAUMA OR OTHER CONDITIONS, AND REVISION OF PREVIOUS ARTHROPLASTY.,BONE CEMENTS- SAMETSET HV(SMARTSET HV BONE CEMENTS)-SMARTEST HV BONE CEMENT IS INDICATED FOR THE FIXATION OF PROSTHESES TO LIVING BONE IN ORTHOPEDIC MUSCULOSKELETAL SURGICAL PROCEDURES FOR RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OSTEOPOROSIS, AVASCULAR NECROSIS, COLLAGEN DISEASE, SEVERE JOINT DESTRUCTION SECONDARY TO TRAUMA OR OTHER

		CONDITIONS, AND REVISION OF PREVIOUS ARTHROPLASTY.,BONE CEMENTS- DEPUY CMW 1(DEPUY CMW 1 BONE CEMENTS)-DEPUY CMW BONE CEMENTS ARE INDICATED FOR THE FIXATION OF PROSTHESES TO LIVING BONE IN ORTHOPEDIC MUSCULOSKELETAL SURGICAL PROCEDURES FOR RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OSTEOPOROSIS, AVASCULAR NECROSIS, COLLAGEN DISEASE, SEVERE JOINT DESTRUCTION SECONDARY TO TRAUMA OR OTHER CONDITIONS, AND REVISION OF PREVIOUS ARTHROPLASTY.
1718	IMP/MD/2019/000280	1.License Holder Name: S.R. INTERNATIONAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRAOCULAR GAS C3F8 (ARCEOLE SET MULTIDOSE C3F8)-THE GAS IS USED IN OPHTHALMIC SURGERY IN THE FRAME OF RETINA DETACHMENT PROCEDURES BY USE OF ENDO TAMPONADE.,INTRAOCULAR GAS SF6(ARCEOLE SET MULTIDOSE SF6)-THE GAS IS USED IN OPHTHALMIC SURGERY IN THE FRAME OF RETINA DETACHMENT PROCEDURES BY USE OF ENDO TAMPONADE.,SILICONE OIL 1300 CST & 5500 CST(ARCIOLANE 1300 CST/ ARCIOLANE 5500 CST)-PROLONGED TAMPONADE AFTER SURGICAL TREATMENT FOR SEVERE RETINAL DETACHMENT (RD) ESPECIALLY : RD WITH GIANT TEARS, RD WITH PROLIFERATIVE VITREORETINOPATHY, TRAUMATIC RD, RD THAT COMPLICATE A DIABETIC RETINOPATHY, RD SECONDARY RETINAL DETACHMENT TO A VIRAL RETINITIS

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1719	IMP/MD/2019/000283	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE GRAFT(INFUSE BONE GRAFT-KIT)-THE INFUSE™ BONE GRAFT/MEDTRONIC INTERBODY FUSION DEVICE IS INDICATED FOR SPINAL FUSION PROCEDURES IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE LEVEL FROM L2-S1. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES. THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE I SPONDYLOLISTHESIS OR GRADE 1 RETROLISTHESIS AT THE INVOLVED LEVEL. PATIENTS RECEIVING THE INFUSE™ BONE GRAFT/MEDTRONIC INTERBODY FUSION DEVICE SHOULD HAVE HAD AT LEAST SIX MONTHS OF NONOPERATIVE TREATMENT PRIOR TO TREATMENT WITH THE INFUSE™ BONE GRAFT/ MEDTRONIC INTERBODY FUSION DEVICE. THE FOLLOWING INTERBODY DEVICES AND SURGICAL APPROACHES MAY BE USED WITH INFUSE™ BONE GRAFT: THE LT-CAGE™ LUMBAR TAPERED FUSION DEVICE, IMPLANTED VIA AN ANTERIOR OPEN OR AN ANTERIOR LAPAROSCOPIC APPROACH AT A SINGLE LEVEL. THE INTER FIX™ OR INTER FIX™ RP THREADED FUSION DEVICE, IMPLANTED VIA AN ANTERIOR OPEN APPROACH AT A SINGLE LEVEL. CERTAIN SIZES OF THE PERIMETER™ INTERBODY FUSION DEVICE IMPLANTED VIA A RETROPERITONEAL ANTERIOR LUMBAR INTERBODY FUSION (ALIF) AT A SINGLE LEVEL FROM L2-S1OR AN OBLIQUE LATERAL INTERBODY FUSION (OLIF) APPROACH AT A SINGLE LEVEL FROM L5-S1. CERTAIN SIZES OF THE CLYDESDALE™ SPINAL SYSTEM, IMPLANTED VIA AN OLIF APPROACH AT A SINGLE LEVEL FROM L2-L5. CERTAIN SIZES OF THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM IMPLANTED VIA AN ALIF APPROACH AT A SINGLE LEVEL FROM L2-S1OR AN OLIF APPROACH AT A SINGLE LEVEL FROM L5-S1. CERTAIN SIZES OF THE PIVOX™ OBLIQUE LATERAL SPINAL SYSTEM IMPLANTED VIA AN OLIF APPROACH AT A SINGLE-LEVEL FROM L2-L5.,BALLOON INFLATION/DEFLATION DEVICE(KYPHON ELEMENT SYRINGE KIT)-THE INFLATION DEVICE IS RECOMMENDED FOR USE WHILE PERFORMING BALLOON DILATION PROCEDURES TO INFLATE THE BALLOON, MONITOR THE PRESSURE WITHIN THE BALLOON AND DEFLATE THE BALLOON. THE VACLOK SYRINGE IS INTENDED TO BE USED BY A CARDIOLOGIST OR RADIOLOGIST DURING AN ANGIOGRAPHIC OR RADIOLOGIC PROCEDURE.,SPINAL INTERVERTEBRAL BODY FIXATION ORTHOSIS (T2 ALTITUDE EXPANDABLE CORPECTOMY SYSTEM)-THE T2 ALTITUDE™ EXPANDABLE CORPECTOMY SYSTEM IS A VERTEBRAL BODY REPLACEMENT SYSTEM INTENDED FOR USE IN THE

	THORACOLUMBAR SPINE (TI-LS5) TO REPLACE A COLLAPSED, DAMAGED, OR UNSTABLE VERTEBRAL BODY DUE TO TUMOR OR TRAUMA (I.E. FRACTURE). THE T2 ALTITUDE™ EXPANDABLE CENTERPIECE MAY BE USED WITH OR WITHOUT OPTIONAL MODULAR ENDCAPS WHICH ACCOMMODATE INDIVIDUAL ANATOMIC REQUIREMENTS. THE DEVICE IS TO BE USED WITH SUPPLEMENTAL FIXATION. SPECIFICALLY, THE CONSTRUCT IS TO BE USED WITH THE VANTAGE® ANTERIOR FIXATION SYSTEM, THE TSRH®& SPINAL SYSTEM, THE CD HORIZON® SPINAL SYSTEM, OR THEIR SUCCESSORS. ADDITIONALLY, THE T2 ALTITUDETM EXPANDABLE CORPECTOMY SYSTEM IS INTENDED TO BE USED WITH ALLOGRAFT AND/OR AUTOGRAFT.,ORTHOSIS CERVICAL PEDICLE SCREW SPINAL FIXATION(THE INFINITY OCCIPITO CERVICAL-UPPER THORACIC SYSTEM (OCT SYSTEM))-THE INFINITY™ OCT SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OF THE CRANIOCERVICAL JUNCTION, THE CERVICAL SPINE (C1 TO C7), AND THE THORACIC SPINE FROM T1-T3: TRAUMATIC SPINAL FRACTURES AND/OR TRAUMATIC DISLOCATIONS. INSTABILITY OR DEFORMITY. FAILED PREVIOUS FUSIONS (E.G. PSEUDARTHROSIS). TUMORS INVOLVING THE CERVICAL SPINE. DEGENERATIVE DISEASE, INCLUDING INTRACTABLE RADICULOPATHY AND/OR MYELOPATHY, NECK AND/OR ARM PAIN OF DISCOGENIC ORIGIN AS CONFIRMED BY RADIOGRAPHIC STUDIES, AND DEGENERATIVE DISEASE OF THE FACETS WITH INSTABILITY. THE INFINITY™ OCT SYSTEM IS ALSO INTENDED TO RESTORE THE INTEGRITY OF THE SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A LIMITED TIME IN PATIENTS WITH ADVANCED STAGE TUMORS INVOLVING THE CERVICAL SPINE IN WHOM LIFE EXPECTANCY IS OF INSUFFICIENT DURATION TO PERMIT ACHIEVEMENT OF FUSION. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE INFINITY™ OCT SYSTEM MAY BE CONNECTED TO THE CD HORIZON™ SPINAL SYSTEM AND VERTEX™ RECONSTRUCTION SYSTEM RODS WITH THE INFINITY™ OCT SYSTEM ROD CONNECTORS. TRANSITION RODS WITH DIFFERING DIAMETERS MAY ALSO BE USED TO CONNECT THE INFINITY™ OCT SYSTEM TO THE CD HORIZON™ SPINAL SYSTEM. REFER TO THE CD HORIZON™ SPINAL SYSTEM PACKAGE INSERT AND VERTEX™ RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE INDICATIONS OF USE. NOTE: THE 3.0MM MULTI AXIAL SCREW (MAS) REQUIRES THE USE OF MAS CROSSLINK™ AT EACH LEVEL IN WHICH THE 3.0MM SCREW IS INTENDED TO BE USED. THE LATERAL OFFSET CONNECTORS AND MAS EXTENSION CONNECTORS ARE INTENDED TO BE USED WITH 3.5 MM AND LARGER DIAMETER MULTI AXIAL SCREWS. THE LATERAL

	OFFSET CONNECTORS AND MAS EXTENSION CONNECTORS ARE NOT INTENDED TO BE USED WITH 3.0MM SCREWS. NOTE: SEGMENTAL FIXATION IS RECOMMENDED FOR THESE CONSTRUCTS.,SPINAL LNTERVERTEBRAL BODY FIXATION ORTHOSIS(T2 STRATOSPHERE EXPANDABLE CORPECTOMY SYSTEM)-THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM IS A VERTEBRAL BODY REPLACEMENT DEVICE INTENDED FOR USE IN THE THORACIC AND LUMBAR SPINE (T1-L5) AND CERVICAL SPINE (C2-C7). THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM IS INTENDED FOR USE IN SKELETALLY MATURE PATIENTS. WHEN USED IN THE CERVICAL SPINE, THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM IS USED TO REPLACE A COLLAPSED, DAMAGED, OR UNSTABLE VERTEBRAL BODY CAUSED BY TUMOR, TRAUMA (I.E. FRACTURE), OR OSTEOMYELITIS, OR FOR RECONSTRUCTION FOLLOWING CORPECTOMY PERFORMED TO ACHIEVE DECOMPRESSION OF THE SPINAL CORD AND NEURAL TISSUES IN CERVICAL DEGENERATIVE DISORDERS. WHEN USED IN THE CERVICAL SPINE, THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM MAY NOT BE USED WITH OPTIONAL MODULAR END CAPS. WHEN USED IN THE CERVICAL SPINE AT SINGLE OR TWO LEVELS, THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM IS INTENDED TO BE USED WITH SUPPLEMENTAL FIXATION FOR USE IN THE CERVICAL SPINE. WHEN USED AT MORE THAN TWO LEVELS, SUPPLEMENTAL FIXATION SHOULD INCLUDE POSTERIOR FIXATION CLEARED FOR USE IN THE CERVICAL SPINE. WHEN USED IN THE THORACIC AND LUMBAR SPINE, THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM IS USED TO REPLACE A COLLAPSED, DAMAGED, OR UNSTABLE VERTEBRAL BODY DUE TO TUMOR OR TRAUMA (I.E. FRACTURE). THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY CENTERPIECE MAY BE USED WITH OR WITHOUT OPTIONAL MODULAR END CAPS WHICH ACCOMMODATE INDIVIDUAL ANATOMIC REQUIREMENTS. THE DEVICE IS TO BE USED WITH SUPPLEMENTAL FIXATION CLEARED FOR USE IN THE THORACIC AND LUMBAR SPINE. WHEN USED IN THE CERVICAL SPINE, THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM IS INTENDED FOR USE WITH AUTOGRAFT OR ALLOGENIC BONE GRAFT COMPRISED OF CANCELLOUS AND/OR CORTICOCANCELLOUS BONE GRAFT AS AN ADJUNCT TO FUSION. WHEN USED IN THE THORACIC AND LUMBAR SPINE, THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM IS INTENDED FOR USE WITH AUTOGRAFT OR ALLOGRAFT AS AN ADJUNCT TO FUSION. THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM IS ALSO INTENDED TO RESTORE THE INTEGRITY OF THE SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A LIMITED TIME IN PATIENTS WITH

	ADVANCED STAGE TUMORS INVOLVING THE CERVICAL AND/OR THORACOLUMBAR SPINE IN WHOM LIFE EXPECTANCY IS OF INSUFFICIENT DURATION TO PERMIT ACHIEVEMENT OF FUSION, WITH BONE GRAFT USED AT THE SURGEON'S DISCRETION.,SPINAL LNTERVERTEBRAL BODY FIXATION ORTHOSIS(T2 STRATOSPHERE EXPANDABLE CORPECTOMY SYSTEM)-THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM-THORACOLUMBAR IS A VERTEBRAL BODY REPLACEMENT DEVICE INTENDED FOR USE IN THE THORACIC AND LUMBAR SPINE (T1-L5) TO REPLACE A COLLAPSED, DAMAGED, OR UNSTABLE VERTEBRAL BODY DUE TO TUMOR OR TRAUMA (I.E. FRACTURE). THE T2 STRATOSPHERE™ EXPANDABLE CENTERPIECE MAY BE USED WITH OR WITHOUT OPTIONAL MODULAR END CAPS WHICH ACCOMMODATE INDIVIDUAL ANATOMIC REQUIREMENTS. THE DEVICE IS TO BE USED WITH SUPPLEMENTAL FIXATION CLEARED FOR USE IN THE THORACIC AND LUMBAR SPINE. THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM-THORACOLUMBAR IS INTENDED FOR USE WITH AUTOGRAFT OR ALLOGRAFT, AS AN ADJUNCT TO FUSION. THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM-THORACOLUMBAR IS ALSO INTENDED TO RESTORE THE INTEGRITY OF THE SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A LIMITED TIME IN PATIENTS WITH ADVANCED STAGE TUMORS INVOLVING THE THORACIC AND LUMBAR SPINE IN WHOM LIFE EXPECTANCY IS OF INSUFFICIENT DURATION TO PERMIT ACHIEVEMENT OF FUSION, WITH BONE GRAFT USED AT THE SURGEON'S DISCRETION.,ORTHOSIS CERVICAL PEDICLE SCREW SPINAL FIXATION(THE INFINITY OCCIPITO CERVICAL-UPPER THORACIC SYSTEM (OCT SYSTEM))-THE INFINITYTM OCT SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OF THE CRANIOCERVICAL JUNCTION, THE CERVICAL SPINE (C1 TO C7), AND THE THORACIC SPINE FROM T1-T3: • TRAUMATIC SPINAL FRACTURES AND/OR TRAUMATIC DISLOCATIONS. • INSTABILITY OR DEFORMITY. • FAILED PREVIOUS FUSIONS (E.G. PSEUDARTHROSIS). • TUMORS INVOLVING THE CERVICAL SPINE. • DEGENERATIVE DISEASE, INCLUDING INTRACTABLE RADICULOPATHY AND/OR MYELOPATHY, NECK AND/OR ARM PAIN OF DISCOGENIC ORIGIN AS CONFIRMED BY RADIOGRAPHIC STUDIES, AND DEGENERATIVE DISEASE OF THE FACETS WITH INSTABILITY. THE INFINITYTM OCT SYSTEM IS ALSO INTENDED TO RESTORE THE INTEGRITY OF THE SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A LIMITED TIME IN PATIENTS WITH ADVANCED STAGE TUMORS INVOLVING THE CERVICAL SPINE IN WHOM LIFE EXPECTANCY IS OF INSUFFICIENT DURATION TO PERMIT ACHIEVEMENT OF FUSION. IN ORDER TO ACHIEVE ADDITIONAL

	LEVELS OF FIXATION, THE INFINITYTM OCT SYSTEM MAY BE CONNECTED TO THE CD HORIZON™ SPINAL SYSTEM AND VERTEX™ RECONSTRUCTION SYSTEM RODS WITH THE INFINITYTM OCT SYSTEM ROD CONNECTORS. TRANSITION RODS WITH DIFFERING DIAMETERS MAY ALSO BE USED TO CONNECT THE INFINITYTM OCT SYSTEM TO THE CD HORIZON™ SPINAL SYSTEM. REFER TO THE CD HORIZON™ SPINAL SYSTEM PACKAGE INSERT AND VERTEX™ RECONSTRUCTION SYSTEM PACKAGE INSERT FOR A LIST OF THE INDICATIONS OF USE. THE 3.0MM MULTI AXIAL SCREW (MAS) REQUIRES THE USE OF MAS CROSSLINK™ AT EACH LEVEL IN WHICH THE 3.0MM SCREW IS INTENDED TO BE USED. THE LATERAL OFFSET CONNECTORS AND MAS EXTENSION CONNECTORS ARE INTENDED TO BE USED WITH 3.5 MM AND LARGER DIAMETER MULTI AXIAL SCREWS. THE LATERAL OFFSET CONNECTORS AND MAS EXTENSION CONNECTORS ARE NOT INTENDED TO BE USED WITH 3.0MM SCREWS. SEGMENTAL FIXATION IS RECOMMENDED FOR THESE CONSTRUCTS.,FENESTRATED SCREW SPINAL SYSTEM(CD HORIZON FENESTRATED SCREW SET)-WHEN USED WITHOUT CEMENT, CD HORIZON™ FENESTRATED SCREWS (WITH OR WITHOUT SEXTANT™ OR LONGITUDE™ INSTRUMENTATION) ARE INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDDDEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TUMOR AND/OR TRAUMA (I.E. FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E. SCOLIOSIS, KYPHOSIS, OR LORDOSIS), PSEUDARTHROSIS, AND/OR FAILED PREVIOUS FUSION. ADDITIONALLY, CD HORIZON™ FENESTRATED SCREWS MAY BE USED FOR IMMOBILIZATION AND STABILIZATION WHEN USED FOR TRAUMA (E.G., FRACTURE OR DISLOCATION) WITH THE USAGE OF BONE GRAFT MATERIAL LEFT TO THE SURGEON'S DISCRETION. WHEN USED IN CONJUNCTION WITH MEDTRONIC HV-R™ FENESTRATED SCREW CEMENT OR KYPHON™ XPEDE™ BONE CEMENT, CD HORIZON™ FENESTRATED SCREWS ARE INTENDED TO RESTORE THE INTEGRITY OF THE SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A LIMITED TIME IN PATIENTS WITH ADVANCED STAGE TUMORS INVOLVING THE THORACIC, LUMBAR, OR SACRAL SPINE IN WHOM LIFE EXPECTANCY IS OF INSUFFICIENT DURATION TO PERMIT ACHIEVEMENT OF FUSION. CD HORIZON™ FENESTRATED SCREWS AUGMENTED WITH MEDTRONIC HV-R™ FENESTRATED SCREW CEMENT OR KYPHON™ XPEDE™ BONE CEMENT ARE FOR USE AT SPINAL LEVELS WHERE THE STRUCTURAL INTEGRITY OF THE SPINE IS NOT SEVERELY COMPROMISED.

1720	IMP/MD/2019/000284	1.License Holder Name: KCI MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PROMOGRAN® PROTEASE MODULATING MATRIX(PROMOGRAN® PROTEASE MODULATING MATRIX)-PROMOGRAN® MATRIX IS INDICATED FOR THE MANAGEMENT OF ALL WOUNDS HEALING BY SECONDARY INTENT WHICH ARE CLEAR OF NECROTIC TISSUE, INCLUDING: • DIABETIC ULCERS • VENOUS ULCERS • PRESSURE ULCERS • ULCERS CAUSED BY MIXED VASCULAR AETIOLOGIES • TRAUMATIC AND SURGICAL WOUNDS. PROMOGRAN® MATRIX HAS DEMONSTRATED HAEMOSTATIC PROPERTIES. PROMOGRAN® MATRIX CAN BE USED UNDER COMPRESSION THERAPY.,ADAPTIC TOUCH® NON-ADHERING SILICONE DRESSING(ADAPTIC TOUCH® NON-ADHERING SILICONE DRESSING)-ADAPTIC TOUCH® NON-ADHERING SILICONE DRESSING IS DESIGNED AS A PRIMARY WOUND CONTACT LAYER FOR USE IN THE MANAGEMENT OF DRY TO HEAVILY EXUDING PARTIAL AND FULL- THICKNESS CHRONIC WOUNDS INCLUDING VENOUS ULCER, DECUBITUS (PRESSURE) ULCERS AND DIABETIC ULCERS AND FOR TRAUMATIC AND SURGICAL WOUNDS, DONOR SITES AND IST AND 2ND DEGREE BURNS. IT IS ALSO SUITABLE FOR USE, UNDER MEDICAL SUPERVISION, WITH NEGATIVE PRESSURE WOUND THERAPY (NPWT)., ACTISORB® PLUS 25 ACTIVATED CHARCOAL DRESSING WITH SILVER (ACTISORB® PLUS 25)-ACTISORB® PLUS 25 DRESSING IS SUITABLE AS THE FIRST THERAPEUTIC STEP IN THE MANAGEMENT OF ALL CHRONIC WOUNDS. IT IS INDICATED FOR FUNGATING CARCINOMAS, ULCERATIVE, TRAUMATIC AND SURGICAL WOUNDS WHERE BACTERIAL CONTAMINATION, INFECTION OR ODOUR OCCURS.,NON ADHERING DRESSING(ADAPTIC® DIGIT NON ADHERING DIGIT DRESSING)-ADAPTIC® DIGIT DRESSING IS INDICATED TO MANAGE A RANGE OF MILD TO SEVERE DIGIT INJURIES.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1721	IMP/MD/2019/000284	1.License Holder Name: KCI MEDICAL INDIA PRIVATE LIMITED ,K. NO. 2606/115 (P. NO. 60/16) GROUND FLOOR, HUSKUR ROAD ELECTRONIC POST ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560100 , INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PROMOGRAN PRISMA® WOUND BALANCING MATRIX(PROMOGRAN PRISMA® WOUND BALANCING MATRIX)-PROMOGRAN PRISMA® MATRIX IS INDICATED FOR THE MANAGEMENT OF ALL WOUNDS HEALING BY SECONDARY INTENT WHICH ARE CLEAR OF NECROTIC TISSUE INCLUDING: • DIABETIC ULCERS • VENOUS ULCERS • PRESSURE ULCERS • ULCERS CAUSED BY MIXED VASCULAR AETIOLOGIES • TRAUMATIC AND SURGICAL WOUNDS PROMOGRAN PRISMA® MATRIX HAS KNOWN HAEMOSTATIC PROPERTIES. PROMOGRAN PRISMA® MATRIX CAN BE USED UNDER COMPRESSION THERAPY.
1722	IMP/MD/2019/000285	1.License Holder Name: M/S DB HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE FISTULA NEEDLES(ABLE)-THE PRODUCT IS INTENDED TO PUNCTURE THE MATURE FISTULA AND CONNECT WITH THE BLOOD LINES TO ESTABLISH BLOOD CIRCULATING PATH OUTSIDE HUMAN BODY IN THE PROCESS OF HEMODIALYSIS.,DISPOSABLE BLOOD LINES(ABLE)-THE PRODUCT IS INTENDED TO ESTABLISH BLOOD CIRCULATION PATH OUTSIDE HUMAN BODY. IT CAN MATCH ALL DIALYSIS MACHINES.,CENTRAL VENOUS CATHETER KIT/SET(ABLECATH)-THE ABLE CENTRAL VENOUS CATHETERS KIT/SET MAY BE APPLICABLE TO THE ONE OF FOLLOWING THERAPY: 1. MONITOR OF CENTRAL VENOUS PRESSURE; 2. CONTINUOUS OR DISCONTINUOUS VENOUS TRANSFUSION; 3. BLOOD SAMPLING THE CATHETER IS SURGICALLY PENETRATED INTO THREE OPTIONAL PUNCTURE POINTS DEPENDED ON THE CLINICAL REQUIREMENT WITH SELDINGER TECHNIQUE. THE INSERTION SITES ARE : 1. INTERNAL JUGULAR VEIN; 2. SUBCLAVIAN VEIN; 3. FEMORAL VEIN. IT IS POSSIBLE TO BE INSERTED INSIDE THE BODY FOR LESS THAN 30DAYS. IF DURATION EXCEEDS 30 DAYS, IT MAY OCCURE THE RISK OF COMBINING THE CATHETER AND INSIDE TISSUE, WHICH RESULT IN SERIOUS INCIDENT.,HEMODIALYSIS CATHETER KIT/SET(ABLECATH)-THE PRODUCT IS APPLICABLE FOR HEMODIALYSIS, VENOUS TRANSFUSION, CONTINUOUS MONITORING THE VENOUS PRESSURE. THE TIME OF USE IS LESS THAN 30 DAYS.

1723	IMP/MD/2019/000286	1.License Holder Name: FUTURZ-MED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISINFECTANT / CLEANING AGENT(HEMOCLEAN C)-IT IS USED FOR DISINFECTANT AND REMOVAL CALCIUM AND MAGNESIUM DEPOSITS DISINFECTANT FROM DIALYSIS SOLUTION PASSAGE OF ARTIFICIAL KIDNEY DIALYZER.,DISINFECTANT/CLEANING AGENT(HEMOCLEAN RP)-DIALYZER REPROCESSING CONCENTRATE USED FOR THE CLEANING AND DISINFECTING OF THE DIALYZER.,DISINFECTANT/CLEANING AGENT(HEMOCLEAN)-IT IS USED AS CLEANER, DISINFECTANT AND STERILANT FOR THE HAEMODIALYSIS UNIT.
1724	IMP/MD/2019/000287	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AXIOM REG/PX(AXIOM ABUTMENT COCR)-THE CAST COCR MULTI- UNIT COPINGS ARE INTENDED FOR IMPLANT- SUPPORTED PROSTHETIC RESTORATION ON ANTHOGYR MULTI-UNIT (Ø4.0 AND Ø4.8) ABUTMENTS IN ORDER TO ENSURE SUPPORT FOR PERMANENT PROSTHETIC RECONSTRUCTIONS USING THE CASTING TECHNIQUE. THEY ARE USED AND PREPARED IN A DENTAL LABORATORY.
1725	IMP/MD/2019/000288	1.License Holder Name: M/S COOK INDIA MEDICAL DEVICES PVT. LTD. , PLOT NO 22(SP), THIRD AND FOURTH FLOOR, KOCHAR JADE, THIRU VI KA INDUSTRIAL ESTATE, GUINDY TALUK ,CHENNAI TAMIL NADU , 600032 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GASTROSTOMY BALLOON RETENTION FEEDING TUBE(ENTUIT® GASTROSTOMY BR BALLOON RETENTION FEEDING TUBE)-THE ENTUIT® GASTROSTOMY TUBE FAMILY (INCLUDING WITH ENFIT® CONNECTION) ARE INTENDED TO PROVIDE GASTRIC ACCESS FOR ENTERAL FEEDING, MEDICATION ADMINISTRATION AND DECOMPRESSION THROUGH AN ESTABLISHED GASTROINTESTINAL STOMA TRACT.,GASTROSTOMY BALLOON RETENTION FEEDING TUBE(ENTUIT® GASTROSTOMY BR BALLOON RETENTION FEEDING TUBE WITH ENFIT® CONNECTION)-THE ENTUIT® GASTROSTOMY TUBE FAMILY (INCLUDING WITH ENFIT® CONNECTION) ARE INTENDED TO PROVIDE GASTRIC ACCESS FOR ENTERAL FEEDING, MEDICATION ADMINISTRATION AND DECOMPRESSION THROUGH AN ESTABLISHED GASTROINTESTINAL STOMA TRACT.

1726	IMP/MD/2019/000289	1.License Holder Name: M/S. INNOVATIVE THERAPEUTICS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABLATION DEVICE (ENDOSCOPIC ELECTRO SURGICAL ELECTRODE)(ELRA ELECTRODE (ENDOLUMINAL RADIO FREQUENCY ABLATION ELECTRODE), EUSURA RF ELECTRODE [ENDOSCOPIC ULTRA SOUND GUIDED RADIOFREQUENCY ABLATION ELECTRODE))-STERILE SINGLE USE RF COAGULATION ELECTRODE IS INTENDED FOR COAGULATION OF TISSUE DURING ENDOSCOPIC, PERCUTANEOUS, LAPAROSCOPIC, AND INTRAOPERATIVE SURGICAL PROCEDURES.,ABLATION DEVICE [RADIO FREQUENCY (RF) COAGULATION ELECTRODE](STAR RF ELECTRODE_FIXED, STAR RF ELECTRODE_UNI-FACED, STAR INJECTABLE RF ELECTRODE, VIVA RF ELECTRODE, OCTOPUS RF ELECTRODE)-STERILE SINGLE - USE RF COAGULATION ELECTRODE IS INTENDED FOR COAGULATION OF TISSUE DURING PERCUTANEOUS, LAPAROSCOPIC, AND INTRAOPERATIVE SURGICAL PROCEDURES.
1727	IMP/MD/2019/000290	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERICARDIAL PATCH(SJM PERICARDIAL PATCH WITH ENCAP TECHNOLOGY)-THE SJM PERICARDIAL PATCH IS WITH ENCAP TECHNOLOGY IS INDICATED FOR PERICARDIAL CLOSURE AND CARDIAC AND GREAT VESSEL RECONSTRUCTION AND REPAIR.

1728	IMP/MD/2019/000291	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RECON FEMORAL NAILING IMPLANTS(NA)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,TROCARS-TROCARS ARE INTENDED FOR PUNCTURING A BODILY POINT AND/OR FOR PARTITION OF SURROUNDING SOFT TISSUE. ,TROCAR(NA)-TROCARS ARE INTENDED FOR PUNCTURING A BODILY ENTRY POINT AND/OR FOR PARTITION OF SURROUNDING SOFT TISSUE.,EXTERNAL FIXATOR IMPLANTS - NAIL-EXTERNAL FIXATOR DEVICES ARE INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS., PROXIMAL FEMORAL NAILING IMPLANTS - ENDCAP (STERILE)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR FEMORAL SHAFT TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,PROXIMAL FEMORAL NAILING IMPLANTS - BLADE-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR FEMORAL SHAFT TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,CERVICAL CAGES - CAGE-CERVIOS IS DESIGNED FOR ANTERIOR CERVICAL INTERBODY FUSION (ACIF).,SCREW IMPLANTS FOR OR WITHOUT PLATES - WASHER (NON-STERILE)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,PROXIMAL FEMORAL NAILING IMPLANTS - ENDCAP (NON STERILE)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR FEMORAL SHAFT TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL

		ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,STERNAL ZIPFIX WITH NEEDLE-CLOSURE OF THE STERNUM FOLLOWING STERNOTOMY TO STABILIZE THE STERNUM AND PROMOTE FUSION.,SCREW IMPLANTS FOR OR WITHOUT PLATES - WASHER (10 YEARS)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,PROXIMAL FEMORAL NAILING IMPLANTS - NAIL-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR FEMORAL SHAFT TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).
1729	IMP/MD/2019/000292	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC SYRINGES(BD ULTRA-FINE II NEEDLE INSULIN SYRINGES, BD ULTRA-FINE NEEDLE INSULIN SYRINGES)-BD INSULIN SYRINGES ARE INTENDED FOR THE SUBCUTANEOUS INJECTION OF INSULINS IN TREATMENT OF DIABETES MELLITUS,ALCOHOL SWABS (BD ALCOHOL SWABS (ISOPROPYL ALCOHOL (70% V/V) USP))-IT IS INTENDED AS ANTISEPTIC FOR PREPARATION OF THE SKIN PRIOR TO INJECTION
1730	IMP/MD/2019/000293	1.License Holder Name: CARL ZEISS INDIA (BANGALORE) PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:POSTERIOR CHAMBER INTRAOCULAR LENS (PSEUDOPHAKIC)(CT SPHERIS 203 P, CT ASPHINA 603 P)-ZEISS HYDROPHILIC ACRYLIC 28% INTRAOCULAR LENSES ARE INTENDED FOR USE IN OPHTHALMIC SURGERY. THEY ARE INSERTED IN THE EYE AS AN ARTIFICIAL LENS IN PLACE OF THE NATURAL CRYSTALLINE LENS. ZEISS HYDROPHILIC ACRYLIC 28% IOLS ARE INTENDED TO BE PLACED INTO THE CAPSULAR BAG TO CORRECT THE SURGICALLY CREATED APHAKIA AFTER EXTRACTING THE NATURAL LENS.

1731	IMP/MD/2019/000294	1.License Holder Name: ALPS INTERNATIONAL PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEURO ZTI COCHLEAR IMPLANT WITH BTE SPEECH PROCESSOR(NEURO)-THE NEURO ZTI COCHLEAR IMPLANT OF OTICON MEDICAL IS DESIGNED FOR ADULTS AND CHILDREN OF ALL AGES WHO HAVE SEVERE TO PROFOUND UNILATERAL OR BILATERAL PERCEPTIVE HEARING LOSS, WITH A LIMITED BENEFIT FROM APPROPRIATELY FITTED HEARING AIDS. THIS COCHLEAR IMPLANT IS COME WITH EXTERNAL NEURO SPEECH PROCESSOR.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1732	IMP/MD/2019/000295	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINAL SYSTEM - SCREW (VIPER PRIME)-THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR, PSEUDARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A POSTERIOR PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION, THE VIPER SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR, PSEUDARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS.,SPINE SYSTEM - CONNECTOR(EXPEDIUM)-THE EXPEDIUM SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM SPINE SYSTEM ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SPINE SYSTEM METALLIC IMPLANTS ARE

	INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SPINE SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH., SPINAL SYSTEM - FENESTRATED SCREWS(VIPER PRIME)-THE VIPER PRIME FENESTRATED SCREWS ARE INTENDED FOR USE WITH CONFIDENCE HIGH VISCOSITY SPINAL CEMENT TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE IN PATIENTS WITH DIMINISHED BONE QUALITY (E.G., OSTEOPOROSIS, OSTEOPENIA, METASTATIC DISEASE). THE SCREWS ARE INTENDED TO PROVIDE TEMPORARY INTERNAL SUPPORT AND FIXATION WHILE THE FUSION MASS IS CONSOLIDATING OR FRACTURE IS HEALING, OR FOR PALLIATIVE RECONSTRUCTION IN TUMOR PATIENTS. THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR, PSEUDARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A POSTERIOR PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION, THE VIPER SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR, PSEUDARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS.,SPINE SYSTEM - WASHER(EXPEDIUM)-THE EXPEDIUM SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR

	DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM SPINE SYSTEM ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SPINE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SPINE SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH., SPINAL SYSTEM - ROD(EXPEDIUM)-THE EXPEDIUM SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION ANDSTABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THETREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE.THE EXPEDIUM SPINE SYSTEM ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATIONFOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGINWITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS;TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/ORLORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHENUSED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SPINESYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHICSCOLIOSIS. THE EXPEDIUM SPINE SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT.PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH,SPINE SYSTEM - ROD(VIPER2)-THE VIPER2 SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE VIPER2 SPINE SYSTEM ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING

	INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SPINE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SPINE SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH, SPINAL SYSTEM - CANNULA(VIPER)-VIPER FENESTRATED SCREW CANNULAS ARE INTENDED FOR USE WITH THE VIPER FENESTRATED SCREW SYSTEM TO FACILITATE DELIVERY OF CEMENT.,SPINE SYSTEM- SCREW(EXPEDIUM)-THE EXPEDIUM SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM SPINE SYSTEM ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SPINE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SPINE SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH.,SPINAL SYSTEM - WASHER(MOSS MIAMI)- THE MOSS MIAMI SPINE SYSTEMS ARE PEDICLE SCREW SYSTEMS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE: DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF

	NEUROLOGICAL IMPAIRMENT, FRACTURE, DISLOCATION, SCOLIOSIS, KYPHOSIS, SPINAL TUMOR, AND FAILED PREVIOUS FUSION (PSEUDARTHROSIS). THE MOSS MIAMI SPINE SYSTEMS ARE ALSO INDICATED FOR PEDICLE SCREW FIXATION FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADES 3 AND 4) OF THE L5–S1 VERTEBRA IN SKELETALLY MATURE PATIENTS RECEIVING FUSION BY AUTOGENOUS BONE GRAFT HAVING IMPLANTS ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 TO SACRUM) WITH REMOVAL OF THE IMPLANTS AFTER THE ATTAINMENT OF A SOLID FUSION. THE MOSS MIAMI SPINE SYSTEMS ARE ALSO A HOOK AND SACRAL/ILIAC SCREW FIXATION SYSTEM OF THE NONCERVICAL SPINE INDICATED FOR DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (FRACTURE AND/OR DISLOCATION), SPINAL STENOSIS, DEFORMITIES (SCOLIOSIS, LORDOSIS AND/OR KYPHOSIS), TUMOR, AND PREVIOUS FAILED FUSION (PSEUDARTHROSIS). THE MOSS MIAMI SPINE SYSTEMS WHEN USED AS ANTERIOR THORACIC/LUMBAR SCREW FIXATION SYSTEMS, ARE INDICATED FOR DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (FRACTURE AND/OR DISLOCATION), SPINAL STENOSIS, DEFORMITIES (SCOLIOSIS, LORDOSIS AND/OR KYPHOSIS), TUMOR, AND PREVIOUS FAILED FUSION (PSEUDARTHROSIS).,SPINE SYSTEM - ROD(EXPEDIUM)-THE EXPEDIUM SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM SPINE SYSTEM ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SPINE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SPINE SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC

	PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH., SPINAL SYSTEM - CANNULA(EXPEDIUM)-EXPEDIUM FENESTRATED SCREW CANNULAS ARE INTENDED FOR USE WITH THE EXPEDIUM FENESTRATED SCREW SYSTEM TO FACILITATE DELIVERY OF CEMENT.,SPINE SYSTEM - HOOK(EXPEDIUM)-– THE EXPEDIUM SPINE SYSTEM ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM SPINE SYSTEM ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM SPINE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLESCENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM SPINE SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH.,SPINAL SYSTEM - CONNECTOR(MOSS MIAMI)-THE MOSS MIAMI SPINE SYSTEMS ARE PEDICLE SCREW SYSTEMS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR, AND SACRAL SPINE: DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, FRACTURE, DISLOCATION, SCOLIOSIS, KYPHOSIS, SPINAL TUMOR, AND FAILED PREVIOUS FUSION (PSEUDARTHROSIS). THE MOSS MIAMI SPINE SYSTEMS ARE ALSO INDICATED FOR PEDICLE SCREW FIXATION FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADES 3 AND 4) OF THE L5–S1 VERTEBRA IN SKELETALLY MATURE PATIENTS RECEIVING FUSION BY AUTOGENOUS BONE GRAFT HAVING IMPLANTS ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 TO SACRUM) WITH REMOVAL OF THE IMPLANTS AFTER THE ATTAINMENT OF A SOLID FUSION. THE MOSS MIAMI SPINE SYSTEMS ARE ALSO A HOOK AND SACRAL/ILIAC SCREW FIXATION SYSTEM OF THE NONCERVICAL SPINE INDICATED FOR DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK

	PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (FRACTURE AND/OR DISLOCATION), SPINAL STENOSIS, DEFORMITIES (SCOLIOSIS, LORDOSIS AND/OR KYPHOSIS), TUMOR, AND PREVIOUS FAILED FUSION (PSEUDARTHROSIS). THE MOSS MIAMI SPINE SYSTEMS WHEN USED AS ANTERIOR THORACIC/LUMBAR SCREW FIXATION SYSTEMS, ARE INDICATED FOR DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (FRACTURE AND/OR DISLOCATION), SPINAL STENOSIS, DEFORMITIES (SCOLIOSIS, LORDOSIS AND/OR KYPHOSIS), TUMOR, AND PREVIOUS FAILED FUSION (PSEUDARTHROSIS).,SPINAL SYSTEM (COCRMO ALLOY ROD) (MOUNTAINEER OCT)-THE SUMMIT SI OCT SPINAL SYSTEM AND MOUNTAINEER OCT SPINAL SYSTEM ARE INTENDED TO PROMOTE FUSION OF THE CERVICAL SPINE AND OCCIPITO-CERVICO-THORACIC JUNCTION (OCCIPUT-T3), AND ARE INDICATED FOR THE FOLLOWING: • DDD (NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC AS CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES) • SPONDYLOLISTHESIS • SPINAL STENOSIS • FRACTURE/DISLOCATION • ATLANTO/AXIAL FRACTURE WITH INSTABILITY • OCCIPITOCERVICAL DISLOCATION • REVISION OF PREVIOUS CERVICAL SPINE SURGERY • TUMORS THE OCCIPITAL BONE SCREWS ARE LIMITED TO OCCIPITAL FIXATION ONLY.THE USE OF THE MONOAXIAL AND POLYAXIAL SCREWS IS LIMITED TO PLACEMENT IN THE UPPER THORACIC SPINE (T1-T3) IN TREATING THORACIC CONDITIONS ONLY. THEY ARE NOT INTENDED TO BE PLACED IN THE CERVICAL SPINE.THE SONGER WIRE/CABLE SYSTEM TO BE USED WITH THE SUMMIT SI OCT SPINAL SYSTEM AND MOUNTAINEER OCT SPINAL SYSTEM ALLOWS FOR WIRE/CABLE ATTACHMENT TO THE POSTERIOR CERVICAL SPINE.THE SUMMIT SI OCT SYSTEM AND MOUNTAINEER OCT SPINAL SYSTEM CAN ALSO BE LINKED TO THE ISOLA, MONARCH, MOSS MIAMI, VIPER AND EXPEDIUM SYSTEMS USING THE DUAL WEDDING BAND AND AXIAL CONNECTORS, AND VIA DUAL DIAMETER RODS.,SPINAL SYSTEM (TITANIUM ALLOY CONNECTOR)(MOUNTAINEER OCT)-THE SUMMIT SI OCT SPINAL SYSTEM AND MOUNTAINEER OCT SPINAL SYSTEM ARE INTENDED TO PROMOTE FUSION OF THE CERVICAL SPINE AND OCCIPITO-CERVICO-THORACIC JUNCTION (OCCIPUT-T3), AND ARE INDICATED FOR THE FOLLOWING: • DDD (NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC AS CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES) • SPONDYLOLISTHESIS • SPINAL STENOSIS • FRACTURE/DISLOCATION • ATLANTO/AXIAL FRACTURE WITH INSTABILITY •

	OCCIPITOCERVICAL DISLOCATION • REVISION OF PREVIOUS CERVICAL SPINE SURGERY • TUMORS THE OCCIPITAL BONE SCREWS ARE LIMITED TO OCCIPITAL FIXATION ONLY.THE USE OF THE MONOAXIAL AND POLYAXIAL SCREWS IS LIMITED TO PLACEMENT IN THE UPPER THORACIC SPINE (T1-T3) IN TREATING THORACIC CONDITIONS ONLY. THEY ARE NOT INTENDED TO BE PLACED IN THE CERVICAL SPINE.THE SONGER WIRE/CABLE SYSTEM TO BE USED WITH THE SUMMIT SI OCT SPINAL SYSTEM AND MOUNTAINEER OCT SPINAL SYSTEM ALLOWS FOR WIRE/CABLE ATTACHMENT TO THE POSTERIOR CERVICAL SPINE.THE SUMMIT SI OCT SYSTEM AND MOUNTAINEER OCT SPINAL SYSTEM CAN ALSO BE LINKED TO THE ISOLA, MONARCH, MOSS MIAMI, VIPER AND EXPEDIUM SYSTEMS USING THE DUAL WEDDING BAND AND AXIAL CONNECTORS, AND VIA DUAL DIAMETER RODS.,SPINAL SYSTEM (TITANIUM ALLOY ROD) (MOUNTAINEER OCT)-THE SUMMIT SI OCT SPINAL SYSTEM AND MOUNTAINEER OCT SPINAL SYSTEM ARE INTENDED TO PROMOTE FUSION OF THE CERVICAL SPINE AND OCCIPITO-CERVICO-THORACIC JUNCTION (OCCIPUT-T3), AND ARE INDICATED FOR THE FOLLOWING: • DDD (NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC AS CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES) • SPONDYLOLISTHESIS • SPINAL STENOSIS • FRACTURE/DISLOCATION • ATLANTO/AXIAL FRACTURE WITH INSTABILITY • OCCIPITOCERVICAL DISLOCATION • REVISION OF PREVIOUS CERVICAL SPINE SURGERY • TUMORS THE OCCIPITAL BONE SCREWS ARE LIMITED TO OCCIPITAL FIXATION ONLY.THE USE OF THE MONOAXIAL AND POLYAXIAL SCREWS IS LIMITED TO PLACEMENT IN THE UPPER THORACIC SPINE (T1-T3) IN TREATING THORACIC CONDITIONS ONLY. THEY ARE NOT INTENDED TO BE PLACED IN THE CERVICAL SPINE.THE SONGER WIRE/CABLE SYSTEM TO BE USED WITH THE SUMMIT SI OCT SPINAL SYSTEM AND MOUNTAINEER OCT SPINAL SYSTEM ALLOWS FOR WIRE/CABLE ATTACHMENT TO THE POSTERIOR CERVICAL SPINE.THE SUMMIT SI OCT SYSTEM AND MOUNTAINEER OCT SPINAL SYSTEM CAN ALSO BE LINKED TO THE ISOLA, MONARCH, MOSS MIAMI, VIPER AND EXPEDIUM SYSTEMS USING THE DUAL WEDDING BAND AND AXIAL CONNECTORS, AND VIA DUAL DIAMETER RODS.,SPINAL SYSTEM - CONNECTOR(EXPEDIUM)-THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC

	DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS] FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A POSTERIOR PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION, THE VIPER SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR HE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E.,SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS;AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS,SPINAL SYSTEM- HOOK(EXPEDIUM) -THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS] FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A POSTERIOR PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION, THE VIPER SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR HE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E.,SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS;AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS,SPINAL SYSTEM- ROD(VIPER)-THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN

	SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS] FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A POSTERIOR PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION, THE VIPER SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR HE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E.,SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS;AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS,SPINAL SYSTEM - ROD(EXPEDIUM)- THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS] FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A POSTERIOR PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION, THE VIPER SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR HE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS;

		TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E.,SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS;AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS,SPINAL SYSTEM - SCREW(VIPER)-THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS] FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A POSTERIOR PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION, THE VIPER SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR HE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E.,SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS;AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS
1733	IMP/MD/2019/000296	1.License Holder Name: PHILIPS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER(STELLAREX 0.035” OTW DRUG-COATED ANGIOPLASTY BALLOON)-THE STELLAREX 0.035” OTW DRUG-COATED ANGIOPLASTY BALLOON IS INDICATED FOR THE TREATMENT OF DE-NOVO OR RESTENOTIC LESIONS IN THE LOWER EXTREMITIES TO ESTABLISH BLOOD FLOW AND TO MAINTAIN VESSEL PATENCY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1734	IMP/MD/2019/000297	1.License Holder Name: M/S COOK INDIA MEDICAL DEVICES PVT. LTD. , PLOT NO 22(SP), THIRD AND FOURTH FLOOR, KOCHAR JADE, THIRU VI KA INDUSTRIAL ESTATE, GUINDY TALUK ,CHENNAI TAMIL NADU , 600032 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAPLE LINE REINFORCEMENT(BIODESIGN® STAPLE LINE REINFORCEMENT)-IT IS INTENDED FOR USE AS PROSTHESIS FOR THE SURGICAL REPAIR OF SOFT TISSUE DEFICIENCIES USING SURGICAL STAPLERS.,SOFT TISSUE REPAIR GRAFTS(BIODESIGN® 4-LAYER TISSUE GRAFT, BIODESIGN® HIATAL HERNIA GRAFT, BIODESIGN® HERNIA GRAFT)-BIODESIGN® 4-LAYER TISSUE GRAFT- IT IS INTENDED FOR IMPLANTATION TO REINFORCE SOFT TISSUES BIODESIGN® HIATAL HERNIA GRAFT- IT IS USED FOR IMPLANTATION TO REINFORCE SOFT TISSUE WHERE WEAKNESS EXISTS, INCLUDING REPAIR OF HIATAL HERNIAS BIODESIGN® HERNIA GRAFT- IT IS INTENDED FOR IMPLANTATION TO REINFORCE SOFT TISSUES WHERE WEAKNESS EXISTS.,FISTULA PLUG(BIODESIGN® FISTULA PLUG WITH BRUSH)-IT IS FOR IMPLANTATION TO REINFORCE SOFT TISSUE FOR REPAIR OF RECTO-VAGINAL OR ANORECTAL FISTULAS. THE DEVICE IS SUPPLIED STERILE AND IS INTENDED FOR ONE TIME USE,FISTULA PLUG (BIODESIGN® ANAL FISTULA PLUG)- IT IS INTENDED FOR IMPLANTATION TO REINFORCE SOFT TISSUES WHERE A ROLLED CONFIGURATION IS REQUIRED, FOR REPAIR OF ANORECTAL FISTULAS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1735	IMP/MD/2019/000298	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VASCULAR CLOSURE DEVICE(ANGIO-SEAL VIP)-THE ANGIO-SEAL DEVICE IS INDICATED FOR USE IN CLOSING FEMORAL ARTERY PUNCTURES RESULTING FROM ARTERIAL ACCESS PROCEDURES. THE ANGIO-SEAL DEVICE IS ALSO INDICATED FOR EARLY AMBULATION OF PATIENTS AFTER SHEATH REMOVAL AND DEVICE PLACEMENT. ,VASCULAR CLOSURE DEVICE(ANGIO SEAL EVOLUTION)-THE ANGIO-SEAL DEVICE IS INDICATED FOR USE IN CLOSING FEMORAL ARTERY PUNCTURES RESULTING FROM ARTERIAL ACCESS PROCEDURES. THE ANGIO-SEAL DEVICE IS ALSO INDICATED FOR EARLY AMBULATION OF PATIENTS AFTER SHEATH REMOVAL AND DEVICE PLACEMENT. , VASCULAR CLOSURE DEVICE(ANGIOSEAL STS PLUS)-THE ANGIO-SEAL DEVICE IS INDICATED FOR USE IN CLOSING FEMORAL ARTERY PUNCTURES RESULTING FROM ARTERIAL ACCESS PROCEDURES. THE ANGIO-SEAL DEVICE IS ALSO INDICATED FOR EARLY AMBULATION OF PATIENTS AFTER SHEATH REMOVAL AND DEVICE PLACEMENT.
1736	IMP/MD/2019/000299	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCESS PORTS(CELSITE)-• CELSITE VENOUS ACCESS PORTS ARE INDICATED FOR REPEATED INTRA VENOUS ADMINISTRATION FOR EG. CHEMOTHERAPY, ANTIBIOTIC, ANTIVIRAL DRUGS, PARENTERAL, NUTRITION , BLOOD SAMPLING OR TRANSFUSION • CERTAIN CELSITE ACCESS PORTS MAY ALSO BE USED FOR CONTRAST ENHANCED COMPUTERIZED TOMOGRAPHY (CECT) USING HIGH PRESSURE INJECTION • ARETERIA ACCESS PORT ARE USED FOR INTRA-ARTERIAL ADMINISTRATION OF CHEMOTHERAPY • EPIDURAL OR INTRA-THECAL PORTS ARE USED FOR SPINAL ADMINISTRATION OF PAIN RELIVING DRUGS • PERITONEAL/ PLEURAL PORT ARE USED FOR INTRA-PERITONEAL ADMINISTRATION OF CHEMOTHERAPY , HYDRATION DRAINAGE OF MALIGNANT ASCITES OR DRAINAGE OF MALIGNANT PLEURAL EFFUSION

1737	IMP/MD/2019/000300	1.License Holder Name: FAITH BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOSTATIC AGENT (TRAUMASTEM FAM OCW, TRAUMASTEM FAM STRATA, TRAUMASTEM FAM TRIUM)-TRAUMASTEM FAM IS USED AS AN ADJUNCT TO STOP CAPILLARY, VENOUS, SMALL ARTERIAL BLEEDING, AND ALSO TO PREVENT EARLY POSTOPERATIVE BLEEDING. IT CAN BE USED IN ALL AREAS OF STOPPING DIFFUSE HAEMORRHAGE FROM RESECTION SURFACES SUCH AS PARENCHYMATOUS ORGANS, MUSCLESOR DEFI NED BODY CAVITIES, ON UNEVEN OR POORLY ACCESSIBLE SURFACE OF THE WOUND. IT CAN BE USED FOR A WIDE VARIETY OF ACTIONS – WRAPPING, LAYERING, COVERING OR FILLING CAVITIES. THE WIDE SCOPE OF APPLICATION ALLOWS THE USE FOR CLASSICAL, LAPAROSCOPIC, ROBOTIC SURGERY AND ENDOSCOPIC TREATMENTS.,HEMOSTATIC AGENT(TRAUMASTEM TAF, TRAUMASTEM TAF LIGHT)-TRAUMASTEM TAF IS USED TO STOP CAPILLARY, VENOUS, OR MINOR ARTERIAL BLEEDING, AND ALSO TO PREVENT EARLY POSTOPERATIVE BLEEDING. TRAUMASTEM TAF REPRESENTS A UNIQUE FORM OF USAGE IN ALL AREAS OF STOPPING THE DIFFUSE BLEEDING FROM RESECTION SURFACES SUCH AS PARENCHYMATOUS ORGANS, MUSCLES OR DEFINED BODY CAVITIES (E.G. THE SMALL PELVIS) WITHOUT CONTRAINDICATIONS. TRAUMASTEM TAF IS SUITABLE FOR USAGE IN GENERAL AND DIGESTIVE SURGERY, PLASTIC SURGERY, VASCULAR AND THORACIC SURGERY, NEUROSURGERY, ORTHOPAEDICS, GYNAECOLOGY, UROLOGY, DENTISTRY AND OTHER RELATED FIELDS. ITS LARGE SCOPE OF APPLICATION ALLOWS THE USE IN PROCEDURES PERFORMED TRADITIONALLY, BY LAPAROSCOPY, ROBOTIC SURGERY AND IN ENDOSCOPIC PROCEDURES.
1738	IMP/MD/2019/000301	1.License Holder Name: CURE SURGICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL SKIN CLOSURE DEVICE(ZIP)-THE ZIP SURGICAL SKIN CLOSURE DEVICE IS INDICATED FOR USE DURING AND AFTER SKIN INCISION PROCEDURES TO APPROXIMATE SKIN AND HOLD TOGETHER THE SKIN EDGES UNTIL HEALING CAN TAKE PLACE

1739	IMP/MD/2019/000302	1.License Holder Name: M/S. ASAHI INTECC CO., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DOUBLE LUMEN CATHETER (RX/OTW)(ASAHI SASUKE)-THIS PRODUCT IS INTENDED TO BE USED IN CONJUNCTION WITH STEERABLE GUIDEWIRES IN ORDER TO ACCESS DISCRETE REGIONS OF THE CORONARY ARTERIAL VASCULATURE, TO FACILITATE PLACEMENT OF GUIDEWIRES, FOR USE DURING TWO GUIDEWIRE PROCEDURES, AND TO INJECT THE CONTRAST MEDIA INTO THE BLOOD VESSELS. NOT FOR USE IN THE NEUROVASCULATURE OR PERIPHERAL VESSELS.. SUPPORT CATHETER(ASAHI TORNUS)-THIS CATHETER IS INTENDED TO BE USED IN CONJUNCTION WITH A STEERABLE GUIDE WIRE TO ACCESS DISCRETE REGIONS OF THE VASCULATURE FOR GUIDING AND SUPPORTING A STEERABLE GUIDE WIRE AND INTENDED TO BE USED FOR GUIDE WIRE EXCHANGE..,PTCA GUIDING CATHETER (SHEATHLESS EAUCATH)-THIS PRODUCT IS DESIGNED TO LEAD A PTCA BALLOON DILATATION CATHETER OR A PTCA GUIDE WIRE TO A TARGET SITE IN A BLOOD VESSEL IN PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY FOR TREATMENT OF CORONARY STENOSIS OR OCCLUSION CAUSED BY ISCHEMIC HEART DISEASES (ANGINA OR MYOCARDIAL INFARCTION). DO NOT USE THIS PRODUCT FOR CEREBRAL BLOOD VASCULATURE.,PERI-VASCULAR GUIDING SYSTEM(SHEATHLESS PV)-THIS PRODUCT IS INTENDED FOR USE IN PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OR THROMBUS ASPIRATION IN THE LIMBS, FOR THE PURPOSE OF DELIVERING TREATMENT CATHETERS TO PERIPHERAL BLOOD VESSELS. DO NOT USE THIS PRODUCT FOR CEREBRAL BLOOD VASCULATURE.,GUIDE WIRE PRE-LOADED MICROCATHETER(ASAHI MASTERS PARKWAY HF KIT)-THIS PRODUCT IS MEDICAL DEVICE INTENDED FOR SUPERSELECTIVE ANGIOGRAPHY AND/OR INFUSION OF VARIOUS SUBSTANCES INCLUDING DIAGNOSIS, EMBOLIZATION AND TREATMENT IN PERIPHERAL VESSELS USING AN APPROPRIATE GUIDE CATHETER. THIS PRODUCT IS NOT INTENDED FOR USE IN THE NEURO AND/OR CORONARY VASCULATURE..

1740	IMP/MD/2019/000303	1.License Holder Name: STRAUMANN DENTAL INDIA LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANTS (NEODENT)-THE NEODENT IMPLANTS ARE RECOMMENDED FOR SURGICAL INTRAORAL INSTALLATION IN BONE IN MAXILLA OR MANDIBLE. IT CAN BE USED AS SUPPORT FOR SINGLE OR MULTIPLE PROSTHESES IN IMMEDIATE OR CONVENTIONAL LOADING PROTOCOL. NOTE: FOR THE PURPOSES OF IMMEDIATE LOADING THE PRIMARY STABILITY SHOULD REACH AT LEAST 32 N.CM AND THE PATIENT MUST PRESENT PHYSIOLOGICAL OCCLUSION. THE GM IMPLANTS ARE COMPATIBLE WITH EVERY LINE OF PROSTHETIC COMPONENTS WHICH HAVE A GRAND MORSE PROSTHETIC INTERFACE,DENTAL IMPLANT SYSTEM(GM ZYGOMATIC IMPLANT SYSTEM)-GM ZYGOMATIC IMPLANT SYSTEM IS INDICATED FOR SURGICAL PROCEDURES IN THE ZYGOMA REGION, IN CASES OF SEVERE MAXILLA RESORPTION, RESTORING THE PATIENT'S ESTHETICS AND CHEWING FUNCTION. ZYGOMATIC IMPLANTS MAY BE USED IN IMMEDIATE LOADING PROCEDURES WHEN THERE IS GOOD PRIMARY STABILITY AND APPROPRIATE OCCLUSAL LOADING.,DENTAL IMPLANTS(NEODENT)-THE NEODENT IMPLANTS ARE RECOMMENDED FOR SURGICAL INTRAORAL INSTALLATION IN BONE IN MAXILLA OR MANDIBLE. IT CAN BE USED AS SUPPORT FOR SINGLE OR MULTIPLE PROSTHESES IN IMMEDIATE OR CONVENTIONAL LOADING PROTOCOL. NOTE: FOR THE PURPOSES OF IMMEDIATE LOADING THE PRIMARY STABILITY SHOULD REACH AT LEAST 32 N. CM AND THE PATIENT MUST PRESENT PHYSIOLOGICAL OCCLUSION. THE GM IMPLANTS ARE COMPATIBLE WITH EVERY LINE OF PROSTHETIC COMPONENTS WHICH HAVE A GRAND MORSE PROSTHETIC INTERFACE,ABUTMENT(NEODENT)-THE TITANIUM BASE ABUTMENT IS A COMPONENT THAT IS PLACED ONTO NEODENT DENTAL IMPLANTS TO PROVIDE SUPPORT FOR CUSTOMIZED PROSTHETIC RESTORATIONS, SUCH AS COPINGS OR CROWNS OR BRIDGES. IT IS INDICATED FOR CEMENTED OR SCREW-RETAINED RESTORATIONS OVER DENTAL IMPLANTS INSTALLED ON THE MAXILLA OR MANDIBLE.,DENTAL IMPLANTS(NEODENT)-THE NEODENT IMPLANTS ARE RECOMMENDED FOR SURGICAL INTRAORAL INSTALLATION IN BONE IN MAXILLA OR MANDIBLE. IT CAN BE USED AS SUPPORT FOR SINGLE OR MULTIPLE PROSTHESES IN IMMEDIATE OR CONVENTIONAL LOADING PROTOCOL. NOTE: FOR THE PURPOSES OF IMMEDIATE LOADING THE PRIMARY STABILITY SHOULD REACH AT LEAST 32 N.CM AND THE PATIENT MUST PRESENT PHYSIOLOGICAL OCCLUSION. THE GM IMPLANTS ARE COMPATIBLE WITH EVERY LINE OF PROSTHETIC COMPONENTS WHICH HAVE A GRAND MORSE PROSTHETIC INTERFACE,DENTAL IMPLANTS

	(NEODENT)-THE NEODENT IMPLANTS ARE RECOMMENDED FOR SURGICAL INTRAORAL INSTALLATION IN BONE IN MAXILLA OR MANDIBLE. IT CAN BE USED AS SUPPORT FOR SINGLE OR MULPLE PROSTHESES IN IMMEDIATE OR CONVETIONAL LOADING PROTOCOL. NOTE: FOR THE PURPOSES OF IMMEDIATE LOADING THE PRIMARY STABILITY SHOULD REACH AT LEAST 32 N.CM AND THE PATIENT MUST PRESENT PHYSIOLOGICAL OCCLUSION. THE GM IMPLANTS ARE COMPATIBLE WITH EVERY LINE OF PROSTHETIC COMPONENTS WHICH HAVE A GRAND MORSE PROSTHETIC INTERFACE

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1741	IMP/MD/2019/000304	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINAL SYSTEM(SYNFIX EVOLUTION)-SYNFIX EVOLUTION SECURED SPACER SYSTEM IS AN IMPLANT AND INSTRUMENT SYSTEM FOR STAND-ALONE ANTERIOR LUMBAR INTERBODY FUSION (ALIF) FOR SKELETALLY MATURE PATIENTS. IT IS INTENDED TO REPLACE LUMBAR INTERBODY DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES AT VERTEBRAL LEVEL L1-S1 FOLLOWING ANTERIOR LUMBAR DISCECTOMY FOR STABILIZATION OF THE LUMBAR SPINE.,RADIUS PLATES - PLATE(NA) -PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,INTERSPINOUS IMPLANT(STENOFIX)-STENOFIX IS INTENDED FOR USE AS A SPACE HOLDER BETWEEN THE SPINOUS PROCESSES FOR ONE OR TWO LUMBAR MOTION SEGMENTS. IT CONTROLS THE SEGMENTAL EXTENSION AND DISTRACTS THE INTERSPINOUS SPACE. THE INTENDED EFFECTS ON THE POSTERIOR ELEMENTS ARE: 1. PRESERVATION OF THE FORAMINAL HEIGHT 2. REDUCTION OF STRESS ON THE FACET JOINTS 3. REDUCTION OF PRESSURE ON THE POSTERIOR ANNULUS. IT CAN BE IMPLANTED AT ONE OR TWO LUMBAR LEVELS FROM L 1 TO SL. FOR IMPLANTATION AT L5/S1, THE PRESENCE OF AN S1-SPINOUS PROCESS OF ADEQUATE SIZE IS A PREREQUISITE TO FULLY SUPPORT THE IMPLANT.,SCREW IMPLANTS FOR PLATES-SCREW (STAINLESS STEEL)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., SCREW IMPLANTS FOR PLATES (TITANIUM ALLOY)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,POSTERIOR ROD- ROD (TICP)(NA)-"OCCIPITO-CERVICAL FUSION SYSTEM THE SYNTHES OCCIPITO-CERVICAL FUSION SYSTEM IN COMBINATION WITH A SYNTHES POSTERIOR SCREW-ROD SYSTEM (E.G. SYNAPSE AND AXON) IS INTENDED TO PROVIDE STABILIZATION TO PROMOTE FUSION OF THE CERVICAL SPINE AND OCCIPITO-CERVICAL JUNCTION (OCCIPUT-TH3) FOR THE FOLLOWING INDICATIONS: OCCIPITO-CERVICAL AND UPPER CERVICAL SPINE INSTABILITIES: - RHEUMATOID ARTHRITIS - CONGENITAL ANOMALIES - POSTTRAUMATIC CONDITIONS - TUMORS - INFECTIONS INSTABILITIES IN THE LOWER CERVICAL AND UPPER THORACIC SPINE: - POSTTRAUMATIC CONDITIONS -TUMORS - IATROGENIC INSTABILITIES FOLLOWING LAMINECTOMY ETC. DEGENERATIVE AND PAINFUL POSTTRAUMATIC CONDITIONS IN THE LOWER CERVICAL AND UPPER THORACIC SPINE. ANTERIOR

	CERVICAL FUSIONS REQUIRING ADDITIONAL POSTERIOR STABILIZATION THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: - TOP-LOADING VARIABLE AXIS SCREWS - HOOKS - TRANSVERSE BARS - RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY." ,SCREW IMPLANTS FOR PLATES (SST)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,LNTERMAXILLARY FIXATION (IMF) SCREWS-SCREW (STAINLESS STEEL)(NA)-TEMPORARY, PERIOPERATIVE STABILISATION OF THE OCCLUSION IN ADULTS. ,SCREWS FOR LNTRAMEDULLARY NAIL- SCREW (TAN)(NA)-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN)." ,UNIVERSAL SPINE SYSTEM (USS) - 3D HEAD (TAN)(NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION." ,DISTAL FEMUR PLATES- PLATE (STAINLESS STEEL) (NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY

	FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,EXPANDABLE CORPECTOMY DEVICE (ECD) (NA)-ECD IS A VERTEBRAL BODY REPLACEMENT FOR THE STABILIZATION OF THE CERVICAL (C3 TO C7) AND UPPER THORACIC (T1 TO T2) SPINE. DEPENDING ON ANATOMICAL AND PATHOLOGICAL REQUIREMENTS, ECD CAN BE USED IN THE REPLACEMENT OF ONE, TWO OR THREE ADJACENT VERTEBRAL BODIES.,CALCANEAL PLATES- PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., MATRIXRIB- SPLINT (TAN)(NA)-"THE SYNTHES MATRIXRIB FIXATION SYSTEM IS INTENDED FOR THE FIXATION AND STABILIZATION OF RIB AND STERNUM FRACTURES, FUSIONS, AND OSTEOTOMIES OF NORMAL AND OSTEOPOROTIC BONE AND RECONSTRUCTIONS OF THE CHEST WALL. ,EXTERNAL FIXATOR IMPLANTS- STEINMANN PIN_ STERILE(NA)-EXTERNAL FIXATOR DEVICES ARE INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS. ,SCREW IMPLANTS FOR PLATES- SCREW HOLE INSERT (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., MATRIXORTHOGNATHIC- PLATE (TICP)(NA)-THE MATRIXORTHOGNATHIC SYSTEM IS INTENDED FOR USE AS A STABLE INTERNAL BONE FIXATION SYSTEM IN ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES). ,SCREW IMPLANTS FOR PLATES-PIN (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., RADIUS PLATES- PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., HUMERAL NAILING IMPLANTS- NAIL(NA)-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",UNIVERSAL SPINE SYSTEM (USS) FRACTURE- SCREW (TAN)(NA)-THE USS FRACTURE SYSTEM IS A POSTERIOR THORACOLUMBAR PEDICLE SCREW FIXATION SYSTEM INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE APPLICATION

	AREA IN PATIENTS SUFFERING FROM TRAUMA OR TUMOR DISEASE IS USUALLY AT THE THORACAL-LUMBAR JUNCTION (T12 /L1), BUT CAN BE EXTENDED FROM T6 DOWN TO THE SACRUM (S1). ,UNIVERSAL SPINE SYSTEM (USS) FRACTURE- CLAMP (TAN)(NA)-THE USS FRACTURE SYSTEM IS A POSTERIOR THORACOLUMBAR PEDICLE SCREW FIXATION SYSTEM INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE APPLICATION AREA IN PATIENTS SUFFERING FROM TRAUMA OR TUMOR DISEASE IS USUALLY AT THE THORACAL-LUMBAR JUNCTION (T12 /L1), BUT CAN BE EXTENDED FROM T6 DOWN TO THE SACRUM (S1). ,PROXIMAL TIBIAL PLATES- PLATE (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR PLATES- SCREW (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREWS FOR LNTRAMEDULLARY NAIL- SCREW- 10 YEARS (TAN)(NA)-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",HUMERAL NAILING IMPLANTS- ENDCAP(NA)-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN)." ,FLAP FIX- CRANIAL CLAMP - 10 YEARS (TICP)(NA)-CLOSURE OF CRANIOTOMIES DUE TO FIXATION OF THE BONE FLAP. , MATRIXORTHOGNATHIC- SLIDER (TICP)(NA)-THE MATRIXORTHOGNATHIC SYSTEM IS INTENDED FOR USE AS A STABLE INTERNAL BONE FIXATION SYSTEM IN ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES). , OLECRANON PLATE- PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS. , LOCKING COMPRESSION PLATES- SPACER (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS

	ANATOMICAL REGIONS.,AXON AND OC FUSION- CLAMP (NA)-"THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: -TOP-LOADING VARIABLE AXIS SCREWS -HOOKS -TRANSVERSE BARS -RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY." ,UNIVERSAL SPINE SYSTEM (USS)- CONNECTOR (TAN)(NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION." ,UNIVERSAL SPINE SYSTEM (USS)- RING (TAN)(NA)-"THE PANGEA SPINE SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE PANGEA PERFORATED SCREWS ARE AN ADDITION TO THE PANGEA SPINE SYSTEM, A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1-S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. PANGEA PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID PANGEA SCREWS AND WITH K-WIRE GUIDANCE AS PANGEA CANNULATED SCREWS INCLUDING A MINIMALLY INVASIVE APPROACH WITH SPIRIT. PANGEA PERFORATED SCREWS DIRECT VERTECEM OR V+ THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL

	BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: - INCREASE THORACIC VOLUME - SCOLIOSIS CORRECTION - THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX - IMPROVE THORACIC FUNCTION - AVOIDING GROWTH INHIBITION PROCEDURES - MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD VEPTR IS BASED ON A THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). ADDITIONALLY VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. VEPTR IS DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). ONCE THE VEPTR DEVICE IS IN PLACE, ITS DESIGN ALLOWS EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS-INVASIVE SURGERY. ALL COMPONENTS OF THE VEPTR II SYSTEM ARE MANUFACTURED FROM A TITANIUM ALLOY (TI-6AL-7NB) WITH THE EXCEPTION OF THE ALA-HOOK AND S-ROD, WHICH ARE MANUFACTURED FROM COMMERCIALLY PURE TITANIUM. GOALS OF TREATMENT 1. INCREASE THORACIC VOLUME 2. SCOLIOSIS CORRECTION 3. IMPROVE THORACIC FUNCTION 4. ESTABLISH THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX 5. AVOID GROWTH-INHIBITING PROCEDURES 6. MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE PATIENT'S GROWTH THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND

	HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION." ,DENS ACCESS- SCREW (NA)-THE DENS ACCESS SYSTEM USES AN ANTERIOR LAG SCREW COMPRESSION TECHNIQUE FOR THE FIXATION OF DENS AND TRANSVERSE FRACTURES. ,CANNULATED SCREW IMPLANTS- SCREW (STAINLESS STEEL)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,FLAPFIX- CRANIAL CLAMP (TICP)(NA)-CLOSURE OF CRANIOTOMIES DUE TO FIXATION OF THE BONE FLAP. , SCREW IMPLANTS FOR OR WITHOUT PLATES- WASHER (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR OR WITHOUT PLATES-SCREW (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DISTAL HUMERUS PLATE- PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS. ,AXON AND OC FUSION- PLATE (NA)-"THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: -TOP-LOADING VARIABLE AXIS SCREWS -HOOKS -TRANSVERSE BARS -RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY. OCCIPITO-

	CERVICAL FUSION SYSTEM THE SYNTHES OCCIPITO-CERVICAL FUSION SYSTEM IN COMBINATION WITH A SYNTHES POSTERIOR SCREW-ROD SYSTEM (E.G. SYNAPSE AND AXON) IS INTENDED TO PROVIDE STABILIZATION TO PROMOTE FUSION OF THE CERVICAL SPINE AND OCCIPITO-CERVICAL JUNCTION (OCCIPUT-TH3) FOR THE FOLLOWING INDICATIONS: OCCIPITO-CERVICAL AND UPPER CERVICAL SPINE INSTABILITIES: – RHEUMATOID ARTHRITIS – CONGENITAL ANOMALIES – POSTTRAUMATIC CONDITIONS – TUMORS – INFECTIONS INSTABILITIES IN THE LOWER CERVICAL AND UPPER THORACIC SPINE: – POSTTRAUMATIC CONDITIONS – TUMORS – IATROGENIC INSTABILITIES FOLLOWING LAMINECTOMY ETC. DEGENERATIVE AND PAINFUL POSTTRAUMATIC CONDITIONS IN THE LOWER CERVICAL AND UPPER THORACIC SPINE. ANTERIOR CERVICAL FUSIONS REQUIRING ADDITIONAL POSTERIOR STABILIZATION.",UNIVERSAL SPINE SYSTEM (USS)- ROD (TAN)(NA)- "THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION." ,SCREW IMPLANTS FOR OR WITHOUT PLATES- NUT· (STAINLESS STEEL)(NA)- PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,CANNULATED SCREW IMPLANTS- SCREW (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,UNIVERSAL SPINE SYSTEM (USS) - SCREW (TAN)(NA)-"THE URS SYSTEM IS A POSTERIOR PEDICLE

	SCREW AND HOOK FIXATION SYSTEM (T1–S2) INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION. THE PANGEA SPINE SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE PANGEA PERFORATED SCREWS ARE AN ADDITION TO THE PANGEA SPINE SYSTEM, A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1-S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. PANGEA PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID PANGEA SCREWS AND WITH K-WIRE GUIDANCE AS PANGEA CANNULATED SCREWS INCLUDING A MINIMALLY INVASIVE APPROACH WITH SPIRIT. PANGEA PERFORATED SCREWS DIRECT VERTECEM OR V+ THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY.",DISTAL TIBIA PLATES- PLATE (STAINLESS STEEL)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS. , SCREW IMPLANTS FOR OR WITHOUT PLATES- WASHER (STAINLESS

	STEEL)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SYNEX- CORPECTOMY DEVICE (NA)-"SYNEX IS A VERTEBRAL BODY REPLACEMENT AND IS IMPLANTED USING AN ANTERIOR APPROACH IN THE THORACIC SPINE FROM T5 TO T12, AND IN THE LUMBAR SPINE FROM L1 TO L4. IT IS USED TO SUPPORT THE ANTERIOR COLUMN OF THE SPINE. DEPENDING ON ANATOMICAL AND PATHOLOGICAL REQUIREMENTS, SYNEX CAN BE USED FOR MONO-, BI- AND TRISEGMENTAL FUSIONS." ,UNIVERSAL SPINE SYSTEM (USS)- NUT (TAN)(NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.", MATRIXRIB- PLATE (TAN)(NA)-"THE SYNTHES MATRIXRIB FIXATION SYSTEM IS INTENDED FOR THE FIXATION AND STABILIZATION OF RIB AND STERNUM FRACTURES, FUSIONS, AND OSTEOTOMIES OF NORMAL AND OSTEOPOROTIC BONE AND RECONSTRUCTIONS OF THE CHEST WALL. ,UNIVERSAL SPINE SYSTEM (USS)- WASHER (TICP) (NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE

	DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION." , UNIVERSAL SPINE SYSTEM (USS)- SLEEVE (TAN)(NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION." ,TIBIAL NAILING IMPLANTS- ENDCAP (TAN)(NA)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,TIBIAL NAILING IMPLANTS- NAIL (TAN)(NA)- INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO

	BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,UNIVERSAL SPINE SYSTEM (USS)- HOOK (TAN)(NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION." ,MATRIXMANDIBLE & MATRIXMANDIBLE PREFORMED RECONSTRUCTION PLATES- PLATE (TICP)(NA)-THE DEPUY SYNTHES MATRIXMANDIBLE PREFORMED RECONSTRUCTION PLATES ARE SPECIFICALLY PREFORMED PLATES INTENDED FOR MANDIBULAR RECONSTRUCTION WITH BONE GRAFT (VASCULARIZED OR NOT), TEMPORARY BRIDGING UNTIL SECONDARY RECONSTRUCTION, THE TREATMENT OF THE COMMINUTED FRACTURES OF THE MANDIBLE AND THE TREATMENT OF FRACTURES IN EDENTULOUS AND ATROPHIC MANDIBLES, AND UNSTABLE AND/OR INFECTED MANDIBULAR FRACTURES. ,ALVEOLAR DISTRACTOR- DISTRACTOR (TAN)(NA)-THE ALVEOLAR DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. , UNIVERSAL SPINE SYSTEM (USS)- WASHER (TAN)(NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS.

	ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION." ,VECTRA T-PLATE(NA)-THE VECTRA SYSTEM IS INTENDED FOR ANTERIOR PLATE AND SCREW FIXATION OF SPECIFIED PART(S): THE CERVICAL SPINE (C2-C7) . ,SCREW IMPLANTS FOR OR WITHOUT PLATES- SCREW (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,POSTERIOR ROD- ROD (TAN)(NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM

	AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION." , MATRIXRIB- SCREW_STERILE (TAN)(NA)-THE SYNTHES MATRIXRIB FIXATION SYSTEM IS INTENDED FOR THE FIXATION AND STABILIZATION OF RIB AND STERNUM FRACTURES, FUSIONS, AND OSTEOTOMIES OF NORMAL AND OSTEOPOROTIC BONE AND RECONSTRUCTIONS OF THE CHEST WALL. ,TITANIUM STERNAL FIXATION SYSTEM- SCREW (TAN)(NA)-FIXATION OF STERNAL HALVES.,ZERO P- SCREW (NA)-THE ZERO-P SYSTEM IS INTENDED FOR USE FOLLOWING ANTERIOR CERVICAL DISCECTOMY FOR REDUCTION AND STABILIZATION OF THE CERVICAL SPINE (C2–C7). , POSTERIOR CONNECTORS- ROD (TICP)(NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION." ,AXON AND OC FUSION - SCREW (NA)-"THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: -TOP-LOADING VARIABLE AXIS SCREWS -HOOKS -TRANSVERSE BARS -RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY. OCCIPITO-CERVICAL FUSION SYSTEM THE SYNTHES OCCIPITO-CERVICAL FUSION SYSTEM IN COMBINATION WITH A SYNTHES POSTERIOR SCREW-ROD SYSTEM (E.G. SYNAPSE AND AXON) IS INTENDED TO PROVIDE STABILIZATION TO PROMOTE FUSION OF THE CERVICAL SPINE AND OCCIPITO-CERVICAL JUNCTION (OCCIPUT-TH3) FOR THE FOLLOWING INDICATIONS: OCCIPITO-CERVICAL AND UPPER

	CERVICAL SPINE INSTABILITIES: – RHEUMATOID ARTHRITIS – CONGENITAL ANOMALIES – POSTTRAUMATIC CONDITIONS – TUMORS – INFECTIONS INSTABILITIES IN THE LOWER CERVICAL AND UPPER THORACIC SPINE: – POSTTRAUMATIC CONDITIONS – TUMORS – IATROGENIC INSTABILITIES FOLLOWING LAMINECTOMY ETC. DEGENERATIVE AND PAINFUL POSTTRAUMATIC CONDITIONS IN THE LOWER CERVICAL AND UPPER THORACIC SPINE. ANTERIOR CERVICAL FUSIONS REQUIRING ADDITIONAL POSTERIOR STABILIZATION." ,ZERO P- CAGE(NA)-THE ZERO-P SYSTEM IS INTENDED FOR USE FOLLOWING ANTERIOR CERVICAL DISCECTOMY FOR REDUCTION AND STABILIZATION OF THE CERVICAL SPINE (C2–C7). ,PROXIMAL HUMERUS PLATE- PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS. ,RECON FEMORAL NAILING IMPLANTS- SCREW (TAN)(NA)-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN)." ,MATRIXRIB- SPLINT_ STERILE (TAN)(NA)-THE SYNTHES MATRIXRIB FIXATION SYSTEM IS INTENDED FOR THE FIXATION AND STABILIZATION OF RIB AND STERNUM FRACTURES, FUSIONS, AND OSTEOTOMIES OF NORMAL AND OSTEOPOROTIC BONE AND RECONSTRUCTIONS OF THE CHEST WALL. ,HAND PLATES- PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DISTAL ULNA PLATES- PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS. ,RECON FEMORAL NAILING IMPLANTS- NAIL- 10 YEARS (TAN)(NA)-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",POSTERIOR CONNECTORS- CLAMP (TAN)(NA)-"THE CLICK'X SYSTEM IS A POSTERIOR THORACOLUMBAR PEDICLE SCREW SYSTEM INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN

	SKELETALLY MATURE PATIENTS. THE PERFORATED CLICK'X SYSTEM IS A TRANSPEDICULAR SCREW/ROD SYSTEM INTENDED FOR THE POSTERIOR STABILIZATION OF THE THORACOLUMBAR AND LUMBAR SPINE. THE PERFORATED CLICK'X SCREWS ARE CANNULATED. HOWEVER, THEY MAY BE INSERTED LIKE STANDARD SOLID CLICK'X SCREWS OR LIKE CANNULATED CLICK'X SCREWS BY MEANS OF KIRSCHNER WIRE GUIDANCE. THE LATERAL PERFORATIONS ALLOW DIRECT CEMENT AUGMENTATION OF THE SCREW IN THE OSTEOPOROTIC BONE. THE PANGEA SPINE SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE PANGEA PERFORATED SCREWS ARE AN ADDITION TO THE PANGEA SPINE SYSTEM, A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1-S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. PANGEA PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID PANGEA SCREWS AND WITH K-WIRE GUIDANCE AS PANGEA CANNULATED SCREWS INCLUDING A MINIMALLY INVASIVE APPROACH WITH SPIRIT. PANGEA PERFORATED SCREWS DIRECT VERTECEM OR V+ THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. THE USS FRACTURE SYSTEM IS A POSTERIOR THORACOLUMBAR PEDICLE SCREW FIXATION SYSTEM INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE APPLICATION AREA IN PATIENTS SUFFERING FROM TRAUMA OR TUMOR DISEASE IS USUALLY AT THE THORACAL-LUMBAR JUNCTION (T12 /L1), BUT CAN BE EXTENDED FROM T6 DOWN TO THE SACRUM (S1). THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO

	AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION." , EXPANDABLE CORPECTOMY DEVICE (ECD)- LOCKING CLIP(NA)-ECD IS A VERTEBRAL BODY REPLACEMENT FOR THE STABILIZATION OF THE CERVICAL (C3 TO C7) AND UPPER THORACIC (T1 TO T2) SPINE. DEPENDING ON ANATOMICAL AND PATHOLOGICAL REQUIREMENTS, ECD CAN BE USED IN THE REPLACEMENT OF ONE, TWO OR THREE ADJACENT VERTEBRAL BODIES. ,VECTRA- SCREW (TAN)(NA)-THE VECTRA SYSTEM IS INTENDED FOR ANTERIOR PLATE AND SCREW FIXATION OF SPECIFIED PART(S): THE CERVICAL SPINE (C2-C7) ., RECON FEMORAL NAILING IMPLANTS- SCREW- 10 YEARS (TAN)(NA)-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN)." ,RECON FEMORAL NAILING IMPLANTS- ENDCAP- 10 YEARS (TAN)-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN)." ,EXTERNAL FIXATOR IMPLANTS- STEINMANN PIN (NA)- EXTERNAL FIXATOR DEVICES ARE INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS.,COMPACT MANDIBLE-PLATE (TICP)(NA)-THE SYNTHES PLATE AND SCREW SYSTEM COMPACT MANDIBLE IS INTENDED FOR ORAL, MAXILLOFACIAL SURGERY, TRAUMA, RECONSTRUCTIVE SURGERY, AND ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES). ,LOCKING COMPRESSION PLATES-SPACER (STAINLESS STEEL)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,

	TITANIUM STERNAL FIXATION SYSTEM- SCREW_ 10 YEARS (TAN)(NA)-FIXATION OF STERNAL HALVES.,TITANIUM STERNAL FIXATION SYSTEM- SCREW (TICP)(NA)-FIXATION OF STERNAL HALVES ,MINI FRAGMENT PLATES- PLATE (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS. , CONNECTING ROD- ROD (TAN)(NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION. CONNECTING RODS ARE INTENDED TO FACILITATE THE CONNECTION OF QUALIFIED POSTERIOR SPINAL STABILIZATION SYSTEMS TOGETHER. CERVIFIX IS A MODULAR TENSION BAND SYSTEM FOR POSTERIOR FIXATION OF THE OCCIPITOCERVICAL SPINE, UPPER AND LOWER CERVICAL SPINE, AND UPPER THORACIC SPINE (T2). A CHOICE OF CLAMPS ARE FIXED ON A ROD BY MEANS OF SET SCREWS. BONE SCREWS CAN BE OPTIMALLY POSITIONED THROUGH THE CLAMPS IN THE DESIRED DIRECTION AT EACH LEVEL. " ,SCREW IMPLANTS FOR PLATES- PIN (STAINLESS STEEL)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,MATRIXRIB- SCREW (TAN)(NA)-"THE SYNTHES MATRIXRIB FIXATION SYSTEM IS INTENDED FOR THE FIXATION AND STABILIZATION OF RIB AND STERNUM FRACTURES, FUSIONS, AND OSTEOTOMIES OF NORMAL AND OSTEOPOROTIC BONE AND RECONSTRUCTIONS OF THE CHEST WALL. ,MATRIXRIB-PLATE_ STERILE (TAN)(NA)-THE SYNTHES MATRIXRIB FIXATION

	SYSTEM IS INTENDED FOR THE FIXATION AND STABILIZATION OF RIB AND STERNUM FRACTURES, FUSIONS, AND OSTEOTOMIES OF NORMAL AND OSTEOPOROTIC BONE AND RECONSTRUCTIONS OF THE CHEST WALL.,SCREW IMPLANTS FOR OR WITHOUT PLATES-SCREW (STAINLESS STEEL)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., POSTERIOR CONNECTORS- ROD (TAN)(NA)-"THE PANGEA SPINE SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE PANGEA PERFORATED SCREWS ARE AN ADDITION TO THE PANGEA SPINE SYSTEM, A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1-S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. PANGEA PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID PANGEA SCREWS AND WITH K-WIRE GUIDANCE AS PANGEA CANNULATED SCREWS INCLUDING A MINIMALLY INVASIVE APPROACH WITH SPIRIT. PANGEA PERFORATED SCREWS DIRECT VERTECEM OR V+ THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM

		AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION." ,VECTRA-PLATE (NA)-THE VECTRA SYSTEM IS INTENDED FOR ANTERIOR PLATE AND SCREW FIXATION OF SPECIFIED PART(S): THE CERVICAL SPINE (C2-C7) . ,DISTAL HUMERUS PLATE- PLATE (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.
1742	IMP/MD/2019/000307	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BALLOON CATHETER (FORTREX 0.035" OTW PTA BALLOON CATHETER)-FORTREX™ 0.035" OTW PTA BALLOON CATHETER IS INTENDED TO DILATE STENOSES IN THE ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA-POPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR STENT POST-DILATATION IN THE PERIPHERAL VASCULATURE
1743	IMP/MD/2019/000308	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OESOPHAGEAL BALLOON CATHETER(RIGIFLEX II SINGLE-USE ACHALASIA BALLOON DILATOR)-THE RIGIFLEX II ACHALASIA BALLOON DILATOR IS INDICATED FOR DILATATION OF THE CARDIA (LES) IN PATIENTS WITH ACHALASIA.

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1744	IMP/MD/2019/000309	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL ABUTMENTS (OMNY ,UNIVERSALE,WAY MILANO ,WAY ROMA ,WAY SLIM)-REUSABLE MEDICAL DEVICES IN STEEL AND/OR TITANIUM INTENDED TO BE USED IN THE CONTEXT OF IMPLANT TREATMENTS WITH GEASS IMPLANTS AND PROSTHETIC COMPONENTS. REFER TO THE RESPECTIVE CATALOGS OR MANUALS FOR THE SPECIFIC INTENDED USE.,DENTAL IMPLANTS(OMNY, WAY EXTRA, WAY MILANO, WAY ROMA, WAY SHORT AND WAY SLIM)-GEASS® ENDOSSEOUS DENTAL IMPLANTS ARE INTENDED TO BE SURGICALLY PLACED IN BONE OF THE MANDIBULAR AND/OR MAXILLARY DENTAL ARCHES IN ORDER TO PROVIDE SUPPORT FOR FIXED AND/OR REMOVABLE RESTORATIONS. THIS ALLOWS RESTORATION OF ORIGINAL FEATURES AND MASTICATORY FUNCTIONS. GEASS® IMPLANT FIXTURES ARE INDICATED FOR PERMANENT USE. GEASS® IMPLANTS ARE SINGLE USE DEVICES, SUPPLIED STERILE WITH A COVER SCREW AND CANNOT BE RE-STERILIZED.,DENTAL HEALING SCREWS (GEADRIVEOMNY, GEADRIVEUNIVERSALE, GEADRIVE WAY , OMNY , UNIVERSALE ,WAY MILANO ,WAY SHORT ,WAY SLIM)-DEVICES FOR HANDLING OF IMPLANTS AND COMPONENTS

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1745	IMP/MD/2019/000310	1.License Holder Name: MITSUI & CO.INDIA PVT.LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE FIXATION DEVICE (GRAND FIX [WASHER- GRAND FIX])-GRAND FIX IS INTENDED TO CONNECT OR FIX BONES. GRAND FIX CAN BE USED FOR GENERAL ORTHOPAEDIC SURGERY, SURGICAL PROCEDURES ON THORACOTOMY OR TRAUMATIC FRACTURES AND FOR CRANIO AND/OR MAXILLOFACIAL SURGERY.,ABSORBABLE POLYGLYCOLIC ACID FELT(NEOVEIL)-NEOVEIL IS INTENDED FOR REINFORCING AND PREVENTING AIR LEAKAGE OF THE SUTURING OR STAPLING REGION., BONE FIXATION DEVICE(GRAND FIX [MINIPLATE- GRAND FIX, MINIPLATE(THIN TYPE)- GRAND FIX,MINIPLATE(FLAT TYPE)- GRAND FIX])-GRAND FIX IS INTENDED TO CONNECT OR FIX BONES. GRAND FIX CAN BE USED FOR GENERAL ORTHOPAEDIC SURGERY, SURGICAL PROCEDURES ON THORACOTOMY OR TRAUMATIC FRACTURES AND FOR CRANIO AND/OR MAXILLOFACIAL SURGERY.,BONE FIXATION DEVICE(GRAND FIX [CANCELLOUS SCREW- GRAND FIX,MALLEOLAR SCREW-GRAND FIX, MINISCREW- GRAND FIX, ACL SCREW- GRAND FIX, CORTICAL SCREW- GRAND FIX])-GRAND FIX IS INTENDED TO CONNECT OR FIX BONES. GRAND FIX CAN BE USED FOR GENERAL ORTHOPAEDIC SURGERY, SURGICAL PROCEDURES ON THORACOTOMY OR TRAUMATIC FRACTURES AND FOR CRANIO AND/OR MAXILLOFACIAL SURGERY.,BONE FIXATION DEVICE(GRAND FIX [STERNUM PIN- GRAND FIX,PIN- GRAND FIX,RIB PIN- GRAND FIX])-GRAND FIX IS INTENDED TO CONNECT OR FIX BONES. GRAND FIX CAN BE USED FOR GENERAL ORTHOPAEDIC SURGERY, SURGICAL PROCEDURES ON THORACOTOMY OR TRAUMATIC FRACTURES AND FOR CRANIO AND/OR MAXILLOFACIAL SURGERY.,ARTIFICIAL DERMIS (PELNAC)-PELNAC IS SUITABLE FOR USE IN FULL-THICKNESS SKIN DEFICIT WOUNDS INCLUDING FULL THICKNESS BURNS, TRAUMATIC SKIN DEFICIT WOUNDS, SKIN DEFICIT AFTER TUMOR OR NEVUS REMOVAL AND THE SITE OF SKIN FLAP HARVEST.

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1746	IMP/MD/2019/000311	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COLLAGEN MEMBRANE (CREOS XENOPROTECT)-CREOS XENOPROTECT IS INTENDED FOR USE DURING THE PROCESS OF GUIDED BONE REGENERATION (GBR) AND GUIDED TISSUE REGENERATION (GTR) AS A BIODEGRADABLE BARRIER MEMBRANE FOR: • RIDGE AUGMENTATION FOR LATER IMPLANT INSERTION • AUGMENTATION AROUND IMPLANTS PLACED IN IMMEDIATE/DELAYED EXTRACTION SOCKETS • LOCALIZED RIDGE AUGMENTATION • ALVEOLAR RIDGE PRESERVATION/ RECONSTRUCTION • OSSEOUS FILL AROUND IMPLANTS IN PERI-IMPLANTITIS BONE DEFECTS • OVER THE WINDOW IN LATERAL WINDOW SINUS ELEVATION PROCEDURES • INTRA-BONY DEFECTS AROUND TEETH • TREATMENT OF RECESSION DEFECTS, TOGETHER WITH CORONALLY POSITIONED FLAP • IN FURCATION DEFECTS IN MULTI-ROOTED TEETH.
1747	IMP/MD/2019/000312	1.License Holder Name: KRISHCO MEDICAL PRODUCTS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOLLICLE ASPIRATION NEEDLES/SET(FAS)-FOLLICLE ASPIRATION NEEDLES ARE USED FOR TRANS-VAGINAL HARVESTING OF OOCYTES FROM FOLLICLES FOR IVF (IN VITRO FERTILIZATION) AND ICSI (INTRA CYTOPLASMIC SPERM INJECTION).,EMBRYO TRANSFER CATHETER(EMTRAC DELPHIN)-INTRODUCTION OF EMBRYOS INTO THE UTERINE CAVITY,INTRA UTERINE INSEMINATION CANNULA(IUI)-USED FOR INTRAUTERINE ARTIFICIAL INSEMINATION,EMBRYO TRANSFER CATHETER(TULIP L)-INTRODUCTION OF EMBRYOS INTO UTERINE CAVITY,EMBRYO TRANSFER CATHETER(TULIP LS)-INTRODUCTION OF EMBRYOS INTO UTERINE CAVITY,EMBRYO TRANSFER CATHETER(EMTRAC C)-INTRODUCTION OF EMBRYOS INTO UTERINE CAVITY,EMBRYO TRANSFER CATHETER(EMTRAC SET)-INTRODUCTION OF EMBRYOS INTO UTERINE CAVITY,EMBRYO TRANSFER CATHETER(TULIP S)-INTRODUCTION OF EMBRYOS INTO UTERINE CAVITY

1748	IMP/MD/2019/000313	1.License Holder Name: DISPO SURGICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EXTENSION LINE (SECUFILL)-PATIENT LINE WITH DOUBLE LEVEL SAFETY VALVE FOR CR AND MRI,EXTENSION LINE(MONO KSB/PI)-INTENDED FOR INTRAVENOUS ADMINISTRATION OF CONTRAST AGENT FOR CT SCAN,EXTENSION LINE(MANY KSB/PI)-INTENDED FOR INTRAVENOUS ADMINISTRATION OF CONTRAST AGENT FOR CT SCAN,EXTENSION LINE.(KSB 25)-INTENDED FOR INTRAVENOUS ADMINISTRATION OF CONTRAST AGENT FOR CT SCAN
1749	IMP/MD/2019/000314	1.License Holder Name: USV PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE (STERILE)(BD HYPAK SCF™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS.
1750	IMP/MD/2019/000315	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERFUSE DECOMPRESSION SYSTEM(PERFUSE DECOMPRESSION SYSTEM)-THE PERFUSE PERCUTANEOUS DECOMPRESSION SYSTEM IS INTENDED TO BE USED FOR THE DELIVERY OF ALLOGRAFT, AUTOGRAFT, OR SYNTHETIC BONE GRAFT MATERIAL TO AN ORTHOPEDIC SURGICAL SITE. IN ADDITION, IT IS DESIGNED TO FACILITATE MIXING AND PRE-MIXING OF BONE GRAFT MATERIAL WITH I.V. FLUIDS, BLOOD, PLASMA CONCENTRATE, PLATELET-RICH PLASMA, BONE MARROW OR OTHER SPECIFIED BLOOD COMPONENTS DEEMED NECESSARY BY THE CLINICAL USE REQUIREMENTS.,AUTOLOGOUS PROTEIN SOLUTION (APS) KIT(NSTRIDE® APS KIT)-THE NSTRIDE APS KIT IS DESIGNED TO BE USED FOR THE SAFE AND RAPID PREPARATION OF AUTOLOGOUS PROTEIN SOLUTION (APS) FROM A SMALL SAMPLE OF BLOOD AT THE PATIENT'S POINT OF CARE. THE APS IS TO BE INJECTED INTRA-ARTICULARLY FOR THE TREATMENT OF KNEE OSTEOARTHRITIS AND ASSOCIATED SYMPTOMS.
1751	IMP/MD/2019/000316	1.License Holder Name: NATCO PHARMA LTD, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK)-COMPONENT OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTAL DRUGS

1752	IMP/MD/2019/000317	1.License Holder Name: M/S. VISHAL SURGICAL EQUIPMENT CO. PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERACETIC ACID GENERATED FROM TETRA ACETYL ETHYLENEDIAMENE (TAED) AND SODIUM PERCARBONATE(RELY+ON PERASAFE)-HIGH-LEVEL DISINFECTANT FOR USE ON INVASIVE AND NON-INVASIVE MEDICAL DEVICES INCLUDING RIGID AND FLEXIBLE ENDOSCOPES, CATHETERS, TRANSDUCERS, AND OTHER THERMOLABILE INSTRUMENTS AND EQUIPMENT.

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1753	IMP/MD/2019/000318	1.License Holder Name: CURE SURGICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CERVICAL PLATE SYSTEM (CASSIOPEIA CERVICAL PLATE SYSTEM)-THE CASSIOPEIA CERVICAL PLATE SYSTEM IS INTENDED FOR ANTERIOR CERVICAL FIXATION (C2-C7) IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: • DEGENERATIVE DISC DISEASE (DEFINED AS NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES) • SPONDYLOLISTHESIS • TRAUMA (INCLUDING FRACTURE OR DISLOCATION) • SPINAL STENOSIS • DEFORMITIES OR CURVATURES (KYPHOSIS, LORDOSIS, OR SCOLIOSIS) • TUMORS • PSEUDOARTHROSIS • FAILED PREVIOUS FUSION,STERILE SINGLE USE INFLATABLE BONE EXPANDER SYSTEM, BALLOON CATHETER AND CEMENT DISPENSER SYSTEM(TRACKER)-TRACKER-I: DEVICES USED FOR PERCUTANEOUS ACCESS TO BONE AND DELIVERY OF BONE CEMENT. TRACKER-X: IT INTENDED TO BE USED AS CONVENTIONAL BONE TAMPS FOR THE REDUCTION OF FRACTURES AND/OR CREATION OF A VOID IN CANCELLOUS BONE IN THE SPINE DURING BALLOON KYPHOPLASTY. TRACKER-P: DEVICES USED TO INFLATE BALLOON CATHETER DURING BALLOON KYPHOPLASYTY. TRACKER KYPHOPLASTY SYSTEM: IT IS USED TO AID IN THE INSERTION OF THE BONE CEMENT INTO CANCELLOUS BONE IN THE SPINE. TRACKER GVP: DEVICE USED FOR PERCUTANEOUS ACCESS TO BONE AND DELIVERY OF BONE CEMENT., PEDICLE SCREW SYSTEM(GSS PEDICLE SCREW SYSTEM)-THE GSS PEDICLE SCREW SYSTEM IS A PEDICLE SCREW SYSTEM INDICATED FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADE 3 AND 4) OF THE L5-SI VERTEBRA IN SKELETALLY MATURE PATIENTS RECEIVING FUSION BY AUTOGENOUS BONE GRAFT HAVING IMPLANTS ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 TO SACRUM) WITH REMOVAL OF THE IMPLANTS AFTER THE ATTAINMENT OF A SOLID FUSION. IN ADDITION, THE GSS PEDICLE SCREW SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE: DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, FRACTURE, DISLOCATION. SCOLIOSIS, KYPHOSIS, SPINAL TUMOR AND FAILED PREVIOUS FUSION (PSEUDARTHROSIS).,STERILE SINGLE USE EPIDURAL CATHETER SYSTEM (ABEL EPIDURAL CATHETER SYSTEM)-INSERTED INTO THE EPIDURAL SPACE OF SPINE AND SERVES AS THE PASSAGEWAY

		THROUGH WHICH THE PAIN MEDICATION IS DELIVERED DIRECTLY TO THE EPIDURAL SPACE.,SPINAL FIXATION SYSTEM (NON-STERILE) (SKY RECONSTRUCTION SYSTEM)-TO STABILIZES THE SINGLE/MULTIPLE SEGMENTED SPINE IN ORDER TO HELP THE SPINE BONE TO BE FIXED OR HARMONIZED,SPINAL FIXATION SYSTEM (NON-STERILE)(ANYPLUS PEDICLE SCREW SYSTEM)-TO STABILIZES THE SINGLE/MULTIPLE SEGMENTED SPINE IN ORDER TO HELP THE SPINE BONE TO BE FIXED OR HARMONIZED.,PEEK CAGE SYSTEM (ANYPLUS PEEK CAGE SYSTEM)-IMPLANTS ARE DESIGNED PRIMARILY FOR RESTORING THE HEIGHT OF THE INTERVERTEBRAL SPACE AFTER RESECTION OF THE DISC.
1754	IMP/MD/2019/000319	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE CEMENT(HI-FATIGUE BONE CEMENT)-HI-FATIGUE BONE CEMENT IS A POLY (METHYL METHACRYLATE) BASED BONE CEMENT FOR FIXATION OF ENDOPROSTHESES IN ARTHROPLASTY SURGERY AND FOR PERMANENT FILLING OF BONE DEFECTS. HI-FATIGUE BONE CEMENT CONSISTS OF A POWDER AND A LIQUID COMPONENT THAT ARE MIXED DIRECTLY BEFORE USE TO FORM A DUCTILE PASTE WITH OPTIMAL HANDLING PROPERTIES. AFTER HARDENING HI-FATIGUE BONE CEMENT PROVIDES A SAVE AND STABLE FIXATION OF ENDOPROSTHESES IN ORTHOPEDIC SURGERY AND FOR THE USE IN TRAUMA APPLICATIONS. HI-FATIGUE BONE CEMENT CONTAINS A RADIOPACIFIER TO ENABLE THE IDENTIFICATION OF THE CEMENT IN RADIOGRAPHS.,BONE CEMENT(HI-FATIGUE G BONE CEMENT)-HI-FATIGUE G BONE CEMENT IS A GENTAMICIN CONTAINING POLY (METHYL METHACRYLATE) BASED BONE CEMENT FOR FIXATION OF ENDOPROSTHESES IN ARTHROPLASTY SURGERY. THE ADDED ANTIBIOTIC, GENTAMICIN SULFATE, PROTECTS THE IMPLANT AND THE SURROUNDING TISSUE FROM COLONIZATION WITH PATHOGENS THAT ARE SENSITIVE TO GENTAMICIN. HI-FATIGUE G BONE CEMENT CONSISTS OF A POWDER AND A LIQUID COMPONENT THAT ARE MIXED DIRECTLY BEFORE USE TO FORM A DUCTILE PASTE WITH OPTIMAL HANDLING PROPERTIES. AFTER HARDENING HI-FATIGUE G BONE CEMENT PROVIDES A SAVE AND STABLE FIXATION OF ENDOPROSTHESES IN ORTHOPEDIC SURGERY. HI-FATIGUE G BONE CEMENT CONTAINS A RADIOPACIFIER TO ENABLE THE IDENTIFICATION OF THE CEMENT IN RADIOGRAPHS.

1755	IMP/MD/2019/000321	1.License Holder Name: M/S. DIO DIGITAL IMPLANT INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT ABUTMENT(UF(II) CCM ABUTMENTS)-FOR THE RECOVERY OF THE PATIENTS MASTICATORY MOVEMENT, THIS IS AN UPPER STRUCTURE OF THE IMPLANT TO SUPPORT THE PROSTHETICS SUCH AS IMPLANTS. (THIS IS THE UPPER PART OF THE DENTAL IMPLANT FOR THE MASTICATORY MOVEMENT RECOVERY OF THE DEFICIT TEETH)., DENTAL IMPLANT FIXTURE(UF(II) IMPLANT FIXTURE)-THIS IS AN IMPLANT FIXTURE TO BE INSERTED IN THE HUMAN BODY IN ORDER TO SUPPORT THE PROSTHETIC APPLIANCE AND TO RECOVER THE MASTICATION FUNCTION OF THE PATIENTS (USE ON MAXILLARY ANTERIOR REGION).,DENTAL IMPLANT ABUTMENT(UF(II) ABUTMENT) -FOR THE RECOVERY OF THE PATIENT'S MASTICATORY MOVEMENT, THIS IS AN UPPER STRUCTURE OF THE IMPLANT TO SUPPORT THE PROSTHETICS SUCH AS IMPLANTS. (THIS IS THE UPPER PART OF THE DENTAL IMPLANT FOR THE MASTICATORY MOVEMENT RECOVERY OF THE DEFICIT TEETH).
1756	IMP/MD/2019/000322	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED ,A-1/50, ROOM NO. 2, 100 SHED AREA, G.L.D.C., VAPI, TAL PARDI (VALSAD) , VALSAD GUJARAT ,396195 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUTURE (SPIRAL PGA PCL)(STRATAFIX)-STRATAFIX SPIRAL PGA-PCL DEVICE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE USE OF ABSORBABLE SUTURE IS APPROPRIATE,SUTURE(SPIRAL POLYPROPYLENE)(STRATAFIX)-STRATAFIX SPIRAL POLYPROPYLENE DEVICE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION, EXCLUDING CLOSURE OF THE EPIDERMIS.,SUTURE (SPIRAL PDO)(STRATAFIX)-STRATAFIX SPIRAL PDO DEVICE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE USE OF ABSORBABLE SUTURE IS APPROPRIATE

1757	IMP/MD/2019/000323	1.License Holder Name: ENVISION SCIENTIFIC PVT. LTD. ,PLOT C1B-108 ICHCHHAPORE GIDC INDUSTRIAL ESTATE, BHATPORE, SACHIN-HAZIRA ROAD, ,SURAT GUJARAT ,394510 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA CATHETER(VEGA)-THE VEGA CATHETER IS INTENDED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. THE VEGA PTCA CATHETER IS THEREFORE INDICATED TO DILATE THE DISEASED SEGMENT(S) IN A CORONARY ARTERY OR A CORONARY BYPASS, TO IMPROVE MYOCARDIAL PERFUSION. THE PATIENTS SHOULD FULFIL ONE OR MORE OF THE FOLLOWING CRITERIA • PATIENTS MUST BE JUDGED TO BE ACCEPTABLE CANDIDATES FOR CORONARY BYPASS SURGERY. • PATIENTS WITH SINGLE VESSEL ATHEROSCLEROTIC LESION(S), NON-CALCIFIED, SUBTOTAL AND ACCESSIBLE TO DILATATION WITH GUIDEWIRE AND CATHETER. • CERTAIN MULTI-VESSEL DISEASED PATIENTS MAY ALSO BE CANDIDATES FOR THIS PROCEDURE. • CERTAIN PATIENTS, WHO HAVE UNDERGONE PREVIOUS CORONARY BYPASS SURGERY WITH RECURRENCE OF SYMPTOMS AND PROGRESSION OF THE DISEASE IN THE CORONARY ARTERY, OR STENOSIS AND CLOSURE OF THE GRAFTS, MAY ALSO BE CANDIDATES.
1758	IMP/MD/2019/000324	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER(PHENOM CATHETER)-THE PHENOM™ CATHETERS ARE INTENDED FOR THE INTRODUCTION OF INTERVENTIONAL DEVICES AND INFUSION OF DIAGNOSTIC OR THERAPEUTIC AGENTS INTO THE NEURO, PERIPHERAL AND CORONARY VASCULATURES.

1759	IMP/MD/2019/000325	1.License Holder Name: NEON LABORATORIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOLEY CATHETER LATEX (BIP FOLEY CATHETER LATEX)-BIP FOLEY CATHETER IS INTENDED TO BE USED BY TRAINED PERSON OR TRAINED MEDICAL STAFF FOR DRAINAGE AND/OR IRRIGATION OF THE PATIENT BLADDER AND/OR FOR COLLECTION / MEASUREMENT OF THE PATIENT URINE. THESE FUNCTIONS ARE ACHIEVED BY INSERTING THE BIP FOLEY CATHETER INTO THE VESICAL CAVITY OF THE BLADDER THROUGH THE URETHRA, OR BY SUPRAPUBIC CATHETERIZATION. THE BIP FOLEY CATHETER HAS BEEN SHOWN TO SIGNIFICANTLY REDUCE THE INCIDENCE OF BACTERIURIA IN CATHETERIZED PATIENTS COMPARED TO PATIENTS USING UNCOATED CATHETERS.,FOLEY CATHETER – SILICONE AND TIEMANN(BIP FOLEY CATHETER – SILICONE BIP FOLEY TIEMANN)-THE BIP FOLEY CATHETER - SILICONE AND BIP FOLEY TIEMANN ARE INTENDED TO BE INSERTED BY TRAINED MEDICAL STAFF, FOR THE DRAINAGE AND/OR IRRIGATION OF THE BLADDER, AND/OR FOR COLLECTION/MEASUREMENT OF PATIENT URINE. THESE FUNCTIONS ARE ACHIEVED BY INSERTING THE CATHETER INTO THE VESICAL CAVITY OF THE BLADDER THROUGH THE URETHRA, OR BY SUPRAPUBIC CATHETERISATION. BIP FOLEY TIEMANN IS ONLY FOR TRANSURETHRAL USE. BACTIGUARD® COATED FOLEY CATHETERS HAVE BEEN SHOWN TO SIGNIFICANTLY REDUCE THE INCIDENCE OF BACTERIURIA, CATHETER ASSOCIATED URINARY TRACT INFECTIONS (CAUTIS) AND ANTIBIOTIC USE IN CATHETERIZED PATIENTS COMPARED TO PATIENTS USING STANDARD CATHETERS.,CENTRAL VENOUS CATHETER KIT(BIP CENTRAL VENOUS CATHETER)-BIP CVCS ARE DESIGNED FOR USE IN CRITICAL CARE PATIENTS TO MONITOR CENTRAL VENOUS PRESSURE, SAMPLE VENOUS BLOOD AND ADMINISTER DRUGS AND SOLUTIONS INTRAVENOUSLY. MULTIPLE-LUMEN CATHETERS PROVIDE MULTIPLE ACCESS CHANNELS TO THE CENTRAL VENOUS CIRCULATION THROUGH A SINGLE INSERTION SITE, ALLOWING SEVERAL FUNCTIONS TO BE PERFORMED SIMULTANEOUSLY. BACTIGUARD®-COATED CVCS HAVE BEEN SHOWN TO REDUCE CATHETER-RELATED INFECTIONS IN HIGH-RISK PATIENTS, WHEN COMPARED TO UNCOATED CVCS.1) THE BACTIGUARD® COATING ON THE BIP CVC HAS BEEN SHOWN TO REDUCE BACTERIAL ADHESION TO THE CATHETER SURFACE IN VITRO. BACTIGUARD KIT CONSIST OF 1 CATHETER, 1 GUIDEWIRE,, 1 NEEDLE, 1 DILATOR, 1 SCALPEL, 1 CLAMP FASTNER, 1 SUTUTRE WINGS, 1 INJECTION PORT, 1 EXTENSION LINE CLAMP, 1 LUER SLIP SYRINGE, 1 BLUE NEEDLE STOPPER, ENDOTRACHEAL TUBE(BIP ENDOTRACHEAL TUBE)-THE BIP ENDOTRACHEAL TUBE IS INDICATED TO BE USED BY TRAINED

	MEDICAL STAFF, FOR USE IN AIRWAY MANAGEMENT BY ORAL OR NASAL INTUBATION OF THE PATIENT TRACHEA TO CREATE AN OPEN AIRWAY. THE BACTIGUARD® COATING ON THE BIP ENDOTRACHEAL TUBE HAS BEEN SHOWN TO SIGNIFICANTLY REDUCE MICROBIAL ADHESION.,ENDOTRACHEAL TUBE (EVAC)(BIP ENDOTRACHEAL TUBE (EVAC))-THE BIP ENDOTRACHEAL TUBE EVAC IS INDICATED FOR USE IN AIRWAY MANAGEMENT BY ORAL INTUBATION OF TRACHEA. THE EVACUATION LUMEN ALLOWS FOR DRAINAGE BY CONTINUOUS OR INTERMITTENT SUCTIONING OF CONTAMINATED MUCOUS AND SUBGLOTTIC SECRETIONS THAT ACCUMULATE ABOVE THE CUFF. BIP ENDOTRACHEAL TUBE EVAC IS INTENDED FOR PATIENTS ANTICIPATED TO NEED PROLONGED MECHANICAL VENTILATION.THE BACTIGUARD® COATING ON THE BIP ENDOTRACHEAL TUBE EVAC IS SIGNIFICANTLY REDUCING MICROBIAL ADHESION. SUBGLOTTIC SECRETION DRAINAGE (SSD) HAS BEEN SHOWN EFFECTIVE FOR PREVENTION OF VENTILATOR-ASSOCIATED PNEUMONIA (VAP).

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1760	IMP/MD/2019/000326	1.License Holder Name: ENVIRO MEDICAL DEVICES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EPIDURAL NEEDLE(FLIX +)-THE EPIDURAL IS PLACED INTO A NERVE OR INTO THE SPINAL CORD. NOTHING COULD BE FURTHER FROM THE TRUTH. THE NEEDLE, CATHETER AND MEDICATION GO INTO THE COMPARTMENT THAT THE NERVES PASS THROUGH. YOUR SPINE IS A PROTECTIVE BONE STRUCTURE SURROUNDING YOUR EPIDURAL SPACE.,SPINAL NEEDLES(FLIX)-SPINAL NEEDLES ARE USED TO INJECT ANALGESIA AND/OR ANAESTHETIC DIRECTLY INTO THE CSF USUALLY AT A POINT BELOW THE SECOND LUMBAR VERTEBRA. SPINAL NEEDLES ENTER THE CEREBRAL SPINAL FLUID (CSF) THROUGH THE MEMBRANES SURROUNDING THESPINAL CORD.,INTRODUCER SHEATH SET TRANSRADIAL / PEELABLE(ADVANTAGE SHEATH)-CORONARY CATHETERIZATION IS A MINIMALLY INVASIVE PROCEDURE TO ACCESS THE CORONARY CIRCULATION USING A CATHETER. THE PROCEDURE USES A SPECIAL DYE THAT HELPS VISUALIZE THE BLOOD FLOW THROUGH THE HEART.,PRESSURE TRANSDUCER(TRANSURE)-RELIABLE HEMODYNAMIC AND CARDIOVASCULAR DATA IS NEEDED TO MANAGE CRITICAL PATIENTS. PRESSURE TRANSDUCERS CONTINUOUSLY RELAY BLOOD PRESSURE INFORMATION FROM A PRESSURE MONITORING CATHETER (ARTERIAL LINE, CENTRAL VENOUS PRESSURE LINE, OR OTHER PRESSURE MONITORING PRODUCTS) TO THE PATIENT'S MONITORING SYSTEM.,HEMOSTASIS Y-CONNECTOR(ADVANTAGE)-HAEMOSTATIC VALVE IS INTENDED TO MAINTAIN HEMOSTASIS DURING THE INTRODUCTION/WITHDRAWAL AND USE OF DIAGNOSTIC ND INTERVENTIONAL DEVICES UP TO AN EXTERNAL DIAMETER OF 7FR, 8FR, 9FR, THE INSERTION TOOL FACILITIES INTRODUCTION OF GUIDEWIRE THROUGH THE HAEMOSTATIC VALVES TO REACH THE GUIDING CATHETER,,HEMODIALYSIS CATHETER KIT SINGLE, DOUBLE AND TRIPLE LUMEN(SELECT)-A DIALYSIS CATHETER IS A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM A HEMODIALYSIS MACHINE AND A PATIENT.,GUIDEWIRE PTFE, PTCA, HYDROPHILIC, ZEBRA, STAINLESS STEEL, NITINOL,(CLEVER)-A DEVICE USED TO ENTER OBSTRUCTED VALVES OR CHANNELS, WITHIN THE BODY, OR TO ASSIST IN INSERTING, POSITIONING, AND MOVING A CATHETER., PTCA BALLOON CATHETER(PATHWAY)-WHEN A BALLOON CATHETER IS USED TO COMPRESS PLAQUE WITHIN A CLOGGED CORONARY ARTERY IT IS REFERRED TO AS A PLAIN OLD BALLOON ANGIOPLASTY OR POBA. BALLOON CATHETERS ARE ALSO UTILIZED IN THE DEPLOYMENT OF STENTS DURING ANGIOPLASTY. BALLOON CATHETERS ARE SUPPLIED TO THE CATH LAB WITH A STENT PRE MOUNTED ON THE BALLOON.,CENTRAL VENOUS CATHETER KIT

		(CENTROFLOW)-CENTRAL VENOUS CATHETERS (CVCS) ARE ALSO CALLED CENTRAL VENOUS ACCESS DEVICES (CVADS), OR CENTRAL LINES. THEY ARE USED TO PUT MEDICINES, BLOOD PRODUCTS, NUTRIENTS, OR FLUIDS RIGHT INTO YOUR BLOOD. THEY CAN ALSO BE USED TO TAKE OUT BLOOD FOR TESTING.,GUIDING CATHETER (ADVANTAGE GUIDE)-THE GUIDE CATHETER PROVIDES SUPPORT FOR DEVICE ADVANCEMENT (STENTS, BALLOONS, ETC.). IT IS THE CONDUIT FOR DEVICE AND WIRE TRANSPORT, A VEHICLE FOR CONTRAST INJECTION AND TAKES MEASUREMENTS., RADIOLOGY/CARDIOLOGY ANGIOGRAPHIC CATHETER (ADVANTAGEANGIO)-THE ANGIOGRAPHIC CATHETER IS A PLASTIC TUBE WHICH FUNCTIONS AS A CONDUIT FOR CONTRAST, FLUIDS, AND PRESSURE MEASUREMENT DURING CARDIAC CATHETERIZATION OF CORONARY ARTERIES AND THE LEFT VENTRICLE,DISPOSABLE INFLATION DEVICE(INFLAIR)-INFLATION DEVICE IS USED FOR THE INFLATION OF BALLOONS AND STENTS DURING ANGIOPLASTY PROCEDURES, AND TO MEASURE THE PRESSURE WITHIN THE BALLOON. KEY FEATURES AND BENEFITS: ERGONOMICALLY DESIGNED TO ENSURE ACCURATE INFLATION OF INTERVENTIONAL DEVICES. ANGLED ANALOGUE GAUGE FOR BETTER VIEWING OF PRESSURE READINGS.,MANIFOLD ONE , TWO, THREE , FOUR PORT(ADVANTAGE II)-MANIFOLDS FEATURE AN INTEGRAL CHECK RELIEF VALVE TO PREVENT THE BACKFLOW OF SOLUTIONS & DESIGNED WITH EASY-TO-GRIP HANDLES
1761	IMP/MD/2019/000327	1.License Holder Name: DIACARE SOLUTIONS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMODIALYSIS MACHINE DISINFECTANT; CITRIC ACID 21%(CITRO PLUS)-THERMOCHEMICAL DISINFECTANT FOR HEMODIALYSIS MACHINES WITH PROPORTIONAL MIXING SYSTEM AND RE-CIRCULATION FUNCTION.,HEMODIALYSIS MACHINE DISINFECTANT; PARACETIC ACID BASED(PEROXY PLUS)-COLD DISINFECTANT (DIALYSIS MACHINE 37 °C) FOR HEMODIALYSIS MACHINES WITH PROPORTIONAL MIXING SYSTEM AND RE-CIRCULATION FUNCTION.,COLD STERILANT FOR DIALYZER REPROCESSING(PEROXY PLUS RP)-INDICATED FOR IN VITRO CLEANING AND STERILIZING OF HOLLOW FIBER DIALYZERS FOR DIALYZER REPROCESSING SYSTEMS. ALSO, IT MAY BE USED FOR DISINFECTING DIALYSIS EQUIPMENT (E.G. KIDNEY MACHINES) AND SUPPLIES (E,G. PORT CAPS)

1762	IMP/MD/2019/000328	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE CEMENT WITH HYDROXYAPATITE AND MIXER(KYPHON ACTIVOS BONE CEMENT WITH HYDROXYAPATITE AND MIXER)-KYPHON ACTIVOS BONE CEMENT WITH HYDROXYAPATITE IS INDICATED FOR USE AS A FIXATION MATERIAL IN VERTEBRAL COMPRESSION FRACTURES UNDERGOING BALLOON KYPHOPLASTY TREATMENT.
1763	IMP/MD/2019/000329	1.License Holder Name: SAHAJANAND MEDICAL TECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:Y CONNECTORS(EASY CATCH PLUS)-EASY CATCH PLUS IS INTENDED TO MAINTAIN HAEMOSTASIS BEFORE AND DURING THE INTRODUCTION / THE USE AND WITHDRAWAL OF DIAGNOSTIC / INTERVENTIONAL DEVICES WITH OUTSIDE DIAMETER GREATER OR EQUAL THAN 7 F (2.33 MM, 0.092") DURING INTERVENTIONAL PROCEDURES.,PTCA CATHETER (MAYA)-FOR "FURTHER MANUFACTURING USE ONLY".,PTCA NC CATHETER(MAYA NC)-FOR "FURTHER MANUFACTURING USE ONLY"., PTA CATHETER(LYNX RX)-THE LYNX RX IS INDICATED FOR IMPROVING PERIPHERAL LUMINAL DIAMETER IN PATIENTS WITH STENOSIS OF THE RENAL ARTERIES AND ARTERIES OF THE LOWER LIMBS, USING DILATATION TECHNIQUE.,ASPIRATION CATHETER (IDENTITY)-IT IS INTENDED FOR USE IN THE CENTRAL & PERIPHERAL CIRCULATORY SYSTEM INCLUDING SAPHENOUS VEIN GRAFTS, TO CONTAIN AND ASPIRATE EMBOLIC MATERIAL (THROMBUS / DEBRIS) WHILE PERFORMING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) OR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) AND/OR ATENTING PROCEDURES.
1764	IMP/MD/2019/000330	1.License Holder Name: M/S ALLERGAN INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLAUCOMA TREATMENT SYSTEM(XEN 45)-THE XEN GEL IMPLANT IS INTENDED TO REDUCE INTRAOCULAR PRESSURE (IOP) IN PATIENTS WITH PRIMARY OPEN ANGLE GLAUCOMA WHERE PREVIOUS MEDICAL TREATMENTS HAVE FAILED.

1765	IMP/MD/2019/000331	1.License Holder Name: SMITHS MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PRESSURE MONITORING KITS(MEDEX TRANSTAR PRESSURE MONITORING KITS)-THE CLOSED BLOOD SAMPLING SET WITH LOGICAL® PRESSURE MONITORING SYSTEM IS A HEMODYNAMIC PRESSURE MONITORING AND BLOOD SAMPLING SYSTEM DESIGNED TO ALLOW EASY WITHDRAWAL OF BLOOD SAMPLES FROM AN ARTERIAL OR CENTRAL VENOUS PRESSURE MONITORING LINE WHILE MAINTAINING A COMPLETELY CLOSED SYSTEM FOR ADULTS AND KIDS,PRESSURE MONITORING KIT (MEDEX TRANSTAR PRESSURE MONITORING KITS)-THE TRANSTAR DISPOSABLE PRESSURE TRANSDUCER IS INTENDED FOR INTRACRANIAL OR BLOOD PRESSURE MONITORING. PRESSURE WAVEFORMS ARE CONDUCTED FROM THE PATIENT TO THE TRANSDUCER THROUGH A COLUMN OF FLUID. THE FLUID PRESSURE WAVEFORM IS CONVERTED INTO ELECTRICAL SIGNALS THAT CAN THEN BE DISPLAYED USING SEPARATE MONITORING EQUIPMENT. THE PRODUCT COMES WITH A 3 WAY STOPCOCK.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1766	IMP/MD/2019/000332	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PATIENT MATCHED IMPLANT(HTR-PMI IMPLANT)-HTR® (HARD TISSUE REPLACEMENT) POLYMER IMPLANTS ARE INTENDED FOR RECONSTRUCTION AND AUGMENTATION IN CRANIOFACIAL PROCEDURES INTENDED TO FILL VOIDS OR DEFECTS IN BONE RESULTING FROM DISEASE, TRAUMATIC INJURY, OR SURGICAL TRAUMA. THESE DEVICES CAN BE USED IN AESTHETIC RECONSTRUCTIVE PROCEDURES WHERE AUGMENTATION OR CHANGE IN BONY CONTOURS IS DESIRED,RESORBABLE FIXATION IMPLANT(LACTOSORB SYSTEM - MESH)-IT IS INDICATED FOR THE TRAUMA PROCEDURES OF THE MIDFACE OR CRANIOFACIAL SKELETON, RECONSTRUCTIVE PROCEDURES OF THE MIDFACE OR CRANIOFACIAL SKELETON, FIXATION IN MANDIBULAR OSTEOTOMY PROCEDURES AND MAINTAINING THE POSITION OF BONY FRAGMENTS OR MORSELIZED BONE GRAFT IN ILIAC CREST AUTOGRAFT PROCEDURES,ORAL AND CRANIO - MAXILLOFACIAL RECONSTRUCTIVE IMPLANTS(TRAUMAONE SYSTEM - SCREWS)-IT IS USED IN THE STABILIZATION AND FIXATION OF MANDIBULAR FRACTURES AND MANDIBULAR RECONSTRUCTIVE SURGICAL PROCEDURES, ORAL MAXILLOFACIAL PROCEDURES, RECONSTRUCTIVE PROCEDURES, REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED AND TEMPORARY (UP TO ONE YEAR) REPLACEMENT OF MANDIBULAR CONDYLAR HEAD OF PATIENTS WITH MALIGNANCY REQUIRING RESECTION OF THE MANDIBULAR CONDYLE.,STERNAL FIXATION RECONSTRUCTIVE IMPLANT (NON-STERILE)(STERNALOCK BLU SYSTEM - SCREWS)-IT IS INTENDED FOR USE IN THE STABILIZATION AND FIXATION OF FRACTURES OF THE ANTERIOR CHEST WALL INCLUDING STERNAL FIXATION FOLLOWING STERNOTOMY AND STERNAL RECONSTRUCTIVE SURGICAL PROCEDURES, TO PROMOTE FUSION., TEMPOROMANDIBULAR JOINT IMPLANT(TMJ SYSTEM - MANDIBULAR COMPONENT)-IT IS INDICATED FOR RECONSTRUCTION OF THE TEMPOROMANDIBULAR JOINT.,RESORBABLE FIXATION IMPLANT (LACTOSORB SYSTEM - SCREWS)-IT IS INDICATED FOR THE TRAUMA PROCEDURES OF THE MIDFACE OR CRANIOFACIAL SKELETON, RECONSTRUCTIVE PROCEDURES OF THE MIDFACE OR CRANIOFACIAL SKELETON, FIXATION IN MANDIBULAR OSTEOTOMY PROCEDURES AND MAINTAINING THE POSITION OF BONY FRAGMENTS OR MORSELIZED BONE GRAFT IN ILIAC CREST AUTOGRAFT PROCEDURES,ORAL AND CRANIO - MAXILLOFACIAL RECONSTRUCTIVE IMPLANTS(TRAUMAONE SYSTEM - PLATE)-IT IS USED IN THE STABILIZATION AND FIXATION OF MANDIBULAR FRACTURES AND MANDIBULAR RECONSTRUCTIVE SURGICAL

	PROCEDURES, ORAL MAXILLOFACIAL PROCEDURES, RECONSTRUCTIVE PROCEDURES, REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED AND TEMPORARY (UP TO ONE YEAR) REPLACEMENT OF MANDIBULAR CONDYLAR HEAD OF PATIENTS WITH MALIGNANCY REQUIRING RESECTION OF THE MANDIBULAR CONDYLE.,ORAL AND CRANIO - MAXILLOFACIAL RECONSTRUCTIVE IMPLANTS(TRAUMAONE SYSTEM - MESH)-IT IS USED IN THE STABILIZATION AND FIXATION OF MANDIBULAR FRACTURES AND MANDIBULAR RECONSTRUCTIVE SURGICAL PROCEDURES, ORAL MAXILLOFACIAL PROCEDURES, RECONSTRUCTIVE PROCEDURES, REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED AND TEMPORARY (UP TO ONE YEAR) REPLACEMENT OF MANDIBULAR CONDYLAR HEAD OF PATIENTS WITH MALIGNANCY REQUIRING RESECTION OF THE MANDIBULAR CONDYLE.,CRANIO-MAXILLOFACIAL IMPLANT (CRANIO-MAXILLOFACIAL SYSTEM - PLATES)-THESE DEVICES ARE IMPLANTABLE BONE PLATES AND BONE SCREWS FOR ORAL, CRANIO-MAXILLOFACIAL PROCEDURES,CRANIO-MAXILLOFACIAL IMPLANT(CRANIO-MAXILLOFACIAL SYSTEM - SCREWS)-THESE DEVICES ARE IMPLANTABLE BONE PLATES AND BONE SCREWS FOR ORAL, CRANIO-MAXILLOFACIAL PROCEDURES,STERNAL FIXATION RECONSTRUCTIVE IMPLANT (NON-STERILE)(STERNALOCK BLU SYSTEM - PLATES)-IT IS INTENDED FOR USE IN THE STABILIZATION AND FIXATION OF FRACTURES OF THE ANTERIOR CHEST WALL INCLUDING STERNAL FIXATION FOLLOWING STERNOTOMY AND STERNAL RECONSTRUCTIVE SURGICAL PROCEDURES, TO PROMOTE FUSION.,RESORBABLE FIXATION IMPLANT(LACTOSORB SYSTEM - PLATE)-IT IS INDICATED FOR THE TRAUMA PROCEDURES OF THE MIDFACE OR CRANIOFACIAL SKELETON, RECONSTRUCTIVE PROCEDURES OF THE MIDFACE OR CRANIOFACIAL SKELETON, FIXATION IN MANDIBULAR OSTEOTOMY PROCEDURES AND MAINTAINING THE POSITION OF BONY FRAGMENTS OR MORSELIZED BONE GRAFT IN ILIAC CREST AUTOGRAFT PROCEDURES, TEMPOROMANDIBULAR JOINT IMPLANT(TMJ SYSTEM - SCREWS)-IT IS INDICATED FOR RECONSTRUCTION OF THE TEMPOROMANDIBULAR JOINT.,TEMPOROMANDIBULAR JOINT IMPLANT(TMJ SYSTEM - FOSSA COMPONENT)-IT IS INDICATED FOR RECONSTRUCTION OF THE TEMPOROMANDIBULAR JOINT.,TEMPOROMANDIBULAR JOINT IMPLANT(TMJ SYSTEM - MANDIBULAR COMPONENT)-IT IS INDICATED FOR RECONSTRUCTION OF THE TEMPOROMANDIBULAR JOINT., CRANIO-MAXILLOFACIAL IMPLANT(CRANIO-MAXILLOFACIAL SYSTEM - MESH)-THESE DEVICES ARE IMPLANTABLE BONE PLATES AND BONE SCREWS FOR ORAL, CRANIO-MAXILLOFACIAL PROCEDURES,RETROTERNAL SYSTEM(PECTUS SUPPORT BAR

		SYSTEM)-1. IT IS INDICATED FOR PECTUS EXCAVATUM AND OTHER STERNAL DEFORMITIES
1767	IMP/MD/2019/000333	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VOID CENTRAILSER-CENTRALISER(C-STEM)-IT IS INDICATED FOR SEVERE ARTHROPATHY DUE TO ADVANCED RHEUMATOID OR OSTEO-ARTHRITIS WHERE CONSERVATIVE THERAPY OR ALTERNATIVE TREATMENTS HAVE FAILED OR ARE CONSIDERED UNSUITABLE, ARTHROPATHY DUE TO DEGENERATIVE DISEASE, ACUTE TRAUMA, AND A PREVIOUS FAILED JOINT REPLACEMENT. THE PATIENT'S JOINT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE SELECTED IMPLANT(S).
1768	IMP/MD/2019/000334	1.License Holder Name: SUSHEN TECHNOLOGIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRA AORTIC BALLOON CATHETER WITH INSERTION KIT(XEMEX IABP BALLOON PLUS)-XEMEX IABP BALLOON PLUS IS A BALLOON CATHETER SET, USED FOR BALLOON PUMPING IN THE AORTA TO ASSIST HEART FUNCTION IN CARDIOGENIC SHOCK OR LOW CARDIAC OUTPUT SYNDROME CASES.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1769	IMP/MD/2019/000335	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANCHOR WITH SUTURE (VERSALOK PEEK ANCHOR WITH ORTHOCORD)-THE VERSALOK PEEK ANCHOR IS INDICATED FOR USE IN THE FOLLOWING PROCEDURES FOR REATTACHMENT OF SOFT TISSUE TO BONE: SHOULDER: REPAIR OF ROTATOR CUFF TEARS AND BICEPS TENODESIS. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS, JOINT CAPSULE CLOSURE. ELBOW: BICEPS TENDON REATTACHMENT,SUTURE(ORTHOCORD)-ORTHOCORD SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, AND/OR LIGATION, INCLUDING ORTHOPEDIC PROCEDURES. IT IS NOT INDICATED FOR CARDIOVASCULAR OR NEUROLOGICAL PROCEDURES.,ANCHOR(VERSALOK PEEK ANCHOR)-THE VERSALOK PEEK ANCHOR IS INDICATED FOR USE IN THE FOLLOWING PROCEDURES FOR REATTACHMENT OF SOFT TISSUE TO BONE: SHOULDER: REPAIR OF ROTATOR CUFF TEARS AND BICEPS TENODESIS. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS, JOINT CAPSULE CLOSURE. ELBOW: BICEPS TENDON REATTACHMENT,SCREW (ABSOLUTE ABSORABLE INTERFERENCE SCREW SYSTEM)-THE DEPUY MITEK ABSOLUTE ABSORBABLE INTERFERENCE SCREW INTENDED FOR ATTACHMENT OF SOFT TISSUE GRAFTS OR BONE-TENDON GRAFTS TO THE TIBIA AND/OR FEMUR DURING CRUCIATE LIGAMENT RECONSTRUCTION SURGERIES.,SCREW(PROFILE INTERFERENCE SCREW)-"THE ADVANTAGE, PROFILE, BIG ADVANTAGE AND M. KUROSAKA INTERFERENCE SCREWS AND THE XACT SET SCREW ARE INTENDED TO BE USED TO PROVIDE INTERFERENCE FIXATION OF BONE-PATELLAR TENDON-BONE GRAFTS IN ACL RECONSTRUCTION. THE PROFILE INTERFERENCE SCREW, 20 MM AND LONGER, IS ALSO INTENDED TO PROVIDE INTERFERENCE FIXATION OF BONE-PATELLAR TENDON-BONE GRAFTS IN PCL RECONSTRUCTION AND TO PROVIDE FIXATION OF SOFT TISSUE GRAFTS IN ACL RECONSTRUCTION. THE XACT CROSS PIN IS INTENDED TO BE USED TO PROVIDE FIXATION OF SOFT TISSUE GRAFTS IN ACL RECONSTRUCTION.",SHEATH AND SCREW SYSTEM (INTRAFIX SHEATH AND SCREW SYSTEM- FEMORAL)-THE FEMORAL INTRAFIX SYSTEM IS INDICATED FOR FIXATION OF SOFT TISSUE GRAFTS DURING CRUCIATE LIGAMENT RECONSTRUCTION.,ANCHOR WITH SUTURE(BIOKNOTLESS BR ANCHOR WITH ORTHOCORD)-THE DEPUY MITEK BIOKNOTLESS BR ANCHOR IS INDICATED FOR USE IN SOFT TISSUE TO BONE FIXATION IN ASSOCIATION WITH ADEQUATE

	POSTOPERATIVE IMMOBILIZATION AS FOLLOWS: SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ACROMIOCLAVICULAR SEPARATION, ROTATOR CUFF REPAIR, CAPSULE SHIFT/ CAPSULO-LABRAL RECONSTRUCTION, BICEPS TENODESIS, AND DELTOID REPAIR. ANKLE: LATERAL INSTABILITY, MEDIAL INSTABILITY, ACHILLES TENDON REPAIR/RECONSTRUCTION, AND MIDFOOT RECONSTRUCTION. FOOT: HALLUX VALGUS RECONSTRUCTION ELBOW: TENNIS ELBOW REPAIR, BICEPS TENDON REATTACHMENT. KNEE: EXTRA-CAPSULAR REPAIRS; REATTACHMENT OF: MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT OR JOINT CAPSULE TO TIBIA AND JOINT CAPSULE CLOSURE TO ANTERIOR PROXIMAL TIBIA; EXTRA CAPSULAR RECONSTRUCTION, ITB TENODESIS; PATELLAR LIGAMENT AND TENDON AVULSIONS.,ANCHOR(HEALIX ADVANCE KNOTLESS BR ANCHOR)-"THE HEALIX ADVANCE KNOTLESS ANCHORS ARE INDICATED FOR USE IN THE FOLLOWING PROCEDURES FOR REATTACHMENT OF SOFT TISSUE TO BONE: BR: ROTATOR CUFF, BICEPS TENODESIS PEEK: ROTATOR CUFF, BICEPS TENODESIS", ANCHOR WITH SUTURE(GRYPHON PEEK ANCHOR WITH PROKNOT TECHNOLOGY)-" THE GRYPHON ANCHOR WITH PROKNOT TECHNOLOGY IS INTENDED FOR: SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR.,ANCHOR WITH SUTURE(FASTIN RC ANCHOR WITH ORTHOCORD)-"SHOULDER: BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, ROTATOR CUFF REPAIR, SLAP REPAIR FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS ELBOW: BICEPS TENDON REATTACHMENT, TENNIS ELBOW ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION" ,ANCHOR WITH SUTURE(GRYPHON BR ANCHOR WITH PROKNOT TECHNOLOGY)-"THE GRYPHON ANCHOR WITH PROKNOT TECHNOLOGY IS INTENDED FOR: SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR." ,ANCHOR WITH SUTURE(GRYPHON BR ANCHOR WITH ORTHOCORD)-"THE GRYPHON BR ANCHOR IS INTENDED FOR: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION;FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES

	TENDON REPAIR;KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS;ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION;HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR.,ANCHOR WITH SUTURE(HEALIX PEEK ANCHOR WITH ORTHOCORD)-THE HEALIX DUAL THREADED SUTURE ANCHOR IS INTENDED FOR: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION. FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS. ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION. HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR.,ANCHOR WITH SUTURE(HEALIX BR ANCHOR WITH ORTHOCORD)-"THE HEALIX BR ANCHOR IS INTENDED FOR: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION. FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS; ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION.",ANCHOR WITH SUTURE(MICRO QUICK ANCHOR PLUS WITH ETHIBOND)-THE DEPUY MITEK 1.3 MM MICRO QUICKANCHOR PLUS IS USED FOR THE FIXATION OF NON-ABSORBABLE BRAIDED POLYESTER SURGICAL SUTURE TO BONE. THIS PRODUCT IS INTENDED FOR THE INDICATIONS LISTED BELOW: HAND: REPAIR/RECONSTRUCTION OF COLLATERAL LIGAMENTS, FLEXOR AND EXTENSOR TENDON AT THE PIP (PROXIMAL INTERPHALANGEAL), DIP (DISTAL INTERPHALANGEAL), AND MCP (METACARPAL INTERPHALANGEAL) JOINTS FOR ALL DIGITS. SKULL: LATERAL CANTHOPLASTY,ANCHOR WITH SUTURE(HEALIX ADVANCE BR ANCHOR WITH PERMACORD)-THE HEALIX ADVANCE ANCHOR IS INDICATED FOR USE IN SOFT TISSUE TO BONE FIXATION IN ASSOCIATION WITH POST-OPERATIVE IMMOBILIZATION AS FOLLOWS: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION,

	FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS, ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR,SCREW(MILAGRO ADVANCE INTERFERENCE SCREW) -"KNEE: ATTACHMENT OF A BONE-TENDONBONE (BTB) GRAFT TO THE TIBIA AND/OR FEMUR DURING CRUCIATE LIGAMENT RECONSTRUCTION PROCEDURES, ATTACHMENT OF A SOFT TISSUE (ST) GRAFT TO THE TIBIA AND/OR FEMUR DURING CRUCIATE LIGAMENT RECONSTRUCTION PROCEDURES, MEDIAL AND LATERAL COLLATERAL LIGAMENT REPAIR, MEDIAL AND LATERAL COLLATERAL LIGAMENT REPAIR; SHOULDER: PROXIMAL BICEP TENODESIS, ELBOW: DISTAL BICEP TENODESIS.",ANCHOR WITH SUTURE(LUPINE ANCHOR WITH ORTHOCORD)-"THE LUPINE ANCHOR SYSTEM IS INDICATED FOR USE IN SOFT TISSUE TO BONE FIXATION IN ASSOCIATION WITH ADEQUATE POSTOPERATIVE IMMOBILIZATION AS FOLLOWS: OPEN PROCEDURES- SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ROTATOR CUFF REPAIR, CAPSULE SHIFT/CAPSULO-LABRAL RECONSTRUCTION, AT THE ANTERIOR GLENOID AT RIM SITE, CAPSULE SHIFT/CAPSULO-LABRAL RECONSTRUCTION AT THE LESSER TUBEROSITY OF THE HUMERUS, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION, DELTOID REPAIR ELBOW: BICEPS TENDON REATTACHMENT, TENNIS ELBOW REPAIR. ANKLE: ACHILLES TENDON REPAIR/RECONSTRUCTION, LATERAL STABILIZATION, MEDIAL STABILIZATION AT THE MEDIAL TALUS SITE; FOOT: HALLUX VALGUS RECONSTRUCTION, MIDFOOT RECONSTRUCTION. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, JOINT CAPSULE CLOSURE TO ANTERIOR PROXIMAL TIBIA, POSTERIOR OBLIQUE LIGAMENT OR JOINT CAPSULE TO TIBIA REPAIR, EXTRA CAPSULAR RECONSTRUCTION/ITB TENODESIS, PATELLAR LIGAMENT AND TENDON AVULSION REPAIRS. ARTHROSCOPIC PROCEDURES SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ROTATOR CUFF REPAIR, CAPSULE SHIFT REPAIR (GLENOID RIM)",ANCHOR WITH SUTURE(GII QUICK ANCHOR PLUS WITH ORTHOCORD)-THE DEPUY MITEK GII ANCHOR (QUICKANCHOR) IS INTENDED FOR FIXATION OF USP SIZE #2 SUTURE TO BONE FOR THE INDICATIONS LISTED BELOW. SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ACROMIO-CLAVICULAR SEPARATION, ROTATOR CUFF REPAIR, CAPSULE SHIFT/CAPSULO-LABRAL RECONSTRUCTION, BICEPS TENODESIS, DELTOID REPAIR. ANKLE: LATERAL INSTABILITY, MEDIAL INSTABILITY, ACHILLES TENDON REPAIR/RECONSTRUCTION,

	MIDFOOT RECONSTRUCTION. FOOT: HALLUX VALGUS RECONSTRUCTION. WRIST: SCAPHOLUNATE LIGAMENT. HAND: ULNAR OR LATERAL COLLATERAL LIGAMENT RECONSTRUCTION. ELBOW: TENNIS ELBOW REPAIR, BICEPS TENDON REATTACHMENT. KNEE: EXTRA CAPSULAR REPAIRS; REATTACHMENT OF: MEDIAL COLLATERAL LIGAMENT, LATERAL COLLATERAL LIGAMENT, POSTERIOR OBLIQUE LIGAMENT OR JOINT CAPSULE TO TIBIA AND JOINT CAPSULE CLOSURE TO ANTERIOR PROXIMAL TIBIA; EXTRA CAPSULAR RECONSTRUCTION, ITB TENODESIS; PATELLAR LIGAMENT AND TENDON AVULSIONS. ,ANCHOR(HEALIX ADVANCE KNOTLESS PEEK ANCHOR)-"THE HEALIX ADVANCE KNOTLESS ANCHORS ARE INDICATED FOR USE IN THE FOLLOWING PROCEDURES FOR REATTACHMENT OF SOFT TISSUE TO BONE: BR: ROTATOR CUFF, BICEPS TENODESIS PEEK: ROTATOR CUFF, BICEPS TENODESIS,SCREW (INTRAFIX SCREW)-THE DEPUY MITEK TIBIAL TAPERED SCREW AND TIBIAL SHEATH ARE INDICATED FOR FIXATION OF SOFT TISSUE GRAFTS DURING CRUCIATE LIGAMENT RECONSTRUCTION.,ANCHOR (GII ANCHOR)-SHOULDER: ACROMIO-CLAVICULAR; BANKART REPAIR; BICEPS TENODESIS; CAPSULE SHIFT/CAPSULOLABRAL RECONSTRUCTION; DELTOID REPAIR; ROTATOR CUFF REPAIR; SLAP LESION REPAIR. ANKLE: ACHILLES TENDON REPAIR/RECONSTRUCTION; LATERAL INSTABILITY; MEDIAL INSTABILITY; MIDFOOT RECONSTRUCTIONS. FOOT: HALLUX VALGUS RECONSTRUCTION. WRIST: SCAPHOLUNATE LIGAMENT RECONSTRUCTION. HAND: ULNAR OR LATERAL COLLATERAL LIGAMENT RECONSTRUCTION. ELBOW: BICEPS TENDON REATTACHMENT; TENNIS ELBOW REPAIR. KNEE: EXTRA CAPSULAR RECONSTRUCTION, ITB TENODESIS; LATERAL COLLATERAL LIGAMENT; PATELLAR LIGAMENT AND TENDON AVULSION REPAIRS; POSTERIOR OBLIQUE LIGAMENT OR JOINT CAPSULE TO TIBIA; JOINT CAPSULE CLOSURE TO ANTERIOR PROXIMAL TIBIA; MEDIAL COLLATERAL LIGAMENT. BNS: FIXATION IN PUBIC BONE FOR BLADDER NECK SUSPENSION USING USP #2 CLASS I NONABSORBABLE SYNTHETIC SUTURE (E.G. POLYPROPYLENE). A MINIMUM OF 2 ANCHORS SHOULD BE USED IN THIS PROCEDURE. , ANCHOR WITH SUTURE(MICRO QUICK ANCHOR PLUS WITH ORTHOCORD)-"THE DEPUY MITEK 1.3MM MICRO QUICKANCHOR PLUS IS USED FOR THE FIXATION OF NON-ABSORBABLE BRAIDED POLYESTER OR PARTIALLY ABSORBABLE BRAIDED COMPOSITE SURGICAL SUTURE TO BONE. THIS PRODUCT IS INTENDED FOR THE INDICATIONS LISTED BELOW: HAND: REPAIR/RECONSTRUCTION OF COLLATERAL LIGAMENTS, FLEXOR AND EXTENSOR TENDON AT THE PIP (PROXIMAL INTERPHALANGEAL), DIP (DISTAL INTERPHALANGEAL), AND MCP (METACARPAL INTERPHALANGEAL)

	JOINTS FOR ALL DIGITS. SKULL: LATERAL CANTHOPLASTY",ANCHOR (MINI ANCHOR)-SHOULDER: BANKART REPAIR; ANKLE: MIDFOOT RECONSTRUCTIONS; FOOT: HALLUX VALGUS RECONSTRUCTION; WRIST: SCAPHOLUNATE LIGAMENT RECONSTRUCTION; HAND: ULNAR OR LATERAL COLLATERAL LIGAMENT RECONSTRUCTION; PUBIS: FIXATION IN THE PUBIS FOR THE PURPOSE OF BLADDER NECK SUSPENSION FOR STRESS URINARY INCONTINENCE DUE TO URETHRAL OR BLADDER NECK HYPERMOBILITY, WITH MINIMAL OR NO CYSTOCELE. A MINIMUM OF 6 DEPUY MITEK ANCHORS SHOULD BE USED IN THE MODIFIED MMK PROCEDURE.,ANCHOR WITH SUTURE (GRYPHON PEEK ANCHOR WITH PERMACORD)-THE GRYPHON PEEK ANCHOR IS INDICATED FOR: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION, FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS, ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR,MENISCAL REPAIR SYSTEM(OMNISPAN MENISCAL REPAIR SYSTEM)-THE OMNISPAN SYSTEM IS INTENDED FOR USE IN THE ARTHROSCOPIC FIXATION OF SOFT TISSUE PROCEDURES SUCH AS MENISCAL REPAIR.,ANCHOR WITH SUTURE(MINI QUICK ANCHOR PLUS WITH ETHIBOND)-THE DEPUY MITEK MINI QUICKANCHOR PLUS IS INTENDED FOR FIXATION OF USP SIZE #0 THROUGH 2/0 SUTURE TO BONE FOR THE INDICATIONS LISTED BELOW. SHOULDER: BANKART REPAIR. ANKLE: MID-FOOT RECONSTRUCTION. FOOT: HALLUX VALGUS RECONSTRUCTION. HAND: ULNAR OR LATERAL COLLATERAL LIGAMENT RECONSTRUCTION. WRIST: SCAPHOLUNATE LIGAMENT RECONSTRUCTION. MAXILLOFACIAL: FOR THE REPAIR, REPOSITIONING OR REATTACHMENT OF SOFT TISSUES, LIGAMENT AND TENDONS TO THE MANDIBLE FOR SURGICAL STABILIZATION OF THE TMJ ARTICULAR DISC.,ANCHOR WITH SUTURE(HEALIX ADVANCE PEEK ANCHOR WITH PERMACORD)-THE HEALIX ADVANCE ANCHOR IS INDICATED FOR USE IN SOFT TISSUE TO BONE FIXATION IN ASSOCIATION WITH POST-OPERATIVE IMMOBILIZATION AS FOLLOWS: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION, FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL

	COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS, ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR,SHEATH(INTRAFIX SHEATH - TIBIAL)-THE DEPUY MITEK TIBIAL TAPERED SCREW AND TIBIAL SHEATH ARE INDICATED FOR FIXATION OF SOFT TISSUE GRAFTS DURING CRUCIATE LIGAMENT RECONSTRUCTION.,ANCHOR WITH SUTURE(GRYPHON BR ANCHOR WITH PERMACORD)-THE GRYPHON BR ANCHOR IS INDICATED FOR: SHOULDER: ROTATOR CUFF REPAIR, BANKART REPAIR, SLAP LESION REPAIR, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION REPAIR, DELTOID REPAIR, CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTION, FOOT/ANKLE: LATERAL STABILIZATION, MEDIAL STABILIZATION, ACHILLES TENDON REPAIR; KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, POSTERIOR OBLIQUE LIGAMENT REPAIR, ILIOTIBIAL BAND TENODESIS, ELBOW: BICEPS TENDON REATTACHMENT, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTION HIP: CAPSULAR REPAIR, ACETABULAR LABRAL REPAIR,SCREW(MILAGRO INTERFERENCE SCREW)-"THE DEPUY MITEK MILAGRO BR INTERFERENCE SCREWS ARE DESIGNED TO ATTACH SOFT TISSUES TO BONE IN ORTHOPEDIC SURGICAL PROCEDURES FOR THE FOLLOWING INDICATIONS: SHOULDER: PROXIMAL BICEPS TENODESIS, ACROMIO-CLAVICULAR REPAIR ELBOW: DISTAL BICEPS TENODESIS, ULNAR COLLATERAL LIGAMENT REPAIR KNEE: COLLATERAL LIGAMENT REPAIR",ANCHOR WITH SUTURE(MICRO QUICK ANCHOR PLUS WITH ORTHOCORD)-"THE DEPUY MITEK 1.3 MM MICRO QUICKANCHOR PLUS IS USED FOR THE FIXATION OF NON-ABSORBABLE BRAIDED POLYESTER SURGICAL SUTURE TO BONE. THIS PRODUCT IS INTENDED FOR THE INDICATIONS LISTED BELOW: HAND: REPAIR/RECONSTRUCTION OF COLLATERAL LIGAMENTS, FLEXOR AND EXTENSOR TENDON AT THE PIP (PROXIMAL INTERPHALANGEAL), DIP (DISTAL INTERPHALANGEAL), AND MCP (METACARPAL INTERPHALANGEAL) JOINTS FOR ALL DIGITS. SKULL: LATERAL CANTHOPLASTY",ANCHOR WITH SUTURE(MINI QUICK ANCHOR PLUS WITH ORTHOCORD)-"THE DEPUY MITEK MINI QUICKANCHOR PLUS IS INTENDED FOR FIXATION OF USP SIZE #0 THROUGH 2/0 SUTURE TO BONE FOR THE INDICATIONS LISTED BELOW. SHOULDER: BANKART REPAIR. ANKLE: MID-FOOT RECONSTRUCTION. FOOT: HALLUX VALGUS RECONSTRUCTION. HAND: ULNAR OR LATERAL COLLATERAL LIGAMENT RECONSTRUCTION. WRIST: SCAPHOLUNATE LIGAMENT RECONSTRUCTION",SCREW(MILAGRO INTERFERENCE SCREW)-"THE MITEK MILAGRO INTERFERENCE SCREW IS INTENDED FOR

	ATTACHMENT OF SOFT TISSUE GRAFTS OR BONE-TENDON-BONE GRAFTS TO THE TIBIA AND/OR FEMUR DURING CRUCIATE LIGAMENT RECONSTRUCTION PROCEDURES. ADDITIONALLY, THE 7, 8 AND 9 MM X 23 MM SCREWS WILL BE INDICATED FOR: MEDIAL AND LATERAL COLLATERAL LIGAMENT REPAIR OF THE KNEE, PROXIMAL BICEP TENODESIS IN THE SHOULDER AND DISTAL BICEP TENODESIS IN THE ELBOW.",SCREW(MILAGRO INTERFERENCE SCREW)-THE DEPUY MITEK MILAGRO INTERFERENCE SCREW IS INDICATED AS FOLLOWS - KNEE: ATTACHMENT OF A BONE-TENDON-BONE (BTB) GRAFT TO THE TIBIA AND/OR FEMUR DURING CRUCIATE LIGAMENT RECONSTRUCTION PROCEDURES, ATTACHMENT OF A SOFT TISSUE (ST) GRAFT TO THE TIBIA AND/OR FEMUR DURING CRUCIATE LIGAMENT RECONSTRUCTION PROCEDURES, MEDIAL AND LATERAL COLLATERAL LIGAMENT REPAIR. SHOULDER: PROXIMAL BICEP TENODESIS. ELBOW: DISTAL BICEP TENODESIS.,ANCHOR WITH SUTURE(MICROFIX QUICK ANCHOR PLUS WITH ETHIBOND)-"THE DEPUY MITEK MICROFIX QUICKANCHOR PLUS IS INTENDED FOR FIXATION OF SOFT TISSUE TO BONE, USING SUTURE, FOR THE INDICATIONS LISTED BELOW. HAND: REPAIR/RECONSTRUCTION OF COLLATERAL LIGAMENTS, FLEXOR AND EXTENSOR TENDON AT THE PIP (PROXIMAL INTERPHALANGEAL), DIP (DISTAL INTERPHALANGEAL), AND MCP (METACARPAL INTERPHALANGEAL) JOINTS FOR ALL DIGITS. SKULL: SOFT TISSUE ATTACHMENT TO THE PARIETAL, TEMPORAL RIDGE, FRONTAL, MANDIBLE, MAXILLA, ZYGOMA, AND PERIORBITAL BONES OF THE SKULL.",ANCHOR WITH SUTURE(LUPINE LOOP PLUS ANCHOR WITH ORTHOCORD)-"THE LUPINE ANCHOR SYSTEM IS INDICATED FOR USE IN SOFT TISSUE TO BONE FIXATION IN ASSOCIATION WITH ADEQUATE POSTOPERATIVE IMMOBILIZATION AS FOLLOWS: OPEN PROCEDURES- SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ROTATOR CUFF REPAIR, CAPSULE SHIFT/CAPSULO-LABRAL RECONSTRUCTION, AT THE ANTERIOR GLENOID AT RIM SITE, CAPSULE SHIFT/CAPSULO-LABRAL RECONSTRUCTION AT THE LESSER TUBEROSITY OF THE HUMERUS, BICEPS TENODESIS, ACROMIO-CLAVICULAR SEPARATION, DELTOID REPAIR ELBOW: BICEPS TENDON REATTACHMENT, TENNIS ELBOW REPAIR. ANKLE: ACHILLES TENDON REPAIR/RECONSTRUCTION, LATERAL STABILIZATION, MEDIAL STABILIZATION AT THE MEDIAL TALUS SITE; FOOT: HALLUX VALGUS RECONSTRUCTION, MIDFOOT RECONSTRUCTION. KNEE: MEDIAL COLLATERAL LIGAMENT REPAIR, LATERAL COLLATERAL LIGAMENT REPAIR, JOINT CAPSULE CLOSURE TO ANTERIOR PROXIMAL TIBIA, POSTERIOR OBLIQUE LIGAMENT OR JOINT CAPSULE TO TIBIA REPAIR, EXTRA CAPSULAR RECONSTRUCTION/ITB TENODESIS, PATELLAR LIGAMENT AND TENDON AVULSION REPAIRS. ARTHROSCOPIC PROCEDURES

		SHOULDER: BANKART REPAIR, SLAP LESION REPAIR, ROTATOR CUFF REPAIR, CAPSULE SHIFT REPAIR (GLENOID RIM)"
1770	IMP/MD/2019/000336	1.License Holder Name: SURGIPLUS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ELASTOMERIC INFUSION PUMP(DOSI-FUSER)-DOSI-FUSER IS DESIGNED TO PROVIDE PARENTERAL DRUG INFUSIONS AT A CONSTANT FLOW WITHOUT IMPEDING PATIENT MOBILITY,I.V. FLOW REGULATOR(DOSI-FLOW)-THE FLOW REGULATOR IS INDICATED FOR GRAVITY FEED INTRAVENOUS INFUSION OF PARENTERAL SOLUTIONS, ALLOWING SELECTION OF A DETERMINATED FLOW RATE (ML/H), WHICH MUST BE VERIFIED THROUGH A DRIP CHAMBER.
1771	IMP/MD/2019/000338	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CARDIOVASCULAR CATHETERS(CLIMBER GUIDING CATHETER)-THE GUIDING CATHETER IS DESIGNED TO PROVIDE A PATHWAY THROUGH WHICH THERAPEUTIC AND DIAGNOSTIC DEVICES ARE INTRODUCED. THE GUIDING CATHETER IS INTENDED TO BE USED IN THE CORONARY OR PERIPHERAL VASCULAR SYSTEM.
1772	IMP/MD/2019/000339	1.License Holder Name: SAHAJANAND MEDICAL TECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA CATHETER (TAMARIN BLUE)-FOR FURTHER MANUFACTURING USE ONLY,RX PTA CATHETER(EBONY 0.014)-FOR FURTHER MANUFACTURING USE ONLY

1773	IMP/MD/2019/000340	1.License Holder Name: ROMSONS SCIENTIFIC & SURGICAL INDUSTRIES PVT LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SILICON FOLEY CATHETER (NON STERILE) (TWO WAY & THREE WAY)(URETHERAL CATHETER)-SILICON FOLEY CATHETER IS USED FOR DRAINAGE OF URINE FROM THE URINARY TRACT AND/OR CONTINUOUS IRRIGATION OF FLUIDS. IT IS ALSO USED FOR PATIENTS SUFFERING FROM MOVING WITH DIFFICULTY OR BEING COMPLETELY BED RIDDEN. ,TRACHEOBRONCHIAL TUBE LEFT/RIGHT(NIL)-AN TRACHEOBRONCHIAL TUBE IS USED IN THORACIC SURGERY OR FOR ANESTHESIA DURING PULMONARY SURGERY, IT IS ALSO USED WHEN SELECTIVE COLLAPSE OR VENTILATION OF THE PULMONARY FIELD CAN ENHANCE SURGICAL EXPOSURE AND USED FOR CRITICALLY ILL PATIENTS WHO HAVE UNI-LATERAL LUNG DISEASE FROM PULMONARY CONTUSION.,LATEX FOLEY CATHETER (NON STERILE) (TWO WAY & THREE WAY)(URETHERAL CATHETER)-LATEX FOLEY CATHETER IS USED FOR DRAINAGE OF URINE AND MEDICATION. IT IS ALSO USED FOR PATIENTS SUFFERING FROM MOVING WITH DIFFICULTY OR BEING COMPLETELY BED RIDDEN. IT IS EASY TO USE RELIABLE IN PERFORMANCE AND IRRITATIONS ETC.
1774	IMP/MD/2019/000341	1.License Holder Name: ADHAR HEALTHCARE AND DEVICES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOLLICLE ASPIRATION NEEDLES/SET(FAS)-FOLLICLE ASPIRATION NEEDLES ARE USED FOR TRANS-VAGINAL HARVESTING OF OOCYTES FROM FOLLICLES FOR IVF (IN VITRO FERTILIZATION) AND ICSI (INTRA CYTOPLASMIC SPERM INJECTION).,EMBRYO TRANSFER CATHETER(EMTRAC SET)-INTRODUCTION OF EMBRYOS INTO THE UTERINE CAVITY,INTRA UTERINE INSEMINATION CANNULA(IUI)-INDICATED FOR INTRAUTERINE ARTIFICIAL INSEMINATION.,EMBRYO TRANSFER CATHETER(TULIP LS)-INTRODUCTION OF EMBRYOS INTO UTERINE CAVITY,EMBRYO TRANSFER CATHETER(EMTRAC C)-INTRODUCTION OF EMBRYOS INTO THE UTERINE CAVITY,EMBRYO TRANSFER CATHETER(EMTRAC DELPHIN)-INTRODUCTION OF EMBRYOS INTO THE UTERINE CAVITY.,EMBRYO TRANSFER CATHETER(TULIP L)-INTRODUCTION OF EMBRYOS INTO UTERINE CAVITY,EMBRYO TRANSFER CATHETER(TULIP S)-INTRODUCTION OF EMBRYOS INTO UTERINE CAVITY

1775	IMP/MD/2019/000343	1.License Holder Name: CALADRIUS MEDICAL PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOREIGN BODY FORCEPS, ENDOSCOPIC FORCEPS, HEMOSTASIS CLIP FOR ENDOSCOPY PROCEDURES(COUNTERTRACTION CLIP)-COUNTERTRACTION CLIP IS USED FOR GRASPING AND PULLING THE TISSUE TO WIDEN OPERATOR'S FIELD OF VIEW DURING THE PROCEDURE.,INTRA-AORTIC BALLOON CATHETER WITH INSERTION KIT(XEMEX IABP BALLOON PLUS)-THE XEMEX IABP BALLOON PLUS IS A BALLOON CATHETER SET,USED FOR BALLOON PUMPING IN THE AORTA TO ASSIST HEART FUNCTION IN CARDIOGENIC SHOCK OR LOW CARDIAC OUTPUT SYNDROME CASES.
1776	IMP/MD/2019/000343	1.License Holder Name: CALADRIUS MEDICAL PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BILARY STONE RETRIEVAL BALLOON CATHETER(XEMEX EXTRACTION BALLOON CATHETER)-THIS PRODUCT IS A CATHETER AIMED AT PERFORMING TREATMENTS SUCH AS STONE REMOVAL OR STONES EXTRACTION BY INSERTING THE DUODENAL PAPILLA INTO THE BILE DUCT. THIS PRODUCT IS A CATHETER USED FOR REMOVING BILIARY STONES BY INSERTING IT INTO THE BILE DUCT. THE CATHETER REMOVES STONES BY USING ORAL ENDOSCOPY. IT IS A TRIPLE-LUMEN CATHETER HAVING A BALLOON STRUCTURE AT THE DISTAL PART OF THE CATHETER FOR STONES REMOVAL.,HEMOSTASIS CLIP(XEMEX ZEOCLIP)-ZEOCLIP IS USED FOR GRASPING TISSUES AND FOREIGN SUBSTANCES, HEMOSTASIS, OCCLUSION OF A GASTROINTESTINAL PERFORATION (SUPPORTIVE TREATMENT), AND GASTROINTESTINAL MARKING.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

1777	IMP/MD/2019/000344	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINAL INTERBODY SYSTEMS(ALEUTIAN® INTERBODY SYSTEMS)-WHEN USED AS A CERVICAL INTERVERTEBRAL BODY FUSION DEVICE, THE ALEUTIAN IMPLANTS ARE INDICATED FOR SPINAL FUSION PROCEDURES TO BE USED WITH AUTOGENOUS BONE GRAFT IN SKELETALLY MATURE PATIENTS. CERVICAL IBF IMPLANTS ARE INTENDED FOR USE AT ONE LEVEL IN THE CERVICAL SPINE, FROM C2 TO T1, FOR THE TREATMENT OF CERVICAL DISC DISEASE (DEFINED AS NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES). THE CERVICAL DEVICE IS INTENDED TO BE USED IN PATIENTS WHO HAVE HAD SIX WEEKS OF NON-OPERATIVE TREATMENT. WHEN USED AS A LUMBAR INTERVERTEBRAL BODY FUSION DEVICE, THE ALEUTIAN IMPLANTS ARE INDICATED FOR SPINAL FUSION PROCEDURES TO BE USED WITH AUTOGENOUS BONE GRAFT IN SKELETALLY MATURE PATIENTS. THE LUMBAR IBF IMPLANTS ARE INTENDED FOR USE AT EITHER ONE LEVEL OR TWO CONTIGUOUS LEVELS IN THE LUMBAR SPINE, FROM L2 TO S1, FOR THE TREATMENT OF DEGENERATIVE DISC DISEASE (DDD) WITH UP TO GRADE 1 SPONDYLOLISTHESIS. DDD IS DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. THE LUMBAR DEVICE IS INTENDED TO BE USED IN PATIENTS WHO HAVE HAD SIX MONTHS OF NONOPERATIVE TREATMENT. WHEN USED AS VERTEBRAL BODY REPLACEMENT DEVICES THE ALEUTIAN IMPLANTS ARE INDICATED FOR USE IN THE THORACOLUMBAR SPINE (T1 TO L5) FOR PARTIAL REPLACEMENT (I.E., PARTIAL VERTEBRECTOMY) OF A DISEASED VERTEBRAL BODY, RESECTED OR EXCISED FOR THE TREATMENT OF TUMORS OR TRAUMA/FRACTURE IN ORDER TO ACHIEVE ANTERIOR DECOMPRESSION OF THE SPINAL CORD AND NEURAL TISSUES, AND TO RESTORE THE HEIGHT OF A COLLAPSED VERTEBRAL BODY. THE ALEUTIAN IMPLANTS ARE DESIGNED TO RESTORE THE BIOMECHANICAL INTEGRITY OF THE ANTERIOR, MIDDLE, AND POSTERIOR SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A PROLONGED PERIOD.,SPINAL FIXATION SYSTEM(MESA SPINAL SYSTEMS)-NON CERVICAL PEDICLE SCREW FIXATION DEVICE FOR POSTERIOR STABILIZATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS TRAUMA (I.E. FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E. SCOLIOSIS, KYPHOSIS; AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION. IT IS ALSO INDICATED FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADES 3 AND 4) OF THE L5-SL VERTEBRA IN SKELETALLY MATURE PATIENTS RECEIVING

	FUSION BY AUTOGENOUS BONE GRAFT HAVING IMPLANTS ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 TO SACRUM) WITH REMOVAL OF THE IMPLANTS AFTER THE ATTAINMENT OF A SOLID FUSION. NON-CERVICAL, NON-PEDICLE SPINAL FIXATION DEVICE INTENDED FOR POSTERIOR OR ANTEROLATERAL THORACOLUMBAR SCREW STABILIZATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E. FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E. SCOLIOSIS, KYPHOSIS; AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION.,CERVICAL FIXATION SYSTEMS(PYRENEES® CERVICAL PLATE SYSTEMS)-INDICATED FOR USE IN ANTERIOR SCREW FIXATION TO THE CERVICAL SPINE (C2-C7) FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (INCLUDING FRACTURES), SPINAL STENOSIS AND TUMORS (PRIMARY AND METASTATIC), FAILED PREVIOUS FUSIONS (PSEUDARTHROSIS) AND DEFORMITY (DEFINED AS SCOLIOSIS, KYPHOSIS OR LORDOSIS).,PEDICLE SCREW FIXATION DEVICE (DENALI® SPINAL SYSTEMS)-NON-CERVICAL, PEDICLE SCREW FIXATION DEVICES FOR POSTERIOR STABILIZATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: TRAUMA (I.E. FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E. SCOLIOSIS, KYPHOSIS; AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION. IT IS ALSO INDICATED FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADES 3 AND 4) OF THE L5-S1 VERTEBRA IN SKELETALLY MATURE PATIENTS RECEIVING FUSION BY AUTOGENOUS BONE GRAFT HAVING IMPLANTS ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 TO SACRUM) WITH REMOVAL OF THE IMPLANTS AFTER THE ATTAINMENT OF A SOLID FUSION. NON-CERVICAL, NON-PEDICLE SPINAL FIXATION DEVICES INTENDED FOR POSTERIOR OR ANTEROLATERAL THORACOLUMBAR SCREW STABILIZATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E. FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E. SCOLIOSIS, KYPHOSIS; AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION.,SPINAL

	FIXATION SYSTEM(MESA ®SPINAL SYSTEMS)-NON-CERVICAL, PEDICLE SCREW FIXATION DEVICES FOR POSTERIOR STABILIZATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: TRAUMA (I.E. FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E. SCOLIOSIS, KYPHOSIS; AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION. IT IS ALSO INDICATED FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADES 3 AND 4) OF THE L5- S1 VERTEBRA IN SKELETALLY MATURE PATIENTS RECEIVING FUSION BY AUTOGENOUS BONE GRAFT HAVING IMPLANTS ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 TO SACRUM) WITH REMOVAL OF THE IMPLANTS AFTER THE ATTAINMENT OF A SOLID FUSION. NON-CERVICAL, NON-PEDICLE SPINAL FIXATION DEVICES INTENDED FOR POSTERIOR OR ANTEROLATERAL THORACOLUMBAR SCREW STABILIZATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E. FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E. SCOLIOSIS, KYPHOSIS; AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION.,SPINAL INTERBODY SYSTEMS(ALEUTIAN® INTERBODY SYSTEMS)-PROCEDURES TO BE USED WITH AUTOGENOUS BONE GRAFT IN SKELETALLY MATURE PATIENTS. CERVICAL IBF IMPLANTS ARE INTENDED FOR USE AT ONE LEVEL IN THE CERVICAL SPINE, FROM C2 TO T1, FOR THE TREATMENT OF CERVICAL DISC DISEASE (DEFINED AS NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES). THE CERVICAL DEVICE IS INTENDED TO BE USED IN PATIENTS WHO HAVE HAD SIX WEEKS OF NON-OPERATIVE TREATMENT. WHEN USED AS A LUMBAR INTERVERTEBRAL BODY FUSION DEVICE, THE ALEUTIAN IMPLANTS ARE INDICATED FOR SPINAL FUSION PROCEDURES TO BE USED WITH AUTOGENOUS BONE GRAFT IN SKELETALLY MATURE PATIENTS. THE LUMBAR IBF IMPLANTS ARE INTENDED FOR USE AT EITHER ONE LEVEL OR TWO CONTIGUOUS LEVELS IN THE LUMBAR SPINE, FROM L2 TO S1, FOR THE TREATMENT OF DEGENERATIVE DISC DISEASE (DDD) WITH UP TO GRADE 1 SPONDYLOLISTHESIS. DDD IS DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. THE LUMBAR DEVICE IS INTENDED TO BE USED IN PATIENTS WHO HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. WHEN USED AS VERTEBRAL BODY REPLACEMENT DEVICES THE ALEUTIAN IMPLANTS ARE INDICATED FOR USE IN THE THORACOLUMBAR SPINE (T1 TO L5) FOR PARTIAL

	REPLACEMENT (I.E., PARTIAL VERTEBRECTOMY) OF A DISEASED VERTEBRAL BODY, RESECTED OR EXCISED FOR THE TREATMENT OF TUMORS OR TRAUMA/FRACTURE IN ORDER TO ACHIEVE ANTERIOR DECOMPRESSION OF THE SPINAL CORD AND NEURAL TISSUES, AND TO RESTORE THE HEIGHT OF A COLLAPSED VERTEBRAL BODY. THE ALEUTIAN IMPLANTS ARE DESIGNED TO RESTORE THE BIOMECHANICAL INTEGRITY OF THE ANTERIOR, MIDDLE, AND POSTERIOR SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A PROLONGED PERIOD.,SPINAL PLATE SYSTEMS(CAYMAN® PLATE SYSTEMS)-THE CAYMAN BUTTRESS PLATES ARE INTENDED FOR USE IN SPINAL FUSION PROCEDURES AS A MEANS TO MAINTAIN THE RELATIVE POSITION OF WEAK BONY TISSUE SUCH AS ALLOGRAFTS OR AUTOGRAFTS. THE DEVICE IS NOT INTENDED FOR LOAD BEARING INDICATIONS. THE CAYMAN THORACOLUMBAR PLATES ARE INDICATED FOR USE VIA THE LATERAL OR ANTEROLATERAL SURGICAL APPROACH IN THE TREATMENT OF THORACIC AND THORACOLUMBAR (T1-L5) SPINE AND FOR USE AS AN ANTERIORLY PLACED SUPPLEMENTAL FIXATION DEVICE FOR THE LUMBOSACRAL LEVEL BELOW THE BIFURCATION OF THE VASCULAR STRUCTURES (L5-S1). THE CAYMAN THORACOLUMBAR PLATE SYSTEM IS INTENDED TO PROVIDE TEMPORARY STABILIZATION DURING FUSION USING AUTOGRAPH OR ALLOGRAFT IN SKELETALLY MATURE PATIENTS IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES AND DEFORMITIES: A) DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), B) PSEUDOARTHROSIS, C) SPONDYLOLYSIS, D) SPONDYLOLISTHESIS, E) FRACTURE, F) NEOPLASTIC DISEASE, G) UNSUCCESSFUL PREVIOUS FUSION SURGERY, H) LORDOTIC DEFORMITIES OF THE SPINE, I) THORACOLUMBAR OR LUMBAR SCOLIOSIS, J) DEFORMITY (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS) ASSOCIATED WITH DEFICIENT POSTERIOR ELEMENTS SUCH AS THAT RESULTING FROM LAMINECTOMY.,PEDICLE SCREW FIXATION DEVICE(DENALI® SPINAL SYSTEMS)-NON-CERVICAL, PEDICLE SCREW FIXATION DEVICES FOR POSTERIOR STABILIZATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: TRAUMA (I.E. FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E. SCOLIOSIS, KYPHOSIS; AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION. IT IS ALSO INDICATED FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADES 3 AND 4) OF THE L5-S1 VERTEBRA IN SKELETALLY MATURE PATIENTS RECEIVING FUSION BY AUTOGENOUS BONE GRAFT HAVING IMPLANTS ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 TO SACRUM) WITH REMOVAL OF

	THE IMPLANTS AFTER THE ATTAINMENT OF A SOLID FUSION. NON-CERVICAL, NON-PEDICLE SPINAL FIXATION DEVICES INTENDED FOR POSTERIOR OR ANTEROLATERAL THORACOLUMBAR SCREW STABILIZATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E. FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E. SCOLIOSIS, KYPHOSIS; AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION.,CERVICAL FIXATION SYSTEMS(BLUE RIDGE™ CERVICAL PLATE SYSTEMS)-INDICATED FOR USE IN ANTERIOR SCREW FIXATION TO THE CERVICAL SPINE (C2-C7) FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (INCLUDING FRACTURES), SPINAL STENOSIS AND TUMORS (PRIMARY AND METASTATIC), FAILED PREVIOUS FUSIONS (PSEUDARTHROSIS) AND DEFORMITY (DEFINED AS SCOLIOSIS, KYPHOSIS OR LORDOSIS).,SPINAL FIXATION SYSTEM (MESA ®SPINAL SYSTEMS)-NON-CERVICAL, PEDICLE SCREW FIXATION DEVICES FOR POSTERIOR STABILIZATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: TRAUMA (I.E. FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E. SCOLIOSIS, KYPHOSIS; AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION. IT IS ALSO INDICATED FOR THE TREATMENT OF SEVERE SPONDYLOLISTHESIS (GRADES 3 AND 4) OF THE L5- S1 VERTEBRA IN SKELETALLY MATURE PATIENTS RECEIVING FUSION BY AUTOGENOUS BONE GRAFT HAVING IMPLANTS ATTACHED TO THE LUMBAR AND SACRAL SPINE (L3 TO SACRUM) WITH REMOVAL OF THE IMPLANTS AFTER THE ATTAINMENT OF A SOLID FUSION. NON-CERVICAL, NON-PEDICLE SPINAL FIXATION DEVICES INTENDED FOR POSTERIOR OR ANTEROLATERAL THORACOLUMBAR SCREW STABILIZATION AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E. FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E. SCOLIOSIS, KYPHOSIS; AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION.

1778	IMP/MD/2019/000345	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRANSCATHETER HEART VALVE(PORTICO™ TRANSCATHETER HEART VALVE)-THE PORTICO™ VALVE IS INDICATED FOR TRANSCATHETER DELIVERY IN PATIENTS WITH SYMPTOMATIC SEVERE NATIVE AORTIC STENOSIS WHO ARE CONSIDERED HIGH SURGICAL RISK.,HEART VALVE(EPIC VALVE MITRAL)-EPIC VALVES ARE INDICATED FOR PATIENTS REQUIRING REPLACEMENT OF A DISEASED, DAMAGED, OR MALFUNCTIONING NATIVE MITRAL HEART VALVE. EPIC VALVES MAY ALSO BE USED AS REPLACEMENTS FOR PREVIOUSLY IMPLANTED MITRAL PROSTHETIC HEART VALVES.,HEART VALVE(EPIC SUPRA VALVE AORTIC)-THE EPIC SUPRA VALVE IS INDICATED FOR PATIENTS REQUIRING REPLACEMENT OF A DISEASED, DAMAGED, OR MALFUNCTIONING NATIVE AORTIC HEART VALVE. THE EPIC SUPRA VALVE MAY ALSO BE USED AS A REPLACEMENT FOR A PREVIOUSLY IMPLANTED AORTIC PROSTHETIC HEART VALVES.,TISSUE HEART VALVE(TRIFECTA VALVE AORTIC)-THE TRIFECTA VALVE IS INTENDED AS A REPLACEMENT FOR A DISEASED, DAMAGED, OR MALFUNCTIONING AORTIC HEART VALVE. THE TRIFECTA VALVE MAY ALSO BE USED AS REPLACEMENT FOR A PREVIOUSLY IMPLANTED AORTIC PROSTHETIC HEART VALVES. , TISSUE HEART VALVE(TRIFECTA VALVE WITH GLIDE TECHNOLOGY AORTIC)-THE VALVE IS INTENDED AS A REPLACEMENT FOR A DISEASED, DAMAGED, OR MALFUNCTIONING AORTIC HEART VALVE. THE VALVE MAY ALSO BE USED AS REPLACEMENT FOR A PREVIOUSLY IMPLANTED AORTIC PROSTHETIC HEART VALVES, HEART VALVE(EPIC VALVE AORTIC)-EPIC VALVES ARE INDICATED FOR PATIENTS REQUIRING REPLACEMENT OF A DISEASED, DAMAGED, OR MALFUNCTIONING NATIVE AORTIC HEART VALVE. EPIC VALVES MAY ALSO BE USED AS REPLACEMENTS FOR PREVIOUSLY IMPLANTED AORTIC PROSTHETIC HEART VALVES

1779	IMP/MD/2019/000346	1.License Holder Name: OLYMPUS MEDICAL SYSTEMS INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BALLOON DILATATION CATHETER(EZDILATE-FIXED WIRE)-THE EZDILATE FIXED WIRE BALLOON IS RECOMMENDED FOR ENDOSCOPIC DILATION OF STRICTURES OF THE ESOPHAGUS IN ADULTS AND ADOLESCENT (>12YEARS).,BALLOON DILATATION CATHETER(EZDILATE-WIRE GUIDED)-THE EZDILATE 3-STAGE BALLOON DILATATION CATHETERS ARE INDICATED FOR USE IN ADULT AND ADOLESCENT (>12YEARS) POPULATIONS TO ENDOSCOPICALLY DILATE STRICTURES OF THE ALIMENTARY TRACT. IT IS ALSO INDICATED IN ADULTS FOR ENDOSCOPIC DILATATION OF THE SPHINCTER OF ODDI WITH OR WITHOUT PRIOR SPHINCTEROTOMY.
1780	IMP/MD/2019/000347	1.License Holder Name: ENVISION SCIENTIFIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA CATHETER(MAYA NC)-IT IS INTENDED TO DILATE A STENOTIC PORTION OF A NATIVE CORONARY ARTERY OR A BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION AND ALSO AND TO BE USED FOR POST-DILATION OF STENTS. MAYA NC CATHETER IS NOT INTENDED TO BE USED AS A DELIVERY SYSTEM FOR BALLOON EXPANDABLE STENT.
1781	IMP/MD/2019/000348	1.License Holder Name: HEMANT SURGICAL INDUSTRIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:A.V. FISTULA NEEDLE SET (JMS A. V FISTULA SET)-IT IS INTENDED FOR USE IN PART OF THE HEMODIALYSIS PROCEDURE, AS A BLOOD ACCESS DEVICE, FOR DRAWING BLOOD AWAY FOR FILTRATION AND RETURNING CLEAN BLOOD TO THE PATIENTS.,SCALP VEIN SET(JMS SCALP VEIN SET)-IT IS INTRODUCED INTO THE PERIPHERAL VENOUS ACCESS FOR SHORT TERMS INFUSIONS, INJECTIONS, AND ADMINISTRATION OF DRUGS, BLOOD SAMPLING AND TRANSFUSION VIA INTRAVENOUS ROUTES, BLOOD TUBING SET(JMS BLOOD TUBING SET)-IT IS INTENDED TO PROVIDE EXTRACORPOREAL ACCESS TO THE PATIENTS BLOOD DURING HEMODIALYSIS,TRANSFUSION SET(JMS TRANSFUSION SET)-IT IS INTENDED TO TRANSFUSE FILTERED BLOOD AND THEIR DERIVATIVES FROM BLOOD BOTTLES OR PACKS INTO THE PATIENTS VEINS,INFUSION SET(JMS INFUSION SET)-IT IS INTENDED FOR THE DELIVERY OF FLUID (MEDICATION AND NUTRIENTS) TO PATIENTS VIA AN INTRAVENOUS ROUTE

1782	IMP/MD/2019/000349	1.License Holder Name: BAUSCH & LOMB INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYDROPHOBIC INTRAOCULAR LENS(ENVISTA WITH BAUSCH + LOMB SIMPLIFEYE PRELOADED DELIVERY SYSTEM)-THE ENVISTA ONE-PIECE HYDROPHOBIC ACRYLIC IOL IS INDICATED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG OF THE EYE IN ADULT PATIENTS FOR VISUAL CORRECTION OF APHAKIA FOLLOWING REMOVAL OF A CATARACTOUS LENS FOR IMPROVED UNCORRECTED DISTANCE VISION. ,MICRO INCISION INTRA OCULAR LENS (ULTRAVIOLET LIGHT ABSORBING)(AKREOS AO)-THE AKREOS POSTERIOR CHAMBER LENS IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN PATIENTS WHERE A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS. THE LENS IS DESIGNED FOR IMPLANTATION IN THE CAPSULAR BAG FOLLOWING EXTRA CAPSULAR CATARACT EXTRACTION.,HYDROPHOBIC ACRYLIC INTRA OCULAR LENS(ENVISTA)-INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM THE CATARACTOUS LENS HAS BEEN REMOVED BY AN EXTRACAPSULAR CATARACT EXTRACTION METHOD. THE LENS IS INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,HYDROPHOBIC ACRYLIC INTRA OCULAR LENS (ONE PIECE)(ENVISTA TORIC)-INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH PRE - EXISTING CORNEAL ASTIGMATISM IN ADULTS PATIENTS IN WHOM THE CATARACTOUS LENS HAS BEEN REMOVED BY AN EXTRACAPSULAR CATARACT EXTRACTION METHOD. THE LENS IS INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,ASPHERIC INTRA OCULAR LENS (ULTRAVIOLET LIGHT ABSORBING)(SOFPORT)-INTENDED TO BE USED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM THE CATARACTOUS LENS HAS BEEN REMOVED BY AN EXTRACAPSULAR CATARACT EXTRACTION METHOD. THEY ARE INTENDED FOR PLACEMENT IN THE CILIARY SULCUS OR CAPSULAR BAG.,ASPHERIC INTRA OCULAR LENS (ULTRAVIOLET LIGHT ABSORBING)(AKREOS ADVANCED OPTICS ASPHERIC LENS)-THE AKREOS POSTERIOR CHAMBER LENS IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN PATIENTS WHERE A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS. THE LENS IS DESIGNED FOR IMPLANTATION IN THE CAPSULAR BAG FOLLOWING EXTRA CAPSULAR CATARACT EXTRACTION.

1783	IMP/MD/2019/000350	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VERTEBROPLASTY NEEDLE KIT-THE “VERTEBROPLASTY NEEDLE KIT” IS INTENDED TO BE USED TO INJECT PMMA CEMENT INTO VERTEBRAL BODIES DURING VERTEBROPLASTY PROCEDURES. THE “VERTEBROPLASTY NEEDLE KIT“IS INTENDED TO BE USED IN CONJUNCTION WITH THE VERTECEM / VERTECEM V+ SYSTEM.,BIOPSY KIT-THE BIOPSY KIT IS DESIGNED FOR TAKING VERTEBRAL BODY BONE BIOPSIES. THE VERTEBROPLASTY BIOPSY KIT IS INTENDED TO ONLY BE USED IN COMBINATION WITH THE VERTEBROPLASTY NEEDLE OF THE VERTECEM / VERTECEM V+ SYSTEM.
1784	IMP/MD/2019/000350	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED ,A-1/50, ROOM NO. 2, 100 SHED AREA, G.L.D.C., VAPI, TAL PARDI (VALSAD) , VALSAD GUJARAT ,396195 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEEDLE KIT (TRAUMACEM)-THE TRAUMA NEEDLE KIT IS DESIGNED FOR THE AUGMENTATION OF SUITABLE SYNTHES GMBH IMPLANTS UTILIZED FOR THE INJECTION OF TRAUMACEM V+ CEMENT IN THE PROXIMAL FEMUR REGION. THE TRAUMA NEEDLE KIT MAY ONLY BE USED WITH SYNTHES GMBH TRAUMA AUGMENTATION SYSTEMS.
1785	IMP/MD/2019/000351	1.License Holder Name: NOVOMED INCORPORATION PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUTURE(GORE-TEX®)-THE GORE-TEX® SUTURE IS INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN CARDIOVASCULAR SURGERY. IT IS RECOMMENDED FOR USE WHERE REDUCED SUTURE LINE BLEEDING DURING CARDIOVASCULAR ANASTOMOTIC PROCEDURES IS DESIRED.

1786	IMP/MD/2019/000352	1.License Holder Name: BL LIFESCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASCENDING AORTIC PROSTHESIS(ON-X)-REPLACEMENT OF A DISEASED, DAMAGED, OR MALFUNCTIONING NATIVE OR PROSTHETIC HEART VALVE IN THE AORTIC POSITION IN CASES THAT INVOLVE AN ASCENDING AORTIC ANEURYSM OR OTHER ASSOCIATED AORTIC DISEASE.,PROSTHETIC AORTIC HEART VALVE WITH ANATOMIC SEWING RING(ON-X)-REPLACEMENT OF DISEASED, DAMAGED, OR MALFUNCTIONING NATIVE OR PROSTHETIC HEART VALVE IN THE AORTIC AND MITRAL POSITIONS.
1787	IMP/MD/2019/000353	1.License Holder Name: ACE CARDIOPATHY SOLUTIONS PRIVATE LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:A STERILE SINGLE-USE FILLING ADAPTOR(COMFORT-IN™)-THIS ADAPTOR ALLOWS THE NEEDLE FREE SYRINGE/NOZZLE TO BE FILLED WITH MEDICINE OR VACCINE FROM THE MEDICINE OR VACCINE STORAGE VIALS. ,A DISPOSABLE SINGLE USE STERILE 0.5 ML NEEDLE-FREE NOZZLE (SYRINGE)(COMFORT-IN)-THE NEEDLE-FREE NOZZLE (SYRINGE) IS A SINGLE USE, TRANSPARENT, DISPOSABLE CONTAINER CONSISTING OF A BARREL TO HOLD 0.5 ML OF MEDICINE OR VACCINE, A PLUNGER TO DISCHARGE THE MEDICINE OR VACCINE THROUGH A SMALL DIAMETER ORIFICE,NEEDLE-FREE SOFT INJECTION SYSTEM (COMFORT-IN)- NEEDLE-FREE SOFT INJECTION SYSTEM IS INTENDED TO DELIVER 0.5ML VOLUMES OF VARIOUS MEDICATIONS AND VACCINES SUBCUTANEOUSLY-(SC) TO ALL PEOPLE OF ALL AGES INCLUDING PATIENTS AUTHORIZED BY THEIR PHYSICIANS TO SELF-INJECT.
1788	IMP/MD/2019/000354	1.License Holder Name: MICRO MEDICAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BALLOON CATHETER FOR PERCUTANEOUS TRANSVENOUS MITRAL COMMISSUROTOMY(INOUE-BALLOON)-THE IBC IS INDICATED FOR PERCUTANEOUS TRANSVENOUS MITRAL COMMISSUROTOMY IN PATIENTS WITH MITRAL STENOSIS.

1789	IMP/MD/2019/000355	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRANSCATHETER AORTIC VALVE (TAV)(COREVALVE EVOLUT R)-THE COREVALVE™ EVOLUT™ R SYSTEM IS INDICATED FOR PATIENTS WITH SYMPTOMATIC NATIVE AORTIC VALVE STENOSIS OR A STENOSED, INSUFFICIENT, OR COMBINED SURGICAL BIOPROSTHETIC VALVE FAILURE NECESSITATING VALVE REPLACEMENT. THE SYSTEM IS INDICATED FOR PATIENTS WHO ARE AT HIGH OR GREATER RISK FOR SURGICAL AORTIC VALVE REPLACEMENT OR ARE GREATER THAN OR EQUAL TO 75 YEARS OF AGE AND AT INTERMEDIATE RISK FOR SURGICAL AVR (SOCIETY OF THORACIC SURGEONS OPERATIVE RISK SCORE GREATER THAN OR EQUAL TO 4% OR WITH AN ESTIMATED HOSPITAL MORTALITY GREATER THAN OR EQUAL TO 4% AS ASSESSED BY THE HEART TEAM).,TRANSCATHETER AORTIC VALVE(COREVALVE EVOLUT PRO)-THE COREVALVE EVOLUT PRO SYSTEM IS INDICATED FOR PATIENTS WITH SYMPTOMATIC NATIVE AORTIC VALVE STENOSIS OR A STENOSED, INSUFFICIENT, OR COMBINED SURGICAL BIOPROSTHETIC VALVE FAILURE NECESSITATING VALVE REPLACEMENT. THE SYSTEM IS INDICATED FOR PATIENTS WHO ARE AT HIGH RISK OR GREATER RISK FOR SURGICAL AORTIC VALVE REPLACEMENT OR ARE 75 YEARS OF AGE AND AT INTERMEDIATE RISK FOR SURGICAL AVR (SOCIETY OF THORACIC SURGEONS OPERATIVE RISK SCORE 4% OR WITH AN ESTIMATED HOSPITAL MORTALITY 4% AS ASSESSED BY THE HEART TEAM)

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1790	IMP/MD/2019/000356	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOTRACHEAL TUBE (NIM FLEX EMG)(NIM FLEX EMG ENDOTRACHEAL TUBE)-THE EMG ENDOTRACHEAL TUBE IS INTENDED FOR USE AS A MEANS OF PROVIDING BOTH AN OPEN AIRWAY FOR PATIENT VENTILATION AND FOR INTRAOPERATIVE MONITORING OF EMG ACTIVITY OF THIS INTRINSIC LARYNGEAL MUSCULATURE WHEN CONNECTED TO AN APPROPRIATE EMG MONITOR. THE EMG TUBE IS INDICATED FOR USE WHERE CONTINUOUS MONITORING OF THE NERVES SUPPLYING THE LARYNGEAL MUSCULATURE IS REQUIRED DURING SURGICAL PROCEDURES. THE EMG TUBE IS NOT INTENDED FOR POSTOPERATIVE USE.,NUVENT™ EM SINUS DILATION SYSTEM FRONTAL(NUVENT)-THE NUVENT EM SINUS DILATION SYSTEM IS INTENDED FOR USE IN SINUS PROCEDURES WHEN SURGICAL NAVIGATION OR IMAGE-GUIDED SURGERY MAY BE NECESSARY TO LOCATE AND MOVE TISSUE, BONE OR CARTILAGINOUS TISSUE SURROUNDING THE DRAINAGE PATHWAYS OF THE FRONTAL, MAXILLARY, AND SPHENOID SINUSES. THE EM SINUS DILATION SYSTEM IS USED IN CONJUNCTION WITH THE MEDTRONIC COMPUTER-ASSISTED SURGERY SYSTEM.THE MEDTRONIC COMPUTER-ASSISTED SURGERY SYSTEM AND ITS ASSOCIATED APPLICATIONS ARE INTENDED AS AN AID FOR PRECISELY LOCATING ANATOMICAL STRUCTURES IN EITHER OPEN OR PERCUTANEOUS PROCEDURES. THEIR USE IS INDICATED FOR ANY MEDICAL CONDITION IN WHICH THE USE OF STEREOTACTIC SURGERY MAY BE APPROPRIATE, AND WHERE REFERENCE TO A RIGID ANATOMICAL STRUCTURE, SUCH AS THE SKULL, CAN BE IDENTIFIED RELATIVE TO A CT- OR MR-BASED MODEL, OR DIGITIZED LANDMARKS OF THE ANATOMY.THE SYSTEM AND ITS ASSOCIATED APPLICATIONS SHOULD BE USED ONLY AS AN ADJUNCT FOR SURGICAL GUIDANCE. THEY DO NOT REPLACE THE SURGEON'S KNOWLEDGE, EXPERTISE, OR JUDGMENT.,NUVENT™ EM SINUS DILATION SYSTEM SPHENOID (NUVENT)-THE NUVENT EM SINUS DILATION SYSTEM IS INTENDED FOR USE IN SINUS PROCEDURES WHEN SURGICAL NAVIGATION OR IMAGE-GUIDED SURGERY MAY BE NECESSARY TO LOCATE AND MOVE TISSUE, BONE OR CARTILAGINOUS TISSUE SURROUNDING THE DRAINAGE PATHWAYS OF THE FRONTAL, MAXILLARY, AND SPHENOID SINUSES. THE EM SINUS DILATION SYSTEM IS USED IN CONJUNCTION WITH THE MEDTRONIC COMPUTER-ASSISTED SURGERY SYSTEM.THE MEDTRONIC COMPUTER-ASSISTED SURGERY SYSTEM AND ITS ASSOCIATED APPLICATIONS ARE INTENDED AS AN AID FOR PRECISELY LOCATING ANATOMICAL STRUCTURES IN EITHER OPEN OR PERCUTANEOUS PROCEDURES. THEIR USE IS INDICATED

	FOR ANY MEDICAL CONDITION IN WHICH THE USE OF STEREOTACTIC SURGERY MAY BE APPROPRIATE, AND WHERE REFERENCE TO A RIGID ANATOMICAL STRUCTURE, SUCH AS THE SKULL, CAN BE IDENTIFIED RELATIVE TO A CT- OR MR-BASED MODEL, OR DIGITIZED LANDMARKS OF THE ANATOMY.THE SYSTEM AND ITS ASSOCIATED APPLICATIONS SHOULD BE USED ONLY AS AN ADJUNCT FOR SURGICAL GUIDANCE. THEY DO NOT REPLACE THE SURGEON'S KNOWLEDGE, EXPERTISE, OR JUDGMENT.,NUVENT™ EM SINUS DILATION SYSTEM MAXILLARY(NUVENT)-THE NUVENT EM SINUS DILATION SYSTEM IS INTENDED FOR USE IN SINUS PROCEDURES WHEN SURGICAL NAVIGATION OR IMAGE-GUIDED SURGERY MAY BE NECESSARY TO LOCATE AND MOVE TISSUE, BONE OR CARTILAGINOUS TISSUE SURROUNDING THE DRAINAGE PATHWAYS OF THE FRONTAL, MAXILLARY, AND SPHENOID SINUSES. THE EM SINUS DILATION SYSTEM IS USED IN CONJUNCTION WITH THE MEDTRONIC COMPUTER-ASSISTED SURGERY SYSTEM.THE MEDTRONIC COMPUTER-ASSISTED SURGERY SYSTEM AND ITS ASSOCIATED APPLICATIONS ARE INTENDED AS AN AID FOR PRECISELY LOCATING ANATOMICAL STRUCTURES IN EITHER OPEN OR PERCUTANEOUS PROCEDURES. THEIR USE IS INDICATED FOR ANY MEDICAL CONDITION IN WHICH THE USE OF STEREOTACTIC SURGERY MAY BE APPROPRIATE, AND WHERE REFERENCE TO A RIGID ANATOMICAL STRUCTURE, SUCH AS THE SKULL, CAN BE IDENTIFIED RELATIVE TO A CT- OR MR-BASED MODEL, OR DIGITIZED LANDMARKS OF THE ANATOMY.THE SYSTEM AND ITS ASSOCIATED APPLICATIONS SHOULD BE USED ONLY AS AN ADJUNCT FOR SURGICAL GUIDANCE. THEY DO NOT REPLACE THE SURGEON'S KNOWLEDGE, EXPERTISE, OR JUDGMENT.

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1791	IMP/MD/2019/000357	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAPLES LOADING UNIT (EEA™ AUTO SUTURE™ HEMORRHOID AND PROLAPSE STAPLER WITH DST SERIES TECHNOLOGY)-THE EEA™ HEMORRHOID AND PROLAPSE STAPLER SET WITH DST SERIES™ TECHNOLOGY HAS APPLICATION THROUGHOUT THE ANAL CANAL TO PERFORM SURGICAL TREATMENT OF HEMORRHOIDAL DISEASE, ALSO HAS APPLICATION IN THE DISTAL ALIMENTARY TRACT FOR THE CREATION OF END-TO-END AND END-TO-SIDE ANASTOMOSES.,CLIPS WITH CLIP APPLIER (ENDO CLIP AUTO SUTURE CLIP APPLIER)-THE ENDO CLIPR .. 5MM CLIP APPLIER HAS APPLICATIONS IN ENDOSCOPIC PROCEDURES TO ACHIEVE OCCLUSION OF VESSELS AND OTHER TUBULAR STRUCTURE AND FOR RADIOGRAPHIC MARKINGS.,LOADING UNIT(ENDO GIA™ AUTO SUTURE™ (GRAY/UNIVERSAL ARTICULATING LOADING UNIT))-ENDO GIA™ AUTO SUTURE UNIVERSAL STAPLER HAVE APPLICATIONS IN ABDOMINAL, GYNECOLOGIC AND THORACIC SURGERY FOR RESECTION AND TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS.

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1792	IMP/MD/2019/000358	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GLUCOSE SENSOR (GUARDIAN SENSOR (3))-THE SENSOR IS INTENDED FOR USE WITH GUARDIAN LINK (3) AND GUARDIAN CONNECT TRANSMITTERS TO CONTINUOUSLY MONITOR GLUCOSE LEVELS IN PERSONS WITH DIABETES.,AMBULATORY INSULIN INFUSION PUMP(PARADIGM 715 INSULIN PUMP)-THE PARADIGM 515/715 PUMP SYSTEM IS INDICATED FOR THE CONTINUOUS DELIVERY OF INSULIN, AT SET AND VARIABLE RATES, FOR THE MANAGEMENT OF DIABETES MELLITUS IN PERSONS REQUIRING INSULIN.,AMBULATORY INSULIN INFUSION PUMP (MINIMED 780G INSULIN PUMP AND PUMP KIT)-THE MINIMED 780G INSULIN PUMP IS INDICATED FOR USE BY PATIENTS AGE 7-80 YEARS WITH TYPE 1 DIABETES, WHOSE TOTAL DAILY DOSE OF INSULIN IS 8 UNITS PER DAY OR MORE. THE MINIMED 780G SYSTEM IS INTENDED FOR THE CONTINUOUS DELIVERY OF BASAL INSULIN AT SELECTABLE RATES, AND THE ADMINISTRATION OF INSULIN BOLUSES AT SELECTABLE AMOUNTS. THE SYSTEM IS ALSO INTENDED TO CONTINUOUSLY MONITOR GLUCOSE VALUES IN THE FLUID UNDER THE SKIN. THE MINIMED 780G SYSTEM INCLUDES SMARTGUARD TECHNOLOGY, WHICH CAN BE PROGRAMMED TO PROVIDE AN AUTOMATIC ADJUSTMENT OF INSULIN DELIVERY BASED ON CONTINUOUS GLUCOSE MONITORING (CGM) AND CAN SUSPEND THE DELIVERY OF INSULIN WHEN THE SG VALUE FALLS BELOW, OR IS PREDICTED TO FALL BELOW, PREDEFINED THRESHOLD VALUES., AMBULATORY INSULIN INFUSION PUMP(PARADIGM 722 INSULIN PUMP)-THE PARADIGM 522/722 PUMP SYSTEMS ARE INDICATED FOR THE CONTINUOUS DELIVERY OF INSULIN AT SET AND VARIABLE RATES, FOR THE MANAGEMENT OF DIABETES MELLITUS IN PERSONS REQUIRING INSULIN. IN ADDITION, THE PUMP SYSTEM IS INDICATED FOR CONTINUOUS OR PERIODIC MONITORING OF GLUCOSE LEVELS IN THE FLUID UNDER THE SKIN, AND POSSIBLE LOW AND HIGH BLOOD GLUCOSE EPISODES. THE PUMP DISPLAYS CONTINUOUS GLUCOSE VALUES AND STORES THIS DATA SO THAT IT CAN BE ANALYZED TO TRACK PATTERNS AND IMPROVE DIABETES MANAGEMENT. PUMP HISTORY CAN BE DOWNLOADED TO A COMPUTER FOR ANALYSIS OF HISTORICAL GLUCOSE VALUES. THE CONTINUOUS GLUCOSE VALUES PROVIDED BY THE PARADIGM 522/722 PUMP SYSTEMS ARE NOT INTENDED TO BE USED DIRECTLY FOR MAKING THERAPY ADJUSTMENTS. RATHER, THEY PROVIDE AN INDICATION THAT A CONFIRMATION FINGERSTICK MEASUREMENT MAY BE REQUIRED. ALL THERAPY ADJUSTMENTS SHOULD BE BASED ON MEASUREMENTS OBTAINED USING A HOME GLUCOSE MONITOR AND NOT BASED ON THE VALUE DISPLAYED BY THE PUMP.,

	AMBULATORY INSULIN INFUSION PUMP RESERVOIRS(MINIMED RESERVOIR, MINIMED RESERVOIR PARADIGM)-THIS RESERVOIR IS INDICATED FOR THE SUBCUTANEOUS INFUSION OF MEDICATION, INCLUDING INSULIN, FROM COMPATIBLE MEDTRONIC INSULIN PUMPS AND INFUSION SETS.,AMBULATORY INSULIN INFUSION PUMP (MEDTRONIC MINIMED PARADIGM VEO)-THE MEDTRONIC MINIMED PARADIGM VEO 554/754 INSULIN PUMPS ARE INTENDED FOR CONTINUOUS DELIVERY OF INSULIN, AT SET AND VARIABLE RATES, FOR THE MANAGEMENT OF DIABETES MELLITUS IN PERSONS REQUIRING INSULIN. IN ADDITION, THE PUMP SYSTEM IS INDICATED FOR CONTINUOUS OR PERIODIC MONITORING OF GLUCOSE LEVELS IN THE FLUID UNDER THE SKIN, AND POSSIBLE LOW AND HIGH BLOOD GLUCOSE EPISODES. THE PUMP DISPLAYS CONTINUOUS GLUCOSE VALUES AND STORES THIS DATA SO THAT IT CAN BE ANALYZED TO TRACK PATTERNS AND IMPROVE DIABETES MANAGEMENT. PUMP HISTORY CAN BE DOWNLOADED TO A COMPUTER FOR ANALYSIS OF HISTORICAL GLUCOSE VALUES. THE CONTINUOUS GLUCOSE VALUES PROVIDED BY THE PARADIGM 554/754 PUMP SYSTEMS ARE NOT INTENDED TO BE USED DIRECTLY FOR MAKING THERAPY ADJUSTMENTS. RATHER, THEY PROVIDE AN INDICATION THAT A CONFIRMATION FINGERSTICK MEASUREMENT MAY BE REQUIRED. ALL THERAPY ADJUSTMENTS SHOULD BE BASED ON MEASUREMENTS OBTAINED USING A HOME GLUCOSE MONITOR AND NOT BASED ON THE VALUE DISPLAYED BY THE PUMP., AMBULATORY INSULIN INFUSION PUMPS(MINIMED 620G INSULIN PUMPS AND PUMP KITS)-THE MINIMED 620G INSULIN PUMP SYSTEM IS INDICATED FOR THE CONTINUOUS DELIVERY OF INSULIN, AT SET AND VARIABLE RATES, FOR THE MANAGEMENT OF DIABETES MELLITUS IN PERSONS REQUIRING INSULIN. IN ADDITION, THE SYSTEM IS INDICATED FOR CONTINUOUS OR PERIODIC MONITORING OF GLUCOSE LEVELS IN THE FLUID UNDER THE SKIN AND DETECTING POSSIBLE LOW AND HIGH BLOOD GLUCOSE EPISODES. WHEN USING A SENSOR AND TRANSMITTER, THE PUMP DISPLAYS CONTINUOUS SENSOR GLUCOSE VALUES AND STORES THIS DATA SO THAT IT CAN BE ANALYZED TO TRACK PATTERNS AND IMPROVE DIABETES MANAGEMENT. THIS DATA CAN BE UPLOADED TO A COMPUTER FOR ANALYSIS OF HISTORICAL GLUCOSE VALUES. THE CONTINUOUS SENSOR GLUCOSE VALUES PROVIDED BY THE MINIMED 620G SYSTEM ARE NOT INTENDED TO BE USED DIRECTLY FOR MAKING THERAPY ADJUSTMENTS. RATHER, THEY PROVIDE AN INDICATION THAT A CONFIRMATION FINGERSTICK MEASUREMENT MAY BE REQUIRED. ALL THERAPY ADJUSTMENTS SHOULD BE BASED ON MEASUREMENTS OBTAINED USING A HOME GLUCOSE MONITOR AND NOT BASED ON THE VALUE DISPLAYED BY THE PUMP.,AMBULATORY

		INSULIN INFUSION PUMP(MINIMED 640G INSULIN PUMP & PUMP KIT)-THE MINIMED 640G SYSTEM IS INDICATED FOR THE CONTINUOUS DELIVERY OF INSULIN, AT SET AND VARIABLE RATES, FOR THE MANAGEMENT OF DIABETES MELLITUS IN PERSONS REQUIRING INSULIN. IN ADDITION, THE SYSTEM IS INDICATED FOR CONTINUOUS OR PERIODIC MONITORING OF GLUCOSE LEVELS IN THE FLUID UNDER THE SKIN, AND POSSIBLE LOW AND HIGH BLOOD GLUCOSE EPISODES. WHEN USING A SENSOR AND TRANSMITTER, THE PUMP DISPLAYS CONTINUOUS GLUCOSE VALUES AND STORES THIS DATA SO THAT IT CAN BE ANALYZED TO TRACK PATTERNS AND IMPROVE DIABETES MANAGEMENT. THIS DATA CAN BE DOWNLOADED TO A COMPUTER FOR ANALYSIS OF HISTORICAL GLUCOSE VALUES. THE CONTINUOUS GLUCOSE VALUES PROVIDED BY THE MINIMED 640G SYSTEM ARE NOT INTENDED TO BE USED DIRECTLY FOR MAKING THERAPY ADJUSTMENTS. RATHER, THEY PROVIDE AN INDICATION THAT A CONFIRMATION FINGER STICK MEASUREMENT MAY BE REQUIRED. ALL THERAPY ADJUSTMENTS SHOULD BE BASED ON MEASUREMENTS OBTAINED USING A HOME GLUCOSE MONITOR AND NOT BASED ON THE VALUE DISPLAYED BY THE PUMP.
1793	IMP/MD/2019/000359	1.License Holder Name: M/S. PLUS MEDICAL DEVICES INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL KNEE REPLACEMENT SYSTEM (CEMENTED/ CEMENTLESS)(GKS- PRIME / GKS PRIME FLEX AND GKS BUTTERFLY)-IMPLANTS FOR TRICOMPARTMENTAL REPLACEMENT DURING ORTHOPEDIC KNEE JOINT SURGERY.,SHOULDER REPLACEMENT SYSTEM(MIRAI)-THE IMPLANTS ARE USED FOR TOTAL OR PARTIAL REPLACEMENT DURING ORTHOPEDIC SHOULDER JOINT SURGERY.,TOTAL HIP REPLACEMENT SYSTEM (CEMENTED/ CEMENTLESS)-IMPLANTS FOR TOTAL OR PARTIAL REPLACEMENT DURING ORTHOPEDIC HIP JOINT SURGERY.

1794	IMP/MD/2019/000360	1.License Holder Name: M/S DENTSPLY INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEALING CAP(HEALING CAP)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. COVER SCREWS ARE INTENDED TO BE USED AS A TEMPORARY COMPONENT TO AN ENDOSSEOUS IMPLANT TO ALLOW HEALING OF THE SOFT TISSUE. , MF5 IMPLANT(LANCE+)-MIS IMPLANTS ARE INTENDED TO BE SURGICALLY PLACED IN THE BONE OF THE UPPER OR LOWER JAW ARCHES FOR ANCHORING OR SUPPORTING TOOTH REPLACEMENT TO RESTORE CHEWING FUNCTION.,ZIRCONIA/PREMOLAR ABUTMENT (ZIRCONIA/PREMOLAR ABUTMENT)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. ,OT EQUATOR(OT EQUATOR)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH ENDOSSEOUS IMPLANTS ARE USED AS THE FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. FOR FULLY EDENTULOUS JAW RETAINING A TISSUE-SUPPORTED OVERDENTURE. ,TEMPORARY ABUTMENT(TEMPORARY ABUTMENT)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH ENDOSSEOUS IMPLANTS ARE USED AS THE FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. INTENDED TO BE USED AS A TEMPORARY AID IN PROSTHETIC RESTORATION FOR A PERIOD OF 180 DAYS. INTENDED FOR TEMPORARY RESTORATIONS RANGING FROM REPLACING ONE SINGLE TOOTH TO FIXED PARTIAL DENTURES USING SCREW-RETAINED SUPRA-CONSTRUCTIONS. ,GOLD ABUTMENT(GOLD ABUTMENT)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. ,MF7 IMPLANT(SEVEN)-MIS IMPLANTS ARE INTENDED TO BE SURGICALLY PLACED IN THE BONE OF THE UPPER OR LOWER JAW ARCHES FOR ANCHORING OR SUPPORTING TOOTH REPLACEMENT TO RESTORE CHEWING FUNCTION.,EZ BASE(EZ BASE)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. ,LOCK IT ABUTMENT /LOCK IT KIT(LOCK IT ABUTMENT /LOCK IT KIT)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR

	SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH ENDOSSEOUS IMPLANTS ARE USED AS THE FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. INTENDED FOR A FULLY EDENTULOUS JAW RETAINING A TISSUE SUPPORTED OVERDENTURE. ,CEMENTING POST(CEMENTING POST)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH TWO-STAGE ENDOSSEOUS IMPLANTS ARE INTENDED TO BE USED AS A FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. RESTORATIONS RANGE FROM REPLACING ONE SINGLE TOOTH TO FIXED PARTIAL DENTURES USING CEMENT-RETAINED SUPRA-CONSTRUCTIONS. ,PROSTHETIC KIT(PROSTHETIC KIT)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH TWO-STAGE ENDOSSEOUS IMPLANTS ARE INTENDED TO BE USED AS A FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. RESTORATIONS RANGE FROM REPLACING ONE SINGLE TOOTH TO FIXED PARTIAL DENTURES USING CEMENT-RETAINED SUPRA-CONSTRUCTIONS.THE ACCESSORIES INCLUDED IN THE SET ARE INTENDED TO BE USED FOR IMPRESSION TAKING AND FABRICATION OF CROWNS AND BRIDGES. ,TRANSGINGIVAL ABUTMENT(TRANSGINGIVAL ABUTMENT)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH TWO-STAGE ENDOSSEOUS IMPLANTS ARE INTENDED TO BE USED AS A FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. RESTORATIONS RANGE FROM REPLACING ONE SINGLE TOOTH TO FIXED PARTIAL DENTURES USING CEMENT-RETAINED SUPRA-CONSTRUCTIONS.THE ACCESSORIES INCLUDED IN THE SET ARE INTENDED TO BE USED FOR IMPRESSION TAKING AND FABRICATION OF CROWNS AND BRIDGES. ,COCR PLASTIC CYLINDER(COCR PLASTIC CYLINDER)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. ,MULTI UNIT ABUTMENT(MULTI UNIT ABUTMENT)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE MULTI-UNIT ABUTMENTS IN COMBINATION WITH ENDOSSEOUS IMPLANTS ARE INDICATED FOR MULTIPLE UNIT RECONSTRUCTIONS WHEN SCREW RETAINED PROSTHETICS IS

	PREFERRED ,TI BASE/ CADCAM CEMENTING CAP(TI BASE/ CADCAM CEMENTING CAP)- DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH TWO-STAGE ENDOSSEOUS IMPLANTS ARE USED AS THE FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. TI-BASE ABUTMENTS ALLOW THE FABRICATION OF CUSTOM MADE PROSTHETIC SOLUTIONS. ANTI-ROTATION TI-BASE IS USED FOR SINGLE-UNIT RESTORATIONS IF SCREW-RETAINED OR CEMENT-RETAINED CROWN IS USED. FREE ROTATION TI-BASE IS USED FOR MULTIPLE UNITS IF SCREW-RETAINED OR CEMENT-RETAINED BRIDGES ARE USED. MIS TI-BASES ARE IMPLEMENTED IN DIFFERENT CAD/CAM LIBRARIES OF 3RD PARTY CAD/CAM SOFTWARE (E.G. 3SHAPE, EXOCAD). ,BALL ATTACHMENT(BALL ATTACHMENT)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH ENDOSSEOUS IMPLANTS ARE USED AS THE FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. FOR FULLY EDENTULOUS JAW RETAINING A TISSUE-SUPPORTED OVERDENTURE. ,PLASTIC HEALING CAP(PLASTIC HEALING CAP)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. , ESTHETIC/ANGULATED ABUTMENT(ESTHETIC/ANGULATED ABUTMENT)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH TWO-STAGE ENDOSSEOUS IMPLANTS ARE INTENDED TO BE USED AS A FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. RESTORATIONS RANGE FROM REPLACING ONE SINGLE TOOTH TO FIXED PARTIAL DENTURES USING CEMENT-RETAINED SUPRA-CONSTRUCTIONS.

1795	IMP/MD/2019/000361	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VIRTUOSAPH® PLUS ENDOSCOPIC VESSEL HARVESTING SYSTEM(TERUMO)-THE VIRTUOSAPH® PLUS ENDOSCOPIC VESSEL HARVESTING SYSTEM VSP550EX IS INDICATED FOR USE IN MINIMALLY INVASIVE SURGERY ALLOWING ACCESS FOR VESSEL HARVESTING, AND IS PRIMARILY INDICATED FOR PATIENTS UNDERGOING ENDOSCOPIC SURGERY FOR ARTERIAL BYPASS. IT IS INDICATED FOR CUTTING TISSUE AND CONTROLLING BLEEDING THROUGH COAGULATION, AND FOR PATIENTS REQUIRING BLUNT DISSECTION OF TISSUE INCLUDING DISSECTION OF BLOOD VESSELS AND DISSECTION OF BLOOD VESSELS OF THE EXTREMITIES. EXTREMITY PROCEDURES INCLUDE TISSUE DISSECTION AND/OR VESSEL HARVESTING ALONG THE SAPHENOUS VEIN FOR CORONARY ARTERY BYPASS GRAFTING AND PERIPHERAL ARTERY BYPASS GRAFTING OR RADIAL ARTERY FOR USE IN CORONARY ARTERY BYPASS GRAFTING.
1796	IMP/MD/2019/000362	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RADIO-FREQUENCY ABLATION SYSTEM(CANNULA)-THE COSMAN CC RF CANNULA AND RFK RF CANNULA IS INDICATED FOR USE IN RF HEAT LESION PROCEDURES FOR THE RELIEF OF PAIN FROM PERIPHERAL NERVE TISSUE ONLY.
1797	IMP/MD/2019/000363	1.License Holder Name: M/S STRYKER INDIA PRIVATE LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUTURE(SHARPSHOOTER SURGICAL SUTURE)-HS FIBER SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR SURGERY, AND THE USE OF ALLOGRAFT TISSUES FOR ORTHOPEDIC SURGERIES. HS FIBER SUTURES ARE INTENDED FOR ONE-TIME USE ONLY, AND ARE NOT TO BE RE-STERILIZED.
1798	IMP/MD/2019/000364	1.License Holder Name: ADLER MEDIEQUIP PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHOPAEDIC PLATES-RAW MATERIAL FOR FURTHER PROCESSING WHICH IS USED FOR INTERNAL FIXATION.,ORTHOPAEDIC SCREWS-RAW MATERIAL FOR FURTHER PROCESSING WHICH IS USED FOR INTERNAL FIXATION.

1799	IMP/MD/2019/000365	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED ,NO. 17, GROUND FLOOR AND MEZZANINE FLOOR, THIRUNEERMALAI ROAD, NAGALKENI, CHROMPET ,CHENNAI TAMIL NADU ,600044 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE CEMENT (WITH ANTIBIOTIC- GENTAMICIN SULPHATE & CLINDAMYCIN HYDROCHLORIDE)(OPTIPAC® REFOBACIN® REVISION)-OPTIPAC IS A MIXING AND APPLICATION SYSTEM PRE- PACKED WITH REFOBACIN REVISION. REFOBACIN REVISION IS USED FOR STABLE ANCHORING OF SUITABLE JOINT PROSTHESES IN PRIMARY OPERATIONS, WITH ADDED PROTECTION AGAINST INFECTION. ALSO IN REVISION OPERATIONS RESULTING FROM ASEPTIC LOOSENING OF THE PROSTHESIS AND INFECTION OF THE PROSTHESIS BY GENTAMICIN- AND/OR CLINDAMYCIN-SENSITIVE STRAINS. REFOBACIN REVISION IS INDICATED FOR USE IN THE FABRICATION AND FIXATION OF SHORT-TERM TOTAL OR HEMI JOINT SPACERS IN PATIENTS WHO REQUIRE A TWO-STAGE REVISION. THE DEVICE IS INTENDED FOR USE IN CONJUNCTION WITH SYSTEMIC ANTIMICROBIAL THERAPY (STANDARD APPROACH TO AN INFECTION). SPACERS ARE UTILIZED TO MAINTAIN THE JOINT´S SOFT TISSUE ENVELOPE. THE SPACERS MAY ALLOW LIMITED WEIGHT BEARING OR OTHER PHYSICAL ACTIVITIES DURING IMPLANTATION DEPENDING ON THE SPACER´S DESIGN AND PATIENT´S ABILITY TO COMPLY WITH PARTIAL WEIGHT BEARING INSTRUCTIONS.,BONE CEMENT (WITHOUT ANTIBIOTIC) (BIOMET BONE CEMENT R)-BIOMET BONE CEMENT R IS USED FOR STABLE ANCHORING OF SUITABLE JOINT PROSTHESES IN PRIMARY OPERATIONS.,BONE CEMENT (WITH ANTIBIOTIC- GENTAMICIN SULPHATE)(OPTIPAC® REFOBACIN® BONE CEMENT R)-OPTIPAC IS A MIXING AND APPLICATION SYSTEM PRE- PACKED WITH REFOBACIN BONE CEMENT R. REFOBACIN BONE CEMENT R IS USED FOR STABLE ANCHORING OF SUITABLE JOINT PROSTHESES IN PRIMARY OPERATIONS, WITH ADDED PROTECTION AGAINST INFECTION AND ALSO IN REVISION OPERATIONS RESULTING FROM ASEPTIC LOOSENING OF THE PROSTHESIS AND INFECTION OF THE PROSTHESIS BY GENTAMICIN-SENSITIVE STRAINS.,BONE CEMENT (WITH ANTIBIOTIC- GENTAMICIN SULPHATE & CLINDAMYCIN HYDROCHLORIDE)(REFOBACIN® REVISION)-REFOBACIN REVISION IS USED FOR STABLE ANCHORING OF SUITABLE JOINT PROSTHESES IN PRIMARY OPERATIONS, WITH ADDED PROTECTION AGAINST INFECTION. ALSO IN REVISION OPERATIONS RESULTING FROM ASEPTIC LOOSENING OF THE PROSTHESIS AND INFECTION OF THE PROSTHESIS BY GENTAMICIN- AND/OR CLINDAMYCIN-SENSITIVE STRAINS. REFOBACIN REVISION IS INDICATED FOR USE IN THE FABRICATION AND FIXATION OF SHORT-TERM TOTAL OR HEMI JOINT

	SPACERS IN PATIENTS WHO REQUIRE A TWO-STAGE REVISION. THE DEVICE IS INTENDED FOR USE IN CONJUNCTION WITH SYSTEMIC ANTIMICROBIAL THERAPY (STANDARD APPROACH TO AN INFECTION). SPACERS ARE UTILIZED TO MAINTAIN THE JOINT´S SOFT TISSUE ENVELOPE. THE SPACERS MAY ALLOW LIMITED WEIGHT BEARING OR OTHER PHYSICAL ACTIVITIES DURING IMPLANTATION DEPENDING ON THE SPACER´S DESIGN AND PATIENT´S ABILITY TO COMPLY WITH PARTIAL WEIGHT BEARING INSTRUCTIONS.,BONE CEMENT (WITHOUT ANTIBIOTIC)(BIOMET BONE CEMENT V)-BIOMET BONE CEMENT V IS USED FOR AUGMENTATION OF VERTEBRAL BODIES: - FOLLOWING PAINFUL VERTEBRAL BODY COMPRESSION FRACTURES IN OSTEOPOROSIS, - AT PAINFUL VERTEBRAL BODY TUMORS (METASTASIS OR MYELOMA), - SYMPTOMATIC VERTEBRAL HEMANGIOMA. IN ALL NAMED INDICATIONS THE PERCUTANEOUS VERTEBROPLASTY IS ONLY A PALLIATIVE TREATMENT THAT STABILIZES THE VERTEBRAL BODY; A THERAPY OF THE SYSTEMATIC ILLNESS (OSTEOPOROSIS, TUMOR) IS NOT ACHIEVED BY THE PERCUTANEOUS VERTEBROPLASTY.,BONE CEMENT (WITH ANTIBIOTIC- GENTAMICIN SULPHATE)(OPTIPAC® REFOBACIN® PLUS BONE CEMENT)-OPTIPAC IS A MIXING AND APPLICATION SYSTEM PRE- PACKED WITH REFOBACIN PLUS BONE CEMENT. REFOBACIN PLUS BONE CEMENT IS USED FOR STABLE ANCHORING OF SUITABLE JOINT PROSTHESES IN PRIMARY OPERATIONS, WITH ADDED PROTECTION AGAINST INFECTION AND ALSO IN REVISION OPERATIONS RESULTING FROM ASEPTIC LOOSENING OF THE PROSTHESIS AND INFECTION OF THE PROSTHESIS BY GENTAMICIN-SENSITIVE STRAINS.,BONE CEMENT (WITH ANTIBIOTIC - GENTAMICIN SULPHATE)(REFOBACIN® BONE CEMENT R)-REFOBACIN BONE CEMENT R IS USED FOR STABLE ANCHORING OF SUITABLE JOINT PROSTHESES IN PRIMARY OPERATIONS, WITH ADDED PROTECTION AGAINST INFECTION, ALSO IN REVISION OPERATIONS RESULTING FROM ASEPTIC LOOSENING OF THE PROSTHESIS AND INFECTION OF THE PROSTHESIS BY GENTAMICIN SENSITIVE STRAINS.,BONE CEMENT (WITH ANTIBIOTIC- GENTAMICIN SULPHATE)(REFOBACIN® PLUS BONE CEMENT)-REFOBACIN PLUS BONE CEMENT IS USED FOR STABLE ANCHORING OF SUITABLE JOINT PROSTHESES IN PRIMARY OPERATIONS, WITH ADDED PROTECTION AGAINST INFECTION, ALSO IN REVISION OPERATIONS RESULTING FROM ASEPTIC LOOSENING OF THE PROSTHESIS AND INFECTION OF THE PROSTHESIS BY GENTAMICIN SENSITIVE STRAINS.

1800	IMP/MD/2019/000367	1.License Holder Name: 3M INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANTIMICROBIAL INCISE DRAPE(3M STERI-DRAPE IOBAN 2)-IOBAN 2 ANTIMICROBIAL INCISE DRAPE IS INDICATED FOR USE AS AN INCISE DRAPE WITH CONTINUOUS ANTIMICROBIAL ACTIVITY. IT IS INTENDED FOR EXTERNAL USE ONLY.
1801	IMP/MD/2019/000368	1.License Holder Name: REINVENT MEDICAL PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TARGET ELUTING CORONARY STENT SYSTEM(FIREHAWKTM RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM)-THE FIREHAWKTM RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO DE NOVO NATIVE CORONARY ARTERY LESIONS LENGTH 60 MM WITH REFERENCE VESSEL DIAMETERS OF 2.25 TO 4.0 MM.,RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM(FIREHAWK LIBERTY)-THE FIREHAWK LIBERTYTM RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM (FIREHAWK LIBERTY RTECSS) IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO DE NOVO NATIVE CORONARY ARTERY LESIONS LENGTH 60 MM WITH REFERENCE VESSEL DIAMETERS OF 2.25 TO 4.0 MM.,PTCA BALLOON CATHETER(FIREFIGHTER NC)-BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION; BALLOON DILATATION OF A STENT AFTER IMPLANTATION.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1802	IMP/MD/2019/000369	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TISSUE ADHESIVE (HISTOACRYL FLEXIBLE)-HISTOACRYL® FLEXIBLE IS INDICATED FOR CLOSURE OF MINIMUM-TENSION SKIN WOUNDS UP TO 25 CM FROM CLEAN SURGICAL INCISIONS AND SIMPLE, THOROUGHLY CLEANSED, TRAUMA-INDUCED LACERATIONS. THE MAXIMUM LENGTH OF THE INCISION, WITHOUT EXCEEDING 25 CM, WHICH CAN BE TREATED WITH HISTOACRYL® FLEXIBLE DEPENDS ON THE WOUND SITE, PATIENT CONDITION AND SURGEON'S CRITERION. HISTOACRYL FLEXIBLE MUST BE USED IN COMBINATION WITH SUBCUTICULAR SUTURES TO RELEASE THE TENSION ALONG THE WOUND LINE.,TISSUE ADHESIVE (HISTOACRYL)-1. SKIN CLOSURE: CLOSURE OF SKIN WOUNDS WITHOUT TENSION (INCLUDING CLEAN SURGICAL INCISIONS AND INCISIONS FROM MINIMALLY INVASIVE SURGERY), AND SIMPLE, THOROUGHLY CLEANSED, TRAUMA-INDUCED LACERATIONS. 2. SCLEROTHERAPY: SCLEROTHERAPY OF LARGE OESOPHAGEAL OR FUNDAL VARICES. 3. MESH FIXATION: FIXATION OF HERNIA MESHES, ESPECIALLY IN INGUINAL HERNIA SURGERY ,HEMOSTAT(GELITA TAMPON)-GELITA TAMPON IS INDICATED: TO STOP VENOUS-CAPILLARY OR PARENCHYMATOUS HAEMORRHAGE, WHEN SUTURE, LIGATURE OR ELECTRO-COAGULATION IS NOT POSSIBLE IN: – NEUROSURGERY – ORTHOPEDIC SURGERY – UROLOGY – VASCULAR SURGERY – HEPATIC SURGERY – EAR NOSE THROAT SURGERY, AND FOR FILLING DEAD SPACES AND/OR CONTROL BLEEDING IN DENTAL COAGULUM.,HAEMOSTAT(LYOSTYPT)-FOR LOCAL HAEMOSTASIS OF CAPILLARY BLEEDING, BLEEDING FROM PARENCHYMAL ORGANS, OOZING HAEMORRHAGES AND AS A SUPPORTIVE MEASURE FOR OTHER TECHNIQUES OF HAEMOSTASIS.,HEMOSTAT(BONE WAX)-IT IS STOP BLEEDING AT BONES: • IN ORTHOPEDICS AND TRAUMATOLOGY • IN THORACIC SURGERY (STERNUM AND RIBS) • IN DENTAL, ORAL AND JAW SURGERY • IN NEUROSURGERY (TREPANATION)

1803	IMP/MD/2019/000370	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUBCUTANEOUS INFUSION ADMINISTRATION SET(SILHOUETTE, SILHOUETTE PARADIGM)-SILHOUETTE AND SILHOUETTE PARADIGM INFUSION SETS ARE INDICATED FOR THE SUBCUTANEOUS INFUSION OF INSULIN FROM AN INFUSION PUMP.,INJECTION PORT(I-PORT ADVANCE)-THE IPORT ADVANCE INJECTION PORT IS INDICATED FOR PATIENTS WHO ADMINISTER OR RECEIVE MULTIPLE DAILY SUBCUTANEOUS INJECTIONS OF PHYSICIAN PRESCRIBED MEDICATIONS, INCLUDING INSULIN. THE DEVICE MAY REMAIN IN PLACE FOR UP TO 72 HOURS TO ACCOMMODATE MULTIPLE INJECTIONS WITHOUT THE DISCOMFORT OF ADDITIONAL NEEDLE STICKS. THE IPORT ADVANCE MAY BE USED ON A WIDE RANGE OF PATIENTS, INCLUDING ADULTS AND CHILDREN.,DISPOSABLE INFUSION SET(QUICK SET, QUICK SET PARADIGM, MIO)-THIS PRODUCT IS INTENDED FOR SUBCUTANEOUS INFUSION OF INSULIN FROM AN INFUSION PUMP.,SUBCUTANEOUS INFUSION ADMINISTRATION SET(SURE T PARADIGM)-SURE T PARADIGM INFUSION SETS ARE INDICATED FOR THE SUBCUTANEOUS INFUSION OF INSULIN, FROM AN INFUSION PUMP.
1804	IMP/MD/2019/000371	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SYRINGE FOR PREFILLED DRUG WITH NEEDLE(PLAJEX SYRINGE 1)-PLAJEX SYRINGE 1 IS A SYRINGE BARREL FOR USE AS A MEDICAL DRUG CONTAINER DESIGNATED AS “READY-TO-BE FILLED”. TERUMO IS MANUFACTURING EMPTY PRE-FILLABLE SYRINGE COMPONENTS ONLY WHICH WILL BE FURTHER PROCESSED BY PHARMACEUTICAL COMPANIES AS PER THEIR FILLING REQUIREMENTS.

1805	IMP/MD/2019/000373	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MATRIXORTHOGNATHIC - SCREW(NA)-THE MATRIXORTHOGNATHIC SYSTEM IS INTENDED FOR USE AS A STABLE INTERNAL BONE FIXATION SYSTEM IN ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES). ,FEMORAL SHAFT NAILING IMPLANTS - ENDCAP-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,SCREW IMPLANTS FOR PLATES - PIN(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS. ,COMPACT MIDFACE- SCREW-THE IMPLANTS (PLATES AND SCREWS) AND THEIR INSTRUMENTS ARE INTENDED FOR TRAUMA REPAIR AND RECONSTRUCTION OF THE CRANIOFACIAL SKELETON.,SYNAPSE - LOCKING SCREW(NA)-"THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: — TOP-LOADING VARIABLE AXIS SCREWS — HOOKS — TRANSVERSE BARS — RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY.' , FEMORAL SHAFT NAILING IMPLANTS- NAIL-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,INTERNAL MIDFACE DISTRACTOR - SCREW(NA)-THE INTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. , HINDFOOT ARTHRODESIS NAILING IMPLANTS- NAIL-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC

	STABLE INTRAMEDULLARY FIXATION (ESIN).,HINDFOOT ARTHRODESIS NAILING IMPLANTS - ENDCAP(NA)- "INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",MATRIXNEURO-SCREW-DEPUY SYNTHES MATRIXNEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION., MATRIXMIDFACE SYSTEM (INCLUDING MATRIXORBITAL SYSTEM) - PLATE(NA)-MATRIXMIDFACE PLATE AND SCREW SYSTEM IS INTENDED FOR USE AS TRAUMA REPAIR AND RECONSTRUCTION OF THE CRANIO-MAXILLOFACIAL SKELETON. ,COMPACT MIDFACE-PLATE-THE IMPLANTS (PLATES AND SCREWS) AND THEIR INSTRUMENTS ARE INTENDED FOR TRAUMA REPAIR AND RECONSTRUCTION OF THE CRANIOFACIAL SKELETON.,PEDIATRIC PLATES - PLATE(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR PLATES- SCREW (STAINLESS STEEL)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., MATRIXMANDIBLE & MATRIXMANDIBLE PREFORMED RECONSTRUCTION PLATES - SCREW(NA)-"THE DEPUY SYNTHES MATRIXMANDIBLE PLATING SYSTEM IS INTENDED FOR ORAL, MAXILLOFACIAL SURGERY. THE DEPUY SYNTHES MATRIXMANDIBLE RECONSTRUCTION PLATES IS INTENDED FOR RECONSTRUCTIVE SURGERY. THE DEPUY SYNTHES MATRIXMANDIBLE SUBCONDYLAR PLATES ARE INTENDED FOR THE TRAUMA OF THE MANDIBLE.", SCREW IMPLANTS FOR OR WITHOUT PLATES- SCREW-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR OR WITHOUT PLATES - NUT(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,MAXILLARY DISTRACTOR-SCREW-THE MAXILLARY DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. THE INTERNAL MIDFACE DISTRACTOR, THE MAXILLARY DISTRACTOR, THE SINGLE VECTOR DISTRACTOR, THE EXTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE

	GRADUAL BONE DISTRACTION IS REQUIRED. THE CRANIOMAXILLOFACIAL (CMF) DISTRACTOR AND SYNTHES MULTI-VECTOR DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING (AND/OR TRANSPORT) DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED.UNIVERSAL SCREW REMOVAL SET IS INTENDED TO BE USED FOR THE REMOVAL OF INTACT AND DAMAGED SCREWS. IT IS NOT INTENDED TO BE USED IN COMBINATION WITH A POWER TOOL.,CONNECTING RODS - ROD(NA)-CONNECTING RODS ARE INTENDED TO FACILITATE THE CONNECTION OF QUALIFIED POSTERIOR SPINAL STABILIZATION SYSTEMS TOGETHER. ,TROCAR-TROCARS ARE INTENDED FOR PUNCTURING A BODILY ENTRY POINT AND/OR FOR PARTITION OF SURROUNDING SOFT TISSUE.,MATRIXMIDFACE SYSTEM (INCLUDING MATRIXORBITAL SYSTEM) - SCREW(NA)-MATRIXMIDFACE PLATE AND SCREW SYSTEM IS INTENDED FOR USE AS TRAUMA REPAIR AND RECONSTRUCTION OF THE CRANIO-MAXILLOFACIAL SKELETON.,PROXIMAL FEMORAL NAILING IMPLANTS- NAIL-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLEINTRAMEDULLARY FIXATION (ESIN).,CONNECTING RODS - ROD (TAN)(NA)-CONNECTING RODS ARE INTENDED TO FACILITATE THE CONNECTION OF QUALIFIED POSTERIOR SPINAL STABILIZATION SYSTEMS TOGETHER.,COMPACT MANDIBLE- SCREW-THE SYNTHES PLATE AND SCREW SYSTEM COMPACT MANDIBLE IS INTENDED FOR ORAL, MAXILLOFACIAL SURGERY, TRAUMA, RECONSTRUCTIVE SURGERY, AND ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES).,REAMER/IRRIGATOR/ ASPIRATOR - TUBE ASSEMBLY(NA)-REAMER/ IRRIGATOR/ ASPIRATOR DEVICES ARE INTENDED TO CLEAR THE MEDULLARY CANAL OF BONE MARROW AND REAMING DEBRIS. TO CLEAR THE MEDULLARY CANAL OF INFECTED BONE TISSUE. TO EFFECTIVELY SIZE THE MEDULLARY CANAL FOR THE ACCEPTANCE OF AN INTRAMEDULLARY IMPLANT OR PROSTHESIS. TO HARVEST FINELY MORSELIZED AUTOGENOUS BONE AND BONE MARROW FOR ANY SURGICAL PROCEDURES THAT REQUIRE BONE GRAFT IN ORDER TO FACILITATE FUSION AND/OR FILL BONE DEFECTS. THESE PROCEDURES INCLUDE SPINAL FUSION, JOINT ARTHRODESIS, TOTAL JOINT REPLACEMENT, FRACTURE REPAIR, NONUNION, MAXILLOFACIAL RECONSTRUCTION, AND TUMOR REMOVAL. ,MATRIXNEURO- PLATE-DEPUY SYNTHES MATRIXNEURO PLATE AND SCREW SYSTEM IS INTENDED FOR

	CRANIAL CLOSURE AND/OR BONE FIXATION.,AXON AND OCCIPITO-CERVICAL(OC) FUSION - LOCKING SCREW(NA)-"THE AXON SYSTEM IS A COMPREHENSIVE SET OF INSTRUMENTS AND IMPLANTS, INCLUDING — TOP-LOADING VARIABLE AXIS SCREWS, — HOOKS, — TRANSVERSE BARS AND — RODS. IT IS DESIGNED FOR POSTERIOR STABILISATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY. THE AXON SYSTEM USES THE EXISTING CERVIFIX RODS, ALLOWING COMPONENTS FROM AXON AND CERVIFIX TO BE COMBINED. THIS ALLOWS A CONSTRUCT TO EXTEND FROM THE OCCIPUT TO THE LOWER SPINE USING THE UNIVERSAL SPINE SYSTEM (USS)."., MATRIXMIDFACE MIDFACE SYSTEM (INCLUDING MATRIXORBITAL SYSTEM)- SCREW-THE MATRIXORTHOGNATHIC SYSTEM IS INTENDED FOR USE AS A STABLE INTERNAL BONE FIXATION SYSTEM IN ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES).THE SYNTHES TRANSPALATAL DISTRACTOR IS INTENDED FOR USE AS A BONE-BORNE MAXILLARY EXPANDER AND RETAINER FOR SURGICALLY ASSISTED, RAPID, PALATAL EXPANSION. THE SYNTHES TRANSPALATAL DISTRACTOR IS INTENDED FOR SINGLE USE ONLY.THE ORTHODONTIC BONE ANCHOR (OBA) SYSTEM IS INTENDED TO BE IMPLANTED INTRAORALLY AND USED AS AN ANCHOR FOR ORTHODONTIC PROCEDURES. THE OBA SYSTEM INCLUDES SCREW ANCHORS, PLATE ANCHORS, INSTRUMENTS, AND A MODULE CASE FOR STORAGE AND STERILIZATION.THE MATRIXORTHOGNATHIC LOCK SYSTEM IS INTENDED FOR USE AS A STABLE INTERNAL BONE FIXATION SYSTEM IN ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES).,LOW PROFILE NEURO- SCREW-DEPUY SYNTHES LOW PROFILE NEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION,TIBIAL NAILING IMPLANTS- NAIL-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,EXTERNAL MIDFACE DISTRACTOR- SCREW-THE DEPUY SYNTHES EXTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED.,EXTERNAL MIDFACE DISTRACTOR-ROD-THE DEPUY SYNTHES EXTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING

	DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED.,LOW PROFILE NEURO- PLATE-DEPUY SYNTHES LOW PROFILE NEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION.,SCREW IMPLANTS FOR PLATES- SCREW (TITANIUM)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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1806	IMP/MD/2019/000374	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER(TURNPIKE CATHETER)-THE TURNPIKE CATHETERS ARE INTENDED TO BE USED TO ACCESS DISCRETE REGIONS OF THE CORONARY AND/OR PERIPHERAL VASCULATURE. THEY MAY BE USED TO FACILITATE PLACEMENT AND EXCHANGE OF GUIDEWIRES AND TO SUBSELECTIVELY INFUSE/DELIVER DIAGNOSTIC AND THERAPEUTIC AGENTS.,CATHETER(SUPERCROSS MICROCATHETER)-THE SUPERCROSS MICROCATHETER IS INTENDED TO BE USED IN CONJUNCTION WITH STEERABLE GUIDEWIRES TO ACCESS DISCRETE REGIONS OF THE CORONARY AND/OR PERIPHERAL VASCULATURE. IT MAY BE USED TO FACILITATE PLACEMENT AND EXCHANGE OF GUIDEWIRES AND OTHER INTERVENTIONAL DEVICES AND TO SUBSELECTIVELY INFUSE/DELIVER DIAGNOSTIC AND THERAPEUTIC AGENTS.,CATHETER(TRAPLINER CATHETER)-THE TRAPLINER CATHETER IS INTENDED FOR USE IN CONJUNCTION WITH GUIDE CATHETERS TO ACCESS DISCRETE REGIONS OF THE CORONARY AND/ OR PERIPHERAL VASCULATURE, TO FACILITATE PLACEMENT OF INTERVENTIONAL DEVICES, AND TO FACILITATE THE EXCHANGE OF AN INTERVENTIONAL DEVICE WHILE MAINTAINING THE POSITION OF A GUIDEWIRE WITHIN THE VASCULATURE.,CATHETER(PRONTO® V4 EXTRACTION CATHETER)-THE PRONTO EXTRACTION CATHETERS ARE INDICATED FOR THE REMOVAL OF FRESH, SOFT EMBOLI AND THROMBI FROM VESSELS IN THE CORONARY AND PERIPHERAL VASCULATURE.,CATHETER(PRONTO® .035 EXTRACTION CATHETER) -THE PRONTO .035" IS INDICATED FOR: • THE REMOVAL/ASPIRATION OF EMBOLIC MATERIAL (THROMBUS/DEBRIS) FROM VESSELS OF THE ARTERIAL SYSTEM. • THE REMOVAL/ASPIRATION OF EMBOLIC MATERIAL (THROMBUS/DEBRIS) FROM VESSELS OF THE DEEP VENOUS SYSTEM. • TO INFUSE/DELIVER DIAGNOSTIC OR THERAPEUTIC AGENTS.,CATHETER(TWIN-PASS® DUAL ACCESS CATHETERS)-THE TWINPASS CATHETER IS INTENDED TO BE USED IN CONJUNCTION WITH STEERABLE GUIDEWIRES IN ORDER TO ACCESS DISCRETE REGIONS OF THE CORONARY AND PERIPHERAL ARTERIAL VASCULATURE, TO FACILITATE PLACEMENT AND EXCHANGE OF GUIDEWIRES AND OTHER INTERVENTIONAL DEVICES, AND FOR USE DURING TWO GUIDEWIRE PROCEDURES. THE TWINPASS CATHETER IS ALSO USED TO SUB SELECTIVELY INFUSE/DELIVER DIAGNOSTIC OR THERAPEUTIC AGENTS.,CATHETER(PRONTO® LP EXTRACTION CATHETER)-THE PRONTO LP CATHETER IS INDICATED FOR THE REMOVAL OF FRESH, SOFT EMBOLI AND THROMBI FROM VESSELS IN THE CORONARY AND PERIPHERAL SYSTEM.,CATHETER(LANGSTON® DUAL LUMEN CATHETERS)-EACH LANGSTON DUAL LUMEN

		CATHETER IS INDICATED FOR DELIVERY OF CONTRAST MEDIUM IN ANGIOGRAPHIC STUDIES AND FOR SIMULTANEOUS PRESSURE MEASUREMENT FROM TWO SITES. THIS TYPE OF PRESSURE MEASUREMENT IS USEFUL IN DETERMINING TRANSVALVULAR, INTRAVASCULAR AND INTRAVENTRICULAR PRESSURE GRADIENTS., CATHETER(GUIDELINER® V3 CATHETER)-GUIDELINER CATHETERS ARE INTENDED TO BE USED IN CONJUNCTION WITH GUIDE CATHETERS TO ACCESS DISCRETE REGIONS OF THE CORONARY AND/OR PERIPHERAL VASCULATURE, AND TO FACILITATE PLACEMENT OF INTERVENTIONAL DEVICES.,CATHETER(TWIN-PASS® TORQUE DUAL ACCESS CATHETER)-THE TWIN-PASS TORQUE CATHETER IS INTENDED TO ACCESS DISCRETE REGIONS OF THE CORONARY AND/ OR PERIPHERAL VASCULATURE. IT MAY BE USED TO FACILITATE PLACEMENT AND EXCHANGE OF GUIDEWIRES AND TO SUB SELECTIVELY INFUSE/DELIVER DIAGNOSTIC OR THERAPEUTIC AGENTS.
1807	IMP/MD/2019/000375	1.License Holder Name: DISPO SURGICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SYRINGE(VECTORIO)-LIPIODOL® RESISTANT MIXING & INJECTION SYSTEM FOR CONVENTIONAL TRANS-ARTERIAL CHEMO-EMBOLIZATION (CTACE).
1808	IMP/MD/2019/000377	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BD VACUTAINER SAFETY LOK BLOOD COLLECTION SET(BD VACUTAINER SAFETY LOK BLOOD COLLECTION SET)-THE BD VACUTAINER@ SAFETY-LOK BLOOD COLLECTION SET IS A WINGED BLOOD COLLECTION NEEDLE AND FLEXIBLE TUBING FOR VENIPUNCTURE TO COLLECT BLOOD SPECIMENS FROM PATIENTS. IT IS ALSO INDICATED FOR THE INTRAVENOUS ADMINISTRATION OF FLUIDS AND MAY BE USED FOR ANY PATIENT POPULATION WITH CONSIDERATION GIVEN TO PATIENT SIZE, APPROPRIATENESS FOR THE SOLUTION BEING INFUSED AND DURATION OF THERAPY. IT IS ALSO RECOMMENDED FOR USE IN PATIENTS WITH SMALL VEINS.
1809	IMP/MD/2019/000378	1.License Holder Name: M/S. PLUS MEDICAL DEVICES INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SOFT TISSUE FIXATION ADJUSTABLE FIXATION DEVICE BUTTON WITH LOOP(COLINK STD/ADJUST)-FIXATION OF BONE AND SOFT IN ORTHOPEDIC PROCEDURES REQUIRING LIGAMENT OF TENDON RECONSTRUCTION.

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1810	IMP/MD/2019/000379	1.License Holder Name: MERIL LIFE SCIENCES INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CEMENTLESS FEMORAL COMPONENTS(FREEDOM)-THE FREEDOM CEMENTLESS FEMORAL COMPONENTS ARE DESIGNED TO BE USED AS A PART OF THE FREEDOM TOTAL KNEE SYSTEM, AND IS INDICATED FOR - SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, CORRECTION OF FUNCTIONAL DEFORMITIES, POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, OR PRIOR PATELLECTOMY, MODERATE VALGUS, VARUS, OR FLEXION TRAUMA, KNEE FRACTURES UNTREATABLE BY OTHER METHODS, REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT;CEMENTLESS FEMORAL COMPONENTS WITH POROUS COATING ARE INDICATED FOR CEMENTED AND CEMENTLESS BIOLOGICAL FIXATION APPLICATION.,PROGRESSIVE CONSTRAINT KNEE (PCK) COMPONENTS(FREEDOM)-FREEDOM PCK COMPONENTS ARE TO BE USED WITH THE FREEDOM STEMMED TIBIAL COMPONENTS AND AS A PART OF THE FREEDOM TOTAL KNEE SYSTEM, AND IS INDICATED FOR - SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, CORRECTION OF FUNCTIONAL DEFORMITIES, POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, OR PRIOR PATELLECTOMY, MODERATE VALGUS, VARUS, OR FLEXION TRAUMA, KNEE FRACTURES UNTREATABLE BY OTHER METHODS, REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT; THE FREEDOM PCK COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY.,HIP REPLACEMENT SYSTEM (LIBERTAS)-THE LIBERTAS HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS AN EVIDENCE OF SUFFICIENT SOUND BONE TO FIX AND SUPPORT THE COMPONENTS.,TOTAL KNEE SYSTEM(FREEDOM)-IT IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO- SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, CORRECTION OF FUNCTIONAL DEFORMITIES, POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, OR PRIOR PATELLECTOMY, MODERATE

		VALGUS, VARUS, OR FLEXION TRAUMA, KNEE FRACTURES UNTREATABLE BY OTHER METHODS, REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT;ALL COMPONENTS ARE INDICATED FOR CEMENTED APPLICATION ONLY.
1811	IMP/MD/2019/000380	1.License Holder Name: YPSOMED INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INFUSION SET(YPSOPUMP ORBIT INFUSION SET SOFT/MICRO)-THE YPSOPUMP ORBIT SOFT AND YPSOPUMP ORBIT MICRO INFUSION SETS ARE STERILE, SINGLE USE INFUSION SETS INTENDED FOR THE SUBCUTANEOUS DELIVERY OF INSULIN FROM THE EXTERNAL YPSOPUMP INSULIN INFUSION PUMP, INFUSION SET CANNULA(YPSOPUMP ORBIT UNIVERSAL INFUSION SET CANNULA SOFT/MICRO)-THE YPSOPUMP ORBIT UNIVERSAL INFUSION SET CANNULA SOFT AND YPSOPUMP ORBIT UNIVERSAL INFUSION SET CANNULA MICRO ARE STERILE, SINGLE USE INFUSION SETS INTENDED FOR THE SUBCUTANEOUS DELIVERY OF INSULIN FROM THE EXTERNAL YPSOPUMP INSULIN INFUSION PUMP
1812	IMP/MD/2019/000381	1.License Holder Name: STRAUMANN DENTAL INDIA LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENAMEL MATRIX DERIVATIVE(EMDOGAIN)-STRAUMANN EMDOGAIN IS INTENDED FOR TOPICAL APPLICATION IN CONJUNCTION WITH PERIODONTAL SURGERY TO PROVIDE FOR REGENERATION OF TOOTH SUPPORT LOST TO PERIODONTAL DISEASE OR TRAUMA. IN ADDITION IT MAY BE USED TO SUPPORT THE SOFT TISSUE WOUND HEALING PROCESS AS PART OF ORAL SURGICAL PROCEDURES.
1813	IMP/MD/2019/000382	1.License Holder Name: BIOCELL MEDICARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABLATION PROBE (DISPOSABLE MICROWAVE THERAPEUTIC ANTENNA)-THE DEVICE IS A STERILE, HAND-HELD SURGICAL INSTRUMENT DESIGNED TO CONNECT TO THE MICROWAVE THERAPEUTIC SYSTEM TO DELIVER MICROWAVES TO A TARGETED OPERATIVE SITE FOR LOCALIZED SOFT-TISSUE ABLATION, TYPICALLY TO TREAT TUMOURS, HYDATID CYSTS AND/OR VARICOSE VEIN. THE PROBE INCLUDES A HANDLE AND COOLING MECHANISM. THE DEVICE IS INTENDED TO BE USED IN PERCUTANEOUS, LAPAROSCOPIC, OR OPEN SURGERY PROCEDURES TO ABLATE TISSUE TYPICALLY IN THE LIVER, LUNG AND KIDNEY. THIS IS A SINGLE-USE DEVICE.

1814	IMP/MD/2019/000383	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INJECTABLE HYDROXYAPATITE (HA) BONE SUBSTITUTE(HYDROSET KIT)-HYDROSET® IS A SELF-SETTING CALCIUM PHOSPHATE CEMENT INDICATED TO FILL BONY VOIDS OR GAPS OF THE SKELETAL SYSTEM (I.E. EXTREMITIES, CRANIOFACIAL, SPINE, AND PELVIS). THESE DEFECTS MAY BE SURGICALLY CREATED OR OSSEOUS DEFECTS CREATED FROM TRAUMATIC INJURY TO THE BONE. HYDROSET® IS INDICATED ONLY FOR BONY VOIDS OR GAPS THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. HYDROSET® CURED IN SITU PROVIDES AN OPEN VOID / GAP FILLER THAT CAN AUGMENT PROVISIONAL HARDWARE (E.G. K-WIRES, PLATES, SCREWS) TO HELP SUPPORT BONE FRAGMENTS DURING THE SURGICAL PROCEDURE. THE CURED CEMENT ACTS ONLY AS A TEMPORARY SUPPORT MEDIA AND IS NOT INTENDED TO PROVIDE STRUCTURAL SUPPORT DURING THE HEALING PROCESS. HYDROSET® IS A SELF-SETTING CALCIUM PHOSPHATE CEMENT INTENDED FOR USE IN THE REPAIR OF NEUROSURGICAL BURR HOLES, CONTIGUOUS CRANIOTOMY CUTS AND OTHER CRANIAL DEFECTS AS WELL AS IN THE AUGMENTATION OR RESTORATION OF BONY CONTOUR IN THE CRANIOFACIAL SKELETON.
1815	IMP/MD/2019/000384	1.License Holder Name: CAREGROUP SIGHT SOLUTION LLP, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOLDABLE HYDROPHOBIC INTRAOCULAR LENS(ACRIVISION ASPHERIC)-FOLDABLE INTRAOCULAR LENS IS INTENDED TO USE AS AN OPTICAL IMPLANT FOR REPLACEMENT OF CATARACT LENS FOR VISUAL CORRECTION OF APHAKIA.,FOLDABLE HYDROPHOBIC INTRAOCULAR LENS(ACRIVISON TRIFOCAL)-FOLDABLE INTRAOCULAR LENS IS INTENDED TO USE AS AN OPTICAL IMPLANT FOR REPLACEMENT OF CATARACT LENS FOR VISUAL CORRECTION OF APHAKIA.,FOLDABLE HYDROPHOBIC INTRAOCULAR LENS(ACRIVISON TORIC)-FOLDABLE INTRAOCULAR LENS IS INTENDED TO USE AS AN OPTICAL IMPLANT FOR REPLACEMENT OF CATARACT LENS FOR VISUAL CORRECTION OF APHAKIA.

1816	IMP/MD/2019/000385	1.License Holder Name: NANO THERAPEUTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA-PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER(VEGA)-THE VEGA CATHETER IS INTENDED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA ELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. IT IS THEREFORE INDICATED TO DILATE THE DISEASED SEGMENT(S) IN A CORONARY ARTERY OR A CORONARY BYPASS, TO IMPROVE MYOCARDIAL PERFUSION.,PTA-PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY CATHETER(LYNX)-THE LYNX PTA IS INDICATED FOR IMPROVING PERIPHERAL LUMINAL DIAMETER IN PATIENTS WITH STENOSIS OF THE CAROTID, VERTEBRAL, SUB-CLAVIAN, VISCERAL, RENAL, ARTERIES OF THE LOWER LIMBS, USING EITHER DILATATION OR STENTING/POST-STENTING TECHNIQUE,PTCA-PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER(MAYA)-THE MAYA CATHETER IS INTENDED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. IT IS THEREFORE INDICATED TO DILATE THE DISEASED SEGMENT(S) IN A CORONARY ARTERY OR A CORONARY BYPASS, TO IMPROVE MYOCARDIAL PERFUSION. , ASPIRATION CATHETER(PEGASE)-THE PEGASE ASPIRATION CATHETER IS INDICATED FOR USE IN THE CENTRAL AND PERIPHERAL CIRCULATORY SYSTEM, INCLUDING SAPHENOUS VEIN GRAFTS, TO CONTAIN AND ASPIRATE EMBOLIC MATERIAL (THROMBUS/DEBRIS) WHILE PERFORMING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTA) AND /OR STENTING PROCEDURES.
1817	IMP/MD/2019/000386	1.License Holder Name: PRYMAX HEALTHCARE LLP, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PRESSURE TRANSDUCER ACCESSORIES NON STERILE BULK(NIL)-APPLY TO CLINICAL FOR TRAUMATIC ARTERIOVENOUS PRESSURE MONITORING.

1818	IMP/MD/2019/000387	1.License Holder Name: SHREYAAS HEALTH CARE PRODUCTS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NASAL PACKING(IVALON) -THE INTENDED USE OF THE IVALON NASAL PACKING DEVICES IS FOR FLUID ADSORPTION POST NASAL SURGERY. PACKINGS USED IN THE SINUS CAVITY (SINUS PACKINGS) ARE USED POST SINUS SURGERY. THE USE IS SHORT TERM WITH A 7-DAY MAXIMUM FOR WICKING EXUDATES. PACKINGS USED IN THE NASAL CAVITY (NASAL AND EPISTAXIS PACKINGS) ARE USED FOR FLUID ABSORPTION POST NASAL SURGERY. THE USE IS SHORT TERM WITH A 3-DAY MAXIMUM FOR WICKING EXUDATES.
1819	IMP/MD/2019/000388	1.License Holder Name: MEDINOVATION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRAOCULAR LENS (LUCIDIS)-LUCIDIS LENSES ARE PRESCRIBED FOR PATIENTS SUFFERING FROM CATARACTS AND REQUIRING SURGERY., INTRAOCULAR LENS(LUCIDIS)-LUCIDIS TORIC LENS ARE PRESCRIBED FOR PATIENTS SUFFERING FROM CATARACTS AND PRE-EXISTING CORNEAL ASTIGMATISM AND ARE REQUIRING SURGERY.

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1820	IMP/MD/2019/000389	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRAVASCULAR GUIDING CATHETER(MACH1 PERIPHERAL GUIDE CATHETERS)-BOSTON SCIENTIFIC GUIDE CATHETERS PROVIDE A PATHWAY THROUGH WHICH MEDICAL INSTRUMENTS, SUCH AS BALLOON DILATATION CATHETERS, GUIDEWIRES OR OTHER THERAPEUTIC DEVICES MAY BE INTRODUCED. THESE DEVICES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE. BOSTON SCIENTIFIC PERIPHERAL GUIDE CATHETERS ARE INTENDED FOR USE IN GENERAL INTRAVASCULAR AND PERIPHERAL APPLICATIONS. BOSTON SCIENTIFIC CORONARY GUIDE CATHETERS ARE INTENDED FOR USE IN GENERAL INTRAVASCULAR AND CORONARY APPLICATIONS.,INTRAVASCULAR GUIDING CATHETER(MACH1 GUIDE CATHETERS)-BOSTON SCIENTIFIC GUIDE CATHETERS PROVIDE A PATHWAY THROUGH WHICH MEDICAL INSTRUMENTS, SUCH AS BALLOON DILATATION CATHETERS, GUIDEWIRES OR OTHER THERAPEUTIC DEVICES MAY BE INTRODUCED. THESE DEVICES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE. BOSTON SCIENTIFIC PERIPHERAL GUIDE CATHETERS ARE INTENDED FOR USE IN GENERAL INTRAVASCULAR AND PERIPHERAL APPLICATIONS. BOSTON SCIENTIFIC CORONARY GUIDE CATHETERS ARE INTENDED FOR USE IN GENERAL INTRAVASCULAR AND CORONARY APPLICATIONS.,CATHETER, ANGIOGRAPHIC(IMPULSE ANGIOGRAPHIC CATHETERS)-BOSTON SCIENTIFIC ANGIOGRAPHIC CATHETERS ARE DESIGNED TO PROVIDE A PATHWAY TO BE USED FOR DELIVERING CONTRAST MEDIA TO SELECTED SITES IN THE VASCULAR SYSTEM DURING AN ANGIOGRAPHIC PROCEDURE., VASCULAR GUIDE CATHETER(RUNWAY GUIDE CATHETERS)-BOSTON SCIENTIFIC GUIDE CATHETERS ARE INTENDED FOR USE IN GENERAL INTRAVASCULAR, CORONARY AND PERIPHERAL APPLICATIONS. THEY PROVIDE A PATHWAY THROUGH WHICH MEDICAL INSTRUMENTS, SUCH AS BALLOON DILATATION CATHETERS, GUIDEWIRES OR OTHER THERAPEUTIC DEVICES MAY BE INTRODUCED. THESE DEVICES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE.
1821	IMP/MD/2019/000391	1.License Holder Name: INMITO MEDITECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REGENERATIVE DURAL REPAIR PATCH(REDURA (TM))-THE PRODUCT IS APPLIED IN SURGICALLY REPAIRING OPERATIONS IN CASE OF DESTRUCTIVE DURAL DEFECTS.

1822	IMP/MD/2019/000392	1.License Holder Name: BIO INDIA INTERVENTIONAL TECHNOLOGIES PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DRUG ELUTING CORONARY STENT SYSTEM(BIOMATRIX NEOFLEX)-THE BIOMATRIX NEOFLEX DES IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER RANGING BETWEEN 2.25 MM AND 4.0 MM. STENTS WITH LENGTH 33 MM AND 36 MM ARE ONLY AVAILABLE FOR ARTERY DIAMETERS RANGING BETWEEN 2.5 MM AND 3.5 MM. THE BIOMATRIX NEOFLEX DES WITH STENT LENGTH UP TO 28 MM IS ALSO INDICATED FOR USE IN PATIENTS WITH: • ST ELEVATED MYOCARDIAL INFARCTION (STEMI) • ACUTE CORONARY SYNDROMES (ACS) INCLUDING ACS-STEMI, ACS-NSTEMI AND UNSTABLE ANGINA • DIABETES MELLITUS,DRUG ELUTING CORONARY STENT SYSTEM(BIOMATRIX ALPHA)-THE BIOMATRIX ALPHA STENT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER RANGING BETWEEN 2.25 MM AND 4.0 MM. STENTS WITH LENGTHS 33 AND 36 MM ARE ONLY AVAILABLE FOR ARTERY DIAMETERS RANGING BETWEEN 2.5 MM AND 3.5 MM.,DRUG COATED CORONARY STENT SYSTEM(BIOFREEDOM)-THE BIOFREEDOM DCS IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER FOR THE TREATMENT OF DE-NOVO LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER RANGING FROM 2.25 MM TO 4.0 MM. STENTS WITH LENGTHS OF 33 MM AND 36 MM ARE ONLY AVAILABLE FOR ARTERY DIAMETERS RANGING FROM 2.5 MM TO 3.5 MM.,DRUG ELUTING CORONARY STENT SYSTEM(BIOMATRIX FLEX)-THE BIOMATRIX FLEX DES IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER RANGING BETWEEN 2.25 MM AND 4.0 MM. STENTS WITH LENGTH 33MM AND 36MM ARE ONLY AVAILABLE FOR ARTERY DIAMETERS RANGING BETWEEN 2.5MM AND 3.5MM. THE BIOMATRIX FLEX DES WITH STENT LENGTH UP TO 28 MM IS ALSO INDICATED FOR USE IN PATIENTS WITH: • ST ELEVATED MYOCARDIAL INFARCTION (STEMI) • ACUTE CORONARY SYNDROMES (ACS) INCLUDING ACS-STEMI, ACS-NSTEMI AND UNSTABLE ANGINA • DIABETES MELLITUS

1823	IMP/MD/2019/000393	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIGATURE(ENDOLOOP)-IT IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE OF OPHTHALMIC PROCEDURES, BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.
1824	IMP/MD/2019/000394	1.License Holder Name: SANDOR MEDICAIDS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORGAN PERFUSION SOLUTION(CUSTODIOL-CE BAGS & BOTTLES)-SOLUTION FOR CARDIOPLEGIA IN CONNECTION WITH CARDIOSURGICAL OPERATIONS, ORGAN PROTECTION DURING OPERATIONS UNDER ISCHEMIA (HEART, KIDNEY, LIVER), PRESERVATION OF ORGAN TRANSPLANTS (HEART, KIDNEY, LIVER, LUNG, PANCREAS), TOGETHER WITH VENOUS OR ARTERIAL SEGMENTS. MULTIORGAN PROTECTION
1825	IMP/MD/2019/000395	1.License Holder Name: BIOCON LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK)-COMPONENT OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS
1826	IMP/MD/2019/000396	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NON-ABSORBABLE DURA SUBSTITUTE(NEUROPATCH)-IT IS EMPLOYED IN NEUROSURGERY AS DURA MATER REPLACEMENT,ABSORBABLE DURA SUBSTITUTE (LYOPLANT)-IT IS INTENDED FOR THE REPLACEMENT AND EXTENSION OF CONNECTIVE TISSUE STRUCTURE IN NEUROSURGERY, VASCULAR GRAFT(UNI-GRAFT KDV)-RECONSTRUCTIVE PROCEDURE ON THE AORTA AND IN THE PERIPHERAL AREA WITH A DIAMETER OF ATLEAST 6MM AND THE AXILLO (BI) FEMORAL BYPASS; ALSO USABLE IN PATIENTS REQUIRING SYSTEMIC HERPARINIZATION, IN PATIENTS WITH COAGULATION DISTURBANCE AND IN EMERGENCY PATIENTS

1827	IMP/MD/2019/000397	1.License Holder Name: VASCULAR CONCEPTS LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BALLOON EXPANDABLE CORONARY STENT SYSTEM (SIROLIMUS ELUTING STENT)(EUCALIMUS - BALLOON EXPANDABLE CORONARY STENT SYSTEM - SIROLIMUS ELUTING STENT (STERILE))-THE EUCALIMUS CORONARY STENT SYSTEM IS A DRUG-COATED CORONARY STENT SYSTEM, INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHAEMIC CORONARY HEART DISEASE DUE TO DE NOVO LESIONS OR RESTENOSISED LESIONS OF THE CORONARY ARTERIES. THE STENT SYSTEMS ARE ALSO INDICATED FOR THE TREATMENT OF ACUTE OR SUSPECTED OCCLUSIONS IN PATIENTS WHO RESPONDED UNSUCCESSFULLY TO AN INTERVENTIONAL THERAPY FOLLOWING BALLOON DILATATION. THE EUCALIMUS STENT IS INTENDED FOR USE IN PATIENTS ELIGIBLE FOR PTCA WITH A REFERENCE VESSEL DIAMETER OF 2.25MM TO 4.00 MM (MAXIMUM STENT DIAMETER AFTER PLACEMENT IS 0.5MM ABOVE THE NOMINAL VALUE) AND IS INTENDED TO EXPAND THE LUMEN OF THE CORONARY ARTERIES AS WELL AS MAINTAINING THE VESSEL PATENCY. THE LESION TO BE TREATED SHOULD BE SHORTER THAN THE NOMINAL LENGTH OF THE STENT AT A REFERENCE VESSEL DIAMETER OF 2.25MM TO 4.00MM.

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1828	IMP/MD/2019/000398	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DYNAMIC HIP PLATING IMPLANTS - PLATE-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR PLATES - SCREW (STAINLESS STEEL)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., FEMORAL NECK SYSTEM (FNS) - IMPLANTS (IMPLANTS KIT)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR OR WITHOUT PLATES - SCREW-IT INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS, SCREWS FOR INTRAMEDULLARY NAIL - BOLT-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,SCREW IMPLANTS FOR PLATES - SCREW (TITANIUM)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,ELASTIC NAILING IMPLANTS - ENDCAP-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,COMPACT MANDIBLE - PLATE(NA)-THE SYNTHES COMPACT 2.0 AND COMPACT 2.4 TRAUMA PLATES AND SCREWS SYSTEM MANDIBLE IS INTENDED FOR ORAL, MAXILLOFACIAL SURGERY, TRAUMA, RECONSTRUCTIVE SURGERY, AND ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES)., FEMORAL NECK SYSTEM (FNS) - IMPLANTS (PLATES)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DYNAMIC HIP PLATING IMPLANTS - SCREW (NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS

	ANATOMICAL REGIONS. ,FEMORAL NECK SYSTEM (FNS) - IMPLANTS (BOLT)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,TOMOFIX PLATES - PLATE(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,FEMORAL NECK SYSTEM (FNS) - IMPLANTS (SCREW)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DYNAMIC HIP PLATING IMPLANTS - BLADE(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., CABLE IMPLANTS - CERCLAGEFIX (NON STERILE)-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE.,SCREW IMPLANTS FOR OR WITHOUT PLATES - SCREW(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,CANNULATED SCREW IMPLANTS - SCREW-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,TOMOFIX PLATES - PLATE (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,MINI FRAGMENT PLATES - PLATE-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DISTAL FEMUR PLATES - PLATE (NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,ANGLED BLADE PLATES - BLADE-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,PROXIMAL TIBIAL PLATES - PLATE(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS. ,CABLE IMPLANTS - CERCLAGEFIX-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE.,RADIUS PLATES - PLATE (NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS. ,ANGLED BLADE PLATES - PLATE-PLATE AND

	SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR OR WITHOUT PLATES - SCREW (TICP)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR PLATES - SCREW-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,LOCKING COMPRESSION PLATES - PLATE(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR OR WITHOUT PLATES - SCREW-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., CANNULATED SCREW IMPLANTS - SCREW(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., ELASTIC NAILING IMPLANTS - ENDCAP (NON-STERILE)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,HEADLESS COMPRESSION SCREW IMPLANTS - SCREW(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS. , DYNAMIC HIP PLATING IMPLANTS - LOCKING DEVICE-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DYNAMIC HIP PLATING IMPLANTS - LOCKING DEVICE(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DYNAMIC COMPRESSION PLATES - PLATE-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,COMPACT MIDFACE - PLATE(NA) -THE IMPLANTS (PLATES AND SCREWS) AND THEIR INSTRUMENTS ARE INTENDED FOR TRAUMA REPAIR AND RECONSTRUCTION OF THE CRANIOFACIAL SKELETON.,LOCKING COMPRESSION PLATES - PLATE-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES

	IN VARIOUS ANATOMICAL REGIONS.,ELASTIC NAILING IMPLANTS - ENDCAP (NA)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,DYNAMIC HIP PLATING IMPLANTS - SCREW-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,FOOT PLATES - PLATE(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,PEDIATRIC PLATES - PLATE-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DYNAMIC COMPRESSION PLATES - PLATE (NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS. ,LOCKING ATTACHMENT PLATES - SCREW (NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS. ,ELASTIC NAILING IMPLANTS - ENDCAP (STERILE)(NA)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN). ,DYNAMIC HIP PLATING IMPLANTS - PLATE(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,HUMERAL NAILING IMPLANTS - SCREW(NA)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN). ,CABLE IMPLANTS - CERCLAGEFIX INSERT(NA)-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL

		REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE. ,SCREW IMPLANTS FOR PLATES - SCREW(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.
1829	IMP/MD/2019/000399	1.License Holder Name: SURGIPLUS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SCALP VEIN SET(TOP WINGED INFUSION SET)-IT IS INTENDED FOR USED IN INTRA VENOUS INJECTION AND INFUSION
1830	IMP/MD/2019/000403	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTI- PURPOSE SOLUTION(COMPLETE EASY RUB)-IT IS INTENDED TO CLEAN, RINSE, DISINFECT, STORE, REMOVE PROTEINS, AND REWET SOFT CONTACT LENSES.,MULTI PURPOSE DISINFECTING SOLUTION(ACUVUE REVITALENS)-IT CLEANS, RINSES, DISINFECTS, STORES, REMOVES LIPIDS AND PROTEINS, REWETS SOFT CONTACT LENSES, INCLUDING SILICONE HYDROGEL LENSES.,HYDROGEN PEROXIDE DISINFECTING SYSTEM(OXYSEPT)-A DISINFECTING, NEUTRALIZING AND STORAGE SYSTEM FOR ALL SOFT CONTACT LENSES.

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1831	IMP/MD/2019/000404	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT (PREMIUM,SHELTA & OUT-LINK2)-IMPLANT SYSTEMS ARE INTENDED FOR BOTH ONE- AND TWO-STAGE SURGICAL PROCEDURES. IMPLANT SYSTEMS ARE INTENDED FOR IMMEDIATE PLACEMENT AND FUNCTION ON SINGLE TOOTH AND/OR MULTIPLE TOOTH APPLICATIONS WHEN GOOD PRIMARY STABILITY IS ACHIEVED, WITH APPROPRIATE OCCLUSAL LOADING, IN ORDER TO RESTORE CHEWING FUNCTION. MULTIPLE TOOTH APPLICATIONS MAY BE SPLINTED WITH A BAR.,DENTAL PROSTHETIC COMPONENTS (ABUTMENTS)(PREMIUM, SHELTA & OUT-LINK2)-ABUTMENTS ARE INTENDED TO BE USED IN CONJUNCTION WITH THE RESPECTIVE IMPLANTS SYSTEMS IN FULLY EDENTULOUS OR PARTIALLY EDENTULOUS MAXILLARY AND/OR MANDIBULAR ARCHES. IT IS USE TO SUPPORT SINGLE AND MULTIPLE TOOTH PROSTHESIS, IN THE MANDIBLE OR MAXILLA. THE PROSTHESIS CAN BE CEMENTED, SCREW RETAINED OR FRICTION FIT TO THE ABUTMENT. THE ABUTMENT SCREW IS INTENDED TO SECURE THE ABUTMENT TO THE ENDOSSEOUS IMPLANT. ALL THE ABUTMENTS ARE COMPATIBLE WITH RESPECTIVE IMPLANTS SYSTEMS.,DENTAL PROSTHETIC COMPONENTS (TRANSGINGIVAL HEALING SCREWS/ CAPS)(PREMIUM, SHELTA & OUT-LINK2)-TO BE USED IN CONJUNCTION WITH A GLOBAL IMPLANTS SYSTEMS IN FULLY EDENTULOUS OR PARTIALLY EDENTULOUS MAXILLARY AND/OR MANDIBULAR ARCHES. THE TRANSGINGIVAL HEALING CAPS CAN BE IDENTIFIED BY A LASER-ETCHED MARKING INDICATING THE DIAMETER, PROTRUSION PROFILE (IF OTHER THAN CYLINDRICAL AND HEIGHT).

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1832	IMP/MD/2019/000405	1.License Holder Name: 3M INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EXUDATE ABSORBENT DRESSING(TEGADERM FOAM ADHESIVE, HIGH PERFORMANCE , FOAM ADHESIVE DRESSING)-TEGADERM FOAM ADHESIVE DRESSING IS DESIGNED TO ALLOW EASY, ONE HANDED APPLICATION TO DIFFICULT BODY CONTOURS, INCLUDING HEELS AND ELBOWS, WITHOUT THE NEED FOR CUTTING. THE DRESSING IS INDICATED FOR USE AS A PRIMARY DRESSING FOR LOW TO HIGHLY EXUDING, PARTIAL AND FULL THICKNESS DERMAL WOUNDS, INCLUDING: • PRESSURE ULCERS • VENOUS LEG ULCERS • ABRASIONS • SUPERFICIAL PARTIAL THICKNESS BURNS • DONOR SITES • ARTERIAL ULCERS • SKIN TEARS • NEUROPATHIC ULCERS ADDITIONAL APPLICATION INCLUDES: • USE AS SECONDARY (COVER) DRESSING IN CONJUNCTION WITH WOUND FILLERS (SUCH AS GAUGE OR ALGINATE DRESSINGS). • USE UNDER COMPRESSION WRAP SYSTEMS FOR VENOUS LEG ULCER TREATMENT THE PRODUCT IS NOT DESIGNED, SOLD OR INTENDED FOR USE EXCEPT AS INDICATED. TEGADERM FOAM ADHESIVE DRESSING IS NOT INTENDED FOR USE IN PRESSURE REDUCTION OR AS A SURGICAL SPONGE.
1833	IMP/MD/2019/000410	1.License Holder Name: LUPIN LIMITED (BIOTECHNOLOGY DIVISION) 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE (STERILE)(BD HYPAK SCF™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS
1834	IMP/MD/2019/000411	1.License Holder Name: M/S LEPUCARE (INDIA) VASCULAR SOLUTIONS PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE CENTRAL VENOUS CATHETER KIT-THE SINGLE AND MULTIPLE-LUMEN CATHETERS PERMIT VENOUS ACCESS TO THE ADULT AND PAEDIATRIC CENTRAL CIRCULATION FOR THE ADMINISTRATION OF MEDICINES, BLOOD SAMPLING AND PRESSURE MONITORING.

1835	IMP/MD/2019/000412	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANTS(HI-TEC IMPLANTS SYSTEM)-HI-TEC IMPLANT SYSTEMS ARE DESIGNED FOR USE IN EDENTULOUS MANDIBLES OR MAXILLAE FOR ATTACHMENT OF COMPLETE DENTURE PROSTHESES, OR AS A TERMINAL OR INTERMEDIARY ABUTMENT FOR FIXED OR REMOVABLE BRIDGEWORK OR AS A FREE STANDING SINGLE TOOTH REPLACEMENT.,DENTAL HEALING CAPS(HI-TEC IMPLANTS SYSTEM)-HEALING CAPS ARE CONNECTED THE TO IMPLANTS USING THE 1.25 MM HEX TOOL (SHT) IN ORDER THAT THE GINGIVA HEALS AROUND THE HEALING CAPS UNTIL PLACING ABUTMENTS.,DENTAL ABUTMENTS(HI-TEC IMPLANTS SYSTEM)-ABUTMENTS ARE USED FOR THE SUPPORT OF FIXED OR REMOVABLE BRIDGEWORK ON IMPLANTS.
1836	IMP/MD/2019/000413	1.License Holder Name: MEDEVOLUTION DEVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE NEEDLE FOR MAMMARY NODULE LOCALIZATION(MARK , REPOMARK)-IT IS INTENDED FOR PREOPERATIVE LOCALIZATION OF NON PALPABLE BREAST LESIONS ,CYTO HISTOLOGY BIOPSY NEEDLE(CYTOCUT)-IT IS INTENDED FOR SOFT TISSUE ASPIRATION,DISPOSABLE SOFT TISSUE BIOPSY NEEDLES(HANDCUT, SEMICUT, THEMY, PALIUM, PALIUM NEEDLE, INTRO)-IT IS INTENDED FOR SOFT TISSUE BIOPSY, DISPOSABLE BONE MARROW BIOPSY NEEDLE(HARVEST PENBONE , ILLY, JAMBLU, OSTEOJ,PICKUP, PRESSTO)-IT IS INTENDED FOR BONE MARROW BIOPSY
1837	IMP/MD/2019/000414	1.License Holder Name: CARL ZEISS INDIA (BANGALORE) PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RETILOCK(RETILOCK TROCAR)-RETILOCK® TROCARS KITS ARE INTENDED FOR TRANSCONJUNCTIVAL SCLEROTOMY IN ORDER TO GAIN ACCESS TO THE POSTERIOR POLE.

1838	IMP/MD/2019/000415	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PCD SYSTEM (PERCUTANEOUS CEMENT DELIVERY)(PCD SYSTEM)-STRYKER'S PCD SYSTEM KITS PROVIDE COMPONENTS FOR MIXING BONE CEMENT AND DELIVERING IT PERCUTANEOUSLY,INFLATABLE VERTEBRAL AUGMENTATION SYSTEM(IVAS)-THE STRYKER IVAS INFLATABLE VERTEBRAL AUGMENTATION SYSTEM (SYSTEM) IS INTENDED TO BE USED FOR THE REDUCTION OF FRACTURES AND/OR CREATION OF A VOID IN CANCELLOUS BONE IN THE SPINE. THIS INCLUDES USE DURING PERCUTANEOUS VERTEBRAL AUGMENTATION. THE SYSTEM IS TO BE USED WITH CLEARED SPINAL POLYMETHYLMETHACRYLATE (PMMA) BONE CEMENTS INDICATED FOR USE DURING PERCUTANEOUS VERTEBRAL AUGMENTATION PROCEDURES, SUCH AS KYPHOPLASTY,BIOPSY KIT-THE STRYKER IVAS BONE BIOPSY KIT CAN BE USED AS A BIOPSY TOOL TO REMOVE SAMPLE TISSUE FROM BONE OR VERTEBRAL BODY USING A CORING, CUTTING OR ASPIRATION TECHNIQUE.,BIOPSY KIT-STRYKER'S BONE BIOPSY KIT IS USED WITH THE ACM® PERCUTANEOUS DELIVERY SYSTEM AND THE PCD® PRECISION SYSTEM. THE KIT REQUIRES THE USE OF A FOUR-FACETED TIP INTRODUCTION NEEDLE. THE BONE BIOPSY KIT IS USED TO REMOVE A SAMPLE OF BONE TISSUE FOR DIAGNOSTIC PURPOSES,DECOMPRESSOR PERCUTANEOUS LUMBAR DISCECTOMY PROBE(DISPOSABLE DISCECTOMY-PROBE)-THE DEKOMPRESSOR PERCUTANEOUS DISCECTOMY PROBE (PROBE) IS INTENDED FOR USE IN ASPIRATION OF DISC MATERIAL DURING PERCUTANEOUS DISCECTOMIES IN THE LUMBAR, THORACIC AND CERVICAL REGIONS OF THE SPINE

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1839	IMP/MD/2019/000416	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE CEMENT (SMARTSET GHV GENTAMICIN)(SMARTSET GHV GENTAMICIN BONE CEMENT)-SMARTSET GHV GENTAMICIN IS INDICATED FOR THE FIXATION OF PROSTHESES TO LIVING BONE IN ARTHROPLASTY PROCEDURES OF JOINTS IN WHICH INFECTION BY GENTAMICIN SENSITIVE ORGANISMS IS A POTENTIAL RISK. THE BONE CEMENTS ARE INDICATED FOR USE IN CHILDREN ONLY IN THE CASE OF LIMB PRESERVATION WHERE NO OTHER PROCEDURE IS LIKELY TO GIVE A GOOD CHANCE OF SUCCESSFUL TREATMENT. THE BONE CEMENT SHOULD BE USED WITH AN APPROPRIATE PROSTHESIS.,BONE CEMENT (DEPUY CMW 3)(DEPUY CMW 3 BONE CEMENT)-DEPUY CMW 3 IS INDICATED FOR THE FIXATION OF PROSTHESES TO LIVING BONE IN ORTHOPAEDIC MUSCULOSKELETAL SURGICAL PROCEDURES FOR RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OSTEOPOROSIS, AVASCULAR NECROSIS, COLLAGEN DISEASE, SEVERE JOINT DESTRUCTION SECONDARY TO TRAUMA OR OTHER CONDITIONS, AND REVISION OF PREVIOUS ARTHROPLASTY.,BONE CEMENT (DEPUY CMW 1 BONE CEMENT)(DEPUY CMW 1 BONE CEMENT)-DEPUY CMW 1 BONE CEMENT IS INDICATED FOR THE FIXATION OF PROSTHESES TO LIVING BONE IN ORTHOPAEDIC MUSCULOSKELETAL SURGICAL PROCEDURES FOR RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OSTEOPOROSIS, AVASCULAR NECROSIS, COLLAGEN DISEASE, SEVERE JOINT DESTRUCTION SECONDARY TO TRAUMA OR OTHER CONDITIONS, AND REVISION OF PREVIOUS ARTHROPLASTY.,BONE CEMENT (CRANIOPLASTIC)(CRANIOPLASTIC)-CRANIOPLASTIC IS A RESINOUS MATERIAL FOR REPAIRING CRANIAL DEFECTS.,BONE CEMENT (DEPUY CMW 1 GENTAMICIN)(DEPUY CMW 1 GENTAMICIN BONE CEMENT)-THE ANTIBIOTIC BONE CEMENTS DEPUY CMW 1 GENTAMICIN IS INDICATED FOR THE FIXATION OF PROSTHESES TO LIVING BONE IN ARTHROPLASTY PROCEDURES OF JOINTS IN WHICH INFECTION BY GENTAMICIN SENSITIVE ORGANISMS IS A POTENTIAL RISK. THE BONE CEMENTS ARE INDICATED FOR USE IN CHILDREN ONLY IN THE CASE OF LIMB PRESERVATION WHERE NO OTHER PROCEDURE IS LIKELY TO GIVE A GOOD CHANCE OF SUCCESSFUL TREATMENT. THE BONE CEMENT SHOULD BE USED WITH AN APPROPRIATE PROSTHESIS.,BONE CEMENT (DEPUY CMW 3 GENTAMICIN)(DEPUY CMW 3 GENTAMICIN BONE CEMENT)-THE ANTIBIOTIC BONE CEMENTS DEPUY CMW 3 GENTAMICIN IS INDICATED FOR THE FIXATION OF PROSTHESES TO LIVING BONE IN ARTHROPLASTY PROCEDURES OF JOINTS IN WHICH INFECTION BY GENTAMICIN SENSITIVE ORGANISMS IS A POTENTIAL RISK. THE BONE

		CEMENTS ARE INDICATED FOR USE IN CHILDREN ONLY IN THE CASE OF LIMB PRESERVATION WHERE NO OTHER PROCEDURE IS LIKELY TO GIVE A GOOD CHANCE OF SUCCESSFUL TREATMENT. THE BONE CEMENT SHOULD BE USED WITH AN APPROPRIATE PROSTHESIS., BONE CEMENT (SMARTSET HV BONE CEMENT)(SMARTSET HV BONE CEMENT)-SMARTSET HV BONE CEMENT IS INDICATED FOR THE FIXATION OF PROSTHESES TO LIVING BONE IN ORTHOPEDIC MUSCULOSKELETAL SURGICAL PROCEDURES FOR RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OSTEOPOROSIS,AVASCULAR NECROSIS, COLLAGEN DISEASE, SEVERE JOINT DESTRUCTION SECONDARY TO TRAUMA OR OTHER CONDITIONS, AND REVISION OF PREVIOUS ARTHROPLASTY.
1840	IMP/MD/2019/000417	1.License Holder Name: EMSURG HEALTHCRE (INDIA) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RADIOPAQUE BONE CEMENT(OPACITY+)-OPACITY+ CEMENT IS INDICATED FOR THE FIXATION OF PATHOLOGICAL FRACTURES OF THE VERTEBRAL BODY USING VERTEBROPLASTY OR KYPHOPLASTY PROCEDURES. PAINFUL VERTEBRAL COMPRESSION FRACTURES OF THE VERTEBRAL BODY MAY RESULT FROM OSTEOPOROSIS, BENIGN LESIONS (HEMANGIOMA), OR MALIGNANT LESIONS (METASTATIC CANCERS, MYELOMA).

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1841	IMP/MD/2019/000418	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED ,NO. 17, GROUND FLOOR AND MEZZANINE FLOOR, THIRUNEERMALAI ROAD, NAGALKENI, CHROMPET ,CHENNAI TAMIL NADU ,600044 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CALCIUM PHOSOHATE BONE SUBSTITUTE(TRIOSITE)-TRIOSITE™ IS INTENDED FOR USE AS A BONE VOID FILLER FOR BONY VOIDS OR GAPS OF THE SKELETAL SYSTEM (E.G. EXTREMITIES, SPINE AND PELVIS) THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. TRIOSITE™ CAN BE USED WITH AUTOGRAFT AS A BONE GRAFT EXTENDER. THESE DEFECTS MAY BE SURGICALLY CREATED OSSEOUS DEFECTS OR OSSEOUS DEFECTS CREATED FROM TRAUMATIC INJURY TO THE BONE. TRIOSITE™ IS A BONE FILLER WITHOUT INITIAL MECHANICAL PROPERTIES. THEREFORE RIGID FIXATION TECHNIQUES MAY OFTEN BE RECOMMENDED. WHEN PACKED INTO A BONY SITE, TRIOSITE™ GRADUALLY RESORBS AND IS REPLACED WITH BONE DURING THE HEALING PROCESS. IN ADDITION, WHEN USED WITH APPROPRIATE OPENING OSTEOTOMY SYSTEM DEVICES, PLATES AND SCREWS, TRIOSITE™ IS INTENDED TO BE USED AS BONE VOID FILLER IN FEMORAL OR TIBIAL OSTEOTOMIES. TRIOSITE™ IS TO BE USED IN ASSOCIATION WITH ADEQUATE POST-OPERATIVE IMMOBILIZATION.
1842	IMP/MD/2019/000419	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SELF-EXPANDING STENT SYSTEM(ABRE™ VENOUS)-THE ABRE™ VENOUS SELF-EXPANDING STENT SYSTEM IS INTENDED FOR USE IN THE ILIOFEMORAL VEINS FOR THE TREATMENT OF SYMPTOMATIC VENOUS OUTFLOW OBSTRUCTION.

1843	IMP/MD/2019/000420	1.License Holder Name: ACCESS DEVICES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABLATION DEVICE (NANOKNIFE SYSTEM)-THE NANOKNIFE SYSTEM IS A MEDICAL DEVICE FOR CELL MEMBRANE ELECTROPORATION. ELECTROPORATION IS A PHENOMENON THAT OCCURS IN CELL MEMBRANES AS CELLS ARE EXPOSED TO AN ELECTRICAL FIELD OF SUFFICIENTLY HIGH INTENSITY. THE ELECTRIC FIELD ACTS AS A PHYSICAL STIMULUS, BRINGING ABOUT ALTERATIONS IN CELL MEMBRANES THAT RESULT IN INCREASED PERMEABILITY. THE SINGLE ELECTRODE PROBE AND SINGLE ELECTRODE ACTIVATION PROBE ARE INTENDED FOR USE WITH THE NANOKNIFE SYSTEM. THE SINGLE ELECTRODE PROBE SPACER IS INTENDED TO HOLD SINGLE ELECTRODE PROBES PARALLEL AND AT A SET DISTANCE APART.
1844	IMP/MD/2019/000421	1.License Holder Name: M/S DR. SCHUMACHER INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLEANISEPT WIPES (CLEANISEPT WIPES)-ALCOHOL FREE READY TO USE DISINFECTION WIPES FOR RAPID DISINFECTION AND CLEANING OF MEDICAL DEVICE AND MEDICAL EQUIPMENT,CLEANISEPT WIPES MAXI(CLEANISEPT WIPES MAXI)-ALCOHOL FREE READY TO USE DISINFECTION WIPES FOR RAPID DISINFECTION AND CLEANING OF MEDICAL DEVICE AND MEDICAL EQUIPMENT

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1845	IMP/MD/2019/000422	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHOPAEDIC IMPLANT HIP SYSTEM(BIOLOX)-1. NON- INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. 2. RHEUMATOID ARTHRITIS. 3. CORRECTION OF FUNCTIONAL DEFORMITY. 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES. 5. REVISION PROCEDURE WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,LIMB SALVAGE SYSTEM(ORTHOPEDIC SALVAGE SYSTEM-AUXILLARY)-IT IS INTENDED FOR PAINFUL AND DISABLED JOINT RESULTING FROM AVASCULAR NECROSIS, OSTEOARTHRITIS, RHEUMATOID ARTHRITIS OR TRAUMATIC ARTHRITIS, CORRECTION OF REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS OR PREVIOUS JOINT REPLACEMENT, LIGAMENT DEFICIENCIES, TUMOR RESECTIONS, TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES, REVISION OF PREVIOUSLY FAILED TOTAL JOINT ARTHROPLASTY AND TRAUMA.,LIMB SALVAGE SYSTEM (ORTHOPEDIC SALVAGE SYSTEM-TIBIAL)-IT IS INTENDED FOR PAINFUL AND DISABLED JOINT RESULTING FROM AVASCULAR NECROSIS, OSTEOARTHRITIS, RHEUMATOID ARTHRITIS OR TRAUMATIC ARTHRITIS, CORRECTION OF REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS OR PREVIOUS JOINT REPLACEMENT, LIGAMENT DEFICIENCIES, TUMOR RESECTIONS, TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES, REVISION OF PREVIOUSLY FAILED TOTAL JOINT ARTHROPLASTY AND TRAUMA.,LIMB SALVAGE SYSTEM(ORTHOPEDIC SALVAGE SYSTEM-POLY AUXILLARY)-IT IS INTENDED FOR PAINFUL AND DISABLED JOINT RESULTING FROM AVASCULAR NECROSIS, OSTEOARTHRITIS, RHEUMATOID ARTHRITIS OR TRAUMATIC ARTHRITIS, CORRECTION OF REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS OR PREVIOUS JOINT REPLACEMENT, LIGAMENT DEFICIENCIES, TUMOR RESECTIONS, TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES, REVISION OF PREVIOUSLY FAILED TOTAL JOINT ARTHROPLASTY AND TRAUMA.,ACTIVE ARTICULATION (ACTIVE ARTICULATION ARCOMXL HIP BEARING)-NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING

	OSTEOARTHRITIS AND AVASCULAR NECROSIS. > RHEUMATOID ARTHRITIS. > CORRECTION OF FUNCTIONAL DEFORMITY. > TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES. > REVISION PROCEDURE WHERE OTHER TREATMENT OR DEVICES HAVE FAILED. > DISLOCATION RISKS,ORTHOPAEDIC IMPLANTS-HIP SYSTEM(MALLORY HEAD HIP SYSTEM-ACETABULAR SHELL)-1. NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. 2. RHEUMATOID ARTHRITIS. 3. CORRECTION OF FUNCTIONAL DEFORMITY. 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES. 5. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,ORTHOPAEDIC IMPLANT HIP SYSTEM(FREEDOM CONSTRAINED)-IT IS INDICATED FOR USE AS A COMPONENT OF A TOTAL HIP PROSTHESIS IN PRIMARY AND REVISION PATIENTS AT HIGH RISK OF DISLOCATION DUE TO A HISTORY OF PRIOR DISLOCATION, BONE LOSS, JOINT OR SOFT TISSUE LAXITY, NEUROMUSCULAR DISEASE, OR INTRAOPERATIVE INSTABILITY, AND FOR WHOM ALL OTHER OPTIONS TO CONSTRAINED ACETABULAR COMPONENTS HAVE BEEN CONSIDERED. PATIENT SELECTION FACTORS TO BE CONSIDERED INCLUDE: 1. NEED TO OBTAIN PAIN RELIEF AND IMPROVE FUNCTION 2. ABILITY AND WILLINGNESS OF THE PATIENT TO FOLLOW INSTRUCTIONS, INCLUDING CONTROL OF WEIGHT AND ACTIVITY LEVELS. 3. A GOOD NUTRITIONAL STATE OF THE PATIENT AND 4. THE PATIENT SHOULD BE SKELETALLY MATURE, LIMB SALVAGE SYSTEM(ORTHOPEDIC SALVAGE SYSTEM-STEM)-IT IS INTENDED FOR PAINFUL AND DISABLED JOINT RESULTING FROM AVASCULAR NECROSIS, OSTEOARTHRITIS, RHEUMATOID ARTHRITIS OR TRAUMATIC ARTHRITIS, CORRECTION OF REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS OR PREVIOUS JOINT REPLACEMENT, LIGAMENT DEFICIENCIES, TUMOR RESECTIONS, TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES, REVISION OF PREVIOUSLY FAILED TOTAL JOINT ARTHROPLASTY AND TRAUMA.,LIMB SALVAGE SYSTEM(ORTHOPEDIC SALVAGE SYSTEM-DIAPHYSEAL SEGMENTS)-IT IS INTENDED FOR PAINFUL AND DISABLED JOINT RESULTING FROM AVASCULAR NECROSIS, OSTEOARTHRITIS, RHEUMATOID ARTHRITIS OR TRAUMATIC ARTHRITIS, CORRECTION OF REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS OR PREVIOUS JOINT REPLACEMENT,

	LIGAMENT DEFICIENCIES, TUMOR RESECTIONS, TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES, REVISION OF PREVIOUSLY FAILED TOTAL JOINT ARTHROPLASTY AND TRAUMA.,LIMB SALVAGE SYSTEM (COMPRESS SYSTEM)-THE COMPRESS SEGMENTAL FEMORAL REPLACEMENT SYSTEM IS INDICATED FOR: 1) CORRECTION OF REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS, OR PREVIOUS JOINT REPLACEMENT. 2) TUMOR RESECTIONS. 3) REVISION OF PREVIOUSLY FAILED TOTAL JOINT ARTHROPLASTY. 4) TRAUMA. THE COMPRESS SEGMENTAL FEMORAL REPLACEMENT SYSTEM COMPONENTS ARE INTENDED FOR UNCEMENTED USE. WHEN COMPONENTS OF THE ORTHOPAEDIC SALVAGE SYSTEM ARE USED WITH BIOMET'S COMPRESS SEGMENTAL FEMORAL REPLACEMENT SYSTEM, THE USER SHOULD REFER TO THE PACKAGE INSERT CONTAINED WITH THE COMPRESS COMPONENTS FOR FULL PRESCRIPTION INFORMATION.,LIMB SALVAGE SYSTEM(ORTHOPEDIC SALVAGE SYSTEM-BEARINGS)-IT IS INTENDED FOR PAINFUL AND DISABLED JOINT RESULTING FROM AVASCULAR NECROSIS, OSTEOARTHRITIS, RHEUMATOID ARTHRITIS OR TRAUMATIC ARTHRITIS, CORRECTION OF REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS OR PREVIOUS JOINT REPLACEMENT, LIGAMENT DEFICIENCIES, TUMOR RESECTIONS, TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES, REVISION OF PREVIOUSLY FAILED TOTAL JOINT ARTHROPLASTY AND TRAUMA.,ORTHOPAEDIC IMPLANT HIP SYSTEM(TAPERLOC)-NON- INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. > RHEUMATOID ARTHRITIS. > CORRECTION OF FUNCTIONAL DEFORMITY. > TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES. > REVISION PROCEDURE WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,LIMB SALVAGE SYSTEM (ORTHOPAEDIC SALVAGE SYSTEM-INTRAMEDULLARY ROD)-IT IS INTENDED FOR PAINFUL AND DISABLED JOINT RESULTING FROM AVASCULAR NECROSIS, OSTEOARTHRITIS, RHEUMATOID ARTHRITIS OR TRAUMATIC ARTHRITIS, CORRECTION OF REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS OR PREVIOUS JOINT REPLACEMENT, LIGAMENT DEFICIENCIES, TUMOR RESECTIONS, TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES,

	REVISION OF PREVIOUSLY FAILED TOTAL JOINT ARTHROPLASTY AND TRAUMA.,LIMB SALVAGE SYSTEM(ORTHOPEDIC SALVAGE SYSTEM-AUGMENTS)-IT IS INTENDED FOR PAINFUL AND DISABLED JOINT RESULTING FROM AVASCULAR NECROSIS, OSTEOARTHRITIS, RHEUMATOID ARTHRITIS OR TRAUMATIC ARTHRITIS, CORRECTION OF REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS OR PREVIOUS JOINT REPLACEMENT, LIGAMENT DEFICIENCIES, TUMOR RESECTIONS, TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES, REVISION OF PREVIOUSLY FAILED TOTAL JOINT ARTHROPLASTY AND TRAUMA.

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1846	IMP/MD/2019/000423	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KNEE SYSTEM - FEMORAL (SIGMA PS 150)-"THE P.F.C.® SIGMA® PS150 ROTATING PLATFORM (RP) TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE RPF INSERTS AND SIGMA PS150 FEMORAL COMPONENTS ARE INDICATED WHERE A HIGHER THAN NORMAL DEGREE OF POST-OPERATIVE FLEXION IS REQUIRED. THE SIGMA PS150 FEMORAL COMPONENTS AND RPF ROTATING PLATFORM INSERTS CAN BE USED WITH EITHER THE MBT PROSTHESIS OR THE MBT REVISION PROSTHESIS AND MODULAR REVISION TIBIAL COMPONENTS WHICH ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES.",KNEE REPLACEMENT SYSTEM- FEMORAL(PFC SIGMA)-THE P.F.C.® SIGMA® RP MOBILE BEARING TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE RPF AND RPS INSERTS AND FEMORAL COMPONENTS ARE INDICATED WHERE A HIGHER THAN NORMAL DEGREE OF POST-OPERATIVE FLEXION IS REQUIRED. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES. THE POROUS COATED KEELED AND NON KEELED M.B.T.™ (MOBILE BEARING TIBIAL) TRAY CONFIGURATIONS OF THE LCS TOTAL KNEE SYSTEM ARE INDICATED FOR NONCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR RECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE ROTATING PLATFORM DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE ABSENT OR ARE IN SUCH CONDITION AS TO JUSTIFY THEIR SACRIFICE. THE P.F.C. SIGMA RP CURVED BEARINGS WHEN USED WITH THE P.F.C. SIGMA CRUCIATE RETAINING FEMORAL COMPONENT CAN BE USED IN POSTERIOR CRUCIATE LIGAMENT RETAINING PROCEDURES.,CR-PS KNEE SYSTEM - FEMOAL (ATTUNE)-IT IS INDICATED FOR TOTAL KNEE REPLACEMENT INCLUDE PATIENTS WITH A SEVERELY PAINFUL AND/OR SEVERELY DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR A FAILED PREVIOUS IMPLANT.,KNEE REPLACEMENT SYSTEM- TIBIAL INSERT(PFC SIGMA)-THE P.F.C.® SIGMA® RP MOBILE BEARING TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE RPF AND RPS INSERTS AND FEMORAL COMPONENTS ARE INDICATED WHERE A HIGHER THAN NORMAL

	DEGREE OF POST-OPERATIVE FLEXION IS REQUIRED. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES. THE POROUS COATED KEELED AND NON KEELED M.B.T.™ (MOBILE BEARING TIBIAL) TRAY CONFIGURATIONS OF THE LCS TOTAL KNEE SYSTEM ARE INDICATED FOR NONCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR RECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE ROTATING PLATFORM DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE ABSENT OR ARE IN SUCH CONDITION AS TO JUSTIFY THEIR SACRIFICE. THE P.F.C. SIGMA RP CURVED BEARINGS WHEN USED WITH THE P.F.C. SIGMA CRUCIATE RETAINING FEMORAL COMPONENT CAN BE USED IN POSTERIOR CRUCIATE LIGAMENT RETAINING PROCEDURES.,CR-PS KNEE SYSTEM - INSERTS(ATTUNE)-IT IS INDICATED FOR TOTAL KNEE REPLACEMENT INCLUDE PATIENTS WITH A SEVERELY PAINFUL AND/OR SEVERELY DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR A FAILED PREVIOUS IMPLANT.,KNEE SYSTEM - STEM(ATTUNE REVISION)-TOTAL KNEE ARTHROPLASTY IS A TOTAL JOINT REPLACEMENT SURGERY DESIGNED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY DISABLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. TOTAL KNEE ARTHROPLASTY MAY INCLUDE SUPPLEMENTAL FIXATION THROUGH STEMS, SLEEVES, AND/OR MODULAR AUGMENTS WHERE BONE LOSS REQUIRES SAID FIXATION IN THE OPINION OF THE SURGEON. TOTAL KNEE ARTHROPLASTY MAY ALSO INCLUDE MORE CONSTRAINED BEARING SURFACES WHERE NECESSARY TO PROVIDE STABILITY WHERE MUSCULOLIGAMENTOUS SUPPORTING STRUCTURES ARE INSUFFICIENT.,HIP SYSTEM - SCREW(GRIPTION TF)-"THE DEPUY

	GRIPTION TF ACETABULAR AUGMENTS, BUTTRESSES AND SHIMS ARE INDICATED FOR USE WITH THE PINNACLE ACETABULAR CUP SYSTEM, THE PINNACLE BANTAM ACETABULAR CUP SYSTEM AND THE PINNACLE REVISION ACETABULAR CUP SYSTEM FOR TOTAL HIP REPLACEMENT IN THE FOLLOWING CONDITIONS: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3. ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK. 4. FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5. CERTAIN CASES OF ANKYLOSIS. THE POROUS GRIPTION TF TITANIUM ACETABULAR AUGMENT IS AFFIXED TO THE MATING ACETABULAR CUP USING BONE CEMENT OR MECHANICAL SCREW FIXATION. THE ASSEMBLED AUGMENT/ACETABULAR CUP CONSTRUCT IS INTENDED FOR CEMENTED OR CEMENTLESS USE. THE POROUS GRIPTION TF TITANIUM SHIM IS AFFIXED TO THE MATING BUTTRESS USING BONE CEMENT. THIS POROUS GRIPTION TF TITANIUM BUTTRESS IS AFFIXED TO THE MATING ACETABULAR CUP USING BONE CEMENT. THE GRIPTION TF TITANIUM BUTTRESS/SHIM IS AFFIXED TO THE BONE USING BONE CEMENT OR MECHANICAL SCREW FIXATION. THE ASSEMBLED BUTTRESS/ACETABULAR CUP CONSTRUCT IS INTENDED FOR CEMENTED OR CEMENTLESS USE."

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1847	IMP/MD/2019/000424	1.License Holder Name: M/S. PLUS MEDICAL DEVICES INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIORESORBABLE SUTURE ANCHOR(A'LINK'S)-A'LINK'S® IS A BIORESORBABLE SCREW-IN SUTURE ANCHOR MOUNTED IN A SINGLE-USE SCREWDRIVER WITH TWO THREADS OF UHMWPE (USP2) SUTURE. THE DEVICE IS STERILE AND READY TO USE. THE A'LINK'S® ANCHORING DEVICE IS INTENDED FOR: SHOULDER: REPAIRS TO THE ROTATOR CUFF & BICEPS TENODESIS,BIOABSORBABLE INTERFERENCE SCREW(EUROSCREW TCP NG)-EUROSCREW TCP NG IS A BIOABSORBABLE CANNULATED SCREW SPECIALLY DESIGNED FOR LIGAMENTOPLASTY SURGICAL TECHNIQUES LIKE ANTERIOR/POSTERIOR CRUCIATE LIGAMENT RECONSTRUCTIONS, REINSERTION OF THE LONG-HEAD OF THE BICEPS TENDON OR ANKLE LIGAMENTS.,BONE CEMENT(CEMFIX 1)-IT IS INDICATED FOR FIXATION OF PROSTHESES TO LIVING BONE IN ORTHOPAEDIC MUSCULOSKELETAL SURGICAL PROCEDURES FOR RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OSTEOPOROSIS, AVASCULAR NECROSIS, COLLAGEN DISEASE, SEVERE JOINT DESTRUCTION SECONDARY TO TRAUMA OR OTHER CONDITIONS, AND REVISION OF PREVIOUS ARTHROPLASTY.,BONE CEMENT WITH GENTAMICIN(GENTAFIX 1)-IT IS INDICATED USE AS BONE CEMENT IN ARTHROPLASTY PROCEDURE OF THE HIP, KNEE AND OTHER JOINTS TO FIX PLASTIC AND METAL PROSTHETIC PARTS TO LIVING BONE WHEN RECONSTRUCTION IS NECESSARY BECAUSE OF REVISION OF PREVIOUS ARTHROPLASTY PROCEDURES DUE TO JOINT INFECTION. THE CEMENTS ARE INTENDED FOR USE TO AFFIX A NEW PROSTHESIS IN THE SECOND PHASE OF A TWO STAGE REVISION AFTER THE INITIAL INFECTION HAS BEEN CLEARED.

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1848	IMP/MD/2019/000425	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIP SYSTEM(TAPERLOC HIP SYSTEM)-• NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, AVASCULAR NECROSIS AND POST TRAUMATIC ARTHRITIS. • RHEUMATOID ARTHRITIS • CORRECTION OF FUNCTIONAL DEFORMITY • REVISION OF FAILED JOINT RECONSTRUCTION OR TREATMENT. • TREATMENT OF FEMORAL NECK AND TROCHANTRIC FRACTURES OF THE PROXIMAL FEMUR WITH FEMORAL HEAD INVOLVEMENT AND WHICH ARE UNMANAGEABLE USING OTHER TECHNIQUE.,HIP SYSTEM(EXCEED ABT ACETABULAR SYSTEM)-• NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, AVASCULAR NECROSIS AND POST TRAUMATIC ARTHRITIS. • RHEUMATOID ARTHRITIS • CORRECTION OF FUNCTIONAL DEFORMITY • REVISION OF FAILED JOINT RECONSTRUCTION OR TREATMENT. • TREATMENT OF FEMORAL NECK AND TROCHANTRIC FRACTURES OF THE PROXIMAL FEMUR WITH FEMORAL HEAD INVOLVEMENT AND WHICH ARE UNMANAGEABLE USING OTHER TECHNIQUE.,HIP SYSTEM(G7 CERAMIC LINERS)-NON-INFLAMMATORY DEGENERATIVE JOINT DISEASES INCLUDING OSTEOARTHIRITIS, AVASCULAR NECROSIS AND POST-TRAUMATIC ARTHIRITIS. -RHEUMATOID ARTHIRITIS -CORRECTION OF FUNCTIONAL DEFORMITY. -TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FEATURES OF PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. -REVISION PROCEDURES WHERE OTHER DEVICES OR TREATMENTS HAVE FAILED.,HIP SYSTEM(MODULAR HEAD)-• NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, AVASCULAR NECROSIS AND POST TRAUMATIC ARTHRITIS. • RHEUMATOID ARTHRITIS • CORRECTION OF FUNCTIONAL DEFORMITY • REVISION OF FAILED JOINT RECONSTRUCTION OR TREATMENT. • TREATMENT OF FEMORAL NECK AND TROCHANTRIC FRACTURES OF THE PROXIMAL FEMUR WITH FEMORAL HEAD INVOLVEMENT AND WHICH ARE UNMANAGEABLE USING OTHER TECHNIQUE.,HIP SYSTEM(RINGLOC ACETABULAR LINERS)-• NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, AVASCULAR NECROSIS AND POST TRAUMATIC ARTHRITIS. • RHEUMATOID ARTHRITIS • CORRECTION OF FUNCTIONAL DEFORMITY • REVISION OF FAILED JOINT RECONSTRUCTION OR TREATMENT. • TREATMENT OF FEMORAL NECK AND TROCHANTRIC FRACTURES OF THE PROXIMAL FEMUR WITH FEMORAL HEAD INVOLVEMENT AND WHICH ARE UNMANAGEABLE USING OTHER TECHNIQUE.,KNEE SYSTEM(OXFORD PARTIAL KNEE SYSTEM)-INTENDED FOR USE IN INDIVIDUALS WITH OSTEOARTHRITIS

		OR AVASCULAR NECROSIS LIMITED TO MEDICAL COMPARTMENT OF THE KNEE AND IS INTENDED TO BE IMPLANTED WITH BONE CEMENT., KNEE SYSTEM(AGC V2 KNEE SYSTEM)-THE INDICATION FOR THE USE OF KNEE JOINT REPLACEMENT PROSTHESIS INCLUDE: - OSTEOARTHRITIS, RHEUMATOID ARTHRITIS OR TRAUMATIC ARTHRITIS. - FAILURE OF PREVIOUS JOINT REPLACEMENT PROCEDURES. -CORRECTION OF VARUS, VALGUS OR POST-TRAUMATIC DEFORMITY. - CORRECTION OR REVISION OF UNSUCCESSFUL OSTEOTOMY OR ARTHRODESIS.
1849	IMP/MD/2019/000426	1.License Holder Name: KCI MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:V.A.C. GRANUFOAM SILVER™ DRESSING(V.A.C. GRANUFOAM SILVER™ DRESSING)-THE ACTIV.A.C.™ INFO V.A.C.™, V.A.C. ATS™ AND V.A.C. FREEDOM™ NEGATIVE PRESSURE WOUND THERAPY SYSTEMS ARE INTEGRATED WOUND MANAGEMENT SYSTEMS FOR USE IN ACUTE, EXTENDED, AND HOME CARE SETTINGS. WHEN USED ON OPEN WOUNDS, THEY ARE INTENDED TO CREATE AN ENVIRONMENT THAT PROMOTES WOUND HEALING BY SECONDARY OR TERTIARY (DELAYED PRIMARY) INTENTION BY PREPARING THE WOUND BED FOR CLOSURE, REDUCING EDEMA, PROMOTING GRANULATION TISSUE FORMATION AND PERFUSION, AND BY REMOVING EXUDATES AND INFECTIOUS MATERIAL. OPEN WOUND TYPES INCLUDE: CHRONIC, ACUTE, TRAUMATIC, SUBACUTE, AND DEHISCED WOUNDS, PARTIAL THICKNESS BURNS, ULCERS (SUCH AS DIABETIC, PRESSURE OR VENOUS INSUFFICIENCY), FLAPS AND GRAFTS. THE V.A.C. GRANUFOAM SILVER™ DRESSING IS AN EFFECTIVE BARRIER TO BACTERIAL PENETRATION AND MAY HELP REDUCE INFECTION IN THE ABOVE WOUND TYPES. WHEN USED ON CLOSED SURGICAL INCISIONS, THEY ARE INTENDED TO MANAGE THE ENVIRONMENT OF SURGICAL INCISIONS THAT CONTINUE TO DRAIN FOLLOWING SUTURED OR STAPLED CLOSED BY MAINTAINING A CLOSED ENVIRONMENT AND REMOVING EXUDATES VIA THE APPLICATION OF NEGATIVE PRESSURE WOUND THERAPY.

1850	IMP/MD/2019/000426	1.License Holder Name: KCI MEDICAL INDIA PRIVATE LIMITED ,K. NO. 2606/115 (P. NO. 60/16) GROUND FLOOR, HUSKUR ROAD ELECTRONIC POST ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560100 , INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:300ML CANISTER (WITH GEL) FOR ACTI V.A.C. THERAPY SYSTEM, FLUID PATH STERILE(ACTI V. A.C.)-THE V.A.C® THERAPY SYSTEM IS AN INTEGRATED WOUND MANAGEMENT SYSTEMS FOR USE IN ACUTE, EXTENDED AND HOME CARE SETTINGS. IT IS INTENDED TO CREATE AN ENVIRONMENT THAT PROMOTES WOUND HEALING BY SECONDARY OR TERTIARY (DELAYED PRIMARY) INTENTION BY PREPARING THE WOUND BED FOR CLOSURE, REDUCING EDEMA, PROMOTING GRANULATION TISSUE FORMATION AND PERFUSION, AND BY REMOVING EXUDATE AND INFECTIOUS MATERIAL. IT IS INDICATED FOR PATIENT WITH CHRONIC, ACUTE TRAUMATIC, SUB ACUTE AND DEHISCED WOUNDS, PARTIAL- THICKNESS BURNS, ULCERS (SUCH AS DIABETIC OR PRESSURE), FLAPS AND GRAFTS.,V.A.C. GRANUFOAM DRESSING SMALL, MEDIUM, LARGE WITH SENSAT.R.A.C TECHNOLOGY(V.A.C. GRANUFOAM)-THE V .A.C.® THERAPY SYSTEMS ARE INTEGRATED WOUND MANAGEMENT SYSTEMS FOR USE IN ACUTE, AND EXTENDED AND HOME CARE SETTINGS. WHEN USED ON OPEN WOUNDS, THE SYSTEMS ARE INTENDED TO CREATE AN ENVIRONMENT THAT PROMOTES WOUND HEALING BY SECONDARY OR TERTIARY (DELAYED PRIMARY) INTENTION BY PREPARING THE WOUND BED FOR CLOSURE, REDUCING EDEMA, PROMOTING GRANULATION TISSUE FORMATION BY PERFUSION, AND BY REMOVING EXUDATES AND INFECTIOUS MATERIAL. OPEN WOUND TYPES INCLUDE: CHRONIC, ACUTE, TRAUMATIC, SUBACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC, PRESSURE OR VENOUS INSUFFICIENCY), FLAPS AND GRAFTS. WHEN USED ON CLOSED SURGICAL INCISIONS, THE SYSTEMS ARE ALSO INTENDED TO MANAGE THE ENVIRONMENT OF THE SURGICAL INCISIONS THAT CONTINUE TO DRAIN FOLLOWING SUTURED OR STAPLED CLOSURE BY MAINTAINING A CLOSED ENVIRONMENT AND REMOVING EXUDATES VIA APPLICATION OF NEGATIVE PRESSURE WOUND THERAPY.,500ML CANISTER (WITH GEL) FOR INFO V.A.C. AND V.A.C. ULTA THERAPY SYSTEMS(INFO V.A.C.)-THE INFO V.A.C.TM THERAPY SYSTEM IS AN INTEGRATED WOUND MANAGEMENT SYSTEMS FOR USE IN ACUTE, EXTENDED SETTINGS. THEY ARE INTENDED TO CREATE AN ENVIRONMENT THAT PROMOTES WOUND HEALING BY SECONDARY OR TERTIARY (DELAYED PRIMARY) INTENTION BY PREPARING THE WOUND BED FOR CLOSURE, REDUCING EDEMA, PROMOTING GRANULATION TISSUE FORMATION AND PERFUSION,

		AND BY REMOVING EXUDATE AND INFECTIOUS MATERIAL. THEY ARE INDICATED FOR PATIENTS WITH CHRONIC, ACUTE, TRAUMATIC, SUBACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC OR PRESSURE), FLAPS AND GRAFTS.
1851	IMP/MD/2019/000427	1.License Holder Name: BIOCON LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD NEOPAK)-COMPONENT OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS,PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAKTM)-COMPONENT OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS

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1852	IMP/MD/2019/000428	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IV CATHETERS(BD NEXIVA CLOSED IV CATHETER SYSTEM)-THE BD NEXIVA INTRAVASCULAR CATHETER IS INSERTED INTO A PATIENT'S VASCULAR SYSTEM FOR SHORT TERM (LESS THAN 30 DAYS) TO SAMPLE BLOOD, MONITOR BLOOD PRESSURE OR ADMINISTER FLUIDS INTRAVASCULARLY. THE NEEDLE SHIELDING FEATURE AND LUER ACCESS PORT AID IN THE PREVENTION OF NEEDLE STICK INJURIES. BLOOD IS CONTAINED WITHIN THE DEVICE DURING THE CATHETER INSERTION PROCESS ADDING IN THE PREVENTION OF BLOOD EXPOSURE. THIS CATHETER MAY BE USED FOR ANY PATIENT POPULATION WITH CONSIDERATION GIVEN TO ADEQUACY OF VASCULAR ANATOMY AND APPROPRIATENESS OF PROCEDURE. THE 18-22 GAUGE NEXIVA™ CATHETERS ARE SUITABLE FOR USE WITH POWER INJECTORS RATED FOR A MAXIMUM OF 300 PSI WHEN THE LEUR ACCESS PORT(S) IS REMOVED AND A DIRECT CONNECTION IS MADE.,INTRAVASCULAR CATHETER(BD INSYTE™ AUTOGUARD™ SHIELDED IV CATHETER)-BD INSYTE™ AUTOGUARD™ SHIELDED IV CATHETERS ARE INTENDED TO BE INSERTED INTO THE PATIENT'S VASCULAR SYSTEM FOR SHORT TERM USE TO SAMPLE BLOOD, MONITOR BLOOD PRESSURE, OR ADMINISTER FLUIDS INTRAVENOUSLY.,INTRAVASCULAR CATHETER (BD INSYTE™ AUTOGUARD™ BC SHIELDED IV CATHETER BLOOD CONTROL TECHNOLOGY)-THE BD INSYTE™ AUTOGUARD™ BC CATHETER IS INSERTED INTO A PATIENT'S VASCULAR SYSTEM TO SAMPLE BLOOD, MONITOR BLOOD PRESSURE, OR ADMINISTER FLUIDS. ,INTRAVASCULAR CATHETER(BD INSYTE-N™ AUTOGUARD™ SHIELDED IV CATHETER)-BD INSYTE™ N AUTOGUARD™ SHIELDED IV CATHETERS ARE INTENDED TO BE INSERTED INTO THE PATIENT'S VASCULAR SYSTEM FOR SHORT TERM USE TO SAMPLE BLOOD, MONITOR BLOOD PRESSURE, OR ADMINISTER FLUIDS INTRAVENOUSLY.

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1853	IMP/MD/2019/000431	1.License Holder Name: M/S LINVATEC INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INSUFFLATOR SYSTEM (AIRSEAL® IFS SYSTEM)-THE SURGIQUESTAIRSEAL® IFS SYSTEM IS INTENDED FOR USE IN DIAGNOSTIC AND/OR THERAPEUTIC ENDOSCOPIC PROCEDURES TO DISTEND A CAVITY BY FILLING IT WITH GAS, TO ESTABLISH AND MAINTAIN A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS AND TO EVACUATE SURGICAL SMOKE. IT IS INDICATED TO FACILITATE THE USE OF VARIOUS LAPAROSCOPIC INSTRUMENTS BY FILLING THE ABDOMINAL CAVITY WITH GAS TO DISTEND IT, BY CREATING AND MAINTAINING A GAS SEALED OBSTRUCTION-FREE INSTRUMENT PATH AND BY EVACUATING SURGICAL SMOKE. THIS INSTRUMENT IS USED TO INSUFFLATE THE RECTUM AND COLON TO FACILITATE ENDOSCOPIC OBSERVATION, DIAGNOSIS AND TREATMENT. THE TROCAR OF THE AIRSEAL® IFS SYSTEM IS INDICATED FOR USE WITH OR WITHOUT VISUALIZATION.
1854	IMP/MD/2019/000433	1.License Holder Name: MERCK SPECIALITIES PVT LTD ,GALA NO. 1 TO 10, BLDG NO. C-9, SHREE ARIHANT COMPOUND, GROUND FLOOR, RETIBUNDER ROAD, , KALHER , TAL -BHIWANDI - 15 (THANE Z5) , THANE MAHARASHTRA ,421302 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INJECTOR PEN(ALUETTA) -TO FACILITATE DELIVERY OF A SET DOSE OF SAIZEN® READY-TO-USE CARTRIDGES SUBCUTANEOUSLY AT THE ABDOMEN, THE THIGH, THE UPPER BUTTOCKS OR THE BACK ARM

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1855	IMP/MD/2019/000435	1.License Holder Name: LG CHEM LIFE SCIENCES INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CROSS LINKED HYALURONIC ACID DERMAL FILLER 22 MG/ML(YVOIRE CONTOUR)-FACIAL TISSUE AUGMENTATION TYPICALLY USED FOR TREATMENT OF EXTREME FACIAL WRINKLES AND FOLDS, AND ALSO REPLACEMENT OF VOLUME DEFECTS, FACIAL LIPOATROPHY AND IMPROVEMENT OF FACIAL CONTOUR DEFORMITIES BY INJECTION IN THE FACIAL SUBCUTANEOUS AND SUPRAPERIOSTEAL FACIAL LAYERS.,CROSS LINKED HYALURONIC ACID DERMAL FILLER 22MG/ML(YVOIRE CLASSIC S)-FACIAL TISSUE AUGMENTATION BY INJECTION INTO AREAS IN WHICH RESTORATION IS REQUIRED. TYPICALLY USED FOR TREATMENT OF WRINKLES AND FOLDS, AND ALSO FOR AUGMENTATION OF LIPS.,CROSS LINKED HYALURONIC ACID DERMAL FILLER 22MG/ML(YVOIRE VOLUME S)-FACIAL TISSUE AUGMENTATION BY INJECTION INTO AREAS IN WHICH RESTORATION IS REQUIRED. TYPICALLY USED FOR TREATMENT OF SEVERE FACIAL WRINKLES AND FOLDS, AND ALSO FOR AUGMENTATION OF LIPS.
1856	IMP/MD/2019/000436	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ULTRASOUND-VISIBLE STIMULATION NEEDLE FOR PERIPHERAL NERVE BLOCKS(STIMUPLEX ULTRA 360)-PLEXUS AND PERIPHERAL NERVE BLOCKS USING ELECTRICAL NERVE STIMULATION AND/OR ULTRASOUND RESPECTIVELY FOR PRECISE DETECTION OF DEFINITE NERVE AREAS. NERVE BLOCKS ARE USED AS ANESTHESIA FOR SURGICAL PROCEDURES AS WELL AS FOR PAIN THERAPY INVOLVING THE UPPER AND LOWER EXTREMITIES WITH VARIOUS BLOCK TECHNIQUES.
1857	IMP/MD/2019/000437	1.License Holder Name: MICROPORT SCIENTIFIC INDIA PVT. LTD., , SHOP NO. 9, KAMLA PALACE, CIVIL LINE, BARFKHANA ,GURGAON HARYANA ,122001 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CARDIAC RF ABLATION CATHETER(FIREMAGIC)-FIREMAGIC CARDIAC RF ABLATION CATHETER IS INDICATED FOR CATHETER-BASED CARDIAC ELECT OR PHYSIOLOGICAL MAPPING (STIMULATING AND RECORDING), AND WHEN USED WITH RADIOFREQUENCY GENERATOR, FOR THE TREATMENT OF ATRIOVENTRICULAR NODAL REENTRANT TACHYCARDIA AND ATRIOVENTRICULAR REENTRANT TACHYCARDIA VIA CATHETER-BASED RADIO FREQUENCY ABLATION.

1858	IMP/MD/2019/000438	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOSTASIS VALVE (GUARDIAN® II HEMOSTASIS VALVE AND GUARDIAN® II NC HEMOSTASIS VALVE)-THE GUARDIAN HEMOSTASIS VALVES ARE INTENDED TO MAINTAIN HEMOSTASIS DURING THE USE OF DIAGNOSTIC OR INTERVENTIONAL DEVICES. GUARDIAN HEMOSTASIS VALVES ARE INDICATED FOR MAINTAINING A SEAL AROUND DIAGNOSTIC/INTERVENTIONAL DEVICES WITH OUTSIDE DIAMETERS UP TO 8F (0.105" OR 2.67MM) DURING DIAGNOSTIC/INTERVENTIONAL PROCEDURES. THE TORQUE DEVICE IS PROVIDED AS AN AID FOR STEERING THE GUIDEWIRE WITHIN THE VASCULAR ANATOMY. THE SIDEARM EXTENSION TUBING INCLUDED IS PROVIDED TO EXTEND THE SIDEARM OF THE GUARDIAN II OR GUARDIAN II NC HEMOSTASIS VALVE.
1859	IMP/MD/2019/000439	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TUBING(FMS FLUID MANAGEMENT SYSTEM)-THE FMS INFLOW TUBING IS INTENDED FOR USE WITH THE FMS VUE PUMP IN A SURGICAL SETTING BY PERSONNEL TRAINED IN ARTHROSCOPY. THE INFLOW TUBING IS AN ACCESSORY TO THE FMS VUE FLUID MANAGEMENT AND TISSUE DEBRIDEMENT SYSTEM. THE FMS OUTFLOW AND INTERMEDIARY TUBINGS ARE ACCESSORIES TO THE FMS FLUID MANAGEMENT SYSTEM. THEY ARE INTENDED FOR USE WITH THE FMS FLUID MANAGEMENT SYSTEMS IN A SURGICAL SETTING BY PERSONNEL TRAINED IN ARTHROSCOPY.

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1860	IMP/MD/2019/000443	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED ,NO. 17, GROUND FLOOR AND MEZZANINE FLOOR, THIRUNEERMALAI ROAD, NAGALKENI, CHROMPET ,CHENNAI TAMIL NADU ,600044 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOWICK SURELOCK IMPLANT(BIOWICK SURELOCK IMPLANT)-BIOWICK SURELOCK IMPLANT IS INTENDED TO BE USED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE IN ROTATOR CUFF REPAIRS.,NON-ABSORBABLE SUTURE ANCHOR(QUATTRO X WITH BROADBAND SUTURE ANCHOR)-QUATTRO X WITH BROADBAND SUTURE ANCHORS ARE INTENDED FOR USE FOR THE REATTACHMENT OF SOFT TISSUE TO BONE IN ROTATOR CUFF REPAIRS.,BIOWICK X IMPLANT(BIOWICK X IMPLANT)-BIOWICK X IMPLANT IS INTENDED TO BE USED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE IN ROTATOR CUFF REPAIRS.
1861	IMP/MD/2019/000444	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IV DRESSING, CHLORHEXIDINE GLUCONATE (CHG) ANTIMICROBIAL(BD CHLORASHIELD™ IV SURROUND DRESSING WITH CHLORHEXIDINE GLUCONATE (CHG) ANTIMICROBIAL)-BD CHLORASHIELD IV DRESSING WITH CHLORHEXIDINE GLUCONATE ANTIMICROBIAL IS INTENDED TO BE USED TO COVER AND PROTECT CATHETER SITES AND TO SECURE DEVICES TO THE SKIN. COMMON APPLICATIONS INCLUDE COVERING AND SECURING IV CATHETERS, OTHER INTRAVASCULAR CATHETERS AND PERCUTANEOUS DEVICES,IV DRESSING, CHLORHEXIDINE GLUCONATE ANTIMICROBIAL(BD CHLORASHIELD™ IV DRESSING WITH CHLORHEXIDINE GLUCONATE (CHG) ANTIMICROBIAL)-BD CHLORASHIELD IV DRESSING WITH CHLORHEXIDINE GLUCONATE ANTIMICROBIAL IS INTENDED TO BE USED TO COVER AND PROTECT CATHETER SITES AND TO SECURE DEVICES TO THE SKIN. COMMON APPLICATIONS INCLUDE COVERING AND SECURING IV CATHETERS, OTHER INTRAVASCULAR CATHETERS AND PERCUTANEOUS DEVICES.

1862	IMP/MD/2019/000445	1.License Holder Name: ASPIROM HEALTHCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMODIALYSIS CATHETER KIT/SET(ABLECATH)-THE ABLE CENTRAL VENOUS CATHETERS KIT/SET MAY BE APPLICABLE TO ONE OF THE FOLLOWING THERAPY: -MONITOR OF CENTRAL VENOUS PRESSURE -CONTINUOUS OR DISCONTINUOUS VENOUS TRANSFUSION -BLOOD SAMPLING THE CATHETER IS SURGICALLY PENETRATED INTO THREE OPTIONAL PUNCTURE POINTS DEPENDED ON THE CLINICAL REQUIREMENT WITH SELDINGER TECHNIQUE. THE INSERTION SITES ARE: 1. INTERNAL JUGULAR VEIN 2. SUBCLAVIAN VEIN 3. FEMORAL VEIN IT IS POSSIBLE TO BE INSERTED INSIDE THE BODY FOR LESS THAN DAYS. IF DURATION EXCEEDS 30 DAYS, IT MAY OCCUR THE RISK OF COMBINING THE CATHETER AND INSIDE TISSUE, WHICH RESULT IN SERIOUS INCIDENT.,CENTRAL VENOUS CATHETER KIT/SET (ABLECATH)-THE ABLE CENTRAL VENOUS CATHETERS KIT/SET MAY BE APPLICABLE TO ONE OF THE FOLLOWING THERAPY: -MONITOR OF CENTRAL VENOUS PRESSURE -CONTINUOUS OR DISCONTINUOUS VENOUS TRANSFUSION -BLOOD SAMPLING THE CATHETER IS SURGICALLY PENETRATED INTO THREE OPTIONAL PUNCTURE POINTS DEPENDED ON THE CLINICAL REQUIREMENT WITH SELDINGER TECHNIQUE. THE INSERTION SITES ARE: 1. INTERNAL JUGULAR VEIN 2. SUBCLAVIAN VEIN 3. FEMORAL VEIN IT IS POSSIBLE TO BE INSERTED INSIDE THE BODY FOR LESS THAN DAYS. IF DURATION EXCEEDS 30 DAYS, IT MAY OCCUR THE RISK OF COMBINING THE CATHETER AND INSIDE TISSUE, WHICH RESULT IN SERIOUS INCIDENT.

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1863	IMP/MD/2019/000446	1.License Holder Name: M/S AFM MEDICALS & DEVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMODIALYSIS CATHETER KIT/SET(ABLECATH)-THE PRODUCT IS APPLICABLE FOR HEMODIALYSIS, VENOUS TRANSFUSION, CONTINUOUS MONITORING THE VENOUS PRESSURE. THE TIME OF USE IS LESS THAN 30 DAYS., DISPOSABLE BLOOD LINES(ABLE)-THE PRODUCT IS INTENDED TO ESTABLISH BLOOD CIRCULATION PATH OUTSIDE HUMAN BODY. I CAN MATCH ALL DIALYSIS MACHINES.,DISPOSABLE FISTULA NEEDLES(ABLE)-THE PRODUCT IS INTENDED TO PUNCTURE THE MATURE FISTULA, AND CONNECT WITH THE BLOOD LINES TO ESTABLISH BLOOD CIRCULATING PATH OUTSIDE HUMAN BODY IN THE PROCESS OF HEMODIALYSIS.,CENTRAL VENOUS CATHETER KIT/SET(ABLECATH)-THE PRODUCT IS USED TO INFUSE HIGHLY OSMOLAR OR GREATLY VEIN-IRRITATING SOLUTIONS, FOR INTERMITTENT OR CONTINUOUS MONITORING OF CENTRAL VENOUS PRESSURE, FOR BLOOD SAMPLING. IT IS POSSIBLE TO BE INSERTED INSIDE THE BODY FOR MORE THAN 30 DAYS.
1864	IMP/MD/2019/000447	1.License Holder Name: CORAL HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONDOMS(OKAMOTO)-IT IS USED AS A BARRIER CONTRACEPTIVE FOR PREVENTION OF PREGNANCY & AND PREVENTION OF SEXUALLY TRANSMITTED DISEASES.
1865	IMP/MD/2019/000448	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALGINATE DRESSING WITH SILVER(COVAWOUND™ ALGINATE AG)-COVAWOUND™ ALGINATE DRESSINGS WITH SILVER CAN BE USED FOR THE MANAGEMENT OF WOUNDS WHICH ARE MODERATE AND HEAVILY EXUDING, INCLUDING SUPERFICIAL OR DEEP WOUNDS, SUCH AS PRESSURE SORES, ARTERIAL ULCERS, VENOUS LEG ULCERS, DIABETIC ULCERS AND POST-OPERATIVE WOUNDS.

1866	IMP/MD/2019/000450	1.License Holder Name: ENVISION SCIENTIFIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA CATHETER (TAMARIN BLUE)-IT IS INDICATED FOR: • BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. • BALLOON DILATATION OF A STENT AFTER IMPLANTATION (BALLOON MODELS 2.00MM - 4.50MM) ,PTA 0.014" OTW, PTA 0.018" OTW CATHETER(EBONY 0.014" OTW, EBONY 0.018" OTW)-EBONY 0.014"OTW CATHETER IS SPECIALLY DESIGNED FOR THE PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF VASCULAR DISTRICTS AS FEMORAL ARTERY AND BELOW THE KNEE VESSELS WITH A REFERENCE DIAMETER EQUAL OR LARGER THAN SELECTED BALLOON SIZES. EBONY 0.018"OTW CATHETER IS INTENDED TO DILATE STENOSIS IN THE PERIPHERAL ARTERIES (ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA POPLITEAL, RENAL ARTERIES) AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE.,RX PTA CATHETER (EBONY 0.014" RX)-IT IS INTENDED FOR DILATATION OF LESIONS IN THE ILIAC, FEMORAL, POPLITEAL, INFRAPOPLITEAL AND RENAL ARTERIES.,PTA 0.035" OTW CATHETER(EBONY 0.035" OTW)-IT IS INTENDED FOR DILATATION OF LESIONS IN THE FEMORAL, ILIAC, POPLITEAL, INFRAPOPLITEAL AND RENAL ARTERIES

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1867	IMP/MD/2019/000451	1.License Holder Name: VIBGYOR HEALTH CARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STENT GRAFT SYSTEM(E-VITA THORACIC 3G)-THE E-VITA THORACIC 3G STENT GRAFT FROM JOTEC GMBH HAS BEEN SPECIALLY DEVELOPED FOR TREATMENT OF ANEURYSMS, DISSECTIONS AND SPECIFIC LESIONS OF THE THORACIC AORTA DESCENDENS. THE MAIN INDICATIONS FOR USE OF A STENT GRAFT FROM JOTEC GMBH WOULD BE, IN PARTICULAR, ACUTELY LIFE-THREATENING PATIENT CONDITIONS DUE TO • ANEURYSM RUPTURE • TRAUMATIC AORTIC RUPTURE • AORTIC DISSECTION • A PLAQUE RUPTURE • A PENETRATING AORTIC ULCER (PAU) • AN INTRAMURAL HAEMATOMA (IMH) • AN AORTOBRONCHIAL FISTULA OR AORTOOESOPHAGEAL FISTULA,STENT GRAFT BALLOON CATHETER(E-XPAND)-THE E-XPAND STENT GRAFT BALLOON CATHETER HAS BEEN DEVELOPED FOR USE WITH JOTEC'S SELF-EXPANDING ENDOVASCULAR STENT GRAFT SYSTEMS AND IS DESIGNED TO FACILITATE STENT GRAFT EXPANSION.,EPTFE VASCULAR GRAFT(FLOWLINE BIPORE)-THE FLOWLINE BIPORE EPTFE VASCULAR GRAFT IS INDICATED IN CASES OF ARTERIAL RECONSTRUCTION, PRIMARILY IN THE PERIPHERAL VASCULAR REGION. IT CAN ALSO BE USED IN EXTRAANATOMICAL RECONSTRUCTIONS – FEMOROFEMORAL AND AXILLOFEMORAL. STANDARDWALL FLOWLINE BIPORE PROSTHESIS ARE ALSO INDICATED FOR USE AS ARTERIOVENOUS SHUNT PROSTHESIS IN HAEMODIALYSIS.,TEXTILE VASCULAR GRAFT(FLOWNIT BIOSEAL)-FLOWNIT BIOSEAL IS INDICATED IN ARTERIAL ANEURYSMS AND VASCULAR OCCLUSIONS. FLOWNIT BIOSEAL IS PRIMARILY INDICATED FOR VASCULAR REPLACEMENT IN THE ENTIRE ABDOMINAL AORTA AND IN PERIPHERAL VASCULAR APPLICATIONS INVOLVING VESSEL DIAMETERS OF AT LEAST 6MM.,STENT GRAFT SYSTEM(E-VITA OPEN PLUS)-THE E-VITA OPEN PLUS STENT GRAFTS FROM JOTEC GMBH HAVE BEEN SPECIFICALLY DEVELOPED FOR THE TREATMENT OF ANEURYSMS, DISSECTIONS AND SPECIFIC LESIONS OF THE THORACIC AORTA. THE INDICATIONS FOR THE USE OF THE E-VITA OPEN PLUS STENT GRAFT FROM JOTEC GMBH PRIMARILY INVOLVE ACUTELY LIFE-THREATENING PATIENT CONDITIONS DUE TO: • ACUTE AORTIC DISSECTIONS (TYPE STANFORD A) EXTENDING DEEP INTO THE DESCENDING AORTA, • ACUTE AORTIC DISSECTIONS (TYPE STANFORD A) IN COMBINATION WITH MARFAN SYNDROME, • EXTENSIVE AORTIC ANEURYSMS OF THE ASCENDING AORTA OR OFTHE AORTIC ARCH EXTENDING TO THE DESCENDING AORTA (ALSOMYCOTIC ANEURYSMS), • COMPLEX AORTIC DISSECTIONS (TYPE STANFORD B) OR • CHRONIC EXTENSIVE AORTIC DISSECTIONS.,TEXTILE VASCULAR GRAFT(FLOWWEAVE BIOSEAL)-

	FLOWWEAVE BIOSEAL IS INDICATED IN ARTERIAL ANEURYSMS AND VASCULAR OCCLUSIONS. THE PRIMARY INDICATION FOR FLOWWEAVE BIOSEAL IS VASCULAR REPLACEMENT IN THE THORACIC AND ABDOMINAL AORTAS, ALTHOUGH IT CAN ALSO BE USED IN PERIPHERAL VASCULAR APPLICATIONS INVOLVING VESSEL DIAMETERS OF AT LEAST 6MM.,STENT GRAFT SYSTEM(E-TEGRA)-THE E-TEGRA STENT GRAFT SYSTEM IS INDICATED FOR THE ENDOVASCULAR TREATMENT OF INFRARENAL AORTIC ANEURYSMS WHICH MAY ALSO AFFECT THE COMMON ILIAC ARTERY PROVIDED THE FOLLOWING PRECONDITIONS ARE MET: • SUITABLE MORPHOLOGY OF THE ILIAC OR FEMORAL ACCESS VESSELS • LENGTH OF THE PROXIMAL LANDING ZONE IN THE INFRARENAL AORTA 15 MM • ANGLE OF THE INFRARENAL AORTA DISTAL TO THE LANDING ZONE 75° • DIAMETER OF THE PROXIMAL LANDING ZONE 19 - 32 MM • LENGTH OF THE DISTAL LANDING ZONE IN THE COMMON ILIAC ARTERY 15 MM • DIAMETER OF THE DISTAL LANDING ZONE IN THE COMMON ILIAC ARTERY 8 - 25 MM • VASCULAR MORPHOLOGY SUITABLE FOR THE USE OF A STENT GRAFT,GUIDE WIRE (E-WIRE)-THE JOTEC GUIDE WIRE FACILITATES THE PLACEMENT AND REPLACEMENT OF CATHETERS IN DIAGNOSTIC AND INTERVENTIONAL PROCEDURES, PARTICULARLY THE TREATMENT OF ABDOMINAL AND THORACIC AORTIC ANEURYSMS INVOLVING ENDOVASCULAR PROSTHESES.,STENT GRAFT SYSTEM(E-LIAC)-THE E-LIAC STENT GRAFT SYSTEM IS INDICATED FOR THE ENDOVASCULAR TREATMENT OF PATIENTS WITH THE FOLLOWING CHARACTERISTICS: • UNILATERAL OR BILATERAL AORTO-ILIAC OR ILIAC ANEURYSM • SUITABLE FOR ENDOVASCULAR REPAIR • PATIENT MUST BE COMPLIANT WITH LIFE- LONG FOLLOW-UP INVESTIGATIONS • > 18 YEARS OLD • ILIAC/FEMORAL ACCESS VESSEL MORPHOLOGY COMPATIBLE WITH THE IMPLANTATION PROCEDURE AND THE 18F (6MM OD) DELIVERY SYSTEM • NON-ANEURYSMAL COMMON ILIAC ARTERY LANDING AREA IN CASE OF ILIAC ARTERY ANEURYSM 20MM • DIAMETER OF THE COMMON ILIAC ARTERY IN THE PROXIMAL LANDING AREA: 12MM TO 17MM • NON-ANEURYSMAL EXTERNAL ILIAC ARTERY SEGMENT DISTAL TO THE ANEURYSM 15MM • DIAMETER OF THE EXTERNAL ILIAC ARTERY IN THE DISTAL LANDING AREA: 8MM TO 13MM • NON-ANEURYSMAL INTERNAL ILIAC ARTERY SEGMENT DISTAL TO THE ANEURYSM 15MM • ANGLE BETWEEN EXTERNAL ILIAC ARTERY AND INTERNAL ILIAC ARTERY 50° • THROMBUS FREE ILIAC LUMEN IN THE AREA OF ILIAC BIFURCATION TO OPEN SIDE BRANCH AND TO IMPLANT COVERED STENT 18MM • SUFFICIENTLY OPEN INTERNAL ILIAC ARTERY OSTIUM

1868	IMP/MD/2019/000452	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CAROTID GUIDING SHEATH(DESTINATION)-DESIGNED TO BE USED FOR THE INTRODUCTION OF INTERVENTIONAL AND DIAGNOSTIC DEVICES INTO THE HUMAN VASCULATURE INCLUDING BUT NOT LIMITED TO THE CAROTID ARTERIES.,PERIPHERAL GUIDING SHEATH (DESTINATION)-DESIGNED TO BE USED FOR THE INTRODUCTION OF INTERVENTIONAL AND DIAGNOSTIC DEVICES INTO THE HUMAN VASCULATURE INCLUDING BUT NOT LIMITED TO LOWER EXTREMITY ACCESS VIA A CONTRALATERAL APPROACH.,RENAL GUIDING SHEATH(DESTINATION)-DESIGNED TO BE USED FOR THE INTRODUCTION OF INTERVENTIONAL AND DIAGNOSTIC DEVICES INTO THE HUMAN VASCULATURE INCLUDING BUT NOT LIMITED TO THE RENAL ARTERIES.
1869	IMP/MD/2019/000453	1.License Holder Name: ROMSONS SCIENTIFIC & SURGICAL INDUSTRIES PVT LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REINFORCED ENDOTRACHEAL TUBE NON STERILE BULK(NIL)-AN REINFORCED ENDOTRACHEAL TUBE IS USED IN GENERAL ANESTHESIA, INTENSIVE CARE AND EMERGENCY MEDICINE FOR AIRWAY MANAGEMENT AND MECHANICAL VENTILATION. THE TUBE IS INSERTED INTO A PATIENT'S TRACHEA THROUGH THE PATIENT'S NOSE OR MOUTH IN ORDER TO ENSURE THAT THE AIRWAY IS NOT CLOSED OFF AND THAT AIR IS ABLE TO REACH THE LUNGS.,SILICONE LARYNGEAL MASK NON STERILE BULK(NIL)-AN SILICONE LARYNGEAL MASK IS USED IN GENERAL ANAESTHESIA, INTENSIVE CARE AND EMERGENCY MEDICINE FOR AIRWAY MANAGEMENT AND MECHANICAL VENTILATION. THE TUBE IS INSERTED INTO A PATIENT'S TRACHEA THROUGH THE PATIENT'S MOUTH IN ORDER TO ENSURE THAT THE AIRWAY IS NOT CLOSED OFF AND THAT AIR IS ABLE TO REACH THE LUNGS.,SILICONE FOLEY CATHETER 2 WAY AND 3 WAY NON STERILE BULK(NIL)-THE SILICONE FOLEY CATHETER IS USED IN DRAINAGE OF URINE FROM THE URINARY TRACT AND/OR CONTINUOUS IRRIGATION OF FLUIDS. IT'S ALWAYS USED IN DEPARTMENTS OF UROLOGY, INTERNAL MEDICINE, SURGERY, OBSTETRICS, AND GYNECOLOGY FOR PATIENTS SUFFERING FORM MOVING WITH DIFFICULTY OR BEING COMPLETELY BED-RIDDEN.

1870	IMP/MD/2019/000454	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SHOULDER PROSTHESIS-GLENOSPHERE(DELTA XTEND)-THE DEPUY DELTA XTEND SHOULDER PROSTHESIS IS INTENDED FOR USE IN TOTAL SHOULDER OR HEMI-SHOULDER REPLACEMENT PROCEDURES IN PATIENTS WITH NON-FUNCTIONAL ROTATOR CUFFS, WITH OR WITHOUT BONE CEMENT. HA COMPONENTS ARE FOR CEMENTLESS USE ONLY.,ORTHOPAEDIC IMPLANT- SCREW(REEF)-THE USE OF METALLIC SURGICAL APPLIANCES PROVIDES THE ORTHOPAEDIC SURGEON WITH A MEANS OF BONE FIXATION AND HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANTS ARE INTENDED AS A GUIDE TO NORMAL HEALING AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURE OR BEAR THE WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING. DELAYED UNIONS OR NON-UNIONS IN THE PRESENCE OF LOAD BEARING OR WEIGHT BEARING MIGHT EVENTUALLY CAUSE THE IMPLANT TO BREAK DUE TO METAL FATIGUE. DURING USE ALL METAL SURGICAL IMPLANTS ARE SUBJECTED TO REPEATED STRESS WHICH CAN RESULT IN METAL FATIGUE.,SHOULDER PROSTHESIS-METAGLENE(DELTA XTEND)-THE DEPUY DELTA XTEND SHOULDER PROSTHESIS IS INTENDED FOR USE IN TOTAL SHOULDER OR HEMI-SHOULDER REPLACEMENT PROCEDURES IN PATIENTS WITH NON-FUNCTIONAL ROTATOR CUFFS, WITH OR WITHOUT BONE CEMENT. HA COMPONENTS ARE FOR CEMENTLESS USE ONLY.,ORTHOPAEDIC IMPLANTS- WING(REEF)-REEF SYSTEM IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY ONLY. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE PROXIMAL BONE CONDITION IS NOT SUFFICIENT AND DISTAL ANCHORAGE IS REQUIRED TO OBTAIN PRIMARY STABILITY. REEF SYSTEM IS INTENDED FOR CEMENTLESS USE ONLY., SHOULDER PROSTHESIS- SCREW(DELTA XTEND)-THE DEPUY DELTA XTEND SHOULDER PROSTHESIS IS INTENDED FOR USE IN TOTAL SHOULDER OR HEMI-SHOULDER REPLACEMENT PROCEDURES IN PATIENTS WITH NON-FUNCTIONAL ROTATOR CUFFS, WITH OR WITHOUT BONE CEMENT. HA COMPONENTS ARE FOR CEMENTLESS USE ONLY.,ORTHOPAEDIC IMPLANT- BASE(REEF)-REEF SYSTEM IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY ONLY. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE PROXIMAL BONE CONDITION IS NOT SUFFICIENT AND DISTAL ANCHORAGE IS REQUIRED TO OBTAIN PRIMARY STABILITY. REEF SYSTEM IS

	INTENDED FOR CEMENTLESS USE ONLY.,SHOULDER PROSTHESIS-SPACER(DELTA XTEND)-THE DEPUY DELTA XTEND SHOULDER PROSTHESIS IS INTENDED FOR USE IN TOTAL SHOULDER OR HEMI-SHOULDER REPLACEMENT PROCEDURES IN PATIENTS WITH NON-FUNCTIONAL ROTATOR CUFFS, WITH OR WITHOUT BONE CEMENT. HA COMPONENTS ARE FOR CEMENTLESS USE ONLY.,SHOULDER PROSTHESIS- EPIPHYSIS(DELTA XTEND)-THE DEPUY DELTA XTEND SHOULDER PROSTHESIS IS INTENDED FOR USE IN TOTAL SHOULDER OR HEMI-SHOULDER REPLACEMENT PROCEDURES IN PATIENTS WITH NON-FUNCTIONAL ROTATOR CUFFS, WITH OR WITHOUT BONE CEMENT. HA COMPONENTS ARE FOR CEMENTLESS USE ONLY.,HIP SYSTEM- STEM(CORAIL AMT)-CORAIL AMT HA COATED STEMS ARE INTENDED FOR USE IN TOTAL AND PARTIAL HIP ARTHROPLASTY. THE STEMS ARE INTENDED ONLY FOR UNCEMENTED USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. PARTIAL HIP ARTHROPLASTY (HIP HEMIARTHROPLASTY) IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM. ,HIP SYSTEM- REVISION STEM(CORAIL)-THE HA-COATED STEM IN THE CORAIL REVISION SYSTEM IS INTENDED FOR USE IN A PRIMARY HIP ARTHROPLASTY OR FOR THE REVISION OF A FAILED PREVIOUS HIP SURGERY. THE CORAIL REVISION STEM IS INTENDED FOR UNCEMENTED USE ONLY. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3. ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK. 4. FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5. CERTAIN CASES OF ANKYLOSIS. HA-COATED STEMS ARE INDICATED FOR CEMENTLESS USE ONLY. , ORTHOPAEDIC IMPLANT- STEM(REEF)-REEF SYSTEM IS INTENDED

	FOR USE IN TOTAL HIP ARTHROPLASTY ONLY. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE PROXIMAL BONE CONDITION IS NOT SUFFICIENT AND DISTAL ANCHORAGE IS REQUIRED TO OBTAIN PRIMARY STABILITY. REEF SYSTEM IS INTENDED FOR CEMENTLESS USE ONLY.,SHOULDER PROSTHESIS-STEM(DELTA XTEND)-THE DEPUY DELTA XTEND SHOULDER PROSTHESIS IS INTENDED FOR USE IN TOTAL SHOULDER OR HEMI-SHOULDER REPLACEMENT PROCEDURES IN PATIENTS WITH NON-FUNCTIONAL ROTATOR CUFFS, WITH OR WITHOUT BONE CEMENT. HA COMPONENTS ARE FOR CEMENTLESS USE ONLY.,SHOULDER PROSTHESIS- CUP(DELTA XTEND)-THE DEPUY DELTA XTEND SHOULDER PROSTHESIS IS INTENDED FOR USE IN TOTAL SHOULDER OR HEMI-SHOULDER REPLACEMENT PROCEDURES IN PATIENTS WITH NON-FUNCTIONAL ROTATOR CUFFS, WITH OR WITHOUT BONE CEMENT. HA COMPONENTS ARE FOR CEMENTLESS USE ONLY.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1871	IMP/MD/2019/000455	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FIXATION STAPLES(NA)-1. TENDON REPAIRS, TRANSFERS, OR TRANSPLANTS, SUCH AS IN THE TREATMENT OF PARALYTIC CONDITIONS, TENDON AVULSIONS OR RUPTURES, IN WHICH THE TENDON IS FIXED TO THE BONE. 2. LIGAMENT REPAIRS, RECONSTRUCTION, OR REPLACEMENT IN WHICH THE LIGAMENT IS FIXED TO THE BONE. 3. ADJUNCTIVE INTERNAL FIXATION OF FRACTURES, OR ARTHRODESIS. 4. OSTEOTOMY STAPLES ARE INDICATED FOR USE IN INTERNAL FIXATION OF BONE FOLLOWING PROXIMAL TIBIAL OSTEOTOMY. 5. THE FIXATION OF AVULSED LIGAMENTS TO BONE SUCH AS THE GREATER HUMERAL TUBEROSITY OR FEMORAL TROCHANTER, THE CALCANEUS, OR THE TIBIAL TUBERCLE.,SMALL FRAGMENT PLATING SYSTEM - PLATES (EVOS)-THE EVOS SMALL FRAGMENT PLATING SYSTEM IS INDICATED FOR ADULT AND PEDIATRIC PATIENTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. IT IS INDICATED FOR FIXATION OF SMALL AND LONG BONE FRACTURES, INCLUDING BUT NOT LIMITED TO, THOSE OF THE TIBIA, FIBULA, FEMUR, HUMERUS, ULNA, RADIUS, PELVIS, ACETABULUM, METACARPALS, METATARSALS, AND CLAVICLE. THE EVOS PARTIAL ARTICULAR AND ANTI-GLIDE PLATES ARE INDICATED FOR THE TREATMENT OF PARTIAL ARTICULAR FRACTURES OF THE DISTAL AND PROXIMAL TIBIA (AO/OTA FRACTURE CLASSIFICATION TYPE B), AND FOR FRACTURE FIXATION OF THE FIBULA.,SMALL FRAGMENT PLATING SYSTEM - PLATES(EVOS)-THE EVOS SMALL FRAGMENT PLATING SYSTEM IS INDICATED FOR ADULT AND PEDIATRIC PATIENTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. IT IS INDICATED FOR FIXATION OF SMALL AND LONG BONE FRACTURES, INCLUDING BUT NOT LIMITED TO, THOSE OF THE TIBIA, FIBULA, FEMUR, HUMERUS, ULNA, RADIUS, PELVIS, ACETABULUM, METACARPALS, METATARSALS, AND CLAVICLE. THE EVOS PARTIAL ARTICULAR AND ANTI-GLIDE PLATES ARE INDICATED FOR THE TREATMENT OF PARTIAL ARTICULAR FRACTURES OF THE DISTAL AND PROXIMAL TIBIA (AO/OTA FRACTURE CLASSIFICATION TYPE B), AND FOR FRACTURE FIXATION OF THE FIBULA.

1872	IMP/MD/2019/000455	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRAMEDULLARY NAIL SYSTEM(TRIGEN)-INDICATIONS FOR INTERLOCKING INTRAMEDULLARY NAILS INCLUDE SIMPLE LONG BONE FRACTURES; SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNIONS AND MALUNIONS; POLYTRAUMA AND MULTIPLE FRACTURES; PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES; RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; SUPRACONDYLAR FRACTURES; BONE LENGTHENING AND SHORTENING. INTERLOCKING INTRAMEDULLARY NAILS ARE INDICATED FOR FIXATION OF FRACTURES THAT OCCUR IN AND BETWEEN THE PROXIMAL AND DISTAL THIRD OF THE LONG BONES BEING TREATED.,KNEE SYSTEM(GENESIS II)-1. RHEUMATOID ARTHRITIS. 2. POST TRAUMATIC ARTHRITIS, OSTEOARTHRITIS, OR DEGENERATIVE ARTHRITIS. 3. FAILED OSTEOTOMIES, UNICOMPARTMENTAL REPLACEMENT, OR TOTAL KNEE REPLACEMENT. 4. POSTERIOR STABILIZED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE INCOMPETENT AND THE COLLATERAL LIGAMENTS REMAIN INTACT. 5. CONSTRAINED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE INCOMPETENT. 6. HINGE KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE ABSENT OR INCOMPETENT.,BONE PLATE SYSTEM(PERI-LOC)-THE PERL-LOC PLATE AND SCREW SYSTEM CAN BE USED FOR ADULT AND PEDIATRIC PATIENTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. PERL-LOC BONE PLATES AND BONE SCREWS ARE INDICATED FOR FIXATION OF PELVIC, SMALL AND LONG BONE FRACTURES, INCLUDING THOSE OF THE TIBIA, FIBULA, FEMUR, PELVIS, ACETABULUM, METACARPALS, METATARSALS, HUMERUS, ULNA, RADIUS, CALCANEUS, AND CLAVICLE. PERL-LOC PERIARTICULAR LOCKED PLATING SYSTEM VLP PLATES AND SCREWS CAN BE USED FOR ADULT AND PEDIATRIC PATIENTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. PERL-LOC CONTOURED VLP PLATES AND

	SCREWS ARE INDICATED FOR PARTIAL ARTICULAR FRACTURES (AO/OTA FRACTURE CLASSIFICATION TYPE B) OF THE DISTAL AND PROXIMAL TIBIA, AND FOR FRACTURE FIXATION OF THE FIBULA. PERL-LOC VLP ONE-THIRD TUBULAR LOCKING PLATES ARE INDICATED FOR, BUT NOT LIMITED TO, FIXATION OF FRACTURES, NON-UNIONS AND OSTEOTOMIES OF THE MEDIAL MALLEOLUS, FIBULA, DISTAL ULNA, OLECRANON, CALCANEUS AND METATARSALS. PERL-LOC PERIARTICULAR LOCKED PLATING SYSTEM PROXIMAL FEMUR BONE PLATES, BONE SCREWS AND CABLE ACCESSORIES CAN BE USED FOR ADULT PATIENTS AS WELL AS PATIENTS WITH OSTEOPENIC BONE. PERL-LOC PROXIMAL FEMUR BONE PLATES, BONE SCREWS AND CABLE ACCESSORIES ARE INDICATED FOR FRACTURES OF THE TROCHANTERIC REGION INCLUDING SIMPLE INTERTROCHANTERIC, REVERSE OBLIQUE TROCHANTERIC, TRANSVERSE TROCHANTERIC, COMPLEX MULTI-FRAGMENTARY, AND FRACTURES WITH MEDIAL CORTEX INSTABILITY; PROXIMAL FEMUR FRACTURES COMBINED WITH IPSILATERAL SHAFT FRACTURES; PATHOLOGICAL FRACTURES OF THE PROXIMAL FEMUR INCLUDING METASTATIC FRACTURES; PROXIMAL FEMUR OSTEOTOMIES; FIXATION OF FRACTURES IN OSTEOPENIC BONE; FIXATION OF NONUNIONS AND MALUNIONS; BASIL TRANSCERVICAL FEMORAL NECK FRACTURES; SUBCAPITAL FEMORAL NECK FRACTURES; AND SUBTROCHANTERIC FEMUR FRACTURES. THE SMITH & NEPHEW VLP FOOT PLATING SYSTEM CAN BE USED IN ADOLESCENT 112-18 YEARS) AND TRANSITIONAL ADOLESCENT (18-21 YEARS) SUBPOPULATIONS AND ADULTS, AS WELL AS PATIENTS WITH OSTEOPENLC BONE. THE VLP FOOT PLATING SYSTEM IS INDICATED FOR FRACTURE FIXATION, RECONSTRUCTION OR ARTHRODESES OF SMALL BONES, INCLUDING THOSE IN THE FOREFOOT, MLDFOOT AND HLNDFOOT. THE SMITH & NEPHEW PERL-LOC ANKLE FUSION PLATING SYSTEM CAN BE USED IN ADOLESCENT 112-18 YEARS) AND TRANSITIONAL ADOLESCENT (18-21 YEARS) SUBPOPULATIONS AND ADULTS, AS WELL AS PATIENTS WITH OSTEOPENIC BONE. THE PERL-LOC ANKLE FUSION PLATING SYSTEM IS INDICATED FOR ANKLE ARTHRODESIS AND FRACTURES, INCLUDING THE DISTAL TIBIA, TALUS AND CALCANEUS., FEMORAL HEADS(NA)-HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT.

	HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTURE-DISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY.,FRACTURE FIXATION DEVICES(CANNULATED SCREW) -BONE PLATES AND SCREWS FROM THE SMITH & NEPHEW BONE PLATE SYSTEM ARE USED FOR ADULT AND PEDIATRIC PATIENTS AS INDICATED FOR PELVIC, SMALL, AND LONG BONE FRACTURE FIXATION. INDICATIONS FOR USE INCLUDE FRACTURES OF THE TIBIA, FIBULA, FEMORAL CONDYLE, PELVIS, ACETABULUM, METACARPALS, METATARSALS, HUMERUS, ULNA, MIDDLE HAND AND MIDDLE FOOT BONES; TREATMENT OF THE CALCANEUS; HIP ARTHRODESIS, AND PROVISIONAL HOLEFIXATION. THE 4.0MM CANNULATED SCREWS AND ASSOCIATED WASHERS ARE ADDITIONALLY INTENDED FOR ARTHRODESIS AND OSTEOTOMIES OF SMALL BONES AND SMALL JOINTS, INCLUDING SCAPHOID AND OTHER CARPAL BONES, METACARPALS, TARSALS, METATARSALS, PATELLA, ULNAR STYLOID, CAPITELLUM, RADIAL HEAD AND RADIAL STYLOID. THE 5.5 MM, 6.5MM, 7.0MM, AND 8.0MM CANNULATED SCREWS AND ASSOCIATED WASHERS ARE ADDITIONALLY INTENDED FOR RECONSTRUCTION, OSTEOTOMY, AND ARTHRODESIS OF VARIOUS BONES AND BONE FRAGMENTS APPROPRIATE FOR THE SIZE OF THE DEVICE INCLUDING JOINT FUSIONS (ARTHRODESIS) IN THE FOOT AND ANKLE. THE SMITH & NEPHEW 2.5MM, 3.0MM CANNULATED SCREWS ARE INTENDED FOR FIXATION OF INTRAARTICULAR AND EXTRA-ARTICULAR FRACTURES AND NON-UNIONS OF SMALL BONES AND SMALL BONE FRAGMENTS; ARTHRODESES OF SMALL JOINTS; BUNIONECTOMIES AND OSTEOTOMIES; SCAPHOID AND OTHER CARPAL BONES, METACARPALS, TARSALS, METATARSALS, PATELLA, ULNAR STYLOID, CAPITELLUM, RADIAL HEAD AND RADIAL STYLOID., FRACTURE FIXATION DEVICES(COMPRESSION HIP SCREWS (CHS))- COMPRESSION HIP SCREWS ARE INDICATED FOR • INTRACAPSULAR FRACTURES OF THE FEMORAL NECK. (FOR HIGH SUBCAPSULAR FRACTURES IT MAY BE MORE PRUDENT TO SELECT A PROSTHESIS IN LIEU OF INTERNAL FIXATION TO REDUCE THE RISK OF A NONUNION OR AVASCULAR NECROSIS OF THE FEMORAL HEAD.) • TROCHANTERIC OR SUBTROCHANTERIC FRACTURES WITH APPROPRIATE ADDITIONAL POSTOPERATIVE PRECAUTIONS ABOUT WEIGHT BEARING AND MORE THAN SEDENTARY ACTIVITY. •

	OSTEOTOMIES FOR PATIENTS WITH DISEASES OR DEFORMITIES OF THE HIP. • HIP ARTHRODESIS. • SUPRACONDYLAR FRACTURES AND DISTAL FEMORAL FRACTURES USING A SUPRACONDYLAR PLATE. • IPSILATERAL FEMORAL SHAFT/NECK FRACTURES. PEDIATRIC AND INTERMEDIATE COMPRESSION HIP SCREWS ARE INDICATED FOR • CONGENITAL COXA VARA. • CONGENITAL DISLOCATION OF THE HIP. • SUBLUXATION OR DISLOCATION SECONDARY TO NEUROLOGIC DISORDERS SUCH AS CEREBRAL PALSY, MYELOMENIGOCELE, POLIOMYELITIS, ETC. USUALLY VALGUS-ANTEVERSION DEFORMITIES. • COXA PLANA (LEGG-CALVE-PERTHES DISEASE) FOR CONTAINMENT OF THE HEAD COMPLETELY WITHIN THE ACETABULUM.,TOTAL HIP SYSTEM(R3)-HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTUREDISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY.,KNEE SYSTEM(LEGION)-1. RHEUMATOID ARTHRITIS. 2. POST TRAUMATIC ARTHRITIS, OSTEOARTHRITIS, OR DEGENERATIVE ARTHRITIS. 3. FAILED OSTEOTOMIES, UNICOMPARTMENTAL REPLACEMENT, OR TOTAL KNEE REPLACEMENT. 4. POSTERIOR STABILIZED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE INCOMPETENT AND THE COLLATERAL LIGAMENTS REMAIN INTACT. 5. CONSTRAINED KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E. MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE INCOMPETENT. 6. HINGE KNEE SYSTEMS ARE DESIGNED FOR USE IN PATIENTS IN PRIMARY AND REVISION SURGERY, WHERE THE POSTERIOR CRUCIATE LIGAMENT AND ONE OR BOTH OF THE COLLATERAL LIGAMENTS (I.E.

	MEDIAL COLLATERAL AND/OR LATERAL COLLATERAL LIGAMENT) ARE ABSENT OR INCOMPETENT.,TOTAL HIP SYSTEM(REFLECTION)- HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLESTONE RESECTION; FRACTURE-DISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1873	IMP/MD/2019/000456	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIP SYSTEM(RINGLOC BI-POLAR- ACETABULAR COMPONENTS-LOCKING RING)-1. NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. 2. RHEUMATOID ARTHRITIS 3. CORRECTION OF FUNCTIONAL DEFORMITY 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES., SHOULDER SYSTEM(COMPREHENSIVE REVERSE SHOULDER SYSTEM-GLENOID COMPONENTS)-BIOMET COMPREHENSIVE REVERSE SHOULDER PRODUCTS ARE INDICATED FOR USE IN PATIENTS WHOSE SHOULDER JOINT HAS A GROSSLY DEFICIENT ROTATOR CUFF WITH SEVERE ARTHROPATHY AND/OR PREVIOUSLY FAILED SHOULDER JOINT REPLACEMENT WITH A GROSSLY DEFICIENT ROTATOR CUFF. THE PATIENT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE IMPLANTS AND A FUNCTIONAL DELTOID MUSCLE IS NECESSARY. THE COMPREHENSIVE REVERSE SHOULDER IS INDICATED FOR PRIMARY, FRACTURE, OR REVISION TOTAL SHOULDER REPLACEMENT FOR THE RELIEF OF PAIN AND SIGNIFICANT DISABILITY DUE TO GROSS ROTATOR CUFF DEFICIENCY. TITANIUM GLENOSPHERES ARE INTENDED FOR PATIENTS WITH COBALT ALLOY MATERIAL SENSITIVITY. THE WEAR OF THESE DEVICES HAS NOT BEEN TESTED BUT, BASED ON PIN ON DISK TESTING, THE WEAR RATE IS INFERIOR TO THAT OF COBALT ALLOY GLENOSPHERES. A COBALT ALLOY GLENOSPHERE IS THE RECOMMENDED COMPONENT FOR REVERSE SHOULDER ARTHROPLASTY PATIENTS WITHOUT MATERIAL SENSITIVITY TO COBALT ALLOY. GLENOID COMPONENTS WITH HYDROXYAPATITE (HA) COATING APPLIED OVER THE POROUS COATING ARE INDICATED ONLY FOR UNCEMENTED BIOLOGICAL FIXATION APPLICATIONS. THE GLENOID BASEPLATE COMPONENTS ARE INTENDED FOR CEMENTLESS APPLICATION WITH THE ADDITION OF SCREW FIXATION. INTERLOK® FINISH HUMERAL STEMS ARE INTENDED FOR CEMENTED USE AND THE MACROBOND® COATED HUMERAL STEMS ARE INTENDED FOR PRESS-FIT OR CEMENTED APPLICATIONS. HUMERAL COMPONENTS WITH POROUS COATED SURFACE COATING ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED BIOLOGICAL FIXATION APPLICATIONS.,SHOULDER SYSTEM (COMPREHENSIVE SHOULDER SYSTEM- GLENOID COMPONENTS)-1. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. 2. RHEUMATOID ARTHRITIS. 3. REVISION WHERE OTHER DEVICES OR TREATMENTS

	HAVE FAILED. 4. CORRECTION OF FUNCTIONAL DEFORMITY. 5. FRACTURES OF THE PROXIMAL HUMERUS, WHERE OTHER METHODS OF TREATMENT ARE DEEMED INADEQUATE. 6. DIFFICULT CLINICAL MANAGEMENT PROBLEMS, INCLUDING CUFF ARTHROPATHY, WHERE OTHER METHODS OF TREATMENT MAY NOT BE SUITABLE OR MAY BE INADEQUATE. HUMERAL COMPONENTS WITH A MACROBOND™ SURFACE COATING ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED PRESS-FIT APPLICATIONS. HUMERAL/GLENOID COMPONENTS WITH A POROUS COATED SURFACE COATING ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED BIOLOGICAL FIXATION APPLICATIONS. (METAL BACKED GLENOID COMPONENTS OFFER OPTIONAL SCREW FIXATION). GLENOID COMPONENTS WITH HYDROXYAPATITE (HA) COATING APPLIED OVER THE POROUS COATING ARE INDICATED ONLY FOR UNCEMENTED BIOLOGICAL FIXATION APPLICATIONS. (METAL BACKED GLENOID COMPONENTS OFFER OPTIONAL SCREW FIXATION). HUMERAL COMPONENTS WITH A NON-COATED (INTERLOK™) SURFACE ARE INDICATED FOR CEMENTED APPLICATION ONLY. POLYETHYLENE GLENOID COMPONENTS NOT ATTACHED TO A METAL BACK ARE INDICATED FOR CEMENTED APPLICATION ONLY. THE COMPREHENSIVE™ MODULAR HYBRID GLENOID IS INTENDED TO BE IMPLANTED WITH BONE CEMENT. THE OPTIONAL POROUS TITANIUM PEG MAY BE INSERTED WITHOUT BONE CEMENT. THE OPTIONAL POLYETHYLENE PEG SHOULD BE INSERTED WITH BONE CEMENT. THE COMPREHENSIVE™ HUMERAL POSITIONING SLEEVES ARE FOR CEMENTED USE ONLY AND ARE INTENDED FOR USE WITH THE COMPREHENSIVE™ FRACTURE STEM. THE COMPREHENSIVE™ SHOULDER STEMS (FRACTURE, PRIMARY AND REVISION) ARE INTENDED FOR USE WITH THE BIO-MODULAR™ HUMERAL HEADS AND GLENOID COMPONENTS AND VERSA-DIAL™ HUMERAL HEADS. THE VERSA-DIAL™ HUMERAL HEAD PROSTHESIS IS INTENDED FOR USE ONLY WITH THE COMPREHENSIVE™ SHOULDER STEMS (FRACTURE, PRIMARY AND REVISION), THE BIO- MODULAR™ SHOULDER STEMS, THE GLENOID COMPONENTS OF THE BIO-MODULAR™ SHOULDER SYSTEM, AND THE GLENOID COMPONENTS OF THE COMPREHENSIVE™ SHOULDER SYSTEM. IN ADDITION TO THOSE SPECIFIED ABOVE, THE PROXIMAL SHOULDER REPLACEMENT PROSTHESES ARE INDICATED FOR USE IN ONCOLOGY APPLICATIONS, COMPLEX HUMERAL FRACTURES AND REVISIONS. WHEN A HUMERAL STEM AND/OR VERSA-DIAL™ TAPER ADAPTER IS BEING USED FOR AREVERSE SHOULDER APPLICATION, THE USER SHOULD REFER TO THE PACKAGE INSERT (01-50-0903) CONTINUED WITH THE REVERSE SHOULDER COMPONENTS FOR ADDITIONAL INFORMATION, INCLUDING ALTERNATE INDICATIONS.,HIP SYSTEM

	(RECOVERY PROTRUSIO CAGE- BONE SCREW)-1. NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. 2. RHEUMATOID ARTHRITIS 3. CORRECTION OF FUNCTIONAL DEFORMITY 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES. 5. REVISION OF PREVIOUSLY FAILED TOTAL HIP ARTHROPLASTY. THE ECHO PRESS-FIT HIP SYSTEM IS INTENDED FOR UNCEMENTED USE ONLY. POLISHED FEMORAL HIP PROSTHESIS WITH PROXIMAL CEMENT SPACER IS INTENDED FOR CEMENTED USE ONLY AND MAY BE USED IN PARTIAL AND TOTAL HIP ARTHROPLASTIES. THE POROUS TITANIUM AUGMENTS ARE INTENDED TO PROVIDE THE ORTHOPEDIC SURGEON WITH A PROSTHETIC ALTERNATIVE TO STRUCTURAL ALLOGRAFT IN CASES OF SEGMENTAL DEFICIENCIES. THE POROUS TITANIUM ACETABULAR AUGMENT IS AFFIXED TO THE MATING ACETABULAR CUP USING BONE CEMENT. THE ASSEMBLED POROUS TITANIUM AUGMENT/ACETABULAR CONSTRUCT IS INTENDED FOR CEMENTED OR UNCEMENTED USE. POROUS COATED DEVICES ARE MARKETED FOR NON-CEMENTED USE IN THE UNITED STATES FOR SKELETALLY MATURE PATIENTS UNDERGOING PRIMARY HIP REPLACEMENT SURGERY AS A RESULT OF NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE. 1. FRESH FRACTURES 2. OSTEOTOMY 3. REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED. 4. ARTHRODESIS PATIENT SELECTION FACTORS TO BE CONSIDERED INCLUDE: 1) NEED FOR ALIGNMENT AND STABILIZATION OF BONE FRACTURES, 2) ABILITY AND WILLINGNESS OF THE PATIENT TO FOLLOW POSTOPERATIVE CARE INSTRUCTIONS UNTIL HEALING IS COMPLETE, AND 3) A GOOD NUTRITIONAL STATE OF THE PATIENT.,KNEE SYSTEM (VANGUARD SSK KNEE SYSTEM - FEMORAL COMPONENT)-6. 1. PAINFUL AND DISABLED KNEE JOINT RESULTING FROM OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AND/OR TRAUMATIC ARTHRITIS WHERE ONE OR MORE COMPARTMENTS ARE INVOLVED. 7. 2. CORRECTION OF VARUS, VALGUS, OR POSTTRAUMATIC DEFORMITY 8. 3. CORRECTION OR REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS, OR FAILURE OF PREVIOUS JOINT REPLACEMENT PROCEDURE THE REGENEREX FEMORAL AUGMENTS ARE INDICATED FOR USE WITH THE VANGUARD TOTAL KNEE SYSTEM. THE REGENEREX TIBIAL AUGMENTS ARE INDICATED FOR USE WITH STANDARD AND OFFSET BIOMET TIBIAL TRAYS. FEMORAL COMPONENTS AND TIBIAL TRAY COMPONENTS WITH POROUS COATINGS ARE INDICATED FOR CEMENTED AND UNCEMENTED BIOLOGICAL FIXATION APPLICATION. NON-COATED (INTERLOK)

	DEVICES AND ALL-POLYETHYLENE PATELLAR COMPONENTS ARE INDICATED FOR CEMENTED APPLICATION ONLY. 9. REGENEREX COMPONENTS* ARE INTENDED ONLY FOR UNCEMENTED BIOLOGIC FIXATION APPLICATION. ,HIP SYSTEM(ARCOM XL-ACETABULAR LINERS)-1. NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. 2. RHEUMATOID ARTHRITIS. 3. CORRECTION OF FUNCTIONAL DEFORMITY. 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES. 5. REVISION OF PREVIOUSLY FAILED TOTAL HIP ARTHROPLASTY. CEMENTED AND UNCEMENTED APPLICATIONS.,HIP SYSTEM(RECOVERY PROTRUSIO CAGE- PROTRUSIO CAGE)-PROTRUSIO CAGE AND ACETABULAR SHELL IMPLANTS ARE INTENDED FOR USE IN RECONSTRUCTION OF THE HIP JOINT DUE TO DISEASE, DEFORMITY OR TRAUMA. THE DEVICES ARE INTENDED FOR GENERAL USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY AND/OR SECONDARY REVISION SURGERY. THE DEVICE IS A SINGLE USE IMPLANT. THE PROTRUSIO CAGE IS TO BE USED IN CONJUNCTION WITH ANY COMMERCIALLY AVAILABLE POLYETHYLENE ACETABULAR CUP. SHELL COMPONENTS ARE TO BE USED WITH BIOMET RINGLOC ACETABULAR LINERS.,KNEE SYSTEM (VANGUARD SSK KNEE SYSTEM - TIBIAL COMPONENT)-6. 1. PAINFUL AND DISABLED KNEE JOINT RESULTING FROM OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AND/OR TRAUMATIC ARTHRITIS WHERE ONE OR MORE COMPARTMENTS ARE INVOLVED. 7. 2. CORRECTION OF VARUS, VALGUS, OR POSTTRAUMATIC DEFORMITY 8. 3. CORRECTION OR REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS, OR FAILURE OF PREVIOUS JOINT REPLACEMENT PROCEDURE THE REGENEREX FEMORAL AUGMENTS ARE INDICATED FOR USE WITH THE VANGUARD TOTAL KNEE SYSTEM. THE REGENEREX TIBIAL AUGMENTS ARE INDICATED FOR USE WITH STANDARD AND OFFSET BIOMET TIBIAL TRAYS. FEMORAL COMPONENTS AND TIBIAL TRAY COMPONENTS WITH POROUS COATINGS ARE INDICATED FOR CEMENTED AND UNCEMENTED BIOLOGICAL FIXATION APPLICATION. NON-COATED (INTERLOK) DEVICES AND ALL-POLYETHYLENE PATELLAR COMPONENTS ARE INDICATED FOR CEMENTED APPLICATION ONLY. 9. REGENEREX COMPONENTS* ARE INTENDED ONLY FOR UNCEMENTED BIOLOGIC FIXATION APPLICATION.,KNEE SYSTEM(VANGUARD KNEE SYSTEM - FEMORAL COMPONENT)-1. 1. PAINFUL AND DISABLED KNEE JOINT RESULTING FROM OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AND/OR TRAUMATIC ARTHRITIS WHERE ONE OR MORE COMPARTMENTS ARE INVOLVED. 2. 2. CORRECTION OF VARUS, VALGUS, OR POSTTRAUMATIC

	DEFORMITY 3. 3. CORRECTION OR REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS, OR FAILURE OF PREVIOUS JOINT REPLACEMENT PROCEDURE THE REGENEREX FEMORAL AUGMENTS ARE INDICATED FOR USE WITH THE VANGUARD TOTAL KNEE SYSTEM. THE REGENEREX TIBIAL AUGMENTS ARE INDICATED FOR USE WITH STANDARD AND OFFSET BIOMET TIBIAL TRAYS. FEMORAL COMPONENTS AND TIBIAL TRAY COMPONENTS WITH POROUS COATINGS ARE INDICATED FOR CEMENTED AND UNCEMENTED BIOLOGICAL FIXATION APPLICATION. NON-COATED (INTERLOK) DEVICES AND ALL-POLYETHYLENE PATELLAR COMPONENTS ARE INDICATED FOR CEMENTED APPLICATION ONLY. 4. REGENEREX COMPONENTS* ARE INTENDED ONLY FOR UNCEMENTED BIOLOGIC FIXATION APPLICATION. THE VANGUARD DA 360 COMPONENTS ARE NOT INTENDED FOR USE WITH THE VANGUARD PS OPEN BOX POROUS FEMORAL COMPONENTS. THE VANGUARD DA 360 COMPONENTS ARE NOT APPROVED FOR SALE IN THE UNITED STATES OR CANADA. ,KNEE SYSTEM(VANGUARD KNEE SYSTEM - TIBIAL COMPONENT)-1. 1. PAINFUL AND DISABLED KNEE JOINT RESULTING FROM OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AND/OR TRAUMATIC ARTHRITIS WHERE ONE OR MORE COMPARTMENTS ARE INVOLVED. 2. 2. CORRECTION OF VARUS, VALGUS, OR POSTTRAUMATIC DEFORMITY 3. 3. CORRECTION OR REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS, OR FAILURE OF PREVIOUS JOINT REPLACEMENT PROCEDURE THE REGENEREX FEMORAL AUGMENTS ARE INDICATED FOR USE WITH THE VANGUARD TOTAL KNEE SYSTEM. THE REGENEREX TIBIAL AUGMENTS ARE INDICATED FOR USE WITH STANDARD AND OFFSET BIOMET TIBIAL TRAYS. FEMORAL COMPONENTS AND TIBIAL TRAY COMPONENTS WITH POROUS COATINGS ARE INDICATED FOR CEMENTED AND UNCEMENTED BIOLOGICAL FIXATION APPLICATION. NON-COATED (INTERLOK) DEVICES AND ALL-POLYETHYLENE PATELLAR COMPONENTS ARE INDICATED FOR CEMENTED APPLICATION ONLY. 4. REGENEREX COMPONENTS* ARE INTENDED ONLY FOR UNCEMENTED BIOLOGIC FIXATION APPLICATION. THE VANGUARD DA 360 COMPONENTS ARE NOT INTENDED FOR USE WITH THE VANGUARD PS OPEN BOX POROUS FEMORAL COMPONENTS. THE VANGUARD DA 360 COMPONENTS ARE NOT APPROVED FOR SALE IN THE UNITED STATES OR CANADA. ,SHOULDER SYSTEM (COMPREHENSIVE SHOULDER SYSTEM- HUMERAL COMPONENTS)-1. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. 2. RHEUMATOID ARTHRITIS. 3. REVISION WHERE OTHER DEVICES OR TREATMENTS HAVE FAILED. 4. CORRECTION OF FUNCTIONAL DEFORMITY. 5. FRACTURES OF THE PROXIMAL HUMERUS, WHERE OTHER METHODS

	OF TREATMENT ARE DEEMED INADEQUATE. 6. DIFFICULT CLINICAL MANAGEMENT PROBLEMS, INCLUDING CUFF ARTHROPATHY, WHERE OTHER METHODS OF TREATMENT MAY NOT BE SUITABLE OR MAY BE INADEQUATE. HUMERAL COMPONENTS WITH A MACROBOND™ SURFACE COATING ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED PRESS-FIT APPLICATIONS. HUMERAL/GLENOID COMPONENTS WITH A POROUS COATED SURFACE COATING ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED BIOLOGICAL FIXATION APPLICATIONS. (METAL BACKED GLENOID COMPONENTS OFFER OPTIONAL SCREW FIXATION). GLENOID COMPONENTS WITH HYDROXYAPATITE (HA) COATING APPLIED OVER THE POROUS COATING ARE INDICATED ONLY FOR UNCEMENTED BIOLOGICAL FIXATION APPLICATIONS. (METAL BACKED GLENOID COMPONENTS OFFER OPTIONAL SCREW FIXATION). HUMERAL COMPONENTS WITH A NON-COATED (INTERLOK™) SURFACE ARE INDICATED FOR CEMENTED APPLICATION ONLY. POLYETHYLENE GLENOID COMPONENTS NOT ATTACHED TO A METAL BACK ARE INDICATED FOR CEMENTED APPLICATION ONLY. THE COMPREHENSIVE™ MODULAR HYBRID GLENOID IS INTENDED TO BE IMPLANTED WITH BONE CEMENT. THE OPTIONAL POROUS TITANIUM PEG MAY BE INSERTED WITHOUT BONE CEMENT. THE OPTIONAL POLYETHYLENE PEG SHOULD BE INSERTED WITH BONE CEMENT. THE COMPREHENSIVE™ HUMERAL POSITIONING SLEEVES ARE FOR CEMENTED USE ONLY AND ARE INTENDED FOR USE WITH THE COMPREHENSIVE™ FRACTURE STEM. THE COMPREHENSIVE™ SHOULDER STEMS (FRACTURE, PRIMARY AND REVISION) ARE INTENDED FOR USE WITH THE BIO-MODULAR™ HUMERAL HEADS AND GLENOID COMPONENTS AND VERSA-DIAL™ HUMERAL HEADS. THE VERSA-DIAL™ HUMERAL HEAD PROSTHESIS IS INTENDED FOR USE ONLY WITH THE COMPREHENSIVE™ SHOULDER STEMS (FRACTURE, PRIMARY AND REVISION), THE BIO- MODULAR™ SHOULDER STEMS, THE GLENOID COMPONENTS OF THE BIO-MODULAR™ SHOULDER SYSTEM, AND THE GLENOID COMPONENTS OF THE COMPREHENSIVE™ SHOULDER SYSTEM. IN ADDITION TO THOSE SPECIFIED ABOVE, THE PROXIMAL SHOULDER REPLACEMENT PROSTHESES ARE INDICATED FOR USE IN ONCOLOGY APPLICATIONS, COMPLEX HUMERAL FRACTURES AND REVISIONS. WHEN A HUMERAL STEM AND/OR VERSA-DIAL™ TAPER ADAPTER IS BEING USED FOR AREVERSE SHOULDER APPLICATION, THE USER SHOULD REFER TO THE PACKAGE INSERT (01-50-0903) CONTINUED WITH THE REVERSE SHOULDER COMPONENTS FOR ADDITIONAL INFORMATION, INCLUDING ALTERNATE INDICATIONS.,KNEE SYSTEM (VANGUARD KNEE SYSTEM - TIBIAL COMPONENT)-1. 1. PAINFUL AND DISABLED KNEE JOINT RESULTING FROM OSTEOARTHRITIS,

	RHEUMATOID ARTHRITIS, AND/OR TRAUMATIC ARTHRITIS WHERE ONE OR MORE COMPARTMENTS ARE INVOLVED. 2. 2. CORRECTION OF VARUS, VALGUS, OR POSTTRAUMATIC DEFORMITY 3. 3. CORRECTION OR REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS, OR FAILURE OF PREVIOUS JOINT REPLACEMENT PROCEDURE THE REGENEREX FEMORAL AUGMENTS ARE INDICATED FOR USE WITH THE VANGUARD TOTAL KNEE SYSTEM. THE REGENEREX TIBIAL AUGMENTS ARE INDICATED FOR USE WITH STANDARD AND OFFSET BIOMET TIBIAL TRAYS. FEMORAL COMPONENTS AND TIBIAL TRAY COMPONENTS WITH POROUS COATINGS ARE INDICATED FOR CEMENTED AND UNCEMENTED BIOLOGICAL FIXATION APPLICATION. NON-COATED (INTERLOK) DEVICES AND ALL-POLYETHYLENE PATELLAR COMPONENTS ARE INDICATED FOR CEMENTED APPLICATION ONLY. 4. REGENEREX COMPONENTS* ARE INTENDED ONLY FOR UNCEMENTED BIOLOGIC FIXATION APPLICATION. THE VANGUARD DA 360 COMPONENTS ARE NOT INTENDED FOR USE WITH THE VANGUARD PS OPEN BOX POROUS FEMORAL COMPONENTS. THE VANGUARD DA 360 COMPONENTS ARE NOT APPROVED FOR SALE IN THE UNITED STATES OR CANADA. ,SHOULDER SYSTEM(COMPREHENSIVE REVERSE SHOULDER SYSTEM- HUMERAL COMPONENTS)-BIOMET COMPREHENSIVE REVERSE SHOULDER PRODUCTS ARE INDICATED FOR USE IN PATIENTS WHOSE SHOULDER JOINT HAS A GROSSLY DEFICIENT ROTATOR CUFF WITH SEVERE ARTHROPATHY AND/OR PREVIOUSLY FAILED SHOULDER JOINT REPLACEMENT WITH A GROSSLY DEFICIENT ROTATOR CUFF. THE PATIENT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE IMPLANTS AND A FUNCTIONAL DELTOID MUSCLE IS NECESSARY. THE COMPREHENSIVE REVERSE SHOULDER IS INDICATED FOR PRIMARY, FRACTURE, OR REVISION TOTAL SHOULDER REPLACEMENT FOR THE RELIEF OF PAIN AND SIGNIFICANT DISABILITY DUE TO GROSS ROTATOR CUFF DEFICIENCY. TITANIUM GLENOSPHERES ARE INTENDED FOR PATIENTS WITH COBALT ALLOY MATERIAL SENSITIVITY. THE WEAR OF THESE DEVICES HAS NOT BEEN TESTED BUT, BASED ON PIN ON DISK TESTING, THE WEAR RATE IS INFERIOR TO THAT OF COBALT ALLOY GLENOSPHERES. A COBALT ALLOY GLENOSPHERE IS THE RECOMMENDED COMPONENT FOR REVERSE SHOULDER ARTHROPLASTY PATIENTS WITHOUT MATERIAL SENSITIVITY TO COBALT ALLOY. GLENOID COMPONENTS WITH HYDROXYAPATITE (HA) COATING APPLIED OVER THE POROUS COATING ARE INDICATED ONLY FOR UNCEMENTED BIOLOGICAL FIXATION APPLICATIONS. THE GLENOID BASEPLATE COMPONENTS ARE INTENDED FOR CEMENTLESS APPLICATION WITH THE ADDITION OF SCREW FIXATION. INTERLOK® FINISH HUMERAL STEMS ARE

	INTENDED FOR CEMENTED USE AND THE MACROBOND® COATED HUMERAL STEMS ARE INTENDED FOR PRESS-FIT OR CEMENTED APPLICATIONS. HUMERAL COMPONENTS WITH POROUS COATED SURFACE COATING ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED BIOLOGICAL FIXATION APPLICATIONS.,HIP SYSTEM (RINGLOC BI-POLAR- ACETABULAR COMPONENTS-ACETABULAR FEMORAL CUP)-1. NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. 2. RHEUMATOID ARTHRITIS 3. CORRECTION OF FUNCTIONAL DEFORMITY 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES.,HIP SYSTEM(RINGLOC ACETABULAR LINERS-ACETABULAR LINERS)-1. NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. 2. RHEUMATOID ARTHRITIS. 3. CORRECTION OF FUNCTIONAL DEFORMITY. 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES. 5. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED. THE ECHO PRESS-FIT HIP SYSTEM IS INTENDED FOR UNCEMENTED USE ONLY. POLISHED FEMORAL HIP PROSTHESIS WITH PROXIMAL CEMENT SPACER IS INTENDED FOR CEMENTED USE ONLY AND MAY BE USED IN PARTIAL AND TOTAL HIP ARTHROPLASTIES. THE POROUS TITANIUM AUGMENTS ARE INTENDED TO PROVIDE THE ORTHOPEDIC SURGEON WITH A PROSTHETIC ALTERNATIVE TO STRUCTURAL ALLOGRAFT IN CASES OF SEGMENTAL DEFICIENCIES. THE POROUS TITANIUM ACETABULAR AUGMENT IS AFFIXED TO THE MATING ACETABULAR CUP USING BONE CEMENT. THE ASSEMBLED POROUS TITANIUM AUGMENT/ACETABULAR CONSTRUCT IS INTENDED FOR CEMENTED OR UNCEMENTED USE. POROUS COATED DEVICES ARE MARKETED FOR NON-CEMENTED USE IN THE UNITED STATES FOR SKELETALLY MATURE PATIENTS UNDERGOING PRIMARY HIP REPLACEMENT SURGERY AS A RESULT OF NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE.,HIP SYSTEM(COCR (MODULAR FEMORAL HEAD) - MODULAR HEAD)-1. NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. 2. RHEUMATOID ARTHRITIS 3. CORRECTION OF FUNCTIONAL DEFORMITY 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES. 5. REVISION OF PREVIOUSLY FAILED TOTAL HIP ARTHROPLASTY. THE ECHO PRESS-FIT HIP SYSTEM IS INTENDED FOR

	UNCEMENTED USE ONLY. POLISHED FEMORAL HIP PROSTHESIS WITH PROXIMAL CEMENT SPACER IS INTENDED FOR CEMENTED USE ONLY AND MAY BE USED IN PARTIAL AND TOTAL HIP ARTHROPLASTIES. THE POROUS TITANIUM AUGMENTS ARE INTENDED TO PROVIDE THE ORTHOPEDIC SURGEON WITH A PROSTHETIC ALTERNATIVE TO STRUCTURAL ALLOGRAFT IN CASES OF SEGMENTAL DEFICIENCIES. THE POROUS TITANIUM ACETABULAR AUGMENT IS AFFIXED TO THE MATING ACETABULAR CUP USING BONE CEMENT. THE ASSEMBLED POROUS TITANIUM AUGMENT/ACETABULAR CONSTRUCT IS INTENDED FOR CEMENTED OR UNCEMENTED USE. POROUS COATED DEVICES ARE MARKETED FOR NON-CEMENTED USE IN THE UNITED STATES FOR SKELETALLY MATURE PATIENTS UNDERGOING PRIMARY HIP REPLACEMENT SURGERY AS A RESULT OF NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE.,KNEE SYSTEM (VANGUARD KNEE SYSTEM - PATELLA COMPONENT)-1. 1. PAINFUL AND DISABLED KNEE JOINT RESULTING FROM OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AND/OR TRAUMATIC ARTHRITIS WHERE ONE OR MORE COMPARTMENTS ARE INVOLVED. 2. 2. CORRECTION OF VARUS, VALGUS, OR POSTTRAUMATIC DEFORMITY 3. 3. CORRECTION OR REVISION OF UNSUCCESSFUL OSTEOTOMY, ARTHRODESIS, OR FAILURE OF PREVIOUS JOINT REPLACEMENT PROCEDURE THE REGENEREX FEMORAL AUGMENTS ARE INDICATED FOR USE WITH THE VANGUARD TOTAL KNEE SYSTEM. THE REGENEREX TIBIAL AUGMENTS ARE INDICATED FOR USE WITH STANDARD AND OFFSET BIOMET TIBIAL TRAYS. FEMORAL COMPONENTS AND TIBIAL TRAY COMPONENTS WITH POROUS COATINGS ARE INDICATED FOR CEMENTED AND UNCEMENTED BIOLOGICAL FIXATION APPLICATION. NON-COATED (INTERLOK) DEVICES AND ALL-POLYETHYLENE PATELLAR COMPONENTS ARE INDICATED FOR CEMENTED APPLICATION ONLY. 4. REGENEREX COMPONENTS* ARE INTENDED ONLY FOR UNCEMENTED BIOLOGIC FIXATION APPLICATION. THE VANGUARD DA 360 COMPONENTS ARE NOT INTENDED FOR USE WITH THE VANGUARD PS OPEN BOX POROUS FEMORAL COMPONENTS. THE VANGUARD DA 360 COMPONENTS ARE NOT APPROVED FOR SALE IN THE UNITED STATES OR CANADA.

1874	IMP/MD/2019/000457	1.License Holder Name: CARTIER HEALTHCARE LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DRUG ELUTING CORONARY STENT SYSTEM(BIOMATRIX NEOFLEX)-THE BIOMATRIX NEOFLEX DES IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER RANGING BETWEEN 2.25 MM AND 4.0 MM. STENTS WITH LENGTH 33 MM AND 36 MM ARE ONLY AVAILABLE FOR ARTERY DIAMETERS RANGING BETWEEN 2.5 MM AND 3.5 MM. THE BIOMATRIX NEOFLEX DES WITH STENT LENGTH UP TO 28 MM IS ALSO INDICATED FOR USE IN PATIENTS WITH: • ST ELEVATED MYOCARDIAL INFARCTION (STEMI) • ACUTE CORONARY SYNDROMES (ACS) INCLUDING ACS-STEMI, ACS-NSTEMI AND UNSTABLE ANGINA • DIABETES MELLITUS,DRUG ELUTING CORONARY STENT SYSTEM(BIOMATRIX ALPHA)-THE BIOMATRIX ALPHA STENT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER RANGING BETWEEN 2.25MM AND 4.0MM. STENTS WITH LENGTHS 33 AND 36MM ARE ONLY AVAILABLE FOR ARTERY DIAMETERS RANGING BETWEEN 2.5 MM AND 3.5 MM.,DRUG COATED CORONARY STENT SYSTEM(BIOFREEDOM)-THE BIOFREEDOM DCS IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER FOR THE TREATMENT OF DE-NOVO LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER RANGING FROM 2.25 MM TO 4.0 MM. STENTS WITH LENGTHS OF 33 MM AND 36 MM ARE ONLY AVAILABLE FOR ARTERY DIAMETERS RANGING FROM 2.5 MM TO 3.5 MM.
1875	IMP/MD/2019/000458	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TUBING(FMS VUE II)-THE FMS VUE II FLUID MANAGEMENT AND TISSUE DEBRIDEMENT SYSTEM IS INTENDED TO PROVIDE CONTROLLED FLUID DISTENTION AND SUCTION, CONTROLLED CUTTING, BURRING, SHAVING AND ABRADING OF BONE AND TISSUE FOR USE IN ARTHROSCOPIC SURGERY OF THE SHOULDER, KNEE, ANKLE, ELBOW, WRIST AND HIP JOINTS

1876	IMP/MD/2019/000459	1.License Holder Name: M/S WIIZ HEALTH TECH LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SOFT HYDROPHOBIC ACRYLIC INTRAOCULAR LENS(PRECISAL)-IT IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULTS PATIENTS WHEN EXTRACAPSULAR CATARACT EXTRACTION OR PHACOEMULSIFICATION IS PERFORMED. THESE LENS ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG

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1877	IMP/MD/2019/000460	1.License Holder Name: NESTLE SKIN HEALTH INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYALURONIC ACID STABILIZED 20 MG/ML(RESTYLANE SKINBOOSTERS VITAL)-TO RESTORE SKIN HYDROBALANCE, IMPROVES SKIN STRUCTURE AND ELASTICITY OF THE SKIN.,HYALURONIC ACID, STABLIZED 20 MG/ML (RESTYLANE, RESTYLANE LYFT)-IT SHOULD BE INJECTED INTO DEEP DERMIS TO SUPERFICIALSUBCUTIS FOR THE CORRECTION OF MODERATE TO SEVERE FACIAL FOLDS AND WRINKLES, SUCH AS NASOLABIAL FOLDS, OR IN THE SUBMUCOSAL LAYER OF THE LIP. FOR CHEEK AUGMENTATION, CORRECTION OF AGE-RELATED MIDFACE CONTOUR DEFICIENCIES AND FACIAL AREAS WITH LIMITED SOFT TISSUE SUPPORT AND SOFT TISSUE COVER, E.G. THE PERIORBITAL REGION, INJECTION INTO THE SUBCUTANEOUS FATTY TISSUE OR SUPRAPERIOSTAL ADMINISTRATION ARE RECOMMENDED, CROSSLINKED HYALURONIC ACID, STABILIZED 20 MG/ML, LIDOCAINE HYDROHLORIDE 3 MG/ML(RESTYLANE KYSSE, RESTYLANE REFYNE, RESTYLANE VOLYME, RESTYLANE DEFYNE)-TO AUGMENT THE VOLUME OF FACIAL TISSUES. IT IS RECOMMENDED TO BE USED FOR CORRECTION OF MODERATE WRINKLES, OR TO REDEFINE THE SHAPE OF THE LIPS, CHEEKS OR TEAR TROUGH. TO AUGMENT THE VOLUME OF FACIAL TISSUES. IT IS RECOMMENDED TO BE USED FOR CORRECTION OF SEVERE WRINKLES, OR TO REDEFINE THE SHAPE OF THE LIPS, CHEEKS OR TEAR TROUGH. TO RESTORE OR AUGMENT THE VOLUME OF LIPS TO AUGMENT THE VOLUME OF FACIAL TISSUES. IT IS RECOMMENDED TO BE USED FRO CORRECTION OF FACIAL VOLUME, FOR INSTANCE CHEEKS AND CHINS., HYALURONIC ACID, STABLIZED 20 MG/ML, LIDOCAINE HYDROCHLORIDE 3 MG/ML(RESTYLANE LIDOCAINE, RESTYLANE LYFT LIDOCAINE)-IT SHOULD BE INJECTED INTO DEEP DERMIS TO SUPERFICIALSUBCUTIS FOR THE CORRECTION OF MODERATE TO SEVERE FACIAL FOLDS AND WRINKLES, SUCH AS NASOLABIAL FOLDS, OR IN THE SUBMUCOSAL LAYER OF THE LIP. FOR CHEEK AUGMENTATION, CORRECTION OF AGE-RELATED MIDFACE CONTOUR DEFICIENCIES AND FACIAL AREAS WITH LIMITED SOFT TISSUE SUPPORT AND SOFT TISSUE COVER, E.G. THE PERIORBITAL REGION, INJECTION INTO THE SUBCUTANEOUS FATTY TISSUE OR SUPRAPERIOSTAL ADMINISTRATION ARE RECOMMENDED

1878	IMP/MD/2019/000461	1.License Holder Name: TRANSLUMINA THERAPEUTICS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAINLESS STEEL CORONARY STENT SYSTEM(NIL)-IT IS INTENDED FOR USE IN THE PATIENT ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). IT IS INTENDED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO LESIONS IN NATIVE CORONARY ARTERIES AND THOSE WHO ARE ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA).

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1879	IMP/MD/2019/000463	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RIGID ENDOSCOPE SHEATH(PUREVUE)-THE DEPUY SYNTHES ARTHROSCOPE AND ACCESSORIES ARE TUBULAR ENDOSCOPIC DEVICES WITH ACCESSORY DEVICES THAT ATTACH TO THE ARTHROSCOPE, AND ARE INTENDED TO EXAMINE AND/OR PERFORM SURGERY ON THE INTERIOR OF A JOINT. ARTHROSCOPIC MINIMALLY INVASIVE PROCEDURES ARE PERFORMED IN THE HIP, KNEE, SHOULDER, WRIST (CARPAL TUNNEL SYNDROME), TEMPOROMANDIBULAR JOINT, ANKLE, ELBOW AND FEET (PLANTAR FASCIA RELEASE). THE DEPUY SYNTHES LAPAROSCOPE IS INTENDED FOR USE IN GENERAL LAPAROSCOPIC SURGERY. LAPAROSCOPIC SURGERY IS A MEANS OF PERFORMING DIAGNOSTIC AND THERAPEUTIC SURGICAL PROCEDURES INTRAABDOMINALLY USING EQUIPMENT THAT MINIMIZES SURGICAL INVASIVENESS. RATHER THAN CREATING LARGE INCISIONS TO GAIN ACCESS TO SURGICAL SITES, SURGEONS VIEW INSIDE THE BODY AND OPERATE BY USING INSTRUMENTS INSERTED THROUGH SMALL SKIN PUNCTURES (INSERTED THROUGH THE LAPAROSCOPE OR THROUGH ANOTHER SMALL INCISION). THIS INCLUDES, BUT IS NOT LIMITED TO SUCH USES AS GALLBLADDER AND APPENDIX REMOVAL, HERNIA REPAIR, AND EXAMINATION OF THE ABDOMINAL CAVITY, APPENDIX, GALLBLADDER AND LIVER. THE DEPUY SYNTHES SINUSCOPE IS INTENDED TO PROVIDE THE PHYSICIAN WITH A MEANS FOR ENDOSCOPIC DIAGNOSTIC AND THERAPEUTIC SINUS SURGICAL PROCEDURES.,ORTHOPEDIC TROCAR (PUREVUE)-HE DEPUY SYNTHES ARTHROSCOPE AND ACCESSORIES ARE TUBULAR ENDOSCOPIC DEVICES WITH ACCESSORY DEVICES THAT ATTACH TO THE ARTHROSCOPE, AND ARE INTENDED TO EXAMINE AND/OR PERFORM SURGERY ON THE INTERIOR OF A JOINT. ARTHROSCOPIC MINIMALLY INVASIVE PROCEDURES ARE PERFORMED IN THE HIP, KNEE, SHOULDER, WRIST (CARPAL TUNNEL SYNDROME), TEMPOROMANDIBULAR JOINT, ANKLE, ELBOW AND FEET (PLANTAR FASCIA RELEASE). THE DEPUY SYNTHES LAPAROSCOPE IS INTENDED FOR USE IN GENERAL LAPAROSCOPIC SURGERY. LAPAROSCOPIC SURGERY IS A MEANS OF PERFORMING DIAGNOSTIC AND THERAPEUTIC SURGICAL PROCEDURES INTRAABDOMINALLY USING EQUIPMENT THAT MINIMIZES SURGICAL INVASIVENESS. RATHER THAN CREATING LARGE INCISIONS TO GAIN ACCESS TO SURGICAL SITES, SURGEONS VIEW INSIDE THE BODY AND OPERATE BY USING INSTRUMENTS INSERTED THROUGH SMALL SKIN PUNCTURES (INSERTED THROUGH THE LAPAROSCOPE OR THROUGH ANOTHER SMALL INCISION). THIS INCLUDES, BUT IS NOT LIMITED TO SUCH USES AS GALLBLADDER AND APPENDIX REMOVAL, HERNIA

	REPAIR, AND EXAMINATION OF THE ABDOMINAL CAVITY, APPENDIX, GALLBLADDER AND LIVER. THE DEPUY SYNTHES SINUSCOPE IS INTENDED TO PROVIDE THE PHYSICIAN WITH A MEANS FOR ENDOSCOPIC DIAGNOSTIC AND THERAPEUTIC SINUS SURGICAL PROCEDURES.

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1880	IMP/MD/2019/000464	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SHOULDER SYSTEM (ANATOMIC BODY)(GLOBAL UNITE)-"THE GLOBAL UNITE PLATFORM SHOULDER SYSTEM IS INTENDED FOR CEMENTED OR UNCEMENTED TOTAL OR HEMISHOULDER ARTHROPLASTY IN TREATMENT OF THE FOLLOWING: • A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS • FRACTURE OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY • IRREDUCIBLE 3- AND 4-PART FRACTURES OF THE PROXIMAL HUMERUS • UNUNITED HUMERAL HEAD FRACTURES • AVASCULAR NECROSIS OF THE HUMERAL HEAD • OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT) HEMI-SHOULDER ARTHROPLASTY IS ALSO INDICATED FOR: • DEFORMITY AND/OR LIMITED MOTION GLOBAL UNITE HUMERAL STEMS, IN CONJUNCTION WITH EXISTING DELTA XTEND™ EPIPHYSEAL COMPONENTS, ARE INDICATED FOR USE IN REVERSE SHOULDER ARTHROPLASTY IN TREATMENT OF A GROSSLY DEFICIENT ROTATOR CUFF JOINT WITH SEVERE ARTHROPATHY OR A PREVIOUSLY FAILED JOINT REPLACEMENT WITH A GROSSLY DEFICIENT ROTATOR CUFF JOINT. THE PATIENT'S JOINT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE SELECTED IMPLANT(S), AND A FUNCTIONAL DELTOID MUSCLE IS NECESSARY TO USE THE DEVICE. WHEN USED IN A TOTAL SHOULDER ARTHROPLASTY, THE GLOBAL UNITE IMPLANTS ARE TO BE USED WITH DEPUY GLENOID COMPONENTS. THE GLENOID COMPONENTS ARE FOR CEMENTED USE ONLY. GLOBAL UNITE HUMERAL IMPLANTS ARE FOR CEMENTED OR UNCEMENTED USE. WHEN USED IN A REVERSE SHOULDER ARTHROPLASTY, THE GLOBAL UNITE AND DELTA XTEND HUMERAL IMPLANTS ARE TO BE USED WITH THE HA-COATED DELTA XTEND METAGLENE DEVICES. THE METAGLENE IMPLANTS ARE INTENDED FOR UNCEMENTED USE ONLY WITH ADDITIONAL SCREW FIXATION. THE HA-COATED DELTA XTEND HUMERAL IMPLANTS ARE INTENDED FOR UNCEMENTED USE ONLY. GLOBAL UNITE HUMERAL IMPLANTS ARE FOR CEMENTED OR UNCEMENTED USE." ,TOTAL HIP SYSTEM- FEMORAL STEM (STERILE) (ACTIS)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE

	IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM., HIP REPLACEMENT SYSTEM - LOCKING BOLT(RECLAIM REVISION)-THE DEPUY RECLAIM REVISION HIP SYSTEM IS INDICATED FOR CEMENTLESS USE IN THE TREATMENT OF FAILED PREVIOUS HIP SURGERY, INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR OTHER TOTAL HIP REPLACEMENT.,HIP REPLACEMENT SYSTEM - AUGMENTS(DEPUY GRIPTION TF ACETABULAR AUGMENT SYSTEM)-"THE DEPUY GRIPTION TF ACETABULAR AUGMENTS, BUTTRESSES AND SHIMS ARE INDICATED FOR USE WITH THE PINNACLE ACETABULAR CUP SYSTEM, THE PINNACLE BANTAM ACETABULAR CUP SYSTEM AND THE PINNACLE REVISION ACETABULAR CUP SYSTEM FOR TOTAL HIP REPLACEMENT IN THE FOLLOWING CONDITIONS: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3. ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK. 4. FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5. CERTAIN CASES OF ANKYLOSIS. THE POROUS GRIPTION TF TITANIUM ACETABULAR AUGMENT IS AFFIXED TO THE MATING ACETABULAR CUP USING BONE CEMENT OR MECHANICAL SCREW FIXATION. THE ASSEMBLED AUGMENT/ACETABULAR CUP CONSTRUCT IS INTENDED FOR CEMENTED OR CEMENTLESS USE. THE POROUS GRIPTION TF TITANIUM SHIM IS AFFIXED TO THE MATING BUTTRESS USING BONE CEMENT. THIS POROUS GRIPTION TF TITANIUM BUTTRESS IS AFFIXED TO THE MATING ACETABULAR CUP USING BONE CEMENT. THE GRIPTION TF TITANIUM BUTTRESS/SHIM IS AFFIXED TO THE BONE USING BONE CEMENT OR MECHANICAL SCREW FIXATION. THE ASSEMBLED BUTTRESS/ACETABULAR CUP CONSTRUCT IS INTENDED FOR CEMENTED OR CEMENTLESS USE." ,HIP REPLACEMENT SYSTEM - STEM(RECLAIM REVISION)-THE DEPUY RECLAIM REVISION HIP SYSTEM IS INDICATED FOR CEMENTLESS USE IN THE TREATMENT OF FAILED PREVIOUS HIP SURGERY, INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR OTHER TOTAL HIP REPLACEMENT., HIP REPLACEMENT SYSTEM -

		PROXIMAL BODY(RECLAIM REVISION)-THE DEPUY RECLAIM REVISION HIP SYSTEM IS INDICATED FOR CEMENTLESS USE IN THE TREATMENT OF FAILED PREVIOUS HIP SURGERY, INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR OTHER TOTAL HIP REPLACEMENT.
1881	IMP/MD/2019/000465	1.License Holder Name: UNLIMITIVE LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARTIFICIAL URINARY SPHINCTERS IMPLANTS(ARTIFICIAL URINARY SPHINCTERS IMPLANTS)-ZSI 375 PF IS MADE OF SILICONE ELASTOMER AND IS FILLED WITH SALINE SOLUTION. IT WAS DESIGNED TO CORRECT URINARY INCONTINENCE SECONDARY TO AN INTRINSIC URINARY SPHINCTER DEFICIENCY,PENILE INFLATABLE IMPLANTS(PENILE INFLATABLE IMPLANTS)-THE PENILE IMPLANT IS A PROSTHESIS THAT PRODUCES ERECTIONS. THIS HYDRAULIC IMPLANT COMPRISES TWO INFLATABLE CYLINDERS (HOLLOW IMPLANTS), WHICH ARE IMPLANTED IN THE PENIS. THEY ARE CONNECTED TO A RESERVOIR FILLED WITH PHYSIOLOGICAL SERUM, IMPLANTED IN THE PELVIS, AND A MANUAL PUMP IMPLANTED IN THE SCROTUM. THIS IMPLANT IS MOSTLY MANUFACTURED FROM SILICONE. THE HOLLOW IMPLANTS ARE FILLED UNDER PRESSURE TO TRIGGER PENILE RIGIDITY.,PENILE RIGIDITY IMPLANTS(MALLEABLE PENILE IMPLANT)-THE MALLEABLE PENILE IMPLANT IS A PROSTHESIS THAT PRODUCES ERECTIONS
1882	IMP/MD/2019/000466	1.License Holder Name: VIBGYOR HEALTH CARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STENT GRAFT SYSTEM (BEGRAFT PERIPHERAL)-THE BEGRAFT PERIPHERAL STENT GRAFT SYSTEM IS INDICATED FOR INTRALUMINAL CHRONIC PLACEMENT IN ILIAC AND RENAL ARTERIES FOR: • RESTORING AND IMPROVING THE PATENCY AND • TREATING ANEURYSMS, ACUTE PERFORATIONS, ACUTE RUPTURES AND FISTULAS.

1883	IMP/MD/2019/000467	1.License Holder Name: M/S MERIT MEDICAL SYSTEMS INDIA PRIVATE LIMITED, ,UNIT NO. 404-405, H. M. GENEVA HOUSE, 4TH FLOOR, NO. 14/84 & 85, CUNNINGHAM ROAD ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560052 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EMBOLIC MICROSPHERES (NON SPHERICAL POLYVINYL ALCOHOL)(BEARING NSPVA EMBOLIZATION PARTICLES)-BEARING NSPVA EMBOLIZATION PARTICLES ARE USED FOR THE EMBOLIZATION OF PERIPHERAL HYPERVASCULARIZED TUMORS, INCLUDING LEIOMYOMA UTERI AND PERIPHERAL ARTERIOVENOUS MALFORMATIONS (AVMS).

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1884	IMP/MD/2019/000468	1.License Holder Name: VYGON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTILUMEN SELDINGER CATHETER(MULTICATH EXPERT)-MULTICATH EXPERT IS INTENDED FOR USE IN PATIENTS REQUIRING SHORT TO MIDTERM INTRAVENOUS THERAPY FOR INJECTING OR INFUSING DIFFERENT SOLUTIONS OR MEDICATIONS SIMULTANEOUSLY.,1 LUMEN CATHETER -SET(SELDIPUR SMARTMIDLINE)-THE SELDIPUR SMARTMIDLINE IS INTENDED FOR USE IN PATIENTS WHO REQUIRE SHORT- TERM AND MID-TERM IV THERAPY UP TO 29 DAYS. IT CAN ALSO BE USED FOR POWER INJECTIONS.,DIALYSIS CATHETER (DUALYSE CATH EXPERT 8132 & TRILYSE CATH EXPERT 8139)-DOUBLE & TRIPLE LUMEN CATHETERS INDICATED FOR TEMPORARY VASCULAR ACCESS.,PERIPHERALLY INSERTED CENTRAL CATHETER (LIFECATH PICC)-LIFECATH PICC MAY BE USED TO ADMINISTER PARENTERAL NUTRITION, ANTIBIOTICS, CHEMOTHERAPY, INTRAVENOUS MEDICATION, FLUIDS OR DRUGS FOR PAIN MANAGEMENT.,EPICUTANEO CATHETER(EPICUTANEO CAVA CATHETER)-FOR TOTAL PARENTERAL NUTRITION AND ADMINISTRATION OF MEDICATION IN PREMATURE BABIES AND NEONATES.,DIALYSIS CATHETER(TRILYSE CATH)-INDICATED FOR TEMPORARY VASCULAR ACCESS FOR HEMODIALYSIS OR HEMOPERFUSION,PERIPHERALLY INSERTED CENTRAL CATHETER (PREMICATH)-USEDFOR SHORT AND MEDIUM-TERM INFUSION OF TOTAL PARENTERAL NUTRITION OR INTRAVENOUS MEDICATIONS, PERIPHERALLY INSERTED CENTRAL CATHETER(NUTRILINE)-THE CATHETER IS USED FOR SHORT AND MEDIUM TERM (30 DAYS) INFUSION OF TPN OR INTRAVENOUS MEDICATIONS. IT IS SUITABLE FOR INSERTION INTO PERIPHERAL VEINS. RECOMMENDED INSERTION SITES INCLUDE THE BASILIC, CEPHALIC AND, IN NEONATES, THE LONG SAPHENOUS VENOUS VEIN, TEMPORAL OR POSTERIOR AURICULAR VEINS.,MULTILUMEN SELDINGER CATHETER(MULTICATH) -MULTICATH IS INTENDED FOR USE IN PATIENTS REQUIRING SHORT TO MIDTERM INTRAVENOUS THERAPY (29 DAYS) FOR INJECTING OR INFUSING DIFFERENT SOLUTIONS OR MEDICATIONS SIMULTANEOUSLY.,DIALYSIS CATHETER(DUALYSE CATH)-DUALYSECATH & TRILYSECATH ARE POLYURETHANE DOUBLE & TRIPLE LUMEN DIALYSIS CATHETERS INDICATED FOR TEMPORARY VASCULAR ACCESS FOR HEMODIALYSIS OR HEMOPERFUSION., IMPLANTABLE CATHETER(LIFECATH)-FOR PARENTERAL NUTRITION, ADMINISTRATION OF DRUGS & CANCER CHEMOTHERAPY., MULTILUMEN SELDINGER CATHETER(MULTISTAR)-MULTISTAR3 IS INTENDED FOR USE IN PATIENTS REQUIRING SHORT TO MIDTERM INTRAVENOUS THERAPY (-29 DAYS) FOR INJECTING OR INFUSING

		DIFFERENT SOLUTIONS OR MEDICATIONS SIMULTANEOUSLY.,SINGLE LUMEN SELDINGER CATHETER(LEADERFLEX)-• ARTERIAL CATHETERIZATION • CENTRAL VENOUS CATHETERIZATION IN CHILDREN • PERIPHERAL VENOUS CATHETERIZATION (MIDLINE) IN ANY PATIENT POPULATION WITH CONSIDERATION GIVEN TO ADEQUACY OF VASCULAR ANATOMY AND APPROPRIATENESS OF PROCEDURE,MULTILUMEN SELDINGER CATHETER(MULTICATH)-INTENDED FOR USE IN PATIENTS REQUIRING SHORT TO MIDTERM IV THERAPY FOR INJECTING DIFFERENT SOLUTIONS OR MEDICATIONS SIMULTANEOUSLY.
1885	IMP/MD/2019/000469	1.License Holder Name: INFINITY ADVISORY SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACNE PATCHES (NON-STERILE)(DERMA ANGEL)-ENHANCES PUS ABSORBANCE AND HEALING FROM ACNES WOUNDS

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1886	IMP/MD/2019/000473	1.License Holder Name: HEALTHIUM MEDTECH PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOSCOPIC LINEAR CUTTER STAPLERS AND LOADING UNITS-ENDOSCOPIC LINEAR CUTTER STAPLERS AND LOADING UNITS HAS APPLICATION IN ABDOMINAL, GYNECOLOGIC, PEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSECTION AND CREATION OF ANASTOMOSIS., DISPOSABLE LINEAR CUTTER STAPLERS AND LOADING UNITS-DISPOSABLE LINEAR CUTTER STAPLERS AND LOADING UNITS HAVE APPLICATION IN GASTROINTESTINAL, GYNECOLOGIC, THORACIC, AND PEDIATRIC SURGERY FOR TRANSECTION, RESECTION, AND THE CREATION OF ANASTOMOSES AND CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIALS, SUCH AS BOVINE PERICARDIUM.,DISPOSABLE CIRCULAR STAPLERS-DISPOSABLE CIRCULAR STAPLER HAS APPLICATIONS THROUGHOUT THE ALIMENTARY TRACT (SUCH AS ESOPHAGUS, STOMACH, INTESTINES) FOR THE CREATION OF END-TO-END, END-TO-SIDE AND SIDE-TO-SIDE ANASTOMOSES IN SURGERIES.,DISPOSABLE PPH STAPLERS-DISPOSABLE PPH STAPLERS HAS APPLICATION THROUGHOUT THE ANAL CANAL TO PERFORM STAPLING AND REPAIRING OF RECTAL MUCOSAL PROLAPSE AND HEMORRHOIDAL MUCOSAL TISSUES., DISPOSABLE SKIN STAPLER(TRUPLER, TRUPLER NEO TRUPLER ECO, SURGIPLER SURGI-PLER, HEALIER HEAL-IER, Q-CLOSE SKIN STAPLER, DERMATOR)-DISPOSABLE SKIN STAPLER HAS APPLICATION FOR SKIN SUTURE DURING SURGICAL OPERATION. A SURGICAL INSTRUMENT DESIGNED FOR THE APPLICATION OF SKIN STAPLE TO APPROXIMATE FREE EDGES OF SKIN FROM AN INCISION OR WOUND.

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1887	IMP/MD/2019/000474	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KNEE SYSTEM- FEMORAL (LCS COMPLETE)-WITH CEMENT: IT IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES. WITHOUT CEMENT: IT IS INDICATED FOR NON-CEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR RECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE ROTATING PLATFORM DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES W HOSE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE ABSENT OR ARE IN SUCH CONDITION AS TO JUSTIFY THEIR SACRIFICE. THE PFC L RP CURVED BEARINGS WHEN USED WITH THE PFC L CRUCIATE RETAINING FEMORAL COMPONENT CAN BE USED IN POSTERIOR CRUCIATE LIGAMENT RETAINING PROCEDURES. IN ADDITION, TITANIUM ALLOY COMPONENTS, COATED WITH TITANIUM NITRIDE ARE AVAILABLE AND MAY BE SELECTED W HERE PATIENT METAL SENSITIVITY TO CO-CR IS SUSPECTED. ,HIP REPLACEMENT SYSTEM- FEMORAL HEAD(S-ROM)-THE FEMORAL HEAD IS INDICATED FOR USE IN TOTAL OR PARTIAL HIP REPLACEMENT PROCEDURES FOR PATIENTS SUFFERING SEVERE PAIN AND DISABILITY DUE TO STRUCTURAL DAMAGE IN THE HIP JOINT FROM RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, POST TRAUMATIC ARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS AND NONUNION OF FEMORAL FRACTURES. USE OF THE PROSTHESIS IS ALSO INDICATED FOR PATIENTS WITH CONGENITAL HIP DYSPLASIA, PROTRUSIO ACETABULI, SLIPPED CAPITAL FEMORAL EPIPHYSIS AND DISABILITY DUE TO PREVIOUS FUSION, WHERE BONE STOCK IS INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES.,KNEE SYSTEM- TIBIAL(LCS COMPLETE)-WITH CEMENT: IT IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES. WITHOUT CEMENT: IT IS INDICATED FOR NON-CEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR RECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE ROTATING

		PLATFORM DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES W HOSE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE ABSENT OR ARE IN SUCH CONDITION AS TO JUSTIFY THEIR SACRIFICE. THE PFC L RP CURVED BEARINGS WHEN USED WITH THE PFC L CRUCIATE RETAINING FEMORAL COMPONENT CAN BE USED IN POSTERIOR CRUCIATE LIGAMENT RETAINING PROCEDURES. IN ADDITION, TITANIUM ALLOY COMPONENTS, COATED WITH TITANIUM NITRIDE ARE AVAILABLE AND MAY BE SELECTED W HERE PATIENT METAL SENSITIVITY TO CO-CR IS SUSPECTED.
1888	IMP/MD/2019/000475	1.License Holder Name: M/S. VITALIS TECHNOLOGIES LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:POLYMER ACCESS PORT (IN-PORT ACCESS PORT KIT)-THE FB MEDICAL ACCESS PORTS ARE TOTALLY IMPLANTABLE VASCULAR ACCESS DEVICES DESIGNED TO PROVIDE REPEATED ACCESS TO THE VASCULAR SYSTEM FOR THE DELIVERY OF MEDICATIONS, INTRAVENOUS FLUIDS, PARENTERAL NUTRITION SOLUTIONS, AND BLOOD PRODUCTS. THEY ARE ALSO INDICATED FOR THE WITHDRAWAL OF BLOOD SAMPLE. PORT ACCESS IS PERFORMED BY PERCUTANEAOUS NEEDLE INSERTION USING A HUBER NEEDLE.,TITANIUM ACCESS PORT(INFU-KT ACCESS PORT KIT) -THE FB MEDICAL ACCESS PORTS ARE TOTALLY IMPLANTABLE VASCULAR ACCESS DEVICES DESIGNED TO PROVIDE REPEATED ACCESS TO THE VASCULAR SYSTEM FOR THE DELIVERY OF MEDICATIONS, INTRAVENOUS FLUIDS, PARENTERAL NUTRITION SOLUTIONS, AND BLOOD PRODUCTS. THEY ARE ALSO INDICATED FOR THE WITHDRAWAL OF BLOOD SAMPLE. PORT ACCESS IS PERFORMED BY PERCUTANEAOUS NEEDLE INSERTION USING A HUBER NEEDLE.

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1889	IMP/MD/2019/000476	1.License Holder Name: GOODWILL DIAGNOSTICS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTION NEEDLES(BLOOD COLLECTION NEEDLES)-IT'S USED TOGETHER WITH VACUUM BLOOD COLLECTION TUBE FOR THE PURPOSE OF VENOUS BLOOD COLLECTION. THE NEEDLE IS A PRODUCT OF STERILIZED MEDICAL DEVICE, FOR SINGLE USE ONLY; AND IT SHOULD BE HANDLED BY MEDICAL PROFESSIONALS.,BLOOD COLLECTION NEEDLES(BLOOD COLLECTION NEEDLES)-IT'S USED TOGETHER WITH VACUUM BLOOD COLLECTION TUBE FOR THE PURPOSE OF VENOUS BLOOD COLLECTION. THE NEEDLE IS A PRODUCT OF STERILIZED MEDICAL DEVICE, FOR SINGLE USE ONLY; AND IT SHOULD BE HANDLED BY MEDICAL PROFESSIONALS. ,BLOOD COLLECTION NEEDLES(BLOOD COLLECTION NEEDLES)-IT'S USED TOGETHER WITH VACUUM BLOOD COLLECTION TUBE FOR THE PURPOSE OF VENOUS BLOOD COLLECTION. THE NEEDLE IS A PRODUCT OF STERILIZED MEDICAL DEVICE, FOR SINGLE USE ONLY; AND IT SHOULD BE HANDLED BY MEDICAL PROFESSIONALS.
1890	IMP/MD/2019/000478	1.License Holder Name: HEMANT SURGICAL INDUSTRIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOLEY CATHETER - SILICONE(SAFECATH)-IT IS INTENDED FOR URETHRAL CATHETERIZATION, DRAINAGE AND DRUG INJECTION

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1891	IMP/MD/2019/000479	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUTURE ANCHOR (HEALICOIL)-INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: 1. SHOULDER ROTATOR CUFF TEAR REPAIRS BICEPS TENODESIS DELTOID REPAIRS,SUTURE ANCHOR(HEALICOIL REGENESORB)-IT IS INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE.,FIXATION SCREW(RCI)-RCI FIXATION SCREWS ARE USED FOR INTERFERENCE FIXATION OF BONE-TENDON-BONE OR SOFT TISSUE GRAFTS IN ANTERIOR OR POSTERIOR CRUCIATE LIGAMENT RECONSTRUCTION.,FIXATION SCREW(SOFTSILK)-THE SMITH & NEPHEW SOFTSILK SCREWS ARE USED FOR INTERFERENCE FIXATION OF BONE-TENDON-BONE OR SOFT TISSUE GRAFTS IN ANTERIORCRUCIATE LIGAMENT RECONSTRUCTION.,SUTURE ANCHOR(SPYROMITE)-INTENDED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: 1. ELBOW, WRIST, AND HAND • BICEPS TENDON REATTACHMENT • ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTIONS • LATERAL EPICONDYLITIS REPAIR • SCAPHOLUNATE LIGAMENT RECONSTRUCTION,SUTURE ANCHOR(TWINFIX TI)-IT IS INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE.,NON-ABSORBABLE SURGICAL SUTURE(ULTRABRAID)-IT IS INDICATED FOR USE IN APPROXIMATION AND/OR LIGATION OF SOFT TISSUES, INCLUDING ALLOGRAFT TISSUE FOR ORTHOPEDIC SURGERIES., FIXATION DEVICE(ENDOBUTTON)-THE ENDOBUTTON FIXATION DEVICE IS INDICATED FOR USE IN SUTURE FIXATION OF LIGAMENTS AND TENDONS IN PATIENTS REQUIRING LIGAMENT OR TENDON REPAIR.,SUTURE ANCHOR(FOOTPRINT ULTRA)-INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: 1. SHOULDER• ROTATOR CUFF TEAR REPAIRS• BICEPS TENODESIS• DELTOID REPAIRS 2. KNEE• EXTRA-CAPSULAR REPAIRS–MEDIAL COLLATERAL LIGAMENT–LATERAL COLLATERAL LIGAMENT–POSTERIOR OBLIQUE LIGAMENT,SUTURE ANCHOR(TWINFIX ULTRA HA)-IT IS INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE.,SUTURE ANCHOR (SUTUREFIX ULTRA)-SUTUREFIX ULTRA SUTURE ANCHOR IS INTENDED FOR THE SECURE FIXATION OF SOFT TISSUE TO BONE., SUTURE ANCHOR(OSTEORAPTOR)-OSTEORAPTOR SUTURE ANCHOR IS INTENDED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE , SUTURE ANCHOR(TWINFIX ULTRA TI)-IT IS INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE.,SUTURE ANCHOR(DYNOMITE)-INTENDED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: 1. FOOT AND

	ANKLE • MEDIAL OR LATERAL INSTABILITY REPAIRS/RECONSTRUCTIONS • ACHILLES TENDON REPAIRS/RECONSTRUCTIONS • BUNIONECTOMY 2. ELBOW, WRIST, AND HAND • BICEPS TENDON REATTACHMENT • ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTIONS • LATERAL EPICONDYLITIS REPAIR,SUTURE ANCHOR(FAST-FIX 360)-THE FAST-FIX 360 SYSTEM IS INTENDED TO BE USED FOR ANCHORING THE ALLOGRAFT TO THE MENISCAL RIM DURING ALLOGRAFT TRANSPLANT PROCEDURES.,SUTURE ANCHOR(BIORAPTOR)-INTENDED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: 1.HIP ACETABULAR LABRUM REATTACHMENT 2. SHOULDER CAPSULAR STABILIZATION BANKART REPAIR ANTERIOR SHOULDER INSTABILITY SLAP LESION REPAIRS CAPSULAR SHIFT OR CAPSULOLABRAL RECONSTRUCTIONS 3. FOOT AND ANKLE HALLUX VALGUS REPAIRS MEDIAL OR LATERAL INSTABILITY REPAIRS/RECONSTRUCTIONS ACHILLES TENDON REPAIRS/RECONSTRUCTIONS MIDFOOT RECONSTRUCTIONS METATARSAL LIGAMENT/TENDON REPAIRS/RECONSTRUCTIONS BUNIONECTOMY 4.ELBOW, WRIST, AND HAND BICEPS TENDON REATTACHMENT ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTIONS LATERAL EPICONDYLITIS REPAIR *BIORAPTOR™ SUTURE ANCHORS WITH NEEDLES AND BIORAPTOR™ KNOTLESS SUTURE ANCHOR ARE ONLY INTENDED FOR THE HIP AND SHOULDER INDICATIONS.**BIORAPTOR™ CURVED 2.3 PK SUTURE ANCHORS ARE ONLY INTENDED FOR THE SHOULDER INDICATIONS.,SUTURE ANCHOR (TWINFIX ULTRA PK)-INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: 1. SHOULDER • ROTATOR CUFF TEAR REPAIRS • BICEPS TENODESIS • DELTOID REPAIRS 2. FOOT AND ANKLE • HALLUX VALGUS REPAIRS • MEDIAL OR LATERAL INSTABILITY REPAIRS/RECONSTRUCTIONS • ACHILLES TENDON REPAIRS/RECONSTRUCTIONS • MIDFOOT RECONSTRUCTIONS • METATARSAL LIGAMENT/TENDON REPAIRS/RECONSTRUCTIONS 3. ELBOW • ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTIONS • LATERAL EPICONDYLITIS REPAIR • BICEPS TENDON REATTACHMENT,SUTURE ANCHOR(TWINFIX AB)-IT IS INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE.,SUTURE(ULTRATAPE)-ULTRATAPE SUTURE IS INDICATED FOR USE IN APPROXIMATION AND/OR LIGATION OF SOFT TISSUES, INCLUDING ALLOGRAFT TISSUE FOR ORTHOPEDIC SURGERIES., SUTURE ANCHOR(ULTRA FAST-FIX)-THE ULTRA FAST-FIX MENISCAL REPAIR SYSTEM IS INTENDED FOR USE AS A SUTURE RETENTION DEVICE TO FACILITATE PERCUTANEOUS OR ENDOSCOPIC SOFT TISSUE PROCEDURES.

1892	IMP/MD/2019/000479	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUTURE ANCHOR(MINI TAC)-THE MINI TAC 2.0 MM SUTURE ANCHORS ARE INTENDED FOR USE ONLY FOR THE REATTACHMENT OF SOFT TISSUE TO BONE FOR THE FOLLOWING INDICATIONS: FOOT AND ANKLE - MEDIAL OR LATERAL INSTABILITY REPAIRS/RECONSTRUCTIONS; ELBOW, WRIST, AND HAND - SCAPHOLUNATE LIGAMENT RECONSTRUCTIONS, ULNAR OR RADIAL COLLATERAL LIGAMENT RECONSTRUCTIONS, LATERAL EPICONDYLITIS REPAIR, BICEPS TENDON REATTACHMENT.,SUTURE ANCHOR(SUTUREFIX CURVED)-THE SMITH & NEPHEW SUTUREFIX CURVED SUTURE ANCHORS ARE INTENDED FOR THE REATTACHMENT OF SOFT TISSUE TO BONE.
1893	IMP/MD/2019/000480	1.License Holder Name: FRESENIUS KABI INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PORTS INTRODUCER (AMBIX INTROCATH PLUS 8 CH/FR INCLUDING TUNNELER)-STERILE SINGLE USE FOR ACCESORIES OF PORT CATHERS USING SELDINGER TECHNIQUE
1894	IMP/MD/2019/000481	1.License Holder Name: ALCON LABORATORIES (INDIA) PVT. LTD. , 11TH FLOOR, RMZ AZURE, BELLARY ROAD, HEBBAL ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560092 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTI-PURPOSE DISINFECTANT SOLUTION(OPTI-FREE REPLENISH)-FOR USE IN THE DAILY CLEANING, CONDITIONING, RINSING, REMOVING PROTEIN DEPOSITS, CHEMICAL (NOT HEAT) DISINFECTION, AND STORAGE OF SILICONE HYDROGEL AND SOFT (HYDROPHILIC) CONTACT LENSES AS RECOMMENDED BY YOUR EYE CARE PRACTITIONER.,MULTI-PURPOSE DISINFECTANT SOLUTION(OPTI-FREE PUREMOIST)-FOR USE IN THE DAILY CLEANING, RECONDITIONING, RINSING, REMOVING PROTEIN DEPOSITS, REDUCING LIPID DEPOSITION, CHEMICAL (NOT HEAT) DISINFECTION, AND STORAGE OF SILICONE HYDROGEL AND SOFT (HYDROPHILIC) CONTACT LENSES AS RECOMMENDED BY YOUR EYE CARE PRACTITIONER.

1895	IMP/MD/2019/000482	1.License Holder Name: MN SOLUTIONS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE CEMENT(RALLY BONE CEMENT)-RALLY BONE CEMENTS ARE INTENDED TO BE USED FOR THE FIXATION OF ARTIFICIAL JOINT PROSTHESES TO THE HOST BONE.,RESIN FOR VERTEBROPLASTY AND KYPHOPLASTY(MENDEC SPINE, MENDEC SPINE KIT)-MENDEC SPINE (AND MENDEC SPINE KIT) IS INDICATED FOR THE TREATMENT OF PATHOLOGICAL FRACTURES OF THE VERTEBRAL BODY USING A VERTEBROPLASTY OR KYPHOPLASTY PROCEDURE. PAINFUL VERTEBRAL COMPRESSION FRACTURES MAY RESULT FROM OSTEOPOROSIS, BENIGN LESIONS (HEMANGIOMA), AND MALIGNANT LESIONS (METASTATIC CANCERS, MYELOMA).,BONE CEMENT WITH GENTAMICIN(RALLY AB BONE CEMENT)-RALLY AB BONE CEMENTS ARE INDICATED FOR THE FIXATION OF JOINT PROSTHESIS IMPLANTS TO THE HOST BONE. IN PARTICULAR, THESE CEMENTS ARE INDICATED WHERE THERE IS THE RISK OR PRESENCE OF INFECTIONS CAUSED BY ORGANISMS SUSCEPTIBLE TO GENTAMICIN.,SPACER FOR HIP(SPACER-G)-SPACER-G IS INDICATED FOR TEMPORARY USE (MAXIMUM 180 DAYS) AS AN ADJUNCT TO TOTAL HIP REPLACEMENT (THR) IN SKELETALLY MATURE PATIENTS UNDERGOING A TWO-STAGE PROCEDURE DUE TO A SEPTIC PROCESS. SPACER-G IS NOT INTENDED FOR USE FOR MORE THAN 180 DAYS, AT WHICH TIME IT MUST BE EXPLANTED AND A PERMANENT DEVICE IMPLANTED OR ANOTHER APPROPRIATE TREATMENT PERFORMED (E.G. RESECTION ARTHROPLASTY, FUSION ETC.). IT IS PARTICULARLY INDICATED FOR OPERATIONS WHICH PRESENT RISKS OF OR EXISTING INFECTIONS CAUSED BY ORGANISMS SENSITIVE TO GENTAMICIN.,SPACER FOR KNEE(SPACER-K)-SPACER-K IS INDICATED FOR TEMPORARY USE (MAXIMUM 180 DAYS) AS AN ADJUNCT TO TOTAL KNEE REPLACEMENT (TKR) IN SKELETALLY MATURE PATIENTS UNDERGOING A TWO-STAGE PROCEDURE DUE TO A SEPTIC PROCESS. SPACER-K IS NOT INTENDED FOR USE FOR MORE THAN 180 DAYS, AT WHICH TIME IT MUST BE EXPLANTED AND A PERMANENT DEVICE IMPLANTED OR ANOTHER APPROPRIATE TREATMENT PERFORMED (E.G. RESECTION ARTHROPLASTY, FUSION ETC.). IT IS PARTICULARLY INDICATED FOR OPERATIONS WHICH PRESENT RISKS OF OR EXISTING INFECTIONS CAUSED BY ORGANISMS SENSITIVE TO GENTAMICIN.

1896	IMP/MD/2019/000483	1.License Holder Name: GENETIX BIOTECH ASIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABSORBENT DRESSING (VLIWAZELL , STERILE)-VLIWAZELL IS INTENDED FOR THE TREATMENT OF MODERATELY TO HEAVILY EXUDING WOUNDS , AND ALSO AS A SECONDARY DRESSING FOR HEAVILY EXUDING WOUNDS IN COMBINATION WITH MOIST WOUND CARE DRESSINGS., SUPERABSORBENT WOUND DRESSING(VLIWASORB® PRO)-VLIWASORB® PRO IS SUITABLE FOR THE CARE OF ACUTE AND CHRONIC WOUNDS WITH VERY HIGH TO MODERATE AMOUNTS OF EXUDATE, SUCH AS: PRESSURE ULCERS, ARTERIAL ULCERS, VENOUS LOWER LEG ULCERS, DIABETIC ULCERS, POSTOPERATIVE WOUNDS HEALING BY SECONDARY INTENTION, POST-TRAUMATIC WOUNDS, SPLIT-SKIN GRAFT DONOR SITES, ONCOLOGICAL WOUNDS, ULCERATING TUMORS, WOUNDS AT RISK OF INFECTION, SUPERFICIAL PARTIAL THICKNESS BURNS AND AS A SECONDARY DRESSING, E.G. ON LAPAROTOMY WOUNDS AND FISTULAS. IT CAN ALSO BE USED AS A SECONDARY DRESSING USED WITH AN APPROPRIATE WOUND FILLER,ABSORBENT DRESSING(VLIWAZELL , NON-STERILE)-VLIWAZELL IS INTENDED FOR THE TREATMENT OF MODERATELY TO HEAVILY EXUDING WOUNDS , AND ALSO AS A SECONDARY DRESSING FOR HEAVILY EXUDING WOUNDS IN COMBINATION WITH MOIST WOUND CARE DRESSINGS.,CALCIUM ALGINATE WOUND DRESSING/ROPE(SUPRASORB® A)-SUPRASORB® A CALCIUM ALGINATE DRESSINGS AND ROPES IS INDICATED FOR THE TREATMENT OF THE FOLLOWING WOUNDS: DECUBITUS ULCERS, ARTERIAL ULCERS, LOWER LEG VENOUS ULCERS, DIABETIC ULCERS, SPLIT-THICKNESS SKIN REMOVAL SITES IF THEY HAVE HEAVY EXUDATE AND ARE SUPERFICIAL OR DEEP.,SUPERABSORBENT WOUND DRESSING, SELF ADHESIVE(VLIWASORB® ADHESIVE)-VLIWASORB® ADHESIVE SUPERABSORBENT WOUND DRESSING ARE FLEXIBLE SOFT WOUND DRESSINGS WHICH ARE USED FOR THE TREATMENT OF HEAVILY EXUDING WOUNDS SUCH AS PRESSURE SORES, ARTERIAL ULCERS, VENOUS LEG ULCERS, DIABETIC ULCERS, POSTOPERATIVE WOUNDS HEALING BY SECOND INTENTION, LAPAROTOMY WOUNDS, ON FISTULAE, AND SUPERFICIAL 2ND DEGREE BURNS.,ABSORBENT ACTIVATED CHARCOAL DRESSINGS (VLIWAKTIV®)-VLIWAKTIV® IS SUITABLE FOR ABSORBING EXUDATE WHEN WOUNDS ARE SUPERFICIAL AND HAVE MODERATE TO HIGH LEVELS OF EXUDATE, AND IN CASES OF MALODOROUS AND / OR, INFECTED WOUNDS AND AS A SECONDARY DRESSING IN COMBINATION WITH A SUITABLE WOUND FILLER ,SUPERABSORBENT WOUND DRESSING(VLIWASORB®)-VLIWASORB® SUPERABSORBENT WOUND DRESSING ARE FLEXIBLE SOFT WOUND DRESSINGS WHICH

	ARE USED FOR THE TREATMENT OF HEAVILY EXUDING WOUNDS SUCH AS PRESSURE SORES, ARTERIAL ULCERS, VENOUS LEG ULCERS, DIABETIC ULCERS, POSTOPERATIVE WOUNDS HEALING BY SECOND INTENTION, LAPAROTOMY WOUNDS, ON FISTULAE, AND SUPERFICIAL 2ND DEGREE BURNS.,ABSORBENT ACTIVATED CHARCOAL DRESSING WITH SILVER(VLIWAKTIV® AG)-VLIWAKITIV® AG ABSORBENT ACTIVATED CHARCOAL DRESSING WITH SILVER IS INTENDED TO BE USED FOR THE TREATMENT OF CRITICALLY COLONIZED, INFECTED AND/OR OFFENSIVE SMELLING WOUNDS AS WELL AS FOR WOUNDS WITH AN INCREASED RISK OF INFECTION AND IT MAY BE USED FOR HEAVILY EXUDING AND SUPERFICIAL WOUNDS (E.G. PRESSURE SORES, ARTERIAL ULCERS, VENOUS LEG ULCERS, DIABETIC ULCERS, POSTOPERATIVE WOUNDS HEALING BY SECOND INTENTION, EXULCERATING TUMORS.),ANTIMICROBIAL CALCIUM ALGINATE WOUND DRESSING & ROPE(SUPRASORB® A+AG)-SUPRASORB® A+AG ANTIMICROBIAL CALCIUM ALGINATE WOUND DRESSINGS AND ROPE CAN BE USED FOR THE TREATMENT OF WOUNDS AT RISK OF INFECTION AND INFECTED WOUNDS (IFU) (PRESSURE SORES, ARTERIAL ULCERS, VENOUS LOWER LEG ULCERS, DIABETIC ULCERS, POST-OPERATIVE WOUNDS, FUNGAL LESIONS)

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1897	IMP/MD/2019/000484	1.License Holder Name: FAITH BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIPOLAR COAGULATION ELECTRODE(CELON PROSURGE (KIT))-THE CELONPROSURGE BIPOLAR COAGULATION ELECTRODE OPERATED WITH THE COMPATIBLE POWER CONTROL UNIT AND THE COMPATIBLE TUBE PUMP IS INDICATED FOR ABLATION AND COAGULATION OF SOFT TISSUE, INCLUDING THERMAL INACTIVATION AND/OR VOLUME REDUCTION OF LOCALLY DEFINED TISSUE AREAS, SUCH AS TUMOURS AND METASTASES. THIS METHOD OF TREATMENT IS ALSO CALLED BIPOLAR RADIOFREQUENCY INDUCED THERMOTHERAPY (RFITT).,BIPOLAR COAGULATION ELECTRODE(CELON PROCURVE V)-THE BIPOLAR APPLICATOR, IN COMBINATION WITH THE COMPATIBLE ELECTROSURGICAL GENERATOR, IS INDICATED FOR ENDOVASCULAR COAGULATION OF BLOOD VESSELS IN PATIENTS WITH SUPERFICIAL VEIN REFLUX.,BIPOLAR COAGULATION ELECTRODE(CELON PROCURVE)-THE CELONPROCURVE BIPOLAR COAGULATION ELECTRODE, TOGETHER WITH THE COMPATIBLE POWER CONTROL UNIT, IS INDICATED FOR ABLATION AND COAGULATION OF SOFT TISSUE, INCLUDING THERMAL INACTIVATION AND/OR VOLUME REDUCTION OF LOCALLY DEFINED TISSUE AREAS, SUCH AS TUMOURS AND METASTASES. IN INTRALUMINAL USE IT IS ALSO INDICATED FOR SHRINKING VESSELS AND LUMENS. THIS METHOD OF TREATMENT IS ALSO CALLED BIPOLAR RADIOFREQUENCY INDUCED THERMOTHERAPY (RFITT).,BIPOLAR COAGULATION ELECTRODE (CELON PROSURGE MICRO)-THE CELONPROSURGE MICRO BIPOLAR COAGULATION ELECTRODE, TOGETHER WITH THE COMPATIBLE POWER CONTROL UNIT, IS INDICATED FOR ABLATION AND COAGULATION OF SOFT TISSUE, INCLUDING THERMAL INACTIVATION AND/OR VOLUME REDUCTION OF LOCALLY DEFINED TISSUE AREAS, SUCH AS TUMOURS AND METASTASES. THIS METHOD OF TREATMENT IS ALSO CALLED BIPOLAR RADIOFREQUENCY INDUCED THERMOTHERAPY (RFITT).

1898	IMP/MD/2019/000485	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CEMENT KIT(CONFIDENCE PLUS)-THE CONFIDENCE SPINAL CEMENT SYSTEM –11CC KIT IS INTENDED FOR PERCUTANEOUS DELIVERY OF CONFIDENCE 11CC SPINAL CEMENT, WHICH IS INDICATED FOR FIXATION OF PATHOLOGICAL FRACTURES OF THE VERTEBRAL BODY DURING VERTEBROPLASTY OR KYPHOPLASTY PROCEDURES. PAINFUL VERTEBRAL COMPRESSION FRACTURES MAY RESULT FROM OSTEOPOROSIS, BENIGN LESIONS (HEMANGIOMA), AND MALIGNANT LESIONS (METASTATIC CANCER, MYELOMA). THE CONFIDENCE HIGH VISCOSITY SPINAL CEMENT MAY ALSO BE USED IN CONJUCTION WITH THE VIPER AND EXPEDIUM FENESTRATED SCREW SYSTEMS, INCLUDING VERSE,SPINAL SYSTEM - CANNULATED SCREW (STERILIZED)(EXPEDIUM VERSE)-THE EXPEDIUM VERSE SPINE SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM VERSE SPINE SYSTEM IS INTENDED FOR NONCER¬VICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR, PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A POSTERIOR PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION, THE EXPEDIUM VERSE SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOL¬LOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CON¬FIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR, PSEUDOARTHRO¬SIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM VERSE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLES¬CENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM VERSE SYSTEMS ARE INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE

	SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH., INTRODUCER NEEDLE(CONFIDENCE SPINAL CEMENT SYSTEM)-BONE MARROW ASPIRATION NEEDLES ARE USED TO ASPIRATE ILIAC CREST BONE MARROW FOR USE WITH A BONE GRAFT MATERIAL SUCH AS HEALOS BONE GRAFT SUBSTITUTE. CONFIDENCE ADAPTERS, INTRODUCER NEEDLESS BIOPSY NEEDLES AND MULTI-DIRECTIONAL NEEDLESS ARE INTENDED FOR USE WITH THE CONFIDENCE SPINAL CEMENT SYSTEM. EXPEDIUM FENESTRATED SCREW CANNULAE ARE INTENDED FOR USE WITH THE EXPEDIUM FENESTRATED SCREW SYSTEM.,SPINAL SYSTEM - SCREW (STERILE) (VIPER PRIME)-THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A POSTERIOR PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION, THE VIPER SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS,SPINAL SYSTEM(CONCORDE SPINE SYSTEM)-THE CONCORDE, CONCORDE BULLET, CONCORDE INLINE, CONCORDE CURVE, COUGAR, DEVEX, AND LEOPARD SYSTEMS ARE INDICATED FOR USE AS INTERVERTEBRAL BODY FUSION DEVICES IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES) AT ONE OR TWO CONTIGUOUS LEVELS OF THE LUMBAR SPINE (L2-S1). PATIENTS SHOULD HAVE SIX MONTHS OF NON-OPERATIVE TREATMENT PRIOR TO SURGERY. THESE IMPLANTS ARE

	USED TO FACILITATE FUSION IN THE LUMBAR SPINE AND ARE PLACED VIA EITHER A PLIF (CONCORDE, CONCORDE BULLET, CONCORDE INLINE), TLIF (CONCORDE, CONCORDE BULLET, CONCORDE INLINE, CONCORDE CURVE, DEVEX, LEOPARD) OR ANTERIOR (COUGAR) APPROACH USING AUTOGENOUS BONE. WHEN USED AS INTERBODY FUSION DEVICES THESE IMPLANTS ARE INTENDED FOR USE WITH DEPUY SPINE SUPPLEMENTAL INTERNAL FIXATION PRODUCTS. THE CONCORDE, CONCORDE BULLET, CONCORDE INLINE, CONCORDE CURVE, COUGAR, DEVEX, AND LEOPARD SYSTEMS ARE INDICATED FOR USE IN THE THORACOLUMBAR SPINE (I.E., T1-L5) TO REPLACE A DISEASED VERTEBRAL BODY RESECTED OR EXCISED FOR THE TREATMENT OF TUMORS, TO ACHIEVE ANTERIOR DECOMPRESSION OF THE SPINAL CORD AND NEURAL TISSUES, AND TO RESTORE THE HEIGHT OF A COLLAPSED VERTEBRAL BODY. THESE SYSTEMS ARE ALSO INDICATED FOR TREATING FRACTURES OF THE THORACIC AND LUMBAR SPINE. THESE SYSTEMS ARE DESIGNED TO RESTORE THE BIOMECHANICAL INTEGRITY OF THE ANTERIOR, MIDDLE AND POSTERIOR SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A PROLONGED PERIOD. WHEN USED AS A VERTEBRAL BODY REPLACEMENT DEVICE THESE SYSTEMS ARE INTENDED FOR USE WITH DEPUY SPINE SUPPLEMENTAL INTERNAL FIXATION PRODUCTS., SPINAL SYSTEM - FENESTRATED SCREW (STERILE)(VIPER PRIME)- THE VIPER PRIME FENESTRATED SCREWS ARE INTENDED FOR USE WITH CONFIDENCE HIGH VISCOSITY SPINAL CEMENT TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE IN PATIENTS WITH DIMINISHED BONE QUALITY (E.G., OSTEOPOROSIS, OSTEOPENIA, METASTATIC DISEASE). THE SCREWS ARE INTENDED TO PROVIDE TEMPORARY INTERNAL SUPPORT AND FIXATION WHILE THE FUSION MASS IS CONSOLIDATING OR FRACTURE IS HEALING, OR FOR PALLIATIVE RECONSTRUCTION IN TUMOR PATIENTS.,CEMENT KIT(CONFIDENCE)-THE CONFIDENCE SPINAL CEMENT SYSTEM –11CC KIT IS INTENDED FOR PERCUTANEOUS DELIVERY OF CONFIDENCE 11CC SPINAL CEMENT, WHICH IS INDICATED FOR FIXATION OF PATHOLOGICAL FRACTURES OF THE VERTEBRAL BODY DURING VERTEBROPLASTY OR KYPHOPLASTY PROCEDURES. PAINFUL VERTEBRAL COMPRESSION FRACTURES MAY RESULT FROM OSTEOPOROSIS, BENIGN LESIONS (HEMANGIOMA), AND MALIGNANT LESIONS (METASTATIC CANCER, MYELOMA). THE CONFIDENCE HIGH VISCOSITY SPINAL CEMENT MAY ALSO BE USED IN CONJUCTION WITH THE VIPER AND EXPEDIUM FENESTRATED SCREW SYSTEMS, INCLUDING VERSE.,SPINAL SYSTEM - FENESTRATED SCREW (NS)

	(EXPEDIUM VERSE)-THE EXPEDIUM® FENESTRATED SCREW SYSTEM IS INTENDED TO BE USED WITH THE CONFIDENCE SPINAL CEMENT SYSTEM® OR THE V-MAX™ MIXING AND DELIVERY SYSTEM AND THE VERTEBROPLASTIC® RADIOPAQUE RESINOUS MATERIAL OR THE VERTECEM V+ CEMENT KIT TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE IN PATIENTS WITH DIMINISHED BONE QUALITY (E.G., OSTEOPOROSIS, OSTEOPENIA, METASTATIC DISEASE). IT IS INTENDED TO PROVIDE TEMPORARY INTERNAL SUPPORT AND FIXATION WHILE FUSION MASS IS CONSOLIDATING OR FRACTURE IS HEALING, OR FOR THE PALLIATIVE RECONSTRUCTION OF THE TUMOR PATIENTS.,SPINAL SYSTEM - CAGE (NS)(COUGAR LS)-THE COUGAR LS LATERAL CAGE SYSTEM IS INDICATED FOR USE IN THE THORACOLUMBAR SPINE(I.E., T1 TO L5) TO REPLACE A DISEASED VERTEBRAL BODY RESECTED OR EXCISED FOR THE TREATMENT OF TUMORS, TO ACHIEVE ANTERIOR DECOMPRESSION OF THE SPINAL CORD AND NEURAL TISSUES, AND TO RESTORE THE HEIGHT OF A COLLAPSED VERTEBRAL BODY. THIS SYSTEM IS ALSO INDICATED FOR TREATING FRACTURES OF THE THORACIC AND LUMBAR SPINE. THE SYSTEM IS DESIGNED TO RESTORE THE BIOMECHANICAL INTEGRITY OF THE ANTERIOR, MIDDLE AND POSTERIOR SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A PROLONGED PERIOD. WHEN USED AS A VERTEBRAL BODY REPLACEMENT DEVICE, THIS SYSTEM IS INTENDED FOR USE WITH DEPUY SPINE SUPPLEMENTAL INTERNAL FIXATION. THE COUGAR LS LATERAL CAGE SYSTEM IS ALSO INDICATED FOR INTERVERTEBRAL BODY FUSION WITH AUTOGENOUS BONE GRAFT IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTIGUOUS LEVELS FROM L2 TO S1. THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THESE IMPLANTS MAY BE IMPLANTED VIA AN OPEN OR A MINIMALLY INVASIVE LATERAL APPROACH. WHEN USED AS AN INTERBODY FUSION DEVICE, THIS SYSTEM IS INTENDED FOR USE WITH DEPUY SPINE SUPPLEMENTAL INTERNAL FIXATION.,SPINAL SYSTEM - FENESTRATED SCREW (STERILIZED)(EXPEDIUM VERSE)-THE EXPEDIUM® FENESTRATED SCREW SYSTEM IS INTENDED TO BE USED WITH THE CONFIDENCE SPINAL CEMENT SYSTEM® OR THE V-MAX™ MIXING AND DELIVERY SYSTEM AND THE VERTEBROPLASTIC® RADIOPAQUE RESINOUS MATERIAL OR THE VERTECEM V+ CEMENT

	KIT TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE IN PATIENTS WITH DIMINISHED BONE QUALITY (E.G., OSTEOPOROSIS, OSTEOPENIA, METASTATIC DISEASE). IT IS INTENDED TO PROVIDE TEMPORARY INTERNAL SUPPORT AND FIXATION WHILE FUSION MASS IS CONSOLIDATING OR FRACTURE IS HEALING, OR FOR THE PALLIATIVE RECONSTRUCTION OF THE TUMOR PATIENTS.,SPINAL SYSTEM - SCREW (NS)(EXPEDIUM VERSE)-THE EXPEDIUM VERSE SPINE SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM VERSE SPINE SYSTEM IS INTENDED FOR NONCER¬VICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR, PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A POSTERIOR PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION, THE EXPEDIUM VERSE SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOL¬LOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CON¬FIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR, PSEUDOARTHRO¬SIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM VERSE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLES¬CENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM VERSE SYSTEMS ARE INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH.,SPINAL SYSTEM - SCREW (STERILIZED)(EXPEDIUM VERSE)-THE EXPEDIUM VERSE SPINE SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE

	AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM VERSE SPINE SYSTEM IS INTENDED FOR NONCER¬VICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR, PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A POSTERIOR PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION, THE EXPEDIUM VERSE SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOL¬LOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CON¬FIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR, PSEUDOARTHRO¬SIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED FOR POSTERIOR NON-CERVICAL PEDICLE SCREW FIXATION IN PEDIATRIC PATIENTS, THE EXPEDIUM VERSE SYSTEM METALLIC IMPLANTS ARE INDICATED AS AN ADJUNCT TO FUSION TO TREAT ADOLES¬CENT IDIOPATHIC SCOLIOSIS. THE EXPEDIUM VERSE SYSTEMS ARE INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGRAFT. PEDIATRIC PEDICLE SCREW FIXATION IS LIMITED TO A POSTERIOR APPROACH.

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1899	IMP/MD/2019/000486	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FLOW DIVERTER(DERIVO EMBOLISATION DEVICE AND DERIVO MINI EMBOLISATION DEVICE)-THE DERIVO EMBOLISATION DEVICE IS INTENDED FOR THE TREATMENT OF INTRACRANIAL ANEURYSMS WHICH CANNOT BE TREATED WITH OTHER ENDOVASCULAR TECHNIQUES OR IN WHICH OTHER ENDOVASCULAR OR NEUROSURGICAL TECHNIQUES PRESENT A HIGHER TREATMENT RISK.,THROMBECTOMY DEVICE(APERIO® HYBRID THROMBECTOMY DEVICE)-THE APERIO® HYBRID THROMBECTOMY DEVICE IS INTENDED FOR RESTORATION OF THE ARTERIAL FLOW IN PATIENTS DIAGNOSED WITH ISCHEMIC STROKE DUE TO LARGE INTRACRANIAL VASCULAR OCCLUSION (I.E. IN THE INTERNAL CAROTID ARTERY, M1 AND M2 SEGMENTS OF THE MCA). PATIENTS WHO FAIL INTRAVENOUS THROMBOLYTIC THERAPY OR WHO ARE INELIGIBLE FOR THROMBOLYSIS MAY BE SUITED FOR TREATMENT WITH THE APERIO® HYBRID THROMBECTOMY DEVICE., MICROCATHETER(NEUROSLIDER MICROCATHETER AND NEUROSLIDER MICROCATHETER DLC)-"THE NEUROSLIDER IS INTENDED FOR CONTROLLED, SELECTIVE INFUSION OF PHYSICIAN-SPECIFIED THERAPEUTIC OR DIAGNOSTIC AGENTS INTO PERIPHERAL AND CEREBRAL VESSELS. THE NEUROSLIDER IS INTENDED FOR CONTROLLED, SELECTIVE INFUSION OF PHYSICIAN-SPECIFIED THERAPEUTIC OR DIAGNOSTIC AGENTS INTO PERIPHERAL AND CEREBRAL VESSELS. THE NEUROSLIDER 17 MICROCATHETER DLC IS OPTIMIZED FOR INTRODUCTION OF THE BRAIDED ACCERO STENT. THE NEUROSLIDER 21 MICROCATHETER DLC IS OPTIMIZED FOR INTRODUCTION OF THE BRAIDED DERIVO MINI EMBOLISATION DEVICE. " ,FLOW DIVERTER(DERIVO 2 EMBOLISATION DEVICE)-THE DERIVO 2 EMBOLISATION DEVICE IS INTENDED FOR THE TREATMENT OF INTRACRANIAL ANEURYSMS WHICH CANNOT BE TREATED WITH OTHER ENDOVASCULAR TECHNIQUES OR IN WHICH OTHER ENDOVASCULAR OR NEUROSURGICAL TECHNIQUES PRESENT A HIGHER TREATMENT RISK.,NEUROVASCULAR STENT(ACCLINO FLEX PLUS STENT)-THE ACCLINO FLEX PLUS STENT IS INTENDED FOR USE WITH EMBOLISATION MATERIALS IN THE TREATMENT OF INTRACRANIAL ANEURYSMS. ,GUIDING / ASPIRATION CATHETER (NEUROBRIDGE A70 CATHETER)-THE NEUROBRIDGE A70 CATHETER IS INTENDED FOR THE INTRODUCTION OF INTERVENTIONAL AND DIAGNOSTIC INSTRUMENTS INTO PERIPHERAL AND CEREBRAL VESSELS. ADDITIONALLY, IT CAN BE USED AS A DIAGNOSTIC ANGIOGRAPHY CATHETER. FURTHERMORE, IT IS SUITABLE FOR THE REMOVAL OR ASPIRATION OF FRESH, SOFT EMBOLI AND THROMBI FROM PERIPHERAL AND CEREBRAL VESSELS.,NEUROVASCULAR

	STENT(CREDO STENT)-"USED IN COMBINATION WITH THE NEUROSPEED® PTA BALLOON CATHETER, THE CREDO® STENT IS INDICATED TO INCREASE THE VESSEL DIAMETER OF INTRACRANIAL ARTERIES (FOR EXAMPLE THE ICA, MCA, VA/V4, BA) THAT ARE SUITABLE FOR AND ACCESSIBLE TO THE SYSTEM (STENT WITH PTA BALLOON CATHETER) IN PATIENTS: • WITH ARTERIOSCLEROTIC (PROBABLE ACCORDING TO CLINICAL, ANAMNESTIC OR LABORATORY CHEMICAL TESTING) VESSEL CONSTRICTIONS (HIGH-GRADE INTRACRANIAL STENOSES > 70%) WITH SIGNIFICANT CIRCULATORY DISTURBANCE (HAEMODYNAMIC INFARCT PATTERN AND/OR INDICATION OF RESTRICTED COLLATERALS), • WITH RECURRENT SYMPTOMS IN SPITE OF ANTIAGGREGATION THERAPY (THERAPY-REFRACTORY) AFTER AT LEAST TWO EVENTS (STROKE). • AGED 18 TO 80. • WHOSE LAST STROKE OCCURRED AT LEAST 7 DAYS BEFORE AND IN WHOM THE IMPAIRMENT AFTER STROKE HAS A RATING OF 3 OR LESS ON THE MODIFIED RANKIN SCALE (MRS) AT THE TIME OF TREATMENT.",BALLOON CATHETER(NEUROSPEED PTA BALLOON CATHETER)-"THE NEUROSPEED PTA BALLOON CATHETER IS INDICATED FOR DILATION OF A STENOSIS IN THE CEREBRAL ARTERIES IN ORDER TO IMPROVE PERFUSION. THE NEUROSPEED PTA BALLOON CATHETER IS INDICATED FOR INTRODUCTION OF THE SELF-EXPANDING CREDO STENT. PLEASE FOLLOW THE USER INSTRUCTIONS FOR THE CREDO STENT. NOTE: ONLY THE CREDO STENT HAS BEEN TESTED FOR COMPATIBILITY WITH THE NEUROSPEED PTA BALLOON CATHETER. THERE CAN BE NO GUARANTEE THE NEUROSPEED® PTA BALLOON CATHETER WILL BE SUITABLE FOR INTRODUCING OTHER INSTRUMENTS OR PRODUCTS.", NEUROVASCULAR STENT(ACCERO STENT)-THE ACCERO STENT IS INTENDED FOR USE WITH EMBOLISATION MATERIALS IN THE TREATMENT OF INTRACRANIAL ANEURYSMS. ,GUIDING CATHETER (NEUROBRIDGE CATHETER)-"THE NEUROBRIDGE CATHETER IS INTENDED FOR THE INTRODUCTION OF INTERVENTIONAL AND DIAGNOSTIC INSTRUMENTS INTO PERIPHERAL AND CEREBRAL VESSELS. ADDITIONALLY, IT CAN BE USED AS A DIAGNOSTIC ANGIOGRAPHY CATHETER. FURTHERMORE, IT IS SUITABLE FOR THE REMOVAL OR ASPIRATION OF FRESH, SOFT EMBOLI AND THROMBI FROM PERIPHERAL AND CEREBRAL VESSELS."

1900	IMP/MD/2019/000487	1.License Holder Name: MONARCH ENTERPRISES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NON ABSORBABLE MONOFILAMENT POLYPROPYLENE MESH(2P)-COMPOSITE PROSTHESIS FOR THE TREATMENT OF ABDOMINAL WALL DEFECTS, WITH INTRA-PERITONEAL POSITIONING.,POLYPROPYLENE URO-GYNECOLOGICAL PROSTHETIC SYSTEM(INGYNE S)-THE URO-GYNAECOLOGICAL PROSTHETIC SYSTEM FOR URETHRAL SUPPORT INGYNE-S IS INDICATED FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE.,NON ABSORBABLE MONOFILAMENT POLYPROPYLENE MESH(BASIC)-MESH FOR THE SURGICAL REPAIR OF HERNIAS AND ABDOMINAL WALL DEFECTS. MESH NOT INDICATED FOR INTRA-PERITONEAL POSITIONING,POLYPROPYLENE URO-GYNECOLOGICAL PROSTHESIS(INGYNE - HALBAMESH)-PARTIALLY COMPOSITE PROSTHESIS FOR THE CORRECTION OF HIGH-GRADE VAGINAL CUPOLA PROLAPSES. IT CAN BE USED IN LAPRAROTOMIC OR LAPROSCOPIC SURGERY

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1901	IMP/MD/2019/000488	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CMF TRAUMA IMPLANTS (SMART LOCK HYBRID MMF)-THE STRYKER UNIVERSAL SMARTLOCKTM HYBRID MMF SYSTEM IS INDICATED FOR THE TREATMENT OF MANDIBULAR AND MAXILLARY FRACTURES IN ADULTS AND ADOLESCENTS (AGE 12 AND HIGHER) IN WHOM PERMANENT TEETH HAVE ERUPTED. THE STRYKER UNIVERSAL SMARTLOCKTM HYBRID MMF SYSTEM IS INTENDED TO BE USED FOR TEMPORARY STABILIZATION OF MANDIBULAR AND MAXILLARY FRACTURES IN ORDER TO MAINTAIN PROPER OCCLUSION DURING FRACTURE HEALING.,CMF TRAUMA IMPLANTS(UNIVERSAL NEURO-III SYSTEM)-THE STRYKER UNIVERSAL NEURO III IMPLANT SYSTEM IS INTENDED FOR RECONSTRUCTION, STABILIZATION AND/OR RIGID FIXATION OF NON LOAD-BEARING BONY AREAS SUBSEQUENT TO CRANIOTOMY, CRANIECTOMY AND CRANIAL FRACTURES IN ADULTS AND ADOLESCENTS (AGE 12 AND HIGHER).,CMF TRAUMA IMPLANTS (DELTA SYSTEM)-THE DELTA RESORBABLE FIXATION SYSTEM IS INTENDED FOR USE IN THE FIXATION OF BONES OF THE CRANIOFACIAL AND MIDFACIAL SKELETON AFFECTED BY TRAUMA OR FOR RECONSTRUCTION. THE SYSTEM CAN BE USED IN BOTH ADULT AND PAEDIATRIC PATIENTS BUT IS NOT INTENDED FOR USE IN THE MANDIBLE AND/OR FULL LOAD BEARING PROCEDURES.,CMF TRAUMA IMPLANTS(UNIVERSAL NEURO-II)-THE STRYKER® UNIVERSAL NEURO II IMPLANT SYSTEM IS INTENDED FOR RECONSTRUCTION, STABILIZATION AND/OR RIGID FIXATION OF NON LOAD-BEARING BONY AREAS SUBSEQUENT TO CRANIOTOMY, CRANIECTOMY AND CRANIAL FRACTURES IN ADULTS AND ADOLESCENTS (AGE 12 AND HIGHER).,CMF TRAUMA IMPLANTS (UNIVERSAL/UNIVERSAL II SYSTEM)-THE STRYKER® UNIVERSAL/UNIVERSAL II SYSTEM IS INTENDED FOR OSTEOTOMY, STABILIZATION AND RIGID FIXATION OF CMF FRACTURES AND RECONSTRUCTION.,MANDIBULAR DISTRACTION SYSTEM (MULTIGUIDE II MANDIBULAR DISTRACTION SYSTEM/ INTERNAL MIDFACE DISTRACTION SYSTEM/UNIVERSAL MANDIBLE SYSTEM)-FOR THE TREATMENT OF SYNDROMIC AND NON-SYNDROMIC CRANIOSYNOSTOSIS, MIDFACE RETRUSION, CONGENITAL MIDFACIAL HYPOPLASIA, AND CRANIOFACIAL DYSOSTOSIS IN PATIENTS TWO YEARS OF AGE AND OLDER.

1902	IMP/MD/2019/000489	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KNEE REPLACEMENT SYSTEM(SIGMA - PATELLA)-THE P.F.C. SIGMA AND P.F.C. MODULAR KNEE SYSTEM — PATELLA COMPONENTS ARE INDICATED FOR USE IN KNEE REPLACEMENTS FOR PATIENTS SUFFERING FROM SEVERE PAIN AND DISABILITY DUE TO PERMANENT STRUCTURAL DAMAGE IN THE KNEE JOINT FROM RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, COLLAGEN DISORDERS, OR PSEUDOGOUT. THIS DAMAGE MAY ALSO BE THE RESULT OF TRAUMA OR FAILED PRIOR SURGICAL INTERVENTION. THE P.F.C. SIGMA AND P. F.C. MODULAR KNEE SYSTEM — PATELLA COMPONENTS ARE INDICATED FOR USE ONLY WITH PMMA BONE CEMENT.,HOLE ELIMINATOR(APEX - HOLE ELIMINATOR)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.,KNEE REPLACEMENT SYSTEM (SIGMA - FEMORAL (10 YEARS))-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,HIP REPLACEMENT SYSTEM(ARTICUL/EZE - HEAD)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE

	USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.,KNEE REPLACEMENT SYSTEM(PFC SIGMA - TIBIAL INSERT)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM(PFC SIGMA - FEMORAL)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM(PFC SIGMA - ROD)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT

	LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,SHOULDER SYSTEM (GLOBAL ADVANTAGE - HEAD)-GLOBAL ADVANTAGE® AND GLOBAL AP™ SHOULDER SYSTEMS THE DEPUY GLOBAL ADVANTAGE AND GLOBAL AP SHOULDER SYSTEMS ARE INDICATED FOR USE IN TOTAL OR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS; 2. FRACTURE-DISLOCATIONS OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY; 3. OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT). THE DEPUY GLOBAL ADVANTAGE, AND GLOBAL AP SHOULDER SYSTEMS ARE ALSO INDICATED FOR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. UNUNITED HUMERAL HEAD FRACTURES; 2. AVASCULAR NECROSIS OF THE HUMERAL HEAD. GLOBAL ADVANTAGE AND GLOBAL AP™ CTA HUMERAL HEADS THE DEPUY GLOBAL ADVANTAGE AND GLOBAL AP CTA HUMERAL HEADS ARE INDICATED ONLY FOR HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE DEPUY GLOBAL ADVANTAGE CTA HUMERAL HEADS CAN BE USED WITH THE GLOBAL FX AND GLOBAL ADVANTAGE HUMERAL STEMS AND THE GLOBAL AP CTA HUMERAL HEAD CAN BE USED WITH THE GLOBAL AP HUMERAL STEM IN HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. GLOBAL FX, GLOBAL ADVANTAGE AND GLOBAL AP™ SHOULDER SYSTEMS FIXATION METHODS THE DEPUY GLOBAL FX, GLOBAL ADVANTAGE, AND GLOBAL AP SHOULDER SYSTEMS ARE INDICATED FOR THE FOLLOWING FIXATION METHODS: • POROCOAT™ POROUS-COATED COMPONENTS - POROCOAT POROUS-COATED HUMERAL STEM PROSTHESES ARE INDICATED FOR CEMENTED OR UNCEMENTED USE WITH FIXATION PROVIDED BY BIOLOGICAL TISSUE INGROWTH INTO THE POROUS COATING. • CEMENTED COMPONENTS - HUMERAL STEM AND GLENOID COMPONENTS LABELED "FOR CEMENTED USE ONLY" ARE INDICATED ONLY FOR USE WITH BONE CEMENT. • PRESS-FIT OR CEMENTED COMPONENTS - HUMERAL STEM PROSTHESES WITHOUT POROUS COATING AND LABELED "FOR PRESS-FIT OR CEMENTED USE ONLY" ARE INDICATED FOR PRESS-FIT UNCEMENTED USE OR FOR USE WITH BONE CEMENT.,KNEE

	REPLACEMENT SYSTEM(PFC SIGMA - STEM)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM(PFC SIGMA - STEM (TI))-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM(PFC SIGMA - TIBIAL COMPONENT)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT

	IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM(PFC SIGMA - PATELLA (PE))-THE P.F.C. SIGMA AND P.F.C. MODULAR KNEE SYSTEM — PATELLA COMPONENTS ARE INDICATED FOR USE IN KNEE REPLACEMENTS FOR PATIENTS SUFFERING FROM SEVERE PAIN AND DISABILITY DUE TO PERMANENT STRUCTURAL DAMAGE IN THE KNEE JOINT FROM RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, COLLAGEN DISORDERS, OR PSEUDOGOUT. THIS DAMAGE MAY ALSO BE THE RESULT OF TRAUMA OR FAILED PRIOR SURGICAL INTERVENTION. THE P.F.C. SIGMA AND P.F.C. MODULAR KNEE SYSTEM — PATELLA COMPONENTS ARE INDICATED FOR USE ONLY WITH PMMA BONE CEMENT.,SHOULDER SYSTEM(GLOBAL ADVANTAGE - STEM)-GLOBAL ADVANTAGE® AND GLOBAL AP™ SHOULDER SYSTEMS THE DEPUY GLOBAL ADVANTAGE AND GLOBAL AP SHOULDER SYSTEMS ARE INDICATED FOR USE IN TOTAL OR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR RHEUMATOID ARTHRITIS; 2. FRACTURE-DISLOCATIONS OF THE PROXIMAL HUMERUS WHERE THE ARTICULAR SURFACE IS SEVERELY COMMINUTED, SEPARATED FROM ITS BLOOD SUPPLY OR WHERE THE SURGEON'S EXPERIENCE INDICATES THAT ALTERNATIVE METHODS OF TREATMENT ARE UNSATISFACTORY; 3. OTHER DIFFICULT CLINICAL PROBLEMS WHERE SHOULDER ARTHRODESIS OR RESECTION ARTHROPLASTY ARE NOT ACCEPTABLE (E.G. REVISION OF A FAILED PRIMARY COMPONENT). THE DEPUY GLOBAL ADVANTAGE, AND GLOBAL AP SHOULDER SYSTEMS ARE ALSO INDICATED FOR HEMI-SHOULDER REPLACEMENT FOR THE TREATMENT OF: 1. UNUNITED HUMERAL HEAD FRACTURES; 2. AVASCULAR NECROSIS OF THE HUMERAL HEAD. GLOBAL ADVANTAGE AND GLOBAL AP™ CTA HUMERAL HEADS THE DEPUY GLOBAL ADVANTAGE AND GLOBAL AP CTA HUMERAL HEADS ARE INDICATED ONLY FOR HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. THE DEPUY GLOBAL ADVANTAGE CTA HUMERAL HEADS CAN BE USED WITH THE GLOBAL FX AND GLOBAL ADVANTAGE HUMERAL STEMS AND THE GLOBAL AP CTA HUMERAL HEAD CAN BE USED WITH THE GLOBAL AP HUMERAL STEM IN HEMI-SHOULDER REPLACEMENT IN PATIENTS WITH ROTATOR CUFF TEARS. GLOBAL FX, GLOBAL ADVANTAGE AND GLOBAL AP™ SHOULDER SYSTEMS FIXATION METHODS THE DEPUY GLOBAL FX, GLOBAL ADVANTAGE, AND GLOBAL AP SHOULDER SYSTEMS ARE INDICATED FOR THE FOLLOWING FIXATION METHODS: • POROCOAT™ POROUS-COATED COMPONENTS - POROCOAT POROUS-COATED HUMERAL STEM PROSTHESES ARE INDICATED FOR CEMENTED OR

	UNCEMENTED USE WITH FIXATION PROVIDED BY BIOLOGICAL TISSUE INGROWTH INTO THE POROUS COATING. • CEMENTED COMPONENTS - HUMERAL STEM AND GLENOID COMPONENTS LABELED “FOR CEMENTED USE ONLY” ARE INDICATED ONLY FOR USE WITH BONE CEMENT. • PRESS-FIT OR CEMENTED COMPONENTS - HUMERAL STEM PROSTHESES WITHOUT POROUS COATING AND LABELED “FOR PRESS-FIT OR CEMENTED USE ONLY” ARE INDICATED FOR PRESS-FIT UNCEMENTED USE OR FOR USE WITH BONE CEMENT.,SCREW (PINNACLE - SCREW)-DEPUY BONE SCREWS ARE INDICATED FOR USE AS AN ANCILLARY FIXATION DEVICE TO BE USED WITH TIBIAL AND ACETABULAR COMPONENTS IN TOTAL KNEE AND HIP ARTHROPLASTY.,KNEE REPLACEMENT SYSTEM(SIGMA - FEMORAL (5 YEARS))-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM AGAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM(PFC SIGMA - PATELLA (UHMWPE))-THE P.F.C. SIGMA AND P.F.C. MODULAR KNEE SYSTEM — PATELLA COMPONENTS ARE INDICATED FOR USE IN KNEE REPLACEMENTS FOR PATIENTS SUFFERING FROM SEVERE PAIN AND DISABILITY DUE TO PERMANENT STRUCTURAL DAMAGE IN THE KNEE JOINT FROM RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, COLLAGEN DISORDERS, OR PSEUDOGOUT. THIS DAMAGE MAY ALSO BE THE RESULT OF TRAUMA OR FAILED PRIOR SURGICAL INTERVENTION. THE P.F.C. SIGMA AND P.F.C. MODULAR KNEE SYSTEM — PATELLA COMPONENTS ARE INDICATED FOR USE ONLY WITH PMMA BONE CEMENT.,KNEE REPLACEMENT SYSTEM(PFC SIGMA - TIBIAL TRAY)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE

	REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1903	IMP/MD/2019/000490	1.License Holder Name: MONARCH ENTERPRISES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE WOUND DRESSING(EURODERM PLUS)-EURODERM PLUS IS A STERILE POST-OPERATIVE ISLAND DRESSING WITH SUPPORT IN POLYURETHANE FILM AND CENTRAL PAD. THE ABSORBENT AND NON-ADHERENT PAD ABSORBS EXUDATES, MINIMIZING THE RISK OF SKIN MACERATION, AND ALLOWS A PAINLESS REMOVAL OF THE DRESSING. THE FILM TRANSPARENCY ENABLES THE OBSERVATION OF THE EXUDATES IN THE PAD WITHOUT HAVING TO REMOVE THE DRESSING. THE THIN FILM IS FLEXIBLE, CONFORMS TO ALL BODY CONTOURS AND GUARANTEES AN EXCELLENT MOISTURE VAPOUR TRANSMISSION RATE, CREATING AN IDEAL ENVIRONMENT FOR WOUND HEALING. MOREOVER, THE FILM PROTECTS THE WOUND FROM EXTERNAL CONTAMINATIONS. EURODERM PLUS IS LATEX FREE.,STERILE WOUND DRESSING(EURODERM)-TO USE AS A MECHANICAL BARRIER FOR WOUNDS, MINOR BURNS AND SKIN ABRASIONS. EURODERM/EURODERM I.V. CAN ALSO USE FOR THE ATTACHMENT OF CATHETERS OR TABLETS AFTER A SURGICAL OPERATION., STERILE WOUND DRESSING(EURODERM IV PLUS)-EURODERM IV PLUS IS A STERILE POST-OPERATIVE ISLAND DRESSING WITH SUPPORT IN POLYURETHANE FILM AND CENTRAL PAD. THE ABSORBENT AND NON-ADHERENT PAD ABSORBS EXUDATES, MINIMIZING THE RISK OF SKIN MACERATION, AND ALLOWS A PAINLESS REMOVAL OF THE DRESSING. THE FILM TRANSPARENCY ENABLES THE OBSERVATION OF THE EXUDATES IN THE PAD WITHOUT HAVING TO REMOVE THE DRESSING. THE THIN FILM IS FLEXIBLE, CONFORMS TO ALL BODY CONTOURS AND GUARANTEES AN EXCELLENT MOISTURE VAPOUR TRANSMISSION RATE, CREATING AN IDEAL ENVIRONMENT FOR WOUND HEALING. MOREOVER, THE FILM PROTECTS THE WOUND FROM EXTERNAL CONTAMINATIONS. EURODERM IV PLUS IS LATEX FREE.,STERILE WOUND DRESSING(EUROMED)-EUROMED IS A STERILE DRESSING THAT ALLOWS TO SEAL THE WOUND ALONG ITS ENTIRE PERIMETER, AS THE BUFFER OF GAUZE IS PLACED AT THE CENTER OF THE ADHESIVE ZONE. EUROMED IS INTENDED TO BE USED AS MECHANICAL BARRIER OF THE WOUND, ULCER OF THE LOW PARTS OF THE BODY, BURNS AND SKIN ABRASIONS IN GENERAL.,STERILE WOUND DRESSING(EURODERM INCISE IODINE)-EURODERM INCISE IODINE IS INTENDED TO BE USED AS MECHANICAL BARRIER FOR SURGICAL INCISIONS.,STERILE WOUND DRESSING(EURODERM IV REINFORCED)-EURODERM IV REINFORCED IS A STERILE POST-OPERATIVE ISLAND DRESSING WITH SUPPORT IN POLYURETHANE FILM AND CENTRAL PAD. THE ABSORBENT AND NON-ADHERENT PAD ABSORBS EXUDATES, MINIMIZING THE RISK OF SKIN MACERATION,

		AND ALLOWS A PAINLESS REMOVAL OF THE DRESSING. THE FILM TRANSPARENCY ENABLES THE OBSERVATION OF THE EXUDATES IN THE PAD WITHOUT HAVING TO REMOVE THE DRESSING. THE THIN FILM IS FLEXIBLE, CONFORMS TO ALL BODY CONTOURS AND GUARANTEES AN EXCELLENT MOISTURE VAPOUR TRANSMISSION RATE, CREATING AN IDEAL ENVIRONMENT FOR WOUND HEALING. MOREOVER, THE FILM PROTECTS THE WOUND FROM EXTERNAL CONTAMINATIONS. EURODERM IV REINFORCED IS LATEX FREE.
1904	IMP/MD/2019/000491	1.License Holder Name: AADVENT 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TELESCOPIC INTRAMEDULLARY SYSTEM(FASSIER-DUVAL INTRAMEDULLARY TELESCOPIC NAIL)-THIS IMPLANT IS INDICATED AS A TEMPORARY IMPLANT TO AID IN THE HEALING OF LONG DIAPHYSIS FRACTURES, OSTEOTOMIES, MALUNIONS AND NONUNIONS AND TO PREVENT FURTHER FRACTURES IN FEMUR, TIBIA AND HUMERUS IN PEDIATRIC PATIENTS SUFFERING FROM OSTEOGENESIS IMPERFECT A WITHOUT DISRUPTING THE BONE GROWTH PLATE. IT CAN BE USED IN PROCEDURES SUCH AS BONE LENGTHENING/SHORTENING CONCOMITANTLY WITH EXTERNAL FIXATORS IN PEDIATRIC OR SMALL STATURE PATIENTS WITH LIMB LENGTH DISCREPANCY.

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1905	IMP/MD/2019/000492	1.License Holder Name: M/S. ASAHI INTECC CO., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROCATHETER(ASAHI CORSAIR PRO XS)-THE ASAHI CORSAIR PRO XS IS INTENDED TO PROVIDE SUPPORT TO FACILITATE THE PLACEMENT OF GUIDE WIRES IN THE CORONARY AND PERIPHERAL VASCULATURE, AND CAN BE USED TO EXCHANGE ONE GUIDE WIRE FOR ANOTHER. THE ASAHI CORSAIR PRO XS IS ALSO INTENDED TO ASSIST IN THE DELIVERY OF CONTRAST MEDIA INTO THE CORONARY, PERIPHERAL AND ABDOMINAL VASCULATURE. THIS DEVICE IS NOT INTENDED FOR USE IN NEUROVASCULATURE,MICROCATHETER(ASAHI CARAVEL)-THIS MICROCATHETER IS INTENDED TO PROVIDE SUPPORT TO FACILITATE THE PLACEMENT OF GUIDE WIRES IN THE CORONARY AND PERIPHERAL VASCULATURES, AND CAN BE USED TO EXCHANGE ONE GUIDE WIRE FOR ANOTHER.THIS MICROCATHETER IS ALSO INTENDED TO ASSIST IN THE DELIVERY OF CONTRAST MEDIA INTO THE CORONARY AND PERIPHERAL VASCULATURES.DO NOT USE THIS MICROCATHETER OTHER THAN FOR USE IN THE CORONARY AND PERIPHERAL VASCULATURES.,ASAHI PERIPHERAL GUIDEWIRE(ASAHI GLADIUS MG-PV)-THIS PRODUCT IS INTENDED TO FACILITATE THE PLACEMENT AND EXCHANGE OF DIAGNOSTIC AND THERAPEUTIC DEVICES DURING INTRAVASCULAR PROCEDURES. THIS DEVICE IS INTENDED FOR PERIPHERAL VASCULAR USE ONLY., NEUROVASCULAR GUIDE CATHETER(ASAHI FUBUKI)-THIS PRODUCT IS INTENDED TO BE USED TO GUIDE A THERAPEUTIC CATHETER OR THE LIKE FOR NEUROVASCULAR THERAPY TO A LESION OR A PROCEDURAL SITE FOR A PERCUTANEOUS INTRAVASCULAR PROCEDURE IN THE NEUROVASCULATURE. THIS PRODUCT IS INTENDED FOR USE ONLY IN THE NEUROVASCULATURE.,ASAHI PTCA GUIDEWIRE(ASAHI GLADIUS MG & EX)-ASAHI PTCA GUIDE WIRES ARE INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). THE ASAHI PTCA GUIDE WIRES ARE NOT INTENDED FOR USE IN THE NEUROVASCULATURE., MICROCATHETER(ASAHI MASTERS PARKWAY)-THIS MICROCATHETER IS MEDICAL DEVICE INTENDED FOR SUPERSELECTIVE ANGIOGRAPHY AND/OR INFUSION OF VARIOUS SUBSTANCES INCLUDING DIAGNOSIS, EMBOLIZATION AND TREATMENT IN PERIPHERAL VESSELS USING AN APPROPRIATE GUIDE CATHETER AND GUIDE WIRE. THIS PRODUCT IS NOT INTENDED FOR USE IN THE NEURO AND/ OR CORONARY VASCULATURE., PERIPHERAL GUIDE WIRE(ASAHI)-THIS PRODUCT IS INTENDED TO FACILITATE THE PLACEMENT AND EXCHANGE OF DIAGNOSTIC AND THERAPEUTIC DEVICES DURING INTRAVASCULAR PROCEDURES.

	THIS DEVICE IS INTENDED FOR PERIPHERAL VASCULAR USE ONLY., MICROCATHETER(ASAHI CORSAIR ARMET)-THE ASAHI CORSAIR ARMET IS INTENDED TO PROVIDE SUPPORT TO FACILITATE THE PLACEMENT OF GUIDE WIRES IN THE PERIPHERAL VASCULATURE, AND CAN BE USED TO EXCHANGE ONE GUIDE WIRE FOR ANOTHER. THE ASAHI CORSAIR ARMET IS ALSO INTENDED TO ASSIST IN THE DELIVERY OF CONTRAST MEDIA INTO THE PERIPHERAL VASCULATURE. THIS DEVICE IS NOT INTENDED FOR USE IN CORONARY VASCULATURE AND NEUROVASCULATURE.,CORONARY GUIDE CATHETER(ASAHI HYPERION)-THIS GUIDE CATHETER IS INTENDED FOR USE IN CORONARY VASCULAR APPLICATIONS AND IS DESIGNED TO PROVIDE A PATHWAY THROUGH WHICH MEDICAL INSTRUMENTS, SUCH AS BALLOON CATHETERS, GUIDE WIRES OR OTHER THERAPEUTIC DEVICES MAY BE INTRODUCED. THIS GUIDE CATHETER IS NOT INTENDED FOR USE IN CEREBRAL VASCULATURE AND PERIPHERAL VASCULATURE SUCH AS ARMS AND LEGS.,PTCA GUIDE WIRE(ASAHI)-ASAHI PTCA GUIDE WIRES ARE INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). THE ASAHI PTCA GUIDE WIRES ARE NOT INTENDED FOR USE IN THE NEUROVASCULATURE. FOR PTCA GW (SION & SION BLUE) ASAHI PTCA GUIDE WIRES ARE INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). THE ASAHI PTCA GUIDE WIRES ARE NOT INTENDED FOR USE IN THE CEREBRAL BLOOD VESSELS.,DISTAL SUPPORT SYSTEM(ASAHI FUBUKI 043)-THIS CATHETER IS INTENDED TO BE USED TO GUIDE A THERAPEUTIC CATHETER OR THE LIKE FOR NEUROVASCULAR THERAPY TO A LESION OR A PROCEDURAL SITE FOR A PERCUTANEOUS INTRAVASCULAR PROCEDURE IN THE NEUROVASCULATURE. THIS CATHETER IS INTENDED FOR USE ONLY IN THE NEUROVASCULATURE.,EXTENSION WIRE(ASAHI)-THE EXTENSION WIRE ACCESSORY IS INTENDED FOR EXTENSION OF THE WORKING LENGTH OF AN ALREADY INTRODUCED GUIDE WIRE WHEN EXCHANGING OVER-THE-WIRE INTERVENTIONAL DEVICES DURING AN ANGIOPLASTY PROCEDURE.,MICROCATHETER(ASAHI CORSAIR AND ASAHI CORSAIR PRO)-THE MICROCATHETER IS INTENDED TO PROVIDE SUPPORT TO FACILITATE THE PLACEMENT OF GUIDE WIRES IN THE CORONARY AND/OR PERIPHERAL VASCULATURES, AND CAN BE USED TO EXCHANGE ONE GUIDE WIRE FOR ANOTHER. THE MICROCATHETER IS ALSO INTENDED TO ASSIST IN THE DELIVERY OF CONTRAST MEDIA INTO THE CORONARY, PERIPHERAL AND

		ABDOMINAL VASCULATURES. THIS MICROCATHETER IS NOT INTENDED FOR USE IN NEURO VASCULATURE.
1906	IMP/MD/2019/000493	1.License Holder Name: LIFETECH (INDIA) INC. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOTRACHEAL TUBE (PREFORMED TRACHEAL TUBE NASAL SOFT WITH CUFF)-A BREATHING TUBE INSERTED INTO A TRACHEA USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,ENDOTRACHEAL TUBE (MICROLARYNGEAL TRACHEAL TUBE WITH CUFF)-A BREATHING TUBE INSERTED INTO A TRACHEA USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,ENDOTRACHEAL TUBE(TRACHEAL TUBE WITH LOW PRESSURE WITH CUFF)-A BREATHING TUBE INSERTED INTO A TRACHEA USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,ENDOTRACHEAL TUBE(TRACHEAL TUBE WITH EXTRA HIGH VOLUME LOW PRESSURE WITH CUFF)-A BREATHING TUBE INSERTED INTO A TRACHEA USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,ENDOTRACHEAL TUBE(TRACHEAL TUBE WITHOUT CUFF)-A BREATHING TUBE INSERTED INTO A TRACHEA USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,ENDOTRACHEAL TUBE (TRACHEAL TUBE WITH SUCTION LUMEN WITH CUFF)-A BREATHING TUBE INSERTED INTO A TRACHEA USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,ENDOTRACHEAL TUBE(REINFORCED TRACHEAL TUBE WITH LOW PRESSURE WITH CUFF)-A BREATHING TUBE INSERTED INTO A TRACHEA USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,ENDOTRACHEAL TUBE(PREFORMED TRACHEAL TUBE ORAL WITH CUFF)-A BREATHING TUBE INSERTED INTO A TRACHEA USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,NASOPHARYNGEAL AIRWAY(NASOPHARYNGEAL AIRWAY)-A CATHETER (FOR ADULTS) PASSED THROUGH THE NARES AND ADVANCED TO THE DEPTH OF THE NASOPHARYNX TO REMOVE AIR CHOKE OR OBSTRUCTION. A RESUSCITATOR

1907	IMP/MD/2019/000494	1.License Holder Name: OPHTHO EQUIP INC. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRA OCULAR LENSES (IMPLANTABLE COLLAMER LENS (MYOPIC) – EVO VISIAN ICL)-INDICATED FOR USE IN PHAKIC EYE TREATMENT IN ADULTS 21-45 YEARS OF AGE.,IMPLANTABLE COLLAMER LENS(EVO VIVA ICL)-INDICATED FOR USE IN PHAKIC EYE TREATMENT IN PATIENTS 21-60 YEARS OF AGE AND PSEUDOPHAKIC EYE TREATMENT IN PATIENTS WITH MONOFOCAL IOLS WITH AND WITHOUT CYLINDER CORRECTION 21 YEARS OF AGE AND OLDER FOR THE CORRECTION/REDUCTION OF MYOPIA WITH OR WITHOUT PRESBYOPIA,INTRA OCULAR LENSES (IMPLANTABLE COLLAMER LENS (MYOPIC) – EVO+ VISIAN ICL)-INDICATED FOR USE IN PHAKIC EYE TREATMENT IN ADULTS 21-45 YEARS OF AGE.,INTRA OCULAR LENSES(IMPLANTABLE COLLAMER LENS (HYPEROPIC) – VISIAN ICL)-INDICATED FOR USE IN PHAKIC EYE TREATMENT IN ADULTS 21-45 YEARS OF AGE.
1908	IMP/MD/2019/000495	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANESTHESIA KIT(BD PERISAFE EPIDURAL KIT)-IT PROVIDES COMPONENTS TO PERFORM EPIDURAL ANESTHESIA

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1909	IMP/MD/2019/000496	1.License Holder Name: M/S STRYKER INDIA PRIVATE LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL HIP REPLACEMENT SYSTEM(EXETER)-THE INDICATIONS FOR USE FOR TOTAL HIP AND HEMI HIP ARTHROPLASTY INCLUDE: 1. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS; 2. RHEUMATOID ARTHRITIS; 3. CORRECTION OF FUNCTIONAL DEFORMITY; 4. REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED; AND, 5. TREATMENT OF NONUNION, FEMORAL NECK AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES,TOTAL HIP REPLACEMENT SYSTEM(ETS)-IT IS INDICATED FOR FOLLOWING INDICATIONS • NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE, INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. • RHEUMATOID ARTHRITIS (EXCEPT THE OSTEOLOCK HA ACETABULAR CUP). • CORRECTION OF FUNCTIONAL DEFORMITY. • REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICE HAVE FAILED AND • NONUNION FEMORAL NECK FRACTURES AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES, RESTORATION HIP REPLACEMENT SYSTEM(RESTORATION ADM/MDM)-HE INDICATIONS FOR USE FOR TOTAL HIP ARTHROPLASTY INCLUDE: • NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS; • RHEUMATOID ARTHRITIS; • CORRECTION OF FUNCTIONAL DEFORMITY; • REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED; AND, • TREATMENT OF NON-UNION, FEMORAL NECK AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD • INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES. • DISLOCATION RISKS, TOTAL HIP REPLACEMENT SYSTEM(FEMORAL STEMS)-IT IS INDICATED FOR FOLLOWING INDICATIONS • NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE, INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. • RHEUMATOID ARTHRITIS (EXCEPT THE OSTEOLOCK HA ACETABULAR CUP). • CORRECTION OF FUNCTIONAL DEFORMITY. • REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICE HAVE FAILED AND • NONUNION FEMORAL NECK FRACTURES AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES,TOTAL HIP REPLACEMENT SYSTEM(FEMORAL HEAD)-IT IS INDICATED FOR FOLLOWING INDICATIONS • NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE, INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS. • RHEUMATOID

		ARTHRITIS (EXCEPT THE OSTEOLOCK HA ACETABULAR CUP). • CORRECTION OF FUNCTIONAL DEFORMITY. • REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICE HAVE FAILED AND • NONUNION FEMORAL NECK FRACTURES AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES,DISTAL FEMORAL GROWING PROSTHESIS(HMRS)-THE STRYKER DISTAL FEMORAL GROWING PROSTHESIS IS INDICATED FOR PEDIATRIC PATIENTS WHO HAVE NOT ACHIEVED FULL SKELETAL MATURITY (OPEN EPIPHYSIS), WHERE RADICAL RESECTION AND REPLACEMENT OF THE DISTAL FEMUR AND OR/PROXIMAL TIBIA IS REQUIRED WITH THE FOLLOWING CONDITIONS: • ONCOLOGY INDICATIONS • SEVERE TRAUMA • NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS • CORRECTION OF FUNCTIONAL DEFORMITY • RHEUMATOID ARTHRITIS • REVISION PROCEDURES WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED • THE DEVICES ARE SINGLE USE IMPLANTS INTENDED ONLY FOR IMPLANTATION WITH BONE CEMENT. • THE HMRS SYSTEM IS INTENDED FOR USE IN PATIENTS REQUIRING EXTENSIVE RECONSTRUCTION OF THE HIP JOINT AND/OR KNEE JOINT, INCLUDING KNEE FUSIONS, NECESSITATED BY EXTENSIVE BONE LOSS DUE TO TRAUMA, FAILED PREVIOUS PROSTHESIS AND/OR TUMOR RESECTION.
1910	IMP/MD/2019/000497	1.License Holder Name: MADISON ORTHO LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MADISON PLATES SYSTEM-BONE SCREWS (STAINLESS STEEL)(MADISON ORTHO)-INTENDED FOR USE IN THE INTERNAL FIXATION OF FRACTURES, OSTEOTOMIES AND NON-UNIONS.,MADISON PLATES SYSTEM-BONE PLATES (TITANIUM)(MADISON ORTHO)-INTENDED FOR USE IN THE INTERNAL FIXATION OF FRACTURES, OSTEOTOMIES AND NON-UNIONS.,INTRAMEDULLARY NAILING SYSTEMS (STAINLESS STEEL)(MADISON ORTHO)-IT IS INTENDED FOR SURGICAL TREATMENT OF FRACTURE OF EXTREMITY LONG BONES,MADISON PLATES SYSTEM-BONE PLATES (STAINLESS STEEL)(MADISON ORTHO)-INTENDED FOR USE IN THE INTERNAL FIXATION OF FRACTURES, OSTEOTOMIES AND NON-UNIONS.,INTRAMEDULLARY NAILING SYSTEMS (TITANIUM)(MADISON ORTHO)-IT IS INTENDED FOR SURGICAL TREATMENT OF FRACTURE OF EXTREMITY LONG BONES,MADISON PLATES SYSTEM-BONE SCREWS (TITANIUM)(MADISON ORTHO)-INTENDED FOR USE IN THE INTERNAL FIXATION OF FRACTURES, OSTEOTOMIES AND NON-UNIONS.

1911	IMP/MD/2019/000498	1.License Holder Name: ARAMEX TRADING CO. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE CEMENT(BIO-GEN)-THE BIO-GEN RANGE OF BONE SUBSTITUTES ACT AS OSTEOCONDUCTIVE MATERIALS TO BE USED IN BONE REGENERATION SURGERY.,BONE CEMENT(OSTEOPLANT)-THE OSTEOPLANT RANGE OF BONE SUBSTITUTES ACT AS BONE CONDUCTORS TO BE USED AS GRAFTS IN BONE REGENERATION SURGERY.,BONE CEMENT(HEART)-HEART® ACTS AS AN ANTI-EPITHELIAL INVASION MEMBRANE. THE HEART® MEMBRANE ACTS TO COVER, STRENGTHEN OR REPLACE CONNECTIVE TISSUE. SPECIFICALLY, IT CAN BE USED AS A DURAL REPLACEMENT (CODES HRT-XXDM),BONE CEMENT(BIOCOLLAGEN)-IT IS TO BE USED AS EPITHELIAL ANTI-INVASION MEMBRANE IN BONE REGENERATION OPERATIONS THROUGH GRAFTS.

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1912	IMP/MD/2019/000499	1.License Holder Name: ALCON LABORATORIES (INDIA) PVT. LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASTIGMATISM INTRA OCULAR LENS(ACRYSOF IQ TORIC ASTIGMATISM IOL)-THE ACRYSOF IQ TORIC POSTERIOR CHAMBER INTRAOCULAR LENSES ARE INTENDED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG OF THE EYE FOR VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM SECONDARY TO REMOVAL OF A CATARACTOUS LENS IN ADULT PATIENTS WITH OR WITHOUT PRESBYOPIA, WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE VISION., CLAREON IOL ASPHERIC HYDROPHOIC ACRYLIC IOL WITH AUTONOME AUTOMATED PRELOADED DELIVERY SYSTEM(CLAREON IOL WITH AUTONOME)-CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) IS A FOLDABLE SINGLE-PIECE POSTERIOR CHAMBER INTRAOCULAR LENS (IOL) INTENDED AS AN OPTICAL IMPLANT FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER OF THE EYE.,NATURAL INTRA OCULAR LENS(ACRYSOF IQ ASPHERIC NATURAL IOL)-THE ACRYSOF IQ POSTERIOR CHAMBER INTRAOCULAR LENS IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY. THIS LENS IS INTENDED FOR PLACEMENT IN THE CAPSULAR BAG. ,UV ABSORBING INTRA OCULAR LENS(ACRYSOF ASPHERIC UV ABSORBING IOL)-THE ACRYSOF ASPHERIC UV-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY. THIS LENS IS INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,INTRA OCULAR LENS(CLAREON IOL)-CLAREON ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (IOL) IS A FOLDABLE SINGLE-PIECE POSTERIOR CHAMBER INTRAOCULAR LENS (IOL) INTENDED AS AN OPTICAL IMPLANT FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER OF THE EYE. ,FOLDABLE INTRA OCULAR LENS(ACRYSOF IOL)-ACRYSOF POSTERIOR CHAMBER INTRAOCULAR LENSES ARE INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING

	CATARACT SURGERY WHEN EXTRACAPSULAR CATARACT EXTRACTION OR PHACOEMULSIFICATION ARE PERFORMED. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG., MULTIFOCAL INTRA OCULAR LENS(ACRYSOF IQ RESTOR MULTIFOCAL IOL)-THE ACRYSOF IQ RESTOR APODIZED DIFFRACTIVE OPTIC IOL IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH OR WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED WHO MAY BENEFIT FROM NEAR VISION WITHOUT A READING AID, AND FROM INCREASED SPECTACLE INDEPENDENCE. THE ACRYSOF IQ RESTOR APODIZED DIFFRACTIVE OPTIC IOL IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS IN REFRACTIVE LENS EXCHANGE (RLE) IN ADULT PATIENTS WHO MAY BENEFIT FROM NEAR VISION WITHOUT A READING AID, AND FROM INCREASED SPECTACLE INDEPENDENCE. THESE LENSES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG.,INTRA OCULAR LENS(CLAREON™ PANOPTIX™ TRIFOCAL HYDROPHOBIC IOL WITH THE AUTONOME™ AUTOMATED PRE-LOADED DELIVERY SYSTEM)-THE CLAREON™ PANOPTIX™ TRIFOCAL HYDROPHOBIC IOL IS INDICATED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER OF THE EYE FOR THE VISUAL CORRECTION OF APHAKIA SECONDARY TO REMOVAL OF A CATARACTOUS LENS OR CLEAR LENS IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA, WHO DESIRE NEAR, INTERMEDIATE AND DISTANCE VISION WITH INCREASED SPECTACLE INDEPENDENCE, INTRA OCULAR LENS(CLAREON™ ASPHERIC UV ABSORBING IOL WITH THE AUTONOME™ AUTOMATED PRE-LOADED DELIVERY SYSTEM)-THE CLAREON™ ASPHERIC UV ABSORBING IOL IS A FOLDABLE SINGLE-PIECE POSTERIOR CHAMBER IOL INTENDED AS AN OPTICAL IMPLANT FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER OF THE EYE.

1913	IMP/MD/2019/000499	1.License Holder Name: ALCON LABORATORIES (INDIA) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRAOCULAR LENS (CLAREON TORIC ASPHERIC HYDROPHOBIC ACRYLIC IOL)-THE CLAREON™ TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENSES ARE INTENDED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG OF THE EYE FOR VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM SECONDARY TO REMOVAL OF A CATARACTOUS LENS IN ADULT PATIENTS WITH OR WITHOUT PRESBYOPIA, WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER, AND INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE VISION., INTRA OCULAR LENS(CLAREON™ PANOPTIX™ TRIFOCAL UV ABSORBING IOL WITH THE AUTONOME™ AUTOMATED PRE-LOADED DELIVERY SYSTEM)-THE CLAREON™ PANOPTIX™ TRIFOCAL UV ABSORBING IOL IS INDICATED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER OF THE EYE FOR THE VISUAL CORRECTION OF APHAKIA SECONDARY TO REMOVAL OF A CATARACTOUS LENS OR CLEAR LENS IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA, WHO DESIRE NEAR, INTERMEDIATE AND DISTANCE VISION WITH INCREASED SPECTACLE INDEPENDENCE., INTRAOCULAR LENS(CLAREON PANOPTIX TRIFOCAL HYDROPHOBIC IOL)-THE CLAREON™ PANOPTIX™ TRIFOCAL IOL IS INDICATED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER OF THE EYE FOR THE VISUAL CORRECTION OF APHAKIA SECONDARY TO REMOVAL OF A CATARACTOUS LENS OR CLEAR LENS IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA, WHO DESIRE NEAR, INTERMEDIATE AND DISTANCE VISION WITH INCREASED SPECTACLE INDEPENDENCE.,INTRA OCULAR LENS (CLAREON™ TORIC ASPHERIC UV ABSORBING IOL WITH THE AUTONOME™ AUTOMATED PRE-LOADED DELIVERY SYSTEM)-THE CLAREON™ TORIC ASPHERIC UV ABSORBING INTRAOCULAR LENSES ARE INTENDED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG OF THE EYE FOR VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM SECONDARY TO REMOVAL OF A CATARACTOUS LENS IN ADULT PATIENTS WITH OR WITHOUT PRESBYOPIA, WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE VISION., INTRA OCULAR LENS(CLAREON™ ASPHERIC UV ABSORBING IOL)-THE CLAREON™ ASPHERIC UV ABSORBING IOL IS A FOLDABLE SINGLE-PIECE POSTERIOR CHAMBER IOL INTENDED AS AN OPTICAL IMPLANT FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS

		FOLLOWING CATARACT SURGERY. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER OF THE EYE.,INTRA OCULAR LENS(CLAREON™ TORIC ASPHERIC HYDROPHOBIC ACRYLIC IOL WITH THE AUTONOME™ AUTOMATED PRE-LOADED DELIVERY SYSTEM)-THE CLAREON™ TORIC ASPHERIC HYDROPHOBIC ACRYLIC INTRAOCULAR LENSES ARE INTENDED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG OF THE EYE FOR VISUAL CORRECTION OF APHAKIA AND PRE-EXITING CORNEAL ASTIGMATISM SECONDARY TO REMOVAL OF A CATARACTOUS LENS IN ADULT PATIENTS WITH OR WITHOUT PRESBYOPIA, WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE VISION.
1914	IMP/MD/2019/000499	1.License Holder Name: ALCON LABORATORIES (INDIA) PVT. LTD. , 11TH FLOOR, RMZ AZURE, BELLARY ROAD, HEBBAL ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560092 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRAOCULAR LENSES (ACRYSOF IQ ASPHERIC IOL WITH THE ULTRASERT PRE-LOADED DELIVERY SYSTEM)-ACRYSOF IQ POSTERIOR CHAMBER INTRAOCULAR LENSES ARE INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.
1915	IMP/MD/2019/000500	1.License Holder Name: M/S LINVATEC INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MENISCAL REPAIR NEEDLES(HI-FI® SUTURE WITH DOUBLE ARMED MENISCAL NEEDLES) -HI-FI SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, AND THE USE OF ALLOGRAFT TISSUES FOR ORTHOPAEDIC SURGERIES. HI-FI SUTURES ARE INTENDED FOR ONE-TIME USE ONLY, AND ARE NOT TO BE RE-STERILIZED.

1916	IMP/MD/2019/000501	1.License Holder Name: M/S STRYKER INDIA PRIVATE LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINE EXPANSION KIT (SPINEJACK® EXPANSION KIT)-THE SPINEJACK® SYSTEM IS INDICATED FOR USE IN THE REDUCTION OF MOBILE SPINAL FRACTURES THAT MAY RESULT FROM OSTEOPOROSIS, TRAUMA (FRACTURES TYPES A1, A2, A3 ACCORDING TO THE MAGERL CLASSIFICATION) AND MALIGNANT LESIONS (MYELOMA OR OSTEOLITIC METASTASIS). THE SPINEJACK® SYSTEM IS INTENDED TO BE USED IN COMBINATION WITH VALIDATED BONE CEMENT, AND TO BE PLACED, USING A TRANSPEDICULAR APPROACH, THROUGH A VERTEBRA PEDICLE WITH A MINIMUM INTERNAL DIAMETER (SEE IFU), AS VERIFIED WITH A PRE-OPERATIVE CT SCAN. CEMENT DISPENSERS: AS PART OF VERTEBROPLASTY OR KYPHOPLASTY. ,SPINE PREPARATION KIT(SPINEJACK® PREPARATION KIT)-THE SPINEJACK® SYSTEM IS INDICATED FOR USE IN THE REDUCTION OF MOBILE SPINAL FRACTURES THAT MAY RESULT FROM OSTEOPOROSIS, TRAUMA (FRACTURES TYPES A1, A2, A3 ACCORDING TO THE MAGERL CLASSIFICATION) AND MALIGNANT LESIONS (MYELOMA OR OSTEOLITIC METASTASIS). THE SPINEJACK® SYSTEM IS INTENDED TO BE USED IN COMBINATION WITH VALIDATED BONE CEMENT, AND TO BE PLACED, USING A TRANSPEDICULAR APPROACH, THROUGH A VERTEBRA PEDICLE WITH A MINIMUM INTERNAL DIAMETER (SEE IFU), AS VERIFIED WITH A PRE-OPERATIVE CT SCAN. CEMENT DISPENSERS: AS PART OF VERTEBROPLASTY OR KYPHOPLASTY. ,CEMENT DISPENSERS(CEMENT DISPENSERS)-THE SPINEJACK® SYSTEM IS INDICATED FOR USE IN THE REDUCTION OF MOBILE SPINAL FRACTURES THAT MAY RESULT FROM OSTEOPOROSIS, TRAUMA (FRACTURES TYPES A1, A2, A3 ACCORDING TO THE MAGERL CLASSIFICATION) AND MALIGNANT LESIONS (MYELOMA OR OSTEOLITIC METASTASIS). THE SPINEJACK® SYSTEM IS INTENDED TO BE USED IN COMBINATION WITH VALIDATED BONE CEMENT, AND TO BE PLACED, USING A TRANSPEDICULAR APPROACH, THROUGH A VERTEBRA PEDICLE WITH A MINIMUM INTERNAL DIAMETER (SEE IFU), AS VERIFIED WITH A PRE-OPERATIVE CT SCAN. CEMENT DISPENSERS: AS PART OF VERTEBROPLASTY OR KYPHOPLASTY.

1917	IMP/MD/2019/000503	1.License Holder Name: DELHI EYE ZONE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SILICONE OIL ENDOTAMPONADE(LSO)-IT IS INDICATED MAINLY FOR THE SURGICAL TREATMENT OF PATHOLOGICAL CHANGES GENERATED BY A PROLIFERATIVE PROCESS SUCH AS PROLIFERATIVE VITREORETINOPATHY (PVR), RETINAL DETACHMENT WITH PVR, GIANT RETINAL TEARS, AND TRACTION DETACHMENT ASSOCIATED WITH DIABETIC RETINOPATHY.,RETINAL IMPLANTS(LABTICIAN)-RETINAL IMPLANTS ARE USED IN THE SURGICAL TREATMENT OF RETINAL DETACHMENTS. THE IMPLANT CREATES AN INDENTATION IN THE SCLERA AND CHOROID WHICH APPROXIMATES THE RETINA TO THE PIGMENT EPITHELIUM. THIS PROCEDURE IS ACCOMPLISHED BY LOCAL INDENTATION OR THROUGH THE USE OF AN IMPLANT THAT ENCIRCLES THE GLOBE. CIRCLING BANDS AND SILICONE STRIPS ENCIRCLE THE EYE AND ARE USED ALONE OR IN COMBINATION WITH OTHER IMPLANTS. GROOVED STRIPS ARE DESIGNED FOR NARROW OR WIDE BEDS OR FOR HIGH SCLERAL BUCKLES. TIRE SHAPED IMPLANTS AND WEDGES ARE USED UNDER ENCIRCLING ELEMENTS FOR WIDE SCLERAL BEDS; FOR BREAKS NEAR THE ORA SERRATA; FOR MULTIPLE BREAKS; AND FOR HIGH SCLERAL BUCKLES. SLEEVES ARE USED TO SECURE THE ENCIRCLING ELEMENTS. BUTTONS ARE INDICATED FOR USE UNDER GROOVED STRIPS TO PRODUCE HIGHER BUCKLES. MERIDIONAL IMPLANTS GIVE ADDITIONAL BUCKLING IN THE MERIDIONAL DIRECTION, AND ARE USED UNDER CURVED OR GROOVED IMPLANTS. THE PAD IS USED TO CLOSE SCLERAL RUPTURES. SILICONE SPONGE IMPLANTS ARE USED ALONE OR IN COMBINATION AND ARE OFTEN INDICATED FOR SEGMENTAL BUCKLING PROCEDURES.

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1918	IMP/MD/2019/000505	1.License Holder Name: SANOFI SYNTHELABO INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYLAN POLYMER A & B G-F 20 PREFILLED SYRINGE 8MG/ML(SYNVISC ONE)-• FOR THE TREATMENT OF PAIN IN OSTEOARTHRITIS OF THE KNEE IN PATIENTS WHO HAVE FAILED TO RESPOND ADEQUATELY TO CONSERVATIVE NON PHARMACOLOGIC THERAPY AND TO SIMPLE ANALGESICS. • FOR THE TREATMENT TO DECREASE PAIN & DISCOMFORT ALLOWING MORE EXTENSIVE MOVEMENT OF THE KNEE,HYLAN POLYMER A & B G-F 20 PREFILLED SYRINGE 8MG/ML(SYNVISC)-• FOR PAIN MANAGEMENT IN PATIENTS SUFFERING WITH OSTEOARTHRITIS OF THE KNEE, HIP, SHOULDER AND ANKLE. • FOR THE TREATMENT OF PAIN IN OSTEOARTHRITIS OF THE KNEE IN PATIENTS WHO HAVE FAILED TO RESPOND ADEQUATELY TO CONSERVATIVE NON PHARMACOLOGIC THERAPY AND TO SIMPLE ANALGESICS. • FOR THE TREATMENT TO DECREASE PAIN & DISCOMFORT ALLOWING MORE EXTENSIVE MOVEMENT OF THE KNEE
1919	IMP/MD/2019/000509	1.License Holder Name: ORIENT MEDICAL DISTRIBUTORS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SIROLIMUS DRUG ELUTING CO-CR STENT CORONARY STENT SYSTEM(RAPSTROM, AKOS, RAPSTROM ELITE)-INTENDED FOR TREATMENT OF ARTHEROSCLERITIC LESIONS EG; STENOSIS, INTIMA FLAPS, DISSECTIONS OR RECANALIZED OCCLUSIONS,PTA BALLOON CATHETER(INDIGO)-THE PTA BALLOON CATHETER IS INTENDED FOR USE IN PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF FEMORAL , ILLIAC, RENAL ARTERIES OR POST DEPLOYMENT DILATION OF PERIPHERAL VASCULAR STENTS OR FOR TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE, GUIDE WIRE(ACCEX)-THE ACCEX GUIDE WIRE IS USED TO FACILITATE THE PLACEMENT OF DEVICES DURING DIAGNOSTIC AND INTERVENTIONAL PROCEDURES. THE GUIDE WIRES ARE INTENDED TO FACILITATE CATHETER PLACEMENT AND EXCHANGE DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURES, WHERE INCREASED SUPPORT, DISTAL FLEXIBILITY AND LOW SURFACE FRICTION OF THE GUIDE WIRE IS NEEDED.,PTCA BALLOON CATHETER(FAST TRACK, HIGH TRACK, VAS TRACK)-THE PTCA BALLOON CATHETERS ARE INTENDED FOR USE IN THE ROUTINE TREATMENT OF LUMINAL OBSTRUCTION OR RESIDUAL STENOSIS IN CORONARY ARTERIES

1920	IMP/MD/2019/000510	1.License Holder Name: TERUMO PENPOL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTION SET (TRIMA ACCEL 80400, 82400)-TRIMA ACCEL DISPOSABLE TUBING SETS ARE INTENDED FOR USE WITH THE TRIMA ACCEL AUTOMATED BLOOD COLLECTION SYSTEM.,BLOOD COLLECTION SET(TRIMA ACCEL 80300, 82300)-TRIMA ACCEL DISPOSABLE TUBING SETS ARE INTENDED FOR USE WITH THE TRIMA ACCEL AUTOMATED BLOOD COLLECTION SYSTEM.,BLOOD COLLECTION SET(TRIMA ACCEL 80406, 82406)-TRIMA ACCEL DISPOSABLE TUBING SETS ARE INTENDED FOR USE WITH THE TRIMA ACCEL AUTOMATED BLOOD COLLECTION SYSTEM.

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1921	IMP/MD/2019/000511	1.License Holder Name: ABBOTT HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) CATHETER(ARMADA 14 PTA CATHETER)-THE DEVICE IS INDICATED TO DILATE STENOSES IN FEMORAL, POPLITEAL, INFRA POPLITEAL AND RENAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THE 2.0 TO 4.0 MM BALLOON DIAMETERS ARE ALSO INDICATED FOR POST-DILATATION OF BALLOON-EXPANDABLE STENTS UP TO 40 MM AND SELF-EXPANDING STENTS UP TO 80 MM IN THE VESSELS LISTED ABOVE., DRUG ELUTING STENT(XIENCE ALPINE EVEROLIMUS ELUTING CORONARY STENT SYSTEM)-THE XIENCE ALPINE EVEROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN THE FOLLOWING: • PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO NATIVE CORONARY ARTERY LESIONS. • FOR RESTORING CORONARY FLOW IN PATIENTS EXPERIENCING ACUTE MYOCARDIAL INFARCTION WHO PRESENT WITHIN 12 HOURS OF SYMPTOM ONSET. • FOR THE TREATMENT OF PATIENTS WITH CONCOMITANT DIABETES, ACUTE CORONARY SYNDROME, DUAL VESSEL LESIONS (TWO LESIONS IN TWO DIFFERENT EPICARDIAL VESSELS), LESIONS RESIDING WITHIN SMALL CORONARY VESSELS; LESIONS WHERE TREATMENT RESULTS IN THE JAILING OF SIDE BRANCHES (LESIONS WITH A SIDE BRANCH LESS THAN 2 MM IN DIAMETER OR AN OSTIAL STENOSIS LESS THAN 50%); FOR THE TREATMENT OF ELDERLY PATIENTS (AGE GREATER THAN EQUAL TO 65), AND FOR TREATMENT OF BOTH MEN AND WOMEN. • FOR THE TREATMENT OF PATIENTS PRESENTING WITH IN-STENT RESTENOSIS IN CORONARY ARTERY LESIONS; CHRONIC TOTAL OCCLUDED CORONARY ARTERY LESIONS (DEFINED AS CORONARY ARTERY LESIONS WITH TIMI FLOW 0 AND LASTING LONGER THAN 3 MONTHS); AND CORONARY ARTERY BIFURCATION LESIONS. IN ALL CASES, THE TREATED LESION LENGTH SHOULD BE LESS THAN THE NOMINAL STENT LENGTH (8 MM, 12 MM, 15 MM, 18 MM, 23 MM, 28 MM, 33 MM, OR 38 MM) WITH A REFERENCE VESSEL DIAMETER OF GREATER THAN EQUAL TO 2.00 MM AND LESS THAN EQUAL TO 4.25 MM.,DRUG ELUTING STENT(XIENCE PRIME , XIENCE PRIME SV AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM)-THE XIENCE PRIME, XIENCE PRIME SV, AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEMS ARE INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN THE FOLLOWING: • PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO NATIVE CORONARY ARTERY LESIONS. • FOR RESTORING CORONARY FLOW

	IN PATIENTS EXPERIENCING ACUTE MYOCARDIAL INFARCTION WHO PRESENT WITHIN 12 HOURS OF SYMPTOM ONSET. • FOR THE TREATMENT OF PATIENTS WITH CONCOMITANT DIABETES, ACUTE CORONARY SYNDROME, DUAL VESSEL LESIONS (TWO LESIONS IN TWO DIFFERENT EPICARDIAL VESSELS), LESIONS RESIDING WITHIN SMALL CORONARY VESSELS; LESIONS WHERE TREATMENT RESULTS IN THE JAILING OF SIDE BRANCHES (LESIONS WITH A SIDE BRANCH 2 MM IN DIAMETER OR AN OSTIAL STENOSIS 50%); FOR THE TREATMENT OF ELDERLY PATIENTS (AGE 65), AND FOR TREATMENT OF BOTH MEN AND WOMEN. • FOR THE TREATMENT OF PATIENTS PRESENTING WITH IN-STENT RESTENOSIS IN CORONARY ARTERY LESIONS; CHRONIC TOTAL OCCLUDED CORONARY ARTERY LESIONS (DEFINED AS CORONARY ARTERY LESIONS WITH TIMI FLOW 0 AND LASTING LONGER THAN 3 MONTHS); AND CORONARY ARTERY BIFURCATION LESIONS. IN ALL CASES, THE TREATED LESION LENGTH SHOULD BE LESS THAN THE NOMINAL STENT LENGTH (8 MM, 12 MM, 15 MM, 18 MM, 23 MM, 28 MM, 33 MM, OR 38 MM) WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM AND 4.25 MM.,CORONARY STENT SYSTEM(GRAFTMASTER RX CORONARY STENT GRAFT SYSTEM)-GRAFTMASTER RX IS A BALLOON-EXPANDABLE PRE-MOUNTED CORONARY STENT GRAFT FOR INTRALUMINAL CHRONIC PLACEMENT IN CORONARY ARTERIES OR AORTO-CORONARY BYPASS GRAFTS FOR THE TREATMENT OF: •CORONARY ARTERY ANEURYSM •CORONARY BYPASS-VEIN GRAFT ANEURYSM •ACUTE CORONARY ARTERY PERFORATION •ACUTE CORONARY ARTERY RUPTURE PATIENTS BEING CONSIDERED FOR STENT GRAFT IMPLANTATION SHOULD BE ACCEPTABLE FOR CORONARY ARTERY BYPASS GRAFT SURGERY, AND / OR FOR CORONARY BALLOON ANGIOPLASTY WITH ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO OR RESTENOTIC NATIVE CORONARY LESIONS.,DRUG ELUTING STENT (XIENCE XPEDITION, XIENCE XPEDITION LL, XIENCE XPEDITION SV, XIENCE XPEDITION 48 AND XIENCE XPEDITION 2.0 EVEROLIMUS ELUTING CORONARY STENT SYSTEM)-THE XIENCE XPEDITION, XIENCE XPEDITION SV, AND XIENCE XPEDITION LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM ARE INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN THE FOLLOWING: • PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO NATIVE CORONARY ARTERY LESIONS. • FOR RESTORING CORONARY FLOW IN PATIENTS EXPERIENCING ACUTE MYOCARDIAL INFARCTION WHO PRESENT WITHIN 12 HOURS OF SYMPTOM ONSET. • FOR THE TREATMENT OF PATIENTS WITH CONCOMITANT DIABETES, ACUTE CORONARY SYNDROME, DUAL VESSEL LESIONS (TWO LESIONS IN TWO DIFFERENT EPICARDIAL VESSELS), LESIONS RESIDING WITHIN SMALL CORONARY VESSELS;

	LESIONS WHERE TREATMENT RESULTS IN THE JAILING OF SIDE BRANCHES (LESIONS WITH A SIDE BRANCH 2 MM IN DIAMETER OR AN OSTIAL STENOSIS 50%); FOR THE TREATMENT OF ELDERLY PATIENTS (AGE 65), AND FOR TREATMENT OF BOTH MEN AND WOMEN. • FOR THE TREATMENT OF PATIENTS PRESENTING WITH IN-STENT RESTENOSIS IN CORONARY ARTERY LESIONS; CHRONIC TOTAL OCCLUDED CORONARY ARTERY LESIONS (DEFINED AS CORONARY ARTERY LESIONS WITH TIMI FLOW 0 AND LASTING LONGER THAN 3 MONTHS); AND CORONARY ARTERY BIFURCATION LESIONS. IN ALL CASES, THE TREATED LESION LENGTH SHOULD BE LESS THAN THE NOMINAL STENT LENGTH (8 MM, 12 MM, 15 MM, 18 MM, 23 MM, 28 MM, 33 MM, OR 38 MM) WITH A REFERENCE VESSEL DIAMETER OF 2.00 MM AND 4.25 MM. THE XIENCE XPEDITION 48 EVEROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING 5 DRUG ELUTING STENT XIENCE XPEDITION, XIENCE XPEDITION LL, XIENCE XPEDITION SV, XIENCE XPEDITION 48 & XX 2.0 (EVEROLIMUS ELUTING CORONARY STENT SYSTEMS) NA NA CORONARY LUMINAL DIAMETER IN THE FOLLOWING: • PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO NATIVE CORONARY ARTERY LESIONS. • FOR RESTORING CORONARY FLOW IN PATIENTS EXPERIENCING ACUTE MYOCARDIAL INFARCTION WHO PRESENT WITHIN 12 HOURS OF SYMPTOM ONSET. • FOR THE TREATMENT OF PATIENTS WITH CONCOMITANT DIABETES, ACUTE CORONARY SYNDROME, DUAL VESSEL LESIONS (TWO LESIONS IN TWO DIFFERENT EPICARDIAL VESSELS), LESIONS RESIDING WITHIN SMALL CORONARY VESSELS; LESIONS WHERE TREATMENT RESULTS IN THE JAILING OF SIDE BRANCHES (LESIONS WITH A SIDE BRANCH 2 MM IN DIAMETER OR AN OSTIAL STENOSIS 50%); FOR THE TREATMENT OF ELDERLY PATIENTS (AGE 65), AND FOR TREATMENT OF BOTH MEN AND WOMEN. • FOR THE TREATMENT OF PATIENTS PRESENTING WITH IN-STENT RESTENOSIS IN CORONARY ARTERY LESIONS; CHRONIC TOTAL OCCLUDED CORONARY ARTERY LESIONS (DEFINED AS CORONARY ARTERY LESIONS WITH TIMI FLOW 0 AND LASTING LONGER THAN 3 MONTHS); AND CORONARY ARTERY BIFURCATION LESIONS. IN ALL CASES, THE TREATED LESION LENGTH SHOULD BE LESS THAN THE NOMINAL STENT LENGTH (48 MM) WITH A REFERENCE VESSEL DIAMETER OF 2.50 MM AND 3.75 MM.,PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) CATHETER(ARMADA 18 PTA CATHETER)-THE ARMADA 18 IS INDICATED TO DILATE STENOSIS IN FEMORAL, POPLITEAL, INFRA-POPLITEAL, TIBIAL, PERONEAL, AND RENAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. IN ADDITION, THE DEVICE IS ALSO INDICATED FOR POST-DILATATION

	OF BALLOON EXPANDABLE AND SELF-EXPANDING STENTS., VASCULAR CLOSURE SYSTEM(STARCLOSE SE)-STARCLOSE SE VASCULAR CLOSURE SYSTEM IS INDICATED FOR THE PERCUTANEOUS DELIVERY OF AN EXTRAVASCULAR CLIP FOR CLOSURE OF FEMORAL ARTERY ACCESS SITES FOLLOWING CATHETER-BASED PROCEDURES.,SUTURE-MEDIATED CLOSURE SYSTEM(PERCLOSE PROGLIDE)-THE PERCLOSE PROGLIDE SMC SYSTEM IS INDICATED FOR PERCUTANEOUS DELIVERY OF SUTURE FOR CLOSING THE COMMON FEMORAL ARTERY AND VEIN ACCESS SITE TO PATIENTS WHO HAVE UNDERGONE DIAGNOSTIC OR INTERVENTIONAL CATHETERIZATION PROCEDURES: • FOR ACCESS SITES IN THE COMMON FEMORAL ARTERY USING 5F TO 21F SHEATHS. FOR SHEATH SIZES GREATER THAN 8F, AT LEAST TWO DEVICES AND THE PRE-CLOSE TECHNIQUE REQUIRED. • FOR THE ACCESS SITES IN THE COMMON FEMORAL VEIN USING 5F TO 24F SHEATHS. FOR SHEATH SIZES GREATER THAN 8F, AT LEAST ONE DEVICE AND THE PRE-CLOSE TECHNIQUE IS REQUIRED.,CORONARY STENT SYSTEM (MULTI-LINK 8, MULTI-LINK 8 SV AND MULTI-LINK 8 LL)-MULTI-LINK 8, MULTI-LINK 8 SV, AND MULTI-LINK 8 LL CORONARY STENT SYSTEMS ARE INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN THE FOLLOWING: MULTI-LINK 8: PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO NATIVE CORONARY ARTERY LESIONS (LENGTH = 25 MM) WITH REFERENCE VESSEL DIAMETERS FROM 2.5 MM TO 4.0 MM. RESTORING CORONARY FLOW IN PATIENTS EXPERIENCING ACUTE MYOCARDIAL INFARCTION, WHO WITHIN 12 HOURS OF SYMPTOM ONSET PRESENT WITH NATIVE CORONARY ARTERY LESIONS (LENGTH = 25 MM) WITH REFERENCE VESSEL DIAMETERS FROM 2.5 MM TO 4.0 MM. PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO LESIONS IN SAPHENOUS VEIN BYPASS GRAFTS (LENGTH = 25 MM) WITH REFERENCE VESSEL DIAMETERS FROM 3.0 MM TO 4.0 MM. MULTI-LINK 8 SV: PATIENTS WITH ABRUPT OR THREATENED ABRUPT CLOSURE WITH FAILED INTERVENTIONAL THERAPY OF DE NOVO AND RESTENOTIC NATIVE CORONARY ARTERY LESIONS (LENGTH = 25 MM) WITH REFERENCE VESSEL DIAMETERS FROM 2.0 MM TO 2.5 MM. PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO NATIVE CORONARY ARTERY LESIONS (LENGTH = 25 MM) WITH REFERENCE VESSEL DIAMETERS FROM 2.25 MM TO 2.5 MM. MULTI-LINK 8 LL: PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO NATIVE CORONARY ARTERY LESIONS (LENGTH = 35 MM) WITH REFERENCE VESSEL DIAMETERS FROM 2.5 MM TO 4.0 MM. RESTORING CORONARY FLOW IN PATIENTS EXPERIENCING ACUTE MYOCARDIAL INFARCTION, WHO WITHIN 12 HOURS OF

	SYMPTOM ONSET PRESENT WITH NATIVE CORONARY ARTERY LESIONS (LENGTH = 35 MM) WITH REFERENCE VESSEL DIAMETERS FROM 2.5 MM TO 4.0 MM. PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO LESIONS IN SAPHENOUS VEIN BYPASS GRAFTS (LENGTH = 35 MM) WITH REFERENCE VESSEL DIAMETERS FROM 3.0 MM TO 4.0 MM.,PERIPHERAL STENT SYSTEM(OMNILINK ELITE PERIPHERAL STENT SYSTEM)-OMNILINK ELITE PERIPHERAL STENT SYSTEM IS INDICATED FOR THE TREATMENT OF DE NOVO OR RESTENOTIC ATHEROSCLEROTIC LESIONS IN PROTECTED PERIPHERAL ARTERIES AND PALLIATION OF MALIGNANT STRUCTURES IN THE BILIARY TREE.,DRUG ELUTING STENT(XIENCE V EVEROLIMUS ELUTING CORONARY STENT SYSTEM)-THE XIENCE V EVEROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN THE FOLLOWING: •• PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO NATIVE CORONARY ARTERY LESIONS. •• FOR RESTORING CORONARY FLOW IN PATIENTS EXPERIENCING ACUTE MYOCARDIAL INFARCTION WHO PRESENT WITHIN 12 HOURS OF SYMPTOM ONSET. •• FOR THE TREATMENT OF PATIENTS WITH CONCOMITANT DIABETES, ACUTE CORONARY SYNDROME, DUAL VESSEL LESIONS (TWO LESIONS IN TWO DIFFERENT EPICARDIAL VESSELS), LESIONS RESIDING WITHIN SMALL CORONARY VESSELS; LESIONS WHERE TREATMENT RESULTS IN THE JAILING OF SIDE BRANCHES (LESIONS WITH A SIDE BRANCH 2 MM IN DIAMETER OR AN OSTIAL STENOSIS 50%); FOR THE TREATMENT OF ELDERLY PATIENTS (AGE 65), AND FOR TREATMENT OF BOTH MEN AND WOMEN. •• FOR THE TREATMENT OF PATIENTS PRESENTING WITH IN-STENT RESTENOSIS IN CORONARY ARTERY LESIONS; CHRONIC TOTAL OCCLUDED CORONARY ARTERY LESIONS (DEFINED AS CORONARY ARTERY LESIONS WITH TIMI FLOW 0 AND LASTING LONGER THAN 3 MONTHS); AND CORONARY ARTERY BIFURCATION LESIONS. IN ALL CASES, THE TREATED LESION LENGTH SHOULD BE LESS THAN THE NOMINAL STENT LENGTH (8 MM, 12 MM, 15 MM, 18 MM, 23 MM, 28 MM) WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM AND 4.25 MM.

1922	IMP/MD/2019/000512	1.License Holder Name: M/S ASIA ACTUAL INDIA (OPC) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RAPICIDE PA HIGH LEVEL DISINFECTANT AND STERILANT(RAPICIDE PA HIGH LEVEL DISINFECTANT AND STERILANT)-RAPICIDE PA HIGH-LEVEL DISINFECTANT & STERILANT IS A CONCENTRATED HIGH-LEVEL DISINFECTING AND STERILIZING AGENT, WITH SPORICIDAL, TUBERCULOCIDAL, VIRUCIDAL AND BACTERICIDAL ACTIVITY WHEN USED IN A VALIDATION AUTOMATED REPROCESSING SYSTEM ONLY. FOR SPORICIDAL AND HIGH-LEVEL DISINFECTANT: CONTACT TIME 5 MINUTES AT ROOM TEMPERATURE (MINIMUM 20°C, MAY ALSO BE USED AT 30°C). FOR STERILIZATION: CONTACT TIME 10 MINUTES AT ROOM TEMPERATURE (MINIMUM 20°C, MAY ALSO BE USED AT 30°C)., RAPICIDE OPA/28 HIGH - LEVEL DISINFECTANT(RAPICIDE OPA/28)-RAPICIDE OPA/28 IS INTENDED TO BE USED AS A REUSABLE LIQUID DISINFECTANT SOLUTION FOR HIGH-LEVEL DISINFECTION OF ENDOSCOPES AND ACCESSORIES IN COMPATIBLE AUTOMATED ENDOSCOPE REPROCESSING SYSTEMS (AERS) AND FOR MANUAL DISINFECTION OF COMPATIBLE MEDICAL AND DENTAL DEVICES. RAPICIDE OPA/28 MUST BE USED IN MANUAL REPROCESSING OR IN COMPATIBLE AERS AT OR ABOVE ITS MINIMUM RECOMMENDED CONCENTRATION (MRC) OF 0.35% OPA WITH A CONTACT TIME OF AT LEAST 5 MINUTES AT A MINIMUM OF 20°C FOR A REUSE PERIOD NOT TO EXCEED 28 DAYS.

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1923	IMP/MD/2019/000513	1.License Holder Name: VENUS SURGICALS AGENCIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISINFECTANT (RELIANCE® HLD HIGH LEVEL DISINFECTANT)-RELIANCE HLD (DRY CHEMISTRY) IS A SINGLE-USE, HIGH LEVEL DISINFECTANT FOR USE ONLY IN THE RELIANCE® EPS PROCESSOR. IT PROVIDES HIGH LEVEL DISINFECTION OF PRE-CLEANED, IMMERSIBLE, REUSABLE, HEAT-SENSITIVE, SEMI-CRITICAL DEVICES SUCH AS GI FLEXIBLE ENDOSCOPES, BRONCHOSCOPES, AND THEIR ACCESSORIES. HIGH LEVEL DISINFECTION IS ACHIEVED WITHIN THE 50-57°C HLD PHASE OF THE ENDOSCOPE PROCESSING CYCLE (4-MINUTE GENERATION SEQUENCE FOLLOWED BY A 6-MINUTE EXPOSURE SEQUENCE)., DISINFECTANT(VAPROX® HC STERILANT)-VAPROX HC STERILANT IS USED EXCLUSIVELY IN THE V-PRO LOW TEMPERATURE STERILIZATION SYSTEMS FOR TERMINAL STERILIZATION OF CLEANED RINSED AND DRIED REUSABLE METAL AND NON-METAL MEDICAL DEVICES USED IN HEALTHCARE FACILITIES.,DISINFECTANT (S40® STERILANT CONCENTRATE)-S40 STERILANT CONCENTRATE IS A SINGLE-USE CHEMISTRY FOR USE ONLY WITH THE SYSTEM 1® EXPRESS AND SYSTEM 1® PLUS STERILE PROCESSING SYSTEMS TO STERILIZE PRE-CLEANED IMMERSIBLE, REUSABLE, SEMI-CRITICAL AND CRITICAL MEDICAL DEVICES, INCLUDING ENDOSCOPES AND THEIR ACCESSORIES IN HOSPITALS AND MEDICAL/SURGICAL CLINICS AND OFFICES. THE S40 STERILANT CONCENTRATE CONTAINER HOLDS BOTH A LIQUID ACTIVE INGREDIENT (35% PERACETIC ACID) AND POWDERED INERT INGREDIENTS. S40 STERILANT CONCENTRATE IS SPORICIDAL, FUNGICIDAL, BACTERICIDAL, VIRICIDAL & TUBERCULOCIDAL.,DISINFECTANT (VAPROX® HC STERILANT)-VAPROX HC STERILANT IS USED EXCLUSIVELY IN THE V-PRO LOW TEMPERATURE STERILIZATION SYSTEMS FOR TERMINAL STERILIZATION OF CLEANED RINSED AND DRIED REUSABLE METAL AND NON-METAL MEDICAL DEVICES USED IN HEALTHCARE FACILITIES.

1924	IMP/MD/2019/000514	1.License Holder Name: NIPRO MEDICAL (INDIA) PRIVATE LIMITED , 2ND FLOOR, GMR AERO TOWER, NEAR RAJIV GANDHI AIRPORT, MAMIDIPALLY VILLAGE, BALAPUR MANDAL, RANGA REDDY DIST, MAMIDPALLY(V), BALAPUR(M), RANGA REDDY(DIST.) ,RANGA REDDY TELANGANA ,501218 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AMBULATORY BALLOON INFUSER(SUREFUSER+)-THIS DEVICE TO BE USED FOR CONTINUOUS DRUG INFUSION THERAPY: POST OPERATIVE PAIN CONTROL, CARCINOMATOUS PAIN CONTROL, CHEMOTHERAPY FOR CANCER ETC.,IV CONNECTOR(SAFETOUCH PLUG)-THIS DEVICE IS CONNECTED TO AN INFUSION SET, AN EXTENSION TUBE, A SYRINGE AND AN IV CATHETER (HEREINAFTER SIMPLY REFERRED TO AS AN INFUSION SET), AND IS USED AS AN INJECTION SITE FOR MIXED MEDICATIONS.

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1925	IMP/MD/2019/000516	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FRACTURE MANAGEMENT SYSTEM(KYPHO PAK TRAYS (I & II))-THE KYPHO PAK TRAYS ARE CONVENIENCE KITS USED IN BONE FRACTURE REDUCTION, THE INDICATIONS FOR THE USE OF THE TRAYS COMPONENTS ARE PROVIDED IN THEIR CORRESPONDING INSTRUCTION FOR USE, WHICH ACCOMPANY THE TRAYS,FRACTURE MANAGEMENT SYSTEM (KYPHON OSTEO INTRODUCER SYSTEM (ELEMENT & XPANDER))-THE KYPHON OSTEO INTRODUCER SYSTEM IS INTENDED ONLY FOR PERCUTANEOUS ACCESS TO BONE, INCLUDING USE DURING A BALLOON KYPHOPLASTY PROCEDURE.,FRACTURE MANAGEMENT SYSTEM(KYPHON BONE FILLER DEVICE (ELEMENT & XPANDER))-THE KYPHON BONE FILLER DEVICE IS INTENDED FOR THE DELIVERY OF BONE CEMENT, INCLUDING USE DURING A BALLOON KYPHOPLASTY PROCEDURE.,FRACTURE MANAGEMENT SYSTEM(KYPHON INFLATABLE BONE TAMP (ELEMENT & XPANDER))-THE KYPHON INFLATABLE BONE TAMP (IBT) IS INTENDED TO BE USED AS A CONVENTIONAL BONE TAMP FOR THE REDUCTION OF FRACTURES AND/OR CREATION OF A VOID IN CANCELLOUS BONE IN THE SPINE (INCLUDING USE DURING A BALLOON KYPHOPLASTY PROCEDURE WITH A PMMA-BASED BONE CEMENT THAT IS CLEARED FOR USE IN KYPHOPLASTY PROCEDURES), HAND, TIBIA, RADIUS, AND CALCANEUS.,FRACTURE MANAGEMENT SYSTEM(KYPHON BONE BIOPSY DEVICE AND KIT)-THE KYPHON BONE BIOPSY DEVICE IS INTENDED FOR OBTAINING A BONE BIOPSY SPECIMEN, INCLUDING USE DURING A BALLOON KYPHOPLASTY PROCEDURE. THE KYPHON BONE BIOPSY DEVICE (BBD) IS ALSO INTENDED FOR THE DELIVERY OF BONE CEMENT, INCLUDING USE DURING A BALLOON KYPHOPLASTY PROCEDURE. THE KYPHON BONE BIOPSY KIT CONTAINS THE KYPHON OSTEO INTRODUCER SYSTEM, THE KYPHON 11 GAUGE BONE ACCESS NEEDLE AND THE KYPHON BONE BIOPSY DEVICE.
1926	IMP/MD/2019/000517	1.License Holder Name: GETINGE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PICCO CATHETER-PICCO CATHETERS ARE USED AS ACCESSORIES FOR THERMODILUTION AND ARTERIAL BLOOD PRESSURE MEASUREMENT

1927	IMP/MD/2019/000518	1.License Holder Name: WAYINIA LIFESCIENCES OPC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD TUBING SET (AQUADEX FLEXFLOW SYSTEM)-FOR USE WITH THE AQUADEX FLEXFLOW SYSTEM. THE AQUADEX FLEXFLOW SYSTEM IS INDICATED FOR TEMPORARY (UPTO8HOURS) ULTRA FILTRATION TREATMENT OF PATIENTS WITH FLUID OVERLOAD WHO HAVE FAILED DIURETIC THERAPY, AND EXTENDED (LONGER THAN 8 HOURS) ULTRA FILTRATION TREATMENT OF PATIENTS WITH FLUID OVERLOAD WHO HAVE FAILED DIURETIC THERAPY AND REQUIRE HOSPITALIZATION. ALL TREATMENTS MUST BE ADMINISTERED BY A HEALTHCARE PROVIDER, UNDER PHYSICIAN PRESCRIPTION, BOTH OF WHOM HAVING RECEIVED TRAINING IN EXTRA CORPOREAL THERAPIES.
1928	IMP/MD/2019/000520	1.License Holder Name: ELEKTA MEDICAL SYSTEMS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEEDLE(LEADER INSERT NEEDLE)-THE LEADER INSERTION NEEDLE IS USED BEFORE INSERTING A PROGUIDE ROUND NEEDLE TO CREATE A PATH THROUGH THE TISSUE,CATHETER(X-RAY CATHETER SET GYN (SS) FOR FLEXITRON/ X-RAY CATHETER SET CT/MR GYN FOR FLEXITRON) -THE X-RAY CATHETER SETS GYN ARE AN AID USING X-RAY OR CT IMAGING INTENDED FOR VERIFICATION AND TREATMENT PLANNING OF SOURCE POSITIONING FOR NUCLETRON GYNECOLOGICAL APPLICATORS. THE X-RAY CATHETER SETS GYN ARE INTENDED TO BE USED WITH THE FLEXITRON AFTERLOADER DEVICE (TDU),NEEDLE (PROGUIDE NEEDLE SET (ROUND AND SHARP))-THE PROGUIDE NEEDLE SET INTENDED USE IS INTERSTITIAL TREATMENT, E.G. FOR BREAST, PROSTATE, VAGINA, RECTUM. THE DEVICE IS INTENDED TO BE USED WITH THE FOLLOWING NUCLETRON AFTERLOADERS: • MICROSELECTRON-HDR / PDR DIGITAL, V3 AND V2 • FLEXITRON , NEEDLE(INTERSTITIAL NEEDLE SET (TROCAR NEEDLES))-THE NEEDLE IS DESIGNED FOR INTERSTITIAL TREATMENT, IE PROSTATE, RECTUM. THE DEVICE IS INTENDED TO BE USED WITH THE FOLLOWING NUCLETRON AFTERLOADERS: • MICROSELECTRON-HDR/PDR DIGITAL, V3 AND V2 • FLEXITRON ,CATHETER(X-RAY CATHETER SET)-THE X-RAY CATHETER SETS ARE AN AID USING X-RAY OR CT IMAGING INTENDED FOR VERIFICATION AND TREATMENT PLANNING OF SOURCE POSITIONING FOR NUCLETRON APPLICATORS

1929	IMP/MD/2019/000521	1.License Holder Name: VASCULAR CONCEPTS LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA CATHETERS (NON-STERILE)(SPEED - PTCA CATHETERS (NON-STERILE))-THE SPEED CATHETERS ARE INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,SIROLIMUS ELUTING STENT SYSTEM- STAINLESS STEEL (NON-STERILE)(PRONOVA SS - SIROLIMUS ELUTING STENT SYSTEM- STAINLESS STEEL (NON-STERILE))-THE PRONOVA SS CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.5MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT.,DRUG ELUTING STENT (NON-STERILE)(SIROLIMUS ELUTING CORONARY STENT (COBALT CHROMIUM WITH POLYSULFONE POLYMER) - NON-STERILE)-THE PRONOVA CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT.,BALLOON EXPANDABLE PERIPHERAL STENT (NON-STERILE)(PROSTAR - BALLOON EXPANDABLE PERIPHERAL STENT (NON-STERILE))-INTENDED FOR USE IN ATHEROSCLEROTIC DE NOVO LESIONS, RE-STENOTIC LESIONS OF THE PERIPHERAL ARTERIES, SUCH AS THE RENAL ARTERY OR SUBCLAVIAN ARTERY.,BALLOON EXPANDABLE CORONARY STENT SYSTEM - COBALT CHROMIUM (NON-STERILE)(PROZETA - BALLOON EXPANDABLE CORONARY STENT SYSTEM - COBALT CHROMIUM (NON-STERILE))-THE PROZETA CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO CORONARY ARTERY LESIONS WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED FOR TREATMENT OF CORONARY ARTERIES.,DRUG ELUTING STENT (NON-STERILE)(SIROLIMUS ELUTING CORONARY STENT (COBALT CHROMIUM WITH 85/15 DL-LACTIDE/GLYCOLIDE POLYMER) - NON-STERILE)-THE PRONOVA XR CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC

	HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.5MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT)AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT.,CORONARY STENT (NON-STERILE)(PROLINK -CORONARY STENT (NON-STERILE))-BALLOON EXPANDABLE COVERED STENT IS INDICATED TO COVER THE DISSECTION (TEAR) CAUSED WHEN A PTCA BALLOON OR STENT IS DEPLOYED IN A LESION. COVERED STENTS ARE USED TO CLOSE RUPTURED ARTERIES, PERFORATED ARTERIES AND TO CLOSE ANEURYSMS., SIROLIMUS ELUTING STENT SYSTEM -COBALT CHROMIUM DEGRADABLE MATRIX (NON-STERILE)(PRONOVA XR - SIROLIMUS ELUTING STENT SYSTEM -COBALT CHROMIUM DEGRADABLE MATRIX (NON-STERILE))-THE PRONOVA XR CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.5MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT)AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT. ,CORONARY STENT SYSTEM- STAINLESS STEEL BALLOON EXPANDABLE (NON -STERILE)(PROLINK LP - CORONARY STENT SYSTEM- STAINLESS STEEL BALLOON EXPANDABLE (NON - STERILE))-THE PROLINK LP CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE CORONARY DE NOVO ARTERY LESIONS WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0MM TO 4.5MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT.,SIROLIMUS ELUTING STENT SYSTEM (COBALT CHROMIUM) - (NON-STERILE)(PRONOVA - SIROLIMUS ELUTING STENT SYSTEM (COBALT CHROMIUM) - (NON-STERILE))-THE PRONOVA CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER). LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT.,DRUG ELUTING STENT (NON-STERILE)(SIROLIMUS ELUTING CORONARY STENT (STAINLESS STEEL WITH POLYSULFONE POLYMER) - NON-STERILE)-THE PRONOVA SS CORONARY STENT

		SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.5MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5 MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT.
1930	IMP/MD/2019/000523	1.License Holder Name: ALLWIN LIFECARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:A.V. FISTULA NEEDLE SET (JMS)-IT IS INDICATED FOR HEMODIALYSIS, HEMOFILTRATION AND HEMODIAFILTRATION. A.V. FISTULA NEEDLES ARE INDICATED FOR USE IN CONJUNCTION WITH OTHER PROCEDURES REQUIRING ACCESS TO THE BLOOD STREAM. ,SCALP VEIN INFUSION SET(JMS)-IT IS INTRODUCED INTO THE PERIPHERAL VENOUS ACCESS FOR SHORT TERM INFUSION, INJECTIONS AND ADMINISTRATION OF DRUG, BLOOD SAMPLING AND TRANSFUSION VIA INTRAVENOUS ROUTE. , HEMODIALYSIS BLOOD TUBING SET(JMS)-IT IS INTENDED TO PROVIDE EXTRACORPOREAL ACCESS TO THE PATIENT'S BLOOD DURING HEMODIALYSIS.
1931	IMP/MD/2019/000524	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SODIUM BICARBONATE CARTRIDGE FOR HAEMODIALYSIS(SOL-CART B)-TO PRODUCE AN ALKALINE BICARBONATE HEMODIALYSIS CONCENTRATE FOR EXTRACORPOREAL BICARBONATE HEMODIALYSIS OR BICARBONATE HEMODIAFILTRATION. THE INDICATIONS BELOW APPLY EXCLUSIVELY TO THE READY-TO-USE HEMODIALYSIS SOLUTION PREPARED FROM ALKALINE AND ACIDIC BICARBONATE HEMODIALYSIS CONCENTRATES DILUTED AS DIRECTED: • ACUTE RENAL FAILURE • CHRONIC RENAL FAILURE • HYPERHYDRATION • INTOXICATIONS • COMPENSATION OF THE ACID-BASE AND ELECTROLYTE BALANCES • ADJUSTMENT OF THE BLOOD / PLASMA / BODY TEMPERATURE

1932	IMP/MD/2019/000525	1.License Holder Name: LEADER BIOMEDICAL AND SURGICALS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACRYLIC ORTHOPAEDIC CEMENT WITH GENTAMICIN(GENTA C-MENT)-FIXING OF SURGICAL IMPLANTS INTO THE BONE DURING ORTHOPAEDIC SURGERY., ACRYLIC ORTHOPAEDIC CEMENT FOR VERTEBROPLASTY (VEBROPLAST®)-VEBROPLAST® IS A CEMENT SPECIFICALLY DEVELOPED FOR STABILIZATION OF VERTEBRAL BODIES IN PERCUTANEOUS VERTEBROPLASTY PROCEDURES IN ORDER TO RELIEVE PAIN. VEBROPLAST® IS NOT CERTIFIED FOR OTHER INDICATIONS THAN PERCUTANEOUS VERTEBROPLASTY. THE APPLICATION IN ANOTHER INDICATION (E.G. ENDOPROTHESIS) HAS NOT BEEN INVESTIGATED. ,ACRYLIC ORTHOPAEDIC CEMENT(C-MENT) -FIXING OF SURGICAL IMPLANTS INTO THE BONE DURING ORTHOPAEDIC SURGERY.
1933	IMP/MD/2019/000526	1.License Holder Name: SURGIPLUS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SINGLE USE SKIN STAPLER(ACOS SKIN STAPLER)-IT HAS THE APPLICATION IN ABDOMINAL, GYNECOLOGICAL ORTHOPEDIC AND THORACIC SURGERY FOR SKIN CLOSURE. ALSO IT COULD BE USED FOR VARIETY SKIN CLOSURE.

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1934	IMP/MD/2019/000527	1.License Holder Name: JINDAL ENTERPRISES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMODIALYSIS CATHETER KIT/SET(ABLECATH-HEMODIALYSIS CATHETER KIT/SET)-THE ABLE HAEMODIALYSIS CATHETERS MAY BE APPLICABLE TO THE ONE OF FOLLOWING THERAPY: - TO SUPPLY THE TEMPORARY BLOOD VESSEL ACCESS IN HAEMODIALYSIS TREATMENT; MONITOR OF CENTRAL VENOUS PRESSURE. -CONTINUOUS OR DISCONTINUOUS VENOUS TRANSFUSION ; THE CATHETER IS SURGICALLY PENETRATED INTO THREE OPTIONAL PUNCTURE POINTS DEPENDED ON THE CLINICAL REQUIREMENT WITH SELDINGER TECHNIQUE . THE INSERTION SITES ARE: 1. INTERNAL JUGULAR VEIN; 2.SUBCLAVIAN VEIN 3. FEMORAL VEIN IT IS POSSIBLE TO BE INSERTED INSIDE THE BODY FOR LESS THAN 30 DAYS .IF DURATION EXCEEDS 30 DAYS. IT MAY OCCUR THE RISK OF COMBINING THE CATHETER AND INSIDE TISSUE, WHICH RESULT IN SERIOUS INCIDENT.,CENTRAL VENOUS CATHETER KIT/SET(ABLECATH-CENTRAL VENOUS CATHETER KIT/SET)-THE ABLE CENTRAL VENOUS CATHETERS KIT/SET MAY BE APPLICABLE TO THE ONE OF FOLLOWING THERAPY: - MONITOR OF CENTRAL VENOUS PRESSURE. -CONTINUOUS OR DISCONTINUOUS VENOUS TRANSFUSION ; -BLOOD SAMPLING. THE CATHETER IS SURGICALLY PENETRATED INTO THREE OPTIONAL PUNCTURE POINTS DEPENDED ON THE CLINICAL REQUIREMENT WITH SELDINGER TECHNIQUE . THE INSERTION SITES ARE: 1. INTERNAL JUGULAR VEIN; 2.SUBCLAVIAN VEIN 3. FEMORAL VEIN IT IS POSSIBLE TO BE INSERTED INSIDE THE BODY FOR LESS THAN 30 DAYS .IF DURATION EXCEEDS 30 DAYS. IT MAY OCCUR THE RISK OF COMBINING THE CATHETER AND INSIDE TISSUE, WHICH RESULT IN SERIOUS INCIDENT.
1935	IMP/MD/2019/000528	1.License Holder Name: M/S. PEERLESS BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VENOUS BLOOD COLLECTION NEEDLE(XLPI (FLASHBACK NEEDLE) AND XLPII (MULTI-SAMPLE NEEDLE))-IT IS USED FOR VENOUS BLOOD SPECIMEN COLLECTION

1936	IMP/MD/2019/000529	1.License Holder Name: IMV INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SET TDT(SET TDT)-EMBRYO TRANSFER,PEARL TIP CLASSIC(PEARL TIP CLASSIC, PEARL TIP SOFT 1323961)-EMBRYO TRANSFER,FRYDMAN CLASSIC 4.5 (FRYDMAN CLASSIC 4.5)-EMBRYO TRANSFER,FRYDMANSOFT WITH GUIDE(FRYDMANSOFT WITH GUIDE)-EMBRYO TRANSFER,SAMPLER FOR ENDOMETRIAL BIOPSY OR SAMPLER FOR ENDOMETRIAL CYTOLOGY AND HISTOLOGY(PIPELLE AND PIPELLE MARK II)-ENDOMETRIUM HISTOLOGICAL SAMPLING,FULL ECHO PRO(FULL ECHO PRO)-EMBRYO TRANSFER
1937	IMP/MD/2019/000530	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RADIO-FREQUENCY ABLATION SYSTEM(RFG-4 RADIOFREQUENCY GENERATOR)-THE COSMAN G4 RADIOFREQUENCY GENERATOR IS INDICATED FOR USE IN PROCEDURES TO CREATE RADIOFREQUENCY LESIONS FOR THE TREATMENT OF PAIN, OR FOR LESIONING NERVE TISSUE FOR FUNCTIONAL NEUROSURGICAL PROCEDURES. THE COSMAN G4 RADIOFREQUENCY GENERATOR IS USED WITH SEPARATELY APPROVED COSMAN RADIOFREQUENCY PROBES.

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1938	IMP/MD/2019/000531	1.License Holder Name: ADVANTIST MEDICAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER (COVERED/ NON-COVERED)(HANAROSTENT DUODENUM/PYLORUS STENT)-THIS STENT IS USED FOR APPLICATION IN PALLIATIVE TREATMENT OF PYLORIC OR DUODENAL STRICTURE CAUSED BY MALIGNANT TUMORS.,CATHETER (COVERED)(HANAROSTENT ESOPHAGUS STENT) -THIS STENT IS INDICATED FOR APPLICATION IN PALLIATIVE TREATMENT OF ESOPHAGEAL STRICTURE AND/OR TRACHEA-ESOPHAGEAL FISTULA CAUSED BY MALIGNANT TUMORS.,CATHETER (COVERED)(HANAROSTENT TRACHEA/BRONCHIUM STENT)-THIS STENT IS INDICATED FOR APPLICATION IN PALLIATIVE TREATMENT OF TRACHEO/BRONCHIAL STRICTURE AND/OR TRACHEA-ESOPHAGEAL FISTULA CAUSED BY MALIGNANT TUMORS.,CATHETER (COVERED/ NON-COVERED)(HANAROSTENT COLON/ RECTUM STENT)-THIS STENT IS INDICATED FOR APPLICATION IN PALLIATIVE TREATMENT OF COLO-RECTAL STRICTURES CAUSED BY MALIGNANT TUMORS.,CATHETER (BENIGN)(HANAROSTENT BILIARY STENT)-THIS STENT IS INDICATED FOR APPLICATION IN PALLIATIVE TREATMENT OF BILE DUCT MALIGNANT AND/OR BENIGN STRICTURES.,CATHETER (COVERED/ NON-COVERED)(HANAROSTENT BILIARY STENT)-THIS STENT IS INDICATED FOR APPLICATION IN PALLIATIVE TREATMENT OF BILE DUCT STRICTURE CAUSED BY MALIGNANT TUMORS.
1939	IMP/MD/2019/000532	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRANSFER CAP FOR STERILE FLUIDS(ECOFLAC MIX)-TRANSFER CAP FOR STERILE FLUIDS, STOPCOCKS SYSTEM(DISCOFIX C/ DISCOFIX)-IT IS INTENDED FOR MULTIDIRECTIONAL STOPCOCKS FOR INFUSION THERAPY AND MONITORING.

1940	IMP/MD/2019/000533	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD TRANSFER DEVICE(BD VACUTAINER® BLOOD TRANSFER DEVICE)-IT IS DESIGNED TO PROVIDE SAFE AND CONVENIENT TRANSFER OF BLOOD SAMPLES DRAWN FROM A SYRINGE INTO AN EVACUATED BD VACUTAINER BLOOD COLLECTION TUBE OR BACTEC BLOOD CULTURE BOTTLE. ,LUER-LOK ACCESS DEVICE(BD VACUTAINER® LUER-LOK™ ACCESS DEVICE)-IT IS DESIGNED TO PROVIDE SAFE AND SECURE CONNECTION OF THE DEVICE TO A CATHETER PORT EQUIPPED WITH A THREADED FEMALE LUER DURING BLOOD OR URINE SAMPLE COLLECTION USING EVACUATED BD VACUTAINER BLOOD COLLECTION OR URINE COLLECTION TUBES.
1941	IMP/MD/2019/000534	1.License Holder Name: M/S LINVATEC INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUTURES(HI-FI ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE NON-ABSORBABLE SURGICAL SUTURES)-NON-ABSORBABLE SURGICAL SUTURES ARE INDICATED FOR USE IN APPROXIMATION AND/OR LIGATION OF SOFT TISSUES, INCLUDING USE OF ALLOGRAFT TISSUE FOR ORTHOPEDIC SURGERIES.

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1942	IMP/MD/2019/000535	1.License Holder Name: SHAH DISTRIBUTORS ,965,14TH CROSS,16TH MAIN,BSK,2ND STAGE,BANGALORE 560070, KARNATAKA, INDIA , BENGALURU (BANGALORE) URBAN KARNATAKA ,560070 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRAOCULAR GAS (OCTAFLUOROPROPANE)(MICRO C3F8)-INTENDED TO REPLACE THE VITREOUS HUMOR IN THE INTERVENTIONS OF VITRECTOMY, WITH MEDIUM RESIDENCE TIMES IN THE EYE, GENERALLY NO MORE THAN 28 DAYS.,SOFT LIQUID PERFLUOROOCTANE(PFCL SOFT)-INTENDED TO WASH THE VITREOUS CHAMBER DURING INTERVENTION OF OPHTHALMIC SURGERY, WITH RESIDENCE TIME IN THE EYE OF MAX ONE HOURS. IT IS USED BY AN OPHTHALMIC SURGEON.,SILICONE OIL (POLYDIMETHYLSILOXANE)(PDMS)-INTENDED TO REPLACE THE VITREOUS HUMOR IN THE INTERVENTIONS OF VITRECTOMY, WITH LONG RESIDENCE TIMES IN TH GREATER THAN 30 DAYS.,SILICONE RUBBER STRIPES(SILIBEND)-THE SILIBEND ARE SILICONE RUBBER STRIPES IN DIFFERENT SHAPES USED FOR THE SURGICAL TREATMENT OF RETINAL DETACHMENT. SILIBEND ARE AVAILABLE EITHER OPEN SHAPE AS “STRIPE” OR CLOSED SHAPE AS “TYRE”., INTRAOCULAR GAS SF6 (SULPHUR HEXA FLUORIDE)(MICRO SF6)-INTENDED TO REPLACE THE VITREOUS HUMOR IN THE INTERVENTIONS OF VITRECTOMY, WITH MEDIUM RESIDENCE TIMES IN THE EYE, GENERALLY NO MORE THAN 7 DAYS. IT IS USED BY THE SURGEON.

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1943	IMP/MD/2019/000537	1.License Holder Name: SUNRISE IMAGING SYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FLOW MODULATION DEVICE(P64)-THE P64 FLOW MODULATION DEVICE IS A SELF-EXPANDING, TUBULAR VASCULAR IMPLANT AND ALLOWS THE CONTROLLED AND SELECTIVE MODULATION OF BLOOD FLOW IN EXTRA- AND INTRACRANIAL ARTERIES. IN ADDITION, THE PHYSICAL PROPERTIES OF THE P64 STRAIGHTEN THE TARGET VESSEL SLIGHTLY AND STRENGTHEN IT. THESE PROPERTIES AID THE ENDOVASCULAR RECONSTRUCTION OF DISEASED ARTERIES ALONG THEIR CERVICAL AND INTRACRANIAL COURSE. INDICATIONS: THE P64 FLOW MODULATION DEVICE IS A SELF-EXPANDING, TUBULAR IMPLANT AND IS USED IN THE ENDOVASCULAR TREATMENT OF VASCULAR DISEASES SUCH AS - SACCULAR AND FUSIFORM ANEURYSMS AND PSEUDOANEURYSMS - VASCULAR DISSECTIONS IN THE ACUTE AND CHRONIC PHASES - VASCULAR PERFORATIONS AND AV FISTULAE,FLOW MODULATION DEVICE(PFMD)-THE P64 MW (HPC) FLOW MODULATION DEVICE IS A SELF-EXPANDING, TUBULAR VASCULAR IMPLANT AND ALLOWS THE CONTROLLED AND SELECTIVE MODULATION OF BLOOD FLOW IN EXTRA- AND INTRACRANIAL ARTERIES. IN ADDITION, THE PHYSICAL PROPERTIES OF THE P64 MW (HPC) STRAIGHTEN THE TARGET VESSEL SLIGHTLY AND REINFORCE IT. THESE PROPERTIES AID THE ENDOVASCULAR RECONSTRUCTION OF DISEASED ARTERIES ALONG THEIR CERVICAL AND INTRACRANIAL COURSE. INDICATIONS: THE P64 MW (HPC) FLOW MODULATION DEVICE IS A SELF-EXPANDING, TUBULAR IMPLANT AND IS USED IN THE ENDOVASCULAR TREATMENT OF VASCULAR DISEASES SUCH AS - SACCULAR AND FUSIFORM ANEURYSMS AND PSEUDOANEURYSMS, - VASCULAR DISSECTIONS IN THE ACUTE AND CHRONIC PHASES AND - VASCULAR PERFORATIONS AND AV FISTULAE.,FLOW MODULATION DEVICE(P48 MW)-THE P48 MW (HPC) FLOW MODULATION DEVICE IS A SELF-EXPANDING, TUBULAR VASCULAR IMPLANT AND ALLOWS THE CONTROLLED AND SELECTIVE MODULATION OF BLOOD FLOW IN EXTRA- AND INTRACRANIAL ARTERIES. IN ADDITION, THE PHYSICAL PROPERTIES OF THE P48 MW STRAIGHTEN THE TARGET VESSEL SLIGHTLY AND REINFORCE IT. THESE PROPERTIES AID THE ENDOVASCULAR RECONSTRUCTION OF DISEASED ARTERIES ALONG THEIR CERVICAL AND INTRACRANIAL COURSE. INDICATIONS: THE P48 MW (HPC) FLOW MODULATION DEVICE IS A SELF-EXPANDING, TUBULAR IMPLANT AND IS USED IN THE ENDOVASCULAR TREATMENT OF VASCULAR DISEASES SUCH AS - SACCULAR AND FUSIFORM ANEURYSMS AND PSEUDOANEURYSMS, - VASCULAR DISSECTIONS IN THE ACUTE AND CHRONIC PHASES AND - VASCULAR PERFORATIONS AND AV

	FISTULAE.,MICROCATHETER(PNOVUS)-THE INTENDED USE OF PNOVUS 21 IS TO SUPPORT THE STABLE ACCESS OF SUITABLE THERAPEUTIC OR DIAGNOSTIC DEVICES, I.E. DEVICES COMPATIBLE WITH THE INNER DIAMETER OF THE MICROCATHETER, AND THE INFUSION OF THERAPEUTIC AND DIAGNOSTIC AGENTS. THE MICROCATHETER IS COMMONLY INSERTED PERCUTANEOUSLY INTO THE FEMORAL ARTERY THROUGH A SHEATH OR GUIDECATHETER. IF TRANSVENOUS ACCESS IS DESIRED, A SHEATH IS INTRODUCED INTO A SUITABLE VENOUS ACCESS SITE (SUCH AS THE FEMORAL VEIN). TIME FOR USE IS TRANSIENT. THEREFORE, THE DEVICE IS NORMALLY INTENDED FOR CONTINUOUS USE OF LESS THAN 60 MINUTES. THE MICROCATHETER CAN ALSO BE USED TO GUIDE A CATHETER WITH LARGER INNER DIAMETER.,THROMBECTOMY DEVICE(PRESET)-THE INTENDED PURPOSE OF PRESET THROMBECTOMY DEVICES IS ACUTE TREATMENT OF ISCHEMIC STROKE BY REMOVAL OF THROMBI FROM INTRACRANIAL VESSELS E.G., THE INTERNAL CAROTID ARTERY, MIDDLE CEREBRAL ARTERY, OR BASILAR ARTERY OR FROM VESSELS SITUATED DISTALLY OF THEM, WITH A TEMPORARY CONTACT DURATION LESS THAN 60 MINUTES. INDICATIONS: THE PRESET THROMBECTOMY DEVICE IS DESIGNED FOR MECHANICAL CLOT RETRIEVAL FROM INTRACRANIAL ARTERIES AS ACUTE ISCHEMIC STROKE TREATMENT FOR PATIENTS WHO ARE INELIGIBLE FOR INTRAVENOUS THROMBOLYSIS OR FOR PATIENTS WHO FAILED THROMBOLYSIS THERAPY AND AS A SUPPLEMENT TREATMENT OF AN INITIATED THROMBOLYSIS THERAPY.,BIFURCATION ANEURYSM IMPLANT(PCONUS)-THE PCONUS BIFURCATION ANEURYSM IMPLANT IS A SELF-EXPANDING, TUBULAR VASCULAR IMPLANT FOR SUPPORTING THE COIL OCCLUSION OF WIDE-NECK INTRACRANIAL BIFURCATION ANEURYSMS. INDICATIONS: THE PCONUS BIFURCATION ANEURYSM IMPLANT IS USED TO SUPPORT THE ENDOVASCULAR COIL OCCLUSION OF WIDE-NECKED BIFURCATION ANEURYSMS IN INTRACRANIAL ARTERIES. TYPICAL LOCATIONS FOR SUCH ANEURYSMS ARE THE BIFURCATION OF THE INTERNAL CAROTID ARTERY, THE ANTERIOR COMMUNICATING ARTERY, THE MIDDLE CEREBRAL ARTERY AND THE BIFURCATION OF THE BASILAR ARTERY. HOWEVER, IN PRINCIPLE, EVERY WIDE-NECKED ANEURYSM IN THE BIFURCATION OF A VESSEL CAN BE SUITABLE. DEPENDING ON THE CLINICAL CIRCUMSTANCES AND THE VASCULAR ANATOMY, BOTH UNRUPTURED AND RUPTURED ANEURYSMS CAN BE TREATED WITH THIS IMPLANT. WHEN TREATING RUPTURED ANEURYSMS, ONE MUST EXAMINE CAREFULLY TO WHAT EXTENT IT IS POSSIBLE TO USE ANTIPLATELET MEDICATION.,BIFURCATION ANEURYSM IMPLANT (PCONUS)-THE PCONUS BIFURCATION ANEURYSM IMPLANT IS A SELF-EXPANDING, TUBULAR VASCULAR IMPLANT FOR SUPPORTING

	THE COIL OCCLUSION OF WIDE-NECK INTRACRANIAL BIFURCATION ANEURYSMS. INDICATIONS: THE PCONUS BIFURCATION ANEURYSM IMPLANT IS USED TO SUPPORT THE ENDOVASCULAR COIL OCCLUSION OF WIDE-NECKED BIFURCATION ANEURYSMS IN INTRACRANIAL ARTERIES. TYPICAL LOCATIONS FOR SUCH ANEURYSMS ARE THE BIFURCATION OF THE INTERNAL CAROTID ARTERY, THE ANTERIOR COMMUNICATING ARTERY, THE MIDDLE CEREBRAL ARTERY AND THE BIFURCATION OF THE BASILAR ARTERY. HOWEVER, IN PRINCIPLE, EVERY WIDE-NECKED ANEURYSM IN THE BIFURCATION OF A VESSEL CAN BE SUITABLE. DEPENDING ON THE CLINICAL CIRCUMSTANCES AND THE VASCULAR ANATOMY, BOTH UNRUPTURED AND RUPTURED ANEURYSMS CAN BE TREATED WITH THIS IMPLANT. WHEN TREATING RUPTURED ANEURYSMS, ONE MUST EXAMINE CAREFULLY TO WHAT EXTENT IT IS POSSIBLE TO USE ANTIPLATELET MEDICATION.,ASPIRATION CATHETER(PHLO AC)-PHLO AC IS A CATHETER INTENDED FOR ASPIRATION OF THROMBI IN NEUROVASCULAR VESSELS AS A STANDALONE DEVICE OR IN CONJUNCTION WITH ANY COMPATIBLE RETRIEVAL DEVICE, COMBINING ASPIRATION AND MECHANICAL THROMBECTOMY. IT CAN ALSO BE USED TO FACILITATE THE INTRODUCTION OF OTHER SUITABLE DEVICES AS WELL AS DIAGNOSTIC AND THERAPEUTIC AGENTS.,STEERABLE HYDROPHILIC GUIDE WIRE(PORTAL)-PORTAL, CONSISTING OF PORTAL STEERABLE HYDROPHILIC GUIDEWIRE AND OPTIONAL PORTAL EXT EXTENSION WIRE, IS INTENDED FOR USE IN EXTRA- AND INTRACRANIAL BRAIN-SUPPLYING ARTERIES AND IN EXTRA AND INTRACRANIAL BRAIN-DRAINING VEINS. IT CAN BE USED TO FACILITATE THE SELECTIVE INTRODUCTION AND POSITIONING OF CATHETERS AND OTHER INTERVENTIONAL DEVICES WITHIN TARGET VESSELS.

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1944	IMP/MD/2019/000538	1.License Holder Name: M/S. AVANA MEDICAL DEVICES PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE MARROW CELL SEPARATOR (AUTOMATE BLOOD CELL)(ANGEL SYSTEM)-SYSTEM USED TO SEPARATE AND COLLECT AN AUTOLOGOUS PLASMA FRACTION RICH IN PLATELETS AND RED BLOOD CELLS FROM THE PATIENT'S WHOLE BLOOD OR A SMALL MIXTURE OF BLOOD AND BONE MARROW PREOPERATIVE TO A ORTHOPEDIC SURGICAL PROCEDURE.,ARTHREX I BALANCE KNEE PROSTHESIS (STERILE)-IT IS INTENDED TO BE USED FOR KNEE ARTHROPLASTRY.,SUTURE FIBREWIRE-ANTHREX SUTURE FAMILY PRODUCTS ARE INTENDED FOR USE IN SOFT TISSUE APPROXIMATION AND / OR LIGATION. THESE SUTURES MAY BE INCORPORATED AS COMPONENTS INTO SURGERIES WHERE CONSTRUCTS INCLUDING THOSE WITH ALLOGRAFT OR AUTO GRAFT TISSUES ARE USED FOR REPAIR.,SOFT TISSUE FIXATION SYSTEM- PEEK IMPLANTS-THESE ARE INDICATED TO PROVIDE SOFT TISSUE REATTACHMENT (I.E. FIXATION OF LIGAMENT AND TENSION GRAFT TISSUE),PLATES & SCREWS - TITANIUM (NON-STERILE)-THESE ARE INDICATED TO BE USED FOR INTERNAL BONE FIXATION FOR BONE FRACTURES, FUSIONS OR OSTEOTOMIES IN THE ANKLE, FOOT, HAND, WRIST, CLAVICLE, SCAPULA, OLECRANON HUMERUS, RADIUS, ULNA, TIBIA, PATELLA, CALCANEOUS, FEMUR AND FIBULA.,PLATES & SCREWS - TITANIUM (STERILE)-THE ARTHREX OPENING WEDGE OSTEOTOMY SYSTEM IS USED IN CONJUNCTION WITH BONE SCREWS TO PROVIDE FIXATION FOLLOWING PROXIMAL TIBIAL OR DISTAL FEMORAL OPENING WEDGE OSTEOTOMIES. THE ARTHREX OPENING WEDGE OSTEOTOMY SYSTEM USING A/ P SLOPED PLATES IS USED IN CONJUNCTION WITH BONE SCREWS TO PROVIDE FIXATION FOLLOWING PROXIMAL TIBIAL OPENING WEDGE OSTEOTOMIES WHERE TIBIAL SLOPE ADJUSTMENTS ARE NEEDED. HTO PLATES & SCREWS ARE INDICATED FOR INTERNAL BONE FIXATION.,SOFT TISSUE FIXATION SYSTEM, BIO ANCHORS (STERILE)-IT IS INTENDED TO BE USED FOR ARTHOSCOPIC AND ORTHOPEDIC SURGERIES.,SOFT TISSUE FIXATION SYSTEM, TI SCREWS (STERILE)-IT IS INTENDED TO BE USED FOR ARTHROSCOPIC AND ORTHOPEDIC SURGERIES.,SOFT TISSUE FIXATION SYSTEM, TI ANCHORS (STERILE)-IT IS INTENDED TO BE USED FOR ARTHROSCOPIC AND ORTHOPEDIC SURGERIES.,ARTHREX UNIVERS SHOULDER PROSTHESIS (STERILE)-IT IS INTENDED TO BE USED FOR SHOULDER ARTHROPLASTY.,SOFT TISSUE FIXATION SYSTEM- BIO SCREWS (STERILE)-IT IS INTENDED TO BE USED FOR ARTHROSCOPIC AND ORTHOPEDIC SURGERIES.

1945	IMP/MD/2019/000539	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VALVED GRAFT(SJM MASTERS HP SERIES VALVED GRAFT WITH GELWEAVE VALSALVA TECHNOLOGY)-THE SJM MASTERS HP VALVED GRAFT IS INDICATED FOR THE REPLACEMENT OF A MALFUNCTIONING NATIVE OR PROSTHETIC AORTIC HEART VALVE AND ASCENDING AORTA., ANNULOPLASTY RING(SJM TAILOR ANNULOPLASTY RING)-THE RING IS INDICATED FOR USE IN THE REPAIR OF A MITRAL OR TRICUSPID VALVE THAT IS DISEASED OR DAMAGED DUE TO ACQUIRED OR CONGENITAL VALVULAR DISEASE. IT IS THE RESPONSIBILITY OF THE SURGEON TO DETERMINE THAT THE VALVE IS REPAIRABLE. THE DECISION TO UNDERTAKE ANNULOPLASTY CAN BE MADE ONLY AFTER VISUAL ANALYSIS OF THE VALVE PATHOLOGY. ONLY SURGEONS WHO HAVE RECEIVED APPROPRIATE TRAINING SHOULD PERFORM VALVE REPAIR USING THE RING.,VALVED GRAFT(SJM MASTER SERIES COATED AORTIC VALVED GRAFT (ROTATABLE))-IT IS INDICATED FOR THE REPLACEMENT OF A MALFUNCTIONING NATIVE OR PROSTHETIC AORTIC HEART VALVE AND ASCENDING AORTA , ANNULOPLASTY RING(SJM SEGUIN ANNULOPLASTY RING)-IT IS INDICATED FOR USE IN THE REPAIR OF MITRAL VALVES THAT ARE DISEASED OR DAMAGED DUE TO ACQUIRED OR CONGENITAL PROCESSES. ,HEART VALVE(SJM MECHANICAL HEART VALVE- SJM MASTER SERIES (ROTATABLE)- AORTIC)-IT IS INTENDED FOR USE AS A REPLACEMENT VALVE IN PATIENTS WITH A DISEASED, DAMAGED, OR MALFUNCTIONING AORTIC OR MITRAL HEART VALVE. THIS DEVICE MAY ALSO BE USED TO REPLACE A PREVIOUSLY IMPLANTED PROSTHETIC HEART VALVE.,HEART VALVE(SJM MECHANICAL HEART VALVE- SJM MASTER SERIES (ROTATABLE)- AORTIC HEMODYNAMIC PLUS)-IT IS INTENDED FOR USE AS A REPLACEMENT VALVE IN PATIENTS WITH A DISEASED, DAMAGED, OR MALFUNCTIONING AORTIC OR MITRAL HEART VALVE. THIS DEVICE MAY ALSO BE USED TO REPLACE A PREVIOUSLY IMPLANTED PROSTHETIC HEART VALVE, HEART VALVE(SJM REGENT MECHANICAL HEART VALVE (ROTATABLE))-IT IS INTENDED FOR USE AS A REPLACEMENT VALVE IN PATIENTS WITH A DISEASED, DAMAGED, OR MALFUNCTIONING AORTIC HEART VALVE. IT MAY ALSO BE USED TO REPLACE A PREVIOUSLY IMPLANTED AORTIC PROSTHETIC HEART VALVE.,HEART VALVE(SJM MECHANICAL HEART VALVE- SJM MASTER SERIES (ROTATABLE)- MITRAL)-IT IS INTENDED FOR USE AS A REPLACEMENT VALVE IN PATIENTS WITH A DISEASED, DAMAGED, OR MALFUNCTIONING AORTIC OR MITRAL HEART VALVE. THIS DEVICE MAY ALSO BE USED TO REPLACE A PREVIOUSLY IMPLANTED PROSTHETIC HEART VALVE.,ANNULOPLASTY RING(SJM RIGID

		SADDLE ANNULOPLASTY RING)-IT IS INDICATED FOR USE TO CORRECT ANNULAR DILATION, INCREASE LEAFLET COAPTATION, AND PREVENT FURTHER DILATION OF THE MITRAL VALVE ANNULUS CAUSED BY DISEASE STATES SUCH AS DEGENERATIVE DISEASE, RHEUMATIC DISEASE, ISCHEMIA, OR VASCULAR DISEASE. THE COMBINATION OF PROSTHETIC RING WITH VALVULOPLASTY MAY BE USED IN ALL ACQUIRED OR CONGENITAL MITRAL INSUFFICIENCIES WITH DILATION AND DEFORMATION OF THE FIBROUS MITRAL ANNULUS. FOR MITRAL INSUFFICIENCIES WITH NO SUB VALVULAR LESIONS AND NORMAL VALVULAR MOVEMENTS, PROSTHETIC RING IMPLANT ALONE MAY BE SUFFICIENT. HOWEVER, ANNULOPLASTY RING IMPLANT ALONG WITH MITRAL VALVULOPLASTY REPAIR MUST BE CONSIDERED FOR INSUFFICIENCIES WITH A PROLAPSED VALVE DUE TO ELONGATION OR RUPTURE OF THE CHORDAE TENDINEAE AND FOR INSUFFICIENCIES WITH LIMITATION OF VALVULAR MOVEMENTS DUE TO FUSION OF THE COMMISSURES OR CHORDAE TENDINEAE, OR CHORDAL HYPERTROPHY
1946	IMP/MD/2019/000540	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED ,A-1/ 50, ROOM NO. 2, 100 SHED AREA, G.L.D.C., VAPI, TAL PARDI (VALSAD) , VALSAD GUJARAT ,396195 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROWAVE ABLATION PROBES(NEUWAVE ABLATION PROBES)-THE NEUWAVE ABLATION PROBES ARE DESIGNED FOR USE ONLY WITH THE NEUWAVE MICROWAVE ABLATION SYSTEM. THE NEUWAVE MICROWAVE ABLATION SYSTEM AND ACCESSORIES ARE INDICATED FOR THE ABLATION (COAGULATION) OF SOFT TISSUE IN PERCUTANEOUS, OPEN SURGICAL AND IN CONJUNCTION WITH LAPAROSCOPIC SURGICAL SETTINGS, INCLUDING THE PARTIAL OR COMPLETE ABLATION OF NON-RESECTABLE LIVER TUMORS. THE NEUWAVE MICROWAVE ABLATION SYSTEM IS NOT INDICATED FOR USE IN CARDIAC PROCEDURES.

1947	IMP/MD/2019/000541	1.License Holder Name: VENUS MEDICAL TECHNOLOGIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER (COVERED/ NON-COVERED)(HANAROSTENT DUODENUM/ PYLORUS STENT)-THIS STENT IS USED FOR APPLICATION IN PALLIATIVE TREATMENT OF PYLORIC OR DUODENAL STRICTURE CAUSED BY MALIGNANT TUMORS.,CATHETER (COVERED/ NON-COVERED)(HANAROSTENT COLON/ RECTUM STENT)-THIS STENT IS INDICATED FOR APPLICATION IN PALLIATIVE TREATMENT OF COLO-RECTAL STRICTURES CAUSED BY MALIGNANT TUMORS.,CATHETER (COVERED)(HANAROSTENT ESOPHAGUS STENT)-THIS STENT IS INDICATED FOR APPLICATION IN PALLIATIVE TREATMENT OF ESOPHAGEAL STRICTURE AND/OR TRACHEA-ESOPHAGEAL FISTULA CAUSED BY MALIGNANT TUMORS.,CATHETER (COVERED/ NON-COVERED)(HANAROSTENT BILIARY STENT)-THIS STENT IS INDICATED FOR APPLICATION IN PALLIATIVE TREATMENT OF BILE DUCT STRICTURE CAUSED BY MALIGNANT TUMORS.,CATHETER (BENIGN) (HANAROSTENT BILIARY STENT)-THIS STENT IS INDICATED FOR APPLICATION IN PALLIATIVE TREATMENT OF BILE DUCT MALIGNANT AND/OR BENIGN STRICTURES.

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1948	IMP/MD/2019/000542	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED ,A-1/50, ROOM NO. 2, 100 SHED AREA, G.L.D.C., VAPI, TAL PARDI (VALSAD) , VALSAD GUJARAT ,396195 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABLATION DEVICE (MEGADYNE)-"STAINLESS STEEL ELECTRODES ARE ACCESSORY DEVICES TO ELECTROSURGICAL GENERATORS. THEY ARE INTENDED TO CONDUCT RADIO FREQUENCY (RF) CURRENT FOR CUTTING AND COAGULATION FROM THE ELECTROSURGICAL GENERATOR TO TARGET TISSUE IN A BROAD RANGE OF GENERAL SURGICAL PROCEDURES REQUIRING THE USE OF ELECTROSURGERY CUTTING AND CAUTERIZATION.",ABLATION DEVICE(MEGADYNE)-THESE DEVICES ARE INTENDED TO BE USED FOR ELECTROSURGICAL COAGULATION WITH SUCTION TO ALLOW FOR REMOVAL OF FLUIDS AND FACILITATING VISIBILITY DURING PROCEDURES.,ABLATION DEVICE(MEGATIP)- THIS PRODUCT IS INTENDED AS AN ACCESSORY TO A GENERAL-PURPOSE ELECTROSURGICAL GENERATOR AND IS DESIGNED TO CONDUCT RADIO FREQUENCY (RF) CURRENT FOR CUTTING AND COAGULATION TO BE DELIVERED TO TARGET TISSUE DURING LAPAROSCOPIC SURGICAL PROCEDURES, FOR USE IN ALL APPLICATIONS WHERE CURRENT DISPOSABLE OR REUSABLE LAPAROSCOPIC ELECTRODES ARE USED.,ABLATION DEVICE(E-Z CLEAN)-E-Z CLEAN ELECTROSURGICAL ELECTRODES ARE INTENDED TO CONDUCT RADIO FREQUENCY (RF) CURRENT FOR MONOPOLAR CUTTING AND COAGULATION FROM THE RF ELECTROSURGICAL GENERATOR TO TARGET SOFT TISSUE IN A BROAD RANGE OF SURGICAL PROCEDURES REQUIRING THE USE OF ELECTROSURGERY FOR CUTTING AND CAUTERIZATION.,ABLATION DEVICE(E-Z CLEAN)-THESE DEVICES ARE INTENDED AS ACCESSORIES TO A GENERAL-PURPOSE ELECTROSURGICAL GENERATOR DESIGNED TO CONDUCT RADIO FREQUENCY (RF) CURRENT FOR MONOPOLAR CUTTING AND COAGULATION TO BE DELIVERED TO TARGET TISSUE DURING GENERAL AND LAPAROSCOPIC SURGICAL PROCEDURES.,ABLATION DEVICE(E-Z CLEAN)-THESE DEVICES ARE INTENDED TO CONDUCT RADIO FREQUENCY (RF) CURRENT FOR MONOPOLAR CUTTING AND COAGULATION FROM THE RF ELECTROSURGICAL GENERATOR TO TARGET SOFT TISSUE IN A BROAD RANGE OF SURGICAL PROCEDURES REQUIRING THE USE OF ELECTROSURGERY FOR CUTTING AND CAUTERIZATION.

1949	IMP/MD/2019/000543	1.License Holder Name: ALCON LABORATORIES (INDIA) PVT. LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IOL PRE-LOADED DELIVERY SYSTEM(ACRYSOF IQ ASPHERIC UV ABSORBING IOL WITH THE ULTRASERT PRE-LOADED DELIVERY SYSTEM)-THE ACRYSOF IQ ASPHERIC UV ABSORBING IOL IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY. THIS LENS IS INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,PRE-LOADED DELIVERY SYSTEM(ACRYSOF IQ ASPHERIC IOL WITH ULTRASERT PRE-LOADED DELIVERY SYSTEM)-ACRYSOF IQ POSTERIOR CHAMBER INTRAOCULAR LENSES ARE INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG., PRESBYOPIA CORRECTING IOL(ACRYSOF IQ PANOPTIX TORIC PRESBYOPIA CORRECTING INTRAOCULAR LENS)-THE ACRYSOF IQ PANOPTIX TORIC PRESBYOPIA-CORRECTING INTRAOCULAR LENS IS INTENDED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER OF THE HUMAN EYE FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM SECONDARY TO REMOVAL OF A CATARACTOUS LENS OR CLEAR LENS IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA, WHO DESIRE NEAR, INTERMEDIATE AND DISTANCE VISION WITH INCREASED SPECTACLE INDEPENDENCE.,ACRYSOF EXPAND SERIES MULTI-PIECE IOL(ALCON EXPAND SERIES)-ACRYSOF POSTERIOR CHAMBER INTRAOCULAR LENSES ARE INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY WHEN EXTRACAPSULAR CATARACT EXTRACTION OR PHACOEMULSIFICATION ARE PERFORMED. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG., ASPHERIC SINGLE PIECE NATURAL INTRAOCULAR LENS(ACRYSOF IQ ASPHERIC NATURAL IOL)-THE ACRYSOF IQ POSTERIOR CHAMBER INTRAOCULAR LENS IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY. THIS LENS IS INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,ACRYLIC FOLDABLE SINGLE-PIECE/MULTI-PIECE INTRAOCULAR LENS (ACRYSOF ACRYLIC FOLDABLE IOL)-ACRYSOF POSTERIOR CHAMBER INTRAOCULAR LENSES ARE INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY WHEN EXTRACAPSULAR CATARACT EXTRACTION OR

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	PHACOEMULSIFICATION ARE PERFORMED. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,PRESBYOPIA CORRECTING IOL(ACRYSOF IQ PANOPTIX PRESBYOPIA CORRECTING INTRAOCULAR LENS)-THE ACRYSOF IQ PANOPTIX PRESBYOPIA-CORRECTING INTRAOCULAR LENS IS INTENDED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER FOR THE VISUAL CORRECTION OF APHAKIA SECONDARY TO REMOVAL OF A CATARACTOUS LENS OR CLEAR LENS IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA, WHO DESIRE NEAR, INTERMEDIATE AND DISTANCE VISION WITH INCREASED SPECTACLE INDEPENDENCE.,ACRYSOF IQ RESTOR MULTIFOCAL TORIC INTRAOCULAR LENS(ACRYSOF IQ RESTOR MULTIFOCAL TORIC IOL)-THE ACRYSOF IQ RESTOR MULTIFOCAL TORIC IOL IS INTENDED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM SECONDARY TO REMOVAL OF A CATARACTOUS LENS IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA, WHO DESIRE NEAR, INTERMEDIATE AND DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER, AND INCREASED SPECTACLE INDEPENDENCE. THE ACRYSOF IQ RESTOR MULTIFOCAL TORIC IOL IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS IN REFRACTIVE LENS EXCHANGE (RLE) IN ADULT PATIENTS WHO MAY BENEFIT FROM NEAR VISION WITHOUT A READING AID, AND FROM INCREASED SPECTACLE INDEPENDENCE. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,ACRYSOF IQ TORIC INTRAOCULAR LENS(ACRYSOF IQ TORIC ASTIGMATISM IOL)-IT IS INTENDED FOR THE PRIMARY IMPLANTATION IN THE CAPSULAR BAG OF THE EYE FOR THE VISUAL CORRECTION OF THE APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM SECONDARY TO REMOVAL OF CATARACTOUS LENS IN ADULT PATIENTS WITH OR WITHOUT PRESBYOPIA, WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE VISION,ACRYSOF IQ RESTOR MULTIFOCAL INTRAOCULAR LENS(ACRYSOF IQ RESTOR MULTIFOCAL IOL)-THE ACRYSOF IQ RESTOR POSTERIOR CHAMBER INTRAOCULAR LENS (IOL) IS INTENDED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA SECONDARY TO REMOVAL OF A CATARACTOUS LENS IN ADULT PATIENTS, WITH AND WITHOUT PRESBYOPIA, WHO DESIRE NEAR, INTERMEDIATE AND DISTANCE VISION WITH INCREASED SPECTACLE INDEPENDENCE. THE ACRYSOF IQ RESTOR POSTERIOR CHAMBER IOL IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS IN REFRACTIVE LENS EXCHANGE (RLE) IN ADULT PATIENTS WHO MAY BENEFIT FROM NEAR VISION WITHOUT A READING AID AND FROM INCREASED SPECTACLE

	INDEPENDENCE. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.

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1950	IMP/MD/2019/000543	1.License Holder Name: ALCON LABORATORIES (INDIA) PVT. LTD. , 11TH FLOOR, RMZ AZURE, BELLARY ROAD, HEBBAL ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560092 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRAOCULAR LENS (ACRYSOF IQ VIVITY EXTENDED VISION UV ABSORBING IOLS)-THE ACRYSOF IQ VIVITY UV ABSORBING IOLS IS INTENDED FOR USE BY A TRAINED OPHTHALMIC SURGEON. THE IOL IS INTENDED TO BE PLACED IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER OF THE EYE, REPLACING THE NATURAL CRYSTALLINE LENS. THIS POSITION ALLOWS THE IOL TO FUNCTION AS A REFRACTIVE MEDIUM IN THE CORRECTION OF APHAKIA. THE ASPHERIC BICONVEX OPTIC COMPENSATES FOR THE POSITIVE SPHERICAL ABERRATION OF THE CORNEA AS COMPARED TO A STANDARD SPHERICAL OPTIC. THE PATENTED WAVEFRONT-SHAPING TECHNOLOGY ON THE ANTERIOR SURFACE PROVIDES AN EXTENDED RANGE OF VISION FROM DISTANCE TO NEAR WITHOUT INCREASING THE INCIDENCE OF VISUAL DISTURBANCES.,INTRAOCULAR LENS(ACRYSOF IQ VIVITY TORIC EXTENDED VISION UV ABSORBING IOLS)-THE ACRYSOF IQ VIVITY TORIC UV ABSORBING IOLS IS INTENDED FOR USE BY A TRAINED OPHTHALMIC SURGEON. THE IOL IS INTENDED TO BE PLACED IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER OF THE EYE, REPLACING THE NATURAL CRYSTALLINE LENS. THIS POSITION ALLOWS THE IOL TO FUNCTION AS A REFRACTIVE MEDIUM IN THE CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM. THE ASPHERIC BICONVEX OPTIC COMPENSATES FOR THE POSITIVE SPHERICAL ABERRATION OF THE CORNEA AS COMPARED TO A STANDARD SPHERICAL OPTIC. THE PATENTED WAVEFRONT-SHAPING TECHNOLOGY ON THE ANTERIOR SURFACE PROVIDES AN EXTENDED RANGE OF VISION FROM DISTANCE TO NEAR WITHOUT INCREASING THE INCIDENCE OF VISUAL DISTURBANCES. ADDITIONALLY, THESE IOLS HAVE A TORIC COMPONENT ON THE POSTERIOR SURFACE WITH AXIS MARKS TO DENOTE THE FLAT MERIDIAN (PLUS CYLINDER AXIS). ALIGNMENT OF THE TORIC AXIS MARKS WITH THE POST-OPERATIVE STEEP CORNEAL MERIDIAN ALLOWS THE LENS TO CORRECT PREEXISTING CORNEAL ASTIGMATISM.,INTRAOCULAR LENS(ACRYSOF IQ VIVITY EXTENDED VISION IOLS)-THE ACRYSOF IQ VIVITY IOLS IS INTENDED FOR USE BY A TRAINED OPHTHALMIC SURGEON. THE IOL IS INTENDED TO BE PLACED IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER OF THE EYE, REPLACING THE NATURAL CRYSTALLINE LENS. THIS POSITION ALLOWS THE IOL TO FUNCTION AS A REFRACTIVE MEDIUM IN THE CORRECTION OF APHAKIA. THE ASPHERIC BICONVEX OPTIC COMPENSATES FOR THE POSITIVE SPHERICAL ABERRATION OF THE

	CORNEA AS COMPARED TO A STANDARD SPHERICAL OPTIC. THE PATENTED WAVEFRONT-SHAPING TECHNOLOGY ON THE ANTERIOR SURFACE PROVIDES AN EXTENDED RANGE OF VISION FROM DISTANCE TO NEAR WITHOUT INCREASING THE INCIDENCE OF VISUAL DISTURBANCES. THE EFFECTIVENESS OF THE BLUE LIGHT FILTERING CHROMOPHORE IN REDUCING THE INCIDENCE OF RETINAL DISORDERS HAS NOT BEEN ESTABLISHED.,INTRAOCULAR LENS (ACRYSOF IQ VIVITY TORIC EXTENDED VISION IOLS)-THE ACRYSOF IQ VIVITY TORIC IOLS IS INTENDED FOR USE BY A TRAINED OPHTHALMIC SURGEON. THE IOL IS INTENDED TO BE PLACED IN THE CAPSULAR BAG IN THE POSTERIOR CHAMBER OF THE EYE, REPLACING THE NATURAL CRYSTALLINE LENS. THIS POSITION ALLOWS THE IOL TO FUNCTION AS A REFRACTIVE MEDIUM IN THE CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM. THE ASPHERIC BICONVEX OPTIC COMPENSATES FOR THE POSITIVE SPHERICAL ABERRATION OF THE CORNEA AS COMPARED TO A STANDARD SPHERICAL OPTIC. THE PATENTED WAVEFRONT-SHAPING TECHNOLOGY ON THE ANTERIOR SURFACE PROVIDES AN EXTENDED RANGE OF VISION FROM DISTANCE TO NEAR WITHOUT INCREASING THE INCIDENCE OF VISUAL DISTURBANCES. ADDITIONALLY, THESE IOLS HAVE A TORIC COMPONENT ON THE POSTERIOR SURFACE WITH AXIS MARKS TO DENOTE THE FLAT MERIDIAN (PLUS CYLINDER AXIS). ALIGNMENT OF THE TORIC AXIS MARKS WITH THE POST-OPERATIVE STEEP CORNEAL MERIDIAN ALLOWS THE LENS TO CORRECT PREEXISTING CORNEAL ASTIGMATISM. THE EFFECTIVENESS OF THE BLUE LIGHT FILTERING CHROMOPHORE IN REDUCING THE INCIDENCE OF RETINAL DISORDER HAS NOT BEEN ESTABLISHED.

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1951	IMP/MD/2019/000544	1.License Holder Name: M/S ASIA ACTUAL INDIA (OPC) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROCATHETERS (PENUMBRA DELIVERY MICROCATHETERS CONSISTING OF PRODUCT FAMILIES: 1. PX 400 MICROCATHETER. 2. PX SLIM DELIVERY MICROCATHETER. 3. VELOCITY DELIVERY MICROCATHETER. 4. LANTERN DELIVERY MICROCATHETER.)- PX 400 MICROCATHETER, PX SLIM DELIVERY MICROCATHETER, AND VELOCITY DELIVERY MICROCATHETER: THE PENUMBRA DELIVERY MICROCATHETERS ARE INTENDED TO ASSIST IN THE DELIVERY OF DIAGNOSTIC AGENTS, SUCH AS CONTRAST MEDIA, AND THERAPEUTIC AGENTS, SUCH AS OCCLUSION COILS TO THE PERIPHERAL AND NEURO VASCULATURE. LANTERN DELIVERY MICROCATHETER: THE PENUMBRA DELIVERY MICROCATHETERS ARE INTENDED TO ASSIST IN THE DELIVERY OF DIAGNOSTIC AGENTS, SUCH AS CONTRAST MEDIA, AND THERAPEUTIC DEVICES, SUCH AS OCCLUSION COILS, TO THE PERIPHERAL AND NEURO VASCULATURE. ,ASPIRATION TUBING (INDIGO SYSTEM- ASPIRATION TUBING)-INDIGO ASPIRATION TUBING AS PART OF THE INDIGO ASPIRATION SYSTEM, THE INDIGO STERILE ASPIRATION TUBING IS INDICATED TO CONNECT THE INDIGO ASPIRATION CATHETERS TO THE PENUMBRA ASPIRATION PUMP. , REVASCULARIZATION DEVICE(PENUMBRA SYSTEM – 3D REVASCULARIZATION DEVICE)-AS PART OF THE PENUMBRA SYSTEM, THE PENUMBRA 3D REVASCULARIZATION DEVICE IS INDICATED FOR USE IN THE REVASCULARIZATION OF PATIENTS WITH ACUTE ISCHEMIC STROKE SECONDARY TO INTRACRANIAL LARGE VESSEL OCCLUSIVE DISEASE (WITHIN THE INTERNAL CAROTID, MIDDLE CEREBRAL – M1 AND M2 SEGMENTS) WITHIN 8 HOURS OF SYMPTOM ONSET. PATIENTS WHO ARE INELIGIBLE FOR INTRAVENOUS TISSUE PLASMINOGEN ACTIVATOR (IV T-PA) OR WHO FAIL IV T-PA THERAPY ARE CANDIDATES FOR TREATMENT.,ASPIRATION CATHETER(INDIGO SYSTEM – ASPIRATION CATHETER)-INDIGO ASPIRATION CATHETERS AND SEPARATORS AS PART OF THE INDIGO ASPIRATION SYSTEM, THE INDIGO ASPIRATION CATHETERS AND SEPARATORS ARE INDICATED FOR THE REMOVAL OF FRESH, SOFT EMBOLI AND THROMBI FROM VESSELS OF THE PERIPHERAL ARTERIAL AND VENOUS SYSTEMS. ,COIL(PENUMBRA COIL 400)-THE PENUMBRA COIL SYSTEM IS INDICATED FOR THE ENDOVASCULAR EMBOLIZATION OF: • INTRACRANIAL ANEURYSMS • OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE • ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE, ASPIRATION CATHETER AND ASPIRATION TUBING (KIT)(INDIGO SYSTEM - ASPIRATION CATHETER AND ASPIRATION TUBING (KIT))-

	INDIGO ASPIRATION CATHETERS AND SEPARATORS AS PART OF THE INDIGO ASPIRATION SYSTEM, THE INDIGO ASPIRATION CATHETERS AND SEPARATORS ARE INDICATED FOR THE REMOVAL OF FRESH, SOFT EMBOLI AND THROMBI FROM VESSELS OF THE PERIPHERAL ARTERIAL AND VENOUS SYSTEMS. INDIGO ASPIRATION TUBING AS PART OF THE INDIGO ASPIRATION SYSTEM, THE INDIGO STERILE ASPIRATION TUBING IS INDICATED TO CONNECT THE INDIGO ASPIRATION CATHETERS TO THE PENUMBRA ASPIRATION PUMP. , ASPIRATION TUBING(PENUMBRA SYSTEM-ASPIRATION TUBING)-AS PART OF THE PENUMBRA SYSTEM, THE PENUMBRA STERILE ASPIRATION TUBING IS INDICATED TO CONNECT THE PENUMBRA REPERFUSION CATHETERS TO THE PENUMBRA ASPIRATION PUMP., SEPARATOR(INDIGO SYSTEM - SEPARATOR)-INDIGO ASPIRATION CATHETERS AND SEPARATORS AS PART OF THE INDIGO ASPIRATION SYSTEM, THE INDIGO ASPIRATION CATHETERS AND SEPARATORS ARE INDICATED FOR THE REMOVAL OF FRESH, SOFT EMBOLI AND THROMBI FROM VESSELS OF THE PERIPHERAL ARTERIAL AND VENOUS SYSTEMS. ,SEPARATOR(PENUMBRA SYSTEM-SEPARATOR)-AS PART OF THE PENUMBRA SYSTEM, THE REPERFUSION CATHETERS AND SEPARATORS ARE INDICATED FOR USE IN THE REVASCULARIZATION OF PATIENTS WITH ACUTE ISCHEMIC STROKE SECONDARY TO INTRACRANIAL LARGE VESSEL OCCLUSIVE DISEASE (WITHIN THE INTERNAL CAROTID, MIDDLE CEREBRAL – M1 AND M2 SEGMENTS, BASILAR, AND VERTEBRAL ARTERIES) WITHIN 8 HOURS OF SYMPTOM ONSET. PATIENTS WHO ARE INELIGIBLE FOR INTRAVENOUS TISSUE PLASMINOGEN ACTIVATOR (IV T-PA) OR WHO FAIL IV T-PA THERAPY ARE CANDIDATES FOR TREATMENT.,KIT (PENUMBRA SYSTEM-REPERFUSION CATHETER AND ASPIRATION TUBING (KIT))-AS PART OF THE PENUMBRA SYSTEM, THE REPERFUSION CATHETERS AND SEPARATORS ARE INDICATED FOR USE IN THE REVASCULARIZATION OF PATIENTS WITH ACUTE ISCHEMIC STROKE SECONDARY TO INTRACRANIAL LARGE VESSEL OCCLUSIVE DISEASE (WITHIN THE INTERNAL CAROTID, MIDDLE CEREBRAL – M1 AND M2 SEGMENTS, BASILAR, AND VERTEBRAL ARTERIES) WITHIN 8 HOURS OF SYMPTOM ONSET. PATIENTS WHO ARE INELIGIBLE FOR INTRAVENOUS TISSUE PLASMINOGEN ACTIVATOR (IV T-PA) OR WHO FAIL IV T-PA THERAPY ARE CANDIDATES FOR TREATMENT. AS PART OF THE PENUMBRA SYSTEM, THE PENUMBRA STERILE ASPIRATION TUBING IS INDICATED TO CONNECT THE PENUMBRA REPERFUSION CATHETERS TO THE PENUMBRA ASPIRATION PUMP ,REPERFUSION CATHETER (PENUMBRA SYSTEM-REPERFUSION CATHETER)-AS PART OF THE PENUMBRA SYSTEM, THE REPERFUSION CATHETERS AND SEPARATORS ARE INDICATED FOR USE IN THE REVASCULARIZATION

		OF PATIENTS WITH ACUTE ISCHEMIC STROKE SECONDARY TO INTRACRANIAL LARGE VESSEL OCCLUSIVE DISEASE (WITHIN THE INTERNAL CAROTID, MIDDLE CEREBRAL – M1 AND M2 SEGMENTS, BASILAR, AND VERTEBRAL ARTERIES) WITHIN 8 HOURS OF SYMPTOM ONSET. PATIENTS WHO ARE INELIGIBLE FOR INTRAVENOUS TISSUE PLASMINOGEN ACTIVATOR (IV T-PA) OR WHO FAIL IV T-PA THERAPY ARE CANDIDATES FOR TREATMENT.
1952	IMP/MD/2019/000545	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGISEAL® TOPICAL SKIN ADHESIVE(SURGISEAL® TOPICAL ADHESIVE AND SURGISEAL STYLUS® TOPICAL SKIN ADHESIVE)-SURGISEAL® IS INTENDED FOR TOPICAL APPLICATIONS ONLY TO HOLD CLOSED EASILY APPROXIMATED SKIN EDGES OF WOUNDS FROM SURGICAL INCISIONS, INCLUDING PUNCTURES FROM MINIMALLY INVASIVE SURGERY, SIMPLE, THOROUGHLY CLEANSED, TRAUMA INDUCED LACERATIONS. SURGISEAL MAY BE USED IN CONJUNCTION WITH, BUT NOT IN PLACE OF, DEEP DERMAL SUTURES.
1953	IMP/MD/2019/000546	1.License Holder Name: RESPICARE SOLUTIONS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NASAL OXYGEN CANNULA(RAM CANNULA)-NASAL OXYGEN CANNULA IS USED FOR DELIVERY OF SUPPLEMENTARY OXYGEN

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1954	IMP/MD/2019/000547	1.License Holder Name: GENETIX BIOTECH ASIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOR WOUND DEBRIDEMENT(DEBRISOFT® LOLLY)-DEBRISOFT® LOLLY IS INTENDED FOR THE DEBRIDEMENT OF DEEP – INCLUDING SURGICALLY INVASIVE – TO SUPERFICIAL WOUNDS FOR WOUND BED PREPARATION E.G., DIABETIC ULCERS, ARTERIAL AND VENOUS ULCERS, PRESSURE ULCERS, POSTOPERATIVE WOUNDS HEALING BY SECONDARY INTENTION AND TRAUMA AS WELL AS BURNS / SCALDS. DEBRISOFT® LOLLY CAN ALSO BE USED TO ABSORB EXUDATE, DEBRIS AND KERATODERMAS DURING DEBRIDEMENT.,ABSORBENT DRESSING(VLIWAZELL , STERILE)-VLIWAZELL IS INTENDED FOR THE TREATMENT OF MODERATELY TO HEAVILY EXUDING WOUNDS , AND ALSO AS A SECONDARY DRESSING FOR HEAVILY EXUDING WOUNDS IN COMBINATION WITH MOIST WOUND CARE DRESSINGS.,FOR WOUND DEBRIDEMENT(DEBRISOFT ® PAD)-DEBRISOFT® PAD IS INTENDED AS A RAPID, HIGHLY EFFECTIVE, SAFE AND VIRTUALLY PAINLESS DEBRIDEMENT METHOD. DEBRISOFT PAD IS USED FOR ABSORBING EXUDATE, CELLULAR DEBRIS AND KERATOSIS DURING· DEBRIDEMENT AND IT IS GENTLE ON INTACT TISSUE.
1955	IMP/MD/2019/000548	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STIMLOC BURR HOLE COVER ACCESSORY KITS(SPARE PARTS KIT FOR STIMLOC BURR HOLE COVER)-THE MEDTRONIC STIMLOC BURR HOLE COVER IS INTENDED FOR USE FOLLOWING CRANIAL SURGERY AS AN IMPLANTABLE 14-MM BURR HOLE COVER FOR THE SKULL AND TO ANCHOR A LEAD WITH AN APPROXIMATE 1.3-MM DIAMETER.,STIMLOC BURR HOLE COVER(BURR HOLE COVER)-THE MEDTRONIC STIMLOC BURR HOLE COVER IS INTENDED FOR USE FOLLOWING CRANIAL SURGERY AS AN IMPLANTABLE 14-MM BURR HOLE COVER FOR THE SKULL AND TO ANCHOR A LEAD WITH AN APPROXIMATE 1.3-MM DIAMETER.

1956	IMP/MD/2019/000549	1.License Holder Name: SCHULKE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISODIUM CARBONATE, COMPOUND WITH HYDROGENPEROXIDE (2:3) 40-50% (SODIUM PERCARBONATE-43.0 GM) AND N,N,N',N'-TETRAACETYLETHLENE DIAMINE-20-30% (TETRAACETYLETHYLENE DIAMINE- 22.0 GM) (GIGASEPT PEARLS)-DISINFECTANT POWDER FOR MANUAL CLEANING AND DISINFECTION, OF THERMOSTABLE AND THERMOLABILE MEDICAL INSTRUMENTS OF ALL TYPES.
1957	IMP/MD/2019/000551	1.License Holder Name: TRIVENI HEALTH CURE ,COMMERCIAL OFFICE/SPACE NO.304, THIRD FLOOR, VARDHMAN CITY CENTRE, PLOT NO.1, CHOWKI NO.2, L.S.C., GULABI BAGH, SHAKTI NAGAR , NORTH DELHI DELHI ,110007 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDEWIRES(EAGLE™ PTCA GUIDE WIRE)-THE EAGLE™ PTCA GUIDE WIRES ARE MAINLY USED FOR INSERTION OF DEVICES FOR INTERVENTIONAL DIAGNOSIS AND TREATMENT. FOR USE IN ANGIOGRAPHIC PROCEDURES OR INTERVENTIONAL PROCEDURES TO INTRODUCE AND POSITION CATHETERS AND INTERVENTIONAL DEVICES WITH IN THE CORONARY AND PERIPHERAL VASCULATURE.,BALLOON DILATATION CATHETER (HAWK™- PTCA BALLOON CATHETER SEMI COMPLIANT (HAWK™- PTCA BALLOON DILATATION CATHETER) • HAWK™- PTCA BALLOON CATHETER NON-COMPLIANT (HAWK™- NC- PTCA BALLOON CATHETER NON-COMPLIANT) • HAWK™- PTCA BALLOON CATHETER CTO (HAWK™- CTO- PTCA BALLOON DILATATION CATHETER))-THE BALLOON DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. OR MALFUNCTIONING NATIVE AND PROSTHETIC AORTIC OR MITRAL VALVES,DRUG ELUTING STENTS (AFFINITY™ MINI STRUT™ (AFFINITY™ MS MINI STRUT COBALT CHROMIUM SIROLIMUS-ELUTING CORONARY STENT SYSTEM))-IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER AND MYOCARDIAL BLOOD FLOW,DRUG ELUTING STENTS(AFFINITY™-CC-COBALT CHROMIUM DRUG ELUTING STENT (AFFINITY™ SIROLIMUS ELUTING CORONARY STENT SYSTEM))-IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER AND MYOCARDIAL BLOOD FLOW.

1958	IMP/MD/2019/000552	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABSORBENT DRESSING (MELOLIN)-FOR THE MANAGEMENT OF A WIDE VARIETY OF LIGHT-TO-MODERATELY EXUDING WOUNDS, INCLUDING CLEAN SUTURED WOUNDS, ABRASIONS, LACERATIONS AND MINOR BURNS.
1959	IMP/MD/2019/000553	1.License Holder Name: TRANSLUMINA THERAPEUTICS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRAVASCULAR LITHOTRIPSY (IVL) GENERATOR AND CONNECTOR CABLE(IVL GENERATOR AND CONNECTOR CABLE)-THE SHOCKWAVE MEDICAL INTRAVASCULAR LITHOTRIPSY (IIVL) GENERATOR AND CONNECTOR CABLE ARE INTENDED FOR USE WITH SHOCKWAVE MEDICAL IVL CATHETERS.,PERIPHERAL INTRAVASCULAR LITHOTRIPSY(M5 IVL CATHETERS)-THE SHOCKWAVE MEDICAL PERIPHERAL IVL CATHETER IS INDICATED FOR LITHOTRIPSY ENHANCED, LOW PRESSURE BALLOON DILATATION OF CALCIFIED, STENOTIC PERIPHERAL ARTERIES IN PATIENTS WHO ARE CANDIDATES FOR PERCUTANEOUS THERAPY.,CORONARY INTRAVASCULAR LITHOTRIPSY(C2 IVL CATHETERS)-THE SHOCKWAVE C2 CORONARY INTRAVASCULAR LITHOTRIPSY SYSTEM IS INDICATED FOR LITHOTRIPSY ENHANCED, LOW-PRESSURE BALLOON DILATATION OF CALCIFIED, STENOTIC DE NOVO CORONARY ARTERIES PRIOR TO STENTING.,PERIPHERAL INTRAVASCULAR LITHOTRIPSY(S4 IVL CATHETERS)-THE SHOCKWAVE MEDICAL PERIPHERAL IVL CATHETER IS INDICATED FOR LITHOTRIPSY ENHANCED, LOW PRESSURE BALLOON DILATATION OF CALCIFIED, STENOTIC PERIPHERAL ARTERIES IN PATIENTS WHO ARE CANDIDATES FOR PERCUTANEOUS THERAPY.
1960	IMP/MD/2019/000554	1.License Holder Name: GLOBAL MEDICAL DEVICES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CANNULAE(IPAS EASYGRIP® CANNULA)-THE IPAS EASYGRIP® CANNULAE ARE INTENDED FOR UTERINE ASPIRATION/UTERINE EVACUATION IN OBSTETRICS AND GYNECOLOGIC PATIENTS. CLINICAL INDICATIONS FOR UTERINE ASPIRATION ARE: TREATMENT OF INCOMPLETE ABORTION FOR UTERINE SIZES UP TO 12 WEEKS FROM LAST MENSTRUAL PERIOD AND ENDOMETRIAL BIOPSY.

1961	IMP/MD/2019/000555	1.License Holder Name: ALCON LABORATORIES (INDIA) PVT. LTD. , 11TH FLOOR, RMZ AZURE, BELLARY ROAD, HEBBAL ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560092 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OPHTHALMIC VISCOSURGICAL DEVICE(DISCOVISC)-DISCOVISC OVD IS INDICATED FOR USE DURING SURGERY IN THE ANTERIOR SEGMENT OF THE EYE. IT IS DESIGNED TO CREATE AND MAINTAIN SPACE, TO PROTECT THE CORNEAL ENDOTHELIUM AND OTHER INTRAOCULAR TISSUES AND TO MANIPULATE TISSUES DURING SURGERY. IT MAY ALSO BE USED TO COAT INTRAOCULAR LENSES AND INSTRUMENTS DURING CATARACT EXTRACTION AND IOL INSERTION.,OPHTHALMIC VISCOSURGICAL DEVICE(VISCOAT)-VISCOAT (OVD) IS INDICATED FOR USE AS A SURGICAL AID IN ANTERIOR SEGMENT PROCEDURES INCLUDING CATARACT EXTRACTION AND INTRAOCULAR LENS IMPLANTATION. VISCOAT (OVD) MAINTAINS A DEEP CHAMBER DURING ANTERIOR SEGMENT SURGERY, ENHANCES VISUALIZATION DURING THE SURGICAL PROCEDURE, AND PROTECTS THE CORNEAL ENDOTHELIUM AND OTHER OCULAR TISSUES. THE VISCOELASTICITY OF THE SOLUTION MAINTAINS THE NORMAL POSITION OF THE VITREOUS FACE AND PREVENTS FORMATION OF A FLAT CHAMBER DURING SURGERY.,OPHTHALMIC VISCOSURGICAL DEVICE(PROVISC)-PROVISC OPHTHALMIC VISCOSURGICAL DEVICE IS INDICATED FOR USE AS AN OPHTHALMIC SURGICAL AID IN THE ANTERIOR SEGMENT DURING CATARACT EXTRACTION AND INTRAOCULAR LENS (IOL) IMPLANTATION. OPHTHALMIC VISCOELASTICS SERVES TO MAINTAIN A DEEP ANTERIOR CHAMBER DURING ANTERIOR SEGMENT SURGERY ALLOWING REDUCED TRAUMA TO THE CORNEAL ENDOTHELIUM AND SURROUNDING OCULAR TISSUES. THEY HELP TO PUSH BACK THE VITREOUS FACE AND PREVENT FORMATION OF A FLAT CHAMBER DURING SURGERY.

1962	IMP/MD/2019/000556	1.License Holder Name: M/S ASIA ACTUAL INDIA (OPC) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTINUOUS GLUCOSE MONITORING SYSTEM(DEXCOM G6 CONTINUOUS GLUCOSE MONITORING SYSTEM (DEXCOM G6 SENSOR))-THE DEXCOM G6 CONTINUOUS GLUCOSE MONITORING SYSTEM (DEXCOM G6 SYSTEM OR G6) IS A GLUCOSE MONITORING SYSTEM INDICATED FOR THE MANAGEMENT OF DIABETES IN PERSONS AGE 2 YEARS AND OLDER. THE DEXCOM G6 CGM SYSTEM IS DESIGNED TO REPLACE FINGERSTICK BLOOD GLUCOSE (BG) TESTING FOR TREATMENT DECISIONS. INTERPRETATION OF THE DEXCOM G6 CGM SYSTEM RESULTS SHOULD BE BASED ON THE GLUCOSE TRENDS AND SEVERAL SEQUENTIAL READINGS OVER TIME. THE DEXCOM G6 CGM SYSTEM ALSO AIDS IN THE DETECTION OF EPISODES OF HYPERGLYCEMIA AND HYPOGLYCEMIA, FACILITATING BOTH ACUTE AND LONG-TERM THERAPY ADJUSTMENTS. THE DEXCOM G6 CGM SYSTEM IS INTENDED FOR USE BY PATIENTS AT HOME AND IN HEALTHCARE FACILITIES.
1963	IMP/MD/2019/000557	1.License Holder Name: NIPRO MEDICAL (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:Y-CONNECTOR(GOODTEC Y-CONNECTOR SET)-THIS PRODUCT IS DESIGNED TO WORK IN CONJUNCTION WITH GUIDING CATHETERS, ETC. TO REDUCE BLOOD LOSS WHILE ASSISTING IN MANIPULATION OF CATHETERS, ETC., INJECTION OF CONTRAST SOLUTION FROM A SIDE PORT, INJECTION OF MEDICINE OR SALINE SOLUTION, AND MEASUREMENT OF BLOOD PRESSURE.,CORONARY DILATATION CATHETER(LACROSSE NSE ALPHA CORONARY DILATATION CATHETER)-THE PURPOSE OF THE USE OF THE PRODUCT IS TO DILATE ATHEROSCLEROTIC OBSTRUCTED SEGMENTS OF CORONARY ARTERIES THAT ARE DIFFICULT TO DILATE BY REGULAR POBA(PLAIN OLD BALLOON ANGIOPLASTY) TO IMPROVE CORONARY ARTERY FLOW. THE DEVICE IS INTENDED TO BE USED IN VESSEL WITH A REFERENCE VESSEL DIAMETER OF 2.00 TO 4.00 MM.
1964	IMP/MD/2019/000558	1.License Holder Name: CORAL HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONDOMS(OKAMOTO)-IT IS USED AS A BARRIER CONTRACEPTIVE FOR PREVENTION OF PREGNANCY & AND PREVENTION OF SEXUALLY TRANSMITTED DISEASES.

1965	IMP/MD/2020/000001	1.License Holder Name: HEALTHIUM MEDTECH PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TITANIZED POLYPROPYLENE MESH(TISURE)-TISURE IS USED TO REPAIR OR PREVENT DEFECTS OF THE DIAPHRAGM IN THE AREA AROUND THE ESOPHAGUS.,TITANIZED POLYPROPYLENE MESH(TILENE)-TILENE GUARD IS USED FOR THE PREVENTION AND TREATMENT OF PARASTOMAL HERNIAS.,TITANIZED POLYPROPYLENE MESH(TIMESH)-TIMESH IS FOR THE SURGICAL CARE OR AVOIDANCE OF TISSUE DEFECTS IN ALL HERNIA INDICATIONS.
1966	IMP/MD/2020/000003	1.License Holder Name: M/S APPASAMY ASSOCIATES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACRYLIC INTRA OCULAR LENS(GALAXY FOLD SUPERPHOB)-IT IS USED FOR THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA. INDICATIONS INCLUDE MONOCULAR CATARACT, MATURE CATARACT, OCCUPATIONAL CATARACT, CONGENITAL CATARACT, TRAUMATIC CATARACT,PMMA INTRA OCULAR LENS(GALAXY LENS)-IT IS CONSISTING OF OPTIC AND HAPTIC COMPONENTS, INTENDED FOR SURGICAL IMPLANTATION INSIDE POSTERIOR CHAMBER OF THE EYE. INDICATIONS INCLUDE MONOCULAR CATARACT, MATURE CATARACT, CONGENITAL CATARACT, OCCUPATIONAL CATARACT, TRAUMATIC CATARACT,HEMA INTRA OCULAR LENS(GALAXY FOLD)-IT IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.

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1967	IMP/MD/2020/000004	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NON-VASCULAR GUIDE WIRE(RADIFOCUS®GUIDE WIRE M NON-VASCULAR)-THE RADIFOCUS GUIDE WIRE M NON-VASCULAR IS INTENDED TO ASSIST IN THE PLACEMENT OR EXCHANGE OF DEVICES DURING NON-VASCULAR PROCEDURES IN ENDOUROLOGY AND FOR THE CANNULATION OR INSERTION OF DEVICES INTO THE BILE DUCTS AND PANCREATIC DUCT (HEREAFTER REFERRED TO AS NON-VASCULAR PROCEDURES).,HYPODERMIC SAFETY NEEDLE(K-PACK SURSHIELDTM NEEDLE)-THE K-PACK SURSHIELDTM NEEDLEIS A STERILE, SINGLE-USE, HYPODERMIC NEEDLE, WITH A PASSIVE SHARPS PROTECTION FEATURE THAT COVERS THE CANNULA IMMEDIATELY AND PERMANENTLY AFTER USE; AND IS INTENDED FOR USE IN COMBINATION WITH HYPODERMIC SYRINGES FOR SUBCUTANEOUS AND INTRAMUSCULAR INJECTIONS.,HYPODERMIC NEEDLE(K-PACK II NEEDLE)-K-PACK II NEEDLES ARE STERILE, SINGLE USE HYPODERMIC NEEDLES INTENDED TO INJECT FLUIDS INTO, OR WITHDRAWN FLUIDS FROM, PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.,HYPODERMIC SYRINGE WITH FIXED NEEDLE (TERUMO SYRINGE 1 ML WITH FIXED NEEDLE TUBE)-TERUMO SYRINGE 1 ML WITH FIXED NEEDLE TUBE IS INTENDED FOR MANUAL ASPIRATION OF 600 IU/ML FSH OR FSH/LH AND FOR THE INJECTION OF THIS SOLUTION INTO PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.
1968	IMP/MD/2020/000006	1.License Holder Name: TWENTY FIRST CENTURY MEDICAL PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOPSY NEEDLES(QUICK-CORE)-THE QUICK-CORE BIOPSY NEEDLES ARE INTENDED TO BE USED FOR SOFT TISSUE ACCESS AND BIOPSY.,BONE BIOPSY NEEDLE (OSTEO-SITE® BONE BIOPSY NEEDLES AND SETS)-USED FOR VERTEBRAL BODY BIOPSY ACCESS, BIOPSY AND INFUSION DURING A VERTEBROPLASTY PROCEDURE.,BREAST LESION LOCALIZATION NEEDLE(KOPANS, X-REIDY, MREYE)-THE IZI BREAST LESION LOCALIZATION NEEDLE IS INTENDED FOR PREOPERATIVE MARKING OF NONPALPABLE BREAST LESIONS.

1969	IMP/MD/2020/000009	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTIPLE CLIP APPLIER (LIGACLIP)-THE LIGACLIP MCA MULTIPLE CLIP APPLIER HAS APPLICATION FOR USE ON VESSELS OR OTHER TUBULAR STRUCTURES WHEREVER A METAL LIGATING CLIP IS INDICATED. THE TISSUE LIGATED SHOULD BE CONSISTENT WITH THE SIZE OF THE CLIP.,DILATING TIP TROCARS(ENDOPATH® XCEL™ WITH OPTIVIEW TECHCNOLOGY)-THE ENDOPATH® XCEL™ DILATING TIP TROCAR HAS APPLICATIONS IN THORACIC, GYNECOLOGIC LAPAROSCOPY AND OTHER ABDOMINAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS.,BLUNT TIP TROCARS (ENDOPATH® XCEL™ WITH OPTIVIEW TECHCNOLOGY)-THE ENDOPATH® XCEL™ BLUNT TIP TROCAR HAS APPLICATION IN THORACIC, GYNECOLOGIC, LAPAROSCOPIC AND OTHER ABDOMINAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR MINIMALLY INVASIVE INSTRUMENTS.,UNIVERSAL TROCAR STABILITY SLEEVE (3 YEARS)(ENDOPATH® XCEL™ WITH OPTIVIEW TECHCNOLOGY)-THE ENDOPATH® XCEL™ UNIVERSAL TROCAR STABILITY SLEEVE HAS APPLICATIONS IN THORACIC, GYNECOLOGIC LAPAROSCOPY AND OTHER ABDOMINAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS.,ENDOSCOPIC MULTIPLE CLIP APPLIER(LIGAMAX5)-THE 5 MM ENDOSCOPIC MULTIPLE CLIP APPLIER IS INTENDED FOR USE ON TUBULAR STRUCTURES OR VESSELS WHEREVER A METAL LIGATING CLIP IS INDICATED., ENDOSCOPIC ROTATING MULTIPLE CLIP APPLIER(LIGACLIP)-THE LIGACLIP ENDOSCOPIC ROTATING MULTIPLE CLIP APPLIER IS INTENDED FOR USE ON TUBULAR STRUCTURES OR VESSELS WHEREVER A METAL LIGATING CLIP IS INDICATED. THE TISSUE BEING LIGATED SHOULD BE CONSISTENT WITH THE SIZE OF THE CLIP., BLADELESS TROCAR & STABILITY SLEEVE(BASX)-THE BASX™ BLADELESS TROCAR HAS APPLICATIONS IN ABDOMINAL AND GYNECOLOGIC MINIMALLY INVASIVE SURGICAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS., UNIVERSAL TROCAR STABILITY SLEEVE(ENDOPATH® XCEL™)-THE ENDOPATH® XCEL™ UNIVERSAL TROCAR STABILITY SLEEVE HAS APPLICATIONS IN THORACIC, GYNECOLOGIC LAPAROSCOPY AND OTHER ABDOMINAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS.,TROCARS - BLADELESS TROCAR WITH STABILITY SLEEVE (3 YEARS)(ENDOPATH® XCEL™ WITH OPTIVIEW TECHCNOLOGY)-THE ENDOPATH® XCEL™ BLADELESS TROCAR HAS APPLICATIONS IN ABDOMINAL, THORACIC, AND GYNECOLOGIC MINIMALLY INVASIVE SURGICAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS. THE

	TROCAR MAY BE USED WITH OR WITHOUT VISUALIZATION FOR PRIMARY AND SECONDARY INSERTIONS.,BLADELESS TROCAR (ENDOPATH® XCEL™)-THE ENDOPATH® XCEL™ BLADELESS TROCAR HAS APPLICATIONS IN ABDOMINAL, THORACIC, AND GYNECOLOGIC MINIMALLY INVASIVE SURGICAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS. THE TROCAR MAY BE USED WITH OR WITHOUT VISUALIZATION FOR PRIMARY AND SECONDARY INSERTIONS.,UNIVERSAL TROCAR STABILITY SLEEVE (5 YEARS)(ENDOPATH® XCEL™ WITH OPTIVIEW TECHCNOLOGY)-THE ENDOPATH® XCEL™ UNIVERSAL TROCAR STABILITY SLEEVE HAS APPLICATIONS IN THORACIC, GYNECOLOGIC LAPAROSCOPY AND OTHER ABDOMINAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS.,BLADELESS TROCAR WITH STABILITY SLEEVE (5 YEARS)(ENDOPATH® XCEL™ WITH OPTIVIEW TECHCNOLOGY)-THE ENDOPATH® XCEL™ BLADELESS TROCAR HAS APPLICATIONS IN ABDOMINAL, THORACIC, AND GYNECOLOGIC MINIMALLY INVASIVE SURGICAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS. THE TROCAR MAY BE USED WITH OR WITHOUT VISUALIZATION FOR PRIMARY AND SECONDARY INSERTIONS.

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1970	IMP/MD/2020/000009	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED ,A-1/50, ROOM NO. 2, 100 SHED AREA, G.L.D.C., VAPI, TAL PARDI (VALSAD) , VALSAD GUJARAT ,396195 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABLATION DEVICE (HARMONIC ACE(CURVED SHEARS))-THE HARMONIC® INSTRUMENTS ARE INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENT CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS, AND STEEL SCALPELS IN GENERAL, PLASTIC, PEDIATRIC, GYNECOLOGIC, UROLOGIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE), AND OTHER OPEN AND ENDOSCOPIC PROCEDURES.,ABLATION DEVICE (HARMONIC ACE (LAPAROSCOPIC SHEARS))-THE HARMONIC ACE® SHEARS + ADAPTIVE TISSUE TECHNOLOGY ARE INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENTS CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS AND STEEL SCALPELS IN GENERAL, PLASTIC, PEDIATRIC, GYNECOLOGIC, UROLOGIC, THORACIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE) AND OTHER OPEN AND ENDOSCOPIC PROCEDURES.,ABLATION DEVICE(HARMONIC (HD1000I SHEARS))-THE HARMONIC HD 1000I SHEARS INSTRUMENT IS INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENTS CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS AND STEEL SCALPELS IN GENERAL, PLASTIC, PEDIATRIC, GYNECOLOGIC, UROLOGIC, THORACIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE), SEALING AND TRANSECTION OF LYMPHATIC VESSELS, AND OTHER OPEN AND ENDOSCOPIC PROCEDURES. THE INSTRUMENTS ALLOW FOR THE COAGULATION OF VESSELS UP TO AND INCLUDING 7 MM IN DIAMETER, USING THE ENERGY BUTTON WITH ADVANCED HEMOSTASIS.,ABLATION DEVICE(HARMONIC FOCUS (LONG CURVED SHEARS))-THE HARMONIC FOCUS® SHEARS ARE INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENT CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS, AND STEEL SCALPELS IN GENERAL, PLASTIC, PEDIATRIC, GYNECOLOGIC, UROLOGIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE), AND OTHER OPEN PROCEDURES.,TISSUE SEALING DEVICE(ENSEAL (TISSUE SEALER G2 SUPER JAW CURVED))-THE ENSEAL® TISSUE SEALING DEVICE IS INDICATED FOR BIPOLAR COAGULATION AND

	MECHANICAL TRANSECTION OF TISSUE DURING OPEN PROCEDURES. IT IS A BIPOLAR INSTRUMENT FOR USE WITH AN ELECTROSURGICAL GENERATOR. IT IS INTENDED FOR USE DURING OPEN GENERAL AND GYNECOLOGICAL SURGERY TO CUT AND SEAL VESSELS, CUT, GRASP AND DISSECT DURING SURGERY. INDICATIONS FOR USE INCLUDE OPEN GENERAL, GYNECOLOGICAL SURGICAL PROCEDURES (INCLUDING UROLOGIC, THORACIC, PLASTIC AND RECONSTRUCTIVE, BOWEL RESECTIONS, HYSTERECTOMIES, CHOLECYSTECTOMIES, GALL BLADDER PROCEDURES, NISSEN FUNDOPLICATION, ADHESIOLYSIS, OOPHORECTOMIES, ETC.), OR ANY PROCEDURE WHERE VESSEL LIGATION (CUTTING AND SEALING), TISSUE GRASPING AND DISSECTION IS PERFORMED. THE DEVICES CAN BE USED ON VESSELS UP TO (AND INCLUDING) 7 MM AND BUNDLES AS LARGE AS WILL FIT IN THE JAWS OF THE INSTRUMENTS.,TISSUE SEALING DEVICE(ENSEAL (TISSUE G2 SEALERS))-THE ENSEAL® G2 TISSUE SEALERS ARE INDICATED FOR BIPOLAR COAGULATION AND MECHANICAL TRANSECTION OF TISSUE DURING LAPAROSCOPIC AND OPEN PROCEDURES. THE DEVICES ARE BIPOLAR ELECTROSURGICAL INSTRUMENTS FOR USE WITH AN ELECTROSURGICAL GENERATOR. THEY ARE INTENDED FOR USE DURING OPEN OR LAPAROSCOPIC, GENERAL AND GYNECOLOGICAL SURGERY TO CUT AND SEAL VESSELS, AND TO CUT, GRASP AND DISSECT TISSUE DURING SURGERY. INDICATIONS FOR USE INCLUDE OPEN AND LAPAROSCOPIC, GENERAL AND GYNECOLOGICAL SURGICAL PROCEDURES (INCLUDING UROLOGIC, THORACIC, PLASTIC AND RECONSTRUCTIVE, BOWEL RESECTIONS, HYSTERECTOMIES, CHOLECYSTECTOMIES, GALL BLADDER PROCEDURES, NISSEN FUNDOPLICATION, ADHESIOLYSIS, OOPHORECTOMIES, ETC.), OR ANY PROCEDURE WHERE VESSEL LIGATION (CUTTING AND SEALING), TISSUE GRASPING AND DISSECTION IS PERFORMED. THE DEVICES CAN BE USED ON VESSELS UP TO (AND INCLUDING) 7 MM AND BUNDLES AS LARGE AS WILL FIT IN THE JAWS OF THE INSTRUMENTS. THE ENSEAL® G2 TISSUE SEALERS HAVE NOT BEEN SHOWN TO BE EFFECTIVE FOR TUBAL STERILIZATION OR TUBAL COAGULATION FOR STERILIZATION PROCEDURES. DO NOT USE THESE DEVICES FOR THESE PROCEDURES.,ELECTROSURGERY PROBE(ENDOPATH)-THE ENDOPATH ELECTROSURGERY PROBE PLUS II SYSTEM HAS APPLICATION IN MINIMALLY INVASIVE PROCEDURES TO FACILITATE TISSUE DISSECTION, COAGULATION, IRRIGATION, AND FLUID EVACUATION THROUGH A COMMON TROCAR SLEEVE.,ABLATION DEVICE(HARMONIC SYNERGY (CURVED BLADE))-THE HARMONIC SYNERGY CURVED BLADE INSTRUMENTS ARE INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENT CAN BE USED AS

	AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS, AND STEEL SCALPELS IN GENERAL, PLASTIC, GYNECOLOGIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE) AND THORACIC SURGERY.,ABLATION DEVICE (HARMONIC SYNERGY (DISSECTING HOOK))-THE HARMONIC SYNERGY DISSECTING HOOK INSTRUMENTS ARE INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENTS CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS, AND STEEL SCALPELS IN GENERAL, PLASTIC, GYNECOLOGIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE), ENT (EARS, NOSE, THROAT), INCLUDING TISSUES OF THE SOFT PALATE, ORAL STRUCTURES, AND OROPHARYNGEAL AIRWAY, AND THORACIC SURGERY, INCLUDING MOBILIZATION OF THE INTERNAL MAMMARY ARTERY (IMA).,TISSUE SEALING DEVICE (ENSEAL (TISSUE SEALING DEVICE))-THE ENSEAL® TISSUE SEALING DEVICE IS INDICATED FOR BIPOLAR COAGULATION AND MECHANICAL TRANSECTION OF TISSUE DURING LAPAROSCOPIC AND OPEN PROCEDURES.,ABLATION DEVICE(HARMONIC(LAPAROSONIC DISSECTING HOOK))-THE HARMONIC 5 MM INSTRUMENT IS INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENT CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS, AND STEEL SCALPELS IN GENERAL, PLASTIC, GYNECOLOGIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE), AND THORACIC SURGERY, INCLUDING MOBILIZATION OF THE INTERNAL MAMMARY ARTERY (IMA).,TISSUE SEALING DEVICE(ENSEAL (G2 ARTICULATING TISSUE SEALERS))-THE ENSEAL® G2 ARTICULATING TISSUE SEALERS ARE INDICATED FOR BIPOLAR COAGULATION AND MECHANICAL TRANSECTION OF TISSUE DURING LAPAROSCOPIC AND OPEN PROCEDURES. THE DEVICES ARE BIPOLAR ELECTROSURGICAL INSTRUMENTS FOR USE WITH THE GENERATOR G11 (GEN11). THEY ARE INTENDED FOR USE DURING OPEN OR LAPAROSCOPIC, GENERAL AND GYNECOLOGICAL SURGERY TO CUT AND SEAL VESSELS, AND TO CUT, GRASP AND DISSECT TISSUE DURING SURGERY. INDICATIONS FOR USE INCLUDE OPEN AND LAPAROSCOPIC, GENERAL AND GYNECOLOGICAL SURGICAL PROCEDURES (INCLUDING UROLOGIC, THORACIC, PLASTIC AND RECONSTRUCTIVE, BOWEL RESECTIONS, HYSTERECTOMIES, CHOLECYSTECTOMIES, GALL BLADDER PROCEDURES, NISSEN FUNDOPLICATION, ADHESIOLYSIS, OOPHORECTOMIES, ETC.), OR ANY PROCEDURE WHERE VESSEL LIGATION (CUTTING AND SEALING), TISSUE GRASPING AND DISSECTION IS PERFORMED. THE DEVICES CAN BE USED ON VESSELS

	UP TO (AND INCLUDING) 7MM AND TISSUE AND/OR VASCULAR BUNDLES AS LARGE AS WILL FIT IN THE JAWS OF THE INSTRUMENTS. THE ENSEAL® G2 ARTICULATING TISSUE SEALERS HAVE NOT BEEN SHOWN TO BE EFFECTIVE FOR TUBAL STERILIZATION OR TUBAL COAGULATION FOR STERILIZATION PROCEDURES. DO NOT USE THESE DEVICES FOR THESE PROCEDURES.,TISSUE SEALING DEVICE (ENSEAL (X1 LARGE JAW TISSUE SEALER))-THE ENSEAL X1 LARGE JAW TISSUE SEALER INSTRUMENT IS A DEDICATED BIPOLAR ELECTROSURGICAL INSTRUMENT INTENDED FOR USE IN OPEN SURGICAL PROCEDURES WHERE LIGATION AND DIVISION OF VESSELS IS DESIRED. IT IS A BIPOLAR INSTRUMENT FOR USE WITH THE ETHICON GENERATOR G11 (GEN11). IT IS INTENDED FOR USE DURING OPEN SURGERY TO CUT AND SEAL VESSELS, CUT, GRASP, AND DISSECT TISSUE DURING SURGERY. INDICATIONS FOR USE INCLUDE OPEN GENERAL, GYNECOLOGIC, UROLOGIC, THORACIC, AND VASCULAR PROCEDURES. THESE PROCEDURES INCLUDE HYSTERECTOMIES, COLECTOMIES, NISSEN FUNDOPLICATION, ADHESIOLYSIS, OOPHORECTOMIES, ETC. THE DEVICES CAN BE USED ON VESSELS (ARTERIES, VEINS, PULMONARY VASCULATURE, LYMPHATICS) UP TO AND INCLUDING 7 MM AND TISSUE BUNDLES., ABLATION DEVICE(HARMONIC FOCUS (SHEARS + ADAPTIVE TISSUE TECHNOLOGY))-THE HARMONIC FOCUS® LONG SHEARS + ADAPTIVE TISSUE TECHNOLOGY ARE INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENT CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS, AND STEEL SCALPELS IN GENERAL, OTORHINOLARYNGOLOGIC (ENT), PLASTIC, PEDIATRIC, GYNECOLOGIC, UROLOGIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE) AND OTHER OPEN PROCEDURES.,ABLATION DEVICE(HARMONIC ACE (SHEARS WITH ADVANCED HEMOSTASIS))-THE HARMONIC ACE®+7, 5 MM DIAMETER SHEARS WITH ADVANCED HEMOSTASIS ARE INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENTS CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS AND STEEL SCALPELS IN GENERAL, PLASTIC, PEDIATRIC, GYNECOLOGIC, UROLOGIC, THORACIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE), SEALING AND TRANSECTION OF LYMPHATIC VESSELS, AND OTHER OPEN AND ENDOSCOPIC PROCEDURES. THE INSTRUMENTS ALLOW FOR THE COAGULATION OF VESSELS UP TO AND INCLUDING 7 MM IN DIAMETER, USING THE ADVANCED HEMOSTASIS HAND CONTROL BUTTON.

1971	IMP/MD/2020/000011	1.License Holder Name: M.S. MEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HAEMODIALYSIS CATHETER KIT/SET(ABLECATH - DISPOSABLE HAEMODIALYSIS CATHETER KIT/SET & ACCESSORIES)-THE ABLE ® HEMODIALYSIS CATHETERS MAY BE APPLICABLE TO THE ONE OF FOLLOWING THERAPY: - TO SUPPLY THE TEMPORARY BLOOD VESSEL ACCESS IN HEMODIALYSIS TREATMENT; - MONITOR OF CENTRAL VENOUS PRESSURE. - CONTINUOUS OR DISCONTINUOUS VENOUS TRANSFUSION. THE CATHETER IS SURGICALLY PENETRATED INTO THREE OPTIONAL PUNCTURE POINTS DEPENDED ON THE CLINICAL REQUIREMENT WITH SELDINGER TECHNIQUE .THE INSERTION SITES ARE: 1. INTERNAL JUGULAR VEIN; 2. SUBCLAVIAN VEIN; 3. FEMORAL VEIN IT IS POSSIBLE TO BE INSERTED INSIDE THE BODY FOR LESS THAN 30 DAYS. IF DURATION EXCEEDS 30 DAYS, IT MAY OCCURE THE RISK OF COMBINING THE CATHETER AND INSIDE TISSUE, WHICH RESULT IN SERIOUS INCIDENT.,CENTRAL VENOUS CATHETER KIT/SET (ABLECATH - DISPOSABLE CENTRAL VENOUS CATHETER & ACCESSORIES)-THE ABLE CENTRAL VENOUS CATHETERS KIT/ SET MAY BE APPLICABLE TO THE ONE OF FOLLOWING THERAPY. - MONITOR CENTRAL VENOUS PRESSURE -CONTINUOUS OR DISCONTINUOUS VENOUS TRANSFUSION -BLOOD SAMPLING THE CATHETER IS SURGICALLY PENETRATED INTO THREE OPTIONAL PUNCTURE POINTS DEPENDED ON THE CLINICAL REQUIREMENT WITH SELDINGER TECHNIQUE. THE INSERTION SITES ARE : 1.INTERNAL JUGULAR VEIN 2. SUBCLAVIAN VEIN 3 .FEMORAL VEIN IT IS POSSIBLE TO BE INSERTED INSIDE THE BODY FOR LESS THAN 30 DAYS. IF DURATION EXCEEDS 30 DAYS, IT MAY OCCURE THE RISK OF COMBINING THE CATHETER AND INSIDE TISSUE, WHICH RESULT IN SERIOUS INCIDENT.
1972	IMP/MD/2020/000013	1.License Holder Name: RADIANT TECHNOLOGIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE MARROW BIOPSY NEEDLE(SNARECOIL)-THE RANFAC BONE MARROW BIOPSY NEEDLE IS INTENDED FOR THE PURPOSE OF HARVESTING BONE MARROW SPECIMENS.

1973	IMP/MD/2020/000016	1.License Holder Name: BIO INDIA INTERVENTIONAL TECHNOLOGIES PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DRUG ELUTING CARBOSTENT(CRE8)-THE CORONARY STENT IS INDICATED FOR THE TREATMENT OF STENOTIC LESIONS IN CORONARY ARTERIES AND CORONARY ARTERY BYPASSES TO MAINTAIN VESSEL PATENCY. RANDOMIZED CLINICAL TRIALS HAVE SHOWN THAT DRUG-ELUTING STENTS CAN SIGNIFICANTLY REDUCE ANGIOGRAPHIC LATE LOSS (LATE LUMEN LOSS), BINARY RESTENOSIS AND REPETITION OF TARGET LESION REVASCULARIZATION.
1974	IMP/MD/2020/000017	1.License Holder Name: HEMANT SURGICAL INDUSTRIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTING NEEDLE FOR SINGLE USE(NIDOVAC)-BLOOD COLLECTION NEEDLES IS INTENDED TO BE USED FOR EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1975	IMP/MD/2020/000018	1.License Holder Name: ABBOTT HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CORONARY DILATATION CATHETER(MINI TREK RX CORONARY DILATATION CATHETER , MINI TREK II OTW CORONARY DILATATION CATHETER)-THE MINI TREK RX AND MINI TREK II OTW CORONARY DILATATION CATHETER IS INDICATED FOR: • BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION • BALLOON DILATATION OF A CORONARY ARTERY OCCLUSION, FOR THE PURPOSE OF RESTORING CORONARY FLOW IN PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION (MI) • BALLOON DILATATION OF A STENT AFTER IMPLANTATION (BALLOON MODELS 2.00 MM ONLY) • BALLOON DILATATION OF DE NOVO CHRONIC TOTAL CORONARY OCCLUSIONS (CTO),CORONARY DILATATION CATHETER(TRAVELER RX CORONARY DILATATION CATHETER , NC TRAVELER RX CORONARY DILATATION CATHETER)-THE TRAVELER RX AND NC TRAVELER CORONARY DILATATION CATHETER IS INDICATED FOR: • BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION • BALLOON DILATATION OF A CORONARY ARTERY OCCLUSION, FOR THE PURPOSE OF RESTORING CORONARY FLOW IN PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION • BALLOON DILATATION OF A STENT AFTER IMPLANTATION (BALLOON MODELS 2.00 MM – 5.00 MM ONLY),BALLOON DILATATION CATHETER (ARMADA 14 XT PTA CATHETER)-THE ARMADA 14 XT PTA CATHETER IS INDICATED TO DILATE STENOSIS IN FEMORAL, POPLITEAL, INFRAPOPLITEAL AND RENAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THE 2.0 MM TO 5.0 MM BALLOON DIAMETERS ARE ALSO INDICATED FOR POST-DILATATION OF STENTS IN THE PERIPHERAL VASCULATURE.,CORONARY DILATATION CATHETER(TREK RX CORONARY DILATATION CATHETER ,TREK OTW CORONARY DILATATION CATHETER , NC TREK RX CORONARY DILATATION CATHETER)-• BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION • BALLOON DILATATION OF A CORONARY ARTERY OCCLUSION, FOR THE PURPOSE OF RESTORING CORONARY FLOW IN PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION • BALLOON DILATATION OF A STENT AFTER IMPLANTATION, BALLOON DILATATION CATHETER(ARMADA 35 PTA CATHETER , ARMADA 35 LL PTA CATHETER)-THE DEVICE IS INTENDED FOR

		DILATATION OF LESIONS IN THE RENAL, ILIAC, FEMORAL, POPLITEAL, TIBIAL, AND PERONEAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR STENT POST-DILATATION IN THE PERIPHERAL VASCULATURE.
1976	IMP/MD/2020/000019	1.License Holder Name: M/S REGENICS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT SYSTEM(ROOTT (SCREW))-DENTAL IMPLANT SYSTEM ROOTT ABUTMENTS ARE INDICATED FOR SINGLE TOOTH REPLACEMENT AND MULTIPLE TOOTH RESTORATIONS OR TO PROVIDE SUPPORT FOR PROSTHETIC RESTORATIONS SUCH AS CROWNS, BRIDGES AND OVERDENTURES. THE PROSTHETIC RESTORATION CAN BE CEMENTED OR SCREW-RETAINED.,DENTAL IMPLANT SYSTEM(ROOTT (ABUTMENTS))-DENTAL IMPLANT SYSTEM ROOTT ABUTMENTS ARE INDICATED FOR SINGLE TOOTH REPLACEMENT AND MULTIPLE TOOTH RESTORATIONS OR TO PROVIDE SUPPORT FOR PROSTHETIC RESTORATIONS SUCH AS CROWNS, BRIDGES AND OVERDENTURES. THE PROSTHETIC RESTORATION CAN BE CEMENTED OR SCREW-RETAINED.,DENTAL IMPLANT SYSTEM(ROOTT DENTAL IMPLANT (ROOT FORM TYPE, COMPRESSIVE TYPE, BASAL TYPE, BASAL SS TYPE))-DENTAL IMPLANTS ARE INTENDED TO REPLACE MISSING OR CORRUPTED TEETH. • THAT ARE NOT POSSIBLE TO BE REPAIRED, REPLACED OR COMPENSATED BY OTHER MEANS; • WHERE OTHER SOLUTIONS HAVE AN UNDESIRED IMPACT TO SOUND TEETH, OR • WHERE IMPLANTS ARE DESIRED FOR OBTAINING AN OPTIMAL COSMETIC RESULT. IN GENERAL, ROOTT IMPLANTS ARE INTENDED FOR SURGICAL PLACEMENT IN THE UPPER OR LOWER JAW TO PROVIDE AN ANCHORAGE FOR PROSTHETIC SUPERSTRUCTURES FOR TOOTH RESTORATIONS OR AS A TERMINAL OR INTERMEDIARY ABUTMENT FOR FIXED OR REMOVABLE BRIDGEWORK, AND TO RETAIN OVERDENTURES.

1977	IMP/MD/2020/000020	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANNULOPLASTY RING (SJM RIGID SADDLE ANNULOPLASTY RING)-IT IS INDICATED FOR USE TO CORRECT ANNULAR DILATION, INCREASE LEAFLET COAPTATION, AND PREVENT FURTHER DILATION OF THE MITRAL VALVE ANNULUS CAUSED BY DISEASE STATES SUCH AS DEGENERATIVE DISEASE, RHEUMATIC DISEASE, ISCHEMIA, OR VASCULAR DISEASE. THE COMBINATION OF PROSTHETIC RING WITH VALVULOPLASTY MAY BE USED IN ALL ACQUIRED OR CONGENITAL MITRAL INSUFFICIENCIES WITH DILATION AND DEFORMATION OF THE FIBROUS MITRAL ANNULUS. FOR MITRAL INSUFFICIENCIES WITH NO SUB VALVULAR LESIONS AND NORMAL VALVULAR MOVEMENTS, PROSTHETIC RING IMPLANT ALONE MAY BE SUFFICIENT. HOWEVER, ANNULOPLASTY RING IMPLANT ALONG WITH MITRAL VALVULOPLASTY REPAIR MUST BE CONSIDERED FOR INSUFFICIENCIES WITH A PROLAPSED VALVE DUE TO ELONGATION OR RUPTURE OF THE CHORDAE TENDINEAE AND FOR INSUFFICIENCIES WITH LIMITATION OF VALVULAR MOVEMENTS DUE TO FUSION OF THE COMMISSURES OR CHORDAE TENDINEAE, OR CHORDAL HYPERTROPHY,DELIVERY SYSTEM (FLEXNAV™ DELIVERY SYSTEM)-THE FLEXNAV™ DELIVERY SYSTEM IS INDICATED FOR TRANSFEMORAL OR SUBCLAVIAN/AXILLARY DELIVERY OF THE PORTICO™ VALVE.,VALVED GRAFT(SJM MASTER SERIES COATED AORTIC VALVED GRAFT (ROTATABLE))-IT IS INDICATED FOR THE REPLACEMENT OF A MALFUNCTIONING NATIVE OR PROSTHETIC AORTIC HEART VALVE AND ASCENDING AORTA , LOADING SYSTEM(FLEXNAV™ LOADING SYSTEM)-THE FLEXNAV™ LOADING SYSTEM IS INDICATED FOR LOADING THE PORTICO™ VALVE IN THE FLEXNAV™ DELIVERY SYSTEM.,TISSUE HEART VALVE (TRIFECTA VALVE AORTIC)-THE TRIFECTA VALVE IS INTENDED AS A REPLACEMENT FOR A DISEASED, DAMAGED, OR MALFUNCTIONING AORTIC HEART VALVE. THE TRIFECTA VALVE MAY ALSO BE USED AS REPLACEMENT FOR PREVIOUSLY IMPLANTED AORTIC PROSTHETIC HEART VALVES. ,HEART VALVE(SJM MECHANICAL HEART VALVE- SJM MASTER SERIES (ROTATABLE)- MITRAL)-IT IS INTENDED FOR USE AS A REPLACEMENT VALVE IN PATIENTS WITH A DISEASED, DAMAGED, OR MALFUNCTIONING AORTIC OR MITRAL HEART VALVE. THIS DEVICE MAY ALSO BE USED TO REPLACE A PREVIOUSLY IMPLANTED PROSTHETIC HEART VALVE.,ANNULOPLASTY RING(SJM SEGUIN ANNULOPLASTY RING)-IT IS INDICATED FOR USE IN THE REPAIR OF MITRAL VALVES THAT ARE DISEASED OR DAMAGED DUE TO ACQUIRED OR CONGENITAL PROCESSES. ,HEART VALVE(SJM MECHANICAL HEART VALVE- SJM MASTER SERIES (ROTATABLE)- AORTIC HEMODYNAMIC PLUS)-IT IS INTENDED FOR USE AS A

		REPLACEMENT VALVE IN PATIENTS WITH A DISEASED, DAMAGED, OR MALFUNCTIONING AORTIC OR MITRAL HEART VALVE. THIS DEVICE MAY ALSO BE USED TO REPLACE A PREVIOUSLY IMPLANTED PROSTHETIC HEART VALVE,HEART VALVE(SJM MECHANICAL HEART VALVE- SJM MASTER SERIES (ROTATABLE)- AORTIC)-IT IS INTENDED FOR USE AS A REPLACEMENT VALVE IN PATIENTS WITH A DISEASED, DAMAGED, OR MALFUNCTIONING AORTIC OR MITRAL HEART VALVE. THIS DEVICE MAY ALSO BE USED TO REPLACE A PREVIOUSLY IMPLANTED PROSTHETIC HEART VALVE.,HEART VALVE(SJM REGENT MECHANICAL HEART VALVE (ROTATABLE))-IT IS INTENDED FOR USE AS A REPLACEMENT VALVE IN PATIENTS WITH A DISEASED, DAMAGED, OR MALFUNCTIONING AORTIC HEART VALVE. IT MAY ALSO BE USED TO REPLACE A PREVIOUSLY IMPLANTED AORTIC PROSTHETIC HEART VALVE.
1978	IMP/MD/2020/000021	1.License Holder Name: SCHULKE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:7.7 G (7.7% W/W) DIDECYLDIMETHYLAMMONIUM CHLORIDE, 0.4 G (0.4% W/W) POLYHEXAMETHYLENE BIGUANIDE (CONTAINS SUBTILISIN, POLYHEXAMETHYLENE BIGUANIDE)(GIGAZYME X-TRA)-DETERGENT CONCENTRATE WITH DISINFECTING EFFECT FOR THE MANUAL CLEANING OF ENDOSCOPES AND SURGICAL INSTRUMENTS.
1979	IMP/MD/2020/000022	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLINICAL SCREWS - TITANIUM AND ITS ALLOYS(ABUTMENT SCREW, PROSTHETIC SCREW) -THESE ARTICLES ARE ACCESSORIES AND DO NOT HAVE A SPECIFIC IFU. 6050, 6051, 6052 - PART OF THE HBC SYSTEM (SINGLE UNIT SCREW RETAINED). THE SCREWS ARE SOLD AS PART OF P/N 6040, 6041, 6042 ; 5121 – IH ABUTMENT SCREW FOR LAB USE; 5122 – IH ABUTMENT SCREW FOR CLINICIAN USE; 5127 – SCREW FOR 35° ABUTMENT; 6092 – SCREW-RETAINED ABUTMENT SCREW FOR CLINICIAN USE; 7345 - CHC ABUTMENT SCREW FOR CLINICIAN USE; 3510 - CS ABUTMENT SCREW FOR CLINICIAN USE; 4994 - THIS SCREW IS USED TO CONNECT DIGITALLY RESTORED CROWN DIRECTLY ON SCREW-RETAINED ABUTMENT (TCT); 6093 - SCREW-RETAINED ABUTMENT SCREW FOR LAB USE

1980	IMP/MD/2020/000023	1.License Holder Name: ABBOTT HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDE WIRE ACCESSORY KIT(• GUIDE WIRE ACCESSORY KIT WITH 0.115" RHV • GUIDE WIRE ACCESSORY KIT WITH 0.096" RHV • GUIDE WIRE ACCESSORY KIT WITH COPILOT BLEEDBACK CONTROL VALVE)-THE GUIDE WIRE ACCESSORY KIT IS RECOMMENDED FOR USE DURING VASCULAR PROCEDURES IN CONJUNCTION WITH INTERVENTIONAL AND / OR DIAGNOSTIC DEVICES (E.G., BALLOON DILATATION CATHETERS, ATHERECTOMY DEVICES, STENT DELIVERY SYSTEMS, INTRAVASCULAR ULTRASOUND DEVICES). THE INTENDED USE FOR THE THREE DISPOSABLE DEVICES IN THE GUIDE WIRE ACCESSORY KIT ARE AS FOLLOWS: COPILOT BLEEDBACK CONTROL VALVE – THE COPILOT BLEEDBACK CONTROL VALVE IS INDICATED FOR MAINTAINING A SEAL AROUND DIAGNOSTIC / INTERVENTIONAL DEVICES WITH AN OUTSIDE DIAMETER 0.096" (2.44 MM) DURING INTERVENTIONAL PROCEDURES. GUIDE WIRE INTRODUCER – THE GUIDE WIRE INTRODUCER IS RECOMMENDED FOR USE DURING VASCULAR PROCEDURES IN CONJUNCTION WITH INTERVENTIONAL DEVICES AND / OR DIAGNOSTIC DEVICES (E.G., BALLOON DILATATION CATHETERS, ATHERECTOMY DEVICES, STENT DELIVERY SYSTEMS, INTRAVASCULAR ULTRASOUND DEVICES) TO ASSIST WITH THE INTRODUCTION OF THE GUIDE WIRE. TORQUE DEVICE – THE TORQUE DEVICE IS RECOMMENDED FOR USE DURING VASCULAR PROCEDURES IN CONJUNCTION WITH INTERVENTIONAL AND / OR DIAGNOSTIC DEVICES (E.G., BALLOON DILATATION CATHETERS, ATHERECTOMY DEVICES, STENT DELIVERY SYSTEMS, INTRAVASCULAR ULTRASOUND DEVICES) TO FACILITATE STEERING THE GUIDE WIRE WITHIN THE VASCULAR ANATOMY.,INFLATION DEVICE(20/30 INDEFLATOR INFLATION DEVICE)-THE 20/30 INDEFLATOR INFLATION DEVICE IS RECOMMENDED FOR USE DURING CARDIOVASCULAR PROCEDURES IN CONJUNCTION WITH INTERVENTIONAL DEVICES SUCH AS BALLOON DILATATION CATHETERS TO CREATE AND MONITOR PRESSURE IN THE BALLOON., 20/30 PRIORITY PACK ACCESSORY KIT(• 20/30 PRIORITY PACK WITH COPILOT BLEEDBACK CONTROL VALVE • 20/30 PRIORITY PACK ACCESSORY KIT WITH 0.115" RHV • 20/30 PRIORITY PACK ACCESSORY KIT WITH 0.096" RHV)-THE INTENDED USES FOR THE FOUR DISPOSABLE DEVICES IN THE ACCESSORY KIT ARE AS FOLLOWS: 20/30 INDEFLATOR INFLATION DEVICE: - THE INFLATION DEVICE IS RECOMMENDED FOR USE DURING VASCULAR PROCEDURES IN CONJUNCTION WITH INTERVENTIONAL DEVICES SUCH AS BALLOON DILATATION CATHETERS TO CREATE AND MONITOR PRESSURE IN THE BALLOON. COPILOT BLEEDBACK

	CONTROL VALVE: - THE COPILOT BLEEDBACK CONTROL VALVE IS INDICATED FOR MAINTAINING A SEAL AROUND DIAGNOSTIC / INTERVENTIONAL DEVICES WITH AN OUTSIDE DIAMETER 0.096" (2.44 MM) DURING INTERVENTIONAL PROCEDURES. GUIDE WIRE INTRODUCER: - THE GUIDE WIRE INTRODUCER IS RECOMMENDED FOR USE DURING VASCULAR PROCEDURES IN CONJUNCTION WITH INTERVENTIONAL DEVICES AND / OR DIAGNOSTIC DEVICES (E.G., BALLOON DILATATION CATHETERS, ATHERECTOMY DEVICES, STENT DELIVERY SYSTEMS, INTRAVASCULAR ULTRASOUND DEVICES) TO ASSIST WITH THE INTRODUCTION OF THE GUIDE WIRE. TORQUE DEVICE: - THE TORQUE DEVICE IS RECOMMENDED FOR USE DURING VASCULAR PROCEDURES IN CONJUNCTION WITH INTERVENTIONAL AND / OR DIAGNOSTIC DEVICES (E.G., BALLOON DILATATION CATHETERS, ATHERECTOMY DEVICES, STENT DELIVERY SYSTEMS, INTRAVASCULAR ULTRASOUND DEVICES) TO FACILITATE STEERING THE GUIDE WIRE WITHIN THE VASCULAR ANATOMY. THE 20/30 PRIORITY PACK ACCESSORY KIT IS RECOMMENDED FOR USE DURING VASCULAR PROCEDURES IN CONJUNCTION WITH INTERVENTIONAL AND / OR DIAGNOSTIC DEVICES (E.G., BALLOON DILATATION CATHETERS, ATHERECTOMY DEVICES, STENT DELIVERY SYSTEMS, INTRAVASCULAR ULTRASOUND DEVICES). THE 20/30 INDEFLATOR INFLATION DEVICE IS RECOMMENDED FOR USE IN CONJUNCTION WITH BALLOON CATHETERS.,HEMOSTATIC VALVE(COPILOT BLEEDBACK CONTROL VALVE)-THE COPILOT BLEEDBACK CONTROL VALVE IS INTENDED TO MAINTAIN HEMOSTASIS DURING THE INTRODUCTION / WITHDRAWAL AND USE OF DIAGNOSTIC /INTERVENTIONAL DEVICES. THE COPILOT BLEEDBACK CONTROL VALVE IS INDICATED FOR MAINTAINING A SEAL AROUND DIAGNOSTIC / INTERVENTIONAL DEVICES WITH AN OUTSIDE DIAMETER 0.096” (2.44 MM) DURING INTERVENTIONAL PROCEDURES.,PLUS 30 PRIORITY PACK ACCESSORY KIT(• PLUS 30 PRIORITY PACK ACCESSORY KIT WITH 0.096” RHV • PLUS 30 PRIORITY PACK ACCESSORY KIT WITH 0.115” RHV)-THE PLUS 30 PRIORITY PACK ACCESSORY KIT IS RECOMMENDED FOR USE DURING VASCULAR PROCEDURES IN CONJUNCTION WITH INTERVENTIONAL AND / OR DIAGNOSTIC DEVICES (E.G., BALLOON DILATATION CATHETERS, ATHERECTOMY DEVICES, STENT DELIVERY SYSTEMS, INTRAVASCULAR ULTRASOUND DEVICES). THE INDEFLATOR PLUS 30 INFLATION DEVICE IS RECOMMENDED FOR USE IN CONJUNCTION WITH BALLOON CATHETERS.,INFLATION DEVICE(INDEFLATOR PLUS 30 INFLATION DEVICE)-THE INDEFLATOR PLUS 30 INFLATION DEVICE IS RECOMMENDED FOR USE DURING VASCULAR PROCEDURES IN CONJUNCTION WITH INTERVENTIONAL DEVICES SUCH AS BALLOON DILATATION CATHETERS TO CREATE AND MONITOR PRESSURE IN

		THE BALLOON.
1981	IMP/MD/2020/000025	1.License Holder Name: VASCULAR CONCEPTS LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRANSCATHETER AORTIC VALVE(HYDRA AORTIC VALVE AND DELIVERY SYSTEM)-THE HYDRA VALVE SYSTEM IS DESIGNED FOR USE IN HIGH SURGICAL RISK PATIENTS WITH SEVERE AORTIC STENOSIS. THE HYDRA VALVE SYSTEM IS INDICATED FOR PATIENTS WITH SEVERE SYMPTOMATIC NATIVE AORTIC VALVE STENOSIS NECESSITATING VALVE REPLACEMENT OF THE NATIVE AORTIC HEART VALVE WITHOUT OPEN HEART SURGERY AND WITHOUT CONCOMITANT SURGICAL REMOVAL OF THE FAILED NATIVE VALVE AND PRESENTING WITH FEMORAL OR SUBCLAVIAN/AXILLARY ACCESS VESSELS WITH DIAMETERS 6MM AND ANATOMICAL DIMENSIONS OF THE AORTIC ANNULUS DIAMETER BETWEEN 18MM TO 27MM.
1982	IMP/MD/2020/000026	1.License Holder Name: BHARAT HEALTHCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIORESORBABLE INTERFERENCE SCREW(EUROSCREW)-EUROSCREW ARE RECOMMENDED FOR LIGAMENT ATTACHMENT, FOR EXAMPLE IN ANTERIOR/POSTERIOR CRUCIATE LIGAMENT RECONSTRUCTIONS, REINSERTION OF THE LONG-HEAD BICEPS OR ANKLE LIGAMENTS., BONE CEMENT(OPACITY+)-THE OPACITY+ IS INDICATED FOR THE FIXATION OF PATHOLOGICAL FRACTURE OF THE VERTEBRAL BODY USING VERTEBROPLASTY OR KYPHOPLASTY PROCEDURES. PAINFUL VERTEBRAL COMPRESSION FRACTURES OF THE VERTEBRAL BODY MAY RESULT FROM OSTEOPOROSIS, BENIGN LESIONS (HEMANGIOMA), OR LESIONS (METASTATIC CANCERS, MYELOMA)

1983	IMP/MD/2020/000027	1.License Holder Name: MATSON SURGICALS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE INJECTION SITE ADAPTERS (OXYFLOW)-THE PRODUCT IS USED TO CLOSE THE TRANSFUSION PORT, SUPPLY LIQUID MEDICINE WHEN THE ADAPTOR IS CLOSED AND PREVENT THE TRANSFUSION SYSTEM FROM POLLUTING DURING INTRAVENOUS INFUSION THERAPY.,CENTRAL VENOUS CATHETER KIT/SET(OXYFLOW)-THE PRODUCT IS USED TO INFUSE HIGHLY OSMOLAR OR GREATLY VEIN-IRRITATING SOLUTIONS, FOR INTERMITTENT OR CONTINUOUS MONITORING OF CENTRAL VENOUS PRESSURE, FOR BLOOD SAMPLING. IT IS POSSIBLE TO BE INSERTED INSIDE THE BODY FOR MORE THAN 30 DAYS., DISPOSABLE BLOOD PRESSURE TRANSDUCERS & ACCESSORIES (OXYFLOW)-THE PRODUCT APPLY TO CLINICAL FOR TRAUMATIC ARTERIOVENOUS PRESSURE MONITORING.,HAEMODIALYSIS CATHETER KIT/SET(OXYFLOW)-THE PRODUCT IS APPLICABLE FOR HEMODIALYSIS, VENOUS TRANSFUSION, CONTINUOUS MONITORING THE VENOUS PRESSURE. THE TIME OF USE IS LESS THAN 30 DAYS.
1984	IMP/MD/2020/000028	1.License Holder Name: NIPRO MEDICAL (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADHESIVE PRESSURE BANDAGE(PUSHBAN)-WOUND SURFACE PROTECTION (THIS PRODUCT IS USED AT THE PUNCTURE SITE AFTER ARTIFICIAL DIALYSIS TREATMENT, AND IS USED TO ABSORB BLOOD AND STOP BLEEDING.)

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1985	IMP/MD/2020/000029	1.License Holder Name: ANAECON INDIA HEALTHCARE PVT. LTD. ,E-57, PHASE-1, SECTOR A-7, TRONICA INDUSTRIAL AREA, SIGNATURE CITY, GHAZIABAD, U.P. ,GHAZIABAD UTTAR PRADESH ,201103 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE PERFUSION SETS(DISPOSABLESFOR INJECTOR CT MOTION XD 8000 / DISPOSABLES FOR INJECTOR XD 200X)-PATIENT HOSE XD 2030, XD 2035, XD 2040, XD 2045: THE PATIENT HOSE FOR ULRICH MEDICAL CT/MRI INJECTORS IS INTENDED FOR THE VENOUS ADMINISTRATION OF CONTRAST MEDIA AND PHYSIOLOGICAL SALINE SOLUTIONS (NACL) DURING A CT/MRI EXAMINATION. THE PATIENT HOSE CREATES THE CONNECTION FROM THE ULRICH MEDICAL PUMP HOSE (DEVICE SIDE) TO THE PATIENT. // PUMP HOSE XD 2020FOR ULRICH MEDICAL CT/MRI INJECTORS: THE PUMP HOSE FOR ULRICH MEDICAL CT/MRI INJECTORS IS INTENDED FOR THE VENOUS ADMINISTRATION OF CONTRAST MEDIA AND PHYSIOLOGICAL SALINE SOLUTION (NACL) DURING A CT/MRI EXAMINATION. THE PUMP HOSE CONNECTS THE INJECTOR (ON THE DEVICE SIDE) TO THE PATIENT HOSE. THE PUMP HOSE CAN BE USED FOR ANY NUMBER OF INJECTIONS WITHIN A 24HOUR PERIOD. // PUMP HOSE XD 8003 FOR ULRICH MEDICAL CT/MRI INJECTORS: THE PUMP TUBING FOR ULRICH MEDICAL CT/MRI INJECTORS IS INTENDED FOR THE VENOUS ADMINISTRATION OF CONTRAST MEDIA AND PHYSIOLOGICAL SALINE SOLUTION (NACL) DURING A CT/MRI EXAMINATION. THE PUMP TUBING CONNECTS THE INJECTOR (ON THE DEVICE SIDE) TO THE PATIENT TUBING. THE PUMP TUBING CAN BE USED FOR ANY NUMBER OF INJECTIONS WITHIN A24HOUR PERIOD. // RESERVOIR FOR CONTRAST MEDIA: (FOR XD 2019): THE RESERVOIR ENSURES THE COMPATIBILITY OF THE PUMP TUBING WITH MEDIA CONTAINERS THAT HAVE A LUER LOCK CONNECTOR, AND WITH SMALL BOTTLES, AND IS EXCLUSIVELY INTENDED FOR USE WITH ULRICH CONTRAST MEDIA INJECTORS. THE RESERVOIR IS CONNECTED BY MEANS OF THE PUMP TUBING'S SPIKE TO THE PLACE PROVIDED FOR THAT PURPOSE, IN ORDER TO THEN COMPLETELY DECANT THE CONTENTS OF THE MEDIA CONTAINER INTO THE RESERVOIR ONE TIME.THE RESERVOIR IS DESIGNED TO BE USED FOR A MAXIMUM OF 24 HOURS, AND FOR ANY DESIRED NUMBER OF INJECTIONS. IT IS NOT INTENDED TO BE RE-USED OR RE-STERILIZED. PLUGGING THE PUMP TUBING'S SPIKE IN MULTIPLE TIMES IS PROHIBITED. IN ADDITION TO CT AND MRI CONTRAST MEDIA, THE RESERVOIR CAN ALSO BE FILLED WITH ISOTONIC SALINE SOLUTION. MIXINGNON ISOTONIC SALINE SOLUTION IN THE RESERVOIR IS NOT ALLOWED. THIS PRODUCT CONTAINS THE PLASTICIZER DEHP. HANDLING BY CHILDREN, PREGNANT WOMEN OR BREASTFEEDING WOMEN IS THEREFORE PROHIBITED. THE

		RESERVOIR MUST ONLY BE USED BY QUALIFED AND MEDICALLY TRAINED PERSONNEL. THE INTENDED PURPOSE FOR ULRICH CONTRAST MEDIA INJECTORS REMAINS IN EFFECT WITHOUT CHANGES, AND IS EXTENDED BY THE INTENDED PURPOSE FOR THE RESERVOIR FOR CONTRAST MEDIA.,DISPOSABLE PERFUSION SETS (DISPOSABLES FOR INJECTORSULRICHEASYINJECT XD 10XXX)-PATIENT TUBING FOR ULRICHEASYINJECT CT/MRI INJECTORS THE PATIENT TUBING FOR ULRICHEASYINJECT CT/MRI INJECTORS IS INTENDED FOR THE VENOUS ADMINISTRATION OF CONTRAST MEDIA AND PHYSIOLOGICAL SALINE SOLUTIONS (NACL) DURING A CT/MRI EXAMINATION. THE PATIENT TUBING CREATES THE CONNECTION BETWEEN THE EASY-CLICK-CASSETTE (ON THE DEVICE SIDE) AND THE PATIENT. EASY-CLICK-CASSETTE FOR ULRICHEASYINJECT MAX 2M / MAX 3 THE EASY-CLICK-CASSETTE FOR ULRICHEASYINJECT MAX 2M / MAX3 IS INTENDED FOR THE VENOUS ADMINISTRATION OF CONTRAST MEDIA AND PHYSIOLOGICAL SALINE SOLUTIONS (NACL) DURING AN MRI EXAMINATION. THE EASY-CLICK-CASSETTE CONNECTS THE INJECTOR (ON THE DEVICE SIDE) TO THE PATIENT TUBING. THE EASY-CLICK-CASSETTE CAN BE USED FOR ANY NUMBER OF INJECTIONS WITHIN A 24 HOUR PERIOD.
1986	IMP/MD/2020/000031	1.License Holder Name: M. ASSOCIATES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER KIT/SET(ABLECATH)-:THE ABLE CENTRAL VENOUS CATHETERS KIT/SET MAY BE APPLICABLE TO THE ONE OF FOLLOWING THERAPY: 1. MONITOR OF CENTRAL VENOUS PRESSURE; 2. CONTINUOUS OR DISCONTINUOUS VENOUS TRANSFUSION; 3. BLOOD SAMPLING THE CATHETER IS SURGICALLY PENETRATED INTO THREE OPTIONAL PUNCTURE POINTS DEPENDED ON THE CLINICAL REQUIREMENT WITH SELDINGER TECHNIQUE. THE INSERTION SITES ARE : 1. INTERNAL JUGULAR VEIN; 2. SUBCLAVIAN VEIN; 3. FEMORAL VEIN. IT IS POSSIBLE TO BE INSERTED INSIDE THE BODY FOR LESS THAN 30DAYS. IF DURATION EXCEEDS 30 DAYS, IT MAY OCCURE THE RISK OF COMBINING THE CATHETER AND INSIDE TISSUE, WHICH RESULT IN SERIOUS INCIDENT.,HAEMODIALYSIS CATHETER KIT/SET (ABLECATH)-THE PRODUCT IS APPLICABLE FOR HEMODIALYSIS, VENOUS TRANSFUSION, CONTINUOUS MONITORING THE VENOUS PRESSURE. THE TIME OF USE IS LESS THAN 30 DAYS.

1987	IMP/MD/2020/000032	1.License Holder Name: BALT INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEUROVASCULAR EMBOLIZATION DEVICE(BARRICADE EMBOLIZATION COIL SYSTEM)-THE BARRICADE COIL SYSTEM (BCS) IS INTENDED FOR THE ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS AND OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE. THE BCS IS ALSO INTENDED FOR VASCULAR OCCLUSION OF BLOOD VESSELS WITHIN THE NEUROVASCULAR SYSTEM TO PERMANENTLY OBSTRUCT BLOOD FLOW TO AN ANEURYSM OR OTHER VASCULAR MALFORMATION AND FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE., NEUROVASCULAR EMBOLIZATION DEVICE(OPTIMA COIL SYSTEM)-THE OPTIMA COIL SYSTEM IS INTENDED FOR THE ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS AND OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE. IT IS ALSO INTENDED FOR VASCULAR OCCLUSION OF BLOOD VESSELS WITHIN THE NEUROVASCULAR SYSTEM TO PERMANENTLY OBSTRUCT BLOOD FLOW TO AN ANEURYSM OR OTHER VASCULAR MALFORMATION AND FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE.,BALLAST 088 LONG SHEATH (BALLAST 088 LONG SHEATH)-IT IS INTENDED FOR THE INTRODUCTION OF INTERVENTIONAL DEVICES INTO THE PERIPHERAL, CORONARY AND NEUROVASCULATURE.

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1988	IMP/MD/2020/000033	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CEMENT KIT(TRAUMACEM V+)-THE TRAUMACEM V+ INJECTABLE BONE CEMENT IS INTENDED FOR THE TREATMENT OF OSTEOPOROTIC FRACTURES IN COMBINATION WITH INTERNAL FIXATION DEVICES INTENDED FOR PMMA AUGMENTATION.,CHRONOS STRIP BONE VOID FILLER (BVF)-CHRONOS STRIP(NA)-CHRONOS STRIP BONE VOID FILLER IS A BONE REPLACEMENT MATERIAL OF BETA-TRICALCIUM PHOSPHATE IMBEDDED IN A MATRIX OF POLY(L-LACTIDE-CO-EPSILON-CAPROLACTONE). IN ITS FUNCTION AS TEMPORARY BONE SUBSTITUTE, IT SERVES TO FILL AND BRIDGE ASEPTIC BONE DEFECTS.,SYNPOR IMPLANTS-PLATE(NA)-SYNPOR IMPLANTS ARE INTENDED TO BE USED FOR MAXILLOFACIAL RECONSTRUCTION AND AUGMENTATION.,ATTACHMENTS - SB PEN SHAPED-IRRIGATION TUBE (NA)-THE AIR PEN DRIVE IS AN AIR-DRIVEN SYSTEM TO BE USED FOR TREATMENT IN GENERAL TRAUMATOLOGY, AS WELL AS FOR SURGERIES IN THE AREAS OF THE HAND, FOOT, SPINE, MAXILLOFACIAL AND NEUROSURGERY. ,SYNFLATE VERTEBRAL BALLOON(NA)-THE SYNFLATE SYSTEM IS INTENDED FOR THE REDUCTION OF FRACTURES AND/OR CREATION OF A VOID IN CANCELLOUS BONE IN THE SPINE. IT IS INTENDED TO BE USED IN COMBINATION WITH A LEGALLY-MARKETED BONE FILLER ADEQUATELY INDICATED FOR USE IN VERTEBROPLASTY OR VERTEBRAL AUGMENTATION PROCEDURES.,VERTEBRAL BODY ACCESS KITS-ACCESS KIT (4.7MM)(NA)-THE ACCESS KIT AND ACCESS DRILL ARE INTENDED TO PREPARE THE ACCESS TO THE VERTEBRAL BODY IN THE SPINE FOR SUBSEQUENT USE OF: – VERTEBRAL AUGMENTATION PROCEDURES – BONE FILLER APPLICATIONS – OTHER APPLICATIONS WHERE MINIMAL INVASIVE ACCESS TO THE VERTEBRAL BODY IS NEEDED THE BIOPSY KIT IS INTENDED FOR TAKING VERTEBRAL BODY BONE BIOPSIES IN CONJUNCTION WITH ACCESS KIT INSTRUMENTS.,VERTECEM V+ CEMENT KIT-CEMENT KIT (NA)-THE VERTECEM V+ CEMENT KIT BONE CEMENT COMPONENT IS A RADIOPAQUE, INJECTABLE POLYMETHYL METHACRYLATE CEMENT, INDICATED FOR USE IN SPINE PATHOLOGIES BEING TREATED USING VERTEBROPLASTY OR KYPHOPLASTY PROCEDURES. IT SHOULD ONLY BE USED WITH DEVICES OR SYSTEMS WITH WHICH IT HAS BEEN TESTED AND VALIDATED. FOR INFORMATION ON COMPATIBILITY, CONSULTATION WITH A DEPUY SYNTHES REPRESENTATIVE IS RECOMMENDED.,VERTEBRAL BODY STENTING SYSTEM (VBS) S/M/L-STENT W/WO BALLOON(NA)-THE VBS SYSTEM IS INTENDED FOR THE REDUCTION OF PAINFUL VERTEBRAL COMPRESSION FRACTURES AND/OR CREATION OF A

		VOID IN CANCELLOUS BONE IN THE SPINE FOR THE TREATMENT OF LEVELS RANGING FROM TH5-L5. IT IS INTENDED TO BE USED IN COMBINATION WITH A LEGALLY-MARKETED PMMA1 BASED BONE CEMENT ADEQUATELY INDICATED FOR USE IN VERTEBROPLASTY OR KYPHOPLASTY PROCEDURES.,SYNPOR IMPLANTS-PLATE (UHMWPE) (NA)-SYNPOR IMPLANTS ARE INTENDED TO BE USED FOR MAXILLOFACIAL RECONSTRUCTION AND AUGMENTATION , VERTEBRAL BODY ACCESS KITS-ACCESS KIT(NA)-THE ACCESS KIT AND ACCESS DRILL ARE INTENDED TO PREPARE THE ACCESS TO THE VERTEBRAL BODY IN THE SPINE FOR SUBSEQUENT USE OF: – VERTEBRAL AUGMENTATION PROCEDURES – BONE FILLER APPLICATIONS – OTHER APPLICATIONS WHERE MINIMAL INVASIVE ACCESS TO THE VERTEBRAL BODY IS NEEDED THE BIOPSY KIT IS INTENDED FOR TAKING VERTEBRAL BODY BONE BIOPSIES IN CONJUNCTION WITH ACCESS KIT INSTRUMENTS.
1989	IMP/MD/2020/000034	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLOSED SYSTEM DRUG TRANSFER DEVICE(PHASEAL - INJECTOR)-THE PHASEAL IS AN AIRTIGHT AND LEAKPROOF CLOSED SYSTEM DRUG TRANSFER DEVICE (CSTD) THAT MECHANICALLY PROHIBITS THE TRANSFER OF ENVIRONMENTAL CONTAMINANTS INTO THE SYSTEM AND THE ESCAPE OF DRUG OR VAPOR CONCENTRATIONS OUTSIDE THE SYSTEM, THEREBY MINIMIZING INDIVIDUAL AND ENVIRONMENTAL EXPOSURE TO DRUG VAPOR, AEROSOLS AND SPILLS. THE PHASEAL SYSTEM ALSO PREVENTS MICROBIAL INGRESS.,CLOSED SYSTEM DRUG TRANSFER DEVICE(PHASEAL - CONNECTOR)-THE PHASEAL IS AN AIRTIGHT AND LEAKPROOF CLOSED SYSTEM DRUG TRANSFER DEVICE (CSTD) THAT MECHANICALLY PROHIBITS THE TRANSFER OF ENVIRONMENTAL CONTAMINANTS INTO THE SYSTEM AND THE ESCAPE OF DRUG OR VAPOR CONCENTRATIONS OUTSIDE THE SYSTEM, THEREBY MINIMIZING INDIVIDUAL AND ENVIRONMENTAL EXPOSURE TO DRUG VAPOR, AEROSOLS AND SPILLS. THE PHASEAL SYSTEM ALSO PREVENTS MICROBIAL INGRESS.,CLOSED SYSTEM DRUG TRANSFER DEVICE(PHASEAL - PROTECTOR)-THE PHASEAL IS AN AIRTIGHT AND LEAKPROOF CLOSED SYSTEM DRUG TRANSFER DEVICE (CSTD) THAT MECHANICALLY PROHIBITS THE TRANSFER OF ENVIRONMENTAL CONTAMINANTS INTO THE SYSTEM AND THE ESCAPE OF DRUG OR VAPOR CONCENTRATIONS OUTSIDE THE SYSTEM, THEREBY MINIMIZING INDIVIDUAL AND ENVIRONMENTAL EXPOSURE TO DRUG VAPOR, AEROSOLS AND SPILLS. THE PHASEAL SYSTEM ALSO PREVENTS MICROBIAL INGRESS.

1990	IMP/MD/2020/000035	1.License Holder Name: M/S. G.C. CHEMIE PHARMIE LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE (STERILE)(BD HYPAK SCFTM)-COMPONENT OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS.
1991	IMP/MD/2020/000039	1.License Holder Name: ADVANCED LIFESCIENCES PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CARDIAC STENTS(CP STENT, COVERED CP STENT, MOUNTED CP STENT, COVERED MOUNTED CP STENT, NUDEL)-THE DEVICES ARE INTENDED FOR IMPLANTATION IN THE NATIVE AND/OR RECURRENT COARCTATION OF THE AORTA.,BALLOON TIPPED CARDIAC CATHETERS(TYSHAK, TYSHAK II, TYSHAK-X, TYSHAK MINI, TYSHAK NUCLEUS, Z-MED, Z-MED II, Z-MED-X, Z-MED II-X, COEFFICIENT, NUCLEUS-X, MULLINS-X, BIB STENT PLACEMENT, GHOST PTA, MINI GHOST, HIGH FIVE, BIB PTA, Z-5, BONHOEFFER MITRAL KIT)-THE DEVICES ARE INDICATED FOR THE FOLLOWING: PERCUTANEOUS TRANSLUMINAL DILATATION (TYSHAK, TYSHAK II, TYSHAK-X, TYSHAK MINI, TYSHAK NUCLEUS, Z-MED, Z-MED II, Z-MED-X, Z-MED II-X, COEFFICIENT, NUCLEUS-X, MULLINS-X, GHOST PTA, MINI GHOST, HIGH FIVE, BIB PTA, BONHOEFFER MITRAL KIT), PERCUTANEOUS TRANSLUMINAL STENT PLACEMENT (BIB STENT PLACEMENT) AND PERCUTANEOUS TRANSLUMINAL CATHETER FOR SEPTOSTOMY (Z-5).,ANGIOGRAPHIC CATHETER(MULTI-TRACK)-THE DEVICE IS INTENDED FOR ANGIOGRAPHY OF CARDIOVASCULAR VESSELS AND/OR CHAMBERS. IT CAN BE USED FOR INJECTION OF CONTRAST MEDIUM AND PRESSURE MEASUREMENT IN ANY CHAMBERS OR VESSELS., INTRODUCER(D'VILL)-THE DEVICE IS INTENDED FOR INTRODUCTION OF INTERVENTIONAL DEVICES.

1992	IMP/MD/2020/000040	1.License Holder Name: M/S ASIA ACTUAL INDIA (OPC) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RAPICIDE PA READY TO USE HIGH LEVEL DISINFECTANT AND STERILANT(RAPICIDE PA READY TO USE)-RAPICIDE PA READY-TO-USE IS REUSABLE LIQUID DISINFECTION SOLUTION FOR ENDOSCOPE REPROCESSING IN AN AUTOMATED REPROCESSING SYSTEM OR FOR MANUAL DISINFECTION OF MEDICAL DEVICES. CONCENTRATED READY-TO-USE HIGH LEVEL DISINFECTING AND STERILIZING AGENT WITH SPORICIDAL, TUBERCULOCIDAL, VIRUCIDAL, FUNGICIDAL, AND BACTERICIDAL ACTIVITY WHEN USED FOR ENDOSCOPE REPROCESSING IN AN AUTOMATED REPROCESSING SYSTEM OR FOR MANUAL DISINFECTION OF MEDICAL DEVICES. THE REUSE PERIOD IS 14 DAYS. THE MINIMUM RECOMMENDED CONCENTRATION (MRC) OF PERACETIC ACID IN THE USE SOLUTION IS 1000 PPM AND MUST BE VERIFIED USING RAPICIDE PA TEST STRIPS PRIOR TO EACH USE. FOR SPORICIDAL AND HIGH-LEVEL DISINFECTION: CONTACT TIME 5 MINUTES AT ROOM TEMPERATURE (20°C). FOR STERILIZATION: CONTACT TIME 10 MINUTES AT ROOM TEMPERATURE (20°C)., RENALIN 100 COLD STERILANT(RENALIN 100 COLD STERILANT)-RENALIN 100 COLD STERILANT IS INDICATED FOR THE IN VITRO CLEANING AND STERILIZING OF HOLLOW FIBER DIALYZERS WITH THE RENATRON PA 100 SERIES AND RENATRON II 100 SERIES DIALYZER REPROCESSING SYSTEM LABELLED FOR USE WITH RENALIN 100. RENALIN 100 COLD STERILANT ALSO MAY BE USED FOR DISINFECTING DIALYSIS EQUIPMENT (E.G. KIDNEY MACHINE) AND SUPPLIES (E.G. PORT CAPS).
1993	IMP/MD/2020/000041	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:METAL LIGATING CLIPS (VESOCCLUDE TITANIUM LIGATION CLIPS)-VESOCCLUDE LIGATING CLIPS ARE INTENDED FOR USE IN PROCEDURES INVOLVING VESSELS OR ANATOMIC STRUCTURES FOR WHICH THE USER DETERMINES LIGATING CLIPS ARE THE BEST CHOICE. USERS SHOULD SELECT THE SIZE AND AMOUNT OF THE CLIPS BASED ON UPON THEIR EXPERIENCE, JUDGMENT, AND NEEDS.,POLYMER LIGATING CLIPS (VESOLOCK POLYMER LIGATION CLIPS)-VESOLOCK POLYMER LIGATION CLIPS ARE INTENDED FOR USE IN PROCEDURES INVOLVING LIGATION OF VESSELS OR TISSUE STRUCTURES. SURGEONS SHOULD APPLY THE APPROPRIATE SIZE CLIP FOR THE SIZE OF THE VESSEL OR TISSUE STRUCTURE TO BE LIGATED SUCH THAT THE CLIP COMPLETELY ENCOMPASSES THE VESSEL OR TISSUE STRUCTURE.

1994	IMP/MD/2020/000042	1.License Holder Name: ORIGIO INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRA-UTERINE INSEMINATION CATHETER(WALLACE)-IT IS INTENDED TO BE USED FOR INTRODUCTION OF WASHED SPERMATOZOA INTO THE UTERINE CAVITY

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1995	IMP/MD/2020/000043	1.License Holder Name: ABBOTT HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HI TORQUE COMMAND GUIDE WIRE FAMILY(HI TORQUE COMMAND, HI TORQUE COMMAND ES)-IT IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN ARTERIES SUCH AS THE FEMORAL, POPLITEAL AND INFRA-POPLITEAL ARTERIES. THIS GUIDE WIRE MAY ALSO BE USED WITH COMPATIBLE STENT DEVICES DURING THERAPEUTIC PROCEDURES. THE GUIDE WIRE MAY ALSO BE USED TO REACH AND CROSS A TARGET LESION, PROVIDE A PATHWAY WITHIN THE VESSEL STRUCTURE, FACILITATE THE SUBSTITUTION OF ONE DIAGNOSTIC OR INTERVENTIONAL DEVICE FOR ANOTHER, AND TO DISTINGUISH THE VASCULATURE.,GUIDE WIRE(HI-TORQUE VERSATURN)-IT IS INTENDED TO FACILITATE THE DELIVERY OF CATHETER BASED INTERVENTIONAL DEVICES DURING THE FOLLOWING PROCEDURES: PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). THIS GUIDE WIRE MAY ALSO BE USED WITH COMPATIBLE STENT DEVICES. THIS DEVICE IS DESIGNED AND INTENDED FOR ONE-TIME USE ONLY. DO NOT RESTERILIZE AND /OR REUSE.,HI-TORQUE GUIDE WIRE FAMILY (NITINOL)(HI-TORQUE BALANCE GUIDE WIRE, HI-TORQUE BALANCE MIDDLEWEIGHT GUIDE WIRE, HI-TORQUE BALANCE HEAVYWEIGHT GUIDE WIRE, HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL GUIDE WIRE, HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSAL II GUIDE WIRE)-IT IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). THIS GUIDE WIRE MAY ALSO BE USED WITH COMPATIBLE STENT DEVICES DURING THERAPEUTIC PROCEDURES., HI-TORQUE GUIDE WIRE FAMILY (STAINLESS STEEL)(HI-TORQUE PILOT 50/150/ 200, HI-TORQUE PROGRESS 40/80/120/140T/ 200T, HI-TORQUE WHISPER LS/ HI-TORQUE WHISPER MS/ HI-TORQUE WHISPER EXTRA SUPPORT, HI-TORQUE WINN 40/80/120/140T/ 200T)-HI-TORQUE PILOT GUIDE WIRE FAMILY AND HI-TORQUE PROGRESS GUIDE WIRE FAMILY: HI-TORQUE PILOT AND HI-TORQUE PROGRESS GUIDE WIRE IS INTENDED TO FACILITATE THE DELIVERY OF CATHETER-BASED INTERVENTIONAL DEVICES DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). THIS GUIDE WIRE MAY BE USED WITH COMPATIBLE STENT DEVICES DURING THERAPEUTIC PROCEDURES. THE GUIDE WIRE MAY BE USED TO REACH AND CROSS A TARGET LESION, PROVIDE A PATHWAY

	WITHIN THE VESSEL STRUCTURE, FACILITATE THE SUBSTITUTION OF ONE DIAGNOSTIC OR INTERVENTIONAL DEVICE FOR ANOTHER, AND TO DISTINGUISH THE VASCULATURE. THIS GUIDE WIRE MAY ALSO BE USED TO CROSS OR ASSIST IN CROSSING DE NOVO CHRONIC TOTAL CORONARY OCCLUSIONS (CTO). HI-TORQUE WHISPER GUIDE WIRE FAMILY: IT IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). HI-TORQUE WINN GUIDE WIRE FAMILY: IT IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). THIS GUIDE WIRE MAY ALSO BE USED WITH COMPATIBLE STENT DEVICES DURING THERAPEUTIC PROCEDURES.

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1996	IMP/MD/2020/000044	1.License Holder Name: GENETIX BIOTECH ASIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:WOUND DRESSINGS (METALLINE®)-METALLINE WOUND DRESSINGS IS INTENDED FOR COVERING ALL TYPES OF WOUNDS. IT IS PARTICULARLY RECOMMENDED FOR ABRASIONS, BURNS, CHEMICAL BURNS, SURGICAL WOUNDS AND FIRST AID(INITIAL TREATMENT OF WOUNDS),COLLAGEN WOUND DRESSING(SUPRASORB® C)-SUPRASORB® C IS INTENDED AS A WOUND DRESSING FOR THE SUPPORT OF WOUND HEALING OR WOUND AREA REDUCTION. IT IS INDICATED FOR APPLICATION TO DIABETIC ULCERS, PRESSURE ULCERS, VENOUS OR MIXED VASCULAR ULCERS, SURGICAL WOUNDS HEALING BY SECONDARY INTENTION. ,ACTIVATED CHARCOAL ROPE WITH SILVER(VLIWAKTIV® AG)-"VLIWAKTIV® AG ACTIVATED CHARCOAL ROPE WITH SILVER IS INTENDED TO BE USED FOR THE TREATMENT OF CRITICALLY COLONIZED, INFECTED AND/OR OFFENSIVE SMELLING WOUNDS AS WELL AS FOR WOUNDS WITH AN INCREASED RISK OF INFECTION (E.G. FROM ENDOGENOUS LOWERED RESISTANCE, ANAL FISTULAE, RUPTURED CARCINOMAS, BURNS, ETC.). IT MAY BE USED FOR LIGHTLY EXUDING WOUNDS OR IN COMBINATION WITH A SECONDARY DRESSING FOR MODERATELY TO HEAVILY EXUDING WOUNDS, AND SUPERFICIAL TO DEEP WOUNDS, E. G. PRESSURE SORES, ARTERIAL ULCERS, VENOUS LEG ULCERS, DIABETIC ULCERS, POSTOPERATIVE WOUNDS HEALING BY SECOND INTENTION, EXULCERATING TUMORS." ,ANTIMICROBIAL HYDROBALANCE WOUND DRESSINGS/ROPE(SUPRASORB® X+ PHMB)-SUPRASORB® X+ PHMB ANTIMICROBIAL HYDROBALANCE WOUND DRESSINGS/ROPE MAY BE USED FOR MANAGEMENT OF WOUNDS-AT-RISK OR INFECTED WOUNDS WHICH SHOW LIGHT TO MODERATE EXUDATION, OR ARE SUPERFICIAL OR PARTIAL TO FULL THICKNESS WOUNDS (PRESSURE ULCERSS, ARTERIAL AND VENOUS ULCERS, DIABETIC ULCERS, POST-OPERATIVE SURGICAL WOUNDS, SKIN GRAFTS & DONOR SITE, MINOR SCALDS AND BURNS(2ND DEGREE), ABRASIONS & LACERATIONS. ,HYDROBALANCE WOUND DRESSINGS/ROPE(SUPRASORB® X)-SUPRASORB® X HYDROBALANCE WOUND DRESSINGS/ROPE MAY BE USED FOR MANAGEMENT OF WOUNDS WHICH SHOW LIGHT TO MODERATE EXUDATION, OR ARE SUPERFICIAL OR PARTIAL TO FULL THICKNESS WOUNDS (PRESSURE ULCERS, ARTERIAL AND VENOUS ULCERS, DIABETIC ULCERS, POST-OPERATIVE SURGICAL WOUNDS, SKIN GRAFTS & DONOR SITE, MINOR SCALDS AND BURNS(2ND DEGREE), ABRASIONS & LACERATIONS. ,FILM WOUND DRESSINGS, OFF THE ROLL(SUPRASORB F)-SUPRASORB® F FILM WOUND DRESSING, OFF THE ROLL IS INTENDED FOR THE SUPPORTIVE PROPHYLAXIS OF SKIN

		AREAS AT RISK OF PRESSURE ULCERS, FIXATION IN WOUND TREATMENT AND FOR THE INITIAL CARE FOR MINOR, SUPERFICIAL WOUNDS
1997	IMP/MD/2020/000045	1.License Holder Name: BALT INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIQUID AMBOLIC AGENT (SQUID)-EMBOLIZATION OF LESIONS IN THE PERIPHERAL AND NEUROVASCULATURE, INCLUDING ARTERIOVENOUS MALFORMATIONS AND HYPERVASCULAR TUMORS.
1998	IMP/MD/2020/000046	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INFLOW/OUTFLOW SHEATH(FMS)-THE INFLOW/OUTFLOW SHEATH SYSTEM IS INDICATED FOR USE WITH A 4 MM ARTHROSCOPE TO ALLOW VIEWING AND FLUID INFLOW AND OUTFLOW THROUGH THE SAME PORTAL OF THE OPERATIVE SITE. ARTHROSCOPY SHEATHS SERVE TO PROVIDE ACCESS FOR VISUALIZATION OF THE INTERIOR OF THE KNEE, SHOULDER AND HIP JOINTS DURING EXAMINATION, DIAGNOSIS AND/OR (IN COMBINATION WITH ARTHROSCOPIC ACCESSORIES) SURGICAL TREATMENT. THE INFLOW/OUTFLOW SHEATH IS INTENDED FOR USE WITH A FLUID MANAGEMENT SYSTEM IN A SURGICAL SETTING BY PERSONNEL TRAINED IN ARTHROSCOPY.

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1999	IMP/MD/2020/000047	1.License Holder Name: PACK DEAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIFURCATION ANEURYSM IMPLANT(PCONUS)-THE PCONUS BIFURCATION ANEURYSM IMPLANT IS USED TO SUPPORT THE ENDOVASCULAR COIL OCCLUSION OF WIDE-NECKED BIFURCATION ANEURYSMS IN INTRACRANIAL ARTERIES. TYPICAL LOCATIONS FOR SUCH ANEURYSMS ARE THE BIFURCATION OF THE INTERNAL CAROTID ARTERY, THE ANTERIOR COMMUNICATING ARTERY, THE MIDDLE CEREBRAL ARTERY AND THE BIFURCATION OF THE BASILAR ARTERY. HOWEVER, IN PRINCIPLE, EVERY WIDE-NECKED ANEURYSM IN THE BIFURCATION OF A VESSEL CAN BE SUITABLE. DEPENDING ON THE CLINICAL CIRCUMSTANCES AND THE VASCULAR ANATOMY, BOTH UNRUPTURED AND RUPTURED ANEURYSMS CAN BE TREATED WITH THIS IMPLANT. WHEN TREATING RUPTURED ANEURYSMS, ONE MUST EXAMINE CAREFULLY TO WHAT EXTENT IT IS POSSIBLE TO USE ANTIPLATELET MEDICATION.,FLOW MODULATION DEVICE(P64)-THE P64 FLOW MODULATION DEVICE IS A SELF-EXPANDING, TUBULAR VASCULAR IMPLANT AND ALLOWS THE CONTROLLED AND SELECTIVE MODULATION OF BLOOD FLOW IN EXTRA- AND INTRACRANIAL ARTERIES. IN ADDITION, THE PHYSICAL PROPERTIES OF THE P64 STRAIGHTEN THE TARGET VESSEL SLIGHTLY AND STRENGTHEN IT. THESE PROPERTIES AID THE ENDOVASCULAR RECONSTRUCTION OF DISEASED ARTERIES ALONG THEIR CERVICAL AND INTRACRANIAL COURSE. INDICATIONS: THE P64 FLOW MODULATION DEVICE IS A SELF-EXPANDING, TUBULAR IMPLANT AND IS USED IN THE ENDOVASCULAR TREATMENT OF VASCULAR DISEASES SUCH AS - SACCULAR AND FUSIFORM ANEURYSMS AND PSEUDOANEURYSMS - VASCULAR DISSECTIONS IN THE ACUTE AND CHRONIC PHASES - VASCULAR PERFORATIONS AND AV FISTULAE,THROMBECTOMY DEVICE(PRESET)-THE INTENDED PURPOSE OF PRESET THROMBECTOMY DEVICES IS ACUTE TREATMENT OF ISCHEMIC STROKE BY REMOVAL OF THROMBI FROM INTRACRANIAL VESSELS E.G., THE INTERNAL CAROTID ARTERY, MIDDLE CEREBRAL ARTERY, OR BASILAR ARTERY OR FROM VESSELS SITUATED DISTALLY OF THEM, WITH A TEMPORARY CONTACT DURATION LESS THAN 60 MINUTES. INDICATIONS: THE PRESET THROMBECTOMY DEVICE IS DESIGNED FOR MECHANICAL CLOT RETRIEVAL FROM INTRACRANIAL ARTERIES AS ACUTE ISCHEMIC STROKE TREATMENT FOR PATIENTS WHO ARE INELIGIBLE FOR INTRAVENOUS THROMBOLYSIS OR FOR PATIENTS WHO FAILED THROMBOLYSIS THERAPY AND AS A SUPPLEMENT TREATMENT OF AN INITIATED THROMBOLYSIS THERAPY.,STEERABLE HYDROPHILIC GUIDE WIRE(PORTAL)-PORTAL, CONSISTING OF PORTAL STEERABLE HYDROPHILIC GUIDEWIRE AND OPTIONAL PORTAL EXT EXTENSION

		WIRE, IS INTENDED FOR USE IN EXTRA- AND INTRACRANIAL BRAIN-SUPPLYING ARTERIES AND IN EXTRA AND INTRACRANIAL BRAIN-DRAINING VEINS. IT CAN BE USED TO FACILITATE THE SELECTIVE INTRODUCTION AND POSITIONING OF CATHETERS AND OTHER INTERVENTIONAL DEVICES WITHIN TARGET VESSELS.,FLOW MODULATION DEVICE(P48 MW)-THE P48 MW (HPC) FLOW MODULATION DEVICE IS A SELF-EXPANDING, TUBULAR IMPLANT AND IS USED IN THE ENDOVASCULAR TREATMENT OF VASCULAR DISEASES SUCH AS - SACCULAR AND FUSIFORM ANEURYSMS AND PSEUDOANEURYSMS, - VASCULAR DISSECTIONS IN THE ACUTE AND CHRONIC PHASES AND - VASCULAR PERFORATIONS AND AV FISTULAE.
2000	IMP/MD/2020/000048	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL ABLATION PEN (CARDIOBLATE)-THIS DEVICE IS INTENDED TO CREATE SPOT OR LINEAR LESIONS IN CARDIAC TISSUE DURING CARDIAC SURGERY USING RADIOFREQUENCY ENERGY FOR THE TREATMENT OF CARDIAC ARRHYTHMIAS,SURGICAL ABLATION SYSTEM (CARDIOBLATE BP2 SYSTEM)-CARDIOBLATE SURGICAL ABLATION PEN: THIS DEVICE IS INTENDED TO CREATE SPOT OR LINEAR LESIONS IN CARDIAC TISSUE DURING CARDIAC SURGERY USING RADIOFREQUENCY ENERGY FOR THE TREATMENT OF CARDIAC ARRHYTHMIAS. SURGICAL BP2 DEVICE: THIS DEVICE IS INTENDED TO CREATE LESIONS IN CARDIAC TISSUE DURING CARDIAC SURGERY USING RADIOFREQUENCY ENERGY FOR THE TREATMENT OF CARDIAC ARRHYTHMIAS. ,SURGICAL ABLATION DEVICE (CARDIOBLATE BP2 DEVICE)-THIS DEVICE IS INTENDED TO CREATE LESIONS IN CARDIAC TISSUE DURING CARDIAC SURGERY USING RADIOFREQUENCY ENERGY FOR THE TREATMENT OF CARDIAC ARRHYTHMIAS.

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2001	IMP/MD/2020/000049	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALGINATE DRESSING (COVAWOUND™ ALGINATE)-COVAWOUND™ ALGINATE DRESSING MAY BE APPLIED TO MODERATE TO HEAVY EXUDING WOUNDS LIKE PARTIAL THICKNESS BURNS, DONOR SITES, LEG, PRESSURE, ARTERIAL, DIABETIC AND VENOUS STASIS ULCERS, CAVITY WOUNDS, POST-SURGICAL INCISIONS, TRAUMA WOUNDS AND MOST OTHER GRANULATING WOUNDS.,TRANSPARENT IV DRESSING(COVAVIEW™ IV)-COVAVIEW™ IV IS INDICATED TO COVER AND PROTECT I.V. SITES, SURGICAL INCISIONS, PRIMARY DRESSING ON PRESSURE ULCERS (STAGES I AND II) WITH MINIMAL DRAINAGE, PARTIAL THICKNESS WOUNDS, AND SKIN TEARS OR ABRASIONS.,CAPILLARY ACTION DRESSING(COVAWOUND™ SUPERABSORBENT)-COVAWOUND™ SUPERABSORBENT DRESSING IS INDICATED FOR THE MANAGEMENT OF MODERATE TO HEAVILY EXUDING WOUNDS SUCH AS LEG ULCERS (VENOUS AND ARTERIAL), FOOT ULCERS, PRESSURE ULCERS, TRAUMATIC AND SURGICAL WOUNDS, AND FIRST AND SECOND-DEGREE BURNS. COVAWOUND™ SUPERABSORBENT DRESSING CAN BE USED IN CONJUNCTION WITH COMPRESSION THERAPY FOR VENOUS LEG ULCERS.,HYDROCOLLOID DRESSING(COVAWOUND™ HYDROCOLLOID)-COVAWOUND™ HYDROCOLLOID DRESSING IS INDICATED FOR THE MANAGEMENT OF LIGHTLY EXUDING WOUNDS SUCH AS PRESSURE, LEG AND FOOT ULCERS, SUPERFICIAL PARTIAL-THICKNESS BURNS, DONOR SITES, DIABETIC ULCERS, POST-OPREATIVE WOUNDS AND SKIN ABRASIONS, COVAWOUND HYDROCOLLOID DRESSING MAY ALSO BE USED ON SMALL WOUNDS TOWARDS THE END OF THE HEALING PHASE.,SELF ADHERENT SILICONE FOAM DRESSING(COVAWOUND™ SILICONE)-IT IS INDICATED FOR THE MANAGEMENT OF LIGHT TO HEAVILY EXUDING WOUNDS SUCH AS LEG AND FOOT ULCERS, PRESSURE ULCERS, TRAUMATIC AND SURGICAL WOUNDS, AND SUPERFICIAL AND PARTIAL THICKNESS BURNS.,NON- ADHERENT FOAM DRESSING (COVAWOUND™ FOAM)-IT IS INDICATED FOR THE MANAGEMENT OF LIGHT TO HEAVILY EXUDING WOUNDS SUCH AS PRESSURE, LEG, DIABETIC AND FOOT ULCERS, SUPERFICIAL AND PARTIAL-THICKNESS BURNS, DONOR SITES, TRAUMA WOUNDS AND POST-OPERATIVE SURGICAL WOUNDS

2002	IMP/MD/2020/000050	1.License Holder Name: INNVOLUTION HEALTHCARE PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CORONARY DILATATION CATHETER (SCOREFLEX NC)-FOR BALLOON DILATATION OF A STENOTIC PORTION OF A CORONARY ARTERY IN PATIENTS EVIDENCING CORONARY ISCHEMIA FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,BALLOON DILATATION CATHETER(JADE PTA)-FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY IN THE PERIPHERAL VASCULATURE, INCLUDING FISTULA SHUNT, ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA-POPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE.,CORONARY DILATATION CATHETER(SAPPHIRE II PRO)-FOR BALLOON DILATATION OF A STENOTIC PORTION OF A CORONARY ARTERY IN PATIENTS EVIDENCING CORONARY ISCHEMIA FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION., MICROCATHETER(TELEPORT)-TELEPORT IS INTENDED TO SUPPORT AND FACILITATE THE PLACEMENT OF GUIDEWIRES IN THE CORONARY AND PERIPHERAL VASCULATURES, AND CAN BE USED TO EXCHANGE GUIDEWIRES. TELEPORT IS ALSO INTENDED FOR THE DELIVERY OF CONTRAST MEDIA INTO THE CORONARY, PERIPHERAL AND ABDOMINAL VASCULATURES.,CORONARY DILATATION CATHETER(SCOREFLEX)-FOR BALLOON DILATATION OF A STENOTIC PORTION OF A CORONARY ARTERY IN PATIENTS EVIDENCING CORONARY ISCHEMIA FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,BALLOON DILATATION CATHETER (SCOREFLEX PTA)-THE SCOREFLEX PTA BALLOON DILATATION CATHETER IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY IN THE PERIPHERAL VASCULATURE, INCLUDING FISTULA / SHUNT, ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA-POPLITEAL, RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE.

2003	IMP/MD/2020/000051	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLINICAL SCREWS - TITANIUM AND ITS ALLOYS(ABUTMENT SCREW, CLINICAL SCREW, PROSTHETIC SCREW)-THE CLINICAL SCREW, ABUTMENT SCREW AND PROSTHETIC SCREW ARE INTENDED TO SECURE A DENTAL ABUTMENT OR FRAMEWORK TO A DENTAL IMPLANT OR ABUTMENT IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION.,ABUTMENTS - TITANIUM AND ITS ALLOYS(ESTHETIC ABUTMENT, MULTI-UNIT ABUTMENT, TEMPORARY ABUTMENT, TEMPORARY COPING)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH TWO-STAGE ENDOSSEOUS IMPLANTS ARE USED AS THE FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. RESTORATIONS RANGE FROM REPLACING ONE SINGLE TOOTH TO FIXED PARTIAL DENTURES USING CEMENT-RETAINED SUPRA-CONSTRUCTIONS. MULTI-UNIT ABUTMENT/PLUS IN COMBINATION WITH ENDOSSEOUS IMPLANTS ARE INDICATED FOR MULTIPLE UNIT RECONSTRUCTIONS WHEN SCREW RETAINED PROSTHETICS IS PREFERRED.
2004	IMP/MD/2020/000052	1.License Holder Name: ESSITY INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRANSPARENT FILM DRESSING(LEUKOMED® CONTROL)-LEUKOMED® CONTROL IS INDICATED FOR DRY AND LOW EXUDING ACUTE WOUNDS SUCH AS SURGICAL WOUNDS, SUPERFICIAL AND PARTIAL-THICKNESS BURNS, SKIN DONOR SITES, LACERATIONS AND ABRASIONS.
2005	IMP/MD/2020/000053	1.License Holder Name: GETINGE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRA AORTIC BALLOON CATHETER- INTRAORTIC BALLOON CATHETER AND ACCESSORIES ARE USED TO PROVIDE COUNTER PULSATION THERAPY IN THE AORTA,WHERE BY BALLOON INFLATION DURING DIASTOLE AND DEFLATION DURING SYSTOLE INCREASES BLOOD SUPPLY TO THE HEART MUSCLE AND DECREASES THE WORK OF LEFT VENTRICLE

2006	IMP/MD/2020/000056	1.License Holder Name: SURGIPLUS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:I. V. CATHETER(TOP I. V. CATHETER)-THE DEVICE IS INTENDED FOR THE INTRODUCTION OF MEDICINE OR WITHDRAWAL OF BLOOD FROM THE PERIPHERAL VASCULAR SYSTEM.,SPINAL NEEDLE(TOP SPINAL NEEDLE)-THIS DEVICE IS USED FOR INTRODUCING ANY ANAESTHETIC DRUG INTO THE SUBARACHNOID SPACE/SAMPLING THE CEREBROSPINAL FLUIDS/MEASURING THE CEREBROSPINAL FLUID PRESSURE, NELATON CATHETER (TOP NELATON CATHETER)-THIS DEVICE IS INTENDED TO BE INTRODUCED INTO THE VESICAL CAVITY THROUGH THE URETHRA IN ORDER TO PROVIDE DRAINAGE AND/OR FLUSHING OF THE BLADDER,SUCTION CATHETER(TOP SUCTION CATHETER)-THIS DEVICE IS INTENDED TO BE INSERTED INTO ORAL OR NASAL CAVITIES AND USED FOR SUCTION OF ORAL, PHARYNX AND TRACHEAL CAVITIES SECRETION.,THREE WAY STOP COCK WITH & WITHOUT EXTENSION TUBE(TOP THREE WAY STOP COCK WITH & WITHOUT EXTENSION TUBE)-THIS DEVICE IS USED FOR DIVERSE NEED OF INFUSION THERAPY AND EXTENSION TUBE IS USED FOR INTRAVENOUS ANAESTHESIA AND TRANSFUSION TREATMENT METHOD. USE TO STOP OR CHANGE THE INFUSION LINE,EXTENSION TUBE(TOP EXTENSION TUBE)-THE DEVICE IS USED FOR THE DIVERSE NEEDS OF INFUSION THERAPY AND EXTENSION TUBE IS USED FOR EXTENDING THE INFUSION LINE
2007	IMP/MD/2020/000057	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRANSCATHETER PULMONARY VALVE (TPV)(MELODY)-THE MELODY™ TPV IS INDICATED FOR USE IN PATIENTS WITH THE FOLLOWING CLINICAL CONDITIONS: PATIENTS WITH REGURGITANT PROSTHETIC RIGHT VENTRICULAR OUTFLOW TRACT (RVOT) CONDUITS OR BIOPROSTHESES WITH A CLINICAL INDICATION FOR INVASIVE OR SURGICAL INTERVENTION, OR PATIENTS WITH STENOTIC PROSTHETIC RVOT CONDUITS OR BIOPROSTHESES WHERE THE RISK OF WORSENING REGURGITATION IS A RELATIVE CONTRAINDICATION TO BALLOON DILATATION OR STENTING

2008	IMP/MD/2020/000058	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER(INQUIRY™ FIXED CURVE DIAGNOSTIC CATHETER)-THE INQUIRY™ FIXED CURVE ELECTROPHYSIOLOGY CATHETERS ARE USED FOR ELECTROGRAM RECORDING AND CARDIAC STIMULATION DURING DIAGNOSTIC ELECTROPHYSIOLOGY STUDIES. THE CATHETERS ARE COMMONLY PLACED AT THE HIGH RIGHT ATRIUM, RIGHT VENTRICULAR APEX, AND HIS BUNDLE.,CATHETER(INQUIRY™ AFOCUS II™ DIAGNOSTIC CATHETER)-INQUIRY™ AFOCUS II™ DIAGNOSTIC CATHETERS ARE USED FOR RECORDING INTRA-CARDIAC SIGNALS AND CARDIAC STIMULATION DURING DIAGNOSTIC ELECTROPHYSIOLOGIC STUDIES. INQUIRY™ AFOCUS II™ CATHETERS ARE ALSO FOR USE IN MAPPING ATRIAL REGIONS OF THE HEART.,CATHETER(THERAPY™ COOL FLEX™ ABLATION CATHETER)-THERAPY™ COOL FLEX™ ABLATION CATHETERS IS INDICATED FOR CREATING FOCAL ENDOCARDIAL LESIONS DURING CARDIAC ABLATION PROCEDURES TO TREAT ARRHYTHMIAS AND FOR CARDIAC ELECTROPHYSIOLOGICAL MAPPING AND DELIVERING DIAGNOSTIC PACING STIMULI.,CATHETER (THERAPY™ COOL PATH™ ABLATION CATHETER)-THERAPY™ COOL PATH™ ABLATION CATHETER IS INTENDED FOR CREATING FOCAL ENDOCARDIAL LESIONS DURING CARDIAC ABLATION PROCEDURE TO TREAT ARRHYTHMIAS AND FOR CARDIAC ELECTROPHYSIOLOGICAL MAPPING AND DELIVERING DIAGNOSTIC PACING STIMULI.,CATHETER (INQUIRY™ CARDIOVERSION DIAGNOSTIC CATHETER)-THE INQUIRY™ CARDIOVERSION CATHETER WHEN USED WITH THE ELECTROPHYSIOLOGY CABLE AND CARDIOVERSION SWITCH BOX IS INTENDED FOR TRANSVENOUS ELECTRICAL CARDIOVERSION AND FOR RECORDING INTRACARDIAC ELECTROGRAM AND CARDIAC STIMULATION DURING ELECTROPHYSIOLOGY STUDIES.,CATHETER (VIEWFLEX™ XTRA ICE CATHETER)-THE VIEWFLEX™ XTRA ICE CATHETER IS INDICATED FOR USE IN ADULT AND ADOLESCENT PEDIATRIC PATIENTS TO VISUALIZE CARDIAC STRUCTURES, BLOOD FLOW AND OTHER DEVICES WITHIN THE HEART.,CATHETER (THERAPY™ ABLATION CATHETER)-STEERABLE ABLATION ELECTROPHYSIOLOGY CATHETERS HAVE BEEN DESIGNED FOR INTRACARDIAC RECORDING OF COMPLEX CONDUCTION DISTURBANCES AS WELL AS FOR THE DELIVERY OF RADIO FREQUENCY ENERGY FOR THERAPEUTIC PURPOSES. THE CATHETERS ARE INDICATED FOR USE IN THE TREATMENT OF AV NODAL REENTRANT TACHYCARDIA, FOR ABLATIONS OF ACCESSORY PATHWAYS, AND FOR THE CREATION OF COMPLETE AV BLOCK IN THE ATRIAL ARRHYTHMIAS.,CATHETER(INQUIRY™ AFOCUS™ DIAGNOSTIC CATHETER)-INQUIRY™ AFOCUS DIAGNOSTIC

	CATHETERS ARE USED FOR RECORDING INTRA-CARDIAC SIGNALS AND CARDIAC STIMULATION DURING DIAGNOSTIC ELECTROPHYSIOLOGIC STUDIES. INQUIRY™ AFOCUS CATHETERS ARE ALSO FOR USE IN MAPPING ATRIAL REGIONS OF THE HEART., CATHETER(INQUIRY™ OPTIMA™ PLUS DIAGNOSTIC CATHETER)-INQUIRY OPTIMA™ PLUS DIAGNOSTIC CATHETERS ARE STEERABLE ELECTROPHYSIOLOGY CATHETERS USED FOR RECORDING INTRA-CARDIAC SIGNALS AND CARDIAC STIMULATION DURING DIAGNOSTIC ELECTROPHYSIOLOGIC STUDIES. INQUIRY OPTIMA™ CATHETERS ARE TO BE USED FOR MAP THE ATRIAL REGIONS OF THE HEART., CATHETER(INQUIRY™ STEERABLE DIAGNOSTIC CATHETER (BI-DIRECTIONAL))-THE INQUIRY™ STEERABLE ELECTROPHYSIOLOGY CATHETER IS USED FOR ELECTROGRAM RECORDING AND CARDIAC STIMULATION DURING DIAGNOSTIC ELECTROPHYSIOLOGY STUDIES. THE CATHETERS ARE COMMONLY PLACED AT THE HIGH RIGHT ATRIUM, RIGHT VENTRICULAR APEX, AND HIS BUNDLE.,CATHETER (INQUIRY™ OPTIMA™ DIAGNOSTIC CATHETER)-INQUIRY™ OPTIMA™ DIAGNOSTIC CATHETERS ARE STEERABLE ELECTROPHYSIOLOGY CATHETERS USED FOR RECORDING INTRA-CARDIAC SIGNALS AND CARDIAC STIMULATION DURING DIAGNOSTIC ELECTROPHYSIOLOGIC STUDIES.INQUIRY™ OPTIMA™ CATHETERS ARE TO BE USED FOR MAP THE ATRIAL REGIONS OF THE HEART.,CATHETER(INQUIRY™ LUMA-CATH™ STEERABLE DIAGNOSTIC CATHETER)-THE INQUIRY™ LUMA-CATH™ STEERABLE ELECTROPHYSIOLOGY CATHETERS ARE USED FOR ELECTROGRAM RECORDING AND CARDIAC STIMULATION DURING DIAGNOSTIC ELECTROPHYSIOLOGY STUDIES. THE CATHETERS ARE COMMONLY PLACED AT THE HIGH RIGHT ATRIUM, RIGHT VENTRICULAR APEX, AND HIS BUNDLE.,CATHETER(THERAPY™ DUAL- 8™ ABLATION CATHETER)-STEERABLE ABLATION ELECTROPHYSIOLOGY CATHETERS HAVE BEEN DESIGNED FOR INTRACARDIAC RECORDING OF COMPLEX CONDUCTION DISTURBANCES AS WELL AS FOR THE DELIVERY OF RADIO FREQUENCY ENERGY FOR THERAPEUTIC PURPOSES. THE CATHETERS ARE INDICATED FOR USE IN THE TREATMENT OF AV NODAL REENTRANT TACHYCARDIA, FOR ABLATIONS OF ACCESSORY PATHWAYS, AND FOR THE CREATION OF COMPLETE AV BLOCK IN THE ATRIAL ARRHYTHMIAS,CATHETER(THERAPY™ COOL PATH™ DUO ABLATION CATHETER)-THE IBI THERAPY™ COOL PATH™DUO ABLATION CATHETER IS INTENDED FOR CREATING FOCAL ENDOCARDIAL LESIONS DURING CARDIAC ABLATION PROCEDURES TO TREAT ARRHYTHMIAS AND FOR CARDIAC ELECTROPHYSIOLOGICAL MAPPING AND DELIVERING DIAGNOSTIC PACING STIMULI.,CATHETER(INQUIRY™STEERABLE DIAGNOSTIC CATHETER)-THE INQUIRY™ STEERABLE ELECTROPHYSIOLOGY

		CATHETERS ARE USED FOR ELECTROGRAM RECORDING AND CARDIAC STIMULATION DURING DIAGNOSTIC ELECTROPHYSIOLOGY STUDIES. THE CATHETERS ARE COMMONLY PLACED AT THE HIGH RIGHT ATRIUM, RIGHT VENTRICULAR APEX, AND HIS BUNDLE.
2009	IMP/MD/2020/000059	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RESIN(CRANIOPLASTIC)-CRANIOPLASTIC™ IS A RESINOUS MATERIAL FOR REPAIRING CRANIAL DEFECTS.
2010	IMP/MD/2020/000062	1.License Holder Name: SAR HEALTHLINE PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER,EMBRYO TRANSFER(KITAZATO ET CATHETER)-THE KITAZATO ET CATHETER IS USED TO PLACE SPERM, OOCYTE OR EMBRYO INTO THE UTERINE CAVITY THROUGH THE CERVIX, THE MYOMETRIUM OR THE ABDOMINAL.,BIOPSY KIT, SOFT TISSUE (KITAZATO OPU NEEDLE)-THE KITAZATO OPU NEEDLE IS INTENDED TO PUNCTURE INTO HUMAN BODY AND PICK UP FOLLICULAR FLUID OR OOCYTE FROM OVARIAN FOLLICLE
2011	IMP/MD/2020/000063	1.License Holder Name: COLOPLAST INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYDROGEL DRESSING (PURILON)-THE PRODUCT IS A HYDROGEL INTENDED FOR AUTOLYTIC DEBRIDEMENT OF NECROTIC TISSUE. THE PRODUCT: • IS INDICATED FOR NECROTIC AND SLOUGHY WOUNDS SUCH AS LEG ULCERS, PRESSURE ULCERS, AND NON-INFECTED DIABETIC FOOT ULCERS. • MAY BE USED FOR FIRST AND SECOND DEGREE BURNS. • MAY BE USED THROUGHOUT THE HEALING PROCESS TO PROVIDE A MOIST WOUND-HEALING ENVIRONMENT FOR THE INDICATED TYPES OF WOUNDS.

2012	IMP/MD/2020/000064	1.License Holder Name: VENUS SURGICALS AGENCIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISINFECTANT(REVITAL-OX® RESERT® HIGH LEVEL DISINFECTANT)-REVITAL-OX RESERT HIGH LEVEL DISINFECTANT IS A READY-TO-USE LIQUID CHEMICAL GERMICIDE. THE PRODUCT IS A 2.0% NOMINAL HYDROGEN PEROXIDE SOLUTION. THE MINIMUM RECOMMENDED CONCENTRATION (MRC) IS 1.5%. IT IS INTENDED TO BE USED BY HEALTHCARE PRACTITIONERS IN CLINICAL SETTINGS AS READY-TO-USE LIQUID CHEMICAL DISINFECTANT FOR THE HIGH-LEVEL DISINFECTION OF SEMI-CRITICAL MEDICAL DEVICES FOR WHICH ALTERNATIVE METHODS OF TERMINAL REPROCESSING ARE NOT SUITABLE OR AVAILABLE.
2013	IMP/MD/2020/000065	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIP SYSTEM – BALL HEAD (CERAMIC BALL HEAD)-"• ADVANCED DEGENERATION OF THE HIP JOINT AS A RESULT OF DEGENERATIVE, POST-TRAUMATIC OR RHEUMATOID ARTHRITIS. • FRACTURE OR AVASCULAR NECROSIS OF THE FEMORAL HEAD • CONDITIONS RESULTING FROM PREVIOUS OPERATIONS, SUCH AS OSTEOSYNTHESIS, JOINT RECONSTRUCTION, ARTHRODESIS, HEMIARTHROPLASTY OR HIP TOTAL PROSTHESIS."

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2014	IMP/MD/2020/000066	1.License Holder Name: M/S COOK INDIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOSCOPIC CLIPPING DEVICE(INSTINCT™ ENDOSCOPIC HEMOCLIP)-THIS DEVICE IS INTENDED FOR ENDOSCOPIC CLIP PLACEMENT WITHIN THE GASTROINTESTINAL TRACT FOR THE PURPOSE OF ENDOSCOPIC MARKING, HEMOSTASIS FOR MUCOSAL/SUBMUCOSAL DEFECTS LESS THAN 3 CM IN THE UPPER GI TRACT, BLEEDING ULCERS, ARTERIES LESS THAN 2 MM, AND POLYPS LESS THAN 1.5 CM IN DIAMETER IN THE GI TRACT. THIS DEVICE IS NOT INTENDED TO REPAIR GI TRACT LUMINAL PERFORATIONS. ,EXTRACTION BALLOONS FOR GASTROENTEROLOGY(FUSION QUATTRO® EXTRACTION BALLOON)-IT IS USED FOR ENDOSCOPIC REMOVAL OF BILIARY STONES., PERCUTANEOUS ENDOSCOPIC GASTROTOMY SETS(PERCUTANEOUS ENDOSCOPIC GASTROTOMY SETS)-PERCUTANEOUS ENDOSCOPIC GASTROSTOMY SETS ARE INTENDED FOR PERCUTANEOUS ENDOSCOPIC GASTROSTOMY PLACEMENT TO PROVIDE ENTERAL NUTRITION TO PATIENTS REQUIRING NUTRITIONAL SUPPORT, EXTRACTION BALLOONS FOR GASTROENTEROLOGY(TRI-EX EXTRACTION BALLOON WITH MULTIPLE SIZING)-IT IS USED FOR ENDOSCOPIC REMOVAL OF BILIARY STONES.,DILATION BALLOON FOR GASTROENTEROLOGY(QUANTUM TTC ESOPHAGEAL BALLOON DILATOR)-TO DILATE STRICTURES OF THE GASTROINTESTINAL TRACT, INCLUDING ESOPHAGUS, PYLORUS, DUODENUM AND COLON, BILIARY DILATION BALLOONS(QUANTUM TTC® BILIARY BALLOON DILATOR)-USED TO DILATE STRICTURES OF THE BILIARY TREE.,ERCP CATHETERS(CLASSIC ERCP CATHETERS, HUIBREGTSE-KATON® ERCP CATHETER, CRAMER ERCP CATHETER, GLO-TIP® ERCP CATHETERS, GLO-TIP® ANGLED ERCP CATHETER, GLO-TIP II® DOUBLE LUMEN ERCP CATHETERS, GLO-TIP II® DOUBLE LUMEN ANGLED ERCP CATHETER, FUSION® GLO-TIP ERCP CATHETER, FUSION® OMNI™ ERCP CATHETER, HABER RAMP™ CATHETER)-THEY ARE USED FOR ENDOSCOPIC CANNULATION OF THE DUCTAL SYSTEM,WIRE GUIDES FOR GASTROENTEROLOGY(ROADRUNNER® WIRE GUIDE)-USED TO ASSIST IN CANNULATION OF BILIARY AND PANCREATIC DUCTS AND TO AID IN BRIDGING DIFFICULT STRICTURES DURING ERCP.,DILATION BALLOON FOR GASTROENTEROLOGY(HERCULES 3 STAGE WIREGUIDED BALLOON ESOPHAGEAL – PYLORIC - COLONIC)-TO DILATE STRICTURES OF THE GASTROINTESTINAL TRACT, INCLUDING STRICTURES OF THE ESOPHAGUS, PYLORUS, DUODENUM AND COLON,WIRE GUIDES FOR GASTROENTEROLOGY(TRACER METRO® DIRECT WIRE GUIDE)-USED TO ASSIST IN CANNULATION OF BILIARY AND PANCREATIC DUCTS AND TO AID IN BRIDGING DIFFICULT STRICTURES DURING ERCP.,

	GASTROSTOMY DEVICES(NASAL JEJUNAL FEEDING TUBE)-THE WILSON-COOK NASAL JEJUNAL FEEDING TUBE IS INTENDED TO PROVIDE SHORT-TERM ENTERAL ACCESS FOR DELIVERY OF NUTRITION AND/OR MEDICATIONS TO SMALL BOWEL.,WIRE GUIDES FOR GASTROENTEROLOGY(ACROBAT® 2 CALIBRATED TIP WIRE GUIDE)-USED TO ASSIST IN CANNULATION OF BILIARY AND PANCREATIC DUCTS AND TO AID IN BRIDGING DIFFICULT STRICTURES DURING ERCP.,NEEDLE KNIFE PAPILLOTOMES (HUIBREGTSE®)-THE SUBJECT DEVICES ARE USED FOR ACCESSING THE COMMON BILE DUCT WHEN STANDARD METHODS OF CANNULATION HAVE BEEN EXHAUSTED AND FOR PAPILLOTOMY., ASPIRATION NEEDLE(ECHOTIP ULTRA)-THIS DEVICE IS USED TO SAMPLE TARGETED SUBMUCOSAL GASTROINTESTINAL LESIONS THROUGH THE ACCESSORY CHANNEL OF AN ULTRASOUND ENDOSCOPE.,BALLOON DILATORS FOR GASTROENTEROLOGY (WILSON-COOK ACHALASIA BALLOON)-TO DILATE STRICTURES OF THE OF THE ESOPHAGUS. [SPECIFICALLY INDICATED FOR PATIENTS WITH ACHALASIA],SPHINCTEROTOMES(TRI-TOME PC®)-THE SUBJECT DEVICES ARE USED FOR CANNULATION OF THE DUCTAL SYSTEM AND FOR SPHINCTEROTOMY. ,DILATION CATHETERS FOR GASTROENTEROLOGY(SOEHENDRA® BILIARY DILATION CATHETERS)-THEY ARE USED TO DILATE BILIARY STRICTURES, SPHINCTEROTOMES(FUSION®)-THE SUBJECT DEVICES ARE USED FOR CANNULATION OF THE DUCTAL SYSTEM AND FOR SPHINCTEROTOMY. IF PRELOADED, ALSO AIDS IN BRIDGING DIFFICULT STRICTURES DURING ERCP.,ENDOSCOPIC LIGATION DEVICES – GASTROENTEROLOGY(SIX SHOOTER SAEED MULTI-BAND LIGATOR)-USED TO ENDOSCOPICALLY LIGATE ESOPHAGEAL VARICES AT OR ABOVE THE GASTROESOPHAGEAL JUNCTION OR TO LIGATE INTERNAL HEMORRHOIDS.,GASTROTOMY FEEDING DEVICES (JEJUNAL FEEDING SET)-JEJUNAL FEEDING SETS ARE USED FOR PERCUTANEOUS ENDOSCOPIC PLACEMENT TO PROVIDE ENTERAL; NUTRITION TO PATIENTS REQUIRING NUTRITIONAL SUPPORT., ENDOSCOPIC LIGATION DEVICES – GASTROENTEROLOGY(SINGLE SAEED MULTI-BAND LIGATOR BARREL)-USED TO ENDOSCOPICALLY LIGATE ESOPHAGEAL VARICES AT OR ABOVE THE GASTROESOPHAGEAL JUNCTION OR TO LIGATE INTERNAL HEMORRHOIDS.,DILATION CATHETERS FOR GASTROENTEROLOGY (COTTON® GRADUATED BILIARY DILATION CATHETERS)-THEY ARE USED TO DILATE BILIARY STRICTURES,DILATION BALLOON FOR GASTROENTEROLOGY(HERCULES 3 STAGE BALLOON DILATOR – ESOPHAGEAL)-TO ENDOSCOPICALLY DILATE STRICTURES OF THE ESOPHAGUS

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2015	IMP/MD/2020/000070	1.License Holder Name: M/S STRYKER INDIA PRIVATE LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE CEMENT(SIMPLEX P BONE CEMENT (SURGICAL SIMPLEX-P))-IT IS INTENDED AS BONE CEMENT IN PROSTHETIC SURGERY,ROTATING HINGE KNEE SYSTEM (MODULAR)-ROTATING HINGE KNEE SYSTEMS ARE INTENDED TO BE IMPLANTED WITH BONE CEMENT FOR THE FOLLOWING CONDITION(S): 1. THERE IS DESTRUCTION OF THE JOINT SURFACES, WITH OR WITHOUT SIGNIFICANT BONE DEFORMITY. 2. THE CRUCIATE AND/OR COLLATERAL LIGAMENTS DO NOT STABILIZE THE KNEE JOINT. 3. THE LIGAMENTS ARE INADEQUATE AND/OR THE MUSCULATURE IS WEAK. AND/OR, 4. REVISION IS REQUIRED OF A FAILED PROSTHESIS WHERE THERE HAS BEEN GROSS INSTABILITY, WITH OR WITHOUT BONE LOSS OR INADEQUATE SOFT TISSUE.,MODULAR REPLACEMENT SYSTEM(HMRS)-IT IS INTENDED FOR USE IN ONCOLOGY PATIENTS REQUIRING EXTENSIVE RECONSTRUCTION OF THE PROXIMAL TIBIA AND/OR PROXIMAL HUMEROUS INCLUDING THE KNEE JOINT ANF KNEE FUSIONS, NECESSITATED BY EXTENSIVE BONE LOSS DUE TO TUMOR RESECTION .THESE PROSTHESIS ARE INTENDED FOR USE WITH BONE CEMENT AS A MEANS OF INTRAMEDULLARY FIXATION, TOTAL KNEE REPLACEMENT SYSTEM – TIBIAL BASEPLATE (TRIATHLON TRITANIUM TIBIAL BASEPLATE)-GENERAL TOTAL KNEE ARTHROPLASTY (TKR) INDICATIONS: • PAINFUL, DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM: NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OR AVASCULAR NECROSIS), RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS. • POST-TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION. • MODERATE VARUS, VALGUS, OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY. • REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURE. • FRACTURE OF THE DISTAL FEMUR AND/OR PROXIMAL TIBIA THAT CANNOT BE STABILIZED BY STANDARD FRACTUREMANAGEMENT TECHNIQUES. THE TRIATHLON TRITANIUM BASEPLATE IS INDICATED FOR BOTH CEMENTLESS AND CEMENTED USE.ADDITIONAL INDICATIONS FOR POSTERIOR STABILIZED (PS) COMPONENTS: • LIGAMENTOUS INSTABILITY REQUIRING IMPLANT BEARING SURFACE GEOMETRIES WITH INCREASED CONSTRAINT. • ABSENT OR NON-FUNCTIONING POSTERIORCRUCIATE LIGAMENT. • SEVERE ANTEROPOSTERIOR INSTABILITY OF THE KNEE JOINT,ROTATING HINGE KNEE SYSTEM - KINEMATIC(KINEMATIC)-HINGE KNEE SYSTEMS ARE INTENDED TO BE IMPLANTED WITH BONE CEMENT FOR THE FOLLOWING CONDITION(S): 1. THERE IS DESTRUCTION OF THE JOINT SURFACES, WITH OR

	WITHOUT SIGNIFICANT BONE DEFORMITY. THE CRUCIATE AND/OR COLLATERAL LIGAMENTS DO NOT STABILIZE THE KNEE JOINT. THE LIGAMENTS ARE INADEQUATE AND/OR THE MUSCULATURE IS WEAK. AND/OR, REVISION IS REQUIRED OF A FAILED PROSTHESIS WHERE THERE HAS BEEN GROSS INSTABILITY, WITH OR WITHOUT BONE LOSS OR INADEQUATE SOFT TISSUE.,MODULAR REPLACEMENT SYSTEM(GMRS)-IT IS INTENDED FOR USE IN ONCOLOGY PATIENTS REQUIRING EXTENSIVE RECONSTRUCTION OF THE PROXIMAL TIBIA AND /OR PROXIMAL HUMERUS INCLUDING THE KNEE JOINT AND KNEE FUSIONS, NECESSITATED BY EXTENSIVE BONE LOSS DUE TO TUMOR RESECTION. THESE PROSTHESIS ARE INTENDED FOR USE WITH BONE CEMENT AS A MEANS OF INTRAMEDULLARY FIXATION, TOTAL KNEE REPLACEMENT SYSTEM – TIBIAL INSERT(SCORPIO-TIBIAL INSERT)-IT IS INDICATED IN PAINFUL, DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM: DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS OR POSTTRAUMATIC ARTHRITIS, POSTTRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION, IN MODERATE VARUS, VALGUS OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY AND IN REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURES,TOTAL KNEE REPLACEMENT SYSTEM-TIBIAL TRAY/BASEPLATE(SCORPIO- TIBIAL TRAY/BASEPLATE)-IT IS INDICATED FOR PAINFUL ,DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS OR POST –TRAUMATIC ARTHRITIS , POST- TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION , IN MODERATE VARUS OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY AND IN REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURES, TOTAL KNEE REPLACEMENT SYSTEM-FEMORAL(SCORPIO - FEMORAL)-IT IS INDICATED IN PAINFUL, DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM: DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS OR POSTTRAUMATIC ARTHRITIS, POSTTRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION, IN MODERATE VARUS, VALGUS OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY AND IN REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURES.,TOTAL KNEE REPLACEMENT SYSTEM-PATELLA (SCORPIO - PATELLA)-IT IS INDICATED IN PAINFUL, DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM: DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS OR POSTTRAUMATIC ARTHRITIS,

	POSTTRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION, IN MODERATE VARUS, VALGUS OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY AND IN REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURES.,ANTIBIOTIC BONE CEMENT(ANTIBIOTIC BONE CEMENT SIMPLEX P (ANTIBIOTIC SIMPLEX))-IT IS INDICATED AS BONE CEMENT IN PROSTHETIC SURGERY,TOTAL KNEE REPLACEMENT SYSTEM (SCORPIO - STEM, FLUTED STEM, STANDARD OFFSET ADAPTOR)-IT IS INDICATED FOR PAINFUL, DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS OR POST- TRAUMATIC ARTHRITIS, POST- TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION , IN MODERATE VARUS , VALGUS OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY AND IN REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURES,BONE CEMENT(SIMPLEX™ P SPEEDSET™ BONE CEMENT)-SIMPLEX™ P SPEEDSET™ BONE CEMENT (METHYL METHACRYLATE: MIXTURE OF POLYMETHYL METHACRYLATE, METHYL-METHACRYLATE-STYRENE-COPOLYMER AND BARIUM SULFATE, U.S.P.) IS INDICATED FOR THE FIXATION OF PROSTHESES TO LIVING BONE IN ORTHOPAEDICMUSCULOSKELETAL SURGICAL PROCEDURES FOR OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, TRAUMATIC ARTHRITIS, AVASCULAR NECROSIS, SICKLE CELL ANEMIA, COLLAGEN DISEASE, SEVERE JOINT DESTRUCTION SECONDARY TO TRAUMA OR OTHER CONDITIONS, AND REVISION OF PREVIOUS ARTHROPLASTY PROCEDURES. THE CEMENT IS ALSO INDICATED FOR THE FIXATION OF PATHOLOGICAL FRACTURES WHERE LOSS OF BONE SUBSTANCE OR RECALCITRANCE OF THE FRACTURE RENDERS MORE CONVENTIONAL PROCEDURES INEFFECTIVE,TOTAL KNEE REPLACEMENT SYSTEM - TIBIAL COMPONENTS(TRIATHLON- TIBIAL COMPONENTS)-PAINFUL, DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM: NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OR AVASCULAR NECROSIS), RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS. • POST-TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION. • MODERATE VARUS, VALGUS, OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY. • REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURE. • FRACTURE OF THE DISTAL FEMUR AND/OR PROXIMAL TIBIA THAT CANNOT BE STABILIZED BY STANDARD FRACTURE MANAGEMENT TECHNIQUES,TOTAL KNEE REPLACEMENT

	SYSTEM - MODULAR STEM EXTENSION STEMS AND OFFSETS (TRIATHLON - MODULAR STEM EXTENSION STEMS AND OFFSETS)-PAINFUL, DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM: NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OR AVASCULAR NECROSIS), RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS. • POST-TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION. • MODERATE VARUS, VALGUS, OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY. • REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURE. • FRACTURE OF THE DISTAL FEMUR AND/OR PROXIMAL TIBIA THAT CANNOT BE STABILIZED BY STANDARD FRACTURE MANAGEMENT TECHNIQUES,TOTAL KNEE REPLACEMENT SYSTEM-PATELLAR COMPONENTS(TRIATHLON- PATELLAR COMPONENTS)-PAINFUL, DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM: NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OR AVASCULAR NECROSIS), RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS. • POST-TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION. • MODERATE VARUS, VALGUS, OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY. • REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURE. • FRACTURE OF THE DISTAL FEMUR AND/OR PROXIMAL TIBIA THAT CANNOT BE STABILIZED BY STANDARD FRACTURE MANAGEMENT TECHNIQUES,TOTAL KNEE REPLACEMENT SYSTEM- BONE AUGMENTATION COMPONENTS(TRIATHLON - BONE AUGMENTATION COMPONENTS)-PAINFUL, DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM: NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OR AVASCULAR NECROSIS), RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS. • POST-TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION. • MODERATE VARUS, VALGUS, OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY. • REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURE. • FRACTURE OF THE DISTAL FEMUR AND/OR PROXIMAL TIBIA THAT CANNOT BE STABILIZED BY STANDARD FRACTURE MANAGEMENT TECHNIQUES, TOTAL KNEE REPLACEMENT SYSTEM - TRIATHLON ALL POLY TIBIAL COMPONENT(TRIATHLON ALL POLY TIBIAL COMPONENT)-GENERAL TOTAL KNEE ARTHROPLASTY (TKR) INDICATIONS: • PAINFUL, DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM: NON-

	INFLAMMATORY DEGENERATIVE JOINT DISEASE (INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OR AVASCULAR NECROSIS), RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS. • POST-TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION. • MODERATE VARUS, VALGUS, OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY. • REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURE. • FRACTURE OF THE DISTAL FEMUR AND/OR PROXIMAL TIBIA THAT CANNOT BE STABILIZED BY STANDARD FRACTURE –MANAGEMENT TECHNIQUES. THE TRIATHLON ALL POLYETHYLENE TIBIAL COMPONENTS ARE INDICATED FOR CEMENTED USE ONLY. ADDITIONAL INDICATIONS FOR POSTERIOR STABILIZED (PS) AND TOTAL STABILIZER (TS) COMPONENTS: • LIGAMENTOUS INSTABILITY REQUIRING IMPLANT BEARING SURFACE GEOMETRIES WITH INCREASED CONSTRAINT. • ABSENT OR NON-FUNCTIONING POSTERIOR CRUCIATE LIGAMENT. • SEVERE ANTEROPOSTERIOR INSTABILITY OF THE KNEE JOINT. ADDITIONAL INDICATIONS FOR TOTAL STABILIZER (TS) COMPONENTS: • SEVERE INSTABILITY OF THE KNEE SECONDARY TO COMPROMISED COLLATERAL LIGAMENT INTEGRITY OR FUNCTION,TOTAL KNEE REPLACEMENT SYSTEM - FEMORAL COMPONENT(TRIATHLON-FEMORAL COMPONENT)-PAINFUL, DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM: NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, OR AVASCULAR NECROSIS), RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS. • POST-TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION. • MODERATE VARUS, VALGUS, OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY. • REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURE. • FRACTURE OF THE DISTAL FEMUR AND/OR PROXIMAL TIBIA THAT CANNOT BE STABILIZED BY STANDARD FRACTURE MANAGEMENT TECHNIQUES,TOTAL HIP REPLACEMENT SYSTEM(EXETER TOTAL)-THE INDICATIONS FOR USE FOR TOTAL HIP ARTHROPLASTY INCLUDE: • PAINFUL, DISABLING JOINT DISEASE OF THE HIP RESULTING FROM: DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS, POST-TRAUMATIC ARTHRITIS OR LATE STAGE AVASCULAR NECROSIS. • REVISION OF PREVIOUS UNSUCCESSFUL FEMORAL HEAD REPLACEMENT, CUP ARTHROPLASTY OR OTHER PROCEDURE. • CLINICAL MANAGEMENT PROBLEMS WHERE ARTHRODESIS OR ALTERNATIVE RECONSTRUCTIVE TECHNIQUES ARE LESS LIKELY TO ACHIEVE SATISFACTORY RESULTS. • WHERE BONE STOCK IS OF POOR QUALITY OR INADEQUATE FOR OTHER

		RECONSTRUCTIVE TECHNIQUES, SUCH AS CEMENTLESS FIXATION, AS INDICATED BY DEFICIENCIES OF THE ACETABULUM. STRYKER'S EXETER X3 RIMFIT ACETABULAR CUP IS INTENDED FOR CEMENTED USE ONLY. STRYKER THR ALL-POLYETHYLENE ACETABULAR CUPS ARE INTENDED FOR CEMENTED USE ONLY.
2016	IMP/MD/2020/000071	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOVENOUS RADIOFREQUENCY STYLET(CLOSURERFS ENDOVENOUS RADIOFREQUENCY STYLET)-THE CLOSURERFS ENDOVENOUS RADIOFREQUENCY STYLET IS INTENDED FOR USE IN VESSEL AND TISSUE COAGULATION INCLUDING TREATMENT OF INCOMPETENT (I. E., REFLUXING) PERFORATOR AND TRIBUTARY VEINS.

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2017	IMP/MD/2020/000072	1.License Holder Name: M/S COOK INDIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOVASCULAR STENT GRAFTS(ZENITH BRANCH ENDOVASCULAR GRAFT ILIAC BIFURCATION)-THE ZENITH® BRANCH ENDOVASCULAR GRAFT-ILIAC BIFURCATION WITH THE H&L-B ONE-SHOT™ INTRODUCTION SYSTEM IS INDICATED FOR THE ENDOVASCULAR TREATMENT OF PATIENTS WITH AN AORTOILIAC OR ILIAC ANEURYSM, AN INSUFFICIENT DISTAL SEALING SITE WITHIN THE COMMON ILIAC ARTERY, AND HAVING MORPHOLOGY SUITABLE FOR ENDOVASCULAR REPAIR, INCLUDING: • ADEQUATE ILIAC/FEMORAL ACCESS COMPATIBLE WITH A 20 FRENCH (7.7 MM O.D.) INTRODUCTION SYSTEM, • NON-ANEURYSMAL EXTERNAL ILIAC ARTERY FIXATION SEGMENT DISTAL TO THE ANEURYSM: - WITH A LENGTH OF AT LEAST 20 MM, - WITH A DIAMETER MEASURED OUTER WALL TO OUTER WALL OF NO GREATER THAN 11 MM AND NO LESS THAN 8 MM. • NON-ANEURYSMAL INTERNAL ILIAC ARTERY SEGMENT DISTAL TO THE ANEURYSM: - WITH A LENGTH OF AT LEAST 10 MM (WITH 20-30 MM BEING PREFERRED) - WITH A DIAMETER ACCEPTABLE FOR PROPER SEALING.,OVUM ASPIRATION NEEDLE(OVUM ASPIRATION NEEDLE DOUBLE LUMEN)-USED TO SIMULTANEOUSLY OR INDEPENDENTLY ASPIRATE AND FLUSH FOLLICLES TO HARVEST OOCYTES, ENDOVASCULAR STENT GRAFTS(ZENITH FENESTRATED AAA ENDOVASCULAR GRAFT)-THE ZENITH FENESTRATED AAA ENDOVASCULAR GRAFT WITH THE H&L-B ONE-SHOT INTRODUCTION SYSTEM IS INDICATED FOR THE TREATMENT OF INFRARENAL ABDOMINAL AORTIC ANEURYSMS (AAAS) IN HIGH- RISK PATIENTS WHO ARE NOT SUITABLE FOR CONVENTIONAL OPEN SURGICAL REPAIR OR WHO ARE NOT SUITABLE FOR REPAIR WITH A STANDARD ZENITH ENDOVASCULAR GRAFT, WHEN THE ANEURYSMAL DISEASE EXTENDS UP TO THE LEVEL OF THE RENAL ARTERIES. THE PATIENT MUST HAVE ANEURYSMAL MORPHOLOGY SUITABLE FOR ENDOVASCULAR REPAIR, INCLUDING: • ADEQUATE FEMORAL/ILIAC ACCESS COMPATIBLE WITH THE REQUIRED DELIVERY SYSTEMS; • A NON-ANEURYSMAL INFRARENAL AORTIC SEGMENT (NECK) PROXIMAL TO THE ANEURYSM WITH: - A LENGTH OF AT LEAST 4 MM, I.E. AT LEAST 4 MM CIRCUMFERENTIAL WALL CONTACT AROUND FENESTRATIONS AND/OR LIMITS OF SCALLOP; - A DIAMETER MEASURED OUTER WALL TO OUTER WALL OF NO GREATER THAN 31 MM AND NO LESS THAN 19 MM; - AN ANGLE LESS THAN 45 DEGREES RELATIVE TO THE LONG AXIS OF THE ANEURYSM; AND - AN ANGLE LESS THAN 45 DEGREES RELATIVE TO THE AXIS OF THE SUPRARENAL AORTA. • AN IPSILATERAL ILIAC ARTERY DISTAL FIXATION SITE GREATER THAN 10 MM IN LENGTH AND 9–21 MM IN

	DIAMETER (MEASURED OUTER WALL TO OUTER WALL); AND A CONTRALATERAL ILIAC ARTERY DISTAL FIXATION SITE GREATER THAN 10 MM IN LENGTH AND 7–21 MM IN DIAMETER (MEASURED OUTER WALL TO OUTER WALL).,OVUM ASPIRATION NEEDLE(OVUM ASPIRATION NEEDLE SINGLE LUMEN)-SINGLE LUMEN OVUM PICK-UP NEEDLES ARE INTENDED FOR USE IN THE FIELD OF ASSISTED REPRODUCTION AND GYNECOLOGY, IN PARTICULAR ASPIRATION OF OVARIAN FOLLICLES FOR THE COLLECTION OF OOCYTES, AND ASPIRATION OF PATHOLOGIC OVARIAN CYSTS,OVUM ASPIRATION NEEDLES(TRANSMYOMETRIAL EMBRYO TRANSFER SET BIFURCATION)-TRANSMYOMETRIAL EMBRYO TRANSFER SETS ARE USED IN CONJUNCTION WITH A TRANSVAGINAL ULTRASOUND TRANSDUCER TO PLACE EMBRYOS INTO THE ENDOMETRIUM OR UTERINE CAVITY

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2018	IMP/MD/2020/000073	1.License Holder Name: LENSAI OPHTHALMIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRASTROMAL CORNEAL IMPLANTS(INTACS ® SK)-INTACS® SK CORNEAL IMPLANTS FOR THE TREATMENT OF KERATOCONUS ARE INTENDED TO REDUCE OR ELIMINATE MYOPIA AND OR ASTIGMATISM IN PATIENTS WHO ARE NO LONGER ABLE TO ACHIEVE ADEQUATE VISION WITH THEIR CONTACT LENSES OR SPECTACLES, SUCH THAT THEIR FUNCTIONAL VISION MAY BE RESTORED AND THE NEED FOR A CORNEAL TRANSPLANT PROCEDURE CAN POTENTIALLY BE DEFERRED. THE SPECIFIC SUBSET OF KERATOCONUS PATIENTS PROPOSED TO BE TREATED WITH INTACS® SK CORNEAL IMPLANTS ARE THOSE PATIENTS. 1. WHO HAVE KERATOMETRIC READING IN THE APEX OF THE CONE BETWEEN 46 D AND 56 D 2. WHO HAVE EXPERIENCED A PROGRESSIVE DETERIORATION IN THEIR VISION, SUCH THAT THEY CAN NO LONGER ACHIEVE ADEQUATE FUNCTIONAL VISION WITH THEIR CONTACT LENSES OR SPECTACLES 3. WHO HAVE CLEAR CENTRAL CORNEAS; AND 4. WHO HAVE, AT THE PROPOSED INCISION SITE, A MINIMUM CORNEAL THICKNESS OF 450M OR FOR 0.500 NM THICKNESS SEGMENTS, A MINIMUM CORNEAL THICKNESS OF 500M,INTRASTROMAL CORNEAL IMPLANTS(INTACS®)-INTACS CORNEAL IMPLANTS FOR THE TREATMENT OF KERATOCONUS ARE INTENDED FOR THE REDUCTION OR ELIMINATION OF MYOPIA AND ASTIGMATISM IN PATIENTS WITH KERATOCONUS, WHO ARE NO LONGER ABLE TO ACHIEVE ADEQUATE VISION WITH THEIR CONTACT LENSES OR SPECTACLES, SO THAT THEIR FUNCTIONAL VISION MAY BE RESTORED AND THE NEED FOR A CORNEAL TRANSPLANT PROCEDURE CAN POTENTIALLY BE DEFERRED. THE SPECIFIC SUBSET OF KERATOCONUS PATIENTS PROPOSED TO BE TREATED WITH INTACS CORNEAL IMPLANTS ARE THOSE PATIENTS: • WHO HAVE EXPERIENCED A PROGRESSIVE DETERIORATION IN THEIR VISION, SUCH THAT THEY CAN NO LONGER ACHIEVE ADEQUATE FUNCTIONAL VISION WITH THEIR CONTACT LENSES OR SPECTACLES; • WHO HAVE CLEAR CENTRAL CORNEAS; • WHO HAVE A CORNEAL THICKNESS OF 450 OR GREATER AT THE PROPOSED INCISION SITE; AND •WHO HAVE CORNEAL TRANSPLANTATION AS THE ONLY REMAINING OPTION TO IMPROVE THEIR FUNCTIONAL VISION.

2019	IMP/MD/2020/000074	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINAL SYSTEM-SCREW (EXPEDIUM)-THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THE THORACIC, LUMBAR AND SACRAL SPINE. THE EXPEDIUM AND VIPER SPINE SYSTEMS ARE INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS. WHEN USED IN A POSTERIOR PERCUTANEOUS APPROACH WITH MIS INSTRUMENTATION, THE VIPER SYSTEM IS INTENDED FOR NONCERVICAL PEDICLE FIXATION AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION IN SKELETALLY MATURE PATIENTS

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2020	IMP/MD/2020/000075	1.License Holder Name: DORA MEDICAL TRADING (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HEMODIALYSIS CARE KITS(DORA)-THIS PRODUCT IS INTENDED TO BE USE FOR PRE AND POST HEMODIALYSIS TREATMENT.,TUBING SETS FOR HEMODIALYSIS(DORA)-TUBING SETS FOR HEMODIALYSIS REFER TO A KIND OF CATHETERS USED FOR CARRYING BLOOD IN VITRO. IN THE PROCESS OF CLINICAL DIALYSIS, THEY ARE CONNECTED TO HEMODIALYZERS AND WORK TOGETHER WITH DIALYSIS MACHINES TO COMPLETE DIALYSIS TREATMENT. THE PRODUCT IS USED FOR HEMODIALYSIS TREATMENT.,HOLLOW FIBER DIALYZER(DORA)-DORA HOLLOW FIBER DIALYZER CAN BE USED FOR THE HEMODIALYSIS TREATMENT OF ACUTE AND CHRONIC RENAL FAILURE.,DISPOSABLE A.V. FISTULA NEEDLE SETS(DORA)-DISPOSABLE DISPOSABLE A.V. FISTULA NEEDLE SETS IS A KIND OF CONSUMABLE USED FOR PUNCTURE DURING THE CONTINUOUS RENAL REPLACEMENT THERAPY.

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2021	IMP/MD/2020/000079	1.License Holder Name: BALT INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRACRANIAL SELF EXPANDABLE STENTS(SILK VISTA BABY)-SILK VISTA BABY STENTS ARE DESIGNED FOR THE TREATMENT OF INTRACRANIAL ANEURYSMS. THE SELF-EXPANDABLE LEO+/LEO+ BABY STENTS ARE DESIGNED FOR THE TREATMENT OF INTRACRANIAL ANEURYSMS IN ASSOCIATION WITH EMBOLIZATION COILS.,SELECTIVE AND HYPERSELECTIVE CATHETERS(GAMA)-THE GAMA REINFORCED MICROCATHETERS ARE INTENDED FOR USE IN INTERVENTIONAL RADIOLOGY PROCEDURES IN THE VASCULAR AND NEUROVASCULAR SYSTEM FOR: THE INJECTION OF DIAGNOSTIC OR THERAPEUTIC PRODUCTS. THE INSERTION OF COMPATIBLE PUSHABLE COILS OR DETACHABLE COILS, THE INSERTION OF COMPATIBLE INTRACRANIAL SELF-EXPANDABLE STENTS, THE INSERTION OF COMPATIBLE THROMBO-EMBOLECTOMY DEVICES.,INTRACRANIAL SELF EXPANDABLE STENTS(SILK+/SILK VISTA BABY, LEO+/LEO+BABY)-THE SELF-EXPANDABLE SILK+/SILK VISTA BABY STENTS ARE DESIGNED FOR THE TREATMENT OF INTRACRANIAL ANEURYSMS. THE SELF-EXPANDABLE LEO+/LEO+ BABY STENTS ARE DESIGNED FOR THE TREATMENT OF INTRACRANIAL ANEURYSMS IN ASSOCIATION WITH EMBOLIZATION COILS.,TEMPORARY OCCLUSION CATHETERS (COPERNIC 2L, ECLIPSE 2L)-THE ECLIPSE 2L AND COPERNIC 2L DOUBLE LUMEN BALLOON CATHETERS ARE INTENDED FOR USE IN THE PERIPHERAL VASCULATURE AND NEUROVASCULATURE FOR TEMPORARY OCCLUSION. THE BALLOON CATHETERS PROVIDE TEMPORARY VASCULAR OCCLUSION WHICH IS USEFUL IN SELECTIVELY STOPPING OR CONTROLLING BLOOD FLOW AND FOR THE VASOSPASM TREATMENT. THE BALLOON CATHETERS ALSO OFFER BALLOON ASSISTED EMBOLIZATION OF INTRACRANIAL ANEURYSMS. THEY ARE ALSO INDICATED FOR: USE IN THE PERIPHERAL VASCULATURE AND NEUROVASCULATURE FOR ADMINISTRATION OF DIAGNOSTIC AGENTS (CONTRAST SOLUTION) AND THERAPEUTIC AGENTS (EMBOLIZATION MATERIALS COMPATIBLE WITH THE INNER DIAMETER OF THE BALLOON CATHETERS ECLIPSE 2L AND COPERNIC 2L). ,TEMPORARY OCCLUSION CATHETERS(COPERNIC, ECLIPSE)-COPERNIC & ECLIPSE OCCLUSION CATHETERS ARE INDICATED FOR USE IN THE NEUROVASCULATURE AND PERIPHERAL SYSTEM TO TEMPORARILY STOP OR CONTROL BLOOD FLOW, TO TREAT VASOSPASMS AND EMBOLIZATION OF ANEURYSMS WITH BALLOONS.,GUIDING CATHETERS(FARGO)-FARGO GUIDING CATHETERS ARE INTENDED TO FACILITATE THE INTRODUCTION OF MICROCATHETERS FOR THERAPEUTIC AND DIAGNOSTIC USE.,CATHETERS FOR DETACHABLE

	BALLOONS(MAGIC FOR DETACHABLE BALLOON)-: MABDTE CATHETERS ALLOW THE INTRODUCTION OF DETACHABLE BALLOONS (GOLDBALLOON) AND ARE INDICATED FOR USE IN THE NEUROVASCULATURE AND PERIPHERAL SYSTEM.,SELECTIVE AND HYPERSELECTIVE CATHETERS(SONIC)-THE SONIC MICRO-CATHETERS ARE INTENDED FOR SELECTIVE AND HYPER SELECTIVE VASCULAR CATHETERIZATION FOR DIAGNOSTIC OR THERAPEUTIC PURPOSES,SELECTIVE AND HYPERSELECTIVE CATHETERS(MAGIC)-THE MAGIC MICRO-CATHETERS ARE INTENDED FOR SELECTIVE AND HYPERSELECTIVE VASCULAR CATHETERIZATION FOR DIAGNOSTIC AND THERAPEUTIC PURPOSES. ,INTRACRANIAL SYSTEMS FOR THROMBOEMBOLECTOMY(CATCHVIEW)-CATCHVIEW ARE DESIGNED FOR USE IN THE FLOW RESTORATION OF PATIENTS WITH ISCHEMIC STROKE DUE TO LARGE INTRACRANIAL VESSEL OCCLUSION. THEY ARE INDICATED TO RESTORE BLOOD FLOW IN THE NEUROVASCULATURE OF PATIENTS WHO ARE INELIGIBLE FOR INTRAVENOUS TISSUE PLASMINOGEN ACTIVATOR (IV T-PA), WHO FAIL IV T-PA THERAPY OR AS A SUPPLEMENT TREATMENT OF INITIATED IV T-PA THERAPY. THE CATCHVIEW THROMBOEMBOLECTOMY DEVICES SHOULD ONLY BE USED BY PHYSICIANS TRAINED IN INTERVENTIONAL NEURORADIOLOGY AND TREATMENT OF ISCHEMIC STROKE. ,CONNECTIONS DEVICES(ANRYV, RYVA & RYVA.LUER)-CONNECTIONS ARE USED AS CONNECTORS OR AS A SOLUTION THAT MAKES THE USE OF OTHER DEVICES EASIER., INTRODUCERS SHEATH(IVA)-: THE INTRODUCERS SHEATH ARE DESIGNED FOR VASCULAR ACCESS OF DEVICES FOR THERAPEUTIC OR DIAGNOSTIC USE.,SELECTIVE AND HYPERSELECTIVE CATHETERS (VASCO+)-THE VASCO+ REINFORCED MICRO-CATHETERS ARE INTENDED FOR INJECTION OF DIAGNOSTIC OR THERAPEUTIC PRODUCTS, TO POSITION PUSHABLE COILS “SPIRALES” OR DETACHABLE COILS ESPECIALLY THE ONES OF MDS « MECHANICAL DETACHMENT SYSTEM » AND FOR THE USE OF THE SELF-EXPANDING STENT LEO+ OR SILK+.,INTRACRANIAL SYSTEMS FOR THROMBOEMBOLECTOMY(CATCH+)-CATCH+ ARE DESIGNED FOR USE IN THE FLOW RESTORATION OF PATIENTS WITH ISCHEMIC STROKE DUE TO LARGE INTRACRANIAL VESSEL OCCLUSION. THEY ARE INDICATED TO RESTORE BLOOD FLOW IN THE NEUROVASCULATURE OF PATIENTS WHO ARE INELIGIBLE FOR INTRAVENOUS TISSUE PLASMINOGEN ACTIVATOR (IV T-PA), WHO FAIL IV T-PA THERAPY OR AS A SUPPLEMENT TREATMENT OF INITIATED IV T-PA THERAPY. THE CATCH+ THROMBOEMBOLECTOMY DEVICES SHOULD ONLY BE USED BY PHYSICIANS TRAINED IN INTERVENTIONAL NEURORADIOLOGY AND TREATMENT OF ISCHEMIC STROKE,HYDROPHILIC GUIDEWIRES(HYBRID)-HYBRID GUIDEWIRES

	ARE DESIGNED TO FACILITATE THE INSERTION OF CATHETERS INTO INTRACRANIAL VASCULAR BRANCHES FOR DIAGNOSTIC OR THERAPEUTIC USE.,DETACHABLE BALLOONS(GOLDBALLOON)-GOLDBALLOON ARE DESIGNED FOR THE EMBOLIZATION OF ARTERIO-VENOUS MALFORMATIONS, IN THE NEUROLOGICAL AND PERIPHERAL REGIONS,EMBOLIZATION COILS(SPIRALES (SPI), FLOW COILS (SPIF))-SPI: FREE SPIRALS ARE DESIGNED FOR INTRAVASCULAR USE. THEY PERMIT THE TREATMENT OF ARTERIO-VASCULAR MALFORMATIONS, FISTULA ARTERIOVENOUS MALFORMATIONS, VARICOCELES, ANEURYSMS. SPIF: THE OCCLUSION DEVICES FLOW COIL ARE INTENDED FOR THE EMBOLIZATION OF VASCULAR MALFORMATIONS OF THE VASCULATURE.

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2022	IMP/MD/2020/000080	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTERBODY FUSION DEVICE(CRESCENT SYSTEM)-THE CRESCENT® SYSTEM IS INDICATED FOR INTERBODY SPINAL FUSION PROCEDURES IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) FROM L2-S1. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES. THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE I SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVEL. THE CRESCENT® SYSTEM IS TO BE USED WITH AUTOGENOUS BONE GRAFT.,RESORBABLE CALCIUM SALT BONE VOID FILLER(MASTERGRAFT GRANULES)-DENTAL: MASTERGRAFT® GRANULES MAY BE USED ALONE OR IN COMBINATION WITH AUTOGRAFT TO PROVIDE A BONE VOID FILLER THAT IS RESORBED/REMODELED AND IS REPLACED BY HOST BONE DURING THE HEALING PROCESS. MASTERGRAFT® GRANULES IS PACKED INTO BONY VOIDS OR GAPS TO FILL AND/OR AUGMENT DENTAL ORAL/MAXILLOFACIAL BONY TISSUE. THESE DEFECTS MAY BE SURGICALLY CREATED OSSEOUS DEFECTS OR OSSEOUS DEFECTS CREATED FROM TRAUMATIC INJURY TO THE BONE. PROCEDURES SPECIFIC TO MASTERGRAFT GRANULES INCLUDE: • FILLING OF DENTAL EXTRACTION SOCKETS • FILLING OF CYSTIC DEFECTS • ORAL/MAXILLOFACIAL AUGMENTATION OR RECONSTRUCTION. PROCEDURES SPECIFIC TO MASTERGRAFT MINI GRANULES INCLUDE: • FILLING OF PERIODONTAL DEFECTS • SINUS LIFTS • ALVEOLAR RIDGE AUGMENTATION • FILLING OF DENTAL EXTRACTION SOCKETS • FILLING OF CYSTIC DEFECTS • ORAL/MAXILLOFACIAL AUGMENTATION OR RECONSTRUCTION. MASTERGRAFT GRANULES MAY BE USED WITH OR WITHOUT INTERNAL FIXATION, AND MAY BE MIXED WITH AUTOGRAFT AS A BONE EXTENDER.,INTERVERTEBRAL BODY FUSION DEVICE(ANATOMIC PEEK™ PTC CERVICAL FUSION SYSTEM)-THE ANATOMIC PEEK™ PTC CERVICAL FUSION SYSTEM IS INDICATED FOR USE IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) OF THE CERVICAL SPINE WITH ACCOMPANYING RADICULAR SYMPTOMS AT ONE DISC LEVEL OR TWO CONTIGUOUS LEVELS. DDD IS DEFINED AS DISCOGENIC PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES. THE ANATOMIC PEEK™ PTC CERVICAL FUSION SYSTEM IS USED TO FACILITATE INTERVERTEBRAL BODY FUSION IN THE CERVICAL SPINE AND IS PLACED VIA AN ANTERIOR APPROACH FROM THE C2-C3 DISC SPACE TO THE C7-T1 DISC SPACE USING AUTOGRAFT OR ALLOGENIC BONE GRAFT COMPRISED OF CANCELLOUS AND/OR CORTICOCANCELLOUS BONE GRAFT. THE

	ANATOMIC PEEK™ PTC CERVICAL FUSION SYSTEM IS TO BE USED WITH SUPPLEMENTAL FIXATION. PATIENTS SHOULD HAVE AT LEAST SIX WEEKS OF NON-OPERATIVE TREATMENT PRIOR TO TREATMENT WITH AN INTERVERTEBRAL CAGE.,RESORBABLE CALCIUM SALT BONE VOID FILLER(MASTERGRAFT GRANULES)-ORTHOPEDIC: MASTERGRAFT® GRANULES IS INDICATED ONLY FOR BONY VOIDS OR GAPS THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. ADDITIONALLY, MASTERGRAFT® GRANULES CAN BE USED WITH AUTOGRAFT AS A BONE GRAFT EXTENDER. MASTERGRAFT® GRANULES IS TO BE GENTLY PACKED INTO BONY VOIDS OR GAPS OF THE SKELETAL SYSTEM (E.G., THE POSTEROLATERAL SPINE, PELVIS, ILIUM AND/OR EXTREMITIES). THESE DEFECTS MAY BE SURGICALLY CREATED OSSEOUS DEFECTS OR OSSEOUS DEFECTS CREATED FROM TRAUMATIC INJURY TO THE BONE. MASTERGRAFT GRANULES PROVIDES A BONE VOID FILLER THAT RESORBS AND IS REPLACED WITH BONE DURING THE HEALING PROCESS.,RESORBABLE CALCIUM SALT BONE VOID FILLER (MASTERGRAFT MINI GRANULES)-DENTAL: MASTERGRAFT® GRANULES MAY BE USED ALONE OR IN COMBINATION WITH AUTOGRAFT TO PROVIDE A BONE VOID FILLER THAT IS RESORBED/REMODELED AND IS REPLACED BY HOST BONE DURING THE HEALING PROCESS. MASTERGRAFT® GRANULES IS PACKED INTO BONY VOIDS OR GAPS TO FILL AND/OR AUGMENT DENTAL ORAL/MAXILLOFACIAL BONY TISSUE. THESE DEFECTS MAY BE SURGICALLY CREATED OSSEOUS DEFECTS OR OSSEOUS DEFECTS CREATED FROM TRAUMATIC INJURY TO THE BONE. PROCEDURES SPECIFIC TO MASTERGRAFT GRANULES INCLUDE: • FILLING OF DENTAL EXTRACTION SOCKETS • FILLING OF CYSTIC DEFECTS • ORAL/MAXILLOFACIAL AUGMENTATION OR RECONSTRUCTION. PROCEDURES SPECIFIC TO MASTERGRAFT MINI GRANULES INCLUDE: • FILLING OF PERIODONTAL DEFECTS • SINUS LIFTS • ALVEOLAR RIDGE AUGMENTATION • FILLING OF DENTAL EXTRACTION SOCKETS • FILLING OF CYSTIC DEFECTS • ORAL/MAXILLOFACIAL AUGMENTATION OR RECONSTRUCTION. MASTERGRAFT GRANULES MAY BE USED WITH OR WITHOUT INTERNAL FIXATION, AND MAY BE MIXED WITH AUTOGRAFT AS A BONE EXTENDER.,INTERVERTEBRAL BODY FUSION DEVICE(DIVERGENCE-L ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM)-THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION PLATE AND BONE SCREW COMPONENTS ARE INDICATED AS A SUPPLEMENTAL FIXATION DEVICE FOR THE LUMBOSACRAL LEVEL, ANTERIOR BELOW THE BIFURCATION (L5-S1) OF THE VASCULAR STRUCTURES OR ANTERIOR OBLIQUE ABOVE THE BIFURCATION (L1-L5) OF THE VASCULAR STRUCTURES. THE INDICATIONS AND CONTRAINDICATIONS OF SPINAL INSTRUMENTATION SYSTEMS

	SHOULD BE WELL UNDERSTOOD BY THE SURGEON. THE PLATE AND BONE SCREW COMPONENTS ARE INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR LUMBAR SPINE DURING THE DEVELOPMENT OF SPINAL FUSIONS IN PATIENTS WITH: 1) DEGENERATIVE DISC DISEASE (DDD) DEFINED BY BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES; 2) TRAUMA (INCLUDING FRACTURES); 3) TUMORS; 4) DEFORMITY DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS; 5) PSEUDARTHROSIS; AND/OR 6) FAILED PREVIOUS FUSIONS. THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM INTERBODY IS INDICATED FOR INTERBODY FUSION IN PATIENTS WITH DDD AT ONE OR TWO CONTIGUOUS LEVELS FROM L2 TO S1. THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THE DIVERGENCE-L™ ANTERIOR/ OBLIQUE LUMBAR FUSION INTERBODY CAGE IS ALSO REQUIRED TO BE USED WITH AUTOGENOUS BONE GRAFT. THESE IMPLANTS MAY BE IMPLANTED VIA A VARIETY OF OPEN OR MINIMALLY INVASIVE APPROACHES. THESE APPROACHES INCLUDE ANTERIOR AND OBLIQUE. THESE DEVICES ARE INTENDED TO BE USED WITH SUPPLEMENTAL FIXATION INSTRUMENTATION, WHICH HAS BEEN CLEARED FOR USE IN THE LUMBAR SPINE. INTERBODY CAGES WITH A LORDOSIS OF 18º OR GREATER MUST BE USED WITH AT LEAST SUPPLEMENTAL, ANTERIOR FIXATION. WHEN USED TOGETHER, THE DIVERGENCE-L™ ANTERIOR/OBLIQUE LUMBAR FUSION SYSTEM COMPONENTS CAN BE USED ONLY TO TREAT PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTIGUOUS LEVELS FROM L2 TO S1. THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS.,INTERVERTEBRAL BODY FUSION DEVICE(CLYDESDALE SPINAL SYSTEM)-THE CLYDESDALE® SPINAL SYSTEM IS INTENDED TO BE USED IN INTERBODY FUSION PROCEDURES FOR PATIENTS DIAGNOSED WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTIGUOUS LEVELS FROM L2 TO S1. DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. WHEN USED FOR THESE INDICATIONS, THE CLYDESDALE® SPINAL SYSTEM IS INTENDED FOR USE WITH

	SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBAR SPINE. CERTAIN SIZES OF THE CLYDESDALE® SPINAL SYSTEM MAY BE USED WITH INFUSE® BONE GRAFT IN SINGLE-LEVEL OBLIQUE LATERAL INTERBODY FUSION (OLIF) PROCEDURES FROM L2 TO L5 IN PATIENTS DIAGNOSED WITH DDD, AS DEFINED ABOVE. CONSULT THE LABELING FOR THE INFUSE® BONE GRAFT/MEDTRONIC INTERBODY FUSION DEVICE FOR INFORMATION ON THE SPECIFIC SIZES OF THE CLYDESDALE® SPINAL SYSTEM APPROVED FOR USE WITH INFUSE® BONE GRAFT, AS WELL AS SPECIFIC INFORMATION REGARDING CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS ASSOCIATED WITH INFUSE® BONE GRAFT. INFUSE® BONE GRAFT IS NOT INDICATED FOR USE IN A DIRECT LATERAL INTERBODY FUSION (DLIF) SURGICAL APPROACH. ADDITIONALLY, THE CLYDESDALE® SPINAL SYSTEM CAN BE USED TO PROVIDE ANTERIOR COLUMN SUPPORT IN PATIENTS DIAGNOSED WITH DEGENERATIVE SCOLIOSIS AS AN ADJUNCT TO PEDICLE SCREW FIXATION. INFUSE® BONE GRAFT IS NOT INDICATED FOR USE IN PATIENTS WITH THIS CONDITION. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THE CLYDESDALE® SPINAL SYSTEM IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGENIC BONE GRAFT COMPRISED OF CANCELLOUS AND/OR CORTICOCANCELLOUS BONE GRAFT WHEN THE SUBJECT DEVICE IS USED AS AN ADJUNCT TO FUSION. THESE IMPLANTS MAY BE IMPLANTED VIA A MINIMALLY INVASIVE LATERAL APPROACH.,INTERVERTEBRAL BODY FUSION DEVICE(CAPSTONE SYSTEM)-THE CAPSTONE® SYSTEM IS INDICATED FOR USE WITH AUTOGENOUS BONE GRAFT FOR INTERBODY SPINAL FUSION PROCEDURE IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO LEVELS FROM L2-S1. THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE I SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVEL. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THESE IMPLANTS MAY BE IMPLANTED VIA AN OPEN OR A MINIMALLY INVASIVE POSTERIOR APPROACH. ALTERNATIVELY, THESE IMPLANTS MAY ALSO BE IMPLANTED VIA A TRANSFORAMINAL APPROACH. ALTERNATIVELY, IMPLANTS LARGER THAN 40 MM LENGTH SHOULD BE IMPLANTED VIA DIRECT LATERAL APPROACH. THESE DEVICES ARE INTENDED TO BE USED WITH SUPPLEMENTAL FIXATION INSTRUMENTATION, WHICH HAS BEEN CLEARED FOR USE IN THE LUMBAR SPINE.,PEEK CAGES(CORNERSTONE -SR CAGE SYSTEM)-THE CORNERSTONE-SR® FUSION DEVICES ARE GENERALLY INDICATED

		FOR: - DEGENERATIVE DISCOPATHY AND INSTABILITY • PRIMARY SURGERY FOR CERTAIN PROGRESSIVE DEGENERATIVE DISCOPATHIES OR EXTENSIVE ANTERIOR DECOMPRESSION • REVISION SURGERY FOR FAILED DISC OPERATION, STENOSIS, POST-OPERATIVE INSTABILITY - PSEUDARTHROSIS OR FAILED ARTHRODESIS.
2023	IMP/MD/2020/000081	1.License Holder Name: RIHIM PHARMA INTERNATIONAL LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABSORBABLE L-LACTIDE--CAPROLACTONE COPOLYMER (P(LA/CL)) SURGICAL SUTURES (LIGHT LIFT NEEDLE METHOD, LIGHT LIFT THREAD METHOD, SOLE SUTURE, LIGHT LIFT SPRING METHOD, LIGHT LIFT LINEA METHOD, VISAGE EXCELLENCE METHOD, VISAGE EXCELLENCE METHOD S, BODY EXCELLENCE METHOD, NANO SPRING METHOD, NANO VITIS METHOD, LIGHT LIFT THREAD METHOD S, LIGHT LIFT SPRING METHOD S, LIGHT LIFT NEEDLE METHOD S, SOLE RHINOPLASTY, NANO EXCELLENCE METHOD, LIGHT LIFT THREAD METHOD B, LIGHT LIFT NEEDLE METHOD B, VISAGE EXCELLENCE METHOD HA)-FIXATION, REPOSITIONING AND APPROXIMATION OF SOFT TISSUES AND SKIN.
2024	IMP/MD/2020/000083	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED ,A-1/50, ROOM NO. 2, 100 SHED AREA, G.L.D.C., VAPI, TAL PARDI (VALSAD) , VALSAD GUJARAT ,396195 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOSCOPIC APPLICATOR(SURGIFLO)-THE SURGIFLO™ ENDOSCOPIC APPLICATOR IS INTENDED FOR USE IN DELIVERING HEMOSTATIC AGENTS TO BLEEDING SURGICAL SITES THROUGH A 5 MM TROCAR OR LARGER.

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2025	IMP/MD/2020/000084	1.License Holder Name: AEON AJANTA INDIA PVT. LTD., ,UNIT 504, PEARLS BEST HEIGHTS II, PLOT NO. C 9, NETAJI SUBHASH PLACE , PITAM PURA, NEW ,NEW DELHI DELHI ,110034 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COLLAGEN MATRIX (OLOGEN)-GLAUCOMA: OLOGEN COLLAGEN MATRIX IS PRIMARILY DESIGNED TO CREATE SUBCONJUCTIVAL SPACE (BLEB) AND MODULATE THE WOUND HEALING PHYSIOLOGICALLY F OR TRABECULECTOMY, N O N PENETRATING DEEP SCLERECTOMY , BLEB REVISION OR DRAINAGE IMPLANTATION SURGERY. THE HOST TISSUE COLLAGEN MATR IX INTERACTION MAY OPTIMIZE AND STABILIZE THE STRUCTURE AND COMPOSITION OF OCULAR TISSUES, CREATING A MATURE BLEB STRUCTURE AND PREVENTING SCAR FORMATION. OTHER OPHTHALMIC SURGERIES: OLOGEN COLLAGEN MATRIX MAY BE USED IN OTHER OPHTHALMIC SURGERIES IN WHICH A PHYSIOLOGICAL AND REINFORCED STRUCTURE IS REQUIRED LIKE STRABISMUS SURGERY, OCULAR SURFACE RECONSTRUCTION, GRAFT DONOR SITES, PTERYGIUM EXCISION OR OCULAR PLASTIC SURGERY.
2026	IMP/MD/2020/000085	1.License Holder Name: DORA MEDICAL TRADING (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE A.V. FISTULA NEEDLE SETS(VITAL)-DISPOSABLE A.V. FISTULA NEEDLE SETS IS A KIND OF CONSUMABLE USED FOR PUNCTURE DURING THE CONTINUOUS RENAL REPLACEMENT THERAPY.,HOLLOW FIBER DIALYZER(VITAL)-DORA HOLLOW FIBER DIALYZER CAN BE USED FOR THE HEMODIALYSIS TREATMENT OF ACUTE AND CHRONIC RENAL FAILURE.,TUBING SETS FOR HEMODIALYSIS(VITAL)-TUBING SETS FOR HEMODIALYSIS REFER TO A KIND OF CATHETERS USED FOR CARRYING BLOOD IN VITRO. IN THE PROCESS OF CLINICAL DIALYSIS, THEY ARE CONNECTED TO HEMODIALYZERS AND WORK TOGETHER WITH DIALYSIS MACHINES TO COMPLETE DIALYSIS TREATMENT. THE PRODUCT IS INTENDED TO CONNECT WITH DIALYZER TO THE PATIENT IN HEMODIALYSIS TREATMENT.

2027	IMP/MD/2020/000086	1.License Holder Name: AVANOS MEDICAL INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROCUFF ENDOTRACHEALTUBEFOR PEDIATRICS, ORAL CURVED(AVANOS)-AVANOS * MICROCUFF* ENDOTRACHEAL TUBES ARE INDICATED FOR AIRWAY MANAGEMENT BY NASAL OR ORAL INTUBATION OF THE TRACHEA IN PEDIATRIC AND ADULT PATIENTS.,MICROCUFF ENDOTRACHEAL TUBE FOR ADULTS, ORAL/NASAL MAGILL(AVANOS) -AVANOS * MICROCUFF* ENDOTRACHEAL TUBES ARE INDICATED FOR AIRWAY MANAGEMENT BY NASAL OR ORAL INTUBATION OF THE TRACHEA IN PEDIATRIC AND ADULT PATIENTS.,MICROCUFF ENDOTRACHEAL TUBE FOR PEDIATRICS, ORAL/NASAL MAGILL (AVANOS)-AVANOS * MICROCUFF* ENDOTRACHEAL TUBES ARE INDICATED FOR AIRWAY MANAGEMENT BY NASAL OR ORAL INTUBATION OF THE TRACHEA IN PEDIATRIC AND ADULT PATIENTS.
2028	IMP/MD/2020/000087	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUCTION ELECTRODE (TUNGSTEN ALLOY)(VAPR VUE)-THE DEPUY MITEK VAPR ELECTRODES FOR USE WITH THE VAPR VUE RADIOFREQUENCY SYSTEM ARE INTENDED FOR RESECTION, ABLATION AND EXCISION OF SOFT TISSUE, HEMOSTASIS OF BLOOD VESSELS AND COAGULATION OF SOFT TISSUE IN PATIENTS REQUIRING ARTHROSCOPIC SURGERY OF THE KNEE, SHOULDER, HIP, ANKLE, ELBOW, OR WRIST. VAPR ELECTRODES ARE INTENDED TO BE USED BY AN ORTHOPEDIC SURGEON IN A SURGICAL SETTING.,SUCTION ELECTRODE (3 YEARS)(VAPR VUE)-THE DEPUY MITEK VAPR ELECTRODES FOR USE WITH THE VAPR VUE RADIOFREQUENCY SYSTEM ARE INTENDED FOR RESECTION, ABLATION AND EXCISION OF SOFT TISSUE, HEMOSTASIS OF BLOOD VESSELS AND COAGULATION OF SOFT TISSUE IN PATIENTS REQUIRING ARTHROSCOPIC SURGERY OF THE KNEE, SHOULDER, HIP, ANKLE, ELBOW, OR WRIST. VAPR ELECTRODES ARE INTENDED TO BE USED BY AN ORTHOPEDIC SURGEON IN A SURGICAL SETTING.,SUCTION ELECTRODE (STAINLESS STEEL)(VAPR VUE)-THE DEPUY MITEK VAPR ELECTRODES FOR USE WITH THE VAPR VUE RADIOFREQUENCY SYSTEM ARE INTENDED FOR RESECTION, ABLATION AND EXCISION OF SOFT TISSUE, HEMOSTASIS OF BLOOD VESSELS AND COAGULATION OF SOFT TISSUE IN PATIENTS REQUIRING ARTHROSCOPIC SURGERY OF THE KNEE, SHOULDER, HIP, ANKLE, ELBOW, OR WRIST. VAPR ELECTRODES ARE INTENDED TO BE USED BY AN ORTHOPEDIC SURGEON IN A SURGICAL SETTING.

2029	IMP/MD/2020/000088	1.License Holder Name: SMITHS MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRACHEOSTOMY TUBES (PORTEX)-A RANGE OF STERILE SINGLE-USE TRACHEOSTOMY TUBES WITH AN ADJUSTABLE FLANGE FOR USE ON PATIENTS WITH ABNORMAL SKIN TO TRACHEA DEPTH AND/OR TO FACILITATE STOMA CARE,SUCTIONPRO 72 CLOSED SUCTION CATHETER(PORTEX) -IT IS INTENDED FOR SINGLE PATIENT USE SUCTIONING DEVICE FOR THE REMOVAL OF SECRETIONS FROM THE TRACHEA-BRONCHIAL TREE OF VENTILATOR DEPENDENT ADULT PATIENTS. INTENDED OF 72 HRS OF MAXIMUM USE.,ENDOBRONCHIAL TUBES(PORTEX)-IT IS INTENDED FOR USE IN THORACIC SURGERY, BRONCHO-SPIROMETRY, FOR THE ADMINISTRATION OF ENDOBRONCHIAL INTUBATION. ENDOBRONCHIAL TUBES ARE INDICATED FOR MAIN STEM BRONCHUS INTUBATION AND ALLOW FOR SELECTIVE INFLATION AND/OR DEFLATION, SUCTIONING, INDEPENDENT LUNG VENTILATION AND BRONCHOSCOPIC VIEWING OF EITHER LUNG. ENDOBRONCHIAL TUBES SHOULD ALWAYS BE USED IN ACCORDANCE WITH CURRENTLY ACCEPTED MEDICAL TECHNIQUES. SWIVEL ADAPTERS ARE INDICATED WHERE IT IS DESIRABLE TO DECREASE THE TRANSMISSION OF UNDESIRABLE TORQUE AND MOTION BETWEEN CIRCUITS AND TRACHEAL OR TRACHEOSTOMY TUBES. THE DUAL-AXIS SWIVEL ADAPTER CAN BE USED FOR SUCTION ACCESS,ENDOTRACHEAL TUBE(PORTEX)-IT IS INTENDED FOR ORAL AND/OR NASAL INTUBATION FOR AIRWAY MANAGEMENT. EXPERT CLINICAL JUDGEMENT SHOULD BE EXERCISED IN THE SELECTION OF THE APPROPRIATE TRACHEAL TUBE SIZE AND STYLE FOR AND INDIVIDUAL PATIENT
2030	IMP/MD/2020/000089	1.License Holder Name: FRESENIUS KABI INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SYRINGE INFUSION PUMP (INFUSIA)-USE IN HEALTHCARE ORGANIZATIONS BY TRAINED PROFESSIONALS ON PATIENTS FOR CONTINUOUS DELIVERY OF MEDICATION, NUTRIENTS OR OTHER PARENTERAL FLUIDS THROUGH CLINICALLY ACCEPTED IV ROUTES OF ADMINISTRATION,INFUSION PUMP(INFUSIA)-USE IN HEALTHCARE ORGANIZATIONS BY TRAINED PROFESSIONALS ON PATIENTS FOR CONTINUOUS DELIVERY OF MEDICATION, NUTRIENTS OR OTHER PARENTERAL FLUIDS THROUGH CLINICALLY ACCEPTED IV ROUTES OF ADMINISTRATION

2031	IMP/MD/2020/000090	1.License Holder Name: NIPRO MEDICAL (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE SINGLE USE SAFETY NEEDLE(SAFETY-CAP NEEDLE)-THIS PRODUCT IS INTENDED SIP(SHARP INJURY PREVENTION) AND RUP(REUSE PREVENTION) BY DISPOSABLE NEEDLES AND SYRINGES DURING WHOLE INJECTIONS.
2032	IMP/MD/2020/000098	1.License Holder Name: GETINGE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADVANTA V12-THE ADVANTA V12 COVERED STENT SYSTEM IS INDICATED FOR RESTORING AND IMPROVING THE PATENCY OF THE ILIAC AND RENAL ARTERIES.RENAL APPROVAL INCLUDES 5MM,6MM AND 7MM DAMETER ADVANTA V12 SIZES.
2033	IMP/MD/2020/000099	1.License Holder Name: SURGIPLUS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MANIFOLD KIT(TOP MANIFOLD KIT)-THE PRODUCT IS USED FOR A CONTRAST STUDY TO OBTAIN DETAILED INFORMATION ON THE CORONARY ARTERY (THE STUDY IS MAINLY INTENDED TO CHECK FOR STENOSIS)
2034	IMP/MD/2020/000100	1.License Holder Name: M/S. DIO DIGITAL IMPLANT INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT FIXTURE(UV ACTIVE)-THIS IS AN IMPLANT FIXTURE TO BE INSERTED IN THE HUMAN BODY IN ORDER TO SUPPORT PROSTHESIS SUCH AS ARTIFICIAL TEETH USED TO REGAIN PATIENTS MASTICATION. TEMPORARY FIXTURE IS AN IMPLANT FIXTURE IN ORDER TO SUPPORT PROSTHETIC APPLIANCE SUCH AS ARTIFICIAL TEETH USED TO RECOVER A PATIENT'S MASTICATION.

2035	IMP/MD/2020/000101	1.License Holder Name: VYGON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SAFETY HUBBER NEEDLE (POLYPERF SAFE- WITHOUT Y SITE & WITH Y SITE)-POLYPERF® SAFE SAFETY HUBER NEEDLES ARE INDICATED FOR THE ADMINISTRATION OR WITHDRAWAL OF FLUIDS THROUGH IMPLANTABLE PORTS, POLYPERF SAFE IS DESIGNED TO PREVENT BLOOD-BORNE PATHOGEN EXPOSURES CAUSED BY ACCIDENTALNEEDLE PUNCTURES.,VENOUS IMPLANTABLE PORT(POLYSITE ECHO)-THE POLYSITE® ECHO PLACEMENT KITS ARE USED IN THE SAME INDICATIONS AND CONSIST OF INSTRUMENTATION SUITABLE FOR PLACEMENT OF IMPLANTABLE PORTS BY ECHO-GUIDED PUNCTURE., VENOUS IMPLANTABLE PORT(POLYSITE & POLYSITE ISP)-A STERILE IMPLANTABLE DEVICE INTENDED TO PROVIDE ACCESS TO THE PERIPHERAL ARTERIES/VEINS FOR INFUSION (E.G, CHEMOTHERAPEUTIC AGENTS, BLOOD TRANSFUSIONS) AND/OR DRAINAGE (E.G.; BLOOD). IT TYPICALLY CONSISTS OF A SUBCUTANEOUS CHAMBER, WITH A SELF-SEALING PUNCTURABLE SEPTUM FOR PERCUTANEOUS INSERTION OF A HYPODERMIC NEEDLE, ATTACHED TO A DISTAL CATHETER WHICH PASSES INTO THE ARTERIES/VEINS. IT MAY CONSIST OF TWO CHAMBERS ATTACHED TO A DUAL-LUMEN CATHETER FOR SIMULTANEOUS INFUSION. IT IS MADE OF METAL [E.G., TITANIUM (TI)] AND SYNTHETIC POLYMERS (E.G., SILICONE); DISPOSABLE DEVICES ASSOCIATED WITH IMPLANTATION MAY BE INCLUDED».)
2036	IMP/MD/2020/000103	1.License Holder Name: SMITHS MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERIPHERAL NERVE BLOCK NEEDLE - CONTINUOUS CATHETER(PORTEX® ECHOGLO TM)-THIS DEVICE IS INTENDED FOR USE IN THE ADMINISTRATION OF REGIONAL ANESTHETIC BLOCKS. INTENDED POPULATION IS ADULTS, NASOPHARYNGEAL AIRWAY(PORTEX)-A STERILE USE OF NASOPHARYNGEAL AIRWAY MANUFACTURED FROM IVORY PVC MATERIAL,PERIPHERAL NERVE BLOCK NEEDLE(PORTEX® ECHOGLO TM)-THIS DEVICE IS INTENDED FOR USE IN THE ADMINISTRATION OF REGIONAL ANESTHETIC BLOCKS. INTENDED POPULATION IS ADULTS.,ORATOR- TRACHEOSTOMY SPEAKING VALVE(PORTEX)-A ONE WAY SPEAKING VALVE INTENDED FOR SINGLE PATIENT USE WHICH CAN BE USED WITH FENESTRATED, CUFFED OR UNCUFFED TRACHEOSTOMY TUBES,TRACHEAL INTUBATION STYLET(PORTEX)-THE STYLET IS INTENDED FOR FACILITATING ORAL INTUBATION OF THE TRACHEA

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2037	IMP/MD/2020/000104	1.License Holder Name: AVANOS MEDICAL INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COOLIEF* SINERGY COOLED RADIOFREQUENCY KIT(AVANOS)-THE COOLIEF* SINERGY* COOLED RADIOFREQUENCY (RF) KIT IS TO BE USED IN CONJUNCTION WITH THE RADIOFREQUENCY (RF) PAIN MANAGEMENT GENERATOR (PMG-ADVANCED) OR THE COOLIEF* RADIOFREQUENCY GENERATOR (CRG-ADVANCED) TO CREATE RF LESIONS IN NERVOUS TISSUE. THE DEVICE INCLUDES A FLUID DELIVERY SYSTEM FOR COMMONLY USED FLUID AGENTS LIMITED TO CONTRAST MEDIUM, SALINE, AND/OR ANESTHETIC SOLUTION DELIVERY AT THE TARGET SITE.,MINI-BAL SAMPLING CATHETER(AVANOS)-IT IS USED IN THE DIAGNOSIS OF LUNG DISEASE BY ALLOWING COLLECTION OF BRONCHOALVEOLAR LAVAGE (BAL) SPECIMENS FROM DEEP WITHIN THE LUNG., RADIOPAQUE RADIOFREQUENCY CANNULA(AVANOS)-THE AVANOS* RADIOPAQUE CANNULA WILL BE USED IN CONJUNCTION WITH AN AVANOS* RADIOFREQUENCY PROBE AND AN RF GENERATOR TO CREATE LESIONS IN NERVOUS TISSUE.,CLOSED SUCTION SYSTEM NEONATES / PEDIATRICS(AVANOS)-INTENDED FOR AIRWAY MANAGEMENT (SUCTIONING) OF NEW BORN/ INFANT PATIENTS WITH ARTIFICIAL AIRWAYS ALLOWING FOR A PATENT AIRWAY. THIS IS 24 HOURS USE CATHETER.,CLOSED SUCTION SYSTEM ADULTS, DOUBLE SWIVEL ELBOW(HALYARD)-INTENDED FOR AIRWAY MANAGEMENT (SUCTIONING) OF PATIENTS WITH ARTIFICIAL AIRWAYS ALLOWING FOR A PATENT AIRWAY. THIS IS 24 HOURS USE CATHETER.,MULTI-ACCESS PORT CLOSED SUCTION SYSTEM ADULTS, DOUBLE SWIVEL ELBOW(AVANOS)-INTENDED TO ALLOW THE CLINICIAN TO ACCESS THE AIRWAY FOR ALTERNATE THERAPIES, SUCH AS MINI BAL AND BRONCHOSCOPY.,MULTI-ACCESS PORT CLOSED SUCTION SYSTEM FOR ADULTS, DOUBLE SWIVEL ELBOW(HALYARD)-INTENDED TO ALLOW THE CLINICIAN TO ACCESS THE AIRWAY FOR ALTERNATE THERAPIES, SUCH AS MINI BAL AND BRONCHOSCOPY.,CLOSED SUCTION SYSTEM ADULTS, DOUBLE SWIVEL ELBOW(AVANOS)-INTENDED FOR AIRWAY MANAGEMENT (SUCTIONING) OF PATIENTS WITH ARTIFICIAL AIRWAYS ALLOWING FOR A PATENT AIRWAY. THIS IS 24 HOURS USE CATHETER.,COOLIEF* TRANSDISCAL* COOLED RADIOFREQUENCY KIT(AVANOS)-THE COOLIEF* TRANSDISCAL* COOLED RADIOFREQUENCY KIT, IN COMBINATION WITH THE RADIOFREQUENCY (RF) PAIN MANAGEMENT GENERATOR (PMG-ADVANCED) OR THE COOLIEF* RADIOFREQUENCY GENERATOR (CRG-ADVANCED), IS INDICATED FOR THE COAGULATION AND DECOMPRESSION OF DISC MATERIAL TO TREAT SYMPTOMATIC PATIENTS WITH CONTAINED HERNIATED DISCS.,TURBO-CLEANING CLOSED SUCTION SYSTEM ADULTS, DOUBLE SWIVEL ELBOW

	(AVANOS)-INTENDED FOR AIRWAY MANAGEMENT (SUCTIONING) OF PATIENTS WITH ARTIFICIAL AIRWAYS ALLOWING FOR A PATENT AIRWAY. THIS IS 3 DAYS EXTENDED USE CATHETER., RADIOFREQUENCY PROBE(AVANOS)-AVANOS* RADIOFREQUENCY PROBE WILL BE USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR TO CREATE LESIONS IN NERVOUS TISSUE.,MULTI-ACCESS PORT REPLACEMENT CATHETER, ADULTS(AVANOS)-INTENDED TO BE USED AS A REPLACEMENT CATHETER FOR THE MULTI-ACCESS PORT(MAP) CLOSED SUCTION SYSTEM(CSS)., COOLIEF* TRANSDISCAL* COOLED RADIOFREQUENCY PROBE (AVANOS)-COOLIEF* TRANSDISCAL* COOLED RADIOFREQUENCY KIT, IN COMBINATION WITH THE RADIOFREQUENCY (RF) PAIN MANAGEMENT GENERATOR (PMG-ADVANCED) OR THE COOLIEF* RADIOFREQUENCY GENERATOR (CRG-ADVANCED), IS INDICATED FOR THE COAGULATION AND DECOMPRESSION OF DISC MATERIAL TO TREAT SYMPTOMATIC PATIENTS WITH CONTAINED HERNIATED DISCS.,MULTI-ACCESS CATHETER(AVANOS)-INTENDED FOR SURFACTANT DELIVERY TO THE DISTAL AIRWAY.,RADIOFREQUENCY CANNULA CURVED SHARP(AVANOS)-AVANOS* RADIOFREQUENCY CANNULA IS INTENDED FOR USE IN RADIOFREQUENCY LESION PROCEDURES FOR RELIEF OF PAIN.,RADIOFREQUENCY NITINOL PROBES(AVANOS)-AVANOS* RADIOFREQUENCY NITINOL PROBE WILL BE USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR TO CREATE LESIONS IN NERVOUS TISSUE., RADIOFREQUENCY CANNULA BLUNT(AVANOS)-AVANOS* RADIOFREQUENCY CANNULA IS INTENDED FOR USE IN RADIOFREQUENCY LESION PROCEDURES FOR RELIEF OF PAIN., COOLIEF* MULTI-COOLED RADIOFREQUENCY KIT(AVANOS)-AVANOS* COOLIEF* RADIOFREQUENCY KIT IS TO BE USED IN CONJUNCTION WITH THE AVANOS* RADIOFREQUENCY (RF) GENERATOR (PMG-ADVANCED) (FORMERLY BAYLIS PAIN MANAGEMENT GENERATOR OR KIMBERLY-CLARK® PAIN MANAGEMENT GENERATOR) TO CREATE LESIONS IN NERVOUS TISSUE. THE DEVICE INCLUDES A FLUID DELIVERY SYSTEM FOR COMMONLY USED FLUID AGENTS LIMITED TO CONTRAST MEDIUM, SALINE, AND/OR ANESTHETIC SOLUTION DELIVERY AT THE TARGET SITE. THIS DEVICE IS ALSO INDICATED FOR CREATING RADIOFREQUENCY LESIONS OF THE GENICULAR NERVES FOR THE MANAGEMENT OF MODERATE TO SEVERE KNEE PAIN OF MORE THAN 6 MONTHS WITH CONSERVATIVE THERAPY, INCLUDING MEDICATION, IN PATIENTS WITH RADIOLOGICALLY-CONFIRMED OSTEOARTHRITIS (GRADE 2-4) AND A POSITIVE RESPONSE (50% REDUCTION IN PAIN) TO A DIAGNOSTIC GENICULAR NERVE BLOCK.,CLOSED SUCTION SYSTEM NEONATES/PEDIATRICS(HALYARD)-INTENDED FOR AIRWAY

	MANAGEMENT (SUCTIONING) IN NEW BORN/INFANT PATIENTS WITH ARTIFICIAL AIRWAYS ALLOWING FOR A PATENT AIRWAY. THIS IS 24 HOURS USE CATHETER.,COOLIEF* COOLED RADIOFREQUENCY KIT (AVANOS)-THE COOLIEF* RADIOFREQUENCY KIT IS TO BE USED IN CONJUNCTION WITH THE RADIOFREQUENCY (RF) PAIN MANAGEMENT GENERATOR (PMG-ADVANCED) OR THE COOLIEF* RADIOFREQUENCY GENERATOR (CRG-ADVANCED) TO CREATE LESIONS IN NERVOUS TISSUE. THE DEVICE INCLUDES A FLUID DELIVERY SYSTEM FOR COMMONLY USED FLUID AGENTS LIMITED TO CONTRAST MEDIUM, SALINE, AND/OR ANESTHETIC SOLUTION DELIVERY AT THE TARGET SITE. THIS DEVICE IS ALSO INDICATED FOR CREATING RADIOFREQUENCY LESIONS OF THE GENICULAR NERVES FOR THE MANAGEMENT OF MODERATE TO SEVERE KNEE PAIN OF MORE THAN 6 MONTHS WITH CONSERVATIVE THERAPY, INCLUDING MEDICATION, IN PATIENTS WITH RADIOLOGICALLY-CONFIRMED OSTEOARTHRITIS (GRADE 2-4) AND A POSITIVE RESPONSE (50% REDUCTION IN PAIN) TO A DIAGNOSTIC GENICULAR NERVE BLOCK., RADIOFREQUENCY CANNULA(AVANOS)-AVANOS* RADIOFREQUENCY CANNULA IS INTENDED FOR USE IN RADIOFREQUENCY LESION PROCEDURES FOR RELIEF OF PAIN., COOLIEF* COOLED RADIOFREQUENCY PROBE(AVANOS)-COOLIEF* RADIOFREQUENCY KIT IS TO BE USED IN CONJUNCTION WITH THE RADIOFREQUENCY (RF) PAIN MANAGEMENT GENERATOR (PMG-ADVANCED) OR THE COOLIEF* RADIOFREQUENCY GENERATOR (CRG-ADVANCED) TO CREATE LESIONS IN NERVOUS TISSUE. THE DEVICE INCLUDES A FLUID DELIVERY SYSTEM FOR COMMONLY USED FLUID AGENTS LIMITED TO CONTRAST MEDIUM, SALINE, AND/OR ANESTHETIC SOLUTION DELIVERY AT THE TARGET SITE. THIS DEVICE IS ALSO INDICATED FOR CREATING RADIOFREQUENCY LESIONS OF THE GENICULAR NERVES FOR THE MANAGEMENT OF MODERATE TO SEVERE KNEE PAIN OF MORE THAN 6 MONTHS WITH CONSERVATIVE THERAPY, INCLUDING MEDICATION, IN PATIENTS WITH RADIOLOGICALLY-CONFIRMED OSTEOARTHRITIS (GRADE 2-4) AND A POSITIVE RESPONSE (50% REDUCTION IN PAIN) TO A DIAGNOSTIC GENICULAR NERVE BLOCK.,RADIOPAQUE RADIOFREQUENCY CANNULA CURVED SHARP(AVANOS)-AVANOS* RADIOPAQUE CANNULA WILL BE USED IN CONJUNCTION WITH AN AVANOS* RADIOFREQUENCY PROBE AND AN RF GENERATOR TO CREATE LESIONS IN NERVOUS TISSUE.,RADIOPAQUE RADIOFREQUENCY CANNULA CURVED BLUNT(AVANOS)-AVANOS* RADIOPAQUE CANNULA WILL BE USED IN CONJUNCTION WITH AN AVANOS* RADIOFREQUENCY PROBE AND AN RF GENERATOR TO CREATE LESIONS IN NERVOUS TISSUE.,RADIOPAQUE RADIOFREQUENCY CANNULA BLUNT(AVANOS)-THE AVANOS* RADIOPAQUE CANNULA

	WILL BE USED IN CONJUNCTION WITH AN AVANOS* RADIOFREQUENCY PROBE AND AN RF GENERATOR TO CREATE LESIONS IN NERVOUS TISSUE.,COOLIEF* COOLED RADIOFREQUENCY FLUID DELIVERY INTRODUCER(AVANOS)-COOLIEF* RADIOFREQUENCY KIT IS TO BE USED IN CONJUNCTION WITH THE RADIOFREQUENCY (RF) PAIN MANAGEMENT GENERATOR (PMG-ADVANCED) OR THE COOLIEF* RADIOFREQUENCY GENERATOR (CRG-ADVANCED) TO CREATE LESIONS IN NERVOUS TISSUE. THE DEVICE INCLUDES A FLUID DELIVERY SYSTEM FOR COMMONLY USED FLUID AGENTS LIMITED TO CONTRAST MEDIUM, SALINE, AND/OR ANESTHETIC SOLUTION DELIVERY AT THE TARGET SITE. THIS DEVICE IS ALSO INDICATED FOR CREATING RADIOFREQUENCY LESIONS OF THE GENICULAR NERVES FOR THE MANAGEMENT OF MODERATE TO SEVERE KNEE PAIN OF MORE THAN 6 MONTHS WITH CONSERVATIVE THERAPY, INCLUDING MEDICATION, IN PATIENTS WITH RADIOLOGICALLY-CONFIRMED OSTEOARTHRITIS (GRADE 2-4) AND A POSITIVE RESPONSE (50% REDUCTION IN PAIN) TO A DIAGNOSTIC GENICULAR NERVE BLOCK.,TURBO-CLEANING CLOSED SUCTION SYSTEM ADULTS, DOUBLE SWIVEL ELBOW(HALYARD)-INTENDED FOR AIRWAY MANAGEMENT (SUCTIONING) OF PATIENTS WITH ARTIFICIAL AIRWAYS ALLOWING FOR A PATENT AIRWAY. THIS IS A 3 DAYS EXTENDED USE CATHETER.,RADIOFREQUENCY SINGLE-USE PROBE (AVANOS)-RADIOFREQUENCY SINGLE-USE PROBE WILL BE USED IN CONJUNCTION WITH A AVANOS* RADIOFREQUENCY GENERATOR CONNECTOR CABLE AND THE AVANOS* RADIOFREQUENCY GENERATOR OR KIMBERLY-CLARK® RADIOFREQUENCY GENERATOR (FORMERLY BAYLIS PAIN MANAGEMENT GENERATOR) TO CREATE RF LESIONS IN NERVOUS TISSUE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MANDAVIYA CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

2038	IMP/MD/2020/000105	1.License Holder Name: MEDAX MEDICAL DEVICES INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE MARROW BIOPSY SYSTEM(MED-L)-MED-L BIOPSY SYSTEM HAS BEEN DESIGNED TO BE USED IN BONE MARROW ASPIRATION AND THE POSTERIOR ILIAC CREST BIOPSY.,SOFT TISSUE FULLY AUTOMATIC BIOPSY SYSTEM (MEDCUT)-FOR HISTOLOGICAL BIOPSY OF SOFT TISSUES,SOFT TISSUE AUTOMATIC BIOPSY SYSTEM(MEDONE ULTRA)-MEDONE ULTRA BIOPSY SYSTEM HAS BEEN DESIGNED TO BE USED FOR HISTOLOGICAL BIOPSY OF SOFT TISSUES (SUCH AS BREAST, KIDNEY, LIVER, PROSTATE AND VARIOUS SOFT TISSUE MASSES). IT IS NOT INTENDED FOR USE IN BONE BIOPSY.,SOFT TISSUE SEMI-AUTOMATIC BIOPSY NEEDLE WITH ADJUSTABLE PENETRATION DEPTH(BIO-FEATHER)-FOR HISTOLOGICAL BIOPSY OF SOFT TISSUES.,SOFT TISSUE SEMI-AUTOMATIC BIOPSY NEEDLE(MEDEASY)-MEDEASY BIOPSY NEEDLE MUST BE USED FOR HISTOLOGICAL BIOPSY OF SOFT TISSUES. IT IS NOT INTENDED FOR USE IN BONE BIOPSY.,BONE MARROW ASPIRATION NEEDLE(PERFECTUS)-FOR BONE MARROW ASPIRATION,BONE MARROW BIOPSY SYSTEM(MED-B)-MED-B BIOPSY SYSTEM HAS BEEN DESIGNED TO BE USED IN BONE MARROW ASPIRATION AND THE POSTERIOR ILIAC CREST BIOPSY.,SOFT TISSUE BIOPSY NEEDLE COMPATIBLE WITH MEDCORE AND BARD® MAGNUM® BIOPSY SYSTEM(UNICORE)-FOR HISTOLOGICAL BIOPSY OF SOFT TISSUES.,SOFT TISSUE SEMI-AUTOMATIC BIOPSY KIT (MEDEASY)-MEDEASY BIOPSY KIT MUST BE USED FOR HISTOLOGICAL BIOPSY OF SOFT TISSUES. IT IS NOT INTENDED FOR USE IN BONE BIOPSY.,COAXIAL INTRODUCER NEEDLE FOR BIOPSIES ON SOFT TISSUE(COX)-USED WHEN MULTIPLE BIOPSIES OF SOFT TISSUE ARE REQUIRED,BONE MARROW BIOPSY SYSTEM(MEDBONE)-FOR BONE MARROW ASPIRATION AND THE POSTERIOR ILIAC CREST BIOPSY, ASPIRATION NEEDLE FOR CYTOLOGICAL BIOPSIES ON SOFT TISSUE (CHIBA)-FOR CYTOLOGICAL AND MICROHISTOLOGICAL BIOPSY OF SOFT TISSUES.,SOFT TISSUE AUTOMATIC BIOPSY SYSTEM(MEDONE)-FOR HISTOLOGICAL BIOPSY OF SOFT TISSUES,DEVICE FOR PREOPERATIVE LOCALIZATION OF NON PALPABLE BREAST LESION (SINUREP)-TO BE USED IN THE PREOPERATIVE LOCALIZATION OF NONPALPABLE BREAST LESION.,BONE MARROW BIOPSY NEEDLE (NEO-OXUS)-FOR BONE MARROW ASPIRATION AND THE POSTERIOR ILIAC CREST BIOPSY.

2039	IMP/MD/2020/000106	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VOID CENTRALISER(C-STEM)-GENERALLY ACCEPTED INDICATIONS FOR JOINT REPLACEMENT INCLUDE: SEVERE ARTHROPATHY DUE TO ADVANCED RHEUMATOID OR OSTEO-ARTHRITIS WHERE CONSERVATIVE THERAPY OR ALTERNATIVE TREATMENTS HAVE FAILED OR ARE CONSIDERED UNSUITABLE, ARTHROPATHY DUE TO DEGENERATIVE DISEASE, ACUTE TRAUMA, AND A PREVIOUS FAILED JOINT REPLACEMENT. THE PATIENT'S JOINT MUST BE ANATOMICALLY AND STRUCTURALLY SUITED TO RECEIVE THE SELECTED IMPLANT(S).
2040	IMP/MD/2020/000108	1.License Holder Name: CBC CORPORATION (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SYNTHETIC BONE VOID FILLER(REBOSSIS / REBOSSIS QDS)-REBOSSIS / REBOSSIS QDS IS INTENDED FOR USE IN BONY VOIDS OR GAPS THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. THESE DEFECTS MAY BE SURGICALLY CREATED OSSEOUS DEFECTS OR OSSEOUS DEFECTS CREATED FROM TRAUMATIC INJURY TO THE BONE. REBOSSIS / REBOSSIS QDS IS INDICATED TO BE PACKED GENTLY INTO BONY VOIDS OR GAPS OF THE SKELETAL SYSTEM (EXTREMITIES, PELVIS AND POSTEROLATERAL SPINE). IN THE EXTREMITIES AND PELVIS REBOSSIS / REBOSSIS QDS MAY BE USED WITHOUT HYDRATION OR HYDRATED WITH BLOOD. IN THE POSTEROLATERAL SPINE REBOSSIS / REBOSSIS QDS IS TO BE USED HYDRATED WITH BONE MARROW ASPIRATE AND MIXED WITH AUTOGRAFT BONE. THE DEVICE PROVIDES A BONE VOID FILLER THAT IS RESORBED AND REPLACED WITH HOST BONE DURING THE HEALING PROCESS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2041	IMP/MD/2020/000109	1.License Holder Name: SMITHS MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETERS-THE CATHETERS ARE INTENDED AS CATHETERIZATION OF THE SUPERIOR VENA CAVA USING THE SELDINGER TECHNIQUE TO GET A CENTRAL VENOUS ACCESS,CENTRAL VENOUS CATHETERS-THE CATHETERS ARE INTENDED AS CATHETERIZATION OF THE SUPERIOR VENA CAVA USING THE SELDINGER TECHNIQUE TO GET A CENTRAL VENOUS ACCESS,CENTRAL VENOUS CATHETERS-THE CATHETERS ARE INTENDED AS CATHETERIZATION OF THE SUPERIOR VENA CAVA USING THE SELDINGER TECHNIQUE TO GET A CENTRAL VENOUS ACCESS,CENTRAL VENOUS CATHETERS-THE CATHETERS ARE INTENDED AS CATHETERIZATION OF THE SUPERIOR VENA CAVA USING THE SELDINGER TECHNIQUE TO GET A CENTRAL VENOUS ACCESS
2042	IMP/MD/2020/000110	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDEWIRE(CONFIDA BRECKER)-THE MEDTRONIC CONFIDA BRECKER GUIDEWIRE IS INTENDED FOR USE TO INTRODUCE AND POSITION CATHETERS DURING DIAGNOSTIC AND INTERVENTIONAL PROCEDURES WITHIN THE CHAMBERS OF THE HEART, INCLUDING TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR).

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2043	IMP/MD/2020/000111	1.License Holder Name: OSSTEM IMPLANT INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT OS SYSTEM(OS SYSTEM)-THIS ORTHANCHOR FUNCTIONS ARE FIXING POST TO MOVE CONNECTED TEETH TO THE DESIRED LOCATION FOR STRAIGHTENING IRREGULAR TEETH.,DENTAL IMPLANT ABUTMENT SYSTEM(TS ABUTMENT SYSTEM)-THE ABUTMENT IS INTENDED FOR USE WITH A DENTAL IMPLANT FIXTURE TO PROVIDE SUPPORT FOR PROSTHETIC RESTORATIONS SUCH AS CROWN, BRIDGE, OR OVERDENTURE,DENTAL IMPLANT OSSBUILDER SYSTEM(OSSBUILDER SYSTEM)-OSSBUILDER SYSTEM IS A METAL DEVICE INTENDED FOR USE WITH A DENTAL IMPLANT TO STABILIZE AND SUPPORT OF BONE GRAFT IN DENTO-ALVEOLAR BONY DEFECT SITES.,OSSBUILDER SYSTEM-USED TO FIX THE PERIODONTAL TISSUE REGENERATION INDUCER.,DENTAL IMPLANT ABUTMENTSYSTEM(TS ABUTMENT SYSTEM, SS ABUTMENT SYSTEM, US ABUTMENT SYSTEM, PROTECT CAP SYSTEM, ATTACHMENT SYSTEM)-THE ABUTMENT IS INTENDED FOR USE WITH A DENTAL IMPLANT FIXTURE TO PROVIDE SUPPORT FOR PROSTHETIC RESTORATIONS SUCH AS CROWN, BRIDGE, OR OVERDENTURE.,DENTAL IMPLANT FIXTURE SYSTEM(TS SA FIXTURE SYSTEM, TS HA FIXTURE SYSTEM, SS SA FIXTURE SYSTEM, SS HA FIXTURE SYSTEM, US SA FIXTURE SYSTEM, MS IMPLANT SYSTEM, HEALING ABUTMENT, COVER SCREW)-DENTAL IMPLANT FIXTURE SYSTEM IS FOR USE IN PARTIALLY OR FULLY EDENTULOUS MANDIBLES AND MAXILLAE, IN SUPPORT OF SINGLE OR MULTIPLE-UNITS RESTORATIONS INCLUDING; CEMENTED RETAINED, SCREW RETAINED, OR OVERDENTURE RESTORATIONS, AND FINAL OR TEMPORARY ABUTMENT SUPPORT FOR FIXED BRIDGEWORK.,DENTAL IMPLANT FIXTURE SYSTEM(TS CA FIXTURE SYSTEM, TS SOI FIXTURE SYSTEM, SS CA FIXTURE SYSTEM, US CA FIXTURE SYSTEM)-DENTAL IMPLANT FIXTURE SYSTEM IS FOR USE IN PARTIALLY OR FULLY EDENTULOUS MANDIBLES AND MAXILLAE, IN SUPPORT OF SINGLE OR MULTIPLE-UNITS RESTORATIONS INCLUDING; CEMENTED RETAINED, SCREW RETAINED, OR OVERDENTURE RESTORATIONS, AND FINAL OR TEMPORARY ABUTMENT SUPPORT FOR FIXED BRIDGEWORK.,DENTAL IMPLANT FIXTURE SYSTEM(TS BA FIXTURE SYSTEM)-DENTAL IMPLANT FIXTURE SYSTEM IS FOR USE IN PARTIALLY OR FULLY EDENTULOUS MANDIBLES AND MAXILLAE, IN SUPPORT OF SINGLE OR MULTIPLE-UNITS RESTORATIONS INCLUDING; CEMENTED RETAINED, SCREW RETAINED, OR OVERDENTURE RESTORATIONS, AND FINAL OR TEMPORARY ABUTMENT SUPPORT FOR FIXED BRIDGEWORK.

2044	IMP/MD/2020/000112	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RESTORATION GAP SYSTEMS(RESTORATION GAP SYSTEMS)-IT IS INDICATED IN PAINFUL ,DISABLING JOINT DISEASE OF THE HIP RESULTING FROM DEGENERATIVE ARTHRITIS , RHEUMATOID ARTHRITIS , POST-TRAUMATIC ARTHRITIS OR LATE STAGE AVASCULAR NECROSIS, REVISION OF PREVIOUS UNSUCCESSFUL FEMORAL HEAD REPLACEMENT ,CUP ARTHROPLASTY OR OTHER PROCEDURES , CLINICAL MANAGEMENT PROBLEMS WHERE ARTHRODESIS OR ALTERNATIVE RECONSTRUCTIVE TECHNIQUES ARE LESS LIKELY TO ACHIEVE SATISFACTORY RESULTS , WHERE BONE STOCK IS OF POOR QUALITY OR INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE ACETABULUM, SEGMENTAL AND/ OR CAVITARY ACETABULAR DEFECTS WHICH MAKE IT DIFFICULT TO RESTORE NORMAL HIP BIOMECHANICS OR TO RECONSTITUTE THE NORMAL STRUCTURAL CONTINUITY AND INTEGRITY OF THE ACETABULUM ,USING STANDARD TOTAL HIP REPLACEMENT ACETABULAR COMPONENTS AND PROCEDURES,HIP REPLACEMENT SYSTEM – LINERS / INSERTS / CUP(TRIDENT)-IT IS INTENDED FOR USE FOR TOTAL HIP ARTHROPLASTY IN CONDITIONS SUCH AS PAINFUL, DISABLING JOINT DISEASE OF THE HIP RESULTING FROM DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS , POST TRAUMATIC ARTHRITIS OR LATE STAGE AVASCULAR NECROSIS , REVISION OF PREVIOUS UNSUCCESSFUL FEMORAL HEAD REPLACEMENT CUP ARTHROPLASTY OR OTHER PROCEDURES WHERE ARTHRODESIS OR ALTERNATIVE RECONSTRUCTIVE TECHNIQUES ARE LESS LIKELY TO ACHIEVE SATISFACTORY RESULTS, WHERE BONE STOCK IS OF POOR QUALITY OR INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE ACETABULUM,HIP REPLACEMENT SYSTEM - SHELLS(TRIDENT)-IT IS INTENDED FOR USE FOR TOTAL HIP ARTHROPLASTY IN CONDITIONS SUCH AS PAINFUL, DISABLING JOINT DISEASE OF THE HIP RESULTING FROM DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS , POST TRAUMATIC ARTHRITIS OR LATE STAGE AVASCULAR NECROSIS , REVISION OF PREVIOUS UNSUCCESSFUL FEMORAL HEAD REPLACEMENT CUP ARTHROPLASTY OR OTHER PROCEDURES WHERE ARTHRODESIS OR ALTERNATIVE RECONSTRUCTIVE TECHNIQUES ARE LESS LIKELY TO ACHIEVE SATISFACTORY RESULTS, WHERE BONE STOCK IS OF POOR QUALITY OR INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE ACETABULUM.,PATELLA – (TOTAL KNEE REPLACEMENT)(SCORPIO)-IT IS INDICATED IN PAINFUL

	,DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM DEGENERATIVE ARTHRITIS RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS, POST TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION , MODERATE VARUS , VALGUS ,OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY, REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURE,: AUGMENTS , BLOCKS ,STEMS, PLUGS, OFFSET ADAPTORS, EXTENSIONS, SCREWS ,WEDGES –(TOTAL KNEE REPLACEMENT)(SCORPIO)-IT IS INDICATED IN PAINFUL ,DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM DEGENERATIVE ARTHRITIS RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS, POST TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION , MODERATE VARUS , VALGUS ,OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY ,REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURE,HIP ENDOPROSTHESIS SYSTEM(UHR BIPOLAR (UNIVERSAL HEAD BIPOLAR))-IT IS INDICATED IN CONDITIONS SUCH AS FEMORAL HEAD/NECK FRACTURES OR NON–UNIONS, ASEPTIC NECROSIS OF THE FEMORAL HEAD, OSTEO, RHEUMATOID AND POST, TRAUMATIC ARTHRITIS OF THE HIP WITH MINIMAL ACETABULAR INVOLVEMENT OR DISTORTION,TIBIAL TRAYS/BASEPLATE (TOTAL KNEE REPLACEMENT)(SCORPIO)-IT IS INDICATED IN PAINFUL , DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM DEGENERATIVE ARTHRITIS RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS, POST TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION , MODERATE VARUS , VALGUS ,OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY , REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURE,INSERTS –(TOTAL KNEE REPLACEMENT) (SCORPIO)-IT IS INDICATED IN PAINFUL ,DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM DEGENERATIVE ARTHRITIS RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS, POST TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION , MODERATE VARUS , VALGUS ,OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY ,REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDURE,MODULAR JOINT REPLACEMENT SYSTEM(GMRS/MRS)-IT IS INTENDED FOR USE IN PATIENTS REQUIRING EXTENSIVE RECONSTRUCTION OF THE HIP JOINT AND/OR KNEE JOINT, INCLUDING KNEE FUSIONS, NECESSITATED BY EXTENSIVE BONE LOSS DUE TO TRAUMA, FAILED

	PREVIOUS PROSTHESIS AND / OR TUMOR RESECTION,FEMORAL COMPONENTS (TOTAL KNEE REPLACEMENT)(SCORPIO)-IT IS INDICATED IN PAINFUL ,DISABLING JOINT DISEASE OF THE KNEE RESULTING FROM DEGENERATIVE ARTHRITIS RHEUMATOID ARTHRITIS OR POST-TRAUMATIC ARTHRITIS, POST TRAUMATIC LOSS OF KNEE JOINT CONFIGURATION AND FUNCTION , MODERATE VARUS, VALGUS, OR FLEXION DEFORMITY IN WHICH THE LIGAMENTOUS STRUCTURES CAN BE RETURNED TO ADEQUATE FUNCTION AND STABILITY ,REVISION OF PREVIOUS UNSUCCESSFUL KNEE REPLACEMENT OR OTHER PROCEDUR,WEDGE AUGMENT SYSTEM (RESTORATION ACETABULAR WEDGE AUGMENT SYSTEM)- ACETABULAR WEDGES ARE INTENDED FOR USE : • AS AN ALTERNATIVE TO STRUCTURAL ALLOGRAFT IN CASES OF SUPERIOR AND SUPERIOR/POSTERIOR SEGMENTAL ACETABULAR DEFICIENCIES. 1) ACETABULAR AUGMENTS ARE INTENDED FOR CEMENTLESS USE ONLY TO THE BONE INTERFACE; AND 2) ARE AFFIXED TO THE MATING CUP USING BONE CEMENT,HIP REPLACEMENT SYSTEM- HEADS(TRIDENT)-IT IS INDICATED FOR USE TOTAL HIP ARTHROPLASTY IN CONDITIONS SUCH AS PAINFUL , DISABLING JOINT DISEASE OF THE HIP RESULTING FROM DEGENERATIVE ARTHRITIS , RHEUMATOID ARTHRITIS POST – TRAUMATIC ARTHRITIS OR LATE STAGE AVASCULAR NECROSIS, REVISION OF PREVIOUS UNSUCCESSFUL FEMORAL HEAD REPLACEMENT, CUP ARTHROPLASTY OR OTHER PROCEDURES , CLINICAL MANAGEMENT PROBLEMS WHERE ARTHRODESIS OR ALTERNATIVE RECONSTRUCTIVE TECHNIQUES ARE LESS LIKELY TO ACHIEVE SATISFACTORY RESULTS , WHERE BONE STOCK IS OF POOR QUALITY OR INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE ACETABULUM, HIP REPLACEMENT SYSTEM – SCREWS STEMS . AUGMENTS , ADAPTOR , SLEEVE , WEDGES PLUG(TRIDENT)-IT IS INDICATED FOR USE TOTAL HIP ARTHROPLASTY IN CONDITIONS SUCH AS PAINFUL , DISABLING JOINT DISEASE OF THE HIP RESULTING FROM DEGENERATIVE ARTHRITIS , RHEUMATOID ARTHRITIS POST – TRAUMATIC ARTHRITIS OR LATE STAGE AVASCULAR NECROSIS, REVISION OF PREVIOUS UNSUCCESSFUL FEMORAL HEAD REPLACEMENT, CUP ARTHROPLASTY OR OTHER PROCEDURES , CLINICAL MANAGEMENT PROBLEMS WHERE ARTHRODESIS OR ALTERNATIVE RECONSTRUCTIVE TECHNIQUES ARE LESS LIKELY TO ACHIEVE SATISFACTORY RESULTS , WHERE BONE STOCK IS OF POOR QUALITY OR INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE ACETABULUM

2045	IMP/MD/2020/000113	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL MESH (PROCEED SURGICAL MESH)-IT IS USED FOR THE REPAIR OF HERNIAS AND OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT.
2046	IMP/MD/2020/000114	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FIXATION DEVICE(ROUND ENDOBUTTON)-IT IS INTENDED FOR THE TREATMENT OF ANTERIOR GLENOID BONE LOSS USING THE LATARJET OR BONE BLOCK PROCEDURE (ALLOGRAFT OR AUTOGRAFT).
2047	IMP/MD/2020/000115	1.License Holder Name: COLOPLAST INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALGINATE DRESSING (BIATAIN ALGINATE)-• BIATAIN ALGINATE WOUND DRESSING IS INDICATED FOR THE FOLLOWING MODERATE TO HEAVILY EXUDING CHRONIC AND ACUTE WOUNDS; PRESSURE ULCERS, VENOUS AND ARTERIAL LEG ULCERS, DIABETIC ULCERS, CAVITY WOUNDS, LACERATIONS, SKIN ABRASIONS, GRAFT AND DONOR SITES, POST OPERATIVE SURGICAL WOUNDS, SUPERFICIAL AND PARTIAL THICKNESS BURNS. • BIATAIN ALGINATE DRESSING CAN ALSO BE USED TO CONTROL MINOR BLEEDING IN SUPERFICIAL WOUNDS. • BIATAIN ALGINATE DRESSING IS SUITABLE FOR USE UNDER COMPRESSION BANDAGING.
2048	IMP/MD/2020/000117	1.License Holder Name: JSR DENTAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT (BIONER)-THE DENTAL IMPLANT IS USED TO REPLACE THE TOOTH ROOT AND THUS PROVIDING SUPPORT FOR THE DENTAL PROSTHESIS.,ABUTMENTS WITH SCREWS(BIONER)-THE ABUTMENTS CONSTITUTE THE FRAMEWORK ON WHICH THE DENTAL PROSTHESIS RESTS,AND NORMALLY,THEY ARE ADAPTED IN THE LABORATORY BEFORE THEIR USE IN CLINIC. THE CLINICAL SCREWS IS NECESSARY BOTH TO FIX THE PROSTHESIS TO THE IMPLANT AND TO JOIN TOGETHER THE DIFFERENT PARTS THAT IT MAY HAVE.

2049	IMP/MD/2020/000118	1.License Holder Name: OSSTEM IMPLANT INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE GRAFTING MATERIAL(A-GRAFT)-A-GRAFT IS APPLICABLE IN THE TREATMENT AND PREVENTION OF THE BONE DEFECT IN THE FOLLOWING DENTAL AREAS. - FILLING IN THE MISSING PART OF A BONE DUE TO PERIODONTAL DISEASE, CYSTECTOMY, OR DENTAL EXTRACTION - FILLING IN THE MISSING PART OF A BONE SURROUNDING AN IMPLANT - MAXILLARY SINUS LIFT FOR IMPLANT,ENDOSSEOUS DENTAL IMPLANT(ET NH DENTAL IMPLANT SYSTEM)-FOR USE IN PARTIALLY OR FULLY EDENTULOUS MANDIBLES AND MAXILLAE, IN SUPPORT OF SINGLE OR MULTIPLE-UNITS RESTORATIONS INCLUDING; CEMENTED RETAINED, SCREW RETAINED, OR OVERDENTURE RESTORATIONS, AND FINAL OR TEMPORARY ABUTMENT SUPPORT FOR FIXED BRIDGEWORK.

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2050	IMP/MD/2020/000119	1.License Holder Name: PHILIPS INDIA LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LASER SHEATH (SPECTRANETICS LASER SHEATH)-THE LASER SHEATH IS INTENDED FOR USE AS AN ADJUNCT TO CONVENTIONAL LEAD EXTRACTION TOOLS IN PATIENTS SUITABLE FOR TRANSVENOUS REMOVAL OF CHRONICALLY IMPLANTED PACING OR DE BRILLATOR LEADS CONSTRUCTED WITH SILICONE OR POLYURETHANE OUTER INSULATION.,EXTRACTION CATHETER(QUICKCAT EXTRACTION CATHETER)-THE QUICKCAT EXTRACTION CATHETER IS INDICATED FOR REMOVAL OF FRESH, SOFT EMBOLI AND THROMBI FROM VESSELS IN THE ARTERIAL SYSTEM.,LEAD LOCKING DEVICE (LLD) (LEAD LOCKING DEVICE (LLD))-THE SPECTRANETICS LEAD LOCKING DEVICES, LLD, ARE INTENDED FOR USE IN PATIENTS SUITABLE FOR TRANSVENOUS REMOVAL OF CHRONICALLY IMPLANTED PACING OR DEFIBRILLATOR LEADS HAVING AN INNER LUMEN AND USING A SUPERIOR VENOUS APPROACH.,SUPPORT CATHETER(QUICK-CROSS SUPPORT CATHETERS)-THE SPECTRANETICS QUICK-CROSS SUPPORT CATHETERS ARE GUIDE WIRE EXCHANGE AND INFUSION DEVICES DESIGNED FOR USE IN THE VASCULAR SYSTEM. THE CATHETERS ARE INTENDED TO SUPPORT A GUIDEWIRE DURING ACCESS OF VASCULATURE, ALLOW FOR EXCHANGE OF GUIDEWIRES, AND PROVIDE A CONDUIT FOR THE DELIVERY OF SALINE SOLUTIONS OR DIAGNOSTIC CONTRAST AGENTS.,DILATOR SHEATH(VISISHEATH DILATOR SHEATH)-THE VISISHEATH DILATOR SHEATH IS INTENDED FOR USE IN PATIENTS REQUIRING THE PERCUTANEOUS DILATION OF TISSUE SURROUNDING CARDIAC LEADS, INDWELLING CATHETERS AND FOREIGN OBJECTS. THE DEVICE IS ALSO INTENDED FOR USE IN THE INTRODUCTION AND SUPPORT OF INTRAVASCULAR CATHETERS.,OCCLUSION BALLOON CATHETER(BRIDGE)-THE BRIDGE OCCLUSION BALLOON CATHETER IS INDICATED FOR USE FOR TEMPORARY VESSEL OCCLUSION OF THE SUPERIOR VENA CAVA IN APPLICATIONS INCLUDING PERIOPERATIVE OCCLUSION AND EMERGENCY CONTROL OF HEMORRHAGE.,GUIDEWIRE RETRIEVER CATHETER(QUICK-CROSS CAPTURE)-THE QUICK-CROSS CAPTURE GUIDEWIRE RETRIEVER IS INTENDED TO BE USED IN CONJUNCTION WITH A STEERABLE GUIDEWIRE TO ACCESS DISCRETE REGIONS OF THE VASCULATURE AND FOR GUIDEWIRE EXCHANGE. THE QUICK-CROSS CAPTURE GUIDEWIRE RETRIEVER IS NOT INTENDED FOR USE IN THE CORONARY, CEREBRAL OR CAROTID VASCULATURE., CORONARY DILATION CATHETER(SIGHTRAIL)-THE SIGHTRAIL MANUAL DIALTOR SHEATH IS INTENDED FOR USE IN PATIENTS REQUIRING PERCUTANEOUS DILATION OF TISSUE TO FACILITATE THE REMOVAL OF CARDIAC LEADS, INDWELLING CATHETERS AND

	FOREIGN OBJECTS. ,DILATOR SHEATH(TIGHTRAIL ROTATING DILATOR SHEATH)-THE LASER SHEATH IS INTENDED FOR USE AS AN ADJUNCT TO CONVENTIONAL LEAD EXTRACTION TOOLS IN PATIENTS SUITABLE FOR TRANSVENOUS REMOVAL OF CHRONICALLY IMPLANTED PACING OR DEBRILLATOR LEADS CONSTRUCTED WITH SILICONE OR POLYURETHANE OUTER INSULATION.,CATHETER(ELCA CORONARY LASER ATHERECTOMY CATHETER)-THE LASER CATHETERS ARE USED IN CONJUNCTION WITH THE SPECTRANETICS CVX-300® EXCIMER LASER SYSTEM AND ARE INTENDED FOR USE IN PATIENTS WITH SINGLE OR MULTIVESSEL CORONARY ARTERY DISEASE, EITHER AS A STAND-ALONE MODALITY OR IN CONJUNCTION WITH PERCUTANEOUS TRANSLUMINAL CORONARY BALLOON ANGIOPLASTY (PTCA), AND WHO ARE ACCEPTABLE CANDIDATES FOR CORONARY ARTERY BYPASS GRAFT (CABG) SURGERY. ADJUNCTIVE BALLOON ANGIOPLASTY WAS PERFORMED, AT THE CLINICAL INVESTIGATOR'S DISCRETION, FOR 85% OF THE LESIONS TREATED.

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2051	IMP/MD/2020/000120	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED ,A-1/50, ROOM NO. 2, 100 SHED AREA, G.L.D.C., VAPI, TAL PARDI (VALSAD) , VALSAD GUJARAT ,396195 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RAPIBSORB RESORBABLE FIXATION SYSTEM (PLATES)(NA)-"THE SYNTHES RESORBABLE PLATE, MESH, FOIL, SCREW AND TACK SYSTEM IS USED FOR BONE FIXATION IN THE MANAGEMENT OF FRACTURES OR RECONSTRUCTIONS OF THE CRANIOFACIAL SKELETON AND AS GRAFT CONTAINMENT. THE PLATES, MESHES, FOILS, SCREWS AND TACKS SHOULD ONLY BE USED IN LOCATIONS SUBJECT TO LOW BIOMECHANICAL LOADING, I.E. NON- LOAD-BEARING OSTEOSYNTHESIS EXCLUSIVELY. EXAMPLES OF APPROPRIATE INDICATIONS INCLUDE: – TRAUMA REPAIR AND RECONSTRUCTIVE PROCEDURES IN THE MID FACIAL AREA, MAXILLA AND CRANIUM. – CONTAINMENT OF BONE GRAFTS OR BONE GRAFT SUBSTITUTES IN OTHER PARTS OF THE BODY IN NON-LOAD-BEARING INDICATIONS.', CERVIOS CHRONOS PREFILLED CAGES(NA)-"CHRONOS PREFILLED CAGES ARE DESIGNED FOR POSTERIOR LUMBAR INTERBODY FUSION (PLIF) AND ANTERIOR CERVICAL INTERBODY FUSION (ACIF). THE POROUS STRUCTURE OF CHRONOS IMPLANTS ACTS AS A MATRIX FOR THE INGROWTH OF BONE. CHRONOS IMPLANTS MUST ALWAYS BE APPLIED BY ENOSSEAL OR SUBPERIOSTEAL IMPLANTATION, I.E. BY DIRECT CONTACT WITH THE VITAL BONE. ANTERIOR CERVICAL INTERBODY FUSION: CERVICAL PATHOLOGIES WHERE SEGMENTAL SPONDYLODESIS IS INDICATED: — RUPTURED AND HERNIATED DISCS — DEGENERATIVE DISC DISEASE AND INSTABILITIES — PSEUDOARTHROSIS OR FAILED SPONDYLODESIS FOR MULTISEGMENTAL ARTHODESIS ADDITIONAL FIXATION WITH A PLATE IS RECOMMENDED. POSTERIOR LUMBAR INTERBODY FUSION: LUMBAR AND LUMBOSACRAL PATHOLOGIES FOR WHICH SEGMENTAL SPONDYLODESIS IS INDICATED, ESPECIALLY: — DEGENERATIVE DISC DISEASE AND INSTABILITY — DEGENERATIVE SPONDYLOLISTHESIS, GRADE I OR II — SPONDYLOLISTHESIS WITH STENOSIS, GRADE I OR II — PSEUDARTHROSIS OR FAILED SPONDYLODESIS AS A RULE, CHRONOS IS RESORBED WITHIN 6 TO 18 MONTHS AND CONVERTED INTO AUTOLOGOUS BONE; DEPENDING ON PATIENT CONDITIONS.",RAPIBSORB RESORBABLE FIXATION SYSTEM (BURR HOLE COVER)(NA)-THE SYNTHES RESORBABLE PLATE, MESH, FOIL, SCREW AND TACK SYSTEM IS USED FOR BONE FIXATION IN THE MANAGEMENT OF FRACTURES OR RECONSTRUCTIONS OF THE CRANIOFACIAL SKELETON AND AS GRAFT CONTAINMENT. THE PLATES, MESHES, FOILS, SCREWS AND TACKS SHOULD ONLY BE USED IN LOCATIONS SUBJECT TO LOW BIOMECHANICAL LOADING, I.

	E. NON- LOAD-BEARING OSTEOSYNTHESIS EXCLUSIVELY. EXAMPLES OF APPROPRIATE INDICATIONS INCLUDE: – TRAUMA REPAIR AND RECONSTRUCTIVE PROCEDURES IN THE MID FACIAL AREA, MAXILLA AND CRANIUM. – CONTAINMENT OF BONE GRAFTS OR BONE GRAFT SUBSTITUTES IN OTHER PARTS OF THE BODY IN NON-LOAD-BEARING INDICATIONS.,RAPIBSORB RESORBABLE FIXATION SYSTEM (FOIL) (NA)-THE SYNTHES RESORBABLE PLATE, MESH, FOIL, SCREW AND TACK SYSTEM IS USED FOR BONE FIXATION IN THE MANAGEMENT OF FRACTURES OR RECONSTRUCTIONS OF THE CRANIOFACIAL SKELETON AND AS GRAFT CONTAINMENT. THE PLATES, MESHES, FOILS, SCREWS AND TACKS SHOULD ONLY BE USED IN LOCATIONS SUBJECT TO LOW BIOMECHANICAL LOADING, I.E. NON- LOAD-BEARING OSTEOSYNTHESIS EXCLUSIVELY. EXAMPLES OF APPROPRIATE INDICATIONS INCLUDE: – TRAUMA REPAIR AND RECONSTRUCTIVE PROCEDURES IN THE MID FACIAL AREA, MAXILLA AND CRANIUM. – CONTAINMENT OF BONE GRAFTS OR BONE GRAFT SUBSTITUTES IN OTHER PARTS OF THE BODY IN NON-LOAD-BEARING INDICATIONS.,RAPIBSORB RESORBABLE FIXATION SYSTEM (SCREWS) (NA)-"THE SYNTHES RESORBABLE PLATE, MESH, FOIL, SCREW AND TACK SYSTEM IS USED FOR BONE FIXATION IN THE MANAGEMENT OF FRACTURES OR RECONSTRUCTIONS OF THE CRANIOFACIAL SKELETON AND AS GRAFT CONTAINMENT. THE PLATES, MESHES, FOILS, SCREWS AND TACKS SHOULD ONLY BE USED IN LOCATIONS SUBJECT TO LOW BIOMECHANICAL LOADING, I.E. NON- LOAD-BEARING OSTEOSYNTHESIS EXCLUSIVELY. EXAMPLES OF APPROPRIATE INDICATIONS INCLUDE: – TRAUMA REPAIR AND RECONSTRUCTIVE PROCEDURES IN THE MID FACIAL AREA, MAXILLA AND CRANIUM. – CONTAINMENT OF BONE GRAFTS OR BONE GRAFT SUBSTITUTES IN OTHER PARTS OF THE BODY IN NON-LOAD-BEARING INDICATIONS.",CHRONOS BONE VOID FILLER IMPLANTS(NA)-CHRONOS BONE VOID FILLER IMPLANTS ARE USED AS TEMPORARY BONE SUBSTITUTE THAT SERVES TO FILL AND BRIDGE BONE DEFECTS IN CHILDREN, ADOLESCENTS AND ADULTS.

2052	IMP/MD/2020/000121	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC SYRINGES WITH NEEDLES(BD EMERALD SYRINGE)-INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS (CORPORAL FLUIDS (BLOOD, ETS) AND DRUGS).,DISPOSABLE HYPODERMIC SYRINGES WITH NEEDLES(BD DISCARDIT II)-INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS (CORPORAL FLUIDS (BLOOD, ETS) AND DRUGS).,DISPOSABLE HYPODERMIC NEEDLE(BD MICROLANCE 3) -INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS (CORPORAL FLUIDS (BLOOD, ETS) AND DRUGS),DISPOSABLE HYPODERMIC SYRINGES(BD EMERALD SYRINGE)-INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS (CORPORAL FLUIDS (BLOOD, ETS) AND DRUGS)., TWO PIECE SYRINGES WITH BREAKABLE PLUNGER (BD SOLOMED)-INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS (CORPORAL FLUIDS (BLOOD, ETS) AND DRUGS).,DISPOSABLE HYPODERMIC REUSE PREVENTION SYRINGES WITH NEEDLES (BD EMERALD PRO)-INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS (CORPORAL FLUIDS (BLOOD, ETS) AND DRUGS).,TWO PIECE SYRINGES WITH BREAKABLE PLUNGER WITH NEEDLE(BD SOLOMED)-INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS (CORPORAL FLUIDS (BLOOD, ETS) AND DRUGS).,AUTO-DISABLE SYRINGES(BD SOLOSHOT IX)-INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS (CORPORAL FLUIDS (BLOOD, ETS) AND DRUGS).,AUTO-DISABLE SYRINGES(BD SOLOSHOT MINI)-INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS (CORPORAL FLUIDS (BLOOD, ETS) AND DRUGS)., DISPOSABLE HYPODERMIC SYRINGE WITH NEEDLE(BD FLU +)-IT IS A STERILE SINGLE USE MEDICAL DEVICE FOR INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS AND DRUGS.,DISPOSABLE HYPODERMIC SYRINGES(BD DISCARDIT II)-INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS (CORPORAL FLUIDS (BLOOD, ETS) AND DRUGS)

2053	IMP/MD/2020/000122	1.License Holder Name: M/S ASIA ACTUAL INDIA (OPC) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DBM (DEMINERALIZED BONE MATRIX)(SUREFUSE)-SUREFUSE GEL & PUTTY ARE INDICATED FOR BONY VOIDS OR GAPS THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. THEY ARE INTENDED TO BE GENTLY PACKED INTO BONY VOIDS OR GAPS OF THE SKELETAL SYSTEM (POSTEROLATERAL SPINE). THESE DEFECTS MAY BE SURGICALLY CREATED OSSEOUS DEFECTS OR OSSEOUS DEFECTS CREATED FROM TRAUMATIC INJURY TO THE BONE. SUREFUSE GEL & PUTTY ARE BONE FILLING MATERIALS INDICATED FOR DENTAL INTRAOSSEOUS, ORAL AND MAXILLOFACIAL DEFECTS, INCLUDING PERIODONTAL/INFRABONY DEFECTS; ALVEOLAR RIDGE AUGMENTATION; DENTAL EXTRACTION SITES; SINUS LIFTS, CYSTIC DEFECTS.,HAIR IMPLANT SYSTEM(LION-HN (SPARE NEEDLE))-TRANSPLANTING PATIENT'S OWN HAIR FOLLICLES TO RESTORE NORMAL HAIR LOSS OR HAIR LOSS CAUSED BY BURN, OTHER TRAUMA, OVER DOSE OF MEDICATIONS OR/AND OTHER DISEASES., DBM (DEMINERALIZED BONE MATRIX) AND PORCINE GELATIN (BELLAFUSE)-BELLAFUSE IS AN IMPLANT INTENDED TO FILL BONY VOIDS OR GAPS OF THE SKELETAL SYSTEM I.E., POSTEROLATERAL SPINE. THESE OSSEOUS DEFECTS ARE SURGICALLY CREATED OR THE RESULT OF TRAUMATIC INJURY TO THE BONE AND ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. BELLAFUSE RESORBS AND IS REPLACED WITH BONE DURING THE HEALING PROCESS. ,HAIR IMPLANT SYSTEM(LION-HT (HAIR TRANSPLANTER))-TRANSPLANTING PATIENT'S OWN HAIR FOLLICLES TO RESTORE NORMAL HAIR LOSS OR HAIR LOSS CAUSED BY BURN, OTHER TRAUMA, OVER DOSE OF MEDICATIONS OR/AND OTHER DISEASES., DBM (DEMINERALIZED BONE MATRIX) WITH CANCELLOUS BONE (EXFUSE)-EXFUSE GEL & PUTTY ARE INDICATED FOR BONY VOIDS OR GAPS THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. THEY ARE INTENDED TO BE GENTLY PACKED INTO BONY VOIDS OR GAPS OF THE SKELETAL SYSTEM (POSTEROLATERAL SPINE). THESE DEFECTS MAY BE SURGICALLY CREATED OSSEOUS DEFECTS OR OSSEOUS DEFECTS CREATED FROM TRAUMATIC INJURY TO THE BONE. EXFUSE GEL & PUTTY ARE BONE FILLING MATERIALS INDICATED FOR DENTAL INTRAOSSEOUS, ORAL AND MAXILLOFACIAL DEFECTS, INCLUDING PERIODONTAL/INFRABONY DEFECTS; ALVEOLAR RIDGE AUGMENTATION; DENTAL EXTRACTION SITES; SINUS LIFTS, CYSTIC DEFECTS. ,SURGICAL SUTURE(MINT POLYDIOXANONE ABSORBABLE SURGICAL SUTURE (MINT EASY))-MINT POLYDIOXANONE ABSORBABLE SURGICAL SUTURE IS INTENDED FOR CORRECTION OF

		DEFECTED SOFT TISSUE CAUSED BY ACCIDENTS OR TRAUMA, SURGICAL SUTURE(MINT POLYDIOXANONE ABSORBABLE SURGICAL SUTURE)-MINT POLYDIOXANONE ABSORBABLE SURGICAL SUTURE IS INTENDED FOR CORRECTION OF DEFECTED SOFT TISSUE CAUSED BY ACCIDENTS OR TRAUMA,SURGICAL SUTURE(MINT POLYDIOXANONE ABSORBABLE SURGICAL SUTURE (MINT FINE))-MINT POLYDIOXANONE ABSORBABLE SURGICAL SUTURE IS INTENDED FOR CORRECTION OF DEFECTED SOFT TISSUE CAUSED BY ACCIDENTS OR TRAUMA.
2054	IMP/MD/2020/000123	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STOPCOCK(BD CONNECTA)-IT IS INTENDED FOR CONNECTIONS IN IV THERAPY AND HEMODYNAMIC PRESSURE MONITORING ONLY

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2055	IMP/MD/2020/000124	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOSTAT(SURGIFLO HAEMOSTATIC MATRIX)-SURGIFLO IS INDICATED FOR SURGICAL PROCEDURES (EXCEPT OPHTHALMIC) FOR HAEMOSTASIS, WHEN CONTROL OF CAPILLARY, VENOUS AND ARTERIOLAR BLEEDING BY PRESSURE, LIGATURE, AND OTHER CONVENTIONAL PROCEDURES IS INEFFECTIVE OR IMPRACTICAL.,GELATIN HEMOSTATIC AGENT (SURGIFLO HAEMOSTATIC MATRIX KIT WITH THROMBIN)-INDICATED IN SURGICAL PROCEDURES (OTHER THAN OPHTHALMIC) AS AN ADJUNCT TO HAEMOSTASIS WHEN CONTROL OF BLEEDING RANGING FROM OOZING TO SPURTING BY LIGATURE OR OTHER CONVENTIONAL METHODS IS INEFFECTIVE OR IMPRACTICAL., HEMOSTAT(SPONGOSTAN ABSORBABLE HAEMOSTATIC GELATIN POWDER)-SPONGOSTAN POWDER, SATURATED WITH STERILE SODIUM CHLORIDE SOLUTION, IS INDICATED FOR SURGICAL PROCEDURES (EXCEPT OPHTHALMIC) FOR HAEMOSTASIS, WHEN CONTROL OF CAPILLARY BLEEDING, OOZING BLEEDING, VENOUS AND ARTERIOLAR BLEEDING BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS INEFFECTIVE OR IMPRACTICAL. ALTHOUGH NOT NECESSARY, SPONGOSTAN POWDER CAN BE USED WITH THROMBIN TO ACHIEVE HAEMOSTASIS.,HEMOSTAT (SPONGOSTAN ABSORBABLE HAEMOSTATIC GELATIN SPONGE)-SPONGOSTAN SPONGE, USED DRY OR SATURATED WITH STERILE SODIUM CHLORIDE SOLUTION, IS INDICATED FOR SURGICAL PROCEDURES (EXCEPT OPHTHALMIC) FOR HAEMOSTASIS, WHEN CONTROL OF CAPILLARY, VENOUS AND ARTERIOLAR BLEEDING BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS INEFFECTIVE OR IMPRACTICAL. ALTHOUGH NOT NECESSARY, SPONGOSTAN SPONGE CAN BE USED WITH THROMBIN TO ACHIEVE HAEMOSTASIS.
2056	IMP/MD/2020/000125	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CIRCULAR MAPPING CATHETER(ADVISOR™ VL, SENSOR ENABLED™ CIRCULAR MAPPING CATHETER)-THE ADVISOR™ VL, SENSOR ENABLED™ CIRCULAR MAPPING CATHETER IS A STEERABLE ELECTROPHYSIOLOGY CATHETER WITH INTEGRATED SENSORS. THE CATHETER IS USED FOR RECORDING INTRACARDIAC SIGNALS AND CARDIAC STIMULATION DURING DIAGNOSTIC ELECTROPHYSIOLOGY STUDIES. THE CATHETER CAN BE USED TO MAP THE ATRIAL REGIONS OF THE HEART.

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2057	IMP/MD/2020/000126	1.License Holder Name: CURE SURGICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LUMBAR DISC PROSTHESIS(BAGUERA® L)-THE BAGUERA®L IS A PROSTHESIS INTENDED AS A REPLACEMENT FOR A LUMBAR INTERVERTEBRAL DISC. PATIENT SUFFERING FROM SYMPTOMATIC LUMBAR DISC DISEASE (SLDD) AFFECTING ONE VERTEBRAL LEVEL BETWEEN L3 AND S1, AS DEFINED BY THE FOLLOWING SIGNS: LOWER BACK PAIN OR LUMBAR RADICULAR PAIN (SCIATICA); FUNCTIONAL AND/OR NEUROLOGICAL DEFICIT ACCOMPANIED BY AT LEAST ONE OF THE FOLLOWING CONDITIONS CONFIRMED BY MRI OR X-RAY: LUMBAR SPONDYLOLISTHESIS LIMITED TO THE TREATED DISC SEGMENT LEVEL, GRADE 1, NO MORE THAN 3 MM; AGE BETWEEN 18 AND 65; NO RESPONSE TO NON-SURGICAL TREATMENT FOR A PERIOD OF AT LEAST SIX WEEKS, OR SYMPTOMS OR SIGNS OF PROGRESSIVE ROOT COMPRESSION DESPITE CONSERVATIVE TREATMENT.,POSTERIOR OSTEOSYNTHESIS SYSTEM(ROMEO®2, ROMEO®2MIS)-ROMEO®2 SYSTEM IMPLANTS ARE DESIGNED TO TREAT THOSE DORSAL AND THORACIC PATHOLOGIES: • SPONDYLOLISTHESIS • DEGENERATIVE DISC DISEASE • THORACIC AND LUMBAR FRACTURES • THORACIC AND LUMBAR VERTEBRA TUMORS • PSEUDARTHROSIS • STENOSIS • SPINE DEFORMITIES: SCOLIOSIS, CYPHOSIS,POSTERIOR CERVICO-THORACIC FIXATION SYSTEM(PERLA®)-THE PERLA® POSTERIOR CERVICO-THORACIC FIXATION SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OF THE CERVICAL SPINE (C1 TO C7) AND THE THORACIC SPINE FROM TL-T3: TRAUMATIC SPINAL FRACTURES AND/OR TRAUMATIC DISLOCATIONS; INSTABILITY OR DEFORMITY; FAILED PREVIOUS FUSIONS (E.G., PSEUDARTHROSIS); TUMORS INVOLVING THE CERVICAL SPINE; AND DEGENERATIVE DISEASE, INCLUDING INTRACTABLE RADICULOPATHY AND/OR MYELOPATHY, NECK AND/OR ARM PAIN OF DISCOGENIC ORIGIN AS CONFIRMED BY RADIOGRAPHIC STUDIES, AND DEGENERATIVE DISEASE OF THE FACETS WITH INSTABILITY. THE PERLA® POSTERIOR CERVICO-THORACIC FIXATION SYSTEM IS ALSO INTENDED TO RESTORE THE INTEGRITY OF THE SPINAL COLUMN EVEN IN THE ABSENCE OF FUSION FOR A LIMITED TIME PERIOD IN PATIENTS WITH ADVANCED STAGE TUMORS INVOLVING THE CERVICAL SPINE IN WHOM LIFE EXPECTANCY IS OF INSUFFICIENT DURATION TO PERMIT ACHIEVEMENT OF FUSION. IN ORDER TO ACHIEVE ADDITIONAL LEVELS OF FIXATION, THE PERLA® POSTERIOR CERVICO-THORACIC FIXATION SYSTEM MAY BE CONNECTED TO THE ROMEO®2 POSTERIOR OSTEOSYNTHESIS SYSTEM WITH ROD CONNECTORS.

		TRANSITION RODS MAY ALSO BE USED TO CONNECT THE PERLA® POSTERIOR CERVICO-THORACIC FIXATION SYSTEM TO THE ROMEO®2 POSTERIOR OSTEOSYNTHESIS SYSTEM. REFER TO THE ROMEO®2 POSTERIOR OSTEOSYNTHESIS SYSTEM PACKAGE INSERT FOR A LIST OF THE ROMEO®2 POSTERIOR OSTEOSYNTHESIS SYSTEM INDICATIONS OF USE. PERLA® POSTERIOR CERVICO-THORACIC FIXATION SYSTEM IS INDICATED FOR SKELETALLY MATURE PATIENTS.
2058	IMP/MD/2020/000128	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HAEMOSTATIC SPONGES (MEROCEL HEMOX)-NASAL DRESSINGS, EPISTAXIS PACKING, SINUS PACKING, EAR PACKING AND EAR WICKS FOR EPISTAXIS, POST-OPERATIVE SURGERY AND TRAUMA, WHICH EXPANDS WHEN MOISTENED TO ASSIST IN TAMPONADE AND HEMOSTATIS, HAEMOSTATIC SPONGES(MEROCEL)-NASAL DRESSINGS, EPISTAXIS PACKING, SINUS PACKING, EAR PACKING AND EAR WICKS FOR EPISTAXIS, POST-OPERATIVE SURGERY AND TRAUMA, WHICH EXPANDS WHEN MOISTENED TO ASSIST IN TAMPONADE AND HEMOSTATIS
2059	IMP/MD/2020/000132	1.License Holder Name: M/S. INDUS MEDICAL INSTRUMENTS PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ESOPHAGEAL SELF EXPANDABLE METAL STENT WITH DELIVERY SYSTEM (POLYMER-METAL OESOPHAGEAL STENT, STERILE)(SX-ELLA STENT DANIS (DANIS PROCEDURE PACK -BASIC))-INTENDED FOR STOPPING THE ACUTE BLEEDING FROM ESOPHAGEAL VARICES. THE STENT IMPLANTATION MAY BE AN OPTION IN REFRACTORY ESOPHAGEAL VARICEAL BLEEDING AS AN ALTERNATIVE METHOD TO THE EARLY TIPS OR THE BALLOON TAMPONADE.
2060	IMP/MD/2020/000133	1.License Holder Name: MOKSHY SURGICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTING NEEDLES FOR SINGLE USE(BERPU)-FOR BLOOD COLLECTION PURPOSE

2061	IMP/MD/2020/000134	1.License Holder Name: TRANSLUMINA THERAPEUTICS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CORONARY STENT SYSTEM(YUKON CC)-THE YUKON CC STENT SYSTEM IS INDICATED FOR INTRALUMINAL CHRONIC PLACEMENT IN STENOSED CORONARY ARTERY OR AORTOCORONARY BYPASS GRAFTS OR THE TIBIAL ANTERIOR AND POSTERIOR ARTERY OF THE LOWER LIMB WITH A MAXIMUM LESION LENGTH OF 45MM, IN ORDER TO OBTAIN VESSEL PATENCY FOLLOWING ACUTE OR SUBACUTE ARTERY OBSTRUCTION. IT IS ALSO INDICATED IN RESTENOSIS OR ARTERIAL DISSECTION AFTER PTCA PROCEDURES. PATIENTS BEING CONSIDERED FOR STENT IMPLANTATION SHOULD BE ACCEPTABLE CANDIDATES FOR BALLOON ANGIOPLASTY.,CORONARY STENT SYSTEM(YUKON CHOICE 4)-THE YUKON® CHOICE 4 STENT SYSTEM IS INDICATED FOR INTRALUMINAL CHRONIC PLACEMENT IN STENOSED CORONARY ARTERY OR AORTO-CORONARY BYPASS GRAFTS OR THE TIBIAL ANTERIOR AND POSTERIOR ARTERY OF THE LOWER LIMB WITH A MAXIMUM LESION LENGTH OF 45 MM, IN ORDER TO OBTAIN VESSEL PATENCY FOLLOWING ACUTE OR SUBACUTE ARTERY OBSTRUCTION. IT IS ALSO INDICATED IN RESTENOSIS OR ARTERIAL DISSECTION AFTER PTCA PROCEDURES. PATIENTS BEING CONSIDERED FOR STENT IMPLANTATION SHOULD BE ACCEPTABLE CANDIDATES FOR BALLOON ANGIOPLASTY.

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2062	IMP/MD/2020/000135	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINAL NEEDLE(BD SPINAL NRFIT™ NEEDLE (WHITACRE & QUINCKE TYPE))-THE BD SPINAL NRFIT NEEDLE (QUINCKE AND WHITACRE) IS INTENDED TO GAIN ENTRY INTO OR PUNCTURE THE SPINAL CAVITY PERMITTING INJECTION (INCLUDING ANESTHESIA) / WITHDRAWAL OF FLUIDS FOR PURPOSES OF DIAGNOSTIC LUMBAR PUNCTURE AND MYELOGRAPHY PROCEDURES.,DISPOSABLE HYPODERMIC SYRINGES(BD PLASTIPAK) -THREE-PIECE SYRINGES BD PLASTIPAK ARE MEDICAL DEVICES USED FOR INJECTION OF MEDICINAL SUBSTANCES, BLOOD EXTRACTION, AND ASPIRATION OF FLUIDS FROM VIALS, AMPOULES AND PARTS OF BODY BELOW THE SURFACE OF THE SKIN.,SPINAL NEEDLE(BD WHITACRE SPINAL NEEDLE)-THE BD WHITACRE SPINAL NEEDLES ARE USED TO ACCESS TO ANATOMICAL STRUCTURES IN ORDER TO INTRODUCE MEDICINES, IMAGE CONTRAST AGENTS, GUIDE WIRES OR CATHETERS.,SPINAL NEEDLES(BD SPINAL NEEDLES)-BD SPINAL NEEDLES ARE STERILE SINGLE USE MEDICAL DEVICES, THESE ARE SPINAL, INTRODUCER OR SPINAL WITH INTRODUCER THAT NEEDS TO BE USED WITH OTHER MEDICAL DEVICES (E.G., TUBING SYRINGES). THE NEEDLES ARE USED FOR PUNCTURE OR INJECTION., DISPOSABLE HYPODERMIC SYRINGES(BD PLASTIPAK)-THREE-PIECE SYRINGES BD PLASTIPAK ARE MEDICAL DEVICES USED FOR INJECTION OF MEDICINAL SUBSTANCES, BLOOD EXTRACTION, AND ASPIRATION OF FLUIDS FROM VIALS, AMPOULES AND PARTS OF BODY BELOW THE SURFACE OF THE SKIN.
2063	IMP/MD/2020/000136	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DELIVERY SYSTEM (ENSEMBLE II)-THE ENSEMBLE DS IS DESIGNED TO ALLOW A PHYSICIAN TO DELIVER A MELODY TPV, VIA VENOUS ACCESS, TO THE AREA OF A FAILED PULMONARY VALVE PREVIOUSLY PLACED SURGICALLY FOR THE REPAIR OF CONGENITAL HEART DISEASE

2064	IMP/MD/2020/000137	1.License Holder Name: INTAS PHARMACEUTICALS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PRE-FILLABLE SYRINGES (EZ-FILL)-THE PRE-FILLABLE SYRINGES CAN BE CONSIDERED A COMPONENT OF THE SO-CALLED PRE-FILLED SYRINGES. THEY WILL BE FILED WITH THE DRUG CLOSED WITH THE PLUNGER AND PUT IN THE COMMERCE BY THE PHARMACEUTICAL INDUSTRY,BULK SYRINGES-THE PRE-FILLABLE SYRINGES CAN BE CONSIDERED A COMPONENT OF THE SO-CALLED PRE-FILLED SYRINGES. THEY WILL BE FILED WITH THE DRUG CLOSED WITH THE PLUNGER AND PUT IN THE COMMERCE BY THE PHARMACEUTICAL INDUSTRY
2065	IMP/MD/2020/000138	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. ,501 TO 509, B WING, DYNASTY BUSINESS PARK, ANDHERI-KURLA ROAD, ANDHERI EAST, TAL -ANDHERI EAST (MUMBAI-ZONE 5) ,MUMBAI CITY MAHARASHTRA ,400059 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTROLLER SYSTEM (QUANTUM 2)-IT IS INDICATED FOR RESECTION, ABLATION, AND COAGULATION OF SOFT TISSUE AND HEMOSTASIS OF BLOOD VESSELS IN ARTHROSCOPIC AND ORTHOPEDIC PROCEDURES., CONTROLLER SYSTEM(COBLATOR II)-IT IS INDICATED FOR ABLATION, RESECTION, AND COAGULATION OF SOFT TISSUE AND HEMOSTASIS OF BLOOD VESSELS IN OTORHINOLARYNGOLOGY (ENT) SURGERY.,COBLATION SYSTEM(WEREWOLF)-IT IS INDICATED FOR THE RESECTION, ABLATION, AND COAGULATION OF TISSUES AND HEMOSTASIS OF BLOOD VESSELS IN ARTHROSCOPIC AND ORTHOPEDIC PROCEDURES.
2066	IMP/MD/2020/000139	1.License Holder Name: M/S NOVO NORDISK INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC NEEDLES(NOVOFINE PLUS 32G NEEDLES)-NOVOFINE® PLUS NEEDLES HAVING A THREAD INTERFACE ARE INTENDED FOR USE WITH NEEDLE-BASED PEN INJECTORS FOR THE SUBCUTANEOUS INJECTION OF DRUGS, INCLUDING INSULIN, GLP-1 AND GROWTH HORMONE PRODUCTS. INDICATIONS FOR USE NOVOFINE® PLUS NEEDLES ARE INDICATED FOR USE WITH NEEDLE-BASED PEN INJECTORS, LIKE NOVOPEN® 4, NOVOPEN ECHO® AND NOVOPEN® 5 AS WELL AS FLEXPEN® AND FLEXTOUCH®, I.E. BOTH DURABLE AND PREFILLED PEN INJECTORS FOR TREATMENT OF DIABETES AND GROWTH HORMONE DEFICIENCY.

2067	IMP/MD/2020/000140	1.License Holder Name: GPC MEDICAL LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SEMI FINISHED BONE PLATES (NON STERILE) FOR FURTHER PROCESS-AFTER COMPLETION OF ALL PROCESS, BONE PLATES ARE USED FOR REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE,SEMI FINISHED BONE SCREWS (NON STERILE) FOR FURTHER PROCESS-AFTER COMPLETION OF ALL PROCESS, BONE SCREWS ARE USED FOR REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE

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2068	IMP/MD/2020/000141	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL MESH (PROCEED SURGICAL MESH)-INDICATED FOR THE REPAIR OF ABDOMINAL WALL HERNIAS AND OTHER ABDOMINAL WALL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT.,VENTRAL PATCH(PROCEED VENTRAL PATCH)-PROCEED™ VENTRAL PATCH IS INDICATED FOR THE REPAIR OF ABDOMINAL WALL HERNIAS AND ABDOMINAL WALL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT.,MESH(ETHICON PHYSIOMESH)-ETHICON PHYSIOMESH™ OPEN MAY BE USED FOR THE REPAIR OF HERNIAS AND OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT.,HERNIA SYSTEM(ULTRAPRO)-THIS PRODUCT IS INDICATED FOR OPEN REPAIR OF ABDOMINAL WALL HERNIA DEFECTS.,SUTURES(VICRYL)-VICRYL™ SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER. THE SAFETY AND EFFECTIVENESS OF VICRYL™ SUTURE IN CARDIOVASCULAR TISSUE HAS NOT BEEN ESTABLISHED.,SUTURES (VICRYL PLUS)-COATED VICRYL™ PLUS ANTIBACTERIAL SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION. THE SAFETY AND EFFECTIVENESS OF COATED VICRYL™ PLUS ANTIBACTERIAL SUTURES IN CARDIOVASCULAR TISSUE, OPHTHALMIC SURGERY AND NEUROLOGICAL TISSUE HAVE NOT BEEN ESTABLISHED,SUTURES(VICRYL RAPIDE)-VICRYL RAPIDE™ IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO ITS ABSORPTION PROFILE VICRYL RAPIDE™ IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. VICRYL RAPIDE™ IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES.,MESH(VYPRO)-IT IS INDICATED FOR THE REPAIR OF ABDOMINAL WALL HERNIAS AND ABDOMINAL WALL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT.,MESH(ULTRAPRO ADVANCED)-ULTRAPRO ADVANCED™ MESH IS INDICATED FOR THE REPAIR OF ABDOMINAL WALL HERNIAS AND ABDOMINAL WALL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING MATERIAL TO OBTAIN THE DESIRED SURGICAL

		RESULT.,MESH(ULTRAPRO)-ULTRAPRO™ MESH IS INDICATED FOR THE REPAIR OF ABDOMINAL WALL HERNIAS AND ABDOMINAL WALL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT.
2069	IMP/MD/2020/000143	1.License Holder Name: M/S. RIDDHI ASSOCIATES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PDO KNOTLESS TISSUE-CLOSURE DEVICE (POLYDIOXANONE)(QUILL)-KNOTLESS TISSUE-CLOSURE DEVICE COMPRISED OF DYED PDO IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE USE OF ABSORBABLE SUTURES IS APPROPRIATE.,POLYPROPYLENE KNOTLESS TISSUE-CLOSURE DEVICE(QUILL)-DEVICE COMPRISED OF POLYPROPYLENE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION EXCLUDING CLOSURE OF THE EPIDERMIS.,MONODERM KNOTLESS TISSUE-CLOSURE DEVICE (PGA-PCL)(QUILL)-MONODERM DEVICE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE USE OF ABSORBABLE SUTURES IS APPROPRIATE.

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2070	IMP/MD/2020/000144	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIP SYSTEM(G7 ACETABULAR SYSTEM-SCREW)-1. NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS 2. RHEUMATOID ARTHRITIS 3. CORRECTION OF FUNCTIONAL DEFORMITY 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES 7. 5. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED POROUS ACETABULAR SHELLS AND FEMORAL STEMS ARE INDICATED FOR UNCEMENTED BIOLOGICAL FIXATION. NON-COATED OR POLYETHYLENE COMPONENTS MAY BE USED WITH MATING COMPONENTS THAT ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED USE. INDICATIONS FOR BIOMET G7 FREEDOM CONSTRAINED LINERS: THE BIOMET G7 FREEDOM CONSTRAINED LINER IS INDICATED FOR USE AS A COMPONENT OF A TOTAL HIP PROSTHESIS IN PRIMARY AND REVISION PATIENTS AT HIGH RISK OF DISLOCATION DUE TO A HISTORY OF PRIOR DISLOCATION, BONE LOSS, JOINT OR SOFT TISSUE LAXITY, NEUROMUSCULAR DISEASE, OR INTRA-OPERATIVE INSTABILITY, AND FOR WHOM ALL OTHER OPTIONS TO CONSTRAINED ACETABULAR COMPONENTS HAVE BEEN CONSIDERED. BIOMET® MODULAR FEMORAL HEADS MAY BE USED WITH MATING COMPONENTS THAT ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED USE.,HIP SYSTEM(G7 ACETABULAR SYSTEM-PLUG)-1. NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS 2. RHEUMATOID ARTHRITIS 3. CORRECTION OF FUNCTIONAL DEFORMITY 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES 7. 5. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED POROUS ACETABULAR SHELLS AND FEMORAL STEMS ARE INDICATED FOR UNCEMENTED BIOLOGICAL FIXATION. NON-COATED OR POLYETHYLENE COMPONENTS MAY BE USED WITH MATING COMPONENTS THAT ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED USE. INDICATIONS FOR BIOMET G7 FREEDOM CONSTRAINED LINERS: THE BIOMET G7 FREEDOM CONSTRAINED LINER IS INDICATED FOR USE AS A COMPONENT OF A TOTAL HIP PROSTHESIS IN PRIMARY AND REVISION PATIENTS AT HIGH RISK OF DISLOCATION DUE TO A HISTORY OF PRIOR DISLOCATION, BONE LOSS, JOINT OR SOFT TISSUE LAXITY, NEUROMUSCULAR DISEASE, OR INTRA-OPERATIVE

	INSTABILITY, AND FOR WHOM ALL OTHER OPTIONS TO CONSTRAINED ACETABULAR COMPONENTS HAVE BEEN CONSIDERED. BIOMET® MODULAR FEMORAL HEADS MAY BE USED WITH MATING COMPONENTS THAT ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED USE.,HIP SYSTEM(SIRIUS POLISHED CEMENTED STEM • HIP STEM)-1. 1. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS 2. 2. RHEUMATOID ARTHRITIS 3. 3. CORRECTION OF FUNCTIONAL DEFORMITY 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES 4. 5. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED 5. 6. THE SIRIUS FEMORAL HIP STEM IS INTENDED FOR CEMENTED USE ONLY AND MAY BE USED IN PARTIAL AND TOTAL HIP ARTHROPLASTIES,HIP SYSTEM(G7 ACETABULAR SYSTEM-LINERS)-1. NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS 2. RHEUMATOID ARTHRITIS 3. CORRECTION OF FUNCTIONAL DEFORMITY 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES 7. 5. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED POROUS ACETABULAR SHELLS AND FEMORAL STEMS ARE INDICATED FOR UNCEMENTED BIOLOGICAL FIXATION. NON-COATED OR POLYETHYLENE COMPONENTS MAY BE USED WITH MATING COMPONENTS THAT ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED USE. INDICATIONS FOR BIOMET G7 FREEDOM CONSTRAINED LINERS: THE BIOMET G7 FREEDOM CONSTRAINED LINER IS INDICATED FOR USE AS A COMPONENT OF A TOTAL HIP PROSTHESIS IN PRIMARY AND REVISION PATIENTS AT HIGH RISK OF DISLOCATION DUE TO A HISTORY OF PRIOR DISLOCATION, BONE LOSS, JOINT OR SOFT TISSUE LAXITY, NEUROMUSCULAR DISEASE, OR INTRA-OPERATIVE INSTABILITY, AND FOR WHOM ALL OTHER OPTIONS TO CONSTRAINED ACETABULAR COMPONENTS HAVE BEEN CONSIDERED. BIOMET® MODULAR FEMORAL HEADS MAY BE USED WITH MATING COMPONENTS THAT ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED USE.,HIP SYSTEM(G7 ACETABULAR SYSTEM-SHELL)-1. NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS 2. RHEUMATOID ARTHRITIS 3. CORRECTION OF FUNCTIONAL DEFORMITY 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER

	TECHNIQUES 7. 5. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED POROUS ACETABULAR SHELLS AND FEMORAL STEMS ARE INDICATED FOR UNCEMENTED BIOLOGICAL FIXATION. NON-COATED OR POLYETHYLENE COMPONENTS MAY BE USED WITH MATING COMPONENTS THAT ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED USE. INDICATIONS FOR BIOMET G7 FREEDOM CONSTRAINED LINERS: THE BIOMET G7 FREEDOM CONSTRAINED LINER IS INDICATED FOR USE AS A COMPONENT OF A TOTAL HIP PROSTHESIS IN PRIMARY AND REVISION PATIENTS AT HIGH RISK OF DISLOCATION DUE TO A HISTORY OF PRIOR DISLOCATION, BONE LOSS, JOINT OR SOFT TISSUE LAXITY, NEUROMUSCULAR DISEASE, OR INTRA-OPERATIVE INSTABILITY, AND FOR WHOM ALL OTHER OPTIONS TO CONSTRAINED ACETABULAR COMPONENTS HAVE BEEN CONSIDERED. BIOMET® MODULAR FEMORAL HEADS MAY BE USED WITH MATING COMPONENTS THAT ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED USE.,HIP SYSTEM(SIRIUS POLISHED CEMENTED STEM • STEM CENTRALIZER)-1. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS 2. RHEUMATOID ARTHRITIS 3. CORRECTION OF FUNCTIONAL DEFORMITY 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES 5. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED 6. THE SIRIUS FEMORAL HIP STEM IS INTENDED FOR CEMENTED USE ONLY AND MAY BE USED IN PARTIAL AND TOTAL HIP ARTHROPLASTIES,HIP SYSTEM(G7 ACETABULAR SYSTEM- FEMORAL HEAD)-1. NONINFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS 2. RHEUMATOID ARTHRITIS 3. CORRECTION OF FUNCTIONAL DEFORMITY 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES 7. 5. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED POROUS ACETABULAR SHELLS AND FEMORAL STEMS ARE INDICATED FOR UNCEMENTED BIOLOGICAL FIXATION. NON-COATED OR POLYETHYLENE COMPONENTS MAY BE USED WITH MATING COMPONENTS THAT ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED USE. INDICATIONS FOR BIOMET G7 FREEDOM CONSTRAINED LINERS: THE BIOMET G7 FREEDOM CONSTRAINED LINER IS INDICATED FOR USE AS A COMPONENT OF A TOTAL HIP PROSTHESIS IN PRIMARY AND REVISION PATIENTS AT HIGH RISK OF DISLOCATION DUE TO A HISTORY OF PRIOR DISLOCATION, BONE LOSS, JOINT OR SOFT

		TISSUE LAXITY, NEUROMUSCULAR DISEASE, OR INTRA-OPERATIVE INSTABILITY, AND FOR WHOM ALL OTHER OPTIONS TO CONSTRAINED ACETABULAR COMPONENTS HAVE BEEN CONSIDERED. BIOMET® MODULAR FEMORAL HEADS MAY BE USED WITH MATING COMPONENTS THAT ARE INDICATED FOR EITHER CEMENTED OR UNCEMENTED USE.
2071	IMP/MD/2020/000146	1.License Holder Name: ADVANCED LIFESCIENCES PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HAEMOSTATIC GAUZE (CELOX RAPID)-PRE-HOSPITAL, TEMPORARY, EXTERNAL USE TO CONTROL LIFE THREATENING EMERGENCY BLEEDING. FOR USE BY TRAINED EMERGENCY RESPONDERS.,HEMOSTATIC PAD(CELOX VASCULAR)-FOR TEMPORARY EXTERNAL USE ONLY. TO CONTROL SURFACE BLEEDING FROM VASCULAR ACCESS SITES, PERCUTANEOUS CATHETERS OR TUBES UTILIZING INTRODUCERS SHEATHS UP TO 16 FRENCH.,HAEMOSTATIC GRANULES(CELOX - A GRANULES IN APPLICATOR)-PRE-HOSPITAL, TEMPORARY, TREATMENT OF NARROW PENETRATING TRAUMA WOUNDS FOR LIFE THREATENING EMERGENCY BLEEDING (NARROW PENETRATING WOUNDS). FOR USE BY TRAINED EMERGENCY RESPONDERS.
2072	IMP/MD/2020/000148	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCESS DEVICE AND EXTENSION SETS(CARESITE LUER ACCESS DEVICE/ CARESITE EXTENSION SETS)-FOR ASPIRATION, INJECTION OR GRAVITY/PUMP FLOW OF IV FLUIDS AND BLOOD UPON INSERTION OF A MALE LUER CONNECTOR.
2073	IMP/MD/2020/000149	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STRYKER HAND PLATING SYSTEM(HAND PROFYLE SYSTEM)-THE STRYKER HAND PLATING SYSTEM IS INTENDED FOR USE IN INTERNAL FIXATION OF THE BONES OF THE HAND AND WRIST. EXAMPLES OF THESE PROCEDURES MAY INCLUDE BUT ARE NOT LIMITED TO REPLANTATION, LAG SCREW TECHNIQUES, JOINT FUSIONS, CORRECTIVE OSTEOTOMIES, AND THE TREATMENT OF FRACTURES.

2074	IMP/MD/2020/000151	1.License Holder Name: PREMIER ENTERPRISES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALCOHOL SWABS-FOR SKIN DISINFECTION & ANTI BACTERIAL ACTION, PRIOR TO INJECTION/INCISION
2075	IMP/MD/2020/000152	1.License Holder Name: GMI IMPLANTOLOGY INDIA PRIVATE LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANTS (FRONTIER DENTAL IMPLANT SYSTEM)-FRONTIER DENTAL IMPLANT SYSTEM IS INTENDED TO BE USED FOR SURGICAL PLACEMENT IN UPPER OR LOWER JAW TO PROVIDE A SUPPORT FOR PROSTHETIC DEVICES SUCH AS ARTIFICAL TEETH, IN ORDER TO RESTORE THE PATIENT'S CHEWING FUNCTION. THESE PRODUCTS SHOULD ONLY BE USED BY TRAINED PROFESSIONALS.,DENTAL IMPLANTS(AVANTGARD DENTAL IMPLANT SYSTEM)-AVANTGARD DENTAL IMPLANT SYSTEM IS INTENDED TO BE USED FOR SURGICAL PLACEMENT IN UPPER OR LOWER JAW TO PROVIDE A SUPPORT FOR PROSTHETIC DEVICES SUCH AS ARTIFICIAL TEETH, IN ORDER TO RESTORE THE PATIENT'S CHEWING FUNCTION. THESE PRODUCTS SHOULD ONLY BE USED BY TRAINED PROFESSIONALS.,DENTAL ABUTMENTS(FRONTIER ABUTMENTS AND AVANTGARD ABUTMENTS)-FRONTIER DENTAL IMPLANT SYSTEMS AND AVANTGARD DENTAL IMPLANT SYSTEMS IS INTENDED TO BE USED FOR SURGICAL PLACEMENT IN UPPER OR LOWER JAW TO PROVIDE A SUPPORT FOR PROSTHETIC DEVICES SUCH AS ARTIFICIAL TEETH, IN ORDER TO RESTORE THE PATIENT'S CHEWING FUNCTION. THESE PRODUCTS SHOULD ONLY BE USED BY TRAINED PROFESSIONALS.,HEALING SCREWS(FRONTIER HEALING SCREWS AND AVANTGARD HEALING SCREWS)-FRONTIER DENTAL IMPLANT SYSTEMS AND AVANTGARD DENTAL IMPLANT SYSTEMS IS INTENDED TO BE USED FOR SURGICAL PLACEMENT IN UPPER OR LOWER JAW TO PROVIDE A SUPPORT FOR PROSTHETIC DEVICES SUCH AS ARTIFICIAL TEETH, IN ORDER TO RESTORE THE PATIENT'S CHEWING FUNCTION. THESE PRODUCTS SHOULD ONLY BE USED BY TRAINED PROFESSIONALS.
2076	IMP/MD/2020/000153	1.License Holder Name: SMITHS MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRACHEOSTOMY TUBES (BIVONA)-IT IS INTENDED TO PROVIDE DIRECT AIRWAY ACCESS FOR A TRACHEOSTOMIZED PATIENT FOR UPTO 29 DAYS. IT MAY BE REPROCESSED UPTO 10 TIMES FOR SINGLE PATIENT USE

2077	IMP/MD/2020/000157	1.License Holder Name: M/S ASIA ACTUAL INDIA (OPC) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRODUCER (INTRODUCER)-THE INTRODUCER IS A MANUAL SURGICAL INSTRUMENT FOR GENERAL USE. THE INTRODUCER NEEDLE IS INTENDED TO BE USED BY MEDICAL PROFESSIONALS AS INTRODUCERS/CANNULA FOR PERCUTANEOUS INTRODUCTION OF SURGICAL DEVICES. THE INTRODUCER NEEDLE IS FOR USE AS AN ACCESSORY IN PERCUTANEOUS PROCEDURE. ,CRYOPROBE (ABLATION DEVICE)(PROSENSE)-ICECURE CRYOABLATION SYSTEM IS INTENDED FOR CRYOGENIC DESTRUCTION OF TISSUE DURING SURGICAL PROCEDURES BY THE APPLICATION OF EXTREME COLD TEMPERATURES. THE ICECURE CRYOABLATION SYSTEM IS INDICATED FOR USE AS A CRYOSURGICAL TOOL IN THE FIELDS OF GENERAL SURGERY (INCLUDING BREAST AND LIVER TISSUE), DERMATOLOGY, THORACIC SURGERY (INCLUDING LUNG TISSUE), GYNECOLOGY, ONCOLOGY (INCLUDING BONE TISSUE), PROCTOLOGY, AND UROLOGY (INCLUDING KIDNEY TISSUE). THE ICECURE CRYOABLATION SYSTEM MAY BE USED WITH AN ULTRASOUND DEVICE TO PROVIDE REAL-TIME VISUALIZATION OF THE CRYOSURGICAL PROCEDURE. THE SYSTEM IS SUITABLE FOR USE IN A NUMBER OF CRYOTHERAPY APPLICATIONS. HOWEVER, IT IS ONLY INDICATED FOR USE IN PATIENTS WHOM THE PRACTITIONER HAS DEEMED ELIGIBLE FOR CRYOTHERAPY.
2078	IMP/MD/2020/000162	1.License Holder Name: SPAN HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:APHERESIS SYSTEM TUBING SET.(HAEMONETICS)-IT IS INTENDED TO BE USED ON THE MCS+ 9000 AND THE TPE PROTOCOL (LN 89967-XX) FOR THE COLLECTION OF PLASMA FROM A PATIENT AND REPLACING IT WITH FLUID, SUCH AS ALBUMIN, FFP OR BALANCED ELECTROLYTE SOLUTIONS.,APHERESIS SYSTEM TUBING SET(HAEMONETICS)-CLOSED SET FOR AUTOMATED BLOOD COMPONENT COLLECTION.

2079	IMP/MD/2020/000163	1.License Holder Name: LUPIN LIMITED (BIOTECHNOLOGY DIVISION) 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PRE-FILLABLE SYRINGES (EZ-FILL)-THE PRE-FILLABLE SYRINGES CAN BE CONSIDERED A COMPONENT OF THE SO CALLED PRE-FILLED SYRINGES. THEY WILL BE FILLED WITH THE DRUG, CLOSED WITH THE PLUNGER AND PUT IN THE COMMERCE BY THE PHARMACEUTICAL INDUSTRY.,BULK SYRINGES-THE PRE-FILLABLE SYRINGES CAN BE CONSIDERED A COMPONENT OF THE SO CALLED PRE-FILLED SYRINGES. THEY WILL BE FILLED WITH THE DRUG, CLOSED WITH THE PLUNGER AND PUT IN THE COMMERCE BY THE PHARMACEUTICAL INDUSTRY.

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2080	IMP/MD/2020/000164	1.License Holder Name: CONVATEC INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADHESIVE SILICON FOAM DRESSING(FOAM LITE CONVATEC)-FOAM LITE CONVATEC DRESSING ARE INDICATED FOR THE MANAGEMENT OF A WIDE RANGE OF LOW/NON EXUDING WOUNDS. UNDER MEDICAL SUPERVISION FOAM LITE CONVATEC DRESSINGS MAY BE USED FOR THE MANAGEMENT OF BOTH CHRONIC AND ACUTE WOUNDS SUCH AS, BUT NOT LIMITED TO: - LEG ULCERS, PRESSURE ULCERS AND DIABETIC ULCERS - SURGICAL WOUNDS (E.G. POST-OPERATIVE WOUNDS LEFT TO HEAL BY SECONDARY INTENT AND DONOR SITES) - PARTIAL THICKNESS (SECOND DEGREE) BURNS - TRAUMATIC WOUNDS (E.G. ABRASIONS, LACERATIONS, BLISTERS, MINOR CUTS AND SKIN TEARS),SURGICAL DRESSING(AQUACEL EXTRA)-USED FOR THE MANAGEMENT OF LEG ULCERS, PRESSURE ULCERS, (STAGE II-IV) AND DIABETIC ULCER, SURGICAL WOUNDS, PARTIAL THICKNESS WOUND, TRAUMATIC WOUND.,SURGICAL DRESSING(AQUACEL AG BURN DRESSING /GLOVE)-USED FOR THE MANAGEMENT OF PARTIAL THICKNESS (SECOND DEGREE) BURNS, DIABETIC FOOT UNCLE, LEG ULCERS AND PRESSURE ULCER/SORES, MANAGEMENT OF PAINFUL WOUNDS, INFECTED WOUNDS.,SURGICAL DRESSING(AQUACEL AG HYDROFIBER DRESSING WITH SILVER)-MANAGEMENT OF WOUNDS AS AN EFFECTIVE BARRIER TO BACTERIAL PENETRATION TO HELP REDUCE INFECTION SUCH INFECTION AS PARTIAL THICKNESS BURNS, DIABETICS FOOT/ LEG AND PRESSURE ULCER/ SORES (PARTIAL & FULL THICKNESS), SURGICAL WOUNDS TRAUMATIC AND PAINFUL WOUNDS.,SURGICAL DRESSING(DUODERM GEL)-DUODERM GEL IS DESIGNED FOR THE HYDRATION AND MANAGEMENT OF PARTIAL AND FULL-THICKNESS WOUNDS SUCH AS PRESSURE SORES, LEG ULCERS, AND DIABETIC ULCERS. IT ENABLE NON TRAUMATIC REMOVAL OF SECONDARY DRESSING WITHOUT DAMAGING NEW TISSUE.,HYDROFIBER FOAM DRESSING (ADHESIVE AND NON ADHESIVE)(AQUACEL FOAM)-IT IS USED FOR THE MANAGEMENT OF BOTH CHRONIC AND ACUTE WOUNDS.,STOMAHESIVE POWDER (STOMAHESIVE POWDER)-USED FOR THE MANAGEMENT OF STOMAS. IT IS APPLIED TO THE INTACT SKIN SURROUNDING THE STOMA TO PROVIDE A SEAL BETWEEN THE STOMA, SKIN BARRIER AND THE SKIN TO PREVENT SKIN IRRITATION,SURGICAL DRESSING(AQUACEL HYDROFIBER DRESSING)-MANAGEMENT OF LEG/ PRESSURE / DIABETIC ULCERS, SURGICAL WOUND, PARTIAL THICKNESS BURNS, TRAUMATIC AND PAINFUL WOUNDS.,HYDROFIBER FOAM DRESSING WITH SILVER (ADHESIVE AND NON ADHESIVE)(AQUACEL AG FOAM)-IT IS USED FOR THE MANAGEMENT OF BOTH CHRONIC AND ACUTE WOUNDS THE SILVER CONTENT PREVENTS OR MINIMIZES MICROBIAL

		GROWTH AND KILL A BROAD SPECTRUM OF WOUND BACTERIA HELD IN THE DRESSING.,SURGICAL DRESSING(KALTOSTAT CALCIUM ALGINATE)-USED FOR THE LOCAL MANAGEMENT OF MODERATE BLEEDING WOUNDS: LACERATIONS, ABRASIONS, NOSE BLEEDS, DENTAL EXTRACTIONS AND AFTER SURGICAL WOUND DEBRIDEMENT.,FAECAL MANAGEMENT SYSTEM(FLEXI-SEAL)-FOR THE FECAL MANAGEMENT OF PATIENT WITH LITTLE OR NO BOWEL CONTROL AND LIQUID OF SEMI-LIQUID STOOL. FOR USE TO MANAGE FAECAL INCONTINENCE THROUGH THE COLLECTION OF LIQUID TO SEMI-LIQUID STOOL AND TO PROVIDE, ACCESS TO ADMINISTER MEDICATIONS.,SURGICAL DRESSING(AQUACEL AG PLUS)-USED FOR THE MANAGEMENT OF WOUNDS AS AN EFFECTIVE BARRIER TO BACTERIAL PENETRATION OF THE DRESSING AS IT MAY HELP TO REDUCE INFECTION, WOUND WHERE THERE IS AN INFECTION OR AN INCREASE RISK OF INFECTION SUCH AS DIABETIC/LEG ULCERS, PRESSURE ULCERS/SORES, SURGICAL WOUNDS, TRAUMATIC WOUNDS.,SURGICAL DRESSING(AQUACEL AG EXTRA)-USED FOR THE MANAGEMENT OF WOUNDS WHERE THERE IS AN INFECTION OR AN INCREASED RISK OF INFECTION, PARTIAL THICKNESS (SECOND DEGREE), SURGICAL WOUND, TRAUMATIC WOUND.
2081	IMP/MD/2020/000165	1.License Holder Name: SMITHS MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMBINED SPINAL EPIDURAL MINIPACK(RAPID PORTEX, PORTEX)-IT IS SINGLE AND EPIDURAL NEEDLES TO PERFORM A SPINAL (SUBARACHNOID) INJECTION THROUGH AN EPIDURAL TUOHY NEEDLE PLACED IN THE EPIDURAL SPACE FOLLOWED BY THE PLACEMENT OF AN EPIDURAL CATHETER TO ALLOW MODIFICATION OF THE SPINAL ANALGESIA IF NECESSARY OR BOLUS INJECTIONS OR CONTINUOUS INFUSION OF LOCAL ANESTHETICS OR OTHER DRUGS INTO THE EPIDURAL SPACE FOR SUBSEQUENT PAIN RELIEF IF REQUIRED.

2082	IMP/MD/2020/000166	1.License Holder Name: M/S LUMINOR MEDICAL DEVICES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:THROMBUS EXTRACTION CATHETER(IVASCULAR CAPTURER)-IT IS ESPECIALLY INDICATED FOR THE REMOVAL OF FRESH, SOFT EMBOLI AND THROMBI FROM THE CORONARY OR PERIPHERAL VASCULATURE, WITH A MINIMUM DIAMETER OF 2 MM.,SELF-EXPANDING PERIPHERAL STENT SYSTEM (NITINOL)(IVASCULAR IVOLUTION PRO)-THE DEVICE IS INDICATED FOR THE TREATMENT OF DE NOVO OR RESTENOTIC ATHEROSCLEROTIC LESIONS IN PERIPHERAL ARTERIES LOCATED UNDER THE AORTIC ARCH AND TO PALLIATE MALIGNANT STRICTURES OF THE BILIARY TRACT WITH A NOMINAL DIAMETER RANGING FROM 4.5 TO 9.5 MM.,PACLITAXEL ELUTING PTA BALLOON DILATATION CATHETER(IVASCULAR LUMINOR 14M, IVASCULAR LUMINOR 18, IVASCULAR LUMINOR 35)-IVASCULAR LUMINOR 14M - THE DEVICE IS INDICATED TO DILATE STENOSIS IN FEMORAL, POPLITEAL INFRA-POPLITEAL ARTERIES, WITH A REFERENCE DIAMETER BALLOON FROM 1.5 AND 4.0MM AND LENGTHS FROM 40 UP TO 200MM. IVASCULAR LUMINOR 18- THE DEVICE IS INDICATED FOR DILATION OF STENOSIS LOCATED IN THE ILIAC, FEMORAL, ILIOFEMORAL, POPLITEAL, INFRA-POPLITEAL AND RENAL ARTERIES, AS WELL AS FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF ARTERIOVENOUS FISTULAS, WHETHER ORIGINAL OR ARTIFICIAL, WITH A REFERENCE DIAMETER BALLOON FROM 2 TO 8 MM AND LENGTHS FROM 20 TO 200 MM. IT IS ALSO INDICATED FOR STENT POSTDILATION IN THE PERIPHERAL VASCULAR SYSTEM. IVASCULAR LUMINOR 35- THE DEVICE IS INDICATED FOR DILATION OF STENOSIS LOCATED IN THE ILIAC, FEMORAL, ILIOFEMORAL, POPLITEAL, INFRA-POPLITEAL AND RENAL ARTERIES, AS WELL AS FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF ARTERIOVENOUS FISTULAS, WHETHER ORIGINAL OR ARTIFICIAL, WITH A REFERENCE DIAMETER BALLOON FROM 5 TO 7 MM AND LENGTHS FROM 20 TO 150 MM. IT IS ALSO INDICATED FOR STENT POSTDILATION IN THE PERIPHERAL VASCULAR SYSTEM. MINOR UPDATE TO INSTRUCTION FOR USE: (1) ADDITION OF A WARNING REGARDING PACLITAXEL USE; (2) INCLUSION OF A NEW SECTION FOR SUMMARIZING THE CLINICAL OUTCOMES OF THE CLINICAL TRIALS CONDUCTED ON IVASCULAR LUMINOR MODELS. ,PACLITAXEL ELUTING CORONARY BALLOON DILATATION CATHETER(IVASCULAR ESSENTIAL PRO)-THE DEVICE IS INDICATED FOR THE DILATATION OF STENOSIS OR CORONARY ARTERY OR BYPASS GRAFTS OCCLUSIONS, INCLUDING SMALL VESSELS, AS WELL AS FOR RESIDUAL STENOSIS AFTER TREATMENT WITH BALLOON OR ENDOPROSTHESIS AND PRE- AND POST-

	DILATION OF CORONARY ENDOVASCULAR PROSTHESIS, IN ORDER TO IMPROVE MYOCARDIAL PERFUSION.,PTA BALLOON DILATATION CATHETER(IVASCULAR OCEANUS 14 PRO, IVASCULAR OCEANUS 18, IVASCULAR OCEANUS 35)-IVASCULAR OCEANUS 14 PRO - THE DEVICE IS INDICATED TO DILATE STENOSIS IN FEMORAL, POPLITEAL, INFRA-POPLITEALAND RENAL ARTERIES AND FOR TREATING OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETICARTERIOVENOUS DIALYSIS FISTULAE, WITH A REFERENCE DIAMETER BALLOON FROM 1.25 AND 4.0 MM AND LENGTHS FROM 10 UP TO 200 MM. IVASCULAR OCEANUS 18 - THE DEVICE IS INDICATED TO DILATE STENOSES IN ILIAC, FEMORAL, POPLITEAL, INFRA-POPLITEAL AND RENAL ARTERIES AND FOR TREATING OBSTRUCTIVE LESIONS OF NATIVE ORSYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE, WITH A DIAMETER FROM 2 TO 8 MM AND LENGTHS FROM 20 UP TO 200MM. IVASCULAR OCEANUS 35 - INDICATED FOR DILATION OF STENOSIS LOCATED IN THE RENAL, ILIAC, FEMORAL, POPLITEALAND INFRAPOPLITEAL ARTERIES, AND FOR TREATING OBSTRUCTIVE LESIONS OF NATIVE ORSYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE.,CORONARY MICROCATHETER(IVASCULAR NAVITIAN)-THE DEVICE IS INDICATED FOR: 1) FACILITATING, GUIDING AND SUPPORTING A GUIDEWIRE DURING ACCESS TO THE CORONARY SYSTEM. 2) EXCHANGING GUIDEWIRES. 3) DELIVERING SALINE OR CONTRAST SOLUTIONS.,SELF-EXPANDING PERIPHERAL STENT SYSTEM (NITINOL)(IVASCULAR IVOLUTION)-THE PERIPHERAL STENT SYSTEM IS INDICATED FOR THE TREATMENT OF DE NOVO OR RESTENOTIC ATHEROSCLEROTIC LESIONS IN PERIPHERAL ARTERIES LOCATED UNDER THE AORTIC ARCH; THAT IS, AND FOR PALLIATION OF BILIARY TRACT MALIGNANT STENOSIS WITH A NOMINAL DIAMETER RANGING FROM 4.5 AND 9.5 MM.,PERIPHERAL SUPPORT CATHETER(IVASCULAR SERGEANT)-THE CATHETER IS INTENDED TO FACILITATE, GUIDE AND SUPPORT A GUIDEWIRE DURING ACCESS INTO THE PERIPHERAL VASCULATURE, ALLOW FOR GUIDEWIRE EXCHANGES, AND/OR PROVIDE A CONDUIT FOR THE DELIVERY OF SALINE SOLUTIONS AND/OR DIAGNOSTIC CONTRAST AGENTS. THE CATHETER IS INDICATED FOR PATIENTS WITH PERIPHERAL ARTERY DISEASE IN SMALL VESSEL OR CHALLENGING ANATOMY DURING DIAGNOSTIC AND INTERVENTIONAL PROCEDURES.,SIROLIMUS ELUTING CORONARY STENT SYSTEM, WITH COCR STENT AND PERMANENT POLYMER(IVASCULAR ANGIOLITE)-THE DEVICE IS INDICATED FOR INCREASING THE INTERNAL DIAMETER OF AN ARTERY WITH THE AIM OF IMPROVING BLOOD FLOW IN THE FOLLOWING CASES: • PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO “DE NOVO” STENOTIC AND RE-STENOTIC LESIONS LOCATED IN ARTERIES WITH DIAMETERS FROM 2MM TO 4.5

	MM. • PATIENTS WITH OCCLUSIVE DISEASE DUE TO ACUTE MYOCARDIAL INFARCTION LOCATED IN ARTERIES WITH DIAMETERS FROM 2MM TO 4.5MM.,COCR PERIPHERAL STENT SYSTEM (IVASCULAR RESTORER)-THE PERIPHERAL STENT SYSTEM IS INDICATED FOR THE TREATMENT OF DE NOVO OR RESTENOTIC ATHEROSCLEROTIC LESIONS IN PROTECTED PERIPHERAL ARTERIES LOCATED UNDER THE AORTIC ARCH; THAT IS, THE ILIAC ARTERY AND THE DEEP FEMORAL ARTERY OR PROXIMAL FEMORAL ARTERY, AND FOR PALLIATION OF BILIARY TRACT MALIGNANT STENOSIS WITH A NOMINAL DIAMETER RANGING FROM 5 AND 10 MM.

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2083	IMP/MD/2020/000167	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KNOTLESS TISSUE CONTROL DEVICE(STRATAFIX SYMMETRIC PDS PLUS)-THE STRATAFIX™ SPIRAL PDS™ PLUS DEVICE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE THE USE OF ABSORBABLE SUTURES IS APPROPRIATE.,SUTURES(MONOCRYL (CE))-MONOCRYL™ SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION WHERE AN ABSORBABLE MATERIAL IS INDICATED.,SUTURES(COATED VICRYL (NON-CE))-VICRYL™ SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER. THE SAFETY AND EFFECTIVENESS OF VICRYL™ SUTURES IN CARDIOVASCULAR TISSUE HAVE NOT BEEN ESTABLISHED.,SUTURES (PDS II (NON-CE))-PDS™ II SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PEDIATRIC CARDIOVASCULAR TISSUE, IN MICROSURGERY AND IN OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE., FIXATION DEVICE(ETHICON SECURESTRAP OPEN (CE))-THE ETHICON SECURESTRAP™ OPEN FIXATION DEVICE IS INTENDED FOR FIXATION OF PROSTHETIC MATERIAL TO SOFT TISSUES IN OPEN SURGICAL PROCEDURES, SUCH AS HERNIA REPAIRS.,SUTURES(PROLENE (CE))-PROLENE™ SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC, AND NEUROLOGICAL PROCEDURES.,SUTURES(PDS PLUS (NON-CE))-PDS™ PLUS ANTIBACTERIAL SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PEDIATRIC CARDIOVASCULAR TISSUE, AND IN OPHTHALMIC SURGERY (OTHER THAN CONTACT WITH CORNEA AND SCLERA). THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO 6 WEEKS) IS DESIRABLE.,FIXATION DEVICE(ETHICON SECURESTRAP (CE))-THE ETHICON SECURESTRAP™ ABSORBABLE FIXATION DEVICE IS INTENDED FOR FIXATION OF PROSTHETIC MATERIAL TO SOFT TISSUES IN VARIOUS MINIMALLY INVASIVE AND OPEN SURGICAL PROCEDURES, SUCH AS HERNIA REPAIRS.,SUTURES(MONOCRYL PLUS (NON-CE))-MONOCRYL™ PLUS ANTIBACTERIAL SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION WHERE AN ABSORBABLE MATERIAL IS

	INDICATED.,SUTURES(PROLENE (NON-CE))-PROLENE™ SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC, AND NEUROLOGICAL PROCEDURES.,SUTURES (ETHIBOND EXCEL (CE))-ETHIBOND EXCEL™ SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,SUTURES(VICRYL PLUS (NON-CE))-COATED VICRYL™ PLUS ANTIBACTERIAL SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION. THE SAFETY AND EFFECTIVENESS OF COATED VICRYL™ PLUS ANTIBACTERIAL SUTURES IN CARDIOVASCULAR TISSUE, OPHTHALMIC SURGERY AND NEUROLOGICAL TISSUE HAVE NOT BEEN ESTABLISHED.,SUTURES(ETHIBOND EXCEL (NON-CE))-ETHIBOND EXCEL™ SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,SUTURES(PDS II (CE))-PDS™ II SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PEDIATRIC CARDIOVASCULAR TISSUE, IN MICROSURGERY AND IN OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE.,SUTURES(COATED VICRYL (CE))-VICRYL™ SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER. THE SAFETY AND EFFECTIVENESS OF VICRYL™ SUTURES IN CARDIOVASCULAR TISSUE HAVE NOT BEEN ESTABLISHED.,SUTURES (MONOCRYL (NON-CE))-THE SUBJECT PRODUCT HAS BEEN CLASSIFIED AS A SYSTEM AS THEY ARE FROM SAME LICENSE HOLDER AND ARE INTENDED TO BE USED IN COMBINATION TO COMPLETE A COMMON INTENDED PURPOSE. THEY ARE COMPATIBLE WHEN USED AS SYSTEM AND SOLD UNDER SINGLE PROPRIETARY SYSTEM NAME.,SUTURES(ETHILON NYLON (NON- CE))-ETHILON™ BLACK/UNDYED SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING CARDIOVASCULAR SURGERY, NEUROSURGERY AND OPHTHALMIC PROCEDURES INCLUDING MICROSURGERY.,SUTURES(ETHILON NYLON (CE))-ETHILON™ BLACK/UNDYED SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING CARDIOVASCULAR SURGERY, NEUROSURGERY AND OPHTHALMIC PROCEDURES INCLUDING MICROSURGERY.

2084	IMP/MD/2020/000168	1.License Holder Name: NAMOHA BIO PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE ABSORBABLE HYALURONIC ACID DERMAL FILLER (HYALURONIC ACID, 20 MG/ML) (HYALDEW ALL, SOLLINE C.7, AMMI CRYSTAL, HYALDEW MID, SOLLINE C.5, AMMI AQUA, HYALDEW FINE, SOLLINE C.3, AMMI HYDRO, HYALDEW SHINE,SOLLINE C.1, SKIN PLUS-HYAL IMPLANT, SOLLINE C. 9, DENEB MODERN, AMMI DESIREE, DENEB MEDIAN, DENEB CLASSIC-H, AMMI B FILLER-H, DENE B CLASSIC-S, AMMI B FILLER-S)-STERILE ABSORBABLE HYALURONIC ACID DERMAL FILLER FOR TISSUE REPAIR IS USED AS INJECTION USING SYRINGE INTO DEEP DERMIS FOR THE TREATMENT OF FACIAL CONTOUR DEFORMITIES (SUCH AS ASYMMETRY TREATMENT) IN CASE OF TISSUE LOSS BY ACCIDENT OR DISEASE. THE DEVICE (MODEL) IS INTENDED TO ADD VOLUME INTO FACIAL DERMIS FOR TREATMENT OF FACIAL LIPOATROPHY
2085	IMP/MD/2020/000169	1.License Holder Name: A & A SURGICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANEURYSM OCCLUSION DEVICE(XCALIBUR - ANEURYSM OCCLUSION DEVICE AND DELIVERY SYSTEM)-THE SYSTEM INDICATED FOR THE TREATMENT OF INTRACRANIAL ANEURYSMS LOCATED PROXIMAL TO THE BIFURCATION OF THE INTERNAL CAROTID ARTERY.,PERCUTANEOUS TRANSLUMINAL BALLOON CATHETER SYSTEM(NCHANT – POST DILATATION BALLOON CATHETER)-THE PDB IS INTENDED FOR NEUROLOGICAL USE IN CONJUNCTION WITH PRODUCTS SUCH AS MERLIN MD'S AOD XCALIBUR. THE PDB SYSTEM IS INDICATED FOR THE BALLOON DILATATION OF PREVIOUSLY DEPLOYED REVASCULARIZATION DEVICES WHEN CLINICIANS CHOOSE TO IMPROVE ARTERIAL PERFUSION.
2086	IMP/MD/2020/000170	1.License Holder Name: M/S HESTER DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASPIRATION CATHETER SET(THROMBUSTER II)-THROMBUSTER IS INTENDED FOR USE TO REMOVE THROMBUS AND DEBRIS IN THE CORONARY OR PERIPHERAL ARTERIES BY PERCUTANEOUS SUCTION.,DUAL LUMEN CATHETER(CRUSADE)-CRUSADE IS INTENDED TO BE USED FOR; - GUIDE WIRE SUPPORT FOR CROSSING SIDE BRANCH - EXCHANGE OF GUIDE WIRES, DURING PERCUTANEOUS CORONARY INTERVENTION (PCI).

2087	IMP/MD/2020/000174	1.License Holder Name: POLY MEDICURE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL IMPLANTABLE CATHETER–PORT(SECUREPORT ARTERIAL)-THE SECUREPORT ARTERIAL IS INDICATED TO BE IMPLANTED IN THE ARTERIAL SYSTEM FOR MID AND LONG-TERM USE, IN ORDER TO PERMIT REPEATED INFUSION OF THERAPEUTIC SOLUTIONS SUCH AS CHEMOTHERAPY., INTRODUCER SET(SECUREPORT)-THE SECUREPORT INTRODUCER SET IS INDICATED FOR PERCUTANEOUS INTRODUCTION OF A SECUREPORT VENOUS INTO THE VASCULAR SYSTEM,,TOTAL IMPLANTABLE CATHETER - PORT(SECUREPORT SPINAL)-THE SECUREPORT SPINAL IS INDICATED TO BE TOTALLY IMPLANTED IN THE BODY IN ORDER TO PERMIT REPEATED INFUSION OF THERAPEUTIC SOLUTIONS SUCH AS ANALGESICS INTO THE SPINAL SYSTEM.,PERIPHERALLY INSERTED CENTRAL VENOUS CATHETER LINES (PICC LINES)(HEALTHPICC)-THE HEALTHPICC CATHETER IS INDICATED TO BE A PERIPHERALLY IMPLANTED ACCESS TO THE CENTRAL VENOUS SYSTEM FOR SHORT TO LONG-TERM USE, IN ORDER TO PERMIT INTRAVENOUS ADMINISTRATION OF FLUIDS, MEDICATIONS, NUTRITIONAL THERAPY AND TO WITHDRAW BLOOD SAMPLES. THE CATHETER SHOULD BE INSERTED THROUGH A VEIN OF THE UPPER ARM. THE HEALTHPICC IS ALSO INDICATED FOR "POWER" INJECTION OF CONTRAST MEDIA,TOTAL IMPLANTABLE CATHETER - PORT(SECUREPORT VENOUS)-THE SECUREPORT VENOUS IS INDICATED TO BE IMPLANTED IN THE CENTRAL VENOUS SYSTEM FOR MID AND LONG-TERM USE, IN ORDER TO PERMIT REPEATED INFUSION OF THERAPEUTIC SOLUTIONS SUCH AS CHEMOTHERAPY, ANTIBIOTICS, NUTRIENTS, BLOOD PRODUCTS, AND IN THE ADDITION THE COLLECTION OF BLOOD SAMPLES.

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2088	IMP/MD/2020/000175	1.License Holder Name: M/S. CORTEX DENTAL IMPLANTS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT (CORTEX DENTAL IMPLANTS AND ABUTMENT)-CORTEX DENTAL IMPLANT SYSTEM IS INTENDED FOR USE IN PARTIALLY OR FULLY ENDENTULOUS MANDIBLES AND MAXILLAE,IN SUPPORT OF SINGLE OR MULTI-UNIT RESTORATIONS INCLUDING: CEMENT-RETAINED, SCREW-RETAINED,AND OVER DENTURE RESTORATIONS,AND TERMINAL OR INTERMEDIATE ABUTMENT SUPPORT FOR FIXED BRIDGEWORK.,DENTAL ABUTMENTS WITH SCREW AND CAPS(CORTEX DENTAL IMPLANTS AND ABUTMENT)-SURGEONS AND ALL PRACTITIONERS SHOULD BE FULLY TRAINED IN SUCH PROCEDURES AND BE COMPETENT IN SUCH IMPLANT PRACTICES. ALL PRACTITIONERS SHOULD ATTEND COURSES OF STUDY TO FAMILIARIZE THEMSELVES WITH IMPLANTOLOGY TECHNIQUES. IMPROPER TECHNIQUE CAN CAUSE BONE LOSS AND IMPLANT FAILURE. CORTEX DENTAL IMPLANT ABUTMENTS, OVERDENTURE BARS AND/OR FRAMEWORKS ARE INTENDED FOR USE AS AN ACCESSORY TO ENDOSSEOUS DENTAL IMPLANTS TO SUPPORT A PROSTHETIC DEVICE IN A PARTIALLY EDENTULOUS OR EDENTULOUS PATIENT. THESE ARE INTENDED FOR USE TO SUPPORT SINGLE- AND MULTIPLE-TOOTH PROSTHESES IN THE JAWS.

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2089	IMP/MD/2020/000177	1.License Holder Name: FRESENIUS KABI INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SYRINGE INFUSION PUMP (AGILIA)-THESE PUMPS ARE INTENDED FOR USE ON ADULTS, PAEDIATRICS, AND NEONATAL PATIENTS FOR THE INTERMITTENT OR CONTINUOUS DELIVERY OF PARENTERAL FLUIDS, MEDICATIONS, BLOOD AND BLOOD DERIVATIVES AND MEDICATIONS THROUGH CLINICALLY ACCEPTED ROUTES OF ADMINISTRATION.,INFUSION PUMP(AGILIA)-THE AGILIA VP LARGE VOLUME INFUSION PUMP IS A PERISTALTIC PUMP INTENDED FOR USE ON ADULTS, PEDIATRICS, AND NEONATAL PATIENTS FOR THE INTERMITTENT OR CONTINUOUS DELIVERY OF PARENTERAL FLUIDS, MEDICATIONS, BLOOD AND BLOOD DERIVATIVES, AND MEDICATIONS THROUGH CLINICALLY ACCEPTED ROUTES OF ADMINISTRATION. ,SYRINGE INFUSION PUMP (AGILIA)-THE AGILIA SP PCA SYRINGE PUMP IS PRIMARILY INTENDED FOR PCA THERAPY, FOR THE ADMINISTRATION OF ANALGESIC DRUGS UNDER THE PATIENT'S OR THE CLINICIAN'S CONTROL. THE AGILIA SP PCA SYRINGE PUMP CAN ALSO BE USED FOR GENERAL INFUSIONS ON ADULTS PAEDIATRICS, AND NEONATAL PATIENTS FOR THE INTERMITTENT OR CONTINUOUS DELIVERY OF PARENTERAL FLUIDS, MEDICATIONS, BLOOD AND BLOOD DERIVATIVES, AND MEDICATIONS THROUGH CLINICALLY ACCEPTED ROUTES OF ADMINISTRATION.

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2090	IMP/MD/2020/000178	1.License Holder Name: EUCARE PHARMACEUTICALS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SOFT-ADHERENT FOAM DRESSING WITH TLC-NOSF(URGOSTART MICRO-ADHESIVE)-URGOSTART MICRO-ADHESIVE IS INDICATED FOR THE TREATMENT OF NON-HEALING, OOZING WOUNDS AND ULCERS.,WOUND DRESSINGS(URGOCLEAN PAD)-URGOCLEAN PAD IS INDICATED FOR THE DESLOUGHING PHASE OF CHRONIC EXUDING WOUNDS (LEG ULCERS, PRESSURE ULCERS, DIABETIC FOOT ULCERS) AND POTENTIALLY SLOUGHY WOUNDS: ACUTE WOUNDS (BURNS, SKIN ABRASIONS, TRAUMATIC WOUNDS), POST-OPERATIVE WOUNDS, CANCEROUS WOUNDS.,FLEXIBLE LIPIDO-COLLOID CONTACT LAYER WITH TLC-NOSF(URGOSTART CONTACT)-URGOSTART CONTACT IS INDICATED FOR THE TREATMENT OF CHRONIC WOUNDS (LEG ULCERS, PRESSURE ULCERS, DIABETIC FOOT ULCERS) AND LONG STANDING ACUTE WOUNDS. FLEXIBLE AND VERY COMFORMABLE, URGOSTART CONTACT IS ESPECIALLY SUITABLE FOR LINING CAVITY OR AWKWARDLY PLACED WOUNDS AND FOR WICKING DEEP WOUNDS. DUE TO ITS NON-ADHESIVE NATURE, URGOSTART CONTACT IS RECOMMENDED IN THE TREATMENT OF WOUNDS IN WHICH THE SURROUNDING SKIN IS FRIABLE.,WOUND DRESSINGS (URGOTUL AG/SILVER)-URGOTUL AG/SILVER IS INDICATED FOR THE LOCAL TREATMENT OF WOUNDS AT RISK OR WITH SIGNS OF LOCAL INFECTION: CHRONIC WOUNDS (PRESSURE ULCERS AND LEG ULCERS) AND ACUTE WOUNDS (PARTIAL THICKNESS BURNS, DERMABRASIONS, TRAUMATIC WOUNDS, SURGICAL WOUNDS, ETC…). DUE TO THE NON-ADHESIVE NATURE OF THE DRESSING, URGOTUL AG/SILVER IS RECOMMENDED IN THE TREATMENT OF WOUNDS IN WHICH THE SKIN AROUND THE LESION IS WEAKENED.,ADHESIVE FOAM DRESSING WITH SOFT ADHERENT TLC-NOSF AND SILICONE BORDER(URGOSTART BORDER (SILICONE))-URGOSTART BORDER IS INDICATED FOR EXUDING CHRONIC WOUNDS (LEG ULCERS, PRESSURE ULCERS, DIABETIC FOOT ULCERS) AND LONG STANDING ACUTE WOUNDS. THE SACRUM VERSION IS RECOMMENDED FOR EXUDING CHRONIC WOUNDS LOCATED IN THE SACRAL AREA (SACRAL PRESSURE ULCERS).,WOUND DRESSINGS(URGOCLEAN AG)-URGOCLEAN AG IS INDICATED FOR THE LOCAL TREATMENT OF CHRONIC (LEG ULCERS, PRESSURE ULCERS, DIABETIC FOOT ULCERS) AND ACUTE (BURNS, TRAUMATIC WOUNDS, SURGICAL WOUNDS,) EXUDATIVE WOUNDS AT RISK OR WITH SIGNS OF LOCAL INFECTION, FROM THE DEBRIDEMENT STAGE.,WOUND DRESSINGS(URGOTUL ABSORB BORDER)-URGOTUL ABSORB BORDER IS INDICATED FOR EXUDING ACUTE WOUNDS (SUCH AS SECOND DEGREE BURNS,

		DERMABRASIONS, TRAUMATIC WOUNDS, POSTOPERATIVE WOUNDS...) AND CHRONIC WOUNDS (SUCH AS LEG ULCERS, PRESSURE ULCERS, DIABETIC FOOT ULCERS). THE SACRUM VERSION IS RECOMMENDED FOR EXUDING WOUNDS LOCATED IN THE SACRAL AREA (SACRAL PRESSURE ULCERS),WOUND DRESSINGS(URGOTUL)- URGOTUL IS INDICATED FOR THE MANAGEMENT OF: - ACUTE WOUNDS (BURNS, TRAUMATIC WOUNDS, ABRASIONS, POST-OPERATIVE WOUNDS) AND CHRONIC WOUNDS (LEG ULCERS, PRESSURE ULCERS AND DIABETIC FOOT ULCERS) AT THE GRANULATION AND EPITHELIALISATION STAGE. -EPIDERMOLYSIS BULLOSA (EB). FLEXIBLE AND VERY COMFORMABLE, URGOTUL IS ESPECIALLY SUITABLE FOR DIFFICULT TO DRESS OR AWKWARDLY PLACED WOUNDS AND FOR PACKING DEEP WOUNDS.
2091	IMP/MD/2020/000179	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IV CATHETERS(BD NEXIVA CLOSED IV CATHETER SYSTEM)-THE BD NEXIVA INTRAVASCULAR CATHETER IS INSERTED INTO A PATIENT'S VASCULAR SYSTEM FOR SHORT TERM (LESS THAN 30 DAYS) TO SAMPLE BLOOD, MONITOR BLOOD PRESSURE OR ADMINISTER FLUIDS INTRAVASCULARLY. THE NEEDLE SHIELDING FEATURE AND LUER ACCESS PORT AID IN THE PREVENTION OF NEEDLE STICK INJURIES. BLOOD IS CONTAINED WITHIN THE DEVICE DURING THE CATHETER INSERTION PROCESS ADDING IN THE PREVENTION OF BLOOD EXPOSURE. THIS CATHETER MAY BE USED FOR ANY PATIENT POPULATION WITH CONSIDERATION GIVEN TO ADEQUACY OF VASCULAR ANATOMY AND APPROPRIATENESS OF PROCEDURE. THE 18-22 GUAGE NEXIVA CATHETERS ARE SUITABLE FOR USE WITH POWER INJECTORS RATED FOR A MAXIMUM OF 300 PSI WHEN THE LUER ACCESS PORT(S) IS REMOVED AND A DIRECT CONNECTION IS MADE. ,INTRAVASCULAR ACCESS DEVICE (BD Q-SYTE)(BD Q-SYTE)-THE BD Q-SYTE™ LUER ACCESS SPLIT SEPTUM ARE INTENDED FOR USE AN ACCESSORY TO AN INTRAVASCULAR ADMINISTRATION SET THAT PERMITS INJECTION, GRAVITY FLOW, AND WITHDRAWAL OF FLUIDS., DISPOSABLE PERFUSION SET(BD Q-SYTE EXTENSION SETS)- EXTENSION SETS WITH AN ATTACHED BD Q-SYTE LUER ACCESS SPLIT SEPTUM ARE INTENDED TO BE USED WITH INTRAVASCULAR CATHETERS TO ASPIRATE BLOOD OR ADMINISTER FLUIDS, INCLUDING MEDICATIONS AND BLOOD OR BLOOD PRODUCTS. THESE DEVICES MAY BE USED WITH ANY PATIENT POPULATION WITH CONSIDERATION GIVEN TO THE PROCEDURE BEING PERFORMED AND FLUIDS BEING INFUSED

2092	IMP/MD/2020/000180	1.License Holder Name: DYNAMESH MEDICAL INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL MESHES MADE UP OF POLYVINYLIDENE FLUORIDE (PVDF)(DYNAMESH®)-1. EXTRAPERITONEAL HERNIA MESHES FOR ABDOMINAL HERNIA REPAIR 2. MESH FOR REPAIR OF INGUINAL HERNIAS ACCORDING TO LICHTENSTEIN 3. MESH FOR REPAIR OF INGUINAL HERNIAS 4. PROLAPSE REPAIR MESH SOFT 5. MALE INCONTINENCE MESH 6. FEMALE URINARY STRESS INCONTINENCE SLING 7. FEMALE URGE & MIXED URINARY INCONTINENCE MESH,SURGICAL MESHES MADE UP OF POLYVINYLIDENE FLUORIDE (PVDF) AND POLYPROPYLENE (DYNAMESH®)-1. INTRAPERITONEAL ONLAY MESH FOR ABDOMINAL HERNIA AND STOMA SURGERY.
2093	IMP/MD/2020/000181	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LARYNGEAL MASK AIRWAY(LMA FASTRACH™)-1. THE LMA FASTRACH IS INDICATED FOR USE AS A GUIDE FOR INTUBATION OF THE TRACHEA. 2. THE LMA FASTRACH IS INDICATED FOR ACHIEVING AND MAINTAINING CONTROL OF THE AIRWAY DURING ROUTINE AND EMERGENCY SITUATIONS, INCLUDING ANTICIPATED OR UNEXPECTED DIFFICULT AIRWAYS. 3. THE LMA FASTRACH IS INDICATED AS A METHOD OF ESTABLISHING AN AIRWAY IN THE PROFOUNDLY UNCONSCIOUS PATIENT WITH ABSENT GLOSSOPHARYNGEAL AND LARYNGEAL REFLEXES.,LARYNGEAL MASK AIRWAY(LMA FASTRACH™ ETT)-THE LMA FASTRACH™ ETT IS INDICATED FOR TRACHEAL INTUBATION THROUGH THE LMA FASTRACH™ OR FOR CONVENTIONAL INTUBATION OF THE TRACHEA USING DIRECT OR INDIRECT LARYNGOSCOPY.
2094	IMP/MD/2020/000182	1.License Holder Name: CORAL HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONDOMS(NA)-IS IS USED AS A BARRIER CONTRACEPTIVE FOR PREVENTION OF PREGNANCY & PREVENTION OF SEXUALLY TRANSMITTED DISEASE.

2095	IMP/MD/2020/000183	1.License Holder Name: BIOCON BIOLOGICS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:POLYMER BASED ADSORBENT CYTOSORB 300 ML DEVICE (CYTOSORB ®)-CYTOSORB 300 ML DEVICE IS INDICATED FOR USE IN CONDITIONS WHERE LEVELS OF CYTOKINES AND/OR BILIRUBIN AND/OR MYOGLOBIN ARE ELEVATED. ALSO INDICATED FOR REMOVAL OF P2Y12 INHIBITOR-TICAGRELOR INTRAOPERATIVELY DURING CARDIO PULMONARY BYPASS. TO TREAT PATIENTS 18 YEARS OF AGE OR OLDER WITH CONFIRMED COVID-19 ADMITTED TO THE ICU WITH CONFIRMED OR IMMINENT RESPIRATORY FAILURE BY REDUCING PROINFLAMMATORY CYTOKINE LEVELS, WHICH MAY AMELIORATE A CYTOKINE STORM DUE TO THE OVERABUNDANCE OF PRO-INFLAMMATORY CYTOKINES AND, IN TURN, PROVIDE CLINICAL BENEFIT TO SUCH PATIENTS.

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2096	IMP/MD/2020/000184	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CERVICAL INTERBODY FUSION SYSTEM(ROI-C - IMPLANT)-THE ROI-C® AND ROI-C® COATED IMPLANTS ARE INDICATED IN SKELETALLY MATURE PATIENTS TO PERFORM A CERVICAL ARTHRODESIS (LIMITED TO THREE LEVELS), IN THE CONTEXT OF DISK(S) TREATMENT: BETWEEN C2 AND T1 VERTEBRA WITH INTRACTABLE SYMPTOMATIC CERVICAL DISC DISEASE (SCDD), DEFINED AS RADICULOPATHY AND/OR MYELORADICULOPATHY (NECK PAIN, ARM PAIN, AND/OR A FUNCTIONAL NEUROLOGICAL DEFICIT IN A SPECIFIC NERVE ROOT SITUATED BETWEEN C2 AND T1 VERTEBRA), AND REFRACTORY TO NON-OPERATIVE TREATMENT CONDUCTED DURING AT LEAST SIX WEEKS. WITH AT LEAST ONE OF THE FOLLOWING CONDITIONS CONFIRMED BY IMAGING (CT, MRI, OR X-RAYS): - HERNIATED NUCLEUS PULPOSUS, - DISCARTHROSIS THE ROI-C® AND ROI-C® COATED IMPLANT ARE IMPLANTED VIA AN OPEN ANTERIOR APPROACH FOLLOWING PARTIAL DISCECTOMY. FOLLOWING THE IMPLANTATION OF THE ROI-C® CAGE OR AND ROI-C® COATED IMPLANT, AND IN ORDER TO ENSURE ITS STABILITY IN THE INTERVERTEBRAL SPACE, THE ROI-C® AND ROI-C® COATED CAGES HAVE TO BE USED WITH ITS ROI-C® ANCHORING PLATE SO AS TO FIX THE CAGE ON THE TWO PROXIMAL VERTEBRAL PLATES.,CERVICAL INTERBODY FUSION SYSTEM(ROI-C - PLATES)-THE ROI-C® AND ROI-C® COATED IMPLANTS ARE INDICATED IN SKELETALLY MATURE PATIENTS TO PERFORM A CERVICAL ARTHRODESIS (LIMITED TO THREE LEVELS), IN THE CONTEXT OF DISK(S) TREATMENT: BETWEEN C2 AND T1 VERTEBRA WITH INTRACTABLE SYMPTOMATIC CERVICAL DISC DISEASE (SCDD), DEFINED AS RADICULOPATHY AND/OR MYELORADICULOPATHY (NECK PAIN, ARM PAIN, AND/OR A FUNCTIONAL NEUROLOGICAL DEFICIT IN A SPECIFIC NERVE ROOT SITUATED BETWEEN C2 AND T1 VERTEBRA), AND REFRACTORY TO NON-OPERATIVE TREATMENT CONDUCTED DURING AT LEAST SIX WEEKS. WITH AT LEAST ONE OF THE FOLLOWING CONDITIONS CONFIRMED BY IMAGING (CT, MRI, OR X-RAYS): - HERNIATED NUCLEUS PULPOSUS, - DISCARTHROSIS THE ROI-C® AND ROI-C® COATED IMPLANT ARE IMPLANTED VIA AN OPEN ANTERIOR APPROACH FOLLOWING PARTIAL DISCECTOMY. FOLLOWING THE IMPLANTATION OF THE ROI-C® CAGE OR AND ROI-C® COATED IMPLANT, AND IN ORDER TO ENSURE ITS STABILITY IN THE INTERVERTEBRAL SPACE, THE ROI-C® AND ROI-C® COATED CAGES HAVE TO BE USED WITH ITS ROI-C® ANCHORING PLATE SO AS TO FIX THE CAGE ON THE TWO PROXIMAL VERTEBRAL PLATES., CERVICAL TOTAL DISC REPLACEMENT PROSTHESIS(MOBI-C

		PLUG&FIT)-THE MOBI-C® CERVICAL DISC PROSTHESIS IS INDICATED IN SKELETALLY MATURE PATIENTS FOR RECONSTRUCTION OF ONE OR TWO DEGENERATED DISC(S): FROM C3 TO C7 WITH INTRACTABLE SYMPTOMATIC CERVICAL DISC DISEASE (SCDD), DEFINED AS RADICULOPATHY AND/OR MYELORADICULOPATHY (NECK PAIN, ARM PAIN, AND/OR A FUNCTIONAL NEUROLOGICAL DEFICIT IN A SPECIFIC NERVE ROOT C3-C7), AND REFRACTORY TO NON-OPERATIVE TREATMENT CONDUCTED DURING AT LEAST SIX WEEKS. WITH AT LEAST ONE OF THE FOLLOWING CONDITIONS CONFIRMED BY IMAGING (CT, MRI, OR X-RAYS): - HERNIATED NUCLEUS PULPOSUS, - DISCARTHROSIS: WITH/WITHOUT FORAMINAL OR CENTRAL OSTEOPHYTOSIS WITH/WITHOUT LOSS OF MOBILITY WITH/WITHOUT KYPHOTIC EVOLUTION (NON STRUCTURAL) WITH/WITHOUT LOSS OF DISC HEIGHT IN COMPARISON TO ADJACENT DISCS. THE MOBI-C® IS IMPLANTED VIA AN OPEN ANTERIOR APPROACH FOLLOWING COMPLETE DISCECTOMY.
2097	IMP/MD/2020/000185	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STEERABLE GUIDE CATHETER(STEERABLE GUIDE CATHETER)-THE MITRACLIP SYSTEM IS INTENDED FOR RECONSTRUCTION OF THE INSUFFICIENT MITRAL VALVE THROUGH TISSUE APPROXIMATION.,CLIP DELIVERY SYSTEM (MITRACLIP XTR CLIP DELIVERY SYSTEM)-THE MITRACLIP SYSTEM IS INTENDED FOR RECONSTRUCTION OF THE INSUFFICIENT MITRAL VALVE THROUGH TISSUE APPROXIMATION,CLIP DELIVERY SYSTEM (MITRACLIP NTR CLIP DELIVERY SYSTEM)-THE MITRACLIP SYSTEM IS INTENDED FOR RECONSTRUCTION OF THE INSUFFICIENT MITRAL VALVE THROUGH TISSUE APPROXIMATION.

2098	IMP/MD/2020/000186	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TEMPORARY ANCHORAGE SYSTEM(VECTOR TAS)-VECTOR TEMPORARY ANCHORAGE SYSTEM IS INTENDED TO PROVIDE A TEMPORARY FIXED ANCHORAGE POINT FOR ATTACHMENT OF ORTHODONTIC APPLIANCES THAT FACILITATES ORTHODONTICS MOVEMENT OF TEETH. THESE SCREWS ARE TEMPORARY AND ARE REMOVED AFTER THE DESIRED MOVEMENT IS ACHIEVED. THESE SCREWS WERE DESIGNED TO BE USED ON THE FOLLOWING TYPES OF CASES: • INTRUSION OR EXTRUSION OF INDIVIDUAL TEETH OR SEGMENTS OF AN ARCH. • PATIENTS IN WHICH PERIODONTAL DISEASE HAS COMPROMISED. • PATIENTS WHERE THERE IS A NEED FOR ABSOLUTE ANCHORAGE, I.E. ONLY THE ACTIVE UNIT SHOULD BE DISPLACED THE REACTIVE UNIT SHOULD REMAIN UNALTERED. • PATIENTS IN WHICH ALL TEETH SHOULD BE DISPLACED IN THE SAME DIRECTION. • PATIENTS WITH AGENESIS OF ONE OR MORE TEETH WHO NEED THE SPACE CLOSURE FROM ONE SIDE ONLY. • PATIENTS WITH NEED FOR THE CORRECTION OF ASYMMETRIES. THE MINI SCREWS CAN BE UTILIZED ON PATIENTS OVER THE AGE OF 13. CAUTION SHOULD BE USED WHEN PERMANENT TEETH HAVE NOT FULLY ERUPTED, AS NOT TO DAMAGE THE UNERUPTED TOOTH. AN UPPER AGE LIMIT DOES NOT EXIST, BUT THE CORTICAL. THICKNESS SHOULD BE SUFFICIENT FOR PRIMARY STABILITY. THE MINI-SCREWS WERE ORIGINALLY DEVELOPED FOR ADULTS IN WHOM INSUFFICIENT TEETH WERE AVAILABLE FOR CONVENTIONAL ANCHORAGE. THE INDICATIONS. HAVE, HOWEVER, WIDENED AND COMPRISE ALSO INDIVIDUALS WHERE THE REACTIVE FORCES FROM CONVENTIONAL ORTHODONTIC APPLIANCES WOULD GENERATE AN ADVERSE EFFECT ON THE ANCHORAGE UNIT. THE SKELETAL ANCHORAGE CAN THUS BE RECOMMENDED IN THE TREATMENT OF YOUNG PATIENTS WITH AGENESIS OF PERMANENT TEETH IN WHICH THE POSTERIOR TEETH ARE TO BE DISPLACED FORWARD WITHOUT GENERATING DISTALLY DIRECTED FORCES ON THE ANTERIOR UNIT . THIS CAN BE DONE FROM THE AGE WHERE THE PERMANENT TEETH TO BE DISPLACED ARE ERUPTED LASTLY THESE SCREWS ARE INTENDED FOR SINGLE USE ONLY.,ORTHODONTIC WIRE (NICKEL TITANIUM)(NITI ARCHWIRE, DAMON ARCHWIRE, TRU-ARCH ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH, ORTHODONTIC WIRE (COPPER NICKEL TITANIUM)(DAMON ARCHWIRE , COPPER NI-TI ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH, ORTHODONTIC WIRE (BETA TITANIUM)(TMA ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT

		MALOCCLUDED TEETH,ORTHODONTIC WIRE (STAINLESS STEEL) (DAMON ARCHWIRE, RESPOND ARCHWIRE, STAINLESS STEEL ARCHWIRE , TRIPLEFLEX ARCHWIRE, TRU-ARCH ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH.
2099	IMP/MD/2020/000187	1.License Holder Name: TECHNOMEDIC 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EMBOLECTOMY CATHETER(ARTERIAL EMBOLECTOMY CATHETER)-THE DEVICE IS INTENDED FOR INTRA-OPERATIVE REMOVAL OF ARTERIAL EMBOLI FROM ARTERIES

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2100	IMP/MD/2020/000188	1.License Holder Name: VASCULAR CONCEPTS LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DELIVERY SYSTEM (COCOON SEPTAL (STERILE), COCOON DUCT (STERILE), COCOON DELIVERY CABLE (STERILE))-IT IS INTENDED FOR PLACEMENT AND IF NECESSARY RETRIEVAL OF THE DEVICE.,SEPTAL OCCLUDER (COCOON SEPTAL OCCLUDER (STERILE))-THE COCOON SEPTAL OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER, ATRIAL SEPTAL DEFECT (ASD) CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF SECUNDUM TYPE ASD.,DUCT OCCLUDER(COCOON DUCT OCCLUDER (STERILE))-THE COCOON DUCT OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER DEVICE SPECIALLY DESIGNED FOR CLOSURE OF NORMALLY LOCATED PATENT DUCTUS ARTERIOSUS WITH THE NARROWEST DIAMETER RANGING FROM 2MM TO 16MM. TREATMENT IS ALSO FEASIBLE IN PEDIATRIC POPULATION.,OCCLUDER(COCOON PFO OCCLUDER (STERILE))-THE COCOON PFO OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF NORMAL AND ANEURYSM TYPE PFOS, IN PATIENTS WITH A HISTORY OF STROKE OR TRANSIENT ISCHEMIC ATTACK, AS DIAGNOSED BY ECHO-CARDIOGRAPHY WITH RIGHT-TO-LEFT SHUNTING DURING VALSALVA MANEUVER.,OCCLUDER (COCOON VSD OCCLUDER (STERILE))-THE COCOON VSD OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER VENTRICULAR SEPTAL DEFECT (VSD) CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF HEMODYNAMICALLY SIGNIFICANT VENTRICULAR SEPTAL DEFECTS., SIZING BALLOON(COCOON SIZING BALLOON (STERILE))-IT IS INTENDED FOR SIZING ATRIAL COMMUNICATION I.E TO MEASURE SIZE OF THE SEPTAL DEFECT.,DELIVERY SYSTEM(COCOON VSD-DELIVERY SYSTEM- COCOON VSD OCCLUDER ACCESSORY SET (STERILE), COCOON VSD- DELIVERY SYSTEM- DELIVERY CABLE INCLUDING CABLE SHEATH (STERILE))-IT IS INTENDED FOR PLACEMENT AND IF NECESSARY RETRIEVAL OF THE DEVICE. INDIVIDUAL FUNCTIONS : 1. A DELIVERY SHEATH WITH HEMOSTASIS VALVE ADAPTER USED TO DELIVER THE DEVICE, 2. A DILATOR USED TO EASE PENETRATION OF TISSUES, 3. A LOADER USED TO INTRODUCE THE DEVICE INTO THE DELIVERY SHEATH, 4. A DELIVERY CABLE WITH A SUPPORTING SHEATH, ON WHICH THE OCCLUDER IS SCREWED AT ITS DISTAL TIP, THAT ALLOWS FOR PLACEMENT AND RETRIEVAL OF THE DEVICE.,DELIVERY SYSTEM(COCOON PFO-DELIVERY SYSTEM- COCOON PFO- OCCLUDER ACCESSORY SET (STERILE) , COCOON PFO- DELIVERY SYSTEM- DELIVERY CABLE (STERILE))-IT IS INTENDED FOR PLACEMENT AND IF NECESSARY RETRIEVAL OF THE DEVICE. INDIVIDUAL FUNCTIONS : 1. A DELIVERY SHEATH WITH HEMOSTASIS VALVE ADAPTER USED TO DELIVER THE

		DEVICE. 2. A DILATOR USED TO EASE PENETRATION OF TISSUE. 3. A LOADER USED TO INTRODUCE THE DEVICE INTO THE DELIVERY SHEATH 4. A DELIVERY CABLE ON WHICH THE DEVICE IS SCREWED AND WHICH ALLOWS FOR PLACEMENT AND RETRIEVAL OF THE DEVICE.
2101	IMP/MD/2020/000189	1.License Holder Name: CYTOCARE TECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COMPONENT BAG (CRYOMACS FREEZING BAG)-THE CRYOMACSFREEZING BAG ARE INTENDED FOR SINGLE CYCLE OF FREEZING, STORAGE (DOWN TO -196 DEGREE CELSIUS) AND SUBSEQUENT THAWING (AT +37 DEGREE CELSIUS) OF HEMATOPOIETIC PROGENITOR CELLS. THE CRYOMACS FREEZING BAG ARE DESIGNED FOR SINGLE USE ONLY.

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2102	IMP/MD/2020/000190	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:WIRE IMPLANTS – K-WIRE (NA)-"WIRE IMPLANTS ARE INTENDED FOR FIXATION OF BONE FRAGMENTS. THE INTERNAL MIDFACE DISTRACTOR, THE MAXILLARY DISTRACTOR, THE SINGLE VECTOR DISTRACTOR, THE EXTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. THE CRANIOMAXILLOFACIAL (CMF) DISTRACTOR AND SYNTHES MULTI-VECTOR DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING (AND/OR TRANSPORT) DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. UNIVERSAL SCREW REMOVAL SET IS INTENDED TO BE USED FOR THE REMOVAL OF INTACT AND DAMAGED SCREWS. IT IS NOT INTENDED TO BE USED IN COMBINATION WITH A POWER TOOL.",WIRES (POWER DRIVEN)(NA)-"THE WIRE INSTRUMENTS ARE INTENDED FOR PROVISIONAL FRACTURE FIXATION AND SHORT TERM INSERTION INTO BONE IN ORDER TO FACILITATE AND GUIDE IMPLANT OR INSTRUMENT APPLICATION DURING ORTHOPEDIC SURGERY.", COMPACTMANDIBLE (COMPACT 2.0, COMPACT 2.0 LOCK MANDIBLE, COMPACT 2.4 TRAUMA, COMPACT 2.4 UNILOCK, AND COMPACT 2.4 UNILOCK WITH CONDYLAR HEAD) - SCREW(NA)-THE SYNTHES COMPACT 2.0 AND COMPACT 2.4 TRAUMA PLATES AND SCREWS SYSTEM MANDIBLE IS INTENDED FOR ORAL, MAXILLOFACIAL SURGERY, TRAUMA, RECONSTRUCTIVE SURGERY, AND ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES).,MAXILLARY DISTRACTOR - SCREW(NA) -THE MAXILLARY DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED.,WIRES (POWER DRIVEN) - GUIDE WIRE (NA)-WIRE IMPLANTS ARE INTENDED FOR FIXATION OF BONE FRAGMENTS.,GUIDE WIRES FOR SPINE- GUIDE WIRE(NA)-"GUIDE WIRES FOR SPINE ARE INTENDED TO GUIDE POSITIONING OF CANNULATED INSTRUMENTS, IMPLANTATION OF CANNULATED SPINAL IMPLANTS OR REMOVAL OF SPINAL IMPLANTS.",DYNAMIC HIP PLATING IMPLANTS - SCREW (NON STERILE- TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DYNAMIC HIP PLATING IMPLANTS - SCREW (NON STERILE- SST)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., DYNAMIC HIP PLATING IMPLANTS - SCREW (STERILE- TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY

		FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,WIRE IMPLANTS – K-WIRE (NON STERILE-SST)(NA)-WIRE IMPLANTS ARE INTENDED FOR FIXATION OF BONE FRAGMENTS.,RECON FEMORAL NAILING IMPLANTS - SCREW(NA)-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",SCREW IMPLANTS FOR OR WITHOUT PLATES - SCREW(NA)-"THE INTERNAL MIDFACE DISTRACTOR, THE MAXILLARY DISTRACTOR, THE SINGLE VECTOR DISTRACTOR, THE EXTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. THE CRANIOMAXILLOFACIAL (CMF) DISTRACTOR AND SYNTHES MULTI-VECTOR DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING (AND/OR TRANSPORT) DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. UNIVERSAL SCREW REMOVAL SET IS INTENDED TO BE USED FOR THE REMOVAL OF INTACT AND DAMAGED SCREWS. IT IS NOT INTENDED TO BE USED IN COMBINATION WITH A POWER TOOL.",WIRE IMPLANTS - K-WIRE (TAV)(NA)-WIRE IMPLANTS ARE INTENDED FOR FIXATION OF BONE FRAGMENTS.,SCREW IMPLANTS FOR OR WITHOUT PLATES - SCREW (TAN)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,WIRE IMPLANTS – K-WIRE (STERILE-SST)(NA)-WIRE IMPLANTS ARE INTENDED FOR FIXATION OF BONE FRAGMENTS.,SCREW IMPLANTS FOR OR WITHOUT PLATES - SCREW (NON STERILE)(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.
2103	IMP/MD/2020/000191	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHOPEDIC TROCAR (RIGIDFIX)-DEPUY MITEK REUSABLE SURGICAL INSTRUMENTS ARE INTENDED TO BE USED FOR GENERAL SURGICAL USE OR IMPLANT INSERTION DURING ORTHOPEDIC PROCEDURES.

2104	IMP/MD/2020/000192	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAPLER(ECHELON CIRCULAR)-THE ECHELON CIRCULAR POWERED STAPLERS HAVE APPLICATION THROUGHOUT THE ALIMENTARY TRACT FOR END-TO-END, END-TO-SIDE, AND SIDE-TO-SIDE ANASTOMOSES.
2105	IMP/MD/2020/000193	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE CATHETER FOR ELECTROSURGERY(WEM)-THE WEM DISPOSABLE CATHETER FOR ELECTROSURGERY IS RECOMMENDED FOR COAGULATION DURING LAPAROSCOPIC AND ENDOSCOPES PROCEDURES, REDUCING BLEEDING WHILE MAINTAINING A CLEANER SURGICAL SITE AND PROVIDING BETTER VISIBILITY. ITS PURPOSE IS TO DIRECT THE FLOW OF ARGON GAS USED DURING SURGICAL PROCEDURES TOWARDS THE AREA TO BE COAGULATED.
2106	IMP/MD/2020/000194	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERITONEAL DIALYSIS CATHETER ADAPTOR(LOCKING TITANIUM ADAPTER FOR PERITONEAL DIALYSIS CATHETER)-THIS ADAPTER IS A DOUBLE SEALING FEMALE LUER LOCK ADAPTER WITH A 2-PIECE, COMBINATION COMPRESSION FIT/BARBED CATHETER CONNECTOR. THE ADAPTER IS USED TO CONNECT THE PD CATHETER TO A SOLUTION TRANSFER SET WITH LOCKING CONNECTOR.
2107	IMP/MD/2020/000195	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MESH(PROLENE (POLYPROPYLENE) HERNIA SYSTEM)-THE PROLENE HERNIA SYSTEM IS INDICATED FOR THE REPAIR OF INGUINAL (DIRECT & INDIRECT) AND ABDOMINAL WALL HERNIA DEFECTS.
2108	IMP/MD/2020/000196	1.License Holder Name: ESSITY INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BACTERIA-BINDING SURGICAL DRESSING(LEUKOMED® SORBACT®)-LEUKOMED® SORBACT® CAN BE USED FOR ALL TYPES OF POST-OPERATIVE AND TRAUMATIC WOUNDS WITH UP TO AND INCLUDING MODERATE LEVELS OF EXUDATE SUCH AS: - SURGICAL INCISIONS - LACERATIONS, CUTS AND ABRASIONS - DEHISCED WOUNDS

2109	IMP/MD/2020/000198	1.License Holder Name: HAITECH MEDICAL SOLUTIONS PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL BONE GRAFTING MATERIAL(OSSIX™ BONE)-OSSIX BONE IS A STERILE, BIOCOMPATIBLE BONE GRAFTING MATERIAL INTENDED TO FILL, AUGUMENT, OR RECONSTRUCT PERIODONTAL AND BONY DEFECTS OF THE MAXILLO-FACIAL COMPLEX.
2110	IMP/MD/2020/000199	1.License Holder Name: BAIHE MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HEMOPERFUSION CARTRIDGE(BIOSKY)-DISPOSABLE HEMOPERFUSION CARTRIDGE IS OF RELATIVELY SPECIFIC RECOGNITION AND ADSORPTION CAPACITY TO THE MACROMOLECULAR UREMIC TOXINS RESULTING FROM LONG TERM HEMODIALYSIS AND HEMOFILTRATION IN BLOOD OF END STAGE RENAL DISEASE (ESRD) PATIENTS.

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2111	IMP/MD/2020/000200	1.License Holder Name: VASCULAR CONCEPTS LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERIPHERAL STENT SYSTEM- SELF EXPANDABLE NITINOL STENT (NON-STERILE) (RESISTANT- SELF EXPANDABLE NITINOL STENT (NON-STERILE))-IT IS INDICATED FOR THE FOLLOWING APPLICATIONS- • ATHEROSCLEROTIC DISEASE OF THE PERIPHERAL ARTERIES, EG ILIAC, FEMORALIS AND FEMORALIS SUPERFICIALIS AND IN OTHER VESSELS WHICH CORRESPOND IN THEIR ANATOMIC DIMENSIONS TO THE AVAILABLE SIZES OF THE STENTS. • TREATMENT OF BILE DUCT STRICTURES. ,CORONARY STENT - AORTIC STENT-SELF EXPANDABLE NITINOL STENT (STERILE)(MC-A AORTIC STENT- SELF EXPANDABLE NITINOL STENT (STERILE))-THE MC-A IS INDICATED FOR THE TREATMENT OF DISSECTIONS, STENOSES AND OTHER SPECIFIC LESIONS OF THE THORACIC DESCENDING AORTA, THE ABDOMINAL AORTA AS WELL AS FOR TREATMENT OF VENA-CAVA SYNDROME. IN ANY CASE THE ANATOMICAL DIMENSIONS MUST MATCH THE AVAILABLE STENT SIZES. FOR THIS REASON ITS APPLICATION IS RESTRICTED TO ADULTS ONLY. INDICATIONS FOR THE USAGE OF THE MC-A CAN BE REGARDED AS EXISTENT IN THE FOLLOWING CASES: -DISSECTIONS (AORTAL TYPE B AND IN THE AREA OF THE KIDNEYS OR VISCERAL ARTERIES) -AORTIC COARCTATIONS -ARTERIOSCLEROTIC AORTIC STENOSES -INSUFFICIENT ANGIOPLASTY RESULTS -ELASTIC STENOSES FROM BYPASS ANASTOMOSES -ENDOLEAKS OF TYPE 1A AND 1B (STABILISATION OF STENT GRAFTS THAT ARE EITHER DISPLAYING SIGNS OF WRINKLING OR BY WHICH, DUE TO INSUFFICIENT HOLD, THERE IS A DANGER OF STENT MIGRATION). -OBSTRUCTIONS OR UPPER AND LOWER INFLOW CONGESTION OF THE VENA CAVA DUE TO MALIGNANT OR BENIGN CAUSES (TUMOUR TREATMENT) PLACES OF INDICATION: -IN THE AORTA ABDOMINALIS, IN THE STRAIGHT AREA OF THE AORTA THORACALIS DESCENDANTS AS WELL AS IN THE AORTIC ARCH DISTAL TO THE EXIT OF THE LEFT ARTERIA SUBCLAVIA -IN THE VENA-CAVA IN CASE OF UPPER AND LOWER VENOUS CONGESTION.
2112	IMP/MD/2020/000202	1.License Holder Name: M/S NOVO NORDISK INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC SYRINGES(NOVOPEN 4)-USED FOR SUBCUTANEOUS ADMINISTRATION OF INSULIN FOR TREATMENT OF INDIVIDUALS WITH DIABETES MELLITUS.

2113	IMP/MD/2020/000203	1.License Holder Name: GLOBE BIO MEDICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OCCLUDER SYSTEM (CARDI-O-FIX)-CHD
2114	IMP/MD/2020/000204	1.License Holder Name: M/S PURE MEDITECH SOLUTION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROWAVE ABLATION ANTENNAS-THE MICROWAVE ABLATION ANTENNAS, IN CONJUNCTION WITH THE COMPATIBLE MICROWAVE ABLATION SYSTEM (KY-2000A) IS INDICATED FOR USE IN PERCUTANEOUS, LAPAROSCOPIC, AND INTRAOPERATIVE COAGULATION (ABLATION) OF SOFT TISSUE. THE MICROWAVE ABLATION SYSTEM IS NOT INTENDED FOR USE IN CARDIAC PROCEDURES.

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2115	IMP/MD/2020/000205	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAPLER RELOAD (VALUTRUS LINEAR CUTTER STAPLER)(VALUTRUS)-THE VALUTRUS™ LINEAR CUTTER STAPLER WITH SAFETY LOCK-OUT HAS APPLICATION IN GASTROINTESTINAL, GYNECOLOGIC, THORACIC, AND PEDIATRIC SURGERY FOR TRANSECTION, RESECTION, AND THE CREATION OF ANASTOMOSES AND CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIALS.,LINEAR CUTTER RELOAD (ECHELON60 ENDOPATH STAPLER ENDOSCOPIC LINEAR CUTTER RELOADS - 3 YEARS)(ECHELON ENDOPATH)-THE ECHELON 60 ENDOSCOPIC LINEAR CUTTER – STRAIGHT, COMPACT ECHELON 60 ENDOSCOPIC LINEAR CUTTER – STRAIGHT, AND THE LONG ECHELON 60 ENDOSCOPIC LINEAR CUTTER – STRAIGHT ARE INTENDED FOR TRANSECTION, RESECTION, AND/OR CREATION OF ANASTOMOSES. THE INSTRUMENTS HAVE APPLICATION IN MULTIPLE OPEN OR MINIMALLY INVASIVE GENERAL, GYNECOLOGIC, UROLOGIC, THORACIC, AND PEDIATRIC SURGICAL PROCEDURES. THEY CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIALS. THE INSTRUMENTS MAY ALSO BE USED FOR TRANSECTION AND RESECTION OF LIVER PARENCHYMA (HEPATIC VASCULATURE AND BILIARY STRUCTURES), PANCREAS, KIDNEY AND SPLEEN.,LINEAR CUTTER AND RELOAD (PROXIMATE LINEAR CUTTER AND RELOADS) (PROXIMATE)-THE PROXIMATE LINEAR CUTTER WITH SAFETY LOCK-OUT HAS APPLICATION IN GASTROINTESTINAL, GYNECOLOGIC, THORACIC, AND PEDIATRIC SURGERY FOR TRANSECTION, RESECTION, AND/OR CREATION OF ANASTOMOSES AND CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIALS, SUCH AS BOVINE PERICARDIUM.,LINEAR CUTTER RELOAD (ECHELON60 ENDOPATH STAPLER ENDOSCOPIC LINEAR CUTTER RELOADS) (ECHELON ENDOPATH)-THE ECHELON 60 ENDOSCOPIC LINEAR CUTTER – STRAIGHT, COMPACT ECHELON 60 ENDOSCOPIC LINEAR CUTTER – STRAIGHT, AND THE LONG ECHELON 60 ENDOSCOPIC LINEAR CUTTER – STRAIGHT ARE INTENDED FOR TRANSECTION, RESECTION, AND/OR CREATION OF ANASTOMOSES. THE INSTRUMENTS HAVE APPLICATION IN MULTIPLE OPEN OR MINIMALLY INVASIVE GENERAL, GYNECOLOGIC, UROLOGIC, THORACIC, AND PEDIATRIC SURGICAL PROCEDURES. THEY CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIALS. THE INSTRUMENTS MAY ALSO BE USED FOR TRANSECTION AND RESECTION OF LIVER PARENCHYMA (HEPATIC VASCULATURE AND BILIARY STRUCTURES), PANCREAS, KIDNEY AND SPLEEN.,STAPLER AND RELOAD (CONTOUR CURVED CUTTER STAPLER AND RELOAD) (CONTOUR)-THE CONTOUR CURVED CUTTER STAPLER IS INTENDED

	FOR TRANSECTION, RESECTION, AND/OR CREATION OF ANASTOMOSES. THE INSTRUMENT HAS APPLICATION IN MULTIPLE OPEN OR MINIMALLY INVASIVE GENERAL (GASTROINTESTINAL AND SKELETAL MUSCLE), GYNECOLOGIC, UROLOGIC, AND THORACIC SURGICAL PROCEDURES,LINEAR CUTTER RELOAD (ECHELON45 ENDOPATH STAPLER ENDOSCOPIC LINEAR CUTTER RELOADS) (ECHELON ENDOPATH)-THE ECHELON 45 ENDOSCOPIC LINEAR CUTTER – STRAIGHT, COMPACT ECHELON 45 ENDOSCOPIC LINEAR CUTTER – STRAIGHT, AND LONG ECHELON 45 ENDOSCOPIC LINEAR CUTTER – STRAIGHT ARE INTENDED FOR TRANSECTION, RESECTION, AND/OR CREATION OF ANASTOMOSES. THE INSTRUMENTS HAVE APPLICATION IN MULTIPLE OPEN OR MINIMALLY INVASIVE GENERAL, GYNECOLOGIC, UROLOGIC, THORACIC, AND PEDIATRIC SURGICAL PROCEDURES. THEY CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIALS. THE INSTRUMENTS MAY ALSO BE USED FOR TRANSECTION AND RESECTION OF LIVER PARENCHYMA (HEPATIC VASCULATURE AND BILIARY STRUCTURES), PANCREAS, KIDNEY AND SPLEEN.,RELOAD (ENDOPATH ETS45 RELOADS) (ENDOPATH)-THE ENDOPATH ETS45 ENDOSCOPIC LINEAR CUTTERS, THE ETS-FLEX45 ENDOSCOPIC ARTICULATING LINEAR CUTTERS, AND THE ETS COMPACT-FLEX45 ARTICULATING LINEAR CUTTERS ARE INTENDED FOR TRANSECTION, RESECTION, AND/ OR CREATION OF ANASTOMOSES. THE INSTRUMENTS HAVE APPLICATION IN MULTIPLE OPEN OR MINIMALLY INVASIVE GENERAL, GYNECOLOGIC, UROLOGIC, THORACIC, AND PEDIATRIC SURGICAL PROCEDURES. THEY CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIALS. THE INSTRUMENTS MAY ALSO BE USED FOR TRANSECTION AND RESECTION OF LIVER PARENCHYMA (HEPATIC VASCULATURE AND BILIARY STRUCTURES), PANCREAS, KIDNEY AND SPLEEN. THE ENDOPATH ETS-FLEX45 NO-KNIFE ARTICULATING LINEAR STAPLERS AND THE ETS COMPACT-FLEX45 NO-KNIFE ARTICULATING LINEAR STAPLERS ARE INTENDED FOR TRANSECTION, RESECTION, AND/OR CREATION OF ANASTOMOSES. THE INSTRUMENTS HAVE APPLICATION IN MULTIPLE OPEN OR MINIMALLY INVASIVE GENERAL, GYNECOLOGIC, UROLOGIC, THORACIC, AND PEDIATRIC SURGICAL PROCEDURES. THEY CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIALS. THE INSTRUMENTS MAY ALSO BE USED FOR TRANSECTION AND RESECTION OF LIVER PARENCHYMA (HEPATIC VASCULATURE AND BILIARY STRUCTURES), PANCREAS, KIDNEY AND SPLEEN.,CLIPS (LIGACLIP)(LIGACLIP)-LIGACLIP EXTRA LIGATING CLIPS HAVE APPLICATION FOR USE ON TUBULAR STRUCTURES OR VESSELS WHEREVER METAL LIGATING CLIPS ARE INDICATED. THE TISSUE BEING LIGATED SHOULD BE CONSISTENT WITH THE SIZE OF THE CLIP.,LINEAR STAPLER AND RELOAD

	(PROXIMATE LINEAR & VASCULAR LINEAR STAPLER AND RELOADS)(PROXIMATE)-THE PROXIMATE® RELOADABLE LINEAR STAPLER HAS APPLICATION THROUGHOUT THE ALIMENTARY TRACT AND IN THORACIC SURGERY FOR TRANSECTION AND RESECTION OF INTERNAL TISSUES. THE PROXIMATE RELOADABLE VASCULAR LINEAR STAPLER HAS APPLICATION IN INTERNAL TISSUE WHICH CAN EASILY BE COMPRESSED TO 1 MM IN THICKNESS AND MAY ALSO BE USED TO LIGATE PULMONARY VESSELS.,STAPLER (INTRALUMINAL STAPLERS (ILS))(NA)-THE ETHICON ENDO-SURGERY CURVED INTRALUMINAL STAPLERS (ILS) HAVE APPLICATION THROUGHOUT THE ALIMENTARY TRACT FOR END-TO-END, END-TO-SIDE, AND SIDE-TO-SIDE ANASTOMOSES ,LINEAR CUTTER AND RELOAD (PROXIMATE LINEAR AND VASCULAR LINEAR CUTTERS AND RELOADS)(PROXIMATE)-THE PROXIMATE LINEAR AND VASCULAR LINEAR CUTTERS WITH SAFETY LOCK-OUT HAVE APPLICATION IN GASTROINTESTINAL, GYNECOLOGIC, THORACIC, AND PEDIATRIC SURGERY FOR TRANSECTION, RESECTION, AND THE CREATION OF ANASTOMOSES AND CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIALS, SUCH AS BOVINE PERICARDIUM.,STAPLER (ENDOSCOPIC CURVED INTRALUMINAL STAPLER (ILS))(NA)-THE ETHICON ENDO-SURGERY ENDOSCOPIC CURVED INTRALUMINAL STAPLER (ILS) HAS APPLICATION THROUGHOUT THE ALIMENTARY TRACT FOR END-TO-END, END-TO-SIDE, AND SIDE-TO-SIDE ANASTOMOSES.,STAPLER (PROXIMATE PPH HEMORRHOIDAL CIRCULAR STAPLER)(PROXIMATE)-THE PROXIMATE PPH HEMORRHOIDAL CIRCULAR STAPLER AND ACCESSORIES HAVE APPLICATION THROUGHOUT THE ANAL CANAL TO PERFORM SURGICAL TREATMENT OF HEMORRHOIDAL DISEASE,SKIN STAPLER (PROXIMATE SKIN STAPLERS)(PROXIMATE)-THE SKIN STAPLER HAS APPLICATION FOR ROUTINE SKIN CLOSURE IN A WIDE VARIETY OF SURGICAL PROCEDURES.,STAPLER (CONTOUR TRANSTAR CURVED CUTTER STAPLER)(CONTOUR TRANSTAR)-THE CONTOUR TRANSTAR CURVED CUTTER STAPLER AND ACCESSORIES HAVE APPLICATION FOR GENERAL SURGICAL TREATMENT OF ANORECTAL WALL DEFECTS BY MEANS OF TRANSANAL STAPLING AND RESECTION OF MUCOSAL AND MUSCULOMUCOSAL TISSUE.,LINEAR CUTTER RELOAD (LINEAR CUTTER RELOAD)(NA)-THE LINEAR CUTTER 55/75 MM AND SELECTABLE CARTRIDGE HAS APPLICATION IN GASTROINTESTINAL, GYNECOLOGIC, THORACIC, AND PEDIATRIC SURGERY FOR TRANSECTION, RESECTION, AND THE CREATION OF ANASTOMOSES AND CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIALS.,LINEAR CUTTER RELOAD (ENDOSCOPIC LINEAR CUTTER RELOADS WITH GRIPPING SURFACE TECHNOLOGY)(ECHELON ENDOPATH)-THE ECHELON, ECHELON ENDOPATH™ AND ECHELON

		FLEX™ FAMILIES OF ENDOSCOPIC LINEAR CUTTERS AND RELOADS ARE INTENDED FOR TRANSECTION, RESECTION, AND/OR CREATION OF ANASTOMOSES. THE INSTRUMENTS HAVE APPLICATION IN MULTIPLE OPEN OR MINIMALLY INVASIVE GENERAL, GYNECOLOGIC, UROLOGIC, THORACIC, AND PEDIATRIC SURGICAL PROCEDURES. THEY CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIALS. THE INSTRUMENTS MAY ALSO BE USED FOR TRANSECTION AND RESECTION OF LIVER PARENCHYMA (HEPATIC VASCULATURE AND BILIARY STRUCTURES), PANCREAS, KIDNEY AND SPLEEN.,RELOAD (ENDOPATH ECHELON VASCULAR RELOAD) (ENDOPATH ECHELON)-THE ECHELON FLEX POWERED VASCULAR STAPLER WITH ADVANCED PLACEMENT TIP (35MM, 4 ROW) AND ITS RELOADS ARE INTENDED FOR TRANSECTION AND RESECTION OF TISSUE AND VASCULATURE. THE INSTRUMENTS HAVE APPLICATION IN MULTIPLE OPEN OR MINIMALLY INVASIVE GENERAL, GYNECOLOGIC, UROLOGIC, THORACIC, AND PEDIATRIC SURGICAL PROCEDURES.
2116	IMP/MD/2020/000206	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER INTRODUCING SHEATH(PTFE PEELABLE INTRODUCER KIT)-PEELABLE INTRODUCER IS INTENDED FOR USE IN THE PERCUTANEOUS INSERTION OF PACING LEADS OR CATHETERS IN THE VENOUS SYSTEM.
2117	IMP/MD/2020/000208	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REVASCULARIZATION DEVICE(EMBOTRAP II)-IT IS INTENDED TO BE USED TO RESTORE BLOOD FLOW IN PATIENTS EXPERIENCING AN ACUTE ISCHEMIC STROKE DUE TO A LARGE VESSEL NEUROVASCULAR OCCLUSION. THE DEVICE IS DESIGNED FOR USE IN THE ANTERIOR AND POSTERIOR NEUROVASCULATURE IN VESSELS OF DIAMETER 1.5MM TO 5MM, SUCH AS THE INTERNAL CAROTID ARTERY, THE M1 AND M2 SEGMENTS OF THE MIDDLE CEREBRAL ARTERY, THE A1 AND A2 SEGMENTS OF THE ANTERIOR CEREBRAL ARTERY, THE BASILAR, THE POSTERIOR CEREBRAL AND THE VERTEBRAL ARTERIES. THE DEVICE SHOULD ONLY BE USED BY PHYSICIANS TRAINED IN NEUROINTERVENTIONAL CATHETERIZATION AND THE TREATMENT OF ISCHEMIC STROKE.

2118	IMP/MD/2020/000209	1.License Holder Name: YPSOMED INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC NEEDLES(PENFINE CLASSIC)-PENFINE CLASSIC PEN NEEDLES ARE STERILE, SINGLE USE DEVICES INTENDED FOR THE HYPODERMIC (SUBCUTANEOUS) ADMINISTRATION OF LIQUID PHARMACEUTICALS IN COMBINATION WITH A PEN-INJECTOR., DISPOSABLE HYPODERMIC NEEDLES(CLICKFINE AUTOPROTECT)-CLICKFINE AUTOPROTECT PEN NEEDLES ARE STERILE, SINGLE USE DEVICES INTENDED FOR THE HYPODERMIC (SUBCUTANEOUS) ADMINISTRATION OF LIQUID PHARMACEUTICALS IN COMBINATION WITH A PEN-INJECTOR. ADDITIONALLY THE CLICKFINE AUTOPROTECT PEN NEEDLES POSSESS A SAFETY MECHANISM TO MINIMIZE THE RISK OF ACCIDENTAL NEEDLES- STICK INJURIES., DISPOSABLE HYPODERMIC NEEDLES(CLICKFINE)-CLICKFINE PEN NEEDLES ARE STERILE, SINGLE USE DEVICES INTENDED FOR THE HYPODERMIC (SUBCUTANEOUS) ADMIN-ISTRATION OF LIQUID PHARMACEUTICALS IN COMBINATION WITH A PEN-INJECTOR.
2119	IMP/MD/2020/000210	1.License Holder Name: SMITHS MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERCUTANEOUS TRACHEOSTOMY KIT(ULTRAPERC)-CONTROLLED, ELECTIVE SUBCRICIOD PERCUTANEOUS INSERTION OF A TRACHEOSTOMY TUBE FOR AIRWAY MANAGEMENT USING A SELDINGER GUIDEWIRE DILATION TECHNIQUE
2120	IMP/MD/2020/000211	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HUBER NEEDLE SET (SAFESTEP)-SAFESTEP HUBER NEEDLE SET IS A DEVICE INTENDED FOR INSERTION INTO THE SEPTUM OF A SUBCUTANEOUSLY IMPLANTED PORT AND FOR THE INFUSION OF FLUIDS INTO THE PORT. THE SAFETY FEATURE IS MANUALLY ACTIVATED DURING NEEDLE REMOVAL AND IS DESIGNED TO AID IN THE PREVENTION OF ACCIDENTAL NEEDLE STICKS

2121	IMP/MD/2020/000212	1.License Holder Name: M/S TAPADIYA INTERVENTIONAL TECHNOLOGIES & HEALTH CARE LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SIROLIMUS ELUTING CORONARY STENT SYSTEM, WITH COCR STENT AND PERMANENT POLYMER.(IVASCULAR ANGIOLITE)-THE DEVICE IS INDICATED FOR INCREASING THE INTERNAL DIAMETER OF AN ARTERY WITH THE AIM OF IMPROVING BLOOD FLOW IN THE FOLLOWING CASES: • PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO “DE NOVO” STENOTIC AND RE-STENOTIC LESIONS LOCATED IN ARTERIES WITH DIAMETERS FROM 2MM TO 4.5MM. • PATIENTS WITH OCCLUSIVE DISEASE DUE TO ACUTE MYOCARDIAL INFARCTION LOCATED IN ARTERIES WITH DIAMETERS FROM 2MM TO 4.5MM.
2122	IMP/MD/2020/000213	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IRRIGATION TUBING(NA)-ANSPACH SURGICAL IRRIGATION SYSTEMS ARE INDICATED FOR USE WITH ANSPACH SURGICAL MOTOR SYSTEMS FOR PROVIDING CONTROLLED, COOLING IRRIGATION DURING CUTTING, SHAPING AND REMOVAL OF BONE, INCLUDING BONES OF THE SKULL AND SPINE.
2123	IMP/MD/2020/000214	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDEWIRE (PRESSUREWIRE X)-THE PRESSUREWIRE X GUIDEWIRE IS DESIGNED TO FIT INSIDE A PERCUTANEOUS CATHETER FOR THE PURPOSE OF DIRECTING THE CATHETER THROUGH A VESSEL. THE SIGNAL OUTPUT FROM THE SENSOR IS TRANSMITTED TO ASSOCIATED EQUIPMENT FOR ANALYSIS, CALCULATIONS, AND DISPLAY OF ANY PHYSIOLOGICAL PARAMETERS OR INDICES BASED ON PRESSURE OR TEMPERATURE; E.G., FRACTIONAL FLOW RESERVE (FFR).

2124	IMP/MD/2020/000215	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTION NEEDLES(BD VACUTAINER FLASHBACK NEEDLE)-THE BD VACUTAINER FLASHBACK BLOOD COLLECTION NEEDLE IS SPECIFICALLY DESIGNED TO ENHANCE HEALTHCARE WORKER'S TECHNIQUE IN THE BLOOD COLLECTION PROCESS. THE NEEDLE CHAMBER ALLOWS HEALTHCARE WORKER TO VISUALIZE BLOOD FLASHBACK DURING VEIN PUNCTURE, CONFIRMING PLACEMENT OF NEEDLE IN THE VEIN THUS MAKING BLOOD DRAWING EASIER., DISPOSABLE HYPODERMIC NEEDLE(BD ECLIPSE NEEDLE)-IT IS INDICATED FOR GENERAL PURPOSE INJECTION AND ASPIRATION OF FLUIDS FROM VIALS, AMPOULES & PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.
2125	IMP/MD/2020/000216	1.License Holder Name: MEDCENTRAL GLOBAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INSUFFLATOR FOR LAPAROSCOPY(LEXION MEDICAL AP50/30 INSUFFLATOR)-THE AP50/30 INSUFFLATOR IS A CO2 INSUFFLATOR INTENDED FOR USE DURING DIAGNOSTIC AND/OR THERAPEUTIC ENDOSCOPIC PROCEDURES TO DISTEND A CAVITY BY FILLING IT WITH GAS. THE STANDARD/HIGH FLOW, PEDIATRIC AND BARIATRIC OPERATING MODES OF THE DEVICE ARE INDICATED TO FILL AND DISTEND A PERITONEAL CAVITY WITH GAS DURING A LAPAROSCOPIC PROCEDURE. THE PEDIATRIC OPERATING MODE IS SPECIFICALLY INDICATED FOR PEDIATRIC LAPAROSCOPIC PROCEDURES. T HE VESSEL HARVESTING OPERATING MODE IS INDICATED FOR USE DURING ENDOSCOPIC VESSEL HARVESTING PROCEDURES TO CREATE A CAVITY ALONG THE SAPHENOUS VEIN OR RADIAL ARTERY. THE INSUFLOW® PORT (5 MM, 8 MM, 10 MM AND 12 MM) DEVICES HAVE APPLICATIONS IN THORACIC, ABDOMINAL AND GYNECOLOGIC MINIMALLY INVASIVE ENDOSCOPIC SURGICAL PROCEDURES TO ESTABLISH A PATH FOR ENDOSCOPIC INSTRUMENTS AND TO HEAT, HUMIDIFY, FILTER AND INTRODUCE CO2 GAS STREAM FOR INSUFFLATION OF THE SURGICAL CAVITY.

2126	IMP/MD/2020/000218	1.License Holder Name: RAYMED TRADING GROUP PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SIROLIMUS ELUTING CORONARY STENT SYSTEM, WITH COCR STENT AND PERMANENT POLYMER.(IVASCULAR ANGIOLITE)-THE DEVICE IS INDICATED FOR INCREASING THE INTERNAL DIAMETER OF AN ARTERY WITH THE AIM OF IMPROVING BLOOD FLOW IN THE FOLLOWING CASES: • PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO “DE NOVO” STENOTIC AND RE-STENOTIC LESIONS LOCATED IN ARTERIES WITH DIAMETERS FROM 2MM TO 4.5MM. • PATIENTS WITH OCCLUSIVE DISEASE DUE TO ACUTE MYOCARDIAL INFARCTION LOCATED IN ARTERIES WITH DIAMETERS FROM 2MM TO 4.5MM.

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2127	IMP/MD/2020/000219	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL SEALANT APPLICATOR(COSEAL REPLACEMENT APPLICATOR 7 CM)-IT IS INDICATED FOR USE IN – 1. SEALING SUTURES LINES ALONG ARTERIAL AND VENOUS RECONSTRUCTIONS. 2. ENFORCEMENT OF SUTURE AND STAPLE LINES IN LUNG RESECTION PROCEDURES 3. PATIENTS UNDERGOING CARDIAC SURGERY TO PREVENT OR REDUCE THE INCIDENCE, SEVERITY AND EXTENT OF THE POST SURGICAL ADHESION FORMATION. 4. PATIENTS UNDERGOING LAPAROTOMY OR LAPROSCOPIC ABDOMINO – PELVIC SURGERY AS AN ADJUNCT TO GOOD SURGICAL TECHNIQUE INTENDED TO REDUCE THE INCIDENCE, SEVERITY AND EXTENT OF POSTSURGICAL ADHESION FORMATION. COSEAL APPLICATOR IS USED FOR MIXING AND DELIVERY OF THE TWO COSEAL SURGICAL SEALANT COMPONENTS. ,APPLICATOR TIP(FLOSEAL)-IT IS INTENDED FOR THE USE FOR DELIVERY HEMOSTATIC AGENTS THAT CAN BE MECHANICALLY MIXED & DELIVERED TO BLEEDING SITES.,SURGICAL SEALANT(COSEAL)-- IT IS INDICATED FOR USE IN – 1. SEALING SUTURES LINES ALONG ARTERIAL AND VENOUS RECONSTRUCTIONS. 2. ENFORCEMENT OF SUTURE AND STAPLE LINES IN LUNG RESECTION PROCEDURES 3. PATIENTS UNDERGOING CARDIAC SURGERY TO PREVENT OR REDUCE THE INCIDENCE, SEVERITY AND EXTENT OF THE POST SURGICAL ADHESION FORMATION. 4. PATIENTS UNDERGOING LAPAROTOMY OR LAPROSCOPIC ABDOMINO – PELVIC SURGERY AS AN ADJUNCT TO GOOD SURGICAL TECHNIQUE INTENDED TO REDUCE THE INCIDENCE, SEVERITY AND EXTENT OF POSTSURGICAL ADHESION FORMATION. ,SURGICAL SEALANT APPLICATOR(COSEAL EXTENDED APPLICATOR 22 CM)-IT IS INDICATED FOR USE IN – 1. SEALING SUTURES LINES ALONG ARTERIAL AND VENOUS RECONSTRUCTIONS. 2. ENFORCEMENT OF SUTURE AND STAPLE LINES IN LUNG RESECTION PROCEDURES 3. PATIENTS UNDERGOING CARDIAC SURGERY TO PREVENT OR REDUCE THE INCIDENCE, SEVERITY AND EXTENT OF THE POST SURGICAL ADHESION FORMATION. 4. PATIENTS UNDERGOING LAPAROTOMY OR LAPROSCOPIC ABDOMINO – PELVIC SURGERY AS AN ADJUNCT TO GOOD SURGICAL TECHNIQUE INTENDED TO REDUCE THE INCIDENCE, SEVERITY AND EXTENT OF POSTSURGICAL ADHESION FORMATION. COSEAL APPLICATOR IS USED FOR MIXING AND DELIVERY OF THE TWO COSEAL SURGICAL SEALANT COMPONENTS.

2128	IMP/MD/2020/000220	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOPICAL SKIN ADHESIVES (LIQUIBAND® OPTIMA)-LIQUIBAND® OPTIMA IS INDICATED FOR CLOSURE OF THE SKIN IN CLEAN, FRESH WOUNDS WITH EASILY APPOSED EDGES. LIQUIBAND® OPTIMA SHOULD BE APPLIED BY TRAINED MEDICAL OR NURSING STAFF.,TOPICAL SKIN ADHESIVES (LIQUIBAND® SURGICAL S)-LIQUIBAND® SURGICAL S IS INDICATED FOR THE CLOSURE OF TOPICAL SKIN INCISIONS INCLUDING LAPAROSCOPIC INCISIONS IN AREAS THAT ARE SIMPLE, THOROUGHLY CLEANSED, AND HAVE EASILY APPROXIMATED EDGES. LIQUIBAND® SURGICAL S MAY BE USED IN CONJUNCTION WITH, BUT NOT IN PLACE OF, DEEP DERMAL STITCHES.,TOPICAL SKIN ADHESIVES(LIQUIBAND® EXCEED™ AND LIQUIBAND® EXCEED™ XS)-LIQUIBAND® EXCEED™ AND LIQUIBAND® EXCEED™ XS IS INTENDED FOR TOPICAL APPLICATIONS ONLY, TO HOLD CLOSED EASILY APPROXIMATED SKIN EDGES OF WOUNDS FROM SURGICAL INCISIONS, INCLUDING PUNCTURES FROM MINIMALLY INVASIVE SURGERY AND SIMPLE, THOROUGHLY CLEANSED, TRAUMA INDUCED LACERATIONS. LIQUIBAND® EXCEED™ AND LIQUIBAND® EXCEED™ XS MAY BE USED IN CONJUNCTION WITH, BUT NOT IN PLACE OF, DEEP DERMAL STITCHES.,HERNIA MESH FIXATION DEVICES (LIQUIBAND FIX8® AND LIQUIBAND FIX8® OPEN HERNIA MESH FIXATION DEVICE)-INTENDED FOR USE IN THE SURGICAL PROCEDURE; REPAIR OF HERNIAS THROUGH MESH FIXATION.
2129	IMP/MD/2020/000222	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COLLAGEN MEMBRANE (CREOS XENOPROTECT)-CREOSTM XENOPROTECT IS INTENDED FOR USE DURING THE PROCESS OF GUIDED BONE REGENERATION (GBR) AND GUIDED TISSUE REGENERATION (GTR) AS A BIODEGRADABLE BARRIER MEMBRANE FOR: • RIDGE AUGMENTATION FOR LATER IMPLANT INSERTION • AUGMENTATION AROUND IMPLANTS PLACED IN IMMEDIATE/DELAYED EXTRACTION SOCKETS • LOCALIZED RIDGE AUGMENTATION • ALVEOLAR RIDGE PRESERVATION/ RECONSTRUCTION • OSSEOUS FILL AROUND IMPLANTS IN PERI-IMPLANTITIS BONE DEFECTS • OVER THE WINDOW IN LATERAL WINDOW SINUS ELEVATION PROCEDURES • INTRA-BONY DEFECTS AROUND TEETH • TREATMENT OF RECESSION DEFECTS, TOGETHER WITH CORONALLY POSITIONED FLAP • IN FURCATION DEFECTS IN MULTI-ROOTED TEETH.

2130	IMP/MD/2020/000223	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE MARROW ASPIRATION /INTRAOSSEOUS INFUSION NEEDLE(BONE MARROW ASPIRATION /INTRAOSSEOUS INFUSION NEEDLE)-INTENDED TO ASPIRATE MARROW FROM EITHER THE STERNUM OR THE ILIAC CREST,BIOPSY NEEDLES (JAMSHIDI BONE MARROW BIOPSY / ASPIRATION NEEDLE)-INTENDED FOR THE POSTERIOR ILIAC CREST BIOPSY TECHNIQUE,BIOPSY NEEDLES (JAMSHIDI CROWN BONE MARROW BIOPSY/ASPIRATION NEEDLE WITH MARROW ACQUISITION CRADLE)-INTENDED FOR THE POSTERIOR ILIAC CREST BIOPSY TECHNIQUE
2131	IMP/MD/2020/000224	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOPSY NEEDLES (CHIBA FINE NEEDLE ASPIRATION)-THESE DEVICES ARE INTENDED FOR USE IN OBTAINING CORE BIOPSY SAMPLES FROM SOFT TISSUE SUCH AS BREAST, KIDNEY, LIVER, LUNG, THYROID, LYMPH NODES AND SOFT TISSUE MASSES. NOT INTENDED FOR USE IN BONE,BONE MARROW BIOPSY/ASPIRATION NEEDLE(JAMSHIDI BONE MARROW BIOPSY/ASPIRATION NEEDLE WITH LUER LOCK ADAPTER)-THE JAMSHIDI BONE MARROW BIOPSY/ ASPIRATION NEEDLES WITH LUER LOCK ADAPTER ARE INTENDED FOR THE POSTERIOR ILIAC CREST BIOPSY TECHNIQUE. THESE NEEDLES ARE NOT TO BE USED FOR A STERNAL PROCEDURE ,BIOPSY NEEDLES (FRANSEEN FINE NEEDLE ASPIRATION)-THESE DEVICES ARE INTENDED FOR USE IN OBTAINING CORE BIOPSY SAMPLES FROM SOFT TISSUE SUCH AS BREAST, KIDNEY, LIVER, LUNG, THYROID, LYMPH NODES AND SOFT TISSUE MASSES. NOT INTENDED FOR USE IN BONE,BONE MARROW ASPIRATION/ LNTRAOSSEOUS INFUSION NEEDLE(ILLINOIS BONE MARROW ASPIRATION /INTRAOSSEOUS INFUSION NEEDLE)-ILLINOIS BONE MARROW ASPIRATION/ LNTRAOSSEOUS INFUSION NEEDLE IS INDICATED TO ASPIRATE MARROW FROM EITHER THE STERNUM OR THE ILIAC CREST

2132	IMP/MD/2020/000225	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE INJECTION SYSTEM(BD UNIJECT PREFILLABLE INJECTION SYSTEM)-THE UNIJECT PREFILLABLE INJECTION SYSTEM IS A DISPOSABLE SYSTEM FOR THE PARENTERAL ADMINISTRATION OF DRUGS AND VACCINES WHICH ALSO SERVES AS A CONTAINER FOR THE DRUGS,DISPOSABLE HYPODERMIC SYRINGES(BD LUER-LOK TIP WITH BD PRECISIONGLIDE NEEDLES)-IT IS INTENDED FOR GENERAL PURPOSE INJECTION AND ASPIRATION OF MEDICAL FLUIDS, OR PHARMACEUTICALS, DISPOSABLE HYPODERMIC NEEDLE(BD PRECISIONGLIDE NEEDLES)-IT IS INTENDED FOR SINGLE USE, THE STERILE DEVICE IS DESIGNED FOR THE HYPODERMIC ADMINISTRATION OF PHARMACEUTICALS, DISPOSABLE HYPODERMIC SYRINGES(BD SLIP TIP WITH PRECISIONGLIDE NEEDLES)-IT IS INTENDED FOR GENERAL PURPOSE INJECTION AND ASPIRATION OF MEDICAL FLUIDS, OR PHARMACEUTICALS,DISPOSABLE HYPODERMIC SYRINGES(BD LUER-LOK TIP SYRINGES)-IT IS INTENDED FOR GENERAL PURPOSE INJECTION AND ASPIRATION OF MEDICAL FLUIDS, OR PHARMACEUTICALS.,DISPOSABLE HYPODERMIC SYRINGES(BD SLIP TIP (TUBERCULIN SYRINGE))-IT IS INTENDED FOR GENERAL PURPOSE INJECTION AND ASPIRATION OF MEDICAL FLUIDS, OR PHARMACEUTICALS,DISPOSABLE HYPODERMIC NEEDLE(BD HYPOINT NEEDLE)-IT IS INTENDED FOR PARENTERAL ADMINISTRATION OF PHARMACEUTICAL PRODUCTS

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2133	IMP/MD/2020/000226	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTV DILATATION CATHETER(VIDA® PTV DILATATION CATHETER)-THE VIDA™ PTV DILATATION CATHETER IS RECOMMENDED FOR PERCUTANEOUS TRANSLUMINAL VALVULOPLASTY OF THE PULMONARY VALVES IN THE FOLLOWING: • A PATIENT WITH ISOLATED PULMONARY VALVE STENOSIS • A PATIENT WITH VALVULAR PULMONARY STENOSIS WITH OTHER MINOR CONGENITAL HEART DISEASE THAT DOES NOT REQUIRE SURGICAL INTERVENTION.,PTA DILATATION CATHETER (ATLAS® GOLD PTA DILATATION CATHETER)-ATLAS® GOLD PTA DILATATION CATHETER IS INDICATED FOR USE IN PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF THE PERIPHERAL VASCULATURE, INCLUDING THE ILIAC ARTERIES AND ILIAC AND FEMORAL VEINS, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR POST-DILATATION OF STENTS AND STENT GRAFTS IN THE PERIPHERAL VASCULATURE. THIS CATHETER IS NOT FOR USE IN CORONARY ARTERIES.
2134	IMP/MD/2020/000227	1.License Holder Name: M/S SAIHEALTH INNOVATION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SIROLIMUS ELUTING CORONARY STENT SYSTEM, WITH COCR STENT AND PERMANENT POLYMER.(IVASCULAR ANGIOLITE)-THE DEVICE IS INDICATED FOR INCREASING THE INTERNAL DIAMETER OF AN ARTERY WITH THE AIM OF IMPROVING BLOOD FLOW IN THE FOLLOWING CASES: • PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO “DE NOVO” STENOTIC AND RE-STENOTIC LESIONS LOCATED IN ARTERIES WITH DIAMETERS FROM 2MM TO 4.5MM. • PATIENTS WITH OCCLUSIVE DISEASE DUE TO ACUTE MYOCARDIAL INFARCTION LOCATED IN ARTERIES WITH DIAMETERS FROM 2MM TO 4.5MM..

2135	IMP/MD/2020/000228	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RESORBABLE CALCIUM SALT BONE VOID FILLER DEVICE(GRAFTON DBM PUTTY)-GRAFTON™ DBM AND GRAFTON PLUS™ DBM ARE INTENDED FOR USE AS A BONE GRAFT EXTENDER, BONE GRAFT SUBSTITUTE, AND BONE VOID FILLER IN BONY VOIDS OR GAPS OF THE SKELETAL SYSTEM (I.E., SPINE, PELVIS, AND EXTREMITIES) NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. THE VOIDS OR GAPS MAY BE SURGICALLY CREATED DEFECTS OR DEFECTS CREATED BY TRAUMATIC INJURY TO THE BONE. GRAFTON™ DBM (EXCLUDING THE ORTHOBLEND FORM) AND GRAFTON PLUS™ DBM ARE ALSO INTENDED TO BE PACKED INTO BONY VOIDS OR GAPS TO FILL AND/OR AUGMENT DENTAL INTRAOSSEOUS, ORAL, AND CRANIO-/MAXILLOFACIAL DEFECTS. THESE DEFECTS MAY BE SURGICALLY CREATED OSSEOUS DEFECTS OR OSSEOUS DEFECTS CREATED FROM TRAUMATIC INJURY TO THE BONE, INCLUDING PERIODONTAL/INFRABONY DEFECTS; ALVEOLAR RIDGE AUGMENTATION (SINUSOTOMY, OSTEOTOMY, CYSTECTOMY); DENTAL EXTRACTION SITES (RIDGE MAINTENANCE, IMPLANT PREPARATION/ PLACEMENT); SINUS LIFTS; CYSTIC DEFECTS; CRANIOFACIAL AUGMENTATION. GRAFTON™ DBM AND GRAFTON PLUS™ DBM MAY BE USED ALONE IN A MANNER COMPARABLE TO AUTOGENOUS BONE CHIPS OR ALLOGRAFT BONE PARTICULATE (DEMINERALIZED FREEZE DRIED BONE), OR THEY MAY BE MIXED WITH EITHER ALLOGRAFT OR AUTOGRAFT BONE OR BONE MARROW AS A BONE GRAFT EXTENDER. GRAFTON™ DBM AND GRAFTON PLUS™ DBM ARE INDICATED ONLY FOR BONY VOIDS OR GAPS THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. GRAFTON™ DBM AND GRAFTON PLUS™ DBM ARE ABSORBED/REMODELED AND REPLACED BY HOST BONE DURING THE HEALING PROCESS. NOTE: THE USER SHOULD CONSIDER THE FACT THAT GRAFTON™ DBM CRUNCH CONTAINS DEMINERALIZED BONE CHIPS APPROXIMATELY 3 MM (±1 MM) IN DETERMINING THE APPROPRIATENESS OF THIS ALLOGRAFT FOR USE IN SMALL DEFECTS.

2136	IMP/MD/2020/000229	1.License Holder Name: SURGIPLUS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE ANESTHESIA BREATHING CIRCUIT(ADLISC)-TO SET UP THE BREATHING TUBE CONNECTION WHEN PRODUCT CONNECTS WITH THE ANESTHESIA MACHINE OR BREATHING MACHINE,DISPOSABLE BREATHING FILTER (ADLISC)-TO FILTER THE MICROPARTICLE, VIRAL AND BACTERIAL OF EXCHANGE AIR FROM THE ANESTHESIA MACHINE, ALSO FILTER CAN WARMER AND HUMIDIFIER THE EXCHANGE AIR.
2137	IMP/MD/2020/000230	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUTURE(COATED VICRYL PLUS ANTIBACTERIAL WITH IRGACARE MP SUTURE)-COATED VICRYL PLUS ANTIBACTERIAL SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, EXCEPT FOR OPHTHALMIC, CARDIOVASCULAR AND NEUROLOGICAL TISSUES, SUTURE(PDS II (POLYDIOXANONE) SUTURE)-PDS SUTURE ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PEDIATRIC, CARDIOVASCULAR TISSUE, WHERE THE GROWTH IS EXPECTED TO OCCUR AND OPHTHALMIC SURGERY. PDS II IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE.THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE.,MESH(VICRYL KNITTED MESH (POLYGLACTIN 910))-VICRYL KNITTED MESH MAY BE USED WHEREVER TEMPORARY WOUND OR ORGAN SUPPORT IS REQUIRED, PARTICULARLY IN INSTANCES IN WHICH COMPLIANT AND STRETCHABLE SUPPORT MATERIAL IS DESIRED AND CONTAINMENT OF WOUND TRANSUDATE IS NOT REQUIRED. VICRYL KNITTED MESH MAY BE CUT TO THE SHAPE OR SIZE DESIRED FOR EACH SPECIFIC APPLICATION.
2138	IMP/MD/2020/000231	1.License Holder Name: LIVANOVA INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOLOGICAL HEART VALVE(PERCEVAL S)-PERCEVAL S HEART VALVE IS A BIOPROSTHETIC VALVE DESIGNED TO REPLACE A DISEASED NATIVE OR A MALFUNCTIONING PROSTHETIC AORTIC VALVE VIA OPEN HEART SURGERY.

2139	IMP/MD/2020/000232	1.License Holder Name: BIOTRONIK MEDICAL DEVICES INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA BALLOON CATHETER(PANTERA)-THE PANTERA PTCA CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION AND FOR POST DILATATION OF CORONARY STENTS.,PERIPHERAL VASCULAR STENT SYSTEM(DYNAMIC RENAL)-THE DYNAMIC RENAL STENT SYSTEM IS INDICATED FOR IMPROVING ARTERIAL LUMINAL DIAMETER IN PATIENTS WITH CLINICAL SYMPTOMS ATTRIBUTABLE TO ATHEROSCLEROTIC STENOSIS OF THE RENAL ARTERIES.,DRUG RELEASING ANGIO-GRAPHIC CATHETER(PANTERA)-THE PANTERA CATHETER IS INDICATED FOR BALLOON DILATATION OF CORONARY ARTERIES WITH A VESSEL DIAMETER FROM 2.0 MM – 4.0 MM FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION IN (A) IN-STENT RESTENOSIS, (B) DENOVO LESIONS, (C) ACUTE OR IMPENDING VASCULAR OCCLUSION AND (D) TREATMENT OF SMALL VESSEL DISEASE.,CORONARY STENT SYSTEM(PK PAPYRUS)-PK PAPYRUS IS INDICATED FOR TREATMENT OF ACUTE CORONARY ARTERY PERFORATIONS.,DRUG ELUTING STENT FOR VASCULAR INTERVENTION(SYNSIRO)-THE SYNSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE-NOVO STENOTIC LESIONS AND IN-STENT RESTENOTIC LESIONS (LENGTH 40 MM*) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM TO 4.0 MM.,DRUG ELUTING STENT FOR VASCULAR INTERVENTION(ORSIRO)-THE ORSIRO SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE-NOVO STENOTIC LESIONS AND IN-STENT RESTENOTIC LESIONS (LENGTH 40 MM*) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM TO 4.0 MM.,PERIPHERAL VASCULAR STENT SYSTEM (DYNAMIC)-THE DYNAMIC STENT SYSTEM IS INDICATED FOR THE TREATMENT OF DE NOVO OR RESTENOTIC ATHEROSCLEROTIC LESIONS IN ILIAC ARTERIES.

2140	IMP/MD/2020/000233	1.License Holder Name: 3M INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EXUDATE-ABSORBENT DRESSING, NON-GEL(3M™ TEGADERM™ SILICONE FOAM BORDER DRESSING)-TEGADERM™ SILICONE FOAM BORDER DRESSING IS DESIGNED FOR MANAGEMENT OF LOW- TO HIGHLY-EXUDING PARTIAL AND FULL THICKNESS WOUNDS SUCH AS PRESSURE ULCERS, VENOUS LEG ULCERS, NEUROPATHIC ULCERS, ARTERIAL ULCERS, SKIN TEARS, SURGICAL WOUNDS. THE DRESSING IS SUITABLE FOR USE ON FRAGILE SKIN AND WITH COMPRESSION THERAPY. THE PRODUCT IS NOT DESIGNED, SOLD, OR INTENDED FOR USE EXCEPT AS INDICATED.,EXUDATE-ABSORBENT DRESSING, NON-GEL(3M™ TEGADERM™ SILICONE FOAM DRESSING)-TEGADERM™ SILICONE FOAM DRESSING IS DESIGNED FOR MANAGEMENT OF LOW- TO HIGHLY-EXUDING PARTIAL AND FULL THICKNESS WOUNDS SUCH AS PRESSURE ULCERS, VENOUS LEG ULCERS, NEUROPATHIC ULCERS, ARTERIAL ULCERS, SKIN TEARS, SURGICAL WOUNDS. THE DRESSING IS SUITABLE FOR USE ON FRAGILE SKIN AND WITH COMPRESSION THERAPY. THE PRODUCT IS NOT DESIGNED, SOLD, OR INTENDED FOR USE EXCEPT AS INDICATED.

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2141	IMP/MD/2020/000235	1.License Holder Name: AVANOS MEDICAL INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MIC-KEY* CONTINUOUS FEED EXTENSION SET WITH SECUR-LOK* RIGHT ANGLE CONNECTOR AND 2 PORT "Y" AND CLAMP(AVANOS)-INTENDED TO WORK WITH MIC-KEY* GASTROSTOMY FEEDING TUBE, LOW PROFILE FOR USE IN PATIENTS WHO REQUIRE LONG TERM FEEDING, ARE UNABLE TO TOLERATE ORAL FEEDING, WHO ARE AT LOW RISK FOR ASPIRATION, REQUIRE GASTRIC DECOMPRESSION AND/ OR MEDICATION DELIVERY DIRECTLY INTO THE STOMACH,NASOGASTRIC FEEDING TUBE(CORTRAK 2 NASOGASTRIC/ NASOINTESTINAL FEEDING TUBE WITH ELECTROMAGNETIC TRANSMITTING STYLET)-THIS TUBE AND TRANSMITTING STYLET HAVE BEEN DESIGNED FOR USE WITH THE CORTRAK* 2 ENTERAL ACCESS SYSTEM. THE TUBE IS INTENDED FOR USE IN PATIENTS WHO REQUIRE INTERMITTENT OR CONTINUOUS TUBE FEEDINGS VIA THE NG OR NE ROUTE. CORTRAK* 2 IS DESIGNED TO AID QUALIFIED OPERATORS IN THE PLACEMENT OF CORTRAK* 2 ENTERAL FEEDING TUBES 8 FR OR GREATER INTO THE STOMACH OR SMALL BOWEL OF PATIENTS REQUIRING ENTERAL FEEDING. CORTRAK* 2 CAN BE USED TO CONFIRM PLACEMENT OF FEEDING TUBES PRIOR TO COMMENCING THE DELIVERY OF ENTERAL NUTRITION.,MIC-KEY* GASTROSTOMY FEEDING TUBE, LOW PROFILE (AVANOS)-MIC-KEY* LOW PROFILE GASTROSTOMY FEEDING TUBE IS INDICATED FOR USE IN PATIENTS WHO REQUIRE LONG-TERM FEEDING, ARE UNABLE TO TOLERATE ORAL FEEDING, WHO ARE AT LOW RISK FOR ASPIRATION, REQUIRE GASTRIC DECOMPRESSION AND/ OR MEDICATION DELIVERY DIRECTLY INTO THE STOMACH ., MIC* BOLUS GASTROSTOMY FEEDING TUBE(AVANOS)-INTENDED FOR USE IN PATIENTS WHO REQUIRE LONG TERM FEEDING, ARE UNABLE TO TOLERATE ORAL FEEDING, WHO ARE AT LOW RISK FOR ASPIRATION, REQUIRED GASTRIC DECOMPRESSION AND/ OR MEDICATION DELIVERY DIRECTLY INTO THE STOMACH.,INTRODUCER KIT FOR GASTROSTOMY FEEDING TUBE(AVANOS)-INTENDED TO FACILITATE THE PRIMARY PLACEMENT OF THE AVANOS* MIC* AND MIC-KEY* BRAND OF GASTROSTOMY FEEDING TUBES.,MIC* JEJUNOSTOMY FEEDING TUBE(AVANOS)-THE MIC* JEJUNOSTOMY TUBE CAN BE USED IN CANCER PATIENTS , SUFFERING FROM HEAD AND NECK PATHOLOGIES, THESE PATIENTS ARE FREQUENTLY ON RIGOROUS PROGRAMS OF CHEMOTHERAPY AND / OR RADIATION THERAPY AND OFTEN DEVELOP ANOREXIA, NAUSEA PHARYNGITIS, ESOPHAGITIS, ETC., THUS PRECLUDING AN ALREADY COMPROMISED ABILITY TO EAT.,GASTROINTESTINAL ANCHOR SET(AVANOS)-INTENDED TO AFFIX THE STOMACH TO THE ANTERIOR ABDOMINAL WALL FACILITATING PRIMARY PLACEMENT OF THE ANABOS* MIC*

	AND MIC-KEY* BRAND ENTERAL FEEDING TUBES. IT IS RECOMMENDED TO BE USED ONLY WITHTHE AVANOS* MIC* AND MIC-KEY* BRAND ENTERAL FEEDING TUBES,MIC-KEY* BOLUS FEED EXTENSION SET WITH CATH TIP, SECUR-LOK STRAIGHT CONNECTOR AND CLAMP(AVANOS)-INTENDED TO WORK WITH MIC-KEY* GASTROSTOMY FEEDING TUBE, LOW PROFILE FOR USE IN PATIENTS WHO REQUIRE LONG TERM FEEDING, ARE UNABLE TO TOLERATE ORAL FEEDING, WHO ARE AT LOW RISK FOR ASPIRATION, REQUIRE GASTRIC DECOMPRESSION AND/ OR MEDICATION DELIVERY DIRECTLY INTO THE STOMACH.,MIC-KEY* EXTENSION SET WITH CATH TIP, SECUR-LOK* STRAIGHT CONNECTOR AND CLAMP(AVANOS)-INTENDED TO WORK WITH MIC-KEY* GASTROSTOMY FEEDING TUBE, LOW PROFILE FOR USE IN PATIENTS WHO REQUIRE LONG TERM FEEDING, ARE UNABLE TO TOLERATE ORAL FEEDING, WHO ARE AT LOW RISK FOR ASPIRATION, REQUIRE GASTRIC DECOMPRESSION AND/ OR MEDICATION DELIVERY DIRECTLY INTO THE STOMACH., ENTERAL ACCESS DILATION SYSTEM(AVANOS)-INTENDED TO FACILITATE STOMA TRACT DILATION PRIOR TO PLACEMENT OF THE AVANOS* MIC* AND MIC-KEY* BRAND ENTERAL FEEDING TUBES. IT IS RECOMMENDED THAT THIS DILATOR BE USED ONLY WITH THE AVANOS* MIC* AND MIC-KEY* BRAND OF ENTERAL FEEDING TUBES., MIC* GASTROSTOMY FEEDING TUBE(AVANOS)-INTENDED FOR USE IN PATIENTS WHO REQUIRE LONG TERM FEEDING, ARE UNABLE TO TOLERATE ORAL FEEDING, WHO ARE AT LOW RISK FOR ASPIRATION, REQUIRED GASTRIC DECOMPRESSION AND/ OR MEDICATION DELIVERY DIRECTLY INTO THE STOMACH.,MIC* GASTRIC-JEJUNAL FEEDING TUBE KIT (ENDOSCOPIC/ RADIOLOGIC PLACEMENT) (AVANOS)-INTENDED FOR USE IN PATIENTS WHO CANNOT ABSORB ADEQUATE NUTRITION THROUGH THE STOMACH, WHO HAVE INTESTINAL MOTILITY PROBLEMS, GASTRIC OUTLET OBSTRUCTION, SEVERE GASTROESOPHAGEAL REFLUX, ARE AT RISK OF ASPIRATION, OR IN THOSE WHO HAVE HAD PREVIOUS ESOPHAGECTOMY OR GASTRECTOMY.,MICROCUFF SUBGLOTTIC SUCTIONING ENDOTRACHEAL TUBE, ORAL, MURPHY EYE(AVANOS)-INDICATED FOR AIRWAY MANAGEMENT BY ORAL INTUBATION OF THE TRACHE AAND FOR THE REMOVAL OF SECRETIONS THAT ACCUMULATE IN THE SUBGLOTTIC SPACE.,MIC-KEY* OVER-THE-WIRE STOMA MEASURING DEVICE(AVANOS)-MIC-KEY* OVER-THE-WIRE STOMA MEASURING DEVICE ALLOWS MEASUREMENT OF THE STOMA SITE FOR CORRECT TUBE LENGTH FACILITATING PRIMARY PLACEMENT OF THE AVANOS* MIC* AND MIC-KEY* BRAND ENTERAL FEEDING TUBES.,MIC* PERCUTANEOUS ENDOSCOPIC GASTROSTOMY (PEG) KIT (AVANOS)-INTENDED AS AN INITIAL PLACEMENT OF A PERCUTANEOUS ENDOSCOPIC GASTROSTOMY TUBE FOR ENTERAL

		NUTRITION AND MEDICATION DELIVERY AS WELL AS DECOMPRESSION.
2142	IMP/MD/2020/000236	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VASCULAR STENT(BRAVO FLOW DIVERTER)-THE BRAVO FD IS INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS.,VASCULAR RECONSTRUCTION DEVICE (STENT)(ENTERPRISE 2)-THE ENTERPRISE 2 VASCULAR RECONSTRUCTION DEVICE IS INTENDED FOR USE WITH OCCLUSIVE DEVICES IN THE TREATMENT OF INTRACRANIAL ANEURYSMS.

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2143	IMP/MD/2020/000238	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHRONIC DRAINAGE CATHETER TRAY(PLEURX PERITONEAL CATHETER MINI KIT)-THE PLEURX PERITONEAL CATHETER MINI KIT SYSTEM IS INDICATED FOR INTERMITTENT, LONG TERM DRAINAGE OF SYMPTOMATIC, RECURRENT, MALIGNANT ASCITES THAT DOES NOT RESPOND TO MEDICAL MANAGEMENT OF THE UNDERLYING DISEASE AND FOR THE PALLIATION OF SYMPTOMS RELATED TO RECURRENT MALIGNANT ASCITES. THE PLEURX PERITONEAL CATHETER IS INDICATED FOR ADULTS ONLY. THE PLEURX LOCKABLE DRAINAGE LINE IS USED TO DRAIN FLUID USING STANDARD WALL SUCTION, WATER SEAL DRAINAGE SYSTEM, VACUUM BOTTLE OR OTHER APPROPRIATE METHOD.,CHRONIC DRAINAGE CATHETER TRAY(PLEURX PLEURAL CATHETER MINI KIT)-THE PLEURX PLEURAL CATHETER MINI KIT IS INDICATED FOR INTERMITTENT, LONG TERM DRAINAGE OF SYMPTOMATIC, RECURRENT, PLEURAL EFFUSION, INCLUDING MALIGNANT PLEURAL EFFUSION AND OTHER RECURRENT EFFUSIONS THAT DO NOT RESPOND TO MEDICAL MANAGEMENT OF THE UNDERLYING DISEASE. THE DEVICES ARE INDICATED FOR THE PALLIATION OF DYSPNEA DUE TO PLEURAL EFFUSION AND PROVIDING PLEURODESIS (RESOLUTION OF THE PLEURAL EFFUSION). THE PLEURX PLEURAL CATHETER IS INDICATED FOR ADULTS ONLY. THE PLEURX LOCKABLE DRAINAGE LINE IS USED TO DRAIN FLUID USING STANDARD WALL SUCTION, WATER SEAL DRAINAGE SYSTEM, VACUUM BOTTLE, OR OTHER APPROPRIATE METHOD.,CHRONIC DRAINAGE ACCESSORIES(PLEURX SUPPLEMENTAL INSERTION KIT)-THE PLEURX SUPPLEMENTAL INSERTION KIT IS INTENDED TO AID IN THE PERCUTANEOUS INSERTION OF A PLEURX CATHETER INTO THE PLEURAL OR PERITONEAL SPACE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2144	IMP/MD/2020/000239	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TEMPORARY ABUTMENT - DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION.,ESTHETIC ABUTMENT-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION AND ESTHETICS. THE ABUTMENTS IN COMBINATION WITH TWO-STAGE ENDOSSEOUS IMPLANTS ARE USED AS THE FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. RESTORATIONS RANGE FROM REPLACING ONE SINGLE TOOTH TO FIXED PARTIAL DENTURES USING CEMENT-RETAINED SUPRA-CONSTRUCTIONS. , CLINICAL SCREWS-THEY ARE INTENDED TO SECURE A DENTAL ABUTMENT OR FRAMEWORK TO A DENTAL IMPLANT OR ABUTMENT IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION.,SNAPPY ABUTMENT-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH TWO-STAGE ENDOSSEOUS IMPLANTS ARE USED AS THE FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. RESTORATIONS RANGE FROM REPLACING ONE SINGLE TOOTH TO FIXED PARTIAL DENTURES USING CEMENT-RETAINED SUPRA-CONSTRUCTIONS. ,DENTAL IMPLANTS (TITANIUM)(NOBELACTIVE®, NOBELREPLACE® CONICAL CONNECTION, NOBELPARALLEL™ CONICAL CONNECTION, REPLACE SELECT™ TAPERED)-THEY ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW BONE (OSSEOINTEGRATION) AND USED FOR ANCHORING OR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION.,HEALING ABUTMENTS AND HEALING CAPS-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. HEALING ABUTMENT AND HEALING CAP IS INTENDED TO BE USED AS A TEMPORARY COMPONENT TO AN ENDOSSEOUS IMPLANT TO ALLOW HEALING OF THE SOFT TISSUE.,COVER SCREWS-DENTAL IMPLANT COVER SCREWS ARE TO BE USED IN THE UPPER OR LOWER JAW CONNECTED TO THE ENDOSSEOUS IMPLANT TO PROTECT THE INTERNAL THREADS AND IMPLANT HEAD DURING THE HEALING PHASE.,HEALING CAPS AND PLASTIC/TEMP COPINGS-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO

		RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH TWO-STAGE ENDOSSEOUS IMPLANTS ARE USED AS THE FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. RESTORATIONS RANGE FROM REPLACING ONE SINGLE TOOTH TO FIXED PARTIAL DENTURES USING CEMENT-RETAINED SUPRA-CONSTRUCTIONS.,UNIVERSAL BASE ABUTMENT-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION AND ESTHETICS.
2145	IMP/MD/2020/000240	1.License Holder Name: ADLER MEDIEQUIP PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CEMENTLESS FEMORAL HIP STEM (COATED/UNCOATED)(NIL)-RAW MATERIAL FOR FURTHER PROCESSING WHICH IS USED FOR HIP REPLACEMENT SURGERY.
2146	IMP/MD/2020/000241	1.License Holder Name: M/S. EASYMED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STRILE SINGLE USE POLYDIOXANONE SUTURE WITH NEEDLE-THE ABSORBABLE POLYDIOXANONE SUTURE WITH NEEDLE IS INTENDED USE FOR THE TREATMENT OF CHEEK LAXITY AND IMPROVEMENT OF NASOLABIAL FOLDS AND FACIAL SOFT TISSUE RECONSTRUCTION IN THE ASYMMETRY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2147	IMP/MD/2020/000242	1.License Holder Name: SPEBA INNOMED PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOACTIVE BONE INTERFERENCE SCREW(LOCKACTIV)-IT IS INTENDED FOR TIBIAL AND FEMORAL FIXATION OF THE TENDON GRAFT OR AUTOGENOUS TENDON USED IN THE RECONSTRUCTION OF THE CRUCIATE LIGAMENTS OF THE KNEE, IN PARTICULAR WITH THE KENNETH JONES AND SEMITENDINOSUS-GRACILIS TECHNIQUES.,BIOACTIVE GLASS DENTAL GRAFT SUBSTITUTE(ACTIVIOSS)-IT IS INTENDED TO FILL TEMPORARILY BONE DEFECTS OF TRAUMATIC, PATHOLOGIC OR SURGICAL ORIGIN UNTIL BONE REGENERATION. INDICATIONS: - FILLING BONE DEFECTS IN ORAL AND CRANIO MAXILLOFACIAL SURGERY. - PERIODENTAL / INFRABONY DEFECTS. - RIDGE AUGMENTATION. - FILLING TOOTH SOCKETS FOR RIDGE MAINTENANCE FOLLOWING EXTRACTION. - FILLING BONE DEFECTS SUCH AS CYST OR DENTAL GRANULOMA. - SINUS FLOOR AUGMENTATION.,BIOACTIVE GLASS BONE GRAFT SUBSTITUTE (GLASSBONE)- IT IS INTENDED TO FILL TEMPORARILY BONE DEFECTS OF TRAUMATIC, PATHOLOGIC OR SURGICAL ORIGIN UNTIL BONE REGENERATION. INDICATIONS: - FILLING BONE DEFECTS IN ORTHOPAEDIC AND CRANIO MAXILLOFACIAL SURGERY. - FILLING BONE DEFECTS (AFTER TUMOUR RESECTION, AFTER REMOVING ILIAC BONE) - VERTEBRAL ARTHRODESIS - PROSTHESIS REVISION - TRAUMATOLOGY - TIBIAL OSTEOTOMY
2148	IMP/MD/2020/000243	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VALVED INFUSION CATHETER(CRAGG-MCNAMARA VALVED INFUSION CATHETERS (CRAGG-MCNAMARA 4F VALVED INFUSION CATHETERS AND CRAGG-MCNAMARA 5F VALVED INFUSION CATHETERS))-THE CRAGG-MCNAMARA™ VALVED INFUSION CATHETER IS INTENDED FOR THE CONTROLLED SELECTIVE INFUSION OF PHYSICIAN-SPECIFIED PHARMACOLOGICAL AGENTS OR RADIOPAQUE CONTRAST MEDIA INTO THE GENERAL VASCULATURE. ALL PHARMACOLOGIC AGENTS UTILIZED WITH THE INFUSION CATHETER SHOULD BE FULLY PREPARED AND USED ACCORDING TO INSTRUCTIONS FOR USE OF THE SPECIFIC PHARMACOLOGIC AGENT. THE INFUSION CATHETER IS NOT INTENDED FOR CORONARY, PEDIATRIC OR NEONATAL USE.

2149	IMP/MD/2020/000244	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL HIP REPLACEMENT SYSTEM(VERSYS HERITAGE® HIP PROSTHESIS - FEMORAL STEM)-• TOTAL HIP ARTHROPLASTY IS INDICATED FOR PATIENTS WITH: – SEVERE HIP PAIN AND DISABILITY DUE TO RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS OF THE FEMORAL HEAD, AND NONUNION OF PREVIOUS FRACTURES OF THE FEMUR. – CONGENITAL HIP DYSPLASIA, PROTRUSIO ACETABULI, OR SLIPPED CAPITAL FEMORAL EPIPHYSIS. – DISABILITY DUE TO PREVIOUS FUSION. – PREVIOUSLY FAILED ENDOPROSTHESES AND/OR TOTAL HIP COMPONENTS IN THE AFFECTED EXTREMITY. – ACUTE FEMORAL NECK FRACTURES. • HEMI-HIP ARTHROPLASTY IS INDICATED FOR: – FRACTURE DISLOCATION OF THE HIP. – ELDERLY, DEBILITATED PATIENTS WHEN A TOTAL HIP REPLACEMENT IS CONTRAINDICATED. – IRREDUCIBLE FRACTURES IN WHICH ADEQUATE FIXATION CANNOT BE OBTAINED. – CERTAIN HIGH SUBCAPITAL FRACTURES AND COMMINUTED FEMORAL FRACTURES IN THE AGED. – NONUNION OF FEMORAL NECK FRACTURES. – SECONDARY AVASCULAR NECROSIS OF THE FEMORAL HEAD. – PATHOLOGICAL FRACTURES OF THE FEMORAL NECK. – OSTEOARTHRITIS IN WHICH THE FEMORAL HEAD IS PRIMARILY AFFECTED.,PLATES AND SCREWS FOR TRAUMA FIXATION (ZIMMER PLATES AND SCREWS)-ZIMMER PLATES AND SCREWS (ZPS) ONE-THIRD TUBULAR PLATES, ONE-QUARTER TUBULAR PLATES, T-PLATES, L-BUTTRESS PLATES, COBRA PLATES, SEMI-TUBULAR PLATES, SYMPHYSEAL BRIDGE PLATES, RECONSTRUCTION PLATES, CONTOURABLE DUAL COMPRESSION PLATES, CLOVERLEAF AND SPOON PLATES ARE INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF OSTEOTOMIES AND FRACTURES SUCH AS: • COMMINUTED FRACTURES • SUPRACONDYLAR FRACTURES • EXTRA-ARTICULAR FRACTURES • FRACTURES IN OSTEOPENIC BONE • NONUNIONS • MALUNIONS SMALLER-SIZED ZPS PLATES ARE USED FOR SMALL BONES AND SMALL FRAGMENTS OF THE HANDS AND FEET. ZPS CALCANEAL PLATES ARE INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF OSTEOTOMIES AND FRACTURES OF THE CALCANEUS. ZPS AND FORTE SCREWS ARE TEMPORARY INTERNAL FIXATION DEVICES DESIGNED TO STABILIZE FRACTURES DURING THE NORMAL HEALING PROCESS. TEMPORARY INTERNAL FIXATION DEVICES DESIGNED TO STABILIZE FRACTURES DURING THE NORMAL HEALING PROCESS., TOTAL KNEE JOINT REPLACEMENT SYSTEM(NEXGEN® COMPLETE KNEE SOLUTION – ARTICULAR SURFACE)-1. THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY

	DUE TO: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. • POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. • THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. 2. CR-FLEX AND LPS-FLEX POROUS COATED FEMORAL AND TIBIAL BASEPLATE COMPONENTS MAY BE USED CEMENTED OR UNCEMENTED (BIOLOGICAL FIXATION). CR-FLEX HA/TCP POROUS COATED FEMORAL AND TIBIAL BASEPLATE COMPONENTS MAY ONLY BE USED UNCEMENTED. ALL OTHER FEMORAL, TIBIAL BASEPLATE AND ALL-POLYETHYLENE PATELLA COMPONENTS ARE INDICATED FOR CEMENTED USE ONLY. 3. SPECIFIC USES WITH CR-FLEX OR LPS-FLEX FEMORALS: • PROVIDES INCREASED FLEXION CAPABILITY FOR PATIENTS WHO HAVE BOTH THE FLEXIBILITY AND DESIRE TO INCREASE THEIR FLEXION RANGE. • THE CR-FLEX FEMORAL, WHEN USED WITH 90-PREFIX NEXGEN CR ARTICULAR SURFACES, 00-PREFIX 10, 12 OR 14 MM OR 90-PREFIX 17 OR 20 MM PROLONG® HIGHLY CROSSLINKED POLYETHYLENE CR ARTICULAR SURFACES, IS DESIGNED FOR USE WITH A FUNCTIONAL POSTERIOR CRUCIATE LIGAMENT AND WHEN LOAD BEARING RANGE OF MOTION (ROM) IS EXPECTED TO BE LESS THAN OR EQUAL TO 155 DEGREES. • THE LPS-FLEX FEMORAL, WHEN USED WITH THE LPS-FLEX ARTICULAR SURFACES, IS DESIGNED FOR USE WITH BOTH CRUCIATE LIGAMENTS EXCISED AND WHEN LOAD BEARING ROM IS EXPECTED TO BE LESS THAN OR EQUAL TO 155 DEGREES. 4. SPECIFIC USES WITH NEXGEN LPS OR LCCK FEMORALS: • THE LPS FEMORAL IS DESIGNED FOR USE WITH BOTH CRUCIATE LIGAMENTS EXCISED AND WHEN LOAD BEARING ROM IS EXPECTED TO BE LESS THAN OR EQUAL TO 130 DEGREES. • THE USAGE OF THE LCCK FEMORAL IS THE SAME AS THE LPS WITH THE EXCEPTION THAT FEMORAL BONE LOSS CAN BE ACCOMMODATED BY FEMORAL STEM EXTENSIONS AND AUGMENTATION. NO VARUS/VALGUS CONSTRAINT OR OTHER STABILITY OTHER THAN THAT PROVIDED BY THE NEXGEN LPS IS PROVIDED WHEN THE LCCK FEMORAL COMPONENT IS USED WITH THE LPS-FLEX ARTICULAR SURFACES.,ACETABULAR CUP SYSTEM (TRILOGY® ACETABULAR SYSTEM – SHELL AND SCREW)-THE TRILOGY ACETABULAR SYSTEM IS INDICATED FOR EITHER CEMENTED OR UNCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY OR REVISION SURGERY FOR REHABILITATING HIPS DAMAGED AS A RESULT OF

	NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, PROTRUSIO ACETABULI, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT.,TOTAL KNEE JOINT REPLACEMENT SYSTEM (PERSONA THE PERSONALIZED KNEE SYSTEM – ARTICULAR SURFACE)-WHEN A MECHANICAL ALIGNMENT APPROACH IS UTILIZED, THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: – RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. – COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. – POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. – MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. – THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. WHEN A KINEMATIC ALIGNMENT APPROACH IS UTILIZED, THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: – RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. – COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. – MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. THE KINEMATIC ALIGNMENT (KA) SURGICAL TECHNIQUE MAY ONLY BE USED WITH PERSONA CR FEMORAL COMPONENTS, PERSONA CR OR UC ARTICULAR SURFACE COMPONENTS, AND CEMENTED NONPOROUS PERSONA TIBIAL COMPONENTS WITHOUT A STEM EXTENSION. POROUS COATED COMPONENTS MAY BE USED CEMENTED OR UNCEMENTED (BIOLOGICAL FIXATION). ALL OTHER FEMORAL, TIBIAL BASEPLATE, AND ALL-POLYETHYLENE (UHMWPE AND VEHXPE) PATELLA COMPONENTS ARE INDICATED FOR CEMENTED USE ONLY.,TOTAL KNEE JOINT REPLACEMENT SYSTEM(NEXGEN® COMPLETE KNEE SOLUTION – TIBIAL COMPONENT AND TAPER STEM PLUG)-1. THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS • COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE • POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY • MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES • THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. 2. CR AND

	LPS POROUS COATED FEMORAL AND TIBIAL BASEPLATE COMPONENTS MAY BE USED CEMENTED OR UNCEMENTED (BIOLOGICAL FIXATION). THE CR HYDROXYAPATITE/TRICALCIUM PHOSPHATE [HA/TCP] COATED FEMORAL OR TIBIAL BASEPLATE COMPONENTS MAY ONLY BE USED UNCEMENTED. ALL OTHER FEMORAL, TIBIAL BASEPLATE AND ALL-POLYETHYLENE PATELLA COMPONENTS ARE INDICATED FOR CEMENTED USE ONLY. 3. NEXGEN AUGMENTS THAT MAY BE USED WITH CEMENTED CR, CRA, PS, LPS, AND LCCK FEMORAL AND TIBIAL BASEPLATE COMPONENTS ARE INDICATED FOR CEMENTED USE ONLY. 4. NEXGEN TM TIBIAL TRAYS MAY BE USED WITH OR WITHOUT BONE CEMENT (BIOLOGICAL FIXATION). NEXGEN MIS TIBIAL PLATES AND KEELS ARE INTENDED FOR CEMENTED USE ONLY.,TOTAL KNEE JOINT REPLACEMENT SYSTEM(NEXGEN® COMPLETE KNEE SOLUTION – ALL POLY PATELLA – PROLONG)-THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. • POST TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. • THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. THIS DEVICE IS INDICATED FOR CEMENTED USE ONLY.,TOTAL KNEE JOINT REPLACEMENT SYSTEM(NEXGEN® COMPLETE KNEE SOLUTION – ALL POLY PATELLA)-THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. • POST TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. • THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. THIS DEVICE IS INDICATED FOR CEMENTED USE ONLY.,TOTAL KNEE JOINT REPLACEMENT SYSTEM(PERSONA THE PERSONALIZED KNEE SYSTEM – TIBIAL COMPONENT)-WHEN A MECHANICAL ALIGNMENT APPROACH IS UTILIZED, THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: – RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. – COLLAGEN DISORDERS, AND/OR AVASCULAR

	NECROSIS OF THE FEMORAL CONDYLE. – POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. – MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. – THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. WHEN A KINEMATIC ALIGNMENT APPROACH IS UTILIZED, THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: – RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. – COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. – MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. THE KINEMATIC ALIGNMENT (KA) SURGICAL TECHNIQUE MAY ONLY BE USED WITH PERSONA CR FEMORAL COMPONENTS, PERSONA CR OR UC ARTICULAR SURFACE COMPONENTS, AND CEMENTED NONPOROUS PERSONA TIBIAL COMPONENTS WITHOUT A STEM EXTENSION. POROUS COATED COMPONENTS MAY BE USED CEMENTED OR UNCEMENTED (BIOLOGICAL FIXATION). ALL OTHER FEMORAL, TIBIAL BASEPLATE, AND ALL-POLYETHYLENE (UHMWPE AND VEHXPE) PATELLA COMPONENTS ARE INDICATED FOR CEMENTED USE ONLY., TOTAL HIP REPLACEMENT SYSTEM(CPT® HIP SYSTEM - FEMORAL STEM)-THE CPT HIP SYSTEM IS INDICATED FOR CEMENTED USE IN: • PATIENTS SUFFERING FROM SEVERE HIP PAIN AND DISABILITY DUE TO RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS OF THE FEMORAL HEAD, AND NONUNION OF PREVIOUS FRACTURES OF THE FEMUR. • PATIENTS WITH CONGENITAL HIP DYSPLASIA, PROTRUSIO ACETABULI, OR SLIPPED CAPITAL FEMORAL EPIPHYSIS. • PATIENTS SUFFERING FROM DISABILITY DUE TO PREVIOUS FUSION. • PATIENTS WITH PREVIOUSLY FAILED ENDOPROSTHESES AND/OR TOTAL HIP COMPONENTS IN THE AFFECTED EXTREMITY. • PATIENTS WITH ACUTE FEMORAL NECK FRACTURES.,TOTAL HIP REPLACEMENT SYSTEM(VERSYS® HIP SYSTEM - CEMENTED REVISION/CALCAR (CRC) FEMORAL STEM AND BUILD UP BLOCKS)-THE VERSYS CRC HIP SYSTEM IS INDICATED FOR TOTAL HIP ARTHROPLASTY IN PATIENTS WHOSE BONE STOCK IS OF POOR QUALITY OR INADEQUATE FOR OTHER RECONSTRUCTION TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE FEMORAL HEAD, NECK, OR PORTIONS OF THE PROXIMAL FEMUR. ARTHROPLASTY SHOULD BE PERFORMED ONLY WHEN MORE CONSERVATIVE METHODS OF TREATMENT HAVE FAILED TO PROVIDE SYMPTOMATIC RELIEF AND WHEN THERE IS PROGRESSIVE DISABILITY.,HIP SYSTEM(MULTIPOLAR® BIPOLAR CUP – LINER)-USE

	OF THE MULTIPOLAR® BIPOLAR CUP IS INDICATED IN: • FRACTURE DISLOCATION OF THE HIP • ELDERLY, DEBILITATED PATIENTS WHEN A TOTAL HIP REPLACEMENT IS CONTRAINDICATED • IRREDUCIBLE FRACTURES IN WHICH ADEQUATE FIXATION CANNOT BE OBTAINED • CERTAIN HIGH SUBCAPITAL FRACTURES AND COMMINUTED FEMORAL NECK FRACTURES IN THE AGED • NON-UNION OF FEMORAL NECK FRACTURES • SECONDARY AVASCULAR NECROSIS OF THE FEMORAL HEAD • PATHOLOGICAL FRACTURES OF THE FEMORAL NECK • OSTEOARTHRITIS IN WHICH THE FEMORAL HEAD IS PRIMARILY AFFECTED.,HIP SYSTEM(MULTIPOLAR® BIPOLAR CUP – SHELL)-USE OF THE MULTIPOLAR® BIPOLAR CUP IS INDICATED IN: • FRACTURE DISLOCATION OF THE HIP • ELDERLY, DEBILITATED PATIENTS WHEN A TOTAL HIP REPLACEMENT IS CONTRAINDICATED • IRREDUCIBLE FRACTURES IN WHICH ADEQUATE FIXATION CANNOT BE OBTAINED • CERTAIN HIGH SUBCAPITAL FRACTURES AND COMMINUTED FEMORAL NECK FRACTURES IN THE AGED • NON-UNION OF FEMORAL NECK FRACTURES • SECONDARY AVASCULAR NECROSIS OF THE FEMORAL HEAD • PATHOLOGICAL FRACTURES OF THE FEMORAL NECK • OSTEOARTHRITIS IN WHICH THE FEMORAL HEAD IS PRIMARILY AFFECTED,TOTAL HIP REPLACEMENT SYSTEM (VERSYS® HIP SYSTEM - FEMORAL HEADS)-FEMORAL HEADS ARE INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY; THE UNIPOLAR ENDOPROSTHESIS FEMORAL HEADS ARE INTENDED FOR USE IN HEMI-HIP ARTHROPLASTY. REFER TO THE FEMORAL STEM PACKAGE INSERT FOR THE FULL DESCRIPTION OF INDICATIONS FOR THE CONSTRUCT.,ACETABULAR CUP SYSTEM(TRILOGY® ACETABULAR SYSTEM – LINER)-THE TRILOGY ACETABULAR SYSTEM IS INDICATED FOR EITHER CEMENTED OR UNCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY OR REVISION SURGERY FOR REHABILITATING HIPS DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, PROTRUSIO ACETABULI, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT.,TOTAL KNEE JOINT REPLACEMENT SYSTEM (PERSONA THE PERSONALIZED KNEE SYSTEM – FEMORAL COMPONENT)-WHEN A MECHANICAL ALIGNMENT APPROACH IS UTILIZED, THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: – RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. – COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. – POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. – MODERATE

	VALGUS, VARUS, OR FLEXION DEFORMITIES. – THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. WHEN A KINEMATIC ALIGNMENT APPROACH IS UTILIZED, THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: – RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. – COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. – MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. THE KINEMATIC ALIGNMENT (KA) SURGICAL TECHNIQUE MAY ONLY BE USED WITH PERSONA CR FEMORAL COMPONENTS, PERSONA CR OR UC ARTICULAR SURFACE COMPONENTS, AND CEMENTED NONPOROUS PERSONA TIBIAL COMPONENTS WITHOUT A STEM EXTENSION. POROUS COATED COMPONENTS MAY BE USED CEMENTED OR UNCEMENTED (BIOLOGICAL FIXATION). ALL OTHER FEMORAL, TIBIAL BASEPLATE, AND ALL-POLYETHYLENE (UHMWPE AND VEHXPE) PATELLA COMPONENTS ARE INDICATED FOR CEMENTED USE ONLY.,TOTAL KNEE JOINT REPLACEMENT SYSTEM(PERSONA THE PERSONALIZED KNEE SYSTEM – PATELLA COMPONENT)-THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: – RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. – COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. – POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. – MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. – THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. POROUS COATED COMPONENTS MAY BE USED CEMENTED OR UNCEMENTED (BIOLOGICAL FIXATION). ALL OTHER FEMORAL, TIBIAL BASEPLATE AND ALL-POLYETHYLENE (UHMWPE AND VEHXPE) PATELLA COMPONENTS ARE INDICATED FOR CEMENTED USE ONLY.,PLATES AND SCREWS FOR TRAUMA FIXATION(ZIMMER PLATES AND SCREWS) -ZIMMER PLATES AND SCREWS (ZPS) ONE-THIRD TUBULAR PLATES, ONE-QUARTER TUBULAR PLATES, T-PLATES, L-BUTTRESS PLATES, COBRA PLATES, SEMI-TUBULAR PLATES, SYMPHYSEAL BRIDGE PLATES, RECONSTRUCTION PLATES, CONTOURABLE DUAL COMPRESSION PLATES, CLOVERLEAF AND SPOON PLATES ARE INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF OSTEOTOMIES AND FRACTURES, SUCH AS: • COMMINUTED FRACTURES • SUPRACONDYLAR FRACTURES • EXTRA-ARTICULAR FRACTURES • FRACTURES IN OSTEOPENIC BONE •

	NONUNIONS • MALUNIONS SMALLER-SIZED ZPS PLATES ARE USED FOR SMALL BONES AND SMALL FRAGMENTS OF THE HANDS AND FEET. ZPS CALCANEAL PLATES ARE INDICATED FOR TEMPORARY INTERNAL FIXATION AND STABILIZATION OF OSTEOTOMIES AND FRACTURES OF THE CALCANEUS. ZPS AND FORTE SCREWS ARE TEMPORARY INTERNAL FIXATION DEVICES DESIGNED TO STABILIZE FRACTURES DURING THE NORMAL HEALING PROCESS. TEMPORARY INTERNAL FIXATION DEVICES DESIGNED TO STABILIZE FRACTURES DURING THE NORMAL HEALING PROCESS.,TOTAL KNEE JOINT REPLACEMENT SYSTEM(NEXGEN® COMPLETE KNEE SOLUTION – STEM EXTENSIONS)-1. THIS DEVICE IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: O RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. O COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. O POST TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY O MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES. O THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS OR FOR A KNEE IN WHICH SATISFACTORY STABILITY IN FLEXION CANNOT BE OBTAINED AT THE TIME OF SURGERY. 2. CR AND LPS POROUS COATED FEMORAL AND TIBIAL BASEPLATE COMPONENTS MAY BE USED CEMENTED OR UNCEMENTED (BIOLOGICAL FIXATION). THE CR HYDROXYAPATITE/TRICALCIUM PHOSPHATE [HA/TCP] COATED FEMORAL OR TIBIAL BASEPLATE COMPONENTS MAY ONLY BE USED UNCEMENTED. ALL OTHER FEMORAL, TIBIAL BASEPLATE AND ALL-POLYETHYLENE PATELLA COMPONENTS ARE INDICATED FOR CEMENTED USE ONLY. 3. NEXGEN AUGMENTS THAT MAY BE USED WITH CEMENTED CR, CRA, PS, LPS, AND LCCK FEMORAL AND TIBIAL BASEPLATE COMPONENTS ARE INDICATED FOR CEMENTED USE ONLY. 4. NEXGEN TM TIBIAL TRAYS MAY BE USED WITH OR WITHOUT BONE CEMENT (BIOLOGICAL FIXATION). NEXGEN MIS TIBIAL PLATES AND KEELS ARE INTENDED FOR CEMENTED USE ONLY.,TOTAL HIP REPLACEMENT SYSTEM (ZIMTRON MODULAR HEAD)-FEMORAL HEADS ARE INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY; THE UNIPOLAR ENDOPROSTHESIS FEMORAL HEADS ARE INTENDED FOR USE IN HEMI-HIP ARTHROPLASTY. REFER TO THE FEMORAL STEM PACKAGE INSERT FOR THE FULL DESCRIPTION OF INDICATIONS FOR THE CONSTRUCT.

2150	IMP/MD/2020/000245	1.License Holder Name: MN SOLUTIONS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DRUG ELUTING BALLOON CATHETERS(ACOART ORCHID)-THE DRUG ELUTING BALLOON (DEB) CATHETERS ARE INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN PATIENTS WITH OBSTRUCTIVE DISEASE OF PERIPHERAL ARTERIES.,DRUG ELUTING BALLOON CATHETERS (ACOART LITOS)-THE DRUG ELUTING BALLOON (DEB) CATHETERS ARE INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN PATIENTS WITH OBSTRUCTIVE DISEASE OF PERIPHERAL ARTERIES.,DRUG ELUTING BALLOON CATHETERS(ACOART TULIP)-THE DRUG ELUTING BALLOON (DEB) CATHETERS ARE INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN PATIENTS WITH OBSTRUCTIVE DISEASE OF PERIPHERAL ARTERIES.
2151	IMP/MD/2020/000246	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENT PLASMA WAND SURGICAL DEVICES(COBLATION HALO WAND)-THE COBLATION HALO WAND, USED WITH THE WEREWOLF COBLATION SYSTEM, IS INDICATED FOR ABLATION, RESECTION AND COAGULATION OF SOFT TISSUE AND HEMOSTASIS OF BLOOD VESSELS IN OTORHINOLARYNGOLOGY (ENT) SURGERY INCLUDING: TONSILLECTOMY, ADENOIDECTOMY, AND UVULOPALATOPHARYNGOPLASTY (UPPP). IT IS INTENDED FOR PROCEDURES USING A CONDUCTIVE MEDIA, SUCH AS NORMAL SALINE OR RINGER'S LACTATE.
2152	IMP/MD/2020/000247	1.License Holder Name: GLAND PHARMA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BULK SYRINGES(NIL)-THE PRE-FILLABLE SYRINGES CAN BE CONSIDERED A COMPONENT OF THE SO-CALLED PRE-FILLED SYRINGES. THEY WILL BE FILED WITH THE DRUG CLOSED WITH THE PLUNGER AND PUT IN THE COMMERCE BY THE PHARMACEUTICAL INDUSTRY,PRE-FILLABLE SYRINGES(EZ-FILL)- THE PRE-FILLABLE SYRINGES CAN BE CONSIDERED A COMPONENT OF THE SO-CALLED PRE-FILLED SYRINGES. THEY WILL BE FILED WITH THE DRUG CLOSED WITH THE PLUNGER AND PUT IN THE COMMERCE BY THE PHARMACEUTICAL INDUSTRY

2153	IMP/MD/2020/000248	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHODONTIC TUBE (TITANIUM) (TITANIUM BUCCAL TUBE)-INTENDED TO BE APPLIED TO A PATIENT'S 1ST AND 2ND MOLARS IN ORDER TO CORRECT MALOCCLUSION.,ORTHODONTIC WIRES (STAINLESS STEEL)(BROAD ARCHWIRE, D-RECT ARCHWIRE , RESPOND ARCHWIRE , STAINLESS STEEL ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH,ORTHODONTIC WIRES (NICKLE TITANIUM) (NI-TI ARCHWIRE, TRU-ARCH ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH ,ORTHODONTIC TUBE (STAINLESS STEEL) (ACCENT MINI BUCCAL TUBES, SL BUCCAL TUBE, SNAPLINK)-INTENDED TO BE APPLIED TO A PATIENT'S 1ST AND 2ND MOLARS IN ORDER TO CORRECT MALOCCLUSION.,ORTHODONTIC WIRES (BETA TITANIUM) (TMA ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH, ORTHODONTIC WIRES (COPPER NICKEL TITANIUM)(BROAD ARCHWIRE , COPPER NI-TI ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH
2154	IMP/MD/2020/000249	1.License Holder Name: BAUSCH & LOMB INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOLDABLE ASPHERIC INTRAOCULAR LENSES(FOCUS FORCE ASPHERIC)-FOCUS FORCE ASPHERIC FOLDABLE POSTERIOR CHAMBER IOLS ARE INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,FOLDABLE LNTRAOCULAR LENS (FOCUS FORCE BASIC)-FOCUS FORCE BASIC F260 FOLDABLE POSTERIOR CHAMBER IOLS ARE INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.
2155	IMP/MD/2020/000250	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NASAL CANNULA (HUDSON RCI® SOFTECH® NASAL CANNULA)-NASAL CANNULAS ARE USED TO DELIVER A LOW FLOW OF OXYGEN TO THE PATIENT THROUGH THE NASAL PASSAGE.

2156	IMP/MD/2020/000251	1.License Holder Name: ABP MEDTECH 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FIBER AND PROBE(LGO)-FIBERS ARE FOR APPLICATION IN THE PHLEBOLOGY IN ORDER TO PERMANENTLY SEAL OR SCLEROSE VARICOSE VEINS UNDER THE SKIN. PROBE IS FOR MEDICAL APPLICATION IN PROCTOLOGY FOR OBLITERATION AND SHRINKAGE OF TISSUE IN THE HEMORRHOIDAL PILE.
2157	IMP/MD/2020/000252	1.License Holder Name: A. MENARINI INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MONOFILAMENT SYNTHETIC ABSORBABLE SKIN SUPPORT AND FILLING THREAD STERILE(DEFINISSE)-DEFINISSE IS INDICATED FOR USE IN PLASTIC AND AESTHETIC MEDICINE AND/OR RECONSTRUCTIVE SURGERY.
2158	IMP/MD/2020/000253	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEBULIZER(HUDSON RCI® MICRO MIST® NEBULIZER)-THE SMALL VOLUME NEBULIZERS ARE USED FOR INTERMITTENT AEROSOL THERAPY TO DELIVER HYDRATING AGENTS OR OTHER PRESCRIBED SOLUTIONS FOR INHALATION.,NASAL CANNULA(HUDSON RCI®)-NASAL CANNULAS ARE USED TO DELIVER A LOW FLOW OF OXYGEN TO THE PATIENT THROUGH THE NASAL PASSAGE.
2159	IMP/MD/2020/000254	1.License Holder Name: STRAUMANN DENTAL INDIA LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANTS (STRAUMANN)-STRAUMANN IMPLANTS ARE SUITABLE FOR THE TREATMENT OF ORAL ENDOSTEAL IMPLANTATION IN THE JAW AND FOR THE FUNCTIONAL ORAL REHABILITATION OF EDENTULOUS AND PARTIAL EDENTULOUS PATIENTS (UNLESS SPECIFIC INDICATIONS AND LIMITATIONS ARE SPECIFIED),DENTAL IMPLANTS(STRAUMANN)-STRAUMANN IMPLANTS ARE SUITABLE FOR THE TREATMENT OF ORAL ENDOSTEAL IMPLANTATION IN THE JAW AND FOR THE FUNCTIONAL ORAL REHABILITATION OF EDENTULOUS AND PARTIAL EDENTULOUS PATIENTS (UNLESS SPECIFIC INDICATIONS AND LIMITATIONS ARE SPECIFIED)

2160	IMP/MD/2020/000255	1.License Holder Name: BAUSCH & LOMB INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRA OCULAR LENS (INCISE MICROINCISION IOL)-THE INCISE MICROINCISION POSTERIOR CHAMBER LENS IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WHERE A CATARACTOUS LENS HAS BEEN REMOVED. THE LENS IS DESIGNED TO BE FOLDED PRIOR TO INSERTION IN THE EYE AND IMPLANTATION IN THE CAPSULAR BAG.
2161	IMP/MD/2020/000256	1.License Holder Name: GLOBE BIO MEDICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTA CATHETER (ANDRABALLOON & ANDRA2BLLOON)-THE ANDRABALLOON PTA CATHETER IS A DOUBLE-LUMEN CATHETER WITH A BALLOON THAT MAINTAINS ITS SHAPE (NON-COMPLIANT). ANDRABALLOON BALLOON DILATATION CATHETERS ARE USED TO DILATE NARROW VESSEL SEGMENTS.,RETRIEVAL DEVICE(ANDRASNARE AND ANDRASNARE MICRO)-THE ANDRASNARE IS A FLEXIBLE SNARE FOR THE INTERVENTIONAL RETRIEVAL OF FOREIGN BODIES FROM VESSELS OR HOLLOW VISCERA.,PERIPHERAL STENT(ANDRASTENT)-THE ANDRASTENT UXL/XXL IS BALLOON-EXPANDABLE AND LASER-CUTED OF COBALT CHROMIUM MP35N. LT IS DELIVERED UN-MOUNTED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). A PTA BALLOON CATHETER IS USED FOR IMPLANTATION OF THE STENT.

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2162	IMP/MD/2020/000257	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHRONIC DRAINAGE ACCESSORIES(PLEURX PROCEDURE PACK)-THE PLEURX PROCEDURE PACK IS INDICATED FOR DRESSING OF THE PLEURX PLEURAL OR PERITONEAL CATHETER AND EXIT SITE.,CHRONIC DRAINAGE ACCESSORIES(PLEURX LOCKABLE DRAINAGE LINE KIT)-THE LOCKABLE DRAINAGE LINE KIT IS INDICATED FOR USE ONLY WITH THE PLEURX CATHETER FOR INTERMITTENT DRAINAGE. THE LOCKABLE DRAINAGE LINE KIT IS USED TO DRAIN FLUID USING STANDARD WALL SUCTION, WATER SEAL DRAINAGE SYSTEM, GLASS VACUUM BOTTLE, OR OTHER APPROPRIATE METHOD (PORTABLE SUCTION).,CHRONIC DRAINAGE ACCESSORIES(PLEURX CATHETER ACCESS KIT)-THE PLEURX CATHETER ACCESS KIT IS INTENDED TO PROVIDE ACCESS TO THE PLEURX CATHETER TO INJECT AND WITHDRAW FLUIDS.,CHRONIC DRAINAGE KIT(PLEURX DRAINAGE KIT) -THE PLEURX DRAINAGE KITS ARE INDICATED FOR USE ONLY WITH THE PLEURX CATHETER FOR INTERMITTENT DRAINAGE.
2163	IMP/MD/2020/000258	1.License Holder Name: COLOPLAST INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERISTOMAL/ PERIWOUND DRESSING - PASTE(BRAVA)-THE BRAVA PASTE IS INTENDED TO FILL IN CAVITIES/FOLDS IN THE INTACT SKIN AROUND THE STOMA. THIS PROVIDES A SEAL BETWEEN THE STOMA AND THE OSTOMY BASEPLATE AND PROTECTS THE SKIN AGAINST THE STOMA OUTPUT.,PERISTOMAL/ PERIWOUND DRESSING - MOULDABLE RING (BRAVA)-BRAVA MOULDABLE RING IS INTENDED TO FILL IN CAVITIES/ FOLDS IN THE INTACT SKIN AROUND THE STOMA. THIS PROVIDES A SEAL BETWEEN THE STOMA AND THE OSTOMY BASEPLATE AND PROTECTS THE SKIN AGAINST THE STOMA OUTPUT., PERISTOMAL/ PERIWOUND DRESSING - PROTECTIVE SEAL(BRAVA)-PROTECTIVE SEAL IS INTENDED TO PROVIDE A SEAL BETWEEN INTACT PERISTOMAL SKIN AND AN OSTOMY BASE PLATE, THEREBY PROTECTING THE SKIN AGAINST STOMA OUTPUT. THE PRODUCT IS DESIGNED TO FILL IN CAVITIES/FOLDS IN THE PERISTOMAL SKIN.

2164	IMP/MD/2020/000259	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINE IMPLANT-NON-STERILE(VBOSS)-THE STRYKER SPINE VERTEBRAL BODY SUPPORT SYSTEM IMPLANT IS A DEVICE INTENDED TO REPLACE A VERTEBRAL BODY OR AN ENTIRE VERTEBRA. IT IS FOR USE IN ALL LEVELS OF SPINE (C1-L5) TO REPLACE A COLLAPSED, DAMAGED, OR UNSTABLE VERTEBRAL BODY OR VERTEBRA DUE TO TUMOR OR TRAUMA (I.E., FRACTURE). FOR BOTH CORPECTOMY AND VERTEBRECTOMY PROCEDURES, THE STRYKER SPINE VERTEBRAL BODY SUPPORT SYSTEM IS INTENDED TO BE USED WITH SUPPLEMENTAL INTERNAL FIXATION SYSTEMS. THE USE OF BONE GRAFT WITH THE STRYKER SPINE VERTEBRAL BODY SUPPORT SYSTEM IS OPTIONAL.,ONE-LEVEL PLATE NON-STERILE(REFLEX HYBRID)-THE ACP SYSTEMS ARE INTENDED FOR ANTERIOR INTERVERTEBRAL SCREW FIXATION OF THE CERVICAL SPINE FROM C2 – T1. THESE SYSTEMS ARE INDICATED FOR TEMPORARY STABILIZATION OF THE ANTERIOR SPINE DURING THE DEVELOPMENT OF CERVICAL SPINE FUSIONS IN PATIENTS WITH THE FOLLOWING INDICATIONS: • DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF ISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES) • DECOMPRESSION OF THE SPINAL CORD FOLLOWING TOTAL OR PARTIAL CERVICAL VERTEBRECTOMY • TRAUMA (INCLUDING FRACTURES) • TUMORS • DEFORMITIES OR CURVATURES (INCLUDING KYPHOSIS, LORDOSIS OR SCOLIOSIS) • PSEUDOARTHROSIS • FAILED PREVIOUS FUSIONS • SPONDYLOLISTHESIS • SPINAL STENOSIS,VITALLIUM ROD-NON-STERILE(OASYS)-: STRYKER SPINE OASYS® SYSTEM IS INDICATED FOR: • DEGENERATIVE DISC DISEASE (AS DE_NED BY NECK OR BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES) • SPONDYLOLISTHESIS • SPINAL STENOSIS • FRACTURE/DISLOCATION • ATLANTOAXIAL FRACTURE WITH INSTABILITY • OCCIPITOCERVICAL DISLOCATION • REVISION OF PREVIOUS SPINE SURGERY • TUMORS THE STRYKER SPINE OASYS® SYSTEM CAN ALSO BE LINKED TO THE XIA®, OPUSTM, DIAPASONTM, SR90D, OSTEONICS AND XIA® 4.5 SPINAL SYSTEMS VIA THE ROD-TO-ROD CONNECTORS OR TRANSITION RODS, AND POLYAXIAL SCREWS OF XIA® II AND XIA® 3 SYSTEMS VIA THE SADDLE CONNECTOR,SELF DRILLING SCREW-NON STERILE(REFLEX HYBRID)-THE ACP SYSTEMS ARE INTENDED FOR ANTERIOR INTERVERTEBRAL SCREW FIXATION OF THE CERVICAL SPINE FROM C2 – T1. THESE SYSTEMS ARE INDICATED FOR TEMPORARY STABILIZATION OF THE ANTERIOR SPINE DURING THE DEVELOPMENT OF CERVICAL SPINE FUSIONS IN PATIENTS WITH THE

	FOLLOWING INDICATIONS: • DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF ISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES) • DECOMPRESSION OF THE SPINAL CORD FOLLOWING TOTAL OR PARTIAL CERVICAL VERTEBRECTOMY • TRAUMA (INCLUDING FRACTURES) • TUMORS • DEFORMITIES OR CURVATURES (INCLUDING KYPHOSIS, LORDOSIS OR SCOLIOSIS) • PSEUDOARTHROSIS • FAILED PREVIOUS FUSIONS • SPONDYLOLISTHESIS • SPINAL STENOSIS,SPINE SCREW (COBALT CHROMIUM MOLYBDENUM)-NON STERILE(XIA)-THE XIA SPINAL SYSTEM IS INTENDED FOR ANTERIOR/ANTEROLATERAL AND POSTERIOR, NONCERVICAL PEDICLE AND NON-PEDICLE FIXATION OF THE SPINE TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E.,SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS), TUMOR, PSEUDOARTHROSIS AND FAILED PREVIOUS FUSION, TITANIUM ROD -NON-STERILE(OASYS)-STRYKER SPINE OASYS® SYSTEM IS INDICATED FOR: • DEGENERATIVE DISC DISEASE (AS DE_NED BY NECK OR BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES) • SPONDYLOLISTHESIS • SPINAL STENOSIS • FRACTURE/DISLOCATION • ATLANTOAXIAL FRACTURE WITH INSTABILITY • OCCIPITOCERVICAL DISLOCATION • REVISION OF PREVIOUS SPINE SURGERY • TUMORS THE STRYKER SPINE OASYS® SYSTEM CAN ALSO BE LINKED TO THE XIA®, OPUSTM, DIAPASONTM, SR90D, OSTEONICS AND XIA® 4.5 SPINAL SYSTEMS VIA THE ROD-TO-ROD CONNECTORS OR TRANSITION RODS, AND POLYAXIAL SCREWS OF XIA® II AND XIA® 3 SYSTEMS VIA THE SADDLE CONNECTOR,SPINE SCREW-MONOAXIAL (STAINLESS STEEL / TITANIUM)-NON-STERILE (XIA)-THE XIA SPINAL SYSTEM IS INTENDED FOR ANTERIOR/ANTEROLATERAL AND POSTERIOR, NONCERVICAL PEDICLE AND NON-PEDICLE FIXATION OF THE SPINE TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E.,

	SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS), TUMOR, PSEUDOARTHROSIS AND FAILED PREVIOUS FUSION,SPINAL IMPLANT NON STERILE(OASYS)-STRYKER SPINE OASYS® SYSTEM IS INDICATED FOR: • DEGENERATIVE DISC DISEASE (AS DE_NED BY NECK OR BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES) • SPONDYLOLISTHESIS • SPINAL STENOSIS • FRACTURE/DISLOCATION • ATLANTOAXIAL FRACTURE WITH INSTABILITY • OCCIPITOCERVICAL DISLOCATION • REVISION OF PREVIOUS SPINE SURGERY • TUMORS THE STRYKER SPINE OASYS® SYSTEM CAN ALSO BE LINKED TO THE XIA®, OPUSTM, DIAPASONTM, SR90D, OSTEONICS AND XIA® 4.5 SPINAL SYSTEMS VIA THE ROD-TO-ROD CONNECTORS OR TRANSITION RODS, AND POLYAXIAL SCREWS OF XIA® II AND XIA® 3 SYSTEMS VIA THE SADDLE CONNECTOR,SPINE IMPLANT-NON-STERILE(XIA)-THE XIA SPINAL SYSTEM IS INTENDED FOR ANTERIOR/ANTEROLATERAL AND POSTERIOR, NONCERVICAL PEDICLE AND NON-PEDICLE FIXATION OF THE SPINE TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS), TUMOR, PSEUDOARTHROSIS AND FAILED PREVIOUS FUSION,AS PEEK SPACER-NON-STERILE(SOLIS)-THE SOLIS® CERVICAL CAGE & SOLIS® AS PEEK SPACER ARE INDICATED FOR THE TREATMENT OF CERVICAL DEGENERATIVE SPINE DISORDERS, DISCAL AND VERTEBRAL INSTABILITY AS WELL AS IN CASES OF CERVICAL SPINE REVISION SURGERY. IT IS RECOMMENDED TO PACK BONE GRAFT MATERIAL INSIDE THE IMPLANT. THE SOLIS® CERVICAL CAGE INCORPORATES SPIKES FOR FIXATION AND IS SUITABLE FOR STAND-ALONE USE ON ONE LEVEL FUSION ONLY. AN ANTERIOR FIXATION IS ECOMMENDED WHILE USING CAGES IN MORE THAN ONE DISC LEVEL. THIS DECISION IS THE SURGEON'S RESPONSIBILITY ACCORDING TO THE SITUATION OF EACH PATIENT (BONE QUALITY, PATHOLOGY, STABILITY OF THE SPINE). WHEN AN ANTERIOR PLATING FIXATION IS COMBINED WITH THE USE OF THE CAGE, THE SURGEON MUST REFER TO THE SPECIFIC RECOMMENDATIONS FOR THIS TYPE OF IMPLANT. THE SOLIS® AS PEEK SPACER IS INTENDED FOR USE WITH SUPPLEMENTAL FIXATION,TL PEEK SPACER-NON-STERILE(AVS)-THE AVSR TL PEEK SPACER IS INDICATED FOR THE TREATMENT OF SPONDYLOLISTHESIS, DEGENERATIVE SPINE DISORDERS, DISCAL

		AND VERTEBRAL INSTABILITY AS WELL AS IN CASES OF SPINE REVISION SURGERY. IT IS RECOMMENDED TO PACK BONE GRAFT MATERIAL INSIDE THE IMPLANT,BONE SCREW NON-STERILE(OASYS)-STRYKER SPINE OASYS® SYSTEM IS INDICATED FOR: • DEGENERATIVE DISC DISEASE (AS DE_NED BY NECK OR BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES) • SPONDYLOLISTHESIS • SPINAL STENOSIS • FRACTURE/DISLOCATION • ATLANTOAXIAL FRACTURE WITH INSTABILITY • OCCIPITOCERVICAL DISLOCATION • REVISION OF PREVIOUS SPINE SURGERY • TUMORS THE STRYKER SPINE OASYS® SYSTEM CAN ALSO BE LINKED TO THE XIA®, OPUSTM, DIAPASONTM, SR90D, OSTEONICS AND XIA® 4.5 SPINAL SYSTEMS VIA THE ROD-TO-ROD CONNECTORS OR TRANSITION RODS, AND POLYAXIAL SCREWS OF XIA® II AND XIA® 3 SYSTEMS VIA THE SADDLE CONNECTOR,SPINE IMPLANT-NON-STERILE(VBOSS)-THE STRYKER SPINE VERTEBRAL BODY SUPPORT SYSTEM IMPLANT IS A DEVICE INTENDED TO REPLACE A VERTEBRAL BODY OR AN ENTIRE VERTEBRA. IT IS FOR USE IN ALL LEVELS OF SPINE (C1-L5) TO REPLACE A COLLAPSED, DAMAGED, OR UNSTABLE VERTEBRAL BODY OR VERTEBRA DUE TO TUMOR OR TRAUMA (I.E., FRACTURE). FOR BOTH CORPECTOMY AND VERTEBRECTOMY PROCEDURES, THE STRYKER SPINE VERTEBRAL BODY SUPPORT SYSTEM IS INTENDED TO BE USED WITH SUPPLEMENTAL INTERNAL FIXATION SYSTEMS. THE USE OF BONE GRAFT WITH THE STRYKER SPINE VERTEBRAL BODY SUPPORT SYSTEM IS OPTIONAL
2165	IMP/MD/2020/000260	1.License Holder Name: YPSOMED INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC SYRINGES(YPSOPUMP RESERVOIR)-THE YPSOPUMP RESERVOIR IS INTENDED TO BE FILLED WITH A INSULIN AT USED WITH AN EXTERNAL COMPATIBLE INSULIN INFUSION PUMP.
2166	IMP/MD/2020/000261	1.License Holder Name: BIOCON BIOLOGICS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK)-COMPONENT OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS

2167	IMP/MD/2020/000266	1.License Holder Name: ADVANCED LIFESCIENCES PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IVAC 2L- PERCUTANEOUS SHORT-TERM LV MECHANICAL ASSIST DEVICE(PULSECATH)-THE IVAC 2L IS INTENDED FOR USE IN PATIENTS WITH IMPAIRED LEFT VENTRICULAR FUNCTION, WHICH REQUIRE LEFT VENTRICULAR MECHANICAL CIRCULATORY SUPPORT FOR A PERIOD UP TO 24 HOURS.
2168	IMP/MD/2020/000267	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOVENOUS RADIOFREQUENCY ABLATION (RFA) CATHETER(CLOSUREFAST)-THE CLOSUREFAST™ ENDOVENOUS RADIOFREQUENCY ABLATION (RFA) CATHETER IS INTENDED FOR ENDOVASCULAR COAGULATION OF BLOOD VESSELS IN PATIENTS WITH SUPERFICIAL VEIN REFLUX.
2169	IMP/MD/2020/000268	1.License Holder Name: TRANSLUMINA THERAPEUTICS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DUAL LUMEN CATHETER (CRUSADE)-CRUSADE IS INTENDED TO BE USED FOR; - GUIDE WIRE SUPPORT FOR CROSSING SIDE BRANCH - EXCHANGE OF GUIDE WIRES, DURING PERCUTANEOUS CORONARY INTERVENTION (PCI) , ASPIRATION CATHETER(THROMBUSTER II)-THROMBUSTER IS INTENDED FOR USE TO REMOVE THROMBUS AND DEBRIS IN THE CORONARY OR PERIPHERAL ARTERIES BY PERCUTANEOUS SUCTION.
2170	IMP/MD/2020/000270	1.License Holder Name: TECHNOMED INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TISSUE EXPANDERS (POLYTECH)-EXPANDERS ARE SURGICALLY INVASIVE PRODUCTS FOR TEMPORARY EXTENSION OF TISSUE AND SKIN.,MAMMARY IMPLANTS(POLYTECH)-MAMMARY IMPLANTS ARE INTENDED TO BE USED IN RECONSTRUCTIVE OR AESTHETIC SURGERY FOR RECONSTRUCTION OR AUGMENTATION OF THE BREAST.

2171	IMP/MD/2020/000271	1.License Holder Name: C V TECHNOLOGIES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTFE VASCULAR GRAFTS (AVATAR)-AVATAR®PTFE VASCULAR GRAFTS ARE INTENDED FOR USE IN ARTERIAL VASCULAR RECONSTRUCTION, SEGMENTAL BYPASS, AND FOR ARTERIOVENOUS VASCULAR ACCESS. THERE IS INSUFFICIENT DATA TO SUPPORT THE USE OF EPTFE GRAFTS IN THE CENTRAL CIRCULATORY SYSTEM E.G AORTOCORONARY BYPASS, OR FOR USE AS A PATCH.
2172	IMP/MD/2020/000272	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IV SETS(INFUSION SET (ALARIS™ PRODUCTS, ALARIS™ GW VOLUMETRIC PUMP, ASENA™ GW VOLUMETRIC PUMP, ALARIS™ GW 800 VOLUMTERIC PUMP))-ALARIS™ GW INFUSION SETS ARE DEDICATED INFUSION ADMINISTRATION SETS PROVIDING A FLEXIBLE STERILE FLUID PATH TO DELIVER INTRAVENOUS SOLUTIONS FROM A RESERVOIR TO THE INFUSION SITE AND ADMINISTER BLOOD FROM A CONTAINER TO PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO A VEIN. DELIVERY RATE IS CONTROLLED THROUGH PERISTALTIC COMPRESSION OF THE TUBING.,IV SETS(EXTENSION SET (ALARIS™ PRODUCTS, ALARIS™CC SYRINGE PUMP, ALARIS™ CC SYRINGE PUMP, IVAC™ 701/711/770/P7000 PUMPS))-THE INTENDED USE OF ALARIS™ CC EXTENSION SETS IS TO CHANNEL LIQUIDS FOR INFUSION PURPOSES. EXTENSION SETS CAN BE CONNECTED TO SYRINGES AND BE USED AS ADD-ON PRODUCTS TO PRIMARY ADMINISTRATION SETS TO LENGTHEN ACCESS PORTS. CONNECTIONS ARE MADE THROUGH MALE AND FEMALE LUER LOCK CONNECTORS.,GRAVITY IV SETS(ALARIS PRODUCTS. SMARTSITE NEEDLE-FREE SYSTEM. INFUSION SET. VENTED. 15M FILTER.)-THE INTENDED USE OF THE GRAVITY ADMINISTRATION SET RANGE IS TO PROVIDE A CONDUIT FOR FLUIDS INTENDED FOR INFUSION ENABLING CONNECTION TO A FLUID RESERVOIR AND A VENOUS-PUNCTURE DEVICE. GRAVITY ALONE PROVIDES THE SOURCE OF ENERGY FOR INFUSION.

2173	IMP/MD/2020/000273	1.License Holder Name: SMITHS MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERCUTANEOUS TRACHEOSTOMY KIT(PORTEX BLUE LINE ULTRA PEDIATRIC TRACHEOSTOMY TUBE)-THE PERCUTANEOUS TRACHEOSTOMY TECHNIQUE IS A NEW, MINIMALLY INVASIVE PROCEDURE WHICH OFFERS AN EASIER, MORE RAPID METHOD OF INSERTION OF A TRACHEOSTOMY TUBE THAN CONVENTIONAL OPEN SURGICAL TECHNIQUES. IT ALSO HAS THE ADVANTAGE IN THAT IT CAN BE PERFORMED AT THE BEDSIDE.,EPIDURAL CATHETERS(PORTEX)-A RANGE OF STERILE, SINGLE USE PACKS CONTAINING A VARIETY OF COMPONENTS FOR THE PLACEMENT OF AN EPIDURAL CATHETER INTO THE EPIDURAL SPACE TO ALLOW BOLUS INJECTIONS OR CONTINUOUS INFUSION OF LOCAL ANAESTHETIC OR OTHER DRUGS FOR PAIN RELIEF. THE RANGE IS AVAILABLE WITH A CHOICE OF COLOUR CODED 16G AND 18G EPIDURAL NEEDLES, CLEAR OR RADIOOPAQUE, CLOSED END, 3-LATERAL EYE AND CLOSER THREE EYE (CTE) OR OPEN END FORMED NYLON EPIDURAL CATHETERS. CONSULT PRODUCT LITERATURE FOR DETAILS/CODE NUMBERS. THE PAEDIATRIC 18G MINIPACK SYSTEM 1 (100/391/180) CONTAINS A PAEDIATRIC LENGTH (50MM) GRADUATED EPIDURAL TUOHY NEEDLE AND 18G EPIDURAL CATHETER (650MM). THE MINIPACK SYSTEM 1 (100/391/516-518) CONTAINS AN EXTRA LENGTH EPIDURAL TUOHY NEEDLE (110MM). THE 16G AND 18G EPIDURAL CATHETERS IN SYSTEM 3 PACKS ARE INTENDED FOR INTRODUCTION THROUGH 16G AND 18G EPIDURAL TUOHY NEEDLES RESPECTIVELY,PRESSURE MONITORING KITS(LOGICAL PRESSURE TRANSDUCERS)-THE SMITHS MEDICAL LOGICAL® PRESSURE TRANSDUCER IS A HEMODYNAMIC PRESSURE MONITORING SYSTEM THAT IS INTENDED FOR BLOOD PRESSURE MONITORING AND BLOOD SAMPLING,TRACHEOSTOMY TUBES(BLUE LINE ULTRA)-A STERILE RANGE OF SINGLE USE TRACHEOSTOMY TUBES MANUFACTURED FROM CLEAR BIOCOMPATIBLE POLYVINYL CHLORIDE (PVC) INCORPORATING THE FOLLOWING FEATURES: SMOOTH ARC SHAPED DESIGN WITH TAPERED TIP TO ASSIST PLACEMENT AND REMOVAL OF BOTH TRACHEOSTOMY TUBE AND SMOOTH INNER CANNULA WITH MINIMAL DISRUPTION TO PATIENT'S ANATOMY. THERMOSENSITIVE MATERIAL WITH SUFFICIENT INITIAL RIGIDITY FOR INSERTION WHICH THEN CONFORMS TO THE INDIVIDUAL PATIENT'S UPPER RESPIRATORY TRACT AT BODY TEMPERATURE ENSURING MINIMUM TRAUMA. 15MM CONNECTOR FOR CONNECTION TO ANAESTHETIC OR VENTILATOR BREATHING CIRCUIT IS LOCATED ON THE TUBE NOT THE INNER CANNULA. ANATOMICALLY SHAPED FLEXIBLE FLANGE FOR IMPROVED PATIENT COMFORT AND IMPROVED SECURITY OF THE TRACHEOSTOMY TUBE.

		NEW PROFILE® SOFT-SEAL® CUFF DESIGN WITH REDUCED BULK AND SMOOTH TRANSITION TO TRACHEOSTOMY TUBE TO IMPROVE EASE OF INSERTION. A HOLLOW OBTURATOR WITH ATRAUMATIC TIP FOR USE WITH OR WITHOUT GUIDE WIRE FOR IMPROVED EASE OF INSERTION. THE OBTURATOR RETAINING CLIPS PREVENT OBTURATOR MOVEMENT DURING INSERTION. THE REUSABLE FENESTRATED AND NON FENESTRATED INNER CANNULAE ARE COLOUR CODED FOR EASE OF IDENTIFICATION. FENESTRATED INNER CANNULAE ARE COLOURED RED. NON FENESTRATED INNER CANNULAE ARE CLEAR. THEY CAN BE EASILY INSERTED AND REMOVED FROM THE OUTER TUBE WITH A “RING PULL”. SELF-ADHESIVE ‘PATIENT NOTES LABEL’ PROVIDING TRACHEOSTOMY TUBE SIZE AND MANUFACTURING BATCH DETAILS. TRACHEOSTOMY FLANGE TAG’ PROVIDES TRACHEOSTOMY TUBE SIZE DETAILS AND INDICATING IF THE TUBE IS FENESTRATED.
2174	IMP/MD/2020/000274	1.License Holder Name: INTUITIVE SURGICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAPLER RELOAD (SUREFORM® 60 RELOAD)-STAPLER RELOADS ARE INTENDED TO BE USED WITH THE DA VINCI XI AND X SURGICAL SYSTEMS (MODELS IS4000 AND IS4200) FOR RESECTION, TRANSECTION AND/OR CREATION OF ANASTOMOSES IN GENERAL, THORACIC, GYNECOLOGIC AND UROLOGIC SURGERY. THE DEVICE CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIAL (NATURAL OR SYNTHETIC).,STAPLER RELOAD(SUREFORM® 45 RELOAD)-STAPLER RELOADS ARE INTENDED TO BE USED WITH THE DA VINCI XI AND X SURGICAL SYSTEMS (MODELS IS4000 AND IS4200) FOR RESECTION, TRANSECTION AND/OR CREATION OF ANASTOMOSES IN GENERAL, THORACIC, GYNECOLOGIC, UROLOGIC AND PEDIATRIC SURGERY. THE DEVICE CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIAL (NATURAL OR SYNTHETIC).,STAPLER RELOAD(ENDOWRIST® STAPLER 30 RELOAD; ENDOWRIST® STAPLER 45 RELOAD;)-STAPLER RELOADS ARE INTENDED TO BE USED WITH THE DA VINCI XI AND X SURGICAL SYSTEMS (MODELS IS4000 AND IS4200) FOR RESECTION, TRANSECTION AND/OR CREATION OF ANASTOMOSES IN GENERAL, THORACIC, GYNECOLOGIC AND UROLOGIC SURGERY. THE DEVICE CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIAL (NATURAL OR SYNTHETIC).

2175	IMP/MD/2020/000275	1.License Holder Name: STERANCO HEALTHCARE PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD-PROCESSING AUTOTRANSFUSION SYSTEM SET(HAEMONETICS CELL SAVER 5/5 + BOWL KIT-225 ML)-IT IS INTENDED TO BE USED ON THE CELL SAVER 5/5+ FOR THE RECOVERY OF BLOOD SHED DURING OR AFTER AN OPERATION, OR AS THE RESULT OF TRAUMA,BLOOD-PROCESSING AUTOTRANSFUSION SYSTEM SET(HAEMONETICS RESERVOIRS, HARD-SHELL,150)-IT IS INTENDED TO BE USED TO COLLECT ANTICOAGULATED WOUND BLOOD FOR SUBSEQUENT PROCESSING IN A CELL SAVER.,BLOOD-PROCESSING AUTOTRANSFUSION SYSTEM SET(HAEMONETICS ASPIRATION / ANTICOAGULATION SETS)-IT IS INTENDED TO BE USED TO ASPIRATE AND ANTI-COAGULATE WOUND BLOOD TO PASS IT THROUGH THE TUBING INTO A COLLECTION RESERVOIR.,BLOOD-PROCESSING AUTOTRANSFUSION SYSTEM SET (HAEMONETICS CELL SAVER ELITE PROCESSING KIT (225ML))-IT IS INTENDED TO BE USED ON THE CELL SAVER ELITE OR CELL SAVER ELITE+ TO RECOVER BLOOD SHED DURING OR SUBSEQUENT TO AN OPERATION OR AS A RESULT OF TRAUMA, PROCESSING THE BLOOD BY A CENTRIFUGATION AND WASHING PROCEDURE, AND PUMPING THIS PROCESSED RED CELL PRODUCT TO EITHER A BAG FOR GRAVITY REINFUSION INTO THE PATIENT OR TO THE ARTERIAL LINE OF AN EXTRACORPOREAL CIRCUIT FOR REINFUSION INTO THE PATIENT.

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2176	IMP/MD/2020/000276	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORAL/NASAL TRACHEAL TUBE CUFFLESS MURPHY EYE(CURITY)-THESE TRACHEAL TUBES ARE DESIGNED FOR ORAL OR NASAL INTUBATION AND ARE INDICATED FOR AIRWAY MANAGEMENT. ALTHOUGH UNCUFFED TRACHEAL TUBES ARE ORDINARILY USED IN PEDIATRIC AIRWAY MANAGEMENT, IN SOME CASES (E.G., PULMONARY FUNCTION TESTING OR ASPIRATION PROTECTION), USE OF A SMALL DIAMETER CUFFED TRACHEAL TUBE MAY BE INDICATED. THE PROPER DESIGNATION, "ORAL", "NASAL", OR "ORAL/NASAL" IS PRINTED ON THE TRACHEAL TUBE.,ORAL/NASAL TRACHEAL TUBE CUFFED MURPHY EYE(CURITY)-THESE TRACHEAL TUBES ARE DESIGNED FOR ORAL OR NASAL INTUBATION AND ARE INDICATED FOR AIRWAY MANAGEMENT. ALTHOUGH UNCUFFED TRACHEAL TUBES ARE ORDINARILY USED IN PEDIATRIC AIRWAY MANAGEMENT, IN SOME CASES (E.G., PULMONARY FUNCTION TESTING OR ASPIRATION PROTECTION), USE OF A SMALL DIAMETER CUFFED TRACHEAL TUBE MAY BE INDICATED. THE PROPER DESIGNATION, "ORAL", "NASAL", OR "ORAL/NASAL" IS PRINTED ON THE TRACHEAL TUBE.,HI-CONTOUR ORAL/NASAL TRACHEAL TUBE CUFFED MURPHY EYE (SHILEY)-STERILE SINGLE USE MEDICAL DEVICE TO ALLOW THE PASSAGE OF GAS MIXTURES DIRECTLY INTO THE LUNGS VIA THE MOUTH OR NOSE AND THE TRACHEA.
2177	IMP/MD/2020/000277	1.License Holder Name: EURASIA HEALTHCARE LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SINGLE USE HIGH PRESSURE ANGIOGRAPHIC SYRINGES AND ACCESSORIES (SYRINGES, COILED PATIENT TUBING AND SPIKES)(APORT)-SYRINGE FOR INJECTION OF CONTRAST MEDIA OR SALINE FOR CT AND MRI.,SINGLE USE HIGH PRESSURE ANGIOGRAPHIC SYRINGES(APORT)-SYRINGE FOR INJECTION OF CONTRAST MEDIA OR SALINE FOR CT AND MRI., SINGLE USE HIGH PRESSURE ANGIOGRAPHIC SYRINGES ACCESSORIES (SYRINGE AND SPIKE)(APORT)-SYRINGE FOR INJECTION OF CONTRAST MEDIA OR SALINE FOR CT AND MRI.,SINGLE USE HIGH PRESSURE ANGIOGRAPHIC SYRINGES ACCESSORIES-(SYRINGE AND J TUBE)(APORT)-SYRINGE FOR INJECTION OF CONTRAST MEDIA OR SALINE FOR CT AND MRI.

2178	IMP/MD/2020/000278	1.License Holder Name: AUSASIA LIFESCIENCES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER (HANAROSTENT BILIARY STENT)-THIS STENT IS INDICATED FOR PALLIATIVE TREATMENT OF BILE DUCT MALIGNANT AND/OR BENIGN STRICTURES.,CATHETER(HANAROSTENT / CHOOSTENT ESOPHAGUS STENT)-THIS STENT IS INDICATED FOR APPLICATION IN PALLIATIVE TREATMENT OF ESOPHAGEAL STRICTURE AND/OR TRACHEA-ESOPHAGEAL FISTULA CAUSED BY MALIGNANT AND/ OR BENIGN TUMORS.

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2179	IMP/MD/2020/000279	1.License Holder Name: HANSTRONICS MEDICAL EQUIPMENTS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VASCULAR SNARE KIT (ATRIEVE)-THE ATRIEVE™ VASCULAR SNARE KIT IS INTENDED FOR USE IN THE CARDIOVASCULAR SYSTEM OR HOLLOW VISCOUS TO RETRIEVE AND MANIPULATE FOREIGN OBJECTS. MANIPULATION PROCEDURES INCLUDE INDWELLING VENOUS CATHETER REPOSITIONING, INDWELLING VENOUS CATHETER FIBRIN SHEATH STRIPPING, AND CENTRAL VENOUS ACCESS VENI-PUNCTURE PROCEDURE ASSISTANCE.,THROMBECTOMY SYSTEM (CLEANER ROTATIONAL)-THE CLEANER ROTATIONAL THROMBECTOMY SYSTEM IS INDICATED FOR MECHANICAL DECLOTTING AND CONTROLLED AND SELECTIVE INFUSION OF PHYSICIAN-SPECIFIED FLUIDS, INCLUDING THROMBOLYTICS, IN THE PERIPHERAL VASCULATURE., BIOPSY INSTRUMENT (SUPERCORE)-DISPOSABLE GUILLOTINE SOFT TISSUE INSTRUMENT FOR OBTAINING PERCUTANEOUS OR SURGICAL HISTOLOGICAL SAMPLES, (E.G. LUNG, LIVER, SPLEEN, KIDNEY, PROSTATE, LYMPH NODES, BREAST, THYROID, AND PANCREAS)., RETRIEVABLE VENA CAVA FILTER(OPTION ELITE)-THE OPTION™ ELITE FILTER IS INDICATED FOR THE PREVENTION OF RECURRENT PULMONARY EMBOLISM (PE) VIA PERCUTANEOUS PLACEMENT IN THE INFERIOR VENA CAVA (IVC) IN THE FOLLOWING CONDITIONS: - PULMONARY THROMBOEMBOLISM WHEN ANTICOAGULANTS ARE CONTRAINDICATED - FAILURE OF ANTICOAGULANT THERAPY IN THROMBOEMBOLIC DISEASE - EMERGENCY TREATMENT FOLLOWING MASSIVE PULMONARY EMBOLISM WHERE ANTICIPATED BENEFITS OF CONVENTIONAL THERAPY ARE REDUCED - CHRONIC, RECURRENT PULMONARY EMBOLISM WHERE ANTICOAGULANT THERAPY HAS FAILED OR IS CONTRAINDICATED.,LIVER BIOPSY SYSTEM(TLAB TRANSJUGULAR)-FOR TRANSJUGULAR LIVER ACCESS BIOPSY.,FULL CORE BIOPSY INSTRUMENTS(BIO PINCE)-THE DISPOSABLE, AUTOMATIC BIOPINCE FULL CORE BIOPSY INSTRUMENT IS USED TO OBTAIN MULTIPLE CORE SAMPLES FROM SOFT TISSUE SUCH AS LIVER, KIDNEY, ABDOMINAL MASSES, ETC.,BIOPSY INSTRUMENT (TRU-CORE II)-THE TRU-CORE II AUTOMATIC BIOPSY INSTRUMENT IS USED TO OBTAIN MULTIPLE CORE SAMPLES FROM SOFT TISSUE SUCH AS LIVER, KIDNEY, PROSTATE, BREAST, ETC. AND NOT INTENDED FOR BONE.

2180	IMP/MD/2020/000280	1.License Holder Name: ADVANCED LIFESCIENCES PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BALLOON TIPPED CARDIAC CATHETERS(TYSHAK, TYSHAK II, TYSHAK-X, TYSHAK MINI, TYSHAK NUCLEUS, Z-MED, Z-MED II, Z-MED-X, Z-MED II-X, COEFFICIENT, NUCLEUS, NUCLEUS-X, MULLINS-X, MINI GHOST, Z-5)-THE DEVICES ARE INDICATED FOR THE FOLLOWING: PERCUTANEOUS TRANSLUMINAL DILATATION (TYSHAK, TYSHAK II, TYSHAK-X, TYSHAK MINI, TYSHAK NUCLEUS, Z-MED, Z-MED II, Z-MED-X, Z-MED II-X, NUCLEUS, NUCLEUS-X, COEFFICIENT, MULLINS-X, MINI GHOST), AND PERCUTANEOUS TRANSLUMINAL CATHETER FOR SEPTOSTOMY (Z-5).
2181	IMP/MD/2020/000281	1.License Holder Name: CARDINAL HEALTH MEDICAL PRODUCTS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTA DILATATION CATHETER(SLEEK)-THE SLEEK® OTW PTA BALLOON CATHETERS ARE INTENDED FOR BALLOON DILATATION OF THE FEMORAL, POPLITEAL AND INFRA-POPLITEAL ARTERIES. THESE CATHETERS ARE NOT DESIGNED TO BE USED IN THE CORONARY ARTERIES.
2182	IMP/MD/2020/000282	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CANNULA(ARGYLE SAFETY FISTULA CANNULA WITH ANTI-REFLUX VALVE)-ARGYLE FISTULA CANNULA IS USED FOR GAINING VASCULAR ACCESS FOR BLOOD REMOVAL AND BLOOD REINFUSION DURING DIALYSIS. THE NEEDLE-STICK PREVENTION FEATURE IS INTENDED TO MINIMIZE ACCIDENTAL NEEDLE-STICK INJURIES.
2183	IMP/MD/2020/000283	1.License Holder Name: MEDIHELP HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL DRESSINGS (EMERGENCY BANDAGE)-THE EMERGENCY BANDAGES, MULTI BANDAGES AND WOUNDSTOP BANDAGES ARE INTENDED TO BE USED AS A MECHANICAL BARRIER, FOR COMPRESSION TO INCREASE HEMORRHAGE CONTROL AND FOR ABSORPTION OF BLOOD FROM OPEN WOUNDS. IN ADDITION, THE MULTI-BANDAGES ARE A LARGE SIZED BANDAGE WITH AN OPTIONAL PLASTIC BARRIER, MAKING IT APPLICABLE FOR TREATING ABDOMINAL/EXPOSED ORGAN WOUNDS AND WOUNDS REQUIRING MOISTURE CONTAINMENT AT THE WOUND SITE.

2184	IMP/MD/2020/000284	1.License Holder Name: ANANTCO ENTERPRISES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE SYRINGE (WITH NEEDLE)(WEGO)-FOR PACKING AND ADMINISTERING PARENTERAL MEDICINAL PRODUCTS.
2185	IMP/MD/2020/000285	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STEERABLE GUIDEWIRE (AGILITY)-IT IS INTENDED FOR SELECTIVE PLACEMENT OF MICROCATHETERS AND OTHER DEVICES IN THE NEURO AND PERIPHERAL VASCULATURE,STEERABLE GUIDEWIRE(NEUROSCOUT)-IT IS INTENDED FOR SELECTIVE PLACEMENT OF MICROCATHETERS AND OTHER DEVICES IN THE NEURO AND PERIPHERAL VASCULATURE
2186	IMP/MD/2020/000286	1.License Holder Name: TRANSLUMINA THERAPEUTICS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SEMI- FINISHED ANGIOGRAPHIC CATHETER (BULK)(NA)-ANGIOGRAHIC CATHETERS ARE DESIGNED TO DELIVER RADIOPAQUE CONTRAST MEDIUM TO SELECTED SITES IN THE VASCULAR SYSTEM.

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2187	IMP/MD/2020/000287	1.License Holder Name: MEDICON SURGICAL TECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANEURYSM IMPLANT CLIP (YASARGIL ANEURYSM CLIPS)-PERMANENT YASARGIL ANEURYSM AND VESSEL CLIPS ARE INTENDED FOR PERMANENT OCCLUSION OF BLOOD VESSEL AND CEREBRAL ANEURYSM. LIKEWISE, TEMPORARY YASARGIL ANEURYSM AND VESSEL CLIPS ARE INTENDED FOR TEMPORARY OCCLUSION OF INTRA CRANIAL BLOOD VESSEL AND CEREBRAL ANEURYSM. BOTH PERMANENT AND TEMPORARY YASARGIL ANEURYSM AND VESSEL CLIPS ARE INTENDED FOR USE IN CLINICS AND PRACTICES BY TRAINED SURGEONS THOROUGHLY FAMILIAR WITH SURGICAL TECHNIQUE AND USE OF THESE DEVICES., ANEURYSM IMPLANT CLIP(YASARGIL ANEURYSM CLIP)-PERMANENT YASARGIL ANEURYSM AND VESSEL CLIPS ARE INTENDED FOR PERMANENT OCCLUSION OF BLOOD VESSEL AND CEREBRAL ANEURYSM. LIKEWISE, TEMPORARY YASARGIL ANEURYSM AND VESSEL CLIPS ARE INTENDED FOR TEMPORARY OCCLUSION OF INTRA CRANIAL BLOOD VESSEL AND CEREBRAL ANEURYSM. BOTH PERMANENT AND TEMPORARY YASARGIL ANEURYSM AND VESSEL CLIPS ARE INTENDED FOR USE IN CLINICS AND PRACTICES BY TRAINED SURGEONS THOROUGHLY FAMILIAR WITH SURGICAL TECHNIQUE AND USE OF THESE DEVICES.

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2188	IMP/MD/2020/000288	1.License Holder Name: FRESENIUS MEDICAL CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAY.SAFE® CATHETER EXTENSION LUER-LOCK-FIELD OF APPLICATION: PERITONEAL DIALYSIS. THE CATHETER ADAPTOR LUER-LOCK IS TO BE CONNECTED WITH THE EXTERNAL ABDOMINAL PART OF A PERITONEAL CATHETER. IT IS SPECIALLY DESIGNED FOR THE CONNECTION TO ANY STAY.SAFE CATHETER EXTENSION LUER-LOCK. THE CATHETER EXTENSION LUER- LOCK IS TO BE CONNECTED WITH THE CATHETER ADAPTOR LUER-LOCK ON THE PD CATHETER AND IS SPECIALLY DESIGNED FOR MULTIPLE CONNECTION TO THE COMPATIBLE PD SYSTEMS FROM FRESENIUS MEDICAL CARE.,STAY. SAFE® DISINFECTION CAP-USED FOR DISINFECTION OF CATHETER ENDS IN CONTINUOUS AMBULATORY PERITONEAL DIALYSIS., CATHETER ADAPTOR LUER-LOCK WITH CLOSURE CAP-FIELD OF APPLICATION: PERITONEAL DIALYSIS. THE CATHETER ADAPTOR LUER-LOCK IS TO BE CONNECTED WITH THE EXTERNAL ABDOMINAL PART OF A PERITONEAL CATHETER. IT IS SPECIALLY DESIGNED FOR THE CONNECTION TO ANY STAY.SAFE CATHETER EXTENSION LUER-LOCK. THE CATHETER EXTENSION LUER- LOCK IS TO BE CONNECTED WITH THE CATHETER ADAPTOR LUER-LOCK ON THE PD CATHETER AND IS SPECIALLY DESIGNED FOR MULTIPLE CONNECTION TO THE COMPATIBLE PD SYSTEMS FROM FRESENIUS MEDICAL CARE.
2189	IMP/MD/2020/000289	1.License Holder Name: FRESENIUS MEDICAL CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOODLINES-BLOODLINES ARE INTENDED FOR SINGLE USE ONLY FOR EXTRACORPOREAL BLOOD PURIFICATION,ACCESSORIES-THIS PRODUCT IS INTENDED FOR SINGLE USE FOR HEMODIALYSIS TREATMENT,BLOODLINES-BLOODLINES ARE INTENDED FOR SINGLE USE ONLY FOR EXTRACORPOREAL BLOOD PURIFICATION., BLOODLINES-BLOODLINES ARE INTENDED FOR SINGLE USE ONLY FOR EXTRACORPOREAL BLOOD PURIFICATION.,BLOODLINES-BLOODLINES ARE INTENDED FOR SINGLE USE ONLY FOR EXTRACORPOREAL BLOOD PURIFICATION.,BLOODLINES-BLOODLINES ARE INTENDED FOR SINGLE USE ONLY FOR EXTRACORPOREAL BLOOD PURIFICATION.,BLOODLINES-BLOODLINES ARE INTENDED FOR SINGLE USE ONLY FOR EXTRACORPOREAL BLOOD PURIFICATION.

2190	IMP/MD/2020/000290	1.License Holder Name: EVENT MEDI SYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BALLOON IN-DEFLATION DEVICE(DEMAX)-BALLOON IN-DEFLATION DEVICE USED FOR THE INFLATION AND DEFLATION OF A BALLOON DILATION CATHETER TO DILATE THE VESSEL OR IMPLANT A STENT.
2191	IMP/MD/2020/000291	1.License Holder Name: FRESENIUS MEDICAL CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOODLINES - AV SET ONLINE PLUS 5008 R(LIFELINE BETA)-BLOODLINES ARE INTENDED FOR SINGLE USE ONLY FOR EXTRA CORPOREAL BLOOD PURIFICATION.,BLOODLINES-AV-SET ONLINEPLUS BVM 5008-R (LIFELINE BETA)-BLOODLINES ARE INTENDED FOR SINGLE USE ONLY FOR EXTRA CORPOREAL BLOOD PURIFICATION.,DRAINAGE SET(STAY SAFE)-THESE TUBING SYSTEMS ARE INTENDED FOR SINGLE USE ONLY FOR EXTRACORPOREAL BLOOD PURIFICATIONS.,BLOODLINES-SAFELINE(NATURAL LINE)-THESE TUBING SYSTEMS ARE INTENDED FOR SINGLE USE ONLY FOR EXTRACORPOREAL BLOOD PURIFICATIONS.
2192	IMP/MD/2020/000293	1.License Holder Name: DURAENT LIFESCIENCES LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORGAN STORAGE SOLUTION(BELZER UW COLD STORAGE SOLUTION)-BELZER UW COLD STORAGE SOLUTION IS INTENDED FOR THE FLUSHING AND COLD STORAGE OF KIDNEY, LIVER AND PANCREAS ORGANS AT THE TIME OF ORGAN REMOVAL FROM THE DONOR IN PREPARATION FOR STORAGE, TRANSPORTATION AND EVENTUAL TRANSPLANTATION INTO A RECIPIENT.
2193	IMP/MD/2020/000296	1.License Holder Name: BL LIFESCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABSORBABLE HEMOSTATIC AGENT(PERCLOT POLYSACCHARIDE HEMOSTATIC SYSTEM)-PERCLOT PHS IS INDICATED FOR USE IN SURGICAL PROCEDURES (EXCEPT NEUROLOGICAL AND OPHTHALMIC) OR INJURIES AS AN ADJUNCT HEMOSTAT WHEN CONTROL OF BLEEDING FROM CAPILLARY, VENOUS, OR ARTERIOLAR VESSELS BY PRESSURE, LIGATURE, AND OTHER CONVENTIONAL MEANS IS EITHER INEFFECTIVE OR IMPRACTICAL.

2194	IMP/MD/2020/000297	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BUTTRESS COMPONENT (TRABECULAR METAL ACETABULAR REVISION SYSTEM- BUTTRESS)-THE TRABECULAR METAL ACETABULAR AUGMENT SYSTEM IS INTENDED TO PROVIDE THE ORTHOPEDIC SURGEON WITH A PROSTHETIC ALTERNATIVE TO STRUCTURAL ALLOGRAFT IN CASES OF SEGMENTAL ACETABULAR DEFICIENCIES.,TIBIAL CONE AUGMENTS(TRABECULAR METAL TIBIAL CONE AUGMENTS)-THE TRABECULAR METAL TIBIAL CONE AUGMENTS ARE INTENDED FOR USE WHERE SEVERE DEGENERATION, TRAUMA, OR OTHER PATHOLOGY OF THE KNEE JOINT INDICATES TOTAL KNEE ARTHROPLASTY. WHEN USED WITH THE NEXGEN COMPLETE KNEE SOLUTION – ROTATING HINGE KNEE (RHK) SYSTEM, THE TRABECULAR METAL TIBIAL CONE AUGMENTS ARE FOR CEMENTED USE ONLY. WHEN USED WITH THE NEXGEN COMPLETE KNEE SOLUTION – LEGACY CONSTRAINED CONDYLAR KNEE SYSTEM, THE TRABECULAR METAL TIBIAL CONE AUGMENTS ARE FOR CEMENTLESS OR CEMENTED USE.,SPINAL SYSTEM(TRABECULAR METAL TM ARDIS INTERBODY SYSTEM-TM ARDIS INTERBODY SYSTEM GRAFT)-THE TM ARDIS® INTERBODY SYSTEM IS INDICATED FOR USE AS AN INTERVERTEBRAL BODY FUSION DEVICE AT ONE OR TWO CONTIGUOUS LEVELS IN THE LUMBOSACRAL REGION (L2-S1) IN THE TREATMENT OF DEGENERATIVE DISC DISEASE (DDD) WITH UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVEL(S). DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. PATIENTS WITH PREVIOUS NON-FUSION SPINAL SURGERY AT INVOLVED LEVEL MAY BE TREATED WITH THE DEVICE. PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THE TM ARDIS® INTERBODY SYSTEM DEVICE IS IMPLANTED USING A POSTERIOR OR TRANSFORAMINAL APPROACH AND IS INTENDED TO BE USED SINGLY OR IN PAIRS WITH SUPPLEMENTAL FIXATION.,FEMORAL CONE AUGMENTS(TRABECULAR METAL FEMORAL CONE AUGMENTS)-THE TRABECULAR METAL FEMORAL CONE AUGMENTS ARE INTENDED FOR USE WHERE SEVERE DEGENERATION, TRAUMA, OR OTHER PATHOLOGY OF THE KNEE JOINT INDICATES TOTAL KNEE ARTHROPLASTY. WHEN USED WITH THE NEXGEN COMPLETE KNEE SOLUTION – ROTATING HINGE KNEE (RHK) SYSTEM, THE TRABECULAR METAL FEMORAL CONE AUGMENTS ARE FOR CEMENTED USE ONLY. WHEN USED WITH THE NEXGEN COMPLETE KNEE SOLUTION – LEGACY CONSTRAINED CONDYLAR KNEE SYSTEM, THE TRABECULAR METAL FEMORAL CONE AUGMENTS ARE FOR

	CEMENTLESS OR CEMENTED USE.,SPINAL SYSTEM(TRABECULAR METAL TM ARDIS INTERBODY SYSTEM SOLID-TM ARDIS INTERBODY SYSTEM SOLID)-THE TM ARDIS® INTERBODY SYSTEM IS INDICATED FOR USE AS AN INTERVERTEBRAL BODY FUSION DEVICE AT ONE OR TWO CONTIGUOUS LEVELS IN THE LUMBOSACRAL REGION (L2-S1) IN THE TREATMENT OF DEGENERATIVE DISC DISEASE (DDD) WITH UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVEL(S). DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. PATIENTS WITH PREVIOUS NON-FUSION SPINAL SURGERY AT INVOLVED LEVEL MAY BE TREATED WITH THE DEVICE. PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NON-OPERATIVE TREATMENT. THE TM ARDIS® INTERBODY SYSTEM DEVICE IS IMPLANTED USING A POSTERIOR OR TRANSFORAMINAL APPROACH AND IS INTENDED TO BE USED SINGLY OR IN PAIRS WITH SUPPLEMENTAL FIXATION.,REVISION SHELL(TRABECULAR METAL ACETABULAR REVISION SHELL)-TRABECULAR METAL REVISION ACETABULAR SHELLS ARE INDICATED FOR: PAINFUL, DISABLING JOINT DISEASE OF THE HIP RESULTING FROM: DEGENERATIVE ARTHRITIS, RHEUMATOID ARTHRITIS OR LATE STAGE AVASCULAR NECROSIS. REVISION OF PREVIOUS UNSUCCESSFUL FEMORAL HEAD REPLACEMENT, CUP ARTHROPLASTY OR OTHER PROCEDURE. CLINICAL MANAGEMENT PROBLEM WHERE ARTHRODESIS OR ALTERNATIVE RECONSTRUCTION TECHNIQUES ARE LESS LIKELY TO ACHIEVE SATISFACTORY RESULTS. WHERE BONE STOCK IS OF POOR QUALITY OR IS INADEQUATE FOR OTHER RECONSTRUCTIVE TECHNIQUES AS INDICATED BY DEFICIENCIES OF THE ACETABULUM., RESTRICTOR COMPONENT(TRABECULAR METAL ACETABULAR RESTRICTOR)-THE TRABECULAR METAL ACETABULAR RESTRICTOR IS A DEVICE INTENDED FOR RESTRICTION OF EFFUSION OF BONE CEMENT, ALLOGRAFT BONE, AND/OR AUTOGRAFT BONE INTO THE PELVIS IF DEFECTS IN THE ACETABULUM ARE ENCOUNTERED.,SHIM COMPONENT(TRABECULAR METAL ACETABULAR REVISION SYSTEM-SHIM AUGMENTS)-THE TRABECULAR METAL ACETABULAR AUGMENT SYSTEM IS INTENDED TO PROVIDE THE ORTHOPEDIC SURGEON WITH A PROSTHETIC ALTERNATIVE TO STRUCTURAL ALLOGRAFT IN CASES OF SEGMENTAL ACETABULAR DEFICIENCIES.,ACETABULAR AUGMENTS(TRABECULAR METAL ACETABULAR REVISION SYSTEM-ACETABULAR AUGMENTS)-THE TRABECULAR METAL ACETABULAR AUGMENT SYSTEM IS INTENDED TO PROVIDE THE ORTHOPEDIC SURGEON WITH A PROSTHETIC ALTERNATIVE TO STRUCTURAL ALLOGRAFT IN CASES OF SEGMENTAL ACETABULAR DEFICIENCIES., SPINAL FUSION DEVICE(TRABECULAR METAL TM-S FUSION DEVICE)-

		THE TM-S FUSION DEVICE IS INTENDED FOR USE IN ANTERIOR CERVICAL DISCECTOMY AND FUSION (ACDF) PROCEDURES IN PATIENTS WITH SYMPTOMATIC CERVICAL DISC DISEASE FROM THE C3-C4 TO THE C7-T1 DISC.
2195	IMP/MD/2020/000298	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERIPHERAL VASCULAR GUIDEWIRE(VICTORY 18 POLYMER TIP GUIDEWIRE WITH HYDROPHILIC COATING)-THE VICTORY GUIDEWIRES ARE INTENDED TO FACILITATE THE PLACEMENT AND EXCHANGE OF BALLOON CATHETERS OR OTHER INTERVENTIONAL DEVICES WITHIN THE PERIPHERAL VASCULATURE DURING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) OR OTHER INTRAVASCULAR INTERVENTIONAL PROCEDURES.,PERIPHERAL VASCULAR GUIDEWIRE(VICTORY 14 POLYMER TIP GUIDEWIRE WITH HYDROPHILIC COATING)-THE VICTORY GUIDEWIRES ARE INTENDED TO FACILITATE THE PLACEMENT AND EXCHANGE OF BALLOON CATHETERS OR OTHER INTERVENTIONAL DEVICES WITHIN THE PERIPHERAL VASCULATURE DURING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) OR OTHER INTRAVASCULAR INTERVENTIONAL PROCEDURES.
2196	IMP/MD/2020/000299	1.License Holder Name: COLOPLAST INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BARRIER CREAM (COMFEEL)-COMFEEL BARRIER CREAM IS INTENDED FOR PROTECTION OF SKIN AROUND WOUNDS AND FOR PROTECTION OF INTACT SKIN EXPOSED TO INTESTINAL CONTENTS, URINE AND PUS IN CONNECTION WITH OSTOMIES AND INCONTINENCE.

2197	IMP/MD/2020/000300	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEALTHPORT FOCUS VENOUS SILICONE 8FR ALL-IN-ONE-THE HEALTHPORT VENOUS IS INDICATED TO BE IMPLANTED IN THE CENTRAL VENOUS SYSTEM FOR MID AND LONG-TERM USE, IN ORDER TO PERMIT REPEATED INFUSION OF THERAPEUTIC SOLUTIONS SUCH AS CHEMOTHERAPY, ANTIBIOTICS, NUTRIENTS, BLOOD PRODUCTS, AND IN THE ADDITION THE COLLECTION OF BLOOD SAMPLES.,HEALTHPORT ETI VENOUS SILICONE 8FR ALL-IN-ONE-THE HEALTHPORT VENOUS IS INDICATED TO BE IMPLANTED IN THE CENTRAL VENOUS SYSTEM FOR MID AND LONG-TERM USE, IN ORDER TO PERMIT REPEATED INFUSION OF THERAPEUTIC SOLUTIONS SUCH AS CHEMOTHERAPY, ANTIBIOTICS, NUTRIENTS, BLOOD PRODUCTS, AND IN THE ADDITION THE COLLECTION OF BLOOD SAMPLES.,HEALTHPORT MINIMAX VENOUS POLYURETHANE 5FR ALL-IN-ONE-THE HEALTHPORT VENOUS IS INDICATED TO BE IMPLANTED IN THE CENTRAL VENOUS SYSTEM FOR MID AND LONG-TERM USE, IN ORDER TO PERMIT REPEATED INFUSION OF THERAPEUTIC SOLUTIONS SUCH AS CHEMOTHERAPY, ANTIBIOTICS, NUTRIENTS, BLOOD PRODUCTS, AND IN THE ADDITION THE COLLECTION OF BLOOD SAMPLES.
2198	IMP/MD/2020/000301	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL DRESSING (BIOPATCH)-BIOPATCH® CONTAINING CHLORHEXIDINE GLUCONATE IS INTENDED FOR USE AS A HYDROPHILIC WOUND DRESSING THAT IS USED TO ABSORB EXUDATE AND TO COVER A WOUND CAUSED BY THE USE OF VASCULAR AND NONVASCULAR PERCUTANEOUS MEDICAL DEVICES SUCH AS: IV CATHETERS, CENTRAL VENOUS LINES, ARTERIAL CATHETERS, DIALYSIS CATHETERS, PERIPHERALLY INSERTED CORONARY CATHETERS, MID-LINE CATHETERS, DRAINS, CHEST TUBES, EXTERNALLY PLACED ORTHOPEDIC PINS, AND EPIDURAL CATHETERS. IT IS ALSO INTENDED TO REDUCE LOCAL INFECTIONS, CATHETER-RELATED BLOOD STREAM INFECTIONS (CRBSI), AND SKIN COLONIZATION OF MICROORGANISMS COMMONLY RELATED TO CRBSI, IN PATIENTS WITH CENTRAL VENOUS OR ARTERIAL CATHETERS.

2199	IMP/MD/2020/000302	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ADHESION BARRIER GEL FOR INTRAUTERINE SURGERY(OXIPLEX/IU)-OXIPLEX/IU IS INTENDED FOR USE AS A MECHANICAL BARRIER TO ADHESION FORMATION., ADHESION BARRIER(OXIPLEX®)-OXIPLEX® IS INTENDED FOR USE AS A MECHNICAL BARRIER TO ADHESION FORMATION.,ADHESION BARRIER(OXIPLEX/AP®)-OXIPLEX/AP® IS INTENDED FOR USE AS A MECHANICAL BARRIER TO ADHESION FORMATION.,ADHESION BARRIER(DYNAVISC®)-DYNAVISC® IS INTENDED TO REDUCE FIBROSIS AND FORMATION OF ADHESIONS FOLLOWING TENDON AND/OR PERIPHERAL NERVE SURGERY.
2200	IMP/MD/2020/000306	1.License Holder Name: BIOCON BIOLOGICS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLED GLASS BARREL WITH NEEDLE(BD NEOPAK)-COMPONENT OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS,PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK)-COMPONENT OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS
2201	IMP/MD/2020/000307	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRAVENOUS ADMINISTRATION SET, SCALP VEIN(SURFLO WINGED INFUSION SET WITH NEEDLE PROTECTION)-THE SURFLO WINGED INFUSION SET WITH NEEDLE PROTECTION (SURSHIELD) IS INTENDED TO ACCESS THE PERIPHERAL VASCULAR SYSTEM, FOR INTRAVENOUS ADMINISTRATION OF FLUIDS AND/OR WITHDRAWAL OF BLOOD SPECIMENS USING A SYRINGE, LUER ADAPTER, OR OTHER COMPATIBLE/APPROPRIATE DEVICES. ADDITIONALLY, AFTER WITHDRAWAL OF THE NEEDLE FROM THE PATIENT'S VEIN, THE SHIELD COVER CAN BE MANUALLY ACTIVATED TO COVER THE NEEDLE TO MINIMIZE RISK OF ACCIDENTAL NEEDLE STICK. THE DEVICE HAS NO COMPONENTS MADE OF NATURAL RUBBER LATEX.

2202	IMP/MD/2020/000308	1.License Holder Name: TERUMO PENPOL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PLATELET ADDITIVE SOLUTION(T-PAS+)-THE TPAS+ SOLUTION IS A PLATELET ADDITIVE SOLUTION INTENDED TO PARTIALLY REPLACE PLASMA IN THE PREPARATION AND STORAGE OF A BUFFY COATDERIVED PLATELET CONCENTRATE OR APHERESIS PLATELET UNITS.,PLATELET ADDITIVE SOLUTION(T-PAS+)-THE TPAS+ SOLUTION IS A PLATELET ADDITIVE SOLUTION INTENDED TO PARTIALLY REPLACE PLASMA IN THE PREPARATION AND STORAGE OF A BUFFY COATDERIVED PLATELET CONCENTRATE OR APHERESIS PLATELET UNITS.,PLATELET ADDITIVE SOLUTION(T-PAS+)-THE TPAS+ SOLUTION IS A PLATELET ADDITIVE SOLUTION INTENDED TO PARTIALLY REPLACE PLASMA IN THE PREPARATION AND STORAGE OF A BUFFY COATDERIVED PLATELET CONCENTRATE OR APHERESIS PLATELET UNITS.

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2203	IMP/MD/2020/000309	1.License Holder Name: CHETAN MEDITECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RESORBABLE FIXATION SYSTEM- COMPOSITE INTERFERENCE SCREW(OSTEOTWIN, BIOTWIN)-IT IS DESIGNED TO PROVIDE FIXATION BY INTERFERENCE BETWEEN THE LIGAMENT/GRAFT AND THE BONE TUNNEL WALLS DURING THE CONSOLIDATION PERIOD THANKS ENHANCED ITS BONE REGENERATION ABILITY. IT IS A TUBULAR SCREW WITH A SPECIFIC 5-BRANCH RECESS WHICH STRETCHES ALONG ALMOST THE ENTIRE LENGTH OF THE SCREW THEREBY ENSURING PROPER DISTRIBUTION OF THE MAKEUP TORQUE.,SYNTHETIC BONE SUBSTITUTE(MBCP, B-WEDGE)-THE SYNTHETIC BONE SUBSTITUTE IS INTENDED FOR USE AS A BONE VOID FILLER FOR BONY VOIDS OR GAPS OF THE SKELETAL SYSTEM (E.G. EXTREMITIES, SPINE AND PELVIS) THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. THE SYNTHETIC BONE SUBSTITUTE CAN BE USED WITH AUTOGRAFT AS A BONE GRAFT EXTENDER. THESE DEFECTS MAY BE SURGICALLY CREATED OSSEOUS DEFECTS OR OSSEOUS DEFECTS CREATED FROM TRAUMATIC INJURY TO THE BONE. THE SYNTHETIC BONE SUBSTITUTE IS A BONE FILLER WITHOUT INITIAL MECHANICAL PROPERTIES. THEREFORE RIGID FIXATION TECHNIQUES MAY OFTEN BE RECOMMENDED. WHEN PACKED INTO A BONY SITE, THE SYNTHETIC BONE SUBSTITUTE GRADUALLY RESORBS AND IS REPLACED WITH BONE DURING THE HEALING PROCESS. IN ADDITION, WHEN USED WITH APPROPRIATE OPENING OSTEOTOMY SYSTEM DEVICES, PLATES AND SCREWS. THE SYNTHETIC BONE SUBSTITUTE IS INTENDED TO BE USED AS A BONE VOID FILLER IN FEMORAL OR TIBIAL OSTEOTOMIES. THE SYNTHETIC BONE SUBSTITUTE IS TO BE USED IN ASSOCIATION WITH ADEQUATE POST-OPERATIVE IMMOBILIZATION.
2204	IMP/MD/2020/000310	1.License Holder Name: ESSITY INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SKIN-FRIENDLY NON-WOVEN TAPE(LEUKOPOR)-FIXATION OF DRESSING,FIXATION OF CANNULA,IV TUBES, CATHETERS .,POROUS SURGICAL TAPE (PE) (LEUKOFIX)-FIXATION OF DRESSING,FIXATION OF CANNULA,IV TUBES,CATHETERS .

2205	IMP/MD/2020/000311	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERITONEAL DIALYSIS TRANSFER SET(MINICAP EXTENDED LIFE PD TRANSFER SET WITH TWISTED CLAMP)-THIS SET IS INDICATED FOR USE WHEN CONNECTING TO CAPD DISPOSABLE DISCONNECT Y-SET, MINICAP DISCONNECT CAP WITH POVIDONE-IODINE SOLUTION OR OTHER COMPATIBLE DISCONNECT SYSTEMS FROM BAXTER HEALTHCARE CORPORATION. THIS SET IS ALSO INDICATED FOR USE WITH CONNECTING TO APD SET WITH CASSETTE.
2206	IMP/MD/2020/000312	1.License Holder Name: SPECIALITY PHARMA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EYEPRO(INNOVGAS EYRPRO)-EYEPRO™ ENSURES RAPID, COMPLETE AND SAFE EYELID CLOSURE. BY SEALING AROUND THE EYE CIRCUMFERENTIALLY, ALL MOISTURE IS RETAINED, THUS PREVENTING THE EYE FROM 'DRYING OUT'.
2207	IMP/MD/2020/000314	1.License Holder Name: SMITHS MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIGH FLOW NASAL CANNULA (INFANT)(INSPIRED)-IT IS INTENDED TO BE USED IN THE ADMINISTRATION OF OXYGEN THROUGH THE NARES TO THE PATIENT (PREEMIE, NEWBORN OR INFANT),HIGH FLOW NASAL CANNULA (ADULT)(INSPIRED)-IT IS INTENDED TO BE USED IN THE ADMINISTRATION OF OXYGEN THROUGH THE NARES TO PATIENTS
2208	IMP/MD/2020/000315	1.License Holder Name: NK HEALTHCARE PVT.LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE GRAFTING MATERIAL(CREOS TM XENOGAIN)-CREOSTM XENOGAIN CANCELLOUS GRANULES ARE RECOMMENDED FOR -AUGMENTATION OR RECONSTRUCTIVE TREATMENT OF THE ALVEOLAR RIDGE. - FILLING OF INFRABONY PERIODONTAL DEFECTS. - FILLING OF DEFECTS AFTER ROOT RESECTION, APICOECTOMY AND CYSTECTOMY. - FILLING OF EXTRACTION SOCKETS TO ENHANCE PRESERVATION OF THE ALVEOLAR RIDGE. - ELEVATION OF THE MAXILLARY SINUS FLOOR. -FILLING OF PERIODONTAL DEFECTS IN CONJUNCTION WITH PRODUCTS INTEND FOR GUIDED TISSUE REGENERATION (GTR) AND GUIDED BONE REGENERATION (GBR). - FILLING OF PERI-IMPLANT DEFECTS IN CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED BONE REGENERATION (GBR)

2209	IMP/MD/2020/000318	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE)(OXITAMP GEL)-OXITAMP IS USED IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE. OXITAMP IS INDICATED IN ALL SURGICAL APPLICATIONS.,ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE)(OXITAMP FIBRILLAR)-OXITAMP IS USED IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE. OXITAMP IS INDICATED IN ALL SURGICAL APPLICATIONS.,POLYPROPLENE MONOFILAMENT, SYNTHETIC NON-ABSORBABLE SMOOTH OR BARBED SELF-RETAINING SURGICAL SUTURE(FILBLOC PERMANENT)-FILBLOC PERMANENT SUTURES ARE INTENDED FOR USE IN ALL SURGICAL PROCEDURES, AT THE USER'S DISCRETION,SYNTHETIC ABSORBABLE SMOOTH OR BARBED SURGICAL SUTURE, SELF-RETAINING POLY (P-DIOXANONE) MONOFILAMENT(FILBLOC)-FILBOC SUTURES ARE INTENDED FOR USE IN ALL SURGICAL PROCEDURES, AT THE USER'S DISCRETION.,ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE)(OXITAMP POWDER)-OXITAMP IS USED IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE. OXITAMP IS INDICATED IN ALL SURGICAL APPLICATIONS.,ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE)(OXITAMP GAUZE)-OXITAMP IS USED IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE. OXITAMP IS INDICATED IN ALL SURGICAL APPLICATIONS.

2210	IMP/MD/2020/000319	1.License Holder Name: ADIN INDIA MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT ACCESSORIES (ABUTMENTS AND SCREWS)-FOR USE WITH A DENTAL IMPLANT FIXTURE TO PROVIDE SUPPORT FOR PROSTHETIC RESTORATIONS SUCH AS CROWN, BRIDGE OR OVERDENTURE, DENTAL IMPLANT ACCESSORIES (ABUTMENTS)(UNP CLOSE FIT)-FOR USE WITH A DENTAL IMPLANT FIXTURE TO PROVIDE SUPPORT FOR PROSTHETIC RESTORATIONS SUCH AS CROWNS, BRIDGE, OR OVERDENTURE.,DENTAL IMPLANT FIXTURE(TOUAREG - S, OS, WP, NP, RP, ONE PIECE, SWELL)-FOR USE IN PARTIALLY OR DULLY EDENTULOUS MANDIBLES AND MAXILLAE, IN SUPPORT OF SINGLE OR MULTIPLE UNIT RESTORATIONS INCLUDING; CEMENTED RETAINED, SCREW RETAINED OR OVERDENTURE RESTORATIONS, AND FINAL OR TEMPORARY ABUTMENT SUPPORT FOR FIXED BRIDGEWORK,DENTAL IMPLANT ACCESSORIES (SCREW)(NA)-FOR USE WITH A DENTAL IMPLANT FIXTURE TO PROVIDE SUPPORT FOR PROSTHETIC RESTORATIONS SUCH AS CROWNS, BRIDGE, OR OVERDENTURE.,DENTAL IMPLANT(TOURAEG CLOSEFIT UNP)-FOR USE IN PARTIALLY OR DULLY EDENTULOUS MANDIBLES AND MAXILLAE, IN SUPPORT OF SINGLE OR MULTIPLE UNIT RESTORATIONS INCLUDING; CEMENTED RETAINED, SCREW RETAINED OR OVERDENTURE RESTORATIONS, AND FINAL OR TEMPORARY ABUTMENT SUPPORT FOR FIXED BRIDGEWORK.,DENTAL IMPLANT ACCESSORIES (BALL ATTACHMENT)(NA)-FOR USE WITH A DENTAL IMPLANT FIXTURE TO PROVIDE SUPPORT FOR PROSTHETIC RESTORATIONS SUCH AS CROWNS, BRIDGE, OR OVERDENTURE.
2211	IMP/MD/2020/000320	1.License Holder Name: M/S. KALYX INDIA HEALTHCARE (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABSORBABLE HAEMOSTAT, OXIDIZED REGENERATED CELLULOSE (ORC)(REOXCEL-REOXCIL SIGMA KNIT - REOXCIL FIBRIL)-ABSORBABLE HAEMOSTAT ARE USED TO ARREST THE BLEEDING AT THE TIME OF SURGERIES.

2212	IMP/MD/2020/000321	1.License Holder Name: SMITHS MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRACHEOSTOMY TUBES (BIVONA)-THE BIVONA® TRACHEOSTOMY TUBE IS INTENDED TO PROVIDE DIRECT AIRWAY ACCESS FOR A TRACHEOTOMIZED PATIENT FOR UP TO 29 DAYS. IT MAY BE REPROCESSED FOR SINGLE-PATIENT USE UP TO 5 TIMES ,INNER CANNULA(BIVONA)-A RANGE OF STERILE SINGLE PATIENT USE REPLACEMENT INNER CANNULA INTENDED TO ASSIST IN THE PROVISION OF A PATENT AIRWAY IN THE TRACHEOSTOMISED PATIENT WHEN USED IN CONJUNCTION WITH BIVONA® ADULT CUFFLESS, MID-RANGE AIRE-CUF® AND TTS™ TRACHEOSTOMY TUBES
2213	IMP/MD/2020/000322	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE GRAFTING MATERIAL(CREOS XENOGAIN)-CREOS XENOGAIN CANCELLOUS GRANULES ARE RECOMMENDED FOR - AUGMENTATION OR RECONSTRUCTIVE TREATMENT OF THE ALVEOLAR RIDGE - FILLING OF INFRABONY PERIODONTAL DEFECTS - FILLING OF DEFECTS AFTER ROOT RESECTION, APICOECTOMY AND CYSTECTOMY - FILLING OF EXTRACTION SOCKETS TO ENHANCE PRESERVATION OF THE ALVEOLAR RIDGE - ELEVATION OF THE MAXILLARY SINUS FLOOR - FILLING OF PERIODONTAL DEFECTS IN CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED TISSUE REGENERATION (GTR) AND GUIDED BONE REGENERATION (GBR) - FILLING OF PERI-IMPLANT DEFECTS IN CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED BONE REGENERATION (GBR)
2214	IMP/MD/2020/000324	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LIGATION CLIP(VAS-Q-CLIP NON ABSORBABLE POLYMER LIGATION CLIP)-VAS-Q-CLIP™ LIGATING CLIPS ARE INTENDED FOR USE IN PROCEDURES INVOLVING LIGATION OF VESSELS OR TISSUE STRUCTURES.
2215	IMP/MD/2020/000325	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMPLANT(ETHICON BONEWAX)-BONE WAX IS INTENDED FOR USE FOR THE CONTROL OF BLEEDING FROM THE DIVIDED, DRILLED OR CHIPPED EDGES OF BONE BY PHYSICALLY PLUGGING THE OSSEOUS CANALS WHICH CONTAIN THE BLEEDING CAPILLARIES

2216	IMP/MD/2020/000327	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RIGID PENILE PROSTHESIS(TACTRA MALLEABLE PENILE PROSTHESIS)-THE TACTRA DEVICE IS DESIGNED TO PROVIDE PENILE RIGIDITY AND MALLEABILITY, AND THE DEVICE CAN BE PLACED IN EITHER AN ERECT OR A CONCEALED POSITION. THE TACTRA PENILE PROSTHESIS IS A STERILE, SINGLE-USE IMPLANT THAT IS INTENDED FOR USE IN THE TREATMENT OF CHRONIC, ORGANIC, ERECTILE DYSFUNCTION (IMPOTENCE) IN ADULT MALES WHO ARE DETERMINED TO BE SUITABLE CANDIDATES FOR IMPLANTATION SURGERY.
2217	IMP/MD/2020/000328	1.License Holder Name: BIOTRONIK MEDICAL DEVICES INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTFE PEELABLE INTRODUCER KIT(LI PLUS)-THE PTFE PEELABLE INTRODUCER KIT LI-XXPLUS IS INTENDED FOR USE IN THE PERCUTANEOUS INSERTION OF PACING LEADS OR CATHETERS IN THE VENOUS SYSTEM.
2218	IMP/MD/2020/000329	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE WAX NON-ABSORBABLE 2.5G(SYNETURE™ BONE WAX)-BONE WAX IS INDICATED FOR USE IN THE CONTROL OF BLEEDING FROM BONE SURFACES.
2219	IMP/MD/2020/000330	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED ,NO. 17, GROUND FLOOR AND MEZZANINE FLOOR, THIRUNEERMALAI ROAD, NAGALKENI, CHROMPET ,CHENNAI TAMIL NADU ,600044 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRAUMA FIXATION DEVICES(CABLE-READY CABLE GRIP SYSTEM-GTR DEVICE W/ CABLES)-GTR DEVICE(S) ARE TEMPORARY IMPLANTS INDICATED FOR REATTACHMENT OF THE GREATER TROCHANTER FOLLOWING OSTEOTOMY IN TOTAL HIP REPLACEMENT AND FOR FRACTURE OF THE GREATER TROCHANTER. THE EXTENDED GTR IS ADDITIONALLY INDICATED FOR REATTACHMENT OF THE GREATER TROCHANTER IN PERIPROSTHETIC FRACTURES OF THE FEMUR.

2220	IMP/MD/2020/000331	1.License Holder Name: SEPTODONT HEALTHCARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL NEEDLE (SEPTOJECT)-IT IS INDICATED FOR ROUTINE LOCAL DENTAL ANAESTHESIA INJECTIONS AND FOR MAXILLOFACIAL INJECTIONS.
2221	IMP/MD/2020/000332	1.License Holder Name: HEALTHIUM MEDTECH PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABLATOR(VELOX RF WAND)-THIS DEVICE IS INTENDED TO BE USED FOR CUTTING, VAPORIZATION, AND COAGULATION OF SOFT TISSUE DURING ARTHROSCOPIC SURGICAL PROCEDURES. THIS DEVICE IS INTENDED TO BE USED WITH A STANDARD ELECTROSURGICAL GENERATOR WITH FOOTSWITCH CONTROL AND A STANDARD RETURN ELECTRODE CONNECTION, AND THE ELECTRODE IS TO BE ACTIVATED ONLY WHEN IMMERSED IN A CONDUCTIVE MEDIA SUCH AS STANDARD SALINE SOLUTION.
2222	IMP/MD/2020/000333	1.License Holder Name: ABA TECHNOLOGIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TITAN IMPLANT(TITAN IMPLANT)-AB DENTAL IMPLANTS ARE DENTAL IMPLANTS INTENDED TO BE USED IN THE UPPER OR LOWER JAW BONE FOR ANCHORING AND PROVIDING SUPPORT TO TOOTH REPLACEMENTS, SUCH AS ARTIFICIAL TEETH, IN ORDER TO RESTORE CHEWING FUNCTION., DENTAL ABUTMENT WITH SCREWS AND HEALING CAPS(DENTAL ABUTMENT WITH SCREWS AND HEALING CAPS)-DENTAL IMPLANTS SYSTEM IS INDICATED FOR USE IN SURGICAL AND RESTORATIVE APPLICATIONS FOR PLACEMENT IN THE BONE OF THE UPPER OR LOWER JAW TO PROVIDE SUPPORT FOR PROSTHETIC DEVICES, SUCH AS ARTIFICIAL TEETH, IN ORDER TO RESTORE THE PATIENTS CHEWING FUNCTION

2223	IMP/MD/2020/000334	1.License Holder Name: EMCO TECH EQUIPMENTS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRAOCULAR GAS (OCTAFLUOROPROPANE)(GOT C3F8 MULTI)-LONG TERM INTRAOCULAR TAMPONADE IN VITREORETINAL SURGERY., PERFLUOROCARBONS (PERFLUORO-N-OCTANE)(HPF8)-INTRAOPERATIVE INTRAOCULAR TAMPONADE IN VITREORETINAL SURGERY.,SILICONE OIL (POLYDIMETHYLSILOXANE)(RS-OIL)-LONG-TERM INTRAOCULAR TAMPONADE IN VITREORETINAL SURGERY., INTRAOCULAR GAS (SULFUR HEXAFLUORIDE)(GOT SF6 MULTI)-LONG TERM INTRAOCULAR TAMPONADE IN VITREORETINAL SURGERY., PERFLUOROCARBONS (PERFLUORO-N-OCTANE)(HPF8)-INTRAOPERATIVE INTRAOCULAR TAMPONADE IN VITREORETINAL SURGERY.
2224	IMP/MD/2020/000337	1.License Holder Name: M/S. PLUS MEDICAL DEVICES INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHOPEDIC TRAUMA IMPLANTS (PLATES AND SCREWS) (TITANIUM)(WINSTA R/WINSTA PH-2/ WINSTA-C/ WINSTA-E/ WINSTA-FIT/ PEDUS-O/L/R/MTP/MIS/ PEDUS-FORE/MIDFOOT/TWIN/ CLIICKOFF/MIS/PIPTREE/LBN)-MARQUARDT SURGICAL TRAUMA IMPLANTS ARE USED FOR THE FIXATION, CORRECTION OR STABILIZATION OF BONES IN FRACTURE SURGERY.,ORTHOPEDIC TRAUMA IMPLANTS - INTRAMEDULLARY IMPLANTS (NAILS AND SCREWS) (TITANIUM)(LBN/VITUS FT/ VITUS PF/ VITUS FI / EIN)-MARQUARDT SURGICAL TRAUMA IMPLANTS ARE USED FOR THE FIXATION, CORRECTION OR STABILIZATION OF BONES IN FRACTURE SURGERY.,ORTHOPEDIC TRAUMA IMPLANTS - INTRAMEDULLARY IMPLANTS (NAILS AND SCREWS) (TITANIUM) (LBN/VITUS FT/ VITUS PF/ VITUS FI / EIN)-MARQUARDT SURGICAL TRAUMA IMPLANTS ARE USED FOR THE FIXATION, CORRECTION OR STABILIZATION OF BONES IN FRACTURE SURGERY.,ORTHOPEDIC TRAUMA IMPLANTS (PLATES AND SCREWS) (STAINLESS STEEL)(NIL) -MARQUARDT SURGICAL TRAUMA IMPLANTS ARE USED FOR THE FIXATION, CORRECTION OR STABILIZATION OF BONES IN FRACTURE SURGERY.

2225	IMP/MD/2020/000339	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IV SETS(BD BODYGUARD™ MICROSET)-THE MICROSET™ INFUSION SETS ARE PART OF THE BODYGUARD™ INFUSION PUMP SYSTEM WHICH IS DESIGNED FOR INFUSION OF MEDICATIONS OR FLUIDS REQUIRING CONTINUOUS OR INTERMITTENT DELIVERY AT PRECISELY-CONTROLLED INFUSION RATES THROUGH CLINICALLY ACCEPTABLE ROUTES OF ADMINISTRATION, INCLUDING INTRAVENOUS, SUBCUTANEOUS, PERCUTANEOUS, INTRA-ARTERIAL, EPIDURAL, ENTERAL, IN CLOSE PROXIMITY TO NERVES, AND INTO AN INTRAOPERATIVE SITE (SOFT TISSUE/BODY CAVITY/SURGICAL WOUND SITE).,IV SETS(BD BODYGUARD™ MICROSET NRFIT™)-THE MICROSET™ INFUSION SETS ARE PART OF THE BODYGUARD™ INFUSION PUMP SYSTEM WHICH IS DESIGNED FOR INFUSION OF MEDICATIONS OR FLUIDS REQUIRING CONTINUOUS OR INTERMITTENT DELIVERY AT PRECISELY-CONTROLLED INFUSION RATES THROUGH CLINICALLY ACCEPTABLE ROUTES OF ADMINISTRATION, INCLUDING INTRAVENOUS, SUBCUTANEOUS, PERCUTANEOUS, INTRA-ARTERIAL, EPIDURAL, ENTERAL, IN CLOSE PROXIMITY TO NERVES, AND INTO AN INTRAOPERATIVE SITE (SOFT TISSUE/BODY CAVITY/SURGICAL WOUND SITE).
2226	IMP/MD/2020/000340	1.License Holder Name: SHREYAAS HEALTH CARE PRODUCTS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRANASAL SPLINT 8 PACK(NEXPAK X)-NEXPAK X INTRANASAL SPLINT IS A NASAL DRESSING INTENDED TO MINIMIZE BLEEDING & EDEMA AND TO PREVENT ADHESIONS BETWEEN THE SEPTUM AND THE NASAL CAVITY AND ACT AS AN ADJUNCT TO AID IN THE NATURAL HEALING PROCESS POST-SURGICAL INTERVENTION. NEXPAK X IS CONSTRUCTED OF A PATIENT-COMFORTABLE SPONGE WHICH IS MANUFACTURED FROM 100% PLANT-BASED POLYSACCHARIDES. NEXPAK IS INTENDED FOR USE UNDER THE DIRECTION OF A LICENSED HEALTHCARE PROVIDER.

2227	IMP/MD/2020/000341	1.License Holder Name: COCHLEAR MEDICAL DEVICE COMPANY INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COCHLEAR IMPLANT WITH CONTOUR ADVANCE ELECTRODE AND COCHLEAR IMPLANT WITH STRAIGHT ELECTRODE(COCHLEAR™ NUCLEUS® FREEDOM®)-PROVIDES AUDITORY SENSATION AND SOUND PERCEPTION BY ELECTRICALLY STIMULATING THE AUDITORY NERVE OF A HEARING-IMPAIRED EAR. ,COCHLEAR IMPLANT WITH STRAIGHT ELECTRODE (COCHLEAR™ NUCLEUS®)-PROVIDES AUDITORY SENSATION AND SOUND PERCEPTION BY ELECTRICALLY STIMULATING THE AUDITORY NERVE OF A HEARING-IMPAIRED EAR.
2228	IMP/MD/2020/000342	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CITRIC ACID 50% (TRICARB C-50)-LIQUID CONCENTRATE FOR CLEANING , DECALCIFICATION AND HEAT - DISINFECTION OF HAEMODIALYSIS MACHINES.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2229	IMP/MD/2020/000343	1.License Holder Name: PHILIPS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER(REVOLUTION 45MHZ ROTATIONAL IVUS IMAGING CATHETER)-THE REVOLUTION® 45MHZ ROTATIONAL IMAGING CATHETER IS INTENDED FOR THE INTRAVASCULAR ULTRASOUND EXAMINATION OF CORONARY ARTERIES. INTRAVASCULAR ULTRASOUND IMAGING IS INDICATED IN PATIENTS WHO ARE CANDIDATES FOR TRANSLUMINAL INTERVENTIONAL PROCEDURES. THE REVOLUTION® ULTRASOUND IMAGING CATHETERS ARE DESIGNED FOR USE AS AN ADJUNCT TO CONVENTIONAL ANGIOGRAPHIC PROCEDURES TO PROVIDE AN IMAGE OF THE VESSEL LUMEN AND WALL STRUCTURES.,CATHETER (EAGLE EYE PLATINUM SHORT TIP DIGITAL IVUS CATHETER)-THE EAGLE EYE® PLATINUM ST CATHETERS ARE DESIGNED FOR USE IN THE EVALUATION OF VASCULAR MORPHOLOGY IN BLOOD VESSELS OF THE CORONARY AND PERIPHERAL VASCULATURE BY PROVIDING A CROSS-SECTIONAL IMAGE OF SUCH VESSELS. THIS DEVICE IS NOT CURRENTLY INDICATED FOR USE IN CEREBRAL VESSELS. THE EAGLE EYT PLATINUM ST ULTRASOUND IMAGING CATHETERS ARE DESIGNED FOR USE AS AN ADJUNCT TO CONVENTIONAL ANGIOGRAPHIC PROCEDURES TO PROVIDE AN IMAGE OF THE VESSEL LUMEN AND WALL STRUCTURES.,CATHETER(VERRATA PLUS PRESSURE GUIDE WIRE)-THE VERRATA PLUS PRESSURE GUIDE WIRE IS INDICATED FOR USE TO MEASURE PRESSURE IN BLOOD VESSELS, INCLUDING BOTH CORONARY AND PERIPHERAL VESSELS, DURING DIAGNOSTIC ANGIOGRAPHY AND/OR ANY INTERVENTIONAL PROCEDURES. BLOOD PRESSURE MEASUREMENTS PROVIDE HEMODYNAMIC INFORMATION FOR THE DIAGNOSIS AND TREATMENT OF BLOOD VESSEL DISEASE.,CATHETER(VISION PV .035 INTRAVASCULAR ULTRASOUND IMAGING)-THE VISIONS5 PV .035 CATHETERS ARE DESIGNED FOR USE IN THE EVALUATION OF VASCULAR MORPHOLOGY IN BLOOD VESSELS OF THE PERIPHERAL VASCULATURE BY PROVIDING A CROSS-SECTIONAL IMAGE OF SUCH VESSELS. THE VISIONS PV .035 ULTRASOUND IMAGING CATHETERS ARE DESIGNED FOR USE AS AN ADJUNCT TO CONVENTIONAL ANGIOGRAPHIC PROCEDURES TO PROVIDE AN IMAGE OF THE VESSEL LUMEN AND WALL STRUCTURES AND DIMENSIONAL MEASUREMENTS FROM THE IMAGE.,CATHETER(REFINITY™ ST ROTATIONAL IVUS IMAGING CATHETER)-THE REFINITY ST ROTATIONAL IVUS CATHETER (REFINITY ST CATHETER) IS INTENDED FOR THE INTRAVASCULAR ULTRASOUND EXAMINATION OF CORONARY ARTERIES. INTRAVASCULAR ULTRASOUND IMAGING IS INDICATED IN PATIENTS WHO ARE CANDIDATES FOR TRANSLUMINAL INTERVENTIONAL PROCEDURES. REFINITY™ ST CATHETERS ARE DESIGNED FOR USE AS

		AN ADJUNCT TO CONVENTIONAL ANGIOGRAPHIC PROCEDURES TO PROVIDE AN IMAGE OF THE VESSEL LUMEN AND WALL STRUCTURES., CATHETER(EAGLE EYE PLATINUM DIGITAL IVUS CATHETERS)-THE EAGLE EYE PLATINUM CATHETERS ARE DESIGNED FOR USE IN THE EVALUATION OF VASCULAR MORPHOLOGY IN BLOOD VESSEL OF THE CORONARY AND PERIPHERAL VASCULATURE BY PROVIDING A CROSS-SECTIONAL IMAGE OF SUCH VESSEL. THIS DEVICE IS NOT CURRENTLY INDICATED FOR USE IN CEREBRAL VESSELS. THE EAGLE EYE ULTRASOUND IMAGING CATHETERS ARE DESIGNED FOR USE AS AN ADJUNCT TO CONVENTIONAL ANGIOGRAPHIC PROCEDURES TO PROVIDE AN IMAGE OF THE VESSEL LUMEN AND WALL STRUCTURES.
2230	IMP/MD/2020/000344	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUTURE(MONOCRYL PLUS ANTIBACTERIAL (POLIGLECAPRONE 25) SUTURE)-MONOCRYL PLUS ANTIBACTERIAL SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION WHERE AN ABSORBABLE MATERIAL IS INDICATED.
2231	IMP/MD/2020/000345	1.License Holder Name: RENOVATE BIOLOGICALS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KIDNEY PERFUSION SOLUTION(KPS-1®)-KPS-1, KIDNEY PERFUSION SOLUTION IS INTENDED TO BE USED FOR FLUSHING AND CONTINUOUS HYPOTHERMIC MACHINE PERFUSION OF KIDNEYS AT THE TIME OF THEIR REMOVAL FROM THE DONOR IN PREPARATION FOR STORAGE, TRANSPORTATION AND EVENTUAL TRANSPLANTATION INTO A RECIPIENT.,STATIC PRESERVATION SOLUTION(SPS-1® (UW SOLUTION))-SPS-1 (UW SOLUTION) IS INTENDED FOR THE FL USHING AND COLD STORAGE OF KIDNEY, LIVER AND PANCREAS ORGANS AT THE TIME OF ORGAN REMOVAL FROM THE DONOR IN PREPARATION FOR STORAGE, TRANSPORTATION AND EVENTUAL TRANSPLANTATION INTO A RECIPIENT.

2232	IMP/MD/2020/000346	1.License Holder Name: CONCEPT MEDICAL RESEARCH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA CATHETER(MAYA)-THE MAYA CATHETER IS INTENDED FOR DILATATION OF DISEASED SEGMENT(S) IN A CORONARY ARTERY OR A CORONARY BYPASS. THE MAYA CATHETER IS INDICATED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. THE MAYA PTCA CATHETER IS THEREFORE INDICATED TO DILATE THE DISEASED SEGMENT(S) IN A CORONARY ARTERY OR A CORONARY BYPASS, TO IMPROVE MYOCARDIAL PERFUSION. IT ALLOWS ALSO FOR RESTORING CORONARY FLOW IN PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION. THE PATENTS SHOULD FULFIL ONE OR MORE OF THE FOLLOWING CRITERIA: • PATIENTS MUST BE JUDGED TO BE ACCEPTABLE CANDIDATES FOR CORONARY BYPASS SURGERY. • PATIENTS WITH SINGLE VESSEL ATHEROSCLEROTIC LESION(S), SUBTOTAL AND ACCESSIBLE TO DILATATION WITH GUIDEWIRE AND CATHETER. • CERTAIN MULTI-VESSEL DISEASED PATIENTS MAY ALSO BE CANDIDATES FOR THIS PROCEDURE. • CERTAIN PATIENTS, WHO HAVE UNDERGONE PREVIOUS CORONARY BYPASS SURGERY WITH RECURRENCE OF SYMPTOMS AND PROGRESSION OF THE DISEASE IN THE CORONARY ARTERY, OR STENOSIS AND CLOSURE OF THE GRAFTS, MAY ALSO BE CANDIDATES.,PTCA CATHETER(MAYA NC)-THE INDICATIONS AND CONTRA-INDICATIONS ARE DEFINED FOR STERILE CATHETERS. IT IS ADVISABLE TO CONFIRM THEM FOR THE FINAL DEVICE. IT IS INTENDED TO DILATE A STENOTIC PORTION OF A NATIVE CORONARY ARTERY OR A BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION AND THE FOR POST-DILATATION OF STENTS (BARE METAL AND DRUG-ELUTING). THE PATIENTS SHOULD FULFILL ONE OR MORE OF THE FOLLOWING CRITERIA: • PATIENTS MUST BE JUDGED TO BE ACCEPTABLE CANDIDATES FOR CORONARY BYPASS SURGERY. • PATIENTS WITH SINGLE VESSEL ATHEROSCLEROTIC LESION(S), SUBTOTAL AND ACCESSIBLE TO DILATATION WITH GUIDEWIRE AND CATHETER. • CERTAIN MULTI-VESSEL DISEASED PATIENTS MAY ALSO BE CANDIDATES FOR THIS PROCEDURE. • CERTAIN PATIENTS, WHO HAVE UNDERGONE PREVIOUS CORONARY BYPASS SURGERY WITH RECURRENCE OF SYMPTOMS AND PROGRESSION OF THE DISEASE IN THE CORONARY ARTERY, OR STENOSIS AND CLOSURE OF THE GRAFTS, MAY ALSO BE CANDIDATES. • PATIENTS WHO ARE UNDERGOING A STENT IMPLANTATION WITH A STENT POST-DILATATION.,ASPIRATION CATHETER(TRANSPORT AC)-THE TRANSPORT AC CATHETER IS INDICATED FOR USE IN THE CENTRAL

		AND PERIPHERAL CIRCULATORY SYSTEM, INCLUDING SAPHENOUS VEIN GRAFTS TO: • CONTAIN AND ASPIRATE EMBOLIC MATERIAL (THROMBUS/DEBRIS) WHILE PERFORMING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY AND/OR STENTING PROCEDURES.
2233	IMP/MD/2020/000350	1.License Holder Name: ABBOTT HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDE WIRE(HI-TORQUE INFILTRAC GUIDE WIRE , HI-TORQUE INFILTRAC PLUS GUIDE WIRE)-INTENDED TO FACILITATE THE DELIVERY OF CATHETER-BASED INTERVENTIONAL DEVICES DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). THIS GUIDE WIRE MAY BE USED WITH COMPATIBLE STENT DEVICES DURING THERAPEUTIC PROCEDURES. THE GUIDE WIRE MAY BE USED TO REACH AND CROSS A TARGET LESION, PROVIDE A PATHWAY WITHIN THE VESSEL STRUCTURE, FACILITATE THE SUBSTITUTION OF ONE DIAGNOSTIC OR INTERVENTIONAL DEVICE FOR ANOTHER, AND TO DISTINGUISH THE VASCULATURE. THIS GUIDE WIRE MAY ALSO BE USED TO CROSS OR ASSIST IN CROSSING DE NOVO CHRONIC TOTAL CORONARY OCCLUSIONS (CTO).,GUIDE WIRE(HI-TORQUE PROCEED 170T ANGLED, HI-TORQUE PROCEED 220T ANGLED)-THIS GUIDE WIRE IS INTENDED TO FACILITATE THE DELIVERY OF CATHETER-BASED INTERVENTIONAL DEVICES DURING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN ARTERIES SUCH AS THE FEMORAL, POPLITEAL, AND INFRA-POPLITEAL ARTERIES. THIS GUIDE WIRE MAY BE USED WITH COMPATIBLE STENT DEVICES DURING THERAPEUTIC PROCEDURES. THE GUIDE WIRE MAY BE USED TO REACH AND CROSS A TARGET LESION, PROVIDE A PATHWAY WITHIN THE VESSEL STRUCTURE, FACILITATE THE SUBSTITUTION OF ONE DIAGNOSTIC OR INTERVENTIONAL DEVICE FOR ANOTHER, AND TO DISTINGUISH THE VASCULATURE.

2234	IMP/MD/2020/000351	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SYNAPSE- BAR(NA)-THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: — TOP-LOADING VARIABLE AXIS SCREWS — HOOKS — TRANSVERSE BARS — RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY., CABLE IMPLANTS - PIN (NON-STERILE) (TICP)(NA)-EXTERNAL FIXATOR DEVICES ARE INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS.,VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)- HOOK (TAN)(NA)-THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD,SYNMESH- END RING(NA)-SYNMESH IS A VERTEBRAL BODY REPLACEMENT DEVICE FOR THE CERVICAL, THORACIC AND LUMBAR SPINE. TITANIUM IMPLANTS IN VARIOUS FOOTPRINTS AND HEIGHTS ENABLE THE SURGEON TO CHOOSE THE CONFIGURATION THAT IS BEST SUITED TO THE PATIENT'S INDIVIDUAL PATHOLOGY AND ANATOMY. THE MESH MAY ALSO BE TRIMMED FOR A CUSTOM FIT. THE IMPLANTS CAN BE INSERTED ANTERIORLY, LATERALLY OR ANTEROLATERALLY.,CABLE IMPLANTS- PIN (STAINLESS STEEL) (10 YEARS)(NA)-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE

	OR TENSION BAND TECHNIQUE.,CABLE IMPLANTS -PIN (NON-STERILE) (STAINLESS STEEL)(NA)-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE.,INTERNAL MIDFACE DISTRACTOR- PLATE(NA)-THE INTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED.,SYNAPSE - SCREW(NA)-THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: — TOP-LOADING VARIABLE AXIS SCREWS — HOOKS — TRANSVERSE BARS — RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY., POSTERIOR RODS- ROD (TAN)(NA)-THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: — TOP-LOADING VARIABLE AXIS SCREWS — HOOKS — TRANSVERSE BARS — RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY.,SYNMESH- SCREW(NA)-SYNMESH IS A VERTEBRAL BODY REPLACEMENT DEVICE FOR THE CERVICAL, THORACIC AND LUMBAR SPINE. TITANIUM IMPLANTS IN VARIOUS FOOTPRINTS AND HEIGHTS ENABLE THE SURGEON TO CHOOSE THE CONFIGURATION THAT IS BEST SUITED TO THE PATIENT'S INDIVIDUAL PATHOLOGY AND ANATOMY. THE MESH MAY ALSO BE TRIMMED FOR A CUSTOM FIT. THE IMPLANTS CAN BE INSERTED ANTERIORLY, LATERALLY OR ANTEROLATERALLY.,CABLE IMPLANTS- PIN (NON-STERILE) (TICP)(NA)-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE.,SYNAPSE - CONNECTORS(NA)-THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: — TOP-LOADING VARIABLE AXIS SCREWS — HOOKS — TRANSVERSE BARS — RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY.,MAXILLARY DISTRACTOR- MAXILLARY DISTRACTOR MAIN BODY(NA)-THE MAXILLARY DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED.,VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR) - HOOK (TICP)(NA)-THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST

	WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD,POSTERIOR RODS- ROD (TICP)(NA)-THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: — TOP-LOADING VARIABLE AXIS SCREWS — HOOKS — TRANSVERSE BARS — RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY.,VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)- CLOSURE(NA)-THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION

	PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD,SYNAPSE- HOOK(NA)-THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: — TOP-LOADING VARIABLE AXIS SCREWS — HOOKS — TRANSVERSE BARS — RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY.,EXTERNAL MIDFACE DISTRACTOR - PLATE(NA)-THE DEPUY SYNTHES EXTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED.,POSTERIOR CONNECTORS- CONNECTOR(NA)-THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.,VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)- LOCK(NA)-THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM

	(INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD,INTERNAL MIDFACE DISTRACTOR - MIDFACE DISTRACTOR(NA)-THE INTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED., MAXILLARY DISTRACTOR- PLATE(NA)-THE MAXILLARY DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED., INTERNAL MIDFACE DISTRACTOR - EXTENSION(NA)-THE INTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED.,VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)- RIB SUPPORT(NA)-THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD,INTERNAL MIDFACE DISTRACTOR - NUT(NA)-THE INTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED.,UNIVERSAL SPINAL SYSTEM(USS)-

	SLEEVE(NA)-THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.,VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)- BAR(NA)-THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD,VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)- EXTENSION RODS(NA)-THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST

	WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD,CABLE IMPLANTS - PIN (TICP) (10 YEARS)(NA)-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE.,VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)- HALF-RING(NA)-THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD,UNIVERSAL SPINAL SYSTEM(USS)-SCREW(NA)-THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND

		HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.
2235	IMP/MD/2020/000352	1.License Holder Name: TRIAGE MEDITECH PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL WOUND DRESSING(CURAPOR®)-THE CURAPOR® SURGICAL WOUND DRESSING IS INTENDED FOR POSTOPERATIVE, ACUTE AND SUPERFICIAL WOUND CARE, AS WELL AS FOR CUTS AND LACERATIONS. THE USE OF THESE SURGICAL WOUND DRESSING IS NON-INVASIVE. THEY ARE APPLIED TO BROKEN SKIN (SUPERFICIAL WOUNDS, SURGICAL SUTURE) IN THE AREA OF THE WOUND PAD. THE SURROUNDING SKIN TO WHICH THE ADHESIVE AREA IS APPLIED IS GENERALLY INTACT, BUT MAY BE THIN AND SENSITIVE IN OLDER PATIENTS, FOR EXAMPLE.,TRANSPARENT SURGICAL WOUND DRESSING(CURAPOR® TRANSPARENT SURGICAL WOUND DRESSING) -CURAPOR® TRANSPARENT SURGICAL WOUND DRESSING IS INTENDED FOR STERILE CARE OF POSTOPERATIVE WOUNDS, ACCIDENTAL INJURIES, AS WELL AS SMALL CUTS AND ABRASIONS.

2236	IMP/MD/2020/000353	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHODONTIC TUBE (STAINLESS STEEL)(ACCENT BUCCAL TUBES ,PEERLESS BUCCAL TUBES)-INTENDED TO BE APPLIED TO A PATIENT'S 1ST AND 2ND MOLARS IN ORDER TO CORRECT MALOCCLUSION.,ORTHODONTIC WIRE (STAINLESS STEEL)(LIGATURE WIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH.
2237	IMP/MD/2020/000355	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANGIOGRAPHIC CATHETER(IMAGER II ANGIOGRAPHIC CATHETER)-THE IMAGER II ANGIOGRAPHIC CATHETERS ARE DESIGNED TO PROVIDE A PATHWAY FOR DELIVERING CONTRAST MEDIA TO SELECTED SITES IN THE VASCULAR SYSTEM, INCLUDING THE CAROTID ARTERIES. ADDITIONALLY, THE 5F SELECTIVE IMAGER II ANGIOGRAPHIC CATHETERS WITHOUT SIDE HOLES CAN ALSO BE USED FOR THE CONTROLLED AND SELECTIVE DELIVERY OF THE BOSTON SCIENTIFIC INTERLOCK - 35 DETACHABLE COILS INTO THE PERIPHERAL VASCULATURE.
2238	IMP/MD/2020/000356	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENOTRACHEAL TUBE (NIM TRIVANTAGE EMG)(NIM TRIVANTAGE ENDOTRACHEAL TUBE)-THE EMG ENDOTRACHEAL TUBE IS INTENDED FOR USE AS A MEANS OF PROVIDING BOTH AN OPEN AIRWAY FOR PATIENT VENTILATION AND FOR INTRAOPERATIVE MONITORING OF EMG ACTIVITY OF THE LARYNGEAL MUSCULATURE DURING SURGERY WHEN CONNECTED TO AN APPROPRIATE EMG MONITOR. THE EMG ENDOTRACHEAL OF THE NERVES SUPPLYING THE LARYNGEAL MUSCULATURE IS REQUIRED DURING SURGICAL PROCEDURES.
2239	IMP/MD/2020/000357	1.License Holder Name: UTANCO INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHOPAEDIC CASTING TAPE(GREEN CAST / GREEN SPLINT)-FOR TEMPORARY IMMOBILIZATION OF FRACTURES, SPRAINS AND STRAINS

2240	IMP/MD/2020/000359	1.License Holder Name: GREINER BIO-ONE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYPODERMIC NEEDLES (VACUETTE® VISIO PLUS NEEDLES)-VACUETTE® VISIO PLUS BLOOD COLLECTION NEEDLES ARE DESIGNED FOR USE IN THE DAILY BLOOD COLLECTION ROUTINE WHEN DELEGATED BY A QUALIFIED PRACTITIONER. THE FLASHBACK WINDOW IS SITUATED IN THE TRANSPARENT PART OF THE CANNULA HUB, WHICH ASSISTS THE USER TO RECOGNISE SUCCESSFUL VEIN PENETRATION. THEY ARE FOR SINGLE-USE ONLY AND SHOULD ONLY BE USED BY ADEQUATELY TRAINED HEALTHCARE PERSONNEL IN ACCORDANCE WITH THESE INSTRUCTIONS.,HYPODERMIC NEEDLES(VACUETTE® LUER ADAPTER)-THE VACUETTE® LUER ADAPTER IS FOR USE IN VENOUS BLOOD COLLECTION WITH ATTACHED BUTTERFLY NEEDLE OR LUER NEEDLE.,HYPODERMIC NEEDLES(VACUETTE® MULTIPLE USE DRAWING NEEDLES)-VACUETTE® MULTIPLE USE DRAWING NEEDLES ARE FOR USE IN VENOUS BLOOD COLLECTION.
2241	IMP/MD/2020/000360	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOPSY NEEDLE(BARD® MISSION DISPOSABLE CORE BIOPSY INSTRUMENT)-THE BARD® MISSION™ DISPOSABLE CORE BIOPSY INSTRUMENT IS INTENDED FOR USE IN OBTAINING BIOPSY SAMPLES FROM SOFT TISSUES SUCH AS FROM THE LUNG, LIVER, SPLEEN, KIDNEY, PROSTATE, LYMPH NODES, BREAST, THYROID, AND VARIOUS SOFT TISSUE TUMORS.,BIOPSY NEEDLE(BARD® MARQUEE® DISPOSABLE CORE BIOPSY INSTRUMENT KIT)-THE BARD® MARQUEE® DISPOSABLE CORE BIOPSY INSTRUMENT KIT ARE INTENDED FOR USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS LIVER, KIDNEY, PROSTATE, SPLEEN, LYMPH NODES AND VARIOUS SOFT TISSUE TUMORS. IT IS NOT INTENDED FOR USE IN BONE.,BIOPSY NEEDLE(BARD® MISSION DISPOSABLE CORE BIOPSY INSTRUMENT KIT)-THE BARD® MISSION™ DISPOSABLE CORE BIOPSY INSTRUMENT KIT IS INTENDED FOR USE IN OBTAINING BIOPSY SAMPLES FROM SOFT TISSUES SUCH AS FROM THE LUNG, LIVER, SPLEEN, KIDNEY, PROSTATE, LYMPH NODES, BREAST, THYROID, AND VARIOUS SOFT TISSUE TUMORS.,BIOPSY NEEDLE(BARD® MARQUEE® DISPOSABLE CORE BIOPSY INSTRUMENT)-THE BARD® MARQUEE® DISPOSABLE CORE BIOPSY INSTRUMENT ARE INTENDED FOR USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS LIVER, KIDNEY, PROSTATE, SPLEEN, LYMPH NODES AND VARIOUS SOFT TISSUE TUMORS. IT IS NOT INTENDED FOR USE IN BONE.

2242	IMP/MD/2020/000361	1.License Holder Name: SP DENTAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT FIXTURE(MINI2SKY)-FOR IMPLANTATION IN HUMAN MAXILLA OR MANDIBLE FOR DENTAL REHABILITATION.,DENTAL IMPLANT PROSTHETICS(MINISKY)-TO BE USED WITH DENTAL IMPLANT SYSTEMS,DENTAL IMPLANT FIXTURE(MINI1SKY)-FOR IMPLANTATION IN HUMAN MAXILLA OR MANDIBLE FOR DENTAL REHABILITATION.
2243	IMP/MD/2020/000362	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LARYNGEAL MASK AIRWAY(LMA PROSEAL™)-THE LMA PROSEAL IS INDICATED FOR USE IN ACHIEVING AND MAINTAINING CONTROL OF AIRWAY DURING ROUTINE AND EMERGENCY ANAESTHETIC PROCEDURES IN FASTED PATIENTS USING EITHER SPONTANEOUS OR POSITIVE PRESSURE VENTILATION. IT IS ALSO INDICATED FOR SECURING THE IMMEDIATE AIRWAY IN KNOWN OR UNEXPECTED DIFFICULT AIRWAY SITUATIONS. THE LMA PROSEAL IS NOT INDICATED FOR USE AS A REPLACEMENT FOR THE ENDOTRACHEAL TUBE AND IS BEST SUITED FOR USE IN ELECTIVE SURGICAL PROCEDURES WHERE TRACHEAL INTUBATION IS NOT NECESSARY. THE LMA PROSEAL MAY BE USED TO ESTABLISH AN IMMEDIATE, CLEAR AIRWAY DURING CARDIOPULMONARY RESUSCITATION (CPR) IN THE PROFOUNDLY UNCONSCIOUS PATIENT WITH ABSENT GLOSSOPHARYNGEAL AND LARYNGEAL REFLEXES REQUIRING ARTIFICIAL VENTILATION. IN THESE CASES, LMA PROSEAL SHOULD BE USED ONLY WHEN TRACHEAL INTUBATION IS NOT POSSIBLE.,LARYNGEAL MASK AIRWAY(LMA CLASSIC™)-IT IS INDICATED FOR USE IN ACHIEVING AND MAINTAINING CONTROL OF THE AIRWAY DURING ROUTINE AND EMERGENCY ANAESTHETIC PROCEDURES IN FASTED PATIENTS USING EITHER SPONTANEOUS OR POSITIVE PRESSURE VENTILATION (PPV). IT IS ALSO INDICATED FOR SECURING THE IMMEDIATE AIRWAY IN KNOWN OR UNEXPECTED DIFFICULT AIRWAY SITUATIONS. IT IS BEST SUITED FOR USE IN ELECTIVE SURGICAL PROCEDURES WHERE TRACHEAL INTUBATION IS NOT NECESSARY. IT MAY BE USED TO ESTABLISH AN IMMEDIATE, CLEAR AIRWAY DURING CARDIOPULMONARY RESUSCITATION (CPR) IN THE PROFOUNDLY UNCONSCIOUS PATIENT WITH ABSENT GLOSSOPHARYNGEAL AND LARYNGEAL REFLEXES REQUIRING ARTIFICIAL VENTILATION. IN THESE CASES, LMA CLASSIC SHOULD BE USED ONLY WHEN TRACHEAL INTUBATION IS NOT POSSIBLE.

2244	IMP/MD/2020/000363	1.License Holder Name: RUPASHREE HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CAST & SPLINT(OPTTY CAST ROYAL, SPLINT AND CASTING TAPE)-IT IS INTENDED FOR EXTERNAL IMMOBILIZATION OF FRACTURE AND SPRAINS OF LIMBS.
2245	IMP/MD/2020/000364	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LARYNGEAL MASK AIRWAY(LMA® PROSEAL™ INTRODUCER)-THE LMA PROSEAL INTRODUCER IS INTENDED TO USE AS A REMOVABLE INTRODUCER TOOL TO AID INSERTION OF LMA PROSEAL WITHOUT PLACING FINGERS IN THE MOUTH.,LARYNGEAL MASK AIRWAY(LMA® FASTRACH™ STABILIZER ROD)-THE LMA FASTRACH™ STABILISER ROD IS INDICATED FOR USE DURING REMOVAL OF THE LMA FASTRACH AFTER INTUBATION TO KEEP THE ENDOTRACHEAL TUBE IN PLACE.,LARYNGEAL MASK AIRWAY(LMA® PROSEAL™)-THE LMA PROSEAL IS INDICATED FOR USE IN ACHIEVING AND MAINTAINING CONTROL OF AIRWAY DURING ROUTINE AND EMERGENCY ANAESTHETIC PROCEDURES IN FASTED PATIENTS USING EITHER SPONTANEOUS OR POSITIVE PRESSURE VENTILATION. IT IS ALSO INDICATED FOR SECURING THE IMMEDIATE AIRWAY IN KNOWN OR UNEXPECTED DIFFICULT AIRWAY SITUATIONS. THE LMA PROSEAL IS NOT INDICATED FOR USE AS A REPLACEMENT FOR THE ENDOTRACHEAL TUBE AND IS BEST SUITED FOR USE IN ELECTIVE SURGICAL PROCEDURES WHERE TRACHEAL INTUBATION IS NOT NECESSARY. THE LMA PROSEAL MAY BE USED TO ESTABLISH AN IMMEDIATE, CLEAR AIRWAY DURING CARDIOPULMONARY RESUSCITATION (CPR) IN THE PROFOUNDLY UNCONSCIOUS PATIENT WITH ABSENT GLOSSOPHARYNGEAL AND LARYNGEAL REFLEXES REQUIRING ARTIFICIAL VENTILATION. IN THESE CASES, LMA PROSEAL SHOULD BE USED ONLY WHEN TRACHEAL INTUBATION IS NOT POSSIBLE.

2246	IMP/MD/2020/000365	1.License Holder Name: APEX MARKETING 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAMMARY IMPLANTS (EUROSILICONE MAMMARY IMPLANTS)-IT IS INDICATED FOR FOLLOWING: COSMETIC AUGMENTATION SURGERY, AUGMENTATION AND CONTOUR CORRECTION OF CONGENITAL ANOMALIES OF THE BREAST, RECONSTRUCTION OF THE BREAST FOLLOWING SUBCUTANEOUS MASTECTOMY AND OTHER SUITABLE MASTECTOMY PROCEDURES OR TRAUMA, COMBINED BREAST AND CHEST WALL ABNORMALITIES, REPLACEMENT OF IMPLANTS FOR MEDICAL AND COSMETIC REASONS,REMOTE VALVE TISSUE EXPANDER (EUROSILICONE REMOTE VALVE TISSUE EXPANDER)-TISSUE EXPANDERS ARE DESIGNED TO GRADUALLY STRETCH THE TISSUE ADJACENT TO THE IMPLANTATION ARE (NORMALLY SKIN). ONCE THE TISSUE HAS EXPANDED SUFFICIENTLY, THE DEVICE IS REMOVED, AND THE EXTRA TISSUE CAN THEN BE USED WHERE IT IS REQUIRED (BURNS, SCARS, ETC.). TISSUE EXPANSION CAN ALSO BE USED IN THE PREPARATION FOR PERMANENT PROSTHESIS IMPLANTATION, FACIAL IMPLANTS(EUROSILICONE FACIAL IMPLANT)-FACIAL IMPLANT IS INTENDED FOR IMPROVEMENT IN THE APPEARANCE OF THE FACE DURING RECONSTRUCTIVE OR COSMETIC SURGERY
2247	IMP/MD/2020/000366	1.License Holder Name: DORA MEDICAL TRADING (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER KITS(GMKEY)-A CENTRAL VENOUS CATHETER KIT IS AN INTRAVASCULAR CATHETER INSERTED INTO THE VENOUS SYSTEM FOR SHORT-TERM USE (LESS THAN 30DAYS) USING A DILATOR AND GUIDE WIRE. THE CATHETER PROVIDES VASCULAR ACCESS USED FOR VENOUS BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING, AND DRUG AND FLUID ADMINISTRATION., HEMODIALYSIS CATHETER KITS(GMKEY)-AN HEMODIALYSIS CATHETER KIT IS INDICATED FOR USE IN ATTAINING SHORT-TERM (INTENDED USE LESS THAN 30 DAYS) VASCULAR ACCESS FOR HEMODIALYSIS, HEMOPERFUSION, INFUSION AND APHERESIS TREATMENTS. THE CATHETER IS INTENDED TO BE INSERTED IN THE JUGULAR, FEMORAL, OR SUBCLAVIAN VEIN AS REQUIRED.

2248	IMP/MD/2020/000367	1.License Holder Name: SMITHS MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEEDLES(GRIPPER NEEDLES)-THIS PRODUCT IS INDICATED FOR ADMINISTRATION INTO OR WITHDRAWAL OF FLUIDS FROM THE IMPLANTED PORTS.,PORTS (SPECILATY PORTS)-PORT-A-CATH® AND PORT-A-CATH® II LOW PROFILE™ EPIDURAL OR INTRASPINAL IMPLANTABLE ACCESS SYSTEMS ARE DESIGNED TO PERMIT REPEATED ACCESS TO THE EPIDURAL OR INTRATHECAL SPACE FOR DRUG DELIVERY. THE SYSTEMS ARE INTENDED FOR LONG-TERM, CONTINUOUS ACCESS TO THE INTRASPINAL SPACE FOR THE DELIVERY OF DRUGS APPROVED FOR INTRASPINAL DELIVERY. THE LABELING FOR THE DRUG GOVERNS THE INDICATIONS, CONTRAINDICATIONS, DOSAGES, AND WARNINGS RELATED TO THE USE OF MEDICATION,PORTS (PORT-A-CATH)-PORT-A-CATH® AND PORT-A-CATH® II SYSTEMS ARE INDICATED WHEN PATIENT THERAPY REQUIRES REPEATED VASCULAR ACCESS FOR INJECTION OR INFUSION THERAPY AND/OR VENOUS BLOOD SAMPLING,PORTS (POWER PORT-A-CATH II)-SMITHS POWER P.A.C.® IMPLANTABLE VENOUS ACCESS SYSTEMS ARE INDICATED WHEN PATIENT THERAPY REQUIRES REPEATED VASCULAR ACCESS FOR INJECTION OR INFUSION THERAPY AND/OR FOR VENOUS BLOOD SAMPLING. WHEN USED WITH A GRIPPER PLUS® POWER P.A.C. SAFETY HUBER NEEDLE OR OTHER POWER INJECTABLE HUBER NEEDLE, THE SMITHS. POWER P.A.C.® IMPLANTABLE VENOUS ACCESS SYSTEMS ARE INDICATED FOR POWER INJECTION OF CONTRAST MEDIA. FOR POWER INJECTION OF CONTRAST MEDIA,MAXIMUM RECOMMENDED INFUSION RATE 5 ML/S, NEEDLES(GRIPPER PLUS SAFETY)-THIS PRODUCT IS INDICATED FOR ADMINISTRATION INTO OR WITHDRAWAL OF FLUIDS FROM THE IMPLANTED PORTS. IT IS DESIGNED TO HELP AGAINST EXPOSURE TO BLOOD BORNE PATHOGENS CAUSED BY ACCIDENTAL NEEDLE STICK INJURIES. ,VA INTRODUCERS(VA INTRODUCERS)-INDICATED FOR THE INTRODUCTION OF CATHETERS INTO THE SUBCLAVIAN VEIN,PORTS (SINGLE LUMEN PORTAL SYSTS)-P.A.S. PORT® SYSTEMS ARE INDICATED WHEN PATIENT THERAPY REQUIRES REPEATED VENOUS ACCESS FOR INJECTION OR INFUSION THERAPY AND/OR VENOUS BLOOD SAMPLING.,PORTS (PROPORT PLASTIC PORTS)-PROPORT® IMPLANTABLE VENOUS ACCESS SYSTEMS ARE INTENDED TO PERMIT REPEATED ACCESS TO THE VENOUS SYSTEM FOR THE PARENTERAL DELIVERY OF MEDICATIONS, FLUIDS, AND NUTRITIONAL SOLUTIONS, AND FOR THE SAMPLING OF VENOUS BLOOD,NEEDLES(GRIPPER PLUS POWER)-THIS PRODUCT IS INDICATED FOR ADMINISTRATION INTO OR WITHDRAWAL OF FLUIDS FROM THE IMPLANTED PORTS. IT IS DESIGNED TO HELP AGAINST EXPOSURE TO BLOOD BORNE

		PATHOGENS CAUSED BY ACCIDENTAL NEEDLE STICK INJURIES. WHEN USED WITH POWER INJECTABLE IMPLANTABLE VENOUS ACCESS PORTS, THIS PRODUCT IS INDICATED FOR POWER INJECTING CONTRAST MEDIA.
2249	IMP/MD/2020/000368	1.License Holder Name: GLOBE BIO MEDICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VALVULOPLASTY BALLOON CATHETERS(CARDIOVASCULAR BALLOON DILATATION CATHETER)-TO BE USED TO DILATE MITRAL AND PULMONARY VALVES.
2250	IMP/MD/2020/000372	1.License Holder Name: VEERSUN MEDICAL DISPOSABLES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:WET WIPES(HOSPICARE)-APPLICATION & USAGE: N.I.C.U/I.C.U: INCUBATORS & WARMERS, SYRINGE PUMPS, INFUSION PUMP, MONITOR PULSE-OXIMETER, VENTILATOR, ACCESSORIES LIKE CABLE, CORDS, ADAPTORS, CONNECTORS, WIRES O.T: OT TABLES, OVERHEAD LIGHTS, TROLLEYS, MONITORS, FIBRILATORS, HEART LUNG MACHINE ETC AKD: HAEMODIALYSIS SYSTEM, RESPIRATOR MONITOR, BLOOD PUMP DENTAL HOMES: DENTAL CHAIR, EQUIPMENT & ACCESSORIES, HAND PIECES, SPITTING AREA OF DENTAL CHAIR ETC OTHERS: C.T. SCANNERS, BLOOD BANK, MEDICAL LABORATORIES, DOOR HANDLES, BED FRAMES, KEYBOARD, TELEPHONES, THERMOMETERS, STETHOSCOPE
2251	IMP/MD/2020/000373	1.License Holder Name: UNITY PHARMA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIGH DENSITY POLYETHYLENE SURGICAL IMPLANT.(OMNIPORE® DUROMAX® SURGICAL IMPLANTS)-OMNIPORE® DUROMAX® SURGICAL IMPLANTS ARE INTENDED FOR NON-WEIGHT BEARING APPLICATIONS OF MAXILLOFACIAL AND ORBITAL RECONSTRUCTION, COSMETIC SURGERY AND REPAIR OF MAXILLOFACIAL AND ORBITAL TRAUMA., HIGH DENSITY POLYETHYLENE SURGICAL IMPLANT(OMNIPORE SURGICAL IMPLANT)-OMNIPORE SURGICAL IMPLANT IN BLOCK, SHEET, AND ANATOMICAL SHAPES ARE INTENDED FOR NON-WEIGHT BEARING APPLICATIONS OF CRANIOFACIAL RECONSTRUCTION/COSMETIC SURGERY AND REPAIR OF CRANIOFACIAL TRAUMA. OMNIPORE SURGICAL IMPLANTS ARE ALSO INTENDED FOR THE AUGMENTATION OR RESTORATION OF CONTOUR IN THE CRANIOMAXILLOFACIAL SKELETON.

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2252	IMP/MD/2020/000374	1.License Holder Name: CAREON HEALTHCARE SOLUTIONS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NON-ABSORBABLE SURGICAL STAINLESS STEEL SUTURE, U.S.P.(DEMESTEEL)-DEMESTEEL IS A STAINLESS STEEL SUTURE COMPOSED OF 316L STAINLESS STEEL, IS INTENDED FOR USE IN ABDOMINAL WOUND CLOSURE, INTESTINAL ANASTOMOSIS, HERNIA REPAIR, STERNAL CLOSURE AND CERTAIN ORTHOPEDIC PROCEDURES, INCLUDING CERCLAGE AND TENDON REPAIR.,POLYGLYCOLIC ACID (PGA) ABSORBABLE SURGICAL SUTURE U.S.P.(DEMESORB TM)-PGA SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUE., PGLA RAPID ABSORBABLE SURGICAL SUTURE U.S.P(DEMEQUICK TM) -DEMEQUICK (RAPID ABSORBABLE) SURGICAL SUTURE IS INDICATED FOR USE IN SUPERFICIAL SOFT TISSUE APPROXIMATION (I.E., MUCOSA AND SKIN) WHERE ONLY SHORT TERM WOUND SUPPORT (7-10 DAYS) IS REQUIRED. DEMEQUICK (RAPID ABSORBABLE) SURGICAL SUTURE IS NOT INTENDED FOR USE IN LIGATION, CARDIOVASCULAR, OPHTHALMIC OR NEUROLOGICAL PROCEDURES.,POLYGLACTIN 910 ABSORBABLE SURGICAL SUTURE U.S.P.(DEMECRYL TM)-POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUE,POLYDIOXANONE ABSORBABLE SURGICAL SUTURE U.S.P.(DEMEDIOX TM)-POLYDIOXANONE MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PEDIATRIC CARDIOVASCULAR TISSUE WHERE GROWTH IS EXPECTED TO OCCUR AND OPHTHALMIC SURGERY. POLYDIOXANONE SUTURE IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTEND WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE,NYLON SUTURE NONABSORBABLE POLYAMIDE SURGICAL SUTURE U.S.P.(DEMELON TM)-THE DEMETECH NONABSORBABLE NYLON SUTURE WITH AND WITHOUT NEEDLES IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES. PRODUCT IS INTENDED FOR LONG TERM USE OVER 30 DAYS. THIS PRODUCT IS NOT INTENDED TO BE USED ON THE HEART OR WITH THE CENTRAL CIRCULATORY AND CENTRAL NERVOUS SYSTEMS., POLYESTER NONABSORBABLE SURGICAL SUTURE U.S.P.(DEMEBOND

		TM)-THE DEMETECH NONABSORBABLE POLYESTER SUTURE WITH AND WITHOUT NEEDLES IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES. PRODUCT IS INTENDED FOR LONG TERM USE OVER 30 DAYS. THIS PRODUCT IS NOT INTENDED TO BE USED ON THE HEART OR WITH THE CENTRAL CIRCULATORY AND CENTRAL NERVOUS SYSTEMS.,POLIGLECAPRONE 25 MONOFILAMENT SYNTHETIC ABSORBABLE SUTURE, U.S.P(DEMECAPRONE TM)-DEMECAPRONE (POLIGLECAPRONE 25) SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL SURGERY, MICROSURGERY, OR OPHTHALMIC SURGERY.,POLYPROPYLENE NONABSORBABLE SURGICAL SUTURE, U.S.P.(DEMELENE TM)-THE DEMETECH NONABSORBABLE POLYPROPYLENE SUTURE WITH AND WITHOUT NEEDLES IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES. PRODUCT IS INTENDED FOR LONG TERM USE OVER 30 DAYS. THIS PRODUCT IS NOT INTENDED TO BE USED ON THE HEART OR WITH THE CENTRAL CIRCULATORY AND CENTRAL NERVOUS SYSTEMS,DEMETECH POLYPROPYLENE SURGICAL MESH (DEMELENE MESH)-THE DEMETECH ™ POLYPROPYLENE MESH HERNIA DEVICE IS INDICATED FOR THE REPAIR OF ABDOMINAL WALL HERNIA DEFECTS,SILK NONABSORBABLE SURGICAL SUTURE U.S.P. (DEMESILK TM)-THE DEMETECH NONABSORBABLE SILK SUTURE WITH AND WITHOUT NEEDLES IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES. PRODUCT IS INTENDED FOR LONG TERM USE OVER 30 DAYS. THIS PRODUCT IS NOT INTENDED TO BE USED ON THE HEART OR WITH THE CENTRAL CIRCULATORY AND CENTRAL NERVOUS SYSTEMS
2253	IMP/MD/2020/000376	1.License Holder Name: EVENT MEDI SYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SHEATH INTRODUCER KIT (BIOTEQ)-SHEATH INTRODUCER KIT IS INTENDED TO PROVIDE ACCESS AND FACILITATE THE PERCUTANEOUS INTRODUCTION OF VARIOUS DEVICES INTO VEINS AND/OR ARTERIES WHILE MAINTAINING HEMOSTASIS FOR A VARIETY OF DIAGNOSTIC AND THERAPEUTIC PROCEDURES,ANGIOGRAPHIC CATHETER(BIOTEQ)-ANGIOGRAPHIC CATHETERS ARE INTENDED FOR USE IN THE DELIVERY OF RADIOPAQUE CONTRAST MEDIA TO THE SELECTED SITES OF CARDIOVASCULAR SYSTEM.

2254	IMP/MD/2020/000377	1.License Holder Name: FRESENIUS MEDICAL CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TUBING SETS FOR HEMODIALYSIS-THIS PRODUCT IS INTENDED TO CONNECT WITH THE DIALYZER TO THE PATIENT IN DIALYSIS TREATMENT. IT CAN BE USED WITH ALL THE DIALYSIS MACHINE.,DISPOSABLE A.V. FISTULA NEEDLE SETS-THIS PRODUCT IS INTENDED TO BE USED AS VEIN PUNCTURE FOR THE HEMODIALYSIS TREATMENT
2255	IMP/MD/2020/000378	1.License Holder Name: BL LIFESCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COR-KNOT®(COR-KNOT®)-THE COR-KNOT® DEVICE (OR COR-KNOT MINI® DEVICE) USED IN CONJUNCTION WITH LSI SOLUTIONS® SPECIFIED 2-0 POLYESTER SUTURE AND COR-KNOT® TITANIUM FASTENER IS INDICATED FOR USE TO FASTEN AND TRIM SUTURE IN CARDIOVASCULAR SURGICAL APPLICATIONS.
2256	IMP/MD/2020/000382	1.License Holder Name: BREDENT GROUP INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT FIXTURE(NARROWSKY)-FOR IMPLANTATION IN HUMAN MAXILLA OR MANDIBLE FOR DENTAL REHABILITATION,DENTAL IMPLANT PROSTHETICS(COPASKY PROSTHETICS)-PROSTHETIC PARTS ARE TO BE USED ALONG WITH IMPLANTS AS BASIS FOR RESTORATION TO FIX CROW, AND BRIDGE CONSTRUCTION, OR PARTS FOR THE FIXATION OF REMOVABLE PROSTHESIS,DENTAL IMPLANT FIXTURE(BLUESKY)-FOR IMPLANTATION IN HUMAN MAXILLA OR MANDIBLE FOR DENTAL REHABILITATION,DENTAL IMPLANT FIXTURE(COPASKY)-FOR IMPLANTATION IN HUMAN MAXILLA OR MANDIBLE FOR DENTAL REHABILITATION,DENTAL IMPLANT PROSTHETIC(BLUESKY PROSTHETICS)-PROSTHETIC PARTS ARE TO BE USED ALONG WITH SKY IMPLANTS AS BASIS FOR RESTORATION TO FIX CROW, AND BRIDGE CONSTRUCTION, OR PARTS FOR THE FIXATION OF REMOVABLE PROSTHESIS,DENTAL IMPLANT PROSTHETIC(BIOHPP SKY ELEGANCE ABUTMENT)-PROSTHETIC PARTS ARE TO BE USED ALONG WITH SKY IMPLANTS AS BASIS FOR RESTORATION TO FIX CROW, AND BRIDGE CONSTRUCTION, OR PARTS FOR THE FIXATION OF REMOVABLE PROSTHESIS

2257	IMP/MD/2020/000383	1.License Holder Name: SANDOR MEDICAIDS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRANSFORMING POWDER DRESSING(ALTRAZEAL)-ALTRAZEAL IS INTENDED TO COVER AND PROTECT MILD TO MODERATELY EXUDING ACUTE AND CHRONIC WOUNDS. ALTRAZEAL IS SUITABLE FOR THE COVERING AND PROTECTION OF: • EXUDING, SUPERFICIAL, ACUTE WOUNDS SUCH AS SKIN GRAFT DONOR SITES AND SECOND-DEGREE BURNS (PARTIAL THICKNESS BURNS WITH EXUDATES) • ABRASIONS AND LACERATIONS • SURGICAL WOUNDS, SUCH AS POST-OPERATIVE WOUNDS OR DERMATOLOGICAL EXCISIONS (ONLY TO BE USED AS A PRIMARY DRESSING OVER THE WOUND, AND NOT AS A REPLACEMENT FOR SUTURES) • CHRONIC, SLOW-HEALING WOUNDS, SUCH AS LEG ULCERS, PRESSURE ULCERS, AND DIABETIC ULCERS
2258	IMP/MD/2020/000384	1.License Holder Name: M/S. EASYMED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYLAN GEL CONTOUR (GENEFILL CONTOUR)-GENEFILL CONTOUR IS INTENDED TO BE USED AS A MEANS OF RESTORING LOST VOLUME AND CONTOURING BODY SURFACES. THE DEPTH OF THE INJECTION CAN VARY DEPENDING ON THE TREATMENT SITE, THE SUBCUTANEOUS APPLICATION AND THE SUPRAPERIOSTAL APPLICATION. • BUTTOCKS • CALVES • CORRECTION OF CONCAVE DEFORMITIES,HYLAN GEL DERMAL (GENEFILL SOFT FILL)-GENEFILL SOFT FILL IS INDICATED FOR THE RESTORATION OF THE FACIAL VOLUME AND CONTOUR: REPLACES LOST HYALURONIC ACID IN THE SKIN, IS USED FOR VOLUME REPLACEMENT (FILLING OF FOLDS), MEDIUM TO DEEP FOLDS, NASOLABIAL FOLDS, CHEEK AREA, LIP AUGMENTATION, GLABELLA FOLDS.,HYLAN GEL DERMAL DX(GENEFILL DX)-VOLUME REPLACEMENT/TISSUE AUGMENTATION, CHEEK AREA, MARIONETTE LINES, DEEP WRINKLES, NASOLABIAL FOLDS, CONTOUR DEFECTS IN THE FACIAL AREA,HYLAN SOLUTION(GENEFILL FINE)-REPLACES LOST HYALURONIC ACID IN THE SKIN, INCREASES ELASTICITY, IMPROVES SKIN HYDRATION, PROVIDES SKIN WITH A FRESH LOOK THROUGH ITS LIFTING EFFECT.,HYLAN GEL DERMAL(GENEFILL SOFT TOUCH)-GENEFILL SOFT TOUCH REPLACES LOST HYALURONIC ACID IN THE SKIN, IS USED FOR VOLUME REPLACEMENT (FILLING OF FOLDS), SUPERFICIAL FOLDS, PERIORBITAL LINES, PERIORAL LINES.

2259	IMP/MD/2020/000386	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIGH RESOLUTION MANOMETRY ESO 3D CATHETER(MANOSCAN ESO 3D CATHETER)-THE MANOSCAN SYSTEM PROVIDES MAPPING OF PRESSURES AND, OPTIONALLY, IMPEDANCE WITHIN ORGANS OF THE HUMAN GASTROINTESTINAL TRACT. THESE INCLUDE THE PHARYNX, UPPER ESOPHAGEAL SPHINCTER (UES), ESOPHAGUS, LOWER ESOPHAGEAL SPHINCTER (LES), STOMACH, SPHINCTER OF ODDI, SMALL BOWEL, COLON, DUODENUM AND ANORECTAL ORGANS. IT IS USED IN A MEDICAL CLINICAL SETTING TO ACQUIRE PRESSURES AND THEN STORE THE CORRESPONDING DATA FOR VISUALIZATION AND ANALYSIS. THE REAL-TIME DATA AS WELL AS THE ANALYSIS INFORMATION CAN BE VIEWED BY MEDICALLY TRAINED PERSONNEL FOR DIAGNOSTIC AND ANALYTIC PURPOSES. THE MANOSCAN HRM MODULES PROVIDE HIGH-RESOLUTION AND/OR 3D (THREE DIMENSIONAL) DISPLAY OF THE PRESSURE AND IMPEDANCE DATA. THE MANOSCAN CLT MODULE PROVIDES CONVENTIONAL LINE TRACE MAPPING OF THE PRESSURE DATA AND CAN BE USED AS A STAND-ALONE SYSTEM OR AS A MODULE OF THE MANOSCAN HIGH-RESOLUTION MANOMETRY SYSTEM.,HIGH RESOLUTION MANOMETRY AR CATHETER(MANOSCAN AR CATHETER (REGULAR, SMALL))-THE MANOSCAN SYSTEM PROVIDES MAPPING OF PRESSURES AND, OPTIONALLY, IMPEDANCE WITHIN ORGANS OF THE HUMAN GASTROINTESTINAL TRACT. THESE INCLUDE THE PHARYNX, UPPER ESOPHAGEAL SPHINCTER (UES), ESOPHAGUS, LOWER ESOPHAGEAL SPHINCTER (LES), STOMACH, SPHINCTER OF ODDI, SMALL BOWEL, COLON, DUODENUM AND ANORECTAL ORGANS. IT IS USED IN A MEDICAL CLINICAL SETTING TO ACQUIRE PRESSURES AND THEN STORE THE CORRESPONDING DATA FOR VISUALIZATION AND ANALYSIS. THE REAL-TIME DATA AS WELL AS THE ANALYSIS INFORMATION CAN BE VIEWED BY MEDICALLY TRAINED PERSONNEL FOR DIAGNOSTIC AND ANALYTIC PURPOSES. THE MANOSCAN HRM MODULES PROVIDE HIGH-RESOLUTION AND/OR 3D (THREE DIMENSIONAL) DISPLAY OF THE PRESSURE AND IMPEDANCE DATA. THE MANOSCAN CLT MODULE PROVIDES CONVENTIONAL LINE TRACE MAPPING OF THE PRESSURE DATA AND CAN BE USED AS A STAND-ALONE SYSTEM OR AS A MODULE OF THE MANOSCAN HIGH-RESOLUTION MANOMETRY SYSTEM. ,HIGH RESOLUTION MANOMETRY ESO Z CATHETER(MANOSCAN ESO Z CATHETER)-THE MANOSCAN SYSTEM PROVIDES MAPPING OF PRESSURES AND, OPTIONALLY, IMPEDANCE WITHIN ORGANS OF THE HUMAN GASTROINTESTINAL TRACT. THESE INCLUDE THE PHARYNX, UPPER ESOPHAGEAL SPHINCTER (UES), ESOPHAGUS, LOWER ESOPHAGEAL

	SPHINCTER (LES), STOMACH, SPHINCTER OF ODDI, SMALL BOWEL, COLON, DUODENUM AND ANORECTAL ORGANS. IT IS USED IN A MEDICAL CLINICAL SETTING TO ACQUIRE PRESSURES AND THEN STORE THE CORRESPONDING DATA FOR VISUALIZATION AND ANALYSIS. THE REAL-TIME DATA AS WELL AS THE ANALYSIS INFORMATION CAN BE VIEWED BY MEDICALLY TRAINED PERSONNEL FOR DIAGNOSTIC AND ANALYTIC PURPOSES. THE MANOSCAN HRM MODULES PROVIDE HIGH-RESOLUTION AND/OR 3D (THREE DIMENSIONAL) DISPLAY OF THE PRESSURE AND IMPEDANCE DATA. THE MANOSCAN CLT MODULE PROVIDES CONVENTIONAL LINE TRACE MAPPING OF THE PRESSURE DATA AND CAN BE USED AS A STAND-ALONE SYSTEM OR AS A MODULE OF THE MANOSCAN HIGH-RESOLUTION MANOMETRY SYSTEM. ,HIGH RESOLUTION MANOMETRY ESO CATHETER(MANOSCAN ESO CATHETER AND ESO WITH EXTENDED TIP)-THE MANOSCAN SYSTEM PROVIDES MAPPING OF PRESSURES AND, OPTIONALLY, IMPEDANCE WITHIN ORGANS OF THE HUMAN GASTROINTESTINAL TRACT. THESE INCLUDE THE PHARYNX, UPPER ESOPHAGEAL SPHINCTER (UES), ESOPHAGUS, LOWER ESOPHAGEAL SPHINCTER (LES), STOMACH, SPHINCTER OF ODDI, SMALL BOWEL, COLON, DUODENUM AND ANORECTAL ORGANS. IT IS USED IN A MEDICAL CLINICAL SETTING TO ACQUIRE PRESSURES AND THEN STORE THE CORRESPONDING DATA FOR VISUALIZATION AND ANALYSIS. THE REAL-TIME DATA AS WELL AS THE ANALYSIS INFORMATION CAN BE VIEWED BY MEDICALLY TRAINED PERSONNEL FOR DIAGNOSTIC AND ANALYTIC PURPOSES. THE MANOSCAN HRM MODULES PROVIDE HIGH-RESOLUTION AND/OR 3D (THREE DIMENSIONAL) DISPLAY OF THE PRESSURE AND IMPEDANCE DATA. THE MANOSCAN CLT MODULE PROVIDES CONVENTIONAL LINE TRACE MAPPING OF THE PRESSURE DATA AND CAN BE USED AS A STAND-ALONE SYSTEM OR AS A MODULE OF THE MANOSCAN HIGH-RESOLUTION MANOMETRY SYSTEM.,HIGH RESOLUTION MANOMETRY AR 3D PROBE(MANOSCAN AR 3D PROBE)-THE MANOSCAN SYSTEM PROVIDES MAPPING OF PRESSURES AND, OPTIONALLY, IMPEDANCE WITHIN ORGANS OF THE HUMAN GASTROINTESTINAL TRACT. THESE INCLUDE THE PHARYNX, UPPER ESOPHAGEAL SPHINCTER (UES), ESOPHAGUS, LOWER ESOPHAGEAL SPHINCTER (LES), STOMACH, SPHINCTER OF ODDI, SMALL BOWEL, COLON, DUODENUM AND ANORECTAL ORGANS. IT IS USED IN A MEDICAL CLINICAL SETTING TO ACQUIRE PRESSURES AND THEN STORE THE CORRESPONDING DATA FOR VISUALIZATION AND ANALYSIS. THE REAL-TIME DATA AS WELL AS THE ANALYSIS INFORMATION CAN BE VIEWED BY MEDICALLY TRAINED PERSONNEL FOR DIAGNOSTIC AND ANALYTIC PURPOSES. THE MANOSCAN HRM MODULES PROVIDE HIGH-RESOLUTION AND/OR 3D (THREE DIMENSIONAL) DISPLAY OF THE PRESSURE AND

		IMPEDANCE DATA. THE MANOSCAN CLT MODULE PROVIDES CONVENTIONAL LINE TRACE MAPPING OF THE PRESSURE DATA AND CAN BE USED AS A STAND-ALONE SYSTEM OR AS A MODULE OF THE MANOSCAN HIGH-RESOLUTION MANOMETRY SYSTEM. ,HIGH RESOLUTION MANOMETRYESO CATHETER(MANOSCAN ESO CATHETER SD (REGULAR, SMALL))-THE MANOSCAN SYSTEM PROVIDES MAPPING OF PRESSURES AND, OPTIONALLY, IMPEDANCE WITHIN ORGANS OF THE HUMAN GASTROINTESTINAL TRACT. THESE INCLUDE THE PHARYNX, UPPER ESOPHAGEAL SPHINCTER (UES), ESOPHAGUS, LOWER ESOPHAGEAL SPHINCTER (LES), STOMACH, SPHINCTER OF ODDI, SMALL BOWEL, COLON, DUODENUM AND ANORECTAL ORGANS. IT IS USED IN A MEDICAL CLINICAL SETTING TO ACQUIRE PRESSURES AND THEN STORE THE CORRESPONDING DATA FOR VISUALIZATION AND ANALYSIS. THE REAL-TIME DATA AS WELL AS THE ANALYSIS INFORMATION CAN BE VIEWED BY MEDICALLY TRAINED PERSONNEL FOR DIAGNOSTIC AND ANALYTIC PURPOSES. THE MANOSCAN HRM MODULES PROVIDE HIGH-RESOLUTION AND/OR 3D (THREE DIMENSIONAL) DISPLAY OF THE PRESSURE AND IMPEDANCE DATA. THE MANOSCAN CLT MODULE PROVIDES CONVENTIONAL LINE TRACE MAPPING OF THE PRESSURE DATA AND CAN BE USED AS A STAND-ALONE SYSTEM OR AS A MODULE OF THE MANOSCAN HIGH-RESOLUTION MANOMETRY SYSTEM.
2260	IMP/MD/2020/000388	1.License Holder Name: SCHILLER HEALTHCARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PRESSURE CONNECTING TUBE(ANTMED)-IT IS FOR USE DURING ANGIOGRAPHY PROCEDURES AS A CONNECTING LINE FOR THE INJECTION OF LIQUID, SUCH AS RADIOPAQUE DYE, SALINE OR OTHER DIAGNOSTIC FLUIDS.,HIGH PRESSURE SYRINGE(ANTMED)-THE CONTENTS OF THIS PACKAGE ARE INTENDED TO BE USED IN THE DELIVERY OF CONTRAST MEDIA. THESE DEVICES ARE INDICATED FOR SINGLE-USE ONLY WITH POWER INJECTORS.,DISPOSABLE PRESSURE TRANSDUCER(ANTMED)-THE DISPOSABLE PRESSURE TRANSDUCER IS INTENDED FOR INTRAVASCULAR, INTRACRANIAL, INTRAUTERINE PRESSURE MONITORING. THE PRESSURE WAVE FORMS ARE CONDUCTED FROM PATIENT TO THE TRANSDUCER THROUGH A COLUMN OF FLUID AND THEN CONVERTED INTO ELECTRICAL SIGNALS THAT CAN BE DISPLAYED ON MONITORING EQUIPMENT.

2261	IMP/MD/2020/000389	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BREAST TISSUE MARKER (SENOMARK ULTRA BREAST TISSUE MARKER)-THE SENOMARK ULTRA BREAST TISSUE MARKER IS INTENDED TO RADIOGRAPHICALLY AND SONOGRAPHICALLY MARK BREAST TISSUE DURING A PERCUTANEOUS BREAST BIOPSY PROCEDURE.
2262	IMP/MD/2020/000390	1.License Holder Name: CLINIEXPERTS SERVICES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SODIUM HYALURONATE LIDOCAINE HYDRO CHLORIDE PREFILLED SYRINGES(BELOTERO BALANCE LIDOCAINE)-BELOTERO BALANCE LIDOCAINE IS AN INJECTABLE BIODEGRADABLE IMPLANT INTENDED FOR FILLING OF MODERATE FACIAL WRINKLES AND FOLDS AS WELL AS FOR LIP ENHANCEMENT. THE PRESENCE OF LIDOCAINE AIMS TO REDUCE LOCAL PAIN ASSOCIATED WITH THE INJECTION OF GEL AND TO IMPROVE PATIENT COMFORT. BELOTERO BALANCE LIDOCAINE IS INDICATED FOR INJECTION INTO THE SUPERFICIAL TO MID-DERMIS FOR TREATMENT OF NASO-LABIAL FOLDS, MARIONETTE LINES, PERIORAL LINES AND MODERATE ORAL COMMISSURES. IT IS INDICATED INJECTION FOR LIP ENHANCEMENT.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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2263	IMP/MD/2020/000391	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PRISMAFLEX HF20 SET-THE PRISMAFLEX SET IS INDICATED FOR USE ONLY WITH THE PRISMAFLEX CONTROL UNIT OR WITH THE PRISMAX CONTROL UNIT (IN COUNTRIES WHERE PRISMAX IS CLEARED OR REGISTERED) IN PROVIDING CONTINUOUS FLUID MANAGEMENT AND RENAL REPLACEMENT THERAPIES. THE SYSTEM IS INTENDED FOR PATIENTS WHO HAVE ACUTE RENAL FAILURE, FLUID OVERLOAD, OR BOTH. THIS SET IS INTENDED FOR USE IN THE FOLLOWING VENO-VENOUS THERAPIES: SCUF; CVVH; CVVHD; CVVHDF.,PRISMAFLEX M SET-THE PRISMAFLEX SET IS INDICATED FOR USE ONLY WITH THE PRISMAFLEX CONTROL UNIT IN PROVIDING CONTINUOUS FLUID MANAGEMENT AND RENAL REPLACEMENT THERAPIES. THE SYSTEM IS INTENDED FOR PATIENTS WHO HAVE ACUTE RENAL FAILURE, FLUID OVERLOAD, OR BOTH. THIS SET IS INTENDED FOR USE IN THE FOLLOWING VENO-VENOUS THERAPIES: SCUF; CVVH; CVVHD; CVVHDF. ALL TREATMENTS ADMINISTERED VIA THE PRISMAFLEX SET MUST BE PRESCRIBED BY A PHYSICIAN. THE SIZE, WEIGHT, STATE OF UREMIA, CARDIAC STATUS, AND GENERAL PHYSICAL CONDITION OF THE PATIENT MUST BE CAREFULLY EVALUATED BY THE PRESCRIBING PHYSICIAN BEFORE EACH TREATMENT,PRISMAFLEX TPE SET-THE PRISMAFLEX TPE1000/TPE2000 SET IS INDICATED FOR USE ONLY WITH THE PRISMAFLEX CONTROL UNIT OR WITH THE PRISMAX CONTROL UNIT (IN COUNTRIES WHERE PRISMAX IS CLEARED OR REGISTERED), AFTER HAVING SELECTED TPE THERAPY (THERAPEUTIC PLASMA EXCHANGE). THE PRISMAFLEX TPE1000/TPE2000 SET IS INTENDED FOR USE IN THERAPEUTIC PLASMA EXCHANGE, THUS IN DISEASES WHERE REMOVAL OF PLASMA COMPONENTS IS INDICATED. THE USE OF THE PRISMAFLEX TPE1000 SET SHOULD BE RESTRICTED TO PATIENTS WITH A BODY WEIGHT GREATER THAN 9KGS (20LBS). THE USE OF THE PRISMAFLEX TPE2000 SET SHOULD BE RESTRICTED TO ADULTS. THE SIZE, WEIGHT, STATE OF UREMIA, CARDIAC STATUS AND GENERAL PHYSICAL CONDITION OF THE PATIENT MUST BE EVALUATED BY THE PRESCRIBING PHYSICIAN BEFORE EACH TREATMENT.,OXIRIS-THE OXIRIS SET IS INDICATED FOR USE ONLY WITH THE PRISMAFLEX CONTROL UNIT OR WITH THE PRISMAX CONTROL UNIT (IN COUNTRIES WHERE PRISMAX IS CLEARED OR REGISTERED). IT IS INTENDED FOR PATIENTS IN NEED OF BLOOD PURIFICATION, INCLUDING CONTINUOUS RENAL REPLACEMENT THERAPY, AND IN CONDITIONS WHERE EXCESSIVE ENDOTOXIN AND INFLAMMATORY MEDIATORS LEVELS EXIST. THIS SET IS INTENDED FOR USE IN THE FOLLOWING VENO-VENOUS THERAPIES: SCUF; CVVH; CVVHD;

	CVVHDF. EXTENSION OF INDICATION APPROVED ON 3 JULY 2020; THE OXIRIS SET IS INDICATED FOR USE ONLY WITH THE PRISMAFLEX CONTROL UNIT OR WITH THE PRISMAX CONTROL UNIT IN COUNTRIES WHERE PRISMAX IS CLEARED OR REGISTERED. IT IS INTENDED FOR USE IN CRITICALLY ILL COVID19 PATIENTS IN NEED OF BLOOD PURIFICATION WHERE EXCESSIVE INFLAMMATORY MEDIATORS ARE PRESENT I.E. CYTOKINE STORM RELEASE. THIS SET IS INTENDED FOR USE IN THE FOLLOWING VENO VENOUS THERAPIES SCUF CVVH CVVHD CVVHDF. CONSIDERATIONS FOR ELIGIBILITY OF OXIRIS USE SUSPECTED OR CONFIRMED COVID19 EARLY ACUTE LUNG INJURY ALI EARLY ACUTE RESPIRATORY DISTRESS SYNDROME ARDS CYTOKINE STORM RELEASE.SEVERE DISEASE SUCH AS DYSPNEA RESPIRATORY FREQUENCY GREATER THAN EQUAL TO 30 PER MIN BLOOD OXYGEN SATURATION LESS THAN EQUAL TO 93 PERCENT PARTIAL PRESSURE OF ARTERIAL OXYGEN TO FRACTION OF INSPIRED OXYGEN RATIO GREATER THAN 300 AND OR LUNG INFILTRATES ON RADIOGRAPHIC IMAGING LIFE THREATENING DISEASE SUCH AS RESPIRATORY FAILURE AND OR SEPTIC SHOCK AND OR MULTIPLE ORGAN DYSFUNCTION OR FAILURE PRESENCE OF EXCESSIVE ENDOTOXIN. ONLY FOR THE DURATION THAT CIRCUMSTANCES OF PANDEMIC (COVID19) EXIST WITHOUT MAKING CHANGES TO ALREADY APPROVED INSTRUCTION FOR USE.

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2264	IMP/MD/2020/000395	1.License Holder Name: CLINIEXPERTS SERVICES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SODIUM HYALURONATE LIDOCAINE HYDRO CHLORIDE PREFILLED SYRINGES(BELOTERO VOLUME LIDOCAINE)-BELOTERO VOLUME LIDOCAINE IS AN INJECTABLE BIODEGRADABLE IMPLANT INTENDED FOR CORRECTING SIGNS OF FACIAL FAT LOSS (LIPOATROPHY) IN PATIENTS WITH HUMAN IMMUNODEFICIENCY VIRUS. IT IS ALSO INTENDED FOR ENHANCEMENT OF THE CHEEKS, THE TEMPLES, THE CHIN, OR TO TREAT SEVERE NASOLABIAL FOLDS ,SODIUM HYALURONATE LIDOCAINE HYDRO CHLORIDE PREFILLED SYRINGES(BELOTERO INTENSE LIDOCAINE)-IT IS AN INJECTABLE BIODEGRADABLE IMPLANT INTENDED FOR FILING OF DEEP FACIAL WRINKLES AND FOLDS AS WELL AS TO RESTORE AND ENHANCE SOFT TISSUE VOLUME. THE PRESENCE OF LIDOCAINE AIMS TO REDUCE LOCAL PAIN ASSOCIATED WITH THE INJECTION OF GEL AND TO IMPROVE PATIENT COMFORT . IT IS INDICATED FOR INJECTION INTO THE DEEP DERMIS FOR TREATMENT OF NASOLABIAL FOLDS AND MARIONETTE LINES. IT IS INDICATED FOR INJECTION FOR LIP ENHANCEMENT., SODIUM HYALURONATE LIDOCAINE HYDRO CHLORIDE PREFILLED SYRINGES(BELOTERO SOFT LIDOCAINE)-BELOTERO SOFT LIDOCAINE IS AN INJECTABLE BIODEGRADABLE IMPLANT INTENDED FOR FILING OF PERIORAL FINE LINES. THE PRESENCE OF LIDOCAINE AIMS TO REDUCE LOCAL PAIN ASSOCIATED WITH THE INJECTION OF GEL AND TO IMPROVE PATIENT COMFORT. IT IS INDICATED FOR INJECTION INTO THE SUPERFICIAL TO MID-DERMIS FOR TREATMENT OF PERIORAL FINE LINES.,SODIUM HYALURONATE LIDOCAINE HYDRO CHLORIDE PREFILLED SYRINGES(BELOTERO BALANCE LIDOCAINE)-BELOTERO BALANCE LIDOCAINE IS AN INJECTABLE BIODEGRADABLE IMPLANT INTENDED FOR FILLING OF MODERATE FACIAL WRINKLES AND FOLDS AS WELL AS FOR LIP ENHANCEMENT. THE PRESENCE OF LIDOCAINE AIMS TO REDUCE LOCAL PAIN ASSOCIATED WITH THE INJECTION OF GEL AND TO IMPROVE PATIENT COMFORT. BELOTERO BALANCE LIDOCAINE IS INDICATED FOR INJECTION INTO THE SUPERFICIAL TO MID-DERMIS FOR TREATMENT OF NASO-LABIAL FOLDS, MARIONETTE LINES, PERIORAL LINES AND MODERATE ORAL COMMISSURES. IT IS INDICATED INJECTION FOR LIP ENHANCEMENT.

2265	IMP/MD/2020/000397	1.License Holder Name: FRESENIUS MEDICAL CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISINFECTANT (PURISTERIL 340)-DISINFECTANTS FOR COLD DISINFECTION OF HEMO DIALYSIS MACHINES. FOR DISINFECTION, CLEANING AND DECALCIFICATION OF HAEMODIALYSIS SYSTEMS.,DISINFECTANT (CITROSTERIL)-DISINFECTANTS FOR HOT DISINFECTION OF HEMO DIALYSIS MACHINES. FOR DISINFECTION, CLEANING AND DECALCIFICATION OF HAEMODIALYSIS SYSTEMS.
2266	IMP/MD/2020/000399	1.License Holder Name: M/S. TRISTEL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DUO OPH(TRISTEL)-TRISTEL DUO OPH IS DESIGNED SPECIFICALLY FOR THE HIGH-LEVEL DISINFECTION OF INSTRUMENTS USED IN OPHTHALMOLOGY SUCH AS DIAGNOSTIC LENSES, TONOMETER PRISMS, SLIT LAMPS, PACHYMETERS, A-SCAN AND B-SCAN BIOMETRY PROBES.,DUO EVE (TRISTEL)-TRISTEL DUO EVE IS A HIGH-LEVEL DISINFECTANT FOAM. IT IS INTENDED FOR THE DISINFECTION OF NON-INVASIVE MEDICAL DEVICES SUCH AS COLPOSCOPES AND NON-POROUS SURFACES OF MEDICAL EQUIPMENT USED IN WOMEN'S HEALTH.,DUO ULT(TRISTEL)-TRISTEL DUO ULT IS DESIGNED SPECIFICALLY FOR THE HIGH-LEVEL DISINFECTION OF ENDOCAVITY ULTRASOUND PROBES SUCH AS TRANSRECTAL AND TRANSVAGINAL PROBES.
2267	IMP/MD/2020/000400	1.License Holder Name: MN SOLUTIONS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDING CATHETER (XCESS GUIDING CATHETER)-THE GUIDING CATHETER IS INTENDED TO USE FOR INTRAVASCULAR INTRODUCTION OF INTERVENTIONAL/DIAGNOSTIC DEVICES INTO THE CORONARY OR PERIPHERAL VASCULAR SYSTEMS.,ANGIOGRAPHIC CATHETER(URSA ANGIOGRAPHIC CATHETER)-THE ANGIOGRAPHIC CATHETERS ARE DESIGNED TO BE USED FOR DELIVERING RADIOPAQUE CONTRAST MEDIA TO THE SELECTED SITES IN THE VASCULAR SYSTEM.
2268	IMP/MD/2020/000401	1.License Holder Name: ACCESS DEVICES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PORT ACCESS INFUSION SET(PORT ACCESS INFUSION SET)-A DEVICE IS USED TO ADMINISTER SOLUTIONS THROUGH A SURGICALLY IMPLANTED PORT.

2269	IMP/MD/2020/000402	1.License Holder Name: M/S ASIA ACTUAL INDIA (OPC) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABSORBABLE HEMOSTAT OXIDIZED REGENERATED CELLULOSE (ORC)(REOXCEL SIGMA KNIT)-REOXCEL SIGMA KNIT (OXIDIZED REGENERATED CELLULOSE – ORC) ABSORBABLE HAEMOSTATS IS DESIGNED TO ARREST CAPILLARY BLEEDING AND BLEEDING FROM PARENCHYMATOUS ORGANS AND RESECTION AREAS AT SURGICAL INTERVENTIONS. IT SHALL BE USED TO STOP BLEEDING WHEN OTHER HAEMOSTATIC PROCEDURES ARE NOT APPLICABLE. IT IS SUITABLE FOR USE IN GENERAL SURGERY AND DIGESTIVE SURGERY, NEUROSURGERY (ESPECIALLY CEREBRAL OPERATIONS), PLASTIC SURGERY, ORTHOPEDY, GYNAECOLOGY, UROLOGY, STOMATOLOGY, OPERATIONS TO THE THROAT OR NOSE, TRAUMATOLOGY, AND ALL OTHER BRANCHES OF SURGERY SUCH AS CARDIOVASCULAR SURGERY, IMPLANTATION OF VASCULAR PROSTHESES, SURGERY TO THE FACE AND JAW, LUNG OPERATIONS, HAEMORRHOIDECTOMY, BIOPSISES, LIVER AND GAIL BLADDER OPERATIONS, GASTRIC RESECTION, THORACIC AND ABDOMINAL SYMPATHECTOMIES. REOXCEL (OXIDIZED REGENERATED CELLULOSE – ORC) ABSORBABLE HAEMOSTAT CAN BE APPLIED INTO CAVITIES (AFTER EXTIRPATION OF TUMORS) AS WELL AS ENDOSCOPIC INTERVENTIONS OR DENTAL PRAXIS. ,ABSORBABLE HEMOSTAT OXIDIZED REGENERATED CELLULOSE (ORC) (REOXCEL FIBRIL)-REOXCEL FIBRIL (OXIDIZED REGENERATED CELLULOSE – ORC) ABSORBABLE HAEMOSTAT IS DESIGNED TO ARREST CAPILLARY BLEEDING AND BLEEDING FROM PARENCHYMATOUS ORGANS AND RESECTION AREAS AT SURGICAL INTERVENTIONS. IT SHALL BE USED TO STOP BLEEDING WHEN OTHER HAEMOSTATIC PROCEDURES ARE NOT APPLICABLE. IT IS SUITABLE FOR USE IN GENERAL SURGERY AND DIGESTIVE SURGERY, NEUROSURGERY (ESPECIALLY CEREBRAL OPERATIONS), PLASTIC SURGERY, ORTHOPEDY, GYNAECOLOGY, UROLOGY, STOMATOLOGY, OPERATIONS TO THE THROAT OR NOSE, TRAUMATOLOGY, AND ALL OTHER BRANCHES OF SURGERY SUCH AS CARDIOVASCULAR SURGERY, IMPLANTATION OF VASCULAR PROSTHESES, SURGERY TO THE FACE AND JAW, LUNG OPERATIONS, HAEMORRHOIDECTOMY, BIOPSISES, LIVER AND GAIL BLADDER OPERATIONS, GASTRIC RESECTION, THORACIC AND ABDOMINAL SYMPATHECTOMIES. REOXCEL FIBRIL (OXIDIZED REGENERATED CELLULOSE – ORC) ABSORBABLE HAEMOSTAT CAN BE APPLIED INTO CAVITIES (AFTER EXTIRPATION OF TUMOURS) AS WELL AS ENDOSCOPIC INTERVENTIONS OR DENTAL PRAXIS.,ABSORBABLE HEMOSTAT OXIDIZED REGENERATED CELLULOSE (ORC)(REOXCEL)-REOXCEL (OXIDIZED REGENERATED CELLULOSE – ORC) ABSORBABLE

	HAEMOSTATS IS DESIGNED TO ARREST CAPILLARY BLEEDING AND BLEEDING FROM PARENCHYMATOUS ORGANS AND RESECTION AREAS AT SURGICAL INTERVENTIONS. IT SHALL BE USED TO STOP BLEEDING WHEN OTHER HAEMOSTATIC PROCEDURES ARE NOT APPLICABLE. IT IS SUITABLE FOR USE IN GENERAL SURGERY AND DIGESTIVE SURGERY, NEUROSURGERY (ESPECIALLY CEREBRAL OPERATIONS), PLASTIC SURGERY, ORTHOPEDY, GYNAECOLOGY, UROLOGY, STOMATOLOGY, OPERATIONS TO THE THROAT OR NOSE, TRAUMATOLOGY, AND ALL OTHER BRANCHES OF SURGERY SUCH AS CARDIOVASCULAR SURGERY, IMPLANTATION OF VASCULAR PROSTHESES, SURGERY TO THE FACE AND JAW, LUNG OPERATIONS, HAEMORRHOIDECTOMY, BIOPSISES, LIVER AND GAIL BLADDER OPERATIONS, GASTRIC RESECTION, THORACIC AND ABDOMINAL SYMPATHECTOMIES. REOXCEL (OXIDIZED REGENERATED CELLULOSE – ORC) ABSORBABLE HAEMOSTAT CAN BE APPLIED INTO CAVITIES (AFTER EXTIRPATION OF TUMORS) AS WELL AS ENDOSCOPIC INTERVENTIONS OR DENTAL PRAXIS.,ABSORBABLE HEMOSTAT OXIDIZED CELLULOSE (OC)(ZEOCEL)-ZEOCEL ABSORBABLE HAEMOSTAT IS DESIGNED TO CONTROL THE OOZING OF THE BLOOD, OTHER DIFFERENT TYPES OF CAPILLARY BLEEDING AND BLEEDING DUE TO RESECTION OF THE TISSUE DURING ANY TYPE OF SURGICAL INTERVENTIONS. ZEOCEL ABSORBABLE HAEMOSTAT CAN BE USED WHEN OTHER METHODS OF HAEMOSTATIC PROCEDURES ARE NOT USABLE. ZEOCEL ABSORBABLE HAEMOSTAT CAN BE USED IN MANY TYPES OF SURGERIES INCLUDING BUT NOT LIMITED TO GENERAL SURGERY, DIGESTIVE SURGERY, PLASTIC SURGERY, ORTHOPEDY, GNYAECOLOGY, UROLOGY, STOMATOLOGY, TRAUMATOLOGY AND ALL OTHER BRANCHES OF SURGERY. HAEMOSTAT CAN BE USED TO FILL CAVITIES FORMED BY REMOVAL OF TUMORS DURING SURGERIES AS WELL AS ENDOSCOPIC INTERVENTIONS AND DENTAL PRAXIS.

2270	IMP/MD/2020/000403	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL ABLATION PEN (CARDIOBLATE PEN)-THE CARDIOBLATE SURGICAL ABLATION PEN IS INTENDED TO CREATE SPOT OR LINEAR LESIONS IN CARDIAC TISSUE DURING CARDIAC SURGERY USING RF ENERGY FOR THE TREATMENT OF CARDIAC ARRHYTHMIAS. ANY SUPRAVENTRICULAR ARRHYTHMIA (SUCH AS ATRIAL FIBRILLATION, ATRIAL FLUTTER, OR ATRIAL TACHYCARDIA) THAT MAY BE RESOLVED BY THE APPLICATION OF ENDOCARDIAL OR EPICARDIAL RADIOFREQUENCY ENERGY CAN BE TREATED BY THE CARDIOBLATE SURGICAL ABLATION PEN.,MULTIPLE PERFUSION SET(DLP)-THESE MULTIPLE PERFUSION SETS ARE INTENDED FOR USE IN CONJUNCTION WITH CARDIOPULMONARY BYPASS SURGERY FOR SIMULTANEOUS PERFUSION OF THE AORTIC ROOT AND 3 OR 4 VEIN GRAFTS., SURGICAL ABLATION SYSTEM(CARDIOBLATE BP2 SYSTEM)-49313-THE CARDIOBLATE SURGICAL ABLATION PEN IS INTENDED TO CREATE SPOT OR LINEAR LESIONS IN CARDIAC TISSUE DURING CARDIAC SURGERY USING RF ENERGY FOR THE TREATMENT OF CARDIAC ARRHYTHMIAS. ANY SUPRAVENTRICULAR ARRHYTHMIA (SUCH AS ATRIAL FIBRILLATION, ATRIAL FLUTTER, OR ATRIAL TACHYCARDIA) THAT MAY BE RESOLVED BY THE APPLICATION OF ENDOCARDIAL OR EPICARDIAL RADIOFREQUENCY ENERGY CAN BE TREATED BY THE CARDIOBLATE SURGICAL ABLATION PEN. 49321-THE CARDIOBLATE BP2 SURGICAL ABLATION DEVICE IS INTENDED TO CREATE LESIONS IN CARDIAC TISSUE DURING CARDIAC SURGERY USING RADIOFREQUENCY ENERGY FOR THE TREATMENT OF CARDIAC ARRHYTHMIAS. ANY SUPRAVENTRICULAR ARRHYTHMIA (SUCH AS ATRIAL FIBRILLATION, ATRIAL FLUTTER, OR ATRIAL TACHYCARDIA) THAT MAY BE RESOLVED BY THE APPLICATION OF ENDOCARDIAL OR EPICARDIAL RADIOFREQUENCY ENERGY CAN BE TREATED BY THE CARDIOBLATE BP2 SURGICAL ABLATION DEVICE.,RETROGRADE CANNULA(DLP)-THIS DEVICE IS INTENDED FOR USE DURING CARDIOPULMONARY BYPASS SURGERY UP TO SIX HOURS OR LESS, FOR THE DELIVERY OF CARDIOPLEGIA RETROGRADELY THROUGH THE CORONARY SINUS.,ANTERGRADE CANNULA (MIAR)-THE MAR™ CANNULA IS INTENDED FOR USE DURING CARDIOPULMONARY BYPASS FOR THE DELIVERY OF CARDIOPLEGIA FOR UP TO 6 HOURS. THE CANNULA MAY ALSO BE USED TO ASPIRATE AIR FROM THE AORTA AT THE CONCLUSION OF THE BYPASS PROCEDURE. IT IS INDICATED FOR USE DURING CARDIAC SURGERY FOR MEDIAN STERNOTOMY OR MINIMALLY INVASIVE (MINI-STERNOTOMY OR RIGHT THORACOTOMY) ACCESS USING DIRECT VISUALIZATION TECHNIQUES.,CARDIOPLEGIA NEEDLE(DLP)-

	THESE ARE INTENDED FOR USE IN CONJUNCTION WITH CARDIOPULMONARY BYPASS SURGERY FOR UP TO SIX HOURS OR LESS FOR DELIVERING CARDIOPLEGIA SOLUTION. ONLY MODEL 10313 MAY BE USED TO ASPIRATE AIR FROM THE AORTA DURING THE DE-AIRING PROCEDURE.,RETROGRADE CANNULA(GUNDARY)-THE CANNULA IS INTENDED FOR USE DURING CARDIOPULMONARY BYPASS SURGERY UP TO SIX HOURS OR LESS FOR THE DELIVERY OF CARDIOPLEGIA RETROGRADELY THROUGH THE CORONARY SINUS., VESSEL CANNULA (DLP)-THESE CANNULAE ARE INTENDED FOR USE UP TO SIX HOURS OR LESS IN CONJUNCTION WITH CARDIOPULMONARY BYPASS SURGERY OR IN VASCULAR SURGERY TO PERFUSE A VEIN GRAFT OR TO HELP CHECK FOR LEAKS IN A HARVESTED VEIN WHICH WILL BE USED FOR A GRAFT.,ANTERGRADE CANNULA (DLP)-THESE CANNULAE ARE INTENDED FOR USE IN CONJUNCTION WITH CARDIOPULMONARY BYPASS SURGERY UP TO SIX HOURS OR LESS FOR DELIVERY OF CARDIOPLEGIA SOLUTION$ DIRECTLY TO THE CORONARY ARTERIES. , SUCTION TUBE(DLP)-THESE SUCTION TUBES ARE INTENDED FOR USE IN CARDIAC SURGERY FOR THE REMOVAL OF BLOOD AT THE OPERATIVE SITE., VENOUS CANNULA(MC2)-THIS CANNULA IS INTENDED FOR USE IN VENOUS DRAINAGE VIA THE RIGHT ATRIUM AND INFERIOR VENA CAVA SIMULTANEOUSLY DURING CARDIOPULMONARY BYPASS SURGERY UP TO SIX HOURS OR LESS.,SUMP(DLP)-THESE SUMPS ARE INTENDED FOR DRAINING THE PERICARDIAL SAC. THE INTRACARDIAC SUMP CAN ALSO BE USED TO DRAIN THE CARDIAC CHAMBERS.,SUCTION TUBE(DLP)-THE MODEL 10060 SUCTION TUBE IS INTENDED FOR USE IN CONJUNCTION WITH CARDIOPULMONARY BYPASS SURGERY. IT IS USED FOR EMPTYING THE CHAMBERS OF THE HEART AND THE PERICARDIUM DURING CARDIAC PROCEDURES. THE MODEL 10061 AND MODEL 10062 SUCTION TUBES ARE INTENDED FOR HAND-HELD USE IN ASPIRATING ACCUMULATED FLUID FROM THE SURGICAL SITE.,VENOUS CANNULA(VC2)-THIS CANNULA IS INTENDED FOR USE IN VENOUS DRAINAGE VIA THE RIGHT ATRIUM AND INFERIOR VENA CAVA SIMULTANEOUSLY DURING CARDIOPULMONARY BYPASS SURGERY UP TO SIX HOURS OR LESS., FEMORAL ARTERIAL CANNULA(DLP)-THESE CANNULAE ARE INTENDED FOR RAPID FEMORAL VENOUS AND ARTERIAL ACCESS FOR SHORT-TERM CARDIOPULMONARY BYPASS. THIS PRODUCT IS INTENDED FOR USE UP TO SIX HOURS OR LESS. ,SINGLE STAGE VENOUS CANNULA(DLP)-THESE CANNULAE ARE INTENDED FOR COLLECTION OF VENOUS BLOOD FROM THE RIGHT SIDE OF THE HEART VIA THE SUPERIOR AND INFERIOR VENA CAVA DURING CARDIOPULMONARY BYPASS SURGERY UP TO SIX HOURS OR LESS., PRESSURE CATHETER PLACEMENT SET (DLP)-THIS PCP SET IS

	INTENDED FOR USE IN PERIOPERATIVE MONITORING OF THE LEFT ATRIAL PRESSURE.,ARTERIOTOMY CANNULA(DLP)-THESE CANNULAE ARE INTENDED FOR THE PERFUSION OF CARDIOPLEGIA SOLUTION DIRECTLY INTO A CARDIAC BYPASS GRAFT OR ARTERY, OR RETROGRADE FLUSHING OF THE FREE INTERNAL MAMMARY ARTERY WITH A VASODILATOR. THESE DEVICES ARE INTENDED FOR USE UP TO SIX HOURS OR LESS.,ARTERIAL CANNULA(SELECT SERIES) -THESE CANNULAE ARE INTENDED FOR USE IN PERFUSION OF THE ASCENDING AORTA DURING SHORT-TERM CARDIOPULMONARY BYPASS THIS PRODUCT IS INTENDED FOR USE UP TO SIX HOURS OR LESS. ,VENOUS CANNULA(MCX)-THIS CANNULA IS INTENDED FOR USE IN VENOUS DRAINAGE VIA THE RIGHT ATRIUM AND INFERIOR VENA CAVA SIMULTANEOUSLY DURING CARDIOPULMONARY BYPASS SURGERY UP TO SIX HOURS OR LESS.,ARTERIAL CANNULA (DLP)-THIS CANNULA IS INTENDED FOR USE IN PERFUSION OF THE ASCENDING AORTA DURING SHORT-TERM CARDIOPULMONARY BYPASS/CARDIOPULMONARY BYPASS SURGERY FOR UP TO SIX HOURS OR LESS. ,LEFT HEART VENT CATHETER(DLP)-THIS CATHETER IS INTENDED FOR USE IN VENTING THE LEFT HEART DURING CARDIOPULMONARY BYPASS SURGERY UP TO SIX HOURS OR LESS., ARTERIAL CANNULA(EOPA 3D)-THESE CANNULAE ARE INTENDED FOR USE IN PERFUSION OF THE ASCENDING AORTA DURING SHORT TERM (6 HOURS OR LESS) CARDIOPULMONARY BYPASS., ANTERGRADE CANNULA (DLP)-THIS CANNULA IS INTENDED FOR SHORT TERM USE (SIX HOURS OR LESS) IN CONJUNCTION WITH CARDIOPULMONARY BYPASS SURGERY FOR DELIVERING CARDIOPLEGIA SOLUTIONS. THE CANNULA MAY ALSO BE USED TO ASPIRATE AIR FROM THE AORTA AT THE CONCLUSION OF THE BYPASS PROCEDURE. THE MODEL 23009 CANNULA MAY ALSO BE USED TO MONITOR PRESSURE IN THE AORTA. ,ANTERGRADE CANNULA (DLP)-FOR USE IN CARDIOPULMONARY BYPASS SURGERY LASTING UP TO 6 HOURS FOR DELIVERING CARDIOPLEGIA SOLUTIONS, VENTING THE LEFT HEART THROUGH THE AORTIC ROOT, AND ASPIRATING AIR FROM THE AORTA ,ARTERIAL CANNULA(EOPA)- THIS PRODUCT IS INTENDED FOR USE WITH CARDIOPULMONARY BYPASS AS AN ARTERIAL RETURN CANNULA,ARTERIAL CANNULA (SELECT 3D)-THESE CANNULAE ARE INTENDED FOR USE IN PERFUSION OF THE ASCENDING AORTA DURING SHORT-TERM CARDIOPULMONARY BYPASS THIS PRODUCT IS INTENDED FOR USE UP TO SIX HOURS OR LESS. ,FEMORAL VENOUS CANNULA(DLP)- THESE CANNULAE ARE INTENDED FOR RAPID FEMORAL VENOUS AND ARTERIAL ACCESS FOR SHORT-TERM CARDIOPULMONARY BYPASS. THIS PRODUCT IS INTENDED FOR USE UP TO SIX HOURS OR LESS. , ANTERGRADE CANNULA (DLP)-THIS CANNULA IS INTENDED FOR USE

		DURING CARDIOPULMONARY BYPASS FOR DELIVERING CARDIOPLEGIA SOLUTIONS AND VENTING OF THE LEFT HEART FOR UP TO 6 HOURS. THE CANNULA MAY BE USED TO ASPIRATE AIR FROM THE AORTA AT THE CONCLUSION OF THE BYPASS PROCEDURE. THE MODEL 24009 CANNULA MAY ALSO BE USED TO MONITOR PRESSURE IN THE
2271	IMP/MD/2020/000406	1.License Holder Name: NUVEOS TECH LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ELLAVI UTERINE BALLOON TAMPONADE (UBT)(ELLAVI UTERINE BALLOON TAMPONADE (UBT))-FOR THE MANAGEMENT OF POST-PARTUM HEMORRHAGE

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2272	IMP/MD/2020/000407	1.License Holder Name: M/S COOK INDIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URETERAL CATHETER (OPEN END URETERAL CATHETER)-URETERAL CATHETERS ARE INDICATED FOR ACCESS AND CATHETERIZATION OF THE URINARY TRACT, INCLUDING THE FOLLOWING APPLICATIONS: • DELIVERY OF CONTRAST MEDIA • DRAINAGE OF FLUIDS FROM THE URINARY TRACT • DELIVERY OF IRRIGATION FLUIDS TO THE URINARY TRACT • NAVIGATION OF A TORTUOUS URETER • ACCESS, ADVANCEMENT, OR EXCHANGE OF WIRE GUIDES (OPEN-ENDED CATHETERS ONLY), DRAINAGE CATHETER/SET(UNIVERSA)-IT IS INTENDED TO PROVIDE PERCUTANEOUS URINE DRAINAGE FROM THE GENITOURINARY SYSTEM.,STONE EXTRACTOR(NCOMPASS®)-IT IS INTENDED FOR STONE MANIPULATION AND REMOVAL IN THE URINARY TRACT., INJECTION NEEDLES FOR UROLOGY(DISPOSABLE TWO-PART TROCAR NEEDLE)-USED UNDER FLUOROSCOPY OR ULTRASOUND FOR INITIAL LOCATION AND POSITIONING WITHIN THE RENAL COLLECTING SYSTEM DURING A PERCUTANEOUS NEPHROSTOMY, STONE EXTRACTOR(NCIRCLE®)-IT IS INTENDED FOR STONE MANIPULATION AND REMOVAL IN THE URINARY TRACT.,STONE EXTRACTOR(NGAGE®)-USED FOR URETERAL STONE EXTRACTION BALLOON CATHETER FOR UROLOGY (BALLOON URETERAL DILATOR) -BALLOON URETERAL DILATORS AND BALLOON URETERAL DILATOR SETS ARE USED FOR URETERAL DILATION PRIOR TO URETERAL STONE MANIPULATION OR URETEROSCOPY, AND DILATION OF THE INTRAMURAL URETER.,IN VITRO FERTILIZATION DEVICES(INSEMI CATH)-INTRAUTERINE INSEMINATION CATHETERS ARE USED FOR THE INTRODUCTION OF WASHED SPERMATOZOA INTO THE UTERINE CAVITY,IN-VITRO FERTILIZATION DEVICES(SOFT-PASS EMBRYO TRANSFER CATHETER)-THE DEVICE IS USED TO PLACE IN VITRO FERTILIZED (IVF) EMBRYOS INTO THE UTERINE CAVITY.,BALLOON CATHETER FOR GYNAECOLOGY(BAKRI POSTPARTUM BALLOON)-THIS DEVICE IS INTENDED TO PROVIDE TEMPORARY CONTROL OR REDUCTION OF POSTPARTUM UTERINE BLEEDING WHEN CONSERVATIVE MANAGEMENT IS WARRANTED.,STONE EXTRACTORS (NTRAP STONE ENTRAPMENT AND EXTRACTION DEVICE)-USED AS AN ENDOSCOPIC ENTRAPMENT AND EXTRACTION DEVICE FOR CALCULI AND OTHER FOREIGN BODIES IN THE URINARY TRACT, AND TO MINIMIZE STONE MIGRATION DURING LASER, ULTRASONIC, ELECTROHYDRAULIC OR PNEUMATIC LITHOTRIPSY.

2273	IMP/MD/2020/000408	1.License Holder Name: CAREWELL MEDICAL SYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSAL SYRINGE WITH HYPODERMIC NEEDLE (AUTO DISPOSABLE SYRINGE)(NIL)-FOR CLINICAL HUMAN SUBCUTANEOUS INJECTION OF LIQUID AND EXTRACT LIQUID,DISPOSAL SYRINGE WITH HYPODERMIC NEEDLE (AUTO DISPOSABLE SYRINGE)(NIL)-FOR CLINICAL HUMAN SUBCUTANEOUS INJECTION OF LIQUID AND EXTRACT LIQUID, DISPOSAL SYRINGE WITHOUT HYPODERMIC NEEDLE (AUTO DISPOSABLE SYRINGE)(NIL)-FOR CLINICAL HUMAN SUBCUTANEOUS INJECTION OF LIQUID AND EXTRACT LIQUID
2274	IMP/MD/2020/000409	1.License Holder Name: BL LIFESCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MANIFOLDS (BULK NON-STERILE)(NA)-IT IS INTENDED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORTS FOR ADMINISTRATION OF SOLUTIONS.,TRANSDUCERS (BULK NON-STERILE)(NA)-IT IS INDICATED FOR PRESSURE SENSING DURING CLINICALLY INVASIVE PROCEDURES.,STOPCOCKS (BULK NON-STERILE)(NA)-IT IS INTENDED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORTS FOR ADMINISTRATION OF SOLUTIONS.,Y-CLICK (BULK NON-STERILE)(NA)-IT IS INTENDED TO MAINTAIN HEMOSTASIS DURING THE INTRODUCTION, USE AND WITHDRAWAL OF DIAGNOSTIC AND INTERVENTIONAL DEVICES.

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2275	IMP/MD/2020/000410	1.License Holder Name: ACCESS DEVICES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABLATION DEVICE (GENERATOR)(CRYOCARE)-THE CRYOCARE CS® SURGICAL SYSTEM IS INTENDED FOR USE IN OPEN, MINIMALLY INVASIVE OR ENDOSCOPIC SURGICAL PROCEDURES IN THE AREAS IN GENERAL SURGERY, UROLOGY, GYNECOLOGY, ONCOLOGY, NEUROLOGY, DERMATOLOGY, ENT, PROCTOLOGY, PULMONARY SURGERY AND THORACIC SURGERY. THE SYSTEM IS DESIGNED TO FREEZE/ABLATE TISSUE BY THE APPLICATION OF EXTREME COLD TEMPERATURES INCLUDING PROSTATE AND KIDNEY TISSUE, LIVER METASTASES, TUMORS, SKIN LESIONS, AND WARTS.,ABLATION DEVICE (GENERATOR)(CRYOCARE)-THE CRYOCARE CS® SURGICAL SYSTEM IS INTENDED FOR USE IN OPEN, MINIMALLY INVASIVE OR ENDOSCOPIC SURGICAL PROCEDURES IN THE AREAS IN GENERAL SURGERY, UROLOGY, GYNECOLOGY, ONCOLOGY, NEUROLOGY, DERMATOLOGY, ENT, PROCTOLOGY, PULMONARY SURGERY AND THORACIC SURGERY. THE SYSTEM IS DESIGNED TO FREEZE/ABLATE TISSUE BY THE APPLICATION OF EXTREME COLD TEMPERATURES INCLUDING PROSTATE AND KIDNEY TISSUE, LIVER METASTASES, TUMORS, SKIN LESIONS, AND WARTS.,ABLATION DEVICE(ENDOCARE) - THE CRYOCARE CS® SURGICAL SYSTEM IS INTENDED FOR USE IN OPEN, MINIMALLY INVASIVE OR ENDOSCOPIC SURGICAL PROCEDURES IN THE AREAS IN GENERAL SURGERY, UROLOGY, GYNECOLOGY, ONCOLOGY, NEUROLOGY, DERMATOLOGY, ENT, PROCTOLOGY, PULMONARY SURGERY AND THORACIC SURGERY. THE SYSTEM IS DESIGNED TO FREEZE/ABLATE TISSUE BY THE APPLICATION OF EXTREME COLD TEMPERATURES INCLUDING PROSTATE AND KIDNEY TISSUE, LIVER METASTASES, TUMORS, SKIN LESIONS, AND WARTS.
2276	IMP/MD/2020/000411	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FILTER RETRIEVAL KIT (BARD SNARE RETRIEVAL KIT)-THE BARD SNARE RETRIEVAL KIT IS INTENDED FOR USE TO PERCUTANEOUSLY REMOVE ALL BARD OPTIONAL VENA CAVA FILTERS WITH A RETRIEVAL HOOK

2277	IMP/MD/2020/000412	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COLLAGEN MATRIX DRESSING WITH SILVER(COLACTIVE® PLUS AG COLLAGEN MATRIX DRESSING WITH SILVER)-COLACTIVE® PLUS AG IS INDICATED FOR MANAGEMENT OF FULL AND PARTIAL THICKNESS WOUNDS INCLUDING PRESSURE ULCERS, DIABETIC ULCERS, ULCERS CAUSED BY MIXED VASCULAR AETIOLOGIES, VENOUS ULCERS, DONOR AND GRAFT SITES, ABRASIONS, TRAUMATIC WOUNDS HEALING BY SECONDARY INTENTION, DEHISCED SURGICAL WOUNDS, FIRST- AND SECONDARY-DEGREE BURNS.,SELF-ADHERENT SILICONE FILM DRESSING FOR SCAR CARE(MEDICLEAR™ SCAR)-MEDICLEAR™ SCAR IS DESIGNED AS A PROPHYLACTIC THERAPY ON CLOSED WOUNDS TO HELP PREVENT HYPERTROPHIC OR KELOID SCARRING AS WELL AS FOR THE MANAGEMENT OF BOTH OLD AND NEW HYPERTROPHIC AND KELOID SCARS, INCLUDING BURN AND SURGICAL SCARS., ANTIMICROBIAL CLEAR SILICONE ADHESIVE SECUREMENT DRESSING WITH CHLORHEXIDINE AND SILVER(IV CLEAR™)-IV CLEAR™ IS INTENDED TO COVER AND PROTECT INSERTION SITES AND SECURE DEVICES TO SKIN. COMMON APPLICATIONS INCLUDE IV CATHETERS, CENTRAL VENOUS LINES, PICCS, SUCTION CATHETERS, EPIDURAL CATHETERS, HEMODIALYSIS CATHETERS, ORTHOPEDIC PINS, OTHER INTRAVASCULAR CATHETERS AND PERCUTANEOUS DEVICES. IV CLEAR™ INHIBITS MICROBIAL GROWTH WITHIN THE DRESSING AND PREVENTS EXTERNAL CONTAMINATION.,COLLAGEN MATRIX DRESSING(COLACTIVE® PLUS)-COLACTIVE® PLUS IS INDICATED FOR MANAGEMENT OF FULL AND PARTIAL THICKNESS WOUNDS INCLUDING: PRESSURE ULCERS, DIABETIC ULCERS, ULCERS CAUSED BY MIXED VASCULAR AETIOLOGIES, VENOUS ULCERS, DONOR AND GRAFT SITES, ABRASIONS, TRAUMATIC WOUNDS HEALING BY SECONDARY INTENTION, DEHISCED SURGICAL WOUNDS, FIRST AND SECONDARY DEGREE BURNS.
2278	IMP/MD/2020/000415	1.License Holder Name: CARDINAL HEALTH MEDICAL PRODUCTS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALCOHOL PREPS (WEBCOL)-THESE ARE PADS PRE-MOISTENED FOR SKIN CLEANSING. THE PREP WIPE IS A PAD SATURATED WITH ALCOHOL FOR CLEANSING SKIN.,ALCOHOL PREPS(WEBCOL)-THESE ARE PADS PRE-MOISTENED FOR SKIN CLEANSING. THE PREP WIPE IS A PAD SATURATED WITH ALCOHOL FOR CLEANSING SKIN.

2279	IMP/MD/2020/000416	1.License Holder Name: TRAVANCORE TRADELINKS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOLLICLE ASPIRATION SET-THE FOLLICLE ASPIRATION SET IS INTENDED FOR FLUSHING AND/OR ASPIRATION OF OOCYTES FROM OVARIAN FOLLICLES.
2280	IMP/MD/2020/000417	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE SUBSTITUTE MATERIAL(ACCUFILL BONE SUBSTITUTE MATERIAL)-ACCUFILL POROUS BONE SUBSTITUTE IS AN INJECTABLE, SELF-SETTING, MACRO-POROUS, OSTEO-CONDUCTIVE, CALCIUM PHOSPHATE BONE GRAFT SUBSTITUTE MATERIAL THAT IS INTENDED FOR USE TO FILL BONY VOIDS OR GAPS OF THE LOWER EXTREMITIES (PELVIS THROUGH FOOT) THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. THESE DEFECTS MAY BE SURGICALLY CREATED OSSEOUS DEFECTS OR OSSEOUS DEFECTS CREATED FROM TRAUMATIC INJURY TO THE BONE INCLUDING BONE MARROW LESIONS. ACCUFILL IS A BONE GRAFT SUBSTITUTE THAT RESORBS AND IS REPLACED WITH NEW BONE DURING THE HEALING PROCESS.
2281	IMP/MD/2020/000419	1.License Holder Name: LIFELONG MEDITECH PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC NEEDLES-A HYPODERMIC SINGLE LUMEN NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN., DISPOSABLE HYPODERMIC SYRINGES-INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.
2282	IMP/MD/2020/000423	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MIRAFILTER IV (PVC FREE ADMINISTRATION SET)(MIRAFILTER IV)-MIRAFILTER IV SET IS USED TO ADMINISTER MEDICINAL PRODUCTS, BLOOD AND BLOOD COMPONENTS TO PATIENTS THROUGH A VASCULAR ACCESS SITE. THE NON-INVASIVE MEDICAL DEVICE IS USED PRIMARILY TO INFUSE INTRAVENOUS SOLUTIONS.

2283	IMP/MD/2020/000424	1.License Holder Name: MAXXAALL MED PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SINGLE USE CLIP APPLIER (SOLID CLIP)-“SINGLE USE CLIP APPLIER” HAS APPLICATION IN MANY TYPES OF ENDOSOPIC PROCEDURE TO ACHIEVE OCCLUSION OF “VESSELS AND OTHER TUBULAR STRUCTURES” AND FOR RADIOGRAPHIC MARKING.
2284	IMP/MD/2020/000425	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INSULIN PEN NEEDLE (FINEGLIDE)-THIS PRODUCT TO BE USED WITH INSULIN INJECTOR IS A SINGLE USE STERILE INSULIN PEN NEEDLE TO BE USED FOR INJECTING INSULIN TO PATIENT WITH DIABETES. THE INTENDED PATIENT POPULATION : PATIENTS WITH DIABETES. THE INTENDED USER : PATIENTS WITH DIABETES
2285	IMP/MD/2020/000426	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SAFETY INFUSION SET (POWERLOC)-POWERLOC SAFETY INFUSION SET IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS AND DRUGS, AS WELL AS BLOOD SAMPLING THROUGH SURGICALLY IMPLANTED VASCULAR PORTS. IT IS ALSO INDICATED FOR POWER INJECTION OF CONTRAST MEDIA INTO THE CENTRAL VENOUS SYSTEM ONLY WITH AN IMPLANTED PORT THAT IS ALSO INDICATED FOR POWER INJECTION. THE MAXIMUM RECOMMENDED INFUSION RATE AT 11.8 CPS IS 5ML/SECOND FOR 19 GA NEEDLES, 5ML/SECOND FOR 20 GA NEEDLES AND 2ML/SECOND FOR 22 GA NEEDLES

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2286	IMP/MD/2020/000427	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RF ABLATION CLUSTER ELECTRODE KIT(COOL-TIP RF ABLATION CLUSTER ELECTRODE KIT E-SERIES)-THE COOL TIP E-SERIES ELECTRODE KITS ARE FOR USE WITH THE COOL-TIP RF ABLATION SYSTEM E-SERIES. THESE ARE USED FOR PERCUTANEOUS, LAPAROSCOPIC OR INTRAOPERATIVE ABLATION OF TISSUE, SUCH AS PARTIAL OR COMPLETE ABLATION OF NON-RESECTABLE LIVER TUMORS AND OSTEOID OSTEOMA TUMORS WITHIN BONE.,RF ABLATION MULTIPLE ELECTRODE KIT (COOL-TIPTM RF ABLATION MULTIPLE ELECTRODE KIT E-SERIES)-THE COOL TIP E-SERIES ELECTRODE KITS ARE FOR USE WITH THE COOL-TIP RF ABLATION SYSTEM E-SERIES. THESE ARE USED FOR PERCUTANEOUS, LAPAROSCOPIC OR INTRAOPERATIVE ABLATION OF TISSUE, SUCH AS PARTIAL OR COMPLETE ABLATION OF NON-RESECTABLE LIVER TUMORS AND OSTEOID OSTEOMA TUMORS WITHIN BONE,RF ABLATION SINGLE ELECTRODE KIT(COOL-TIP RF ABLATION SINGLE ELECTRODE KIT E-SERIES)-THE COOL TIP E-SERIES ELECTRODE KITS ARE FOR USE WITH THE COOL-TIP RF ABLATION SYSTEM E-SERIES. THESE ARE USED FOR PERCUTANEOUS, LAPAROSCOPIC OR INTRAOPERATIVE ABLATION OF TISSUE, SUCH AS PARTIAL OR COMPLETE ABLATION OF NON-RESECTABLE LIVER TUMORS AND OSTEOID OSTEOMA TUMORS WITHIN BONE
2287	IMP/MD/2020/000428	1.License Holder Name: SB MEDICARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE LIGATION CLIPS (POLYMER)-THE DISPOSABLE LIGATION CLIPS ARE INTENDED FOR USE IN PROCEDURES INVOLVING LIGATION OF VESSELS OR TISSUE STRUCTURES
2288	IMP/MD/2020/000429	1.License Holder Name: M/S. SUMMIT HEALTHCARE PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INVIA FOAM DRESSING KIT WITH FITPAD(INVIA FOAM DRESSING KIT WITH FITPAD)-THE INVIA FOAM DRESSING KIT WITH FITPAD IS INTENDED FOR USE IN CONJUNCTION WITH INVIA NEGATIVE PRESSURE WOUND THERAPY (NPWT) SYSTEMS. THE INVIA NPWT SYSTEMS ARE INTENDED FOR USE IN ACUTE, EXTENDED AND HOME CARE SETTINGS.

2289	IMP/MD/2020/000430	1.License Holder Name: INNVOLUTION HEALTHCARE PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CORONARY DILATATION CATHETER(SAPPHIRE II NC)-FOR BALLOON DILATATION OF A STENOTIC PORTION OF A CORONARY ARTERY IN PATIENTS EVIDENCING CORONARY ISCHEMIA FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,CORONARY DILATATION CATHETER(SAPPHIRE II RX)-FOR BALLOON DILATATION OF A STENOTIC PORTION OF A CORONARY ARTERY IN PATIENTS EVIDENCING CORONARY ISCHEMIA FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,CORONARY DILATATION CATHETER(SAPPHIRE II PRO)-FOR BALLOON DILATATION OF A STENOTIC PORTION OF A CORONARY ARTERY IN PATIENTS EVIDENCING CORONARY ISCHEMIA FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.
2290	IMP/MD/2020/000431	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INJECTABLE RESORBABLE CALCIUM PHOSPHATE BONE VOID FILLERS(GRAFTYS® QUICKSET)-MEDICAL DEVICE INTENDED FOR FILLING OR REINFORCING BONY VOIDS OR DEFECTS OF THE SKELETAL SYSTEM THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE (ORTHOPEDIC, CRANIO-FACIAL, MAXILLO-FACIAL, OR PARONDOTOLOGICAL). THESE DEFECTS MAY BE SURGICALLY CREATED OSSEOUS DEFECTS OR OSSEOUS DEFECTS CREATED FROM TRAUMATIC INJURY TO THE BONE. THESE PRODUCTS PROVIDE A BONE VOID FILLER THAT RESORBS AND IS REPLACED WITH BONE DURING THE HEALING PROCESS. GRAFTYS® QUICKSET CONSTITUTES A PROCEDURE KIT. THE INJECTION CAN BE FACILITATED BY THE USE GRAFTYS® CURVED CANNULA 7G (EUCAN7G).

2291	IMP/MD/2020/000435	1.License Holder Name: HEARTWAVE MEDICAL PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:L605 (COBALT CHROMIUM) SIROLIMUS ELUTING STENT(ALIS CR)-INTENDED FOR IMPROVING LUMINAL DIAMETER FOR THE TREATMENT OF DE NOVO LESIONS 42MM IN LENGTH IN NATIVE CORONARY ARTERIES > 2.5 TO 4.0 MM IN DIAMETER. THE SUMMARY OF THE INDICATIONS ARE: • DE NOVO (PRIMARY EMPLOYMENT IN CASE OF STENOSIS OR CLOSURES) • RESTENOSIS AFTER PTCA • VEIN BYPASS STENOSIS OR CLOSURE • HIGH RISK OF RESTENOSIS AFTER PTCA • DISSECTION AFTER PTCA • RECOIL AFTER PTCA • ACUTE VASCULAR OCCLUSION • SUB-OPTIMAL RESULT AFTER PTCA • THE TREATMENT OF STENOSES IN LESIONS WITH BRANCH ARTERIES,PTA – SIROLIMUS ELUTING CATHETER(ALEX PTA)-INTENDED FOR DILATATION OF LESIONS IN THE FEMORAL, RENAL, ILIAC, POPLITEAL, PERONEAL, AND PROFUNDA ARTERIES AND NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULA. THIS CATHETER IS NOT INTENDED FOR THE EXPANSION OR DELIVERY OF STENTS.,PTCA – SIROLIMUS ELUTING CATHETER(ALEX PTCA)-INTENDED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO CORONARY ARTERY LESIONS WITH A REFERENCE VESSEL DIAMETER RANGING FROM 1.5 MM TO 4.0 MM AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER.
2292	IMP/MD/2020/000439	1.License Holder Name: N-VASCULAR TECHNOLOGY PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SACCULAR INTRACRANIAL ANEURYSMS (NEQSTENT)-USE IN CONJUNCTION WITH CONVENTIONAL EMBOLIC COIL FOR ENDOVASCULAR EMBOLIZATION OF SACCULAR INTRACRANIAL ANEURYSMS , ANEURYSM EMBOLIZATION SYSTEM(CONTOUR NEUROVASCULAR SYSTEM™)-CONTOUR NEUROVASCULAR SYSTEM™ IS INDICATED FOR THE ENDOVASCULAR EMBOLIZATION

2293	IMP/MD/2020/000441	1.License Holder Name: M/S LINVATEC INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TUBING AND TROCARS FOR INSUFFLATOR SYSTEM(AIRSEAL® IFS SYSTEM)-THE CONMED AIRSEAL® IFS SYSTEM IS INTENDED FOR USE IN DIAGNOSTIC AND/OR THERAPEUTIC ENDOSCOPIC PROCEDURES TO DISTEND A CAVITY BY FILLING IT WITH GAS, TO ESTABLISH AND MAINTAIN A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS AND TO EVACUATE SURGICAL SMOKE. IT IS INDICATED TO FACILITATE THE USE OF VARIOUS LAPAROSCOPIC INSTRUMENTS BY FILLING THE ABDOMINAL CAVITY WITH GAS TO DISTEND IT, BY CREATING AND MAINTAINING A GAS SEALED OBSTRUCTION-FREE INSTRUMENT PATH AND BY EVACUATING SURGICAL SMOKE. THIS INSTRUMENT IS USED TO INSUFFLATE THE RECTUM AND COLON TO FACILITATE ENDOSCOPIC OBSERVATION, DIAGNOSIS AND TREATMENT. THE TROCAR OF THE AIRSEAL® IFS SYSTEM IS INDICATED FOR USE WITH OR WITHOUT VISUALIZATION.,DISPOSABLES FOR ELECTROSURGICAL UNIT(ARAGON BEAM COAGULATION ACCESSORIES)-THE CONMED HEALIXAR ABC SYSTEM IS INTENDED TO DELIVER ARGON GAS, AS WELL AS A HIGH FREQUENCY ELECTRICAL CURRENT FOR THE CUTTING AND/OR COAGULATION OF TISSUE. SPECIFIC INTENDED USE IS AS BELOW: THE ABC BEND-A BEAM SINGLE FUNCTION HANDPIECES HAVE APPLICATION IN OPEN ELECTROSURGICAL PROCEDURES TO PROVIDE A MEANS OF COAGULATION. MAXIMUM GENERATOR VOLTAGE 6,500 V @ 3% DUTY CYCLE (FOR 134003,134006,134009 REFER IFU 62-7533-001) THESE DEVICES ARE STERILE, SINGLE USE ELECTROSURGICAL ACCESSORIES USED IN CONJUNCTION WITH ARGON BEAM COAGULATION GENERATOR FOR DELIVERY OF ARGON GAS AND ELECTROSURGICAL CURRENT TO ACHIEVE CUTTING AND COAGULATION OF TISSUE. THE ABC DISSECTING ELECTRODE CAN ONLY BE USED WITH CONMED ABC HANDPIECES CAT NO. : 130342, 130343, 130344, 130345NN (ORDERED SEPARAETELY) MAXIMUM GENERATOR VOLTAGE 6.5 KVPK (FOR 139330,139331 REFER IFU 62-9655-001) THE TRIPLE OPTION ABC HANDCONTROL PENCIL IS INTENDED FOR USE AS AN ELECTROSURGICAL HANDSWITCHING PENCIL WITH CUT AND COAGULATION CAPABILITIES. IN ADDITION, THE TRIPLE OPTION ABC HANDCONTROL PENCIL ALSO HAS THE MEANS OF CONDUCTING ARGON GAS AND ELECTROSURGICAL CURRENT TO THE SURGICAL SITE FOR THE PURPOSE OF COAGULATION. MAXIMUM GENERATOR VOLTAGE: 6.5 KVPK (FOR 130321 REFER IFU 62-9656-001) HANDPIECE IS INTENDED FOR USE WITH CONMED ABC ELECTROSURGICAL GENERATOR FOR NON-CONTACT SUPERFICIAL ABLATION AND HEMOSTASIS AT THE OPERATIVE SITE. MAXIMUM

	GENERATOR VOLTAGE: 6.5KV PEAK. (FOR 130344 REFER IFU 62-9657-001) USE THE LAPAROSCOPIC ABC EXTENDED PROBE ONLY IN SITUATIONS WHERE YOU WOULD NORMALLY USE MONOPOLAR ENERGY. FOR USE WITH CONMED ELECTROSURGICAL GENERATORS WITH ABC AND ABC MODULES MAXIMUM GENERATOR VOLTAGE 6.5 KV PEAK @ 3% DUTY CYCLE. (FOR 160655 160656, 160636, 160644, 130342 REFER IFU 62-9658-001) HANDPIECE IS INTENDED FOR USE WITH CONMED ABC ELECTROSURGICAL GENERATOR FOR NON-CONTACT SUPERFICIAL ABLATION AND HEMOSTASIS AT THE OPERATIVE SITE. MAXIMUM GENERATOR VOLTAGE 6.5V @ 3% DUTY CYCLE. (FOR 130345 REFER IFU 800063002),DISPOSABLES FOR ELECTROSURGICAL UNIT(GOLDLINE PENCILS)-THESE DEVICES ARE DESIGNED TO BE USED AS ACCESSORIES IN CONJUNCTION WITH ELECTROSURGICAL UNITS AND ELECTRODES WITH WHICH THEY ARE KNOWN TO BE COMPATIBLE. THEIR USE ENABLES THE OPERATOR TO REMOTELY CONDUCT AN ELECTROSURGICAL CURRENT FROM THE OUTPUT CONNECTOR OF AN ELECTROSURGICAL UNIT TO THE OPERATIVE SITE FOR THE DESIRED SURGICAL EFFECT. SPECIFIC INTENDED USE AS BELOW: FOR SINGLE PATIENT USE DEVICES, 130326A, 130303A, 130302A, 1388114A, 131307A, 131327A, 130307A, 130327A, 130304A, 130301A, 138650A, 138652A, 138659A REFER IFU 62-9654-001 THESE DEVICES ARE DESIGNED TO BE USED AS ACCESSORIES IN CONJUNCTION WITH ELECTROSURGICAL UNITS AND ELECTRODES WITH WHICH THEY ARE KNOWN TO BE COMPATIBLE. THEIR USE ENABLES THE OPERATOR TO REMOTELY CONDUCT AN ELECTROSURGICAL CURRENT FROM THE OUTPUT CONNECTOR OF AN ELECTROSURGICAL UNIT TO THE OPERATIVE SITE FOR THE DESIRED SURGICAL EFFECT. MAXIMUM VOLTAGE IS NOT TO EXCEED 5.5 KVPEAK THESE DEVICES ARE COMPATIBLE WITH CONMED DISPOSABLE STANDARD AND ULTRACLEAN ACTIVE ELECTRODES. FOR REUSABLE DEVICES, 130316, 130316-15, 130317, 130317-15 REFER IFU 62-5856-001 THESE DEVICES ARE DESIGNED TO BE USED AS ACCESSORIES IN CONJUNCTION WITH THOSE ELECTROSURGICAL UNITS AND ELECTRODES WITH WHICH THEY ARE KNOWN TO BE COMPATIBLE. THEIR USE ENABLES THE OPERATOR TO REMOTELY CONDUCT AN ELECTROSURGICAL CURRENT TO THE OPERATIVE SITE FOR THE DESIRED SURGICAL EFFECT. MAXIMUM VOLTAGE IS NOT TO EXCEED 5.5 KVPEAK FOR REUSABLE DEVICES, 139100, 139104EXT, 139112, 139112EXT, 139321, 139102, 139105EXT, 139321, 139102, 139105EXT, 139108, 139105EXT, 139107, 139110EXT REFER IFU 62-9660-001 THESE DEVICES ENABLE THE OPERATOR TO REMOTELY CONDUCT AN ELECTROSURGICAL CURRENT FROM AN ELECTROSURGICAL HANDPIECE THROUGH THE ELECTRODE TO THE OPERATIVE SITE FOR THE DESIRED SURGICAL EFFECT. MAXIMUM

		VOLTAGE NOT TO EXCEED 5.5 KV PEAK. CONMED ELECTRODES HAVE A 3/32 IN (2.38 MM) DIAMETER SHAFT AND ARE DESIGNED TO FIT CONMED AND MOST OTHER ELECTROSURGICAL PENCILS AND ACCESSORIES. HOWEVER, PRIOR TO USE, IT IS IMPORTANT TO CHECK THE ELECTRODE CONNECTION TO THE ACCESSORY YOU ARE USING TO ASSURE PROPER FIT AND COMPATIBILITY. FOR SINGLE PATIENT USE DEVICE, 138025 REFER TO IFU 62-7265-001 THESE DEVICES ENABLE THE OPERATOR TO REMOTELY CONDUCT AN ELECTROSURGICAL CURRENT FROM AN ELECTROSURGICAL HANDPIECE THROUGH THE ELECTRODE TO THE OPERATIVE SITE FOR THE DESIRED SURGICAL EFFECT. MAXIMUM VOLTAGE NOT TO EXCEED 5.5 KV PEAK. CONMED ELECTRODES HAVE A 3/32 IN (2.38 MM) DIAMETER SHAFT AND ARE DESIGNED TO FIT CONMED AND MOST OTHER ELECTROSURGICAL PENCILS AND ACCESSORIES. HOWEVER, PRIOR TO USE, IT IS IMPORTANT TO CHECK THE ELECTRODE CONNECTION TO THE ACCESSORY YOU ARE USING TO ASSURE PROPER FIT AND COMPATIBILITY.
2294	IMP/MD/2020/000442	1.License Holder Name: SOLCO BIOMEDICAL COMPANY INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINAL ALIGNMENT SYSTEM FOR VCF(LIBRA)-LIBRA INFLATABLE BONE EXPANDER SYSTEM FOR VCF WITH THE BALLOON, IS DEVICE INTENDED TO INSERT THE BONE CEMENT INTO THE CAVITY MADE BY THE BALLOON TIP IN THE FRACTURES OF THE SPINAL BONE.
2295	IMP/MD/2020/000443	1.License Holder Name: SMITHS MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARTERIAL BLOOD SAMPLING(PRO-VENT, LINE-DRAW)-THE ARTERIAL BLOOD SAMPLING SYRINGE FOR CALCIUM NEUTRALIZED DRY LITHIUM HEPARIN SYRINGES IS INTENDED FOR SAMPLING OF ARTERIAL BLOOD FOR THE MEASUREMENT OF PO2, PCO2, PH, COOXIMETRY, ELECTROLYTES (CA++, NA+, K+, CL-, AND MG++), TOTAL MAGNESIUM, AND THE METABOLITES (GLUCOSE AND LACTATE). DRY LITHIUM HEPARIN IS NEUTRALIZED FOR IONIC CALCIUM. THE SYRINGE IS HEPARINIZED FOR ANTICOAGULANT EFFECT.

2296	IMP/MD/2020/000444	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OLECRANON PLATES - PLATE (TICP)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR OR WITHOUT PLATES - WASHER (TAN)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR OR WITHOUT PLATES - WASHER (TICP)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,PROXIMAL HUMERUS PLATES - PLATE (TICP)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., EXTERNAL FIXATOR IMPLANTS - SCREW (TICP)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS.,RADIUS PLATES - PLATE (TICP)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., DISTAL TIBIA PLATES - PLATE (STAINLESS STEEL)(NA)-IT INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS,EXTERNAL FIXATOR IMPLANTS -PIN (STAINLESS STEEL)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS.,PROXIMAL HUMERUS PLATES - PLATE (STAINLESS STEEL)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR OR WITHOUT PLATES-WASHER (STAINLESS STEEL)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,LOCKING COMPRESSION PLATES - PLATE (STAINLESS STEEL)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,LOCKING COMPRESSION PLATES - PLATE (TICP)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., FOOT PLATES- PLATE (TAN)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,LOCKING ATTACHMENT PLATES-PLATE (TICP)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., PROXIMAL TIBIA PLATES- PLATE (STAINLESS STEEL)(NA)-IT IS

	INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., TOMOFIX PLATE IMPLANTS - PLATE (TICP)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,MATRIXMIDFACE INCL. MXORBITAL -PLATE (TICP)(NA)-IT IS INTENDED FOR USE AS TRAUMA REPAIR AND RECONSTRUCTION OF THE CRANIO-MAXILLOFACIAL SKELETON.,DISTAL HUMERUS PLATE -PLATE (TICP)(NA)-IT INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS,DISTAL HUMERUS PLATE-PLATE (TAN)(NA)-IT INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS,DISTAL TIBIA PLATES - PLATE (TICP)(NA)-IT INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS, PEDIATRIC PLATES- PLATE (STAINLESS STEEL)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,TOMOFIX IMPLANTS - PLATE(NA)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,RECON FEMORAL NAILING IMPLANTS- WASHER (TAN)(NA)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN),SCREW IMPLANTS FOR OR WITHOUT PLATES - WASHER_STERILE (STAINLESS STEEL)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., CARPAL FUSION PLATES- PLATE (TAN)(NA)-IT INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,RECON FEMORAL NAILING IMPLANTS - WASHER_STERILE (TAN)(NA)-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",EXTERNAL FIXATOR IMPLANTS - SCREW (STAINLESS STEEL)(NA)-IT IS INTENDED FOR TEMPORARY

		FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS.,EXTERNAL FIXATOR IMPLANTS - SCREW (TAN)(NA)-IT IS INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS.,CLAVICLE PLATES - PLATE (TICP)(NA)-IT INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS,USS FRACTURE- SCREW (TAN)(NA)-THE USS FRACTURE SYSTEM IS A POSTERIOR THORACOLUMBAR PEDICLE SCREW FIXATION SYSTEM INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE APPLICATION AREA IN PATIENTS SUFFERING FROM TRAUMA OR TUMOR DISEASE IS USUALLY AT THE THORACAL-LUMBAR JUNCTION (T12 /L1), BUT CAN BE EXTENDED FROM T6 DOWN TO THE SACRUM (S1).
2297	IMP/MD/2020/000445	1.License Holder Name: ALMA MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYALURONIC ACID PREFILLED SYRINGE(PROFHILO)-PROFHILO, HYALURONIC ACID SODIUM SALT FOR INTRADERMAL USE ACTING THROUGH A CORRECTIVE AND FILLING ACTION OF THE NATURAL AND INDUCED CUTANEOUS DEPRESSIONS, INTERVENES: IN THE PHYSIOLOGICAL PROCESS OF SKIN AGING, THE EFFECTS OF WHICH INCLUDE REDUCED SKIN HYDRATION , THE ALTERATION OF ELASTIC FIBERS AND COLLAGEN OF THE DERMIS WITH LOSS OF TURGOR AND SKIN TONE; IN THE DERMAL TISSUE REPAIR PROCESS, IN CASES OF SCARS RESULTING FROM SUPERFICIAL CUTANEOUS TRAUMA (E.G ACNE AND CHICKENPOX SCARS)
2298	IMP/MD/2020/000446	1.License Holder Name: PANACEA BIOTEC LTD. (VACCINE DIVISION) 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYPODERMIC NEEDLE(K-PACK II NEEDLE)-K-PACK II NEEDLES ARE STERILE, SINGLE USE HYPODERMIC NEEDLES INTENDED TO INJECT FLUIDS INTO, OR WITHDRAWN FLUIDS FROM, PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN

2299	IMP/MD/2020/000447	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYALURONIC ACID GEL (PERFECTHA)-PERFECTHA IS A LINE OF RESORBABLE HYALURONIC ACID (HA) GEL IMPLANTS INTENDED FOR RECONSTRUCTIVE PURPOSES IN THE TREATMENT, FOR INSTANCE, OF FACIAL LIPOATROPHY, OR MORPHOLOGICAL ASYMMETRY ASSOCIATED WITH THE AGING PROCESS OR OTHER UNDERLYING CONDITIONS. PERFECTHA IS FOR INTRADERMAL AND SUBCUTANEOUS APPLICATION AND IS IMPLANTED IN THE AREAS OF THE FACE AND HANDS TO FILL SKIN DEPRESSIONS AND ALSO FOR THE AUGMENTATION OF TISSUE VOLUME.
2300	IMP/MD/2020/000448	1.License Holder Name: ENVISION SCIENTIFIC PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA CATHETER (TAMARIN BLUE)-IT IS INDICATED FOR: • BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. • BALLOON DILATATION OF A STENT AFTER IMPLANTATION (BALLOON MODELS 2.00MM - 4.50MM),PTA 0.018” OTW CATHETER(EBONY 0.018” OTW)-IT IS INTENDED TO DILATE STENOSIS IN THE PERIPHERAL ARTERIES (ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA POPLITEAL, RENAL ARTERIES) AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE.,RX PTA CATHETER (EBONY 0.014” RX)-IT IS INTENDED FOR DILATATION OF LESIONS IN THE ILIAC, FEMORAL, POPLITEAL, INFRAPOPLITEAL AND RENAL ARTERIES.,PTA 0.014” OTW CATHETER(EBONY 0.014” OTW)-IT IS SPECIALLY DESIGNED FOR THE PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF VASCULAR DISTRICTS AS FEMORAL ARTERY AND BELOW THE KNEE VESSELS WITH A REFERENCE DIAMETER EQUAL OR LARGER THAN SELECTED BALLOON SIZES.,PTA 0.035” OTW CATHETER(EBONY 0.035” OTW)-IT IS INTENDED FOR DILATATION OF LESIONS IN THE FEMORAL, ILIAC, POPLITEAL, INFRAPOPLITEAL AND RENAL ARTERIES

2301	IMP/MD/2020/000449	1.License Holder Name: SIMPLADENT IMPLANT SOLUTIONS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SIMPLADENT DENTAL IMPLANT SYSTEM(BECES,BECES N,BECES EX,BECESMU)-INTENDED IN ALVEOLAR AND CORTICAL BONE OF JAW VERTICALLY, IMMEDIATE LOADING,SIMPLADENT DENTAL IMPLANT SYSTEM(ZDI)-INTENDED IN ALVEOLAR AND CORTICAL BONE OF JAW VERTICALLY, IMMEDIATE LOADING.,SIMPLADENT DENTAL IMPLANT SYSTEM(HEXACONE HC, HEXACONE HC2,HEXACONE PLUS MU)-INTENDED FOR THE GENERATION OF OSSEO-INTEGRATED ANCHORAGE POINTS IN THE MANDIBLE AND IN THE MAXILLA, FOR THE FIXATION OF CROWNS, BRIDGES, DENTURES, BAR AND ORTHODONTIC APPLIANCES, SIMPLADENT DENTAL IMPLANT SYSTEM(KOC MICRO,KOC PLUS,KOC X,KOC CLASSIC,KOC MU)-INTENDED IN ALVEOLAR BONE OF JAW VERTICALLY, IMMEDIATE LOADING.
2302	IMP/MD/2020/000451	1.License Holder Name: ONCOCARE SCIENTIFICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:URINARY CATHETER FOR SINGLE USE ONLY (FOLEY)(FOLEYSIL)-IT IS SUITABLE FOR MEDICAL UNITS FOR CLINICAL CATHETERIZATION, BLADDER IRRIGATION AND COMPRESSION AND HEMOSTASIS DURING THE OPERATION OF THE DEPARTMENT OF UROLOGY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2303	IMP/MD/2020/000453	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASPIRATION CATHETER (EXPORT ADVANCE)-THE EXPORT™ ASPIRATION CATHETER IS INDICATED FOR USE IN THE CENTRAL AND PERIPHERAL CIRCULATORY SYSTEM, INCLUDING SAPHENOUS VEIN GRAFTS TO CONTAIN AND ASPIRATE EMBOLIC MATERIAL (THROMBUS/DEBRIS) WHILE PERFORMING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY, PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY AND/OR STENTING PROCEDURES, AND TO SUBSELECTIVELY INFUSE/DELIVER DIAGNOSTIC OR THERAPEUTIC FLUIDS WITH OR WITHOUT VESSEL OCCLUSION. ,GUIDING CATHETER(LAUNCHER)-THE MEDTRONIC GUIDING CATHETER IS DESIGNED TO PROVIDE A PATHWAY THROUGH WHICH THE THERAPEUTIC DEVICES ARE INTRODUCED. THE GUIDING CATHETER IS INTENDED TO BE USED IN THE CORONARY OR PERIPHERAL VASCULAR SYSTEM,GUIDING CATHETER (SHERPA NX BALANCED)-THE MEDTRONIC GUIDING CATHETER IS DESIGNED TO PROVIDE A PATHWAY THROUGH WHICH THE THERAPEUTIC DEVICES ARE INTRODUCED. THE GUIDING CATHETER IS INTENDED TO BE USED IN THE CORONARY OR PERIPHERAL VASCULAR SYSTEM
2304	IMP/MD/2020/000455	1.License Holder Name: COCHLEAR MEDICAL DEVICE COMPANY INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BAHA BONE CONDUCTION HEARING IMPLANT SYSTEM(BAHA)-IT IS USED TO TREAT PATIENTS WITH CONDUCTIVE AND MIXED HEARING LOSS, AND SINGLE SIDED SENSORINEURAL DEAFNESS.,BAHA BONE CONDUCTION HEARING IMPLANT SYSTEM(BAHA)-IT IS USED TO TREAT PATIENTS WITH CONDUCTIVE AND MIXED HEARING LOSS, AND SINGLE SIDED SENSORINEURAL DEAFNESS.

2305	IMP/MD/2020/000456	1.License Holder Name: BL LIFESCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEUROSURGICAL RIGID FIXATION SYSTEM (NON-STERILE) - SCREW(NEUROPRO®)-1. INTERNAL FIXATION OF FRACTURES AND OSTEOTOMIES OF THE CRANIOFACIAL SKELETON. 2. INTERNAL FIXATION OF CRANIAL BONE FLAP OSTEOTOMIES. 3. RECONSTRUCTION OF BONY DEFECTS AND DEFICITS IN THE CRANIOFACIAL SKELETON.,NEUROSURGICAL RIGID FIXATION SYSTEM (NON-STERILE) - PANEL(NEUROPRO®)-1. INTERNAL FIXATION OF FRACTURES AND OSTEOTOMIES OF THE CRANIOFACIAL SKELETON. 2. INTERNAL FIXATION OF CRANIAL BONE FLAP OSTEOTOMIES. 3. RECONSTRUCTION OF BONY DEFECTS AND DEFICITS IN THE CRANIOFACIAL SKELETON.,NEUROSURGICAL RIGID FIXATION SYSTEM (NON-STERILE) - BONE PLATE(NEUROPRO®)-1. INTERNAL FIXATION OF FRACTURES AND OSTEOTOMIES OF THE CRANIOFACIAL SKELETON. 2. INTERNAL FIXATION OF CRANIAL BONE FLAP OSTEOTOMIES. 3. RECONSTRUCTION OF BONY DEFECTS AND DEFICITS IN THE CRANIOFACIAL SKELETON.

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2306	IMP/MD/2020/000457	1.License Holder Name: KCI MEDICAL INDIA PRIVATE LIMITED ,K. NO. 2606/115 (P. NO. 60/16) GROUND FLOOR, HUSKUR ROAD ELECTRONIC POST ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560100 , INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:V.A.C.® WHITEFOAM DRESSING LARGE (FOAM ONLY) & V.A.C.® WHITEFOAM DRESSING SMALL (FOAM ONLY)(V.A.C.® WHITEFOAM DRESSING LARGE (FOAM ONLY) & V.A.C.® WHITEFOAM DRESSING SMALL (FOAM ONLY))-THE ACTIV.A.C.®, INFOV.A.C.®, V.A.C. ATS® AND V.A.C. FREEDOM® NEGATIVE PRESSURE WOUND THERAPY SYSTEMS ARE INTEGRATED WOUND MANAGEMENT SYSTEMS FOR USE IN ACUTE, EXTENDED AND HOME CARE SETTINGS. WHEN USED ON OPEN WOUNDS, THEY ARE INTENDED TO CREATE AN ENVIRONMENT THAT PROMOTES WOUND HEALING BY SECONDARY OR TERTIARY (DELAYED PRIMARY) INTENTION BY PREPARING THE WOUND BED FOR CLOSURE, REDUCING EDEMA, PROMOTING GRANULATION TISSUE FORMATION AND PERFUSION, AND BY REMOVING EXUDATE AND INFECTIOUS MATERIAL. OPEN WOUND TYPES INCLUDE: CHRONIC, ACUTE, TRAUMATIC, SUBACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC, PRESSURE OR VENOUS INSUFFICIENCY), FLAPS AND GRAFTS. WHEN USED ON CLOSED SURGICAL INCISIONS, THEY ARE INTENDED TO MANAGE THE ENVIRONMENT OF THE SURGICAL INCISIONS THAT CONTINUE TO DRAIN FOLLOWING SUTURED OR STAPLED CLOSURE BY MAINTAINING A CLOSED ENVIRONMENT AND REMOVING EXUDATES VIA THE APPLICATION OF NEGATIVE PRESSURE WOUND THERAPY

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2307	IMP/MD/2020/000458	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KNEE JOINT REPLACEMENT SYSTEM(MPS-FLEX® TOTAL KNEE JOINT PROSTHESES - MPS-FLEX ARTICULAR SURFACE)-MPS-FLEX® TOTAL KNEE JOINT PROSTHESES IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. • POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES.,KNEE JOINT REPLACEMENT SYSTEM(MPS-FLEX® TOTAL KNEE JOINT PROSTHESES - PATELLA COMPONENT)-MPS-FLEX® TOTAL KNEE JOINT PROSTHESES IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. • POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES.,KNEE JOINT REPLACEMENT SYSTEM(MPS-FLEX® TOTAL KNEE JOINT PROSTHESES - MPS-FLEX FEMORAL COMPONENT)-MPS-FLEX® TOTAL KNEE JOINT PROSTHESES IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. • POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES.,KNEE JOINT REPLACEMENT SYSTEM(MPS-FLEX® TOTAL KNEE JOINT PROSTHESES - TIBIAL COMPONENT)-MPS-FLEX® TOTAL KNEE JOINT PROSTHESES IS INDICATED FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • COLLAGEN DISORDERS, AND/OR AVASCULAR NECROSIS OF THE FEMORAL CONDYLE. • POST-TRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION DEFORMITIES.

2308	IMP/MD/2020/000461	1.License Holder Name: CARDINAL HEALTH MEDICAL PRODUCTS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERIPHERAL STENT (PALMAZ®)-THE PALMAZ® PERIPHERAL STENT (BALLOON EXPANDABLE STENT FOR LARGE VESSELS) IS INDICATED FOR USE IN PERIPHERAL VESSELS BELOW THE AORTIC ARCH IN PATIENTS WHO ARE ACCEPTABLE CANDIDATES FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY. THE LUMEN DIAMETER OF ALL VESSELS BETWEEN THE ENTRY SITE AND THE LESION SITE MUST BE LARGE ENOUGH TO ACCEPT A 12F OR 13F INTRODUCER SHEATH. IF THE VESSELS ARE NOT LARGE ENOUGH DUE TO A LESION, AN ANGIOPLASTY PROCEDURE MUST BE PERFORMED TO PRODUCE A LUMEN OF SUFFICIENT SIZE. THE TARGET VESSEL MUST BE LARGE ENOUGH TO ACCOMMODATE THE STENT EXPANDED TO 15MM. IN ORDER TO PERFORM A SUCCESSFUL STENT IMPLANTATION, A CT SCAN IS RECOMMENDED TO ENSURE THE ACCURATE MEASUREMENT OF THE PASSAGE VESSELS AND THE TARGET VESSEL.
2309	IMP/MD/2020/000462	1.License Holder Name: NIPRO MEDICAL (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISINFECTANT (SANACIDE-R7)-COLD DISINFECTANT (DIALYSIS MACHINE OVER 20' C) MICROBIOCIDAL ACTIVITY AND WORKS BACTERCIDAL , VIRUS INACTIVATING AND FUNGICIDAL. ,DISINFECTANT(CITRIX-LA)-HEAT DISINFECTANT(DIALYSIS MACHINE 85 °C) MICROBIOCIDAL ACTIVITY AND WORKS BACTERICIDAL, VIRUS INACTIVATING AND FUNGICIDAL., DISINFECTANT(CITRIX-50H)-HEAT DISINFECTANT(DIALYSIS MACHINE 85 °C)MICROBIOCIDAL ACTIVITY AND WORKS BACTERICIDAL, VIRUS INACTIVATINGAND FUNGICIDAL.

2310	IMP/MD/2020/000463	1.License Holder Name: SHUNMEI MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTFE COATED GUIDE WIRE (SHUNMEI)-PTFE COATED GUIDE WIRE IS APPLICABLE AS AN INVASIVE MEDICAL DEVICES. IT IS INDICATED FOR GUIDING AND ASSISTING INSERTION OF PERCUTANEOUS CATHETER. ,MANIFOLDS (SHUNMEI)-MANIFOLDS IS A KIND OF TRANSFUSION DEVICE, T SHAPE WITH AN “OFF” RIGHT HANDLE, CAN CONTROL THE DIRECTION OF FLOW OF FLUID, WITH THE HIGH PRESSURE OF 500PSI, THIS MANIFOLD GENERALLY USED AS AN IMPORTANT ACCESSORY DURING THE PROCESS OF ANGIOGRAPHY OPERATION OR INTERVENTIONAL OPERATION. IT WILL BE INNOCUOUS DISPOSED IMMEDIATELY AFTER SINGLE USE. ,DOSE CONTROL SYRINGE (SHUNMEI)-DOSE CONTROL SYRINGE IS INJECTION OF CONTRAST ANGIOCARDIOGRAPHY, LIQUID INJECTION THERMODILUTION CATHETER OR INPUT OTHER LIQUID/MEDIUM OR DRUG. ,DISPOSABLE PRESSURE TRANSDUCER(SHUNMEI)-DISPOSABLE PRESSURE TRANSDUCER IS INTENDED TO CONVERT THE HEMODYNAMIC WAVE FROM THE PATIENT’S CATHETER, THROUGH INTEGRATED PRESSURE SENSOR, INTO ELECTRICAL SIGNALS WHICH CAN BE DISPLAYED USING SEPARATE MONITORING EQUIPMENT. ,PTCA GUIDE WIRE (SHUNMEI)-THE PTCA GUIDE WIRE IS INTENDED TO FACILITATE THE PLACEMENT AND EXCHANGE OF BALLOON CATHETERS OR OTHER INTERVENTIONAL DEVICES DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) OR OTHER INTRAVASCULAR INTERVENTIONAL PROCEDURES. ,HEMODIALYSIS CATHETER KITS (SHUNMEI)-THE HEMODIALYSIS CATHETER KITSS ARE PROVIDE TEMPORARY VASCULAR ACCESS FOR HEMODIALYSIS UNTIL A PERMANENT ACCESS IS AVAILABLE OR UNTIL ANOTHER TYPE OF DIALYSIS THERAPY IS SUBSTITUTED.,ANGIOGRAPHIC SYRINGE (SHUNMEI)-ANGIOGRAPHIC SYRINGE IS USED FOR EACH PART OF THE ENTIRE BODY OF ANGIOGRAPHY(DAS) AND CT ENHANCED SCAN AND CT VASCULAR IMAGING ,TR-CLOSURE BAND(SHUNMEI)-THE TR-CLOSURE BAND IS AN AUXILIARY EQUIPMENT USED FOR RADIAL ARTERY OPPRESSION HEMOSTASIS AFTER THE RADIAL ARTERY PUNCTURE INTERVENTIONAL SURGERY. ,CENTRAL VENOUS CATHETER(SHUNMEI)-THE CENTRAL VENOUS CATHETER KIT IS INTENDED FOR THE PURPOSE OF PROVIDING SHORT TERM ACCESS (NO MORE THAN 30 DAYS) TO THE CENTRAL VENOUS VASCULAR SYSTEM FOR THE INFUSION OF FLUIDS, MONITORING OF CENTRAL VENOUS AND SAMPLING OF BLOOD. ,INTRODUCER SETS(SHUNMEI)-INTRODUCER SETS ARE SINGLE USE DEVICE ALLOWING FOR INTRODUCTION, MANIPULATION, AND REMOVAL OF SIMULATION LEADS AFTER PERCUTANEOUS ENTRY IS GAINED WITH A NEEDLE.

	HEMOSTASIS VALVE SET(SHUNMEI)-THE HEMOSTASIS VALVE SET IS INTENDED FOR INTERVENTIONAL EFFECT ON INTRAVASCULAR AND CHECK THE GUIDE WIRE OR AS THE DIAGNOSIS INSTRUMENT. , BALLOON DILATATION CATHETER(SHUNMEI)-THE PTCA BALLOON DILATATION CATHETER IS INTENDED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. THE NC CORONARY DILATATION CATHETER IS INTENDED FOR BALLOON DILATATION OF STENOTIC PORTION OF CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION, AND IS ALSO INDICATED FOR BALLOON DILATATION OF A CORONARY OCCLUSION FOR THE PURPOSE OF RESTORING CORONARY FLOW IN PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION AND USED FOR BALLOON DILATATION OF STENT AFTER IMPLANTATION., BALLOON INFLATION DEVICES(SHUNMEI)-BALLOON INFLATION DEVICES ARE INTENDED TO BE USED IN PTCA OPERATION, THE BALLOON DILATATION CATHETER IS PRESSURIZED IN ORDER TO ACHIEVE THE EXPANSION OF BLOOD VESSELS OR THE PLACEMENT OF INTRAVASCULAR STENT. IN MINIMALLY INVASIVE BALLOON DILATION PROCEDURE, THE BALLOON INFLATION DEVICES CAN BE USED TO INFLATE THE BALLOON WITH FLUID, TO MONITOR THE PRESSURE IN THE BALLOON DURING THE PROCEDURE AND TO DEFLATE THE BALLOON AFTER DILATION. ,GUIDING CATHETER (SHUNMEI)-THE GUIDING CATHETER INTENDED FOR THE PURPOSE OF PROVIDING A PATHWAY THROUGH WHICH THERAPEUTIC AND DIAGNOSTIC DEVICES ARE INTRODUCED. THE GUIDING CATHETER IS INTENDED TO BE USED IN THE CORONARY OR PERIPHERAL VASCULAR SYSTEM. ,HYDROPHILIC COATED GUIDE WIRE(SHUNMEI)-HYDROPHILIC COATED GUIDE WIRE INTENDED FOR THE PURPOSE OF PROVIDING A PATHWAY THROUGH WHICH THERAPEUTIC AND DIAGNOSTIC DEVICES ARE INTRODUCED. HYDROPHILIC COATED GUIDE WIRE IS INTENDED TO BE USED IN THE CORONARY OR PERIPHERAL VASCULAR SYSTEM,ANGIOGRAPHIC CATHETER (SHUNMEI)-ANGIOGRAPHIC CATHETER IS INTENDED FOR USE IN ANGIOGRAPHIC PROCEDURES TO DELIVER RADIOPAQUE MEDIA TO SELECTED SITES IN THE VASCULAR SYSTEM.

2311	IMP/MD/2020/000464	1.License Holder Name: SPAN HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD BAG(JMS)-INTENDED FOR COLLECTION PROCESSING AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,TRANSFER BAG(JMS)-INTENDED FOR COLLECTION, TRANSFER, SEPARATION OR STORAGE OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG(JMS)-INTENDED FOR COLLECTION PROCESSING AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.
2312	IMP/MD/2020/000466	1.License Holder Name: SERUM INSTITUTE OF INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYPODERMIC NEEDLE(K-PACK II NEEDLE)-K-PACK II NEEDLES ARE STERILE, SINGLE USE HYPODERMIC NEEDLES INTENDED TO INJECT FLUIDS INTO, OR WITHDRAWN FLUIDS FROM, PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.
2313	IMP/MD/2020/000467	1.License Holder Name: INDELOX GLOBAL DISTRIBUTION PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PROSOFT NASAL CANNULAS(PROSOFT NASAL CANNULAS)-THE PROSOFT DUAL PRONG CANNULAS ARE INTENDED TO ADMINISTER BREATHING GASES TRANSNASALLY. INDICATED FOR USE WITH PRECISION FLOW (CLASSIC , PLUS & HELIOX), AND PRECISION FLOW HI-VNI.

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2314	IMP/MD/2020/000468	1.License Holder Name: MEDMARK ELIXIR LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUPERSTRUCTURES (ABUTMENTS WITH SCREWS AND HEALING CAP)(COVER SCREW, TEMPORARY ABUTMENT (PEEK), 150 TEMPORARY ABUTMENT (PEEK), 250 TEMPORARY ABUTMENT (PEEK), TITANIUM ABUTMENT SCREW, SHOULDERED ABUTMENT SCREW, GOLD SCREW FOR INTERNAL HEX. ABUTMENT, ANATOMIC ABUTMENT , ANATOMIC ABUTMENT (WIDE) TITANIUM UNIVERSAL ABUTMENT, UNIVERSAL ABUTMENT, ESTHETIC ABUTMENT (TI) , 150 ESTHETIC ABUTMENT (TI), 250 ESTHETIC ABUTMENT (TI), ESTHETIC ABUTMENT (BURN-OUT), 150 ESTHETIC ABUTMENT (BURN-OUT), 250 ESTHETIC ABUTMENT (BURN-OUT), ESTHETIC ABUTMENT BURN-OUT ROUND , 150 ANGULATED ABUTMENT, 250 ANGULATED ABUTMENT, 150 ANGULATED ABUTMENT TI WIDE, 250 ANGULATED ABUTMENT TI WIDE, NARROW ABUTMENT, 250 NARROW ABUTMENT, 150 NARROW ABUTMENT, NARROW SOLID ABUTMENT, DIRECT GOLD PLASTIC ABUTMENT CYLINDER WITH HEX., DIRECT GOLD PLASTIC ABUTMENT CYLINDER ROUND, BALL ATTACHMENT, BALL ATTACHMENT 170, BALL ATTACHMENT 300, TI SCREW FOR M.U. & BALLS, MULTI –UNIT, MULTI-UNIT 170, MULTI-UNIT 300, MULTI-UNIT TI SCREW, MULTI-UNIT GOLD SCREW, CAD/CAM ABUTMENT KIT NARROW, CAD/CAM ABUTMENT KIT NARROW ROUND, EQUATOR ABUTMENT, CAD/CAM MULTI UNIT ABUTMENT KIT, ANATOMIC ABUTMENT WIDE, DIRECT COCR PLASTIC ABUTMENT CYLINDER ROUND, DIRECT COCR PLASTIC ABUTMENT CYLINDER HEX,)-DENTAL IMPLANT SYSTEMS ARE INTENDED TO REPLACE SINGLE OR MULTIPLE TEETH IN THE FULLY OR PARTIALLY ENDENTULOUS MANDIBULAR OR MAXILLARY ALVEOLAR PROCESS. THE IMPLANTS ARE APPROPRIATE FOR IMMEDIATE LOADING WHEN GOOD PRIMARY STABILITY IS ACHIEVED AND WITH APPROPRIATE OCCLUSAL LOADING. ,DENTAL IMPLANT SYSTEMS(MASSIF, AXIS, CRESTONE ,)-DENTAL IMPLANT SYSTEMS ARE INTENDED TO REPLACE SINGLE OR MULTIPLE TEETH IN THE FULLY OR PARTIALLY ENDENTULOUS MANDIBULAR OR MAXILLARY ALVEOLAR PROCESS. THE IMPLANTS ARE APPROPRIATE FOR IMMEDIATE LOADING WHEN GOOD PRIMARY STABILITY IS ACHIEVED AND WITH APPROPRIATE OCCLUSAL LOADING.

2315	IMP/MD/2020/000469	1.License Holder Name: CARDINAL HEALTH MEDICAL PRODUCTS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VASCULAR STENT SYSTEM(S.M.A.R.T.® FLEX)-THE STENT IS INTENDED AS A TREATMENT FOR ATHEROSCLEROTIC SUPERFICIAL FEMORAL ARTERY LESIONS AND PROXIMAL POPLITEAL LESIONS.

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2316	IMP/MD/2020/000471	1.License Holder Name: GSR MEDICO PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:POLYPROPYLENE NONABSORBABLE SURGICAL SUTURE(DEMELENE)-GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES. PRODUCT IS INTENDED FOR LONG TERM USE OVER 30 DAYS. THIS PRODUCT IS NOT INTENDED TO BE USED ON THE HEART OR WITH THE CENTRAL CIRCULATORY AND CENTRAL NERVOUS SYSTEMS.,NYLON NONABSORBABLE SURGICAL SUTURE (DEMELON)-GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES. PRODUCT IS INTENDED FOR LONG TERM USE OVER 30 DAYS. THIS PRODUCT IS NOT INTENDED TO BE USED ON THE HEART OR WITH THE CENTRAL CIRCULATORY AND CENTRAL NERVOUS SYSTEMS.,POLYESTER NONABSORBABLE SURGICAL SUTURE(DEMEBOND)-GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES. PRODUCT IS INTENDED FOR LONG TERM USE OVER 30 DAYS. THIS PRODUCT IS NOT INTENDED TO BE USED ON THE HEART OR WITH THE CENTRAL CIRCULATORY AND CENTRAL NERVOUS SYSTEMS,POLIGLECAPRONE 25 SYNTHETIC MONOFILAMENT ABSORBABLE SURGICAL SUTURE(DEMECAPRONE)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL SURGERY, MICROSURGERY, OR OPHTHALMIC SURGERY.,POLYDIOXANONE SYNTHETIC MONOFILAMENT ABSORBABLE SURGICAL SUTURE(DEMEDIOX)-IT IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PEDIATRIC CARDIOVASCULAR TISSUE WHERE GROWTH IS EXPECTED TO OCCUR AND OPHTHALMIC SURGERY.,POLYGLACTIN 910 ABSORBABLE SURGICAL SUTURES (G)(DEMECRYL)-GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUE.,SILK NONABSORBABLE SURGICAL SUTURE (DEMESILK)-GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES. PRODUCT IS INTENDED FOR LONG TERM USE OVER 30 DAYS. THIS PRODUCT IS NOT INTENDED TO BE USED ON THE HEART OR WITH THE CENTRAL CIRCULATORY AND CENTRAL NERVOUS SYSTEMS.,POLYGLYCOLIC ACID ABSORBABLE SURGICAL SUTURE(DEMESORB)-USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUE,RAPID ABSORBABLE ABSORBABLE SURGICAL SUTURE(DEMEQUICK)-GENERAL SOFT TISSUE APPROXIMATION (I.E., MUCOSA AND SKIN) WHERE ONLY SHORT

	TERM WOUND SUPPORT (7-10 DAYS) IS REQUIRED. DEMEQUICK (RAPID ABSORBABLE) SURGICAL SUTURE IS NOT INTENDED FOR USE IN LIGATION, CARDIOVASCULAR, OPHTHALMIC OR NEUROLOGICAL PROCEDURES.

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2317	IMP/MD/2020/000472	1.License Holder Name: M/S LEPUCARE (INDIA) VASCULAR SOLUTIONS PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYDROPHILIC GUIDEWIRE (ULTRASKIN)-THE ULTRASKIN HYDROPHILIC GUIDE WIRE IS DESIGNED TO DIRECT A CATHETER TO THE DESIRED CORONARY ARTERIES DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURE., SIROLIMUS-ELUTING CORONARY STENT SYSTEM(PARTNER)-THE PARTNER® STENT IS INDICATED FOR USE IN: • PATIENTS ELIGIBLE FOR BALLOON ANGIOPLASTY WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO AND/OR RESTENOTIC NATIVE CORONARY ARTERY LESIONS WITH REFERENCE VESSEL DIAMETERS RANGING FROM 2.5 MM TO 4.0 MM, AND WITH TARGET VESSEL STENOSIS DEGREE MORE THAN 70% , OR HAVING EVIDENT ISCHEMIC SYMPTOM AND TARGET LESION STENOSIS DEGREE MORE THAN 50%. • PATIENTS WITH ACUTE OCCLUSION OR ON THE VERGE OF OCCLUSION DURING PERCUTANEOUS CORONARY INTERVENTION. • PATIENTS WITH SIGNIFICANT RESIDUAL STENOSIS AFTER SIMPLE BALLOON DILATATION • PATIENTS WITH ACUTE CORONARY SYNDROMES.,PTA BALLOON DILATATION CATHETER(SUPERCROSS)-PTA BALLOON CATHETER IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN PATIENTS WITH OBSTRUCTIVE DISEASE OF PERIPHERAL ARTERIES, I.E. SUBCLAVIAN, ILIAC, FEMORAL, POPLITEAL, TIBIAL, AND RENAL ARTERIES.,COCR SIROLIMUS-ELUTING CORONARY STENT SYSTEM(GUREATER)-GUREATER™ COCR SIROLIMUS-ELUTING CORONARY STENT SYSTEM ARE INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN THE FOLLOWING: • PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO NATIVE CORONARY ARTERY LESIONS (LENGTH~32MM) WITH REFERENCE VESSEL DIAMETERS RANGING FROM 2.25 MM TO 4.5 MM; • PATIENTS WITH RESTORING ACUTE CORONARY OCCLUSION OR ENDANGERED CORONARY OCCLUSION DURING PERCUTANEOUS CORONARY INTERVENTION; • PATIENTS WITH ACUTE CORONARY ARTERY SYNDROME (UNSTABLE ANGINA AND ACUTE MYOCARDIAL INFARCTION) RELEVANT LESIONS; • PATIENTS WITH VASCULAR DISSECTION AND/OR LACERATION., INTRODUCER KIT(BRILLIANT)-THE BRILLIANT INTRODUCER KITS ARE INTENDED FOR USE TO FACILITATE THE INTRODUCTION OF GUIDE WIRES, CATHETERS AND OTHER ACCESSORY MEDICAL DEVICES THROUGH THE SKIN INTO A VEIN OR ARTERY AND MINIMIZE BLOOD LOSS ASSOCIATED WITH SUCH INTRODUCTION.,GUIDING CATHETER (ORION)-THE DISPOSABLE GUIDING CATHETER IS APPLICABLE FOR PERCUTANEOUS PUNCTURE AND IS USED TO PROVIDE AN INTERVENTIONAL PASSAGE FOR MEDICAL INSTRUMENTS AND TO

	INTRODUCE INTERVENTIONAL/DIAGNOSTIC EQUIPMENT INTO CORONARY PERIPHERAL VASCULAR SYSTEM INSIDE THE BLOOD VESSEL.,CORONARY DILATATION CATHETER(TADPOLE)-THE MINI TADPOLE AND TADPOLE CORONARY DILATATION CATHETER IS INDICATED FOR: • BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION • BALLOON DILATATION OF A CORONARY ARTERY OCCLUSION, FOR THE PURPOSE OF RESTORING CORONARY FLOW IN PATIENTS WITH ST SEGMENT ELEVATION MYOCARDIAL INFARCTION • BALLOON DILATATION OF A STENT AFTER IMPLANTATION (BALLOON MODELS 2.00 MM - 5.00 MM ONLY),CORONARY STENT DELIVERY SYSTEM(H-STENT)-H-STENT™ CORONARY STENT DELIVERY SYSTEM IS INDICATED FOR USE IN: • PATIENTS ELIGIBLE FOR BALLOON ANGIOPLASTY WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO AND/OR RESTENOTIC NATIVE CORONARY ARTERY LESIONS WITH REFERENCE VESSEL DIAMETERS RANGING FROM 2.5 MM TO 4.0 MM, AND WITH TARGET VESSEL STENOSIS DEGREE MORE THAN 70% , OR HAVING EVIDENT ISCHEMIC SYMPTOM AND TARGET LESION STENOSIS DEGREE MORE THAN 50%. • PATIENTS WITH ACUTE OCCLUSION OR ON THE VERGE OF OCCLUSION DURING PERCUTANEOUS CORONARY INTERVENTION. • ·PATIENTS WITH SIGNIFICANT RESIDUAL STENOSIS AFTER SIMPLE BALLOON DILATATION. • ·PATIENTS WITH ACUTE CORONARY SYNDROMES. ,MANIFOLD(ANGIOWAY)-MANIFOLD IS INDICATED TO PROVIDE INJECTOR PORTS AND CHANNEL FOR FLUID AND MEDICINE TRANSPORTATION IN INTERVENTIONAL OPERATION.,CORONARY DILATATION CATHETER(NC TADPOLE)-• BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. • BALLOON DILATATION OF A CORONARY ARTERY OCCLUSION, FOR THE PURPOSE OF RESTORING CORONARY FLOW IN PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFRACTION. • BALLOON DILATATION OF A STENT AFTER IMPLANTATION (BALLOON MODELS 2.00 MM – 5.00 MM ONLY) ,INFLATION DEVICE KITS(ANGIOPOWER)-INFLATION DEVICE KITS IS INDICATED FOR USE IN PERCUTANEOUS CORONARY INTERVENTION (PCI) TREATMENT (SUCH AS PERCUTANEOUS CORONARY ANGIOPLASTY, PTCA; STENT IMPLANTATION OPERATION) PROVIDES THE PRESSURE INSIDE THE BALLOON. ,POLYMER-FREE SIROLIMUS-ELUTING CORONARY STENT SYSTEM(NANO+)-THE NANO+ STENT SYSTEM IS INDICATED FOR USE IN: • PATIENTS WITH LOCALIZED STENOSIS LESIONS WHOSE REFERENCE VESSEL DIAMETERS ARE LARGER THAN 2.25 MM AND NEED STENTING TO PREVENT RESTENOSIS. • PATIENTS WITH

	VASCULAR DISSECTION AND (OR) TEAR. • PATIENTS WITH RESTENOSIS AFTER SIMPLE BALLOON DILATATION. • PATIENTS WITH ACUTE VASCULAR OCCLUSION AND CLOSE TO VASCULAR OCCLUSION WITHIN CORONARY INTERVENTION SURGERY.,PTCA GUIDEWIRE(BALANCIUM)-BALANCIUM PTCA GUIDE WIRE IS INDICATED FOR USE IN THE PROCEDURE FOR ANGIOGRAPHY TO FACILITATE GUIDANCE AND LOCATION OF THE CATHETER AND OTHER INTERVENTIONAL DEVICES IN CORONARY ARTERIES AND PERIPHERAL VASCULAR SYSTEM.,INTRODUCER KIT(SHOOCIN)-THE INTRODUCER KIT IS INDICATED FOR USE IN ARTERIAL PROCEDURES REQUIRING PERCUTANEOUS INTRODUCTION OF INTRAVASCULAR DEVICES.,Y-HEMOSTASIS VALVE SET(ANGIOWAY)-AS INTERVENTIONAL ACCESSORIES, Y-HEMOSTASIS VALVE SET IS INTENDED TO PROVIDE INJECTOR PORT AND CHANNELS FOR GUIDEWIRE, FLUID AND MEDICINE TRANSPORTATION IN INTERVENTIONAL OPERATION.,PTCA BALLOON DILATATION CATHETER(HOPER)-• THE BALLOON DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. • THE BALLOON DILATATION CATHETER IS ALSO INDICATED FOR POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2318	IMP/MD/2020/000473	1.License Holder Name: ENCARTA PHARMA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TORIC INTRAOCULAR LENS(VISTOR)-THE LENS IS INDICATED FOR PATIENTS WITH PRE-EXISTING CORNEAL ASTIGMATISM WHO DESIRE TO BENEFIT FROM REDUCTION OF SPECTACLE DEPENDENCY FOR DISTANCE VISION BY DECREASE OF RESIDUAL REFRACTIVE CYLINDER.,SPHERICAL INTRAOCULAR LENS(SEELENS)-THE IOL IS INDICATED FOR REPLACEMENT OF THE CRYSTALLINE LENS TO ATTAIN VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED.,ASPHERIC INTRAOCULAR LENS(BUNNYLENS AF EASY)-THE IOL IS INDICATED FOR REPLACEMENT OF THE CRYSTALLINE LENS TO ATTAIN VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED.,ASPHERIC INTRAOCULAR LENS(SEELENS AF, BUNNYLENS AF)-THE IOL IS INDICATED FOR REPLACEMENT OF THE CRYSTALLINE LENS TO ATTAIN VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED.,MULTIFOCAL INTRAOCULAR LENS(SEELENS MF, BUNNYLENS MF)-THE LENS IS INDICATED FOR PATIENTS WHO DESIRE TO BENEFIT FROM CORRECTION OF PRESBYOPIA AND FROM REDUCTION OF SPECTACLE DEPENDENCY.,DELIVERY SYSTEM(SOFTJECT)-THE SOFTJECT DELIVERY SYSTEM IS AN OPHTHALMIC DEVICE, USED DURING CATARACT SURGERY. IT IS USED FOR INSERTION AND IMPLANTATION OF A FOLDABLE ONE-PIECE INTRAOCULAR LENS (IOL) THROUGH AN INCISION IN THE CORNEA. THE STANDARD PROCEDURE INCLUDES FOLDING THE IOL INTO THE CARTRIDGE AND INJECTION INTO THE CAPSULAR BAG FOLLOWING CAPSULAR CATARACT EXTRACTION. THE SOFTJECT 2.4-1P IS INTENDED FOR AN INCISION SIZE OF 2.4 MM. THE SOFTJECT 1.8-1P IS INTENDED FOR AN INCISION SIZE OF 1.8 MM.,ASPHERIC HYDROPHOBIC INTRAOCULAR LENS(SEELENS HP, BUNNYLENS HP)-HP IOL IS INDICATED FOR SURGICAL TREATMENT OF CATARACT OR CRYSTALLINE LENS EXCHANGE ACCORDING TO SURGEON CONSIDERATIONS. HP IOL, IS INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,ASPHERIC HYDROPHOBIC INTRAOCULAR LENS(SEELENS HP EASY, BUNNYLENS HP EASY)-HYDROPHOBIC (HP) IOL IS INDICATED FOR SURGICAL TREATMENT OF CATARACT OR CRYSTALLINE LENS EXCHANGE ACCORDING TO SURGEON CONSIDERATIONS. HP IOL, IS INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.

2319	IMP/MD/2020/000474	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COLLAGEN MEMBRANE(T-BARRIER COLLAGEN)-T-BARRIER MEMBRANE COLLAGEN IS A REABSORBABLE MEMBRANE; DUE TO ITS PHYSICAL CHARACTERISTICS, IT FITS ALL APPLICATIONS INVOLVING A GUIDED GROWTH OF TISSUES. THANKS TO ITS HEMOSTATIC PROPERTIES, IT CAN BE USED AS A LOCAL HEMOSTATIC,ALTHOUGH IT DOES NOT REPLACE LIGATION OR DIRECT COMPRESSION IN THE CASE OF SEVERE BLEEDING. T-BARRIER MEMBRANE COLLAGEN CAN BE REMODELED AND APPLIED TO THE BONE DEFECT WITH TOTAL EASE.,DENTAL PROSTHETIC COMPONENTS (COVER SCREW AND HEALING SCREW)(COVER SCREW AND HEALING SCREW)-IT IS USED ON UNCOVERED IMPLANT TO BE SCREWED ON, THEN IT REMAINS AT REST TILL GUMS' HEALING. GUMS SHOULD BE PROPERLY SUTURED AROUND THE HEALING ABUTMENT. THESE COMPONENTS ARE USED TO REHABILITATE SOFT TISSUE UPON THE IMPLANT IN ORDER TO INSERT THE FINAL PROSTHETIC ABUTMENT.,DENTAL IMPLANTS AND ACCESSORIES(DURAVIT 3P IMPLANT, DURAVIT SLIM LINE IMPLANT, DURAVIT WIDE IMPLANT, DURAVIT EV IMPLANT, MUA IMPLANT, MONOBLOCK IMPLANT, MIDI-MEDIUM IMPLANT, PTERYGOID IMPLANT, MINI DURAVIT IMPLANT AND OTHER "MINI" IMPLANT)-THE DENTAL IMPLANT SYSTEM IS MADE FOR USE IN A TOTAL OR PARTIAL, MANDIBULAR OR MAXILLARY EDENTULISM. IT IS USED AS A SUPPORT FOR A FIXED OR REMOVABLE PROSTHESIS.,DENTAL PROSTHETIC COMPONENTS (ABUTMENTS)(PEEK TEMPORARY ABUTMENTS, TITANIUM TEMPORARY NON-ROTATING ABUTMENTS, TITANIUM STRAIGHT ABUTMENTS, TITANIUM ANGLED ABUTMENT(15°-25°), CASTABLE ABUTMENTS, MULTI-SCAN ABUTMENTS,MULTI-USE ABUTMENTS AND FLAT ABUTMENTS)-THE ABUTMENTS ARE FASTENED TO THE DENTAL IMPLANT WITH AN ABUTMENT SCREW, THUS ALLOWING THE PROSTHETIC ANCHORAGE

2320	IMP/MD/2020/000475	1.License Holder Name: DKT HEALTHCARE INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CANNULAE(IPAS EASYGRIP® CANNULAE)-IPAS EASYGRIP® CANNULAE DEVICES ARE SEMI-RIGID, SINGLE-USE OR MULTIPLE USE CANNULAE, MANUFACTURED IN POLYPROPYLENE, APPROXIMATELY 22-24 CM LONG, AVAILABLE IN A RANGE OF EIGHT DIAMETERS WHICH INCLUDES SR4 - 4 MM OUTER DIAMETER ,SR5 - 5MM OUTER DIAMETER ,SR6 - 6MM OUTER DIAMETER ,SR7 - 7MM OUTER DIAMETER ,SR8 - 8MM OUTER DIAMETE8 ,SR9 - 9MM OUTER DIAMETER ,SR10 - 10MM OUTER DIAMETER ,SR12 - 12MM OUTER DIAMETER. THESE ARE INTENDED TO USE FOR UTERINE ASPIRATION/UTERINE EVACUATION IN OBSTETRICS AND GYNAECOLOGIC PATIENTS. CLINICAL INDICATIONS FOR UTERINE ASPIRATION ARE TREATMENT OF INCOMPLETE ABORTION FOR UTERINE SIZES UP TO 12 WEEKS FROM LAST MENSTRUAL PERIOD AND ENDOMETRIAL BIOPSY. THE DEVICES ARE ALL SUPPLIED IN A STERILE CONDITION FOR SINGLE OR MULTIPLE USE TO MANY COUNTRIES IN THE WORLD
2321	IMP/MD/2020/000476	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SIMPLEX® HV WITH GENTAMICIN(SIMPLEX® HV)-SIMPLEX® HV WITH GENTAMICIN IS INDICATED FOR FIXATION OF SYNTHETIC RESIN AND METAL PROSTHESIS COMPONENTS DURING PARTIAL OR TOTAL REPLACEMENT OF THE HIP AND KNEE AS WELL AS OTHER JOINTS, IF AN INFECTION WITH ORGANISMS THAT ARE SENSITIVE TO GENTAMICIN IS DIAGNOSED OR SUSPECTED. THE ANTIBIOTIC PROVIDES PROTECTION AGAINST BACTERIAL COLONIZATION OF THE IMPLANT AND THE SURROUNDING TISSUE. SIMPLEX® HV WITH GENTAMICIN CAN BE USED FOR FILLING AND STABILIZING BONE DEFECTS WITHIN THE SCOPE OF INTERNAL FIXATION TREATMENT. IF THERE IS AN INCREASED RISK OF INFECTION WITH PATHOGENS THAT ARE SENSITIVE TO GENTAMICIN.
2322	IMP/MD/2020/000477	1.License Holder Name: BL LIFESCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDEWIRE (BULK NON-STERILE)(NA)-IT IS FOR THE INSERTION INTO HUMAN BODY VIA BLOOD VESSELS TOGETHER WITH OTHER STIFFER INSTRUMENTS SURGICAL PURPOSE.

2323	IMP/MD/2020/000478	1.License Holder Name: M/S COOK INDIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PANCREATIC STENT AND STENT SET(GEENEN PANCREATIC STENT)-THIS DEVICE IS USED TO DRAIN OBSTRUCTED PANCREATIC DUCTS.,COLONIC STENT SYSTEM - UNCOVERED(EVOLUTION® COLONIC STENT SYSTEM - UNCOVERED)-THIS DEVICE IS USED FOR PALLIATIVE TREATMENT OF COLONIC OBSTRUCTION OR COLONIC STRICTURES CAUSED BY MALIGNANT NEOPLASMS, AND TO RELIEVE LARGE BOWEL OBSTRUCTION PRIOR TO COLECTOMY IN PATIENTS WITH MALIGNANT STRICTURES., ESOPHAGEAL STENT SYSTEM(EVOLUTION® ESOPHAGEAL STENT SYSTEM - FULLY COVERED)-THIS DEVICE IS USED TO MAINTAIN PATENCY OF MALIGNANT ESOPHAGEAL STRICTURES AND / OR TO SEAL TRACHEOESOPHAGEAL FISTULAS.,CATHETERS FOR ENDOSCOPIC GASTEROENTEROLOGY – LIGATION DEVICES (SHORTSHOT SAEED HEMORRHOIDIAL MULTI-BAND LIGATOR WITH TRIVIEW ANOSCOPE)-THE SHORTSHOT SAEED HEMORRHOIDAL MULTI-BAND LIGATOR WITH TRIVIEW ANOSCOPE IS USED TO LIGATE INTERNAL HEMORRHOIDS FACILITATED BY AN ANOSCOPE, FOR USE IN ADULT PATIENTS ONLY.,ESOPHAGEAL STENT SYSTEM (EVOLUTION® ESOPHAGEAL STENT SYSTEM- PARTIALLY COVERED)-THIS DEVICE IS USED TO MAINTAIN PATENCY OF MALIGNANT ESOPHAGEAL STRICTURES AND / OR TO SEAL TRACHEOESOPHAGEAL FISTULAS.,CATHETERS FOR ENDOSCOPIC GASTROENTEROLOGY -LIGATION DEVICES(DUETTE® MULTI BAND MUCOSECTOMY DEVICE)-THIS DEVICE IS FOR ENDOSCOPIC MUCOSAL RESECTION IN THE UPPER GI TRACT. THIS DEVICE IS INTENDED FOR SINGLE USE ONLY,ENDOSCOPIC ULTRASOUND NEEDLE(ECHOTIP® ULTRA HIGH DEFINITION ULTRASOUND ACCESS NEEDLE)-THE ECHOTIP® ULTRA HIGH DEFINITION ULTRASOUND ACCESS NEEDLE IS USED TO ACCESS OR SAMPLE SUBMUCOSAL AND EXTRAMURAL LESIONS OF THE GASTROINTESTINAL TRACT, ACCESS OF THE FOLLOWING: INTRA- OR EXTRA-HEPATIC BILE DUCTS, PANCREATIC DUCTS, CYSTIC DUCT, GALLBLADDER OR FOR DELIVERY OF INJECTABLE MATERIALS INTO TISSUES THOUGH THE ACCESSORY CHANNEL OF AN ULTRASOUND ENDOSCOPE.,VASCULAR STENT – PERIPHERAL INTERVENTIONS(ZILVER® 635 VASCULAR STENT)-THE PRODUCT IS INTENDED FOR USE IN THE ILIAC ARTERIES FOR THE FOLLOWING TREATMENTS: • ARTERIOSCLEROTIC STENOSIS • TOTAL OCCLUSIONS THAT HAVE BEEN RECANALIZATED. THE PRODUCT PROVIDES MECHANICAL SUPPORT TO MAINTAIN CONSTANT BLOOD FLOW OF THE VESSEL.,URINARY TRACT STENTS / STENT SETS (UNIVERSA® SOFT)-USED FOR TEMPORARY INTERNAL DRAINAGE FROM THE URETEROPELVIC JUNCTION TO THE BLADDER. URETERAL

	STENTS HAVE BEEN EMPLOYED TO RELIEVE OBSTRUCTION IN A VARIETY OF BENIGN, MALIGNANT, AND POST-TRAUMATIC CONDITIONS. THESE STENTS MAY BE PLACED USING ENDOSCOPIC, PERCUTANEOUS, OR OPEN SURGICAL TECHNIQUES. THE MULTI-LENGTH STENTS WILL ACCOMMODATE URETERS FROM APPROXIMATELY 22-32 CM IN LENGTH.,CATHETERS FOR ENDOSCOPIC GASTROENTEROLOGY(COLON DECOMPRESSION SET)-THIS DEVICE IS USED FOR TREATMENT OF ACUTE NON-TOXIC MEGACOLON, PSEUDO-OBSTRUCTION (OGILVIE'S SYNDROME) AND COLONIC STRICTURES.,CATHETER FOR BILIARY DRAINAGE FOR GASTROENTEROLOGY(PUSHING CATHETER)-FUSION PUSHING CATHETER USED FOR ENDOSCOPIC BILIARY STENT PLACEMENT TO DRAIN OBSTRUCTED BILE DUCTS. PUSHING CATHETER (PC-XX) THE DEVICE IS USED FOR ENDOSCOPIC BILIARY AND PANCREATIC STENT PLACEMENT. PUSHING CATHETER (PC-XE) THE DEVICE IS USED FOR ENDOSCOPIC BILIAY STENT PLACEMENT.,ENDOSCOPIC ULTRASOUND NEEDLE(ECHOTIP ULTRA ENDOSCOPIC ULTRASOUND NEEDLE)-THIS DEVICE IS USED TO SAMPLE TARGETED SUBMUCOSAL GASTROINTESTINAL LESIONS THROUGH THE ACCESSORY CHANNEL OF AN ULTRASOUND ENDOSCOPE.,PLASTIC STENTS WITH CATHETER FOR BILIARY DRAINAGE FOR GASTROENTEROLOGY(ST2 SOEHENDRA TANNENBAUM BILIARY STENT)-THIS DEVICE IS USED TO DRAIN OBSTRUCTED BILIARY DUCTS,URETERAL STENT INTRODUCER (RESONANCE STENT INTRODUCER)-USED FOR TEMPORARY STENTING OF THE URETER IN ADULT PATIENT WITH EXTRINSIC URETERAL OBSTRUCTION. INTENDED FOR ONE-TIME USE.,PLASTIC STENTS WITH CATHETER FOR BILIARY DRAINAGE FOR GASTROENTEROLOGY(COTTON LEUNG)-THIS DEVICE IS USED TO DRAIN OBSTRUCTED BILIARY DUCTS,HIGH DEFINITION ULTRASOUND BIOPSY NEEDLE(ECHOTIP PROCORE® HD ULTRASOUND BIOPSY NEEDLE)-THIS DEVICE IS USED WITH AN ULTRASOUND ENDOSCOPE FOR FINE NEEDLE BIOPSY (FNB), OF SUBMUCOSAL LESIONS, MEDIASTINAL MASSES, LYMPH NODES AND INTRAPERITONEAL MASSES WITHIN OR ADJACENT TO THE GASTROINTESTINAL TRACT., PLASTIC STENTS WITH CATHETER FOR BILIARY DRAINAGE FOR GASTROENTEROLOGY(ZIMMON BILIARY STENT)-THIS DEVICE IS USED TO DRAIN OBSTRUCTED BILIARY DUCTS,DUODENAL STENT SYSTEM - UNCOVERED(EVOLUTION® DUODENAL STENT SYSTEM - UNCOVERED)-THIS DEVICE IS USED FOR PALLIATIVE TREATMENT OF DUODENAL OR GASTRIC OUTLET OBSTRUCTION AND DUODENAL STRICTURES CAUSED BY MALIGNANT NEOPLASMS.,CATHETER FOR BILIARY DRAINAGE FOR GASTROENTEROLOGY(OASIS ONE ACTION STENT INTRODUCTION SYSTEM)-THIS DEVICE IS INTENDED FOR ENDOSCOPIC BILIARY STENT PLACEMENT TO DRAIN OBSTRUCTED

	BILE DUCTS.,URETERAL STENT AND INTRODUCER(RESONANCE® METALLIC URETERAL STENT AND INTRODUCER)-USED FOR TEMPORARY STENTING OF THE URETER IN ADULT PATIENT WITH EXTRINSIC URETERAL OBSTRUCTION. INTENDED FOR ONE-TIME USE., ESOPHAGEAL STENT SYSTEM(EVOLUTION® ESOPHAGEAL STENT SYSTEM- FULLY COVERED)-THIS DEVICE IS USED TO MAINTAIN LUMINAL PATENCY OF THE ESOPHAGUS IN CASES OF: OBSTRUCTION CAUSED BY INTRINSIC OR EXTRINSIC MALIGNANCIES, REFRACTORY BENIGN STRICTURES, OR TO SEAL TRACHEOESOPHAGEAL FISTULAS., ELECTROSURGICAL CATHETERS FOR ENDOSCOPIC GASTROENTEROLOGY(CYSTOTOME)-THE DEVICE IS DESIGNED TO ELECTROSURGICALLY PUNCTURE A HOLE IN THE TRANSGASTRIC OR TRANSDUODENAL WALL INTO A PANCREATIC PSEUDOCYST, WHEN IT IS VISBLY BULGING INTO THE GASTROINTESTINAL TRACT.,CELIAC PLEXUS NEUROLYSIS NEEDLE(ECHOTIP® ULTRA CELIAC PLEXUS NEUROLYSIS NEEDLE)-THIS DEVICE IS USED TO DELIVER NEUROLYSING AGENTS TO THE CELIAC PLEXUS UNDER GUIDANCE BY ENDOSCOPIC ULTRASOUND.,VASCULAR STENT – PERIPHERAL INTERVENTIONS(ZILVERFLEX 35 VASCULAR STENT)-THE PRODUCT IS INTENDED FOR USE IN THE ILIAC, SUPERFICIAL FEMORAL ARTERY (SFA) AND ABOVE-THE-KNEE POPLITEAL ARTERY FOR THE FOLLOWING TREATMENTS: • ARTERIOSCLEROTIC STENOSIS • TOTAL OCCLUSIONS THAT HAVE BEEN RECANALIZED. THE PRODUCT PROVIDES MECHANICAL SUPPORT TO MAINTAIN CONSTANT BLOOD FLOW OF THE VESSEL.,SELF-EXPANDING BILIARY STENT (EVOLUTION® BILIARY STENT SYSTEM-PARTIALLY COVERED)-THIS DEVICE IS USED IN PALLIATION OF MALIGNANT NEOPLASMS IN THE BILIARY TREE.,ENDOBRONCHIAL ULTRASOUND NEEDLE(ECHOTIP® ULTRA ENDOBRONCHIAL HIGH DEFINITION ULTRASOUND NEEDLE)-ECHO-HD-22/25-EBUS-O: THIS DEVICE IS USED TO SAMPLE TARGETED SUBMUCOSAL AND EXTRAMURAL LESIONS WITHIN OR ADJACENT TO THE TRACHEOBRONCHIAL TREE OR GASTROINTESTINAL TRACT THROUGH THE ACCESSORY CHANNEL OF AN ULTRASOUND ENDOSCOPE FOR FINE NEEDLE ASPIRATION (FNA). ECHO-HD-22/25-EBUS-P: THIS DEVICE IS USED TO SAMPLE TARGETED SUBMUCOSAL AND EXTRAMURAL LESIONS WITHIN OR ADJACENT TO THE TRACHEOBRONCHIAL TREE THROUGH THE ACCESSORY CHANNEL OF AN ULTRASOUND ENDOSCOPE FOR FINE NEEDLE ASPIRATION (FNA).,SELF-EXPANDING BILIARY STENT (EVOLUTION® BILIARY STENT SYSTEM- FULLY COVERED)-THIS DEVICE IS USED IN PALLIATION OF MALIGNANT NEOPLASMS IN THE BILIARY TREE.,SELF-EXPANDING BILIARY STENT(EVOLUTION® BILIARY STENT SYSTEM- UNCOVERED)-THIS DEVICE IS USED IN PALLIATION OF MALIGNANT NEOPLASMS IN THE BILIARY TREE.

2324	IMP/MD/2020/000479	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MENISCAL REPAIR SYSTEM(NOVOSTITCH PRO)-THE NOVOSTITCH PRO MENISCAL REPAIR SYSTEM IS INTENDED FOR APPROXIMATION OF SOFT TISSUE IN MENISCAL REPAIR PROCEDURES.
2325	IMP/MD/2020/000480	1.License Holder Name: 3M INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:3M™ CAVILON™ NO STING BARRIER FILM-3M™ CAVILON™ NO STING BARRIER FILM IS A LIQUID INTENDED FOR USE AS A FILM FORMING PRODUCT THAT UPON APPLICATION TO INTACT OR DAMAGED SKIN FORMS A LONG LASTING WATERPROOF BARRIER, WHICH ACTS AS A PROTECTIVE INTERFACE BETWEEN THE SKIN AND BODILY WASTES, FLUIDS, ADHESIVE PRODUCTS, AND FRICTION AND SHEAR. IT IS INTENDED AS A PRIMARY BARRIER AGAINST IRRITATION FROM BODY FLUIDS. THE PRODUCT MAY BE USED ON ADULTS, CHILDREN AND INFANTS OVER ONE MONTH OF AGE.

2326	IMP/MD/2020/000481	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERSONA PARTIAL KNEE (PPK) SYSTEM(PERSONA PARTIAL KNEE (PPK) SYSTEM -FEMORAL)-THE PERSONA PARTIAL KNEE SYSTEM IS LIMITED TO THE MEDIAL TIBIOFEMORAL COMPARTMENT OF THE KNEE INTENDED FOR PATIENTS WITH PAINFUL AND/OR DISABLING KNEE JOINTS DUE TO THE FOLLOWING INDICATIONS: NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., OSTEOARTHRITIS, AVASCULAR NECROSIS; TRAUMATIC ARTHRITIS; PREVIOUS TIBIAL CONDYLE OR PLATEAU FRACTURES WITH LOSS OF ANATOMY OR FUNCTION; VARUS DEFORMITIES; AND REVISION OF THE ARTICULAR SURFACE OF A PREVIOUSLY IMPLANTED PERSONA PARTIAL KNEE SYSTEM PROVIDING THAT THE TIBIAL PLATE LOCKING MECHANISM IS NOT COMPROMISED AND THE FEMORAL AND TIBIAL PLATE COMPONENTS REMAIN WELL FIXED AND UNDAMAGED. THE PERSONA PARTIAL KNEE SYSTEM IS A SINGLE USE IMPLANT INTENDED FOR IMPLANTATION WITH BONE CEMENT. INDICATIONS FOR COMBINED PERSONA PARTIAL KNEE SYSTEM AND ZIMMER GENDER SOLUTIONS PATELLO-FEMORAL JOINT (PFJ): OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, AND/OR SEVERE CHONDROCALCINOSIS OF THE PATELLOFEMORAL JOINT. THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS (E.G., ARTHROSCOPY, LATERAL RELEASE, CARTILAGE TRANSPLANTATION). HISTORY OF PATELLAR DISLOCATION OR PATELLA FRACTURE. DYSPLASIA-INDUCED DEGENERATION. THESE INDICATIONS WILL BE USED FOR THE COMBINED MEDIAL UNICOMPARTMENTAL AND PATELLO-FEMORAL IMPLANT DEVICE, WHEREBY A SINGLE CONDYLE AND PATELLO-FEMORAL REGIONS HAVE BEEN AFFECTED BY ONE OR MORE OF THESE CONDITIONS. COMBINED PERSONA PARTIAL KNEE SYSTEM AND ZIMMER GENDER SOLUTIONS PATELLO-FEMORAL JOINT (PFJ) IMPLANTS ARE INTENDED FOR IMPLANTATION WITH BONE CEMENT.
2327	IMP/MD/2020/000482	1.License Holder Name: BAUSCH & LOMB INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BAUSCH+LOMB EASYSEPT PEROXIDE SOLUTION(BAUSCH+LOMB EASYSEPT PEROXIDE SOLUTION)-THE BAUSCH+ LOMB EASYSEPT IS INTENDED FOR USE IN CLEANING, DISINFECTING, REMOVING PROTEINS, AND STORING ALL SOFT CONTACT LENSES, INCLUDING SILICONE HYDROGELS.

2328	IMP/MD/2020/000486	1.License Holder Name: M/S AVHA LIFESCIENCES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PRE-FILLABLE SYRINGES (EZ-FILL)-THE PRE-FILLABLE SYRINGES CAN BE CONSIDERED A COMPONENT OF THE SO-CALLED PREFILLED SYRINGES. THEY WILL BE FILED WITH THE DRUG CLOSED WITH THE PLUNGER AND PUT IN THE COMMERCE BY THE PHARMACEUTICAL INDUSTRY

2329	IMP/MD/2020/000488	1.License Holder Name: PURPLE MEDICAL SOLUTIONS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA BALLOON CATHETER(FIREFIGHTERTM PTCA BALLOON CATHETER)-FIREFIGHTERTM IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION IN PATIENTS WITH CORONARY ARTERY DISEASES.,RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM(FIREHAWKTM RAPAMYCIN TARGET ELUTING CORONARY STENT)-THE FIREHAWKTM RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO DE NOVO NATIVE CORONARY ARTERY LESIONS.,PTCA BALLOON CATHETER(FOXTROTTM PRO PTCA BALLOON CATHETER)-FOXTROTTM PRO IS INDICATED FOR BALLOON PRE-DILATATION OF THE STENOTIC ATHEROSCLEROTIC LESIONS IN PATIENTS WITH FOLLOWING CORONARY ARTERY DISEASES: • ANGINA PECTORIS (STABLE OR UNSTABLE) • MYOCARDIAL INFARCTION (ACUTE OR CHRONIC) • ONE OR MORE STENOSIS IN ONE VESSEL; • MULTI-VESSEL STENOSIS AND DISTAL VESSEL STENOSIS • CORONARY ARTERY RESTENOSIS AFTER CORONARY ARTERY BYPASS GRAFT (CABG) • CORONARY ARTERY RE-STENOSIS AFTER PTCA • PROTECTED LEFT MAIN CORONARY ARTERY STENOSIS,RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM(FIREHAWKTM LIBERTY RAPAMYCIN TARGET ELUTING CORONARY STENT)-THE FIREHAWK LIBERTYTM RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM (FIREHAWK LIBERTY RTECSS) IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO DE NOVO NATIVE CORONARY ARTERY LESIONS.,RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM (FIREHAWKTM RAPAMYCIN TARGET ELUTING CORONARY STENT)-THE FIREHAWKTM RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO DE NOVO NATIVE CORONARY ARTERY LESIONS.,PTCA BALLOON CATHETER(FOXTROTTM NC PTCA BALLOON CATHETER)-FOXTROTTMNC IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION AND BALLOON DILATATION OF A STENT AFTER IMPLANTATION.,PTCA BALLOON CATHETER(FIREFIGHTERTM NC PTCA BALLOON CATHETER)-FIREFIGHTERTM NC IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY

		ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION; BALLOON DILATATION OF A STENT AFTER IMPLANTATION.
2330	IMP/MD/2020/000489	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RESORBABLE COLLAGEN BASED SEALING HEMOSTAT(HEMOPATCH SEALING HEMOSTAT)-HEMOPATCH SEALING HEMOSTAT IS INDICATED AS A HEMOSTATIC DEVICE AND SURGICAL SEALANT FOR PROCEDURES IN WHICH CONTROL OF BLEEDING OR LEAKAGE OF OTHER BODY FLUIDS OR AIR BY CONVENTIONAL SURGICAL TECHNIQUES IS EITHER INEFFECTIVE OR IMPRACTICAL. HEMOPATCH MAY BE USED TO CLOSE DURAL DEFECTS FOLLOWING TRAUMATIC INJURY, EXCISION, RETRACTION OR SHRINKAGE OF THE DURA MATER.
2331	IMP/MD/2020/000490	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIGH DENSITY MAPPING CATHETER(ADVISOR HD GRID, SENSOR ENABLED)-THE ADVISOR™ HD GRID MAPPING CATHETER, SENSOR ENABLED™, IS INDICATED FOR MULTIPLE ELECTRODE ELECTROPHYSIOLOGICAL MAPPING OF CARDIAC STRUCTURES IN THE HEART, I.E., RECORDING OR STIMULATION ONLY. THIS CATHETER IS INTENDED TO OBTAIN ELECTROGRAMS IN THE ATRIAL AND VENTRICULAR REGIONS OF THE HEART,CATHETER(TACTICATH SENSOR ENABLED, CONTACT FORCE ABLATION CATHETER)-THE TACTICATH CONTACT FORCE ABLATION CATHETER, SENSOR ENABLED IS INDICATED FOR USE IN CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATION AND RECORDING), AND, WHEN USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION OF SUPRAVENTRICULAR ARRHYTHMIAS IN RIGHT AND LEFT ATRIUM INCLUDING ATRIAL FIBRILLATION,CATHETERS(FLEXABILITY ABLATION CATHETER)-THE FLEXABILITY™ ABLATION CATHETER IS INTENDED FOR USE WITH THE COMPATIBLE IRRIGATION PUMP AND A COMPATIBLE RF CARDIAC ABLATION GENERATOR. THE CATHETER IS INTENDED FOR CREATING FOCAL LESIONS DURING CARDIAC ABLATION PROCEDURES (MAPPING, STIMULATION, AND ABLATION) FOR THE TREATMENT OF ARRHYTHMIAS. EPICARDIAL ABLATION SHOULD BE LIMITED TO APPROPRIATELY SELECTED PATIENTS WITH VENTRICULAR TACHYCARDIA

2332	IMP/MD/2020/000491	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CMF IMPLANTS(MEDPOR)-MEDPOR IMPLANTS IN BLOCK, SHEET AND PRE-FORMED SHAPES ARE INTENDED FOR NON-WEIGHT-BEARING APPLICATIONS OF CRANIOFACIAL RECONSTRUCTION SURGERY AND REPAIR OF CRANIOFACIAL TRAUMA. MEDPOR SURGICAL IMPLANTS AND MEDPOR BARRIER IMPLANTS ARE INTENDED FOR THE AUGMENTATION OR RESTORATION OF BONY CONTOUR IN THE CRANIOFACIAL SKELETON. RECONSTRUCTION OF THE ORBITAL SKELETAL FRAMEWORK, INCLUDING ORBITAL FLOORS, WALLS, RIMS AND ROOF. INLAY AND ONLAY GRAFTS TO RESTORE OR AUGMENT DEFICIENT TISSUE REGIONS IN THE ZYGOMATIC ARCH (CHEEK BONE, MALAR REGION), CHIN, MANDIBLE (ANGLE AUGMENTATION AND OSTEOTOMY VOID VOLUME DEFECTS), NASAL LABIAL AND NASAL REGIONS. TO RESTORE DEFECTS IN THE CRANIUM, INCLUDING FRONTAL AND TEMPORAL DEFECTS, SOFT TISSUE DEFECTS RESULTING FROM ATROPHY OF THE TEMPORALIS MUSCLE, AND CRANIAL DRILL HOLES (BURR HOLES) CREATED BY SURGICAL CRANIAL PERFORATORS. RECONSTRUCTION OF THE AURICLE (EXTERNAL EAR) WHERE DEFECTS OCCURRED FROM TRAUMA RELATED ACCIDENTS, INCLUDING BURNS AND BIRTH DEFECTS, INCLUDING, MICROTIA. VOID VOLUME REPLACEMENT FOLLOWING ENUCLEATION AND/OR EVISCERATION OF THE EYE. THE PTERIONAL IMPLANT IS INDICATED TO CORRECT TEMPORAL HOLLOWING IN PATIENTS WHO HAVE HAD SURGERY INVOLVING THE PTERIONAL APPROACH TO THE CRANIUM, INCLUDING PTERIONAL CRANIOTOMY. THIS PTERIONAL IMPLANT AUGMENTS THE SPACE NORMALLY OCCUPIED BY THE TEMPORALIS MUSCLE. THE IMPLANT IS USED FOR THE RECONSTRUCTION OF TEMPORAL DEFORMITIES; THE RECONSTRUCTION OF TEMPORAL CRANIOTOMY DEFECTS AND/OR THE AUGMENTATION/RESTORATION OF THE SPACE NORMALLY OCCUPIED BY THE TEMPORALIS MUSCLE/ TEMPORAL AREA(S). INDICATIONS FOR THE MEDPOR BARRIER SURGICAL IMPLANT INCLUDE SITUATIONS IN WHICH A BIOMATERIAL MAY BE USED FOR AUGMENTATION OR RESTORATION OF BONY CONTOUR IN THE CRANIOFACIAL SKELETON, WHEN THE SURGEON WISHES TO PREVENT TISSUE INGROWTH INTO ONE AREA OF THE IMPLANT.

2333	IMP/MD/2020/000492	1.License Holder Name: M/S VASCULAR CONCEPTS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTMC BALLOON CATHETER AND ACCESSORIES (NON-STERILE)(ACCURA PTMC BALLOON CATHETER- DOUBLE LUMEN BALLOON DILATATION CATHETER AND ACCESSORIES (NON-STERILE) ALONG WITH COMPONENTS/ ACCESSORIES- STYLET (NON STERILE), METAL STRETCHING TUBE (NON STERILE), DILATOR (NON STERILE), LA WIRE (NON STERILE), SYRINGE (NON STERILE))-IT IS INTENDED FOR THE TREATMENT OF MITRAL VALVE.
2334	IMP/MD/2020/000493	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINAL FIXATION SYSTEM (UCENTUM SPINAL FIXATION SYSTEM)-THE UCENTUM IS AN IMPLANT SYSTEM WITH POLYAXAIL MONOAXIAL,PRE-FIXATION AND LONGARM SCREWS,STRAIGHT AND PERFORMED RODS, AND CROSS STABILIZER FOR SURGICAL STABILIZATION,ANCHORAGE AND CORRECTION OF THE THORACIC AND LUMBAR SPINE

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2335	IMP/MD/2020/000494	1.License Holder Name: M/S MOLNLYCKE HEALTHCARE INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SELF-ADHERENT SOFT SILICONE FOAM DRESSING(MEPILEX BORDER FLEX LITE)-MEPILEX BORDER FLEX LITE IS DESIGNED FOR THE MANAGEMENT OF A WIDE RANGE OF NON- TO MODERATELY EXUDING WOUNDS, SUCH AS LEG AND FOOT ULCERS, PRESSURE ULCERS, SURGICAL WOUNDS AND TRAUMATIC WOUNDS E.G. ABRASIONS, BLISTERS AND SKIN TEARS. MEPILEX BORDER FLEX LITE CAN ALSO BE USED AS PROTECTION OF COMPROMISED AND/OR FRAGILE SKIN.,SOFT SILICONE FOAM DRESSING(MEPILEX, MEPILEX HEEL)-MEPILEX IS INTENDED FOR A WIDE RANGE OF EXUDING WOUNDS SUCH AS LEG AND FOOT ULCERS, PRESSURE ULCERS AND TRAUMATIC WOUNDS, E.G. SKIN TEARS AND SECONDARY HEALING WOUNDS. MEPILEX CAN BE USED AS A PROTECTION OF COMPROMISED AND/OR FRAGILE SKIN AND MAY ALSO BE USED AS PART OF A PROPHYLACTIC THERAPY TO HELP PREVENT SKIN DAMAGE, E.G. PRESSURE ULCERS.,SELF-ADHERENT SOFT SILICONE FOAM DRESSING(MEPILEX BORDER FLEX)-MEPILEX BORDER FLEX IS DESIGNED FOR A WIDE RANGE OF EXUDING WOUNDS SUCH AS PRESSURE ULCERS, LEG AND FOOT ULCERS, TRAUMATIC WOUNDS (E.G. SKIN TEARS) AND SURGICAL WOUNDS. MEPILEX BORDER FLEX CAN ALSO BE USED ON DRY/NECROTIC WOUNDS IN COMBINATION WITH GELS. MEPILEX BORDER FLEX REDUCES POSTOPERATIVE BLISTERING, AND MAY ALSO BE USED AS PART OF A PROPHYLACTIC THERAPY TO HELP PREVENT SKIN DAMAGE, E.G. PRESSURE ULCERS.,SELF-ADHERENT SOFT SILICONE FOAM DRESSING(MEPILEX BORDER LITE)-MEPILEX BORDER LITE IS DESIGNED FOR THE MANAGEMENT OF A WIDE RANGE OF NON/LOW EXUDING WOUNDS, SUCH AS LEG AND FOOT ULCERS, PRESSURE ULCERS, SURGICAL WOUNDS AND TRAUMATIC WOUNDS E.G. ABRASIONS, BLISTERS AND SKIN TEARS. MEPILEX BORDER LITE CAN ALSO BE USED AS PROTECTION OF COMPROMISED AND/OR FRAGILE SKIN.,ADHESIVE SURGICAL DRESSING(MEPORE)-SELF-ADHESIVE STERILE ABSORBENT DRESSING IS DESIGNED FOR LOW TO MODERATELY EXUDING WOUNDS, SUCH AS SURGICAL WOUNDS, CUTS AND ABRASIONS.,SELF-ADHERENT SOFT SILICONE FOAM DRESSING(MEPILEX BORDER, MEPILEX BORDER SACRUM, MEPILEX BORDER HEEL)-MEPILEX BORDER AND MEPILEX BORDER SACRUM: MEPILEX BORDER IS DESIGNED FOR A WIDE RANGE OF EXUDING WOUNDS SUCH AS PRESSURE ULCERS, LEG AND FOOT ULCERS AND TRAUMATIC WOUNDS E.G. SKIN TEARS AND SURGICAL WOUNDS. MEPILEX BORDER CAN ALSO BE USED ON DRY/NECROTIC WOUNDS IN COMBINATION WITH GELS. MEPILEX BORDER REDUCES

	POSTOPERATIVE BLISTERING, AND MAY ALSO BE USED AS PART OF A PROPHYLACTIC THERAPY TO HELP PREVENT SKIN DAMAGE, E.G. PRESSURE ULCERS. MEPILEX BORDER SACRUM AND HEEL : MEPILEX BORDER IS DESIGNED TO BE PART OF A PROPHYLACTIC THERAPY TO PREVENT SKIN DAMAGE, E.G. PRESSURE ULCERS AND TO REDUCE POSTOPERATIVE BLISTERING. MEPILEX BORDER IS ALSO DESIGNED FOR A WIDE RANGE OF EXUDING WOUNDS SUCH AS PRESSURE ULCERS, LEG ULCERS, FOOT ULCERS, TRAUMATIC WOUNDS (E.G. SKIN TEARS) AND SURGICAL WOUNDS. MEPILEX BORDER CAN ALSO BE USED ON DRY/NECROTIC WOUNDS IN COMBINATION WITH GELS., ANTIMICROBIAL SOFT SILICONE FOAM DRESSING(MEPILEX AG, MEPILEX HEEL AG)-MEPILEX AG IS AN ANTIMICROBIAL SOFT SILICONE FOAM DRESSING THAT IS DESIGNED FOR THE MANAGEMENT OF LOW TO MODERATELY EXUDING WOUNDS SUCH AS LEG AND FOOT ULCERS, PRESSURE ULCERS AND PARTIAL THICKNESS BURNS. MEPILEX AG MAY BE USED ON INFECTED WOUNDS AS PART OF A TREATMENT REGIMEN UNDER SUPERVISION OF A QUALIFIED HEALTH CARE PROFESSIONAL. MEPILEX AG CAN BE USED UNDER COMPRESSION BANDAGING.,SELF-ADHERENT SOFT SILICONE DRESSING FOR SCAR CARE(MEPIFORM)-MEPIFORM IS DESIGNED FOR THE MANAGEMENT OF BOTH OLD AND NEW HYPERTROPHIC AND KELOIDS SCARS. IT CAN ALSO BE USED AS A PROPHYLACTIC THERAPY ON CLOSED WOUNDS FOR PREVENTION OF HYPERTROPHIC OR KELOID SCARRING.,SELF-ADHERENT SOFT SILICONE DRESSING FOR SCAR CARE(MEPIFORM)-MEPIFORM IS DESIGNED FOR THE MANAGEMENT OF BOTH OLD AND NEW HYPERTROPHIC AND KELOID SCARS. IT CAN ALSO BE USED AS A PROPHYLACTIC THERAPY ON CLOSED WOUNDS FOR PREVENTION OF HYPERTROPHIC OR KELOID SCARRING.,SELF-ADHERENT SOFT SILICONE SURGICAL DRESSING(MEPILEX BORDER POST-OP)-MEPILEX BORDER POST-OP IS A SELF-ADHESIVE ABSORBENT SURGICAL DRESSING DESIGNED FOR EXUDING WOUNDS. IT IS INTENDED FOR ACUTE WOUNDS, SUCH AS SURGICAL WOUNDS, CUTS AND ABRASIONS.,SOFT SILICONE WOUND CONTACT LAYER(MEPITEL ONE)-MEPITEL ONE IS A WOUND CONTACT LAYER DESIGNED FOR THE MANAGEMENT OF A WIDE RANGE OF EXUDING WOUNDS SUCH AS; SKIN TEARS, SKIN ABRASIONS, SURGICAL INCISIONS, PARTIAL THICKNESS BURNS, TRAUMATIC WOUNDS, PARTIAL AND FULL THICKNESS GRAFTS, RADIATED SKIN, LEG AND FOOT ULCERS. IT CAN ALSO BE USED AS A PROTECTIVE LAYER ON NON-EXUDING WOUNDS, BLISTERS AND ON AREAS WITH FRAGILE SKIN.,SELF-ADHERENT ANTIMICROBIAL SOFT SILICONE FOAM DRESSING(MEPILEX BORDER AG, MEPILEX BORDER SACRUM AG)-MEPILEX BORDER AG IS DESIGNED FOR THE MANAGEMENT OF MEDIUM TO HIGH EXUDING

	WOUNDS SUCH AS LEG AND FOOT ULCERS, PRESSURE ULCERS, MALIGNANT WOUNDS, PARTIAL THICKNESS BURNS, TRAUMATIC AND SURGICAL WOUNDS WHERE A MOIST ENVIRONMENT, EXUDATE HANDLING, GENTLE FIXATION AND AN ANTIMICROBIAL ACTION IS INDICATED. MEPILEX BORDER AG MAY BE USED ON INFECTED WOUNDS AS PART OF A TREATMENT REGIMEN UNDER SUPERVISION OF A QUALIFIED HEALTH CARE PROFESSIONAL. MEPILEX BORDER AG CAN BE USED UNDER COMPRESSION BANDAGING,SOFT SILICONE FOAM DRESSING(MEPILEX LITE)-MEPILEX LITE IS DESIGNED FOR THE MANAGEMENT OF A WIDE RANGE OF NON TO LOW EXUDING WOUNDS SUCH AS LEG AND FOOT ULCERS, PRESSURE ULCERS, PARTIAL THICKNESS BURNS, RADIATION SKIN REACTIONS AND EPIDERMOLYSIS BULLOSA. MEPILEX LITE CAN ALSO BE USED AS A PROTECTION OF COMPROMISED AND/OR FRAGILE SKIN.

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2336	IMP/MD/2020/000495	1.License Holder Name: MEDIKRAFT SERVICES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETERS(XCELA PICC WITH PASV VALVE TECHNOLOGY)-THE XCELA PICC WITH PASV VALVE TECHNOLOGY IS INDICATED FOR SHORT OR LONG-TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, INCLUDING BUT NOT LIMITED TO, THE ADMINISTRATION OF FLUIDS, MEDICATIONS AND NUTRIENTS; THE SAMPLING OF BLOOD; AND POWER INJECTION OF CONTRAST MEDIA., CATHETERS(XCELA POWER INJECTABLE PICC)-THE XCELA POWER INJECTABLE PICC IS INDICATED FOR SHORT OR LONG-TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, INCLUDING BUT NOT LIMITED TO, THE ADMINISTRATION OF FLUIDS, MEDICATIONS AND NUTRIENTS; THE SAMPLING OF BLOOD; AND POWER INJECTION OF CONTRAST MEDIA, CATHETERS(VAXCEL MINI STICK KIT)-THE INTRODUCER SHEATH AND DILATOR KIT IS INDICATED FOR USE IN THE PERCUTANEOUS INSERTION OF CATHETERS FOLLOWING A NEEDLE INTRODUCTION AND PLACEMENT OF GUIDEWIRE IN THE VENOUS SYSTEM., CATHETERS(PASV MS KIT WITH PRESSURE ACTIVATED SAFETY VALVE)-THE PASV MS (MODIFIED SELDINGER) KIT IS DESIGNED AS A PLACEMENT KIT FOR PASV PICC CATHETERS. THIS PROCEDURE IS INDICATED FOR USE IN ESTABLISHING PERIPHERAL ACCESS VIA THE MODIFIED SELDINGER TECHNIQUE TO THE CENTRAL VENOUS SYSTEM FOR ADMINISTRATION OF INTRAVENOUS FLUIDS., CATHETERS(SMART PORT CT (LOW-PROFILE & MINI-PROFILE))-THE SMART PORT® CT POWER INJECTABLE PORT LINE IS INDICATED FOR ANY PATIENT REQUIRING REPEATED ACCESS OF THE VASCULAR SYSTEM, FOR DELIVERY OF MEDICATIONS, NUTRITIONAL SUPPLEMENTATION, FLUIDS, BLOOD, BLOOD PRODUCTS, AND SAMPLING OF BLOOD AND POWER INJECTION OF CONTRAST MEDIA FOR IMAGING.,CATHETERS(BIOFLO PICC WITH ENDEXO AND PASV VALVE TECHNOLOGY)-THE BIOFLO PICC WITH ENDEXO AND PASV VALVE TECHNOLOGY IS INDICATED FOR SHORT TERM OR LONG-TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, INCLUDING BUT NOT LIMITED TO THE ADMINISTRATION OF FLUIDS, MEDICATIONS AND NUTRIENTS; THE SAMPLING OF BLOOD, AND FOR POWER INJECTION OF CONTRAST MEDIA. ,CATHETERS(VORTEX VX VASCULAR ACCESS PORT)-THE ANGIODYNAMICS PORT LINE IS INDICATED FOR ANY PATIENT REQUIRING REPEATED ACCESS OF THE VASCULAR SYSTEM FOR DELIVERY OF MEDICATIONS, NUTRITIONAL SUPPLEMENTATION, FLUIDS, BLOOD, BLOOD PRODUCTS, AND SAMPLING OF BLOOD. DUAL MODELS ARE INDICATED FOR COMBINATION THERAPY,

		SIMULTANEOUS INFUSIONS, WITHDRAWAL OF BODY FLUIDS, AND BOLUS DELIVERY DURING CONTINUOUS INFUSION. ,CATHETERS (BIOFLO PICC WITH ENDEXO TECHNOLOGY)-THE BIOFLO PICC WITH ENDEXO TECHNOLOGY IS INDICATED FOR SHORT TERM OR LONG-TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, INCLUDING BUT NOT LIMITED TO THE ADMINISTRATION OF FLUIDS, MEDICATIONS AND NUTRIENTS; THE SAMPLING OF BLOOD; CENTRAL VENOUS PRESSURE MONITORING AND FOR POWER INJECTION OF CONTRAST MEDIA.
2337	IMP/MD/2020/000496	1.License Holder Name: PHARMALEAF INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IONIC SILVERSTREAM (SILVERSTREAM)-IT IS INTENDED FOR USE UNDER THE SUPERVISION OF A HEALTHCARE PROFESSIONAL FOR MECHANICAL CLEANSING AND REMOVAL OF FOREIGN MATERIAL INCLUDING MICRO-ORGANISMS AND DEBRIS FROM WOUNDS SUCH AS STAGE I-IV PRESSURE ULCERS, STASIS ULCERS, DIABETIC FOOT ULCERS, POST-SURGICAL WOUNDS, FIRST AND SECOND DEGREE BURNS, CUTS ABRASIONS AND MINOR SKIN IRRITATIONS.
2338	IMP/MD/2020/000497	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LINES FOR DIALYSIS AND HEMO (DIA) FILTRATION(HDF ON LINE TUBING)-INFUSION LINE IN HEMOFILTRATION AND HEMODIAFILTRATION EXTRACORPOREAL TREATMENTS WITH DIALOG ON LINE.,BLOODLINE SYSTEMS FOR HEMOFILTRATION / HEMODIALYSIS(DIAPACT CRRT KIT (HEMOFILTRATION / HEMODIALYSIS KIT))-IT IS INTENDED FOR HEMOFILTRATION AND HEMODIALYSIS.

2339	IMP/MD/2020/000498	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EMBOLISATION IMPLANT, CHEMOTHERAPEUTIC(DC BEAD EMBOLIC DRUG-ELUTING BEAD)-DC BEAD AND DC BEADM1 ARE PRIMARILY INTENDED AS AN EMBOLIC AGENT FOR THE LOCAL TREATMENT OF MALIGNANT HYPERVASCULARISED TUMOUR(S) IN THE LIVER. DC BEAD AND DC BEADM1 ARE COMPATIBLE WITH DOXORUBICIN FOR THE LOCAL TREATMENT OF TUMOURS IN PATIENTS WITH HEPATOCELLULAR CARCINOMA (HCC). DOXORUBICIN CAN BE LOADED PRIOR TO EMBOLISATION AND AS A SECONDARY ACTION, WILL ELUTE A LOCAL, CONTROLLED AND SUSTAINED DOSE TO THE TUMOUR AFTER EMBOLISATION. DC BEAD AND DC BEADM1 ARE ALSO INTENDED TO EMBOLISE THE VESSELS SUPPLYING MALIGNANT COLORECTAL CANCER METASTASISED TO THE LIVER (MCRC). DC BEAD AND DC BEADM1 ARE COMPATIBLE WITH IRINOTECAN WHICH CAN BE LOADED PRIOR TO EMBOLISATION AND THEN AS A SECONDARY ACTION, ELUTE A LOCAL, CONTROLLED AND SUSTAINED DOSE TO THE LIVER METASTASES FROM COLORECTAL CANCER AFTER EMBOLISATION.

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2340	IMP/MD/2020/000499	1.License Holder Name: DEENA ENTERPRISE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VOICE PROSTHESIS WITH INSERTION SYSTEM(PROVOX VEGA PUNCTURE SET)-THE PROVOX VEGA PUNCTURE SET IS INTENDED FOR CREATION OF A TRACHEOESOPHAGEAL PUNCTURE FOR PLACEMENT OF A PRELOADED PROVOX VEGA VOICE PROSTHESIS AS THE TIME OF THE PUNCTURE.,VOICE PROSTHESIS WITH INSERTION SYSTEM(PROVOX VEGA)-THE PROVOX VEGA VOICE PROSTHESIS IS A STERILE SINGLE USE INDWELLING VOICE PROSTHESIS INTENDED FOR VOICE REHABILITATION AFTER SURGICAL REMOVAL OF THE LARYNX (LARYNGECTOMY). CLEANING OF THE VOICE PROSTHESIS IS PERFORMED BY THE PATIENT WHILE IT REMAINS IN SITU. THE PROVOX INSERTION SYSTEM IS A STERILE SINGLE USE DEVICE INTENDED FOR ANTEROGRADE REPLACEMENT OF THE PROVOX VEGA VOICE PROSTHESIS. THIS REPLACEMENT PROCEDURE IS CARRIED OUT BY A MEDICAL PROFESSIONAL IN ACCORDANCE WITH LOCAL OR NATIONAL GUIDELINES. THE PROVOX INSERTION SYSTEM IS NOT INTENDED TO BE USED FOR INSERTION OF A VOICE PROSTHESIS IN A FRESHLY MADE PUNCTURE.,VOICE PROSTHESIS WITH INSERTION SYSTEM(PROVOX VEGA XTRASEAL)-THE PROVOX VEGA VOICE PROSTHESIS IS A STERILE SINGLE USE INDWELLING VOICE PROSTHESIS INTENDED FOR VOICE REHABILITATION AFTER SURGICAL REMOVAL OF THE LARYNX (LARYNGECTOMY). CLEANING OF THE VOICE PROSTHESIS IS PERFORMED BY THE PATIENT WHILE IT REMAINS IN SITU. THE PROVOX INSERTION SYSTEM IS A STERILE SINGLE USE DEVICE INTENDED FOR ANTEROGRADE REPLACEMENT OF THE PROVOX VEGA VOICE PROSTHESIS. THIS REPLACEMENT PROCEDURE IS CARRIED OUT BY A MEDICAL PROFESSIONAL IN ACCORDANCE WITH LOCAL OR NATIONAL GUIDELINES. THE PROVOX INSERTION SYSTEM IS NOT INTENDED TO BE USED FOR INSERTION OF A VOICE PROSTHESIS IN A FRESHLY MADE PUNCTURE., TRACHEOSTOMA BUTTON(PROVOX LARYBUTTON)-THE PROVOX LARYBUTTON IS A SELF-RETAINING HOLDER FOR DEVICES IN THE PROVOX HME SYSTEM INTENDED FOR VOCAL AND PULMONARY REHABILITATION AFTER TOTAL LARYNGECTOMY. FOR PATIENTS WITH A SHRINKING TRACHEOSTOMA IT IS ALSO USED TO MAINTAIN THE TRACHEOSTOMA FOR BREATHING. THE PROVOX LARYBUTTON IS INTENDED FOR SINGLE PATIENT USE.,BASIC TRACHEOSTOMY TUBE, REUSABLE(PROVOX LARYTUBE)-THE PROVOX LARYTUBE IS A HOLDER FOR DEVICES IN THE PROVOX HME SYSTEM INTENDED FOR VOCAL AND PULMONARY REHABILITATION AFTER TOTAL LARYNGECTOMY. FOR PATIENTS WITH A SHRINKING TRACHEOSTOMA IT IS ALSO USED TO MAINTAIN THE

		TRACHEOSTOMA FOR BREATHING. THE PROVOX LARYTUBE IS INTENDED FOR SINGLE PATIENT USE.
2341	IMP/MD/2020/000500	1.License Holder Name: WEST PHARMACEUTICAL PACKAGING INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER(VIAL ADAPTER (WITHOUT FILTER))-THE VIAL ADAPTER IS INTENDED TO BE USED FOR TRANSFER AND MIXING OF DRUGS IN A VIAL.,CATHETER (MIX2VIAL TRANSFER DEVICE)-THE MIX2VIAL TRANSFER DEVICE WILL ALLOW FAST, EFFICIENT AND SAFE TRANSFER OF DRUG FROM ONE VIAL TO ANOTHER, FOLLOWED BY ASPIRATION INTO A SYRINGE WITHOUT USING ANY NEEDLES.,CATHETER(VIAL ADAPTER WITH FILTER)-THE VIAL ADAPTER IS INTENDED TO BE USED FOR TRANSFER AND MIXING OF DRUG IN A VIAL.

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2342	IMP/MD/2020/000501	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE PERFUSION SETS (INFUSION SYSTEM)(CE INFUSOR LV 1.5 ML/H)-THE INTENDED USE OF THE INFUSOR LV AND SV SYSTEMS INCLUDE THE SLOW, CONTINUOUS INTRAVENOUS, INTRA-ARTERIAL, SUBCUTANEOUS, OR EPIDURAL ADMINISTRATION OF MEDICATIONS. IT MAY ALSO INCLUDE THE SLOW, CONTINUOUS INFUSION OF MEDICATIONS DIRECTLY INTO AN INTRAOPERATIVE SITE OR SUBCUTANEOUSLY FOR POSTOPERATIVE PAIN MANAGEMENT.,DISPOSABLE PERFUSION SETS (INFUSION SYSTEM)(CE INFUSOR SV 2 ML/H)-THE INTENDED USE OF THE INFUSOR LV AND SV SYSTEMS INCLUDE THE SLOW, CONTINUOUS INTRAVENOUS, INTRA-ARTERIAL, SUBCUTANEOUS, OR EPIDURAL ADMINISTRATION OF MEDICATIONS. IT MAY ALSO INCLUDE THE SLOW, CONTINUOUS INFUSION OF MEDICATIONS DIRECTLY INTO AN INTRAOPERATIVE SITE OR SUBCUTANEOUSLY FOR POSTOPERATIVE PAIN MANAGEMENT.,DISPOSABLE PERFUSION SETS (INFUSION SYSTEM)(CE MULTIRATE INFUSOR SV 1,2,3 ML/H)-THE INTENDED USE OF THE MULTIRATE INFUSOR SYSTEM INCLUDES THE SLOW, CONTINUOUS INTRAVENOUS, INTRA-ARTERIAL, SUBCUTANEOUS OR EPIDURAL ADMINISTRATION OF MEDICATIONS. IT MAY ALSO INCLUDE THE SLOW, CONTINUOUS INFUSION OF MEDICATIONS DIRECTLY INTO AN INTRAOPERATIVE SITE OR SUBCUTANEOUSLY FOR POSTOPERATIVE PAIN MANAGEMENT., DISPOSABLE PERFUSION SETS (INFUSION SYSTEM)(CE INFUSOR LV 2 ML/H)-THE INTENDED USE OF THE INFUSOR LV AND SV SYSTEMS INCLUDE THE SLOW, CONTINUOUS INTRAVENOUS, INTRA-ARTERIAL, SUBCUTANEOUS, OR EPIDURAL ADMINISTRATION OF MEDICATIONS. IT MAY ALSO INCLUDE THE SLOW, CONTINUOUS INFUSION OF MEDICATIONS DIRECTLY INTO AN INTRAOPERATIVE SITE OR SUBCUTANEOUSLY FOR POSTOPERATIVE PAIN MANAGEMENT., DISPOSABLE PERFUSION SETS (INFUSION SYSTEM)(CE INFUSOR LV 10 ML/H)-THE INTENDED USE OF THE INFUSOR LV AND SV SYSTEMS INCLUDE THE SLOW, CONTINUOUS INTRAVENOUS, INTRA-ARTERIAL, SUBCUTANEOUS, OR EPIDURAL ADMINISTRATION OF MEDICATIONS. IT MAY ALSO INCLUDE THE SLOW, CONTINUOUS INFUSION OF MEDICATIONS DIRECTLY INTO AN INTRAOPERATIVE SITE OR SUBCUTANEOUSLY FOR POSTOPERATIVE PAIN MANAGEMENT., DISPOSABLE PERFUSION SETS (INFUSION SYSTEM)(CE INFUSOR LV 5 ML/H)-THE INTENDED USE OF THE INFUSOR LV AND SV SYSTEMS INCLUDE THE SLOW, CONTINUOUS INTRAVENOUS, INTRA-ARTERIAL, SUBCUTANEOUS, OR EPIDURAL ADMINISTRATION OF MEDICATIONS. IT MAY ALSO INCLUDE THE SLOW, CONTINUOUS INFUSION OF MEDICATIONS DIRECTLY INTO AN INTRAOPERATIVE SITE OR

		SUBCUTANEOUSLY FOR POSTOPERATIVE PAIN MANAGEMENT., DISPOSABLE PERFUSION SETS (INFUSION SYSTEM)(CE MULTIRATE INFUSOR LV 2,3,5 ML/H)-THE INTENDED USE OF THE MULTIRATE INFUSOR SYSTEM INCLUDES THE SLOW, CONTINUOUS INTRAVENOUS, INTRA-ARTERIAL, SUBCUTANEOUS OR EPIDURAL ADMINISTRATION OF MEDICATIONS. IT MAY ALSO INCLUDE THE SLOW, CONTINUOUS INFUSION OF MEDICATIONS DIRECTLY INTO AN INTRAOPERATIVE SITE OR SUBCUTANEOUSLY FOR POSTOPERATIVE PAIN MANAGEMENT.,DISPOSABLE PERFUSION SETS (INFUSION SYSTEM) (CE MULTIRATE INFUSOR LV 5,7,12 ML/H)-THE INTENDED USE OF THE MULTIRATE INFUSOR SYSTEM INCLUDES THE SLOW, CONTINUOUS INTRAVENOUS, INTRA-ARTERIAL, SUBCUTANEOUS OR EPIDURAL ADMINISTRATION OF MEDICATIONS. IT MAY ALSO INCLUDE THE SLOW, CONTINUOUS INFUSION OF MEDICATIONS DIRECTLY INTO AN INTRAOPERATIVE SITE OR SUBCUTANEOUSLY FOR POSTOPERATIVE PAIN MANAGEMENT.
2343	IMP/MD/2020/000502	1.License Holder Name: KOYE PHARMACEUTICALS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL MANOMETER(AG CUFFILL)-THE HOSPITECH AG CUFFILL IS INTENDED TO MEASURE AND REGULATE THE INTRA-CUFF PRESSURE OF ENDOTRACHEAL TUBES, TRACHEOTOMY TUBES AND LARYNGEAL MASKS AIRWAYS (LMAS) (SUPRAGLOTTIC AIRWAYS).
2344	IMP/MD/2020/000504	1.License Holder Name: 3M INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:3M™ TEGADERM™ AG MESH DRESSING WITH SILVER-UNDER THE SUPERVISION OF A HEALTHCARE PROFESSIONAL, THIS DRESSING MAY BE USED AS PRIMARY WOUND DRESSING OVER: • ABRASIONS • ULCERS • TRAUMA WOUNDS • SURGICAL WOUNDS • FIRST & SECOND DEGREE BURNS • DONOR SITES THIS PRODUCT IS NOT DESIGNED,SOLD OR INTENDED FOR USE EXCEPT AS INDICATED

2345	IMP/MD/2020/000505	1.License Holder Name: CARL ZEISS INDIA (BANGALORE) PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SODIUM HYALURONATE PREFILLED SYRINGE(Z HYALIN)-OPHTHALMIC VISCOELASTIC DEVICE (OVD) APPROVED FOR USE IN INTRAOCULAR SURGERY TO REMOVE CATARACTS, CORNEAL TRANSPLANTS AND GLAUCOMA OPERATIONS,SODIUM HYALURONATE PREFILLED SYRINGE(Z-HYALIN PLUS)-OPHTHALMIC VISCOELASTIC DEVICE (OVD) APPROVED FOR USE IN INTRAOCULAR SURGERY TO REMOVE CATARACTS, CORNEAL TRANSPLANTS AND GLAUCOMA OPERATIONS.,SODIUM HYALURONATE PREFILLED SYRINGE (TWINVISC)-OPHTHALMIC VISCOELASTIC DEVICE APPROVED FOR USE IN INTRAOCULAR SURGERY

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2346	IMP/MD/2020/000506	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERSONA PARTIAL KNEE (PPK) SYSTEM(PERSONA PARTIAL KNEE (PPK) SYSTEM – ARTICULAR SURFACE)-THE PERSONA PARTIAL KNEE SYSTEM IS LIMITED TO THE MEDIAL TIBIOFEMORAL COMPARTMENT OF THE KNEE INTENDED FOR PATIENTS WITH PAINFUL AND/OR DISABLING KNEE JOINTS DUE TO THE FOLLOWING INDICATIONS: NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., OSTEOARTHRITIS, AVASCULAR NECROSIS; TRAUMATIC ARTHRITIS; PREVIOUS TIBIAL CONDYLE OR PLATEAU FRACTURES WITH LOSS OF ANATOMY OR FUNCTION; VARUS DEFORMITIES; AND REVISION OF THE ARTICULAR SURFACE OF A PREVIOUSLY IMPLANTED PERSONA PARTIAL KNEE SYSTEM PROVIDING THAT THE TIBIAL PLATE LOCKING MECHANISM IS NOT COMPROMISED AND THE FEMORAL AND TIBIAL PLATE COMPONENTS REMAIN WELL FIXED AND UNDAMAGED. THE PERSONA PARTIAL KNEE SYSTEM IS A SINGLE USE IMPLANT INTENDED FOR IMPLANTATION WITH BONE CEMENT. INDICATIONS FOR COMBINED PERSONA PARTIAL KNEE SYSTEM AND ZIMMER GENDER SOLUTIONS PATELLO-FEMORAL JOINT (PFJ): OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, AND/OR SEVERE CHONDROCALCINOSIS OF THE PATELLOFEMORAL JOINT. THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS (E.G., ARTHROSCOPY, LATERAL RELEASE, CARTILAGE TRANSPLANTATION). HISTORY OF PATELLAR DISLOCATION OR PATELLA FRACTURE. DYSPLASIA-INDUCED DEGENERATION. THESE INDICATIONS WILL BE USED FOR THE COMBINED MEDIAL UNICOMPARTMENTAL AND PATELLO-FEMORAL IMPLANT DEVICE, WHEREBY A SINGLE CONDYLE AND PATELLO-FEMORAL REGIONS HAVE BEEN AFFECTED BY ONE OR MORE OF THESE CONDITIONS. COMBINED PERSONA PARTIAL KNEE SYSTEM AND ZIMMER GENDER SOLUTIONS PATELLO-FEMORAL JOINT (PFJ) IMPLANTS ARE INTENDED FOR IMPLANTATION WITH BONE CEMENT.
2347	IMP/MD/2020/000507	1.License Holder Name: MANI MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE SKIN STAPLER(MANIPLER)-TO BE USED FOR SKIN SUTURE IN GENERAL SURGERY AND EMERGENCY MEDICAL CARE.

2348	IMP/MD/2020/000508	1.License Holder Name: BECTON DICKINSON INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC NEEDLE(BULK NON STERILE NEEDLE)-USED AS A COMPONENT FOR THE PRODUCTION OF OTHER MEDICAL DEVICES AND AFTER STERILIZATION INTENDED FOR INJECTION AND/OR ASPIRATION OF MEDICAL FLUIDS (CORPORAL FLUIDS BLOOD, ETC) AND DRUGS
2349	IMP/MD/2020/000509	1.License Holder Name: FRESENIUS MEDICAL CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISINFECTANT (CITROSTERIL)-DISINFECTANTS FOR HOT DISINFECTION OF MACHINES, CLEANING AND DECLACIFICATION OF HAEMODIALYSIS SYSTEM.
2350	IMP/MD/2020/000510	1.License Holder Name: BIOTRONIK MEDICAL DEVICES INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACCESSORY KIT (SELECTRA ACCESSORY KIT)-IN CONJUNCTION WITH THE SELECTRA ACCESSORY KIT, SELECTRA GUIDING CATHETERS ARE USED TO FACILITATE LEAD IMPLANTATION IN THE HEART CHAMBERS OR IN THE CORONARY VEINS VIA THE CORONARY SINUS.,LEAD IMPLANTABLE SYSTEM(SELECTRA)-IN CONJUNCTION WITH THE SELECTRA ACCESSORY KIT, SELECTRA GUIDING CATHETERS ARE USED TO FACILITATE LEAD IMPLANTATION IN THE HEART CHAMBERS OR IN THE CORONARY VEINS VIA THE CORONARY SINUS

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2351	IMP/MD/2020/000513	1.License Holder Name: ZB DENTAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ZIMMER DENTAL ABUTMENT(HEX-LOCK CONTOUR ABUTMENT, HEX-LOCK CONTOUR 17° ANGLED ABUTMENT)-THE HEX-LOCK® CONTOUR ABUTMENT IS USED AS A TERMINAL OR INTERMEDIATE ABUTMENT FOR A CEMENTED PROSTHESIS. THE HEX-LOCK® CONTOUR 17° ANGLED ABUTMENT IS USED AS A TERMINAL OR INTERMEDIATE ABUTMENT FOR A CEMENTED PROSTHESIS WHERE THE ANGLE NEEDS TO BE OFFSET BY 17°.,ZIMMER DENTAL EZTETIC DENTAL IMPLANTS SYSTEM (EZTETIC DENTAL IMPLANTS, HEALING SCREW AND SURGICAL COVER SCREW, RETAINING SCREW, HEALING COLLAR, TITANIUM TEMPORARY ABUTMENTS, CONTOUR ABUTMENTS, CONTOUR ABUTMENTS, ANGLED 17, ANGLED ABUTMENT, 20°, CAST-TO" GOLD/PLASTIC COMPONENTS, ENGAGING, BALL ABUTMENT & CAP ATTACHMENT SYSTEM)-EZTETIC DENTAL IMPLANTS ARE DESIGNED FOR USE IN THE ANTERIOR MAXILLA OR MANDIBLE FOR IMMEDIATE LOADING OR FOR LOADING AFTER A CONVENTIONAL HEALING PERIOD.,TRABECULAR METAL™ IMPLANT(TRABECULAR METAL™ IMPLANT)-TRABECULAR METAL™ DENTAL IMPLANTS ARE DESIGNED FOR USE IN THE MAXILLA OR MANDIBLE FOR IMMEDIATE LOADING OR FOR LOADING AFTER A CONVENTIONAL HEALING PERIOD., ZIMMER DENTAL SCREW-VENT DENTAL IMPLANTS - TAPERED SCREW-VENT® IMPLANT SYSTEM(TAPERED SCREW-VENT® IMPLANTS, HEALING SCREW, SURGICAL COVER SCREW, RETAINING SCREW, HEALING COLLAR, FIXTURE MOUNT/ TRANSFER, ZIMMER PLASTIC TEMPORARY ABUTMENT, CONTOUR ZIRCONIA ABUTMENT, HEX-LOCK CONTOUR ABUTMENT, HEX-LOCK CONTOUR 17° ANGLED ABUTMENT, CONTOUR PROVISIONAL COPING, HEX-LOCK SHORT ABUTMENT, SHORT PROVISIONAL COPING, HEX-LOCK, FIXED AND STRAIGHT ABUTMENTS, PREANGLED ABUTMENTS, CAST-TO" GOLD/PLASTIC COMPONENTS, ENGAGING, CAST-TO" GOLD/PLASTIC COMPONENTS, NON-ENGAGING, TAPERED ABUTMENT, ANGLED TAPERED ABUTMENT, COMFORT CAP (HEALING CAP), TAPERED ABUTMENT TITANIUM TEMPORARY COPING, TITANIUM BAR COPINGS, BALL ABUTMENT & CAP ATTACHMENT SYSTEM)-ZIMMER DENTAL IMPLANT SYSTEMS ARE DESIGNED FOR USE IN THE MAXILLA OR MANDIBLE FOR IMMEDIATE LOADING OR FOR LOADING AFTER A CONVENTIONAL HEALING PERIOD.

2352	IMP/MD/2020/000516	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KNOTLESS TISSUE CONTROL DEVICE(STRATAFIX™ SPIRAL PDS™ PLUS)-IT IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE USE OF ABSORBABLE SUTURES IS APPROPRIATE.,KNOTLESS TISSUE CONTROL DEVICE(STRATAFIX™ SPIRAL MONOCRYL™ PLUS)-IT IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE USE OF ABSORBABLE SUTURES IS APPROPRIATE.

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2353	IMP/MD/2020/000517	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANNULOPLASTY BAND (DURAN ANCORE ANNULOPLASTY BAND 620B)-THE DURAN ANCORE ANNULOPLASTY BAND ARE INDICATED FOR THE RECONSTRUCTION OR REMODELING OF PATHOLOGICAL MITRAL AND TRICUSPID VALVES. APPROPRIATE REPAIR AND ANNULAR REMODELING MAY CORRECT COMBINED VALVULAR INSUFFICIENCY AND STENOSIS., ANNULOPLASTY RING(DURAN ANCORE ANNULOPLASTY RING 620R)-THE DURAN ANCORE ANNULOPLASTY RING ARE INDICATED FOR THE RECONSTRUCTION OR REMODELING OF PATHOLOGICAL MITRAL AND TRICUSPID VALVES. APPROPRIATE REPAIR AND ANNULAR REMODELING MAY CORRECT COMBINED VALVULAR INSUFFICIENCY AND STENOSIS.,ANNULOPLASTY RING(CG FUTURE ANNULOPLASTY RING 638R)-THE CG FUTURE ANNULOPLASTY RING ARE INDICATED FOR THE RECONSTRUCTION AND/OR REMODELING OF PATHOLOGICAL MITRAL VALVES. VALVULAR INSUFFICIENCY AND/OR STENOSIS MAY BE CORRECTED BY APPROPRIATE REPAIR AND ANNULAR REMODELING.,ANNULOPLASTY RING(CONTOUR 3D 690R)-THE CONTOUR 3D RING IS INDICATED FOR THE RECONSTRUCTION AND/OR REMODELING OF PATHOLOGICAL TRICUSPID VALVES,ANNULOPLASTY RING(PROFILE 3D 680R)-THE PROFILE 3D™ RING IS INDICATED FOR THE RECONSTRUCTION AND/OR REMODELING OF PATHOLOGICAL MITRAL VALVES. VALVULAR INSUFFICIENCY AND/OR STENOSIS MAY BE CORRECTED BY APPROPRIATE REPAIR AND ANNULAR REMODELING, BIOPROSTHESIS(MOSAIC)-THE MOSAIC BIOPROSTHESIS ARE INDICATED FOR THE REPLACEMENT OF PATHOLOGIC OR PROSTHETIC AORTIC AND MITRAL VALVES,ANNULOPLASTY BAND (CG FUTURE ANNULOPLASTY BAND 638B)-THE CG FUTURE® ANNULOPLASTY BAND ARE INDICATED FOR THE RECONSTRUCTION AND/OR REMODELING OF PATHOLOGICAL MITRAL VALVES. VALVULAR INSUFFICIENCY AND/OR STENOSIS MAY BE CORRECTED BY APPROPRIATE REPAIR AND ANNULAR REMODELING., BIOPROSTHESIS(HANCOCK II ULTRA)-THE HANCOCK II BIOPROSTHESIS ARE INDICATED FOR THE REPLACEMENT OF PATHOLOGIC OR PROSTHETIC AORTIC AND MITRAL VALVES., PULMONARY VALVED CONDUIT (CONTEGRA 200)-THE CONTEGRA PULMONARY VALVED CONDUIT IS INDICATED FOR IMPLANTATION INTO PATIENTS UNDER 18 YEARS OF AGE, PRESENTING WITH THE FOLLOWING CLINICAL CONDITIONS: CORRECTION OR RECONSTRUCTION OF THE RIGHT VENTRICULAR OUTFLOW TRACT (RVOT) IN CONGENITAL HEART MALFORMATIONS (PULMONARY ATRESIA, PULMONARY STENOSIS, TETRALOGY OF FALLOT, ETC.)

		PULMONARY VALVE REPLACEMENT DURING THE ROSS PROCEDURE REPLACEMENT OF A PREVIOUSLY IMPLANTED BUT DYSFUNCTIONAL PULMONARY HOMOGRAFT OR A FAILED PULMONARY PROSTHESIS ,BIOPROSTHESIS(FREESTYLE 995)-THE FREESTYLE BIOPROSTHESIS IS INDICATED FOR THE REPLACEMENT OF PATHOLOGIC OR PROSTHETIC AORTIC VALVES, PULMONARY VALVE REPLACEMENT, AND RIGHT VENTRICULAR OUTFLOW TRACT (RVOT) RECONSTRUCTION.,BIOPROSTHESIS(MOSAIC ULTRA)-THE MOSAIC BIOPROSTHESIS ARE INDICATED FOR THE REPLACEMENT OF PATHOLOGIC OR PROSTHETIC AORTIC AND MITRAL VALVES, BIOPROSTHESIS(HANCOCK II)-THE HANCOCK II BIOPROSTHESIS ARE INDICATED FOR THE REPLACEMENT OF PATHOLOGIC OR PROSTHETIC AORTIC AND MITRAL VALVES.
2354	IMP/MD/2020/000518	1.License Holder Name: EVENT MEDI SYSTEMS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HAEMOSTATIC VALVE KIT-HAEMOSTATIC VALVE KIT IS INTENDED TO BE USED IN CORONARY ANGIOPLASTY (PTCA) AS A ASSEMBLY CONNECTOR TO GUIDING CATHETER TO PASS VARIOUS HARDWARES LIKE GUIDE WIRES, PTCA BALLOON CATHETERS, CORONARY STENTS INSIDE THE CORONARY ARTERY & ALSO PREVENTS BLOOD LOSS / BACK FLOW OF BLOOD. IT CAN BE USED TO CONNECT TO THE PERFUSION STETS /CATHETERS TO INFUSE CONTRAST MEDIUM ETC.

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2355	IMP/MD/2020/000519	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:POLYPROPYLENE MESH, NON- ABSORBABLE(OPTILENE MESH)-RE-INFORCEMENT MATERIAL IN CONNECTIVE TISSUE WEAKNESS: - FOR INCISIONAL HERNIA REPAIR AND INGUINAL HERNIA REPAIR OPTILENE® MESH IS SUITABLE FOR BOTH CONVENTIONAL AND LAPAROSCOPIC APPLICATION.,TISSUE ADHESIVE(HISTOACRYL LAPFIX)-HISTOACRYL® LAPFIX –CANNULA IS INDICATED TO DELIVER HISTOACRYL® FOR THE LAPAROSCOPIC FIXATION OF SURGICAL MESHES, ESPECIALLY IN INGUINAL HERNIA SURGERY (TAPP AND TEP).,POLYGLACTIN 910, BRAIDED, COATED, FAST ABSORBABLE SURGICAL SUTURE(NOVOSYN QUICK)-NOVOSYN®QUICK IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHEN ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHEN THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO ITS ABSORPTION PROFILE NOVOSYN®QUICK IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PAEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISIONS AND CLOSURE OF ORAL MUCOSA.,POLYGLACTIN 910, CHLORHEXIDINE DIACETATE COATED, BRAIDED, ABSORBABLE SURGICAL SUTURE(NOVOSYN CHD)-NOVOSYN CHD IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION. NOVOSYN CHD IS COATED WITH THE ANTIBACTERIAL AGENT CHLORHEXIDINE DIACETATE TO REDUCE THE RISK OF BACTERIAL ATTACHMENT AND COLONIZATION OF THE SUTURE. NOVOSYN CHD IS INDICATED FOR USE IN APPLICATIONS WHERE SURGICAL PRACTICE REQUIRES THE USE OF SYNTHETIC, ABSORBABLE, BRAIDED SUTURE MATERIALS, PARTICULARLY IN SOFT TISSUE APPROXIMATION AND/OR LIGATION, ESPECIALLY IN THE REGION OF THE GASTRO-INTESTINAL TRACT, IN GYNAECOLOGY, UROLOGY AND LIGATURES.,STEEL WIRE MONOFILAMENT, NON-ABSORBABLE, SURGICAL SUTURE(STEELEX)-STEELEX IS INDICATED IN ABDOMINAL SURGERY, FOR ORTHOPAEDIC PROCEDURES (TENDON OPERATIONS AND CERCLAGES), HERNIA SURGERY AND STERNAL CLOSURE.,POLYPROPYLENE MESH, NON-ABSORBABLE(PREMILENE MESH)-IT IS USED AS RE-INFORCEMENT MATERIAL IN CONNECTIVE TISSUE WEAKNESS: - FOR PROSTHETIC HERNIOPLASTY - FOR RECONSTRUCTION OF THE CHEST WALL - FOR RE-INFORCEMENT OF FASCIAL TISSUE IF A NON-ABSORBABLE RE-INFORCEMENT MATERIAL IS REQUIRED. PREMILENE® MESH IS SUITABLE FOR BOTH CONVENTIONAL AND LAPAROSCOPIC APPLICATION. ,POLY(4- HYDROXYBUTYRATE) MONOFILAMENT, ABSORBABLE SURGICAL SUTURE(MONOMAX)-MONOMAX® ABSORBABLE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION WHEN EXTENDED WOUND SUPPORT IS

	NEEDED (MORE THAN 3 MONTHS) IN ABDOMINAL FASCIAL CLOSURE. NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY, OPHTHALMIC SURGERY, AS WELL AS FOR USE IN TISSUES IN CONTACT TO ACIDIC BODY FLUIDS. ,POLYPROPYLENE-POLYETHYLENE MONOFILAMENT, NON-ABSORBABLE SURGICAL SUTURE(OPTILENE)-OPTILENE IS INDICATED FOR SOFT TISSUE APPROXIMATION AND/OR LIGATION, WHEN SURGICAL PRACTICE REQUIRES THE USE OF A NONABSORBABLE SUTURE MATERIAL. OPTILENE SUTURES ARE ALSO FOR USE IN CARDIOVASCULAR SURGERY AND NEUROSURGICAL PROCEDURES, WHERE THE LOW THROMBOGENIC PROPERTIES OF POLYPROPYLENEHAVE A POSITIVE INFLUENCE ON WOUND HEALING. OTHER INDICATIONS FOR OPTILENE INCLUDE MICROSURGERY AND OPHTHALMOLOGY. , POLYESTER, BRAIDED, COATED, NON-ABSORBABLE SURGICAL SUTURE(PREMICRON)-PREMICRON® IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION OF THE WOUND EDGES TO RENDER POSSIBLE AN UNDISTURBED WOUND HEALING. PREMICRON® IS INDICATED FOR USE IN GENERAL SURGERY, CARDIOVASCULAR AND VASCULAR INDICATIONS, WHEN SURGICAL PRACTICE REQUIRES THE USE OF A NONABSORBABLE SUTURE MATERIAL. THE PTFE PLEDGETS HAVE BEEN DESIGNED TO ELIMINATE THE RISK OF SUTURE MATERIAL CUTTING THROUGH CARDIAC OR VASCULAR TISSUE., GLYCONATE MONOFILAMENT, FAST ABSORBABLE SURGICAL SUTURE(MONOSYN QUICK)-MONOSYN® QUICK IS USED FOR THE ADAPTATION OF SOFT TISSUES AND MUCOUS MEMBRANES, WHEN WOUND SUPPORT OVER A PERIOD OF 7 DAYS IS CONSIDERED ADEQUATE. THE MAIN INDICATIONS ARE: - MUCOSAL SUTURES IN FACIAL AND ORAL SURGERY - DERMAL SUTURES, PARTICULARLY IN PEDIATRIC SURGERY - EPISIOTOMY (GYNAECOLOGY) - CIRCUMCISION (UROLOGY) ,90/10 POLY(GLYCOLIDE- CO-L-LACTIDE), BRAIDED, COATED, ABSORBABLE SURGICAL SUTURE(NOVOSYN)-NOVOSYN® IS INDICATED FOR SOFT TISSUE APPROXIMATION AND/OR LIGATION IN GENERAL SURGERY, WHEN SURGICAL PRACTICE REQUIRES THE USE OF SYNTHETIC, ABSORBABLE, BRAIDED SUTURE MATERIAL. NOVOSYN® SUTURES ARE ALSO FOR USE PARTICULARLY IN GYNAECOLOGY AND UROLOGY. NOVOSYN® IS ALSO INDICATED FOR OPHTHALMOLOGY AND FOR MICROSURGERY IF AN ABSORBABLE SUTURE MATERIAL IS PREFERRED.,GLYCONATE MONOFILAMENT, ABSORBABLE SURGICAL SUTURE(MONOSYN)-MONOSYN® IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL SURGERY. TYPICAL APPLICATIONS ARE: - SUBCUTANEOUS AND INTRACUTANEOUS SUTURES - CLOSING OF EPISIOTOMY - GASTRO-INTESTINAL

	ANASTOMOSIS ,POLY-P- DIOXANONE MONOFILAMENT ABSORBABLE SURGICAL SUTURE(MONOPLUS)-MONOPLUS® IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, SPECIALLY IN CASES WHERE AN EXTENDED WOUND SUPPORT OF MORE THAN 4 WEEKS IS DESIRABLE. MONOPLUS® CAN ALSO BE USED IN THE PAEDIATRIC CARDIOVASCULAR SURGERY. IN VASCULAR SURGERY, MONOPLUS® IS INDICATED FOR THE SUTURING OF AUTOLOGOUS PERIPHERAL VESSELS.

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2356	IMP/MD/2020/000521	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GENTAMYCIN LOADED KNEE PROSTHESIS(SUBITON KNEE SPACER)-THE SUBITON KNEE SPACER IS A TEMPORARY IMPLANT WHICH MAIN FUNCTION IS TO PRESERVE THE ARTICULAR SPACE DURING A TWO STAGE REVISION ARTHROPLASTY. FURTHERMORE IT ALSO AIDS IN THE TREATMENT OF THE INFECTION THAT EMERGED DUE TO THE IMPLANT OF THE HIP PROSTHESIS. THIS PROCEDURE CONSISTS OF A FIRST STAGE DURING WHICH THE INFECTED PROSTHESIS IS REMOVED, AND THE SPACER IS IMPLANTED. DURING THE SECOND STAGE, ONCE THE PATIENT HAS FINISHED THE SPECIFIC TREATMENT AND NO SIGNS OF THE INFECTION REMAIN, THE SPACER IS REMOVED TO BE REPLACED BY A DEFINITIVE NEW PROSTHESIS.,BONE CEMENT WITH ANTIBIOTIC (SUBITON BONE CEMENT WITH GENTAMYCIN)-SUBITON G AND SUBITON GUN G ARE USED FOR BONE CEMENTATIONS AND FIXATIONS. ITS USE IS ADVISED IN ORTHOPAEDICS AND OTHER SURGICAL SPECIALITIES, WHEN FIXATION OF PROSTHESIS ELEMENTS WITH STERILE SETTING MATERIAL IS SOUGHT,GENTAMYCIN LOADED HIP PROSTHESIS(SUBITON HIP SPACER)-THE SUBITON HIP SPACER IS A TEMPORARY IMPLANT WHICH MAIN FUNCTION IS TO PRESERVE THE ARTICULAR SPACE DURING A TWO STAGE REVISION ARTHROPLASTY. FURTHERMORE IT ALSO AIDS IN THE TREATMENT OF THE INFECTION THAT EMERGED DUE TO THE IMPLANT OF THE HIP PROSTHESIS. THIS PROCEDURE CONSISTS OF A FIRST STAGE DURING WHICH THE INFECTED PROSTHESIS IS REMOVED, AND THE SPACER IS IMPLANTED. DURING THE SECOND STAGE, ONCE THE PATIENT HAS FINISHED THE SPECIFIC TREATMENT AND NO SIGNS OF THE INFECTION REMAIN, THE SPACER IS REMOVED TO BE REPLACED BY A DEFINITIVE NEW PROSTHESIS.,BONE CEMENT(SUBITON BONE CEMENT)-SUBITON RO AND SUBITON GUN ARE USED FOR BONE CEMENTATIONS AND FIXATIONS. THEIR USE IS ADVISED IN ORTHOPAEDICS AND OTHER SURGICAL SPECIALITIES, WHEN FIXATION OF PROSTHETIST ELEMENTS WITH STERILE SETTING MATERIAL IS SOUGHT.,VERTEBROPLASTY CEMENT(SUBITON VTP)-SUBITON VTP ACRYLIC BONE CEMENT HAS BEEN DESIGNED AND IS RECOMMENDED FOR FILLING VERTEBRAL BODIES WITH SECONDARY STRUCTURAL ALTERATIONS TO OSTEOPOROSIS, TUMOUR INFILTRATION (BENIGN OR MALIGNANT) VASCULAR MALFORMATIONS AND SELECTED TRAUMA CASES.

2357	IMP/MD/2020/000522	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTION SET (BD VACUTAINER® ULTRATOUCH™ PUSH BUTTON BLOOD COLLECTION SET)-THE BD VACUTAINER® ULTRATOUCH™ PUSH BUTTON BLOOD COLLECTION SET IS A STERILE, MULTIPLE SAMPLE, SINGLE-USE FIXED WINGED BLOOD COLLECTION SET INTENDED FOR VENIPUNCTURE TO OBTAIN BLOOD SPECIMENS FROM PATIENTS. WHEN USED WITHOUT THE MALE ADAPTER, THE DEVICE ALLOWS THE CLINICIAN TO OBTAIN BLOOD SAMPLING TO THE FEMALE HUB WITH A SYRINGE, IF NECESSARY, OR CAN BE USED FOR SHORT-TERM, SINGLE INFUSIONS WITH CONSIDERATION GIVEN TO PATIENT SIZE AND APPROPRIATENESS FOR THE SOLUTION BEING INFUSED. THE DEVICE IS NOT TO BE LEFT IN PLACE AND REMAIN UNDER THE DIRECT SUPERVISION OF A CLINICIAN. THE RECOMMENDED USE OF THE DEVICE IS TO ACTIVATE THE NEEDLE SAFETY FEATURE PRIOR TO REMOVAL FROM THE VENIPUNCTURE SITE. THE RETRACTION OF THE INTRAVENOUS (IV) END OF THE NEEDLE AIDS IN THE PREVENTION OF ACCIDENTAL NEEDLESTICK INJURY.
2358	IMP/MD/2020/000523	1.License Holder Name: ERIS LIFESCIENCES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMPOSITE BONE GRAFT (NOVOSIS)-NOVOSIS IS INDICATED ONLY FOR BONY VOIDS OR GAPS THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. NOVOSIS IS INDICATED TO BE GENTLY PACKED INTO BONY VOID OR GAPS OF THE SKELETAL SYSTEM (I.E., THE EXTREMITIES, SPINE AND PELVIS). THESE DEFECTS MAY BE SURGICALLY CREATED OSSEOUS DEFECTS OR OSSEOUS DEFECTS CREATED FROM TRAUMATIC INJURY TO THE BONE. THE PRODUCT PROVIDES A BONE VOID FILLER THAT RESORBS AND IS REPLACED WITH BONE DURING THE HEALING PROCESS.

2359	IMP/MD/2020/000524	1.License Holder Name: KLS MARTIN INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHOPEDIC IMPLANT - ORAL & MAXILLO FACIAL (NON STERILE) - SCREWS(NIL)-IT IS INDICATED FOR SURGICAL TREATMENT OF MAXILLOFACIAL TRAUMA AND FACIAL SKELETAL DEFORMITIES.,ORTHOPEDIC IMPLANT - ORAL & MAXILLO FACIAL (NON STERILE) - PLATES(NIL)-IT IS INDICATED FOR SURGICAL TREATMENT OF MAXILLOFACIAL TRAUMA AND FACIAL SKELETAL DEFORMITIES.,ORTHOPEDIC IMPLANT - ORAL & MAXILLO FACIAL (RESORBABLE FIXATION SYSTEM) STERILE-RX PINS(RESORB X)-IT IS INDICATES FOR SURGICAL TREATMENT OF MAXILLOFACIAL TRAUMA AND FACIAL SKELETAL DEFORMITIES, ORTHOPEDIC IMPLANT - ORAL & MAXILLO FACIAL (RESORBABLE FIXATION SYSTEM) STERILE- MESH/FOIL(RESORB X)-IT IS INDICATED FOR SURGICAL TREATMENT OF MAXILLOFACIAL TRAUMA AND FACIAL SKELETEL DEFORMITIES.,ORTHOPEDIC IMPLANT - ORAL & MAXILLO FACIAL (NON STERILE) -MESH(NIL)-IT IS INDICATED FOR SURGICAL TREATMENT OF MAXILLOFACIAL TRAUMA AND FACIAL SKELETAL DEFORMITIES.,ORTHOPEDIC IMPLANT - ORAL & MAXILLO FACIAL (NON STERILE) -DISTRACTORS(NIL)-IT IS INDICATED FOR SURGICAL TREATMENT OF MAXILLOFACIAL TRAUMA AND FACIAL SKELETAL DEFORMITIES.,ORTHOPEDIC IMPLANT - ORAL & MAXILLO FACIAL (RESORBABLE FIXATION SYSTEM) STERILE- PLATES(RESORB X)-IT IS INDICATED FOR SURGICAL TREATMENT OF MAXILLOFACIAL, TRAUMA AND FACIAL SKELETAL DEFORMITIES.
2360	IMP/MD/2020/000525	1.License Holder Name: WAYINIA LIFESCIENCES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EXTRACORPOREAL HEMOPERFUSION ADSORPTION DEVICE(ALTECO® LPS ADSORBER)-THE ALTECO® LPS ADSORBER IS INTENDED FOR THE TREATMENT OF ENDOTOXEMIA AND/OR SEPSIS OR SEPTIC SHOCK CAUSED BY SUSPECTED OR VERIFIED GRAM NEGATIVE BACTERIA.

2361	IMP/MD/2020/000527	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERNAL FIXATION RECONSTRUCTIVE IMPLANT(STERNALOCK 360 STERNAL CLOSURE SYSTEM)-THE STERNALOCK® 360 STERNAL CLOSURE SYSTEM IS INTENDED FOR USE IN THE STABILIZATION AND FIXATION OF FRACTURES OF THE STERNUM INCLUDING STERNAL FIXATION FOLLOWING STERNOTOMY AND STERNAL RECONSTRUCTIVE SURGICAL PROCEDURES, TO PROMOTE FUSION. THE SYSTEM IS INTENDED FOR USE IN PATIENTS WITH NORMAL AND/OR POOR BONE QUALITY.
2362	IMP/MD/2020/000529	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OVARIAN BIOPSY SETS AND NEEDLES(LABOTECT OVARIAN BIOPSY SETS AND NEEDLES)-THE LABOTECT OVARIAN BIOPSY SET AND NEEDLES ARE USED FOR TRANSVAGINAL, ULTRASOUND GUIDED ASPIRATION AND FLUSHING OF OOCYTES FROM OVARIAN FOLLICLES

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2363	IMP/MD/2020/000531	1.License Holder Name: SHAZE HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOSSEOUS DENTAL IMPLANTS(BEGO SEMADOS IMPLANT, TIPUREPLUS (S-LINE), BEGO SEMADOS IMPLANT TIPUREPLUS (RI-LINE), BEGO SEMADOS IMPLANT (MINI-LINE), BEGO SEMADOS PROVISIONAL IMPLANT (PI-LINE), BEGO SEMADOS IMPLANT TIPUREPLUS (RS-RSX-LINE), BEGO SEMADOS SC/ BEGO SEMADOS SCX (SC/SCX-LINE))-AN ENDOSSEOUS DENTAL IMPLANT IS A PRESCRIPTION DEVICE MADE OF A MATERIAL SUCH AS TITANIUM OR TITANIUM ALLOY THAT IS INTENDED TO BE SURGICALLY PLACED IN THE BONE OF THE UPPER OR LOWER JAW ARCHES TO PROVIDE SUPPORT FOR PROSTHETIC DEVICES, SUCH AS ARTIFICIAL TEETH, IN ORDER TO RESTORE A PATIENT'S CHEWING FUNCTION.,ENDOSSEOUS DENTAL IMPLANT ABUTMENTS(IMPLANT COVER SCREW/ ICS, HEALING POST/ HEALING POST CONICAL, PS HP/ PS HPW, HEALING POST, PS OCP, SUB-TEC MULTIPLUS ABUTMENT, PS MULTI PLUS, MULTIPLUS HEALING POST, MULTIPLUS TITANIUM ABUTMENT, PI PROTECTION CAP, - INDIVIDUAL HEALING POST, SUB-TEC PROVISIONAL ABUTMENT, SUB-TEC TEMP. PEEK ABUTMENT, SUB-TEC TEMP. ABUT., SUB-TEC TEMP. ABUT. NO HEX, PS TTIA/ PS TTIA NH, PS ITA, PS PPA/ PS TPA, SUB-TEC PLUS TI-ABUTMENT, PS TIA/ PS TIAA, TIA, SUB-TEC UNIVERSAL/ SUB-TEC UNIVERSAL NO HEX, PS UNI/ PS UNI NH, SUB-TEC GOLD CAST-ON/ SUB-TEC GOLD CAST-ON NO HEX, GOLD CAST-ON, PS GCO/ PS GCO NH, SUB-TEC BALL ATTACHMENT, BALL ATTACHMENT, PS BA, TIBA, SUB-TEC EASY-CON, EASY-CON MINI ABUTMENT, PS EASY-CON, EASY-CON RETENTION INSERT, SECONDARY SCREW MULTIPLUS, PROSTHESIS SCREW MULTIPLUS, MULTI PLUS UNIVERSAL, SUB-TEC CAD-CAM TITANIUM ADHESIVE ABUTMENT/ SUB-TEC CAD-CAM TITANIUM ADHESIVE ABUTMENT NO HEX, SUB-TEC CAD-CAM TIBASE L, PS TIB/ PS TIB NH, ST PMB, PS PMB, PI MULTIFUNCTIONAL CAP)-AN ENDOSSEOUS DENTAL IMPLANT ABUTMENT IS A PREMANUFACTURED PROSTHETIC COMPONENT DIRECTLY CONNECTED TO THE ENDOSSEOUS DENTAL IMPLANT AND IS INTENDED FOR USE AS AN AID IN PROSTHETIC REHABILITATION.

2364	IMP/MD/2020/000532	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SYRINGE INFUSION PUMP SYSTEM(PERFUSOR COMPACT PLUS)-THE PERFUSOR COMPACT PLUS INFUSION SYRINGE PUMP SYSTEM IS A TRANSPORTABLE INFUSION SYRINGE PUMP USED TOGETHER WITH AUTHORISED SYRINGES AND ACCESSORIES. THE PUMP IS INTENDED FOR USE IN ADULTS, CHILDREN AND NEWBORNS FOR THE INTERMITTENT OR CONTINUOUS ADMINISTRATION OF PARENTERAL AND ENTERAL SOLUTIONS THROUGH STANDARD MEDICAL ACCESS ROUTES. THESE ACCESS ROUTES INCLUDE, BUT ARE NOT LIMITED TO, INTRAVENOUS, INTRA-ARTERIAL, SUBCUTANEOUS, EPIDURAL AND ENTERAL ROUTES. THE SYSTEM IS USED FOR THE DELIVERY OF MEDICATIONS INDICATED FOR INFUSION THERAPY INCLUDING BUT NOT LIMITED TO DRUGS LIKE ANESTHETICS, SEDATIVES, ANALGESICS, CATECHOLAMINES, ANTICOAGULANTS ETC.; BLOOD AND BLOOD COMPONENTS; TOTAL PARENTERAL NUTRITION (TPN); LIPIDS, AND ENTERAL FLUIDS,VOLUMETRIC INFUSION PUMP SYSTEM(INFUSOMAT SPACE P)-THE INFUSOMAT® SPACE P VOLUMETRIC INFUSION PUMP SYSTEM INCLUDES AN EXTERNAL TRANSPORTABLE ELECTRONIC VOLUMETRIC INFUSION PUMP, ADMINISTRATION SETS, AND PUMP ACCESSORIES. THE SYSTEM IS INTENDED FOR USE ON ADULTS, PEDIATRICS, AND NEONATES FOR THE INTERMITTENT OR CONTINUOUS DELIVERY OF PARENTERAL AND ENTERAL FLUIDS THROUGH CLINICALLY ACCEPTED ROUTES OF ADMINISTRATION. THESE ROUTES INCLUDE, BUT ARE NOT LIMITED TO INTRAVENOUS, IRRIGATION/ ABLATION, AND ENTERAL. THE SYSTEM IS USED FOR THE DELIVERY OF MEDICATIONS INDICATED FOR INFUSION THERAPY INCLUDING BUT NOT LIMITED TO COLLOIDS AND CRISTALLOIDS, BLOOD AND BLOOD COMPONENTS, TOTAL PARENTERAL NUTRITION (TPN), LIPIDS, AND ENTERAL FLUIDS.,:VOLUMETRIC INFUSION PUMP SYSTEM(INFUSOMAT COMPACT PLUS)-THE INFUSOMAT COMPACT PLUS VOLUMETRIC INFUSION PUMP SYSTEM INCLUDES AN EXTERNAL TRANSPORTABLE ELECTRONIC VOLUMETRIC INFUSION PUMP, ADMINISTRATION SETS, AND PUMP ACCESSORIES. THE SYSTEM IS INTENDED FOR USE ON ADULTS, PEDIATRICS, AND NEONATES FOR THE INTERMITTENT OR CONTINUOUS DELIVERY OF PARENTERAL AND ENTERAL FLUIDS THROUGH CLINICALLY ACCEPTED ROUTES OF ADMINISTRATION. THESE ROUTES INCLUDE, BUT ARE NOT LIMITED TO INTRAVENOUS, IRRIGATION/ ABLATION, AND ENTERAL. THE SYSTEM IS USED FOR THE DELIVERY OF MEDICATIONS INDICATED FOR INFUSION THERAPY INCLUDING BUT NOT LIMITED TO COLLOIDS AND CRISTALLOIDS, BLOOD AND BLOOD COMPONENTS, TOTAL PARENTERAL NUTRITION (TPN), LIPIDS, AND

	ENTERAL FLUIDS.,SYRINGE INFUSION PUMP SYSTEM(PERFUSOR SPACE)-THE PERFUSOR SPACE INFUSION SYRINGE PUMP SYSTEM IS A TRANSPORTABLE INFUSION SYRINGE PUMP USED TOGETHER WITH AUTHORISED SYRINGES AND ACCESSORIES. THE PUMP IS INTENDED FOR USE IN ADULTS, CHILDREN AND NEWBORNS FOR THE INTERMITTENT OR CONTINUOUS ADMINISTRATION OF PARENTERAL AND ENTERAL SOLUTIONS THROUGH STANDARD MEDICAL ACCESS ROUTES. THESE ACCESS ROUTES INCLUDE, BUT ARE NOT LIMITED TO, INTRAVENOUS, INTRA-ARTERIAL, SUBCUTANEOUS, EPIDURAL AND ENTERAL ROUTES. THE SYSTEM IS USED FOR THE DELIVERY OF MEDICATIONS INDICATED FOR INFUSION THERAPY INCLUDING BUT NOT LIMITED TO DRUGS LIKE ANESTHETICS, SEDATIVES, ANALGESICS, CATECHOLAMINES, ANTICOAGULANTS ETC.; BLOOD AND BLOOD COMPONENTS; TOTAL PARENTERAL NUTRITION (TPN), LIPIDS, AND ENTERAL FLUIDS

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2365	IMP/MD/2020/000533	1.License Holder Name: VASCULAR CONCEPTS LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OCCLUDER(COCOON PFO OCCLUDER (STERILE))-THE COCOON PFO OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF NORMAL AND ANEURYSM TYPE PFOS, IN PATIENTS WITH A HISTORY OF STROKE OR TRANSIENT ISCHEMIC ATTACK, AS DIAGNOSED BY ECHO-CARDIOGRAPHY WITH RIGHT-TO-LEFT SHUNTING DURING VALSALVA MANEUVER.,DELIVERY SYSTEM (COCOON SEPTAL DELIVERY SYSTEM- COCOON SEPTAL OCCLUDER ACCESSORY SET (STERILE), COCOON DUCT DELIVERY SYSTEM- COCOON DUCT OCCLUDER ACCESSORY SET (STERILE), COCOON DELIVERY CABLE (STERILE) ALONG WITH COMPONENTS/ ACCESSORIES ASD SHEATH/ PDA SHEATH, ASD DILATOR/ PDA DILATOR, LOADER, HEMOSTATIS VALVE)-IT IS INTENDED FOR PLACEMENT AND IF NECESSARY RETRIEVAL OF THE DEVICE. INDIVIDUAL FUNCTIONS : 1. A DELIVERY SHEATH WITH HEMOSTASIS VALVE ADAPTER IS USED TO DELIVER THE DEVICE. 2. A DILATOR USED TO EASE PENETRATION OF TISSUE. 3. A LOADER USED TO INTRODUCE THE DEVICE INTO THE DELIVERY SHEATH 4. A DELIVERY CABLE- THE DEVICE IS SCREWED ONTO THE DISTAL TIP OF THE DELIVERY CABLE, WHICH ALLOWS FOR PLACEMENT AND RETRIEVAL OF THE DEVICE.,SEPTAL OCCLUDER(COCOON SEPTAL OCCLUDER (STERILE))-THE COCOON SEPTAL OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER, ATRIAL SEPTAL DEFECT (ASD) CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF SECUNDUM TYPE ASD.,DUCT OCCLUDER(COCOON DUCT OCCLUDER (STERILE))-THE COCOON DUCT OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER DEVICE SPECIALLY DESIGNED FOR CLOSURE OF NORMALLY LOCATED PATENT DUCTUS ARTERIOSUS WITH THE NARROWEST DIAMETER RANGING FROM 2MM TO 16MM. TREATMENT IS ALSO FEASIBLE IN PEDIATRIC POPULATION.,SIZING BALLOON(COCOON SIZING BALLOON (STERILE))-IT IS INTENDED FOR SIZING ATRIAL COMMUNICATION I.E TO MEASURE SIZE OF THE SEPTAL DEFECT., DELIVERY SYSTEM(COCOON PFO- DELIVERY SYSTEM- COCOON PFO-OCCLUDER ACCESSORY SET (STERILE), COCOON PFO- DELIVERY SYSTEM- COCOON DELIVERY CABLE (STERILE) ALONG WITH COMPONENTS/ ACCESSORIES PFO SHEATH, PFO DILATOR, LOADER, HEMOSTASIS VALVE)-IT IS INTENDED FOR PLACEMENT AND IF NECESSARY RETRIEVAL OF THE DEVICE. INDIVIDUAL FUNCTIONS : 1. A DELIVERY SHEATH WITH HEMOSTASIS VALVE ADAPTER USED TO DELIVER THE DEVICE. 2. A DILATOR USED TO EASE PENETRATION OF TISSUE. 3. A LOADER USED TO INTRODUCE THE DEVICE INTO THE DELIVERY SHEATH 4. A DELIVERY CABLE ON WHICH THE DEVICE IS

	SCREWED AND WHICH ALLOWS FOR PLACEMENT AND RETRIEVAL OF THE DEVICE.,OCCLUDER(COCOON VSD OCCLUDER (STERILE))-THE COCOON VSD OCCLUDER IS A PERCUTANEOUS, TRANSCATHETER VENTRICULAR SEPTAL DEFECT (VSD) CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF HEMODYNAMICALLY SIGNIFICANT VENTRICULAR SEPTAL DEFECTS.,TRANSCATHETER AORTIC VALVE (HYDRA AORTIC VALVE AND DELIVERY SYSTEM ALONG WITH COMPONENTS/ ACCESSORIES HYDRA AORTIC VALVE, HYDRA AORTIC VALVE DELIVERY CATHETER, HYDRA AORTIC VALVE LOADING SYSTEM)-THE HYDRA VALVE SYSTEM IS INDICATED FOR PATIENTS WITH SEVERE DEGENERATIVE AORTIC STENOSIS PRESENTING A HIGH PREDICTABLE OPERATIVE MORTALITY RISK FOR SURGICAL AORTIC VALVE REPLACEMENT AND THEREFORE IS REFERRED TO TRANSCATHETER AORTIC VALVE IMPLANTATION. THE DECISION IS BASED ON THE CLINICAL JUDGMENT OF THE HEART TEAM. THE HYDRA VALVE SYSTEM IS INDICATED FOR PATIENTS WITH SEVERE DEGENERATIVE AORTIC STENOSIS PRESENTING A HIGH PREDICTABLE OPERATIVE MORTALITY RISK FOR SURGICAL AORTIC VALVE REPLACEMENT. THE HYDRA VALVE TRANSCATHETER AORTIC VALVE IMPLANTATION NECESSITATES VALVE REPLACEMENT OF THE NATIVE AORTIC HEART VALVE WITHOUT OPEN HEART SURGERY AND WITHOUT CONCOMITANT SURGICAL REMOVAL OF THE FAILED NATIVE VALVE AND PRESENTING WITH FEMORAL ACCESS VESSELS WITH DIAMETERS 6 MM AND ANATOMICAL DIMENSIONS OF THE AORTIC ANNULUS DIAMETER BETWEEN 18MM TO 27MM.,DELIVERY SYSTEM(COCOON VSD- DELIVERY SYSTEM- COCOON VSD OCCLUDER ACCESSORY SET / COCOON VSD OCCLUDER ACCESSORY SET II (STERILE), COCOON VSD- DELIVERY SYSTEM- COCOON DELIVERY CABLE INCLUDING CABLE SHEATH (STERILE) ALONG WITH COMPONENTS/ ACCESSORIES VSD SHEATH, VSD DILATOR, LOADER, HEMOSTASIS VALVE, CABLE SHEATH)-IT IS INTENDED FOR PLACEMENT AND IF NECESSARY RETRIEVAL OF THE DEVICE. INDIVIDUAL FUNCTIONS : 1. A DELIVERY SHEATH WITH HEMOSTASIS VALVE ADAPTER USED TO DELIVER THE DEVICE, 2. A DILATOR USED TO EASE PENETRATION OF TISSUES, 3. A LOADER USED TO INTRODUCE THE DEVICE INTO THE DELIVERY SHEATH, 4. A DELIVERY CABLE WITH A SUPPORTING SHEATH, ON WHICH THE OCCLUDER IS SCREWED AT ITS DISTAL TIP, THAT ALLOWS FOR PLACEMENT AND RETRIEVAL OF THE DEVICE.

2366	IMP/MD/2020/000534	1.License Holder Name: M/S ASIA ACTUAL INDIA (OPC) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DBM (DEMINERALIZED BONE MATRIX)(RAFUGEN DBM)-RAFUGEN DBM IS INTENDED FOR USE AS A BONE VOID FILLER IN BONY VOIDS OR GAPS OF THE SKELETAL SYSTEM (I.E., PELVIS AND EXTREMITIES) NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. THE VOIDS OR GAPS MAY BE SURGICALLY CREATED DEFECTS OR DEFECTS CREATED BY TRAUMATIC INJURY TO THE BONE. RAFUGEN DBM IS RESORBED/REMODELLED AND IS REPLACED BY HOST BONE DURING THE HEALING PROCESS.

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2367	IMP/MD/2020/000535	1.License Holder Name: LEADING HEALTH TECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETERS(PASV MS KIT WITH PRESSURE ACTIVATED SAFETY VALVE)-THE PASV MS (MODIFIED SELDINGER) KIT IS DESIGNED AS A PLACEMENT KIT FOR PASV PICC CATHETERS. THIS PROCEDURE IS INDICATED FOR USE IN ESTABLISHING PERIPHERAL ACCESS VIA THE MODIFIED SELDINGER TECHNIQUE TO THE CENTRAL VENOUS SYSTEM FOR ADMINISTRATION OF INTRAVENOUS FLUIDS.,CATHETERS(XCELA PICC WITH PASV VALVE TECHNOLOGY)-THE XCELA PICC WITH PASV VALVE TECHNOLOGY IS INDICATED FOR SHORT OR LONG-TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, INCLUDING BUT NOT LIMITED TO, THE ADMINISTRATION OF FLUIDS, MEDICATIONS AND NUTRIENTS; THE SAMPLING OF BLOOD; AND POWER INJECTION OF CONTRAST MEDIA., CATHETERS(VAXCEL MINI STICK KIT)-THE INTRODUCER SHEATH AND DILATOR KIT IS INDICATED FOR USE IN THE PERCUTANEOUS INSERTION OF CATHETERS FOLLOWING A NEEDLE INTRODUCTION AND PLACEMENT OF GUIDEWIRE IN THE VENOUS SYSTEM., CATHETERS(BIOFLO PICC WITH ENDEXO TECHNOLOGY)-THE BIOFLO PICC WITH ENDEXO TECHNOLOGY IS INDICATED FOR SHORT TERM OR LONG-TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, INCLUDING BUT NOT LIMITED TO THE ADMINISTRATION OF FLUIDS, MEDICATIONS AND NUTRIENTS; THE SAMPLING OF BLOOD; CENTRAL VENOUS PRESSURE MONITORING AND FOR POWER INJECTION OF CONTRAST MEDIA, CATHETERS(BIOFLO PICC WITH ENDEXO AND PASV VALVE TECHNOLOGY)-THE BIOFLO PICC WITH ENDEXO AND PASV VALVE TECHNOLOGY IS INDICATED FOR SHORT TERM OR LONG-TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, INCLUDING BUT NOT LIMITED TO THE ADMINISTRATION OF FLUIDS, MEDICATIONS AND NUTRIENTS; THE SAMPLING OF BLOOD, AND FOR POWER INJECTION OF CONTRAST MEDIA. ,CATHETERS(XCELA POWER INJECTABLE PICC)-THE XCELA POWER INJECTABLE PICC IS INDICATED FOR SHORT OR LONG-TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, INCLUDING BUT NOT LIMITED TO, THE ADMINISTRATION OF FLUIDS, MEDICATIONS AND NUTRIENTS; THE SAMPLING OF BLOOD; AND POWER INJECTION OF CONTRAST MEDIA, CATHETERS(SMART PORT CT (LOW- PROFILE & MINI- PROFILE))-THE SMART PORT® CT POWER INJECTABLE PORT LINE IS INDICATED FOR ANY PATIENT REQUIRING REPEATED ACCESS OF THE VASCULAR SYSTEM, FOR DELIVERY OF MEDICATIONS, NUTRITIONAL

		SUPPLEMENTATION, FLUIDS, BLOOD, BLOOD PRODUCTS, AND SAMPLING OF BLOOD AND POWER INJECTION OF CONTRAST MEDIA FOR IMAGING.,CATHETERS(VORTEX VX VASCULAR ACCESS PORT)-THE ANGIODYNAMICS PORT LINE IS INDICATED FOR ANY PATIENT REQUIRING REPEATED ACCESS OF THE VASCULAR SYSTEM FOR DELIVERY OF MEDICATIONS, NUTRITIONAL SUPPLEMENTATION, FLUIDS, BLOOD, BLOOD PRODUCTS, AND SAMPLING OF BLOOD. DUAL MODELS ARE INDICATED FOR COMBINATION THERAPY, SIMULTANEOUS INFUSIONS, WITHDRAWAL OF BODY FLUIDS, AND BOLUS DELIVERY DURING CONTINUOUS INFUSION.
2368	IMP/MD/2020/000536	1.License Holder Name: M/S. VATSKA MEDTECH PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IGL-1 ORGAN PRESERVATION SOLUTION-SOLUTION INTENDED FOR HYPOTHERMIC FLUSHING AND STORAGE OF ORGANS (KIDNEYS, LIVER, AND PANCREAS) AT THE TIME OF ORGAN REMOVAL FROM THE DONOR IN PREPARATION FOR STORAGE, TRANSPORT AND POTENTIAL TRANSPLANTATION INTO A RECIPIENT.
2369	IMP/MD/2020/000538	1.License Holder Name: M/S CELERA PHARMA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INFUSION PUMPS AMBULANT WITH STERILE RESERVOIR(D MINE® PUMP)-THE EVER PHARMA DMINE® PUMP IS INTENDED FOR THE INFUSION OF 5 MG/ML APOMORPHINE, WHICH IS AVAILABLE AS A MEDICINAL PRODUCT IN A 20-ML VIAL FROM EVER NEURO PHARMA GMBH. THE EVER PHARMA DMINE® PUMP IS INTENDED FOR USE BY ADULT PATIENTS, RELATIVES AND MEDICAL PROFESSIONALS. PATIENTS WITH LIMITED DEXTERITY SHOULD SEEK ASSISTANCE FROM THEIR CARERS.

2370	IMP/MD/2020/000541	1.License Holder Name: 3M INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CASTING TAPE(3M™ SCOTCHCAST™ SOFT CAST)-3M™ SCOTCHCAST™ SOFT CAST IS INTENDED TO CONSTRUCT CASTS FOR MANAGEMENT OF FRACTURES AS WELL AS SPECIALIZED PROSTHETICS AND ORTHOTIC DEVICES. IT CAN ALSO BE USED FOR THE FOLLOWING SPECIFIC APPLICATIONS: *ORTHOPEDIC/TRAUMA CAST APPLICATIONS IN A SO CALLED “FUNCTIONAL STABILIZATION” IN FRACTURE MANAGEMENT, *SPECIALIZED PEDIATRIC INDICATIONS, FOR SERIAL CASTING IN NEURO-SPASTIC PATIENTS, PROSTHETICS AND ORTHOTIC DEVICES * IN THE SO CALLED “TOTAL CONTACT CAST” APPLICATIONS IN DIABETIC FOOT ULCER TREATMENT. SUITABILITY OF THE DEVICE FOR THE PARTICULAR APPLICATION IS THE RESPONSIBILITY OF A QUALIFIED, ON-SITE MEDICAL PROFESSIONAL. INTENDED USER: THE INTENDED USER IS A QUALIFIED MEDICAL PROFESSIONAL.,CASTING TAPE(3M™ SCOTCHCAST™ PLUS)-3M™ SCOTCHCAST™ PLUS IS INTENDED TO CONSTRUCT RIGID CASTS IN ORDER TO IMMOBILIZE FRACTURES. 3M™ SCOTCHCAST™ PLUS TAPE CAN BE USED IN THE CONSTRUCTION OF MOST COMMON ORTHOPEDIC CASTS, AS WELL AS SPECIALIZED PROSTHETICS AND ORTHOTIC DEVICES. SUITABILITY OF THE DEVICE FOR THE PARTICULAR APPLICATION IS THE RESPONSIBILITY OF A QUALIFIED, ON-SITE MEDICAL PROFESSIONAL. INTENDED USER: THE INTENDED USER IS A QUALIFIED MEDICAL PROFESSIONAL.
2371	IMP/MD/2020/000542	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MARS TREATMENT KIT-THE MARS METHOD IS USED TO REMOVE PROTEIN-BOUND AND/OR WATER-SOLUBLE TOXINS FROM THE BLOOD, PRIMARILY IN PATIENTS WITH ACUTE OR CHRONIC LIVER FAILURE, FREQUENTLY ACCOMPANIED BY ENDOGENOUS INTOXICATION, JAUNDICE (ICTERUS) OR COMATOSE CONDITIONS.

2372	IMP/MD/2020/000543	1.License Holder Name: EVOLUTIS INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CAPTIV DM COATED CUP (NA)-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEMS OF THE HIP IN PATIENTS WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLER MEDICAMENTATION AND CORRECTLY FOLLOWED CONSERVATIVE TREATMENT HAVE FAILED. FOR THE PATIENT, THEIR ANATOMY AND THE STRUCTURE OF THEIR ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S). INDICATIONS FOR TOTAL OR PARTIAL HIP ARTHROPLASTY ARE: - DEGENERATIVE NON INAMMATORY HIP DISEASE (COXARTHROSIS, ARTHRITIS OF THE HIP). - INAMMATORY HIP DISEASE (RHEUMATOID ARTHRITIS, POST TRAUMATIC ARTHRITIS). - METABOLIC HIP DISEASE (CHONDROCALCINOSIS). - POST TRAUMATIC DEGENERATIVE ARTHRITIS. - AVASCULAR NECROSIS. - CONGENITAL DYSPLASIA OF THE HIP. - FUNCTIONAL REPAIR OF A RECENT TRAUMA (FRACTURE, DISLOCATION) - REVISION OF A FAILED CONSERVATIVE SURGERY, OSTEOSYNTHESIS, PARTIAL OR TOTAL ARTHROPLASTY. - TUMORAL SURGERY WHEN AFFECTING THE HIP JOINT. THE UN-COATED CEMENTLESS SAND-BLASTED VARIANT OF FEMORAL STEM IS INDICATED ONLY FOR THE TREATMENT OF THE FEMORAL NECK FRACTURE AT THE ELDERLY. ACCORDING TO THIS LIMIT OF INDICATION, ITS BENEFIT/RISK RATIO IS ESTIMATED ONLY IN THE SHORT TERM. THE RECOMMENDED INDICATIONS FOR DUAL MOBILITY CUP ARE: - PRIMARY ARTHROPLASTIES FOR PATIENTS AT HIGH RISK OF DISLOCATION (SEVERE NEUROLOGICAL AFICTION, NEUROPSYCHIATRIC DISORDERS, ADDICTIONS AND SEVERE NEUROMUSCULAR DEFICIENCIES), - REVISION ARTHROPLASTIES IN CASES OF RECURRENT DISLOCATIONS FOR PATIENTS AT HIGH RISK OF ARTICULAR INSTABILITY. THE TROCHANTERIC GRIP PLATE IS USED IN COMBINATION WITH THE PRIUS STEM AND CORTICAL SCREWS Ø 4.5MM (SEE SURGICAL TECHNIQUE) IN CASE OF: - FRACTURES OF THE TROCHANTERIC REGION FOLLOWING THE IMPLANTATION OF A FEMORAL STEM, - TROCHANTEROTOMY FOR IMPLANTATION OR REMOVAL OF A FEMORAL STEM (MAINTENANCE OF THE TROCHANTER OR FEMORAL COMPONENT). TREATMENT OF TROCHANTER PSEUDARTHROSIS AFTER PRIMARY PROSTHESIS OR REVISION PROSTHESIS. IN PRIMARY SURGERY OF THE HIP JOINT, AND EVEN MORE IN REVISION OR TUMORAL SURGERY, THE QUALITY OF THE BONE STOCK AND THE BONE DEFECTS DUE TO THE ABLATION OF ANY PREVIOUSLY IMPLANTED MATERIAL CAN COMPROMISE THE PRIMARY FIXATION OF THE IMPLANTABLE DEVICE AND THUS LIMIT

	ITS INDICATIONS. DEPENDING ON THE LOCATION AND THE EXTENSION OF THE BONE DEFECT, A LONGER CEMENTED OR CEMENTLESS FEMORAL COMPONENT INCLUDING A VARIETY OF COMPLEMENTARY FIXATION MEANS OR AN ACETABULAR COMPONENT INCLUDING PERIPHERAL ANGES AND HOOKS CAN BE CONSIDERED. ,PRIUS FEMORAL STEM(NA)-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEMS OF THE HIP IN PATIENTS WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLER MEDICAMENTATION AND CORRECTLY FOLLOWED CONSERVATIVE TREATMENT HAVE FAILED. FOR THE PATIENT, THEIR ANATOMY AND THE STRUCTURE OF THEIR ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S). INDICATIONS FOR TOTAL OR PARTIAL HIP ARTHROPLASTY ARE: - DEGENERATIVE NON INAMMATORY HIP DISEASE (COXARTHROSIS, ARTHRITIS OF THE HIP). - INAMMATORY HIP DISEASE (RHEUMATOID ARTHRITIS, POST TRAUMATIC ARTHRITIS). - METABOLIC HIP DISEASE (CHONDROCALCINOSIS). - POST TRAUMATIC DEGENERATIVE ARTHRITIS. - AVASCULAR NECROSIS. - CONGENITAL DYSPLASIA OF THE HIP. - FUNCTIONAL REPAIR OF A RECENT TRAUMA (FRACTURE, DISLOCATION) - REVISION OF A FAILED CONSERVATIVE SURGERY, OSTEOSYNTHESIS, PARTIAL OR TOTAL ARTHROPLASTY. - TUMORAL SURGERY WHEN AFFECTING THE HIP JOINT. THE UN-COATED CEMENTLESS SAND-BLASTED VARIANT OF FEMORAL STEM IS INDICATED ONLY FOR THE TREATMENT OF THE FEMORAL NECK FRACTURE AT THE ELDERLY. ACCORDING TO THIS LIMIT OF INDICATION, ITS BENEFIT/RISK RATIO IS ESTIMATED ONLY IN THE SHORT TERM. THE RECOMMENDED INDICATIONS FOR DUAL MOBILITY CUP ARE: - PRIMARY ARTHROPLASTIES FOR PATIENTS AT HIGH RISK OF DISLOCATION (SEVERE NEUROLOGICAL AFICTION, NEUROPSYCHIATRIC DISORDERS, ADDICTIONS AND SEVERE NEUROMUSCULAR DEFICIENCIES), - REVISION ARTHROPLASTIES IN CASES OF RECURRENT DISLOCATIONS FOR PATIENTS AT HIGH RISK OF ARTICULAR INSTABILITY. THE TROCHANTERIC GRIP PLATE IS USED IN COMBINATION WITH THE PRIUS STEM AND CORTICAL SCREWS Ø 4.5MM (SEE SURGICAL TECHNIQUE) IN CASE OF: - FRACTURES OF THE TROCHANTERIC REGION FOLLOWING THE IMPLANTATION OF A FEMORAL STEM, - TROCHANTEROTOMY FOR IMPLANTATION OR REMOVAL OF A FEMORAL STEM (MAINTENANCE OF THE TROCHANTER OR FEMORAL COMPONENT). TREATMENT OF TROCHANTER PSEUDARTHROSIS AFTER PRIMARY PROSTHESIS OR REVISION PROSTHESIS. IN PRIMARY SURGERY OF THE HIP JOINT, AND EVEN MORE IN REVISION OR TUMORAL SURGERY, THE QUALITY OF THE BONE STOCK AND THE BONE DEFECTS DUE TO THE ABLATION

	OF ANY PREVIOUSLY IMPLANTED MATERIAL CAN COMPROMISE THE PRIMARY FIXATION OF THE IMPLANTABLE DEVICE AND THUS LIMIT ITS INDICATIONS. DEPENDING ON THE LOCATION AND THE EXTENSION OF THE BONE DEFECT, A LONGER CEMENTED OR CEMENTLESS FEMORAL COMPONENT INCLUDING A VARIETY OF COMPLEMENTARY FIXATION MEANS OR AN ACETABULAR COMPONENT INCLUDING PERIPHERAL ANGES AND HOOKS CAN BE CONSIDERED.,CEMTIV FEMORAL STEM(NA)-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEMS OF THE HIP IN PATIENTS WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLER MEDICAMENTATION AND CORRECTLY FOLLOWED CONSERVATIVE TREATMENT HAVE FAILED. FOR THE PATIENT, THEIR ANATOMY AND THE STRUCTURE OF THEIR ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S). INDICATIONS FOR TOTAL OR PARTIAL HIP ARTHROPLASTY ARE: - DEGENERATIVE NON INAMMATORY HIP DISEASE (COXARTHROSIS, ARTHRITIS OF THE HIP). - INAMMATORY HIP DISEASE (RHEUMATOID ARTHRITIS, POST TRAUMATIC ARTHRITIS). - METABOLIC HIP DISEASE (CHONDROCALCINOSIS). - POST TRAUMATIC DEGENERATIVE ARTHRITIS. - AVASCULAR NECROSIS. - CONGENITAL DYSPLASIA OF THE HIP. - FUNCTIONAL REPAIR OF A RECENT TRAUMA (FRACTURE, DISLOCATION) - REVISION OF A FAILED CONSERVATIVE SURGERY, OSTEOSYNTHESIS, PARTIAL OR TOTAL ARTHROPLASTY. - TUMORAL SURGERY WHEN AFFECTING THE HIP JOINT. THE UN-COATED CEMENTLESS SAND-BLASTED VARIANT OF FEMORAL STEM IS INDICATED ONLY FOR THE TREATMENT OF THE FEMORAL NECK FRACTURE AT THE ELDERLY. ACCORDING TO THIS LIMIT OF INDICATION, ITS BENEFIT/RISK RATIO IS ESTIMATED ONLY IN THE SHORT TERM. THE RECOMMENDED INDICATIONS FOR DUAL MOBILITY CUP ARE: - PRIMARY ARTHROPLASTIES FOR PATIENTS AT HIGH RISK OF DISLOCATION (SEVERE NEUROLOGICAL AFICTION, NEUROPSYCHIATRIC DISORDERS, ADDICTIONS AND SEVERE NEUROMUSCULAR DEFICIENCIES), - REVISION ARTHROPLASTIES IN CASES OF RECURRENT DISLOCATIONS FOR PATIENTS AT HIGH RISK OF ARTICULAR INSTABILITY. THE TROCHANTERIC GRIP PLATE IS USED IN COMBINATION WITH THE PRIUS STEM AND CORTICAL SCREWS Ø 4.5MM (SEE SURGICAL TECHNIQUE) IN CASE OF: - FRACTURES OF THE TROCHANTERIC REGION FOLLOWING THE IMPLANTATION OF A FEMORAL STEM, - TROCHANTEROTOMY FOR IMPLANTATION OR REMOVAL OF A FEMORAL STEM (MAINTENANCE OF THE TROCHANTER OR FEMORAL COMPONENT). TREATMENT OF TROCHANTER PSEUDARTHROSIS AFTER PRIMARY PROSTHESIS OR REVISION PROSTHESIS. IN PRIMARY SURGERY OF THE HIP JOINT,

	AND EVEN MORE IN REVISION OR TUMORAL SURGERY, THE QUALITY OF THE BONE STOCK AND THE BONE DEFECTS DUE TO THE ABLATION OF ANY PREVIOUSLY IMPLANTED MATERIAL CAN COMPROMISE THE PRIMARY FIXATION OF THE IMPLANTABLE DEVICE AND THUS LIMIT ITS INDICATIONS. DEPENDING ON THE LOCATION AND THE EXTENSION OF THE BONE DEFECT, A LONGER CEMENTED OR CEMENTLESS FEMORAL COMPONENT INCLUDING A VARIETY OF COMPLEMENTARY FIXATION MEANS OR AN ACETABULAR COMPONENT INCLUDING PERIPHERAL ANGES AND HOOKS CAN BE CONSIDERED. ,UNIC SHOULDER PROTHESIS(NA)-HEMI AND TOTAL ANATOMIC SHOULDER ARTHROPLASTY ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEMS OF THE SHOULDER IN PATIENTS WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLERS AND CONSERVATIVE TREATMENT USED CORRECTLY HAVE FAILED. THE ANATOMY AND STRUCTURE OF THE PATIENT'S ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S). THE INDICATIONS FOR TOTAL ANATOMIC OR PARTIAL SHOULDER ARTHROPLASTY ARE: -DEGENERATIVE NON -INFLAMMATORY ARTHROPATHY: CENTERED SHOULDER ARTHRITIS, OSTEONECROSIS OF THE HUMERAL HEAD. -INFLAMMATORY ARTHROPATHY SUCH AS RHEUMATOID ARTHRITIS, OR POST TRAUMATIC ARTHRITIS. -POST TRAUMATIC DEGENERATIVE ARTHRITIS. -FUNCTIONAL REPAIR OF RECENT COMPLEX PROXIMAL HUMERAL FRACTURES AT THE ELDERLY. -REVISION OF A PREVIOUS FAILED PARTIAL OR TOTAL ARTHROPLASTY. WHATEVER IS THE PATHOLOGY THE PRESENCE OF A FUNCTIONAL OR REPAIRABLE ROTATOR CUFF IS ABSOLUTELY NECESSARY FOR THE ESTABLISHMENT OF AN INDICATION OF PARTIAL OR TOTAL ANATOMIC SHOULDER ARTHROPLASTY., MOONSTONE BIPOLAR CUP(NA)-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEMS OF THE HIP IN PATIENTS WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLER MEDICAMENTATION AND CORRECTLY FOLLOWED CONSERVATIVE TREATMENT HAVE FAILED. FOR THE PATIENT, THEIR ANATOMY AND THE STRUCTURE OF THEIR ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S). INDICATIONS FOR TOTAL OR PARTIAL HIP ARTHROPLASTY ARE: - DEGENERATIVE NON INAMMATORY HIP DISEASE (COXARTHROSIS, ARTHRITIS OF THE HIP). - INAMMATORY HIP DISEASE (RHEUMATOID ARTHRITIS, POST TRAUMATIC ARTHRITIS). - METABOLIC HIP DISEASE (CHONDROCALCINOSIS). - POST TRAUMATIC DEGENERATIVE ARTHRITIS. - AVASCULAR NECROSIS. - CONGENITAL DYSPLASIA OF THE HIP. - FUNCTIONAL REPAIR OF A RECENT TRAUMA (FRACTURE,

	DISLOCATION) - REVISION OF A FAILED CONSERVATIVE SURGERY, OSTEOSYNTHESIS, PARTIAL OR TOTAL ARTHROPLASTY. - TUMORAL SURGERY WHEN AFFECTING THE HIP JOINT. THE UN-COATED CEMENTLESS SAND-BLASTED VARIANT OF FEMORAL STEM IS INDICATED ONLY FOR THE TREATMENT OF THE FEMORAL NECK FRACTURE AT THE ELDERLY. ACCORDING TO THIS LIMIT OF INDICATION, ITS BENEFIT/RISK RATIO IS ESTIMATED ONLY IN THE SHORT TERM. THE RECOMMENDED INDICATIONS FOR DUAL MOBILITY CUP ARE: - PRIMARY ARTHROPLASTIES FOR PATIENTS AT HIGH RISK OF DISLOCATION (SEVERE NEUROLOGICAL AFICTION, NEUROPSYCHIATRIC DISORDERS, ADDICTIONS AND SEVERE NEUROMUSCULAR DEFICIENCIES), - REVISION ARTHROPLASTIES IN CASES OF RECURRENT DISLOCATIONS FOR PATIENTS AT HIGH RISK OF ARTICULAR INSTABILITY. THE TROCHANTERIC GRIP PLATE IS USED IN COMBINATION WITH THE PRIUS STEM AND CORTICAL SCREWS Ø 4.5MM (SEE SURGICAL TECHNIQUE) IN CASE OF: - FRACTURES OF THE TROCHANTERIC REGION FOLLOWING THE IMPLANTATION OF A FEMORAL STEM, - TROCHANTEROTOMY FOR IMPLANTATION OR REMOVAL OF A FEMORAL STEM (MAINTENANCE OF THE TROCHANTER OR FEMORAL COMPONENT). TREATMENT OF TROCHANTER PSEUDARTHROSIS AFTER PRIMARY PROSTHESIS OR REVISION PROSTHESIS. IN PRIMARY SURGERY OF THE HIP JOINT, AND EVEN MORE IN REVISION OR TUMORAL SURGERY, THE QUALITY OF THE BONE STOCK AND THE BONE DEFECTS DUE TO THE ABLATION OF ANY PREVIOUSLY IMPLANTED MATERIAL CAN COMPROMISE THE PRIMARY FIXATION OF THE IMPLANTABLE DEVICE AND THUS LIMIT ITS INDICATIONS. DEPENDING ON THE LOCATION AND THE EXTENSION OF THE BONE DEFECT, A LONGER CEMENTED OR CEMENTLESS FEMORAL COMPONENT INCLUDING A VARIETY OF COMPLEMENTARY FIXATION MEANS OR AN ACETABULAR COMPONENT INCLUDING PERIPHERAL ANGES AND HOOKS CAN BE CONSIDERED. ,REACTIV FEMORAL STEM(NA)-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEMS OF THE HIP IN PATIENTS WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLER MEDICAMENTATION AND CORRECTLY FOLLOWED CONSERVATIVE TREATMENT HAVE FAILED. FOR THE PATIENT, THEIR ANATOMY AND THE STRUCTURE OF THEIR ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S). INDICATIONS FOR TOTAL OR PARTIAL HIP ARTHROPLASTY ARE: - DEGENERATIVE NON INAMMATORY HIP DISEASE (COXARTHROSIS, ARTHRITIS OF THE HIP). - INAMMATORY HIP DISEASE (RHEUMATOID ARTHRITIS, POST TRAUMATIC ARTHRITIS). - METABOLIC HIP DISEASE (CHONDROCALCINOSIS). - POST TRAUMATIC DEGENERATIVE

	ARTHRITIS. - AVASCULAR NECROSIS. - CONGENITAL DYSPLASIA OF THE HIP. - FUNCTIONAL REPAIR OF A RECENT TRAUMA (FRACTURE, DISLOCATION) - REVISION OF A FAILED CONSERVATIVE SURGERY, OSTEOSYNTHESIS, PARTIAL OR TOTAL ARTHROPLASTY. - TUMORAL SURGERY WHEN AFFECTING THE HIP JOINT. THE UN-COATED CEMENTLESS SAND-BLASTED VARIANT OF FEMORAL STEM IS INDICATED ONLY FOR THE TREATMENT OF THE FEMORAL NECK FRACTURE AT THE ELDERLY. ACCORDING TO THIS LIMIT OF INDICATION, ITS BENEFIT/RISK RATIO IS ESTIMATED ONLY IN THE SHORT TERM. THE RECOMMENDED INDICATIONS FOR DUAL MOBILITY CUP ARE: - PRIMARY ARTHROPLASTIES FOR PATIENTS AT HIGH RISK OF DISLOCATION (SEVERE NEUROLOGICAL AFICTION, NEUROPSYCHIATRIC DISORDERS, ADDICTIONS AND SEVERE NEUROMUSCULAR DEFICIENCIES), - REVISION ARTHROPLASTIES IN CASES OF RECURRENT DISLOCATIONS FOR PATIENTS AT HIGH RISK OF ARTICULAR INSTABILITY. THE TROCHANTERIC GRIP PLATE IS USED IN COMBINATION WITH THE PRIUS STEM AND CORTICAL SCREWS Ø 4.5MM (SEE SURGICAL TECHNIQUE) IN CASE OF: - FRACTURES OF THE TROCHANTERIC REGION FOLLOWING THE IMPLANTATION OF A FEMORAL STEM, - TROCHANTEROTOMY FOR IMPLANTATION OR REMOVAL OF A FEMORAL STEM (MAINTENANCE OF THE TROCHANTER OR FEMORAL COMPONENT). TREATMENT OF TROCHANTER PSEUDARTHROSIS AFTER PRIMARY PROSTHESIS OR REVISION PROSTHESIS. IN PRIMARY SURGERY OF THE HIP JOINT, AND EVEN MORE IN REVISION OR TUMORAL SURGERY, THE QUALITY OF THE BONE STOCK AND THE BONE DEFECTS DUE TO THE ABLATION OF ANY PREVIOUSLY IMPLANTED MATERIAL CAN COMPROMISE THE PRIMARY FIXATION OF THE IMPLANTABLE DEVICE AND THUS LIMIT ITS INDICATIONS. DEPENDING ON THE LOCATION AND THE EXTENSION OF THE BONE DEFECT, A LONGER CEMENTED OR CEMENTLESS FEMORAL COMPONENT INCLUDING A VARIETY OF COMPLEMENTARY FIXATION MEANS OR AN ACETABULAR COMPONENT INCLUDING PERIPHERAL ANGES AND HOOKS CAN BE CONSIDERED. ,EMERGENCE CEMENTED CUP(NA)-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEMS OF THE HIP IN PATIENTS WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLER MEDICAMENTATION AND CORRECTLY FOLLOWED CONSERVATIVE TREATMENT HAVE FAILED. FOR THE PATIENT, THEIR ANATOMY AND THE STRUCTURE OF THEIR ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S). INDICATIONS FOR TOTAL OR PARTIAL HIP ARTHROPLASTY ARE: - DEGENERATIVE NON INAMMATORY HIP DISEASE (COXARTHROSIS, ARTHRITIS OF THE HIP). - INAMMATORY HIP DISEASE (RHEUMATOID

	ARTHRITIS, POST TRAUMATIC ARTHRITIS). - METABOLIC HIP DISEASE (CHONDROCALCINOSIS). - POST TRAUMATIC DEGENERATIVE ARTHRITIS. - AVASCULAR NECROSIS. - CONGENITAL DYSPLASIA OF THE HIP. - FUNCTIONAL REPAIR OF A RECENT TRAUMA (FRACTURE, DISLOCATION) - REVISION OF A FAILED CONSERVATIVE SURGERY, OSTEOSYNTHESIS, PARTIAL OR TOTAL ARTHROPLASTY. - TUMORAL SURGERY WHEN AFFECTING THE HIP JOINT. THE UN-COATED CEMENTLESS SAND-BLASTED VARIANT OF FEMORAL STEM IS INDICATED ONLY FOR THE TREATMENT OF THE FEMORAL NECK FRACTURE AT THE ELDERLY. ACCORDING TO THIS LIMIT OF INDICATION, ITS BENEFIT/RISK RATIO IS ESTIMATED ONLY IN THE SHORT TERM. THE RECOMMENDED INDICATIONS FOR DUAL MOBILITY CUP ARE: - PRIMARY ARTHROPLASTIES FOR PATIENTS AT HIGH RISK OF DISLOCATION (SEVERE NEUROLOGICAL AFICTION, NEUROPSYCHIATRIC DISORDERS, ADDICTIONS AND SEVERE NEUROMUSCULAR DEFICIENCIES), - REVISION ARTHROPLASTIES IN CASES OF RECURRENT DISLOCATIONS FOR PATIENTS AT HIGH RISK OF ARTICULAR INSTABILITY. THE TROCHANTERIC GRIP PLATE IS USED IN COMBINATION WITH THE PRIUS STEM AND CORTICAL SCREWS Ø 4.5MM (SEE SURGICAL TECHNIQUE) IN CASE OF: - FRACTURES OF THE TROCHANTERIC REGION FOLLOWING THE IMPLANTATION OF A FEMORAL STEM, - TROCHANTEROTOMY FOR IMPLANTATION OR REMOVAL OF A FEMORAL STEM (MAINTENANCE OF THE TROCHANTER OR FEMORAL COMPONENT). TREATMENT OF TROCHANTER PSEUDARTHROSIS AFTER PRIMARY PROSTHESIS OR REVISION PROSTHESIS. IN PRIMARY SURGERY OF THE HIP JOINT, AND EVEN MORE IN REVISION OR TUMORAL SURGERY, THE QUALITY OF THE BONE STOCK AND THE BONE DEFECTS DUE TO THE ABLATION OF ANY PREVIOUSLY IMPLANTED MATERIAL CAN COMPROMISE THE PRIMARY FIXATION OF THE IMPLANTABLE DEVICE AND THUS LIMIT ITS INDICATIONS. DEPENDING ON THE LOCATION AND THE EXTENSION OF THE BONE DEFECT, A LONGER CEMENTED OR CEMENTLESS FEMORAL COMPONENT INCLUDING A VARIETY OF COMPLEMENTARY FIXATION MEANS OR AN ACETABULAR COMPONENT INCLUDING PERIPHERAL ANGES AND HOOKS CAN BE CONSIDERED. ,CEMENTED DUAL MOBILITY CUP(CAPITOLE C)-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEMS OF THE HIP IN PATIENTS WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLER MEDICAMENTATION AND CORRECTLY FOLLOWED CONSERVATIVE TREATMENT HAVE FAILED. FOR THE PATIENT, THEIR ANATOMY AND THE STRUCTURE OF THEIR ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S). INDICATIONS FOR TOTAL OR PARTIAL HIP

	ARTHROPLASTY ARE: - DEGENERATIVE NON INAMMATORY HIP DISEASE (COXARTHROSIS, ARTHRITIS OF THE HIP). - INAMMATORY HIP DISEASE (RHEUMATOID ARTHRITIS, POST TRAUMATIC ARTHRITIS). - METABOLIC HIP DISEASE (CHONDROCALCINOSIS). - POST TRAUMATIC DEGENERATIVE ARTHRITIS. - AVASCULAR NECROSIS. - CONGENITAL DYSPLASIA OF THE HIP. - FUNCTIONAL REPAIR OF A RECENT TRAUMA (FRACTURE, DISLOCATION) - REVISION OF A FAILED CONSERVATIVE SURGERY, OSTEOSYNTHESIS, PARTIAL OR TOTAL ARTHROPLASTY. - TUMORAL SURGERY WHEN AFFECTING THE HIP JOINT. THE UN-COATED CEMENTLESS SAND-BLASTED VARIANT OF FEMORAL STEM IS INDICATED ONLY FOR THE TREATMENT OF THE FEMORAL NECK FRACTURE AT THE ELDERLY. ACCORDING TO THIS LIMIT OF INDICATION, ITS BENEFIT/RISK RATIO IS ESTIMATED ONLY IN THE SHORT TERM. THE RECOMMENDED INDICATIONS FOR DUAL MOBILITY CUP ARE: - PRIMARY ARTHROPLASTIES FOR PATIENTS AT HIGH RISK OF DISLOCATION (SEVERE NEUROLOGICAL AFICTION, NEUROPSYCHIATRIC DISORDERS, ADDICTIONS AND SEVERE NEUROMUSCULAR DEFICIENCIES), - REVISION ARTHROPLASTIES IN CASES OF RECURRENT DISLOCATIONS FOR PATIENTS AT HIGH RISK OF ARTICULAR INSTABILITY. THE TROCHANTERIC GRIP PLATE IS USED IN COMBINATION WITH THE PRIUS STEM AND CORTICAL SCREWS Ø 4.5MM (SEE SURGICAL TECHNIQUE) IN CASE OF: - FRACTURES OF THE TROCHANTERIC REGION FOLLOWING THE IMPLANTATION OF A FEMORAL STEM, - TROCHANTEROTOMY FOR IMPLANTATION OR REMOVAL OF A FEMORAL STEM (MAINTENANCE OF THE TROCHANTER OR FEMORAL COMPONENT). TREATMENT OF TROCHANTER PSEUDARTHROSIS AFTER PRIMARY PROSTHESIS OR REVISION PROSTHESIS. IN PRIMARY SURGERY OF THE HIP JOINT, AND EVEN MORE IN REVISION OR TUMORAL SURGERY, THE QUALITY OF THE BONE STOCK AND THE BONE DEFECTS DUE TO THE ABLATION OF ANY PREVIOUSLY IMPLANTED MATERIAL CAN COMPROMISE THE PRIMARY FIXATION OF THE IMPLANTABLE DEVICE AND THUS LIMIT ITS INDICATIONS. DEPENDING ON THE LOCATION AND THE EXTENSION OF THE BONE DEFECT, A LONGER CEMENTED OR CEMENTLESS FEMORAL COMPONENT INCLUDING A VARIETY OF COMPLEMENTARY FIXATION MEANS OR AN ACETABULAR COMPONENT INCLUDING PERIPHERAL ANGES AND HOOKS CAN BE CONSIDERED.,CAPITOLE T DUAL MOBILITY COATED CUP(NA)-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEMS OF THE HIP IN PATIENTS WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLER MEDICAMENTATION AND CORRECTLY FOLLOWED CONSERVATIVE TREATMENT HAVE FAILED. FOR THE

	PATIENT, THEIR ANATOMY AND THE STRUCTURE OF THEIR ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S). INDICATIONS FOR TOTAL OR PARTIAL HIP ARTHROPLASTY ARE: - DEGENERATIVE NON INAMMATORY HIP DISEASE (COXARTHROSIS, ARTHRITIS OF THE HIP). - INAMMATORY HIP DISEASE (RHEUMATOID ARTHRITIS, POST TRAUMATIC ARTHRITIS). - METABOLIC HIP DISEASE (CHONDROCALCINOSIS). - POST TRAUMATIC DEGENERATIVE ARTHRITIS. - AVASCULAR NECROSIS. - CONGENITAL DYSPLASIA OF THE HIP. - FUNCTIONAL REPAIR OF A RECENT TRAUMA (FRACTURE, DISLOCATION) - REVISION OF A FAILED CONSERVATIVE SURGERY, OSTEOSYNTHESIS, PARTIAL OR TOTAL ARTHROPLASTY. - TUMORAL SURGERY WHEN AFFECTING THE HIP JOINT. THE UN-COATED CEMENTLESS SAND-BLASTED VARIANT OF FEMORAL STEM IS INDICATED ONLY FOR THE TREATMENT OF THE FEMORAL NECK FRACTURE AT THE ELDERLY. ACCORDING TO THIS LIMIT OF INDICATION, ITS BENEFIT/RISK RATIO IS ESTIMATED ONLY IN THE SHORT TERM. THE RECOMMENDED INDICATIONS FOR DUAL MOBILITY CUP ARE: - PRIMARY ARTHROPLASTIES FOR PATIENTS AT HIGH RISK OF DISLOCATION (SEVERE NEUROLOGICAL AFICTION, NEUROPSYCHIATRIC DISORDERS, ADDICTIONS AND SEVERE NEUROMUSCULAR DEFICIENCIES), - REVISION ARTHROPLASTIES IN CASES OF RECURRENT DISLOCATIONS FOR PATIENTS AT HIGH RISK OF ARTICULAR INSTABILITY. THE TROCHANTERIC GRIP PLATE IS USED IN COMBINATION WITH THE PRIUS STEM AND CORTICAL SCREWS Ø 4.5MM (SEE SURGICAL TECHNIQUE) IN CASE OF: - FRACTURES OF THE TROCHANTERIC REGION FOLLOWING THE IMPLANTATION OF A FEMORAL STEM, - TROCHANTEROTOMY FOR IMPLANTATION OR REMOVAL OF A FEMORAL STEM (MAINTENANCE OF THE TROCHANTER OR FEMORAL COMPONENT). TREATMENT OF TROCHANTER PSEUDARTHROSIS AFTER PRIMARY PROSTHESIS OR REVISION PROSTHESIS. IN PRIMARY SURGERY OF THE HIP JOINT, AND EVEN MORE IN REVISION OR TUMORAL SURGERY, THE QUALITY OF THE BONE STOCK AND THE BONE DEFECTS DUE TO THE ABLATION OF ANY PREVIOUSLY IMPLANTED MATERIAL CAN COMPROMISE THE PRIMARY FIXATION OF THE IMPLANTABLE DEVICE AND THUS LIMIT ITS INDICATIONS. DEPENDING ON THE LOCATION AND THE EXTENSION OF THE BONE DEFECT, A LONGER CEMENTED OR CEMENTLESS FEMORAL COMPONENT INCLUDING A VARIETY OF COMPLEMENTARY FIXATION MEANS OR AN ACETABULAR COMPONENT INCLUDING PERIPHERAL ANGES AND HOOKS CAN BE CONSIDERED. ,JUST UNIC SHOULDER PROTHESIS(NA)-SHOULDER OSTEOSYNTHESIS IMPLANTABLE DEVICES ARE INDICATED FOR THE TREATMENT OF ACUTE AND FRESH TRAUMA OF THE PROXIMAL

	HUMERUS. THE JUST UNIC DEVICE IS INDICATED FOR NEER 3 AND 4 COMMINUTED FRACTURES OF THE PROXIMAL HUMERUS (3 OR 4 FRAGMENTS) IN OSTEOPOROTIC BONE FOR PATIENTS ABOVE 55 YEARS OLD, AND IN FRACTURE DISLOCATION CASES WITH AUTOLOGOUS BONE-GRAFT FOR PATIENTS UNDER 55 YEARS OLD. THE ANATOMY AND STRUCTURE OF THE PATIENT'S ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANTABLE DEVICE(S).,HACTIV FEMORAL STEM(NA)-HEMI AND TOTAL HIP ARTHROPLASTIES ARE INDICATED FOR THE TREATMENT OF SYMPTOMATIC PAIN AND/OR FUNCTIONAL PROBLEMS OF THE HIP IN PATIENTS WHOSE SKELETON IS MATURE AND ONLY WHEN PAIN KILLER MEDICAMENTATION AND CORRECTLY FOLLOWED CONSERVATIVE TREATMENT HAVE FAILED. FOR THE PATIENT, THEIR ANATOMY AND THE STRUCTURE OF THEIR ARTICULATION WILL NEED TO BE ADAPTED TO RECEIVE THE SELECTED IMPLANT(S). INDICATIONS FOR TOTAL OR PARTIAL HIP ARTHROPLASTY ARE: - DEGENERATIVE NON INAMMATORY HIP DISEASE (COXARTHROSIS, ARTHRITIS OF THE HIP). - INAMMATORY HIP DISEASE (RHEUMATOID ARTHRITIS, POST TRAUMATIC ARTHRITIS). - METABOLIC HIP DISEASE (CHONDROCALCINOSIS). - POST TRAUMATIC DEGENERATIVE ARTHRITIS. - AVASCULAR NECROSIS. - CONGENITAL DYSPLASIA OF THE HIP. - FUNCTIONAL REPAIR OF A RECENT TRAUMA (FRACTURE, DISLOCATION) - REVISION OF A FAILED CONSERVATIVE SURGERY, OSTEOSYNTHESIS, PARTIAL OR TOTAL ARTHROPLASTY. - TUMORAL SURGERY WHEN AFFECTING THE HIP JOINT. THE UN-COATED CEMENTLESS SAND-BLASTED VARIANT OF FEMORAL STEM IS INDICATED ONLY FOR THE TREATMENT OF THE FEMORAL NECK FRACTURE AT THE ELDERLY. ACCORDING TO THIS LIMIT OF INDICATION, ITS BENEFIT/RISK RATIO IS ESTIMATED ONLY IN THE SHORT TERM. THE RECOMMENDED INDICATIONS FOR DUAL MOBILITY CUP ARE: - PRIMARY ARTHROPLASTIES FOR PATIENTS AT HIGH RISK OF DISLOCATION (SEVERE NEUROLOGICAL AFICTION, NEUROPSYCHIATRIC DISORDERS, ADDICTIONS AND SEVERE NEUROMUSCULAR DEFICIENCIES), - REVISION ARTHROPLASTIES IN CASES OF RECURRENT DISLOCATIONS FOR PATIENTS AT HIGH RISK OF ARTICULAR INSTABILITY. THE TROCHANTERIC GRIP PLATE IS USED IN COMBINATION WITH THE PRIUS STEM AND CORTICAL SCREWS Ø 4.5MM (SEE SURGICAL TECHNIQUE) IN CASE OF: - FRACTURES OF THE TROCHANTERIC REGION FOLLOWING THE IMPLANTATION OF A FEMORAL STEM, - TROCHANTEROTOMY FOR IMPLANTATION OR REMOVAL OF A FEMORAL STEM (MAINTENANCE OF THE TROCHANTER OR FEMORAL COMPONENT). TREATMENT OF TROCHANTER PSEUDARTHROSIS AFTER PRIMARY PROSTHESIS OR REVISION PROSTHESIS. IN PRIMARY SURGERY OF THE HIP JOINT,

		AND EVEN MORE IN REVISION OR TUMORAL SURGERY, THE QUALITY OF THE BONE STOCK AND THE BONE DEFECTS DUE TO THE ABLATION OF ANY PREVIOUSLY IMPLANTED MATERIAL CAN COMPROMISE THE PRIMARY FIXATION OF THE IMPLANTABLE DEVICE AND THUS LIMIT ITS INDICATIONS. DEPENDING ON THE LOCATION AND THE EXTENSION OF THE BONE DEFECT, A LONGER CEMENTED OR CEMENTLESS FEMORAL COMPONENT INCLUDING A VARIETY OF COMPLEMENTARY FIXATION MEANS OR AN ACETABULAR COMPONENT INCLUDING PERIPHERAL ANGES AND HOOKS CAN BE CONSIDERED.
2373	IMP/MD/2020/000545	1.License Holder Name: COLOPLAST INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERISTOMAL/ PERIWOUND DRESSING - POWDER(BRAVA)-BRAVA POWDER IS INTENDED FOR MOISTURE ABSORPTION ON INTACT PERISTOMAL SKIN.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2374	IMP/MD/2020/000546	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERSONA PARTIAL KNEE (PPK) SYSTEM(PERSONA PARTIAL KNEE (PPK) SYSTEM - TIBIAL)-THE PERSONA PARTIAL KNEE SYSTEM IS LIMITED TO THE MEDIAL TIBIOFEMORAL COMPARTMENT OF THE KNEE INTENDED FOR PATIENTS WITH PAINFUL AND/OR DISABLING KNEE JOINTS DUE TO THE FOLLOWING INDICATIONS: NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G., OSTEOARTHRITIS, AVASCULAR NECROSIS; TRAUMATIC ARTHRITIS; PREVIOUS TIBIAL CONDYLE OR PLATEAU FRACTURES WITH LOSS OF ANATOMY OR FUNCTION; VARUS DEFORMITIES; AND REVISION OF THE ARTICULAR SURFACE OF A PREVIOUSLY IMPLANTED PERSONA PARTIAL KNEE SYSTEM PROVIDING THAT THE TIBIAL PLATE LOCKING MECHANISM IS NOT COMPROMISED AND THE FEMORAL AND TIBIAL PLATE COMPONENTS REMAIN WELL FIXED AND UNDAMAGED. THE PERSONA PARTIAL KNEE SYSTEM IS A SINGLE USE IMPLANT INTENDED FOR IMPLANTATION WITH BONE CEMENT. INDICATIONS FOR COMBINED PERSONA PARTIAL KNEE SYSTEM AND ZIMMER GENDER SOLUTIONS PATELLO-FEMORAL JOINT (PFJ): OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS, AND/OR SEVERE CHONDROCALCINOSIS OF THE PATELLOFEMORAL JOINT. THE SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS (E.G., ARTHROSCOPY, LATERAL RELEASE, CARTILAGE TRANSPLANTATION). HISTORY OF PATELLAR DISLOCATION OR PATELLA FRACTURE. DYSPLASIA-INDUCED DEGENERATION. THESE INDICATIONS WILL BE USED FOR THE COMBINED MEDIAL UNICOMPARTMENTAL AND PATELLO-FEMORAL IMPLANT DEVICE, WHEREBY A SINGLE CONDYLE AND PATELLO-FEMORAL REGIONS HAVE BEEN AFFECTED BY ONE OR MORE OF THESE CONDITIONS. COMBINED PERSONA PARTIAL KNEE SYSTEM AND ZIMMER GENDER SOLUTIONS PATELLO-FEMORAL JOINT (PFJ) IMPLANTS ARE INTENDED FOR IMPLANTATION WITH BONE CEMENT.

2375	IMP/MD/2020/000547	1.License Holder Name: TUOREN MEDICAL DEVICE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:I.V. CANNULA(TUOREN)-TO MEET THE NEEDS OF THE LONG TIME CONTINUOUS OR INTERMITTENT INFUSION.,ENDOTRACHEAL INTUBATION KIT (TUOREN)-USED FOR THE PATIENTS WHO NEED IMPLEMENT TRACHEAL CANNULA TO MAKE THE MECHANICAL VENTILATION WHEN IMPLEMENTING THE OPERATION,GUEDEL AIRWAY(TUOREN)-IT IS MAINLY USED BY HUMAN TO MAINTAIN THE SMOOTH OF OROPHARYNGEAL RESPIRATORY TRACT.,DISPOSABLE PRESSURE TRANSDUCER(TUOREN)-MAINLY USED IN THE DEPARTMENT OF ANESTHESIOLOGY, INTRACARDIAC AND CARDIAC SURGERY AND OTHER MEDICAL DEPARTMENTS, THIS PRODUCT IS USED FOR THE PATIENT'S ARTERIAL PRESSURE, CENTRAL VENOUS PRESSURE MONITORING, A DIRECT ACCESS TO THE PHYSIOLOGICAL PARAMETERS OF BLOOD PRESSURE CAN PROVIDE AN OBJECTIVE BASIS FOR CLINICAL DIAGNOSIS, TREATMENT AND PROGNOSIS OF THE DISEASE.
2376	IMP/MD/2020/000548	1.License Holder Name: M/S CELERA PHARMA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PEN INJECTOR(D-MINE PEN)-PEN INJECTOR IS USED BY SELF INJECTING ADULT PATIENTS, HEALTHCARE PROFESSIONAL FOR DELIVERY OF DRUG APOMORPHINE HYDROCHLORIDE MEDICATION USED TO TREAT PARKINSON'S DISEASE
2377	IMP/MD/2020/000549	1.License Holder Name: MYOVATEC SURGICAL SYSTEMS LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OSTEOPORE PCL SCAFFOLD BONE FILLER(OSTEOMESH, OSTEOPLUG, OSTEOPLUG-C, OSTEOMESH-OSTEOSTRIP)-THE OSTEOPORE PCL SCAFFOLD BONE FILLERIS BONE VOID FILLER. IT IS INTENDED FOR USE IN THE REPAIR OF NEUROSURGICAL BURR HOLES, CRANIOTOMY CUTS AND OTHER CRANIAL DEFECTS. IT IS ALSO FOR USE IN THE AUGMENTATION OR RESTORATION OF BONY CONTOUR IN THE CRANIOFACIAL SKELETON. THIS INCLUDES RHINOPLASTY, WHICH IS THE AUGMENTATION OF BONY CONTOUR IN THE NASAL REGION. IT IS ALSO INTENDED FOR DENTAL PURPOSES; FOR USE IN THE FILING AND/OR AUGMENTING INTRAORAL OSSEOUS DEFECTS, SUCH AS FILLING OF TOOTH EXTRACTION SITES.

2378	IMP/MD/2020/000552	1.License Holder Name: CLINIEXPERTS SERVICES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BOVINE PERICARDIAL TISSUE PATCH-TISGENX'S BOVINE PERICARDIAL TISSUE PATCH IS INTENDED FOR USE AS A SURGICAL PATCH FOR CARDIAC AND VASCULAR RECONSTRUCTION AND REPAIR, SOFT TISSUE DEFICIENCY REPAIR, AND REINFORCING THE SUTURE LINE DURING GENERAL SURGICAL PROCEDURES.
2379	IMP/MD/2020/000554	1.License Holder Name: OLYMPUS MEDICAL SYSTEMS INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ASPIRATION NEEDLE (VIZISHOT 2 FLEX)-THIS VIZISHOT 2 FLEX HAS BEEN DESIGNED TO BE USED WITH AN OLYMPUS ULTRASOUND ENDOSCOPE FOR ULTRASONIC GUIDE FINE NEEDLE ASPIRATION (FNA) AND FINE NEEDLE BIOPSY (FNB) OF SUBMUCOSAL AND EXTRAMURAL LESIONS OF THE TRACHEOBRONCHIAL TREE.,GENERATOR AND TRANSDUCER (SHOCKPULSE-SE LITHOTRIPSY SYSTEM- SHOCKPULSE-SE LITHOTRIPSY GENERATOR AND SHOCKPULSE-SE LITHOTRIPSY TRANSDUCER)-THE SHOCKPULSE-SE LITHOTRIPSY SYSTEM IS INTENDED TO BE USED FOR FRAGMENTATION OF URINARY TRACT CALCULI IN THE KIDNEY, URETER, AND BLADDER.,PROBE (SHOCKPULSE-SE LITHOTRIPSY PROBE, REUSABLE)-THE SHOCKPULSE-SE LITHOTRIPSY SYSTEM IS INTENDED TO BE USED FOR FRAGMENTATION OF URINARY TRACT CALCULI IN THE KIDNEY, URETER, AND BLADDER.,PROBE(SHOCKPULSE-SE LITHOTRIPSY PROBE, STERILE SINGLE USE)-THE SHOCKPULSE-SE LITHOTRIPSY SYSTEM IS INTENDED TO BE USED FOR FRAGMENTATION OF URINARY TRACT CALCULI IN THE KIDNEY, URETER, AND BLADDER.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2380	IMP/MD/2020/000556	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:KNEE REPLACEMENT SYSTEM-TIBIAL WEDGE(PFC)-THE P.F.C MODULAR PLUS TIBIAL WEDGES AND P.F.C SIGMA FEMORAL AUGMENTS ARE INDICATED FOR USE AS A TOTAL KNEE REPLACEMENT FOR PATIENTS SUFFERING FROM SEVERE PAIN AND DISABILITY DUE TO PERMANENT STRUCTURAL DAMAGE RESULTING FROM RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, POST- TRAUMATIC ARTHRITIS, COLLAGEN DISORDERS OR PSEUDOGOUT. THIS DAMAGE MAY ALSO BE THE RESULT OF TRAUMA OR FAILED PRIOR SURGICAL INTERVENTION. CHOICE OF SPECIFIC FEMORAL AND TIBIAL COMPONENTS WILL DEPEND UPON WHETHER THE POSTERIOR CRUCIATE LIGAMENT IS RETAINED OR EXCISED, THE EXTENT AND NATURE OF ANTERIOR/ POSTERIOR ANS MEDIAL/LATERAL STABILIZATION, THE FEMORAL AND / OR TIBIAL AURMENTATION REQUIRED, AND THE NEED FOR ENHANCED MECHANICAL FIXATION PROVIDED BY FEMORAL AND TIBIAL STEMS OR FLUTED RODS. COMPONENTS ARE INDICATED FOR USE ONLY WITH POYMETHYLMETHACRYLATE(PMMA) BONE CEMENT. THE P.F.C TIBIAL WEDGE IS INDICATED TO PROVIDE AUGMENTATION OF TIBIAL PLATEAU WITH BONY DEFECTS.,KNEE REPLACEMENT SYSTEM-TIBIAL INSERT(PFC SIGMA FB)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-FEMORAL(SIGMA PS)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION

	FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-TIBIAL INSERT(PFC SIGMNA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-TBIAL INSERT(LPS)-THE DEPUY LPS SYSTEM IS INTENDED FOR USE IN REPLACEMENT OF THE MID-SHAFT PORTION OF THE FEMUR, PROXIMAL, DISTAL AND/OR TOTAL FEMUR, AND PROXIMAL TIBIA, ESPECIALLY IN CASES THAT REQUIRE EXTENSIVE RESECTION AND REPLACEMENT. SPECIFIC DIAGNOSTIC INDICATIONS FOR USE INCLUDE: • MALIGNANT TUMORS (E.G., OSTEOSARCOMAS, CHONDROSARCOMAS, GIANT CELL TUMORS, BONE TUMORS) REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; • PATIENT CONDITIONS OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD), E.G. AVASCULAR NECROSIS, OSTEOARTHRITIS, AND INFLAMMATORY JOINT DISEASE (IJD), E.G., RHEUMATOID ARTHRITIS, REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; • REVISION CASES FOR A FAILED PREVIOUS PROSTHESIS REQUIRING EXTENSIVE RESECTION AND REPLACEMENT; • SEVERE TRAUMA REQUIRING EXTENSIVE RESECTION AND REPLACEMENT. THE LPS SYSTEM IS ALSO INTENDED FOR USE IN BONE LOSS POST-INFECTION, WHERE THE SURGEON HAS ELECTED TO EXCISE THE BONE AND REPLACEMENT IS REQUIRED. THE S-ROM TIBIAL TRAY AND THE NON-POROUS COATED STRAIGHT AND BOWED STEMS ARE INTENDED FOR CEMENTED USE ONLY. THE POROUS-COATED METAPHYSEAL SLEEVES ARE INTENDED FOR EITHER CEMENTED OR CEMENTLESS APPLICATIONS.,KNEE REPLACEMENT SYSTEM-FEMORAL(SIGMA CR)-

	TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-ROTATING HINGE DISTAL FEMORAL AUGMENT(S-ROM NOILES)-THE NOILES ROTATING HINGE KNEE IS INDICATED FOR USE WITH PMMA BONE CEMENT IN PRIMARY OR REVISION CASES IN PATIENTS: • WHO HAVE REACHED SKELETAL MATURITY AND • FOR WHOM THE SURGEON HAS DECIDED TO RESECT BOTH CRUCIATE LIGAMENTS OR WHOSE CRUCIATE LIGAMENTS ARE ABSENT OR INCOMPETENT AND • WHO EXHIBIT INSUFFICIENCY OF LATERAL/COLLATERAL LIGAMENTS AND OTHER SOFT SUPPORTING TISSUE DUE TO THE FOLLOWING CONDITIONS: O RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, AND ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES O FAILURE OF A PREVIOUS KNEE RECONSTRUCTION PROCEDURE O TRAUMA,KNEE REPLACEMENT SYSTEM-FEMORAL(PFC SIGMA CS)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-AUGMENT(PFC SIGMA)-THE P.F.C MODULAR PLUS TIBIAL WEDGES AND P.F.C SIGMA FEMORAL AUGMENTS ARE

	INDICATED FOR USE AS A TOTAL KNEE REPLACEMENT FOR PATIENTS SUFFERING FROM SEVERE PAIN AND DISABILITY DUE TO PERMANENT STRUCTURAL DAMAGE RESULTING FROM RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, POST- TRAUMATIC ARTHRITIS, COLLAGEN DISORDERS OR PSEUDOGOUT. THIS DAMAGE MAY ALSO BE THE RESULT OF TRAUMA OR FAILED PRIOR SURGICAL INTERVENTION. CHOICE OF SPECIFIC FEMORAL AND TIBIAL COMPONENTS WILL DEPEND UPON WHETHER THE POSTERIOR CRUCIATE LIGAMENT IS RETAINED OR EXCISED, THE EXTENT AND NATURE OF ANTERIOR/ POSTERIOR ANS MEDIAL/LATERAL STABILIZATION, THE FEMORAL AND / OR TIBIAL AURMENTATION REQUIRED, AND THE NEED FOR ENHANCED MECHANICAL FIXATION PROVIDED BY FEMORAL AND TIBIAL STEMS OR FLUTED RODS. COMPONENTS ARE INDICATED FOR USE ONLY WITH POYMETHYLMETHACRYLATE(PMMA) BONE CEMENT. THE P.F.C TIBIAL WEDGE IS INDICATED TO PROVIDE AUGMENTATION OF TIBIAL PLATEAU WITH BONY DEFECTS.,KNEE REPLACEMENT SYSTEM-FEMORAL STEM BOLT(PFC SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-TIBIAL TRAY(PFC SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN

	IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-TIBIAL INSERT(PFC SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-ROD(PFC SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-TIBIAL TRAY(PFC)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED

	PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-TIBIAL COMPONENT(PFC SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,BONE SCREW-SCREW(CANCELLOUS BONE SCREWS)-DEPUY BONE SCREWS ARE INDICATED FOR USE AS AN ANCILLARY FIXATION DEVICE TO BE USED WITH TIBIAL AND ACETABULAR COMPONENTS IN TOTAL KNEE AND HIP ARTHROPLASTY.,KNEE REPLACEMENT SYSTEM-FEMORAL (SIGMA)-THE DEPUY SIGMA HIGH PERFORMANCE PARTIAL KNEE SYSTEM IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS.,KNEE REPLACEMENT SYSTEM-FEMORAL STEM(PFC SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-TIBIAL INSERT(SIGMA RP)-INDICATIONS FOR

	USE WITH CEMENT THE LCS® COMPLETE™ – P.F.C.® SIGMA® RP MOBILE BEARING TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE RPF AND RPS INSERTS AND FEMORAL COMPONENTS ARE INDICATED WHERE A HIGHER THAN NORMAL DEGREE OF POST-OPERATIVE FLEXION IS REQUIRED. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES. INDICATIONS FOR USE WITHOUT CEMENT THE POROUS COATED KEELED AND NON KEELED M.B.T.™ (MOBILE BEARING TIBIAL) TRAY CONFIGURATIONS OF THE LCS TOTAL KNEE SYSTEM ARE INDICATED FOR NONCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR RECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE ROTATING PLATFORM DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE ABSENT OR ARE IN SUCH CONDITION AS TO JUSTIFY THEIR SACRIFICE. THE P.F.C. SIGMA RP CURVED BEARINGS WHEN USED WITH THE P.F.C. SIGMA CRUCIATE RETAINING FEMORAL COMPONENT CAN BE USED IN POSTERIOR CRUCIATE LIGAMENT RETAINING PROCEDURES.,KNEE REPLACEMENT SYSTEM-TIBIAL TRAY(SIGMA)-THE DEPUY SIGMA HIGH PERFORMANCE PARTIAL KNEE SYSTEM IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS.,KNEE REPLACEMENT SYSTEM-TIBIAL INSERT(LCS)-INDICATIONS FOR USE WITH CEMENT THE LCS® COMPLETE™ – P.F.C. ® SIGMA® RP MOBILE BEARING TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASES OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE RPF AND RPS INSERTS AND FEMORAL COMPONENTS ARE INDICATED WHERE A HIGHER THAN NORMAL DEGREE OF POST-OPERATIVE FLEXION IS REQUIRED. THE ROTATING PLATFORM PROSTHESIS AND MODULAR REVISION COMPONENTS ARE INDICATED FOR REVISION OF FAILED KNEE PROSTHESES. INDICATIONS FOR USE WITHOUT CEMENT THE POROUS COATED KEELED AND NON KEELED M.B.T.™ (MOBILE BEARING TIBIAL) TRAY CONFIGURATIONS OF THE LCS TOTAL KNEE SYSTEM ARE INDICATED FOR NONCEMENTED USE IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR RECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSES

	OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE ROTATING PLATFORM DEVICE CONFIGURATION IS INDICATED FOR USE IN KNEES WHOSE ANTERIOR AND POSTERIOR CRUCIATE LIGAMENTS ARE ABSENT OR ARE IN SUCH CONDITION AS TO JUSTIFY THEIR SACRIFICE. THE P.F.C. SIGMA RP CURVED BEARINGS WHEN USED WITH THE P.F.C. SIGMA CRUCIATE RETAINING FEMORAL COMPONENT CAN BE USED IN POSTERIOR CRUCIATE LIGAMENT RETAINING PROCEDURES.,KNEE REPLACEMENT SYSTEM-TIBIAL COMPONENT(PFC SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-STEM(PFC SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-FEMORAL ROTATING HINGE(S-ROM NOILES)-THE NOILES ROTATING HINGE KNEE IS INDICATED FOR USE WITH PMMA BONE CEMENT IN PRIMARY OR REVISION CASES IN PATIENTS: • WHO HAVE REACHED SKELETAL MATURITY AND • FOR WHOM THE SURGEON HAS DECIDED TO RESECT BOTH CRUCIATE LIGAMENTS OR WHOSE CRUCIATE LIGAMENTS ARE ABSENT OR INCOMPETENT AND •

	WHO EXHIBIT INSUFFICIENCY OF LATERAL/COLLATERAL LIGAMENTS AND OTHER SOFT SUPPORTING TISSUE DUE TO THE FOLLOWING CONDITIONS: O RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, AND ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES O FAILURE OF A PREVIOUS KNEE RECONSTRUCTION PROCEDURE O TRAUMA,KNEE REPLACEMENT SYSTEM-FEMORAL(SIGMA CR)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,BONE SCREW-SCREW(SOLUTION SYSTEM)-DEPUY BONE SCREWS ARE INDICATED FOR USE AS AN ANCILLARY FIXATION DEVICE TO BE USED WITH TIBIAL AND ACETABULAR COMPONENTS IN TOTAL KNEE AND HIP ARTHROPLASTY.,KNEE REPLACEMENT SYSTEM-STEM(PFC)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.,KNEE REPLACEMENT SYSTEM-FEMORAL(SIGMA)-TOTAL OR UNICOMPARTMENTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT

	AND SUPPORT THE COMPONENTS. TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL OR UNICOMPARTMENTAL KNEE REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES.

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2381	IMP/MD/2020/000557	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STEERABLE GUIDEWIRE (THUNDER)-IT IS USED FOR THE INTRODUCTION AND PLACEMENT OF DIAGNOSTIC OR INTERVENTIONAL DEVICES IN THE CORONARY AND PERIPHERAL VASCULATURE, AND MAY BE USED TO REACH AND CROSS A TARGET LESION. MEDTRONIC GUIDE WIRES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE. MEDTRONIC STEERABLE EXCHANGE GUIDE WIRES ARE USED TO FACILITATE THE SUBSTITUTION OF ONE DIAGNOSTIC OR INTERVENTIONAL DEVICE FOR ANOTHER.,STEERABLE GUIDEWIRE(PROVIA)-IT IS USED FOR THE INTRODUCTION AND PLACEMENT OF DIAGNOSTIC OR INTERVENTIONAL DEVICES IN THE CORONARY AND PERIPHERAL VASCULATURE, AND MAY BE USED TO REACH AND CROSS A TARGET LESION. MEDTRONIC GUIDE WIRES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE. MEDTRONIC STEERABLE EXCHANGE GUIDE WIRES ARE USED TO FACILITATE THE SUBSTITUTION OF ONE DIAGNOSTIC OR INTERVENTIONAL DEVICE FOR ANOTHER., STEERABLE GUIDEWIRE(COUGAR LS)-IT IS USED FOR THE INTRODUCTION AND PLACEMENT OF DIAGNOSTIC OR INTERVENTIONAL DEVICES IN THE CORONARY AND PERIPHERAL VASCULATURE, AND MAY BE USED TO REACH AND CROSS A TARGET LESION. MEDTRONIC GUIDE WIRES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE. MEDTRONIC STEERABLE EXCHANGE GUIDE WIRES ARE USED TO FACILITATE THE SUBSTITUTION OF ONE DIAGNOSTIC OR INTERVENTIONAL DEVICE FOR ANOTHER., STEERABLE GUIDEWIRE(COUGAR XT)-IT IS USED FOR THE INTRODUCTION AND PLACEMENT OF DIAGNOSTIC OR INTERVENTIONAL DEVICES IN THE CORONARY AND PERIPHERAL VASCULATURE, AND MAY BE USED TO REACH AND CROSS A TARGET LESION. MEDTRONIC GUIDE WIRES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE. MEDTRONIC STEERABLE EXCHANGE GUIDE WIRES ARE USED TO FACILITATE THE SUBSTITUTION OF ONE DIAGNOSTIC OR INTERVENTIONAL DEVICE FOR ANOTHER., STEERABLE GUIDEWIRE(INTUITION)-IT IS USED FOR THE INTRODUCTION AND PLACEMENT OF DIAGNOSTIC OR INTERVENTIONAL DEVICES IN THE CORONARY AND PERIPHERAL VASCULATURE, AND MAY BE USED TO REACH AND CROSS A TARGET LESION. MEDTRONIC GUIDE WIRES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE. MEDTRONIC STEERABLE EXCHANGE GUIDE WIRES ARE USED TO FACILITATE THE SUBSTITUTION OF ONE DIAGNOSTIC OR INTERVENTIONAL DEVICE FOR ANOTHER., STEERABLE GUIDEWIRE(ZINGER)-IT IS USED FOR THE INTRODUCTION AND PLACEMENT OF DIAGNOSTIC OR INTERVENTIONAL DEVICES IN

		THE CORONARY AND PERIPHERAL VASCULATURE, AND MAY BE USED TO REACH AND CROSS A TARGET LESION. MEDTRONIC GUIDE WIRES ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE. MEDTRONIC STEERABLE EXCHANGE GUIDE WIRES ARE USED TO FACILITATE THE SUBSTITUTION OF ONE DIAGNOSTIC OR INTERVENTIONAL DEVICE FOR ANOTHER.
2382	IMP/MD/2020/000558	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHOPAEDIC CANNULA (CLEAR CANNULA)-DESIGNED FOR GENERAL ARTHROSCOPIC SURGICAL USE TO MAINTAIN PORTALS DURING INSERTION OR EXTRACTION OF INSTRUMENTS.
2383	IMP/MD/2020/000559	1.License Holder Name: NORIS MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL ABUTMENTS-INTENDED TO ATTACH CROWNS , BRIDGES OR REMOVABLE DENTURES TO THE DENTAL IMPLANTS. ALL ABUTMENTS ARE INTENDED FOR SINGLE USE,DENTAL IMPLANTS SYSTEM-DENTAL IMPLANT SYSTEMS ARE INTENDED TO REPLACE MISSING TOOTH/TEETH IN EITHER JAW FOR SUPPORTING PROSTHETIC DEVICES THAT MAY AID IN RESTORING THE PATIENT'S CHEWING FUNCTION. THE PROCEDURE CAN BE ACCOMPLISHED IN A ONE-STAGE OR TWO-STAGE SURGICAL OPERATION. ALL IMPLANTS ARE APPROPRIATE FOR IMMEDIATE LOADING WHEN GOOD PRIMARY STABILITY IS ACHIEVED AND WITH APPROPRIATE OCCLUSAL LOADING
2384	IMP/MD/2020/000560	1.License Holder Name: M/S. TERUMO INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:60938 - EMBOLIZATION PARTICLE, NON-BIOABSORBABLE(LIFEPEARL™ MICROSPHERES)-LIFEPEARL MICROSPHERES ARE INDICATED FOR EMBOLIZATION OF BLOOD VESSELS SUPPLYING PRIMARY HYPERVASCULAR TUMORS OR METASTASES IN THE LIVER. NOTE: LIFEPEARL CAN BE LOADED WITH CHEMOTHERAPEUTIC DRUGS. WHEN USED FOR DRUG LOADING, DRUG LOADING SHOULD BE DONE UNDER A PHYSICIAN'S DIRECTION, CHOICE AND RESPONSIBILITY, BASED ON TYPE AND DOSE OF DRUG MOST BENEFICIAL TO THE PATIENT

2385	IMP/MD/2020/000562	1.License Holder Name: MEDIZONE AESTHETICS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE SINGLE USE POLYDIOXANONE SUTURE WITH NEEDLE(BIO-MEYISUN)-IT IS INTENDED TO FIXATE SUBDERMAL TISSUE IN ELEVATED POSITION IN PLASTIC AND RECONSTRUCTIVE SURGERY. POLYDIOXANONE SUTURE PROVIDES WOUND SUPPORT FOR LONGER PERIOD COMPARED TO OTHER SYNTHETIC ABSORBABLE SUTURES. IT ALSO PROLONGS STIMULATION THAT INCREASES TREATMENT EFFECTS ON THE BODY

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2386	IMP/MD/2020/000565	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ELECTROPHYSIOLOGY CATHETER(LASSO NAV ECO CATHETER (NAV))-THE LASSO™ NAV ECO CATHETER IS INDICATED FOR MULTIPLE ELECTRODE ELECTROPHYSIOLOGICAL MAPPING OF THE CARDIAC STRUCTURES OF THE HEART, I.E. RECORDING OR STIMULATION ONLY. THIS CATHETER IS DESIGNED TO OBTAIN ELECTROGRAMS IN THE ATRIAL REGIONS OF THE HEART.,ELECTROPHYSIOLOGY CATHETER (WEBSTER WITH AUTO ID ELECTROPHYSIOLOGY CATHETER (NON-NAV))-THE CATHETER IS INDICATED FOR ELECTROPHYSIOLOGICAL MAPPING OF CARDIAC STRUCTURES; I.E., STIMULATION AND RECORDING ONLY.,ELECTROPHYSIOLOGY CATHETER(EZ STEER THERMOCOOL BI-DIRECTIONAL ELECTROPHYSIOLOGY CATHETER (NON-NAV))-THE BIOSENSE WEBSTER EZ STEER™ THERMOCOOL® DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETER AND RELATED ACCESSORIES ARE INDICATED FOR USE IN CATHETER-BASED CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATING AND RECORDING) AND, WHEN USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION., ELECTROPHYSIOLOGY CATHETER(WEBSTER)-THE BIOSENSE WEBSTER DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETER IS INDICATED FOR CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATION AND RECORDING) AND, WHEN USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION, ELECTROPHYSIOLOGY CATHETER(THERMOCOOL SMARTTOUCH UNI-DIRECTIONAL NAVIGATIONAL CATHETER (NAV))-THE BIOSENSE WEBSTER THERMOCOOL SMARTTOUCH™ UNI-DIRECTIONAL NAVIGATION CATHETER IS INDICATED FOR USE IN CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATION AND RECORDING) AND, WHEN USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION. THE BIOSENSE WEBSTER THERMOCOOL SMARTTOUCH™ UNI-DIRECTIONAL NAVIGATION CATHETER PROVIDES A REAL-TIME MEASUREMENT OF CONTACT FORCE BETWEEN THE CATHETER TIP AND HEART WALL, AS WELL AS LOCATION INFORMATION WHEN USED WITH CARTO™ 3 NAVIGATION SYSTEM,ELECTROPHYSIOLOGY CATHETERS(WEBSTER WITH AUTO ID ELECTROPHYSIOLOGY CATHETER)-THE CATHETER IS INDICATED FOR ELECTROPHYSIOLOGICAL MAPPING OF CARDIAC STRUCTURES; I.E., STIMULATION AND RECORDING ONLY.,ELECTROPHYSIOLOGY CATHETERS(WEBSTER ELECTROPHYSIOLOGY CATHETER (NON-NAV)) -THE CATHETER IS INDICATED FOR ELECTROPHYSIOLOGICAL MAPPING OF CARDIAC STRUCTURES; I.E., STIMULATION AND RECORDING ONLY. IN ADDITION, THE FIXED ORTHOGONAL CATHETER

	IS DESIGNED FOR USE IN THE CORONARY SINUS., ELECTROPHYSIOLOGY CATHETER(EZ STEER BI-DIRECTIONAL ELECTROPHYSIOLOGY CATHETER (NON-NAV))-THE BIOSENSE WEBSTER EZ STEER™ BI-DIRECTIONAL AND EZ STEER™ DS BI-DIRECTIONAL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS ARE INDICATED FOR CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATION AND RECORDING) AND, WHEN USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION.,ELECTROPHYSIOLOGY CATHETER(HALO XP ELECTROPHYSIOLOGY CATHETER (NON-NAV))-THE CATHETER IS INDICATED FOR ELECTROPHYSIOLOGICAL MAPPING OF CARDIAC STRUCTURES; I.E., STIMULATION AND RECORDING ONLY. IN ADDITION, THE HALO® XP AND HALO® CATHETERS' PREFORMED HALO SHAPE OF THE TIP SECTION IS DESIGNED SPECIFICALLY FOR THE TRICUSPID ANNULUS.,ELECTROPHYSIOLOGY CATHETER(EZ STEER NAV DS BI-DIRECTIONAL ELECTROPHYSIOLOGY CATHETER (NAV))-THE BIOSENSE WEBSTER EZ STEER™ NAV BI-DIRECTIONAL AND EZ STEER™ NAV DS BI-DIRECTIONAL CATHETERS ARE INDICATED FOR CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATION AND RECORDING) AND, WHEN USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION.,ELECTROPHYSIOLOGY CATHETER(LASSO VARIABLE CIRCULAR MAPPING CATHETER (NON-NAV))-THE CATHETER IS INDICATED FOR MULTIPLE ELECTRODE ELECTROPHYSIOLOGICAL MAPPING OF THE CARDIAC STRUCTURES OF THE HEART, I.E. RECORDING OR STIMULATION ONLY. THE LASSO™ 2515 VARIABLE CIRCULAR MAPPING CATHETER IS DESIGNED TO OBTAIN ELECTROGRAMS IN THE ATRIAL REGION OF THE HEART.,ELECTROPHYSIOLOGY CATHETER(THERMOCOOL SMARTTOUCH BI-DIRECTIONAL NAVIGATION CATHETER (NAV))-THE BIOSENSE WEBSTER THERMOCOOL SMARTTOUCH™ BI-DIRECTIONAL NAVIGATION CATHETER AND RELATED ACCESSORIES ARE INDICATED FOR CATHETER-BASED CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATING AND RECORDING) AND, WHEN USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION. THE THERMOCOOL SMARTTOUCH™ BI-DIRECTIONAL NAVIGATION CATHETER PROVIDES A REAL-TIME MEASUREMENT OF CONTACT FORCE BETWEEN THE CATHETER TIP AND HEART WALL, AS WELL AS LOCATION INFORMATION WHEN USED WITH CARTO™ 3 NAVIGATION SYSTEM.,ELECTROPHYSIOLOGY CATHETER(LASSO ELECTROPHYSIOLOGY CATHETER WITH AUTO ID (NON-NAV))-THE CATHETER IS INDICATED FOR MULTIPLE ELECTRODE ELECTROPHYSIOLOGICAL MAPPING THE CARDIAC STRUCTURES OF THE HEART, I.E. RECORDING OR STIMULATION ONLY. THE BIOSENSE

	WEBSTER LASSO™ CIRCULAR MAPPING CATHETER IS DESIGNED TO OBTAIN ELECTROGRAMS IN THE ATRIAL REGION OF THE HEART., ELECTROPHYSIOLOGY CATHETER(LASSO ELECTROPHYSIOLOGY CATHETER (NON-NAV))-THE CATHETER IS INDICATED FOR MULTIPLE ELECTRODE ELECTROPHYSIOLOGICAL MAPPING THE CARDIAC STRUCTURES OF THE HEART, I.E. RECORDING OR STIMULATION ONLY. THE BIOSENSE WEBSTER LASSO® CIRCULAR MAPPING CATHETER IS DESIGNED TO OBTAIN ELECTROGRAMS IN THE ATRIAL REGION OF THE HEART.,ELECTROPHYSIOLOGY CATHETER(NAVISTAR THERMOCOOL ELECTROPHYSIOLOGY CATHETER (NAV))-THE BIOSENSE WEBSTER NAVISTAR® THERMOCOOL® DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETER IS INDICATED FOR USE IN CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATION AND RECORDING) AND, WHEN USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION., ELECTROPHYSIOLOGICAL CATHETER(PENTARAY HIGH DENSITY MAPPING CATHETER (NAV))-THE BIOSENSE WEBSTER PENTARAY™ NAV ECO HIGH-DENSITY MAPPING CATHETER IS INDICATED FOR MULTIPLE ELECTRODE ELECTROPHYSIOLOGICAL MAPPING OF CARDIAC STRUCTURES IN THE HEART, I.E., RECORDING OR STIMULATION ONLY. THIS CATHETER IS INTENDED TO OBTAIN ELECTROGRAMS IN THE ATRIAL AND VENTRICULAR REGIONS OF THE HEART. THE PENTARAY™ NAV ECO HIGH-DENSITY MAPPING CATHETER PROVIDES LOCATION INFORMATION WHEN USED WITH COMPATIBLE CARTO™ 3 EP NAVIGATION SYSTEMS. (THIS CATHETER IS NOT COMPATIBLE WITH CARTO™ 3 EP NAVIGATION SYSTEMS PRIOR TO VERSION 3.X).,ELECTROPHYSIOLOGY CATHETER(CELSIUS THERMOCOOL ELECTROPHYSIOLOGY CATHETER (NON-NAV))-THE BIOSENSE WEBSTER CELSIUS™THERMOCOOL® DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETER IS INDICATED FOR USE IN CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATION AND RECORDING) AND, WHEN USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION., ELECTROPHYSIOLOGY CATHETER(NAVISTAR RMT THERMOCOOL ELECTROPHYSIOLOGY CATHETER (NAV))-THE BIOSENSE WEBSTER NAVISTAR RMT THERMOCOOL DIAGNOSTIC/ABLATION STEERABLE TIP CATHETER IS INDICATED FOR USE IN CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATION AND RECORDING) AND, WHEN USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION.,ELECTROPHYSIOLOGY CATHETER(CELSIUS ELECTROPHYSIOLOGY CATHETER (NON-NAV))-THE BIOSENSE WEBSTER® DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETER IS INDICATED FOR CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATION AND RECORDING) AND, WHEN USED IN

	CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION.,ELECTROPHYSIOLOGY CATHETERS(WEBSTER DUO-DECAPOLAR ELECTROPHYSIOLOGY CATHETER (NON-NAV))-THE CATHETER IS INDICATED FOR ELECTROPHYSIOLOGICAL MAPPING OF CARDIAC STRUCTURES; I.E. STIMULATION AND RECORDING ONLY. IN ADDITION, THE WEBSTER™ DUO-DECAPOLA CATHETER IS DESIGNED TO FACILITATE ELECTROGRAM MAPPING IN THE ATRIAL REGION OF THE HEART AND THE CORONARY SINUS., ELECTROPHYSIOLOGY CATHETER(EZ STEER THERMOCOOL NAV BI-DIRECTIONAL ELECTROPHYSIOLOGY CATHETER (NAV))-HE BIOSENSE WEBSTER EZ STEER™ THERMOCOOL® NAV DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETER AND RELATED ACCESSORIES ARE INDICATED FOR CATHETER-BASED CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATING AND RECORDING) AND, WHEN USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION.,ELECTROPHYSIOLOGY CATHETER(LASSO 2515 NAV ECO VARIABLE CATHETER (NAV))-THE LASSO™ 2515 NAV ECO VARIABLE CATHETER IS INDICATED FOR MULTIPLE ELECTRODE ELECTROPHYSIOLOGICAL MAPPING OF THE CARDIAC STRUCTURES OF THE HEART, I.E. RECORDING OR STIMULATION ONLY. THE CATHETER IS DESIGNED TO OBTAIN ELECTROGRAMS IN THE ATRIAL REGIONS OF THE HEART., ELECTROPHYSIOLOGY CATHETER(THERMOCOOL SMARTTOUCH SF BI-DIRECTIONAL NAVIGATION CATHETER (NAV))-THE BIOSENSE WEBSTER THERMOCOOL SMARTTOUCH™ SF BI-DIRECTIONAL NAVIGATION CATHETER AND RELATED ACCESSORIES ARE INDICATED FOR CATHETER-BASED CARDIAC ELECTROPHYSIOLOGICAL MAPPING (STIMULATING AND RECORDING) AND, WHEN USED IN CONJUNCTION WITH A RADIOFREQUENCY GENERATOR, FOR CARDIAC ABLATION. THE THERMOCOOL SMARTTOUCH™ SF BI-DIRECTIONAL NAVIGATION CATHETER PROVIDES A REAL-TIME MEASUREMENT OF CONTACT FORCE BETWEEN THE CATHETER TIP AND HEART WALL, AS WELL AS LOCATION INFORMATION WHEN USED WITH CARTO™ 3 NAVIGATION SYSTEM.

2387	IMP/MD/2020/000566	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SILVER-COATED ANTIMICROBIAL BARRIER DRESSING(ACTICOAT FLEX 7)-ACTICOAT FLEX 7 IS INDICATED AS AN ANTIMICROBIAL BARRIER DRESSING OVER PARTIAL AND FULL THICKNESS WOUNDS SUCH AS BURNS, SURGICAL SITES, PRESSURE ULCERS, VENOUS ULCERS AND DIABETIC ULCERS. ACTICOAT FLEX 7 MAY BE USED ON INFECTED WOUNDS. WHERE THE PRODUCT IS USED ON INFECTED WOUNDS THE INFECTION SHOULD BE INSPECTED AND TREATED AS PER LOCAL CLINICAL PROTOCOL. ACTICOAT FLEX 7 MAY BE USED AS A WOUND CONTACT LAYER IN COMBINATION WITH NEGATIVE PRESSURE WOUND THERAPY (NPWT) FOR A PERIOD OF UP TO 3 DAYS.,SILVER-COATED ANTIMICROBIAL BARRIER DRESSING(ACTICOAT 7)-ACTICOAT 7 IS INDICATED AS AN ABSORBENT ANTIMICROBIAL BARRIER DRESSING OVER PARTIAL AND FULL THICKNESS WOUNDS SUCH AS PRESSURE ULCERS, VENOUS ULCERS, DIABETIC ULCERS, BURNS, AND RECIPIENT GRAFT SITES. ACTICOAT 7 MAY BE USED ON INFECTED WOUNDS. WHERE THE PRODUCT IS USED ON INFECTED WOUNDS THE INFECTION SHOULD BE INSPECTED AND TREATED AS PER LOCAL CLINICAL PROTOCOL.,SILVER-COATED ANTIMICROBIAL BARRIER DRESSING(ACTICOAT FLEX 3)-ACTICOAT FLEX 3 IS INDICATED AS AN ANTIMICROBIAL BARRIER DRESSING OVER PARTIAL AND FULL THICKNESS WOUNDS SUCH AS BURNS, SURGICAL SITES, PRESSURE ULCERS, VENOUS ULCERS AND DIABETIC ULCERS. ACTICOAT FLEX 3 MAY BE USED ON INFECTED WOUNDS. WHERE THE PRODUCT IS USED ON INFECTED WOUNDS THE INFECTION SHOULD BE INSPECTED AND TREATED AS PER LOCAL CLINICAL PROTOCOL. ACTICOAT FLEX 3 MAY BE USED AS A WOUND CONTACT LAYER IN COMBINATION WITH NEGATIVE PRESSURE WOUND THERAPY (NPWT) FOR A PERIOD OF UP TO 3 DAYS.,ABSORBENT, GELLING, FIBROUS DRESSING(DURAFIBER)-DURAFIBER IS INDICATED AS AN ABSORBENT, GELLING DRESSING FOR THE MANAGEMENT OF CHRONIC AND ACUTE, FULL THICKNESS, PARTIAL THICKNESS, OR SHALLOW GRANULATING EXUDING WOUNDS. FOR EXAMPLE: LEG ULCERS; PRESSURE ULCERS; DIABETIC ULCERS; SURGICAL WOUNDS; WOUNDS LEFT TO HEAL BY SECONDARY INTENT; DONOR SITES; TUNNELING AND FISTULAE WOUNDS; PARTIAL THICKNESS BURNS; TRAUMATIC WOUNDS; AND WOUNDS THAT ARE PRONE TO BLEEDING SUCH AS WOUNDS THAT HAVE BEEN SURGICALLY OR MECHANICALLY DEBRIDED. DURAFIBER IS DESIGNED TO BE LEFT IN PLACE FOR UP TO 7 DAYS.,SILVER-COATED ANTIMICROBIAL BARRIER DRESSING(ACTICOAT)-ACTICOAT IS INDICATED AS AN ABSORBENT ANTIMICROBIAL BARRIER DRESSING OVER PARTIAL AND FULL

		THICKNESS WOUNDS SUCH AS PRESSURE ULCERS, VENOUS ULCERS, DIABETIC ULCERS, BURNS, AND RECIPIENT GRAFT SITES. ACTICOAT MAY BE USED ON INFECTED WOUNDS. WHERE THE PRODUCT IS USED ON INFECTED WOUNDS THE INFECTION SHOULD BE INSPECTED AND TREATED AS PER LOCAL CLINICAL PROTOCOL. ACTICOAT MAY BE SLIT AND USED AS A WOUND CONTACT LAYER IN COMBINATION WITH NEGATIVE PRESSURE WOUND THERAPY (NPWT) FOR A PERIOD OF UP TO 3 DAYS. ,TRANSPARENT DRESSING(OPSITE FLEXIGRID)-OPSITE FLEXIGRID IS INDICATED FOR: • THE MANAGEMENT OF SUPERFICIAL WOUNDS (E.G. MINOR BURNS, SCALDS, ABRASIONS, LACERATIONS AND LEG ULCERS IN THE FINAL STAGE OF HEALING). • THE PROTECTION OF SKIN FROM FRICTION AND EXTERNAL CONTAMINATION. FOR PROPHYLAXIS AGAINST PRESSURE SORES. • THE RETENTION OF PRIMARY DRESSINGS E.G. INTRASITE™ GEL, ALLEVYN™ CAVITY, ALLEVYN NON-ADHESIVE. • THE FIXATION OF CATHETERS. • THE PROTECTION OF SKIN AROUND STOMA AND UNDER LEG BAGS. • THE DRESSING OF POST-OPERATIVE WOUNDS, SKIN GRAFTS AND DONOR SITES.
2388	IMP/MD/2020/000567	1.License Holder Name: ACCREDITED CONSULTANT PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:1.8% SODIUM HYALURONATE WITH 2% GLYCEROL(SAYPHA RICH)-THE DEVICE IS A VISCOELASTIC SOLUTION TO REPLENISH THE LOSS OF HYALURONIC ACID DUE TO AGEING, TO MAINTAIN HYDRATION, TO IMPROVE TONE AND ELASTICITY OF THE SKIN AND TO ACT AS A FILLER FOR SMALL LINES SUCH AS CROW'S FEET, SMILE LINES OR SMOKE LINES SURROUNDING THE MOUTH. IT IS INDICATED TO BE INJECTED INTO THE SUPERFICIAL DERMAL TISSUE.,CROSSLINKED HYALURONIC ACID 2.3%(SAYPHA FILLER)-THE DEVICE IS A VISCOELASTIC SOLUTION FOR CORRECTING MODERATE TO SEVERE NASOLABIAL FOLDS. IT IS INDICATED TO BE INJECTED INTO THE MID TO DEEP DERMIS. IT IS USED FOR COSMETIC PURPOSES BUT SUCH DEVICE CAN ALSO ADDRESS MEDICAL RECONSTRUCTIVE PURPOSES IN THE TREATMENT OF E.G. FACIAL LIPOATROPHY, DEBILITATING SCARS OR MORPHOLOGICAL ASYMMETRY.,2.3% HIGHLY CROSSLINKED SODIUM HYALURONATE(SAYPHA VOLUME)-THE DEVICE IS A VISCOELASTIC SOLUTION FOR CORRECTING MODERATE TO SEVERE NASOLABIAL FOLDS. IT IS INDICATED TO BE INJECTED INTO THE DEEP DERMIS OR SUBCUTIS. IT IS USED FOR COSMETIC PURPOSES BUT SUCH DEVICE CAN ALSO ADDRESS MEDICAL RECONSTRUCTIVE PURPOSES IN THE TREATMENT OF E.G. FACIAL LIPOATROPHY, DEBILITATING SCARS OR MORPHOLOGICAL ASYMMETRY.

2389	IMP/MD/2020/000568	1.License Holder Name: ELEKTA MEDICAL SYSTEMS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER INSERTION NEEDLE KIT(BACKLUND CATHETER INSERTION NEEDLE KIT)-THE BACKLUND CATHETER INSERTION NEEDLE KIT CONSIST OF NEUROSURGICAL INSTRUMENTS WHICH ARE USED TO OBTAIN STANDARDIZED AND SAFE ROUTINES FOR PUNCTURING INTRACRANIAL CAVITIES USING STEREOTACTIC TECHNIQUE.,BIOPSY NEEDLE KIT(SEDAN SIDE-CUTTING BIOPSY NEEDLE KIT)-THE SEDAN SIDE-CUTTING BIOPSY NEEDLE KIT CONSISTS OF A SET OF NEUROSURGICAL INSTRUMENTS DESIGNED TO TAKE MULTIPLE BIOPSIES FROM ONE OR MORE TARGETS IN ONE TRAJECTORY., DISPOSABLE BIOPSY NEEDLE KIT(DISPOSABLE BIOPSY NEEDLE KIT)-THE DISPOSABLE BIOPSY NEEDLE KIT IS INTENDED TO TAKE INTRACRANIAL BIOPSIES IN USE WITH LEKSELL STEREOTACTIC SYSTEM. THE DISPOSABLE BIOPSY NEEDLE KIT IS A SINGLE USE ALTERNATIVE TO REUSABLE NEUROSURGICAL INSTRUMENTS., INSERTION CANNULA KIT(INSERTION CANNULA KIT)-THE INSERTION CANNULA KIT L=190 / D=1.6 MM KIT CONSISTS OF NEUROSURGICAL INSTRUMENTS WHICH ARE USED TO OBTAIN SAFE GUIDANCE OF IMPLANTS, E.G. ELECTRODES OR CATHETERS USING STEREOTACTIC TECHNIQUE.,INJECTION ASPIRATION NEEDLE KIT(INJECTION ASPIRATION NEEDLE KIT)-THE INJECTION/ ASPIRATION NEEDLE KIT CONSISTS OF A SET OF NEUROSURGICAL INSTRUMENTS DESIGNED TO MAKE POSSIBLE DIAGNOSTIC AND THERAPEUTIC PUNCTURES, INJECTIONS/ ASPIRATIONS AND EVACUATIONS.,HAEMATOMA EVACUATOR KIT(BACKLUND HAEMATOMA EVACUATOR KIT)-THE BACKLUND HAEMATOMA EVACUATOR KIT CONSISTS OF A NEUROSURGICAL INSTRUMENT WHICH ALLOW THE EVACUATION OF HAEMATOMAS THROUGH A SINGLE BURR HOLE USING STEREOTACTIC TECHNIQUES.

2390	IMP/MD/2020/000569	1.License Holder Name: LEADER MEDICAL SYSTEMS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SODIUM HYALURONATE LIDOCAINE HYDRO CHLORIDE PREFILLED SYRINGES(BELOTERO® BALANCE LIDOCAINE)-BELOTERO BALANCE LIDOCAINE IS AN INJECTABLE BIODEGRADABLE IMPLANT INTENDED FOR FILLING OF MODERATE FACIAL WRINKLES AND FOLDS AS WELL AS FOR LIP ENHANCEMENT. THE PRESENCE OF LIDOCAINE AIMS TO REDUCE LOCAL PAIN ASSOCIATED WITH THE INJECTION OF GEL AND TO IMPROVE PATIENT COMFORT. BELOTERO BALANCE LIDOCAINE IS INDICATED FOR INJECTION INTO THE SUPERFICIAL TO MID-DERMIS FOR TREATMENT OF NASOLABIAL FOLDS, MARIONETTE LINES, PERIORAL LINES AND MODERATE ORAL COMMISSURES. IT IS INDICATED INJECTION FOR LIP ENHANCEMENT.
2391	IMP/MD/2020/000572	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEEDLE + STABILIZER KIT (ARROW® EZ-IO LNTRAOSSEOUS VASCULAR ACCESS)-INTENDED FOR INTRAOSSEOUS ACCESS ANYTIME IN WHICH VASCULAR ACCESS IS DIFFICULT TO OBTAIN IN EMERGENT, URGENT OR MEDICALLY NECESSARY CASES FOR UP TO 24 HOURS.,NEEDLE SET(ARROW® EZ-IO LNTRAOSSEOUS VASCULAR ACCESS)-INTENDED FOR INTRAOSSEOUS ACCESS ANYTIME IN WHICH VASCULAR ACCESS IS DIFFICULT TO OBTAIN IN EMERGENT, URGENT OR MEDICALLY NECESSARY CASES IN ADULT AND PEDIATRICS.

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2392	IMP/MD/2020/000573	1.License Holder Name: SERCHEBON IMPLANTSWISS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT(I-SYSTEM)-DENTAL IMPLANT/FIXTURE SYSTEM IS INDICATED TO USE FOR SURGICAL PLACEMENT IN THE UPPER AND LOWER JAW ARCHES, TO PROVIDE A ROOT FORM MEANS FOR SINGLE AND MULTIPLE UNITS' PROSTHETIC APPLIANCE ATTACHMENT TO RESTORE A PATIENT'S CHEWING FUNCTION.,DENTAL ABUTMENT & SCREWS (IMPLANTSWISS)-DENTAL ABUTMENTS & SCREWS PROVIDE THE LINK BETWEEN THE ENDOSSEOUS FIXTURE AND THE PROSTHESIS THAT FORMS THE SUPERSTRUCTURE AND ALLOWS CHEWING.,DENTAL IMPLANT(IMPLANTSWISS)-DENTAL IMPLANT/FIXTURE SYSTEM IS INDICATED TO USE FOR SURGICAL PLACEMENT IN THE UPPER AND LOWER JAW ARCHES, TO PROVIDE A ROOT FORM MEANS FOR SINGLE AND MULTIPLE UNITS' PROSTHETIC APPLIANCE ATTACHMENT TO RESTORE A PATIENT'S CHEWING FUNCTION.,DENTAL ABUTMENT & SCREWS(I-SYSTEM)-DENTAL ABUTMENTS & SCREWS PROVIDE THE LINK BETWEEN THE ENDOSSEOUS FIXTURE AND THE PROSTHESIS THAT FORMS THE SUPERSTRUCTURE AND ALLOWS CHEWING.
2393	IMP/MD/2020/000577	1.License Holder Name: WALDEMAR LINK INDIA PRIVATE LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RECONSTRUCTION PROSTHESIS(NOT APPLICABLE)-FOR TOTAL HIP REPLACEMENT, TOTAL KNEE REPLACEMENT(NOT APPLICABLE)-FOR TOTAL KNEE REPLACEMENT,UNICONDYLAR KNEE REPLACEMENT(NOT APPLICABLE)-FOR TOTAL KNEE REPLACEMENT,FEMUR STEM -NON CEMENTED(NOT APPLICABLE)-FOR TOTAL HIP REPLACEMENT,TOTAL KNEE REPLACEMENT(NOT APPLICABLE)-FOR TOTAL KNEE REPLACEMENT,HEAD(NOT APPLICABLE)-FOR TOTAL HIP REPLACEMENT,PARTIAL PELVIS REPLACEMENT(NOT APPLICABLE)-FOR TOTAL HIP REPLACEMENT,ACETABULAR CUPS - NON CEMENTED / CEMENTED(NOT APPLICABLE)-FOR TOTAL HIP REPLACEMENT, TOTAL KNEE REPLACEMENT(NOT APPLICABLE)-FOR TOTAL KNEE REPLACEMENT,FEMUR STEM -CEMENTED(NOT APPLICABLE)-FOR TOTAL HIP REPLACEMENT,TOTAL KNEE REPLACEMENT(NOT APPLICABLE)-FOR TOTAL KNEE REPLACEMENT

2394	IMP/MD/2020/000578	1.License Holder Name: BIOCOMPOSITES INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CALCIUM SULPHATE BEADS OR PASTE(STIMULAN)-FILLING VOIDS OR GAPS OF THE SKELETAL SYSTEM. USE IN AN INFECTED SITE,INJECTABLE BONE GRAFT WITH ZPC (ZETA POTENTIAL CONTROL)(GENEX)-GENEX® INJECTABLE PASTE PROVIDES A BONE GRAFT SUBSTITUTE THAT RESORBS AND IS REPLACED WITH BONE DURING THE HEALING PROCESS.,SUTURE ANCHOR(BIOSTEON INTRALINE (WITHOUT NEEDLES))-INTENDED TO SECURE A SUTURE OR SUTURES TO BONE THAT ARE THEN USED TO REATTACH DAMAGED SOFT TISSUE., FIXATION SCREW(BIOSTEON SCREW)-INDICATED FOR USE IN ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION.,SUTURE ANCHOR(BIOSTEON INTRALINE (WITH NEEDLE))-INTENDED TO SECURE A SUTURE OR SUTURES TO BONE THAT ARE THEN USED TO REATTACH DAMAGED SOFT TISSUE.,- TRICALCIUM PHOSPHATE RESORBABLE BONE GRAFT (ALLOGRAN)-ALLOGRAN-R® GRANULES ARE INDICATED ONLY FOR BONY VOIDS OR DEFECTS/GAPS THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. ALLOGRAN-R® GRANULES ARE INDICATED TO BE GENTLY PACKED INTO BONY VOIDS OR DEFECTS OF THE SKELETAL SYSTEM (I.E. LONG BONES, EXTREMITIES, SPINE AND PELVIS). GRANULES SHOULD NOT BE CRUSHED, SHAVED OR CUT. THE BONY DEFECTS OR CAVITIES MAY BE SURGICALLY CREATED OR THE RESULT OF TRAUMATIC INJURY. ALLOGRAN-R® GRANULES PROVIDE A BONE GRAFT SUBSTITUTE THAT RESORBS AND IS REPLACED WITH BONE DURING THE HEALING PROCESS.
2395	IMP/MD/2020/000579	1.License Holder Name: M/S MODI MUNDIPHARMA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CROSS LINKED SODIUM HYALURONATE 22MG/ML(MONOVISC)-IT IS INDICATED AS A VISCOELASTIC SUPPLEMENT OR A REPLACEMENT FOR SYNOVIAL FLUID IN HUMAN JOINTS. IT IS WELL DYSFUNCTIONS SUCH AS OSTEOARTHRITIS. THE ACTIONS OF THE PRODUCT ARE LUBRICATION AND MECHANICAL SUPPORT.

2396	IMP/MD/2020/000580	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDEWIRE(NITREX)-THE 0.36 MM (0.014 IN) AND 0.46 MM (0.018 IN) DIAMETER NITREX NITINOL GUIDEWIRES ARE INTENDED FOR USE IN THE PERIPHERAL AND CORONARY VASCULATURE. THE 0.64 MM(0.025 IN) AND 0.89 MM (0.035 IN) DIAMETER NITREX NITINOL GUIDEWIRES ARE INDICATED FOR USE IN THE PERIPHERAL VASCULATURE.
2397	IMP/MD/2020/000581	1.License Holder Name: CLINIEXPERTS SERVICES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ESU-110 ELECTROSURGICAL GENERATOR-THE ESU-110 ELECTROSURGICAL GENERATOR IS INTENDED TO DELIVER HIGH-FREQUENCY ELECTRICAL CURRENT FOR SURGICAL PROCEDURES THAT CAN BE PERFORMED WITH MONOPOLAR CUTTING AND/OR COAGULATION OF TISSUE. ONE INTENDED USE OF THEESU-110 ELECTROSURGICAL GENERATOR IS LLETZ AKA LEEP (LARGE LOOP EXCISION OF THE TRANSFORMATION ZONE AKA LOOPELECTROSURGICAL EXCISION PROCEDURE).,HTU -110 HANDHELD THERMOCOAGULATOR UNIT(TC THERMOCOAGULATOR)-THE THERMOCOAGULATOR IS INTENDED FOR THE DESTRUCTION OF HUMAN TISSUE WITH HIGH TEMPERATURES BY TISSUE CONTACT WITH AN ELECTRICALLY HEATED PROBE.

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2398	IMP/MD/2020/000586	1.License Holder Name: LEADER MEDICAL SYSTEMS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SODIUM HYALURONATE LIDOCAINE HYDRO CHLORIDE PREFILLED SYRINGES(BELOTERO® INTENSE LIDOCAINE)-BELOTERO® INTENSE LIDOCAINE IS AN INJECTABLE BIODEGRADABLE IMPLANT INTENDED FOR FILING OF DEEP FACIAL WRINKLES AND FOLDS AS WELL AS TO RESTORE AND ENHANCE SOFT TISSUE VOLUME. THE PRESENCE OF LIDOCAINE AIMS TO REDUCE LOCAL PAIN ASSOCIATED WITH THE INJECTION OF GEL AND TO IMPROVE PATIENT COMFORT . BELOTERO INTENSE LIDOCAINE IS INDICATED FOR INJECTION INTO THE DEEP DERMIS FOR TREATMENT OF NASOLABIAL FOLDS AND MARIONETTE LINES. IT IS INDICATED FOR INJECTION FOR LIP ENHANCEMENT.,SODIUM HYALURONATE LIDOCAINE HYDRO CHLORIDE PREFILLED SYRINGES (BELOTERO® BALANCE LIDOCAINE)-BELOTERO® BALANCE LIDOCAINE IS AN INJECTABLE BIODEGRADABLE IMPLANT INTENDED FOR FILLING OF MODERATE FACIAL WRINKLES AND FOLDS AS WELL AS FOR LIP ENHANCEMENT. THE PRESENCE OF LIDOCAINE AIMS TO REDUCE LOCAL PAIN ASSOCIATED WITH THE INJECTION OF GEL AND TO IMPROVE PATIENT COMFORT. BELOTERO® BALANCE LIDOCAINE IS INDICATED FOR INJECTION INTO THE SUPERFICIAL TO MID-DERMIS FOR TREATMENT OF NASO-LABIAL FOLDS, MARIONETTE LINES, PERIORAL LINES AND MODERATE ORAL COMMISSURES. IT IS INDICATED INJECTION FOR LIP ENHANCEMENT.,SODIUM HYALURONATE LIDOCAINE HYDRO CHLORIDE PREFILLED SYRINGES (BELOTERO® VOLUME LIDOCAINE)-BELOTERO® VOLUME LIDOCAINE IS AN INJECTABLE BIODEGRADABLE IMPLANT INTENDED FOR CORRECTING SIGNS OF FACIAL FAT LOSS (LIPOATROPHY) IN PATIENTS WITH HUMAN IMMUNODEFICIENCY VIRUS. BELOTERO® VOLUME LIDOCAINE IS ALSO INTENDED FOR RESTORATION OF FACIAL VOLUMES. THE PRESENCE OF LIDOCAINE AIMS TO REDUCE LOCAL PAIN ASSOCIATED WITH THE INJECTION OF THE GEL AND TO IMPROVE PATIENT COMFORT. BELOTERO® VOLUME LIDOCAINE IS INDICATED FOR ENHANCEMENT OF THE CHEEKS, THE TEMPLES, THE CHIN, OR TO TREAT SEVERE NASOLABIAL FOLDS (NLFS),SODIUM HYALURONATE LIDOCAINE HYDRO CHLORIDE PREFILLED SYRINGES (BELOTERO® SOFT LIDOCAINE)-BELOTERO® SOFT LIDOCAINE IS AN INJECTABLE BIODEGRADABLE IMPLANT INTENDED FOR FILING OF PERIORAL FINE LINES. THE PRESENCE OF LIDOCAINE AIMS TO REDUCE LOCAL PAIN ASSOCIATED WITH THE INJECTION OF GEL AND TO IMPROVE PATIENT COMFORT. BELOTERO® SOFT LIDOCAINE IS INDICATED FOR INJECTION INTO THE SUPERFICIAL TO MID-DERMIS FOR TREATMENT OF PERIORAL FINE LINES

2399	IMP/MD/2020/000587	1.License Holder Name: BIBAWO MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABLATION DEVICE : CRYOTHERAPY(HYDROZID)-USED AS CRYOTHERAPY FOR WARTS AND OTHER SKIN LESIONS
2400	IMP/MD/2020/000588	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SCREWS(NA)-THE SMITH & NEPHEW PARTIALLY-THREADED SCREWS ARE INTENDED FOR USE FOR INTERNAL BONE FIXATION INCLUDING FRACTURES OF THE TIBIA, FIBULA, CLAVICLE, SCAPULA, OLECRANON, METACARPALS, METATARSALS, HUMERUS, ULNA, MIDDLE HAND BONES, MIDDLE FOOT BONES, AND CALCANEOUS. SCREWS ARE ADDITIONALLY INTENDED FOR ARTHRODESES AND OSTEOTOMIES OF SMALL BONES AND SMALL JOINTS INCLUDING SCAPHOID AND OTHER CARPAL BONES, METACARPALS, TARSALS, METATARSALS, CLAVICLE, SCAPULA, OLECRANON, ULNAR STYLOID, RADIAL HEAD, AND RADIAL STYLOID.

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2401	IMP/MD/2020/000591	1.License Holder Name: TRANSLUMINA THERAPEUTICS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMPELLA(IMPELLA CP SET)-THE IMPELLA® (INTRACARDIAC PUMP FOR SUPPORTING THE LEFT VENTRICLE) IS INTENDED FOR CLINICAL USE IN CARDIOLOGY AND IN CARDIAC SURGERY FOR UP TO 5 DAYS FOR THE FOLLOWING INDICATIONS, AS WELL AS OTHERS: • THE IMPELLA® IS A CIRCULATORY SUPPORT SYSTEM FOR PATIENTS WITH REDUCED LEFT VENTRICULAR FUNCTION, EG, POSTCARDIOTOMY, LOW OUTPUT SYNDROME, CARDIOGENIC SHOCK AFTER ACUTE MYOCARDIAL INFARCTION, OR FOR MYOCARDIAL PROTECTION AFTER ACUTE MYOCARDIAL INFARCTION • THE IMPELLA® MAY ALSO BE USED AS A CARDIOVASCULAR SUPPORT SYSTEM DURING CORONARY BYPASS SURGERY ON THE BEATING HEART, PARTICULARLY IN PATIENTS WITH LIMITED PREOPERATIVE EJECTION FRACTION WITH A HIGH RISK OF POSTOPERATIVE LOW OUTPUT SYNDROME • SUPPORT DURING HIGH-RISK PERCUTANEOUS CORONARY INTERVENTION (PCI) • POST-PCI,IMPELLA(IMPELLA CP SET WITH SMARTASSIST)-THE IMPELLA (INTRACARDIAC PUMP FOR SUPPORTING THE LEFT VENTRICLE) IS INTENDED FOR CLINICAL USE IN CARDIOLOGY AND IN CARDIAC SURGERY FOR UP TO 5 DAYS FOR THE FOLLOWING INDICATIONS, AS WELL AS OTHERS: • THE IMPELLA IS A CIRCULATORY SUPPORT SYSTEM FOR PATIENTS WITH REDUCED LEFT VENTRICULAR FUNCTION, EG, POST-CARDIOTOMY, LOW OUTPUT SYNDROME, CARDIOGENIC SHOCK AFTER ACUTE MYOCARDIAL INFARCTION, OR FOR MYOCARDIAL PROTECTION AFTER ACUTE MYOCARDIAL INFARCTION • THE IMPELLA MAY ALSO BE USED AS A CARDIOVASCULAR SUPPORT SYSTEM DURING CORONARY BYPASS SURGERY ON THE BEATING HEART, PARTICULARLY IN PATIENTS WITH LIMITED PREOPERATIVE EJECTION FRACTION WITH A HIGH RISK OF POSTOPERATIVE LOW OUTPUT SYNDROME • SUPPORT DURING HIGH RISK PERCUTANEOUS CORONARY INTERVENTION (PCI) • POST PCI,IMPELLA(IMPELLA 2.5 SET)-THE IMPELLA® (INTRACARDIAC PUMP FOR SUPPORTING THE LEFT VENTRICLE) IS INTENDED FOR CLINICAL USE IN CARDIOLOGY AND IN CARDIAC SURGERY FOR UP TO 5 DAYS FOR THE FOLLOWING INDICATIONS, AS WELL AS OTHERS: • THE IMPELLA® IS A CIRCULATORY SUPPORT SYSTEM FOR PATIENTS WITH REDUCED LEFT VENTRICULAR FUNCTION, EG, POSTCARDIOTOMY, LOW OUTPUT SYNDROME, CARDIOGENIC SHOCK AFTER ACUTE MYOCARDIAL INFARCTION, OR FOR MYOCARDIAL PROTECTION AFTER ACUTE MYOCARDIAL INFARCTION • THE IMPELLA® MAY ALSO BE USED AS A CARDIOVASCULAR SUPPORT SYSTEM DURING CORONARY BYPASS SURGERY ON THE BEATING HEART, PARTICULARLY IN PATIENTS

		WITH LIMITED PREOPERATIVE EJECTION FRACTION WITH A HIGH RISK OF POSTOPERATIVE LOW OUTPUT SYNDROME • SUPPORT DURING HIGH-RISK PERCUTANEOUS CORONARY INTERVENTION (PCI) • POST-PCI,IMPELLA(IMPELLA 5.0 SET)-THE IMPELLA® 5.0 (INTRACARDIAC PUMP FOR SUPPORTING THE LEFT VENTRICLE) IS INTENDED FOR CLINICAL USE IN CARDIOLOGY AND IN CARDIAC SURGERY FOR UP TO 10 DAYS FOR THE FOLLOWING INDICATIONS, AS WELL AS OTHERS: • THE IMPELLA® 5.0 IS A CARDIOVASCULAR SUPPORT SYSTEM FOR PATIENTS WITH REDUCED LEFT VENTRICULAR FUNCTION, EG, POST CARDIOTOMY, LOW OUTPUT SYNDROME, CARDIOGENIC SHOCK AFTER ACUTE MYOCARDIAL INFARCTION • THE IMPELLA® 5.0 MAY ALSO BE USED AS A CARDIOVASCULAR SUPPORT SYSTEM DURING CORONARY BYPASS SURGERY ON THE BEATING HEART, PARTICULARLY IN PATIENTS WITH LIMITED PREOPERATIVE EJECTION FRACTION WITH A HIGH RISK OF POSTOPERATIVE LOW OUTPUT SYNDROME
2402	IMP/MD/2020/000592	1.License Holder Name: M/S. RENGENCY LIFESCIENCES INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DURAGRAFT VASCULAR CONDUIT SOLUTION (DURAGRAFT (SOMVC001))-INTENDED FOR THE PRESERVATION, STORAGE AND FLUSHING OF VASCULAR CONDUITS PRIOR TO GRAFTING IN VASCULAR SURGERIES.
2403	IMP/MD/2020/000593	1.License Holder Name: PETERS SURGICAL INDIA (P) LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE EXTRAPERITONEAL NON-RESORBABLE PARIETAL REINFORCEMENT IMPLANT(PROMESH SURG FLEXIL)-IMPLANTS ARE INDICATED IN PARIETAL REINFORCEMENT AND REPAIR OF INGUAL,CRURAL, VENTRAL AND INCISIONAL HERNIAS,STERILE EXTRAPERITONEAL NON-RESORBABLE PARIETAL REINFORCEMENT IMPLANT(PROMESH SURG LI)-IMPLANTS ARE INDICATED IN PARIETAL REINFORCEMENT AND REPAIR OF INGUAL,CRURAL, VENTRAL AND INCISIONAL HERNIAS,STERILE EXTRAPERITONEAL NON-RESORBABLE PARIETAL REINFORCEMENT IMPLANT(PROMESH SURG INTRA)-INDICATED IN PARIETAL REINFORCEMENT AND REPAIR OF UMBILICAL AND VENTRAL HERNIAS,STERILE EXTRAPERITONEAL NON-RESORBABLE PARIETAL REINFORCEMENT IMPLANT(PROMESH SURG ST)-REPAIR AND PARIETAL REINFORCEMENT FOR INGUINAL, CRURAL AND VENTRAL HERNIAS.

2404	IMP/MD/2020/000594	1.License Holder Name: ABBOTT HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FLASH GLUCOSE MONITORING SYSTEM(FREESTYLE LIBRE PRO)-THE FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM IS A GLUCOSE MONITORING DEVICE INDICATED FOR DETECTING TRENDS AND TRACKING PATTERNS IN PERSONS (AGE 4 AND OLDER) WITH DIABETES. THE INDICATION FOR CHILDREN (AGE 4 - 17) IS LIMITED TO THOSE WHO ARE SUPERVISED BY A CAREGIVER WHO IS AT LEAST 18 YEARS OF AGE. THE SYSTEM IS INTENDED FOR USE BY HEALTH CARE PROFESSIONALS.,FLASH GLUCOSE MONITORING SYSTEM(FREESTYLE LIBRE)-THE FREESTYLE LIBRE FLASH GLUCOSE MONITORING SYSTEM READER (“READER”) WHEN USED WITH A FREESTYLE LIBRE SYSTEM SENSOR (“SENSOR”) IS INDICATED FOR MEASURING INTERSTITIAL FLUID GLUCOSE LEVELS IN PEOPLE (AGE 4 AND OLDER) WITH DIABETES MELLITUS, INCLUDING PREGNANT WOMEN. THE READER AND SENSOR ARE DESIGNED TO REPLACE BLOOD GLUCOSE TESTING IN THE SELF-MANAGEMENT OF DIABETES, INCLUDING DOSING OF INSULIN.
2405	IMP/MD/2020/000595	1.License Holder Name: DR. REDDYS LABORATORIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER (TRANSDUCER)(CODMAN MICROSENSOR)-INDICATED WHEN DIRECT ICP MONITORING IS REQUIRED. THE KITS ARE INDICATED FOR USE IN BOTH SUBDURAL AND INTRAPARENCHYMAL PRESSURE MONITORING APPLICATIONS ONLY.,PROGRAMMABLE VALVES (CODMAN HAKIM PROGRAMMABLE VALVES)-THE CODMAN HAKIM PROGRAMMABLE VALVES ARE IMPLANTABLE DEVICES THAT PROVIDE CONSTANT INTRAVENTRICULAR PRESSURE AND DRAINAGE OF CSF FOR THE MANAGEMENT OF HYDROCEPHALUS.

2406	IMP/MD/2020/000596	1.License Holder Name: SPAN HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:APHERESIS SYSTEM TUBING SET(PLT & PLS SET W/FILTER, CONC PLT & PLS SET W/FILTER)-THE DISPOSABLE SET WERE INTRODUCED ALONG WITH THE UPP (UNIVERSAL PLATELET PROTOCOL). UPP IS AN ENHANCED VERSION OF THE C-SDP PROTOCOL AND OFFERS A FEW ADVANTAGES OVER C-SDP INCLUDING AN EXTRACORPOREAL VOLUME (ECV) MANAGEMENT, A NEW SUPER SURGE DRAW MODE AND A PLATELET POST-COUNT ESTIMATE WHICH ALLOWS THE ESTIMATION OF THE CONCENTRATION OF PLATELETS IN THE DONOR' S BLOOD AFTER COMPLETION OF THE COLLECTION PROCEDURE. IN ADDITION, THE PROTOCOL ALLOWS THE INITIATION OF THE PLASMA RETURN SEQUENCE IN PARALLEL WITH THE PLATELET COLLECTION SEQUENCE (DWELL AND SURGE) IN ORDER TO SPREAD THE RETURN OF PLASMA OVER A LONGER TIME PERIOD. UPP WILL REPLACE THE OTHER PLATELET COLLECTION DEVICES OVER TIME.
2407	IMP/MD/2021/000003	1.License Holder Name: PHILIPS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SCORING BALLOON CATHETER(ANGIOSCULPT PTA WITH HYDROCROSS COATING)-THE ANGIOSCULPT PTA SCORING BALLOON CATHETER IS INTENDED FOR DILATATION OF LESIONS IN THE ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA POPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. NOT FOR USE IN THE CORONARY OR NEURO-VASCULATURE,SCORING BALLOON CATHETER(ANGIOSCULPT PTA OTW)-THE ANGIOSCULPT PTA SCORING BALLOON CATHETER IS INTENDED FOR DILATATION OF LESIONS IN THE ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA POPLITEAL, AND RENAL ARTERIES, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. NOT FOR USE IN THE CORONARY OR NEURO-VASCULATURE,SCORING BALLOON CATHETER(ANGIOSCULPT PTCA SCORING BALLOON CATHETER)-THE ANGIOSCULPT SCORING BALLOON CATHETER IS INTENDED FOR THE TREATMENT OF A HEMODYNAMICALLY SIGNIFICANT CORONARY ARTERY STENOSIS, INCLUDING IN-STENT RESTENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION

2408	IMP/MD/2021/000004	1.License Holder Name: VEIVA SCIENTIFIC INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BALLOON DILATATION CATHETER(ARTIMES)-THE BALLOON DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,BALLOON DILATATION CATHETER(APOLLO)-THE BALLOON DILATATION CATHETER IS INTENDED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION, AND ALSO INTENDED FOR BALLOON DILATATION OF A STENT AFTER IMPLANTATION (BALLOON MODELS 2.0 MM -5.0 MM ONLY).
2409	IMP/MD/2021/000005	1.License Holder Name: TRANSLUMINA THERAPEUTICS LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PBMV BALLOON CATHETER SET(PBMV BALLOON CATHETER SETS)-THE PBMV BALLOON CATHETER SET IS INTENDED TO DILATE THE MITRAL STENOSIS USING PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY (PBMV) TECHNIQUE, WHICH OFFERS MINIMAL INVASIVE THERAPY FOR PATIENTS WITH MITRAL STENOSIS.
2410	IMP/MD/2021/000006	1.License Holder Name: DR. REDDYS LABORATORIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER (TRANSDUCER)(CODMAN MICROSENSOR (MICROSENSOR VENTRICULAR CATHETER KIT WITH ICP SENSOR))-USE OF THE VENTRICULAR CATHETER KIT IS INDICATED WHEN DIRECT INTRAVENTRICULAR PRESSURE MONITORING IS REQUIRED. THE KITS ARE INDICATED FOR USE IN ICP MONITORING AND CEREBROSPINAL FLUID (CSF) DRAINAGE APPLICATIONS.
2411	IMP/MD/2021/000007	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FIXATION DEVICE(ROUND ENDOBUTTON)-IT IS INTENDED FOR THE TREATMENT OF ANTERIOR GLENOID BONE LOSS USING THE LATARJET OR BONE BLOCK PROCEDURE (ALLOGRAFT OR AUTOGRAFT).

2412	IMP/MD/2021/000008	1.License Holder Name: 3M INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:3M™ TEGADERM™ IV ADVANCED ADVANCED SECUREMENT DRESSING-CAN BE USED TO COVER AND PROTECT CATHETER INSERTION SITES AND MINOR WOUNDS AND TO SECURE DEVICES TO THE SKIN. DO NOT USE AS A REPLACEMENT FOR PRIMARY WOUND CLOSURE METHODS., SURGICAL TAPE(TRANSPORE SURGICAL TAPE)-A GENERAL-PURPOSE TAPE FOR THE HOSPITAL AND HOME CARE PATIENT USED TO SECURE MOST DRESSINGS, TUBING AND DEVICES TO SKIN,3M™ TEGADERM™ FOAM ADHESIVE HIGH PERFORMANCE FOAM ADHESIVE DRESSING-TEGADERM™ FOAM ADHESIVE DRESSING IS DESIGNED TO ALLOW EASY, ONE-HANDED APPLICATION TO DIFFICULT BODY CONTOURS, INCLUDING HEELS AND ELBOWS, WITHOUT THE NEED FOR CUTTING. THE DRESSING IS INDICATED FOR USE AS A PRIMARY DRESSING FOR LOW TO HIGHLY EXUDING, PARTIAL AND FULL THICKNESS DERMAL WOUNDS, INCLUDING: • PRESSURE ULCERS • VENOUS LEG ULCERS • ABRASIONS • ARTERIAL ULCERS • SKIN TEARS • NEUROPATHIC ULCERS USE AS A SECONDARY (COVER) DRESSING IN CONJUNCTION WITH WOUND FILTERS; USE UNDER COMPRESSION WRAP SYSTEMS FOR VENOUS LEG ULCER TREATMENT.,SURGICAL TAPE(3M MICROFOAM SURGICAL TAPE)-A GENERAL-PURPOSE TAPE USED TO SECURE DRESSINGS IN COMPRESSION APPLICATIONS AND DEVICES TO PATIENTS,3M™ TEGADERM™ + PAD FILM DRESSING WITH NON-ADHERENT PAD-USED FOR COVERING SUPERFICIAL AND PARTIAL THICKNESS WOUNDS, SURGICAL INCISIONS AND IV CATHETER SITES. THIS PRODUCT IS NOT DESIGNED, SOLD OR INTENDED FOR USE EXCEPT AS INDICATED., SURGICAL TAPE(3M MEDIPORE H SOFT CLOTH SURGICAL TAPE)-TO SECURE DRESSINGS, LIGHTWEIGHT TUBING AND DEVICES TO SKIN, 3M™ IOBAN™ 2-INDICATED FOR USE AS INCISE DRAPE WITH CONTINUOUS ANTI-MICROBIAL ACTIVITY. IT IS INTENDED FOR EXTERNAL USE ONLY.,SURGICAL TAPE(3M MICROPORE SURGICAL TAPE)-3M™ MICROPORE™ SURGICAL TAPE IS A GENERAL-PURPOSE GENTLE TAPE USED TO SECURE DRESSINGS, LIGHTWEIGHT TUBING, AND DEVICES TO SKIN.,3M™ TEGADERM™ HYDROCOLLOID HYDROCOLLOID DRESSING-INDICATED FOR PARTIAL AND FULL THICKNESS DERMAL ULCERS, LEG ULCERS, SUPERFICIAL WOUNDS, ABRASIONS, FIRST AND SECOND DEGREE BURNS AND DONOR SITES. IT CAN ALSO BE USED AS PROTECTIVE DRESSING ON AT RISK, UNDAMAGED SKIN OR SKIN BEGINNING TO SHOW SIGNS OF DAMAGE FROM FRICTION OR SHEAR.,3M™ STERI STRIPS SKIN CLOSURES (REINFORCED)-INDICATED FOR USE AS SKIN CLOSURE DEVICES IN THE TREATMENT OF LACERATIONS AND SURGICAL INCISIONS. MAY

	ALSO BE USED IN CONJUNCTION WITH SKIN SUTURES AND STAPLES OR AFTER THEIR REMOVAL FOR WOUND SUPPORT,3M™ STERI-STRIPS WOUND CLOSURE SYSTEM-INDICATED FOR USE AS A SKIN CLOSURE DEVICES IN THE TREATMENT OF SMALL WOUNDS OR SMALL SURGICAL INCISIONS. CAN BE USED TO COVER AND PROTECT WOUNDS.,3M™ TEGADERM™ ABSORBENT CLEAR ACRYLIC DRESSING-INDICATED FOR PARTIAL AND FULL THICKNESS DERMAL ULCERS INCLUDING SKIN TEARS, PRESSURE ULCERS, SUPERFICIAL WOUNDS, ABRASIONS, SUPERFICIAL AND PARTIAL THICKNESS BURNS, DONOR SITES, AND CLEAN, CLOSED APPROXIMATED SURGICAL INCISIONS AND LAPAROSCOPIC INCISIONS. IT MAY ALSO BE USED AS A PROTECTIVE DRESSING ON AT RISK, UNDAMAGED SKIN OR SKIN BEGINNING TO SHOW SIGNS OF DAMAGE FROM FRICTION OR SHEAR., 3M™ TEGADERM™ HP HP TRANSPARENT FILM DRESSING FRAME STYLE-USED TO COVER AND PROTECT CATHETER SITES AND WOUNDS, TO MAINTAIN A MOIST ENVIRONMENT FOR WOUND HEALING OR TO FACILITATE AUTOLYTIC DEBRIDEMENT AS A SECONDARY DRESSING, AS A PROTECTIVE COVER OVER AT RISK SKIN, TO SECURE DEVICES TO SKIN , TO COVER FIRST AND SECOND DEGREE BURNS AND AS A PROTECTIVE EYE COVERING.,3M™ TEGADERM™ FILM TRANSPARENT FILM DRESSING FRAME STYLE.-TEGADERM™ FILM CAN BE USED TO COVER AND PROTECT CATHETER SITES AND WOUNDS, TO MAINTAIN A MOIST ENVIRONMENT FOR WOUND HEALING OR TO FACILITATE AUTOLYTIC DEBRIDEMENT, AS A SECONDARY DRESSING, AS A PROTECTIVE COVER OVER ATRISK SKIN, TO SECURE DEVICES TO THE SKIN, TO COVER FIRST AND SECOND DEGREE BURNS, AND AS A PROTECTIVE EYE COVERING. DO NOT USE THE DRESSING AS A REPLACEMENT FOR SUTURES AND OTHER PRIMARY WOUND CLOSURE METHODS,3M™ TEGADERM™ CHG CHLORHEXIDINE GLUCONATE IV SECUREMENT DRESSING-CAN BE USED TO COVER AND PROTECT CATHETER SITES AND TO SECURE DEVICES TO SKIN. COMMON APPLICATIONS INCLUDE CENTRAL VENOUS AND ARTERIAL CATHETERS, OTHER INTRAVASCULAR CATHETERS AND PERCUTANEOUS DEVICES. TEGADERM™ CHG DRESSING IS INTENDED TO REDUCE SKIN COLONIZATION AND CATHETER COLONIZATION AND TO SUPPRESS REGROWTH OF MICROORGANISMS COMMONLY RELATED TO BLOODSTREAM INFECTIONS. TEGADERM™ CHG IS INTENDED TO REDUCE CATHETER RELATED BLOODSTREAM INFECTIONS (CRBSI) IN PATIENTS WITH CENTRAL VENOUS OR ARTERIAL CATHETERS.,3M™ TEGADERM™ FILM TRANSPARENT FILM DRESSING FRAME STYLE-TEGADERM™ FILM CAN BE USED TO COVER AND PROTECT CATHETER SITES AND WOUNDS, TO MAINTAIN A MOIST ENVIRONMENT FOR WOUND HEALING OR TO FACILITATE AUTOLYTIC DEBRIDEMENT, AS A SECONDARY DRESSING,

		AS A PROTECTIVE COVER OVER ATRISK SKIN, TO SECURE DEVICES TO THE SKIN, TO COVER FIRST AND SECOND DEGREE BURNS, AND AS A PROTECTIVE EYE COVERING. DO NOT USE THE DRESSING AS A REPLACEMENT FOR SUTURES AND OTHER PRIMARY WOUND CLOSURE METHODS.,3M™ TEGADERM™ IV IV TRANSPARENT FILM DRESSING WITH BORDER-USED TO COVER AND PROTECT CATHETER SITES AND WOUNDS TO MAINTAIN A MOIST ENVIRONMENT FOR WOUND HEALING OR TO FACILITATE AUTOLYTIC DEBRIDEMENT, AS A SECONDARY DRESSING, AS A PROTECTIVE COVER OVER AT RISK SKIN, TO SECURE DEVICES TO SKIN, TO COVER FIRST AND SECOND DEGREE BURNS, AND AS PROTECTIVE EYE COVERING. DO NOT USE THE DRESSING AS A REPLACEMENT FOR SUTURES AND OTHER PRIMARY WOUND CLOSURE METHODS.,3M™ TEGADERM™ IV IV TRANSPARENT FILM DRESSING WITH BORDER.-USED TO COVER AND PROTECT CATHETER SITES AND WOUNDS TO MAINTAIN A MOIST ENVIRONMENT FOR WOUND HEALING OR TO FACILITATE AUTOLYTIC DEBRIDEMENT, AS A SECONDARY DRESSING, AS A PROTECTIVE COVER OVER AT RISK SKIN, TO SECURE DEVICES TO SKIN, TO COVER FIRST AND SECOND DEGREE BURNS, AND AS PROTECTIVE EYE COVERING. DO NOT USE THE DRESSING AS A REPLACEMENT FOR SUTURES AND OTHER PRIMARY WOUND CLOSURE METHODS.
2413	IMP/MD/2021/000011	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTA BALLOON DILATATION CATHETERS(SIMPASS ENDO)-THE PTA BALLOON CATHETER IS DESIGNED TO DILATATION OF STENOSIS IN THE PERIPHERAL VASCULAR, FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE AND POST-DEPLOYED STENT EXPANSION OF SELF-EXPANDING AND BALLOON EXPANDABLE PERIPHERAL VASCULAR STENTS. THESE DEVICES ARE ALSO RECOMMENDED FOR POST-DILATATION OF BALLOON EXPANDABLE AND SELF-EXPANDING STENTS IN THE PERIPHERAL VASCULATURE.,PTCA BALLOON DILATATION CATHETERS(SIMPASS)-THE PTCA BALLOON DILATATION CATHETER WITH MATERIAL NYLON 12 (BALLOON), PEBAX (SHAFT, INNER LUMEN, SOFT TIP), PT-IR ALLOY (MARKER BAND), PTFE COATED STAINLESS STEEL (HYPOTUBE) IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.

2414	IMP/MD/2021/000012	1.License Holder Name: HICKS THERMOMETERS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (NA)-DIGITAL THERMOMETER PROVIDES A QUICK AND HIGHLY ACCURATE READING OF AN INDIVIDUAL'S BODY TEMPERATURE. THE DIGITAL THERMOMETER IS INTENDED TO MEASURE THE HUMAN BODY'S TEMPERATURE IN REGULAR MODE ORALLY, RECTALLY OR UNDER THE ARM, AND THE DEVICE IS REUSABLE FOR CLINICAL OR HOME USE ON PEOPLE OF ALL AGES,ARM TYPE AUTOMATIC DIGITAL BLOOD PRESSURE MONITOR(NA)-TEST HUMAN BODY BLOOD PRESSURE AND HEART BEAT.
2415	IMP/MD/2021/000013	1.License Holder Name: OMRON HEALTHCARE INDIA PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITORING DEVICE(OMRON)-THIS DEVICE IS A DIGITAL MONITOR INTENDED FOR USE IN MEASURING BLOOD PRESSURE AND PULSE RATE IN ADULT AND PAEDIATRIC PATIENT POPULATION WITH ARM CIRCUMFERENCE RANGING FROM 12 CM,BLOOD PRESSURE MONITORING DEVICE(OMRON)-THIS MONITOR TAKES NON-INVASIVE MEASUREMENT OF ARTERIAL BLOOD PRESSURE ON THE UPPER ARM, DISPLAYING SYSTOLIC (HIGHEST) AND DIASTOLIC (LOWEST) BLOOD PRESSURE.
2416	IMP/MD/2021/000014	1.License Holder Name: MICROGENE DIAGNOSTIC SYSTEMS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AUTOMATIC DIGITAL BLOOD PRESSURE MONITOR(ACCUSURE)-IT IS A DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES AND HEART BEAT RATES IN PATIENT POPULATION.,INFRARED FOREHEAD THERMOMETER(ACCUSURE)-IT IS A DEVICE USED TO RECORD THE BODY TEMPERATURE.
2417	IMP/MD/2021/000015	1.License Holder Name: OMRON HEALTHCARE INDIA PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMPRESSOR NEBULIZER WITH NASAL ASPIRATOR(OMRON)-THE PRODUCT IS INTENDED TO ALLOW FOR NEBULIZATION TREATMENT OF RESPIRATORY TRACT DISORDERS AND REMOVE MUCUS FROM THE NASAL ACTIVITIES TO EASE BREATHING.

2418	IMP/MD/2021/000016	1.License Holder Name: TWINS DIGITAL SERVICES INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITORING SYSTEM(MBH MOBILE HEALTH)-TD-3140 BLOOD PRESSURE MONITORING SYSTEM IS A SYSTEM DESIGNED TO MEASURE THE SYSTOLIC AND DIASTOLIC BLOOD PRESSURE AND PULSE RATE BY USING A NON-INVASIVE TECHNIQUE IN WHICH AN INFLATABLE CUFF IS WRAPPED ON THE UPPER ARM. IT IS INTENDED FOR INDIVIDUALS AGE 18 AND UP, FOR USE IN A HOME OR CLINICAL SETTING. THE DEVICE IS NOT TO BE USED FOR THE DIAGNOSIS OF HYPERTENSION OR FOR TESTING ON NEWBORNS.
2419	IMP/MD/2021/000017	1.License Holder Name: ERIS LIFESCIENCES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ELECTRONIC BLOOD PRESSURE MONITORING DEVICE(ABPM)-TO MAKE SCHEDULED BP READING AT CIRCUMSTANCES OF THE NORMAL LIFE OF THE PATIENT DURING THE MONITORING PERIOD WHICH CAN A 24H, UP TO 72H INTERVAL. DURING THE MONITORING PERIOD THE PATIENT CAN INITIATE BP READINGS MANUALLY, AS WELL AS MARK THE EXACT TIME ANY EVENTS AS IT WAS DISCUSSED WITH THE MEDICAL STAFF. IT IS SUGGESTED TO MAKE A NOTICE IN A DIARY ABOUT THE IMPORTANT EVENTS OF MONITORING PERIOD.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2420	IMP/MD/2021/000018	1.License Holder Name: ERIS LIFESCIENCES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ELECTRONIC BLOOD PRESSURE MONITORING DEVICE-THIS OSCILLOMETRIC BLOOD PRESSURE MONITOR IS INTENDED FOR MEASURING NON-INVASIVE BLOOD PRESSURE IN PEOPLE AGED 12 YEARS OR OLDER., ELECTRONIC BLOOD PRESSURE MONITORING DEVICE(CIRCA 120/80 EXCLUSIO)-BLOOD PRESSURE MEASUREMEMT,ELECTRONIC BLOOD PRESSURE MONITORING DEVICE-TO MEASURE SYSTOLIC AND DIASTOLIC BLOOD PRESSURES, PULSE RATE, MEAN ARTERIAL PRESSURE (MAP) FOR USE IN ADULTS AND PEDIATRICS (BUT NOT NEONATES) WITH ARM CUFF CIRCUMFERENCE SIZES RANGING FROM 14 -52 CM,ELECTRONIC BLOOD PRESSURE MONITORING DEVICE (CIRCA 120/180 PREMIER)-BLOOD PRESSURE MEASUREMEMT, ELECTRONIC BLOOD PRESSURE MONITORING DEVICE-THIS OSCILLOMETRIC BLOOD PRESSURE MONITOR IS INTENDED FOR MEASURING NON-INVASIVE BLOOD PRESSURE IN PEOPLE AGED 12 YEARS OR OLDER.,ELECTRONIC BLOOD PRESSURE MONITORING DEVICE-BLOOD PRESSURE MEASUREMENT,ELECTRONIC BLOOD PRESSURE MONITORING DEVICE(CIRCA 120/180 PRACTO)-BLOOD PRESSURE MEASUREMEMT,ELECTRONIC BLOOD PRESSURE MONITORING DEVICE-BLOOD PRESSURE MEASUREMEMT
2421	IMP/MD/2021/000019	1.License Holder Name: OMRON HEALTHCARE INDIA PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (OMRON)-THIS PRODUCT IS INTENDED TO BE MEASURED USER'S TEMPERATURE THROUGH FOREHEAD., FOREHEAD THERMOMETER (OMRON)-THIS PRODUCT IS INTENDED TO BE MEASURED USER'S TEMPERATURE THROUGH FOREHEAD.
2422	IMP/MD/2021/000020	1.License Holder Name: MAXLIFE HEALTH ENTERPRISES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CLINICAL INFRARED EAR THERMOMETER(WELCH ALLYN BRAUN THERMOSCAN PRO 6000)-BRAUN THERMOSCAN® PRO 6000 EAR THERMOMETERS IS INDICATED FOR THE INTERMITTENT MEASUREMENT OF HUMAN BODY TEMPERATURE FOR PATIENTS HAVING AGES RANGING FROM NORMAL WEIGHT (FULL TERM) NEW-BORN TO GERIATRIC ADULTS IN A PROFESSIONAL USE ENVIRONMENT. THE PROBE COVER IS USED AS A SANITARY BARRIER BETWEEN THE INFRARED THERMOMETER AND THE EAR CANAL.

2423	IMP/MD/2021/000021	1.License Holder Name: OMRON HEALTHCARE INDIA PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OMRON MESH NEBULIZER (OMRON)-THIS PRODUCT IS INTENDED TO BE USED FOR INHALING MEDICATION FOR RESPIRATORY DISORDERS.,DIGITAL THERMOMETER(OMRON)-THIS PRODUCT IS INTENDED TO BE MEASURED USER'S TEMPERATURE THROUGH ORAL, RECTAL OR UNDERARM,LUPIN NEBSTER MESH NEBULIZER(OMRON)-THIS PRODUCT IS INTENDED TO BE USED FOR INHALING MEDICATION FOR RESPIRATORY DISORDERS.,NEBULIZER(OMRON)-THIS PRODUCT IS INTENDED TO BE USED FOR INHALING MEDICATION FOR RESPIRATORY DISORDERS.
2424	IMP/MD/2021/000022	1.License Holder Name: MAXLIFE HEALTH ENTERPRISES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL BLOOD PRESSURE MONITORING DEVICE(WELCH ALLYN PROBP 2000)-THE WELCH ALLYN PROBP 2000 DIGITAL BLOOD PRESSURE DEVICE IS INTENDED FOR USE IN MEASURING BLOOD PRESSURE AND HEART RATE IN PATIENTS AT LEAST 3 YEARS OF AGE OR OLDER. THE WELCH ALLYN PROBP 2000 AUTOMATICALLY MEASURES SYSTOLIC AND DIASTOLIC PRESSURE AND PULSE RATE. THE DEVICE IS INTENDED TO BE USED BY CLINICIANS AND MEDICALLY QUALIFIED PERSONNEL.
2425	IMP/MD/2021/000023	1.License Holder Name: TAEVAS LIFE SCIENCES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEBULIZER (AEROECLIPSE XL BREATH ACTUATED NEBULIZER (BAN))-THE AEROECLIPSE XL BREATH ACTUATED NEBULIZER (BAN) IS INTENDED TO ADMINISTER PRESCRIBED AEROSOLIZED MEDICATION TO SPONTANEOUSLY BREATHING PATIENTS UNDER THE CARE OR TREATMENT OF A LICENSED HEALTHCARE PROFESSIONAL.

2426	IMP/MD/2021/000024	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MATRIXMIDFACE SYSTEM (INCLUDING MATRIXORBITAL SYSTEM)-THE MATRIXORTHOGNATHIC SYSTEM IS INTENDED FOR USE AS A STABLE INTERNAL BONE FIXATION SYSTEM IN ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES). THE SYNTHES TRANSPALATAL DISTRACTOR IS INTENDED FOR USE AS A BONE-BORNE MAXILLARY EXPANDER AND RETAINER FOR SURGICALLY ASSISTED, RAPID, PALATAL EXPANSION. THE SYNTHES TRANSPALATAL DISTRACTOR IS INTENDED FOR SINGLE USE ONLY. THE MATRIXORTHOGNATHIC LOCK SYSTEM IS INTENDED FOR USE AS A STABLE INTERNAL BONE FIXATION SYSTEM IN ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES)., SCREW IMPLANTS FOR PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., EXTERNAL MIDFACE DISTRACTOR-THE DEPUY SYNTHES EXTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED.,COMPACT MIDFACE-THE IMPLANTS (PLATES AND SCREWS) AND THEIR INSTRUMENTS ARE INTENDED FOR TRAUMA REPAIR AND RECONSTRUCTION OF THE CRANIOFACIAL SKELETON., COMPACT MIDFACE-THE IMPLANTS (PLATES AND SCREWS) AND THEIR INSTRUMENTS ARE INTENDED FOR TRAUMA REPAIR AND RECONSTRUCTION OF THE CRANIOFACIAL SKELETON.,MAXILLARY DISTRACTOR-THE MAXILLARY DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. THE INTERNAL MIDFACE DISTRACTOR, THE MAXILLARY DISTRACTOR, THE SINGLE VECTOR DISTRACTOR, THE EXTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. THE CRANIOMAXILLOFACIAL (CMF) DISTRACTOR AND SYNTHES MULTI-VECTOR DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING (AND/OR TRANSPORT) DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. UNIVERSAL SCREW REMOVAL SET IS INTENDED TO BE USED FOR THE REMOVAL OF INTACT AND DAMAGED SCREWS. IT IS NOT INTENDED TO BE USED IN COMBINATION WITH A POWER TOOL.,FEMORAL SHAFT NAILING IMPLANTS-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE

	FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",SCREW IMPLANTS FOR OR WITHOUT PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,CONNECTING RODS-CONNECTING RODS ARE INTENDED TO FACILITATE THE CONNECTION OF QUALIFIED POSTERIOR SPINAL STABILIZATION SYSTEMS TOGETHER.,SYNMESH-"SYNMESH IS A VERTEBRAL BODY REPLACEMENT DEVICE FOR THE CERVICAL, THORACIC AND LUMBAR SPINE. TITANIUM IMPLANTS IN VARIOUS FOOTPRINTS AND HEIGHTS ENABLE THE SURGEON TO CHOOSE THE CONFIGURATION THAT IS BEST SUITED TO THE PATIENT'S INDIVIDUAL PATHOLOGY AND ANATOMY. THE MESH MAY ALSO BE TRIMMED FOR A CUSTOM FIT. THE IMPLANTS CAN BE INSERTED ANTERIORLY, LATERALLY OR ANTEROLATERALLY.", INTERNAL MIDFACE DISTRACTOR-THE INTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED.,SYNAPSE-"THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: — TOP-LOADING VARIABLE AXIS SCREWS — HOOKS — TRANSVERSE BARS — RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY.",AXON AND OCCIPITO-CERVICAL(OC) FUSION-"THE AXON SYSTEM IS A COMPREHENSIVE SET OF INSTRUMENTS AND IMPLANTS, INCLUDING — TOP-LOADING VARIABLE AXIS SCREWS, — HOOKS, — TRANSVERSE BARS AND — RODS. IT IS DESIGNED FOR POSTERIOR STABILISATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY. THE AXON SYSTEM USES THE EXISTING CERVIFIX RODS, ALLOWING COMPONENTS FROM AXON AND CERVIFIX TO BE COMBINED. THIS ALLOWS A CONSTRUCT TO EXTEND FROM THE OCCIPUT TO THE LOWER SPINE USING THE UNIVERSAL SPINE SYSTEM (USS).",TIBIAL NAILING IMPLANTS-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL

	ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,LOW PROFILE NEURO-DEPUY SYNTHES LOW PROFILE NEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION.,SCREW IMPLANTS FOR PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,HINDFOOT ARTHRODESIS NAILING IMPLANTS-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,LOW PROFILE NEURO-DEPUY SYNTHES LOW PROFILE NEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION., MATRIXNEURO-DEPUY SYNTHES MATRIXNEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION.,EXTERNAL MIDFACE DISTRACTOR-THE DEPUY SYNTHES EXTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED.,MATRIXMIDFACE MIDFACE SYSTEM (INCLUDING MATRIXORBITAL SYSTEM)-"THE MATRIXORTHOGNATHIC SYSTEM IS INTENDED FOR USE AS A STABLE INTERNAL BONE FIXATION SYSTEM IN ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES). THE SYNTHES TRANSPALATAL DISTRACTOR IS INTENDED FOR USE AS A BONE-BORNE MAXILLARY EXPANDER AND RETAINER FOR SURGICALLY ASSISTED, RAPID, PALATAL EXPANSION. THE SYNTHES TRANSPALATAL DISTRACTOR IS INTENDED FOR SINGLE USE ONLY. THE ORTHODONTIC BONE ANCHOR (OBA) SYSTEM IS INTENDED TO BE IMPLANTED INTRAORALLY AND USED AS AN ANCHOR FOR ORTHODONTIC PROCEDURES. THE OBA SYSTEM INCLUDES SCREW ANCHORS, PLATE ANCHORS, INSTRUMENTS, AND A MODULE CASE FOR STORAGE AND STERILIZATION. THE MATRIXORTHOGNATHIC LOCK SYSTEM IS INTENDED FOR USE AS A STABLE INTERNAL BONE FIXATION SYSTEM IN ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES).", REAMER/IRRIGATOR/ ASPIRATOR-"REAMER/ IRRIGATOR/ ASPIRATOR DEVICES ARE INTENDED -TO CLEAR THE MEDULLARY CANAL OF BONE MARROW AND REAMING DEBRIS. -TO CLEAR THE MEDULLARY CANAL OF INFECTED BONE TISSUE. -TO EFFECTIVELY SIZE THE MEDULLARY CANAL FOR THE ACCEPTANCE OF AN

	INTRAMEDULLARY IMPLANT OR PROSTHESIS. -TO HARVEST FINELY MORSELIZED AUTOGENOUS BONE AND BONE MARROW FOR ANY SURGICAL PROCEDURES THAT REQUIRE BONE GRAFT IN ORDER TO FACILITATE FUSION AND/OR FILL BONE DEFECTS. THESE PROCEDURES INCLUDE SPINAL FUSION, JOINT ARTHRODESIS, TOTAL JOINT REPLACEMENT, FRACTURE REPAIR, NONUNION, MAXILLOFACIAL RECONSTRUCTION, AND TUMOR REMOVAL.", CONNECTING RODS-CONNECTING RODS ARE INTENDED TO FACILITATE THE CONNECTION OF QUALIFIED POSTERIOR SPINAL STABILIZATION SYSTEMS TOGETHER.,MATRIXNEURO-DEPUY SYNTHES MATRIXNEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION.,COMPACT MANDIBLE-THE SYNTHES PLATE AND SCREW SYSTEM COMPACT MANDIBLE IS INTENDED FOR ORAL, MAXILLOFACIAL SURGERY, TRAUMA, RECONSTRUCTIVE SURGERY, AND ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES)., PROXIMAL FEMORAL NAILING IMPLANTS-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,FEMORAL SHAFT NAILING IMPLANTS-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN)., MATRIXORTHOGNATHIC-THE MATRIXORTHOGNATHIC SYSTEM IS INTENDED FOR USE AS A STABLE INTERNAL BONE FIXATION SYSTEM IN ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES).,MATRIXMANDIBLE & MATRIXMANDIBLE PREFORMED RECONSTRUCTION PLATES-THE DEPUY SYNTHES MATRIXMANDIBLE PLATING SYSTEM IS INTENDED FOR ORAL, MAXILLOFACIAL SURGERY. THE DEPUY SYNTHES MATRIXMANDIBLE RECONSTRUCTION PLATES IS INTENDED FOR RECONSTRUCTIVE SURGERY. THE DEPUY SYNTHES MATRIXMANDIBLE SUBCONDYLAR PLATES ARE INTENDED FOR THE TRAUMA OF THE MANDIBLE.,MATRIXMIDFACE SYSTEM (INCLUDING MATRIXORBITAL SYSTEM)-MATRIXMIDFACE PLATE AND SCREW SYSTEM IS INTENDED FOR USE AS TRAUMA REPAIR AND

		RECONSTRUCTION OF THE CRANIO-MAXILLOFACIAL SKELETON., PEDIATRIC PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,HINDFOOT ARTHRODESIS NAILING IMPLANTS-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",MATRIXMIDFACE SYSTEM (INCLUDING MATRIXORBITAL SYSTEM)-MATRIXMIDFACE PLATE AND SCREW SYSTEM IS INTENDED FOR USE AS TRAUMA REPAIR AND RECONSTRUCTION OF THE CRANIO-MAXILLOFACIAL SKELETON., SCREW IMPLANTS FOR OR WITHOUT PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.
2427	IMP/MD/2021/000025	1.License Holder Name: VYGON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VY-P SYRINGE FOR NUTRISAFE2 ENTERAL CONNECTION(VY-P SYRINGE FOR NUTRISAFE2 ENTERAL CONNECTION)-ENTERAL FEEDING FOR NEONATES, NEWBORNS AND CHILDREN.,VY-P SYRINGE FOR NUTRISAFE2 ENTERAL CONNECTION(VY-P SYRINGE FOR NUTRISAFE2 ENTERAL CONNECTION)-ENTERAL FEEDING FOR NEONATES, NEWBORNS AND CHILDREN.
2428	IMP/MD/2021/000026	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYALURONIC ACID, STABILIZED SINGLE INJECTION 60MG/3ML(DUROLANE®)-DUROLANE IS INTENDED TO BE USED FOR INTRA-ARTICULAR INJECTION FOR THE SYMPTOMATIC TREATMENT OF MILD TO MODERATE KNEE OR HIP OSTEOARTHRITIS.

2429	IMP/MD/2021/000027	1.License Holder Name: SAFETIX PROTECTIVE EQUIPMENTS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYDROCONDUCTIVE DRESSING(DRAWTEX)-DRAWTEX CAN BE USED AS A WOUND DRESSING ON: ACUTE WOUNDS, SURGICAL WOUNDS, PENETRATING INJURIES, SKIN TEARS, BURNS, PRESSURE SORES, DIABETIC AND FOOT ULCERS, CANCER WOUNDS, HIV WOUNDS, GANGRENE WOUNDS AND NON-HEALINGS WOUNDS.
2430	IMP/MD/2021/000028	1.License Holder Name: FRESENIUS MEDICAL CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HAEMODIALYSIS CONCENTRATE(GRANUDIAL)-FOR EXTRACORPOREAL BICARBONATE HAEMODIALYSIS OR HAEMODIAFILTRATION.,SODIUM BICARBONATE FOR HAEMODIALYSIS(BIBAG)-FOR EXTRACORPOREAL BICARBONATE HAEMODIALYSIS OR HAEMODIAFILTRATION.
2431	IMP/MD/2021/000029	1.License Holder Name: CHETAN MEDITECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:POLYBLEND NON-ABSORBABLE SURGICAL SUTURE(HS FIBER)-HS FIBER SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION AND THE USE OF ALLOGRAFT TISSUES FOR ORTHOPEDIC SURGERIES. HS FIBER SUTURES ARE INTENDED FOR ONE TIME USE ONLY, AND ARE NOT TO BE RE-STERILIZED.
2432	IMP/MD/2021/000032	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRANSURETHRAL DELIVERY DEVICE & IMPLANT(UROLIFT® SYSTEM)-THE UROLIFT SYSTEM IS INDICATED FOR THE TREATMENT OF SYMPTOMS DUE TO URINARY OUTFLOW OBSTRUCTION SECONDARY TO BENIGN PROSTATIC HYPERPLASIA (BPH) IN MEN 50 YEARS OF AGE OR OLDER.

2433	IMP/MD/2021/000033	1.License Holder Name: ELITE MEDICAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE NON-ABSORBABLE POLYMER LIGATING CLIPS(META CLIP-P(ML), META CLIP-P(L), META CLIP-P(XL))-META CLIP-P IS A DISPOSABLE AND NONABSORBABLE POLYMER DEVICE USED FOR GENERAL SURGICAL PROCEDURES REQUIRING VASCULAR OR TISSUE LIGATION
2434	IMP/MD/2021/000034	1.License Holder Name: CONVATEC INDIA PVT. LTD. ,SY. NO.-217, NEXT LOGISTICS DOCK-4, SOUKYA ROAD, NEXT TO POLICE STATION, KORALLUR VILLAGE, ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560067 ,INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHY CLOSED SUCTION SYSTEM(CATHY CLOSED SUCTION SYSTEM)-IT IS INTENDED TO BE USED FOR THE REMOVAL OF ACCUMULATED SECRETION IN THE LOWER RESPIRATORY TRACTS IN PATIENTS RECEIVING VENTILATOR TREATMENT.
2435	IMP/MD/2021/000037	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERCUTANEOUS LEAD INTRODUCER-THE MEDTRONIC INTRODUCER KIT IS DESIGNED TO PROVIDE A RAPID, AND RELATIVELY ATRAUMATIC, METHOD FOR IMPLANTING ONE OR MORE IMPLANTABLE, ENDOCARDIAL, PACEMAKER LEADS.
2436	IMP/MD/2021/000038	1.License Holder Name: MYOVATEC SURGICAL SYSTEMS LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE SILICONE BREAST IMPLANT MOTIVA IMPLANT MATRIX®(MOTIVA IMPLANT MATRIX®)-BREAST AUGMENLATION FOR WOMEN OF AT LEAST 18 YEARS OF AGE, INCLUDING PREVIOUS AUGMENTALION TO INCREASE THE BREAST SIZE AND REVISION SURGERY TO CORRECT OR IMPROVE THE RESULT OF A PREVIOUS BREAST AUGMENTATION SURGERY. BREASL RECONSTRUCTION, INCLUDING PREVIOUS RECONSTTUCTION TO REOLACE BREAST TISSUE THAT HAS BEEN FEMOVED DUE TO CANCEL OR TRAUMA, OR THAT HAS FAILED TO DEVELOP PROPERLY DUE TO A SEVERE BREAST ANOMALY, AS WELL AS REVISION SURGERY TO CONECL OR IMPROVE THE RESULTS OF A PREVIOUS BREAST RECONSTRUCTION SURGER

2437	IMP/MD/2021/000043	1.License Holder Name: M/S MEDIFOCUS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REGENERATIVE DURAL REPAIR PATCH(REDURA)-REGENERATIVE DURAL REPAIR PATCH IS APPLIED IN SURGICALLY REPAIRING OPERATIONS IN CASE OF DESTRUCTIVE DURAL EFFECTS

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2438	IMP/MD/2021/000044	1.License Holder Name: FAITH BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROCATHETER (HEADWAY)-[HEADWAY 17 ADVANCED SOFT, HEADWAY 17 ADVANCED, HEADWAY 21, HEADWAY 27: THE HEADWAY MICROCATHETER IS INTENDED FOR GENERAL INTRAVASCULAR USE, INCLUDING THE PERIPHERAL, CORONARY AND NEURO VASCULATURE FOR THE INFUSION OF DIAGNOSTIC AGENTS, SUCH AS CONTRAST MEDIA, AND THERAPEUTIC AGENTS, SUCH AS OCCLUSION COILS.], [HEADWAY DUO: THE HEADWAY DUO MICROCATHETER IS INTENDED FOR GENERAL INTRAVASCULAR USE, INCLUDING THE PERIPHERAL AND CORONARY VASCULATURE FOR THE INFUSION OF DIAGNOSTIC AGENTS, SUCH AS CONTRAST MEDIA, AND THERAPEUTIC AGENTS, SUCH AS EMBOLIZATION MATERIALS. THE HEADWAY DUO MICROCATHETER IS INTENDED FOR NEUROVASCULAR USE, FOR THE INFUSION OF DIAGNOSTIC AGENTS, SUCH AS CONTRAST MEDIA, AND THERAPEUTIC AGENTS THAT HAVE BEEN CLEARED OR APPROVED FOR USE IN THE NEUROVASCULATURE AND ARE COMPATIBLE WITH THE INNER DIAMETER OF THE HEADWAY DUO MICROCATHETER.], ENDOVASCULAR EMBOLIZATION COIL(MICROPLEX COIL SYSTEM (MCS))-THE MICROPLEX COIL SYSTEM (MCS) IS INTENDED FOR THE ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS AND OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE. THE MCS IS ALSO INTENDED FOR VASCULAR OCCLUSION OF BLOOD VESSELS WITHIN THE NEUROVASCULAR SYSTEM TO PERMANENTLY OBSTRUCT BLOOD FLOW TO AN ANEURYSM OR OTHER VASCULAR MALFORMATION AND FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE., OCCLUSION BALLOON CATHETER(SCEPTER)-THE SCEPTER C AND SCEPTER XC OCCLUSION BALLOON CATHETERS ARE INTENDED: • FOR USE IN THE PERIPHERAL AND NEURO VASCULATURE WHERE TEMPORARY OCCLUSION IS DESIRED. THE BALLOON CATHETERS PROVIDE TEMPORARY VASCULAR OCCLUSION WHICH IS USEFUL IN SELECTIVELY STOPPING OR CONTROLLING BLOOD FLOW. THE BALLOON CATHETERS ALSO OFFER BALLOON ASSISTED EMBOLIZATION OF INTRACRANIAL ANEURYSMS. • FOR USE IN THE PERIPHERAL VASCULATURE FOR THE INFUSION OF DIAGNOSTIC AGENTS, SUCH AS CONTRAST MEDIA, AND THERAPEUTIC AGENTS SUCH AS EMBOLIZATION MATERIALS. • FOR NEUROVASCULAR USE FOR THE INFUSION OF DIAGNOSTIC AGENTS SUCH AS CONTRAST MEDIA, AND THERAPEUTIC AGENTS, SUCH AS EMBOLIZATION MATERIALS, THAT HAVE BEEN APPROVED OR CLEARED FOR USE IN

		THE NEUROVASCULATURE AND ARE COMPATIBLE WITH THE INNER DIAMETER OF THE SCEPTER C/XC BALLOON CATHETER., ENDOVASCULAR EMBOLIZATION COIL(HYDROCOIL EMBOLIC SYSTEM (HES))-THE HYDROCOIL EMBOLIC SYSTEM (HES) IS INTENDED FOR THE ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL ANEURYSMS AND OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE. THE HES IS ALSO INTENDED FOR VASCULAR OCCLUSION OF BLOOD VESSELS WITHIN THE NEUROVASCULAR SYSTEM TO PERMANENTLY OBSTRUCT BLOOD FLOW TO AN ANEURYSM OR OTHER VASCULAR MALFORMATION AND FOR ARTERIAL AND VENOUS EMBOLIZATIONS IN THE PERIPHERAL VASCULATURE.
2439	IMP/MD/2021/000045	1.License Holder Name: RENNEX MEDICAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITORING DEVICES(BPX PLUS)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES,BLOOD PRESSURE MONITORING DEVICES(BP 10)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES
2440	IMP/MD/2021/000046	1.License Holder Name: OLYMPUS MEDICAL SYSTEMS INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ULTRASONIC GENERATOR-THE ELECTROSURGICAL &ULTRASONIC GENERATOR (USG-410) IS INTENDED TO BE USED WITH THE THUNDERBEAT, TRANSDUCER, THE SONICBEAT FOR OPEN, LAPAROSCOPIC (INCLUDING SINGLE-SITE SURGERY) AND ENDOSCOPIC SURGERY TO CUT (DISSECT) OR COAGULATE SOFT TISSUE OR TO LIGATE (SEAL AND CUT) VESSELS.

2441	IMP/MD/2021/000047	1.License Holder Name: HOYA MEDICAL INDIA PRIVATE LIMITED (GODOWN) 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HOYA VIVINEX ISERT (HOYA VIVINEX ISERT)-HOYA VIVINEX ISERT IOL IS INTENDED TO BE PLACED INTO THE CAPSULAR BAG OF THE EYE AFTER EXTRACAPSULAR CATARACT REMOVAL, FUNCTIONING AS A REFRACTIVE MEDIUM TO REPLACE THE NATURAL CRYSTALLINE LENS.,HOYA-PS AF-1 (UV)(HOYA-PS AF-1 (UV))-HOYA-PS AF-1 IOL IS INTENDED TO BE PLACED INTO THE CAPSULAR BAG OF THE EYE AFTER EXTRACAPSULAR CATARACT REMOVAL, FUNCTIONING AS A REFRACTIVE MEDIUM TO REPLACE THE NATURAL CRYSTALLINE LENS.,HOYA ISERT(HOYA ISERT)-HOYA ISERT IOL IS INTENDED TO BE PLACED INTO THE CAPSULAR BAG OF THE EYE AFTER EXTRACAPSULAR CATARACT REMOVAL, FUNCTIONING AS A REFRACTIVE MEDIUM TO REPLACE THE NATURAL CRYSTALLINE LENS.,HOYA VIVINEX MULTISERT(HOYA VIVINEX MULTISERT)-HOYA VIVINEX MULTISERT IOL IS INTENDED TO BE PLACED INTO THE CAPSULAR BAG OF THE EYE AFTER EXTRACAPSULAR CATARACT REMOVAL, FUNCTIONING AS A REFRACTIVE MEDIUM TO REPLACE THE NATURAL CRYSTALLINE LENS.
2442	IMP/MD/2021/000048	1.License Holder Name: MICROGENE DIAGNOSTIC SYSTEMS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITOR(ACCUSURE)-THIS DEVICE IS INTENDED FOR USE IN MEASURING SYSTOLIC AND DIASTOLIC BLOOD PRESSURE AND PULSE RATE IN PATIENT POPULATION. .
2443	IMP/MD/2021/000049	1.License Holder Name: M/S SR MEDICARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CERVICAL COLD COAGULATORS (THERMAL ABLATION DEVICES FOR GYNAECOLOGY WITH ACCESSORIES)(WISAP-C3 SET)-THE WISAP CERVICAL COLD COAGULATOR IS USED IN CONJUNCTION WITH THE WISAP THERAPY PROBE (REF 612X) EXCLUSIVELY FOR THE THERMAL ABLATION OF CERVICAL LESIONS OR CIN 1-3

2444	IMP/MD/2021/000050	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOPSY NEEDLE(BARD® MAGNUM® DISPOSABLE CORE TISSUE BIOPSY NEEDLES)-THE MAGNUM® BIOPSY SYSTEM (INSTRUMENT AND NEEDLES) IS INTENDED FOR USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS LIVER, KIDNEY, PROSTATE, BREAST, SPLEEN, LYMPH NODES AND VARIOUS SOFT TISSUE TUMORS.
2445	IMP/MD/2021/000051	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VENOGRAM BALLOON CATHETER(ATTAIN)-THE VENOGRAM BALLOON CATHETER IS INDICATED FOR USE WITHIN THE CORONARY SINUS; IT IS INTENDED FOR INFUSING CONTRAST SOLUTIONS INTO THE CORONARY VASCULATURE FOR VENOGRAM IMAGING.

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2446	IMP/MD/2021/000052	1.License Holder Name: OMRON HEALTHCARE INDIA PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITOR(OMRON)-THIS PRODUCT IS DESIGNED TO MEASURE THE BLOOD PRESSURE AND PULSE RATE OF PEOPLE WITHIN THE RANGE OF THE DESIGNATED ARM CUFF, FOLLOWING THE INSTRUCTION IN THE INSTRUCTION MANUAL.,BLOOD PRESSURE MONITORING DEVICE (OMRON)-THIS DEVICE IS A DIGITAL MONITOR INTENDED FOR USE IN MEASURING BLOOD PRESSURE AND PULSE RATE IN ADULT PATIENT POPULATION WHO CAN UNDERSTAND THIS INSTRUCTION MANUAL WITH THE ARM CIRCUMFERENCE RANGE PRINTED ON THE ARM CUFF. THE DEVICE DETECTS THE APPEARANCE OF IRREGULAR HEARTBEATS DURING MEASUREMENT AND GIVES A WARNING SIGNAL WITH MEASUREMENT RESULT. IT IS MAINLY DESIGNED FOR GENERAL HOUSEHOLD USE.,COMPRESSOR NEBULISER(OMRON)-THIS PRODUCT IS INTENDED TO BE USED FOR INHALING MEDICATION FOR RESPIRATORY DISORDER,BLOOD PRESSURE MONITORING DEVICE (OMRON)-THIS PRODUCT IS DESIGNED TO MEASURE THE BLOOD PRESSURE AND PULSE RATE OF PEOPLE WITHIN THE RANGE OF DESIGNATED ARM CUFF , FOLLOWING THE INSTRUCTION IN THE INSTRUCTION MANUAL,NEBULIZER (OMRON)-THE PRODUCT IS INTENDED TO BE USED FOR INHALING MEDICATION FOR RESPIRATORY DISORDERS,NEBULIZER(OMRON)-THIS PRODUCT IS INTENDED TO BE USED FOR INHALING MEDICATION FOR RESPIRATORY DISORDERS.,BLOOD PRESSURE MONITORING DEVICE (OMRON)-THIS PRODUCT IS DESIGNED TO MEASURE THE BLOOD PRESSURE AND PULSE RATE. ,BLOOD PRESSURE MONITORING DEVICE(OMRON)-THIS DEVICE IS A DIGITAL MONITOR INTENDED FOR USE IN MEASURING BLOOD PRESSURE AND PULSE RATE IN ADULT PATIENT POPULATION. THE DEVICE DETECTS THE APPEARANCE OF IRREGULAR HEARTBEATS DURING MEASUREMENT AND GIVES A WARNING SIGNAL WITH READINGS. IT IS MAINLY DESIGNED FOR GENERAL HOUSEHOLD USE. THE DEVICE CAN DETECT AN IRREGULAR PULSE SUGGESTIVE OF ATRIAL FIBRILLATION (AFIB) PLEASE NOTE THAT THE DEVICE IS NOT INTENDED TO DIAGNOSE AFIB CAN ONLY BE CONFIRMED BY ELECTROCARDIOGRAM (ECG). IF THE AFIB SYMBOL APPEARS, CONSULT YOUR PHYSICIAN.,BLOOD PRESSURE MONITORING DEVICE(OMRON)-THIS DEVICE IS DIGITAL MONITOR INTENDED FOR USE IN MEASURING BLOOD PRESSURE AND PULSE RATE IN THE ADULT PATIENT POPULATION. THE DEVICE DETECTS THE APPEARANCE OF IRREGULAR HEARTBEATS DURING MEASUREMENT AND INDICATES THIS VIA A SYMBOL WITH MEASUREMENT RESULT. IT IS MAINLY DESIGNED FOR GENERAL HOUSEHOLD USE.

2447	IMP/MD/2021/000053	1.License Holder Name: OMRON HEALTHCARE INDIA PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITORING DEVICE(OMRON)-THIS PRODUCT IS DESIGNED TO MEASURE THE BLOOD PRESSURE AND PULSE RATE OF PEOPLE WITHIN THE RANGE OF DESIGNATED ARM CUFF, FOLLOWING THE INSTRUCTION IN THIS INSTRUCTION MANUAL. IT IS MAINLY DESIGNED FOR GENERAL HOUSEHOLD USE.,NEBULIZER(OMRON)-THE PRODUCT IS INTENDED TO BE USED FOR INHALING MEDICATION FOR RESPIRATORY DISORDERS,BLOOD PRESSURE MONITORING DEVICE (OMRON)-THE DEVICE IS A DIGITAL MONITOR INTENDED FOR USE IN MEASURING BLOOD PRESSURE AND PULSE RATE IN ADULT PATIENT POPULATION. THE DEVICE DETECTS THE APPEARANCE OF IRREGULAR HEARTBEATS DURING MEASUREMENT AND GIVES A WARNING SIGNAL WITH READINGS.
2448	IMP/MD/2021/000058	1.License Holder Name: MICROGENE DIAGNOSTIC SYSTEMS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANEROID BLOOD PRESSURE MONITOR (ANEROID SPHYGMOMANOMETER)(ACCUSURE) -IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.

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2449	IMP/MD/2021/000059	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GRASPING FORCEPS (UROLIFT)-THE GRASPERS ARE INDICATED TO PROVIDE THE USER WITH THE MEANS FOR ENDOSCOPIC DIAGNOSTIC AND THERAPEUTIC SURGICAL PROCEDURES. EXAMPLES FOR THE USE OF THE DEVICES INCLUDE THE VISUALIZATION AND MANIPULATION OF ANATOMY AS THE SURGEON DEEMS APPROPRIATE. THE DEVICES ARE INTENDED TO BE USED IN GENERAL UROLOGICAL SURGERY THROUGH A MINIMALLY INVASIVE APPROACH BY UTILIZING NATURAL ORIFICES TO ACCESS THE SURGICAL SITE.,SHEATH(UROLIFT)-THE SHEATHS ARE INDICATED TO PROVIDE THE USER WITH THE MEANS FOR ENDOSCOPIC DIAGNOSTIC AND THERAPEUTIC SURGICAL PROCEDURES. EXAMPLES FOR THE USE OF THE DEVICES INCLUDE THE VISUALIZATION AND MANIPULATION OF ANATOMY AS THE SURGEON DEEMS APPROPRIATE. THE DEVICES ARE INTENDED TO BE USED IN GENERAL UROLOGICAL SURGERY THROUGH A MINIMALLY INVASIVE APPROACH BY UTILIZING NATURAL ORIFICES TO ACCESS THE SURGICAL SITE.
2450	IMP/MD/2021/000060	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BALLOON CATHETER FOR THE TUBA EUSTACHII(TUBAVENT)-THE CATHETER IS USED FOR BALLOON DILATATION OF THE EUSTACHIAN TUBE (TUBA EUSTACHII) IN THE EVENT OF AN OBSTRUCTIVE TUBE DYSFUNCTION.

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2451	IMP/MD/2021/000066	1.License Holder Name: KCI MEDICAL INDIA PRIVATE LIMITED ,K. NO. 2606/115 (P. NO. 60/16) GROUND FLOOR, HUSKUR ROAD ELECTRONIC POST ,BENGALURU (BANGALORE) URBAN KARNATAKA ,560100 , INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:V.A.C.® GRANUFOAM™ BRIDGE DRESSINGS(V.A.C.® GRANUFOAM™ BRIDGE DRESSINGS)-THE ACTIV.A.C.®, INFOV.A.C.®, V.A.C. ATS® AND V.A.C. FREEDOM® THERAPY SYSTEMS ARE INTEGRATED WOUND MANAGEMENT SYSTEMS FOR USE IN ACUTE AND EXTENDED AND HOME CARE SETTINGS. THEY ARE INTENDED TO CREATE AN ENVIRONMENT THAT PROMOTES WOUND HEALING BY SECONDARY OR TERTIARY (DELAYED PRIMARY) INTENTION BY PREPARING THE WOUND BED FOR CLOSURE, REDUCING EDEMA, PROMOTING GRANULATION TISSUE FORMATION AND PERFUSION, AND BY REMOVING EXUDATE AND INFECTIOUS MATERIAL. THEY ARE INDICATED FOR PATIENTS WITH CHRONIC, ACUTE, TRAUMATIC, SUBACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC, PRESSURE OR VENOUS INSUFFICIENCY), FLAPS AND GRAFTS.,V.A.C.® GRANUFOAM™ DRESSINGS(V.A.C.® GRANUFOAM™ DRESSING SMALL, MEDIUM, LARGE, ROUND AND THIN FEATURING SENSAT.R.A.C.™ TECHNOLOGY)-THE ACTIV.A.C.®, INFOV.A.C.®, V.A.C. ATS® AND V.A.C. FREEDOM® NEGATIVE PRESSURE WOUND THERAPY SYSTEMS ARE INTEGRATED WOUND MANAGEMENT SYSTEMS FOR USE IN ACUTE AND EXTENDED AND HOME CARE SETTINGS. WHEN USED ON OPEN WOUNDS, THEY ARE INTENDED TO CREATE AN ENVIRONMENT THAT PROMOTES WOUND HEALING BY SECONDARY OR TERTIARY (DELAYED PRIMARY) INTENTION BY PREPARING THE WOUND BED FOR CLOSURE, REDUCING EDEMA, PROMOTING GRANULATION TISSUE FORMATION AND PERFUSION, AND BY REMOVING EXUDATE AND INFECTIOUS MATERIAL. OPEN WOUND TYPES INCLUDE: CHRONIC, ACUTE, TRAUMATIC, SUBACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC, PRESSURE OR VENOUS INSUFFICIENCY), FLAPS AND GRAFTS. WHEN USED ON CLOSED SURGICAL INCISIONS, THEY ARE ALSO INTENDED TO MANAGE THE ENVIRONMENT OF THE SURGICAL INCISIONS THAT CONTINUE TO DRAIN FOLLOWING SUTURED OR STAPLED CLOSURE BY MAINTAINING A CLOSED ENVIRONMENT AND REMOVING EXUDATES VIA THE APPLICATION OF NEGATIVE PRESSURE WOUND THERAPY.,V.A.C.® CANISTERS(500 ML & 1000 ML CANISTER (WITH GEL) FOR INFOV.A.C.™ AND V.A.C.ULTA™ THERAPY SYSTEMS)-THE V. A.C.® THERAPY SYSTEM IS AN INTEGRATED WOUND MANAGEMENT SYSTEM FOR USE IN ACUTE AND EXTENDED AND HOME CARE SETTINGS. THEY ARE INTENDED TO CREATE AN ENVIRONMENT THAT

	PROMOTES WOUND HEALING BY SECONDARY OR TERTIARY (DELAYED PRIMARY) INTENTION BY PREPARING THE WOUND BED FOR CLOSURE, REDUCING EDEMA, PROMOTING GRANULATION TISSUE FORMATION AND PERFUSION, AND BY REMOVING EXUDATE AND INFECTIOUS MATERIAL. THEY ARE INDICATED FOR PATIENTS WITH CHRONIC, ACUTE, TRAUMATIC, SUBACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC, PRESSURE OR VENOUS INSUFFICIENCY), FLAPS AND GRAFTS., ABTHERA™ SENSAT.R.A.C.™ OPEN ABDOMEN DRESSING(ABTHERA™ SENSAT.R.A.C.™ OPEN ABDOMEN DRESSING)-THE ABTHERA™ SENSAT.R.A.C.™ OPEN ABDOMEN DRESSING IS INDICATED FOR TEMPORARY BRIDGING OF ABDOMINAL WALL OPENINGS WHERE PRIMARY CLOSURE IS NOT POSSIBLE AND OR REPEAT ABDOMINAL ENTRIES ARE NECESSARY. THE INTENDED USE OF THIS DRESSING IS IN OPEN ABDOMINAL WOUNDS WITH EXPOSED VISCERA INCLUDING, BUT NOT LIMITED TO, ABDOMINAL COMPARTMENT SYNDROME. THE INTENDED CARE SETTING IS A CLOSELY MONITORED AREA WITHIN THE ACUTE CARE HOSPITAL, SUCH AS THE ICU. THE ABDOMINAL DRESSING WILL MOST OFTEN BE APPLIED IN THE OPERATING THEATER.,V.A.C.® ACCESSORIES(V.A.C.® TUBING CAP)-THE V.A.C.® TUBING CAP IS USED WHEN TEMPORARILY DISCONNECTING THE V.A. C.® DRESSING FROM THE V.A.C.® THERAPY UNIT.,ACTIV.A.C.™ CANISTERS(300 ML CANISTER (WITH GEL) FOR ACTIV.A.C.™ THERAPY SYSTEM, FLUID PATH STERILE)-THE V.A.C.® THERAPY SYSTEM IS AN INTEGRATED WOUND MANAGEMENT SYSTEM FOR USE IN ACUTE AND EXTENDED AND HOME CARE SETTINGS. THEY ARE INTENDED TO CREATE AN ENVIRONMENT THAT PROMOTES WOUND HEALING BY SECONDARY OR TERTIARY (DELAYED PRIMARY) INTENTION BY PREPARING THE WOUND BED FOR CLOSURE, REDUCING EDEMA, PROMOTING GRANULATION TISSUE FORMATION AND PERFUSION, AND BY REMOVING EXUDATE AND INFECTIOUS MATERIAL. THEY ARE INDICATED FOR PATIENTS WITH CHRONIC, ACUTE, TRAUMATIC, SUBACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC, PRESSURE OR VENOUS INSUFFICIENCY), FLAPS AND GRAFTS.,V.A.C.® ACCESSORIES(V.A.C.® DRAPE & SENSAT.R.A.C.™ PAD FEATURING SENSAT.R.A.C.™ TECHNOLOGY)-THE ACTIV.A.C.®, INFOV.A.C.®, V.A.C. ATS® AND V.A.C. FREEDOM® NEGATIVE PRESSURE WOUND THERAPY SYSTEMS ARE INTEGRATED WOUND MANAGEMENT SYSTEMS FOR USE IN ACUTE AND EXTENDED AND HOME CARE SETTINGS. WHEN USED ON OPEN WOUNDS, THEY ARE INTENDED TO CREATE AN ENVIRONMENT THAT PROMOTES WOUND HEALING BY SECONDARY OR TERTIARY (DELAYED PRIMARY) INTENTION BY PREPARING THE WOUND BED FOR CLOSURE, REDUCING EDEMA, PROMOTING GRANULATION TISSUE FORMATION

	AND PERFUSION, AND BY REMOVING EXUDATE AND INFECTIOUS MATERIAL. OPEN WOUND TYPES INCLUDE: CHRONIC, ACUTE, TRAUMATIC, SUBACUTE AND DEHISCED WOUNDS, PARTIAL-THICKNESS BURNS, ULCERS (SUCH AS DIABETIC, PRESSURE OR VENOUS INSUFFICIENCY), FLAPS AND GRAFTS. WHEN USED ON CLOSED SURGICAL INCISIONS, THEY ARE ALSO INTENDED TO MANAGE THE ENVIRONMENT OF THE SURGICAL INCISIONS THAT CONTINUE TO DRAIN FOLLOWING SUTURED OR STAPLED CLOSURE BY MAINTAINING A CLOSED ENVIRONMENT AND REMOVING EXUDATES VIA THE APPLICATION OF NEGATIVE PRESSURE WOUND THERAPY.,V.A.C.® ACCESSORIES(V.A.C.® Y- CONNECTOR)-THE V.A.C.® Y-CONNECTOR IS USED TO CONNECT TWO SENSAT.R.A.C.™ PADS TO A SINGLE V.A.C.® THERAPY UNIT.

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2452	IMP/MD/2021/000067	1.License Holder Name: CAREGROUP SIGHT SOLUTION LLP, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TRABECULAR MICRO-BYPASS SYSTEM(ISTENT INJECT® TRABECULAR MICRO-BYPASS SYSTEM)-THE ISTENT INJECT® TRABECULAR MICRO-BYPASS SYSTEM IS INTENDED TO REDUCE INTRAOCULAR PRESSURE SAFELY AND EFFECTIVELY IN PATIENTS DIAGNOSED WITH PRIMARY OPEN-ANGLE GLAUCOMA, PSEUDO-EXFOLIATIVE GLAUCOMA OR PIGMENTARY GLAUCOMA. THE ISTENT INJECT CAN DELIVER TWO (2) STENTS ON A SINGLE PASS, THROUGH A SINGLE INCISION. THE DEVICE IS SAFE AND EFFECTIVE WHEN IMPLANTED IN COMBINATION WITH CATARACT SURGERY IN THOSE SUBJECTS WHO REQUIRE INTRAOCULAR PRESSURE REDUCTION AND/OR WOULD BENEFIT FROM GLAUCOMA MEDICATION REDUCTION. THE DEVICE MAY ALSO BE IMPLANTED IN PATIENTS WHO CONTINUE TO HAVE ELEVATED INTRAOCULAR PRESSURE DESPITE PRIOR TREATMENT WITH GLAUCOMA MEDICATIONS AND CONVENTIONAL GLAUCOMA SURGERY.,TRABECULAR MICRO-BYPASS STENT SYSTEM(ISTENT® TRABECULAR MICRO-BYPASS STENT SYSTEM)-THE ISTENT® TRABECULAR MICRO-BYPASS STENT SYSTEM IS INTENDED TO REDUCE INTRAOCULAR PRESSURE SAFELY AND EFFECTIVELY IN PATIENTS DIAGNOSED WITH PRIMARY OPEN-ANGLE GLAUCOMA, PSEUDO-EXFOLIATIVE GLAUCOMA OR PIGMENTARY GLAUCOMA. THE DEVICE IS SAFE AND EFFECTIVE WHEN IMPLANTED IN COMBINATION WITH CATARACT SURGERY IN THOSE SUBJECTS WHO REQUIRE INTRAOCULAR PRESSURE REDUCTION AND/OR WOULD BENEFIT FROM GLAUCOMA MEDICATION REDUCTION. THE DEVICE MAY ALSO BE IMPLANTED IN PATIENTS WHO CONTINUE TO HAVE ELEVATED INTRAOCULAR PRESSURE DESPITE PRIOR TREATMENT WITH GLAUCOMA MEDICATIONS AND CONVENTIONAL GLAUCOMA SURGERY.
2453	IMP/MD/2021/000068	1.License Holder Name: V.M. MEDITECH PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE CIRCUMCISION SUTURE DEVICE-DISPOSABLE CIRCUMCISION SUTURE DEVICE IS INTENDED USED FOR MALE CIRCUMCISION. STERILE PRODUCT AND SINGLE USE. THIS PRODUCT SHOULD BE USED BY EXPERIENCED SURGEONS IN CLINICAL.

2454	IMP/MD/2021/000069	1.License Holder Name: XTRACARE PRODUCTS PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (NA)-IT PROVIDES QUICK, HIGHLY ACCURATE READING OF HUMAN BODY TEMPERATURE AND DISPLAY ON THE LCD.

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2455	IMP/MD/2021/000071	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RECON FEMORAL NAILING IMPLANTS- STERILE-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,ZIPFIX- STERILE-CLOSURE OF THE STERNUM FOLLOWING STERNOTOMY TO STABILIZE THE STERNUM AND PROMOTE FUSION., PROXIMAL FEMORAL NAILING IMPLANTS- END CAP (NON STERILE)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,CERVICAL CAGES (STERILE)-CERVIOS IS DESIGNED FOR ANTERIOR CERVICAL INTERBODY FUSION (ACIF),PROXIMAL FEMORAL NAILING IMPLANTS-NAIL (STERILE)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,TROCARS- SS -TROCARS ARE INTENDED FOR PUNCTURING A BODILY ENTRY POINT AND/OR FOR PARTITION OF SURROUNDING SOFT TISSUE,TROCARS (NITINOL)-TROCARS ARE INTENDED FOR PUNCTURING A BODILY ENTRY POINT AND/OR FOR PARTITION OF SURROUNDING SOFT TISSUE,SCREW IMPLANTS FOR OR WITHOUT PLATES-WASHER (STERILE)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., EXTERNAL FIXATOR IMPLANTS- NAIL (SS)-EXTERNAL FIXATOR DEVICES ARE INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS., PROXIMAL FEMORAL NAILING IMPLANTS- END CAP (STERILE)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN

	VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,SCREW IMPLANTS FOR OR WITHOUT PLATES- WASHER (SS)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., PROXIMAL FEMORAL NAILING IMPLANTS- BLADE (STERILE)- INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).

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2456	IMP/MD/2021/000072	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT ABUTMENT - TITANIUM AND ITS ALLOYS(NA)-THE ALPHA-BIO ABUTMENT SYSTEM AND THE ALPHA-BIO MULTI-UNIT ABUTMENT SYSTEM IS INDICATED FOR USE IN RESTORATIVE APPLICATIONS FOR PLACEMENT IN THE UPPER OR LOWER JAW TO PROVIDE SUPPORT FOR PROSTHETIC DEVICES IN ORDER TO AID IN PROSTHETIC REHABILITATION. THE ALPHA UNIVERSE ANGULAR ABUTMENT IS INTENDED TO BE USED ON AN IMPLANT IN FULLY OR PARTIALLY EDENTULOUS PATIENTS FOR PROSTHETIC REHABILITATION. THE PRODUCT IS INTENDED TO SUPPORT PROSTHETIC DEVICES AND TO RESTORE THE PATIENT'S CHEWING FUNCTION. THE ALPHALOC IMPLANT ATTACHMENT SYSTEM IS DESIGNED FOR USE WITH OVERDENTURES OR PARTIAL DENTURES, RETAINED IN WHOLE OR IN PART, BY ENDOSSEOUS IMPLANTS IN THE MANDIBLE OR MAXILLA. HEALING CAPS ARE PLACED ON THE IMPLANT BEFORE FINAL RESTORATION PLACEMENT ALLOWING THE SOFT TISSUE TO GROW IN SUCH A WAY TO PREPARE THE RESTORATION AREA FOR FINAL RESTORATION. CAD/CAM TITANIUM BASES AND ADHESIVE COPINGS ARE USED AS BONDING BASIS FOR FINAL ABUTMENTS BY MEANS OF ADHESIVE CONNECTION OF THE PROSTHETIC RESTORATION AND IMPLANTS CONNECTION ON THE OTHER SIDE. PREFACE COMPATIBLE BLANK ABUTMENT - CYLINDRICAL ABUTMENTS USED BY THE MILLING CENTERS/MACHINES AS RAW ABUTMENTS TO FABRICATE CUSTOMIZED ABUTMENTS PER CLINICAL CASE ACCORDING TO THE TECHNICIAN DESIGN. THE ALPHALOC ABUTMENT IS PART OF AN ELASTIC RETAINING SYSTEM FOR THE CONSTRUCTION OF DENTAL PROSTHESES. ANTI-ROTATIONAL (HEXAGON) THE CASTING ANTI-ROTATIONAL (HEXAGON) ABUTMENTS WITH A PRESS-FIT PLASTIC SLEEVE ARE INTENDED TO BE USED FOR CUSTOM CASTING PROSTHETIC RESTORATIONS ON SINGLE IMPLANT OR MULTIPLE IMPLANTS. ROTATIONAL (CYLINDRICAL) THE CASTING ROTATIONAL (CYLINDRICAL) ABUTMENTS WITH A PRESS-FIT PLASTIC SLEEVE IS INTENDED TO BE USED FOR CUSTOM CASTING PROSTHETIC RESTORATIONS ONLY ON MULTIPLE IMPLANT PROSTHETIC RESTORATION. ,DENTAL IMPLANT – TITANIUM AND ITS ALLOYS(ATID - ALPHA-TEC DUAL IMPLANT, DFI - DUAL FIT IMPLANT, ICE -IMPLANT CLASSICAL ESTHETIC, MULTINEO, SPIRAL)-THE DENTAL IMPLANTS ARE INTENDED FOR REHABILITATING FULLY OR PARTIALLY EDENTULOUS PATIENTS. DENTAL IMPLANTS ARE INTENDED TO BE USED IN A MANNER THAT THEY WILL INTEGRATE THE BONE (OSSEOINTEGRATION). ,DENTAL IMPLANT ABUTMENT - COBALT CHROME & TITANIUM AND ITS ALLOYS(NA)-ANTI-ROTATIONAL

	(HEXAGON) THE CASTING ANTI-ROTATIONAL (HEXAGON) ABUTMENTS WITH A PRESS-FIT PLASTIC SLEEVE ARE INTENDED TO BE USED FOR CUSTOM CASTING PROSTHETIC RESTORATIONS ON SINGLE IMPLANT OR MULTIPLE IMPLANTS. ROTATIONAL (CYLINDRICAL) THE CASTING ROTATIONAL (CYLINDRICAL) ABUTMENTS WITH A PRESS-FIT PLASTIC SLEEVE IS INTENDED TO BE USED FOR CUSTOM CASTING PROSTHETIC RESTORATIONS ONLY ON MULTIPLE IMPLANT PROSTHETIC RESTORATION. ,CLINICAL SCREWS – TITANIUM AND ITS ALLOYS(NA)-THESE ARTICLES ARE ACCESSORIES AND DO NOT HAVE A SPECIFIC IFU. ABT4994 – THIS SCREW IS USED TO CONNECT DIGITALLY RESTORED CROWN DIRECTLY ON SCREW-RETAINED ABUTMENT (TCT) ABT5121 – IH ABUTMENT SCREW FOR LAB USE ABT5122 – IH ABUTMENT SCREW FOR CLINICIAN USE ABT5127 – SCREW FOR 35° ABUTMENT ABT6050, ABT6051, ABT6052 - PART OF THE HBC SYSTEM (SINGLE UNIT SCREW RETAINED). THE SCREWS ARE SOLD AS PART OF P/N 6040, 6041, 6042 ABT6092 – SCREW-RETAINED ABUTMENT SCREW FOR CLINICIAN USE ABT6093 – SCREW-RETAINED ABUTMENT SCREW FOR LAB USE ABT7345 – CHC ABUTMENT SCREW FOR CLINICIAN USE ,DENTAL IMPLANT ABUTMENT - COBALT CHROME (NA)-ANTI-ROTATIONAL (HEXAGON) THE CASTING ANTI-ROTATIONAL (HEXAGON) ABUTMENTS WITH A PRESS-FIT PLASTIC SLEEVE ARE INTENDED TO BE USED FOR CUSTOM CASTING PROSTHETIC RESTORATIONS ON SINGLE IMPLANT OR MULTIPLE IMPLANTS. ROTATIONAL (CYLINDRICAL) THE CASTING ROTATIONAL (CYLINDRICAL) ABUTMENTS WITH A PRESS-FIT PLASTIC SLEEVE IS INTENDED TO BE USED FOR CUSTOM CASTING PROSTHETIC RESTORATIONS ONLY ON MULTIPLE IMPLANT PROSTHETIC RESTORATION.

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2457	IMP/MD/2021/000073	1.License Holder Name: DR. REMEDIES LIFE SCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DRUG ELUTING CORONARY STENT SYSTEM(BIOMATRIX NEOFLEX)-THE BIOMATRIX NEOFLEX DES IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER RANGING BETWEEN 2.25 MM AND 4.0 MM. THE STENT LENGTH (MM): 8, 11, 14, 18, 24, 28, 33*, 36*,42,48 ARE AVAILABLE. THE STENTS WITH LENGTH 33 MM AND 36 MM ARE ONLY AVAILABLE FOR ARTERY DIAMETERS RANGING BETWEEN 2.5 MM AND 3.5 MM. THE BIOMATRIX NEOFLEX DES WITH STENT LENGTH UP TO 28 MM IS ALSO INDICATED FOR USE IN PATIENTS WITH: • ST ELEVATED MYOCARDIAL INFARCTION (STEMI) • ACUTE CORONARY SYNDROMES (ACS) INCLUDING ACS-STEMI, ACS-NSTEMI AND UNSTABLE ANGINA • DIABETES MELLITUS,DRUG COATED CORONARY STENT SYSTEM (BIOFREEDOM)-THE BIOFREEDOM DCS IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER FOR THE TREATMENT OF DE-NOVO LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER RANGING FROM 2.25 MM TO 4.0 MM. STENTS WITH LENGTHS OF 33 MM AND 36 MM ARE ONLY AVAILABLE FOR ARTERY DIAMETERS RANGING FROM 2.5 MM TO 3.5 MM.,DRUG ELUTING CORONARY STENT SYSTEM (BIOMATRIX ALPHA)-THE BIOMATRIX ALPHA STENT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER RANGING BETWEEN 2.25 MM AND 4.0 MM. STENTS WITH LENGTHS 33 AND 36 MM ARE ONLY AVAILABLE FOR ARTERY DIAMETERS RANGING BETWEEN 2.5 MM AND 3.5 MM.
2458	IMP/MD/2021/000074	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LOADING SYSTEM (PORTICO TRANSFEMORAL/ALTERNATIVE ACCESS LOADING SYSTEM)-THE PORTICO™ TRANSFEMORAL/ALTERNATIVE ACCESS LOADING SYSTEM IS INDICATED FOR LOADING THE PORTICO™ VALVE IN THE PORTICO™ TRANSFEMORAL DELIVERY SYSTEM,DELIVERY SYSTEM(PORTICO TRANSFEMORAL DELIVERY SYSTEM)-THE PORTICO™ TRANSFEMORAL DELIVERY SYSTEM IS INDICATED FOR TRANSFEMORAL DELIVERY OF THE PORTICO™ VALVE.

2459	IMP/MD/2021/000076	1.License Holder Name: DOU TECHNOCARE PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL KNEE REPLACEMENT SYSTEM-TOTAL KNEE REPLACEMENT SYSTEM INTENDED FOR CEMENTED KNEE ARTHROPLASTY, AND SERVES TO REPLACE THE PATIENT'S NATURAL KNEE JOINT
2460	IMP/MD/2021/000077	1.License Holder Name: CIPLA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PORTABLE MESH NEBULIZER(NEBUFLO)-THE PORTABLE MESH NEBULIZER SHOULD BE USED FOR MEDICATIONS MEANT FOR NEBULIZATION PRESCRIBED BY YOUR PHYSICIAN. IT IS INTENDED FOR ADULTS AND PEDIATRIC PATIENTS AND MAY BE USED AT HOME, IN HOSPITALS, CLINICS AND NURSING HOME.
2461	IMP/MD/2021/000078	1.License Holder Name: FAITH BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRALUMINAL SUPPORT DEVICE(FRED (FLOW RE-DIRECTION ENDOLUMINAL DEVICE), FRED JR. (FLOW RE-DIRECTION ENDOLUMINAL DEVICE JUNIOR))-FRED: [THE FRED SYSTEM IS INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL NEUROVASCULAR ANEURYSMS. THE FRED SYSTEM MAY ALSO BE USED WITH EMBOLIC COILS FOR THE TREATMENT OF INTRACRANIAL NEUROVASCULAR LESIONS.], FRED JR.:[THE FRED JR. SYSTEM IS INTENDED FOR ENDOVASCULAR EMBOLIZATION OF INTRACRANIAL NEUROVASCULAR ANEURYSMS. THE FRED JR. SYSTEM MAY ALSO BE USED WITH EMBOLIC COILS FOR THE TREATMENT OF INTRACRANIAL NEUROVASCULAR LESIONS.], INTRALUMINAL SUPPORT DEVICE(LVIS, LVIS JR.)-LVIS: [THE LVIS DEVICE IS INTENDED FOR USE WITH EMBOLIC COILS FOR THE TREATMENT OF INTRACRANIAL NEUROVASCULAR DISEASES.], LVIS JR.: [THE LVIS JR. DEVICE IS INTENDED FOR USE WITH EMBOLIC COILS FOR THE TREATMENT OF INTRACRANIAL NEUROVASCULAR DISEASES.]

2462	IMP/MD/2021/000079	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRODUCER SHEATH WITH HYDROPHILIC COATING(SENTRANT)-THE SENTRANT INTRODUCER SHEATH WITH HYDROPHILIC COATING IS INTENDED TO PROVIDE A CONDUIT FOR THE INSERTION OF DIAGNOSTIC OR ENDOVASCULAR DEVICES INTO THE VASCULATURE AND TO MINIMIZE BLOOD LOSS ASSOCIATED WITH SUCH INSERTIONS. , INTRODUCER SHEATH(MICRA™ INTRODUCER)-THE MICRA INTRODUCER IS INTENDED TO PROVIDE A CONDUIT FOR THE INSERTION OF DEVICES INTO THE VENOUS SYSTEM AND TO MINIMIZE BLOOD LOSS ASSOCIATED WITH SUCH INSERTIONS.
2463	IMP/MD/2021/000080	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RETURN (ARTERIAL) CANNULA(CENTRIMAG 24FR RETURN (ARTERIAL) CANNULA KIT)-THE CENTRIMAG RETURN (ARTERIAL) CANNULA IS INDICATED FOR USE ONLY WITH THE CENTRIMAG BLOOD PUMP. THE CANNULA IS INDICATED FOR USE FOR UP TO 30 DAYS.,DRAINAGE (VENOUS) CANNULA(CENTRIMAG 34FR DRAINAGE (VENOUS) CANNULA KIT)-THE CENTRIMAG DRAINAGE (VENOUS) CANNULA IS INDICATED FOR USE WITH THE CENTRIMAG BLOOD PUMP. THE CANNULA IS INDICATED FOR USE FOR UP TO 30 DAYS.
2464	IMP/MD/2021/000081	1.License Holder Name: PRYMAX HEALTHCARE LLP, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER & ACCESSORIES (NON STERILE BULK)-THE PRODUCT IS APPLICABLE FOR MONITORING THE CENTRAL VENOUS PRESSURE, COLLECTING THE BLOOD SAMPLE AND INJECTING THE DRUG OR SOLUTION. THE DESIGN OF MULTICAVITY CAN GO ON THE PROCESS ABOVE AT THE SAME TIME. THE TIME OF USE IS LESS THAN 30 DAYS.

2465	IMP/MD/2021/000082	1.License Holder Name: FAITH BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DOCKING WIRE (TRAXCESS)-THE TRAXCESS DOCKING WIRE IS INTENDED FOR GENERAL INTRAVASCULAR USE, INCLUDING THE NEURO AND PERIPHERAL VASCULATURE. THE TRAXCESS DOCKING WIRE CAN BE USED WITH TRAXCESS GUIDEWIRES TO FACILITATE THE PLACEMENT OF DIAGNOSTIC OR THERAPEUTIC CATHETERS. THIS DEVICE IS NOT INTENDED FOR USE IN CORONARY ARTERIES.,GUIDEWIRE(TRAXCESS) -TRAXCESS GUIDEWIRE IS INTENDED FOR GENERAL INTRAVASCULAR USE, INCLUDING THE NEURO AND PERIPHERAL VASCULATURE. THE GUIDEWIRE CAN BE STEERED TO FACILITATE THE SELECTIVE PLACEMENT OF DIAGNOSTIC OR THERAPEUTIC CATHETERS. THIS DEVICE IS NOT INTENDED FOR USE IN CORONARY ARTERIES.,GUIDING CATHETER SYSTEM(CHAPERON)-THE CHAPERON GUIDING CATHETER SYSTEM AND CHAPERON GUIDING CATHETER ARE INTENDED FOR GENERAL INTRAVASCULAR USE, INCLUDING THE NEURO AND PERIPHERAL VASCULATURE. THE CHAPERON GUIDING CATHETER SYSTEM AND CHAPERON GUIDING CATHETER CAN BE USED TO FACILITATE INTRODUCTION OF DIAGNOSTIC OR THERAPEUTIC DEVICES. THE CHAPERON GUIDING CATHETER SYSTEM AND CHAPERON GUIDING CATHETER ARE NOT INTENDED FOR USE IN CORONARY ARTERIES.
2466	IMP/MD/2021/000085	1.License Holder Name: M/S MOLNLYCKE HEALTHCARE INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SELF-ADHERENT SOFT SILICONE FOAM DRESSING(MEPILEX BORDER FLEX)-MEPILEX BORDER FLEX IS DESIGNED FOR A WIDE RANGE OF EXUDING WOUNDS SUCH AS PRESSURE ULCERS, LEG AND FOOT ULCERS, TRAUMATIC WOUNDS (E.G. SKIN TEARS) AND SURGICAL WOUNDS. MEPILEX BORDER FLEX CAN ALSO BE USED ON DRY/NECROTIC WOUNDS IN COMBINATION WITH GELS. MEPILEX BORDER FLEX REDUCES POSTOPERATIVE BLISTERING, AND MAY ALSO BE USED AS PART OF A PROPHYLACTIC THERAPY TO HELP PREVENT SKIN DAMAGE, E.G. PRESSURE ULCERS.

2467	IMP/MD/2021/000086	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EAR DRESSING (OTOPORE)-OTOPORE IS INTENDED FOR SINGLE-USE AS A MEANS OF A TEMPORARY WOUND DRESSING IN THE OUTER EAR AFTER EAR SURGERY,NASAL DRESSING(NASOPORE FD)-NASOPORER FD NASAL DRESSING IS INTENDED FOR USE IN PATIENTS UNDERGOING NASAL/SINUS SURGERY AS A TEMPORARY WOUND DRESSING. IT CONTROLS MINIMAL BLEEDING BY TAMPONADE EFFECT AND BLOOD ABSORPTION. NASOPORER FD IS INTENDED TO ACT AS AN ADJUNCT TO AID IN THE NATURAL HEALING PROCESS BY PROVIDING TISSUE SUPPORT, MINIMIZING EDEMA AND PREVENTION OF ADHESION FORMATION BETWEEN MUCOSAL SURFACES.,NASAL DRESSING (NASOPORE)-NASOPORE NASAL DRESSING IS INTENDED FOR USE IN PATIENTS UNDERGOING NASAL/SINUS SURGERY AS A TEMPORARY WOUND DRESSING. IT CONTROLS MINIMAL BLEEDING BY TAMPONADE EFFECT AND BLOOD ABSORPTION. NASOPORER IS INTENDED TO ACT AS AN ADJUNCT TO AID IN THE NATURAL HEALING PROCESS BY PROVIDING TISSUE SUPPORT, MINIMIZING EDEMAAND PREVENTION OF ADHESION FORMATION BETWEEN MUCOSAL SURFACES. NASOPORE R CAN BE SOAKED IN SALINE, ANTI-INFLAMMATORIES, ANTIBIOTICS OR OTHER AGENTS OF THE PHYSICIAN'S CHOICE

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2468	IMP/MD/2021/000087	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PROXIMAL HUMERUS PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,MATRIXMANDIBLE-PLATE-THE DEPUY SYNTHES MATRIXMANDIBLE PLATING SYSTEM IS INTENDED FOR ORAL- MAXILLOFACIAL SURGERY. THE DEPUY SYNTHES MATRIXMANDIBLE RECONSTRUCTION PLATES IS INTENDED FOR RECONSTRUCTIVE SURGERY. THE DEPUY SYNTHES MATRIXMANDIBLE SUBCONDYLAR PLATES ARE INTENDED FOR THE TRAUMA OF THE MANDIBLE.,SYNMESH-END RING-SYNMESH IS A VERTEBRAL BODY REPLACEMENT DEVICE FOR THE CERVICAL-THORACIC AND LUMBAR SPINE. TITANIUM IMPLANTS IN VARIOUS FOOTPRINTS AND HEIGHTS ENABLE THE SURGEON TO CHOOSE THE CONFIGURATION THAT IS BEST SUITED TO THE PATIENT'S INDIVIDUAL PATHOLOGY AND ANATOMY. THE MESH MAY ALSO BE TRIMMED FOR A CUSTOM FIT. THE IMPLANTS CAN BE INSERTED ANTERIORLY- LATERALLY OR ANTEROLATERALLY.,WIRES (POWER DRIVEN)-WIRE IMPLANTS ARE INTENDED FOR FIXATION OF BONE FRAGMENTS.,TROCHANTERIC FEMORAL NAIL IMPLANTS (TFNA)-SCREW (NON-STERILE)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,DISTAL TIBIAL PLATES-(NON-STERILE) (STAINLESS STEEL)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,CALCANEAL PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., GUIDE WIRES FOR SPINE- KIRSCHNER WIRE-GUIDE WIRES INCLUDEING K-WIRES AND KIRSCHNER WIRES FOR SPINE ARE INTENDED TO GUIDE POSITIONING OF CANNULATED INSTRUMENTS-IMPLANTATION OF CANNULATED SPINAL IMPLANTS OR REMOVAL OF SPINAL IMPLANTS,FOOT PLATES-(NON-STERILE) (TICP)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION-CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,OLECRANON PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,

	COMPACT MANDIBLE-PLATE (SE_657237)-THE SYNTHES COMPACT 2.0 AND COMPACT 2.4 TRAUMA PLATES AND SCREWS SYSTEM MANDIBLE IS INTENDED FOR ORAL- MAXILLOFACIAL SURGERY- TRAUMA- RECONSTRUCTIVE SURGERY- AND ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES)., TITANIUM STERNAL FIXATION SYSTEM – PLATE (STERILE- 10 YEARS) (TAN -TICP)-FIXATION OF STERNAL HALVES,FIBULA PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,ELASTIC NAILING IMPLANTS- INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,TITANIUM STERNAL FIXATION SYSTEM-PLATE (STERILE- 5 YEARS) (TICP)-FIXATION OF STERNAL HALVES,DISTAL HUMERUS PLATES- (NON-STERILE) (TICP)- PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,FOOT PLATES-(NON-STERILE) (TI AL6 NB7)- PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DISTAL HUMERUS PLATES-(NON-STERILE) (TI AL6 NB7)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,MATRIXNEURO-BURR HOLE COVER-DEPUY SYNTHES MATRIXNEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION.,LOW PROFILE NEURO-PLATE-DEPUY SYNTHES LOW PROFILE NEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION.,PELVIC IMPLANTS-PLATE (STERILE- 10 YEARS)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,CLAVICLE PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,RADIUS PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., SYNMESH-CORPECTOMY DEVICE-SYNMESH IS A VERTEBRAL BODY REPLACEMENT DEVICE FOR THE CERVICAL- THORACIC AND LUMBAR SPINE. TITANIUM IMPLANTS IN VARIOUS FOOTPRINTS AND HEIGHTS

	ENABLE THE SURGEON TO CHOOSE THE CONFIGURATION THAT IS BEST SUITED TO THE PATIENT'S INDIVIDUAL PATHOLOGY AND ANATOMY. THE MESH MAY ALSO BE TRIMMED FOR A CUSTOM FIT. THE IMPLANTS CAN BE INSERTED ANTERIORLY- LATERALLY OR ANTEROLATERALLY.,PELVIC IMPLANTS-PLATE (NON-STERILE)- PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,COMPACT MANDIBLE- (SE_530571)-THE SYNTHES PLATE AND SCREW SYSTEM COMPACT MANDIBLE IS INTENDED FOR ORAL- MAXILLOFACIAL SURGERY- TRAUMA- RECONSTRUCTIVE SURGERY- AND ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES).,DISTAL TIBIAL PLATES- (NON-STERILE) (TI AL6 NB7)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., TITANIUM STERNAL FIXATION SYSTEM– PLATE (STERILE- 10 YEARS) (TICP)-FIXATION OF STERNAL HALVES,TROCHANTERIC FEMORAL NAIL IMPLANTS (TFNA)- BLADE (STERILE- 10 YEARS)- INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,TITANIUM STERNAL FIXATION SYSTEM– PIN (NON-STERILE)-FIXATION OF STERNAL HALVES,TROCHANTERIC FEMORAL NAIL IMPLANTS (TFNA)- BLADE (NON-STERILE)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,FEMORAL SHAFT NAILING IMPLANTS-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,HAND PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS

	ANATOMICAL REGIONS.,TROCHANTERIC FEMORAL NAIL IMPLANTS (TFNA)-SCREW (STERILE- 10 YEARS)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,PROXIMAL TIBIAL PLATES (NON-STERILE) (STAINLESS STEEL)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,LOW PROFILE NEURO- BURR HOLE COVER-DEPUY SYNTHES LOW PROFILE NEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION.,MATRIXMIDFACE-MATRIXMIDFACE PLATE AND SCREW SYSTEM IS INTENDED FOR USE AS TRAUMA REPAIR AND RECONSTRUCTION OF THE CRANIO-MAXILLOFACIAL SKELETON.,TITANIUM STERNAL FIXATION SYSTEM– PIN (STERILE- 10 YEARS)-FIXATION OF STERNAL HALVES, MATRIXNEURO- PLATE-DEPUY SYNTHES MATRIXNEURO PLATE AND SCREW SYSTEM IS INTENDED FOR CRANIAL CLOSURE AND/OR BONE FIXATION.,PROXIMAL TIBIAL PLATES-(NON-STERILE) (TICP)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION-CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,TITANIUM STERNAL FIXATION SYSTEM-PLATE (STERILE- 5 YEARS) (TAN -TICP)-FIXATION OF STERNAL HALVES,WRIST FUSION PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., TITANIUM STERNAL FIXATION SYSTEM – PLATE (NON-STERILE) (TICP) -FIXATION OF STERNAL HALVES,TITANIUM STERNAL FIXATION SYSTEM – PLATE (NON-STERILE) (TAN -TICP)-FIXATION OF STERNAL HALVES

2469	IMP/MD/2021/000088	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DRUG COATED BALLOON PTA CATHETER(LUTONIX 035 DRUG COATED BALLOON PTA CATHETER)-THE LUTONIX 035 DRUG COATED BALLOON CATHETER IS INTENDED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE PERIPHERAL VASCULATURE AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS AND DECREASING THE INCIDENCE OF RESTENOSIS. IN ADDITION, THE LUTONIX 035 DRUG COATED BALLOON CATHETER IS INTENDED FOR PTA OF NATIVE DIALYSIS FISTULAE OR SYNTHETIC GRAFTS, OPENING NARROWING AND IMMATURE FISTULAE, TO IMPROVE BLOOD FLOW, AND DECREASING THE INCIDENCE OF RESTENOSIS. ,DRUG COATED BALLOON PTA CATHETER(LUTONIX 014 DRUG COATED BALLOON PTA CATHETER)-THE LUTONIX 014 DRUG COATED BALLOON CATHETER IS INTENDED FOR USE AS A PTA CATHETER TO DILATE STENOTIC OR OBSTRUCTIVE VASCULAR LESIONS IN THE LOWER EXTREMITIES, FOR THE PURPOSE OF IMPROVING LIMB PERFUSION AND DECREASING THE INCIDENCE OF RESTENOSIS.
2470	IMP/MD/2021/000090	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL ABLATION DEVICE(CARDIOBLATE BP2 DEVICE)-THE CARDIOBLATE BP2 SURGICAL ABLATION DEVICE IS INTENDED TO CREATE LESIONS IN CARDIAC TISSUE DURING CARDIAC SURGERY USING RADIOFREQUENCY ENERGY FOR THE TREATMENT OF CARDIAC ARRHYTHMIAS. ANY SUPRAVENTRICULAR ARRHYTHMIA (SUCH AS ATRIAL FIBRILLATION, ATRIAL FLUTTER, OR ATRIAL TACHYCARDIA) THAT MAY BE RESOLVED BY THE APPLICATION OF ENDOCARDIAL OR EPICARDIAL RADIOFREQUENCY ENERGY CAN BE TREATED BY THE CARDIOBLATE BP2 SURGICAL ABLATION DEVICE.

2471	IMP/MD/2021/000092	1.License Holder Name: RENNEX MEDICAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITORING DEVICES(MERCURY FREE SPHYGMOMANOMETERS)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES,BLOOD PRESSURE MONITORING DEVICES(DIALEX ANEROID SPHYGMOMANOMETER)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.,BLOOD PRESSURE MONITORING DEVICES(DIAL CHEK PALM TYPE ANEROID SPHYGMOMANOMETER)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.
2472	IMP/MD/2021/000093	1.License Holder Name: SCHULKE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:100 G OF GIGASEPT PAA CONTAINS: 0.1 G PERACETIC ACID(GIGASEPT PAA)-READY-TO-USE HIGH LEVEL DISINFECTANT FOR THE DISINFECTION OF FLEXIBLE ENDOSCOPES AND MEDICAL INSTRUMENTS

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2473	IMP/MD/2021/000094	1.License Holder Name: CONVATEC INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PROTECTIVE SKIN BARRIER AND FILLER(STOMAHESIVE PASTE)-STOMAHESIVE PASTE IS A CONVENIENT, HIGHLY EFFECTIVE FILLER, SEALANT, AND PROTECTIVE SKIN BARRIER SPECIFICALLY DESIGNED FOR USE AROUND COLOSTOMY, ILEOSTOMY, OR URINARY STOMAS., HYDROFIBER SURGICAL COVER DRESSING(AQUACEL SURGICAL)-AQUACEL SURGICAL COVER DRESSING MAY BE USED FOR THE MANAGEMENT OF WOUNDS HEALING BY PRIMARY INTENT (EX.: TRAUMATIC AND ELECTIVE POST-OPERATIVE WOUNDS / INCISION$) AND AS AN EFFECTIVE BARRIER TO BACTERIAL PENETRATION TO HELP REDUCE INFECTION.,HYDROFIBER SURGICAL COVER DRESSING WITH SILVER(AQUACEL AG SURGICAL)-AQUACEL AG SURGICAL COVER DRESSING MAY BE USED FOR THE MANAGEMENT OF WOUNDS HEALING BY PRIMARY INTENT (EX.: TRAUMATIC AND ELECTIVE POST-OPERATIVE WOUNDS / INCISIONS) AND AS AN EFFECTIVE BARRIER TO BACTERIAL PENETRATION TO HELP REDUCE INFECTION., CONTROL GEL FORMULA DRESSING(DUODERM CGF)-DUODERM CGF MAY BE USED IN: - MINOR ABRASIONS, LACERATIONS, MINOR CUT$, MINOR SCALDS AND BURNS, SKIN TEARS. - LEG ULCERS, DIABETIC ULCERS AND PRESSURE ULCERS - SURGICAL WOUNDS, TRAUMATIC WOUNDS AND BURNS (FIRST & SECOND DEGREE) - MINIMIZES THE POTENTIAL OF EXPOSURE TO NOSOCOMIAL OR INFECTIOUS AGENTS.,EXTRA THIN CGF DRESSING(DUODERM EXTRA THIN)-MANAGEMENT OF SUPERFICIAL, DRY TO LIGHTLY EXUDATING DERMAL ULCERS, POST-OPERATIVE WOUNDS AND PROTECTIVE DRESSINGS.

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2474	IMP/MD/2021/000095	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INFUSION CATHETER (PROWLER SELECT PLUS)-IT IS INTENDED TO BE USED AS A MECHANISM FOR THE INFUSION OF VARIOUS DIAGNOSTIC, EMBOLIC, AND THERAPEUTIC AGENTS INTO THE VASCULAR SYSTEMS (NEURO, PERIPHERAL, CORONARY AND GUIDEWIRE EXCHANGE/SUPPORT) AND FOR SUPERSELECTIVE ANGIOGRAPHY OF THE PERIPHERAL AND CORONARY VASCULATURES.,GUIDING CATHETER(CEREBASE DA)-THE CEREBASE DA GUIDE SHEATH IS INDICATED FOR THE INTRODUCTION OF INTERVENTIONAL DEVICES INTO THE NEURO VASCULATURE.,DETACHABLE COIL(ORBIT GALAXY - FILL AND FRAME)-IT IS INDICATED FOR EMBOLIZING INTRACRANIAL ANEURYSMS AND OTHER VASCULAR MALFORMATIONS SUCH AS ARTERIOVENOUS MALFORMATIONS AND ARTERIOVENOUS FISTULAE OF THE NEUROVASCULATURE. IT IS ALSO INTENDED FOR ARTERAIL AND VENOUS EMBOLIZATION IN THE PERIPHERAL VASCULATURE., INFUSION CATHETER(PROWLER 10 14)-IT IS INTENDED TO BE USED AS A MECHANISM FOR THE INFUSION OF VARIOUS DIAGNOSTIC, EMBOLIC, AND THERAPEUTIC AGENTS INTO THE VASCULAR SYSTEMS (NEURO, PERIPHERAL, CORONARY AND GUIDEWIRE EXCHANGE/SUPPORT) AND FOR SUPERSELECTIVE ANGIOGRAPHY OF THE PERIPHERAL AND CORONARY VASCULATURES,GUIDING CATHETER(ENVOY)-IT IS INTENDED FOR USE IN THE PERIPHERAL, CORONARY, AND NEUROVASCULATURE FOR THE INTRAVASCULAR INTRODUCTION OF INTERVENTIONAL/DIAGNOSTIC DEVICES., INFUSION CATHETER(PROWLER SELECT LP)-IT IS INTENDED TO BE USED AS A MECHANISM FOR THE INFUSION OF VARIOUS DIAGNOSTIC, EMBOLIC, AND THERAPEUTIC AGENTS INTO THE VASCULAR SYSTEMS (NEURO, PERIPHERAL, CORONARY AND GUIDEWIRE EXCHANGE/SUPPORT) AND FOR SUPERSELECTIVE ANGIOGRAPHY OF THE PERIPHERAL AND CORONARY VASCULATURES.,DETACHABLE COIL(ORBIT GALAXY - XTRASOFT)-IT IS INDICATED FOR EMBOLIZING INTRACRANIAL ANEURYSMS.

2475	IMP/MD/2021/000101	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMODIALYSIS CATHETERS 7(ARROW®)-THE LARGE-BORE TWO-LUMEN CATHETER IS INDICATED FOR TEMPORARY OR SHORT-TERM HEMODIALYSIS AND APHERESIS. IT MAY BE INSERTED INTO THE SUBCLAVIAN OR FEMORAL VEINS ,CENTRAL VENOUS CATHETER 6(ARROW®)- THE LARGE-BORE MULTIPLE-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION FOR RAPID FLUID ADMINISTRATION. IT MAY BE INSERTED INTO THE JUGULAR, SUBCLAVIAN, OR FEMORAL VEINS. THE ARROWG+ARD ANTIMICROBIAL SURFACE IS INTENDED TO HELP PROVIDE PROTECTION AGAINST CATHETER-RELATED INFECTIONS. THE CATHETER IS NOT INTENDED TO BE USED AS A TREATMENT FOR EXISTING INFECTIONS NOR AS A SUBSTITUTE FOR A TUNNELED CATHETER IN THOSE PATIENTS REQUIRING LONG-TERM THERAPY. ONE CLINICAL STUDY INDICATES THAT THE ANTIMICROBIAL PROPERTIES OF THE CATHETER MAY NOT BE EFFECTIVE WHEN IT IS USED TO ADMINISTER TPN ,ARTERIAL CATHETERIZATION SET 10 (ARROW®)-THE ARROW® SELDINGER ARTERIAL CATHETERIZATION DEVICES PERMIT ACCESS TO THE PERIPHERAL ARTERIAL CIRCULATION OR TO OTHER SMALL VESSELS.,CENTRAL VENOUS ACCESS SHEATH(ARROW®)-THE ARROW® CENTRAL VENOUS ACCESS PRODUCT PERMITS VENOUS ACCESS AND CATHETER INTRODUCTION TO THE CENTRAL CIRCULATION.,CENTRAL VENOUS CATHETER 4(ARROW®)- INTENDED USE: THE ARROWG+ARD TECHNOLOGY IS INTENDED TO PROVIDE PROTECTION AGAINST CATHETER-RELATED BLOODSTREAM INFECTIONS. IT IS NOT INTENDED TO BE USED AS A TREATMENT FOR EXISTING INFECTIONS NOR IS IT INDICATED FOR LONG-TERM USE (> 30 DAYS). INDICATION: THE ARROW CVC IS INTENDED TO PROVIDE SHORT-TERM (30 DAYS) CENTRAL VENOUS ACCESS FOR TREATMENT OF DISEASES OR CONDITIONS REQUIRING CENTRAL VENOUS ACCESS, INCLUDING, BUT NOT LIMITED TO THE FOLLOWING: • LACK OF USABLE PERIPHERAL IV SITES • CENTRAL VENOUS PRESSURE MONITORING • TOTAL PARENTERAL NUTRITION (TPN) • INFUSIONS OF FLUIDS, MEDICATIONS, OR CHEMOTHERAPY • FREQUENT BLOOD SAMPLING OR RECEIVING BLOOD TRANSFUSIONS/BLOOD PRODUCTS , HEMODIALYSIS CATHETERS 8(ARROW®)-THE LARGE-BORE TWO-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION FOR RAPID FLUID ADMINISTRATION, TEMPORARY OR ACUTE HEMODIALYSIS, APHERESIS AND HEMOFILTRATION. IT MAY BE INSERTED INTO THE JUGULAR, SUBCLAVIAN, OR FEMORAL VEINS. THE ARROWG+ARD BLUE ANTIMICROBIAL SURFACE CATHETER

	HELPS PROVIDE PROTECTION AGAINST CATHETER-RELATED INFECTIONS RESULTING FROM MICROORGANISMS MIGRATING THE SUBCUTANEOUS TRACT ALONG THE EXTERIOR SURFACE OF THE CATHETER WHEN USED FOR INFUSION. CLINICAL DATA HAVE NOT BEEN COLLECTED THAT DEMONSTRATE THE USE OF THE ARROWG+ARD BLUE ANTIMICROBIAL SURFACE IN DECREASING CATHETER RELATED INFECTIONS IN HEMODIALYSIS PATIENTS. THE CATHETER IS NOT INTENDED TO BE USED AS A TREATMENT FOR EXISTING INFECTIONS, NOR IS IT INDICATED FOR LONG-TERM USE , CENTRAL VENOUS CATHETER 3(ARROW®)-THE LARGE-BORE MULTIPLE-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION FOR RAPID FLUID ADMINISTRATION. IT MAY BE INSERTED INTO THE JUGULAR, SUBCLAVIAN, OR FEMORAL VEINS., CENTRAL VENOUS CATHETER 5(ARROW®)-INTENDED USE: • THE ARROWG+ARD BLUE PLUS® CATHETER PERMITS VENOUS ACCESS TO CENTRAL CIRCULATION BY WAY OF SUBCLAVIAN, JUGULAR, AND FEMORAL VEINS. • THE ARROWG+ARD TECHNOLOGY IS INTENDED TO PROVIDE PROTECTION AGAINST CATHETER-RELATED BLOODSTREAM INFECTIONS (CRBSIS). IT IS NOT INTENDED TO BE USED AS A TREATMENT FOR EXISTING INFECTIONS NOR IS IT INDICATED FOR LONG-TERM USE (> 30 DAYS). CLINICAL EFFECTIVENESS OF THE ARROWG+ARD BLUE PLUS® CATHETER IN PREVENTING CRBSIS COMPARED TO THE ORIGINAL ARROWG+ARD BLUE® CATHETER HAS NOT BEEN STUDIED. INDICATION: THE ARROW CVC IS INTENDED TO PROVIDE SHORT-TERM (30 DAYS) CENTRAL VENOUS ACCESS FOR TREATMENT OF DISEASES OR CONDITIONS REQUIRING CENTRAL VENOUS ACCESS, INCLUDING, BUT NOT LIMITED TO THE FOLLOWING: • LACK OF USABLE PERIPHERAL IV SITES • CENTRAL VENOUS PRESSURE MONITORING • TOTAL PARENTERAL NUTRITION (TPN) • INFUSIONS OF FLUIDS, MEDICATIONS, OR CHEMOTHERAPY • FREQUENT BLOOD SAMPLING OR RECEIVING BLOOD TRANSFUSIONS/BLOOD PRODUCTS,ARTERIAL CATHETERIZATION SET 9(ARROW®)-THE ARROW® ARTERIAL CATHETERIZATION DEVICE PERMITS ACCESS TO THE PERIPHERAL ARTERIAL CIRCULATION,CENTRAL VENOUS CATHETER 1(ARROW®)-1. THE ARROW® SINGLE-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION. 2. THE ARROW® MULTIPLE-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION. 3. THE MULTIPLE-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION OF PEDIATRIC PATIENTS. , CENTRAL VENOUS CATHETER 2(ARROW®)-THE ARROW CVC IS INTENDED TO PROVIDE SHORT-TERM (30 DAYS) CENTRAL VENOUS ACCESS FOR TREATMENT OF DISEASES OR CONDITIONS REQUIRING CENTRAL VENOUS ACCESS, INCLUDING, BUT NOT LIMITED TO THE

	FOLLOWING: • LACK OF USABLE PERIPHERAL IV SITES • CENTRAL VENOUS PRESSURE MONITORING • TOTAL PARENTERAL NUTRITION (TPN) • INFUSIONS OF FLUIDS, MEDICATIONS, OR CHEMOTHERAPY • FREQUENT BLOOD SAMPLING OR RECEIVING BLOOD TRANSFUSIONS/BLOOD PRODUCTS

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2476	IMP/MD/2021/000102	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RADIUS PLATES-TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR OR WITHOUT PLATES- WASHER (TITANIUM ALLOY)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., SCREW IMPLANTS FOR OR WITHOUT PLATES- WASHER- SS (STERILE)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR OR WITHOUT PLATES-WASHER- SS-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,MATRIXMIDFACE INCL. MXORBITAL- PLATE-MATRIXMIDFACE PLATE AND SCREW SYSTEM IS INTENDED FOR USE AS TRAUMA REPAIR AND RECONSTRUCTION OF THE CRANIO-MAXILLOFACIAL SKELETON.,DISTAL HUMERUS PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,EXTERNAL FIXATOR IMPLANTS- SCREW (SS)-EXTERNAL FIXATOR DEVICES ARE INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS.,USS FRACTURE- SCREW-THE USS FRACTURE SYSTEM IS A POSTERIOR THORACOLUMBAR PEDICLE SCREW FIXATION SYSTEM INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE APPLICATION AREA IN PATIENTS SUFFERING FROM TRAUMA OR TUMOR DISEASE IS USUALLY AT THE THORACAL-LUMBAR JUNCTION (T12 /L1)- BUT CAN BE EXTENDED FROM T6 DOWN TO THE SACRUM (S1).,CARPAL FUSION PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., EXTERNAL FIXATOR IMPLANTS- PIN (SS)-EXTERNAL FIXATOR DEVICES ARE INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS., PROXIMAL HUMERUS PLATES- TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., DISTAL TIBIA PLATES- SS-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR

	STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., PROXIMAL HUMERUS PLATES- SS-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., RECON FEMORAL NAILING IMPLANTS- WASHER (STERILE)- INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,DISTAL TIBIA PLATES- TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,PROXIMAL TIBIAL PLATES-SS-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,PEDIATRIC PLATES-SS-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., DISTAL HUMERUS PLATES-TITANIUM-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., LOCKING COMPRESSION PLATES- SS-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., TOMOFIX IMPLANTS- TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., EXTERNAL FIXATOR IMPLANTS- SCREW (TITANIUM ALLOY)- EXTERNAL FIXATOR DEVICES ARE INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS.,OLECRANON PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., RECON FEMORAL NAILING IMPLANTS- WASHER-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,EXTERNAL FIXATOR IMPLANTS-

		SCREW (TITANIUM ALLOY)-EXTERNAL FIXATOR DEVICES ARE INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS.,SCREW IMPLANTS FOR OR WITHOUT PLATES- WASHER (TITANIUM)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., CLAVICLE PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,LOCKING COMPRESSION PLATES- TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., LOCKING ATTACHMENT PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,FOOT PLATES- TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.
2477	IMP/MD/2021/000103	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TIBIAL FUSION CAGES, SCREWS & PLATES(ACTIV MOTION RANGE AND ASSOCIATED INSTRUMENTATION)-THE IMPLANTS OF THE ACTIVMOTION RANGE ARE INTENDED FOR KNEE OSTEOTOMY IN ADULTS.
2478	IMP/MD/2021/000104	1.License Holder Name: HARSONS SURGICAL AND MEDICO 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESURE MONITORING DEVICES(NIL)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES

2479	IMP/MD/2021/000108	1.License Holder Name: FAITH BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ANEURYSM EMBOLIZATION SYSTEM(WEB)-THE WEB ANEURYSM EMBOLIZATION SYSTEM IS INTENDED FOR THE ENDOVASCULAR EMBOLIZATION OF RUPTURED AND UNRUPTURED INTRACRANIAL ANEURYSMS AND OTHER NEUROVASCULAR ABNORMALITIES SUCH AS ARTERIOVENOUS FISTULAE (AVF). THE WEB ANEURYSM EMBOLIZATION SYSTEM IS ALSO INTENDED FOR VASCULAR OCCLUSION OF BLOOD VESSELS WITHIN THE NEUROVASCULAR SYSTEM TO PERMANENTLY OBSTRUCT BLOOD FLOW TO AN ANEURYSM OR OTHER VASCULAR MALFORMATION., THROMBECTOMY SUCTION CATHETER(SOFIA)-THE SOFIA™ CATHETER IS INDICATED FOR GENERAL INTRAVASCULAR USE, INCLUDING THE NEURO AND PERIPHERAL VASCULATURE. THE SOFIA™ CATHETER CAN BE USED TO FACILITATE INTRODUCTION OF DIAGNOSTIC OR THERAPEUTIC AGENTS. THE SOFIA™ CATHETER IS NOT INTENDED FOR USE IN CORONARY ARTERIES. MOREOVER, THE SOFIA™ CATHETER IS INTENDED FOR USE IN REMOVAL/ASPIRATION OF EMBOLI AND THROMBI FROM SELECTED BLOOD VESSELS IN THE ARTERIAL SYSTEM, INCLUDING THE PERIPHERAL AND NEURO VASCULATURES.,INTRACRANIAL SUPPORT CATHETER(SOFIA EX)-THE SOFIA® EX CATHETER IS INDICATED FOR GENERAL INTRAVASCULAR USE, INCLUDING THE NEURO AND PERIPHERAL VASCULATURE. THE SOFIA® EX CATHETER CAN BE USED TO FACILITATE INTRODUCTION OF DIAGNOSTIC AGENTS OR THERAPEUTIC DEVICES. THE SOFIA® EX CATHETER IS NOT INTENDED FOR USE IN CORONARY ARTERIES.,INTRALUMINAL SUPPORT DEVICE (LVIS EVO)-THE LVIS EVO DEVICE IS INTENDED FOR USE WITH EMBOLIC COILS FOR THE TREATMENT OF INTRACRANIAL NEUROVASCULAR DISEASES.
2480	IMP/MD/2021/000109	1.License Holder Name: AAKAAR MEDICAL TECHNOLOGIES PVT.LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE POLYDIOXANONE SUTURE WITH NEEDLE(ALFA AQULIFT)-THIS DEVICE IS INTENDED TO FIXATE SUB DERMAL TISSUE IN AN ELEVATED POSITION IN PLASTIC AND RECONSTRUCTIVE SURGERY. POLYDIOXANONE SUTURE PROVIDES WOUND SUPPORT FOR LONGER PERIOD AS COMPARED TO OTHER SYNTHETIC ABSORBABLE SUTURE. IT ALSO PROLONGS THE STIMULATION TIME THAT INCREASES THE TREATMENT EFFECT ON THE BODY.

2481	IMP/MD/2021/000110	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ATTACHMENT SYSTEM (LOCATOR® IMPLANT)-THE LOCATOR® IMPLANT ATTACHMENT SYSTEM IS DESIGNED FOR USE WITH OVERDENTURES OR PARTIAL DENTURES, RETAINED IN WHOLE OR IN PART, BY ENDOSSEOUS IMPLANTS IN THE MANDIBLE OR MAXILLA.,ATTACHMENT SYSTEM (LOCATOR R-TX®)-THE LOCATOR RTX® ATTACHMENT SYSTEM IS DESIGNED FOR USE WITH OVERDENTURES OR PARTIAL DENTURES, RETAINED IN WHOLE OR IN PART, BY ENDOSSEOUS IMPLANTS IN THE MANDIBLE OR MAXILLA.
2482	IMP/MD/2021/000111	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FIXATION SYSTEM FOR SPINAL OSTEOSYNTHESIS FIXATION SYSTEM FOR SPINAL OSTEOSYNTHESIS (INCLUDING SCREWS AND STEMS)(SAXXO AND ASSOCIATED INSTRUMENTS)-1. THORACO-LUMBAR DEGENERATIVE DISC DISEASE 2. THORACO-LUMBAR STENOSIS 3. RECURRING LOMBARDISCAL HERNIA 4. DEFORMITIES (SCOLIOSIS, KYPHOSIS) 5. SPONDYLOLISTHESIS 6. THORACO-LUMBAR FRACTURE 7. PSEUDARTHROSIS DUE TO FUSION FAILURE 8. INTERVERTEBRAL INSTABILITY 9. DEGENERATION OF THE DISTAL SEGMENT AFTER ANTERIOR SURGERY,STERILE CERVICAL ANTERIOR CAGES(SQUALE AND ASSOCIATED INSTRUMENTS)-1. DEGENERATIVE CERVICAL DISEASE 2. CERVICAL STENOSIS 3. DISC HERNIATION 4. SPONDYLOSIS 5. TRAUMATIC INJURY,ANTERIOR CERVICAL PLATES AND ASSOCIATED SCREWS(ORIGIN AND ASSOCIATED INSTRUMENTS) -1. DEGENERATIVE DISC PATHOLOGY 2. DISCAL HERNIA 3. SPONDYLOLISTHESIS 4. FRACTURE 5. STENOSIS 6. FORMATION OF OSTEOPHYTES 7. HYPERTROPHY OF THE POSTERIOR LONGITUDINAL LIGAMENT

2483	IMP/MD/2021/000115	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STEERABLE SHEATH (FLEXCATH ADVANCE)-THE FLEXCATH ADVANCE STEERABLE SHEATH IS INTENDED FOR PERCUTANEOUS CATHETER INTRODUCTION INTO THE VASCULATURE AND INTO THE CHAMBERS OF THE HEART. THE SHEATH DEFLECTION FACILITATES CATHETER POSITIONING.,CARDIAC CRYOABLATION CATHETER(ARCTIC FRONT ADVANCE PRO)-THE ARCTIC FRONT ADVANCE PRO CARDIAC CRYOABLATION CATHETER IS INDICATED FOR THE TREATMENT OF PATIENTS WITH ATRIAL FIBRILLATION.,CARDIAC CRYOABLATION CATHETER(FREEZOR XTRA)-THE FREEZOR XTRA CARDIAC CRYOABLATION CATHETER IS INTENDED FOR USE IN TREATMENT OF CARDIAC ARRHYTHMIAS.,NITROUS OXIDE (N2O) REFRIGERANT TANK-THE REFRIGERANT TANK SUPPLIES LIQUEFIED NITROUS OXIDE (N2O) TO THE CRYOCONSOLE.,CARDIAC CRYOABLATION CATHETER (FREEZOR)-THE FREEZOR CARDIAC CRYOABLATION CATHETER IS INTENDED FOR USE IN TREATMENT OF CARDIAC ARRHYTHMIAS., CARDIAC CRYOABLATION CATHETER(FREEZOR MAX)-THE FREEZOR MAX CARDIAC CRYOABLATION CATHETER IS INTENDED FOR USE IN TREATMENT OF CARDIAC ARRHYTHMIAS.
2484	IMP/MD/2021/000116	1.License Holder Name: INTUITIVE SURGICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAPLER RELOAD (SUREFORM® 45 RELOAD)-STAPLER RELOADS ARE INTENDED TO BE USED WITH THE DA VINCI XI AND X SURGICAL SYSTEMS (MODELS IS4000 AND IS4200) FOR RESECTION, TRANSECTION AND/OR CREATION OF ANASTOMOSES IN GENERAL, THORACIC, GYNECOLOGIC AND UROLOGIC SURGERY. THE DEVICE CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIAL (NATURAL OR SYNTHETIC).

2485	IMP/MD/2021/000117	1.License Holder Name: SWAR ENTERPRISES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MALLEABLE PENILE PROSTHESIS(RIGI 10)-RIGI10™ HYDROPHILIC MALLEABLE PENILE PROSTHESIS IS INTENDED FOR IMPLANTATION INTO THE CORPORA CAVERNOSA OF THE PENIS IN MEN WHO ARE DIAGNOSED WITH ERECTILE DYSFUNCTION. THE PROSTHESIS IS IMPLANTED TO PROVIDE ADEQUATE PENILE RIGIDITY FOR SEXUAL INTERCOURSE., INFLATABLE PENILE PROSTHESIS(INFLA 10)-INFLA10® THREE-PIECE INFLATABLE PENILE PROSTHESIS IS INDICATED FOR PATIENTS SUFFERING FROM ORGANIC ERECTILE DYSFUNCTION (IMPOTENCE) AND ARE CANDIDATES FOR A PENILE PROSTHESIS IMPLANTATION
2486	IMP/MD/2021/000118	1.License Holder Name: MITOCON BIOMED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GEL-FILLED MAMMARY IMPLANTS(ROUND GELFILLED MAMMARY IMPLANT(PURITY, SUBLIMITY,VOLUPTY) AND ANATOMICAL GEL FILLED MAMMARY IMPLANT (SENSITY))-GEL-FILLED MAMMARY IMPLANTS ARE MEDICAL DEVICES INTENDED FOR PLASTIC, RECONSTRUCTIVE AND AESTHETIC SURGERY. BREAST RECONSTRUCTION, INCLUDING PREVIOUS RECONSTRUCTION TO REPLACE BREAST TRAUMA , OR THAT HAS FAILED TO DEVELOP PROPERLY DUE TO A SEVERE BREAST ANOMALY, AS WELL AS REVISION SURGERY TO CONCEAL OR IMPROVE THE RESULTS OF A PREVIOUS BREAST RECONSTRUCTION SURGERY,GEL-FILLED MAMMARY IMPLANTS(ROUND GELFILLED MAMMARY IMPLANT (INTEGRITY))-GEL-FILLED MAMMARY IMPLANTS ARE MEDICAL DEVICES INTENDED FOR PLASTIC, RECONSTRUCTIVE AND AESTHETIC SURGERY. BREAST RECONSTRUCTION, INCLUDING PREVIOUS RECONSTRUCTION TO REPLACE BREAST TRAUMA, OR THAT HAS FAILED TO DEVELOP PROPERLY DUE TO A SEVERE BREAST ANOMALY, AS WELL AS REVISION SURGERY TO CONCEAL OR IMPROVE THE RESULTS OF A PREVIOUS BREAST RECONSTRUCTION SURGERY

2487	IMP/MD/2021/000119	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAPPING CATHETER (ACHIEVE ADVANCE)-THE ACHIEVE ADVANCE MAPPING CATHETER IS INDICATED FOR MULTIPLE ELECTRODE ELECTROPHYSIOLOGICAL MAPPING OF THE CARDIAC STRUCTURES OF THE HEART, I.E. RECORDING OR STIMULATION ONLY. THE ACHIEVE ADVANCE MAPPING CATHETER IS DESIGNED TO OBTAIN ELECTROGRAMS IN THE ATRIAL REGIONS OF THE HEART.
2488	IMP/MD/2021/000120	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOSCOPIC GUIDEWIRE, SINGLE USE(NOVAGOLD HIGH PERFORMANCE GUIDEWIRE)-THE NOVAGOLD GUIDEWIRE IS INTENDED FOR USE IN SELECTIVE CANNULATION OF THE BILIARY DUCTS INCLUDING THE COMMON BILE, PANCREATIC, CYSTIC, RIGHT AND LEFT HEPATIC DUCTS, AND TO AID IN THE PLACEMENT OF DIAGNOSTIC AND THERAPEUTIC DEVICES DURING ENDOSCOPIC PROCEDURES.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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2489	IMP/MD/2021/000121	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTERVERTEBRAL BODY FUSION DEVICE(ADAPTIX™ INTERBODY SYSTEM WITH TITAN NANOLOCK™)-THE ADAPTIX™ INTERBODY SYSTEM WITH TITAN NANOLOCK™ SURFACE TECHNOLOGY IS INTENDED TO BE USED IN SPINAL FUSION PROCEDURES FOR PATIENTS DIAGNOSED WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTIGUOUS LEVELS FROM L2 TO S1. DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVELS. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. THE ADAPTIX™ INTERBODY SYSTEM WITH TITAN NANOLOCK™ SURFACE TECHNOLOGY IS INTENDED FOR USE WITH SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBAR SPINE. THESE PATIENTS SHOULD BE SKELETALLY MATURE AND HAVE HAD SIX MONTHS OF NONOPERATIVE TREATMENT. THE ADAPTIX™ INTERBODY SYSTEM WITH TITAN NANOLOCK™ SURFACE TECHNOLOGY IS INTENDED TO BE USED WITH AUTOGRAFT AND/OR ALLOGENIC BONE GRAFT COMPRISED OF CANCELLOUS AND/OR CORTICO CANCELLOUS BONE GRAFT AND/OR DEMINERALIZED ALLOGRAFT BONE WITH BONE MARROW ASPIRATE. THESE IMPLANTS MAY BE IMPLANTED VIA AN OPEN OR A MINIMALLY INVASIVE POSTERIOR APPROACH AND/OR TRANSFORAMINAL APPROACH.

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2490	IMP/MD/2021/000122	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERIPHERAL VASCULAR GUIDEWIRE(V-18 CONTROLWIRE GUIDEWIRE WITH ICE HYDROPHILIC COATING)-THE V-18 CONTROL WIRE GUIDEWIRE IS AVAILABLE IN 110, 150, 200 AND 300 CM LENGTHS. THE WIRE CAN BE TORQUED TO FACILITATE THE SELECTIVE PLACEMENT OF DIAGNOSTIC OR THERAPEUTIC CATHETERS. THIS DEVICE IS INTENDED FOR PERIPHERAL USE ONLY. A TORQUE DEVICE (PIN VISE) IS INCLUDED WITH EACH WIRE TO FACILITATE DIRECTIONAL MANIPULATION OF THE GUIDEWIRE. THE 110 CM V-18 CONTROL WIRE GUIDEWIRE IS INTENDED FOR GENERAL INTRAVASCULAR USE INCLUDING THE PLACEMENT OF PTA BALLOON CATHETERS REQUIRING AN 0.018 IN GUIDEWIRE IN HEMODIALYSIS AV ACCESS PROCEDURES. THE 150, 200 AND 300 CM V-18 CONTROL WIRE GUIDEWIRE ARE INTENDED FOR GENERAL INTRAVASCULAR USE.,CARDIO RADIO-FREQUENCY ABLATION SYSTEM CATHETER(BLAZER PRIME XP TEMPERATURE ABLATION CATHETERS)-THE BOSTON SCIENTIFIC CARDIAC ABLATION SYSTEM IS INDICATED FOR INTERRUPTION OF ACCESSORY ATRIOVENTRICULAR (AV) CONDUCTION PATHWAYS ASSOCIATED WITH TACHYCARDIA, FOR TREATMENT OF AV NODAL REENTRANT TACHYCARDIA, FOR TREATMENT OF ATRIAL FLUTTER TACHYCARDIA, AND FOR CREATION OF COMPLETE AV BLOCK IN PATIENTS WITH A RAPID VENTRICULAR RESPONSE TO AN ATRIAL ARRHYTHMIA – TYPICALLY CHRONIC, DRUG REFRACTORY ATRIAL FIBRILLATION.,PERIPHERAL VASCULAR GUIDEWIRE(V-14 CONTROLWIRE GUIDEWIRE WITH ICE HYDROPHILIC COATING)-BOSTON SCIENTIFIC V-14 CONTROLWIRE GUIDEWIRE IS INTENDED TO FACILITATE THE PLACEMENT AND EXCHANGE OF BALLOON DILATATION CATHETERS OR OTHER THERAPEUTIC DEVICES DURING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) OR OTHER INTRAVASCULAR INTERVENTIONAL PROCEDURES. THE V-14 CONTROLWIRE GUIDEWIRE IS NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE.,CARDIO RADIO-FREQUENCY ABLATION SYSTEM CATHETER(BLAZER PRIME HTD TEMPERATURE ABLATION CATHETERS)-THE BOSTON SCIENTIFIC CARDIAC ABLATION SYSTEM IS INDICATED FOR INTERRUPTION OF ACCESSORY ATRIOVENTRICULAR (AV) CONDUCTION PATHWAYS ASSOCIATED WITH TACHYCARDIA, FOR TREATMENT OF AV NODAL REENTRANT TACHYCARDIA AND FOR CREATION OF COMPLETE AV BLOCK IN PATIENTS WITH A RAPID VENTRICULAR RESPONSE TO AN ATRIAL ARRHYTHMIA - TYPICALLY CHRONIC, DRUG REFRACTORY ATRIAL FIBRILLATION.,CARDIAC RADIO-FREQUENCY ABLATION SYSTEM CATHETER(BLAZER II TEMPERATURE ABLATION CATHETER)-THE

	BOSTON SCIENTIFIC CARDIAC ABLATION SYSTEM IS INDICATED FOR INTERRUPTION OF ACCESSORY ATRIOVENTRICULAR (AV) CONDUCTION PATHWAYS ASSOCIATED WITH TACHYCARDIA, FOR TREATMENT OF AV NODAL REENTRANT TACHYCARDIA AND FOR CREATION OF COMPLETE AV BLOCK IN PATIENTS WITH A RAPID VENTRICULAR RESPONSE TO AN ATRIAL ARRHYTHMIA - TYPICALLY CHRONIC, DRUG REFRACTORY ATRIAL FIBRILLATION.,CATHETER GUIDEWIRE(BACK-UP MEIER STEERABLE GUIDEWIRE)-THE BACK-UP MEIER STEERABLE GUIDEWIRE FACILITATES CATHETER PLACEMENT AND EXCHANGE DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURES, INCLUDING ABDOMINAL AORTIC ANEURYSM (AAA) ENDOVASCULAR GRAFT PROCEDURES.,CATHETER GUIDEWIRE (ACUITY WHISPER VIEW GUIDE WIRE)-BOSTON SCIENTIFIC ACUITY WHISPER VIEW GUIDE WIRES WITH HYDROPHILIC COATING ARE INTENDED TO FACILITATE THE PLACEMENT OF BOSTON SCIENTIFIC OR GUIDANT LEFT VENTRICULAR (LV) LEADS WITHIN THE CORONARY VENOUS VASCULATURE.,GASTRO-UROLOGICAL GUIDEWIRE, SINGLE-USE(AMPLATZ SUPER STIFF GUIDEWIRE)-UROLOGICAL GUIDEWIRES ARE INTENDED TO FACILITATE THE PLACEMENT OF ENDOUROLOGICAL INSTRUMENTS DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURES. THESE GUIDEWIRES ARE NOT INTENDED FOR CORONARY ARTERY, VASCULAR OR NEUROLOGICAL USE.,CATHETER GUIDEWIRE(CHOICE GUIDEWIRES WITH ICE HYDROPHILIC COATING)-BOSTON SCIENTIFIC CHOICE GUIDEWIRES WITH ICE HYDROPHILIC COATING ARE INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS OR OTHER THERAPEUTIC DEVICES DURING PTCA OR OTHER INTRAVASCULAR INTERVENTIONAL PROCEDURES. THEY ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE.,CATHETER GUIDEWIRE(CHOICE PT GUIDEWIRE WITH ICE HYDROPHILIC COATING)-BOSTON SCIENTIFIC CHOICE PT GUIDEWIRES WITH ICE HYDROPHILIC COATING ARE INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS OR OTHER THERAPEUTIC DEVICES DURING PTCA OR OTHER INTRAVASCULAR INTERVENTIONAL PROCEDURES. THEY ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE.,PERIPHERAL VASCULAR GUIDEWIRE(TRANSEND GUIDEWIRE WITH ICE HYDROPHILIC COATING)-THE TRANSEND GUIDEWIRE IS INTENDED FOR GENERAL INTRAVASCULAR USE, INCLUDING THE PERIPHERAL VASCULATURE. THE WIRE CAN BE TORQUED TO FACILITATE THE SELECTIVE PLACEMENT OF DIAGNOSTIC OR THERAPEUTIC CATHETERS.,CATHETER GUIDEWIRE (ROTAWIRE AND WIRECLIP TORQUER GUIDEWIRE AND GUIDEWIRE MANIPULATION DEVICE)-THESE GUIDEWIRES ARE INTENDED FOR USE WITH THE ROTABLATOR ROTATIONAL ATHERECTOMY SYSTEM.,

	CATHETER GUIDEWIRE(AMPLATZ SUPER STIFF GUIDEWIRE)-THE AMPLATZ SUPER STIFF GUIDEWIRE FACILITATES CATHETER PLACEMENT AND EXCHANGE DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURES. NOT INTENDED FOR USE IN CORONARY ARTERIES.,CARDIAC RADIO-FREQUENCY ABLATION SYSTEM CATHETER(BLAZER II XP TEMPERATURE ABLATION CATHETER)-THE BOSTON SCIENTIFIC CARDIAC ABLATION SYSTEM IS INDICATED FOR INTERRUPTION OF ACCESSORY ATRIOVENTRICULAR (AV) CONDUCTION PATHWAYS ASSOCIATED WITH TACHYCARDIA, FOR TREATMENT OF AV NODAL REENTRANT TACHYCARDIA, FOR TREATMENT OF ATRIAL FLUTTER TACHYCARDIA, AND FOR CREATION OF COMPLETE AV BLOCK IN PATIENTS WITH A RAPID VENTRICULAR RESPONSE TO AN ATRIAL ARRHYTHMIA – TYPICALLY CHRONIC, DRUG REFRACTORY ATRIAL FIBRILLATION.,CATHETER GUIDEWIRE (LUGE GUIDEWIRE WITH ICE HYDROPHILIC COATING)-BOSTON SCIENTIFIC LUGE GUIDEWIRES WITH ICE HYDROPHILIC COATING ARE INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS OR OTHER THERAPEUTIC DEVICES DURING PTCA OR OTHER INTRAVASCULAR INTERVENTIONAL PROCEDURES. THEY ARE NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE.,CARDIAC RADIO-FREQUENCY ABLATION SYSTEM CATHETER(BLAZER II HTD TEMPERATURE ABLATION CATHETER)-THE BOSTON SCIENTIFIC CARDIAC ABLATION SYSTEM IS INDICATED FOR INTERRUPTION OF ACCESSORY ATRIOVENTRICULAR (AV) CONDUCTION PATHWAYS ASSOCIATED WITH TACHYCARDIA, FOR TREATMENT OF AV NODAL REENTRANT TACHYCARDIA AND FOR CREATION OF COMPLETE AV BLOCK IN PATIENTS WITH A RAPID VENTRICULAR RESPONSE TO AN ATRIAL ARRHYTHMIA - TYPICALLY CHRONIC, DRUG REFRACTORY ATRIAL FIBRILLATION.

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2491	IMP/MD/2021/000125	1.License Holder Name: FAITH BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROCATHETER(VIA)-[VIA 17, 17 PRESHAPED 45°, 17 PRESHAPED 90° - THE VIA MICROCATHETER IS INTENDED FOR THE INTRODUCTION OF INTERVENTIONAL DEVICES (SUCH AS WEB DEVICE / COILS / STENTS) AND INFUSION OF DIAGNOSTIC AGENTS (SUCH AS CONTRAST MEDIA) INTO THE NEURO, PERIPHERAL, AND CORONARY VASCULATURE.], [VIA 21, 27, 33 - THE VIA MICROCATHETER IS INTENDED FOR THE INTRODUCTION OF INTERVENTIONAL DEVICES (SUCH AS THE WEB DEVICE/STENTS/FLOW DIVERTERS) AND INFUSION OF DIAGNOSTIC AGENTS (SUCH AS CONTRAST MEDIA) INTO THE NEURO, PERIPHERAL, AND CORONARY VASCULATURE.],OCCLUSION BALLOON CATHETER(SCEPTER MINI)-THE SCEPTER MINI OCCLUSION BALLOON CATHETER IS INTENDED: • FOR USE IN THE PERIPHERAL AND NEURO VASCULATURE WHERE TEMPORARY OCCLUSION IS DESIRED. THE BALLOON CATHETER PROVIDES TEMPORARY VASCULAR OCCLUSION WHICH IS USEFUL IN SELECTIVELY STOPPING OR CONTROLLING BLOOD FLOW. THE BALLOON CATHETERS ALSO OFFER BALLOON ASSISTED EMBOLIZATION OF INTRACRANIAL ANEURYSMS. • FOR USE IN THE PERIPHERAL VASCULATURE FOR THE INFUSION OF DIAGNOSTIC AGENTS, SUCH AS CONTRAST MEDIA, AND THERAPEUTIC AGENTS SUCH AS EMBOLIZATION MATERIALS. • FOR NEUROVASCULAR USE FOR THE INFUSION OF DIAGNOSTIC AGENTS SUCH AS CONTRAST MEDIA, AND THERAPEUTIC AGENTS, SUCH AS EMBOLIZATION MATERIALS, THAT HAVE BEEN APPROVED OR CLEARED FOR USE IN THE NEUROVASCULATURE AND ARE COMPATIBLE WITH THE INNER LUMEN OF THE SCEPTER MINI OCCLUSION BALLOON CATHETER.
2492	IMP/MD/2021/000129	1.License Holder Name: VENUS REMEDIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE SYRINGES (EZ-FILL)-THE PRE-FILLABLE SYRINGES CAN BE CONSIDERED A COMPONENT OF THE SO CALLED PRE-FILLED SYRINGES. THEY WILL BE FILED WITH THE DRUG, CLOSED WITH THE PLUNGER AND PUT IN THE COMMERCE BY THE PHARMACEUTICAL INDUSTRY.

2493	IMP/MD/2021/000131	1.License Holder Name: M/S DENTSPLY INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDODONTIC IRRIGATION NEEDLE(TRUNATOMY IRRIGATION NEEDLE)-THE DEVICE IS AN ENDODONTIC NEEDLE FOR ROOT CANAL IRRIGATION. IT IS INTENDED FOR USE IN DENTISTRY IN THE ROOT CANAL PREPARATION PROCEDURE, WHICH IS A CRUCIAL STEP OF THE ENDODONTIC TREATMENT.
2494	IMP/MD/2021/000132	1.License Holder Name: ANITA MEDICAL SYSTEMS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SINGLE USE HIGH PRESSURE ANGIOGRAPHIC SYRINGES ACCESSORIES (SYRINGE AND SPIKE)(APORT)-SYRINGE FOR INJECTION OF CONTRAST MEDIA OR SALINE FOR CT AND MRI.,SINGLE USE HIGH PRESSURE ANGIOGRAPHIC SYRINGES AND ACCESSORIES (SYRINGES, COILED PATIENT TUBING AND SPIKES)(APORT)-SYRINGE FOR INJECTION OF CONTRAST MEDIA OR SALINE FOR CT AND MRI.,SINGLE USE HIGH PRESSURE ANGIOGRAPHIC SYRINGES ACCESSORIES-(SYRINGE AND J TUBE)(APORT)-SYRINGE FOR INJECTION OF CONTRAST MEDIA OR SALINE FOR CT AND MRI,SINGLE USE HIGH PRESSURE ANGIOGRAPHIC SYRINGES(APORT)-SYRINGE FOR INJECTION OF CONTRAST MEDIA OR SALINE FOR CT AND MRI.

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2495	IMP/MD/2021/000133	1.License Holder Name: EURO MEDI TOOLS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL IMPLANTS FOR SYNTHETIC BONE RECONSTRUCTION(PULLUP®)-THE PULLUP® DEVICES ARE DESIGNED TO BE USED AS JUXTA-CORTICAL FIXATION FOR ACL RECONSTRUCTION, AND ARE INTENDED FOR SINGLE USE ONLY.,BONE SUBSTITUTE(BIO 1®)-BIO-1® ARE ABSORBABLE CALCIUM SALT BONE VOID FILLERS INTENDED TO FILL BONY VOIDS OR GAPS OF THE SKELETAL SYSTEM (I.E. THE EXTREMITIES, SPINE AND PELVIS,) CAUSED BY TRAUMA OR SURGERY, THAT ARE NOT INTRINSIC TO THE STABILITY OF THE BONY STRUCTURE. BIO-1® BONE SUBSTITUTES DO NOT POSSESS SUFFICIENT MECHANICAL STRENGTH TO SUPPORT THE REDUCTION OF A DEFECT PRIOR TO COMPLETE BONE HEALING. RIGID FIXATION TECHNIQUES MUST BE USED TO ENSURE STABILIZATION OF THE DEFECT IN ALL PLANES.,IMPLANT FOR HIGH TIBIAL OSTEOTOMY(OTIS / OTIS 50)-OTIS®/OTIS 50® IMPLANTS ARE USED IN VALGUS OSTEOTOMY OF THE TIBIA USING A MEDIAL METAPHYSEAL INCISION. AN OSTEOSYNTHESIS DEVICE SUCH AS OTIS-C® OR OTIS-C-PLUS® MUST ALWAYS BE ASSOCIATED. OTIS® IMPLANTS CAN BE USED WITH STAPLE-TYPE OSTEOSYNTHESIS DEVICES. HOWEVER, OTIS 50® IMPLANTS, WHICH OFFER LESSER MECHANICAL PERFORMANCES, MUST ALWAYS BE ASSOCIATED WITH A PLATE-AND-SCREW OSTEOSYNTHESIS DEVICE SUCH AS OTIS-C® AND OTIS-C PLUS®.,PLATE AND SCREW FIXATION SYSTEM(OTIS-C/ OTIS-CPLUS/ OTIS-F)-OTIS-C-PLUS® AND OTIS-F® PLATES ARE INTENDED FOR USE IN THE TEMPORARY STABILIZATION OF LONG BONE FRACTURES. OTIS-C-PLUS® PLATES HAVE BEEN DESIGNED FOR OPENING WEDGE HIGH TIBIAL OSTEOTOMIES (OWHTO). OTIS-F® PLATES HAVE BEEN DESIGNED FOR DISTAL FEMORAL OSTEOTOMIES AND ARE SUITABLE FOR OPENING AS WELL AS CLOSING OSTEOTOMIES, WITH A MEDIAL OR LATERAL APPROACH. THE OTIS-F® PLATES AND OTIS-C-PLUS® PLATES PROVIDE A COMPLETE SOLUTION FOR DOUBLE LEVEL OSTEOTOMIES AROUND THE KNEE. TO BE USED WITH ASSOCIATED SCREWS.,RESORBABLE INTERFERENCE SCREW(LIGAFIX®)-THE LIGAFIX® 30 INTERFERENCE SCREW IS DESIGNED FOR INTERFERENCE FIXATION IN ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION. THE LIGAFIX® 60 INTERFERENCE SCREW IS EXCLUSIVELY USED FOR INTERFERENCE FIXATION OF A SOFT TISSUE TRANSPLANT, FOR INSTANCE FROM THE HAMSTRING TENDON, WHEN RECONSTRUCTING THE ANTERIOR CRUCIATE LIGAMENT. THE SCREWS ARE CANNULATED AND ARE AVAILABLE IN DIFFERENT SIZES (SEE COMMERCIAL DOCUMENTATION). THEY HAVE A SPECIFIC HEAD, WHICH ALLOWS FOR A MORE EVEN DISTRIBUTION OF THE TORSIONAL STRESSES. TO

		ACHIEVE AN OPTIMAL RESULT, THE LIGAFIX® INTERFERENCE SCREWS SHOULD BE IMPLANTED USING THE DEDICATED SCREWDRIVER CONTAINED IN THE INSTRUMENTATION SET. - FLAT HEAD SCREWS ARE RECOMMENDED TO REDUCE THE STRESSES ON THE SCREW. USING LIGAFIX® SCREWS IS APPROPRIATE WHEN IMPLANTING 10-11MM DIAMETER SCREWS AND IN THE KJ TECHNIQUE (TENDON-BONE GRAFT) FOR LIGAFIX® 30. - ROUND HEAD SCREWS ARE RECOMMENDED TO LIMIT FRICTION ON THE GRAFT, SPECIFICALLY FOR FEMORAL FIXATION AND SOFT TISSUE GRAFTS FOR LIGAFIX® 60.
2496	IMP/MD/2021/000134	1.License Holder Name: HARSONS SURGICAL AND MEDICO 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEBULIZER COMPRESSOR SYSTEM(HARSONS)-IT IS DEVICE USED TO ADMINISTER MEDICATIONS IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDERS

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2497	IMP/MD/2021/000135	1.License Holder Name: EDWARDS LIFESCIENCES (INDIA) PRIVATE LIMITED, 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITORING DEVICE(HEMOSPHERE ADVANCED MONITORING PLATFORM)-THE HEMOSPHERE ADVANCED MONITORING PLATFORM IS INTENDED TO BE USED BY QUALIFIED PERSONNEL OR TRAINED CLINICIANS IN A CRITICAL CARE ENVIRONMENT IN A HOSPITAL SETTING. THE HEMOSPHERE ADVANCED MONITORING PLATFORM IS INTENDED FOR USE WITH COMPATIBLE EDWARDS SWAN-GANZ AND OXIMETRY CATHETERS AND PRESSURE MONITORING SENSORS AND CATHETERS.,BLOOD PRESSURE MONITORING DEVICE(EV1000 CLINICAL PLATFORM (EV1000A AND EV1000NI))-INTENDED USE – THE INTENDED USE OF THE EV1000 CLINICAL PLATFORM (MINIMALLY INVASIVE VERSION) IS TO CALCULATE AND DISPLAY CONTINUOUS AND INTERMITTENT CARDIAC OUTPUT, OXIMETRY (OXYGEN SATURATION), AND COMPUTE DERIVED HEMODYNAMIC AND OXYGENATION PARAMETERS. INDICATION - THE EV1000 PLATFORM IS INDICATED FOR USE PRIMARILY FOR CRITICAL CARE PATIENTS IN WHICH THE BALANCE BETWEEN CARDIAC FUNCTION, FLUID STATUS AND VASCULAR RESISTANCE NEEDS CONTINUOUS OR INTERMITTENT ASSESSMENT. ANALYSIS OF THE THERMODILUTION CURVE IN TERMS OF MEAN TRANSIT TIME AND THE SHAPE IS USED TO DETERMINE INTRAVASCULAR AND EXTRAVASCULAR FLUID VOLUMES. WHEN CONNECTED TO AN EDWARDS OXIMETRY CATHETER, THE MONITOR MEASURES OXIMETRY IN ADULTS AND PEDIATRICS. THE EV1000 PLATFORM MAY BE USED IN ALL SETTINGS IN WHICH CRITICAL CARE IS PROVIDED. INTENDED USE – THE INTENDED USE OF THE EV1000 NONINVASIVE SYSTEM IS TO CONTINUOUSLY AND NONINVASIVELY MEASURE BLOOD PRESSURE AND ASSOCIATED HEMODYNAMIC PARAMETERS. INDICATION - THE EV1000 CLINICAL PLATFORM NI OR NONINVASIVE SYSTEM AND CLEARSIGHT™ FINGER CUFFS ARE INDICATED FOR PATIENTS OVER 18 YEARS OF AGE IN WHICH THE BALANCE BETWEEN CARDIAC FUNCTION, FLUID STATUS AND VASCULAR RESISTANCE NEEDS CONTINUOUS ASSESSMENT. THE EV1000 CLINICAL PLATFORM MAY BE USED FOR THE MONITORING OF HEMODYNAMIC PARAMETERS IN CONJUNCTION WITH A PERIOPERATIVE GOAL DIRECTED THERAPY PROTOCOL. IN ADDITION, THE NONINVASIVE SYSTEM IS INDICATED FOR USE IN PATIENTS WITH CO-MORBIDITIES FOR WHICH HEMODYNAMIC OPTIMIZATION IS DESIRED AND INVASIVE MEASUREMENTS ARE DIFFICULT. THE EV1000 CLINICAL PLATFORM NI AND CLEARSIGHT™ FINGER CUFFS NONINVASIVELY MEASURE BLOOD PRESSURE AND ASSOCIATED HEMODYNAMIC PARAMETERS.

2498	IMP/MD/2021/000136	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARM- TYPE FULLY AUTOMATIC DIGITAL BLOOD PRESSURE MONITOR-TEST HUMAN BODY BLOOD PRESSURE AND HEART BEAT,DIGITAL THERMOMETER-TEST HUMAN BODY TEMPERATURE

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2499	IMP/MD/2021/000137	1.License Holder Name: M/S DENTSPLY INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:XIVE® S PLUS IMPLANT D 3.4 - D 5.5(XIVE® S PLUS IMPLANT D 3.4 - D 5.5)-THE XIVE® S PLUS IMPLANTS D 3.4 – D 5.5 ARE FOR SINGLE-STAGE OR TWO-STAGE SURGICAL PROCEDURES AND CEMENTED, REMOVABLE OR SCREW RETAINED RESTORATIONS. THE XIVE® S PLUS IMPLANTS D 3.4 – D 5.5 MAY BE USED FOR IMMEDIATE PLACEMENT AND FUNCTION ON SINGLE TOOTH AND/OR MULTIPLE TOOTH APPLICATIONS WHEN ADEQUATE PRIMARY STABILITY IS ACHIEVABLE, WITH APPROPRIATE OCCLUSAL LOADING, IN ORDER TO RESTORE CHEWING FUNCTION. MULTIPLE TOOTH APPLICATIONS MAY BE SPLINTED.,DENTAL SCREW (ANKYLOS C/X COVER SCREW)-TO CLOSE THE IMPLANT IN CASE OF SUBMERGED HEALING PROTOCOL.,ANKYLOS® C/X IMPLANTS L 8-17 MM(ANKYLOS® C/X IMPLANTS L 8-17 MM)-ANKYLOS® C/X LMPLANTS OF 8 MM IN LENGTH OR LONGER ARE FOR SINGLE-STAGE OR TWO-STAGE SURGICAL PROCEDURES AND CEMENTED, REMOVABLE OR SCREW RETAINED RESTORATIONS. THE ANKYLOS® C/X LMPLANTS MAY BE USED FOR IMMEDIATE PLACEMENT AND FUNCTION ON SINGLE TOOTH AND/OR MULTIPLE TOOTH APPLICATIONS WHEN ADEQUATE PRIMARY STABILITY IS ACHIEVABLE, WITH APPROPRIATE OCCLUSAL LOADING, IN ORDER TO RESTORE CHEWING FUNCTION. MULTIPLE TOOTH APPLICATIONS MAY BE SPLINTED.,ANKYLOS® C/X IMPLANTS L 6.6 MM(ANKYLOS® C/X IMPLANTS L 6.6 MM)-ANKYLOS® C/X LMPLANTS OF 6.6 MM IN LENGTH ARE FOR TWO-STAGE SURGICAL PROCEDURES AND CEMENTED, REMOVABLE OR SCREW RETAINED RESTORATIONS. THE ANKYLOS® C/X LMPLANTS MAY BE USED FOR IMMEDIATE PLACEMENT ON SINGLE TOOTH AND/OR MULTIPLE TOOTH APPLICATIONS WHEN ADEQUATE PRIMARY STABILITY IS ACHIEVABLE, WITH APPROPRIATE OCCLUSAL LOADING, IN ORDER TO RESTORE CHEWING FUNCTION. MULTIPLE TOOTH APPLICATIONS MAY BE SPLINTED. ,XIVE® S PLUS IMPLANTS D 3.0(XIVE® S PLUS IMPLANTS D 3.0)-PROSTHETIC CONCEPT: SINGLE-TOOTH RESTORATION ANTERIOR REGION (TIGHT GAPS) 12 + 22 AND 32 - 42; SPLINTED SINGLE-TOOTH RESTORATION REGION 32 - 42 PROSTHETIC TREATMENT: NON-FUNCTIONAL IMMEDIATE LOADING; TWO-STAGE PROCEDURE TIME OF IMPLANT PLACEMENT: DELAYED IMMEDIATE IMPLANT PLACEMENT; LATE IMPLANT PLACEMENT HEALING METHOD: SUBMERGED; TRANSGINGIVAL WITH GINGIVAL FORMING COMPONENTS ,XIVE® TG PLUS IMPLANT(XIVE® TG PLUS)-THE XIVE® TG IMPLANT SYSTEM IS FOR SINGLE-STAGE SURGICAL PROCEDURES AND CEMENTED, REMOVABLE OR SCREW RETAINED RESTORATIONS. THE XIVE® TG IMPLANT SYSTEM MAY BE USED FOR

		IMMEDIATE PLACEMENT AND FUNCTION ON SINGLE TOOTH AND/OR MULTIPLE TOOTH APPLICATIONS WHEN ADEQUATE PRIMARY STABILITY IS ACHIEVABLE, WITH APPROPRIATE OCCLUSAL LOADING, IN ORDER TO RESTORE CHEWING FUNCTION. MULTIPLE TOOTH APPLICATIONS MAY BE SPLINTED.
2500	IMP/MD/2021/000138	1.License Holder Name: ADITYA PHARMA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:THERMAL VAPOR LUNG TREATMENT SYSTEM CATHETER(INTERVAPOR CATHETER)-THE INTERVAPOR® CATHETER IS INTENDED FOR TREATMENT OF PATIENTS WITH HETEROGENEOUS UPPER LOBE EMPHYSEMA TO ACHIEVE BRONCHOSCOPIC LUNG VOLUME REDUCTION WORKING WITH INTERVAPOR GENERATOR.
2501	IMP/MD/2021/000139	1.License Holder Name: ADITYA PHARMA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:THERMAL VAPOR LUNG TREATMENT SYSTEM GENERATOR(INTERVAPOR GENERATOR)-THE INTERVAPOR GENERATOR IS INTENDED FOR TREATMENT OF PATIENTS WITH HETEROGENEOUS UPPER LOBE EMPHYSEMA TO ACHIEVE BRONCHOSCOPIC LUNG VOLUME REDUCTION BY THE APPLICATION OF HEATED WATER VAPOR TO THE MOST DISEASED LUNG SEGMENT(S) TARGETED FOR TREATMENT.
2502	IMP/MD/2021/000140	1.License Holder Name: M/S. VATSKA MEDTECH PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERFADEX PLUS (ORGAN PRESERVATION SOLUTION)(PERFADEX PLUS)-PERFADEX® PLUS BUFFERED, CALCIUM CONTAINING SOLUTION FOR LUNG PRESERVATION. INTENDED USE PERFADEX® PLUS IS INDICATED FOR THE FLUSHING, COLD STATIC STORAGE AND TRANSPORTATION OF ISOLATED LUNGS AFTER REMOVAL FROM THE DONOR IN PREPARATION FOR EVENTUAL TRANSPLANTATION INTO A RECIPIENT.

2503	IMP/MD/2021/000141	1.License Holder Name: BAUSCH & LOMB INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYDROPHOBIC INTRAOCULAR LENS MONOFOCAL (LUXGOOD CRYSTAL PRELOADED)-THE LUXGOOD POSTERIOR CHAMBER LENS IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS. THE LENS IS DESIGNED FOR IMPLANTATION IN THE CAPSULAR BAG.,HYDROPHOBIC INTRAOCULAR LENS(LUXSMART CRYSTAL PRELOADED)-THE LUXSMART POSTERIOR CHAMBER LENS IS INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS. THE LENS IS DESIGNED FOR IMPLANTATION IN THE CAPSULAR BAG.
2504	IMP/MD/2021/000146	1.License Holder Name: INFINITY MEDIQUIP INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITORING DEVICES(INFI)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES
2505	IMP/MD/2021/000153	1.License Holder Name: POLY MEDICURE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINAL NEEDLE (BULK) (N/A)-SUB-ARACHNOID INJECTION OF LOCAL ANESTHETICS FOR SPINAL ANESTHESIA BEFORE SURGERY, AND IN LUMBAR PUNCTURE FOR PAIN MANAGEMENT, AND DIAGNOSIS ON THE BASIS OF CEREBROSPINAL FLUID.
2506	IMP/MD/2021/000154	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHODONTIC TUBE (STAINLESS STEEL)(ACCENT BUCCAL TUBES ,PEERLESS BUCCAL TUBES)-INTENDED TO BE APPLIED TO A PATIENT'S 1ST AND 2ND MOLARS IN ORDER TO CORRECT MALOCCLUSION.,ORTHODONTIC WIRE (STAINLESS STEEL)(LIGATURE WIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH.

2507	IMP/MD/2021/000155	1.License Holder Name: MICROGENE DIAGNOSTIC SYSTEMS (P) LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (ACCUSURE MT)-THE DIGITAL THERMOMETER MEASURES THE BODY TEMPERATURE OF A PATIENT BY MEANS OF A SENSOR (TRANSDUCER) COUPLED WITH AN ELECTRONIC SIGNAL PROCESSOR AND DIGITAL LCD (DISPLAY) UNIT. THE DEVICE IS REUSABLE AND INTENDED FOR ORAL, RECTAL, OR ARMPIT TEMPERATURE MEASUREMENT FOR HOME OR CLINICAL USE ON PEOPLE AT ALL AGES.,BLOOD PRESSURE MONITOR(ACCUSURE TD)-THE DIGITAL BLOOD PRESSURE MONITOR IS FOR USE BY MEDICAL PROFESSIONALS OR AT HOME IS INTENDED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES AND PULSE RATE OF AN INDIVIDUAL BY USING A NON-INVASIVE TECHNIQUE IN WHICH AN INFLATABLE CUFF IS WRAPPED AROUND THE UPPER ARM.
2508	IMP/MD/2021/000156	1.License Holder Name: M/S SEQUENCE MEDICAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GUIDEWIRES(EAGLE™ PTCA GUIDE WIRE)-THE EAGLE™ PTCA GUIDE WIRES ARE MAINLY USED FOR INSERTION OF DEVICES FOR INTERVENTIONAL DIAGNOSIS AND TREATMENT. FOR USE IN ANGIOGRAPHIC PROCEDURES OR INTERVENTIONAL PROCEDURES TO INTRODUCE AND POSITION CATHETERS AND INTERVENTIONAL DEVICES WITH IN THE CORONARY AND PERIPHERAL VASCULATURE. ,DRUG ELUTING STENTS (AFFINITY™ MINI STRUT™ (AFFINITY™ MS MINI STRUT COBALT CHROMIUM SIROLIMUS-ELUTING CORONARY STENT SYSTEM))-IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER AND MYOCARDIAL BLOOD FLOW,BALLOON DILATATION CATHETER (HAWK™- PTCA BALLOON CATHETER SEMI COMPLIANT (HAWK™- PTCA BALLOON DILATATION CATHETER) • HAWK™- PTCA BALLOON CATHETER NON-COMPLIANT (HAWK™- NC- PTCA BALLOON CATHETER NON-COMPLIANT) • HAWK™- PTCA BALLOON CATHETER CTO (HAWK™- CTO- PTCA BALLOON DILATATION CATHETER))-THE BALLOON DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. OR MALFUNCTIONING NATIVE AND PROSTHETIC AORTIC OR MITRAL VALVES

2509	IMP/MD/2021/000157	1.License Holder Name: HESTER DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CAROTID EMBOLIC PREVENTION STENT SYSTEM(CGUARD)-THE CGUARD EPS IS INDICATED FOR: IMPROVING CAROTID LUMINAL DIAMETER IN PATIENTS AT HIGH RISK FOR ADVERSE EVENTS FROM CAROTID ENDARTERECTOMY WHO REQUIRE CAROTID REVASCULARIZATION AND MEET BOTH CRITERIA OUTLINED BELOW: • PATIENTS WITH NEUROLOGICAL SYMPTOMS AND >50% STENOSIS OF THE COMMON OR INTERNAL CAROTID ARTERY BY EITHER ULTRASOUND OR ANGIOGRAM OR PATIENTS WITHOUT NEUROLOGICAL SYMPTOMS AND > 80% STENOSIS OF THE COMMON OR INTERNAL CAROTID ARTERY BY EITHER ULTRASOUND OR ANGIOGRAM. • PATIENTS HAVING A VESSEL WITH REFERENCE DIAMETERS BETWEEN 4.8 MM AND 9.0 MM AT THE TARGET LESION.
2510	IMP/MD/2021/000159	1.License Holder Name: CURATEQ BIOLOGICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE (STERILE) (BD HYPAK SCF™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKAGING AND ADMINISTRATION OF PARENTERAL DRUGS
2511	IMP/MD/2021/000160	1.License Holder Name: M/S. AVANA MEDICAL DEVICES PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SODIUM HYALURONATE 10MG (1%) IN 1 ML(HYALUR)-THE PRODUCT IS A MEDICAL DEVICE USED IN HUMANS FOR INTRA-ARTICULAR INJECTION IN THE KNEE. THE DEVICE IS INTENDED TO REDUCE THE FUNCTIONAL IMPAIRMENT, TO EASE THE PAIN AND THUS TO IMPROVE QUALITY OF LIFE.

2512	IMP/MD/2021/000165	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PACEMAKER(SPHERA SR MRI SURE SCAN)-THE MEDTRONIC SPHERA MRI SURESCAN IPGS IMPLANTABLE PULSE GENERATOR (IPG) ARE INDICATED FOR USE TO IMPROVE CARDIAC OUTPUT, PREVENT SYMPTOMS, OR PROTECT AGAINST ARRHYTHMIAS RELATED TO CARDIAC IMPULSE FORMATION OR CONDUCTION DISORDERS. THIS DEVICE IS INDICATED FOR USE IN PATIENTS WHO ARE EXPERIENCING EXERCISE INTOLERANCE OR EXERCISE RESTRICTIONS RELATED TO AN ARRHYTHMIA. USING RATE RESPONSE MODES MAY RESTORE HEART RATE VARIABILITY AND IMPROVE CARDIAC OUTPUT.,PACEMAKER (ATTESTA™ SR MRI SURESCAN™)-THE MEDTRONIC ATTESTA MRI SURESCAN IMPLANTABLE PULSE GENERATORS (IPGS) ARE INDICATED FOR USE TO IMPROVE CARDIAC OUTPUT, PREVENT SYMPTOMS, OR PROTECT AGAINST ARRHYTHMIAS RELATED TO CARDIAC IMPULSE FORMATION OR CONDUCTION DISORDERS. THE DEVICES AREINDICATED FOR USE IN PATIENTS WHO ARE EXPERIENCING EXERCISE INTOLERANCE OR EXERCISE RESTRICTIONS RELATED TO AN ARRHYTHMIA. USING RATE RESPONSE MODES MAY RESTORE HEART RATE VARIABILITY AND IMPROVE CARDIAC OUTPUT. THIS IS INDICATED FOR SINGLE USE ONLY.,PACEMAKER(ATTESTA™ L DR MRI SURESCAN™)-THE MEDTRONIC ATTESTA MRI SURESCAN IMPLANTABLE PULSE GENERATORS (IPGS) ARE INDICATED FOR USE TO IMPROVE CARDIAC OUTPUT, PREVENT SYMPTOMS, OR PROTECT AGAINST ARRHYTHMIAS RELATED TO CARDIAC IMPULSE FORMATION OR CONDUCTION DISORDERS. THE DEVICES AREINDICATED FOR USE IN PATIENTS WHO ARE EXPERIENCING EXERCISE INTOLERANCE OR EXERCISE RESTRICTIONS RELATED TO AN ARRHYTHMIA. USING RATE RESPONSE MODES MAY RESTORE HEART RATE VARIABILITY AND IMPROVE CARDIAC OUTPUT.,PACEMAKER(SPHERA L DR MRI SURE SCAN)-THE MEDTRONIC SPHERA MRI SURESCAN IPGS IMPLANTABLE PULSE GENERATOR (IPG) ARE INDICATED FOR USE TO IMPROVE CARDIAC OUTPUT, PREVENT SYMPTOMS, OR PROTECT AGAINST ARRHYTHMIAS RELATED TO CARDIAC IMPULSE FORMATION OR CONDUCTION DISORDERS. THIS DEVICE IS INDICATED FOR USE IN PATIENTS WHO ARE EXPERIENCING EXERCISE INTOLERANCE OR EXERCISE RESTRICTIONS RELATED TO AN ARRHYTHMIA. USING RATE RESPONSE MODES MAY RESTORE HEART RATE VARIABILITY AND IMPROVE CARDIAC OUTPUT.

2513	IMP/MD/2021/000168	1.License Holder Name: DEVYOG IMPEX PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:WOUND DRESSING (EPICITE HYDRO)-EPICITE HYDRO IS INTENDED FOR THE MANAGEMENT OF ACUTE, SURGICAL AND CHRONIC WOUNDS AS WELL AS BURN WOUNDS TO ABSORB EXCESS WOUND EXUDATE AND THUS KEEPS THE MOIST ENVIRONMENT OF THE WOUND IN BALANCE.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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2514	IMP/MD/2021/000169	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SCREW IMPLANTS FOR PLATES- SCREW (NON STERILE)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., CABLE IMPLANTS- CERCLAGEFIX INSERT (TITANIUM ALLOY)-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE.,FEMORAL NECK SYSTEM (FNS) - IMPLANTS- PLATE (TITANIUM ALLOY)- STERILE-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,HEADLESS COMPRESSION SCREW IMPLANTS- TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., ELASTIC NAILING IMPLANTS- END CAP (TITANIUM ALLOY)- INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,DYNAMIC HIP PLATING IMPLANTS- PLATE (TITANIUM ALLOY)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., SCREW IMPLANTS FOR OR WITHOUT PLATES- SCREW (STAINLESS STEEL)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DISTAL FEMUR PLATES- TITANIUM ALLOY (NON STERILE)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., CANNULATED SCREW IMPLANTS- SCREW (SS)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., ELASTIC NAILING IMPLANTS- END CAP (SS)- NON STERILE- "INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN

	NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",SCREWS FOR INTRAMEDULLARY NAIL-BOLT (SS)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,HUMERAL NAILING IMPLANTS-SCREW-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,LOCKING COMPRESSION PLATES- TITANIUM ALLOY (NON STERILE)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., DYNAMIC HIP PLATING IMPLANTS-BLADE (STERILE)- TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,PROXIMAL TIBIAL PLATES-TITANIUM ALLOY (NS)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,FOOT PLATES- TITANIUM ALLOY (NON STERILE)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,COMPACT MIDFACE-PLATE (TITANIUM ALLOY)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., DYNAMIC COMPRESSION PLATES- STAINLESS STEEL (NON STERILE)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,ANGLED BLADE PLATES- (SS)- NON STERILE-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,LOCKING COMPRESSION PLATES- SS (NON STERILE)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DYNAMIC HIP PLATING IMPLANTS- PLATE (SS)-PLATE AND SCREW IMPLANTS ARE INTENDED

	FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,ELASTIC NAILING IMPLANTS- END CAP (STERILE)- SS-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",SCREW IMPLANTS FOR PLATES- SCREW (STAINLESS STEEL)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., SCREW IMPLANTS FOR PLATES- SCREW (TITANIUM ALLOY)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,CABLE IMPLANTS- CERCLAGEFIX INSERT (SS) - NON STERILE-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE., CANNULATED SCREW IMPLANTS- SCREW (TITANIUM ALLOY)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,COMPACT MANDIBLE- PLATE (TITANIUM ALLOY)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,FEMORAL NECK SYSTEM (FNS) - IMPLANTS-KIT (STERILE)- TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., DYNAMIC HIP PLATING IMPLANTS- SCREW (TITANIUM ALLOY)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,MINI FRAGMENT PLATES- SS-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,PEDIATRIC PLATES- SS-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., TOMOFIX IMPLANTS- PLATE (NON STERILE)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., DYNAMIC COMPRESSION PLATES- TITANIUM ALLOY (NON STERILE)- PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY

	FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,LOCKING ATTACHMENT PLATES- SCREW (TITANIUM ALLOY)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,TOMOFIX IMPLANTS-PLATES (TITANIUM ALLOY)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., DYNAMIC HIP PLATING IMPLANTS- SCREW (SS)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., ANGLED BLADE PLATES- BLADE (STAINLESS STEEL)- NON STERILE-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,FEMORAL NECK SYSTEM (FNS) - IMPLANTS-SCREW (TITANIUM ALLOY)- STERILE-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., SCREW IMPLANTS FOR OR WITHOUT PLATES-SCREW (TITANIUM ALLOY)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,DYNAMIC HIP PLATING IMPLANTS- LOCKING DEVICE (TITANIUM ALLOY)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., FEMORAL NECK SYSTEM (FNS) - IMPLANTS-BOLT (STERILE)-TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,ELASTIC NAILING IMPLANTS-END CAP (STERILE)- TITANIUM ALLOY-"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",DYNAMIC HIP PLATING IMPLANTS- LOCKING DEVICE (SS)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., CABLE IMPLANTS- CERCLAGEFIX INSERT (SS)- STERILE-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE.,RADIUS PLATES-

		TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.
2515	IMP/MD/2021/000170	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PRISMAFLEX (PRISMAFLEX)-THE PRISMAFLEX CONTROL UNIT IS INTENDED FOR: 1. CONTINUOUS RENAL REPLACEMENT THERAPY FOR PATIENTS WITH ACUTE RENAL FAILURE AND/OR FLUID OVERLOAD. 2. THERAPEUTIC PLASMA EXCHANGE THERAPY FOR PATIENTS WITH DISEASES WHERE REMOVAL OF PLASMA COMPONENTS IS INDICATED. 3. HEMOPERFUSION FOR PATIENTS WITH CONDITIONS WHERE IMMEDIATE REMOVAL OF SUBSTANCES BY ADSORPTION IS INDICATED. 4. HEMOPURIFICATION FOR PATIENTS WITH CONDITIONS WHERE EXTRACORPOREAL ELIMINATION OF CARBON DIOXIDE IS INDICATED. ALL TREATMENTS ADMINISTERED VIA THE PRISMAFLEX CONTROL UNIT MUST BE PRESCRIBED BY A PHYSICIAN.,AK 98(AK 98) -THE AK 98 DIALYSIS MACHINE IS INTENDED FOR USE AS A SINGLE PATIENT MACHINE TO PERFORM HAEMODIALYSIS TREATMENTS OF PATIENTS WITH RENAL FAILURE OR FLUID OVERLOAD UPON PRESCRIPTION BY A PHYSICIAN. PATIENT COUNSELLING AND TEACHING OF TREATMENT TECHNIQUES ARE DIRECTLY UNDER THE SUPERVISION AND DISCRETION OF THE PHYSICIAN. THE AK 98 DIALYSIS MACHINE IS INTENDED FOR THE IN-CENTER ENVIRONMENT AND CARE IN A HOME HEALTHCARE ENVIRONMENT.
2516	IMP/MD/2021/000171	1.License Holder Name: KOB MEDICAL TEXTILES PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COHESIVE ELASTIC SUPPORT BANDAGE(NOWOPRESS LF-T 752)-MAIN USES FOR THIS PRODUCT ARE NON-SLIPPING FIXATION, SUPPORT AND RELIEF DRESSINGS OF ALL TYPES, ESPECIALLY ON JOINTS. NOWOPRESS LF-T IS ALSO WELL SUITED AS COMPRESSION BANDAGE. IT CAN BE USED UNIVERSALLY FOR SPORTS INJURIES AND IS IDEALLY SUITED FOR APPLICATIONS COMBINED WITH TAPING. THE BANDAGE IS TO BE USED ON INTACT SKIN

2517	IMP/MD/2021/000172	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SUTURELESS PACING LEAD(MYOPORE BIPOLAR)-IT IS INDICATED FOR USE WHEN VENTRICULAR EPICARDIAL ATTACHMENT IS REQUIRED, OR WHEN A TRANSVENOUS LEAD CANNOT PROVIDE EFFECTIVE PACING. THIS TYPE OF LEAD IS USEFUL IN SITUATIONS WHERE IT IS REQUIRED THAT THE POTENTIAL FOR LEAD DISLODGEMENT BE DIMINISHED, OR THAT PACING AND/OR SENSING WILL BE ESTABLISHED SUBSEQUENT TO OPEN HEART SURGERY.
2518	IMP/MD/2021/000173	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INTRA-AORTIC BALLOON CATHETER KIT 3(ARROW®)-THE ARROW® IAB IS UTILIZED FOR INTRA-AORTIC BALLOON COUNTERPULSATION THERAPY IN THE AORTA, WHEREBY BALLOON INFLATION, DURING DIASTOLE AND DEFLATION, DURING SYSTOLE INCREASES BLOOD SUPPLY TO THE HEART MUSCLE AND DECREASES WORK OF THE LEFT VENTRICLE., INTRA-AORTIC BALLOON CATHETER KIT 1(ARROW®)-THE ARROW® IAB IS UTILIZED FOR INTRA-AORTIC BALLOON COUNTERPULSATION THERAPY IN THE AORTA, WHEREBY BALLOON INFLATION, DURING DIASTOLE AND DEFLATION, DURING SYSTOLE INCREASES BLOOD SUPPLY TO THE HEART MUSCLE AND DECREASES WORK OF THE LEFT VENTRICLE.,INTRA-AORTIC BALLOON CATHETER KIT 2(ARROW®)-THE ARROW® IAB IS UTILIZED FOR INTRA-AORTIC BALLOON COUNTERPULSATION THERAPY IN THE AORTA, WHEREBY BALLOON INFLATION, DURING DIASTOLE AND DEFLATION, DURING SYSTOLE INCREASES BLOOD SUPPLY TO THE HEART MUSCLE AND DECREASES WORK OF THE LEFT VENTRICLE.

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2519	IMP/MD/2021/000176	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LEADS(SPRINT QUATTRO™)-THE LEAD IS INTENDED FOR SINGLE, LONG-TERM USE IN THE RIGHT VENTRICLE. THIS LEAD HAS APPLICATION FOR PATIENTS FOR WHOM IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS) ARE INDICATED,PIN PLUG(PIN PLUG)-THE MEDTRONIC PIN PLUG IS A SILICONE PIN PLUG DESIGNED TO SEAL THE UNUSED PORT [MODEL 6725 FOR IS-1 POST AND 6719 FOR DF-1 PORT] OF A MEDTRONIC DEVICE.,LEAD END CAP KIT(LEAD END CAP KIT)-THE 5867-3M LEAD END CAP KIT CONSISTS OF THREE TYPES OF LEAD END CAPS—ONE INTENDED TO SEAL OFF LEADS WITH MEDTRONIC UNIPOLAR CONNECTORS 5 MM (0.2 IN) OR BIPOLAR CONNECTORS 5 MM (0.2 IN) BIFURCATED, ONE INTENDED TO SEAL OFF LEADS WITH UNIPOLAR CONNECTORS (IS-11 UNI) OR BIPOLAR CONNECTORS (IS-1 BI), AND ONE INTENDED TO SEAL OFF LEADS WITH MEDTRONIC BIPOLAR CONNECTORS (3.2 MM LOW PROFILE) OR SEVERED LEAD BODIES WITH AN OUTER DIAMETER OF 1.5 TO 2.8 MM (4.6 TO 8.4 FR).,LEAD END CAP(LEAD END CAP)-THE 6701 LEAD END CAP IS A 6.5 MM (0.26 IN) SILICONE RUBBER CAP DESIGNED TO COVER THE CONNECTOR PIN OF IMPLANTABLE CARDIOVERSION/DEFIBRILLATION LEAD SYSTEMS WITH CONNECTORS FROM 6.1 TO 6.5 MM (0.24 TO 0.26 IN) IN DIAMETER. IT IS USED TO INSULATE THE CONNECTOR PINS OF LEADS THAT HAVE BEEN IMPLANTED BUT NOT CONNECTED TO AN IMPLANTABLE ARRHYTHMIA MANAGEMENT DEVICE (I.E. PROPHYLACTIC PLACEMENT) OR TO SEAL OFF LEADS THAT ARE TO BE ABANDONED. THE CAP IS INTENDED TO PREVENT CURRENT FLOW THROUGH THE LEAD AND TO PROTECT SURROUNDING TISSUE FROM BEING DAMAGED BY THE EXPOSED CONNECTOR PIN.
2520	IMP/MD/2021/000177	1.License Holder Name: MOREPEN LABORATORIES LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITOR(DR.MOREPEN BPONE)-MEASUREMENT OF BLOOD PRESSURE

2521	IMP/MD/2021/000185	1.License Holder Name: CARDIOMED INDIA LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL DRESSING (PHARMAPORE &PROTECT FILM)-PHARMAPORE STERILE IS IDEALLY SUITED FOR POSTOPERATIVE USE. IN CASE OF EMERGENCY IT CAN BE USED FOR CUTS, LACERATIONS AND SUTURED WOUNDS, HYDROCOLLOID WOUND DRESSING(PHARMACOLL)-SUITABLE FOR MOIST WOUND CARE USED TO TRAET LIGHT TO MODERATELY EXUDATING WOUNDS,SECOND DEGREE BURNS,LEG ULCERS, PRESSURE ULCERS,CHRONIC SLOW HEALING WOUNDS AND ABRASIONS.USED FOR BLISTERS TREATMENT,DRESSING MATERIAL (EPSUMA)-ESPUMA® GENTLE FAMILY ARE SUITABLE FOR DRESSING MANY TYPES OF ODOURLESS AND MALODOROUS FROM LOW TO HIGHLY EXUDING WOUNDS INCLUDING LEG AND PRESSURE ULCERS, DIABETIC ULCERS, FIRST AND SECOND DEGREE BURNS, SURGICAL INCISIONS AND TRAUMATIC WOUNDS RESULTING IN SKIN LOSS, ALSO MAY BE USED UNDER COMPRESSION BANDAGING

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2522	IMP/MD/2021/000186	1.License Holder Name: PHILIPS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMPUTED TOMOGRAPHY EQUIPMENT(INCISIVE CT)-THE INCISIVE CT IS A COMPUTED TOMOGRAPHY X-RAY SYSTEM INTENDED TO PRODUCE IMAGES OF THE HEAD AND BODY BY COMPUTER RECONSTRUCTION OF XRAY TRANSMISSION DATA TAKEN AT DIFFERENT ANGLES AND PLANES. THESE DEVICES MAY INCLUDE SIGNAL ANALYSIS AND DISPLAY EQUIPMENT, PATIENT AND EQUIPMENT SUPPORTS, COMPONENTS AND ACCESSORIES. THE INCISIVE CT IS INDICATED FOR HEAD, WHOLE BODY, CARDIAC AND VASCULAR X-RAY COMPUTED TOMOGRAPHY APPLICATIONS IN PATIENTS OF ALL AGES. THESE SCANNERS ARE INTENDED TO BE USED FOR DIAGNOSTIC IMAGING AND FOR LOW DOSE CT LUNG CANCER SCREENING FOR THE EARLY DETECTION OF LUNG NODULES THAT MAY REPRESENT CANCER. THE SCREENING MUST BE PERFORMED WITHIN THE ESTABLISHED INCLUSION CRITERIA OF PROGRAMS / PROTOCOLS THAT HAVE BEEN APPROVED AND PUBLISHED BY EITHER A GOVERNMENTAL BODY OR PROFESSIONAL MEDICAL SOCIETY. *PLEASE REFER TO CLINICAL LITERATURE, INCLUDING THE RESULTS OF THE NATIONAL LUNG SCREENING TRIAL (N ENGI J MED 2011; 365: 395-409) AND SUBSEQUENT LITERATURE, FOR FURTHER INFORMATION.,MAGNETIC RESONANCE EQUIPMENT(PRODIVA)-THIS SYSTEM IS A MAGNETIC RESONANCE MEDICAL ELECTRICAL SYSTEMS INDICATED FOR USE AS A DIAGNOSTIC DEVICE. THE SYSTEM CAN PRODUCE CROSS-SECTIONAL IMAGES, SPECTROSCOPIC IMAGES, AND/OR SPECTRA IN ANY ORIENTATION OF THE INTERNAL STRUCTURE OF THE HEAD, BODY OR EXTREMITIES. MAGNETIC RESONANCE IMAGES REPRESENT THE SPATIAL DISTRIBUTION OF PROTONS OR OTHER NUCLEI WITH SPIN. IMAGE APPEARANCE IS DETERMINED BY MANY DIFFERENT PHYSICAL PROPERTIES OF THE TISSUE AND THE ANATOMY, AND THE MR SCAN TECHNIQUE APPLIED. THE IMAGE ACQUISITION PROCESS CAN BE SYNCHRONIZED WITH THE PATIENTS BREATHING OR CARDIAC CYCLE. THE SYSTEMS CAN USE COMBINATIONS OF IMAGES TO PRODUCE PHYSICAL PARAMETERS, AND RELATED DERIVED IMAGES. IMAGES, SPECTRA, AND MEASUREMENTS OF PHYSICAL PARAMETERS, WHEN INTERPRETED BY A TRAINED PHYSICIAN, PROVIDE INFORMATION THAT MAY ASSIST THE DIAGNOSIS AND THERAPY PLANNING. THE ACCURACY OF DETERMINED PHYSICAL PARAMETERS DEPENDS ON SYSTEM AND SCAN PARAMETERS, AND MUST BE CONTROLLED AND VALIDATED BY THE CLINICAL USER. THE USE OF CONTRAST AGENTS FOR DIAGNOSTIC IMAGING APPLICATIONS SHOULD BE PERFORMED CONSISTENT WITH THE APPROVED LABELING FOR THE CONTRAST

	AGENT. IN ADDITION THE PHILIPS MR SYSTEMS PROVIDE IMAGING CAPABILITIES, SUCH AS MR FLUOROSCOPY, TO GUIDE AND EVALUATE INTERVENTIONAL AND MINIMALLY INVASIVE PROCEDURES IN THE HEAD, BODY AND EXTREMITIES. MR INTERVENTIONAL PROCEDURES, PERFORMED INSIDE OR ADJACENT TO THE PHILIPS MR SYSTEM, MUST BE PERFORMED WITH MR CONDITIONAL OR MR SAFE INSTRUMENTATION AS SELECTED AND EVALUATED BY THE CLINICAL USER FOR USE WITH THE SPECIFIC MR SYSTEM CONFIGURATION IN THE HOSPITAL. THE APPROPRIATENESS AND USE OF INFORMATION FROM A PHILIPS MR SYSTEM FOR A SPECIFIC INTERVENTIONAL PROCEDURE AND SPECIFIC MR SYSTEM CONFIGURATION MUST BE VALIDATED BY THE CLINICAL USER., DIAGNOSTIC X-RAY SYSTEM(DIGITALDIAGNOST C50)-THE DIGITALDIAGNOST C50 SYSTEM IS INTENDED FOR USE IN GENERATING RADIOGRAPHIC IMAGES OF HUMAN ANATOMY BY QUALIFIED/TRAINED DOCTOR OR TECHNICIAN. APPLICATIONS CAN BE PERFORMED WITH THE PATIENT SITTING, STANDING, OR LYING IN THE PRONE OR SUPINE POSITION. THIS DEVICE IS NOT INTENDED FOR MAMMOGRAPHIC APPLICATIONS. ALL STANDARD RADIOGRAPHY PROCEDURES (DR) MUST BE POSSIBLE: • X-RAY EXAMINATIONS OF THE SKELETON INCLUDING UPPER EXTREMITIES, LOWER EXTREMITIES, SPINE, PELVIS, SKULL, RIBS, ETC. (E.G. ELBOW LAT, SHOULDER AXIAL ETC.) • X-RAY EXAMINATIONS OF THE THORAX. (E. G. CHEST PA ETC.) • X-RAY OF SOFT TISSUES (E.G. ABDOMEN) BUT EXCLUDING MAMMOGRAPHY. SPECIAL EXAMINATIONS LIKE TOMOGRAPHY DO NOT BELONG TO THIS DIGITALDIAGNOST C50 SYSTEM. THIS IS NOT THE MAIN FOCUS OF EXAMINATION WORKFLOW.,COMPUTED TOMOGRAPHY EQUIPMENT(ACCESS CT)-THE ACCESS CT SCANNER SYSTEM CAN BE USED AS A WHOLE BODY (EXCEPT CARDIAC) COMPUTED TOMOGRAPHY X-RAY SYSTEM FEATURING A CONTINUOUSLY ROTATING X-RAY TUBE AND DETECTOR ARRAY WITH MULTISLICE CAPABILITY UP TO 6/16 SLICES SIMULTANEOUSLY. THE ACQUIRED X-RAY TRANSMISSION DATA IS RECONSTRUCTED BY COMPUTER INTO CROSS-SECTIONAL IMAGES OF THE BODY FROM THE SAME AXIAL PLANE TAKEN AT DIFFERENT ANGLES. THE SYSTEM IS SUITABLE FOR ALL PATIENTS.,DIAGNOSTIC X-RAY SYSTEM(DURADIAGNOST)-THE DURADIAGNOST SYSTEM IS INTENDED FOR USE IN GENERATING RADIOGRAPHIC IMAGES OF HUMAN ANATOMY BY QUALIFIED/TRAINED DOCTOR OR TECHNICIAN. APPLICATIONS CAN BE PERFORMED WITH THE PATIENT SITTING, STANDING, OR LYING IN THE PRONE OR SUPINE POSITION. THIS DEVICE IS NOT INTENDED FOR MAMMOGRAPHIC APPLICATIONS. ALL STANDARD RADIOGRAPHY PROCEDURES (DR) MUST BE POSSIBLE: • X-RAY EXAMINATIONS OF THE SKELETON INCLUDING UPPER

		EXTREMITIES, LOWER EXTREMITIES, SPINE, PELVIS, SKULL, RIBS, ETC. (EG. ELBOW LAT, SHOULDER AXIAL ETC.) • X-RAY EXAMINATIONS OF THE THORAX. (E.G. CHEST PA ETC.) • X-RAY OF SOFT TISSUES (E.G. ABDOMEN) BUT EXCLUDING MAMMOGRAPHY. SPECIAL EXAMINATIONS LIKE TOMOGRAPHY DO NOT BELONG TO THIS DURADIAGNOST F30 SYSTEM. THIS IS NOT THE MAIN FOCUS OF EXAMINATION WORKFLOW.,DIAGNOSTIC X-RAY SYSTEM (DURADIAGNOST F30)-THE DURADIAGNOST F30 SYSTEM IS INTENDED FOR USE IN GENERATING RADIOGRAPHIC IMAGES OF HUMAN ANATOMY BY QUALIFIED/TRAINED DOCTOR OR TECHNICIAN. APPLICATIONS CAN BE PERFORMED WITH THE PATIENT SITTING, STANDING, OR LYING IN THE PRONE OR SUPINE POSITION. THIS DEVICE IS NOT INTENDED FOR MAMMOGRAPHIC APPLICATIONS. ALL STANDARD RADIOGRAPHY PROCEDURES (DR) MUST BE POSSIBLE: • X-RAY EXAMINATIONS OF THE SKELETON INCLUDING UPPER EXTREMITIES, LOWER EXTREMITIES, SPINE, PELVIS, SKULL, RIBS, ETC. (EG. ELBOW LAT, SHOULDER AXIAL ETC.) • X-RAY EXAMINATIONS OF THE THORAX. (E.G. CHEST PA ETC.) • X-RAY OF SOFT TISSUES (E.G. ABDOMEN) BUT EXCLUDING MAMMOGRAPHY. SPECIAL EXAMINATIONS LIKE TOMOGRAPHY DO NOT BELONG TO THIS DURADIAGNOST F30 SYSTEM. THIS IS NOT THE MAIN FOCUS OF EXAMINATION WORKFLOW.
2523	IMP/MD/2021/000194	1.License Holder Name: BRYOGEN PHARMACEUTICAL PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DEVICE CONTAINING PARTS OF COLLOIDAL SILVER AND HYALURONIC ACID SODIC SALT (FARMACTIVE SILVER SPRAY)-TEMPORARY AND SKIN LEVEL TREATING OF NOT INFECTED SKIN WOUNDS, AND IRRITATIONS DUE TO INCONTINENCE OR A DIAPER

2524	IMP/MD/2021/000195	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TROCARS-TROCARS ARE INTENDED FOR PUNCTURING A BODILY ENTRY POINT AND/OR FOR PARTITION OF SURROUNDING SOFT TISSUE,USS-POSTERIOR CONNECTORS ARE INTENDED TO FACILITATE THE CONNECTION OF QUALIFIED POSTERIOR SPINAL STABILIZATION SYSTEMS TOGETHER. NOTE: FOR USE OF THE POSTERIOR CONNECTORS IN CONJUNCTION WITH THE QUALIFIED POSTERIOR SPINAL STABILIZATION SYSTEMS- PLEASE REFER TO THE CORRESPONDING SYSTEM'S DIRECTIONS FOR SPECIFIC INFORMATION ON ITS COMPATIBILITY- USE- PRECAUTIONS- WARNINGS AND SIDE EFFECTS.,TRANSFORAMINAL POSTERIOR ATRAUMATIC LUMBAR (T-PAL) CAGES-THE T-PAL IMPLANT IS INTENDED TO REPLACE LUMBAR INTERVERTEBRAL DISCS AND TO FUSE THE ADJACENT VERTEBRAL BODIES TOGETHER AT VERTEBRAL LEVELS L1–S1. THE T-PAL IMPLANT IS DESIGNED FOR A TRANSFORAMINAL APPROACH.,POSTERIOR RODS-POSTERIOR RODS ARE INTENDED TO FACILITATE THE CONNECTION OF QUALIFIED SPINAL STABILIZATION SYSTEMS TOGETHER. CERVIFIX IS A MODULAR TENSION BAND SYSTEM FOR POSTERIOR FIXATION OF THE OCCIPITOCERVICAL SPINE, UPPER AND LOWER CERVICAL SPINE, AND UPPER THORACIC SPINE (T2). A CHOICE OF CLAMPS ARE FIXED ON A ROD BY MEANS OF SET SCREWS. BONE SCREWS CAN BE OPTIMALLY POSITIONED THROUGH THE CLAMPS IN THE DESIRED DIRECTION AT EACH LEVEL. THE AXON SYSTEM IS A COMPREHENSIVE SET OF INSTRUMENTS AND IMPLANTS, INCLUDING –TOP-LOADING VARIABLE AXIS SCREWS, –HOOKS, –TRANSVERSE BARS AND –RODS. IT IS DESIGNED FOR POSTERIOR STABILISATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY. THE AXON SYSTEM USES THE EXISTING CERVIFIX RODS, ALLOWING COMPONENTS FROM AXON AND CERVIFIX TO BE COMBINED. THIS ALLOWS A CONSTRUCT TO EXTEND FROM THE OCCIPUT TO THE LOWER SPINE USING THE UNIVERSAL SPINE SYSTEM (USS). THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: – TOP-LOADING VARIABLE AXIS SCREWS – HOOKS – TRANSVERSE BARS – RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY.,SYNFIX EVOLUTION- SPACER- SYNFIX® EVOLUTION SECURED SPACER SYSTEM IS AN IMPLANT AND INSTRUMENT SYSTEM FOR STAND-ALONE ANTERIOR LUMBAR INTERBODY FUSION (ALIF) FOR SKELETALLY MATURE PATIENTS. IT IS

		INTENDED TO REPLACE LUMBAR INTERBODY DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES AT VERTEBRAL LEVELS L1-S1 FOLLOWING ANTERIOR LUMBAR DISCECTOMY FOR STABILIZATION OF THE LUMBAR SPINE.,POSTERIOR CONNECTORS-THE PANGEA SPINE SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE PANGEA PERFORATED SCREWS ARE AN ADDITION TO THE PANGEA SPINE SYSTEM- A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1-S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. PANGEA PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID PANGEA SCREWS AND WITH K-WIRE GUIDANCE AS PANGEA CANNULATED SCREWS INCLUDING A MINIMALLY INVASIVE APPROACH WITH SPIRIT. PANGEA PERFORATED SCREWS DIRECT VERTECEM OR V+ THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE- ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY.,CABLE IMPLANTS-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE.,CABLE IMPLANTS-COIL WITH CERCLAGE WIRE-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE.
2525	IMP/MD/2021/000196	1.License Holder Name: OLYMPUS MEDICAL SYSTEMS INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:GENERATORS-THE ELECTROSURGICAL GENERATOR, IN CONJUNCTION WITH ELECTROSURGICAL ACCESSORIES AND ANCILLARY EQUIPMENT, IS INTENDED FOR CUTTING AND COAGULATION OF TISSUE IN THE FOLLOWING MEDICAL FIELDS: -OPEN SURGERY -LAPAROSCOPIC SURGERY -ENDOSCOPIC SURGERY

2526	IMP/MD/2021/000197	1.License Holder Name: NIHON KOHDEN INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DEFIBRILLATOR (CARDIOLIFE DEFIBRILLATOR)-THE DEFIBRILLATORS DELIVER SHORT-DURATION HIGH-CURRENT ELECTRICAL SHOCK TO PATIENTS TO TREAT VENTRICULAR FIBRILLATION AND VENTRICULAR TACHYCARDIA.
2527	IMP/MD/2021/000200	1.License Holder Name: SD BIOSENSOR HEALTHCARE PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITORING DEVICE(STANDARD BP CARE PLUS)-IT IS AN AUTOMATIC MEASURING DEVICE TO BE USED ON THE UPPER ARM. IT ENABLE SIMPLE, ACCURATE AND FAST MEASUREMENT OF BLOOD PRESSURE AND PULSE RATE BY USE OF THE OSCILLOMETRIC METHOD AND PEOPLE-ORIENTATED DESIGN.,DIGITAL THERMOMETER (STANDARD DIGITAL THERMOMETER)-PLACE THE PROBE WELL UNDER THE PATIENT'S TONGUE, INSTRUCT THE PATIENT TO KEEP THEIR MOUTH CLOSED WHILE THE THERMOMETER IS READING. A NORMAL TEMPERATURE BY THIS METHOD IS USUALLY CONSIDERED BETWEEN 96.8 TO 99.5,BLOOD PRESSURE MONITORING DEVICE (STANDARD BP CARE COMFORT)-IT IS AN AUTOMATIC MEASURING DEVICE TO BE USED ONLY ON THE WRIST. IT ENABLE SIMPLE, ACCURATE AND FAST MEASUREMENT OF BLOOD PRESSURE AND PULSE RATE BY USE OF THE OSCILLOMETRIC METHOD AND PEOPLE-ORIENTED DESIGN.,BLOOD PRESSURE MONITORING DEVICE (STANDARD BP CARE)-IT IS AN AUTOMATIC MEASURING DEVICE TO BE USED ON THE UPPER ARM. IT ENABLE SIMPLE, ACCURATE AND FAST MEASUREMENT OF BLOOD PRESSURE AND PULSE RATE BY USE OF OSCILLOMETRIC METHOD AND PEOPLE-ORIENTED DESIGN.

2528	IMP/MD/2021/000201	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CARDIAC RESYNCHRONIZATION THERAPY-PACEMAKER(QUADRA ALLURE MP RF)-IMPLANTATION OF A SINGLE CHAMBER PULSE GENERATOR, DUAL CHAMBER PULSE GENERATOR, OR CRTP (CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER) IS INDICATED IN ONE OR MORE OF THE FOLLOWING PERMANENT CONDITIONS OR ANY COMBINATION OF THESE SYMPTOMS:SYNCOPE PRESYNCOPE FATIGUE DISORIENTATION DUE TO ARRHYTHMIA OR BRADYCARDIA IMPLANTATION OF A CRTP IS INDICATED FOR PATIENTS WHO: WOULD BENEFIT FROM RESYNCHRONIZATION OF THE RIGHT AND LEFT VENTRICLES. HAVE ONE OR MORE CONVENTIONAL INDICATIONS FOR THE IMPLANTATION OF A PACEMAKER. MR CONDITIONAL PULSE GENERATOR IS CONDITIONALLY SAFE FOR USE IN THE MRI ENVIRONMENT WHEN USED IN A COMPLETE MR CONDITIONAL PACING SYSTEM AND ACCORDING TO THE INSTRUCTIONS IN THE MRIREADY SYSTEM MANUAL FOR THE ST. JUDE MEDICAL™ MR CONDITIONAL PACING SYSTEM. RATEMODULATED PACING IS INDICATED FOR PATIENTS WITH CHRONOTROPIC INCOMPETENCE, AND FOR THOSE WHO WOULD BENEFIT FROM INCREASED STIMULATION RATES CONCURRENT WITH PHYSICAL ACTIVITY. DUALCHAMBER PACING (DUALCHAMBER PULSE GENERATORS, CRTPS) IS INDICATED FOR THOSE PATIENTS EXHIBITING: SICK SINUS SYNDROME CHRONIC, SYMPTOMATIC SECONDAND THIRDDEGREE AV BLOCK RECURRENT ADAMS STOKES SYNDROME SYMPTOMATIC BILATERAL BUNDLE BRANCH BLOCK WHEN TACHYARRHYTHMIA AND OTHER CAUSES HAVE BEEN RULED OUT ATRIAL PACING IS INDICATED FOR PATIENTS WITH SINUS NODE DYSFUNCTION AND NORMAL AV AND INTRAVENTRICULAR CONDUCTION SYSTEMS. VENTRICULAR PACING IS INDICATED FOR PATIENTS WITH SIGNIFICANT BRADYCARDIA AND: NORMAL SINUS RHYTHM WITH ONLY RARE EPISODES OF AV BLOCK OR SINUS ARREST CHRONIC ATRIAL FIBRILLATION (AF) SEVERE PHYSICAL DISABILITY AF SUPPRESSION™ PACING (DUALCHAMBER PULSE GENERATORS, CRTPS) IS INDICATED FOR SUPPRESSION OF PAROXYSMAL OR PERSISTENT ATRIAL FIBRILLATION EPISODES IN PATIENTS WITH ONE OR MORE OF THE ABOVE PACING INDICATIONS. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF. FOR SPECIFIC INDICATIONS ASSOCIATED WITH INDIVIDUAL MODES, REFER TO THE

	PROGRAMMER'S ONSCREEN HELP.,CARDIAC RESYNCHRONIZATION THERAPY- CARDIOVERTER/DEFIBRILLATOR(QUADRA ASSURA MP)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRTDS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,CARDIAC RESYNCHRONIZATION THERAPY- CARDIOVERTER/DEFIBRILLATOR(UNIFY)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. • AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,INSERTABLE CARDIAC MONITOR (CONFIRM RX)-THE CONFIRM RX™ ICM IS INDICATED FOR THE MONITORING AND DIAGNOSTIC EVALUATION OF PATIENTS WHO EXPERIENCE UNEXPLAINED SYMPTOMS SUCH AS: DIZZINESS, PALPITATIONS, CHEST PAIN, SYNCOPE, AND SHORTNESS OF BREATH, AS WELL AS PATIENTS WHO ARE AT RISK FOR OTHER CARDIAC ARRHYTHMIAS. IT IS ALSO INDICATED FOR PATIENTS WHO HAVE BEEN PREVIOUSLY DIAGNOSED WITH ATRIAL FIBRILLATION OR WHO ARE SUSCEPTIBLE TO DEVELOPING ATRIAL FIBRILLATION.,CARDIAC RESYNCHRONIZATION THERAPY- CARDIOVERTER/DEFIBRILLATOR (UNIFY)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. • AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS

	WITHOUT PRIOR HISTORY OF AF.,CARDIAC RESYNCHRONIZATION THERAPY- CARDIOVERTER/DEFIBRILLATOR(QUADRA ASSURA)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRTDS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,PULSE GENERATOR(ASSURITY MRI) -IMPLANTATION OF A SINGLE-CHAMBER PULSE GENERATOR, DUAL-CHAMBER PULSE GENERATOR, OR CRT-P (CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER) IS INDICATED IN ONE OR MORE OF THE FOLLOWING PERMANENT CONDITIONS OR ANY COMBINATIONS OF THESE SYMPTOMS: • SYNCOPE • PRESYNCOPE • FATIGUE • DISORIENTATION DUE TO ARRHYTHMIA OR BRADYCARDIA. IMPLANTATION OF A CRT-P IS INDICATED FOR PATIENTS WHO: • WOULD BENEFIT FROM RESYNCHRONIZATION OF THE RIGHT AND LEFT VENTRICLES. • HAVE ONE OR MORE CONVENTIONAL INDICATIONS FOR THE IMPLANTATION OF A PACEMAKER. MR CONDITIONAL PULSE GENERATOR IS CONDITIONALLY SAFE FOR USE IN THE MRI ENVIRONMENT WHEN USED IN A COMPLETE MR CONDITIONAL PACING SYSTEM AND ACCORDING TO THE INSTRUCTIONS IN THE MRI-READY SYSTEM MANUAL FOR THE ST. JUDE MEDICAL MR CONDITIONAL PACING SYSTEM. RATE-MODULATED PACING IS INDICATED FOR PATIENTS WITH CHRONOTROPIC INCOMPETENCE, AND FOR THOSE WHO WOULD BENEFIT FROM INCREASED STIMULATION RATES CONCURRENT WITH PHYSICAL ACTIVITY. DUAL-CHAMBER PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR THOSE PATIENTS EXHIBITING: • SICK SINUS SYNDROME • CHRONIC, SYMPTOMATIC SECOND- AND THIRD-DEGREE AV BLOCK • RECURRENT ADAMS-STOKES SYNDROME • SYMPTOMATIC BILATERAL BUNDLE BRANCH BLOCK WHEN TACHYARRHYTHMIA AND OTHER CAUSES HAVE BEEN RULED OUT. ATRIAL PACING IS INDICATED FOR PATIENTS WITH SINUS NODE DYSFUNCTION AND NORMAL AV AND INTRAVENTRICULAR CONDUCTION SYSTEMS. VENTRICULAR PACING IS INDICATED FOR PATIENTS WITH SIGNIFICANT BRADYCARDIA AND: • NORMAL SINUS RHYTHM WITH ONLY RARE EPISODES OF AV BLOCK OR SINUS ARREST • CHRONIC ATRIAL FIBRILLATION (AF) • SEVERE PHYSICAL DISABILITY. AF SUPPRESSION PACING (DUAL-CHAMBER

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	STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF. FOR SPECIFIC INDICATIONS ASSOCIATED WITH INDIVIDUAL MODES, REFER TO THE PROGRAMMER'S ON-SCREEN HELP.,PACING LEAD(TENDRIL STS)-THE TENDRIL™ STS MODEL 2088TC LEAD IS DESIGNED FOR PERMANENT SENSING AND PACING IN EITHER THE RIGHT ATRIUM OR THE RIGHT VENTRICLE, IN COMBINATION WITH A COMPATIBLE DEVICE. ACTIVE LEADS SUCH AS TENDRIL STS MODEL 2088TC LEADS MAY BE INDICATED FOR PATIENTS WHERE PERMANENT FIXATION OF PASSIVE LEADS IS SUSPECTED TO BE UNSTABLE. IN ATRIAL APPLICATIONS, THE USE OF A SCREW-IN LEAD SUCH AS TENDRIL STS MODEL 2088TC LEADS MAY BE INDICATED IN THE PRESENCE OF AN ABNORMAL, SURGICALLY ALTERED OR EXCISED ATRIAL APPENDAGE.,PULSE GENERATOR(ENDURITY)-IMPLANTATION OF A SINGLE-CHAMBER PULSE GENERATOR, DUAL-CHAMBER PULSE GENERATOR, OR CRT-P (CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER) IS INDICATED IN ONE OR MORE OF THE FOLLOWING PERMANENT CONDITIONS OR ANY COMBINATIONS OF THESE SYMPTOMS: • SYNCOPE • PRESYNCOPE • FATIGUE • DISORIENTATION DUE TO ARRHYTHMIA OR BRADYCARDIA. IMPLANTATION OF A CRT-P IS INDICATED FOR PATIENTS WHO: • WOULD BENEFIT FROM RESYNCHRONIZATION OF THE RIGHT AND LEFT VENTRICLES. • HAVE ONE OR MORE CONVENTIONAL INDICATIONS FOR THE IMPLANTATION OF A PACEMAKER. MR CONDITIONAL PULSE GENERATOR IS CONDITIONALLY SAFE FOR USE IN THE MRI ENVIRONMENT WHEN USED IN A COMPLETE MR CONDITIONAL PACING SYSTEM AND ACCORDING TO THE INSTRUCTIONS IN THE MRI-READY SYSTEM MANUAL FOR THE ST. JUDE MEDICAL MR CONDITIONAL PACING SYSTEM. RATE-MODULATED PACING IS INDICATED FOR PATIENTS WITH CHRONOTROPIC INCOMPETENCE, AND FOR THOSE WHO WOULD BENEFIT FROM INCREASED STIMULATION RATES CONCURRENT WITH PHYSICAL ACTIVITY. DUAL-CHAMBER PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR THOSE PATIENTS EXHIBITING: • SICK SINUS SYNDROME • CHRONIC, SYMPTOMATIC SECOND- AND THIRD-DEGREE AV BLOCK • RECURRENT ADAMS-STOKES SYNDROME • SYMPTOMATIC BILATERAL BUNDLE BRANCH BLOCK WHEN TACHYARRHYTHMIA AND OTHER CAUSES HAVE BEEN RULED OUT. ATRIAL PACING IS INDICATED FOR PATIENTS WITH SINUS NODE DYSFUNCTION AND NORMAL AV AND INTRAVENTRICULAR CONDUCTION SYSTEMS. VENTRICULAR PACING IS INDICATED FOR PATIENTS WITH SIGNIFICANT BRADYCARDIA AND: • NORMAL SINUS RHYTHM WITH ONLY RARE EPISODES OF AV BLOCK OR SINUS ARREST • CHRONIC ATRIAL FIBRILLATION (AF) • SEVERE PHYSICAL

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	PATIENTS WITH ONE OR MORE OF THE ABOVE PACING INDICATIONS. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF. FOR SPECIFIC INDICATIONS ASSOCIATED WITH INDIVIDUAL MODES, REFER TO THE PROGRAMMER'S ON-SCREEN HELP.,PACING LEAD(ISOFLEX)-ISOFLEX LEADS ARE DESIGNED FOR USE IN COMBINATION WITH A COMPATIBLE PULSE GENERATOR TO PROVIDE PERMANENT PACING AND SENSING IN EITHER THE ATRIUM OR VENTRICLE. ISOFLEX MODEL 1948 IS INTENDED TO BE PLACED IN EITHER THE RIGHT ATRIUM OR THE RIGHT VENTRICLE. ,CARDIAC RESYNCHRONIZATION THERAPY -CARDIOVERTER/DEFIBRILLATOR(UNIFY ASSURA)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,CARDIAC RESYNCHRONIZATION THERAPY-PACEMAKER(ALLURE)-IMPLANTATION OF A SINGLE CHAMBER PULSE GENERATOR, DUAL CHAMBER PULSE GENERATOR, OR CRTP (CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER) IS INDICATED IN ONE OR MORE OF THE FOLLOWING PERMANENT CONDITIONS OR ANY COMBINATION OF THESE SYMPTOMS: SYNCOPE PRESYNCOPE FATIGUE DISORIENTATION DUE TO ARRHYTHMIA OR BRADYCARDIA IMPLANTATION OF A CRTP IS INDICATED FOR PATIENTS WHO: WOULD BENEFIT FROM RESYNCHRONIZATION OF THE RIGHT AND LEFT VENTRICLES. HAVE ONE OR MORE CONVENTIONAL INDICATIONS FOR THE IMPLANTATION OF A PACEMAKER. MR CONDITIONAL PULSE GENERATOR IS CONDITIONALLY SAFE FOR USE IN THE MRI ENVIRONMENT WHEN USED IN A COMPLETE MR CONDITIONAL PACING SYSTEM AND ACCORDING TO THE INSTRUCTIONS IN THE MRI READY SYSTEM MANUAL FOR THE ST. JUDE MEDICAL™ MR CONDITIONAL PACING SYSTEM. RATEMODULATED PACING IS INDICATED FOR PATIENTS WITH CHRONOTROPIC INCOMPETENCE, AND FOR THOSE WHO WOULD BENEFIT FROM INCREASED STIMULATION RATES CONCURRENT WITH PHYSICAL ACTIVITY. DUAL

	CHAMBER PACING (DUALCHAMBER PULSE GENERATORS, CRTPS) IS INDICATED FOR THOSE PATIENTS EXHIBITING: SICK SINUS SYNDROME CHRONIC, SYMPTOMATIC SECONDAND THIRDDEGREE AV BLOCK RECURRENT ADAMS STOKES SYNDROME SYMPTOMATIC BILATERAL BUNDLE BRANCH BLOCK WHEN TACHYARRHYTHMIA AND OTHER CAUSES HAVE BEEN RULED OUT ATRIAL PACING IS INDICATED FOR PATIENTS WITH SINUS NODE DYSFUNCTION AND NORMAL AV AND INTRAVENTRICULAR CONDUCTION SYSTEMS. VENTRICULAR PACING IS INDICATED FOR PATIENTS WITH SIGNIFICANT BRADYCARDIA AND: NORMAL SINUS RHYTHM WITH ONLY RARE EPISODES OF AV BLOCK OR SINUS ARREST CHRONIC ATRIAL FIBRILLATION (AF) SEVERE PHYSICAL DISABILITY AF SUPPRESSION™ PACING (DUALCHAMBER PULSE GENERATORS, CRTPS) IS INDICATED FOR SUPPRESSION OF PAROXYSMAL OR PERSISTENT ATRIAL FIBRILLATION EPISODES IN PATIENTS WITH ONE OR MORE OF THE ABOVE PACING INDICATIONS. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF. FOR SPECIFIC INDICATIONS ASSOCIATED WITH INDIVIDUAL MODES, REFER TO THE PROGRAMMER'S ONSCREEN HELP.,CARDIAC RESYNCHRONIZATION THERAPY -PACEMAKER(ALLURE RF)-IMPLANTATION OF A SINGLE-CHAMBER PULSE GENERATOR, DUAL-CHAMBER PULSE GENERATOR, OR CRT-P (CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER) IS INDICATED IN ONE OR MORE OF THE FOLLOWING PERMANENT CONDITIONS OR ANY COMBINATIONS OF THESE SYMPTOMS: • SYNCOPE • PRESYNCOPE • FATIGUE • DISORIENTATION DUE TO ARRHYTHMIA OR BRADYCARDIA IMPLANTATION OF A CRT-P IS INDICATED FOR PATIENTS WHO: • WOULD BENEFIT FROM RESYNCHRONIZATION OF THE RIGHT AND LEFT VENTRICLES. • HAVE ONE OR MORE CONVENTIONAL INDICATIONS FOR THE IMPLANTATION OF A PACEMAKER. MR CONDITIONAL PULSE GENERATOR IS CONDITIONALLY SAFE FOR USE IN THE MRI ENVIRONMENT WHEN USED IN A COMPLETE MR CONDITIONAL PACING SYSTEM AND ACCORDING TO THE INSTRUCTIONS IN THE MRI-READY SYSTEM MANUAL FOR THE ST. JUDE MEDICAL MR CONDITIONAL PACING SYSTEM. RATE-MODULATED PACING IS INDICATED FOR PATIENTS WITH CHRONOTROPIC INCOMPETENCE, AND FOR THOSE WHO WOULD BENEFIT FROM INCREASED STIMULATION RATES CONCURRENT WITH PHYSICAL ACTIVITY. DUAL-CHAMBER PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR THOSE PATIENTS EXHIBITING: • SICK SINUS

	SYNDROME • CHRONIC, SYMPTOMATIC SECOND- AND THIRD-DEGREE AV BLOCK • RECURRENT ADAMS-STOKES SYNDROME • SYMPTOMATIC BILATERAL BUNDLE BRANCH BLOCK WHEN TACHYARRHYTHMIA AND OTHER CAUSES HAVE BEEN RULED OUT ATRIAL PACING IS INDICATED FOR PATIENTS WITH SINUS NODE DYSFUNCTION AND NORMAL AV AND INTRAVENTRICULAR CONDUCTION SYSTEMS. VENTRICULAR PACING IS INDICATED FOR PATIENTS WITH SIGNIFICANT BRADYCARDIA AND: • NORMAL SINUS RHYTHM WITH ONLY RARE EPISODES OF AV BLOCK OR SINUS ARREST • CHRONIC ATRIAL FIBRILLATION (AF) • SEVERE PHYSICAL DISABILITY AF SUPPRESSION PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR SUPPRESSION OF PAROXYSMAL OR PERSISTENT ATRIAL FIBRILLATION EPISODES IN PATIENTS WITH ONE OR MORE OF THE ABOVE PACING INDICATIONS. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF. FOR SPECIFIC INDICATIONS ASSOCIATED WITH INDIVIDUAL MODES, REFER TO THE PROGRAMMER'S ON-SCREEN HELP.,PULSE GENERATOR(ENDURITY CORE)-IMPLANTATION OF A SINGLE-CHAMBER PULSE GENERATOR, DUAL-CHAMBER PULSE GENERATOR, OR CRT-P (CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER) IS INDICATED IN ONE OR MORE OF THE FOLLOWING PERMANENT CONDITIONS OR ANY COMBINATIONS OF THESE SYMPTOMS: • SYNCOPE • PRESYNCOPE • FATIGUE • DISORIENTATION DUE TO ARRHYTHMIA OR BRADYCARDIA. IMPLANTATION OF A CRT-P IS INDICATED FOR PATIENTS WHO: • WOULD BENEFIT FROM RESYNCHRONIZATION OF THE RIGHT AND LEFT VENTRICLES. • HAVE ONE OR MORE CONVENTIONAL INDICATIONS FOR THE IMPLANTATION OF A PACEMAKER. MR CONDITIONAL PULSE GENERATOR IS CONDITIONALLY SAFE FOR USE IN THE MRI ENVIRONMENT WHEN USED IN A COMPLETE MR CONDITIONAL PACING SYSTEM AND ACCORDING TO THE INSTRUCTIONS IN THE MRI-READY SYSTEM MANUAL FOR THE ST. JUDE MEDICAL MR CONDITIONAL PACING SYSTEM. RATE-MODULATED PACING IS INDICATED FOR PATIENTS WITH CHRONOTROPIC INCOMPETENCE, AND FOR THOSE WHO WOULD BENEFIT FROM INCREASED STIMULATION RATES CONCURRENT WITH PHYSICAL ACTIVITY. DUAL-CHAMBER PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR THOSE PATIENTS EXHIBITING: • SICK SINUS SYNDROME • CHRONIC, SYMPTOMATIC SECOND- AND THIRD-DEGREE AV BLOCK • RECURRENT ADAMS-STOKES SYNDROME • SYMPTOMATIC BILATERAL BUNDLE BRANCH

	BLOCK WHEN TACHYARRHYTHMIA AND OTHER CAUSES HAVE BEEN RULED OUT. ATRIAL PACING IS INDICATED FOR PATIENTS WITH SINUS NODE DYSFUNCTION AND NORMAL AV AND INTRAVENTRICULAR CONDUCTION SYSTEMS. VENTRICULAR PACING IS INDICATED FOR PATIENTS WITH SIGNIFICANT BRADYCARDIA AND: • NORMAL SINUS RHYTHM WITH ONLY RARE EPISODES OF AV BLOCK OR SINUS ARREST • CHRONIC ATRIAL FIBRILLATION (AF) • SEVERE PHYSICAL DISABILITY. AF SUPPRESSION PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR SUPPRESSION OF PAROXYSMAL OR PERSISTENT ATRIAL FIBRILLATION EPISODES IN PATIENTS WITH ONE OR MORE OF THE ABOVE PACING INDICATIONS. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF. FOR SPECIFIC INDICATIONS ASSOCIATED WITH INDIVIDUAL MODES, REFER TO THE PROGRAMMER'S ON-SCREEN HELP.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR(FORTIFY ASSURA VR)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,PACING LEAD(ISOFLEX)-ISOFLEX™ LEADS ARE DESIGNED FOR USE IN COMBINATION WITH A COMPATIBLE PULSE GENERATOR TO PROVIDE PERMANENT PACING AND SENSING IN EITHER THE ATRIUM OR VENTRICLE. ISOFLEX MODEL 1944 IS INTENDED TO BE PLACED IN THE RIGHT ATRIUM,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR(FORTIFY ASSURA DR)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF

	STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,PULSE GENERATOR(ENDURITY CORE)-IMPLANTATION OF A SINGLE-CHAMBER PULSE GENERATOR, DUAL-CHAMBER PULSE GENERATOR, OR CRT-P (CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER) IS INDICATED IN ONE OR MORE OF THE FOLLOWING PERMANENT CONDITIONS OR ANY COMBINATIONS OF THESE SYMPTOMS: • SYNCOPE • PRESYNCOPE • FATIGUE • DISORIENTATION DUE TO ARRHYTHMIA OR BRADYCARDIA. IMPLANTATION OF A CRT-P IS INDICATED FOR PATIENTS WHO: • WOULD BENEFIT FROM RESYNCHRONIZATION OF THE RIGHT AND LEFT VENTRICLES. • HAVE ONE OR MORE CONVENTIONAL INDICATIONS FOR THE IMPLANTATION OF A PACEMAKER. MR CONDITIONAL PULSE GENERATOR IS CONDITIONALLY SAFE FOR USE IN THE MRI ENVIRONMENT WHEN USED IN A COMPLETE MR CONDITIONAL PACING SYSTEM AND ACCORDING TO THE INSTRUCTIONS IN THE MRI-READY SYSTEM MANUAL FOR THE ST. JUDE MEDICAL MR CONDITIONAL PACING SYSTEM. RATE-MODULATED PACING IS INDICATED FOR PATIENTS WITH CHRONOTROPIC INCOMPETENCE, AND FOR THOSE WHO WOULD BENEFIT FROM INCREASED STIMULATION RATES CONCURRENT WITH PHYSICAL ACTIVITY. DUAL-CHAMBER PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR THOSE PATIENTS EXHIBITING: • SICK SINUS SYNDROME • CHRONIC, SYMPTOMATIC SECOND- AND THIRD-DEGREE AV BLOCK • RECURRENT ADAMS-STOKES SYNDROME • SYMPTOMATIC BILATERAL BUNDLE BRANCH BLOCK WHEN TACHYARRHYTHMIA AND OTHER CAUSES HAVE BEEN RULED OUT. ATRIAL PACING IS INDICATED FOR PATIENTS WITH SINUS NODE DYSFUNCTION AND NORMAL AV AND INTRAVENTRICULAR CONDUCTION SYSTEMS. VENTRICULAR PACING IS INDICATED FOR PATIENTS WITH SIGNIFICANT BRADYCARDIA AND: • NORMAL SINUS RHYTHM WITH ONLY RARE EPISODES OF AV BLOCK OR SINUS ARREST • CHRONIC ATRIAL FIBRILLATION (AF) • SEVERE PHYSICAL DISABILITY. AF SUPPRESSION PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR SUPPRESSION OF PAROXYSMAL OR PERSISTENT ATRIAL FIBRILLATION EPISODES IN PATIENTS WITH ONE OR MORE OF THE ABOVE PACING INDICATIONS. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF. FOR SPECIFIC INDICATIONS ASSOCIATED WITH INDIVIDUAL MODES, REFER TO THE PROGRAMMER'S ON-SCREEN HELP.,PULSE GENERATOR(ENDURITY MRI)-IMPLANTATION OF A SINGLE-CHAMBER PULSE GENERATOR,

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		ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.
2529	IMP/MD/2021/000202	1.License Holder Name: FRESENIUS MEDICAL CARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ACUTE DIALYSIS MACHINE / MULTIFILTRATE PRO-THE DEVICE IS USED IN CONTINUOUS RENAL REPLACEMENT THERAPY, HAEMOPERFUSION PROCEDURES AND THERAPEUTIC PLASMA EXCHANGE.,ACUTE DIALYSIS MACHINE / MULTIFILTRATE-THE DEVICE IS DESIGNED FOR THE PERFORMANCE OF EXTRACORPOREAL BLOOD PURIFICATION (DIALYSIS AND APHERESIS) IN CLINICS AND IN THE AREA OF INTENSIVE CARE MEDICINE IN PARTICULAR.,HAEMODIALYSIS MACHINE-THE DEVICE IS USED FOR THE EXTRACORPOREAL BLOOD TREATMENT OF PATIENTS SUFFERING FROM RENAL INSUFFICIENCY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2530	IMP/MD/2021/000203	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CHRONIC HEMODIALYSIS CATHETERIZATION SET(ARROW®)-THE ARROW-CLARK VECTORFLOW ANTEGRADE CATHETER IS INDICATED FOR USE IN ATTAINING LONG-TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS. THE ARROW-CLARK VECTORFLOW ANTEGRADE CATHETER IS INSERTED PERCUTANEOUSLY AND IS PREFERENTIALLY PLACED INTO THE INTERNAL JUGULAR (IJ) VEIN. ALTERNATELY, THIS CATHETER MAY BE INSERTED INTO THE SUBCLAVIAN VEIN ALTHOUGH THE JUGULAR VEIN IS THE PREFERRED SITE. CATHETERS GREATER THAN 40 CM ARE INTENDED FOR FEMORAL VEIN INSERTION. THE ARROW-CLARK VECTORFLOW ANTEGRADE CATHETER IS INTENDED FOR USE IN ADULT PATIENTS.,CENTRAL VENOUS CATHETER 3(ARROW® PICC SET)-THE PRESSURE INJECTABLE PICC IS INDICATED FOR SHORT OR LONG TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, BLOOD SAMPLING, INFUSION AND PRESSURE INJECTION OF CONTRAST MEDIA. THE MAXIMUM PRESSURE OF PRESSURE INJECTOR EQUIPMENT USED WITH THE PRESSURE INJECTABLE PICC MAY NOT EXCEED 300 PSI. THE MAXIMUM PRESSURE INJECTION FLOW RATE RANGES FROM 4 ML/SEC TO 6 ML/SEC. REFER TO THE PRODUCT SPECIFIC LABELING FOR THE MAXIMUM PRESSURE INJECTION FLOW RATE FOR THE SPECIFIC LUMEN BEING USED FOR PRESSURE INJECTION. ,CENTRAL VENOUS CATHETER 8(ARROW®)-INDICATIONS FOR USE: THE ARROW PICC WITH ARROWG+ARD BLUE ADVANCE PROTECTION IS INDICATED FOR SHORT-TERM OR LONG-TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, BLOOD SAMPLING, INFUSION, PRESSURE INJECTION OF CONTRAST MEDIA, AND ALLOWS FOR CENTRAL VENOUS PRESSURE MONITORING. THE MAXIMUM PRESSURE OF PRESSURE INJECTOR EQUIPMENT USED WITH THE ARROW PICC WITH ARROWG+ARD BLUE ADVANCE PROTECTION MAY NOT EXCEED 300 PSI (2068.4 KPA). THE MAXIMUM PRESSURE INJECTION FLOW RATE RANGES FROM 4 ML/SEC TO 6 ML/SEC. REFER TO THE PRODUCT SPECIFIC LABELING FOR THE MAXIMUM PRESSURE INJECTION FLOW RATE FOR THE SPECIFIC LUMEN BEING USED FOR PRESSURE INJECTION. ARROWG+ARD BLUE ADVANCE PROTECTION TREATMENT ON THE EXTERNAL SURFACE OF THE CATHETER BODY AS WELL AS THE ENTIRE FLUID PATHWAY OF THE CATHETER HAS BEEN SHOWN TO BE EFFECTIVE IN REDUCING MICROBIAL COLONIZATION AND THROMBUS ACCUMULATION ON CATHETER SURFACES. ANTIMICROBIAL AND ANTITHROMBOGENIC EFFECTIVENESS WERE EVALUATED USING IN VITRO AND IN VIVO

	TEST METHODS, AND NO CORRELATION BETWEEN THESE TEST METHODS AND CLINICAL OUTCOME HAS CURRENTLY BEEN ASCERTAINED. IT IS NOT INTENDED TO BE USED FOR THE TREATMENT OF EXISTING INFECTIONS OR VEIN THROMBOSIS. INDICATION: - THE PRESSURE INJECTABLE PICC IS INDICATED FOR SHORT OR LONG TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, BLOOD SAMPLING, INFUSION, PRESSURE INJECTION OF CONTRAST MEDIA AND ALLOWS FOR CENTRAL VENOUS PRESSURE MONITORING. THE MAXIMUM PRESSURE OF PRESSURE INJECTOR EQUIPMENT USED WITH THE PRESSURE INJECTABLE PICC MAY NOT EXCEED 300 PSI (2068.4 KPA). THE MAXIMUM PRESSURE INJECTION FLOW RATE RANGES FROM 4 ML/SEC TO 6 ML/SEC. REFER TO THE PRODUCT SPECIFIC LABELING FOR THE MAXIMUM PRESSURE INJECTION FLOW RATE FOR THE SPECIFIC LUMEN BEING USED FOR PRESSURE INJECTION., CHRONIC HEMODIALYSIS CATHETERIZATION SET 2(ARROW®)-THE ARROW-CLARK VECTORFLOW RETROGRADE REPLACEMENT HUB SET IS INDICATED FOR USE IN THE REPLACEMENT OF AN ARROW-CLARK VECTORFLOW RETROGRADE HUB CONNECTION ASSEMBLY THAT HAS BEEN DAMAGED.,CHRONIC HEMODIALYSIS CATHETERIZATION SET(ARROW®)-THE ARROW-CLARK VECTORFLOW RETROGRADE CATHETER IS INDICATED FOR USE IN ATTAINING LONG-TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS. THE ARROW-CLARK VECTORFLOW RETROGRADE CATHETER IS INSERTED PERCUTANEOUSLY AND IS PREFERENTIALLY PLACED INTO THE INTERNAL JUGULAR (IJ) VEIN. ALTERNATELY, THIS CATHETER MAY BE INSERTED INTO THE SUBCLAVIAN VEIN ALTHOUGH THE JUGULAR VEIN IS THE PREFERRED SITE. CATHETERS GREATER THAN 40 CM ARE INTENDED FOR FEMORAL VEIN INSERTION. THE ARROW-CLARK VECTORFLOW RETROGRADE CATHETER IS INTENDED FOR USE IN ADULT PATIENTS.,INTRODUCER NEEDLES(ARROW®)-ARROW INTRODUCER NEEDLES ARE INTENDED TO PROVIDE ACCESS INTO THE VASCULATURE, AFTER REMOVAL OF THE SYRINGE ALLOWS PASSAGE OF A SPRING-WIRE GUIDE INTO THE VESSEL.,CENTRAL VENOUS CATHETER 7(ARROW®)-INDICATIONS FOR USE: - THE ARROW PICC WITH ARROWG+ARD BLUE ADVANCE PROTECTION IS INDICATED FOR SHORT-TERM OR LONG-TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, BLOOD SAMPLING, INFUSION, PRESSURE INJECTION OF CONTRAST MEDIA, AND ALLOWS FOR CENTRAL VENOUS PRESSURE MONITORING. THE MAXIMUM PRESSURE OF PRESSURE INJECTOR EQUIPMENT USED WITH THE ARROW PICC WITH ARROWG+ARD BLUE ADVANCE PROTECTION MAY NOT EXCEED 300 PSI. ARROWG+ARD BLUE ADVANCE PROTECTION ON THE EXTERNAL SURFACE OF THE

	CATHETER BODY AS WELL AS THE ENTIRE FLUID PATHWAY OF THE CATHETER HAS BEEN SHOWN TO BE EFFECTIVE IN REDUCING MICROBIAL COLONIZATION AND THROMBUS ACCUMULATION ON CATHETER SURFACES. ANTIMICROBIAL AND ANTITHROMBOGENIC EFFECTIVENESS WERE EVALUATED USING IN VITRO AND IN VIVO TEST METHODS, AND NO CORRELATION BETWEEN THESE TEST METHODS AND CLINICAL OUTCOME HAS CURRENTLY BEEN ASCERTAINED. IT IS NOT INTENDED TO BE USED FOR THE TREATMENT OF EXISTING INFECTIONS OR VEIN THROMBOSIS. INDICATION: - THE PRESSURE INJECTABLE PICC IS INDICATED FOR SHORT OR LONG TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR INTRAVENOUS THERAPY, BLOOD SAMPLING, INFUSION, PRESSURE INJECTION OF CONTRAST MEDIA AND ALLOWS FOR CENTRAL VENOUS PRESSURE MONITORING. THE MAXIMUM PRESSURE OF POWER INJECTOR EQUIPMENT USED WITH THE PRESSURE INJECTABLE PICC MAY NOT EXCEED 300 PSI.,CENTRAL VENOUS ACCESS SHEATH(ARROW®)-THE ARROW CENTRAL VENOUS ACCESS PRODUCT PERMITS VENOUS ACCESS AND CATHETER INTRODUCTION TO THE CENTRAL CIRCULATION.,CHRONIC HEMODIALYSIS CATHETERIZATION SET 1(ARROW®)-THE ARROW-CLARK VECTORFLOW ANTEGRADE CATHETER IS INDICATED FOR USE IN ATTAINING LONG-TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS. THE ARROW-CLARK VECTORFLOW ANTEGRADE CATHETER IS INSERTED PERCUTANEOUSLY AND IS PREFERENTIALLY PLACED INTO THE INTERNAL JUGULAR (IJ) VEIN. ALTERNATELY, THIS CATHETER MAY BE INSERTED INTO THE SUBCLAVIAN VEIN ALTHOUGH THE JUGULAR VEIN IS THE PREFERRED SITE. CATHETERS GREATER THAN 40 CM ARE INTENDED FOR FEMORAL VEIN INSERTION. THE ARROW-CLARK VECTORFLOW ANTEGRADE CATHETER IS INTENDED FOR USE IN ADULT PATIENTS.,CHRONIC HEMODIALYSIS CATHETERIZATION SET(ARROW®)-THE ARROW-CLARK VECTORFLOW RETROGRADE CATHETER IS INDICATED FOR USE IN ATTAINING LONG-TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS. THE ARROW-CLARK VECTORFLOW RETROGRADE CATHETER IS INSERTED PERCUTANEOUSLY AND IS PREFERENTIALLY PLACED INTO THE INTERNAL JUGULAR (IJ) VEIN. ALTERNATELY, THIS CATHETER MAY BE INSERTED INTO THE SUBCLAVIAN VEIN ALTHOUGH THE JUGULAR VEIN IS THE PREFERRED SITE. CATHETERS GREATER THAN 40 CM ARE INTENDED FOR FEMORAL VEIN INSERTION. THE ARROW-CLARK VECTORFLOW RETROGRADE CATHETER IS INTENDED FOR USE IN ADULT PATIENTS., CENTRAL VENOUS CATHETER 4(ARROW® PICC SET)-THE PRESSURE INJECTABLE PICC IS INDICATED FOR SHORT OR LONG TERM PERIPHERAL ACCESS TO THE CENTRAL VENOUS SYSTEM FOR

		INTRAVENOUS THERAPY, BLOOD SAMPLING, INFUSION, PRESSURE INJECTION OF CONTRAST MEDIA AND ALLOWS FOR CENTRAL VENOUS PRESSURE MONITORING. THE MAXIMUM PRESSURE OF PRESSURE INJECTOR EQUIPMENT USED WITH THE PRESSURE INJECTABLE PICC MAY NOT EXCEED 300 PSI. THE MAXIMUM PRESSURE INJECTION FLOW RATE RANGES FROM 4 ML/SEC TO 6 ML/SEC. REFER TO THE PRODUCT SPECIFIC LABELING FOR THE MAXIMUM PRESSURE INJECTION FLOW RATE FOR THE SPECIFIC LUMEN BEING USED FOR PRESSURE INJECTION.
2531	IMP/MD/2021/000204	1.License Holder Name: CURATEQ BIOLOGICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD NEOPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKING AND ADMINISTRATION OF PARENTAL DRUGS, PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKING AND ADMINISTRATION OF PARENTAL DRUGS
2532	IMP/MD/2021/000205	1.License Holder Name: M/S. PLUS MEDICAL DEVICES INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL KNEE REPLACEMENT SYSTEM(KAM TITAN)-THE KAM-TITAN SYSTEM IS USED FOR OSTEOSYNTHESIS TO FIX THE KNEE JOINT BETWEEN TIBIA AND FEMUR.,TOTAL HIP REPLACEMENT SYSTEM - CEMENTLESS IMPLANTS(---)-INTENDED FOR CONGENITAL OR ACQUIRED HIP JOINT DEFECTS REPLACEMENT REVISION SURGERY.
2533	IMP/MD/2021/000206	1.License Holder Name: POLY MEDICURE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTING NEEDLE/BLOOD COLLECTION NEEDLE (BULK)-DRAWING BLOOD FROM PATIENTS

2534	IMP/MD/2021/000207	1.License Holder Name: BLUE STAR ENGINEERING & ELECTRONICS LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CT SCAN EQUIPMENT (WHOLE BODY X-RAY CT SYSTEM)-FOR SCENARIA VIEW: INTENDED USE: THIS EQUIPMENT IS INTENDED TO BE USED FOR COMPUTER TOMOGRAPHY OF THE HEAD OR OF THE ENTIRE BODY. INDICATION FOR USE: THE SCENARIA VIEW SYSTEM IS INDICATED TO ACQUIRE AXIAL VOLUMES OF THE WHOLE BODY INCLUDING THE HEAD. IMAGES CAN BE ACQUIRED IN AXIAL, HELICAL, OR DYNAMIC MODES. THE SCENARIA VIEW SYSTEM CAN ALSO BE USED FOR INTERVENTIONAL NEEDLE GUIDANCE. VOLUME DATASETS ACQUIRED BY A SCENARIA VIEW SYSTEM CAN BE POST-PROCESSED IN THE SCENARIA VIEW SYSTEM TO PROVIDE ADDITIONAL INFORMATION. POST-PROCESSING CAPABILITIES OF THE SCENARIA VIEW SOFTWARE INCLUDE, MULTI-PLANAR RECONSTRUCTION (MPR), AND VOLUME RENDERING. VOLUME DATASETS ACQUIRED BY A SCENARIA VIEW SYSTEM CAN BE TRANSFERRED TO EXTERNAL DEVICES VIA A DICOM STANDARD INTERFACE. NOTE THAT THIS SYSTEM IS INTENDED TO BE USED TO SCAN INFANTS AND INCLUDES A PROTOCOL FOR INFANTS. FOR SCENARIA: INTENDED USE: THIS SYSTEM IS INTENDED TO USE AT ANY PART OF THE WHOLE BODY TO GET COMPUTED TOMOGRAPHY IMAGES AND THOSE IMAGES ARE USED FOR DIAGNOSTIC PURPOSES. INDICATION FOR USE: THE SCENARIA SYSTEM IS INDICATED TO ACQUIRE AXIAL VOLUMES OF THE WHOLE BODY INCLUDING THE HEAD. IMAGES CAN BE ACQUIRED IN AXIAL, HELICAL, GATED, OR DYNAMIC MODES. THE SCENARIA SYSTEM CAN ALSO BE USED FOR INTERVENTIONAL NEEDLE GUIDANCE. VOLUME DATASETS ACQUIRED BY A SCENARIA SYSTEM CAN BE POST-PROCESSED IN THE SCENARIA SYSTEM TO PROVIDE ADDITIONAL INFORMATION. POST-PROCESSING CAPABILITIES OF THE SCENARIA SOFTWARE INCLUDE CT ANGIOGRAPHY (CTA), MULTI-PLANAR RECONSTRUCTION (MPR), AND VOLUME RENDERING. VOLUME DATASETS ACQUIRED BY A SCENARIA SYSTEM CAN BE TRANSFERRED TO EXTERNAL DEVICES VIA A DICOM STANDARD INTERFACE. NOTE THAT THIS SYSTEM IS INTENDED TO BE USED TO SCAN INFANTS AND INCLUDES A PROTOCOL FOR INFANTS. FOR SUPRIA: INTENDED USE: THIS SYSTEM IS INTENDED TO USE AT ANY PART OF THE WHOLE BODY TO GET COMPUTED TOMOGRAPHY IMAGES AND THOSE IMAGES ARE USED FOR DIAGNOSTIC PURPOSES. INDICATION FOR USE: THIS SYSTEM COLLECTS VOLUME DATA OF THE ENTIRE BODY INCLUDING THE HEAD ALONG THE BODY AXIS VIA THE AXIAL, HELICAL OR DYNAMIC SCAN. POST PROCESSING BY THE SOFTWARE INCLUDES MPR, VOLUME RENDERING, AND ANALYTICAL

	PROCESSING. CONDUCTING POST PROCESSING ON THE IMAGES OBTAINED PROVIDES SEPARATE TRANSVERSE SECTION IMAGES AND ANALYTICAL RESULTS. YOU CAN ALSO TRANSFER THE IMAGES TO EXTERNAL EQUIPMENT VIA THE INTERFACE COMPLIED WITH DICOM STANDARD. THIS SYSTEM ENABLES COMPUTED TOMOGRAPHY OF A PATIENT'S HEAD, ENTIRE BODY, BLOOD VESSELS, AND INTERNAL ORGANS SINCE IT IS CAPABLE OF PRODUCING IMAGES REGARDLESS OF WHETHER OR NOT CONTRAST MEDIUM IS USED. NOTE THAT THIS SYSTEM IS INTENDED TO BE USED TO SCAN INFANTS AND INCLUDES A PROTOCOL FOR INFANTS.

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2535	IMP/MD/2021/000212	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHODONTIC WIRES (COPPER NICKEL TITANIUM)(BROAD ARCHWIRE , COPPER NI-TI ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH,ORTHODONTIC WIRE (BETA TITANIUM)(TMA ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH, ORTHODONTIC TUBE (TITANIUM)(TITANIUM BUCCAL TUBE)-INTENDED TO BE APPLIED TO A PATIENT'S 1ST AND 2ND MOLARS IN ORDER TO CORRECT MALOCCLUSION.,ORTHODONTIC WIRE (STAINLESS STEEL)(BROAD ARCHWIRE, D-RECT ARCHWIRE , RESPOND ARCHWIRE , STAINLESS STEEL ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH,ORTHODONTIC TUBE (STAINLESS STEEL) (ACCENT MINI BUCCAL TUBES, SL BUCCAL TUBE, SNAPLINK)-INTENDED TO BE APPLIED TO A PATIENT'S 1ST AND 2ND MOLARS IN ORDER TO CORRECT MALOCCLUSION,ORTHODONTIC WIRES (NICKLE TITANIUM(NI-TI ARCHWIRE, TRU-ARCH ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH,TEMPORARY ANCHORAGE SYSTEM(VECTOR TAS)-VECTOR TEMPORARY ANCHORAGE SYSTEM IS INTENDED TO PROVIDE A TEMPORARY FIXED ANCHORAGE POINT FOR ATTACHMENT OF ORTHODONTIC APPLIANCES THAT FACILITATES ORTHODONTICS MOVEMENT OF TEETH. THESE SCREWS ARE TEMPORARY AND ARE REMOVED AFTER THE DESIRED MOVEMENT IS ACHIEVED. THESE SCREWS WERE DESIGNED TO BE USED ON THE FOLLOWING TYPES OF CASES: • INTRUSION OR EXTRUSION OF INDIVIDUAL TEETH OR SEGMENTS OF AN ARCH. • PATIENTS IN WHICH PERIODONTAL DISEASE HAS COMPROMISED. • PATIENTS WHERE THERE IS A NEED FOR ABSOLUTE ANCHORAGE, I.E. ONLY THE ACTIVE UNIT SHOULD BE DISPLACED THE REACTIVE UNIT SHOULD REMAIN UNALTERED. • PATIENTS IN WHICH ALL TEETH SHOULD BE DISPLACED IN THE SAME DIRECTION. • PATIENTS WITH AGENESIS OF ONE OR MORE TEETH WHO NEED THE SPACE CLOSURE FROM ONE SIDE ONLY. • PATIENTS WITH NEED FOR THE CORRECTION OF ASYMMETRIES. THE MINI SCREWS CAN BE UTILIZED ON PATIENTS OVER THE AGE OF 13. CAUTION SHOULD BE USED WHEN PERMANENT TEETH HAVE NOT FULLY ERUPTED, AS NOT TO DAMAGE THE UNERUPTED TOOTH. AN UPPER AGE LIMIT DOES NOT EXIST, BUT THE CORTICAL. THICKNESS SHOULD BE SUFFICIENT FOR PRIMARY STABILITY. THE MINI-SCREWS WERE ORIGINALLY DEVELOPED FOR ADULTS IN WHOM INSUFFICIENT TEETH WERE AVAILABLE FOR CONVENTIONAL ANCHORAGE. THE INDICATIONS. HAVE, HOWEVER, WIDENED AND COMPRISE ALSO

		INDIVIDUALS WHERE THE REACTIVE FORCES FROM CONVENTIONAL ORTHODONTIC APPLIANCES WOULD GENERATE AN ADVERSE EFFECT ON THE ANCHORAGE UNIT. THE SKELETAL ANCHORAGE CAN THUS BE RECOMMENDED IN THE TREATMENT OF YOUNG PATIENTS WITH AGENESIS OF PERMANENT TEETH IN WHICH THE POSTERIOR TEETH ARE TO BE DISPLACED FORWARD WITHOUT GENERATING DISTALLY DIRECTED FORCES ON THE ANTERIOR UNIT . THIS CAN BE DONE FROM THE AGE WHERE THE PERMANENT TEETH TO BE DISPLACED ARE ERUPTED LASTLY THESE SCREWS ARE INTENDED FOR SINGLE USE ONLY.
2536	IMP/MD/2021/000213	1.License Holder Name: CURATEQ BIOLOGICS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PREFILLABLE GLASS BARREL WITH NEEDLE(BD HYPAK™)-COMPONENTS OF DISPOSABLE SYSTEM FOR PACKING AND ADMINISTRATION OF PARENTAL DRUGS
2537	IMP/MD/2021/000214	1.License Holder Name: PHILIPS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITALDIAGNOST C90 (DIGITALDIAGNOST C90)-THE DIGITALDIAGNOST C90 IS INTENDED TO ACQUIRE, PROCESS, STORE, DISPLAY AND EXPORT DIGITAL RADIOGRAPHIC IMAGES. THE DIGITALDIAGNOST C90 IS SUITABLE FOR ALL ROUTINE RADIOGRAPHY EXAMINATIONS, INCLUDING SPECIALIST AREAS LIKE INTENSIVE CARE, TRAUMA OR PEDIATRIC WORK, EXCLUDING FLUOROSCOPY, ANGIOGRAPHY AND MAMMOGRAPHY.,DIGITALDIAGNOST(DIGITALDIAGNOST)-THIS SYSTEM IS USED FOR MAKING DIGITAL X-RAY EXPOSURES. ITS OPERATION MODE IS CONTINUOUS OPERATION.
2538	IMP/MD/2021/000215	1.License Holder Name: FRESENIUS KABI INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AUTOMATED BLOOD CELL SEPARATOR(AMICORE)-THE AMICORE APHERESIS SYSTEM IS AN AUTOMATED BLOOD CELL SEPARATOR INTENDED FOR USE IN THE COLLECTION OF BLOOD COMPONENTS

2539	IMP/MD/2021/000216	1.License Holder Name: ALLERGAN HEALTHCARE INDIA PRIVATE LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYALURONIC ACID 20 MG + LIDOCAINE HYDROCHLORIDE 3MG(JUVÉDERM VOLUMA WITH LIDOCAINE)-INJECTABLE IMPLANT INDICATED TO RESTORE VOLUME OF THE FACE BY INJECTION BY AN AUTHORIZED MEDICAL PRACTITIONER IN ACCORDANCE WITH LOCAL APPLICABLE REGULATION. THE PRESENCE OF LIDOCAINE IS MEANT TO REDUCE THE PATIENT'S PAIN DURING TREATMENT.,HYALURONIC ACID 17.5MG + LIDOCAINE HYDROCHLORIDE 3MG(JUVÉDERM VOLIFT WITH LIDOCAINE)-TREATMENT OF DEEP SKIN DEPRESSIONS, FACE CONTOURING AND VOLUME RESTORATION VIA DEEP DERMIS INJECTION AS WELL AS FOR RESTORATION OF LIP VOLUME BY AN AUTHORIZED MEDICAL PRACTITIONER IN ACCORDANCE WITH LOCAL APPLICABLE REGULATION. THE PRESENCE OF LIDOCAINE IS MEANT TO REDUCE THE PATIENTS PAIN DURING TREATMENT.,HYALURONIC ACID 24 MG + LIDOCAINE HYDROCHLORIDE 3MG(JUVÉDERM ULTRA PLUS XC)-IT IS AN INTENDED FOR FILLING MID AND /OR DEEP DEPRESSION OF THE SKIN VIA MID AND/OR DEEP DERMIS INJECTION AND LIP DEFINITION AND ENHANCEMENT. THE PRESENCE OF LIDOCAINE IS MEANT TO REDUCE THE PATIENT'S PAIN DURING TREATMENT.

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2540	IMP/MD/2021/000217	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DEFIBRILLATOR LEAD IMPLANTABLE(RELIANCE 4 FRONT INTEGRATED BIPOLAR PACE/SENSE AND DEFIBRILLATION LEAD)-THIS BOSTON SCIENTIFIC LEAD IS INDICATED FOR USE AS FOLLOWS: INTENDED FOR PACING, RATE-SENSING, AND DELIVERY OF CARDIOVERSION AND DEFIBRILLATION SHOCKS WHEN USED WITH A COMPATIBLE PULSE GENERATOR,ENDOCARDIAL PACING LEAD(ACUITY X4 PACE/SENSE LEAD)-THIS BOSTON SCIENTIFIC LEAD IS INDICATED FOR USE AS FOLLOWS: • INTENDED FOR CHRONIC, LEFT-VENTRICULAR PACING AND SENSING VIA THE CORONARY VENOUS SYSTEM WHEN USED IN CONJUNCTION WITH A COMPATIBLE PULSE GENERATOR , ENDOCARDIAL LEADS(FINELINE II STEROX EZ IMPLANTABLE ENDOCARDIAL PACING LEAD)-THE LEAD IS INTENDED FOR CHRONIC PACING AND SENSING OF THE ATRIUM OR VENTRICLE WHEN USED WITH A COMPATIBLE PULSE GENERATOR.,DEFIBRILLATOR, IMPLANTABLE, DUAL-CHAMBER(ORIGEN ICD)-BOSTON SCIENTIFIC IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS) ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING (ATP) AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS., ENDOCARDIAL LEADS(FINELINE II STEROX IMPLANTABLE ENDOCARDIAL PACING LEAD)-THE LEAD IS INTENDED FOR CHRONIC PACING AND SENSING OF THE VENTRICLE (4456, 4457, 4458, 4459) OR THE ATRIUM (4479, 4480) WHEN USED WITH A COMPATIBLE PULSE GENERATOR.,PACING LEAD, IMPLANTABLE, ENDOCARDIAL (ACUITY SPIRAL IMPLANTABLE LEAD FOR CARDIAC PACING)-THE ACUITY SPIRAL CORONARY VENOUS, STEROID-ELUTING, SINGLE-ELECTRODE PACE/SENSE LEADS, MODELS 4591/4592/4593, ARE TRANSVENOUS LEADS INTENDED FOR CHRONIC, LEFT-VENTRICULAR PACING AND SENSING VIA THE CORONARY VEINS WHEN USED IN CONJUNCTION WITH A COMPATIBLE PULSE GENERATOR.,CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR(VIGILANT X4 CRT-D)-THESE BOSTON SCIENTIFIC CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS (CRT-DS) ARE INDICATED FOR PATIENTS WHO ARE AT RISK FOR SUDDEN CARDIAC DEATH CAUSED BY VENTRICULAR ARRHYTHMIAS AND WHO HAVE HEART FAILURE (INCLUDING ASYMPTOMATIC [NYHA CLASS I] ISCHEMIC HEART FAILURE) WITH VENTRICULAR DYSSYNCHRONY.,DEFIBRILLATOR, IMPLANTABLE, DUAL-CHAMBER(DYNAGEN CRT-D)-THESE BOSTON SCIENTIFIC CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS (CRT-DS) ARE INDICATED FOR PATIENTS WHO ARE AT RISK FOR SUDDEN CARDIAC DEATH CAUSED BY VENTRICULAR

	ARRHYTHMIAS AND WHO HAVE HEART FAILURE (INCLUDING ASYMPTOMATIC [NYHA CLASS I] ISCHEMIC HEART FAILURE) WITH VENTRICULAR DYSSYNCHRONY.,CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR(CHARISMA CRT-D)-THESE BOSTON SCIENTIFIC CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS (CRT-DS) ARE INDICATED FOR PATIENTS WHO ARE AT RISK FOR SUDDEN CARDIAC DEATH CAUSED BY VENTRICULAR ARRHYTHMIAS AND WHO HAVE HEART FAILURE (INCLUDING ASYMPTOMATIC [NYHA CLASS I] ISCHEMIC HEART FAILURE) WITH VENTRICULAR DYSSYNCHRONY,DEFIBRILLATOR, IMPLANTABLE, DUAL-CHAMBER(DYNAGEN ICD)-BOSTON SCIENTIFIC IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS) ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING (ATP) AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR(VIGILANT ICD)-BOSTON SCIENTIFIC IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS) ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING (ATP) AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS., CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR (RESONATE CRT-D)-THESE BOSTON SCIENTIFIC CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS (CRT-DS) ARE INDICATED FOR PATIENTS WHO ARE AT RISK FOR SUDDEN CARDIAC DEATH CAUSED BY VENTRICULAR ARRHYTHMIAS AND WHO HAVE HEART FAILURE(INCLUDING ASYMPTOMATIC [NYHA CLASS I] ISCHEMIC HEART FAILURE) WITH VENTRICULAR DYSSYNCHRONY., DEFIBRILLATOR, IMPLANTABLE, DUAL-CHAMBER(INOGEN CRT-D)-THESE BOSTON SCIENTIFIC CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS (CRT-DS) ARE INDICATED FOR PATIENTS WHO ARE AT RISK FOR SUDDEN CARDIAC DEATH CAUSED BY VENTRICULAR ARRHYTHMIAS AND WHO HAVE HEART FAILURE (INCLUDING ASYMPTOMATIC [NYHA CLASS I] ISCHEMIC HEART FAILURE) WITH VENTRICULAR DYSSYNCHRONY.,CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR(MOMENTUM CRT-D)-THESE BOSTON SCIENTIFIC CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS (CRT-DS) ARE INDICATED FOR PATIENTS WHO ARE AT RISK FOR SUDDEN CARDIAC DEATH CAUSED BY VENTRICULAR ARRHYTHMIAS AND WHO HAVE HEART FAILURE (INCLUDING ASYMPTOMATIC [NYHA CLASS I] ISCHEMIC HEART FAILURE) WITH VENTRICULAR DYSSYNCHRONY.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR(CHARISMA ICD)-BOSTON SCIENTIFIC IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS) ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA

	PACING (ATP) AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS., IMPLANTABLE CARDIOVERTER DEFIBRILLATOR(RESONATE ICD)-BOSTON SCIENTIFIC IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS) ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING (ATP) AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR(MOMENTUM ICD)-BOSTON SCIENTIFIC IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS) ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING (ATP) AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS., DEFIBRILLATOR, IMPLANTABLE, DUAL-CHAMBER(INOGEN ICD)-BOSTON SCIENTIFIC IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS) ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING (ATP) AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS.,DEFIBRILLATOR, IMPLANTABLE, DUAL-CHAMBER(ORIGEN CRT-D)-THESE BOSTON SCIENTIFIC CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS (CRT-DS) ARE INDICATED FOR PATIENTS WHO ARE AT RISK FOR SUDDEN CARDIAC DEATH CAUSED BY VENTRICULAR ARRHYTHMIAS AND WHO HAVE HEART FAILURE (INCLUDING ASYMPTOMATIC [NYHA CLASS I] ISCHEMIC HEART FAILURE) WITH VENTRICULAR DYSSYNCHRONY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2541	IMP/MD/2021/000218	1.License Holder Name: WIPRO GE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMPUTED TOMOGRAPHY(DISCOVERY RT)-THE SYSTEM IS INTENDED TO BE USED FOR HEAD AND WHOLE BODY COMPUTED TOMOGRAPHY. THE DISCOVERY RT COMPUTED TOMOGRAPHY SYSTEMS ARE INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA TAKEN AT DIFFERENT ANGLES AND PLANES, INCLUDING AXIAL, CINE, HELICAL (VOLUMETRIC), AND GATED (RESPIRATORY AND CARDIAC) ACQUISITIONS FOR ALL AGES. THESE IMAGES MAY BE OBTAINED EITHER WITH OR WITHOUT CONTRAST. THIS DEVICE MAY INCLUDE SIGNAL ANALYSIS AND DISPLAY EQUIPMENT, PATIENT AND EQUIPMENT SUPPORT, COMPONENTS AND ACCESSORIES. THIS DEVICE MAY INCLUDE DATA AND IMAGE PROCESSING TO PRODUCE IMAGES IN A VARIETY OF TRANS-AXIAL AND REFORMATTED PLANES. FURTHER THE IMAGES CAN BE POST PROCESSED TO PRODUCE ADDITIONAL IMAGING PLANES OR ANALYSIS RESULTS. THE DEVICE OUTPUT IS A VALUABLE MEDICAL TOOL FOR THE DIAGNOSIS OF DISEASE, TRAUMA, OR ABNORMALITY AND FOR PLANNING, GUIDING, AND MONITORING THERAPY.THE SYSTEM IS CAPABLE OF ASSISTING WITH MINIMALLY INVASIVE PROCEDURES SUCH AS BIOPSY AND ABLATION OF TUMORS AND PATHOLOGY. THE SYSTEM ALLOWS IMAGING OF BARIATRICS PATIENTS, UP TO AND INCLUDING THE MORBIDLY OBESE POPULATION (BMI > 40). THE SYSTEM CAN ACQUIRE CT ANATOMICAL IMAGES THAT ARE CLINICALLY USEFUL IN THE SIMULATION AND PLANNING OF RADIATION THERAPY FOR THE TREATMENT OF CANCER.,COMPUTED TOMOGRAPHY(OPTIMA CT 540) -THE SYSTEM IS INTENDED TO BE USED FOR HEAD AND WHOLE BODY COMPUTED TOMOGRAPHY. THE GE OPTIMA CT540 COMPUTED TOMOGRAPHY X-RAY SYSTEM IS INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA TAKEN AT DIFFERENT ANGLES AND PLANES, PATIENT FOR ALL AGES, INCLUDING AXIAL, CINE, HELICAL, CARDIAC, AND GATED (RESPIRATORY AND CARDIAC) ACQUISITIONS. THESE IMAGES MAY BE OBTAINED EITHER WITH OR WITHOUT CONTRAST.,COMPUTED TOMOGRAPHY(REVOLUTION MAXIMA)-THE SYSTEM IS INTENDED TO BE USED FOR HEAD, WHOLE BODY COMPUTED TOMOGRAPHY APPLICATIONS.,COMPUTED TOMOGRAPHY(OPTIMA CT 520)-THE OPTIMA CT520 CT SCANNER SYSTEM IS INDICATED FOR HEAD, WHOLE BODY, CARDIAC AND VASCULAR X-RAY COMPUTED TOMOGRAPHY APPLICATIONS., COMPUTED TOMOGRAPHY(REVOLUTION FRONTIER)-THE SYSTEM IS INTENDED FOR HEAD, WHOLE BODY, CARDIAC AND VASCULAR X-RAY

		COMPUTED TOMOGRAPHY APPLICATIONS.,COMPUTED TOMOGRAPHY(REVOLUTION ACT (32 SLICE))-THE SYSTEM IS INTENDED TO BE USED FOR HEAD AND WHOLE BODY COMPUTED TOMOGRAPHY. THE REVOLUTION ACT COMPUTED TOMOGRAPHY X-RAY SYSTEM IS INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA TAKEN AT DIFFERENT ANGLES AND PLANES, FOR ALL PATIENTS OF ALL AGES, INCLUDING AXIAL, CINE, HELICAL. THESE IMAGES MAY BE OBTAINED EITHER WITH OR WITHOUT CONTRAST. THIS DEVICE MAY INCLUDE SIGNAL ANALYSIS AND DISPLAY EQUIPMENT, PATIENT, AND EQUIPMENT SUPPORTS, COMPONENTS AND ACCESSORIES. THIS DEVICE MAY INCLUDE DATA AND IMAGE PROCESSING TO PRODUCE IMAGES IN A VARIETY OF TRANS-AXIAL AND REFORMATTED PLANES. FURTHER THE IMAGES CAN BE POST PROCESSED TO PRODUCE ADDITIONAL IMAGING PLANES OR ANALYSIS RESULTS. THE REVOLUTION ACT CT SCANNER SYSTEM IS INDICATED FOR HEAD, WHOLE BODY, AND VASCULAR X-RAY COMPUTED TOMOGRAPHY APPLICATIONS. THE DEVICE OUTPUT IS A VALUABLE MEDICAL TOOL FOR THE DIAGNOSIS OF DISEASE, TRAUMA, OR ABNORMALITY AND FOR PLANNING, GUIDING, AND MONITORING THERAPY.
2542	IMP/MD/2021/000219	1.License Holder Name: EMSURG HEALTHCARE (INDIA) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SOFT TISSUE BIOPSY NEEDLE(THEMYQ)-NEEDLE FOR MANUAL DIAGNOSTIC SAMPLING OF SOFT TISSUES SUCH AS LIVER, KIDNEY, BREAST, PROSTATE, SPLEEN, LIMPH NODES AND VARIOUS SOFT TISSUE TUMORS.,SOFT TISSUE BIOPSY NEEDLE(THEMY)-NEEDLE FOR MANUAL DIAGNOSTIC SAMPLING OF SOFT TISSUES SUCH AS LIVER, KIDNEY, BREAST, LUNG, PROSTATE, SPLEEN, LYMPH NODES.,BONE MARROW BIOPSY NEEDLE (PICKUP)-BIOPSY DEVICE FOR MANUAL SAMPLING OF BONE MARROW.,BONE MARROW BIOPSY NEEDLE(OSTEOJ)-BIOPSY DEVICE FOR MANUAL SAMPLING OF BONE MARROW.,BONE MARROW BIOPSY NEEDLE(ILLY)-NEEDLE FOR STERNAL OR ILIAC CREST MARROW ASPIRATION.,BONE MARROW BIOPSY NEEDLE(JAMBLU)-BIOPSY DEVICE FOR MANUAL SAMPLING OF BONE MARROW.,SOFT TISSUE BIOPSY NEEDLE(SEMICUT)-NEEDLE FOR MANUAL DIAGNOSTIC SAMPLING OF SOFT TISSUES SUCH AS LIVER, SPLEEN, KIDNEY, PROSTATE, LUNG , BREAST AND LIMPH NODES.

2543	IMP/MD/2021/000221	1.License Holder Name: BHARAT SERUMS & VACCINES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IONIC SILVERSTREAM (SILVERSTREAM)-IT IS INTENDED FOR USE UNDER THE SUPERVISION OF A HEALTHCARE PROFESSIONAL FOR MECHANICAL CLEANSING AND REMOVAL OF FOREIGN MATERIAL INCLUDING MICRO-ORGANISMS AND DEBRIS FROM WOUNDS SUCH AS STAGE I-IV PRESSURE ULCERS, STASIS ULCERS, DIABETIC FOOT ULCERS, POST-SURGICAL WOUNDS, FIRST AND SECOND DEGREE BURNS, CUTS ABRASIONS AND MINOR SKIN IRRITATIONS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2544	IMP/MD/2021/000222	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PULSE GENERATOR (ENDURITY CORE)-IMPLANTATION OF A SINGLE-CHAMBER PULSE GENERATOR, DUAL-CHAMBER PULSE GENERATOR, OR CRT-P (CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER) IS INDICATED IN ONE OR MORE OF THE FOLLOWING PERMANENT CONDITIONS OR ANY COMBINATIONS OF THESE SYMPTOMS: • SYNCOPE • PRESYNCOPE • FATIGUE • DISORIENTATION DUE TO ARRHYTHMIA OR BRADYCARDIA. IMPLANTATION OF A CRT-P IS INDICATED FOR PATIENTS WHO: • WOULD BENEFIT FROM RESYNCHRONIZATION OF THE RIGHT AND LEFT VENTRICLES. • HAVE ONE OR MORE CONVENTIONAL INDICATIONS FOR THE IMPLANTATION OF A PACEMAKER. MR CONDITIONAL PULSE GENERATOR IS CONDITIONALLY SAFE FOR USE IN THE MRI ENVIRONMENT WHEN USED IN A COMPLETE MR CONDITIONAL PACING SYSTEM AND ACCORDING TO THE INSTRUCTIONS IN THE MRI-READY SYSTEM MANUAL FOR THE ST. JUDE MEDICAL MR CONDITIONAL PACING SYSTEM. RATE-MODULATED PACING IS INDICATED FOR PATIENTS WITH CHRONOTROPIC INCOMPETENCE, AND FOR THOSE WHO WOULD BENEFIT FROM INCREASED STIMULATION RATES CONCURRENT WITH PHYSICAL ACTIVITY. DUAL-CHAMBER PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR THOSE PATIENTS EXHIBITING: • SICK SINUS SYNDROME • CHRONIC, SYMPTOMATIC SECOND- AND THIRD-DEGREE AV BLOCK • RECURRENT ADAMS-STOKES SYNDROME • SYMPTOMATIC BILATERAL BUNDLE BRANCH BLOCK WHEN TACHYARRHYTHMIA AND OTHER CAUSES HAVE BEEN RULED OUT. ATRIAL PACING IS INDICATED FOR PATIENTS WITH SINUS NODE DYSFUNCTION AND NORMAL AV AND INTRAVENTRICULAR CONDUCTION SYSTEMS. VENTRICULAR PACING IS INDICATED FOR PATIENTS WITH SIGNIFICANT BRADYCARDIA AND: • NORMAL SINUS RHYTHM WITH ONLY RARE EPISODES OF AV BLOCK OR SINUS ARREST • CHRONIC ATRIAL FIBRILLATION (AF) • SEVERE PHYSICAL DISABILITY. AF SUPPRESSION PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR SUPPRESSION OF PAROXYSMAL OR PERSISTENT ATRIAL FIBRILLATION EPISODES IN PATIENTS WITH ONE OR MORE OF THE ABOVE PACING INDICATIONS. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF. FOR SPECIFIC INDICATIONS ASSOCIATED WITH INDIVIDUAL MODES, REFER TO THE

	PROGRAMMER'S ON-SCREEN HELP.,LEFT HEART LEAD(QUICKFLEX) -THE LEAD IS DESIGNED FOR USE IN COMBINATION WITH A COMPATIBLE PULSE GENERATOR TO PROVIDE LONG-TERM STIMULATION AND SENSING OF THE LEFT VENTRICLE VIA THE GREAT CARDIAC VEIN OR ONE OF ITS TRIBUTARIES .,DEFIBRILLATION LEADS (DURATA)-THE DURATA TRANSVENOUS LEADS ARE INDICATED FOR USE WITH COMPATIBLE PULSE GENERATOR (REFER TO THE APPLICABLE DEFIBRILLATOR MANUAL FOR SYSTEM INDICATIONS). THEY PROVIDE PACING AND SENSING AND DELIVER CARDIOVERSION/DEFIBRILLATION THERAPY TO THE HEART. A TRANSVENOUS LEAD SYSTEM MAY OFFER THE PATIENT THE BENEFIT OF AVOIDING A THORACOTOMY FOR LEAD IMPLANTATION. IF THE INITIAL LEAD CONFIGURATION IS NOT EFFECTIVE, REPOSITIONING OF THE LEAD OR OTHER LEAD CONFIGURATION SHOULD BE ATTEMPTED. IN SOME PATIENTS, A NONTHORACOTOMY LEAD CONFIGURATION MAY NOT PROVIDE RELIABLE CONVERSION OF ARRHYTHMIAS, AND THE USE OF SUBCUTANEOUS OR EPICARDIAL PATCH DEFIBRILLATION LEADS SHOULD BE CONSIDERED.,PULSE GENERATOR(ENDURITY MRI)-IMPLANTATION OF A SINGLE-CHAMBER PULSE GENERATOR, DUAL-CHAMBER PULSE GENERATOR, OR CRT-P (CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER) IS INDICATED IN ONE OR MORE OF THE FOLLOWING PERMANENT CONDITIONS OR ANY COMBINATIONS OF THESE SYMPTOMS: • SYNCOPE • PRESYNCOPE • FATIGUE • DISORIENTATION DUE TO ARRHYTHMIA OR BRADYCARDIA. IMPLANTATION OF A CRT-P IS INDICATED FOR PATIENTS WHO: • WOULD BENEFIT FROM RESYNCHRONIZATION OF THE RIGHT AND LEFT VENTRICLES. • HAVE ONE OR MORE CONVENTIONAL INDICATIONS FOR THE IMPLANTATION OF A PACEMAKER. MR CONDITIONAL PULSE GENERATOR IS CONDITIONALLY SAFE FOR USE IN THE MRI ENVIRONMENT WHEN USED IN A COMPLETE MR CONDITIONAL PACING SYSTEM AND ACCORDING TO THE INSTRUCTIONS IN THE MRI-READY SYSTEM MANUAL FOR THE ST. JUDE MEDICAL MR CONDITIONAL PACING SYSTEM. RATE-MODULATED PACING IS INDICATED FOR PATIENTS WITH CHRONOTROPIC INCOMPETENCE, AND FOR THOSE WHO WOULD BENEFIT FROM INCREASED STIMULATION RATES CONCURRENT WITH PHYSICAL ACTIVITY. DUAL-CHAMBER PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR THOSE PATIENTS EXHIBITING: • SICK SINUS SYNDROME • CHRONIC, SYMPTOMATIC SECOND- AND THIRD-DEGREE AV BLOCK • RECURRENT ADAMS-STOKES SYNDROME • SYMPTOMATIC BILATERAL BUNDLE BRANCH BLOCK WHEN TACHYARRHYTHMIA AND OTHER CAUSES HAVE BEEN RULED OUT. ATRIAL PACING IS INDICATED FOR PATIENTS WITH SINUS NODE

	DYSFUNCTION AND NORMAL AV AND INTRAVENTRICULAR CONDUCTION SYSTEMS. VENTRICULAR PACING IS INDICATED FOR PATIENTS WITH SIGNIFICANT BRADYCARDIA AND: • NORMAL SINUS RHYTHM WITH ONLY RARE EPISODES OF AV BLOCK OR SINUS ARREST • CHRONIC ATRIAL FIBRILLATION (AF) • SEVERE PHYSICAL DISABILITY. AF SUPPRESSION PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR SUPPRESSION OF PAROXYSMAL OR PERSISTENT ATRIAL FIBRILLATION EPISODES IN PATIENTS WITH ONE OR MORE OF THE ABOVE PACING INDICATIONS. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF. FOR SPECIFIC INDICATIONS ASSOCIATED WITH INDIVIDUAL MODES, REFER TO THE PROGRAMMER'S ON-SCREEN HELP.,LEFT HEART LEAD(QUARTET)-THE QUARTET LEADS ARE DESIGNED FOR USE IN COMBINATION WITH A COMPATIBLE PULSE GENERATOR TO PROVIDE LONG-TERM STIMULATION AND SENSING OF THE LEFT VENTRICLE VIA THE GREAT CARDIAC VEIN OR ONE OF ITS TRIBUTARIES.,CARDIAC RESYNCHRONIZATION THERAPY -CARDIOVERTER/DEFIBRILLATOR (UNIFY ASSURA)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,PACING LEAD(ISOFLEX)-ISOFLEX LEADS ARE DESIGNED FOR USE IN COMBINATION WITH A COMPATIBLE PULSE GENERATOR TO PROVIDE PERMANENT PACING AND SENSING IN EITHER THE ATRIUM OR VENTRICLE. ISOFLEX MODEL 1948 IS INTENDED TO BE PLACED IN EITHER THE RIGHT ATRIUM OR THE RIGHT VENTRICLE.,PACING LEAD(ISOFLEX)-ISOFLEX LEADS ARE DESIGNED FOR USE IN COMBINATION WITH A COMPATIBLE PULSE GENERATOR TO PROVIDE PERMANENT PACING AND SENSING IN EITHER THE ATRIUM OR VENTRICLE. ISOFLEX MODEL 1944 IS INTENDED TO BE PLACED IN THE RIGHT ATRIUM,DEFIBRILLATION LEADS(DURATA)-THE DURATA TRANSVENOUS LEADS ARE INDICATED FOR USE WITH COMPATIBLE PULSE GENERATOR (REFER

	TO THE APPLICABLE DEFIBRILLATOR MANUAL FOR SYSTEM INDICATIONS). THEY PROVIDE PACING AND SENSING AND DELIVER CARDIOVERSION/DEFIBRILLATION THERAPY TO THE HEART. A TRANSVENOUS LEAD SYSTEM MAY OFFER THE PATIENT THE BENEFIT OF AVOIDING A THORACOTOMY FOR LEAD IMPLANTATION. IF THE INITIAL LEAD CONFIGURATION IS NOT EFFECTIVE, REPOSITIONING OF THE LEAD OR OTHER LEAD CONFIGURATION SHOULD BE ATTEMPTED. IN SOME PATIENTS, A NONTHORACOTOMY LEAD CONFIGURATION MAY NOT PROVIDE RELIABLE CONVERSION OF ARRHYTHMIAS, AND THE USE OF SUBCUTANEOUS OR EPICARDIAL PATCH DEFIBRILLATION LEADS SHOULD BE CONSIDERED.,TIERED-THERAPY CARDIOVERTER/DEFIBRILLATOR(ELLIPSE DR)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,DEFIBRILLATION LEADS(DURATA)-THE DURATA TRANSVENOUS LEADS ARE INDICATED FOR USE WITH COMPATIBLE PULSE GENERATOR (REFER TO THE APPLICABLE DEFIBRILLATOR MANUAL FOR SYSTEM INDICATIONS). THEY PROVIDE PACING AND SENSING AND DELIVER CARDIOVERSION/DEFIBRILLATION THERAPY TO THE HEART. A TRANSVENOUS LEAD SYSTEM MAY OFFER THE PATIENT THE BENEFIT OF AVOIDING A THORACOTOMY FOR LEAD IMPLANTATION. IF THE INITIAL LEAD CONFIGURATION IS NOT EFFECTIVE, REPOSITIONING OF THE LEAD OR OTHER LEAD CONFIGURATION SHOULD BE ATTEMPTED. IN SOME PATIENTS, A NONTHORACOTOMY LEAD CONFIGURATION MAY NOT PROVIDE RELIABLE CONVERSION OF ARRHYTHMIAS, AND THE USE OF SUBCUTANEOUS OR EPICARDIAL PATCH DEFIBRILLATION LEADS SHOULD BE CONSIDERED.,PULSE GENERATOR(ENDURITY CORE)-IMPLANTATION OF A SINGLE-CHAMBER PULSE GENERATOR, DUAL-CHAMBER PULSE GENERATOR, OR CRT-P (CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER) IS INDICATED IN ONE OR MORE OF THE FOLLOWING PERMANENT CONDITIONS OR ANY COMBINATIONS OF THESE SYMPTOMS: • SYNCOPE • PRESYNCOPE • FATIGUE • DISORIENTATION DUE TO ARRHYTHMIA OR BRADYCARDIA. IMPLANTATION OF A CRT-P IS INDICATED FOR PATIENTS WHO: • WOULD BENEFIT FROM

	RESYNCHRONIZATION OF THE RIGHT AND LEFT VENTRICLES. • HAVE ONE OR MORE CONVENTIONAL INDICATIONS FOR THE IMPLANTATION OF A PACEMAKER. MR CONDITIONAL PULSE GENERATOR IS CONDITIONALLY SAFE FOR USE IN THE MRI ENVIRONMENT WHEN USED IN A COMPLETE MR CONDITIONAL PACING SYSTEM AND ACCORDING TO THE INSTRUCTIONS IN THE MRI-READY SYSTEM MANUAL FOR THE ST. JUDE MEDICAL MR CONDITIONAL PACING SYSTEM. RATE-MODULATED PACING IS INDICATED FOR PATIENTS WITH CHRONOTROPIC INCOMPETENCE, AND FOR THOSE WHO WOULD BENEFIT FROM INCREASED STIMULATION RATES CONCURRENT WITH PHYSICAL ACTIVITY. DUAL-CHAMBER PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR THOSE PATIENTS EXHIBITING: • SICK SINUS SYNDROME • CHRONIC, SYMPTOMATIC SECOND- AND THIRD-DEGREE AV BLOCK • RECURRENT ADAMS-STOKES SYNDROME • SYMPTOMATIC BILATERAL BUNDLE BRANCH BLOCK WHEN TACHYARRHYTHMIA AND OTHER CAUSES HAVE BEEN RULED OUT. ATRIAL PACING IS INDICATED FOR PATIENTS WITH SINUS NODE DYSFUNCTION AND NORMAL AV AND INTRAVENTRICULAR CONDUCTION SYSTEMS. VENTRICULAR PACING IS INDICATED FOR PATIENTS WITH SIGNIFICANT BRADYCARDIA AND: • NORMAL SINUS RHYTHM WITH ONLY RARE EPISODES OF AV BLOCK OR SINUS ARREST • CHRONIC ATRIAL FIBRILLATION (AF) • SEVERE PHYSICAL DISABILITY. AF SUPPRESSION PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR SUPPRESSION OF PAROXYSMAL OR PERSISTENT ATRIAL FIBRILLATION EPISODES IN PATIENTS WITH ONE OR MORE OF THE ABOVE PACING INDICATIONS. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF. FOR SPECIFIC INDICATIONS ASSOCIATED WITH INDIVIDUAL MODES, REFER TO THE PROGRAMMER'S ON-SCREEN HELP.,PULSE GENERATOR(ENDURITY MRI)-IMPLANTATION OF A SINGLE-CHAMBER PULSE GENERATOR, DUAL-CHAMBER PULSE GENERATOR, OR CRT-P (CARDIAC RESYNCHRONIZATION THERAPY PACEMAKER) IS INDICATED IN ONE OR MORE OF THE FOLLOWING PERMANENT CONDITIONS OR ANY COMBINATIONS OF THESE SYMPTOMS: • SYNCOPE • PRESYNCOPE • FATIGUE • DISORIENTATION DUE TO ARRHYTHMIA OR BRADYCARDIA. IMPLANTATION OF A CRT-P IS INDICATED FOR PATIENTS WHO: • WOULD BENEFIT FROM RESYNCHRONIZATION OF THE RIGHT AND LEFT VENTRICLES. • HAVE ONE OR MORE CONVENTIONAL INDICATIONS FOR THE IMPLANTATION OF A

	PACEMAKER. MR CONDITIONAL PULSE GENERATOR IS CONDITIONALLY SAFE FOR USE IN THE MRI ENVIRONMENT WHEN USED IN A COMPLETE MR CONDITIONAL PACING SYSTEM AND ACCORDING TO THE INSTRUCTIONS IN THE MRI-READY SYSTEM MANUAL FOR THE ST. JUDE MEDICAL MR CONDITIONAL PACING SYSTEM. RATE-MODULATED PACING IS INDICATED FOR PATIENTS WITH CHRONOTROPIC INCOMPETENCE, AND FOR THOSE WHO WOULD BENEFIT FROM INCREASED STIMULATION RATES CONCURRENT WITH PHYSICAL ACTIVITY. DUAL-CHAMBER PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR THOSE PATIENTS EXHIBITING: • SICK SINUS SYNDROME • CHRONIC, SYMPTOMATIC SECOND- AND THIRD-DEGREE AV BLOCK • RECURRENT ADAMS-STOKES SYNDROME • SYMPTOMATIC BILATERAL BUNDLE BRANCH BLOCK WHEN TACHYARRHYTHMIA AND OTHER CAUSES HAVE BEEN RULED OUT. ATRIAL PACING IS INDICATED FOR PATIENTS WITH SINUS NODE DYSFUNCTION AND NORMAL AV AND INTRAVENTRICULAR CONDUCTION SYSTEMS. VENTRICULAR PACING IS INDICATED FOR PATIENTS WITH SIGNIFICANT BRADYCARDIA AND: • NORMAL SINUS RHYTHM WITH ONLY RARE EPISODES OF AV BLOCK OR SINUS ARREST • CHRONIC ATRIAL FIBRILLATION (AF) • SEVERE PHYSICAL DISABILITY. AF SUPPRESSION PACING (DUAL-CHAMBER PULSE GENERATORS, CRT-PS) IS INDICATED FOR SUPPRESSION OF PAROXYSMAL OR PERSISTENT ATRIAL FIBRILLATION EPISODES IN PATIENTS WITH ONE OR MORE OF THE ABOVE PACING INDICATIONS. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF. FOR SPECIFIC INDICATIONS ASSOCIATED WITH INDIVIDUAL MODES, REFER TO THE PROGRAMMER'S ON-SCREEN HELP.,DEFIBRILLATION LEADS (DURATA)-THE DURATA TRANSVENOUS LEADS ARE INDICATED FOR USE WITH COMPATIBLE PULSE GENERATOR (REFER TO THE APPLICABLE DEFIBRILLATOR MANUAL FOR SYSTEM INDICATIONS). THEY PROVIDE PACING AND SENSING AND DELIVER CARDIOVERSION/DEFIBRILLATION THERAPY TO THE HEART. A TRANSVENOUS LEAD SYSTEM MAY OFFER THE PATIENT THE BENEFIT OF AVOIDING A THORACOTOMY FOR LEAD IMPLANTATION. IF THE INITIAL LEAD CONFIGURATION IS NOT EFFECTIVE, REPOSITIONING OF THE LEAD OR OTHER LEAD CONFIGURATION SHOULD BE ATTEMPTED. IN SOME PATIENTS, A NONTHORACOTOMY LEAD CONFIGURATION MAY NOT PROVIDE RELIABLE CONVERSION OF ARRHYTHMIAS, AND THE USE OF SUBCUTANEOUS OR EPICARDIAL PATCH DEFIBRILLATION LEADS SHOULD BE CONSIDERED.,LEFT

	HEART LEAD(QUARTET)-THE QUARTET LEADS ARE DESIGNED FOR USE IN COMBINATION WITH A COMPATIBLE PULSE GENERATOR TO PROVIDE LONG-TERM STIMULATION AND SENSING OF THE LEFT VENTRICLE VIA THE GREAT CARDIAC VEIN OR ONE OF ITS TRIBUTARIES.,CARDIAC RESYNCHRONIZATION THERAPY - CARDIOVERTER/DEFIBRILLATOR(UNIFY ASSURA)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,TIERED-THERAPY CARDIOVERTER/DEFIBRILLATOR (ELLIPSE DR)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,TIERED-THERAPY CARDIOVERTER/DEFIBRILLATOR (ELLIPSE VR)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,DEFIBRILLATION LEADS(OPTISURE)-THE OPTISURE TRANSVENOUS LEADS ARE INDICATED FOR USE WITH COMPATIBLE PULSE GENERATORS (REFER TO THE APPLICABLE DEFIBRILLATOR MANUAL FOR SYSTEM INDICATIONS). THEY PROVIDE PACING AND

	SENSING AND DELIVER CARDIOVERSION/DEFIBRILLATION THERAPY TO THE HEART. A TRANSVENOUS LEAD SYSTEM MAY OFFER THE PATIENT THE BENEFIT OF AVOIDING A THORACOTOMY FOR LEAD IMPLANTATION. IF THE INITIAL LEAD CONFIGURATION IS NOT EFFECTIVE, REPOSITIONING OF THE LEAD OR OTHER LEAD CONFIGURATIONS SHOULD BE ATTEMPTED. IN SOME PATIENTS, A NONTHORACOTOMY LEAD CONFIGURATION MAY NOT PROVIDE RELIABLE CONVERSION OF ARRHYTHMIAS, AND THE USE OF SUBCUTANEOUS OR EPICARDIAL PATCH DEFIBRILLATION LEADS SHOULD BE CONSIDERED,TIERED-THERAPY CARDIOVERTER/DEFIBRILLATOR(ELLIPSE VR)-THE DEVICES ARE INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR ARRHYTHMIAS. CARDIAC RESYNCHRONIZATION THERAPY DEVICES (CRT-DS) ARE ALSO INTENDED TO RESYNCHRONIZE THE RIGHT AND LEFT VENTRICLES IN PATIENTS WITH CONGESTIVE HEART FAILURE. AT/AF DETECTION ALGORITHM. THE AT/AF DETECTION ALGORITHM IS INDICATED FOR DETECTING ATRIAL TACHYARRHYTHMIAS WHICH HAVE BEEN FOUND TO BE ASSOCIATED WITH AN INCREASED RISK OF STROKE IN ELDERLY, HYPERTENSIVE, PACEMAKER PATIENTS WITHOUT PRIOR HISTORY OF AF.,DEFIBRILLATION LEADS(OPTISURE)-THE OPTISURE TRANSVENOUS LEADS ARE INDICATED FOR USE WITH COMPATIBLE PULSE GENERATORS (REFER TO THE APPLICABLE DEFIBRILLATOR MANUAL FOR SYSTEM INDICATIONS). THEY PROVIDE PACING AND SENSING AND DELIVER CARDIOVERSION/DEFIBRILLATION THERAPY TO THE HEART. A TRANSVENOUS LEAD SYSTEM MAY OFFER THE PATIENT THE BENEFIT OF AVOIDING A THORACOTOMY FOR LEAD IMPLANTATION. IF THE INITIAL LEAD CONFIGURATION IS NOT EFFECTIVE, REPOSITIONING OF THE LEAD OR OTHER LEAD CONFIGURATIONS SHOULD BE ATTEMPTED. IN SOME PATIENTS, A NONTHORACOTOMY LEAD CONFIGURATION MAY NOT PROVIDE RELIABLE CONVERSION OF ARRHYTHMIAS, AND THE USE OF SUBCUTANEOUS OR EPICARDIAL PATCH DEFIBRILLATION LEADS SHOULD BE CONSIDERED,DEFIBRILLATION LEADS(OPTISURE)-THE OPTISURE TRANSVENOUS LEADS ARE INDICATED FOR USE WITH COMPATIBLE PULSE GENERATORS . THEY PROVIDE PACING AND SENSING AND DELIVER CARDIOVERSION/DEFIBRILLATION THERAPY TO THE HEART. A TRANSVENOUS LEAD SYSTEM MAY OFFER THE PATIENT THE BENEFIT OF AVOIDING A THORACOTOMY FOR LEAD IMPLANTATION. IF THE INITIAL LEAD CONFIGURATION IS NOT EFFECTIVE, REPOSITIONING OF THE LEAD OR OTHER LEAD CONFIGURATIONS SHOULD BE ATTEMPTED. IN SOME PATIENTS, A NONTHORACOTOMY LEAD CONFIGURATION MAY NOT PROVIDE

		RELIABLE CONVERSION OF ARRHYTHMIAS, AND THE USE OF SUBCUTANEOUS OR EPICARDIAL PATCH DEFIBRILLATION LEADS SHOULD BE CONSIDERED.,DEFIBRILLATION LEADS(OPTISURE)-THE OPTISURE TRANSVENOUS LEADS ARE INDICATED FOR USE WITH COMPATIBLE PULSE GENERATORS (REFER TO THE APPLICABLE DEFIBRILLATOR MANUAL FOR SYSTEM INDICATIONS). THEY PROVIDE PACING AND SENSING AND DELIVER CARDIOVERSION/DEFIBRILLATION THERAPY TO THE HEART. A TRANSVENOUS LEAD SYSTEM MAY OFFER THE PATIENT THE BENEFIT OF AVOIDING A THORACOTOMY FOR LEAD IMPLANTATION. IF THE INITIAL LEAD CONFIGURATION IS NOT EFFECTIVE, REPOSITIONING OF THE LEAD OR OTHER LEAD CONFIGURATIONS SHOULD BE ATTEMPTED. IN SOME PATIENTS, A NONTHORACOTOMY LEAD CONFIGURATION MAY NOT PROVIDE RELIABLE CONVERSION OF ARRHYTHMIAS, AND THE USE OF SUBCUTANEOUS OR EPICARDIAL PATCH DEFIBRILLATION LEADS SHOULD BE CONSIDERED.,PACING LEAD(TENDRIL STS)-THE TENDRIL STS MODEL 2088TC LEAD IS DESIGNED FOR PERMANENT SENSING AND PACING IN EITHER THE RIGHT ATRIUM OR THE RIGHT VENTRICLE, IN COMBINATION WITH A COMPATIBLE DEVICE. ACTIVE LEADS SUCH AS TENDRIL STS MODEL 2088TC LEADS MAY BE INDICATED FOR PATIENTS WHERE PERMANENT FIXATION OF PASSIVE LEADS IS SUSPECTED TO BE UNSTABLE. IN ATRIAL APPLICATIONS, THE USE OF A SCREW-IN LEAD SUCH AS TENDRIL STS MODEL 2088TC LEADS MAY BE INDICATED IN THE PRESENCE OF AN ABNORMAL, SURGICALLY ALTERED OR EXCISED ATRIAL APPENDAGE
2545	IMP/MD/2021/000223	1.License Holder Name: ACCESS DEVICES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMPLANTABLE CATHETER PORTS(DISTRICATH TITANIUM-POLYSULFONE RANGE (TI/PSU))-IT IS DESIGNED FOR CHEMOTHERAPY INJECTIONS. ANTI-CANCEROUS CHEMOTHERAPY, LONG TIME PERFUSIONS, LONG TIME ANTI-BIOTHERAPY PARENTERAL NUTRITION, AIDS TREATMENT, PAIN THERAPY

2546	IMP/MD/2021/000224	1.License Holder Name: M/S DENTSPLY INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NICR BASED CERAMIC BONDING ALLOY(STARLOY N)-STARLOY N IS A HIGHLY CORROSION-RESISTANT NICR-BASED NPM DEFLAGRATION ALLOY. IT CAN BE VENEERED WITH ALL DENTAL CERAMIC MASSES COVERING THE CTE RANGE FROM 14.4 M/M·K (25 – 600 °C).,ZIRCONIA DISC-SHAPED BLANKS(CERCON (CERCON BASE/CERCON HT/CERCON HT ML/CERCON XT/CERCON XT ML))-CERCON BASE IS INDICATED FOR CROWNS, MULTI-UNIT BRIDGES AND INLAY BRIDGES. APPLICATIONS INCLUDE BOTH ANTERIOR AND POSTERIOR REGIONS. CERCON HT IS INDICATED IN THE ANTERIOR AND POSTERIOR SEGMENTS FOR: CROWNS, TELESCOPIC PRIMARY CROWNS, MULTI-UNIT BRIDGES (WITH NO MORE THAN TWO PONTICS BETWEEN ABUTMENT CROWNS; WITH NO MORE THAN 6 UNITS), TWO PIECE ABUTMENTS. CERCON XT IS INDICATED FOR ALL CERAMIC RESTORATIONS FOR ANTERIOR AND POSTERIOR LOCATIONS: CROWNS, 3-UNIT BRIDGES (UP TO THE 2ND PREMOLAR),ZIRCONIA-REINFORCED LITHIUM-SILICATE (ZLS) (CELTRA PRESS/CELTRA PRESS STARTER KIT)-CELTRA PRESS IS AN ALL-CERAMIC SYSTEM FOR THE CREATION OF OCCLUSAL VENEERS, THIN VENEERS, VENEERS, INLAYS, ONLAYS, CROWNS IN THE ANTERIOR AND POSTERIOR REGION, 3-UNIT BRIDGES IN THE ANTERIOR REGION, 3-UNIT BRIDGES UP TO THE SECOND PREMOLAR AS THE TERMINAL ABUTMENT, CROWNS OR 3-UNIT BRIDGES UP TO THE SECOND PREMOLAR ON IMPLANT ABUTMENTS
2547	IMP/MD/2021/000225	1.License Holder Name: TTK HEALTHCARE LIMITED HEART VALVE DIVISION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MITRAL VALVE WITH INTRASUPRA-ANNULAR SEWING CUFF AND TISSUE ANNULUS (CARDIAMED)-IT IS INTENDED FOR REPLACEMENT OF THE DISEASED MITRAL NATIVE HUMAN HEART VALVE.,AORTIC VALVE WITH INTRASUPRA-ANNULAR SEWING CUFF AND TISSUE ANNULUS (CARDIAMED)-IT IS INTENDED FOR REPLACEMENT OF THE DISEASED AORTIC NATIVE HUMAN HEART VALVE.

2548	IMP/MD/2021/000226	1.License Holder Name: INDIAN ORTHOCARE SURGICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE PLATES & BONE SCREWS- (ARIX SYSTEM - NON STERILE)(ARIX SYSTEM)-THE ARIX SYTEM IS USED FOR STABILIZATION OF FRACTURES, OSTEOTOMIES FOR ANKLE, FOOT, HAND AND WRIST.,BONE PLATES & BONE SCREWS (LEFORTE NEURO SYSTEM (NON- STERILE))-THE LEFORTE NEURO SYSTEM IS INTENDED FOR USE IN SELECTIVE TRAUMA OF THE CARNIAL SKELETON, CARNIAL SURGERY AND RECONSTRUCTIVE PROCEDURES.,BONE PLATES & BONE SCREWS- (LEFORTE SYSTEM - NON STERILE)(LEFORTE SYSTEM)-THIS DEVICE IS INTENDED FOR USE IN SELECTIVE TRAUMA OF THE MID-FACE; RECONSTRUCTION PROCEDURES; AND SELECTIVE ORTHOGNATHIC SURGERY OF THE MAXILLA AND CHIN.
2549	IMP/MD/2021/000228	1.License Holder Name: AXON MEDICAL SOLUTIONS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STAPLERS(ENDOSCOPIC LINEAR CUTTING STAPLERS WITH SINGLE USE LOADING UNITS)-THE ENDO REACH TM ENDOSCOPIC LINEAR CUTTING STAPLERS WITH SINGLE USE LOADING UNITS CAN BE USED IN ABDOMINAL, GYNECOLOGIC, THORACIC AND PEDIATRIC SURGERIES FOR TRANSECTION, RESECTION, AND CREATION OF ANASTOMOSIS., STAPLERS(LINEAR CUTTING STAPLERS WITH SINGLE USE LOADING UNIT)-THE LINEAR STAPLERS WITH SINGLE USE LOADING UNITS HAVE APPLICATIONS IN ALIMENTARY TRACT, LUNGS AND BRONCHI FOR TRANSECTION AND SUTURING OF TISSUE OR ORGAN.,STAPLERS (PROCEDURE SETS FOR PROLAPSE AND HEMORRHOIDS)-THE PROCEDURE SETS FOR PROLAPSE AND HEMORRHOIDS HAVE APPLICATIONS FOR GENERAL SURGICAL TREATMENT OF ANORECTAL WALL DEFECTS BY TRANSANAL STAPLING AND RESECTION OF MUCOSAL AND MUSCULOMUCOSAL TISSUE., STAPLERS(CIRCULAR STAPLER WITH STAPLES)-THE CIRCULAR STAPLERS WITH STAPLES HAVE APPLICATION THROUGHOUT THE ALIMENTARY TRACT FOR THE CREATION OF END-TO-END, SIDE-TO-SIDE AND END-TO-SIDE ANASTOMOSES IN BOTH OPEN AND LAPAROSCOPIC SURGERIES.

2550	IMP/MD/2021/000229	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TOTAL KNEE REPLACEMENT SYSTEM(SUPERADIUS)-SUPERADIUS TOTAL KNEE SYSTEM IS INTENDED FOR THE REPLACEMENT OF THE BEARING AND/OR ARTICULATING SURFACES OF THE DISTAL FEMUR, PROXIMAL TIBIA, AND PATELLA TO RELIEVE PAIN, INSTABILITY, AND THE RESTRICTION OF MOTION DUE TO DEGENERATIVE BONE DISEASES.,GENERAL SPINE SYSTEM (NON-STERILE)(NIL)-THE GENERAL SPINE SYSTEM COMPRISES A VARIETY OF SPINAL FIXATION DEVICES THAT ARE INTENDED TO STABILIZE THE SPINE TO ACT AS AN ADJUNCT TO FUSION. INDICATIONS FOR THE USE OF THIS GENERAL SPINE SYSTEM INCLUDE DEGENERATIVE DISC DISEASE, SPONDYLOLISTHESIS, TRAUMA, STENOSIS, FRACTURE, DEFORMITY, TUMOR, PSEUDARTHROSIS OR FAILED PREVIOUS FUSION,ANTERIOR CERVICAL PLATE SYSTEM (NON-STERILE)(NIL)-THE ANTERIOR CERVICAL PLATE SYSTEM IS INDICATED FOR STABILIZATION OF THE CERVICAL SPINE BY ACHIEVING SCREW FIXATION AT THE ANTERIOR SIDE OF THE CERVICAL VERTEBRAL BODIES. INDICATIONS FOR THE USE OF THIS IMPLANT SYSTEM INCLUDE DEGENERATIVE DISC DISEASE, SPONDYLOLISTHESIS, TRAUMA, SPINAL CANAL STENOSIS AND CERVICAL MYELOPATHY, DEFORMITY, TUMOR, PSEUDARTHROSIS OR FAILED PREVIOUS FUSION. LEVEL OF SCREW FIXATION FOR THESE INDICATIONS ARE FROM C2 TO C7, INTERVERTEBRAL FUSION CAGE(NIL)-THIS PRODUCT IS INDICATED FOR INTERVERTEBRAL BODY FUSION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE LUMBAR CAGES ARE INTENDED FOR USE AT EITHER ONE LEVEL OR CONTIGUOUS LEVELS IN THE LUMBAR SPINE, FROM L2 TO S1, FOR THE TREATMENT OF DEGENERATIVE DISC DISEASE (DDD) WITH UP TO GRADE I SPONDYLOLISTHESIS. DDD IS DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. THE LUMBAR DEVICES ARE TO BE USED IN PATIENTS WHO HAVE HAD AT LEAST SIX MONTHS OF NON-OPERATIVE TREATMENT. THE CERVICAL CAGES ARE INTENDED FOR USE FOR ANTERIOR CERVICAL INTERBODY FUSION IN PATIENTS WITH CERVICAL DDD AT ONE LEVEL FROM LEVELS C2-C3 TO C7- T1. THE CERVICAL DEVICES ARE TO BE USED IN PATIENTS WHO HAVE HAD AT LEAST SIX WEEKS OF NON-OPERATIVE TREATMENT. THE SYSTEM IS INTENDED TO BE USED WITH SUPPLEMENTAL FIXATION AND AUTOGENOUS BONE GRAFT ONLY TO FACILITATE THE FUSION., BONE PLATES (NON-STERILE)(CAPITULUM PLATE)-THE BONE PLATE SYSTEM INCLUDING LOCKING PLATES, ANATOMICAL PLATES, STRAIGHT PLATES, MINI PLATES, AND DHS/DCS PLATE ARE

	DESIGNED TO PROVIDE FIXATION FOR FRACTURES, FUSIONS OR OSTEOTOMIES. IN GENERAL, THESE PLATES ARE INDICATED FOR FRACTURES REQUIRING ADDITIONAL STABILITY,PERCUTANEOUS KYPHOPLASTY SYSTEM(NIL)-THE PERCUTANEOUS KYPHOPLASTY SYSTEM IS INDICATED TO BE USED FOR THE REDUCTION OF FRACTURES, CREATION OF A VOID IN CANCELLOUS BONE IN THE SPINE AND INJECT THE BONE CEMENT IN THIS CAVITY. THIS INCLUDES USE DURING PERCUTANEOUS VERTEBRAL,BONE SCREWS (NON-STERILE)(NIL)-THE BONE SCREW SYSTEM INCLUDING CORTICAL SCREWS, CANCELLOUS SCREWS, CANNULATED SCREWS, WASHER, LAG SCREW, COMPRESSION SCREW, LOCKING SCREWS, AND SCREW HOLE INSERTER, IS DESIGNED TO PROVIDE FIXATION FOR FRACTURES, FUSIONS OR OSTEOTOMIES. IN GENERAL, THESE SCREWS ARE INDICATED FOR FRACTURES REQUIRING ADDITIONAL STABILITY.,BONE - PINS (NON-STERILE)(NIL)-FIXATION PINS ARE INTENDED TO PERFORM AS A FIXATION AND STABILIZATION UNIT OF BONE FRACTURES OR AS GUIDANCE AT INSERTION OF PINS INTO THE SKELETAL SYSTEM,CABLE GRIP (NON-STERILE)(NIL)-THE CABLE SYSTEM IS INTENDED TO PERFORM AS A FIXATION AND STABILIZATION UNIT OF BONE FRACTURES INCLUDING: ANKLE, ELBOW, HIP, KNEE AND SHOULDER FRACTURE FIXATION. SUPPLEMENTARY CERCLAGE FIXATION IN CONJUNCTION OF USING PLATES AND SCREWS. PERIPROSTHETIC FRACTURE FIXATION. TROCHANTERIC REATTACHMENT. BONE GRAFT MATERIAL STABILIZATION. ,POSTERIOR CERVICAL SYSTEM(NIL)-THE POSTERIOR CERVICAL SYSTEM IS INDICATED FOR USE IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION USING SCREWS AND RODS FIXATION IN THE POSTERIOR OCCIPITOCERVICAL SEGMENT AND CERVICAL SPINE. THE POSTERIOR CERVICAL SYSTEM CAN ALSO BE LINKED TO OTHER SCREW RODS SYSTEM, SUCH AS GSS-VII, DEVINE TL5.5/6.0 SYSTEM,TITANIUM MESH(NIL)-THE TITANIUM MESH IS INDICATED FOR USE TO REPLACE A DISEASED VERTEBRAL BODY RESECTED OR EXCISED FOR THE TREATMENT OF TUMORS AND FRACTURES, TO ACHIEVE THE DECOMPRESSION OF THE SPINAL CORD AND NEURAL TISSUES, AND TO RESTORE THE HEIGHT OF A COLLAPSED VERTEBRAL BODY. TITANIUM MESH ALSO INTENDED FOR USE WITH SUPPLEMENTAL INTERNAL FIXATION, SUCH AS GSS TANLOR-I SYSTEM,LOCKABLE INTRAMEDULLARY NAILS (NON-STERILE)(NIL)-THE INTRAMEDULLARY NAIL SYSTEM IS INTENDED TO PERFORM AS A FIXATION AND STABILIZATION UNIT OF BONE FRACTURES INCLUDING: 1. ACUTE FRACTURES 2. OSTEOTOMY. 3. NONUNIONS AND MALUNIONS. 4. BONE RECONSTRUCTION FOLLOWING TUMOR RESECTION, GRAFTING AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGICAL FRACTURES. 5. REVISION

	PROCEDURES WHERE OTHER TREATMENTS AND DEVICES HAVE FAILED. 6. IT IS INDICATED FOR SHAFT FRACTURES AND PERI-ARTICULAR FRACTURES

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2551	IMP/MD/2021/000230	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TEMPORARY ABUTMENT AND COPING(NA)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION AND ESTHETICS.,CLINICAL, PROSTHETIC AND ABUTMENT SCREWS(NA)-THE CLINICAL SCREW, ABUTMENT SCREW AND PROSTHETIC SCREW ARE INTENDED TO SECURE A DENTAL ABUTMENT OR FRAMEWORK TO A DENTAL IMPLANT OR ABUTMENT IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION.,DENTAL IMPLANTS (TITANIUM) (NOBELACTIVE®, NOBELPARALLEL™ CONICAL CONNECTION, NOBELSPEEDY®, REPLACE SELECT TAPERED PMC, BRÅNEMARK SYSTEM® MK III)-THESE IMPLANTS INTENDED TO BE USED IN THE UPPER OR LOWER JAW BONE (OSSEOINTEGRATION) AND USED FOR ANCHORING OR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION.,DENTAL IMPLANT(NOBELZYGOMA™)-NOBELZYGOMA™ IMPLANTS ARE ENDOSSEOUS IMPLANTS AND ARE INTEGRATED IN THE ZYGOMATIC BONE (OSSEOINTEGRATION). THEY ARE INTENDED TO BE USED FOR ANCHORING OR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION.,MULTI-UNIT ABUTMENT(NA)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. MULTI-UNIT ABUTMENT/XEAL™/PLUS IN COMBINATION WITH ENDOSSEOUS IMPLANTS ARE INDICATED FOR MULTIPLE UNIT RECONSTRUCTIONS WHEN SCREW-RETAINED PROSTHETICS IS PREFERRED.,TEMPORARY ABUTMENT AND COPING(NA)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION AND ESTHETICS.,CLINICAL, PROSTHETIC AND ABUTMENT SCREWS(NA)-THE CLINICAL SCREW, ABUTMENT SCREW AND PROSTHETIC SCREW ARE INTENDED TO SECURE A DENTAL ABUTMENT OR FRAMEWORK TO A DENTAL IMPLANT OR ABUTMENT IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION.,ON1 IOS HEALING CAPS(NA)-THE ON1 IOS HEALING CAP IS INTENDED TO BE USED IN THE UPPER OR LOWER JAW TO FACILITATE IN THE SCULPTURING OF SOFT TISSUE, DURING THE HEALING PHASE POST DENTAL IMPLANT SURGERY. THE ON1 IOS HEALING CAP IS INTENDED TO BE USED IN THE UPPER OR LOWER JAW TO FACILITATE DIGITAL CAPTURING OF THE INTRAORAL SITUATION USING AN APPROVED NOBEL BIOCARE INTRAORAL SCANNER, SO THAT AN

	INDIVIDUALIZED CAD/CAM RESTORATION CAN BE DESIGNED AND ORDERED ELECTRONICALLY, USING A NOBEL BIOCARE APPROVED CAD SYSTEM, AND THE INDIVIDUALIZED RESTORATION FABRICATED IN THE DENTAL LABORATORY, CLINIC OR HOSPITAL. THE ON1 IOS HEALING CAP HANDLE IS INTENDED TO BE USED TO FACILITATE THE INSERTION AND MOUNTING OF THE ON1 IOS HEALING CAP ONTO THE ON1 BASE INTRAORALLY. THE CLINICAL PROSTHETIC SCREW IS INTENDED TO FASTEN THE ON1 IOS HEALING CAP ONTO THE ON1 BASE.,COVER SCREWS(NA)-DENTAL IMPLANT COVER SCREWS ARE TO BE USED IN THE UPPER OR LOWER JAW CONNECTED TO THE ENDOSSEOUS IMPLANT TO PROTECT THE INTERNAL THREADS AND IMPLANT HEAD DURING THE HEALING PHASE.,GUIDED ABUTMENTS (NA)-THE NOBELGUIDE® GUIDED SURGERY SYSTEM IS INTENDED TO TRANSFER A TREATMENT PLANNING DONE BY THE CLINICIAN INTO A PHYSICAL/CLINICAL REALITY. THE SYSTEM IS INTENDED TO FACILITATE IMPLANT INSTALLATION WITH HIGH PREDICTABILITY AND CONTRIBUTE TO BETTER RESTORATION OF THESE IMPLANTS PLACED IN BOTH MANDIBLE AND MAXILA.,HEALING ABUTMENT, SCREW AND CAPS(NA)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. HEALING ABUTMENT AND HEALING CAP IS INTENDED TO BE USED AS A TEMPORARY COMPONENT TO AN ENDOSSEOUS IMPLANT TO ALLOW HEALING OF THE SOFT TISSUE.,ON1 BASE XEAL (NA)-THEY ARE INDICATED FOR USE IN THE MAXILLA OR MANDIBLE FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION.,ESTHETIC ABUTMENT(NA)-DENTAL IMPLANT ABUTMENTS ARE INTENDED TO BE USED IN THE UPPER OR LOWER JAW AND USED FOR SUPPORTING TOOTH REPLACEMENTS TO RESTORE CHEWING FUNCTION. THE ABUTMENTS IN COMBINATION WITH TWO-STAGE ENDOSSEOUS IMPLANTS ARE USED AS THE FOUNDATION FOR ANCHORING TOOTH REPLACEMENTS IN EITHER JAW. RESTORATIONS RANGE FROM REPLACING ONE SINGLE TOOTH TO FIXED PARTIAL DENTURES USING CEMENT-RETAINED SUPRA-CONSTRUCTIONS.

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2552	IMP/MD/2021/000232	1.License Holder Name: MIL MEDICAL DENTAL SYSTEMS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT ACCESSORIES (ABUTMENTS AND SCREWS)(NA)-FOR USE WITH A DENTAL IMPLANT FIXTURE TO PROVIDE SUPPORT FOR PROSTHETIC RESTORATIONS SUCH AS CROWNS, BRIDGE, OR OVERDENTURE, DENTAL IMPLANT FIXTURE(TOUAREG - S, OS, WP, NP, RP, ONE PIECE, SWELL)-FOR USE IN PARTIALLY OR DULLY EDENTULOUS MANDIBLES AND MAXILLAE, IN SUPPORT OF SINGLE OR MULTIPLE UNIT RESTORATIONS INCLUDING; CEMENTED RETAINED, SCREW RETAINED OR OVERDENTURE RESTORATIONS, AND FINAL OR TEMPORARY ABUTMENT SUPPORT FOR FIXED BRIDGEWORK

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2553	IMP/MD/2021/000233	1.License Holder Name: WIPRO GE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:X-RAY(OPTIMA XR200 AMX)-THE GE AUTOMATIC MOBILE X-RAY (AMX) OPTIMA XR200AMX IS INTENDED TO TAKE EXPOSURES UTILIZING FILM OR COMPUTED RADIOGRAPHY (CR); HOWEVER, THE OPTIMA XR200AMX CAN BE UPGRADED TO UTILIZE THE GE WIRELESS DETECTOR, WHICH IS INTENDED TO REPLACE RADIOGRAPHIC FILM SCREEN SYSTEMS IN ALL GENERAL-PURPOSE DIAGNOSTIC PROCEDURES, FOR DIGITAL RADIOGRAPHY (DR). OPTIMA XR200AMX IS A SELF-CONTAINED; BATTERY OPERATED MOBILE RADIOGRAPHIC IMAGING SYSTEMS DESIGNED TO GENERATE DIAGNOSTIC RADIOGRAPHIC IMAGES (MEDICAL X-RAYS) THAT MAY INCREASE THE ABILITY TO DETECT DISEASE OR INJURY EARLY ENOUGH FOR A MEDICAL PROBLEM TO BE MANAGED, TREATED, OR CURED. MEDICAL X-RAYS ARE USED IN MANY TYPES OF EXAMINATIONS AND PROCEDURES, SOME EXAMPLES INCLUDE: X-RAY RADIOGRAPHY,COMPUTED TOMOGRAPHY(REVOLUTION CT)-THE SYSTEM IS INTENDED FOR HEAD, WHOLE BODY, CARDIAC AND VASCULAR X-RAY COMPUTED TOMOGRAPHY APPLICATIONS.,COMPUTED TOMOGRAPHY (REVOLUTION DISCOVERY CT)-THE SYSTEM IS INTENDED FOR HEAD, WHOLE BODY, CARDIAC AND VASCULAR X-RAY COMPUTED TOMOGRAPHY APPLICATIONS. THE COMPUTED TOMOGRAPHY X-RAY SYSTEM IS INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA TAKEN AT DIFFERENT ANGLES AND PLANES, INCLUDING AXIAL, CINE, HELICAL (VOLUMETRIC), CARDIAC, SPECTRAL, AND GATED ACQUISITIONS FOR ALL AGES. THESE IMAGES MAY BE OBTAINED EITHER WITH OR WITHOUT CONTRAST. THIS DEVICE MAY INCLUDE SIGNAL ANALYSIS AND DISPLAY EQUIPMENT, PATIENT AND EQUIPMENT SUPPORTS, COMPONENTS AND ACCESSORIES. THIS DEVICE MAY INCLUDE DATA AND IMAGE PROCESSING TO PRODUCE IMAGES IN A VARIETY OF TRANS-AXIAL AND REFORMATTED PLANES. FURTHER THE IMAGES CAN BE POST PROCESSED TO PRODUCE ADDITIONAL IMAGING PLANES OR ANALYSIS RESULTS. THE SYSTEM IS INDICATED FOR HEAD, WHOLE BODY, CARDIAC AND VASCULAR X-RAY COMPUTED TOMOGRAPHY APPLICATIONS FOR BOTH SINGLE KV ACQUISITIONS AND WITH FAST KV SWITCHING SPECTRAL IMAGING OPTION (GSI).,COMPUTED TOMOGRAPHY(REVOLUTION APEX)-THE SYSTEM IS INTENDED FOR HEAD, WHOLE BODY, CARDIAC AND VASCULAR X-RAY COMPUTED TOMOGRAPHY APPLICATIONS.,PETCT(DISCOVERY MI)-THE DISCOVERY MI PET/CT SYSTEM IS INTENDED FOR CT ATTENUATION CORRECTED, ANATOMICALLY LOCALIZED PET IMAGING OF THE

		DISTRIBUTION OF POSITRON-EMITTING RADIOPHARMACEUTICALS. IT IS INTENDED TO IMAGE THE WHOLE BODY, HEAD, HEART, BRAIN, LUNG, BREAST, BONE, THE GASTROINTESTINAL AND LYMPHATIC SYSTEMS, AND OTHER ORGANS. THE SYSTEM IS ALSO INTENDED FOR STAND-ALONE, DIAGNOSTIC CT IMAGING,X-RAY(OPTIMA XR 240 AMX)-OPTIMA XR240AMX IS A SELF-CONTAINED; BATTERY OPERATED MOBILE RADIOGRAPHIC IMAGING SYSTEMS DESIGNED TO GENERATE DIAGNOSTIC RADIOGRAPHIC IMAGES (MEDICAL X-RAY$) THAT MAY INCREASE THE ABILITY TO DETECT DISEASE OR INJURY EARLY ENOUGH FOR A MEDICAL PROBLEM TO BE MANAGED, TREATED, OR CURED. MEDICAL X-RAYS ARE USED IN MANY TYPES OF EXAMINATIONS AND PROCEDURES, SOME EXAMPLES INCLUDE: X-RAY RADIOGRAPHY (TO FIND ORTHOPEDIC DAMAGE, TUMORS, PNEUMONIAS, FOREIGN OBJECTS).,X-RAY SYSTEM(OPTIMA XR220AMX)-THE GE AUTOMATIC MOBILE X-RAY (AMX) OPTIMA XR220AMX IS INTENDED TO TAKE EXPOSURES UTILIZING FILM, COMPUTED RADIOGRAPHY (CR), AND THE GE WIRELESS DETECTOR, WHICH IS INTENDED TO REPLACE RADIOGRAPHIC FILM SCREEN SYSTEMS IN ALL GENERAL-PURPOSE DIAGNOSTIC PROCEDURES, FOR DIGITAL RADIOGRAPHY (DR).THE SYSTEM IS INDICATED FOR TAKING RADIOGRAPHIC EXPOSURES OF THE SKULL, SPINAL COLUMN, CHEST, ABDOMEN, EXTREMITIES, AND OTHER BODY PARTS WITH THE PATIENT SITTING, STANDING, OR LYING IN THE PRONE OR SUPINE POSITION.,COMPUTED TOMOGRAPHY(REVOLUTION CT ES)-THE SYSTEM IS INTENDED FOR HEAD, WHOLE BODY, CARDIAC AND VASCULAR X-RAY COMPUTED TOMOGRAPHY APPLICATIONS.
2554	IMP/MD/2021/000234	1.License Holder Name: CARDIOMED INDIA LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABSORBABLE GELATIN SPONGE HEMOSTAT(GELITA-SPON®)-TOPICAL HEMOSTAT FOR USE AS AN ADJUNCT TO HEMOSTASIS BY TAMPONADE EFFECT, IN PARTICULAR WHERE CONTROL OF CAPILLARY, VENOUS, /AND ARTERIOLAR BLEEDING, BY PRESSURE, LIGATURE, AND OTHER CONVENTIONAL PROCEDURES, IS EITHER INEFFECTIVE OR IMPRACTICAL.,ABSORBABLE OXIDIZED CELLULOSE HEMOSTAT (GELITA-CEL®)-TOPICAL HEMOSTAT FOR USE AS AN ADJUNCT TO HEMOSTASIS BY TAMPONADE EFFECT, IN PARTICULAR WHERE CONTROL OF CAPILLARY, VENOUS, AND ARTERIOLAR BLEEDING, BY PRESSURE, LIGATURE, AND OTHER CONVENTIONAL PROCEDURES, IS EITHER INEFFECTIVE OR IMPRACTICAL.

2555	IMP/MD/2021/000235	1.License Holder Name: MEDENTIS DENTAL SOLUTIONS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL SCREWS WITH HEALING CAPS(ICX)-DENTAL HEALING CAPS AND COVER SCREWS ARE INDICATED FOR USE IN RESTORATIVE APPLICATIONS FOR THE UPPER OR LOWER JAW TO COVER THE IMPLANT DURING SUBMERGED HEALING AND/OR FORM A GINGIVAL PROFILE DURING THE HEALING PERIOD,DENTAL ABUTMENT(ICX)-DENTAL ABUTMENTS ARE INDICATED FOR USE IN SURGICAL AND RESTORATIVE APPLICATIONS FOR THE UPPER OR LOWER JAW TO PROVIDE SUPPORT FOR PROSTHETIC DEVICES FOR THE RECONSTRUCTION OF FUNCTION AND ESTHETICS.,DENTAL IMPLANT(ICX)-THE DENTAL IMPLANTS ARE PLACED IN MAXILLA AND/OR MANDIBLE AND ARE USED FOR THE FIXATION OF DENTAL PROSTHESES FOR THE REHABILITATION OF CHEWING FUNCTION AND AESTHETICS.

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2556	IMP/MD/2021/000236	1.License Holder Name: AVANOS MEDICAL INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ON-Q* PAIN RELIEF SYSTEM WITH SELECT-A-FLOW AND ONDEMAND(AVANOS)-ON-Q PUMP IS INTENDED TO PROVIDE CONTINUOUS DELIVERY OF MEDICATION (SUCH AS LOCAL ANAESTHETICS) TO OR AROUND SURGICAL WOUND SITES AND/OR CLOSE PROXIMITY TO NERVES FOR PREOPERATIVE, PERIOPERATIVE AND POSTOPERATIVE REGIONAL ANAESTHESIA AND/OR PAIN MANAGEMENT. ROUTES OF ADMINISTRATION INCLUDE: INTRAOPERATIVE SITE, PERINEURAL, PERCUTANEOUS AND EPIDURAL. ON-Q* PUMP IS INDICATED TO SIGNIFICANTLY DECREASE PAIN AND NARCOTIC USE WHEN USED TO DELIVER LOCAL ANESTHETICS TO OR AROUND SURGICAL WOUND SITES, OR CLOSE PROXIMITY TO NERVES, WHEN COMPARED TO NARCOTIC ONLY PAIN MANAGEMENT.,ON-Q* PAIN RELIEF SYSTEM WITH SOAKER CATHETER(AVANOS)-ON-Q* CATHETERS ARE INDICATED FOR THE DELIVERY OF MEDICATION (SUCH AS LOCAL ANESTHETICS) TO OR AROUND SURGICAL WOUND SITES FOR PREOPERATIVE, PERIOPERATIVE AND POSTOPERATIVE PAIN MANAGEMENT. IN ADDITION TO THESE INDICATIONS, THE SPECIFIC CATHETERS BELOW HAVE THE FOLLOWING ADDITIONAL INDICATIONS: ON-Q* SOAKER, NON-SOAKER AND EPIDURAL CATHETERS ARE ALSO INDICATED FOR PERINEURAL DELIVERY.,ON-Q* PAIN RELIEF SYSTEM WITH SELECT-A-FLOW*(AVANOS)-ON-Q PUMP IS INTENDED TO PROVIDE CONTINUOUS DELIVERY OF MEDICATION (SUCH AS LOCAL ANAESTHETICS) TO OR AROUND SURGICAL WOUND SITES AND/OR CLOSE PROXIMITY TO NERVES FOR PREOPERATIVE, PERIOPERATIVE AND POSTOPERATIVE REGIONAL ANAESTHESIA AND/OR PAIN MANAGEMENT. ROUTES OF ADMINISTRATION INCLUDE: INTRAOPERATIVE SITE, PERINEURAL, PERCUTANEOUS AND EPIDURAL. ON-Q* PUMP IS INDICATED TO SIGNIFICANTLY DECREASE PAIN AND NARCOTIC USE WHEN USED TO DELIVER LOCAL ANESTHETICS TO OR AROUND SURGICAL WOUND SITES, OR CLOSE PROXIMITY TO NERVES, WHEN COMPARED TO NARCOTIC ONLY PAIN MANAGEMENT,ON-Q* T-PEEL INTRODUCER NEEDLES(AVANOS)-ON-Q* INTRODUCERS ARE INTENDED FOR THE PERCUTANEOUS INTRODUCTION AND PLACEMENT OF ON-Q* CATHETERS. INTRODUCERS, WITH A LUER HUB MAY BE USED TO ASPIRATE OR INJECT A BOLUS OF FLUID OR MEDICATION PRIOR TO PLACING THE CATHETER,ON-Q* TUNNELERS AND SHEATHS, DISPOSABLE(AVANOS)-ON-Q* INTRODUCERS ARE INTENDED FOR THE PERCUTANEOUS INTRODUCTION AND PLACEMENT OF ON-Q* CATHETERS. INTRODUCERS, WITH A LUER HUB MAY BE USED TO ASPIRATE OR INJECT A BOLUS OF FLUID OR MEDICATION PRIOR TO

	PLACING THE CATHETER,ON-Q* TUNNELER INTRODUCER SHEATHS (AVANOS)-ON-Q* INTRODUCERS ARE INTENDED FOR THE PERCUTANEOUS INTRODUCTION AND PLACEMENT OF ON-Q* CATHETERS. INTRODUCERS, WITH A LUER HUB MAY BE USED TO ASPIRATE OR INJECT A BOLUS OF FLUID OR MEDICATION PRIOR TO PLACING THE CATHETER,ON-Q* EXPANSION KITS WITH SOAKER CATHETER(AVANOS)-ON-Q* CATHETERS ARE INDICATED FOR THE DELIVERY OF MEDICATION (SUCH AS LOCAL ANAESTHETICS) TO OR AROUND SURGICAL WOUND SITES FOR PREOPERATIVE, PERIOPERATIVE AND POSTOPERATIVE PAIN MANAGEMENT. IN ADDITION TO THESE INDICATIONS, THE SPECIFIC CATHETERS BELOW HAVE THE FOLLOWING ADDITIONAL INDICATIONS: ON-Q* SOAKER, NON-SOAKER AND EPIDURAL CATHETERS ARE ALSO INDICATED FOR PERINEURAL DELIVERY. ON-Q* SILVERSOAKER* CONTAINS AN ANTIMICROBIAL AGENT WHICH MAY DESTROY OR INHIBIT THE GROWTH OF MICROORGANISMS ON BOTH THE INNER AND OUTER SURFACES OF THE CATHETER. THE ANTIMICROBIAL AGENT IS INTENDED TO REDUCE THE POSSIBILITY THAT THE CATHETER MAY BECOME MICROBIALLY COMPROMISED. THE ANTIMICROBIAL AGENT IS NOT INTENDED TO BE USED AS A TREATMENT FOR EXISTING INFECTIONS.,ON-Q* PAIN RELIEF SYSTEM WITH DUAL SOAKER CATHETER(AVANOS)-ON-Q* CATHETERS ARE INDICATED FOR THE DELIVERY OF MEDICATION (SUCH AS LOCAL ANESTHETICS) TO OR AROUND SURGICAL WOUND SITES FOR PREOPERATIVE, PERIOPERATIVE AND POSTOPERATIVE PAIN MANAGEMENT. IN ADDITION TO THESE INDICATIONS, THE SPECIFIC CATHETERS BELOW HAVE THE FOLLOWING ADDITIONAL INDICATIONS: ON-Q* SOAKER, NON-SOAKER AND EPIDURAL CATHETERS ARE ALSO INDICATED FOR PERINEURAL DELIVERY.,ON-Q* ANTIMICROBIAL EXPANSION KITS WITH SILVERSOAKER ANTIMICROBIAL CATHETER(AVANOS)-ON-Q* CATHETERS ARE INDICATED FOR THE DELIVERY OF MEDICATION (SUCH AS LOCAL ANAESTHETICS) TO OR AROUND SURGICAL WOUND SITES FOR PREOPERATIVE, PERIOPERATIVE AND POSTOPERATIVE PAIN MANAGEMENT. IN ADDITION TO THESE INDICATIONS, THE SPECIFIC CATHETERS BELOW HAVE THE FOLLOWING ADDITIONAL INDICATIONS: ON-Q* SOAKER, NON-SOAKER AND EPIDURAL CATHETERS ARE ALSO INDICATED FOR PERINEURAL DELIVERY. ON-Q* SILVERSOAKER* CONTAINS AN ANTIMICROBIAL AGENT WHICH MAY DESTROY OR INHIBIT THE GROWTH OF MICROORGANISMS ON BOTH THE INNER AND OUTER SURFACES OF THE CATHETER. THE ANTIMICROBIAL AGENT IS INTENDED TO REDUCE THE POSSIBILITY THAT THE CATHETER MAY BECOME MICROBIALLY COMPROMISED. THE ANTIMICROBIAL AGENT IS NOT INTENDED TO BE USED AS A TREATMENT FOR EXISTING INFECTIONS.,ON-Q* PAIN RELIEF SYSTEM

	PUMP WITH FIXED FLOW RATE(AVANOS)-ON-Q PUMP IS INTENDED TO PROVIDE CONTINUOUS DELIVERY OF MEDICATION (SUCH AS LOCAL ANAESTHETICS) TO OR AROUND SURGICAL WOUND SITES AND/OR CLOSE PROXIMITY TO NERVES FOR PREOPERATIVE, PERIOPERATIVE AND POSTOPERATIVE REGIONAL ANAESTHESIA AND/OR PAIN MANAGEMENT. ROUTES OF ADMINISTRATION INCLUDE: INTRAOPERATIVE SITE, PERINEURAL, PERCUTANEOUS AND EPIDURAL. ON-Q* PUMP IS INDICATED TO SIGNIFICANTLY DECREASE PAIN AND NARCOTIC USE WHEN USED TO DELIVER LOCAL ANAESTHETICS TO OR AROUND SURGICAL WOUND SITES, OR CLOSE PROXIMITY TO NERVES, WHEN COMPARED TO NARCOTIC ONLY PAIN MANAGEMENT.,ON-Q* PAIN RELIEF SYSTEM WITH ONDEMAND (AVANOS)-ON-Q PUMP IS INTENDED TO PROVIDE CONTINUOUS DELIVERY OF MEDICATION (SUCH AS LOCAL ANAESTHETICS) TO OR AROUND SURGICAL WOUND SITES AND/OR CLOSE PROXIMITY TO NERVES FOR PREOPERATIVE, PERIOPERATIVE AND POSTOPERATIVE REGIONAL ANAESTHESIA AND/OR PAIN MANAGEMENT. ROUTES OF ADMINISTRATION INCLUDE: INTRAOPERATIVE SITE, PERINEURAL, PERCUTANEOUS AND EPIDURAL. ON-Q* PUMP IS INDICATED TO SIGNIFICANTLY DECREASE PAIN AND NARCOTIC USE WHEN USED TO DELIVER LOCAL ANESTHETICS TO OR AROUND SURGICAL WOUND SITES, OR CLOSE PROXIMITY TO NERVES, WHEN COMPARED TO NARCOTIC ONLY PAIN MANAGEMENT.,ON-Q* PAIN RELIEF SYSTEM WITH DUAL SITES(AVANOS)-ON-Q PUMP IS INTENDED TO PROVIDE CONTINUOUS DELIVERY OF MEDICATION (SUCH AS LOCAL ANAESTHETICS) TO OR AROUND SURGICAL WOUND SITES AND/OR CLOSE PROXIMITY TO NERVES FOR PREOPERATIVE, PERIOPERATIVE AND POSTOPERATIVE REGIONAL ANAESTHESIA AND/OR PAIN MANAGEMENT. ROUTES OF ADMINISTRATION INCLUDE: INTRAOPERATIVE SITE, PERINEURAL, PERCUTANEOUS AND EPIDURAL. ON-Q* PUMP IS INDICATED TO SIGNIFICANTLY DECREASE PAIN AND NARCOTIC USE WHEN USED TO DELIVER LOCAL ANAESTHETICS TO OR AROUND SURGICAL WOUND SITES, OR CLOSE PROXIMITY TO NERVES, WHEN COMPARED TO NARCOTIC ONLY PAIN MANAGEMENT

2557	IMP/MD/2021/000237	1.License Holder Name: DORA MEDICAL TRADING (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HAEMODIALYSIS MACHINE(DORA)-DORA- 6000 HAEMODIALYSIS MACHINE IS USED FOR BLOOD DIALYSIS TREATMENT FOR THE PATIENTS WITH CHRONIC KIDNEY FAILURE. IT CAN BE USED IN VARIOUS MEDICAL CENTERS AND CLINICS.
2558	IMP/MD/2021/000238	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DURAL REPAIR PATCH (DURA-GUARD)-DURA-GUARD IS USED AS DURA SUBSTITUTE FOR THE CLOSURE OF DURA MATER DURING NEUROSURGERY
2559	IMP/MD/2021/000239	1.License Holder Name: MAXLIFE HEALTH ENTERPRISES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (INFRARED)(WELCH ALLYN CARETEMP™ TOUCH FREE THERMOMETER)-THE CARETEMP™ TOUCH FREE THERMOMETER IS A CLINICAL-GRADE DEVICE INTENDED FOR THE INTERMITTENT MEASUREMENT OF HUMAN BODY TEMPERATURE IN PATIENTS OF ALL AGES IN A PROFESSIONAL-USE ENVIRONMENT.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2560	IMP/MD/2021/000240	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)(NA)-"THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD" ,SYNAPSE(NA)-"THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: — TOP-LOADING VARIABLE AXIS SCREWS — HOOKS — TRANSVERSE BARS — RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY." ,VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)(NA)-"THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF

	COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD" ,CABLE IMPLANTS(NA)-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE.,INTERNAL MIDFACE DISTRACTOR(NA)-THE INTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. ,SYNAPSE(NA)-"THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: — TOP-LOADING VARIABLE AXIS SCREWS — HOOKS — TRANSVERSE BARS — RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY." ,INTERNAL MIDFACE DISTRACTOR(NA)-THE INTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. ,INTERNAL MIDFACE DISTRACTOR(NA)-THE INTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. ,VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)(NA)-"THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION

	PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD" ,UNIVERSAL SPINE SYSTEM (USS)(NA)- "THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION. " ,CABLE IMPLANTS(NA)-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE., VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)(NA)- "THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX —

	IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD" ,EXTERNAL MIDFACE DISTRACTOR(NA)-THE DEPUY SYNTHES EXTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. ,AXON AND OC FUSION (NA)-"THE AXON SYSTEM IS A COMPREHENSIVE SET OF INSTRUMENTS AND IMPLANTS, INCLUDING — TOP-LOADING VARIABLE AXIS SCREWS, — HOOKS, — TRANSVERSE BARS AND — RODS. IT IS DESIGNED FOR POSTERIOR STABILISATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY. THE AXON SYSTEM USES THE EXISTING CERVIFIX RODS, ALLOWING COMPONENTS FROM AXON AND CERVIFIX TO BE COMBINED. THIS ALLOWS A CONSTRUCT TO EXTEND FROM THE OCCIPUT TO THE LOWER SPINE USING THE UNIVERSAL SPINE SYSTEM (USS)." ,CABLE IMPLANTS(NA)-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE.,UNIVERSAL SPINE SYSTEM (USS)(NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION. " ,VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)(NA)-"THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL

	DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD" ,POSTERIOR RODS(NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION. " ,POSTERIOR RODS(NA)-"THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: — TOP-LOADING VARIABLE AXIS SCREWS — HOOKS — TRANSVERSE BARS — RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS

	PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY. CERVIFIX IS A MODULAR TENSION BAND SYSTEM FOR POSTERIOR FIXATION OF THE OCCIPITOCERVICAL SPINE, UPPER AND LOWER CERVICAL SPINE, AND UPPER THORACIC SPINE (T2). A CHOICE OF CLAMPS ARE FIXED ON A ROD BY MEANS OF SET SCREWS. BONE SCREWS CAN BE OPTIMALLY POSITIONED THROUGH THE CLAMPS IN THE DESIRED DIRECTION AT EACH LEVEL. THE AXON SYSTEM IS A COMPREHENSIVE SET OF INSTRUMENTS AND IMPLANTS, INCLUDING —TOP-LOADING VARIABLE AXIS SCREWS, —HOOKS, —TRANSVERSE BARS AND —RODS. IT IS DESIGNED FOR POSTERIOR STABILISATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY. THE AXON SYSTEM USES THE EXISTING CERVIFIX RODS, ALLOWING COMPONENTS FROM AXON AND CERVIFIX TO BE COMBINED. THIS ALLOWS A CONSTRUCT TO EXTEND FROM THE OCCIPUT TO THE LOWER SPINE USING THE UNIVERSAL SPINE SYSTEM (USS). THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION." ,SYNAPSE(NA)-"THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: —TOP-LOADING VARIABLE AXIS SCREWS — HOOKS — TRANSVERSE BARS — RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE

	VARIATIONS IN PATIENT ANATOMY." ,CABLE IMPLANTS(NA)-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE. ,MAXILLARY DISTRACTOR (NA)-"THE MAXILLARY DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. THE INTERNAL MIDFACE DISTRACTOR, THE MAXILLARY DISTRACTOR, THE SINGLE VECTOR DISTRACTOR, THE EXTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. THE CRANIOMAXILLOFACIAL (CMF) DISTRACTOR AND SYNTHES MULTI-VECTOR DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING (AND/OR TRANSPORT) DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. UNIVERSAL SCREW REMOVAL SET IS INTENDED TO BE USED FOR THE REMOVAL OF INTACT AND DAMAGED SCREWS. IT IS NOT INTENDED TO BE USED IN COMBINATION WITH A POWER TOOL." ,VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)(NA)-"THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD" ,CABLE IMPLANTS(NA)-CABLE IMPLANTS ARE INTENDED FOR FIXATION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS BY USING STANDARD CERCLAGE OR TENSION BAND TECHNIQUE. ,VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)(NA)-"THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL

	DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD" ,SYNMESH(NA)-"SYNMESH IS A VERTEBRAL BODY REPLACEMENT DEVICE FOR THE CERVICAL, THORACIC AND LUMBAR SPINE. TITANIUM IMPLANTS IN VARIOUS FOOTPRINTS AND HEIGHTS ENABLE THE SURGEON TO CHOOSE THE CONFIGURATION THAT IS BEST SUITED TO THE PATIENT'S INDIVIDUAL PATHOLOGY AND ANATOMY. THE MESH MAY ALSO BE TRIMMED FOR A CUSTOM FIT. THE IMPLANTS CAN BE INSERTED ANTERIORLY, LATERALLY OR ANTEROLATERALLY." ,MAXILLARY DISTRACTOR(NA)-"THE MAXILLARY DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. THE INTERNAL MIDFACE DISTRACTOR, THE MAXILLARY DISTRACTOR, THE SINGLE VECTOR DISTRACTOR, THE EXTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. THE CRANIOMAXILLOFACIAL (CMF) DISTRACTOR AND SYNTHES MULTI-VECTOR DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING (AND/OR TRANSPORT) DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. UNIVERSAL SCREW REMOVAL SET IS INTENDED TO BE USED FOR THE REMOVAL OF INTACT AND DAMAGED SCREWS. IT IS NOT INTENDED TO BE USED IN COMBINATION WITH A POWER TOOL." ,SYNAPSE(NA)-"THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: — TOP-LOADING VARIABLE AXIS SCREWS — HOOKS — TRANSVERSE BARS — RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS

	PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY." ,POSTERIOR CONNECTORS(NA)-"THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION." ,SYNMESH (NA)-"SYNMESH IS A VERTEBRAL BODY REPLACEMENT DEVICE FOR THE CERVICAL, THORACIC AND LUMBAR SPINE. TITANIUM IMPLANTS IN VARIOUS FOOTPRINTS AND HEIGHTS ENABLE THE SURGEON TO CHOOSE THE CONFIGURATION THAT IS BEST SUITED TO THE PATIENT'S INDIVIDUAL PATHOLOGY AND ANATOMY. THE MESH MAY ALSO BE TRIMMED FOR A CUSTOM FIT. THE IMPLANTS CAN BE INSERTED ANTERIORLY, LATERALLY OR ANTEROLATERALLY." , INTERNAL MIDFACE DISTRACTOR(NA)-THE INTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED. ,VERTICAL EXPANDABLE PROSTHETIC TITANIUM RIB (VEPTR)(NA)-"THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR

		VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: — INCREASE THORACIC VOLUME — SCOLIOSIS CORRECTION — THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX — IMPROVE THORACIC FUNCTION — AVOIDING GROWTH INHIBITION PROCEDURES — MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD"
2561	IMP/MD/2021/000243	1.License Holder Name: M/S VASCULAR CONCEPTS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PERIPHERAL STENT SYSTEM- SELF EXPANDABLE NITINOL STENT SYSTEM (NON-STERILE) (RESISTANT- SELF EXPANDABLE NITINOL STENT SYSTEM (NON-STERILE))-IT IS INDICATED FOR THE FOLLOWING APPLICATIONS- • ATHEROSCLEROTIC DISEASE OF THE PERIPHERAL ARTERIES, EG ILIAC, FEMORALIS AND FEMORALIS SUPERFICIALIS AND IN OTHER VESSELS WHICH CORRESPOND IN THEIR ANATOMIC DIMENSIONS TO THE AVAILABLE SIZES OF THE STENTS. • TREATMENT OF BILE DUCT STRICTURES.
2562	IMP/MD/2021/000244	1.License Holder Name: SARA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL BLOOD PRESSURE MONITOR (ARM TYPE)(SARA+CARE)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.
2563	IMP/MD/2021/000245	1.License Holder Name: STERIS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISINFECTANT(VAPROX® HC STERILANT)-VAPROX HC STERILANT IS USED EXCLUSIVELY IN THE V-PRO LOW TEMPERATURE STERILIZATION SYSTEMS FOR TERMINAL STERILIZATION OF CLEANED RINSED AND DRIED REUSABLE METAL AND NONMETAL MEDICAL DEVICES USED IN HEALTHCARE FACILITIES,DISINFECTANT(VAPROX® HC STERILANT)-VAPROX HC STERILANT IS USED EXCLUSIVELY IN THE V-PRO LOW TEMPERATURE STERILIZATION SYSTEMS FOR TERMINAL STERILIZATION OF CLEANED RINSED AND DRIED REUSABLE METAL AND NONMETAL MEDICAL DEVICES USED IN HEALTHCARE FACILITIES.

2564	IMP/MD/2021/000246	1.License Holder Name: M/S DENTSPLY INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:METAL VENEERING PORCELAIN(CERAMCO 3)-CERAMCO 3 VENEERING PORCELAINS MAY BE USED FOR ALL SINGLE AND MULTIPLE UNIT PORCELAIN FUSED-TO-METAL FIXED PROSTHODONTICS.,ALL-CERAMIC VENEERING PORCELAIN(CELTRA CERAM)-CELTRA CERAM IS SUITABLE FOR VENEERING ALL-CERAMIC FRAMEWORKS.,UNIVERSAL STAIN AND GLAZE/OVERGLAZE(UNIVERSAL STAIN AND GLAZE/OVERGLAZE)-DENTSPLY SIRONA UNIVERSAL STAIN AND GLAZE ARE INDICATED FOR STAINING AND GLAZING THE FOLLOWING RESTORATIONS: CELTRA PRESS ZIRCONIA REINFORCED LITHIUM SILICATE (ZLS); CELTRA DUO ZIRCONIA REINFORCED LITHIUM SILICATE (ZLS); CERCON HT ZIRCONIA; CERAMCO PFZ PORCELAIN FOR ZIRCONIA; CERCON CERAM KISS PORCELAIN; CERAMCO 3 PORCELAIN; CERAMCO IC PORCELAIN; DUCERAM KISS PORCELAIN

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2565	IMP/MD/2021/000247	1.License Holder Name: WIPRO GE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAGNETIC RESONANCE (SIGNA EXPLORER)-SIGNA EXPLORER IS A WHOLE BODY MAGNETIC RESONANCE SCANNERS DESIGNED TO SUPPORT HIGH RESOLUTION, HIGH SIGNAL-TO-NOISE RATIO, AND SHORT SCAN TIMES. IT IS INDICATED FOR USE AS A DIAGNOSTIC IMAGING DEVICE TO PRODUCE AXIAL, SAGITTAL, CORONAL, AND OBLIQUE IMAGES, SPECTROSCOPIC IMAGES, PARAMETRIC MAPS, AND/OR SPECTRA, DYNAMIC IMAGES OF THE STRUCTURES AND/OR FUNCTIONS OF THE ENTIRE BODY, INCLUDING, BUT NOT LIMITED TO, HEAD, NECK, TMJ, SPINE, BREAST, HEART, ABDOMEN, PELVIS, JOINTS, PROSTATE, BLOOD VESSELS, AND MUSCULOSKELETAL REGIONS OF THE BODY. DEPENDING ON THE REGION OF INTEREST BEING IMAGED, CONTRAST AGENTS MAY BE USED.,MAGNETIC RESONANCE(SIGNA VOYAGER)-THE SIGNA VOYAGER IS A WHOLE BODY MAGNETIC RESONANCE SCANNER DESIGNED TO SUPPORT HIGH RESOLUTION, HIGH SIGNAL-TO-NOISE RATIO, AND SHORT SCAN TIME IMAGING. THE SIGNA VOYAGER IS INDICATED FOR USE AS A DIAGNOSTIC IMAGING DEVICE TO PRODUCE AXIAL, SAGITTAL, CORONAL, AND OBLIQUE IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, DYNAMIC IMAGES, AND PARAMETRIC MAPS OF THE INTERNAL STRUCTURES AND ORGANS OF THE ENTIRE BODY. BODY STRUCTURES FOR EVALUATION INCLUDE, BUT ARE NOT LIMITED TO: HEAD, NECK, TMJ, SPINE, BREAST, HEART, ABDOMEN, PELVIS, JOINTS, PROSTATE, BLOOD VESSELS, AND MUSCULOSKELETAL REGIONS OF THE BODY. DEPENDING ON THE REGION OF INTEREST BEING IMAGED, CONTRAST AGENTS MAY BE USED. THE IMAGES PRODUCED BY THE SIGNA VOYAGER REFLECT THE SPATIAL DISTRIBUTION AND/OR MOLECULAR ENVIRONMENT OF NUCLEI EXHIBITING MAGNETIC RESONANCE. THESE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS.,MAGNETIC RESONANCE(SIGNA CREATOR)-SIGNA CREATOR IS A WHOLE BODY MAGNETIC RESONANCE SCANNERS DESIGNED TO SUPPORT HIGH RESOLUTION, HIGH SIGNAL-TO-NOISE RATIO, AND SHORT SCAN TIMES. IT IS INDICATED FOR USE AS A DIAGNOSTIC IMAGING DEVICE TO PRODUCE AXIAL, SAGITTAL, CORONAL, AND OBLIQUE IMAGES, SPECTROSCOPIC IMAGES, PARAMETRIC MAPS, AND/OR SPECTRA, DYNAMIC IMAGES OF THE STRUCTURES AND/OR FUNCTIONS OF THE ENTIRE BODY, INCLUDING, BUT NOT LIMITED TO, HEAD, NECK, TMJ, SPINE, BREAST, HEART, ABDOMEN, PELVIS, JOINTS, PROSTATE, BLOOD VESSELS, AND MUSCULOSKELETAL REGIONS OF THE BODY. DEPENDING ON THE REGION OF INTEREST BEING IMAGED, CONTRAST AGENTS MAY BE USED.

2566	IMP/MD/2021/000248	1.License Holder Name: MAXLIFE HEALTH ENTERPRISES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE CUFFS (WELCH ALLYN FLEXIPORT)-THE CUFF CAN BE USED IN CONJUNCTION WITH NON-AUTOMATED AND AUTOMATED SPHYGMOMANOMETERS TO DETERMINE A SUBJECT'S BLOOD PRESSURE. THE CUFF CAN BE USED AS A VENOUS TOURNIQUET FOR INSERTING INTRAVENOUS CANNULA.,ELECTRONIC THERMOMETER (WELCH ALLYN SURE TEMP® PLUS)-THE WELCH-ALLYN SURETEMP PLUS THERMOMETER MEASURES PATIENT'S TEMPERATURE IN THE ORAL, AXILLARY, AND RECTAL BODY SITES OF ADULT, PAEDIATRIC, AND NEW-BORN PATIENTS. THE DEVICE IS NOT DESIGNED, SOLD, OR INTENDED FOR USE EXCEPT AS INDICATED,ANEROID SPHYGMOMANOMETER (HANDHELD- INTEGRATED)(WELCH ALLYN DURA SHOCK™)-WELCH ALLYN NON-AUTOMATED SPHYGMOMANOMETERS ARE NON- INVASIVE BLOOD PRESSURE MEASURING DEVICES INTENDED FOR USE IN CONJUNCTION WITH AN INFLATABLE CUFF AND STETHOSCOPE TO DETERMINE SYSTOLIC AND DIASTOLIC BLOOD PRESSURE IN HUMANS AND ANIMALS, ANEROID SPHYGMOMANOMETER (HANDHELD -THUMBSCREW MODEL)(WELCH ALLYN DURA SHOCK™)-WELCH ALLYN NON-AUTOMATED SPHYGMOMANOMETERS ARE NON- INVASIVE BLOOD PRESSURE MEASURING DEVICES INTENDED FOR USE IN CONJUNCTION WITH AND INFLATABLE CUFF AND STETHOSCOPE TO DETERMINE SYSTOLIC AND DIASTOLIC BLOOD PRESSURE IN HUMANS AND ANIMALS,ANEROID SPHYGMOMANOMETER (MOUNTED-WALL, MOBILE AND DESK)(WELCH ALLYN 767 WALL AND MOBILE ANEROIDS)-WELCH ALLYN ANEROID SPHYGMOMANOMETERS ARE USED BY PROFESSIONAL HEALTHCARE PROVIDERS AND INDIVIDUALS TRAINED IN AUSCULTATORY BLOOD PRESSURE TECHNIQUE TO DETERMINE SYSTOLIC AND DIASTOLIC BLOOD PRESSURE IN HUMANS AND ANIMALS.,ANEROID SPHYGMOMANOMETER (HANDHELD - TRIGGER MODEL)(WELCH ALLYN DURA SHOCK™)-WELCH ALLYN NON-AUTOMATED SPHYGMOMANOMETERS ARE NON- INVASIVE BLOOD PRESSURE MEASURING DEVICES INTENDED FOR USE IN CONJUNCTION WITH AND INFLATABLE CUFF AND STETHOSCOPE TO DETERMINE SYSTOLIC AND DIASTOLIC BLOOD PRESSURE IN HUMANS AND ANIMALS.

2567	IMP/MD/2021/000249	1.License Holder Name: ASHOK ENTERPRISES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL BLOOD PRESSURE MONITOR (ARM TYPE)(NA)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.
2568	IMP/MD/2021/000255	1.License Holder Name: CJ MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ATOMS-ADJUSTABLE CUSHION SYSTEM FOR THE SURGICAL TREATMENT OF INTRINSIC SPHINCTER INSUFFICIENCY

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2569	IMP/MD/2021/000256	1.License Holder Name: ZB DENTAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL RESTORATIVE DEVICES(BELLATEK, CERTAIN, ENCODE, EP, GINGIHUE, GOLD-TITE, PREFORMANCE, PREP-TITE, LOCATOR ABUTMENT)-BIOMET 3I RESTORATIVE DEVICES ARE INTENDED FOR USE AS AN ACCESSORY TO ENDOSSEOUS DENTAL IMPLANTS FOR PLACEMENT IN THE MAXILLA AND MANDIBLE.,DENTAL RESTORATIVE DEVICES (BELLATEK, CERTAIN, ENCODE, EP, GINGIHUE, PREFORMANCE, PREP-TITE, LOCATOR ABUTMENT)-BIOMET 3I RESTORATIVE DEVICES ARE INTENDED FOR USE AS AN ACCESSORY TO ENDOSSEOUS DENTAL IMPLANTS FOR PLACEMENT IN THE MAXILLA AND MANDIBLE., DENTAL RESTORATIVE DEVICES- SCREW(GOLD-TITE)-BIOMET 3I RESTORATIVE PRODUCTS ARE INTENDED FOR USE AS AN ACCESSORY TO ENDOSSEOUS DENTAL IMPLANTS FOR PLACEMENT IN THE MAXILLA AND MANDIBLE.,DENTAL RESTORATIVE DEVICES-SCREW(GOLD-TITE)-BIOMET 3I RESTORATIVE PRODUCTS ARE INTENDED FOR USE AS AN ACCESSORY TO ENDOSSEOUS DENTAL IMPLANTS FOR PLACEMENT IN THE MAXILLA AND MANDIBLE.,BIOMET 3I DENTAL IMPLANT(3I T3, OSSEOTITE, 3I T3 SHORT IMPLANTS, CERTAIN, PREVAIL, DCD)-BIOMET 3I™ DENTAL IMPLANTS, INCLUDING THE BIOMET 3I T3®, OSSEOTITE® AND 3I T3® SHORT IMPLANTS, ARE INTENDED FOR SURGICAL PLACEMENT IN THE UPPER OR LOWER JAW TO PROVIDE A MEANS FOR PROSTHETIC ATTACHMENT IN SINGLE TOOTH RESTORATIONS AND IN PARTIALLY OR FULLY EDENTULOUS SPANS WITH MULTIPLE SINGLE TEETH UTILIZING DELAYED LOADING, OR WITH A TERMINAL OR INTERMEDIARY ABUTMENT FOR FIXED OR REMOVABLE BRIDGEWORK, AND TO RETAIN OVERDENTURES. THE BIOMET 3I T3® AND OSSEOTITE® DENTAL IMPLANTS MAY ALSO UTILIZE IMMEDIATE LOADING FOR THESE INDICATIONS. BIOMET 3I T3® AND OSSEOTITE® DENTAL IMPLANTS ARE INTENDED FOR IMMEDIATE FUNCTION ON SINGLE TOOTH AND/OR MULTIPLE TOOTH APPLICATIONS WHEN GOOD PRIMARY STABILITY IS ACHIEVED, WITH APPROPRIATE OCCLUSAL LOADING, IN ORDER TO RESTORE CHEWING FUNCTION.

2570	IMP/MD/2021/000257	1.License Holder Name: LOTUS SURGICAL PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SINGLE USE CIRCULAR STAPLER(PROSEC®)-IT IS USED THROUGHOUT THE ALIMENTARY TRACT FOR THE CREATION OF END-TO-END AND END-TO-SIDE ANASTOMOSES IN GASTROINTESTINAL OR THORACIC SURGERIES., SINGLE USE HEMORRHOIDAL STAPLER(PROSEC®)-IT CAN BE USED FOR THE GENERAL TREATMENT OF ANORECTAL WALL DEFECTS BY MEANS OF TRANSANAL STAPLING AND RESECTION OF MUCOSAL AND MUSCULOMUCOSAL TISSUE.,SINGLE USE ENDOSCOPIC LINEAR CUTTERS AND RELOADS(PROSEC®)-IT CAN BE USED IN THE GASTROINTESTINAL, GYNECOLOGICAL, PEDIATRIC AND THORACIC SURGERIES FOR RESECTION, TRANSECTION AND CREATION OF ANASTOMOSIS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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2571	IMP/MD/2021/000258	1.License Holder Name: WIPRO GE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMPUTED TOMOGRAPHY(REVOLUTION ASCEND)-THE SYSTEM IS INTENDED TO BE USED FOR HEAD, WHOLE BODY COMPUTED TOMOGRAPHY APPLICATIONS. THE SYSTEM IS INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA TAKEN AT DIFFERENT ANGLES AND PLANES, INCLUDING AXIAL, CINE, HELICAL (VOLUMETRIC), CARDIAC, AND GATED ACQUISITIONS. THESE IMAGES MAY BE OBTAINED EITHER WITH OR WITHOUT CONTRAST. THIS DEVICE MAY INCLUDE SIGNAL ANALYSIS AND DISPLAY EQUIPMENT, PATIENT AND EQUIPMENT SUPPORT, COMPONENTS AND ACCESSORIES. THIS DEVICE MAY INCLUDE DATA AND IMAGE PROCESSING TO PRODUCE IMAGES IN A VARIETY OF TRANS-AXIAL AND REFORMATTED PLANES. FURTHER THE IMAGES CAN BE POST PROCESSED TO PRODUCE ADDITIONAL IMAGING PLANES OR ANALYSIS RESULTS. THE SYSTEM IS INDICATED FOR HEAD, WHOLE BODY, CARDIAC AND VASCULAR X-RAY COMPUTED TOMOGRAPHY APPLICATIONS IN PATIENTS OF ALL AGES. THE DEVICE OUTPUT IS A VALUABLE MEDICAL TOOL FOR THE DIAGNOSIS OF DISEASE, TRAUMA, OR ABNORMALITY AND FOR PLANNING, GUIDING, AND MONITORING THERAPY.,COMPUTED TOMOGRAPHY(REVOLUTION EVO)-THE SYSTEM IS INTENDED TO BE USED FOR HEAD, WHOLE BODY COMPUTED TOMOGRAPHY APPLICATIONS. THE SYSTEM IS INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA TAKEN AT DIFFERENT ANGLES AND PLANES, INCLUDING AXIAL, CINE, HELICAL (VOLUMETRIC), CARDIAC, AND GATED ACQUISITIONS. THESE IMAGES MAY BE OBTAINED EITHER WITH OR WITHOUT CONTRAST. THIS DEVICE MAY INCLUDE SIGNAL ANALYSIS AND DISPLAY EQUIPMENT, PATIENT AND EQUIPMENT SUPPORT, COMPONENTS AND ACCESSORIES. THIS DEVICE MAY INCLUDE DATA AND IMAGE PROCESSING TO PRODUCE IMAGES IN A VARIETY OF TRANS-AXIAL AND REFORMATTED PLANES. FURTHER THE IMAGES CAN BE POST PROCESSED TO PRODUCE ADDITIONAL IMAGING PLANES OR ANALYSIS RESULTS. THE SYSTEM IS INDICATED FOR HEAD, WHOLE BODY, CARDIAC AND VASCULAR X-RAY COMPUTED TOMOGRAPHY APPLICATIONS IN PATIENTS OF ALL AGES. THE DEVICE OUTPUT IS A VALUABLE MEDICAL TOOL FOR THE DIAGNOSIS OF DISEASE, TRAUMA, OR ABNORMALITY AND FOR PLANNING, GUIDING, AND MONITORING THERAPY.

2572	IMP/MD/2021/000259	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER 10(ARROW®)-INTENDED USE: THE ARROWG+ARD BLUE PLUS® CATHETER PERMITS VENOUS ACCESS TO CENTRAL CIRCULATION BY WAY OF SUBCLAVIAN, JUGULAR, AND FEMORAL VEINS. THE ARROWG+ARD TECHNOLOGY IS INTENDED TO PROVIDE PROTECTION AGAINST CATHETER-RELATED BLOODSTREAM INFECTIONS (CRBSIS). IT IS NOT INTENDED TO BE USED AS A TREATMENT FOR EXISTING INFECTIONS NOR IS IT INDICATED FOR LONG-TERM USE (> 30 DAYS). CLINICAL EFFECTIVENESS OF THE ARROWG+ARD BLUE PLUS® CATHETER IN PREVENTING CRBSIS COMPARED TO THE ORIGINAL ARROWG+ARD BLUE® CATHETER HAS NOT BEEN STUDIED. INDICATIONS FOR USE: - THE ARROW CVC IS INTENDED TO PROVIDE SHORT-TERM (30 DAYS) CENTRAL VENOUS ACCESS FOR TREATMENT OF DISEASES OR CONDITIONS REQUIRING CENTRAL VENOUS ACCESS, INCLUDING, BUT NOT LIMITED TO THE FOLLOWING: • LACK OF USABLE PERIPHERAL IV SITES • CENTRAL VENOUS PRESSURE MONITORING • TOTAL PARENTERAL NUTRITION (TPN) • INFUSIONS OF FLUIDS, MEDICATIONS, OR CHEMOTHERAPY • FREQUENT BLOOD SAMPLING OR RECEIVING BLOOD TRANSFUSIONS/BLOOD PRODUCTS,CENTRAL VENOUS CATHETER 8 (ARROW®)-INTENDED USE: THE ARROWG+ARD TECHNOLOGY IS INTENDED TO PROVIDE PROTECTION AGAINST CATHETER-RELATED BLOODSTREAM INFECTIONS. IT IS NOT INTENDED TO BE USED AS A TREATMENT FOR EXISTING INFECTIONS NOR IS IT INDICATED FOR LONG-TERM USE (> 30 DAYS). INDICATION FOR USE: THE ARROW CVC IS INTENDED TO PROVIDE SHORT-TERM (30 DAYS) CENTRAL VENOUS ACCESS FOR TREATMENT OF DISEASES OR CONDITIONS REQUIRING CENTRAL VENOUS ACCESS, INCLUDING, BUT NOT LIMITED TO THE FOLLOWING: • LACK OF USABLE PERIPHERAL IV SITES • CENTRAL VENOUS PRESSURE MONITORING • TOTAL PARENTERAL NUTRITION (TPN) • INFUSIONS OF FLUIDS, MEDICATIONS, OR CHEMOTHERAPY • FREQUENT BLOOD SAMPLING OR RECEIVING BLOOD TRANSFUSIONS/BLOOD PRODUCTS.,CENTRAL VENOUS CATHETER 2(ARROW®)-THE ARROW CVC IS INTENDED TO PROVIDE SHORT-TERM (30 DAYS) CENTRAL VENOUS ACCESS FOR TREATMENT OF DISEASES OR CONDITIONS REQUIRING CENTRAL VENOUS ACCESS, INCLUDING, BUT NOT LIMITED TO THE FOLLOWING: • LACK OF USABLE PERIPHERAL IV SITES • CENTRAL VENOUS PRESSURE MONITORING • TOTAL PARENTERAL NUTRITION (TPN) • INFUSIONS OF FLUIDS, MEDICATIONS, OR CHEMOTHERAPY • FREQUENT BLOOD SAMPLING OR RECEIVING BLOOD TRANSFUSIONS/BLOOD PRODUCTS.,INTRODUCER SHEATHS 12

	(ARROW®)-THE ARROW® PERCUTANEOUS SHEATH INTRODUCER IS INTENDED FOR USE IN THE HOSPITAL CATHETERIZATION LABORATORY FOR THE PERCUTANEOUS INTRODUCTION OF VARIOUS DEVICES INTO VEINS AND/OR ARTERIES IN A VARIETY OF DIAGNOSTIC AND THERAPEUTIC PROCEDURES.,CENTRAL VENOUS CATHETER 1(ARROW®)-1. THE ARROW® SINGLE-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION. 2. THE SINGLE-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION OF PEDIATRIC PATIENTS. 3. THE MULTIPLE-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION OF PEDIATRIC PATIENTS,CENTRAL VENOUS CATHETER 3(ARROW®)-THE SLIC® IS A TWO-PIECE ASSEMBLY CONSISTING OF AN INFUSION CATHETER AND AN OBTURATOR. WITH SLIC® OBTURATOR REMOVED, THE ARROW SLIC® PERMITS ACCESS TO THE CENTRAL VENOUS CIRCULATION THROUGH AN INDWELLING SHEATH/HEMOSTASIS VALVE. WITH THE SLIC® OBTURATOR IN PLACE, THE SLIC® OCCLUDES THE HEMOSTASIS VALVE PREVENTING AIR ENTRY AND BLOOD LOSS THROUGH THE VALVE.,HYPODERMIC SYRINGE(ARROW®)-THE ARROW RAULERSON SYRINGE IS INDICATED FOR USE WITH SPRING-WIRE GUIDES RANGING FROM .025" (.64 MM) TO .038" (.96 MM) AND SPRING-WIRE GUIDE INTRODUCTION NEEDLES SIZED TO PLACE THESE WIRES. THE SYRINGE ALLOWS FOR VESSEL LOCATION AND PASSAGE OF THE GUIDE WIRE THROUGH THE SYRINGE OBVIATING THE NEED FOR SEPARATING THE INTRODUCER NEEDLE FROM THE SYRINGE.,HEMODIALYSIS CATHETER 5(ARROW®)-THE LARGE-BORE TWO-LUMEN CATHETER IS INDICATED FOR TEMPORARY OR SHORT-TERM HEMODIALYSIS AND APHERESIS. IT MAY BE INSERTED INTO THE SUBCLAVIAN OR FEMORAL VEINS., CENTRAL VENOUS CATHETER 9(ARROW®)-THE LARGE-BORE MULTIPLE-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION FOR RAPID FLUID ADMINISTRATION. IT MAY BE INSERTED INTO THE JUGULAR, SUBCLAVIAN, OR FEMORAL VEINS. THE ARROWG+ARD ANTIMICROBIAL SURFACE IS INTENDED TO HELP PROVIDE PROTECTION AGAINST CATHETER-RELATED INFECTIONS. THE CATHETER IS NOT INTENDED TO BE USED AS A TREATMENT FOR EXISTING INFECTIONS NOR AS A SUBSTITUTE FOR A TUNNELED CATHETER IN THOSE PATIENTS REQUIRING LONG-TERM THERAPY. ONE CLINICAL STUDY INDICATES THAT THE ANTIMICROBIAL PROPERTIES OF THE CATHETER MAY NOT BE EFFECTIVE WHEN IT IS USED TO ADMINISTER TPN.,CENTRAL VENOUS ACCESS SHEATH (ARROW®)-THE ARROW® CENTRAL VENOUS ACCESS PRODUCT PERMITS VENOUS ACCESS AND CATHETER INTRODUCTION TO THE CENTRAL CIRCULATION.,INTRODUCER SHEATHS 13(ARROW®)-THE ARROW® PERCUTANEOUS SHEATH INTRODUCER WITH LUER-LOCK

	HUB IS INTENDED FOR USE FOR THE PERCUTANEOUS INTRODUCTION OF VARIOUS DEVICES INTO VEINS AND ARTERIES IN A VARIETY OF DIAGNOSTIC AND THERAPEUTIC PROCEDURES. THE Y-CONNECTOR WITH TUOHY-BORST (T-B) HEMOSTASIS VALVE AND SIDE ARM ALLOWS DEVICE SECUREMENT WITHIN THE SHEATH AND SIMULTANEOUS INFUSION DURING THE PROCEDURE.,ARTERIAL CATHETERIZATION SET(ARROW®)-THE ARROW ARTERIAL CATHETERIZATION DEVICE PERMITS ACCESS TO PERIPHERAL ARTERIAL CIRCULATION.,HEMODIALYSIS CATHETER 6(ARROW®)-THE LARGE-BORE TWO-LUMEN CATHETER PERMITS VENOUS ACCESS TO THE CENTRAL CIRCULATION FOR RAPID FLUID ADMINISTRATION, TEMPORARY OR ACUTE HEMODIALYSIS, APHERESIS AND HEMOFILTRATION. IT MAY BE INSERTED INTO THE JUGULAR, SUBCLAVIAN, OR FEMORAL VEINS. THE ARROWG+ARD BLUE ANTIMICROBIAL SURFACE CATHETER HELPS PROVIDE PROTECTION AGAINST CATHETER-RELATED INFECTIONS RESULTING FROM MICROORGANISMS MIGRATING THE SUBCUTANEOUS TRACT ALONG THE EXTERIOR SURFACE OF THE CATHETER WHEN USED FOR INFUSION. CLINICAL DATA HAVE NOT BEEN COLLECTED THAT DEMONSTRATE THE USE OF THE ARROWG+ARD BLUE ANTIMICROBIAL SURFACE IN DECREASING CATHETER RELATED INFECTIONS IN HEMODIALYSIS PATIENTS. THE CATHETER IS NOT INTENDED TO BE USED AS A TREATMENT FOR EXISTING INFECTIONS, NOR IS IT INDICATED FOR LONG-TERM USE.

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2573	IMP/MD/2021/000261	1.License Holder Name: 3M INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DRESSING(3M™ TEGADERM™ IV TRANSPARENT FILM DRESSING WITH BORDER)-TEGADERM™ FILM CAN BE USED TO COVER AND PROTECT CATHETER SITES AND WOUNDS, TO MAINTAIN A MOIST ENVIRONMENT FOR WOUND HEALING OR TO FACILITATE AUTOLYTIC DEBRIDEMENT, AS A SECONDARY DRESSING, AS A PROTECTIVE COVER OVER AT-RISK SKIN, TO SECURE DEVICES TO THE SKIN, TO COVER FIRST AND SECOND-DEGREE BURNS, AND AS A PROTECTIVE EYE COVERING. DO NOT USE THE DRESSING AS A REPLACEMENT FOR SUTURES AND OTHER PRIMARY WOUND CLOSURE METHODS.,DRESSING(3M™ TEGADERM™ FILM TRANSPARENT FILM DRESSING FRAME STYLE)-TEGADERM™ FILM CAN BE USED TO COVER AND PROTECT CATHETER SITES AND WOUNDS, TO MAINTAIN A MOIST ENVIRONMENT FOR WOUND HEALING OR TO FACILITATE AUTOLYTIC DEBRIDEMENT, AS A SECONDARY DRESSING, AS A PROTECTIVE COVER OVER AT-RISK SKIN, TO SECURE DEVICES TO THE SKIN, TO COVER FIRST AND SECOND-DEGREE BURNS, AND AS A PROTECTIVE EYE COVERING. DO NOT USE THE DRESSING AS A REPLACEMENT FOR SUTURES AND OTHER PRIMARY WOUND CLOSURE METHODS.,ADHESIVE TAPE(3M DURAPORE SURGICAL TAPE)-INTENDED FOR SECURING REGULAR AND BULKY DRESSINGS, TUBING AND IMMOBILIZATION.
2574	IMP/MD/2021/000263	1.License Holder Name: KATARA DENTAL PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL ABUTMENTS AND IMPRESSION POSTS(CAM LOG®)-CAMLOG® AND CONELOG® PROSTHETIC COMPONENTS ARE USED FOR THE FABRICATION OF PROSTHETIC RESTAURATIONS AND SERVE AS SUPPLY UNIT WITH DENTAL PROSTHESES ON CAMLOG® AND CONELOG® IMPLANTS IN THE UPPER AND LOWER JAW.,DENTAL IMPLANT SYSTEM(CAM LOG®) -CAMLOG AND CONELOG IMPLANTS ARE INTENDED FOR THE FUNCTIONAL AND/OR ESTHETIC ORAL REHABILITATION OF EDENTULOUS AND PARTIALLY EDENTULOUS PATIENTS AS ENOSSAL IMPLANTS IN THE MAXILLA AND/OR MANDIBLE.

2575	IMP/MD/2021/000264	1.License Holder Name: CADILA HEALTHCARE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEEDLE-FREE SYRINGE, FILLING ADAPTER, INJECTOR. (SYSTEM)(TROPIES NEEDLE FREE SYSTEM)-THE PHARMAJET TROPIS 0.1 ML NEEDLE-FREE INJECTION SYSTEM IS INTENDED TO DELIVER VARIOUS MEDICATIONS AND VACCINES INTRADERMALLY BY MEANS OF A NARROW, HIGH VELOCITY FLUID JET, WHICH PENETRATES THE SKIN AND DELIVERS THE MEDICINE OR VACCINE TO THE BODY. HEALTHCARE PROVIDERS WHO ROUTINELY ADMINISTER INJECTIONS MAY USE THE PHARMAJET NFIS. IT MAY BE USED FOR ADULTS AND CHILDREN. IT MAY BE USED IN ADULTS AND CHILDREN. IT CAN ALSO BE USED BY PATIENTS AUTHORIZED BY THEIR PHYSICIANS TO SELF-INJECT, OR HAVE OTHER INDIVIDUALS ADMINISTER INJECTIONS OF PRESCRIBED MEDICATIONS.
2576	IMP/MD/2021/000265	1.License Holder Name: WIPRO GE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMPUTER TOMOGRAPHY(BRIGHTSPEED ELITE SELECT)-THE GE BRIGHTSPEED ELITE SELECT COMPUTED TOMOGRAPHY X-RAY SYSTEM IS INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA TAKEN AT DIFFERENT ANGLES AND PLANES, PATIENT FOR ALL AGES, INCLUDING AXIAL, CINE, HELICAL, AND GATED (RESPIRATORY) ACQUISITIONS.

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2577	IMP/MD/2021/000266	1.License Holder Name: ZB DENTAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ABSORBABLE WOUND DRESSINGS FOR DENTAL SURGERY(ZIMMER COLLAGEN PLUG, ZIMMER COLLAGEN TAPE, ZIMMER COLLAGEN PATCH)-ZIMMER COLLAGEN PLUG, TAPE AND PATCH ARE INDICATED FOR THE MANAGEMENT OF ORAL WOUNDS AND SORES, INCLUDING: • DENTURE SORES • ORAL ULCERS (NON-INFECTED OR VIRAL) • PERIODONTAL SURGICAL WOUNDS • SUTURE SITES • BURNS • EXTRACTION SITES • SURGICAL WOUNDS • TRAUMATIC WOUNDS, REGENEROSS RESORBABLE XENOGRAFT(REGENEROSS RESORBABLE XENOGRAFT)-REGENEROSS® RESORBABLE XENOGRAFT IS INDICATED FOR: - AUGMENTATION OR RECONSTRUCTIVE TREATMENT OF THE ALVEOLAR RIDGE. - FILLING OF INFRABONY PERIODONTAL DEFECTS. - FILLING OF DEFECTS AFTER ROOT RESECTION, APICOECTOMY, AND CYSTECTOMY. - FILLING OF EXTRACTION SOCKETS TO ENHANCE PRESERVATION OF THE ALVEOLAR RIDGE. - ELEVATION OF THE MAXILLARY SINUS FLOOR. - FILLING OF PERIODONTAL DEFECTS IN CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED TISSUE REGENERATION (GTR) AND GUIDED BONE REGENERATION (GBR). - FILLING OF PERI-IMPLANT DEFECTS IN CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED BONE REGENERATION (GBR).,REGENEROSS RESORBABLE XENOGRAFT SYRINGE(REGENEROSS RESORBABLE XENOGRAFT SYRINGE)-REGENEROSS® RESORBABLE XENOGRAFT SYRINGE IS INDICATED FOR: - AUGMENTATION OR RECONSTRUCTIVE TREATMENT OF THE ALVEOLAR RIDGE. - FILLING OF INFRABONY PERIODONTAL DEFECTS. - FILLING OF DEFECTS AFTER ROOT RESECTION, APICOECTOMY, AND CYSTECTOMY. - FILLING OF EXTRACTION SOCKETS TO ENHANCE PRESERVATION OF THE ALVEOLAR RIDGE. - ELEVATION OF THE MAXILLARY SINUS FLOOR. - FILLING OF PERIODONTAL DEFECTS IN CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED TISSUE REGENERATION (GTR) AND GUIDED BONE REGENERATION (GBR). - FILLING OF PERI-IMPLANT DEFECTS IN CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED BONE REGENERATION (GBR).,SYNTHETIC MINERAL-COLLAGEN COMPOSITE BONE GRAFT(REGENEROSS SYNTHETIC)-REGENEROSS SYNTHETIC IS RECOMMENDED FOR: - AUGMENTATION OR RECONSTRUCTIVE TREATMENT OF THE ALVEOLAR RIDGE. - FILLING OF INFRABONY PERIODONTAL DEFECTS. - FILLING OF DEFECTS AFTER ROOT RESECTION, APICOECTOMY, AND CYSTECTOMY. - FILLING OF EXTRACTION SOCKETS TO ENHANCE PRESERVATION OF THE ALVEOLAR RIDGE. - ELEVATION OF THE MAXILLARY SINUS FLOOR. - FILLING OF PERIODONTAL DEFECTS IN

		CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED TISSUE REGENERATION (GTR) AND GUIDED BONE REGENERATION (GBR). - FILLING OF PERI-IMPLANT DEFECTS IN CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED BONE REGENERATION (GBR).
2578	IMP/MD/2021/000267	1.License Holder Name: MNT HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:OTHER IMPLANTECH IMPLANTS-INDIVIDUALIZED, CARVABLE BLOCK USED TO AUGMENT OR RECONSTRUCT UNDER DEVELOPED OR TRAUMATIZED FACIAL AREAS.,IMPLANTECH NASAL IMPLANTS-TO AUGMENT OR RECONSTRUCT THE BONY CARTILAGINOUS FRAME.,IMPLANTECH MALAR, SUBMALAR & MID-FACIAL IMPLANTS-TO AUGMENT OR RECONSTRUCT UNDERDEVELOPED OR TRAUMATIZED MALAR REGIONS.,IMPLANTECH CHIN & MANDIBULAR IMPLANTS-TO AUGMENT OR RECONSTRUCT UNDERDEVELOPED OR TRAUMATIZED MANDIBULAR REGIONS.,IMPLANTECH BODY CONTOURING IMPLANTS CONT.-PECTORALIS IMPLANTS, INCLUDING POWERFLEXTM ARE INDICATED FOR AUGMENTATION OR RECONSTRUCTION OF THE PECTORALIS REGION. CONTOURFLEX™ GLUTEAL AND CALF IMPLANTS (SILICONE CARVING BLOCKS) ARE INDICATED FOR AUGMENTATION AND RECONSTRUCTIVE SURGERY. THE DEVICE IS CARVABLE TO ALLOW THE SURGEON TO SHAPE THE DEVICE SHOULD ADDITIONAL SHAPING BE DESIRED.
2579	IMP/MD/2021/000271	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIALYSIS MACHINE (DIALOG+ SINGLE PUMP, DIALOG+ DOUBLE-PUMP, DIALOG+ HDF-ONLINE)-THE DIALYSIS MACHINE CAN BE USED FOR IMPLEMENTING AND MONITORING HAEMODIALYSIS TREATMENTS FOR PATIENTS WITH ACUTE OR CHRONIC KIDNEY FAILURE. THE SYSTEM CAN BE USED FOR HOSPITAL, HEALTH CENTRE, LIMITED-CARE OR HOME DIALYSIS. DEPENDING ON THE MODEL, THE FOLLOWING TYPES OF THERAPY CAN BE CARRIED OUT WITH THE SYSTEM: HEMODIALYSIS (HD), ISOLATED ULTRAFILTRATION (ISO UF): SEQUENTIAL THERAPY (BERGSTROEM), HEMODIAFILTRATION (HDF) , HEMOFILTRATION (HF)

2580	IMP/MD/2021/000272	1.License Holder Name: SHREYAAS HEALTH CARE PRODUCTS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE TALC (STERITALC)-STERITALC® IS INSOLUBLE MINERAL POWDER WHICH IS APPLIED INTO THE PLEURAL CAVITY TO CAUSE PERMANENT PLEURODESIS. INDICATION FOR USE: •PNEUMOTHORAX •MALIGNANT PLEURAL EFFUSION,TRACHEO-BRONCHIAL SILICONE STENT (NOVATECH GSS)-STENT FOR USE IN THE TRACHEA OR BRONCHUS. THE PRODUCT IS USED TO KEEP THE AIRWAY OPEN. THE PRODUCT IS FOR LONG-TERM USE (APPLICATION DURATION > 29 DAYS). INDICATIONS FOR USE • TRACHEOBRONCHIAL TUMORS • TRACHEAL STENOSES WITH SCARRING • TRACHEABRONCHIAL STENOSES AFTER ANASTOMOSIS, RESECTION OR LUNG TRANSPLANTATION • DIAMETER REDUCTION FROM INTRALUMINAL, EXTRALUMINAL AND INTRAMURAL CHANGES
2581	IMP/MD/2021/000273	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FINE NEEDLE BIOPSY SYSTEM(SHARKCORE ™)-THE DEVICE IS USED WITH AN ULTRASOUND ENDOSCOPE FOR FINE NEEDLE BIOPSY (FNB) OF SUBMUCOSAL LESIONS, MEDIASTINAL MASSES, LYMPH NODES AND INTRAPERITONEAL MASSES WITHIN OR ADJACENT TO THE GASTROINTESTINAL TRACT. THE NEEDLE IS DESIGNED WITH A PASSIVE (I.E., AUTOMATIC) SAFETY SHIELDING FEATURE TO AID IN THE PREVENTION OF NEEDLE STICK INJURY.,FINE NEEDLE ASPIRATION SYSTEM(BNX)-THE DEVICE IS USED TO SAMPLE TARGETED SUB-MUCOSAL AND EXTRAMURAL GASTROINTESTINAL LESIONS THROUGH THE ACCESSORY CHANNEL OF AN ULTRASOUND ENDOSCOPE. THE NEEDLE IS DESIGNED WITH A PASSIVE (I.E., AUTOMATIC) SAFETY SHIELDING FEATURE TO AID IN THE PREVENTION OF NEEDLE STICK INJURY. THE 19GA. AND 22GA. BNX™ ASPIRATION NEEDLES ARE ALSO INTENDED TO IMPLANT FIDUCIAL MARKERS UNDER ENDOSCOPIC ULTRASOUND TO RADIOGRAPHICALLY MARK SOFT TISSUE FOR FUTURE THERAPEUTIC PROCEDURES.,FINE NEEDLE FIDUCIAL SYSTEM(BEACON™)-THE DEVICE IS INTENDED TO IMPLANT FIDUCIAL MARKERS UNDER ENDOSCOPIC ULTRASOUND TO RADIOGRAPHICALLY MARK SUBMUCOSAL AND EXTRAMURAL GASTROINTESTINAL LESION FOR FUTURE THERAPEUTIC PROCEDURES. THE NEEDLE IS DESIGNED WITH A PASSIVE (I.E. AUTOMATIC) SAFETY SHIELDING FEATURE TO AID IN THE PREVENTION OF NEEDLE STICK INJURY.

2582	IMP/MD/2021/000274	1.License Holder Name: OTIC HEARING SOLUTIONS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COCHLEAR IMPLANT (NEURO)-THE NEURO ZTI COCHLEAR IMPLANT IS DESIGNED FOR ADULTS AND CHILDREN OF ALL AGES WHO HAVE UNILATERAL OR BILATERAL SEVERE-TO-PROFOUND SENSORINEURAL HEARING LOSS, WITH LIMITED BENEFIT FROM APPROPRIATELY FITTED HEARING AID(S).
2583	IMP/MD/2021/000275	1.License Holder Name: MACO PHARMA INDIA TRANSFUSION SOLUTIONS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SYNOVIAL FLUID SUPPLEMENT (SODIUM HYALURONATE 1.0% AND 2.0%)(HYAJOINT, HYAJOINT PLUS)-INTENDED FOR TREATMENT OF PAIN IN OSTEOARTHRITIS OF THE KNEE JOINTS.
2584	IMP/MD/2021/000276	1.License Holder Name: M/S. TIMPAC HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:POLYDIOXANONE SUTURE(RENEW BY MONO)-IT IS INTENDED TO FIXATE SUB DERMAL TISSUE IN AN ELEVATED POSITION IN PLASTIC AND RECONSTRUCTIVE SURGERY. IT PROVIDES WOUND SUPPORT FOR LONGER PERIOD AS COMPARED TO OTHER SYNTHETIC ABSORBABLE SUTURES,POLYDIOXANONE SUTURE(RENEW BY COG, CORSET)-IT IS INTENDED TO FIXATE SUB DERMAL TISSUE IN AN ELEVATED POSITION IN PLASTIC AND RECONSTRUCTIVE SURGERY. IT PROVIDES WOUND SUPPORT FOR LONGER PERIOD AS COMPARED TO OTHER SYNTHETIC ABSORBABLE SUTURES

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2585	IMP/MD/2021/000280	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAGNETOM TERRA (MAGNETOM TERRA)-THE MAGNETOM TERRA SYSTEM IS INDICATED FOR USE AS A MAGNETIC RESONANCE DIAGNOSTIC DEVICE (MRDD) THAT PRODUCES TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-SECTIONAL IMAGES AND THAT DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HEAD OR EXTREMITIES. OTHER PHYSICAL PARAMETERS DERIVED FROM THE IMAGES MAY ALSO BE PRODUCED. ADDITIONALLY,THE MAGNETOM TERRA IS INTENDED TO PRODUCE SODIUM IMAGES FOR THE HEAD AND PHOSPHORUS SPECTROSCOPIC IMAGES AND/OR SPECTRA FOR WHOLE BODY, EXCLUDING THE HEAD. THESE IMAGES AND/OR SPECTRA AND THE PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS. THE DEVICE IS INTENDED FOR PATIENTS > 30KG/661BS. ,MAGNETOM SOLA(MAGNETOM SOLA AND MAGNETOM SOLA FIT)-THE MAGNETOM MR SYSTEMS ARE INTENDED FOR USE PER GMDN CODE 37654, FULL-BODY MAGNETIC RESONANCE IMAGING (MRI) SYSTEM. MAGNETOM MR SYSTEM IS INDICATED FOR USE AS A MAGNETIC RESONANCE DIAGNOSTIC DEVICE (MRDD) THAT PRODUCE TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-SECTIONAL IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, AND THAT DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HEAD, BODY, OR EXTREMITIES. OTHER PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA MAY ALSO BE PRODUCED. DEPENDING ON THE REGION OF INTEREST, CONTRAST AGENTS MAY BE USED. THESE IMAGES AND/OR SPECTRA AND THE PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS. MAGNETOM MR SYSTEM MAY ALSO BE USED FOR IMAGING DURING INTERVENTIONAL PROCEDURES WHEN PERFORMED WITH MR COMPATIBLE DEVICES SUCH AS IN-ROOM DISPLAYS AND MR SAFE BIOPSY NEEDLES. ,MAGNETOM LUMINA (MAGNETOM LUMINA)-THE MAGNETOM MR SYSTEMS ARE INTENDED FOR USE PER GMDN CODE 37654, FULL-BODY MAGNETIC RESONANCE IMAGING (MRI) SYSTEM. MAGNETOM MR SYSTEM IS INDICATED FOR USE AS A MAGNETIC RESONANCE DIAGNOSTIC DEVICE (MRDD) THAT PRODUCE TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-SECTIONAL IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, AND THAT DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HEAD, BODY, OR EXTREMITIES. OTHER PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR

	SPECTRA MAY ALSO BE PRODUCED. DEPENDING ON THE REGION OF INTEREST, CONTRAST AGENTS MAY BE USED. THESE IMAGES AND/OR SPECTRA AND THE PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS. MAGNETOM MR SYSTEM MAY ALSO BE USED FOR IMAGING DURING INTERVENTIONAL PROCEDURES WHEN PERFORMED WITH MR COMPATIBLE DEVICES SUCH AS IN-ROOM DISPLAYS AND MR SAFE BIOPSY NEEDLES. ,MAGNETOM PRISMA(MAGNETOM PRISMA AND MAGNETOM PRISMA FIT)-THE MAGNETOM MR SYSTEMS ARE INTENDED FOR USE PER GMDN CODE 37654, FULL-BODY MAGNETIC RESONANCE IMAGING (MRI) SYSTEM. MAGNETOM MR SYSTEM IS INDICATED FOR USE AS A MAGNETIC RESONANCE DIAGNOSTIC DEVICE (MRDD) THAT PRODUCE TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-SECTIONAL IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, AND THAT DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HEAD, BODY, OR EXTREMITIES. OTHER PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA MAY ALSO BE PRODUCED. DEPENDING ON THE REGION OF INTEREST, CONTRAST AGENTS MAY BE USED. THESE IMAGES AND/OR SPECTRA AND THE PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS. MAGNETOM MR SYSTEM MAY ALSO BE USED FOR IMAGING DURING INTERVENTIONAL PROCEDURES WHEN PERFORMED WITH MR COMPATIBLE DEVICES SUCH AS IN-ROOM DISPLAYS AND MR SAFE BIOPSY NEEDLES. ,BIOGRAPH MMR(BIOGRAPH MMR)-THE SIEMENS MR-PET SYSTEM COMBINES MAGNETIC RESONANCE DIAGNOSTIC DEVICES (MRDD) AND POSITRON EMISSION TOMOGRAPHY (PET) SCANNERS THAT PROVIDE REGISTRATION AND FUSION OF HIGH RESOLUTION PHYSIOLOGIC AND ANATOMIC INFORMATION, ACQUIRED SIMULTANEOUSLY AND ISOCENTRICALLY. THE COMBINED SYSTEM MAINTAINS INDEPENDENT FUNCTIONALITY OF THE MR AND PET DEVICES, ALLOWING FOR SINGLE MODALITY MR AND / OR PET IMAGING. THE MR IS INTENDED TO PRODUCE TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-SECTIONAL MR-IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, AND DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HUMAN BODY. OTHER PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA MAY ALSO BE PRODUCED. DEPENDING ON THE REGION OF INTEREST, APPROVED CONTRAST AGENTS MAY BE USED, AS DESCRIBED IN THEIR LABELING. THIS SYSTEM MAY ALSO BE USED FOR IMAGING DURING INTERVENTIONAL PROCEDURES WHEN PERFORMED WITH MR COMPATIBLE DEVICES,SUCH AS MR-SAFE

	BIOPSY NEEDLES. THE PET IMAGES AND MEASURES THE DISTRIBUTION OF PET RADIOPHARMACEUTICALS IN HUMANS TO AID THE PHYSICIAN IN DETERMINING VARIOUS METABOLIC (MOLECULAR) AND PHYSIOLOGIC FUNCTIONS WITHIN THE HUMAN BODY FOR EVALUATION OF DISEASES AND DISORDERS SUCH AS, BUT NOT LIMITED TO, CARDIOVASCULAR DISEASE, NEUROLOGICAL DISORDERS AND CANCER. THE COMBINED SYSTEM UTILIZES THE MR FOR RADIATION-FREE ATTENUATION CORRECTION MAPS FOR PET STUDIES.THE SYSTEM PROVIDES INHERENT ANATOMICAL REFERENCE FOR THE FUSED PET AND MR IMAGES DUE TO PRECISELY ALIGNED MR AND PET IMAGE COORDINATE SYSTEMS.,MAGNETOM VERIO(MAGNETOM VERIO)-THE MAGNETOM MR SYSTEMS ARE INTENDED FOR USE PER GMDN CODE 37654, FULL-BODY MAGNETIC RESONANCE IMAGING (MRI) SYSTEM. MAGNETOM MR SYSTEM IS INDICATED FOR USE AS A MAGNETIC RESONANCE DIAGNOSTIC DEVICE (MRDD) THAT PRODUCE TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-SECTIONAL IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, AND THAT DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HEAD, BODY, OR EXTREMITIES. OTHER PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA MAY ALSO BE PRODUCED. DEPENDING ON THE REGION OF INTEREST, CONTRAST AGENTS MAY BE USED. THESE IMAGES AND/OR SPECTRA AND THE PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS. MAGNETOM MR SYSTEM MAY ALSO BE USED FOR IMAGING DURING INTERVENTIONAL PROCEDURES WHEN PERFORMED WITH MR COMPATIBLE DEVICES SUCH AS IN-ROOM DISPLAYS AND MR SAFE BIOPSY NEEDLES.,MAGNETOM VIDA(MAGNETOM VIDA)-THE MAGNETOM MR SYSTEMS ARE INTENDED FOR USE PER GMDN CODE 37654, FULL-BODY MAGNETIC RESONANCE IMAGING (MRI) SYSTEM. MAGNETOM MR SYSTEM IS INDICATED FOR USE AS A MAGNETIC RESONANCE DIAGNOSTIC DEVICE (MRDD) THAT PRODUCE TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-SECTIONAL IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, AND THAT DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HEAD, BODY, OR EXTREMITIES. OTHER PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA MAY ALSO BE PRODUCED. DEPENDING ON THE REGION OF INTEREST, CONTRAST AGENTS MAY BE USED. THESE IMAGES AND/OR SPECTRA AND THE PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS. MAGNETOM MR SYSTEM MAY ALSO BE USED FOR IMAGING DURING

	INTERVENTIONAL PROCEDURES WHEN PERFORMED WITH MR COMPATIBLE DEVICES SUCH AS IN-ROOM DISPLAYS AND MR SAFE BIOPSY NEEDLES.,MAGNETOM AERA(MAGNETOM AERA)-THE MAGNETOM MR SYSTEMS ARE INTENDED FOR USE PER GMDN CODE 37654, FULL-BODY MAGNETIC RESONANCE IMAGING (MRI) SYSTEM. MAGNETOM MR SYSTEM IS INDICATED FOR USE AS A MAGNETIC RESONANCE DIAGNOSTIC DEVICE (MRDD) THAT PRODUCE TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-SECTIONAL IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, AND THAT DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HEAD, BODY, OR EXTREMITIES. OTHER PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA MAY ALSO BE PRODUCED. DEPENDING ON THE REGION OF INTEREST, CONTRAST AGENTS MAY BE USED. THESE IMAGES AND/OR SPECTRA AND THE PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS. MAGNETOM MR SYSTEM MAY ALSO BE USED FOR IMAGING DURING INTERVENTIONAL PROCEDURES WHEN PERFORMED WITH MR COMPATIBLE DEVICES SUCH AS IN-ROOM DISPLAYS AND MR SAFE BIOPSY NEEDLES.,MAGNETOM SKYRA(MAGNETOM SKYRA)-THE MAGNETOM MR SYSTEMS ARE INTENDED FOR USE PER GMDN CODE 37654, FULL-BODY MAGNETIC RESONANCE IMAGING (MRI) SYSTEM. MAGNETOM MR SYSTEM IS INDICATED FOR USE AS A MAGNETIC RESONANCE DIAGNOSTIC DEVICE (MRDD) THAT PRODUCE TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-SECTIONAL IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, AND THAT DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HEAD, BODY, OR EXTREMITIES. OTHER PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA MAY ALSO BE PRODUCED. DEPENDING ON THE REGION OF INTEREST, CONTRAST AGENTS MAY BE USED. THESE IMAGES AND/OR SPECTRA AND THE PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS. MAGNETOM MR SYSTEM MAY ALSO BE USED FOR IMAGING DURING INTERVENTIONAL PROCEDURES WHEN PERFORMED WITH MR COMPATIBLE DEVICES SUCH AS IN-ROOM DISPLAYS AND MR SAFE BIOPSY NEEDLES.,MAGNETOM AVANTO(MAGNETOM AVANTO)-THE MAGNETOM MR SYSTEMS ARE INTENDED FOR USE PER GMDN CODE 37654, FULL-BODY MAGNETIC RESONANCE IMAGING (MRI) SYSTEM. MAGNETOM MR SYSTEM IS INDICATED FOR USE AS A MAGNETIC RESONANCE DIAGNOSTIC DEVICE (MRDD) THAT PRODUCE TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-

	SECTIONAL IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, AND THAT DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HEAD, BODY, OR EXTREMITIES. OTHER PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA MAY ALSO BE PRODUCED. DEPENDING ON THE REGION OF INTEREST, CONTRAST AGENTS MAY BE USED. THESE IMAGES AND/OR SPECTRA AND THE PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS. MAGNETOM MR SYSTEM MAY ALSO BE USED FOR IMAGING DURING INTERVENTIONAL PROCEDURES WHEN PERFORMED WITH MR COMPATIBLE DEVICES SUCH AS IN-ROOM DISPLAYS AND MR SAFE BIOPSY NEEDLES.,MAGNETOM ALTEA(MAGNETOM ALTEA)-THE MAGNETOM MR SYSTEMS ARE INTENDED FOR USE PER GMDN CODE 37654, FULL-BODY MAGNETIC RESONANCE IMAGING (MRI) SYSTEM. MAGNETOM MR SYSTEM IS INDICATED FOR USE AS A MAGNETIC RESONANCE DIAGNOSTIC DEVICE (MRDD) THAT PRODUCE TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-SECTIONAL IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, AND THAT DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HEAD, BODY, OR EXTREMITIES. OTHER PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA MAY ALSO BE PRODUCED. DEPENDING ON THE REGION OF INTEREST, CONTRAST AGENTS MAY BE USED. THESE IMAGES AND/OR SPECTRA AND THE PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS. MAGNETOM MR SYSTEM MAY ALSO BE USED FOR IMAGING DURING INTERVENTIONAL PROCEDURES WHEN PERFORMED WITH MR COMPATIBLE DEVICES SUCH AS IN-ROOM DISPLAYS AND MR SAFE BIOPSY NEEDLES.

2586	IMP/MD/2021/000281	1.License Holder Name: AGFA HEALTHCARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL RADIOGRAPHY X-RAY SYSTEM(DR 600)-THE DR 600 SYSTEM IS A GENERAL RADIOGRAPHY X-RAY IMAGING SYSTEM USED IN HOSPITALS, CLINICS AND MEDICAL PRACTICES BY RADIOGRAPHERS, RADIOLOGISTS AND PHYSICISTS TO MAKE, PROCESS AND VIEW STATIC X-RAY RADIOGRAPHIC IMAGES OF THE SKELETON (INCLUDING SKULL, SPINAL COLUMN AND EXTREMITIES), CHEST, ABDOMEN AND OTHER BODY PARTS ON ADULTS AND PEDIATRIC PATIENTS. IN ADDITION, THE SYSTEM PROVIDES THE AGFA TOMOSYNTHESIS OPTION, WHICH IS INTENDED TO ACQUIRE TOMOGRAPHIC SLICES OF HUMAN ANATOMY AND TO BE USED WITH AGFA DR X-RAY SYSTEMS. DIGITAL TOMOSYNTHESIS IS USED TO SYNTHESIZE TOMOGRAPHIC SLICES FROM A SINGLE TOMOGRAPHIC SWEEP. APPLICATIONS CAN BE PERFORMED WITH THE PATIENT IN SITTING, STANDING OR LYING POSITION. THE SYSTEM IS NOT INTENDED FOR USE IN MAMMOGRAPHY APPLICATIONS.,DIGITAL RADIOGRAPHY X-RAY SYSTEM(DR 400)-THE DR 400 SYSTEM IS A GENERAL RADIOGRAPHY X-RAY IMAGING SYSTEM USED IN HOSPITALS, CLINICS AND MEDICAL PRACTICES BY PHYSICISTS, RADIOGRAPHERS AND RADIOLOGISTS TO MAKE, PROCESS AND VIEW STATIC X-RAY RADIOGRAPHIC IMAGES OF THE SKELETON (INCLUDING SKULL, SPINAL COLUMN AND EXTREMITIES), CHEST, ABDOMEN AND OTHER BODY PARTS ON ADULT OR PEDIATRIC PATIENTS. APPLICATIONS CAN BE PERFORMED WITH THE PATIENT IN THE SITTING, STANDING OR LYING POSITION. THIS DEVICE IS NOT INTENDED FOR MAMMOGRAPHY APPLICATIONS.

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2587	IMP/MD/2021/000288	1.License Holder Name: AGFA HEALTHCARE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL RADIOGRAPHY X-RAY SYSTEM(DX-D 100)-THE DX-D 100 SYSTEM IS A MOBILE X-RAY IMAGING SYSTEM USED IN HOSPITALS, CLINICS AND MEDICAL PRACTICES BY PHYSICISTS, RADIOGRAPHERS AND RADIOLOGISTS TO MAKE, PROCESS AND VIEW STATIC X-RAY RADIOGRAPHIC IMAGES OF THE SKELETON (INCLUDING SKULL, SPINAL COLUMN AND EXTREMITIES), CHEST, ABDOMEN AND OTHER BODY PARTS ON ADULT, PEDIATRIC OR NEONATAL PATIENTS. APPLICATIONS CAN BE PERFORMED WITH THE PATIENT IN THE SITTING, STANDING OR LYING POSITION. THIS DEVICE IS NOT INTENDED FOR MAMMOGRAPHY APPLICATIONS.,DIGITAL RADIOGRAPHY X-RAY SYSTEM(DX-D 300)-THE DX-D 300 SYSTEM IS AN INTEGRATED X-RAY IMAGING SYSTEM USED IN HOSPITALS, CLINICS AND MEDICAL PRACTICES BY PHYSICISTS, RADIOGRAPHERS AND RADIOLOGISTS TO MAKE, PROCESS AND VIEW STATIC X-RAY RADIOGRAPHIC IMAGES OF THE SKELETON (INCLUDING SKULL, SPINAL COLUMN AND EXTREMITIES), CHEST, ABDOMEN AND OTHER BODY PARTS ON ADULT, PEDIATRIC OR NEONATAL PATIENTS. APPLICATIONS CAN BE PERFORMED WITH THE PATIENT IN THE SITTING, STANDING OR LYING POSITION. THIS DEVICE IS NOT INTENDED FOR MAMMOGRAPHY APPLICATIONS., DIGITAL RADIOGRAPHY X-RAY SYSTEM(DX-D 600)-THE DX-D 600 SYSTEM IS A CEILING MOUNTED GENERAL RADIOGRAPHY X-RAY IMAGING SYSTEM USED IN HOSPITALS, CLINICS AND MEDICAL PRACTICES BY PHYSICISTS, RADIOGRAPHERS AND RADIOLOGISTS TO MAKE, PROCESS AND VIEW STATIC X-RAY RADIOGRAPHIC IMAGES OF THE SKELETON (INCLUDING SKULL, SPINAL COLUMN AND EXTREMITIES), CHEST, ABDOMEN AND OTHER BODY PARTS ON ADULT, PEDIATRIC OR NEONATAL PATIENTS. APPLICATIONS CAN BE PERFORMED WITH THE PATIENT IN SITTING, STANDING OR LYING POSITION. THIS DEVICE IS NOT INTENDED FOR MAMMOGRAPHY APPLICATIONS.
2588	IMP/MD/2021/000289	1.License Holder Name: MEDEVICE TECHNOLOGIES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANTS (K3PRO)-K3PRO IMPLANT SYSTEM IS INDICATED FOR SURGICAL PLACEMENT IN PARTIALLY OR COMPLETELY EDENTULOUS UPPER OR LOWER JAWS TO PROVIDE A MEANS FOR PROSTHETIC ATTACHMENT IN SINGLE -TOOTH RESTORATIONS AS WELL AS REMOVABLE OR NON-REMOVABLE BRIDGE CONSTRUCTIONS AND PROSTHESIS.TO RESTORE PATIENT'S CHEWING FUNCTION.

2589	IMP/MD/2021/000290	1.License Holder Name: PHARMALEAF INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ENDOSSEOUS DENTAL IMPLANTS(ALFA GATE® DENTAL IMPLANTS SYSTEM)-REPLACEMENT OF A ROOT OF A MISSING TOOTH AS PART OF A DENTAL RESTORATION PROCEDURE.
2590	IMP/MD/2021/000291	1.License Holder Name: OSSTEM IMPLANT INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL X-RAY SYSTEM (T1)-T1 IS DIGITAL X-RAY IMAGING EQUIPMENT FOR DENTAL PROFESSIONALS THAT CONVERTS X-RAY SIGNALS INTO DIGITAL SIGNALS TO ACQUIRE 2D IMAGES AND RECONSTRUCT THEM INTO 3D IMAGES, USING PANORAMIC (PANO), CEPHALOMETRIC(CEPH), AND COMPUTED TOMOGRAPHY (CT) TECHNOLOGY FOR THE DIAGNOSIS OF THE ANATOMICAL STRUCTURE OF THE ORAL AND MAXILLOFACIAL AREA. T1-CS PROVIDES ALL THREE MODES, WHEREAS T1-C PROVIDES THE FIRST TWO MODES AND EXCLUDES THE CEPH MODE.

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2591	IMP/MD/2021/000292	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIGH RESOLUTION MANOMETRY ESO 3D CATHETER(MANOSCAN ESO 3D CATHETER)-THE MANOSCAN SYSTEM PROVIDES MAPPING OF PRESSURES AND, OPTIONALLY, IMPEDANCE WITHIN ORGANS OF THE HUMAN GASTROINTESTINAL TRACT. THESE INCLUDE THE PHARYNX, UPPER ESOPHAGEAL SPHINCTER (UES), ESOPHAGUS, LOWER ESOPHAGEAL SPHINCTER (LES), STOMACH, SPHINCTER OF ODDI, SMALL BOWEL, COLON, DUODENUM, AND ANORECTAL ORGANS. IT IS USED IN A MEDICAL CLINICAL SETTING TO ACQUIRE PRESSURES AND THEN STORE THE CORRESPONDING DATA FOR VISUALIZATION AND ANALYSIS. THE REAL-TIME DATA AS WELL AS THE ANALYSIS INFORMATION CAN BE VIEWED BY MEDICALLY-TRAINED PERSONNEL FOR DIAGNOSTIC AND ANALYTIC PURPOSES. THE MANOSCAN HRM MODULES PROVIDE HIGH-RESOLUTION AND/OR 3D (THREE DIMENSIONAL) DISPLAY OF THE PRESSURE AND IMPEDANCE DATA. THE MANOSCAN CLT MODULE PROVIDES CONVENTIONAL LINE TRACE MAPPING OF THE PRESSURE DATA AND CAN BE USED AS A STAND-ALONE SYSTEM OR AS A MODULE OF THE MANOSCAN HIGH-RESOLUTION MANOMETRY SYSTEM.,HIGH RESOLUTION MANOMETRYESO CATHETER(MANOSCAN ESO CATHETER SD (REGULAR, SMALL))-THE MANOSCAN SYSTEM PROVIDES MAPPING OF PRESSURES AND, OPTIONALLY, IMPEDANCE WITHIN ORGANS OF THE HUMAN GASTROINTESTINAL TRACT. THESE INCLUDE THE PHARYNX, UPPER ESOPHAGEAL SPHINCTER (UES), ESOPHAGUS, LOWER ESOPHAGEAL SPHINCTER (LES), STOMACH, SPHINCTER OF ODDI, SMALL BOWEL, COLON, DUODENUM, AND ANORECTAL ORGANS. IT IS USED IN A MEDICAL CLINICAL SETTING TO ACQUIRE PRESSURES AND THEN STORE THE CORRESPONDING DATA FOR VISUALIZATION AND ANALYSIS. THE REAL-TIME DATA AS WELL AS THE ANALYSIS INFORMATION CAN BE VIEWED BY MEDICALLY-TRAINED PERSONNEL FOR DIAGNOSTIC AND ANALYTIC PURPOSES. THE MANOSCAN HRM MODULES PROVIDE HIGH-RESOLUTION AND/OR 3D (THREE DIMENSIONAL) DISPLAY OF THE PRESSURE AND IMPEDANCE DATA. THE MANOSCAN CLT MODULE PROVIDES CONVENTIONAL LINE TRACE MAPPING OF THE PRESSURE DATA AND CAN BE USED AS A STAND-ALONE SYSTEM OR AS A MODULE OF THE MANOSCAN HIGH-RESOLUTION MANOMETRY SYSTEM.,HIGH RESOLUTION MANOMETRY AR CATHETER(MANOSCAN AR CATHETER (REGULAR, SMALL))-THE MANOSCAN SYSTEM PROVIDES MAPPING OF PRESSURES AND, OPTIONALLY, IMPEDANCE WITHIN ORGANS OF THE HUMAN GASTROINTESTINAL TRACT. THESE INCLUDE THE PHARYNX, UPPER ESOPHAGEAL SPHINCTER (UES), ESOPHAGUS,

	LOWER ESOPHAGEAL SPHINCTER (LES), STOMACH, SPHINCTER OF ODDI, SMALL BOWEL, COLON, DUODENUM, AND ANORECTAL ORGANS. IT IS USED IN A MEDICAL CLINICAL SETTING TO ACQUIRE PRESSURES AND THEN STORE THE CORRESPONDING DATA FOR VISUALIZATION AND ANALYSIS. THE REAL-TIME DATA AS WELL AS THE ANALYSIS INFORMATION CAN BE VIEWED BY MEDICALLY-TRAINED PERSONNEL FOR DIAGNOSTIC AND ANALYTIC PURPOSES. THE MANOSCAN HRM MODULES PROVIDE HIGH-RESOLUTION AND/OR 3D (THREE DIMENSIONAL) DISPLAY OF THE PRESSURE AND IMPEDANCE DATA. THE MANOSCAN CLT MODULE PROVIDES CONVENTIONAL LINE TRACE MAPPING OF THE PRESSURE DATA AND CAN BE USED AS A STAND-ALONE SYSTEM OR AS A MODULE OF THE MANOSCAN HIGH-RESOLUTION MANOMETRY SYSTEM.,HIGH RESOLUTION MANOMETRY ESO Z CATHETER(MANOSCAN ESO Z CATHETER)-THE MANOSCAN SYSTEM PROVIDES MAPPING OF PRESSURES AND, OPTIONALLY, IMPEDANCE WITHIN ORGANS OF THE HUMAN GASTROINTESTINAL TRACT. THESE INCLUDE THE PHARYNX, UPPER ESOPHAGEAL SPHINCTER (UES), ESOPHAGUS, LOWER ESOPHAGEAL SPHINCTER (LES), STOMACH, SPHINCTER OF ODDI, SMALL BOWEL, COLON, DUODENUM, AND ANORECTAL ORGANS. IT IS USED IN A MEDICAL CLINICAL SETTING TO ACQUIRE PRESSURES AND THEN STORE THE CORRESPONDING DATA FOR VISUALIZATION AND ANALYSIS. THE REAL-TIME DATA AS WELL AS THE ANALYSIS INFORMATION CAN BE VIEWED BY MEDICALLY-TRAINED PERSONNEL FOR DIAGNOSTIC AND ANALYTIC PURPOSES. THE MANOSCAN HRM MODULES PROVIDE HIGH-RESOLUTION AND/OR 3D (THREE DIMENSIONAL) DISPLAY OF THE PRESSURE AND IMPEDANCE DATA. THE MANOSCAN CLT MODULE PROVIDES CONVENTIONAL LINE TRACE MAPPING OF THE PRESSURE DATA AND CAN BE USED AS A STAND-ALONE SYSTEM OR AS A MODULE OF THE MANOSCAN HIGH-RESOLUTION MANOMETRY SYSTEM.,HIGH RESOLUTION MANOMETRY AR 3D PROBE(MANOSCAN AR 3D PROBE)-THE MANOSCAN SYSTEM PROVIDES MAPPING OF PRESSURES AND, OPTIONALLY, IMPEDANCE WITHIN ORGANS OF THE HUMAN GASTROINTESTINAL TRACT. THESE INCLUDE THE PHARYNX, UPPER ESOPHAGEAL SPHINCTER (UES), ESOPHAGUS, LOWER ESOPHAGEAL SPHINCTER (LES), STOMACH, SPHINCTER OF ODDI, SMALL BOWEL, COLON, DUODENUM, AND ANORECTAL ORGANS. IT IS USED IN A MEDICAL CLINICAL SETTING TO ACQUIRE PRESSURES AND THEN STORE THE CORRESPONDING DATA FOR VISUALIZATION AND ANALYSIS. THE REAL-TIME DATA AS WELL AS THE ANALYSIS INFORMATION CAN BE VIEWED BY MEDICALLY-TRAINED PERSONNEL FOR DIAGNOSTIC AND ANALYTIC PURPOSES. THE MANOSCAN HRM MODULES PROVIDE HIGH-RESOLUTION AND/OR 3D (THREE DIMENSIONAL) DISPLAY OF THE PRESSURE AND

	IMPEDANCE DATA. THE MANOSCAN CLT MODULE PROVIDES CONVENTIONAL LINE TRACE MAPPING OF THE PRESSURE DATA AND CAN BE USED AS A STAND-ALONE SYSTEM OR AS A MODULE OF THE MANOSCAN HIGH-RESOLUTION MANOMETRY SYSTEM.,HIGH RESOLUTION MANOMETRY ESO CATHETER(MANOSCAN ESO CATHETER AND ESO WITH EXTENDED TIP)-THE MANOSCAN SYSTEM PROVIDES MAPPING OF PRESSURES AND, OPTIONALLY, IMPEDANCE WITHIN ORGANS OF THE HUMAN GASTROINTESTINAL TRACT. THESE INCLUDE THE PHARYNX, UPPER ESOPHAGEAL SPHINCTER (UES), ESOPHAGUS, LOWER ESOPHAGEAL SPHINCTER (LES), STOMACH, SPHINCTER OF ODDI, SMALL BOWEL, COLON, DUODENUM, AND ANORECTAL ORGANS. IT IS USED IN A MEDICAL CLINICAL SETTING TO ACQUIRE PRESSURES AND THEN STORE THE CORRESPONDING DATA FOR VISUALIZATION AND ANALYSIS. THE REAL-TIME DATA AS WELL AS THE ANALYSIS INFORMATION CAN BE VIEWED BY MEDICALLY-TRAINED PERSONNEL FOR DIAGNOSTIC AND ANALYTIC PURPOSES. THE MANOSCAN HRM MODULES PROVIDE HIGH-RESOLUTION AND/OR 3D (THREE DIMENSIONAL) DISPLAY OF THE PRESSURE AND IMPEDANCE DATA. THE MANOSCAN CLT MODULE PROVIDES CONVENTIONAL LINE TRACE MAPPING OF THE PRESSURE DATA AND CAN BE USED AS A STAND-ALONE SYSTEM OR AS A MODULE OF THE MANOSCAN HIGH-RESOLUTION MANOMETRY SYSTEM.

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2592	IMP/MD/2021/000295	1.License Holder Name: M/S VASCULAR CONCEPTS LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CORONARY STENT (NON-STERILE)(PROLINK -CORONARY STENT (NON-STERILE))-BALLOON EXPANDABLE COVERED STENT IS INDICATED TO COVER THE DISSECTION (TEAR) CAUSED WHEN A PTCA BALLOON OR STENT IS DEPLOYED IN A LESION. COVERED STENTS ARE USED TO CLOSE RUPTURED ARTERIES, PERFORATED ARTERIES AND TO CLOSE ANEURYSMS.,BALLOON EXPANDABLE PERIPHERAL STENT (NON-STERILE)(PROSTAR - BALLOON EXPANDABLE PERIPHERAL STENT (NON-STERILE))-INTENDED FOR USE IN ATHEROSCLEROTIC DE NOVO LESIONS, RE-STENOTIC LESIONS OF THE PERIPHERAL ARTERIES, SUCH AS THE RENAL ARTERY OR SUBCLAVIAN ARTERY.,SIROLIMUS ELUTING STENT SYSTEM -COBALT CHROMIUM DEGRADABLE MATRIX (NON-STERILE)(PRONOVA XR - SIROLIMUS ELUTING STENT SYSTEM - COBALT CHROMIUM DEGRADABLE MATRIX (NON-STERILE))-THE PRONOVA XR CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO CORONARY ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.5MM TO 4.0 MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT.,PTCA CATHETERS (NON-STERILE)(SPEED - PTCA CATHETERS (NON-STERILE))-THE SPEED CATHETERS ARE INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,DRUG ELUTING STENT (NON-STERILE)(SIROLIMUS ELUTING CORONARY STENT (STAINLESS STEEL WITH POLYSULFONE POLYMER)- NON-STERILE ALONG WITH COMPONENTS/ ACCESSORIES - DISTAL CATHETER, HYPOTUBE, KINK PROTECTOR, HUB, PROTECTIVE WIRE WITH SHEATH (NON-STERILE))-THE PRONOVA SS CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO CORONARY ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.5MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5 MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT.,DRUG ELUTING STENT (NON-STERILE)(SIROLIMUS ELUTING CORONARY STENT (COBALT CHROMIUM WITH 85/15 DL-LACTIDE/GLYCOLIDE POLYMER) - NON-STERILE ALONG WITH COMPONENTS/ ACCESSORIES - DISTAL CATHETER, HYPOTUBE, KINK PROTECTOR, HUB, PROTECTIVE WIRE

	WITH SHEATH (NON-STERILE))-THE PRONOVA XR CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO CORONARY ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.5MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT., SIROLIMUS ELUTING STENT SYSTEM (COBALT CHROMIUM) - (NON-STERILE)(PRONOVA - SIROLIMUS ELUTING STENT SYSTEM (COBALT CHROMIUM) - (NON-STERILE))-THE PRONOVA CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO CORONARY ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER). LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT., SIROLIMUS ELUTING STENT SYSTEM- STAINLESS STEEL (NON-STERILE)(PRONOVA SS - SIROLIMUS ELUTING STENT SYSTEM- STAINLESS STEEL (NON-STERILE))-THE PRONOVA SS CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO CORONARY ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.5MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT.,CORONARY STENT SYSTEM- STAINLESS STEEL BALLOON EXPANDABLE (NON -STERILE)(PROLINK LP - CORONARY STENT SYSTEM- STAINLESS STEEL BALLOON EXPANDABLE (NON - STERILE))-THE PROLINK LP CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE CORONARY DE NOVO ARTERY LESIONS WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0MM TO 4.5 MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT.,BALLOON EXPANDABLE CORONARY STENT SYSTEM - COBALT CHROMIUM (NON-STERILE)(PROZETA - BALLOON EXPANDABLE CORONARY STENT SYSTEM - COBALT CHROMIUM (NON-STERILE))-THE PROZETA CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO CORONARY ARTERY

		LESIONS WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0 MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED FOR TREATMENT OF CORONARY ARTERIES.,BALLOON EXPANDABLE CORONARY STENT SYSTEM (SIROLIMUS ELUTING STENT)(“EUCALIMUS” - BALLOON EXPANDABLE CORONARY STENT SYSTEM - SIROLIMUS ELUTING STENT (STERILE))-THE EUCALIMUS CORONARY STENT SYSTEM IS A DRUG-COATED CORONARY STENT SYSTEM, INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHAEMIC CORONARY HEART DISEASE DUE TO DE NOVO LESIONS OR RE-STENOSISED LESIONS OF THE CORONARY ARTERIES. THE STENT SYSTEMS ARE ALSO INDICATED FOR THE TREATMENT OF ACUTE OR SUSPECTED OCCLUSIONS IN PATIENTS WHO RESPONDED UNSUCCESSFULLY TO AN INTERVENTIONAL THERAPY FOLLOWING BALLOON DILATATION. THE EUCALIMUS STENT IS INTENDED FOR USE IN PATIENTS ELIGIBLE FOR PTCA WITH A REFERENCE VESSEL DIAMETER OF 2.25MM TO 4.00MM (MAXIMUM STENT DIAMETER AFTER PLACEMENT IS 0.5MM ABOVE THE NOMINAL VALUE) AND IS INTENDED TO EXPAND THE LUMEN OF THE CORONARY ARTERIES AS WELL AS MAINTAINING THE VESSEL PATENCY. THE LESION TO BE TREATED SHOULD BE SHORTER THAN THE NOMINAL LENGTH OF THE STENT AT A REFERENCE VESSEL DIAMETER OF 2.25MM TO 4.00MM.,DRUG ELUTING STENT (NON-STERILE)(SIROLIMUS ELUTING CORONARY STENT (COBALT CHROMIUM WITH POLYSULFONE POLYMER) - NON-STERILE ALONG WITH COMPONENTS/ ACCESSORIES - DISTAL CATHETER, HYPOTUBE, KINK PROTECTOR, HUB, PROTECTIVE WIRE WITH SHEATH (NON-STERILE))-THE PRONOVA CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO CORONARY ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT.
2593	IMP/MD/2021/000297	1.License Holder Name: CLINIEXPERTS SERVICES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORGAN CARE SYSTEM - HEART(OCS HEART)-ORGAN CARE SYSTEM IS A PORTABLE ORGAN PERFUSION AND MONITORING SYSTEM INTENDED TO PRESERVE A DONATED HEART IN A NEAR-NORMAL PHYSIOLOGICAL FUNCTIONING STATE DURING TRANSPORT FOR EVENTUAL TRANSPLANTATION INTO A RECIPIENT.

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2594	IMP/MD/2021/000298	1.License Holder Name: WIPRO GE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NUCLEAR MEDICINE SYSTEM(NM/CT 870 DR)-THE GE NM/CT 870 DR SYSTEM IS A MEDICAL TOOL INTENDED FOR USE BY APPROPRIATELY TRAINED HEALTHCARE PROFESSIONALS TO AID IN DETECTING, LOCALIZING, DIAGNOSING OF DISEASES AND ORGAN FUNCTION FOR THE EVALUATION OF DISEASES, TRAUMA, ABNORMALITIES, AND DISORDERS SUCH AS, BUT NOT LIMITED TO, CARDIOVASCULAR DISEASE, NEUROLOGICAL DISORDERS AND CANCER. THE SYSTEM OUTPUT CAN ALSO BE USED BY THE PHYSICIAN FOR STAGING AND RESTAGING OF TUMORS, PLANNING, GUIDING, AND MONITORING THERAPY,NUCLEAR MEDICINE SYSTEM(NM/CT 860)-THE GE NM/CT 860 SYSTEM IS INTENDED FOR GENERAL NUCLEAR MEDICINE IMAGING PROCEDURES FOR DETECTION OF RADIOISOTOPE TRACER UPTAKE IN THE PATIENT BODY. IT INCLUDES A GENERAL PURPOSE NUCLEAR MEDICINE SYSTEM USING A VARIETY OF SCANNING MODES SUPPORTED BY VARIOUS ACQUISITION TYPES, AND A COMPUTED TOMOGRAPHY SYSTEM WHICH IS INTENDED FOR ENABLING ATTENUATION CORRECTION AND ANATOMICAL LOCALIZATION OF SPECT IMAGES AND FOR STANDALONE HEAD, WHOLE BODY AND VASCULAR X-RAY COMPUTED TOMOGRAPHY APPLICATIONS., NUCLEAR MEDICINE IMAGING SYSTEM(DISCOVERY NM 530C)-THE INTENDED USE OF THE DISCOVERY NM 530C SYSTEM IS TO PERFORM NUCLEAR IMAGING PROCEDURES FOR DETECTION AND IMAGING OF RADIOISOTOPE TRACER UPTAKE IN THE PATIENT BODY FOR CLINICAL DIAGNOSTIC PURPOSES. INDICATIONS FOR USE: DISCOVERY NM 530C IS PRIMARILY INTENDED FOR CARDIAC APPLICATIONS.,NUCLEAR MEDICINE IMAGING SYSTEM(DISCOVERY NM 630)-THE GE DISCOVERY NM 630 AND NM 830 SYSTEM MAY INCLUDE SIGNAL ANALYSIS AND DISPLAY EQUIPMENT, PATIENT AND EQUIPMENT SUPPORTS, COMPONENTS AND ACCESSORIES. THE SYSTEM MAY BE USED FOR PATIENTS OF ALL AGES,NUCLEAR MEDICINE IMAGING SYSTEM(NM 830)-THE GE NM 830 SYSTEM ARE A MEDICAL TOOL INTENDED FOR USE BY APPROPRIATELY TRAINED HEALTHCARE PROFESSIONALS TO AID IN DETECTING, LOCALIZING, DIAGNOSING OF DISEASES AND IN ASSESSMENT OF ORGAN FUNCTION FOR THE EVALUATION OF DISEASES, TRAUMA, ABNORMALITIES, AND DISORDERS SUCH AS, BUT NOT LIMITED TO, CARDIOVASCULAR DISEASE, NEUROLOGICAL DISORDERS AND CANCER. THE SYSTEM OUTPUT CAN ALSO BE USED BY THE PHYSICIAN FOR STAGING AND RESTAGING OF TUMORS, PLANNING, GUIDING, AND MONITORING THERAPY.,SPECT/CT - SINGLE-PHOTON EMISSION COMPUTERIZED TOMOGRAPHY(NM/CT 850)-THE GE

	NM/CT 850 SYSTEM IS INTENDED FOR GENERAL NUCLEAR MEDICINE IMAGING PROCEDURES FOR DETECTION OF RADIOISOTOPE TRACER UPTAKE IN THE PATIENT BODY. IT INCLUDES A GENERAL-PURPOSE NUCLEAR MEDICINE SYSTEM USING A VARIETY OF SCANNING MODES SUPPORTED BY VARIOUS ACQUISITION TYPES, AND A COMPUTED TOMOGRAPHY COMPONENT WHICH IS INTENDED SPECIFICALLY FOR ENABLING ATTENUATION CORRECTION AND ANATOMICAL LOCALIZATION OF SPECT IMAGES.

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2595	IMP/MD/2021/000299	1.License Holder Name: LIVANOVA INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMPLANTABLE LEAD(VNS THERAPY® PERENNIAFLEX® MODEL 304 LEAD)-INDICATED FOR USE AS AN ADJUNCTIVE THERAPY IN REDUCING THE FREQUENCY OF SEIZURES IN PATIENTS WHOSE EPILEPTIC DISORDER IS DOMINATED BY PARTIAL SEIZURES (WITH OR WITHOUT SECONDARY GENERALIZATION) OR GENERALIZED SEIZURES THAT ARE REFRACTORY TO SEIZURE MEDICATIONS.,IMPLANTABLE GENERATOR (VNS THERAPY® SENTIVA MODEL 1000 GENERATOR)-INDICATED FOR USE AS AN ADJUNCTIVE THERAPY IN REDUCING THE FREQUENCY OF SEIZURES IN PATIENTS WHOSE EPILEPTIC DISORDER IS DOMINATED BY PARTIAL SEIZURES (WITH OR WITHOUT SECONDARY GENERALIZATION) OR GENERALIZED SEIZURES THAT ARE REFRACTORY TO SEIZURE MEDICATIONS SENTIVA® FEATURES AN AUTOMATIC STIMULATION MODE WHICH IS INTENDED FOR PATIENTS WHO EXPERIENCE SEIZURES THAT ARE ASSOCIATED WITH CARDIAC RHYTHM INCREASES KNOWN AS ICTAL TACHYCARDIA., IMPLANTABLE LEAD(VNS THERAPY® PERENNIADURA® MODEL 303 LEAD)-INDICATED FOR USE AS AN ADJUNCTIVE THERAPY IN REDUCING THE FREQUENCY OF SEIZURES IN PATIENTS WHOSE EPILEPTIC DISORDER IS DOMINATED BY PARTIAL SEIZURES (WITH OR WITHOUT SECONDARY GENERALIZATION) OR GENERALIZED SEIZURES THAT ARE REFRACTORY TO SEIZURE MEDICATIONS., IMPLANTABLE GENERATOR(VNS THERAPY® ASPIRE SR® MODEL 106 GENERATOR)-INDICATED FOR USE AS AN ADJUNCTIVE THERAPY IN REDUCING THE FREQUENCY OF SEIZURES IN PATIENTS WHOSE EPILEPTIC DISORDER IS DOMINATED BY PARTIAL SEIZURES (WITH OR WITHOUT SECONDARY GENERALIZATION) OR GENERALIZED SEIZURES THAT ARE REFRACTORY TO SEIZURE MEDICATIONS ASPIRESR® FEATURES AN AUTOMATIC STIMULATION MODE WHICH IS INTENDED FOR PATIENTS WHO EXPERIENCE SEIZURES THAT ARE ASSOCIATED WITH CARDIAC RHYTHM INCREASES KNOWN AS ICTAL TACHYCARDIA.,IMPLANTABLE GENERATOR(VNS THERAPY® DEMIPULSE® MODEL 103 GENERATOR)-INDICATED FOR USE AS AN ADJUNCTIVE THERAPY IN REDUCING THE FREQUENCY OF SEIZURES IN PATIENTS WHOSE EPILEPTIC DISORDER IS DOMINATED BY PARTIAL SEIZURES (WITH OR WITHOUT SECONDARY GENERALIZATION) OR GENERALIZED SEIZURES THAT ARE REFRACTORY TO SEIZURE MEDICATIONS

2596	IMP/MD/2021/000300	1.License Holder Name: WIPRO GE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAMMOGRAPHY (SENOGRAPHE CRYSTAL NOVA)-SENOGRAPHE CRYSTAL NOVA GENERATES DIGITAL MAMMOGRAPHIC IMAGES THAT CAN BE USED FOR SCREENING AND IN THE DIAGNOSIS OF BREAST CANCER. SENOGRAPHE CRYSTAL NOVA IS INTENDED TO BE USED IN THE SAME CLINICAL APPLICATIONS AS TRADITIONAL FILM-BASED MAMMOGRAPHIC SYSTEMS.

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2597	IMP/MD/2021/000301	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RADIO-FREQUENCY ABLATION SYSTEM(G4 RADIOFREQUENCY GENERATOR KIT)-THE BOSTON SCIENTIFIC G4 RADIOFREQUENCY GENERATOR IS INDICATED FOR USE IN PROCEDURES TO CREATE RADIOFREQUENCY LESIONS FOR THE TREATMENT OF PAIN, OR FOR LESIONING NERVE TISSUE FOR FUNCTIONAL NEUROSURGICAL PROCEDURES. THE BOSTON SCIENTIFIC G4 RADIOFREQUENCY GENERATOR IS USED WITH SEPARATELY APPROVED BOSTON SCIENTIFIC RADIOFREQUENCY PROBES.,IMPANTABLE PULSE GENERATOR (VERCISE PC IMPANTABLE PULSE GENERATOR KIT)-THE VERCISE PC DBS SYSTEM IS INDICATED FOR USE IN THE FOLLOWING: • UNILATERAL OR BILATERAL STIMULATION OF THE SUBTHALAMIC NUCLEUS (STN) OR INTERNAL GLOBUS PALLIDUS (GPI) FOR LEVODOPA-RESPONSIVE PARKINSON'S DISEASE WHICH IS NOT ADEQUATELY CONTROLLED WITH MEDICATION. • UNILATERAL OR BILATERAL STIMULATION OF THE SUBTHALAMIC NUCLEUS (STN) OR INTERNAL GLOBUS PALLIDUS (GPI) FOR INTRACTABLE PRIMARY AND SECONDARY DYSTONIA, FOR PERSONS 7 YEARS OF AGE AND OLDER. • THALAMIC STIMULATION FOR THE SUPPRESSION OF TREMOR NOT ADEQUATELY CONTROLLED BY MEDICATIONS IN PATIENTS DIAGNOSED WITH ESSENTIAL TREMOR OR PARKINSON'S DISEASE., IMPANTABLE PULSE GENERATOR(VERCISE GEVIA 16 CONTACT IMPANTABLE PULSE GENERATOR KIT)-THE VERCISE GEVIA DBS SYSTEM IS INDICATED FOR USE IN THE FOLLOWING: • UNILATERAL OR BILATERAL STIMULATION OF THE SUBTHALAMIC NUCLEUS (STN) OR INTERNAL GLOBUS PALLIDUS (GPI) FOR LEVODOPA-RESPONSIVE PARKINSON'S DISEASE WHICH IS NOT ADEQUATELY CONTROLLED WITH MEDICATION. • UNILATERAL OR BILATERAL STIMULATION OF THE SUBTHALAMIC NUCLEUS (STN) OR INTERNAL GLOBUS PALLIDUS (GPI) FOR INTRACTABLE PRIMARY AND SECONDARY DYSTONIA, FOR PERSONS 7 YEARS OF AGE AND OLDER. • THALAMIC STIMULATION FOR THE SUPPRESSION OF TREMOR NOT ADEQUATELY CONTROLLED BY MEDICATIONS IN PATIENTS DIAGNOSED WITH ESSENTIAL TREMOR OR PARKINSON'S DISEASE.

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2598	IMP/MD/2021/000314	1.License Holder Name: PHILIPS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DEFIBIRILLATOR(EFFICIA) -THE EFFICIA DFM100 IS INTENDED FOR USE IN A HOSPITAL OR EMS SETTING BY USERS TRAINED IN THE OPERATION OF THE DEVICE AND QUALIFIED BY TRAINING IN BLS AND ALS. THE EFFICIA DFM100 IS INTENDED FOR USE FOR EMERGENCY RESUSCITATION AS FOLLOWS: • IN AED MODE, THE EFFICIA DFM100 IS INTENDED TO DETECT A SHOCKABLE RHYTHM AND DELIVER A SHOCK. • IN MANUAL MODE, THE EFFICIA DFM100 IS INTENDED TO DELIVER SYNCHRONIZED AND ASYCHRONIZED DEFIBRILLATION. • IN PACING MODE, THE EFFICIA DFM100 IS INTENDED TO DELIVER EXTERNAL CARDIAC PACING. • IN MONITOR MODE, THE EFFICIA DFM100 IS INTENDED TO MEASURE HEART RATE AND HEART RHYTHM VIA ECG, MEASURE BLOOD OXYGEN SATURATION VIA SPO2, MEASURE EXHALED CO2 VIA ETCO2, AND MEASURE SYSTOLIC, DIASTOLIC, AND MEAN BLOOD PRESSURE VIA NBP.,DEFIBRILLATOR(HEARTSTART INTREPID)-THE HEARTSTART INTREPID IS INTENDED FOR USE IN AN EMS OR HOSPITAL SETTING BY QUALIFIED MEDICAL PERSONNEL TRAINED IN THE OPERATION OF THE DEVICE AND QUALIFIED BY CERTIFIED TRAINING IN BASIC LIFE SUPPORT OR ADVANCED LIFE SUPPORT. THIS HEARTSTART INTREPID IS INTENDED FOR USE IN EMERGENCY RESUSCITATION AS FOLLOWS: •IN AED MODE, TO DETECT A SHOCKABLE RHYTHM AND DELIVER A SHOCK •IN MANUAL MODE, TO DELIVER SYNCHRONIZED AND ASYCHRONIZED DEFIBRILLATION. •THE OPTIONAL Q-CPR METER 2 TO PROVIDE THE USER FEEDBACK IN PERFORMING CHEST COMPRESSION DURING CPR •IN PACING MODE TO DELIVER EXTERNAL CARDIAC PACING •IN MONITOR MODE, THE INTREPID IS INTENDED TO –MEASURE HEART RATE AND HEART RHYTHM VIA ECG –MEASURE BLOOD OXYGEN SATURATION VIA SPO2 –MEASURE EXHALED CO2 VIA ETCO2 –MEASURE SYSTOLIC, DIASTOLIC, AND MEAN BLOOD PRESSURE VIA NBP –MEASURE TEMPERATURE

2599	IMP/MD/2021/000315	1.License Holder Name: HESTER DIAGNOSTICS PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SELECT CATHETER (SELECT CATHETER (NEURON 5F SELECT CATHETER AND NEURON 6F SELECT CATHETER))-INDICATED FOR THE INTRODUCTION OF INTERVENTIONAL DEVICES INTO THE PERIPHERAL, CORONARY, AND NEURO VASCULATURE.,DELIVERY CATHETER AND SELECT CATHETER (KIT)(BENCHMARK 6F DELIVERY CATHETER AND 5F SELECT CATHETER (KIT))-INDICATED FOR THE INTRODUCTION OF INTERVENTIONAL DEVICES INTO THE PERIPHERAL, CORONARY, AND NEURO VASCULATURE.,DELIVERY CATHETER(DELIVERY CATHETER (BENCHMARK 6F DELIVERY CATHETER, NEURON 6F DELIVERY CATHETER, NEURON MAX 8F DELIVERY CATHETER AND NEURON MAX 6F LONG SHEATH))-INDICATED FOR THE INTRODUCTION OF INTERVENTIONAL DEVICES INTO THE PERIPHERAL, CORONARY, AND NEURO VASCULATURE.
2600	IMP/MD/2021/000317	1.License Holder Name: BARD INDIA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOPSY NEEDLE(BARD TRUGUIDE DISPOSABLE COAXIAL BIOPSY NEEDLE)-INTENDED FOR USE AS A GUIDING NEEDLE IN OBTAINING CORE BIOPSY SAMPLES FROM SOFT TISSUE SUCH AS LIVER, KIDNEY, SPLEEN, LYMPH NODES AND VARIOUS SOFT TISSUE LESIONS.
2601	IMP/MD/2021/000321	1.License Holder Name: CJ MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STRETTA-THE STRETTA SYSTEM IS INTENDED FOR USE SPECIFICALLY IN THE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE (GERD).,GENERATOR(MEDERI RF LLC)-THE MEDERI-RF GENERATOR IS INTENDED FOR GENERAL USE IN THE ELECTROSURGICAL COAGULATION OF TISSUE, SPECIFICALLY: • THE MEDERI-RF GENERATOR WHEN USED WITH THE STRETTA DISPOSABLE CATHETER IS INTENDED FOR THE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE (GERD). • THE MEDERI-RF GENERATOR WHEN USED WITH THE SECCA DISPOSABLE HANDPIECE IS INTENDED FOR THE TREATMENT OF BOWEL INCONTINENCE IN PATIENTS WITH INCONTINENCE TO SOLID OR LIQUID STOOL AT LEAST ONCE PER WEEK AND WHO HAVE FAILED MORE CONSERVATIVE THERAPY.

2602	IMP/MD/2021/000322	1.License Holder Name: CLOUDTAIL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITOR(AMAZON BASICS)-THE TRANSTEK BLOOD PRESSURE MONITOR IS DIGITAL MONITORS INTENDED FOR USE IN MEASURING BLOOD PRESSURE AND HEARTBEAT RATE WITH ARM CIRCUMSTANCE RANGING FROM 22 CM TO 32 CM OR 22 CM TO 42 CM. IT IS INTENDED FOR ADULT INDOOR USE ONLY.
2603	IMP/MD/2021/000326	1.License Holder Name: M/S. JAYCOT INDUSTRIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AUTOMATIC BLOOD PRESSURE MONITOR(JAYCOT)-AUTOMATIC UPPER ARM BLOOD PRESSURE MONITOR IS INTENDED FOR THE NONINVASIVE MEASUREMENT OF BLOOD PRESSURE AND PULSE RATE IN ADULTS.

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2604	IMP/MD/2021/000327	1.License Holder Name: WIPRO GE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAMMOGRAPHY (SENOGRAPHE PRISTINA)-SENOGRAPHE PRISTINA GENERATES DIGITAL MAMMOGRAPHIC IMAGES THAT CAN BE USED FOR SCREENING AND IN THE DIAGNOSIS OF BREAST CANCER. SENOGRAPHE PRISTINA IS INTENDED TO BE USED IN THE SAME CLINICAL APPLICATIONS AS TRADITIONAL FILM-BASED MAMMOGRAPHIC SYSTEMS.,ANGIOGRAPHIC X-RAY SYSTEM(INNOVA IGS 5)-THE ANGIOGRAPHIC X-RAY SYSTEMS ARE INDICATED FOR USE FOR PATIENTS FROM NEWBORN TO GERIATRIC IN GENERATING FLUOROSCOPIC AND ROTATIONAL IMAGES OF HUMAN ANATOMY FOR CARDIOVASCULAR, VASCULAR AND NON-VASCULAR, DIAGNOSTIC AND INTERVENTIONAL PROCEDURES.,ANGIOGRAPHIC X-RAY SYSTEM(DISCOVERY IGS 7 OR)-THE ANGIOGRAPHIC X-RAY SYSTEMS ARE INDICATED FOR USE FOR PATIENTS FROM NEWBORN TO GERIATRIC IN GENERATING FLUOROSCOPIC AND ROTATIONAL IMAGES OF HUMAN ANATOMY FOR CARDIOVASCULAR, VASCULAR AND NON-VASCULAR, DIAGNOSTIC AND INTERVENTIONAL PROCEDURES. ADDITIONALLY, WITH THE OR TABLE, THE ANGIOGRAPHIC X-RAY SYSTEMS ARE INDICATED FOR USE IN GENERATING FLUOROSCOPIC AND ROTATIONAL IMAGES OF HUMAN ANATOMY FOR IMAGE-GUIDED SURGICAL PROCEDURES, ANGIOGRAPHIC X-RAY SYSTEM(INNOVA IGS 6)-THE ANGIOGRAPHIC X-RAY SYSTEMS ARE INDICATED FOR USE FOR PATIENTS FROM NEWBORN TO GERIATRIC IN GENERATING FLUOROSCOPIC AND ROTATIONAL IMAGES OF HUMAN ANATOMY FOR CARDIOVASCULAR, VASCULAR AND NON-VASCULAR, DIAGNOSTIC AND INTERVENTIONAL PROCEDURES.
2605	IMP/MD/2021/000328	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLADDER CATHETER (RUSCH PVC CATHETER TIEMANN PATTERN)-THESE CATHETERS ARE INDICATED FOR THE ROUTINE DRAINAGE OF URINE FROM THE BLADDER. THESE CATHETERS ARE NOT INTENDED OR DESIGNED FOR INDWELLING USE.

2606	IMP/MD/2021/000329	1.License Holder Name: MEDYSSEY INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SPINAL INTERNAL FIXATION SYSTEM, INTERVERTEBRAL BODY(ZENIUS SPINAL SYSTEM) -IT IS INDICATED FOR TEMPORARY CORRECTION OR STABILIZATION OF THE VERTEBRAL COLUMN AND WITH THE AIM OF HELPING CONSOLIDATION OF BONE FUSION.,SPINAL INTERVERTEBRAL BODY FIXATION ORTHOSIS(KORA SPINAL SYSTEM)-KORA SPINAL SYSTEM ARE INDICATED FOR TEMPORARY OR PERMANENT CORRECTION OR STABILIZATION OF THE VERTEBRAL COLUMN AND WITH THE AIM OF HELPING CONSOLIDATION OF BONE FUSION. THIS SPINAL SYSTEM MUST BE USED WITH INTERBODY FUSION CAGE AT THE SURGERY FOR SUCCESSFUL FUSION THEY ARE INDICATED FOR: PRIMARY SURGERY FOR ADVANCED DISCOPATHIES OR EXTENSIVE DECOMPRESSIONS (LAMINECTOMY, FACETECTOMY, FORAMINOTOMY, ETC.) SPONDYLOTIC SPINAL STENOSIS REVISION SURGERY FOR FAILED DISC OPERATION POST-OPERATIVE INSTABILITY DISC HERNIATION SPONDYLOSIS WITH BONE SPURRING, FORAMINAL NARROWING AND NERVE ROOT IMPINGEMENT CHRONIC AND DISABLING DISCOGENIC LOW BACK PAIN SPINAL PSEUDARTHROSIS.,SPINAL INTERVERTEBRAL BODY FIXATION ORTHOSIS(LP CAGE)-THE LP CAGE IS INDICATED FOR USE WITH AUTOGENOUS BONE GRAFT PATIENTS WITH DEGENERATIVE DISC DISEASE AND THIS LP CAGE IS DESIGNED TO UTILIZING THE MANAGEMENT ON THE DEGENERATIVE DISC DISEASE OF THE EXTENSIVE SPINAL COLUMN, FROM THORACIC TO SACRAL SPINE, INCLUDE ISOLATED DISC RESORPTION, PRIMARY AND SECONDARY INSTABILITY, RECURRENT DISC HERNIATION, AND PSEUDARTHOSIS. THE LP CAGE IS AN INTERBODY FUSION CAGE OF IMPLANTS AND INSTRUMENTS DESIGNED FOR POSTERIOR LUMBAR INTERBODY FUSION(PLIF). THIS LP CAGE MUST BE USED WITH SPINAL SUPPLEMENTAL FIXATION FOR STABILITY. THERE ARE GENERAL SYMPTOMS OF INTENDED USE WHICH IN INDICATIONS. THEY ARE INDICATED FOR: PRIMARY SURGERY FOR ADVANCED DISCOPATHIES OR EXTENSIVE DECOMPRESSIONS (LAMINECTOMY, FACETETOMY, FORAMINOTOMY, ETC.) SPONDYLOTIC SPINAL STENOSIS REVISION SURGERY FOR FAILED DISC OPERATION POST-OPERATIVE INSTABILITY DISC HERNIATION SPONDYLOSIS WITH BONE SPURRING, FORAMINAL NARROWING AND NERVE ROOT IMPINGENMENT CHRONIC AND DISABLING DISCOGENIC LOW BACK PAIN SPINAL PSEUDARTHROSIS,SPINAL INTERVERTEBRAL BODY FIXATION ORTHOSIS(C7 CAGE)-THE C7 CAGE IS INDICATED FOR USE WITH AUTOGENOUS BONE GRAFT PATIENTS WITH DEGENERATIVE DISC DISEASE. THEY ARE INDICATED FOR: RUPTURED AND HERNIATED

		DISC DEGENERATIVE DISC DISEASE AND INSTABILITIES PSEUDARTHROSIS OR FAILED SPONDYLODESIS.
2607	IMP/MD/2021/000330	1.License Holder Name: HARSONS SURGICAL AND MEDICO 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (NIL)-IT IS A DEVICE USED TO MEASURE BODY TEMPERATURE., FOREHEAD THERMOMETER(NIL)-FOREHEAD THERMOMETER IS DESIGNED FOR BODY SURFACE AND TEMPERATURE MEASUREMENT FOR INFANT AND ADULT WITHOUT CONTACT TO HUMAN BODY

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2608	IMP/MD/2021/000332	1.License Holder Name: WIPRO GE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGERY(BRIVO OEC 715) -BRIVO OEC 715 IS DESIGNED TO PROVIDE DIGITAL SPOT-FILM IMAGING AND FLUOROSCOPIC IMAGE GUIDANCE ACROSS ALL ADULT AND PEDIATRIC POPULATIONS FOR ORIENTATIONS BETWEEN PATIENT ANATOMY AND SURGICAL INSTRUMENTS. THE PRODUCT IS USED FOR GENERAL SURGICAL APPLICATIONS AND MUSCULOSKELETAL PROCEDURES TO VISUALIZE, FOR EXAMPLE, IMPLANT LOCALIZATION/S OR NEEDLE POSITIONS FOR ASPIRATIONS, INJECTIONS OR BIOPSY.,MOBILE DIAGNOSTIC X-RAY AND FLUOROSCOPIC SYSTEM(OEC ONE/OEC ONE CFD)-THE PRODUCT IS INTENDED TO PROVIDE FLUOROSCOPIC AND DIGITAL SPOT/FILM IMAGES OF THE PATIENT ANATOMY, INTERVENTIONAL TOOLS/DEVICES, AND/OR CONTRAST AGENTS DURING DIAGNOSTIC, INTERVENTIONAL, AND SURGICAL PROCEDURES.,INTERVENTIONAL RADIOLOGY - X-RAY SYSTEM/MEDICAL X-RAY ANGIOGRAPHY EQUIPMENT(OPTIMA IGS 330)-THE ANGIOGRAPHIC X-RAY SYSTEMS ARE INDICATED FOR USE FOR PATIENTS FROM NEWBORN TO GERIATRIC IN GENERATING FLUOROSCOPIC AND ROTATIONAL IMAGES OF HUMAN ANATOMY FOR CARDIOVASCULAR, VASCULAR AND NON-VASCULAR, DIAGNOSTIC AND INTERVENTIONAL PROCEDURES.,X- RAY(OPTIMA XR 646 HD)-GENERAL PURPOSE DIGITAL RADIOGRAPHIC IMAGING SYSTEM THE OPTIMA XR646 HD IS INTENDED TO GENERATE DIGITAL RADIOGRAPHIC IMAGES OF THE SKULL, SPINAL COLUMN, CHEST, ABDOMEN, EXTREMITIES, AND OTHER BODY PARTS IN PATIENTS OF ALL AGES. APPLICATIONS CAN BE PERFORMED WITH THE PATIENT SITTING, STANDING, OR LYING IN THE PRONE OR SUPINE POSITION AND THE SYSTEM IS INTENDED FOR USE IN ALL ROUTINE RADIOGRAPHY EXAMS. OPTIONAL IMAGE PASTING FUNCTION ENABLES THE OPERATOR TO STITCH SEQUENTIALLY ACQUIRED RADIOGRAPHS INTO A SINGLE IMAGE. THE OPTIMA XR646 HD INCORPORATES AUTOGRID, WHICH IS AN OPTIONAL IMAGE PROCESSING SOFTWARE INSTALLED AS A PART OF THE SYSTEMS HELIX IMAGE PROCESSING SOFTWARE. AUTOGRID CAN BE USED IN LIEU OF AN ANTI-SCATTER GRID TO IMPROVE IMAGE CONTRAST IN GENERAL RADIOGRAPHIC IMAGES BY REDUCING THE EFFECTS OF SCATTER RADIATION.,X-RAY SYSTEM(DISCOVERY XR656 HD)-THE DISCOVERY XR656 HD IS INTENDED TO GENERATE DIGITAL RADIOGRAPHIC IMAGES OF THE SKULL, SPINAL COLUMN, CHEST, ABDOMEN, EXTREMITIES, AND OTHER BODY PARTS IN PATIENTS OF ALL AGES. APPLICATIONS CAN BE PERFORMED WITH THE PATIENT SITTING, STANDING, OR LYING IN THE PRONE OR SUPINE POSITION AND THE SYSTEM IS INTENDED FOR USE IN ALL ROUTINE

		RADIOGRAPHY EXAMS. OPTIONAL IMAGE PASTING FUNCTION ENABLES THE OPERATOR TO STITCH SEQUENTIALLY ACQUIRED RADIOGRAPHS INTO A SINGLE IMAGE.,MOBILE DIGITAL X-RAY SYSTEM DIAGNOSTIC RADIOSCOPIC AND FLUOROSCOPIC(BRIVO OEC 785)-THE BRIVO OEC 785 MOBILE C-ARM X-RAY PRODUCT IS DESIGNED TO PROVIDE DIGITAL SPOT-FILM IMAGING AND FLUOROSCOPIC IMAGE GUIDANCE ACROSS ALL ADULT AND PEDIATRIC POPULATIONS FOR ORIENTATIONS BETWEEN PATIENT ANATOMY AND SURGICAL INSTRUMENTS. THE PRODUCT IS USED FOR GENERAL SURGICAL APPLICATIONS AND MUSCULOSKELETAL PROCEDURES TO VISUALIZE, FOR EXAMPLE, IMPLANT LOCALIZATION/S OR NEEDLE POSITIONS FOR ASPIRATIONS, INJECTIONS OR BIOPSY. NOT FOR INTERVENTIONAL USE.
2609	IMP/MD/2021/000336	1.License Holder Name: PHILIPS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEBULIZER(PHILIPS HOME NEBULIZER)-PHILIPS HOME NEBULIZER IS AN AC-POWERED AIR COMPRESSOR NEBULIZER SYSTEM INTENDED TO PROVIDE A SOURCE OF COMPRESSED AIR FOR MEDICAL PURPOSES FOR USE IN HOME HEALTHCARE. IT IS TO BE USED WITH A PNEUMATIC NEBULIZER TO PRODUCE AEROSOL PARTICLES OF MEDICATION FOR RESPIRATORY THERAPY FOR BOTH CHILDREN AND ADULTS. THE USER (PATIENT) IS THE INTENDED OPERATOR OF THE PHILIPS HOME NEBULIZER.
2610	IMP/MD/2021/000337	1.License Holder Name: SKY MARKETING 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HYPROCURE® SINUS TARSI IMPLANT SYSTEM(HYPROCURE® SINUS TARSI STENT)-HYPROCURE IS A TALOTARSAL STABILIZATION DEVICE USED IN THE TREATMENT OF TALOTARSAL DISLOCATION AND RESULTING SEQUELA. THE IMPLANT IS DESIGNED TO STABILIZE THE TALUS ON THE TARSAL MECHANISM TO PREVENT EXCESSIVE ANTERIOR, AND/OR MEDIAL, AND/OR PLANTAR FLEXION OF THE TALUS ON THE TARSAL MECHANISM, WHILE ALLOWING NORMAL TALOTARSAL JOINT MOTION.

2611	IMP/MD/2021/000338	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:WIRE IMPLANTS- K WIRE (SS)-WIRE IMPLANTS ARE INTENDED FOR FIXATION OF BONE FRAGMENTS.,WIRE IMPLANTS- KIRSCHENER WIRE-SS-WIRE IMPLANTS ARE INTENDED FOR FIXATION OF BONE FRAGMENTS., SCREW IMPLANTS FOR OR WITHOUT PLATES- SS-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., SCREW IMPLANTS FOR OR WITHOUT PLATES- SCREW (SS)-THE INTERNAL MIDFACE DISTRACTOR- THE MAXILLARY DISTRACTOR- THE SINGLE VECTOR DISTRACTOR- THE EXTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE- WHERE GRADUAL BONE DISTRACTION IS REQUIRED. THE CRANIOMAXILLOFACIAL (CMF) DISTRACTOR AND SYNTHES MULTI-VECTOR DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING (AND/OR TRANSPORT) DEVICE- WHERE GRADUAL BONE DISTRACTION IS REQUIRED. UNIVERSAL SCREW REMOVAL SET IS INTENDED TO BE USED FOR THE REMOVAL OF INTACT AND DAMAGED SCREWS. IT IS NOT INTENDED TO BE USED IN COMBINATION WITH A POWER TOOL.,WIRES (POWER DRIVEN)- GUIDE WIRE (SS)-WIRE IMPLANTS ARE INTENDED FOR FIXATION OF BONE FRAGMENTS.,WIRES (POWER DRIVEN)- GUIDE WIRE-THE WIRE INSTRUMENTS ARE INTENDED FOR PROVISIONAL FRACTURE FIXATION AND SHORT TERM INSERTION INTO BONE IN ORDER TO FACILITATE AND GUIDE IMPLANT OR INSTRUMENT APPLICATION DURING ORTHOPEDIC SURGERY.,SCREW IMPLANTS FOR OR WITHOUT PLATES- TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., DYNAMIC HIP PLATING IMPLANTS- SCREW-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., MAXILLARY DISTRACTOR- SCREW-INTERNAL MIDFACE DISTRACTOR- THE MAXILLARY DISTRACTOR- THE SINGLE VECTOR DISTRACTOR- THE EXTERNAL MIDFACE DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE- WHERE GRADUAL BONE DISTRACTION IS REQUIRED. THE CRANIOMAXILLOFACIAL (CMF) DISTRACTOR AND SYNTHES MULTI-VECTOR DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING (AND/OR TRANSPORT) DEVICE- WHERE GRADUAL BONE DISTRACTION IS REQUIRED. UNIVERSAL SCREW REMOVAL SET IS INTENDED TO BE USED FOR THE REMOVAL OF INTACT AND DAMAGED SCREWS. IT IS NOT INTENDED TO BE USED IN COMBINATION WITH A

	POWER TOOL.,RECON FEMORAL NAILING IMPLANTS- SCREW-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR-FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,DYNAMIC HIP PLATING IMPLANTS-SCREW-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,WIRE IMPLANTS-KIRSCHENER WIRE (TITANIUM ALLOY)-WIRE IMPLANTS ARE INTENDED FOR FIXATION OF BONE FRAGMENTS.,DYNAMIC HIP PLATING IMPLANTS-SCREW (STERILE)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,COMPACT MANDIBLE- SCREW-THE SYNTHES COMPACT 2.0 AND COMPACT 2.4 TRAUMA PLATES AND SCREWS SYSTEM MANDIBLE IS INTENDED FOR ORAL-MAXILLOFACIAL SURGERY- TRAUMA- RECONSTRUCTIVE SURGERY-AND ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES).,GUIDE WIRES FOR SPINE-GUIDE WIRES FOR SPINE ARE INTENDED TO GUIDE POSITIONING OF CANNULATED INSTRUMENTS- IMPLANTATION OF CANNULATED SPINAL IMPLANTS OR REMOVAL OF SPINAL IMPLANTS.

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2612	IMP/MD/2021/000339	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMPLANTABLE PULSE GENERATOR(INFINITY 7 IMPLANTABLE PULSE GENERATOR)-THIS NEUROSTIMULATION SYSTEM IS DESIGNED TO DELIVER LOW-INTENSITY ELECTRICAL IMPULSES TO NERVE STRUCTURES. THE SYSTEM IS INTENDED TO BE USED WITH LEADS AND ASSOCIATED EXTENSIONS THAT ARE COMPATIBLE WITH THE SYSTEM. THIS NEUROSTIMULATION SYSTEM IS INDICATED FOR UNILATERAL OR BILATERAL STIMULATION OF THE THALAMUS, INTERNAL GLOBUS PALLIDUS (GPI), OR SUBTHALAMIC NUCLEUS (STN) IN PATIENTS WITH LEVODOPA-RESPONSIVE PARKINSON'S DISEASE. THE ST. JUDE MEDICAL™ DEEP BRAIN STIMULATION SYSTEM IS INDICATED FOR UNILATERAL OR BILATERAL STIMULATION OF THE VENTRAL INTERMEDIATE NUCLEUS (VIM) OF THE THALAMUS FOR THE MANAGEMENT OF DISABLING TREMOR. THE ST. JUDE MEDICAL™ DEEP BRAIN STIMULATION SYSTEM IS INDICATED FOR UNILATERAL OR BILATERAL STIMULATION OF THE INTERNAL GLOBUS PALLIDUS (GPI) OR THE SUBTHALAMIC NUCLEUS (STN) FOR THE MANAGEMENT OF INTRACTABLE, CHRONIC DYSTONIA, INCLUDING PRIMARY AND SECONDARY DYSTONIA, FOR PATIENTS WHO ARE AT LEAST 7 YEARS OLD.,ST. JUDE MEDICAL INFINITY DBS SYSTEM(SINGLE 8CH ADAPTER EXTENSION)-THE ST. JUDE MEDICAL™ SINGLE 8-CH ADAPTER EXTENSION IS DESIGNED TO CONNECT A ST. JUDE MEDICAL™ DBS EXTENSION TO A ST. JUDE MEDICAL INFINITY™ DBS IMPLANTABLE PULSE GENERATOR (IPG, MODELS 6660 AND 6662).,DBS LEAD(4CH DBS LEAD)-ST. JUDE MEDICAL™ DEEP BRAIN STIMULATION LEADS ARE INTENDED TO DELIVER STIMULATION TO TARGET AREAS IN THE BRAIN. DEEP BRAIN STIMULATION EXTENSIONS ARE INTENDED TO CONNECT THE LEADS TO IMPLANTABLE PULSE GENERATORS (IPGS)., IPG ACCESSORIES(GUARDIAN CRANIAL BURR HOLE COVER SYS.)-THE GUARDIAN™ BURR HOLE COVER SYSTEM IS INTENDED FOR USE AS A METHOD TO SECURE A COMPATIBLE ST. JUDE MEDICAL™ DBS LEAD.,ST. JUDE MEDICAL INFINITY DBS SYSTEM(8CH DIRECTIONAL LEAD)-ST. JUDE MEDICAL™ DEEP BRAIN STIMULATION LEADS ARE INTENDED TO DELIVER STIMULATION TO TARGET AREAS IN THE BRAIN. DEEP BRAIN STIMULATION EXTENSIONS ARE INTENDED TO CONNECT THE LEADS TO IMPLANTABLE PULSE GENERATORS (IPGS), IMPLANTABLE PULSE GENERATOR(INFINITY 5 IMPLANTABLE PULSE GENERATOR)-THIS NEUROSTIMULATION SYSTEM IS DESIGNED TO DELIVER LOW-INTENSITY ELECTRICAL IMPULSES TO NERVE STRUCTURES. THE SYSTEM IS INTENDED TO BE USED WITH LEADS AND ASSOCIATED EXTENSIONS THAT ARE COMPATIBLE WITH THE SYSTEM. THIS NEUROSTIMULATION SYSTEM IS INDICATED FOR

	UNILATERAL OR BILATERAL STIMULATION OF THE THALAMUS, INTERNAL GLOBUS PALLIDUS (GPI), OR SUBTHALAMIC NUCLEUS (STN) IN PATIENTS WITH LEVODOPA-RESPONSIVE PARKINSON'S DISEASE. THE ST. JUDE MEDICAL™ DEEP BRAIN STIMULATION SYSTEM IS INDICATED FOR UNILATERAL OR BILATERAL STIMULATION OF THE VENTRAL INTERMEDIATE NUCLEUS (VIM) OF THE THALAMUS FOR THE MANAGEMENT OF DISABLING TREMOR. THE ST. JUDE MEDICAL™ DEEP BRAIN STIMULATION SYSTEM IS INDICATED FOR UNILATERAL OR BILATERAL STIMULATION OF THE INTERNAL GLOBUS PALLIDUS (GPI) OR THE SUBTHALAMIC NUCLEUS (STN) FOR THE MANAGEMENT OF INTRACTABLE, CHRONIC DYSTONIA, INCLUDING PRIMARY AND SECONDARY DYSTONIA, FOR PATIENTS WHO ARE AT LEAST 7 YEARS OLD.,IPG ACCESSORIES(GUARDIAN SCREW BURR HOLE COVER)-THE GUARDIAN™ BURR HOLE COVER SYSTEM IS INTENDED FOR USE AS A METHOD TO SECURE A COMPATIBLE ST. JUDE MEDICAL™ DBS LEAD.,POCKET ADAPTER(IS-1 POCKET ADAPTER)-THE IS-1 POCKET ADAPTER IS DESIGNED TO ADAPT A MEDTRONIC EXTENSION (SERIES 7471, 7472, 7482, 7489, 7495, 7496, AND 7498) TO A ST. JUDE MEDICAL NEUROSTIMULATOR., ST. JUDE MEDICAL INFINITY DBS SYSTEM(8CH FLEX EXTN)-ST. JUDE MEDICAL™ DEEP BRAIN STIMULATION LEADS ARE INTENDED TO DELIVER STIMULATION TO TARGET AREAS IN THE BRAIN. DEEP BRAIN STIMULATION EXTENSIONS ARE INTENDED TO CONNECT THE LEADS TO IMPLANTABLE PULSE GENERATORS (IPGS).,DBS EXTENSION KIT(4CH DBS EXTENSION KIT)-ST. JUDE MEDICAL DEEP BRAIN STIMULATION LEADS ARE INTENDED TO DELIVER STIMULATION TO TARGET AREAS IN THE BRAIN. DEEP BRAIN STIMULATION EXTENSIONS ARE INTENDED TO CONNECT THE LEADS TO IMPLANTABLE PULSE GENERATORS (IPGS).,IPG ACCESSORIES (PORT PLUG)-THIS NEUROSTIMULATION SYSTEM IS DESIGNED TO DELIVER LOW-INTENSITY ELECTRICAL IMPULSES TO NERVE STRUCTURES. THE SYSTEM IS INTENDED TO BE USED WITH LEADS AND ASSOCIATED EXTENSIONS THAT ARE COMPATIBLE WITH THE SYSTEM.

2613	IMP/MD/2021/000340	1.License Holder Name: ACCREDITED CONSULTANT PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SODIUM HYALURONATE WITH LIDOCAINE HYDROCHLORIDE I.D. (INJECTABLE GEL IMPLANT) (SAYPHA FILLER LIDOCAINE)-THE DEVICE IS INDICATED TO CORRECT MODERATE TO SEVERE NASOLABIAL FOLDS AND TO INCREASE LIP VOLUME. IT IS INDICATED TO BE INJECTED INTO THE MID TO DEEP DERMIS AND SUBMUCOSA.,SODIUM HYALURONATE WITH LIDOCAINE HYDROCHLORIDE I.D. (INJECTABLE GEL IMPLANT)(SAYPHA VOLUME LIDOCAINE)-THE DEVICE IS INDICATED TO CORRECT MODERATE TO SEVERE NASOLABIAL FOLDS. IT IS INDICATED TO BE INJECTED INTO THE DEEP DERMIS OR SUBCUTIS.
2614	IMP/MD/2021/000344	1.License Holder Name: M/S MICROTEK INTERNATIONAL PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ELECTRONIC BLOOD PRESSURE MONITOR(MICROTEK)-TO MEASURE SYSTOLIC AND DIASTOLIC BLOOD PRESSURE OF HUMANS

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2615	IMP/MD/2021/000345	1.License Holder Name: MINDRAY MEDICAL INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BENE HEART D SERIES (MINDRAY)-THE EQUIPMENT CONFIGURED WITH AED, MANUAL DEFIBRILLATION AND ECG MONITORING FUNCTIONS IS INTENDED FOR AUTOMATIC DEFIBRILLATION (AED) AND MANUAL DEFIBRILLATION TREATMENTS. IT GUIDES OPERATORS THROUGH CARDIOPULMONARY RESUSCITATION (CPR) AND CAN ALSO BE USED FOR ECG MONITORING. THE EQUIPMENT CONFIGURED WITH ONLY AED FUNCTION IS INTENDED FOR AED. IT ALSO GUIDES OPERATORS THROUGHOUT CPR.THE EQUIPMENT IS FOR USE IN PRE-HOSPITAL SETTINGS BY QUALIFIED MEDICAL PERSONNEL TRAINED IN THE OPERATION OF THE EQUIPMENT AND QUALIFIED BY TRAINING IN BASIC LIFE SUPPORT, ADVANCED CARDIAC LIFE SUPPORT OR DEFIBRILLATION.,BENEHEART C SERIES(MINDRAY)-THE BENEHEART C & D SERIES DEFIBRILLATOR, HEREAFTER CALLED THE EQUIPMENT, IS INTENDED TO BE USED ON ADULTS AND CHILDREN IN A SUDDEN CARDIAC ARREST. THE PATIENTS MUST BE: UNRESPONSIVE NOT BREATHING OR NOT BREATHING NORMALLY THE EQUIPMENT ALSO GUIDES THE OPERATOR THROUGHOUT CARDIOPULMONARY RESUSCITATION (CPR) WITH VOICE AND/OR VISUAL GUIDANCE. THE EQUIPMENT IS TO BE USED IN PUBLIC PLACES AND FACILITIES BY PERSONS WHO HAVE BEEN TRAINED IN ITS OPERATION. THE OPERATOR SHOULD BE TRAINED IN BASIC LIFE SUPPORT, ADVANCED CARDIAC LIFE SUPPORT OR OTHER EMERGENCY MEDICAL RESPONSE.
2616	IMP/MD/2021/000346	1.License Holder Name: CARDINAL HEALTH MEDICAL PRODUCTS INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INSULIN/TUBERCULIN SYRINGE WITH PERMANENT NEEDLE(MONOJECT)-THESE ARE INTENDED TO BE USED FOR THE INJECTION OF MEDICATIONS AND OTHER FLUIDS AND TO ASPIRATE MEDICINE. IT IS INTENDED TO BE USED BY QUALIFIED MEDICAL PROFESSIONAL(S) OR, IN RARE CASES, BY INDIVIDUAL USERS. THE PRODUCT WILL BE AVAILABLE BY PRESCRIPTION ONLY.,INSULIN/TUBERCULIN SAFETY SYRINGE WITH PERMANENT NEEDLE(MAGELLAN)-THESE ARE INTENDED TO BE USED FOR THE INJECTION OF MEDICATIONS AND OTHER FLUIDS AND TO ASPIRATE MEDICINE. IT IS INTENDED TO BE USED BY QUALIFIED MEDICAL PROFESSIONAL(S) OR, IN RARE CASES, BY INDIVIDUAL USERS. THE PRODUCT WILL BE AVAILABLE BY PRESCRIPTION ONLY.

2617	IMP/MD/2021/000347	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HUBER NEEDLE SET (SAFESTEP)-SAFESTEP HUBER NEEDLE SET IS A DEVICE INTENDED FOR INSERTION INTO THE SEPTUM OF A SUBCUTANEOUSLY IMPLANTED PORT AND FOR THE INFUSION OF FLUIDS INTO THE PORT. THE SAFETY FEATURE IS MANUALLY ACTIVATED DURING NEEDLE REMOVAL AND IS DESIGNED TO AID IN THE PREVENTION OF ACCIDENTAL NEEDLE STICKS
2618	IMP/MD/2021/000348	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FILTER RETRIEVAL KIT (BARD SNARE RETRIEVAL KIT)-THE BARD SNARE RETRIEVAL KIT IS INTENDED FOR USE TO PERCUTANEOUSLY REMOVE ALL BARD OPTIONAL VENA CAVA FILTERS WITH A RETRIEVAL HOOK
2619	IMP/MD/2021/000349	1.License Holder Name: MEDICARE PRODUCTS INC. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL BLOOD PRESSURE MONITOR (ARM TYPE)(MCP)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.
2620	IMP/MD/2021/000350	1.License Holder Name: PHILIPS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AUTOMATED EXTERNAL DEFIBRILLATOR(HEARTSTART HS1)-THE HEARTSTART IS INDICATED FOR THE TERMINATION OF VENTRICULAR FIBRILLATION (VF), VENTRICULAR FLUTTER AND SOME VENTRICULAR TACHYCARDIA (VT) IN THE FOLLOWING POPULATIONS: • INFANTS AND CHILDREN UNDER 25 KILOGRAMS / 55 POUNDS OR 0-8 YEARS OLD • CHILDREN AND ADULTS OVER 25 KILOGRAMS / 55 POUNDS OR GREATER THAN 8 YEARS OLD,AUTOMATED EXTERNAL DEFIBRILLATOR(HEARTSTART FRX)-THE FRX IS INDICATED FOR THE TERMINATION OF VENTRICULAR FIBRILLATION (VF), VENTRICULAR FLUTTER AND SOME VENTRICULAR TACHYCARDIA (VT) IN THE FOLLOWING POPULATIONS: • INFANTS AND CHILDREN UNDER 25 KILOGRAMS / 55 POUNDS OR 0-8 YEARS OLD • CHILDREN AND ADULTS OVER 25 KILOGRAMS / 55 POUNDS OR GREATER THAN 8 YEARS OLD

2621	IMP/MD/2021/000351	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ELECTROSURGICAL HANDPIECES AND ELECTRODES(MEGADYNE TELESCOPING SOFT TISSUE DISSECTOR)-THE PRODUCT IS A MONOPOLAR DEVICE DESIGNED FOR GENERAL ELECTROSURGICAL APPLICATIONS INCLUDING CUTTING AND COAGULATION (COAG). THIS DEVICE CONDUCTS AN ELECTROSURGICAL CURRENT FROM AN ELECTROSURGICAL UNIT (ESU) AND DELIVERS IT TO THE TARGET TISSUE TO ACHIEVE THE DESIRED SURGICAL EFFECT. THE ELECTROSURGICAL ACTIVE ELECTRODES ARE INTENDED TO CONDUCT RADIO FREQUENCY (RF) CURRENT FOR CUTTING AND COAGULATION FROM THE ESU TO TARGET SOFT TISSUE IN A BROAD RANGE OF SURGICAL PROCEDURES REQUIRING THE USE OF ELECTROSURGERY FOR CUTTING AND CAUTERIZATION. THE ELECTROSURGICAL ACTIVE ELECTRODES HAVE A SPECIFIC GEOMETRY THAT MINIMIZES BLANCHING AND THERMAL DAMAGE IN SKIN INCISIONS WHEN USED IN CONJUNCTION WITH THE MEGADYNE™ ESU'S ADVANCED CUTTING EFFECT (ACE) MODE OR THE MEGADYNE™ ESU'S GEOMETRIC ELECTRON MODULATION (GEM) MODE.,ELECTROSURGICAL HANDPIECES AND ELECTRODES (MEGADYNE TELESCOPING SMOKE EVACUATION PENCIL)-MEGADYNE™ TELESCOPING SMOKE EVACUATION PENCIL IS A MONOPOLAR DEVICE DESIGNED FOR GENERAL ELECTROSURGICAL APPLICATIONS INCLUDING CUTTING AND COAGULATION (COAG) AND FOR REMOVING SMOKE GENERATED BY ELECTROSURGERY WHEN USED IN CONJUNCTION WITH A SMOKE EVACUATION SYSTEM. THIS DEVICE CONDUCTS AN ELECTROSURGICAL CURRENT FROM AN ELECTROSURGICAL UNIT (ESU) AND DELIVERS IT TO THE TARGET TISSUE TO ACHIEVE THE DESIRED SURGICAL EFFECT. MEGADYNE™ PTFE COATED ELECTROSURGICAL (ACTIVE) ELECTRODES ARE INTENDED TO CONDUCT RADIO FREQUENCY (RF) CURRENT FOR CUTTING AND COAGULATION FROM THE ESU TO TARGET SOFT TISSUE IN A BROAD RANGE OF SURGICAL PROCEDURES REQUIRING THE USE OF ELECTROSURGERY FOR CUTTING AND CAUTERIZATION., ELECTROSURGICAL HANDPIECES AND ELECTRODES(MEGADYNE TELESCOPING SMOKE EVACUATION SOFT TISSUE DISSECTOR)-THE PRODUCT IS A MONOPOLAR DEVICE DESIGNED FOR GENERAL ELECTROSURGICAL APPLICATIONS INCLUDING CUTTING AND COAGULATION (COAG) AND FOR REMOVING SMOKE GENERATED BY ELECTROSURGERY WHEN USED IN CONJUNCTION WITH A SMOKE EVACUATION SYSTEM. THIS DEVICE CONDUCTS AN ELECTROSURGICAL CURRENT FROM AN ELECTROSURGICAL UNIT (ESU) AND DELIVERS IT TO THE TARGET TISSUE TO ACHIEVE THE

		DESIRED SURGICAL EFFECT. THE ELECTROSURGICAL ACTIVE ELECTRODES ARE INTENDED TO CONDUCT RADIO FREQUENCY (RF) CURRENT FOR CUTTING AND COAGULATION FROM THE ESU TO TARGET SOFT TISSUE IN A BROAD RANGE OF SURGICAL PROCEDURES REQUIRING THE USE OF ELECTROSURGERY FOR CUTTING AND CAUTERIZATION. THE ELECTROSURGICAL ACTIVE ELECTRODES HAVE A SPECIFIC GEOMETRY THAT MINIMIZES BLANCHING AND THERMAL DAMAGE IN SKIN INCISIONS WHEN USED IN CONJUNCTION WITH THE MEGADYNE™ ESU'S ADVANCED CUTTING EFFECT (ACE) MODE OR THE MEGADYNE™ ESU'S GEOMETRIC ELECTRON MODULATION (GEM) MODE.
2622	IMP/MD/2021/000360	1.License Holder Name: M/S. PEERLESS BIOTECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STERILE WOUND DRESSINGS(HYNAUT)-FOR USE ON LARGE WOUND SUCH AS AFTER SURGERY.,STERILE WOUND PLASTERS(HYNAUT)-FOR USE ON WOUND SUCH AS CUTS, SCRATCHES AND GRAZES.

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2623	IMP/MD/2021/000365	1.License Holder Name: M/S BROWNDOVE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMODIALYSIS CATHETER LONG TERM (CUFFED)(SPLIT CATH -III)-THE MEDCOMP SPLIT CATH III IS INDICATED FOR USE IN ATTAINING LONG-TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS IN THE ADULT POPULATION. IT MAY BE INSERTED PERCUTANEOUSLY AND IS PRIMARILY PLACED IN THE INTERNAL JUGULAR VEIN. ALTERNATE INSERTION SITES INCLUDE THE SUBCLAVIAN VEIN AND INFERIOR VENA CAVA AS REQUIRED. CATHETERS GREATER THAN 40CM ARE INTENDED FOR FEMORAL VEIN INSERTION OR INFERIOR VENA CAVA INSERTION. FEMORAL AND TRANSLUMBAR VEIN PLACEMENT ARE ASSOCIATED WITH HIGHER INFECTION RATES COMPARED TO OTHER SITES. TRANSLUMBAR INSERTION VIA INFERIOR VENA CAVA IS ONLY INDICATED,HEMODIALYSIS CATHETER (SHORT TERM) NON CUFFED (DUO-FLOW SOFT-LINE)-THE MEDCOMP SOFT-LINE CATHETER IS INDICATED FOR USE IN ATTAINING SHORT-TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS. IT MAY BE INSERTED PERCUTANEOUSLY AND IS PRIMARILY PLACED IN THE INTERNAL JUGULAR VEIN OF AN ADULT PATIENT. ALTERNATE INSERTION SITES INCLUDE SUBCLAVIAN VEIN OR FEMORAL VEIN AS REQUIRED. THE CURVED SOFT-LINE® CATHETER IS INTENDED FOR INTERNAL JUGULAR VEIN INSERTION. THIS CATHETER IS INDICATED FOR A DURATION LESS THAN (30) DAYS. FOR FEMORAL PLACEMENT, MONITOR CATHETER CONDITION CLOSELY.,HEMODIALYSIS CATHETER (SHORT TERM) NON CUFFED(DUO-FLOW SIDE BY SIDE)-THE MEDCOMP DUO-FLOW CATHETER IS INDICATED FOR USE IN ATTAINING SHORT-TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS. IT MAY BE INSERTED PERCUTANEOUSLY AND IS PRIMARILY PLACED IN THE INTERNAL JUGULAR VEIN OF AN ADULT PATIENT. ALTERNATE INSERTION SITES INCLUDE SUBCLAVIAN VEIN OR FEMORAL VEIN AS REQUIRED. THE CURVED DUO-FLOW CATHETER IS INTENDED FOR INTERNAL JUGULAR VEIN INSERTION. THIS CATHETER IS INDICATED FOR A DURATION LESS THAN (30) DAYS. FOR FEMORAL PLACEMENT, MONITOR CATHETER CONDITION CLOSELY.,HEMODIALYSIS CATHETER (SHORT TERM) NON CUFFED (FEMORAL)-FEMORAL CATHETER IS DESIGNED FOR ACUTE HEMODIALYSIS AND APHERESIS. IT MAY BE INSERTED PERCUTANEOUSLY AND THE PREFERRED SITE IS THE FEMORAL VEIN. THIS CATHETER IS INDICATED FOR A DURATION LESS THAN (30) DAYS.,HEMODIALYSIS CATHETER LONG TERM (CUFFED)(HEMO-FLOW)-THE HEMO-FLOW DIALYSIS CATHETER IS INDICATED FOR USE IN ATTAINING LONG-TERM VASCULAR ACCESS FOR HEMODIALYSIS

	AND APHERESIS. IT MAY BE INSERTED PERCUTANEOUSLY AND IS PRIMARILY PLACED IN THE INTERNAL JUGULAR VEIN OF AN ADULT PATIENT. ALTERNATE INSERTION SITES INCLUDE SUBCLAVIAN VEIN AS REQUIRED. THE CURVED HEMO-FLOW CATHETER IS INTENDED FOR INTERNAL JUGULAR VEIN INSERTION. CATHETERS GREATER THAN 40CM ARE INTENDED FOR FEMORAL VEIN INSERTION, HEMODIALYSIS CATHETER (SHORT TERM) NON CUFFED(DUO- FLOW)- THE MEDCOMP DUO-FLOW CATHETER IS INDICATED FOR USE IN ATTAINING SHORT-TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS. IT MAY BE INSERTED PERCUTANEOUSLY AND IS PRIMARILY PLACED IN THE INTERNAL JUGULAR VEIN OF AN ADULT PATIENT. ALTERNATE INSERTION SITES INCLUDE SUBCLAVIAN VEIN OR FEMORAL VEIN AS REQUIRED. THE CURVED DUO-FLOW CATHETER IS INTENDED FOR INTERNAL JUGULAR VEIN INSERTION. THIS CATHETER IS INDICATED FOR A DURATION LESS THAN (30) DAYS. FOR FEMORAL PLACEMENT, MONITOR CATHETER CONDITION CLOSELY.,HEMODIALYSIS CATHETER (SHORT TERM) NON CUFFED (TRI- FLOW)-THE MEDCOMP TRI-FLOW CATHETER IS INDICATED FOR USE IN ATTAINING SHORT-TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS. IT MAY BE INSERTED PERCUTANEOUSLY AND IS PRIMARILY PLACED IN THE INTERNAL JUGULAR VEIN OF AN ADULT PATIENT. ALTERNATE INSERTION SITES INCLUDE SUBCLAVIAN VEIN OR FEMORAL VEIN AS REQUIRED. THE MEDCOMP TRI-FLOW CATHETER IS INTENDED TO BE USED LESS THAN (30) DAYS.

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2624	IMP/MD/2021/000366	1.License Holder Name: MAXLIFE HEALTH ENTERPRISES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VITAL SIGNS MONITOR CORE DEVICE(WELCH ALLYN CONNEX® SPOT MONITOR)-THE CONNEX SPOT MONITORS ARE INTENDED TO BE USED BY CLINICIANS AND MEDICALLY QUALIFIED PERSONNEL FOR MONITORING OF NON-INVASIVE: BLOOD PRESSURE, PULSE RATE, FUNCTIONAL OXYGEN SATURATION OF ARTERIOLAR HAEMOGLOBIN (SPO2), AND BODY TEMPERATURE IN NORMAL AND AXILLARY MODES OF NEONATAL, PAEDIATRIC AND ADULT PATIENTS. THE MOST LIKELY LOCATIONS FOR PATIENTS TO BE MONITORED ARE GENERAL MEDICAL OR SURGICAL FLOORS AND GENERAL HOSPITAL AND ALTERNATE CARE ENVIRONMENTS. THIS PRODUCT IS AVAILABLE FOR SALE ONLY UPON THE ORDER OF PHYSICIAN OR LICENSED HEALTHCARE PROFESSIONAL.,DIGITAL BLOOD PRESSURE MONITORING DEVICE (WELCH ALLYN PROBP™ 3400)-THE PROBP 3400 AUTOMATICALLY MEASURES SYSTOLIC AND DIASTOLIC PRESSURE (EXCLUDING NEONATES) AND PULSE RATE, AS WELL AS CALCULATES MEAN ARTERIAL PRESSURE (MAP). 01690-400, 01692-400. THE DEVICE IS INTENDED TO BE USED BY CLINICIANS AND MEDICALLY QUALIFIED PERSONNEL. IT IS AVAILABLE FOR SALE UPON ONLY THE ORDER OF PHYSICIAN OR LICENSED HEALTHCARE PROVIDER. THIS DEVICE IS NOT INTENDED FOR USE ON NEONATES, INFANTS, OR CHILDREN UNDER THE AGE OF 3 YEARS. THE EFFECTIVENESS OF THIS DEVICE HAS NOT BEEN ESTABLISHED IN PREGNANT, INCLUDING PRE-ECLAMPTIC PATIENTS.
2625	IMP/MD/2021/000367	1.License Holder Name: ADVANCED STERILIZATION PRODUCTS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISINFECTANTS (AERO OPA)-AERO-OPA™ SOLUTION IS A HIGH-LEVEL DISINFECTANT FOR REPROCESSING HEAT SENSITIVE MEDICAL DEVICES (ENDOSCOPES) WHEN USED ACCORDING TO THE DIRECTIONS FOR USE. AERO-OPA™ SOLUTION IS INTENDED FOR USE ONLY WITH THE ASP AEROFLEX™ AER WITH AUTOSURE MRC MONITOR. THIS PRODUCT IS NOT INTENDED FOR MANUAL USE.

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2626	IMP/MD/2021/000368	1.License Holder Name: RESPICARE SOLUTIONS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REINFORCED ENDOTRACHEAL TUBE(RESPI-FLEX)-REINFORCED ENDOTRACHEAL TUBE, IN COMBINATION WITH RESPIRATORY SYSTEM, ARE INTENDED FOR RESPIRATION DURING OPERATION FOR PATIENTS WHO LOSE ACTIVE BREATH ABILITY. ,ENDOTRACHEAL TUBES WITH SUCTION LUMEN(RESPI-EVAC)-THE ENDOTRACHEAL TUBES WITH SUCTION LUMEN, IN COMBINATION WITH RESPIRATORY SYSTEM, ARE INTENDED FOR RESPIRATION DURING OPERATION FOR PATIENTS WHO LOSE ACTIVE BREATH ABILITY.
2627	IMP/MD/2021/000369	1.License Holder Name: SARA HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITOR(SARA+CARE)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.
2628	IMP/MD/2021/000370	1.License Holder Name: VATECH INDIA PRIVATE LIMITED(GODOWN) 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PHT-35LHS(SMART PLUS) -SMART PLUS (PHT-35LHS) IS INTENDED TO PRODUCE PANORAMIC, CEPHALOMETRIC OR 3D DIGITAL X-RAY IMAGES. IT PROVIDES DIAGNOSTIC DETAILS OF THE DENTO-MAXILLOFACIAL,SINUS AND TMJ FOR ADULT AND PEDIATRIC PATIENTS. THE SYSTEM ALSO UTILIZES CARPAL IMAGES FOR ORTHODONTIC TREATMENT.THE DEVICE IS TO BE OPERATED BY HEALTHCARE PROFESSIONALS.
2629	IMP/MD/2021/000371	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMODIALYSIS EQUIPMENT(NIKKISO HEMODIALYSIS EQUIPMENT)-TO BE USED FOR HEMODIALYSIS FOR PATIENTS WITH RENAL FAILURE. , HEMODIALYZER(NIKKISO PEPA DIALYZER)-TO BE USED FOR HEMODIALYSIS FOR PATIENTS WITH RENAL FAILURE.

2630	IMP/MD/2021/000372	1.License Holder Name: WIPRO GE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAGNETIC RESONANCE (SIGNA PREMIER)-THE SIGNA PREMIER SYSTEM IS A WHOLE BODY MAGNETIC RESONANCE SCANNER DESIGNED TO SUPPORT HIGH RESOLUTION, HIGH SIGNAL-TO-NOISE RATIO, AND SHORT SCAN TIMES. IT IS INDICATED FOR USE AS A DIAGNOSTIC IMAGING DEVICE TO PRODUCE AXIAL, SAGITTAL, CORONAL, AND OBLIQUE IMAGES, SPECTROSCOPIC IMAGES, PARAMETRIC MAPS, AND/OR SPECTRA, DYNAMIC IMAGES OF THE STRUCTURES AND/OR FUNCTIONS OF THE ENTIRE BODY, INCLUDING, BUT NOT LIMITED TO, HEAD, NECK, TMJ, SPINE, BREAST, HEART, ABDOMEN, PELVIS, JOINTS, PROSTATE, BLOOD VESSELS, AND MUSCULOSKELETAL REGIONS OF THE BODY., NUCLEAR MEDICINE SYSTEM(SIGNA PET/MR)-THESE SYSTEMS ARE INTENDED TO BE UTILIZED BY APPROPRIATELY TRAINED HEALTH CARE PROFESSIONALS TO AID IN THE DETECTION, LOCALIZATION, AND DIAGNOSIS OF DISEASES AND DISORDERS. MR IS INTENDED TO PRODUCE TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-SECTIONAL MR IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, AND DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HUMAN BODY.THE COMBINED SYSTEM UTILIZES THE MR FOR RADIATION-FREE ATTENUATION CORRECTION MAPS FOR PET STUDIES. THE SYSTEM PROVIDES INHERENT ANATOMICAL REFERENCE FOR THE FUSED PET AND MR IMAGES DUE TO PRECISELY ALIGNED MR AND PET IMAGE COORDINATE SYSTEMS.
2631	IMP/MD/2021/000373	1.License Holder Name: ZB DENTAL INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL RESTORATIVE DEVICES(BELLATEK® EXPRESS (ABUTMENT), BELLATEK® FLEX (ABUTMENT) , LOW PROFILE ABUTMENTS)-BIOMET 3I RESTORATIVE DEVICES ARE INTENDED FOR USE AS AN ACCESSORY TO ENDOSSEOUS DENTAL IMPLANTS FOR PLACEMENT IN THE MAXILLA AND MANDIBLE.,DENTAL RESTORATIVE DEVICES(TSV™,BELLATEK® ENCODE® HEALING ABUTMENTS, LOW PROFILE ABUTMENTS, QUICKBRIDGE)-BIOMET 3I RESTORATIVE DEVICES ARE INTENDED FOR USE AS AN ACCESSORY TO ENDOSSEOUS DENTAL IMPLANTS FOR PLACEMENT IN THE MAXILLA AND MANDIBLE.

2632	IMP/MD/2021/000376	1.License Holder Name: G R HEALTH AIDS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MATRIDERM(MATRIDERM DERMAL MATRIX)-MATRIDERM DERMAL MATRIX IS USED IN COMBINATION WITH AUTOLOGOUS SPLIT-THICKNESS SKIN GRAFTS FOR THE RECONSTRUCTION OF DEEP DERMAL DEFECTS AND FULL-THICKNESS SKIN WOUNDS IN PLASTIC RECONSTRUCTIVE SURGERY AND IN THE SURGICAL TREATMENT OF BURNS, TRAUMA AND DERMATOLOGICAL DISEASES.IT IS ALSO USED IN THE TREATMENT OF GRAFT-REQUIRING POORLY HEALING WOUNDS(E.G. CHRONIC WOUNDS).ADDITIONALLY, MATRIDERM DERMAL MATRIX CAN BE USED FOR THE RECONSTRUCTION OF MUCOSAL DEFECTS. THE AIM OF TREATMENT IS TO CONSTRUCT A NEODERMIS IN ORDER TO IMPROVE THE QUALITY OF RECONSTITUTED TISSUE, REDUCE SCARRING, PREVENT WOUND CONTRACTION AND RESTORE FUNCTIONALITY. MATRIDERM DERMAL MATRIX CAN ALSO BE USED UNDER INTACT SKIN FOR THE TEMPORARY SEPARATION OF TISSUES, THEREBY PREVENTING ADHERENCE, ESPECIALLY OF TENDONS AND THEIR SURROUNDING CONNECTIVE TISSUE, AFTER INJURIES OR SURGICAL PROCEDURES.
2633	IMP/MD/2021/000377	1.License Holder Name: MOREPEN LABORATORIES LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITOR(DR.MOREPEN BPONE)-THE DEVICE IS INTENDED FOR THE MEASUREMENT OF SYSTOLIC BLOOD PRESSURE, DIASTOLIC BLOOD PRESSURE AND PULSE RATED ON THE UPPER-ARM

CENTRAL DRUGS STANDARD CONTROL ORGANISATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2634	IMP/MD/2021/000379	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)(EVERA)-THE EVERA S DR SYSTEM IS INTENDED TO PROVIDE ATRIAL AND/OR VENTRICULAR ANTITACHYCARDIA PACING, CARDIOVERSION, AND DEFIBRILLATION FOR AUTOMATED TREATMENT OF ATRIAL AND/OR LIFE-THREATENING VENTRICULAR TACHYARRHYTHMIAS.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)(VISIA AF MRI™ S VR SURESCAN™)-THE VISIA AF MRI SURESCAN SYSTEM IS INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR TACHYARRHYTHMIAS., INSERTABLE CARDIAC MONITOR (ICM)(REVEAL LINQ)-THE REVEAL LINQ ICM IS AN INSERTABLE AUTOMATICALLY-ACTIVATED AND PATIENT-ACTIVATED MONITORING SYSTEM THAT RECORDS SUBCUTANEOUS ECG AND IS INDICATED IN THE FOLLOWING CASES: - PATIENTS WITH CLINICAL SYNDROMES OR SITUATIONS AT INCREASED RISK OF CARDIAC ARRHYTHMIAS - PATIENTS WHO EXPERIENCE TRANSIENT SYMPTOMS THAT MAY SUGGEST A CARDIAC ARRHYTHMIA,IMPLANTABLE CARDIOVERTER DEFIBRILLATORS WITH CARDIAC RESYNCHRONIZATION THERAPY (CRT-D)(AMPLIA MRI QUAD CRT-D SURESCAN)-THE AMPLIA MRI QUAD SYSTEM IS INDICATED FOR USE IN PATIENTS WHO ARE AT HIGH RISK OF SUDDEN DEATH DUE TO VENTRICULAR TACHYARRHYTHMIAS AND WHO HAVE ANY OF THE FOLLOWING TYPES OF HEART FAILURE: PATIENTS WITH VENTRICULAR DYSSYNCHRONY PATIENTS WITH REDUCED EJECTION FRACTION (EF), REGARDLESS OF NEW YORK HEART ASSOCIATION (NYHA) CLASS, WHO ARE INDICATED FOR VENTRICULAR PACING, AND HAVE HIGH DEGREE AV BLOCK PATIENTS WITH REDUCED EF AND ALL OF THE FOLLOWING CHARACTERISTICS: – HAVE RECEIVED A CONVENTIONAL PACEMAKER OR AN ICD – HAVE SUBSEQUENTLY DEVELOPED WORSENING HF DESPITE OPTIMAL MEDICAL THERAPY – HAVE A HIGH PROPORTION OF RV PACING THE DEVICE IS INTENDED TO PROVIDE ATRIAL OR VENTRICULAR ANTITACHYCARDIA PACING, CARDIOVERSION, AND DEFIBRILLATION FOR AUTOMATED TREATMENT OF ATRIAL OR LIFE-THREATENING VENTRICULAR TACHYARRHYTHMIAS.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)(EVERA)-THE EVERA S VR SYSTEM IS INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR TACHYARRHYTHMIAS., IMPLANTABLE CARDIOVERTER DEFIBRILLATOR WITH CARDIAC

	RESYNCHRONIZATION THERAPY(COBALT™ HF QUAD CRT-D MRI SURESCAN™)-INDICATED FOR USE IN PATIENTS WHO ARE AT SIGNIFICANT RISK OF DEVELOPING ATRIAL AND/OR LIFE-THREATENING VENTRICULAR ARRHYTHMIAS AND WHO HAVE HEART FAILURE WITH VENTRICULAR ARRHYTHMIAS. HEART FAILURE PATIENTS MUST HAVE EXPERIENCED ONE OR MORE OF THE FOLLOWING CONDITIONS: • VENTRICULAR DYSSYNCHRONY • REDUCED EJECTION FRACTION, REGARDLESS OF NEW YORK HEART ASSOCIATION (NYHA) CLASS, WHO ARE INDICATED FOR VENTRICULAR PACING AND HAVE HIGH DEGREE AV BLOCK • REDUCED EJECTION FRACTION AND ALL THE FOLLOWING CHARACTERISTICS: – HAVE RECEIVED A CONVENTIONAL PACEMAKER OR AN ICD – HAVE SUBSEQUENTLY DEVELOPED WORSENING HEART FAILURE DESPITE OPTIMAL MEDICAL THERAPY – HAVE A HIGH PROPORTION OF RV PACING ,IMPLANTABLE PACEMAKER WITH CARDIAC RESYNCHRONIZATION THERAPY (CONSULTA CRT P)-THE CONSULTA CRT-P SYSTEM IS INDICATED FOR ANY OF THE FOLLOWING TYPES OF HEART FAILURE PATIENTS: PATIENTS WITH VENTRICULAR DYSSYNCHRONY PATIENTS WITH REDUCED EJECTION FRACTION (EF), REGARDLESS OF NEW YORK HEART ASSOCIATION (NYHA) CLASS, WHO ARE INDICATED FOR VENTRICULAR PACING, AND HAVE HIGH DEGREE AV BLOCK PATIENTS WITH REDUCED EF AND ALL OF THE FOLLOWING CHARACTERISTICS: – HAVE RECEIVED A CONVENTIONAL PACEMAKER OR ICD – HAVE SUBSEQUENTLY DEVELOPED WORSENING HF DESPITE OPTIMAL MEDICAL THERAPY – HAVE A HIGH PROPORTION OF RV PACING RATE ADAPTIVE PACING IS PROVIDED FOR PATIENTS WHO MAY BENEFIT FROM INCREASED PACING RATES CONCURRENT WITH INCREASES IN ACTIVITY. DUAL CHAMBER AND ATRIAL TRACKING MODES ARE INDICATED FOR PATIENTS WHO MAY BENEFIT FROM MAINTENANCE OF AV SYNCHRONY.,IMPLANTABLE PACEMAKER WITH CARDIAC RESYNCHRONIZATION THERAPY (CRT-P)(SERENA QUAD CRT-P MRI SURESCAN)-THE SERENA CRT-P MRI SURESCAN SYSTEM IS INDICATED FOR ANY OF THE FOLLOWING TYPES OF HEART FAILURE PATIENTS: PATIENTS WITH VENTRICULAR DYSSYNCHRONY PATIENTS WITH REDUCED EJECTION FRACTION (EF), REGARDLESS OF NEW YORK HEART ASSOCIATION (NYHA) CLASS, WHO ARE INDICATED FOR VENTRICULAR PACING, AND HAVE HIGH DEGREE AV BLOCK PATIENTS WITH REDUCED EF AND ALL OF THE FOLLOWING CHARACTERISTICS: – HAVE RECEIVED A CONVENTIONAL PACEMAKER OR AN ICD – HAVE SUBSEQUENTLY DEVELOPED WORSENING HEART FAILURE DESPITE OPTIMAL MEDICAL THERAPY – HAVE A HIGH PROPORTION OF RV PACING RATE ADAPTIVE PACING IS

	PROVIDED FOR PATIENTS WHO MAY BENEFIT FROM INCREASED PACING RATES CONCURRENT WITH INCREASES IN ACTIVITY. DUAL CHAMBER AND ATRIAL TRACKING MODES ARE INDICATED FOR PATIENTS WHO MAY BENEFIT FROM MAINTENANCE OF AV SYNCHRONY.,PACEMAKER(AZURE)-THE AZURE MRI SURE SCAN SYSTEM IS INDICATED FOR USE IN PATIENTS WHO MAY BENEFIT FROM RATE RESPONSIVE OR NON-RATE RESPONSIVE PACING TO RESTORE PHYSIOLOGIC HEART RATES, IMPROVE CARDIAC OUTPUT, PREVENT SYMPTOMS, OR PROTECT AGAINST ARRHYTHMIAS RELATED TO CARDIAC IMPULSE FORMATION OR CONDUCTION DISORDERS.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR(MIRRO MRI DR SURE SCAN)-MIRRO SURESCAN DEVICE IS INTENDED FOR AUTOMATED TREATMENT OF PATIENTS WHO HAVE EXPERIENCED, OR ARE AT SIGNIFICANT RISK OF DEVELOPING LIFE-THREATENING VENTRICULAR ARRHYTHMIAS AND TRANSIENT ATRIAL ARRHYTHMIAS.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (MIRRO MRI VR SURE SCAN)-MIRRO SURESCAN DEVICE IS INTENDED FOR AUTOMATED TREATMENT OF PATIENTS WHO HAVE EXPERIENCED, OR ARE AT SIGNIFICANT RISK OF DEVELOPING LIFE-THREATENING VENTRICULAR ARRHYTHMIAS AND TRANSIENT ATRIAL ARRHYTHMIAS.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)(EVERA MRI S DR SURESCAN)-THE EVERA SURESCAN SYSTEM IS INTENDED TO PROVIDE ATRIAL AND/OR VENTRICULAR ANTITACHYCARDIA PACING, CARDIOVERSION, AND DEFIBRILLATION FOR AUTOMATED TREATMENT OF ATRIAL AND/OR LIFE-THREATENING VENTRICULAR TACHYARRHYTHMIAS., IMPLANTABLE CARDIOVERTER DEFIBRILLATOR WITH CARDIAC RESYNCHRONIZATION THERAPY(CROME™ HF QUAD CRT-D MRI SURESCAN™)-INDICATED FOR USE IN PATIENTS WHO ARE AT SIGNIFICANT RISK OF DEVELOPING ATRIAL AND/OR LIFE-THREATENING VENTRICULAR ARRHYTHMIAS AND WHO HAVE HEART FAILURE WITH VENTRICULAR ARRHYTHMIAS. HEART FAILURE PATIENTS MUST HAVE EXPERIENCED ONE OR MORE OF THE FOLLOWING CONDITIONS: • VENTRICULAR DYSSYNCHRONY • REDUCED EJECTION FRACTION, REGARDLESS OF NEW YORK HEART ASSOCIATION (NYHA) CLASS, WHO ARE INDICATED FOR VENTRICULAR PACING AND HAVE HIGH DEGREE AV BLOCK • REDUCED EJECTION FRACTION AND ALL THE FOLLOWING CHARACTERISTICS: – HAVE RECEIVED A CONVENTIONAL PACEMAKER OR AN ICD – HAVE SUBSEQUENTLY DEVELOPED WORSENING HEART FAILURE DESPITE OPTIMAL MEDICAL THERAPY – HAVE A HIGH PROPORTION OF RV PACING,MPLANTABLE CARDIOVERTER DEFIBRILLATOR WITH CARDIAC RESYNCHRONIZATION THERAPY(CROME™ DR MRI SURESCAN™)-THE

	CROME DR MRI SURESCAN DEVICE IS INDICATED FOR THE AUTOMATED TREATMENT OF PATIENTS WHO HAVE EXPERIENCED, OR ARE AT SIGNIFICANT RISK OF DEVELOPING, LIFE-THREATENING VENTRICULAR ARRHYTHMIAS THROUGH THE DELIVERY OF ANTITACHYCARDIA PACING, CARDIOVERSION, AND DEFIBRILLATION THERAPIES.,IMPLANTABLE CARDIOVERTER DEFIBRILLATORS WITH CARDIAC RESYNCHRONIZATION THERAPY (CRT-D)(BRAVA QUAD CRTD)-THE BRAVA CRT-D SYSTEM IS INDICATED FOR USE IN PATIENTS WHO ARE AT HIGH RISK OF SUDDEN DEATH DUE TO VENTRICULAR TACHYARRHYTHMIAS AND WHO HAVE ANY OF THE FOLLOWING TYPES OF HEART FAILURE: PATIENTS WITH VENTRICULAR DYSSYNCHRONY PATIENTS WITH REDUCED EJECTION FRACTURE (EF), REGARDLESS OF NEW YORK HEART ASSOCIATION (NYHA) CLASS, WHO ARE INDICATED FOR VENTRICULAR PACING, AND HAVE HIGH DEGREE AV BLOCK PATIENTS WITH REDUCED EF AND ALL OF THE FOLLOWING CHARACTERISTICS: – HAVE RECEIVED A CONVENTIONAL PACEMAKER OR AN ICD – HAVE SUBSEQUENTLY DEVELOPED WORSENING HF DESPITE OPTIMAL MEDICAL THERAPY – HAVE A HIGH PROPORTION OF RV PACING THE DEVICE IS INTENDED TO PROVIDE ATRIAL OR VENTRICULAR ANTITACHYCARDIA PACING, CARDIOVERSION, AND DEFIBRILLATION FOR AUTOMATED TREATMENT OF ATRIAL OR LIFE-THREATENING VENTRICULAR TACHYARRHYTHMIAS.,IMPLANTABLE CARDIOVERTER DEFIBRILLATORS WITH CARDIAC RESYNCHRONIZATION THERAPY (CRT-D)(COMPIA MRI CRT-D SURESCAN)-THE COMPIA MRI SYSTEM IS INDICATED FOR USE IN PATIENTS WHO ARE AT HIGH RISK OF SUDDEN DEATH DUE TO VENTRICULAR TACHYARRHYTHMIAS AND WHO HAVE ANY OF THE FOLLOWING TYPES OF HEART FAILURE: PATIENTS WITH VENTRICULAR DYSSYNCHRONY PATIENTS WITH REDUCED EJECTION FRACTION (EF), REGARDLESS OF NEW YORK HEART ASSOCIATION (NYHA) CLASS, WHO ARE INDICATED FOR VENTRICULAR PACING, AND HAVE HIGH DEGREE AV BLOCK PATIENTS WITH REDUCED EF AND ALL OF THE FOLLOWING CHARACTERISTICS: – HAVE RECEIVED A CONVENTIONAL PACEMAKER OR AN ICD – HAVE SUBSEQUENTLY DEVELOPED WORSENING HF DESPITE OPTIMAL MEDICAL THERAPY – HAVE A HIGH PROPORTION OF RV PACING THE DEVICE IS INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING, CARDIOVERSION, AND DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR TACHYARRHYTHMIAS.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR WITH CARDIAC RESYNCHRONIZATION THERAPY(CROME™ HF CRT-D MRI SURESCAN™)-INDICATED FOR USE IN PATIENTS WHO ARE AT

	SIGNIFICANT RISK OF DEVELOPING ATRIAL AND/OR LIFE-THREATENING VENTRICULAR ARRHYTHMIAS AND WHO HAVE HEART FAILURE WITH VENTRICULAR ARRHYTHMIAS. HEART FAILURE PATIENTS MUST HAVE EXPERIENCED ONE OR MORE OF THE FOLLOWING CONDITIONS: • VENTRICULAR DYSSYNCHRONY • REDUCED EJECTION FRACTION, REGARDLESS OF NEW YORK HEART ASSOCIATION (NYHA) CLASS, WHO ARE INDICATED FOR VENTRICULAR PACING AND HAVE HIGH DEGREE AV BLOCK • REDUCED EJECTION FRACTION AND ALL THE FOLLOWING CHARACTERISTICS: – HAVE RECEIVED A CONVENTIONAL PACEMAKER OR AN ICD – HAVE SUBSEQUENTLY DEVELOPED WORSENING HEART FAILURE DESPITE OPTIMAL MEDICAL THERAPY – HAVE A HIGH PROPORTION OF RV PACING ,IMPLANTABLE PACEMAKER WITH CARDIAC RESYNCHRONIZATION THERAPY (CRT-P)(SERENA CRT-P MRI SURESCAN)-THE SERENA CRT-P MRI SURESCAN SYSTEM IS INDICATED FOR ANY OF THE FOLLOWING TYPES OF HEART FAILURE PATIENTS: PATIENTS WITH VENTRICULAR DYSSYNCHRONY PATIENTS WITH REDUCED EJECTION FRACTION (EF), REGARDLESS OF NEW YORK HEART ASSOCIATION (NYHA) CLASS, WHO ARE INDICATED FOR VENTRICULAR PACING, AND HAVE HIGH DEGREE AV BLOCK PATIENTS WITH REDUCED EF AND ALL OF THE FOLLOWING CHARACTERISTICS: – HAVE RECEIVED A CONVENTIONAL PACEMAKER OR AN ICD – HAVE SUBSEQUENTLY DEVELOPED WORSENING HEART FAILURE DESPITE OPTIMAL MEDICAL THERAPY – HAVE A HIGH PROPORTION OF RV PACING RATE ADAPTIVE PACING IS PROVIDED FOR PATIENTS WHO MAY BENEFIT FROM INCREASED PACING RATES CONCURRENT WITH INCREASES IN ACTIVITY. DUAL CHAMBER AND ATRIAL TRACKING MODES ARE INDICATED FOR PATIENTS WHO MAY BENEFIT FROM MAINTENANCE OF AV SYNCHRONY.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)(VISIA AF MRI™ XT VR SURESCAN™)-THE VISIA AF MRI SURESCAN SYSTEM IS INTENDED TO PROVIDE VENTRICULAR ANTITACHYCARDIA PACING AND VENTRICULAR DEFIBRILLATION FOR AUTOMATED TREATMENT OF LIFE-THREATENING VENTRICULAR TACHYARRHYTHMIAS.,PACEMAKER(ASTRA)-THE ASTRA XT DR MRI SURESCAN SYSTEM IS INDICATED FOR USE IN PATIENTS WHO MAY BENEFIT FROM RATE RESPONSIVE OR NON-RATE RESPONSIVE PACING TO RESTORE PHYSIOLOGIC HEART RATES, IMPROVE CARDIAC OUTPUT, PREVENT SYMPTOMS, OR PROTECT AGAINST ARRHYTHMIAS RELATED TO CARDIAC IMPULSE FORMATION OR CONDUCTION DISORDERS.,IMPLANTABLE CARDIOVERTER DEFIBRILLATORS WITH CARDIAC RESYNCHRONIZATION THERAPY (CRT-D)(AMPLIA MRI CRT-D SURESCAN)-THE AMPLIA MRI SYSTEM IS

	INDICATED FOR USE IN PATIENTS WHO ARE AT HIGH RISK OF SUDDEN DEATH DUE TO VENTRICULAR TACHYARRHYTHMIAS AND WHO HAVE ANY OF THE FOLLOWING TYPES OF HEART FAILURE: PATIENTS WITH VENTRICULAR DYSSYNCHRONY PATIENTS WITH REDUCED EJECTION FRACTION (EF), REGARDLESS OF NEW YORK HEART ASSOCIATION (NYHA) CLASS, WHO ARE INDICATED FOR VENTRICULAR PACING, AND HAVE HIGH DEGREE AV BLOCK PATIENTS WITH REDUCED EF AND ALL OF THE FOLLOWING CHARACTERISTICS: – HAVE RECEIVED A CONVENTIONAL PACEMAKER OR AN ICD – HAVE SUBSEQUENTLY DEVELOPED WORSENING HF DESPITE OPTIMAL MEDICAL THERAPY – HAVE A HIGH PROPORTION OF RV PACING THE DEVICE IS INTENDED TO PROVIDE ATRIAL OR VENTRICULAR ANTITACHYCARDIA PACING, CARDIOVERSION, AND DEFIBRILLATION FOR AUTOMATED TREATMENT OF ATRIAL OR LIFE-THREATENING VENTRICULAR TACHYARRHYTHMIAS. ,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR WITH CARDIAC RESYNCHRONIZATION THERAPY (COBALT™ HF CRT-D MRI SURESCAN™)-INDICATED FOR USE IN PATIENTS WHO ARE AT SIGNIFICANT RISK OF DEVELOPING ATRIAL AND/OR LIFE-THREATENING VENTRICULAR ARRHYTHMIAS AND WHO HAVE HEART FAILURE WITH VENTRICULAR ARRHYTHMIAS. HEART FAILURE PATIENTS MUST HAVE EXPERIENCED ONE OR MORE OF THE FOLLOWING CONDITIONS: • VENTRICULAR DYSSYNCHRONY • REDUCED EJECTION FRACTION, REGARDLESS OF NEW YORK HEART ASSOCIATION (NYHA) CLASS, WHO ARE INDICATED FOR VENTRICULAR PACING AND HAVE HIGH DEGREE AV BLOCK • REDUCED EJECTION FRACTION AND ALL THE FOLLOWING CHARACTERISTICS: – HAVE RECEIVED A CONVENTIONAL PACEMAKER OR AN ICD – HAVE SUBSEQUENTLY DEVELOPED WORSENING HEART FAILURE DESPITE OPTIMAL MEDICAL THERAPY – HAVE A HIGH PROPORTION OF RV PACING ,PACEMAKER(RELIA)-MEDTRONIC RELIA SERIES IMPLANTABLE PULSE GENERATORS (IPGS) ARE INDICATED FOR USE TO IMPROVE CARDIAC OUTPUT, PREVENT SYMPTOMS, OR PROTECT AGAINST ARRHYTHMIAS RELATED TO CARDIAC IMPULSE FORMATION OR CONDUCTION DISORDERS. THESE DEVICES ARE INDICATED FOR USE IN PATIENTS WHO ARE EXPERIENCING EXERCISE INTOLERANCE OR EXERCISE RESTRICTIONS RELATED TO AN ARRHYTHMIA. USING RATE RESPONSE MODES MAY RESTORE HEART RATE VARIABILITY AND IMPROVE CARDIAC OUTPUT. RELIA SR SERIES IMPLANTABLE PULSE GENERATORS ARE INDICATED FOR SINGLE USE ONLY.,IMPLANTABLE PACEMAKER WITH CARDIAC RESYNCHRONIZATION THERAPY (CRT-P)(SOLARA QUAD CRT-P MRI SURESCAN)-THE SOLARA CRT-P MRI SURESCAN SYSTEM IS INDICATED FOR ANY OF THE FOLLOWING

	TYPES OF HEART FAILURE PATIENTS: PATIENTS WITH VENTRICULAR DYSSYNCHRONY PATIENTS WITH REDUCED EJECTION FRACTION (EF), REGARDLESS OF NEW YORK HEART ASSOCIATION (NYHA) CLASS, WHO ARE INDICATED FOR VENTRICULAR PACING, AND HAVE HIGH DEGREE AV BLOCK PATIENTS WITH REDUCED EF AND ALL OF THE FOLLOWING CHARACTERISTICS: – HAVE RECEIVED A CONVENTIONAL PACEMAKER OR AN ICD – HAVE SUBSEQUENTLY DEVELOPED WORSENING HEART FAILURE DESPITE OPTIMAL MEDICAL THERAPY – HAVE A HIGH PROPORTION OF RV PACING RATE ADAPTIVE PACING IS PROVIDED FOR PATIENTS WHO MAY BENEFIT FROM INCREASED PACING RATES CONCURRENT WITH INCREASES IN ACTIVITY. DUAL CHAMBER AND ATRIAL TRACKING MODES ARE INDICATED FOR PATIENTS WHO MAY BENEFIT FROM MAINTENANCE OF AV SYNCHRONY.,PACEMAKER(ENSURA)-THE ENSURA MRI SURESCAN SYSTEM IS INDICATED TO RESTORE PHYSIOLOGIC HEART RATES, IMPROVE CARDIAC OUTPUT, PREVENT SYMPTOMS, OR PROTECT AGAINST ARRHYTHMIAS RELATED TO CARDIAC IMPULSE FORMATION OR CONDUCTION DISORDERS. THE DEVICE IS INDICATED FOR USE IN PATIENTS WHO MAY BENEFIT FROM RATE-RESPONSIVE PACING TO SUPPORT CARDIAC OUTPUT DURING VARYING LEVELS OF ACTIVITY.,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) (EVERA MRI XT DR SURESCAN)-THE EVERA SURESCAN SYSTEM IS INTENDED TO PROVIDE ATRIAL AND/OR VENTRICULAR ANTITACHYCARDIA PACING, CARDIOVERSION, AND DEFIBRILLATION FOR AUTOMATED TREATMENT OF ATRIAL AND/OR LIFE-THREATENING VENTRICULAR TACHYARRHYTHMIAS,IMPLANTABLE CARDIOVERTER DEFIBRILLATOR WITH CARDIAC RESYNCHRONIZATION THERAPY(CROME™ VR MRI SURESCAN™)-THE CROME VR MRI SURESCAN DEVICE IS INDICATED FOR THE AUTOMATED TREATMENT OF PATIENTS WHO HAVE EXPERIENCED, OR ARE AT SIGNIFICANT RISK OF DEVELOPING, LIFE-THREATENING VENTRICULAR ARRHYTHMIAS THROUGH THE DELIVERY OF ANTITACHYCARDIA PACING, CARDIOVERSION, AND DEFIBRILLATION THERAPIES.,IMPLANTABLE CARDIOVERTER DEFIBRILLATORS WITH CARDIAC RESYNCHRONIZATION THERAPY (CRT-D)(BRAVA CRT-D)-THE BRAVA CRT-D SYSTEM IS INDICATED FOR USE IN PATIENTS WHO ARE AT HIGH RISK OF SUDDEN DEATH DUE TO VENTRICULAR TACHYARRHYTHMIAS AND WHO HAVE ANY OF THE FOLLOWING TYPES OF HEART FAILURE: -PATIENTS WITH VENTRICULAR DYSSYNCHRONY - PATIENTS WITH REDUCED EJECTION FRACTURE (EF), REGARDLESS OF NEW YORK HEART ASSOCIATION (NYHA) CLASS, WHO ARE INDICATED FOR VENTRICULAR PACING, AND HAVE HIGH DEGREE AV BLOCK -PATIENTS WITH REDUCED EF AND ALL OF

	THE FOLLOWING CHARACTERISTICS: –HAVE RECEIVED A CONVENTIONAL PACEMAKER OR AN ICD – HAVE SUBSEQUENTLY DEVELOPED WORSENING HF DESPITE OPTIMAL MEDICAL THERAPY – HAVE A HIGH PROPORTION OF RV PACING. THE DEVICE IS INTENDED TO PROVIDE ATRIAL OR VENTRICULAR ANTITACHYCARDIA PACING, CARDIOVERSION, AND DEFIBRILLATION FOR AUTOMATED TREATMENT OF ATRIAL OR LIFE-THREATENING VENTRICULAR TACHYARRHYTHMIAS.,IMPLANTABLE PACEMAKER WITH CARDIAC RESYNCHRONIZATION THERAPY (CRT-P)(SOLARA CRT-P MRI SURESCAN)-THE SOLARA CRT-P MRI SURESCAN SYSTEM IS INDICATED FOR ANY OF THE FOLLOWING TYPES OF HEART FAILURE PATIENTS: PATIENTS WITH VENTRICULAR DYSSYNCHRONY PATIENTS WITH REDUCED EJECTION FRACTION (EF), REGARDLESS OF NEW YORK HEART ASSOCIATION (NYHA) CLASS, WHO ARE INDICATED FOR VENTRICULAR PACING, AND HAVE HIGH DEGREE AV BLOCK PATIENTS WITH REDUCED EF AND ALL OF THE FOLLOWING CHARACTERISTICS: – HAVE RECEIVED A CONVENTIONAL PACEMAKER OR AN ICD – HAVE SUBSEQUENTLY DEVELOPED WORSENING HEART FAILURE DESPITE OPTIMAL MEDICAL THERAPY – HAVE A HIGH PROPORTION OF RV PACING RATE ADAPTIVE PACING IS PROVIDED FOR PATIENTS WHO MAY BENEFIT FROM INCREASED PACING RATES CONCURRENT WITH INCREASES IN ACTIVITY. DUAL CHAMBER AND ATRIAL TRACKING MODES ARE INDICATED FOR PATIENTS WHO MAY BENEFIT FROM MAINTENANCE OF AV SYNCHRONY,PACEMAKER(SENSIA)-THESE DEVICES ARE INDICATED FOR USE IN PATIENTS WHO ARE EXPERIENCING EXERCISE INTOLERANCE OR EXERCISE RESTRICTIONS RELATED TO AN ARRHYTHMIA. USING RATE RESPONSE MODES MAY RESTORE HEART RATE VARIABILITY AND IMPROVE CARDIAC OUTPUT. SENSIA DR SERIES IMPLANTABLE PULSE GENERATORS ARE INDICATED FOR SINGLE USE ONLY.

2635	IMP/MD/2021/000380	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MULTI-PROGRAM NEUROSTIMULATOR(ACTIVA PC)-MEDTRONIC® DBS THERAPY FOR EPILEPSY BILATERAL ANTERIOR THALAMIC NUCLEUS (ANT) STIMULATION USING THE MEDTRONIC DBS SYSTEM FOR EPILEPSY IS INDICATED AS ADJUNCTIVE THERAPY FOR REDUCING THE FREQUENCY OF SEIZURES IN ADULTS DIAGNOSED WITH EPILEPSY CHARACTERIZED BY PARTIAL-ONSET SEIZURES, WITH OR WITHOUT SECONDARY GENERALIZATION, THAT ARE REFRACTORY TO ANTIEPILEPTIC MEDICATIONS. MEDTRONIC® DBS THERAPY FOR MOVEMENT DISORDERS MEDTRONIC DBS THERAPY FOR MOVEMENT DISORDERS IS INDICATED FOR STIMULATION OF THE VENTRAL INTERMEDIATE NUCLEUS (VIM) FOR PATIENTS WITH DISABLING ESSENTIAL TREMOR OR PARKINSONIAN TREMOR, OR STIMULATION OF THE INTERNAL GLOBUS PALLIDUS (GPI) OR THE SUBTHALAMIC NUCLEUS (STN) FOR PATIENTS WITH SYMPTOMS OF PARKINSON'S DISEASE. STUDIES HAVE SHOWN THAT DEEP BRAIN STIMULATION WITH THE MEDTRONIC DBS THERAPY SYSTEM IS EFFECTIVE IN CONTROLLING ESSENTIAL TREMOR AND SYMPTOMS OF PARKINSON'S DISEASE THAT ARE NOT ADEQUATELY CONTROLLED WITH MEDICATIONS. ADDITIONALLY, DEEP BRAIN STIMULATION IS EFFECTIVE IN CONTROLLING DYSKINESIAS AND FLUCTUATIONS ASSOCIATED WITH MEDICAL THERAPY FOR PARKINSON'S DISEASE. MEDTRONIC DBS THERAPY FOR MOVEMENT DISORDERS IS ALSO INDICATED FOR STIMULATION OF THE INTERNAL GLOBUS PALLIDUS (GPI) OR THE SUBTHALAMIC NUCLEUS (STN) AS AN AID IN THE MANAGEMENT OF CHRONIC, INTRACTABLE (DRUG REFRACTORY) PRIMARY DYSTONIA, INCLUDING GENERALIZED AND SEGMENTAL DYSTONIA, HEMIDYSTONIA, AND CERVICAL DYSTONIA (TORTICOLLIS) FOR INDIVIDUALS 7 YEARS OF AGE AND OLDER. ,MULTI-PROGRAM RECHARGEABLE NEUROSTIMULATOR(ACTIVA RC)-MEDTRONIC® DBS THERAPY FOR MOVEMENT DISORDERS MEDTRONIC DBS THERAPY FOR MOVEMENT DISORDERS IS INDICATED FOR STIMULATION OF THE VENTRAL INTERMEDIATE NUCLEUS (VIM) FOR PATIENTS WITH DISABLING ESSENTIAL TREMOR OR PARKINSONIAN TREMOR, OR STIMULATION OF THE INTERNAL GLOBUS PALLIDUS (GPI) OR THE SUBTHALAMIC NUCLEUS (STN) FOR PATIENTS WITH SYMPTOMS OF PARKINSON'S DISEASE. STUDIES HAVE SHOWN THAT DEEP BRAIN STIMULATION WITH THE MEDTRONIC DBS THERAPY SYSTEM IS EFFECTIVE IN CONTROLLING ESSENTIAL TREMOR AND SYMPTOMS OF PARKINSON'S DISEASE THAT ARE NOT ADEQUATELY CONTROLLED WITH MEDICATIONS. ADDITIONALLY, DEEP BRAIN STIMULATION IS EFFECTIVE IN CONTROLLING DYSKINESIAS AND

		FLUCTUATIONS ASSOCIATED WITH MEDICAL THERAPY FOR PARKINSON'S DISEASE. MEDTRONIC DBS THERAPY FOR MOVEMENT DISORDERS IS ALSO INDICATED FOR STIMULATION OF THE INTERNAL GLOBUS PALLIDUS (GPI) OR THE SUBTHALAMIC NUCLEUS (STN) AS AN AID IN THE MANAGEMENT OF CHRONIC, INTRACTABLE (DRUG REFRACTORY) PRIMARY DYSTONIA, INCLUDING GENERALIZED AND SEGMENTAL DYSTONIA, HEMIDYSTONIA, AND CERVICAL DYSTONIA (TORTICOLLIS) FOR INDIVIDUALS 7 YEARS OF AGE AND OLDER. , NEUROSTIMULATOR(INTERSTIM II)-SACRAL NEUROMODULATION THERAPY PROVIDED BY THE INTERSTIM™ SYSTEM IS INDICATED FOR THE MANAGEMENT OF THE FOLLOWING CHRONIC INTRACTABLE (FUNCTIONAL) DISORDERS OF THE PELVIS AND LOWER URINARY OR INTESTINAL TRACT: OVERACTIVE BLADDER, FECAL INCONTINENCE, AND NONOBSTRUCTIVE URINARY RETENTION.
2636	IMP/MD/2021/000381	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FOLEY CATHETERS (BARDEX FOLEY CATHETERS)-THE FOLEY CATHETERS ARE INDICATED FOR THE DRAINAGE AND/OR COLLECTION AND/OR MEASUREMENT OF URINE.,SUPRAPUBIC CATHETER(BARD BIOCATH SUPRAPUBIC CATHETERISATION SET)-BARD BIOCATH SUPRAPUBIC CATHETERISATION SET IS INDICATED FOR URETHRAL STRICTURES OR FISTULA, OUTFLOW OBSTRUCTION, CHRONIC RETENTION, URETHRAL TRAUMA, PRE-, INTRA- AND POST-OPERATIVE BLADDER DRAINAGE AS REQUESTED BY PHYSICIAN,FOLEY CATHETERS (BARDIA FOLEY CATHETERS)-THE FOLEY CATHETERS ARE INDICATED FOR THE DRAINAGE AND/OR COLLECTION AND/OR MEASUREMENT OF URINE.
2637	IMP/MD/2021/000382	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SAFETY INFUSION SET (POWERLOC)-POWERLOC SAFETY INFUSION SET IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS AND DRUGS, AS WELL AS BLOOD SAMPLING THROUGH SURGICALLY IMPLANTED VASCULAR PORTS. IT IS ALSO INDICATED FOR POWER INJECTION OF CONTRAST MEDIA INTO THE CENTRAL VENOUS SYSTEM ONLY WITH AN IMPLANTED PORT THAT IS ALSO INDICATED FOR POWER INJECTION. THE MAXIMUM RECOMMENDED INFUSION RATE AT 11.8 CPS IS 5ML/SECOND FOR 19 GA NEEDLES, 5ML/SECOND FOR 20 GA NEEDLES AND 2ML/SECOND FOR 22 GA NEEDLES

2638	IMP/MD/2021/000388	1.License Holder Name: MEHAR HEALTHCARE CORPORATION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL BLOOD PRESSURE MONITOR (ARM TYPE)(MEHAR READY MATIC MH 737)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.

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2639	IMP/MD/2021/000389	1.License Holder Name: N-VASCULAR TECHNOLOGY PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEUROVASCULAR STENT (ACCLINO FLEX)-THE ACCLINO FLEX STENT IS INTENDED FOR USE WITH EMBOLISATION MATERIALS IN THE TREATMENT OF INTRACRANIAL ANEURYSMS,THROMBECTOMY DEVICE(APERIO HYBRID THROMBECTOMY DEVICE & APERIO HYBRID17 THROMBECTOMY DEVICE)-THROMBECTOMY DEVICE IS INTENDED FOR RESTORATION OF THE ARTERIAL FLOW IN PATIENTS DIAGNOSED WITH ISCHEMIC STROKE DUE TO LARGE INTRACRANIAL VASCULAR OCCLUSION (I.E. IN THE INTERNAL CAROTID ARTERY, M1 AND M2 SEGMENTS OF THE MCA). PATIENTS WHO FAIL INTRAVENOUS THROMBOLYTIC THERAPY OR WHO ARE INELIGIBLE FOR THROMBOLYSIS MAY BE SUITED FOR TREATMENT WITH THE APERIO® HYBRID THROMBECTOMY DEVICE.,BALLOON CATHETER (NEURO SPEED PTA BALLOON CATHETER)-THE NEUROSPEED PTA BALLOON CATHETER IS INDICATED FOR DILATION OF A STENOSIS IN THE CEREBRAL ARTERIES IN ORDER TO IMPROVE PERFUSION. THE NEUROSPEED PTA BALLOON CATHETER IS INDICATED FOR INTRODUCTION OF THE SELF-EXPANDING CREDO STENT, NEUROVASCULAR STENT(CREDO STENT)-USED IN COMBINATION WITH THE NEUROSPEED PTA BALLOON CATHETER, THE CREDO STENT IS INDICATED TO INCREASE THE VESSEL DIAMETER OF INTRACRANIAL ARTERIES (FOR EXAMPLE THE ICA, MCA, VA/V4, BA) THAT ARE SUITABLE FOR AND ACCESSIBLE TO THE SYSTEM (STENT WITH PTA BALLOON CATHETER) IN PATIENTS: • WITH ARTERIOSCLEROTIC (PROBABLE ACCORDING TO CLINICAL, ANAMNESTIC OR LABORATORY CHEMICAL TESTING) VESSEL CONSTRICTIONS (HIGH-GRADE INTRACRANIAL STENOSES > 70%) WITH SIGNIFICANT CIRCULATORY DISTURBANCE (HAEMODYNAMIC INFARCT PATTERN AND/OR INDICATION OF RESTRICTED COLLATERALS), • WITH RECURRENT SYMPTOMS IN SPITE OF ANTIAGGREGATION THERAPY (THERAPY-REFRACTORY) AFTER AT LEAST TWO EVENTS (STROKE). • OVER 18 YEARS OLD • WHOSE LAST STROKE OCCURRED AT LEAST 7 DAYS BEFORE AND IN WHOM THE IMPAIRMENT AFTER STROKE HAS A RATING OF 3 OR LESS ON THE MODIFIED RANKIN SCALE (MRS) AT THE TIME OF TREATMENT OR • WITH ACUTE VASCULAR OCCLUSION DUE TO HIGH-GRADE INTRACRANIAL STENOSIS IN WHICH ALTERNATIVE THERAPY CONCEPTS ARE NOT CONSIDERED OR FAIL,FLOW DIVERTER(DERIVO EMBOLISATION DEVICE, DERIVO MINI EMBOLISATION DEVICE, DERIVO 2 EMBOLISATION DEVICE, DERIVO HEAL EMBOLISATION DEVICE & DERIVO 2 HEAL EMBOLISATION DEVICE)-THE DERIVO EMBOLISATION DEVICE IS INTENDED FOR THE TREATMENT OF INTRACRANIAL

		ANEURYSMS WHICH CANNOT BE TREATED WITH OTHER ENDOVASCULAR TECHNIQUES OR IN WHICH OTHER ENDOVASCULAR OR NEUROSURGICAL TECHNIQUES PRESENT A HIGHER TREATMENT RISK.,MICRO CATHETER(NEUROSLIDER MICROCATHETER AND NEUROSLIDER MICROCATHETER DLC)-THE NEUROSLIDER IS INTENDED FOR CONTROLLED, SELECTIVE INFUSION OF PHYSICIAN-SPECIFIED THERAPEUTIC OR DIAGNOSTIC AGENTS INTO PERIPHERAL AND CEREBRAL VESSELS.,GUIDING CATHETER(NEUROBRIDGE CATHETER)-THE NEUROBRIDGE CATHETER IS INTENDED FOR THE INTRODUCTION OF INTERVENTIONAL AND DIAGNOSTIC INSTRUMENTS INTO PERIPHERAL AND CEREBRAL VESSELS. ADDITIONALLY, IT CAN BE USED AS A DIAGNOSTIC ANGIOGRAPHY CATHETER. FURTHERMORE, IT IS SUITABLE FOR THE REMOVAL OR ASPIRATION OF FRESH, SOFT EMBOLI AND THROMBI FROM PERIPHERAL AND CEREBRAL VESSELS.,NEUROVASCULAR STENT (ACCERO STENT)-THE ACCERO STENT IS INTENDED FOR USE WITH EMBOLISATION MATERIALS IN THE TREATMENT OF INTRACRANIAL ANEURYSMS
2640	IMP/MD/2021/000390	1.License Holder Name: M/S RAHUL INTERNATIONAL 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:INFLATABLE BONE EXPANDER SYSTEM FOR VCF WITH THE BALLOON(SPASY)--VCF (VERTEBRAL COMPRESSION FRACTURE) DUE TO OSTEOPOROSIS - OSTEOLYTIC FRACTURE -METASTATIC BONE FRACTURES
2641	IMP/MD/2021/000391	1.License Holder Name: MYOVATEC SURGICAL SYSTEMS LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TISSUE EXPANDER(PMT INTEGRA)-EXPANSION TISSUE FOR RECONSTRUCTIVE OR COSMETIC SURGERY
2642	IMP/MD/2021/000392	1.License Holder Name: NIPRO MEDICAL (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SINGLE PATIENT DIALYSIS MACHINE(NCU-18)-THIS MACHINE CAN BE USED FOR PATIENTS WITH ACUTE OR CHRONIC RENAL FAILURE AND WHEN HEMODIALYSIS IS PRESCRIBED BY A PHYSICIAN. THIS MACHINE IS INTENDED TO BE USED BY TRAINED OPERATORS FOR HOSPITAL, HEALTH CENTER OR LIMITED CARE. THE SYSTEM IS A SINGLE PATIENT HEMODIALYSIS SYSTEM, WHICH PROVIDES DIALYSIS FLUID WITH A PRESCRIBED CONCENTRATION AND TEMPERATURE TO BE USED FOR HEMODIALYSIS TREATMENT.

2643	IMP/MD/2021/000393	1.License Holder Name: LIVANOVA INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMAGING AND VOLUME FLOWMETER PROBES(MEDISTIM DOPPLER PROBE)-THE PROBES ARE DESIGNED TO BE USED TOGETHER WITH THE MEDISTIM SYSTEMS TO PERFORM INTRAOPERATIVE GUIDANCE AND QUALITY CONTROL DURING CARDIOVASCULAR SURGICAL PROCEDURES AND MEETS THE DEMANDS FOR DOCUMENTATION OF SURGICAL PROCEDURES., IMAGING AND VOLUME FLOWMETER PROBES(MEDISTIM ULTRASOUND IMAGING PROBE)-THE PROBES ARE DESIGNED TO BE USED TOGETHER WITH THE MEDISTIM SYSTEMS TO PERFORM INTRAOPERATIVE GUIDANCE AND QUALITY CONTROL DURING CARDIOVASCULAR SURGICAL PROCEDURES AND MEETS THE DEMANDS FOR DOCUMENTATION OF SURGICAL PROCEDURES., IMAGING DEVICES UTILIZING NON-IONIZING RADIATION(MEDISTIM MIRAQ SYSTEM, AVAILABLE IN DIFFERENT CONFIGURATION AS FOLLOWS: 1). MEDISTIM MIRAQ CARDIAC SYSTEM, 2).MEDISTIM MIRAQ VASCULAR SYSTEMS, 3).MEDISTIM MIRAQ ULTIMATE SYSTEMS)-THE SYSTEM IS DESIGNED TO BE USED TOGETHER WITH THE MEDISTIM PROBES TO PERFORM INTRAOPERATIVE GUIDANCE AND QUALITY CONTROL DURING CARDIOVASCULAR SURGICAL PROCEDURES AND MEETS THE DEMANDS FOR DOCUMENTATION OF SURGICAL PROCEDURES.,IMAGING AND VOLUME FLOWMETER PROBES (MEDISTIM TTFM PROBES , AVAILABLE IN DIFFERENT CONFIGURATION AS FOLLOWS: 1).MEDISTIM VASCULAR TTFM PROBES, 2). MEDISTIM QUICKFIT TTFM PROBES)-THE PROBES ARE DESIGNED TO BE USED TOGETHER WITH THE MEDISTIM SYSTEMS TO PERFORM INTRAOPERATIVE GUIDANCE AND QUALITY CONTROL DURING CARDIOVASCULAR SURGICAL PROCEDURES AND MEETS THE DEMANDS FOR DOCUMENTATION OF SURGICAL PROCEDURES.

2644	IMP/MD/2021/000394	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL MESH (GYNECARE TVT OBTURATOR SYSTEM)-INTENDED FOR USE IN WOMEN AS SUBURETHRAL SLING FOR USE FOR THE TREATMENT OF STRESS URINARY INCONTINENCE SUI RESULTING FROM URETHRAL HYPERMOBILITY AND/OR INTRINSIC SPHINCTER DEFICIENCY., ABSORBABLE HAEMOSTAT(SURGICEL ABSORBABLE HAEMOSTAT)-THIS PRODUCT IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE. SURGICEL HEMOSTAT CAN BE CUT FOR USE IN ENDOSCOPIC PROCEDURES. IT CAN BE USED IN MANY AREAS OF SURGERY, E.G. CARDIOVASCULAR SURGERY, HAEMORRHOIDECTOMY, IMPLANTATION OF VASCULAR PROSTHESES, BIOPSIES, LUNG OPERATIONS, SURGERY TO THE FACE AND JAW, GASTRIC RESECTION, OPERATIONS TO THE THROAT AND NOSE , LIVER AND GALL BLADDER OPERATIONS, GYNECOLOGICAL OPERATIONS, THORACIC AND ABDOMINAL SYMPATHECTOMIES, NEUROSURGERY ESPECIALLY CEREBRAL OPERATIONS, THYROID OPERATIONS, SKIN TRANSPLANTATIONS, TREATMENT OF SUPERFICIAL INJURIES. IT IS INDICATED ALSO FOR ADJUNCTIVE USE IN DENTAL APPLICATION TO ASSIST IN THE CONTROL OF BLEEDING IN EXODONTIA AND ORAL SURGERY. IT MAY ALSO BE USED TO HELP ACHIEVE HAEMOSTASIS AFTER SINGLE OR MULTIPLE TOOTH EXTRACTIONS, ALVEOLOPLASTY, GINGIVAL HAEMORRHAGE, IMPLICATIONS, BIOPSIES AND OTHER PROCEDURES IN THE ORAL CAVITY.,SURGICAL MESH(GYNECARE TVT EXACT CONTINENCE SYSTEM)-INTENDED TO BE USED AS A PUBOURETHRAL SLING FOR TREATMENT OF FEMALE STRESS URINARY INCONTINENCE, RESULTING FROM URETHRAL HYPERMOBILITY AND/OR INTRINSIC SPHINCTER DEFICIENCY.,SURGICAL MESH(GYNECARE TVT ABBREVO CONTINENCE SYSTEM)-INTENDED FOR USE IN WOMEN AS SUBURETHRAL SLING FOR USE FOR THE TREATMENT OF STRESS URINARY INCONTINENCE (SUI) RESULTING FROM URETHRAL HYPERMOBILITY AND/OR INTRINSIC SPHINCTER DEFICIENCY., SURGICAL MESH(GYNECARE TVT DEVICE)-INTENDED TO BE USED AS A PUBOURETHRAL SLING FOR TREATMENT FOR USE IN WOMEN AS STRESS URINARY INCONTINENCE SUI, FOR FEMALE URINARY INCONTINENCE RESULTING FROM URETHRAL HYPERMOBILITY AND/OR INTRINSIC SPHINCTER DEFICIENCY.

2645	IMP/MD/2021/000395	1.License Holder Name: ZB DENTAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ZFX GENTEK RESTORATIVE COMPONENTS(ZFX GENTEK TIBASE & ZFX GENTEK PRE-MILLED ABUTMENT BLANK)-ZFX GENTEK™ RESTORATIVE COMPONENTS ARE INTENDED FOR USE AS AN INTERFACE BETWEEN DENTAL IMPLANTS AND RESTORATION.
2646	IMP/MD/2021/000396	1.License Holder Name: ZIMMER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ELECTROSURGICAL SYSTEM(ELECTRO SURGERY VELOX™ RADIO FREQUENCY ABLATOR - ZEOS EFFECUT)-THIS DEVICE IS INTENDED TO BE USED FOR CUTTING, VAPORIZATION, AND COAGULATION OF SOFT TISSUE DURING ARTHROSCOPIC SURGICAL PROCEDURES. THIS DEVICE IS INTENDED TO BE USED WITH A STANDARD ELECTROSURGICAL GENERATOR WITH FOOTSWITCH CONTROL AND A STANDARD RETURN ELECTRODE CONNECTION, AND THE ELECTRODE IS TO BE ACTIVATED ONLY WHEN IMMERSED IN A CONDUCTIVE MEDIA SUCH AS STANDARD SALINE SOLUTION. NOTICE: THE DEVICE IS NOT INTENDED FOR USE WITH STERILE WATER.

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2647	IMP/MD/2021/000397	1.License Holder Name: STRYKER INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:REABSORBABLE FIXATION DEVICE(BIOSTEON INTRALINE SUTURE W/O NEEDLES)-THE BIOSTEON INTRALINE SUTURE ANCHOR IS INTENDED FOR FIXATION OF TISSUE TO BONE IN ORTHOPEDIC PROCEDURES IN THE SHOULDER, FOOT/ANKLE, KNEE, HAND/WRIST, ELBOW AND PELVIS, REABSORBABLE FIXATION DEVICE(BIOSTEON INTRALINE SUTURE WITH NEEDLES)-THE BIOSTEON INTRALINE SUTURE ANCHOR IS INTENDED FOR FIXATION OF TISSUE TO BONE IN ORTHOPEDIC PROCEDURES IN THE SHOULDER, FOOT/ANKLE, KNEE, HAND/WRIST, ELBOW AND PELVIS BIOSTEON INTRALINE SUTURE ANCHOR., REABSORBABLE FIXATION DEVICE(BIOSTEON SCREW)-IT IS INDICATED FOR USE IN ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION PROCEDURE WHERE THE SURGEON: --PLACES THE GRAFT IN THE TIBIAL AND/ OR FEMORAL TUNNELS; AND --INSERTS SCREWS BETWEEN THE TUNNEL WALL AND GRAFT TO HOLD THE GRAFT IN THE PLACE. IT IS USED TO PROVIDE INTERFERENCE FIXATION IN PATELLAR BONE TENDON-BONE GRAFTS IN ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION. IT IS USED TO PROVIDE INTERFERENCE FIXATION DURING FEMORAL AND/OR TIBIAL FIXATION IN ACL RECONSTRUCTION USING A SOFT TISSUE GRAFT (SEMITENDONOSIS-GRACILLIS)

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2648	IMP/MD/2021/000401	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIP SYSTEM(BIOLOX DELTA- HEADS)-INTENDED USE – TOTAL HIP PROSTHESIS TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. INDICATIONS – TOTAL HIP PROSTHESIS TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3. ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK. 4. FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5. CERTAIN CASES OF ANKYLOSIS. POROUS-COATED PINNACLE ACETABULAR CUPS ARE INDICATED FOR CEMENTLESS APPLICATIONS. SELF-CENTERING HIP PROSTHESES AND HEMI-HIP PROSTHESES ARE INTENDED TO BE USED FOR HEMI-HIP ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM. HEMI-HIP ARTHROPLASTY IS INDICATED IN THE FOLLOWING CONDITIONS: 1. ACUTE FRACTURE OF THE FEMORAL HEAD OR NECK THAT CANNOT BE APPROPRIATELY REDUCED AND TREATED WITH INTERNAL FIXATION. 2. FRACTURE DISLOCATION OF THE HIP THAT CANNOT BE APPROPRIATELY REDUCED AND TREATED WITH INTERNAL FIXATION. 3. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 4. NON-UNION OF FEMORAL NECK FRACTURES. 5. CERTAIN HIGH SUBCAPITAL AND FEMORAL NECK FRACTURES IN THE ELDERLY. 6. DEGENERATIVE ARTHRITIS INVOLVING ONLY THE FEMORAL HEAD IN WHICH THE ACETABULUM DOES NOT REQUIRE REPLACEMENT. 7. PATHOLOGY INVOLVING ONLY THE FEMORAL HEAD/NECK AND/OR PROXIMAL FEMUR THAT CAN BE ADEQUATELY TREATED BY HEMI-HIP ARTHROPLASTY. TOTAL OR HEMI-HIP ARTHROPLASTY MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR HEMI-HIP REPLACEMENT OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT AND IF LIMITED DEMANDS REGARDING ACTIVITY AND HIP JOINT LOADING CAN BE ASSURED.,HIP SYSTEM(BIOLOX DELTA- REVISION HEADS)-BIOLOX DELTA TS CERAMIC FEMORAL HEAD TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE

	INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. THE TAPER SLEEVED CERAMIC HEAD HIP ASSEMBLY IS INTENDED FOR HIP REPLACEMENT SURGERY AND CASES OF FAILED FEMORAL HIP HEAD AND/OR ACETABULAR COMPONENTS, WITH THE PRESENCE OF A WELL-FIXED FEMORAL STEM. INTENDED USE: THE DEPUY BIOLOX DELTA TS CERAMIC FEMORAL HEAD IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY APPLICATIONS TO REPLACE THE ARTICULAR SURFACE OF THE FEMORAL HEAD IN PRIMARY HIP SURGERY AND FOR THE SALVAGE OF A FAILED PREVIOUS HIP SURGERY. INDICATIONS: THE DEPUY BIOLOX DELTA TS CERAMIC FEMORAL HEAD IS INDICATED FOR USE AS THE FEMORAL HEAD COMPONENT IN TOTAL HIP ARTHROPLASTY PROCEDURES. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3. ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK. 4. FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5. CERTAIN CASES OF ANKYLOSIS. MODULAR FEMORAL HEADS AND ACETABULAR COMPONENTS A DEPUY BIOLOX DELTA TS CERAMIC FEMORAL HEAD IS TO BE USED WITH A DEPUY FEMORAL STEM COMPONENT. THE ACETABULUM IS TO BE REPLACED WITH A DEPUY TWO-PIECE METAL BACKED UHMWPE, OR CERAMIC CUP OR ALL UHMWPE ACETABULAR CUP COMPONENT WITH AN INSIDE DIAMETER THAT MATCHES THE OUTSIDE DIAMETER OF THE MODULAR FEMORAL HEAD THAT IS UTILIZED.,HIP SYSTEM(BIOLOX DELTA- INSERTS)- TOTAL HIP PROSTHESIS TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS: 1. A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS, OR CONGENITAL HIP DYSPLASIA. 2. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 3.

	ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK. 4. FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. 5. CERTAIN CASES OF ANKYLOSIS. POROCOAT® POROUS COATED COMPONENTS POROCOAT® POROUS COATED FEMORAL HIP STEM AND METAL BACKED ACETABULAR CUP TOTAL HIP COMPONENTS ARE INDICATED FOR CEMENTLESS USE WITH FIXATION PROVIDED BY BIOLOGICAL TISSUE INGROWTH INTO THE POROUS COATING OR FOR CEMENTED USE IN WHICH THE POROUS COATING SERVES AS A MEANS TO AUGMENT THE FIXATION OF THE PROSTHESIS TO THE BONE CEMENT. CEMENTED COMPONENTS FEMORAL STEM AND ACETABULAR CUP TOTAL HIP COMPONENTS LABELED "FOR CEMENTED USE ONLY" ARE INDICATED ONLY FOR USE WITH BONE CEMENT. NON-POROUS COATED PRESS FIT OR CEMENTED COMPONENTS NON-POROUS COATED FEMORAL HIP STEM PROSTHESES LABELED "FOR PRESS FIT OR CEMENTED USE ONLY" ARE INDICATED FOR PRESS FIT UNCEMENTED USE OR FOR USE WITH BONE CEMENT. CERAMIC COATED FEMORAL COMPONENTS CERAMIC COATED FEMORAL STEM PROSTHESES ARE INDICATED FOR UNCEMENTED PRESS FIT FIXATION. CAUTION: DO NOT USE BONE CEMENT FOR FIXATION OF A CERAMIC COATED PROSTHESIS. MODULAR FEMORAL HEADS AND ACETABULAR COMPONENTS A DEPUY METAL OR CERAMIC MODULAR FEMORAL HEAD IS TO BE USED WITH THE DEPUY FEMORAL STEM COMPONENT. THE ACETABULUM IS TO BE REPLACED WITH A DEPUY ACETABULAR COMPONENT COMPRISING EITHER AN ALL UHMWPE CUP OR 2 PIECE METAL SHELL WITH EITHER AN UHMWPE, METAL OR CERAMIC LINER WITH AN INSIDE DIAMETER CORRESPONDING TO THE OUTSIDE DIAMETER OF THE MODULAR FEMORAL THAT IS UTILIZED.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2649	IMP/MD/2021/000402	1.License Holder Name: BIOTRONIK MEDICAL DEVICES INDIA PVT LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMPLANTABLE PACEMAKER(EVITY)-EVITY IS AN IMPLANTABLE PACEMAKER THAT CAN BE IMPLANTED FOR ALL BRADYCARDIA ARRHYTHMIA INDICATIONS. THE PRIMARY OBJECTIVE OF THE THERAPY CONSISTS OF IMPROVING PATIENTS' SYMPTOMS THAT CAN BE CLINICALLY MANIFESTED. THE IMPLANTATION OF THE PACEMAKER IS A SYMPTOMATIC THERAPY WITH THE FOLLOWING OBJECTIVE: •COMPENSATION OF BRADYCARDIA BY ATRIAL, VENTRICULAR, OR AV SEQUENTIAL PACING •ADDITIONAL TRIPLE-CHAMBER FEATURES: RE SYNCHRONIZATION OF VENTRICULAR CHAMBER CONTRACTION VIA BI VENTRICULAR PACING,BIPOLAR, STEROID ELUTING ENDOCARDIAL LEAD(SOLIA)-IN COMBINATION WITH A COMPATIBLE IMPLANTABLE PACEMAKER OR ICD THE SOLIA S LEADS ARE INDICATED FOR THE FOLLOWING: PERMANENT SENSING AND PACING IN THE RIGHT VENTRICLE OR THE RIGHT ATRIUM. WITH ITS ACTIVE FIXATION SCREW, THIS LEAD IS ESPECIALLY SUITED FOR POSITIONING IN THE ATRIUM AND FOR PATIENTS WITH DETERIORATING VENTRICULAR TRABECULAE FOR WHOM PASSIVE FIXATION WITH SILICONE TINES IS NOT POSSIBLE. IN COMBINATION WITH A COMPATIBLE PACEMAKER OR ICD THE SOLIA T/JT LEADS ARE INDICATED FOR THE FOLLOWING: PERMANENT SENSING AND PACING IN THE RIGHT VENTRICLE (STRAIGHT DESIGN) OR ATRIUM (J-SHAPED DESIGN),IMPLANTABLE PACEMAKER(ENTICOS)-ENTICOS IS AN IMPLANTABLE PACEMAKER THAT CAN BE IMPLANTED FOR ALL BRADYCARDIA ARRHYTHMIA INDICATIONS. THE PRIMARY OBJECTIVE OF THE THERAPY CONSISTS OF IMPROVING PATIENTS' SYMPTOMS THAT CAN BE CLINICALLY MANIFESTED. THE IMPLANTATION OF THE PACEMAKER IS A SYMPTOMATIC THERAPY WITH THE FOLLOWING OBJECTIVE: •COMPENSATION OF BRADYCARDIA BY ATRIAL, VENTRICULAR, OR AV SEQUENTIAL PACING,BIPOLAR, STEROID ELUTING ENDOCARDIAL LEAD(SOLIA)-IN COMBINATION WITH A COMPATIBLE IMPLANTABLE PACEMAKER OR ICD THE SOLIA S LEADS ARE INDICATED FOR THE FOLLOWING: PERMANENT SENSING AND PACING IN THE RIGHT VENTRICLE OR THE RIGHT ATRIUM. WITH ITS ACTIVE FIXATION SCREW, THIS LEAD IS ESPECIALLY SUITED FOR POSITIONING IN THE ATRIUM AND FOR PATIENTS WITH DETERIORATING VENTRICULAR TRABECULAE FOR WHOM PASSIVE FIXATION WITH SILICONE TINES IS NOT POSSIBLE. IN COMBINATION WITH A COMPATIBLE PACEMAKER OR ICD THE SOLIA T/JT LEADS ARE INDICATED FOR THE FOLLOWING: PERMANENT SENSING AND PACING IN THE RIGHT VENTRICLE (STRAIGHT DESIGN) OR ATRIUM (J-SHAPED DESIGN),IMPLANTABLE PACEMAKER(ENITRA)

	-ENITRA IS AN IMPLANTABLE PACEMAKER THAT CAN BE IMPLANTED FOR ALL BRADYCARDIA ARRHYTHMIA INDICATIONS. THE PRIMARY OBJECTIVE OF THE THERAPY CONSISTS OF IMPROVING PATIENTS' SYMPTOMS THAT CAN BE CLINICALLY MANIFESTED. THE IMPLANTATION OF THE PACEMAKER IS A SYMPTOMATIC THERAPY WITH THE FOLLOWING OBJECTIVE: •COMPENSATION OF BRADYCARDIA BY ATRIAL, VENTRICULAR, OR AV SEQUENTIAL PACING •ADDITIONAL TRIPLE-CHAMBER FEATURES: RESYNCHRONIZATION OF VENTRICULAR CHAMBER CONTRACTION VIA BIVENTRICULAR PACING,STEROID ELUTING ICD LEAD WITH ACTIVE FIXATION(PLEXA)-IN COMBINATION WITH A COMPATIBLE ICD THE PLEXA LEADS ARE INTENDED FOR THE FOLLOWING: PERMANENT PACING AND SENSING IN THE RIGHT VENTRICLE DELIVERY OF DEFIBRILLATION/CARDIOVERSION THERAPIES WITH ITS ACTIVE FIXATION SCREW, THIS LEAD IS ESPECIALLY SUITABLE FOR PATIENTS WITH DEGENERATEDTRABECULAE IN THE VENTRICLE FOR WHOM PASSIVE FIXATION WITH SILICONE OR POLYURETHANE TINES IS NOT POSSIBLE.,IMPLANTABLE, STEROID ELUTING, MR CONDITIONAL CORONARY SINUS LEADS(SENTUS)-IN COMBINATION WITH A COMPATIBLE IMPLANTABLE TRIPLE-CHAMBER PACEMAKER OR ICD, THIS LEAD IS INTENDED INDICATED FOR THE FOLLOWING: •PERMANENT, TRANSVENOUS IMPLANTATION IN THE CORONARY VENOUS SYSTEM VIA THE CORONARY SINUS OF THE LEFT SIDE OF THE HEART •PERMANENT SENSING AND PACING OF THE LEFT VENTRICLE,IMPLANTABLE CARDIOVERTER/ DEFIBRILLATOR(INLEXA) -INLEXA' IS A CARDIOVERTER/DEFIBRILLATOR (ICD). PRIMARY OBJECTIVE OF THIS ICD IS THE PREVENTION OF SUDDEN CARDIAC DEATH. FURTHERMORE, THIS DEVICE IS CAPABLE OF TREATING BRADYCARDIA ARRHYTHMIAS AND CARDIAC RESYNCHRONIZATION THERAPY WITH MULTISITE VENTRICULAR PACING ('HF-T' AND 'HF-T QP' VARIANTS). THE IMPLANTATION OF AN ICD IS A SYMPTOMATIC THERAPY WITH THE FOLLOWING OBJECTIVES: - TERMINATION OF SPONTANEOUS VENTRICULAR FIBRILLATION (VF) THROUGH SHOCK DELIVERY - TERMINATION OF SPONTANEOUS VENTRICULAR TACHYCARDIA (VT) THROUGH ANTITACHYCARDIA PACING (ATP); IN CASE OF INEFFECTIVE ATP OR HEMODYNAMICALLY NOT TOLERATED VT, WITH SHOCK DELIVERY - CARDIAC RESYNCHRONIZATION THROUGH MULTISITE VENTRICULAR PACING (TRIPLE-CHAMBER DEVICES) - COMPENSATION OF BRADYCARDIA THROUGH VENTRICULAR (SINGLE-CHAMBER DEVICES) OR AV SEQUENTIAL PACING (DUAL- AND TRIPLE-CHAMBER DEVICES),IMPLANTABLE CARDIOVERTER/ DEFIBRILLATOR(RIVACOR)-RIVACOR IS AN IMPLANTABLE CARDIOVERTER/DEFIBRILLATOR (ICD). PRIMARY OBJECTIVE OF THIS ICD IS THE PREVENTION OF SUDDEN CARDIAC

		DEATH. FURTHERMORE, THE DEVICE IS CAPABLE OF TREATING BRADYCARDIA ARRHYTHMIAS AND CARDIAC RESYNCHRONIZATION THERAPY WITH MULTISITE VENTRICULAR PACING ('HF-T' AND 'HF-T QP' VARIANTS). THE IMPLANTATION OF AN ICD IS A SYMPTOMATIC THERAPY WITH THE FOLLOWING OBJECTIVES: - TERMINATION OF SPONTANEOUS VENTRICULAR FIBRILLATION (VF) THROUGH SHOCK DELIVERY - TERMINATION OF SPONTANEOUS VENTRICULAR TACHYCARDIA (VT) THROUGH ANTITACHYCARDIA PACING (ATP); IN CASE OF INEFFECTIVE ATP OR HEMODYNAMICALLY NOT TOLERATED VT, WITH SHOCK DELIVERY - CARDIAC RESYNCHRONIZATION THROUGH MULTISITE VENTRICULAR PACING (TRIPLE-CHAMBER DEVICES) - COMPENSATION OF BRADYCARDIA THROUGH VENTRICULAR (SINGLE-CHAMBER DEVICES) OR AV SEQUENTIALPACING (DX, DUAL- AND TRIPLE-CHAMBER DEVICES), IMPLANTABLE CARDIOVERTER/ DEFIBRILLATOR(INTICA NEO)-INTICA NEO IS A CARDIOVERTER/DEFIBRILLATOR (ICD). PRIMARY OBJECTIVE OF THIS ICD IS THE PREVENTION OF SUDDEN CARDIAC DEATH. FURTHERMORE, THIS DEVICE IS CAPABLE OF TREATING BRADYCARDIA ARRHYTHMIAS AND CARDIAC RESYNCHRONIZATION THERAPY WITH MULTISITE VENTRICULAR PACING ('HF-T' AND 'HF-T QP' VARIANTS). THE IMPLANTATION OF AN ICD IS A SYMPTOMATIC THERAPY WITH THE FOLLOWING OBJECTIVES: - TERMINATION OF SPONTANEOUS VENTRICULAR FIBRILLATION (VF) THROUGH SHOCK DELIVERY - TERMINATION OF SPONTANEOUS VENTRICULAR TACHYCARDIA (VT) THROUGH ANTITACHYCARDIA PACING (ATP); IN CASE OF INEFFECTIVE ATP OR HEMODYNAMICALLY NOT TOLERATED VT, WITH SHOCK DELIVERY - CARDIAC RESYNCHRONIZATION THROUGH MULTISITE VENTRICULAR PACING (TRIPLE-CHAMBER DEVICES) - COMPENSATION OF BRADYCARDIA THROUGH VENTRICULAR (SINGLE-CHAMBER DEVICES) OR AV SEQUENTIAL PACING (DX DUAL- AND TRIPLE-CHAMBER DEVICES)
2650	IMP/MD/2021/000403	1.License Holder Name: D. S. OVERSEAS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE SKIN STAPLER(PARAKIN)-THE STERILE DISPOSABLE SKIN STAPLE (HEREINAFTER REFERRED AS PRODUCTS) IS SUITABLE FOR SKIN CLOSURE OF WOUND AND SURGICAL INCISION.

2651	IMP/MD/2021/000404	1.License Holder Name: WIPRO GE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAGNETIC RESONANCE IMAGING SYSTEM(SIGNA PIONEER)-THE SIGNA PIONEER IS A WHOLE BODY MAGNETIC RESONANCE SCANNER DESIGNED TO SUPPORT HIGH RESOLUTION, HIGH SIGNAL-TO-NOISE RATIO, AND SHORT SCAN TIMES. IT IS INDICATED FOR USE AS A DIAGNOSTIC IMAGING DEVICE TO PRODUCE AXIAL, SAGITTAL, CORONAL, AND OBLIQUE IMAGES, SPECTROSCOPIC IMAGES, PARAMETRIC MAPS, AND/OR SPECTRA, DYNAMIC IMAGES OF THE STRUCTURES AND/OR FUNCTIONS OF THE ENTIRE BODY, INCLUDING, BUT NOT LIMITED TO, HEAD, NECK, TMJ, SPINE, BREAST, HEART, ABDOMEN, PELVIS, JOINTS, PROSTATE, BLOOD VESSELS, AND MUSCULOSKELETAL REGIONS OF THE BODY. DEPENDING ON THE REGION OF INTEREST BEING IMAGED, CONTRAST AGENTS MAY BE USED. THE IMAGES PRODUCED BY THE SIGNA PIONEER REFLECT THE SPATIAL DISTRIBUTION OR MOLECULAR ENVIRONMENT OF NUCLEI EXHIBITING MAGNETIC RESONANCE. THESE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS.
2652	IMP/MD/2021/000405	1.License Holder Name: CAMBINDIA BIOTECH KITS (PVT) LTD. ,SHOP NO.208 AND 209, SECOND FLOOR, A-WING,PRATIK IND.ESTATE, MULUND-GOREGAON LINK ROAD, NEAR WOCKHARDT HOSPITAL, BHABDUP WEST, ,MUMBAI SUBURBAN MAHARASHTRA ,400078 , INDIA 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BLOOD COLLCETION SET-TO COLLECT THE SAMPLE FROM THE PATIENT THROUGH VENI PUNCTURE FOR FURTHER ANALYSIS IN LABORATORY,BLOOD COLLECTION NEEDLE-TO COLLECT THE SAMPLE FROM THE PATIENT THROUGH VENI PUNCTURE FOR FURTHER ANALYSIS IN LABORATORY
2653	IMP/MD/2021/000406	1.License Holder Name: SILVERLINE MEDI-TECH PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARM TYPE ELECTRONIC BLOOD PRESSURE MONITOR(NA)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.

2654	IMP/MD/2021/000408	1.License Holder Name: DR. REDDYS LABORATORIES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FILM FORMING SILICONE WOUND DRESSING(STRATA CTX)-STRATACTX IS USED TO RELIEVE LOW GRADE INFLAMMATORY CHANGES SUCH AS DRY, ITCHING, FLAKING, PEELING AND IRRITATED SKIN. FOR MORE SEVERE INFLAMMATORY CHANGES, STRATACTX REDUCES PAIN, REDNESS AND HEAT SENSATION. STRATACTX WAS DEVELOPED FOR USE ON ALL TYPES OF WOUNDS, TOXIC AND COMPROMISED SKIN INCLUDING: • CUTANEOUS REACTIONS • PRURITIC, ITCHY SKIN • XEROTIC, DRY SKIN • DESQUAMATION • FISSURES OF SKIN AND NAIL FOLDS • BLISTERS • MEDICAL ADHESIVE-RELATED SKIN INJURIES (MARSI) • ERYTHEMA • INFUSION REACTIONS • RASHES, INCLUDING: MACULOPAPULAR RASH, HAND-FOOT SYNDROME, GVHD, ACNEIFORM REACTION, PERI – AND APPENDAGEAL (HAIR FOLLICLES, SWEAT GLANDS). STRATACTX CAN BE USED WITH OR WITHOUT A SECONDARY PROTECTIVE DRESSING. STRATACTX IS SUITABLE FOR CHILDREN AND PEOPLE WITH SENSITIVE SKIN. STRATACTX IS INTENDED FOR SINGLE PATIENT USE. STRATACTX IS IDEAL FOR LARGE SURFACE AREAS AND CONTOURED SKIN LIKE HEAD, FACE, HAND AND FOOT, AS WELL AS JOINTS AND HAIRY AREAS WITHOUT THE NEED FOR SHAVING. STRATACTX IS TRANSPARENT ALLOWING USERS TO MONITOR THERAPY PROGRESS WITHOUT REMOVAL OF THE DRESSING.,FILM FORMING SILICONE WOUND DRESSING(STRATA XRT)-STRATAXRT IS USED TO RELIEVE LOW GRADE INFLAMMATORY CHANGES SUCH AS DRY, ITCHING, FLAKING, PEELING AND IRRITATED SKIN. FOR MORE SEVERE INFLAMMATORY CHANGES, STRATAXRT REDUCES PAIN, REDNESS, HEAT SENSATION AND HELPS SOOTHE THE EXPOSED SKIN AREAS. STRATAXRT WAS DEVELOPED FOR USE ON ALL TYPES OF RADIATION DERMATITIS, TOXIC AND COMPROMISED SKIN, SUPERFICIAL WOUNDS AND BURNS, INCLUDING THOSE RESULTING FROM: • RADIATION THERAPY • FIRST AND SECOND DEGREE BURNS STRATAXRT MAY BE APPLIED TO SUPERFICIAL WOUNDS, BURNS AND AREAS WHERE SKIN INTEGRITY HAS BEEN COMPROMISED. STRATAXRT MAY ALSO BE USED IN CONJUNCTION WITH OTHER ADJUNCTIVE TREATMENTS TO IMPROVE OVERALL RESULTS. STRATAXRT CONTAINS NO ALCOHOLS, PARABENS OR FRAGRANCES AND IS TRANSPARENT AND ODORLESS. STRATAXRT CAN BE USED WITH OR WITHOUT A SECONDARY PROTECTIVE DRESSING. STRATAXRT IS SUITABLE FOR CHILDREN AND PEOPLE WITH SENSITIVE SKIN. STRATAXRT IS INTENDED FOR SINGLE PATIENT USE.

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2655	IMP/MD/2021/000409	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COBLATION SYSTEM (WEREWOLF)-THE WEREWOLF COBLATION SYSTEM CONTROLLER IS INDICATED FOR THE RESECTION, ABLATION, AND COAGULATION OF SOFT TISSUES AND HEMOSTASIS OF BLOOD VESSELS IN ARTHROSCOPIC, ORTHOPEDIC AND OTORHINOLARYNGOLOGY (ENT) PROCEDURES (REFER USER MANUAL FOR DETAILED INDICATIONS)., COBLATION SYSTEM(WEREWOLF)-THE WEREWOLF SYSTEM CONTROLLER IS INDICATED FOR THE RESECTION, ABLATION, AND COAGULATION OF SOFT TISSUES AND HEMOSTASIS OF BLOOD VESSELS IN THE FOLLOWING ARTHROSCOPIC AND ORTHOPEDIC PROCEDURES. (REFER USER MANUAL FOR DETAILED INDICATIONS).
2656	IMP/MD/2021/000410	1.License Holder Name: ZB DENTAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:RESORBABLE COLLAGEN MEMBRANE FOR DENTAL SURGERY(OSSEOGUARD)-RESORBABLE COLLAGEN MEMBRANE FOR DENTAL SURGERY - OSSEOGUARD10. INTENDED USE:OSSEOGUARD® IS A BIORESORBABLE, IMPLANTABLE COLLAGEN MATERIAL THAT IS INTENDEDFORUSE IN PERIODONTAL AND/OR DENTAL SURGERY PROCEDURES AS A MATERIAL FOR PLACEMENT INTHE AREA OFPERIODONTAL DEFECTS, DENTAL IMPLANT, BONE DEFECT OR RIDGE RECONSTRUCTIONTO AID IN WOUND HEALINGPOST SURGERY.,RESORBABLE COLLAGEN MEMBRANE(OSSEOGUARD FLEX)-OSSEOGUARD FLEX™ IS INTENDED FOR USE IN ORAL SURGICAL PROCEDURES AS ARESORBABLEMEMBRANE MATERIAL FOR USE IN AUGMENTATION AROUND IMPLANTS PLACED INIMMEDIATE EXTRACTIONSOCKETS, DELAYED EXTRACTION SOCKETS; LOCALIZED RIDGEAUGMENTATION FOR LATER IMPLANTATION; ALVEOLARRIDGE RECONSTRUCTION FOR PROSTHETICTREATMENT; FI LLING OF BONE DEFECTS; GUIDED BONE REGENERATION INDEHISCENCE DEFECTSAND GUIDED TISSUE REGENERATION PROCEDURES IN PERIODONTAL DEFECTS

2657	IMP/MD/2021/000412	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SCREW IMPLANTS FOR PLATES - STERILE (SS)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,POSTERIOR ROD - TITANIUM (NON STERILE)-OCCIPITO-CERVICAL FUSION SYSTEM THE SYNTHES OCCIPITO-CERVICAL FUSION SYSTEM IN COMBINATION WITH A SYNTHES POSTERIOR SCREW-ROD SYSTEM (E.G. SYNAPSE AND AXON) IS INTENDED TO PROVIDE STABILIZATION TO PROMOTE FUSION OF THE CERVICAL SPINE AND OCCIPITOCERVICAL JUNCTION (OCCIPUT-TH3) FOR THE FOLLOWING INDICATIONS: OCCIPITO-CERVICAL AND UPPER CERVICAL SPINE INSTABILITIES: - RHEUMATOID ARTHRITIS - CONGENITAL ANOMALIES - POSTTRAUMATIC CONDITIONS - TUMORS - INFECTIONS INSTABILITIES IN THE LOWER CERVICAL AND UPPER THORACIC SPINE: - POSTTRAUMATIC CONDITIONS -TUMORS -IATROGENIC INSTABILITIES FOLLOWING LAMINECTOMY ETC. DEGENERATIVE AND PAINFUL POSTTRAUMATIC CONDITIONS IN THE LOWER CERVICAL AND UPPER THORACIC SPINE. ANTERIOR CERVICAL FUSIONS REQUIRING ADDITIONAL POSTERIOR STABILIZATION THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: - TOP-LOADING VARIABLE AXIS SCREWS - HOOKS - TRANSVERSE BARS - RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY.",HUMERAL NAILING IMPLANTS - END CAP (TITANIUM ALLOY)-:" INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",VECTRA -PLATE (TI AL6 NB7 COCRFENI ALLOY)-THE VECTRA SYSTEM IS INTENDED FOR ANTERIOR PLATE AND SCREW FIXATION OF SPECIFIED PART(S): THE CERVICAL SPINE (C2-C7).,UNIVERSAL SPINE SYSTEM (USS) -3D HEAD-THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II

	POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.",VECTRA T PLATE- TAN/ TICP COCRFENI ALLOY-THE VECTRA SYSTEM IS INTENDED FOR ANTERIOR PLATE AND SCREW FIXATION OF SPECIFIED PART(S): THE CERVICAL SPINE (C2-C7).,EXTERNAL FIXATOR IMPLANTS - NON - STERILE-EXTERNAL FIXATOR DEVICES ARE INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS.,CANNULATED SCREW IMPLANTS - TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., SCREW IMPLANTS FOR OR WITHOUT PLATES - WASHER (SS)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS,DISTAL TIBIA PLATES - SS-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., SCREWS FOR INTRAMEDULLARY NAIL -SCREW-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN),SCREW IMPLANTS FOR PLATES - SCREW (SS)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,POSTERIOR CONNECTORS - CLAMP-THE CLICK'X SYSTEM IS A POSTERIOR THORACOLUMBAR PEDICLE SCREW SYSTEM INTENDED TO PROVIDE PRECISE AND

	SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE PERFORATED CLICK'X SYSTEM IS A TRANSPEDICULAR SCREW/ROD SYSTEM INTENDED FOR THE POSTERIOR STABILIZATION OF THE THORACOLUMBAR AND LUMBAR SPINE. THE PERFORATED CLICK'X SCREWS ARE CANNULATED. HOWEVER, THEY MAY BE INSERTED LIKE STANDARD SOLID CLICK'X SCREWS OR LIKE CANNULATED CLICK'X SCREWS BY MEANS OF KIRSCHNER WIRE GUIDANCE. THE LATERAL PERFORATIONS ALLOW DIRECT CEMENT AUGMENTATION OF THE SCREW IN THE OSTEOPOROTIC BONE. THE PANGEA SPINE SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS.THE PANGEA PERFORATED SCREWS ARE AN ADDITION TO THE PANGEA SPINE SYSTEM, A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1-S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS.PANGEA PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID PANGEA SCREWS AND WITH K-WIRE GUIDANCE AS PANGEA CANNULATED SCREWS INCLUDING A MINIMALLY INVASIVE APPROACH WITH SPIRIT. PANGEA PERFORATED SCREWS DIRECT VERTECEM OR V+ THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY THE USS FRACTURE SYSTEM IS A POSTERIOR THORACOLUMBAR PEDICLE SCREW FIXATION SYSTEM INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE APPLICATION AREA IN PATIENTS SUFFERING FROM TRAUMA OR TUMOR DISEASE IS USUALLY AT THE THORACAL-LUMBAR JUNCTION (T12 /L1), BUT CAN BE EXTENDED FROM T6 DOWN TO THE SACRUM (S1). THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT

	THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.",MATRIXMANDIBLE & MATRIXMANDIBLE PREFORMED RECONSTRUCTION PLATES -TITANIUM-THE DEPUY SYNTHES MATRIXMANDIBLE PREFORMED RECONSTRUCTION PLATES ARE SPECIFICALLY PREFORMED PLATES INTENDED FOR MANDIBULAR RECONSTRUCTION WITH BONE GRAFT (VASCULARIZED OR NOT), TEMPORARY BRIDGING UNTIL SECONDARY RECONSTRUCTION, THE TREATMENT OF THE COMMINUTED FRACTURES OF THE MANDIBLE AND THE TREATMENT OF FRACTURES IN EDENTULOUS AND ATROPHIC MANDIBLES, AND UNSTABLE AND/OR INFECTED MANDIBULAR FRACTURES.,ZERO P -SCREW (NON-STERILE) - TITANIUM ALLOY-THE ZERO-P SYSTEM IS INTENDED FOR USE FOLLOWING ANTERIOR CERVICAL DISCECTOMY FOR REDUCTION AND STABILIZATION OF THE CERVICAL SPINE (C2–C7).,DISTAL HUMERUS PLATE -TITANIUM-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., UNIVERSAL SPINE SYSTEM (USS) - NUT- THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD

	CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.",SCREWS FOR INTRAMEDULLARY NAIL -SCREW (STERILE)-:"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",INTERMAXILLARY FIXATION (IMF) SCREWS - SS-TEMPORARY, PERIOPERATIVE STABILISATION OF THE OCCLUSION IN ADULTS.,RECON FEMORAL NAILING IMPLANTS -SCREW (NON -STERILE)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",UNIVERSAL SPINE SYSTEM (USS) -RING-THE PANGEA SPINE SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE PANGEA PERFORATED SCREWS ARE AN ADDITION TO THE PANGEA SPINE SYSTEM, A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1-S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. PANGEA PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID PANGEA SCREWS AND WITH K-WIRE GUIDANCE AS PANGEA CANNULATED SCREWS INCLUDING A MINIMALLY INVASIVE APPROACH WITH SPIRIT. PANGEA PERFORATED SCREWS DIRECT VERTECEM OR V+ THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS

	(SUPERIOR ATTACHMENT POINT) AND TO MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). THIS IS DONE THROUGH A STANDARD THORACOTOMY INCISION BY PERFORMING AN OPENING WEDGE THORACOSTOMY. REGULAR EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS INVASIVE SURGERY. GOALS OF TREATMENT: - INCREASE THORACIC VOLUME - SCOLIOSIS CORRECTION - THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX - IMPROVE THORACIC FUNCTION - AVOIDING GROWTH INHIBITION PROCEDURES - MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE GROWTH OF THE CHILD VEPTR IS BASED ON A THREE-DIMENSIONAL THORACIC APPROACH TO TREAT PATIENTS WITH COMPLEX CHEST WALL AND/OR SPINAL DEFORMITIES WHERE THE THORAX IS UNABLE TO SUPPORT NORMAL RESPIRATION OR LUNG GROWTH (THORACIC INSUFFICIENCY SYNDROME). ADDITIONALLY VEPTR DEVICES CONTROL AND MAY CORRECT SCOLIOSIS. VEPTR IS DESIGNED TO MECHANICALLY STABILIZE AND DISTRACT THE THORAX TO IMPROVE RESPIRATION AND LUNG GROWTH IN INFANTILE AND JUVENILE PATIENTS. DEVICES ARE ATTACHED PERPENDICULARLY TO THE PATIENT'S NATURAL RIBS (SUPERIOR ATTACHMENT POINT) AND MORE CAUDAL RIBS, A LUMBAR VERTEBRA OR TO THE ILIUM (INFERIOR ATTACHMENT POINT). ONCE THE VEPTR DEVICE IS IN PLACE, ITS DESIGN ALLOWS EXPANSION, ANATOMIC DISTRACTION, AND REPLACEMENT OF COMPONENTS THROUGH LESS-INVASIVE SURGERY. ALL COMPONENTS OF THE VEPTR II SYSTEM ARE MANUFACTURED FROM A TITANIUM ALLOY (TI-6AL-7NB) WITH THE EXCEPTION OF THE ALA-HOOK AND S-ROD, WHICH ARE MANUFACTURED FROM COMMERCIALLY PURE TITANIUM. GOALS OF TREATMENT 1. INCREASE THORACIC VOLUME 2. SCOLIOSIS CORRECTION 3. IMPROVE THORACIC FUNCTION 4. ESTABLISH THORACIC SYMMETRY BY LENGTHENING THE CONCAVE, RESTRICTED HEMITHORAX 5. AVOID GROWTH-INHIBITING PROCEDURES 6. MAINTAIN THESE IMPROVEMENTS THROUGHOUT THE PATIENT'S GROWTH THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE.THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED

	TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.",LOCKING COMPRESSION PLATES-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., CALCANEAL PLATES -TITANIUM (NS)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., MATRIXRIB -PLATE (STERILE) -TITANIUM ALLOY-THE SYNTHES MATRIXRIB FIXATION SYSTEM IS INTENDED FOR THE FIXATION AND STABILIZATION OF RIB AND STERNUM FRACTURES, FUSIONS, AND OSTEOTOMIES OF NORMAL AND OSTEOPOROTIC BONE AND RECONSTRUCTIONS OF THE CHEST WALL.,RECON FEMORAL NAILING IMPLANTS -END CAP (STERILE) -TITANIUM ALLOY-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",SCREW IMPLANTS FOR PLATES -SCREW HOLE INSERT -PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,RECON FEMORAL NAILING IMPLANTS -NAIL (STERILE)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",AXON AND OC FUSION - PLATE-THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: -TOP-LOADING VARIABLE AXIS SCREWS -HOOKS -TRANSVERSE BARS -RODS IT IS DESIGNED FOR POSTERIOR

	STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY. OCCIPITO-CERVICAL FUSION SYSTEM THE SYNTHES OCCIPITO-CERVICAL FUSION SYSTEM IN COMBINATION WITH A SYNTHES POSTERIOR SCREW-ROD SYSTEM (E.G. SYNAPSE AND AXON) IS INTENDED TO PROVIDE STABILIZATION TO PROMOTE FUSION OF THE CERVICAL SPINE AND OCCIPITO-CERVICAL JUNCTION (OCCIPUT-TH3) FOR THE FOLLOWING INDICATIONS: OCCIPITOCERVICAL AND UPPER CERVICAL SPINE INSTABILITIES: – RHEUMATOID ARTHRITIS – CONGENITAL ANOMALIES – POSTTRAUMATIC CONDITIONS – TUMORS – INFECTIONS INSTABILITIES IN THE LOWER CERVICAL AND UPPER THORACIC SPINE: – POSTTRAUMATIC CONDITIONS – TUMORS – IATROGENIC INSTABILITIES FOLLOWING LAMINECTOMY ETC. DEGENERATIVE AND PAINFUL POSTTRAUMATIC CONDITIONS IN THE LOWER CERVICAL AND UPPER THORACIC SPINE. ANTERIOR CERVICAL FUSIONS REQUIRING ADDITIONAL POSTERIOR STABILIZATION,UNIVERSAL SPINE SYSTEM (USS) - ROD (NON - STERILE)-THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS I POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.",ZERO P - CAGE (STERILE) - PEEK/TAN/TAV-THE ZERO-P SYSTEM IS INTENDED FOR USE FOLLOWING ANTERIOR CERVICAL DISCECTOMY FOR REDUCTION AND STABILIZATION OF THE CERVICAL SPINE (C2–C7)., SCREW IMPLANTS FOR OR WITHOUT PLATES - WASHER (HEMISPHERICAL) - TITANIUM ALLOY-PLATE AND SCREW IMPLANTS

	ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., OLECRANON PLATE -TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., SCREW IMPLANTS FOR PLATES - PIN (TITANIUM ALLOY)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,UNIVERSAL SPINE SYSTEM (USS) - CONNECTOR-THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.",DENS ACCESS-THE DENS ACCESS SYSTEM USES AN ANTERIOR LAG SCREW COMPRESSION TECHNIQUE FOR THE FIXATION OF DENS AND TRANSVERSE FRACTURES.,POSTERIOR CONNECTORS - ROD (TITANIUM ALLOY)-THE PANGEA SPINE SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE PANGEA PERFORATED SCREWS ARE AN ADDITION TO THE PANGEA SPINE SYSTEM, A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1-S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. PANGEA PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID PANGEA SCREWS AND WITH K-WIRE GUIDANCE AS PANGEA CANNULATED SCREWS INCLUDING A MINIMALLY INVASIVE

	APPROACH WITH SPIRIT. PANGEA PERFORATED SCREWS DIRECT VERTECEM OR V+ THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES.USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.", AXON AND OC FUSION - CLAMP-THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: -TOP-LOADING VARIABLE AXIS SCREWS -HOOKS -TRANSVERSE BARS -RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY. OCCIPITO-CERVICAL FUSION SYSTEM THE SYNTHES OCCIPITO-CERVICAL FUSION SYSTEM IN COMBINATION WITH A SYNTHES POSTERIOR SCREW-ROD SYSTEM (E. G. SYNAPSE AND AXON) IS INTENDED TO PROVIDE STABILIZATION TO PROMOTE FUSION OF THE CERVICAL SPINE AND OCCIPITO-CERVICAL JUNCTION (OCCIPUT-TH3) FOR THE FOLLOWING INDICATIONS: OCCIPITOCERVICAL AND UPPER CERVICAL SPINE INSTABILITIES: – RHEUMATOID ARTHRITIS – CONGENITAL ANOMALIES – POSTTRAUMATIC CONDITIONS – TUMORS – INFECTIONS INSTABILITIES IN THE LOWER CERVICAL AND UPPER THORACIC SPINE: – POSTTRAUMATIC CONDITIONS – TUMORS – IATROGENIC INSTABILITIES FOLLOWING LAMINECTOMY ETC. DEGENERATIVE AND

	PAINFUL POSTTRAUMATIC CONDITIONS IN THE LOWER CERVICAL AND UPPER THORACIC SPINE. ANTERIOR CERVICAL FUSIONS REQUIRING ADDITIONAL POSTERIOR STABILIZATION,SYNEX-SYNEX IS A VERTEBRAL BODY REPLACEMENT AND IS IMPLANTED USING AN ANTERIOR APPROACH IN THE THORACIC SPINE FROM T5 TO T12, AND IN THE LUMBAR SPINE FROM L1 TO L4. IT IS USED TO SUPPORT THE ANTERIOR COLUMN OF THE SPINE. DEPENDING ON ANATOMICAL AND PATHOLOGICAL REQUIREMENTS, SYNEX CAN BE USED FOR MONO-, BI- AND TRISEGMENTAL FUSIONS.",UNIVERSAL SPINE SYSTEM (USS) FRACTURE - SCREW (TITANIUM ALLOY)- NS-THE USS FRACTURE SYSTEM IS A POSTERIOR THORACOLUMBAR PEDICLE SCREW FIXATION SYSTEM INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE APPLICATION AREA IN PATIENTS SUFFERING FROM TRAUMA OR TUMOR DISEASE IS USUALLY AT THE THORACAL-LUMBAR JUNCTION (T12 /L1), BUT CAN BE EXTENDED FROM T6 DOWN TO THE SACRUM (S1).,ALVEOLAR DISTRACTOR -TITANIUM ALLOY-THE ALVEOLAR DISTRACTOR IS INTENDED FOR USE AS A BONE STABILIZER AND LENGTHENING DEVICE, WHERE GRADUAL BONE DISTRACTION IS REQUIRED.,UNIVERSAL SPINE SYSTEM (USS) -WASHER-THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.",DISTAL ULNA PLATES -TITANIUM-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS. ,

	TITANIUM STERNAL FIXATION SYSTEM -SCREW - TITANIUM ALLOY (STERILE)-FIXATION OF STERNAL HALVES.,MATRIXRIB-PLATE (NON STERILE) - TITANIUM ALLOY-THE SYNTHES MATRIXRIB FIXATION SYSTEM IS INTENDED FOR THE FIXATION AND STABILIZATION OF RIB AND STERNUM FRACTURES, FUSIONS, AND OSTEOTOMIES OF NORMAL AND OSTEOPOROTIC BONE AND RECONSTRUCTIONS OF THE CHEST WALL.,VECTRA -NON STERILE (TITANIUM ALLOY)-THE VECTRA SYSTEM IS INTENDED FOR ANTERIOR PLATE AND SCREW FIXATION OF SPECIFIED PART(S): THE CERVICAL SPINE (C2-C7) ., RADIUS PLATES - TITANIUM (NS)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., POSTERIOR CONNECTORS - ROD -TITANIUM-THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.",AXON AND OC FUSION - SCREW-THE SYNAPSE SYSTEM IS AN ENHANCED SET OF INSTRUMENTS AND IMPLANTS, INCLUDING: -TOP-LOADING VARIABLE AXIS SCREWS -HOOKS - TRANSVERSE BARS -RODS IT IS DESIGNED FOR POSTERIOR STABILIZATION OF THE CERVICAL SPINE AND UPPER THORACIC SPINE. THE IMPLANTS PROVIDE THE FLEXIBILITY REQUIRED TO ACCOMMODATE VARIATIONS IN PATIENT ANATOMY. OCCIPITO-CERVICAL FUSION SYSTEM THE SYNTHES OCCIPITO-CERVICAL FUSION SYSTEM IN COMBINATION WITH A SYNTHES POSTERIOR SCREW-ROD SYSTEM (E.G. SYNAPSE AND AXON) IS INTENDED TO PROVIDE STABILIZATION TO PROMOTE FUSION OF THE CERVICAL

	SPINE AND OCCIPITO-CERVICAL JUNCTION (OCCIPUT-TH3) FOR THE FOLLOWING INDICATIONS: OCCIPITOCERVICAL AND UPPER CERVICAL SPINE INSTABILITIES: – RHEUMATOID ARTHRITIS – CONGENITAL ANOMALIES – POSTTRAUMATIC CONDITIONS – TUMORS – INFECTIONS INSTABILITIES IN THE LOWER CERVICAL AND UPPER THORACIC SPINE: – POSTTRAUMATIC CONDITIONS – TUMORS – IATROGENIC INSTABILITIES FOLLOWING LAMINECTOMY ETC. DEGENERATIVE AND PAINFUL POSTTRAUMATIC CONDITIONS IN THE LOWER CERVICAL AND UPPER THORACIC SPINE. ANTERIOR CERVICAL FUSIONS REQUIRING ADDITIONAL POSTERIOR STABILIZATION,DISTAL FEMUR PLATES -TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,COMPACT MANDIBLE TITANIUM-THE SYNTHES PLATE AND SCREW SYSTEM COMPACT MANDIBLE IS INTENDED FOR ORAL, MAXILLOFACIAL SURGERY, TRAUMA, RECONSTRUCTIVE SURGERY, AND ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES)., UNIVERSAL SPINE SYSTEM (USS) - WASHER (TITANIUM)-THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.",DISTAL HUMERUS PLATE -TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., STENOFIX - INTERSPINOUS IMPLANT (STERILE) -TITANIUM ALLOY-

	STENOFIX IS INTENDED FOR USE AS A SPACE HOLDER BETWEEN THE SPINOUS PROCESSES FOR ONE OR TWO LUMBAR MOTION SEGMENTS. IT CONTROLS THE SEGMENTAL EXTENSION AND DISTRACTS THE INTERSPINOUS SPACE. THE INTENDED EFFECTS ON THE POSTERIOR ELEMENTS ARE: — PRESERVATION OF THE FORAMINAL HEIGHT — REDUCTION OF STRESS ON THE FACET JOINTS — REDUCTION OF PRESSURE ON THE POSTERIOR ANNULUS IT CAN BE IMPLANTED AT ONE OR TWO LUMBAR LEVELS FROM L1 TO S1. FOR IMPLANTATION AT L5/S1- THE PRESENCE OF AN S1-SPINOUS PROCESS OF ADEQUATE SIZE IS A PREREQUISITE TO FULLY SUPPORT THE IMPLANT.,PROXIMAL TIBIAL PLATES - TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,RECON FEMORAL NAILING IMPLANTS -SCREW (STERILE) -TITANIUM ALLOY-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",MATRIXRIB - SPLINT (NON-STERILE) - TITANIUM ALLOY-THE SYNTHES MATRIXRIB FIXATION SYSTEM IS INTENDED FOR THE FIXATION AND STABILIZATION OF RIB AND STERNUM FRACTURES, FUSIONS, AND OSTEOTOMIES OF NORMAL AND OSTEOPOROTIC BONE AND RECONSTRUCTIONS OF THE CHEST WALL.,UNIVERSAL SPINE SYSTEM (USS) FRACTURE - CLAMP (TITANIUM ALLOY)-THE USS FRACTURE SYSTEM IS A POSTERIOR THORACOLUMBAR PEDICLE SCREW FIXATION SYSTEM INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE APPLICATION AREA IN PATIENTS SUFFERING FROM TRAUMA OR TUMOR DISEASE IS USUALLY AT THE THORACAL-LUMBAR JUNCTION (T12 /L1), BUT CAN BE EXTENDED FROM T6 DOWN TO THE SACRUM (S1).,TIBIAL NAILING IMPLANTS - NAIL (TITANIUM ALLOY)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,TITANIUM STERNAL FIXATION SYSTEM - SCREW -TITANIUM ALLOY (NON - STERILE)-FIXATION OF STERNAL HALVES.,TITANIUM STERNAL FIXATION SYSTEM - SCREW

	(TITANIUM)-FIXATION OF STERNAL HALVES.,MINI FRAGMENT PLATES -TITANIUM-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,RADIUS PLATE - STERILE (TITANIUM)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,CANNULATED SCREW IMPLANTS - SS-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR OR WITHOUT PLATES - CORTEX SCREW -SS-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS,MATRIXRIB - SPLINT (STERILE) -TITANIUM ALLOY-THE SYNTHES MATRIXRIB FIXATION SYSTEM IS INTENDED FOR THE FIXATION AND STABILIZATION OF RIB AND STERNUM FRACTURES, FUSIONS, AND OSTEOTOMIES OF NORMAL AND OSTEOPOROTIC BONE AND RECONSTRUCTIONS OF THE CHEST WALL.,SCREW IMPLANTS FOR OR WITHOUT PLATES - CORTEX SCREW (TITANIUM)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., SCREW IMPLANTS FOR PLATES -STERILE (TITANIUM ALLOY)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,UNIVERSAL SPINE SYSTEM (USS) - HOOK (TITANIUM ALLOY)-THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II

	ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.",LOCKING COMPRESSION PLATES -TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,HAND PLATES -TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,UNIVERSAL SPINE SYSTEM (USS) - SLEEVE-THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.",MATRIXRIB - SCREW (STERILE) -TITANIUM ALLOY-THE SYNTHES MATRIXRIB FIXATION SYSTEM IS INTENDED FOR THE FIXATION AND STABILIZATION OF RIB AND STERNUM FRACTURES, FUSIONS, AND OSTEOTOMIES OF NORMAL AND OSTEOPOROTIC BONE AND RECONSTRUCTIONS OF THE CHEST WALL.,PROXIMAL HUMERUS PLATE - TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., POSTERIOR ROD -TITANIUM ALLOY-THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED

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	SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION.",UNIVERSAL SPINE SYSTEM (USS) - SCREW-"THE URS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION. THE PANGEA SPINE SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. THE PANGEA PERFORATED SCREWS ARE AN ADDITION TO

	THE PANGEA SPINE SYSTEM, A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1-S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. PANGEA PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID PANGEA SCREWS AND WITH K-WIRE GUIDANCE AS PANGEA CANNULATED SCREWS INCLUDING A MINIMALLY INVASIVE APPROACH WITH SPIRIT. PANGEA PERFORATED SCREWS DIRECT V RTECEM OR V+ THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY.", CONNECTING ROD - TITANIUM ALLOY-THE USS SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM (T1–S2) DESIGNED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. ADDITIONALLY, VERTEBRAL BODY SCREWS CAN BE USED ANTERIORLY IN THE THORACOLUMBAR SPINE. THE USS II POLYAXIAL PERFORATED SCREWS ARE AN ADDITION TO THE USS II POLYAXIAL SYSTEM, A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1–S2) SUITABLE FOR THE TREATMENT OF DEGENERATIVE DISEASES AS WELL AS FOR CORRECTING DEFORMITIES. USS II POLYAXIAL PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID USS II POLYAXIAL SCREWS AND WITH K-WIRE GUIDANCE. USS II POLYAXIAL PERFORATED SCREWS DIRECT VERTECEM V+ BONE CEMENT THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREW WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY. USS SMALL STATURE/PEDIATRIC WAS DEVELOPED SPECIALLY FOR CHILDREN AND ADULTS OF SMALL STATURE. USS II ILIO-SACRAL IS INDICATED FOR FIXATION OF LONG POSTERIOR ROD CONSTRUCTS IN THE ILIUM AND IN S2, BOTH IN COMBINATION WITH AN S1 FIXATION. CONNECTING RODS ARE INTENDED TO FACILITATE THE CONNECTION OF QUALIFIED POSTERIOR SPINAL STABILIZATION SYSTEMS TOGETHER. CERVIFIX IS A MODULAR TENSION BAND SYSTEM FOR POSTERIOR FIXATION OF THE OCCIPITOCERVICAL SPINE, UPPER AND LOWER CERVICAL SPINE, AND UPPER THORACIC SPINE (T2). A CHOICE OF CLAMPS ARE FIXED ON A ROD BY MEANS OF SET SCREWS. BONE SCREWS CAN BE OPTIMALLY POSITIONED THROUGH THE CLAMPS IN THE DESIRED DIRECTION AT EACH LEVEL. ",SYNFIX EVOLUTION - STERILE (TITANIUM ALLOY)-SYNFIX® EVOLUTION SECURED SPACER SYSTEM IS AN IMPLANT AND INSTRUMENT SYSTEM FOR STAND-ALONE ANTERIOR LUMBAR

	INTERBODY FUSION (ALIF) FOR SKELETALLY MATURE PATIENTS. IT IS INTENDED TO REPLACE LUMBAR INTERBODY DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES AT VERTEBRAL LEVELS L1-S1 FOLLOWING ANTERIOR LUMBAR DISCECTOMY FOR STABILIZATION OF THE LUMBAR SPINE.,TIBIAL NAILING IMPLANTS - END CAP (TITANIUM ALLOY)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR- FEMORAL SHAFT- TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).,MATRIXORTHOGNATHIC - SLIDER (TITANIUM)-THE MATRIXORTHOGNATHIC SYSTEM IS INTENDED FOR USE AS A STABLE INTERNAL BONE FIXATION SYSTEM IN ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES)., EXPANDABLE CORPECTOMY DEVICE (ECD) - LOCKING CLIP-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATIECD IS A VERTEBRAL BODY REPLACEMENT FOR THE STABILIZATION OF THE CERVICAL (C3 TO C7) AND UPPER THORACIC (T1 TO T2) SPINE. DEPENDING ON ANATOMICAL AND PATHOLOGICAL REQUIREMENTS, ECD CAN BE USED IN THE REPLACEMENT OF ONE, TWO OR THREE ADJACENT VERTEBRAL BODIESON, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR PLATES - PIN -SS-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,MATRIXRIB - SCREW (NON-STERILE) -TITANIUM ALLOY-THE SYNTHES MATRIXRIB FIXATION SYSTEM IS INTENDED FOR THE FIXATION AND STABILIZATION OF RIB AND STERNUM FRACTURES, FUSIONS, AND OSTEOTOMIES OF NORMAL AND OSTEOPOROTIC BONE AND RECONSTRUCTIONS OF THE CHEST WALL.,HUMERAL NAILING IMPLANTS - NAIL (UHMWPE/TAN)-:"INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRAMEDULLARY FIXATION (ESIN).",SCREW IMPLANTS FOR OR WITHOUT PLATES - SCREW (CANCELL) - TITANIUM ALLOY-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,MATRIXORTHOGNATHIC -PLATE (TITANIUM)-

	THE MATRIXORTHOGNATHIC SYSTEM IS INTENDED FOR USE AS A STABLE INTERNAL BONE FIXATION SYSTEM IN ORTHOGNATHIC SURGERY (SURGICAL CORRECTION OF DENTOFACIAL DEFORMITIES)., EXPANDABLE CORPECTOMY DEVICE (ECD)-ECD IS A VERTEBRAL BODY REPLACEMENT FOR THE STABILIZATION OF THE CERVICAL (C3 TO C7) AND UPPER THORACIC (T1 TO T2) SPINE. DEPENDING ON ANATOMICAL AND PATHOLOGICAL REQUIREMENTS, ECD CAN BE USED IN THE REPLACEMENT OF ONE, TWO OR THREE ADJACENT VERTEBRAL BODIES,SCREW IMPLANTS FOR PLATES - SCREW (TITANIUM ALLOY)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION- CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,SCREW IMPLANTS FOR OR WITHOUT PLATES - NUT (SS)-PLATE AND SCREW IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., EXTERNAL FIXATOR IMPLANTS - STERILE-EXTERNAL FIXATOR DEVICES ARE INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS.

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2658	IMP/MD/2021/000413	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMPUTED TOMOGRAPHY(SOMATOM GO.UP)-THE SIEMENS SOMATOM CT SYSTEMS IS INTENDED TO GENERATE AND PROCESS CROSS-SECTIONAL IMAGES OF PATIENTS BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA. THE IMAGES DELIVERED BY THE SYSTEM CAN BE USED BY A TRAINED PHYSICIAN AS AN AID IN DIAGNOSIS.,COMPUTED TOMOGRAPHY(SOMATOM GO.TOP)-THE SIEMENS SOMATOM CT SYSTEMS IS INTENDED TO GENERATE AND PROCESS CROSS-SECTIONAL IMAGES OF PATIENTS BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA. THE IMAGES DELIVERED BY THE SYSTEM CAN BE USED BY A TRAINED PHYSICIAN AS AN AID IN DIAGNOSIS.,COMPUTED TOMOGRAPHY(SOMATOM GO. NOW)-THE SIEMENS SOMATOM CT SYSTEMS IS INTENDED TO GENERATE AND PROCESS CROSS-SECTIONAL IMAGES OF PATIENTS BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA. THE IMAGES DELIVERED BY THE SYSTEM CAN BE USED BY A TRAINED PHYSICIAN AS AN AID IN DIAGNOSIS.,COMPUTED TOMOGRAPHY (SOMATOM GO.ALL)-THE SIEMENS SOMATOM CT SYSTEMS IS INTENDED TO GENERATE AND PROCESS CROSS-SECTIONAL IMAGES OF PATIENTS BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA. THE IMAGES DELIVERED BY THE SYSTEM CAN BE USED BY A TRAINED PHYSICIAN AS AN AID IN DIAGNOSIS., PORTABLE GENERAL-PURPOSE FLUOROSCOPIC X-RAY SYSTEM, ANALOGUE AND DIGITAL(CIOS SELECT)-THE CIOS SELECT IS A MOBILE X-RAY SYSTEM INTENDED FOR USE IN THE OPERATION ROOM, TRAUMATOLOGY, ENDOSCOPY, INTENSIVE CARE STATION, PEDIATRICS, AMBULATORY PATIENT CARE AND IN VETERINARY MEDICINE. THE CIOS SELECT CAN OPERATE IN FOUR DIFFERENT MODES, DIGITAL RADIOGRAPHY, FLUOROSCOPY AND PULSED FLUOROSCOPY AND CASSETTE EXPOSURE WHICH ARE NECESSARY IN PERFORMING WIDE VARIETY OF CLINICAL PROCEDURES, SUCH AS INTRAOPERATIVE BILE DUCT DISPLAY, FLUOROSCOPIC DISPLAY OF INTRA-MEDULLARY NAIL IMPLANT IN VARIOUS POSITIONS, LOW DOSE FLUOROSCOPY IN PEDIATRICS, FLUOROSCOPIC TECHNIQUES UTILIZED IN PAIN THERAPY AND POSITIONING OF CATHETERS AND PROBES.

2659	IMP/MD/2021/000414	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIALYSIS FLUID FILTER (DIACAP ULTRA)-THE DIACAP ULTRA DIALYSIS FLUID FILTER IS A BACTERIAL AND PYROGEN FILTER AND IS USED TO PRODUCE HIGHLY PURE DIALYSIS FLUID AND TO PREPARE REPLACEMENT SOLUTION FOR ONLINE HDF AND HF PROCEDURES DURING THE TREATMENT., HAEMOFILTER FOR CRRT(DIACAP ACUTE)-THE DIACAP ACUTE HAEMOFILTER IS INDICATED FOR USE IN PATIENTS WITH FLUID OVERLOAD, URAEMIA AND / OR ELECTROLYTE DISTURBANCES ASSOCIATED WITH OLIGOANURIC ACUTE RENAL FAILURE. IT MAY ALSO BE USED WHEN REMOVAL OF EXCESS FLUID IS INDICATED, SUCH AS IN PATIENTS WITH PULMONARY OEDEMA OR CONGESTIVE HEART FAILURE REFRACTORY TO DIURETIC THERAPY.,DIALYSER (DIACAP PRO)-THE DIACAP PRO DIALYZERS ARE INTENDED TO REMOVE WASTE SOLUTES AND FLUID FROM THE BLOOD IN CHRONIC HEMODIALYSIS OR HEMO(DIA)FILTRATION. DIACAP PRO L DIALYZERS CAN ONLY BE USED IN HEMODIALYSIS (HD).
2660	IMP/MD/2021/000415	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VASCULAR GRAFTS (EXGRAFT® AND EXGRAFT® CARBON EPTFE VASCULAR GRAFTS)-THE EXGRAFT® AND EXGRAFT® CARBON EPTFE VASCULAR GRAFTS ARE INDICATED FOR USE AS VASCULAR PROSTHESES. THE EXGRAFT® AND EXGRAFT® CARBON EPTFE VASCULAR GRAFTS ARE INTENDED FOR USE AS SUBCUTANEOUS ARTERIOVENOUS CONDUITS FOR BLOOD ACCESS, BYPASS, OR RECONSTRUCTION OF PERIPHERAL ARTERIAL BLOOD VESSELS.
2661	IMP/MD/2021/000416	1.License Holder Name: M/S SWASTH KARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOSTATIC AGENT (SERASEAL)-SERASEAL IS INDICATED FOR CONTROLLING HEMORRHAGES FOR MOST FORMS OF BLEEDING (ARTERIAL AND VENOUS), OCCURRING IN INVASIVE AND NONINVASIVE PROCEDURES. SERASEAL IS AN EFFECTIVE HAEMOSTATIC AGENT IN FULLY ANTICOAGULANT AND FACTOR DEFICIENT PATIENTS

2662	IMP/MD/2021/000417	1.License Holder Name: AEROGEN LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEBULIZER(AEROGEN PRO NEBULIZER SYSTEM)(NEBULIZER(AEROGEN PRO NEBULIZER SYSTEM))-THE AEROGEN® PRO IS A PORTABLE MEDICAL DEVICE FOR MULTIPLE PATIENT USE THAT IS INTENDED TO AEROSOLISE PHYSICIAN-PRESCRIBED SOLUTIONS FOR INHALATION TO PATIENTS ON AND OFF VENTILATION OR OTHER POSITIVE PRESSURE BREATHING ASSISTANCE IN THE HOSPITAL ENVIRONMENT AND ON VENT ONLY IN THE HOMECARE ENVIRONMENT. THE AEROGEN PRO IS SUITABLE FOR USE IN ADULT, PAEDIATRIC AND NEONATE PATIENTS., NEBULIZER (AEROGEN SOLO USB CONTROLLER STARTER KIT)(AEROGEN SOLO USB CONTROLLER STARTER KIT)-THE AEROGEN® SOLO BELONGS TO THE AEROGEN PRO FAMILY, THE AEROGEN SOLO NEBULISER IS A SINGLE PATIENT USE DEVICE INTENDED FOR BOTH INTERMITTENT AND CONTINUOUS NEBULISATION. IT IS INTENDED TO NEBULISE PHYSICIAN-PRESCRIBED MEDICATIONS FOR INHALATION WHICH ARE APPROVED FOR USE WITH A GENERAL PURPOSE NEBULISER. THE AEROGEN SOLO IS SUITABLE FOR USE WITH NEONATE, PAEDIATRIC AND ADULT PATIENTS. IT IS INTENDED FOR ON AND OFF VENTILATION OR OTHER POSITIVE PRESSURE BREATHING ASSISTANCE IN THE HOSPITAL ENVIRONMENT AND ON VENT ONLY IN THE HOMECARE ENVIRONMENT.,NEBULIZER (AEROGEN PRO USB CONTROLLER STARTER KIT)(AEROGEN PRO USB CONTROLLER STARTER KIT)-THE AEROGEN PRO SYSTEM IS A PORTABLE MEDICAL DEVICE FOR MULTIPLE PATIENT USE THAT IS INTENDED TO AEROSOLISE PHYSICIAN-PRESCRIBED SOLUTIONS FOR INHALATION TO PATIENTS ON AND OFF VENTILATION OR OTHER POSITIVE PRESSURE BREATHING ASSISTANCE. THE AEROGEN PRO SYSTEM IS SUITABLE FOR USE IN ADULT, PAEDIATRIC AND NEONATE PATIENTS.,NEBULIZER(AEROGEN SOLO STARTER KIT)(AEROGEN SOLO STARTER KIT)-THE AEROGEN® SOLO BELONGS TO THE AEROGEN PRO FAMILY, THE AEROGEN SOLO NEBULISER IS A SINGLE PATIENT USE DEVICE INTENDED FOR BOTH INTERMITTENT AND CONTINUOUS NEBULISATION. IT IS INTENDED TO NEBULISE PHYSICIAN-PRESCRIBED MEDICATIONS FOR INHALATION WHICH ARE APPROVED FOR USE WITH A GENERAL PURPOSE NEBULISER. THE AEROGEN SOLO IS SUITABLE FOR USE WITH NEONATE, PAEDIATRIC AND ADULT PATIENTS. IT IS INTENDED FOR ON AND OFF VENTILATION OR OTHER POSITIVE PRESSURE BREATHING ASSISTANCE IN THE HOSPITAL ENVIRONMENT AND ON VENT ONLY IN THE HOMECARE ENVIRONMENT.

2663	IMP/MD/2021/000419	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:EXTENSION KIT FOR DEEP BRAIN STIMULATION(NIL)-MEDTRONIC® DBS THERAPY FOR MOVEMENT DISORDERS MEDTRONIC DBS THERAPY FOR MOVEMENT DISORDERS IS INDICATED FOR STIMULATION OF THE VENTRAL INTERMEDIATE NUCLEUS (VIM) FOR PATIENTS WITH DISABLING ESSENTIAL TREMOR OR PARKINSONIAN TREMOR, OR STIMULATION OF THE INTERNAL GLOBUS PALLIDUS (GPI) OR THE SUBTHALAMIC NUCLEUS (STN) FOR PATIENTS WITH SYMPTOMS OF PARKINSON'S DISEASE. STUDIES HAVE SHOWN THAT DEEP BRAIN STIMULATION WITH THE MEDTRONIC DBS THERAPY SYSTEM IS EFFECTIVE IN CONTROLLING ESSENTIAL TREMOR AND SYMPTOMS OF PARKINSON'S DISEASE THAT ARE NOT ADEQUATELY CONTROLLED WITH MEDICATIONS. ADDITIONALLY, DEEP BRAIN STIMULATION IS EFFECTIVE IN CONTROLLING DYSKINESIAS AND FLUCTUATIONS ASSOCIATED WITH MEDICAL THERAPY FOR PARKINSON'S DISEASE. MEDTRONIC DBS THERAPY FOR MOVEMENT DISORDERS IS ALSO INDICATED FOR STIMULATION OF THE INTERNAL GLOBUS PALLIDUS (GPI) OR THE SUBTHALAMIC NUCLEUS (STN) AS AN AID IN THE MANAGEMENT OF CHRONIC, INTRACTABLE (DRUG REFRACTORY) PRIMARY DYSTONIA, INCLUDING GENERALIZED AND SEGMENTAL DYSTONIA, HEMIDYSTONIA, AND CERVICAL DYSTONIA (TORTICOLLIS) FOR INDIVIDUALS 7 YEARS OF AGE AND OLDER. MEDTRONIC® DBS THERAPY FOR EPILEPSY BILATERAL ANTERIOR THALAMIC NUCLEUS (ANT) STIMULATION USING THE MEDTRONIC DBS SYSTEM FOR EPILEPSY IS INDICATED AS ADJUNCTIVE THERAPY FOR REDUCING THE FREQUENCY OF SEIZURES IN ADULTS DIAGNOSED WITH EPILEPSY CHARACTERIZED BY PARTIAL-ONSET SEIZURES, WITH OR WITHOUT SECONDARY GENERALIZATION, THAT ARE REFRACTORY TO ANTIEPILEPTIC MEDICATIONS.,EXTENSION KIT-NEUROSTIMULATION FOR SPINAL CORD STIMULATION (SCS) - THE MEDTRONIC SCS NEUROSTIMULATION SYSTEM IS INDICATED FOR SCS AS AN AID IN THE MANAGEMENT OF THE FOLLOWING CONDITIONS: CHRONIC, INTRACTABLE PAIN OF THE TRUNK AND/OR LIMBS. STABLE INTRACTABLE ANGINA PECTORIS IN PATIENTS WHO ARE NOT CANDIDATES FOR REVASCULARIZATION.* STABLE INTRACTABLE PERIPHERAL VASCULAR DISEASE OF FONTAINE STAGE II OR HIGHER IN PATIENTS WHO ARE NOT CANDIDATES FOR REVASCULARIZATION.* * PHYSICIANS USING SCS TO TREAT THESE CONDITIONS ARE ENCOURAGED TO SHARE THEIR RESULTS IN SCIENTIFIC EXCHANGE OR WITH MEDTRONIC. NEUROSTIMULATION FOR PERIPHERAL NERVE STIMULATION (PNS) USING PERCUTANEOUS LEADS - A MEDTRONIC PNS NEUROSTIMULATION SYSTEM IS

	INDICATED FOR PNS AS AN AID IN THE MANAGEMENT OF CHRONIC, INTRACTABLE PAIN OF THE POSTERIOR TRUNK. NEUROSTIMULATION FOR PERIPHERAL NERVE STIMULATION (PNS) USING SURGICAL LEADS - A MEDTRONIC PNS NEUROSTIMULATION SYSTEM IS INDICATED FOR PNS AS AN AID IN THE MANAGEMENT OF CHRONIC, INTRACTABLE PAIN OF THE TRUNK AND/OR LIMBS. ,POCKET ADAPTOR KIT FOR DEEP BRAIN STIMULATION-DEEP BRAIN STIMULATION,IMPLANTED LEAD(VECTRIS SURESCAN MRI LEAD)- NEUROSTIMULATION FOR SPINAL CORD STIMULATION (SCS) - THE MEDTRONIC SCS NEUROSTIMULATION SYSTEM IS INDICATED FOR SCS AS AN AID IN THE MANAGEMENT OF THE FOLLOWING CONDITIONS: CHRONIC, INTRACTABLE PAIN OF THE TRUNK AND/OR LIMBS. STABLE INTRACTABLE ANGINA PECTORIS IN PATIENTS WHO ARE NOT CANDIDATES FOR REVASCULARIZATION.* STABLE INTRACTABLE PERIPHERAL VASCULAR DISEASE OF FONTAINE STAGE II OR HIGHER IN PATIENTS WHO ARE NOT CANDIDATES FOR REVASCULARIZATION.* * PHYSICIANS USING SCS TO TREAT THESE CONDITIONS ARE ENCOURAGED TO SHARE THEIR RESULTS IN SCIENTIFIC EXCHANGE OR WITH MEDTRONIC.,LEAD KIT FOR DEEP BRAIN STIMULATION(NIL)-3387 (3387-28, 3387-40)- MEDTRONIC® DBS THERAPY FOR EPILEPSY BILATERAL ANTERIOR THALAMIC NUCLEUS (ANT) STIMULATION USING THE MEDTRONIC DBS SYSTEM FOR EPILEPSY IS INDICATED AS ADJUNCTIVE THERAPY FOR REDUCING THE FREQUENCY OF SEIZURES IN ADULTS DIAGNOSED WITH EPILEPSY CHARACTERIZED BY PARTIAL-ONSET SEIZURES, WITH OR WITHOUT SECONDARY GENERALIZATION, THAT ARE REFRACTORY TO ANTIEPILEPTIC MEDICATIONS. MEDTRONIC® DBS THERAPY FOR MOVEMENT DISORDERS MEDTRONIC DBS THERAPY FOR MOVEMENT DISORDERS IS INDICATED FOR STIMULATION OF THE VENTRAL INTERMEDIATE NUCLEUS (VIM) FOR PATIENTS WITH DISABLING ESSENTIAL TREMOR OR PARKINSONIAN TREMOR, OR STIMULATION OF THE INTERNAL GLOBUS PALLIDUS (GPI) OR THE SUBTHALAMIC NUCLEUS (STN) FOR PATIENTS WITH SYMPTOMS OF PARKINSON'S DISEASE. STUDIES HAVE SHOWN THAT DEEP BRAIN STIMULATION WITH THE MEDTRONIC DBS THERAPY SYSTEM IS FFECTIVE IN CONTROLLING ESSENTIAL TREMOR AND SYMPTOMS OF PARKINSON'S DISEASE THAT ARE NOT ADEQUATELY CONTROLLED WITH MEDICATIONS. ADDITIONALLY, DEEP BRAIN STIMULATION IS EFFECTIVE IN CONTROLLING DYSKINESIAS AND FLUCTUATIONS ASSOCIATED WITH MEDICAL THERAPY FOR PARKINSON'S DISEASE. MEDTRONIC DBS THERAPY FOR MOVEMENT DISORDERS IS ALSO INDICATED FOR STIMULATION OF THE INTERNAL GLOBUS PALLIDUS (GPI) OR THE SUBTHALAMIC NUCLEUS (STN) AS AN AID IN THE MANAGEMENT OF CHRONIC, INTRACTABLE (DRUG REFRACTORY)

	PRIMARY DYSTONIA, INCLUDING GENERALIZED AND SEGMENTAL DYSTONIA, HEMIDYSTONIA, AND CERVICAL DYSTONIA (TORTICOLLIS) FOR INDIVIDUALS 7 YEARS OF AGE AND OLDER. 3389 (3389-15, 3389-28, 3389-40) MEDTRONIC® DBS THERAPY FOR MOVEMENT DISORDERS MEDTRONIC DBS THERAPY FOR MOVEMENT DISORDERS IS INDICATED FOR STIMULATION OF THE VENTRAL INTERMEDIATE NUCLEUS (VIM) FOR PATIENTS WITH DISABLING ESSENTIAL TREMOR OR PARKINSONIAN TREMOR, OR STIMULATION OF THE INTERNAL GLOBUS PALLIDUS (GPI) OR THE SUBTHALAMIC NUCLEUS (STN) FOR PATIENTS WITH SYMPTOMS OF PARKINSON'S DISEASE. STUDIES HAVE SHOWN THAT DEEP BRAIN STIMULATION WITH THE MEDTRONIC DBS THERAPY SYSTEM IS EFFECTIVE IN CONTROLLING ESSENTIAL TREMOR AND SYMPTOMS OF PARKINSON'S DISEASE THAT ARE NOT ADEQUATELY CONTROLLED WITH MEDICATIONS. ADDITIONALLY, DEEP BRAIN STIMULATION IS EFFECTIVE IN CONTROLLING DYSKINESIAS AND FLUCTUATIONS ASSOCIATED WITH MEDICAL THERAPY FOR PARKINSON'S DISEASE. MEDTRONIC DBS THERAPY FOR MOVEMENT DISORDERS IS ALSO INDICATED FOR STIMULATION OF THE INTERNAL GLOBUS PALLIDUS (GPI) OR THE SUBTHALAMIC NUCLEUS (STN) AS AN AID IN THE MANAGEMENT OF CHRONIC, INTRACTABLE (DRUG REFRACTORY) PRIMARY DYSTONIA, INCLUDING GENERALIZED AND SEGMENTAL DYSTONIA, HEMIDYSTONIA, AND CERVICAL DYSTONIA (TORTICOLLIS) FOR INDIVIDUALS 7 YEARS OF AGE AND OLDER.,IMPLANTED SURGICAL LEADS(SPECIFY SURESCAN MRI LEADS)-NEUROSTIMULATION FOR SPINAL CORD STIMULATION (SCS) - THE MEDTRONIC SCS NEUROSTIMULATION SYSTEM IS INDICATED FOR SCS AS AN AID IN THE MANAGEMENT OF THE FOLLOWING CONDITIONS: CHRONIC, INTRACTABLE PAIN OF THE TRUNK AND/OR LIMBS. STABLE INTRACTABLE ANGINA PECTORIS IN PATIENTS WHO ARE NOT CANDIDATES FOR REVASCULARIZATION.* STABLE INTRACTABLE PERIPHERAL VASCULAR DISEASE OF FONTAINE STAGE II OR HIGHER IN PATIENTS WHO ARE NOT CANDIDATES FOR REVASCULARIZATION. * * PHYSICIANS USING SCS TO TREAT THESE CONDITIONS ARE ENCOURAGED TO SHARE THEIR RESULTS IN SCIENTIFIC EXCHANGE OR WITH MEDTRONIC.,QUADRIPOLAR LEAD FOR ELECTRICAL STIMULATION(INTERSTIM)-SACRAL NEUROMODULATION THERAPY PROVIDED BY THE INTERSTIM™ SYSTEM IS INDICATED FOR THE MANAGEMENT OF THE FOLLOWING CHRONIC INTRACTABLE (FUNCTIONAL) DISORDERS OF THE PELVIS AND LOWER URINARY OR INTESTINAL TRACT: OVERACTIVE BLADDER, FECAL INCONTINENCE, AND NONOBSTRUCTIVE URINARY RETENTION.

2664	IMP/MD/2021/000420	1.License Holder Name: PASSIM MEDICHEM AGENCIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (DR.ODIN)-MEASUREMENT OF BODY TEMPERATURE
2665	IMP/MD/2021/000421	1.License Holder Name: PETERS SURGICAL INDIA (P) LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:TITANIUM HEAMOSTATIC CLIP(SLS-CLIP VITALITEC)-THE TITANIUM HEMOSTATIC CLIP IS INTENDED TO BE USED BY CLINICALLY TRAINED SURGICAL STAFF. IT CAN BE USED IN EVERY SURGICAL SPECIALTY AND FOR ANY PATIENT WHEN COMPLETE OCCLUSION OF A VESSEL OR TISSUE IS REQUIRED, EXCEPT FOR FALLOPIAN TUBE LIGATION.,SURGICAL AND TISSUE GLUE FOR INTERNAL USE(IFABOND)-IFABOND® IS AN IMPLANTABLE MEDICAL PRODUCT INTENDED TO BE USED DURING SURGICAL PROCEDURES, IN OPEN SURGERY AND IN LAPAROSCOPIC SURGERY, FOR ITS ADHESIVE AND HAEMOSTATIC SEALANT ACTION. IFABOND® MAY BE APPLIED ALONE OR IN COMBINATION WITH SUTURES. THIS MEDICINAL PRODUCT IS DESIGNED TO OFFER AN ALTERNATIVE TO STAPLING, SUTURES AND ANY OTHER MEANS USED DURING SURGICAL PROCEDURES. IT THEREFORE MAKES IT POSSIBLE NOT ONLY TO CLOSE SUPERFICIAL OR DEEPER WOUNDS WITHOUT TENSION ON THEM BUT ALSO TO FIT A PROSTHESIS TO MUSCLES, TENDONS OR OTHER ORGANS IN VIVO.,TITANIUM HEAMOSTATIC CLIP (CLIP 9 VITALITEC)-THE TITANIUM HEMOSTATIC CLIP IS INTENDED TO BE USED BY CLINICALLY TRAINED SURGICAL STAFF. IT CAN BE USED IN EVERY SURGICAL SPECIALTY AND FOR ANY PATIENT WHEN COMPLETE OCCLUSION OF A VESSEL OR TISSUE IS REQUIRED, EXCEPT FOR FALLOPIAN TUBE LIGATION.

2666	IMP/MD/2021/000422	1.License Holder Name: KATARA DENTAL PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COLLAGEN DENTAL MEMBRANE PORCINE PERITONEUM(MEM-LOK PLIABLE)-MEM-LOK PLIABLE IS A BIORESORBABLE, IMPLANTABLE COLLAGEN MATERIAL THAT IS INTENDED FOR USE IN ORAL SURGICAL PROCEDURES AS A RESORBABLE MEMBRANE MATERIAL FOR USE IN: - SIMULTANEOUS USE OF GUIDED BONE REGENERATION (GBR)-MEMBRANE AND IMPLANTS; - AUGMENTATION AROUND IMPLANTS PLACED IN IMMEDIATE EXTRACTION SOCKETS; - AUGMENTATION AROUND IMPLANTS PLACED IN DELAYED EXTRACTION SOCKETS; - LOCALIZED RIDGE AUGMENTATION FOR LATER IMPLANTATION; - ALVEOLAR RIDGE RECONSTRUCTION FOR PROSTHETIC TREATMENT; - FILLING OF BONE DEFECTS AFTER ROOT RESECTION, CYSTECTOMY OR REMOVAL OF RETAINED TEETH; - GUIDED BONE REGENERATION IN DEHISCENCE DEFECTS; AND - GUIDED TISSUE REGENERATION PROCEDURES IN PERIODONTAL DEFECTS.,PORCINE ANORGANIC BONE MINERAL(MINEROSSXP)-MINEROSS XP IS INTENDED FOR USE IN DENTAL SURGERY. THE PRODUCTS MAY BE USED IN SURGICAL PROCEDURES SUCH AS: -AUGMENTATION OR RECONSTRUCTIVE TREATMENT OF ALVEOLAR RIDGE -FILLING OF INFRABONY PERIODONTAL DEFECTS -FILLING OF DEFECTS AFTER ROOT RESECTION, APICOECTOMY, AND CYSTECTOMY -FILLING OF EXTRACTION SOCKETS TO ENHANCE PRESERVATION OF ALVEOLAR RIDGE -ELEVATION OF THE MAXILLARY SINUS FLOOR -FILLING OF PERIODONTAL DEFECTS IN CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED TISSUE REGENERATION (GTR) AND GUIDED BONE REGENERATION (GBR) -FILLING OF PERI-IMPLANT DEFECTS IN CONJUNCTION WITH PRODUCTS INTENDED FOR GUIDED BONE REGENERATION (GBR)

2667	IMP/MD/2021/000423	1.License Holder Name: NIPRO MEDICAL (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SINGLE PATIENT DIALYSIS MACHINE(SURDIAL X)-THIS MACHINE CAN BE USED FOR PATIENTS WITH ACUTE OR CHRONIC RENAL FAILURE AND WHEN HEMODIALYSIS IS PRESCRIBED BY A PHYSICIAN. THIS MACHINE IS INTENDED TO BE USED BY TRAINED OPERATORS FOR HOSPITAL, HEALTH CENTER OR LIMITED CARE. THE SYSTEM IS A SINGLE PATIENT HEMODIALYSIS SYSTEM, WHICH PROVIDES DIALYSIS FLUID WITH A PRESCRIBED CONCENTRATION AND TEMPERATURE TO BE USED FOR HEMODIALYSIS TREATMENT. ,SINGLE PATIENT DIALYSIS MACHINE(SURDIAL 55 PLUS)-THIS MACHINE CAN BE USED FOR PATIENTS WITH ACUTE OR CHRONIC RENAL FAILURE AND WHEN HEMODIALYSIS IS PRESCRIBED BY A PHYSICIAN. THIS MACHINE IS INTENDED TO BE USED BY TRAINED OPERATORS FOR HOSPITAL, HEALTH CENTER OR LIMITED CARE. THE SYSTEM IS A SINGLE PATIENT HEMODIALYSIS SYSTEM, WHICH PROVIDES DIALYSIS FLUID WITH A PRESCRIBED CONCENTRATION AND TEMPERATURE TO BE USED FOR HEMODIALYSIS TREATMENT.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2668	IMP/MD/2021/000424	1.License Holder Name: TS COMPROZONE PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SURGICAL LASER FIBERS (PRECIVEIN)-SURGICAL FIBER OPTIC DELIVERY DEVICE IS INDICATED FOR USE IN LITHOTRIPSY WITH A COMPATIBLE LASER CLEARED FOR THE DESIRED APPLICATION. IT IS INDICATED FOR USE WITH ARGON, KTP/532, HO;YAG, ND;YAG, 1.44YAG, THULIUM AND DIODE LASERS (440NM – 2200NM) WITH PEAK AND CONTINUOUS POWER FROM 1 – 300 WATT. SURGICAL LASER FIBER IS INDICATED FOR USE IN GENERAL SURGERY, UROLOGY, GASTROENTEROLOGY, GYNECOLOGY, DERMATOLOGY, VASCULAR SURGERY, NEUROSURGERY, PLASTIC SURGERY, ENT/OTOLARYNGOLOGY, ENDOVENOUS OCCLUSION OF THE GREATER SAPHENOUS VEIN IN THE PATIENT WITH SUPERFICIAL VEIN REFLUX AND LASER ASSISTED LIPOLYSIS WITH AN APPROVED COMPATIBLE LASER MARKETED FOR USE IN THE DESIRED APPLICATION. THE SURGICAL FIBER OPTIC LASER DELIVERY DEVICE, ENDO-ENT FIBERS, SIDE FIRE LASER DELIVERY FIBERS AND ENDO PROBES ARE INTENDED FOR DELIVERY OF LASER LIGHT TO SOFT TISSUE IN THE CONTACT AND NON-CONTACT MODE DURING SURGICAL PROCEDURES INCLUDING VIA ENDOSCOPES AND CYSTOSCOPES. THE SURGICAL FIBER OPTIC LASER DELIVERY DEVICE IS INTENDED FOR USE WITH ANY CLEARED SURGICAL LASER WITH A STANDARD, DAMAGE RESISTANT AND OR MODIFIED SMA 905 CONNECTORS. THE SURGICAL FIBER OPTIC LASER DELIVERY DEVICES ARE INDICATED FOR USE IN GENERAL SURGERY APPLICATIONS FOR: INCISION, EXCISION, VAPORIZATION, ABLATION, HEMOSTASIS OR COAGULATION OF SOFT TISSUE IN A CONTACT OR NON-CONTACT MODE. IT IS ALSO INDICATED FOR USE IN OPEN OR CLOSED ENDOSCOPIC APPLICATIONS WHERE INCISION, EXCISION, TISSUE DISSECTION, EXCISION OF EXTERNAL TUMORS AND LESIONS, COMPLETE OR PARTIAL RESECTION OF INTERNAL ORGANS, TUMORS OR LESIONS, TISSUE VAPORIZATION, HEMOSTASIS AND OR COAGULATION MAY BE INDICATED. (DIODE LASER 440NM – 2200NM) SURGICAL FIBER OPTIC LASER DELIVERY DEVICES IS ALSO INTENDED AS AN AID FOR OTOLOGIC PROCEDURES, FOR USE IN INCISION, EXCISION, COAGULATION AND VAPORIZATION OF SOFT AND FIBROUS TISSUE INCLUDING OSSEOUS TISSUE (DIODE LASER 440NM – 2200NM). SURGICAL FIBER OPTIC DELIVERY DEVICES ARE ALSO INTENDED FOR INTRAOCULAR PHOTOCOAGULATION WITH OR WITHOUT SIMULTANEOUS ASPIRATING/IRRIGATING AS AN ADJUNCT TO VITRECTOMY SURGERY (DIODE LASER 440NM – 2200NM). SPECIFIC INDICATIONS INCLUDE THE TREATMENT OF PROLIFERATIVE VITREORETINOPATHY,TRACTIONAL RETINAL DETACHMENTS, PROLIFERATIVE DIABETIC RETINOPATHY AND VARIOUS VASCULAR

		TUMORS (DIODE LASER 440NM – 2200NM)
2669	IMP/MD/2021/000425	1.License Holder Name: WIPRO GE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:X-RAY BONE DENSITOMETER SYSTEM(ARIA)-INTENDED USE/INDICATIONS FOR USE:•THE BONE DENSITOMETER IS DESIGNED TO ESTIMATE THE BONE MINERAL DENSITY OF PATIENTS WHEN MEDICALLY INDICATED BY THEIR PHYSICIANS. THE X-RAY BONE DENSITOMETER SUPPORTS THE FOLLOWING INDICATIONS FOR USE:• 1.PROVIDES AN ESTIMATE OF BONE MINERAL DENSITY AT VARIOUS ANATOMICAL SITES (SPINE, FEMUR, FOREARM). THESE VALUES CAN THEN BE COMPARED TO AN ADULT REFERENCE POPULATION AT THE SOLE DISCRETION OF THE PHYSICIAN. • 2.PROVIDES AN ASSESSMENT OF RELATIVE FRACTURE RISK BASED ON THE PATIENT'S T-SCORE VALUE USING THE CATEGORIES OF FRACTURE RISK DEFINED BY THE WORLD HEALTH ORGANIZATION (WHO). • 3.PROVIDES AN ASSESSMENT OF 10-YEAR FRACTURE RISK USING WHO FRAX MODEL.• 4.PROVIDES A STANDARDIZED BONE DENSITY REPORT USING DATA FROM THE DENSITOMETER AND PHYSICIAN-GENERATED ASSESSMENTS BASED ON THE PATIENT'S DEMOGRAPHICS, WHICH CAN ASSIST THE PHYSICIAN IN COMMUNICATING SCAN RESULTS TO THE PATIENT AND THE PATIENT'S REFERRING PHYSICIAN.
2670	IMP/MD/2021/000427	1.License Holder Name: BAXTER (INDIA) PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MARS MONITOR 1 TC-THE MARS METHOD IS USED TO REMOVE PROTEIN-BOUND AND/OR WATER-SOLUBLE TOXINS FROM THE BLOOD, PRIMARILY IN PATIENTS WITH ACUTE OR CHRONIC LIVER FAILURE, FREQUENTLY ACCOMPANIED BY ENDOGENOUS INTOXICATION, JAUNDICE (ICTERUS) OR COMATOSE CONDITIONS.

2671	IMP/MD/2021/000430	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CAPILLARY DIALYZER (THERALITE)-THE THERALITE DIALYZER IS ONLY INTENDED TO BE USED FOR BLOOD PURIFICATION IN HEMODIALYSIS MODE IN DISEASES WHERE REMOVAL OF PLASMA COMPONENTS WITH MOLECULAR WEIGHTS UP TO A VALUE OF 45 KDA IS INDICATED. THE THERALITE DIALYZER IS INTENDED TO BE USED IN HEMODIALYSIS MODE ON MONITORS WITH CONTROLLED ULTRAFILTRATION., HEMOPERFUSION CARTRIDGE(ADSORBA 300C)-HEMOPERFUSION SHOULD BE CONSIDERED IF: 1. AFTER TAKING LIFE THREATENING AMOUNTS OF ADSORBABLE DRUGS, DEEP COMA AND ONE OF THE FOLLOWING SYMPTOMS ARE OBSERVED: • HYPOVENTILATION • HYPOTONIA • HYPOTHERMIA • WORSENING OF THE CLINICAL STATE DESPITE CONSERVATIVE MEDICAL MANAGEMENT; 2. THE PATIENT HAS TAKEN DRUGS OF WHICH THE AMOUNT, COMPOSITION AND KIND ARE UNKNOWN AND THE PATIENT IS DEEPLY COMATOSE. THE ADSORBA HAS PROVEN A HIGH DEGREE OF EFFICACY FOR THE FOLLOWING DRUGS: • BARBITURATES • ORGANOPHOSPHATES • BROMOCARBAMIDE • PARACETAMOL • ETHCHLORVYNOL • PARAQUAT • MEPROBAMATE • PHENACETIN • METHAQUALONE • SALICYLATE THE USE OF HEMOPERFUSION AS A SUPPLEMENTARY TREATMENT DOES NOT MEAN THAT OTHER CONVENTIONAL METHODS OF TREATMENT SHOULD BE OMITTED; MEASURES SUCH AS GASTRIC LAVAGE, ESTABLISHMENT OF FREE AIRWAY AND ASSISTED RESPIRATION, CONTROLLED ELECTROLYTE AND WATER BALANCE, AND FORCED DIURESIS SHOULD BE ADMINISTERED WHENEVER INDICATED. FUTHERMORE IT MIGHT BE NECESSARY TO MONITOR CAREFULLY THE BLOOD LEVELS OF VITAL SUBSTANCES OR DRUGS WHICH ALSO COULD BE ADSORBED DURING THE HEMOPERFUSION TREATMENT. ACCESS TO THE BLOOD STREAM FOR HEMOPERFUSION TREATMENT CAN BE OBTAINED BY NORMAL HEMODIALYSIS METHODS. ,ULTRAFILTER(U9000)-THE U9000 IS INDICATED FOR PURIFICATION OF INCOMING WATER FOR DIALYSIS FLUID AS WELL AS PURIFICATION OF DIALYSIS FLUID TO OBTAIN MICROBIOLOGICAL HIGH QUALITY DIALYSIS FLUID. THE RISK OF EXPOSURE TO BACTERIA AND ENDOTOXINS CAN THEREBY BE MINIMIZED. THE U9000 IS INTENDED TO BE USED IN CONJUNCTION WITH WATER TREATMENT SYSTEM.,CAPILLARY DIALYZER(POLYFLUX)-THE POLYFLUX L CAPILLARY DIALYZER IS INTENDED FOR USE IN HAEMODIALYSIS FOR THE TREATMENT OF CHRONIC AND ACUTE RENAL FAILURE.,PLASMAFILTER(PF 2000 N)-THE PF 2000N PLASMAFILTER IS INTENDED FOR USE IN THERAPEUTIC PLASMAFILTRATION, THUS IN DISEASES WHERE REMOVAL OF

		PLASMA COMPONENTS IS INDICATED. IT CAN ALSO BE USED IN PLASMAFILTRATION PROCEDURES WHERE FILTERED PLASMA IS REINFUSED. THE SIZE, WEIGHT, CARDIAC STATUS AND GENERAL PHYSICAL CONDITION OF THE PATIENT MUST BE EVALUATED BY THE PRESCRIBING PHYSICIAN BEFORE EACH TREATMENT. THE CHOICE OF THE APPROPRIATE PLASMAFILTER AND ASSOCIATED EQUIPMENT AS WELL AS THE TREATMENT OPERATING PARAMETERS ARE THE SOLE RESPONSIBILITY OF THE PHYSICIAN. SPECIAL ATTENTION MUST BE PAID IN CONNECTION WITH PEDIATRIC USE. IT IS RECOMMENDED THAT THE PLASMAFILTER IS USED TOGETHER WITH A MACHINE THAT COMPLIES WITH NATIONAL OR INTERNATIONAL STANDARDS., CAPILLARY DIALYZER(POLYFLUX)-THE CAPILLARY DIALYZER/FILTER IS INTENDED FOR USE IN HEMODIALYSIS, HEMODIAFILTRATION AND HEMOFILTRATION FOR THE TREATMENT OF CHRONIC OR ACUTE RENAL FAILURE.
2672	IMP/MD/2021/000431	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PRISMAFLEX-THE PRISMAFLEX CONTROL UNIT IS INTENDED FOR: • CONTINUOUS RENAL REPLACEMENT THERAPY FOR PATIENTS WITH ACUTE RENAL FAILURE AND/OR FLUID OVERLOAD. • THERAPEUTIC PLASMA EXCHANGE THERAPY FOR PATIENTS WITH DISEASES WHERE REMOVAL OF PLASMA COMPONENTS IS INDICATED. • HEMOPERFUSION FOR PATIENTS WITH CONDITIONS WHERE IMMEDIATE REMOVAL OF SUBSTANCES BY ADSORPTION IS INDICATED. • HEMOPURIFICATION FOR PATIENTS WITH CONDITIONS WHERE EXTRACORPOREAL ELIMINATION OF CARBON DIOXIDE IS INDICATED. ALL TREATMENTS ADMINISTERED VIA THE PRISMAFLEX CONTROL UNIT MUST BE PRESCRIBED BY A PHYSICIAN.,AK98-THE BAXTER AK 98 DIALYSIS MACHINE IS INTENDED FOR USE FOR HEMODIALYSIS TREATMENTS OF PATIENTS WITH RENAL FAILURE OR FLUID OVERLOAD UPON PRESCRIPTION BY A PHYSICIAN. THE AK 98 HEMODIALYSIS MACHINE IS INDICATED TO BE USED ON PATIENTS WITH A BODY WEIGHT OF 25 KG OR MORE. THE AK 98 DIALYSIS MACHINE IS INTENDED FOR THE IN-CENTER ENVIRONMENT AND CARE IN A HOME HEALTHCARE ENVIRONMENT. PATIENT COUNSELING AND TEACHING OF TREATMENT TECHNIQUES ARE DIRECTLY UNDER THE SUPERVISION AND DISCRETION OF THE PHYSICIAN.

2673	IMP/MD/2021/000432	1.License Holder Name: NSI TECH 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIPHASICAL CONICAL IMPLANT(LIGHT)-THE ENDO-OSSEOUS IMPLANT IN TITANIUM IS INTENDED TO BE INSERTED SURGICALLY IN THE MANDIBULAR OR MAXILLARY BONE TO OFFER RESISTANCE TO THE DISPLACEMENT OF A DENTURE.,MONOPHASIC CONICAL IMPLANT(MAXIFIX COMPRESSIVE)-THE ENDO-OSSEOUS IMPLANT IN TITANIUM IS INTENDED TO BE INSERTED SURGICALLY IN THE MANDIBULAR OR MAXILLARY BONE TO OFFER RESISTANCE TO THE DISPLACEMENT OF A DENTURE.,MONOPHASIC CILINDRIC IMPLANT(BASALE)-THE ENDO-OSSEOUS IMPLANT IN TITANIUM IS INTENDED TO BE INSERTED SURGICALLY IN THE MANDIBULAR OR MAXILLARY BONE TO OFFER RESISTANCE TO THE DISPLACEMENT OF A DENTURE.
2674	IMP/MD/2021/000433	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BONE ACCESS NEEDLE(11 GAUGE BONE ACCESS NEEDLE)-THE 11 GAUGE BONE ACCESS NEEDLES ARE INTENDED ONLY FOR PERCUTANEOUS ACCESS TO BONE.
2675	IMP/MD/2021/000434	1.License Holder Name: MANJU ENTERPRISES PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COLLAGEN IMPLANT (CHONDROFILLER LIQUID)-CHONDROFILLER LIQUID IS FOR THE TREATMENT OF CLEAR DEFINED CARTILAGE DEFECTS AT DIFFERENT JOINTS LIKE KNEE, ANKLE AND SHOULDER WITH A SURFACE OF UP TO 3 CM2 (CHONDROFILLER LIQUID, HCFL-23), RESPECTIVELY UP TO 2 CM2 (CHONDROFILLER LIQUID, HCFL-15), RESPECTIVELY UP TO 1.5 CM2 (CHONDROFILLER LIQUID, HCFL-10) AND AN OUTERBRIDGE CLASSIFICATION OF GRADE III OR IV: PARTIAL INJURIES OR ARTICULAR CARTILAGE DEEP AND/OR SUBCHONDRAL DEFECTS OSTEOCHONDRAL DEFECTS

2676	IMP/MD/2021/000435	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DUAL MOBILITY HIP INSERT(OR3O)-• ADVANCED DEGENERATION OF THE HIP JOINT AS A RESULT OF DEGENERATIVE, POST-TRAUMATIC, OR RHEUMATOID ARTHRITIS. • FRACTURE OR AVASCULAR NECROSIS OF THE FEMORAL HEAD. • FAILURE OF PREVIOUS HIP SURGERY: JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. • ALL FORMS OF OSTEOARTHRITIS. • PATIENTS WITH HIPS AT RISK OF DISLOCATION. • FEMORAL NECK FRACTURE OR PROXIMAL HIP JOINT FRACTURE. THE OR3O DUAL MOBILITY SYSTEM IS INTENDED FOR SINGLE USE ONLY. THE MODULAR OR3O DUAL MOBILITY LINERS AND INSERTS ARE TO BE IMPLANTED WITHOUT BONE CEMENT.
2677	IMP/MD/2021/000436	1.License Holder Name: BPL MEDICAL TECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AUTOMATIC BLOOD PRESSURE MONITOR(BPL MEDICAL)-THE BLOOD PRESSURE MONITOR IS FOR USE BY MEDICAL PROFESSIONALS OPERATOR OR AT HOME AND IS A NON-INVASIVE BLOOD PRESSURE MEASUREMENT SYSTEM INTENDED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES AND PULSE RATE OF AN ADULT INDIVIDUAL BY USING A NON-INVASIVE TECHNIQUE IN WHICH AN INFLATABLE CUFF IS WRAPPED AROUND THE ARM.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2678	IMP/MD/2021/000437	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMPUTED TOMOGRAPHY(SOMATOM DRIVE)-THE SIEMENS SOMATOM CT SYSTEMS ARE INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA FROM EITHER THE SAME AXIAL PLANE TAKEN AT DIFFERENT ANGLES OR SPIRAL PLANES TAKEN AT DIFFERENT ANGLES. IN ADDITION, THE SOMATOM CT ARE ABLE TO PRODUCE ADDITIONAL IMAGE PLANES AND ANALYSIS RESULTS BY EXECUTING OPTIONAL POST PROCESSING FEATURES, WHICH OPERATE ON DICOM IMAGES. THE IMAGES DELIVERED BY THE SYSTEM CAN BE USED BY TRAINED STAFF/PHYSICIAN AS AN AID IN DIAGNOSIS, TREATMENT PREPARATION AND RADIATION THERAPY PLANNING., COMPUTED TOMOGRAPHY(SOMATOM FORCE)-THE SIEMENS SOMATOM CT SYSTEMS ARE INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA FROM EITHER THE SAME AXIAL PLANE TAKEN AT DIFFERENT ANGLES OR SPIRAL PLANES TAKEN AT DIFFERENT ANGLES. IN ADDITION, THE SOMATOM CT ARE ABLE TO PRODUCE ADDITIONAL IMAGE PLANES AND ANALYSIS RESULTS BY EXECUTING OPTIONAL POST PROCESSING FEATURES, WHICH OPERATE ON DICOM IMAGES. THE IMAGES DELIVERED BY THE SYSTEM CAN BE USED BY TRAINED STAFF/PHYSICIAN AS AN AID IN DIAGNOSIS, TREATMENT PREPARATION AND RADIATION THERAPY PLANNING.,COMPUTED TOMOGRAPHY(SOMATOM DEFINITION FLASH) -THE SIEMENS SOMATOM CT SYSTEMS ARE INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA FROM EITHER THE SAME AXIAL PLANE TAKEN AT DIFFERENT ANGLES OR SPIRAL PLANES TAKEN AT DIFFERENT ANGLES. IN ADDITION, THE SOMATOM CT ARE ABLE TO PRODUCE ADDITIONAL IMAGE PLANES AND ANALYSIS RESULTS BY EXECUTING OPTIONAL POST PROCESSING FEATURES, WHICH OPERATE ON DICOM IMAGES. THE IMAGES DELIVERED BY THE SYSTEM CAN BE USED BY TRAINED STAFF/PHYSICIAN AS AN AID IN DIAGNOSIS, TREATMENT PREPARATION AND RADIATION THERAPY PLANNING.,COMPUTED TOMOGRAPHY(SOMATOM DEFINITION EDGE)-THE SIEMENS SOMATOM CT SYSTEMS ARE INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA FROM EITHER THE SAME AXIAL PLANE TAKEN AT DIFFERENT ANGLES OR SPIRAL PLANES TAKEN AT DIFFERENT ANGLES. IN ADDITION, THE SOMATOM CT ARE ABLE TO PRODUCE ADDITIONAL IMAGE PLANES AND ANALYSIS RESULTS BY

	EXECUTING OPTIONAL POST PROCESSING FEATURES, WHICH OPERATE ON DICOM IMAGES. THE IMAGES DELIVERED BY THE SYSTEM CAN BE USED BY TRAINED STAFF/PHYSICIAN AS AN AID IN DIAGNOSIS, TREATMENT PREPARATION AND RADIATION THERAPY PLANNING,COMPUTED TOMOGRAPHY(SOMATOM DEFINITION AS)-THE SIEMENS SOMATOM CT SYSTEMS ARE INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA FROM EITHER THE SAME AXIAL PLANE TAKEN AT DIFFERENT ANGLES OR SPIRAL PLANES TAKEN AT DIFFERENT ANGLES. IN ADDITION, THE SOMATOM CT ARE ABLE TO PRODUCE ADDITIONAL IMAGE PLANES AND ANALYSIS RESULTS BY EXECUTING OPTIONAL POST PROCESSING FEATURES, WHICH OPERATE ON DICOM IMAGES. THE IMAGES DELIVERED BY THE SYSTEM CAN BE USED BY TRAINED STAFF/PHYSICIAN AS AN AID IN DIAGNOSIS, TREATMENT PREPARATION AND RADIATION THERAPY PLANNING.,COMPUTED TOMOGRAPHY(SOMATOM CONFIDENCE)-THE SIEMENS SOMATOM CT SYSTEMS ARE INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA FROM EITHER THE SAME AXIAL PLANE TAKEN AT DIFFERENT ANGLES OR SPIRAL PLANES TAKEN AT DIFFERENT ANGLES. IN ADDITION, THE SOMATOM CT ARE ABLE TO PRODUCE ADDITIONAL IMAGE PLANES AND ANALYSIS RESULTS BY EXECUTING OPTIONAL POST PROCESSING FEATURES, WHICH OPERATE ON DICOM IMAGES. THE IMAGES DELIVERED BY THE SYSTEM CAN BE USED BY TRAINED STAFF/PHYSICIAN AS AN AID IN DIAGNOSIS, TREATMENT PREPARATION AND RADIATION THERAPY PLANNING

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2679	IMP/MD/2021/000438	1.License Holder Name: BAYER PHARMACEUTICALS PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SINGLE USE HIGH PRESSURE ANGIOGRAPHIC SYRINGE(MEDRAD SALIENT, MEDRAD VISTRON PLUS (ZY5154))-THE CONTENTS OF THIS PACKAGE ARE INTENDED TO BE USED IN THE DELIVERY OF CONTRAST MEDIA OR SALINE. THEY ARE INDICATED FOR SINGLE USE ON ONE PATIENT ONLY.,SINGLE USE HIGH PRESSURE ANGIOGRAPHIC SYRINGE (MEDRAD SALIENT, MEDRAD VISTRON PLUS (ZY5151, ZY5152, ZY6322))-THE CONTENTS OF THIS PACKAGE ARE INTENDED TO BE USED IN THE DELIVERY OF CONTRAST MEDIA OR SALINE. THEY ARE INDICATED FOR SINGLE USE ON ONE PATIENT ONLY WITH MEDRAD SALIENT AND MEDRAD VISTRON PLUS INJECTORS. THE TRANSFER SET IS INTENDED FOR USE FOR ONE CONTAINER OF MEDIA ONLY AND MUST BE DISCARDED WHEN THE CONTAINER BECOMES EMPTY OR AFTER SIX HOURS WHICHEVER COMES FIRST. REFER TO THE MEDIA MANUFACTURER'S INSTRUCTIONS FOR USE FOR ADDITIONAL INDICATIONS.
2680	IMP/MD/2021/000439	1.License Holder Name: BENISON MEDTECH 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SIROLIMUS ELUTING STENT(INSPIRON)-THE INSPIRON SIROLIMUS ELUTING STENT IS INDICATED TO IMPROVE THE LUMEN DIAMETER IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY AND STENTS PROCEDURES WITH SYMPTOMATIC ISCHEMIA HEART DISEASE DUE TO RESTENOTIC AND INTERNAL LESIONS IN NATIVE CORONARY ARTERY WITH REFERENCE VESSEL DIAMETERS OF 2.25 MM TO 4.00MM.
2681	IMP/MD/2021/000440	1.License Holder Name: SWAMI ORTHO AIDS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARM TYPE ELECTRONIC BLOOD PRESSURE MONITOR(EZ-LIFE)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.

2682	IMP/MD/2021/000441	1.License Holder Name: M/S DENTSPLY INDIA PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ALL-CERAMIC VENEERING PORCELAIN(CELTRA CERAM KITS)-CELTRA CERAM IS SUITABLE FOR VENEERING ALL-CERAMIC FRAMEWORKS,METAL VENEERING PORCELAIN(CERAMCO 3 KITS)-CERAMCO 3 VENEERING PORCELAINS MAY BE USED FOR ALL SINGLE AND MULTIPLE UNIT PORCELAIN FUSED-TO-METAL FIXED PROSTHODONTICS.,UNIVERSAL STAIN AND GLAZE KITS(UNIVERSAL STAIN AND GLAZE KITS)-DENTSPLY SIRONA UNIVERSAL STAIN AND GLAZE ARE INDICATED FOR STAINING AND GLAZING THE FOLLOWING RESTORATIONS: CELTRA PRESS ZIRCONIA REINFORCED LITHIUM SILICATE (ZLS); CELTRA DUO ZIRCONIA REINFORCED LITHIUM SILICATE (ZLS); CERCON HT ZIRCONIA; CERAMCO PFZ PORCELAIN FOR ZIRCONIA; CERCON CERAM KISS PORCELAIN; CERAMCO 3 PORCELAIN; CERAMCO IC PORCELAIN; DUCERAM KISS PORCELAIN
2683	IMP/MD/2021/000442	1.License Holder Name: HICKS THERMOMETERS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARM TYPE ELECTRONIC BLOOD PRESSURE MONITOR(HICKS)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.
2684	IMP/MD/2021/000443	1.License Holder Name: ADVANCED STERILIZATION PRODUCTS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISINFECTANTS(CIDEX OPA)-CIDEX OPA SOLUTION IS A HIGH LEVEL DISINFECTANT FOR REPROCESSING HEAT SENSITIVE MEDICAL DEVICES USED IN THE MEDICAL AREA, WHEN USED ACCORDING TO THE DIRECTIONS FOR USE. CIDEX OPA SOLUTION IS INTENDED FOR USE IN MANUAL (BUCKET AND TRAY) SYSTEMS MADE FROM POLYPROPYLENE, ACRYLONITRILE-BUTADIENE- STYRENE (ABS), OLYETHYLENE, GLASS-FILLED POLYPROPYLENE AND/OR POLYCARBONATE PLASTICS. CIDEX OPA SOLUTION MAY ALSO BE USED IN AUTOMATED ENDOSCOPE REPROCESSORS
2685	IMP/MD/2021/000445	1.License Holder Name: COMFO CARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NEBULIZER COMPRESSOR SYSTEM (COMFO-CARE)-IT IS DEVICE USED TO ADMINISTER MEDICATIONS IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDERS

2686	IMP/MD/2021/000447	1.License Holder Name: ESSITY INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:WOUND DRESSINGS (CUTIMED® SORBION® SACHET EXTRA)-FORMATION OF A STERILE, MECHANICAL BARRIER OVER THE WOUND WITH ABSORPTION OF EXUDATES. ALSO APPLICABLE ON EXUDING WOUNDS SUCH AS DECUBITUS, ULCUS CRURIS, DIABETIC FOOT ULCERS AND OTHER WOUNDS HEALING THROUGH SECONDARY INTENTION, DEHISCED WOUNDS, SECOND DEGREE BURNS, FISTULAE, DRAINAGES, ULCERATING CARCINOMAS AND OTHER TYPES OF EXUDING WOUNDS,WOUND DRESSINGS(CUTIMED® SORBION® SACHET S DRAINAGE)-FORMATION OF A STERILE, MECHANICAL BARRIER OVER THE WOUND WITH ABSORPTION OF EXUDATES. ALSO APPLICABLE ON EXUDING WOUNDS SUCH AS DECUBITUS, ULCUS CRURIS, DIABETIC FOOT ULCERS AND OTHER WOUNDS HEALING THROUGH SECONDARY INTENTION, DEHISCED WOUNDS, SECOND DEGREE BURNS, FISTULAE, DRAINAGES, ULCERATING CARCINOMAS AND OTHER TYPES OF EXUDING WOUNDS.,WOUND DRESSINGS(CUTIMED® SORBION® SACHET S)-FORMATION OF A STERILE, MECHANICAL BARRIER OVER THE WOUND WITH ABSORPTION OF EXUDATES. ALSO APPLICABLE ON EXUDING WOUNDS SUCH AS DECUBITUS, ULCUS CRURIS, DIABETIC FOOT ULCERS AND OTHER WOUNDS HEALING THROUGH SECONDARY INTENTION, DEHISCED WOUNDS, SECOND DEGREE BURNS, FISTULAE, DRAINAGES, ULCERATING CARCINOMAS AND OTHER TYPES OF EXUDING WOUNDS.,WOUND DRESSINGS (CUTIMED® SORBION® SACHET MULTI STAR)-FORMATION OF A STERILE, MECHANICAL BARRIER OVER THE WOUND WITH ABSORPTION OF EXUDATES. ALSO APPLICABLE ON EXUDING WOUNDS SUCH AS DECUBITUS, ULCUS CRURIS, DIABETIC FOOT ULCERS AND OTHER WOUNDS HEALING THROUGH SECONDARY INTENTION, DEHISCED WOUNDS, SECOND DEGREE BURNS, FISTULAE, DRAINAGES, ULCERATING CARCINOMAS AND OTHER TYPES OF EXUDING WOUNDS
2687	IMP/MD/2021/000448	1.License Holder Name: INNVOLUTION HEALTHCARE PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MICROCATHETER(ACIST NAVVUS II)-THE ACIST RXI SYSTEM AND THE RXI MINI ARE INDICATED FOR OBTAINING INTRAVASCULAR PRESSURE MEASUREMENTS FOR USE IN THE DIAGNOSIS AND TREATMENT OF CORONARY AND PERIPHERAL ARTERY DISEASE. THE ACIST NAVVUS II MICROCATHETER IS INTENDED FOR USE WITH THE ENTIRE FAMILY OF ACIST RXI SYSTEMS.

2688	IMP/MD/2021/000449	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:STIMULATOR, ELECTRICAL, ANALGESIC, SPINAL CORD(SURETEK BURR HOLE COVER KIT)-THE SURETEK BURR HOLE COVER IS A LEAD ANCHORING DEVICE FOR USE WITH THE BOSTON SCIENTIFIC VERCISE DEEP BRAIN STIMULATION (DBS) SYSTEM.
2689	IMP/MD/2021/000450	1.License Holder Name: ABBOTT HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTINUOUS GLUCOSE MONITORING SYSTEM SENSOR(FREESTYLE LIBRE PRO IQ)-THE FREESTYLE LIBRE PRO IQ CONTINUOUS GLUCOSE MONITORING SYSTEM IS A FACTORY CALIBRATED CONTINUOUS GLUCOSE RECORDING DEVICE INDICATED FOR THE RETROSPECTIVE DISCOVERY, ANALYSIS AND INTERPRETATION OF GLYCAEMIC VARIABILITY IN PERSONS AGED 4 AND OLDER UNDER THE SUPERVISION OF A HEALTHCARE PROFESSIONAL. THE SYSTEM COLLECTS AND PROCESSES DATA FOR AIDING IN THE MANAGEMENT OF A DISEASE OR CONDITION RELATED TO GLYCAEMIC CONTROL. INTERPRETATION OF THE DATA RECORDED BY THE SYSTEM SHOULD BE MADE ONLY BY A QUALIFIED HEALTHCARE PROFESSIONAL BASED ON GLUCOSE TRENDS AND SEVERAL SEQUENTIAL READINGS OVER TIME. THE SYSTEM AIDS IN DETECTING GLUCOSE EXCURSIONS FACILITATING CARE PLAN ADJUSTMENTS. THE SYSTEM IS ALSO INTENDED TO INTERFACE WITH DIGITALLY CONNECTED DEVICES. THE SYSTEM HAS BEEN EVALUATED FOR USE IN PREGNANT WOMEN.
2690	IMP/MD/2021/000451	1.License Holder Name: ZB DENTAL INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT ABUTMENTS(LOCATOR IMPLANT)-THE LOCATOR IMPLANT ATTACHMENT SYSTEM IS MADE UP TITANIUM OF AND DESIGNED FOR USE WITH OVERDENTURES OR PARTIAL DENTURES, RETAINED IN WHOLE OR IN PART, BY ENDOSSEOUS IMPLANTS IN MANDIBLE OR MAXILLA.

2691	IMP/MD/2021/000452	1.License Holder Name: SMITH & NEPHEW HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DUAL MOBILITY HIP LINER(OR3O)-• ADVANCED DEGENERATION OF THE HIP JOINT AS A RESULT OF DEGENERATIVE, POST-TRAUMATIC, OR RHEUMATOID ARTHRITIS. • FRACTURE OR AVASCULAR NECROSIS OF THE FEMORAL HEAD. • FAILURE OF PREVIOUS HIP SURGERY: JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. • ALL FORMS OF OSTEOARTHRITIS. • PATIENTS WITH HIPS AT RISK OF DISLOCATION. • FEMORAL NECK FRACTURE OR PROXIMAL HIP JOINT FRACTURE. THE OR3O DUAL MOBILITY SYSTEM IS INTENDED FOR SINGLE USE ONLY. THE MODULAR OR3O DUAL MOBILITY LINERS AND INSERTS ARE TO BE IMPLANTED WITHOUT BONE CEMENT.
2692	IMP/MD/2021/000453	1.License Holder Name: KARL STORZ ENDOSCOPY INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MODULITH SLX F2 (MODULITH SLX-F2 «FD21» AND MODULITH SLX-F2 «CONNECT»)-MODULITH SLX-F2 «FD21» AND MODULITH SLX-F2 «CONNECT» - THE SYSTEM MODULITH SLX-F2 »FD21« AND MODULITH SLX-F2 «CONNECT» OFFER A MODULAR AND MULTIFUNCTIONAL STATIONARY UROLOGICAL X-RAY WORKSTATION WITH AN INTEGRATED SHOCK WAVE UNIT (LITHOTRIPTER) AND OPTIONAL REMOTE CONTROL FUNCTIONALITY. THE SYSTEM IS INTENDED FOR THE USE IN CLINICAL, SEMI-STERILE SURGERY ENVIRONMENTS FOR ENDO-UROLOGICAL AND PERCUTANE PROCEDURES (AS URS OR PCNL) AS WELL AS LITHOTRIPSY TREATMENT.

2693	IMP/MD/2021/000456	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CIOS ALPHA(CIOS ALPHA) -CIOS ALPHA IS A MOBILE X-RAY SYSTEM DESIGNED TO PROVIDE X-RAY IMAGING OF THE ANATOMICAL STRUCTURES OF PATIENT DURING FOLLOWING CLINICAL APPLICATIONS: INTERVENTIONAL FLUOROSCOPIC, GASTRO-INTESTINAL, ENDOSCOPIC, UROLOGIC, PAIN MANAGEMENT, ORTHOPEDIC, NEUROLOGIC, VASCULAR, CARDIAC, CRITICAL CARE AND EMERGENCY ROOM PROCEDURES., CIOS SPIN(CIOS SPIN)-CIOS SPIN IS A MOBILE X-RAY SYSTEM DESIGNED TO PROVIDE X-RAY IMAGING OF THE ANATOMICAL STRUCTURES OF PATIENT DURING FOLLOWING CLINICAL APPLICATIONS: INTERVENTIONAL FLUOROSCOPIC, GASTRO-INTESTINAL, ENDOSCOPIC, UROLOGIC, PAIN MANAGEMENT, ORTHOPEDIC, NEUROLOGIC, VASCULAR, CARDIAC, CRITICAL CARE AND EMERGENCY ROOM PROCEDURES.,CIOS FUSION(CIOS FUSION)-CIOS FUSION IS A MOBILE X-RAY SYSTEM DESIGNED TO PROVIDE X-RAY IMAGING OF THE ANATOMICAL STRUCTURES OF PATIENT DURING FOLLOWING CLINICAL APPLICATIONS: INTERVENTIONAL FLUOROSCOPIC, GASTRO-INTESTINAL, ENDOSCOPIC, UROLOGIC, PAIN MANAGEMENT, ORTHOPEDIC, NEUROLOGIC, VASCULAR, CARDIAC, CRITICAL CARE AND EMERGENCY ROOM PROCEDURES., CIOS CONNECT(CIOS CONNECT)-CIOS CONNECT IS A MOBILE X-RAY SYSTEM DESIGNED TO PROVIDE X-RAY IMAGING OF THE ANATOMICAL STRUCTURES OF PATIENT DURING FOLLOWING CLINICAL APPLICATIONS: INTERVENTIONAL FLUOROSCOPIC, GASTRO-INTESTINAL, ENDOSCOPIC, UROLOGIC, PAIN MANAGEMENT, ORTHOPEDIC, NEUROLOGIC, VASCULAR, CARDIAC, CRITICAL CARE AND EMERGENCY ROOM PROCEDURES
2694	IMP/MD/2021/000457	1.License Holder Name: B.BRAUN MEDICAL (INDIA) PVT., LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTCA DILATATION CATHETERS(SEQUENT NEO NC)-THE SEQUENT® NEO NC PTCA RX DILATATION CATHETERS ARE INDICATED FOR: • BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. • BALLOON DILATATION OF A STENT AFTER IMPLANTATION (BALLOON MODELS 2.00MM - 4.50MM)

2695	IMP/MD/2021/000458	1.License Holder Name: BOSTON SCIENTIFIC INDIA PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DEFIBRILLATOR LEAD IMPLANTABLE(ENDOTAK RELIANCE)-THE ENDOTAK RELIANCE LEAD, PROVIDE PACING AND RATE-SENSING AND DELIVER CARDIOVERSION AND DEFIBRILLATION SHOCKS FOR ICD AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEMS.,ENDOCARDIAL LEADS (FINELINE II STEROX)-THIS BOSTON SCIENTIFIC LEAD IS INDICATED FOR USE AS FOLLOWS: • INTENDED FOR CHRONIC PACING AND SENSING IN THE RIGHT ATRIUM (PREFORMED ATRIAL J) OR RIGHT VENTRICLE (STRAIGHT) WHEN USED WITH A COMPATIBLE PULSE GENERATOR,ENDOCARDIAL LEADS(FINELINE II STEROX EZ)-THE LEAD IS INTENDED FOR CHRONIC PACING AND SENSING OF THE ATRIUM OR VENTRICLE WHEN USED WITH A COMPATIBLE PULSE GENERATOR.,ENDOCARDIAL DEFIBRILLATION LEAD(EMBLEM S-ICD)-THE S-ICD SYSTEM IS INTENDED TO PROVIDE DEFIBRILLATION THERAPY FOR THE TREATMENT OF LIFE THREATENING VENTRICULAR TACHYARRHYTHMIAS IN PATIENTS WHO DO NOT HAVE SYMPTOMATIC BRADYCARDIA, INCESSANT VENTRICULAR TACHYCARDIA, OR SPONTANEOUS, FREQUENTLY RECURRING VENTRICULAR TACHYCARDIA THAT IS RELIABLY TERMINATED WITH ANTI-TACHYCARDIA PACING.
2696	IMP/MD/2021/000459	1.License Holder Name: ESSITY INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:WOUND DRESSINGS (CUTIMED® SORBION® SACHET XL)-FORMATION OF A STERILE, MECHANICAL BARRIER OVER THE WOUND WITH ABSORPTION OF EXUDATES. ALSO APPLICABLE ON EXUDING WOUNDS SUCH AS DECUBITUS, ULCUS CRURIS, DIABETIC FOOT ULCERS AND OTHER WOUNDS HEALING THROUGH SECONDARY INTENTION, DEHISCED WOUNDS, SECOND DEGREE BURNS, FISTULAE, DRAINAGES, ULCERATING CARCINOMAS AND OTHER TYPES OF EXUDING WOUNDS

2697	IMP/MD/2021/000461	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DRUG COATED BALLOON PTA CATHETER(LUTONIX 014 DRUG COATED BALLOON PTA CATHETER)-THE LUTONIX 014 DRUG COATED BALLOON CATHETER IS INTENDED FOR USE AS A PTA CATHETER TO DILATE STENOTIC OR OBSTRUCTIVE VASCULAR LESIONS IN THE LOWER EXTREMITIES, FOR THE PURPOSE OF IMPROVING LIMB PERFUSION AND DECREASING THE INCIDENCE OF RESTENOSIS.,DRUG COATED BALLOON PTA CATHETER(LUTONIX 035 DRUG COATED BALLOON PTA CATHETER)-THE LUTONIX 035 DRUG COATED BALLOON CATHETER IS INTENDED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN THE PERIPHERAL VASCULATURE AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS AND DECREASING THE INCIDENCE OF RESTENOSIS. IN ADDITION, THE LUTONIX 035 DRUG COATED BALLOON CATHETER IS INTENDED FOR PTA OF NATIVE DIALYSIS FISTULAE OR SYNTHETIC GRAFTS, OPENING NARROWING AND IMMATURE FISTULAE, TO IMPROVE BLOOD FLOW, AND DECREASING THE INCIDENCE OF RESTENOSIS.
2698	IMP/MD/2021/000462	1.License Holder Name: M/S DENTEX SERVICES LLP 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT(NA)-JDENTAL CARE IMPLANTS ARE INTENDED FOR SURGICAL PLACEMENT IN UPPER OR LOWER JAW, THEY PROVIDE A MEAN FOR PROSTHETIC ATTACHMENT IN SINGLE OR MULTIPLE TOOTH REPLACEMENT

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2699	IMP/MD/2021/000463	1.License Holder Name: TELEFLEX MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HEMOSTATIC DRESSING 5 (QUIKCLOT)-IT IS INTENDED FOR TEMPORARY EXTERNAL USE TO CONTROL TRAUMATIC BLEEDING.,HEMOSTATIC DRESSING 1 (QUIKCLOT)-QUIKCLOT HEMOSTATIC DRESSING IS INTENDED FOR USE AS A TOPICAL DRESSING FOR LOCAL MANAGEMENT OF BLEEDING WOUNDS SUCH AS CUTS, LACERATIONS, AND ABRASIONS. IT MAY ALSO BE USED FOR TEMPORARY TREATMENT OF SEVERELY BLEEDING WOUNDS SUCH AS SURGICAL WOUNDS (OPERATIVE, POSTOPERATIVE, DERMATOLOGICAL, ETC.) AND TRAUMATIC INJURIES.,HEMOSTATIC DRESSING 4(QUIKCLOT)-IT IS INTENDED FOR TEMPORARY EXTERNAL USE TO CONTROL TRAUMATIC BLEEDING., HEMOSTATIC DRESSING 3(QUIKCLOT)-IT IS APPLIED TOPICALLY AS AN ADJUNCT TO MANUAL COMPRESSION AND IS INDICATED FOR THE LOCAL MANAGEMENT AND CONTROL OF SURFACE BLEEDING FROM VASCULAR ACCESS SITES, PERCUTANEOUS CATHETERS OR TUBES UTILIZING INTRODUCER SHEATHS UP TO 12 FR OR UP TO 7 FR FOR PATIENTS ON DRUG/INDUCED ANTICOAGULATION TREATMENT., HEMOSTATIC DRESSING 6(QUIKCLOT)-IT IS INTENDED FOR USE AS A TOPICAL DRESSING FOR LOCAL MANAGEMENT OF BLEEDING WOUNDS SUCH AS CUTS, LACERATIONS AND ABRASIONS. IT MAY ALSO BE USED FOR TEMPORARY TREATMENT OF SEVERELY BLEEDING WOUNDS SUCH AS SURGICAL WOUNDS (OPERATIVE, POSTOPERATIVE, DERMATOLOGICAL, ETC.) AND TRAUMATIC INJURIES.,HEMOSTATIC DRESSING 2(QUIKCLOT)-IT IS APPLIED TOPICALLY AS AN ADJUNCT TO MANUAL COMPRESSION AND IS INDICATED FOR THE LOCAL MANAGEMENT AND CONTROL OF SURFACE BLEEDING FROM VASCULAR ACCESS SITES, PERCUTANEOUS CATHETERS OR TUBES UTILIZING INTRODUCER SHEATHS UP TO 12 FR OR UP TO 7 FR FOR PATIENTS ON DRUG/INDUCED ANTICOAGULATION TREATMENT.
2700	IMP/MD/2021/000464	1.License Holder Name: UNIVERSAL CORPORATION LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (AGARO)-THE DIGITAL THERMOMETER IS INTENDED TO MEASURE THE HUMAN BODY'S TEMPERATURE IN REGULAR MODE ORALLY, RECTALLY OR UNDER THE ARM, AND THE DEVICE IS REUSABLE FOR CLINICAL OR HOME USE ON PEOPLE OF ALL AGES

2701	IMP/MD/2021/000465	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHODONTIC WIRES (COPPER NICKEL TITANIUM)(DAMON ARCHWIRE , COPPER NI-TI ARCHWIRE, SMART ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH, ORTHODONTIC WIRE (STAINLESS STEEL)(RESPOND ARCHWIRE, STAINLESS STEEL ARCHWIRE, TRIPLEFLEX ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH,ORTHODONTIC WIRE (BETA TITANIUM)(TMA ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH,TEMPORARY ANCHORAGE SYSTEM(VECTOR TAS)-VECTOR TEMPORARY ANCHORAGE SYSTEM IS INTENDED TO PROVIDE A TEMPORARY FIXED ANCHORAGE POINT FOR ATTACHMENT OF ORTHODONTIC APPLIANCES THAT FACILITATES ORTHODONTICS MOVEMENT OF TEETH. THESE SCREWS ARE TEMPORARY AND ARE REMOVED AFTER THE DESIRED MOVEMENT IS ACHIEVED. THESE SCREWS WERE DESIGNED TO BE USED ON THE FOLLOWING TYPES OF CASES: • INTRUSION OR EXTRUSION OF INDIVIDUAL TEETH OR SEGMENTS OF AN ARCH. • PATIENTS IN WHICH PERIODONTAL DISEASE HAS COMPROMISED. • PATIENTS WHERE THERE IS A NEED FOR ABSOLUTE ANCHORAGE, I.E. ONLY THE ACTIVE UNIT SHOULD BE DISPLACED THE REACTIVE UNIT SHOULD REMAIN UNALTERED. • PATIENTS IN WHICH ALL TEETH SHOULD BE DISPLACED IN THE SAME DIRECTION. • PATIENTS WITH AGENESIS OF ONE OR MORE TEETH WHO NEED THE SPACE CLOSURE FROM ONE SIDE ONLY. • PATIENTS WITH NEED FOR THE CORRECTION OF ASYMMETRIES. THE MINI SCREWS CAN BE UTILIZED ON PATIENTS OVER THE AGE OF 13. CAUTION SHOULD BE USED WHEN PERMANENT TEETH HAVE NOT FULLY ERUPTED, AS NOT TO DAMAGE THE UNERUPTED TOOTH. AN UPPER AGE LIMIT DOES NOT EXIST, BUT THE CORTICAL. THICKNESS SHOULD BE SUFFICIENT FOR PRIMARY STABILITY. THE MINI-SCREWS WERE ORIGINALLY DEVELOPED FOR ADULTS IN WHOM INSUFFICIENT TEETH WERE AVAILABLE FOR CONVENTIONAL ANCHORAGE. THE INDICATIONS. HAVE, HOWEVER, WIDENED AND COMPRISE ALSO INDIVIDUALS WHERE THE REACTIVE FORCES FROM CONVENTIONAL ORTHODONTIC APPLIANCES WOULD GENERATE AN ADVERSE EFFECT ON THE ANCHORAGE UNIT. THE SKELETAL ANCHORAGE CAN THUS BE RECOMMENDED IN THE TREATMENT OF YOUNG PATIENTS WITH AGENESIS OF PERMANENT TEETH IN WHICH THE POSTERIOR TEETH ARE TO BE DISPLACED FORWARD WITHOUT GENERATING DISTALLY DIRECTED FORCES ON THE ANTERIOR UNIT . THIS CAN BE DONE FROM THE AGE WHERE THE PERMANENT TEETH TO BE DISPLACED ARE ERUPTED LASTLY THESE

		SCREWS ARE INTENDED FOR SINGLE USE ONLY.
2702	IMP/MD/2021/000466	1.License Holder Name: FRESENIUS KABI INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AUTOMATED BLOOD CELL SEPARATOR(AMICUS SEPARATOR)-THE AMICUS SEPARATOR IS AN AUTOMATED BLOOD CELL SEPARATOR INDICATED FOR THE COLLECTION OF BLOOD COMPONENTS AND MONONUCLEAR CELLS
2703	IMP/MD/2021/000467	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:IMAGING SYSTEM(O-ARM O2 IMAGING SYSTEM)-THE O-ARM O2 IMAGING SYSTEM IS A MOBILE X-RAY SYSTEM DESIGNED FOR 2D FLUOROSCOPIC AND 3D IMAGING AND IS INTENDED TO BE USED WHERE A PHYSICIAN BENEFITS FROM 2D AND 3D INFORMATION OF ANATOMIC STRUCTURES AND OBJECTS WITH HIGH X-RAY ATTENUATION SUCH AS BONY ANATOMY AND METALLIC OBJECTS. THE O-ARM O2 IMAGING SYSTEM IS COMPATIBLE WITH CERTAIN IMAGE GUIDED SURGERY SYSTEMS.
2704	IMP/MD/2021/000468	1.License Holder Name: NURECA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (DR TRUST)-INTENDED TO BE USED FOR DIAGNOSING THE BODY TEMPERATURE OR IT'S A DEVICE TO RECORD THE BODY TEMPERATURE
2705	IMP/MD/2021/000469	1.License Holder Name: M/S. ERBIS ENGINEERING COMPANY LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:X-RAY SYSTEM, DIAGNOSTIC, FLUOROSCOPIC, ANGIOGRAPHIC, STATIONARY, DIGITAL(CANON INTERVENTIONAL ANGIOGRAPHY SYSTEM)-THESE SYSTEMS ARE DIAGNOSTIC X-RAY SYSTEMS DESIGNED FOR MULTIDIRECTIONAL OBSERVATION OF THE FLOW OF CONTRAST MEDIUM INJECTED INTO THE BLOOD VESSELS OF A PATIENT.,X-RAY SYSTEM, DIAGNOSTIC, COMPUTED TOMOGRAPHY, FULL-BODY (CANON CT SCANNER)-THESE DEVICES ARE INDICATED TO ACQUIRE AND DISPLAY CROSS-SECTIONAL VOLUMES OF THE WHOLE BODY, TO INCLUDE THE HEAD. THESE DEVICES HAVE THE CAPABILITY TO PROVIDE VOLUME SETS. THESE VOLUME SETS CAN BE USED TO PERFORM SPECIALIZED STUDIES, USING INDICATED SOFTWARE/HARDWARE, BY A TRAINED AND QUALIFIED PHYSICIAN.

2706	IMP/MD/2021/000471	1.License Holder Name: BAXTER INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HOME CHOICE CLARIA APD CYCLER(HOME CHOICE CLARIA APD CYCLER)-BAXTER'S HOMECHOICE CLARIA APD SYSTEM IS INTENDED FOR AUTOMATIC CONTROL OF DIALYSIS SOLUTION EXCHANGES IN THE TREATMENT OF PEDIATRIC AND ADULT RENAL FAILURE PATIENTS UNDERGOING PERITONEAL DIALYSIS. THE SYSTEM WILL BE INTENDED TO DELIVER THE FOLLOWING THERAPIES: CCPD - CONTINUOUS CYCLIC PERITONEAL DIALYSIS; NIPD - NIGHTLY INTERMITTENT PERITONEAL DIALYSIS; IPD - INTERMITTENT PERITONEAL DIALYSIS; TIDAL PERITONEAL DIALYSIS (TPD); HIGH VOLUME / ACUTE THERAPY; PEDIATRIC THERAPY / LOW VOLUME SET; HI-DOSE CCPD / HI-DOSE TIDAL.,TUBING SET, PERITONEAL DIALYSIS (HOMECHOICE LOW RECIRCULATION VOLUME APD SET WITH CASSETTE)-THE HOMECHOICE LOW RECIRCULATION VOLUME APD SET WITH CASSETTE IS INTENDED FOR USE IN PAEDIATRIC PATIENTS, OR OTHER PATIENTS REQUIRING FILL VOLUMES OF 60 - 1000 ML, USING ONLY THE HOMECHOICE APD SYSTEM WITH LOW FILL MODE. ,TUBING SET PERITONEAL DIALYSIS(HOMECHOICE AUTOMATED PD SET WITH CASSETTE AND 4- PRONG LUERS)-THE HOMECHOICE AUTOMATED PERITONEAL DIALYSIS (APD) SET WITH CASSETTE AND 4 PRONG LUERS IS USED FOR THE TRANSFER OF FLUIDS FOR PERITONEAL DIALYSIS THERAPY.

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2707	IMP/MD/2021/000472	1.License Holder Name: AADI HEALTH CARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER(BIP CENTRAL VENOUS CATHETER)-BIP CVCS ARE DESIGNED FOR USE IN CRITICAL CARE PATIENTS TO MONITOR CENTRAL VENOUS PRESSURES; SAMPLE VENOUS BLOOD; AND ADMINISTER MEDICATIONS AND SOLUTIONS INTRAVENOUSLY. MULTIPLE LUMEN CATHETERS PROVIDE MULTIPLE ACCESS CHANNELS TO THE CENTRAL VENOUS CIRCULATION THROUGH A SINGLE INSERTION SITE, PERMITTING SEVERAL FUNCTIONS TO BE PERFORMED SIMULTANEOUSLY. BIP CVC HAS BEEN SHOWN TO REDUCE BACTERIAL ADHESION TO THE DEVICE SURFACE IN VITRO COMPARED TO AN UNCOATED CVC. BACTIGUARD® COATED CVCS HAS BEEN SHOWN TO REDUCE CATHETER RELATED INFECTIONS IN HIGH RISK PATIENTS, WHEN COMPARED TO UNCOATED CVCS. THE BIP CVC IS FOR SHORT-TERM USE ONLY. THE BIP CVC IS NOT INTENDED TO BE USED AS A TREATMENT FOR EXISTING INFECTIONS NOR AS A SUBSTITUTE FOR A TUNNELED CATHETER IN PATIENTS REQUIRING LONG-TERM THERAPY.,ENDOTRACHEAL TUBE(BIP ENDOTRACHEAL TUBE)-THE BIP ENDOTRACHEAL TUBE IS INDICATED TO BE USED BY TRAINED MEDICAL STAFF, FOR USE IN AIRWAY MANAGEMENT BY ORAL OR NASAL INTUBATION OF THE PATIENT TRACHEA TO CREATE AN OPEN AIRWAY. THE BACTIGUARD® COATING ON THE BIP ENDOTRACHEAL TUBE HAS BEEN SHOWN TO SIGNIFICANTLY REDUCE MICROBIAL ADHESION.,FOLEY CATHETER-SILICONE(BIP FOLEY CATHETER- SILICONE)-THE BIP FOLEY CATHETER - SILICONE IS INTENDED TO BE INSERTED BY TRAINED MEDICAL STAFF, FOR THE DRAINAGE AND/OR IRRIGATION OF THE BLADDER, AND/OR FOR COLLECTION/ MEASUREMENT OF PATIENT URINE. THESE FUNCTIONS ARE ACHIEVED BY INSERTING THE CATHETER INTO THE VESICAL CAVITY OF THE BLADDER THROUGH THE URETHRA, OR BY SUPRAPUBIC CATHETERISATION. BACTIGUARD® COATED FOLEY CATHETERS HAVE BEEN SHOWN TO SIGNIFICANTLY REDUCE THE INCIDENCE OF BACTERIURIA, CATHETER ASSOCIATED URINARY TRACT INFECTIONS (CAUTIS) AND ANTIBIOTIC USE IN CATHETERIZED PATIENTS COMPARED TO PATIENTS USING STANDARD CATHETERS.,FOLEY TIEMANN(BIP FOLEY TIEMANN)-THE BIP FOLEY TIEMANN IS INTENDED TO BE INSERTED BY TRAINED MEDICAL STAFF, FOR THE DRAINAGE AND/OR IRRIGATION OF THE BLADDER, AND/OR FOR COLLECTION/ MEASUREMENT OF PATIENT URINE. THESE FUNCTIONS ARE ACHIEVED BY INSERTING THE CATHETER INTO THE VESICAL CAVITY OF THE BLADDER THROUGH THE URETHRA. BIP FOLEY TIEMANN IS ONLY FOR TRANSURETHRAL USE. BACTIGUARD® COATED FOLEY CATHETER HAVE BEEN SHOWN

		TO SIGNIFICANTLY REDUCE THE INCIDENCE OF BACTERIURIA, CATHETER ASSOCIATED URINARY TRACT INFECTIONS (CAUTIS) AND ANTIBIOTIC USE IN CATHETERIZED PATIENTS COMPARED TO PATIENTS USING STANDARD CATHETERS.,FOLEY CATHETER(BIP FOLEY CATHETER)-BIP FOLEY CATHETER IS INTENDED TO BE USED BY TRAINED PERSON OR TRAINED MEDICAL STAFF FOR DRAINAGE AND/OR IRRIGATION OF THE PATIENT BLADDER AND/OR FOR COLLECTION / MEASUREMENT OF THE PATIENT URINE. THESE FUNCTIONS ARE ACHIEVED BY INSERTING THE BIP FOLEY CATHETER INTO THE VESICAL CAVITY OF THE BLADDER THROUGH THE URETHRA, OR BY SUPRAPUBIC CATHETERIZATION. THE BIP FOLEY CATHETER HAS BEEN SHOWN TO SIGNIFICANTLY REDUCE THE INCIDENCE OF BACTERIURIA IN CATHETERIZED PATIENTS COMPARED TO PATIENTS USING UNCOATED CATHETERS. , ENDOTRACHEAL TUBE EVAC(BIP ENDOTRACHEAL TUBE EVAC)-THE BIP ENDOTRACHEAL TUBE EVAC IS INDICATED FOR USE IN AIRWAY MANAGEMENT BY ORAL INTUBATION OF THE TRACHEA. THE EVACUATION LUMEN ALLOWS FOR DRAINAGE BY CONTINUOUS OR INTERMITTENT SUCTIONING OF CONTAMINATED MUCOUS AND SUBGLOTTIC SECRETIONS THAT ACCUMULATE ABOVE THE CUFF. BIP ENDOTRACHEAL TUBE EVAC IS INTENDED FOR PATIENTS ANTICIPATED TO NEED PROLONGED MECHANICAL VENTILATION. THE BACTIGUARD® COATING ON THE BIP ENDOTRACHEAL TUBE EVAC IS SIGNIFICANTLY REDUCING MICROBIAL ADHESION. SUBGLOTTIC SECRETION DRAINAGE (SSD) HAS BEEN SHOWN EFFECTIVE FOR THE PREVENTION OF VENTILATOR-ASSOCIATED PNEUMONIA (VAP).
2708	IMP/MD/2021/000473	1.License Holder Name: MICRO & NANO TECHNOLOGIES 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARM TYPE ELECTRONIC BLOOD PRESSURE MONITOR(NA)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.

2709	IMP/MD/2021/000474	1.License Holder Name: M/S ST. JUDE MEDICAL INDIA PVT. LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:LVAS IMPLANT KIT (HEARTMATE II)-THE HEARTMATE II LVAS IS INTENDED TO PROVIDE HEMODYNAMIC SUPPORT IN PATIENTS WITH ENDSTAGE, REFRACTORY LEFT VENTRICULAR HEART FAILURE; EITHER FOR TEMPORARY SUPPORT, SUCH AS A BRIDGE TO CARDIAC TRANSPLANTATION OR MYOCARDIAL RECOVERY, OR AS PERMANENT DESTINATION THERAPY. THE HEARTMATE II IS INTENDED FOR USE INSIDE OR OUTSIDE THE HOSPITAL.,LVAS IMPLANT KIT(HEARTMATE 3)-THE HEARTMATE 3 LEFT VENTRICULAR ASSIST SYSTEM IS INTENDED TO PROVIDE LONG TERM HEMODYNAMIC SUPPORT IN PATIENTS WITH ADVANCED, REFRACTORY LEFT VENTRICULAR HEART FAILURE; EITHER FOR TEMPORARY SUPPORT, SUCH AS A BRIDGE TO CARDIAC TRANSPLANTATION (BTT), OR AS PERMANENT DESTINATION THERAPY (DT). THE HM3 IS INTENDED FOR USE INSIDE OR OUTSIDE THE HOSPITAL.
2710	IMP/MD/2021/000476	1.License Holder Name: MICROTEK INTERNATIONAL PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (MICROTEK)-THE DIGITAL THERMOMETER OFFERS A SAFE, ACCURATE & QUICK TEMPERATURE READING.
2711	IMP/MD/2021/000477	1.License Holder Name: NOBEL BIOCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ORTHODONTIC WIRE (NICKEL TITANIUM)(NITI ARCHWIRE, DAMON ARCHWIRE, TRU-ARCH ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH.,ORTHODONTIC WIRE (STAINLESS STEEL)(TRU-ARCH ARCHWIRE)-INTENDED TO BE USED WITH ORTHODONTIC BRACKETS TO CORRECT MALOCCLUDED TEETH.
2712	IMP/MD/2021/000478	1.License Holder Name: POINT OF CARE BIOMEDICAL PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:UPPER ARM BLOOD PRESSURE MONITOR(POCT)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.

2713	IMP/MD/2021/000479	1.License Holder Name: M/S VERTECH HEALTH SOLUTIONS INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (PERFECXA)-IT PROVIDES QUICK, HIGHLY ACCURATE READING OF HUMAN BODY TEMPERATURE AND DISPLAY ON THE LCD.
2714	IMP/MD/2021/000480	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PTA DILATATION CATHETER(ATLAS GOLD PTA DILATATION CATHETER)-ATLAS GOLD PTA DILATATION CATHETER IS INDICATED FOR USE IN PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY OF THE PERIPHERAL VASCULATURE, INCLUDING THE ILIAC ARTERIES AND ILIAC AND FEMORAL VEINS, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO INDICATED FOR POST-DILATATION OF STENTS AND STENT GRAFTS IN THE PERIPHERAL VASCULATURE. THIS CATHETER IS NOT FOR USE IN CORONARY ARTERIES,PTV DILATATION CATHETER(VIDA PTV DILATATION CATHETER)-THE VIDA PTV DILATATION CATHETER IS RECOMMENDED FOR PERCUTANEOUS TRANSLUMINAL VALVULOPLASTY OF THE PULMONARY VALVE IN THE FOLLOWING: • A PATIENT WITH ISOLATED PULMONARY VALVE STENOSIS • A PATIENT WITH VALVULAR PULMONARY STENOSIS WITH OTHER MINOR CONGENITAL HEART DISEASE THAT DOES NOT REQUIRE SURGICAL INTERVENTION.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2715	IMP/MD/2021/000481	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:VENTRICULAR CATHETER (OPUS VENTRICULAR CATHETER)-OPUS VENTRICULAR CATHETERS ARE DESIGNED FOR USE AS THE PROXIMAL COMPONENT OF THE CSF-FLOW CONTROL SHUNT FOR USE IN SHUNTING CEREBROSPINAL FLUID FROM THE VENTRICLES OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR TO THE PERITONEAL CAVITY. THE OPUS VENTRICULAR CATHETER, SMALL IS RECOMMENDED FOR USE WITH PREMATURE AND FULL-TERM INFANTS, WHERE A SMALLER DIAMETER CATHETER IS PREFERRED.,CSF SHUNTS(CSF-SNAP SHUNT ASSEMBLY)-MEDTRONIC NEUROSURGERY SNAP SHUNT ASSEMBLIES ARE COMPONENTS OF A SHUNT SYSTEM, DESIGNED TO PROVIDE CONTROLLED CSF FLOW FROM THE VENTRICLES OF THE BRAIN INTO THE PERITONEAL CAVITY. A COMPLETE SHUNT PROVIDES DIRECT ACCESS TO THE LATERAL CEREBRAL VENTRICLES. THE DISTAL PERITONEAL CATHETER, WITH ITS OPEN END AND WALL SLITS, IS NOT RECOMMENDED FOR PLACEMENT INTO THE RIGHT ATRIUM OF THE HEART. THE BUTTON SNAP SHUNT ASSEMBLY IS RECOMMENDED FOR USE IN PREMATURE INFANTS IN WHOM THE SMALL VALVE AND SMALL DIAMETER CATHETER IS INDICATED. THE SNAP SHUNT ASSEMBLY, ULTRA SMALL IS RECOMMENDED FOR USE IN INFANTS AND CHILDREN IN WHOM A SMALL SIZED VALVE IS INDICATED., VENTRICULAR CATHETER(SNAP SHUNT VENTRICULAR CATHETER)-MEDTRONIC NEUROSURGERY SNAP SHUNT ASSEMBLIES ARE COMPONENTS OF A SHUNT SYSTEM, DESIGNED TO PROVIDE CONTROLLED CSF FLOW FROM THE VENTRICLES OF THE BRAIN INTO THE PERITONEAL CAVITY. A COMPLETE SHUNT PROVIDES DIRECT ACCESS TO THE LATERAL CEREBRAL VENTRICLES. THE DISTAL PERITONEAL CATHETER, WITH ITS OPEN END AND WALL SLITS, IS NOT RECOMMENDED FOR PLACEMENT INTO THE RIGHT ATRIUM OF THE HEART. THE BUTTON SNAP SHUNT ASSEMBLY IS RECOMMENDED FOR USE IN PREMATURE INFANTS IN WHOM THE SMALL VALVE AND SMALL DIAMETER CATHETER IS INDICATED. THE SNAP SHUNT ASSEMBLY, ULTRA SMALL IS RECOMMENDED FOR USE IN INFANTS AND CHILDREN IN WHOM A SMALL SIZED VALVE IS INDICATED., EXTERNAL DRAINAGE CATHETER(EDM VENTRICULAR CATHETER)-THE EDM VENTRICULAR CATHETERS ARE DESIGNED FOR USE AS THE PROXIMAL COMPONENT FOR CEREBROSPINAL FLUID (CSF) DRAINAGE AND/OR MONITORING FROM THE LATERAL VENTRICLES OF THE BRAIN.,L/P SHUNTS(CSF-LUMBOPERITONEAL CATHETER SYSTEM)-CSF-LUMBOPERITONEAL SHUNT PRODUCTS ARE DESIGNED FOR THE MANAGEMENT OF COMMUNICATING HYDROCEPHALUS. THEY ARE NOT APPROPRIATE FOR THE TREATMENT OF

	OBSTRUCTIVE HYDROCEPHALUS UNLESS THE PATIENT HAS HAD PRIOR SURGERY ESTABLISHING A FUNCTIONING SHUNT BETWEEN THE CEREBRAL VENTRICLES AND THE SUBARACHNOID SPACE. LUMBOPERITONEAL SHUNTING IS OF VALUE IN BOTH THE DIAGNOSIS AND TREATMENT OF NORMAL PRESSURE (OCCULT) HYDROCEPHALUS. PERSISTENT OTORRHEA AND RHINORRHEA MAY OFTEN BE SATISFACTORILY CONTROLLED BY LUMBOPERITONEAL SHUNTING. OTHER INDICATIONS INCLUDE HYDROCEPHALUS SECONDARY TO MENINGITIS AND SUBARACHNOID HEMORRHAGE. LUMBOPERITONEAL SHUNTING IS ALSO OF VALUE IN REDUCING ELEVATED INTRACRANIAL PRESSURE (ICP), WHICH CAUSES BULGING AT CRANIOTOMY OR CRANIECTOMY SITES, AND IN THE TREATMENT OF PSEUDOTUMOR CEREBRI.,STRATA NSC(STRATA NSC VALVE)-THE STRATA NSC VALVE IS A SHUNT COMPONENT DESIGNED TO PROVIDE CONTINUED CEREBROSPINAL FLUID (CSF) FLOW FROM THE VENTRICLES OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR THE PERITONEAL CAVITY. THE STRATA NSC VALVE ALLOWS THE PHYSICIAN TO NON-INVASIVELY ADJUST THE PRESSURE/FLOW PERFORMANCE LEVEL PRE- AND POST-IMPLANTATION WITHOUT THE NEED FOR RADIOGRAPHIC CONFIRMATION IN ORDER TO ADDRESS CHANGING PATIENT NEEDS.,STRATA(STRATA II VALVE)-THE STRATA II VALVE IS A SHUNT COMPONENT DESIGNED TO PROVIDE CONTINUED CEREBROSPINAL FLUID (CSF) FLOW FROM THE VENTRICLES OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR THE PERITONEAL CAVITY. THE STRATA II VALVE ALLOWS THE PHYSICIAN TO NON-INVASIVELY ADJUST THE PRESSURE/FLOW PERFORMANCE LEVEL PRE- AND POST-IMPLANTATION WITHOUT THE NEED FOR RADIOGRAPHIC CONFIRMATION IN ORDER TO ADDRESS CHANGING PATIENT NEEDS.,DISTAL CATHETER(CARDIAC/ PERITONEAL CATHETER)-THE CARDIAC/PERITONEAL CATHETERS, STANDARD, BARIUM IMPREGNATED AND TRANSLUCENT, THE CARDIAC/PERITONEAL CATHETER, SMALL, BARIUM IMPREGNATED, AND THE CARDIAC CATHETER, REDUCED TIP, ARE DESIGNED AS DISTAL COMPONENTS OF CSF FLOW CONTROL SHUNTS FOR USE IN SHUNTING CEREBROSPINAL FLUID FROM THE VENTRICLES OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR TO THE PERITONEAL CAVITY. THE REDUCED-TIP CATHETER IS RECOMMENDED FOR USE WITH PATIENTS IN WHOM THE CATHETER IS TO BE PLACED IN A VESSEL WITH A LUMEN TOO SMALL TO ACCEPT LARGER DIAMETER CATHETERS.,VENTRICULAR CATHETER (INNERVISION SNAP SHUNT VENTRICULAR CATHETER)-THE INNERVISION VENTRICULAR CATHETER IS DESIGNED TO BE USED WITH THE NEUROPEN™ ENDOSCOPE OR OTHER COMPATIBLE MEDTRONIC NEUROSURGERY ENDOSCOPE WHEN THE PHYSICIAN

	DESIRES DIRECT VISION FROM THE TIP OF A VENTRICULAR CATHETER DURING ITS PLACEMENT. DIRECT VISION FACILITATES PLACEMENT OF THE CATHETER TIP AT A SPECIFIC INTRAVENTRICULAR LOCATION. THE CATHETER IS DESIGNED TO BE USED AS PROXIMAL COMPONENT OF A CSF-FLOW CONTROL SHUNT FOR USE IN SHUNTING CEREBROSPINAL FLUID FROM THE VENTRICLES OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR TO THE PERITONEAL CAVITY. MEDTRONIC NEUROSURGERY SNAP SHUNT ASSEMBLIES ARE COMPONENTS OF A SHUNT SYSTEM, DESIGNED TO PROVIDE CONTROLLED CSF FLOW FROM THE VENTRICLES OF THE BRAIN INTO THE PERITONEAL CAVITY. A COMPLETE SHUNT PROVIDES DIRECT ACCESS TO THE LATERAL CEREBRAL VENTRICLES. THE DISTAL PERITONEAL CATHETER, WITH ITS OPEN END AND WALL SLITS, IS NOT RECOMMENDED FOR PLACEMENT INTO THE RIGHT ATRIUM OF THE HEART. THE BUTTON SNAP SHUNT ASSEMBLY IS RECOMMENDED FOR USE IN PREMATURE INFANTS IN WHOM THE SMALL VALVE AND SMALL DIAMETER CATHETER IS INDICATED. THE SNAP SHUNT ASSEMBLY, ULTRA SMALL IS RECOMMENDED FOR USE IN INFANTS AND CHILDREN IN WHOM A SMALL SIZED VALVE IS INDICATED.,CATHETER(PERITONEAL CATHETER)-THE PERITONEAL CATHETER, OPEN END WITH WALL SLITS, STANDARD AND STANDARD, PLIANT, BARIUM IMPREGNATED, IS DESIGNED AS THE DISTAL COMPONENT OF A CSF FLOW CONTROL SHUNT FOR USE IN SHUNTING CEREBROSPINAL FLUID. THE SMALL LUMEN PERITONEAL CATHETER IS DESIGNED AS A DISTAL COMPONENT OF A CEREBROSPINAL FLUID SHUNT SYSTEM FOR USE IN SHUNTING CEREBROSPINAL FLUID INTO THE PERITONEAL CAVITY.,VENTRICULAR CATHETER(VENTRICULAR CATHETER)-THE VENTRICULAR CATHETERS, STANDARD, SMALL, FLANGED AND PLIANT, ARE DESIGNED FOR USE AS PROXIMAL COMPONENTS OF CSF FLOW CONTROL SHUNTS FOR USE IN SHUNTING CEREBROSPINAL FLUID FROM THE VENTRICLES OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR TO THE PERITONEAL CAVITY. THE SMALL CATHETER IS RECOMMENDED FOR USE IN PATIENTS WHERE A SMALLER DIAMETER IS INDICATED.,EXTERNAL DRAINAGE CATHETER (EDM LUMBAR CATHETER)-THE EDM LUMBAR CATHETERS ARE DESIGNED FOR USE AS THE PROXIMAL COMPONENT FOR CSF DRAINAGE AND/OR MONITORING FROM THE LUMBAR SUBARACHNOID SPACE.,CSF SHUNTS(DELTA SHUNT ASSEMBLY)-DELTA SHUNT ASSEMBLIES ARE DESIGNED FOR USE IN SHUNTING CSF FROM THE LATERAL VENTRICLE OF THE BRAIN INTO THE PERITONEAL CAVITY. THE DISTAL CATHETER WITH WALL SLITS IS NOT RECOMMENDED FOR PLACEMENT INTO THE RIGHT ATRIUM OF THE HEART. ADDITIONALLY, THE DELTA VALVE MINIMIZES THE

	EXCESSIVE REDUCTION OF INTRAVENTRICULAR PRESSURE AND VOLUME DUE TO EXCESSIVE DRAINAGE OF CSF, WHICH MAY BE CAUSED BY THE SIPHONING EFFECT OF HYDROSTATIC PRESSURE OF THE DISTAL CATHETER. THE SIPHON EFFECT MAY BE CREATED BY THE ELEVATION OF THE VENTRICULAR CATHETER WITH RESPECT TO THE DISTAL CATHETER (I.E., WHEN THE PATIENT SITS, STANDS, OR IS HELD ERECT).,STRATA ADJUSTABLE SHUNTS(STRATA NSC LUMBOPERITONEAL SHUNT KIT)-THE STRATA NSC LUMBOPERITONEAL SHUNT SYSTEM PROVIDES CONTINUED CEREBROSPINAL FLUID FLOW FROM SUBARACHNOID SPACE INTO THE PERITONEAL CAVITY. THE STRATA NSC LUMBOPERITONEAL VALVE ALLOWS THE PHYSICIAN TO NON-INVASIVELY ADJUST THE PRESSURE/FLOW PERFORMANCE LEVEL PRE- AND POST-IMPLANTATION IN ORDER TO ADDRESS CHANGING PATIENT NEEDS. THE STRATA NSC LUMBOPERITONEAL SHUNT SYSTEM IS DESIGNED FOR MANAGEMENT OF COMMUNICATING HYDROCEPHALUS AND MAY BE USED IN THE TREATMENT OF IDIOPATHIC INTRACRANIAL HYPERTENSION (PSEUDOTUMOR CEREBRI) WHEN SHUNTING IS AN OPTION.,CSF SHUNTS(CSF- FLOW CONTROL SHUNT KIT)-CSF FLOW CONTROL VALVE- THE CSF-FLOW CONTROL VALVES, CONTOURED, BURR HOLE, AND ULTRA SMALL, ARE THE COMPONENTS OF CSF-FLOW CONTROL SHUNTS DESIGNED TO PROVIDE CONTROLLED CSF FLOW FROM THE VENTRICLES OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR THE PERITONEUM. VENTRICULAR CATHETER- THE VENTRICULAR CATHETERS, STANDARD, SMALL, FLANGED, AND PLIANT, ARE DESIGNED FOR USE AS PROXIMAL COMPONENTS OF CSF-FLOW CONTROL SHUNTS FOR USE IN SHUNTING CEREBROSPINAL FLUID FROM THE VENTRICLES OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR TO THE PERITONEAL CAVITY. THE SMALL CATHETER IS RECOMMENDED FOR USE IN PATIENTS WHERE A SMALLER DIAMETER IS INDICATED. CARDIAC/ PERITONEAL CATHETER- THE CARDIAC/PERITONEAL CATHETERS, STANDARD, BARIUM-IMPREGNATED, AND TRANSLUCENT, THE CARDIAC/PERITONEAL CATHETER, SMALL, BARIUM-IMPREGNATED, AND THE CARDIAC CATHETER, REDUCED TIP, ARE DESIGNED AS DISTAL COMPONENTS OF CSF-FLOW CONTROL SHUNTS FOR USE IN SHUNTING1 CEREBROSPINAL FLUID FROM THE VENTRICLES OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR TO THE PERITONEAL CAVITY. THE REDUCED-TIP CATHETER IS RECOMMENDED FOR USE WITH PATIENTS IN WHOM THE CATHETER IS TO BE PLACED IN A VESSEL WITH A LUMEN TOO SMALL TO ACCEPT LARGER DIAMETER CATHETERS.,CSF SHUNTS(CSF- SHUNT ASSEMBLY)-CSF-SHUNT ASSEMBLIES ARE DESIGNED AS COMPONENTS OF CSF-FLOW CONTROL SHUNTS FOR USE IN

	SHUNTING CSF FROM THE VENTRICLES OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR TO THE PERITONEAL CAVITY. THE CSF-SHUNT ASSEMBLY WITH SMALL CONTOURED VALVE IS RECOMMENDED FOR USE WITH PATIENTS (E.G. INFANTS) IN WHOM A SMALL-SIZED VALVE IS INDICATED.,STRATA ADJUSTABLE SHUNTS (STRATA II)-THE STRATA II VALVE IS A SHUNT COMPONENT DESIGNED TO PROVIDE CONTINUED CEREBROSPINAL FLUID (CSF) FLOW FROM THE VENTRICLES OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR THE PERITONEAL CAVITY. THE STRATA II VALVE ALLOWS THE PHYSICIAN TO NON-INVASIVELY ADJUST THE PRESSURE/FLOW PERFORMANCE LEVEL PRE- AND POST-IMPLANTATION WITHOUT THE NEED FOR RADIOGRAPHIC CONFIRMATION IN ORDER TO ADDRESS CHANGING PATIENT NEEDS., CSF SHUNTS(DELTA SHUNT ASSEMBLY, NEONATAL)-NEONATAL DELTA SNAP SHUNT ASSEMBLIES ARE COMPONENTS OF CSF-FLOW CONTROL SHUNT SYSTEMS DESIGNED TO PROVIDE CONTROLLED CSF FLOW FROM THE VENTRICLES OF THE BRAIN INTO THE PERITONEAL CAVITY. A COMPLETE SHUNT ALLOWS DIRECT ACCESS TO THE LATERAL CEREBRAL VENTRICLES. THE DISTAL PERITONEAL CATHETER, WITH ITS OPEN END AND WALL SLITS, IS NOT RECOMMENDED FOR PLACEMENT INTO THE RIGHT ATRIUM OF THE HEART. THE DELTA VALVE COMPONENT IS DESIGNED TO MINIMIZE THE EXCESSIVE REDUCTION OF INTRAVENTRICULAR PRESSURE AND VOLUME DUE TO EXCESSIVE DRAINAGE OF CSF, WHICH MAY BE CAUSED BY THE SIPHONING EFFECT OF HYDROSTATIC PRESSURE OF THE DISTAL CATHETER. THE SIPHON EFFECT MAY BE CREATED BY THE ELEVATION OF THE VENTRICULAR CATHETER WITH RESPECT TO THE DISTAL CATHETER (I.E., WHEN THE PATIENT IS HELD ERECT). THE NEONATAL DELTA SNAP SHUNT ASSEMBLY IS RECOMMENDED FOR USE IN PREMATURE INFANTS IN WHOM THE SMALL-SIZED VALVE IS INDICATED.,BIOGLIDE CATHETERS(EDM VENTRICULAR CATHETER WITH BIOGLIDE)-THE EDM VENTRICULAR CATHETERS WITH BIOGLIDE ARE DESIGNED FOR USE AS THE PROXIMAL COMPONENT FOR CEREBROSPINAL FLUID (CSF) DRAINAGE AND/OR MONITORING FROM THE LATERAL VENTRICLES OF THE BRAIN.,BIOGLIDE CATHETERS(VENTRICULAR CATHETER WITH BIOGLIDE)-THE VENTRICULAR CATHETER WITH BIOGLIDE IS DESIGNED AS A PROXIMAL COMPONENT OF THE SHUNT FOR USE IN SHUNTING CEREBROSPINAL FLUID (CSF) FROM THE LATERAL VENTRICLE OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR TO THE PERITONEAL CAVITY.,BIOGLIDE CATHETERS(PERITONEAL CATHETER WITH BIOGLIDE)-THE PERITONEAL CATHETER WITH BIOGLIDE IS DESIGNED AS THE DISTAL COMPONENT OF A SHUNT FOR USE IN SHUNTING CSF FROM THE LATERAL VENTRICLES OF THE BRAIN INTO

		THE PERITONEAL CAVITY. IT IS NOT RECOMMENDED FOR PLACEMENT INTO THE RIGHT ATRIUM OF THE HEART. PS MEDICAL® DISTAL CATHETERS ARE DESIGNED AS DISTAL COMPONENTS OF CSF-FLOW CONTROL SHUNTS FOR USE IN SHUNTING CEREBROSPINAL FLUID FROM THE VENTRICLES OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR TO THE PERITONEAL CAVITY. THE REDUCED-TIP CATHETER IS RECOMMENDED FOR USE WITH PATIENTS IN WHOM THE CATHETER IS TO BE PLACED IN A VESSEL WITH A LUMEN TOO SMALL TO ACCEPT LARGER DIAMETER CATHETERS. THE OPEN TIP DISTAL CATHETERS ARE NOT RECOMMENDED FOR PLACEMENT INTO THE RIGHT ATRIUM OF THE HEART.,STRATA ADJUSTABLE SHUNTS (STRATA NSC SHUNT ASSEMBLY)-THE STRATA NSC VALVE IS A SHUNT COMPONENT DESIGNED TO PROVIDE CONTINUED CEREBROSPINAL FLUID (CSF) FLOW FROM THE VENTRICLES OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR THE PERITONEAL CAVITY. THE STRATA NSC VALVE ALLOWS THE PHYSICIAN TO NON-INVASIVELY ADJUST THE PRESSURE/FLOW PERFORMANCE LEVEL PRE- AND POST-IMPLANTATION WITHOUT THE NEED FOR RADIOGRAPHIC CONFIRMATION IN ORDER TO ADDRESS CHANGING PATIENT NEEDS.,VENTRICULAR CATHETER(INNERVISION VENTRICULAR CATHETER WITH BIOGLIDE)-THE INNERVISION VENTRICULAR CATHETER WITH BIOGLIDE IS DESIGNED FOR USE WITH THE NEUROPEN ENDOSCOPE OR OTHER COMPATIBLE MEDTRONIC NEUROSURGERY ENDOSCOPE WHEN THE PHYSICIAN DESIRES DIRECT VISION FROM THE TIP OF A VENTRICULAR CATHETER DURING ITS PLACEMENT. DIRECT VISION FACILITATES PLACEMENT OF THE CATHETER TIP AT A SPECIFIC INTRAVENTRICULAR LOCATION. THE CATHETER IS DESIGNED TO BE THE PROXIMAL COMPONENT OF A CSF-FLOW CONTROL SHUNT FOR USE IN SHUNTING CEREBROSPINAL FLUID FROM THE VENTRICLES OF THE BRAIN INTO THE RIGHT ATRIUM OF THE HEART OR TO THE PERITONEAL CAVITY.
2716	IMP/MD/2021/000484	1.License Holder Name: AARK PHARMACEUTICALS 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DEEP BRAIN STIMULATION SYSTEM(SCENERAY)-THE DBS SYSTEM IS USED TO DELIVER ELECTRICAL STIMULATION TO THE SUBTHALAMIC NUCLEUS (STN) AND IS INDICATED AS AN ADJUNCTIVE THERAPY IN REDUCING SOME OF THE SYMPTOMS OF ADVANCED, LEVODOPA-RESPONSIVE PARKINSON'S DISEASE THAT ARE NOT ADEQUATELY CONTROLLED WITH MEDICATION.

2717	IMP/MD/2021/000485	1.License Holder Name: M/S ASIA ACTUAL INDIA (OPC) PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:AUTOMATED EXTERNAL DEFIBRILLATOR(LIFELINE)-THE DDU-100 AUTOMATED EXTERNAL DEFIBRILLATORS (AEDS) IS INDICATED FOR USE ON VICTIMS OF SUDDEN CARDIAC ARREST (SCA) WHO ARE: • UNCONSCIOUS AND UNRESPONSIVE • NOT BREATHING OR NOT BREATHING NORMALLY FOR PATIENTS UNDER 8 YEARS OLD, OR WEIGHING LESS THAN 55 LBS (25 KG), USE CHILD/INFANT DEFIBRILLATION PADS, IF AVAILABLE. DO NOT DELAY THERAPY TO DETERMINE EXACT AGE OR WEIGHT. APPLY THE PADS AS SHOWN FOR A CHILD/INFANT AND USE THE AED. FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN,AUTOMATED EXTERNAL DEFIBRILLATOR(LIFELINE VIEW)-THE DDU-2000 SERIES AUTOMATED EXTERNAL DEFIBRILLATOR (AED) IS INDICATED FOR USE ON VICTIMS OF SUDDEN CARDIAC ARREST (SCA) WHO ARE: • UNCONSCIOUS AND UNRESPONSIVE • NOT BREATHING OR NOT BREATHING NORMALLY FOR PATIENTS UNDER 8 YEARS OLD, OR WEIGHING LESS THAN 55 LBS (25 KG), USE CHILD/ INFANT DEFIBRILLATION PADS, IF AVAILABLE. DO NOT DELAY THERAPY TO DETERMINE EXACT AGE OR WEIGHT. APPLY THE PADS AS SHOWN FOR A CHILD/INFANT AND USE THE AED. FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN,AUTOMATED EXTERNAL DEFIBRILLATOR(LIFELINE ECG)-THE DDU-2000 SERIES AUTOMATED EXTERNAL DEFIBRILLATOR (AED) IS INDICATED FOR USE ON VICTIMS OF SUDDEN CARDIAC ARREST (SCA) WHO ARE: • UNCONSCIOUS AND UNRESPONSIVE • NOT BREATHING OR NOT BREATHING NORMALLY FOR PATIENTS UNDER 8 YEARS OLD, OR WEIGHING LESS THAN 55 LBS (25 KG), USE CHILD/ INFANT DEFIBRILLATION PADS, IF AVAILABLE. DO NOT DELAY THERAPY TO DETERMINE EXACT AGE OR WEIGHT. APPLY THE PADS AS SHOWN FOR A CHILD/INFANT AND USE THE AED. FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.,AUTOMATED EXTERNAL DEFIBRILLATOR(LIFELINE AUTO)-THE DDU-120 AUTOMATED EXTERNAL DEFIBRILLATORS (AEDS) IS INDICATED FOR USE ON VICTIMS OF SUDDEN CARDIAC ARREST (SCA) WHO ARE: • UNCONSCIOUS AND UNRESPONSIVE • NOT BREATHING OR NOT BREATHING NORMALLY FOR PATIENTS UNDER 8 YEARS OLD, OR WEIGHING LESS THAN 55 LBS (25 KG), USE CHILD/INFANT DEFIBRILLATION PADS, IF AVAILABLE. DO NOT DELAY THERAPY TO DETERMINE EXACT AGE OR WEIGHT. APPLY THE PADS AS SHOWN FOR A CHILD/INFANT AND USE THE AED. FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.,AUTOMATED EXTERNAL DEFIBRILLATOR(LIFELINE PRO)-

		THE DDU-2000 SERIES AUTOMATED EXTERNAL DEFIBRILLATOR (AED) IS INDICATED FOR USE ON VICTIMS OF SUDDEN CARDIAC ARREST (SCA) WHO ARE: • UNCONSCIOUS AND UNRESPONSIVE • NOT BREATHING OR NOT BREATHING NORMALLY FOR PATIENTS UNDER 8 YEARS OLD, OR WEIGHING LESS THAN 55 LBS (25 KG), USE CHILD/ INFANT DEFIBRILLATION PADS, IF AVAILABLE. DO NOT DELAY THERAPY TO DETERMINE EXACT AGE OR WEIGHT. APPLY THE PADS AS SHOWN FOR A CHILD/INFANT AND USE THE AED. FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.
2718	IMP/MD/2021/000486	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COLLAGEN DRESSING (ENDOFORM® ANTIMICROBIAL DERMAL TEMPLATE)-ENDOFORM® ANTIMICROBIAL DERMAL TEMPLATE IS A STERILE, SINGLE USE OVINE FORESTOMACH-DERIVED EXTRACELLULAR MATRIX INTENDED TO COVER, PROTECT, AND PROVIDE A MOIST WOUND ENVIRONMENT, COLLAGEN DRESSING/COLLAGEN MESH(MYRIAD™)-MYRIAD IS INTENDED FOR APPLICATIONS IN PLASTIC AND RECONSTRUCTIVE SURGERY OR TO COVER, PROTECT, AND PROVIDE A MOIST WOUND ENVIRONMENT. THE DEVICE MAY BE FIXED, VIA SUTURES, STAPLES, OR TACKS TO THE SURROUNDING TISSUE, IF DESIRED.,COLLAGEN DRESSING(ENDOFORM® NATURAL DERMAL TEMPLATE)-ENDOFORM® NATURAL DERMAL TEMPLATE IS A STERILE, SINGLE USE OVINE FORESTOMACH-DERIVED EXTRACELLULAR MATRIX INTENDED TO COVER, PROTECT, AND PROVIDE A MOIST WOUND ENVIRONMENT.

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2719	IMP/MD/2021/000487	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MALE EXTERNAL CATHETER(ULTRAFLEX)-THE SELF-ADHERING MALE EXTERNAL CATHETER IS DESIGNED FOR THE MANAGEMENT OF ADULT MALE URINARY INCONTINENCE.,INTERMITTENT CATHETER(PERSONAL CATHETER ANTIBACTERIAL)-THE CATHETER IS INTENDED FOR URINARY BLADDER DRAINAGE IN ADULT MALES AND FEMALES REQUIRING CATHETERIZATION FOR MANAGEMENT OF INCONTINENCE, VOIDING DYSFUNCTION, AND SURGICAL PROCEDURES. EFFICACY OF THE CATHETER IN PREVENTING URINARY TRACT INFECTION DURING INTERMITTENT USE HAS NOT BEEN ESTABLISHED. THE DEVICE IS NOT INTENDED TO BE USED AS A TREATMENT FOR ACTIVE URINARY TRACT INFECTION,INTERMITTENT CATHETER(PERSONAL CATHETER)-URINARY CATHETERS ARE INTENDED FOR USE FOR BLADDER MANAGEMENT INCLUDING URINE DRAINAGE, COLLECTION AND MEASUREMENT.
2720	IMP/MD/2021/000488	1.License Holder Name: INDIA MEDTRONIC PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:PEDICLE ACCESS NEEDLE (PAK/XPAK NEEDLE)-THE PAK/XPAK NEEDLE IS INTENDED TO PUNCTURE AND CREATE ACCESS TO THE VERTEBRAL BODY VIA THE PEDICLE.

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2721	IMP/MD/2021/000489	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CATHETER(UROFORCE BALLOON DILATION CATHETER)-RECOMMENDED FOR DILATION OF THE URINARY TRACT,TEMPORARY PACING ELECTRODE CATHETER (WITHOUT BALLOON)(SEMI-FLOATING)-BARD TEMPORARY PACING CATHETERS ARE DESIGNED TO TRANSMIT AN ELECTRICAL SIGNAL FROM AN EXTERNAL PULSE GENERATOR TO THE HEART OR FROM THE HEART TO A MONITORING DEVICE. WHEN AN INTERNAL LUMEN IS PRESENT (OTHER THAN THE ONE USED FOR BALLOON INFLATION), IT MAY BE USED FOR FLUID INFUSION, PRESSURE MONITORING, OR BLOOD SAMPLING.,TEMPORARY PACING ELECTRODE CATHETER (WITHOUT BALLOON)(NBIH)-BARD TEMPORARY PACING CATHETERS ARE DESIGNED TO TRANSMIT AN ELECTRICAL SIGNAL FROM AN EXTERNAL PULSE GENERATOR TO THE HEART OR FROM THE HEART TO A MONITORING DEVICE. WHEN AN INTERNAL LUMEN IS PRESENT (OTHER THAN THE ONE USED FOR BALLOON INFLATION), IT MAY BE USED FOR FLUID INFUSION, PRESSURE MONITORING, OR BLOOD SAMPLING.,TEMPORARY PACING ELECTRODE CATHETER (WITH BALLOON)(BALLOON BIPOLAR ELECTRODE CATHETER)-BARD TEMPORARY PACING CATHETERS ARE DESIGNED TO TRANSMIT AN ELECTRICAL SIGNAL FROM AN EXTERNAL PULSE GENERATOR TO THE HEART OR FROM THE HEART TO A MONITORING DEVICE. WHEN AN INTERNAL LUMEN IS PRESENT (OTHER THAN THE ONE USED FOR BALLOON INFLATION), IT MAY BE USED FOR FLUID INFUSION, PRESSURE MONITORING, OR BLOOD SAMPLING.,GUIDEWIRE(BARD HYDRO-GLIDE GUIDEWIRE)-BARD® GUIDEWIRES ARE INDICATED TO PROVIDE TRANSURETHRAL AND/OR PERCUTANEOUS ACCESS INTO THE BLADDER, URETER OR RENAL PELVIS.

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2722	IMP/MD/2021/000490	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:SLEEVE(ENDOPATH XCEL) -THE ENDOPATH XCEL UNIVERSAL TROCAR STABILITY SLEEVE HAS APPLICATIONS IN THORACIC, GYNECOLOGIC LAPAROSCOPY AND OTHER ABDOMINAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS.,TROCAR(ENDOPATH XCEL)-THE ENDOPATH® XCEL™ BLADELESS TROCAR HAS APPLICATIONS IN ABDOMINAL, THORACIC, AND GYNECOLOGIC MINIMALLY INVASIVE SURGICAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS. THE TROCAR MAY BE USED WITH OR WITHOUT VISUALIZATION FOR PRIMARY AND SECONDARY INSERTIONS.,ABLATION DEVICE(HARMONIC ACE®)-THE HARMONIC ACE® SHEARS + ADAPTIVE TISSUE TECHNOLOGY ARE INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENTS CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS AND STEEL SCALPELS IN GENERAL, PLASTIC, PEDIATRIC, GYNECOLOGIC, UROLOGIC, THORACIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE) AND OTHER OPEN AND ENDOSCOPIC PROCEDURES.,ABLATION DEVICE(HARMONIC®)-THE HARMONIC HD 1000I SHEARS INSTRUMENT IS INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENTS CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS AND STEEL SCALPELS IN GENERAL, PLASTIC, PEDIATRIC, GYNECOLOGIC, UROLOGIC, THORACIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE), SEALING AND TRANSECTION OF LYMPHATIC VESSELS, AND OTHER OPEN AND ENDOSCOPIC PROCEDURES. THE INSTRUMENTS ALLOW FOR THE COAGULATION OF VESSELS UP TO AND INCLUDING 7 MM IN DIAMETER, USING THE ENERGY BUTTON WITH ADVANCED HEMOSTASIS.,TROCAR(ENDOPATH BASX)-THE ENDOPATH BASX™ BLADELESS TROCAR HAS APPLICATIONS IN ABDOMINAL AND GYNECOLOGIC MINIMALLY INVASIVE SURGICAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS., TROCAR(ENDOPATH XCEL)-THE ENDOPATH® XCEL™ BLADELESS TROCAR HAS APPLICATIONS IN ABDOMINAL, THORACIC, AND GYNECOLOGIC MINIMALLY INVASIVE SURGICAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS. THE TROCAR MAY BE USED WITH OR WITHOUT VISUALIZATION FOR PRIMARY AND SECONDARY INSERTIONS.,ABLATION DEVICE (HARMONIC FOCUS®)-THE HARMONIC FOCUS® LONG SHEARS + ADAPTIVE TISSUE TECHNOLOGY ARE INDICATED FOR SOFT TISSUE

	INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENT CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS, AND STEEL SCALPELS IN GENERAL, OTORHINOLARYNGOLOGIC (ENT), PLASTIC, PEDIATRIC, GYNECOLOGIC, UROLOGIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE) AND OTHER OPEN PROCEDURES.,SLEEVE(BASX)-THE BASX™ BLADELESS TROCAR HAS APPLICATIONS IN ABDOMINAL AND GYNECOLOGIC MINIMALLY INVASIVE SURGICAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS.,MULTIPLE CLIP APPLIER(LIGACLIP)-THE LIGACLIP ENDOSCOPIC ROTATING MULTIPLE CLIP APPLIER IS INTENDED FOR USE ON TUBULAR STRUCTURES OR VESSELS WHEREVER A METAL LIGATING CLIP IS INDICATED. THE TISSUE BEING LIGATED SHOULD BE CONSISTENT WITH THE SIZE OF THE CLIP.,SLEEVE(ENDOPATH XCEL)-THE ENDOPATH XCEL UNIVERSAL TROCAR STABILITY SLEEVE HAS APPLICATIONS IN THORACIC, GYNECOLOGIC LAPAROSCOPY AND OTHER ABDOMINAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS.,MULTIPLE CLIP APPLIER(LIGAMAX) -THE 5 MM ENDOSCOPIC MULTIPLE CLIP APPLIER IS INTENDED FOR USE ON TUBULAR STRUCTURES OR VESSELS WHEREVER A METAL LIGATING CLIP IS INDICATED.,MULTIPLE CLIP APPLIER(LIGACLIP)- THE LIGACLIP MCA MULTIPLE CLIP APPLIER HAS APPLICATION FOR USE ON VESSELS OR OTHER TUBULAR STRUCTURES WHEREVER A METAL LIGATING CLIP IS INDICATED. THE TISSUE LIGATED SHOULD BE CONSISTENT WITH THE SIZE OF THE CLIP.,ABLATION DEVICE (HARMONIC ACE®)-THE HARMONIC ACE®+7, 5 MM DIAMETER SHEARS WITH ADVANCED HEMOSTASIS ARE INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENTS CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS AND STEEL SCALPELS IN GENERAL, PLASTIC, PEDIATRIC, GYNECOLOGIC, UROLOGIC, THORACIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE), SEALING AND TRANSECTION OF LYMPHATIC VESSELS, AND OTHER OPEN AND ENDOSCOPIC PROCEDURES. THE INSTRUMENTS ALLOW FOR THE COAGULATION OF VESSELS UP TO AND INCLUDING 7 MM IN DIAMETER, USING THE ADVANCED HEMOSTASIS HAND CONTROL BUTTON.,ELECTROSURGERY PROBE(ENDOPATH®)-THE ENDOPATH ELECTROSURGERY PROBE PLUS II SYSTEM HAS APPLICATION IN MINIMALLY INVASIVE PROCEDURES TO FACILITATE TISSUE DISSECTION, COAGULATION, IRRIGATION, AND FLUID EVACUATION THROUGH A COMMON TROCAR SLEEVE.,ABLATION DEVICE (HARMONIC SYNERGY®)-THE HARMONIC SYNERGY CURVED BLADE

	INSTRUMENTS ARE INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENT CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS, AND STEEL SCALPELS IN GENERAL, PLASTIC, GYNECOLOGIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE) AND THORACIC SURGERY., ABLATION DEVICE(HARMONIC SYNERGY®)-THE HARMONIC SYNERGY DISSECTING HOOK INSTRUMENTS ARE INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENTS CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS, AND STEEL SCALPELS IN GENERAL, PLASTIC, GYNECOLOGIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE), ENT (EARS, NOSE, THROAT), INCLUDING TISSUES OF THE SOFT PALATE, ORAL STRUCTURES, AND OROPHARYNGEAL AIRWAY, AND THORACIC SURGERY, INCLUDING MOBILIZATION OF THE INTERNAL MAMMARY ARTERY (IMA).,TROCAR(ENDOPATH XCEL)-THE ENDOPATH XCEL BLADELESS TROCAR HAS APPLICATIONS IN ABDOMINAL, THORACIC, AND GYNECOLOGIC MINIMALLY INVASIVE SURGICAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS. THE TROCAR MAY BE USED WITH OR WITHOUT VISUALIZATION FOR PRIMARY AND SECONDARY INSERTIONS.,TROCAR(ENDOPATH XCEL)-THE ENDOPATH® XCEL DILATING TIP TROCAR HAS APPLICATIONS IN THORACIC, GYNECOLOGIC LAPAROSCOPY AND OTHER ABDOMINAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS.,SLEEVE(ENDOPATH XCEL)-THE ENDOPATH XCEL UNIVERSAL TROCAR STABILITY SLEEVE HAS APPLICATIONS IN THORACIC, GYNECOLOGIC LAPAROSCOPY AND OTHER ABDOMINAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS.,ABLATION DEVICE(HARMONIC FOCUS®)-THE HARMONIC FOCUS® SHEARS + ADAPTIVE TISSUE TECHNOLOGY ARE INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENT CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS, AND STEEL SCALPELS IN GENERAL, OTORHINOLARYNGOLOGIC (ENT), PLASTIC, PEDIATRIC, GYNECOLOGIC, UROLOGIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE) AND OTHER OPEN PROCEDURES.,TISSUE SEALING DEVICE(ENSEAL®)-THE ENSEAL X1 LARGE JAW TISSUE SEALER INSTRUMENT IS A DEDICATED BIPOLAR ELECTROSURGICAL INSTRUMENT INTENDED FOR USE IN OPEN SURGICAL PROCEDURES WHERE LIGATION AND DIVISION OF VESSELS IS DESIRED. IT IS A BIPOLAR INSTRUMENT FOR USE WITH

		THE ETHICON GENERATOR G11 (GEN11). IT IS INTENDED FOR USE DURING OPEN SURGERY TO CUT AND SEAL VESSELS, CUT, GRASP, AND DISSECT TISSUE DURING SURGERY. INDICATIONS FOR USE INCLUDE OPEN GENERAL, GYNECOLOGIC, UROLOGIC, THORACIC, AND VASCULAR PROCEDURES. THESE PROCEDURES INCLUDE HYSTERECTOMIES, COLECTOMIES, NISSEN FUNDOPLICATION, ADHESIOLYSIS, OOPHORECTOMIES, ETC. THE DEVICES CAN BE USED ON VESSELS (ARTERIES, VEINS, PULMONARY VASCULATURE, LYMPHATICS) UP TO AND INCLUDING 7 MM AND TISSUE BUNDLES., TROCAR(ENDOPATH XCEL)-THE ENDOPATH® XCEL™ BLUNT TIP TROCAR HAS APPLICATION IN THORACIC, GYNECOLOGIC, LAPAROSCOPIC AND OTHER ABDOMINAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR MINIMALLY INVASIVE INSTRUMENTS.,TROCAR(ENDOPATH XCEL)-THE ENDOPATH XCEL BLADELESS TROCAR HAS APPLICATIONS IN ABDOMINAL, THORACIC, AND GYNECOLOGIC MINIMALLY INVASIVE SURGICAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS. THE TROCAR MAY BE USED WITH OR WITHOUT VISUALIZATION FOR PRIMARY AND SECONDARY INSERTIONS.,ABLATION DEVICE (HARMONIC)-THE HARMONIC 5 MM INSTRUMENT IS INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENT CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS, AND STEEL SCALPELS IN GENERAL, PLASTIC, GYNECOLOGIC, EXPOSURE TO ORTHOPEDIC STRUCTURES (SUCH AS SPINE AND JOINT SPACE), AND THORACIC SURGERY, INCLUDING MOBILIZATION OF THE INTERNAL MAMMARY ARTERY (IMA).
2723	IMP/MD/2021/000491	1.License Holder Name: FLORENCE MEDTECH 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER SETS(ALTIUS)-CENTRAL VENOUS CATHETER SETS ARE A COMBINATION OF STERILE SINGLE USE SURGICALLY INVASIVE DEVICES INTENDED FOR SHORT TERM USE. CENTRAL VENOUS CATHETERS ARE INDICATED FOR USE IN ATTAINING ACCESS TO THE CENTRAL VENOUS SYSTEM, AND ARE USED FOR THE PURPOSE OF: • ADMINISTRATION OF VASOACTIVE/INOTROPIC DRUGS, • ADMINISTRATION OF INCOMPATIBLE MEDICATIONS, • ADMINISTRATION OF HYPERTONIC SOLUTIONS INCLUDING TOTAL PARENTAL NUTRITION, • FREQUENT BLOOD SAMPLING, • BLOOD TRANSFUSION, • MEASUREMENT OF CENTRAL VENOUS PRESSURE (CVP).

2724	IMP/MD/2021/000493	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DIGITAL MAMMOGRAPHY SYSTEM(3DIMENSIONS SYSTEM & ACCESSORIES)-THE HOLOGIC 3DIMENSIONS SYSTEM GENERATES DIGITAL MAMMOGRAPHIC IMAGES THAT CAN BE USED FOR SCREENING AND DIAGNOSIS OF BREAST CANCER. THE 3DIMENSIONS (2D OR 3D) SYSTEM IS INTENDED FOR USE IN THE SAME CLINICAL APPLICATIONS AS A 2D MAMMOGRAPHY SYSTEM FOR SCREENING MAMMOGRAMS. SPECIFICALLY, THE 3DIMENSIONS SYSTEM CAN BE USED TO GENERATE 2D DIGITAL MAMMOGRAMS AND 3D MAMMOGRAMS. EACH SCREENING EXAMINATION MAY CONSIST OF: • A 2D FFDM IMAGE SET, OR • A 2D AND 3D IMAGE SET, WHERE THE 2D IMAGE CAN BE EITHER A FFDM OR A 2D IMAGE GENERATED FROM THE 3D IMAGE SET THE 3DIMENSIONS SYSTEM MAY ALSO BE USED FOR ADDITIONAL DIAGNOSTIC WORKUP OF THE BREAST.,DIGITAL MAMMOGRAPHY SYSTEM(SELENIA DIMENSIONS 3D SYSTEM & ACCESSORIES)-THE HOLOGIC SELENIA DIMENSIONS SYSTEM GENERATES DIGITAL MAMMOGRAPHIC IMAGES THAT CAN BE USED FOR SCREENING AND DIAGNOSIS OF BREAST CANCER. THE SELENIA DIMENSIONS (2D OR 3D) SYSTEM IS INTENDED FOR USE IN THE SAME CLINICAL APPLICATIONS AS A 2D MAMMOGRAPHY SYSTEM FOR SCREENING MAMMOGRAMS. SPECIFICALLY, THE SELENIA DIMENSIONS SYSTEM CAN BE USED TO GENERATE 2D DIGITAL MAMMOGRAMS AND 3D MAMMOGRAMS. EACH SCREENING EXAMINATION MAY CONSIST OF: • A 2D FFDM IMAGE SET, OR • A 2D AND 3D IMAGE SET, WHERE THE 2D IMAGE CAN BE EITHER A FFDM OR A 2D IMAGE GENERATED FROM THE 3D IMAGE SET THE SELENIA DIMENSIONS SYSTEM MAY ALSO BE USED FOR ADDITIONAL DIAGNOSTIC WORKUP OF THE BREAST., DIGITAL MAMMOGRAPHY SYSTEM(SELENIA DIMENSIONS 2D SYSTEM & ACCESSSORIES)-THE HOLOGIC SELENIA DIMENSIONS SYSTEM GENERATES DIGITAL MAMMOGRAPHIC IMAGES THAT CAN BE USED FOR SCREENING AND DIAGNOSIS OF BREAST CANCER. THE SELENIA DIMENSIONS (2D OR 3D) SYSTEM IS INTENDED FOR USE IN THE SAME CLINICAL APPLICATIONS AS A 2D MAMMOGRAPHY SYSTEM FOR SCREENING MAMMOGRAMS. SPECIFICALLY, THE SELENIA DIMENSIONS SYSTEM CAN BE USED TO GENERATE 2D DIGITAL MAMMOGRAMS AND 3D MAMMOGRAMS. EACH SCREENING EXAMINATION MAY CONSIST OF: • A 2D FFDM IMAGE SET, OR • A 2D AND 3D IMAGE SET, WHERE THE 2D IMAGE CAN BE EITHER A FFDM OR A 2D IMAGE GENERATED FROM THE 3D IMAGE SET THE SELENIA DIMENSIONS SYSTEM MAY ALSO BE USED FOR ADDITIONAL DIAGNOSTIC WORKUP OF THE BREAST.

2725	IMP/MD/2021/000494	1.License Holder Name: MERIL LIFE SCIENCES PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:FIXED BOVINE PERICARDIUM-FOR FURTHER MANUFACTURING USE ONLY
2726	IMP/MD/2021/000496	1.License Holder Name: MEHAR HEALTHCARE CORPORATION 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:ARM TYPE ELECTRONIC BLOOD PRESSURE MONITOR(MEHAR READY MATIC MH 787)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.
2727	IMP/MD/2021/000497	1.License Holder Name: BOSTON IVY HEALTHCARE SOLUTION PVT. LTD. 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMPUTED TOMOGRAPHY X-RAY SYSTEM(UNITED IMAGING)-THE UCT COMPUTED TOMOGRAPHY X-RAY SYSTEM UCT520/UCT528 IS A COMPUTED TOMOGRAPHY X-RAY SYSTEM INTENDED TO PRODUCE CROSSSECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA TAKEN AT DIFFERENT ANGLES AND PLANES AND INDICATED FOR THE WHOLE BODY (INCLUDING HEAD, NECK, VASCULAR).
2728	IMP/MD/2021/000499	1.License Holder Name: SIMPLADENT IMPLANT SOLUTIONS PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DR. IHDE DENTAL AG IMPLANT SYSTEM(BCS)-ENDOSSEOUS JAW-IMPLANT SYSTEM,DR. IHDE DENTAL AG IMPLANT SYSTEM(KOS MICRO, KOS PLUS, KOS X, KOS CLASSIC)-ENDOSSEOUS JAW-IMPLANT SYSTEM

2729	IMP/MD/2021/000500	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOPSY NEEDLE(BARD® MISSION DISPOSABLE CORE BIOPSY INSTRUMENT)-THE BARD® MISSION™ DISPOSABLE CORE BIOPSY INSTRUMENT IS INTENDED FOR USE IN OBTAINING BIOPSY SAMPLES FROM SOFT TISSUES SUCH AS FROM THE LUNG, LIVER, SPLEEN, KIDNEY, PROSTATE, LYMPH NODES, BREAST, THYROID, AND VARIOUS SOFT TISSUE TUMORS,DISPOSABLE CORE BIOPSY INSTRUMENT(BARD® MARQUEE® DISPOSABLE CORE BIOPSY INSTRUMENT)-THE BARD® MARQUEE® DISPOSABLE CORE BIOPSY INSTRUMENT ARE INTENDED FOR USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS LIVER, KIDNEY, PROSTATE, SPLEEN, LYMPH NODES AND VARIOUS SOFT TISSUE TUMORS. IT IS NOT INTENDED FOR USE IN BONE.,BIOPSY NEEDLE(BARD® MISSION DISPOSABLE CORE BIOPSY INSTRUMENT KIT)-THE BARD® MISSION™ DISPOSABLE CORE BIOPSY INSTRUMENT KIT IS INTENDED FOR USE IN OBTAINING BIOPSY SAMPLES FROM SOFT TISSUES SUCH AS FROM THE LUNG, LIVER, SPLEEN, KIDNEY, PROSTATE, LYMPH NODES, BREAST, THYROID, AND VARIOUS SOFT TISSUE TUMORS., DISPOSABLE CORE BIOPSY INSTRUMENT KIT(BARD® MARQUEE® DISPOSABLE CORE BIOPSY INSTRUMENT KIT)-THE BARD® MARQUEE® DISPOSABLE CORE BIOPSY INSTRUMENT KIT ARE INTENDED FOR USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS LIVER, KIDNEY, PROSTATE, SPLEEN, LYMPH NODES AND VARIOUS SOFT TISSUE TUMORS. IT IS NOT INTENDED FOR USE IN BONE.

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2730	IMP/MD/2021/000501	1.License Holder Name: A. MENARINI INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:HIGHLY CROSS-LINKED SODIUM HYALURONATE 23 MG/ ML WITH 0.3% LIDOCAINE HYDROCHLORIDE(DEFINISSE RESTORE FILLER + LIDOCAINE)-THE DEVICE IS INDICATED TO CORRECT MODERATE TO SEVERE NASOLABIAL FOLDS. IT IS INDICATED TO BE INJECTED INTO THE DEEP DERMIS OR SUBCUTIS. THE INTENDED PURPOSE OF THE DEVICE IS TO CREATE VOLUME IN ORDER TO CORRECT WRINKLES AND FOLDS, AND TO CORRECT MODERATE TO SEVERE NASOLABIAL FOLDS TO TREAT SIGNS OF AGEING.,CROSS-LINKED SODIUM HYALURONATE 23 MG/ML WITH 0.3% LIDOCAINE HYDROCHLORIDE (DEFINISSE TOUCH FILLER + LIDOCAINE)-THE DEVICE IS INDICATED TO CORRECT MODERATE TO SEVERE NASOLABIAL FOLDS AND TO INCREASE LIP VOLUME. IT IS INDICATED TO BE INJECTED INTO THE MID TO DEEP DERMIS AND SUBMUCOSA. THE INTENDED PURPOSE OF THE DEVICE IS TO CREATE VOLUME IN ORDER TO CORRECT WRINKLES AND FOLDS, TO CORRECT MODERATE TO SEVERE NASOLABIAL FOLDS, AND TO IMPROVE LIP VOLUME TO TREAT SIGNS OF AGEING.

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2731	IMP/MD/2021/000502	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAGNETOM AMIRA (MAGNETOM AMIRA)-THE MAGNETOM MR SYSTEMS ARE INTENDED FOR USE PER GMDN CODE 37654, FULL-BODY MAGNETIC RESONANCE IMAGING (MRI) SYSTEM. MAGNETOM MR SYSTEM IS INDICATED FOR USE AS A MAGNETIC RESONANCE DIAGNOSTIC DEVICE (MRDD) THAT PRODUCES TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-SECTIONAL IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, AND THAT DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HEAD, BODY, OR EXTREMITIES. OTHER PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA MAY ALSO BE PRODUCED. DEPENDING ON THE REGION OF INTEREST, CONTRAST AGENTS MAY BE USED. THESE IMAGES AND/OR SPECTRA AND THE PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS. MAGNETOM MR SYSTEM MAY ALSO BE USED FOR IMAGING DURING INTERVENTIONAL PROCEDURES WHEN PERFORMED WITH MR COMPATIBLE DEVICES SUCH AS IN-ROOM DISPLAYS AND MR SAFE BIOPSY NEEDLES. ,MAGNETOM SEMPRA(MAGNETOM SEMPRA)-THE MAGNETOM MR SYSTEMS ARE INTENDED FOR USE PER GMDN CODE 37654, FULL-BODY MAGNETIC RESONANCE IMAGING (MRI) SYSTEM. MAGNETOM MR SYSTEM IS INDICATED FOR USE AS A MAGNETIC RESONANCE DIAGNOSTIC DEVICE (MRDD) THAT PRODUCES TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-SECTIONAL IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, AND THAT DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HEAD, BODY, OR EXTREMITIES. OTHER PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA MAY ALSO BE PRODUCED. DEPENDING ON THE REGION OF INTEREST, CONTRAST AGENTS MAY BE USED. THESE IMAGES AND/OR SPECTRA AND THE PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS. MAGNETOM MR SYSTEM MAY ALSO BE USED FOR IMAGING DURING INTERVENTIONAL PROCEDURES WHEN PERFORMED WITH MR COMPATIBLE DEVICES SUCH AS IN-ROOM DISPLAYS AND MR SAFE BIOPSY NEEDLES.,MAGNETOM ESSENZA(MAGNETOM ESSENZA)-THE MAGNETOM MR SYSTEMS ARE INTENDED FOR USE PER GMDN CODE 37654, FULL-BODY MAGNETIC RESONANCE IMAGING (MRI) SYSTEM. MAGNETOM MR SYSTEM IS INDICATED FOR USE AS A MAGNETIC RESONANCE DIAGNOSTIC DEVICE (MRDD) THAT PRODUCES TRANSVERSE, SAGITTAL, CORONAL AND OBLIQUE CROSS-

		SECTIONAL IMAGES, SPECTROSCOPIC IMAGES AND/OR SPECTRA, AND THAT DISPLAYS THE INTERNAL STRUCTURE AND/OR FUNCTION OF THE HEAD, BODY, OR EXTREMITIES. OTHER PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA MAY ALSO BE PRODUCED. DEPENDING ON THE REGION OF INTEREST, CONTRAST AGENTS MAY BE USED. THESE IMAGES AND/OR SPECTRA AND THE PHYSICAL PARAMETERS DERIVED FROM THE IMAGES AND/OR SPECTRA WHEN INTERPRETED BY A TRAINED PHYSICIAN YIELD INFORMATION THAT MAY ASSIST IN DIAGNOSIS. MAGNETOM MR SYSTEM MAY ALSO BE USED FOR IMAGING DURING INTERVENTIONAL PROCEDURES WHEN PERFORMED WITH MR COMPATIBLE DEVICES SUCH AS IN-ROOM DISPLAYS AND MR SAFE BIOPSY NEEDLES.
2732	IMP/MD/2021/000503	1.License Holder Name: ABBOTT HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CONTINUOUS GLUCOSE MONITORING SYSTEM(FREESTYLE LIBRE PRO IQ (READER))-THE FREESTYLE LIBRE PRO IQ CONTINUOUS GLUCOSE MONITORING SYSTEM IS A FACTORY-CALIBRATED CONTINUOUS GLUCOSE RECORDING DEVICE INDICATED FOR THE RETROSPECTIVE DISCOVERY, ANALYSIS AND INTERPRETATION OF GLYCAEMIC VARIABILITY IN PERSONS AGED 4 AND OLDER UNDER THE SUPERVISION OF A HEALTHCARE PROFESSIONAL. THE SYSTEM COLLECTS AND PROCESSES DATA FOR AIDING IN THE MANAGEMENT OF A DISEASE OR CONDITION RELATED TO GLYCAEMIC CONTROL. INTERPRETATION OF THE DATA RECORDED BY THE SYSTEM SHOULD BE MADE ONLY BY A QUALIFIED HEALTHCARE PROFESSIONAL BASED ON GLUCOSE TRENDS AND SEVERAL SEQUENTIAL READINGS OVER TIME. THE SYSTEM AIDS IN DETECTING GLUCOSE EXCURSIONS FACILITATING CARE PLAN ADJUSTMENTS. THE SYSTEM IS ALSO INTENDED TO INTERFACE WITH DIGITALLY CONNECTED DEVICES. THE SYSTEM HAS BEEN EVALUATED FOR USE IN PREGNANT WOMEN.
2733	IMP/MD/2021/000504	1.License Holder Name: M/S. PRINCIPIA HEALTHCARE 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DISPOSABLE BLOOD COMPONENT APHERESIS SET(NIGALE)-THE DISPOSABLE BLOOD COMPONENT APHERESIS SET IS INDICATED IN SEPARATION, COLLECTION AND RETURN TRANSFUSION OF HUMAN BLOOD COMPONENTS

2734	IMP/MD/2021/000505	1.License Holder Name: FISHER AND PAYKEL HEALTHCARE INDIA PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:NASAL CANNULA (OXYGEN THERAPY NASAL CANNULA)-A SINGLE USE NASAL CANNULA INTENDED FOR USE WITH A NASAL HIGH FLOW THERAPY SYSTEM TO DELIVER HEATED AND HUMIDIFIED NASAL HIGH FLOW THERAPY TO SPONTANEOUSLY BREATHING PATIENTS WHO REQUIRE BREATHING SUPPORT. ,NASAL CANNULA(OPTIFLOW JUNIOR 2)-A SINGLE USE NASAL CANNULA INTENDED FOR USE WITH A NASAL HIGH FLOW THERAPY SYSTEM TO DELIVER HEATED AND HUMIDIFIED NASAL HIGH FLOW THERAPY TO SPONTANEOUSLY BREATHING PATIENTS WHO REQUIRE BREATHING SUPPORT.,NASAL CANNULA (OPTIFLOW +)-NASAL CANNULA PATIENT INTERFACE FOR DELIVERY OF HUMIDIFIED RESPIRATORY GASES.
2735	IMP/MD/2021/000506	1.License Holder Name: MORULAA HEALTH TECH PVT LTD 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:MAGNETIC RESONANCE GUIDED FOCUSED ULTRASOUND (MRGFUS)(EXABLATE NEURO MODEL 4000 SYSTEM)-INTENDED FOR THERMAL ABLATION OF TARGETS IN THALAMUS, SUBTHALAMUS AND PALLIDUM REGIONS OF THE BRAIN. EXABLATE 4000 TRANSCRANIAL MR GUIDED FOCUSED ULTRASOUND CAN BE USED FOR THE TREATMENT OF NEUROLOGICAL DISORDERS (ESSENTIAL TREMORS, TREMOR DOMINANT IDIOPATHIC PARKINSON'S DISEASE-UNILATERAL) AND NEUROPATHIC PAIN IN THE BRAIN BY HEAT INDUCED FOCUSING USING ULTRASOUND ENERGY UNDER FULL MR PLANNING AND THERMAL IMAGING CONTROL
2736	IMP/MD/2021/000511	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:BIOPSY NEEDLE(BARD TRUGUIDE DISPOSABLE COAXIAL BIOPSY NEEDLE)-INTENDED FOR USE AS A GUIDING NEEDLE IN OBTAINING CORE BIOPSY SAMPLES FROM SOFT TISSUE SUCH AS LIVER, KIDNEY, SPLEEN, LYMPH NODES AND VARIOUS SOFT TISSUE LESIONS

2737	IMP/MD/2021/000512	1.License Holder Name: BECTON DICKINSON INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DRAINAGE CATHETER (NAVARRE PERCUTANEOUS BILIARY DRAINAGE CATHETER)-THIS CATHETER IS INTENDED TO BE USED FOR STANDARD PERCUTANEOUS TRANSHEPATIC BILIARY DRAINAGE PROCEDURES THAT REQUIRE INTERNAL RETENTION (EXAMPLES: OBSTRUCTIVE JAUNDICE, SEPSIS, HEPATIC DECOMPENSATION, AND PREOPERATIVE DECOMPRESSION).,DRAINAGE CATHETER(NAVARRE OPTI-DRAIN MULTI-USE DRAINAGE CATHETER)-THE BARD NAVARRE OPTI-DRAIN MULTI-USE DRAINAGE CATHETER ARE INTENDED TO BE USED FOR ABSCESS, CYST, AND OTHER GENERAL PURPOSE DRAINAGE APPLICATIONS.,DRAINAGE CATHETER(NAVARRE UNIVERSAL DRAINAGE CATHETER)-THE BARD NAVARRE UNIVERSAL DRAINAGE CATHETER WITH NITINOL ARE INTENDED TO BE USED FOR ABSCESS, CYST, AND OTHER GENERAL PURPOSE DRAINAGE APPLICATIONS

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2738	IMP/MD/2021/000513	1.License Holder Name: PHILIPS INDIA LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:COMPUTED TOMOGRAPHY X-RAY SYSTEM(BRILLIANCE ICT)-THE BRILLIANCE ICT AND BRILLIANCE ICT-SP ARE COMPUTED TOMOGRAPHY X-RAY SYSTEMS INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA TAKEN AT DIFFERENT ANGLES AND PLANES. THESE DEVICES MAY INCLUDE SIGNAL ANALYSIS AND DISPLAY EQUIPMENT, PATIENT AND EQUIPMENT SUPPORTS, COMPONENT PARTS, AND ACCESSORIES. THE PATIENT AGE MAY RANGE FROM A NEWBORN TO AN ELDERLY PATIENT. THE PATIENT MAY BE CONSCIOUS, UNCONSCIOUS, OR SEDATED. IN ADDITION TO EXTERNAL MEDICAL DEVICES, THE PATIENT MAY HAVE INTERNAL MEDICAL DEVICES (E.G. PACEMAKER, ORTHOPEDIC IMPLANTS). THE SCAN EITHER MAY BE SCHEDULED OR UNSCHEDULED (E.G. TRAUMA). THE PATIENT GENERALLY DOES NOT INTERACT WITH THE SYSTEM (PRODUCT REQUIREMENTS SPECIFICATION FOR BRILLIANCE ICT, COMPUTED TOMOGRAPHY(INGENUITY CT)-INGENUITY CT SYSTEMS ARE INTENDED FOR USE AS DIAGNOSTIC PATIENT IMAGING DEVICES THAT PRODUCE IMAGES THAT CORRESPOND TO TISSUE DENSITY. THE QUALITY OF THE IMAGES DEPENDS ON THE LEVEL AND AMOUNT OF X-RAY ENERGY DELIVERED TO THE TISSUE. CT IMAGING DISPLAYS BOTH HIGH-DENSITY TISSUE, SUCH AS BONE, AND SOFT TISSUE. WHEN INTERPRETED BY A TRAINED PHYSICIAN, CT IMAGES YIELD USEFUL DIAGNOSTIC INFORMATION. THE SYSTEMS ARE INTENDED FOR USE FOR THE HEAD AND WHOLE BODY. NO PATIENTS ARE CONTRAINDICATED FOR SCANNING ON THE INGENUITY FAMILY OF SCANNERS.,COMPUTED TOMOGRAPHY(BRILLIANCE BIG BORE CT)-BRILLIANCE BIG BORE CT SYSTEM IS INTENDED FOR USE AS A DIAGNOSTIC AND RADIATION TREATMENT PLANNING PATIENT IMAGING DEVICE THAT PRODUCES IMAGES THAT CORRESPOND TO TISSUE DENSITY. THE QUALITY OF THE IMAGES DEPENDS ON THE LEVEL AND AMOUNT OF X-RAY ENERGY DELIVERED TO THE TISSUE. CT IMAGING DISPLAYS BOTH HIGH-DENSITY TISSUE, SUCH AS BONE, AND SOFT TISSUE. WHEN INTERPRETED BY A TRAINED PHYSICIAN, CT IMAGES YIELD USEFUL DIAGNOSTIC INFORMATION. THE SYSTEMS ARE INTENDED FOR USE FOR THE HEAD AND WHOLE BODY. THE 85CM BORE ON THE BRILLIANCE CT BIG BORE CAN ACCOMMODATE PATIENTS THAT MAY HAVE SPECIAL IMMOBILIZATION DEVICES AND ARE POSITIONED IN THE BORE TO SIMULATE THEIR TREATMENT POSTURE. THIS WOULD NOT BE POSSIBLE ON SMALLER BORE (70CM) CT SCANNERS. THE BRILLIANCE CT BIG BORE INCLUDES SOFTWARE TO FACILITATE THE RADIATION ONCOLOGY CT SIMULATION

	PROCESS.,COMPUTED TOMOGRAPHY X-RAY SYSTEM(IQON SPECTRAL CT)-THE IQON SPECTRAL CT IS A COMPUTED TOMOGRAPHY X-RAY SYSTEM INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA TAKEN AT DIFFERENT ANGLES AND PLANES. THIS DEVICE MAY INCLUDE SIGNAL ANALYSIS AND DISPLAY EQUIPMENT, PATIENT AND EQUIPMENT SUPPORTS, COMPONENT PARTS, AND ACCESSORIES. THE IQON SPECTRAL CT SYSTEM ACQUIRES ONE CT DATASET – COMPOSED OF DATA FROM A HIGHER-ENERGY DETECTED XRAY SPECTRUM AND A LOWER-ENERGY DETECTED X-RAY SPECTRUM. THE TWO SPECTRA MAY BE USED TO ANALYZE THE DIFFERENCES IN THE ENERGY DEPENDENCE OF THE ATTENUATION COEFFICIENT OF DIFFERENT MATERIALS. THIS ALLOWS FOR THE GENERATION OF IMAGES AT ENERGIES SELECTED FROM THE AVAILABLE SPECTRUM AND TO PROVIDE INFORMATION ABOUT THE CHEMICAL COMPOSITION OF THE BODY MATERIALS AND/OR CONTRAST AGENTS. ADDITIONALLY, MATERIALS ANALYSIS PROVIDES FOR THE QUANTIFICATION AND GRAPHICAL DISPLAY OF ATTENUATION, MATERIAL DENSITY, AND EFFECTIVE ATOMIC NUMBER.,COMPUTED TOMOGRAPHY X-RAY SYSTEM(VEREOS PET/CT SYSTEM)-THE VEREOS PET/CT SYSTEM IS A DIAGNOSTIC IMAGING DEVICE THAT COMBINES POSITRON EMISSION TOMOGRAPHY (PET) AND X-RAY COMPUTED TOMOGRAPHY (CT) SYSTEMS. THE CT SUBSYSTEM IMAGES ANATOMICAL CROSS-SECTIONS BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA. THE PET SUBSYSTEM IMAGES THE DISTRIBUTION OF PET ANATOMY-SPECIFIC RADIOPHARMACEUTICALS IN THE PATIENT. THE PET/CT SYSTEM IS USED FOR THE PURPOSES OF DETECTING, LOCALIZING, DIAGNOSING, STAGING, RE-STAGING, AND FOLLOW-UP FOR MONITORING THERAPY RESPONSE OF VARIOUS DISEASES IN ONCOLOGY, CARDIOLOGY, AND NEUROLOGY. THE SYSTEM IS INTENDED TO IMAGE THE WHOLE BODY, HEART, BRAIN, LUNG, GASTROINTESTINAL, BONE, LYMPHATIC, AND OTHER MAJOR ORGANS FOR A WIDE RANGE OF PATIENT TYPES, SIZES, AND EXTENT OF DISEASES. BOTH SUBSYSTEMS CAN ALSO BE OPERATED AS FULLY FUNCTIONAL, INDEPENDENT DIAGNOSTIC TOOLS, INCLUDING APPLICATION OF THE CT SCANNER FOR DIAGNOSIS AND FOR USE IN RADIATION THERAPY PLANNING.

2739	IMP/MD/2021/000514	1.License Holder Name: INNVOLUTION HEALTHCARE PVT. LTD., 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:CORONARY AND PERIPHERAL IMAGING CATHETER(ACIST KODAMA CORONARY AND PERIPHERAL IMAGING CATHETER)-THE ACIST KODAMA INTRAVASCULAR ULTRASOUND CATHETER IS A MEDICAL DEVICE FOR USE BY OR ON THE ORDER OF A PHYSICIAN AND IS INTENDED FOR ULTRASOUND EXAMINATION OF CORONARY AND PERIPHERAL INTRAVASCULAR PATHOLOGY. INTRAVASCULAR ULTRASOUND IMAGING IS INDICATED IN PATIENTS WHO ARE CANDIDATES FOR TRANSLUMINAL INTERVENTIONAL PROCEDURES.
2740	IMP/MD/2021/000515	1.License Holder Name: SANRAD MEDICAL SYSTEMS PRIVATE LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:XRAY COMPUTED TOMOGRAPHY SYSTEM(HITACHI, LTD., MODEL : SUPRIA)-INTENDED USE: THIS SYSTEM IS INTENDED TO USE AT ANY PART OF THE WHOLE BODY TO GET COMPUTED TOMOGRAPHY IMAGES AND THOSE IMAGES ARE USED FOR DIAGNOSTIC PURPOSES. INDICATION FOR USE: THIS SYSTEM COLLECTS VOLUME DATA OF THE ENTIRE BODY INCLUDING THE HEAD ALONG THE BODY AXIS VIA THE AXIAL, HELICAL OR DYNAMIC SCAN. POST PROCESSING BY THE SOFTWARE INCLUDES MPR, VOLUME RENDERING, AND ANALYTICAL PROCESSING. CONDUCTING POST PROCESSING ON THE IMAGES OBTAINED PROVIDES SEPARATE TRANSVERSE SECTION IMAGES AND ANALYTICAL RESULTS. YOU CAN ALSO TRANSFER THE IMAGES TO EXTERNAL EQUIPMENT VIA THE INTERFACE COMPLIED WITH DICOM STANDARD. THIS SYSTEM ENABLES COMPUTED TOMOGRAPHY OF A PATIENT'S ENTIRE BODY, BLOOD VESSELS, AND INTERNAL ORGANS SINCE IT IS CAPABLE OF PRODUCING IMAGES REGARDLESS OF WHETHER OR NOT CONTRAST MEDIUM IS USED. NOTE THAT THIS SYSTEM IS INTENDED TO BE USED TO SCAN INFANTS AND INCLUDES A PROTOCOL FOR INFANTS.

2741	KTK/28/298/98	1.License Holder Name: BHAT BIO-TECH INDIA PRIVATE LIMITED 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:URINE GLUCOSE- KETONE TEST STRIP(BHAT BIO- SCAN)-URINE GLUCOSE, KETONE TEST IS A RAPID TEST FOR SEMIQUANTITATIVE DETERMINATION FOR THE PRESENCE AND CONCENTRATION OF GLUCOSE AND KETONE IN URINE,URINE GLUCOSE TEST STRIP(BHAT BIO- SCAN)-URINE GLUCOSE TEST IS A RAPID TEST FOR SEMIQUANTITATIVE DETERMINATION FOR THE PRESENCE AND CONCENTRATION OF GLUCOSE IN URINE,URINE GLUCOSE, KETONE, SPECIFIC GRAVITY, PH PROTEIN TEST STRIP(BHAT BIO- SCAN)-URINE GLUCOSE-KETONE SPECIFIC GRAVITY-PH PROTEIN TEST IS A RAPID TEST FOR THE SEMIQUANTITATIVE DETERMINATION FOR THE PRESENCE AND CONCENTRATION OF GLUCOSE, KETONE, SPECIFIC GRAVITY, PH AND PROTEIN IN URINE,RHEUMATOID FACTOR (RF) LATEX SLIDE TEST KIT (BHAT BIO- SCAN)-RF LATEX SLIDE TEST IS A LATEX AGGLUTINATION TEST FOR QUALITATIVE AND SEMI QUANTITATIVE IN VITRO DETERMINATION OF RHEUMATOID FACTOR IN HUMAN SERUM.,URINE GLUCOSE- PROTEIN TEST STRIP(BHAT BIO- SCAN)-URINE GLUCOSE, PROTEIN TEST IS A RAPID TEST FOR SEMIQUANTITATIVE DETERMINATION FOR THE PRESENCE AND CONCENTRATION OF GLUCOSE AND PROTEIN IN URINE,DENGUE IGG/IGM CARD TEST(BHAT BIO- SCAN)-DENGUE IGG/IGM RAPID CARD TEST IS A SOLID PHASE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE RAPID, QUALITATIVE AND DIFFERENTIAL DETECTION OF IGG AND IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM OR PLASMA OR WHOLE BLOOD. THIS TEST IS INTENDED FOR PROFESSIONAL USE AS AID IN THE PRESUMPTIVE DIAGNOSIS BETWEEN PRIMARY AND SECONDARY DENGUE INFECTION.,URINE-10 PARAMETERS TEST STRIPS(BHAT BIO-SCAN)-URINE 10P STRIPS ARE FIRM PLASTIC STRIPS TO WHICH SEVERAL DIFFERENT REAGENT AREAS ARE AFFIXED. THE STRIPS PROVIDES TESTS FOR THE SEMI QUANTITATIVE DETERMINATION FOR THE PRESENCE AND CONCENTRATION OF GLUCOSE, BILIRUBIN, KETONE, SPECIFIC GRAVITY, BLOOD, PH, PROTEIN, UROBILINOGEN, NITRITE AND LEUKOCYTES
2742	KTK/28/298/98	1.License Holder Name: BHAT BIO-TECH INDIA PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:HIV-1/2 OMT RAPID ANTIBODY TEST-HIV-1/2 OMT RAPID ANTIBODY TEST IS AN IMMUNOCHROMATOGRAPHIC BASED ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HIV-1/2IN HUMAN ORAL MUCOSAL TRANSUDATE

2743	KTK/28/395/2009	1.License Holder Name: DEVON INNOVATIONS PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:ORTHOPEDIC IMPLANT (FEMORAL COMPONENT-UNCEMENTED, HA COATED AND FEMORAL HEAD-FEMORAL COMPONENT-USE IN TOTAL OR PARTIAL HIP ORTHOPLASTY IN PRIMARY OR REVISION SURGERY. HEAD-HIP IMPLANT
2744	KTK/28/452/2017	1.License Holder Name: RIVARP MEDICAL PVT LTD 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:INTRODUCER NEEDLE-INTRODUCER NEEDLE ALLOWS ACCESS TO THE VASCULAR SYSTEM FOR THE INTRODUCTION OF A GUIDEWIRE TO FACILITATE CATHETER PLACEMENT.,Y CONNECTOR-Y CONNECTOR INTENDS TO PROVIDE TWO TUNNELS INTO THE BLOOD VESSEL, THIS CAN INTRODUCE THE CONTRAST AND GUIDE- WIRE OR CATHETERS DURING THE INTERVEN ONAL SURGERY. Y CONNECTOR VALVE INTENDS TO PREVENT BLOOD LOS.,GUIDING CATHETER-GUIDING CATHETER IS INTENDED FOR THE INTRAVASCULAR INTRODUCTION OF INTERVENTIONAL/DIAGNOSTIC DEVICES INTO THE CORONARY OR PERIPHERAL VASCULAR SYSTEMS,MANIFOLDS-THIS DEVICE IS USED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT(S) FOR ADMINISTRATION OF SOLUTIONS. TYPICAL USES INCLUDE PRESSURE MONITORING, INTRAVENOUS FLUID ADMINISTRATION AND TRANSFUSION.

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2745	KTK/28/452/2017	1.License Holder Name: RIVARP MEDICAL PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:ANTERIOR DISTRACTABLE CAGES-IT IS USED FOR SUPPORT OF THE INTERVERTEBRAL SPACE IN THE CERVICAL AND THORACOLUMBAR SPINE WITH THE PURPOSE OF SUPPORTING BONE FUSION OF THE VERTEBRAL BODIES.,OCCIPITAL PLATE SYSTEM-IT IS INTENDED TO PROVIDE STABILIZATION AND PROMOTE FUSION OF THE OCCIPITO-CERVICAL JUNCTION. THE OCCIPITOPLATE SYSTEM INCLUDES A COMPLETE SET OF IMPLANTS AND INSTRUMENTS DESIGNED TO OPTIMIZE FIXATION TO THE OCCIPUT AND EASILY CONNECT WITH ALL POSTERIOR CERVICAL AND THORACIC ROD-SCREW SYSTEMS.,ANTERIOR CERVICAL PLATE SYSTEM-ANTERIOR CERVICAL PLATE SYSTEM IS INDICATED FOR STABILIZATION OF THE CERVICAL SPINE FROM C2 TO C7 EMPLOYING UNICORTICAL SCREW FIXATION AT THE ANTERIOR FACE OF THE VERTEBRAL BODIES. SPECIFIC CLINICAL INDICATIONS FOR ANTERIOR PLATING INCLUDE: INSTABILITY CAUSED BY TRAUMA; INSTABILITY ASSOCIATED WITH CORRECTION OF CERVICAL LORDOSIS AND KYPHOSIS DEFORMITY; INSTABILITY ASSOCIATED WITH PSEUDOARTHOSIS AS A RESULT OF PREVIOUSLY FAILED CERVICAL SPINE SURGERY; INSTABILITY ASSOCIATED WITH MAJOR RECONSTRUCTIVE SURGERY FOR PRIMARY TUMORS OR METASTATIC MALIGNANT TUMORS OF THE CERVICAL SPINE; INSTABILITY ASSOCIATED WITH SINGLE OR MULTIPLE LEVEL CORPECTOMY IN ADVANCED DEGENERATIVE DISC DISEASE, SPINAL CANAL STENOSIS AND CERVICAL MYELOPATHY.,SPINAL FIXATION RODS-IT IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF CERVICAL, THORACIC, LUMBAR, AND SACRAL SPINAL SEGMENTS AS AN ADJUNCT TO FUSION.,HEART LUNG PACK (CUSTOM PACK)-THIS DEVICE IS USED EXCLUSIVELY FOR TRANSPORTATION OF BLOOD & OTHER LIQUIDS BETWEEN THE PATIENT & EXTRACORPOREAL SYSTEM.,PEDICAL SCREW SYSTEM-IT IS A PART OF SPINAL FIXATION SYSTEM INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF CERVICAL, THORACIC, LUMBAR, AND SACRAL SPINAL SEGMENTS AS AN ADJUNCT TO FUSION.,INTRODUCER SHEATH KIT-IT IS USED AS A PERCUTANEOUS INTRODUCER FOR USE WITH PTCA GUIDING CATHETER AND ANY OTHER INTRAVASCULAR THERAPEUTIC PROCEDURES.,LUMBAR INTERBODY FUSION CAGES-IT IS INTENDED FOR USE AT EITHER ONE LEVEL OR TWO CONTIGUOUS LEVELS FOR THE TREATMENT OF DEGENERATIVE DISC DISEASE (DDD) WITH UP TO GRADE I SPONDYLOLISTHESIS OR RETROLISTHESIS & ALSO THE DEVICE IS INTENDED FOR USE WITH SUPPLEMENTAL FIXATION AND WITH AUTO GRAFT TO FACILITATE FUSION,MESH CAGE-IT IS INTENDED FOR

	SUPPORT OF THE INTERVERTEBRAL SPACE IN THE THORACOL LUMBAR AND LUMBOSACRAL SPINE WITH THE PURPOSE OF SUPPORTING BONE FUSION OF THE VERTEBRAL BODIES.,PTCA GUIDEWIRE-THIS DEVICE IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA), ANGIOGRAPHIC CATHETER-ANGIOGRAPHIC CATHETERS ARE INTENDED FOR USE IN THE DELIVERY OF RADIOPAQUE CONTRAST MEDIA TO THE SELECTED SITES, SUCH AS CORONARY ARTERIES OR PERIPHERAL VASCULAR SYSTEMS,CRANIAL FIXATION SYSTEM-CRANIAL PLATING SYSTEM IS INTENDED FOR USE IN FIXATION OF THE CRANIAL BONES IN PROCEDURES SUCH AS RECONSTRUCTION, FRACTURE REPAIR. CRANIOTOMIES, AND OSTEOTOMIES THAT REQUIRE POSITIONAL AND FUNCTIONAL STABILITY IN THE UPPER MIDFACE AND SKULL CAP,ANTERIOR CERVICAL CAGE SYSTEM-ANTERIOR CERVICAL CAGE SYSTEM IS INDICATED FOR USE IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DOD) OF THE CERVICAL SPINE WITH ACCOMPANYING RADICULAR SYMPTOMS AT ONE DISC LEVEL. DDD IS DEFINED AS DISCOGENIC PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES ANTERIOR CERVICAL CAGE IMPLANTS ARE USED TO FACILITATE INTERVERTEBRAL BODY FUSION IN THE CERVICAL SPINE AND ARE PLACED VIA AN ANTERIOR APPROACH AT THE C2 TO TI DISC LEVELS USING AUTOGRAFT BONE. ANTERIOR CERVICAL CAGE IMPLANTS ARE TO BE USED WITH SUPPLEMENTAL FIXATION. PATIENTS SHOULD HAVE AT LEAST SIX (6) WEEKS OF NON-OPERATIVE TREATMENT PRIOR TO TREATMENT WITH AN INTERVERTEBRAL CAGE.,ANGIOGRAPHY GUIDEWIRE-ANGIOGRAPHY GUIDEWIRE IS DESIGNED FOR PERCUTANEOUS VESSEL ENTRY USING SELDINGER TECHNIQUE TO FACILIATE THE SUBSEQUENT INTRODUCTION OF AN INTRAVASCULAR DEVICE DURING INVASIVE CARDIOLOGY PROCESS. THE GUIDEWIRE IS MANUFACTURED FROM STAINLESS STEEL WHICH COULD BE COATED WITH PTFE SILICONE OR NOT.,OCCLUDER DELIVERY SYSTEM-THE DELIVERY SYSTEM IS USED TO DELIVER THE ASD, OCCLUDER TO THE DEFECT.PDA OCCLUDER TO THE DEFECT AND VSD OCCLUDER TO THE DEFECT.,OCCLUDER-THE OCCLUDER IS A PERCUTANEOUS TRANSCATHETER CLOSURE DEVICE INTENDED FOR THE OCCLUSION OF ATRIAL SEPTAL DEFECT,THE NON-SURGICAL CLOSURE OF PDA AND NON-SURGICAL CLOSURE OF VENTRICULAR SEPTAL DEFECT OF HEART.,PTCA BALLOON DILATION (DILATATION) CATHETER-IT IS USED FOR MINIMALLY INVASIVE PROCEDURE TO OPEN UP BLOCKED CORONARY ARTERIES, ALLOWING BLOOD TO CIRCU STENISIS LATE

		UNOBSTRUCTED TO THE HEART MUSCLE.
2746	MB/08/700	1.License Holder Name: APPASAMY OCULAR DEVICES PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BADDI 3.Device Name(Brand Name)-Intended Use:RIBOFLAVIN AND DEXTRAN STERILE SOLUTION(K-LINK)-IT IS INTENDED TO TREAT KERATOCONUS AND CORNEAL ECTASIA FOLLOWING REFRACTIVE SURGERY.
2747	MEG/MD/2018/000030	1.License Holder Name: PETERS SURGICAL INDIA (P) LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:NON ABSORBABLE MESH (STERILENE MESH)-STERILENE MESH IS INDICATED FOR THE SURGICAL RECONSTRUCTION OF TISSUE DEFECTS LIKE HERNIA REPAIR.

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2748	MFG/IVD/2018/000001	1.License Holder Name: AVECON HEALTHCARE PVT. LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:VITAMIN B12 ELISA (MAXLISA AND OTHER OEM BRAND)-THE VITAMIN B12 ELISA IS THE QUANTITATIVE DETERMINATION OF VITAMIN B12 CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, COLORIMETRIC,G-6-PDH (QUALITATIVE)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUALITATIVE DETERMINATION OF G6PDH IN HUMAN SERUM, /PLASMA/ERYTHROCYTES,HS CRP(TURBIMAX AND OTHER OEM BRAND)-HS-CRP TEST IS INTENDED TO USE FOR EVALUATION OF CONDITIONS THOUGHT TO BE ASSOCIATED WITH INFLAMMATION, IN OTHERWISE HEALTHY INDIVIDUALS.,MICROPROTEIN - SLR(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF MICROPROTEIN IN HUMAN URINE AND CEREBRO SPINAL FLUID (CSF),INFLUENZA ANTIBODY TEST KIT(MAXLINE AND OTHER OEM BRAND)-INFLUENZA ANTIBODY RAPID TEST CASSETTE IS A CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES AGAINST INFLUENZA A, B, AND C IN HUMAN SERUM/PLASMA. IT IS THE SCREENING TEST FOR INFLUENZA AND CAN BE CORRELATE THE SYMPTOMS, GLYCOSYLATED HEMOGLOBIN (A1)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE DETERMINATION OF HEMOGLOBIN A1 (GLYCOHEMOGLOBIN) CONCENTRATION IN HUMAN BLOOD.,H PYLORI ANTIBODY TEST KIT(MAXLINE AND OTHER OEM BRAND)-H. PYLORI ANTIBODY RAPID TEST CASSETTE IS A CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HELICOBACTER PYLORI (H. PYLORI) IGG, IGA AND IGM ANTIBODIES IN HUMAN SERUM PLASMA AS AN AID OF DIAGNOSIS OF H. PYLORI INFECTION IN PATIENTS WITH GASTROINTESTINAL,UREA-GLDH(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE KINETIC DETERMINATION OF UREA IN HUMAN SERUM AND PLASMA,D-DIMER ESTIMATION KIT (TURBIMAX AND OTHER OEM BRAND)-D-DIMER IS USED FOR QUANTITATIVE IN-VITRO DETERMINATION OF D-DIMER IN HUMAN CITRATE PLASMA.,ALKALINE PHOSPHATASE (IFCC)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE DETERMINATION OF ALKALINE PHOSPHATASE IN SERUM AND PLASMA. ,HEMOCYSTEIN TEST KIT(LIQUIMAX AND OTHER OEM BRAND)-HOMOCYSTEINE TEST KIT IS USED FOR QUANTITATIVE IN - VITRO DETERMINATION OF HOMOCYSTEINE IN HUMAN SERUM AND PLASMA ON THE ANALYZER OR PHOTOMETERS.,SODIUM (NA+) SLR OPTIMIZED(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE ESTIMATION OF

	SODIUM (NA+) IN HUMAN SERUM,DILUENT REAGENT(MAXCOUNT AND OTHER OEM BRAND)-LIQUIMAX HAEMATOLOGY DILUENT IS INTENDED TO DILUTION OF WHOLE BLOOD SAMPLE WHEN ANALYZED THROUGH HAEMATOLOGY ANALYZER.,TYPHOID ANTIBODY(MAXLINE OR OTHER OEM BRAND)-THE TYPHOID TEST KIT IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBOTY (IGG/IGM) TO SALMONELLA TYPHI IN HUMAN SERUM/PLASMA ,CHIKUNGUNYA ANTIBODY RAPID TEST(MAXLINE AND OTHER OEM BRAND)-MAXLINE CHIKUNGUNYA ANTIBODY KIT IS DESIGNED TO QUALITATIVE DETECTION OF ANTIBODY AGAINST CHIKUNGUNYA PRESENT IN HUMAN WHOLE BLOOD/SERUM/PLASMA,PREGNANCY (DEVICE/STRIP)(MAXLINE OR OTHER OEM BRAND)-PREGNANCY TEST KIT IS A RAPID IMMUNOCHROMATOGRAPHY TEST FOR QUALITATIVE DETECTION OF HCG IN HUMAN URINE (PREGNANCY). ,VITAMIN D3 ELISA(MAXLISA AND OTHER OEM BRAND)-THE VITAMIN D3 ELISA IS THE QUANTITATIVE DETERMINATION OF VITAMIN D3 CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, COLORIMETRIC,HBA1C(TURBIMAX AND ANY OTHER OEM BRAND)-REAGENT KIT FOR THE MEASUREMENT OF HEMOGLOBIN A1C CONCENTRATION IN HUMAN BLOOD.,LYSE REAGENT(MAXCOUNT AND OTHER OEM BRAND)-CF-LYSE-DIFF IS USED FOR HEMATOLOGICAL ANALYSIS BY THE HEMATOLOGICAL ANALYZER AS A RED BLOOD CELL HEMOLYSING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTES COUNT, AND GRANULOCYTE COUNT. ,ETHANOL UV(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF ETHANOL IN HUMAN SERUM , PLASMA AND BODY FLUID ,FOB TEST(MAXLINE AND OTHER OEM BRAND)-FAECAL OCCULT BLOOD TEST IS A RAPID, QUALITATIVE; TWO SITE SANDWICH IMMUNOASSAY FOR THE DETECTION OF FAECAL OCCULT BLOOD CONCENTRATION IN HUMAN FACES,DENGUE IGM/IGG ANTIBODY(MAXLINE OR OTHER OEM BRAND)-DENGUE IGM/IGG IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION AND DEFFERENCIATES PRIMARY & SECONDARY DENGUE INFECTION IN HUMAN SERUM/PLASMA ,PCT ESTIMATION KIT (TURBIMAX AND OTHER OEM BRAND)- TURBIMAX PCT KIT IS DESIGNED TO ESTIMATE PCT LEVEL IN HUMAN SERUM/PLASMA ,RA TURBIDOMETRIC(TURBIMAX AND ANY OTHER OEM BRAND)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS IN HUMAN SERUM,DENGUE IGM ELISA(MAXLISA AND OTHER OEM)-DENGUE IGM ELISA IS DESIGNED FOR IN-VITRO QUALITATIVE DETECTION OF DENGUE IGM ANTIBODIES IN HUMAN SERUM OR PLASMA AND IS USED AS A SCREENING TEST FOR TESTING

	OF COLLECTED BLOOD SAMPLES SUSPECTED FOR DENGUE,RA-AGGLUTINATION SLIDE(SEROMAX AND ANY OTHER OEM BRAND)-REAGENT KIT FOR THE QUALITATIVE AND SEMI QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS IN HUMAN SERUM, PROBE CLEANER(MAXCOUNT AND OTHER OEM BRAND)-PROBE CLEANER IS USED IN HEMATOLOGICAL ANALYZERS BEFORE SWITCHING OFF AND AFTER SWITCHING ON HEMATOLOGY ANALYZER,URIC ACID - SLR (TBHBA)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM AND URINE,FERRITIN ESTIMATION KIT(TURBIMAX AND OTHER OEM BRAND)-FERRITIN TEST IS A TURBIDOMETRIC IMMUNOASSAY FOR THE QUANTITATIVE DETECTION OF FERRITIN IN HUMAN SERUM. IT CAN BE USED AID IN THE DIAGNOSIS OF IRON METABOLISM RELATED DISEASES,UREA BERTHELOT(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE KINETIC DETERMINATION OF UREA IN HUMAN SERUM AND PLASMA, FILARIASIS DETECTION TEST KIT(MAXLINE AND OTHER OEM BRAND)-MAXLINE FILARIASIS KIT IS DESIGNED TO DETECT FILARIA INFECTION IN HUMAN SERUM/PLASMA/WHOLE BLOOD,TRIGLYCERIDES – SLR (TBHBA 10 MIN)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA.,CARBON DI OXIDE ESTIMATION KIT(LIQUIMAX AND OTHER OEM BRAND)-LIQUIMAX TOTAL CO2 ASSAY IS USED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF CO2 IN SERUM AND PLASMA. IT AIDS IN DIAGNOSING DISEASES ASSOCIATED WITH HIGH AND LOW LEVELS OF CO2 IN THE BLOODSTREAM. ,TOTAL PROTEIN - SLR(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM AND PLASMA.,CYSTATIN C ESTIMATION KIT(TURBIMAX AND OTHER OEM BRAND)-THIS ASSAY IS A TURBIDIMETRIC IMMUNOASSAY FOR THE QUANTITATIVE MEASUREMENT OF CYSTATIN C IN HUMAN SERUM,SODIUM (NA+) + POTASSIUM (K+) (LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE ESTIMATION OF SODIUM (NA+) AND POTASSIUM (K+) IN HUMAN SERUM,SGPT (COLORIMETRIC) (LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE COLORIMETRIC QUANTITATIVE DETERMINATION OF ALT IN HUMAN SERUM AND PLASMA.,SGPT (ALT) (LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE KINETIC QUANTITATIVE DETERMINATION OF ALT IN HUMAN SERUM AND PLASMA.,SGOT (COLORIMETRIC) (LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-

	REAGENT KIT FOR THE COLORIMETRIC QUANTITATIVE DETERMINATION OF AST IN HUMAN SERUM AND PLASMA.,SGOT (AST) (LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE KINETIC QUANTITATIVE DETERMINATION OF AST IN HUMAN SERUM AND PLASMA.,POTASSIUM (K+)-SLR (OPTIMIZED)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE ESTIMATION OF POTASSIUM (K+) IN HUMAN SERUM,PHOSPHORUS – SLR(LIQUIMAX LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF PHOSPHORUS IN HUMAN SERUM,MICROALBUMIN TURBIDOMETRIC(TURBIMAX AND ANY OTHER OEM BRAND)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION MICROALBUMIN IN HUMAN SERUM,MAXCLEAN (LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENTS KIT FOR THE CLEANING OF ANALYSERS,MAGNESIUM - SLR (OPTIMIZED)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM,LIPOPROTEIN-A (ULTRA) TURBIDOMETRIC(TURBIMAX AND ANY OTHER OEM BRAND)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION LIPOPROTEIN –A IN HUMAN SERUM,LIPASE(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE DIRECT DETERMINATION OF LIPASE IN HUMAN SERUM AND PLASMA,LDL CHOLESTEROL -DIRECT(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF LDL- CHOLESTEROL IN HUMAN SERUM AND PLASMA.,LDH (P) / (L—>P)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE DETERMINATION OF LDH IN HUMAN SERUM AND PLASMA,LACTATE-COLORIMETRIC (LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE DETERMINATION OF LACTATE IN HUMAN SERUM AND PLASMA,IRON & TIBC(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE DETERMINATION OF IRON AND TIBC IN HUMAN SERUM AND PLASMA,HEMOGLOBIN-SLR(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN IN HUMAN BLOOD.,HDL CHOLESTEROL -DIRECT (LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF HDL-CHOLESTEROL IN HUMAN SERUM AND PLASMA.,HDL CHOLESTEROL (LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF HDL-CHOLESTEROL IN HUMAN SERUM AND PLASMA.,GLUCOSE - SLR (LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-

	REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM AND PLASMA.,GAMMA - GT (OPTIMIZED)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE OPTIMIZED KINETIC DETERMINATION OF G-GLUTAMYL TRANSFERASE IN HUMAN SERUM AND PLASMA.,G-6-PDH (QUANTITATIVE)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF G6PDH IN HUMAN SERUM, /PLASMA/ERYTHROCYTES.,CREATININE (END POINT)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE.,CREATININE - SLR(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE.,CK - NAC (LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF THE CREATINE KINASE ISO ENZYME IN HUMAN SERUM AND PLASMA.,CK - MB(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF THE CK-MB ISO ENZYME IN HUMAN SERUM AND PLASMA.,CHOLINESTERASE (LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE DETERMINATION OF CHOLINESTERASE IN HUMAN SERUM AND PLASMA,CHOLESTEROL-SLR (5 MIN)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA.,CHLORIDE - SLR(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF CHLORIDE IN HUMAN SERUM AND URINE.,CALCIUM ARSENAZO III(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM AND URINE.,CALCIUM - (OCPC)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM AND URINE., BILIRUBIN - (TOTAL)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM.,BILIRUBIN - (TOTAL & DIRECT)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN AND TOTAL BILIRUBIN IN HUMAN SERUM.,BILIRUBIN - (DIRECT)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM.,AMYLASE - SLR(LIQUIMAX, LYPHOMAX, AUTOMAX AND

	OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF -AMYLASE IN HUMAN SERUM AND PLASMA.., AMMONIA UV(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN SERUM, PLASMA AND URINE.,APOLIPOPROTEIN (B) TURBIDOMETRIC(TURBIMAX AND ANY OTHER OEM BRAND)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN (B) IN HUMAN SERUM,APOLIPOPROTEIN (A1) TURBIDOMETRIC(TURBIMAX AND ANY OTHER OEM BRAND)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPROTEIN (A1) IN HUMAN SERUM,ALKALINE PHOSPHATASE (DGKC)(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE DETERMINATION OF ALKALINE PHOSPHATASE IN SERUM AND PLASMA.,ALBUMIN - SLR(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM AND PLASMA.,ADA KINETIC(LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF ADA IN HUMAN SERUM AND PLASMA..,ACID PHOSPHATASE (LIQUIMAX, LYPHOMAX, AUTOMAX AND OTHER OEM BRANDS)-REAGENT KIT FOR THE DETERMINATION OF PROSTATIC AND NON PROSTATIC ACID PHOSPHATASE IN SERUM AND PLASMA.

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2749	MFG/IVD/2018/000002	1.License Holder Name: KILPEST INDIA LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:ALL PANEL PCR KIT (TRUPCR® ALL PANEL KIT)-TRUPCR® ALL PANEL KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF DIAGNOSTIC AND PROGNOSTIC MARKERS OF ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN PERIPHERAL BLOOD SAMPLES USING REAL TIME PCR SYSTEM., AML PANEL PCR KIT(TRUPCR® AML PANEL KIT)-TRUPCR® AML PANEL KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF DIAGNOSTIC AND PROGNOSTIC MARKERS OF ACUTE MYELOGENOUS LEUKEMIA (AML) IN PERIPHERAL BLOOD SAMPLES USING REAL TIME AND CONVENTIONAL PCR SYSTEM.,MPN PANEL PCR KIT(TRUPCR® MPN PANEL KIT)-TRUPCR® MPN PANEL KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF JAK2-V617F, CALR, MPL W515K/L/A S505N MUTATIONS AND BCR ABL1 TRANSLOCATION IN MYELOPROLIFERATIVE NEOPLASMS (MPNS) IN PERIPHERAL BLOOD SAMPLES USING REAL TIME PCR SYSTEM. ,EGFR PCR KIT(TRUPCR® EGFR KIT)-TRUPCR® EGFR KIT IS AN IN-VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE DETECTION OF EGFR SOMATIC MUTATIONS IN THE GENOMIC DNA ISOLATED FROM TUMOR TISSUE (FRESH, FROZEN OR FORMALIN FIXED PARAFFIN-EMBEDDED (FFPE) TISSUE OR LIQUID BIOPSY).,CYTOMEGALOVIRUS DETECTION & QUANTITATIVE PCR KIT(TRUPCR® CMV QT KIT)-TRUPCR® CMV QT KIT IS IN VITRO NUCLEIC ACID AMPLIFICATION ASSAY FOR THE QUALITATIVE & QUANTITATIVE DETECTION OF CYTOMEGALOVIRUS (CMV) SPECIFIC DNA IN HUMAN PLASMA/ SERUM.,KRAS PCR KIT (TRUPCR® KRAS KIT)-TRUPCR® KRAS KIT IS AN IN-VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE DETECTION OF KRAS SOMATIC MUTATIONS IN THE GENOMIC DNA EXTRACTED FROM FRESH, FROZEN OR FORMALIN FIXED PARAFFIN EMBEDDED (FFPE) TISSUE.,HCV VIRAL LOAD KIT(TRUPCR® HCV VIRAL LOAD KIT)-FOR THE ESTIMATION OF HCV VIRAL LOAD IN HUMAN SERUM OR PLASMA, HCV GENOTYPE DETECTION PCR KIT(TRUPCR® HCV GENOTYPING KIT)-TRUPCR® HCV GENOTYPING KIT IS AN IN-VITRO NUCLEIC ACID AMPLIFICATION ASSAY FOR THE QUALITATIVE DETECTION AND DIFFERENTIATION OF HEPATITIS C VIRUS (HCV) GENOTYPES 1, 1A, 2 (2A/2B), 3, 4, 5A AND 6 RNA IN HUMAN SERUM OR PLASMA (EDTA) FROM HCV INFECTED INDIVIDUAL SPECIMENS USING REAL TIME PCR SYSTEM.,HBV VIRAL LOAD KIT(TRUPCR® HBV VIRAL LOAD KIT)-TRUPCR® HBV VIRAL LOAD PCR KIT IS INTENDED FOR THE ESTIMATION OF HBV VIRAL LOAD IN HUMAN SERUM OR PLASMA,HLA B27 PCR KIT(TRUPCR® HLA-B27 KIT)-TRUPCR® HLA-B27 KIT IS DESIGNED FOR THE QUALITATIVE DETECTION OF HLA-B27 ALLELE IN

	HUMAN BLOOD.,CHIKUNGUNYA PCR KIT(TRUPCR® CHIKUNGUNYA KIT)-TRUPCR® CHIKUNGUNYA KIT IS AN IN-VITRO NUCLEIC ACID AMPLIFICATION ASSAY FOR THE QUALITATIVE DETECTION OF CHIKUNGUNYA RNA IN HUMAN SERUM OR PLASMA (EDTA) FROM CHIKUNGUNYA - INFECTED INDIVIDUAL SPECIMENS USING REAL TIME PCR SYSTEM.,PML-RARA PCR KIT(TRUPCR® PML-RARA QUANTITATIVE KIT)-TRUPCR® PML-RARA QUANTITATIVE KIT IS INTENDED FOR THE QUANTITATIVE DETECTION AND DIFFERENTIATION OF PML-RARA FUSION LONG (BCR1), VARIANT (BCR2) AND SHORT (BCR3) TRANSCRIPT IN BONE MARROW OR PERIPHERAL BLOOD SAMPLES OF ACUTE PROMYELOCYTIC (M3) LEUKEMIA (APL) USING REAL TIME PCR SYSTEM. THIS KIT ALSO DIFFERENTIATES BETWEEN BCR 2 VARIANT WITH 5' BREAK POINT OR 3' BREAK POINT.,JAK-2 V617F PCR KIT(TRUPCR® JAK-2 KIT)-TRUPCR® JAK-2 V617F IS AN IN-VITRO DIAGNOSTIC KIT DESIGNED FOR THE QUALITATIVE DETECTION OF THE V617F MUTATION IN THE JANUS KINASE 2 GENE BY REAL TIME PCR ON GENOMIC DNA OF PATIENTS SUSPECTED WITH MYELOPROLIFERATIVE DISORDER., RIFAMPICIN RESISTANT MTB DETECTION PCR KIT(TRUPCR® RIFAMPICIN RESISTANT MTB DETECTION KIT)-TRUPCR® RIFAMPICIN RESISTANT MTB DETECTION KIT ACCURATELY IDENTIFIED MYCOBACTERIUM TUBERCULOSIS COMPLEX (MTBC) AND THERE RIFAMPICIN RESISTANCE/ SUSCEPTIBLE STATUS FROM VARIOUS SOURCES OF CLINICAL SAMPLES USING REAL TIME NESTED PCR., MTBC/NTM DETECTION PCR KIT(TRUPCR® MTBC ONE STEP NESTED KIT)-TRUPCR® MTBC ONE STEP NESTED KIT ACCURATELY DIFFERENTIATES MYCOBACTERIUM TUBERCULOSIS COMPLEX (MTBC) FROM NON-TUBERCULOSIS MYCOBACTERIUM SPECIES (NTM) IN A QUALITATIVE FORM FROM VARIOUS SOURCES OF CLINICAL SAMPLES USING REAL TIME PCR.,BCR-ABL1 QUANTITATIVE PCR KIT (TRUPCR® BCR-ABL1 QUANTITATIVE KIT)-TRUPCR® BCR-ABL1 QUANTITATIVE KIT IS INTENDED FOR THE QUANTITATIVE DETECTION AND DIFFERENTIATION OF BCR-ABL1 FUSION GENE TRANSCRIPT MAJOR (M), MINOR (M), AND MICRO () IN BONE MARROW OR PERIPHERAL BLOOD SAMPLES OF CHRONIC MYELOID LEUKEMIA (CML) OR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) OR ACUTE MYELOGENOUS LEUKEMIA (AML) USING REAL TIME PCR SYSTEM. THIS KIT CAN ALSO BE USED TO EVALUATE THE LEVEL OF MOLECULAR RESPONSE UP TO 5-LOG REDUCTION (DEEP MOLECULAR RESPONSE); RESULTS CAN BE USED FOR MINIMAL RESIDUAL DISEASE FOLLOW-UP.,H1N1 PCR KIT(TRUPCR® H1N1 DETECTION KIT)-TRUPCR® H1N1 DETECTION KIT ACCURATELY IDENTIFIED TYPE A INFLUENZA VIRUSES, PANDEMIC (PDM) INFLUENZA A VIRUSES AND PANDEMIC H1 INFLUENZA VIRUS FROM

	RESPIRATORY SPECIMENS AND VIRAL CULTURES USING REAL TIME PCR. THE HUMAN RNASEP GENE SERVES AS AN INTERNAL POSITIVE CONTROL FOR HUMAN NUCLEIC ACID, ALSO INCLUDED IN THIS KIT.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2750	MFG/IVD/2018/000003	1.License Holder Name: RECOMBIGEN LABORATORIES PRIVATE LIMITED 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:AST (SGOT) TEST (RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF SERUM GLUTAMIC OXALOACETIC TRANSAMINASE ACTIVITY IN HUMAN SERUM OR PLASMA SAMPLE,TRIGLYCERIDES TEST (RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF TRIGLYCERIDES IN HUMAN SERUM OR PLASMA SAMPLE ,LIPASE TEST (RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF LIPASE IN HUMAN SERUM, PLASMA SAMPLES,RAPID LUTEINIZING HORMONE (LH) TEST (RECOMBIGEN)-IT IS INTENDED FOR QUALITATIVE DETECTION OF LUTEINIZING HORMONE (LH) IN HUMAN URINE SAMPLES ,RAPID HUMAN CHORIONIC GONADOTROPIN TEST (RECOMBIGEN)-IT IS INTENDED FOR QUALITATIVE DETECTION OF HUMAN CHORIONIC GONADOTROPIN IN HUMAN URINE SAMPLES , GLUCOSE TEST(RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF GLUCOSE IN HUMAN SERUM OR PLASMA SAMPLE , GAMMA GLUTAMYL TRANSFERASE(RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF GAMMA GLUTAMYL TRANSFERASE IN HUMAN SERUM SAMPLE,RAPID FSH (MENOPAUSE) TEST (RECOMBIGEN)-IT IS INTENDED FOR QUALITATIVE DETECTION OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN URINE SAMPLES ,UREA TEST(RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF UREA IN HUMAN SERUM, PLASMA AND URINE SAMPLES,LACTATE DEHYDROGENASE TEST (RECOMBIGEN)- IT IS INTENDED FOR QUANTITATIVE DETECTION OF LACTATE DEHYDROGENASE IN HUMAN SERUM SAMPLE ,HDL CHOLESTEROL TEST(RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF HDL-CHOLESTEROL IN HUMAN SERUM, PLASMA SAMPLES,ALT (SGPT) TEST(RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF SERUM GLUTAMATE PYRUVATE TRANSAMINASE ACTIVITY IN HUMAN SERUM OR PLASMA SAMPLE,RAPID DENGUE ANTIBODY TEST (RECOMBIGEN)-IT IS INTENDED FOR QUALITATIVE DETECTION OF DENGUE IGG/IGM ANTIBODY IN HUMAN SERUM AND PLASMA SAMPLES ,CREATININE TEST(RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE SAMPLES,CK-NAC TEST(RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF ISOENZYME CREATINE KINASE IN HUMAN SERUM SAMPLE,URIC ACID TEST(RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF URIC ACID IN HUMAN SERUM, PLASMA AND URINE SAMPLE,CK-MB TEST (RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF ISOENZYME CREATINE KINASE IN HUMAN SERUM SAMPLE,

		MICROPROTEIN TEST PRODUCT (RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF MICROPROTEIN IN HUMAN URINE AND CSF (CEREBRO SPINAL FLUID) SAMPLE ,CHOLESTEROL TEST (RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA SAMPLE,RHEUMATOID FACTOR (RF) TEST(RECOMBIGEN)-IT IS INTENDED FOR QUALITATIVE AND SEMI QUANTITATIVE DETECTION OF RHEUMATOID FACTORS IN HUMAN SERUM SAMPLE,BILIRUBIN TEST(RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF BILIRUBIN IN HUMAN SERUM OR PLASMA SAMPLE,TOTAL PROTEIN TEST PRODUCT (RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA SAMPLE,ANTI STREPTOLYSIN-O (ASO) TEST(RECOMBIGEN)-IT IS INTENDED FOR QUALITATIVE AND SEMI QUANTITATIVE DETECTION OF ANTI STREPTOLYSIN-O IN HUMAN SERUM SAMPLE ,RAPID TYPHOID ANTIBODY (RECOMBIGEN)-IT IS INTENDED FOR QUALITATIVE DETECTION OF TYPHOID IGG/IGM ANTIBODY IN HUMAN SERUM AND PLASMA SAMPLES ,AMYLASE TEST(RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF AMYLASE IN HUMAN SERUM, PLASMA AND URINE SAMPLE,RAPID URINALYSIS REAGENT STRIP TEST(RECOMBIGEN)-IT IS INTENDED FOR SEMI-QUANTITATIVE DETECTION OF URINE PARAMETERS IN HUMAN URINE SAMPLES , ALBUMIN TEST(RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF ALBUMIN IN HUMAN SERUM OR PLASMA SAMPLE, WIDAL (TYPHOID ANTIBODY) TEST(RECOMBIGEN)-IT IS INTENDED FOR QUALITATIVE AND SEMI QUANTITATIVE DETECTION OF ANTIBODIES SPECIFIC TO SALMONELLA TYPHI AND PARATYPHI IN HUMAN SERUM SAMPLE,ALKALINE PHOSPHATASE TEST (RECOMBIGEN)-IT IS INTENDED FOR QUANTITATIVE DETECTION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR PLASMA SAMPLE
2751	MFG/IVD/2018/000003	1.License Holder Name: RECOMBIGEN LABORATORIES PVT. LTD 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:PRE-INJECTION SWAB (ALCOHOL SWAB)(RECOMBIGEN)-THE ALCOHOL SWAB IS A SINGLE USE, STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL. WHEN USED FOR SCRUBBING FOR 5 SECONDS AND ALLOWING DRYING FOR 5 SECONDS, THE ALCOHOL SWAB WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE. IT MAY BE USED IN THE HOME OR HEALTHCARE FACILITY.

2752	MFG/IVD/2018/000004	1.License Holder Name: GENUINE BIOSYSTEM PRIVATE LIMITED 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM (VTM) KIT(GB'S SURE)-A VIRAL TRANSPORT MEDIUM (VTM) KIT IS A MEDICAL DEVICE, INTENDED FOR COLLECTION AND TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING VIRUSES FROM COLLECTION CENTER TO LABORATORY,LEPTOSPIRA ANTIBODY ELISA KIT-A LEPTOSPIRA ELISA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF LEPTOSPIRA ANTIBODY IN SERUM,ADENOSINE DEAMINASE (ADA) KIT(N-BIO)-ADENOSINE DEAMINASE (ADA) ASSAY KIT IS AN IN-VITRO DIAGNOSTIC MEDICAL DEVICE FOR DETERMINATION OF ADENOSINE DEAMINASE (ADA) ACTIVITY IN SERUM AND BODY FLUIDS,HEMATOLOGY BLOOD CONTROL SET-A HEMATOLOGY BLOOD CONTROL SET IS A MEDICAL DEVICE, INTENDED FOR THE USE OF VALIDATION OF BLOOD CELL COUNTING PARAMETERS OF LEVEL 1, LEVEL 2 AND LEVEL 3,VITAMIN-D KIT(N-BIO)-A VITAMIN-D IS THE IVD MEDIAL DEVICE, INTENDED FOR THE ESTIMATION OF VITAMIN-D IN HUMAN PLASMA,TOTAL PROTEIN KIT(N-BIO)-A TOTAL PROTEIN IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF TOTAL PROTEIN IN SERUM,INTERLEUKIN-6 (IL-6) RAPID QUANTITATIVE TEST KIT(FLUROCHEM)-AN INTERLEUKIN-6 (IL-6) RAPID QUANTITATIVE TEST KIT IS THE IVD MEDICAL DEVICE, INTENDED FOR THE DETERMINATION OF INTERLEUKIN-6 (IL-6) IN HUMAN SERUM ,UREA (E.P) KIT(N-BIO)-AN UREA KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF UREA IN SERUM, FERRITIN RAPID QUANTITATIVE TEST KIT(FLUROCHEM)-A FERRITIN RAPID QUANTITATIVE TEST KIT IS THE IVD MEDIAL DEVICE, INTENDED FOR THE ESTIMATION OF FERRITIN IN HUMAN SERUM, WHOLE BLOOD ETC.,,GLYCO HEMOGLOBIN KIT(N-BIO)-A GLYCO HEMOGLOBIN KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF GLYCOSYLATED HEMOGLOBIN (HBA1C) IN BLOOD,INTERLEUKIN-6 (IL-6) ELISA KIT(GBLISA)-AN INTERLEUKIN-6 (IL-6) ELISA KIT IS THE IVD MEDICAL DEVICE, INTENDED FOR THE DETECTION OF INTERLEUKIN-6 (IL-6) IN HUMAN SERUM,GLUCOSE KIT(N-BIO)-A GLUCOSE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF GLUCOSE IN SERUM/PLASMA,LAMININ (LN) CLIA MICROPARTICLES KIT(AUTOBIO)-A LN (LAMININ) CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF LN (LAMININ) IN HUMAN SERUM,DILUENT FOR HEMATOLOGY ANALYZER-A DILUENT IS A MEDICAL DEVICE, INTENDED FOR DILUTING BLOOD AND MAINTAINING THE SHAPE AND SIZE OF BLOOD CELLS FOR ESTIMATION OF COMPLETE BLOOD COUNT (CBC),COLLAGEN IV (COL IV) CLIA MICROPARTICLES KIT (AUTOBIO)-A COL IV (COLLAGEN IV) CLIA MICROPARTICLES IS A

	MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF COL IV (COLLAGEN IV) IN HUMAN SERUM,SGOT (ASAT) KIT(N-BIO)-A SGOT (ASAT) KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ENZYME ASPARTATE AMINO TRANSFERASE (AST/SGOT) IN SERUM, SEX HORMONE BINDING GLOBULIN (SHBG) CLIA MICROPARTICLES KIT(AUTOBIO)-A SHBG (SEX HORMONE BINDING GLOBULIN) CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF SHBG IN HUMAN SERUM,NEUTROPHIL GELATINASE ASSOCIATED LIPOCALIN (NGAL) KIT(TURBICHEM / NEPHCHEM)-A NGAL KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF NEUTROPHIL GELATINASE ASSOCIATED LIPOCALIN (NGAL) IN URINE, DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) CLIA MICROPARTICLES KIT(AUTOBIO)-A DHEA-S (DEHYDROEPIANDROSTERONE SULFATE) CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF DHEA-S IN HUMAN SERUM,FREE T3 (FT3) ELISA KIT(GBLISA)-A FT3 KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF FREE TRIIODOTHYRONINE (T3) IN SERUM,HYALURONIC ACID (HA) CLIA MICROPARTICLES KIT(AUTOBIO)-A HA (HYALURONIC ACID) CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF HA (HYALURONIC ACID) IN HUMAN SERUM, ENZYMATIC CREATININE KIT(N-BIO)-AN ENZYMATIC CREATININE IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CREATININE IN SERUM/URINE,FOLATE CLIA MICROPARTICLES KIT(AUTOBIO)-A FOLATE CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF FOLATE IN HUMAN SERUM,INSULIN ELISA KIT (GBLISA)-AN INSULIN KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF INSULIN IN SERUM,PROCOLLAGEN III N-TERMINAL PEPTIDE (PIIINP) CLIA MICROPARTICLES KIT(AUTOBIO)-A PIIINP (PROCOLLAGEN III N-TERMINAL PEPTIDE) CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF PIIINP IN HUMAN SERUM,CERULOPLASMIN KIT(TURBICHEM)-A CERULOPLASMIN KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CERULOPLASMIN IN SERUM,17-HYDROXYPROGESTERONE (17-OHP) CLIA MICROPARTICLES KIT (AUTOBIO)-A 17-OHP (17-HYDROXYPROGESTERONE) CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF 17-OHP IN HUMAN SERUM,TSH ELISA KIT(GBLISA)-A TSH KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF HUMAN THYROID STIMULATING HORMONE (TSH) IN SERUM,DENGUE VIRUS ANTIBODY IGG/ IGM RAPID TEST-A DENGUE ANTIBODY IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF DENGUE ANTIBODY LEVEL IN BLOOD/BODY FLUIDS,ANTI MULLERION HORMONE (AMH) ELISA KIT(GBLISA)-AN AMH KIT IS A MEDICAL

	DEVICE, INTENDED FOR THE ESTIMATION OF ANTI MULLERION HORMONE (AMH) IN SERUM,ANTI-CYCLIC CITRULLINATED PEPTIDE (ANTI -CCP) ELISA KIT(GBLISA)-AN ANTI-CCP KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ANTI-CYCLIC CITRULLINATED PEPTIDE (CCP) ANTIBODIES IN SERUM,FSH ELISA KIT (GBLISA)-A FSH KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF FOLLICLE STIMULATING HORMONE (FSH) IN SERUM, T3 ELISA KIT(GBLISA)-A T3 ELISA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF TOTAL TRIIODOTHYRONINE (T3) IN SERUM,RUBELLA IGG/ IGM ELISA KIT(GBLISA)-A RUBELLA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF RUBELLA ANTIBODY IN BODY FLUIDS,FREE T4 (FT4) ELISA KIT(GBLISA)-A FT4 KIT IS A MEDICAL DEVICE, INTENDED FOR THE DETERMINATION OF FREE THYROXINE (T4) IN SERUM,T4 ELISA KIT(GBLISA)-A T4 ELISA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF TOTAL THYROXINE (T4) IN SERUM,CHEMISTRY CONTROL ABNORMAL(GB PATH)-A CHEMISTRY CONTROL ABNORMAL IS A MEDICAL DEVICE, INTENDED FOR THE USE OF QUALITY CONTROL VALIDATION OF ABNORMAL CHEMISTRY ASSAY,FOLATE ELISA KIT(GBLISA)-A FOLATE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF FOLATE IN SERUM,DETERGENT / RINSE FOR HEMATOLOGY ANALYZER-A DETERGENT/RINSE IS A MEDICAL DEVICE INTENDED FOR RINSING THE FECULENCE AND FIBRIN IN HEMATOLOGY ANALYZER FOR COMPLETE BLOOD COUNT (CBC),ALKALINE PHOSPHATASE KIT(N-BIO)-AN ALKALINE PHOSPHATASE IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ALKALINE PHOSPHATASE IN SERUM,CREATININE (KIN.) KIT(N-BIO)-A CREATININE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CREATININE IN URINE/SERUM,HEMOGLOBIN REAGENT (DRABKINS REAGENT)(HAEMOGB)-A HEMOGLOBIN REAGENT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF HEMOGLOBIN VALUE IN WHOLE BLOOD,HCG RAPID TEST (PREGNANCY)-A HCG RAPID TEST IS A MEDICAL DEVICE, INTENDED TO DETECT HUMAN CHORIONIC GONADOTROPIN (HCG) LEVEL IN URINE,ALBUMIN KIT(N-BIO)-AN ALBUMIN KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ALBUMIN IN SERUM,LEPTOSPIRA ANTIBODY IGG/IGM RAPID TEST-A LEPTOSPIRA AB KIT IS MEDICAL DEVICE, INTENDED FOR THE DETECTION OF LEPTOSPIRA ANTIBODY IN BLOOD/BODY FLUIDS,CALIBRATION A/B REAGENT-A CALIBRATION A/B REAGENT IS A MEDICAL DEVICE, INTENDED FOR USE OF CALIBRATION AND ESTIMATION OF IONS IN AUTOMATED ION SELECTIVE ELECTRODE (ISE) ANALYZER,SODIUM KIT(N-BIO)-A SODIUM IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF SODIUM IN SERUM/URINE,ETHANOL KIT(N-BIO)-AN ETHANOL KIT IS A

	MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ETHYL ALCOHOL I IN BLOOD/BODY FLUIDS,CHLORIDE KIT(N-BIO)-A CHLORIDE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CHLORIDE IN SERUM/URINE,DIRECT HDL CHOLESTEROL KIT(N-BIO)-A DIRECT HDL CHOLESTEROL IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF HDL CHOLESTEROL IN SERUM,MAGNESIUM KIT(N-BIO)-A MAGNESIUM KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF MAGNESIUM IN URINE/SERUM,PANCREATIC AMYLASE KIT(N-BIO)-A PANCREATIC AMYLASE IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF PANCREATIC AMYLASE IN SERUM,ALPHA-1-MICROGLOBULIN (A1MG) KIT(TURBICHEM)-AN A1MG KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ALPHA-1-MICROGLOBULIN (A1MG) IN SERUM,VITAMIN-D ELISA KIT (GBLISA)-A VITAMIN-D KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF VITAMIN-D IN SERUM,LH ELISA KIT(GBLISA)-A LH KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF LUTEINIZING HORMONE (LH) IN SERUM,TYPHOID ANTIBODY (S.TYPHI AB) RAPID TEST-A TYPHOID ANTIBODY IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF S.TYPHI ANTIBODY IN BLOOD/BODY FLUIDS,PYRUVATE KIT(N-BIO)-A PYRUVATE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF PYRUVATE IN SERUM,C-PEPTIDE ELISA KIT(GBLISA)-A C-PEPTIDE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF C-PEPTIDE IN SERUM, ALPHA AMYLASE KIT(N-BIO)-AN ALPHA AMYLASE IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ENZYME ALPHA AMYLASE IN SERUM,WIDAL O,H, AH, BH, AO, BO, CO, CH(COMBIWIDAL) -A WIDAL IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF OF TYPHOID ANTIBODIES IN SERUM,CALCIUM OCPC KIT(N-BIO)-A CALCIUM IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CALCIUM IN SERUM,MICROALBUMIN UREA KIT (MALB) KIT (TURBICHEM / NEPHCHEM)-A MICROALBUMIN UREA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF MICRO-ALBUMIN (MALB) IN URINE,ALPHA-1 ANTITRYPSIN KIT(TURBICHEM)-AN ALPHA-1 ANTITRYPSIN KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ALPHA-1 ANTITRYPSIN IN SERUM,MYOGLOBIN KIT(TURBICHEM)-A MYOGLOBIN KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF MYOGLOBIN IN SERUM,DIRECT HBA1C KIT (TURBICHEM / NEPHCHEM DIRECT HBA1C KIT)-A DIRECT HBA1C KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF HBA1C IN BLOOD,CHOLESTEROL WITH HDL KIT(N-BIO)-A CHOLESTEROL WITH HDL KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CHOLESTEROL TOTAL IN SERUM,LIPASE KIT(N-BIO)-A LIPASE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF LIPASE IN SERUM,TRIGLYCERIDES KIT(N-BIO)-A TRIGLYCERIDES KIT IS A

	MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF TRIGLYCERIDES IN SERUM,GLUCOSE (HEXOKINASE) KIT(N-BIO)-A GLUCOSE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF GLUCOSE IN SERUM/PLASMA,ADENOSINE DEAMINASE KIT(N-BIO) -AN ADA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ADENOSINE DEAMINASE (ADA) IN BLOOD/BODY FLUIDS, HEMATOLOGY BLOOD CALIBRATOR-A HEMATOLOGY BLOOD CALIBRATOR IS A MEDICAL DEVICE, INTENDED TO USE FOR CALIBRATION OF BLOOD CELL COUNTING PARAMETERS, CYTOMEGAVIRUS (CMV) ELISA KIT(GBLISA)-A CMV KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CYTOMEGAVIRUS (CMV) ANTIBODIES IN SERUM,TRANSFERRIN KIT(TURBICHEM)-A TRANSFERRIN KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF TRANSFERRIN IN SERUM,AMMONIA KIT(N-BIO)-AN AMMONIA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF AMMONIA IN BLOOD/BODY FLUIDS,LACTATE KIT(N-BIO)-A LACTATE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF LACTATE KIT IN SERUM,CHOLINESTERASE KIT(N-BIO)-AN CHOLINESTERASE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATIONOF CHOLINESTERASE IN SERUM,LDH KIT(N-BIO)-A LDH KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ENZYME LACTATE DEHYDROGENASE (LDH) IN SERUM,ACID PHOSPHATASE KIT(N-BIO)-AN ACID PHOSPHATASE IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ACID PHOSPHATASE IN SERUM,HAPTOGLOBIN KIT(TURBICHEM)-A HAPTOGLOBIN KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF HAPTOGLOBIN IN SERUM,BILIRUBIN TOTAL & DIRECT KIT(N-BIO)-A BILIRUBIN TOTAL & DIRECT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF BILIRUBIN TOTAL & DIRECT IN SERUM,ZINC KIT(N-BIO)-A ZINC KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ZINC IN SERUM / URINE,CHEMISTRY CONTROL NORMAL(GB NORM)-A CHEMISTRY CONTROL IS A MEDICAL DEVICE, INTENDED FOR THE USE OF QUALITY CONTROL VALIDATION OF CHEMISTRY ASSAYS,ALPHA 1 ACID GLYCOPROTEIN KIT(TURBICHEM / NEPHCHEM)-AN ALPHA 1 ACID GLYCOPROTEIN KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATIONOF ALPHA 1 ACID GLYCOPROTEIN (ALPHA 1 AG) IN SERUM,FRUCTOSAMINE KIT(N-BIO)-A FRUCTOSAMINE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF FRUCTOSAMINE IN SERUM,PRE ALBUMIN KIT(TURBICHEM)-A PRE ALBUMIN KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF PRE ALBUMIN IN SERUM,FAECAL OCCULT BLOOD (FOB) RAPID TEST-A FOB RAPID KIT IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF FAECAL OCCULT BLOOD (FOB) IN FAECES,PROTEUS OX19, OX2, OXK-A PROTEUS KIT IS A MEDICAL DEVICE, INTENDED FOR

	THE DIAGNOSIS OF RICKETTISIAL INFECTION AND DIFFERENTIAL DIAGNOSIS IN PATIENT'S SERUM FOR FEBRILE FEVER,HEART TYPE FATTY ACID BINDING PROTEIN (H-FABP) KIT(TURBICHEM / NEPHCHEM)-A H-FABP KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF HEART-TYPE FATTY ACID BINDING PROTEIN (H-FABP) IN SERUM,ANTI NUCLEAR ANTIBODY (ANA) ELISA KIT(GBLISA)-AN ANTI-ANA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF AUTO-ANTIBODIES TO NUCLEAR ANTIGEN (ANTI NUCLEAR ANTIBODIES) IN SERUM,IMMUNOLOGY MULTICALIBRATOR-AN IMMUNOLOGY CALIBRATOR IS A MEDICAL DEVICE INTENDED TO DO CALIBRATION OF IMMUNO CHEMISTRY ASSAYS OTHER THAN INFECTIOUS AGENTS,IMMUNOLOGY CONTROL SET (LEVEL 1, LEVEL 2) -AN IMMUNOLOGY CONTROL SET IS A MEDICAL DEVICE, INTENDED FOR THE VALIDATION OF IMMUNO CHEMISTRY NORMAL AND ABNORMAL VALUES (OTHER THAN INFECTIOUS AGENTS),CHEMISTRY CALIBRATOR(GB'S MULTICAL)-A CHEMISTRY CALIBRATOR IS A MEDICAL DEVICE, INTENDED FOR THE PURPOSE OF CALIBRATION OF CHEMISTRY ASSAYS,HELICOBACTER PYLORI (H.PYLORI) ANTIBODY RAPID TEST-A H.PYLORI RAPID TEST IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF H.PYLORI ANTIBODY IN BODY FLUIDS/FAECES,IMMUNOGLOBULIN M (IGM) KIT(TURBICHEM / NEPHCHEM)-AN IGM IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF IMMUNOGLOBULIN M (IGM) IN SERUM, IMMUNOGLOBULIN-G (IGG) KIT(TURBICHEM / NEPHCHEM)-AN IGG KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF IMMUNOGLOBULIN-G (IGG) IN SERUM,KAPPA & LAMBDA LIGHT CHAINS KIT(TURBICHEM / NEPHCHEM)-A KAPPA & LAMBDA LIGHT CHAINS IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF KAPPA & LAMBDA LIGHT CHAINS IN SERUM,LIPOPROTEIN (A) LP (A) KIT(TURBICHEM / NEPHCHEM)-A LP (A) KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF LIPOPROTEIN (A) (LP(A)) IN SERUM,EPSTEIN-BARR VIRUS (EBV-VCA) IGG/IGM ELISA KIT(GBLISA)-AN EBV-VCA IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF EPSTEIN-BARR VIRUS (EBV-VCA) ANTIBODIES IN SERUM, APOLIPOPROTEIN E KIT (APO-E)(TURBICHEM / NEPHCHEM)-AN APO-E IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF APOLIPOPROTEIN E (APO-E) IN SERUM,COMPLEMENT COMPONENT-4 C4 KIT(TURBICHEM / NEPHCHEM)-A C4 KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF COMPLEMENT COMPONENT-4 (C4) IN SERUM,BENGAL ROSE-A BENGAL ROSE IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ANTIBODIES TO BRUCELLA SMOOOTH IN SERUM,CYSTANIN-C KIT(TURBICHEM / NEPHCHEM)-A CYSTANIN-C KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CYSTANIN-C IN SERUM/URINE,ANGIOTENSIN

	CONVERTING ENZYME (ACE) KIT(N-BIO)-AN ACE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ANGIOTENSIN CONVERTING ENZYME (ACE) IN SERUM,INFECTIOUS MONONUCLEOSIS KIT-AN INFECTIOUS MONONUCLEOSIS KIT IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF HETEROPHILE ANTIBODIES IN SERUM,HOMOCYSTEINE (HCY) KIT(N-BIO)-A HCY KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF HOMOCYSTEINE (HCY) IN SERUM,IMMUNOGLOBULIN-E (IGE) KIT (TURBICHEM / NEPHCHEM)-AN IGE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF IMMUNOGLOBULIN-E (IGE) IN SERUM,APOLIPOPROTEIN B KIT (APO-B)(TURBICHEM / NEPHCHEM)-AN APO B IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF APOLIPOPROTEIN B (APO-B) IN SERUM,OXALATE KIT(N-BIO)-AN OXALATE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF OXALATE IN SERUM,ESTRADIOL ELISA KIT(GBLISA)-A ESTRADIOL KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ESTRADIOL IN SERUM,CALCIUM ARSENAZO III KIT(N-BIO)-A CALCIUM IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CALCIUM IN SERUM,IRON / TIBC KIT(N-BIO)-AN IRON / TIBC KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF IRON / TIBC (TOTAL IRON BINDING CAPACITY) IN SERUM,NON ESTERIFIED FATTY ACID (NEFA) KIT(TURBICHEM)-A NEFA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF NON ESTERIFIED FATTY ACID (NEFA) IN SERUM,RHEUMATOID FACTOR (RF) KIT(TURBICHEM / NEPHCHEM)-A RF IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF RHEUMATOID FACTOR (RF) IN SERUM,BETA-HCG ELISA KIT(GBLISA)-A BETA-HCG KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF BETA HUMAN CHORIONIC GONADOTROPIN (BETA-HCG) IN URINE,ANTI SPERMATOZOA ANTIBODY (ANTI ASA) ELISA KIT (GBLISA)-AN ANTI-ASA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF AUTO-ANTIBODIES TO SPERMATOZA (ANTI-ASA) IN HUMAN SPECIMENS,TESTOSTERONE ELISA KIT(GBLISA)-A TESTOSTERONE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF TESTOSTERONE (FREE AND TOTAL) IN SERUM,ANTI-CYCLIC CITRULLINATED PEPTIDE (ANTI -CCP) KIT(TURBICHEM)-AN ANTI-CCP KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ANTI-CYCLIC CITRULLINATED PEPTIDE (CCP) ANTIBODIES IN SERUM,G6PDH KIT(N-BIO)-A G6PDH KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PDH) IN SERUM,FERRITIN KIT(N-BIO)-A FERRITIN KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF FERRITIN IN SERUM,ANTI CARDIOLIPIN IGG/IGM ELISA KIT (GBLISA)-AN ANTI-CARDIOLIPIN IGG / IGM ELISA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ANTI-CARDIOLIPIN

	ANTIBODIES IN SERUM,PROLACTIN ELISA KIT(GBLISA)-A PROLACTIN KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF PROLACTIN IN SERUM,DS-DNA IGG ELISA KIT(GBLISA)-A DS-DNA IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF AUTOBODIES TO DOUBLE STANDED DNA (ANTI-DS-DNA) IN SERUM,ANTI STREPTOLYSIN O (ASO) KIT(TURBICHEM / NEPHCHEM)-AN ASO IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ANTI STREPTOLYSIN O (ASO) IN SERUM,APOLIPOPROTEIN A1 KIT (APO A1) (TURBICHEM / NEPHCHEM)-AN APO-A1 IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF APOLIPOPROTEIN A1 (APO A1) IN SERUM,TOTAL BILE ACIDS (TBA) KIT(N-BIO)-A TBA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF TOTAL BILE ACIDS (TBA) IN SERUM,BRUCELLA ABORTUS & MELINTENSIS KIT-A BRUCELLA ABORTUS & MELINTENSIS IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ANTIBODIES TO BRUCELLA ABORTUS & MELINTENSIS IN SERUM,URINE STRIPS-URINE STRIPS IS A MEDICAL DEVICE, INTENDED FOR THE URINARY ESTIMATION OF GLUCOSE, BILIRUBIN, PH, PROTEIN, UROBILINOGEN, SPECIFIC GRAVITY, NITRITE, KETONE, BLOOD, LEUCOCYTES, ASCORBIC ACID, CREATININE, MICROALBUMINUREA, CALCIUM,COPPER KIT(N-BIO)-A COPPER KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF COPPER IN SERUM/URINE,POTASSIUM KIT(N-BIO)-A POTASSIUM KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF POTASSIUM IN SERUM/URINE,MICRO PROTEIN KIT(N-BIO)-A MICRO PROTEIN KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF MICRO PROTEIN IN URINE,UREA (KIN.) KIT(N-BIO)-AN UREA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF UREA IN SERUM,DIRECT LDL CHOLESTEROL KIT(N-BIO)-A DIRECT LDL CHOLESTEROL KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF LDL CHOLESTEROL IN SERUM,SGPT (ALAT) KIT(N-BIO)-A SGPT (ALAT) KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ENZYME ALANINE AMINO TRANSFERASE (ALT/SGPT) IN SERUM,GAMMA GT KIT(N-BIO)-A GAMMA GT KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ENZYME GAMMA GLUTAMYL TRANSFERASE (GGT) IN SERUM,PHOSPHORUS KIT(N-BIO) -A PHOSPHORUS KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF PHOSPHORUS IN SERUM,BICARBONATE KIT(N-BIO)-A BICARBONATE KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF BICARBONATE IN URINE/SERUM,CKNAC KIT(N-BIO)-A CKNAC KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ENZYME CREATINE KINASE TOTAL (CKNAC) IN SERUM,LYSE FOR HEMATOLOGY ANALYZER-A LYSE IS A MEDICAL DEVICE, INTENDED FOR THE WHITE BLOOD CELL COUNTING , DIFFERENTIAL AND ESTIMATION OF HEMOGLOBIN,ALPHA HBDH KIT(N-BIO)-AN ALPHA

	HBDH KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ALPHA HYDROXYBUTYRATE DEHYDROGENASE (ALPHA HBDH) IN SERUM,RETINOL BINDING PROTEIN (RBP) KIT(TURBICHEM)-A RBP KIT IS A MEDICAL DEVICE INTENDED FOR THE DETERMINATION OF RETINOL BINDING PROTEIN (RBP) IN SERUM,BENEDICTS REAGENT-A BENEDICTS REAGENT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF URINE SUGAR,RHEUMATOID FACTOR (RF) SLIDE LATEX KIT(GB'S RF)-A RF IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF RHEUMATOID FACTOR (RF) IN SERUM,BILIRUBIN TOTAL & DIRECT KIT(N-BIO)-A BILIRUBIN TOTAL & DIRECT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF BILIRUBIN TOTAL & DIRECT IN SERUM,COMPLEMENT COMPONENT-3 C3 KIT (TURBICHEM / NEPHCHEM)-A C3 KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF COMPLEMENT COMPONENT-3 (C3) IN SERUM,IMMUNOGLOBULIN A (IGA) KIT(TURBICHEM / NEPHCHEM)-AN IGA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF IMMUNOGLOBULIN A (IGA) KIT IN SERUM,CKMB KIT(N-BIO)-A CKMB KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CKMB IN SERUM,SS-DNA ELISA IGG/IGM KIT(GBLISA)-A SS-DNA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF AUTOBODIES TO SINGLE STANDED DNA (ANTI-SS-DNA) IN SERUM,ANTI STREPTOLYSIN O (ASO) SLIDE LATEX KIT(GB'S ASO)-AN ASO SLIDE LATEX IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF ANTI STREPTOLYSIN O (ASO) IN SERUM,URIC ACID KIT(N-BIO)-AN URIC ACID IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF URIC ACID IN SERUM,DENGUE ANTIBODY ELISA KIT-A DENGUE ELISA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF DENGUE ANTIBODY IN SERUM,PROBE / ENZYME (EZ) CLEANER-A PROBE/ENZYME CLEANER IS A MEDICAL DEVICE, INTENDED FOR CLEANING THE APERTURE AND COUNTING CHAMBER OF THE HEMATOLOGY ANALYZER

2753	MFG/IVD/2018/000005	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:AB STANDARD-IT CAN BE USED WITH ELECTROLYTE ANALYZERS BY PROFESSIONALS, FOR THE DETECTION OF POTASSIUM (K+), SODIUM (NA+), CHLORIDE (CL-), CALCIUM (CA2+), LITHIUM (LI+), PH (PH VALUE) AND TCO2 CONCENTRATION IN HUMAN SERUM.,CONTROL SOLUTION (L N H)-THIS 3-LEVEL QUALITY CONTROL IS USED TO MONITOR AND DETECT THE ELECTROLYTE ANALYZERS' PERFORMANCE,SCRUB TYPHUS(Q-LINE TEST)-SCRUB TYPHUS TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE SCREENING OF SCRUB TYPHUS IN BLOOD/BODY FLUIDS ,URINE STRIP(Q-LINE TEST)-URINE STRIPS TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE SCREENING OF VARIOUS PARAMETER IN HUMAN URINE ,FOB(Q-LINE TEST)-FOB TYPHUS TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE SCREENING OF FOB IN BLOOD/BODY FLUIDS , LEPTOSPIRAIGG/GM(Q-LINE TEST)-LEPTOSPIRA TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE SCREENING OF LEPTOSPIRA IN BLOOD/BODY FLUIDS ,HCG(Q-LINE TEST)-HCG TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE SCREENING OF HCG IN BLOOD/BODY FLUIDS ,DENGUE AB (Q- LINE TEST)-DENGUE AB TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE SCREENING OF DENGUE IN BLOOD/BODY FLUIDS ,PVC ELECTRODE ACTIVATING SOLUTION-USED FOR NEW ELECTRODE ACTIVATION.,REFERENCE FILLING SOLUTION-USED AS FILLING SOLUTION FOR REFERENCE ELECTRODE,ISE REFILLING SOLUTION-USED AS FILLING SOLUTION FOR ION ELECTRODE(K+, NA+, CL-, CA2+, LI+, PH).,CLEANING SOLUTION-CLEAN THE TUBES OF ELECTROLYTE ANALYZER.,DEPROTEIN SOLUTION-USED FOR CLEANING AND MAINTENANCE OF ELECTROLYTE ANALYZER TUBES AND ELECTRODES.
2754	MFG/IVD/2018/000006	1.License Holder Name: WRIG NANOSYSTEMS PRIVATE LIMITED 2.Approving Authority: EAST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:HAEMOGLOBIN TEST STRIPS(TRUEHB)-TRUEHB HEMOMETER IS INTENDED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF HAEMOGLOBIN IN FRESH CAPILLARY AND VENOUS WHOLE BLOOD SAMPLES. THE TRUEHB HEMOMETER MONITORING SYSTEM IS INTENDED FOR USE OUTSIDE THE BODY (IN VITRO DIAGNOSTICS USE) BY TRAINED PROFESSIONALS AND INDIVIDUALS. TRUEHB HEMOMETER IS USED WITH GENUINE TRUEHB STRIPS TO MEASURE HAEMOGLOBIN IN A BLOOD.

2755	MFG/IVD/2018/000066	1.License Holder Name: HESTER BIOSCIENCES LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BRUCELLA ABORTUS ROSE BENGAL ANTIGEN I.P.-FOR IN VITRO SEROLOGICAL DIAGNOSIS OF BRUCELLOSIS (B. MELITENSIS, B. ABORTUS AND B. SUIS) BY RAPID SLIDE AGGLUTINATION METHOD
2756	MFG/IVD/2019/000001	1.License Holder Name: DIABETOMICS MEDICAL (P) LTD 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:C-PEPTIDE TESTING KIT (INSUDEX C-PEPTIDE)-THE INSUDEX® C-PEPTIDE TEST KIT IS INTENDED TO BE AN AID IN THE DIAGNOSIS OF PATIENTS WITH ABNORMAL INSULIN SECRETION BY QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM.,PREECLAMPSIA TEST SYSTEM (LUMELLA)-RAPID TEST TO DETERMINE THE RISK FOR DEVELOPING PREECLAMPSIA,ANTICYCLIC CITRULLINATED PROTEINS RAPID TEST (ACCP)-ANTICYCLIC CITRULLINATED PROTEINS (ACCP) TEST KIT IS A LATERAL FLOW IMMUNOASSAY INTENDED TO BE USED FOR AS AN AID TO DIAGNOSIS BY QUALITATIVE DETECTION OF IGG ANTIBODIES TO CITRULLINATED PROTEINS IN SERUM FROM PATIENTS SUSPECTED OF RHEUMATOID ARTHRITIS.,GLUTAMIC ACID DECARBOXYLASE TEST(INSUDEX® GAD)-THE INSUDEX® GAD TEST IS FOR THE SEMI-QUANTITATIVE DETERMINATION OF GLUTAMIC ACID DECARBOXYLASE ANTIBODY (GAD AB) IN HUMAN SERUM. THE ASSAY IS USEFUL AS AN AID IN THE DIAGNOSIS OF TYPE I DIABETES MELLITUS (AUTOIMMUNE MEDIATED DIABETES). THE GAD TEST IS NOT TO BE USED ALONE AND IS TO BE USED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS.

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2757	MFG/IVD/2019/000002	1.License Holder Name: IMMUNOSCIENCE INDIA PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:RAPID SYPHILIS ANTIBODY TEST-FOR SYPHILIS CASSETTE: RAPID SYPHILIS ANTIBODY TEST(DEVICE) IS AN IMMUNOASSAY FOR THE RAPID AND VISUAL DETECTION OF ANTIBODIES TO TREPONEMA PALLIDUM IN HUMAN SERUM OR PLASMA OR WHOLE BLOOD TO AID IN THE DIAGNOSIS OF SYPHILIS. FOR SYPHILIS DIPSTICK: RAPID SYPHILIS ANTIBODY TEST(DIPSTICK) IS AN IMMUNOASSAY FOR THE RAPID AND VISUAL DETECTION OF ANTIBODIES TO TREPONEMA PALLIDUM IN HUMAN SERUM OR PLASMA TO AID IN THE DIAGNOSIS OF SYPHILIS.,RAPID MALARIA PF(HRP2) ANTIGEN TEST-THIS IS A RAPID, IN VITRO, QUALITATIVE LATERAL FLOW IMMUNOASSAY FOR THE DETECTION OF P.FALCIPARUM SPECIFIC HISTIDINE RICH PROTEIN-2 (PF.HRP-2) ANTIGEN FROM HUMAN WHOLE BLOOD SAMPLES.,RAPID DENGUE COMBO TEST (AG + AB)-RAPID DENGUE COMBO TEST IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF NS1 ANTIGEN AND IGM/IGG ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM/PLASMA.,RAPID MALARIA PF (HRP 2)/PAN (PLDH) ANTIGEN TEST -DEVICE & COMPONENTS-FOR DIAGNOSIS OF MALERIA,RAPID DENGUE NS1 ANTIGEN TEST- DEVICE & COMPONENTS-FOR DIAGNOSIS OF DENGUE,RAPIDRAPID MALARIA PF (HRP 2)/PV (PLDH) ANTIGEN TEST -DEVICE & COMPONENTS-FOR DIAGNOSIS OF MALERIA

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2758	MFG/IVD/2019/000003	1.License Holder Name: MOLBIO DIAGNOSTICS PVT. LTD. 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:CONTROL KIT FOR TRUENAT™ CHIP-BASED MICRO PCR TESTS: CT, NG, TRICH, HPV-HR, GBS AND SALMONELLA(TRUENAT™ POSITIVE CONTROL KIT - PANEL III)-TRUENAT™ POSITIVE CONTROL KIT - PANEL III IS A SET OF POSITIVE AND NEGATIVE CONTROL FOR VALIDATING THE PERFORMANCE OF TRUENAT™ CHIP BASED MICRO PCR TESTS - CT, NG, TRICH, HPV-HR, GBS AND SALMONELLA AS WELL AS TRUELAB® REAL TIME MICRO PCR ANALYZERS.,SAMPLE PRE-TREATMENT PACK FOR MTB SAMPLES(TRUEPREP™ AUTO MTB SAMPLE PRE-TREATMENT PACK)-TRUEPREP™ AUTO MTB SAMPLE PRE-TREATMENT PACK IS USED TO LIQUEFY AND PRETREAT THE PULMONARY AND EPTB SPECIMEN BEFORE PROCEEDING FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP™ AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP™ AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE.,CONTROL KIT FOR TRUENAT™ CHIP-BASED MICRO PCR TESTS: MTB, MTB PLUS, MTB-RIF DX, BETA COV, SARS COV-2, COVID-19 AND H1N1(TRUENAT™ POSITIVE CONTROL KIT - PANEL I)-TRUENAT™ POSITIVE CONTROL KIT - PANEL I IS A SET OF POSITIVE AND NEGATIVE CONTROL FOR VALIDATING THE PERFORMANCE OF TRUENAT™ CHIP BASED MICRO PCR TESTS - MTB, MTB PLUS, MTB-RIF DX, BETA COV, SARS COV-2, COVID-19 AND H1N1 AS WELL AS TRUELAB® REAL TIME MICRO PCR ANALYZERS.,SAMPLE PREP KIT FOR BLOOD/SERUM/PLASMA/OTHER BODY FLUIDS(TRUEPREP™ MAG BLOOD)-TRUEPREP™ MAG BLOOD IS A SAMPLE PREPARATION KIT MEANT FOR USE WITH TRUEPREP™ MAG SAMPLE PREP DEVICE FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS FROM BLOOD / SERUM / PLASMA / OTHER BODY FLUIDS SPECIMEN AS A PART OF THE TRUELAB™ REAL TIME MICRO PCR SYSTEM FOR THE DETECTION AND DIAGNOSIS OF TRUENAT™ DISEASE SPECIFIC CHIP BASED REAL TIME PCR ASSAYS.,CONTROL KIT FOR TRUENAT™ CHIP-BASED MICRO PCR TESTS: HAV, HEV, RABIES, LTS, NIPAH AND MALARIA PV/PF(TRUENAT™ POSITIVE CONTROL KIT - PANEL IV)-TRUENAT™ POSITIVE CONTROL KIT - PANEL IV IS A SET OF POSITIVE AND NEGATIVE CONTROL FOR VALIDATING THE PERFORMANCE OF TRUENAT™ CHIP BASED MICRO PCR TESTS - HAV, HEV, RABIES, LTS, NIPAH AND MALARIA PV/PF AS WELL AS TRUELAB® REAL TIME MICRO PCR ANALYZERS.,CONTROL KIT FOR TRUENAT™ CHIP-BASED MICRO PCR TESTS(TRUENAT™ UNIVERSAL CONTROL KIT)-TRUENAT™ UNIVERSAL CONTROL KIT IS A SET OF POSITIVE AND NEGATIVE CONTROL FOR VALIDATING THE PERFORMANCE OF TRUENAT™ CHIP BASED MICRO PCR TESTS AND TRUELAB™ REAL TIME MICRO PCR

	ANALYZERS.,CONTROL KIT FOR TRUENAT™ CHIP-BASED MICRO PCR TESTS: HBV, HCV, HIV-1, HLA-B27, DENGUE, CHIKUNGUNYA AND INFLUENZA A/B(TRUENAT™ POSITIVE CONTROL KIT - PANEL II)-TRUENAT™ POSITIVE CONTROL KIT - PANEL II IS A SET OF POSITIVE AND NEGATIVE CONTROL FOR VALIDATING THE PERFORMANCE OF TRUENAT™ CHIP BASED MICRO PCR TESTS - HBV, HCV, HIV-1, HLA-B27, DENGUE, CHIKUNGUNYA AND INFLUENZA A/B AS WELL AS TRUELAB® REAL TIME MICRO PCR ANALYZERS.,SAMPLE PRETREATMENT PACK FOR SWAB SPECIMEN(TRUEPREP™ MAG BLOOD)-TRUEPREP™ MAG BLOOD SAMPLE PRETREATMENT PACK FOR SWAB SPECIMEN IS USED TO DECONTAMINATE THE SWAB SPECIMEN AND MAKES IT READY FOR STORAGE/TRANSPORT BEFORE PROCEEDING FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP™ MAG BLOOD SAMPLE PREP KIT AND TRUEPREP™ MAG SAMPLE PREP DEVICE.,SAMPLE PREPARATION KIT FOR NUCLEIC ACID EXTRACTION ON TRUEPREP® AUTO V2(TRUEPREP® AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT)-TRUEPREP® AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT WORKS WITH TRUEPREP® AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE AND IS USED FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS FROM A WIDE RANGE OF BIOLOGICAL SPECIMENS.,REAGENT PACK FOR LIQUEFACTION OF SPUTUM SAMPLES.(TRUEPREP™ MAG SPUTUM-LIQUEFACTION REAGENT)-TRUEPREP™ MAG SPUTUM-LIQUEFACTION REAGENT IS USED TO LIQUIFY SPUTUM SAMPLE OF VARYING CONSISTENCIES.,UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE(TRUEPREP® AUTO V2)-TRUEPREP® AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT WORKS WITH TRUEPREP® AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE AND IS USED FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS FROM A WIDE RANGE OF BIOLOGICAL SPECIMENS. IT IS FOR IN VITRO DIAGNOSTICS (IVD) LABORATORY USE ONLY., UNIVERSAL SAMPLE PRE-TREATMENT PACK FOR NON MTB SAMPLES (TRUEPREP™ AUTO UNIVERSAL SAMPLE PRE-TREATMENT PACK)-TRUEPREP™ AUTO UNIVERSAL SAMPLE PRE-TREATMENT PACK IS USED TO PRETREAT THE SAMPLES SUCH AS WHOLE BLOOD/ SERUM/ PLASMA/URINE/SWAB SPECIMEN BEFORE PROCEEDING FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP™ AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP™ AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE.,CHIP-BASED REAL TIME PCR TEST FOR HLA-B27 (TRUENAT™ HLA-B27)-TRUENAT™ HLA-B27 IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE QUALITATIVE DETECTION OF HLA-B27 IN HUMAN BLOOD SPECIMEN

	AND AIDS IN THE DIAGNOSIS OF HLA-B27 TYPING. TRUENAT™HLA-B27 RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,REAGENT PACK FOR PROCESSING NON-SPUTUM SAMPLES FOR EXTRACTION WITH SAMPLE PREP KIT FOR SPUTUM (TRUEPREP™ MAG SPUTUM - EPTB PACK)-TRUEPREP™ MAG SPUTUM EPTB SAMPLE PROCESSING PACK IS AN ADD-ON PACK CONTAINING REAGENTS FOR DNA EXTRACTION FROM NON-SPUTUM SAMPLES USING TRUEPREP™ MAG SPUTUM SAMPLE PREP KIT AND TRUEPREP™ MAG SPUTUM SAMPLE PREP DEVICE FOR FURTHER REAL TIME PCR ANALYSIS ON TRUENAT™ MTB CHIP-BASED REAL TIME PCR TEST FOR QUANTITATIVE DETECTION AND DIAGNOSIS OF MYCOBACTERIUM TUBERCULOSIS (MTB).,SAMPLE PREP KIT FOR SPUTUM(TRUEPREP™ MAG SPUTUM)-TRUEPREP™ MAG SPUTUM IS A SAMPLE PREPARATION KIT MEANT FOR USE WITH TRUEPREP™ MAG SAMPLE PREP DEVICE FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS FROM SPUTUM SPECIMEN AS A PART OF THE TRUELAB™ REAL TIME MICRO PCR SYSTEM FOR THE DETECTION AND DIAGNOSIS OF MYCOBACTERIUM TUBERCULOSIS (MTB).,TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR SYSTEM COMPRISING OF TRUELAB™ UNO DX DEVICE, TRUEPREP™ AUTO DEVICE, AND ACCESSORIES(TRUELAB™ UNO DX WORKSTATION)-TRUELAB™ REAL TIME MICRO PCR WORK STATION HOUSES INSTRUMENTS AND ACCESSORIES THAT HELPS IN NUCLEIC ACID EXTRACTION AND USES MICROCHIP BASED REAL TIME PCR TECHNOLOGY FOR POINT OF CARE DIAGNOSIS OF INFECTIOUS DISEASE IN CLINICAL SAMPLES., UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE(TRUEPREP™ AUTO)-TRUEPREP™ AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE WORKS IN COMBINATION WITH TRUEPREP™ AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS FROM A WIDE RANGE OF BIOLOGICAL SPECIMENS. IT IS FOR IN VITRO DIAGNOSTIC (IVD) USE ONLY.,REAL TIME QUANTITATIVE MICRO PCR ANALYZER(TRUELAB™ DUO)-THE TRUELAB™ DUO REAL TIME QUANTITATIVE MICRO PCR ANALYZER IS INTENDED FOR PERFORMING REAL TIME PCR AS WELL AS REAL TIME RT-PCR OF TARGET NUCLEIC ACIDS DERIVED FROM A BROAD VARIETY OF HUMAN/ ANIMAL PATHOGENS USING THE TRUENAT™ DISEASE SPECIFIC MICRO PCR CHIPS. IT IS FOR IN VITRO DIAGNOSTIC (IVD) USE ONLY. TRUENAT™ CHIP-BASED REAL TIME PCR TEST RUNS ON THE TRUELAB™ DUO REAL TIME QUANTITATIVE MICRO PCR ANALYZER.,REAL TIME QUANTITATIVE MICRO PCR ANALYZER(TRUELAB™ QUATTRO)-THE TRUELAB™ QUATTRO REAL TIME QUANTITATIVE MICRO PCR ANALYZER IS INTENDED FOR PERFORMING REAL TIME PCR AS WELL AS REAL TIME RT-PCR OF TARGET NUCLEIC ACIDS DERIVED FROM A BROAD VARIETY OF

	HUMAN/ ANIMAL PATHOGENS USING THE TRUENAT™ DISEASE SPECIFIC MICRO PCR CHIPS. IT IS FOR IN VITRO DIAGNOSTIC (IVD) USE ONLY. TRUENAT™ CHIP-BASED REAL TIME PCR TEST RUNS ON THE TRUELAB™ QUATTRO REAL TIME QUANTITATIVE MICRO PCR ANALYZER.,TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR SYSTEM COMPRISING OF TRUELAB™ DUO DEVICE, TRUEPREP™ AUTO DEVICE, AND ACCESSORIES(TRUELAB™ DUO WORKSTATION)-TRUELAB™ REAL TIME MICRO PCR WORK STATION HOUSES INSTRUMENTS AND ACCESSORIES THAT HELPS IN NUCLEIC ACID EXTRACTION AND USES MICROCHIP BASED REAL TIME PCR TECHNOLOGY FOR POINT OF CARE DIAGNOSIS OF INFECTIOUS DISEASE IN CLINICAL SAMPLES.,MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF SWAB SPECIMEN FOR TRUEPREP™ AUTO(TRUEPREP™ AUTO TRANSPORT MEDIUM FOR SWAB SPECIMEN PACK)-TRUEPREP™ AUTO TRANSPORT MEDIUM FOR SWAB SPECIMEN PACK IS USED AS A MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF VARIOUS TYPES OF SWAB SPECIMEN BEFORE PROCEEDING FOR PRE-TREATMENT USING LYSIS BUFFER, EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP™ AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP™ AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE.,TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR SYSTEM COMPRISING OF A TRUELAB™ QUATTRO DEVICE, TWO TRUEPREP™ AUTO DEVICES, AND ACCESSORIES(TRUELAB™ QUATTRO WORKSTATION II)-TRUELAB™ REAL TIME MICRO PCR WORK STATION HOUSES INSTRUMENTS AND ACCESSORIES THAT HELPS IN NUCLEIC ACID EXTRACTION AND USES MICROCHIP BASED REAL TIME PCR TECHNOLOGY FOR POINT OF CARE DIAGNOSIS OF INFECTIOUS DISEASE IN CLINICAL SAMPLES.,REAL TIME QUANTITATIVE MICRO PCR ANALYZER(TRUELAB™ UNO DX)-THE TRUELAB™ UNO DX REAL TIME QUANTITATIVE MICRO PCR ANALYZER IS INTENDED FOR PERFORMING REAL TIME PCR AS WELL AS REAL TIME RT-PCR OF TARGET NUCLEIC ACIDS DERIVED FROM A BROAD VARIETY OF HUMAN/ ANIMAL PATHOGENS USING THE TRUENAT™ DISEASE SPECIFIC MICRO PCR CHIP. IT IS FOR IN VITRO DIAGNOSTIC (IVD) USE ONLY. TRUENAT™ CHIP-BASED REAL TIME PCR TEST RUNS ON THE TRUELAB™ UNO DX REAL TIME QUANTITATIVE MICRO PCR ANALYZER.,TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR SYSTEM COMPRISING OF TRUELAB™ QUATTRO DEVICE, TRUEPREP™ AUTO DEVICE, AND ACCESSORIES (TRUELAB™ QUATTRO WORKSTATION I)-TRUELAB™ REAL TIME MICRO PCR WORK STATION HOUSES INSTRUMENTS AND ACCESSORIES THAT HELPS IN NUCLEIC ACID EXTRACTION AND USES MICROCHIP BASED REAL TIME PCR TECHNOLOGY FOR POINT OF

		CARE DIAGNOSIS OF INFECTIOUS DISEASE IN CLINICAL SAMPLES., SAMPLE PREPARATION KIT FOR NUCLEIC ACID EXTRACTION ON TRUEPREP™ AUTO(TRUEPREP™ AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT)-TRUEPREP™ AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT WORKS WITH TRUEPREP™ AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE AND IS USED FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS FROM A WIDE RANGE OF BIOLOGICAL SPECIMENS.
2759	MFG/IVD/2019/000005	1.License Holder Name: MYLAB DISCOVERY SOLUTIONS PVT. LTD. LONAVLA 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NUCLEIC ACID BASED MULTIPLEX SCREENING KIT FOR HIV 1/2, HBV, AND HCV(NATSPERT ID TRIPLEH DETECTION KIT)-SCREENING OF HIV RNA, HCV RNA AND HBV DNA IN BLOOD DONORS, BLOOD PRODUCTS AND SUSPECTED INDIVIDUAL,NUCLEIC ACID BASED QUANTITATIVE DETECTION KITS FOR HIV1(HIV-1 QUANTITATIVE PCR KIT)-TESTING OF HIV-1 VIRAL LOAD,NUCLEIC ACID BASED QUANTITATIVE DETECTION KITS FOR HCV(HCV QUANTITATIVE PCR KIT)-TESTING OF HCV VIRAL LOAD, NUCLEIC ACID BASED QUANTITATIVE DETECTION KITS FOR HBV(HBV QUANTITATIVE PCR KIT)-TESTING OF HBV VIRAL LOAD
2760	MFG/IVD/2019/000006	1.License Holder Name: NUCLEUS DIAGNOSYS LLP 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:DIAGNOSTICS TEST REAGENT/ KITS FOR ALPHA AMYLASE-AN AMYLASE TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF THE ENZYME AMYLASE IN SERUM / PLASMA.,DIAGNOSTICS TEST REAGENT /KITS FOR ALKALINE PHOSPHATASE-AN ALKALINE PHOSPHATASE TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALKALINE PHOSPHATASE IN SERUM / PLASMA.,DIAGNOSTICS TEST REAGENT/ KITS FOR BILIRUBIN-AN BILIRUBIN (TOTAL AND DIRECT) TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF BILIRUBIN (TOTAL AND DIRECT) IN SERUM / PLASMA.

2761	MFG/IVD/2019/000007	1.License Holder Name: NUCLEUS DIAGNOSYS LLP 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:DIAGNOSTICS TEST REAGENT / KITS FOR TOTAL IGE (BIOTIN-STREPTAVIDIN)-THE TOTAL IGE TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGE IN HUMAN SERUM OR PLASMA. THE RESULTS ADD TO THE DIAGNOSIS OF TYPE I ALLERGIES. FURTHERMORE, DETERMINATION OF TOTAL IGE IS RECOMMENDED IN PATIENTS WITH SUSPECTED PARASITIC DISEASES,DIAGNOSTIC REAGENT/KIT FOR THYROXIN T4-THE THYROXIN KIT IS PROVIDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXIN (T4) IN HUMAN SERUM, SPECIFIC IGE BIOTINYLATED MULTI ALLERGENS-THE SPECIFIC IGE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF MULTI ALLERGENS IN BLOOD/BODY FLUIDS, DIAGNOSTIC REAGENT/KITS IMMUNOGLOBULIN G (IGM)-THE IGM IS A QUANTITATIVE TURBIDIMETRIC TEST FOR THE MEASUREMENT OF IGM IN HUMAN SERUM OR PLASMA.,DIAGNOSTICS TEST REAGENT / KITS FOR SPECIFIC IGG4-THE IGG4 - ELISA IS INTENDED FOR THE DETERMINATION OF SPECIFIC IGG4 IN HUMAN SERUM OR PLASMA AND DESIGNED TO MONITOR SPECIFIC IGG4-TITRES DURING HYPERSENSITISATION TREATMENT.,DIAGNOSTICS TEST REAGENT / KITS FOR CHIKUNGUNYA IGM ELISA-CHIKUNGUNYA IGM ELISA TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF IGM ANTIBODIES AGAINST CHIKUNGUNYA VIRUS IN HUMAN SERUM/PLASMA SAMPLES,SPECIFIC IGE BIOTINYLATED MULTI ALLERGENS-THE SPECIFIC IGE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF MULTI ALLERGENS IN BLOOD/BODY FLUIDS,DIAGNOSTIC REAGENT/KITS FOR CHOLINESTERASE (CHE)-QUANTITATIVE DETERMINATION OF CHOLINESTERASE (CHE) IN SERUM AND PLASMA,DIAGNOSTICS TEST REAGENT / KITS FOR TOTAL IGE (HRP-TMB)-INTENDED USE THE TOTAL IGE-HRP EIA IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGE IN HUMAN SERUM OR PLASMA. THE RESULTS ADD TO THE DIAGNOSIS OF TYPE I ALLERGIES. FURTHERMORE, DETERMINATION OF TOTAL IGE IS RECOMMENDED IN PATIENTS WITH SUSPECTED PARASITIC DISEASES.,DIAGNOSTIC REAGENT/KITS FOR IMMUNOGLOBULIN A (IGA)-THE IGA IS A QUANTITATIVE TURBIDIMETRIC TEST FOR THE MEASUREMENT OF IGA IN HUMAN SERUM OR PLASMA.,DIAGNOSTICS TEST REAGENT / KITS FOR SPECIFIC IGE-SPECIFIC IGE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALLERGENS IN BLOOD/BODY FLUIDS,DIAGNOSTICS TEST REAGENT / KITS FOR ANA BLOT-ANA BLOT TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ANTI NUCLEAR ANTIBODIES IN

	SERUM/PLASMA/BODY FLUIDS,IN-VITRO DIAGNOSTICS DEVICE FOR MAGNETIC DNA/RNA EXTRACTION KIT-DNA/RNA EXTRACTION KIT IS DESIGNED FOR SIMULTANEOUS ISOLATION OF VIRAL, BACTERIAL AND HUMAN DNA AND RNA OR ANY ONE DNA AND RNA FROM CLINICAL SAMPLES,DIAGNOSTICS TEST REAGENT / KITS FOR RENIN.-RENIN TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF RENIN (HUMAN MATURE AND PRO-RENIN) IN CELL CULTURE SUPERNATANT, SERUM, PLASMA AND URINE SAMPLES, SPECIFIC IGG4 CONTROLS-THE IGG4 - ELISA IS INTENDED FOR THE DETERMINATION OF SPECIFIC IGG4 IN HUMAN SERUM OR PLASMA AND DESIGNED TO MONITOR SPECIFIC IGG4-TITRES DURING HYPERSENSITISATION TREATMENT.,DIAGNOSTICS TEST REAGENT / KITS FOR ANTI-ACA IGM ELISA-ANTI CARDIOLIPIN ANTIBODIES (ANTI-ACA) IGM TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGM ANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SPECIMENS, DIAGNOSTICS TEST REAGENT / KITS FOR SCRUB TYPHUS-THE SCRUB TYPHUS KIT IS A RAPID AND QUALITATIVE TEST FOR THE DETECTION OF SCRUB TYPHUS ANTIGEN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA,DIAGNOSTICS TEST REAGENT / KITS FOR ANTI-ACA IGG ELISA-ANTI CARDIOLIPIN ANTIBODIES (ANTI-ACA) IGG TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG ANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SPECIMENS, DIAGNOSTICS TEST REAGENT KITS FOR VIRAL TRANSPORT MEDIUM (VTM)-IT IS INTENDED FOR THE COLLECTION AND TRANSPORT OF VIRUSES,DIAGNOSTIC REAGENT/KITS FOR IMMUNOGLOBULIN G (IGG) -THE IGG IS A QUANTITATIVE TURBIDIMETRIC TEST FOR THE MEASUREMENT OF IGG IN HUMAN SERUM OR PLASMA,SANITIZING SOLUTION FOR DISINFECTING SKIN SURFACE (HAND SANITIZER)-THE SOLUTION IS INTENDED FOR PROVIDING THE TOPICAL SANITIZING/CLEANING OF SURFACE (HAND RUBS),IN-VITRO DIAGNOSTICS DEVICE FOR 1,5-ANHYDROGLUCITOL (1,5-AG)-1,5-ANHYDROGLUCITOL REAGENT/KIT IS AN ENZYMATIC METHOD INTENDED FOR THE QUANTITATIVE DETERMINATION OF 1,5-ANHYDROGLUCITOL (1,5-AG) IN SERUM OR PLASMA.,IN-VITRO DIAGNOSTICS DEVICE FOR PRIM DNA/RNA EXTRACTION KIT-DNA/RNA EXTRACTION KIT IS DESIGNED FOR SIMULTANEOUS ISOLATION OF VIRAL, BACTERIAL AND HUMAN DNA AND RNA OR ANY ONE DNA AND RNA FROM CLINICAL SAMPLES,DIAGNOSTICS TEST REAGENT ELISA KITS FOR 17-OH PROGESTERONE-17-OH PROGESTERONE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF 17-OH PROGESTERONE IN BLOOD/BODY FLUIDS,SPECIFIC IGE CONTROL-THE SPECIFIC IGE TEST

	REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALLERGENS IN BLOOD/BODY FLUIDS,IN-VITRO DIAGNOSTICS DEVICE FOR -L FLUCOSIDASE--L FLUCOSIDASE REAGENT/KIT IS FOR DETERMINATION OF AFU ACTIVITY IN SERUM SAMPLES,SPECIFIC IGG4 CALIBRATORS -THE IGG4 - ELISA IS INTENDED FOR THE DETERMINATION OF SPECIFIC IGG4 IN HUMAN SERUM OR PLASMA AND THUS DESIGNED TO MONITOR SPECIFIC IGG4-TITRES DURING HYPERSENSITISATION TREATMENT, DIAGNOSTICS TEST REAGENT KITS FOR 1, 25 DIHYDROXY VITAMIN D-1, 25 DIHYDROXY VITAMIN D TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF 1, 25 DIHYDROXY VITAMIN CONCENTRATIONS IN HUMAN SERUM OR PLASMA SAMPLES,SPECIFIC IGG4 FOOD CALIBRATORS -THE IGG4 – FOOD – SCREENING IS INTENDED TO DETECT FOOD ANTIGEN-SPECIFIC IGG4 IN HUMAN SERUM OR PLASMA,SPECIFIC IGE SCREENING TEST KIT FOR THE DETECTION OF FOOD ALLERGENS-FOOD ALLERGEN PANEL IS FOR THE SEMI-QUANTITATIVE MEASUREMENT OF THE RELATIVE AMOUNT OF SPECIFIC IGE ANTIBODIES TO 26 FOOD ALLERGENS AS WELL AS CROSS-REACTIVE CARBOHYDRATE DETERMINANT (CCD) IN HUMAN SERUM.,DIAGNOSTICS TEST REAGENT / KITS FOR IGG4-FOOD SCREENING-THE IGG4 – FOOD – SCREENING IS INTENDED TO DETECT FOOD ANTIGEN-SPECIFIC IGG4 IN HUMAN SERUM OR PLASMA, SANITIZING SOLUTION FOR DISINFECTING SKIN SURFACE (HAND SANITIZER)-THE SOLUTION IS INTENDED FOR PROVIDING THE TOPICAL SANITIZING/CLEANING OF SURFACE (MAINLY HANDS)., SPECIFIC IGG4 ANTIGEN COATED STRIP/PLATES-THE IGG4 - ELISA IS INTENDED FOR THE DETERMINATION OF SPECIFIC IGG4 IN HUMAN SERUM OR PLASMA AND THUS DESIGNED TO MONITOR SPECIFIC IGG4-TITRES DURING HYPERSENSITISATION TREATMENT.,IN-VITRO DIAGNOSTICS DEVICE FOR FOLATE-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF FOLATE IN SERUM ON PHOTOMETRIC SYSTEMS.,SPECIFIC IGE BIOTINYLATED ALLERGENS-THE SPECIFIC IGE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALLERGENS IN BLOOD/BODY FLUIDS,IMMUNOASSAY DIAGNOSTICS ELISA TEST REAGENT KITS FOR 1,25-(OH)2-VITAMIN D-THE 1,25-DIHYDROXY VITAMIN D EIA KIT IS A COMPLETE ASSAY SYSTEM INTENDED FOR THE PURIFICATION OF 1,25-DIHYDROXYVITAMIN D (1,25D) IN HUMAN SERUM OR PLASMA BY IMMUNOEXTRACTION FOLLOWED BY QUANTITATION BY ENZYME IMMUNOASSAY,SPECIFIC IGE BIOTINYLATED ALLERGENS-SPECIFIC IGE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALLERGENS IN BLOOD/BODY FLUIDS,DIAGNOSTICS TEST REAGENT / KITS FOR ANTI-APA IGG/IGM ELISA-ANTI

	PHOSPHOLIPID ANTIBODIES (ANTI-APA) IGG/IGM TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF IGG AND IGM ANTIBODIES AGAINST CARDIOLIPIN, PHOSPHATIDYL SERINE, PHOSPHATIDYL INOSITOL, PHOSPHATIDIC ACID AND ß2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA SAMPLES,SPECIFIC IGG CALIBRATORS-THE SPECIFIC IGG TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGG IN HUMAN SERUM AND PLASMA AGAINST INHALATION ANTIGENS AND HELP TO DIAGNOSE SO CALLED TYPE III REACTIONS OF THE LUNG (E.G. FARMER´S LUNG, MALT AND PAPER WORKER´S LUNG AND BIRD FANCIER´S DISEASE,DIAGNOSTICS TEST REAGENT ELISA KITS FOR 25-OH VITAMIN D-25-OH VITAMIN D ELISA TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE QUALITATIVE AND QUANTITATIVE DETERMINATION OF TOTAL 25-OH VITAMIN D (VITAMIN D2 AND VITAMIN D3) CONCENTRATIONS IN HUMAN SERUM OR PLASMA SAMPLES,SPECIFIC IGE BIOTINYLATED MULTI ALLERGENS-THE SPECIFIC IGE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF MULTI ALLERGENS IN BLOOD/BODY FLUIDS,IN-VITRO DIAGNOSTICS DEVICE FOR HUMAN LAMBDA ()-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HUMAN LAMBDA ()IN SERUM ON PHOTOMETRIC SYSTEMS,SPECIFIC IGE BIOTINYLATED ALLERGENS-SPECIFIC IGE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALLERGENS IN BLOOD/BODY FLUIDS,IN-VITRO DIAGNOSTICS DEVICE FOR CARBON DIOXIDE (CO2)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CARBON DIOXIDE (CO2)IN SERUM/PLASMA ON PHOTOMETRIC SYSTEMS,SPECIFIC IGG4 ANTIGEN COATED STRIPS/PLATES-THE IGG4 - ELISA IS INTENDED FOR THE DETERMINATION OF SPECIFIC IGG4 IN HUMAN SERUM OR PLASMA AND THUS DESIGNED TO MONITOR SPECIFIC IGG4-TITRES DURING HYPERSENSITISATION TREATMENT.,QUALITATIVE ANALYSIS OF ANTINUCLEAR ANTIBODIES (07 PANEL) IN HUMAN SERUM.-THE LIA-ANA TEST IS FOR THE QUALITATIVE MEASUREMENT OF OF IGG CLASS ANTINUCLEAR ANTIBODIES AGAINST ANY 07 OF NRNP/SM, SM, SS-A/60KDA, SS-A/52KDA, SS-B/LA, SCL-70, PM-SCL, JO-1, CENP-B, PCNA, DSDNA, NUCLEOSOME, HISTONE, P0 & AMA M2 IN HUMAN SERUM. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF AUTOIMMUNE DISEASE., SPECIFIC IGE CALIBRATORS -THE SPECIFIC IGE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALLERGENS IN BLOOD/BODY FLUIDS,QUALITATIVE ANALYSIS OF AUTOANTIBODIES IN LIVER DISEASES (8 PANEL) IN HUMAN SERUM-

	THE LIA-LIVER TEST IS FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES AGAINST AMA M2, CENP-B, SP100, GP210, LKM-1, LC-1, SLA/LP, SS-A/52KDA IN HUMAN SERUM. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF AUTOIMMUNE LIVER DISEASE.,SPECIFIC IGG CONTROLS-THE SPECIFIC IGG - ELISA TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGG IN HUMAN SERUM AND PLASMA AGAINST INHALATION ANTIGENS AND HELP TO DIAGNOSE SO CALLED TYPE III REACTIONS OF THE LUNG (E.G. FARMER´S LUNG, MALT AND PAPER WORKER´S LUNG AND BIRD FANCIER´S DISEASE), DIAGNOSTICS TEST REAGENT ELISA KITS FOR NGAL (NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN)-THE KIT IS A SANDWICH ENZYME IMMUNOASSAY FOR IN VITRO QUANTITATIVE MEASUREMENT OF NGAL IN HUMAN SERUM, PLASMA, URINE, FECES, TISSUE HOMOGENATES, CELL LYSATES, CELL CULTURE SUPERNATES AND OTHER BIOLOGICAL FLUIDS,DIAGNOSTICS TEST REAGENT / KITS FOR ENA PROFILE 8-THE ENA PROFILE 8 ELISA IS INTENDED FOR THE SEMI QUANTITATIVE DETERMINATION OF ENAS AND ADDS TO THE DIAGNOSIS OF SYSTEMIC, RHEUMATIC AUTOIMMUNE DISORDERS. A) DSDNA, B) RNP/SM, C) SM, D) RO52, E) LA (SS-B), F) SCL-70, G) CENP-B, H) JO-1,QUALITATIVE ANALYSIS OF AUTOANTIBODIES IN LIVER DISEASES (4 PANEL) IN HUMAN SERUM-THE LIA-LIVER 4 PANEL TEST IS FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES AGAINST FOR ANY 4 (AMA M2, CENP-B, SP100, GP210, LKM-1, LC-1, SLA/LP, SS-A/52KDA) IN HUMAN SERUM. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF AUTOIMMUNE LIVER DISEASES.,SPECIFIC IGG4 FOOD CONTROLS-THE IGG4 – FOOD – SCREENING IS INTENDED TO DETECT FOOD ANTIGEN-SPECIFIC IGG4 IN HUMAN SERUM OR PLASMA,QUALITATIVE ANALYSIS OF ANTINUCLEAR ANTIBODIES (09 PANEL) IN HUMAN SERUM-THE LIA-ANA TEST IS FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS ANTINUCLEAR ANTIBODIES AGAINST ANY 09 OF NRNP/SM, SM, SS-A/60KDA, SS-A/52KDA, SS-B/LA, SCL-70, PM-SCL, JO-1, CENP-B, PCNA, DSDNA, NUCLEOSOME, HISTONE, P0 & AMA M2 IN HUMAN SERUM. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF AUTOIMMUNE DISEASES.,SPECIFIC IGE RECOMBINANT ALLERGENS-SPECIFIC IGE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALLERGENS IN BLOOD/BODY FLUIDS, QUALITATIVE ANALYSIS OF ANTINUCLEAR ANTIBODIES (13 PANEL) IN HUMAN SERUM-THE LIA-ANA TEST IS FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS ANTINUCLEAR ANTIBODIES AGAINST ANY 13 OF NRNP/SM, SM, SS-A/60KDA, SS-A/52KDA, SS-B/LA, SCL-

	70, PM-SCL, JO-1, CENP-B, PCNA, DSDNA, NUCLEOSOME, HISTONE, P0 & AMA M2 IN HUMAN SERUM. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF AUTOIMMUNE DISEASES.,DIAGNOSTICS TEST REAGENT / KITS FOR SPECIFIC IGG-THE SPECIFIC IGG - ELISA TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE QUANTITATIVE DETERMINATION OF SPECIFIC IGG IN HUMAN SERUM AND PLASMA AGAINST INHALATION ANTIGENS AND HELP TO DIAGNOSE SO CALLED TYPE III REACTIONS OF THE LUNG (E.G. FARMER´S LUNG, MALT AND PAPER WORKER´S LUNG AND BIRD FANCIER´S DISEASE), DIAGNOSTICS TEST REAGENT / KITS FOR CHIKUNGUNYA IGG ELISA-CHIKUNGUNYA IGG ELISA TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF IGG ANTIBODIES AGAINST CHIKUNGUNYA VIRUS IN HUMAN SERUM/PLASMA SAMPLES., DIAGNOSTICS TEST REAGENT KITS FOR HBA1C CONTROL/ CALIBRATOR-A HBA1C CALIBRATOR TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HBA1C CALIBRATOR IN BLOOD,IN-VITRO DIAGNOSTICS DEVICE FOR -HYDROXYBUTYRATE--HYDROXYBUTYRATE ASSAY REAGENT/KIT IS FOR THE QUANTITATIVE DETERMINATION OF -HYDROXYBUTYRATE IN HUMAN SERUM OR PLASMA SAMPLES.,DIAGNOSTICS TEST REAGENT/ KITS FOR HOMOCYSTEINE CALIBRATOR-USE DETECTION OF HOMOCYSTEINE,IN-VITRO DIAGNOSTICS DEVICE FOR NON-ESTERIFIED FATTY ACIDS (NEFA)-NON-ESTERIFIED FATTY ACIDS (NEFA) ASSAY REAGENT/KIT IS QUANTITATIVE IN VITRO DETERMINATION OF NON-ESTERIFIED FATTY ACIDS (NEFA) IN SERUM OR PLASMA ON PHOTOMETRIC SYSTEMS.,DIAGNOSTICS TEST REAGENT KITS FOR HBA1C-A HBA1C TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HBA1C IN BLOOD.,IN-VITRO DIAGNOSTICS DEVICE FOR ADIPONECTIN-ADIPONECTIN REAGENT /KIT OF DETERMINATION OF TOTAL ADIPONECTIN CONCENTRATION IN SERUM.,DIAGNOSTICS TEST REAGENT/ KITS FOR MICRO ALBUMIN CAIBRATOR-USE DETECTION OF MICRO ALBUMIN,DIAGNOSTICS TEST REAGENT/ KITS FOR URIC ACID-A URIC ACID TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF URIC ACID IN SERUM/PLASMA/URINE.,DIAGNOSTICS TEST REAGENT/ KITS FOR APOLIPOPROTEIN (B)-USE DETECTION OF APOLIPOPROTEIN B IN HUMAN SERUM OR PLASMA,DIAGNOSTICS TEST REAGENT ELISA KITS FOR FREE TESTOSTERONE-FREE TESTOSTERONE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF FREE TESTOSTERONE IN HUMAN BLOOD/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR FERRITIN CONTROL-USE DETECTION OF FERRITIN IN HUMAN SERUM OR PLASMA,IN-VITRO DIAGNOSTICS

	DEVICE FOR CYSTATIN C-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF CYSTATIN C IN SERUM/PLASMA ON PHOTOMETRIC SYSTEMS,DIAGNOSTICS TEST REAGENT/ KITS FOR LIPOPROTEIN (A) CALIBRATOR-USE DETECTION OF HOMOCYSTEINE, IN-VITRO DIAGNOSTICS DEVICE FOR TRANSFERRIN-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF TRANSFERRIN IN SERUM/PLASMA ON PHOTOMETRIC SYSTEMS, DIAGNOSTICS TEST REAGENT/ KITS FOR RINSE-A RINSE REAGENT/KIT IS A MEDICAL DEVICE USED FOR CLEANING VARIOUS PARTS OF HEMATOLOGY ANALYZERS LIKE PROBES. NEEDLES, BATHS, TUBING ETC.,IN-VITRO DIAGNOSTICS DEVICE FOR 25-OH VITAMIN D-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF 25-OH VITAMIN D IN SERUM/PLASMA ON PHOTOMETRIC SYSTEMS.,DIAGNOSTICS TEST REAGENT/ KITS FOR APOLIPOPROTEIN (A1)-USE DETECTION OF APOLIPOPROTEIN A1 IN HUMAN SERUM OR PLASMA,DIAGNOSTICS TEST REAGENT / KITS FOR PLASMA METANEPHRINE-METANEPHRINE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF METANEPHRINE AND NORMETANEPHRINE IN PLASMA SAMPLES, DIAGNOSTICS TEST REAGENT KITS FOR ADENOSINE DEAMINASE (ADA)-AN ADENOSINE DEAMINASE (ADA) TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ADENOSINE DEAMINASE IN SERUM / PLASMA.,IN-VITRO DIAGNOSTICS DEVICE FOR LACTATE-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LACTATE IN SERUM/PLASMA ON PHOTOMETRIC SYSTEMS,DIAGNOSTICS TEST REAGENT/ KITS FOR LIPID CALIBRATOR-USE DETECTION OF LIPID PARAMETER,QUALITATIVE ANALYSIS OF ANTINUCLEAR ANTIBODIES (15 PANEL) IN HUMAN SERUM-THE LIA-ANA TEST IS FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS ANTINUCLEAR ANTIBODIES AGAINST NRNP/SM, SM, SS-A/60KDA, SS-A/52KDA, SS-B/LA, SCL-70, PM-SCL, JO-1, CENP-B, PCNA, DSDNA, NUCLEOSOME, HISTONE, P0 & AMA M2 IN HUMAN SERUM. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF AUTOIMMUNE DISEASES., DIAGNOSTICS TEST REAGENT/ KITS FOR URINE STRIP 10 PARA - ASCORBIC ACID, BILIRUBIN, BLOOD CELLS, GLUCOSE, KETONE, LEUKOCYTE, PROTEIN, ALBUMIN OTHER UTINARY ANALYTES TEST STRIP/KITS ARE MEDICAL DEVICE INTENDED FOR THE PRELIMINARY ESTIMATION OF DIAGNOSTIC MARKERS IN URINE.,IN-VITRO DIAGNOSTICS DEVICE FOR ANGIOTENSIN CONVERTING ENZYME (ACE)-ANGIOTENSIN CONVERTING ENZYME (ACE) REAGENT /KIT OF DETERMINATION OF TOTAL ANGIOTENSIN CONVERTING ENZYME CONCENTRATION IN SERUM OR HEPARINIZED PLASMA,DIAGNOSTICS TEST REAGENT/ KITS FOR URINE STRIP 12 PARA-ASCORBIC ACID,

	BILIRUBIN, BLOOD CELLS, GLUCOSE, KETONE, LEUKOCYTE, PROTEIN, ALBUMIN OTHER UTINARY ANALYTES TEST STRIP/KITS ARE MEDICAL DEVICE INTENDED FOR THE PRELIMINARY ESTIMATION OF DIAGNOSTIC MARKERS IN URINE.,: IN-VITRO DIAGNOSTICS DEVICE FOR FIBRIN DEGRADATION PRODUCT (FDP)-FIBRIN DEGRADATION PRODUCT (FDP) ASSAY REAGENT/KIT IS FOR THE QUANTITATIVE DETERMINATION OF FIBRIN/FIBRINOGEN DEGRADATION PRODUCTS IN HUMAN PLASMA.,DIAGNOSTICS TEST REAGENT/ KITS FOR C-REACTIVE PROTEIN (CRP) CONTROL-IN VITRO QUANTITATIVE DETERMINATION OF CRP IN HUMAN SERUM OR PLASMA, DIAGNOSTICS TEST REAGENT ELISA KITS FOR PEPSINOGEN I-PEPSINOGEN I ELISA ASSAY KIT (ENZYME-LINKED IMMUNOASSAY) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN PEPSINOGEN I LEVELS IN SERUM.,DIAGNOSTICS TEST REAGENT/ KITS FOR POTASSIUM-USE DETECTION OF POTASSIUM IN SERUM/PLASMA, QUALITATIVE ANALYSIS OF ANTIBODIES IN AUTOIMMUNE VASCULITIS (2 PANEL) IN HUMAN SERUM.-THE ANTIBODIES AGAINST ANY TWO PR3, MPO AND GBM LINE IMMUNO ASSAY IS FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES AGAINST PROTEINASE 3 (PR3), MYELOPEROXIDASE (MPO) AND GLOMERULAR BASEMENT MEMBRANE (GBM) IN HUMAN SERUM.,DIAGNOSTICS TEST REAGENT KITS FOR COPPER-A COPPER TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF COPPER IN SERUM/PLASMA.,IN-VITRO DIAGNOSTICS DEVICE FOR HUMAN KAPPA FLC-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HUMAN KAPPA FLC IN SERUM ON PHOTOMETRIC SYSTEMS,DIAGNOSTICS TEST REAGENT KITS FOR PROTEIN MICRO-A PROTEIN MICRO TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF PROTEIN MICRO IN SERUM/PLASMA/URINE.,IN-VITRO DIAGNOSTICS DEVICE FOR HEART-TYPE FATTY ACID BINDING PROTEIN (H-FABP)-HEART-TYPE FATTY ACID BINDING PROTEIN (H-FABP) ASSAY REAGENT/KIT IS FOR THE DETERMINATION OF HEART-TYPE FATTY ACID-BINDING PROTEIN CONCENTRATION IN SERUM OR LITHIUM-HEPARIN PLASMA BY LATEX ENHANCED IMMUNOTURBIDIMETRIC METHOD,DIAGNOSTICS TEST REAGENT/ KITS FOR UIBC-USE DETECTION OF UIBC IN SERUM/PLASMA,QUALITATIVE ANALYSIS OF ANTIBODIES IN AUTOIMMUNE VASCULITIS (3 PANEL) IN HUMAN SERUM-THE ANTIBODIES AGAINST PR3, MPO AND GBM LINE IMMUNO ASSAY IS FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES AGAINST PR3, MPO AND GBM IN HUMAN SERUM,DIAGNOSTICS TEST REAGENT/ KITS FOR FERRITIN -USE DETECTION OF FERRITIN IN HUMAN SERUM OR PLASMA,DIAGNOSTICS TEST REAGENT KITS FOR ANTI NUCLEAR ANTIBODIES (ANA)-ANA TEST REAGENT / KIT IS A

	MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ANTI NUCLEAR ANTIBODIES IN SERUM/PLASMA/BODY FLUIDS,DIAGNOSTICS TEST REAGENT/ KITS FOR C-REACTIVE PROTEIN (CRP) CALIBRATOR-USE DETECTION OF CRP IN HUMAN SERUM OR PLASMA,IN-VITRO DIAGNOSTICS DEVICE FOR VITAMIN B12-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF VITAMIN B12 IN SERUM ON PHOTOMETRIC SYSTEMS.,DIAGNOSTICS TEST REAGENT KITS FOR ZINC-A ZINC TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ZINC IN SERUM/PLASMA.,DIAGNOSTICS TEST REAGENT / KITS FOR ACTIVE RENIN-ACTIVE RENIN TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ACTIVE RENIN IN HUMAN SERUM/PLASMA SAMPLES, DIAGNOSTICS TEST REAGENT/ KITS FOR LIPID CONTROL-USE DETECTION OF LIPID PARAMETER,DIAGNOSTIC REAGENT/KIT FOR TSH-THE TSH KIT IS PROVIDED FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN HUMAN SERUM,DIAGNOSTICS TEST REAGENT/ KITS FOR DENGUE IGG/IGM. -DENGUE ANTIBODY TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF DENGUE ANTIBODY IN BLOOD/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT / KITS FOR SCRUB TYPHUS IGG ELISA.-SCRUB TYPHUS IGG ELISA TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF IGG ANTIBODIES AGAINST SCRUB TYPHUS (ORIENTIA TSUTSUGAMUSHI-OT) IN HUMAN SERUM/PLASMA SAMPLES,DIAGNOSTICS TEST REAGENT/ KITS FOR MULTI ANALYTE CALIBRATOR-USE DETECTION OF CHEMISTRY PARAMETER,DIAGNOSTIC REAGENT/KIT FOR FREE T4-THE FREE THYROXIN KIT IS PROVIDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL FREE THYROXIN (T4) IN HUMAN SERUM, DIAGNOSTICS TEST REAGENT/ KITS FOR HEMATOLOGY CONTROL-USE DETECTION OF TOTAL BLOOD CELL,DIAGNOSTICS TEST REAGENT/ KITS FOR TOTAL PROTEIN-A TOTAL PROTEIN TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TOTAL PROTEIN IN SERUM/PLASMA,DIAGNOSTICS TEST REAGENT/ KITS FOR DILUENTS-A BLOOD CELL DILUENT IS A MEDICAL DEVICE USED TO DILUTE BLOOD FOR FURTHER TESTING, SUCH AS COMPLETE BLOOD COUNT (CBC),DIAGNOSTICS TEST REAGENT / KITS FOR ALBUMIN-AN ALBUMIN TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALBUMIN IN SERUM/PLASMA.,DIAGNOSTICS TEST REAGENT/ KITS FOR URINE STRIP 4 PARA-S-USE DETECTION OF 4 PARA IN URINE,SPECIFIC IGE SCREENING TEST KIT FOR THE DETECTION OF INHALANT ALLERGENS-INHALANT ALLERGEN PANEL IS FOR THE SEMI-QUANTITATIVE MEASUREMENT OF THE RELATIVE AMOUNT OF SPECIFIC IGE ANTIBODIES TO 26 ALLERGENS AS WELL AS CROSS-

	REACTIVE CARBOHYDRATE DETERMINANT (CCD) IN HUMAN SERUM., DIAGNOSTICS TEST REAGENT KITS FOR CK NAC-A CK NAC TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CK NAC IN PLASMA/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR CHOLESTEROL-A CHOLESTEROL (TOTAL) TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHOLESTEROL IN SERUM OR PLASMA.,DIAGNOSTICS TEST REAGENT KITS FOR LACTATE DEHYDROGENASE-A LACTATE DEHYDROGENASE TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF LACTATE DEHYDROGENASE IN SERUM/PLASMA., DIAGNOSTICS TEST REAGENT / KITS FOR SCRUB TYPHUS IGM ELISA-SCRUB TYPHUS IGM ELISA TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF IGM ANTIBODIES AGAINST SCRUB TYPHUS (ORIENTIA TSUTSUGAMUSHI-OT) IN HUMAN SERUM/PLASMA SAMPLES,DIAGNOSTICS TEST REAGENT/ KITS FOR URINE STRIP 11 PARA-ASCORBIC ACID, BILIRUBIN, BLOOD CELLS, GLUCOSE, KETONE, LEUKOCYTE, PROTEIN, ALBUMIN OTHER UTINARY ANALYTES TEST STRIP/KITS ARE MEDICAL DEVICE INTENDED FOR THE PRELIMINARY ESTIMATION OF DIAGNOSTIC MARKERS IN URINE., DIAGNOSTICS TEST REAGENT / KITS FOR TESTOSTERONE-TESTOSTERONE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TESTOSTERONE IN HUMAN BLOOD/BODY FLUIDS,DIAGNOSTICS TEST REAGENT/ KITS FOR BILIRUBIN DIRECT-AN BILIRUBIN (DIRECT) TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF BILIRUBIN (DIRECT) IN SERUM / PLASMA.,DIAGNOSTICS TEST REAGENT / KITS FOR DENGUE IGG ELISA.-DENGUE IGG ELISA TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF IGG ANTIBODIES AGAINST DENGUE VIRUS IN HUMAN SERUM/PLASMA SAMPLES,DIAGNOSTICS TEST REAGENT KITS FOR SODIUM-A SODIUM TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF SODIUM IN SERUM/PLASMA.,DIAGNOSTICS TEST REAGENT/ KITS FOR UREA-A UREA UV TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF UREA (BUN) IN SERUM/PLASMA/URINE,DIAGNOSTICS TEST REAGENT /KITS FOR GLUCOSE-A GLUCOSE TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF GLUCOSE IN PLASMA/BODY FLUIDS.,DIAGNOSTIC REAGENT/KIT FOR FREE TRIIODOTHYRONINE T3-THE FREE TRIIODOTHYRONINE KIT IS PROVIDED FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (T3) IN HUMAN SERUM,DIAGNOSTICS TEST REAGENT/ KITS FOR URINE CONTROL (NORMAL AND ABNORMAL)-USE DETECTION OF CLINICAL PARAMETER IN URINE,DIAGNOSTICS TEST REAGENT/ KITS FOR UREA-A UREA BERTHELOT TEST REAGENT/ KIT IS A MEDICAL DEVICE

	INTENDED FOR THE ESTIMATION OF UREA (BUN) IN SERUM/PLASMA/URINE,DIAGNOSTICS TEST REAGENT/ KITS FOR HEMATOLOGY CALIBRATOR-USE DETECTION OF TOTAL BLOOD CELL, DIAGNOSTICS TEST REAGENT /KITS FOR CALCIUM-A CALCIUM ARS TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TOTAL CALCIUM IN SERUM OR PLASMA, DIAGNOSTICS TEST REAGENT KITS FOR ADENOSINE DEAMINASE CONTROL-AN ADENOSINE DEAMINASE CONTROL TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ADENOSINE DEAMINASE IN SERUM OR PLASMA,DIAGNOSTICS TEST REAGENT /KITS FOR TRIGLYCERIDES-A TRIGLYCERIDES TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TRIGLYCERIDES IN SERUM/PLASMA,DIAGNOSTICS TEST REAGENT KITS FOR MAGNESIUM.-A CHLORIDE TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHLORIDE IN SERUM/PLASMA.,ALANINE AMINOTRANSFERASE (ALT/SGPT)-AN ALANINE AMINO TRANSFERASE (ALT/SGPT) TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME ALANINE AMINO TRANSFERASE (ALT/SGPT) IN SERUM / PLASMA., DIAGNOSTICS TEST REAGENT KITS FOR HOMOCYSTEINE CALIBRATOR/CONTROL-A HOMOCYSTEINE CALIBRATOR/CONTROL TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HOMOCYSTEINE IN SERUM OR PLASMA., DIAGNOSTICS TEST REAGENT/ KITS FOR AST/SGOT-AN ASPARTATE AMINO TRANSFERASE (AST/SGOT) TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME ASPARTATE AMINO TRANSFERASE (AST/SGOT) IN SERUM / PLASMA., DIAGNOSTICS TEST REAGENT KITS FOR LDL CHOLESTEROL-LDL-CHOLESTEROL DIRECT TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF LDL CHOLESTEROL IN SERUM/PLASMA.,DIAGNOSTICS TEST REAGENT /KITS FOR CREATININE -A CREATININE TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CREATININE IN SERUM, PLASMA/URINE.,DIAGNOSTICS TEST REAGENT KITS FOR CHLORIDE-A CHLORIDE TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHLORIDE IN SERUM/PLASMA.,DIAGNOSTICS TEST REAGENT / KITS FOR VITAMIN D ELISA-VITAMIN D ELISA TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL VITAMIN D CONCENTRATIONS IN HUMAN SERUM OR PLASMA SAMPLES, DIAGNOSTICS TEST REAGENT KITS FOR PHOSPHORUS-A PHOSPHORUS TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF PHOSPHORUS IN SERUM/PLASMA., DIAGNOSTICS TEST REAGENT / KITS FOR DENGUE IGM ELISA-

	DENGUE IGM ELISA TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF IGM ANTIBODIES AGAINST DENGUE VIRUS IN HUMAN SERUM/PLASMA SAMPLES,DIAGNOSTICS TEST REAGENT KITS FOR HDL/LDL CHOLESTEROL CALIBRATOR-AN HDL/LDL CHOLESTEROL CALIBRATOR TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HDL/LDL CHOLESTEROL IN SERUM / PLASMA.,DIAGNOSTICS TEST REAGENT KITS FOR ANTI NUCLEAR ANTIBODIES (ANA) PROFILE-ANA TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ANTI NUCLEAR ANTIBODIES IN SERUM/PLASMA/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR URINE STRIP 2 PARA GLUCOSE AND PROTEIN -ASCORBIC ACID, BILIRUBIN, BLOOD CELLS, GLUCOSE, KETONE, LEUKOCYTE, PROTEIN, ALBUMIN OTHER UTINARY ANALYTES TEST STRIP/KITS ARE MEDICAL DEVICE INTENDED FOR THE PRELIMINARY ESTIMATION OF DIAGNOSTIC MARKERS IN URINE.,DIAGNOSTICS TEST REAGENT / KITS FOR PROGESTERONE-PROGESTERONE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF PROGESTERONE IN BLOOD/BODY FLUIDS,DIAGNOSTICS TEST REAGENT/ KITS FOR CLEANER-A CLEANER REAGENT/KIT IS A MEDICAL DEVICE USED FOR CLEANING VARIOUS PARTS OF HEMATOLOGY ANALYZERS LIKE PROBES. NEEDLES, BATHS, TUBING ETC.,DIAGNOSTICS TEST REAGENT / KITS FOR URINE METANEPHRINE-METANEPHRINE TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF METANEPHRINE AND NORMETANEPHRINE IN URINE SAMPLES,DIAGNOSTICS TEST REAGENT/ KITS FOR URINE STRIP 4 MAU-ASCORBIC ACID, BILIRUBIN, BLOOD CELLS, GLUCOSE, KETONE, LEUKOCYTE, PROTEIN, ALBUMIN OTHER UTINARY ANALYTES TEST STRIP/KITS ARE MEDICAL DEVICE INTENDED FOR THE PRELIMINARY ESTIMATION OF DIAGNOSTIC MARKERS IN URINE.,DIAGNOSTICS TEST REAGENT ELISA KITS FOR PEPSINOGEN II-PEPSINOGEN II ELISA ASSAY KIT (ENZYME-LINKED IMMUNOASSAY KIT) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN PEPSINOGEN II LEVELS IN SERUM, DIAGNOSTICS TEST REAGENT/ KITS FOR URINE STRIP 4 PARA-ASCORBIC ACID, BILIRUBIN, BLOOD CELLS, GLUCOSE, KETONE, LEUKOCYTE, PROTEIN, ALBUMIN OTHER UTINARY ANALYTES TEST STRIP/KITS ARE MEDICAL DEVICE INTENDED FOR THE PRELIMINARY ESTIMATION OF DIAGNOSTIC MARKERS IN URINE.,DIAGNOSTICS TEST REAGENT / KITS FOR DSDNA-DSDNA TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ANTI DOUBLE STRANDED DNA (ANTI-DSDNA) IN HUMAN SPECIMENS,DIAGNOSTICS TEST REAGENT/ KITS FOR HDL CHOLESTEROL.-A HDL CHOLESTEROL PRECIPITATING TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED

	FOR THE ESTIMATION OF HDL CHOLESTEROL IN SERUM/PLASMA., DIAGNOSTIC REAGENT/KIT FOR TRIIODOTHYRONINE T3-THE TRIIODOTHYRONINE KIT IS PROVIDED FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) IN HUMAN SERUM, DIAGNOSTICS TEST REAGENT /KITS FOR CREATININE -A CREATININE TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CREATININE IN SERUM, PLASMA/URINE.,DIAGNOSTIC REAGENT/KITS FOR IMMUNOGLOBULIN E (IGE).-THE IGE IS A QUANTITATIVE TURBIDIMETRIC TEST FOR THE MEASUREMENT OF IGE IN HUMAN SERUM OR PLASMA.,DIAGNOSTICS TEST REAGENT KITS FOR ADENOSINE DEAMINASE CALIBRATOR-AN ADENOSINE DEAMINASE CALIBRATOR TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ADENOSINE DEAMINASE IN SERUM OR PLASMA,VIRAL TRANSPORT MEDIA-THE KIT IS USED BY LABORATORY PROFESSIONAL FOR COLLECTION OF VIRUS AND TRANSPORT OF THE SAME.,DIAGNOSTICS TEST REAGENT KITS FOR LIPASE-AN LIPASE TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF LIPASE IN SERUM / PLASMA., DIAGNOSTICS TEST REAGENT KITS FOR G6PDH-A G6PDH TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF G6PDH IN SERUM/PLASMA.,DIAGNOSTICS TEST REAGENT/ KITS FOR BILIRUBIN TOTAL -AN BILIRUBIN (TOTAL) TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF BILIRUBIN (TOTAL) IN SERUM / PLASMA,DIAGNOSTICS TEST REAGENT/ KITS FOR BIOCARBONATE (C02)-USE DETECTION OF BICARBONATE IN HUMAN SERUM OR PLASMA,DIAGNOSTICS TEST REAGENT/ KITS FOR RHEUMATOID FACTORS (RF) CALIBRATOR-USE DETECTION OF RHEUMATOID FACTORS (RF),DIAGNOSTICS TEST REAGENT/ KITS FOR CREATINE KINASE (CKMB)-A CREATINE KINASE (CK) AND CKMB TEST REAGENT/KIT ARE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF CREATINE KINASE (CK) AND CKMB IN BLOOD/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR RHEUMATOID FACTORS (RF) CONTROL-USE DETECTION OF RHEUMATOID FACTORS (RF),DIAGNOSTICS TEST REAGENT/ KITS FOR C-REACTIVE PROTEIN (CRP)-USE DETECTION OF CRP IN HUMAN SERUM OR PLASMA, DIAGNOSTICS TEST REAGENT/ KITS FOR IMMUNOLOGY CONTROL-USE DETECTION OF IMMUNOLOGY ASSAY,DIAGNOSTICS TEST REAGENT/ KITS FOR IRON-USE DETECTION OF IRON IN SERUM/PLASMA,DIAGNOSTICS TEST REAGENT/ KITS FOR MICRO ALBUMIN CONTROL-USE DETECTION OF MICRO ALBUMIN, DIAGNOSTICS TEST REAGENT/ KITS FOR MULTI ANALYTE CONTROL (NORMAL/ABNORMAL)-USE DETECTION OF CHEMISTRY PARAMETER, DIAGNOSTICS TEST REAGENT/ KITS FOR HUMAN CHORIONIC GONADOTROPIN (HCG).-A HUMAN CHORIONIC GONADOTROPIN (HCG)

	TEST REAGENT/KIT IS MEDICAL DEVICE INTENDED FOR PRELIMINARY SELF TESTING OF HCG IN URINE/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT /KITS FOR TYPHOID.-TYPHOID ANTIGEN TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF TYPHOID ANTIBODY IN BLOOD/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/KITS FOR CHIKUNGUNYA. -CHIKUNGUNYA ANTIBODY TEST REAGENTS AND KITS REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION CHIKUNGUNYA ANTIBODY IN BLOOD/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR RHEUMATOID FACTORS (RF)-USE DETECTION OF RF IN SERUM/PLASMA, DIAGNOSTICS TEST REAGENT/ KITS FOR FERRITIN CALIBRATOR-USE DETECTION OF FERRITIN IN HUMAN SERUM OR PLASMA, DIAGNOSTICS TEST REAGENT/ KITS FOR URINE STRIP GLUCOSE-ASCORBIC ACID, BILIRUBIN, BLOOD CELLS, GLUCOSE, KETONE, LEUKOCYTE, PROTEIN, ALBUMIN OTHER UTINARY ANALYTES TEST STRIP/KITS ARE MEDICAL DEVICE INTENDED FOR THE PRELIMINARY ESTIMATION OF DIAGNOSTIC MARKERS IN URINE.,DIAGNOSTICS TEST REAGENT/ KITS FOR MYOGLOBIN-MYOGLOBIN TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF MYOGLOBIN IN BLOOD/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT KITS FOR AMMONIA-AN AMMONIA TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF AMMONIA IN SERUM/PLASMA/URINE.,DIAGNOSTICS TEST REAGENT/ KITS FOR LIPOPROTEIN (A)-USE DETECTION OF LIPOPROTEIN (A) IN SERUM/PLASMA,DIAGNOSTICS TEST REAGENT/ KITS FOR LEPTOSPIRA-A LEPTOSPIRA ANTIBODY TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF LEPTOSPIRA ANTIBODY IN BLOOD/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR ZIKA VIRUS-ZIKA ANTIBODY TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF ZIKA SPECIFIC ANTIBODIES IN BLOOD/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR IMMUNOLOGY CALIBRATOR-USE DETECTION OF IMMUNOLOGY ASSAY,DIAGNOSTICS TEST REAGENT KITS FOR LIPASE CALIBRATOR-AN LIPASE CALIBRATOR TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF THE LIPASE CALIBRATOR IN SERUM / PLASMA.,DIAGNOSTICS TEST REAGENT KITS FOR HDL - CHOLESTEROL-HDL-C DIRECT TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HDL CHOLESTEROL IN SERUM/PLASMA.,DIAGNOSTICS TEST REAGENT KITS FOR HOMOCYSTEINE-A HOMOCYSTEINE TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HOMOCYSTEINE IN SERUM OR PLASMA,DIAGNOSTICS TEST REAGENT /KITS FOR HEMOGLOBIN-A HEMOGLOBIN TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HEMOGLOBIN

	IN BLOOD.,DIAGNOSTICS TEST REAGENT KITS FOR CK MB-A CK MB TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CK MB IN SERUM, PLASMA/URINE.,DIAGNOSTICS TEST REAGENT/ KITS FOR URINE STRIP 2 PARA GLUCOSE AND KETONE -ASCORBIC ACID, BILIRUBIN, BLOOD CELLS, GLUCOSE, KETONE, LEUKOCYTE, PROTEIN, ALBUMIN OTHER UTINARY ANALYTES TEST STRIP/KITS ARE MEDICAL DEVICE INTENDED FOR THE PRELIMINARY ESTIMATION OF DIAGNOSTIC MARKERS IN URINE., DIAGNOSTICS TEST REAGENT/ KITS FOR URINE STRIP 11 ACR-ASCORBIC ACID, BILIRUBIN, BLOOD CELLS, GLUCOSE, KETONE, LEUKOCYTE, PROTEIN, ALBUMIN OTHER UTINARY ANALYTES TEST STRIP/KITS ARE MEDICAL DEVICE INTENDED FOR THE PRELIMINARY ESTIMATION OF DIAGNOSTIC MARKERS IN URINE.,DIAGNOSTICS TEST REAGENT/ KITS FOR MICRO ALBUMIN-USE DETECTION OF MICRO ALBUMIN IN SERUM/PLASMA, URINE,DIAGNOSTICS TEST REAGENT/ KITS FOR LYSE-A LYSE REAGENT/KIT IS A MEDICAL DEVICE USED FOR LYSING OF CELL FOR THE ESTIMATION OF COMPLETE BLOOD COUNT (CBC).,DIAGNOSTICS TEST REAGENT KITS FOR IRON AND UIBC. -A IRON AND UIBC TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF IRON AND UIBC IN SERUM/PLASMA.,DIAGNOSTICS TEST REAGENT /KITS FOR VITAMIN D-VITAMIN D TEST REAGENT/KIT IS A REAGENTS/KITS MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF VITAMIN D IN BLOOD/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT KITS FOR GAMMA GT-A GAMMA GT TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF URIC ACID IN SERUM/PLASMA.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2762	MFG/IVD/2019/000008	1.License Holder Name: BIOLINE DIAGNOSTICS LLP 2.Approving Authority: NORTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:UREA (BUN) TEST REAGENT/KIT(FIRSTVIEW)-ESTIMATION OF UREA/BLOOD UREA NITROGEN IN PLASMA/SERUM/URINE,URINE REAGENT STRIP-GLUCOSE, PROTEIN AND KETONE (FIRST VIEW)-URINE REAGENT STRIPS ARE FIRM PLASTIC STRIPS ONTO WHICH SEVERAL SEPARATE REAGENT AREAS ARE AFFIXED. THE TEST IS FOR THE DETECTION OF ONE OR MORE OF THE FOLLOWING ANALYTES IN URINE: GLUCOSE, KETONE (ACETOACETIC ACID) AND PROTEIN.,CHOLESTEROL TEST REAGENT/KIT(FIRSTVIEW)-ESTIMATION OF CHOLESTEROL IN BLOOD/BODY FLUIDS,ACID PHOSPHATASE TEST KIT(FIRST VIEW)-ACID PHOSPHATASE TEST KIT IS FOR QUANTITY ESTIMATION OF ACID PHOSPHATASE,URINE STRIP (GLUCOSE)(FIRSTVIEW)-URINE STRIP FOR THE DETECTION OF GLUCOSE IN URINE,G-6-PD TEST KIT (FIRST VIEW)-G-6-PD IS USED FOR THE QUANTITATION OF G-6-PDH LEVELS IN HUMAN ERYTHROCYTES,POTASSIUM TEST REAGENT/KIT (FIRSTVIEW)-ESTIMATION OF POTASSIUM IN SERUM PLASMA/URINE, BLOOD URIC ACID TEST STRIP(FIRST VIEW)-BLOOD URIC ACID TEST STRIPS ARE USED WITH METERS FOR QUANTITATIVE MEASURING OF URIC ACID IN FRESH CAPILLARY WHOLE BLOOD,UREA (BUN) TEST REAGENT/KIT (UREA GLDH)(FIRSTVIEW)-ESTIMATION OF UREA/BLOOD UREA NITROGEN (BUN) IN PLASMA/SERUM/URINE, URINE REAGENT STRIP- GLUCOSE, PROTEIN & PH (FIRST VIEW)-URINE REAGENT STRIPS ARE FIRM PLASTIC STRIPS ONTO WHICH SEVERAL SEPARATE REAGENT AREAS ARE AFFIXED. THE TEST IS FOR THE DETECTION OF ONE OR MORE OF THE FOLLOWING ANALYTES IN URINE: GLUCOSE, PROTEIN AND PH.,CHLORIDE TEST REAGENT/KIT (FIRSTVIEW)-ESTIMATION OF CHLORIDE IN PLASMA/SERUM, SWEAT/URINE,LDH (L-P) TEST KIT(FIRST VIEW)-LDH IS USED FOR THE QUANTITATION OF LDH LEVELS IN HUMAN SERUM / PLASMA, GLUCOSE TEST REAGENT/KIT(FIRSTVIEW)-ESTIMATION OF GLUCOSE IN BLOOD/PLASMA/BODY FLUIDS, AMYLASE TEST REAGENT(FIRST VIEW)- AMYLASE IS USED FOR THE QUANTITATION OF AMYLASE LEVELS IN HUMAN SERUM,URINE STRIP/KIT (CREATINE AND ALBUMIN)(FIRSTVIEW)-DETECTION OF CREATINE AND ALBUMIN IN URINE,LIPASE TEST KIT(FIRST VIEW)-LIPASE IS USED FOR THE QUANTITATION OF LIPASE LEVELS IN HUMAN SERUM / PLASMA, TRIGLYCERIDES TEST REAGENT/KIT (TRIGLYCERIDES LS)(FIRSTVIEW) -ESTIMATION OF TRIGLYCERIDES IN SERUM/PLASMA,GAMMA GT TEST KIT(FIRST VIEW)-GAMMA GT TEST KIT IS USED TO MEASURE GAMMAGT LEVELS WHICH ARE ELEVATED IN ANY AND ALL FORMS OF LIVER DISEASE,TOTAL PROTEIN TEST REAGENT/KIT(FIRSTVIEW)-ESTIMATION OF TOTAL PROTEIN IN SERUM/PLASMA,

	ANTISTREPTOLYSIN-O (ASO) TEST KIT(FIRST VIEW)-FIRST VIEW ANTISTREPTOLYSIN-O (ASO) TEST KIT IS USED FOR THE QUALITATIVE AND QUANTITATIVE MEASUREMENT OF ANTIBODIES TO ANTISTREPTOLYSIN-O IN HUMAN SERUM.,ALBUMIN TEST REAGENT/KIT(FIRSTVIEW)-ESTIMATION OF ALBUMIN IN SERUM/PLASMA,HBA1C TEST KIT(FIRST VIEW)-FIRST VIEW HBA1C TEST KIT IS USED FOR QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C IN HUMAN BLOOD.,ALANINE AMINO TRANSFERASE (ALT/SGPT) TEST REAGENT/KIT (SGPT)(FIRSTVIEW)-ESTIMATION OF ENZYME ALANINE AMINO TRANSFERASE (ALT/SGPT) IN SERUM/PLASMA,BLOOD GLUCOSE TEST STRIPS(FIRST VIEW)-BLOOD GLUCOSE TEST STRIPS ARE USED WITH METERS FOR QUANTITATIVE MEASURING OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD., SODIUM TEST REAGENT/KIT(FIRSTVIEW)-ESTIMATION OF SODIUM IN SERUM/PLASMA/URINE,CALCIUM (OCPC) TEST KIT(FIRST VIEW)-THE REAGENT KIT IS INTENDED FOR "IN VITRO" QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM/PLASMA/ URINE.,BILIRUBIN (TOTAL AND DIRECT) TEST REAGENT/KIT(FIRSTVIEW)-ESTIMATION OF BILIRUBIN (TOTAL AND DIRECT) IN SERUM/PLASMA,HBA1C (BORONATE AFFINITY CHROMATOGRAPHY) TEST KIT(FIRST VIEW)-FIRST VIEW HBA1C QUANTITATIVE TEST (BORONATE AFFINITY CHROMATOGRAPHY) IS AN IN VITRO DIAGNOSTIC TEST FOR QUANTITATIVE DETERMINATION OF GLYCATED HEMOGLOBIN (% HEMOGLOBIN A1C, HBA1C) IN HUMAN WHOLE BLOOD. THE MEASUREMENT OF % HBA1C IS RECOMMENDED AS A MARKER OF LONG-TERM METABOLIC CONTROL IN PERSON WITH DIABETES MELLITUS.,ALKALINE PHOSPHATASE TEST REAGENT/KIT(FIRSTVIEW) -ESTIMATION OF ALKALINE PHOSPHATASE LEVEL PRESENT IN SERUM/PLASMA,URINE REAGENT STRIP (11 PARAMETERS) LEUKOCYTES, GLUCOSE, KETONE (ACETOACETIC ACID), BILIRUBIN, BLOOD, SPECIFIC GRAVITY, PROTEIN, UROBILINOGEN, NITRITE, MICROALBUMIN AND PH(FIRST VIEW)-URINE REAGENT STRIPS ARE FIRM PLASTIC STRIPS ONTO WHICH SEVERAL SEPARATE REAGENT AREAS ARE AFFIXED. THE TEST IS FOR THE DETECTION OF ONE OR MORE OF THE FOLLOWING ANALYTES IN URINE: LEUKOCYTES, GLUCOSE, KETONE (ACETOACETIC ACID), BILIRUBIN, BLOOD, SPECIFIC GRAVITY, PROTEIN, UROBILINOGEN, NITRITE, ASCORBIC ACID, AND PH.,HDL CHOLESTEROL TEST REAGENT/KIT (HDL-C DIRECT)(FIRSTVIEW)-ESTIMATION OF HDL CHOLESTEROL IN SERUM/PLASMA,SCRUB TYPHUS RAPID TEST DEVICE(FIRST VIEW)-FIRST VIEW SCRUB TYPHUS RAPID TEST IS AN IMMUNOCHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF ANTIBODIES (IGG, IGM AND IGA) SPECIFIC TO O. TSUTSUGAMUSHI IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD,

	LDL CHOLESTEROL TEST REAGENT/KIT (LDL C DIRECT)(FIRSTVIEW)-ESTIMATION OF LDL CHOLESTEROL IN SERUM/PLASMA,H. PYLORI AB RAPID TEST DEVICE(FIRST VIEW)-FIRST VIEW RAPID HELICOBACTER PYLORI (H. PYLORI, OR HP) ANTIBODY TEST IS A RAPID AND CONVENIENT IMMUNOCHROMATOGRAPHIC ASSAY USED FOR THE QUALITATIVE DETECTION OF H.PYLORI ANTIBODY IN HUMAN WHOLE BLOOD, SERUM OR PLASMA SAMPLES,PHOSPHORUS(INORGANIC) TEST REAGENT/KIT(FIRSTVIEW)-ESTIMATION OF INORGANIC PHOSPHORUS IN SERUM PLASMA/URINE,FERRITIN TEST REAGENT/KIT(FIRST VIEW)-FERRITIN TEST REAGENT/KIT IS USED TO DETERMINE THE LEVEL OF FERRITIN IN SERUM AND PLASMA. , OXALATE TEST REAGENT/KIT(FIRSTVIEW)-IT IS INDICATOR TO ESTIMATE THE KIDNEY STONE IN URINE,D-DIMER TEST REAGENT/KIT (FIRST VIEW)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN SERUM ON AUTOMATED CLINICAL CHEMISTRY ANALYZERS FOR CLINICAL LABORATORIES., HDL CHOLESTEROL TEST REAGENT/KIT (CHOLESTEROL LS WITH HDL)(FIRSTVIEW)-ESTIMATION OF HDL CHOLESTEROL IN SERUM/PLASMA,VIRAL TRANSPORT MEDIUM KIT(NA)-VIRAL TRANSPORT MEDIUM IS INTENDED FOR THE COLLECTION, TRANSPORTATION AND PRESERVATION OF VIRAL NUCLEIC ACID IN CLINICAL SAMPLES.,AMMONIA TEST REAGENT/KIT(FIRSTVIEW)-ESTIMATION OF AMMONIA IN SERUM/PLASMA/URINE,HEMOGLOBIN TEST REAGENT/KIT(FIRSTVIEW)-ESTIMATION OF HEMOGLOBIN IN BLOOD,TYPHOID IGG/IGM (ANTIBODY) RAPID TEST KIT(FIRSTVIEW)-DETECTION OF TYPHOID ANTIBODY,CREATINE KINASE AND ITS ISOENZYMES TEST REAGENTS/KIT (CK-MB)(FIRSTVIEW)-ESTIMATION OF THE ENZYME CREATINE PHOSPHOKINASE OR ITS ISOENZYMES IN SERUM/PLASMA,CREATINE KINASE AND ITS ISOENZYMES TEST REAGENTS/KIT (CK-NAC)(FIRSTVIEW)-TO ESTIMATE THE ENZYME CREATINE PHOSPHOKINASE OR ITS ISOENZYMES IN SERUM/PLASMA, HUMAN CHORIONIC GONADOTROPIN (HCG) TEST/KIT (PREGNANCY STRIP AND CARD)(FIRSTVIEW)-TO DETECT PREGNANCY BY CHECKING PRESENCE OF HCG IN URINE,ASPARTATE AMINO TRANSFERASE(AST/SGOT) TEST REAGENTS/KIT (SGOT)(FIRSTVIEW)-ESTIMATION OF THE ENZYME ASPARTATE AMINO TRANSFERASE (AST/SGOT) IN SERUM/PLASMA,A HDL CHOLESTEROL TEST REAGENT/KIT(FIRSTVIEW)-ESTIMATION OF HDL CHOLESTEROL IN SERUM/PLASMA,RHEUMATOID FACTOR (RF) IMMUNOLOGICAL TEST REAGENTS/KIT(FIRSTVIEW)-SCREENING OF RHEUMATOID FACTOR IN HUMAN SPECIMENS,CREATININE TEST REAGENT/KIT(FIRSTVIEW)-ESTIMATION OF CREATININE IN SERUM, PLASMA/URINE,URINE REAGENT STRIP (LEUKOCYTES, GLUCOSE,KETONE,BILIRUBIN,BLOOD, SPECIFIC GRAVITY,PROTEIN,UROBILINOGEN, NITRITE, PH) TEST KIT

		(FIRSTVIEW)-DETECTION OF LEUKOCYTES, GLUCOSE,KETONE, BILIRUBIN,BLOOD,SPECIFIC GRAVITY,PROTEIN,UROBILINOGEN, NITRITE, PH IN URINE,DENGUE IGG/IGM (ANTIBODY) RAPID TEST KIT (FIRSTVIEW)-DETECTION OF DENGUE IGG/IGM (ANTIBODY) IN PLASMA/BLOOD/SERUM,VITAMIN B 12 TEST KIT(FIRSTVIEW)-FOR THE DETECTION OF VITAMIN B12,URINE REAGENT STRIP TEST (LEUKOCYTES, GLUCOSE, KETONE, BILIRUBIN, BLOOD, SPECIFIC GRAVITY, PROTEIN, UROBILINOGEN, NITRITE, PH, ASCORBIC ACID) (FIRSTVIEW)-FOR THE DETECTION OF LEUKOCYTES, GLUCOSE, KETONE, BILIRUBIN, BLOOD, SPECIFIC GRAVITY, PROTEIN, UROBILINOGEN, NITRITE, PH, ASCORBIC ACID IN URINE,VITAMIN D TEST KIT(FIRSTVIEW)-FOR THE DETECTION OF VITAMIN D,URINE STRIP/KIT GLUCOSE AND KETONE TEST(FIRSTVIEW)-DETECTION OF GLUCOSE AND KETONE IN URINE,URINE STRIP/KIT (GLUCOSE AND PROTEIN)(FIRSTVIEW)-FOR THE DETECTION OF GLUCOSE AND PROTEIN IN URINE,URIC ACID TEST REAGENT/KIT(FIRSTVIEW)-ESTIMATION OF URIC ACID IN SERUM/PLASMA/URINE
2763	MFG/IVD/2019/000009	1.License Holder Name: HELICO INTERNATIONAL 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:SCRUB TYPHUS RAPID TEST(HI-QUIK)-QUALITATIVE DETECTION OF ANTIBODIES AGAINST ORIENTIA TSUTSUGAMUSHI IN THE PATIENT'S PLASMA, SERUM OR BLOOD,VITAMIN D RAPID TEST(HI-QUIK)-SEMI-QUANTITATIVE DETECTION OF 25-HYDROXYVITAMIN D (25 (OH) D) IN HUMAN FINGERSTICK WHOLE BLOOD,FECAL OCCULT BLOOD (FOB) TEST(HI-QUIK)-QUALITATIVE DETECTION OF HUMAN OCCULT BLOOD IN FECES.,RHEUMATOID FACTOR RAPID TEST(HI-QUIK)-QUALITATIVE DETECTION OF RHEUMATOID FACTOR IN HUMAN SERUM OR PLASMA., URINE STRIPS FOR GLUCOSE, BILIRUBIN, KETONE, SP. GRAVITY, BLOOD, PH, PROTEIN, UROBILINOGEN, NITRITE & LEUKOCYTES ANALYSIS TEST(HI-QUIK)-A RAPID TEST FOR THE SEMIQUANTITATIVE DETERMINATION FOR THE PRESENCE & CONCENTRATION OF GLUCOSE, BILIRUBIN, KETONE, SP. GRAVITY, BLOOD, PH, PROTEIN, UROBILINOGEN, NITRITE & LEUKOCYTES IN URINE,HELICOBACTER PYLORI ANTIBODY RAPID TEST(HI-QUIK)-QUALITATIVE DETECTION OF ANTIBODIES TO H. PYLORI IN WHOLE BLOOD, SERUM, OR PLASMA TO AID IN THE DIAGNOSIS OF H. PYLORI INFECTION.,LUTEINIZING HORMONE (LH) TEST(HI-QUIK)-QUALITATIVE DETECTION OF LUTEINIZING HORMONE (LH) IN URINE TO AID IN THE DETECTION OF OVULATION.

2764	MFG/IVD/2019/000010	1.License Holder Name: EXCEL DIAGNOSTICS PVT LTD 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:HEMOGLOBIN TEST KIT-ESTIMATION OF HEMOGLOBIN IN HUMAN BLOOD,UREA TEST KIT (UREA - EGD TEST KIT)-ESTIMATION OF UREA IN HUMAN SERUM, ALBUMIN TEST KIT-ESTIMATION OF ALBUMIN IN HUMAN SERUM, AMYLASE TEST KIT-ESTIMATION OF AMYLASE IN HUMAN SERUM, TOTAL PROTEIN TEST KIT-ESTIMATION OF TOTAL PROTEIN IN HUMAN SERUM,BILIRUBIN TEST KIT-ESTIMATION OF BILIRUBIN IN HUMAN SERUM,ALKALINE PHOSPHATASE TEST KIT-ESTIMATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM,CHLORIDE TEST KIT-ESTIMATION OF CHLORIDE IN HUMAN SERUM,CALCIUM TEST KIT-ESTIMATION OF CALCIUM IN HUMAN SERUM,CHOLESTEROL TEST KIT (CHOLESTEROL - EGD TEST KIT)-ESTIMATION OF CHOLESTEROL IN HUMAN SERUM,GLYCOSYLATED TEST KIT-ESTIMATION OF HBA1 IN HUMAN BLOOD,URIC ACID TEST KIT(URIC ACID - EGD TEST KIT)-ESTIMATION OF URIC ACID IN HUMAN SERUM,TRIGLYCERIDES TEST KIT(TRIGLYCERIDES - EGD TEST KIT)-ESTIMATION OF TRIGLYCERIDES IN HUMAN SERUM,CREATININE TEST KIT-ESTIMATION OF CREATININE IN HUMAN SERUM,GLUCOSE TEST KIT(GLUCOSE - EGD TEST KIT)-ESTIMATION OF GLUCOSE IN HUMAN SERUM,POTASSIUM TEST KIT-ESTIMATION OF POTASSIUM IN HUMAN SERUM,SGOT TEST KIT(SGOT - EGD TEST KIT)-ESTIMATION OF SGOT IN HUMAN SERUM,SGPT TEST KIT(SGPT - EGD TEST KIT)-ESTIMATION OF SGPT IN HUMAN SERUM, SODIUM & POTASSIUM TEST KIT-ESTIMATION OF SODIUM & POTASSIUM IN HUMAN SERUM,PHOSPHORUS TEST KIT-ESTIMATION OF PHOSPHORUS IN HUMAN SERUM,ELECTROLYTES TEST KIT (ELECYT TEST KIT)-ESTIMATION OF ELECTROLYTES IN HUMAN SERUM

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2765	MFG/IVD/2019/000012	1.License Holder Name: CAREWELL BIOTECH PVT LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:DETERGENT REAGENTS (ENZYMATIC CLEANER)-CLEANER, THEY ARE EFFECTIVE IN BREAKING DOWN THE PROTEINS AND BLOOD DEBRIS BY ENZYMATIC REACTIONS. SURFACTANTS ARE COMMONLY USED IN THE CLEANING REAGENTS FOR DISSOLVING OR DISPERSING THE DEBRIS AND LARGE ORGANIC MOLECULES. WITH THE GOOD MOIST FUNCTION, IT ALSO CAN DISCHARGE BUBBLES FROM ENTIRE MEASUREMENT APPARATUS AND PROVIDE THE CORRECT WORKING PERFORMANCE OF ANALYSER. ,RINSE REAGENTS-RINSE IS A BUFFERED, STABILIZED AND MICRO FILTERED DETERGENT SOLUTION FOR EMULSIFYING THE FAT, DISTRIBUTE THE SOLIDIFIED DIRT AND TRANSFORM THE PROTEIN INTO A WATER-SOLUBILITY AMINO ACID TO MAINTAIN THE CLEANNESS OF PIPELINES OF ANALYSER AND FLOW-CELL. WITH THE GOOD MOIST FUNCTION, IT ALSO CAN DISCHARGE BUBBLES FROM ENTIRE SOLUTION SYSTEM AND PROVIDE THE CORRECT WORKING PERFORMANCE. ,BLOOD CELL DILUENT (DILUENT FOR HEMATOLOGY ANALYSER)-DILUENTS ARE THE BUFFERED, STABILIZED AND MICRO FILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, TO HELP FULLY & SEMIAUTOMATIC ANALYZERS TO QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN (HGB) CONCENTRATION.,CLEANER -CLEANER THEY ARE EFFECTIVE IN BREAKING DOWN THE PROTEINS AND BLOOD DEBRIS BY CHEMICAL REACTIONS. SURFACTANTS ARE COMMONLY USED IN THE CLEANING REAGENTS FOR DISSOLVING OR DISPERSING THE DEBRIS AND LARGE ORGANIC MOLECULES. WITH THE GOOD MOIST FUNCTION, IT ALSO CAN DISCHARGE BUBBLES FROM ENTIRE MEASUREMENT APPARATUS AND PROVIDE THE CORRECT WORKING PERFORMANCE,LYSE REAGENTS-LYSE REAGENT HAS THE FUNCTIONS OF LYSING THE RED CELL PROMPTLY AND RELEASING THE HAEMOGLOBIN TO KEEP THE WHITE CELL COUNTING FROM THE INTERFERENCE OF THE RED CELL FRAGMENTS ,TO HELP FULLY & SEMIAUTOMATIC ANALYZERS TO QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN (HGB) CONCENTRATION.

2766	MFG/IVD/2019/000013	1.License Holder Name: QUALPRO DIAGNOSTICS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETERMINATION OF HEV IGM ANTIBODY IN HUMAN SERUM(QUALISA HEV IGM)-QUALISA HEV IGM ANTIBODY ELISA IS AN ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETERMINATION OF IGM CLAS ANTIBODY SPECIFIC TO THE HEPATITIS E VIRUS IN HUMAN SERUM , ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUANTITATIVE DETECTION OF TOTAL 25-OH VITAMIN D IN HUMAN SERUM(QUALISA 25-OH VITAMIN D ELISA)-THE PRODUCT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM AND IS BASED ON THE ENZYME LINKED IMMUNOSORBENT ASSAY ALSO KNOWN AS ELISA, CHEMILUMINESCENCE ASSAY FOR QUANTITATIVE DETERMINATION OF TOTAL 25-OH VITAMIN D IN HUMAN SERUM(ELECTRA 25-OH VITAMIN D CLIA)-ELECTRA 25-OH VITAMIN D CLIA TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25-OH VITAMIN D IN HUMAN SERUM

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2767	MFG/IVD/2019/000014	1.License Holder Name: BIOLAB DIAGNOSTICS (I) PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:RAPID DIAGNOSTICS KIT FOR COVID 19 ANTIGEN(RAPID COVID 19 AG)-RAPID COVID-19AG KIT - RAPID COVID-19AG IS A CHROMATOGRAPHIC IMMUNOASSAY TEST KIT FOR QUALITATIVE DETECTION OF SARS-NCOV-2 ANTIGENS PRESENT IN HUMAN NASOPHARYNX, BRONCHIAL LAVAGE OR THROAT.,RAPID DIAGNOSTIC KITS FOR HCV(RAPID HCV)-BIOLAB'S RAPID HCV IS A SINGLE USE IMMUNO-CHROMATOGRAPHIC, SCREENING TEST FOR THE DETECTION OF ANTIBODIES TO HCV IN SERUM OR PLASMA OR WHOLE BLOOD SPECIMENS.,BLOOD GROUPING SERA(BLOOD GROUPING SERA ANTI-ABD)-REAGENT CONSISTS OF MONOCLONAL BLOOD GROUPING ANTI-A, ANTI-B, ANTI-D (RHO) (IGG/IGM, IGG+IGM) REAGENTS. THESE REAGENTS CAN BE USED FOR IN VITRO DETERMINATION OF THE PRESENCE OR ABSENCE OF A, B AND D (RHO) ANTIGEN ON HUMAN RED BLOOD CELLS.,RAPID DIAGNOSTIC KITS FOR HBSAG(RAPID HBSAG)-HEPATITIS B VIRUS (HBV) IS A MAJOR PUBLIC HEALTH PROBLEM WORLDWIDE, WITH SIGNIFICANT TRANSMISSION OF THE VIRUS OCCURRING THROUGH THE USE OF CONTAMINATED DONOR BLOOD AND PLASMA. THE TRANSMISSION OF HBV AND OTHER INFECTIOUS DISEASES THROUGH TISSUE TRANSPLANTATION THE PRESENCE OF CIRCULATING HEPATITIS B SURFACE ANTIGEN (HBSAG) CLOSELY FOLLOWS THE COURSE OF INFECTION. RAPID HBSAG IS AN IMMUNO-CHROMATOGRAPHIC, QUALITATIVE SCREENING TEST TO DETECT HEPATITIS B SURFACE ANTIGEN FROM HUMAN SERUM OR PLASMA., RAPID DIAGNOSTIC KITS FOR HIV 1/2(RAPID HIV 1/2)-BIOLAB'S RAPID HIV 1/2 IS A SINGLE USE IMMUNO-CHROMATOGRAPHIC, SCREENING TEST FOR THE DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPES 1, SUBTYPE “O” AND HIV 2 (HIV 1/2) IN FINGER PRICK WHOLE BLOOD, VENOUS WHOLE BLOOD, SERUM OR PLASMA SPECIMENS.
2768	MFG/IVD/2019/000015	1.License Holder Name: RECOMBIGEN LABORATORIES PRIVATE LIMITED 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:RAPID HUMAN CHORIONIC GONADOTROPIN TEST-IT IS INTENDED FOR QUALITATIVE DETECTION OF HUMAN CHORIONIC GONADOTROPIN IN HUMAN URINE SAMPLES

2769	MFG/IVD/2019/000016	1.License Holder Name: GENUINE BIOSYSTEM PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:C REACTIVE PROTEIN KIT (CRP)(TURBICHEM / NEPHCHEM)-A C REACTIVE PROTEIN KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CRP IN SERUM, ANTI TP CLIA MICROPARTICLES KIT(AUTOBIO)-A ANTI TP CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF ANTI-TP (ANTIBODY TO TREPONEMA PALLIDUM) IN HUMAN SERUM AND PLASMA,ANTI HIV 1&2 ELISA KIT(GBLISA)-AN ANTI HIV 1&2 ELISA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ANTI HIV 1&2 IN SERUM,ANTI HCV CLIA MICROPARTICLES KIT(AUTOBIO)-A ANTI HCV CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF ANTI-HCV (IGG ANTIBODY TO HEPATITIS C VIRUS) IN HUMAN SERUM AND PLASMA,FACTOR VIII KIT-A FACTOR VIII IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF FACTOR VIII DEFICIENT IN PLASMA,HIV AG/AB COMBO CLIA MICROPARTICLES KIT(AUTOBIO)-A HIV AG/AB COMBO CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) P24 ANTIGEN AND ANTIBODIES TO HIV TYPE 1 (HIV-1 GROUP M AND GROUP O) AND/OR TYPE 2 (HIV-2) IN HUMAN SERUM AND PLASMA (EDTA),PROTHROMBIN TIME (PT) KIT-A PROTHROMBIN TIME KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF PROTHROMBIN TIME IN PLASMA,HBSAG CLIA MICROPARTICLES KIT (AUTOBIO)-A HBSAG CLIA MICROPARTICLES IS A MEDIAL DEVICE, INTENDED FOR THE DETERMINATION OF HBSAG (HEPATITIS B SURFACE ANTIGEN) IN HUMAN SERUM OR PLASMA.,RPR KIT(GB'S RPR KIT)-A RPR KIT IS A MEDICAL DEVICE, INTENDED FOR THE DIAGNOSIS OF SYPHILIS INFECTION,COVID-19 S1 RBD IGG ELISA KIT (GBLISA)-A COVID-19 S1 RBD IGG ELISA KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF COVID-19 IGG ANTIBODY IN HUMAN SERUM,ANTI HBEAG ELISA KIT(GBLISA)-AN ANTI HBEAG ELISA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ANTI HBEAG IN BLOOD/BODY FLUIDS,PROCALCITONIN (PCT) KIT (TURBICHEM / NEPHCHEM)-A PROCALCITONIN (PCT) KIT IS THE IVD MEDICAL DEVICE, INTENDED FOR THE DETERMINATION OF PROCALCITONIN (PCT) IN HUMAN SERUM.,FACTOR IX KTI-A FACTOR IX IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF FACTOR IX DEFICIENT IN PLASMA,RUBELLA IGG CLIA MICROPARTICLES KIT (AUTOBIO)-A RUBELLA IGG CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF RUBELLA IGG (SPECIFIC IGG ANTIBODIES TO RUBELLA VIRUS) IN HUMAN SERUM,ANTI THROMBIN III KIT-AN ANTITHROMBIN III KIT IS A MEDICAL DEVICE,

	INTENDED FOR THE ESTIMATION OF ANTI THROMBIN III IN PLASMA. FPSA CLIA MICROPARTICLES KIT(AUTOBIO)-A FPSA CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF FPSA (FREE PROSTATE SPECIFIC ANTIGEN) IN HUMAN SERUM,HELICOBACTER PYLORI ANTIGEN RAPID TEST (H. PYLORI AG)-A HELICOBACTER PYLORI ANTIGEN RAPID TEST IS A MEDICAL DEVICE FOR THE DETECTION OF H.PYLORI IN BLOOD/BODY FLUIDS.,TOXO IGM CLIA MICROPARTICLES KIT(AUTOBIO)-A TOXO IGM CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF TOXO IGM (SPECIFIC IGM ANTIBODIES TO TOXOPLASMA GONDII) IN HUMAN SERUM,BETA-2- MICROGLOBULIN (B2MG) KIT(TURBICHEM / NEPHCHEM)-A B2MG IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF B2MG IN SERUM,PAPP-A CLIA MICROPARTICLES KIT(AUTOBIO)-A PAPP-A CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF PAPP-A (PREGNANCY ASSOCIATED PLASMA PROTEIN A) IN HUMAN SERUM, PROTEIN C KIT-A PROTEIN C IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION PROTEIN C IN PLASMA,CMV IGM CLIA MICROPARTICLES KIT(AUTOBIO)-A CMV IGM CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CMV IGM (SPECIFIC IGM ANTIBODIES TO CYTOMEGAVIRUS) IN HUMAN SERUM OR PLASMA,ANTI HBC IGG / IGM ELISA KIT(GBLISA)-AN ANTI HBS KIT IS A MEDICAL DEVICE, INTENDED FOR THE DETERMINATION OF ANTI HBS IN BLOOD/BODY FLUIDS,FREE BETA-HCG CLIA MICROPARTICLES KIT(AUTOBIO)-A FREE BETA HCG CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF FREE BETA-HCG ((FREE BETA-HUMAN CHORIONIC GONADOTROPIN) IN HUMAN SERUM,ANTI HBS IGG / IGM ELISA KIT(GBLISA)-AN ANTI HBS IGG / IGM KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ANTI HBS IN BLOOD / BODY FLUIDS,TB-IGRA CLIA MICROPARTICLES KIT(AUTOBIO)-A TB-IGRA CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF INTERFERON-GAMMA (IFN-) IN FRESH PERIPHERAL VENOUS ANTICOAGULANT BLOOD., LUPUS ANTICOAGULANT KIT-A LUPUS ANTICOAGULANT KIT IS A MEDICAL DEVICE, INTENDED FOR THE SCREENING OF LUPUS ANTICOAGULANT IN PLASMA,TOXO IGG CLIA MICROPARTICLES KIT (AUTOBIO)-A TOXO IGG CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF TOXO IGG (SPECIFIC IGG ANTIBODIES TO TOXOPLASMA GONDII) IN HUMAN SERUM,HBSAG RAPID TEST-A HBSAG RAPID TEST IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF HBSAG IN BLOOD/BODY FLUIDS,SARS-COV-2 CORONAVIRUS (COVID-19) VIRAL RNA ISOLATION KIT (GB PURE SPIN)-A SARS-COV-2 CORONAVIRUS (COVID-19) VIRAL RNA ISOLATION KIT IS THE MEDICAL DEVICE, INTENDED FOR THE

	ISOLATION OF RNA FROM NASAL/THROAT SWABS COLLECTED IN VIRAL TRANSFER MEDIUM (VTM),COOMB'S REAGENT-A COOMB'S REAGENT IS A MEDICAL DEVICE, INTENDED FOR ANTI HUMAN GLOBULIN SERUM WITH MONOCLONAL ANTI C.,P-AFP CLIA MICROPARTICLES KIT(AUTOBIO)-A P-AFP CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF P-A FP (PREGNANCY ALPHA FETOPROTEIN) CLIA MICROPARTICLES IN HUMAN SERUM,ANTI D IGG + IGM(GBCLONE)-AN ANTI D IGG + IGM IS A MEDICAL DEVICE, INTENDED FOR THE ABO BLOOD GROUP TYING, TPSA CLIA MICROPARTICLES KIT(AUTOBIO)-A TPSA CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF TPSA (TOTAL PROSTATIC SPECIFIC ANTIGEN) IN HUMAN SERUM,THROMBIN TIME (TT)-A THROMBIN TIME (TT) KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF THROMBIN CLOTTING TIME IN PLASMA,CMV IGG CLIA MICROPARTICLES KIT (AUTOBIO)-A CMV IGG CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CMV IGG (SPECIFIC IGG ANTIBODIES TO CYTOMEGAVIRUS) IN HUMAN SERUM OR PLASMA, CARCINO EMBRYONIC ANTIGEN (CEA) ELISA KIT(GBLISA)-A CEA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CEA IN BLOOD/BODY FLUIDS,NT-PROBNP CLIA MICROPARTICLES KIT (AUTOBIO)-A NT-PROBNP CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF NT-PROBNP (N-TERMINAL PRO B-TYPE NATRIURETIC PEPTIDE) IN HUMAN SERUM, MALARIA ANTIGEN PF/PV RAPID TEST-A MALARIA AG PF/PV RAPID TEST IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF MALARIA ANTIGEN IN BLOOD/BODY FLUIDS,BETA 2-MICROGLOBULIN CLIA MICROPARTICLES KIT(AUTOBIO)-A BETA 2-MICROGLOBULIN CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF BETA 2-MICROGLOBULIN IN HUMAN SERUM,ANTI A IGM(GBCLONE)-AN ANTI A IGM IS A MEDICAL DEVICE, INTENDED FOR THE ABO BLOOD GROUP TYING,SARS-COV-2 CORONAVIRUS (COVID-19) VIRAL RNA ISOLATION KIT(AURA PURE)-A SARS-COV-2 CORONAVIRUS (COVID-19) VIRAL RNA ISOLATION KIT IS THE MEDICAL DEVICE, INTENDED FOR THE ISOLATION OF RNA FROM NASAL/THROAT SWABS COLLECTED IN VIRAL TRANSFER MEDIUM (VTM),C REACTIVE PROTEIN SLIDE LATEX KIT (CRP)(GB'S CRP SLIDE LATEX KIT)-AN C REACTIVE PROTEIN LATEX SLIDE LATEX KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CRP IN SERUM, RUBELLA IGM CLIA MICROPARTICLES KIT(AUTOBIO)-A RUBELLA IGM CLIA MICROPARTICLES IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF RUBELLA IGM (SPECIFIC IGM ANTIBODIES TO RUBELLA VIRUS) IN HUMAN SERUM,SYPHILIS RAPID TEST-A SYPHILIS RAPID TEST IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF

	TREPONEMA PALLADIUM/SYPHILIS (TP) IN SERUM/BLOOD,ANTI H LECTIN(GBCLONE)-AN ANTI H LECTIN IS A MEDICAL DEVICE, INTENDED FOR DETERMINATION AND SUB-GROUP BY PHYTOHAEMAGGLUTININ,COAGULATION CONTROL SET (LEVEL 1, LEVEL 2, LEVEL 3)-A COAGULATION CONTROL SET IS A MEDICAL DEVICE, INTENDED TO USE AS CONTROL PLASMA OF COAGULATION REAGENTS.,CA 19-9 (CANCER ANTIGEN 19-9) ELISA KIT(GBLISA)-A CA 19-9 IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CA 19-9 IN BODY FLUIDS,HELICOBACTER PYLORI IGG/IGM ELISA KIT (GBLISA)-A H.PYLORI IGG / IGM IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF H.PYLORI IGG / IGM IN BLOOD/BODY FLUIDS, ANTI HCV ELISA KIT(GBLISA)-AN ANTI-HCV ELISA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ANTI HCV IN BLOOD/BODY FLUIDS,HBV (HEPATITIS B VIRUS) RAPID TEST-A HBV KIT IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF HBV IN BLOOD/BODY FLUIDS,ANTI A1 LECTIN(GBCLONE)-AN ANTI A1 LECTIN IS A MEDICAL DEVICE, INTENDED FOR DIFFERENTIATING A1 AND A2 SUB-GROUPS BY PHYTOHAEMAGGLUTININ,FIBRINOGEN KIT-A FIBRINOGEN KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF FIBRINOGEN IN PLASMA,TYPHOID ANTIGEN IGG+IGM RAPID TEST (SALMONELLA TYPHI ANTIGEN)-A TYPHOID ANTIGEN IGG+IGM RAPID TEST IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF SALMONELLA TYPHI ANTIGEN IGG+IGM IN BLOOD/BODY FLUIDS,ANTI AB IGM(GBCLONE)-AN ANTI AB IGM IS A MEDICAL DEVICE, INTENDED FOR THE ABO BLOOD GROUP TYING, ANTI B IGM(GBCLONE)-AN ANTI B IGM IS A MEDICAL DEVICE, INTENDED FOR THE ABO BLOOD GROUP TYING,BOVINE ALBUMIN 22%-A BOVINE ALBUMIN 22% IS A MEDICAL DEVICE, INTENDED FOR USE OF A RED CELL SUSPENDING MEDIUM IN IMMUNOHEMATOLOGY, HIGH SENSTIVITY C REACTIVE PROTEIN (HSCRP)(TURBICHEM / NEPHCHEM)-A HIGH SENSITIVITY CRP IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF HSCRP IN SERUM,TROPONIN I ELISA KIT(GBLISA)-A TROPONIN I KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF TROPONIN I IN BLOOD/BODY FLUIDS,FACTOR VII KIT-A FACTOR VII IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATIONN OF FACTOR VII DEFICIENT IN PLASMA,TOXOPLASMA (TOXO) IGG / IGM ELISA KIT(GBLISA)-A TOXO IGG / IGM KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF TOXO IGG / IGM IN BODY FLUIDS,ANTI-E OR ANTI-E(GBCLONE)-AN ANTI-E OR ANTI-E IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF ABO BLOOD GROUP TYPE ANTIGENS ON HUMAN RED BLOOD CELLSS,FREE PROSTATE SPECIFIC ANTIGEN (FREE PSA) ELISA KIT(GBLISA)-A FREE PSA IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF FREE PSA IN BODY FLUIDS,HEPATITIS B VIRUS (HBV

	IGG / IGM)ELISA KIT(GBLISA)-THE ANTI HBV IGG / IGM KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF HBV IN BLOOD/BODY FLUIDS,ALFA FETO PROTEIN (AFP) RAPID TEST KIT-AN ALFA FETO PROTEIN (AFP) RAPID TEST IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF AFP IN SERUM/BODY FLUIDS, TOXOPLASMA GONDII SLIDE LATEX KIT-A TOXOPLASMA GONDII IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF TOXOPLASMA GONDII IN SERUM,CA 125 (CANCER ANTIGEN 125) ELISA KIT(GBLISA)-A CA 125 KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CA 125 IN BODY FLUIDS,BETA 2 MICROGLOBULIN (B2MG) ELISA KIT(GBLISA)-A B2MG KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF B2MG IN BODY FLUIDS,PARTIAL THROMBOPLASTIN (APTT) KIT-A PARTIAL THROMBOPLASTIN (APTT) KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF APTT IN PLASMA,CA 15-3 (CANCER ANTIGEN 15-3) ELISA KIT(GBLISA)-A CA 15-3 KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF CA 15-3 IN BODY FLUIDS,SYPHILIS ELISA KIT(GBLISA)-A SYPHILIS ELISA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF SYPHILIS IN BLOOD/BODY FLUIDS,HERPES SIMPLE VIRUS (HSV 1) ELISA KIT (GBLISA)-A HSV 1 KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF HSV 1 IN BLOOD/BODY FLUIDS,HERPES SIMPLE VIRUS 2 (HSV 2) ELISA KIT(GBLISA)-A HERPES SIMPLE VIRUS 2 (HSV 2) KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION HSV 2 IN BLOOD/BODY FLUIDS,PROSTATE SPECIFIC ANTIGEN (PSA) ELISA KIT(GBLISA)-A PSA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF PSA IN BODY FLUIDS,TROPONIN I RAPID TEST-A TROPONIN I RAPID TEST IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF TROPONIN I IN BLOOD/BODY FLUIDS.,ANTI-C OR ANTI-C(GBCLONE)-AN ANTI-C OR ANTI-C IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF ABO BLOOD GROUP TYPE ANTIGENS ON HUMAN RED BLOOD CELLS.,MALARIA ANTIGEN PF/PV ELISA KIT(GBLISA)-A MALARIA KIT PF/PV IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF MALARIA PF/PV IGG/IGM IN BLOOD/BODY FLUIDS,ALFA FETO PROTEIN (AFP) ELISA KIT(GBLISA)-AN ALFA FETO PROTEIN (AFP) KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF AFP IN BLOOD/BODY FLUIDS.,DENGUE NS1 ANTIGEN ELISA KIT(GBLISA)-THE DENGUE NS1 ANTIGEN ELISA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF DENGUE VIRUS IN BLOOD/BODY FLUID,TROPONIN I KIT (TROP-I)(TURBICHEM / NEPHCHEM)-A TROPONIN-I KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF TROPONIN-I IN SERUM,PROSTATE SPECIFIC ANTIGEN RAPID TEST (PSA)-A PROSTATE SPECIFIC ANTIGEN RAPID TEST IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF PSA IN BLOOD/BODY FLUIDS,D DIMER KIT(TURBICHEM / NEPHCHEM)-A D-

	DIMER KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF D-DIMER IN PLASMA,DENGUE ANTIGEN RAPID TEST-A DENGUE RAPID TEST IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF DENGUE VIRUS IN BLOOD/SERUM FLUIDS,HIV 1 & 2 RAPID TEST-A HIV 1 & 2 RAPID TEST IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF HIV 1 & 2 IN BLOOD/BODY FLUIDS,ANTI HBSAG ELISA KIT(GBLISA)-AN ANTI HBSAG ELISA KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ANTI HBSAG IN BLOOD/BODY FLUIDS,FIBRINOGEN DEGRADATION PRODUCT (FDP) KIT(TURBICHEM) -A FIBRINOGEN DEGRADATION PRODUCT KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF FDP IN BODY FLUIDS,PROTEIN S KIT-A PROTEIN-S IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF PROTEIN-S IN PLASMA,HCV RAPID TEST-A HCV RAPID TEST IS A MEDICAL DEVICE, INTENDED FOR THE DETECTION OF HCV IN BLOOD/BODY FLUIDS.,ANTI HBE IGG / IGM ELISA KIT(GBLISA)-AN ANTI HBE IGG / IGM KIT IS A MEDICAL DEVICE, INTENDED FOR THE ESTIMATION OF ANTI HBE IN BLOOD/ BODY FLUIDS

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2770	MFG/IVD/2019/000017	1.License Holder Name: CORAL CLINICAL SYSTEMS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:ALBUMIN KIT (BROMOCRESOL GREEN (BCG) METHOD)-ALBUMIN KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE BROMOCRESOL GREEN (BCG) METHOD FOR THE DETERMINATION OF ALBUMIN IN SERUM OR PLASMA.,SGPT (ALAT) KIT (REITMAN & FRANKELS METHOD)-SGPT (ALAT) (R&F) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON REITMANN & FRANKEL'S METHOD FOR THE DETERMINATION OF SGPT (ALAT) ACTIVITY IN SERUM.,IRON & TIBC KIT (FERROZINE METHOD)-IRON & TIBC KIT IS CLINICAL CHEMISTRY ASSAY BASED ON (FERROZINE / MAGNESIUM CARBONATE METHOD) METHOD FOR THE DETERMINATION OF IRON AND TOTAL IRON BINDING CAPACITY IN SERUM.,PHOSPHORUS KIT (MOLYBDATE UV METHOD)-PHOSPHORUS KIT (UV) IS A CLINICAL CHEMISTRY ASSAY BASED ON MOLYBDATE U. V. METHOD FOR THE DETERMINATION OF INORGANIC PHOSPHORUS IN SERUM, PLASMA AND URINE.,REAGENT FOR QUANTITATIVE ESTIMATION OF HEMOGLOBIN(HEMOCOR-D)-HEMOCOR-D KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE CYANMETHAEMOGLOBIN METHOD FOR THE DETERMINATION OF HAEMOGLOBIN IN WHOLE BLOOD.,MAGNESIUM KIT (CALMAGITE METHOD)-MAGNESIUM KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON CALMAGITE METHOD FOR THE DETERMINATION OF MAGNESIUM IN SERUM, URINE AND CSF.,LDH (P-L) KIT (MOD. IFCC METHOD)-LDH (P-L) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON MODIFIED IFCC METHOD FOR THE DETERMINATION OF LACTATE DEHYDROGENASE ACTIVITY IN SERUM.,SGOT (ASAT) KIT (MODIFIED IFCC METHOD)-SGOT (ASAT) (MODIFIED IFCC) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON MODIFIED IFCC METHOD FOR THE DETERMINATION OF SGOT (ASAT) ACTIVITY IN SERUM.,ALKALINE PHOSPHATASE KIT (PNPP KINETIC (DEA) METHOD)-THE ALKALINE PHOSPHATASE (ALP) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE PNPP KINETIC METHOD FOR THE DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY IN SERUM.,GAMMA GLUTAMYL TRANSFERASE KIT (CARBOXY SUBSTRATE METHOD)-GAMMA GLUTAMYL TRANSFERASE KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE CARBOXY SUBSTRATE METHOD FOR THE DETERMINATION OF GAMMA GLUTAMYL TRANSFERASE ACTIVITY IN SERUM.,GAMMA GLUTAMYL TRANSFERASE KIT (CARBOXY SUBSTRATE METHOD).-GLUTAMYL TRANSFERASE KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE CARBOXY SUBSTRATE METHOD FOR THE DETERMINATION GLUTAMYL TRANSFERASE ACTIVITY IN SERUM.,SGPT (ALAT) KIT (MODIFIED IFCC METHOD)-SGPT (ALAT) (MODIFIED IFCC) KIT IS A

	CLINICAL CHEMISTRY ASSAY BASED ON MODIFIED IFCC METHOD FOR THE DETERMINATION OF SGPT (ALAT) ACTIVITY IN SERUM.,BILIRUBIN T & D KIT (MOD. JENDRASSIK & GROF'S METHOD)-BILIRUBIN KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE MOD. JENDRASSIK ANF GROF'S METHOD FOR THE DETERMINATION OF DIRECT AND TOTAL BILIRUBIN IN SERUM,ALKALINE PHOSPHATASE KIT (PNPP KINETIC METHOD)-THE ALKALINE PHOSPHATASE LS (ALP) KIT IS CLINICAL CHEMISTRY ASSAY BASED ON THE PNPP KINETIC METHOD FOR THE DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY IN SERUM. CALCIUM KIT (ARSENAZO-III METHOD)-CALCIUM KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE ARSENAZO III METHOD FOR THE DETERMINATION OF CALCIUM IN SERUM OR PLASMA.,SGOT (ASAT) KIT (REITMAN & FRANKELS METHOD)-SGOT (ASAT) (R&F) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON REITMANN & FRANKEL'S METHOD FOR THE DETERMINATION OF SGOT (ASAT) ACTIVITY IN SERUM.,CHOLESTEROL KIT (CHOD/PAP METHOD)-CHOLESTEROL KIT IS CLINICAL CHEMISTRY ASSAY BASED ON THE CHOD/PAP METHOD FOR THE DETERMINATION OF CHOLESTEROL IN SERUM OR PLASMA., CARD CENTRIFUGE(MATRIX CARD CENTRIFUGE)-THE MATRIX CARD CENTRIFUGE IS USED FOR CENTRIFUGATION OF MATRIX GEL CARDS, ECOGLUCO KIT (GOD/POD METHOD)-ECOGLUCO KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE GOD/POD (GLUCOSE OXIDASE/ PEROXIDASE) METHOD FOR THE DETERMINATION OF GLUCOSE IN SERUM, PLASMA AND CSF,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR DETERMINATION OF FERRITIN IN HUMAN SERUM (QUANTIA FERRITIN)-QUANTIA FERRITIN IS A TURBIDIMETRIC IMMUNOASSAY FOR THE DETERMINATION OF FERRITIN AND IS BASED ON THE PRINCIPLE OF AGGLUTINATION REACTION., PHOSPHORUS KIT (MOD. GOMORRI'S METHOD)-PHOSPHORUS KIT (GMORRIS) IS A CLINICAL CHEMISTRY ASSAY BASED ON MOD. GOMORRIS METHOD FOR THE DETERMINATION OF INORGANIC PHOSPHORUS IN SERUM, PLASMA AND URINE.,SODIUM KIT (COLORIMETRIC METHOD)-FOR THE DETERMINATION OF SODIUM IN SERUM. FOR INVITRO DIAGNOSTIC USE ONLY.,RNA EXTRACTION KIT FOR RT-PCR TESTING (MAGNETIC BEADS METHOD)(EX-RNA-MAG)-THIS KIT IS RECOMMENDED TO USE FOR ISOLATION OF VIRAL RNA FROM VARIOUS SAMPLES LIKE FRESH AND FROZEN PLASMA, SERUM, NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, SPUTUM, BRONCO-ALVEOLAR LAVAGE IN VIRAL TRANSPORT MEDIUM AND OTHER BODY FLUIDS.,POTASSIUM KIT (COLORIMETRIC METHOD)-POTASSIUM KIT (COLORIMETRIC METHOD) IS USED FOR THE DETERMINATION OF POTASSIUM IN SERUM. IT IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR MONITORING AND DIAGNOSIS. INCREASED POTASSIUM LEVELS ARE FOUND IN RENAL FAILURE,

	DEHYDRATION, SHOCK AND ADRENAL INSUFFICIENCY. DECREASED LEVELS ARE FOUND IN MALNUTRITION, GASTRO-INTESTINAL FLUID LOSS, AND HYPERACTIVITY OF THE ADRENAL CORTEX. POTASSIUM KIT (COLORIMETRIC METHOD) IS A QUANTITATIVE ASSAY, CAN BE USED ON SEMI AUTOMATED OR AUTOMATED SYSTEM. THE TESTING SYSTEM IS FOR GENERAL POPULATION AND FOR PROFESSIONAL USE ONLY.,CREATININE (E.P.) KIT (ALKALINE PICRATE METHOD)-CREATININE (E.P.) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE ALKALINE PICRATE METHOD FOR THE DETERMINATION OF CREATININE IN SERUM AND URINE.,DIRECT BILIRUBIN KIT (MOD JENDRASSIK & GROF'S METHOD)-FOR THE DETERMINATION OF DIRECT BILIRUBIN IN SERUM. FOR INVITRO DIAGNOSTIC USE ONLY., RNA EXTRACTION KIT FOR RT-PCR TESTING (TRIZOL METHOD)(EX-RNA-TRIZOL)-THIS KIT IS RECOMMENDED TO USE FOR ISOLATION OF VIRAL RNA FROM VARIOUS SAMPLES LIKE FRESH AND FROZEN PLASMA, SERUM, NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, SPUTUM, BRONCOALVEOLAR LAVAGE IN VIRAL TRANSPORT MEDIUM AND OTHER BODY FLUIDS.,ASSAYED CONTROL FOR QUALITY CONTROL PROCEDURES OF FERRITIN IMMUNOASSAYS (SEROQUANT FERRITIN LEVEL-I)-SEROQUANT FERRITIN LEVEL -1 IS A CONTROL USEFUL FOR VALIDATING THE CALIBRATION AND PERFORMANCE OF THE QUANTIA FERRITIN REAGENT. ITS A QUANTITATIVE SCREENING TEST AND IT IS USED FOR IN-VITRO DIAGNOSTICS ONLY AND PROFESSIONAL USE ONLY. QUANTIA FERRITIN IS A TURBIDIMETRIC IMMUNOASSAY FOR THE DETERMINATION OF FERRITIN IN HUMAN SERUMA AND IS BASED ON THE PRINCIPLE OF AGGLUTINATION REACTION. IT IS QUANTITATIVE, SCREENING TEST USED FOR IN VITRO DIAGNOSTICS ONLY AND FOR PROFESSIONAL USE ONLY. SERUM FERRITIN CONCENTRATION USUALLY REFLECTS BODY IRON STORES AND IS CONSIDERED ONE OF THE MOST RELIABLE INDICATORS OF IRON STATUS OF PATIENTS. WHEREAS LOW SERUM CONCENTRATIONS OF FERRITIN ARE ALWAYS INDICATIVE OF AN IRON DEFICIENCY, ELEVATED CONCENTRATIONS OFTEN INDICATE AN EXCESSIVE IRON INTAKE, THEY ARE ALSO CAUSED BY LIVER DISEASE, CHRONIC INFLAMMATION AND MALIGNANCIES.,RNA EXTRACTION KIT FOR RT-PCR TESTING (ACID PH METHOD)(EX-RNA-APH)-THIS KIT IS RECOMMENDED TO USE ISOLATION OF VIRAL RNA FROM VARIOUS SAMPLES LIKE FRESH AND FROZEN PLASMA, SERUM, NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, SPUTUM, BRONCOALVEOLAR LAVAGE IN VIRAL TRANSPORT MEDIUM AND OTHER BODY FLUIDS.,TOTAL BILIRUBIN KIT (MOD JENDRASSIK & GROF'S METHOD)-FOR THE DETERMINATION OF TOTAL BILIRUBIN IN SERUM. FOR INVITRO DIAGNOSTIC USE ONLY. ,CK-MB (NAC ACT.) KIT-CK-MB (NAC ACT.)KIT

	IS A CLINICAL CHEMISTRY ASSAY BASED ON THE IMMUNOINHIBITION / MODIFIED IFCC METHOD FOR THE DETERMINATION OF CK-MB ACTIVITY IN SERUM,GAMMA GLUTAMYL TRANSFERASE KIT (SOLUBLE/ CARBOXY SUBSTRATE METHOD)(CALKINE GAMMA GLUTAMYL TRANSFERASE KIT)-CALKINE GMMA GLUTAMYL TRANSFERASE KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE CARBOXY SUBSTRATE METHOD FOR THE DETERMINATION GMMA GLUTAMYL TRANSFERASE ACTIVITY IN SERUM.,HAEMOGLOBIN REAGENT FOR HAEMOGLOBIN ESTIMATION(HEMOCOR-C)-HEMOCOR-C KIT IS CLINICAL CHEMISTRY ASSAY BASED ON THE CYANMETHAEMOGLOBIN METHOD FOR THE DETERMINATION OF HAEMOGLOBIN IN WHOLE BLOOD.,ENZYMATIC CREATININE KIT (ENZYMATIC CREATININE KIT)-CREATININE ENZY. KIT (ENZYMATIC PAP METHOD) IS USED FOR THE DETERMINATION OF CREATININE IN SERUM AND URINE.,CALCIUM KIT (OCPC)-CALCIUM KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE O-CRESOLPHTHALEIN COMPLEXONE (OCPC) METHOD FOR THE DETERMINATION OF CALCIUM IN SERUM OR PLASMA,SEMI AUTOMATIC TURBIDIMETRY AND CLINICAL CHEMISTRY ANALYZER(GR8LAB 1.0)-SEMI AUTOMATIC TURBIDIMETRY AND CLINICAL CHEMISTRY ANALYZER FOR CHEMISTRY AND HAEMATOLOGY TESTING OF PATIENT SAMPLES.,CK (NAC ACT.) KIT-CK (NAC ACT) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE MODIFIED IFCC METHOD FOR THE DETERMINATION OF CREATININE KINASE (CK) ACTIVITY IN SERUM,2 CHANNEL HAEMOSTASIS ANALYZER(HEMOSTAR XF 2.0)-TWO CHANNEL HAEMOSTASIS ANALYZER FOR CLOT BASED ASSAYS, GLYCOSYLATED HEMOGLOBIN KIT (ION EXCHANGE RESIN METHOD)-GLYCOSYLATED HEMOGLOBIN (GHB) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE ION EXCHANGE RESIN METHOD FOR THE QUANTITATIVE DETERMINATION OF GLYCOHEMOGLOBIN IN BLOOD., TURBIDIMETRY AND NEPHELOMETRY ANALYZER(TURBODYNE SC)-THE TURBODYNE SC IS USED TO ANALYSIS OF VARIOUS IMMUNOCHEMISTRY ANALYTES BY TURBIDIMETRIC OR NEPHELOMETRIC ASSAYS USING PRE-CALIBRATED ASSAY SPECIFIC SMART CARD WITH INTEGRATED CHIP TECHNOLOGY.,ACID PHOSPHATASE KIT (ALPHA NAPHTHYLPHOSPHATE METHOD)-THE ACID PHOSPHATASE (ACP) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON ALPHA NAPHTHYLPHOSPHATE KINETIC METHOD FOR THE DETERMINATION OF ACID PHOSPHATASE ACTIVITY IN SERUM,CARD WARMER(MATRIX CARD WARMER)-THE MATRIX CARD WARMER IS USED FOR INCUBATION OF MATRIX COOMB'S CARDS. ITS PURPOSE IS TO INCUBATE CARDS AT 37ºC FOR IAT, CROSS MATCH, ANTIBODY IDENTIFICATION AND DU TESTING FOR THE DESIRED TIME (15 MINUTES) WITH AN ALARM,RNA EXTRACTION KIT FOR RT-PCR

	TESTING (SPIN TUBE METHOD)(EX-RNA-SPINTUBE)-THE KIT IS RECOMMENDED TO USE FOR ISOLATION OF VIRAL RNA FROM VARIOUS SAMPLES LIKE FRESH AND FROZEN PLASMA, SERUM, NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, SPUTUM, BROCO-ALVEOLAR LAVAGE IN VIRAL TRANSPORT MEDIUM AND OTHER BODY FLUIDS.,CARD CENTRIFUGE(MATRIX JUNIOR CARD CENTRIFUGE)-THE MATRIX JUNIOR CARD CENTRIFUGE IS USED FOR CENTRIFUGATION OF MATRIX GEL CARDS. IT CAN ACCOMMODATE 8 MATRIX GEL CARDS AT A TIME.,AUTO BILIRUBIN T & D KIT (MOD. JENDRASSIK & GROF'S METHOD)-AUTO BILIRUBIN KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE MOD. JENDRASSIK AND GROF'S METHOD FOR THE DETERMINATION OF DIRECT AND TOTAL BILIRUBIN IN SERUM.,FULLY AUTOMATIC BIOCHEMISTRY ANALYZER (CORALYZER MINI)-THE CORALYZER MINI FULLY AUTOMATIC BIOCHEMISTRY ANALYZER IS USED FOR PERFORMING CLINICAL CHEMISTRY TESTS WITH A THROUGHPUT OF 100 TEST PER HOUR., GLUCOSE KIT (GOD/POD METHOD)-GLUCOSE KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE GOD/POD (GLUCOSE OXIDASE/ PEROXIDASE) METHOD FOR THE DETERMINATION GLUCOSE IN SERUM, PLASMA AND CSF,FULLY AUTOMATIC BIOCHEMISTRY ANALYZER(CORALYZER 200)-THE CORALYZER 200 FULLY AUTOMATIC BIOCHEMISTRY ANALYZER IS USED FOR PERFORMING CLINICAL CHEMISTRY TESTS WITH A THROUGHPUT OF 200 TEST PER HOUR.,ALPHA AMYLASE KIT (DIRECT SUBSTRATE METHOD)-AMYLASE KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE DIRECT SUBSTRATE METHOD FOR THE DETERMINATION OF AMYLASE ACTIVITY IN SERUM, PLASMA, OR URINE,FULLY AUTOMATED PROCESSOR FOR GEL CARDS(MATRIX AUTOMAX 80)-THE MATRIX AUTOMAX-80 FULLY AUTOMATED PROCESSOR IS USED FOR DETERMINATION OF ABO/RHO(D) BLOOD GROUP SYSTEMS (FORWARD AND REVERSE GROUPING) , RH ANTIGENS DETECTION (RH PHENOTYPE DETERMINATION), COOMB'S TEST (DIRECT ANTIGLOBULIN TEST & INDIRECT ANTIGLOBULIN TEST), COMPATIBILITY TESTING AND ANTIBODY SCREENING AND IDENTIFICATION,CREATININE (KIN) KIT (MOD JAFFE'S KINETIC METHOD)-CREATININE (KIN.) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE MOD. JAFFE'S KINETIC METHOD FOR THE DETERMINATION OF CREATININE IN SERUM AND URINE, TURBIDIMETRY AND NEPHELOMETRY ANALYZER(TURBOSMART)-THE TURBOSMART TURBIDIMETRY AND NEPHELOMETRY ANALYZER IS USED FOR ANALYSIS OF VARIOUS IMMUNOCHEMISTRY ANALYTES BY TURBIDIMETRIC OR NEPHELOMETRIC ASSAYS USING PRE-CALIBRATED ASSAY SPECIFIC SMART CARD WITH INTEGRATED CHIP TECHNOLOGY.,LIPASE KIT (TURBIDIMETRIC METHOD)-LIPASE KIT IS

	CLINICAL CHEMISTRY ASSAY BASED ON TURBIDIMETRIC U.V. METHOD FOR THE DETERMINATION OF LIPASE ACTIVITY IN SERUM., CARD READER(MATRIX CARD READER)-MATRIX CARD READER CR-6800 IS A SEMI-AUTOMATED READER FOR MATRIX GEL CARDS. MATRIX CARD READER CR- 6800 IS CAPABLE OF READING THE REACTION, INTERPRETATION OF RESULTS AND DOCUMENTATION OR PRINTING. MATRIX CARD READER CR- 6800 IS OPERATED THROUGH MATRIX PRO-SCAN, A USER FRIENDLY SOFTWARE INSTALLED IN A DEDICATED STANDALONE DESKTOP.,MICRO PROTEIN KIT (PYROGALLOL RED METHOD)-MICRO PROTEIN KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON PYROGALLOL RED METHOD FOR THE DETERMINATION OF PROTEINS IN URINE AND CSF.,SGOT (ASAT) KIT (MODIFIED IFCC METHOD)(CALKINE SGOT (ASAT) KIT)-CALKINE SGOT (ASAT) (MOD. IFCC) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON MOD. IFCC METHOD FOR THE DETERMINATION OF SGOT (ASAT) ACTIVITY IN SERUM.,URIC ACID KIT (URICASE/PAP METHOD)-URIC ACID KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE URICASE/PAP METHOD FOR THE DETERMINATION OF URIC ACID IN SERUM OR PLASMA.,LDH(P-L) KIT (MOD.IFCC METHOD) (CALKINE LDH (P-L) KIT)-CALKINE LDH (P - L) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON MOD. IFCC METHOD FOR THE DETERMINATION OF LACTATE DEHYDROGENASE ACTIVITY IN SERUM.,BILIRUBIN T & D KIT (DCA METHOD)-BILIRUBIN KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON DICHLOROANILINE METHOD FOR THE DETERMINATION OF DIRECT AND TOTAL BILIRUBIN IN SERUM.,SGPT (ALAT) KIT (MODIFIED IFCC METHOD)(CALKINE SGPT (ALAT) KIT)-CALKINE SGPT (ALAT) (MOD. IFCC) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON MOD. IFCC METHOD FOR THE DETERMINATION OF SGPT (ALAT) ACTIVITY IN SERUM.,DIRECT BILIRUBIN KIT (DCA METHOD)-DIRECT BILIRUBIN KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON DICHLOROANILINE METHOD FOR THE DETERMINATION OF DIRECT BILIRUBIN IN SERUM, SINGLE CHANNEL HAEMOSTASIS ANALYZER(HEMOSTAR XF 1.0)-SINGLE CHANNEL HAEMOSTASIS ANALYZER FOR CLOT BASED ASSAYS,TOTAL BILIRUBIN KIT (DCA METHOD)-TOTAL BILIRUBIN KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON DICHLOROANILINE METHOD FOR THE DETERMINATION OF TOTAL BILIRUBIN IN SERUM, HEMOLYSING REAGENT FOR ASSAY OF HAEMOGLOBIN AND WBC COUNT FOR USE ON HAEMOTOLOGY ANALYZERS(LYSE)-LYSE IS USED BY THE HEMATOLOGICAL ANALYZER RED BLOOD CELL HEMOLYSING REAGENT FOR THE ASSAY OF HEMOGLOBIN, WHITE BLOOD CELL COUNT, LYMPHOCYTES COUNT, MID CELL, GRANULOCYTE COUNT.,UREA KIT (GLDH KINETIC METHOD)-UREA (GLDH+UV) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE GLDH KINETIC METHOD FOR THE DETERMINATION OF UREA IN

	SERUM, PLASMA AND URINE.,DILUTING REAGENT FOR WHOLE BLOOD SAMPLES FOR USE ON HAEMATOLOGY ANALYZERS (DILUENT)-FOR INVITRO DIAGNOSTIC USE ONLY.DILUENT IS USED BY HEMATOLOGICAL ANALYZER AS A WHOLE BLOOD SAMPLE DILUTING AND SHEATH REAGENT.,TRIGLYCERIDES KIT (GPO/PAP METHOD)-TRIGLYCERIDES KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON GPO/PAP METHOD FOR THE DETERMINATION OF TRIGLYCERIDES IN SERUM OR PLASMA,REAGENT FOR DETERMINATION OF GLUCOSE IN SERUM OR PLASMA(ECOGLUCO PLUS KIT)-FOR THE DETERMINATION OF GLUCOSE IN SERUM, PLASMA AND CSF. FOR INVITRO DIAGNOSTIC USE ONLY.,TOTAL PROTEINS KIT (BIURET METHOD)-TOTAL PROTEIN KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON BIURET METHOD FOR THE DETERMINATION OF TOTAL PROTEINS IN SERUM AND PLASMA.,GLUCOSE 6 PHOSPHATE DEHYDROGENASE (G6PDH) KIT (KINETIC METHOD)(G-SIX KIT)-FOR THE DETERMINATION OF G6PDH IN RBC'S. FOR INVITRO DIAGNOSTIC USE ONLY.,HDL CHOLESTEROL PPT. SET (PEG PRECIPITATION METHOD)-HDL CHOLESTEROL PPT. SET IS A CLINICAL CHEMISTRY ASSAY BASED ON PEG PRECIPITATION METHOD FOR THE DETERMINATION OF HDL CHOLESTEROL IN SERUM OR PLASMA.,SODIUM AND POTASSIUM KIT(ELYTE 2 KIT)-FOR THE DETERMINATION OF SODIUM, POTASSIUM IN SERUM. FOR INVITRO DIAGNOSTIC USE ONLY.,HDL CHOLESTEROL KIT (PEG/CHOD-PAP METHOD)-HDL CHOLESTEROL KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON PEG/CHOD/PAP METHOD FOR THE DETERMINATION OF HDL CHOLESTEROL IN SERUM OR PLASMA,CLEANING SOLUTION FOR USE ON HEMATOLOGY ANALYZERS FOR CLEANING BETWEEN MEASUREMENT(CLEANER)-TO CLEAN THE COUNTING UNITS OF THE HEMATOLOGY ANALYZERS AFTER THE SAMPLE IS ANALYZED.,UREA KIT (MODIFIED BERTHELOT METHOD)-UREA (BERTHELOT) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE MOD.BERTHELOT METHOD FOR THE DETERMINATION OF UREA IN SERUM, PLASMA AND URINE.,RNA EXTRACTION KIT WITH CARRIER RNA FOR RT-PCR TESTING (SPIN TUBE METHOD)(EX-RNA-SPINTUBE CR)-THIS KIT IS RECOMMENDED TO USE FOR ISOLATION OF VIRAL RNA FROM VARIOUS SAMPLES LIKE FRESH AND FROZEN PLASMA, SERUM, NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, SPUTUM, BRONCO-ALVEOLAR LAVAGE IN VIRAL TRANSPORT MEDIUM AND OTHER BODY FLUIDS.,A TWO-FIELD TEST FOR OCCULT BLOOD IN STOOL. (STANDARD GUAIAC METHOD)(HEMOSPOT)-HEMOSPOT KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE TWO FIELD GUAIAC METHOD FOR THE QUALITATIVE DETERMINATION OF FECAL OCCULT BLOOD IN HUMAN STOOL SPECIMEN,SODIUM, POTASSIUM AND CHLORIDE KIT(ELYTE 3 KIT)-FOR THE DETERMINATION OF SODIUM, POTASSIUM, CHLORIDE IN SERUM. FOR INVITRO DIAGNOSTIC USE

	ONLY.,HLD-D CHOLESTEROL KIT (DIRECT ENZYMATIC METHOD)-HDL-D CHOLESTEROL KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON DIRECT ENZYMATIC METHOD FOR THE DETERMINATION OF HDL CHOLESTEROL IN SERUM OR PLASMA.,ADENOSINE DEAMINASE KIT FOR THE DETERMINATION OF ADENOSINE DEAMINASE ACTIVITY IN SERUM, PLASMA AND BIOLOGICAL FLUIDS (ENZYMATIC METHOD) (ADAZYME-LS)-INCREASED CONCENTRATION OF SERUM ADA HAS SHOWN THE POTENTIAL OF USABLE SCREENING TEST AND CAN BE USED IN THE DIAGNOSIS OF LIVER DISEASES IN COMBINATION WITH ALT OR G-GT (GGT) TESTS.,LDL-D CHOLESTEROL KIT (DIRECT ENZYMATIC METHOD)-LDL_D CHOLESTEROL KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON DIRECT ENZYMATIC METHOD FOR THE DETERMINATION OF LDL CHOLESTEROL IN SERUM.,CHLORIDE KIT (THIOCYANATE METHOD)-FOR THE DETERMINATION OF CHLORIDE IN SERUM. FOR INVITRO DIAGNOSTIC USE ONLY.,CHOLESTEROL SR KIT (CHOD/PAP METHOD)-CHOLESTEROL SR KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE CHOD/PAP METHOD FOR THE DETERMINATION OF CHOLESTEROL IN SERUM OR PLASMA,UREA KIT (DAM METHOD)-UREA (DAM) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE DAM (DIACETYLMONOXIME) METHOD FOR THE DETERMINATION OF UREA IN SERUM, PLASMA AND URINE., TRIGLYCERIDES SR KIT (GPO/PAP METHOD)-TRIGLYCERIDES SR KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON GPO/PAP METHOD FOR THE DETERMINATION OF TRIGLYCERIDES IN SERUM OR PLASMA, ENZYMATIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL GALACTOSE LEVELS IN NEW BORN DRIED BLOOD SPOTS (BORNSAFE T.GAL)-BORNSAFE T,GAL NEONATAL TOTAL GALACTOSE SCREENING ASSAY IS AN ENZYMATIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF TOTAL GALACTOSE (GALACTOSE AND GALACTOSE-1-PHOSPHATE) CONCENTRATION IN NEONATES USING BLOOD SPOT SAMPLE DRIED ON WHATMAN S&S 903 FILTER COLLECTION PAPER.

2771	MFG/IVD/2019/000018	1.License Holder Name: MOLBIO DIAGNOSTICS PVT. LTD. 2.Approving Authority: SUB ZONAL GOA 3.Device Name(Brand Name)-Intended Use:CHIP-BASED REAL TIME PCR TEST FOR BETA CORONAVIRUS(TRUENAT™ BETA COV)-REAL TIME PCR ASSAY FOR BETA CORONAVIRUS IS A POINT-OF-CARE, DISPOSABLE CHIP BASED IN-VITRO DIAGNOSTIC MEDICAL DEVICE FOR DETECTION OF NUCLEIC ACID SPECIFIC TO THE GENOME OF THE NOVEL CORONA VIRUS. THE INTENDED CLINICAL SPECIMEN IS BODY FLUID. THE INTENDED TESTING POPULATION IS THE CLINICALLY SYMPTOMATIC GENERAL POPULATION.. EVEN THE PERIPHERAL LABORATORIES WITH THE MINIMAL INFRASTRUCTURE AND MINIMALLY TRAINED TECHNICIAN CAN EASILY PERFORM THESE TESTS ROUTINELY IN THEIR FACILITIES AND REPORT PCR RESULTS IN LESS THAN AN HOUR.,CHIP-BASED REAL TIME PCR TEST FOR HIV-1 VIRUS(TRUENAT™ HIV-1)-TRUENAT™ HIV-1 IS A CHIP-BASED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT PCR) TEST FOR THE QUANTITATIVE DETECTION AND DIAGNOSIS OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) IN WHOLE BLOOD/PLASMA AND AIDS IN THE MONITORING OF THE HIV-1 VIRAL LOAD OF PATIENTS WITH HIV-1 INFECTION. TRUENAT™ HIV-1 RUNS ON THE TRUELAB® REAL TIME MICRO PCR ANALYZERS ,CHIP BASED REAL TIME PCR TEST FOR COVID-19(TRUENAT™ SARS COV-2)-TRUENAT™ SARS COV-2 IS A POINT-OF-CARE, DISPOSABLE CHIP BASED REAL TIME REVERSE TRANSCRIPTION PCR TEST FOR QUALITATIVE DETECTION AND CONFIRMATION OF COVID 19 IN TRUENAT™ BETA COV POSITIVE HUMAN SPECIMEN. THE INTENDED CLINICAL SPECIMEN IS EXTRACTED NUCLEIC ACIDS FROM HUMAN THROAT OR NASAL SWAB. THE INTENDED TESTING POPULATION IS THE CLINICALLY SYMPTOMATIC GENERAL POPULATION. EVEN THE PERIPHERAL LABORATORIES WITH THE MINIMAL INFRASTRUCTURE AND MINIMALLY TRAINED TECHNICIAN CAN EASILY PERFORM THESE TESTS ROUTINELY IN THEIR FACILITIES AND REPORT PCR RESULTS IN LESS THAN AN HOUR. TRUENAT™ SARS COV-2 RUNS ON TRUELAB® REAL TIME QUANTITATIVE MICRO PCR ANALYZER AND THE ASSAY TARGETS RDRP GENE OF COVID 19. EVEN THE PERIPHERAL LABORATORIES WITH THE MINIMAL INFRASTRUCTURE AND MINIMALLY TRAINED TECHNICIAN CAN EASILY PERFORM THESE TESTS ROUTINELY IN THEIR FACILITIES AND REPORT PCR RESULTS IN LESS THAN AN HOUR.,CHIP-BASED REAL TIME DUPLEX PCR TEST FOR COVID-19(TRUENAT™ COVID-19)-TRUENAT™ COVID-19 IS A POINT-OF-CARE, DISPOSABLE CHIP BASED IN-VITRO DIAGNOSTIC MEDICAL DEVICE FOR SEMIQUANTITATIVE DETECTION AND CONFIRMATION OF COVID-19. TRUENAT™ COVID-19 RT PCR TEST USES E GENE AND ORF1A AS GENE TARGET. THE INTENDED CLINICAL

	SPECIMEN IS HUMAN THROAT AND NASAL SWAB. THE INTENDED TESTING POPULATION IS CLINICALLY SYMPTOMATIC GENERAL POPULATION. EVEN THE PERIPHERAL LABORATORIES WITH THE MINIMAL INFRASTRUCTURE AND MINIMALLY TRAINED TECHNICIAN CAN EASILY PERFORM THESE TESTS ROUTINELY IN THEIR FACILITIES AND REPORT PCR RESULTS IN LESS THAN AN HOUR. TRUENAT™ COVID-19 RT PCR KIT RUNS ON TRUELAB® REAL TIME PCR ANALYZERS,CHIP-BASED REAL TIME PCR TEST FOR LEPTOSPIRA (TRUENAT™ LTS)-TRUENAT™ LTS IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMI QUANTITATIVE DETECTION OF LEPTOSPIRA AND AIDS IN THE DIAGNOSIS OF LEPTOSPIROSIS IN HUMAN BLOOD/ SERUM/ PLASMA, CEREBROSPINAL FLUID (CSF) AND URINE SPECIMEN. TRUENAT™ LTS RUNS ON TRUELAB® REAL TIME QUANTITATIVE MICRO PCR ANALYZERS,CHIP-BASED REAL TIME DUPLEX PCR TEST FOR CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE (TRUENAT™ CT/NG)-TRUENAT™ CT/NG IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMIQUANTITATIVE DETECTION OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE IN FEMALE ENDOCERVICAL AND VAGINAL SWAB SPECIMENS, MALE URETHRAL SWAB SPECIMEN, MALE AND FEMALE URINE SPECIMEN. IT AIDS IN THE DIAGNOSIS OF SYMPTOMATIC OR ASYMPTOMATIC INFECTION WITH CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE. TRUENAT™ CT/NG RUNS ON TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZER.,CHIP-BASED REAL TIME PCR TEST FOR NIPAH VIRUS (TRUENAT® NIPAH)-TRUENAT® NIPAH IS A CHIP-BASED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT PCR) TEST FOR SEMIQUANTITATIVE DETECTION AND THE DIAGNOSIS OF NIPAH VIRUS IN THROAT SWABS AND AIDS IN THE DIAGNOSIS OF INFECTION WITH NIPAH VIRUS. TRUENAT® NIPAH RUNS ON THE TRUELAB® REAL TIME MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR TRICHOMONAS VAGINALIS(TRUENAT™ TRICH)-TRUENAT™ TRICH IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMIQUANTITATIVE DETECTION OF TRICHOMONAS VAGINALIS IN FEMALE ENDOCERVICAL AND VAGINAL SWAB SPECIMENS, MALE URETHRAL SWAB SPECIMEN AND MALE AND FEMALE URINE SPECIMEN. IT AIDS IN THE DIAGNOSIS OF SYMPTOMATIC OR ASYMPTOMATIC INFECTION WITH TRICHOMONAS VAGINALIS. TRUENAT™ TRICH RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR RIFAMPICIN RESISTANT MYCOBACTERIUM TUBERCULOSIS (TRUENAT™ MTB-RIF DX)-TRUENAT™ MTB-RIF DX IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE

	DETECTION OF RIFAMPICIN RESISTANCE IN MYCOBACTERIUM TUBERCULOSIS (MTB) IN TRUENAT™ MTB/MTB PLUS POSITIVE HUMAN SPECIMEN AND AIDS IN THE DIAGNOSIS OF MDR-TB. THIS TEST DETECTS THE PRESENCE OF MAJOR MUTATIONS (SNPS) IN THE MTB GENOME THAT ARE KNOWN TO CAUSE RESISTANCE TO RIFAMPICIN. TRUENAT™ MTB-RIF DX RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZER. THIS IS A FOLLOW ON TEST, TO BE PERFORMED ONLY ON THE EXTRACTED DNA FROM TRUENAT™ MTB/MTB PLUS POSITIVE SAMPLE.,CHIP-BASED REAL TIME DUPLEX PCR TEST FOR INFLUENZA A AND INFLUENZA B VIRUS (TRUENAT™ INFLUENZA A/B)-TRUENAT™ INFLUENZA A/B IS A CHIP-BASED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) TEST FOR THE SEMI QUANTITATIVE DETECTION OF INFLUENZA A AND INFLUENZA B VIRUS IN HUMAN THROAT AND NASAL SWAB SPECIMEN AND AIDS IN DIFFERENTIAL DIAGNOSIS OF INFECTION WITH INFLUENZA A AND/OR INFLUENZA B VIRUS. TRUENAT™ INFLUENZA A/B RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZER.,CHIP-BASED REAL TIME PCR TEST FOR STREPTOCOCCUS PNEUMONIAE(TRUENAT™ S. PNEUMONIAE)-TRUENAT™ S.PNEUMONIAE IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMI QUANTITATIVE DETECTION OF STREPTOCOCCUS PNEUMONIAE IN BLOOD/ SERUM/ PLASMA, CEREBROSPINAL FLUID (CSF) AND SWABS SPECIMENS. IT AIDS IN THE DIAGNOSIS OF INFECTIONS WITH STREPTOCOCCUS PNEUMONIAE. TRUENAT™ S.PNEUMONIAE RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR GROUP B STREPTOCOCCUS(TRUENAT™ GBS)-TRUENAT™ GBS IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMI QUANTITATIVE DETECTION AND DIAGNOSIS OF GROUP B STREPTOCOCCUS IN VAGINO-RECTAL SWAB SPECIMEN AND AIDS IN THE DIAGNOSIS OF INFECTION WITH GROUP B STREPTOCOCCUS. TRUENAT™ GBS RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP – BASED REAL TIME DUPLEX PCR TEST FOR STAPHYLOCOCCUS AUREUS AND PSEUDOMONAS AERUGINOSA (TRUENAT™ STAPH/PA)-TRUENAT™ STAPH/PA IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMI QUANTITATIVE DETECTION OF STAPHYLOCOCCUS AUREUS AND PSEUDOMONAS AERUGINOSA IN BLOOD/ SERUM/ PLASMA AND SWABS SPECIMENS. IT AIDS IN THE DIFFERENTIAL DIAGNOSIS OF INFECTIONS WITH STAPHYLOCOCCUS AUREUS AND/OR PSEUDOMONAS AERUGINOSA. TRUENAT™ STAPH/PA RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR PSEUDOMONAS AERUGINOSA

	(TRUENAT™ PA)-TRUENAT™ PA IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMI QUANTITATIVE DETECTION OF PSEUDOMONAS AERUGINOSA IN BLOOD/ SERUM/ PLASMA AND SWABS SPECIMENS. IT AIDS IN THE DIAGNOSIS OF INFECTIONS WITH PSEUDOMONAS AERUGINOSA. TRUENAT™ PA RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR HEPATITIS E VIRUS(TRUENAT™ HEV)-TRUENAT™ HEV IS A CHIP-BASED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT PCR) TEST FOR THE QUANTITATIVE DETECTION OF HEPATITIS E VIRUS IN BLOOD/ SERUM/ PLASMA AND AIDS IN MONITORING OF HEV VIRAL LOAD OF PATIENTS WITH HEV INFECTION. TRUENAT™ HEV RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR HEPATITIS A VIRUS(TRUENAT™ HAV)-TRUENAT™ HAV IS A CHIP-BASED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT PCR) TEST FOR THE QUANTITATIVE DETECTION AND DIAGNOSIS OF HEPATITIS A VIRUS IN HUMAN BLOOD /SERUM/ PLASMA SPECIMEN AND AIDS IN THE DIAGNOSIS OF INFECTION WITH HEPATITIS A VIRUS. TRUENAT™ HAV RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR HAEMOPHILUS INFLUENZAE TYPE B(TRUENAT™ HIB)-TRUENAT™ HIB IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMI QUANTITATIVE DETECTION OF HAEMOPHILUS INFLUENZAE TYPE B IN BLOOD/ SERUM/ PLASMA, CEREBROSPINAL FLUID (CSF) AND SWABS SPECIMENS. IT AIDS IN THE DIAGNOSIS OF INFECTIONS WITH HAEMOPHILUS INFLUENZAE TYPE B. TRUENAT™ HIB RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR NEISSERIA MENINGITIDIS (TRUENAT™ NM)-TRUENAT™ NM IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE QUANTITATIVE DETECTION OF NEISSERIA MENINGITIDIS IN BLOOD AND CEREBROSPINAL FLUID (CSF) SPECIMENS. IT AIDS IN THE DIAGNOSIS OF INFECTIONS WITH NEISSERIA MENINGITIDIS. TRUENAT™ NM RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME DUPLEX PCR TEST FOR DENGUE AND CHIKUNGUNYA(TRUENAT™ DENGUE/CHIKUNGUNYA)-TRUENAT™ DENGUE/CHIKUNGUNYA IS A CHIP-BASED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT PCR) TEST FOR THE QUANTITATIVE DETECTION OF DENGUE AND CHIKUNGUNYA VIRUS IN HUMAN BLOOD/SERUM/PLASMA SPECIMEN AND AIDS IN THE DIFFERENTIAL DIAGNOSIS OF INFECTION WITH DENGUE AND/OR CHIKUNGUNYA VIRUS. TRUENAT™

	DENGUE/CHIKUNGUNYA RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZER.,CHIP-BASED REAL TIME PCR TEST FOR RABIES VIRUS(TRUENAT™ RABIES)-TRUENAT™ RABIES IS A CHIP-BASED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT PCR) TEST FOR THE SEMIQUANTITATIVE DETECTION OF RABIES VIRUS IN CEREBROSPINAL FLUID (CSF), SALIVA, BRAIN TISSUE, CORNEAL SWABS SPECIMENS OF ANIMALS AND AIDS IN THE DIAGNOSIS OF INFECTION WITH RABIES VIRUS. TRUENAT™ RABIES RUNS ON THE TRUELAB™ REAL TIME MICRO QUANTITATIVE PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR H1N1(TRUENAT™ H1N1)-TRUENAT™ H1N1 IS A CHIP-BASED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT PCR) TEST FOR THE SEMIQUANTITATIVE DETECTION OF H1N1 VIRUS IN HUMAN THROAT AND NASAL SWAB SPECIMEN AND AIDS IN THE DIAGNOSIS OF INFECTION WITH H1N1. TRUENAT™ H1N1 RUNS ON TRUELAB™ REAL TIME MICRO QUANTITATIVE PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR MYCOBACTERIUM TUBERCULOSIS (TRUENAT™ MTB PLUS)-TRUENAT™ MTB PLUS IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMIQUANTITATIVE DETECTION AND DIAGNOSIS OF MYCOBACTERIUM TUBERCULOSIS (MTB) IN HUMAN PULMONARY (SPUTUM/NON-SPUTUM) AND EPTB SPECIMEN AND AIDS IN THE DIAGNOSIS OF INFECTION WITH MTB. TRUENAT™ MTB PLUS RUNS ON THE TRUELAB™ REAL TIME MICRO QUANTITATIVE PCR ANALYZERS., CHIP-BASED REAL TIME PCR TEST FOR DENGUE(TRUENAT™ DENGUE) -TRUENAT™ DENGUE IS A CHIP-BASED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT PCR) TEST FOR THE QUANTITATIVE DETECTION AND DIAGNOSIS OF DENGUE VIRUS IN HUMAN BLOOD/SERUM/PLASMA SPECIMEN AND AIDS IN THE DIAGNOSIS OF INFECTION WITH DENGUE. TRUENAT™ DENGUE RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR CHIKUNGUNYA (TRUENAT™ CHIKUNGUNYA)-TRUENAT™ CHIKUNGUNYA IS A CHIP-BASED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT PCR) TEST FOR THE QUANTITATIVE DETECTION AND DIAGNOSIS OF CHIKUNGUNYA VIRUS IN HUMAN BLOOD/SERUM/PLASMA SPECIMEN AND AIDS IN THE DIAGNOSIS OF INFECTION WITH CHIKUNGUNYA. TRUENAT™ CHIKUNGUNYA RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR ZIKA VIRUS (TRUENAT™ ZIKA)-TRUENAT™ ZIKA IS A CHIP-BASED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT PCR) TEST FOR THE QUANTITATIVE DETECTION AND DIAGNOSIS OF ZIKA VIRUS INFECTION IN HUMAN BLOOD /SERUM/ PLASMA SPECIMEN

	AND AIDS IN THE DIAGNOSIS OF INFECTION WITH ZIKA VIRUS. TRUENAT™ ZIKA RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR RIFAMPICIN RESISTANT MYCOBACTERIUM TUBERCULOSIS (TRUENAT™ MTB-RIF)-TRUENAT™ MTB-RIF IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE DETECTION OF RIFAMPICIN RESISTANCE IN MYCOBACTERIUM TUBERCULOSIS (MTB) IN TRUENAT™ MTB/MTB PLUS POSITIVE HUMAN SPECIMEN AND AIDS IN THE DIAGNOSIS OF MDR-TB. THIS TEST DETECTS THE PRESENCE OF MAJOR MUTATIONS (SNPS) IN THE MTB GENOME THAT ARE KNOWN TO CAUSE RESISTANCE TO RIFAMPICIN. TRUENAT™ MTB-RIF RUNS ON THE TRUELAB™ UNO REAL TIME MICRO PCR ANALYZER. THIS IS A FOLLOW ON TEST, TO BE PERFORMED ONLY ON THE EXTRACTED DNA FROM TRUENAT™ MTB/MTB PLUS POSITIVE SAMPLE.,CHIP-BASED REAL TIME DUPLEX PCR TEST FOR PLASMODIUM VIVAX AND PLASMODIUM FALCIPARUM (TRUENAT™ MALARIA PV/PF)-TRUENAT™ MALARIA PV/PF IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE QUANTITATIVE DETECTION OF PLASMODIUM VIVAX AND PLASMODIUM FALCIPARUM IN HUMAN BLOOD SPECIMEN AND AIDS IN THE DIFFERENTIAL DIAGNOSIS OF INFECTION WITH MALARIA CAUSED BY PLASMODIUM VIVAX AND PLASMODIUM FALCIPARUM. TRUENAT™ MALARIA PV/PF RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZER.,CHIP – BASED REAL TIME DUPLEX PCR TEST FOR STAPHYLOCOCCUS AUREUS AND METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS(TRUENAT™ STAPH/MRSA)-TRUENAT™ STAPH/MRSA IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMI QUANTITATIVE DETECTION OF STAPHYLOCOCCUS AUREUS AND METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS IN BLOOD/ SERUM/ PLASMA AND SWABS SPECIMENS. IT AIDS IN THE DIFFERENTIAL DIAGNOSIS OF INFECTIONS WITH STAPHYLOCOCCUS AUREUS AND/OR METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS. TRUENAT™ STAPH/MRSA RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR CHLAMYDIA TRACHOMATIS(TRUENAT™ CT)-TRUENAT™ CT IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMIQUANTITATIVE DETECTION OF CHLAMYDIA TRACHOMATIS IN FEMALE ENDOCERVICAL AND VAGINAL SWAB SPECIMENS, MALE URETHRAL SWAB SPECIMEN AND MALE AND FEMALE URINE SPECIMEN. IT AIDS IN THE DIAGNOSIS OF SYMPTOMATIC OR ASYMPTOMATIC INFECTION WITH CHLAMYDIA TRACHOMATIS. TRUENAT™ CT RUNS ON THE TRUELAB™ REAL TIME MICRO QUANTITATIVE PCR ANALYZERS.,CHIP-BASED REAL TIME PCR

	TEST FOR MYCOBACTERIUM TUBERCULOSIS(TRUENAT™ MTB)-TRUENAT™ MTB IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE QUANTITATIVE DETECTION AND DIAGNOSIS OF MYCOBACTERIUM TUBERCULOSIS (MTB) IN HUMAN PULMONARY AND EPTB SPECIMEN AND AIDS IN THE DIAGNOSIS OF INFECTION WITH MTB. TRUENAT™ MTB RUNS ON THE TRUELAB™ REAL TIME MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR HEPATITIS B VIRUS(TRUENAT™ HBV)-TRUENAT™ HBV IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE QUANTITATIVE ESTIMATION OF THE HEPATITIS B VIRUS (HBV) IN HUMAN BLOOD /SERUM/ PLASMA SPECIMEN AND AIDS IN THE DIAGNOSIS OF INFECTION WITH HEPATITIS B VIRUS AND IN THE ESTIMATION OF VIRAL LOAD. TRUENAT™ HBV RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR PLASMODIUM FALCIPARUM (TRUENAT™ MALARIA PF)-TRUENAT™ MALARIA PF IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE QUANTITATIVE DETECTION AND DIAGNOSIS OF PLASMODIUM FALCIPARUM (PF) IN HUMAN BLOOD SPECIMEN AND AIDS IN THE DIAGNOSIS OF INFECTION WITH MALARIA CAUSED BY PLASMODIUM FALCIPARUM (PF). TRUENAT™ MALARIA PF RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR NEISSERIA GONORRHOEAE(TRUENAT™ NG) -TRUENAT™ NG IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMIQUANTITATIVE DETECTION OF NEISSERIA GONORRHOEAE IN FEMALE ENDOCERVICAL AND VAGINAL SWAB SPECIMENS, MALE URETHRAL SWAB SPECIMENS AND MALE AND FEMALE URINE SPECIMEN. IT AIDS IN THE DIAGNOSIS OF SYMPTOMATIC OR ASYMPTOMATIC INFECTION WITH NEISSERIA GONORRHOEAE. TRUENAT™ NG RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME DUPLEX PCR TEST FOR H3N2 AND H1N1(TRUENAT™ H3N2/H1N1)-TRUENAT™ H3N2/H1N1 IS A CHIP-BASED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT PCR) TEST FOR THE SEMI QUANTITATIVE DETECTION OF H3N2 AND H1N1 VIRUS IN HUMAN THROAT AND NASAL SWAB SPECIMEN AND AIDS IN DIFFERENTIAL DIAGNOSIS OF INFECTION WITH H3N2 AND/OR H1N1 VIRUS. TRUENAT™ H3N2/H1N1 RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR SALMONELLA SPP.(TRUENAT™ SALMONELLA)-TRUENAT™ SALMONELLA IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE QUALITATIVE DETECTION AND DIAGNOSIS OF SALMONELLA IN HUMAN BLOOD AND AIDS IN THE DIAGNOSIS OF INFECTION WITH SALMONELLA. TRUENAT™

	SALMONELLA RUNS ON THE TRUELAB™ REAL TIME MICRO QUANTITATIVE PCR ANALYZERS.,CHIP-BASED REAL TIME DUPLEX PCR TEST FOR NEISSERIA MENINGITIDES AND STREPTOCOCCUS PNEUMONIAE(TRUENAT™ NM/S.PNEUMONIAE)-TRUENAT™ NM/S. PNEUMONIAE IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE QUANTITATIVE DETECTION OF NEISSERIA MENINGITIDES AND STREPTOCOCCUS PNEUMONIAE IN BLOOD/SERUM/PLASMA AND CEREBROSPINAL FLUID (CSF) SPECIMENS. IT AIDS IN THE DIFFERENTIAL DIAGNOSIS OF INFECTIONS WITH NEISSERIA MENINGITIDES AND/OR STREPTOCOCCUS PNEUMONIAE. TRUENAT™ NM/S.PNEUMONIAE RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME DUPLEX PCR TEST FOR HUMAN PAPILLOMAVIRUS HIGH RISK TYPES 16, 31 AND 18, 45(TRUENAT™ HPV- HR)-TRUENAT™ HPV-HR IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMIQUANTITATIVE DETECTION OF HIGH RISK HUMAN PAPILLOMAVIRUS (HPV) TYPES 16, 18, 31 AND 45 IN FEMALE CERVICAL SPECIMENS COLLECTED BY A CLINICIAN. IT AIDS IN THE DIFFERENTIAL DIAGNOSIS OF SYMPTOMATIC OR ASYMPTOMATIC INFECTION WITH HIGH RISK HPV TYPES 16, 31 AND 18, 45. TRUENAT™ HPV-HR RUNS ON THE TRUELAB™ REAL TIME QUANTITATIVE MICRO PCR ANALYZER.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2772	MFG/IVD/2019/000020	1.License Holder Name: DIAGNOSTIC ENTERPRISES 2.Approving Authority: SUB ZONAL BADDI 3.Device Name(Brand Name)-Intended Use:COMBI PACK-3 (A UNIQUE COMBINATION OF HIV, HCV AND HBSAG RAPID TEST(COMBI PACK-3 (A UNIQUE COMBINATION OF HIV, HCV AND HBSAG RAPID TEST)-HIV TRI-DOT DETECTS HIV-1 & HIV-2 ANTIBODIES IN HUMAN SERUM/PLASMA. HCV TRI-DOT DETECTS HEPATITIS-C ANTIBODIES IN HUMAN SERUM OR PLASMA. HEPACARD DETECT HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OR PLASMA.,HCV TRI -DOT(HCV TRI- DOT)-HCV TRI-DOT IS A RAPID, VISUAL, SENSITIVE AND QUALITATIVE IN VITRO DIAGNOSTIC TEST FOR THE DETECTION OF ANTIBODIES TO HEPATITIS C VIRUS IN HUMAN SERUM OR PLASMA., COVID 19 ANTIGEN CARD(COVID 19 ANTIGEN CARD)-COIVD 19 ANTIGEN CARD IS A VISUAL, RAPID AND SENSITIVE IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF COVID-19 (SARS- COV-2) ANTIGEN IN HUMAN NASOPHARYNGEAL, NASAL SWAB SPECIMEN. THE TEST IS A SCREENING TEST ONLY AND IS AN AID FOR THE EARLY DIAGNOSTIC OF SARS-COV-2 INFECTION IN PATIENT WITH CLINICAL SYMPTOMS. MORE SPECIC AND ALTERNATE DIAGNOSTIC METHOD SHOULD ALSO BE PERFORMED FOR CONRMATION OF SARS -COV-2 INFECTION.,DIAGNOS THROMBO 1.0(DIAGNOS THROMBO 1.0)-DIAGNOS THROMBO 1.0 IS A THROMBOPLASTIN REAGENT FOR USE IN THE IN VITRO TESTING OF PROTHROMBIN TIME BY PHOTO-OPTICAL OR MECHANICAL CLOT DETECTION SYSTEM. ,HEPACARD(HEPACARD) -HEPACARD IS A RAPID, VISUAL, SENSITIVE AND ACCURATE ONE STEP IMMUNOASSAY FOR THE QUANTITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OR PLASMA.,DIAGNOS APTT(DIAGNOS APTT)-DIAGNOS APTT IS A READY TO USE ACTIVATED CEPHALOPLASTIN REAGENT FOR USE IN THE IN VITRO TESTING OF ACTIVATED PARTIAL THROMBOPLASTIN TIME BY MECHANICAL CLOT DETECTION SYSTEM.,HIV TRI -DOT(HIV TRI- DOT)-RAPID VISUAL TEST FOR THE DETECTION OF HIV-1 & HIV-2 ANTIBODIES (IGG) IN HUMAN SERUM OR PLASMA

2773	MFG/IVD/2019/000021	1.License Holder Name: SENSA CORE MEDICAL INSTRUMENTATION PVT. LTD. 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:ELECTROLYTE ANLAYZER HCO3-SENSACORE'S ELECTROLYTE ANALYZER HCO3 REAGENT PACK IS INTENDED FOR IN - VITRO QUANTITATIVE MEASUREMENT OF VARIOUS COMBINATIONS OF SODIUM, POTASSIUM, IONIZED CALCIUM, LITHIUM, PH, CHLORIDE AND BICARBONATE IN WHOLE BLOOD, SERUM, CSF, PLASMA, AND URINE. THESE REAGENT PACKS ARE USED WITH ELECTROLYTE ANALYZER HCO3 INSTRUMENTS MANUFACTURED BY SENSACORE AND ARE INTENDED FOR CLINICAL LABORATORY USE ONLY.,ELECTROLYTE ANALYZER-ELECTROLYTE ANALYZER IN COMBINATION WITH A REAGENT PACK IS INTENDED FOR IN – VITRO QUANTITATIVE MEASUREMENT OF VARIOUS COMBINATIONS OF SODIUM, POTASSIUM, IONIZED CALCIUM, LITHIUM, PH AND CHLORIDE IN WHOLE BLOOD, SERUM, CSF, PLASMA, AND URINE. THESE REAGENT PACKS ARE USED WITH ELECTROLYTE ANALYZER INSTRUMENTS MANUFACTURED BY SENSACORE AND ARE INTENDED FOR CLINICAL LABORATORY USE ONLY.

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2774	MFG/IVD/2019/000022	1.License Holder Name: ASRITHA DIATECH INDIA PRIVATED LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:CARBON DIOXIDE (CO2) TEST REAGENTS/KITS-CARBON DIOXIDE (CO2) TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CARBON DIOXIDE (CO2) IN SERUM/PLASMA/WHOLE BLOOD,MICROALBUMIN CALIBRATOR/CONTROL(MICROALBUMIN CALIBRATOR/CONTROL)-MICROALBUMIN CALIBRATOR/ CONTROL IS AN IN VITRO DIAGNOSTIC DEVICE INTENDED TO BE USED WITH MICROALBUMIN REAGENT FOR ESTIMATION OF MICROALBUMIN IN URINE.,CALIBRATOR/ STANDARD FOR IN VITRO TEST REAGENTS/KITS-CALIBRATORS/ STANDARDS FOR ALL IN VITRO MEDICAL DEVICES,CRP CALIBRATOR/CONTROL (CRP CALIBRATOR/CONTROL)-CRP CALIBRATOR/ CONTROL IS IN VITRO DIAGNOSTIC DEVICE INTENDED TO BE USED WITH CRP LATEX REAGENT FOR SCREENING OF CRP IN HUMAN SPECIMEN. IT IS INTENDED FOR IN VITRO DIAGNOSTICS USE BY TRAINED HEALTHCARE PROFESSIONALS IN IVD LABORATORY ONLY AND NOT NEAR PATIENT.,IRON BINDING CAPACITY TEST REAGENTS/KITS-IRON-BINDING CAPACITY TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF IRON-BINDING CAPACITY IN SERUM OR PLASMA.,CHOLINESTERASE TEST REAGENTS/KITS-CHOLINESTERASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHOLINESTERASE IN SERUM OR PLASMA,LIPASE TEST REAGENTS/KITS-LIPASE TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF LIPASE TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF LIPASE IN SERUM OR PLASMA.,GAMMA GLUTAMYL TRANSFERASE (GGT) AND ISOZYMES TEST REAGENTS/KITS-GAMMA GLUTAMYL TRANSFERASE (GGT) AND ISOZYMES TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF GAMMA GLUTAMYL TRANSFERASE (GGT) AND ISOZYMES IN SERUM/PLASMA., CREATININE KINASE (CK NAC) OR CK MB TEST REAGENTS/KITS-CREATINE PHOSPHOKINASE OR CREATINE KINASE OR IT ISOZYMES INCLUDING CKMB, CKBB TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME CREATINE PHOSPHOKINASE OR CREATINE KINASE OR CK MB AND ITS ISOZYMES IN SERUM OR PLASMA ,ASO CALIBRATOR/CONTROL(ASO CALIBRATOR/CONTROL)-ASO CALIBRATOR/ CONTROL IS IN VITRO DIAGNOSTIC DEVICE INTENDED TO BE USED WITH ASO LATEX REAGENT FOR SCREENING OF ASO IN HUMAN SPECIMEN. IT IS INTENDED FOR IN VITRO DIAGNOSTICS USE BY TRAINED HEALTHCARE PROFESSIONALS IN IVD LABORATORY ONLY.,TOTAL PROTEIN TEST REAGENTS/KITS-TOTAL PROTEIN TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE

	ESTIMATION OF TOTAL PROTEIN (S) IN SERUM OR PLASMA., CREATININE TEST REAGENTS/KITS-CREATININE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CREATININE IN SERUM/PLASMA OR URINE.,GLYCOSYLATED HEMOGLOBIN TEST REAGENTS/KITS-GLYCOSYLATED HEMOGLOBIN OR ITS VARIANTS TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF GLYCOSYLATED HEMOGLOBIN OR ITS VARIANTS INCLUDING A1A, A1B, AND A1C IN WHOLE BLOOD, CHOLESTEROL (TOTAL) TEST REAGENTS/KITS-CHOLESTEROL (TOTAL)TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TOTAL CHOLESTEROL IN SERUM OR PLASMA, -AMYLASE TEST REAGENTS/ KITS-AMYLASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF AMYLASE IN SERUM/SALIVA.,ALKALINE PHOSPHATASE TEST REAGENTS/ KITS-ALKALINE PHOSPHATASE OR ISOZYME TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALKALINE PHOSPHATASE OR IT ISOZYME IN SERUM/PLASMA,URIC ACID TEST REAGENTS/KITS-URIC ACID TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF URIC ACID IN SERUM/PLASMA.,DENGUE ANTIBODY TEST REAGENTS/KITS-DENGUE ANTIBODY TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF DENGUE ANTIBODY IN BLOOD/ BODY FLUIDS, HUMAN CHORIONIC GONADOTROPIN (HCG) TEST REAGENTS/KITS-A HUMAN CHORIONIC GONADOTROPIN (HCG) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE PRELIMINARY SELF-TESTING OF HCG IN URINE OR BODY FLUIDS,MICRO ALBUMIN TEST REAGENTS/KITS-MICRO-ALBUMIN TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF MICRO-ALBUMIN IN URINE.,DILUENT REAGENTS/KITS-A BLOOD CELL DILUENT IS A MEDICAL DEVICE USED TO DILUTE BLOOD FOR FURTHER TESTING, SUCH AS COMPLETE BLOOD COUNT (CBC).,HOMOCYSTEIN TEST REAGENTS/KITS-HOMOCYSTEIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HOMOCYSTEIN IN BLOOD/BODY FLUIDS,CLEANSER REAGENTS/KITS-CLEANSER REAGENT/KITS IS A MEDICAL DEVICE USED FOR CLEANING VARIOUS PARTS OF HEMATOLOGY ANALYZERS LIKE PROBES, NEEDLES, BATHS, TUBING ETC.,GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PDH) TEST REAGENTS/KITS-GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PDH) TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PDH) IN SERUM/PLASMA.,IRON TEST REAGENTS/KITS-IRON TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF IRON IN SERUM/PLASMA.,RF (RHEUMATOID FACTOR) IMMUNOLOGICAL TEST REAGENTS/KITS-RF –

	RHEUMATOID FACTOR TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR NEAR PATIENT TESTING IS A MEDICAL DEVICE FOR THE SCREENING OF RF- RHEUMATOID FACTOR IN HUMAN SPECIMEN, ASO (A-STREPTOLYSIN O) IMMUNOLOGICAL TEST REAGENTS/KITS-ASO – A -STREPTOLYSIN O TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR NEAR PATIENT TESTING IS A MEDICAL DEVICE FOR THE SCREENING OF A- STREPTOLYSIN O IN HUMAN SPECIMEN, SODIUM TEST REAGENTS/KITS-SODIUM TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF SODIUM IN SERUM, PLASMA.,ALANINE AMINO TRANSFERASE (ALT/SGPT) TEST REAGENTS/KITS-ALANINE AMINO TRANSFERASE (ALT/SGPT) TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALANINE AMINO TRANSFERASE (ALT/SGPT) IN SERUM OR PLASMA.,ASPARTATE AMINO TRANSFERASE (AST/SGOT) TEST REAGENTS/KITS-ASPARTATE AMINO TRANSFERASE (AST/SGOT) TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ASPARTATE AMINO TRANSFERASE (AST/SGOT) IN SERUM OR PLASMA.,FERRITIN TEST REAGENTS/KITS-FERRITIN TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF FERRITIN IN SERUM OR PLASMA.,MAGNESIUM TEST REAGENTS/KITS-MAGNESIUM TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF MAGNESIUM IN SERUM OR PLASMA.,HEMOGLOBIN TEST REAGENTS/KITS-HEMOGLOBIN TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HEMOGLOBIN IN WHOLE BLOOD,GLUCOSE TEST REAGENTS/KITS-GLUCOSE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF GLUCOSE IN SERUM/PLASMA/BLOOD/BODY FLUIDS,LIPOPROTEIN (A) TEST REAGENTS/KITS-LIPOPROTEIN (A) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF LIPOPROTEIN (A) IN SERUM OR PLASMA,LDL CHOLESTEROL TEST REAGENTS/KITS-LDL CHOLESTEROL TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF LDL CHOLESTEROL IN SERUM OR PLASMA, LACTATE DEHYDROGENASE (LDH) TEST REAGENTS/KITS-LACTATE DEHYDROGENASE (LDH) TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME LACTATE DEHYDROGENASE (LDH) AND ITS ISOZYMES IN SERUM OR PLASMA., ALBUMIN TEST REAGENTS/KITS-AN ALBUMIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALBUMIN IN SERUM/PLASMA.,HDL CHOLESTEROL TEST REAGENTS/KITS-HDL CHOLESTEROL TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HDL CHOLESTEROL IN SERUM OR PLASMA, CHLORIDE TEST REAGENTS/KITS-CHLORIDE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHLORIDE IN

	PLASMA/SERUM,BILIRUBIN (TOTAL & DIRECT) TEST REAGENTS/KITS-BILIRUBIN (TOTAL & DIRECT) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF BILIRUBIN (TOTAL & DIRECT) IN SERUM/PLASMA,CALCIUM TEST REAGENTS/KITS-CALCIUM TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TOTAL CALCIUM IN SERUM.,POTASSIUM TEST REAGENTS/KITS-POTASSIUM TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF POTASSIUM IN SERUM, PLASMA.,AMMONIA TEST REAGENTS/KITS-AMMONIA TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF AMMONIA IN BLOOD/SERUM/PLASMA.,ADA-ADENOSINE DEAMINASE TEST REAGENTS/KITS-ADA- ADENOSINE DEAMINASE TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ADA- ADENOSINE DEAMINASE IN SERUM/PLASMA.,UREA TEST REAGENTS/KITS-UREA TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF UREA/ BLOOD UREA NITROGEN (BUN) IN SERUM OR PLASMA.,LDL CALIBRATOR/ CONTROL(LDL CALIBRATOR/ CONTROL) -LDL CALIBRATOR/ CONTROL IS AN IN VITRO DIAGNOSTIC DEVICE INTENDED TO BE USED WITH LDL REAGENT FOR ESTIMATION OF LDL CHOLESTEROL IN SERUM OR PLASMA.,RF CALIBRATOR/ CONTROL (RF CALIBRATOR/ CONTROL)-RF CALIBRATOR/ CONTROL IS IN VITRO DIAGNOSTIC DEVICE INTENDED TO BE USED WITH RF LATEX REAGENT FOR SCREENING OF RF IN HUMAN SPECIMEN. IT IS INTENDED FOR IN VITRO DIAGNOSTICS USE BY TRAINED HEALTHCARE PROFESSIONALS IN IVD LABORATORY ONLY.,MICRO-PROTEIN TEST REAGENTS/KITS-MICRO-PROTEIN TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF MICRO-PROTEIN IN URINE.,HDL CALIBRATOR/ CONTROL(HDL CALIBRATOR/ CONTROL)-HDL CALIBRATOR/ CONTROL IS AN IN VITRO DIAGNOSTIC DEVICE INTENDED TO BE USED WITH HDL REAGENT FOR ESTIMATION OF HDL CHOLESTEROL IN SERUM OR PLASMA.,PHOSPHORUS (INORGANIC) TEST REAGENTS/KITS-PHOSPHORUS (INORGANIC) TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF PHOSPHORUS (INORGANIC)IN SERUM, PLASMA OR URINE., TRIGLYCERIDES TEST REAGENTS/KITS-TRIGLYCERIDES TEST REAGENT/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TRIGLYCERIDES IN SERUM OR PLASMA.,CRP (C-REACTIVE PROTEIN) TEST REAGENTS/KITS(CRP (C- REACTIVE PROTEIN))-CRP IS IN VITRO DIAGNOSTIC MEDICAL DEVICE REAGENTS/ KITS FOR THE DETECTION AND SCREENING OF C-REACTIVE PROTEIN LEVELS IN VARIOUS CONDITIONS INCLUDING AUTOIMMUNE DISORDER IN HUMAN SPECIMEN. IT IS INTENDED FOR

		IN VITRO DIAGNOSTICS USE BY TRAINED HEALTHCARE PROFESSIONALS IN IVD LABORATORY ONLY AND NOT NEAR PATIENT.,LYSE REAGENTS/KITS-LYSE REAGENT/KITS IS A MEDICAL DEVICE USED FOR LYSING OF CELLS FOR THE ESTIMATION OF COMPLETE BLOOD COUNT (CBC),LUTEINIZING HORMONE TEST REAGENTS/KITS-A LUTEINIZING HORMONE (LH) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE PRELIMINARY SELF-TESTING OF LUTEINIZING HORMONE (LH) IN URINE/BODY FLUIDS , TYPHOID ANTIBODY TEST REAGENTS/KITS-TYPHOID ANTIBODY TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF TYPHOID ANTIBODY IN BLOOD/ BODY FLUIDS
2775	MFG/IVD/2019/000023	1.License Holder Name: QUALPRO DIAGNOSTICS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:CHEMILUMINESCENCE ASSAY FOR QUANTITATIVE DETERMINATION OF TOTAL 25-OH VITAMIN D IN HUMAN SERUM(CHEMI-D 25-OH VITAMIN D CLIA)-CHEMI-D 25-OH VITAMIN D CLIA TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25-HYDROXY (25-OH) VITAMIN D IN HUMAN SERUM,25-OH VITAMIN D ELISA(MICRO-D)-THE PRODUCT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM AND IS BASED ON THE ENZYME LINKED IMMUNOSORBENT ASSAY ALSO KNOWN AS ELISA
2776	MFG/IVD/2019/000024	1.License Holder Name: TOSOH INDIA PVT. LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:AIA-PACK DILUENT CONCENTRATE-THE AIA-PACK DILUENT CONCENTRATE IS INTENDED FOR USE IN VITRO DIAGNOSTIC USE ONLY FOR THE AIA-PACK OR THE ST-AIA PACK ASSAY,AIA-PACK WASH CONCENTRATE-THE AIA-PACK WASH CONCENTRATE IS INTENDED FOR USE IN VITRO DIAGNOSTIC USE ONLY FOR THE AIA-PACK OR THE ST-AIA PACK ASSAY,HSI HEMOLYSIS & WASH SOLUTION (L)-HEMOLYSIS & WASH SOLUTION ARE DESIGNED FOR EXCLUSIVE USE WITH THE TOSOH AUTOMATED GLYCOHEMOGLOBIN ANALYZER HLC-723 SERIES.

2777	MFG/IVD/2019/000025	1.License Holder Name: ARKRAY HEALTHCARE PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:FLOW THROUGH ANTI-HIV SPOT/IMMUNODOT TEST KIT(SIGNAL HIV 3D VER. 1.0)-SIGNAL HIV 3D VER. 1.0 – FLOWTHROUGH ANTI-HIV SPOT/IMMUNODOT TEST KIT IS AN IN VITRO QUALITATIVE SCREENING TEST FOR DIAGNOSIS OF HIV-1 (INCLUDING GROUP O) AND HIV-2 INFECTION USING HUMAN SERUM OR PLASMA. THIS ASSAY IS INTENDED FOR USE BY SKILLED HEALTH CARE WORKERS / LABORATORY PROFESSIONALS, FOR AN INITIAL SCREENING ONLY. REACTIVE SAMPLES SHOULD BE CONFIRMED BY A CONFIRMATORY ASSAY. ,RAPID TEST FOR P. FALCIPARUM MALARIA - DIPSTICK(PARAHIT F VER. 1.0)-PARAHIT F VER. 1.0 - RAPID TEST FOR P. FALCIPARUM MALARIA PROVIDES A SIMPLE, RAPID AND AN IN VITRO QUALITATIVE SCREENING TEST FOR THE DETECTION OF PLASMODIUM FALCIPARUM SPECIFIC HRP-II (HISTIDINE-RICH PROTEIN II) IN HUMAN BLOOD. IT DOES NOT REQUIRE ADDITIONAL INSTRUMENT. THE ASSAY IS INTENDED FOR USE BY HEALTH CARE WORKERS / LABORATORY PROFESSIONALS, ONLY FOR AN INITIAL SCREENING. THE ASSAY IS TO BE USED IN THE DIAGNOSIS OF MALARIA IN SYMPTOMATIC PATIENTS. THIS TEST KIT IS STANDARDIZED TO WITHSTAND TROPICAL CONDITIONS. ,ELLAGIC ACID ACTIVATED REAGENT FOR PARTIAL THROMBOPLASTIN TIME (THROMBOSPAN LS APTT - EA)-FOR IN VITRO DETERMINATION OF PARTIAL THROMBOPLASTIN TIME IN HUMAN PLASMA,RAPID TEST FOR P. FALCIPARUM AND PAN MALARIAL SPECIES-DEVICE(PARAHIT TOTAL VER. 1.0)-THE PARAHIT TOTAL VER. 1.0 - RAPID TEST FOR P. FALCIPARUM AND PAN MALARIAL SPECIES PROVIDES A SIMPLE, RAPID AND IN VITRO QUALITATIVE SCREENING TEST FOR DETECTION OF ALL FOUR SPECIES OF PLASMODIUM GENUS THAT CAUSE MALARIA IN HUMANS, VIZ. PLASMODIUM FALCIPARUM, PLASMODIUM VIVAX, PLASMODIUM OVALE AND PLASMODIUM MALARIAE. THE TEST IS INTENDED FOR USE WITH WHOLE BLOOD AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. THE ASSAY IS INTENDED FOR USE BY HEALTH CARE WORKERS / LABORATORY PROFESSIONALS, FOR AN INITIAL SCREENING OF MALARIA IN SYMPTOMATIC PATIENTS. , BLOOD GLUCOSE METER(GLUCOCARD G+)-FOR QUANTITATIVELY MEASURING THE GLUCOSE LEVEL IN FRESH CAPILLARY WHOLE BLOOD,RAPID IMMUNOCHROMATOGRAPHIC TEST FOR DETECTION OF ANTIBODIES AGAINST SYPHILIS - DIPSTICK(CRYSTAL TP+)-CRYSTAL® TP+- RAPID IMMUNOCHROMATOGRAPHIC TEST FOR DETECTION OF ANTIBODIES AGAINST SYPHILIS IS A SIMPLE, RAPID AN IN VITRO QUALITATIVE SCREENING TEST TO DIAGNOSE SYPHILIS USING HUMAN SERUM / PLASMA / WHOLE BLOOD. THE TEST DOES

	NOT REQUIRE ANY ADDITIONAL INSTRUMENT. THE ASSAY IS INTENDED FOR USE BY HEALTH CARE WORKERS / LABORATORY PROFESSIONALS, ONLY FOR AN INITIAL SCREENING. REACTIVE SAMPLES SHOULD BE CONFIRMED BY A CONFIRMATORY ASSAY., BLOOD GLUCOSE TEST METER(GLUCOCARD SIGMA)-FOR QUANTITATIVELY MEASURING THE GLUCOSE LEVEL IN FRESH CAPILLARY WHOLE BLOOD,ANTI-D (RH0) MONOCLONAL IGG (SPANCLONE)-SPANCLONE ANTI-D (RH0) MONOCLONAL IGG ANTIBODY(ANTISERUM) IS AN AGGLUTINATING ANTISERUM FOR DETECTION OF D(RH0) ANTIGEN, WEAK D(D0) AND PARTIAL D (DVI) ANTIGENS ON HUMAN RED BLOOD CELLS. ,BLOOD GLUCOSE METER WITH BLUETOOTH(GLUCOCARD G+ LINK)-FOR QUANTITATIVELY MEASURING THE GLUCOSE LEVEL IN FRESH CAPILLARY WHOLE BLOOD,ANTI-D (RH0) MONOCLONAL - IGM(SPANCLONE)-SPANCLONE ANTI-D (RHO) MONOCLONAL IGM ANTIBODY (ANTISERUM) IS AN AGGLUTINATING ANTISERUM FOR DETECTION OF D (RHO) ANTIGEN ON HUMAN RED BLOOD CELLS,ANTI-A+B+D (RHO) MONOCLONAL (SPANCLONE)-MONOCLONAL AGGLUTINATING ANTIBODIES (ANTISERA) FOR THE DETERMINATION OF HUMAN BLOOD GROUP (ABO) AND ANTI-D (RH0) MONOCLONAL IGM ANTIBODY (ANTISERUM) IS AN AGGLUTINATING ANTISERUM FOR DETECTION OF D (RH0) ANTIGEN ON HUMAN RED BLOOD CELLS. IT IS INTENDED FOR ROUTINE BLOOD GROUPING TEST PROCEDURES AND SCREENING OF BLOOD DONORS.,ANTI-D (RH0) MONOCLONAL IGG+IGM(SPANCLONE) -SPANCLONE ANTI-D (RH0) MONOCLONAL IGG+IGM ANTIBODIES ARE SPECIFICALLY DESIGNED TO DETECT WEAK D (DU) AND PARTIAL D (DVI) ANTIGENS PRESENT ON HUMAN RED BLOOD CELLS WHICH ARE NOT DETECTED BY ANTI-D (RH0) MONOCLONAL IGM ALONE. ,ANTI A1 LECTIN-FOR IN VITRO DETECTION OF A1 ANTIGEN (SUBGROUP OF A) ON HUMAN RED BLOOD CELLS.,FLOW THROUGH HIV 1+2 SPOT / IMMUNODOT TEST KIT - FOR NACO(SIGNAL HIV)-SIGNAL® HIV - FLOW THROUGH HIV 1+2 SPOT / IMMUNODOT TEST KIT IS A SIMPLE, RAPID & AN IN VITRO QUALITATIVE SCREENING TEST FOR THE DETECTION OF ANTIBODIES TO HIV-1 AND / OR HIV-2 USING HUMAN SERUM OR PLASMA TO DIAGNOSE HIV INFECTION. THE TEST DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT.,ANTI HUMAN SERUM (POLY SPECIFIC) : COOMB'S SERUM READY TO USE-IN VITRO DIAGNOSTIC SERUM FOR PERFORMING DIRECT & INDIRECT ANTIGLOBULIN TEST,IMMUNOCHROMATOGRAPHIC ONE STEP RAPID VISUAL TEST FOR HEPATITIS-B SURFACE ANTIGEN - DIPSTICK (CRYSTAL HBSAG)-: CRYSTAL® HBSAG - IMMUNOCHROMATOGRAPHIC ONE STEP RAPID VISUAL TEST FOR HEPATITIS-B SURFACE ANTIGEN - DIPSTICK IS AN IN VITRO QUALITATIVE SCREENING TEST TO DIAGNOSE HEPATITIS B USING

	HUMAN SERUM OR PLASMA. IT IS INTENDED FOR SCREENING OF BLOOD DONORS AND INDIVIDUALS SUSPECTED OF HEPATITIS B VIRUS INFECTION. ,RAPID TEST FOR P. FALCIPARUM AND PAN MALARIAL SPECIES-DEVICE(PARAHIT TOTAL+)-THE PARAHIT TOTAL+ RAPID TEST FOR P. FALCIPARUM AND PAN MALARIAL SPECIES PROVIDES A SIMPLE, RAPID AND IN VITRO QUALITATIVE SCREENING TEST FOR DETECTION OF ALL FOUR SPECIES OF PLASMODIUM GENUS THAT CAUSE MALARIA IN HUMANS, VIZ. PLASMODIUM FALCIPARUM, PLASMODIUM VIVAX, PLASMODIUM OVALE AND PLASMODIUM MALARIAE. THE TEST IS INTENDED FOR USE WITH WHOLE BLOOD AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. THE ASSAY IS INTENDED FOR USE BY HEALTH CARE WORKERS/LABORATORY PROFESSIONALS, FOR AN INITIAL SCREENING OF MALARIA IN SYMPTOMATIC PATIENTS. ,HIV 1+2 IMMUNODOT TEST KIT(COMBAIDS RS ADVANTAGE)-COMBAIDS- RS ADVANTAGE-ST - HIV 1+2 IMMUNODOT TEST KIT IS AN IN VITRO SCREENING QUALITATIVE TEST TO DIAGNOSE HIV INFECTION USING WHOLE BLOOD, SERUM OR PLASMA. IT IS INTENDED FOR SCREENING OF BLOOD DONORS AND HIV SUSPECTED INDIVIDUALS.,FLOW THROUGH ANTI-HCV SPOT / IMMUNODOT TEST KIT(SIGNAL HCV VER. 3.0)-SIGNAL® HCV VER. 3.0 - FLOW THROUGH ANTI-HCV SPOT / IMMUNODOT TEST KIT IS SIMPLE, RAPID AND AN IN VITRO QUALITATIVE SCREENING TEST FOR DETECTION OF ANTIBODIES TO HEPATITIS C VIRUS (HCV) USING SAMPLES OF HUMAN SERUM OR PLASMA TO DIAGNOSE HCV INFECTION. THE TEST DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. THE ASSAY IS INTENDED FOR USE BY SKILLED HEALTH CARE WORKERS / LABORATORY PROFESSIONALS, FOR AN INITIAL SCREENING ONLY. REACTIVE SAMPLES SHOULD BE CONFIRMED BY A CONFIRMATORY ASSAY . , FLOW THROUGH HIV 1+2 SPOT / IMMUNODOT TEST KIT(SIGNAL HIV)-SIGNAL® HIV - FLOW THROUGH HIV 1+2 SPOT / IMMUNODOT TEST KIT IS A SIMPLE, RAPID & AN IN VITRO QUALITATIVE SCREENING TEST FOR THE DETECTION OF ANTIBODIES TO HIV-1 AND / OR HIV-2 USING HUMAN SERUM OR PLASMA TO DIAGNOSE HIV INFECTION. THE TEST DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT.,BOVINE SERUM ALBUMIN (22% SOLUTION)-BOVINE SERUM ALBUMIN (22 % SOLUTION) IS USED FOR IN VITRO DETECTION OF INCOMPLETE ANTIBODY.,IMMUNOCHROMATOGRAPHIC ONE STEP RAPID VISUAL TEST FOR HEPATITIS-B SURFACE ANTIGEN - DEVICE(CRYSTAL HBSAG)-CRYSTAL® HBSAG - IMMUNOCHROMATOGRAPHIC ONE STEP RAPID VISUAL TEST FOR HEPATITIS-B SURFACE ANTIGEN - DEVICE IS AN IN VITRO QUALITATIVE SCREENING TEST TO DIAGNOSE HEPATITIS-B USING HUMAN SERUM OR PLASMA. IT IS INTENDED FOR SCREENING OF BLOOD DONORS AND INDIVIDUALS SUSPECTED OF

	HEPATITIS B VIRUS INFECTION. ,HIV 1+2 IMMUNODOT TEST KIT (COMBAIDS RS ADVANTAGE ST)-COMBAIDS® - RS ADVANTAGE-ST - HIV 1+2 IMMUNODOT TEST KIT IS AN IN VITRO SCREENING QUALITATIVE TEST TO DIAGNOSE HIV INFECTION USING WHOLE BLOOD, SERUM OR PLASMA. IT IS INTENDED FOR SCREENING OF BLOOD DONORS AND HIV SUSPECTED INDIVIDUALS., IMMUNOCHROMATOGRAPHIC ONE STEP RAPID VISUAL TEST FOR VIBRIO CHOLERAE O1- DIPSTICK(CRYSTAL VC-O1)-CRYSTAL VC -O1- IS A SIMPLE, RAPID AND VISUAL IN VITRO QUALITATIVE SCREENING TEST FOR DETECTION OF LIPOPOLYSACCHARIDE (LPS) ANTIGEN OF VIBRIO CHOLERAE O1 IN HUMAN STOOL TO DIAGNOSE CHOLERA. THE TEST IS BASED ON THE PRINCIPLE OF LATERAL FLOW IMMUNOCHROMATOGRAPHY AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT FOR ITS PERFORMANCE. THIS TEST IS DESIGNED FOR RAPID DIAGNOSIS OF CHOLERA IN ENDEMIC OR EPIDEMIC AREAS. IT IS INTENDED FOR USE BY HEALTH CARE WORKERS IN FIELD CONDITIONS AS WELL AS IN THE LABORATORIES BY TRAINED TECHNICIANS. ,BRAIN THROMBOPLASTIN WITH CALCIUM REAGENT FOR PROTHROMBIN TIME(THROMBOSPAN LS PT)-FOR IN VITRO DETERMINATION OF PROTHROMBIN TIME (PT) IN HUMAN PLASMA. ,IMMUNOCHROMATOGRAPHIC ONE STEP RAPID VISUAL TEST FOR VIBRIO CHOLERAE – DIPSTICK(CRYSTAL VC)-CRYSTAL VC - IS A SIMPLE, RAPID AND VISUAL IN VITRO QUALITATIVE SCREENING TEST FOR DETECTION OF LIPOPOLYSACCHARIDE (LPS) ANTIGEN OF VIBRIO CHOLERAE O1 & O139 IN HUMAN STOOL TO DIAGNOSE CHOLERA. THE TEST IS BASED ON THE PRINCIPLE OF LATERAL FLOW IMMUNOCHROMATOGRAPHY AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT FOR ITS PERFORMANCE. THIS TEST IS DESIGNED FOR RAPID DIAGNOSIS OF CHOLERA IN ENDEMIC OR EPIDEMIC AREAS. ,HIV 1+2 ELISA TEST KIT(ENZAIDS)-ENZAIDS HIV 1+2 ELISA TEST KIT IS AN IN VITRO SCREENING QUALITATIVE TEST TO DIAGNOSE HIV INFECTION USING HUMAN SERUM OR PLASMA. IT IS INTENDED FOR SCREENING OF BLOOD DONORS AND HIV SUSPECTED INDIVIDUALS. THE ASSAY IS INTENDED FOR USE BY SKILLED HEALTH CARE WORKERS/LABORATORY PROFESSIONALS, FOR AN INITIAL SCREENING ONLY. REACTIVE SAMPLES SHOULD BE CONFIRMED BY A CONFIRMATORY ASSAY.,HBSAG (HEPATITIS-B) ELISA TEST KIT (MICROSCREEN)-MICROSCREEN HBSAG (HEPATITIS-B) ELISA TEST KIT IS AN IN VITRO QUALITATIVE TEST TO DIAGNOSE PRESENCE OF HEPATITIS B VIRUS SURFACE ANTIGEN IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR SCREENING OF BLOOD DONORS AND INDIVIDUALS SUSPECTED OF HEPATITIS B VIRUS INFECTION.,RAPID TEST FOR P. FALCIPARUM MALARIA - DEVICE(PARAHIT F VER. 1.0)-PARAHIT F VER. 1.0 - RAPID TEST FOR P. FALCIPARUM MALARIA

	PROVIDES A SIMPLE, RAPID AND AN IN VITRO QUALITATIVE SCREENING TEST FOR THE DETECTION OF PLASMODIUM FALCIPARUM SPECIFIC HRP II (HISTIDINE RICH PROTEIN II) IN HUMAN BLOOD. IT DOES NOT REQUIRE ADDITIONAL INSTRUMENT. THE ASSAY IS INTENDED FOR USE BY HEALTH CARE WORKERS / LABORATORY PROFESSIONALS, FOR AN INITIAL SCREENING FOR MALARIAL INFECTION IN SYMPTOMATIC PATIENTS , IMMUNOCHROMATOGRAPHIC ONE STEP RAPID VISUAL TEST FOR HIV 1 & 2 ANTIBODY IN HUMAN SERUM, PLASMA OR WHOLE BLOOD-DEVICE(CRYSTAL HIV-1/2)-CRYSTAL HIV-1/2 IS AN IN VITRO RAPID QUALITATIVE SCREENING TEST FOR DIAGNOSIS OF HIV-1 (INCLUDING GROUP O) AND HIV-2 INFECTION USING HUMAN SERUM, PLASMA OR WHOLE BLOOD.,RAPID TEST FOR P. FALCIPARUM AND PAN MALARIAL SPECIES-DIPSTICK(PARAHIT TOTAL VER. 1.0)-THE PARAHIT TOTAL VER. 1.0 - RAPID TEST FOR P. FALCIPARUM AND PAN MALARIAL SPECIES - DIPSTICK PROVIDES A SIMPLE, RAPID AND AN IN VITRO QUALITATIVE SCREENING TEST FOR DETECTION OF ALL FOUR SPECIES OF PLASMODIUM GENUS THAT CAUSE MALARIA IN HUMANS, VIZ. PLASMODIUM FALCIPARUM, PLASMODIUM VIVAX, PLASMODIUM OVALE AND PLASMODIUM MALARIAE. THE TEST IS INTENDED FOR USE WITH WHOLE BLOOD AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. THE ASSAY IS INTENDED FOR USE BY HEALTH CARE WORKERS / LABORATORY PROFESSIONALS, FOR AN INITIAL SCREENING OF MALARIA IN SYMPTOMATIC PATIENTS ,ANTI-AB MONOCLONAL(SPANCLONE)-MONOCLONAL AGGLUTINATING ANTIBODIES (ANTISERA) FOR THE DETERMINATION OF HUMAN BLOOD GROUP (ABO).,ANTI-B MONOCLONAL(SPANCLONE)-MONOCLONAL AGGLUTINATING ANTIBODIES (ANTISERA) FOR THE DETERMINATION OF HUMAN BLOOD GROUP (B).,ANTI-A MONOCLONAL(SPANCLONE)-MONOCLONAL AGGLUTINATING ANTIBODIES (ANTISERA) FOR THE DETERMINATION OF HUMAN BLOOD GROUP (A).

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2778	MFG/IVD/2019/000026	1.License Holder Name: NUCLEUS DIAGNOSYS LLP 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:SARS-COV-2-REAL TIME FLUORESCENT RT-PCR KIT-CORONAVIRUS BELONGS TO THE FAMILY OF CORONAVIRIDAE, IN THE ORDER OF NIDOVIRALES. IT IS FORMED BY A POSITIVE-SENSE SINGLE-STRANDED RNA, USUALLY APPEARS SPHERICAL WITH A SIZE OF 80-120NM AND WITH CROWN-LIKE SPIKES ON THE SURFACE. THIS LARGE FAMILY OF VIRUS IS COMMONLY CIRCULATING AMONG VERTEBRATES, SUCH AS CAMELS, CATS AND BATS. NOVEL CORONAVIRUS (COVID-19) HAS BEEN IDENTIFIED AS A NEW STRAIN OF CORONAVIRUS. IT CAN CAUSE VIRAL PNEUMONIA AND DYSPNEA IN HUMANS. THIS KIT IS DESIGNED TO DETECT COVID-19 USING REAL TIME PCR. THE RESULTS CAN BE USED TO ASSIST DIAGNOSIS OF PATIENTS WITH COVID-19 INFECTION, AND PROVIDE MOLECULAR DIAGNOSTIC BASIS FOR INFECTED PATIENTS,DIAGNOSTICS TEST REAGENT/ KITS FOR MALARIA PAN AND PF ANTIGENS-MALARIA PAN/PF REAGENT TEST/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF MALARIA ANTIGEN IN BLOOD/BODYFLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR TROPONIN I(NUVISION RAPID)-USE DETECTION OF CARDIAC TROPONIN I IN HUMAN WHOLE BLOOD, SERUM OR PLASMA, DIAGNOSTICS TEST REAGENT/KIT FOR HEPATITIS B VIRUS SURFACE ANTIGEN (HBSAG)-HEPATITIS B VIRUS SURFACE ANTIGEN (HBSAG) TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF HEPATITIS B VIRUS SURFACE ANTIGEN (HBSAG) IN BLOOD/BODY FLUIDS.,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING METHAMPHETAMINE DRUG LEVELS USED FOR THERAPY OR ABUSE-METHAMPHETAMINE (MET) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF METHAMPHETAMINE (MET) AND ITS METABOLITES IN SERUM/BODY FLUIDS,DIAGNOSTICS TEST REAGENT/ KITS FOR RUBELLA VIRUS-USED FOR THE DETECTION OF RUBELLA VIRUS IN HUMAN BLOOD/BODY FLUIDS,CORONAVIRUS 2019 (COVID-19) IGG/IGM RAPID TEST-NUVISION COVID-19 RAPID TEST IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE AND DIFFERENTIAL DETECTION OF IGG AND IGM ANTIBODIES IN HUMAN WHOLE BLOOD/SERUM/PLASMA SAMPLES. IT IS INTENDED FOR PROFESSIONAL USE AS A TOOL IN THE DIAGNOSIS OF RECENT OR PREVIOUS EXPOSURE TO COVID-19 VIRUS,DIAGNOSTICS TEST REAGENT/ KITS FOR RF, ASO AND CRP CALIBRATOR-USE DETECTION OF RF, ASO AND CRP IN HUMAN SERUM OR PLASMA,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING METHADONE DRUG LEVELS USED FOR THERAPY OR ABUSE.-METHADONE (MTD) TEST

	REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF METHADONE (MTD) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR TOXOPLASMA GONDII-USED FOR THE DETECTION OF TOXOPLASMA GONDII IN HUMAN BLOOD/BODY FLUIDS,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING METHAQUALONE DRUG LEVELS USED FOR THERAPY OR ABUSE.-METHAQUALONE (MQL) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF METHAQUALONE (MQL) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR TYPHOID ANTIGEN-TYPHOID ANTIGEN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF TYPHOID ANTIGENS IN BLOOD/BODY FLUIDS,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING OXYCODONE DRUG LEVELS USED FOR THERAPY OR ABUSE.-OXYCODONE (OXY) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF OXYCODONE (OXY) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR PROCALCITONIN (PCT)-PROCALCITONIN (PCT) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF PROCALCITONIN (PCT) IN SERUM/BODY FLUIDS.,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING BARBITURATES DRUG LEVELS USED FOR THERAPY OR ABUSE.-BARBITURATES (BAR) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF BARBITURATES (BAR) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR CYTOMEGALOVIRUS-USED FOR THE DETECTION OF CYTOMEGALOVIRUS IN HUMAN BLOOD/BODY FLUIDS,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING PHENCYCLIDINE DRUG LEVELS USED FOR THERAPY OR ABUSE.-PHENCYCLIDINE (PCP) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF PHENCYCLIDINE (PCP) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST FOR SYPHILIS RAPID TEST-SYPHILIS TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE SCREENING OF SYPHILIS IN BLOOD/BODY FLUIDS.,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING MORPHINE DRUG LEVELS USED FOR THERAPY OR ABUSE.-MORPHINE (MOP) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF MORPHINE (MOP) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR RF, ASO AND CRP CONTROL-USE DETECTION OF RF, ASO AND CRP IN HUMAN SERUM OR PLASMA,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING AMPHETAMINE DRUG LEVELS USED FOR THERAPY OR ABUSE-AMPHETAMINE (AMP) TEST REAGENT/KITS ARE THE

	MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF AMPHETAMINE (AMP) AND ITS METABOLITES IN SERUM/BODY FLUIDS,DIAGNOSTIC TEST FOR HEPATITIS C VIRUS (HCV) RAPID TEST-HCV TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF HCV IN BLOOD/BODY FLUIDS,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING BUPRENORPHINE DRUG LEVELS USED FOR THERAPY OR ABUSE-BUPRENORPHINE (BUP) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF BUPRENORPHINE (BUP) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR DENGUE NS1 ANTIGEN AND DENGUE IGG & IGM ANTIBODIES-DENGUE COMBO TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF DENGUE VIRUS ANTIGEN (NS1) AND ANTIBODIES AGAINST DENGUE VIRUS (IGG & IGM) IN BLOOD/BODY FLUIDS, DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING TRAMADOL DRUG LEVELS USED FOR THERAPY OR ABUSE.-TRAMADOL (TRA) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF TRAMADOL (TRA) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR MALARIA PV AND PF ANTIGENS-MALARIA PV/PF REAGENT TEST/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF MALARIA ANTIGEN IN BLOOD/BODYFLUIDS.,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING ECSTASY (3,4-METHYLENEDIOXYMETHAMPHETAMINE: MDMA) DRUG LEVELS USED FOR THERAPY OR ABUSE.-ECSTASY (MDMA) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF 3,4-METHYLENEDIOXYMETHAMPHETAMINE (MDMA) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR APTT-INTENDED FOR THE ESTIMATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME IN PLASMA/BODY FLUIDS.,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING FENTANYL DRUG LEVELS USED FOR THERAPY OR ABUSE.-FENATNYL (FEN) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF FENTANYL (FEN) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR ASO-USE FOR DETERMINATION OF ASO IN HUMAN SERUM,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING PROPOXYPHENE DRUG LEVELS USED FOR THERAPY OR ABUSE.-PROPOXYPHENE (PPX) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF PROPOXYPHENE (PPX) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR PT-INTENDED FOR THE ESTIMATION OF PROTHROMBIN TIME IN PLASMA/BODY FLUIDS.,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING TRICYCILIC ANTIDEPRESSANTS DRUG LEVELS USED

	FOR THERAPY OR ABUSE.-TRICYCILIC ANTIDEPRESSANTS (TCA) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF TRICYCILIC ANTIDEPRESSANTS (TCA) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR ANTISTREPTOLYSIN O (ASO) CONTROL-USE DETECTION OF ANTISTREPTOLYSIN O (ASO) IN HUMAN SERUM OR PLASMA,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING BENZODIAZEPINE DRUG LEVELS USED FOR THERAPY OR ABUSE.-BENZODIAZEPINE (BZO) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF BENZODIAZEPINE (BZO) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR HERPES SIMPLEX VIRUS-USED FOR THE DETECTION OF HERPES SIMPLEX VIRUS IN HUMAN BLOOD/BODY FLUIDS,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING OPIATES DRUG LEVELS USED FOR THERAPY OR ABUSE.-OPIATES (OPT) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF OPIATES (OPT) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR PROSTATE SPECIFIC ANTIGEN (PSA)-PROSTATE SPECIFIC ANTIGEN (PSA) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF PROSTATE SPECIFIC ANTIGEN (PSA) IN SERUM/BODY FLUIDS,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING COCAINE DRUG LEVELS USED FOR THERAPY OR ABUSE.-COCAINE (COC) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF COCAINE (COC) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR DENGUE NS1 ANTIGEN-DENGUE NS1 ANTIGEN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF DENGUE VIRUS ANTIGEN (NS1) IN BLOOD/BODY FLUIDS,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING MARIJUANA (CANNABINOIDS) DRUG LEVELS USED FOR THERAPY OR ABUSE.-MARIJUANA (THC) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF MARIJUANA (THC: -9 TETRAHYDROCANNABINOL) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTICS TEST REAGENT/ KITS FOR ANTISTREPTOLYSIN O (ASO) CALIBRATOR-USE DETECTION OF ANTISTREPTOLYSIN O (ASO) IN HUMAN SERUM OR PLASMA,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING KETAMINE DRUG LEVELS USED FOR THERAPY OR ABUSE.-KETAMINE (KET) TEST REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF KETAMINE (KET) AND ITS METABOLITES IN SERUM/BODY FLUIDS.,DIAGNOSTIC TESTS/REAGENTS/KITS FOR MONITORING METHADONE METABOLITES DRUG LEVELS USED FOR THERAPY OR ABUSE.-METHADONE METABOLITES (EDDP) TEST

	REAGENT/KITS ARE THE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF METHADONE METABOLITES: 2-ETHYLIDINE-1,5-DIMETHYL-3,3-DIPHENYLPYRROLIDINE (EDDP) AND ITS METABOLITES IN SERUM/BODY FLUIDS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2779	MFG/IVD/2019/000027	1.License Holder Name: ZEPHYR BIOMEDICALS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:RAPID TEST FOR DETECTION OF TOTAL SERUM BILIRUBIN(TSB CHEK)-THE SYSTEM IS INTENDED FOR USE IN HOSPITALS, CLINICS, DOCTOR'S OFFICES OR FAMILY COUNSELING UNDER A PHYSICIAN SUPERVISION/ DIRECTION TO ASSIST CLINICIANS IN MONITORING THE BILIRUBIN LEVELS IN THE BLOOD,CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE HORMONE IN HUMAN SERUM OR PLASMA(ELECTRA FT4)-CHEMILUMINESCENCE IMMUNOASSAY (CLIA) DETECTION USING MICROPLATE LUMINOMETERS PROVIDES A SENSITIVE, HIGH TRHOUGHPUT, AND ECONOMICAL ALTERNATIVE TO CONVENTIONAL COLORIMETRIC METHODOLOGICAL, SUCH AS ENZYME LINKED IMMUNOSORBENT ASSAYS (ELISA),RAPID TEST FOR DETECTION OF TOTAL SERUM BILIRUBIN.(BABYSAFE TSB)-THE SYSTEM IS INTENDED FOR USE IN HOSPITALS, CLINICS, DOCTOR'S OFFICES OR FAMILY COUNSELING UNDER A PHYSICIAN SUPERVISION/ DIRECTION TO ASSIST CLINICIANS IN MONITORING THE BILIRUBIN LEVELS IN THE BLOOD,CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF BETA HUMAN CHORIONIC GONADOTROPIN IN HUMAN SERUM OR PLASMA (ELECTRA BETA HCG)-THE BETA HCG CHEMILUMINESCENCE ENZYME IMMUNOASSAY KIT IS MAINLY INTENDED TO QUANTITATIVELY DETERMINE TOTAL BETA-HCG CONCENTRATION IN HUMAN SERUM., RAPID TEST FOR DETECTION OF HUMAN THYROID STIMULATING HORMONE (TSH) IN HUMAN WHOLE BLOOD(TSH CHEK)-THIS TEST KIT IS AN IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN WHOLE BLOOD.,CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE IN HUMAN SERUM OR PLASMA(ELECTRA FSH)-CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE-STIMULATING HORMONE (FSH) CONCENTRATIONS N HUMAN SERUM.,CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO RUBELLA IN HUMAN SERUM(ELECTRA RUBELLA IGG)-ELECTRA RUBELLA IGG CLIA TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO RUBELLA IN HUMAN SERUM.,CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE IN HUMAN SERUM OR PLASMA(ELECTRA LH)-CHEMILUMINESCENCE ENZME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF LUTEININZING HORMONE (LH) IN HUMAN SERUM OR PLASMA,

	ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF IGG ANTIBODIES TO RUBELLA IN HUMAN SERUM OR PLASMA(QUALISA RUBELLA IGG)-QUALISA RUBELLA IGG TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODY TO THE RUBELLA VIRUS.,CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN HORMONE IN HUMAN SERUM OR PLASMA(ELECTRA PRL) -CHEMILUMINESCENCE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETETMINATION OF PROLACTIN HORMONE IN HUMAN SERUM OR PLASMA.,ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF IGM ANTIBODIES TO RUBELLA IN HUMAN SERUM OR PLASMA (QUALISA RUBELLA IGM)-QUALISA RUBELLA IGM TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGM ANTIBODY TO THE RUBELLA VIRUS., CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) HORMONE IN HUMAN SERUM OR PLASMA(ELECTRA T3)-CHEMILUMINESCENCE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) IN HUMAN SERUM,RAPID TEST FOR GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD) DEFICIENCY IN HUMAN WHOLE BLOOD.(BABYSAFE G6PD)-THIS TEST KIT IS AN IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF GLUCOSE-6-DEHYDOGENASE DEFICIENCY IN HUMAN WHOLE BLOOD.,CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF TETRAIODOTHYRONINE (T4) HORMONE IN HUMAN SERUM OR PLASMA(ELECTRA T4)-CHEMILUMINESCENCE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TETRAIODOTHYRONINE (T4) IN HUMAN SERUM OR PLASMA,CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF HUMAN INSULIN IN HUMAN SERUM(ELECTRA INSULIN)-ELECTRA INSULIN CLIA TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN INSULIN IN HUMAN SERUM. ,ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM(QUALISA FERRITIN)-QUALISA FERRITIN SANDWICH ELISA TEST KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN CONCENTRATION IN HUMAN SERUM.,CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) IN HUMAN SERUM(ELECTRA IGE)-ELECTRA IGE TEST KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION IGE IN HUMAN SERUM.,RAPID TEST FOR GLUCOSE-6-PHOSPHATE DEHYDROGENASE DEFICIENCY IN HUMAN WHOLE BLOOD(G6CHEK)-THIS TEST IS A RAPID, QUALITATIVE, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE SIMULTANEOUS DETECTION OF GLUCOSE-6-

	DEHYDROGENASE DEFICIENCY IN HUMAN WHOLE BLOOD.,RAPID TEST FOR DETECTION OF IGG AND IGM ANTIBODIES TO S.TYPHI (DEVICE)(ENTEROSCREEN (DEVICE))-RAPID TEST FOR DETECTION OF IGG AND IGM ANTIBODIES TO S.TYPHI (DEVICE),CHEMILUMINESCENCE ASSAY FOR QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM(ELECTRA FT3)-ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM,ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM OR PLASMA(QUALISA CMV IGG)-QUALISA CMV IGG TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM OR PLASMA, CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM OR PLASMA(ELECTRA TSH)-CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM OR PLASMA,CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM(ELECTRA CMV IGG)-ELECTRA CMV IGG CLIA TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM,ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM(QUALISA TESTOSTERONE)-QUALISA TESTOSTERONE SANDWICH ELISA TEST KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM.,RAPID TEST FOR DETECTION OF IGM ANTIBODIES TO S.TYPHI (DEVICE)(ENTEROCHECK-WB (DEVICE))-RAPID TEST FOR DETECTION OF IGM ANTIBODIES TO S.TYPHI (DEVICE),ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) CONCENTRATION IN HUMAN SERUM(QUALISA IMMUNOGLOBULIN E (IGE))-QUALISA IGE SANDWICH ELISA TEST KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION IGE IN HUMAN SERUM.,RAPID TEST FOR DETECTION OF ANTIBODIES TO H.PYLORI (DEVICE) (HELICOCHECK (DEVICE))-HELICOCHECK IS A RAPID, SELF PERFORMING, DOUBLE ANTIGEN SANDWICH IMMUNO-ASSAY FOR THE DETECTION OF ANTIBODIES TO HELICOBACTER PYLORI IN HUMAN SERUM OR PLASMA.,CHEMILUMINESCENCE ASSAY FOR QUALITATIVE DETECTION OF ANTI DSDNA ANTIBODIES IN HUMAN SERUM(ELECTRA ANTI DS-DNA)-CHEMILUMINESCENCE ASSAY FOR QUANLLITATIVE DETECTION OF ANTI DSDNA ANTIBODIES IN HUMAN SERUM,RAPID TEST FOR V. LEISHMANIASIS (DEVICE)(LEISHCHECK

	(DEVICE))-LEISHCHECK IS A RAPID, SELF PERFORMING TWO SITE QUALITATIVE IMMUNOASSAY FOR THE DETECTION OF ANTIBODIES TO L. DONOVANI IN HUMAN SERUM/PLASMA. THE TEST IS INTENDED FOR THE PRESUMPTIVE DIAGNOSIS OF VISCERAL LEISHMANIASIS.,RAPID TEST FOR DETECTION OF IGM AND IGG ANTIBODIES TO DENGUE VIRUS (DEVICE)(DENGUCHECK WB)-DENGUCHECK WB IS A RAPID, QUALITATIVE IMMUNOCHROMATOGRAPHIC TEST FOR SIMULTANEOUS DETECTION OF IGM AND IGG ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM/PLASMA/WHOLE BLOOD.,RAPID TEST FOR DETECTION OF HUMAN THYROID STIMULATING HORMONE (TSH) IN HUMAN WHOLE BLOOD.(BABYSAFE TSH)-THIS TEST KIT IS AN IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY FOR THE SEMI- QUALITATIVE DETECTION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN WHOLE BLOOD.,RAPID TEST FOR IGM ANTIBODIES TO LEPTOSPIRA (DEVICE)(LEPTOCHECK WB)-LEPTOCHCEK WB IS A RAPID, QUALITATIVE, SANDWICH IMMUNOASSAY FOR THE DETECTION OF DETECTION SPECIFIC IGM ANTIBODIES IN HUMAN SERUM/PLASMA OR WHOLE BLOOD SPECIMEN.,ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM OR PLASMA(QUALISA CMV IGM)-QUALISA CMV IGM TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM,CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETECTION OF ANTI-CYCLIC CITRULLINATED PEPTIDE (CCP) IN HUMAN SERUM(ELECTRA ANTI-CCP)-HEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETECTION OF ANTI-CYCLIC CITRULLINATED PEPTIDES (CCP) PRESENT IN HUMAN SERUM,CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM(ELECTRA CMV IGM)-ELECTRA CMV IGM CLIA TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM,ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM(QUALISA PROGESTERONE)-QUALISA PROGESTERONE SANDWICH ELISA TEST KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION PROGESTERONE IN HUMAN SERUM.,RAPID TEST FOR DETECTION OF ANTIBODIES TO H.PYLORI (DEVICE)(HELICOCHECK (DEVICE))-HELICOCHECK IS A RAPID TEST FOR THE DETECTION OF IGG AND/OR IGM ANTIBODIES TO HELICOBACTER PYLORI IN HUMAN WHOLE BLOOD /SERUM /PLASMA. IT HELPS DIAGNOSE INFECTION IN PATIENTS WITH CLINICAL SYMPTOMS RELATING TO GASTROINTESTINAL TRACT AND SERVES AS AN ADJUNCT TO

	ENDOSCOPY.,CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF ULTRASENSITIVE THYROID STIMULATING HORMONE (UTSH) IN HUMAN SERUM OR PLASMA(ELECTRA UTSH)-CHEMILUMINESCENCE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF ULTRASENSITIVE THYROID STIMULATING HORMONE (UTSH) IN HUMAN SERUM OR PLASMA, CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM(ELECTRA PROGESTERONE)-ELECTRA PROGESTERONE THE TEST KIT IS A CHEMILUMINSECENCE ASSAY INTENDED FOR THE QUANTITATIVE DETERMINATION PROGESTERONE IN HUMAN SERUM .,ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF FREE TRIIODOTHYRONINE HORMONE IN HUMAN SERUM(QUALISA FT3)-QUALISA FT3 IS AN ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF FREE TRIIODOTHYRONINE HORMONE IN HUMAN SERUM., CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM(ELECTRA TOXO IGG)-ELECTRA TOXO IGG CLIA TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM,RAPID TEST FOR SIMULTANEOUS DETECTION OF HB S AND HB A IN HUMAN WHOLE BLOOD.(SICKLECHECK)-RAPID TEST FOR SIMULTANEOUS DETECTION OF HB S AND HB A IN HUMAN WHOLE BLOOD, CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM(ELECTRA FERRITIN) -ELECTRA FERRITIN IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF DS-DNA ANTIBODIES IN HUMAN SERUM OR PLASMA(QUALISA ANTI DS-DNA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF DS-DNA ANTIBODIES IN HUMAN SERUM OR PLASMA,RAPID TEST FOR DETECTION OF 17 ALPHA-HYDROXYPROGESTRONE (17-OHP) IN HUMAN WHOLE BLOOD(17-OHP CHEK)-THIS TEST KIT IS AN IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF 17A-OH PROGESTERONE IN HUMAN WHOLE BLOOD , ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF FOLLICLE-STIMULATING HORMONE IN HUMAN SERUM OR PLASMA(QUALISA FSH)-FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE-STIMULATING HORMONE (FSH) CONCENTRATIONS IN HUMAN SERUM,RAPID TEST FOR DETECTION OF 17ALPHA-HYDROXYPROGESTRONE (17-OHP) IN HUMAN WHOLE BLOOD. (BABYSAFE 17-OHP)-THIS TEST KIT IS AN IN-VITRO DIAGNOSTIC

	IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF 17A-OH PROGESTERONE IN HUMAN WHOLE BLOOD,NEONATAL TSH SCREENING ASSAY (ELISA)(BORNSAFE TSH)-BORNSAFE TSH KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROID STIMULATING HORMONE (HTSH) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS AN AID IN SCREENING.,ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING C-PEPTIDE IN HUMAN SERUM (QUALISA C-PEPTIDE)-ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING C-PEPTIDE IN HUMAN SERUM,ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF PROLACTIN HORMONE IN HUMAN SERUM OR PLASMA(QUALISA PRL)-FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN CONCENTRATION IN HUMAN SERUM. ,ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-MULLERIN HORMONE (AMH) IN HUMAN SERUM(QUALISA AMH)-QUALISA TM AFP SANDWICH ELISA TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ALPHA-FETOPROTEIN (AFP) IN HUMAN SERUM., ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF BETA-HUMAN CHORIONIC GONADOTROPIN HORMONE IN HUMAN SERUM OR PLASMA(QUALISA HCG)-BETA-HCG EIA TEST KIT IS MAINLY INTENDED TO QUANTITATIVELY DETERMINE TOTAL BETA-HCG CONCENTRATION IN HUMAN SERUM., CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM(ELECTRA TESTOSTERONE)-ELECTRA TESTOSTERONE SANDWICH ELISA TEST KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM.,ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF LUTEINIZING HORMONE IN HUMAN SERUM OR PLASMA(QUALISA LH)-FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE-STIMULATING HORMONE (FSH) CONCENTRATIONS IN HUMAN SERUM., ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUANTITATIVE DETERMINATION OF HUMAN INSULIN IN HUMAN SERUM(QUALISA INSULIN)-ENZYME LINKED IMMUNOSORBENT ASSAY (ELISA) FOR THE QUANTITATIVE DETERMINATION OF HUMAN INSULIN IN HUMAN SERUM,RAPID TEST FOR SIMULTANEOUS DETECTION OF HB S AND HB A IN HUMAN WHOLE BLOOD.(SCDCHEK)-RAPID TEST FOR SIMULTANEOUS DETECTION OF HB S AND HB A IN HUMAN WHOLE BLOOD,CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF ANTI-MULLERIAN HORMONE (AMH) IN HUMAN SERUM (ELECTRA AMH)-ELECTRA TM AHM CLIA TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF

		ANTI-MULLERIAN (AMH) IN HUMAN SERUM. ,ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS AUTO ANTIBODIES AGAINST CYCLIC CITRULLINATED PEPTIDES IN HUMAN SERUM.(QUALISA ANTI CCP)-ENZYME LINKED IMMUNOSORBENT ASSAY (ELIZA) FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS AUTO ANTIBODIES AGAINST CYCLIC CITRULLINATED PEPTIDES IN HUMAN SERUM.,ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM OR PLASMA(QUALISA TOXO IGM)-QUALISA TOXO IGM TEST IS INTENDED FOR THE DETECTION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM OR PLASMA,NEONATAL 17-OH PROGESTERONE SCREENING ASSAY (ELISA)(BORNSAFE 17-OHP)-BORN SAFE NEONATAL 17-OHP ELISA IS AN ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF 17 ALPHA-HYDROXYPROGESTERONE IN BLOOD SAMPLES DRIED ON S&S 903 FILTER PAPER. THIS TEST IS INTENDED AS A SCREENING METHOD FOR THE DETERMINATION OF 17-OHP CONCENTRATIONS IN NEWBORN DRIED BLOOD SPOT SPECIMENS AS AN AID TO THE DIAGNOSIS CONGENITAL ADRENAL HYPERPLASIA (CAH),ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM OR PLASMA(QUALISA TOXO IGG)-QUALISA TOXO IGG TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM OR PLASMA, CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF IGM ANTIBODIES TO RUBELLA IN HUMAN SERUM (ELECTRA RUBELLA IGM)-ELECTRA RUBELLA IGM CLIA TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGM ANTIBODIES TO RUBELLA IN HUMAN SERUM.,CHEMILUMINESCENCE ASSAY FOR THE QUANTITATIVE DETERMINATION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM(ELECTRA TOXO IGM)-ELECTRA TOXO IGM CLIA TEST IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM.
2780	MFG/IVD/2019/000028	1.License Holder Name: LEVRAM LIFESCIENCES PVT. LTD. 2.Approving Authority: DADRA AND NAGAR HAVELI 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTION TUBE(NA)-BLOOD COLLECTION

2781	MFG/IVD/2019/000031	1.License Holder Name: ACTORIUS INNOVATIONS AND RESEARCH PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:KIT FOR IN VITRO DIAGNOSIS OF CIRCULATING TUMOR CELLS (CTC) BY LIQUID BIOPSY TECHNOLOGY(ONCOVIU LIQUID BIOPSY KIT)-LIQUID BIOPSY TECHNOLOGY IS INTENDED FOR THE ENUMERATION OF CIRCULATING TUMOR CELLS (CTC) OF EPITHELIAL ORIGIN (CD45-, EPCAM+, AND CYTOKERATINS 8, 18+ AND/OR 19+) IN PERIPHERAL BLOOD OF CANCER PATIENTS.
2782	MFG/IVD/2019/000032	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:LIPASE(Q-LINE)-QUANTITATIVE DETERMINATION OF LIPASE ACTIVITY IN HUMAN SAMPLE,LYSE(HEMA-Q)-LYSE IS USED FOR QUANTIFICATION OF DIFFERENT CELLS IN HUMAN SAMPLES BY ANALYZER.,VITAMIN D(Q-LINE PLATINUM)-QUANTITATIVE DETERMINATION OF VITAMIN D ACTIVITY IN HUMAN SAMPLE,HB STRIPS-HEMOGLOBIN TEST STRIPS USED TO TESTING OF HEMOGLOBIN LEVEL INWHOLE BLOOD,LIPID STRIPS-LIPID TEST STRIPS USED TO TESTING OF TOTAL CHOLESTEROL, TRIGLYCERIDE,HIGH DENSITY LIPOPROTEIN, LOW DENSITY LIPOPROTEIN IN WHOLE BLOOD,GLUCOSE STRIPS-GLUCOSTRIPS GLUCOMETER USE TO QUANTITATIVELY MEASURE GLUCOSE IN WHOLE BLOOD.,ACE(Q-LINE)-QUANTITATIVE DETERMINATION OF ACE ACTIVITY IN HUMAN SAMPLE,DILUENT (HEMA-Q)-DILUENT IS USED FOR DILUTION OF HUMAN SAMPLES DURING BLOOD CELL COUNTING IN ANALYZER.,GLUCOSE-6PDH LQ (Q-LINE)-QUANTITATIVE DETERMINATION OF G6PDH ACTIVITY IN HUMAN SAMPLE,AMMONIA (NH3)(Q-LINE)-QUANTITATIVE DETERMINATION OF AMMONIA ACTIVITY IN HUMAN SAMPLE

2783	MFG/IVD/2019/000033	1.License Holder Name: BIOTROL LABORATORIES PVT. LTD. 2.Approving Authority: WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:URINE REAGENT STRIP (4 PARAMETERS) GLUCOSE, ALBUMIN, SPECIFIC GRAVITY AND PH(AM I RAPID)-URINE REAGENT STRIPS ARE FIRM PLASTIC STRIPS ONTO WHICH SEVERAL SEPARATE REAGENT AREAS ARE AFFIXED. THE TEST IS FOR THE DETECTION OF ONE OR MORE OF THE FOLLOWING ANALYTES IN URINE: GLUCOSE, SPECIFIC GRAVITY, ALBUMIN, AND PH.,URINE REAGENT STRIP GLUCOSE AND KETONE (2 PARAMETERS) (AM I RAPID)-URINE REAGENT STRIPS ARE FIRM PLASTIC STRIPS ONTO WHICH SEVERAL SEPARATE REAGENT AREAS ARE AFFIXED. THE TEST IS FOR THE DETECTION OF ONE OR MORE OF THE FOLLOWING ANALYTES IN URINE: GLUCOSE AND KETONE.,SCRUB TYPHUS AB RAPID TEST DEVICE/STRIP(AM I RAPID)-AM I RAPID SCRUB TYPHUS AB TEST IS AN IMMUNOCHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF ANTIBODIES (IGG, IGM AND IGA) SPECIFIC TO O. TSUTSUGAMUSHI IN HUMAN SERUM, PLASMA, AND WHOLE BLOOD.,URINE REAGENT STRIP GLUCOSE AND PROTEIN (2 PARAMETERS)(AM I RAPID)-URINE REAGENT STRIPS ARE FIRM PLASTIC STRIPS ONTO WHICH SEVERAL SEPARATE REAGENT AREAS ARE AFFIXED. THE TEST IS FOR THE DETECTION OF ONE OR MORE OF THE FOLLOWING ANALYTES IN URINE: GLUCOSE AND PROTEIN., URINE REAGENT STRIP GLUCOSE(AM I RAPID)-URINE REAGENT STRIPS ARE FIRM PLASTIC STRIPS ONTO WHICH SEVERAL SEPARATE REAGENT AREAS ARE AFFIXED. THE TEST IS FOR THE DETECTION GLUCOSE IN URINE SAMPLE.,URINE REAGENT STRIP FOR LEUKOCYTES, GLUCOSE, KETONE (ACETOACETIC ACID), BILIRUBIN, BLOOD, SPECIFIC GRAVITY, PROTEIN, UROBILINOGEN, NITRITE AND PH (10 PARAMETERS)(AM I RAPID)-URINE REAGENT STRIPS ARE FIRM PLASTIC STRIPS ONTO WHICH SEVERAL SEPARATE REAGENT AREAS ARE AFFIXED. THE TEST IS FOR THE DETECTION OF ONE OR MORE OF THE FOLLOWING ANALYTES IN URINE: LEUKOCYTES, GLUCOSE, KETONE (ACETOACETIC ACID), BILIRUBIN, BLOOD, SPECIFIC GRAVITY, PROTEIN, UROBILINOGEN, NITRITE AND PH.,URINE REAGENT STRIP FOR LEUKOCYTES, GLUCOSE, KETONE (ACETOACETIC ACID), BILIRUBIN, BLOOD, SPECIFIC GRAVITY, PROTEIN, UROBILINOGEN, NITRITE, ASCORBIC ACID, AND PH (11 PARAMETERS)(AM I RAPID)-URINE REAGENT STRIPS ARE FIRM PLASTIC STRIPS ONTO WHICH SEVERAL SEPARATE REAGENT AREAS ARE AFFIXED. THE TEST IS FOR THE DETECTION OF ONE OR MORE OF THE FOLLOWING ANALYTES IN URINE: LEUKOCYTES, GLUCOSE, KETONE (ACETOACETIC ACID), BILIRUBIN, BLOOD, SPECIFIC GRAVITY, PROTEIN, UROBILINOGEN, NITRITE, ASCORBIC ACID, AND PH.,H. PYLORI AB RAPID TEST DEVICE/STRIP(AM I RAPID)-AM I RAPID HELICOBACTER PYLORI (H.

	PYLORI, OR HP) ANTIBODY TEST IS A RAPID DETECTION OF H.PYLORI ANTIBODY IN HUMAN SERUM OR PLASMA SAMPLES.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2784	MFG/IVD/2019/000034	1.License Holder Name: ADI DIAGNOSTICS PVT LTD 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:CALCIUM TEST REAGENT/KIT-ESTIMATION OF TOTAL CALCIUM IN SERUM ,LACTATE DEHYDROGENASEAND TEST REAGENT/KIT(LDH)-ESTIMATION OF ENZYME LACTATE DEHYDROGENASE AND ITS ISOENZYMES IN SERUM / PLASMA. ,SODIUM TEST REAGENT/KIT-ESTIMATION OF SODIUM IN SERUM/ PLASMA / URINE. ,ALKALINE PHOSPHATASE TEST REAGENT/KIT-ESTIMATION OF ALKALINE PHOSPHATASE LEVEL PRESENT IN SERUM/PLASMA ,BILIRUBIN (TOTAL AND DIRECT) TEST REAGENT/KIT-ESTIMATION OF BILIRUBIN (TOTAL AND DIRECT) IN SERUM/PLASMA ,ASPARTATE AMINO TRANSFERASE(AST/SGOT) TEST REAGENTS/KIT (SGOT)-ESTIMATION OF THE ENZYME ASPARTATE AMINO TRANSFERASE (AST/SGOT) IN SERUM/PLASMA , ALPHA AMYLASE-IT IS USED FOR THE QUANTITATION OF AMYLASE IN HUMAN SERUM, PLASMA, OR URINE. ,CREATININE TEST REAGENT/KIT-ESTIMATION OF CREATININE IN SERUM, PLASMA/URINE ,CREATININE S.R. TEST REAGENT/KIT -ESTIMATION OF CREATININE IN SERUM, PLASMA/URINE ,TOTAL IRON TEST REAGENT/KIT-ESTIMATION OF IRON IN SERUM /PLASMA. ,HDL CHOLESTEROL SET-ESTIMATION OF HDL CHOLESTEROL IN SERUM/PLASMA ,CHLORIDE TEST REAGENT/KIT-ESTIMATION OF CHLORIDE IN PLASMA/SERUM,SWEAT/URINE ,GLUCOSE TEST REAGENT/KIT-ESTIMATION OF GLUCOSE IN BLOOD/PLASMA/ BODY FLUIDS. ,RF-TURBILATEX-FOR THE" INVITRO" QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR IN HUMAN SERUM , BILIRUBIN (DIRECT) TEST REAGENT/KIT-ESTIMATION OF BILIRUBIN (DIRECT) IN SERUM/PLASMA ,TRIGLYCERIDES TEST REAGENT/KIT (GPO-PAP)-ESTIMATION OF TRIGLYCERIDES IN SERUM/PLASMA ,ADI LYSE (LYSE FOR HEMATOLOGY ANALYZER)-QUANTITATIVE DETECTION OF WHITE BLOOD CELLS NUMBER IN WHOLE BLOOD AND HEMOGLOBIN CONCENTRATION ,UREA (KINETIC) TEST REAGENT/KIT (UREA GLDH)-ESTIMATION OF UREA/BLOOD UREA NITROGEN IN PLASMA/SERUM/URINE ,BILIRUBIN (TOTAL) TEST REAGENT/KIT-ESTIMATION OF BILIRUBIN (TOTAL) IN SERUM/PLASMA ,PREGNANCY TEST (HCG) CARD/STRIP (ONE STEP RAPID TEST)-TO DETECT PREGNANCY BY CHECKING PRESENCE OF HCG IN URINE ,DIRECT LDL CHOLESTEROL TEST REAGENT/KIT-ESTIMATION OF LDL CHOLESTEROL IN SERUM/PLASMA ,CREATINE KINASE TEST REAGENTS/KIT (CK-MB)-ESTIMATION OF THE ENZYME CREATINE PHOSPHOKINASE OR ITS ISOENZYMES IN SERUM/PLASMA ,GAMMA (GT) TEST REAGENT/KIT-ESTIMATION OF THE ENZYME GAMMA GLUTAMYL TRANSFERASE (GGT) IN SERUM / PLASMA. ,ASO-TURBILATEX-MEASURING THE ANTI-STREPTOLYSIN O (ASO)

	ANTIBODIES ,DENGUE IGG/IGM CARD (ONE STEP RAPID TEST)-DETECTION OF DENGUE IGG/IGM (ANTIBODY) IN PLASMA/BLOOD/SERUM ,AUTO-DIL (DILUENTS FOR HEMATOLOGY ANALYZER)-TO DILUTE BLOOD SAMPLES, TO KEEP THE BLOOD CELL IN ORIGINAL VOLUME COMPLETELY WITHIN A CERTAIN PERIOD AND TO GUARANTEE PULSE OBTAINED CORRESPONDING TO THE CELL VOLUME BY APPROPRIATE CONDUCTIVITY. ,ASO-LATEX AGGLUTINATION KIT-INTENDED FOR THE QUALITATIVE AND SEMI-QUANTITATIVE MEASUREMENT OF ANTIBODIES TO STREPTOCOCCAL EXOENZYMES IN HUMAN SERUM. ,CHOLESTEROL TEST REAGENT/KIT-ESTIMATION OF CHOLESTEROL IN BLOOD/BODY FLUIDS ,PHOSPHORUS (INORGANIC)TEST REAGENT/KIT-ESTIMATION OF INORGANIC PHOSPHORUS IN SERUM PLASMA / URINE ,RF- LATEX AGGLUTINATION KIT-FOR THE QUALITATIVE AND SEMI-QUANTITATIVE MEASUREMENT OF RF IN HUMAN SERUM. ,UREA (BERTHELOT) TEST REAGENT/KIT- ESTIMATION OF UREA/BLOOD UREA NITROGEN IN PLASMA/SERUM/URINE ,DIRECT HDL CHOLESTEROL TEST REAGENT/KIT-ESTIMATION OF HDL CHOLESTEROL IN SERUM/PLASMA ,MICRO-PROTEIN TEST REAGENT/KIT-ESTIMATION OF MICRO-PROTEINS IN URINE. , CREATINE KINASE TEST REAGENTS/KIT (CK-NAC)-TO ESTIMATE THE ENZYME CREATINE PHOSPHOKINASE OR ITS ISOENZYMES IN SERUM/PLASMA ,ADI RIN (RINSE FOR HEMATOLOGY ANALYZER)-TO CLEAN AND WASH THE SAMPLE-ASPIRATING PROBE, PIPELINE AND DETECTION PART OF BCC SERIES HEMATOLOGY ANALYZERS. , MAGNESIUM TEST REAGENT/KIT-ESTIMATION OF MAGNESIUM LEVELS IN SERUM / PLASMA. ,TOTAL PROTEIN TEST REAGENT/KIT-ESTIMATION OF TOTAL PROTEIN IN SERUM/PLASMA ,POTASSIUM TEST REAGENT/KIT-ESTIMATION OF POTASSIUM IN SERUM PLASMA / URINE. ,URIC ACID TEST REAGENT/KIT-ESTIMATION OF URIC ACID IN SERUM/PLASMA/URINE ,ALBUMIN TEST REAGENT/KIT-ESTIMATION OF ALBUMIN IN SERUM/PLASMA ,ALANINE AMINO TRANSFERASE (ALT/SGPT) TEST REAGENT/KIT (SGPT)-ESTIMATION OF ENZYME ALANINE AMINO TRANSFERASE (ALT/SGPT) IN SERUM/PLASMA

2785	MFG/IVD/2019/000036	1.License Holder Name: M/S STEDMAN PHARMACEUTICALS PVT. LTD. 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:CALCIUM TEST KIT (SEDONA)-CALCIUM TEST KIT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM, PLASMA AND URINE,ALBUMIN REAGENT TEST KIT(SEDONA)-ALBUMIN REAGENT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ALBUMIN IN SERUM, PLASMA ON MANUAL SYSTEMS.,BILIRUBIN TOTAL & DIRECT TEST KIT(SEDONA)-DIAGNOSTIC TEST KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF BILIRUBIN TOTAL & DIRECT IN HUMAN SERUM AND PLASMA.,URIC ACID REAGENT TEST KIT(SEDONA)-DIAGNOSTIC REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA AND URINE ,LOW DENSITY LIPOPROTEIN - CHOLESTEROL LDL-C TEST KIT(SEDONA)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LDL CHOLESTEROL IN HUMAN SERUM AND PLASMA.,CREATININE REAGENT TEST KIT(SEDONA)-CREATININE REAGENT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CREATININE IN SERUM, PLASMA AND URINE ON MANUAL SYSTEMS.,LIPASE TEST KIT(SEDONA)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPASE IN HUMAN SERUM AND PLASMA.,GLUCOSE TEST REAGENT KIT (SEDONA)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM, PLASMA AND CEREBROSPINAL FLUID (CSF).,HIGH DENSITY LIPOPROTEIN - CHOLESTEROL (HDL-C) TEST KIT(SEDONA)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM AND PLASMA.,BILIRUBIN TOTAL & DIRECT REAGENT TEST KIT(SEDONA)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF BILIRUBIN TOTAL & DIRECT IN HUMAN SERUM AND PLASMA.,MAGNESIUM TEST KIT (SEDONA)-MAGNESIUM TEST KIT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF MAGNESIUM IN SERUM, PLASMA & URINE.,TOTAL PROTEIN REAGENT TEST KIT(SEDONA)-TOTAL PROTEIN REAGENT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN SERUM, PLASMA ON MANUAL SYSTEMS.,PHOSPHORUS TEST KIT(SEDONA)-DIAGNOSTIC TEST KIT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PHOSPHORUS IN HUMAN SERUM, PLASMA.,TRIGLYCERIDES REAGENT TEST KIT(SEDONA)-DIAGNOSTIC REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA.,CREATINE KINASE -MYOCARDIAL BAND (CK-MB) TEST KIT(SEDONA)-CREATINE KINASE-MYOCARDIAL

		BAND (CK-MB) TEST KIT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CK-MB IN SERUM, PLASMA.,SGPT (ALT) REAGENT TEST KIT(SEDONA)-SERUM GLUTAMATE PYRUVATE TRANSAMINASE ALANINE AMINO TRANSAMINASE SGPT (ALT) REAGENT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF SGPT/ALT IN SERUM, PLASMA.,LACTATE DEHYDROGENASE-PYRUVATE (LDH-P) TEST KIT(SEDONA)-LACTATE DEHYDROGENASE -PYRUVATE (LDH-P) TEST KIT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF LDH-P IN SERUM, PLASMA.,SGOT (AST) REAGENT TEST KIT(SEDONA)-SERUM GLUTAMIC-OXALOACETIC TRANSAMINASE ASPARTATE TRANSAMINASE SGOT (AST) REAGENT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF SGOT(AST) IN SERUM, PLASMA.,CREATINE KINASE N-ACETYLCYSTEINE (CK-NAC) TEST KIT (SEDONA)-CREATINE KINASE N-ACETYLCYSTEINE (CK NAC) TEST KIT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CK NAC IN SERUM, PLASMA.,CHOLESTEROL REAGENT TEST KIT (SEDONA)-DIAGNOSTIC REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA.,AMYLASE TEST REAGENT(SEDONA)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF AMYLASE IN HUMAN SERUM , PLASMA AND URINE.,UREA REAGENT TEST KIT(SEDONA)-UREA REAGENT TEST IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF UREA IN SERUM, PLASMA.,ALKALINE PHOSPHATASE TEST REAGENT (SEDONA)-DIAGNOSTIC REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ALP IN HUMAN SERUM AND PLASMA.,GAMMA GLUTAMYL TRANSFERASE (GGT) TEST KIT (SEDONA)-GAMMA GLUTAMYL TRANSFERASE (GGT)TEST KIT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF GAMMA GT IN SERUM, PLASMA.
2786	MFG/IVD/2019/000037	1.License Holder Name: M/S.AVANTOR PERFORMANCE MATERIALS INDIA LTD 2.Approving Authority: UTTARAKHAND 3.Device Name(Brand Name)-Intended Use:ELITE H CLEAN(ERBA CEL- CLENZ)-IT IS DESIGNED FOR PERIODIC AND ROUTINE CLEANING THE MEASURING SYSTEM OF HAEMATOLOGY ANALYSER.,ELITE H360 DIL(ERBA CEL – PK)-IT IS REAGENT, WHICH HELP TO DILUTE THE WHOLE-BLOOD SAMPLE AND PROVIDE THE CONDUCTIVE ENVIRONMENT FOR BLOOD CELL ENUMERATION.,ELITE H360 LYSE (ERBA STR-LYSE WH)-FOR ACCURATE COUNT OF WBC, ESTIMATION OF HB, TRIMODAL DIFFERENTIAL OF WBCS.

2787	MFG/IVD/2019/000039	1.License Holder Name: CADILA HEALTHCARE LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:IN VITRO DIAGNOSTICS KIT FOR DETECTION OF MEASLES VIRUS (ZYDX MEASLES (HUMAN) IGM ELISA KIT)-IN VITRO DIAGNOSTIC KIT FOR DETECTION OF IGM ANTIBODY AGAINST MEASLES INFECTION IN HUMAN., CCHF (SHEEP AND GOAT) ELISA(ZYDX CCHF (SHEEP AND GOAT) ELISA)-IN VITRO DIAGNOSTIC KIT FOR THE DETECTION OF CRIMEAN-CONGO HEMORRHAGIC FEVER (CCHF) VIRUS INFECTION IN SHEEP AND GOAT SERUM/PLASMA SAMPLES.,CCHF (CATTLE) ELISA(ZYDX CCHF (CATTLE) ELISA)-IN VITRO DIAGNOSTIC KIT FOR THE DETECTION OF CRIMEAN-CONGO HEMORRHAGIC FEVER (CCHF) VIRUS INFECTION IN CATTLES SERUM/PLASMA SAMPLES., JEV (MOSQUITO) ELISA(ZYDX JEV (MOSQUITO) ELISA)-IN VITRO DIAGNOSTICS KIT FOR THE DETECTION OF JAPANESE ENCEPHALITIS VIRUS (JEV) IN MOSQUITO SLURRY SAMPLES., CHPV (HUMAN) ELISA(ZYDX CHPV (HUMAN) ELISA)-IN VITRO DIAGNOSTIC KIT FOR THE DETECTION OF CHANDIPURA VIRUS (CHPV) INFECTION IN HUMAN SERUM/PLASMA SAMPLE., CCHF (HUMAN) IGM ELISA(ZYDX CCHF (HUMAN) IGM ELISA)-IN VITRO DIAGNOSTIC KIT FOR THE DETECTION OF IGM ANTIBODIES AGAINST CRIMEAN-CONGO HEMORRHAGIC FEVER (CCHF) VIRUS IN HUMAN SERUM/PLASMA SAMPLES., KFDV IGM (HUMAN) ELISA(ZYDX KFDV IGM (HUMAN) ELISA)-IN VITRO DIAGNOSTIC KIT FOR THE DETECTION IGM ANTIBODIES AGAINST KYASANUR FOREST DISEASE VIRUS (KFDV) IN HUMAN SERUM/PLASMA SAMPLES, CCHF (HUMAN) IGG ELISA(ZYDX CCHF (HUMAN) IGG ELISA)-IN VITRO DIAGNOSTIC KIT FOR THE DETECTION OF IGG ANTIBODIES AGAINST CRIMEAN-CONGO HEMORRHAGIC FEVER (CCHF) VIRUS IN HUMAN SERUM/PLASMA SAMPLES., HEV (HUMAN) ELISA(ZYDX HEV (HUMAN) ELISA)-IN VITRO DIAGNOSTIC KIT FOR THE DETECTION OF IGM ANTIBODIES AGAINST HEPATITIS E VIRUS (HEV) IN HUMAN SERUM/PLASMA SAMPLES.

2788	MFG/IVD/2019/000040	1.License Holder Name: MOLBIO DIAGNOSTICS PVT. LTD. 2.Approving Authority: SUB ZONAL GOA 3.Device Name(Brand Name)-Intended Use:CHIP-BASED REAL TIME PCR TEST FOR HEPATITIS C VIRUS(TRUENAT™ HCV)-TRUENAT™ HCV IS A CHIP-BASED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT PCR) TEST FOR THE QUANTITATIVE DETECTION OF HEPATITIS C VIRUS (HCV) RNA IN HUMAN PLASMA, SERUM AND WHOLE BLOOD SAMPLES. TRUENAT™ HCV AIDS IN THE DIAGNOSIS AND CONFIRMATION OF HCV INFECTION (IN CONJUNCTION WITH HCV ANTIBODY TEST) AND IN ESTIMATION OF VIRAL LOAD. IT IS NOT INTENDED AS A BLOOD DONOR SCREENING TEST. TRUENAT™ HCV RUNS ON THE TRUELAB™ REAL TIME MICRO PCR ANALYZERS.

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2789	MFG/IVD/2019/000041	1.License Holder Name: AVECON HEALTHCARE PVT. LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:CRP LATEX TEST (SEROMAX & OEM)-REAGENT KIT FOR THE QUALITATIVE AND SEMI QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM,ANTI D(MAXCLONE & OEM)-REAGENT KIT FOR THE DETECTION OF ANTISERA IN HUMAN BLOOD,ANTI A,B,D(MAXCLONE & OEM)-REAGENT KIT FOR THE DETECTION OF ANTISERA IN HUMAN BLOOD,WIDAL SLIDE TEST KIT(SEROMAX & OEM)-REAGENT KIT FOR THE QUALITATIVE AND SEMI QUANTITATIVE DETERMINATION OF ANTIBODIES TO SALMONELLA TYPHI AND PARA TYPHI IN HUMAN SERUM,TYPHOID ANTIGEN TEST KIT(MAXLINE & OEM)-TYPHOID TEST KIT IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF SALMONELLA TYPHI ANTIGEN IN HUMAN SERUM/PLASMA/ WHOLE BLOOD,CRP TURBIDOMETRIC (TURBIMAX & OEM)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF C - REACTIVE PROTEIN IN HUMAN SERUM,ANTI A (MAXCLONE & OEM)-REAGENT KIT FOR THE DETECTION OF ANTISERA IN HUMAN BLOOD,ASO LATEX TEST(SEROMAX & OEM)-REAGENT KIT FOR THE QUALITATIVE AND SEMI QUANTITATIVE DETERMINATION OF ANTI STREPTOLYSIN-O ANTIBODIES IN HUMAN SERUM,ASO TURBIDOMETRIC(TURBIMAX & OEM)-REAGENT KIT FOR THE QUANTITATIVE DETERMINATION OF ANTI STREPTOLYSIN – O ANTIBODIES IN HUMAN SERUM,HBSAG TEST KIT (DEVICE /STRIPS) (MAXLINE & OEM)-HBSAG TEST KIT IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF HEPATITIS B VIRUS(HEPATITIS B SURFACE ANTIGEN) IN HUMAN SERUM/PLASMA/ WHOLE BLOOD,HIV 1/2 TRILINE RAPID TEST(MAXLINE & OEM)-HIV 1/2 TRILINE RAPID TEST KIT IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DIFFERENTIAL DETECTION OF ANTIBODIES TO HIV-1 AND HIV-2 IN HUMAN SERUM/PLASMA/ WHOLE BLOOD,TROPONIN I(MAXLINE & OEM)-TROPONIN I TEST KIT IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF CARDIAC TROPONO I IN HUMAN SERUM/PLASMA/ WHOLE BLOOD,ANTI B(MAXCLONE & OEM)-REAGENT KIT FOR THE DETECTION OF ANTISERA IN HUMAN BLOOD, SYPHILIS / TP (DEVICE/STRIPS)(MAXLINE & OEM)-SYPHILIS /T P TEST KIT IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES(IGG/IGM/IGA) TO TREPONEMA PALLIDUM IN HUMAN SERUM/PLASMA / WHOLE BLOOD, RPR ANTIGEN TEST(SEROMAX & OEM)-REAGENT KIT FOR THE QUALITATIVE AND SEMI QUANTITATIVE DETERMINATION OF RAPID PLASMA REAGIN IN HUMAN SERUM / PLASMA,MALARIA ANTIGEN PF-PV(MAXLINE & OEM)-MALRIA AG (PF/PV) TEST KIT IS A RAPID

	IMMUNOCHROMATOGRAPHIC ASSAY FOR QUALITATIVE DETECTION OF PLASMODIUM SPECIES IN HUMAN WHOLE BLOOD,MALARIA ANTIGEN PF-PAN TEST KIT(MAXLINE & OEM)-MALRIA ANTIGEN (PF/PAN) RAPID TEST KIT FOR QUANTITATIVE DETECTION OF PLASMODIUM SPECIES IN HUMAN WHOLE BLOOD,HCV TEST KIT (MAXLINE & OEM)-HCV TEST KIT IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HEPATITIS C VIRUS (HCV) IN HUMAN SERUM/PLASMA/ WHOLE BLOOD,DENGUE ANTIGEN NS1 TEST KIT (MAXLINE & OEM)-DENGUE NS1 IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF NON-STRUCTURAL PROTEIN 1(NS1) IN HUMAN SERUM/PLASMA/WHOLE BLOOD

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2790	MFG/IVD/2019/000042	1.License Holder Name: BECKMAN COULTER INDIA PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:REAGENT FOR AID TO DIFFERENTIAL DIAGNOSIS OF HEMATOPOIETIC NEOPLASMS (CLEARLLAB 10C B CELL TUBE)-THE CLEARLLAB 10C PANELS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE FOR QUALITATIVE IDENTIFICATION OF CELL POPULATIONS BY MULTIPARAMETER IMMUNOPHENOTYPING ON THE NAVIOS AND NAVIOS EXFLOW CYTOMETERS. THESE REAGENTS ARE USED AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF HEMATOLOGICALLY ABNORMAL PATIENTS HAVING, OR SUSPECTED OF HAVING, THE FOLLOWING HEMATOPOIETIC NEOPLASMS:CHRONIC LEUKEMIA, ACUTE LEUKEMIA, NON-HODGKIN LYMPHOMA, MYELOMA, MYELODYSPLASTIC SYNDROME (MDS), AND/OR MYELOPROLIFERATIVE NEOPLASMS (MPN). THE REAGENTS CAN BE USED WITHPERIPHERAL WHOLE BLOOD (COLLECTED IN K2EDTA, ACID CITRATE DEXTROSE (ACD) OR HEPARIN), BONE MARROW (COLLECTED IN K2EDTA, ACD OR HEPARIN) AND LYMPH NODE SPECIMENS. INTERPRETATION OF THERESULTS SHOULD BE CONFIRMED BY A PATHOLOGIST OR EQUIVALENT PROFESSIONAL IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS., CD3/CD4/CD8 LYMPHOCYTE ENUMERATION REAGENT FOR FLOW CYTOMETERS(DURACLONE TRI-T-STAT CD3/CD4/CD8 REAGENT KIT) -THE DURACLONE TRI T-STAT CD3/CD4/CD8 REAGENT IS A THREE COLOR IMMUNOFLUORESCENCE STAIN FOR THE IDENTIFICATIONAND ENUMERATION OF HELPER/INDUCER (CD4+), CYTOTOXIC/SUPPRESSOR (CD8+), AND TOTAL T-LYMPHOCYTES (CD3+) COMBINED WITH A PRECISE NUMBER OF FLUORESCENT COUNTING BEADS FOR DETERMINATION OF ABSOLUTE CD3+,CD4+, CD8+, T-CELLS COUNTS. THIS REAGENT IS INTENDED FOR FLOW CYTOMETRY BASED ANALYSIS OF HUMAN WHOLE BLOOD SAMPLES., REAGENT FOR AID TO DIFFERENTIAL DIAGNOSIS OF HEMATOPOIETIC NEOPLASMS(CLEARLLAB 10C M2 CELL TUBE)-THE CLEARLLAB 10C PANELS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE FOR QUALITATIVE IDENTIFICATION OF CELL POPULATIONS BY MULTIPARAMETERIMMUNOPHENOTYPING ON THE NAVIOS AND NAVIOS EXFLOW CYTOMETERS. THESE REAGENTS ARE USED AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF HEMATOLOGICALLY ABNORMAL PATIENTS HAVING, OR SUSPECTED OF HAVING, THE FOLLOWING HEMATOPOIETIC NEOPLASMS:CHRONIC LEUKEMIA, ACUTE LEUKEMIA, NON-HODGKIN LYMPHOMA, MYELOMA, MYELODYSPLASTIC SYNDROME (MDS), AND/OR MYELOPROLIFERATIVE NEOPLASMS (MPN). THE REAGENTS CAN BE USED WITHPERIPHERAL WHOLE BLOOD (COLLECTED IN K2EDTA,

	ACID CITRATE DEXTROSE (ACD) OR HEPARIN), BONE MARROW (COLLECTED IN K2EDTA, ACD OR HEPARIN) AND LYMPH NODE SPECIMENS. INTERPRETATION OF THERESULTS SHOULD BE CONFIRMED BY A PATHOLOGIST OR EQUIVALENT PROFESSIONAL IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS., HAEMATOLYMPHOID MALIGNANCIES SCREENING REAGENT (CLEARLLAB LS)-THE CLEARLLAB LS (LYMPHOID SCREEN) REAGENT IS INTENDED FOR IN VITRO DIAGNOSTIC USE AS A SCREENING PANEL FOR IDENTIFICATION OF VARIOUS HEMATOLYMPHOID CELL POPULATIONS BY IMMUNOPHENOTYPING ON NAVIOS AND NAVIOS EX FLOW CYTOMETERS. THE REAGENT IS USED AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF PATIENTS WITH SIGNS AND/OR SYMPTOMS OF HEMATOLYMPHOID MALIGNANCIES. THE REAGENT CAN BE USED WITH PERIPHERAL WHOLE BLOOD (COLLECTED IN EDTA, ACD AND HEPARIN), BONE MARROW SPECIMENS (COLLECTED IN EDTA, ACD AND HEPARIN) AND LYMPH NODE SPECIMENS FOR IMMUNOPHENOTYPING. THE RESULTS SHOULD BE INTERPRETED ALONG WITH ADDITIONAL CLINICAL AND LABORATORY FINDINGS. THE REAGENTS PROVIDE QUALITATIVE RESULTS FOR B, T, AND NK LINEAGES.,REAGENT FOR AID TO DIFFERENTIAL DIAGNOSIS OF HEMATOPOIETIC NEOPLASMS(CLEARLLAB 10C M1 CELL TUBE)-THE CLEARLLAB 10C PANELS ARE INTENDED FOR IN VITRO DIAGNOSTIC USE FOR QUALITATIVE IDENTIFICATION OF CELL POPULATIONS BY MULTIPARAMETER IMMUNOPHENOTYPING ON THE NAVIOS AND NAVIOS EXFLOW CYTOMETERS. THESE REAGENTS ARE USED AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF HEMATOLOGICALLY ABNORMAL PATIENTS HAVING, OR SUSPECTED OF HAVING, THE FOLLOWING HEMATOPOIETIC NEOPLASMS:CHRONIC LEUKEMIA, ACUTE LEUKEMIA, NON-HODGKIN LYMPHOMA, MYELOMA, MYELODYSPLASTIC SYNDROME (MDS), AND/OR MYELOPROLIFERATIVE NEOPLASMS (MPN). THE REAGENTS CAN BE USED WITHPERIPHERAL WHOLE BLOOD (COLLECTED IN K2EDTA, ACID CITRATE DEXTROSE (ACD) OR HEPARIN), BONE MARROW (COLLECTED IN K2EDTA, ACD OR HEPARIN) AND LYMPH NODE SPECIMENS. INTERPRETATION OF THERESULTS SHOULD BE CONFIRMED BY A PATHOLOGIST OR EQUIVALENT PROFESSIONAL IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS., COMPENSATION SETUP REAGENT(CLEARLLAB COMPENSATION KIT)-N. THE CLEARLLAB COMPENSATION KIT MAY BE USED TO ESTABLISH COLOR COMPENSATION SETTINGS ON THE NAVIOS AND THE NAVIOS EX CYTOMETER(S) PRIOR TO MULTI-COLOR ANALYSIS WITH TEN COLOR APPLICATIONS SUCH AS CLEARLLAB LS.,REAGENT FOR AID TO DIFFERENTIAL DIAGNOSIS OF HEMATOPOIETIC NEOPLASMS (CLEARLLAB 10C T CELL TUBE)-THE CLEARLLAB 10C PANELS ARE

	INTENDED FOR IN VITRO DIAGNOSTIC USE FOR QUALITATIVE IDENTIFICATION OF CELL POPULATIONS BY MULTIPARAMETERI MMUNOPHENOTYPING ON THE NAVIOS AND NAVIOS EXFLOW CYTOMETERS. THESE REAGENTS ARE USED AS AN AID IN THE DIFFERENTIAL DIAGNOSIS OF HEMATOLOGICALLY ABNORMAL PATIENTS HAVING, OR SUSPECTED OF HAVING, THE FOLLOWING HEMATOPOIETIC NEOPLASMS:CHRONIC LEUKEMIA, ACUTE LEUKEMIA, NON-HODGKIN LYMPHOMA, MYELOMA, MYELODYSPLASTIC SYNDROME (MDS), AND/OR MYELOPROLIFERATIVE NEOPLASMS (MPN). THE REAGENTS CAN BE USED WITHPERIPHERAL WHOLE BLOOD (COLLECTED IN K2EDTA, ACID CITRATE DEXTROSE (ACD) OR HEPARIN), BONE MARROW (COLLECTED IN K2EDTA, ACD OR HEPARIN) AND LYMPH NODE SPECIMENS. INTERPRETATION OF THERESULTS SHOULD BE CONFIRMED BY A PATHOLOGIST OR EQUIVALENT PROFESSIONAL IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2791	MFG/IVD/2019/000044	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:WIDAL ANTIGENS FOR SLIDE & TUBE TESTS(TYDAL PLUS)-TYDAL PLUS IS A WIDAL SLIDE AND TUBE AGGLUTINATION TEST FOR THE DETECTION OF ANTIBODIES TO S. TYPHI 'O', S. TYPHI 'H', S.PARATYPHI 'AH', S. PARATYPHI 'BH', S. PARATYPHI 'CH', S. PARATYPHI 'AO', S. PARATYPHI 'BO', S. PARATYPHI 'CO' IN SERUM,WIDAL S. TYPHI & S. PARATYPHI ANTIGENS FOR TUBE TESTS(VITAL WIDAL)-VITAL WIDAL IS A STANDARDIZED WIDAL ANTIGEN TUBE TEST SET FOR THE DETECTION OF ANTIBODIES TO S. TYPHI 'O', S. TYPHI 'H', S. PARATYPHI 'AH', S. PARATYPHI 'BH' IN SERUM,FEBRILE ANTIGEN SET FOR SERODIAGNOSIS OF ANTIBODIES TO S.TYPHI, S.PARATYPHI, BRUCELLA AND PROTEUS ANTIGENS(TULIP'S FEBRILE ANTIGEN SET)-TULIP'S FEBRILE ANTIGEN SET CONTAINS READY TO USE STANDARDIZED, KILLED STAINED, SMOOTH ANTIGEN SUSPENSIONS OF THE SALMONELLA BACILLI; S.TYPHI O, S.TYPHI H, S.PARATYPHI AH, S.PARATYPHI BH, BRUCELLA ABORTUS ANTIGEN AND PROTEUS OX19 ANTIGEN ALONG WITH A POLYSPECIFIC FEBRILE ANTIGEN POSITIVE CONTROL REACT WITH THESE ANTIGENS AND FEBRILE ANTIGEN NEGATIVE CONTROL NONREACTIVE WITH THESE ANTIGEN. , WIDAL S. TYPHI ANTIGENS FOR TUBE TESTS(VITAL WIDAL)-VITAL WIDAL IS A STANDARDIZED WIDAL ANTIGEN TUBE TEST SET FOR THE DETECTION OF ANTIBODIES TO S. TYPHI 'O' AND S. TYPHY 'H' IN SERUM,WIDAL NEGATIVE CONTROL-WIDAL NEGATIVE CONTROL CAN BE USED TO VALIDATE THE PERFORMANCE OF WIDAL ANTIGEN SUSPENSIONS (SUCH AS TYDAL / TYPHOCHEK / VITAL WIDAL),WIDAL TEST SLIDE / TUBE(TYDAL)-TYDAL IS A WIDAL SLIDE AND TUBE AGGLUTINATION TEST THAT DETECTS THE PRESENCE THE SERUM AGGLUTININS (O,H) IN THE PATIENTS SERUM WITH TYPHOID AND PARATYPHOID FEVER.,TYPHOID ANTIBODY TEST KIT WITH POSITIVE & NEGATIVE CONTROL (TYDAL PN)-TYDAL PN IS A SLIDE AND TUBE AGGLUTINATION TEST FOR THE DETECTION OF TYPHOID ANTIBODIES TO S. TYPHI 'O' AND S. TYPHI 'H' IN SERUM.,WIDAL ANTIGENS FOR SLIDE & TUBE TESTS(TYDAL OH)-TYDAL IS A WIDAL SLIDE AND TUBE AGGLUTINATION TEST THAT DETECTS THE PRESENCE THE SERUM AGGLUTININS (O, H) IN THE PATIENTS SERUM WITH TYPHOID AND PARATYPHOID FEVER.,BRUCELLOSIS NEGATIVE CONTROL-BRUCELLOSIS NEGATIVE CONTROL CAN BE USED FOR VALIDATING THE PERFORMANCE OF BRUCEL A/ BRUCEL M/ BRUCEL RB ANTIGEN SUSPENSIONS.,SLIDE TEST FOR BRUCELLA MELITENSIS COLOURED ANTIBODIES(BRUCEL-M)-BRUCEL M IS SLIDE AND TUBE TEST FOR THE DETECTION OF SPECIFIC ANTIBODIES TO BRUCELLA MELITENSIS IN HUMAN AND ANIMAL SERUM.,TYPHOID ANTIBODY TEST KIT WITH

	POSITIVE CONTROL (TYDAL P)-TYDAL P IS A SLIDE AND TUBE AGGLUTINATION TEST FOR THE DETECTION OF TYPHOID ANTIBODIES TO S. TYPHI 'O' AND S. TYPHI 'H' IN SERUM.,TYPHOID ANTIBODY TEST REAGENT FOR DETECTION OF ANTIBODIES TO WIDAL S.PARATYPHI BO(TYDAL BO)-WIDAL S.PARATYPHI 'BO' IS A SLIDE AND TUBE AGGLUTINATION TEST FOR THE DETECTION OF ANTIBODIES TO S. PARATYPHI 'BO' IN THE PATIENT'S SERUM, WITH PARATYPHOID FEVER.,WIDAL S.TYPHI O ANTIGEN FOR SLIDE AND TUBE TESTS (TYDAL O ANTIGEN)-WIDAL S. TYPHI O ANTIGEN IS A SLIDE AND TUBE AGGLUTINATION TEST FOR THE DETECTION OF ANTIBODIES TO S. TYPHI O IN THE PATIENTS SERUM WITH TYPHOID FEVER.,WIDAL S. TYPHI H ANTIGEN FOR SLIDE AND TUBE TESTS(TYDAL H ANTIGEN)-WIDAL S. TYPHI H ANTIGEN IS A SLIDE AND TUBE AGGLUTINATION TEST FOR THE DETECTION OF ANTIBODIES TO S. TYPHI H IN THE PATIENTS SERUM WITH TYPHOID FEVER.,SLIDE TEST FOR BRUCELLA ABORTUS COLOURED ANTIBODIES(BRUCEL-A)-BRUCEL A IS SLIDE AND TUBE TEST FOR THE DETECTION OF SPECIFIC ANTIBODIES TO BRUCELLS ABORTUS IN HUMAN AND ANIMAL SERUM.,WIDAL POSITIVE CONTROL-WIDAL POSITIVE CONTROL CAN BE USED TO VALIDATE THE PERFORMANCE OF WIDAL ANTIGEN SUSPENSIONS (SUCH AS TYDAL / TYPHOCHEK / VITAL WIDAL).,BRUCELLOSIS POSITIVE CONTROL-BRUCELLOSIS POSITIVE CONTROL CAN BE USED TO VALIDATING THE PERFORMANCE OF BRUCEL-A/ BRUCEL-M/ BRUCEL-RB ANTIGEN SUSPENSION.,POLYSPECIFIC POSITIVE CONTROL FOR PROTEUS ANTIGENS(PROGEN POSITIVE CONTROL)-PROGEN POLYSPECIFIC POSITIVE CONTROL CAN BE USED FOR VALIDATING THE PERFORMANCE OF PROGEN OX19, PROGEN OX2 AND PROGEN OXK ANTIGEN SUSPENSIONS.,TYPHOID ANTIBODY TEST REAGENT FOR DETECTION OF ANTIBODIES TO WIDAL S.PARATYPHI CO(TYDAL CO)-WIDAL S.PARATYPHI 'CO' IS A SLIDE AND TUBE AGGLUTINATION TEST FOR THE DETECTION OF ANTIBODIES TO S. PARATYPHI 'CO' IN THE PATIENT'S SERUM, WITH PARATYPHOID FEVER.,WIDAL TUBE TEST(TYPHOCHECK)-TYPHOCHECK IS A WIDAL TUBE AGGLUTINATION TEST THAT DETECTS THE PRESENCE THE SERUM AGGLUTINATION (O,H) FOUND IN THE SERUM OF PATIENTS WITH TYPHOID AND PARATYPHOID FEVER.,WIDAL S.PARATYPHI BH ANTIGEN FOR SLIDE AND TUBE TESTS(TYDAL BH ANTIGEN)-WIDAL S. PARATYPHI BH ANTIGEN IS A SLIDE AND TUBE AGGLUTINATION TEST FOR THE DETECTION OF ANTIBODIES TO S. PARATYPHI BH IN THE PATIENTS SERUM WITH TYPHOID FEVER.,TYPHOID ANTIBODY TEST REAGENT FOR DETECTION OF ANTIBODIES TO WIDAL S.PARATYPHI CH(TYDAL CH)-WIDAL S.PARATYPHI 'CH' IS A SLIDE AND TUBE AGGLUTINATION TEST FOR THE DETECTION OF ANTIBODIES TO S. PARATYPHI 'CH' IN THE PATIENT'S SERUM, WITH PARATYPHOID

	FEVER.,SLIDE SCREENING TEST FOR BRUCELLA ANTIBODIES (BRUCEL-RB)-BRUCEL-RB IS A RAPID SLIDE AGGLUTINATION TEST FOR SCREENING OF ANTOBODIES TO BRUCELLA IN HUMAN AND ANIMAL SERUM,PROTEUS OX19 ANTIGEN FOR WEIL-FELIX TEST (PROGEN OX19)-PROGEN ANTIGEN SUSPENSIONS EMPLOYED IN THE WEIL-FELIX TEST, ARE USED FOR THE DIAGNOSIS OF RICKETTSIAL INFECTION AND DIFFERENTIAL DIAGNOSIS IN PATIENTS WITH FEBRILE FEVER.,TYPHOID ANTIBODY TEST REAGENT FOR DETECTION OF ANTIBODIES TO WIDAL S.PARATYPHI AO(TYDAL AO)-WIDAL S. PARATYPHI 'AO' IS A SLIDE AND TUBE AGGLUTINATION TEST FOR THE DETECTION OF ANTIBODIES TO S. PARATYPHI 'AO' IN THE PATIENT'S SERUM, WITH PARATYPHOID FEVER.,WIDAL S.PARATYPHI AH ANTIGEN FOR SLIDE AND TUBE TESTS(TYDAL AH ANTIGEN)-WIDAL S. PARATYPHI AH ANTIGEN IS A SLIDE AND TUBE AGGLUTINATION TEST FOR THE DETECTION OF ANTIBODIES TO S. PARATYPHI AH IN THE PATIENTS SERUM WITH TYPHOID FEVER., PROTEUS OX2 ANTIGEN FOR WEIL-FELIX TEST(PROGEN OX2)-PROGEN ANTIGEN SUSPENSIONS EMPLOYED IN THE WEIL-FELIX TEST, ARE USED FOR THE DIAGNOSIS OF RICKETTSIAL INFECTION AND DIFFERENTIAL DIAGNOSIS IN PATIENTS WITH FEBRILE FEVER., SCREENING TEST FOR ENTERIC FEVER, BRUCELLOSIS AND SCRUB TYPHUS FEVER(PUO SCREEN)-PUO SCREEN TEST CAN BE USED FOR SCREENING OF ANTIBODIES PRODUCED IN FEBRILE DISEASE SUCH AS TYPHOID, BRUCELLOSIS AND SCRUB TYPHUS. THE SCREENING HELPS IN DETECTION OR RULING OUT THE PRESENCE OF ANY OR ALL OF THESE FEBRILE DISEASES.,PROTEUS OXK ANTIGEN FOR WEIL-FELIX TEST(PROGEN OXK)-PROGEN ANTIGEN SUSPENSIONS EMPLOYED IN THE WEIL-FELIX TEST, ARE USED FOR THE DIAGNOSIS OF RICKETTSIAL INFECTION AND DIFFERENTIAL DIAGNOSIS IN PATIENTS WITH FEBRILE FEVER.

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2792	MFG/IVD/2019/000045	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:SLIDE TEST FOR INFECTIOUS MONONUCLEOSIS(IMMUTEX)-IMMUTEX IS A QUALITATIVE HAEMAGGLUTINATION SLIDE TEST FOR DETECTION OF HETEROPHILE ANTIBODIES IN INFECTIOUS MONONUCLEOSIS.,RED BLOOD CELL PRESERVING SOLUTION FOR SEROLOGICAL APPLICATIONS(ERYWELL)-ERYWELL IS USED FOR RED BLOOD CELLS PRESERVING SOLUTION FOR SEROLOGICAL APPLICATIONS. ERYWELL RED CELL PRESERVING SOLUTION IS A STANDARDIZED ALSEVER'S SOLUTION FOR MAINTAINING RED CELL INTEGRITY AND SURVIVAL.,SLIDE TEST FOR RHEUMATOID FACTORS(RHELAX RF)-RHELAX RF IS A QUALITATIVE AND SEMI QUANTITATIVE LATEX AGGLUTINATION SLIDE TEST FOR DETECTION OF IGM RHEUMATOID FACTORS.,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF COCAINE IN HUMAN URINE(INSIGHT COC (DEVICE))-INSIGHT COC IS A RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF COCAINE IN HUMAN URINE.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR RHEUMATOID FACTORS (SINGLE POINT METHOD)(TURBILYTE RF)-TURBILYTE-RF IS A TURBIDIMETRIC IMMUNOASSAY FOR QUANTITATIVE DETECTION OF RHEUMATOID FACTORS OF THE IGM CLASS.,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF AMPHETAMINE IN HUMAN URINE(INSIGHT AMP (DEVICE))-INSIGHT AMP IS A RAPID, SELF-PERFORMING, QUALITATIVE, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF AMPHETAMINE IN HUMAN URINE.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR ANTI STREPTOLYSIN-O (TURBOSMART ASO)-TURBOSMART ASO IS A QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR DETERMINATION OF SERUM ASO AND IS SPECIFIC FOR ANTI-STREPTOLYSIN 'O' ANTIBODIES.,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF BARBITURATES IN HUMAN URINE(INSIGHT BAR (DEVICE))-INSIGHT BAR IS A RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF BARBITURATES IN HUMAN URINE.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR DETERMINATION OF FERRITIN IN HUMAN SERUM (QUANTIA FERRITIN)-QUANTIA FERRITIN IS A TURBIDIMETRIC IMMUNOASAY FOR THE DETERMINATION OF FERRITIN AND IS BASED ON THE PRINCIPLE OF AGGLUTINATION REACTION.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR CRP (C-REACTIVE PROTEIN) (QUANTIA CRP)-QUANTIA-CRP IS A TURBIDIMETRIC IMMUNOASSAY FOR THE DETEMINATION OF C-REACTIVE PROTEIN BASED ON THE

	PRINCIPLE OF AGGLUTINATION REACTION.,LYOPHILIZED PAPAIN ENZYME SOLUTION FOR SEROLOGICAL APPLICATIONS(LYOPAP)-LYOPAP IS A LYOPHILIZED PAPAIN ENZYME REAGENT FOR SEROLOGICAL APPLICATIONS IN WHOLE BLOOD SPECIMENS. ,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF BENZODIAPINES IN HUMAN URINE(INSIGHT BZO (DEVICE))-INSIGHT BZO IS A RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF BENZODIAZAPINES IN HUMAN URINE.,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF OPIATES IN HUMAN URINE(INSIGHT OPI (DEVICE))-INSIGHT OPI IS A RAPID, QUALITATIVE, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF OPIATES IN HUMAN URINE.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR CRP UV (C-REACTIVE PROTEIN ULTRA VIOLET)(QUANTIA CRP UV)-QUANTIA-CRP UV IS A TURBIDIMETRIC IMMUNOASSAY FOR DETERMINATION OF C-REACTIVE PROTEIN BASED ON THE PRINCIPLE OF AGGLUTINATION REACTION.,ONE STEP PREGNANCY TEST (DIPSTICK)(TINA HCG (DIPSTICK))-TINA HCG ONE STEP PREGNANCY TEST IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG), A MARKER FOR PREGNANCY, IN URINE SPECIMENS.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR IGE(QUANTIA IGE)-QUANTIA-IGE IS A TURBIDIMETRIC IMMUNOASSAY FOR THE DETERMINATION OF IMMUNOGLOBULIN IGE BASED ON THE PRINCIPLE OF AGGLUTINATION REACTION.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR IGM(QUANTIA IGM)-QUANTIA-IGM IS A TURBIDIMETRIC IMMUNOASSAY FOR THE DETECTION OF IMMUNOGLOBULIN IGM IN HUMAN SERUM AND IS BASED ON THE PRINCIPLE OF AGGLUTINATION REACTION.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR ANTI-STREPTOLYSIN O (QUANTIA-ASO)-QUANTIA-ASO IS A TURBIDIMETRICIMMUNO ASSAY FOR DETERMINATION ANTI-STREPTOLYSIN 'O' BASED ON THE PRINCIPLE OF AGGLUTINATION REACTION.,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF PHENCYCLIDINE IN HUMAN URINE(INSIGHT PCP (DEVICE))-INSIGHT PCP IS A RAPID, QUALITATIVE, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF PHENCYCLIDINE IN HUMAN URINE.,LOW IONIC SALT SOLUTION FOR SEROLOGICAL APPLICATIONS (LISS) (TULISS)-TULISS IS BUFFERED LOW IONIC SALT SOLUTION OF APPROPRIATE SODIUM CHLORIDE MOLARITY USEFUL IN SEROLOGICAL APPLICATIONS SUCH AS ANTIBODY DETECTION AND CROSS MATCH TECHNIQUES.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR IGG(QUANTIA IGG)-QUANTIA-IGG IS A

	TURBIDIMETRIC IMMUNOASSAY FOR THE DETECTION OF IMMUNOGLOBULIN IGG IN HUMAN SERUM AND IS BASED ON THE PRINCIPLE OF AGGLUTINATION REACTION.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR RHEUMATOID FACTORS (QUANTIA RF)-QUANTIA RF IS A TURBIDIMETRIC IMMUNOASSAY FOR THE DETERMINATION OF RHEUMATOID FACTORS BASED ON THE PRINCIPLE OF AGGLUTINATION REACTION.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR C-REACTIVE PROTEIN (SINGLE POINT METHOD)(TURBILYTE CRP)-TURBILYTE-CRP IS A TURBIDIMETRIC IMMUNOASSAY FOR THE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM AND IS BASED ON THE PRINCIPLE OF AGGLUTINATION REACTION.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR C-REACTIVE PROTEIN ULTRA VIOLET(TURBODYNE CRP-UV)-TURBODYNE CRP UV IS A QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR DETERMINATION OF SERUM CRP UV ON TURBODYNE SC.,: QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR IGA(QUANTIA IGA)-QUANTIA-IGA IS A TURBIDIMETRIC IMMUNOASSAY FOR THE DETECTION OF IMMUNOGLOBULIN IGA IN HUMAN SERUM AND IS BASED ON THE PRINCIPLE OF AGGLUTINATION REACTION.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR RHEUMATOID FACTORS (TURBODYNE RF)-TURBODYNE RF IS A QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR RHEUMATOID FACTORS ON TURBODYNE SC AND IS SPECIFIC FOR SUITABLY MODIFIED FC FACTION OF HUMAN IGG SPECIFIC FOR IGM RHEUMATOID FACTORS., RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF PROPOXYPHENE IN HUMAN URINE(INSIGHT PPX (DEVICE))-INSIGHT PXP IS A RAPID, QUALITATIVE, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF PROPOXYPHENE IN HUMAN URINE.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR ANTI STREPTOLYSIN-O(TURBODYNE ASO)-TURBODYNE ASO IS A QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR DETERMINATION OF SERUM ASO ON TURBODYNE SC AND IS SPECIFIC FOR ANTI-STREPTOLYSIN 'O' ANTIBODIES.,ONE STEP PREGNANCY TEST (DEVICE)(TINA HCG (DEVICE))-TINA HCG ONE STEP PREGNANCY TEST IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG), A MARKER FOR PREGNANCY, IN URINE SPECIMENS.,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF TRAMADOL IN HUMAN URINE(INSIGHT TRA (DEVICE))-THE RAPID TEST DEVICE IS A RAPID VISUAL IMMUNOASSAY FOR THE QUALITATIVE, PRESUMPTIVE DETECTION OF TARAMADOL IN HUMAN URINE SPECIMENS,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY

	FOR IGE(TURBODYNE IGE)-TURBODYNE IGE IS A QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR ESTIMATION OF IGE IN HUMAN SERUM ON TURBODYNE SC AND IS SPECIFIC FOR IGE IN SERUM SPECIMEN.IT IS QUANTITATIVE, SCREENING TEST USED FOR IN VITRO DIAGNOSTICS ONLY AND FOR PROFESSIONAL USE ONLY.,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF OXYCODONE IN HUMAN URINE(INSIGHT OXY (DEVICE))-THE ONE STEP RAPID OXYCODONE TEST IS A RAPID, VISUAL, QUALITATIVE, COMPETITIVE BINDING IMMUNOASSAY FOR THE PRELIMINARY DETECTION OF OXYCODONE (PERCODAN, PERCOCET, ROXICODONE, OXYCONTIN) AND ITS METABOLITES IN HUMAN URINE,SLIDE TEST FOR C-REACTIVE PROTEIN(RHELAX CRP)-RHELAX CRP IS A QUALITATIVE AND SEMIQUANTITATIVE LATEX AGGLUTINATION SLIDE TEST FOR DETECTION OF C-REACTIVE PROTEIN.,ASSAYED CONTROL FOR QUALITY CONTROL PROCEDURES OF FERRITIN IMMUNOASSAYS (TURBODYNE FERRITIN CONTROL LEVEL 1)-TURBODYNE FERRITIN CONTROL IS USEFUL FOR VALIDATING THE CALIBRATION AND PERFORMANCE OF THE TURBODYNE FERRITIN REAGENT USING TURBODYNE SC ANALYZER, LATEX SLIDE TEST FOR ANTI DEOXYRIBONUCLEOPROTEIN(RHELAX-SLE)-LATEX SLIDE TEST FOR ANTI DEOXYRIBONUCLEOPROTEIN, SLIDE TEST FOR ANTI STREPTOLYSIN-O(RHELAX ASO)-RHELAX ASO IS A QUALITATIVE AND SEMIQUANTITATIVE LATEX AGGLUTINATION SLIDE TEST FOR DETECTION OF ANTI-STREPTOLYSIN O.,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF BUPRENORPHINE IN HUMAN URINE(INSIGHT BUP (DEVICE))-INSIGHT BUP IS A RAPID QUALITATIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF BUPRENORPHINE IN HUMAN URINE. THIS TEST IS USED TO SCREEN THE BUPRENORPHINE INTOXICATION.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR ANTI STREPTOLYSIN-O (SINGLE POINT METHOD)(TURBILYTE ASO)-TURBILYTE-ASO IS A TURBIDIMETRIC IMMUNOASSAY FOR THE DETERMINATION OF ANTISTREPTOLYSIN 'O' AND IS BASED ON THE PRINCIPLE OF AGGLUTINATION REACTION.,CALCIUM CHLORIDE READY TO USE REAGENT FOR USE WITH APTT REAGENTS-CALCIUM CHLORIDE IS A READY TO USE SOLUTION FOR USE WITH APTT REAGENTS ONLY, RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF METHADONE IN HUMAN URINE(INSIGHT MTD (DEVICE))-INSIGHT MTD IS A RAPID, QUALITATIVE, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF METHADONE IN HUMAN URINE.,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF KETAMINE IN HUMAN URINE(INSIGHT KET (DEVICE))-INSIGHT KET IS A

	RAPID, QUALITATIVE, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF KETAMINE IN HUMAN URINE.,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF NICOTINE (COTININE) IN HUMAN URINE(INSIGHT COT (DEVICE))-INSIGHT COT IS A RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY TO DETECT THE PRESENCE OF COTININE (NICOTINE METABOLITE) IN HUMAN URINE SPECIMEN.,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF METAMPHETAMINE IN HUMAN URINE(INSIGHT MET (DEVICE))-INSIGHT MET IS A RAPID, QUALITATIVE, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF METHAMPHETAMINE IN HUMAN URINE.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR C4 (TURBODYNE C4)-CLINICALLY COMPLEMENT DETERMINATION HELPS TO DETECT WHETHER THE COMPLEMENT SYSTEM HAS BEEN ACTIVATED. A DECREASE IN COMPLEMENT COMPONENTS DUE TO ACTIVATION OF COMPLEMENT SYSTEM OR A HEREDITARY DEFICIENCY AND/OR DYSFUNCTION OF A COMPLEMENT COMPONENT IS OF CLINICAL SIGNIFICANCE. C4 IS A CENTRAL COMPONENT OF THE COMPLEMENT SYSTEM. C4 IS THE RATE-LIMITING FACTOR FOR BOTH THE ALTERNATE AND THE CLASSICAL COMPLEMENT PATHWAYS. C4 IS OFTEN DECREASED IN ACTIVE FORMS OF SLE AND MEMBRANOPROLIFERATIVE GLOMERULONEPHRITIS. C4 FIXATION ON RED CELLS AND ON TISSUE MAY RESULT IN AUTOIMMUNE HAEMOLYTIC DISORDER OR SEVERE TISSUE DAMAGE. INCREASED LEVELS OF C4 ARE OBSERVED IN BILIARY OBSTRUCTION, NEPHROTIC SYNDROME AND DURING CORTCOSTEROID THERAPY. INFORMATION REGARDING THE CONCENTRATION OF C4 CAN BE OBTAINED BY USING TURBODYNE C4 REAGENTS. TURBODYNE C4 IS AN IMMUNOTURBIDIMETRIC ASSAY FOR THE MEASUREMENT OF TOTAL C4 IN HUMAN SERUM., QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR MICROALBUMINURIA (TURBODYNE MA)-TURBODYNE MA IS A QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR DETERMINATION OF MICROALBUMINURIA ON TURBODYNE SC AND IS SPECIFIC FOR HUMAN ALBUMIN IN URINE SPECIMEN.IT IS QUANTITATIVE, SCREENING TEST USED FOR IN VITRO DIAGNOSTICS ONLY AND FOR PROFESSIONAL USE.,DILUTE RUSSELL'S VIPERS VENOM TEST (DRVVT) FOR CONFIRMATION OF LUPUS ANTICOAGULANTS(L A CONFIRM)-DILUTE RUSSELL'S VIPERS VENOM TEST (DRVVT) FOR CONFIRMATION OF LUPUS ANTICOAGULANTS,LISS SOLUTION (MATRIX DILUENT 2)-MATRIX DILUENT – 2 LISS IS A MODIFIED LOW IONIC STRENGTH SALINE SOLUTION FOR PREPARATION OF RED CELL SUSPENSION USED FOR MATRIX GEL SYSTEM. IT IS USED FOR IN VITRO DIAGNOSTICS ONLY AND FOR PROFESSIONAL USE.,

	QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR IGE (TURBOSMART IGE)-TURBOSMART IGE IS A IMMUNOTURBIDIMETRIC ASSAY FOR DETERMINATION OF IGE IN SERUM ON TURBOSMART SC ANALYSER. IT IS IMMUNOTURBIDIMETRIC, SCREENING TEST USED FOR IN VITRO DIAGNOSTICS ONLY AND FOR PROFESSIONAL USE ONLY.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR C3 (TURBODYNE C3)-TURBODYNE C3 IS A QUANTITATIVE TURBIDIMETRIC IMMUNOTURBIDIMETRIC ASSAY FOR DETERMINATION OF C3 IN HUMAN SERUM ON TURBODYNE SC IN SERUM SPECIMENS. IT IS QUANTITATIVE, SCREENING TEST USED FOR IN VITRO DIAGNOSTICS ONLY AND FOR PROFESSIONAL USE ONLY., RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF IGM ANTIBODIES TO HAV IN HUMAN SERUM/PLASMA(INSIGHT HAV IGM (DEVICE))-INSIGHT HAV IGM IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF IGM ANTIBODIES TO HEPATITIS A VIRUS IN HUMAN SERUM/PLASMA,RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF HEPATITIS B SURFACE ANTIBODIES (HBSAB) IN HUMAN SERUM(INSIGHT HBSAB (DEVICE))-INSIGHT HBSAB IS A RAPID, SELF-PERFORMING, QUALITATIVE, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF HBSAB IN HUMAN SERUM.,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF HEPATITIS B ENVELOPE ANTIBODIES (HBEAB) IN HUMAN SERUM(INSIGHT HBEAB (DEVICE))-INSIGHT HBEAB IS A RAPID, SELF-PERFORMING, QUALITATIVE, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF HBEAB IN HUMAN SERUM.,DILUTE RUSSELL'S VIPERS VENOM TEST (DRVVT) FOR SCREENING OF LUPUS ANTICOAGULANTS (L A SCREEN)-DILUTE RUSSELL'S VIPERS VENOM TEST (DRVVT) FOR SCREENING OF LUPUS ANTICOAGULANTS,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF HEPATITIS B CORE ANTIBODIES (HBCAB) IN HUMAN SERUM(INSIGHT HBCAB (DEVICE))-INSIGHT HBCAB IS A RAPID, SELF-PERFORMING, QUALITATIVE, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF HBCAB IN HUMAN SERUM.,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE SIMULTANEOUS DETECTION OF AMPHETAMINE, BARBITURATES, BENZODIAZEPINE, COCAINE, TETRAHYDROCANNABINOL AND OPIATES IN URINE (INSIGHT DOA PANEL 6.1)-INSIGHT DOA PANEL 6.1 IS A RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE SIMULTANEOUS DETECTION OF TETRAHYDROCANNABINOL, AMPHETAMINE, BARBITURATES, BENZODIAZEPINE, COCAINE AND OPIATES IN URINE SPECIMEN. IT IS A QUALITATIVE, SCREENING TEST USED FOR IN VITRO DIAGNOSTICS ONLY AND FOR PROFESSIONAL USE.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR

	DETERMINATION OF FERRITIN IN HUMAN SERUM(TURBOSMART FERRITIN)-TURBOSMART FERRITIN IS A TURBIDIMETRIC IMMUNOASSAY FOR THE DETECTION OF FERRITIN IN HUMAN SERUM AND IS BASED ON THE PRINCIPLE OF AGGLUTINATION REACTION, STABILIZED ACTIVATED PAPAIN ENZYME SOLUTION FOR SEROLOGICAL APPLICATIONS(LIQUIPAP)-LIQUIPAP IS A LIQUID STABLE PAPAIN ENZYME REAGENT FOR SEROLOGICAL APPLICATIONS IN WHOLE BLOOD SPECIMENS. .,DILUTE RUSSELL'S VIPERS VENOM TEST (DRVVT) FOR SCREENING AND CONFIRMATION OF LUPUS ANTICOAGULANTS(LADS)-DILUTE RUSSELL'S VIPERS VENOM TEST (DRVVT) FOR SCREENING AND CONFIRMATION OF LUPUS ANTICOAGULANTS,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR RHEUMATOID FACTORS (TURBOSMART RF)-TURBOSMART RF IS A QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR RHEUMATOID FACTORS AND IS SPECIFIC FOR SUITABLY MODIFIED FC FACTION OF HUMAN IGG SPECIFIC FOR IGM RHEUMATOID FACTORS. ,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR HBA1C(TURBOSMART HBA1C)-TURBOSMART HBA1C IS A QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR DETERMINATION OF HBA1C IN HUMAN BLOOD. IT IS QUANTITATIVE, SCREENING TEST USED FOR IN VITRO DIAGNOSTICS ONLY AND FOR PROFESSIONAL USE,RAPID COMPETITIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF THC IN URINE(INSIGHT THC (DEVICE))-INSIGHT THC IS A RAPID, SELF-PERFORMING, QUALITATIVE, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF TETRAHYDROCANNABINOL IN HUMAN URINE.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR DETERMINATION OF FERRITIN IN HUMAN SERUM(TURBODYNE FERRITIN)-TURBODYNE FERRITIN IS A QUANTITATIVE TURBIDIMETRIC IMMUNOASAY FOR THE DETERMINATION OF FERRITIN ON TURBODYNE SC..,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR LIPOPROTEIN A(QUANTIA LP(A))-TURBIDIMETRIC IMMUNOASSAY FOR ESTIMATION OF LIPO PROTEIN (A) IN HUMAN SERUM.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR MICROALBUMINURIA(QUANTIA MA)-TURBIDIMETRIC IMMUNOASSAY FOR DETERMINATION OF MICROALBUMINURIA,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR CYSTATIN-C(QUANTIA CYSTATIN C)-QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR ESTIMATION OF COMPLEMENT CYSTATIN C IN HUMAN SERUM.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY HBA1C (TURBODYNE HBA1C)-TURBODYNE HBA1C IS A QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR DETERMINATION OF HBA1C IN HUMAN BLOOD.IT IS QUANTITATIVE, SCREENING TEST USED FOR IN VITRO DIAGNOSTICS ONLY AND FOR PROFESSIONAL

	USE.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR MICROALBUMINURIA (SINGLE POINT METHOD)(TURBILYTE MA)-TURBILYTE-MA IS A TURBIDIMETRIC IMMUNOASSAY FOR THE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM AND IS BASED ON THE PRINCIPLE OF AGGLUTINATION REACTION.,LATEX SLIDE TEST FOR ANTIBODIES TO TOXOPLASMA GONDII(TOXOGEN)-LATEX SLIDE TEST FOR ANTIBODIES TO TOXOPLASMA GONDII, QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR MICROALBUMINURIA(TURBOSMART MA)-TURBOSMART MA IS A QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR DETERMINATION OF MICROALBUMINURIA AND IS SPECIFIC FOR HUMAN ALBUMIN, RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF IGM ANTIBODIES TO HEV IN HUMAN SERUM/PLASMA(INSIGHT HEV IGM (DEVICE))-INSIGHT HEV IGM IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF IGM ANTIBODIES TO HEPATITIS E VIRUS IN HUMAN SERUM/PLASMA,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR C3(QUANTIA C3)-TURBIDIMETRIC IMMUNOASSAY FOR ESTIMATION OF COMPLEMENT C3 IN HUMAN SERUM.,INDIRECT LATEX SLIDE TEST FOR MICROLBUMINURIA (MICROTEX)-INDIRECT LATEX SLIDE TEST FOR MICROLBUMINURIA, QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR C-REACTIVE PROTEIN ULTRA-SENSITIVE(QUANTIA CRP-US)-C-REACTIVE PROTEIN (CRP), THE CLASSICAL ACUTE PHASE PROTEIN IS AN EXTREMELY VALUABLE MARKER FOR UNDERLYING SYSTEMIC INFLAMMATION. THE MEDIAN VALUE FOR SERUM CRP IN APPARENTLY HEALTHY ADULTS IS ~ 0.08 MG/DL, THE 90TH CENTILE OF DISTRIBUTION IN SUCH SUBJECTS IS ~ 0.03 MG/DL. THE BASELINE VALUES FOR CRP IN A HEALTHY INDIVIDUAL REMAIN STABLE OVER A LONG PERIOD'S TIME. THE BASELINE SERUM CONCENTRATION OF CRP PREDICTS THE RISK OF FUTURE MYOCARDIAL INFARCTION AND STROKE INDEPENDENT OF OTHER RISK FACTORS, IN APPARENTLY HEALTHY SUBJECTS.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR C4 (TURBOSMART C4)-TURBOSMART C4 IS A QUANTITATIVE TURBIDIMETRIC IMMUNOTURBIDIMETRIC ASSAY FOR DETERMINATION OF C4 IN HUMAN SERUM,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR C4(QUANTIA C4)-TURBIDIMETRIC IMMUNOASSAY FOR ESTIMATION OF COMPLEMENT C4 IN HUMAN SERUM.,QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR C-REACTIVE PROTEIN ULTRA VIOLET(TURBOSMART CRP-UV)-TURBOSMART CRP IS A TURBIDIMETRIC IMMUNOASSAY FOR THE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM, QUANTITATIVE TURBIDIMETRIC IMMUNOASSAY FOR C3 (TURBOSMART C3)-TURBOSMART C3 IS A QUANTITATIVE TURBIDIMETRIC IMMUNOTURBIDIMETRIC ASSAY FOR

		DETERMINATION OF C3 IN HUMAN SERUM
2793	MFG/IVD/2019/000046	1.License Holder Name: SENSA CORE MEDICAL INSTRUMENTATION PVT. LTD. 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:BLOOD HEMOGLOBIN MEASURING TEST STRIPS(HEMO SPARK BLOOD HEMOGLOBIN MEASURING TEST STRIPS)-SENSA CORE'S HEMO SPARK TEST STRIPS ARE FIRM PLASTIC STRIPS ONTO WHICH A MULTI LAYER DRY REAGENT IS AFFIXED AND ARE INTENDED TO BE READ ON THE HEMO SPARK METER. THE TEST STRIPS FUNCTION BY LYSING ERYTHROCYTES AND CONVERTING THE RELEASED HEMOGLOBIN INTO METHEMOGLOBIN. THIS TEST IS FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN (HB) AND CALCULATED HEMATOCRIT (HCT) IN CAPILLARY AND VENOUS WHOLE BLOOD BY USING REFLECTANCE PHOTOMETRY PRINCIPLE.,BLOOD GLUCOSE TEST STRIPS(GLUCO SPARK, BEATO, CONTROL D, GLUCOSPHERA, GLUCOMETER TEST STRIPS, GLUCOSPOT, XPRESSGLUCO)-BLOOD GLUCOSE TEST STRIPS ARE INTENDED TO BE USED FOR QUANTITATIVE BLOOD GLUCOSE TESTS IN FRESH CAPILLARY BLOOD.

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2794	MFG/IVD/2019/000047	1.License Holder Name: ROBONIK (INDIA) PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:HDL CHOLESTEROL (PRECIPITANT)-ESTIMATION OF HDL CHOLESTEROL BY PRECIPITATION METHOD IN SERUM OR PLASMA,HDL CHOLESTEROL (DIRECT) TEST KIT-ESTIMATION OF ESTIMATION OF HDL CHOLESTEROL IN SERUM OR PLASMA ,GLUCOSE TEST KIT-ESTIMATION OF GLUCOSE IN SERUM OR PLASMA,RHEUMATOID FACTOR (RF) TEST KIT-FOR DETERMINATION OF RF IN SERUM, PLASMA, OR BODY FLUID,HBA1C TEST KIT-ESTIMATION OF HBA1C IN PLASMA OR SERUM,PHOSPHORUS (INORGANIC) TEST KIT-ESTIMATION OF PHOSPHORUS IN SERUM OR PLASMA,HEMOGLOBIN TEST KIT-ESTIMATION OF HEMOGLOBIN IN BLOOD,TOTAL CHOLESTEROL TEST KIT-ESTIMATION OF TOTAL CHOLESTEROL IN PLASMA OR SERUM,AST/SGOT TEST KIT-ESTIMATION OF SGOT ENZYME IN SERUM OR PLASMA,TRIGLYCERIDES TEST KIT-ESTIMATION OF TRIGLYCERIDES IN PLASMA OR SERUM,CREATININE TEST KIT-ESTIMATION OF CREATININE IN SERUM OR PLASMA, ALBUMIN TEST KIT-ESTIMATION OF ALBUMIN IN PLASMA , SERUM, CALCIUM CHLORIDE SOLUTION-USED AS FIBRIN CLOT FORMATION IN THE DETERMINATION OF APTT,UREA (GLDH-UV KINATIC) TEST KIT-ESTIMATION OF UREA IN SERUM OR PLASMA,URIC ACID TEST KIT-ESTIMATION OF URIC ACID IN SERUM OR PLASMA,TOTAL PROTEIN TEST KIT-ESTIMATION OF TOTAL PROTEIN IN SERUM OR PLASMA, MICRO PROTEIN TEST KIT-ESTIMATION OF MICRO PROTEIN IN SERUM OR PLASMA ,UREA (MOD. BERTHELOT) TEST KIT-ESTIMATION OF UREA IN PLASMA OR SERUM,GAMMA GT TEST KIT-ESTIMATION OF GAMMA GT IN SERUM OR PLASMA,LDL CHOLESTEROL (DIRECT) TEST KIT-ESTIMATION OF LDL CHOLESTEROL IN SERUM OR PLASMA, AMYLASE TEST KIT-ESTIMATION OF ENZYME AMYLASE IN SERUM OR PLASMA,ALT/SGPT TEST KIT-ESTIMATION OF GPT IN SERUM OR PLASMA ,ALKALINE PHOSPHATASE TEST KIT-ESTIMATION OF ALKALINE PHOSPHATE IN SERUM, PLASMA,CALCIUM (OCPC) TEST KIT-ESTIMATION OF CALCIUM IN PLASMA & SERUM,BILIRUBIN (TOTAL & DIRECT) TEST KIT-ESTIMATION OF BILIRUBIN TOTAL & DIRECT IN SERUM & PLASMA ,BILIRUBIN TOTAL TEST KIT-ESTIMATION OF BILIRUBIN TOTAL IN SERUM, PLASMA,CHLORIDE TEST KIT-ESTIMATION OF CHLORIDE IN PLASMA OR SERUM,CALCIUM (ARTSENAZO) TEST KIT-ESTIMATION OF CALCIUM IN PLASMA OR SERUM

2795	MFG/IVD/2019/000048	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF C-REACTIVE PROTEIN IN HUMAN SERUM(INSIGHT CRP)-INSIGHT CRP IS A RAPID, SELF PERFORMING, IMMUNOCHROMATOGRAHIC ASSAY FOR THE DETECTION OF C-REACTIVE PROTEIN IN HUMAN SERUM.,RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF RHEUMATOID FACTORS IN HUMAN SERUM(INSIGHT RF)-INSIGHT RF IS A RAPID, SELF-PERFORMING, IMMUNOCHROMATOGRAHIC ASSAY FOR THE DETECTION OF RHEUMATOID FACTORS IN HUMAN SERUM
2796	MFG/IVD/2019/000049	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF ANTI STREPTOLYSIN O IN HUMAN SERUM(INSIGHT ASO)-INSIGHT ASO IS A RAPID, SELF-PERFORMING, IMMUNOCHROMATOGRAHIC ASSAY FOR THE DETECTION OF ANTI - STREPTOLYSIN O IN HUMAN SERUM

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2797	MFG/IVD/2019/000050	1.License Holder Name: INDRA CHEMICAL MANUFACTURING PRIVATE LIMITED 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:SODIUM (COLORIMETRIC) TEST KIT(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF SODIUM IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS.(MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,GLUCOSE TEST KIT (GOD/POD METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE IN HUMAN SERUM, PLASMA BASED ON GOD/POD METHOD ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,BILIRUBIN DIRECT (MODIFIED JENDRASSIK GROF) TEST KIT(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF BILIRUBIN DIRECT IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,ALKALINE PHOSPHATASE SINGLE REAGENT TEST KIT (AMP METHOD)(NIL)-:IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM, PLASMA BASED ON AMP METHOD ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,AMYLASE (CNPG3) TEST KIT(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF AMYLASE IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS.(MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,ALBUMIN TEST KIT(BCG METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN HUMAN SERUM, PLASMA BASED ON BCG METHOD ON PHOTOMETRIC SYSTEMS.(MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,CREATINE KINASE - NAC (IFCC - NAC ACTIVATED) TEST KIT(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF CK (IFCC - NAC ACTIVATED) IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,CREATININE TEST KIT (MODIFIED JAFFE METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA BASED ON MODIFIED JAFFE METHOD ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC). ,CHLORIDE (THIOCYANATE) TEST KIT(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF CHLORIDE IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS.(MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,UREA (BUN) TEST KIT (METHOD - UREASE, UV)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF UREA/ BLOOD UREA NITROGEN IN HUMAN SERUM, PLASMA BASED ON UREASE, UV METHOD ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,POTASSIUM (TPB - COLORIMETRIC) TEST KIT(NIL)-:IT IS INTENDED FOR QUANTITATIVE IN VITRO

	DETERMINATION OF POTASSIUM IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS.(MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,CALCIUM TEST KIT(ARSENAZO III METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN HUMAN SERUM, PLASMA BASED ON ARSENAZO III METHOD ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,PHOSPHOROUS (MOLYBDATE, UV) TEST KIT(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF PHOSPHOROUS IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS.(MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,ASPARTATE AMINOTRANSFERASE(AST/SGOT) TEST KIT (MODIFIED IFCC METHOD) (NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF SERUM GLUTAMIC-OXALOACETIC TRANSAMINASE(SGOT) (ALSO CALLED AS ASPARTATE AMINOTRANSFERASE(AST)) IN HUMAN SERUM, PLASMA BASED ON MODIFIED IFCC METHOD ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,CLEANER REAGENT FOR HEMATOLOGY ANALYZERS (NIL)-CLEANING REAGENT IS A STABILIZED AND MICRO FILTERED DETERGENT SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON HEMATOLOGY ANALYZERS.,ALANINE AMINOTRANSFERASE (ALT/SGPT) TEST KIT (MODIFIED IFCC METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF SERUM GLUTAMIC PYRUVIC TRANSAMINASE(SGPT) (ALSO CALLED ALANINE AMINOTRANSFERASE(ALT)) IN HUMAN SERUM, PLASMA BASED ON MODIFIED IFCC METHOD ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,ADENOSINE DEAMINASE TEST KIT (ENZYMATIC METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF ADENOSINE DEAMINASE IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,ALKALINE PHOSPHATASE TEST KIT (IFCC METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM, PLASMA BASED ON IFCC METHOD ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,CREATINE KINASE-MB TEST KIT (IMMUNOINHIBITION METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATINE KINASE-MB IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,BILIRUBIN TOTAL TEST KIT (JENDRASSIK GROF METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF BILIRUBIN TOTAL IN HUMAN SERUM, PLASMA BASED ON JENDRASSIK AND GROF METHOD

	ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,CS-ANTI BACTERIAL PHOSPHOR-FREE DETERGENT (NIL)-IT IS INTENDED FOR CLEANING REAGENT PROBE, REACTION CUVETTE AND SOAKING REACTION CUP OF THE CS SERIES AUTO-CHEMISTRY ANALYZER.,URIC ACID TEST KIT (TBHBA METHOD)(NIL)-: IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA BASED ON TBHBA METHOD ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,URIC ACID TEST KIT (TOPS METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,TOTAL CHOLESTEROL TEST KIT (CHOD/PAP METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL CHOLESTEROL IN HUMAN SERUM, PLASMA BASE ON CHOD/PAP METHOD ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,DILUENTS REAGENT FOR HEMATOLOGY ANALYZERS (NIL)-IT IS INTENDED FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUB POPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN (HGB) CONCENTRATION ON HEMATOLOGY ANALYZERS.,TOTAL PROTEIN TEST KIT (BIURET METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM, PLASMA BASED ON BIURET METHOD ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,LYSE REAGENT FOR HEMATOLOGY ANALYZERS(NIL)-IT IS INTENDED FOR CREATING THE HEMOLYSATES FOR 3-PART DIFFERENTIAL, TOTAL WBC COUNT AND HEMOGLOBIN (HGB) ESTIMATION IN HUMAN BLOOD ON HEMATOLOGY ANALYZERS, TRIGLYCERIDES TEST KIT (GPO/PAP METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM, PLASMA BASED ON GPO/PAP METHOD ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,HDL CHOLESTEROL DIRECT TEST KIT (ELIMINATION METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,LIPASE TEST KIT(COLORIMETRIC METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF LIPASE IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS (MANUAL SEMI-AUTOMATIC OR AUTOMATIC).,CREATININE SINGLE REAGENT TEST KIT(MODIFIED JAFFE METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF CREATININE IN HUMAN

	SERUM, PLASMA ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,GAMMA-GLUTAMYL TRANSPEPTIDASE TEST KIT (GLUPA C METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF GAMMA-GLUTAMYL TRANSPEPTIDASE(GGT) IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS.(MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,CS-ALKALINE DETERGENT(NIL)-IT IS INTENDED FOR TO CLEAN SAMPLE PROBE AND REACTION CUVETTE OF CS SERIES AUTO-CHEMISTRY ANALYZER.,LDL CHOLESTEROL DIRECT TEST KIT(SELECTIVE DETERGENT METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF LDL CHOLESTEROL IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,TRIGLYCERIDES TEST KIT (TOPS METHOD)(NIL)-IT IS INTENDED FOR QUANTITATIVE IN VITRO DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2798	MFG/IVD/2019/000052	1.License Holder Name: KARWA ENTERPRISES PRIVATE LIMITED 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:FILARIA RAPID CARD TEST-TEST KIT FOR DETECTION OF FILARIA,VIRAL RNA EXTRACTION KIT-VIRAL RNA EXTRACTION KIT IS DESIGNED FOR RAPID ISOLATION AND PURIFICATION OF NUCLEIC ACIDS FROM SERUM, PLASMA OR SWABS,T4 ELISA KIT-TEST KIT FOR DETECTION OF T4,POTASSIUM REAGENT KIT-KIT FOR ESTIMATION OF POTASSIUM,T3 ELISA KIT-TEST KIT FOR DETECTION OF T3,OXALATE CALIBRATOR KIT-KIT FOR CALIBRATION OF OXALATE PARAMETER,DENGUE IGM ELISA KIT-TEST KIT FOR DETECTION OF DENGUE IGM ANTIBODIES,DIRECT HDL CHOLESTEROL REAGENT KIT-KIT FOR ESTIMATION OF HDL CHOLESTEROL,DENGUE IGG/IGM ANTIBODY CARD TEST-TEST KIT FOR DETECTION OF DENGUE IGG/IGM ANTIBODIES,SEMEN FRUCTOSE REAGENT KIT-KIT FOR ESTIMATION OF FRUCTOSE IN SEMEN,DENGUE IGG/IGM ELISA KIT-TEST KIT FOR DETECTION OF DENGUE IGG/IGM ANTIBODIES,ANTI STREPTOLYSIN -O (ASO) TEST-KIT FOR DETECTION OF ASO,DENGUE/CHIKUNGUNYA RAPID COMBO CARD TEST-TEST KIT FOR DETECTION OF DENGUE AND CHIKUNGUNYA,TRIGLYCERIDE REAGENT KIT-KIT FOR ESTIMATION OF TRIGLYCERIDES, CHIKUNGUNYA RAPID CARD TEST-TEST KIT FOR DETECTION OF CHIKUNGUNYA,GLUCOSE REAGENT KIT-KIT FOR ESTIMATION OF GLUCOSE,TYPHOID RAPID CARD TEST-TEST KIT FOR DETECTION OF TYPHOID INFECTION,HDL CHOLESTEROL (PRECIPITATING) REAGENT KIT-KIT FOR ESTIMATION OF HDL CHOLESTEROL,FREE T3 ELISA KIT-TEST KIT FOR DETECTION OF FREE T3,DIRECT BILIRUBIN REAGENT KIT-KIT FOR ESTIMATION OF DIRECT BILIRUBIN,LH RAPID TEST-KIT FOR ESTIMATION OF LUTEINIZING HORMONE (LH),AMYLASE REAGENT KIT-KIT FOR ESTIMATION OF AMYLASE,TSH ELISA KIT-TEST KIT FOR DETECTION OF TSH,LIPASE REAGENT KIT-KIT FOR ESTIMATION OF LIPASE,ULTRA TSH (UTSH) ELISA KIT-TEST KIT FOR DETECTION OF TSH,HEMATOLOGY CONTROL KIT-TEST KIT FOR QUALITY CONTROL OF HEMATOLOGY ANALYZERS,FREE T4 ELISA KIT-TEST KIT FOR DETECTION OF FREE T4,ALBUMIN REAGENT KIT-KIT FOR ESTIMATION OF ALBUMIN,DENGUE IGG ELISA KIT-TEST KIT FOR DETECTION OF DENGUE IGG ANTIBODIES,GAMMA GT REAGENT KIT-KIT FOR ESTIMATION OF GAMMA GT,HCG RAPID TEST-TEST KIT FOR THE DETECTION OF PREGNANCY IN URINE,GLYCOHEMOGLOBIN (HBA1C) REAGENT KIT-KIT FOR ESTIMATION OF GLYCOHEMOGLOBIN (HBA1C),GLUCOSE STRIPS KIT-FOR MEASUREMENT OF GLUCOSE LEVEL IN BLOOD,IRON / TIBC REAGENT KIT-KIT FOR ESTIMATION OF IRON / TIBC,IMMUNOASSAY MICRO ALBUMIN KIT-FOR QUANTITATIVE DETERMINATION OF MICRO ALBUMIN IN HUMAN URINE,KALA AZAR RAPID CARD TEST-KIT FOR DETECTION OF KALA AZAR,HEMOGLOBIN

	CUVETTES KIT-THE HEMOGLOBIN CUVETTES KIT IS USED FOR QUANTITATIVELY MEASURING HEMOGLOBIN IN HUMAN WHOLE BLOOD.,CHOLINE- ESTERASE REAGENT KIT-KIT FOR ESTIMATION OF CHOLINE ESTERASE,HEMOGLOBIN STRIPS KIT-THE HEMOGLOBIN STRIPS KIT IS USED FOR QUANTITATIVELY MEASURING HEMOGLOBIN IN HUMAN WHOLE BLOOD.,TOTAL BILIRUBIN REAGENT KIT-KIT FOR ESTIMATION OF TOTAL BILIRUBIN,IMMUNOASSAY INTERLEUKIN-6 (IL6) KIT-IMMUNOASSAY INTERLEUKIN-6 (IL-6) KIT IS USED FOR QUANTITATIVE DETERMINATION OF INTERLEUKIN-6 (IL-6) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.,H. PYLORI RAPID CARD TEST-KIT FOR DETECTION OF H. PYLORI,LIPID PANEL TEST KIT-LIPID PANEL TEST KIT IS USED TO MEASURE THE LIPID CONCENTRATION IN WHOLE BLOOD, PLASMA AND SERUM.,CHLORIDE REAGENT KIT-KIT FOR ESTIMATION OF CHLORIDE,IMMUNOASSAY D-DIMER KIT-FOR QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN WHOLE BLOOD AND PLASMA.,CK-MB RAPID CARD TEST-KIT FOR DETECTION OF CK-MB,RF RAPID CARD TEST-KIT FOR DETECTION OF RHEUMATOID FACTOR (RF),UREA/BUN REAGENT KIT-KIT FOR ESTIMATION OF UREA/BUN,AMMONIA REAGENT KIT-KIT FOR ESTIMATION OF AMMONIA,ALKALINE PHOSPHATASE REAGENT KIT-KIT FOR ESTIMATION OF ALKALINE PHOSPHATASE,RHEUMATOID FACTOR (RF) TEST-KIT FOR DETECTION OF RHEUMATOID FACTOR (RF),DIRECT LDL CHOLESTEROL REAGENT KIT-KIT FOR ESTIMATION OF LDL CHOLESTEROL,URINALYSIS CONTROL – NEGATIVE-KIT FOR QUALITY CONTROL OF URINE TEST STRIPS,G6PDH REAGENT KIT-KIT FOR ESTIMATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PDH),CHEMISTRY CONTROL – ABNORMAL-KIT FOR QUALITY CONTROL OF VARIOUS BIOCHEMISTRY PARAMETERS,URINE TEST STRIPS-KIT FOR DETECTION OF VARIOUS COMBINATION OF URINE ANALYSIS PARAMETERS E.G. UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH, ASCORBIC ACID, MICRO ALBUMIN, CALCIUM, CREATININE ETC. IN URINE,CK-MB REAGENT KIT-KIT FOR ESTIMATION OF CREATINE KINASE (MB),CREATININE REAGENT KIT-KIT FOR ESTIMATION OF CREATININE,MYOGLOBIN RAPID CARD TEST-KIT FOR DETECTION OF MYOGLOBIN,LEPTOSPIRA RAPID CARD TEST-KIT FOR DETECTION OF LEPTOSPIRA,CALCIUM REGENT KIT-KIT FOR ESTIMATION OF CALCIUM,CREATINE KINASE (CK-NAC) REAGENT KIT-KIT FOR ESTIMATION OF CREATINE KINASE (NAC),ALT (SGPT) REAGENT KIT-KIT FOR ESTIMATION OF ALT (SGPT),AST (SGOT) REAGENT KIT-CLINICAL CHEMISTRY REAGENTS/KITS,CSF/MICRO PROTEIN REAGENT KIT-KIT FOR ESTIMATION OF CSF/MICRO PROTEIN,BILIRUBIN (DIRECT & TOTAL) REAGENT KIT-KIT FOR ESTIMATION OF TOTAL AND DIRECT BILIRUBIN,LYSE-REAGENT FOR

	USE IN HEMATOLOGY ANALYZER,LDH REAGENT KIT-KIT FOR ESTIMATION OF LDH,CHOLESTEROL REAGENT KIT-KIT FOR ESTIMATION OF CHOLESTEROL,WIDAL TEST KIT-KIT FOR DETECTION OF S.TYPHI / PARATYPHI ANTIBODY,PHOSPHORUS REAGENT KIT-KIT FOR ESTIMATION OF PHOSPHORUS,MAGNESIUM REAGENT KIT-KIT FOR ESTIMATION OF MAGNESIUM,HEMOGLOBIN REAGENT KIT-KIT FOR ESTIMATION OF HEMOGLOBIN,PROBE CLEANER-REAGENT FOR USE IN HEMATOLOGY ANALYZER,HDL/LDL CALIBRATOR-KIT FOR CALIBRATION OF HDL/LDL,DILUENT-REAGENT FOR USE IN HEMATOLOGY ANALYZER,TOTAL PROTEIN REAGENT KIT-KIT FOR ESTIMATION OF TOTAL PROTEIN,URIC ACID REAGENT KIT-KIT FOR ESTIMATION OF URIC ACID,SODIUM REAGENT KIT-KIT FOR ESTIMATION OF SODIUM,ACID PHOSPHATASE REAGENT KIT-KIT FOR ESTIMATION OF ACID PHOSPHATASE,CHEMISTRY CONTROL – NORMAL-KIT FOR QUALITY CONTROL OF VARIOUS BIOCHEMISTRY PARAMETERS,ACE REAGENT KIT-KIT FOR ESTIMATION OF ANGIOTENSIN CONVERTING ENZYME (ACE) ACTIVITY,OXALATE CONTROL KIT-KIT FOR QUALITY CONTROL OF OXALATE PARAMETER, G6PDH CALIBRATOR-KIT FOR CALIBRATION OF G6PDH PARAMETER, CALCIUM CHLORIDE REAGENT-AUXILIARY REAGENT FOR LABORATORY USE,OXALATE REAGENT KIT-KIT FOR ESTIMATION OF OXALATE,LEO (I) LYSE-REAGENT FOR USE IN HEMATOLOGY ANALYZER,C-REACTIVE PROTEIN (CRP) TEST-KIT FOR DETECTION OF C-REACTIVE PROTEIN,LBA LYSE-REAGENT FOR USE IN HEMATOLOGY ANALYZER,CHEMISTRY CALIBRATOR-KIT FOR CALIBRATION OF VARIOUS BIOCHEMISTRY PARAMETERS,G6PDH CONTROL KIT-KIT FOR QUALITY CONTROL OF G6PDH PARAMETER,EZ CLEANER-REAGENT FOR USE IN HEMATOLOGY ANALYZER,RINSE (CLEANER)-REAGENT FOR USE IN HEMATOLOGY ANALYZER,LEO (II) LYSE-REAGENT FOR USE IN HEMATOLOGY ANALYZER,LH LYSE-REAGENT FOR USE IN HEMATOLOGY ANALYZER,HBA1C CONTROL KIT-KIT FOR QUALITY CONTROL OF HBA1C PARAMETER,UREA BERTHELOT REAGENT KIT-KIT FOR ESTIMATION OF UREA,URINALYSIS CONTROL – POSITIVE-KIT FOR QUALITY CONTROL OF URINE TEST STRIPS,HBA1C CALIBRATOR-KIT FOR CALIBRATION OF HBA1C PARAMETER

2799	MFG/IVD/2019/000053	1.License Holder Name: CORAL CLINICAL SYSTEMS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:ALPHA AMYLASE KIT (DIRECT SUBSTRATE METHOD)-AMYLASE KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE DIRECT SUBSTRATE METHOD FOR THE DETERMINATION OF AMYLASE ACTIVITY IN SERUM, PLASMA, OR URINE,BILIRUBIN T & D KIT (MOD. JENDRASSIK & GROF'S METHOD)-BILIRUBIN KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE MOD. JENDRASSIK ANF GROF'S METHOD FOR THE DETERMINATION OF DIRECT AND TOTAL BILIRUBIN IN SERUM
2800	MFG/IVD/2019/000054	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:SLIDE TEST FOR C-REACTIVE PROTEIN(RHELAX CRP)-RHELAX CRP IS A QUALITATIVE AND SEMIQUANTITATIVE LATEX AGGLUTINATION SLIDE TEST FOR DETECTION OF C-REACTIVE PROTEIN.,SLIDE TEST FOR ANTI STREPTOLYSIN-O(RHELAX ASO)-RHELAX ASO IS A QUALITATIVE AND SEMIQUANTITATIVE LATEX AGGLUTINATION SLIDE TEST FOR DETECTION OF ANTI-STREPTOLYSIN O.
2801	MFG/IVD/2019/000056	1.License Holder Name: CORAL CLINICAL SYSTEMS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:CK-MB (NAC ACT.) KIT-CK-MB (NAC ACT.)KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE IMMUNOINHIBITION / MODIFIED IFCC METHOD FOR THE DETERMINATION OF CK-MB ACTIVITY IN SERUM,CK (NAC ACT.) KIT-CK (NAC ACT) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE MODIFIED IFCC METHOD FOR THE DETERMINATION OF CREATININE KINASE (CK) ACTIVITY IN SERUM

2802	MFG/IVD/2019/000057	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:D DIMER(NA)-IMMUNOTURBIDIMETRIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF D-DIMER CONCENTRATION IN HUMAN PLASMA ON COAGULOMETER.,HCV TEST-HCV RAPID TEST IS AN IMMUNOCHROMATOGRAPHIC ASSAY USED FOR DETECTION FOR HCV ANTIBODIES IN HUMAN SPECIMEN,HBSAG ELISA KIT (HBSAG ELISA KIT)-HBSAG ELISA KIT IS AN ENZYME IMMUNOASSAY INTENDED USED FOR THE QUALITATIVE DETECTION OF HBSAG (HEPATITIS B SURFACE ANTIGEN) IN HUMAN SERUM OR PLASMA. IT IS A SCREENING TEST FOR THE DETECTION OF HBSAG AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HBV. FOR PROFESSIONAL AND IN-VITRO DIAGNOSTIC USE ONLY. ,ANTI-D(IGM) BLOOD GROUPING REAGENT-THE MONOCLONAL BLOOD GROUPING REAGENT IS USED FOR DETECTION OF RH D ANTIGENS IN BLOOD BY AGGLUTINATION OF HUMAN RED BLOOD CELLS.,D-DIMER(NA)-IMMUNOTURBIDIMETRIC REAGENT FOR THE QUANTITATIVE DETERMINATION OF D-DIMER CONCENTRATION IN HUMAN PLASMA/BODY FLUID ON BIOCHEMISTRY ANALYZER ,ANTI-AB BLOOD GROUPING REAGENT-THE MONOCLONAL BLOOD GROUPING REAGENT IS USED FOR DETECTION OF AB ANTIGENS IN BLOOD BY AGGLUTINATION OF HUMAN RED BLOOD CELLS.,ABO RH (BLOOD GROUP) TEST CARD(NA) -THIS CARD IS USED FOR BED SIDE CONFIRMATION OF THE HUMAN BLOOD GROUP I.E. A, B, AB AND O INCLUDING RH FACTOR. THE TEST IS A TOOL TO RECONFIRM AN EARLIER KNOWN ABO- AND D-BLOOD TYPE FOR A PATIENT JUST BEFORE TRANSFUSION. THE TEST IS NOT TO BE USED AS THE SOLE DETERMINANT FOR BLOOD TYPING AND MUST BE CONFIRMED BY A LABORATORY REFERENCE METHOD BEFORE DECISIONS ON BLOOD TRANSFUSIONS OR BLOOD DONATION ARE BEING TAKEN.,SYPHILIS STRIP-SYPHILIS STRIP IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY USED FOR DETECTION OF ANTIBODIES (IGG & IGM) TO TREPONEMA PALLIDUM (TP) IN HUMAN SPECIMEN.,HIV 1&2 ELISA KIT (HIV 1&2 ELISA KIT)-HIV 1&2 ELISA KIT IS A 3RD GENERATION ENZYME IMMUNO ASSAY INTENDED USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HIV-1 AND HIV-2 IN HUMAN SERUM OR PLASMA. IT IS A SCREENING TEST FOR THE DETECTION OF ANTIBODIES AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HIV. FOR PROFESSIONAL AND IN-VITRO DIAGNOSTIC USE ONLY. ,ANTI-B BLOOD GROUPING REAGENT-THE MONOCLONAL BLOOD GROUPING REAGENT IS USED FOR DETECTION OF 'B' ANTIGENS IN BLOOD BY AGGLUTINATION OF HUMAN RED BLOOD CELLS.,HCV ELISA TEST (HCV ELISA TEST)-HCV ELISA KIT IS

	AN ENZYME IMMUNOASSAY INTENDED USED FOR THE QUALITATIVE DETECTION OF ANTIBODIES OF HCV (HEPATITIS C VIRUS) IN HUMAN SERUM OR PLASMA. IT IS A SCREENING TEST FOR THE DETECTION OF ANTIBODIES AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HCV. FOR PROFESSIONAL AND IN-VITRO DIAGNOSTIC USE ONLY. ,ANTI-D (IGG+ IGM) BLOOD GROUPING REAGENT-THE MONOCLONAL BLOOD GROUPING REAGENT IS USED FOR DETECTION OF RH D ANTIGENS IN BLOOD BY AGGLUTINATION OF HUMAN RED BLOOD CELLS.,MALARIA PF/ PV ANTIGEN-IT IS RAPID KIT FOR QUALITATIVE DETECTION AND DIFFERENTIATION OF PLASMODIUM FALCIPARUM, PLASMODIUM VIVAX, PLASMODIUM MALARIAE AND PLASMODIUM OVALE IN HUMAN WHOLE BLOOD.,HBSAG TEST-HBSAG RAPID TEST KIT IS AN IMMUNOCHROMATOGRAPHIC ASSAY USED FOR DETECTION FOR HEPATITIS B SURFACE ANTIGEN IN HUMAN SPECIMEN.,RPR-RPR TEST KIT IS USED FOR QUALITATIVE AND SEMI QUANTITATIVE DETECTION FOR REAGIN ANTIBODIES IN HUMAN SERUM.,SYPHILIS DEVICE-SYPHILIS RAPID TEST IS AN IMMUNOCHROMATOGRAPHIC ASSAY USED FOR DETECTION OF ANTIBODIES (IGG & IGM) TO TREPONEMA PALLIDUM (TP) IN HUMAN SPECIMEN,HELICOBACTER PYLORI ANTIGEN-THE H. PYLORI ANTIGEN IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF H. PYLORI (HELICOBACTER PYLORI) ANTIGEN IN HUMAN FECES. ,HIV 1/2 TEST-HIV 1/2 RAPID TEST IS AN IMMUNOCHROMATOGRAPHIC ASSAY USED FOR DETECTION OF ANTIBODIES SPECIFIC TO HIV-1 AND HIV-2 IN HUMAN SPECIMEN, ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT)- APTT (ACTIVATED PARTIAL THROMBOPLASTIN TIME) ASSAY KIT IS USED FOR DETERMINATION OF ACTIVATED PARTIAL THROMBOPLASTIN TIME IN HUMAN PLASMA,ANTI-A BLOOD GROUPING REAGENT-THE MONOCLONAL BLOOD GROUPING REAGENT IS USED FOR DETECTION OF ‘A’ ANTIGENS IN BLOOD BY AGGLUTINATION OF HUMAN RED BLOOD CELLS.,DENGUE NS1 ANTIGEN-DENGUE NS1 RAPID TEST KIT IS AN IMMUNOCHROMATOGRAPHIC ASSAY USED FOR DETECTION FOR DENGUE NS1 ANTIGEN IN HUMAN SERUM/PLASMA/WHOLE BLOOD., MALARIA PF/PAN ANTIGEN-MALARIA PF/PAN ANTIGEN IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION AND DIFFERENTIATION OF PLASMODIUM FALCIPARUM AND/OR PLASMODIUM VIVAX, PLASMODIUM OVALE AND PLASMODIUM MALARIAE ANTIGEN IN HUMAN WHOLE BLOOD,DENGUE COMBO (NS1 ANTIGEN + IGG/IGM ANTIBODY)-THE DENGUE COMBO RAPID TEST KIT IS AN IMMUNOCHROMATOGRAPHIC ASSAY USED FOR DETECTION FOR DENGUE NS1 ANTIGEN AND IGG/IGM ANTIBODIES SPECIFIC TO DENGUE IN HUMAN SPECIMEN.,RUBELLA IGG/IGM ANTIBODY-RUBELLA IGG/IGM IS AN IMMUNOCHROMATOGRAPHIC ASSAY USED

		FOR DETECTION FOR IGG AND IGM ANTIBODIES TO RUBELLA VIRUS IN HUMAN SERUM/PLASMA,PROTHROMBIN TIME (PT)-PT (THROMBOPLASTIN TIME) ASSAY KIT IS USED FOR DETERMINATION OF PROTHROMBIN TIME IN HUMAN PLASMA.,MALARIA PF ANTIGEN -MALARIA PF ANTIGEN TEST IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF PLASMODIUM FALCIPARUM IN HUMAN WHOLE BLOOD,DENGUE NS1 ANTIGEN ELISA-DENGUE NS1 ANTIGEN ELISA ASSAY IS USED FOR IN VITRO QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN SERUM OR PLASMA .,MALARIA PF-PV ANTIGEN -MALARIA PF/PV ANTIGEN IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION AND DIFFERENTIATION OF PLASMODIUM FALCIPARUM AND PLASMODIUM VIVAX IN HUMAN WHOLE BLOOD.,TYPHOID ANTIGEN-TYPHOID ANTIGEN TEST IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF S.TYPHI AND PARATYPHI ANTIGENS IN HUMAN SPECIMEN.,MALARIA PAN ANTIGEN-MALARIA PAN ANTIGEN TEST IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF PLASMODIUM FALCIPARUM, PLASMODIUM VIVAX, PLASMODIUM OVALE AND PLASMODIUM MALARIAE IN HUMAN WHOLE BLOOD, TROPONIN I-TROPONIN I IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF CARDIAC TROPONIN I (CTNI) AND ITS COMPLEX IN HUMAN SERUM, PLASMA OR WHOLE BLOOD., TOXOPLASMA IGG/IGM ANTIBODY-TOXOPLASMA IGG/IGM IS AN IMMUNOCHROMATOGRAPHIC ASSAY USED FOR DETECTION FOR IGG AND IGM ANTIBODIES TO TOXOPLASMA GONDII IN HUMAN SERUM/PLASMA
2803	MFG/IVD/2019/000059	1.License Holder Name: CORAL CLINICAL SYSTEMS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:CALCIUM KIT (ARSENAZO-III METHOD)-CALCIUM KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE ARSENAZO III METHOD FOR THE DETERMINATION OF CALCIUM IN SERUM OR PLASMA.,CALCIUM KIT (OCPC)-CALCIUM KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE O-CRESOLPHTHALEIN COMPLEXONE (OCPC) METHOD FOR THE DETERMINATION OF CALCIUM IN SERUM OR PLASMA

2804	MFG/IVD/2019/000060	1.License Holder Name: CORAL CLINICAL SYSTEMS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:GLUCOSE KIT (GOD/POD METHOD)-GLUCOSE KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE GOD/POD (GLUCOSE OXIDASE/ PEROXIDASE) METHOD FOR THE DETERMINATION GLUCOSE IN SERUM, PLASMA AND CSF,ECOGLUCO KIT (GOD/POD METHOD)-ECOGLUCO KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE GOD/POD (GLUCOSE OXIDASE/ PEROXIDASE) METHOD FOR THE DETERMINATION OF GLUCOSE IN SERUM, PLASMA AND CSF

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2805	MFG/IVD/2019/000061	1.License Holder Name: ARKRAY HEALTHCARE PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:AMPICILLIN / SULBACTUM SENSITIVITY DISC (SAM), 10 + 10 G/ DISC (CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,STAINED SALMONELLA S. PARATYPHI 'A(H)' ANTIGEN : FOR WIDAL TEST-DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TESTS,CHLORAMPHENICOL SENSITIVITY DISC (C), 30 G/ DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,STAINED SALMONELLA S.PARATYPHI "C(O)" ANTIGEN FOR WIDAL TEST-DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TESTS.,IMMUNOTURBIDIMETRIC LATEX TEST, END POINT ASSAY(AUTOSPAN TURBI GOLD HBA1C DIRECT TEST KIT)-AUTOSPAN TURBI GOLD HBA1C DIRECT TEST KIT IS AN IN VITRO QUANTITATIVE DETERMINATION OF HAEMOGLOBIN A1C (HBA1C) IN HUMAN BLOOD FOR EVALUATION OF GLYCEMIC CONTROL

	IN DIABETES MELLITUS. IT PROVIDES INDICATION OF GLUCOSE LEVELS OVER THE PRECEDING 4 TO 8 WEEKS. FULLY AUTOMATED AND SEMI AUTOMATED PHOTOMETRIC ANALYSERS ARE REQUIRED TO PERFORM THIS TEST.,ASO (ANTISTREPTOLYSIN 'O') LATEX TEST KIT-THE ASO ANTISTREPTOLYSIN “O” LATEX TEST KIT IS LATEX AGGLUTINATION ASSAY FOR THE QUALITATIVE AND SEMI QUANTITATIVE DETECTION OF ANTISTREPTOLYSIN ANTIBODIES (ASO) IN HUMAN SERUM. IT IS INTENDED FOR IN VITRO DIAGNOSTICS USE BY TRAINED HEALTHCARE PROFFEIONALS.,UREASE, BERTHELOT, END POINT ASSAY(AUTOSPAN UREA)-AUTOSPAN UREA IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM / PLASMA AND URINE. FULLY AUTOMATED, SEMI AUTOMATED PHOTOMETRIC ANALYSERS, SPECTROPHOTOMETER AND COLORIMETER ARE REQUIRED TO PERFORM THIS TEST.,STAINED SALMONELLA S. TYPHI ‘O’ ANTIGEN : FOR WIDAL TEST-DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TESTS, CEFTAZIDIME SENSITIVITY DISC (CAZ), 30 G/ DISC (CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,STAINED SALMONELLA ANTIGEN SET : FOR WIDAL TEST-DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TEST.,COMBINED MICROBIAL SENSITIVITY DISCS FOR GRAM POSITIVE ISOLATES (GP1)(CLAIRO COMBI)-CLAIRO COMBI - COMBINED MICROBIAL SENSITIVITY DISCS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,CRP (C-REACTIVE PROTEIN) LATEX TEST KIT-CRP (C-REACTIVE PROTEIN) LATEX TEST KIT IS USED AS IN VITRO QUALITATIVE AND SEMI-

	QUANTITATIVE LATEX SLIDE TEST TO DETECT CRP. THIS KIT IS INTENDED TO BE USED BY TRAINED LABORATORY PROFESSIONALS , CEPHALEXIN SENSITIVITY DISC (CFM), 30 G/ DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW. ,STAINED SALMONELLA ANTIGEN SET : FOR WIDAL TEST-DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TEST.,LEVOFLOXACIN SENSITIVITY DISC (LE), 5 G/DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,STAINED SALMONELLA S.PARATYPHI “B(O)” ANTIGEN FOR WIDAL TEST-DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TESTS.,STAINED SALMONELLA ANTIGEN SET : FOR WIDAL TEST-DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TESTS.,MODIFIED UV (IFCC), KINETIC ASSAY(AUTOSPAN LIQUID GOLD AST (ASPARTATE TRANSAMINASE))

	-AUTOSPAN® LIQUID GOLD AST (ASPARTATE TRANSMINASE) IS AN IN VITRO QUANTITATIVE DETERMINATION OF ASPARTATE TRANSAMINASE (AST) IN HUMAN SERUM / PLASMA. FULLY AUTOMATED AND SEMI-AUTOMATED ANALYSERS ARE REQUIRED TO PERFORM THIS TEST. THIS TEST IS INTENDED TO BE USED BY TRAINED LABORATORY PROFESSIONALS. ,TRUST (TOLUDINE RED UNHEATED SERUM TEST) KIT-TRUST (TOLUDINE RED UNHEATED SERUM TEST) KIT IS AN IN VITRO QUALITATIVE AND SEMI QUANTITATIVE TEST TO DIAGNOSE SYPHILIS USING HUMAN SERUM / PLASMA ,STAINED SALMONELLA S.PARATYPHI “C(H)” ANTIGEN FOR WIDAL TEST-DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TESTS.,ERYTHROMYCIN SENSITIVITY DISC (EM), 15 G/ DISC(CLAIRO MONO)-CLAIRO® MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW. ,CNPG3, KINETIC ASSAY (AUTOSPAN LIQUID GOLD -AMYLASE)-AUTOSPAN® LIQUID GOLD -AMYLASE IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF A-AMYLASE IN HUMAN SERUM / PLASMA AND URINE. FULLY AUTOMATED, SEMI-AUTOMATED, SPECTROPHOTOMETERS AND COLORIMETERS ANALYSERS ARE REQUIRED TO PERFORM THIS TEST. ,FEBRILE ANTIGEN SET: FOR WIDAL TUBE TEST-FEBRILE ANTIGEN SET- 2 ANTIGEN SET FOR WIDAL TUBE TEST IS SET OF DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY CONVENTIONAL TUBE TESTS,MODIFIED UV (IFCC), KINETIC ASSAY(AUTOSPAN LIQUID GOLD LDH (LACTATE DEHYDROGENASE))-AUTOSPAN® LIQUID GOLD LACTATE DEHYDROGENASE (LDH) IS AN IN VITRO QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE (LDH) IN HUMAN SERUM. FULLY AUTOMATED AND SEMI-AUTOMATED ANALYSERS ARE REQUIRED TO PERFORM THIS TEST. THIS KIT IS INTENDED TO BE USED BY TRAINED LABORATORY

	PROFESSIONALS ,GENTAMICIN SENSITIVITY DISC (GM), 10 G / DISC (CLAIRO MONO)-CLAIRO® MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,MODIFIED BIURET, END POINT ASSAY (AUTOSPAN LIQUID GOLD TOTAL PROTEIN)-AUTOSPAN LIQUID GOLD TOTAL PROTEIN IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM / PLASMA. FULLY AUTOMATED, SEMI AUTOMATED PHOTOMETRIC ANALYSERS, SPECTROPHOTOMETER AND COLORIMETER ARE REQUIRED TO PERFORM THIS TEST. THIS KIT IS INTENDED TO BE USED BY TRAINED LABORATORY PROFESSIONALS. ,NITROFURANTOIN SENSITIVITY DISC (NI), 300 G/DISC(CLAIRO MONO)-CLAIRO® MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW. ,GLDH-UREASE, INITIAL RATE ASSAY (AUTOSPAN UREA)-AUTOSPAN® UREA IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM / PLASMA AND URINE. FULLY AUTOMATED, SEMI-AUTOMATED PHOTOMETRIC ANALYSERS ARE REQUIRED TO PERFORM THIS TEST. THIS KIT IS INTENDED TO BE USED BY TRAINED LABORATORY PROFESSIONALS.,CEFIXIME SENSITIVITY DISC (FIX), 5 G/ DISC (CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT

	PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,QUANTITATIVE VITAMIN D TEST(POCKEETCHEM VITA-D)-POCKETCHEM VITA-D QUANTITATIVE VITAMIN D TEST IS AN IMMUNOCHROMATOGRAPHY- BASED ONE STEP IN VITRO TEST. IT IS DESIGNED FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25-HYDRAXY VITAMIN D (25-OH VITAMIN D) IN HUMAN FINGER-PRICK BLOOD. THIS ASSAY PROVIDES A PRELIMINARY DIAGNOSTIC TEST RESULT AND CAN BE USED FOR SCREENING OF VITAMIN D DEFICIENCY. THE LIQUID CHROMATOGRAPHY WITH TANDEM MASS SPECTROMETRY (LC-MS/MS) ASSAYS OR OTHER QUANTITATIVE IMMUNOASSAYS ARE RECOMMENDED TO FURTHER CONFIRM THE DIAGNOSTIC TEST RESULTS. THIS TEST IS INTENDED TO BE USED BY TRAINED LABORATORY PERSONNEL,OPT. DGKC / IFCC(AUTOSPAN LIQUID GOLD CK-MB)-AUTOSPAN LIQUID GOLD CK-MB IS AN IN VITRO QUANTITATIVE DETERMINATION OF CK-MB IN HUMAN SERUM / PLASMA. FULLY AUTOMATED AND SEMI AUTOMATED ANALYSERS ARE REQUIRED TO PERFORM THIS TEST.,NED-DYE, INITIAL RATE ASSAY(AUTOSPAN LIQUID GOLD UREA)-AUTOSPAN® LIQUID GOLD UREA IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM / PLASMA AND URINE. FULLY AUTOMATED AND SEMI-AUTOMATED PHOTOMETRIC ANALYZERS ARE REQUIRED TO PERFORM THIS TEST. THIS TEST IS INTENDED TO BE USED BY TRAINED LABORATORY PROFESSIONALS ,MODIFIED PHOSPHOTUNGSTATE ASSAY(MBK URIC ACID)-MBK URIC ACID IS A SIMPLE, RAPID, ONE STEP METHOD AND IT'S USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM, PLASMA AND URINE. SPECTROPHOTOMETER AND COLORIMETER ANALYSERS ARE REQUIRED TO PERFORM THIS TEST,PNPP-AMP (IFCC), KINETIC ASSAY (AUTOSPAN ALP (ALKALINE PHOSPHATASE))-AUTOSPAN® ALP (ALKALINE PHOSPHATASE) IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF ALP (ALKALINE PHOSPHATASE) IN HUMAN SERUM / PLASMA. FULLY AUTOMATED AND SEMI AUTOMATED ANALYSERS ARE REQUIRED TO PERFORM THIS TEST. THIS KIT IS INTENDED TO BE USED BY TRAINED

	LABORATORY PROFESSIONALS.,BROMOCRESOL GREEN, END POINT ASSAY (AUTOSPAN LIQUID GOLD ALBUMIN)-AUTOSPAN LIQUID GOLD ALBUMIN IS AN IN VITRO QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM / PLASMA. FULLY AUTOMATED, SEMI AUTOMATED, SPECTROPHOTOMETER AND COLORIMETER ANALYSERS ARE REQUIRED TO PERFORM THIS TEST. THIS TEST IS INTENDED TO BE USED BY TRAINED LABORATORY PROFESSIONALS, MODIFIED UV (IFCC), KINETIC ASSAY(AUTOSPAN LIQUID GOLD ALT (ALANINIE TRANSAMINASE))-AUTOSPAN® LIQUID GOLD ALT (ALANINE TRANSMINASE) IS AN IN VITRO QUANTITATIVE DETERMINATION OF ALANINE TRANSAMINASE (ALT) IN HUMAN SERUM / PLASMA. FULLY AUTOMATED AND SEMI-AUTOMATED ANALYSERS ARE REQUIRED TO PERFORM THIS TEST. THIS TEST IS INTENDED TO BE USED BY TRAINED LABORATORY PROFESSIONALS , CIPROFLOXACIN SENSITIVITY DISC (CI), 5 G / DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,STAINED SALMONELLA S. PARATYPHI 'B(H)' ANTIGEN : FOR WIDAL TEST-DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TESTS,LIQUID CALIBRATION SERUM (AUTOCAL HOMOCYSTEINE CALIBRATOR SET)-AUTOCAL HOMOCYSTEINE CALIBRATOR SET LIQUID FOR QUANTITATIVE IN VITRO DETERMINATION OF HOMOCYSTEINE ON PHOTOMETRIC ANALYSERS,KANAMYCIN SENSITIVITY DISC (KM), 30 G/ DISC (CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND

	NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,SELECTIVE DETERGENT, END POINT ASSAY (AUTOSPAN LIQUID GOLD DIRECT LDL CHOLESTEROL)-AUTOSPAN LIQUID GOLD DIRECT LDL CHOLESTEROL IS USED AN IN VITRO QUANTITATIVE DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) IN HUMAN SERUM / PLASMA. FULLY AUTOMATED, SEMI AUTOMATED PHOTOMETRIC ANALYSERS, SPECTROPHOTOMETER AND COLORIMETER ARE REQUIRED TO PERFORM THIS TEST.,STAINED SALMONELLA S. TYPHI 'H' ANTIGEN : FOR WIDAL TEST-DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TESTS,PIPERACILLIN SENSITIVITY DISC (PI), 100 G/ DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,TEICOPLANIN SENSITIVITY DISC (TP), 30 G/DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED

	LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,FLOW THROUGH FILARIAL ANTIBODY SPOT / IMMUNODOT TEST KIT–DEVICE(SIGNAL MF)-SIGNAL® MF - FLOW THROUGH FILARIAL ANTIBODY SPOT / IMMUNODOT TEST KIT IS AN IN VITRO QUALITATIVE SCREENING TEST TO DIAGNOSE LYMPHATIC FILARIASIS USING HUMAN SERUM OR PLASMA AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. THE ASSAY IS INTENDED FOR USE BY HEALTH CARE WORKERS / LABORATORY PROFESSIONALS, FOR AN INITIAL SCREENING OF FILARIA IN SYMPTOMATIC PATIENTS,CEFAZOLIN SENSITIVITY DISC (CFZ), 30 G/ DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,O-CRESOLPHTHALEIN COMPLEXONE, END POINT ASSAY(AUTOSPAN LIQUID GOLD CALCIUM)-AUTOSPAN LIQUID GOLD CALCIUM IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM / PLASMA AND URINE. FULLY AUTOMATED, SEMI AUTOMATED PHOTOMETRIC ANALYSERS, SPECTROPHOTOMETER AND COLORIMETER ARE REQUIRED TO PERFORM THIS TEST.,CEFOPERAZONE SENSITIVITY DISC (CPZ), 75 G/ DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,SODIUM: TRINDER'S, POTASSIUM :

	TETRAPHENYL BORON, END POINT ASSAY(AUTOSPAN LIQUID GOLD SP TWIN ELECTROLYTES)-AUTOSPAN LIQUID GOLD SP TWIN ELECTROLYTE IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF SODIUM AND POTASSIUM IN HUMAN SERUM / PLASMA. FULLY AUTOMATED, SEMI AUTOMATED PHOTOMETRIC ANALYSERS, SPECTROPHOTOMETER AND COLORIMETER ARE REQUIRED TO PERFORM THIS TEST.,BLOOD GLUCOSE TEST STRIPS (GLUCOCARD G+/GLUCOCARD G2)-GLUCOCARD G+ BLOOD GLUCOSE TEST STRIPS ARE FOR QUANTITATIVELY MEASURING THE GLUCOSE LEVEL IN FRESH CAPILLARY WHOLE BLOOD. THEY ARE INTENDED FOR USE OUTSIDE OF THE BODY (IN VITRO DIAGNOSTIC USE) AT HOME OR IN A CLINICAL SETTING AS AN AID TO MONITOR AND CONTROL BLOOD GLUCOSE LEVELS. ARE NOT USED TO DIAGNOSE DIABETES ALSO ALTER TREATMENT BASED ON THE TEST RESULTS OF THIS SYSTEM WITHOUT INSTRUCTIONS FROM YOUR DOCTOR OR HEALTHCARE PROFESSIONAL. THIS SYSTEM IS NOT INTENDED FOR NEONATES,IMMUNOTURBIDIMETRIC, TWO POINT END ASSAY (AUTOSPAN TURBIGOLD CYSTATIN C TEST KIT)-FOR IN VITRO QUANTITATIVE DETERMINATION OF CYSTATIN C (CYS C) IN HUMAN SERUM OR PLASMA. FULLY AUTOMATED, SEMI AUTOMATED PHOTOMETRIC ANALYSERS ARE REQUIRED TO PERFORM THIS TEST , LINCOMYCIN SENSITIVITY DISC (LN), 15 G/DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,RF (RHEUMATOID FACTOR) TEST KIT : PARTICLE ENHANCED IMMUNOTURBIDIMETRY, INITIAL RATE ASSAY (AUTOSPAN TURBIGOLD)-AUTOSPAN TURBI GOLD RF (RHEUMATOID FACTOR) TEST KIT IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR IN HUMAN SERUM. FULLY AUTOMATED AND SEMI AUTOMATED PHOTOMETRIC ANALYSERS ARE REQUIRED TO PERFORM THIS TEST. THIS KIT IS INTENDED TO BE USED BY TRAINED LABORATORY PROFESSIONALS.,CEFACLOR SENSITIVITY DISC (CEC), 30 G/ DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL

	QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,CEFUROXIME SENSITIVITY DISC (XM), 30 G/ DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,CEFADROXIL SENSITIVITY DISC (CFR), 30 G/ DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,ASO (ANTI STREPTOLYSIN O) TEST KIT : PARTICLE ENHANCED IMMUNOTURBIDIMETRY, INITIAL RATE ASSAY (AUTOSPAN TURBIGOLD)-AUTOSPAN TURBI GOLD ASO (ANTI STREPTOLYSIN O) TEST KIT IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF ANTI STREPTOLYSIN O IN HUMAN SERUM BY

	PARTICLE ENHANCED TURBIDIMITRIC IMMUNOASSAY. FULLY AUTOMATED AND SEMI AUTOMATED PHOTOMETRIC ANALYSERS ARE REQUIRED TO PERFORM THIS TEST,IMMUNOCHROMATOGRAPHIC TEST FOR QUALITATIVE DETECTION OF YERSINIA PESTIS ANTIGEN - DIPSTICK(CRYSTAL YPES)-IMMUNOCHROMATOGRAPHIC TEST FOR QUALITATIVE DETECTION OF YERSINIA PESTIS ANTIGEN IS AN IN VITRO QUALITATIVE SCREENING TEST TO DIAGNOSE PLAGUE, USING HUMAN SERUM / PLASMA / BUBO ASPIRATES / SPUTUM SWAB SAMPLE OR SAMPLES SUSPENDED IN CARY BLAIR MEDIUM.,ASSAYED CALIBRATION HEMOLYSATE(TURBICAL HBA1C DIRECT CALIBRATOR SET)-TURBICAL HBA1C DIRECT CALIBRATOR SET CONTAINS CALIBRATED HEMOLYSATE FOR USE IN THE QUANTITATIVE IN VITRO DETERMINATION OF HAEMOGLOBIN A1C (HBA1C) IN BLOOD ON PHOTOMETRIC SYSTEMS,SPARFLOXACIN SENSITIVITY DISC (SO), 5 G/DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,URICASE / POD, END POINT ASSAY(AUTOSPAN LIQUID GOLD URIC ACID)-AUTOSPANLIQUID GOLD URIC ACID IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM / PLASMA AND URINE. FULLY AUTOMATED, SEMI AUTOMATED, SPECTROPHOTOMETER AND COLORIMETER ANALYSERS ARE REQUIRED TO PERFORM THIS TEST.,RIFAMPIN SENSITIVITY DISC (RI), 5 G/ DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO.

	CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,COMBINED MICROBIAL SENSITIVITY DISCS (ANTIBIOTIKA TESTRINGS 68)-ANTIBIOTIKA TESTRINGS ARE MADE FROM SPECIAL GRADE STERILE FILTER PAPER HAVING 8 PROJECTING ARMS. THE TIP OF EACH ARM IS IMPREGNATED ACCURATELY WITH THE SPECIFIED AMOUNT OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT AND DRIED AT LOW TEMPERATURE UNDER VACUUM. THE ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT AND ITS CONCENTRATION IMPREGNATED ON THE TIP OF EVERY ARM OF TESTRING IS CLEARLY IDENTIFIED BY CODE NUMBERS PRINTED ON EACH OF THEM. THUS, ANTIBIOTIKA TESTRING MAKE IT POSSIBLE IN ONE SINGLE STEP TO TEST SENSITIVITY OF A GIVEN MICROORGANISM FOR 8 DIFFERENT ANTIMICROBIAL AGENTS, CLOXACILLIN SENSITIVITY DISC (CV), 5 G/DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,LINEZOLID SENSITIVITY DISC (LZ), 30 G / DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW. ,STAINED SALMONELLA S.PARATYPHI ”A(O)” ANTIGEN FOR WIDAL TEST-DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC

	ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TESTS.,TICARCILLIN / CLAVULANIC ACID SENSITIVITY DISC (TCC), 75 + 2.5 G/ DISC (CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,LOMEFLOXACIN SENSITIVITY DISC (LOM), 10 G/DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,OFLOXACIN SENSITIVITY DISC (OF), 5 G/DISC (CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH

	LAMINAR AIR FLOW ,ROXITHROMYCIN SENSITIVITY DISC (RO), 30 G/ DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,FEBRILE ANTIGEN SET: FOR WIDAL TUBE TEST-FEBRILE ANTIGEN SET- 4 ANTIGEN SET FOR WIDAL TUBE TEST IS SET OF DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY CONVENTIONAL TUBE TESTS., TOBRAMYCIN SENSITIVITY DISC (TO), 10 G/DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,RPR (RAPID PLASMA REAGIN) TEST KIT - RPR (RAPID PLASMA REAGIN) TEST KIT (18 MM CIRCLE CARD TEST) IS AN IN VITRO QUALITATIVE AND SEMI QUANTITATIVE TEST TO DIAGNOSE SYPHILIS USING HUMAN SERUM / PLASMA.,AMOXYCILLIN SENSITIVITY DISC (AMX), 10 G/ DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT.

	CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW,ACCELERATOR SELECTIVE DETERGENT, END POINT ASSAY(AUTOSPAN LIQUID GOLD DIRECT HDL CHOLESTEROL)-AUTOSPAN LIQUID GOLD DIRECT HDL CHOLESTEROL IS USED AN IN VITRO QUANTITATIVE DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) IN HUMAN SERUM / PLASMA. FULLY AUTOMATED, SEMI AUTOMATED PHOTOMETRIC ANALYSERS, SPECTROPHOTOMETER AND COLORIMETER ARE REQUIRED TO PERFORM THIS TEST,AZITHROMYCIN SENSITIVITY DISC (AZ), 15 G/DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,2,4-DNPH ASSAY(MBK GOT (AST))-MBK GOT (AST) IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF ASPARTATE AMINOTRANSFERASE (AST) IN HUMAN SERUM/PLASMA. SPECTROPHOTOMETER AND COLORIMETER ANALYSERS ARE REQUIRED TO PERFORM THIS TEST.,CEFPODOXIME SENSITIVITY DISC (CPD), 10 G/ DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH

	LAMINAR AIR FLOW.,AMPICILLIN SENSITIVITY DISC (AM), 10 G/ DISC (CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,AZTREONAM SENSITIVITY DISC (AT), 30 G/DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,MEROPENEM SENSITIVITY DISC (MP), 10 G/ DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW. ,CLARITHROMYCIN SENSITIVITY DISC (CLM), 15 G/ DISC(CLAIRO MONO)-SENSITIVITY DISCS ARE PREPARED BY

	ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,RHEUMATOID FACTOR TEST KIT-RHEUMATOID FACTOR LATEX TEST KIT IS USED AS IN VITRO QUALITATIVE AND SEMI-QUANTITATIVE LATEX SLIDE TEST TO DETECT RHEUMATOID FACTOR, WHICH ARE IMMUNOGLOBULINS OF PREDOMINANTLY LGM CLASS, WHICH COMBINES WITH FC PORTION OF IMMUNOGLOBULIN LGG MOLECULES., TEST STRIPS(GLUCOCARD)-GLUCOCARD TEST STRIPS ARE FOR QUANTITATIVELY MEASURING THE GLUCOSE LEVEL IN FRESH CAPILLARY WHOLE BLOOD. THEY ARE INTENDED FOR USE OUTSIDE OF THE BODY (IN VITRO DIAGNOSTIC USE) AT HOME OR IN A CLINICAL SETTING AS AN AID TO MONITOR AND CONTROL BLOOD GLUCOSE LEVELS. DO NOT USE THEM TO DIAGNOSE DIABETES. ALSO, DO NOT ALTER TREATMENT BASED ON THE TEST RESULTS OF THIS SYSTEM WITHOUT INSTRUCTIONS FROM YOUR DOCTOR OR HEALTHCARE PROFESSIONAL. THIS SYSTEM IS NOT INTENDED FOR NEONATES.,COMBINED MICROBIAL SENSITIVITY DISCS FOR RESISTANT GRAM NEGATIVE ISOLATES/ UTI (GN2) (CLAIRO COMBI)-CLAIRO COMBI - COMBINED MICROBIAL SENSITIVITY DISCS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD, ENZYMATIC COLORIMETRIC, KINETIC ASSAY WITH MULTICHEM (AUTOSPAN LIQUID GOLD LIPASE)-AUTOSPAN® LIQUID GOLD LIPASE IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF LIPASE IN HUMAN SERUM / PLASMA. FULLY AUTOMATED AND SEMI AUTOMATED PHOTOMETRIC ANALYSERS ARE REQUIRED TO PERFORM THIS TEST.,DAM ASSAY(MBK UREA)-MBK UREA IS A SIMPLE, RAPID, ONE STEP METHOD AND IT'S USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF UREA IN HUMAN SERUM, PLASMA AND URINE. SPECTROPHOTOMETER AND COLORIMETER ANALYSERS ARE REQUIRED TO PERFORM THIS TEST. ,CHOD-PAP ENZYMATIC END POINT ASSAY(AUTOSPAN LIQUID GOLD CHOLESTEROL)-AUTOSPAN LIQUID GOLD CHOLESTROL IS AN IN

	VITRO QUANTITATIVE DETERMINATION OF TOTAL CHOLESTROL AND HDL-CHOLESTROL IN HUMAN SERUM/PLASMA. FULLY AUTOMATED, SEMI AUTOMATED, SPECTROPHOTOMETERS AND COLORIMETERS ANALYSERS ARE REQUIRED TO PERFORM THIS TEST. ,OPT. DGKC (AUTOSPAN LIQUID GOLD CK-NAC)-AUTOSPAN LIQUID GOLD CK-NAC IS AN IN VITRO QUANTITATIVE DETERMINATION OF CK-NAC IN HUMAN SERUM / PLASMA. FULLY AUTOMATED AND SEMI AUTOMATED ANALYSERS ARE REQUIRED TO PERFORM THIS TEST. THIS TEST IS INTENDED TO BE USED BY TRAINED LABORATORY PROFESSIONALS.,VITAL TEST STRIPS(GLUCOCARD)-GLUCOCARD VITAL TEST STRIPS ARE INTENDED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN FRESH CAPILLARY WHOLE BLOOD SAMPLES DRAWN FROM THE FINGERTIPS OR PALM. GLUCOCARD VITAL TEST STRIPS MUST BE USED WITH THE GLUCOCARD VITAL BLOOD GLUCOSE METER. TESTING IS DONE OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE). THEY ARE INDICATED FOR USE AT HOME (OVER THE COUNTER [OTC]) BY PERSONS WITH DIABETES, OR IN CLINICAL SETTINGS BY HEALTHCARE PROFESSIONALS, AS AN AID TO MONITOR THE EFFECTIVENESS OF DIABETES CONTROL. ,CEFOTAXIME SENSITIVITY DISC (CTX), 30 G/ DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,GOD-POD, END POINT ASSAY AND KINETIC ASSAY(AUTOSPAN LIQUID GOLD GLUCOSE)-AUTOSPAN® LIQUID GOLD GLUCOSE IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM / PLASMA. FULLY AUTOMATED, SEMI AUTOMATED PHOTOMETRIC ANALYSERS, SPECTROPHOTOMETER AND COLORIMETER ARE REQUIRED TO PERFORM THIS TEST. ,ALKALINE PICRATE ASSAY(MBK CREATININE)-MBK CREATININE IS A SIMPLE, CONVENIENT AND HIGHLY REPRODUCIBLE METHOD AND IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE. SPECTROPHOTOMETER AND COLORIMETER

	ANALYSERS ARE REQUIRED TO PERFORM THIS TEST.,GOD-POD, END POINT ASSAY AND KINETIC ASSAY(AUTOSPAN GLUCOSE)-AUTOSPAN® GLUCOSE IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM / PLASMA. FULLY AUTOMATED, SEMI AUTOMATED PHOTOMETRIC ANALYSERS, SPECTROPHOTOMETER AND COLORIMETER ARE REQUIRED TO PERFORM THIS TEST. ,AMIKACIN SENSITIVITY DISC (AK), 30 G / DISC (CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW,QUALITATIVE ASSAY(MBK G-6PD)-MBK G-6PD IS A SIMPLE, MORE SPECIFIC AND VISUAL METHOD IS USED FOR AN IN VITRO QUALITATIVE DETERMINATION OF THE ACTIVITY OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE FROM THE RED CELL HEMOLYSATE,AMOXYCILLIN / CLAVULANIC ACID SENSITIVITY DISC (AMC), 20+10 G/ DISC (CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,IMIPENEM / CILASTATIN SENSITIVITY DISC (I/S), 10+10 G/ DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD

	AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,CEFTRIAXONE SENSITIVITY DISC (CRO), 30 G/ DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,CRP (C REACTIVE PROTEIN) TEST KIT: PARTICLE ENHANCED IMMUNOTURBIDIMETRY, INITIAL RATE ASSAY(AUTOSPAN TURBIGOLD)-AUTOSPAN TURBI GOLD CRP (C REACTIVE PROTEIN) TEST KIT IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF C REACTIVE PROTEIN IN HUMAN SERUM BY PARTICLE ENHANCED TURBIDIMETRIC IMMUNOASSAY. FULLY AUTOMATED AND SEMI AUTOMATED PHOTOMETRIC ANALYSERS ARE REQUIRED TO PERFORM THIS TEST,VANCOMYCIN SENSITIVITY DISC (VA), 30 G/ DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,PIPERACILLIN / TAZOBACTUM SENSITIVITY DISC

	(P/T), 100 + 10 G/ DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,CEFOPERAZONE + SULBACTUM SENSITIVITY DISC (CS), 75+30 G / DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW.,STAINED BRUCELLA SUSPENSIONS BRUCELLA MELITENSIS – FOR RAPID SLIDE & TUBE TESTS-DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO BRUCELLA MELITENSIS PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TESTS.,CO-TRIMOXAZOLE SENSITIVITY DISC (SXT), 25 G/DISC (CLAIRO MONO)-CLAIRO® MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT

	CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,KIND AND KINGS ASSAY(MBK ALKALINE PHOSPHATASE)-MBK ALKALINE PHOSPHATASE IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM. SPECTROPHOTOMETER AND COLORIMETER ANALYSERS ARE REQUIRED TO PERFORM THIS TEST.,MODIFIED JAFFE'S REACTION, INITIAL RATE ASSAY(AUTOSPAN LIQUID GOLD CREATININE MONO REAGENT)-AUTOSPAN LIQUID GOLD CREATININE MONO REAGENT IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE. FULLY AUTOMATED AND SEMI AUTOMATED PHOTOMETRIC ANALYSERS ARE REQUIRED TO PERFORM THIS TEST.,NALIDIXIC ACID SENSITIVITY DISC (NA), 30 G/DISC(CLAIRO MONO)-CLAIRO® MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,ONE STEP RAPID IMMUNOCHROMATOGRAPHIC TEST FOR KALA AZAR - DIPSTICK(CRYTSAL KA)-CRYSTAL KA - ONE STEP RAPID IMMUNOCHROMATOGRAPHIC TEST FOR KALA AZAR IS AN IN VITRO QUALITATIVE SCREENING TEST TO DIAGNOSE KALA-AZAR OR VISCERAL LEISHMANIASIS USING HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR USE BY HEALTH CARE WORKERS / LABORATORY PROFESSIONALS, FOR AN INITIAL SCREENING FOR KALA AZAR OR VISCERAL LEISHMANIASIS IN SYMPTOMATIC PATIENTS ,JENDRASSIK & GROFF, END POINT ASSAY (AUTOSPAN LIQUID GOLD TOTAL AND DIRECT BILIRUBIN)-AUTOSPAN® LIQUID GOLD TOTAL AND DIRECT BILIRUBIN IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF TOTAL AND DIRECT BILIRUBIN IN HUMAN SERUM / PLASMA. FULLY AUTOMATED AND SEMI AUTOMATED PHOTOMETRIC ANALYSERS, SPECTROPHOTOMETER AND COLORIMETER ARE REQUIRED TO PERFORM THIS TEST.,2,4-DNPH ASSAY(MBK GPT (ALT))-MBK GPT

	(ALT) IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF ALANINE AMINOTRANSFERASE (ALT) IN HUMAN SERUM/PLASMA. SPECTROPHOTOMETER AND COLORIMETER ANALYSERS ARE REQUIRED TO PERFORM THIS TEST,STAINED SALMONELLA ANTIGEN SET : FOR WIDAL TEST-DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TESTS.,DOXYCYCLIN SENSITIVITY DISC (DC), 30 G/ DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW. ,STAINED BRUCELLA SUSPENSIONS BRUCELLA ABORTUS – FOR RAPID SLIDE & TUBE TESTS -DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO BRUCELLA ABORTUS PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TESTS.,MODIFIED JAFFE'S REACTION, INITIAL RATE ASSAY (AUTOSPAN LIQUID GOLD CREATININE)-AUTOSPAN LIQUID GOLD CREATININE IS USED FOR AN IN VITRO QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE. FULLY AUTOMATED, SEMI AUTOMATED PHOTOMETRIC ANALYSERS ARE REQUIRED TO PERFORM THIS TEST. THIS KIT IS INTENDED TO BE USED BY TRAINED LABORATORY PROFESSIONALS., STAINED SALMONELLA ANTIGEN SET : FOR WIDAL TEST-DIAGNOSTIC REAGENTS FOR THE IN VITRO DETECTION AND QUANTITATIVE ESTIMATION OF SPECIFIC ANTIBODIES TO SALMONELLA PRESENT IN SERUM BY RAPID SLIDE AND CONVENTIONAL TUBE TESTS., NORFLOXACIN SENSITIVITY DISC (NOR), 10 G/DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON

	BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW ,GPO-PAP, END POINT ASSAY(AUTOSPAN LIQUID GOLD TRIGLYCERIDE)-AUTOSPAN LIQUID GOLD TRIGLYCERIDE IS AN IN VITRO QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM / PLASMA. FULLY AUTOMATED, SEMI AUTOMATED, SPECTROPHOTOMETERS AND COLORIMETERS ANALYSERS ARE REQUIRED TO PERFORM THIS TEST,CLINDAMYCIN SENSITIVITY DISC (CM), 2 G / DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW,ASSAYED UNIVERSAL CALIBRATION SERUM (AUTOCAL MULTICHEM)-AUTOCAL MULTICHEM LYOPHILISED UNIVERSAL CALIBRATION SERUM IS MEANT USED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF VARIOUS ANALYTES ON PHOTOMETRIC SYSTEMS.,COMBINED MICROBIAL SENSITIVITY DISCS FOR RESISTANT GRAM POSITIVE ISOLATES (GP2)(CLAIRO COMBI)-CLAIRO COMBI - COMBINED MICROBIAL SENSITIVITY DISCS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD.,COMBINED MICROBIAL SENSITIVITY DISCS FOR GRAM NEGATIVE ISOLATES/ UTI (GN1)(CLAIRO COMBI)-CLAIRO COMBI - COMBINED MICROBIAL SENSITIVITY DISCS ARE USED TO SEMI QUANTITATIVELY EVALUATE THE IN VITRO SUSCEPTIBILITY TO ANTIMICROBIAL AGENTS OF RAPIDLY GROWING BACTERIA AND SEVERAL DIFFICULT SPECIES BY AN AGAR DIFFUSION METHOD, TETRACYCLINE SENSITIVITY DISC (TE), 30 G / DISC(CLAIRO MONO)-CLAIRO MONO - SENSITIVITY DISCS ARE PREPARED BY ACCURATELY

	IMPREGNATING SPECIAL QUALITY ABSORBENT PAPER OF THICKNESS (1 MM) AND DIAMETER OF DISC (6.2 MM) AS PER RECOMMENDATION OF CLINICAL AND LABORATORY STANDARDS INSTITUTE (CLSI), WITH STANDARD AMOUNTS OF ANTIBIOTIC / CHEMOTHERAPEUTIC AGENT. DISCS ARE CLEARLY MARKED ON BOTH SIDES WITH CODE DESIGNATING THE ACTIVE INGREDIENT AND NUMBER DESIGNATING ITS AMOUNT. CLAIRO® MONO - SENSITIVITY DISCS ARE AVAILABLE FOR A WIDE RANGE OF ANTIBIOTICS AND CHEMOTHERAPEUTIC AGENTS IN LEVELS THAT CLOSELY APPROXIMATE THOSE ATTAINABLE IN VIVO. CLAIRO® MONO - SENSITIVITY DISCS ARE INTENDED FOR USE BY TRAINED LABORATORY PERSONNEL IN LABORATORY EQUIPPED WITH LAMINAR AIR FLOW,ENZYMATIC RECYCLING, TWO POINT KINETIC ASSAY(AUTOSPAN LIQUID GOLD HOMOCYSTEINE)-AUTOSPAN LIQUID GOLD HOMOCYSTEINE IS AN IN VITRO QUANTITATIVE DETERMINATION OF TOTAL L-HOMOCYSTEINE IN HUMAN SERUM / PLASMA. FULLY AUTOMATED AND SEMI AUTOMATED PHOTOMETRIC ANALYSERS ARE REQUIRED TO PERFORM THIS TEST

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2806	MFG/IVD/2019/000062	1.License Holder Name: COSARA DIAGNOSTICS PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:NOVEL CORONAVIRUS (2019-NCOV) TEST KIT(SARAGENE COVID-19)-SARAGENE CORONA VIRUS (2019 NCV) TEST KIT, BASED ON REAL TIME PCR TECHNOLOGY IS INTENDED FOR QUALITATIVE DETECTION OF 2019 NOVEL CORONA VIRUS,MALARIA (MAL) TEST KIT-FOR THE DETECTION OF MALARIA, CHIKUNGUNYA VIRUS (CHIKV) REAL-TIME PCR TEST KIT(SARAGENE)-THE CHIKUNGUNYA (CHIKV) TEST KIT IS AN IN VITRO DIAGNOSTIC TEST, BASED ON REAL-TIME POLYMERASE CHAIN REACTION TECHNOLOGY. IT TESTS FOR THE PRESENCE OR ABSENCE OF RIBONUCLEIC ACID (RNA) OF CHIKUNGUNYA VIRUSES. SPECIFICALLY, IN SERUM OR PLASMA FROM PATIENTS SUSPECTED OF CHIKUNGUNYA VIRAL INFECTIONS. SEROLOGY TEST CONFIRMATION MAY BE NEEDED IF ONSET OF INFECTION HAS PASSED THE EARLY STAGES OF THESE DISEASES,HEPATITIS B VIRUS (HBV) TEST KIT-FOR THE DETECTION OF HEPATITIS B VIRUS (HBV), NOVEL CORONAVIRUS (2019-NCOV) V.2 TEST KIT(SARAGENE COVID-19 V.2)-SARAGENE CORONA VIRUS (2019 NCV) V.2 TEST KIT, BASED ON REAL TIME PCR TECHNOLOGY IS INTENDED FOR QUALITATIVE DETECTION OF 2019 NOVEL CORONA VIRUS,HUMAN PAPILLOMAVIRUS (HPV 16/18) TEST KIT-FOR THE DETECTION OF HUMAN PAPILLOMAVIRUS (HPV 16/18),MYCOBACTERIA TUBERCULOSIS (MTB) TEST KIT-FOR DETECTION OF TUBERCULOSIS, HEPATITIS C VIRUS (HCV) TEST KIT-FOR THE DETECTION OF HEPATITIS C VIRUS (HCV)
2807	MFG/IVD/2019/000063	1.License Holder Name: CORAL CLINICAL SYSTEMS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:IRON & TIBC KIT (FERROZINE METHOD)-IRON & TIBC KIT IS CLINICAL CHEMISTRY ASSAY BASED ON (FERROZINE / MAGNESIUM CARBONATE METHOD) METHOD FOR THE DETERMINATION OF IRON AND TOTAL IRON BINDING CAPACITY IN SERUM.,CHOLESTEROL KIT (CHOD/PAP METHOD)-CHOLESTEROL KIT IS CLINICAL CHEMISTRY ASSAY BASED ON THE CHOD/PAP METHOD FOR THE DETERMINATION OF CHOLESTEROL IN SERUM OR PLASMA.

2808	MFG/IVD/2019/000064	1.License Holder Name: CORAL CLINICAL SYSTEMS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:CREATININE (E.P.) KIT (ALKALINE PICRATE METHOD)-CREATININE (E.P.) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE ALKALINE PICRATE METHOD FOR THE DETERMINATION OF CREATININE IN SERUM AND URINE., CREATININE (KIN) KIT (MOD JAFFE'S KINETIC METHOD)-CREATININE (KIN.) KIS IS ACLINICAL CHEMISTRY ASSAY BASED ON THE MOD. JAFFE'S KINETIC METHOD FOR THE DETERMINATION OF CREATININE IN SERUM AND URINE
2809	MFG/IVD/2019/000065	1.License Holder Name: CORAL CLINICAL SYSTEMS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:ALBUMIN KIT (BROMOCRESOL GREEN (BCG) METHOD)-ALBUMIN KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE BROMOCRESOL GREEN (BCG) METHOD FOR THE DETERMINATION OF ALBUMIN IN SERUM OR PLASMA,ALKALINE PHOSPHATASE KIT (PNPP KINETIC (DEA) METHOD)-THE ALKALINE PHOSPHATASE (ALP) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE PNPP KINETIC METHOD FOR THE DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY IN SERUM
2810	MFG/IVD/2019/000066	1.License Holder Name: CORAL CLINICAL SYSTEMS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:GAMMA GLUTAMYL TRANSFERASE KIT (CARBOXY SUBSTRATE METHOD)-GLUTAMYL TRANSFERASE LS KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON THE CARBOXY SUBSTRATE METHOD FOR THE DETERMINATION GLUTAMYL TRANSFERASE ACTIVITY IN SERUM,LDH (P-L) KIT (MOD. IFCC METHOD)-LDH (P-L) KIT IS A CLINICAL CHEMISTRY ASSAY BASED ON MOD. IFCC METHOD FOR THE DETERMINATION OF LACTATE DEHYDROGENASE ACTIVITY IN SERUM

2811	MFG/IVD/2019/000068	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:READY TO USE REAGENT FOR USE WITH APTT DETERMINATION(CALCIUM CHLORIDE)-CALCIUM CHLORIDE IS A READY TO USE SOLUTION STANDARDIZED AT 0.025 ML/L CONCENTRATION FOR USE WITH APTT REAGENTS ONLY., STABILIZED ACTIVATED PAPAIN ENZYME SOLUTION FOR SEROLOGICAL APPLICATIONS(LIQUIPAP)-LIQUIPAP IS A LIQUID STABLE PAPAIN ENZYME REAGENT FOR SEROLOGICAL APPLICATION,LYOPHILIZED PAPAIN ENZYME SOLUTION FOR SEROLOGICAL APPLICATIONS(LYOPAP)-LYOPAP IS A LYOPHILIZED PAPAIN ENZYME REAGENT FOR SEROLOGICAL APPLICATIONS
2812	MFG/IVD/2019/000069	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF IGM ANTIBODIES TO HEV IN HUMAN SERUM/PLASMA(INSIGHT HEV IGM (DEVICE))-INSIGHT HEV IGM IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF IGM ANTOBODIES TO HEPATITIS E VIRUS IN HUMAN SERUM/PLASMA,RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF IGM ANTIBODIES TO HAV IN HUMAN SERUM/PLASMA(INSIGHT HAV IGM (DEVICE))-INSIGHT HAV IGM IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF IGM ANTOBODIES TO HEPATITIS A VIRUS IN HUMAN SERUM/PLASMA

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2813	MFG/IVD/2019/000070	1.License Holder Name: J. MITRA & CO. PVT. LTD. 2.Approving Authority: SOUTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:CHIKUNGUNYA IGM MICROLISA(CHIKUNGUNYA IGM MICROLISA)-CHIKUNGUNYA IGM MICROLISA IS DESIGNED FOR AN IN-VITRO QUALITATIVE DETECTION OF CHIKUNGUNYA IGM ANTIBODIES IN HUMAN SERUM OR PLASMA AND IS USED AS A SCREENING TEST FOR TESTING OF COLLECTED BLOOD SAMPLES SUSPECTED FOR CHIKUNGUNYA,DENGUE IGG MICROLISA(DENGUE IGG MICROLISA)-DENGUE IGG MICROLISA IS DESIGNED FOR AN IN-VITRO QUALITATIVE DETECTION OF DENGUE IGG ANTIBODIES IN HUMAN SERUM OR PLASMA AND IS USED AS A SCREENING TEST FOR TESTING OF COLLECTED BLOOD SAMPLES SUSPECTED FOR DENGUE. THE KIT DETECTS ALL FOUR SEROTYPES; DEN1, DEN2, DEN3 AND DEN4 OF DENGUE VIRUS,DENGUE IGG QUANTI CARD(DENGUE IGG QUANTI CARD)-DENGUE IGG QUANTI CARD IS A SENSITIVE IMMUNE-CHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF DENGUE IGG ANTIBODIES IN HUMAN SERUM/PLASMA WITH I-QUANT ANALYZER. THIS TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY AND IS INTENDED AS AN AID IN THE EARLIER DIAGNOSIS OF DENGUE INFECTION. ,DENGUE IGM QUANTI CARD(DENGUE IGM QUANTI CARD)-DENGUE IGM QUANTI CARD IS A SENSITIVE IMMUNE-CHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF DENGUE IGM ANTIBODIES IN HUMAN SERUM/PLASMA WITH IQUANT ANALYZER. THIS TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY AND IS INTENDED AS AN AID IN THE EARLIER DIAGNOSIS OF DENGUE INFECTION.,LEPTO IGM MICROLISA (LEPTO IGM MICROLISA)-LEPTO IGM MICROLISA IS DESIGNED FOR AN IN-VITRO QUALITATIVE DETECTION OF LEPTOSPIRA IGM ANTIBODIES IN HUMAN SERUM OR PLASMA AND IS USED AS A SCREENING TEST FOR TESTING OF COLLECTED BLOOD SAMPLES SUSPECTED FOR LEPTOSPIROSIS.,ADVANTAGE CHIKUNGUNYA IGM CARD(ADVANTAGE CHIKUNGUNYA IGM CARD)-ADVANTAGE CHIKUNGUNYA IGM CARD IS A VISUAL, RAPID, SENSITIVE, QUALITATIVE IMMUNOASSAY FOR THE DETECTION OF CHIKUNGUNYA SPECIFIC IGM ANTIBODIES IN HUMAN SERUM OR PLASMA.,CELIAC MICROLISA(CELIAC MICROLISA)-CELIAC MICROLISA IS DESIGNED FOR AN IN-VITRO QUALITATIVE DETECTION OF CELIAC ANTIBODIES (ANTI ITG IGA ANTIBODIES) IN HUMAN SERUM OR PLASMA AND IS USED AS A SCREENING TEST FOR TESTING OF COLLECTED BLOOD SAMPLES SUSPECTED FOR CELIAC,DENGUE IGM MICROLISA(DENGUE IGM MICROLISA)-DENGUE IGM MICROLISA IS DESIGNED FOR AN IN-VITRO QUALITATIVE DETECTION OF DENGUE IGM ANTIBODIES IN HUMAN SERUM OR PLASMA AND IS USED AS A SCREENING TEST FOR TESTING OF COLLECTED BLOOD SAMPLES SUSPECTED FOR DENGUE. THE KIT DETECTS ALL FOUR SEROTYPES;

	DEN1, DEN2, DEN3 AND DEN4 OF DENGUE VIRUS,VITAMIN D QUANTI CARD(VITAMIN D QUANTI CARD)-VITAMIN D QUANTI CARD IS A SENSITIVE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF VITAMIN D (TOTAL) IN HUMAN SERUM WITH DEVICE READER.,TSH QUANTI MICROLISA(TSH QUANTI MICROLISA)-TSH QUANTI MICROLISA IS DESIGNED FOR IN-VITRO QUANTITATIVE DETECTION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM., VITAMIN D QUANTI MICROLISA(VITAMIN D QUANTI MICROLISA)-VITAMIN-D QUANTI MICROLISA IS DESIGNED FOR IN-VITRO QUANTITATIVE DETERMINATION OF VITAMIN D (TOTAL) IN HUMAN SERUM.,VITAMIN B12 QUANTI MICROLISA(VITAMIN B12 QUANTI MICROLISA)-VITAMIN B12 QUANTI MICROLISA IS DESIGNED FOR IN-VITRO QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM.,T4 QUANTI MICROLISA(T4 QUANTI MICROLISA)-T4 QUANTI MICROLISA IS DESIGNED FOR IN-VITRO QUANTITATIVE DETERMINATION OF TRIIODOTHYRONIN (T4) IN HUMAN SERUM OR PLASMA.,T3 QUANTI MICROLISA(T3 QUANTI MICROLISA)-T3 QUANTI MICROLISA IS DESIGNED FOR IN-VITRO QUANTITATIVE DETERMINATION OF TRIIODOTHYRONIN (T3) IN HUMAN SERUM OR PLASMA.,TSH QUANTI CARD(TSH QUANTI CARD)-TSH QUANTI CARD IS A SENSITIVE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THYROID STIMULATING HORMONE (TSH) IN HUMAN SERUM/PLASMA WITH IQUANT ANALYZER.,T4 QUANTI CARD (T4 QUANTI CARD)-T4 QUANTI CARD IS A SENSITIVE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF T4 (THYROXINE) IN HUMAN SERUM/PLASMA WITH IQUANT ANALYZER.,T3 QUANTI CARD (T3 QUANTI CARD)-T3 QUANTI CARD IS A SENSITIVE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF TRIIODOTHYRONIN (T3) IN HUMAN SERUM/PLASMA WITH IQUANT ANALYZER.,DIAGNOS CELIAC CARD(DIAGNOS CELIAC CARD)-DIAGNOS CELIAC CARD IS A VISUAL, RAPID, SENSITIVE AND ACCURATE ONE STEP IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTI TTG IGA, IGG & IGM ANTIBODIES IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED TO BE USED AS AN AID IN THE RECOGNITION AND DIAGNOSIS OF CELIAC DISEASE.,DIAGNOS DENGUE CARD(DIAGNOS DENGUE CARD)-DIAGNOS DENGUE CARD IS A RAPID SOLID PHASE IMMUNE-CHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE AND DIFFERENTIAL DETECTION OF IGM AND IGG ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM / PLASMA. THIS TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY AND IS INTENDED AS AN AID IN THE PRESUMPTIVE DIAGNOSIS BETWEEN PRIMARY AND SECONDARY DENGUE INFECTION.,ADVANTAGE LEPTOSPIRA IGM & IGG CARD (ADVANTAGE LEPTOSPIRA IGM & IGG CARD)-ADVANTAGE LEPTOSPIRA IGM & IGG CARD IS A VISUAL, RAPID, SENSITIVE,

	QUALITATIVE IMMUNOASSAY FOR THE DETECTION OF LEPTOSPIRA IGM & IGG ANTIBODIES IN HUMAN SERUM OR PLASMA,ADVANTAGE TYPHI IGM & IGG CARD(ADVANTAGE TYPHI IGM & IGG CARD)- ADVANTAGE TYPHI IGM & IGG CARD IS A RAPID SOLID PHASE IMMUNE-CHROMATOGRAPHIC TEST FOR THE QUALITATIVE DIFFERENTIAL AND SIMULTANEOUS DETECTION OF SALMONELLA TYPHI (S. TYPHI) IGM AND IGG ANTIBODIES IN HUMAN SERUM / PLASMA. THIS TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY AND IS INTENDED AS AN AID IN THE EARLIER DIAGNOSIS OF TYPHOID INFECTION AND IN THE DETERMINATION OF RECENT AND PAST INFECTION

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2814	MFG/IVD/2019/000071	1.License Holder Name: ASPEN LABORATORIES PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ASPEN SARS-COV-2 NUCLEIC ACID DETECTION KIT (RT-PCR)-FOR QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN OROPHARYNGEAL SWAB, NASOPHARYNGEAL SWAB OR DEEP COUGH SPUTUM SPECIMENS,ANTI-A BLOOD GROUPING REAGENT-TEST KIT FOR BLOOD GROUPING,ASPEN SARS-COV-2 IGG ELISA KIT-FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES AGAINST THE SARS COV-2 VIRUS IN THE HUMAN SERUM/PLASMA USING ELISA METHOD.,MALARIA PF/PV (BIVALENT) ANTIGEN RAPID TEST-TEST KIT FOR DETECTION OF MALARIA PF/PV ANTIGEN(S),TOXOPLASMA RAPID CARD TEST KIT-TEST KIT FOR DETECTION OF TOXOPLASMA, TORCH RANGE RAPID CARD TEST-TEST KIT FOR DETECTION OF TORCH PARAMETERS,THROMBOPLASTIN (PROTHROMBIN TIME) REAGENT KIT-TEST KIT FOR ESTIMATION OF PROTHROMBIN TIME, HCV ELISA TEST KIT-TEST KIT FOR DETECTION OF HEPATITIS C VIRUS,PSA RAPID CARD TEST KIT-TEST KIT FOR DETECTION OF PROSTATE-SPECIFIC ANTIGEN (PSA),ANTI-B BLOOD GROUPING REAGENT-TEST KIT FOR BLOOD GROUPING,RPR/VDRL REAGENT KIT-TEST KIT FOR DETECTION OF TREPONEMA PALLIDUM,FILARIA ANTIGEN RAPID CARD TEST-TEST KIT FOR DETECTION OF FILARIA ANTIGEN,H. PYLORI ANTIGEN RAPID CARD TEST-TEST KIT FOR DETECTION OF H. PYLORI,HCV RAPID CARD TEST KIT-TEST KIT FOR DETECTION OF HEPATITIS C VIRUS,ANTI-A/B/D BLOOD GROUPING COMBO REAGENT KIT-COMBO REAGENT KIT FOR BLOOD GROUPING , DENGUE NS1+IGG/IGM COMBO RAPID CARD TEST-TEST KIT FOR DETECTION OF DENGUE NS1+IGG/IGM,DENGUE NS1 ELISA-TEST KIT FOR DETECTION OF DENGUE NS1 ANTIGEN,DENGUE NS1 ANTIGEN RAPID CARD TEST-TEST KIT FOR DETECTION OF DENGUE NS1 ANTIGEN,CHIKUNGUNYA ANTIGEN RAPID CARD TEST-TEST KIT FOR DETECTION OF CHIKUNGUNYA ANTIGEN,TROPONIN-I RAPID CARD TEST-TEST KIT FOR DETECTION OF TROPONIN-I,DRUGS OF ABUSE RAPID TEST ((1 PARAMETER TO MULTIPARAMETER)-TEST KIT FOR DETECTION OF VARIOUS COMBINATIONS OF DRUG OF ABUSE PARAMETERS AND DRUG METABOLITES IN URINE E.G. AMPHETAMINE, BARBITURATES, BENZODIAZEPINES, COCAINE, ECSTASY (MDMA), MORPHINE, MARIJUANA, OPIATE , TRICYCLIC ANTIDEPRESSANTS, PHENCYCLIDINE, METHADONE ETC.,ANTI-D BLOOD GROUPING REAGENT-TEST KIT FOR BLOOD GROUPING,SYPHILIS ELISA KIT-TEST KIT FOR DETECTION OF SYPHILIS,HBSAG RAPID TEST-TEST KIT FOR DETECTION OF HEPATITIS B SURFACE ANTIGEN,APTT (ACTIVATED PARTIAL THROMBOPLASTIN) REAGENT KIT-TEST KIT FOR ESTIMATION OF APTT,MALARIA PF ANTIGEN RAPID TEST-TEST KIT

	FOR DETECTION OF MALARIA PF. ANTIGEN,CEA ELISA KIT-TEST KIT FOR DETECTION OF CARCINOEMBRYONIC ANTIGEN (CEA), CHLAMYDIA ANTIGEN RAPID CARD TEST-TEST KIT FOR DETECTION OF CHLAMYDIA ANTIGEN,DENGUE/CHIKUNGUNYA ANTIGEN RAPID COMBO CARD TEST-TEST KIT FOR DETECTION OF DENGUE AND CHIKUNGUNYA ANTIGENS,KALA AZAR ANTIGEN RAPID CARD TEST-TEST KIT FOR DETECTION OF KAAL AZAR,HCG (TOTAL & BETA) ELISA KIT-TEST KIT FOR DETECTION OF TOTAL AND BETA HCG,TYPHOID ANTIGEN RAPID CARD TEST-TEST KIT FOR DETECTION OF TYPHOID ANTIGEN,MALARIA PF/PAN ANTIGEN RAPID TEST-TEST KIT FOR DETECTION OF MALARIA PF/PAN ANTIGEN,SYPHILIS RAPID TEST-TEST KIT FOR DETECTION OF SYPHILIS,MALARIA PAN ANTIGEN RAPID TEST-TEST KIT FOR DETECTION OF MALARIA PAN ANTIGEN, HIV ELISA TEST KIT-TEST KIT FOR DETECTION OF HIV,HIV RAPID CARD TEST-TEST KIT FOR DETECTION OF HIV,HBSAG ELISA TEST KIT-TEST KIT FOR DETECTION OF HEPATITIS B SURFACE ANTIGEN

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2815	MFG/IVD/2020/000001	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ACE (ANGIOTENSIN CONVERTING ENZYME)(NA)-KIT FOR QUANTITATIVE DETERMINATION OF ANGIOTENSIN CONVERTING ENZYME IN HUMAN SERUM/PLASMA , RAPID TEST FOR DENGUE IGG/IGM-DENGUE IGG/IGM IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF IGG & IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SPECIMEN,CHOLERA RAPID TEST(NA)-TEST FOR QUALITATIVE DETECTION AND DIFFERENTIATION OF VIBRIO CHOLERAE (V. CHOLERAE) O139 ANTIGEN AND O1 ANTIGEN IN HUMAN FECAL SPECIMEN. , CHIKUNGUNYA REAL TIME PCR-CHIKUNGUNYA DETECTION KIT INCLUDES ALL THE REAGENTS FOR DETECTION OF CHIKUNGUNYA VIRUS BY REAL TIME PCR IN HUMAN SPECIMEN.,VIRAL TRANSPORT MEDIUM(NA)-VIRAL TRANSPORT MEDIUM (SAMPLE PREPARATION MEDIA) IS INTENDED FOR THE COLLECTION, TRANSPORTATION AND PRESERVATION OF VIRAL NUCLEIC ACID IN CLINICAL SAMPLES., HEMATOLOGY DILUENT (FOR 5 PART ANALYZER)-KIT FOR THE DILUENT SOLUTION FOR HEMATOLOGY ANALYZER,ANTI-CCP (NA)-KIT FOR THE QUANTITATIVE DETERMINATION OF ANTI CYCLIC CITRULLINATED PEPTIDE (CCP) ANTIBODIES IN HUMAN SERUM OR PLASMA. ,HAV IGG/IGM RAPID TEST-RAPID IMMUNOCHROMATOGRAPHIC ASSAY KIT USED FOR QUALITATIVE DETECTION OF ANTIBODIES SPECIFIC FOR HEPATITIS A VIRUS (IGG AND IGM) IN HUMAN SERUM/PLASMA/WHOLE BLOOD , HOMOCYSTEINE CALIBRATOR(NA)-CALIBRATOR USED FOR CALIBRATION OF ENZYMATIC HOMOCYSTEINE ASSAYS ONLY. , BILIRUBIN DIRECT (DPD)-KIT FOR QUANTITATIVE ESTIMATION OF BILIRUBIN DIRECT IN HUMAN SERUM OR PLASMA,ACE CONTROL(NA)-CONTROL USED FOR EXAMINING THE ACCURACY AND PRECISION OF QUANTITATIVE ACE ASSAYS. ,HAV IGM RAPID TEST-RAPID IMMUNOCHROMATOGRAPHIC ASSAY KIT USED FOR QUALITATIVE DETECTION OF ANTIBODIES SPECIFIC FOR HEPATITIS A VIRUS (IGM) IN HUMAN SERUM/PLASMA/WHOLE BLOOD ,HEMATOLOGY CALIBRATOR(NA)-CALIBRATOR USED TO ASSESS AND CALIBRATE HEMATOLOGY ANALYZERS TO ENSURE THE DELIVERY OF ACCURATE DIAGNOSTIC RESULTS ,HEV IGG/IGM RAPID TEST-RAPID IMMUNOCHROMATOGRAPHIC ASSAY KIT USED FOR QUALITATIVE DETECTION OF ANTIBODIES SPECIFIC FOR HEPATITIS E VIRUS (IGG AND IGM) IN HUMAN SERUM/PLASMA/WHOLE BLOOD , HOMOCYSTEINE(NA)-KIT FOR QUANTITATIVE DETERMINATION OF TOTAL L-HOMOCYSTEINE IN SERUM OR PLASMA. ,GAMMA GT-KIT FOR QUANTITATIVE DETECTION OF GAMMA GLUTAMYL TRANSFERASE

	(GGT) IN HUMAN SERUM/PLASMA,VITAMIN-D (NA)-KIT FOR QUANTITIVE DETERMINATION OF 25-OH VITAMIN D IN HUMAN SERUM AND PLASMA. ,LACTATE DEHYDROGENASE (LDH)-KIT FOR QUANTITATIVE IN VITRO DETERMINATION LACTATE DEHYDROGENASE IN SERUM OR PLASMA.,ACE CALIBRATOR(NA)-CALIBRATOR USED FOR CALIBRATION OF ACE ASSAYS , BILIRUBIN TOTAL & DIRECT (JENDRASSIK GROF'S METHOD)-KIT FOR QUANTITATIVE ESTIMATION OF BILIRUBIN TOTAL AND DIRECT IN HUMAN SERUM OR PLASMA,CCP CONTROL(NA)-CONTROL USED FOR EXAMINING THE ACCURACY AND PRECISION OF QUANTITATIVE CCP ASSAYS. ,ALKALINE PHOSPHATASE-IFCC METHOD-KIT FOR QUANTITATIVE ESTIMATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM.,FERRITIN(NA)-FERRITIN TEST IS USED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF FERRITIN IN SERUM AND PLASMA.,CHOLESTEROL-KIT FOR QUANTITATIVE ESTIMATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA,HOMOCYSTEINE CONTROL(NA)-CONTROL EXAMINING THE ACCURACY AND PRECISION OF QUANTITATIVE HOMOCYSTEINE ASSAYS. , CLEANER (FOR 5 PART ANALYZER)-KIT FOR THE CLEARING SOLUTION FOR HEMATOLOGY ANALYZER,VITAMIN-D CALIBRATOR(NA)-CALIBRATOR USED FOR CALIBRATION OF VITAMIN-D ASSAYS. , CREATININE - 2R-KIT FOR QUANTITATIVE ESTIMATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE.,CCP CALIBRATOR(NA)-CALIBRATOR USED FOR CALIBRATION OF CCP ASSAYS ,DS DNA ELISA-DS DNA ELISA KIT IS AN INVITRO DIAGNOSTIC ASSAY FOR QUANTITATIVE DETERMINATION OF ANTIBODIES TO DOUBLE STRANDED DNA IN HUMAN SERUM/PLASMA,VITAMIN-D CONTROL(NA)-CONTROL FOR EXAMINING THE ACCURACY AND PRECISION OF QUANTITATIVE VITAMIN-D ASSAYS. ,TOTAL PROTEIN-KIT FOR QUANTITATIVE ESTIMATION OF PROTEIN IN HUMAN SERUM/PLASMA.,DIGITAL BLOOD PRESSURE MONITOR-THE DIGITAL BLOOD PRESSURE MONITOR ARE FOR CLINICAL AND HOME USE AND ARE NONINVASIVE BLOOD PRESSURE MEASUREMENT SYSTEMS DESIGNED TO MEASURE THE SYSTOLIC AND DIASTOLIC BLOOD PRESSURE AND PULSE RATE OF AN ADULT INDIVIDUAL BY USING A NON-INVASIVE TECHNIQUE.,UREA NED DYE-KIT FOR QUANTITATIVE ESTIMATION OF UREA IN HUMAN SERUM OR PLASMA.,DIGITAL THERMOMETER-DIGITAL THERMOMETER IS INTENDED TO MEASURE THE HUMAN BODY TEMPERATURE IN REGULAR MODE ORALLY OR UNDER THE ARM AND THE DEVICES ARE REUSABLE FOR CLINICAL OR HOME USE ON PEOPLE OF ALL AGES.,CREATININE ENZYMATIC-KIT FOR QUANTITATIVE ESTIMATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE.,(RF) RHEUMATOID FACTOR RAPID TEST-RF RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE

	QUALITATIVE DETECTION OF ALL SUBTYPES OF RHEUMATOID FACTOR (RF) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD AT A SENSITIVITY OF 8 IU/ML.,CHOLESTEROL & HDL CHOLESTEROL-KIT FOR QUANTITATIVE ESTIMATION OF CHOLESTEROL & HDL CHOLESTEROL IN HUMAN SERUM AND PLASMA,TIBC (TOTAL IRON BINDING CAPACITY)-KIT FOR DETERMINATION OF IRON AND TOTAL IRON BINDING CAPACITY IN SERUM/HEPARINISED PLASMA.,CK (NAC ACTIVATED)-KIT FOR DETERMINATION OF CREATININE KINASE IN HUMAN SERUM/PLASMA,WIDAL-OH (AGGLUTINATION SLIDE TEST)-KIT FOR QUALITATIVE AND SEMI QUANTITATIVE DETECTION FOR SALMONELLA TYPHI IN HUMAN SERUM.,AMMONIA-KIT FOR THE QUANTITIVE ESTIMATION OF AMMONIA IN HUMAN PLASMA,G6PDH-G6PDH (GLUCOSE 6 PHOSPHATE DEHYDROGENASE) ASSAY KIT IS AN INVITRO DIAGNOSTIC ASSAY FOR THE QUANTITATIVE DETERMINATION OF G6PDH IN HUMAN SERUM/PLASMA,CLINICAL CHEMISTRY CONTROL (PATHOLOGICAL)-LYOPHILIZED ASSAYED CHEMISTRY CONTROL BASED ON HUMAN SERUM WITH ASSAYED VALUE FOR ALL COMPONENT OF ROUTINE CHEMISTRY PARAMETERS.,LEPTOSPIRA(IGG + IGM) RAPID TEST KIT-RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR QUALITATIVE DETECTION OF ANTIBODIES (IGG & IGM) TO LEPTOSPIRA INTEROGANS IN HUMAN SERUM/ PLASMA. IT IS INTENDED TO BE USED AS A SCREENING TEST., PHOSPHORUS-KIT FOR QUANTITATIVE ESTIMATION OF PHOSPHORUS IN HUMAN SERUM.,CLEANER-KIT FOR THE CLEARING SOLUTION FOR HEMATOLOGY ANALYZER,PHOSPHATE BUFFER-TO BE USED AS A DILUENTS .,LIVER LIA-LINE IMMUNO ASSAY KIT FOR DETECTION OF AUTOANTIBODIES IN AUTO IMMUNE LIVER DISEASE, ALBUMIN-KIT FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM AND PLASMA.,HDL CHOLESTEROL PRECIPITATING-KIT FOR QUANTITATIVE DETECTION OF HDL CHOLESTEROL IN HUMAN SERUM/PLASMA,VASCULITIS LIA-LINE IMMUNO ASSAY KIT FOR DETECTION OF AUTOANTIBODIES IN AUTO IMMUNE VASCULITIS DISEASE,DILUENT -TO BE USED AS A DILUENTS FOR RBC'S , FILARIASIS RAPID TEST -FILARASIS IGG/IGM IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR QUALITATIVE DETECTION AND DIFFERENTIATION OF IGG & IGM ANTI-LYMPHATIC FILARIAL PARASITES (W.BANCROFTI AND B. MALAYI) IN HUMAN SERUM/ PLASMA/ WHOLE BLOOD. ,WIDAL KIT (AGGLUTINATION SLIDE TEST)-KIT FOR THE IDENTIFICATION AND SEMI QUANTITATIVE DETERMINATION OF SPECIFIC ANTIBODIES IN HUMAN SERA FOLLOWING INFECTION WITH CERTAIN SALMONELLA PATHOGENS,-AMYLASE-KIT FOR QUANTITATIVE ESTIMATION OF AMYLASE IN HUMAN SERUM.,URINE STRIPS-4P-KIT FOR THE DETECTION OF GLUCOSE+PROTEIN+KETONE+BLOOD IN HUMAN URINE,SODIUM- MR

	-KIT FOR THE QUANTITATIVE ESTIMATION OF SODIUM IN HUMAN SERUM.,CK-MB-KIT FOR DETERMINATION OF CK-MB ACTIVITY IN HUMAN SERUM/PLASMA BY IMMUNOINHIBITION METHOD,VITAMIN D RAPID TEST- THE VITAMIN D RAPID TEST DEVICE IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE SEMI- QUANTITATIVE DETECTION OF 25-HYDROXYVITAMIN D (25 (OH) D) IN HUMAN WHOLE BLOOD. ,PROCALCITONIN RAPID TEST KIT-RAPID IMMUNOCHROMATOGRAPHIC TEST KIT FOR THE SEMI-QUANTITATIVE DETECTION OF PCT (PROCALCITONIN), WHICH IS USED FOR DIAGNOSING AND CONTROLLING THE TREATMENT OF SEVERE BACTERIAL INFECTION AND SEPSIS IN HUMAN SERUM/PLASMA,SODIUM(NA+) & POTASSIUM(K+) (COLORIMETRIC ASSAY-KIT FOR THE QUANTITATIVE ESTIMATION OF SODIUM & POTASSIUM IN HUMAN SERUM.,ALKALINE PHOSPHATASE (DGKC-DEA)-KIT FOR QUANTITATIVE ESTIMATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM.,URIC ACID-KIT FOR QUANTITATIVE DETECTION OF URIC ACID IN HUMAN SERUM/PLASMA,CLINICAL CHEMISTRY CALIBRATOR-LYOPHILIZED ASSAYED CHEMISTRY CALIBRATOR INTENDED FOR CALIBRATION OF CLINICAL CHEMISTRY PARAMETERS.,HBA1C-KIT FOR THE QUANTITATIVE ESTIMATION OF DIRECT ENZYMATIC HBA1C ASSAY IN HUMAN WHOLE BLOOD., CALCIUM (OCPC)-KIT FOR QUANTITATIVE DETECTION OF CALCIUM IN HUMAN SERUM.,MICROPROTEIN-KIT FOR QUANTITATIVE ESTIMATION OF MICROPROTEIN IN HUMAN URINE AND CEREBRO SPINAL FLUID., SGOT (COLORIMETRIC)-KIT FOR QUANTITATIVE ESTIMATION OF SERUM GLUTAMATE OXALOACETATE TRANSAMINASE (AST) IN SERUM.,SODIUM & POTASSIUM –MR -KIT FOR THE QUANTITATIVE ESTIMATION OF SODIUM & POTASSIUM IN HUMAN SERUM.,PROTEUS OX19 (AGGLUTINATION SLIDE TEST)-PROTEUS ANTIGEN SUSPENSION FOR WEIL FELIX TEST USED FOR DIAGNOSIS OF RICKETTSIAL INFECTION AND DIFFRENTIAL DIAGNOSIS OF PATIENT WITH TYPHUS GROUP RICKETTSIAE AND ROCKY MOUNTAIN SPOTTED FEVER, MAGNESIUM-KIT FOR QUANTITATIVE ESTIMATION OF MAGNESIUM IN HUMAN SERUM/ PLASMA,LYSE-KIT FOR THE LYSING SOLUTION FOR HEMATOLOGY ANALYZER,CREATININE-KIT FOR QUANTITATIVE ESTIMATION OF CREATININE IN HUMAN SERUM, PLASMA AND URINE., URINE STRIPS- 3P-KIT FOR THE DETECTION OF GLUCOSE + PROTEIN + KETONE IN HUMAN URINE,POTASSIUM-KIT FOR THE QUANTITATIVE ESTIMATION OF POTASSIUM IN HUMAN SERUM.,UREA UV-KIT FOR QUANTITATIVE ESTIMATION OF UREA IN HUMAN SERUM OR PLASMA., BRUCELLA (AGGLUTINATION SLIDE TEST)-KIT IS USED FOR QUALITATIVE AND SEMI QUANTITATIVE DETECTION FOR INFECTION WITH CERTAIN BRUCELLA PATHOGENS IN HUMAN SERUM.,FOB RAPID TEST KIT-RAPID CHROMATOGRAPHIC IMMUNOASSAY KIT FOR THE

	QUALITATIVE DETECTION OF HUMAN HEMOGLOBIN IN FECES. ,H. PYLORI ANTIBODY RAPID TEST KIT.-KIT FOR DETECTION OF HELICOBACTER ANTIBODIES IN HUMAN SERUM/PLASMA,CK-MB RAPID TEST KIT-KIT FOR QUALITATIVE DETECTION OF HUMAN CK-MB ACTIVITY IN HUMAN SERUM/PLASMA/WHOLE BLOOD.IT IS INTENDED TO BE USED AS A SCREENING TEST.,GLUCOSE-KIT FOR QUANTITATIVE ESTIMATION OF GLUCOSE IN HUMAN SERUM AND PLASMA,ALAT -KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALAT (GPT) IN SERUM OR PLASMA.,HLAB27 REAL TIME PCR-HLAB*27 ANTIGEN TEST IS AN IN VITRO QUANTITATIVE TEST FOR THE DETECTION OF HLAB*27 SPECIFIC GENOTYPES IN HUMAN SERUM/ PLASMA,ADENOSINE DEAMINASE (ADA)-KIT FOR DETECTION OF ADENOSINE DEAMINASE IN HUMAN SERUM/PLASMA/CSF FLUID, GLYCOSYLATED HEMOGLOBIN(A1 FAST FRACTION)-KIT FOR QUANTITATIVE DETERMINATION OF PERCENT GLYCOSYLATED HEMOGLOBIN IN HUMAN WHOLE BLOOD.,URINE STRIPS-2P-KIT FOR THE DETECTION OF GLUCOSE+PROTEIN IN HUMAN URINE,HCG RAPID TEST DEVICE-RAPID IMMUNOCHROMATOGRAPHIC ASSAY KIT FOR THE QUALITATIVE DETECTION OF HCG (HUMAN CHORIONIC GONADOTROPIN) IN URINE TO AID IN EARLY DIAGNOSIS OF PREGNANCY. ,PROTEUS OXK (AGGLUTINATION SLIDE TEST)-PROTEUS ANTIGEN SUSPENSION FOR WEIL FELIX TEST USED FOR DIAGNOSIS OF RICKETTSIAL INFECTION AND DIFFRENTIAL DIAGNOSIS OF PATIENT WITH SCRUB TYPHUS,UREA BERTHELOT-KIT FOR QUANTITATIVE ESTIMATION OF UREA IN HUMAN SERUM OR PLASMA.,FSH RAPID TEST KIT-RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF FSH (FOLLICAL STIMULATING HORMONE) IN URINE. ,PROTEUS OX2 (AGGLUTINATION SLIDE TEST)-PROTEUS ANTIGEN SUSPENSION FOR WEIL FELIX TEST USED FOR DIAGNOSIS OF RICKETTSIAL INFECTION AND DIFFRENTIAL DIAGNOSIS OF PATIENT WITH SPOTTED FEVER INFECTION, TRIGLYCERIDES- KIT FOR THE QUANTITATIVE ESTIMATION OF TRIGLYCERIDES IN HUMAN SERUM / PLASMA., BILIRUBIN TOTAL (DPD)-KIT FOR QUANTITATIVE ESTIMATION OF BILIRUBIN TOTAL IN HUMAN SERUM OR PLASMA,CHLORIDE-KIT FOR QUANTITATIVE ESTIMATION OF CHLORIDE IN HUMAN SERUM.,GASTRO LIA-LINE IMMUNO ASSAY KIT FOR DETECTION OF AUTOANTIBODIES IN AUTO IMMUNE GASTROINTESTINAL DISEASE,ASAT-KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF ASAT (GOT) IN SERUM OR PLASMA., IRON-KIT FOR QUANTITATIVE ESTIMATION OF IRON IN HUMAN SERUM/ HEPARINISED PLASMA., LIPASE-KIT FOR QUANTITATIVE ESTIMATION OF LIPASE IN HUMAN SERUM/PLASMA.,CALCIUM (ARSENAZO III)-KIT FOR QUANTITATIVE DETECTION OF CALCIUM IN HUMAN SERUM.,SCRUB TYPHUS RAPID TEST -RAPID TEST

	IMMUNOCHROMATOGRAPHIC ASSAY KIT FOR QUALITATIVE DETECTION OF IGM, IGG ANTIBODIES TO ORIENTIA TSUTSUGAMUSHI IN THE PATIENT'S SERUM / PLASMA SAMPLE.,CLINICAL CHEMISTRY CONTROL (NORMAL)-LYOPHILIZED ASSAYED CHEMISTRY CONTROL BASED ON HUMAN SERUM WITH ASSAYED VALUE FOR ALL COMPONENT OF ROUTINE CHEMISTRY PARAMETERS.,CHIKUNGUNYA IGG/IGM RAPID TEST KIT-RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR QUALITATIVE DETECTION OF ANTIBODIES (IGG & IGM) TO CHIKUNGUNYA IN HUMAN SERUM/ PLASMA/ WHOLE BLOOD., HEMOTOLOGY CONTROL- HEMATOLOGY CONTROL IS A CONTROL DESIGNED TO MONITOR ACCURACY AND PRECISION OF AUTOMATED AND SEMI-AUTOMATED HEMATOLOGY ANALYZERS. ,HCG RAPID TEST STRIP-RAPID IMMUNOCHROMATOGRAPHIC ASSAY KIT FOR THE QUALITATIVE DETECTION OF HCG (HUMAN CHORIONIC GONADOTROPIN) IN URINE TO AID IN EARLY DIAGNOSIS OF PREGNANCY. ,RF (AGGLUTINATION SLIDE TEST)-KIT FOR QUALITATIVE AND SEMI QUANTITATIVE DETECTION FOR RHEMATOID ARTHIRITIS IN HUMAN SERUM,URINE STRIPS- 11P-KIT FOR THE DETECTION OF ASCORBIC ACID+BLOOD+BILIRUBIN+GLUCOSE+KETONE+ LEUKOCYTE +NITRITE+PH+ PROTEIN+ SPECIFIC GRAVITY +UROBILINOGEN IN HUMAN URINE,ASO (AGGLUTINATION SLIDE TEST)-KIT FOR QUALITATIVE AND SEMI QUANTITATIVE DETECTION FOR ANTI-STREPTOLYSIN-O IN HUMAN SERUM,HDL CHOLESTEROL DIRECT-KIT FOR QUANTITATIVE DETECTION OF HDL CHOLESTEROL IN HUMAN SERUM/PLASMA,CRP (AGGLUTINATION SLIDE TEST)-KIT FOR QUALITATIVE AND SEMI QUANTITATIVE DETECTION FOR C REACTIVE PROTEIN IN HUMAN SERUM.,SGPT (COLORIMETRIC)-KIT FOR QUANTITATIVE ESTIMATION OF GLUTAMATE PYRUVATE TRANSAMINASE (ALT) IN HUMAN SERUM.,URINE STRIPS- GLUCOSE-KIT FOR THE DETECTION OF GLUCOSE IN HUMAN URINE,RF IMMUNOTURBIDIMETRIC KIT-IN VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN SERUM BY MEANS OF LATEX-ENHANCED TURBIDIMETRIC IMMUNOASSAY.,URINE STRIPS- MICROALBUMIN + CREATININE-KIT FOR THE DETECTION OF MICROALBUMIN + CREATININE IN HUMAN URINE,TOTAL PROTEIN & ALBUMIN -KIT FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN & ALBUMIN IN HUMAN SERUM / PLASMA.,LH RAPID TEST KIT-RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR QUALITATIVE DETECTION OF LEUTINISING HORMONE (LH) IN HUMAN URINE. ,ASO IMMUNOTURBIDIMETRIC KIT-IN VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN O (ASO) IN SERUM BY MEANS OF LATEX-ENHANCED TURBIDIMETRIC IMMUNOASSAY.,ANA LIA-LINE IMMUNO

	ASSAY KIT FOR DETECTION OF AUTOANTIBODIES IN AUTO IMMUNE ANTI NUCLEAR ANTIBODIES,LEPTOSPIRA IGM RAPID TEST KIT-LEPTOSPIRA IGM IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR QUALITATIVE DETECTION OF ANTIBODIES (IGM) TO LEPTOSPIRA INTEROGANS IN HUMAN SERUM/ PLASMA.,TYPHOID (IGG/IGM) RAPID TEST KI-RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR QUALITATIVE DETECTION AND DIFFERENTIATION OF IGG & IGM ANTIBODIES OF SALMONELLA TYPHI AND PARATYPHI IN HUMAN SERUM/ PLASMA. ,CRP IMMUNOTURBIDIMETRIC KIT-IN VITRO DIAGNOSTIC REAGENTS FOR THE QUANTITATIVE DETERMINATION OF C REACTIVE PROTEIN (CRP) IN SERUM BY MEANS OF LATEX-ENHANCED TURBIDIMETRIC IMMUNOASSAY.,HEMOGLOBIN TEST STRIP-HEMOGLOBIN TEST STRIP IS USED FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN (HB) AND CALCULATED HEMOTOCRIT (HCT) IN CAPILLARY AND VENOUS WHOLE BLOOD., LEISHMANIA IGG/IGM RAPID TEST KIT-LEISHMANIA IGG/IGM COMBO RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF IGG AND IGM TO THE SUBSPECIES OF THE LEISHMANIA DONOVANI (L. DONOVANI), THE VISCERAL LEISHMANIASIS CAUSATIVE PROTOZOANS, IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF THE DISEASE OF VISCERAL LEISHMANIASIS,TTG ELISA-TTG ELISA KIT IS AN INVITRO DIAGNOSTIC ASSAY FOR QUANTITATIVE DETERMINATION OF IGA TYPE ANTIBODIES TO TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM/PLASMA, LYSE - D (FOR 5 PART ANALYZER)-KIT FOR THE LYSING SOLUTION FOR HEMATOLOGY ANALYZER,CCP RAPID TEST-RAPID TEST KIT FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO CYCLIC CITRULLINATED PEPTIDE LEVELS IN HUMAN SERUM/ PLASMA.,LDL CHOLESTEROL DIRECT-KIT FOR QUANTITATIVE DETECTION OF LDL CHOLESTEROL IN HUMAN SERUM/PLASMA,URINE STRIPS - 10P-KIT FOR THE DETECTION OF GLUCOSE, BILIRUBIN, KETONE, SPECIFIC GRAVITY, BLOOD, PH, PROTEIN, UROBILINOGEN, NITRITE AND LEUKOCYTE IN HUMAN URINE,HEV IGM RAPID TEST-RAPID IMMUNOCHROMATOGRAPHIC ASSAY KIT USED FOR QUALITATIVE DETECTION OF ANTIBODIES SPECIFIC FOR HEPATITIS E VIRUS (IGM) IN HUMAN SERUM/PLASMA/WHOLE BLOOD ,LYSE - H (FOR 5 PART ANALYZER)-KIT FOR THE LYSING SOLUTION FOR HEMATOLOGY ANALYZER,CCP ELISA-CCP ELISA KIT IS AN INVITRO DIAGNOSTIC ASSAY FOR QUANTITATIVE DETERMINATION OF ANTIBODIES TO CYCLIC CITRULLINATED PEPTIDE (CCP) IN HUMAN SERUM/PLASMA,WIDAL (AGGLUTINATION SLIDE TEST)-KIT FOR QUALITATIVE AND SEMI QUANTITATIVE DETECTION FOR SALMONELLA TYPHI & PARA TYPHI

	IN HUMAN SERUM.,DILUENT-KIT FOR THE DILUENT SOLUTION FOR HEMATOLOGY ANALYZER

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2816	MFG/IVD/2020/000002	1.License Holder Name: AVANTOR PERFORMANCE MATERIALS INDIA LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:HIV ADVANCE (AG-AB) MICROWELL ELISA (IHF)(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HIV 1 & 2 AND P24 ANTIGEN TO HIV-1 VIRUS IN HUMAN SERUM AND PLASMA.,PRO HIV ½ ANTIBODY 3.1 RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-BENESPHERA PRO HIV1/2 ANTIBODY 3.1 RAPID CARD TEST IS A RAPID AND VISUAL IMMUNOCHROMATOGRAPHIC ASSAY, INTENDED FOR THE QUALITATIVE DETECTION OF ANTIBODIES AGAINST HIV 1 (INCLUDING GROUP O) AND /OR HIV 2 FROM HUMAN WHOLE BLOOD, SERUM AND PLASMA.,HCV MICROWELL ELISA(BENESPHERA)-QUALITATIVE DETECTION OF ANTIBODIES TO HCV IN HUMAN SERUM AND PLASMA, MALARIA PV/PF 2.0 ANTIGEN RAPID CARD TEST (LATERAL FLOW)-MALARIA PV/PF 2.0 ANTIGEN RAPID CARD TEST IS A QUICK IMMUNO-CHROMATOGRAPHIC QUALITATIVE, SENSITIVE AND SPECIFIC TEST FOR THE DISTINCT DIAGNOSIS OF PV SPECIFIC LDH AND PF SPECIFIC HRP2, ALLOWING IT TO DETECT PV AND PF DISTINCTLY. THIS TEST IS ONLY A PRELIMINARY SCREENING TEST FOR MALARIA DIFFERENTIAL DIAGNOSIS AND FOR IN-VITRO DIAGNOSTICS USE ONLY.,HCV MICROWELL ELISA(BENESPHERA)-QUALITATIVE DETECTION OF ANTIBODIES TO HCV IN HUMAN SERUM AND PLASMA,MALARIA PV/PF 2.0 ANTIGEN RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-MALARIA PV/PF 2.0 ANTIGEN RAPID CARD TEST IS A QUICK IMMUNO-CHROMATOGRAPHIC QUALITATIVE, SENSITIVE AND SPECIFIC TEST FOR THE DISTINCT DIAGNOSIS OF PV SPECIFIC LDH AND PF SPECIFIC HRP2, ALLOWING IT TO DETECT PV AND PF DISTINCTLY. THIS TEST IS ONLY A PRELIMINARY SCREENING TEST FOR MALARIA DIFFERENTIAL DIAGNOSIS AND FOR IN-VITRO DIAGNOSTICS USE ONLY.,HIV ADVANCE (AG-AB) MICROWELL ELISA (IHF)(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HIV 1 & 2 AND P24 ANTIGEN TO HIV-1 VIRUS IN HUMAN SERUM AND PLASMA.,PRO HIV ½ ANTIBODY 3.1 RAPID CARD TEST (LATERAL FLOW)-PRO HIV1/2 ANTIBODY 3.1 RAPID CARD TEST IS A RAPID AND VISUAL IMMUNOCHROMATOGRAPHIC ASSAY, INTENDED FOR THE QUALITATIVE DETECTION OF ANTIBODIES AGAINST HIV 1 (INCLUDING GROUP O) AND /OR HIV 2 FROM HUMAN WHOLE BLOOD, SERUM AND PLASMA,HCV MICROWELL ELISA (IHF)(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HCV VIRUS IN HUMAN SERUM AND PLASMA,HIV ADVANCE (AG-AB) (IHF) MICROWELL ELISA (BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE

	QUALITATIVE DETECTION OF ANTIBODIES TO HIV 1 & 2 AND P24 ANTIGEN TO HIV-1 VIRUS IN HUMAN SERUM AND PLASMA.,HBSAG MICROWELL ELISA(BENESPHERA)-QUALITATIVE DETECTION OF ANTIGEN TO HBSAG IN HUMAN SERUM AND PLASMA,HIV ADVANCE (AG-AB) (IHF) MICROWELL ELISA(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HIV 1 & 2 AND P24 ANTIGEN TO HIV-1 VIRUS IN HUMAN SERUM AND PLASMA.,MALARIA PV/PF RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-RAPID CARDS TEST FOR DETECTION OF MALARIA P.FALCIPARUM SPECIFIC HRP-II AND P.VIVEX SPECIFIC PLDH ANTIGEN IN HUMAN BLOOD,HCV RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID AND QUALITATIVE DETECTION OF ANTIBODIES TO HCV IN HUMAN SERUM AND PLASMA..,MALARIA PAN/PF RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-RAPID CARDS TEST FOR DETECTION OF MALARIA PLDH AND HRP-II ANTIGEN IN HUMAN BLOOD,MALARIA PAN RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-RAPID CARDS TEST FOR DETECTION OF MALARIA PLDH ANTIGEN IN HUMAN BLOOD,CTROPONIN I RAPID CARD TEST(LATERAL FLOW)-RAPID CARD TEST FOR DETECTION OF TROPONIN I SPECIFIC ANTIGEN IN HUMAN SERUM OR PLASMA,DENGUE NS1 AND IGG/IGM RAPID CARD TEST (LATERAL FLOW)-RAPID CARDS TEST (LATERAL FLOW) FOR DETECTION OF DENGUE NS1 ANTIGEN, IGG/IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM AND PLASMA,RPR TEST (FOR SCREENING OF SYPHILIS)(BENESPHERA)-DETERMINATION OF SYPHILIS IN HUMAN SERUM AND PLASMA,MALARIA PAN/PF RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-RAPID CARDS TEST FOR DETECTION OF MALARIA PLDH AND HRP-II ANTIGEN IN HUMAN BLOOD,RPR TEST (FOR SCREENING OF SYPHILIS)(BENESPHERA)-DETERMINATION OF SYPHILIS IN HUMAN SERUM AND PLASMA, MALARIA PV/PF RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-RAPID CARDS TEST FOR DETECTION OF MALARIA P.FALCIPARUM SPECIFIC HRP-II AND P.VIVAX SPECIFIC PLDH ANTIGEN IN HUMAN BLOOD,HIV ½ MICROWELL ELISA(BENESPHERA)-QUALITATIVE DETECTION OF ANTIBODIES TO HIV 1AND 2 IN HUMAN SERUM AND PLASMA,HIV ½ ANTIBODY 3.0 RAPID CARD TEST (LATERAL FLOW)-3 RD GENERATION SOLID PHASE IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE AND DIFFERENTIAL DETECTION OF ANTIBODIES (IGG, IGM, IGA) TO HIV-1 AND HIV-2 IN SERUM, PLASMA AND WHOLE BLOOD.,CHIKUNGUNYA IGM RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-QUALITATIVE IMMUNOCHROMATOGRAPHIC TEST (LATERAL FLOW) FOR THE DETECTION OF IGM ANTIBODIES SPECIFIC TO CHIKUNGUNYA VIRUS IN HUMAN SERUM OR PLASMA.. HEPATITIS B RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-

	RAPID CARDS TEST FOR DETECTION OF HEPATITIS-B SURFACE ANTIGEN IN HUMAN SERUM AND PLASMA,HBSAG MICROWELL ELISA (IHF)(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF SURFACE ANTIGEN TO HEPATITIS-B VIRUS IN HUMAN SERUM AND PLASMA,HIV ADVANCE (AG-AB) (IHF) MICROWELL ELISA(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HIV 1 & 2 AND P24 ANTIGEN TO HIV-1 VIRUS IN HUMAN SERUM AND PLASMA.,MICROWELL ELISA HBSAG (IHF) (BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF SURFACE ANTIGEN TO HEPATITIS-B VIRUS IN HUMAN SERUM AND PLASMA,MICROWELL ELISA HBSAG (IHF)(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF SURFACE ANTIGEN TO HEPATITIS-B VIRUS IN HUMAN SERUM AND PLASMA,HBSAG MICROWELL ELISA (IHF)(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF SURFACE ANTIGEN TO HEPATITIS-B VIRUS IN HUMAN SERUM AND PLASMA,HEPATITIS B RAPID CARD TEST (LATERAL FLOW)-RAPID CARDS TEST FOR DETECTION OF HEPATITIS-B SURFACE ANTIGEN IN HUMAN SERUM AND PLASMA, MICROWELL ELISA HBSAG (IHF)(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF SURFACE ANTIGEN TO HEPATITIS-B VIRUS IN HUMAN SERUM AND PLASMA,MALARIA PAN RAPID CARD TEST (LATERAL FLOW)-RAPID CARDS TEST FOR DETECTION OF MALARIA PLDH ANTIGEN IN HUMAN BLOOD,HCV RAPID CARD TEST (LATERAL FLOW)-IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID AND QUALITATIVE DETECTION OF ANTIBODIES TO HCV IN HUMAN SERUM AND PLASMA.., MALARIA PAN RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-RAPID CARDS TEST FOR DETECTION OF MALARIA PLDH ANTIGEN IN HUMAN BLOOD,SYPHILIS ANTIBODY RAPID CARD TEST (LATERAL FLOW)-IMMUNOCHROMATOGRAPHIC TEST (LATERAL FLOW) FOR THE DETECTION OF ANTIBODIES TO SYPHILIS (TREPONEMA PALLIDUM) VIRUS IN HUMAN SERUM AND PLASMA,HIV ADVANCE MICROWELL ELISA (AG-AB)(BENESPHERA)-QUALITATIVE DETECTION OF ANTIBODIES AND ANTIGEN TO HIV 1AND 2 IN HUMAN SERUM AND PLASMA,HIV 1/2 MICROWELL ELISA (IHF)(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HIV 1AND 2 VIRUS IN HUMAN SERUM AND PLASMA,HIV ADVANCE MICROWELL ELISA (AG-AB)(BENESPHERA)-QUALITATIVE DETECTION OF ANTIBODIES AND ANTIGEN TO HIV 1AND 2 IN HUMAN SERUM AND PLASMA,MALARIA PAN/PF RAPID CARD TEST (LATERAL FLOW)-RAPID CARDS TEST FOR DETECTION OF MALARIA PLDH AND HRP-II ANTIGEN IN HUMAN BLOOD,DENGUE

	IGG/IGM RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-RAPID CARD TEST (LATERAL FLOW) FOR DETECTION OF IGG & IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM, PLASMA AND WHOLE BLOOD.,HCV MICROWELL ELISA (IHF)(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HCV VIRUS IN HUMAN SERUM AND PLASMA, DENGUE NS1 RAPID CARD TEST (LATERAL FLOW)-RAPID CARDS TEST (LATERAL FLOW) FOR DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN SERUM, PLASMA AND WHOLE BLOOD.,HIV ½ MICROWELL ELISA(BENESPHERA)-QUALITATIVE DETECTION OF ANTIBODIES TO HIV 1AND 2 IN HUMAN SERUM AND PLASMA,DENGUE NS1 AG MICROWELL ELISA (IHF)(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF SURFACE ANTIGEN TO DENGUE VIRUS (SEROTYPES 1-4) IN HUMAN SERUM AND PLASMA,HIV 1/2 MICROWELL ELISA (IHF)(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HIV 1AND 2 VIRUS IN HUMAN SERUM AND PLASMA,DENGUE NS1 AND IGG/IGM CARD(BENESPHERA)-RAPID CARD TEST (LATERAL FLOW) FOR DETECTION OF DENGUE NS1 ANTIGEN, IGG & IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM , PLASMA OR WHOLE BLOOD.,HIV 1/2 MICROWELL ELISA (IHF) (BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HIV 1 AND 2 VIRUS IN HUMAN SERUM AND PLASMA,DENGUE NS1 ANTIGEN CARD (BENESPHERA)-RAPID CARD TEST (LATERAL FLOW) FOR DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN SERUM , PLASMA OR WHOLE BLOOD.,HIV 1/2 MICROWELL ELISA (IHF)(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HIV 1AND 2 VIRUS IN HUMAN SERUM AND PLASMA,DENGUE NS1 AND IGG/IGM RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-RAPID CARDS TEST (LATERAL FLOW) FOR DETECTION OF DENGUE NS1 ANTIGEN, IGG/IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM , PLASMA OR WHOLE BLOOD.,HIV ½ ANTIBODY 3.0 RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-3 RD GENERATION SOLID PHASE IMMUNOCHROMATOGRAPHIC ASSAY FOR RAPID, QUALITATIVE AND DIFFERENTIAL DETECTION OF ANTIBODIES (IGG, IGM, IGA) TO HIV-1 AND HIV-2 IN SERUM, PLASMA AND WHOLE BLOOD.,TROPONIN I RAPID CARD TEST (LATERAL FLOW) (BENESPHERA)-RAPID CARD TEST FOR DETECTION OF TROPONIN I SPECIFIC ANTIGEN IN HUMAN SERUM OR PLASMA,HBSAG MICROWELL ELISA(BENESPHERA)-QUALITATIVE DETECTION OF ANTIGEN TO HBSAG IN HUMAN SERUM AND PLASMA,DENGUE NS1 ANTIGEN RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-RAPID CARDS TEST (LATERAL FLOW) FOR DETECTION OF DENGUE NS1

	ANTIGEN IN HUMAN SERUM, PLASMA AND WHOLE BLOOD.,HIV 1/2 MICROWELL ELISA (IHF)(BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HIV 1AND 2 VIRUS IN HUMAN SERUM AND PLASMA, WIDAL SLIDE TEST(BENESPHERA)-DETERMINATION OF ANTIBODIES S-TYPHI & S-PARATYPHI IN HUMAN SERUM,MALARIA PAN RAPID CARD TEST (LATERAL FLOW)-RAPID CARDS TEST FOR DETECTION OF MALARIA PLDH ANTIGEN IN HUMAN BLOOD,WIDAL TUBE TEST (BENESPHERA)-DETERMINATION OF ANTIBODIES S-TYPHI & S-PARATYPHI IN HUMAN SERUM,HCV MICROWELL ELISA (IHF) (BENESPHERA)-ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HCV VIRUS IN HUMAN SERUM AND PLASMA,ASO (LATEX SLIDE TEST)(BENESPHERA)-DETERMINATION OF ANTI STREPTOLYSIN O IN HUMAN SERUM, MALARIA PV/PF RAPID CARD TEST (LATERAL FLOW)-RAPID CARDS TEST FOR DETECTION OF MALARIA P.FALCIPARUM SPECIFIC HRP-II AND P.VIVEX SPECIFIC PLDH ANTIGEN IN HUMAN BLOOD,CRP (LATEX SLIDE TEST)(BENESPHERA)-DETERMINATION OF C REACTIVE PROTEIN IN HUMAN SERUM,SYPHILIS ANTIBODY RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-IMMUNOCHROMATOGRAPHIC TEST (LATERAL FLOW) FOR THE DETECTION OF ANTIBODIES TO SYPHILIS (TREPONEMA PALLIDUM)VIRUS IN HUMAN SERUM AND PLASMA

CENTRAL DRUG STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2817	MFG/IVD/2020/000003	1.License Holder Name: AVANTOR PERFORMANCE MATERIALS INDIA LIMITED 2.Approving Authority: UTTARAKHAND 3.Device Name(Brand Name)-Intended Use:HAEMOGLOBIN CN FREE (AZIDE-METHAEMOGLOBIN METHOD) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF HAEMOGLOBIN IN HUMAN WHOLE BLOOD,UNIVERSAL (VIRAL) TRANSPORT MEDIUM (UTM) (BENESPHERA)-UNIVERSAL (VIRAL) TRANSPORT MEDIUM IS RECOMMENDED FOR COLLECTION, TRANSPORT, STORAGE AND RECOVERY OF CLINICAL SPECIMEN CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. IT IS USED TO MAINTAIN THE IDEAL VIABILITY AND VIRULENCE OF THE SAMPLE EVEN AT ROOM TEMPERATURE DURING TRANSPORT.,FSH MICROWELL ELISA(BENESPHERA)-QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE CONCENTRATION IN HUMAN SERUM.,UNIVERSAL (VIRAL) TRANSPORT MEDIUM (UTM)-UNIVERSAL (VIRAL) TRANSPORT MEDIUM IS RECOMMENDED FOR COLLECTION, TRANSPORT, STORAGE AND RECOVERY OF CLINICAL SPECIMEN CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. IT IS USED TO MAINTAIN THE IDEAL VIABILITY AND VIRULENCE OF THE SAMPLE EVEN AT ROOM TEMPERATURE DURING TRANSPORT.,PROLACTIN MICROWELL ELISA(BENESPHERA)-QUANTITATIVE DETERMINATION OF PROLACTIN CONCENTRATION IN HUMAN SERUM.,FSH MICROWELL ELISA(BENESPHERA)-QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE CONCENTRATION IN HUMAN SERUM.,GLUCOSE (GOD-POD) SYSTEM PACK LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF GLUCOSE IN HUMAN SERUM AND PLASMA,TSH MICROWELL ELISA(BENESPHERA)-QUANTITATIVE DETERMINATION OF TOTAL THYROID STIMULATING HORMONE CONCENTRATION IN HUMAN SERUM.,CHIKUNGUNYA IGM RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-QUALITATIVE IMMUNOCHROMATOGRAPHIC TEST (LATERAL FLOW) FOR THE DETECTION OF IGM ANTIBODIES SPECIFIC TO CHIKUNGUNYA VIRUS IN HUMAN SERUM OR PLASMA.,CHLORIDE (MERCURIC THIOCYANATE) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF CHLORIDE IN HUMAN SERUM, ALBUMIN (BCG) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF ALBUMIN IN HUMAN SERUM AND PLASMA,UREA / BUN (BERTHELOT)(BENESPHERA)-QUANTITATIVE ESTIMATION OF UREA / BUN IN HUMAN SERUM AND PLASMA,ALKALINE PHOSPHATASE (DGKC) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF ALKALINE PHOSPHATASE IN HUMAN

	SERUM,BILIRUBIN T & D (JENDRASSIK AND GROFF.) LIQUID STABLE (BENESPHERA)-QUANTITATIVE ESTIMATION OF BILIRUBIN TOTAL & DIRECT IN HUMAN SERUM AND PLASMA,CLEANER (5-PART DIFFERENTIAL)(BENESPHERA)-TO CLEAN THE TUBE AND BATH OF HEMATOLOGY ANALYZER,SGPT/ALT (IFCC/KINETIC) LIQUID STABLE (BENESPHERA)-QUANTITATIVE ESTIMATION OF GPT IN HUMAN SERUM AND PLASMA,EZ CLEANER (3-PART DIFFERENTIAL) (BENESPHERA)-TO CLEAN THE TUBE AND BATH,ALKALINE PHOSPHATASE (DGKC) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM,SGPT/ALT (IFCC/KINETIC) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF GPT IN HUMAN SERUM AND PLASMA, -AMYLASE (CNP-G3) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF AMYLASE ACTIVITY IN HUMAN SERUM,DEO (II) LYSE (5-PART DIFFERENTIAL)(BENESPHERA)-IT IS WHOLE BLOOD LYSING REAGENT SUITABLE TO LYSE THE RBC,S AND 4- DIFFERENTIAL OF WBC'S, WHICH HELPS IN STAINING,URIC ACID (URICASE-POD) SYSTEM PACK LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF URIC ACID IN HUMAN SERUM AND PLASMA,PROLACTIN MICROWELL ELISA(BENESPHERA)-QUANTITATIVE DETERMINATION OF PROLACTIN CONCENTRATION IN HUMAN SERUM.,TRIGLYCERIDES (GPO-POD) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA,LDL CHOLESTEROL(BENESPHERA)-QUANTITATIVE ESTIMATION OF LDL CHOLESTEROL IN HUMAN SERUM AND PLASMA,BILIRUBIN T AND D CALIBRATOR(BENESPHERA)-HUMAN BILIRUBIN CALIBRATOR IS FOR THE PURPOSE OF STANDARDIZING RESULTS OBTAINED FROM RUN TO RUN IN THE QUANTITATIVE DETERMINATION OF HUMAN TOTAL AND DIRECT BILIRUBIN IN SERUM AND PLASMA.,DEO (I) LYSE (H51 SERIES)(BENESPHERA)-IT IS WHOLE BLOOD LYSING REAGENT SUITABLE TO LYSE THE RBC,S AND 4- DIFFERENTIAL OF WBC'S, WHICH HELPS IN SIZING,TRIGLYCERIDES (GPO-POD) SYSTEM PACK LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA,DH LYSE (H51 SERIES)(BENESPHERA)-WHOLE BLOOD LYSING REAGENT FOR DETERMINATION OF HEMOGLOBIN,HDL CHOLESTEROL (BENESPHERA)-QUANTITATIVE ESTIMATION OF HDL CHOLESTEROL IN HUMAN SERUM AND PLASMA,DBA LYSE (H51 SERIES) (BENESPHERA)-WHOLE BLOOD LYSING REAGENT FOR DETERMINATION OF BASOPHILLS AND WBCS COUNTS,DEO (II) LYSE (H51 SERIES)(BENESPHERA)-IT IS WHOLE BLOOD LYSING REAGENT SUITABLE TO LYSE THE RBC,S AND 4- DIFFERENTIAL OF WBC'S, WHICH HELPS IN STAINING,URINE STRIPS 10P(BENESPHERA)-TEST FOR THE SEMI-QUANTITATIVE MEASUREMENT OF LEUKOCYTES,

	KETONE, NITRITE, UROBILINOGEN, BILIRUBIN, PROTEIN, GLUCOSE, SPECIFIC GRAVITY, BLOOD AND PH IN URINE,URINE STRIPS 11P (BENESPHERA)-TEST FOR THE SEMI-QUANTITATIVE MEASUREMENT OF LEUKOCYTES, KETONE, NITRITE, UROBILINOGEN, BILIRUBIN, PROTEIN, GLUCOSE, SPECIFIC GRAVITY, BLOOD, PH AND ASCORBIC ACID IN URINE,DILUENT (SYSMAX KX-21)(BENESPHERA)-TO DILUTE THE BLOOD SAMPLE,3D – S – LYSE (IHF)(BENESPHERA)-FOR ACCURATE COUNT OF WBCS, ESTIMATION OF HB AND TRIMODAL DIFFERENTIAL OF WBCS,ALKALINE PHOSPHATASE (GSCC/KINETIC) (BENESPHERA)-QUANTITATIVE ESTIMATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM,BILIRUBIN T & D (JENDRASSIK AND GROFF.)LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF BILIRUBIN TOTAL & DIRECT IN HUMAN SERUM AND PLASMA, CHOLESTEROL (CHOD-POD) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA,SGOT/AST (IFCC/KINETIC)(BENESPHERA)-QUANTITATIVE ESTIMATION OF GOT IN HUMAN SERUM AND PLASMA, CHOLESTEROL (CHOD–PAP)(BENESPHERA)-QUANTITATIVE ESTIMATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA, CREATININE LIQUID STABLE SINGLE REAGENT(BENESPHERA)-QUANTITATIVE ESTIMATION OF CREATININE IN HUMAN SERUM AND PLASMA,LIPID CALIBRATOR(BENESPHERA)-DETERMINATION OF HDL-CHOLESTEROLLDL- CHOLESTEROLTRIGLYCERIDETOTAL CHOLESTEROLFREE CHOLESTEROL AND PHOSPHOLIPID,UREA UV (GLDH) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF UREA IN HUMAN SERUM AND PLASMA,GLUCOSE (DPEC-GOD/POD) (BENESPHERA)-QUANTITATIVE ESTIMATION OF GLUCOSE IN HUMAN SERUM AND PLASMA,SGPT/ALT (IFCC/KINETIC) SYSTEM PACK LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF GPT IN HUMAN SERUM AND PLASMA,TRIGLYCERIDES (GPO-POD) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA,HDL CHOLESTEROL PRECIPITATING REAGENT (PEG) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF HDL CHOLESTEROL IN HUMAN SERUM AND PLASMA,DBA LYSE (5-PART DIFFERENTIAL) (BENESPHERA)-WHOLE BLOOD LYSING REAGENT FOR DETERMINATION OF BASOPHILLS AND WBCS COUNTS,CHOLESTEROL (CHOD-POD) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA,3D – S – DILUENT (IHF)(BENESPHERA)-TO DILUTE THE BLOOD SAMPLE, SGOT/AST (IFCC/KINETIC) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF GOT IN HUMAN SERUM AND PLASMA, PROCLEAN(BENESPHERA)-FILTERED, NON-STERILE CLEANING FLUID FOR USE IN CLEANING OF CELL COUNTERS.,ALKALINE

	PHOSPHATASE (DGKC) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM,DILUENT (H51 SERIES)(BENESPHERA)-TO DILUTE THE BLOOD SAMPLE,DETECTOTERGE(BENESPHERA)-FILTERED, NON-STERILE CLEANING FLUID FOR USE IN CLEANING OF CELL COUNTERS.,URIC ACID (URICASE-POD) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF URIC ACID IN HUMAN SERUM AND PLASMA, HAEMOGLOBIN CN FREE (AZIDE-METHAEMOGLOBIN METHOD) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF HAEMOGLOBIN IN HUMAN WHOLE BLOOD,RFS (LATEX SLIDE TEST) (BENESPHERA)-DETERMINATION OF RF FACTOR IN HUMAN SERUM, ALKALINE PHOSPHATASE (GSCC/KINETIC)(BENESPHERA)-QUANTITATIVE ESTIMATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM,CREATININE LIQUID STABLE SINGLE REAGENT(BENESPHERA) -QUANTITATIVE ESTIMATION OF CREATININE IN HUMAN SERUM AND PLASMA,SGPT/ALT (IFCC/KINETIC)(BENESPHERA)-QUANTITATIVE ESTIMATION OF GPT IN HUMAN SERUM AND PLASMA,URINE STRIPS 14P(BENESPHERA)-TEST FOR THE SEMI-QUANTITATIVE MEASUREMENT OF LEUKOCYTES, KETONE, NITRITE, UROBILINOGEN, BILIRUBIN, PROTEIN, GLUCOSE, SPECIFIC GRAVITY, BLOOD, PH, ASCORBIC ACID, MICROALBUMIN, CALCIUM AND CREATININE IN URINE,GLUCOSE (GOD-POD) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF GLUCOSE IN HUMAN SERUM AND PLASMA,BILIRUBIN T & D(JENDRASSIK AND GROF)(BENESPHERA)-QUANTITATIVE ESTIMATION OF BILIRUBIN TOTAL & DIRECT IN HUMAN SERUM AND PLASMA,DH LYSE (5-PART DIFFERENTIAL) (BENESPHERA)-WHOLE BLOOD LYSING REAGENT FOR DETERMINATION OF HEMOGLOBIN,GLUCOSE (GOD-POD) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF GLUCOSE IN HUMAN SERUM AND PLASMA,RINSE (MINDRAY 3 PART) (BENESPHERA)-TO CLEAN THE BATH AND MEASURING TUBES, VITAMIN D TOTAL ELISA(BENESPHERA)-IMMUNOENZYMETRIC ASSAY FOR THE INVITRO QUANTITATIVE MEASUREMENT OF 25-HYDROXYVITAMIN D2 AND D3 (25OH-D2 AND 25OH-D3) IN SERUM AND PLASMA,HDL/LDL CONTROLS(BENESPHERA)-REFERENCE MATERIAL FOR THE DETERMINATION OF HDL/LDL CHOLESTEROL USING HDL/LDL CHOLESTEROL REAGENTS,TSH MICROWELL ELISA (BENESPHERA)-QUANTITATIVE DETERMINATION OF TOTAL THYROID STIMULATING HORMONE CONCENTRATION IN HUMAN SERUM.,-AMYLASE (CNP-G3) SYSTEM PACK LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF AMYLASE ACTIVITY IN HUMAN SERUM,ALBUMIN (BCG) SYSTEM PACK LIQUID STABLE(BENESPHERA) -QUANTITATIVE ESTIMATION OF ALBUMIN IN HUMAN SERUM AND PLASMA,CF LYSE (MINDRAY 3 PART)(BENESPHERA)-WHOLE BLOOD

	LYSING REAGENT FOR DETERMINATION OF HEMOGLOBIN,CYMET III DIFF(BENESPHERA)-FILTERED, NON-STERILE BLOOD LYSING FLUID FOR USE IN CELL COUNTING & SIZING,TOTAL PROTEIN (BIURET) SYSTEM PACK LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF TOTAL PROTEIN IN HUMAN SERUM AND PLASMA,HDL CHOLESTEROL (PEG-PAP)(BENESPHERA)-QUANTITATIVE ESTIMATION OF HDL CHOLESTEROL IN HUMAN SERUM AND PLASMA, CALCIUM (ARSENAZO III) SYSTEM PACK LIQUID STABLE (BENESPHERA)-QUANTITATIVE ESTIMATION OF CALCIUM IN HUMAN SERUM,CHOLESTEROL (CHOD-POD) SYSTEM PACK LIQUID STABLE (BENESPHERA)-QUANTITATIVE ESTIMATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA,RINSE (3-PART DIFFERENTIAL) (BENESPHERA)-TO CLEAN THE BATH AND MEASURING TUBES,TOTAL PROTEIN (BIURET) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF TOTAL PROTEIN IN HUMAN SERUM AND PLASMA,HDL CHOLESTEROL(BENESPHERA)-QUANTITATIVE ESTIMATION OF HDL CHOLESTEROL IN HUMAN SERUM AND PLASMA,LH MICROWELL ELISA (BENESPHERA)-QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE CONCENTRATION IN HUMAN SERUM.,SGOT/AST (IFCC/KINETIC) SYSTEM PACK LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF GOT IN HUMAN SERUM AND PLASMA, CREATININE (JAFFE'S/KINETIC) SYSTEM PACK LIQUID STABLE (BENESPHERA)-QUANTITATIVE ESTIMATION OF CREATININE IN HUMAN SERUM AND PLASMA,UREA UV (GLDH) SYSTEM PACK LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF UREA IN HUMAN SERUM AND PLASMA,PROCLEAN(BENESPHERA)-FILTERED, NON-STERILE CLEANING FLUID FOR USE IN CLEANING OF CELL COUNTERS.,UREA UV (GLDH/KINETIC)(BENESPHERA)-QUANTITATIVE ESTIMATION OF UREA IN HUMAN SERUM AND PLASMA,CYMET KX-21 (BENESPHERA)-FILTERED, NON-STERILE BLOOD LYSING FLUID FOR USE IN CELL COUNTING & SIZING,3D – S – CLEAN (IHF)(BENESPHERA)-FOR REMOVING BLOOD PROTEINS, RESIDUAL LYSING REAGENTS AND CELLULAR RESIDUALS,SODIUM (COLORIMETRIC) LIQUID STABLE (BENESPHERA)-FOR QUANTITATIVE ESTIMATION OF SODIUM IN HUMAN SERUM,UREA UV (GLDH) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF UREA IN HUMAN SERUM AND PLASMA,FREE T3 MICROWELL ELISA(BENESPHERA)-QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE CONCENTRATION IN HUMAN SERUM.,CYMET BS3 CN FREE(BENESPHERA)-FILTERED, NON-STERILE BLOOD LYSING FLUID FOR USING IN CELL COUNTING & SIZING,SGOT/AST (IFCC/KINETIC) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF GOT IN HUMAN SERUM AND PLASMA, H33S DILUENT (3-PART DIFFERENTIAL)(BENESPHERA)-TO DILUTE THE BLOOD SAMPLE,CREATININE (JAFFE'S/KINETIC) LIQUID STABLE

	(BENESPHERA)-QUANTITATIVE ESTIMATION OF CREATININE IN HUMAN SERUM AND PLASMA,URIC ACID (URICASE-POD) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF URIC ACID IN HUMAN SERUM AND PLASMA,TOTAL PROTEIN (BIURET) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF TOTAL PROTEIN IN HUMAN SERUM AND PLASMA,H33S PROBE CLEANER (3-PART DIFFERENTIAL)(BENESPHERA)-FOR PERIODIC CLEANING OF HEMATOLOGY ANALYZER,ALBUMIN (BCG) LIQUID STABLE (BENESPHERA)-QUANTITATIVE ESTIMATION OF ALBUMIN IN HUMAN SERUM AND PLASMA,CHLORIDE (MERCURIC THIOCYANATE) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF CHLORIDE IN HUMAN SERUM,CALCIUM (ARSENAZO III) (IHF) LIQUID STABLE (BENESPHERA)-QUANTITATIVE ESTIMATION OF CALCIUM IN HUMAN SERUM,TRIGLYCERIDES (GPO-POD) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA,BILIRUBIN T AND D CALIBRATOR(BENESPHERA)-HUMAN BILIRUBIN CALIBRATOR IS FOR THE PURPOSE OF STANDARDIZING RESULTS OBTAINED FROM RUN TO RUN IN THE QUANTITATIVE DETERMINATION OF HUMAN TOTAL AND DIRECT BILIRUBIN IN SERUM AND PLASMA.,PROBE CLEANER (3-PART DIFFERENTIAL)(BENESPHERA)-FOR PERIODIC CLEANING OF HEMATOLOGY ANALYZER,H33S LYSE (3-PART DIFFERENTIAL) (BENESPHERA)-WHOLE BLOOD LYSING REAGENT FOR DETERMINATION OF HEMOGLOBIN,HDL CHOLESTEROL(PEG-PAP) (BENESPHERA)-QUANTITATIVE ESTIMATION OF HDL CHOLESTEROL IN HUMAN SERUM AND PLASMA,DILUENT III DIFF(BENESPHERA)-"FILTERED, NON-STERILE BLOOD DILUTING FLUID FOR USE IN CELL COUNTING & SIZING ",FREE T3 MICROWELL ELISA(BENESPHERA)-QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE CONCENTRATION IN HUMAN SERUM.,TRIGLYCERIDES (GPO/ESPAS) (BENESPHERA)-QUANTITATIVE ESTIMATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA,CYMET KX(BENESPHERA)-FILTERED, NON-STERILE BLOOD LYSING FLUID FOR USE IN CELL COUNTING & SIZING,T3 MICROWELL ELISA(BENESPHERA)-QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE CONCENTRATION IN HUMAN SERUM.,UREA UV (GLDH) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF UREA IN HUMAN SERUM AND PLASMA,FREE T4 MICROWELL ELISA(BENESPHERA)-QUANTITATIVE DETERMINATION OF FREE THYROXIN CONCENTRATION IN HUMAN SERUM.,CLEAN (SYSMEX KX-21)(BENESPHERA)-FOR REMOVING BLOOD PROTEINS, RESIDUAL LYSING REAGENTS AND CELLULAR RESIDUALS,FREE T4 MICROWELL ELISA(BENESPHERA)-QUANTITATIVE DETERMINATION OF FREE THYROXIN CONCENTRATION IN HUMAN SERUM.,T4 MICROWELL ELISA

	(BENESPHERA)-QUANTITATIVE DETERMINATION OF TOTAL THYROXIN CONCENTRATION IN HUMAN SERUM.,T4 MICROWELL ELISA(BENESPHERA)-QUANTITATIVE DETERMINATION OF TOTAL THYROXIN CONCENTRATION IN HUMAN SERUM.,LYSE (SYSMEX KX-21)(BENESPHERA)-FOR ACCURATE COUNT OF WBCS, ESTIMATION OF HB AND TRIMODAL DIFFERENTIAL OF WBCS,BENESPHERA DENGUE IGG/IGM CARD(BENESPHERA)-RAPID CARD TEST (LATERAL FLOW) FOR DETECTION OF IGG & IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM OR PLASMA.,T3 MICROWELL ELISA(BENESPHERA)-QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE CONCENTRATION IN HUMAN SERUM.,LDL CHOLESTEROL (BENESPHERA)-QUANTITATIVE ESTIMATION OF LDL CHOLESTEROL IN HUMAN SERUM AND PLASMA,UREA/ BUN (UREASE/SALICYLATE) (BENESPHERA)-QUANTITATIVE ESTIMATION OF UREA / BUN IN HUMAN SERUM AND PLASMA,DILUENT III DIFF(BENESPHERA)-FILTERED, NON-STERILE BLOOD DILUTING FLUID FOR USE IN CELL COUNTING & SIZING,CYMET III DIFF(BENESPHERA)-FILTERED, NON-STERILE BLOOD LYSING FLUID FOR USE IN CELL COUNTING & SIZING, PROBE CLEANER (H51 SERIES)(BENESPHERA)-PERIODIC CLEANING OF HEMATOLOGY ANALYZER,UREA UV (GLDH/KINETIC) (BENESPHERA)-QUANTITATIVE ESTIMATION OF UREA IN HUMAN SERUM AND PLASMA,UREA/ BUN (UREASE/SALICYLATE) (BENESPHERA)-QUANTITATIVE ESTIMATION OF UREA / BUN IN HUMAN SERUM AND PLASMA,HDL/LDL CONTROLS(BENESPHERA)-REFERENCE MATERIAL FOR THE DETERMINATION OF HDL/LDL CHOLESTEROL USING HDL/LDL CHOLESTEROL REAGENTS,DILUENT (5-PART DIFFERENTIAL)(BENESPHERA)-TO DILUTE THE BLOOD SAMPLE,BILIRUBIN T & D (JENDRASSIK AND GROF)(BENESPHERA)-QUANTITATIVE ESTIMATION OF BILIRUBIN TOTAL & DIRECT IN HUMAN SERUM AND PLASMA,POTASSIUM (COLORIMETRIC) LIQUID STABLE(BENESPHERA)-FOR QUANTITATIVE ESTIMATION OF POTASSIUM IN HUMAN SERUM,LYSE (SYSMAX KX-21)(BENESPHERA)-FOR ACCURATE COUNT OF WBCS, ESTIMATION OF HB AND TRIMODAL DIFFERENTIAL OF WBCS,-AMYLASE (CNP-G3) LIQUID STABLE (BENESPHERA)-QUANTITATIVE ESTIMATION OF AMYLASE ACTIVITY IN HUMAN SERUM,URIC ACID (URICASE/PAP)(BENESPHERA)-QUANTITATIVE ESTIMATION OF URIC ACID IN HUMAN SERUM AND PLASMA,CALCIUM (ARSENAZO III) (IHF) LIQUID STABLE (BENESPHERA)-QUANTITATIVE ESTIMATION OF CALCIUM IN HUMAN SERUM,GLUCOSE (DPEC-GOD/POD)(BENESPHERA)-QUANTITATIVE ESTIMATION OF GLUCOSE IN HUMAN SERUM AND PLASMA,UREA / BUN (BERTHELOT)(BENESPHERA)-QUANTITATIVE ESTIMATION OF UREA / BUN IN HUMAN SERUM AND PLASMA,TOTAL PROTEIN (BIURET) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION

	OF TOTAL PROTEIN IN HUMAN SERUM AND PLASMA,CHOLESTEROL (CHOD–PAP)(BENESPHERA)-QUANTITATIVE ESTIMATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA,MAGNESIUM (CALMAGITE DYE) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF MAGNESIUM IN HUMAN SERUM,LIPID CALIBRATOR (BENESPHERA)-DETERMINATION OF HDL-CHOLESTEROLLDL-CHOLESTEROLTRIGLYCERIDETOTAL CHOLESTEROLFREE CHOLESTEROL AND PHOSPHOLIPID,DENGUE IGG/IGM RAPID CARD TEST (LATERAL FLOW)(BENESPHERA)-RAPID CARD TEST (LATERAL FLOW) FOR DETECTION OF IGG & IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM, PLASMA AND WHOLE BLOOD.,TRIGLYCERIDES (GPO/ESPAS)(BENESPHERA)-QUANTITATIVE ESTIMATION OF TRIGLYCERIDES IN HUMAN SERUM AND PLASMA,SGPT/ALT (IFCC/KINETIC)(BENESPHERA)-QUANTITATIVE ESTIMATION OF GPT IN HUMAN SERUM AND PLASMA,DILUENT (SYSMEX KX-21) (BENESPHERA)-TO DILUTE THE BLOOD SAMPLE,DEO (I) LYSE (5-PART DIFFERENTIAL)(BENESPHERA)-IT IS WHOLE BLOOD LYSING REAGENT SUITABLE TO LYSE THE RBC,S AND 4- DIFFERENTIAL OF WBC'S, WHICH HELPS IN SIZING,CREATININE (JAFFE'S/KINETIC) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF CREATININE IN HUMAN SERUM AND PLASMA,PHOSPHORUS (AMMONIUM MOLYBDATE) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF PHOSPHOROUS IN HUMAN SERUM,PROBE CLEANER (5-PART DIFFERENTIAL)(BENESPHERA)-PERIODIC CLEANING OF HEMATOLOGY ANALYZER,DILUENT (3-PART DIFFERENTIAL) (BENESPHERA)-TO DILUTE THE BLOOD SAMPLE,URIC ACID (URICASE/PAP)(BENESPHERA)-QUANTITATIVE ESTIMATION OF URIC ACID IN HUMAN SERUM AND PLASMA,PROBE CLEANER (MINDRAY 3 PART)(BENESPHERA)-FOR PERIODIC CLEANING OF HEMATOLOGY ANALYZER,HDL CHOLESTEROL PRECIPITATING REAGENT (PEG) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF HDL CHOLESTEROL IN HUMAN SERUM AND PLASMA,LH MICROWELL ELISA (BENESPHERA)-QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE CONCENTRATION IN HUMAN SERUM.,DETECTOTERGE (BENESPHERA)-FILTERED, NON-STERILE CLEANING FLUID FOR USE IN CLEANING OF CELL COUNTERS.,CALCIUM (ARSENAZO III) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF CALCIUM IN HUMAN SERUM,SGOT/AST (IFCC/KINETIC)(BENESPHERA)-QUANTITATIVE ESTIMATION OF GOT IN HUMAN SERUM AND PLASMA, EZ CLEANER (MINDRAY 3 PART)(BENESPHERA)-TO CLEAN THE TUBE AND BATH,GLUCOSE (GOD-POD) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF GLUCOSE IN HUMAN SERUM AND PLASMA,DILUID 100 PLUS(BENESPHERA)-FILTERED, NON-STERILE BLOOD DILUTING FLUID FOR USING IN CELL COUNTING & SIZING,

	CREATININE LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF CREATININE IN HUMAN SERUM AND PLASMA,CF LYSE (3-PART DIFFERENTIAL)(BENESPHERA)-WHOLE BLOOD LYSING REAGENT FOR DETERMINATION OF HEMOGLOBIN,DILUENT (MINDRAY 3 PART)(BENESPHERA)-TO DILUTE THE BLOOD SAMPLE,CLEAN (SYSMAX KX-21)(BENESPHERA)-FOR REMOVING BLOOD PROTEINS, RESIDUAL LYSING REAGENTS AND CELLULAR RESIDUALS,ALBUMIN (BCG) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF ALBUMIN IN HUMAN SERUM AND PLASMA,CYMET BS3 CN FREE (BENESPHERA)-FILTERED, NON-STERILE BLOOD LYSING FLUID FOR USING IN CELL COUNTING & SIZING,URINE STRIPS 11P(BENESPHERA)-TEST FOR THE SEMI-QUANTITATIVE MEASUREMENT OF LEUKOCYTES, KETONE, NITRITE, UROBILINOGEN, BILIRUBIN, PROTEIN, GLUCOSE, SPECIFIC GRAVITY, BLOOD, PH AND ASCORBIC ACID IN URINE,URIC ACID (URICASE-POD) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF URIC ACID IN HUMAN SERUM AND PLASMA, CHOLESTEROL (CHOD–PAP) LIQUID STABLE(BENESPHERA)-QUANTITATIVE ESTIMATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA

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2818	MFG/IVD/2020/000004	1.License Holder Name: KARWA ENTERPRISES PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:SARS COV-2 IGG ELISA KIT-SARS COV-2 IGG ELISA KIT IS INTENDED FOR QUALITATIVE DETECTION OF IGG ANTIBODIES IN SERUM/PLASMA.,HIV ELISA TEST KIT (3RD GENERATION)-TEST KIT FOR DETECTION OF HIV ANTIBODIES,KARWA SARS-COV-2 NUCLEIC ACID DETECTION KIT (RT-PCR)-FOR QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN OROPHARYNGEAL SWAB, NASOPHARYNGEAL SWAB OR DEEP COUGH SPUTUM SPECIMENS.,HCV RAPID CARD TEST KIT-TEST KIT FOR DETECTION OF HEPATITIS C VIRUS,CHIKUNGUNYA ANTIGEN RAPID CARD TEST-TEST KIT FOR DETECTION OF CHIKUNGUNYA ANTIGEN,TYPHOID ANTIGEN RAPID CARD TEST-TEST KIT FOR DETECTION OF TYPHOID ANTIGEN,MALARIA PF/PV (BIVALENT) ANTIGEN RAPID TEST-TEST KIT FOR DETECTION OF MALARIA PF/PV ANTIGEN(S),TROPONIN-I RAPID CARD TEST-TEST KIT FOR DETECTION OF TROPONIN-I,HBSAG ELISA TEST KIT-TEST KIT FOR DETECTION OF HEPATITIS B SURFACE ANTIGEN,SYPHILIS RAPID CARD TEST-TEST KIT FOR DETECTION OF SYPHILIS,DENGUE NS1+IGG/IGM RAPID COMBO TEST-TEST KIT FOR DETECTION OF DENGUE NS1+IGG/IGM,HIV RAPID CARD TEST-TEST KIT FOR DETECTION OF HIV,FOB RAPID CARD TEST-TEST KIT FOR DETECTION OF FECAL OCCULT BLOOD,HCV ELISA TEST KIT-TEST KIT FOR DETECTION OF HEPATITIS C VIRUS,HIV ELISA TEST KIT (4TH GENERATION)-TEST KIT FOR DETECTION OF HIV ANTIGEN/ANTIBODIES,MALARIA PF ANTIGEN RAPID TEST-TEST KIT FOR DETECTION OF MALARIA PF. ANTIGEN,HBSAG RAPID CARD TEST-TEST KIT FOR DETECTION OF HEPATITIS B SURFACE ANTIGEN,HBSAG RAPID STRIP TEST-TEST KIT FOR DETECTION OF HEPATITIS B SURFACE ANTIGEN,FILARIA ANTIGEN RAPID CARD TEST-TEST KIT FOR DETECTION OF FILARIA ANTIGEN,MALARIA PF/PAN ANTIGEN RAPID TEST-TEST KIT FOR DETECTION OF MALARIA PF/PAN ANTIGEN,SYPHILIS RAPID STRIP TEST-TEST KIT FOR DETECTION OF SYPHILIS,DENGUE NS1 ANTIGEN RAPID CARD TEST-TEST KIT FOR DETECTION OF DENGUE NS1 ANTIGEN,MALARIA PAN ANTIGEN RAPID TEST-TEST KIT FOR DETECTION OF MALARIA PAN ANTIGEN,SYPHILIS ELISA KIT-TEST KIT FOR DETECTION OF SYPHILIS,DENGUE NS1 ELISA TEST KIT-TEST KIT FOR DETECTION OF DENGUE NS1 ANTIGEN,DRUGS OF ABUSE RAPID TEST-TEST KIT FOR DETECTION OF VARIOUS COMBINATIONS OF DRUG OF ABUSE PARAMETERS AND DRUG METABOLITES IN URINE E.G. AMPHETAMINE, BARBITURATES, BENZODIAZEPINES, COCAINE, ECSTASY (MDMA), MORPHINE, MARIJUANA, OPIATE , TRICYCLIC ANTIDEPRESSANTS, PHENCYCLIDINE, METHADONE ETC.,DENGUE/CHIKUNGUNYA ANTIGEN RAPID COMBO CARD TEST-TEST KIT FOR DETECTION OF

	DENGUE AND CHIKUNGUNYA ANTIGENS

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2819	MFG/IVD/2020/000005	1.License Holder Name: AGAPPE DIAGNOSTICS LTD 2.Approving Authority: KERALA 3.Device Name(Brand Name)-Intended Use:DEPROTENIZER FOR HEMATOLOGY ANALYZER-FINAL CLEANING AND DEPROTEINISING OF MISPA COUNT X -HEMATOLOGY ANALYZER AND OTHER SUITABLE HEMATOLOGY ANALYZERS .,LAMBDA LIGHT CHAIN REAGENT-LAMBDA LIGHT CHAIN KIT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF LAMBDA LIGHT CHAIN IN SAMPLES. THE KIT IS PRESENTED WITH OR WITH OUT CALIBRATOR. THE KIT IS USED AS SYSTEM PACK FOR MISPA SERIES EQUIPMENT , OTHER IVD ANALYSERS AND AS NORMAL PACK FOR GENERAL CLINICAL CHEMISTRY ESTIMATIONS,LYSE FOR HEMATOLOGY ANALYZER-USED FOR LYSING OF THE CELLS FOR TESTING IN MISPA COUNT X - 3 PART HEMATOLOGY ANALYZER AND OTHER SUITABLE HEMATOLOGY ANALYZERS.,KAPPA LIGHT CHAIN REAGENT -KAPPA LIGHT CHAIN KIT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF KAPPA LIGHT CHAIN IN SAMPLES. THE KIT IS PRESENTED WITH OR WITH OUT CALIBRATOR. THE KIT IS USED AS SYSTEM PACK FOR MISPA SERIES EQUIPMENT , OTHER IVD ANALYSERS AND AS NORMAL PACK FOR GENERAL CLINICAL CHEMISTRY ESTIMATIONS.,DILUENT FOR HEMATOLOGY ANALYZER-USED TO DILUTE BLOOD FOR FURTHER TESTING IN MISPA COUNT X - 3 PART HEMATOLOGY ANALYZER AND OTHER SUITABLE HEMATOLOGY ANALYZERS ., ALPHA-2-MACROGLOBULIN REAGENT-ALPHA-2-MACROGLOBULIN KIT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ALPHA-2-MACROGLOBULIN IN SAMPLES. THE KIT IS PRESENTED WITH OR WITH OUT C.ALIBRATOR. THE KIT IS USED AS SYSTEM PACK FOR MISPA SERIES EQUIPMENT , OTHER IVD ANALYSERS AND AS NORMAL PACK FOR GENERAL CLINICAL CHEMISTRY ESTIMATIONS., CLEANER/RINSE FOR HEMATOLOGY ANAYZER -TO CLEAN THE TUBES, BATHS, VALVES AND APERTURES OF MISPA COUNT X-HEMATOLOGY ANALYZER AND OTHER SIMILAR HEMATOLOGY ANALYZERS.,APO B (APOLIPOPROTEIN B) REAGENT -APO B (APOLIPOPROTEIN B) REAGENT KIT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF APO B IN SAMPLES. THE KIT IS PRESENTED WITH OR WITH OUT CALIBRATOR. THE KIT IS USED AS SYSTEM PACK FOR MISPA SERIES EQUIPMENT , OTHER IVD ANALYSERS AND AS NORMAL PACK FOR GENERAL CLINICAL CHEMISTRY ESTIMATIONS.,HAPTOGLOBIN REAGENT-HAPTOGLOBIN KIT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HAPTOGLOBIN IN SAMPLES. THE KIT IS PRESENTED WITH OR WITH OUT CALIBRATOR. THE KIT IS USED AS SYSTEM PACK FOR MISPA SERIES EQUIPMENT , OTHER IVD ANALYSERS AND AS NORMAL PACK FOR GENERAL CLINICAL CHEMISTRY ESTIMATIONS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2820	MFG/IVD/2020/000005	1.License Holder Name: M/S. AGAPPE DIAGNOSTICS LTD. 2.Approving Authority: KERALA 3.Device Name(Brand Name)-Intended Use:IMMUNOLOGY CONTROL LEVEL 1(IMMUNOLOGY CONTROL LEVEL 1)-IMMUNOLOGY CONTROL LEVEL 1 IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURES OF SPECIFIC PROTEINS.,ENZYMATIC BILIRUBIN CALIBRATOR-USED FOR CALIBRATION OF CLINICAL CHEMISTRY TEST USING ENZYMATIC BILIRUBIN REAGENTS . ,FERRITIN TURBILATEX KIT (WITH CALIBRATOR)(FERRITIN TURBILATEX KIT (WITH CALIBRATOR))-THE REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF FERRITIN IN SERUM, HEMOGLOBIN MICROCUVETTE-IT IS INTENDED TO BE USED AS SAMPLE PROCESSING CONTAINER FOR IN VITRO QUANTITATIVE DETECTION OF HEMOGLOBIN IN HUMAN WHOLE BLOOD. ,CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 3(CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 3)-CLINICAL CHEMISTRY CONTROL LEVEL 3 IS AN ASSAYED HUMAN SERUM USED FOR QUALITY CONTROL CHECKING OF CLINICAL CHEMISTRY ASSAYS SUITABLE FOR MANUAL PROCEDURE AND AUTOMATED ANALYZERS., LIPOPROTEIN PHOSPHOLIPASE A2 (LP-PLA2 REAGENT)-LP-PLA2 REAGENT IS A CARDIAC MARKER INTENDED FOR THE QUANTIFICATION OF LPLA2 IN SERUM AND PLASMA,MISPA I3 WASHING SOLUTION(MISPA I3 WASHING SOLUTION)-MISPA I3 WASH SOLUTION IS INTENDED FOR CLEANSING AND MAINTENANCE OF ASPIRATION PROBES OF MISPA I3 SPECIFIC PROTEIN ANALYZER, ENZYMATIC BILIRUBIN DIRECT-ENZYMATIC BILIRUBIN DIRECT REAGENT IS INTENDED FOR THE QUANTIFICATION OF DIRECT BILIRUBIN IN SERUM AND PLASMA,CALCIUM KIT(CALCIUM KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM,PLASMA & URINE., ENZYMATIC BILIRUBIN TOTAL-ENZYMATIC BILIRUBIN TOTAL REAGENT IS INTENDED FOR THE QUANTIFICATION OF TOTAL BILIRUBIN IN SERUM AND PLASMA,EZ CLEANER FOR 3-PART HEMATOLOGY ANALYZER, EZ CLEANER(EZ CLEANER FOR 3-PART HEMATOLOGY ANALYZER, EZ CLEANER)-EZ CLEANER IS INTENDED FOR DAILY CLEANING OF MINDRAY- 3 PART DIFFERENTIAL HEMATOLOGY ANALYZERS OF BC SERIES.,URINE STRIP CONTROL-URINE STRIP CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE ACCURACY AND PRECISION OF URINALYSIS TEST PROCEDURES FOR THE ANALYTES: UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, MICRO ALBUMIN, NITRITE, LEUCOCYTES, GLUCOSE, SPECIFIC GRAVITY & PH, CALCUIM (ARSENAZO) KIT(CALCUIM (ARSENAZO) KIT)-THIS

	REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM, PLASMA & URINE., HOMOCYSTEIN 2 REAGENT ENZYMATIC CONTROL SET (4 LEVELS) (LIQUID)(HOMOCYSTEIN 2 REAGENT ENZYMATIC CONTROL SET (4 LEVELS)(LIQUID))-THE LIQUID STABLE (LS) 2-PART HOMOCYSTEINE REAGENT IS INTENDED FOR INVITRO QUANTITATIVE DETERMINATION OF TOTAL HOMOCYSTEINE IN HUMAN SERUM AND PLASMA., MYOGLOBIN LIQUID STABLE [SL] REAGENT KIT(MYOGLOBIN LIQUID STABLE [SL] REAGENT KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETECTION OF MYOGLOBIN IN SERUM.,INORGANIC PHOSPHOROUS KIT(INORGANIC PHOSPHOROUS KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHOROUS , IN SERUM, PLASMA & URINE.,POTASSIUM KIT (POTASSIUM KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF POTASSIUM IN SERUM OR PLASMA.,COUNT C3 CLEANING SOLUTION FOR 3-PART HEMATOLOGY ANALYZER(COUNT C3 CLEANING SOLUTION FOR 3-PART HEMATOLOGY ANALYZER)-COUNT C3 IS INTENDED FOR CLEANING THE TUBING'S OF MISPA COUNT-3 PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS AN AZIDE FREE FILTERED SOLUTION., PROBE CLEANER FOR 3 - PART DIFFERENTIAL HEMATOLOGY ANALYZER COUNT P3(PROBE CLEANER FOR 3 - PART DIFFERENTIAL HEMATOLOGY ANALYZER COUNT P3)-COUNT P3 IS INTENDED FOR PERIODICAL CLEANING OF SAMPLE PROBE, COUNTING CHAMBER, OPTICAL BENCH AND TUBING IN MISPA COUNT 5 PART DIFFERENTIAL HEMATOLOGY ANALYZER.,HOMOCYSTEINE 2 REAGENT ENZYMATIC CALIBRATOR SET (5 LEVELS)(HOMOCYSTEINE 2 REAGENT ENZYMATIC CALIBRATOR SET (5 LEVELS))-DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR HOMOCYSTEINE 2 REAGENT ENZYMATIC ESTIMATION.,LP (A) CALIBRATOR(LP (A) CALIBRATOR)-LP (A) CALIBRATOR IS INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR LP (A) ESTIMATION.,COMPLIMENT C4(C4) (WITH CALIBRATOR) (COMPLIMENT C4(C4) (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF COMPLEMENT C4 IN HUMAN SERUM.,APO A1/APO B CALIBRATOR (APO A1/APO B CALIBRATOR)-THIS REAGENT IS INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR APO A1 & APO B ESTIMATION.,PROTEIN CONTROL (IMMUNOLOGY CONTROL)(PROTEIN CONTROL (IMMUNOLOGY CONTROL))-PROTEIN CONTROL (IMMUNOLOGY CONTROL) IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURES OF SPECIFIC PROTEINS.,BASE WASHING SOLUTION (WASHING SOLUTION(AL))(BASE WASHING SOLUTION

	(WASHING SOLUTION(AL)))-ALKALINE WASHING DETERGENT INTENDED FOR CLEANSING AND MAINTENANCE OF REACTION CUVETTE AND ASPIRATION PROBES OF BIOLIS 24I AUTOMATED CLINICAL ANALYZER.,PROTEIN CONTROL (IMMUNOLOGY CONTROL, LEVEL 1)(PROTEIN CONTROL (IMMUNOLOGY CONTROL, LEVEL 1))-PROTEIN CONTROL (IMMUNOLOGY CONTROL, LEVEL 1) IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURES OF SPECIFIC PROTEINS.,PROTEIN CONTROL (LYPHO)(PROTEIN CONTROL (LYPHO)) -IMMUNOLOGY CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURES.,ZINC REAGENT KIT(ZINC REAGENT KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ZINC IN SERUM, PLASMA & URINE.,PROBE CLEANER FOR 5 - PART DIFFERENTIAL HEMATOLOGY ANALYZER (DIFF. P5)(PROBE CLEANER FOR 5 - PART DIFFERENTIAL HEMATOLOGY ANALYZER (DIFF. P5))-DIFF P5 IS INTENDED FOR PERIODICAL CLEANING OF SAMPLE PROBE, COUNTING CHAMBER, OPTICAL BENCH AND TUBING IN MISPA COUNT PLUS 5 PART DIFFERENTIAL HEMATOLOGY ANALYZER.,SERUM PROTEIN CONTROL (BI-LEVEL PROTEIN CONTROL)(SERUM PROTEIN CONTROL (BI-LEVEL PROTEIN CONTROL))-SERUM PROTEIN CONTROL (BILEVEL PROTEIN CONTROL) IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURES OF SPECIFIC PROTEINS.,TOTAL IRON BINDING CAPACITY(TOTAL IRON BINDING CAPACITY)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF TOTAL IRON,MISPA NANO WASHING SOLUTION (WASHING SOLUTION(AL) (MISPA NANO WASHING SOLUTION (WASHING SOLUTION(AL)))-THIS REAGENT IS INTENDED FOR CLEANSING AND MAINTENANCE OF REACTION CUVETTE AND ASPIRATION PROBES OF MISPA NANO - RANDOM ACCESS CLINICAL CHEMISTRY ANALYZER.,URIN STRIP LEUKOCYTES,KETONE,NITRITE,UROBILINOGEN,BILIRUBIN,GLUCOSE, PROTEIN,SPECIFIC GRAVITY,PH ,BLOOD,ASCORBIC ACID, MICROALBUMIN,CALCIUM AND CREATININE STRIPSULTRA STIK, ECO STIK(URIN STRIP LEUKOCYTES,KETONE,NITRITE,UROBILINOGEN, BILIRUBIN,GLUCOSE,PROTEIN,SPECIFIC GRAVITY,PH ,BLOOD, ASCORBIC ACID,MICROALBUMIN,CALCIUM AND CREATININE STRIPSULTRA STIK, ECO STIK)-THIS PACK INSERT IS FOR ULTRASTIK (GLUCOSE, BILIRUBIN, KETONE, SPECIFIC GRAVITY,BLOOD, PH, PROTEIN, UROBILINOGEN, NITRITE, LEUKOCYTES AND MICRO ALBUMIN)AGAPPE REAGENT STRIPS ARE MADE FOR URINALYSIS BOTH QUALITATIVE AND SEMI QUANTITATIVE WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. THE STRIPS ARE FOR PROFESSIONAL

	USE ONLY.,ENZYMATIC CREATININE(ENZYMATIC CREATININE)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF ENZYMATIC CREATININE IN HUMAN SERUM, ANTITHROMBIN III REAGENT KIT(ANTITHROMBIN III REAGENT KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETECTION OF ANTITHROMBIN III IN SERUM.,ALPHA 1 ANTITRYPSIN (AAT)(ALPHA 1 ANTITRYPSIN (AAT))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF ALPHA 1 ANTITRYPSIN (AAT) IN HUMAN SERUM,PROTEIN CONTROL(PROTEIN CONTROL)-PROTEIN CONTROL (IMMONOLOGY CONTROL) IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURES OF SPECIFIC PROTEINS.,25-HYDROXY VITAMIN D CALIBRATOR(25- HYDROXY VITAMIN D CALIBRATOR)-DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR 25- HYDROXY VITAMIN D ESTIMATION.,IMMUNOLOGY CONTROL LEVEL 2(IMMUNOLOGY CONTROL LEVEL 2)-IMMUNOLOGY CONTROL LEVEL 2 IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURES OF SPECIFIC PROTEINS.,HDL-CHOLESTEROL DIRECT KIT (WITH CALIBRATOR)(HDL-CHOLESTEROL DIRECT KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN SERUM OR PLASMA.,ALPHA AMYLASE(AMYLASE)KIT(ALPHA AMYLASE(AMYLASE)KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF AMYLASE IN HUMAN SERUM,RF CALIBRATOR (IMMUNOLOGY CALIBRATOR)(RF CALIBRATOR (IMMUNOLOGY CALIBRATOR))-THIS REAGENT IS INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR RF ESTIMATION.,DILUENT SOLUTION FOR 5-PART HEAMATOLOGY ANALYZER(DILUENT SOLUTION FOR 5-PART HEAMATOLOGY ANALYZER)-DIFF D5 IS INTENDED FOR COUNTING AND SIZING OF BLOOD CELLS IN MISPA COUNT PLUS 5 - PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS AN AZIDE FREE FILTERED ISOTONIC SOLUTION.,UREA-UV KIT(UREA-UV KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF UREA-U. V IN HUMAN SERUM,HOMOCYSTEINE 2 REAGENT ENZYMATIC KIT (HOMOCYSTEINE 2 REAGENT ENZYMATIC KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETECTION OF HOMOCYSTEINE IN SERUM., QUALICHECK NORM & PATH (COMBINATION KIT OF QUALICHECK PATH)(QUALICHECK NORM & PATH (COMBINATION KIT OF QUALICHECK PATH))-IMMUNOLOGY CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURES.,IGE CALIBRATOR(IGE CALIBRATOR)-IGE CALIBRATOR IS INTENDED FOR THE PREPARATION

	OF CALIBRATION CURVE FOR IGE ESTIMATION.,UREA-B KIT(UREA-B KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF UREA-B IN HUMAN SERUM,HEMOGLOBIN KIT (HEMOGLOBIN KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HEMOGLOBIN IN SERUM, PLASMA & URINE.,URINE STRIP GLUCOSE, KETONE(ECOSTICK)STRIPS (URINE STRIP GLUCOSE, KETONE(ECOSTICK)STRIPS)-THIS PACK INSERT IS TO BE USED WITH THE FOLLOWING PRODUCTS: MRP (GLUCOSE), PRODUAL(GLUCOSE, PROTEIN), KETODUAL (KETONE, GLUCOSE) AND ECOSTIK (KETONE, GLUCOSE &PROTEIN).URINE TEST STRIPS ARE USED TO MEASURE CERTAIN CONSTITUENTS IN URINE WHICH ARE SIGNIFICANT OF RENAL, URINARY, HEPATIC AND METABOLIC DISORDERS.,HBA1C CONTROL KIT(HBA1C CONTROL KIT)-HBA1C CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURES.,IMMUNOGLOBULIN A(IGA) KIT(IMMUNOGLOBULIN A (IGA) KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF IMMUNOGLOBULIN A (IMMUNOGLOBULIN A(IGA) KIT) IN HUMAN SERUM,APOLIPOPROTEIN C-III REAGENT (APOLIPOPROTEIN C-III REAGENT)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETECTION OF APOLIPOPROTEIN C-III IN SERUM.,SGPT (SL) KIT(SGPT (SL) KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF SGOT IN HUMAN SERUM,SGOT TEST KIT (SGOT TEST KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF SGOT IN SERUM OR PLASMA., ENZYMATIC LITHIUM CALIBRATOR SET(ENZYMATIC LITHIUM CALIBRATOR SET)-DIAGNOSTIC MEDICAL DEVICE FOR THE CALIBRATION OF LITHIUM ESTIMATION IN HUMAN SERUM.,SGPT (SL) KIT(SGPT (SL) KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF SGPT IN HUMAN SERUM,APO B (APOLIPOPROTEIN B) REAGENT KIT(APO B (APOLIPOPROTEIN B) REAGENT KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF APO B (APOLIPOPROTEIN B)KIT IN HUMAN SERUM,ALPHA-2- MACROGLOBULIN(ALPHA-2-MACROGLOBULIN)-THE AGAPPE -MISPA I, ALPHA-2-MACROGLOBULIN TEST SYSTEM IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ALPHA-2-MACROGLOBULIN IN SERUM.,HDL CHOLESTEROL DIRECT(HDL CHOLESTEROL DIRECT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF HDLCHOLESTEROL IN HUMAN SERUM,ALPHA 1 ANTITRYPSIN I3(AAT I3)(ALPHA 1 ANTITRYPSIN I3(AAT I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF ALPHA 1 ANTITRYPSIN I3(AAT I3) IN HUMAN SERUM,ALPHA 1-ACID GLYCOPROTEIN TEST KIT (WITH CALIBRATOR)

	(ALPHA 1-ACID GLYCOPROTEIN TEST KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ALPHA1- ACID GLYCOPROTEIN IN HUMAN SERUM.,URINE STRIP GLUCOSE, KETONE(KETODUAL)STRIPS(URINE STRIP GLUCOSE, KETONE(KETODUAL)STRIPS)-URINE TEST STRIPS ARE USED TO MEASURE CERTAIN CONSTITUENTS IN URINE WHICH ARE SIGNIFICANT OF RENAL, URINARY, HEPATIC AND METABOLIC DISORDERS .URINE STRIP GLUCOSE, KETONE (KETODUAL) STRIPS IS INTENDED FOR THE SEMI QUANTITATIVE DETERMINATION OF GLUCOSE, KETONE IN URINE.,ASO CALIBRATOR(ASO CALIBRATOR)-THIS REAGENT IS INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR ASO ESTIMATION.,APO A1-B DUAL CONTROL(APO A1-B DUAL CONTROL)-APO A1-B DUAL CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURE OF APO A AND APO B IN HUMAN SERUM.,CYSTATIN-C(CYSTATIN-C)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CYSTATIN C IN HUMAN SERUM,ENZYMATIC LITHIUM CONTROL SET (ENZYMATIC LITHIUM CONTROL SET)-DIAGNOSTIC MEDICAL DEVICE FOR THE CALIBRATION OF LITHIUM ESTIMATION IN HUMAN SERUM , ALPHA-2-MACROGLOBULIN - I3(ALPHA-2-MACROGLOBULIN - I3)-THE AGAPPE -MISPA I, ALPHA-2-MACROGLOBULIN -I3TEST SYSTEM IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ALPHA-2-MACROGLOBULIN -I3IN SERUM.,MYOGLOBIN CALIBRATOR SET (6 LEVELS) (LIQUID)(MYOGLOBIN CALIBRATOR SET (6 LEVELS) (LIQUID))-DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR MYOGLOBIN ESTIMATION.,MYOGLOBIN CONTROL SET (2 LEVELS) (LIQUID) (MYOGLOBIN CONTROL SET (2 LEVELS) (LIQUID))-MYOGLOBIN CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURE OF MYOGLOBIN IN HUMAN SERUM.,GENERAL PURPOSE DILUENT FOR HEMATOLOGY ANALYZER(GENERAL PURPOSE DILUENT FOR HEMATOLOGY ANALYZER)-DILUENT IS INTENDED FOR COUNTING AND SIZING OF BLOOD CELLS IN MINDRAY- 3 PART DIFFERENTIAL HEMATOLOGY ANALYZERS OF BC SERIES. IT IS AN AZIDE FREE FILTERED ISOTONIC SOLUTION.,MISPA I3 PROBE CLEANER(MISPA I3 PROBE CLEANER)-MISPA I3 PROBE CLEANER IS INTENDED FOR PERIODIC AND ROUTINE CLEANING OF ASPIRATION PROBE AND WASHING STATION OF MISPA I3 SPECIFIC PROTEIN ANALYZER. MISPA I3 PROBE CLEANER IS A STRONG ALKALINE CLEANING AGENT USED TO REMOVE RESIDUAL SPECIMEN AND THE REMAINING REAGENTS CONTAINED IN THE ASPIRATION PROBE AND WASHING PROBE OF ANALYZER. IT REMOVES ANY RESIDUAL CELLULAR,

	PROTEINACEOUS DEPOSITS (SERUM ALBUMIN) AND THE REMAINING REAGENTS THAT MAY APPEAR DURING THE OPERATION OF THE ANALYZER.,DILUENT SOLUTION FOR 5-PART HEAMATOLOGY ANALYZER (DILUENT DS5000)(DILUENT SOLUTION FOR 5-PART HEAMATOLOGY ANALYZER (DILUENT DS5000))-DIFF D5 IS INTENDED FOR COUNTING AND SIZING OF BLOOD CELLS IN MISPA COUNT PLUS 5 - PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS AN AZIDE FREE FILTERED ISOTONIC SOLUTION.,URINE STRIP GLUCOSE, PROTEIN, KETONE, PH AND BLOOD(SMART STICK) STRIPS(URINE STRIP GLUCOSE, PROTEIN, KETONE, PH AND BLOOD(SMART STICK) STRIPS)-THIS PACK INSERT IS TO BE USED WITH THE FOLLOWING PRODUCTS: MRP (GLUCOSE), PRODUAL(GLUCOSE, PROTEIN), KETODUAL (KETONE, GLUCOSE) AND ECOSTIK (KETONE, GLUCOSE &PROTEIN).URINE TEST STRIPS ARE USED TO MEASURE CERTAIN CONSTITUENTS IN URINE WHICH ARE SIGNIFICANT OF RENAL, URINARY, HEPATIC AND METABOLIC DISORDERS.,IMMUNOGLOBULIN G (IGG) KIT (WITH CALIBRATOR)(IMMUNOGLOBULIN G (IGG) KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF IGG ANTIBODIES IN SERUM, CUVETTE CLEANING SOLUTION(CUVETTE CLEANING SOLUTION)-BIANCH C IS INTENDED FOR CLEANSING OF REACTION CUVETTE IN STARTUP OF TOSHIBA (TBA) FULLY AUTOMATED RANDOM ACCESS CLINICAL CHEMISTRY ANALYZER SERIES. BIANCH C IS ALSO USED AS THE DETERGENT FOR MINIMIZING CARRYOVER.,IGE CARTRIDGE (MISPA- I3)(IGE CARTRIDGE (MISPA- I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF IMMUNOGLOBULIN A (IGE CARTRIDGE (MISPA- I3)) IN HUMAN SERUM,LYSE FOR BC 2800 (LYSE (BC-2800)(LYSE FOR BC 2800 (LYSE (BC-2800))-LYSE IS INTENDED FOR LYSING OF CELLS FOR WBC COUNT AND HEMOGLOBIN MEASUREMENT IN MINDRAY-3 PART DIFFERENTIAL HEMATOLOGY ANALYZERS OF BC SERIES.,ENZYMATIC SODIUM REAGENT KIT(ENZYMATIC SODIUM REAGENT KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETERMINATION OF SODIUM IN HUMAN SERUM.,APOLIPOPROTEIN C II (APO C II)(APOLIPOPROTEIN C II (APO C II))-DIAGNOSTIC MEDICAL DEVICE FOR THE DETECTION OF APOLIPOPROTEIN C II IN SERUM.,ENZYMATIC POTASSIUM CALIBRATOR(ENZYMATIC POTASSIUM CALIBRATOR)-DIAGNOSTIC MEDICAL DEVICE FOR THE QUALITY CONTROL OF IVD DETERMINATION OF POTASSIUM IN HUMAN SERUM THROUGH ENZYMATIC METHOD.,HDL CHOLESTEROL KIT(HDL CHOLESTEROL KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF HDL-CHOLESTEROL IN HUMAN SERUM.,HBA1C DIRECT MULTI CALIBRATOR(HBA1C DIRECT MULTI CALIBRATOR)-HBA1C DIRECT CALIBRATOR IS INTENDED FOR THE PREPARATION OF

	CALIBRATION CURVE FOR HBA1C DIRECT ESTIMATION, CERULOPLASMIN (MISPA-I3)(CERULOPLASMIN (MISPA-I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CERULOPLASMIN (MISPA-I3) IN HUMAN SERUM, APOLIPOPROTEIN E REAGENT(APOLIPOPROTEIN E REAGENT)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETECTION OF APOLIPOPROTEIN E IN SERUM.,HEMATOLOGY ANALYZER PROBE CLEANER(HEMATOLOGY ANALYZER PROBE CLEANER)-PROBE CLEANER IS INTENDED FOR PERIODICAL CLEANING OF SAMPLE PROBE IN MINDRAY-3 PART DIFFERENTIAL HEMATOLOGY ANALYZERS OF BC SERIES.,CHOLINESTERASE S.L KIT (CHOLINESTERASE S.L KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CHOLINESTERASE S.L IN SERUM,PLASMA & URINE.,CYSTATIN CONTROL(CYSTATIN CONTROL)-CYSTATIN CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE ACCURACY AND PRECISION OF CYSTATIN C ASSAY.,UREA-B (SL) KIT(UREA-B (SL) KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF UREA IN SERUM, PLASMA & URINE,IMMUNOLOGY CALIBRATOR HUMAN SERUM (IMMUNOLOGY CALIBRATOR HUMAN SERUM)-THIS REAGENT IS INTENDED FOR THE PREPARATION OF REFERENCE CURVES FOR QUANTITATIVE IMMUNOCHEMICAL DETERMINATION OF PROTEIN IN HUMAN SERUM.,RF LATEX SLIDE KIT (RF)(RF LATEX SLIDE KIT (RF))-THIS REAGENT IS INTENDED FOR IN VITRO QUALITATIVE & SEMI QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN SERUM.,ALPHA 1 -ANTI TRYPSIN (WITH CALIBRATOR)(ALPHA 1 -ANTI TRYPSIN (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF A1- ANTITRYPSIN (AAT) IN HUMAN SERUM BY NEPHELOMETRIC IMMUNOASSAY., IMMUNOGLOBULIN G(IGG)KIT(IMMUNOGLOBULIN G(IGG)KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF IMMUNOGLOBULIN G IN HUMAN SERUM,ALPHA 1-ACID GLYCOPROTEIN MISPA I3(ALPHA 1-ACID GLYCOPROTEIN MISPA I3)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ALPHA1- ACID GLYCOPROTEIN IN HUMAN SERUM.,ACID WASHING SOLUTION (WASHING SOLUTION (AC)(ACID WASHING SOLUTION (WASHING SOLUTION (AC))-ACID WASH DETERGENT IS INTENDED FOR CLEANSING AND MAINTENANCE OF REACTION CUVETTES AND ASPIRATION PROBES OF BIOLIS 24I AUTOMATED CLINICAL ANALYZER.,COMPONENT C4 (C4) (COMPONENT C4 (C4))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF COMPLEMENT COMPONENT C4 (C4) IN HUMAN SERUM,DILUENT (DILUENT SOLUTION FOR 3-PART HEMATOLOGY ANALYZER)(DILUENT (DILUENT SOLUTION FOR 3-

	PART HEMATOLOGY ANALYZER))-DILUENT IS INTENDED FOR COUNTING AND SIZING OF BLOOD CELLS IN MINDRAY- 3 PART DIFFERENTIAL HEMATOLOGY ANALYZERS OF BC SERIES. IT IS AN AZIDE FREE FILTERED ISOTONIC SOLUTION.,IRON REAGENT KIT(IRON REAGENT KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF IRON IN SERUM.,BILIRUBIN TOTAL (TAB KIT)(BILIRUBIN TOTAL (TAB KIT))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF BILIRUBIN IN SERUM OR PLASMA.,PROTEIN CALIBRATOR (IMMUNOLOGY CALIBRATOR)(PROTEIN CALIBRATOR (IMMUNOLOGY CALIBRATOR))-THIS REAGENT IS INTENDED FOR THE PREPARATION OF REFERENCE CURVES FOR QUANTITATIVE IMMUNOCHEMICAL DETERMINATION OF PROTEIN IN HUMAN SERUM.,GLUCOSE KIT (GLUCOSE KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF GLUCOSE IN SERUM, PLASMA & CSF.,IMMUNOGLOBULIN M(IGM)KIT(IMMUNOGLOBULIN M(IGM)KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF IMMUNOGLOBULIN M (IGM) IN HUMAN SERUM, GLUCOSE HEXOKINASE(GLUCOSE HEXOKINASE)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETECTION OF GLUCOSE IN SERUM., ENZYMATIC SODIUM CONTROL KIT(ENZYMATIC SODIUM CONTROL KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE QUALITY CONTROL IN THE DETERMINATION OF SODIUM IN HUMAN SERUM., IMMUNOGLOBULIN M (IGM) KIT (WITH CALIBRATOR) (IMMUNOGLOBULIN M (IGM) KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF IGM ANTIBODIES IN SERUM,FERRITIN CALIBRATOR(FERRITIN CALIBRATOR)-FERRITIN CALIBRATOR IS INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR FERRITIN ESTIMATION., COMPLEMENT 4 (C4) (MISPA -I3)(COMPLEMENT 4 (C4) (MISPA -I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF COMPLEMENT COMPONENT COMPLEMENT 4 (C4) (MISPA -I3) (COMPLEMENT 4 (C4) (MISPA -I3)) IN HUMAN SERUM, CHOLINESTERASE KIT(CHOLINESTERASE KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CHOLINESTERASE IN SERUM, PLASMA & URINE.,CYSTATIN C CONTROL(CYSTATIN C CONTROL)-CYSTATIN C CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE ACCURACY AND PRECISION OF CYSTATIN C ASSAY.,IMMUNOLOGY CONTROL LEVEL 3(IMMUNOLOGY CONTROL LEVEL 3)-IMMUNOLOGY CONTROL LEVEL 3 IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURES OF SPECIFIC PROTEINS.,MICRPROTIEN KIT (MICRPROTIEN KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-

	VITRO DETERMINATION OF MICROPROTEIN IN HUMAN SERUM,HBA1C HEMOLYSING REAGENT(HBA1C HEMOLYSING REAGENT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF % HBA1C IN HUMAN BLOOD.,QUALICHECK PATH (CLINICAL CHEMISTRY CONTROL, LEVEL 1)(QUALICHECK PATH (CLINICAL CHEMISTRY CONTROL, LEVEL 1))-QUALICHECK PATH IS AN ASSAYED HUMAN SERUM USED FOR QUALITY CONTROL CHECKING OF CLINICAL CHEMISTRY ASSAYS SUITABLE FOR MANUAL PROCEDURE AND AUTOMATED ANALYZERS.,MYOGLOBIN (MISPA I3) REAGENT KIT(MYOGLOBIN (MISPA I3) REAGENT KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETECTION OF MYOGLOBIN (MISPA I3) IN SERUM.,MISPA MINI DETERGENT SOLUTION(MISPA MINI DETERGENT SOLUTION)-THIS REAGENT IS INTENDED FOR CLEANSING AND MAINTENANCE OF REACTION CUVETTE AND ASPIRATION PROBES OF MISPA MINI - RANDOM ACCESS CLINICAL CHEMISTRY ANALYZER.,CK-NAC (CREATINEKINASE KIT (SL))(CK-NAC (CREATINEKINASE KIT (SL)))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CK-NAC IN HUMAN SERUM,HEMATOLOGY ANALYZER LYSE(HEMATOLOGY ANALYZER LYSE)-LYSE IS INTENDED FOR LYSING OF CELLS FOR WBC COUNT AND HEMOGLOBIN MEASUREMENT IN MINDRAY-3 PART DIFFERENTIAL HEMATOLOGY ANALYZERS OF BC SERIES.,CREATININE KIT(CREATININE KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CREATININE IN SERUM PLASMA AND URINE., HAPTOGLOBIN (MISPA-I3)(HAPTOGLOBIN (MISPA-I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF HAPTOGLOBIN (MISPA-I3) IN HUMAN SERUM,LDL CHOLESTEROL DIRECT(LDL CHOLESTEROL DIRECT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF LDL-CHOLESTEROL IN HUMAN SERUM,CUVETTE CLEANING SOLUTION BIANCH C(CUVETTE CLEANING SOLUTION BIANCH C)-BIANCH C IS INTENDED FOR CLEANSING OF REACTION CUVETTE IN STARTUP OF TOSHIBA (TBA) FULLY AUTOMATED RANDOM ACCESS CLINICAL CHEMISTRY ANALYZER SERIES. BIANCH C IS ALSO USED AS THE DETERGENT FOR MINIMIZING CARRYOVER.,ENZYMATIC POTASSIUM REAGENT KIT (ENZYMATIC POTASSIUM REAGENT KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETERMINATION OF POTASSIUM IN HUMAN SERUM., APO B (MISPA -I3)(APO B (MISPA -I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF APO B (MISPA -I3) IN HUMAN SERUM,PROCALCITONIN REAGENT KIT(PROCALCITONIN REAGENT KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF PCT IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,PREALBUMIN KIT(PREALBUMIN KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO

	DETERMINATION OF PREALBUMIN IN HUMAN SERUM,CLINICAL CHEMISTRY ANALYZER CELL WASH(CLINICAL CHEMISTRY ANALYZER CELL WASH)-ACID WASH DETERGENT IS INTENDED FOR CLEANSING AND MAINTENANCE OF REACTION CUVETTES AND ASPIRATION PROBES OF BIOLIS 24I AUTOMATED CLINICAL ANALYZER.,LDL-CHOLESTEROL CALIBRATOR SERUM(LDL-CHOLESTEROL CALIBRATOR SERUM)-THIS CALIBRATOR IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IN SERUM OR PLASMA.,URIC ACID(URIC ACID)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF URIC ACID IN HUMAN SERUM,N- ACETYL--D-GLUCOSAMINIDASE (NAG) CALIBRATOR SET(N- ACETYL--D-GLUCOSAMINIDASE (NAG) CALIBRATOR SET)-DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR N- ACETYL--D-GLUCOSAMINIDASE (NAG) ESTIMATION., CLEANING SOLUTION FOR 5- PART HEMATOLOGY DIFFERENTIAL ANALYZER (CLEANER DS5000)(CLEANING SOLUTION FOR 5- PART HEMATOLOGY DIFFERENTIAL ANALYZER (CLEANER DS5000))-CLEANING SOLUTION IS INTENDED FOR CLEANING THE TUBING'S OF MISPA COUNT PLUS 5 PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS AN AZIDE FREE FILTERED SOLUTION., PROCALCITONIN CONTROL SET(PROCALCITONIN CONTROL SET)-PROCALCITONIN CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURE OF PROCALCITONIN IN HUMAN SERUM., BILIRUBIN TOTAL KIT KIT(BILIRUBIN TOTAL KIT KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF BILIRUBIN IN SERUM OR PLASMA.,HBA1C DIRECT KIT(HBA1C DIRECT KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF % HBA1C IN HUMAN BLOOD.,HEMATOLOGY CONTROL (L) (HEMATOLOGY CONTROL LEVEL 1)WHOLE HUMAN BLOOD(HEMATOLOGY CONTROL (L) (HEMATOLOGY CONTROL LEVEL 1)WHOLE HUMAN BLOOD)-HEMATOLOGY CONTROL USED IN MONITORING OF BLOOD CELL VALUES ON IMPEDANCE CELL COUNTERS.,HBA1C (WITH CALIBRATOR)(HBA1C (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF % HBA1C IN HUMAN BLOOD.,PREALBUMIN (MISPA I3) REAGENT KIT(PREALBUMIN (MISPA I3) REAGENT KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF PREALBUMIN IN SERUM,LDL-CHOLESTEROL DIRECT KIT (WITH CALIBRATOR)(LDL-CHOLESTEROL DIRECT KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IN SERUM OR PLASMA.,HEMATOLOY CONTROL,WHOLE HUMAN BLOOD LEVEL 3

	(HEMATOLOY CONTROL,WHOLE HUMAN BLOOD LEVEL 3)-HEMATOLOGY CONTROL USED IN MONITORING OF BLOOD CELL VALUES ON IMPEDANCE CELL COUNTERS.,HBA1C DIRECT KIT (WITH CALIBRATOR)(HBA1C DIRECT KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF % HBA1C IN HUMAN BLOOD.,HBA1C DIRECT MULTI CALIBRATOR (4 LEVELS)(HBA1C DIRECT MULTI CALIBRATOR (4 LEVELS))-HBA1C DIRECT CALIBRATOR IS INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR HBA1C DIRECT ESTIMATION,CYSTATIN C CALIBRATOR(CYSTATIN C CALIBRATOR)-THIS CALIBRATOR IS INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR CYSTATIN C ESTIMATION.,PREALBUMIN (WITH CALIBRATOR)(PREALBUMIN (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PREALBUMIN IN HUMAN SERUM,CLINICAL CHEMISTRY MULTICALIBRATOR(CLINICAL CHEMISTRY MULTICALIBRATOR)-MULTICALIBRATOR IS A CALIBRATION SERUM INTENDED FOR CALIBRATION OF CLINICAL CHEMISTRY ASSAYS SUITABLE FOR MANUAL PROCEDURE AND AUTOMATED ANALYZERS., HEMATOLOGY CONTROL (TRILEVEL)(COMBINATION KIT OF HEMATOLOGY CONTROL (LOW), HEMATOLOGY CONTROL (NORMAL), HEMATOLOGY CONTROL (HIGH).(HEMATOLOGY CONTROL (TRILEVEL) (COMBINATION KIT OF HEMATOLOGY CONTROL (LOW), HEMATOLOGY CONTROL (NORMAL), HEMATOLOGY CONTROL (HIGH).)-HEMATOLOGY CONTROL USED IN MONITORING OF BLOOD CELL VALUES ON IMPEDANCE CELL COUNTERS.,HEMATOLOGY CONTROL (H) (HEMATOLOGY CONTROL LEVEL 3)WHOLE HUMAN BLOOD (HEMATOLOGY CONTROL (H) (HEMATOLOGY CONTROL LEVEL 3) WHOLE HUMAN BLOOD)-HEMATOLOGY CONTROL USED IN MONITORING OF BLOOD CELL VALUES ON IMPEDANCE CELL COUNTERS.,HDL-CHOLESTEROL CALIBRATOR SERUM(HDL-CHOLESTEROL CALIBRATOR SERUM)-THIS CALIBRATOR IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN SERUM OR PLASMA.,HEMATOLOY CONTROL, WHOLE HUMAN BLOOD LEVEL 1(HEMATOLOY CONTROL,WHOLE HUMAN BLOOD LEVEL 1)-HEMATOLOGY CONTROL USED IN MONITORING OF BLOOD CELL VALUES ON IMPEDANCE CELL COUNTERS.,MULTICALIBRATOR (CLINICAL CHEMISTRY MULTICALIBRATOR)(MULTICALIBRATOR (CLINICAL CHEMISTRY MULTICALIBRATOR))-MULTICALIBRATOR IS A CALIBRATION SERUM INTENDED FOR CALIBRATION OF CLINICAL CHEMISTRY ASSAYS SUITABLE FOR MANUAL PROCEDURE AND AUTOMATED ANALYZERS., GLUCOSE STRIPS(GLUCOSE STRIPS)-URINE TEST STRIPS ARE USED TO MEASURE CERTAIN CONSTITUENTS IN URINE WHICH ARE

	SIGNIFICANT OF RENAL, URINARY, HEPATIC AND METABOLIC DISORDERS,SHEATH SOLUTION (CLEANING AND FLOW CONTROL MEDIUM SOLUTION FOR 5-PART HEMATOLOGY ANALYZER)(SHEATH SOLUTION (CLEANING AND FLOW CONTROL MEDIUM SOLUTION FOR 5-PART HEMATOLOGY ANALYZER))-SHEATH SOLUTION IS INTENDED FOR CLEANING THE TUBING'S OF MISPA COUNT-5 PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS AN AZIDE FREE FILTERED SOLUTION.,ALPHA 1 ACID GLYCOPROTEIN (AGP)(ALPHA 1 ACID GLYCOPROTEIN (AGP))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF ALPHA 1 ACID GLYCOPROTEIN (AGP) IN HUMAN SERUM,25- HYDROXY VITAMIN D CONTROL(25- HYDROXY VITAMIN D CONTROL)-25- HYDROXY VITAMIN D CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURE OF 25-HYDROXY VITAMIN D IN HUMAN SERUM.,ACID PHOSPHATASE KIT(ACID PHOSPHATASE KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ACID PHOSPHATASE IN SERUM OR PLASMA. - DIRECT BIURET METHOD - LINEAR UP TO 15 G/DL,ACID WASHING SOLUTION BIANCH 3(ACID WASHING SOLUTION BIANCH 3)-BIANCH 3 IS INTENDED FOR CLEANSING AND MAINTENANCE OF REACTION CUVETTE AND ASPIRATION PROBES. (FOR EXTENSIVE CLEANING OF CUVETTES) OF TOSHIBA (TBA SERIES) FULLY AUTOMATED RANDOM ACCESS CLINICAL CHEMISTRY ANALYZER SERIES.,PROCALCITONIN CALIBRATOR SET (2 LEVELS) LYOPHILIZED(PROCALCITONIN CALIBRATOR SET (2 LEVELS) LYOPHILIZED)-DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR PROCALCITONIN ESTIMATION.,CYSTAITN-C CARTRIDGE(MISPA -I3)(CYSTAITN-C CARTRIDGE(MISPA -I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CYSTATIN C IN HUMAN SERUM,LIPASE (SL) KIT(LIPASE (SL) KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF LIPASE IN HUMAN SERUM,IGG(MISPA-I3)(IGG(MISPA-I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF IGG(MISPA-I3) IN HUMAN SERUM,CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 1(CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 1)-CLINICAL CHEMISTRY CONTROL LEVEL 1 IS AN ASSAYED HUMAN SERUM USED FOR QUALITY CONTROL CHECKING OF CLINICAL CHEMISTRY ASSAYS SUITABLE FOR MANUAL PROCEDURE AND AUTOMATED ANALYZERS.,ALBUMIN KIT(ALBUMIN KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ALBUMIN IN SERUM OR PLASMA.,HAPTOGLOBIN TEST KIT(HAPTOGLOBIN TEST KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF HAPTOGLOBIN IN

	HUMAN SERUM,AGA1C(HBA1C REAGENT)(AGA1C(HBA1C REAGENT))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF % HBA1C IN HUMAN BLOOD.,FERRITIN KIT (FERRITIN KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF IN FERRITIN HUMAN SERUM,ENZYMATIC POTASSIUM CONTROL KIT(ENZYMATIC POTASSIUM CONTROL KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE QUALITY CONTROL OF IVD DETERMINATION OF POTASSIUM IN HUMAN SERUM THROUGH ENZYMATIC METHOD.,ALKALINE WASHING SOLUTION FOR TBA SERIES OF FULLY AUTO ANALYZERS (TBA WASH SOLUTION 14) (ALKALINE WASHING SOLUTION FOR TBA SERIES OF FULLY AUTO ANALYZERS (TBA WASH SOLUTION 14))-BIANCH 14 IS THE ALKALINE DETERGENT INTENDED FOR CLEANSING AND MAINTENANCE OF REACTION CUVETTE AND ASPIRATION PROBES OF TOSHIBA (TBA) FULLY AUTOMATED RANDOM ACCESS CLINICAL CHEMISTRY ANALYZER SERIES.,ALKALINE PHOSPHATASE S.L. KIT(ALKALINE PHOSPHATASE S.L. KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN SERUM OR PLASMA.,HEMATOLOY CONTROL,WHOLE HUMAN BLOOD LEVEL 2(HEMATOLOY CONTROL,WHOLE HUMAN BLOOD LEVEL 2)-HEMATOLOGY CONTROL USED IN MONITORING OF BLOOD CELL VALUES ON IMPEDANCE CELL COUNTERS.,URIC ACID (SL) KIT(URIC ACID (SL) KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF URIC ACID IN HUMAN SERUM,ACID WASHING SOLUTION(ACID WASHING SOLUTION)-ACID WASH DETERGENT IS INTENDED FOR CLEANSING AND MAINTENANCE OF REACTION CUVETTES AND AS BIOLIS 24I AUTOMATED CLINICAL ANALYZER.,LDH-P (SL) KIT(LDH-P (SL) KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF LDH-P IN HUMAN SERUM,COMPLEMENT 3 (C3) (MISPA-I3)(COMPLEMENT 3 (C3) (MISPA-I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF COMPLEMENT COMPONENT COMPLEMENT 3 (C3) (MISPA-I3) (COMPLEMENT 3 (C3) (MISPA-I3)) IN HUMAN SERUM,ZINC CALIBRATOR(ZINC CALIBRATOR)-THIS CALIBRATOR IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ZINC IN SERUM, PLASMA.,SODIUM KIT(SODIUM KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF SODIUM IN SERUM., RETINOL BINDING PROTEIN (RBP) CONTROL SET 2 LEVELS(RETINOL BINDING PROTEIN (RBP) CONTROL SET 2 LEVELS)-RETINOL BINDING PROTEIN (RBP) CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURE OF RETINOL BINDING PROTEIN (RBP) IN HUMAN SERUM.,IGE CARTRIDGE (MISPA- I3) (IGE CARTRIDGE (MISPA-I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO

	DETERMINATION OF IMMUNOGLOBULIN (IGE CARTRIDGE (MISPA- I3) IN HUMAN SERUM,LP (A) LIPOPROTEIN (A) KIT (WITH CALIBRATOR) (LP (A) LIPOPROTEIN (A) KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF LIPOPROTEIN (A) IN SERUM.,QUALICHECK NORM (CLINICAL CHEMISTRY CONTROL LEVEL 2)(QUALICHECK NORM (CLINICAL CHEMISTRY CONTROL LEVEL 2))-QUALICHECK NORM IS AN ASSAYED HUMAN SERUM USED FOR QUALITY CONTROL CHECKING OF CLINICAL CHEMISTRY ASSAYS SUITABLE FOR MANUAL PROCEDURE AND AUTOMATED ANALYZERS.,GLUCOSE (SL) KIT(GLUCOSE (SL) KIT) -DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF GLUCOSE IN HUMAN SERUM,CHOLESTEROL (SL) KIT(CHOLESTEROL (SL) KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CHOLESTEROL IN HUMAN SERUM.,CARBON DIOXIDE (CO2) CONTROL(CARBON DIOXIDE (CO2) CONTROL)-CARBON DIOXIDE CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURE OF CARBON DIOXIDE IN HUMAN SERUM.,COUNT L3 REAGENT (LYSE FOR 3- PART HEMATOLOGY ANALYZER FOR MISPA COUNT)(COUNT L3 REAGENT (LYSE FOR 3-PART HEMATOLOGY ANALYZER FOR MISPA COUNT))-DIFF L5 IS INTENDED FOR LYSING OF CELLS FOR WBC COUNT, WBC DIFFERENTIALS AND HEMOGLOBIN MEASUREMENT IN MISPA COUNT PLUS -5 PART DIFFERENTIAL HEMATOLOGY ANALYZER.,URINE STRIP GLUCOSE, PROTEIN (PRODUAL STRIPS)(URINE STRIP GLUCOSE, PROTEIN (PRODUAL STRIPS))-THIS PACK INSERT IS TO BE USED WITH THE FOLLOWING PRODUCTS: MRP (GLUCOSE), PRODUAL(GLUCOSE, PROTEIN), KETODUAL (KETONE, GLUCOSE) AND ECOSTIK (KETONE, GLUCOSE &PROTEIN).URINE TEST STRIPS ARE USED TO MEASURE CERTAIN CONSTITUENTS IN URINE WHICH ARE SIGNIFICANT OF RENAL, URINARY, HEPATIC AND METABOLIC DISORDERS., MICROALBUMIN LATEX(MICROALBUMIN LATEX)-QUANTITATIVE DETERMINATION OF MICROALBUMIN (ALB) – IVD,CK-NAC TEST KIT (CK-NAC KIT (CREATININE KINASE NAC KIT) ,)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CK-NAC IN HUMAN SERUM/PLASMA.,MICROALBUMIN CALIBRATOR (MICROALBUMIN CALIBRATOR)-MICROALBUMIN CALIBRATOR IS INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR MICROALBUMIN ESTIMATION.,PROCALCITONIN (MISPA I3) REAGENT KIT(PROCALCITONIN (MISPA I3) REAGENT KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF PCT IN HUMAN SERUM. FOR IN VITRO DIAGNOSTIC USE ONLY.,GAMMA GT KIT (GAMMA GT KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF GAMMA GT , IN SERUM, PLASMA

	& URINE.,CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 2 (CLINICAL CHEMISTRY CONTROL HUMAN SERUM LEVEL 2)-CLINICAL CHEMISTRY CONTROL LEVEL 2 IS AN ASSAYED HUMAN SERUM USED FOR QUALITY CONTROL CHECKING OF CLINICAL CHEMISTRY ASSAYS SUITABLE FOR MANUAL PROCEDURE AND AUTOMATED ANALYZERS., APOA1(APOLIPOPROTIEN A1 KIT)(WITH CALIBRATOR)(APOA1 (APOLIPOPROTIEN A1 KIT)(WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF APO LIPOPROTEIN A1 (APO-A1) IN SERUM.,DILUENT SOLUTION FOR 5-PART HEAMATOLOGY ANALYZER(DILUENT SOLUTION FOR 5-PART HEAMATOLOGY ANALYZER)-DIFF D5 IS INTENDED FOR COUNTING AND SIZING OF BLOOD CELLS IN MISPA COUNT PLUS 5 - PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS AN AZIDE FREE FILTERED ISOTONIC SOLUTION.,TOTAL BILE ACID REAGENT KIT (TOTAL BILE ACID REAGENT KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETECTION OF BILE ACID IN SERUM.,CHLORIDE KIT(CHLORIDE KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CHLORIDE IN SERUM, PLASMA & URINE., HEMATOLOGY CALIBRATOR ,WHOLE HUMAN BLOOD(HEMATOLOGY CALIBRATOR ,WHOLE HUMAN BLOOD)-HEMATOLOGY CALIBRATOR WHOLE HUMAN BLOOD IS INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR DETERMINATION OF HEMATOLOGY PARAMETERS.,CK MB LATEX BASED REAGENT KIT(CK MB LATEX BASED REAGENT KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CK-MB IN SERUM.,TOTAL BILE ACID (TBA) CONTROL SET 2 LEVELS(TOTAL BILE ACID (TBA) CONTROL SET 2 LEVELS)-TOTAL BILE ACID (TBA) CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURE OF TOTAL BILE ACID (TBA) IN HUMAN SERUM.,MICROALBUMIN TEST KIT(MICROALBUMIN IT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF MICROALBUMIN IN HUMAN URINE,BATH ADDITIVE(BATH ADDITIVE)-BIANCH R IS INTENDED AS BATH ADDITIVE FOR THE ISOTHERMAL BATH OF TOSHIBA (TBA) FULLY AUTOMATED RANDOM ACCESS CLINICAL CHEMISTRY ANALYZER SERIES.,N-ACETYL-B-D- GLUCOSAMINIDASE (NAG) CONTROL SET 2 LEVELS(N-ACETYL-B-D- GLUCOSAMINIDASE (NAG) CONTROL SET 2 LEVELS)-N-ACETYL-B-D- GLUCOSAMINIDASE (NAG) CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURE OF N-ACETYL-B-D- GLUCOSAMINIDASE (NAG) IN HUMAN SERUM.,UEA-UV (SL) KIT (UEA-UV (SL) KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF UREA U V IN HUMAN SERUM,FERRITIN CARTRIDGE (MISPA I3)(FERRITIN CARTRIDGE (MISPA I3))-

	DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF IN FERRITIN HUMAN SERUM,IMMUNOGLOBULIN E (IGE) KIT (WITH CALIBRATOR)(IMMUNOGLOBULIN E (IGE) KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF IGE IN HUMAN SERUM.,ASO CARTRIDGE MISPA I3(ASO CARTRIDGE MISPA I3)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF ASO IN HUMAN SERUM,COUNT L3 LYSING REAGENT FOR 3 - PART HEMATOLOGY ANALYZER(COUNT L3 LYSING REAGENT FOR 3 - PART HEMATOLOGY ANALYZER)-DIFF L3 IS INTENDED FOR LYSING OF CELLS FOR WBC COUNT, AND HEMOGLOBIN MEASUREMENT IN MISPA COUNT PLUS -3 PART DIFFERENTIAL HEMATOLOGY ANALYZER.,CK-MB (SL) CREATNE KINASE MB KIT(SL)(CK-MB (SL) CREATNE KINASE MB KIT(SL))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CK-MB (SL) CREATNE KINASE MB KIT(SL) IN HUMAN SERUM,TRIGLYCERIDES KIT(TRIGLYCERIDES KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN SERUM OR PLASMA.,CK-MB KIT(CREATINE KINASE MB KIT)(CK-MB KIT(CREATINE KINASE MB KIT)) -DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CK-MB KIT(CREATINE KINASE MB KIT) IN HUMAN SERUM,CK-MB KIT (CREATININE KINASE MB KIT) (WITH CALIBRATOR) (CK-MB KIT (CREATININE KINASE MB KIT) (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CK-MB IN HUMAN SERUM/PLASMA.,URIN STRIP LEUKOCYTES,KETONE,NITRITE,UROBILINOGEN,BILIRUBIN,GLUCOSE, PROTEIN,SPECIFIC GRAVITY,PH ,BLOOD (U-SMART-10 AC)(URIN STRIP LEUKOCYTES,KETONE,NITRITE,UROBILINOGEN,BILIRUBIN,GLUCOSE, PROTEIN,SPECIFIC GRAVITY,PH ,BLOOD (U-SMART-10 AC))-THIS PACK INSERT IS FOR ULTRASTIK (GLUCOSE, BILIRUBIN, KETONE, SPECIFIC GRAVITY,BLOOD, PH, PROTEIN, UROBILINOGEN, NITRITE, LEUKOCYTES AND MICRO ALBUMIN)AGAPPE REAGENT STRIPS ARE MADE FOR URINALYSIS BOTH QUALITATIVE AND SEMI QUANTITATIVE WHICH ARE IN VITRO REAGENT FOR DIAGNOSTICS. THE STRIPS ARE FOR PROFESSIONAL USE ONLY.,ALBUMIN & TOTAL PROTEIN TEST KIT (ALBUMIN & TOTAL PROTEIN TEST KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ALBUMIN & TOTAL PROTEIN IN SERUM OR PLASMA.,RF LATEX CONTROL(RF LATEX CONTROL)-QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IVD,LAMBDA LIGHT CHAIN(LAMBDA LIGHT CHAIN)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF LAMBDA LIGHT CHAIN IN HUMAN SERUM, BILIRUBIN TOTAL AND DIRECT KIT-COMBINATION KIT(BILIRUBIN TOTAL AND DIRECT TAB) AND DIRECT KIT-COMBINATION KIT

	(BILIRUBIN TOTAL AND DIRECT KIT-COMBINATION KIT(BILIRUBIN TOTAL AND DIRECT TAB) AND DIRECT KIT-COMBINATION KIT(BILIRUBIN TOTAL AND DIRECT KIT-COMBINATION KIT(BILIRUBIN TOTAL AND DIRECT TAB) AND DIRECT TAB))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF BILIRUBIN IN SERUM OR PLASMA.,CLEANER FOR 5-PART DIFF. HEMATOLOGY ANALYZER (DIFF. C5)(CLEANER FOR 5-PART DIFF. HEMATOLOGY ANALYZER (DIFF. C5))-SHEATH SOLUTION IS INTENDED FOR CLEANING THE TUBING'S OF MISPA COUNT-5 PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS AN AZIDE FREE FILTERED SOLUTION.,HEMATOLOGY CONTROL (H) (HEMATOLOGY CONTROL LEVEL 3)WHOLE HUMAN BLOOD(HEMATOLOGY CONTROL (H) (HEMATOLOGY CONTROL LEVEL 3)WHOLE HUMAN BLOOD)-HEMATOLOGY CONTROL USED IN MONITORING OF BLOOD CELL VALUES ON IMPEDANCE CELL COUNTERS.,MICROALBUMIN LATEX CONTROL(MICROALBUMIN LATEX CONTROL)-MICROALBUMIN LATEX CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE ACCURACY AND PRECISION OF MICROALBUMIN ASSAY.,LAMBDA LIGHT CHAIN (MISPA -I3)(LAMBDA LIGHT CHAIN (MISPA -I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF LAMBDA LIGHT CHAIN IN HUMAN SERUM, CARBON DIOXIDE (CO2) CALIBRATOR(CARBON DIOXIDE (CO2) CALIBRATOR)-DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR CARBON DIOXIDE ESTIMATION.,IRON/TIBC CALIBRATOR(IRON/TIBC CALIBRATOR)-IRON/TIBC CALIBRATOR IS INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR IRON /TIBC ESTIMATION.,ALPHA AMLASE (AMYLASE) (SL) KIT(ALPHA AMLASE (AMYLASE) (SL) KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF AMYLASE IN SERUM, PLASMA & URINE., MICROPROTEIN CALIBRATOR(MICROPROTEIN CALIBRATOR)-MICROPROTEIN CALIBRATOR IS INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR IRON ESTIMATION.,LP(A) (MISPA-I3)(LP (A) (MISPA-I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF LIPOPROTEIN(A) [LP(A)] IN HUMAN SERUM,CARBON DIOXIDE (CO2) ENZYMATIC ASSAY(CARBON DIOXIDE (CO2) ENZYMATIC ASSAY)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETECTION OF CARBON DIOXIDE IN SERUM.,CHOLESTEROL KIT(CHOLESTEROL KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CHOLESTEROL IN SERUM OR PLASMA.,LP (A) LATEX CONTROL(LP (A) LATEX CONTROL)-LP (A) LATEX CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURES.,CK-MB/CTNL/MYO FAST TEST KIT(CK-MB/CTNL/MYO

	FAST TEST KIT)-CK-MB/CTNI/MYO FAST TEST KIT (IMMUNOFLUORESCENCE ASSAY) APPLIES FLUORESCENCE IMMUNOCHROMATOGRAPHY TO DETECT CK-MB/CTNI/MYO IN SERUM, PLASMA OR WHOLE BLOOD SAMPLES QUANTITATIVELY. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS AND ACUTE CORONARY SYNDROME (ACS).,HBA1C CONTROL LEVEL 1&2(HBA1C CONTROL LEVEL 1&2)-HBA1C CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURES.,ACID WASHING SOLUTION FOR TBA SERIES OF FULLY AUTO ANALYZERS (TBA WASH SOLUTION 3)(ACID WASHING SOLUTION FOR TBA SERIES OF FULLY AUTO ANALYZERS (TBA WASH SOLUTION 3))-BIANCH 3 IS INTENDED FOR CLEANSING AND MAINTENANCE OF REACTION CUVETTE AND ASPIRATION PROBES. (FOR EXTENSIVE CLEANING OF CUVETTES) OF TOSHIBA (TBA SERIES) FULLY AUTOMATED RANDOM ACCESS CLINICAL CHEMISTRY ANALYZER SERIES.,BILIRUBIN DIRECT KIT (BILIRUBIN DIRECT KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF BILIRUBIN IN SERUM OR PLASMA.,APO A1 (MISPA - I3)(APO A1 (MISPA - I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF APOLIPOPROTEIN A1 IN HUMAN SERUM.,APOLIPOPROTEIN A1 REAGENT KIT(APOLIPOPROTEIN A1 REAGENT KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF APOLIPOPROTEIN A1 IN HUMAN SERUM,CERULOPLASMIN KIT (CERULOPLASMIN KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CERULOPLASMIN IN HUMAN SERUM, ENZYMATIC SODIUM CALIBRATOR KIT(ENZYMATIC SODIUM CALIBRATOR KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE QUALITY CONTROL IN THE DETERMINATION OF SODIUM IN HUMAN SERUM., LIPID CONTROL, HUMAN SERUM LEVEL 2(LIPID CONTROL, HUMAN SERUM LEVEL 2)-LIPID CONTROL IS AN ASSAYED LYOPHILIZED QUALITY CONTROL SERUM INTENDED TO MONITOR THE ACCURACY AND PRECISION OF APOA1, APO B, LP (A), HDL-D, LDL-D, TGL & CHOLESTEROL.,CERULOPLASMIN KIT (WITH CALIBRATOR) (CERULOPLASMIN KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CERULOPLASMIN IN SERUM,ACID WASHING SOLUTION (WASHING SOLUTION (AC)(ACID WASHING SOLUTION (WASHING SOLUTION (AC)) -ACID WASH DETERGENT IS INTENDED FOR CLEANSING AND MAINTENANCE OF REACTION CUVETTES AND ASPIRATION PROBES OF BIOLIS 24I AUTOMATED CLINICAL ANALYZER.,IGM (MISPA-I3)(IGM (MISPA-I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO

	DETERMINATION OF IMMUNOGLOBULIN M (IGM (MISPA-I3)) IN HUMAN SERUM,VITAMIN D REAGENT KIT(VITAMIN D REAGENT KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE ESTIMATION OF VITAMIN D IN HUMAN SERUM.,MICROALBUMIN CONTROL(MICROALBUMIN CONTROL)-MICROALBUMIN CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE ACCURACY AND PRECISION OF MICROALBUMIN ASSAY.,KAPPA LIGHT CHAIN(MISPA-I3) (KLC)(KAPPA LIGHT CHAIN(MISPA-I3) (KLC))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF KAPPA LIGHT CHAIN(MISPA-I3) IN HUMAN SERUM.,ASO LATEX SLIDE KIT (ASO) (ASO LATEX SLIDE KIT (ASO))-THIS REAGENT IS INTENDED FOR IN VITRO QUALITATIVE & SEMI QUANTITATIVE DETERMINATION OF ANTI STREPTOLYSIN O (ASO) IN SERUM.,HBA1C CARTRIDGE MISPA I3 (HBA1C CARTRIDGE MISPA I3)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF GLUCOSE IN HUMAN SERUM,TRANSFERRIN KIT (WITH CALIBRATOR)(TRANSFERRIN KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF TRANSFERRIN IN HUMAN SERUM, BATH ADDITIVE BIANCH R(BATH ADDITIVE BIANCH R)-BIANCH R IS INTENDED AS BATH ADDITIVE FOR THE ISOTHERMAL BATH OF TOSHIBA (TBA) FULLY AUTOMATED RANDOM ACCESS CLINICAL CHEMISTRY ANALYZER SERIES.,LYSE SOLUTION FOR 5-PART HEMATOLOGY ANALYZER(LYSE DS500)(LYSE SOLUTION FOR 5-PART HEMATOLOGY ANALYZER(LYSE DS500))-DIFF L5 IS INTENDED FOR LYSING OF CELLS FOR WBC COUNT, WBC DIFFERENTIALS AND HEMOGLOBIN MEASUREMENT IN MISPA COUNT PLUS -5 PART DIFFERENTIAL HEMATOLOGY ANALYZER.,ENZYMATIC LITHIUM (ENZYMATIC LITHIUM)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETERMINATION OF LITHIUM IN HUMAN SERUM.,HBA1C KIT(HBA1C KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF GLUCOSE IN HUMAN SERUM,ASO LEIT WITH CALIBRATOR(ASO LEIT WITH CALIBRATOR)-THIS REAGENT IS INTENDED FOR IN VITRO QUALITATIVE & SEMI QUANTITATIVE DETERMINATION OF ANTI STREPTOLYSIN O (ASO) IN SERUM.,LIPID CONTROL HUMAN SERUM LEVEL 1(LIPID CONTROL HUMAN SERUM LEVEL 1)-LIPID CONTROL IS AN ASSAYED LYOPHILIZED QUALITY CONTROL SERUM INTENDED TO MONITOR THE ACCURACY AND PRECISION OF APOA1, APO B, LP (A), HDL-D, LDL-D, TGL & CHOLESTEROL.,MYOGLOBIN REAGENT KIT(MYOGLOBIN REAGENT KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETECTION OF MYOGLOBIN IN SERUM.,RF LATEX SLIDE KIT(RF LATEX SLIDE KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUALITATIVE & SEMI QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN SERUM.,ASO LATEX(ASO LATEX)-DIAGNOSTIC DEVICE FOR THE

	QUANTITATIVE IN-VITRO DETERMINATION OF ASO IN HUMAN SERUM.,SGPT TEST KIT(SGPT TEST KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF SGPT IN SERUM OR PLASMA.,TOTAL PROTEIN KIT(TOTAL PROTEIN KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN SERUM OR PLASMA.,MICROALBUMIN IT (WITH CALIBRATOR)(MICROALBUMIN IT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF MICROALBUMIN IN HUMAN URINE,TRANSFERRIN KIT(TRANSFERRIN KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF TRANSFERRIN IN HUMAN SERUM, RF WITH CALIBRATOR(RF WITH CALIBRATOR)-THIS REAGENT IS INTENDED FOR IN VITRO QUALITATIVE & SEMI QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN SERUM.,N-ACETYL--D-GLUCOSAMINIDASE (NAG) REAGENT KIT(N- ACETYL--D-GLUCOSAMINIDASE (NAG) REAGENT KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETECTION OF N- ACETYL--D-GLUCOSAMINIDASE ANTIBODY IN SERUM.,LYSE SOLUTION FOR 5-PART HEMATOLOGY ANALYZER (DIFF. L5 ANALYZER)(LYSE SOLUTION FOR 5-PART HEMATOLOGY ANALYZER (DIFF. L5 ANALYZER))-DIFF L5 IS INTENDED FOR LYSING OF CELLS FOR WBC COUNT, WBC DIFFERENTIALS AND HEMOGLOBIN MEASUREMENT IN MISPA COUNT PLUS -5 PART DIFFERENTIAL HEMATOLOGY ANALYZER.,LP(A) LIPOPROTEIN (A) KIT(LP(A) LIPOPROTEIN (A) KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF LIPOPROTEIN(A) [LP(A)] IN HUMAN SERUM,HEMATOLOGY ANALYZER E-Z CLEANER(HEMATOLOGY ANALYZER E-Z CLEANER)-EZ CLEANER IS INTENDED FOR DAILY CLEANING OF MINDRAY- 3 PART DIFFERENTIAL HEMATOLOGY ANALYZERS OF BC SERIES.,URINE GLUCOSE (MRP)STRIPS(URINE GLUCOSE (MRP)STRIPS)-THIS PACK INSERT IS TO BE USED WITH PRODUCT: MRP (GLUCOSE), URINE TEST STRIPS ARE USED TO MEASURE CERTAIN CONSTITUENTS IN URINE WHICH ARE SIGNIFICANT OF RENAL, URINARY, HEPATIC AND METABOLIC DISORDERS,AGLDL LDL CHOLESTEROL(AGLDL LDL CHOLESTEROL)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF LDL-CHOLESTEROL IN HUMAN SERUM.,RF TURBILATEX KIT (WITH CALIBRATOR)(RF TURBILATEX KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR IN SERUM.,LDH-P KIT(LDH-P KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF LDH-P IN HUMAN SERUM,KIT PROTEIN CONTROL BI-LEVEL(KIT PROTEIN CONTROL BI-LEVEL)-KIT PROTEIN CONTROL BI-LEVEL (IMMUNOLOGY CONTROL) IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE

	PRECISION OF LABORATORY TESTING PROCEDURES OF SPECIFIC PROTEINS.,RF CARTRIDGE (MISPA - I3)(RF CARTRIDGE (MISPA - I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF RF IN HUMAN SERUM,GAMMA GT S.L KIT(GAMMA GT S.L KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF GAMMA GT S.L IN SERUM, PLASMA & URINE., DIAGNOSTIC KIT FOR COPPER(DIAGNOSTIC KIT FOR COPPER)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF COPPER IN SERUM OR PLASMA.,LP (A) LATEX(LP (A) LATEX)-QUANTITATIVE DETERMINATION OF LIPOPROTEIN (A) (LP (A)) IVD,LIPASE KIT(LIPASE KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF LIPASE IN HUMAN SERUM,LIPID CALIBRATOR SERUM(LIPID CALIBRATOR SERUM)-LIPID CALIBRATOR IS INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR LIPID ESTIMATION.,CYSTATIN C KIT (WITH CALIBRATOR) (CYSTATIN C KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM,25- HYDROXY VITAMIN D(25- HYDROXY VITAMIN D)-DIAGNOSTIC MEDICAL DEVICE FOR THE ESTIMATION OF VITAMIN D IN HUMAN SERUM.,HEMATOLOGY ANALYZER RINSE(HEMATOLOGY ANALYZER RINSE)-RINSE IS INTENDED FOR CLEANING THE VOLUMETRIC TUBES OF MINDRAY-3 PART DIFFERENTIAL HEMATOLOGY ANALYZERS OF BC SERIES. IT IS AN AZIDE FREE FILTERED SOLUTION.,COUNT D3 REAGENT (DILUENT SOLUTION FOR 3-PART HEMATOLOGY ANALYZER FOR MISPA COUNT)(COUNT D3 REAGENT (DILUENT SOLUTION FOR 3-PART HEMATOLOGY ANALYZER FOR MISPA COUNT))-COUNT D3 IS INTENDED FOR DILUENT THE TUBING'S OF MISPA COUNT-3 PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS AN AZIDE FREE FILTERED SOLUTION., FERRITIN CONTROL(FERRITIN CONTROL)-FERRITIN CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURES.,IGA MISPA I3 (IGA MISPA I3)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF I (IGA I3) IN HUMAN SERUM,CK-MB CALIBRATION TEST KIT(CK-MB CALIBRATION TEST KIT)-CK-MB CALIBRATOR IS INTENDED FOR THE CALIBRATION OF MANUAL AND AUTOMATED ANALYTICAL PROCEDURES.,IMMUNOGLOBULIN A (IGA) KIT (WITH CALIBRATOR)(IMMUNOGLOBULIN A (IGA) KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF IGA ANTIBODIES, IN SERUM,ASO TURBILATEX KIT (ASO)(WITH CALIBRATOR)(ASO TURBILATEX KIT (ASO)(WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ANTI STREPTOLYSIN-O (ASO) IN HUMAN SERUM.,RF TEST KIT(RF LATEX)-THIS REAGENT IS

	INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN HUMAN SERUM USING THE TURBI-QUICK SYSTEM.,COUNT D3 DILUENT SOLUTION FOR 3-PART HEMATOLOGY ANALYZER(COUNT D3 DILUENT SOLUTION FOR 3-PART HEMATOLOGY ANALYZER)-COUNT D3 IS INTENDED FOR DILUENT THE TUBING'S OF MISPA COUNT-3 PART DIFFERENTIAL HEMATOLOGY ANALYZER. IT IS AN AZIDE FREE FILTERED SOLUTION., TOTAL BILE ACID (TBA) CALIBRATOR SET(TOTAL BILE ACID (TBA) CALIBRATOR SET)-DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR TOTAL BILE ACID (TBA) ESTIMATION.,MICROALBUMIN CARTRIDGE (MISPA -I3) (MICROALBUMIN CARTRIDGE (MISPA -I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF MICROPROTEIN IN HUMAN SERUM,KAPPA LIGHT CHAIN(KAPPA LIGHT CHAIN)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF KAPPA LIGHT CHAIN IN HUMAN SERUM.,BATH ADDITIVE FOR TBA SERIES OF FULLY AUTO ANALYZERS (TBA WASH SOLUTION R)(BATH ADDITIVE FOR TBA SERIES OF FULLY AUTO ANALYZERS (TBA WASH SOLUTION R))-BIANCH R IS INTENDED AS BATH ADDITIVE FOR THE ISOTHERMAL BATH OF TOSHIBA (TBA) FULLY AUTOMATED RANDOM ACCESS CLINICAL CHEMISTRY ANALYZER SERIES.,RETINOL BINDING PROTEIN (RBP) CALIBRATOR SET (5 LEVELS) (LIQUID)(RETINOL BINDING PROTEIN (RBP) CALIBRATOR SET (5 LEVELS) (LIQUID))-DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR RETINOL BINDING PROTEIN (RBP) ESTIMATION.,RETINOL BINDING PROTEIN (RBP) REAGENT KIT(RETINOL BINDING PROTEIN (RBP) REAGENT KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE MEASUREMENT OF RETINOL BINDING PROTEIN (RBP) IN SERUM., CUVETTE WASH SOLUTION FOR TBA SERIES OF FULLY AUTO ANALYZERS (TBA WASH SOLUTION C)(CUVETTE WASH SOLUTION FOR TBA SERIES OF FULLY AUTO ANALYZERS (TBA WASH SOLUTION C))-BIANCH C IS INTENDED FOR CLEANSING OF REACTION CUVETTE IN STARTUP OF TOSHIBA (TBA) FULLY AUTOMATED RANDOM ACCESS CLINICAL CHEMISTRY ANALYZER SERIES. BIANCH C IS ALSO USED AS THE DETERGENT FOR MINIMIZING CARRYOVER.,ALKALINE PHOSPHATASE KIT(ALKALINE PHOSPHATASE KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN SERUM OR PLASMA.,ALKALINE CLEANING SOLUTION BIANCH 14(ALKALINE CLEANING SOLUTION BIANCH 14)-BIANCH 14 IS THE ALKALINE DETERGENT INTENDED FOR CLEANSING AND MAINTENANCE OF REACTION CUVETTE AND ASPIRATION PROBES OF TOSHIBA (TBA) FULLY AUTOMATED RANDOM ACCESS CLINICAL CHEMISTRY ANALYZER SERIES.,

	COMPLIMENT C3 (C3) (WITH CALIBRATOR)(COMPLIMENT C3 (C3) (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF COMPLEMENT C3 IN HUMAN SERUM.,BASE WASHING SOLUTION (WASHING SOLUTION(AL)(BASE WASHING SOLUTION (WASHING SOLUTION(AL))-ALKALINE WASHING DETERGENT INTENDED FOR CLEANSING AND MAINTENANCE OF REACTION CUVETTE AND ASPIRATION PROBES OF BIOLIS 24I AUTOMATED CLINICAL ANALYZER.,ALKALINE CLEANING SOLUTION (ALKALINE CLEANING SOLUTION)-ALKALINE WASHING DETERGENT INTENDED FOR CLEANSING AND MAINTENANCE OF REACTION CUVETTE AND ASPIRATION PROBES OF BIOLIS 24I AUTOMATED CLINICAL ANALYZER.,AGHDL HDL-CHOLESTEROL(AGHDL HDL-CHOLESTEROL)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF AGHDL HDL-CHOLESTEROL IN HUMAN SERUM,MAGNESIUM KIT(MAGNESIUM KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF MAGNESIUM IN SERUM ,PLASMA AND URINE.,MICROALBUMIN TURBILATEX KIT (WITH CALIBRATOR)(MICROALBUMIN TURBILATEX KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ALPHA1- ACID GLYCOPROTEIN IN HUMAN SERUM.,TRIGLYCERIDE KIT (SL)(TRIGLYCERIDE KIT (SL))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM,WASHING SOLUTION(WASHING SOLUTION)-ACID WASH DETERGENT IS INTENDED FOR CLEANSING AND MAINTENANCE OF REACTION CUVETTES AND ASPIRATION PROBES OF BIOLIS 24I AUTOMATED CLINICAL ANALYZER.,COMPLEMENT C3 (C3)(COMPLEMENT C3 (C3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF COMPLEMENT COMPONENT C3 (C3) IN HUMAN SERUM

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2821	MFG/IVD/2020/000006	1.License Holder Name: ZEPHYR BIOMEDICALS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF TRIIODOTHYRONINE HORMONE IN HUMAN SERUM OR PLASMA (QUALISA T3)-FOR THE QUANTITATIVE MEASUREMENT OF TOTAL TRIIODOTHYRONINE (T3) IN HUMAN SERUM,ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF ULTRASENSITIVE THYROID STIMULATING HORMONE IN HUMAN SERUM OR PLASMA(QUALISA UTSH)-FOR THE QUANTITATIVE DETERMINATION OF THE THYROID STIMULATING HORMONE (TSH) CONCENTRATION IN HUMAN SERUM.,ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF TETRAIODOTHYRONINE HORMONE IN HUMAN SERUM OR PLASMA (QUALISA T4)-FOR THE QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM,ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF FREE TETRA IODOTHYRONINE HORMONE IN HUMAN SERUM OR PLASMA(QUALISA FT4)-THE QUANTITATIVE DETERMINATION OF FREE THYROXINE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY. LEVELS OF FT4 ARE THOUGHT TO REFLECT THE AMOUNT OF T4 AVAILABLE TO THE CELLS AND MAY THEREFORE DETERMINE THE CLINICAL METABOLIC STATUS OF T4 , ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETECTION OF THYROID STIMULATING HORMONE IN HUMAN SERUM OR PLASMA(QUALISA TSH)-FOR THE QUANTITATIVE DETERMINATION OF THE THYROID STIMULATING HORMONE (TSH) CONCENTRATION IN HUMAN SERUM

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2822	MFG/IVD/2020/000007	1.License Holder Name: VECTOR BIOTEK PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use: APOLIPOPROTEIN-A (UNICORN APOLIPOPROTEIN-A)-FOR THE MEASUREMENT OF APOLIPOPROTEIN A IN HUMAN SERUM OR PLASMA ,DILUENT (DILUENT-MR)-DILUENT FOR MINDRAY 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,RF CONTROL(UNICORN RF CONTROL(HIGH))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,LYSE(VEC LYSE 1800)-LYSE FOR MINDRAY BC 1800 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,IGA(UNICORN IMMUNOGLOBULIN A (IGA) TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A IN HUMAN SERUM OR PLASMA ,LYSE(LYSE-MR)-LYSE FOR MINDRAY 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, SHEATH(UNICORN 5 PART SHEATH)-FOR THE PURPOSE OF UNIFORM FLOW OF CELLS ,DILUENT(BONAVERA COUNT DILUENT)-DILUENT FOR BONAVERA COUNT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,BIOCHEMISTRY CONTROL PATH(UNICORN BIOCHEMISTRY CONTROL PATH)-CONTROL TO BE USED IN INTERNAL QUALITY CONTROL SCHEMES, TO MONITOR THE PRECISION.,LYSE (VEC LYSE 2300)-LYSE FOR MINDRAY BC 2300 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CK -MB CONTROL(UNICORN CK-MB CONTROL LEVEL 1)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,CLEANER(VEC EZ 18)-CLEANER FOR MINDRAY BC 1800 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, FERRITIN CONTROL(UNICORN FERRITIN CONTROL)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,STRONG CLEANER-STRONG CLEANER FOR NIHON KOHDEN 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,POTASSIUM(UNICORN ENZYMATIC POTASSIUM)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF POTASSIUM IN SERUM ,LYSE(BONAVERA COUNT LYSE)-LYSE FOR BONAVERA COUNT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,ADA CONTROL(UNICORN ADA CONTROL (HIGH))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,LYSE (LYSE-URT)-LYSE FOR URIT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CERULOPLASMIN(UNICORN CERULOPLASMIN TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF CERULOPLASMIN IN HUMAN SERUM OR PLASMA,LYSE(LYSE-M60)-LYSE FOR ABX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, CHOLINESTERASE(UNICORN CHOLINESTERASE)-FOR THE QUANTITATIVE DETERMINATION OF CHOLINESTERASE IN HUMAN SERUM AND PLASMA. ,LYSE(LYSE-SY)-LYSE FOR SYSMEX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CKMB CALIBRATOR(UNICORN CKMB CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE

	,CLEANER-CLEANER (FOR ALL 3-PART DIFFERENTIAL BLOOD CELL COUNTER),1-ANTITRYPSIN (UNICORN 1-ANTITRYPSIN)-FOR QUANTITATIVE DETERMINATION OF 1 -ANTITRIPSIN IN HUMAN SERUM OR PLASMA ,CLEANER(BONAVERA COUNT EZ)-CLEANER FOR BONAVERA COUNT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, LDL CALIBRATOR(UNICORN LDL CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,CLEANER(EZ-MR)-CLEANER FOR MINDRAY 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, MICROALBUMIN CALIBRATOR(UNICORN MICROALBUMIN CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,CLEANER(VEC EZ 23)-CLEANER FOR MINDRAY BC 2300 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CYSTATIN C CALIBRATOR (UNICORN CYSTATIN C CALIBRATOR SET)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE,LYSE(VECTOR LYSE 10E)-LYSE FOR MINDRAY BC-10E 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, ALBUMIN(UNICORN ALBUMIN)-FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM OR PLASMA. ,RINSE (RINSE-URT)-RINSE FOR URIT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,ELECTROLYTE STANDARD A(UNICORN ELECTROLYTE STANDARD A)-TO PROVIDE CALIBRATION POINT FOR NA+,K+,CA++, CL-,LI+ ,CLEANER(CELL CLEANER- ERM)-CLEANER FOR ERMA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,HDL / LDL CALIBRATOR(UNICORN HDL/LDL CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,CLEANER(CELL CLEANER- M60)-CLEANER FOR ABX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, APOLIPOPROTEIN CII(UNICORN APOLIPOPROTEIN CII)-FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPRETEIN C II IN HUMAN SERUM OR PLASMA ,PROBE CLEANER(VEC PROBE CLEANER)-PROBE CLEANER FOR MINDRAY BC 1800/BC 2300 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CK-NAC CONTROL(UNICORN CK-NAC CONTROL LEVEL 2)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS,PROBE CLEANER(PROBE CLEANER-MR)-PROBE CLEANER FOR MINDRAY 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, CREATININE(ALKALINE PICRATE)(UNICORN CREATININE (ALKALINE PICRATE))-FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM OR URINE. ,CLEANER(CLEANER-HRB)-CLEANER FOR HORIBA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CYSTACIN -C(UNICORN CYSTATIN -C)-QUANTITATIVE TURBIDIMETRIC TEST FOR THE MEASUREMENT OF CYSTATIN C IN SERUM OR PLASMA,DILUENT(DILUENT-ERM)-DILUENT FOR ERMA 3-

	PART DIFFERENTIAL BLOOD CELL COUNTERS, CHOLESTEROL (UNICORN CHOLESTEROL)-FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA. ,PROBE CLEANER (VECTOR PROBE CLEANER 10E)-PROBE CLEANER FOR MINDRAY BC-10E 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, SODIUM (UNICORN SODIUM)-FOR THE QUANTITATIVE DETERMINATION OF SODIUM IN SERUM. ,PROBE CLEANER(VECTOR PROBE CLEANER 30)-PROBE CLEANER FOR MINDRAY BC-30 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, MAGNESIUM(UNICORN MAGNESIUM)-FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM OR PLASMA. ,CLEANER(CELL CLEANER-SY)-CLEANER FOR SYSMEX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,ELECTROLYTE STANDARD B(UNICORN ELECTROLYTE STANDARD B)-TO PROVIDE CALIBRATION POINT FOR NA+,K+,CA++,CL-,LI+ ,LYSE(LYSE-DIA)-LYSE FOR DIATRON 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, URINALYZER(UNICORN URINALYZER)-IT IS USED TO DETECT AND QUANTIFY A NUMBER OF ANALYTES INCLUDING BILIRUBIN, PROTEIN, GLUCOSE AND RED BLOOD CELLS IN URINE,LYSE(LYSE-MED)-LYSE FOR MEDONIC 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,IGE CONTROL(UNICORN IGE CONTROL)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,RINSE(RINSE-MR)-RINSE FOR MINDRAY 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, DIRECT HBA1C(UNICORN DIRECT HBA1C ENZYMATIC TEST KIT)-FOR USE IN THE QUANTITATIVE DETERMINATION OF HBA1C IH HUMAN WHOLE BLOOD SAMPLE ,RINSE(BONAVERA COUNT RINSE)-RINSE FOR BONAVERA COUNT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,HBDH(UNICORN HBDH)-FOR THE QUANTITATIVE DETERMINATION OF - HYDROXYBUTYRATE DEHYDROGENASE (HBDH) IN HUMAN SERUM OR PLASMA. ,DILUENT(DILUENT-MED)-DILUENT FOR MEDONIC 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,ETHANOL CALIBRATOR(UNICORN ETHANOL CALIBRATOR SET)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,RINSE(VEC RINSE 18)-RINSE FOR MINDRAY BC 1800 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CYSTATIN C CONTROL(UNICORN CYSTATIN C CONTROL (HIGH))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS , LYSE(LYSE-HRB)-LYSE FOR HORIBA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,LYSE(UNICORN 5 PART LYSE)-FOR THE PURPOSE OF LYSING RED BLOOD CELL,RELEASING HEMOGLOBIN AND PRESERVES THE INTEGRITY OF WBC NUCLEUS,CLEANER(CLEANER-DIA)-CLEANER FOR DIATRON 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, TRIGLYCERIDES(UNICORN TRIGLYCERIDES)-FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM OR PLASMA. ,DILUENT-DILUENT (FOR ALL 3-PART

	DIFFERENTIAL BLOOD CELL COUNTER),DETERGENT(UNICORN 5 PART DETERGENT)-FOR THE PURPOSE OF MAINTAINING CLEANLINESS OF TUBINGS. ,DILUENT(VEC DILUENT 3D)-DILUENT FOR MINDRAY BC 1800/ BC 2300 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, CREATININE ENZYMATIC(UNICORN CREATININE ENZYMATIC)-FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM OR URINE. ,LYSE(LYSE-ERM)-LYSE FOR ERMA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,ASO/CRP/RF CONTROL(UNICORN ASO/CRP/RF CONTROL (HIGH))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,DILUENT(DILUENT-HRB)-DILUENT FOR HORIBA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, MULTI CALIBRATOR(UNICORN MULTI CALIBRATOR)-FOR THE PURPOSE OF CALIBRATING BIOCHEMISTRY REAGENT IN SEMI AUTOMATED AND FULLY AUTOMATED BIOCHEMISTRY ANALYZER , DILUENT(DILUENT-URT)-DILUENT FOR URIT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,MYOGLOBIN CALIBRATOR (ULTIMA MYOGLOBIN CALIBRATOR SET)-FOR THE PURPOSE OF CALIBRATING MYOGLOBIN REAGENT IN SEMI AND FULLY AUTOMATED BIOCHEMISTRY ANALYZER ,DILUENT(DILUENT-M60)-DILUENT FOR ABX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CK -MB CONTROL(UNICORN CK-MB CONTROL LEVEL 2)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS,DILUENT(VECTOR DILUENT 10E)-DILUENT FOR MINDRAY BC-10E 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, BICARBONATE(UNICORN BICARBONATE)-FOR THE QUANTITATIVE DETERMINATION OF CARBON DIOXIDE IN HUMAN SERUM OR HEPARINIZED PLASMA. ,DILUENT(DILUENT-DIA)-DILUENT FOR DIATRON 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,FULLY AUTO BIOCHEMISTRY ANALYZERS(UNICORN -480)-DEVICES WHICH ARE USED TO MEASURE THE CONCENTRATION OF CHEMICALS IN A BIOLOGICAL PROCESS ,DILUENT(DILUENT-NK)-DILUENT FOR NIHON KOHDEN 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, APOLIPOPROTEIN CONTROL(UNICORN APOLIPOPROTEIN CONTROL)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,DILUENT (DILUENT-SWL)-DILUENT FOR SWELAB 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CK-NAC CONTROL (UNICORN CK-NAC CONTROL LEVEL 1)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS , DILUENT(DILUENT-MDC)-DILUENT FOR MDC(AL SYSTEMEO) 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,PROCALCITONIN(UNICORN PROCALCITONIN TURBILATEX)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PROCALCITONIN IN SERUM OR PLASMA , DILUENT(DILUENT-SY)-DILUENT FOR SYSMEX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, CHLORIDE(UNICORN CHLORIDE)-FOR THE QUANTITATIVE DETERMINATION OF CHLORIDE IN SERUM. ,CLEANER (CLEANER-URT)-CLEANER FOR URIT 3-PART DIFFERENTIAL BLOOD

	CELL COUNTERS,ADA CONTROL(UNICORN ADA CONTROL (LOW))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS,RINSE-RINSE (FOR ALL 3-PART DIFFERENTIAL BLOOD CELL COUNTER), APOLIPOPROTEIN CALIBRATOR(UNICORN APOLIPOPROTEIN CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,CLEANER(CLEANAC-NK)-CLEANER FOR NIHON KOHDEN 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, APOLIPOPROTEIN-B (UNICORN APOLIPOPROTEIN-B)-FOR THE MEASUREMENT OF APOLIPOPROTEIN B IN HUMAN SERUM OR PLASMA ,LYSE-LYSE (FOR ALL 3-PART DIFFERENTIAL BLOOD CELL COUNTER),DILUENT (UNICORN 5 PART DILUENT)-ISOTONIC SOLUTION FOR DILUTING CELLS AND FOR PRESERVING INTEGRITY AND VOLUME OF CELLS. , LYSE(VECTOR LYSE 30)-LYSE FOR MINDRAY BC-30 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,COMPLEMENT C4(UNICORN COMPLEMENT C4 TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT C 4 IN HUMAN SERUM OR PLASMA ,LYSE(LYSE-SWL)-LYSE FOR SWELAB 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,ANTITHROMBIN III(UNICORN ANTITHROMBIN III TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF ANTITHROMBIN III IN HUMAN SERUM OR PLASMA ,DILUENT(VECTOR DILUENT 30)-DILUENT FOR MINDRAY BC-30 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,ELECTROLYTE REFERENCE SOLUTION (UNICORN ELECTROLYTE REFERENCE SOLUTION)-FOR CALIBRATION PURPOSE ,RINSE(CLEANER-ERM)-RINSE FOR ERMA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, URIC ACID(UNICORN URIC ACID)-FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM,PLASMA AND URINE. ,LYSE(LYSE-NK)-LYSE FOR NIHON KOHDEN 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, COPPER(UNICORN COPPER)-FOR THE QUANTITATIVE DETERMINATION OF COPPER IN SERUM . ,GLUCOSE HEXOKINASE(UNICORN GLUCOSE HEXOKINASE)-FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM OR PLASMA. ,FULLY AUTO BIOCHEMISTRY ANALYZERS(UNICORN -230)-DEVICES WHICH ARE USED TO MEASURE THE CONCENTRATION OF CHEMICALS IN A BIOLOGICAL PROCESS ,BIOCHEMISTRY CONTROL NORM(UNICORN BIOCHEMISTRY CONTROL NORM)-CONTROL TO BE USED IN INTERNAL QUALITY CONTROL SCHEMES, TO MONITOR THE PRECISION.,CRP TURBILATEX(UNICORN CRP TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM.,CRP CONTROL(UNICORN CRP CONTROL (HIGH))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,COMPLEMENT C3 (UNICORN COMPLEMENT C3 TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT C 3 IN HUMAN SERUM OR PLASMA

	,FERRITIN (UNICORN FERRITIN TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION FERRITIN HUMAN SERUM OR PLASMA. ,ETHANOL CONTROL(UNICORN ETHANOL CONTROL SET)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,CK -MB CONTROL(UNICORN CK-MB CONTROL SET)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,HOMOCYSTEINE(UNICORN HOMOCYSTEINE)-FOR THE QUANTITATIVE DETERMINATION OF HOMOCYSTEINE IN HUMAN SERUM OR PLASMA.,MICROALBUMIN(UNICORN MICROALBUMIN)-FOR THE QUANTITATIVE DETERMINATION OF MICROALBUMIN IN HUMAN URINE.,TOTAL BILE ACIDS CALIBRATOR(UNICORN TOTAL BILE ACIDS CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE,ZINC(UNICORN ZINC)-FOR THE QUANTITATIVE DETERMINATION OF ZINC IN HUMAN SERUM OR PLASMA,TOTAL BILE ACIDS(UNICORN TOTAL BILE ACIDS)-FOR QUANTITATIVE DETERMINATION OF TOTAL BILE ACIDS IN HUMAN SERUM OR PLASMA,HOMOCYSTEIN CALIBRATOR(UNICORN HOMOCYSTEIN CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,PREALBUMIN(UNICORN PREALBUMIN)-FOR THE QUANTITATIVED ETERMINATION OF PREALBUMIN IN HUMAN SERUM OR PLASMA. , ETHANOL(UNICORN ETHANOL)-FOR QUANTITATIVE DETERMINATION OF ETHANOL IN HUMAN SERUM OR PLASMA,CYSTATIN C CONTROL(UNICORN CYSTATIN C CONTROL SET)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,LP (A)(UNICORN LP (A) TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF LP (A) IN HUMAN SERUM OR PLASMA. , ALKALINE PHOSPHATASE MONO (UNICORN ALKALINE PHOSPHATASE MONO)-FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR PLASMA ,HDL PRECIPITATING REAGEMT(UNICORN HDL PRECIPITATING REAGENT)-FOR THE QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM OR PLASMA. , GLUCOSE (UNICORN GLUCOSE)-FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM AND PLASMA (PREFERABLY SODIUM FLUORIDE). , AMMONIA(UNICORN AMMONIA)-FOR THE QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN PLASMA. , LDH(UNICORN LDH)-FOR THE QUANTITATIVE DETERMINATION OF LDH IN HUMAN SERUM OR PLASMA. ,LP (A) CONTROL(UNICORN LP (A) CONTROL)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS , ADA CALIBRATOR(UNICORN ADA CALIBRATOR)-FOR THE PURPOSE OF CALIBRATING UNICORN ADENOSINE DEAMINASE KIT IN SEMI AUTOMATED AND FULLY AUTOMATED BIOCHEMISTRY ANALYZER , MICROALBUMIN CONTROL(UNICORN MICROALBUMIN CONTROL)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,PROTEIN

	CONTROL(UNICORN PROTEIN CONTROL)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,FERRITIN CALIBRATOR(UNICORN FERRITIN CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE , CALCIUM(ARSENAZO- III)(UNICORN CALCIUM(ARSENAZO- III))-FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM. ,SODIUM(UNICORN ENZYMATIC SODIUM)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF SODIUM IN SERUM , TIBC(UNICORN TIBC)-FOR MEASURING THE TOTAL IRON BINDING CAPACITY IN HUMAN. ,IGE CALIBRATOR(UNICORN IGE CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE , ALKALINE PHOSPHATASE LYPHO(UNICORN ALKALINE PHOSPHATASE LYPHO)-FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR HEPARIN PLASMA , LYTE 5(UNICORN LYTE 5)-THE ELECTROLYTE ANALYZERS IS A DEVICE FOR MEASURING THE ELECTROLYTES IN THE HUMAN BODY., HAPTOGLOBIN(UNICORN HAPTOGLOBIN TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF HAPTOGLOBIN IN HUMAN SERUM OR PLASMA., POTASSIUM(UNICORN POTASSIUM)-FOR THE QUANTITATIVE DETERMINATION OF POTASSIUM IN SERUM. , MYOGLOBIN(UNICORN MYOGLOBIN)-FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM ON PLASMA. , V CHEM NEXT(UNICORN V CHEM NEXT)-FOR IN VITRO QUANTITATIVE DETERMINATION OF CLINICAL CHEMISTRIES IN SERUM, PLASMA, URINE OR CEREBROSPINAL FLUID SAMPLES. , CALCIUM OCPC (UNICORN CALCIUM OCPC)-FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM. ,ASO TURBILATEX(UNICORN ASO TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN -O ACTIVITY IN HUMAN SERUM., HBA1C CONTROL(UNICORN HBA1CCONTROL)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS , CK-NAC(UNICORN CK-NAC)-FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE IN HUMAN SERUM OR PLASMA. ,1-GLYCOPROTEIN (UNICORN 1- ACID GLYCOPROTEIN)-FOR QUANTITATIVE DETERMINATION OF 1 -ACID GLYCOPROTEIN IN HUMAN SERUM OR PLASMA ,PROTEIN CALIBRATOR(UNICORN PROTEIN CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE , TOTAL PROTEIN(UNICORN TOTAL PROTEIN)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA. ,RF CALIBRATOR(UNICORN RF CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,3 PART CELL COUNTER(UNICORN 3)-FOR THE QUANTITATIVE

	DETERMINATION OF RBC, WBC AND PLATELETS , VCLOT(UNICORN VCLOT)-SEMI-AUTOMATED MECHANICAL CLOT DETECTION SYSTEM DESIGNED FOR THE DETERMINATION OF PT, APTT, FIBRINOGEN CONCENTRATIONS ,IGE(UNICORN IMMUNOGLOBULIN E (IG E) TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E IN HUMAN SERUM OR PLASMA ,CK-NAC CONTROL(UNICORN CK-NAC CONTROL SET)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,HDL CALIBRATOR(UNICORN HDL CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE , LIPASE(UNICORN LIPASE)-FOR THE QUANTITATIVE DETERMINATION OF LIPASE IN HUMAN SERUM OR PLASMA. ,CRP CONTROL(UNICORN CRP CONTROL (LOW))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS , HBA1C(UNICORN HBA1C)-FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN BLOOD. , ASO CONTROL(UNICORN ASO CONTROL(HIGH))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,ASO/CRP/RF CONTROL(UNICORN ASO/CRP/RF CONTROL (LOW))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS , UREA (UV)(UNICORN UREA (UV))-FOR THE QUANTITATIVE DETERMINATION OF UREA IN SERUM, PLASMA AND URINE. ,IGG(UNICORN IMMUNOGLOBULIN G (IGG) TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G IN HUMAN SERUM OR PLASMA ,ELECTROLYTE EZ CLEANER(UNICORN ELECTROLYTE EZ CLEANER)-TO CLEAN THE SAMPLE PATH,CRP CALIBRATOR(UNICORN CRP CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,PHOSPHORUS(UNICORN PHOSPHORUS)-FOR THE QUANTITATIVE DETERMINATION OF PHOSPHOROUS IN HUMAN SERUM,PLASMA AND URINE., TRANSFERRIN(UNICORN TRANSFERRIN TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF TRANSFERRIN IN HUMAN SERUM OR PLASMA. , HDL CHOLESTEROL(UNICORN HDL CHOLESTEROL)-FOR THE QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM OR PLASMA. , IRON (UNICORN IRON)-FOR QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM OR HEPARINIZED PLASMA. ,RF TURBILATEX(UNICORN RF TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR IN HUMAN SERUM., G6PD QUALITATIVE(UNICORN G6PD QUALITATIVE)-OR THE QUALITATIVE DETERMINATION OF G6PDH DEFICIENCY IN RED BLOOD CELLS. ,BILIRUBIN TOTAL & DIRECT /J& G (UNICORN BILIRUBIN TOTAL & DIRECT (J& G))-FOR THE QUANTITATIVE DETERMINATION OF BILIRUBIN TOTAL & DIRECT IN HUMAN SERUM.,PROCALCITONIN CALIBRATOR(UNICORN PROCALCITONIN CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE

	CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE,ALKALINE PHOSPHATASE(UNICORN ALKALINE PHOSPHATASE)-FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR PLASMA, ELECTROLYTE FLUSH CLEANER(UNICORN ELECTROLYTE FLUSH CLEANER)-FOR CLEANING THE FLUID PATH ON THE ELECTROLYTE ANALYZER , LYTE 3(UNICORN LYTE 3)-THE ELECTROLYTE ANALYZERS IS A DEVICE FOR MEASURING THE ELECTROLYTES IN THE HUMAN BODY. ,LACTATE(UNICORN LACTATE)-FOR THE QUANTITATIVE DETERMINATION OF LACTATE IN HUMAN PLASMA., BILIRUBIN CALIBRATOR(UNICORN BILIRUBIN CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,URINARY PROTEIN (UNICORN URINARY PROTEIN)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL URINARY AND CSF PROTEIN .,ASO CALIBRATOR(UNICORN ASO CALIBRATOTR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE , GAMMA-GT(UNICORN GAMMA-GT)-FOR THE QUANTITATIVE DETERMINATION OF GGT IN HUMAN SERUM OR PLASMA. ,IGM(UNICORN IMMUNOGLOBULIN M (IGM) TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M IN HUMAN SERUM OR PLASMA ,COLORIMETER(UNICORN COLORIMETER) -INSTRUMENT INTENDED TO MEASURE LIGHT EMITTED, TRANSMITTED, ABSORBED, OR REFLECTED UNDER CONTROLLED CONDITIONS, SGOT(UNICORN SGOT)-FOR THE QUANTITATIVE DETERMINATION OF AST/GOT (ASPARTATE AMINOTRANSFERASE) IN HUMAN SERUM. ,ELECTROLYTE CONTROL(UNICORN ELECTROLYTE CONTROL SET)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,APOLIPOPROTEIN E(UNICORN APOLIPOPROTEIN E)-FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPRETEIN E IN HUMAN SERUM OR PLASMA ,ALPHA AMYLASE(UNICORN AMYLASE)-FOR THE QUANTITATIVE DETERMINATION OF ALPHA-AMYLASE IN HUMAN SERUM ,PLASMA AND URINE.,HOMOCYSTEIN CONTROL(UNICORN HOMOCYSTEIN CONTROL)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,LP (A) CALIBRATOR(UNICORN LP (A) CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE , ADENOSINE DEAMINASE(UNICORN ADENOSINE DEAMINASE)-FOR THE QUANTITATIVE DETERMINATION OF ADENOSINE DEAMINASE (ADA) IN HUMAN SERUM,PLASMA, PLEURAL FLUID,CSF, PERICARDIAL FLUID AND ASCITIC FLUID. ,APOLIPOPROTEIN CIII(UNICORN APOLIPOPROTEIN CIII)-FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPRETEIN C III IN HUMAN SERUM OR PLASMA , V CHEM PLUS (UNICORN V CHEM PLUS)-FOR IN VITRO QUANTITATIVE

	DETERMINATION OF CLINICAL CHEMISTRIES IN SERUM, PLASMA, URINE OR CEREBROSPINAL FLUID SAMPLES. ,ASO CONTROL(UNICORN ASO CONTROL (LOW))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,RF CONTROL(UNICORN RF CONTROL (LOW)) -USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS , BILIRUBIN TOTAL & DIRECT DMSO(UNICORN BILIRUBIN TOTAL & DIRECT (DMSO))-FOR THE QUANTITATIVE DETERMINATION OF BILIRUBIN IN HUMAN SERUM., CK-MB(UNICORN CK-MB)-FOR THE QUANTITATIVE DETERMINATION OF CK-MB LEVELS IN SERUM OR PLASMA. ,SGPT(UNICORN SGPT)-FOR THE QUANTITATIVE DETERMINATION OF ALT/GPT (ALANINE AMINOTRANSFERASE) IN HUMAN SERUM.,ADA CONTROL(UNICORN ADA CONTROL SET)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,CYSTATIN C CONTROL(UNICORN CYSTATIN C CONTROL (LOW))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS , LDL CHOLESTEROL(UNICORN LDL CHOLESTEROL)-FOR THE QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IN HUMAN SERUM OR PLASMA. ,FULLY AUTO BIOCHEMISTRY ANALYZERS (UNICORN -120)-DEVICES WHICH ARE USED TO MEASURE THE CONCENTRATION OF CHEMICALS IN A BIOLOGICAL PROCESS , ALKALINE PHOSPHATASE DEA METHOD(UNICORN ALKALINE PHOSPHATASE DEA METHOD)-FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR PLASMA. , UREA NED(UNICORN UREA NED)-FOR THE QUANTITATIVE DETERMINATION OF UREA IN SERUM,PLASMA AND URINE. ,5 PART CELL COUNTER(UNICORN 5)-FOR THE QUANTITATIVE DETERMINATION OF RBC, WBC AND PLATELETS

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2823	MFG/IVD/2020/000008	1.License Holder Name: ATHENESE-DX PRIVATE LIMITED 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:SCRUB TYPHUS IGG/IGM RAPID TEST KIT(TRUSTLINE)-THE SCRUB TYPHUS IGG/IGM RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF IGG AND IGM ANTIBODIES FOR ORIENTIA TSUTSUGAMUSHI (SCRUB TYPHUS) IN HUMAN SERUM/ PLASMA/ WHOLE BLOOD SPECIMEN. THIS DEVICE IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH SCRUB TYPHUS.,HEMATOLOGY CONTROLS KIT(TRUECHEMIE)-FOR DETERMINATION OF ASSAYED QUALITY CONTROL TO MONITOR THE ACCURACY AND THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE HEMATOLOGY ANALYTES (ERYTHROCYTES (RBC), LEUKOCYTES (WBC), THROMBOCYTES (PLT) AND HAEMOGLOBIN (HGB)).,VIRAL TRANSPORT MEDIUM KIT(ARIDIA)-FOR COLLECTION AND TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING VIRUSES FROM COLLECTION CENTER TO LABORATORIES.,BIOCHEMISTRY MULTI CALIBRATOR KIT(TRUECHEMIE)-FOR DETERMINATION OF ASSAYED CALIBRATE THE BIOCHEMISTRY ANALYSER (ADA, ALBUMIN, ALP, ALPHA AMYLASE, ALT, AST, BIL-TOTAL, BIL-DIRECT, CALCIUM, CHOLESTEROL, CKMB, CKNAC, CREATININE, DHDL, DLDL, GGT, GLUCOSE, LIPASE, MAGNESIUM, PHOSPHORUS, POTASSIUM, SODIUM, TOTAL PROTEINS, TRIGLYCERIDES, UREA KINETIC, UREA ENDPOINT).,HEMATOLOGY REAGENTS KIT(TRUECHEMIE)-FOR QUANTITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HAEMOGLOBIN (HGB).,BIOCHEMISTRY CONTROLS KIT(TRUECHEMIE)-FOR DETERMINATION OF ASSAYED QUALITY CONTROL TO MONITOR THE ACCURACY AND THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE BIOCHEMISTRY ANALYTES (ADA, ALBUMIN, ALP, ALPHA AMYLASE, ALT, AST, BIL-TOTAL, BIL-DIRECT, CALCIUM, CHOLESTEROL, CKMB, CKNAC, CREATININE, DHDL, DLDL, GGT, GLUCOSE, LIPASE, MAGNESIUM, PHOSPHORUS, POTASSIUM, SODIUM, TOTAL PROTEINS, TRIGLYCERIDES, UREA KINETIC, UREA ENDPOINT)., HEMATOLOGY CONTROLS KIT(TRUECHEMIE)-FOR DETERMINATION OF ASSAYED QUALITY CONTROL TO MONITOR THE ACCURACY AND THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE HEMATOLOGY ANALYTES (ERYTHROCYTES (RBC), LEUKOCYTES (WBC), THROMBOCYTES (PLT) AND HAEMOGLOBIN (HGB)).,FREE T4 (FT4) ELISA KIT(RECOMBILISA)-THE FREE T4 (FT4) ELISA IS A SOLID-PHASE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF FT4 CONCENTRATION IN HUMAN

	SERUM. IT IS INTENDED TO BE USED BY PROFESSIONALS AS AN AID IN THE DIAGNOSIS OF THYROID DYSFUNCTION.,SCRUB TYPHUS IGG/IGM RAPID TEST KIT(ONSITE)-THE SCRUB TYPHUS IGG/IGM RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF IGG AND IGM ANTIBODIES FOR ORIENTIA TSUTSUGAMUSHI (SCRUB TYPHUS) IN HUMAN SERUM/ PLASMA/ WHOLE BLOOD SPECIMEN. THIS DEVICE IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH SCRUB TYPHUS.,FREE T3 (FT3) ELISA KIT(RECOMBILISA)-THE FREE T3 (FT3) ELISA IS A SOLID-PHASE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) CONCENTRATION IN HUMAN SERUM. IT IS INTENDED TO BE USED BY PROFESSIONALS AS AN AID IN THE DIAGNOSIS OF THYROID DYSFUNCTION.,BIOCHEMISTRY MULTI CALIBRATOR KIT(TRUECHEMIE)-FOR DETERMINATION OF ASSAYED CALIBRATE THE BIOCHEMISTRY ANALYSER (ADA, ALBUMIN, ALP, ALPHA AMYLASE, ALT, AST, BIL-TOTAL, BIL-DIRECT, CALCIUM, CHOLESTEROL, CKMB, CKNAC, CREATININE, DHDL, DLDL, GGT, GLUCOSE, LIPASE, MAGNESIUM, PHOSPHORUS, POTASSIUM, SODIUM, TOTAL PROTEINS, TRIGLYCERIDES, UREA KINETIC, UREA ENDPOINT)., FREE T4 (FT4) ELISA KIT(TRUSTWELL)-THE FREE T4 (FT4) ELISA IS A SOLID-PHASE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF FT4 CONCENTRATION IN HUMAN SERUM. IT IS INTENDED TO BE USED BY PROFESSIONALS AS AN AID IN THE DIAGNOSIS OF THYROID DYSFUNCTION.,BIOCHEMISTRY CONTROLS KIT(TRUECHEMIE)-FOR DETERMINATION OF ASSAYED QUALITY CONTROL TO MONITOR THE ACCURACY AND THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE BIOCHEMISTRY ANALYTES (ADA, ALBUMIN, ALP, ALPHA AMYLASE, ALT, AST, BIL-TOTAL, BIL-DIRECT, CALCIUM, CHOLESTEROL, CKMB, CKNAC, CREATININE, DHDL, DLDL, GGT, GLUCOSE, LIPASE, MAGNESIUM, PHOSPHORUS, POTASSIUM, SODIUM, TOTAL PROTEINS, TRIGLYCERIDES, UREA KINETIC, UREA ENDPOINT).,FREE T3 (FT3) ELISA KIT(TRUSTWELL)-THE FREE T3 (FT3) ELISA IS A SOLID-PHASE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) CONCENTRATION IN HUMAN SERUM. IT IS INTENDED TO BE USED BY PROFESSIONALS AS AN AID IN THE DIAGNOSIS OF THYROID DYSFUNCTION.

2824	MFG/IVD/2020/000009	1.License Holder Name: LEVRAM LIFESCIENCES PVT. LTD. 2.Approving Authority: DADRA AND NAGAR HAVELI 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTION TUBE (BCT)(BENESPHERA)-IT IS USED FOR BLOOD COLLECTION.

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2825	MFG/IVD/2020/000010	1.License Holder Name: PATHOZYME DIAGNOSTICS 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:RAPICHEK GLYCOSYLATED HEMOGLOBIN OR ITS VARIANTS TEST REAGENTS/KITS (HBA1C)(GLYCOSYLATED HEMOGLOBIN OR ITS VARIANTS TEST REAGENTS/KITS (HBA1C))-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF HBA1C IN HUMAN WHOLE BLOOD WITH EDTA ON PHOTOMETRIC ANALYZERS.,GLUCOSE (GOD-PAP METHOD) KIT-GLUCOSE REAGENT KIT FOR QUANTITATIVE ESTIMATION OF GLUCOSE IN BLOOD SERUM OR PLASMA.,LIQVIPATH PHOSPHORUS (INORGANIC) TEST REAGENTS/KITS(PHOSPHORUS TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF PHOSPHORUSIN HUMAN SERUM OR URINE ON PHOTOMETRIC ANALYZERS.,ALKALINE PHOSPHATASE (DEA-PNPP/DGKC METHOD) KIT-ALKALINE PHOSPHATASE REAGENT KIT FOR QUANTITATIVE ESTIMATION OF ALKALINE PHOSPHATASE IN BLOOD SERUM OR PLASMA.,LIQVIPATH CALCIUM TEST REAGENTS/KITS (OCPC METHOD)(CALCIUM TEST REAGENTS/KITS (OCPC METHOD))-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN HUMAN SERUM ON PHOTOMETRIC ANALYZERS.,TRIGLYCERIDES (GPO-PAP METHOD) KIT-TRIGLYCERIDES REAGENT KIT FOR QUANTITATIVE ESTIMATION OF TRIGLYCERIDES IN BLOOD SERUM OR PLASMA.,LIQVIPATH UREA (BUN) TEST REAGENTS/KITS (MODIFIED BERTHELOT METHOD)(UREA (BUN) TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF UREA (MODIFIED BERTHELOT)IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC ANALYZERS.,CREATININE (MIDIFIED JAFFE'S METHOD) KIT-CREATININE REAGENT KIT FOR QUANTITATIVE ESTIMATION OF CREATININE IN SERUM OR PLASMA OR URINE.,LIQVIPATH MAGNESIUM TEST REAGENTS/KITS (MAGNESIUM TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF MAGNESIUM IN HUMAN SERUM OR PLASMA ON PHOTOMETRIC ANALYZERS.,CHOLESTEROL (CHOD-PAP METHOD) KIT-CHOLESTEROL REAGENT KIT FOR QUANTITATIVE ESTIMATION OF CHOLESTEROL IN SERUM OR PLASMA.,RAPICHEK ANTI-STERPTOLYSIN-O / ASO TEST REAGENTS/KITS (AGGLUTINATION METHOD)(ANTI-STERPTOLYSIN-O / ASO TEST REAGENTS/KITS (AGGLUTINATION METHOD))-IVD KIT FOR QUALITATIVE & SEMI-QUANTITATIVE IN VITRO DETERMINATION OF ANTI-STERPTOLYSIN-O / ASO IN HUMAN SERUM.,CK NAC (IFCC KINETIC METHOD) KIT-CK NAC REAGENT KIT FOR QUANTITATIVE ESTIMATION OF CK-NAC IN BLOOD SERUM OR PLASMA.,LIQVIPATH HDL CHOLESTEROL TEST REAGENTS/KITS (DIRECT SINGLE METHOD) (HDL CHOLESTEROL TEST REAGENTS/KITS (DIRECT SINGLE

	METHOD))-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF DIRECT HDL CHOLESTEROL (SINGLE REAGENT) IN HUMAN SERUM, PLASMA ON PHOTOMETRIC ANALYZERS.,UREA (UV-GLDH METHOD) KIT-UREA REAGENT KIT FOR QUANTITATIVE ESTIMATION OF UREA IN BLOOD SERUM OR PLASMA.,LIQVIPATH LITHIUM TEST REAGENTS/KITS(LITHIUM TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF LITHIUM IN HUMAN SERUM, PLASMA ON PHOTOMETRIC ANALYZERS.,SGOT (IFCC METHOD) KIT-SGOT REAGENT KIT FOR QUANTITATIVE ESTIMATION OF SGOT (AST) IN SERUM OR PLASMA.,LIQVIPATH PROTEIN (FRACTIONATION) TEST REAGENTS/KITS(PROTEIN (FRACTIONATION) TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF CSF PROTEIN IN HUMAN SAMPLE ON PHOTOMETRIC ANALYZERS.,SGPT (IFCC METHOD) KIT-SGPT REAGENT KIT FOR QUANTITATIVE ESTIMATION OF SGPT (ALT) IN SERUM OR PLASMA.,LIQVIPATH LDL CHOLESTEROL TEST REAGENTS/KITS(LDL CHOLESTEROL TEST REAGENTS/KITS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF DIRECT LDL CHOLESTEROL (R1 & R2) IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS.,CK MB (IMMUNOINHIBITION METHOD) KIT-CK MB REAGENT KIT FOR QUANTITATIVE ESTIMATION OF CK-MB IN SERUM OR PLASMA., RAPICHEK MICROPROTEIN/MICROALBUM TEST REAGENTS/KITS (TURBIDIMETRY METHOD)(MICROPROTEIN/MICROALBUM TEST REAGENTS/KITS (TURBIDIMETRY METHOD))-IVD KIT FOR QUANTITATIVE DETERMINATION OF MICROALBUMIN IN HUMAN FRESH URINE,URIC ACID (URICASE-PAP METHOD) KIT-URIC ACID REAGENT KIT FOR QUANTITATIVE ESTIMATION OF URIC ACID IN BLOOD SERUM OR PLASMA.,LIQVIPATH CHOLINESTERASE TEST REAGENTS/KITS(CHOLINESTERASE TEST REAGENTS/KITS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF CHOLINESTERASE IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS.,LIQVIPATH GLUCOSE -6-PHOSPHATE DEHYDROGENASE (G6PD) AND ITS ISOENZYMES TEST REAGENTS/KITS (QUANTITATIVE) (GLUCOSE -6-PHOSPHATE DEHYDROGENASE (G6PD) AND ITS ISOENZYMES TEST REAGENTS/KITS (QUANTITATIVE))-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF G6PDH IN HUMAN WHOLE BLOOD ON PHOTOMETRIC ANALYZERS.,LIQVIPATH IRON TEST REAGENTS/KITS(IRON TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF IRON / TIBC (FERROZINE)IN HUMAN SERUM ON PHOTOMETRIC ANALYZERS.,LIQVIPATH AMMONIA TEST REAGENTS/KITS(AMMONIA TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF AMMONIA IN HUMAN

	SERUM, PLASMA ON PHOTOMETRIC ANALYZERS.,RAPICHEK ANTISTREPTOLYSIN TEST REAGENTS/KITS (IMMUNOTURBIDIMETRIC/TURBIDIMETRY METHOD (ANTISTREPTOLYSIN TEST REAGENTS/KITS (IMMUNOTURBIDIMETRIC/TURBIDIMETRY METHOD)-IVD KIT FOR QUANTITATIVE IN-VITRO DETERMINATION OF ASO IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS.,LIQVIPATH HDL CHOLESTEROL TEST REAGENTS/KITS (DIRECT R1&R2)(HDL CHOLESTEROL TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF DIRECT HDL CHOLESTEROL (R1 & R2) IN HUMAN SERUM, PLASMA ON PHOTOMETRIC ANALYZERS,LIQVIPATH ACID PHOSPHATASE (TOTAL OR PROSTATIC) TEST REAGENTS/KITS (KINETIC)(LIQVIPATH ACID PHOSPHATASE (TOTAL OR PROSTATIC) TEST REAGENTS/KITS (KINETIC))-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF ACID PHOSPHATASE IN HUMAN SERUM ON PHOTOMETRIC ANALYZERS.,LIQVIPATH GLUCOSE TEST REAGENTS/KITS (HEXOKINASE METHOD)(GLUCOSE TEST REAGENTS/KITS (HEXOKINASE METHOD))-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF GLUCOSE IN HUMAN SERUM, PLASMA ON PHOTOMETRIC ANALYZERS.,LIQVIPATH ADENOSINE DEAMINASE TEST REAGENTS/KITS(ADENOSINE DEAMINASE TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF ADENOSINE DEAMINASE (ADA) IN HUMAN SERUM/ PLEURIC LIQUID/ PLASMA / PERICARDIAL / CSF OR ASCETIC FLUIDS ON PHOTOMETRIC ANALYZERS.,LIQVIPATH HOMOCYSTEINE TEST REAGENTS/KITS (ENZYMATIC)(HOMOCYSTEINE TEST REAGENTS/KITS (ENZYMATIC))-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF HOMOCYSTEINE IN HUMAN FRESH SERUM OR HEPARIN PLASMA ON PHOTOMETRIC ANALYZERS.,LIQVIPATH CALCIUM TSET REAGENTS/KITS (ARSENAZO III METHOD)(CALCIUM TSET REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF CALCIUM IN HUMAN SERUM ON PHOTOMETRIC ANALYZERS.,RAPICHEK TYPHOID ANTIBODY TEST REAGENTS/KITS (QUALITATIVE AND SEMIQUANTITATIVE WIDAL)(TYPHOID ANTIBODY TEST REAGENTS/KITS (QUALITATIVE AND SEMIQUANTITATIVE WIDAL))-IVD KIT FOR QUALITATIVE &SEMI-QUANTITATIVE IN VITRO DETERMINATION OF WIDALIN HUMAN SERUM.,LIQVIPATH AMYLASE TEST REAGENTS/KITS(AMYLASE TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF AMYLASE IN HUMAN SERUM ON PHOTOMETRIC ANALYZERS.,LIQVIPATH HDL CHOLESTEROL TEST REAGENTS/KITS (PTA / PRECIPITATION METHOD)(HDL CHOLESTEROL TEST REAGENTS/KITS (PTA / PRECIPITATION METHOD))-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM, PLASMA

	ON PHOTOMETRIC ANALYZERS.,LIQVIPATH HAEMOGLOBIN TEST REAGENTS/KITS(HAEMOGLOBIN TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF HAEMOGLOBIN REAGENT IN HUMAN BLOOD ON PHOTOMETRIC ANALYZERS., LIQVIPATH LACTATE TEST REAGENTS/KITS(LACTATE TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF LACTATE-LIN HUMAN SERUM, PLASMA ON PHOTOMETRIC ANALYZERS.,LIQVIPATH SODIUM TEST REAGENTS/KITS(SODIUM TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN-VITRO DETERMINATION OF SODIUM IN HUMAN SERUM ON PHOTOMETRIC SYSTEMS.,LIQVIPATH UREA (BUN) TEST REAGENTS /KITS (DAM METHOD)(UREA (BUN) TEST REAGENTS /KITS (DAM METHOD))-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF UREA (DAM) IN HUMAN SERUM, PLASMA OR URINE ON PHOTOMETRIC ANALYZERS.,LIQVIPATH GAMMA GLUTAMYLTRANSFERASE (GGT) AND ISOENZYMES TEST REAGENTS/KITS(GAMMA GLUTAMYLTRANSFERASE (GGT) AND ISOENZYMES TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF GAMMA GT IN HUMAN SERUM, PLASMA ON PHOTOMETRIC,LIQVIPATH ALBUMIN TEST REAGENTS/KITS (ALBUMIN TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF ALBUMIN IN HUMAN SERUM, PLASMA ON PHOTOMETRIC ANALYZERS.,LIQVIPATH BILIRUBIN (TOTAL AND DIRECT) TEST REAGENTS/KITS(BILIRUBIN TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF BILIRUBIN IN HUMAN SERUM, PLASMA ON PHOTOMETRIC ANALYZERS.,LIQVIPATH CHLORIDE TEST REAGENTS/KITS(CHLORIDE TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF CHLORIDE IN HUMAN SERUM, HEPARIN PLASMA ON PHOTOMETRIC ANALYZERS.,LIQVIPATH POTASSIUM TEST REAGENTS/ KITS (POTASSIUM TEST REAGENTS/ KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF POTASSIUM IN HUMAN SERUM ON PHOTOMETRIC,RAPICHEK RHEUMATOID FACTOR (RF) IMMUNOLOGICAL TEST REAGENTS/KITS (AGGLUTINATION METHOD) (RHEUMATOID FACTOR (RF) IMMUNOLOGICAL TEST REAGENTS/KITS (AGGLUTINATION METHOD))-IVD KIT FOR QUALITATIVE & SEMI-QUANTITATIVE IN VITRO DETERMINATION OF RHEUMATOID FACTOR / RA / RF IN HUMAN SERUM.,RAPICHEK RHEUMATOID FACTOR (RF) IMMUNOLOGICAL TEST REAGENTS/KITS (IMMUNOTURBIDIMETRY METHOD)(RHEUMATOID FACTOR (RF) IMMUNOLOGICAL TEST REAGENTS/KITS (IMMUNOTURBIDIMETRY METHOD))-IVD KIT FOR QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS (RF) IN HUMAN SERUM,LIQVIPATH LACTATE DEHYDROGENASE AND ITS ISOENZYMES TEST REAGENTS TESTS/KITS(LACTATE

	DEHYDROGENASE AND ITS ISOENZYMES TEST REAGENTS TESTS/KITS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF LDH IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS.,LIQVIPATH TOTAL PROTEIN TEST REAGENTS/KITS(TOTAL PROTEIN TEST REAGENTS/KITS)-IVD KIT FOR QUANTITATIVE IN VITRO DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM, PLASMA ON PHOTOMETRIC SYSTEMS (MANUAL, SEMI-AUTOMATIC OR AUTOMATIC).,LIQVIPATH LIPASE TEST REAGENTS/KITS(LIPASE TEST REAGENTS/KITS)-DIAGNOSTIC REAGENT FOR QUANTITATIVE IN-VITRO DETERMINATION OF LIPASE IN HUMAN SERUM, HEPARIN PLASMA ON PHOTOMETRIC,RAPICHEK CHIKUNGUNYA ANTIBODY TEST REAGENTS/KITS (RAPID TEST) (CHIKUNGUNYA ANTIBODY TEST REAGENTS/KITS (RAPID TEST))-IVD KIT FOR QUALITATIVE DETERMINATION OF CHIKUNGUNYA ANTIBODIES IN HUMAN SERUM / PLASMA.,LIQVIPATH GLUCOSE -6-PHOSPHATE DEHYDROGENASE (G6PD) AND ITS ISOENZYMES TEST REAGENTS/KITS(QUALITATIVE) (GLUCOSE -6-PHOSPHATE DEHYDROGENASE (G6PD) AND ITS ISOENZYMES TEST REAGENTS/KITS(QUALITATIVE))-IVD KIT FOR QUALITATIVE IN VITRO DETERMINATION OF G6PDH IN HUMAN WHOLE BLOOD.,RAPICHEK TYPHOID ANTIBODY TEST REAGENTS/KITS (IGG+IGM RAPID TEST)(TYPHOID ANTIBODY TEST REAGENTS/KITS (IGG+IGM RAPID TEST)-IVD KIT FOR QUALITATIVE DETERMINATION OF TYPHOID IGG+IGM ANTIBODIES IN HUMAN SERUM & PLASMA,RAPICHEK DENGUE ANTIBODY TEST REAGENTS/KITS (IGG/IGM)(DENGUE ANTIBODY TEST REAGENTS/KITS (IGG/IGM))-IVD KIT FOR QUALITATIVE DETERMINATION OF DENGUE IGG+IGM ANTIBODY IN HUMAN WHOLE BLOOD, SERUM & PLASMA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2826	MFG/IVD/2020/000011	1.License Holder Name: IMMUNOSCIENCE INDIA PRIVATE LIMITED 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE, KETONE, PROTEIN, PH AND BLOOD FROM URINE TEST AND COMPONENTS(IMMUNOQUICK)-STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE, KETONE, PROTEIN, PH AND BLOOD FROM URINE. THE TEST RESULTS MAY PROVIDE INFORMATION REGARDING THE STATUS OF CARBOHYDRATE METABOLISM, KIDNEY INFORMATION, LIVER INFECTION, ACID BASE AND URINARY TRACT INFECTION.,STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE, PROTEIN, PH AND SPECIFIC GRAVITY FROM URINE TEST AND COMPONENTS (IMMUNOQUICK)-STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE, PROTEIN, PH AND SPECIFIC GRAVITY FROM URINE. THE TEST RESULTS MAY PROVIDE INFORMATION REGARDING THE STATUS OF CARBOHYDRATE METABOLISM, KIDNEY INFORMATION, LIVER INFECTION, ACID BASE AND URINARY TRACT INFECTION., STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE, KETONE, PROTEIN, PH, BLOOD, SPECIFIC GRAVITY, BILIRUBIN, UROBILINOGEN, NITRITE, LEUCOCYTES FROM URINE TEST AND COMPONENTS(IMMUNOQUICK)-STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE, KETONE, PROTEIN, PH, BLOOD, SPECIFIC GRAVITY, BILIRUBIN, UROBILINOGEN, NITRITE, LEUCOCYTES FROM URINE. THE TEST RESULTS MAY PROVIDE INFORMATION REGARDING THE STATUS OF CARBOHYDRATE METABOLISM, KIDNEY INFORMATION, LIVER INFECTION, ACID BASE AND URINARY TRACT INFECTION.,STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE AND KETONE FROM URINE & COMPONENTS(IMMUNOQUICK)-STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE AND KETONE FROM URINE. THE TEST RESULTS MAY PROVIDE INFORMATION REGARDING THE STATUS OF CARBOHYDRATE METABOLISM, KIDNEY INFORMATION, LIVER INFECTION, ACID BASE AND URINARY TRACT INFECTION.,STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE, PROTEIN, PH AND BLOOD FROM URINE TEST AND COMPONENTS(IMMUNOQUICK)-STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE, PROTEIN, PH AND BLOOD FROM URINE. THE TEST RESULTS MAY PROVIDE INFORMATION REGARDING THE STATUS OF CARBOHYDRATE METABOLISM, KIDNEY INFORMATION, LIVER INFECTION, ACID BASE AND URINARY TRACT INFECTION.,STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE AND PROTEIN FROM URINE TEST & COMPONENTS(IMMUNOQUICK)-STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE AND PROTEIN FROM URINE. THE TEST RESULTS MAY PROVIDE INFORMATION REGARDING

	THE STATUS OF CARBOHYDRATE METABOLISM, KIDNEY INFORMATION, LIVER INFECTION, ACID BASE AND URINARY TRACT INFECTION.,ONE STEP PREGNANCY TEST-DEVICE & COMPONENTS (IMMUNOQUICK)-ONE STEP PREGNANCY TEST IS A SELF-TESTING IMMUNOASSAY MADE FOR THE RAPID AND VISUAL DETERMINATION OF HCG (HUMAN CHORIONIC GONADOTROPIN) HORMONE IN HUMAN URINE SPECIMEN TO AID IN THE EARLY DETECTION OF PREGNANCY., RAPID DENGUE IGG/IGM TEST - DEVICE & COMPONENTS (IMMUNOQUICK)-RAPID DENGUE IGG/IGM TEST IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF DENGUE IGG/IGM ANTIBODIES IN HUMAN SERUM/PLASMA.,STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE FROM URINE - TEST & COMPONENTS(IMMUNOQUICK)-STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE FROM URINE. THE TEST RESULTS MAY PROVIDE INFORMATION REGARDING THE STATUS OF CARBOHYDRATE METABOLISM, KIDNEY INFORMATION, LIVER INFECTION, ACID BASE AND URINARY TRACT INFECTION.,STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE, PROTEIN AND PH FROM URINE TEST & COMPONENTS (IMMUNOQUICK)-STRIPS FOR SEMI QUANTITATIVE DETERMINATION OF GLUCOSE, PROTEIN AND PH FROM URINE. THE TEST RESULTS MAY PROVIDE INFORMATION REGARDING THE STATUS OF CARBOHYDRATE METABOLISM, KIDNEY INFORMATION, LIVER INFECTION, ACID BASE AND URINARY TRACT INFECTION.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2827	MFG/IVD/2020/000012	1.License Holder Name: J. MITRA & CO. PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:SCRUB TYPHUS IGM MICROLISA(SCRUB TYPHUS IGM MICROLISA)-SCRUB TYPHUS IGM MICROLISA IS AN ENZYME IMMUNO ASSAY FOR IN-VITRO QUALITATIVE DETECTION OF SCRUB TYPHUS SPECIFIC IGM ANTIBODIES IN HUMAN SERUM OR PLASMA AND IS USED AS A SCREENING TEST FOR TESTING OF COLLECTED BLOOD SAMPLES SUSPECTED FOR SCRUB TYPHUS INFECTION.,PCT QUANTI MICROLISA (PCT QUANTI MICROLISA)-PCT QUANTI MICROLISA IS AN ENZYME IMMUNO ASSAY FOR IN-VITRO QUANTITATIVE DETERMINATION OF PCT IN HUMAN SERUM OR PLASMA.,MICROLISA HIV AG & AB (MICROLISA HIV AG & AB)-4TH GENERATION MICROLISA HIV AG & AB IS AN IN-VITRO QUALITATIVE ENZYME IMMUNOASSAY FOR THE DETECTION OF ANTIBODIES TO HIV-1 AND/OR HIV-2 AND HIV-1 P24 ANTIGEN IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR SCREENING OF BLOOD DONORS OR OTHER INDIVIDUALS AT RISK FOR HIV-1 AND/OR HIV-2 INFECTION AND FOR CLINICAL DIAGNOSTIC TESTING.,HBA1C CONTROL (LEVEL 2)(HBA1C CONTROL (LEVEL 2))-HBA1C CONTROL (LEVEL 2) IS INTENDED FOR IN-VITRO DIAGNOSTIC USE IN QUALITY CONTROL OF HBA1C ON IQUANT FLUORESCENCE IMMUNOASSAY ANALYZER. THIS PRODUCT CAN ONLY BE USED WITH HBA1C QUANTI CARD MANUFACTURED BY J.MITRA & CO. PVT. LTD. , ANTI-D (IGM+IGG) MONOCLONAL ANTISERA/ANTIBODIES(ANTI-D (IGM+IGG) MONOCLONAL ANTISERA/ANTIBODIES)-THE ANTI-D (IGM+IGG) MONOCLONAL ANTIBODIES ARE USED IN FORWARD TYPING TO DETECT THE RH FACTOR FOR DEFINING THE RH +VE OR RH –VE BLOOD GROUP IN HUMAN WHOLE BLOOD. THE TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY.,HBA1C CONTROL (LEVEL 1)(HBA1C CONTROL (LEVEL 1))-HBA1C CONTROL (LEVEL1) IS INTENDED FOR IN-VITRO DIAGNOSTIC USE IN QUALITY CONTROL OF HBA1C ON IQUANT FLUORESCENCE IMMUNOASSAY ANALYZER. THIS PRODUCT CAN ONLY BE USED WITH HBA1C QUANTI CARD MANUFACTURED BY J. MITRA & CO. PVT. LTD. ,ANTI-D (IGG) MONOCLONAL ANTISERA/ ANTIBODIES(ANTI-D (IGG) MONOCLONAL ANTISERA/ ANTIBODIES)-ANTI-D (IGG) MONOCLONAL ANTIBODIES ARE USED IN RH TYPING TO DETECT THE RH FACTOR FOR DEFINING THE RH +VE OR RH –VE BLOOD GROUP IN HUMAN WHOLE BLOOD. .IT IS USED FOR THE PREPARATION OF CONTROL CELLS USED IN DIRECT AND INDIRECT COOMB'S TEST (INDIRECT COOMB'S TECHNIQUE).THE TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY.,COVID KAWACH IGG MICROLISA (COVID KAWACH IGG MICROLISA)-COVID KAWACH IGG MICROLISA KIT IS INTENDED FOR QUALITATIVE DETECTION OF IGG ANTIBODIES IN SERUM/PLASMA OF PATIENTS PRESENTING CLINICAL SIGNS AND

	SYMPTOMS CONSISTENT WITH SARS COV-2 INFECTION.,COMBINED ABD MONOCLONAL ANTISERA /ANTIBODIES(COMBINED ABD MONOCLONAL ANTISERA /ANTIBODIES)-COMBINED ABD MONOCLONAL ANTIBODIES ARE USED IN FORWARD TYPING TO DETECT THE ABO BLOOD GROUP & RH FACTOR FOR DEFINING THE RH +VE OR RH –VE BLOOD GROUP IN HUMAN WHOLE BLOOD. THE TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY. ,COVID-19 NEUTRALIZING ANTIBODY MICROLISA(COVID-19 NEUTRALIZING ANTIBODY MICROLISA)-COVID 19 NEUTRALIZING ANTIBODY MICROLISA IS DESIGNED FOR IN VITRO SEMI-QUANTITATIVE DETECTION OF NEUTRALIZING ANTIBODIES DEVELOPED AGAINST SARS-COV-2 IN HUMAN SERUM/ PLASMA THAT PREVENT THE INTERACTION BETWEEN RECEPTOR BINDING DOMAIN VIRAL SPIKE GLYCOPROTEIN (RBD) AND CELL SURFACE RECEPTOR ANGIOTENSIN CONVERTING ENZYME-2 (ACE2).,ANTI-AB MONOCLONAL ANTISERA/ANTIBODIES (ANTI-AB MONOCLONAL ANTISERA/ANTIBODIES)-THE ANTI-AB MONOCLONAL ANTIBODIES ARE USED IN FORWARD TYPING TO DETECT THE ABO BLOOD GROUP IN HUMAN WHOLE BLOOD. THE TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY,SCRUB TYPHUS IGM QUANTI CARD(SCRUB TYPHUS IGM QUANTI CARD)-SCRUB TYPHUS IGM QUANTI CARD IS A SENSITIVE IMMUNO- CHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF SCRUB TYPHUS IGM ANTIBODIES IN HUMAN SERUM/ PLASMA WITH IQUANT ANALYZER. THIS TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY AND IS INTENDED AS AN AID IN THE DIAGNOSIS OF SCRUB TYPHUS INFECTION., HEPALISA ULTRA(HEPALISA ULTRA)-4TH GENERATION HEPALISA ULTRA IS AN ENZYME IMMUNOASSAY FOR IN-VITRO QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OR PLASMA AND IS USED AS A SCREENING TEST FOR TESTING OF COLLECTED BLOOD PRIOR TO TRANSFUSION.,D-DIMER QUANTI CARD(D-DIMER QUANTI CARD)-D-DIMER QUANTI CARD IS A SENSITIVE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA WITH IQUANT ANALYZER ONLY.,HCV TRI-DOT(HCV TRI-DOT)-THE 4TH GENERATION HCV TRI-DOT IS A RAPID, VISUAL, SENSITIVE AND QUALITATIVE IN VITRO DIAGNOSTIC TEST FOR THE DETECTION OF ANTIBODIES TO HEPATITIS C VIRUS IN HUMAN SERUM OR PLASMA.,COVID 19 AG MICROLISA(COVID 19 AG MICROLISA)-COVID 19 AG MICROLISA IS DESIGNED FOR IN VITRO QUALITATIVE DETECTION OF COVID 19 NUCLEOCAPCID ANTIGEN IN HUMAN NASOPHARYNGEAL, NASAL, OROPHARYNGEAL SWAB SPECIMEN COLLECTED IN VTM OR IN SAMPLE DILUENT FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 . THE TEST IS A SCREENING TEST ONLY AND IS AN AID FOR THE EARLY DIAGNOSIS OF SARS-COV-2 INFECTION IN PATIENT WITH CLINICAL SYMPTOMS.

	MORE SPECIFIC AND ALTERNATE DIAGNOSTIC METHOD SHOULD ALSO BE PERFORMED FOR CONFIRMATION OF SARS -COV-2 INFECTION.,ANTI-D (IGM) MONOCLONAL ANTISERA/ANTIBODIES (ANTI-D (IGM) MONOCLONAL ANTISERA/ANTIBODIES)-THE ANTI-D (IGM) MONOCLONAL ANTIBODIES ARE USED IN FORWARD TYPING TO DETECT THE RH FACTOR FOR DEFINING THE RH +VE OR RH –VE BLOOD GROUP IN HUMAN WHOLE BLOOD. THE TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY.,D-DIMER MICROLISA(D-DIMER MICROLISA)-D-DIMER MICROLISA IS DESIGNED FOR IN-VITRO QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN PLASMA.,HBA1C QUANTI CARD(HBA1C QUANTI CARD)-HBA1C QUANTI CARD IS A SENSITIVE IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF HBA1C (GLYCATED HEMOGLOBIN) IN HUMAN WHOLE BLOOD WITH IQUANT ANALYZER. THIS TEST IS USED FOR ROUTINE MONITORING OF LONG TERM GLYCEMIC STATUS IN PATIENT WITH DIABETES MELLITUS., DIAGNOS HIV BI -DOT(DIAGNOS HIV BI -DOT)-THE DIAGNOS HIV BI-DOT IS A RAPID, VISUAL, SENSITIVE AND ACCURATE IMMUNOASSAY FOR THE DETECTION OF HIV-1 & HIV-2 ANTIBODIES (IGM,IGG & IGA) IN HUMAN SERUM OR PLASMA USING HIV-1 & HIV-2 ANTIGENS IMMOBILIZED ON AN IMMUNOFILTRATION MEMBRANE. THE TEST IS A SCREENING TEST FOR ANTI-HIV-1 & ANTI-HIV-2 AND IS FOR IN VITRO DIAGNOSTIC USE ONLY.,DENGUE NS1 AG QUANTI CARD(DENGUE NS1 AG QUANTI CARD)-DENGUE NS1 AG QUANTI CARD IS A SENSITIVE IMMUNE-CHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF DENGUE NS1 AG IN HUMAN SERUM/PLASMA WITH IQUANT ANALYZER. THIS TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY AND IS INTENDED AS AN AID IN THE EARLIER DIAGNOSIS OF DENGUE INFECTION.,ANTI-A1 LECTIN(ANTI-A1 LECTIN)-ANTI-A1 LECTIN IS A QUALITATIVE TEST FOR THE DETECTION OF A1 ANTIGEN IN HUMAN RED BLOOD CELLS.,HIV MICROLISA 3.0(HIV MICROLISA 3.0)-HIV MICROLISA 3.0 IS AN IN-VITRO QUALITATIVE ENZYME IMMUNOASSAY FOR THE DETECTION OF IGM, IGG & IGA ANTIBODIES TO HIV-1 AND / OR HIV-2 IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR SCREENING OF BLOOD DONORS OR OTHER INDIVIDUALS AT RISK FOR HIV-1 AND / OR HIV-2 INFECTION AND FOR CLINICAL DIAGNOSTIC TESTING.,ANTI-H LECTIN(ANTI-H LECTIN)-ANTI-H LECTIN IS USED TO DEMONSTRATE THE PRESENCE OF H ANTIGEN ON HUMAN RED BLOOD CELLS AND IS ASSESSING THE H SECRETOR OF GROUP ‘O’ INDIVIDUALS.,CRP QUANTI CARD (CRP QUANTI CARD)- CRP QUANTI CARD IS A SENSITIVE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF CRP IN HUMAN SERUM/PLASMA WITH IQUANT ANALYZER,COMBINED ABD (IGM+IGG) MONOCLONAL ANTISERA /ANTIBODIES(COMBINED ABD (IGM+IGG) MONOCLONAL ANTISERA /ANTIBODIES)-COMBINED ABD (IGM+IGG)

	MONOCLONAL ANTIBODIES ARE USED IN FORWARD TYPING TO DETECT THE ABO BLOOD GROUP & RH FACTOR FOR DEFINING THE RH +VE OR RH –VE BLOOD GROUP IN HUMAN WHOLE BLOOD. THE TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY.,ANTI-B MONOCLONAL ANTISERA/ ANTIBODIES(ANTI-B MONOCLONAL ANTISERA/ ANTIBODIES)-THE ANTI-B MONOCLONAL ANTIBODIES ARE USED IN FORWARD TYPING TO DETECT THE ABO BLOOD GROUP IN HUMAN WHOLE BLOOD. THE TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY., HS-CRP QUANTI MICROLISA(HS-CRP QUANTI MICROLISA)-HS-CRP QUANTI MICROLISA IS AN ENZYME IMMUNO ASSAY FOR IN-VITRO QUANTITATIVE DETERMINATION OF CRP IN HUMAN SERUM OR PLASMA.,HCV MICROLISA(HCV MICROLISA)-THE 3RD GENERATION HCV MICROLISA IS AN IN-VITRO QUALITATIVE ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE DETECTION OF ANTIBODIES AGAINST HCV (ANTI-HCVS) IN HUMAN SERUM OR PLASMA. THE KIT IS BASICALLY INTENDED TO SCREEN BLOOD DONATIONS TO IDENTIFY AND ELIMINATE THE INFECTED UNITS OF BLOOD AND FOR CLINICAL DIAGNOSTIC TESTING.,ANTI-A MONOCLONAL ANTISERA/ANTIBODIES (ANTI-A MONOCLONAL ANTISERA/ANTIBODIES)-THE ANTI-A MONOCLONAL ANTIBODIES ARE USED IN FORWARD TYPING TO DETECT THE ABO BLOOD GROUP IN HUMAN WHOLE BLOOD. THE TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY.,DENGUE DAY 1 TEST (DENGUE DAY 1 TEST)-DENGUE DAY 1 TEST IS A RAPID SOLID PHASE IMMUNE-CHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN & DIFFERENTIAL DETECTION OF IGM AND IGG ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM/PLASMA. THIS TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY AND IS INTENDED AS AN AID TO AN EARLY DIAGNOSE OF DENGUE INFECTION & PRESUMPTIVE DIAGNOSIS BETWEEN PRIMARY AND SECONDARY DENGUE INFECTION.,PCT QUANTI CARD(PCT QUANTI CARD)-PCT QUANTI CARD IS A SENSITIVE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF PCT IN HUMAN SERUM/PLASMA WITH IQUANT ANALYZER.,BOVINE ALBUMIN(BOVINE ALBUMIN)-BOVINE ALBUMIN IS PRIMARILY USED TO ENHANCE THE REACTIVITY OF BLOOD GROUP ANTIBODIES, EITHER IN DIRECT AGGLUTINATION TESTS OR INDIRECT ANTIGLOBULIN TEST. BOVINE ALBUMIN IS FREQUENTLY USED AS A CONTROL FOR RH TYPING, FOR COMPATIBILITY TESTING, ANTIBODY DETECTION, IDENTIFICATION AND TITRATION. IT IS ALSO USED AS A SURFACE COATING AGENT. BOVINE ALBUMIN STABILIZES THE PROTEIN/ANTIBODIES., ADVANTAGE PAN MALARIA CARD(ADVANTAGE PAN MALARIA CARD) -ADVANTAGE PAN MALARIA CARD IS A VISUAL, RAPID, SENSITIVE AND ACCURATE SOLID PHASE IMMUNOASSAY AND IS AN AID FOR THE QUALITATIVE DETECTION OF PLDH BASED PAN SPECIES(P.

	VIVAX, P.FALCIPARUM,P.OVALE & P.MALARIAE) MALARIA ANTIGENS IN HUMAN WHOLE BLOOD SPECIMENS. THE KIT IS INTENDED FOR PROFESSIONAL USE AND AS A SCREENING TEST. ALL REACTIVE SAMPLES SHOULD BE CONFIRMED BY A SUPPLEMENTAL ASSAY LIKE MICROSCOPIC EXAMINATION OF THICK SMEAR AND THIN BLOOD FILMS. IT ASSISTS TRAINED USERS IN DETECTING PLASMODIUM SPECIES AND IS FOR IN VITRO DIAGNOSTIC USE ONLY.,ANTI-HUMAN SERUM (COOMB'S ANTISERA)(ANTI-HUMAN SERUM (COOMB'S ANTISERA))-ANTI HUMAN SERUM IS USED IN THE DIRECT AND INDIRECT ANTIGLOBULIN TEST TO DETECT ANTIBODIES AND/OR COMPLEMENT ON RBC'S. .,HIV TRI -DOT(HIV TRI -DOT)-THE HIV TRI-DOT TEST IS A VISUAL, RAPID, SENSITIVE AND ACCURATE IMMUNOASSAY FOR THE DIFFERENTIAL DETECTION OF HIV-1 & HIV-2 ANTIBODIES (IGM,IGG& IGA) IN HUMAN SERUM OR PLASMA USING HIV-1 & HIV-2 ANTIGENS IMMOBILIZED ON AN IMMUNOFILTRATION MEMBRANE. THE TEST IS A SCREENING TEST FOR ANTI-HIV-1 & ANTI-HIV-2 AND IS FOR IN VITRO DIAGNOSTIC USE ONLY.,ADVANTAGE P.F MALARIA CARD(ADVANTAGE P.F MALARIA CARD)-ADVANTAGE P.F MALARIA CARD IS A VISUAL, RAPID QUALITATIVE AND SENSITIVE SOLID PHASE IMMUNE CHROMATOGRAPHIC ASSAY BASED ON ANTIGEN DETECTION AND IS AS AN AID IN DIAGNOSIS OF INFECTION WITH HRP-2 (HISTIDINE RICH PROTIEN-2) SPECIFIC P. FALCIPARUM IN HUMAN WHOLE BLOOD SPECIMENS. THE KIT IS INTENDED FOR PROFESSIONAL USE AND AS A SCREENING TEST AND NOT TO BE USED FOR CARRIERS. ALL REACTIVE SAMPLES SHOULD BE CONFIRMED BY A SUPPLENTAL ASSAY LIKE MICROSCOPIC EXAMINATION OF THICK SMEAR AND THIN BLOOD FILMS. IT ASSISTS TRAINED COMPETENT USERS IN DETECTING PLASMODIUM INFECTIONS.,ADVANTAGE MAL CARD(ADVANTAGE MAL CARD)-ADVANTAGE MAL CARD TEST IS A VISUAL, RAPID, SENSITIVE AND ACCURATE IMMUNOASSAY FOR THE QUALITATIVE DIFFERENTIAL DETECTION OF PLDH BASED P. FALCIPARUM AND PAN SPECIES(P. VIVAX, P. FALCIPARUM, P.OVALE & P.MALARIAE)MALARIA ANTIGENS IN HUMAN WHOLE BLOOD. THE KIT IS INTENDED FOR PROFESSIONAL USE AND AS A SCREENING TEST. ALL REACTIVE SAMPLES SHOULD BE CONFIRMED BY A SUPPLEMENTAL ASSAY LIKE MICROSCOPIC EXAMINATION OF THICK SMEAR AND THIN BLOOD FILMS. IT ASSISTS TRAINED USERS IN DETECTING PLASMODIUM SPECIES AND IS FOR IN VITRO DIAGNOSTIC USE ONLY.,HEPACARD(HEPACARD)-HEPACARD IS A VISUAL, RAPID, SENSITIVE AND ACCURATE ONE STEP IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OF PLASMA. THE ASSAY IS INTENDED TO BE USED AS AN AID IN THE RECOGNITION AND DIAGNOSIS OF ACUTE INFECTIONS AND CHRONIC INFECTIOUS

	CARRIES OF THE HEPATITIS B VIRUS (HBV).,SCRUB TYPHUS (TSUTSUGAMUSHI) IGM & IGG CARD(SCRUB TYPHUS (TSUTSUGAMUSHI) IGM & IGG CARD)-SCRUB TYPHUS (TSUTSUGAMUSHI) IGM &IGG CARD IS A RAPID SOLID PHASE IMMUNE-CHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE AND DIFFERENTIAL DETECTION OF IGM AND IGG ANTIBODIES TO SCRUB TYPHUS IN HUMAN SERUM / PLASMA. THIS TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY AND IS INTENDED AS AN AID IN THE PRESUMPTIVE DIAGNOSIS OF SCRUB TYPHUS INFECTION., ADVANTAGE DENGUE NS1 AG CARD(ADVANTAGE DENGUE NS1 AG CARD)-ADVANTAGE DENGUE NS1 AG CARD IS A RAPID SOLID PHASE IMMUNE-CHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN SERUM / PLASMA. THIS TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY AND IS INTENDED AS AN AID IN THE PRESUMPTIVE DIAGNOSIS OF DENGUE INFECTION., ADVANTAGE MALARIA PAN+PF CARD(ADVANTAGE MALARIA PAN+PF CARD)-ADVANTAGE MALARIA PAN + PF CARD IS A VISUAL, RAPID, SENSITIVE AND ACCURATE SOLID PHASE IMMUNOASSAY AND IS AN AID FOR THE QUALITATIVE DIFFERENTIAL DETECTION OF HRP-2 (HISTIDINE RICH PROTEIN-2) SPECIFIC P. FALCIPARUM AND PLDH BASED PAN SPECIES(P.VIVAX, P.FALCIPARUM,P.OVALE & P. MALARIAE) MALARIA ANTIGENS IN HUMAN WHOLE BLOOD SPECIMENS. THE KIT IS INTENDED FOR PROFESSIONAL USE AND AS A SCREENING TEST AND IS NOT TO BE USED FOR CARRIERS. ALL REACTIVE SAMPLES SHOULD BE CONFIRMED BY A SUPPLEMENTAL ASSAY LIKE MICROSCOPIC EXAMINATION OF THICK SMEAR AND THIN BLOOD FILMS. IT ASSISTS TRAINED USERS IN DETECTING PLASMODIUM SPECIES AND IS FOR IN VITRO DIAGNOSTIC USE ONLY., DIAGNOS HCV BI -DOT(DIAGNOS HCV BI -DOT)-THE 4TH GENERATION DIAGNOS HCV BI-DOT IS A RAPID, VISUAL, SENSITIVE AND QUALITATIVE IN VITRO DIAGNOSTIC TEST FOR THE DETECTION OF ANTIBODIES TO HEPATITIS C VIRUS IN HUMAN SERUM OR PLASMA., ADVANTAGE MALARIA CARD(ADVANTAGE MALARIA CARD)-ADVANTAGE MALARIA CARD IS A VISUAL, RAPID, SENSITIVE AND ACCURATE SOLID PHASE IMMUNOASSAY AND IS AN AID FOR THE QUALITATIVE DIFFERENTIAL DETECTION OF HRP-2(HISTIDINE RICH PROTEIN-2) SPECIFIC P. FALCIPARUM AND PLDH BASED P.VIVAX MALARIA ANTIGENS IN HUMAN WHOLE BLOOD SPECIMENS. THE KIT IS INTENDED FOR PROFESSIONAL USE AND AS A SCREENING TEST AND IS NOT TO BE USED FOR CARRIERS. ALL REACTIVE SAMPLES SHOULD BE CONFIRMED BY A SUPPLEMENTAL ASSAY LIKE MICROSCOPIC EXAMINATION OF THICK SMEAR AND THIN BLOOD FILMS. IT ASSISTS TRAINED USERS IN DETECTING PLASMODIUM SPECIES AND IS FOR IN VITRO DIAGNOSTIC USE ONLY.,HIV 1 & 2

	WESTERN BLOT(HIV 1 & 2 WESTERN BLOT)-HIV 1&2 WESTERN BLOT IS AN IN VITRO QUALITATIVE IMMUNOASSAY FOR THE DETECTION OF ANTIBODIES TO HIV-2 & CONFIRMATORY TEST FOR HIV-1 ANTIBODIES IN HUMAN SERUM / PLASMA. IT IS INTENDED TO BE USED AS A MORE SPECIFIC & SUPPLEMENTAL ASSAY ON SAMPLES FOUND INITIALLY REACTIVE USING ELISA AND OTHER SCREENING TESTS .,HEPALISA(HEPALISA)-HEPALISA IS AN ENZYME IMMUNOASSAY FOR IN-VITRO QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OR PLASMA AND IS USED AS A SCREENING TEST FOR TESTING OF COLLECTED BLOOD PRIOR TO TRANSFUSION.,DENGUE NS1 AG MICROLISA(DENGUE NS1 AG MICROLISA)-DENGUE NS1 AG MICROLISA IS AN ENZYME IMMUNOASSAY FOR IN-VITRO QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN SERUM OR PLASMA AND IS USED AS A SCREENING TEST FOR TESTING OF COLLECTED BLOOD SAMPLES SUSPECTED FOR DENGUE. THE KIT DETECTS ALL FOUR SEROTYPES; DEN1, DEN2, DEN3 AND DEN4 OF DENGUE VIRUS., MALARIA AG MICROLISA(MALARIA AG MICROLISA)-MALARIA AG MICROLISA IS AN IN-VITRO QUALITATIVE ENZYME IMMUNOASSAY FOR DETECTING INFECTION WITH PLASMODIUM SPECIES (P. FALCIPARUM /P.VIVAX/ P.MALARIAE/ P.OVALE) BASED ON PLDH ANTIGEN IN HUMAN BLOOD. IT IS INTENDED FOR SCREENING OF BLOOD DONORS OR OTHER INDIVIDUALS AT RISK FOR MALARIA INFECTION AND FOR CLINICAL DIAGNOSTIC TESTING.,HIV TRI -DOT+AG(HIV TRI -DOT+AG)-THE 4TH GENERATION HIV TRI-DOT + AG TEST IS A RAPID, VISUAL, SENSITIVE AND ACCURATE IMMUNOASSAY FOR THE DETECTION OF HIV-1 P24 ANTIGEN AND HIV-1 & HIV-2 ANTIBODIES (IGM, IGG & IGA) IN HUMAN SERUM OR PLASMA. THE TEST IS A SCREENING TEST FOR HIV AND IS FOR IN VITRO DIAGNOSTIC USE ONLY. IT IS INTENDED FOR SCREENING OF BLOOD DONORS OR OTHERS INDIVIDUAL AT RISK FOR HIV-1 & HIV-2 INFECTION AND FOR CLINICAL DIAGNOSTIC TESTING.,DENGUE NS1 ANTIGEN FP(DENGUE NS1 ANTIGEN FP)-DENGUE NS1 ANTIGEN FP IS A RAPID SOLID PHASE IMMUNE-CHROMATOGRAPHIC TEST FOR THE QUALITATIVE AND DIFFERENTIAL DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN WHOLE BLOOD / SERUM / PLASMA. THIS TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY AND IS INTENDED AS AN AID IN THE EARLIER DIAGNOSIS OF DENGUE INFECTION.,MICROLISA HIV (MICROLISA HIV)-MICROLISA HIV IS AN IN-VITRO QUALITATIVE ENZYME IMMUNOASSAY FOR THE DETECTION OF ANTIBODIES TO HIV-1 AND/OR HIV-2 IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR SCREENING OF BLOOD DONORS OR OTHER INDIVIDUALS AT RISK FOR HIV-1 AND/OR HIV-2 INFECTION AND FOR CLINICAL DIAGNOSTIC TESTING.,COVID 19 (IGM+IGG+IGA) MICROLISA(COVID 19

	(IGM+IGG+IGA) MICROLISA)-COVID 19 (IGM + IGG + IGA) MICROLISA IS DESIGNED FOR IN VITRO QUALITATIVE DETECTION OF COVID IGM, IGG & IGA ANTIBODIES IN HUMAN SERUM OR PLASMA AND IS USED AS A SCREENING TEST FOR TESTING OF COLLECTED BLOOD SAMPLES SUSPECTED FOR COVID-19 INFECTION.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2828	MFG/IVD/2020/000013	1.License Holder Name: BHAT BIO-TECH INDIA PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:ANTI STREPTOLYSIN O (ASO) LATEX SLIDE TEST KIT(BHAT BIO-SCAN)-ASO LATEX SLIDE TEST IS A LATEX AGGLUTINATION TEST FOR QUALITATIVE AND SEMI QUANTITATIVE IN VITRO DETERMINATION OF ANTI-STREPTOLYSIN O IN HUMAN SERUM,GENEASY VIRAL RNA ISOLATION KIT(GENEASY)-GENEASY® VIRAL RNA ISOLATION KIT CAN QUICKLY AND CONVENIENTLY EXTRACT VIRAL RNA FROM SERUM OR PLASMA., MALARIA P.F/P. V3 LINE ANTIGEN TEST(MALERSCAN)-A RAPID CARD TEST TO DETECT HRP II, PLDH ANTIGENS SPECIFIC TO MALARIA PARASITE IN HUMAN WHOLE BLOOD.,COVID 19 RT PCR TEST(BHAT BIOSCAN)-COVID19 RT PCR TEST KIT IS BASED ON MOLECULAR BIOLOGY BASED CONFORMATRY TEST INTENDED FOR INVITRO DIAGNOSIS OF PRESENCE OF COVID ANTIGEN PRESENT IN HUMAN BLOOD/SERUM /PLASMA.,DENGUE NS1 ANTIGEN ELISA TEST(BHAT BIO-SCAN)-ELISA TEST FOR THE DETECTION DENGUE NS1 ANTIGEN IN HUMAN SERUM OR PLASMA,HIV 4TH GEN AG & AB COMBO RAPID CARD TEST(PAREEKSHAK)-HIV- 4 GEN. AG & AB COMBO RAPID CARD TEST KITIS AN IMMUNOCHROMATOGRAPATIC BASED ASSAY FOR THE QUALITATIVEDETECTION OF HIV P24 ANTIGEN & ANTIBODIES TO HIV-1&2 IN HUMANSERUM/PLASMA/WHOLE BLOOD.,ANTI A 1 LECTIN (BHAT BIO-SCAN)-ANTI-A1LECTIN DB IS FOR IN VITRO RECOGNITION OF HUMAN RED CELL SUB GROUPING TO DIFFERENTIATE 'A1' SUBGROUP FROM OTHER WEAKER SUBGROUPS OF 'A' RED BLOOD CELLS LIKE A2,AX,AEM,AEL OR A2B,AXB ETC,ANTI H LECTIN(BHAT BIO-SCAN)-ANTI H LECTIN IS USED FOR THE RECOGNITION OF H ANTIGEN ON THE HUMAN RED BLOOD CELLS. IT IS ESPECIALLY FOR ASSESSING THE H SECRETOR STATUS OF GROUP 'O' INDIVIDUALS AND ALSO IN DIFFERENTIAL GROUPING OF SUBGROUP ALONG WITH THE ANTI-A1 LECTIN,DENGUE NS1 AND IGG+ IGM TEST KIT(BHAT BIO-SCAN)-A RAPID CARD TEST TO DETECT DENGUE NS1 ANTIGEN AND DIFFERENTIAL DETECTION OF IGG/IGM ANTIBODIES IN HUMAN SERUM OR PLASMA,SYPHILIS CARD TEST(BHAT BIO-SCAN)-A RAPID CARD TEST TO DETECT ANTIBODIES TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM OR PLASMA,C-REACTIVE PROTEIN (CRP) LATEX SLIDE TEST KIT (BHAT BIO-SCAN)-CRP LATEX SLIDE TEST IS A LATEX AGGLUTINATION TEST FOR QUALITATIVE AND SEMI QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM,MALARIA P.F ANTIGEN TEST(MALERSCAN)-A RAPID CARD TEST FOR THE QUALITATIVE DETECTION OF HRP II, PLDH ANTIGENS SPECIFIC TO MALARIA PF PARASITE IN HUMAN WHOLE BLOOD. , DENGUE NS1 ANTIGEN CARD TEST(BHAT BIO-SCAN)-A RAPID CARD TEST FOR THE DETECTION DENGUE NS1 ANTIGEN IN HUMAN SERUM

	OR PLASMA,ANTI HUMAN GLOBULIN(BHAT BIO-SCAN)-(COOMB'S ANTISERA) ANTI-HUMAN SERUM IS AN IMPORTANT DIAGNOSTIC AID IN DETERMINING THE PRESENCE OR ABSENCE OF RED BLOOD CELL ANTIBODY OR COMPONENT OF HUMAN COMPLEMENT ON RED BLOOD CELLS. ACCORDINGLY (COOMB'S ANTISERA) ANTI-HUMAN SERUM IS USED FOR COMPATIBILITY TEST, ANTIBODY DETECTION, ANTIBODY IDENTIFICATION, TESTING FOR RHO (D) ANTIGEN (DU TESTS) AND UMBILICAL CORD RED BLOOD CELL TESTING. (COOMB'S ANTI SERA) ANTI- HUMAN SERUM MAY BE USED IN THE DIRECT ANTIGLOBULIN TEST AND IN THE INDIRECT ANTIGLOBULIN TEST TO DETECT ANTIBODIES AND/OR COMPLEMENT ON RED BLOOD CELLS., CHIKUNGUNYA IGG SPOT TEST(BHAT BIO-SCAN)-A RAPID SPOT TEST FOR DETECTION OF IGG ANTIBODIES TO CHIKUNGUNYA IN HUMAN SERUM OR PLASMA,CHIKUNGUNYA IGM SPOT TEST KIT(BHAT BIO-SCAN)-A RAPID SPOT TEST FOR DETECTION OF IGM ANTIBODIES TO CHIKUNGUNYA IN HUMAN SERUM OR PLASMA,MALARIA P.F/PAN (PV, PM, PO)3 LINE ANTIGEN TEST(MALERSCAN)-MALARIA P.F/P.V. 3 LINE TEST ANTIGEN IS AN IMMUNOCHROMATOGRAPHIC BASED ASSAY FOR THE QUALITATIVE DETECTION OF PLASMODIUM LACTATE DEHYDROGENASE (PLDH) SPECIFIC TO MALARIA P.V., P.M., P.O. AND HRP II ANTIGENS SPECIFIC TO P.F. IN HUMAN WHOLE BLOOD.,TYPHO (WIDAL) SLIDE TEST KIT(BHAT BIO-SCAN)-TYPHO (WIDAL) TEST IS A RAPID SLIDE TEST FOR QUALITATIVE AND SEMI QUANTITATIVE, IN VITRO DETERMINATION OF SPECIFIC ANTIBODIES PRESENT IN SERUM AGAINST SALMONELLA TYPHI “O”, “H” AND SALMONELLA PARATYPHI A(H) & B(H) ANTIGEN.,RPR TEST (RAPID PLASMA REAGIN) (BHAT BIO-SCAN)-RPR (RAPID PLASMA REAGIN) IS A RAPID NON – TREPONEMAL TEST FOR QUALITATIVE AND SEMI QUANTITATIVE IN VITRO DETERMINATION OF REAGIN ANTIBODIES IN SERUM OR PLASMA FOR SYPHILIS USING MODIFIED CARDIOLIPIN ANTIGEN, TROPONIN-I CARD TEST(HEARTSCAN)-HEARTSCAN TROPONIN-I CARD TEST IS AN IMMUNOCHROMATOGRAPHIC (RAPID) TEST FOR THE QUALITATIVE DETECTION OF TROPONIN-I IN HUMAN SERUM OR PLASMA.

2829	MFG/IVD/2020/000014	1.License Holder Name: M/S.TRANSASIA BIO-MEDICALS LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:COVID-19 REAL TIME PCR DETECTION KIT(ERBAMDX COVID-19 RT-PCR KIT)-DETECTION OF PRESENCE OF SARS-COV-2 VIRUS IN THE PATIENT SAMPLES ,HIV 1+2 TEST CARD(ERBAQIK HIV 1+2 TEST CARD)-ERBAQIK HIV 1+2 TEST IS A QUALITATIVE SCREENING, IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF ANTIBODIES SPECIFIC TO HIV-1 AND HIV-2 IN HUMAN SERUM/PLASMA OR WHOLE BLOOD.,HBSAG TEST CARD(ERBAQIK HBSAG TEST CARD)-"ERBAQIK HBSAG TEST CARD IS A QUALITATIVE SCREENING, IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY DESIGNED FOR QUALITATIVE DETERMINATION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OR PLASMA. " ,HCV TEST CARD(ERBAQIK HCV TEST CARD)-ERBAQIK HCV TEST IS A QUALITATIVE SCREENING, IN-VITRO DIAGNOSTICS IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF ANTIBODIES SPECIFIC TO HCV IN HUMAN SERUM/PLASMA OR WHOLE BLOOD.,SYPHILIS TEST CARD(ERBAQIK SYPHILIS TEST CARD)-ERBAQIK SYPHILIS TEST IS A QUYALITATIVE SCREENING, IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY DESIGNED FOR QUALITATIVE DETERMINATION OF ANTIBODIES (IGG, IGM AND IGA) AGAINST TREPONEMA PALLIDUM (TP) IN HUMAN SERUM/PLASMA AND WHOLE BLOOD ,ERBA LISA® COVID-19 IGG(ERBA LISA)-CORONAVIRUS COVID-19 IGG ANTIBODY TEST KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF HUMAN ANTI–COVID 19 IGG ANTIBODY IN HUMAN SERUM WITH CORONAVIRUS INFECTION.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

2830	MFG/IVD/2020/000015	1.License Holder Name: ASPEN LABORATORIES PRIVATE LIMITED 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:IMMUNOASSAY D-DIMER KIT-IMMUNOASSAY D-DIMER KIT IS INTENDED FOR QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN WHOLE BLOOD AND PLASMA.,UREA BERTHELOT REAGENT KIT-KIT FOR ESTIMATION OF UREA,GLUCOSE STRIPS KIT-IT IS A DEVICE TO MEASURE THE CONCENTRATION OF GLUCOSE IN BLOOD.,AMYLASE REAGENT KIT-KIT FOR ESTIMATION OF AMYLASE,IMMUNOASSAY MICRO ALBUMIN KIT-IMMUNOASSAY MICRO ALBUMIN KIT IS INTENDER FOR QUANTITATIVE DETERMINATION OF MICRO ALBUMIN IN HUMAN URINE.,GAMMA GT REAGENT KIT-KIT FOR ESTIMATION OF GAMMA GT, LH CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM OR PLASMA.,CHEMISTRY CALIBRATOR-KIT FOR CALIBRATION OF VARIOUS BIOCHEMISTRY PARAMETERS,FN DYE-FN DYE PARTICIPATES IN THE MEASUREMENT OF NRBC-RELATED PARAMETERS TOGETHER WITH LN LYSE USING HEMATOLOGY ANALYSER.,TSH ELISA KIT-TEST KIT FOR DETECTION OF TSH,DS DILUENT-DS DILUENT PARTICIPATES IN MEASUREMENT OF PARAMETERS RELATED TO RBC, PLT, WBC, RET AND NRBC USING HEMATOLOGY ANALYZER.,DENGUE IGG ELISA KIT-TEST KIT FOR DETECTION OF DENGUE IGG ANTIBODIES,ANTI-TG CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTIBODY TO THYROGLOBULIN (ANTI-TG) IN HUMAN SERUM OR PLASMA.,CSF/MICRO PROTEIN REAGENT KIT-KIT FOR ESTIMATION OF CSF/MICRO PROTEIN,LD LYSE-LD LYSE PARTICIPATES IN WBC DIFFERENTIATION IN THE DIFF CHANNEL TOGETHER WITH FD DYE USING HEMATOLOGY ANALYSER.,DIRECT LDL-CHOLESTEROL REAGENT KIT-KIT FOR ESTIMATION OF LDL CHOLESTEROL,FR DYE-FR DYE PARTICIPATES IN THE MEASUREMENT OF MEASUREMENT OF RET-RELATED PARAMETERS TOGETHER WITH DS DILUENT USING HEMATOLOGY ANALYSER.,AST (SGOT) REAGENT KIT-TEST KIT FOR ESTIMATION OF AST (SGOT),ANTI-TG CALIBRATORS-ANTI-TG CALIBRATORS (ANTI-TG CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE ANTIBODY TO THYROGLOBULIN (ANTI-TG) ASSAY.,DIRECT HDL-CHOLESTEROL REAGENT KIT-KIT FOR ESTIMATION OF HDL CHOLESTEROL,FSH CALIBRATORS-FSH CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE FOLLICLE STIMULATING HORMONE (FSH) ASSAY.,LYSE-REAGENT FOR USE IN HEMATOLOGY ANALYZER,PROLACTIN CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN HUMAN SERUM OR PLASMA,LEO (I) LYSE-REAGENT FOR USE IN HEMATOLOGY

	ANALYZER,PROLACTIN CALIBRATORS-PROLACTIN CALIBRATORS (PRL CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE PROLACTIN (PRL) ASSAY.,PROLACTIN ELISA KIT-TEST KIT FOR DETECTION OF PROLACTIN,FREE T4 CALIBRATORS-FREE T4 CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE FREE THYROXINE (FT4) ASSAY.,DENGUE IGM ELISA KIT-TEST KIT FOR DETECTION OF DENGUE IGM ANTIBODIES,FERRITIN CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FERRITIN (FERR) IN HUMAN SERUM OR PLASMA, LDH REAGENT KIT-KIT FOR ESTIMATION OF LDH,FOLATE CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FOLATE IN HUMAN SERUM, PLASMA OR RED BLOOD CELLS.,URINALYSIS CONTROL – POSITIVE-KIT FOR QUALITY CONTROL OF URINE TEST STRIPS,CORTISOL CALIBRATORS-CORTISOL CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE CORTISOL ASSAY.,PHOSPHORUS REAGENT KIT-KIT FOR ESTIMATION OF PHOSPHORUS,T4 CALIBRATORS-T4 CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE TOTAL THYROXINE (T4) ASSAY.,TRIGLYCERIDE REAGENT KIT-KIT FOR ESTIMATION OF TRIGLYCERIDE,CORTISOL CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM, PLASMA OR URINE.,LEO (II) LYSE-REAGENT FOR USE IN HEMATOLOGY ANALYZER, THYROID FUNCTION MULTI CONTROL (H)-THYROID FUNCTION MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF THYROID FUNCTION ANALYTES.,MAGNESIUM REAGENT KIT-KIT FOR ESTIMATION OF MAGNESIUM,ANTI-THYROID ANTIBODIES CONTROL (L)-ANTI-THYROID ANTIBODIES CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF ANTI-THYROID ANTIBODIES ANALYTES.,DIRECT BILIRUBIN-KIT FOR ESTIMATION OF DIRECT BILIRUBIN,ESTRADIOL CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL (E2) IN HUMAN SERUM.,SODIUM REAGENT KIT-KIT FOR ESTIMATION OF SODIUM,PROGESTERONE CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE (PROG) IN HUMAN SERUM.,GLYCOHEMOGLOBIN (HBA1C) REAGENT KIT-KIT FOR ESTIMATION OF GLYCOHEMOGLOBIN (HBA1C),INSULIN CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM OR PLASMA.,

	HEMATOLOGY CONTROL KIT-TEST KIT FOR QUALITY CONTROL OF HEMATOLOGY ANALYZERS,FOLATE CALIBRATORS-FOLATE CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE FOLATE ASSAY.,LIPASE REAGENT KIT-KIT FOR ESTIMATION OF LIPASE,FERRITIN CALIBRATORS-FERRITIN CALIBRATORS (FERR CAL) ARE INTENDED TO CALIBRATE THE QUANTITATIVE FERRITIN (FERR) ASSAY.,TOTAL PROTEIN REAGENT KIT-KIT FOR ESTIMATION OF TOTAL PROTEIN,FSH CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN SERUM OR PLASMA., BILIRUBIN (DIRECT & TOTAL)-KIT FOR ESTIMATION OF TOTAL AND DIRECT BILIRUBIN,VITAMIN B12 CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 IN HUMAN SERUM OR PLASMA.,TOTAL BILIRUBIN-KIT FOR ESTIMATION OF TOTAL BILIRUBIN,PCT CALIBRATORS-PCT CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE PROCALCITONIN ASSAY.,TESTOSTERONE ELISA KIT-TEST KIT FOR DETECTION OF TESTOSTERONE,SARS-COV-2 SURROGATE VIRUS NEUTRALIZATION ELISA KIT-SARS-COV-2 SURROGATE VIRUS NEUTRALIZATION TEST (SVNT) KIT CAN DETECT CIRCULATING NEUTRALIZING ANTIBODIES AGAINST SARS-COV-2 THAT BLOCK THE INTERACTION BETWEEN THE RECEPTOR BINDING DOMAIN OF THE VIRAL SPIKE GLYCOPROTEIN (RBD) WITH THE ACE2 CELL SURFACE RECEPTOR. THE ASSAY DETECTS ANY ANTIBODIES IN SERUM AND PLASMA THAT NEUTRALIZE THE RBDACE2 INTERACTION.,RINSE (CLEANER)-REAGENT FOR USE IN HEMATOLOGY ANALYZER, IMMUNOASSAY INTERLEUKIN-6 (IL6) KIT-IMMUNOASSAY INTERLEUKIN-6 (IL-6) KIT IS USED FOR QUANTITATIVE DETERMINATION OF INTERLEUKIN-6 (IL-6) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA.,HBA1C CALIBRATOR-KIT FOR CALIBRATION OF HBA1C PARAMETER,LB LYSE-LB LYSE PARTICIPATES IN WBC COUNTING AND MEASUREMENT OF BASOPHIL-RELATED PARAMETERS USING HEMATOLOGY ANALYSER.,CK-MB REAGENT KIT-KIT FOR ESTIMATION OF CREATINE KINASE (MB),FREE T3 CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) IN HUMAN SERUM.,FSH ELISA KIT-TEST KIT FOR DETECTION OF FOLLICLE STIMULATING HORMONE (FSH),FD DYE-FD DYE PARTICIPATES IN WBC DIFFERENTIATION IN THE DIFF CHANNEL TOGETHER WITH LD LYSE USING HEMATOLOGY ANALYSER,UREA/BUN REAGENT KIT-KIT FOR ESTIMATION OF UREA/BUN,LN LYSE-LN LYSE PARTICIPATES IN THE MEASUREMENT OF NRBC-RELATED PARAMETERS TOGETHER WITH FN DYE USING HEMATOLOGY ANALYSER,PROBE CLEANER-REAGENT FOR USE IN HEMATOLOGY ANALYZER,HEMOGLOBIN CUVETTES KIT-

	THE HEMOGLOBIN CUVETTES KIT IS USED FOR QUANTITATIVELY MEASURING HEMOGLOBIN IN HUMAN WHOLE BLOOD.,LEPTOSPIRA RAPID CARD TEST-KIT FOR DETECTION OF LEPTOSPIRA,LIPID PANEL TEST KIT-LIPID PANEL TEST KIT IS USED TO MEASURE THE LIPID CONCENTRATION IN WHOLE BLOOD, PLASMA AND SERUM.,TOTAL IGE ELISA KIT-FOR DETECTION OF TOTAL IGE,PCT CONTROL (L)-PCT CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF PCT).,PROGESTERONE ELISA KIT-TEST KIT FOR DETECTION OF PROGESTERONE,LH CALIBRATORS-LH CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE LUTEINIZING HORMONE (LH) ASSAY.,EZ CLEANER-REAGENT FOR USE IN HEMATOLOGY ANALYZER,METABOLIC MULTI CONTROL (H)-METABOLIC MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF PTH, CT, 25-OH-VITAMIN D TOTAL, VB12, FOLATE, FERRITIN ANALYTES.,POTASSIUM REAGENT KIT-KIT FOR ESTIMATION OF POTASSIUM,T4 CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE (T4) LEVELS IN HUMAN SERUM OR PLASMA.,C-REACTIVE PROTEIN (CRP) TEST-KIT FOR DETECTION OF C-REACTIVE PROTEIN,HEMOGLOBIN STRIPS KIT-THE HEMOGLOBIN STRIPS KIT IS USED FOR QUANTITATIVELY MEASURING HEMOGLOBIN IN HUMAN WHOLE BLOOD.,AMMONIA REAGENT KIT-KIT FOR ESTIMATION OF AMMONIA,REPRODUCTIVE MULTI CONTROL (L)-REPRODUCTIVE MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF REPRODUCTIVE HORMONE ANALYTES., CHEMISTRY CONTROL – ABNORMAL-KIT FOR QUALITY CONTROL OF VARIOUS BIOCHEMISTRY PARAMETERS,REPRODUCTIVE MULTI CONTROL (H)-REPRODUCTIVE MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF REPRODUCTIVE HORMONE ANALYTES.,HDL/LDL CALIBRATOR-KIT FOR CALIBRATION OF HDL/LDL,ANTI-TPO CALIBRATORS-ANTI-TPO CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE ANTIBODIES TO THYROID PEROXIDASE (ANTI-TPO) ASSAY.,CALCIUM CHLORIDE REAGENT-AUXILIARY REAGENT FOR LABORATORY USE, ESTRADIOL CALIBRATORS-ESTRADIOL CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE ESTRADIOL (E2) ASSAY.,

	ALKALINE PHOSPHATASE REAGENT KIT-KIT FOR ESTIMATION OF ALKALINE PHOSPHATASE,TSH CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH) IN HUMAN SERUM., CHOLINE-ESTERASE REAGENT KIT-KIT FOR ESTIMATION OF CHOLINE ESTERASE,ANTI-TPO CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF ANTI-TPO IN HUMAN SERUM OR PLASMA.,GLUCOSE REAGENT KIT-KIT FOR ESTIMATION OF GLUCOSE,PCT CONTROL (H)-PCT CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF PCT).,LUETEINIZING HORMONE ELISA KIT-TEST KIT FOR DETECTION OF LUETEINIZING HORMONE,THYROID FUNCTION MULTI CONTROL (L) -THYROID FUNCTION MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF THYROID FUNCTION ANALYTES.,ULTRA TSH (UTSH) ELISA KIT-TEST KIT FOR DETECTION OF TSH,METABOLIC MULTI CONTROL (L)-METABOLIC MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF PTH, CT, 25-OH-VITAMIN D TOTAL, VB12, FOLATE, FERRITIN ANALYTES.,DILUENT-REAGENT FOR USE IN HEMATOLOGY ANALYZER,DR DILUENT-DR DILUENT PARTICIPATES IN THE MEASUREMENT OF RET-RELATED PARAMETERS TOGETHER WITH FR DYE USING HEMATOLOGY ANALYZER.,URINALYSIS CONTROL – NEGATIVE-KIT FOR QUALITY CONTROL OF URINE TEST STRIPS, VITAMIN B12 CALIBRATORS-VITAMIN B12 CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE VB12 ASSAY.,HDL-CHOLESTEROL (PRECIPITATING) REAGENT KIT-KIT FOR ESTIMATION OF HDL CHOLESTEROL,FREE T3 CALIBRATORS-FREE T3 CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE FREE TRIIODOTHYRONINE (FT3) ASSAY.,HEMOGLOBIN REAGENT KIT-KIT FOR ESTIMATION OF HEMOGLOBIN,TESTOSTERONE CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE (TESTO) IN HUMAN SERUM AND PLASMA.,CREATINE KINASE (CK-NAC) REAGENT KIT-KIT FOR ESTIMATION OF CREATINE KINASE (NAC),IMMUNOASSAY MULTI CONTROL (L)-IMMUNOASSAY MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF

	IMMUNOASSAY MULTI ANALYTES.,URINE TEST STRIPS (1 PARAMETER TO MULTIPARAMETER)-KIT FOR DETECTION OF VARIOUS COMBINATION OF URINE ANALYSIS PARAMETERS E.G. UROBILINOGEN, BILIRUBIN, KETONE, BLOOD, PROTEIN, NITRITE, LEUKOCYTES, GLUCOSE, SPECIFIC GRAVITY, PH, ASCORBIC ACID, MICRO ALBUMIN, CALCIUM, CREATININE ETC. IN URINE,HCG CALIBRATORS-TOTAL HCG CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE TOTAL HUMAN CHORIONIC GONADOTROPHIN (TOTAL HCG) ASSAY.,MYOGLOBIN RAPID CARD TEST-KIT FOR DETECTION OF MYOGLOBIN,PROGESTERONE CALIBRATORS-PROGESTERONE CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE PROGESTERONE (PROG) ASSAY.,T3 ELISA KIT-TEST KIT FOR DETECTION OF T3,IMMUNOASSAY MULTI CONTROL (H)-IMMUNOASSAY MULTI CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF IMMUNOASSAY MULTI ANALYTES.,CHOLESTEROL REAGENT KIT-KIT FOR ESTIMATION OF CHOLESTEROL,T3 CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE (T3) IN HUMAN SERUM.,CK-MB RAPID CARD TEST-KIT FOR DETECTION OF CK-MB,ANTI-THYROID ANTIBODIES CONTROL (H)-ANTI-THYROID ANTIBODIES CONTROL IS USED FOR QUALITY CONTROL BY MONITORING THE ACCURACY AND PRECISION OF IMMUNOASSAY ANALYZER AND TEST ABILITY OF CLINICAL LABORATORY IN THE QUANTITATIVE MEASUREMENT OF ANTI-THYROID ANTIBODIES ANALYTES.,URIC ACID REAGENT KIT-KIT FOR ESTIMATION OF URIC ACID,T3 CALIBRATORS-T3 CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE TOTAL TRIIODOTHYRONINE (T3) ASSAY.,HGH ELISA KIT-TEST KIT FOR DETECTION OF HUMAN GROWTH HORMONE,TSH CALIBRATORS-TSH CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE THYROID-STIMULATING HORMONE (TSH) ASSAY., DENGUE/CHIKUNGUNYA RAPID COMBO CARD TEST-KIT FOR DETECTION OF DENGUE AND CHIKUNGUNYA,PCT CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF PROCALCITONINPCT IN HUMAN SERUM OR PLASMA.,G6PDH CALIBRATOR-KIT FOR CALIBRATION OF G6PDH PARAMETER,FREE T4 CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM OR PLASMA.,CREATININE REAGENT KIT-KIT FOR ESTIMATION OF CREATININE,INSULIN CALIBRATORS-INSULIN CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE INSULIN ASSAY.,SEMEN FRUCTOSE REAGENT

	KIT-KIT FOR ESTIMATION OF FRUCTOSE IN SEMEN,HCG CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF TOTAL HUMAN CHORIONIC GONADOTROPIN (TOTAL HCG) IN HUMAN SERUM.,LH RAPID TEST-KIT FOR ESTIMATION OF LUTEINIZING HORMONE (LH),VITAMIN D CLIA-CHEMILUMINESCENT IMMUNOASSAY (CLIA) FOR THE QUANTITATIVE DETERMINATION OF VITAMIN D IN HUMAN SERUM OR PLASMA. , RHEUMATOID FACTOR (RF) TEST-KIT FOR DETECTION OF RHEUMATOID FACTOR (RF),VITAMIN D CALIBRATORS-VITAMIN D CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE VITAMIN D ASSAY.,ACID PHOSPHATASE REAGENT KIT-KIT FOR ESTIMATION OF ACID PHOSPHATASE,TESTOSTERONE CALIBRATORS-TESTOSTERONE CALIBRATORS ARE INTENDED TO CALIBRATE THE QUANTITATIVE TESTOSTERONE (TESTO) ASSAY.,KALA AZAR RAPID CARD TEST-KIT FOR DETECTION OF KALA AZAR,H. PYLORI RAPID CARD TEST-KIT FOR DETECTION OF H. PYLORI,LBA LYSE-REAGENT FOR USE IN HEMATOLOGY ANALYZER,ANTI STREPTOLYSIN -O (ASO) TEST -KIT FOR DETECTION OF ASO ,DENGUE IGG/IGM ELISA KIT-TEST KIT FOR DETECTION OF DENGUE IGG/IGM ANTIBODIES,TYPHOID RAPID CARD TEST-KIT FOR DETECTION OF TYPHOID INFECTION, ALBUMIN REAGENT KIT-KIT FOR ESTIMATION OF ALBUMIN,WIDAL TEST KIT-KIT FOR DETECTION OF S.TYPHI / PARATYPHI ANTIBODY , DENGUE IGG/IGM ANTIBODY CARD TEST-KIT FOR DETECTION OF DENGUE IGG/IGM ANTIBODIES,G6PDH CONTROL KIT-KIT FOR QUALITY CONTROL OF G6PDH PARAMETER,CHLORIDE REAGENT KIT-KIT FOR ESTIMATION OF CHLORIDE,FREE T4 ELISA KIT-TEST KIT FOR DETECTION OF FREE T4,ALT (SGPT) REAGENT KIT-KIT FOR ESTIMATION OF ALT (SGPT),CHEMISTRY CONTROL – NORMAL-KIT FOR QUALITY CONTROL OF VARIOUS BIOCHEMISTRY PARAMETERS, FILARIA RAPID CARD TEST-KIT FOR DETECTION OF FILARIA,HBA1C CONTROL KIT-KIT FOR QUALITY CONTROL OF HBA1C PARAMETER,T4 ELISA KIT-TEST KIT FOR DETECTION OF T4,IRON / TIBC REAGENT KIT-KIT FOR ESTIMATION OF IRON / TIBC,LH LYSE-REAGENT FOR USE IN HEMATOLOGY ANALYZER,FREE T3 ELISA KIT-TEST KIT FOR DETECTION OF FREE T3,RF RAPID CARD TEST-KIT FOR DETECTION OF RHEUMATOID FACTOR (RF),CHIKUNGUNYA RAPID CARD TEST-KIT FOR DETECTION OF CHIKUNGUNYA,CALCIUM REGENT KIT-KIT FOR ESTIMATION OF CALCIUM,HCG RAPID TEST-TEST KIT FOR THE DETECTION OF PREGNANCY IN URINE

2831	MFG/IVD/2020/000016	1.License Holder Name: BIOLINE DIAGNOSTICS LLP 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:WIDAL ANTIGEN TEST KIT (FIRST VIEW)-FIRST VIEW WIDAL ANTIGEN TEST KIT DETECTS THE PRESENCE OF SALMONELLA GENUS WHICH CAUSES ENTERIC OR TYPHOID FEVER BY USING SLIDE QUALITATIVE AGGLUTINATION TEST. ,SYPHILIS RAPID TEST DEVICE(FIRST VIEW)-FIRST VIEW SYPHILIS IS A RAPID SELF-PERFORMING, QUALITATIVE DETERMINATION OF SYPHILIS IN HUMAN BLOOD AS AN AID FOR IN VITRO DIAGNOSIS.,MALARIA PF/PV ANTIGEN RAPID TEST DEVICE (FIRST VIEW)-FIRSTVIEW MALARIA PF/PV ANTIGEN TEST IS A RAPID SELF-PERFORMING, QUALITATIVE DETERMINATION OF MALARIA ANTIGEN IN HUMAN BLOOD AS AN AID FOR IN VITRO DIAGNOSIS OF MALARIA INFECTION.,HBSAG RAPID TEST DEVICE(FIRST VIEW)-HBSAG RAPID TEST DEVICE IS RAPID CHROMATOGRAPHY IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN IN SERUM AND PLASMA.,C- REACTIVE PROTEIN (CRP) LATEX KIT(FIRST VIEW)-C- REACTIVE PROTEIN (CRP) LATEX KIT IS USED TO MEASURE THE CRP IN HUMAN SERUM QUALITATIVELY AND QUANTITATIVELY.,HCV RAPID TEST DEVICE(FIRST VIEW)-THE HCV RAPID DEVICE KIT IS A RAPID AND CONVENIENT IMMUNE CHROMATOGRAPHIC IN VITRO ASSAY FOR DETECTION OF HCV ANTIBODY IN HUMAN SERUM, PLASMA. THE TEST PROVIDES A VISUAL, QUALITATIVE RESULT, AND ALL POSITIVE SPECIMENS ARE ADVISED TO BE CONFIRMED WITH OTHER QUALIFIED ASSAYS., DENGUE NS1 ANTIGEN RAPID TEST DEVICE(FIRST VIEW)-THE DENGUE NS1ANTIGEN RAPID TEST DEVICE IS A RAPID AND CONVENIENT IMMUNOCHROMATOGRAPHIC IN VITRO ASSAY FOR DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN SERUM, PLASMA. THE TEST PROVIDES A VISUAL, QUALITATIVE RESULT, AND ALL POSITIVE SPECIMENS ARE ADVISED TO BE CONFIRMED WITH OTHER QUALIFIED ASSAYS.,DENGUE IGG/IGM & NS1 ANTIGEN COMBO RAPID TEST DEVICE(FIRST VIEW)-DENGUE IGG/IGM & NS1 ANTIGEN COMBO RAPID TEST DEVICE IS AN IN VITRO QUALITATIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE RAPID DETECTION OF DENGUE NS1 ANTIGENS AND ANTI-DENGUE IGG/IGM ANTIBODIES IN HUMAN BLOOD, SERUM AND PLASMA SPECIMENS SIMULTANEOUSLY. ,TROPONIN I RAPID TEST DEVICE(FIRST VIEW)-THE TROPONIN I RAPID TEST DEVICE IS A RAPID ONE-STEP CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HUMAN CARDIAC TROPONIN I IN WHOLE BLOOD, SERUM OR PLASMA AS AN AID IN THE DETERMINATION OF MYOCARDIAL INFARCTION (MI). , MALARIA PF/PAN ANTIGEN RAPID TEST DEVICE(FIRST VIEW)-FIRST VIEW MALARIA PF/ PAN ANTIGEN TEST IS A RAPID SELF-

	PERFORMING, QUALITATIVE DETERMINATION OF MALARIA ANTIGEN IN HUMAN BLOOD AS AN AID FOR IN VITRO DIAGNOSIS OF MALARIA INFECTION.,TYPHOID ANTIGEN RAPID TEST DEVICE(FIRST VIEW)-FIRST VIEW TYPHOID ANTIGEN RAPID TEST IS A RAPID SELF-PERFORMING, QUALITATIVE DETERMINATION OF TYPHOID ANTIGEN IN HUMAN SERUM AS AN AID FOR IN VITRO DIAGNOSIS OF MALARIA INFECTION.,C- REACTIVE PROTEIN (CRP) TURBIDIMETRIC TEST KIT (FIRST VIEW)-C-REACTIVE PROTEIN TURBIDIMETRIC TEST KIT IS USED TO MEASURE THE CRP IN HUMAN SERUM.

2832	MFG/IVD/2020/000017	1.License Holder Name: SD BIOSENSOR HEALTHCARE PVT. LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:STANDARD Q FOB TEST (NA)-IT IS A RAPID, QUALITATIVE IMMUNOASSAY TO DETECT HEMOGLOBIN IN HUMAN FECAL SPECIMENS.,ONE STEP RAPID TEST FOR THE DETECTION OF HCG IN URINE.(STANDARD Q HCG (RAPID), ULTRA HCG (RAPID))-IT IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HUMAN CHORIONIC GONADOTROPIN (HCG) HORMONE IN URINE TO AID IN THE EARLY DETECTION OF PREGNANCY.,STANDARD F VITAMIN D(NA) -IT IS AN IN VITRO DIAGNOSTIC USE TO MEASURES THE VITAMIN D IN THE HUMAN SERUM/PLASMA SPECIMEN.,BLOOD GLUCOSE TEST STRIP(SD CHECK GOLD BLOOD GLUCOSE TEST STRIP)-IT IS DESIGNED FOR SELF-TESTING BLOOD GLUCOSE USING THE FRESH CAPILLARY WHOLE BLOOD FROM THE FINGER PRICK. ,STANDARD F IFOB FIA(NA)-IT IS A FECAL IMMUNOCHEMICAL TEST (FIT) FOR DETECTION AND QUANTIFICATION OF HEMOGLOBIN (HB) IN FECAL SPECIMEN.,BLOOD GLUCOSE TEST STRIP(STANDARD MENTOR BLOOD GLUCOSE TEST STRIP)-IT IS DESIGNED FOR SELF-TESTING BLOOD GLUCOSE USING THE FRESH CAPILLARY WHOLE BLOOD FROM THE FINGER PRICK, PALM, FOREARM OR UPPER ARM.,STANDARD Q H. PYLORI AB(NA)-IT IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES TO H. PYLORI PRESENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,TSH TEST (STANDARD F TSH FIA)-IT IS AN IN VITRO DIAGNOSTIC USE TO MEASURES THE TSH IN HUMAN SERUM.,HBA1C TEST(STANDARD F HBA1C)-STANDARD F HBA1C IS AN IN VITRO DIAGNOSTIC SYSTEM FOR QUANTITATIVE MEASUREMENT OF HBA1C IN HUMAN CAPILLARY OR VENOUS WHOLE BLOOD.,BLOOD GLUCOSE TEST STRIP (STANDARD GLUCONAVII GDH BLOOD GLUCOSE TEST STRIP)-IT IS USED FOR QUANTITATIVE DETERMINATION OF GLUCOSE IN BLOOD., ONE STEP RAPID TEST FOR THE DETECTION OF HCG IN URINE. (STANDARD Q HCG (MIDSTREAM), ULTRA HCG (MIDSTREAM))-IT IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HUMAN CHORIONIC GONADOTROPIN (HCG) HORMONE IN URINE TO AID IN THE EARLY DETECTION OF PREGNANCY,ONE STEP RAPID TEST KIT FOR THE DETECTION OF IGM/IGG ANTIBODIES AGAINST LEPTOSPIRA BACTERIA(STANDARD Q LEPTOSPIRA IGM/IGG TEST, ULTRA LEPTOSPIRA IGM/IGG TEST)-IT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF IGM/IGG ANTIBODIES AGAINST LEPTOSPIRA BACTERIA IN HUMAN SERUM, PLASMA OR WHOLE BLOOD SAMPLES.,ONE STEP RAPID TEST KIT FOR THE DETECTION OF IGM/IGG ANTIBODIES TO O. TSUTSUGAMUSHI(STANDARD Q TSUTSUGAMUSHI IGM/IGG TEST,

		ULTRA TSUTSUGAMUSHI IGM/IGG TEST)-IT IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE SIMULTANEOUS DETECTION OF IGM/IGG ANTIBODIES AGAINST ORIENTIA TSUTSUGAMUSHI (SCRUB TYPHUS) PRESENT IN SERUM/PLASMA OR WHOLE BLOOD.,ONE STEP RAPID TEST KIT FOR THE QUALITATIVE DETECTION AND DIFFERENTIATION OF ANTI-SALMONELLA TYPHI (S. TYPHI) AND PARATYPHI IGG AND IGM(STANDARD Q S. TYPHI IGM/IGG, ULTRA S. TYPHI IGM/IGG)-IT IS A LATERAL FLOW IMMUNOASSAY FOR THE QUALITATIVE DETECTION AND DIFFERENTIATION OF ANTI-SALMONELLA TYPHI (S. TYPHI) AND PARATYPHI IGG AND IGM IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,BLOOD GLUCOSE TEST STRIP(SD CODE FREE BLOOD GLUCOSE TEST STRIP)-IT IS DESIGNED FOR SELF TESTING OF BLOOD GLUCOSE LEVEL USING FRESH CAPILLARY WHOLE BLOOD FROM FINGER TRICK, PALM, FOREARM OR UPPER ARM.,ONE STEP RAPID TEST KIT FOR DIFFERENTIAL DETECTION OF CHIKUNGUNYA IGM & IGG AB(STANDARD Q CHIKUNGUNYA IGM/IGG, ULTRA CHIKUNGUNYA IGM/IGG)-IT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF IGM/IGG ANTIBODIES AGAINST CHIKUNGUNYA VIRUS IN HUMAN SERUM, PLASMA OR WHOLE BLOOD SPECIMEN.,IGM ANTIBODY DETECTION ELISA KIT(STANDARD E DENGUE IGM CAPTURE ELISA, ULTRA DENGUE IGM CAPTURE ELISA)-IT IS AN ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE DETECTION OF ANTI-DENGUE IGG IN HUMAN SERUM OR PLASMA,IGG ANTIBODY DETECTION ELISA KIT (STANDARD E DENGUE IGG CAPTURE ELISA, ULTRA DENGUE IGG CAPTURE ELISA)-IT IS AN ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE DETECTION OF ANTI-DENGUE IGG IN HUMAN SERUM OR PLASMA,ONE STEP DENGUE IGM-IGG RAPID TEST(STANDARD Q DENGUE IGM-IGG, ULTRA DENGUE IGM-IGG)-IT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION IGM/IGG ANTIBODIES AGAINST DENGUE VIRUS IN HUMAN SERUM, PLASMA OR WHOLE BLOOD SPECIMEN.
2833	MFG/IVD/2020/000018	1.License Holder Name: BIOSENSE TECHNOLOGIES PVT.LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:HEMOGLOBIN METER WITH HBCHECK CONSUMABLE (A REAGENT LESS SPECIMEN RECEPTICLE)(HBCHECK)-HBCHEK IS INTENDED TO BE USED AS HEMOGLOBIN MEASUREMENT SYSTEM FOR ANEMIA DETECTION. , HEMOGLOBIN METER WITH HBCHECK CONSUMABLE (A REAGENT LESS SPECIMEN RECEPTICLE)(HBCHECK)-HBCHEK IS INTENDED TO BE USED AS HEMOGLOBIN MEASUREMENT SYSTEM FOR ANEMIA DETECTION.

2834	MFG/IVD/2020/000019	1.License Holder Name: ROBONIK INDIA PRIVATE LIMITED 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:GAZELLE HB-VARIANT DEVICE(GAZELLE)-GAZELLE IS AN IN VITRO DIAGNOSTIC DEVICE INTENDED FOR QUANTITATIVE MEASUREMENT OF HEMOGLOBIN A, F, S, A2/C/E USING CELLULOSE ACETATE ELECTROPHORESIS. THE TEST ALSO PROVIDES AN INTERPRETATION OF THE RESULTS. THE DEVICE IS FOR HEALTHCARE PROFESSIONAL USE IN A LAB SETTING, AND REQUIRES HUMAN VENOUS OR CAPILLARY WHOLE BLOOD. SOME HEMOGLOBIN'S WITH SIMILAR ELECTROPHORETIC MOBILITIES, AND THOSE OCCURRING IN SMALL PROPORTIONS MUST BE DETECTED BY OTHER METHODOLOGIES.,HB VARIANT TEST MULTIPACK(GAZELLE)-GAZELLE™ HB VARIANT IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR QUANTITATIVE MEASUREMENT OF HEMOGLOBIN A, F, S, A2/ C/E USING CELLULOSE ACETATE ELECTROPHORESIS. IT USES THE HB VARIANT TEST MULTIPACK, INCLUDING CARTRIDGES. THE TEST ALSO PROVIDES AN INTERPRETATION OF THE RESULTS. THE TEST IS FOR PROFESSIONAL USE IN A LAB SETTING AND REQUIRES HUMAN WHOLE BLOOD FROM PATIENTS

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2835	MFG/IVD/2020/000020	1.License Holder Name: GENOMIX CARL PVT LTD 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:GENOMIX CALPROTECTIN PI RAPID TEST KIT-FOR THE DETECTION OF CALPROTECTIN IN HUMAN FECES SPECIMEN WHICH MIGHT BE USEFUL FOR THE DIAGNOSIS OF INFLAMMATORY GASTROINTESTINAL DISORDERS., GENOMIX VIRAL RNA EXTRACTION KIT-THE GENOMIX VIRAL RNA EXTRACTION KIT IS INTENDED FOR IS DESIGNED FOR RAPID HIGH THROUGHPUT PURIFICATION OF VIRAL RNA AND DNA FROM BIOFLUID SAMPLES SUCH AS SERUM, PLASMA, NASAL FLUIDS AND SWAB SAMPLES,GENOMIX TRICHOMONAS ANTIBODY RAPID TEST KIT-INTENDED FOR THE QUALITATIVE DETECTION OF TRICHOMONAS SPS (T. VAGINALIS AND T. FOETUS) SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,GENOMIX VIRAL TRANSPORT MEDIUM (VTM) KIT-THE GENOMIX VIRAL TRANSPORT MEDIUM (VTM) IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. IT IS READY TO USE TRANSPORT SWAB KIT, DESIGNED TO MAINTAIN VIRAL VIABILITY AND TRANSPORT VIRUSES IN ACTIVE FORM FOR ISOLATION. THE PECULIAR DESIGN OF THE SWAB ENSURES OPTIMAL ELUTION OF THE SPECIMEN INTO THE TRANSPORT MEDIUM.,GENOMIX PARA TUBERCULOSIS ANTIBODY RAPID TEST KIT-FOR THE RAPID DETECTION OF ANTIBODIES TO M. PARATUBERCULOSIS SUBSP. AVIUM (JOHNE'S DISEASE) IN WHOLE BLOOD, SERUM OR PLASMA,GENOMIX BRUCELLA ANTIBODY RAPID DIAGNOSTIC TEST KIT-FOR DETECTION OF BRUCELLA SPECIFIC ANTIBODIES IN WHOLE BLOOD /SERUM OR PLASMA,GENOMIX TUBERCULOSIS INTERFERON GAMMA RELEASE ASSAY (TB IGRA)-FOR QUANTITATIVE DETECTION OF INTERFERON GAMMA (IFN-) THAT RESPOND TO IN-VITRO STIMULATION BY M. TUBERCULOSIS ANTIGENS IN WHOLE BLOOD. IT IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF TUBERCULOSIS (TB) INFECTION.,GENOMIX CANINE DISTEMPER ANTIBODY RAPID TEST KIT-FOR IN-VITRO DETECTION OF CANINE DISTEMPER VIRUS SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,GENOMIX IBR ANTIBODY ELISA TEST KIT-FOR DETECTION OF BOVINE HERPES VIRUS-1 SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA WITH CLINICAL SYMPTOMS IN CONSISTENT WITH INFECTIOUS BOVINE RHINOTRACHEITIS (IBR),GENOMIX CANINE PARVO ANTIBODY RAPID TEST KIT-FOR THE QUALITATIVE DETECTION OF CPV SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,GENOMIX BOVINE TUBERCULOSIS ANTIBODY RAPID TEST KIT-FOR THE RAPID DETECTION OF ANTIBODIES TO MYCOBACTERIUM BOVIS (MTB)

	COMPLEX ANTIGEN(S) IN WHOLE BLOOD, SERUM OR PLASMA OF BOVINES,GENOMIX BOVINE LEPTOSPIRA ANTIBODY INDIRECT ELISA TEST KIT-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN SERUM OF CATTLE, BUFFALOES, SHEEP AND GOATS WITH CLINICAL SYMPTOMS CONSISTENT WITH LEPTOSPIROSIS,GENOMIX LEPTOSPIRA IGG/IGM ANTIBODY RAPID DIAGNOSTIC TEST KIT-FOR THE DETECTION OF LEPTOSPIRA SPECIFIC IGM AND IGG ANTIBODIES IN HUMAN SERUM OR PLASMA,GENOMIX WILD TB ANTIBODY RAPID DIAGNOSTIC TEST KIT -FOR THE DETECTION OF ANTIBODIES TO MYCOBACTERIUM TUBERCULOSIS COMPLEX IN WHOLE BLOOD, SERUM AND PLASMA FROM WILD ANIMALS,GENOMIX FILARIASIS IGG/IGM ANTIBODY RAPID DIAGNOSTIC TEST KIT-FOR SIMULTANEOUS DETECTION AND DIFFERENTIATION OF IGG AND IGM ANTI-LYMPHATIC FILARIAL PARASITES (W. BANCROFTI AND B. MALAYI) IN HUMAN SERUM OR PLASMA,GENOMIX CCP ANTIBODY RAPID TEST KIT-FOR THE DETERMINATION OF ANTI-CYCLIC CITRULLINATED PEPTIDE (CCP) ANTIBODY IN HUMAN SERUM AND PLASMA AS AN AIDING TOOL FOR DIAGNOSING AND CONTROLLING THE TREATMENT OF RHEUMATOID ARTHRITIS,GENOMIX LP-PLA2 ELISA TEST KIT-FOR THE QUANTITATIVE MEASUREMENT OF HUMAN LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 IN SERUM, PLASMA AND CELL CULTURE SUPERNATANTS.,GENOMIX SALMONELLA ANTIBODY ELISA TEST KIT-FOR DETECTION OF SALMONELLA SPS. SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA, GENOMIX BRUCELLA MILK DIPSTICK RAPID TEST KIT-FOR DETECTION OF BRUCELLA ANTIBODIES IN MILK AND BODY FLUIDS (BLOOD/SERUM/PLASMA),GENOMIX CAMPYLOBACTER ANTIBODY ELISA TEST KIT-FOR DETECTION OF ANTIBODIES TO COMPYLOBACTER JEJUNI IN STOOL SAMPLES,GENOMIX CAMPYLOBACTER ANTIBODY RAPID TEST KIT-FOR THE IN-VITRO QUALITATIVE DETECTION OF ANTIBODIES TO COMPYLOBACTER JEJUNI IN STOOL SAMPLES ,GENOMIX LISTERIA ANTIBODY ELISA TEST KIT-FOR QUANTITATIVE DETECTION OF ANTIBODIES TO LISTERIA MONOCYTOGENES IN STOOL SAMPLES ,GENOMIX RHODOCOCCUS ANTIBODY ELISA TEST KIT-FOR DETECTION OF RHODOCOCCUS SPS. SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,GENOMIX CHIKUNGUNYA VIRUS IGG ANTIBODY ELISA TEST KIT-FOR THE DETERMINATION OF IGG CLASS ANTIBODIES TO CHIKUNGUNYA IN HUMAN SERUM OR PLASMA,GENOMIX BRUCELLA CANIS ANTIBODY ELISA TEST KIT-FOR DETECTION OF BRUCELLA CANIS SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA, GENOMIX BRUCELLA CANIS ANTIBODY RAPID TEST KIT-FOR IN-VITRO ASSAY DETECTION OF BRUCELLA CANIS SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,GENOMIX ANTHRAX

	ANTIBODY ELISA TEST KIT-FOR DETECTION OF BACILLUS ANTHRACIS SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA, GENOMIX ANTHRAX ANTIBODY RAPID TEST KIT-FOR IN-VITRO DETECTION OF BACILLUS ANTHRACIS ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA ,GENOMIX TOXOPLASMA ANTIBODY RAPID TEST KIT-FOR IN-VITRO DETECTION OF TOXOPLASMA GONDII SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,GENOMIX CHIKUNGUNYA VIRUS IGM ANTIBODY ELISA TEST KIT-FOR THE DETECTION OF CHIKUNGUNYA SPECIFIC IGM ANTIBODIES IN HUMAN SERUM OR PLASMA,GENOMIX HYDATID ANTIBODY ELISA TEST KIT-FOR DETECTION OF ECHINOCOCCUS SPS. SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,GENOMIX LISTERIA ANTIBODY RAPID TEST KIT-FOR THE IN-VITRO QUALITATIVE DETECTION OF ANTIBODIES TO LISTERIA MONOCYTOGENES IN STOOL SAMPLES , GENOMIX RHODOCOCCUS ANTIBODY RAPID TEST KIT-FOR IN-VITRO ASSAY DETECTION OF RHODOCOCCUS SPS. SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,GENOMIX TOXOPLASMA ANTIBODY ELISA TEST KIT-FOR DETECTION OF TOXOPLASMA GONDII SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA, GENOMIX CHIKUNGUNYA IGG/IGM ANTIBODY RAPID DIAGNOSTIC TEST KIT-FOR IN VITRO DETECTION OF IGG AND IGM ANTIBODIES TO CHIKUNGUNYA VIRUS IN HUMAN SERUM, PLASMA OR WHOLE BLOOD, GENOMIX THEILERIA TA/TO ANTIBODY RAPID TEST KIT-FOR IN VITRO DETECTION OF THEILERIA ANTIBODIES IN PLASMA OR SERUM, GENOMIX RABIES ANTIBODY ELISA TEST KIT-FOR DETERMINATION OF HUMAN RABIES VIRUS (ANTIBODY CONCENTRATIONS IN SERUM, PLASMA,GENOMIX RABIES ANTIBODY RAPID TEST KIT-FOR QUALITATIVE DETECTION OF RABIES VIRUS ANTIBODIES IN PLASMA OR SERUM,GENOMIX CANINE LEPTOSPIRA ANTIBODY ELISA TEST KIT-FOR DETECTION OF LEPTOSPIRA SPECIFIC ANTIBODIES IN SERUM OR PLASMA OF CANINES,GENOMIX FOOT AND MOUTH DISEASE (FMD) ANTIBODY RAPID TEST KIT-FOR DETECTION OF FMD VIRAL SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA, GENOMIX CANINE LEPTOSPIRA ANTIBODY RAPID TEST KIT-FOR DETECTION OF LEPTOSPIRA SPECIFIC ANTIBODIES IN SERUM OR PLASMA OF CANINES,GENOMIX IBR ANTIBODY RAPID TEST KIT-FOR IN-VITRO ASSAY DETECTION OF BOVINE HERPES VIRUS-1 (BHV-1) SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA WITH CLINICAL SYMPTOMS IN CONSISTENT WITH INFECTIOUS BOVINE RHINOTRACHEITIS (IBR),GENOMIX EIA ANTIBODY RAPID TEST KIT-FOR THE QUALITATIVE DETECTION OF EQUINE INFECTIOUS ANAEMIA (EIA) SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA, GENOMIX CANINE DISTEMPER ANTIBODY ELISA TEST KIT-FOR DETECTION OF CANINE DISTEMPER VIRUS SPECIFIC ANTIBODIES IN

	WHOLE BLOOD, SERUM OR PLASMA,GENOMIX GLANDERS ANTIBODY ELISA TEST KIT-FOR QUANTITATIVE DETECTION OF SPECIFIC ANTIBODIES IN SERUM WITH CLINICAL SYMPTOMS CONSISTENT WITH GLANDERS,GENOMIX FMD DIVA ANTIBODY RAPID TEST KIT-INTENDED FOR DIFFERENTIATION OF VACCINATED AND INFECTED ANIMALS WITH FOOT AND MOUTH DISEASE VIRUS,GENOMIX BOVINE PREGNANCY ELISA TEST KIT-GENOMIX BOVINE PREGNANCY ELISA TEST KIT IS FOR THE QUALITATIVE DETECTION OF PREGNANCY SPECIFIC PROTEIN B (PSPB) IN SERUM OR PLASMA OF CATTLE AS EARLY AS 28 DAYS AFTER BREEDING IN COWS WITH NO INTERFERENCE FROM A PREVIOUS PREGNANCY AS EARLY AS 60 DAYS AFTER CALVING. IT CAN GOATS, BUFFALOES AND SHEEP, GENOMIX BOVINE LEPTOSPIRA ANTIBODY RAPID TEST KIT-FOR DETECTION OF LEPTOSPIRA SPECIFIC ANTIBODIES IN SERUM OR PLASMA OF BOVINES,GENOMIX BOVINE PREGNANCY RAPID TEST KIT-INTENDED FOR THE QUALITATIVE DETECTION OF SPECIFIC PREGNANCY ASSOCIATED GLYCOPROTEINS (PGPS) IN WHOLE BLOOD, SERUM OR PLASMA OF CATTLE,GENOMIX FOOT AND MOUTH ANTIBODY DIVA IELISA TEST KIT-FOR THE DETECTION OF FMDV 3ABC SPECIFIC ANTIBODIES IN SERUM AND PLASMA SAMPLES FROM BOVINE, OVINE AND CAPRINE. THE KIT CAN BE USED FOR DIFFERENTIATING NATURALLY INFECTED ANIMALS FROM THOSE VACCINATED WITH FMDV VACCINE.,GENOMIX CANINE PARVO ANTIBODY ELISA TEST KIT-FOR DETECTION OF PARVO VIRAL SPECIFIC ANTIBODIES PRESENT IN SERUM / PLAMA OF CANINES , GENOMIX BRUCELLA MILK ELISA TEST KIT-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN MILK OF CATTLE, BUFFALOES AND GOAT WITH CLINICAL SYMPTOMS CONSISTENT WITH BRUCELLOSIS, GENOMIX ANA ELISA TEST KIT-FOR THE DETECTION OF IGG CLASS ANTIBODIES TO ANTI-NUCLEAR ANTIBODIES (ANA) IN HUMAN SERUM OR PLASMA. ,GENOMIX ANTI-MULLERIAN HORMONE (AMH) ELISA TEST KIT-FOR THE QUANTITATIVE MEASUREMENT OF AMH IN HUMAN SERUM AND PLASMA,GENOMIX PPRV ANTIBODY ELISA TEST KIT-FOR QUANTITATIVE DETECTION OF PPRV ANTIBODIES IN PLASMA OR SERUM,GENOMIX SALMONELLA ANTIBODY RAPID TEST KIT-INTENDED FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES AGAINST SALMONELLA LIPOPOLYSACCHARIDE ANTIGENS PRESENT IN BLOOD SAMPLE,GENOMIX CLASSICAL SWINE FEVER ANTIBODY RAPID TEST KIT -INTENDED FOR THE QUALITATIVE DETECTION OF CLASSICAL SWINE FEVER VIRUS (CSFV) SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA OF BOVINE, GENOMIX DENGUE IGG ANTIBODY ELISA TEST KIT-FOR IN-VITRO QUALITATIVE DETECTION OF DENGUE IGG ANTIBODIES IN HUMAN SERUM OR PLASMA,GENOMIX EQUINE LEPTOSPIRA ANTIBODY RAPID

	TEST KI-INTENDED FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES AGAINST EQUINE LEPTOSPIRA LIPOPOLYSACCHARIDE (LPS) AND EQUINE LEPTOSPIRA RECOMBINANT MULTI EPITOPE PROTEIN (MEP) ANTIGENS PRESENT IN THE WHOLE BLOOD, SERUM OR PLASMA OF EQUINES WITH CLINICAL SYMPTOMS,GENOMIX DENGUE IGM ANTIBODY ELISA TEST KIT-FOR DETECTION OF DENGUE IGM ANTIBODIES ANTIGEN IN SERUM OR PLASMA,GENOMIX TYPHOID IGG & IGM ANTIBODY RAPID DIAGNOSTIC TEST KIT-FOR IN VITRO DETECTION OF ANTIBODIES TO SALMONELLA TYPHI IN HUMAN SERUM OR PLASMA,GENOMIX HAEMORRHAGIC SEPTECAEMIA ANTIBODY RAPID TEST KIT-INTENDED FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES AGAINST PURIFIED LPS PASTEURELLA MULTOCIDA ANTIGEN ANTIGENS PRESENT IN THE WHOLE BLOOD, SERUM OR PLASMA,GENOMIX THEILERIA ANTIBODY ELISA TEST KIT-FOR QUANTITATIVE DETECTION OF THEILERIA SPS. ANTIBODIES IN PLASMA OR SERUM,GENOMIX FMD ANTIBODY ELISA TEST KIT-FMD ANTIBODY ELISA KIT IS FOR DETECTION OF FMD SEROVARS LIKE FMD A, O, ASIA 1 ANTIGENS SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,GENOMIX GLANDERS ANTIBODY RAPID TEST KIT-FOR THE QUALITATIVE DETECTION OF GLANDERS SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA, GENOMIX EQUINE LEPTOSPIRA ANTIBODY INDIRECT ELISA TEST KIT-INTENDED FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES AGAINST LEPTOSPIRA ANTIGENS PRESENT IN THE WHOLE BLOOD, SERUM OR PLASMA OF EQUINE WITH CLINICAL SYMPTOMS,GENOMIX LEPTOSPIRA ANTIBODY ELISA TEST KIT-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN SERUM WITH CLINICAL SYMPTOMS CONSISTENT WITH LEPTOSPIROSIS,GENOMIX CCP ANTIBODY ELISA TEST KIT-FOR IN VITRO DETERMINATION OF HUMAN CCP-AB CONCENTRATIONS IN SERUM, PLASMA AND OTHER BIOLOGICAL FLUIDS.,GENOMIX CLASSICAL SWINE FEVER (CSF) ANTIBODY ELISA KIT -FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA WITH CLINICAL SYMPTOMS CONSISTENT WITH CLASSICAL SWINE FEVER VIRUS (CSFV) DISEASE.,GENOMIX EIA ANTIBODY ELISA TEST KIT-FOR QUANTITATIVE DETECTION OF SPECIFIC ANTIBODIES IN SERUM, PLASMA AND WHOLE BLOOD WITH CLINICAL SYMPTOMS CONSISTENT WITH EIA ,GENOMIX PARA TUBERCULOSIS ANTIBODY ELISA TEST KIT-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN SERUM / PLAMA OF CATTLE, BUFFALOES, SHEEP, GOAT AND CAMELS WITH CLINICAL SYMPTOMS CONSISTENT WITH PARA TUBERCULOSIS (JOHNE'S DISEASE) ,GENOMIX BOVINE TUBERCULOSIS ANTIBODY ELISA TEST KIT-FOR DETECTION OF ANTIBODIES TO MYCOBACTERIUM TUBERCULOSIS (MTB) COMPLEX

	ANTIGEN(S) IN WHOLE BLOOD, SERUM OR PLASMA OF BOVINES, GENOMIX BRUCELLA ELISA ANTIBODY TEST KIT-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN SERUM, PLASMA OR WHOLE BLOOD OF CATTLE, BUFFALOES AND GOAT WITH CLINICAL SYMPTOMS CONSISTENT WITH BRUCELLOSIS

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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2836	MFG/IVD/2020/000021	1.License Holder Name: MYLAB DISCOVERY S0LUTIONS PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:DETECTION OF NOVEL CORONAVIRUS 2019-NCOV/SARS-COV-2 FROM CLINICAL SAMPLES (MULTIGENE-MULTIPLEX SINGLE TUBE FORMAT) (PATHODETECT COVID-19 QUALITATIVE PCR KIT)-DETECTION OF 2019-NOVEL CORONAVIRUS/SARS-COV-2 IN RESPIRATORY SPECIMENS AND SERA.,DETECTION OF NOVEL CORONAVIRUS 2019-NCOV/SARS-COV-2 FROM CLINICAL SAMPLES(PATHODETECT COVID-19 QUALITATIVE PCR KIT)-DETECTION OF 2019-NOVEL CORONAVIRUS/SARS-COV-2 IN RESPIRATORY SPECIMENS AND SERA.,COVID-19 ANTIGEN LATERAL FLOW TEST DEVICE(PATHOCATCH TM)-COVID-19 ANTIGEN LATERAL FLOW TEST DEVICE IS USED AS AN AID FOR THE DETECTION OF NOVEL COVID-19 VIRUS IN NASAL AND THROAT SWAB SPECIMENS, AS AN AID IN THE DIAGNOSIS OF INFECTION WITH CORONA VIRUS. , COVID-19 ANTIGEN LATERAL FLOW TEST DEVICE OTC HOME TEST (COVISELF TM)-THE COVISELF™ COVID-19 ANTIGEN LATERAL FLOW TEST (OTC HOME TEST) IS AN IN VITRO IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF NUCLEOCAPSID PROTEIN ANTIGEN FROM SARS-COV-2 IN DIRECT NASAL SWAB SPECIMENS DIRECTLY FROM INDIVIDUALS WITH OR WITHOUT SYMPTOMS OR OTHER EPIDEMIOLOGICAL REASONS TO SUSPECT COVID-19. ,BULK PRE COATED NCM SHEETS & ANTIGEN EXTRACTION BUFFER (FOR COVID-19 ANTIGEN LATERAL FLOW TEST DEVICE OTC HOME TEST)(COVISELF TM)-THE BULK PRE COATED NCM SHEETS & ANTIGEN EXTRACTION BUFFER ARE INTENDED TO BE USED IN COVID-19 ANTIGEN LATERAL FLOW TEST (OTC HOME TEST) AFTER ITS FILLING AND PACKAGING AS PER COMPANY SOP; WHICH IS AN IN VITRO IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF NUCLEOCAPSID PROTEIN ANTIGEN FROM SARS-COV-2 IN DIRECT NASAL SWAB SPECIMENS DIRECTLY FROM INDIVIDUALS WITH OR WITHOUT SYMPTOMS OR OTHER EPIDEMIOLOGICAL REASONS TO SUSPECT COVID-19. THIS FINAL TEST KIT AFTER ITS SECONDARY PACKAGING AND FILLING WILL BE AUTHORIZED FOR NONPRESCRIPTION HOME USE WITH SELF-COLLECTED NASAL SWAB SPECIMENS FROM INDIVIDUALS AGED 18 YEARS AND OLDER OR WITH ADULT-COLLECTED NASAL SWAB SAMPLES FROM INDIVIDUALS AGED 2 YEARS OR OLDER.

2837	MFG/IVD/2020/000022	1.License Holder Name: UBIO BIOTECHNOLOGY SYSTEMS PRIVATE LIMITED 2.Approving Authority: KERALA 3.Device Name(Brand Name)-Intended Use:LH RAPID TEST(SENSIT LH TEST)-SENSIT LH TEST KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF HUMAN LUTEINIZING HORMONE IN URINE SAMPLE, HELPFUL IN DETECTING OVULATION,BRUCELLOSIS AB (CAPRINE) TEST(QUICKVET BRUCELLOSIS AB (CAPRINE) TEST)-QUICKVET BRUCELLOSIS AB (CAPRINE) TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF BRUCELLOSIS ANTIBODIES IN CAPRINE WHOLE BLOOD/SERUM OR PLASMA,WSSV AG RAPID TEST (QUICKVET WSSVAG TEST)-QUICKVET WSSV AG TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF WHITE SPOT SYNDROME VIRUS (WSSV) ANTIGEN IN SHRIMP BLOOD OR MACERATED SHRIMP SPECIMEN,BRUCELLA IGM TEST(SENSIT BRUCELLA IGM TEST)-SENSIT BRUCELLA IGM TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF BRUCELLA IGM ANTIBODY IN HUMAN WHOLE BLOOD/SERUM/ PLASMA,FT-IGG/IGM TEST (QUICKVET FT-IGG/IGM TEST)-QUICKVET FELINE TOXOPLASMA IGG/IGM AB TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE SIMULTANEOUS AND DIFFERENTIAL DETECTION OF FELINE TOXOPLASMA IGG AND IGM ANTIBODIES IN FELINE WHOLE BLOOD/SERUM/ PLASMA,NDV AB TEST (QUICKVET NDV AB TEST)-QUICKVET NDV AB TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF NDV (NEW CASTLE DISEASE VIRUS) ANTIBODIES IN AVIAN CLOACAL AND TRACHEAL ,BRUCELLOSIS AB (SWINE) TEST(QUICKVET BRUCELLOSIS AB(SWINE) TEST)-QUICKVET BRUCELLOSIS AB (SWINE) TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF BRUCELLOSIS ANTIBODIES IN SWINE WHOLE BLOOD/SERUM OR PLASMA,HCG RAPID TEST(MAGIC PINK D TEST)-MAGIC PINK D TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF HCG (HUMAN CHORIONIC GONADOTROPIN) IN HUMAN URINE SPECIMEN, WHICH SERVES AS A PREGNANCY DETECTION TEST,LEPTOSPIRA IGM RAPID TEST(SENSIT LEPTOSPIRA IGM TEST)-SENSIT LEPTOSPIRA IGM TEST IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF LEPTOSPIRA IGM ANTIBODY IN HUMAN WHOLE BLOOD/ SERUM OR PLASMA,FHW AG TEST(QUICKVET FHW AG TEST)-QUICKVET FHW AG TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF FHW (FELINE HEART WORM) ANTIGEN IN FELINE WHOLE BLOOD/PLASMA/SERUM, CANINE E. CANIS AB TEST(QUICKVET CANINE E. CANIS AB TEST)-QUICKVET CANINE E. CANIS AB TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF CANINE E. CANIS ANTIBODIES IN CANINE WHOLE BLOOD/SERUM/PLASMA ,LEPTOSPIRA IGG/IGM

	RAPID TEST(SENSIT LEPTOSPIRA IGG/IGM TEST)-SENSIT LEPTOSPIRA IGG/IGM TEST IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF LEPTOSPIRA IGG AND IGM ANTIBODIES IN HUMAN WHOLE BLOOD/ SERUM OR PLASMA,RABIES AG TEST(QUICKVET RABIES AG TEST)-QUICKVET RABIES AG TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF ANIMAL RABIES ANTIGEN IN SALIVA AND BRAIN HOMOGENATES,CANINE ROTA VIRUS TEST (QUICKVET CANINE ROTA VIRUS TEST)-QUICKVET CANINE ROTA VIRUS ANTIGEN TEST IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF CANINE ROTA VIRUS ANTIGEN IN CANINE FAECAL SAMPLE,BRUCELLOSIS AB (BOVINE) TEST(QUICKVET BRUCELLOSIS AB(BOVINE) TEST)-QUICKVET BRUCELLOSIS AB (BOVINE) TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF BRUCELLOSIS ANTIBODIES IN BOVINE WHOLE BLOOD/SERUM OR PLASMA,LEISHMANIASIS AB TEST(SENSIT LEISHMANIASIS AB TEST)-SENSIT LEISHMANIASIS AB TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF LEISHMANIASIS ANTIBODIES AGAINST L. DONOVANI IN HUMAN WHOLE BLOOD/SERUM/PLASMA, TYPHOID IGM TEST(SENSIT TYPHOID IGM TEST)-SENSIT TYPHOID IGM TEST KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF TYPHOID IGM ANTIBODY IN HUMAN WHOLE BLOOD/SERUM/PLASMA, CANINE PARVO AG TEST(QUICKVET CANINE PARVO AG TEST)-QUICKVET CANINE PARVO AG TEST IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF CPV (CANINE PARVOVIRUS) ANTIGEN IN CANINE FAECAL SAMPLE,DENGUE IGG/IGM RAPID TEST (SENSIT DENGUE IGG/IGM TEST)-SENSIT DENGUE IGG/IGM TEST IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF DENGUE IGG AND IGM ANTIBODIES IN HUMAN WHOLE BLOOD/ SERUM OR PLASMA, FMD NSP AB (SWINE) TEST (QUICKVET FMD NSP AB (SWINE) TEST)-QUICKVET FMD NSP AB (SWINE) TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF FOOT AND MOUTH DISEASE NSP ANTIBODIES IN SWINE WHOLE BLOOD/ SERUM OR PLASMA,FMD 3ABC NSP AB ELISA KIT(QUICKVET FMD 3ABC NSP AB ELISA KIT)-QUICKVET FMD 3ABC NSP AB ELISA KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF FOOT AND MOUTH DISEASE (FMD) 3ABC NSP ANTIBODIES IN SERUM OR PLASMA,NDV AG TEST (QUICKVET NDV AG TEST)-QUICKVET NDV AG TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF NDV (NEW CASTLE DISEASE VIRUS) ANTIGEN IN AVIAN CLOACAL AND TRACHEAL SECRETIONS,BOVINE TB AB TEST (QUICKVET BOVINE TB AB TEST)-QUICKVET BOVINE TB AB TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF M. TUBERCULOSIS ANTIBODIES IN BOVINE WHOLE BLOOD/SERUM/PLASMA,FMD NSP AB TEST(QUICKVET FMD NSP AB TEST)-QUICKVET FMD NSP AB TEST KIT

	IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF FMD NSP (FOOT AND MOUTH DISEASE NON-STRUCTURAL PROTEINS) ANTIBODIES IN BOVINE, CAPRINE OR OVINE WHOLE BLOOD/SERUM OR PLASMA,FELINE PARVO AG TEST(QUICKVET FELINE PARVO AG TEST)-QUICKVET FELINE PARVO AG TEST IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF FELINE PARVOVIRUS (FPV) ANTIGEN IN FELINE FAECAL SAMPLE,SYPHILIS AB TEST(SENSIT SYPHILIS AB TEST)-SENSIT SYPHILIS ANTIBODY TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF SYPHILIS ANTIBODIES IN HUMAN WHOLE BLOOD/SERUM/PLASMA,CANINE GIARDIA AG TEST(QUICKVET CANINE GIARDIA AG TEST)-QUICKVET CANINE GIARDIA ANTIGEN TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF CANINE GIARDIA ANTIGEN IN CANINE FAECES,HEPATITIS B AB RAPID TEST(SENSIT HEPATITIS B AB TEST)-SENSIT HEPATITIS B AB TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF HEPATITIS B VIRUS ANTIBODIES IN HUMAN WHOLE BLOOD/SERUM OR PLASMA,CANINE DISTEMPER AG TEST(QUICKVET CANINE DISTEMPER AG TEST)-QUICKVET CANINE DISTEMPER AG TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF CDV (CANINE DISTEMPER VIRUS) ANTIGEN IN CANINE EYE/NASAL/RESPIRATORY TRACT SECRETIONS, BRUCELLOSIS AB (CANINE) TEST (QUICKVET BRUCELLOSIS AB (CANINE) TEST)-QUICKVET BRUCELLOSIS AB(CANINE) TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF CANINE BRUCELLOSIS ANTIBODIES IN CANINE WHOLE BLOOD/SERUM/PLASMA,BRUCELLOSIS AB (OVINE) TEST (QUICKVET BRUCELLOSIS AB (OVINE) TEST)-QUICKVET BRUCELLOSIS AB (OVINE) TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF OVINE BRUCELLOSIS ANTIBODIES IN OVINE WHOLE BLOOD/SERUM OR PLASMA,BOVINE BRUCELLA/TB COMBO TEST (QUICKVET BOVINE BRUCELLA/TB COMBO TEST)-QUICKVET BOVINE BRUCELLA/TB COMBO TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF ANTIBODIES AGAINST BRUCELLA ABORTUS AND MYCOBACTERIUM TUBERCULOSIS IN BOVINE WHOLE BLOOD/SERUM OR PLASMA. ,BRUCELLA IGG TEST(SENSIT BRUCELLA IGG TEST)-SENSIT BRUCELLA IGG TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF BRUCELLA IGG ANTIBODY IN HUMAN WHOLE BLOOD/SERUM/ PLASMA,FILARIASIS AB RAPID TEST(SENSIT FILARIASIS AB TEST)-SENSIT FILARIASIS ANTIBODY TEST IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF FILARIASIS ANTIBODIES AGAINST W. BANCROFTI AND B. MALAYI IN HUMAN WHOLE BLOOD/ SERUM OR PLASMA,H. PYLORI AB TEST (SENSIT H. PYLORI AB TEST)-SENSIT H.PYLORI AB TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF HELICOBACTER

	PYLORI ANTIBODIES IN HUMAN WHOLE BLOOD/SERUM OR PLASMA, CANINE LEPTOSPIRA IGM TEST(QUICKVET CANINE LEPTOSPIRA IGM TEST)-QUICKVET CANINE LEPTOSPIRA IGM AB TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF CANINE LEPTOSPIRA IGM ANTIBODY IN CANINE WHOLE BLOOD/SERUM/ PLASMA,CANINE LEISHMANIA AB TEST(QUICKVET CANINE LEISHMANIA AB TEST)-QUICKVET CANINE LEISHMANIA AB TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF CANINE LEISHMANIASIS ANTIBODIES IN CANINE WHOLE BLOOD/SERUM/ PLASMA,HIV 1/2 AB RAPID TEST(SENSIT HIV 1/2 AB TEST)-SENSIT HIV 1/2 AB TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF HIV 1 AND 2 ANTIBODIES IN HUMAN WHOLE BLOOD/SERUM/PLASMA,BRUCELLA IGG/IGM TEST (SENSIT BRUCELLA IGG/IGM TEST)-SENSIT BRUCELLA IGG/IGM TEST IS AN IVD MEDICAL DEVICE INTENDED FOR THE SIMULTANEOUS AND DIFFERENTIAL DETECTION OF BRUCELLA IGG/IGM ANTIBODIES IN HUMAN WHOLE BLOOD/SERUM/PLASMA,MAREK'S AG TEST (QUICKVET MAREK'S AG TEST)-QUICKVET MAREK'S AG TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF MAREK'S DISEASE VIRUS ANTIGEN IN AVIAN TISSUES,HCV AB TEST(SENSIT HCV AB TEST)-SENSIT HCV ANTIBODY TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF HCV (HEPATITIS C VIRUS) ANTIBODIES IN HUMAN WHOLE BLOOD/SERUM/PLASMA,FIP TEST (QUICKVET FIP TEST)-QUICKVET FIP AB TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF FELINE INFECTIOUS PERITONITIS (FIP) ANTIBODIES IN FELINE WHOLE BLOOD/PLASMA/SERUM,IBDV AG TEST(QUICKVET IBDV AG TEST)-QUICKVET IBDV AG TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF INFECTIOUS BURSAL DISEASE VIRUS (IBDV) ANTIGEN IN AVIAN CLOACAL AND BURSA OF FABRICUS SECRETIONS, CAV TEST(QUICKVET CAV TEST)-QUICKVET CANINE ADENO VIRUS AG TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF CAV (CANINE ADENO VIRUS) ANTIGEN IN CANINE BLOOD/RESPIRATORY TRACT SECRETIONS,CHW AG TEST(QUICKVET CHW AG TEST)-QUICKVET CHW AG TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF CHW (CANINE HEART WORM) ANTIGEN IN CANINE WHOLE BLOOD/PLASMA/SERUM,CCVAG TEST(QUICKVET CCV AG TEST)-QUICKVET CANINE CORONA VIRUS ANTIGEN TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF CCV (CANINE CORONA VIRUS) ANTIGEN IN CANINE FAECES,BOVINE PREGNANCY TEST(QUICKVET BOVINE PREGNANCY TEST)-QUICKVET BOVINE PREGNANCY TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF BOVINE PREGNANCY ASSOCIATED GLYCOPROTEIN IN BOVINE SERUM OR PLASMA,CANINE

	LYME AB TEST(QUICKVET CANINE LYME AB TEST)-QUICKVET CANINE LYME AB TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF CANINE LYME IN CANINE WHOLE BLOOD/SERUM/ PLASMA,FIV AB TEST(QUICKVET FIV AB TEST)-QUICKVET FIV AB TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF FIV (FELINE IMMUNODEFICIENCY VIRUS) ANTIBODIES IN FELINE WHOLE BLOOD/SERUM OR PLASMA,FELV AG TEST(QUICKVET FELV AG TEST) -QUICKVET FELV AG TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF FELV (FELINE LEUKEMIA VIRUS) ANTIGEN IN FELINE WHOLE BLOOD/SERUM OR PLASMA

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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2838	MFG/IVD/2020/000024	1.License Holder Name: KILPEST INDIA LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:DETECTION OF NOVEL CORONAVIRUS 2019-NCOV/SARS-COV-2 FROM CLINICAL SAMPLES (TRUPCR® SARS-COV-2 RT QPCR KIT)-TRUPCR® SARS-COV-2 RT QPCR KIT IS AN IN-VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) SPECIFIC RNA FROM RESPIRATORY SPECIMENS (INCLUDING: NASOPHARYNGEAL OR OROPHARYNGEAL ASPIRATES OR WASHES, NASOPHARYNGEAL OR OROPHARYNGEAL SWABS, BRONCHOALVEOLAR LAVAGE, TRACHEAL ASPIRATES & SPUTUM) USING REAL TIME PCR. THE HUMAN RNASEP GENE SERVES AS AN INTERNAL POSITIVE CONTROL FOR HUMAN NUCLEIC ACID, ALSO INCLUDED IN THIS KIT. THE RESULT FROM TRUPCR® SARS-COV-2 RT QPCR KIT SHOULD BE INTERPRETED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS., DETECTION OF NOVEL CORONAVIRUS 2019-NCOV/SARS-COV-2 FROM CLINICAL SAMPLES(TRUPCR® SARS-COV-2 RT QPCR KIT (VERSION-2.0-IMPROVED))-TRUPCR® SARS-COV-2 RT QPCR KIT (V-2.0-IMPROVED) IS AN IN-VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUALITATIVE DETECTION OF SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) SPECIFIC RNA FROM RESPIRATORY SPECIMENS (INCLUDING: NASOPHARYNGEAL OR OROPHARYNGEAL ASPIRATES OR WASHES, NASOPHARYNGEAL OR OROPHARYNGEAL SWABS, BRONCHOALVEOLAR LAVAGE, TRACHEAL ASPIRATES & SPUTUM) USING REAL TIME PCR. THE HUMAN RNASEP GENE SERVES AS AN INTERNAL POSITIVE CONTROL FOR HUMAN NUCLEIC ACID, ALSO INCLUDED IN THIS KIT. THE RESULT FROM TRUPCR® SARS-COV-2 RT QPCR KIT (V-2.0-IMPROVED) SHOULD BE INTERPRETED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS.,VIRAL RNA EXTRACTION KIT(TRUPCR® VIRAL RNA EXTRACTION KIT)-TRUPCR® VIRAL RNA EXTRACTION KIT IS INTENDED TO EXTRACT VIRAL RNA FROM BIOLOGICAL SAMPLES E. G. RESPIRATORY SPECIMENS (NASOPHARYNGEAL, OROPHARYNGEAL- SWABS & WASHES), BAL, SPUTUM, PLASMA, SERUM, CSF, OTHER BODY FLUIDS AND CELL- CULTURE SUPERNATANTS. THE PREPARED NUCLEIC ACIDS ARE SUITABLE FOR APPLICATIONS LIKE RT-PCR & FOR OTHER MOLECULAR DIAGNOSTIC METHODS.,DETECTION OF NOVEL CORONAVIRUS 2019-NCOV/SARS-COV-2 FROM CLINICAL SAMPLES(TRUPCR® SARS-COV-2 RT QPCR KIT (V-3.2) (SINGLE TUBE MULTIPLEX FORMAT))-TRUPCR® SARS-COV-2 RT QPCR KIT (V-3.2) IS AN IN-VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUALITATIVE DETECTION OF SEVERE

		ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) SPECIFIC RNA FROM RESPIRATORY SPECIMENS (INCLUDING: NASOPHARYNGEAL OR OROPHARYNGEAL ASPIRATES OR WASHES, NASOPHARYNGEAL OR OROPHARYNGEAL SWABS, BRONCHOALVEOLAR LAVAGE, TRACHEAL ASPIRATES & SPUTUM) USING REAL TIME PCR. THE HUMAN RNASEP GENE SERVES AS AN INTERNAL POSITIVE CONTROL FOR HUMAN NUCLEIC ACID, ALSO INCLUDED IN THIS KIT. THE RESULT FROM TRUPCR® SARS-COV-2 RT QPCR KIT (V-3.2) SHOULD BE INTERPRETED IN CONJUNCTION WITH OTHER CLINICAL AND LABORATORY FINDINGS.
2839	MFG/IVD/2020/000025	1.License Holder Name: S.S.SERUMS 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ASO POSITIVE SERUM(NA) -FOR FURTHER MANUFACTURING FOR DIAGNOSTIC COMPANIES OR INHOUSE TESTING FOR THEIR TESTING KITS,RA POSITIVE SERUM(NA) -FOR FURTHER MANUFACTURING FOR DIAGNOSTIC COMPANIES OR INHOUSE TESTING FOR THEIR TESTING KITS,NORMAL SERUM(NA)-FOR FURTHER MANUFACTURING FOR DIAGNOSTIC COMPANIES OR INHOUSE TESTING FOR THEIR TESTING KITS,CRP POSITIVE SERUM (NA)-FOR FURTHER MANUFACTURING FOR DIAGNOSTIC COMPANIES OR INHOUSE TESTING FOR THEIR TESTING KITS
2840	MFG/IVD/2020/000026	1.License Holder Name: VOXTUR BIO LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:ELISA TEST FOR THE DETECTION OF SARS COV-2 HUMAN IGG IN HUMAN SERUM/PLASMA (VOXEL - COVID KAVACH, OR ANY OTHER BRAND)-SARS COV-2 HUMAN IGG ELISA KIT IS INTENDED FOR QUALITATIVE DETECTION OF IGG ANTIBODIES IN SERUM/PLASMA OF PATIENTS PRESENTING CLINICAL SIGNS AND SYMPTOMS CONSISTENT WITH SARS COV-2 INFECTION.,NEW CORONAVIRUSCOVID-19 IGG / IGM RAPID TEST DEVICE (VOXPRESS)-FOR THE QUALITATIVE ASSESSMENT OF COVID-19 IGG/IGM IN HUMAN SERUM/PLASMA/WHOLE BLOOD

2841	MFG/IVD/2020/000027	1.License Holder Name: IMMUNOSCIENCE INDIA PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:RAPID TEST FOR DETECTION OF SYPHILIS ANTIBODY AND MALARIA PAN (PLDH) ANTIGEN COMBO TEST-DEVICE CASSETTE AND COMPONENTS. (IMMUNOQUICK)-RAPID TEST FOR DETECTION OF SYPHILIS ANTIBODY AND MALARIA PAN (PLDH) ANTIGEN COMBO TEST-DEVICE IS A RAPID, IN VITRO, QUALITATIVE LATERAL FLOW IMMUNOASSAY FOR THE DETECTION OF PAN MALARIA SPECIFIC PLDH ANTIGEN FROM HUMAN WHOLE BLOOD SAMPLES AND SYPHILIS ANTIBODIES FROM HUMAN SERUM/PLASMA/WHOLE BLOOD SAMPLES. ,RAPID TEST FOR TROPONIN I-DEVICE/ CASSETTE AND COMPONENTS. (IMMUNOQUICK)-RAPID TEST FOR TROPONIN I -DEVICE IS AN IMMUNOASSAY FOR THE RAPID AND VISUAL DETECTION OF TROPONIN I (CTNI) IN HUMAN SERUM/PLASMA/ WHOLE BLOOD FOR THE DIAGNOSIS OF MYOCARDIAL INFARCTION. ,RAPID MALARIA PAN (PLDH) ANTIGEN TEST-DEVICE/ CASSETTE AND COMPONENTS. (IMMUNOQUICK)-THIS IS A RAPID, IN VITRO, QUALITATIVE LATERAL FLOW IMMUNOASSAY FOR THE DETECTION OF PAN MALARIA SPECIFIC PLDH ANTIGEN FROM HUMAN WHOLE BLOOD SAMPLES. ,RAPID TEST FOR DETECTION OF ANTIBODIES TO HIV 1 AND HIV 2-DEVICE/CASSETTE AND COMPONENTS.(IMMUNOQUICK)-“RAPID TEST FOR DETECTION OF ANTIBODIES TO HIV 1 AND HIV 2 (DEVICE)” IS AN IMMUNOASSAY FOR THE RAPID AND VISUAL DETECTION OF ANTIBODIES TO HIV 1 AND HIV 2 IN HUMAN SERUM/PLASMA/WHOLE BLOOD FOR THE DIAGNOSIS OF HUMAN IMMUNODEFICIENCY VIRUS INFECTION (HIV). ,RAPID TEST FOR DETECTION OF ANTIBODIES TO HCV- DEVICE/CASSETTE AND COMPONENTS.(IMMUNOQUICK)-"RAPID TEST FOR DETECTION OF ANTIBODIES TO HCV (DEVICE)” IS AN IMMUNOASSAY FOR THE RAPID AND VISUAL DETECTION OF ANTIBODIES TO HCV IN HUMAN SERUM/ PLASMA/WHOLE BLOOD FOR THE DIAGNOSIS OF HEPATITIS C VIRUS INFECTION. ,RAPID TEST FOR DETECTION OF HBSAG- DEVICE/CASSETTE AND COMPONENTS. (IMMUNOQUICK)-"RAPID TEST FOR DETECTION OF HBSAG (DEVICE)” IS AN IMMUNOASSAY FOR THE RAPID AND VISUAL DETECTION OF HEPATITIS B SURFACE ANTIGEN IN HUMAN SERUM/ PLASMA/WHOLE BLOOD FOR THE DIAGNOSIS OF HEPATITIS B VIRUS INFECTION.

2842	MFG/IVD/2020/000028	1.License Holder Name: VANGUARD DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:COVID-19 IGM-IGG RAPID TEST KIT(COVID-19 IGM-IGG RAPID TEST KIT)-COVID-19 IGM-IGG RAPID TEST KIT, IS AN IN-VITRO DIAGNOSTIC, IMMUNOCHROMATOGRAPHY BASED TEST, INTENDED FOR THE QUALITATIVE DETECTION OF IGM AND IGG ANTIBODIES AGAINST THE CORONA VIRUS, COVID- 19, IN HUMAN SERUM, PLASMA AND WHOLE BLOOD.
2843	MFG/IVD/2020/000029	1.License Holder Name: HLL LIFECARE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:CORONAVIRUS (COVID-19) IGG/IGM ANTIBODY DETECTION KIT(MAKESURE)-CORONAVIRUS (COVID-19) IGG/IGM ANTIBODY DETECTION KITS AS A QUALITATIVE LATERAL FLOW TEST DEVICE FOR THE DETECTION OF COVID-19 IN HUMAN WHOLE BLOOD/SERUM / PLASMA
2844	MFG/IVD/2020/000030	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:SARS-COV2 RT PCR KIT (NA)-KIT USED FOR THE DETECTION OF NUCLEIC ACID RNA OF NOVEL CORONAVIRUS 2019-NCOV IN HUMAN SPECIMENS SUCH AS NASOPHARYNGEAL SWABS, THROAT SWAB, NASOPHARYNGEAL SECRETION ETC

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2845	MFG/IVD/2020/000031	1.License Holder Name: PERFEXN CHEM SCIENCE MFD PRIVATE LTD 2.Approving Authority: NASHIK DIVISION 3.Device Name(Brand Name)-Intended Use:HEMOGLOBIN TEST KIT-ESTIMATION OF HEMOGLOBIN IN BLOOD,LYSE-ESTIMATION OF HEMOGL;OBIN AND WBC COUNTING ON BLOOD CELL COUNTER, ALT/SGPT TEST KIT-ESTIMATION OF GPT IN SERUM OR PLASMA, DILUENT-WHOLE BLOOD COUNTING ON HEMATOLOGY ANALYSER, HDL CHOLESTEROL (PRECIPITANT) TEST KIT-ESTIMATION OF HDL CHOLESTEROL IN SERUM OR PLASMA,RINSE / CLEANER-CLEANING & RINSING OF BLOOD CELL COUNTER,TOTAL CHOLESTEROL TEST KIT-TO ESTIMATE CHOLESTEROL IN PLASMA OR SERUM SAMPLE,CK -NAC TEST KIT-ESTIMATION OF CK NAC IN SERUM OR PLASMA,ALBUMIN TEST KIT-TO ESTIMATE ALBUMIN IN BLOOD OR SERUM SAMPLE, GLUCOSE TEST KIT-TO ESTIMATE GLUCOSE CONTENT IN PLASMA, SERUM SAMPLE,TRIGLYCERIDES TEST KIT-TO ESTIMATE TRIGLYCERIDES IN PLASMA OR SERUM SAMPLE.,AST/ SGOT TEST KIT-ESTIMATION OF GOT IN SERUM OR PLASMA,E Z CLEANER-CLEANING OF BLOOD CELL COUNTER BATH AND FLUIDIC PATH, SODIUM TEST KIT-ESTIMATION OF SODIUM IN SERUM ,MICROPROTEIN TEST KIT-ESTIMATION OF MICROPROTEIN IN SERUM OR PLASMA, BILIRUBIN (TOTAL) TEST KIT-ESTIMATION OF BILIRUBIN TOTAL IN PLASMA OR SERUM SAMPLE,CHOLINESTERASE TEST KIT-ESTIMATION OF CHOLINESTERASE ACTIVITY IN SERUM OR PLASMA SAMPLE,PHOSPHORUS TEST KIT-ESTIMATION OR PHOSPHORUS IN PLASMA OR SERUM SAMPLE,UREA (GLDH-UV) KINETIC TEST KIT-ESTIMATION OF UREA IN PLASMA & SERUM,CALCIUM (ARSENAZO) TEST KIT-ESTIMATION OF CALCIUM IN SERUM SAMPLE.,CALCIUM (OCPC) TEST KIT-ESTIMATION OF CALCIUM IN SERUM SAMPLE.,URIC ACID TEST KIT-TO ESTIMATE URIC ACID IN SERUM OR PLASMA SAMPLE,AMYLASE TEST KIT-ESTIMATION OF AMYLASE IN SERUM OR PLASMA SAMPLE,LDL CHOLESTEROL (DIRECT) TEST KIT-ESTIMATION OF LDL CHOLESTEROL IN PLASMA, SERUM SAMPLE.,HDL CHOLESTEROL (DIRECT) TEST KIT-ESTIMATION OF HDL CHOLESTEROL IN SERUM OR PLASMA SAMPLE,GAMMA GT TEST KIT-ESTIMATION OF GAMMA GT IN PLAMA , SERUM SAMPLE,ALKALINE PHOSPHATASE TEST KIT-TO ESTIMATE ACTIVITY OF ALKALINE PHOSPHATASE IN PLASMA OR SERUM SAMPLE,CK -MB TEST KIT-ESTIMATION OF CK MB IN PLASMA OR SERUM,POTASSIUM TEST KIT-ESTIMATION OF POTASSIUM IN SERUM OR PLASMA SAMPLE, CREATININE TEST KIT-TO ESTIMATE CREATININE IN SERUM OR PLASMA OR URINE SAMPLE,UREA (MODIFIED BERTHELOT) TEST KIT-ESTIMATION UREA IN SERUM OR PLAMA,BILIRUBIN (TOTAL & DIRECT) TEST KIT-ESTIMATION OF TOTAL & DIRECT BILIRUBIN IN PLASMA OR SERUM,CHLORIDE TEST KIT-ESTIMATION OF CHLORIDE IN PLASMA

		OR SERUM SAMPLE.,TOTAL PROTEIN TEST KIT-TO ESTIMATE TOTAL PROTEIN IN SERUM OR PLASMA SAMPLE.
2846	MFG/IVD/2020/000032	1.License Holder Name: IMMUNOSCIENCE INDIA PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:RAPID TEST FOR DETECTION OF NOVEL CORONAVIRUS (COVID-19) IGM/IGG ANTIBODIES-DEVICE & COMPONENTS.(IMMUNOQUICK)-IT IS RAPID, QUALITATIVE, IMMUNOCHROMATOGRAPHIC TEST FOR DETECTION OF IGM AND IGG ANTIBODIES TO COVID-19 VIRUS IN HUMAN SERUM/PLASMA/WHOLE BLOOD. THIS TEST IS FOR HEALTHCARE PROFESSIONAL USE ONLY.
2847	MFG/IVD/2020/000033	1.License Holder Name: M/S. MEDSOURCE OZONE BIOMEDICALS PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:COVID 19 IGG/IGM RAPID TEST(NA)-COVID 19 IGG/IGM TEST KIT IS A RAPID IMMUNOCHROMATOGRAPHY ASSAY USED FOR QUALITATIVE DETERMINATION OF IGG AND IGM ANTIBODIES TO 2019 NOVEL CORONAVIRUS IN HUMAN SERUM, PLASMA, OR WHOLE BLOOD.

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2848	MFG/IVD/2020/000034	1.License Holder Name: ATHENESE-DX PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:SYPHILIS AB ELISA KIT (TRUSTWELL)-THE TRUSTWELL SYPHILIS AB KIT IS A SOLID PHASE ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES (IGG, IGM, IGA) AGAINST TREPONEMA PALLIDUM (TP) IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR PROFESSIONAL USE ONLY AS AN AID IN THE DIAGNOSIS OF INFECTION WITH TP.,DNA/RNA COMPLETE EXTRACTION KIT(ARIDIA)-THE ARIDIA DNA/RNA COMPLETE EXTRACTION SPIN COLUMN KIT USES KNOWN TECHNOLOGY FOR SIMULTANEOUS PURIFICATION OF VIRAL DNA AND RNA FROM A WIDE VARIETY OF SAMPLES. ARIDIA DNA/RNA COMPLETE EXTRACTION SPIN COLUMN KIT IS ESPECIALLY DESIGNED TO PROVIDE HIGH YIELDS OF DNA/RNA FROM BLOOD, SERUM, PLASMA & CELL CULTURE, VTM.,COVID-19 REAL TIME PCR DETECTION KIT(ARIDIA)-ARIDIA COVID-19 REAL TIME PCR DETECTION KIT IS DESIGNED FOR THE SPECIFIC IDENTIFICATION AND DIFFERENTIATION OF 2019 NOVEL CORONAVIRUS (SARS-COV-2) IN RESPIRATORY SAMPLES FROM PATIENTS WITH SIGNS AND SYMPTOMS OF COVID-19 INFECTION. THIS TEST IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF SARS-COV-2 IN COMBINATION WITH CLINICAL AND EPIDEMIOLOGICAL RISK FACTORS. RNA IS EXTRACTED FROM RESPIRATORY SPECIMENS, AMPLIFIED USING RT-PCR AND DETECTED USING FLUORESCENT REPORTER DYE PROBES SPECIFIC FOR SARS-COV-2.,VIRAL DNA/RNA EXTRACTION KIT(ARIDIA)-THE ARIDIA VIRAL DNA/RNA EXTRACTION KIT IS INTENDED FOR RAPIDLY EXTRACTING VIRAL RNA/DNA FROM SERUM AND OTHER LIQUID SAMPLES.,D-DIMER CONTROL KIT(TRUECHEMIE)-TRUECHEMIE D-DIMER CONTROL KIT IS INTENDED FOR IN VITRO USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE ACCURACY AND THE PRECISION OF LABORATORY TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT.,DENGUE AG (NS1) ELISA KIT(TRUSTWELL)-THE DENGUE AG (NS1) ELISA IS A SOLID-PHASE ENZYME-LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN (DEN1, 2, 3, 4) IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR PROFESSIONAL USE ONLY AS AN AID IN THE DIAGNOSIS OF AN ACUTE INFECTION WITH DENGUE VIRUSES.,COVID-19 IGG ELISA KIT(TRUSTWELL)-THE TRUSTWELL COVID-19 IGG ELISA KIT IS A SOLID PHASE ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF COVID-19 IGG ANTIBODIES IN HUMAN SERUM OR PLASMA. ,D-DIMER TEST KIT(TRUECHEMIE)-TRUECHEMIE D-DIMER IS INTENDED FOR IN VITRO USE AS AN ASSAYED D-DIMER IN SERUM OF LABORATORY

		TESTING PROCEDURES FOR THE ANALYTES LISTED IN THIS PACKAGE INSERT.,COVID-19 AB RAPID TEST(TRUSTLINE)-THE TRUSTLINE COVID-19 AB RAPID TEST IS A SINGLE USE LATERAL FLOW IMMUNOASSAY RAPID TEST INTENDED FOR QUALITATIVE DETECTION OF ANTI-SARS-COV-2 ANTIBODIES IN HUMAN SERUM AND PLASMA OR WHOLE BLOOD CONTAINING EDTA, HEPARIN OR CITRATE ANTI-COAGULANTS. THE TRUSTLINE COVID-19 AB RAPID TEST IS INTENDED FOR USE AS AN AID IN IDENTIFYING INDIVIDUALS WITH AN ADAPTIVE IMMUNE RESPONSE TO SARS-COV-2 INFECTION.
2849	MFG/IVD/2020/000035	1.License Holder Name: HLL BIOTECH LIMITED, INTEGRATED VACCINE COMPLEX 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM KIT 1(VIRO-TRANSIT KIT 1)-FOR COLLECTION AND TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING VIRUSES FOR NASAL AND NASOPHARYNGEAL SAMPLING.FROM COLLECTION CENTER TO LABORATORY,VIRAL TRANSPORT MEDIUM KIT 3(VIRO-TRANSIT KIT 3)-FOR COLLECTION AND TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING VIRUSES FOR NASO-PHARYNGEAL AND THROAT SAMPLING FROM COLLECTION CENTER TO LABORATORY,VIRAL TRANSPORT MEDIUM KIT 2(VIRO-TRANSIT KIT 2)-FOR COLLECTION AND TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING VIRUSES FOR TRACHEAL SAMPLING FROM COLLECTION CENTER TO LABORATORY

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2850	MFG/IVD/2020/000037	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:AMMONIA TEST REAGENT KIT (BY KINETIC METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA AMMONIA TEST REAGENT KIT (BY KINETIC METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN PLASMA., VIRAL TRANSPORT MEDIUM KIT(VISURE TRANSPORT KIT)-FOR COLLECTION & TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING VIRUSES FROM COLLECTION CENTER TO LABORATORY., FERRITIN TEST REAGENT KIT (BY TURBILATEX METHOD) (CLINREACT ITA)-CLINREACT ITA FERRITIN TEST REAGENT KIT (BY TURBILATEX METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM BY SPECTROPHOTOMETRY.,-GLUTAMYL TRANSFERASE (GAMMA-GT) TEST REAGENT KIT (BY IFCC METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA -GLUTAMYL TRANSFERASE (GAMMA-GT) TEST REAGENT KIT (BY IFCC METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF GAMMA GLUTAMYLTRANSFERASE ACTIVITY IN SERUM, PLASMA OR URINE SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER., DILUENT REAGENT FOR HEMATOLOGY ANALYZER (CELLENIUM 5DR) (DILUCEL 5DR™)-DILUCEL 5DR™ DILUENT IS A BUFFERED, STABILIZED AND MICROFILTERED ELECTROLYTE SOLUTION FOR AUTOMATED DILUTION OF HUMAN BLOOD SAMPLES, QUANTITATIVE AND QUALITATIVE DETERMINATION OF ERYTHROCYTES (RBC), LEUKOCYTES (WBC) AND THE LEUKOCYTE SUBPOPULATIONS, THROMBOCYTES (PLT) AND MEASUREMENT OF HEMOGLOBIN (HGB) CONCENTRATION ON THREE PART HEMATOLOGY ANALYZERS. (CELLENIUM 5D RETIC & CELLENIUM 5D). DILUCEL 5DR™ DILUENT SHOULD BE USED WITH ONLY RINCEL 5DR™ AND LYCEL 5DR™ REAGENTS,C-REACTIVE PROTEIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA C-REACTIVE PROTEIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF C REACTIVE PROTEIN (CRP) IN HUMAN SERUM OR PLASMA, SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYSER.,RHEUMATOID FACTORS TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER (CLINREACT SYPA)-CLINREACT SYPA RHEUMATOID FACTORS TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN HUMAN SERUM., ALKALINE PHOSPHATASE TEST REAGENT KIT (BY IFCC METHOD) FOR

	NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA ALKALINE PHOSPHATASE TEST REAGENT KIT (BY IFCC METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALKALINE PHOSPHATASE ACTIVITY IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYSER.,ALBUMIN TEST REAGENT (BY BCG METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA ALBUMIN TEST REAGENT (BY BCG METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALBUMIN CONCENTRATIONS IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYSER.,RETIC STAINING REAGENT TUBE FOR HEMATOLOGY ANALYZER (CELLENIUM 5DR)(RETIC 5DR™)-THE RETIC STAINING REAGENT TUBE IS INTENDED TO BE USED FOR STAINING THE RETICULOCYTE (RETIC) IN HUMAN BLOOD, SO AS TO OBSERVE THEIR MORPHOLOGY AND STRUCTURE, AND MAKES THE HEMATOLOGY ANALYZERS TO COUNT THE BLOOD CELLS.,ENZYMATIC CREATININE TEST REAGENT KIT (BY ENZYMATIC METHOD) FOR NANOLAB 200 ANALYZER (CLINREACT SYPA)-CLINREACT SYPA ENZYMATIC CREATININE TEST REAGENT KIT (BY ENZYMATIC METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM OR URINE, SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYSER.,CLEANING REAGENT FOR HEMATOLOGY ANALAYZER (CELLENIUM 5DR)(RINCEL 5DR™)-RINCEL 5DR™ CLEANING REAGENT IS A STABILIZED AND MICROFILTERED DETERGENT SOLUTION FOR REGULAR AUTOMATED CLEANING, RINSING AND WASHING OF HEMATOLOGY ANALYZERS' CAPILLARIES, TUBING AND CHAMBERS, REMOVING BLOOD COMPONENT PRECIPITATES AND LIPOPROTEIN DEPOSITS ON THREE PART HEMATOLOGY ANALYZERS(CELLENIUM 5D RETIC & CELLENIUM 5D). RINCEL 5DR™ CLEANING REAGENT SHOULD BE USED WITH ONLY DILUCEL 5DR™ AND LYCEL 5DR™ REAGENTS.,AMMONIA TEST REAGENT KIT (BY KINETIC METHOD) FOR NANOLAB 200 ANALYZER (CLINREACT SYPA)-CLINREACT SYPA AMMONIA TEST REAGENT KIT (BY KINETIC METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN PLASMA.,HBA1C TEST REAGENT KIT (BY TURBILATEX METHOD) (CLINREACT ITA)-CLINREACT ITA HBA1C TEST REAGENT KIT (BY TURBILATEX METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE HBA1C IN THE HUMAN BLOOD BY SPECTROPHOTOMETRY.,ADENOSINE DEAMINASE TEST REAGENT KIT (BY PNP-XOD METHOD)(CLINREACT™)-CLINREACT™ ADENOSINE DEAMINASE TEST REAGENT KIT (BY PNP-XOD METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ADENOSINE

	DEAMINASE IN HUMAN SERUM BY SPECTROPHOTOMETRY., ENZYMATIC CREATININE TEST REAGENT KIT (BY ENZYMATIC METHOD) (CLINREACT™)-CLINREACT™ ENZYMATIC CREATININE TEST REAGENT KIT (BY ENZYMATIC METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM OR URINE BY SPECTROPHOTOMETRY.,CALCIUM TEST REAGENT (BY ARSENAZO III METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA CALCIUM TEST REAGENT (BY ARSENAZO III METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF CALCIUM CONCENTRATIONS IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER.,-AMYLASE TEST REAGENT (BY DIRECT METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA -AMYLASE TEST REAGENT (BY DIRECT METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF -AMYLASE CONCENTRATIONS IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER.,URIC ACID REAGENT TEST KIT BY AOX METHOD (CLINREACT™)-CLINREACT™ URIC ACID (AOX) KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF URIC ACID CONCENTRATIONS IN SERUM OR PLASMA SAMPLES BY SPECTROPHOTOMETRY.,TOTAL PROTEIN REAGENT TEST KIT BY BIURET METHOD(CLINREACT™)-CLINREACT™ TOTAL PROTEIN (BIURET) KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF TOTAL PROTEIN CONCENTRATION IN SERUM OR PLASMA SAMPLES BY SPECTROPHOTOMETRY., BILIRUBIN TOTAL TEST REAGENT KIT (BY DIAZO METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA BILIRUBIN TOTAL TEST REAGENT KIT (BY DIAZO METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF TOTAL BILIRUBIN IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER.,C-REACTIVE PROTEIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA C-REACTIVE PROTEIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF CREACTIVE PROTEIN (CRP) IN HUMAN SERUM OR PLASMA, SPECIFICALLY FOR USE WITH NANOLAB 500 ANALYSER., ANTI-STREPTOLYSIN O TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER (CLINREACT SYPA)-CLINREACT SYPA ANTI-STREPTOLYSIN O TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN O (ASO) IN HUMAN SERUM OR PLASMA.,TRIGLYCERIDES REAGENT TEST KIT BY GPO/PAP METHOD(CLINREACT™)-CLINREACT™

	TRIGLYCERIDES (GPO/PAP) KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF TRIGLYCERIDES CONCENTRATIONS IN SERUM OR PLASMA SAMPLES BY SPECTROPHOTOMETRY.,ANTI-STREPTOLYSIN O TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA ANTI-STREPTOLYSIN O TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN O (ASO) IN HUMAN SERUM OR PLASMA.,MAGNESIUM TEST REAGENT (BY XYLIDYL BLUE METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREAC SYPA MAGNESIUM TEST REAGENT (BY XYLIDYL BLUE METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM AND PLASMA.,CHOLESTEROL TEST REAGENT (BY CHOD/POD METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA CHOLESTEROL TEST REAGENT (BY CHOD/POD METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF TOTAL CHOLESTEROL CONCENTRATIONS IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 500 ANALYZER,HDL CHOLESTEROL TEST KIT (BY DIRECT METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA HDL CHOLESTEROL TEST KIT (BY DIRECT METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HDL CHOLESTEROL CONCENTRATIONS IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 500 ANALYZER.,C-REACTIVE PROTEIN TEST REAGENT KIT (BY TURBILATEX METHOD)(CLINREACT ITA)-CLINREACT ITA C-REACTIVE PROTEIN TEST REAGENT KIT (BY TURBILATEX METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM OR PLASMA BY SPECTROPHOTOMETRY.,MICROALBUMIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA MICROALBUMIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE TURBIDIMETRIC TEST FOR THE MEASUREMENT OF MICROALBUMIN IN HUMAN URINE, SPECIFICALLY FOR USE WITH NANOLAB 500 ANALYSER.,HBA1C TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER (CLINREACT SYPA)-CLINREACT SYPA HBA1C TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE HBA1C IN THE HUMAN BLOOD BY SPECTROPHOTOMETRY, SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYSER., MICROALBUMIN TEST REAGENT KIT (BY TURBILATEX METHOD)

	(CLINREACT ITA)-CLINREACT ITA MICROALBUMIN TEST REAGENT KIT (BY TURBILATEX METHOD) IS INTENDED FOR THE QUANTITATIVE TURBIDIMETRIC TEST FOR THE MEASUREMENT OF MICROALBUMIN IN HUMAN URINE BY SPECTROPHOTOMETRY.,SODIUM TEST KIT (BY END POINT METHOD)(CLINREACT™)-CLINREACT™ SODIUM TEST REAGENT KIT (BY END POINT METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF SODIUM IN HUMAN SERUM BY SPECTROPHOTOMETRY.,D-DIMER TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA D-DIMER TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN SERUM, SPECIFICALLY USED FOR NANOLAB 200 ANALYZER, POTASSIUM TEST KIT (BY END POINT METHOD)(CLINREACT™)-CLINREACT™ POTASSIUM TEST REAGENT KIT (BY END POINT METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF POTASSIUM IN HUMAN SERUM BY SPECTROPHOTOMETRY., ADENOSINE DEAMINASE TEST REAGENT KIT (BY PNP-XOD METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA ADENOSINE DEAMINASE TEST REAGENT KIT (BY PNP-XOD METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ADENOSINE DEAMINASE IN HUMAN SERUM SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER,FERRITIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA FERRITIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM, SPECIFICALLY USED FOR NANOLAB 200 ANALYZER,ENZYMATIC CREATININE TEST REAGENT KIT (BY ENZYMATIC METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA ENZYMATIC CREATININE TEST REAGENT KIT (BY ENZYMATIC METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM OR URINE, SPECIFICALLY USED FOR NANOLAB 500 ANALYSER.,LIPASE TEST REAGENT KIT (BY METHYL RESORUFIN METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA LIPASE TEST REAGENT KIT (BY METHYL RESORUFIN METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF LIPASE IN SERUM OR PLASMA SPECIFICALLY USED FOR NANOLAB 200 ANALYZER.,LYSING REAGENT FOR HEMATOLOGY ANALYZER (CELLENIUM 5DR)(LYCEL 5DR™)-LYCEL 5DR™ LYSING REAGENT IS A STABILIZED AND MICRO-FILTERED LYSING AGENT FOR STROMATOLYSIS OF ERYTHTROCYTES (RBC), FOR QUANTITATIVE DETERMINATION OF LEUKOCYTES (WBC),

	LEUKOCYTE THREE-PART DIFFERENTIATION (LYM, MID, GRAN) AND HEMOGLOBIN (HGB) CONCENTRATION MEASUREMENT IN HUMAN BLOOD ON THREE PART HEMATOLOGY ANALYZERS(CELLENIUM 21 5D RETIC & CELLENIUM 5D). LYCEL 5DR™ LYSING REAGENT SHOULD BE USED WITH ONLY DILUCEL 5DR™ AND RINCEL 5DR™ REAGENTS, SHEATH REAGENT FOR HEMATOLOGY ANALYZER (CELLENIUM 5DR) (SHEATH 5DR™)-SHEATH IS A BUFFER SOLUTION THAT ALLOWS CELLS TO FLOW UNIFORMLY AND AVOID AGGREGATION. ITS OSMOTIC CONCENTRATION AND IONIC STRENGTH KEEPS THE INTEGRITY AND THE VOLUME OF WBCS. IT LYSES THE RBCS TO FORM GHOST CELLS WHICH WOULD NOT SCATTER THE LASER LIGHT TO AVOID AFFECTING WBC MEASUREMENT. SHEATH SPHERIZES WBCS AND OPTIMIZES THEIR SCATTERING PROPERTY. IT ALSO HAS HUMIDIFYING EFFECT TO PREVENT ACCUMULATION OF AIR BUBBLES IN WOC FLOW SYSTEM ON FIVE PART HEMATOLOGY ANALYZERS. (CELLENIUM 5D RETIC & CELLENIUM 5D).,PHOSPHORUS TEST REAGENT (BY UV METHOD) FOR NANOLAB 200 ANALYZER (CLINREACT SYPA)-CLINREACT SYPA PHOSPHORUS TEST REAGENT (BY UV METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF PHOSPHORUS CONCENTRATIONS IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER.,CREATININE TEST REAGENT KIT (BY ALKALINE PICRATE METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA CREATININE TEST REAGENT KIT (BY ALKALINE PICRATE METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF CREATININE CONCENTRATIONS IN SERUM, PLASMA OR URINE SAMPLES SPECIFICALLY FOR USE WITH FOR NANOLAB 200 ANALYZER,ALBUMIN TEST REAGENT (BY BCG METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA ALBUMIN TEST REAGENT (BY BCG METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALBUMIN CONCENTRATIONS IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 500 ANALYZER.,-GLUTAMYL TRANSFERASE (GAMMA-GT) TEST REAGENT KIT (BY IFCC METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA -GLUTAMYL TRANSFERASE (GAMMA-GT) TEST REAGENT KIT (BY IFCC METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF GAMMA GLUTAMYLTRANSFERASE ACTIVITY IN SERUM, PLASMA OR URINE SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 500 ANALYZER., ALKALINE PHOSPHATASE TEST REAGENT KIT (BY IFCC METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA ALKALINE PHOSPHATASE TEST REAGENT KIT (BY IFCC METHOD) FOR

	NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALKALINE PHOSPHATASE ACTIVITY IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 500 ANALYSER.,-AMYLASE TEST REAGENT (BY DIRECT METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA -AMYLASE TEST REAGENT (BY DIRECT METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF -AMYLASE CONCENTRATIONS IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 500 ANALYZER.,BILIRUBIN TOTAL TEST REAGENT KIT (BY DIAZO METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA BILIRUBIN TOTAL TEST REAGENT KIT (BY DIAZO METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF TOTAL BILIRUBIN IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 500 ANALYZER.,TOTAL PROTEIN TEST REAGENT (BY BIURET METHOD) FOR NANOLAB 200 ANALYZER (CLINREACT SYPA)-CLINREACT SYPA TOTAL PROTEIN TEST REAGENT (BY BIURET METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF TOTAL PROTEIN CONCENTRATION IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER.,ANTI-STREPTOLYSIN O TEST REAGENT KIT (BY TURBILATEX METHOD) (CLINREACT ITA)-CLINREACT ITA ANTI-STREPTOLYSIN O TEST REAGENT KIT (BY TURBILATEX METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN O (ASO) IN HUMAN SERUM OR PLASMA BY SPECTROPHOTOMETRY., CHOLESTEROL TEST REAGENT (BY CHOD/POD METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA CHOLESTEROL TEST REAGENT (BY CHOD/POD METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF TOTAL CHOLESTEROL CONCENTRATIONS IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER,URINE PROTEIN TEST KIT (BY PYROGALLOL RED METHOD) FOR NANOLAB 200 ANALYZER (CLINREACT SYPA)-CLINREACT SYPA URINE PROTEIN TEST KIT (BY PYROGALLOL RED METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF PROTEIN CONCENTRATION IN URINE SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER.,SGPT/ALT TEST REAGENT KIT (BY IFCC METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA SGPT/ALT TEST REAGENT KIT (BY IFCC METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALANINE AMINOTRANSFERASE (GPT) IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER.,

	TRIGLYCERIDES TEST REAGENT (BY GPO/PAP METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA TRIGLYCERIDES TEST REAGENT (BY GPO/PAP METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF TRIGLYCERIDES CONCENTRATIONS IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER.,SODIUM TEST KIT (BY END POINT METHOD) (CLINREACT™)-CLINREACT™ SODIUM TEST REAGENT KIT (BY END POINT METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF SODIUM IN HUMAN SERUM BY SPECTROPHOTOMETRY.,LIPASE TEST REAGENT KIT (BY METHYL RESORUFIN METHOD)(CLINREACT™)-CLINREACT™ LIPASE TEST REAGENT KIT (BY METHYL RESORUFIN METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF LIPASE IN SERUM OR PLASMA BY SPECTROPHOTOMETRY.,HDL CHOLESTEROL REAGENT TEST KIT BY DIRECT METHOD(CLINREACT™)-CLINREACT™ HDL CHOLESTEROL KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HDL CHOLESTEROL CONCENTRATIONS IN SERUM OR PLASMA SAMPLES BY SPECTROPHOTOMETRY.,UREA REAGENT TEST KIT BY GLDH METHOD(CLINREACT™)-CLINREACT™ UREA (GLDH) KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF UREA CONCENTRATION IN SERUM OR PLASMA BY SPECTROPHOTOMETRY.,ALBUMIN REAGENT TEST KIT BY BCG METHOD(CLINREACT™)-CLINREACT™ ALBUMIN (BCG) KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ALBUMIN CONCENTRATIONS IN SERUM OR PLASMA SAMPLES BY SPECTROPHOTOMETRY.,POTASSIUM TEST KIT (BY END POINT METHOD)(CLINREACT™)-CLINREACT™ POTASSIUM TEST REAGENT KIT (BY END POINT METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF POTASSIUM IN HUMAN SERUM BY SPECTROPHOTOMETRY.,HDL CHOLESTEROL TEST KIT (BY DIRECT METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA HDL CHOLESTEROL TEST KIT (BY DIRECT METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF HDL CHOLESTEROL CONCENTRATIONS IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER.,CHOLESTEROL REAGENT TEST KIT BY CHOD/POD METHOD(CLINREACT™)-CLINREACT™ CHOLESTEROL (CHOD/POD) KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF TOTAL CHOLESTEROL CONCENTRATIONS IN SERUM OR PLASMA SAMPLES BY SPECTROPHOTOMETRY.,LDL CHOLESTEROL TEST KIT (BY DIRECT METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA LDL CHOLESTEROL TEST KIT (BY DIRECT METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE

	MEASUREMENT OF LDL CHOLESTEROL CONCENTRATION IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER,SGOT/AST TEST REAGENT KIT (BY IFCC METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA SGOT/AST TEST REAGENT KIT (BY IFCC METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF ASPARTATE AMINOTRANSFERASE (ASAT/AST) IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER.,LDH-P TEST REAGENT KIT (BY P L METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA LDH-P TEST REAGENT KIT (BY P L METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF LACTATE DEHYDROGENASE (LDH) CONCENTRATION IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER.,D-DIMER TEST REAGENT KIT (BY TURBILATEX METHOD) (CLINREACT ITA)-CLINREACT ITA D-DIMER TEST REAGENT KIT (BY TURBILATEX METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN SERUM BY SPECTROPHOTOMETRY.,MAGNESIUM TEST REAGENT (BY XYLIDYL BLUE METHOD) FOR NANOLAB 200 ANALYZER (CLINREACT SYPA)-CLINREACT SYPA MAGNESIUM TEST REAGENT (BY XYLIDYL BLUE METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM AND PLASMA.,URIC ACID TEST REAGENT (BY AOX METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA URIC ACID TEST REAGENT (BY AOX METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF URIC ACID CONCENTRATIONS IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER.,BILIRUBIN TOTAL REAGENT TEST KIT BY DIAZO METHOD(CLINREACT™)-CLINREACT™ BILIRUBIN TOTAL (DIAZO) KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF TOTAL BILIRUBIN IN SERUM OR PLASMA SAMPLES BY SPECTROPHOTOMETRY.,UREA TEST REAGENT KIT (BY GLDH-UV METHOD) FOR NANOLAB 200 ANALYZER (CLINREACT SYPA)-CLINREACT SYPA UREA TEST REAGENT KIT (BY GLDH-UV METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF UREA CONCENTRATION IN SERUM OR PLASMA SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER.,RHEUMATOID FACTORS TEST REAGENT KIT (BY TURBILATEX METHOD)(CLINREACT ITA)-CLINREACT ITA RHEUMATOID FACTORS TEST REAGENT KIT (BY TURBILATEX METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN HUMAN SERUM BY SPECTROPHOTOMETRY.,GLUCOSE TEST REAGENT (BY GOD/POD

	METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA GLUCOSE TEST REAGENT (BY GOD/POD METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE CONCENTRATION IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 500 ANALYZER.,BILIRUBIN DIRECT TEST REAGENT KIT (BY DIAZO METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA BILIRUBIN DIRECT TEST REAGENT KIT (BY DIAZO METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF CONJUGATED (DIRECT) BILIRUBIN IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 500 ANALYZER.,LIPASE TEST REAGENT KIT (BY METHYL RESORUFIN METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA LIPASE TEST REAGENT KIT (BY METHYL RESORUFIN METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF LIPASE SERUM OR PLASMA, SPECIFICALLY USED FOR NANOLAB 500 ANALYZER., MICROALBUMIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA MICROALBUMIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE TURBIDIMETRIC TEST FOR THE MEASUREMENT OF MICROALBUMIN IN HUMAN URINE, SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYSER.,GLUCOSE TEST REAGENT (BY GOD/POD METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA GLUCOSE TEST REAGENT (BY GOD/POD METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE CONCENTRATION IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER,HBA1C TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER (CLINREACT SYPA)-CLINREACT SYPA HBA1C TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF THE HBA1C IN THE HUMAN BLOOD BY SPECTROPHOTOMETRY, SPECIFICALLY FOR USE WITH NANOLAB 500 ANALYSER.,FERRITIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA FERRITIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM SPECIFICALLY USED FOR NANOLAB 500 ANALYZER,CREATININE TEST REAGENT KIT (BY ALKALINE PICRATE METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA) -CLINREACT SYPA CREATININE TEST REAGENT KIT (BY ALKALINE PICRATE METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR

	THE QUANTITATIVE MEASUREMENT OF CREATININE CONCENTRATIONS IN SERUM, PLASMA OR URINE SAMPLES SPECIFICALLY FOR USE WITH FOR NANOLAB 500 ANALYZER, RHEUMATOID FACTORS TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA RHEUMATOID FACTORS TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN HUMAN SERUM.,VIRAL TRANSPORT MEDIUM KIT(VISURE ECO TRANSPORT KIT)-VISURE ECO TRANSPORT KIT IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES FROM THE COLLECTION SITE TO THE PROCESSING LABORATORY.,D-DIMER TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA D-DIMER TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN SERUM, SPECIFICALLY USED FOR NANOLAB 500 ANALYZER.,BILIRUBIN DIRECT TEST REAGENT KIT (BY DIAZO METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA BILIRUBIN DIRECT TEST REAGENT KIT (BY DIAZO METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF CONJUGATED (DIRECT) BILIRUBIN IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYZER.,BILIRUBIN DIRECT REAGENT TEST KIT BY DIAZO METHOD(CLINREACT™)-CLINREACT™BILIRUBIN DIRECT (DIAZO) KIT IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF CONJUGATED (DIRECT) BILIRUBIN IN SERUM OR PLASMA SAMPLES BY SPECTROPHOTOMETRY., CALCIUM TEST REAGENT (BY ARSENAZO III METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA CALCIUM TEST REAGENT (BY ARSENAZO III METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE MEASUREMENT OF CALCIUM CONCENTRATIONS IN SERUM OR PLASMA SAMPLES SPECIFICALLY FOR USE WITH NANOLAB 500 ANALYZER.,ADENOSINE DEAMINASE TEST REAGENT KIT (BY PNP-XOD METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA ADENOSINE DEAMINASE TEST REAGENT KIT (BY PNP-XOD METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF ADENOSINE DEAMINASE IN HUMAN SERUM SPECIFICALLY USED FOR NANOLAB 500 ANALYZER

2851	MFG/IVD/2020/000038	1.License Holder Name: ATHENESE-DX PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:HCV IGG ELISA KIT (TRUSTWELL)-THE HCV IGG ELISA KIT IS A SOLID PHASE ENZYME LINKED IMMUNOABSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF IGG TO HEPATITIS C VIRUS (HCV) IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR PROFESSIONAL USE ONLY AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HCV. ANY REACTIVE SPECIMEN WITH THE HCV IGG ELISA KIT MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS.,HBSAG ELISA KIT(TRUSTWELL)-THE HBSAG ELISA KIT IS A SOLID PHASE ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF HEPATITIS B VIRUS SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR PROFESSIONAL USE ONLY AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HBV. ANY REACTIVE SPECIMEN WITH THE HBSAG ELISA KIT MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS,HIV AG-AB ELISA KIT(TRUSTWELL)-THE HIV AG-AB ELISA KIT IS A SOLID PHASE ENZYME LINKED IMMUNOABSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF HIV-1 P24 ANTIGEN, ANTI-HIV-1 INCLUDING SUBTYPE O AND ANTI-HIV-2 ANTIBODIES (INCLUDING ISOTYPE IGG, IGM AND IGA) IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR PROFESSIONAL USE ONLY AS AN AID IN THE EARLY IDENTIFICATION OF INFECTION WITH HIV-1 AND HIV-2 VIRUSES. ANY REACTIVE SPECIMEN WITH THE HIV AG-AB ELISA KIT MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS,HIV 1+2 AB ELISA KIT(TRUSTWELL)-THE HIV 1+2 AB ELISA KIT IS A SOLID PHASE ENZYME LINKED IMMUNOABSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF ANTI-HIV-1 INCLUDING SUBTYPE O AND ANTI-HIV-2 ANTIBODIES (INCLUDING ISOTYPE IGG, IGM AND IGA) IN HUMAN SERUM OR PLASMA. IT IS INTENDED FOR PROFESSIONAL USE ONLY AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HIV-1 AND HIV-2 VIRUSES. ANY REACTIVE SPECIMEN WITH THE HIV 1+2 AB ELISA KIT MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS.

2852	MFG/IVD/2020/000039	1.License Holder Name: ALPINE BIOMEDICALS PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ONE STEP NOVEL CORONAVIRUS (COVID-19) ANTIGEN RAPID TEST KIT(ALPINE ONE STEP NOVEL CORONAVIRUS (COVID-19) ANTIGEN RAPID TEST KIT)-ALPINE ONE STEP NOVEL CORONAVIRUS (COVID-19) ANTIGEN KIT IS A RAPID AND CONVENIENT IMMUNO- CHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF COVID-19 ANTIGEN (VIRAL NUCLEOPROTEIN) FROM NASAL SWAB, NASOPHARYNGEAL SWAB OBTAINED FROM PATIENT WITH SIGNS AND SYMPTOMS OF RESPIRATORY INFECTION. THE DEVICE IS DESIGNED TO AID IN THE RAPID DIFFERENTIAL DIAGNOSIS OF COVID-19 VIRUS INFECTION, NOVEL CORONAVIRUS (COVID-19) IGG/IGM ANTIBODY DETECTION RAPID TEST KIT(ALPINE LET'S CONFIRM IT)-COVID-19 ANTIBODY IGG/IGM KIT WILL BE A RAPID, QUALITATIVE AND CONVENIENT IMMUNOCHROMATOGRAPHIC IN VITRO ASSAY FOR THE DIFFERENTIAL DETECTION OF IGM & IGG ANTIBODIES TO COVID-19 VIRUS IN HUMAN SERUM, PLASMA AND/OR WHOLE BLOOD SAMPLES OBTAINED FROM PATIENT WITH SIGNS AND SYMPTOMS OF RESPIRATORY INFECTION. THE DEVICE IS DESIGNED TO AID IN THE RAPID DIFFERENTIAL DIAGNOSIS OF COVID-19 VIRUS INFECTION
2853	MFG/IVD/2020/000040	1.License Holder Name: HUWEL LIFESCIENCES PVT LTD 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:QUANTIPLUS CORONA VIRUS (COVID-19) DETECTION KIT VER 2.0(QUANTIPLUS)-QUANTIPLUS@ CORONAVIRUS (COVID 19) REAL TIME RT-PCR KIT IS USED FOR THE QUALITATIVE DETECTION OF A NOVEL CORONAVIRUS, WHICH WAS IDENTIFIED IN 2019 AT WUHAN CITY, HUBEI PROVINCE, CHINA, IN UPPER RESPIRATORY TRACT SPECIMENS (NASOPHARYNGEAL EXTRACTS, DEEP COUGH SPUTUM, ETC.) AND LOWER RESPIRATORY TRACT SPECIMENS (ALVEOLI IRRIGATION FLUID, ETC.) BY REAL TIME PCR SYSTEMS.

2854	MFG/IVD/2020/000041	1.License Holder Name: LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:COVID-19 NEUTRALIZING ANTIBODY ELISA KIT-THE COVID-19 NEUTRALIZING ANTIBODY ELISA KIT CAN DETECT CIRCULATING NEUTRALIZING ANTIBODIES AGAINST SARS-COV-2 THAT BLOCK THE INTERACTION BETWEEN THE RECEPTOR BINDING DOMAIN OF THE VIRAL SPIKE GLYCOPROTEIN (RBD) WITH THE ACE2 CELL SURFACE RECEPTOR. THE ASSAY DETECTS ANY ANTIBODIES IN SERUM AND PLASMA THAT NEUTRALIZE THE RBD- ACE2 INTERACTION. THE TEST IS BOTH SPECIES AND ISOTYPE INDEPENDENT. FOR IN VITRO DIAGNOSTIC USE ONLY. ,BLOOD GROUPING SERA ANTI-D (IGG + IGM)(ACCUCARE ANTI-D (IGG + IGM))-ANTI-D IGG/IGM IS DESIGNED FOR IN VITRO DIAGNOSTIC AND PROFESSIONAL USE ONLY. IT IS INTENDED FOR DETECTION OF RHESUS D ANTIGEN AND WEAK DU HUMAN RED BLOOD CELLS.,D-DIMER ASSAY KIT-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN SERUM., BLOOD GROUPING SERA ANTI-A(ACCUCARE ANTI-A (IGM))-¬ANTI-A IS MONOCLONAL ANTIBODY OF IGM TYPE SPECIFIC AGAINST RED BLOOD ANTIGENS A. THE MONOCLONAL TEST REAGENTS ARE USED TO DETERMINE THE ANTIGENS OF THE ABO BLOOD GROUP SYSTEM BY AGGLUTINATION OF HUMAN RED BLOOD CELLS.,BLOOD GROUPING SERA ANTI-B(ACCUCARE ANTI-B (IGM))-ANTI-B IS MONOCLONAL ANTIBODY OF IGM TYPE SPECIFIC AGAINST RED BLOOD ANTIGENS B. THE MONOCLONAL TEST REAGENTS ARE USED TO DETERMINE THE ANTIGENS OF THE ABO BLOOD GROUP SYSTEM BY AGGLUTINATION OF HUMAN RED BLOOD CELLS.,BLOOD GROUPING SERA ANTI-AB(ACCUCARE ANTI-AB)-ANTI-AB IS MONOCLONAL ANTIBODY OF IGM TYPE SPECIFIC AGAINST RED BLOOD ANTIGENS A AND B. THE MONOCLONAL TEST REAGENTS ARE USED TO DETERMINE THE ANTIGENS OF THE ABO BLOOD GROUP SYSTEM BY AGGLUTINATION OF HUMAN RED BLOOD CELLS.,NOVEL CORONAVIRUS (2019-NCOV) RT-PCR KIT (ACCUCARE NOVEL CORONAVIRUS (2019-NCOV) RT-PCR KIT)-NOVEL CORONAVIRUS (2019-NCOV) RT-PCR KIT IS DESIGNED TO DETECT COVID-19 USING REAL TIME PCR. THE RESULTS CAN BE USED TO ASSIST DIAGNOSIS OF PATIENTS WITH COVID-19 INFECTION, AND PROVIDE MOLECULAR DIAGNOSTIC BASIS FOR INFECTED PATIENTS.,HIV 1/2 RAPID CARD/STRIP TEST-ONE STEP RAPID CARD TEST FOR DETECTION AND SUBTYPING OF ANTIBODY TO HUMAN IMMUNODEFICIENCY VIRUS-1 AND/OR VIRUS-2 IN WHOLE BLOOD/SERUM/PLASMA,HEPATITIS C VIRUS ANTIBODY RAPID CARD / STRIP TEST-ONE STEP RAPID CARD TEST FOR DETECTION OF ANTIBODY AGAINST HEPATITIS C VIRUS IN

		WHOLE BLOOD/SERUM/PLASMA,COVID-19 ANTIGEN LATERAL FLOW TEST DEVICE-COVID-19 ANTIGEN LATERAL FLOW TEST DEVICE IS USED AS AN AID FOR THE DETECTION OF NOVEL COVID-19 VIRUS IN NASAL AND THROAT SWAB SPECIMENS, AS AN AID IN THE DIAGNOSIS OF INFECTION WITH CORONA VIRUS,NOVEL CORONAVIRUS COVID-19 IGG ELISA KIT-THE ACCUCARE NOVEL CORONAVIRUS COVID-19 IGG ELISA KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF HUMAN ANTI-COVID- 19 IGG ANTIBODY IN HUMAN SERUM/PLASMA. ANY REACTIVE SPECIMEN WITH THE ACCUCARE NOVEL CORONAVIRUS COVID-19 IGG ELISA KIT MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S).,HEPATITIS B SURFACE ANTIGEN RAPID CARD / STRIP TEST-ONE STEP RAPID CARD TEST FOR DETECTION OF HEPATITIS B (HBSAG) IN HUMAN WHOLE BLOOD/SERUM/PLASMA, COVID-19 IGG / IGM LATERAL FLOW ASSAY TEST KIT(ACCUCARE COVID-19 IGG / IGM AB CARD TEST)-ONE STEP RAPID CARD TEST FOR DETECTION OF IGG AND IGM ANTIBODIES AGAINST CORONAVIRUS IN HUMAN SERUM / PLASMA / WHOLE BLOOD,DIRECT AND INDIRECT COOMB'S TEST (AHG)(ACCUCARE AHG COOMB'S SERA)-DIRECT AND INDIRECT COOMB'S SERA (AHG) IS INTENDED FOR QUALITATIVE DETERMINATION OF HUMAN ANTI-IGG AND ANTI-C3 ON RED BLOOD CELLS. FOR IN VITRO DIAGNOSTIC TEST USE ONLY.
2855	MFG/IVD/2020/000042	1.License Holder Name: NULIFE, D- 118, SECTOR 7, GAUTAM BUDDHA NAGAR, UTTAR PRADESH, 201301, INDIA 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:COVID-19 ANTIGEN RAPID TEST(ABCHEK COVID-19 ANTIGEN RAPID TEST KIT)-ABCHEK COVID-19 ANTIGEN TEST IS A RAPID AND CONVENIENT IMMUNO-CHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF COVID-19 ANTIGEN (VIRAL NUCLEOPROTEIN) FROM NASOPHARYNGEAL SWAB OBTAINED FROM PATIENT WITH SIGNS AND SYMPTOMS OF RESPIRATORY INFECTION. THE DEVICE IS DESIGNED TO AID IN THE RAPID DIFFERENTIAL DIAGNOSIS OF COVID-19 VIRUS INFECTION. THIS ASSAY IS NOT INTENDED TO BE USED FOR SCREENING PATIENTS OR AS AN AID FOR DIAGNOSIS OF PATIENTS WITH SUSPECTED COVID-19 AG INFECTION, THIS ASSAY IS NOT INTENDED FOR HOME TESTING (OR SELF-TESTING).THE TEST RESULTS SHOULD BE CONFIRMED BY REAL-TIME REVERSE TRANSCRIPTASE (RT)-PCR DIAGNOSTIC KIT; THEY DO NOT PRECLUDE COVID-19 VIRUS INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISIONS. THE TEST IS INTENDED FOR PROFESSIONAL AND LABORATORY USE.

2856	MFG/IVD/2020/000042	1.License Holder Name: NULIFE, D-22 & 118, SECTOR 7, GAUTAM BUDDHA NAGAR, UTTAR PRADESH, 201301, INDIA 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:COVID-19 IGM/IGG ANTIBODY RAPID TEST(ABCHEK COVID-19 IGM/IGG ANTIBODY RAPID TEST)-ONE STEP NOVEL CORONA VIRUS (COVID-19) ANTIBODY KIT IS A RAPID, QUALITATIVE AND CONVENIENT IMMUNOCHROMATOGRAPHIC IN VITRO ASSAY FOR THE DIFFERENTIAL DETECTION OF IGM & IGG ANTIBODIES TO COVID-19 VIRUS IN HUMAN SERUM, PLASMA AND/OR WHOLE BLOOD SAMPLES OBTAINED FROM PATIENT WITH SIGNS AND SYMPTOMS OF RESPIRATORY INFECTION. THE DEVICE IS DESIGNED TO AID IN THE RAPID DIFFERENTIAL DIAGNOSIS OF COVID-19 VIRUS INFECTION. THIS ASSAY ONLY PROVIDES A PRELIMINARY RESULT. POSITIVE RESULTS SHOULD BE CONFIRMED BY REAL-TIME REVERSE TRANSCRIPTASE (RT)-PCR DIAGNOSTIC KIT; THEY DO NOT PRECLUDE COVID-19 VIRUS INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISIONS. THE TEST IS INTENDED FOR PROFESSIONAL AND LABORATORY USE. , COVID-19 IGM/IGG ANTIBODY RAPID TEST(COVIWOK RAPID)-ONE STEP NOVEL CORONA VIRUS (COVID-19) ANTIBODY KIT IS A RAPID, QUALITATIVE AND CONVENIENT IMMUNOCHROMATOGRAPHIC IN VITRO ASSAY FOR THE DIFFERENTIAL DETECTION OF IGM & IGG ANTIBODIES TO COVID-19 VIRUS IN HUMAN SERUM, PLASMA AND/OR WHOLE BLOOD SAMPLES OBTAINED FROM PATIENT WITH SIGNS AND SYMPTOMS OF RESPIRATORY INFECTION. THE DEVICE IS DESIGNED TO AID IN THE RAPID DIFFERENTIAL DIAGNOSIS OF COVID-19 VIRUS INFECTION. THIS ASSAY ONLY PROVIDES A PRELIMINARY RESULT. POSITIVE RESULTS SHOULD BE CONFIRMED BY REAL-TIME REVERSE TRANSCRIPTASE (RT)-PCR DIAGNOSTIC KIT; THEY DO NOT PRECLUDE COVID-19 VIRUS INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISIONS. THE TEST IS INTENDED FOR PROFESSIONAL AND LABORATORY USE.

2857	MFG/IVD/2020/000043	1.License Holder Name: ZEPHYR BIOMEDICALS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: SUB ZONAL GOA 3.Device Name(Brand Name)-Intended Use:RAPID DOUBLE ANTIGEN SCREENING TEST FOR THE DETECTION OF IGM / IGG / IGA ANTIBODIES TO COVID-19 IN HUMAN SERUM/ PLASMA/ WHOLE BLOOD(COVISCREEN)-COVISCREEN IS AN INVITRO, RAPID, SELF PERFORMING, QUALITATIVE, DOUBLE ANTIGEN SANDWICH IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION OF TOTAL ANTIBODIES (IGM+IGG+IGA) TO SARS-COV-2 VIRUS IN SERUM, PLASMA AND WHOLE BLOOD. IT IS TO BE USED FOR SCREENING OR TO AID IN THE DIAGNOSIS OF COVID-19 DISEASE AND EXPOSURE TO THE VIRUS. DOUBLE ANTIGEN SANDWICH ASSAYS ARE ALSO KNOWN TO DETECT THE ANTIGEN SPECIFIC IGA ISOTYPE ANTIBODIES AND CONTRIBUTE TO DETECT THE SEROCONVERSION IN PATIENTS SAMPLES EARLIER AS COMPARED TO THE OTHER TESTS AS DETECTION OF TOTAL ANTIBODIES (IGM+IGG+IGA) IS POSSIBLE., RAPID TEST FOR DETECTION OF SARS-COV-2 ANTIGEN IN HUMAN NASOPHARYNGEAL SWAB SPECIMENS (DEVICE)(COVIRAT (DEVICE))-COVIRAT IS AN INVITRO, RAPID, QUALITATIVE IMMUNOASSAY FOR THE DETECTION OF NUCLEOCAPSID PROTEIN ANTIGENS EXPRESSED BY THE SARS-COV-2 VIRUS PRESENT IN HUMAN NASOPHARYNGEAL SWAB AND NASAL SWAB SPECIMENS. IT IS TO BE USED FOR SCREENING OR TO AID IN THE DIAGNOSIS OF COVID-19 DISEASE. THIS RAPID ANTIGEN DETECTION TEST TAKES 15-30 MINUTES FOR PRODUCING A POSITIVE OR NEGATIVE TEST RESULT. POSITIVE RESULTS INDICATE THE PRESENCE OF VIRAL ANTIGENS, BUT CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE INFECTION STATUS. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. THE RESULT OF THIS TEST SHOULD NOT BE THE SOLE BASIS FOR THE DIAGNOSIS. PRESUMPTIVE POSITIVE OR NEGATIVE RESULT MAY NEED TO BE FURTHER CONFIRMED WITH A MOLECULAR TEST. ,RAPID TEST FOR MALARIA PAN (DEVICE)(PARABANK DEVICE)-PARABANK IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY UTILIZING WHOLE BLOOD FOR THE DETECTION OF PAN SPECIFIC PLDH.,RAPID TEST FOR MALARIA PAN (DIPSTICK)(PARABANK DIPSTICK)-PARABANK IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY UTILIZING WHOLE BLOOD FOR THE DETECTION OF PAN SPECIFIC PLDH.,ANTI-SARS CORONAVIRUS

	COVID-19 IGG ELISA FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO SARS COV-2 IN HUMAN SERUM/PLASMA(QUALISA COVID 19 IGG ELISA)-THE QUALISA COVID IGG ELISA ASSAY IS INTENDED FOR THE QUALITATIVE IN-VITRO DETECTION OF NOVEL CORONAVIRUS INFECTED CASES. THE CASES ARE SCREENED BASED ON THE DETECTION OF HUMAN ANTIBODIES (IGG) SPECIFICALLY AGAINST NEW CORONAVIRUS (SARS-COV-2) IN SERUM/PLASMA SAMPLES FROM COVID-19 SUSPECTED/INFECTED PERSON. THE KIT IS FOR LABORATORY PROFESSIONAL USE OR HEALTH-CARE PROFESSIONALS,RAPID TEST FOR MALARIA PAN/PV/PF (DEVICE) (PARAMAX-3 DEVICE)-PARAMAX-3 IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY UTILIZING WHOLE BLOOD FOR THE DETECTION OF P.FALCIPARUM SPECIFIC HISTIDINE RICH PROTEIN-2 (PF. HRP-2), P.VIVAX SPECIFIC PLDH AND PAN MALARIA SPECIFIC PLDH.,RAPID TEST FOR MALARIA PAN/PF (DEVICE)(PARASCREEN DEVICE)-PARASCREEN IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY UTILIZING WHOLE BLOOD FOR THE DETECTION OF P.FALCIPARUM SPECIFIC HISTIDINE RICH PROTEIN-2 (PF. HRP-2) AND PAN MALARIA SPECIFIC PLDH.,RAPID TEST FOR MALARIA PV/PF (DEVICE)(FALCIVAX DEVICE)-FALCIVAX IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY UTILIZING WHOLE BLOOD FOR THE DETECTION OF P.FALCIPARUM SPECIFIC HISTIDINE RICH PROTEIN-2 (PF. HRP-2), P.VIVAX SPECIFIC PLDH., RAPID TEST FOR DETECTION OF SARS-COV-2 ANTIGEN IN HUMAN NASAL SWAB (NS) AND NASOPHARYNGEAL (NP) SWAB SPECIMENS (PERKINELMER COVID-19 ANTIGEN TEST (NS, NP))-PERKINELMER COVID-19 ANTIGEN TEST (NS, NP) IS AN INVITRO, RAPID, QUALITATIVE IMMUNOASSAY FOR THE DETECTION OF SPECIFIC ANTIGENS EXPRESSED BY THE SARS-COV-2 VIRUS PRESENT IN HUMAN NASOPHARYNGEAL SWAB AND NASAL SWAB SPECIMENS. IT IS TO BE USED FOR SCREENING OR TO AID IN THE DIAGNOSIS OF COVID-19 DISEASE AND EXPOSURE TO THE VIRUS. THIS RAPID ANTIGEN DETECTION TEST TAKES 20-30 MINUTES FOR PRODUCING A POSITIVE OR NEGATIVE TEST RESULT. POSITIVE RESULTS INDICATE THE PRESENCE OF VIRAL ANTIGENS, BUT CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE INFECTION STATUS. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. THE RESULT OF THIS TEST SHOULD NOT BE THE SOLE BASIS FOR THE DIAGNOSIS. PRESUMPTIVE POSITIVE OR NEGATIVE RESULT WITH THE RAPID ANTIGEN. TEST MAY NEED TO BE FURTHER

		CONFIRMED WITH A MOLECULAR TEST, AS NEEDED.
2858	MFG/IVD/2020/000044	1.License Holder Name: MICROXPRESS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM KIT III(MICROXPRESS VIRAL TRANSPORT MEDIUM KIT III)-VIRAL TRANSPORT MEDIUM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. THIS DEVICE IS INCLUDES VIRAL TRANSPORT MEDIUM THAT IS ROOM TEMPERATURE STABLE AND CAN SUSTAIN VIABILITY OF ORGANISMS.,VIRAL LYSIS TRANSPORT MEDIUM(SAFESHIELD VIRAL LYSIS TRANSPORT MEDIUM)-SAFESHIELD-VLTM IS INTENDED FOR COLLECTION, INACTIVATION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES AND BACTERIA FROM THE COLLECTION SITE TO THE TESTING LABORATORY.
2859	MFG/IVD/2020/000045	1.License Holder Name: SIDAK LIFECARE PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:COVID 19 RT-PCR (SARS-COV-2 RNA)(SIDAK)-FOR DETECTION OF CORONA VIRUS,COVID-19 TEST DEVICE(SIDAK LIFECARE)-FOR DETECTION OF CORONA VIRUS, ANTIGEN TEST KIT (COVID 19)(SIDAK)-FOR DETECTION OF CORONA VIRUS

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2860	MFG/IVD/2020/000046	1.License Holder Name: ATHENESE-DX PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:MALARIA PF/PV AG RAPID TEST(TRUSTLINE)-THE TRUSTLINE MALARIA PF/PV AG RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF PLASMODIUM FALCIPARUM (PF) AND VIVAX (PV) ANTIGEN IN HUMAN BLOOD SPECIMEN. THIS DEVICE IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH PLASMODIUM. ANY REACTIVE SPECIMEN WITH THE TRUSTLINE MALARIA PF/PV AG RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS,COVID-19 AG RAPID TEST(TRUSTLINE)-THE TRUSTLINE COVID-19 AG RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID ANTIGENS IN NASOPHARYNGEAL (NP) SWAB SPECIMENS FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19. THIS TEST IS AN AID TO EARLY DIAGNOSIS OF SARS-COV-2 INFECTION ALONG WITH CLINICAL SYMPTOMS AND OTHER CONFIRMATORY ASSAYS.,HIV 1/2 AB RAPID TEST(TRUSTLINE)-THE TRUSTLINE HIV 1/2 AB RAPID TEST IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS AND A RAPID, QUALITATIVE, SCREENING LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION & DIFFERENTIATION OF HIV-1 & HIV-2 ANTIBODIES (IGG, IGM, IGA) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST KIT IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. ANY REACTIVE SPECIMEN WITH THE TRUSTLINE HIV 1/2 AB RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) SUCH AS ELISA, WESTERN BLOT ASSAY OR PCR AND CLINICAL FINDINGS.,SYPHILIS AB RAPID TEST(TRUSTLINE)-THE TRUSTLINE SYPHILIS AB RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES (IGG, IGM AND IGA) TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM OR PLASMA. IT IS INTENDED TO BE USED BY HEALTHCARE PROFESSIONALS AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH TP. THE TEST IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. ANY REACTIVE SPECIMEN WITH THE TRUSTLINE SYPHILIS AB RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS,HIV-AB/AG 4TH GEN RAPID TEST(TRUSTLINE)-THE TRUSTLINE HIV - AB/AG 4TH GEN RAPID TEST IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS AND A RAPID, QUALITATIVE, SCREENING LATERAL FLOW

	CHROMATOGRAPHIC IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION & DIFFERENTIATION OF HIV-1 & HIV-2 ANTIBODIES (IGG, IGM, IGA) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST KIT IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. ANY REACTIVE SPECIMEN WITH THE TRUSTLINE HIV-AB/AG 4TH GEN RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) SUCH AS ELISA, WESTERN BLOT ASSAY OR PCR AND CLINICAL FINDINGS,SYPHILIS AB RAPID TEST - DIP STRIP(TRUSTLINE)-THE TRUSTLINE SYPHILIS AB RAPID TEST - DIP STRIP IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES (IGG, IGM AND IGA) TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM OR PLASMA. IT IS INTENDED TO BE USED BY HEALTHCARE PROFESSIONALS AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH TP. THE TEST IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. ANY REACTIVE SPECIMEN WITH THE TRUSTLINE SYPHILIS AB RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS., MALARIA PF/PAN AG RAPID TEST(TRUSTLINE)-THE TRUSTLINE MALARIA PF/PAN AG RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF PLASMODIUM FALCIPARUM (PF) AND P.VIVAX (PV),P.OVALE (PO), OR P.MALARIAE (PM) ANTIGENS IN HUMAN BLOOD SPECIMEN. THIS DEVICE IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH PLASMODIUM. ANY REACTIVE SPECIMEN WITH THE TRUSTLINE MALARIA PF/PAN AG RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS, HBSAG RAPID TEST(TRUSTLINE)-THE TRUSTLINE HBSAG RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OR PLASMA AT LEVEL EQUAL TO OR HIGHER THAN 0.5 NG/ML. IT IS INTENDED TO BE USED BY HEALTHCARE PROFESSIONALS AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HBSAG. THE TEST KIT IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. ANY REACTIVE SPECIMEN WITH THE TRUSTLINE HBSAG RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS,HCV AB RAPID TEST (TRUSTLINE)-THE TRUSTLINE HCV AB RAPID TEST IS A DOUBLE ANTIGEN LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTI-HEPATITIS C VIRUS ANTIBODIES (IGG, IGM, IGA) IN HUMAN SERUM OR PLASMA. IT IS INTENDED TO BE USED BY HEALTHCARE PROFESSIONALS AS A

		SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HCV. THE TEST KIT IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. ANY REACTIVE SPECIMEN WITH THE TRUSTLINE HCV AB RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS.
2861	MFG/IVD/2020/000047	1.License Holder Name: ORCHID BIOMEDICAL SYSTEMS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE TEST STRIP(BIOSENSE SYNC)-BIOSENSE SYNS BLOOD GLUCOSE TEST STRIPS IS USED WITH BLOOD GLUCOSE METER TO MEASURE GLUCOSE LEVELS IN WHOLE BLOOD.,RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF IGM ANTIBODIES TO HEV IN HUMAN SERUM/PLASMA(INSIGHT HEV IGM (DEVICE))-INSIGHT HEV IGM IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF IGM ANTOBODIES TO HEPATITIS E VIRUS IN HUMAN SERUM/PLASMA,ONE STEP TEST FOR DETECTION OF HCG IN URINE/ SERUM (DEVICE)(GRAVICHECK (DEVICE))-GRAVICHECK ONE STEP PREGNANCY TEST IS A RAPID, SELF PERFORMANCE, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) A MARKER FOR PREGNANCY, IN URINE/ SERUM SPECIMENS., RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF IGM ANTIBODIES TO HAV IN HUMAN SERUM/PLASMA(INSIGHT HAV IGM (DEVICE))-INSIGHT HAV IGM IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF IGM ANTOBODIES TO HEPATITIS A VIRUS IN HUMAN SERUM/PLASMA,HEMOGLOBIN TEST STRIPS FOR QUANTITATIVE MEASUREMENT OF HEMOGLOBIN IN CAPILLARY AND VENOUS WHOLE BLOOD(HBCHEK)-HBCHEK TEST STRIP IS USED WITH HBCHECK METER FOR QUANTITATIVE MEASUREMENT OF HEMOGLOBIN IN CAPILLARY AND VENOUS WHOLE BLOOD.,ONE STEP PREGNANCY TEST (DIPSTICK)(CLUE DIPSTICK)-CLUE ONE STEP PREGNANCY TEST IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG), A MARKER FOR PREGNANCY IN URINE SPECIMENS.,ONE STEP PREGNANCY TEST (DEVICE)(CLUE DEVICE)-CLUE ONE STEP PREGNANCY TEST IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG), A MARKER FOR PREGNANCY IN URINE SPECIMEN.

2862	MFG/IVD/2020/000048	1.License Holder Name: RECOMBIGEN LABORATORIES PVT LTD 2.Approving Authority: NORTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM(GENERIC)-VIRAL TRANSPORT MEDIUM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSED, CHLAMYDIAE,MYCOPLASMAS OR UREAPLASMA AND OTHERS FROM THE COLLECTION SITE TO THE TESTING LABORATORY.
2863	MFG/IVD/2020/000049	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:NUCLEIC ACID EXTRACTION KIT(Q-LINE)-THE EXPRESS NUCLEIC ACID EXTRACTION TUBE IS FOR PRETREATMENT OF SPECIMENS AND TO RELEASE TARGETED NUCLEIC ACID (DNA/RNA) FROM VARIOUS TYPES OF SPECIMENS FOR DETECTION.,VIRAL TRANSPORT KIT(Q-LINE)-Q-LINE VIRAL TRANSPORT KIT IS SPECIALLY DESIGNED TRANSPORT SYSTEM TO COLLECT AND TRANSPORT VIRUSES IN AN ACTIVE FORM TO THE LABORATORY FOR ITS ISOLATION AND IDENTIFICATION. IT IS DESIGNED TO MAINTAIN THE VIABILITY AND THE VIRULENCE OF THE VIRAL SAMPLES.
2864	MFG/IVD/2020/000050	1.License Holder Name: HELINI BIOMOLECULES 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:HELINI CORONAVIRUS [COVID-19] REAL-TIME PCR KIT(HELINI)-THE HELINI CORONAVIRUS [COVID-19] REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF NOVEL 2019 CORONAVIRUS SPECIFIC RNA.
2865	MFG/IVD/2020/000051	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM KIT(VISURE TRANSPORT KIT)-FOR COLLECTION & TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING VIRUSES FOR NASAL & NASOPHARYNGEAL SAMPLING FROM COLLECTION CENTER TO LABORATORY.

2866	MFG/IVD/2020/000052	1.License Holder Name: LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM(ACCUVIRAL TRANSPORT KIT)-VIRAL TRANSPORT MEDIUM IS A SPECIALLY DESIGNED TRANSPORT SYSTEM TO COLLECT AND TRANSPORT VIRUSES IN AN ACTIVE FORM TO THE LABORATORY FOR ISOLATION. IT IS DESIGNED TO MAINTAIN THE VIABILITY AND THE VIRULENCE OF THE VIRAL SAMPLE. FOR IN VITRO DIAGNOSTICS TEST ONLY.

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2867	MFG/IVD/2020/000053	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:COVID KAVACH ANTI-SARS COV-2 HUMAN IGG ELISA KIT(COVID KAVACH ANTI-SARS COV-2 HUMAN IGG ELISA KIT)-COVID KAVACH ANTI-SARS COV-2 HUMAN IGG ELISA KIT FOR IN VITRO DIAGNOSTICS, A SENSITIVE ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF IGG ANTIBODIES TO NOVEL COVID – 19 (SARS- COV-2 VIRUS) IN HUMAN SERUM OR PLASMA SAMPLES TO IDENTIFY E INFECTED UNITS OF BLOOD AND FOR CLINICAL DIAGNOSTIC TESTING., COVIDSURE PRO MULTIPLEX RT PCR KIT(COVIDSURE PRO MULTIPLEX RT PCR KIT)-COVIDSURE PRO MULTIPLEX RT PCR KIT IS DEVELOPED FOR THE RAPID DETECTION OF COVIDSURE PRO VIRAL INFECTION BY SIMULTANEOUS TARGETING OF THREE MAJOR GENES ORF 1AB, ENVELOPE (E), AND NUCLEOCAPSID (N). THE KIT ALSO INCLUDES AN INTERNAL CONTROL TO INSURE SUCCESSFUL EXTRACTION AND AMPLIFICATION OF VIRAL RNA.,D-DIMER TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA D-DIMER TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN SERUM, SPECIFICALLY USED FOR NANOLAB 200 ANALYZER,HBSAG ELISA KIT(HBSAG ELISA KIT, LABSYSTEMS DIAGNOSTICS)-HBSAG ELISA KIT IS AN IN VITRO DIAGNOSTICS QUALITATIVE IMMUNOASSAY FOR THE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OR PLASMA. THE KIT IS BASICALLY INTENDED TO SCREEN BLOOD DONATION SAMPLES TO IDENTIFY AND ELIMINATE THE INFECTED UNITS OF BLOOD AND FOR CLINICAL DIAGNOSTIC TESTING.,BIOCARD PRO COVID-19 RAPID ANTIGEN TEST KIT (BIOCARD PRO COVID-19 RAPID ANTIGEN TEST KIT)-BIOCARD PRO COVID-19 RAPID ANTIGEN TEST KIT IS AN IN VITRO DIAGNOSTIC MEDICAL DEVICE BASED ON IMMUNO-CHROMATOGRAPHIC ASSAY (ICA) FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIGEN IN HUMAN NASOPHARYNGEAL SPECIMENS.,COVIDSURE MULTIPLEX REALTIME RT-PCR KIT (COVIDSURE MULTIPLEX REALTIME RT-PCR KIT)-THE COVIDSURE MULTIPLEX REALTIME RT-PCR KIT, IS AN OPEN PLATFORM, QUALITATIVE, RT-PCR TEST, INTENDED TO BE USED FOR IN VITRO DETECTION OF SARS-COV-2 (COVID-19) IN RESPIRATORY SPECIMENS (NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, OROPHARYNGEAL WASH, SPUTUM, ENDOTRACHEAL ASPIRATE, BRONCHOALVEOLAR LAVAGE ETC.) OF SUSPECTED CASES OF COVID-19 DISEASE.,D-DIMER TEST REAGENT KIT (BY TURBILATEX

	METHOD)(CLINREACT ITA)-CLINREACT ITA D-DIMER TEST REAGENT KIT (BY TURBILATEX METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN SERUM BY SPECTROPHOTOMETRY,COVID SCREEN PLUS ELISA KIT(COVID SCREEN PLUS ELISA KIT)-A SENSITIVE ENZYME LINKED IMMUNOSORBENT ASSAY FOR THE QUALITATIVE DETECTION OF IGG, IGM, IGA ANTIBODIES TO NOVEL COVID – 19 (SARS- COV-2 VIRUS) IN HUMAN SERUM OR PLASMA THE KIT IS BASICALLY INTENDED TO SCREEN SAMPLES TO IDENTIFY THE INFECTED UNITS OF BLOOD AND FOR CLINICAL DIAGNOSTIC TESTING.,C-REACTIVE PROTEIN TEST REAGENT KIT (BY TURBILATEX METHOD)(CLINREACT ITA)-CLINREACT ITA C-REACTIVE PROTEIN TEST REAGENT KIT (BY TURBILATEX METHOD) IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM OR PLASMA BY SPECTROPHOTOMETRY.,HIV 1&2 ELISA KIT(HIV 1&2 ELISA KIT, LABSYSTEM DIAGNOSTICS)-HIV 1&2 ELISA KIT IS AN 3RD GENERATION IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO HIV-1 AND HIV-2 IN HUMAN SERUM OR PLASMA. THE KIT IS BASICALLY INTENDED TO SCREEN BLOOD DONATION SAMPLES TO IDENTIFY AND ELIMINATE THE INFECTED UNITS OF BLOOD AND FOR CLINICAL DIAGNOSTIC TESTING.,C-REACTIVE PROTEIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA C-REACTIVE PROTEIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 200 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF C REACTIVE PROTEIN (CRP) IN HUMAN SERUM OR PLASMA, SPECIFICALLY FOR USE WITH NANOLAB 200 ANALYSER.,RNA EXTRACTION KIT(RNASURE RNA EXTRACTION KIT)-RNASURE CORONA VIRUS (SARS-COV-2) RNA EXTRACTION KIT IS INTENDED FOR MOLECULAR BIOLOGY APPLICATIONS. ALL DUE CARE AND ATTENTION SHOULD BE EXERCISED IN THE HANDLING OF THE PRODUCTS.,D-DIMER TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA D-DIMER TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN SERUM, SPECIFICALLY USED FOR NANOLAB 500 ANALYZER.,HBSAG LATERAL FLOW ASSAY KIT IN HUMAN SERUM/PLASMA.(BIOCARDTM HEPATITIS B SURFACE ANTIGEN LATERAL FLOW ASSAY KIT IN HUMAN SERUM/PLASMA.)-BIOCARDTM HBSAG RAPID TEST IS A, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE VISUAL DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN SERUM OR PLASMA. IT IS USED AS AN AID IN THE DIAGNOSIS OF HEPATITIS B INFECTION. THE BIOCARDTM HBSAG TEST IS BASED ON

	THE PRINCIPLE OF SANDWICH IMMUNOCHROMATOGRAPHIC ASSAY FOR DETERMINATION OF HBSAG IN SERUM OR PLASMA. THIS ONE STEP TEST IS VERY SENSITIVE AND ONLY TAKES 5-20 MINUTES. TEST RESULTS CAN BE READ VISUALLY WITHOUT ANY INSTRUMENT.,C-REACTIVE PROTEIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER(CLINREACT SYPA)-CLINREACT SYPA C-REACTIVE PROTEIN TEST REAGENT KIT (BY TURBILATEX METHOD) FOR NANOLAB 500 ANALYZER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF CREACTIVE PROTEIN (CRP) IN HUMAN SERUM OR PLASMA, SPECIFICALLY FOR USE WITH NANOLAB 500 ANALYSER., NEOSCREEN HTSH EIA (ENZYME IMMUNOASSAY) KIT(NEOSCREEN HTSH EIA KIT, LABSYSTEM DIAGNOSTICS)-THIS NEOSCREEN HTSH EIA (ENZYME IMMUNOASSAY) KIT IS FOR THE QUANTITATIVE DETERMINATION OF HUMAN THYROTROPIN (HTSH) IN BLOOD SPECIMENS DRIED ON FILTER PAPER AS A PRIMARY TEST FOR SCREENING OF BABIES FOR CONGENITAL HYPOTHYROIDISM (CH). MONITORING OF L-THYROXINE REPLACEMENT THERAPY CAN ALSO BE PERFORMED USING THIS TEST, ESPECIALLY IN CASES WHEN TRANSPORTATION OF SERUM SAMPLES TO THE LABORATORY IS DIFFICULT.,NEOSCREEN 17 OHP EIA (ENZYME IMMUNOASSAY) KIT (NEOSCREEN 17OHP EIA (ENZYME IMMUNOASSAY) KIT, LABSYSTEM DIAGNOSTICS)-ENZYME IMMUNOASSAY FOR THE DETERMINATION OF HUMAN 17-HYDROXYPROGESTERONE FROM BLOOD SAMPLES DRIED ON FILTER PAPER.,NEOSCREEN GALACTOSE KIT(NEOSCREEN GALACTOSE KIT, LABSYSTEM DIAGNOSTICS)-ENZYME IMMUNOASSAY FOR THE DETERMINATION OF GALACTOSE FROM BLOOD SPECIMENS DRIED ON FILTER PAPER. ,HIV AG-AB ELISA KIT (HIV AG-AB ELISA KIT, LABSYSTEM DIAGNOSTICS)-HIV AG-AB ELISA KIT IS AN 4TH GENERATION IN VITRO DIAGNOSTIC IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIGENS & ANTIBODIES TO HIV-1, HIV-1 & AG-P24 GROUP O, AND HIV-2 IN HUMAN SERUM OR PLASMA. THE KIT IS BASICALLY INTENDED TO SCREEN BLOOD DONATION SAMPLES TO IDENTIFY AND ELIMINATE THE INFECTED UNITS OF BLOOD AND FOR CLINICAL DIAGNOSTIC TESTING., NEOSCREEN G6PD KIT(GLUCOSE-6-PHOSPHATE DEHYDROGENASE) (NEOSCREEN G6PD KIT, LABSYSTEM DIAGNOSTICS)-ENZYME IMMUNOASSAY FOR THE DETERMINATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE FROM BLOOD SPECIMENS DRIED ON FILTER PAPER. ,HCV ELISA KIT(HCV ELISA KIT, LABSYSTEM DIAGNOSTICS)-HCV ELISA KIT FOR IN VITRO DIAGNOSTICS QUALITATIVE IMMUNOASSAY FOR THE DETECTION OF ANTIBODIES AGAINST HCV (ANTI-HCVS) IN HUMAN SERUM OR PLASMA. THE KIT IS BASICALLY INTENDED TO SCREEN BLOOD DONATION SAMPLES TO IDENTIFY AND ELIMINATE THE INFECTED UNITS OF BLOOD AND FOR

		CLINICAL DIAGNOSTIC TESTING.,NEOSCREEN IRT (IMMUNOREACTIVE TRIPSINOGEN)EIA KIT (NEOSCREEN IRT EIA KIT, LABSYSTEM DIAGNOSTICS)-LABSYSTEM DIAGNOSTICS NEOSCREEN IRT EIA TEST IS A SIMPLE COMPETITION ENZYME IMMUNOASSAY ENABLING THE QUANTIFICATION OF IMMUNOREACTIVE TRYPSINOGEN PRESENT IN BLOOD SAMPLES DRIED ON FILTER PAPER.
2868	MFG/IVD/2020/000054	1.License Holder Name: MICROMASTER LABS PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:VIRO-MASTER VIRAL TRANSPORT MEDIUM (TM006NT) WITH NYLON FLOCKED NASOPHARYNGEAL & OROPHARYNGEAL SWABS, WITH BREAKABLE POINT (VIROMASTER)-THE VIRO-MASTER VIRAL TRANSPORT MEDIUM WITH NYLON FLOCKED SWAB IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMA OR UREAPLASMA FROM THE COLLECTION SITE TO THE TESTING LABORATORY.
2869	MFG/IVD/2020/000055	1.License Holder Name: AGAPPE DIAGNOSTICS LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:PREFILLED VIRAL RNA EXTRACTION KIT (ACM AUTO)-THIS READY TO USE REAGENT IS INTENDED FOR ISOLATION AND PURIFICATION OF VIRAL RNA FROM SAMPLES COLLECTED IN VIRAL TRANSPORT MEDIUM(VTM). ,RNA ISOLATION KIT(AGAPPE CHITRA MAGNA)-FOR RNA ISOLATION IN DETECTION OF COVID 19 AND OTHER INFECTIOUS DISEASE .,AG-Q COVID-19 N ANTIGEN RAPID DIAGNOSTIC TEST KIT-AG-Q COVID-19 N-ANTIGEN RAPID TEST IS A LATERAL FLOW IMMUNOCHROMATOGRAPHY ASSAY SPECIFICALLY DETECTING THE NUCLEOCAPSID ANTIGEN OF THE NOVEL CORONAVIRUS, SARS-COV-2. THE KIT CAN BE USED FOR MASS SCREENING AND EARLY DIAGNOSIS OF COVID-19 DISEASE.,REAL TIME RT – LAMP COVID 19 TESTING KIT (COVID 19 TEST KIT - ISOTHERMAL AMPLIFICATION METHOD)(LUME SCREEN - NCOV)-REAL TIME DETECTION OF SARS-COV-2 RNA IN THE GIVEN SAMPLE FOR DIAGNOSIS OF COVID 19 INFECTION.

2870	MFG/IVD/2020/000056	1.License Holder Name: HIMEDIA LABORATORIES PVT LTD 2.Approving Authority: NASHIK DIVISION 3.Device Name(Brand Name)-Intended Use:VIRUS INACTIVATION MEDIUM(COVIDSAFE)-TO BE USED FOR SAMPLE COLLECTION AND TRANSPORT FOR COVID-19 SUSPECTED PATIENTS USE OF THIS MEDIUM ENABLES INACTIVATION OF VIRULENCE OF INFECTIOUS PARTICLES AT THE POINT OF COLLECTION, THEREBY ASSURING SAFE AND RISK-FREE HANDLING OF SUSPECTED SAMPLES.. ,INSTA Q SERIES(INSTA Q96® REAL-TIME PCR, INSTA Q96® PLUS REAL-TIME PCR, INSTA Q96® 6.0 REAL-TIME PCR, INSTA Q48® M2 REAL-TIME PCR, INSTA Q48® M4 REAL-TIME PCR)-RECOMMENDED FOR USE IN QUANTITATIVE REAL TIME PCR. IT ENABLES QPCR ANALYSIS OF NUCLEIC ACIDS TO FIND OUT UNKNOWN CONCENTRATIONS OF DNA/RNA IN A GIVEN SAMPLES BY CAPTURING THE FLUORESCENCE GENERATED BY DYES AND PROBES WHICH ARE CONVERTED INTO GRAPHICAL VALUES USING THE INSTAQ SOFTWARE,VIRAL TRANSPORT MEDIUM(HIVIRAL)-FOR COLLECTION AND TRANSPORTATION OF SAMPLES CONTAINING VIRUSES CHLAMYDIAE, MYCOPLASMA AND UREAPLASMA FROM THE COLLECTION SITE TO THE LABORATORY,SALINE GARGLE KIT(HIGARGLE)-FOR COLLECTION & TRANSPORTATION OF POTENTIALLY INFECTIOUS SALIVA SAMPLES CONTAINING SARS-COV-2 VIRUS (CORONA VIRUS) FROM THE COLLECTION SITE TO THE LABORATORY AND EXTRACTION OF RNA FOR RT-PCR TEST.,INSTANX(INSTA NX® MAG32 INSTA NX® MAG96)-THE INSTA NX® MAG 32 AND INSTA NX® MAG 96 ARE INTENDED FOR USE IN COMBINATION WITH EXTRACTIONS KITS TO PERFORM AUTOMATED PURIFICATION OF NUCLEIC ACIDS. THE NUCLEIC ACIDS PURIFIED USING THESE INSTRUMENTS ARE SUITABLE FOR DIRECT DOWNSTREAM ANALYSIS BY STANDARD AMPLIFICATION METHODS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2871	MFG/IVD/2020/000057	1.License Holder Name: CADILA HEALTHCARE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ANTI-SARS COV-2-IGG ANTIBODY DETECTION ELISA(ZYDX ANTI-SARS COV-2-IGG ANTIBODY DETECTION ELISA)-ANTI-SARS COV-2-IGG ANTIBODY DETECTION ELISA IS AN IN VITRO DIAGNOSTIC KIT FOR THE DETECTION OF ANTI-SARS COV-2 (COVID-19) VIRUS INFECTION IN HUMAN SERUM/PLASMA SAMPLES.,ANTI-SARS COV-2-IGG ANTIBODY DETECTION ELISA(COVID KAVACH)-ANTI-SARS COV-2-IGG ANTIBODY DETECTION ELISA IS AN IN VITRO DIAGNOSTIC KIT FOR THE DETECTION OF ANTI-SARS COV-2 (COVID-19) VIRUS INFECTION IN HUMAN SERUM/PLASMA SAMPLES.,SARS COV-2 ANTIGEN RAPID TEST(ZYCORAP)-SARS COV-2 ANTIGEN RAPID TEST IS AN IMMUNOCHROMATOGRAPHIC ASSAY KIT FOR THE QUALITATIVE DETECTION OF SARS COV-2 ANTIGEN IN HUMAN NASOPHARYNGEAL SWAB SPECIMENS.
2872	MFG/IVD/2020/000058	1.License Holder Name: BIOGENOMICS LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:REAL TIME PCR KIT FOR DETECTION ON COVID-19(BIOCOV-ID)-BIOCOV-ID REAL-TIME RT-PCR (RT-PCR) DETECTION KIT BY BIOGENOMICS LIMITED IS DESIGNED TO DETECT THE PRESENCE OF SARS-COV-2 CORONAVIRUS IN RESPIRATORY SPECIMENS AND SERUM SAMPLE. THE KIT IS DESIGNED AS PER RECOMMENDED CDC STANDARD GUIDELINES.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2873	MFG/IVD/2020/000059	1.License Holder Name: HELINI BIOMOLECULES 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:HELINI ENTEROVIRUS REAL TIME PCR KIT(HELINI)-THE HELINI ENTEROVIRUS REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF ENTEROVIRUS IN HUMAN BIOLOGICAL SAMPLES., HELINI NOROVIRUS I & II REAL TIME PCR KIT(HELINI)-THE HELINI NOROVIRUS 1 & II REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF NOROVIRUS GENOTYPES 1 & II IN HUMAN BIOLOGICAL SAMPLES.,HELINI DENGUE VIRUS GENOTYPING REAL TIME PCR KIT(HELINI)-THE HELINI DENGUE VIRUS GENOTYPING REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF DENGUE VIRUS GENOTYPES [1 TO 4] IN HUMAN BIOLOGICAL SAMPLES.,HELINI BACTERIAL DNA MINI SPIN PREP KIT(HELINI)-HELINI PUREFAST BACTERIAL DNA MINISPIN PREP KIT IS DESIGNED FOR RAPID AND COST-EFFECTIVE SMALL-SCALE PREPARATION OF HIGH QUALITY NUCLEIC ACID FROM BACTERIA AND HUMAN BIOLOGICAL SAMPLES., HELINI HLA-B27 REAL TIME PCR KIT(HELINI)-THE HELINI HLA-B27 REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF HLA-B27 GENOTYPES IN HUMAN BIOLOGICAL SAMPLES.,HELINI JEV REAL TIME PCR KIT(HELINI)-THE HELINI JEV REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF JAPANESE ENCEPHALITIS VIRUS [JEV] IN HUMAN BIOLOGICAL SAMPLES.,HELINI SWINE FLU H1N1 REAL-TIME PCR KIT [SINGLE TUBE ASSAY](HELINI)-THE HELINI SWINE FLU [H1N1] REAL-TIME PCR KIT [SINGLE TUBE ASSAY] IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF SWINE FLU H1N1 IN HUMAN BIOLOGICAL SAMPLES., HELINI WNV REAL TIME PCR KIT(HELINI)-THE HELINI WNV REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF WEST NILE VIRUS IN HUMAN BIOLOGICAL SAMPLES., HELINI HPV 16 & 18 REAL TIME PCR KIT(HELINI)-THE HELINI HPV 16 & 18 REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF HUMAN PAPILLOMAVIRUS GENOTYPES 16 & 18 IN HUMAN BIOLOGICAL SAMPLES.,HELINI SALMONELLA REAL TIME PCR KIT(HELINI)-THE HELINI SALMONELLA REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF SALMONELLA TYPHI IN HUMAN BIOLOGICAL SAMPLES.,HELINI EBV REAL TIME PCR KIT(HELINI)-THE HELINI EBV REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF EPSTEIN–BARR VIRUS (HHV-4) IN HUMAN BIOLOGICAL SAMPLES.,HELINI BCR-ABL REAL TIME PCR KIT(HELINI)-

	THE HELINI BCR-ABL REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF BCR-ABL TRANSCRIPTS IN HUMAN BIOLOGICAL SAMPLES.,HELINI CMV REAL TIME PCR KIT(HELINI)-THE HELINI CMV REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF CYTOMEGALOVIRUS [CMV] IN HUMAN BIOLOGICAL SAMPLES.,HELINI BKV REAL TIME PCR KIT(HELINI)-THE HELINI BKV REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF BK VIRUS IN HUMAN BIOLOGICAL SAMPLES.,HELINI CLOSTRIDIUM DIFFICILE REAL TIME PCR KIT(HELINI)-THE HELINI CLOSTRIDIUM DIFFICILE REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF CLOSTRIDIUM DIFFICILE BACTERIA IN HUMAN BIOLOGICAL SAMPLES.,HELINI HSV1 REAL TIME PCR KIT(HELINI)-THE HELINI HSV1 REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF HUMAN SIMPLEX VIRUS TYPE-1 IN HUMAN BIOLOGICAL SAMPLES., HELINI MTB REAL TIME PCR KIT(HELINI)-THE HELINI MTB REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF MYCOBACTERIUM TUBERCULOSIS COMPLEX IN HUMAN BIOLOGICAL SAMPLES.,HELINI HUMAN BLOOD DNA MINI SPIN PREP KIT(HELINI)-HELINI PUREFAST HUMAN BLOOD DNA MINI SPIN PREP KIT IS DESIGNED FOR RAPID AND COST-EFFECTIVE SMALL-SCALE PREPARATION OF HIGH QUALITY NUCLEIC ACID FROM HUMAN BLOOD AND BIOLOGICAL SAMPLES.,HELINI ROTAVIRUS-A REAL TIME PCR KIT(HELINI)-THE HELINI ROTAVIRUS-A REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF ROTAVIRUS TYPE-A IN HUMAN BIOLOGICAL SAMPLES.,HELINI HELICOBACTER PYLORI REAL TIME PCR KIT(HELINI)-THE HELINI HELICOBACTER PYLORI REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF HELICOBACTER PYLORI IN HUMAN BIOLOGICAL SAMPLES.,HELINI PUREFAST VIRAL NUCLEIC ACID MINI SPIN PREP KIT(HELINI)-HELINI PUREFAST VIRAL NUCLEIC ACID MINISPIN PREP KIT IS DESIGNED FOR RAPID AND COST-EFFECTIVE SMALL-SCALE PREPARATION OF HIGH QUALITY VIRAL NUCLEIC ACID FROM HUMAN BIOLOGICAL SAMPLES.,HELINI HSV2 REAL TIME PCR KIT(HELINI)-THE HELINI HSV2 REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF HUMAN SIMPLEX VIRUS TYPE-2 [HSV2] IN HUMAN BIOLOGICAL SAMPLES.,HELINI SWINE FLU H1N1 REAL-TIME PCR KIT [FOUR TARGETS ASSAY](HELINI)-THE HELINI SWINE FLU [H1N1] REAL-TIME PCR KIT [SINGLE TUBE ASSAY] IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF SWINE FLU H1N1 & H3N2 IN HUMAN BIOLOGICAL SAMPLES.,HELINI JAK2 REAL TIME PCR KIT(HELINI)-THE HELINI JAK2 REAL-TIME PCR KIT IS AN IN VITRO

	NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF JAK2 MUTATION IN HUMAN BIOLOGICAL SAMPLES.,HELINI SWINE FLU H1N1 REAL-TIME PCR KIT [THREE TUBE ASSAY](HELINI)-THE HELINI SWINE FLU [H1N1] REAL-TIME PCR KIT [SINGLE TUBE ASSAY] IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF SWINE FLU H1N1 IN HUMAN BIOLOGICAL SAMPLES.,HELINI CHLAMYDIA TRACHOMATIS REAL TIME PCR KIT(HELINI)-THE HELINI CHLAMYDIA TRACHOMATIS REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF CHLAMYDIA TRACHOMATIS IN HUMAN BIOLOGICAL SAMPLES.,HELINI HSV1&2 REAL TIME PCR KIT(HELINI)-THE HELINI HSV 1 & 2 REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF HUMAN SIMPLEX VIRUS TYPES 1 & 2 [HSV1&2] IN HUMAN BIOLOGICAL SAMPLES.,HELINI ADENOVIRUS REAL TIME PCR KIT(HELINI)-THE HELINI ADENOVIRUS [UNIVERSAL] REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF ADENOVIRUS [GENOTYPE A TO G] IN HUMAN BIOLOGICAL SAMPLES.,HELINI DENGUE VIRUS REAL TIME PCR KIT (HELINI)-THE HELINI DENGUE VIRUS REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF DENGUE VIRUS [GENOTYPES 1 TO 4] IN HUMAN BIOLOGICAL SAMPLES.,HELINI LEPTOSPIRA REAL TIME PCR KIT(HELINI)-THE HELINI LEPTOSPIRA REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF LEPTOSPIRA PATHOGENIC SEROVAR IN HUMAN BIOLOGICAL SAMPLES.,HELINI BRAF REAL TIME PCR KIT(HELINI)-THE HELINI BRAF REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF BRAF MUTATION IN HUMAN BIOLOGICAL SAMPLES.,HELINI SWINE FLU H1N1 REAL-TIME PCR KIT [TWO TUBE ASSAY] (HELINI)-THE HELINI SWINE FLU [H1N1] REAL-TIME PCR KIT [SINGLE TUBE ASSAY] IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF SWINE FLU H1N1 IN HUMAN BIOLOGICAL SAMPLES.,HELINI LEPROSY REAL TIME PCR KIT(HELINI)-THE HELINI LEPROSY REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF MYCOBACTERIUM LEPRAE IN HUMAN BIOLOGICAL SAMPLES.,HELINI CHIKUNGUNYA VIRUS REAL TIME PCR KIT(HELINI)-THE HELINI CHIKUNGUNYA VIRUS REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF CHIKUNGUNYA VIRUS IN HUMAN BIOLOGICAL SAMPLES.

2874	MFG/IVD/2020/000060	1.License Holder Name: GENOMIX MOLECULAR DIAGNOSTICS PVT LTD 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:DENGUE IGG ANTIBODY ELISA TEST KIT-FOR IN-VITRO QUALITATIVE DETECTION OF DENGUE IGG ANTIBODIES IN HUMAN SERUM OR PLASMA,ANA ELISA TEST KIT-FOR THE DETECTION OF IGG CLASS ANTIBODIES TO ANTI-NUCLEAR ANTIBODIES (ANA) IN HUMAN SERUM OR PLASMA.,LISTERIA ANTIBODY RAPID TEST KIT-FOR THE IN-VITRO QUALITATIVE DETECTION OF ANTIBODIES TO LISTERIA MONOCYTOGENES IN STOOL SAMPLES,LP-PLA2 ELISA TEST KIT-FOR THE QUANTITATIVE MEASUREMENT OF HUMAN LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 IN SERUM, PLASMA AND CELL CULTURE SUPERNATANTS,PPRV ANTIBODY ELISA TEST KIT-FOR QUANTITATIVE DETECTION OF PPRV ANTIBODIES IN PLASMA OR SERUM,IBR ANTIBODY RAPID TEST KIT-FOR IN-VITRO DETECTION OF BOVINE HERPES VIRUS-1 (BHV-1) SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA WITH CLINICAL SYMPTOMS IN CONSISTENT WITH INFECTIOUS BOVINE RHINOTRACHEITIS (IBR), THEILERIA ANTIBODY ELISA TEST KIT-FOR QUANTITATIVE DETECTION OF THEILERIA SPS. ANTIBODIES IN PLASMA OR SERUM, BOVINE TUBERCULOSIS ANTIBODY RAPID TEST KIT-FOR THE RAPID DETECTION OF ANTIBODIES TO MYCOBACTERIUM BOVIS (MTB) COMPLEX ANTIGEN(S) IN WHOLE BLOOD, SERUM OR PLASMA OF BOVINES,CHIKUNGUNYA VIRUS IGM ANTIBODY ELISA TEST KIT-FOR THE DETECTION OF CHIKUNGUNYA SPECIFIC IGM ANTIBODIES IN HUMAN SERUM OR PLASMA,THEILERIA TA/TO ANTIBODY RAPID TEST KIT-FOR IN VITRO DETECTION OF THEILERIA ANTIBODIES IN PLASMA OR SERUM,CHIKUNGUNYA IGG/IGM ANTIBODY RAPID DIAGNOSTIC TEST KIT-FOR IN-VITRO DETECTION OF IGG AND IGM ANTIBODIES TO CHIKUNGUNYA VIRUS IN HUMAN SERUM, PLASMA OR WHOLE BLOOD, BRUCELLA CANIS ANTIBODY RAPID TEST KIT-FOR IN-VITRO ASSAY DETECTION OF BRUCELLA CANIS SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,EIA ANTIBODY RAPID TEST KIT-FOR THE QUALITATIVE DETECTION OF EQUINE INFECTIOUS ANAEMIA (EIA) SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA, HAEMORRHAGIC SEPTECAEMIA ANTIBODY RAPID TEST KIT-THE GENOMIX HAEMORRHAGIC SEPTECAEMIA ANTIBODY RAPID TEST KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES AGAINST PURIFIED LPS PASTEURELLA MULTOCIDA ANTIGEN ANTIGENS PRESENT IN THE WHOLE BLOOD, SERUM OR PLASMA OF CATTLE, AND WATER BUFFALO, PIGS SMALL RUMINANTS , AND HOOF STOCK WITH CLINICAL SYMPTOMS,RABIES ANTIBODY ELISA TEST KIT-FOR DETERMINATION OF HUMAN RABIES VIRUS (ANTIBODY CONCENTRATIONS IN SERUM, PLASMA,EIA ANTIBODY

	DETECTION ELISA TEST KIT-FOR QUANTITATIVE DETECTION OF SPECIFIC ANTIBODIES IN SERUM, PLASMA AND WHOLE BLOOD WITH CLINICAL SYMPTOMS CONSISTENT WITH EIA,RABIES ANTIBODY RAPID TEST KIT-FOR QUALITATIVE DETECTION OF RABIES VIRUS ANTIBODIES IN PLASMA OR SERUM,ANTHRAX ANTIBODY ELISA TEST KIT-FOR DETECTION OF BACILLUS ANTHRACIS SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,DENGUE IGM ANTIBODY ELISA TEST KIT-FOR DETECTION OF DENGUE IGM ANTIBODIES ANTIGEN IN SERUM OR PLASMA,SALMONELLA ANTIBODY RAPID DETECTION KIT-THE GENOMIX SALMONELLA ANTIBODY RAPID TEST KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES AGAINST SALMONELLA LIPOPOLYSACCHARIDE ANTIGENS PRESENT IN THE WHOLE BLOOD, SERUM OR PLASMA OF BOVINE, SMALL RUMINANT SPECIES, SWINE AND IN HUMANS,EQUINE LEPTOSPIRA ANTIBODY ELISA TEST KIT-FOR DETECTION OF LEPTOSPIRA SPECIFIC ANTIBODIES IN SERUM OR PLASMA OF EQUINES,BRUCELLA ANTIBODY RAPID DIAGNOSTIC TEST KIT-FOR DETECTION OF BRUCELLA SPECIFIC ANTIBODIES IN WHOLE BLOOD /SERUM OR PLASMA,FMD ANTIBODY RAPID TEST KIT-THE GENOMIX FMD ANTIBODY RAPID TEST KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES AGAINST FMD ANTIGENS PRESENT IN THE WHOLE BLOOD, SERUM OR PLASMA OF BOVINE, SMALL RUMINANT SPECIES, SWINE WITH CLINICAL SYMPTOMS, TOXOPLASMA ANTIBODY ELISA TEST KIT-FOR DETECTION OF TOXOPLASMA GONDII SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,CANINE DISTEMPER ANTIBODY RAPID TEST KIT-FOR IN-VITRO DETECTION OF CANINE DISTEMPER VIRUS SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,CALPROTECTIN PI RAPID TEST KIT-FOR THE DETECTION OF CALPROTECTIN IN HUMAN FECES SPECIMEN WHICH MIGHT BE USEFUL FOR THE DIAGNOSIS OF INFLAMMATORY GASTROINTESTINAL DISORDERS, GLANDERS ANTIBODY DETECTION RAPID TEST KIT-FOR THE QUALITATIVE DETECTION OF GLANDERS SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,TYPHOID IGG & IGM ANTIBODY RAPID DIAGNOSTIC TEST KIT-FOR IN VITRO DETECTION OF ANTIBODIES TO SALMONELLA TYPHI IN HUMAN SERUM OR PLASMA., CANINE DISTEMPER ANTIBODY ELISA TEST KIT-FOR DETECTION OF CANINE DISTEMPER VIRUS SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,RHODOCOCCUS ANTIBODY RAPID TEST KIT-FOR IN-VITRO ASSAY DETECTION OF RHODOCOCCUS SPS. SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,BRUCELLA MILK DIPSTICK RAPID TEST KIT-FOR DETECTION OF BRUCELLA ANTIBODIES IN MILK AND BODY FLUIDS (BLOOD/SERUM/PLASMA), CCP ANTIBODY ELISA TEST KIT-FOR IN VITRO DETERMINATION OF

	HUMAN CCP-AB CONCENTRATIONS IN SERUM, PLASMA AND OTHER BIOLOGICAL FLUIDS,ANTHRAX ANTIBODY RAPID TEST KIT-FOR IN-VITRO DETECTION OF BACILLUS ANTHRACIS ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,BRUCELLA ELISA ANTIBODY TEST KIT-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN SERUM, PLASMA OR WHOLE BLOOD OF CATTLE, BUFFALOES AND GOAT WITH CLINICAL SYMPTOMS CONSISTENT WITH BRUCELLOSIS,RUMINANT BRUCELLA ANTIBODY ELISA TEST KIT-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN SERUM, PLASMA OR WHOLE BLOOD OF RUMINANTS WITH CLINICAL SYMPTOMS CONSISTENT WITH BRUCELLOSIS,FILARIASIS IGG/IGM ANTIBODY RAPID DIAGNOSTIC TEST KIT-FOR SIMULTANEOUS DETECTION AND DIFFERENTIATION OF IGG AND IGM ANTI-LYMPHATIC FILARIAL PARASITES (W. BANCROFTI AND B. MALAYI) IN HUMAN SERUM OR PLASMA.,SALMONELLA ANTIBODY ELISA TEST KIT-THE SALMONELLA INDIRECT ELISA KIT IS FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES IN SERUM OF WITH CLINICAL SYMPTOMS. THIS KIT IS INTENDED TO BE USED AS A SCREENING TEST TO OBTAIN A VISUAL, QUALITATIVE RESULT FOR ANIMAL HEALTHCARE PROFESSIONAL USE ONLY,FOOT AND MOUTH ANTIBODY IELISA TEST KIT (DIVA TEST)-FOR THE DETECTION OF FMDV 3ABC SPECIFIC ANTIBODIES IN SERUM AND PLASMA SAMPLES FROM BOVINE, OVINE AND CAPRINE. THE KIT CAN BE USED FOR DIFFERENTIATING NATURALLY INFECTED ANIMALS FROM THOSE VACCINATED WITH FMDV VACCINE,HYDATID ANTIBODY ELISA TEST KIT-FOR DETECTION OF ECHIOCOCCUS SPS. SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,ANTI-MULLERIAN HORMONE (AMH) ELISA TEST KIT-FOR THE QUANTITATIVE MEASUREMENT OF AMH IN HUMAN SERUM AND PLASMA, CAMPYLOBACTER ANTIBODY ELISA TEST KIT-FOR DETECTION OF ANTIBODIES TO COMPYLOBACTER JEJUNI IN STOOL SAMPLES, LISTERIA ANTIBODY ELISA TEST KIT-FOR QUANTITATIVE DETECTION OF ANTIBODIES TO LISTERIA MONOCYTOGENES IN STOOL SAMPLES, BOVINE LEPTOSPIRA ANTIBODY INDIRECT ELISA TEST KIT-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN SERUM OF CATTLE, BUFFALOES, SHEEP AND GOATS WITH CLINICAL SYMPTOMS CONSISTENT WITH LEPTOSPIROSIS,BOVINE LEPTOSPIRA ANTIBODY RAPID TEST KIT-FOR DETECTION OF LEPTOSPIRA SPECIFIC ANTIBODIES IN SERUM OR PLASMA OF BOVINES,CAMPYLOBACTER ANTIBODY RAPID TEST KIT-FOR THE IN-VITRO QUALITATIVE DETECTION OF ANTIBODIES TO COMPYLOBACTER JEJUNI IN STOOL SAMPLES,PARA TUBERCULOSIS ANTIBODY ELISA TEST KIT-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN SERUM / PLAMA OF CATTLE, BUFFALOES, SHEEP, GOAT AND CAMELS WITH CLINICAL SYMPTOMS CONSISTENT WITH PARA TUBERCULOSIS (JOHNE'S

	DISEASE),BOVINE TUBERCULOSIS ANTIBODY ELISA TEST KIT-FOR DETECTION OF ANTIBODIES TO MYCOBACTERIUM TUBERCULOSIS (MTB) COMPLEX ANTIGEN(S) IN WHOLE BLOOD, SERUM OR PLASMA OF BOVINES,LEPTOSPIRA ANTIBODY RAPID TEST KIT-FOR THE DETECTION OF LEPTOSPIRA SPECIFIC ANTIBODIES IN SERUM OR PLASMA SAMPLE,FMD DIVA RAPID TEST KIT-THE GENOMIX FMD DIVA RAPID TEST KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES AGAINST FMD ANTIGENS PRESENT IN THE WHOLE BLOOD, SERUM OR PLASMA OF BOVINE, SMALL RUMINANT SPECIES, SWINE WITH CLINICAL SYMPTOMS CONSISTENT WITH FMD, LEPTOSPIRA ANTIBODY ELISA TEST KIT-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN SERUM WITH CLINICAL SYMPTOMS CONSISTENT WITH LEPTOSPIROSIS,WILD TB ANTIBODY RAPID DIAGNOSTIC TEST KIT-FOR THE DETECTION OF ANTIBODIES TO MYCOBACTERIUM TUBERCULOSIS COMPLEX IN WHOLE BLOOD, SERUM AND PLASMA FROM WILD ANIMALS,IBR ANTIBODY ELISA TEST KIT-FOR DETECTION OF BOVINE HERPES VIRUS-1 SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA WITH CLINICAL SYMPTOMS IN CONSISTENT WITH INFECTIOUS BOVINE RHINOTRACHEITIS (IBR),TUBERCULOSIS INTERFERON GAMMA RELEASE ASSAY (TB IGRA)-FOR QUANTITATIVE DETECTION OF INTERFERON GAMMA (IFN-) THAT RESPOND TO IN-VITRO STIMULATION BY M. TUBERCULOSIS ANTIGENS IN WHOLE BLOOD. IT IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF TUBERCULOSIS (TB) INFECTION,TOXOPLASMA ANTIBODY RAPID TEST KIT-FOR IN-VITRO DETECTION OF TOXOPLASMA GONDII SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,CANINE PARVO ANTIBODY RAPID TEST KIT-FOR THE QUALITATIVE DETECTION OF CPV SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,CANINE PARVO ANTIBODY ELISA TEST KIT-FOR DETECTION OF PARVO VIRAL SPECIFIC ANTIBODIES PRESENT IN SERUM / PLAMA OF CANINES,RHODOCOCCUS ANTIBODY ELISA TEST KIT-FOR DETECTION OF RHODOCOCCUS SPS. SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,BRUCELLA CANIS ANTIBODY ELISA TEST KIT-FOR DETECTION OF BRUCELLA CANIS SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,CANINE LEPTOSPIRA ANTIBODY ELISA TEST KIT-FOR DETECTION OF LEPTOSPIRA SPECIFIC ANTIBODIES IN SERUM OR PLASMA OF CANINES,CCP ANTIBODY RAPID TEST KIT-FOR THE DETERMINATION OF ANTI-CYCLIC CITRULLINATED PEPTIDE (CCP) ANTIBODY IN HUMAN SERUM AND PLASMA AS AN AIDING TOOL FOR DIAGNOSING AND CONTROLLING THE TREATMENT OF RHEUMATOID ARTHRITIS, BRUCELLA MILK ELISA TEST KIT-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN MILK OF CATTLE, BUFFALOES AND GOAT

		WITH CLINICAL SYMPTOMS CONSISTENT WITH BRUCELLOSIS, GLANDERS ANTIBODY DETECTION ELISA TEST KIT-FOR QUANTITATIVE DETECTION OF SPECIFIC ANTIBODIES IN SERUM WITH CLINICAL SYMPTOMS,PARA TUBERCULOSIS ANTIBODY RAPID TEST KIT-FOR THE RAPID DETECTION OF ANTIBODIES TO M. PARATUBERCULOSIS SUBSP. AVIUM (JOHNE'S DISEASE) IN WHOLE BLOOD, SERUM OR PLASMA,CANINE LEPTOSPIRA ANTIBODY RAPID TEST KIT-FOR DETECTION OF LEPTOSPIRA SPECIFIC ANTIBODIES IN SERUM OR PLASMA OF CANINES,CLASSICAL SWINE FEVER ANTIBODY ELISA TEST KIT-THE CLASSICAL SWINE FEVER (CSF) ANTIBODY ELISA KIT IS FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES IN SERUM OF WITH CLINICAL SYMPTOMS,FMD ANTIBODY ELISA TEST KIT-THE FMD ANTIBODY ELISA KIT IS FOR DETECTION OF FMD SEROVARS . SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,LEPTOSPIRA IGG/IGM ANTIBODY RAPID DIAGNOSTIC TEST KIT-FOR THE DETECTION OF LEPTOSPIRA SPECIFIC IGM AND IGG ANTIBODIES IN HUMAN SERUM OR PLASMA,EQUINE LEPTOSPIRA RAPID TEST KIT-FOR DETECTION OF SPECIFIC ANTIBODIES AGAINST LEPTOSPIROSIS PRESENT IN EQUINE BLOOD, SERUM. FOR VETERINARY USE ONLY,CLASSICAL SWINE FEVER ANTIBODY RAPID TEST KIT-THE GENOMIX CLASSICAL SWINE FEVER ANTIBODY RAPID TEST KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF CLASSICAL SWINE FEVER VIRUS (CSFV) SPECIFIC ANTIBODIES IN WHOLE BLOOD, SERUM OR PLASMA,CHIKUNGUNYA VIRUS IGG ANTIBODY ELISA TEST KIT-FOR THE DETERMINATION OF IGG CLASS ANTIBODIES TO CHIKUNGUNYA IN HUMAN SERUM OR PLASMA, BOVINE PREGNANCY ELISA TEST KIT-FOR THE DETECTION OF PREGNANCY IN THE BOVINES BLOOD. FOR IN-VITRO DIAGNOSTIC USE FOE VETERINARY HEALTHCARE PROFESSIONAL.,BOVINE PREGNANCY RAPID TEST KIT-FOR DETECTION OF PREGNANCY STATUS IN BOVINES. FOR VETERINARY USE ONLY,TRICHOMONAS ANTIBODY RAPID TEST KIT-FOR DETECTION OF SPECIFIC ANTIBODIES OF TRYCHOMONAS. VETERINARY IN VITRO DIAGNOSTIC PURPOSE ONLY
2875	MFG/IVD/2020/000061	1.License Holder Name: ORIGIN DIAGNOSTICS AND RESEARCH 2.Approving Authority: KERALA 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM-SPECIMEN COLLECTION AND TRANSPORT MEDIUM FOR VIRUSES. THE VIRAL SAMPLES SO COLLECTED MAY BE USED FOR CULTURE FOLLOWING STANDARD PROCEDURES AND PROTOCOLS.

2876	MFG/IVD/2020/000062	1.License Holder Name: MEDICLONE BIOTECH PRIVATE LIMITED 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM KIT(INNOVTM)-FOR COLLECTION, STORAGE AND TRANSPORATION OF CLINICAL SPECIMENS CONTAINING VIRUSES FROM COLLECTION SITE TO LABORATORY.

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2877	MFG/IVD/2020/000063	1.License Holder Name: KEE DIAGNOSTICS PVT. LTD. 2.Approving Authority: SOUTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:IRON (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF IRON.,RINSE SOLUTION CVT(NA)-FOR THE USE IN AUTO ANALYZER WASHING,TSH ELISA KIT(NA)-KIT FOR DETECTION OF TSH,AMMONIA REAGENT KIT (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF AMMONIA.,CREATININE REAGENT KIT(NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF CREATININE, HDL/LDL CALIBRATOR(NA)-FOR THE USE IN LIPID CHEMISTRY CALIBRATION,WIDAL KIT(NA)-FOR THE USE IN QUALITATIVE ESTIMATION OF WIDAL,HDL CHOLESTEROL (DIRECT) (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL FRACTION BY DIRECT METHOD,G6PDH REAGENT KIT (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF GLUCOSE 6 PHOSPHATE DEHYDROGENASE,CHEMISTRY CONTROL- NORMAL (NA) -FOR THE USE IN QUALITY CHECK FOR CLINICAL CHEMISTRIES, RHEUMATOID FACTORS (RF) TEST(NA)-FOR THE USE IN QUALITATIVE ESTIMATION OF RHEUMATOID FACTORS,URIC ACID (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF URIC ACID,TRIGLYCERIDES REAGENT KIT(NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF TRIGLYCERIDES,CHEMISTRY CALIBRATOR(NA)-FOR THE USE IN AUTO ANALYZERS CALIBRATION ,CHOLESTEROL (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF CHOLESTEROL,BILIRUBIN(N/A)-FOR THE USE IN QUANTITATIVE ESTIMATION OF BILIRUBIN TOTAL & DIRECT.,TRIGLYCERIDES (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF TRIGLYCERIDES,UREA BERTHELOT(NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF UREA BY BERTHELOT METHOD, CHEMISTRY CONTROL -ABNORMAL (NA)-FOR THE USE IN QUALITY CHECK FOR CLINICAL CHEMISTRIES,RINSE SOLUTION PRB(NA)-FOR THE USE IN AUTO ANALYZER WASHING,HDL CHOLESTEROL PRECIPITANT(N/A)-FOR THE USE IN QUANTITATIVE ESTIMATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL FRACTION BY PRECIPITATING METHOD,MAGNESIUM(N/A)-FOR THE USE IN QUANTITATIVE ESTIMATION OF MAGNESIUM,DILUENTS(NA)-FOR THE USE IN BLOOD CELL COUNTING,FREE T4 (FT4) ELISA KIT(NA)-KIT FOR DETECTION OF FREE T4,ALKALINE PHOSPHATASE (ALP)(NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF ALP,CHOLESTEROL REAGENT KIT(NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF CHOLESTEROL,TOTAL BILIRUBIN (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF TOTAL BILIRUBIN,LIPASE (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF LIPASE,DENGUE IGG/IGM ANTIBODY CARD/DIPSTICK TEST(NA)-KIT FOR DETECTION OF DENGUE IGG/IGM ANTIBODIES,URIC ACID REAGENT KIT(NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF URIC ACID,LYSE(NA)-FOR THE

	USE IN BLOOD CELL COUNTING,UREA UV (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF UREA BY GLDH METHOD,UREA/BUN REAGENT KIT(NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF UREA/BUN,CALCIUM (OCPC METHOD)(N/A)-FOR THE USE IN QUANTITATIVE ESTIMATION OF CALCIUM BY O-CPC METHOD.,TOTAL PROTEIN(N/A)-FOR THE USE IN QUANTITATIVE ESTIMATION OF TOTAL PROTEIN,CREATININE (MODIFIED JAFFE METHOD)(N/A)-FOR THE USE IN QUANTITATIVE ESTIMATION OF CREATININE,RINSE(NA)-FOR THE USE IN BLOOD CELL COUNTING,T4 ELISA KIT(NA)-KIT FOR DETECTION OF T4,GLUCOSE REAGENT KIT(NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF GLUCOSE,DIRECT BILIRUBIN (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF DIRECT BILIRUBIN., POTASSIUM REAGENT KIT(NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF POTASSIUM.,LDH - P (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF LACTATE DEHYDROGENASE,T3 ELISA KIT(NA)-KIT FOR DETECTION OF T3,ACID PHOSPHATASE(N/A)-FOR THE USE IN QUANTITATIVE ESTIMATION OF ACID PHOSPHATASE, DENGUE IGM ELISA(NA)-KIT FOR DETECTION OF DENGUE IGM ANTIBODIES,ALT(SGPT) REAGENT KIT(NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF SGPT.,ALBUMIN(NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF ALBUMIN.,CREATINE KINASE (CK-NAC) (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF TOTAL CREATININE KINASE,AMYLASE(N/A)-FOR THE USE IN QUANTITATIVE ESTIMATION OF AMYLASE,CREATINE KINASE – MB (CK-MB)(NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF CREATININE KINASE MB, FREE T3(FT3) ELISA KIT(NA)-KIT FOR DETECTION OF FREE T3, HAEMOGLOBIN - CMG (N/A)-FOR THE USE IN QUANTITATIVE ESTIMATION OF HAEMOGLOBIN BY CMG METHOD,PHOSPHOROUS UV (N/A)-FOR THE USE IN QUANTITATIVE ESTIMATION OF PHOSPHORUS, CHLORIDE(N/A)-FOR THE USE IN QUANTITATIVE ESTIMATION OF CHLORIDE,AST (SGOT) (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF SGOT,GAMMA - GT (N/A)-FOR THE USE IN QUANTITATIVE ESTIMATION OF GAMMA- GLUTAMYLTRANSFERASE, CALCIUM – ARS III (N/A)-FOR THE USE IN QUANTITATIVE ESTIMATION OF CALCIUM BY ARSENAZO – III METHOD,LDL CHOLESTEROL (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL FRACTION BY DIRECT METHOD,DENGUE IGG ELISA(NA)-KIT FOR DETECTION OF DENGUE IGG ANTIBODIES,AST (SGOT) REAGENT KIT(NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF SGOT,SODIUM REAGENT KIT(NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF SODIUM,ALT (SGPT) (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF SGPT,GLUCOSE REAGENT KIT (NA)-FOR THE USE IN QUANTITATIVE ESTIMATION OF GLUCOSE., PROTEIN (MICRO) (N/A)-FOR THE USE IN QUANTITATIVE ESTIMATION

		OF MICRO PROTEIN.
2878	MFG/IVD/2020/000064	1.License Holder Name: VANGUARD DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: SOUTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use: VIRAL TRANSPORT KIT (VDX VIRAL TRANSPORT KIT)-VIRAL TRANSPORT KIT IS USED FOR THE COLLECTION & TRANSPORT OF CLINICAL SPECIMENS OF COVID 19.

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2879	MFG/IVD/2020/000065	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:HIV ELISA TEST(Q-LISA)-FOR IN-VITRO DIAGNOSTIC USE BY PROFESSIONALS ONLY. IT IS INTENDED FOR SCREENING BLOOD DONORS BEFORE TRANSFUSION AND THE INDIVIDUALS AT RISK FOR HIV-1 AND HIV-2 INFECTION OR BOTH, IN A CLINICAL LAB SETUP.,NCOV-19 RT-PCR DETECTION KIT(Q-LINE MOLECULAR ER)-THIS PROTOCOL DESCRIBES THE IN-VITRO DETECTION OF 2019 - NOVEL CORONAVIRUS (2019-NCOV) BASED ON MULTIPLEX REALTIME RT PCR (RRT-PCR) ASSAYS IN RESPIRATORY AND SERUM SPECIMENS. THE KIT UTILIZES THE PRIMERS AND PROBES SPECIFIC FOR 2019-NCOV: E-GENE AND RDRP AND INTERNAL CONTROL RNASEP (IPC).,ELISA HBSAG TEST (Q-LISA)-FOR IN-VITRO DIAGNOSTIC USE BY PROFESSIONALS ONLY. IT IS INTENDED FOR SCREENING BLOOD DONORS BEFORE TRANSFUSION AND THE INDIVIDUALS AT RISK FOR HEPATITIS B, IN A CLINICAL LAB SETUP.,ONE STEP NOVEL CORONAVIRUS (COVID-19) IGG ANTIBODY TEST(Q-LINE)-Q LINE ONE STEP NOVEL CORONAVIRUS (COVID-19) ANTIBODY KIT IS A RAPID, QUALITATIVE AND CONVENIENT IMMUNOCHROMATOGRAPHIC IN VITRO ASSAY FOR THE DETECTION OF IGG ANTIBODIES TO COVID-19 VIRUS IN HUMAN SERUM, PLASMA AND/OR WHOLE BLOOD SAMPLES OBTAINED FROM PATIENT WITH SIGNS AND SYMPTOMS OF RESPIRATORY INFECTION. THE DEVICE IS DESIGNED TO AID IN THE RAPID DIAGNOSIS OF COVID-19 VIRUS INFECTION. THIS ASSAY ONLY PROVIDES A PRELIMINARY RESULT. NEGATIVE RESULTS SHOULD BE CONFIRMED BY REALTIME REVERSE TRANSCRIPTASE (RT)-PCR DIAGNOSTIC KIT; THEY DO NOT PRECLUDE COVID-19 VIRUS INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISIONS. THE TEST IS INTENDED FOR PROFESSIONAL AND LABORATORY USE.,HCV ELISA TEST(Q-LISA)-FOR IN-VITRO DIAGNOSTIC USE BY PROFESSIONALS ONLY. IT IS INTENDED FOR SCREENING BLOOD DONORS BEFORE TRANSFUSION AND THE INDIVIDUALS AT RISK FOR HCV INFECTION IN A CLINICAL LAB SETUP.,COVID-19 PCR KIT(Q-LINE) -Q-LINE® MOLECULAR NOVEL CORONAVIRUS (COVID-19) RT-PCR KIT IS DESIGNED TO DETECT COVID-19 USING REAL TIME PCR. THE RESULTS CAN BE USED TO ASSIST DIAGNOSIS OF PATIENTS WITH COVID-19 INFECTION, AND PROVIDE MOLECULAR DIAGNOSTIC BASIS FOR INFECTED PATIENTS. THE TEST RESULTS OF THIS KIT ARE FOR CLINICAL REFERENCE ONLY AND SHOULD NOT BE USED AS THE ONLY STANDARD FOR CLINICAL DIAGNOSIS. IT IS RECOMMENDED TO CONDUCT A COMPREHENSIVE ANALYSIS BY COMBINING THE TEST RESULTS WITH PATIENTS' SYMPTOMS AND OTHER LABORATORY TESTS.

2880	MFG/IVD/2020/000067	1.License Holder Name: SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT KIT (Q-LINE)-Q-LINE® MOLECULAR VIRUS SAMPLE COLLECTION AND TRANSPORT KIT IS A SPECIALLY DESIGNED TRANSPORT SYSTEM TO COLLECT AND TRANSPORT CHALMYDIA, MYCOPLASMA, UREAPLASMA & VIRUSES TO THE LABORATORY FOR ISOLATION. IT IS DESIGNED TO MAINTAIN THE VIABILITY AND THE VIRULENCE OF THE VIRAL SAMPLE.

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2881	MFG/IVD/2020/000068	1.License Holder Name: BIOGENIX INC. PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:MALARIA PF/PV AG RAPID TEST(BIOGENIX)-FOR DETECTION OF MALARIA PF/PV ANTIGEN IN HUMAN SERUM AND PLASMA,ELISA KIT FOR DETECTION OF IGM ANTIBODIES TO TOXOPLASMA IN HUMAN SERUM/PLASMA (BIOGENIX)-A TOXOPLASMA GONDII TEST OF TORCH & REAGENTS/KITS IS A MEDICAL DEVICE OTHER INTENDED FOR THE DETECTION OF INFECTIOUS TOXOPLASMA GONDII IN SERUM/BODY AGENTS FLUIDS.,DENGUE NS1 RAPID TEST (BIOGENIX)-FOR DETECTION OF DENGUE NS1 VIRUS IN HUMAN SERUM AND PLASMA, ELISA KIT FOR DETECTION OF ALPHA-FETOPROTEIN IN HUMAN SERUM/PLASMA(BIOGENIX)-MATERNAL SERUM ALPHA-FETOPROTEIN (MSAFP) TEST REAGENTS/KITS FOR IS A MEDICAL DEVICE INTENDED FOR THE SPINA BIFIDA SCREENING OF SPINA BIFIDA IN SERUM.,DENGUE NS1+IGG/M RAPID TEST(BIOGENIX)-FOR DETECTION OF DENGUE IGG/IGM+ NS1 VIRUS IN HUMAN SERUM AND PLASMA,ELISA KIT FOR DETECTION OF IGM ANTIBODIES TO RUBELLA IN HUMAN SERUM/PLASMA(BIOGENIX)-A RUBELLA VIRUS TEST REAGENT/KIT IS MEDICAL DEVICE INTENDED FOR THE DETECTION OF RUBELLA VIRUS IN SERUM/BODY FLUIDS.,SYPHILIS RAPID TEST (BIOGENIX)-FOR DETECTION OF SYPHILIS ANTIGEN IN HUMAN SERUM AND PLASMA,ELISA KIT FOR DETECTION OF CARCINOEMBRYONIC ANTIGEN IN HUMAN SERUM/PLASMA(BIOGENIX)-A CARCINOEMBRYONIC ANTIGEN (CEA) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF CARCINOEMBRYONIC ANTIGEN (CEA) IN SERUM/BODY FLUIDS, MALARIA PF/PAN AG RAPID TEST(BIOGENIX)-FOR DETECTION OF MALARIA PF/PAN ANTIGEN IN HUMAN SERUM AND PLASMA,RAPID IMMUNOCHROMATOGRAPHY LATERAL FLOW TEST FOR H.PYLORI AG IN HUMAN SERUM/PLASMA/WHOLE BLOOD(CASSETTE FORMAT) (BIOGENIX)-FOR DETECTION OF H.PYLORI ANTIGEN IN HUMAN SERUM AND PLASMA,HCV RAPID TEST(BIOGENIX (BSURE))-THE REAGENT IS USED TO DETECT THE HEPATITIS C VIRUS ANTIBODY IN SERUM/PLASMA/WHOLE BLOOD QUALITATIVELY.,COVID-19 RT PCR KIT(BIOGENIX)-THE COVID-19 RT-PCR TEST IS A REAL-TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RRT-PCR) TEST FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN UPPER AND LOWER RESPIRATORY SPECIMENS (SUCH AS NASAL, NASOPHARYNGEAL OR OROPHARYNGEAL SWABS, SPUTUM, LOWER RESPIRATORY TRACT ASPIRATES, BRONCHOALVEOLAR LAVAGE, AND NASOPHARYNGEAL WASH/ASPIRATE OR NASAL ASPIRATE) COLLECTED FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER.,HBSAG RAPID TEST(BIOGENIX

	(BSURE))-THE DEVICE IS USED TO DETECT THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN IN SERUM/PLASMA/WHOLE BLOOD.,RAPID IMMUNOCHROMATOGRAPHY LATERAL FLOW TEST FOR CHLAMYDIA AG IN HUMAN SERUM/PLASMA/WHOLE BLOOD(CASSETTE FORMAT) (BIOGENIX)-FOR DETECTION OF CHLAMYDIA AG VIRUS IN HUMAN SERUM AND PLASMA,HIV 1/2 RAPID TEST(BIOGENIX (BSURE))-HIV1/2 RAPID TEST DEVICE (SERUM/PLASMA) IS A RAPID TEST TO QUALITATIVELY DETECT AND DIFFERENTIATE THE PRESENCE OF ANTIBODIES TO HIV-1 AND/OR HIV-2 IN SERUM OR PLASMA SPECIMENS,ELISA KIT FOR DETECTION OF IGM ANTIBODIES TO HERPES SIMPLEX VIRUS 1/2 IN HUMAN SERUM/PLASMA(BIOGENIX)-A HERPES SIMPLEX VIRUS TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF HERPES SIMPLEX VIRUS IN SERUM/BODY FLUIDS,RAPID IMMUNOCHROMATOGRAPHY LATERAL FLOW TEST FOR DETECTION OF TOXOPLASMA IGG/IGM ANTIBODIES IN HUMAN SERUM/PLASMA/WHOLE BLOOD(CASSETTE FORMAT) (BIOGENIX)-FOR DETECTION OF TOXOPLASMA IGG/IGM ANTIBODIES IN HUMAN SERUM AND PLASMA,ELISA KIT FOR DETECTION OF TOTAL PSA IN HUMAN SERUM/PLASMA(BIOGENIX)-A PROSTATE-SPECIFIC ANTIGEN (PSA) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF PROSTATE-SPECIFIC ANTIGEN (PSA) IN SERUM/BODY FLUIDS.,ELISA KIT FOR DETECTION OF IGG ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM/PLASMA(BIOGENIX)-A CYTOMEGALOVIRUS TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF CYTOMEGALOVIRUS IN SERUM/BODY FLUIDS.,D-DIMER TURBIDIMETRY KIT FOR QUANTITATIVE DETERMINATION OF D-DIMER IN HUMAN SERUM/PLASMA(BIOGENIX)-A D-DIMER TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF D-DIMER TEST IN PLASMA/BODY FLUIDS,ELISA KIT FOR DETECTION OF FREE PSA IN HUMAN SERUM/PLASMA(BIOGENIX)-A PROSTATE-SPECIFIC ANTIGEN (PSA) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF PROSTATE-SPECIFIC ANTIGEN (PSA) IN SERUM/BODY FLUIDS.,ELISA KIT FOR DETECTION OF IGG ANTIBODIES TO HERPES SIMPLEX VIRUS 1/2 IN HUMAN SERUM/PLASMA(BIOGENIX)-A HERPES SIMPLEX VIRUS TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF HERPES SIMPLEX VIRUS IN SERUM/BODY FLUIDS.,RAPID IMMUNOCHROMATOGRAPHY LATERAL FLOW TEST FOR TROPONIN I IN HUMAN SERUM/PLASMA/WHOLE BLOOD(CASSETTE FORMAT) RAPID TEST(BIOGENIX)-FOR DETECTION OF TROPONIN I IN HUMAN SERUM AND PLASMA,ELISA KIT FOR DETECTION OF IGM ANTIBODIES TO CYTOMEGALOVIRUS IN HUMAN SERUM/PLASMA(BIOGENIX)-A CYTOMEGALOVIRUS TEST

		REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF CYTOMEGALOVIRUS IN SERUM/BODY FLUIDS.,ELISA KIT FOR DETECTION OF IGG ANTIBODIES TO TOXOPLASMA IN HUMAN SERUM/PLASMA(BIOGENIX)-A TOXOPLASMA GONDII TEST OF TORCH & REAGENTS/KITS IS A MEDICAL DEVICE OTHER INTENDED FOR THE DETECTION OF INFECTIOUS TOXOPLASMA GONDII IN SERUM/BODY AGENTS FLUIDS.,ELISA KIT FOR DETECTION OF IGG ANTIBODIES TO RUBELLA IN HUMAN SERUM/PLASMA(BIOGENIX)-A RUBELLA VIRUS TEST REAGENT/KIT IS MEDICAL DEVICE INTENDED FOR THE DETECTION OF RUBELLA VIRUS IN SERUM/BODY FLUIDS.
2882	MFG/IVD/2020/000069	1.License Holder Name: ANGSTROM BIOTECH PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:COVID 19 ANTIGEN KIT (ANG CARD)-COVID-19 ANTIGEN DETECTION KIT IS A RAPID IMMUNOCHROMATOGRAPHIC TEST ASSAY FOR QUALITATIVE DETECTION OF COVID-19 ANTIGEN (VIRAL NUCLEOPROTEIN) FROM NASAL SWAB, NASOPHARANGIAL SWAB, ENDOTRACHIAL ASPIRATES OR BRONCHOALVEOLAR LAVAGE OBTAINED FROM PATIENT.,COVID 19 PCR KIT (ANG COVID)-THIS PRODUCT IS DESIGNED TO DETECT COVID-19 USING REAL TIME PCR. THE RESULT CAN BE USED TO ASSIST DIAGNOSIS OF PATIENTS WITH COVID-19 INFECTION, AND PROVIDE MOLECULAR DIAGNOSTIC BASIS OF INFECTED PATIENTS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2883	MFG/IVD/2020/000070	1.License Holder Name: CEPHEID INDIA PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:XPERT XPRESS SARS-COV-2(XPERT XPRESS SARS-COV-2)-THE XPERT XPRESS SARS-COV-2 TEST IS A REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN NASOPHARYNGEAL SWAB, NASAL SWAB, OR NASAL WASH/ASPIRATE SPECIMEN COLLECTED FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 INFECTION. RESULTS ARE FOR THE IDENTIFICATION OF SARS-COV-2 RNA. POSITIVE RESULTS ARE INDICATIVE OF THE PRESENCE OF SARS-COV-2 RNA; CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER PATIENT MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. THE XPERT XPRESS SARS-COV-2 TEST IS INTENDED TO BE PERFORMED BY TRAINED USERS IN BOTH LABORATORY AND NEAR PATIENT TESTING SETTINGS.,XPERT MTB/RIF ULTRA(XPERT MTB/RIF ULTRA)-THE XPERT MTB/RIF ULTRA ASSAY, PERFORMED ON THE GENEXPERT INSTRUMENT SYSTEMS, IS A SEMI-QUANTITATIVE, NESTED REAL-TIME POLYMERASE CHAIN REACTION (PCR) IN VITRO DIAGNOSTIC TEST FOR THE DETECTION OF MYCOBACTERIUM TUBERCULOSIS (MTB) COMPLEX DNA IN UNPROCESSED SPUTUM SAMPLES OR CONCENTRATED SEDIMENTS PREPARED FROM INDUCED OR EXPECTORATED SPUTUM. IN SPECIMENS WHERE MYCOBACTERIUM TUBERCULOSIS COMPLEX IS DETECTED, THE XPERT MTB/RIF ULTRA ASSAY CAN ALSO DETECT RIFAMPIN-RESISTANCE ASSOCIATED MUTATIONS OF THE RPOB GENE. THE XPERT MTB/RIF ULTRA ASSAY IS INTENDED FOR USE WITH SPECIMENS FROM PATIENTS FOR WHOM THERE IS CLINICAL SUSPICION OF TUBERCULOSIS (TB) AND WHO HAVE RECEIVED NO ANTITUBERCULOSIS THERAPY, OR LESS THAN 3 DAYS OF THERAPY IN THE LAST 6 MONTHS. THIS TEST IS INTENDED AS AN AID IN THE DIAGNOSIS OF PULMONARY TUBERCULOSIS WHEN USED IN CONJUNCTION WITH CLINICAL AND OTHER LABORATORY FINDINGS., XPERT MTB/RIF(XPERT MTB/RIF)-THE XPERT MTB/RIF ASSAY FOR USE WITH THE CEPHEID GENEXPERT® SYSTEM IS A SEMIQUANTITATIVE, NESTED REAL-TIME PCR IN-VITRO DIAGNOSTIC

	TEST FOR THE DETECTION OF: • MYCOBACTERIUM TUBERCULOSIS COMPLEX DNA IN SPUTUM SAMPLES OR CONCENTRATED SEDIMENTS PREPARED FROM INDUCED OR EXPECTORATED SPUTA THAT ARE EITHER ACID-FAST BACILLI (AFB) SMEAR POSITIVE OR NEGATIVE • RIFAMPIN RESISTANCE ASSOCIATED MUTATIONS OF THE RPOB GENE IN SAMPLES FROM PATIENTS AT RISK FOR RIFAMPIN RESISTANCE THE XPERT MTB/RIF ASSAY IS INTENDED FOR USE WITH SPECIMENS FROM UNTREATED PATIENTS FOR WHOM THERE IS CLINICAL SUSPICION OF TUBERCULOSIS (TB). USE OF THE XPERT MTB/RIF ASSAY FOR THE DETECTION OF M. TUBERCULOSIS (MTB) OR DETERMINATION OF RIFAMPIN SUSCEPTIBILITY HAS NOT BEEN VALIDATED FOR PATIENTS WHO ARE RECEIVING TREATMENT FOR TUBERCULOSIS.

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2884	MFG/IVD/2020/000072	1.License Holder Name: PATHNSITU BIOTECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:P53(BP-53-12) (PATHNSITU)-FOR IN VITRO DIAGNOSTIC USE; P53 IS A MOUSE MONOCLONAL ANTIBODY THAT IS INTENDED FOR LABORATORY USE IN THE QUALITATIVE IDENTIFICATION OF P53 PROTEIN BY IMMUNOHISTOCHEMISTRY (IHC) IN FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) HUMAN TISSUES. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,P63(PATHNSITU)-FOR IN VITRO DIAGNOSTIC USE; P63 IS A MOUSE MONOCLONAL ANTIBODY THAT IS INTENDED FOR LABORATORY USE IN THE QUALITATIVE IDENTIFICATION OF P63 PROTEIN BY IMMUNOHISTOCHEMISTRY (IHC) IN FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) HUMAN TISSUES. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,HER2/ERBB2 (EP3)(PATHNSITU)-FOR IN VITRO DIAGNOSTIC USE; HER2IS A RABBIT MONOCLONAL ANTIBODY THAT IS INTENDED FOR LABORATORY USE IN THE QUALITATIVE IDENTIFICATION OF HER2 PROTEIN BY IMMUNOHISTOCHEMISTRY (IHC) IN FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) HUMAN TISSUES. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,POLYEXCEL HRP/DAB DETECTION SYSTEM -TWO STEP(PATHNSITU)-FOR IN VITRO DIAGNOSTIC USE POLYEXCEL DETECTION SYSTEM IS INTENDED TO USE WITH PRIMARY ANTIBODIES RAISED AGAINST MOUSE AND RABBIT FOR THE QUALITATIVE IDENTIFICATION OF ANTIGENS BY LIGHT MICROSCOPY IN NORMAL AND PATHOLOGICAL PARAFFIN-EMBEDDED TISSUES, CRYOSTAT TISSUES OR CELL PREPARATIONS.,PROGESTRON RECEPTOR (EP2)(PATHNSITU)-FOR IN VITRO DIAGNOSTIC USE; PR IS A RABBIT MONOCLONAL ANTIBODY THAT IS INTENDED FOR LABORATORY USE IN THE QUALITATIVE IDENTIFICATION OF PR PROTEIN BY IMMUNOHISTOCHEMISTRY (IHC) IN FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) HUMAN TISSUES. THE CLINICAL

	INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST,TTF1(EP229)(PATHNSITU)-FOR IN VITRO DIAGNOSTIC USE; TTF1 IS A RABBIT MONOCLONAL ANTIBODY THAT IS INTENDED FOR LABORATORY USE IN THE QUALITATIVE IDENTIFICATION OF TTF1 PROTEIN BY IMMUNOHISTOCHEMISTRY (IHC) IN FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) HUMAN TISSUES. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,KI67 (MIB1)(PATHNSITU)-FOR IN VITRO DIAGNOSTIC USE; KI67 IS A MOUSE MONOCLONAL ANTIBODY THAT IS INTENDED FOR LABORATORY USE IN THE QUALITATIVE IDENTIFICATION OF KI67 PROTEIN BY IMMUNOHISTOCHEMISTRY (IHC) IN FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) HUMAN TISSUES. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,ESTROGEN RECEPTOR (ER1)(PATHNSITU)-FOR IN VITRO DIAGNOSTIC USE; ER IS A RABBIT MONOCLONAL ANTIBODY THAT IS INTENDED FOR LABORATORY USE IN THE QUALITATIVE IDENTIFICATION OF ER PROTEIN BY IMMUNOHISTOCHEMISTRY (IHC) IN FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) HUMAN TISSUES. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,EGFR(EP22) (PATHNSITU)-FOR IN VITRO DIAGNOSTIC USE; EGFR IS A RABBIT MONOCLONAL ANTIBODY THAT IS INTENDED FOR LABORATORY USE IN THE QUALITATIVE IDENTIFICATION OF EGFR PROTEIN BY IMMUNOHISTOCHEMISTRY (IHC) IN FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) HUMAN TISSUES. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.,P40 (P) CONCENTRATED AND PREDILUTED POLYCLONAL ANTIBODY(PATHNSITU)-FOR IN VITRO DIAGNOSTIC

		USE P40 (P) IS A RABBIT POLYCLONAL ANTIBODY THAT IS INTENDED FOR LABORATORY USE IN THE QUALITATIVE IDENTIFICATION OF P40 PROTEIN BY IMMUNOHISTOCHEMISTRY (IHC) IN FORMALIN-FIXED PARAFFIN-EMBEDDED (FFPE) HUMAN TISSUES. THE CLINICAL INTERPRETATION OF ANY STAINING OR ITS ABSENCE SHOULD BE COMPLEMENTED BY MORPHOLOGICAL STUDIES USING PROPER CONTROLS AND SHOULD BE EVALUATED WITHIN THE CONTEXT OF THE PATIENT'S CLINICAL HISTORY AND OTHER DIAGNOSTIC TESTS BY A QUALIFIED PATHOLOGIST.
2885	MFG/IVD/2020/000073	1.License Holder Name: RAY LIFE SCIENCES PRIVATE LIMITED 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF SWAB SPECIMEN FOR TRUEPREP® AUTO(TRUEPREP® AUTO TRANSPORT MEDIUM FOR SWAB SPECIMEN PACK)-TRUEPREP® AUTO TRANSPORT MEDIUM FOR SWAB SPECIMEN PACK IS USED AS A MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF VARIOUS TYPES OF SWAB SPECIMENS BEFORE PROCEEDING FOR PRE-TREATMENT USING LYSIS BUFFER, EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE.
2886	MFG/IVD/2020/000074	1.License Holder Name: SAVI RAPID DIAGNOSTICS COMPANY 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:URINE MULTIPARAMETER STRIPS(URISIGN)-QUALITATIVE TESTING OF ALBUMIN, GIUCOSE, PROTEIN, UROBILINOGEN, BILLRUBIN, SPECIFIC GRAVITY, PH, KETONE, BLOOD, NITRATE, LEUCOCYTES, ASCORBIC ACID, CREATININE AND CALCIUM.,HCG (PREGNANCY TEST) RAPID TEST (SAVISIGN)-QUALITATIVE TESTING OF HCG (PREGNANCY TEST) IN HUMAN SPECIMEN.

2887	MFG/IVD/2020/000075	1.License Holder Name: ADVANCED MICRODEVICES PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:MDI VIRAL RNA EXTRACTION MINIPREP KIT(MDI)-MDI VIRAL RNA EXTRACTION MINIPREP KIT IS INTENDED TO BE USED FOR THE EXTRACTION OF VIRAL RNA FROM SAMPLES INCLUDING NON CELLULAR BODY FLUIDS (E.G. NASAL AND THROAT SWABS) FOR DETECTION OF INFECTIOUS DISEASES SUCH AS COVID-19 THROUGH RT-QPCR. THE PURIFIED VIRAL RNA IS SUITABLE FOR 1. RT-PCR,QRT-PCR,Q-PCR, 2. VIRAL GENOTYPING, 3. VIRAL DETECTION, 4. VIRAL LOAD MONITORING, 5. VIRAL EPIDEMIOLOGY
2888	MFG/IVD/2020/000076	1.License Holder Name: GCC BIOTECH INDIA PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUGS STANDARD CONTROL ORGANIZATION(EAST ZONE) 3.Device Name(Brand Name)-Intended Use:REAL-TIME PCR KIT FOR COVID-19 DETECTION(DIAGSURE)-THE DIAGSURE NCOV-19 DETECTION ASSAY (TAQMAN BASED), DEVELOPED BY GCC BIOTECH INDIA PRIVATE LIMITED IS AN IN VITRO DIAGNOSTIC (IVD) REAL-TIME REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION (RT-PCR) TEST INTENDED FOR THE QUANTITATIVE DETECTION OF NUCLEIC ACID FROM SEVERE ACUTE RESPIRATORY SYNDROME-RELATED CORONAVIRUS 2 (SARS-COV-2) IN HUMAN NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, ANTERIOR NASAL SWAB, MID-TURBINATE AND SPUTUM SPECIMENS FROM INDIVIDUALS WITH SIGNS AND SYMPTOMS OF INFECTION WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTH CARE PROVIDER.
2889	MFG/IVD/2020/000078	1.License Holder Name: OSCAR MEDICARE PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:CORONA ANTIGEN TEST (CORONA ANTIGEN TEST)-OSCAR CORONA ANTIGEN TEST IS A ONE-STEP RAPID, QUALITATIVE, SANDWICH IMMUNOASSAY. IT IS USED FOR THE DETECTION OF N ANTIGEN OF CORONA VIRUS IN HUMAN NASOPHARYNGEAL SWAB SPECIMEN. FOR PROFESSIONAL USE ONLY ,CORONA VIRUS RT PCR KIT(OSCAR-CORONA VIRUS RT PCR KIT)-CORONA VIRUS RT PCR KIT IS A KIT BASED ON THE PRINCIPLE OF REAL TIME PCR FOR THE DETECTION OF SARS-COV-2 (2019-NCOV). PRIMERS AND PROBES FOR AMPLIFICATION OF E GENE AND RDRP GENE WILL BE USED IN THE KIT. FOR PROFESSIONAL USE ONLY.

2890	MFG/IVD/2020/000079	1.License Holder Name: AJAY BIO-TECH (INDIA) LTD 2.Approving Authority: BILASPUR,SHIMLA,KINNAUR ,SOLAN(OTHER THAN BBN) 3.Device Name(Brand Name)-Intended Use:STERILE VIRUS TRANSPORT MEDIUM(VIRO TRAP VTM)-FOR COLLECTION AND TRANSPORT OF CLINICAL SPECIMEN FOR RECOVERY OF VIRAL AGENTS.

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2891	MFG/IVD/2020/000080	1.License Holder Name: OSCAR MEDICARE PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:HCV RAPID TEST KIT(HCV RAPID TEST)-OSCAR HCV TEST IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY INTENDED TO BE USED FOR QUALITATIVE DETECTION OF ANTIBODIES TO HEPATITIS C VIRUS (HCV) IN HUMAN SERUM / PLASMA. FOR PROFESSIONAL USE ONLY., CORONA IGG ELISA(OSCOLISA)-CORONA IGG ELISA IS INTENDED TO BE USED FOR THE DETECTION OF ANTIBODIES TO CORONA VIRUS IN HUMAN SERUM OR PLASMA. FOR PROFESSIONAL USE ONLY ,HBS AG RAPID TEST KIT (CARD / DEVICE)(HBS AG RAPID TEST)-OSCAR HBSAG TEST IS A ONE-STEP RAPID, QUALITATIVE, SANDWICH IMMUNOASSAY. IT IS USED FOR THE DETECTION OF HEPATITIS B SURFACE ANTIGEN IN HUMAN SERUM/PLASMA SPECIMEN. FOR PROFESSIONAL USE ONLY,ELISA KIT-DENGUE NS1(ELISA KIT-DENGUE NS1)-DENGUE NS1 ELISA IS INTENDED TO BE USED FOR THE DETECTION OF DENGUE NS1 IN HUMAN SERUM OR PLASMA. FOR PROFESSIONAL USE ONLY ,HIV RAPID TEST KIT(HIV RAPID TEST)-OSCAR HIV-1 AND HIV-2 TEST IS A RAPID, QUALITATIVE, SANDWICH IMMUNOASSAY FOR SIMULTANEOUS AND DIFFERENTIAL DETECTION OF TOTAL ANTIBODIES (IGM / IGG / IGA) TO HIV-1 AND HIV-2 IN HUMAN SERUM / PLASMA OR WHOLE BLOOD. FOR PROFESSIONAL USE ONLY.,CORONA ANTIBODY DETECTION TEST (CORONA ANTIBODY DETECTION TEST)-CORONA ANTIBODY DETECTION TEST IS AN IN-VITRO DIAGNOSTIC RAPID TEST BASED UPON THE PRINCIPLE OF IMMUNOCHROMATOGRAPHY ON A MEMBRANE, FOR DETECTION OF NOVEL CORONA VIRUS (COVID-19) SPECIFIC ANTIBODY IN HUMAN SERUM / PLASMA / WHOLE BLOOD FOR DIAGNOSIS OF CORONA VIRUS INFECTION. FOR PROFESSIONAL USE ONLY.,DENGUE ANTIGEN NS-1 TEST(DENGUE ANTIGEN NS-1 TEST)-DENGUE NS1AG TEST DEVICE IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNOCHROMATOGRAPHY ON A MEMBRANE , FOR THE DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN SERUM / PLASMA. FOR PROFESSIONAL USE ONLY., TROPONIN-I TEST(TROPONIN-I TEST)-TROPONIN-I TEST IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNOCHROMATOGRAPHY ON A MEMBRANE , FOR QUALITATIVE DETERMINATION OF CARDIAC TROPONIN-I (CTNI) A MARKER OF ACUTE MYOCARDIAL INFARCTION (AMI) IN HUMAN SERUM / PLASMA . FOR PROFESSIONAL USE ONLY.,CORONA IGG ANTIBODY DETECTION TEST (OSCOVID)-CORONA IGG ANTIBODY DETECTION TEST IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNOCHROMATOGRAPHY ON A MEMBRANE FOR QUALITATIVE DETECTION OF CORONA VIRUS SPECIFIC IGG ANTIBODY IN HUMAN

	SERUM / PLASMA / WHOLE BLOOD. FOR PROFESSIONAL USE ONLY., DENGUE ANTIGEN (NS-1) PLUS ANTIBODY (IGM/IGG) TEST(DENGUE ANTIGEN (NS-1) PLUS ANTIBODY (IGM/IGG) TEST)-DENGUE AG (NS-1) AND AB (IGM/IGG) TEST DEVICE IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNOCHROMATOGRAPHY ON A MEMBRANE , FOR SIMULTANEOUS AND DIFFERENTIAL DETECTION OF DENGUE SPECIFIC ANTIGEN (NS-1) AND ANTIBODY (IGM/IGG) IN HUMAN SERUM / PLASMA FOR DIAGNOSIS OF DENGUE INFECTION . FOR PROFESSIONAL USE ONLY.,MALARIA TEST-PV/PF(MALARIA TEST-PV/PF)-MALARIA PV/PF ANTIGEN TEST IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNOCHROMATOGRAPHY ON A MEMBRANE, FOR SIMULTANEOUS AND DIFFERENTIAL DETECTION OF SPECIFIC ANTIGENS OF PLASMODIUM VIVAX (PV) PLDH AND PLASMODIUM FALCIPARUM (PF) HRP-2, IN HUMAN WHOLE BLOOD. FOR PROFESSIONAL USE ONLY., MALARIA ANTIGEN TEST (PF)(MALARIA ANTIGEN TEST (PF))-MALARIA ANTIGEN TEST (PF) IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNE-CHROMATOGRAPHY ON A MEMBRANE FOR THE DETECTION OF HRP-II ANTIGEN OF PLASMODIUM FALCIPARUM, IN HUMAN WHOLE BLOOD.,MALARIA PAN/PF ANTIGEN TEST(MALARIA PAN/PF ANTIGEN TEST)-MALARIA PAN/PF ANTIGEN TEST IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNE-CHROMATOGRAPHY ON A MEMBRANE, FOR SIMULTANEOUS AND DIFFERENTIAL DETECTION OF PAN LDH ANTIGENS OF PLASMODIUM VIVAX, PLASMODIUM FALCIPARUM, PLASMODIUM OVALE AND PLASMODIUM MALARIAE AND PLASMODIUM FALCIPARUM HRP-II, IN HUMAN WHOLE BLOOD. , MALARIA PAN ANTIGEN TEST(MALARIA PAN ANTIGEN TEST)-MALARIA PAN ANTIGEN TEST IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNE-CHROMATOGRAPHY ON A MEMBRANE THE DETECTION OF PAN LDH ANTIGENS OF PLASMODIUM VIVAX, PLASMODIUM FALCIPARUM, PLASMODIUM OVALE AND PLASMODIUM MALARIAE AND PLASMODIUM FALCIPARUMIN HUMAN WHOLE BLOOD. ,SYPHILIS RAPID TEST (OSCAR SYPHILIS RAPID TEST)-SYPHILIS / TP TEST DEVICE IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNOCHROMATOGRAPHY ON A MEMBRANE, FOR QUALITATIVE DETERMINATION OF ANTIBODIES (IGG/ IGM/ IGA) TO TREPONEMA PALLIDUM (TP) A MARKER FOR DIAGNOSIS OF SYPHILIS. FOR PROFESSIONAL USE ONLY.,HIV RAPID TEST KIT (4TH GENERATION) (HIV RAPID TEST KIT (4TH GENERATION))-HIV RAPID TEST KIT 4TH GENERATION IS INTENDED TO BE USED FOR THE DETECTION OF ALL SUBTYPES (IGG, IGA, IGM) OF ANTIBODIES TO HIV 1 AND HIV 2 VIRUSES AND HIV P24 ANTIGEN IN HUMAN SERUM OR PLASMA.,

	OPTRA SHIELD-COVID-19 (IGG) RAPID TEST KIT (OPTRA SHIELD-COVID-19 (IGG) RAPID TEST KIT)-OPTRA SHIELD-COVID-19 (IGG) RAPID TEST IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNOCHROMATOGRAPHY ON A MEMBRANE FOR QUALITATIVE DETECTION OF COVID-19 SPECIFIC IGG ANTIBODY IN HUMAN SERUM / PLASMA / WHOLE BLOOD. FOR PROFESSIONAL USE ONLY.,HIV ELISA- 4TH GENERATION(HIV ELISA- 4TH GENERATION)-4 TH GENERATION HIV 1 & HIV 2 ELISA IS INTENDED TO BE USED FOR THE DETECTION OF ALL SUBTYPES (IGG, IGA, IGM) OF ANTIBODIES TO HIV 1 AND HIV 2 VIRUSES AND HIV-1 P24 ANTIGEN IN HUMAN SERUM OR PLASMA..FOR PROFESSIONAL USE ONLY. ,HBS AG ELISA (HBS AG ELISA)-HBSAG ELISA IS INTENDED TO BE USED FOR THE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OR PLASMA. FOR PROFESSIONAL USE ONLY ,SYPHILIS ELISA(SYPHILIS ELISA)-SYPHILIS ELISA IS INTENDED TO BE USED FOR QUALITATIVE DETERMINATION OF ANTIBODIES (IGG/ IGM/ IGA) TO TREPONEMA PALLIDUM (TP) A MARKER FOR DIAGNOSIS OF SYPHILIS. FOR PROFESSIONAL USE ONLY. ,HCV ELISA(HCV ELISA)-HCV ELISA IS INTENDED TO BE USED FOR THE DETECTION OF ANTIBODIES TO HCV (HEPATITIS C VIRUS) IN HUMAN SERUM OR PLASMA. FOR PROFESSIONAL USE ONLY ,HIV ELISA- 3RD GENERATION (HIV ELISA-3RD GENERATION)-3RD GENERATION HIV 1 & HIV 2 ELISA IS INTENDED TO BE USED FOR THE DETECTION OF ALL SUBTYPES (IGG, IGA, IGM) OF ANTIBODIES TO HIV 1 AND HIV 2 VIRUSES IN HUMAN SERUM OR PLASMA. FOR PROFESSIONAL USE ONLY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2892	MFG/IVD/2020/000081	1.License Holder Name: M/S HIMEDIA LABORATORIES PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:HIPURA ® VIRAL RNA PURIFICATION KIT(HIPURA ® VIRAL RNA PURIFICATION KIT)-INTENDED FOR SENSITIVE AND SPECIFIC DETECTION OF VIRAL RNA IN CLINICAL SAMPLES.,HI-PCR® CORONAVIRUS (COVID-19) MULTIPLEX PROBE PCR KIT(HI-PCR®)-HI-PCR® CORONAVIRUS (COVID-19) MULTIPLEX PROBE PCR KIT IS INTENDED FOR USE BY QUALIFIED CLINICAL LABORATORY PERSONNEL TRAINED IN THE TECHNIQUES OF REAL-TIME PCR AND IN VITRO DIAGNOSTIC PROCEDURES. THE KIT IS RECOMMENDED FOR SENSITIVE AND SPECIFIC DETECTION OF SARS-COV-2 IN CLINICAL SAMPLES., HIPURA® VIRAL RNA PURIFICATION KIT (MAGNETIC BEAD BASED) (HIPURA® VIRAL RNA PURIFICATION KIT (MAGNETIC BEAD BASED))-RECOMMENDED FOR ISOLATION OF VIRAL RNA FROM VARIOUS SAMPLES LIKE NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB IN VIRAL TRANSPORT MEDIUM AND OTHER BODY FLUIDS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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2893	MFG/IVD/2020/000082	1.License Holder Name: BIOGENIX INC. PVT. LTD. 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:TYPHOID IGG/IGM RAPID TEST-FOR DETECTION OF TYPHOID IGG/IGM VIRUS IN HUMAN SERUM AND PLASMA,C-REACTIVE PROTEIN (CRP) TURBIDIMETRY KIT FOR QUANTITATIVE DETECTION OF ANTIBODY TO CRP IN HUMAN SERUM/PLASMA(BIOGENIX)-A C- REACTIVE PROTEIN (CRP) TEST REAGENTS/KITS FOR NEAR PATIENT TESTING, IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF C REACTIVE PROTEIN (CRP) IN SERUM AND OTHER BODY FLUIDS,CHIKUNGUNYA RAPID TEST-FOR DETECTION OF CHIKUNGUNYA IGM VIRUS IN HUMAN SERUM AND PLASMA,ANTI CCP ELISA TEST KIT-ANTI CYCLIC CITRULLINATED PEPTIDE (CCP) ANTIBODIES TEST REAGENT/KIT IS A MEDICAL DEVICE FOR THE SCREENING OF AUTO-ANTIBODIES IN HUMAN SPECIMENS., DENGUE IGG/IGM RAPID TEST-FOR DETECTION OF DENGUE IGG/IGM VIRUS IN HUMAN SERUM AND PLASMA,TESTOSTERONE ELISA TEST KIT-TESTOSTERONE TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TESTOSTERONE IN BLOOD/BODY FLUIDS,FOB (FECAL OCCULT BLOOD) RAPID TEST-FOR DETECTION OF HUMAN OCCULT BLOOD IN FECES,TOTAL IGE ELISA TEST KIT-TOTAL IGE ANTIBODY TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF TOTAL IGE ANTIBODY IN HUMAN BLOOD/SERUM,HAV IGM ELISA TEST KIT-HEPATITIS A TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HEPATITIS A VIRUS IN BLOOD/BODY FLUIDS,ANTI-DSDNA ELISA TEST KIT-THE ANTI-DOUBLE STRANDED DNA TEST REAGENT/KIT IS A MEDICAL DEVICE FOR THE SCREENING OF AUTO-ANTIBODIES TO DOUBLE STRANDED DNA IN HUMAN SPECIMENS,AMYLASE REAGENT KIT-AN AMYLASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF AMYLASE IN SERUM, SALIVA/URINE,FOLLICLE STIMULATING HORMONE (FSH) TEST KITS-A FOLLICLE STIMULATING HORMONE (FSH) TEST IS A MEDICAL REAGENTS/KITS DEVICE INTENDED FOR THE PRELIMINARY SELF TESTING OF FOLLICLE STIMULATING HORMONE (FSH) IN URINE /BODY FLUIDS,URIC ACID REAGENT KIT-AN URIC ACID TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF URIC ACID IN SERUM, URINE/PLASMA,CALCIUM REAGENT KIT-AN CALCIUM TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CALCIUM IN SERUM,GLUCOSE REAGENT KIT-AN GLUCOSE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF GLUCOSE IN BLOOD/PLASMA/ BODY FLUIDS, VITAMIN D ELISA TEST KIT-VITAMIN D TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF VITAMIN B IN BLOOD/BODY FLUIDS,RPR LATEX REAGENT KIT-RAPID PLASMA

	REAGIN (RPR) TEST REAGENT/KIT IS A MEDICAL DEVICE FOR THE QUALITATIVE DETECTION OF OF ANTIBODY TO RPR IN HUMAN SERUM/PLASMA,CREATININE TEST REAGENT KIT-AN CREATININE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CREATININE IN SERUM, URINE/PLASMA, FRUCTOSAMINE REAGENT KIT-AN FRUCTOSAMINE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF FRUCTOSAMINE IN SERUM, SALIVA/PLASMA,COPPER TEST REAGENT KIT-AN COPPER TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF COPPER IN SERUM, URINE/PLASMA,PROLACTIN ELISA-PROLACTIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF PROLACTIN IN BLOOD/BODY FLUIDS,IRON REAGENT KIT-AN IRON TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF IRON IN SERUM/PLASMA,GAMMA GT REAGENT KIT-AN GAMMA GT TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME GAMMA GLUTAMYLTRANSFERASE IN SERUM/PLASMA,LACTATE DEHYDROGENASE – P REAGENT KIT-AN LACTATE DEHYDROGENASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF LACTATE DEHYDROGENASE IN SERUM/PLASMA,RHEUMATOID FACTOR (RF) IMMUNOLOGICAL TEST REAGENTS-RHEUMATOID FACTOR (RF) IMMUNOLOGICAL TEST REAGENT/KIT IS A MEDICAL DEVICE FOR THE SCREENING OF RHEUMATOID FACTOR IN HUMAN SPECIMENS., CORTISOL ELISA TEST KIT-CORTISOL TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CORTISOL IN BLOOD/BODY FLUIDS,CITRIC ACID REAGENT KIT-AN CITRIC ACID TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CITRIC ACID IN SERUM/PLASMA,TRIGLYCERIDES REAGENT KIT-AN TRIGLYCERIDE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TRIGLYCERIDE SERUM/PLASM,ANTI TPO ELISA TEST KIT-FOR DETECTION OF THYROID PEROXIDASE IN HUMAN SERUM/PLASMA,ANTI-MULLERIAN HORMONE (AMH) ELISA TEST KIT-ANTI-MULLERIAN HORMONE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF ANTI-MULLERIAN HORMONE IN HUMAN BLOOD/SERUM,DHEA-S ELISA TEST KIT-DEHYDROEPIANDROSTERONE (DHEA-S) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF DHEA-S (FREE AND SULFATE) IN BLOOD/BODY FLUIDS,ANTI CARDIOLIPIN ELISA TEST KIT-CARDIOLIPIN ANTIBODIES TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF CARDIOLIPIN ANTIBODIES IN HUMAN BLOOD/SERUM,DRABKIN'S REAGENT KIT-AN DRABKIN SOLUTION TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HEMOGLOBIN

	IN WHOLE BLOOD,URINE STRIP (PROTEIN)-MEMBRANE STRIP CONTAINS REAGENTS FOR DETECTION OF PROTEIN,HCG RAPID TEST (STRIP FORMAT)-FOR DETECTION OF PREGNANCY(HCG) IN HUMAN URINE IN HUMAN SERUM AND PLASMA,UREA BERTHELOT REAGENT KIT-AN UREA BERTHELOT REAGENT KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF UREA/BLOOD UREA NITROGEN SERUM, URINE/PLASMA,HEMOGLOBIN A1C (HBA1C) TURBIDIMETRY KIT FOR QUANTITATIVE DETERMINATION OF (HEMOGLOBIN A1C) IN HUMAN SERUM/PLASMA(BIOGENIX)-A HEMOGLOBIN A1C (HBA1C) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HEMOGLOBIN IN BLOOD.,ANTISTREPTOLYSIN O (ASO) TURBIDIMETRY KIT FOR QUANTITATIVE DETECTION OF ANTIBODY TO ASO IN HUMAN SERUM/PLASMA(BIOGENIX)-ANTISTREPTOLYSIN O (ASO) TURBIDIMETRY TEST REAGENTS/KITS FOR NEAR PATIENT TESTING, IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ANTISTREPTOLYSIN O TURBIDIMETRY IN SERUM AND OTHER BODY FLUIDS,FILARIASIS IGG/IGM RAPID TEST(BIOGENIX)-FOR DETECTION OF FILARIASIS ANTIBODY IN HUMAN SERUM AND PLASMA,UREA UV REAGENT KIT-UREA UV REAGENT KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF UREA/BLOOD UREA NITROGEN SERUM, URINE/PLASMA,RAPID IMMUNOCHROMATOGRAPHY LATERAL FLOW TEST FOR LEISHMANIA ANTIBODIES IN HUMAN SERUM/PLASMA/WHOLE BLOOD(CASSETTE FORMAT)(BIOGENIX)-FOR DETECTION OF LEISHMANIA ANTIBODY IN HUMAN SERUM AND PLASMA,ZINC REAGENT KIT-AN ZINC TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ZINC IN SERUM/PLASMA,FERRITIN TURBILATEX REAGENT KIT-FERRITIN TURBILATEX REAGENT KIT IS A MEDICAL DEVICE INTENDED FOR THE QUANTITATIVE ESTIMATION OF FERRITIN IN SERUM / PLASMA, LEPTOSPIRA ANTIBODY TEST REAGENTS-FOR DETECTION OF LEPTOSPIRA IGG/IGM IN HUMAN SERUM AND PLASMA,VTM (VIRAL TRANSPORT MEDIUM)-VIRAL TRANSPORT MEDIUM IS A SPECIALLY DESIGNED TRANSPORT SYSTEM TO COLLECT AND TRANSPORT VIRUSES IN AN ACTIVE FORM TO THE LABORATORY FOR ISOLATION. IT IS DESIGNED TO MAINTAIN THE VIABILITY AND THE VIRULENCE OF THE VIRAL SAMPLE. FOR IN VITRO DIAGNOSTICS TEST ONLY., MICROPROTEIN REAGENT KIT-AN MICROPROTEIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF MICROPROTEIN INCLUDING MICRO-ALBUMIN IN URINE,SODIUM REAGENT KIT-AN SODIUM TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF SODIUM IN SERUM, PLASMA/URINE,CYSTATIN C TURBIDIMETRY KIT FOR QUANTITATIVE DETECTION OF CYSTATIN C IN HUMAN SERUM/PLASMA(BIOGENIX)-FOR DETECTION OF CYSTATIN C IN HUMAN SERUM/PLASMA,RF

	TURBILATEX REAGENT KIT-RHEUMATOID FACTOR (RF) IMMUNOLOGICAL TEST REAGENT/KIT IS A MEDICAL DEVICE FOR THE SCREENING OF RHEUMATOID FACTOR IN HUMAN SPECIMENS.,BETA HCG ELISA-A HUMAN CHORIONIC GONADOTROPIN (HCG) TEST REAGENT/KIT IS A MEDICAL KITS DEVICE INTENDED FOR THE PRELIMINARY SELF TESTING OF HCG IN URINE/BODY FLUIDS., THYROGLOBULIN ELISA TEST KIT-A THYROGLOBULIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF THYROGLOBULIN IN SERUM/BODY FLUIDS,TURBIDIMETRY KIT FOR QUANTITATIVE DETECTION OF IGG/IGA/IGM/IGE IN HUMAN SERUM/PLASMA(BIOGENIX)-FOR DETECTION OF IGG/IGA/IGM/IGE IN HUMAN SERUM/PLASMA,HCG RAPID TEST (CASSETTE FLOW)-FOR DETECTION OF PREGNANCY (HCG) IN HUMAN URINE,ASO LATEX REAGENT KIT-ANTISTREPTOLYSIN O (ASO LATEX) TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ANTISTREPTOLYSIN O IN SERUM,TSH ELISA-TSH TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION DEVICES TSH IN BLOOD/BODY FLUIDS.,LIPASE REAGENT KIT-AN LIPASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF LIPASE IN SERUM/PLASMA,HDL CHOLESTEROL REAGENT KIT-AN CHOLESTEROL HDL DIRECT TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHOLESTEROL HDL DIRECT TEST IN SERUM,/PLASMA, PROGESTERONE ELISA TEST KIT-PROGESTERONE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF PROGESTERONE IN BLOOD/BODY FLUIDS,LEISHMANIA IGG/IGM RAPID TEST-FOR DETECTION OF LEISHMANIA IGG/IGM IN HUMAN SERUM AND PLASMA,ANTI PHOSPHOLIPID ELISA TEST KIT-ANTI PHOSPHOLIPID TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF ANTI PHOSPHOLIPID IN HUMAN BLOOD/SERUM,LACTATE REAGENT KIT-AN LACTATE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF LACTATE IN SERUM/PLASMA,URINE STRIP 2 PARAMETER-MEMBRANE STRIP CONTAINS REAGENTS FOR DETECTION OF GLUCOSE, PROTEIN,ALKALINE PHOSPHATASE REAGENT KIT-AN ALKALINE PHOSPHATASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALKALINE PHOSPHATASE IN SERUM/PLASMA,AMMONIA REAGENT KIT-AN AMMONIUM TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF AMMONIUM IN BLOOD, SERUM/PLASMA,C - REACTIVE PROTEIN (CRP) TEST KITS-A C- REACTIVE PROTEIN (CRP) TEST REAGENTS/KITS FOR NEAR PATIENT TESTING, IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF C -REACTIVE PROTEIN (CRP) IN SERUM AND OTHER BODY FLUIDS,CHLORIDE REAGENT KIT-AN

	CHLORIDE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHLORIDE IN SERUM, SWEAT, URINE/PLASMA, FT3 ELISA-TOTAL /FREE TRIIODOTHYRONINE (T3) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION TOTAL /FREE TRIIODOTHYRONINE (T3) IN BLOOD/BODY FLUIDS, MICROALBUMIN TURBIDIMETRY KIT FOR QUANTITATIVE DETECTION OF MICROALBUMIN IN URINE(BIOGENIX)-ALBUMIN TEST REAGENTS /KITS ARE MEDICAL DEVICES INTENDED FOR THE URINARY ANALYTES TEST PRELIMINARY ESTIMATION OF DIAGNOSTIC MARKERS IN URINE. ,HEV IGM RAPID TEST-FOR DETECTION OF HEV IGM ANTIBODY IN HUMAN SERUM AND PLASMA,BILIRUBIN TOTAL AND DIRECT REAGENT KIT-AN BILIRUBIN (TOTAL/DIRECT)TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF BILIRUBIN (TOTAL/DIRECT) IN SERUM/PLASMA,FERRITIN ELISA TEST KIT-AN FERRITIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF FERRITIN IN SERUM/ PLASMA, LIPOPROTEIN REAGENT KIT-A LIPOPROTEIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF LIPOPROTEINS IN SERUM / PLASMA.,SGPT REAGENT KIT-AN ALALINE AMINO TRANSFERASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME ALALINE AMINO TRANSFERASE IN SERUM/PLASMA,HEV IGM ELISA TEST KIT-HEPATITIS E TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HEPATITIS E VIRUS IN BLOOD/BODY FLUIDS,VITAMIN B12 ELISA TEST KIT-VITAMIN B TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF VITAMIN B IN BLOOD/BODY FLUIDS,FOLIC ACID ELISA TEST KIT-FOLIC ACID TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF FOLIC ACID IN HUMAN BLOOD/SERUM,GONORRHEA RAPID TEST(BIOGENIX)-FOR DETECTION OF GHONORRHEA ANTIBODY IN HUMAN SERUM AND PLASMA,CHOLESTEROL TOTAL REAGENT KIT-AN CHOLESTEROL TOTAL TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHOLESTEROL TOTAL IN SERUM/PLASMA, PHOSPHORUS REAGENT KIT-AN PHOSPHORUS TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF INORGANIC PHOSPHORUS IN SERUM, PLASMA/URINE,LDL CHOLESTEROL REAGENT KIT-AN CHOLESTEROL LDL TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHOLESTEROL LDL TEST IN SERUM/PLASMA,HAV IGG ELISA TEST KIT-HEPATITIS A TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HEPATITIS A VIRUS IN BLOOD/BODY FLUIDS,LH ELISA-A LUTEINIZING HORMONE (LH) TEST (LH) TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE PRELIMINARY SELF TESTING OF LUTEINIZING HORMONE (LH) IN

	URINE/BODY FLUIDS,POTASSIUM REAGENT KIT-AN POTASSIUM TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF POTASSIUM IN SERUM, PLASMA/URINE.,CK-MB REAGENT KIT-AN CREATINE KINASE MB INCLUDING CKMB,CKBB, CKMM TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CREATINE PHOSPHOKINASE IN SERUM/PLASMA,URINE STRIP (KETONE)-MEMBRANE STRIP CONTAINS REAGENTS FOR DETECTION OF KETONE,TOTAL T3 ELISA-ANTI THYROID GLAND ANTIBODIES REAGENT/KIT IS A MEDICAL DEVICE FOR THE SCREENING OF AUTO-ANTIBODIES TO THYROID GLAND ANTIGENS IN HUMAN SPECIMENS, TOTAL T4 ELISA-ANTI THYROID GLAND ANTIBODIES REAGENT/KIT IS A MEDICAL DEVICE FOR THE SCREENING OF AUTO-ANTIBODIES TO THYROID GLAND ANTIGENS IN HUMAN SPECIMENS,TOTAL PROTEIN REAGENT KIT-AN TOTAL PROTEIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME TOTAL PROTEIN IN SERUM/PLASMA,HBA1C REAGENT KIT-AN HBA1C TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF DIABETES IN SERUM/PLASMA,URINE STRIP 5 PARAMETER-MEMBRANE STRIP CONTAINS REAGENTS FOR DETECTION OF GLUCOSE, ALBUMIN, KETONE, BILIRUBIN, PROTEIN,ADENOSINE DEAMINASE REAGENT KIT-AN ADENOSINE DEAMINASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ADENOSINE DEAMINASE IN SERUM/PLASMA,ACID PHOSPHATASE REAGENT KIT-AN ACID PHOSPHATASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ACID PHOSPHATASE IN SERUM/PLASMA.,HEV IGG ELISA TEST KIT-HEPATITIS E TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HEPATITIS E VIRUS IN BLOOD/BODY FLUIDS,ESTROGEN TEST REAGENTS-ESTROGEN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ESTROGEN IN BLOOD/BODY FLUIDS,H. PYLORI ANTIBODY TEST KITS-FOR DETECTION OF H.PYLORI ANTIBODY IN HUMAN SERUM AND PLASMA, HDL CHOLESTEROL REAGENT KIT-AN CHOLESTEROL HDL TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHOLESTEROL HDL TEST IN SERUM/PLASMA,CHOLINESTERASE REAGENT KIT-AN CHOLINESTERASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHOLINESTERASE IN SERUM/PLASMA,URINE STRIP 10 PARAMETER-MEMBRANE STRIP CONTAINS REAGENTS FOR DETECTION OF GLUCOSE, ALBUMIN, UROBILINOGEN, BILIRUBIN, KETONES, NITRITE, BLOOD, PH, SPECIFIC GRAVITY, LEUCOCYTES,SGOT REAGENT KIT-AN ASPARTATE AMINO TRANSFERASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME ASPARTATE AMINO TRANSFERASE IN SERUM/PLASMA,GLUCOSE-6-PHOSPHATE

	DEHYDROGENASE (G6PD) REAGENT KIT-AN G6PD TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF G6PD IN SERUM/PLASMA,CK NAC REAGENT KIT-AN CREATINE KINASE NAC TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CREATINE PHOSPHOKINASE IN SERUM/PLASMA, MAGNESIUM REAGENT KIT-AN MAGNESIUM TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF MAGNESIUM IN SERUM/PLASMA,HAV IGM RAPID TEST-FOR DETECTION OF HAV IGM ANTIBODY IN HUMAN SERUM AND PLASMA,URINE STRIP(GLUCOSE)-MEMBRANE STRIP CONTAINS REAGENTS FOR DETECTION OF GLUCOSE,FT4 ELISA-TOTAL / FREE THYROXINE (T4)TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TOTAL / FREE THYROXINE (T4)IN BLOOD/BODY, RAPID IMMUNOCHROMATOGRAPHY LATERAL FLOW TEST FOR CHOLERA AG IN HUMAN SERUM/PLASMA/WHOLE BLOOD(CASSETTE FORMAT)(BIOGENIX)-FOR DETECTION OF VIBRIO CHOLERA VIRUS IN HUMAN SERUM AND PLASMA,VENEREAL DISEASE RESEARCH LABORATORY (VDRL) KIT FOR QUALITATIVE DETECTION OF ANTIBODY TO VDRL IN HUMAN SERUM/PLASMA(BIOGENIX)-VENEREAL DISEASE RESEARCH LABORATORY (VDRL) TEST REAGENT/KIT IS A MEDICAL DEVICE FOR THE QUALITATIVE DETECTION OF OF ANTIBODY TO VDRL IN HUMAN SERUM/PLASMA, TRANSFERRIN REAGENT KIT-AN TRANSFERRIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME TRANSFERRIN IN BLOOD,LDL DIRECT CHOLESTEROL REAGENT KIT-AN CHOLESTEROL LDL DIRECT TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHOLESTEROL LDL DIRECT TEST IN SERUM/PLASMA,ALBUMIN REAGENT KIT-AN ALBUMIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALBUMIN IN SERUM/PLASMA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2894	MFG/IVD/2020/000083	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:D-DIMER(Q-LINE)-Q-LINE® CLINICAL SYSTEMS D-DIMER KIT IS FOR THE QUANTITATIVE DETERMINATION OF PLATINUM FIBRINOGEN/FIBRIN DEGRADATION PRODUCTS (D-DIMER) IN HUMAN PLASMA. MEASUREMENT OF D-DIMER IS USED AS AN AID IN DETECTING THE PRESENCE OF INTRAVASCULAR COAGULATION AND FIBRINOLYSIS. FOR IN VITRO DIAGNOSTIC USE ONLY,HCV(Q-LINE ICT TEST)-HCV TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OFHCV IN BLOOD/BODY FLUIDS ,SYPHILIS(Q-LINE ICT TEST)-SYPHILIS TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE SCREENING OFSYPHILIS IN BLOOD/BODY FLUIDS ,HBSAG (HEPATITIS B SURFACE ANTIGEN)(Q-LINE ICT TEST)-HBSAG CARD IS A RAPID, IMMUNE CHROMATIC, IN VITRO AND ONE STEP ASSAY DESIGNED FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN IN HUMAN BLOOD SERUM OR PLASMA.,HIV(Q-LINE ICT TEST)-HIV TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OFHIV IN BLOOD/BODY FLUIDS, MALARIA ANTIGEN (PF/PAN)(Q-LINE ICT TEST)-MALARIA ANTIGEN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THEDETECTION OF MALARIA ANTIGEN INBLOOD/BODY FLUIDS. (PF/PAN),DENGUE COMBO(Q-LINE ICT TEST)-DENGUE COMBO IS AN ANTIGEN ANTIBODY TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF DENGUE ANTIGEN /ANTIBODY IN BLOOD/BODY FLUIDS,MALARIA ANTIGEN (PF/PV)(Q-LINE ICT TEST)-MALARIA ANTIGEN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THEDETECTION OF MALARIA ANTIGEN INBLOOD/BODY FLUIDS. (PF/PV),DENGUE ANTIGEN NS1(Q-LINE ICT TEST)-DENGUE VIRUS ANTIGEN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OFDENGUE VIRUS ANTIGEN IN BLOOD/BODY FLUIDS,COVID ELISA TEST FOR THE DETECTION OF IGG ANTIBODIES(Q-LISA)-Q-LISA- COVID IS AN IN-VITRO QUALITATIVE ENZYME IMMUNOASSAY FOR THE DETECTION OF IGG CLASS OF ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM OR PLASMA. IGG ANTIBODIES TO SARS-COV-2 ARE GENERALLY DETECTABLE IN BLOOD SEVERAL DAYS AFTER INITIAL INFECTION, ALTHOUGH THE DURATION OF TIME ANTIBODIES ARE PRESENT POST-INFECTION IS NOT WELL CHARACTERIZED. INDIVIDUALS MAY HAVE DETECTABLE VIRUS PRESENT FOR SEVERAL WEEKS FOLLOWING SEROCONVERSION.

2895	MFG/IVD/2020/000084	1.License Holder Name: GENESTORE INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:GENESTORE DETECTION EXPERT© SARS-COV-2(GENESTORE)-THE GENESTORE DETECTION EXPERT © SARS COV-2 KIT IS A REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RRT-PCR) TEST FOR THE QUALITATIVE DETECTION OF SARS COV-2 VIRAL NUCLEIC ACID IN UPPER AND LOWER RESPIRATORY SPECIMENS (SUCH AS NASOPHARYNGEAL SWAB, NASOPHARYNGEAL ASPIRATE, AND BRONCHOALVEOLAR LAVAGE (BAL)) FROM INDIVIDUALS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. RESULTS ARE FOR THE IDENTIFICATION OF SARS-COV-2 RNA. THE SARS-COV-2 RNA IS GENERALLY DETECTABLE IN NASOPHARYNGEAL SWABS IN TRANSPORT MEDIA DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS ARE INDICATIVE OF THE PRESENCE OF SARS-COV-2 RNA; CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE PATIENT INFECTION STATUS. POSITIVE RESULTS DO NOT RULE OUT BACTERIAL INFECTION OR CO-INFECTION WITH OTHER VIRUSES. THE AGENT DETECTED MAY NOT BE THE DEFINITE CAUSE OF DISEASE. LABORATORIES ARE REQUIRED TO REPORT ALL POSITIVE RESULTS TO THE APPROPRIATE PUBLIC HEALTH AUTHORITIES. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR PATIENT MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. TESTING WITH THE COVID-19 RT-PCR TEST IS INTENDED FOR USE BY TRAINED CLINICAL LABORATORY PERSONNEL SPECIFICALLY INSTRUCTED AND TRAINED IN THE TECHNIQUES OF REAL-TIME PCR AND IN VITRO DIAGNOSTIC PROCEDURES.

2896	MFG/IVD/2020/000085	1.License Holder Name: GENES2ME PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:RAPICOV RAPID ANTIGEN TEST KIT FOR COVID-19(RAPICOV)-RAPICOV RAPID ANTIGEN TEST KIT FOR COVID-19 IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIGEN IN HUMAN NASOPHARYNX. THIS TEST IS FOR IN-VITRO PROFESSIONAL DIAGNOSTIC USE AND INTENDED AS AN AID TO EARLY DIAGNOSIS OF SARS-COV-2 INFECTION IN PATIENT WITH CLINICAL SYMPTOMS., MULTIPLEX REAL TIME PCR KIT FOR COVID-19 (TARGETING ORF1AB, E AND N GENE OF SARS-COV-2)(VIRALDTECT)-FOR IN VITRO QUALITATIVE DETECTION OF SARS-COV-2 (ALSO KNOWN AS 2019-NCOV) ORF1AB, E, AND N GENE IN OROPHARYNGEAL SWABS AND SPUTUM SPECIMENS OF SUSPECTED SARS-COV-2-INFECTED PNEUMONIA CASES, SUSPECTED CLUSTERED INFECTION CASES, AND OTHERS WHO NEED SARS-COV-2 INFECTION DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS.
2897	MFG/IVD/2020/000088	1.License Holder Name: GENES2ME PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:MULTIPLEX REAL TIME PCR KIT FOR COVID-19(VIRALDTECT-II)-FOR IN VITRO QUALITATIVE DETECTION OF SARS-COV-2 (ALSO KNOWN AS 2019-NCOV) RDRP, E, AND N GENE IN OROPHARYNGEAL SWABS AND SPUTUM SPECIMENS OF SUSPECTED SARS-COV-2-INFECTED PNEUMONIA CASES, SUSPECTED CLUSTERED INFECTION CASES, AND OTHERS WHO NEED SARS-COV-2 INFECTION DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS.
2898	MFG/IVD/2020/000089	1.License Holder Name: GENES2ME PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:MAGRNA-II VIRAL RNA EXTRACTION KIT(MAGRNA-II)-THIS PRODUCT IS SUITABLE FOR EXTRACTING TOTAL VIRAL NUCLEIC ACID FROM CELL-FREE /LOW-CONTENT CELL BIOLOGICAL SAMPLES SUCH AS BODY FLUIDS, SERUMS, PLASMA, SOAKING SOLUTIONS, TISSUE HOMOGENATE SUPERNATANT, AND CULTURE SUPERNATANT. THE EXTRACTED PRODUCTS CAN BE USED FOR CLINICAL IN VITRO DETECTION

2899	MFG/IVD/2020/000090	1.License Holder Name: GENES2ME PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:MAGRNA VIRAL RNA EXTRACTION KIT(MAGRNA)-FOR EXTRACTION, ENRICHMENT, PURIFICATION AND OTHER STEPS OF NUCLEIC ACID WHICH IS USED FOR IN VITRO CLINICAL TESTS
2900	MFG/IVD/2020/000091	1.License Holder Name: M/S. JEEV DIAGNOSTICS PVT. LTD, 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM (VTM) KIT(IDENTIVTM)-FOR COLLECTION AND TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING VIRUSES FROM COLLECTION CENTER TO TESTING LABORATORY.
2901	MFG/IVD/2020/000092	1.License Holder Name: UNIVERSAL MEDICAP LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM KIT(TESTPAC)-SAMPLE ACQUISITION FROM NASOPHARYNGEAL AND/OR OROPHARYNGEAL AREA OF THE PATIENT. THE SAMPLE IS THEN TRANSFERRED INTO SPECIALLY FORMULATED MEDIA FOR ELUTION, STORAGE AND TRANSPORT.
2902	MFG/IVD/2020/000093	1.License Holder Name: BHAT BIO-TECH INDIA PRIVATE LIMITED 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM (VTM)(BHAT BIOSCAN)-BHAT BIO-SCAN VIRAL TRANSPORT MEDIUM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES FROM THE COLLECTION SITE TO THE TESTING LABORATORY.
2903	MFG/IVD/2020/000094	1.License Holder Name: GENES2ME PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:VIRALCOLLECT TRANSPORT KIT(VIRALCOLLECT)-FOR COLLECTION AND TRANSPORT OF CLINICAL SPECIMEN FOR RECOVERY OF VIRAL AGENTS.

2904	MFG/IVD/2020/000095	1.License Holder Name: UBIO BIOTECHNOLOGY SYSTEMS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:COVID-19 AG TEST(SENSIT RAPID)-COVID-19 AG TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE QUALITATIVE DETECTION OF SARS-COV2 ANTIGEN IN HUMAN NASOPHARYNGEAL OR THROAT SPECIMEN, WHICH INDICATES COVID-19 INFECTION,COVID-19 IGG/IGM RAPID TEST-COVID-19 IGG/IGM RAPID TEST KIT IS AN IVD MEDICAL DEVICE INTENDED FOR THE DETECTION OF IGG AND IGM ANTIBODIES PRODUCED AGAINST COVID -19 VIRUS(SARS- COV2) IN HUMAN WHOLE BLOOD/ SERUM OR PLASMA,COVID-19 REAL TIME RT- PCR TEST-COVID-19 REAL TIME RT-PCR TEST KIT IS INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN UPPER AND LOWER RESPIRATORY SPECIMENS
2905	MFG/IVD/2020/000096	1.License Holder Name: GENETIX BIOTECH ASIA PVT LTD 2.Approving Authority: WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM(CELLCLONE VIRAL TRANSPORT MEDIUM KIT)-CELLCLONE VIRAL TRANSFER MEDIUM KIT IS SPECIALLY DESIGNED TRANSPORT SYSTEM TO COLLECT AND TRANSPORT VIRUSES, CHLAMYDIA, AND MYCOPLASMA FOR FURTHER RESEARCH INCLUDING CLASSICAL CELL CULTURE METHODS, DIAGNOSTICS TESTING, AS WELL AS MOLECULAR BIOLOGY TECHNIQUES. (PHENOL RED OPTIONAL)
2906	MFG/IVD/2020/000097	1.License Holder Name: MEDIPOL PHARMACEUTICAL INDIA PVT. LTD 2.Approving Authority: SUB ZONAL BADDI 3.Device Name(Brand Name)-Intended Use:ONE STEP TR-QPCR COVID-19 DIAGNOSTIC KIT(MEDIPOL)-THIS KIT IS INTENDED FOR THE DETECTION OF SARS-COV-2 IN NASOPHARYNGEAL SWABS (NPS), NASAL SWABS (NS), BRONCHOALVEOLAR LAVAGE (BAL) OR OTHER APPROPRIATE CLINICAL SPECIMENS BY A ONE-STEP REVERSE TRANSCRIPTION REAL TIME PCR.

2907	MFG/IVD/2020/000098	1.License Holder Name: SWAGENE PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:VIRUS AND CELL-FREE RNA AND DNA KIT (SPIN COLUMN)(SATOGEN)-THE KIT IS FOR IN VITRO DIAGNOSTIC APPLICATIONS FOR VARIOUS RNA AND DNA VIRUSES INCLUDING SARS-COV-2 (NOVEL CORONAVIRUS CAUSING COVID-19). THE KIT IS ALSO FOR USE IN OBTAINING CELL-FREE RNA AND DNA FROM VARIOUS SAMPLES FOR DIAGNOSTIC USE. THE KIT IS INTENDED FOR SPIN-COLUMN BASED RAPID AND EFFICIENT EXTRACTION OF VIRAL AND TOTAL NUCLEIC ACID (RNA AND DNA) FROM THE FOLLOWING SAMPLE TYPES: • PLASMA • SERUM • URINE • CSF (CEREBROSPINAL FLUID) • BALF (BRONCHOALVEOLAR LAVAGE FLUID) • CELL-FREE BODY FLUIDS • VTM (VIRAL TRANSPORT MEDIA) • SWABS (NASOPHARYNGEAL ETC.) • WATER • STOOL
2908	MFG/IVD/2020/000099	1.License Holder Name: WRIG NANOSYSTEMS PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ONE STEP PROBE FREE RT PCR KIT FOR COVID(TRUECOV-RTPCR-SG)-THIS KIT IS INTENDED FOR THE DETECTION OF SARS-COV-2 IN NASOPHARYNGEAL SWABS (NPS), NASAL SWABS (NS), BRONCHOALVEOLAR LAVAGE (BAL) OR OTHER APPROPRIATE CLINICAL SPECIMENS BY A ONE-STEP REVERSE TRANSCRIPTION REAL-TIME PCR. THIS KIT IS FOR IN-VITRO DIAGNOSIS ONLY.

CENTRAL DRUG STANDARD CONTROL ORGANIZATION
CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2909	MFG/IVD/2020/000100	1.License Holder Name: AGAPPE DIAGNOSTICS LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:HIGH SENSITIVE C-REACTIVE PROTEIN (CRP) KIT(HIGH SENSITIVE C- REACTIVE PROTEIN (CRP) KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM,ANTI A ,B & D (IGG+IGM) BLOOD GROUPING REAGENT - COMBI KIT (ANTI-A,B&D (IGG+IGM))-INDENTED FOR BLOOD GROUPING OR TISSUE TYING, PROSTATE SPECIFIC ANTIGEN (PSA) CONTROL SET 3 LEVELS (PROSTATE SPECIFIC ANTIGEN (PSA) CONTROL SET 3 LEVELS)-PROSTATE SPECIFIC ANTIGEN (PSA) CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURE OF PROSTATE SPECIFIC ANTIGEN (PSA) IN HUMAN SERUM.,ANTI D MONOCLONAL (IGM+IGG) SERUM IP (ANTI D MONOCLONAL (IGM+IGG) SERUM)(ANTI D MONOCLONAL (IGM+IGG) SERUM IP (ANTI D MONOCLONAL (IGM+IGG) SERUM))-THIS REAGENT IS IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE. THE ANTI D (IGG+IGM) REAGENT IS INTENDED FOR THE IN VITRO DETECTION OF PRESENCE OR ABSENCE OF RHO (D) ANTIGEN ON HUMAN RED BLOOD CELLS.,ANTI A MONOCLINICAL SERUM, ANTI A(ANTI A MONOCLINICAL SERUM, ANTI A)-THIS REAGENT IS IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE. THE ANTI-A REAGENT IS INTENDED FOR THE IN VITRO DETECTION AND IDENTIFICATION OF THE HUMAN A BLOOD GROUP ANTIGEN BY DIRECT AGGLUTINATION.,SALMONELLE ANTIGEN TEST (WIDAL SLIDE) KIT(SALMONELLE ANTIGEN TEST (WIDAL SLIDE) KIT)-THIS REAGENT IS INTENDED FOR IN VITRO QUALITATIVE & SEMI QUANTITATIVE DETERMINATION OF SALMONELLA TYPHI & SALMONELLA PARATYPHI INFECTION,ANTI B BLOOD GROUPING SERUM IP (ANTI B MONOCLONAL SERUM)(ANTI B BLOOD GROUPING SERUM IP (ANTI B MONOCLONAL SERUM))-THIS REAGENT IS IN VITRO DIAGNOSTIC MEDICAL DEVICE FOR PROFESSIONAL USE. THE ANTI-B REAGENT IS INTENDED FOR THE IN VITRO DETECTION AND IDENTIFICATION OF THE HUMAN B BLOOD GROUP ANTIGEN BY DIRECT AGGLUTINATION,CARDIAC TROPONIN-I (CTNL) CALIBRATOR SET (5 LEVELS) LIQUID(CARDIAC TROPONIN-I (CTNL) CALIBRATOR SET (5 LEVELS) LIQUID)-DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR CARDIAC TROPONIN-I (CTNL) ESTIMATION.,FIBRINOGEN CONTROL(FIBRINOGEN CONTROL)-FIBRINOGEN CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE ACCURACY AND PRECISION FIBRINOGEN ASSAY.,TROPONIN I MISPA I3(TROPONIN I MISPA I3)-TROPONIN I IS INTENDED FOR THE

	QUALITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN HUMAN WHOLE BLOOD, SERUM AND PLASMA.,CRP LATEX SLIDE KIT (CRP)(CRP LATEX SLIDE KIT (CRP))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM.,-2-MICROGLOBULIN LATEX CONTROL(-2-MICROGLOBULIN LATEX CONTROL)--2-MICROGLOBULIN LATEX CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURE OF -2-MICROGLOBULIN LATEX IN HUMAN SERUM.,CRP ULTRA (HIGH SENSITIVITY CRP KIT)(CRP ULTRA (HIGH SENSITIVITY CRP KIT))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM,CRP TURBILATEX KIT (CRP)(CRP TURBILATEX KIT (CRP))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM,RPR SLIDE KIT (RPR)(RPR SLIDE KIT (RPR))-RPR (RAPID PLASMA REAGIN) TEST IS A NON-TREPONEMAL TEST FOR THE SEROLOGICAL DIAGNOSIS OF SYPHILIS. SPECIFICITY, REACTIVITY AND SENSITIVITY ARE SIMILAR TO THAT OF CLASSICAL VDRL TEST. IT IS A RELIABLE, ECONOMICAL AND RAPID TEST AND HENCE RECOMMENDED AS A SCREENING TEST.,PROSTATE SPECIFIC ANTIGEN (PSA) CALIBRATOR SET (3 LEVELS)(PROSTATE SPECIFIC ANTIGEN (PSA) CALIBRATOR SET (3 LEVELS))-DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR PROSTATE SPECIFIC ANTIGEN (PSA) ESTIMATION.,PT/APTT CONTROL(S) (PROTHROMBIN ACTIVATED PARTIAL THROMBOPLASTIN TIME CONTROL)(PT/APTT CONTROL(S) (PROTHROMBIN ACTIVATED PARTIAL THROMBOPLASTIN TIME CONTROL))-PT/APTT CONTROL(S) (PROTHROMBIN/ ACTIVATED PARTIAL THROMBOPLASTIN TIME CONTROL) IS AN ASSAYED HUMAN PLASMA USED FOR QUALITY CONTROL CHECKING OF COAGULATION ASSAYS SUITABLE FOR MANUAL PROCEDURE AND AUTOMATED ANALYZERS.,CRP ULTRA CALIBRATOR(CRP ULTRA CALIBRATOR)-THIS REAGENT IS INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR CRP ULTRA ESTIMATION.,CRP LEIT WITH CALIBRATOR(CRP LEIT WITH CALIBRATOR)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM.,D-DIMER TEST KIT(D-DIMER TEST KIT)-THIS REAGENT IS USED FOR IN VITRO QUANTITATIVE DETERMINATION OF FIBRIN DEGRADATION PRODUCT D-DIMER IN HUMAN PLASMA BY NEPHELOMETRIC IMMUNOASSAY.,CRP ULTRA (HIGH SENSITIVE CRP KIT) (WITH CALIBRATOR)(CRP ULTRA (HIGH SENSITIVE CRP KIT) (WITH CALIBRATOR))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM,DENGUE NS1 RAPID TEST

	(DENGUE NS1 RAPID TEST– 25 TEST KIT)-AGAPPE DENGUE NS1 DEVICE IS A CHROMATOGRAPHIC IMMUNOASSAY KIT FOR RAPID DETECTION OF NS1 ANTIGEN AND DIFFERENTIAL DETECTION OF IMMUNOGLOBULIN G (LGG) AND IMMUNOGLOBULIN M (LGM) AGAINST ALL TYPES OF DENGUE VIRUSES USING HUMAN SERUM, PLASMA AND WHOLE BLOOD.,COAGULATION CONTROL (COAGULATION CONTROL)-COAGULATION CONTROL IS AN ASSAYED HUMAN PLASMA USED FOR QUALITY CONTROL CHECKING OF COAGULATION ASSAYS SUITABLE FOR MANUAL PROCEDURE AND AUTOMATED ANALYZERS.,CARDIAC TROPONIN-I (CTNL) IMMUNOTURBIDIMETRIC LATEX ASSAY(CARDIAC TROPONIN-I (CTNL) IMMUNOTURBIDIMETRIC LATEX ASSAY)-IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFRACTION, UNSTABLE ANGINA, ACUTE MYOCARDITIS AND ACUTE CORONARY SYNDROME.,CARDIAC TROPONIN-I (CTNL) CALIBRATOR SET (5 LEVELS) LYOPHILIZED(CARDIAC TROPONIN-I (CTNL) CALIBRATOR SET (5 LEVELS) LYOPHILIZED)-DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR CARDIAC TROPONIN-I (CTNL) ESTIMATION.,CARDIAC TROPONIN-I FAST TEST KIT(CARDIAC TROPONIN-I FAST TEST KIT)-CARDIAC TROPONIN-I FAST TEST KIT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INJURY SUCH AS ACUTE MYOCARDIAL INFARCTION (AMI), UNSTABLE ANGINA, ACUTE MYOCARDITIS AND ACUTE CORONARY SYNDROME (ACS)., PROTHROMBIN TIME (PT) KIT(PROTHROMBIN TIME (PT) KIT)-PROTHROMBIN TIME (PT) KIT IS AN ASSAYED HUMAN PLASMA USED FOR COAGULATION ASSAYS SUITABLE FOR MANUAL PROCEDURE AND AUTOMATED ANALYZERS.,TROPONIN I (STRIP/ CARD) (TROPONIN I (STRIP/ CARD))-TROPONIN I TEST IS A RAPID IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF CARDIAC TROPONIN I (CTNI) IN HUMAN WHOLE BLOOD, SERUM AND PLASMA, CRP ULTRASENSITIVE CONTROL(CRP ULTRASENSITIVE CONTROL)-HSCRP CONTROL IS AN ASSAYED LIQUID STABLE QUALITY CONTROL SERUM INTENDED TO MONITOR THE ACCURACY AND PRECISION OF HSCRP ASSAY.,THROMBIN TIME KIT(THROMBIN TIME KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETERMINATION OF THROMBIN TIME (TT) IN CITRATED HUMAN PLASMA.,NT-PROBNP FAST TEST KIT(NT-PROBNP FAST TEST KIT)-NT-PROBNP FAST TEST KIT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF N-TERMINAL B-TYPE NATRIURETIC PEPTIDE PRECURSOR (NT-

	PROBNP) IN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS USED AS AN AID IN THE CLINICAL DIAGNOSIS, PROGNOSIS AND EVALUATION OF HEART FAILURE (HF),PCT FAST TEST KIT (PROCALCITONIN)(PCT)(PCT FAST TEST KIT (PROCALCITONIN)(PCT))-PCT FAST TEST KIT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PROCALCITONIN (PCT) IN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS USED AS AN AID IN THE ASSESSMENT AND EVALUATION OF PATIENTS SUSPECTED OF BACTERIAL INFECTION, TRAUMA OR SHOCK.,D-DIMER STRIP/KIT(D-DIMER STRIP/KIT)-THIS REAGENT IS USED FOR IN VITRO QUANTITATIVE DETERMINATION OF FIBRIN DEGRADATION PRODUCT D-DIMER IN HUMAN PLASMA BY NEPHELOMETRIC IMMUNOASSAY.,H. PYLORI CONTOL SET (2 LEVELS)(H. PYLORI CONTOL SET (2 LEVELS))-H. PYLORI CONTROL IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURE OF H. PYLORI IN HUMAN SERUM.,FIBRINOGEN KIT(FIBRINOGEN KIT)-QUANTITATIVE DETERMINATION OF FIBRINOGEN IVD,DENGUE IGG/IGM(STRIP/KIT)(DENGUE IGG/IGM(STRIP/KIT))-DENGUE IGGIGM (STRIPKIT)IS A CHROMATOGRAPHIC IMMUNOASSAY KIT FOR RAPID DIFFERENTIAL DETECTION OF IMMUNOGLOBULIN G (LGG) AND IMMUNOGLOBULIN M (LGM) AGAINST ALL TYPES OF DENGUE VIRUSES USING HUMAN SERUM, PLASMA AND WHOLE BLOOD.,CRP CALIBRATOR(CRP CALIBRATOR)-CRP CALIBRATOR IS INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR CRP ESTIMATION., D-DIMER CARTRIDGE (MISPA -I3)(D-DIMER CARTRIDGE (MISPA -I3))-THIS REAGENT IS USED FOR IN VITRO QUANTITATIVE DETERMINATION OF FIBRIN DEGRADATION PRODUCT D-DIMER IN HUMAN PLASMA BY NEPHELOMETRIC IMMUNOASSAY.,HSCRP (MISPA-I3)(HSCRP (MISPA-I3))-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF C-REACTIVE PROTEIN (HSCRP) IN HUMAN SERUM,CRP LATEX(CRP LATEX)-DIAGNOSTIC DEVICE FOR QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP),ADENOSINE DEAMINASE (ADA)(ADENOSINE DEAMINASE (ADA))-ADENOSINE DEAMINASE (ADA) ASSAY KIT IS FOR DETERMINATION OF ADA ACTIVITY IN HUMAN SERUM OR PLASMA SAMPLES.,COMBI KIT DENGUE NS1 AG CASETTE & DENGUE/IGG/IGM CASSETTE(COMBI KIT DENGUE NS1 AG CASETTE & DENGUE/IGG/IGM CASSETTE)-AGAPPE DENGUE COMBI DEVICE IS A CHROMATOGRAPHIC IMMUNOASSAY KIT FOR RAPID DETECTION OF NS1 ANTIGEN AND DIFFERENTIAL DETECTION OF IMMUNOGLOBULIN G (LGG) AND IMMUNOGLOBULIN M (LGM) AGAINST ALL TYPES OF DENGUE VIRUSES USING HUMAN SERUM, PLASMA AND WHOLE BLOOD.,CRP CONTROL(CRP CONTROL)-CRP CONTROL IS AN ASSAYED LIQUID STABLE QUALITY CONTROL SERUM INTENDED TO

	MONITOR THE ACCURACY AND PRECISION OF CRP ASSAY., ADENOSINE DEAMINASE (ADA) CALIBRATOR SET LYOPHILIZED (ADENOSINE DEAMINASE (ADA) CALIBRATOR SET LYOPHILIZED)-ADENOSINE DEAMINASE (ADA) CALIBRATOR SET LYOPHILIZED SET LIQUID IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADA ASSAY ON CLINICAL CHEMISTRY SYSTEMS.,H. PYLORI CALIBRATOR SET(H. PYLORI CALIBRATOR SET)-DIAGNOSTIC MEDICAL DEVICE INTENDED FOR THE PREPARATION OF CALIBRATION CURVE FOR H. PYLORI ESTIMATION.,D-DIMER CONTROL(BI-LEVEL)(D-DIMER CONTROL(BI-LEVEL))-D-DIMER CONTROL (BI-LEVEL) IS AN ASSAYED LYOPHILIZED QUALITY CONTROL SERUM INTENDED FOR MONITORING THE ACCURACY AND PRECISION OF D-DIMER ASSAY.,H. PYLORI AB REAGENT KIT(H. PYLORI AB REAGENT KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETECTION OF H. PYLORI ANTIBODY IN SERUM. ANTI-H. PYLORI ANTIBODY DETECTION IS USEFUL IN THE DIAGNOSIS AND TREATMENT OF H. PYLORI INFECTION.,D-DIMER CALIBRATOR(D-DIMER CALIBRATOR)-D-DIMER CALIBRATOR IS A STANDARD SUBSTANCE FOR ESTABLISHMENT OF THE CALIBRATION CURVE., DENGUE IGG/IGM(STRIPCARD)(DENGUE IGG/IGM(STRIPCARD))-DENGUE IGGIGM(STRIPKIT)IS A CHROMATOGRAPHIC IMMUNOASSAY KIT FOR RAPID DIFFERENTIAL DETECTION OF IMMUNOGLOBULIN G (LGG) AND IMMUNOGLOBULIN M (LGM) AGAINST ALL TYPES OF DENGUE VIRUSES USING HUMAN SERUM, PLASMA AND WHOLE BLOOD.,-2-MICROGLOBULIN LATEX REAGENT KIT(-2-MICROGLOBULIN LATEX REAGENT KIT)-DIAGNOSTIC MEDICAL DEVICE FOR THE DETERMINATION OF -2-MICROGLOBULIN (2M) IN HUMAN SERUM.,CARDIAC TROPONIN I (CTNL) CONTROL SET (2 LEVELS) LIQUID(CARDIAC TROPONIN I (CTNL) CONTROL SET (2 LEVELS) LIQUID)-CARDIAC TROPONIN I (CTNL) CONTROL SET (2 LEVELS) LIQUID IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURE OF CARDIAC TROPONIN I (CTNL) LIQUID IN HUMAN SERUM.,CARDIAC TROPONIN I (CTNL) CONTROL SET (2 LEVELS) LYOPHILIZED(CARDIAC TROPONIN I (CTNL) CONTROL SET (2 LEVELS) LYOPHILIZED)-CARDIAC TROPONIN I (CTNL) CONTROL SET (2 LEVELS) LYOPHILIZED IS AN ASSAYED QUALITY CONTROL INTENDED FOR MONITORING THE PRECISION OF LABORATORY TESTING PROCEDURE OF CARDIAC TROPONIN I (CTNL) LIQUID IN HUMAN SERUM.,APTT(ACTIVATED PARTIAL THROMBOPLASTIN TIME)KIT(APTT(ACTIVATED PARTIAL THROMBOPLASTIN TIME)KIT)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF CERULOPLASMIN IN HUMAN SERUM,CRP TURBILATEX KIT (WITH CALIBRATOR)(CRP TURBILATEX KIT (WITH CALIBRATOR))-THIS REAGENT IS INTENDED

		FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM,ADENOSINE DEAMINASE (ADA) CALIBRATOR SET LIQUID(ADENOSINE DEAMINASE (ADA) CALIBRATOR SET LIQUID)-ADENOSINE DEAMINASE (ADA) CALIBRATOR SET LIQUID SET LIQUID IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADA ASSAY ON CLINICAL CHEMISTRY SYSTEMS.,CRP CARTRIDGE MISPA I3(CRP CARTRIDGE MISPA I3)-DIAGNOSTIC DEVICE FOR THE QUANTITATIVE IN-VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM, ADENOSINE DEAMINASE (ADA) CONTROL SET (2LEVELS) LYOPHILIZED(ADENOSINE DEAMINASE (ADA) CONTROL SET (2LEVELS) LYOPHILIZED)-ADENOSINE DEAMINASE (ADA) CONTROL SET (2LEVELS) LYOPHILIZED SET LIQUID IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADA ASSAY ON CLINICAL CHEMISTRY SYSTEMS.,D-DIMER CONTROL(D-DIMER CONTROL)-D-DIMER CONTROL IS AN ASSAYED LYOPHILIZED QUALITY CONTROL SERUM INTENDED FOR MONITORING THE ACCURACY AND PRECISION OF D-DIMER ASSAY.,AGCRP CRP TURBILATEX(AGCRP CRP TURBILATEX)-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN SERUM,FIBRINOGEN KIT(FIBRINOGEN KIT)-QUANTITATIVE DETERMINATION OF FIBRINOGEN IVD,ADENOSINE DEAMINASE (ADA) CONTROL SET (2LEVELS) LIQUID(ADENOSINE DEAMINASE (ADA) CONTROL SET (2LEVELS) LIQUID)-ADENOSINE DEAMINASE (ADA) CONTROL SET (2LEVELS) LIQUID SET LIQUID IS INTENDED FOR IN VITRO DIAGNOSTIC USE IN THE CALIBRATION OF ADA ASSAY ON CLINICAL CHEMISTRY SYSTEMS.
2910	MFG/IVD/2020/000101	1.License Holder Name: METADESIGN SOLUTIONS PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 RT-PCR DETECTION KIT(MDS RT-PCR KIT (COVID DETECT))-THE MDS RT-PCR KIT (COVID DETECT) IS A REAGENT SYSTEM, BASED ON REAL- TIME PCR TECHNOLOGY, FOR THE QUALITATIVE DETECTION AND DIFFERENTIATION OF LINEAGE B-BETACORONAVIRUS (B-ßCOV) AND SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-COV-2) SPECIFIC RNA.,RNA EXTRACTION KIT(MDS VIRAL RNA EXTRACTION KIT)-MDS VIRAL RNA EXTRACTION KIT IS INTENDED FOR MOLECULAR BIOLOGY APPLICATIONS. THIS PRODUCT IS NOT INTENDED FOR THE DIAGNOSIS, PREVENTION, OR TREATMENT OF A DISEASE.

2911	MFG/IVD/2020/000102	1.License Holder Name: GCC BIOTECH INDIA PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUGS STANDARD CONTROL ORGANIZATION(EAST ZONE) 3.Device Name(Brand Name)-Intended Use:DIAGSURE NCOV-19 DETECTION ASSAY (MULTIPLEX, TAQMAN BASED)(DIAGSURE)-THE DIAGSURE NCOV-19 DETECTION ASSAY (MULTIPLEX, TAQMAN BASED), DEVELOPED BY GCC BIOTECH INDIA PRIVATE LIMITED IS AN IN VITRO DIAGNOSTIC (IVD) REAL-TIME REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION (RT-PCR) TEST OPTIMISED FOR SINGLE-PLEX AND/OR MULTIPLEX TAQMAN PRIMER/PROBE SETS INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SEVERE ACUTE RESPIRATORY SYNDROME-RELATED CORONAVIRUS 2 (SARS-COV-2) IN HUMAN NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, ANTERIOR NASAL SWAB, MID-TURBINATE AND SPUTUM SPECIMENS FROM INDIVIDUALS WITH SIGNS AND SYMPTOMS OF INFECTION WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTH CARE PROVIDER.
2912	MFG/IVD/2020/000103	1.License Holder Name: BIOSENSE TECHNOLOGIES PVT LIMITED 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:HEMOGLOBIN ANALYSER (HBCHECK ANALYSER)-HEMOGLOBIN ANALYSER IS INTENDED TO READ HEMOGLOBIN STRIPS/SPECIMEN RECEPTACLE USING ABSORBANCE PHOTOMETRY.,HEMOGLOBIN ANALYSER-HB CHEK (A REAGENT LESS SPECIMEN RECEPTACLE) IS INTENDED TO BE USED FOR QUANTITATIVE MEASUREMENT OF HEMOGLOBIN FOR ANEMIA DETECTION AND OTHER HEMOGLOBIN RELATED SCREENING

CENTRAL DRUGS STANDARD CONTROL ORGANISATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2913	MFG/IVD/2020/000104	1.License Holder Name: VITHAI PHARMACEUTICAL PRIVATE LIMITED 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF SWAB SPECIMEN FOR TRUEPREP® AUTO-TRUEPREP® AUTO TRANSPORT MEDIUM FOR SWAB SPECIMEN PACK IS USED AS A MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF VARIOUS TYPES OF SWAB SPECIMENS BEFORE PROCEEDING FOR PRE-TREATMENT USING LYSIS BUFFER, EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE.,MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF SWAB SPECIMEN FOR NUCLEIC ACID TESTS-MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF SWAB SPECIMEN FOR NUCLEIC ACID TESTS IS INTENDED FOR USE WITH ENDOCERVICAL, VAGINAL, ANORECTAL, NASAL AND THROAT SWAB SPECIMENS AS A MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF VARIOUS TYPES OF SWABS SPECIMENS FOR NUCLEIC ACID ASSAYS. THE TRANSPORT MEDIUM WHICH IS ALSO A LYSIS MEDIUM, INACTIVATES THE VIRUS AND BACTERIA IN THE SAMPLE WHILE MAINTAINING THE INTEGRITY OF THE NUCLEIC ACIDS. THE MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF SWAB SPECIMEN FOR NUCLEIC ACID TESTS NOT ONLY ENSURES SAFE TRANSPORT OF THE SAMPLE FROM THE SITE OF COLLECTION TO THE TESTING CENTRE BUT ALSO MINIMIZES BIO-SAFETY REQUIREMENTS FOR FURTHER PROCESSING OF THE SAMPLE AND CONDUCTING NUCLEIC ACID TESTS BY THE TESTING CENTER. ,UNIVERSAL SAMPLE PRE-TREATMENT PACK FOR NON MTB SAMPLES-UNIVERSAL SAMPLE PRE-TREATMENT PACK FOR NON MTB SAMPLES IS USED TO PRE-TREAT THE SAMPLES BEFORE PROCEEDING FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE ,SAMPLE PRE-TREATMENT PACK FOR MTB SAMPLES-SAMPLE PRE-TREATMENT PACK FOR MTB SAMPLES IS USED TO LIQUEFY AND PRETREAT THE PULMONARY AND EPTB SPECIMEN BEFORE PROCEEDING FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE.

2914	MFG/IVD/2020/000105	1.License Holder Name: GCC BIOTECH INDIA PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUGS STANDARD CONTROL ORGANIZATION(EAST ZONE) 3.Device Name(Brand Name)-Intended Use:MAGB VIRAL RNA ISOLATION KIT(MAGB)-THE MAGB VIRAL RNA ISOLATION KIT IS AN IN VITRO DIAGNOSTIC (IVD) KIT CAN EFFICIENTLY ISOLATE VIRAL RNA FROM SAMPLES AS LARGE AS 100 AND 200 L. RNA RECOVERY IS TYPICALLY GREATER THAN 95%, BUT MAY VARY DEPENDING ON SAMPLE TYPE. THE RNA RECOVERED WITH THE KIT IS OF HIGH QUALITY AND PURITY AND IS SUITABLE FOR REAL-TIME RT-PCR. THIS KIT CAN ISOLATE NUCLEIC ACID FROM SEVERE ACUTE RESPIRATORY SYNDROME-RELATED CORONAVIRUS 2 (SARS-COV-2) IN HUMAN NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, ANTERIOR NASAL SWAB, MID-TURBINATE AND SPUTUM SPECIMENS FROM INDIVIDUALS WITH SIGNS AND SYMPTOMS OF INFECTION WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTH CARE PROVIDER. MAGB VIRAL RNA ISOLATION KIT HAS BEEN OPTIMIZED FOR USE WITH BIOLOGICAL FLUIDS AND CELL-FREE SAMPLES SUCH AS SERUM, PLASMA, SWABS, AND CELL CULTURE MEDIA.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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2915	MFG/IVD/2020/000106	1.License Holder Name: ADVY CHEMICAL PVT. LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:RF TURBI LATEX. QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR IN HUMAN SERUM OR PLASMA (QUALAX)-LATEX ENHANCED TURBIDIMETRIC TEST FOR THE MEASUREMENT OF RHEUMATOID FACTOR IN HUMAN SERUM OR PLASMA,RF SLIDE LATEX QUALITATIVE DETERMINATION OF RHEUMATOID FACTOR IN HUMAN SERUM(QUALAX)-LATEX AGGLUTINATION SLIDE TEST FOR QUALITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) IN HUMAN SERUM,DENGUE IGM /IGG RAPID AND PRECISE CARD TEST. DETECTION OF DENGUE IGM AND IGG ANTIBODIES IN HUMAN SERUM, PLASMA OR WHOLE BLOOD (EZDX)-EZDX DENGUE IGM / IGG RAPID AND PRECISE CARD TEST IS INTENDED FOR DETECTION OF DENGUE IGM AND IGG ANTIBODIES IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE ASSAY IS USED AS A SCREENING TEST FOR DENGUE VIRAL INFECTION AND AS AN AID IN DIFFERENTIAL DIAGNOSIS OF PRIMARY AND SECONDARY INFECTIONS IN CONJUNCTION WITH OTHER CRITERIA,HBA1C IMMUNOTURBIDIMETRIC KIT. QUANTITATIVE DETERMINATION OF HBA1C (GLYCOSYLATED HAEMOGLOBIN) BY IMMUNOTURBIDIMETRIC ASSAY IN HUMAN WHOLE BLOOD(TURBITEST)-HBA1C IMMUNOTURBIDIMETRIC ASSAY IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HBA1C (GLYCOSYLATED HAEMOGLOBIN) I.E. HEMOGLOBIN FRACTION BY IMMUNOTURBIDIMETRIC ASSAY IN HUMAN WHOLE BLOOD.PERCENT HBA1C MEASUREMENTS ARE USED FOR MONITORING LONG-TERM GLYCEMIC CONTROL IN DIABETIC PATIENTS.,CRP TURBI LATEX. QUANTITATIVE DETERMINATION OF C. REACTIVE PROTEIN IN HUMAN SERUM OR PLASMA (QUALAX)-LATEX ENHANCED TURBIDIMETRIC TEST FOR THE MEASUREMENT OF C-REACTIVE PROTEIN IN HUMAN SERUM OR PLASMA,CRP SLIDE LATEX. QUALITATIVE DETERMINATION OF C. REACTIVE PROTEIN IN HUMAN SERUM (QUALAX)-LATEX AGGLUTINATION SLIDE TEST FOR QUALITATIVE DETERMINATION OF C.REACTIVE PROTEIN (CRP) IN HUMAN SERUM

2916	MFG/IVD/2020/000107	1.License Holder Name: M/S ASTAM DIAGNOSTICS PVT. LTD. 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:LH FERTILITY MIDSTREAM OVULATION TEST/KIT(PRATHAM)-FOR DETECTION OF LH (LUTEINIZING HORMONE) IN HUMAN FEMALE URINE,HCG (HUMAN CHORIONIC GONADOTROPIN) URINE TEST KIT/DEVICE(PRATHAM)-FOR THE DETECTION OF HCG IN FEMALE URINE SAMPLE,HCG (HUMAN CHORIONIC GONADOTROPIN) URINE TEST STRIP(PRATHAM)-FOR THE DETECTION OF HCG IN FEMALE URINE SAMPLE,SALMONELLA TYPHI IGG &IGM TEST/DEVICE(PRATHAM)-FOR DETECTION OF S.TYPHI (SALMONELLA TYPHI) IN HUMAN SERUM/ PLASMA/ WHOLE BLOOD., URINE STRIP (GLUCOSE & PROTEIN) 2P(PRATHAM)-FOR DETECTION OF GLUCOSE & PROTEIN IN HUMAN URINE
2917	MFG/IVD/2020/000108	1.License Holder Name: SHRIMPEX BIOTECH SERVICES PRIVATE LIMITED 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIA (SBS VIRAL TRANSPORT MEDIA)-FOR COLLECTION AND TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING VIRUSES FOR NASOPHARYNGEAL AND THROAT SAMPLING FROM THE COLLECTION CENTER TO THE LABORATORY.
2918	MFG/IVD/2020/000109	1.License Holder Name: PROMEA THERAPEUTICS PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:RINSE (3 PART DIFFERENTIAL)-FOR RINSE OF HEMATOLOGY ANALYSER PROBE TO REMOVE REMNANTS OF WHOLE BLOOD SAMPLE.,RINSE (3 PART DIFFERENTIAL)-FOR RINSE OF HEMATOLOGY ANALYSER PROBE TO REMOVE REMNANTS OF WHOLE BLOOD SAMPLE.,DILUENT (3 PART DIFFERENTIAL)-FOR DILUTION OF WHOLE BLOOD SAMPLE FOR HEMATOLOGICAL ANALYSIS BY HEMATOLOGY ANALYSER,DILUENT (3 PART DIFFERENTIAL)-FOR DILUTION OF WHOLE BLOOD SAMPLE FOR HEMATOLOGICAL ANALYSIS BY HEMATOLOGY ANALYSER,CF-LYSE (3 PART DIFFERENTIAL)-LYSIS OF BLOOD CELLS IN WHOLE BLOOD SAMPLES FOR HEMATOLOGICAL ANALYSIS BY HEMATOLOGY ANALYSER.

2919	MFG/IVD/2020/000110	1.License Holder Name: SHRIMPEX BIOTECH SERVICES PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:VIRAL RNA EXTRACTION KIT(MINI VIRAL RNA EXTRACTION KIT (COLUMN) (SBS-C))-USED FOR EXTRACTION OF RNA FROM SAMPLES AND SAMPLES CONTAINING RNA VIRUS PARTICLES OR INTRACELLULAR PATHOGENS. THIS KIT IS DESIGNED TO EXTRACT COVID-19 VIRAL RNA FROM THE SAMPLES, VIRAL RNA EXTRACTION KIT (COLUMN)(SBS- VIRAL RNA EXTRACTION KIT (COLUMN))-USED FOR EXTRACTION OF RNA FROM SAMPLES AND SAMPLES CONTAINING RNA VIRUS PARTICLES OR INTRACELLULAR PATHOGENS. THIS KIT IS DESIGNED TO EXTRACT COVID-19 VIRAL RNA FROM THE SAMPLES BASED ON COLUMN METHOD.

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2920	MFG/IVD/2020/000111	1.License Holder Name: SIDAK LIFECARE PVT LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:RF LATEX(SIDAK LIFECARE)-DETECTION OF RHEUMATOID FACTOR IN BLOOD SERUM, VIRAL TRANSPORT MEDIUM (VTM) COLLECTION KIT-FOR COLLECTION AND TRANSPORT OF VIRUS SAMPLE,HEMOGLOBIN REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF HEMOGLOBIN IN BLOOD,H PYLORI AB-IT IS USED FOR DETECTION OF H. PYLORI ANTIGEN IN HUMAN FECAL SPECIMEN,DIRECT LDL CHOLESTEROL REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF LDL CHOLESTEROL IN SERUM/PLASMA, VIRAL/PATHOGEN NUCLEIC ACIDS EXTRACTION KIT-FOR PURIFICATION OF VIRAL AND BACTERIAL NUCLEIC ACIDS FROM HUMAN CELL FREE BIO SPECIMEN, SUCH AS SERUM, PLASMA, URINE ETC.,PREGNANCY CARD/STRIP TEST (MINI)(PREG CLEAR)-FOR THE DETECTION OF HCG IN FEMALE URINE SAMPLE ,GLUCOSE REAGENT/KIT (POWDER)(SIDAK LIFECARE)-ESTIMATION OF GLUCOSE IN BLOOD/PLASMA/BODY FLUIDS,DENGUE IGG/IGM CARD/STRIP TEST(SIDAK LIFECARE)-DETECTION OF DENGUE IGG/IGM (ANTIBODY) IN PLASMA/BLOOD/SERUM,BUN (UREA) REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF UREA/BLOOD UREA NITROGEN IN PLASMA/SERUM/URINE,TOTAL PROTEIN REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF TOTAL PROTEIN IN SERUM/PLASMA,CHLORIDE REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF CHLORIDE IN PLASMA/SERUM,SWEAT/URINE,GLUCOSE REAGENT/KIT (LIQUID) (SIDAK LIFECARE)-ESTIMATION OF GLUCOSE IN BLOOD/PLASMA/BODY FLUIDS,ALKALINE PHOSPHATASE REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF ALKALINE PHOSPHATASE LEVEL PRESENT IN SERUM/PLASMA,LIPASE REAGENT/KIT (POWDER)(SIDAK LIFECARE)-DETERMINATION OF LIPASE ACTIVITY IN SERUM AND PLASMA,CREATININE REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF CREATININE IN SERUM, PLASMA/URINE ,BUN (UREA) REAGENT/KIT (POWDER)(SIDAK LIFECARE)-ESTIMATION OF UREA/BLOOD UREA NITROGEN IN PLASMA/SERUM/URINE,URINE STRIP (LEUKOCYTE, NITRITE, UROBILINOGEN, PROTEIN, PH, BLOOD, SPECIFIC GRAVITY, KETONE, BILIRUBIN, GLUCOSE) 10P(SIDAK LIFECARE)-FOR THE DETECTION OF LEUKOCYTE, NITRITE, UROBILINOGEN, PROTEIN, PH, BLOOD, SPECIFIC GRAVITY, KETONE, BILIRUBIN, GLUCOSE IN URINE SAMPLE., SGOT/AST REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF THE ENZYME ASPARTATE AMINO TRANSFERASE (AST/SGOT) IN SERUM/PLASMA,LIPASE REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-DETERMINATION OF LIPASE ACTIVITY IN SERUM AND PLASMA,

	BILIRUBIN DIRECT & TOTAL REAGENT/KIT (LIQUID)(SIDAK LIFECARE) -ESTIMATION OF BILIRUBIN (TOTAL AND DIRECT) IN SERUM/PLASMA, CK-NAC REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-TO ESTIMATE THE ENZYME CREATINE PHOSPHOKINASE OR ITS ISOENZYMES IN SERUM/PLASMA,INORGANIC PHOSPHORUS REAGENT/KIT (LIQUID) (SIDAK LIFECARE)-ESTIMATION OF INORGANIC PHOSPHORUS IN SERUM PLASMA/URINE,ADA FOR TB REAGENT/KIT(SIDAK LIFECARE)- DETERMINATION OF ADENOSINE DEAMINASE (ADA) IN HUMAN SERUM OR PLASMA.,CK-NAC REAGENT/KIT (MONO-VIAL)(SIDAK LIFECARE)-TO ESTIMATE THE ENZYME CREATINE PHOSPHOKINASE OR ITS ISOENZYMES IN SERUM/PLASMA,URINE STRIP (GLUCOSE) 1P (SIDAK LIFECARE)-FOR THE DETECTION OF GLUCOSE IN URINE SAMPLE.,CHOLESTEROL REAGENT/KIT (LIQUID)(SIDAK LIFECARE)- ESTIMATION OF CHOLESTEROL IN BLOOD/BODY FLUIDS, TRIGLYCERIDES REAGENT/KIT (LIQUID)(SIDAK LIFECARE)- ESTIMATION OF TRIGLYCERIDES IN SERUM/PLASMA,CALCIUM REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF TOTAL CALCIUM IN SERUM.,DIRECT HDL CHOLESTEROL REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF HDL CHOLESTEROL IN SERUM/PLASMA,POTASSIUM REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF POTASSIUM IN SERUM PLASMA/URINE, PREGNANCY CARD/STRIP TEST (PREG CLEAR)-FOR THE DETECTION OF HCG IN FEMALE URINE SAMPLE,LEISHMANIA TEST(SIDAK LIFECARE)-DETECTION OF LEISHMANIA(KALA AZAR)ANTIBODY IN BLOOD/BODY FLUIDS,URINE STRIP (GLUCOSE & KETONE) 2P(SIDAK LIFECARE)-FOR THE DETECTION GLUCOSE AND KETONE IN URINE SAMPLE.,URIC ACID REAGENT/KIT (POWDER)(SIDAK LIFECARE)- ESTIMATION OF URIC ACID IN SERUM/PLASMA/URINE,TOTAL LIPID REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-DETERMINATION OF THE TOTAL LIPID INDEX IN SERUM ,SGOT/AST REAGENT/KIT (POWDER) (SIDAK LIFECARE)-ESTIMATION OF THE ENZYME ASPARTATE AMINO TRANSFERASE (AST/SGOT) IN SERUM/PLASMA,AMYLASE REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF AMYLASE LEVEL IN HUMAN SERUM/SALIVA,URINE STRIP (GLUCOSE & PROTEIN) 2P(SIDAK LIFECARE)-FOR THE DETERMINATION OF GLUCOSE AND PROTEIN IN URINE SAMPLE.,SODIUM REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF SODIUM IN SERUM/PLASMA/URINE,SGPT/ALT REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF ENZYME ALANINE AMINO TRANSFERASE (ALT/SGPT) IN SERUM/PLASMA,CK-MB REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-DETERMINATION OF CK-MB ACTIVITY IN SERUM AND PLASMA,CK-MB REAGENT/KIT (MONO-VIAL)(SIDAK LIFECARE)-TO ESTIMATE THE ENZYME CREATINE PHOSPHOKINASE OR ITS ISOENZYMES IN SERUM/PLASMA,RF TURBI LATEX(SIDAK LIFECARE)-

	FOR THE MEASUREMENT OF RHEUMATOID FACTOR IN BLOOD SERUM, TRIGLYCERIDES REAGENT/KIT (POWDER)(SIDAK LIFECARE)-ESTIMATION OF TRIGLYCERIDES IN SERUM/PLASMA,ALBUMIN TEST REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF ALBUMIN IN HUMAN SERUM/PLASMA,TYPHOID IGG/IGM TEST(SIDAK LIFECARE) -DETECTION OF TYPHOID ANTIBODY, URINE STRIP (GLUCOSE, PH, PROTEIN, SPECIFIC GRAVITY) 4P(SIDAK LIFECARE)-FOR THE DETECTION OF GLUCOSE, PH, PROTEIN, SPECIFIC GRAVITY IN URINE SAMPLE.,CHOLESTEROL REAGENT/KIT (POWDER)(SIDAK LIFECARE)-ESTIMATION OF CHOLESTEROL IN BLOOD/BODY FLUIDS,URIC ACID REAGENT/KIT (LIQUID)(SIDAK LIFECARE)-ESTIMATION OF URIC ACID IN SERUM/PLASMA/URINE

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2921	MFG/IVD/2020/000112	1.License Holder Name: GENETIX BIOTECH ASIA PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:NUCLEIC ACID EXTRACTION KIT(RNASURE VIRUS KIT)-RNASURE VIRUS KIT IS A SYSTEM FOR THE ISOLATION AND PURIFICATION OF VIRAL NUCLEIC ACIDS FROM BIOLOGICAL SAMPLES E.G. PLASMA, SERUM, URINE, CELL CULTURE SUPERNATANT AND TRANSPORT MEDIUM OF NASOPHARYNGEAL AND OROPHARYNGEAL SWABS. THE KIT IS DESIGNED TO BE USED WITH ANY DOWNSTREAM APPLICATION EMPLOYING ENZYMATIC AMPLIFICATION AND DETECTION OF RNA AND DNA (E.G. RT-PCR, PCR).,COVID-19 REAL TIME PCR KIT(COVISURE (VERSION 2) COVID-19 REAL TIME PCR KIT)-COVISURE (VERSION 2) COVID 19 REAL-TIME PCR KIT IS A REAL TIME PCR BASED DIAGNOSTIC KIT FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS SARS NCOV-2 RNA FROM NASOPHARYNGEAL, OROPHARYNGEAL, SWABS, SPUTUM SAMPLES FROM PATIENTS. IT IS INTENDED FOR USE BY QUALIFIED AND TRAINED CLINICAL LABORATORY PERSONNEL.,COVID-19 REAL TIME PCR KIT(COVISURE (COVID-19 REAL TIME PCR DETECTION KIT))-COVISURE IS A REAL TIME PCR BASED DIAGNOSTIC KIT FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS SARS COV-2 RNA FROM NASOPHARYNGEAL, OROPHARYNGEAL, SWABS AND SPUTUM SAMPLES FROM PATIENTS. IT IS RECOMMENDED TO USE A STANDARD VIRAL RNA EXTRACTION KIT (MAGNETIC BEAD OR SPIN COLUMN BASED) FOR ISOLATION OF VIRAL RNA. THE KIT IS INTENDED TO BE USED BY TRAINED LABORATORY TECHNICIAN., COVID-19 REAL TIME PCR KIT(COVISURE (LYO MIX) COVID-19 REAL TIME PCR KIT)-COVISURE (LYO MIX) IS A REAL TIME PCR BASED DIAGNOSTIC KIT FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS SARS NCOV-2 RNA FROM NASOPHARYNGEAL, OROPHARYNGEAL, SWABS, SPUTUM SAMPLES FROM PATIENTS. THE KIT IS INTENDED FOR USE BY QUALIFIED AND TRAINED CLINICAL LABORATORY PERSONNEL SPECIFICALLY INSTRUCTED AND TRAINED IN THE TECHNIQUES OF REAL-TIME PCR AND IN VITRO DIAGNOSTIC PROCEDURES.,VIRAL NUCLEIC ACID EXTRACTION KIT (GENEMAG VIRAL DNA/RNA PURIFICATION KIT(PREFILLED))-THE GENEMAG VIRAL DNA/RNA PURIFICATION KIT(PREFILLED) IS DESIGNED FOR RAPID PURIFICATION OF HIGH QUALITY NUCLEIC ACID (RNA AND DNA) FROM VIRUS IN SAMPLES SUCH AS SWABS, SALIVA, BLOOD, BODILY FLUID, PLASMA/SERUM, URINE, AND VIRAL TRANSPORT MEDIA (VTM).,VIRAL NUCLEIC ACID EXTRACTION KIT (GENEMAG VIRAL DNA/RNA PURIFICATION KIT(NON-PREFILLED))-GENEMAG VIRAL DNA/RNA PURIFICATION KIT(NON-PREFILLED) IS INTENDED FOR ISOLATION OF NUCLEIC ACIDS (DNA AND RNA) FROM

		A WIDE RANGE OF SAMPLES. IT IS SUITABLE FOR USE WITH BIOLOGICAL SAMPLES (E.G. PLASMA, SERUM, URINE, SWAB WASHES, TISSUE SAMPLES)
2922	MFG/IVD/2020/000113	1.License Holder Name: SYSMEX INDIA PRIVATE LIMITED 2.Approving Authority: SOLAN(BBN) 3.Device Name(Brand Name)-Intended Use:CELLCLEAN(CELLCLEAN)-FOR IN INVITRO DIAGNOSTIC USE ONLY. CELLCLEAN IS TO BE USED AS STRONG ALKALINE DETERGENT TO REMOVE SYSMEX LYSING REAGENTS, CELLULAR RESIDUALS AND BLOOD PROTEINS REMAINING IN THE HYDRAULICS OF SYSMEX FULLY AUTOMATED HEMATOLOGY ANALYZERS. CELLCLEAN IS TO BE USED AS STRONG ALKALINE DETERGENT TO CLEAN FLUID SYSTEM COMPONENTS OF SYSMEX FULL AUTOMATED URINE CHEMISTRY ANALYZER, FULLY AUTOMATED URINE PARTICLE ANALYZER AND FULLY AUTOMATED URINE PARTICLE DIGITAL IMAGING DEVICE.

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2923	MFG/IVD/2020/000114	1.License Holder Name: NULIFE, D-22 & 118, SECTOR 7, GAUTAM BUDDHA NAGAR, UTTAR PRADESH, 201301, INDIA 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:SYPHILIS RAPID TEST KIT (ABCHEK)-ABCHEK SYPHILIS RAPID TEST (DEVICE) KIT IS AN IMMUNOASSAY FOR THE RAPID AND VISUAL DETECTION OF ANTIBODIES TO TREPONEMA PALLIDUM IN HUMAN SERUM OR PLASMA TO AID IN THE DIAGNOSIS OF SYPHILIS.,MALARIA PF (HRP 2) / PV(PLDH) ANTIGEN RAPID TEST KIT(ABCHEK)-ABCHEK MALARIA PF (HRP 2) / PV(PLDH) ANTIGEN RAPID TEST KIT IS A RAPID, IN VITRO, QUALITATIVE LATERAL FLOW IMMUNOASSAY FOR THE DETECTION OF P.FALCIPARUM SPECIFIC HISTIDINE RICH PROTEIN-2 (PF. HRP-2) AND P. VIVAX SPECIFIC PLDH FROM HUMAN WHOLE BLOOD SAMPLES. THE TEST MAY ALSO BE USED FOR THE DIFFERENTIATION OF P. FALCIPARUMAND P. VIVAX INFECTION.,DENGUE NS1 RAPID TEST KIT(ABCHEK)-ABCHEK DENGUE NS1 ANTIGEN RAPID TEST KIT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF NON-STRUCTURAL PROTEIN 1 (NS1) IN HUMAN SERUM/PLASMA, DENGUE COMBO RAPID TEST KIT(ABCHEK)-ABCHEK DENGUE COMBO RAPID TEST KIT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF NS1 ANTIGEN AND IGM/IGG ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM/PLASMA. , HIV 1 & 2 RAPID TEST KIT(ABCHEK)-ABCHEK HIV 1&2 RAPID TEST KIT IS A LATERAL FLOW IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF HIV-1 AND HIV-2 ANTIBODIES (IGG, IGM,IGA) IN HUMAN SERUM,PLASMA AND WHOLE BLOOD. IT IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HIV. ANY REACTIVE SPECIMEN WITH THE ABCHEK HIV 1 &2 RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) SUCH AS ELISA OR PCR., TYPHOID RAPID TEST KIT(ABCHEK)-ABCHEK TYPHOID RAPID TEST (IGG/IGM) KIT IS A LATERAL FLOW IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION AND DIFFERENTIATION OF ANTI-SALMONELLA TYPHI(S. TYPHI) IGG AND IGM IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH S. TYPHI. ANY REACTIVE SPECIMEN WITH THE ABCHEK TYPHOID IGG/IGM RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S)., HCV RAPID TEST KIT(ABCHEK)- ABCHEK HCV AB RAPID TEST KIT IS A DOUBLE ANTIGEN LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTI-HEPATITIS C VIRUS ANTIBODIES (IGG,IGM, IGA) IN HUMAN SERUM OR PLASMA. IT IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION

		WITH HCV. ANY REACTIVE SPECIMEN WITH ABCHEK HCV AB RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS. , CHIKUNGUNYA RAPID TEST KIT(ABCHEK)-ABCHEK CHIKUNGUNYA RAPID TEST KIT IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGM ANTI-CHIKUNGUNYA VIRUS CHIK IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH CHIK. ANY REACTIVE SPECIMEN WITH THE CHIKUNGUNYA IGM COMBO RAPID TEST-SHEET MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS. , HEPATITIS B SURFACE ANTIGEN RAPID TEST KIT(ABCHEK)-ABCHEK HBSAG RAPID TEST KIT IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OR PLASMA AT A LEVEL EQUAL TO OR HIGHER THAN 1 NG/ML. IT IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HEPATITIS B VIRUS (HBV). ANY REACTIVE SPECIMEN WITH THE ABCHEK HBSAG RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS
2924	MFG/IVD/2020/000116	1.License Holder Name: ASPEN LABORATORIES PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:MALARIA PF/PV (BIVALENT) ANTIGEN RAPID TEST-TEST KIT FOR DETECTION OF MALARIA PF/PV ANTIGEN(S)
2925	MFG/IVD/2020/000117	1.License Holder Name: SPM MEDICARE 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM-THE ACCU VTM VIRAL TRANSPORT MEDIUM IS A SPECIALLY DESIGNED TRANSPORT SYSTEM TO COLLECT AND TRANSPORT VIRUSES IN AN ACTIVE FORM TO THE LABORATORY FOR ISOLATION. IT IS DESIGNED TO MAINTAIN THE VIABILITY AND THE VIRULENCE OF THE VIRAL SAMPLE. FOR IN VITRO DIAGNOSTICS TEST ONLY.,VIRAL TRANSPORT MEDIUM-THE ACCU-VTM VIRAL TRANSPORT MEDIUM IS A SPECIALLY DESIGNED TRANSPORT SYSTEM TO COLLECT AND TRANSPORT VIRUSES IN AN ACTIVE FORM TO THE LABORATORY FOR ISOLATION. IT IS DESIGNED TO MAINTAIN THE VIABILITY AND THE VIRULENCE OF THE VIRAL SAMPLE. FOR IN-VITRO DIAGNOSTICS TEST ONLY.

2926	MFG/IVD/2020/000118	1.License Holder Name: ORCHID BIOMEDICAL SYSTEMS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: SUB ZONAL GOA 3.Device Name(Brand Name)-Intended Use:RAPID TEST FOR P. FALCIPARUM MALARIA(PARACHECK PF DEVICE)-PARACHECK PF IS A RAPID SELF PERFORMING, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF P. FALCIPARUM SPECIFIC HISTIDINE RICH PROTEIN –2 (PF HRP-2) IN WHOLE BLOOD SAMPLES. PARACHECK PF DETECTS THE PRESENCE OF PF HRP-2 IN WHOLE BLOOD SPECIMEN AND IS A SENSITIVE AND SPECIFIC TEST FOR THE DETECTION OF P. FALCIPARUM MALARIA.,RAPID DOUBLE ANTIGEN SCREENING TEST FOR THE DETECTION OF IGM / IGG / IGA ANTIBODIES TO COVID-19 IN HUMAN SERUM/ PLASMA/ WHOLE BLOOD(COVISCREEN)-COVISCREEN IS AN INVITRO, RAPID, SELF PERFORMING, QUALITATIVE, DOUBLE ANTIGEN SANDWICH IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION OF TOTAL ANTIBODIES (IGM+IGG+IGA) TO SARS-COV-2 VIRUS IN SERUM, PLASMA AND WHOLE BLOOD. IT IS TO BE USED FOR SCREENING OR TO AID IN THE DIAGNOSIS OF COVID-19 DISEASE AND EXPOSURE TO THE VIRUS. DOUBLE ANTIGEN SANDWICH ASSAYS ARE ALSO KNOWN TO DETECT THE ANTIGEN SPECIFIC IGA ISOTYPE ANTIBODIES AND CONTRIBUTE TO DETECT THE SEROCONVERSION IN PATIENTS SAMPLES EARLIER AS COMPARED TO THE OTHER TESTS AS DETECTION OF TOTAL ANTIBODIES (IGM+IGG+IGA) IS POSSIBLE.,ONE STEP TEST FOR HBSAG (DEVICE)(SENSAHEP-B DEVICE)-RAPID QUALITATIVE TWO SITE SANDWICH IMMUNASSAY FOR THE DETECTION OF HEPATITIS B SURFACE ANTIGEN , A MARKER OF HEPATITIS B INFECTIONS SERUM / PLASMA SPECIMEN.,RAPID TEST FOR P. FALCIPARUM MALARIA(PARACHECK PF DIPSTICK)-PARACHECK PF IS A RAPID SELF PERFORMING, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF P. FALCIPARUM SPECIFIC HISTIDINE RICH PROTEIN –2 (PF HRP-2) IN WHOLE BLOOD SAMPLES. PARACHECK PF DETECTS THE PRESENCE OF PF HRP-2 IN WHOLE BLOOD SPECIMEN AND IS A SENSITIVE AND SPECIFIC TEST FOR THE DETECTION OF P. FALCIPARUM MALARIA. ONE STEP TEST FOR HBSAG (DEVICE)(VIRUCHECK HBSAG (DEVICE))-RAPID QUALITATIVE TWO SITE SANDWICH IMMUNASSAY FOR THE DETECTION OF HEPATITIS B SURFACE ANTIGEN , A MARKER OF HEPATITIS B INFECTIONS

2927	MFG/IVD/2020/000119	1.License Holder Name: VITHAI PHARMACEUTICALS PRIVATE LIMITED 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:SAMPLE PRE-TREATMENT PACK FOR MTB SAMPLES(TRUEPREP® AUTO MTB SAMPLE PRE-TREATMENT PACK)-TRUEPREP® AUTO MTB SAMPLE PRE-TREATMENT PACK IS USED TO LIQUEFY AND PRETREAT THE PULMONARY AND EPTB SPECIMEN BEFORE PROCEEDING FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE.,UNIVERSAL SAMPLE PRE-TREATMENT PACK FOR NON MTB SAMPLES(TRUEPREP® AUTO UNIVERSAL SAMPLE PRE-TREATMENT PACK)-TRUEPREP® AUTO UNIVERSAL SAMPLE PRE-TREATMENT PACK IS USED TO PRE-TREAT THE SAMPLES BEFORE PROCEEDING FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE,MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF SWAB SPECIMEN FOR NUCLEIC ACID TESTS(TRUEPREP® LTM LYSIS CUM TRANSPORT MEDIUM FOR SWAB SPECIMEN PACK)-TRUEPREP® LTM LYSIS CUM TRANSPORT MEDIUM FOR SWAB SPECIMEN IS INTENDED FOR USE WITH ENDOCERVICAL, VAGINAL, ANORECTAL, NASAL AND THROAT SWAB SPECIMENS AS A MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF VARIOUS TYPES OF SWABS SPECIMENS FOR NUCLEIC ACID ASSAYS. THE TRANSPORT MEDIUM WHICH IS ALSO A LYSIS MEDIUM, INACTIVATES THE VIRUS AND BACTERIA IN THE SAMPLE WHILE MAINTAINING THE INTEGRITY OF THE NUCLEIC ACIDS. THE MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF SWAB SPECIMEN FOR NUCLEIC ACID TESTS NOT ONLY ENSURES SAFE TRANSPORT OF THE SAMPLE FROM THE SITE OF COLLECTION TO THE TESTING CENTRE BUT ALSO MINIMIZES BIO-SAFETY REQUIREMENTS FOR FURTHER PROCESSING OF THE SAMPLE AND CONDUCTING NUCLEIC ACID TESTS BY THE TESTING CENTER.,MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF SWAB SPECIMEN FOR TRUEPREP® AUTO(TRUEPREP® AUTO TRANSPORT MEDIUM FOR SWAB SPECIMEN PACK)-TRUEPREP® AUTO TRANSPORT MEDIUM FOR SWAB SPECIMEN PACK IS USED AS A MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF VARIOUS TYPES OF SWAB SPECIMENS BEFORE PROCEEDING FOR PRE-TREATMENT USING LYSIS BUFFER, EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED

		SAMPLE PREP DEVICE.
2928	MFG/IVD/2020/000120	1.License Holder Name: HELINI BIOMOLECULES 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:HELINI CORONAVIRUS [COVID-19] REAL-TIME PCR KIT(HELINI)-THE HELINI CORONAVIRUS REAL-TIME PCR KIT IS AN IN VITRO NUCLEIC ACID AMPLIFICATION KIT FOR THE DETECTION OF NOVEL CORONAVIRUS-2019 SPECIFIC RNA.
2929	MFG/IVD/2020/000121	1.License Holder Name: ACHIRA LABS PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:COVID-19 ONE-TUBE MULTIPLEX RT-QPCR KIT(COVIDXONE)-GENEPATH COVIDXONE RT-QPCR V2.1.2 KIT IS A SINGLE-TUBE MULTIPLEXED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-QPCR) INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN NASOPHARYNGEAL (NP), OROPHARYNGEAL (OP), NASOPHARYNGEAL + OROPHARYNGEAL (NP+OP), OR NASAL SWAB SPECIMENS. SARS-COV-2 RNA IS GENERALLY DETECTABLE IN NASOPHARYNGEAL (NP), OROPHARYNGEAL (OP), NASOPHARYNGEAL + OROPHARYNGEAL (NP+OP), OR NASAL SWAB SPECIMENS DURING THE ACUTE PHASE OF INFECTION. OTHER SAMPLE TYPES SUCH AS SPUTUM, BRONCHOALVEOLAR LAVAGE (BAL), ENDOTRACHEAL ASPIRATE (ETA) AND SALIVA MAY ALSO CONTAIN COVID-19 IN INFECTED OR ASYMPTOMATIC INDIVIDUALS BUT HAVE NOT BEEN VALIDATED WITH THIS KIT. POSITIVE RESULTS ARE INDICATIVE OF ACTIVE INFECTION. NEGATIVE RESULTS DO NOT PRECLUDE 2019-NCOV INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR PATIENT MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. THIS GENEPATH COVIDXONE RT-QPCR KIT IS INTENDED FOR USE BY TRAINED CLINICAL LABORATORY PERSONNEL SPECIFICALLY INSTRUCTED AND TRAINED IN THE TECHNIQUES OF REAL-TIME PCR AND IN VITRO DIAGNOSTIC PROCEDURES.

2930	MFG/IVD/2020/000122	1.License Holder Name: PROMEA THERAPEUTICS PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:INACTIVATION TRANSPORT MEDIUM-IT IS USED TO COLLECT AND TRANSPORT OF SAMPLES CONTAINING VIRUSES MYCOPLASMA AND UREAPLASMA FROM THE COLLECTION SITE TO THE LABORATORY.
2931	MFG/IVD/2020/000123	1.License Holder Name: KRUPA LABEQUI 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:VTM -VIRAL TRANSPORT MEDIA(VIROMOVE PRO)-FOR COLLECTION AND TRANSPORTATION OF SAMPLES CONTAINING VIRUSES CHLAMYDIAE, MYCOPLASMA AND UREAPLASMA FROM THE COLLECTION SITE TO THE LABORATORY,BLOOD COLLECTION TUBE(EQUIVAC & EQUITUBE)-BLOOD COLLECTION TUBE TO USED WITH BLOOD COLLECTION NEEDLE AND A HOLDER AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2932	MFG/IVD/2020/000124	1.License Holder Name: BIOGENY DIAGNOSTICS PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:DILUENT(BONAVERA DILUENT MR-10E)-DILUENT FOR MINDRAY BC 10 E 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,UNICORN 5 - 5 PART DILUENT(BONAVERA DILUENT 5PDM)-ISOTONIC SOLUTION FOR DILUTING CELLS AND FOR PRESERVING INTEGRITY AND VOLUME OF CELLS. ,DILUENT(BONAVERA DILUENT-SWB)-DILUENT FOR SWELAB 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,ELECTROLYTE STANDARD A(BONAVERA ELECTROLYTE REAGENT STD.A)-TO PROVIDE CALIBRATION POINT FOR NA+,K+,CA++,CL-,LI+ ,LYSE (BONAVERA LYSE-NKD)-LYSE FOR NIHON KOHDEN 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,ELECTROLYTE STANDARD B (BONAVERA ELECTROLYTE REAGENT STD.B)-TO PROVIDE CALIBRATION POINT FOR NA+,K+,CA++,CL-,LI+ ,BONAVERA LYSE (BONAVERA LYSE - HBA)-LYSE FOR HORIBA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,URIT 5 PART DETERGENT(BONAVERA DETERGENT SYSTEM PACK)-FOR THE PURPOSE OF MAINTAINING CLEANLINESS OF TUBINGS ,PROBE CLEANER(BONAVERA PROBE CLEANER MR -10E)-PROBE CLEANER FOR MINDRAY BC 10 E 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,URIT 5 PART SHEATH (BONAVERA SHEATH SYSTEM PACK)-FOR THE PURPOSE OF UNIFORM FLOW OF CELLS,LYSE(BONAVERA LYSE -BCT)-LYSE FOR BONAVERA COUNT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS , ELECTROLYTE REFERENCE SOLUTION(BONAVERA REFERENCE SOLUTION)-FOR CALIBRATION PURPOSE ,CLEANER(BONAVERA CLEANER-ERA)-CLEANER FOR ERMA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,SYSMEX LYSERCELL WNR(BONAVERA LC WNR)-FOR USE WITH SYSMEX 5 - PART HEMATOLOGY ANALYZER,DILUENT (BONAVERA DILUENT MR-1800)-DILUENT FOR MINDRAY BC 1800 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,SYSMEX SULFOLYSER (BONAVERA S.LYSER)-FOR USE WITH SYSMEX 5 - PART HEMATOLOGY ANALYZER,RINSE(BONAVERA RINSE-BCT)-RINSE BONAVERA COUNT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS , SYSMEX LYSE 1(BONAVERA LYSE 1)-FOR USE WITH SYSMEX 5 - PART HEMATOLOGY ANALYZER,STRONG CLEANER(BONAVERA STRONG CLEANER-NKD)-STRONG CLEANER FOR NIHON KOHDEN 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,SYSMEX FLUROCELL DYE (BONAVERA FC DYE)-FOR USE WITH SYSMEX 5 - PART HEMATOLOGY ANALYZER,DILUENT(BONAVERA DILUENT - URI)-DILUENT FOR URIT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,ELECTROLYTE CALIBRATOR(BONAVERA ELECTROLYTE CALIBRATOR)-TO PROVIDE CALIBRATION POINT FOR NA+,K+,CA++,CL-,LI+,CLEANER(BONAVERA CLEANER - BCA)- CLEANER FOR BIOCHEMISTRY ANALYZER ,SYSMEX

	REAGENT PACK(BONAVERA REAGENT PACK)-FOR USE WITH SYSMEX 5 - PART HEMATOLOGY ANALYZER,CLEANER(BONAVERA EZ - MDR)-CLEANER FOR MINDRAY 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,SYSMEX FLUROCELL WNR(BONAVERA FC WNR)-FOR USE WITH SYSMEX 5 - PART HEMATOLOGY ANALYZER,DILUENT (BONAVERA DILUENT -MCR)-DILUENT FOR ABX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,FLOW CELL CLEANER (BONAVERA FLOW CELL CLEANER)-FLOW CELL CLEANER USED FOR CLEANING MICRO FLOW-THROUGH CELLS AND CUVETTS IN SEMI AUTO ANALYZER. ,RINSE(BONAVERA RINSE-URI)-RINSE FOR URIT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,SYSMEX LYSE 2 (BONAVERA LYSE 2)-FOR USE WITH SYSMEX 5 - PART HEMATOLOGY ANALYZER,CLEANER(BONAVERA CLEANER-NKD)-CLEANER FOR NIHON KOHDEN 3-PART DIFFERENTIAL BLOOD CELL COUNTERS , UNICORN 5 - 5 PART LYSE 2(BONAVERA LYSE 2 5PDM)-FOR THE PURPOSE OF LYSING RED BLOOD CELL AND RELEASING HEMOGLOBIN. THE LYSE PRESERVES THE INTEGRITY OF WBC NUCLEUS,LYSE(BONAVERA LYSE MR-30)- LYSE FOR MINDRAY BC-30 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,UNICORN 5 - 5 PART PROBE CLEANER(BONAVERA PROBE CLEANER 5PDM)-PROBE CLEANER FOR BONAVERA 5 PART DIFFERENTIAL BLOOD CELL COUNTERS,DILUENT(BONAVERA DILUENT MR-2300)-DILUENT FOR MINDRAY BC 2300 3-PART DIFFERENTIAL BLOOD CELL COUNTERS , UNICORN 5 - 5 PART LYSE 1(BONAVERA LYSE 1 5PDM)-FOR THE PURPOSE OF LYSING RED BLOOD CELL AND RELEASING HEMOGLOBIN. THE LYSE PRESERVES THE INTEGRITY OF WBC NUCLEUS,DILUENT(BONAVERA DILUENT - SYS)-DILUENT FOR SYSMEX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,SYSMEX CELL CLEAN(BONAVERA CELL CLEAN)-FOR USE WITH SYSMEX 5 - PART HEMATOLOGY ANALYZER,LYSE(LYSE)-LYSE (FOR ALL 3-PART DIFFERENTIAL BLOOD CELL COUNTER) ,ELECTROLYTE URINE DILUTOR(BONAVERA ELECTROLYTE URINE DILUTOR)-FOR THE DILUTION OF URINE SAMPLE,DILUENT(DILUENT)-DILUENT (FOR ALL 3-PART DIFFERENTIAL BLOOD CELL COUNTER) ,SYSMEX DYE (BONAVERA DYE)-FOR USE WITH SYSMEX 5 - PART HEMATOLOGY ANALYZER,LYSE(BONAVERA LYSE -ERA)-LYSE FOR ERMA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,URIT 5 PART LYSE (BONAVERA LYSE SYSTEM PACK)-FOR THE PURPOSE OF LYSING RED BLOOD CELL ,RELEASING HAEMOGLOBIN AND PRESERVES THE INTEGRITY OF WBC NUCLEUS,LYSE(BONAVERA LYSE MR-2300)-LYSE FOR MINDRAY BC-2300 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,WASH CONCENTRATE (BONAVERA WASH CONCENTRATE)-WASH CONCENTRATE USED FOR CLEANING CUVETTES IN FULLY AUTOMATED ANALYZER. ,RINSE(BONAVERA RINSE - MDR)-RINSE

	FOR MINDRAY 3-PART DIFFERENTIAL BLOOD CELL COUNTERS , SYSMEX LYSERCELL WDF(BONAVERA LC WDF)-FOR USE WITH SYSMEX 5 - PART HEMATOLOGY ANALYZER,DILUENT(BONAVERA DILUENT - MDR)-DILUENT FOR MINDRAY 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,ELECTROLYTE FLUSH CLEANER(BONAVERA FLUSH CLEANER)-FOR CLEANING THE FLUID PATH ON THE ELECTROLYTE ANALYZER ,DILUENT(BONAVERA DILUENT - ERA)-DILUENT FOR ERMA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS , ELECTROLYTE REAGENT PACK(BONAVERA ELECTROLYTE REAGENT PACK)-FOR USE WITH ELECTROLYTE ANALYZER ,LYSE(BONAVERA LYSE MR -10E)- LYSE FOR MINDRAY BC-10 E 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,ELECTROLYTE CONTROL(BONAVERA CONTROL)-FOR MONITORING THE MEASURMENT OF ELECTROLYTE ANLYZER ,LYSE(BONAVERA LYSE MR-1800)- LYSE FOR MINDRAY BC-1800 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,URIT 5 PART DILUENT(BONVERA DILUENT SYSTEM PACK)-ISOTONIC SOLUTION FOR DILUTING CELLS AND FOR PRESERVING INTEGRITY AND VOLUME OF CELLS. ,LYSE(BONAVERA LYSE-SYS)-LYSE FOR SYSMEX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,SYSMEX FLUROCELL WDF (BONAVERA FC WDF)-FOR USE WITH SYSMEX 5 - PART HEMATOLOGY ANALYZER,CLEANER(BONAVERA RINSE-ERA)-RINSE FOR ERMA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,ELECTROLYTE EZ CLEANER(BONAVERA EZ CLEANER)-FOR TO CLEAN THE SAMPLE PATH ,DILUENT(BONAVERA DILUENT-MDA)-DILUENT FOR MDC(AL SYSTEMEO) 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,DILUENT (BONAVERA DILUENT-DTN)-DILUENT FOR DIATRON 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,DILUENT(BONAVERA DILUENT-BCT)-DILUENT FOR BONAVERA COUNT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,CLEANER(BONAVERA CLEANER-DTN)-CLEANER FOR DIATRON 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,DILUENT(BONAVERA DILUENT MR -30)-DILUENT FOR MINDRAY BC 30 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,CLEANER(BONAVERA CLEANER-SYS)-CLEANER FOR SYSMEX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CLEANER (CLEANER)-CLEANER (FOR ALL 3-PART DIFFERENTIAL BLOOD CELL COUNTER) ,RINSE(RINSE)-RINSE (FOR ALL 3-PART DIFFERENTIAL BLOOD CELL COUNTER) ,CLEANER(BONAVERA CLEANER-URI)-CLEANER FOR URIT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS , DILUENT(BONAVERA DILUENT-HBA)-DILUENT FOR HORIBA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,CLEANER(BONAVERA EZ-BCT)-CLEANER BONAVERA COUNT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,CLEANER(BONAVERA CLEANER -HBA)-CLEANER FOR HORIBA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,LYSE (BONAVERA LYSE - MDR)-LYSE FOR MINDRAY 3-PART DIFFERENTIAL

		BLOOD CELL COUNTERS ,DILUENT(BONAVERA DILUENT -MDN)-DILUENT FOR MEDONIC 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,DILUENT(BONAVERA DILUENT - NKD)-DILUENT FOR NIHON KOHDEN 3-PART DIFFERENTIAL BLOOD CELL COUNTERS , CLEANER(BONAVERA EZ MR-2300)- CLEANER FOR MINDRAY BC-2300 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,LYSE (BONAVERA LYSE-SWB)-LYSE FOR SWELAB 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,LYSE(BONAVERA LYSE -DTN)-LYSE FOR DIATRON 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,LYSE (BONAVERA LYSE -MCR)-LYSE FOR ABX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,LYSE(BONAVERA LYSE-URI)-LYSE FOR URIT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,LYSE(BONAVERA LYSE -MDN)-LYSE FOR MEDONIC 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,CLEANER(BONAVERA CLEANER- MCR)-CLEANER FOR ABX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,PROBE CLEANER(BONAVERA PROBE CLEANER MR- 30)-PROBE CLEANER FOR MINDRAY BC 30 3-PART DIFFERENTIAL BLOOD CELL COUNTERS ,PROBE CLEANER(BONAVERA PROBE CLEANER-MDR)-PROBE CLEANER FOR MINDRAY 3-PART DIFFERENTIAL BLOOD CELL COUNTERS
2933	MFG/IVD/2020/000125	1.License Holder Name: ENSURE BIOTECH PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:CREATININE K TEST KIT -DETERMINATION OF CREATININE (RENAL DISEASE),GLUCOSE TEST KIT -ESTIMATION OF SUGAR LEVELS IN BLOOD ,CHOLESTEROL WITH HDL TEST KIT -ESTIMATION OF CHOLESTEROL IN BLOOD ,ANTI-STREPTOLYSIN 'O' (ASO) TEST KIT-QUALITATIVE DETERMINATION OF ASO IN SERUM ,V D R L TEST KIT -QUALITATIVE DETERMINATION OF SYPHILIS IN SERUM ,UREA (GLDH) TEST KIT-QUANTITATIVE DETERMINATION OF UREA - KIDNEY FUNCTION TEST ,TRIGLYCERIDES TEST KIT -QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN BLOOD ,HEMOGLOBIN TEST KIT -ESTIMATION OF HEMOGLOBIN IN BLOOD ,BILIRUBIN TEST KIT -DIFFERENTIATION AND FOLLOW-UP OF JAUNDICE ,S G P T TEST KIT -QUANTITATIVE DETERMINATION OF SGPT (ALT) - LIVER FUNCTION TEST,S G O T TEST KIT -QUANTITATIVE DETERMINATION OF SGOT (AST) - LIVER FUNCTION TEST , CREATININE EP TEST KIT -DETERMINATION OF CREATININE (RENAL DISEASE)

2934	MFG/IVD/2020/000126	1.License Holder Name: DIATEK HEALTHCARE PRIVATE LIMITED ,P-54/PH-I, INDUSTRIAL AREA, PHASE-I, POST OFFICE-KALYANI, POLICE STATION-KALYANI, WARD NO-14,,NADIA ,NADIA WEST BENGAL , 741235 ,INDIA 2.Approving Authority: WEST BENGAL 3.Device Name(Brand Name)-Intended Use:ADENOSINE DEAMINASE (ADA) TEST KIT(ADENOSINE DEAMINASE (ADA))-ADENOSINE DEAMINASE (ADA) TEST REAGENT/KIT IS A MEDICAL DEVICE , INTENDED FOR THE ESTIMATION OF ADENOSINE DEAMINASE IN SERUM/PLASMA AND OTHER BODY FLUIDS.,URIC ACID TEST KIT(URIC ACID)-URIC ACID TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF URIC ACID IN SERUM/PLASMA/URINE,LDL CHOLESTEROL TEST KIT(LDL-DIRECT)-LDL CHOLESTEROL TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF LDL CHOLESTEROL IN SERUM/PLASMA,LACTATE DEHYDROGENASE TEST KIT(LDH)-LACTATE DEHYDROGENASE AND ITS ISOENZYMES TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME LACTATE DEHYDROGENASE AND ITS ISOENZYMES IN SERUM/PLASMA,HOMOCYSTEINE TEST KIT(HOMOCYSTEINE)-HOMOCYSTEINE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HOMOCYSTEINE IN SERUM/BODY FLUIDS, RHEUMATOID FACTOR (RF) IMMUNOLOGICAL TEST KIT(RF-PROTEIN)-RHEUMATOID FACTOR (RF) IMMUNOLOGICAL TEST REAGENT/KIT IS A MEDICAL DEVICE FOR THE SCREENING OF RHEUMATOID FACTOR IN HUMAN SPECIMENS.,BILIRUBIN (TOTAL) TEST KIT(BILIRUBIN (TOTAL)) -BILIRUBIN (TOTAL) TEST REAGENT/KIT IS A MEDICAL DEVICE FOR THE ESTIMATION OF BILIRUBIN (TOTAL) IN SERUM/PLASMA,CK-MB TEST KIT(CK-MB)-CREATINE PHOSPHOKINASE/CREATINE KINASE MB ISOZYMES INCLUDING CK-MB TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME CREATINE PHOSPHOKINASE/CREATINE KINASE MB ISOZYMES IN SERUM AND PLASMA,HDL CHOLESTEROL TEST KIT(HDL-DIRECT)-HDL CHOLESTEROL TEST REAGENT/KIT IS MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF HDL CHOLESTEROL IN SERUM / PLASMA, MICROALBUMIN TEST KIT(MICROALBUMIN)-MICROALBUMIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF MICROALBUMIN IN URINE,CHOLESTEROL (TOTAL) TEST KIT (CHOLESTEROL)-CHOLESTEROL(TOTAL) REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHOLESTEROL IN SERUM OR PLASMA,CK-NAC TEST KIT(CK-NAC)-CREATINE PHOSPHOKINASE/CREATINE KINASE OR ISOZYMES INCLUDING CK-MB,CKBB AND CKMM TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME CREATINE

	PHOSPHOKINASE IN SERUM AND PLASMA,CALCIUM TEST KIT (CALCIUM ARSENAZO)-CALCIUM TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TOTAL CALCIUM IN SERUM,BILIRUBIN (TOTAL AND DIRECT) TEST KIT(BILIRUBIN (TOTAL AND DIRECT))-BILIRUBIN (TOTAL AND DIRECT) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF BILIRUBIN (TOTAL AND DIRECT) IN SERUM/PLASMA,HBA1C TEST KIT(HBA1C)-HBA1C TEST REAGENT/KIT ARE MEDICAL DEVICES INTENDED FOR THE ESTIMATION OF HBA1C IN BLOOD,BICARBONATE/CARBON DIOXIDE TEST KIT(CARBON DIOXIDE)-BICARBINATE / CARBON DIOXIDE IS A MEDICAL DEVICE FOR THE ESTIMATION OF BICARBONATE/CARBON DIOXIDE IN PLASMA/SERUM,UREA BERTHELOT TEST KIT(UREA BERTHELOT)-UREA (BUN) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF UREA/BLOOD UREA NITROGEN (BUN) IN PLASMA/SERUM/URINE, TOTAL PROTEIN TEST KIT(TOTAL PROTEIN)-TOTAL PROTEIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TOTAL PROTEIN(S) IN SERUM/PLASMA,MICROPROTEIN TEST KIT (MICROPROTEIN)-MICROPROTEIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF MICROPROTEINS IN URINE,PHOSPHOROUS (INORGANIC) TEST KIT(PHOSPHOROUS)-PHOSPHOROUS (INORGANIC) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF INORGANIC PHOSPHOROUS IN SERUM/PLASMA/URINE,MAGNESIUM TEST KIT (MAGNESIUM)-MAGNESIUM TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF MAGNESIUM LEVELS IN SERUM/PLASMA,CREATININE TEST KIT(CREATININE SL)-CREATININE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CREATININE IN SERUM,PLASMA,URINE,AMYLASE TEST KIT(AMYLASE)-AMYLASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF THE ENZYME AMYLASE IN SERUM,SALIVA/URINE.,ALBUMIN TEST KIT(ALBUMIN)-ALBUMIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALBUMIN IN SERUM/PLASMA,C-REACTIVE PROTEIN (CRP) TEST KIT(C-REACTIVE PROTEIN (CRP))-C-REACTIVE PROTEIN (CRP) ASSAY IS USED FOR THE QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN IN SERUM CATEGORISED AS OTHER CLINICAL CHEMISTRY TEST REAGENT/KIT INTENDED FOR THE ESTIMATION OF ANALYTE/PARAMETER(CRP) IN SERUM / PLASMA,CREATININE TEST KIT(CREATININE)-CREATININE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CREATININE IN SERUM/PLASMA/URINE,GAMMA GLUTAMYL TRANSFERASE (GGT) TEST KIT(GAMMA GT)-GAMMA GLUTAMYL TRANSFERASE (GGT) AND ISOENZYMES TEST REAGENT/KIT IS A

	MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF THE ENZYME GAMMA GLUTAMYL TRANSFERASE (GGT) IN SERUM/PLASMA,LIPASE TEST KIT(LIPASE)-LIPASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF LIPASE IN SERUM/PLASMA, GLUCOSE TEST KIT(GLUCOSE)-GLUCOSE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF GLUCOSE IN PLASMA/BODY FLUIDS,BILIRUBIN (DIRECT) TEST KIT(BILIRUBIN (DIRECT))-BILIRUBIN (DIRECT) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF BILIRUBIN (DIRECT) IN SERUM/PLASMA,TRIGLYCERIDE TEST KIT(TRIGLYCERIDES)-TRIGLYCERIDE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TRIGLYCERIDES IN SERUM / PLASMA,UREA GLDH TEST KIT(UREA GLDH)-UREA (BUN) TEST KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF UREA/BLOOD UREA NITROGEN (BUN) IN PLASMA/SERUM/URINE,ASPARTATE AMINO TRANSFERASE (AST/SGOT) TEST KIT(SGOT(AST))-ASPARTATE AMINO TRANSFERASE (AST/SGOT) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF THE ENZYME ASPARTATE AMINO TRANSFERASE (AST/SGOT) IN SERUM/PLASMA,ALKALINE PHOSPHATASE TEST KIT(ALKALINE PHOSPHATASE AMP (IFCC))-ALKALINE PHOSPHATASE OR ISOENZYMES TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALKALINE PHOSPHATASE IN SERUM/PLASMA,ALANINE AMINO TRANSFERASE (ALT/SGPT) TEST KIT(SGPT (ALT))-ALANINE AMINO TRANSFERASE (ALT/SGPT) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME ALANINE AMINO TRANSFERASE (ALT/SGPT) IN SERUM/PLASMA

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2935	MFG/IVD/2020/000127	1.License Holder Name: KUTE WELLNESS INC 2.Approving Authority: NORTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:-HCG PREGNANCY TEST (Q-LINE)-Q-LINE® HUMAN CHORIONIC GONADOTROPIN (HCG) IS A GLYCOPROTEIN HORMONE PRODUCED BY THE DEVELOPING PLACENTA SHORTLY AFTER FERTILIZATION. IN NORMAL PREGNANCY, HCG CAN BE DETECTED IN BOTH URINE AND SERUM AS EARLY AS 7 TO 10 DAYS AFTER CONCEPTION (1-4). HCG LEVELS CONTINUE TO RISE VERY RAPIDLY, FREQUENTLY EXCEEDING 100 MIU/ML BY THE FIRST MISSED MENSTRUAL PERIOD (2- 4), AND PEAKING IN THE 100,000-200,000 MIU/ML RANGE ABOUT 10-12 WEEKS INTO PREGNANCY. THE APPEARANCE OF HCG IN BOTH URINE AND SERUM SOON AFTER CONCEPTION, AND ITS SUBSEQUENT RAPID RISE IN CONCENTRATION DURING EARLY GESTATIONAL GROWTH, MAKE IT AN EXCELLENT MARKER FOR THE EARLY DETECTION OF PREGNANCY.
2936	MFG/IVD/2020/000128	1.License Holder Name: BIOSYSTEMS DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM KIT(CONCEPTA VIRAL TRANSPORT MEDIA)-CONCEPTA VIRAL TRANSPORT MEDIA KITS ARE A FORMULATED MEDIUM FOR COLLECTION AND TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING VIRUSES FROM THE COLLECTION CENTER TO THE LABORATORY.
2937	MFG/IVD/2020/000129	1.License Holder Name: AFFIGENIX BIOSOLUTIONS PVT LTD., 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:COVID-19 VIRAL RNA ISOLATION BY SPIN COLUMN METHOD(AFFISPIN COVID-19 VIRAL RNA ISOLATION KIT BY SPIN COLUMN METHOD)-COVID-19 VIRAL RNA ISOLATION BY SPIN COLUMN METHOD,ONE-STEP RT-QPCR KIT FOR DETECTION OF CORONAVIRUS (COVID-19) IN HUMANS-SINGLE TUBE TEST(AFFIGENIX COVID 19 TEST (ACT-1) 3 GENES MULTIPLEX KIT)-ONE-STEP RT-QPCR KIT FOR DETECTION OF CORONAVIRUS (COVID-19) IN HUMANS-SINGLE TUBE TEST ,ONE-STEP RT-QPCR ASSAY FOR DETECTION OF CORONAVIRUS(COVID-19)IN HUMANS(AFFIGENIX COVID 19 TEST (ACT) KIT)-ONE-STEP RT-QPCR ASSAY FOR DETECTION OF CORONAVIRUS(COVID-19)IN HUMANS,COVID-19 VIRAL RNA ISOLATION BY MAGNETIC BEAD METHOD(AFFIMAG COVID-19 VIRAL RNA ISOLATION KIT BY MAGNETIC BEAD METHOD)-COVID-19 VIRAL RNA ISOLATION BY MAGNETIC BEAD METHOD

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2938	MFG/IVD/2020/000130	1.License Holder Name: VIOLA DIAGNOSTIC SYSTEMS - A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED, 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:RAPID TEST FOR DETECTION OF SARS-COV-2 ANTIGEN IN HUMAN NASAL SWAB (NS) AND NASOPHARYNGEAL (NP) SWAB SPECIMENS [CASSETTE TEST] (FOR EXPORT ONLY)(PERKINELMER COVID-19 ANTIGEN TEST (NS, NP) (FOR EXPORT ONLY))-PERKINELMER COVID-19 ANTIGEN TEST (NS, NP) IS AN INVITRO, RAPID, QUALITATIVE IMMUNOASSAY FOR THE DETECTION OF NUCLEOCAPSID PROTEIN ANTIGENS EXPRESSED BY THE SARS-COV-2 VIRUS PRESENT IN HUMAN NASOPHARYNGEAL SWAB AND NASAL SWAB SPECIMENS. IT IS TO BE USED FOR SCREENING OR TO AID IN THE DIAGNOSIS OF COVID-19 DISEASE. THIS RAPID ANTIGEN DETECTION TEST TAKES 15-30 MINUTES FOR PRODUCING A POSITIVE OR NEGATIVE TEST RESULT. POSITIVE RESULTS INDICATE THE PRESENCE OF VIRAL ANTIGENS, BUT CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE INFECTION STATUS. NEGATIVE RESULTS DO NOT PRECLUDE SARS-COV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR OTHER MANAGEMENT DECISIONS. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY, AND EPIDEMIOLOGICAL INFORMATION. THE RESULT OF THIS TEST SHOULD NOT BE THE SOLE BASIS FOR THE DIAGNOSIS. PRESUMPTIVE POSITIVE OR NEGATIVE RESULT MAY NEED TO BE FURTHER CONFIRMED WITH A MOLECULAR TEST. ,ONE STEP TEST FOR HBSAG (DEVICE)(VIRUCHECK HBSAG (DEVICE))-RAPID QUALITATIVE TWO SITE SANDWICH IMMUNASSAY FOR THE DETECTION OF HEPATITIS B SURFACE ANTIGEN , A MARKER OF HEPATITIS B INFECTIONS,RAPID TEST FOR SYPHILIS-WB (MODIFIED TPHA) (DEVICE)(SYPHICHECK WB (DEVICE))-SYPHICHECK-WB (DEVICE) IS A MODIFIED TPHA, WHICH QUALITATIVELY DETECTS THE PRESENCE OF IGM AND IGG CLASS OF TREPONEMA SPECIFIC ANTIBODIES DURING SYPHILIS IN WHOLE BLOOD, SERUM OR PLASMA SPECIMENS,RAPID DOUBLE ANTIGEN SCREENING TEST FOR THE DETECTION OF IGM / IGG / IGA ANTIBODIES TO COVID-19 IN HUMAN SERUM/ PLASMA/ WHOLE BLOOD(COVISCREEN)-COVISCREEN IS AN INVITRO, RAPID, SELF PERFORMING, QUALITATIVE, DOUBLE ANTIGEN SANDWICH IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION OF TOTAL ANTIBODIES (IGM+IGG+IGA) TO SARSCOV- 2 VIRUS IN SERUM, PLASMA AND WHOLE BLOOD. IT IS TO BE USED FOR SCREENING OR TO AID IN THE DIAGNOSIS OF COVID-19 DISEASE AND EXPOSURE TO THE VIRUS. DOUBLE ANTIGEN SANDWICH ASSAYS ARE ALSO KNOWN TO DETECT THE ANTIGEN SPECIFIC IGA ISOTYPE ANTIBODIES AND

	CONTRIBUTE TO DETECT THE SEROCONVERSION IN PATIENTS SAMPLES EARLIER AS COMPARED TO THE OTHER TESTS AS DETECTION OF TOTAL ANTIBODIES (IGM+IGG+IGA) IS POSSIBLE., RAPID TEST FOR SYPHILIS (MODIFIED TPHA) (DEVICE)(SEROCHECK TP (DEVICE))-SEROCHECK TP (DEVICE) IS A MODIFIED TPHA, WHICH QUALITATIVELY DETECTS THE PRESENCE OF IGM AND IGG CLASS OF TREPONEMA SPECIFIC ANTIBODIES DURING SYPHILIS IN SERUM OR PLASMA SPECIMENS,RAPID TEST FOR SYPHILIS (MODIFIED TPHA) (DIPSTICK)(SEROCHECK TP (DIPSTICK))-SEROCHECK TP (DIPSTICK) IS A MODIFIED TPHA, WHICH QUALITATIVELY DETECTS THE PRESENCE OF IGM AND IGG CLASS OF TREPONEMA SPECIFIC ANTIBODIES DURING SYPHILIS IN SERUM OR PLASMA SPECIMENS,RAPID TEST FOR SYPHILIS (MODIFIED TPHA) (DIPSTICK)(SYPHICHECK (DIPSTICK))-SYPHICHECK-WB (DIPSTICK) IS A MODIFIED TPHA, WHICH QUALITATIVELY DETECTS THE PRESENCE OF IGM AND IGG CLASS OF TREPONEMA SPECIFIC ANTIBODIES DURING SYPHILIS IN WHOLE BLOOD, SERUM OR PLASMA SPECIMENS,RAPID TEST FOR DETECTION OF SARS-COV-2 ANTIGEN IN HUMAN NASOPHARYNGEAL SWAB SPECIMENS (DEVICE)(COVIRAT (DEVICE))-COVIRAT IS AN INVITRO, RAPID, QUALITATIVE IMMUNOASSAY FOR THE DETECTION OF NUCLEOCAPSID PROTEIN ANTIGENS EXPRESSED BY THE SARS-COV-2 VIRUS PRESENT IN HUMAN NASOPHARYNGEAL SWAB SPECIMENS. IT IS TO BE USED FOR SCREENING OR TO AID IN THE DIAGNOSIS OF COVID-19 DISEASE. THIS RAPID ANTIGEN DETECTION TEST TAKES 15-30 MINUTES FOR PRODUCING A POSITIVE OR NEGATIVE TEST RESULT. POSITIVE RESULTS INDICATE THE PRESENCE OF VIRAL ANTIGENS, BUT CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE INFECTION STATUS. PRESUMPTIVE POSITIVE OR NEGATIVE RESULT MAY NEED TO BE FURTHER CONFIRMED WITH A MOLECULAR TEST.,RAPID IMMUNOCHROMATOGRAPHIC TEST FOR HIV 1/2(1. QUALPRO HIV; 2. RETROSCREEN HIV)-QUALPRO HIV IS A RAPID 3RD GENERATION QUALITATIVE SANDWICH IMMUNOASSAY FOR THE SIMULTANEOUS AND DIFFERENTIAL DETECTION OF TOTAL ANTIBODIES EG IGG, IGM, IGA ETC TO HIV-1 AND HIV-2 VIRUS IN HUMAN SERUM/PLASMA,ONE STEP TEST FOR HBSAG (DIPSTICK) (VIRUCHECK HBSAG DIPSTICK)-VIRUCHECK ONE STEP TEST FOR HBSAG IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETECTION OF HEPATITIS B SURFACE ANTIGEN, A MARKER OF HEPATITIS B INFECTIONS IN SERUM/PLASMA SPECIMENS,RAPID IMMUNOCONCENTRATION TEST FOR HIV 1/2 (RETROQUIC HIV)-RETROQUIC HIV IS A MEMBRANE BASED FLOW THROUGH IMMUNOASSAY FOR THE VISUAL, QUALITATIVE, SIMULTANEOUS DETECTION AND DIFFERENTIATION OF ANTIBODIES

		TO HIV 1 AND HIV 2 IN HUMAN SERUM AND PLASMA.,RAPID TEST FOR PAN/PF MALARIA ANTIGEN DEVICE(BRAND NAME1: MALASCAN PLUS DEVICE / BRAND NAME 2: PARASCREEN DEVICE)-THIS TEST IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY UTILIZING WHOLE BLOOD FOR THE DETECTION OF P. FALCIPARUM SPECIFIC HISTIDINE RICH PROTEIN-2 (PF. HRP.-2) AND PAN MALARIA SPECIFIC PLDH. ,RAPID TEST FOR PF/PV MALARIA ANTIGEN DEVICE(BRAND NAME 1: SATYA 2.0 DEVICE / BRAND NAME 2: FALCIVAX DEVICE)-THIS TEST IS USED FOR SPECIFIC DETECTION AND DIFFERENTIATION OF P. VIVAX MALARIA AND P. FALCIPARUM MALARIA IN AREAS WITH HIGH RATES OF MIXED INFECTION.,RAPID TEST FOR PF MALARIA ANTIGEN DEVICE(PARACHECK PF DEVICE)-PARACHECK PF DEVICE IS AN INVITRO, RAPID, QUALITATIVE TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF PLASMODIUM SPECIFIC HISTIDINE RICH PROTEIN-2 (PF HRP-2) IN WHOLE BLOOD FOR THE DIAGNOSIS OF FALCIPARUM MALARIA IN INDIVIDUALS WITH SIGN AND SYMPTOMS CONSISTENT WITH MALARIA INFECTION.,ONE STEP TEST FOR HBSAG DEVICE(HEPAVIEW HBSAG DEVICE)-HEPAVIEW HBSAG DEVICE IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR DETECTION OF HEPATITIS B SURFACE ANTIGEN, A MARKER FOR HEPATITIS B INFECTIONS, IN SERUM/PLASMA SPECIMEN.
2939	MFG/IVD/2020/000131	1.License Holder Name: UBIO BIOTECHNOLOGY SYSTEMS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 RT PCR KIT (COVI-DETECT)-THIS KIT IS INTENDED FOR THE DETECTION OF SARS-COV-2 IN NASOPHARYNGEAL SWABS (NPS), NASAL SWABS (NS), BRONCHOALVEOLAR LAVAGE (BAL) OR OTHER APPROPRIATE CLINICAL SPECIMENS BY A ONE-STEP REVERSE TRANSCRIPTION REAL TIME PCR.

2940	MFG/IVD/2020/000132	1.License Holder Name: STRUMED SOLUTIONS PRIVATE LIMITED 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM TYPE A(INSTAXPORT)-INSTAXPORT VIRAL TRANSPORT KIT IS INTENDED FOR COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES FROM COLLECTION SITE TO THE TESTING LABORATORY. IT IS DESIGNED TO MAINTAIN THE VIABILITY OF THE VIRAL SAMPLE. FOR PROFESSIONAL AND DIAGNOSTIC USE ONLY.,VIRAL TRANSPORT MEDIUM TYPE B(INSTAXPORT)-INSTAXPORT VIRAL TRANSPORT KIT IS INTENDED FOR COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES FROM COLLECTION SITE TO THE TESTING LABORATORY. IT IS DESIGNED TO MAINTAIN THE VIABILITY OF THE VIRAL SAMPLE. FOR PROFESSIONAL AND DIAGNOSTIC USE ONLY.,VIRAL TRANSPORT MEDIUM TYPE C(INSTAXPORT)-INSTAXPORT VIRAL TRANSPORT KIT IS INTENDED FOR COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES FROM COLLECTION SITE TO THE TESTING LABORATORY. IT IS DESIGNED TO MAINTAIN THE VIABILITY OF THE VIRAL SAMPLE. FOR PROFESSIONAL AND DIAGNOSTIC USE ONLY.
2941	MFG/IVD/2020/000133	1.License Holder Name: ACCUREX BIOMEDICAL PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM KIT(NA)-ACCUREX VIRAL TRANSPORT KIT IS INTEDED FOR THE COLLECTION OF CLINICAL SPECIMENTS CONTAINING VIRUSES SUCH AS SARS-COVID19, CHLAMYDIAE, MYCOPLASMA OR UREAPLASMA, INFLUENZA FROM THE COLLCTION SITE TO THE LABORATORY IN A SAFE AND STABLE MANNER. ANY STANDARD CLINICAL PROCEDURE CAN BE PERFORMED ON THE THE SAME INSIDE A LABORATORY BY A REGISTERED MEDICAL PRACTITIONER, LABORATRY TECHNOLOGIST AND/OR AUTHORIZED PERSONNEL AS PER LABORATORY GUIDELINES AND PROCEDURES.

2942	MFG/IVD/2020/000134	1.License Holder Name: VOXTUR BIO LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:WIDAL SLIDE TEST FOR DETERMINATION OF SALMONELLA TYPHI ANTIBODIES(O,H,AH, BH, AO,BO, CO AND CH) IN HUMAN SERUM/PLASMA.(VOXBANK AND OTHER BRANDS)-THE WIDAL TEST IS USED FOR RAPID VISUAL TEST FOR THE QUALITATIVE AND SEMI QUANTITATIVE DETECTION OF FOR THE PRESENCE OR ABSENCE OF SALMONELLA SPECIFIC ANTIBODY IN HUMAN SERUM SPECIMENS. ,ASO(ANTI STREPTOLYSIN O) TEST FOR QUALITATIVE AND SEMI QUANTITATIVE DETECTION OF ANTIBODY TO ASO IN HUMAN SERUM/PLASMA.(VOXBANK AND OTHER BRANDS)-THE ASO TEST IS USED FOR RAPID VISUAL TEST FOR THE QUALITATIVE AND SEMI QUANTITATIVE DETECTION OF FOR THE PRESENCE OR ABSENCE OF ASO ANTIBODY IN HUMAN SERUM SPECIMENS. ,RAPID TEST FOR DETECTION OF ANTIBODIES TO S.TYPHI IGG/IGM IN HUMAN SERUM/PLASMA/WHOLE BLOOD (VOXPRESS, AND OTHER BRANDS)-THE OF S.TYPHI IGG/IGM TEST CARD IS USED AS RAPID VISUAL TEST FOR SIMULTANEOUS AND DIFFERENTIAL DETECTION OF IGG & IGM ANTIBODIES TO SPECIFIC S. TYPHI ANTIGENS IN WHOLE BLOOD /SERUM OF HUMANS IN HUMAN SPECIMENS. ,WIDAL SLIDE TEST FOR DETERMINATION OF SALMONELLA TYPHI ANTIBODIES (O,H,AH AND BH) IN HUMAN SERUM/PLASMA.(VOXBANK AND OTHER BRANDS)-THE WIDAL TEST IS USED FOR RAPID VISUAL TEST FOR THE QUALITATIVE AND SEMI QUANTITATIVE DETECTION OF FOR THE PRESENCE OR ABSENCE OF SALMONELLA SPECIFIC ANTIBODY IN HUMAN SERUM SPECIMENS.,RA (RHEUMATOID ARTHRITIS) TEST FOR QUALITATIVE AND SEMI QUANTITATIVE DETECTION OF ANTIBODIES TO RA IN HUMAN SERUM/PLASMA.(VOXBANK AND OTHER BRANDS)- THE RA LATEX SLIDE TEST IS USED FOR RAPID VISUAL TEST FOR THE QUALITATIVE AND SEMI QUANTITATIVE DETECTION OF FOR THE PRESENCE OR ABSENCE OF RA IN HUMAN SERUM SPECIMENS. ,RAPID IMMUNO CHROMATOGRAPHY LATERAL FLOW TEST FOR DETECTION OF ANTIBODIES TO CHICKUNGUNYA IGG/IGM IN HUMAN SERUM/PLASMA/WHOLE BLOOD (VOXPRESS, AND OTHER BRANDS)-RAPID IMMUNO CHROMATOGRAPHY LATERAL FLOW TEST FOR DETECTION OF ANTIBODIES TO CHICKUNGUNYA IGG/IGM IN HUMAN SERUM/PLASMA/WHOLE BLOOD ,RAPID TEST FOR DETECTION OF ANTIBODIES TO HCG(HUMAN CHORIONIC GONADOTROPIN) IN HUMAN URINE(VOXPRESS, MUM TO BE, AND OTHER BRANDS)-THE HCG RAPID TEST CARD IS A VISUAL TEST FOR THE QUALITATIVE DETECTION FOR THE PRESENCE OR ABSENCE OF HCG HORMONES IN FEMALE URINE SPECIMENS. ,RAPID TEST FOR DETECTION OF ANTIBODIES TO DENGUE IGG/IGM IN HUMAN

		SERUM/PLASMA/WHOLE BLOOD(VOXPRESS, AND OTHER BRANDS)-THE DENGUE IGG/IGM ANTIBODY TEST CARD IS USED FOR RAPID VISUAL TEST FOR THE QUALITATIVE DETECTION OF FOR THE PRESENCE OR ABSENCE OF ANTIBODIES, SPECIFIC TO DENGUE IGG/IGM ANTIBODY IN HUMAN WHOLE BLOOD /SERUM/PLASMA SPECIMENS. ,WIDAL SLIDE TEST FOR DETERMINATION OF SALMONELLA TYPHI ANTIBODIES(O AND H) IN HUMAN SERUM/PLASMA.(VOXBANK AND OTHER BRANDS)-THE WIDAL TEST IS USED FOR RAPID VISUAL TEST FOR THE QUALITATIVE AND SEMI QUANTITATIVE DETECTION OF FOR THE PRESENCE OR ABSENCE OF SALMONELLA SPECIFIC ANTIBODY IN HUMAN SERUM SPECIMENS. ,RAPID IMMUNO CHROMATOGRAPHY LATERAL FLOW TEST FOR DETECTION OF ANTIBODIES TO H.PYLORI IN HUMAN SERUM/PLASMA/WHOLE BLOOD (VOXPRESS, AND OTHER BRANDS)-THE H.PYLORI ANTIBODY TEST CARD IS USED FOR RAPID VISUAL TEST FOR THE QUALITATIVE DETECTION OF FOR THE PRESENCE OR ABSENCE OF ANTIBODIES SPECIFIC TO H.PYLORI IN HUMAN WHOLE BLOOD /SERUM SPECIMENS.,VIRAL TRANSPORT MEDIUM (VOXMIC OR ANY OTHER BRAND)-VIRAL TRANSPORT MEDIUM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, FROM THE COLLECTION SITE TO THE TESTING LABORATORY.
2943	MFG/IVD/2020/000135	1.License Holder Name: RELIANCE LIFE SCIENCES PVT. LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:MOLECULAR TRANSPORT MEDIUM-THIS WILL BE USED AS A TRANSPORTING MEDIA FOR SAMPLE IN A SAFER CONDITION BY DEACTIVATING THE VIRUS/BACTERIA
2944	MFG/IVD/2020/000136	1.License Holder Name: J.K. DIAGNOSTICS 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:DRABKIN'S REAGENT-FOR HEMOGLOBIN DETERMINATION,BILIRUBIN KIT-FOR BILIRUBIN DETERMINATION,CREATINE KIT-FOR CREATINE DETERMINATION
2945	MFG/IVD/2020/000137	1.License Holder Name: TATA MEDICAL AND DIAGNOSTICS LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 CRISPR KIT 1.0(TATA)-TATA SARS-COV-2 CRISPR KIT 1.0 IS AN IN VITRO DIAGNOSTIC KIT THAT HELPS DIAGNOSE COVID-19.

2946	MFG/IVD/2020/000138	1.License Holder Name: BIOSYSTEMS DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:REAL TIME PCR (CONCEPTA COVID 19 MULTIPLEX RT PCR KIT)-CONCEPTA COVID 19 MULTIPLEX RT PCR KIT IS DEVELOPED FOR THE DETECTION OF COVID-19 VIRAL INFECTION BY SIMULTANEOUS TRAGETTING OF THREE MAJOR GENES ORF1AB, ENVELOPE (E), AND NUCLEOCAPSID (N). THE KIT ALSO INCLUDES AN INTERNAL CONTROL TO INSURE SUCCESSFUL EXTRACTION AND AMPLIFICATIION OF VIRAL RNA. THE KIT IS FOR PROFESSIONAL USE ONLY.
2947	MFG/IVD/2020/000139	1.License Holder Name: TITAN BIOTECH LIMITED 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM KIT(TM MEDIA)-FOR COLLECTION AND TRANSPORTATION OF SAMPLES CONTAINING VIRUSES IN AN ACTIVE FORM FROM THE COLLECTION SITE TO THE LABORATORY MAINTAINING THE VIABILITY OF THE VIRAL SAMPLES.

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2948	MFG/IVD/2020/000140	1.License Holder Name: EXCEL DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:SGOT TEST KIT-ESTIMATION OF SGOT IN HUMAN SERUM,ELECTROLYTES TEST KIT-ESTIMATION OF ELECTROLYTES IN HUMAN SERUM,ALBUMIN TEST KIT-ESTIMATION OF ALBUMIN IN HUMAN SERUM,CHOLESTEROL TEST KIT-ESTIMATION OF CHOLESTEROL IN HUMAN SERUM,BILIRUBIN TEST KIT-ESTIMATION OF BILIRUBIN IN HUMAN SERUM,POTASSIUM TEST KIT-ESTIMATION OF POTASSIUM IN HUMAN SERUM,SODIUM & POTASSIUM TEST KIT-ESTIMATION OF SODIUM & POTASSIUM IN HUMAN SERUM,URIC ACID TEST KIT-ESTIMATION OF URIC ACID IN HUMAN SERUM,AMYLASE TEST KIT-ESTIMATION OF AMYLASE IN HUMAN SERUM,UREA TEST KIT-ESTIMATION OF UREA IN HUMAN SERUM,SGPT TEST KIT-ESTIMATION OF SGPT IN HUMAN SERUM, CHLORIDE TEST KIT-ESTIMATION OF CHLORIDE IN HUMAN SERUM, PHOSPHORUS TEST KIT-ESTIMATION OF PHOSPHORUS IN HUMAN SERUM,HEMOGLOBIN TEST KIT-ESTIMATION OF HEMOGLOBIN IN HUMAN BLOOD,ALKALINE PHOSPHATASE TEST KIT-ESTIMATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM,GLYCOSYLATED HAEMOGLOBIN TEST KIT-ESTIMATION OF HBA1 IN HUMAN BLOOD, CREATININE TEST KIT-ESTIMATION OF CREATININE IN HUMAN SERUM,CALCIUM TEST KIT-ESTIMATION OF CALCIUM IN HUMAN SERUM,GLUCOSE TEST KIT-ESTIMATION OF GLUCOSE IN HUMAN SERUM,TOTAL PROTEIN TEST KIT-ESTIMATION OF TOTAL PROTEIN IN HUMAN SERUM,TRIGLYCERIDES TEST KIT-ESTIMATION OF TRIGLYCERIDES IN HUMAN SERUM
2949	MFG/IVD/2020/000141	1.License Holder Name: GENES2ME PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:SPINRNA VIRAL RNA EXTRACTION KIT(SPINRNA)-THIS PRODUCT IS SUITABLE FOR EXTRACTING VIRAL NUCLEIC ACID FROM CLINICAL SAMPLES WITH LOW CELL CONTENT. THE PRODUCT CAN BE USED FOR CLINICAL IN VITRO DETECTION.
2950	MFG/IVD/2020/000142	1.License Holder Name: AGD BIOMEDICALS P LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT KIT (AGD VT-M001)-A VIRAL TRANSPORT KIT IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS.

2951	MFG/IVD/2020/000143	1.License Holder Name: GCC BIOTECH INDIA PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUGS STANDARD CONTROL ORGANIZATION(EAST ZONE) 3.Device Name(Brand Name)-Intended Use:GSURE® VIRAL RNA ISOLATION KIT (FAST)(GSURE®)-THE GSURE® VIRAL RNA ISOLATION KIT (FAST) IS DESIGNED FOR THE RAPID SIMULTANEOUS PURIFICATION OF VIRAL RNA. THE SENSITIVITY OF THE KIT WAS 100% AND THE SPECIFICITY WAS 100%. RNA RECOVERY IS TYPICALLY GREATER THAN 100%, BUT MAY VARY DEPENDING ON SAMPLE TYPE. THE RNA RECOVERED WITH THE KIT IS OF HIGH QUALITY AND PURITY AND IS SUITABLE FOR REAL-TIME RT-PCR. THIS KIT CAN ISOLATE NUCLEIC ACID FROM SEVERE ACUTE RESPIRATORY SYNDROME-RELATED CORONAVIRUS 2 (SARS-COV-2) IN HUMAN SERUM, PLASMA, URINE, NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, ANTERIOR NASAL SWAB, MID-TURBINATE AND SPUTUM SPECIMENS FROM INDIVIDUALS WITH SIGNS AND SYMPTOMS OF INFECTION WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTH CARE PROVIDER.
2952	MFG/IVD/2020/000144	1.License Holder Name: PROMEA THERAPEUTICS PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:REAL TIME POLYMERASE CHAIN REACTION-IT IS USED TO DETECT FOR GENE SPECIFIC AMPLIFICATION THROUGH GENE SPECIFIC PRIMERS AND PROBES BY USING TAQ MAN BIOCHEMIST METHOD.,RNA EXTRACTION KIT-THE RNA EXTRACTION KIT IS DESIGNED TO ISOLATE RNA FROM PLASMA, SERUM, SPUTUM, NASAL SECRETIONS, FROM ANY OTHER BIOLOGICAL FLUID.
2953	MFG/IVD/2020/000145	1.License Holder Name: NANZ MED SCIENCE PHARMA PRIVATE LIMITED. 2.Approving Authority: SIRMOUR 3.Device Name(Brand Name)-Intended Use:HCG TEST REAGENT/KIT-HCG TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR PRELIMINARY SELF TESTING OF HCG IN URINE,LUTEINIZING HORMONE (LH) TEST REAGENTS/KITS -A LUTEINIZING HORMONE (LH) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE PRELIMINARY SELF TESTING OF LUTEINIZING HORMONE (LH) IN URINE/BODY FLUIDS.

2954	MFG/IVD/2020/000146	1.License Holder Name: UBIO BIOTECHNOLOGY SYSTEMS PRIVATE LIMITED 2.Approving Authority: KERALA 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM [VTM]-VIRAL TRANSPORT MEDIUM [VTM] IS INTENDED FOR VIRAL SPECIMEN COLLECTION, TRANSPORT AND PRESERVATION OF MANY BACTERIAL AND VIRAL SPECIES INCLUDING COVID-19 VIRUS [SARS- COV2] . FOR PROFESSIONAL DIAGNOSTIC USE ONLY.,RNA EXTRACTION KIT-RNA EXTRACTION KIT IS INTENDED FOR MOLECULAR BIOLOGY APPLICATION FOR EXTRACTION OF RNA FROM SPECIMEN, INCLUDING SPECIMEN TRANSPORTED IN VTM- VIRAL TRANSPORT MEDIUM
2955	MFG/IVD/2020/000147	1.License Holder Name: HIMEDIA LABORATORIES PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:ELISA ANTIBODY TEST KIT FOR COVID-19 DETECTION(ELISAFE 19)-FOR DETECTION OF IGG ANTIBODIES AGAINST S1 FRAGMENT OF SARS-COV-2 BY STANDARD ELISA METHOD FROM HUMAN SERUM SAMPLES. THE KIT HAS TO BE USED BY TRAINED HEALTHCARE PROFESSIONALS.
2956	MFG/IVD/2020/000148	1.License Holder Name: ALCHEM DIAGNOSTICS 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM KIT(BIOPRO)-FOR COLLECTION AND TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING VIRUSES FROM COLLECTION CENTER TO LABORATORY
2957	MFG/IVD/2020/000149	1.License Holder Name: NEODX BIOTECH LABS PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:RNA EXTRACTION KIT (NUCLEODX)-THE KIT IS INTENDED TO PURIFY THE VIRAL RNA/DNA FROM DIFFERENT SOURCE OF BIOLOGICAL SAMPLES

2958	MFG/IVD/2020/000150	1.License Holder Name: NEODX BIOTECH LABS PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use: COVIDXTM MPLEX-4R SARS-COV-2 RT-PCR DETECTION KIT(COVIDX)-THE KIT IS INTENDED FOR USE FOR IN-VITRO RT-PCR QUALITATIVE ASSAY FOR THE SPECIFIC DETECTION OF SARS-COV-2 IN HUMAN RESPIRATORY AND SERUM SPECIMENS. THIS SARS-COV-2 PRIMER AND PROBE SETS ARE DESIGNED FOR THE DETECTION OF E-GENE, N-GENE AND RDRP-GENE ALONG WITH INTERNAL CONTROL RNASE P IN A SINGLE TUBE ASSAY, BASED ON BERLIN PROTOCOL., IN-VITRO TESTING ONLY.
2959	MFG/IVD/2020/000151	1.License Holder Name: CHROMOUS BIOTECH PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:VIRAL RNA EXTRACTION KIT(CHROMOUS VIRAL RNA EXTRACTION KIT)-THE KIT IS USED FOR EXTRACTION OF VIRAL RNA (INCLUDING COVID-SPECIFIC) FROM HUMAN SAMPLES LIKE BLOOD, TISSUES AND SWABS. THE ISOLATED RNA IS OF GOOD QUALITY SUCH THAT REACTIONS LIKE RT-PCR BASED DETECTION OF VIRUSES CAN BE PERFORMED SUBSEQUENTLY.
2960	MFG/IVD/2020/000152	1.License Holder Name: DNA XPERTS PRIVATE LIMITED 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIA (COVIDO XPERT VTM)-FOR COLLECTION OF VIRAL SPECIMEN SAMPLES FOR MOLECULAR OR MICORBIOLOGICAL TESTING
2961	MFG/IVD/2020/000153	1.License Holder Name: PONTIKA AEROTECH LTD 2.Approving Authority: SUB ZONAL BADDI 3.Device Name(Brand Name)-Intended Use:ONE STEP RT-PCR COVID-19 DIAGNOSTIC KIT(COVI-DETECT)-THIS KIT IS INTENDED FOR THE DETECTION OF SARS-COV-2 IN NASOPHARYNGEAL SWABS (NPS), NASAL SWABS (NS), BRONCHO ALVEOLAR LAVAGE (BAL) OR OTHER APPROPRIATE CLINICAL SPECIMENS BY A ONE-STEP REVERSE TRANSCRIPTION REAL TIME PCR. THIS KIT IS FOR IN-VITRO DIAGNOSIS ONLY.

2962	MFG/IVD/2020/000154	1.License Holder Name: AXIVA SICHEM BIOTECH 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM (RED)-FOR COLLECTION AND TRANSPORT OF CLINICAL SPECIMEN FOR RECOVERY OF VIRAL AGENTS.,VIRAL TRANSPORT MEDIUM KIT (RED)(VIRAL TRANSPORT MEDIUM KIT)-FOR COLLECTION AND TRANSPORT OF CLINICAL SPECIMEN FOR RECOVERY OF VIRAL AGENTS.,VIRAL TRANSPORT MEDIUM KIT (CLEAR)(VIRAL TRANSPORT MEDIUM KIT)-FOR COLLECTION AND TRANSPORT OF CLINICAL SPECIMEN FOR RECOVERY OF VIRAL AGENTS

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2963	MFG/IVD/2020/000155	1.License Holder Name: BIOSCI HEALTH CARE 2.Approving Authority: MADHYA PRADESH 3.Device Name(Brand Name)-Intended Use:LEPTOSPIRA ANTIBODY IGG & IGM TEST REAGENT & KITS(BIOSCI TRUE -DETECT LEPTOSPIRA ANTIBODY IGG & IGM TEST)-LEPTOSPIRA ANTIBODY TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF LEPTOSPIRA ANTIBODY IN BLOOD/BODY FLUIDS,URINE ANALYSIS STRIP 2K (GLUCOSE/ KETONE)(BIOSCI® TRUE-DETECT URINE STRIP 2K (GLUCOSE/ KETONE))-URINE ANALYSIS STRIP 2K (GLUCOSE/ KETONE) FOR THE SEMI-QUANTITATIVE DETERMINATION OF GLUCOSE &KETONE IN HUMAN URINE,URINE ANALYSIS STRIP 10P (BLO, BIL, URO, KET, PRO, NIT, GLU, PH, SG & LEU)(BIOSCI® TRUE-DETECT URINE STRIP 10P)-SEMI-QUANTITATIVE DETERMINATION OF BLOOD, BILIRUBIN, UROBILINOGEN, KETONE, PROTEIN, NITRITE, GLUCOSE, PH, SPECIFIC GRAVITY & LEUCOCYTES IN HUMAN URINE., URINE ANALYSIS STRIP 11P (BLO, BIL, URO, KET, PRO, NIT, GLU, PH, SG, LEU & ASC)(BIOSCI® TRUE-DETECT URINE STRIP 11P)-SEMI-QUANTITATIVE DETERMINATION OF BLOOD, BILIRUBIN, UROBILINOGEN, KETONE, PROTEIN, NITRATE, GLUCOSE, PH, SPECIFIC GRAVITY, LEUCOCYTES & ASCORBIC ACID IN HUMAN URINE.,BIOSCI TRUE-DETECT CHIKUNGUNYA ANTIBODIES (IGM) RAPID TEST DEVICE (BIOSCI® TRUE-DETECT CHIKUNGUNYA ANTIBODY (IGM) TEST)-LATERAL FLOW THROUGH IMMUNOCHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF CHIKUNGUNYA ANTIBODIES (IGM) IN HUMAN WHOLE BLOOD/ SERUM/ PLASMA,BIOSCI TRUE-DETECT TYPHOID ANTIBODIES (IGM & IGG) RAPID TEST DEVICE(BIOSCI® TRUE-DETECT TYPHOID ANTIBODIES (IGM & IGG) RAPID TEST)-LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGM & IGG ANTIBODIES SPECIFIC TO SALMONELLA TYPHI IN HUMAN SERUM/PLASMA.,BIOSCI TRUE-DETECT DENGUE ANTIBODIES (IGM & IGG) RAPID TEST DEVICE (BIOSCI® TRUE-DETECT DENGUE ANTIBODIES (IGM & IGG) RAPID TEST DEVICE)-LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGM & IGG ANTIBODIES SPECIFIC TO DENGUE IN HUMAN WHOLE BLOOD/SERUM/PLASMA., URINE ANALYSIS STRIP 1G (GLUCOSE)(BIOSCI® TRUE-DETECT URINE STRIP 1G (GLUCOSE))-SEMI-QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN URINE.,BIOSCI TRUE-DETECT CHIKUNGUNYA ANTIBODIES (IGM & IGG) RAPID TEST DEVICE(BIOSCI® TRUE-DETECT CHIKUNGUNYA ANTIBODY (IGM & IGG) TEST)-LATERAL FLOW THROUGH IMMUNOCHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF CHIKUNGUNYA ANTIBODIES (IGM & IGG) IN HUMAN WHOLE BLOOD/ SERUM/ PLASMA.,VIRAL TRANSPORT MEDIUM (BIOSCI VTM/BIOSCI® TRUE-DETECT VIRAL TRANSPORT MEDIUM)-

	VIRAL TRANSPORT MEDIUM FOR STABILIZE VIRUSES AND SUPPRESS MICROBIAL CONTAMINATION DURING TRANSPORT OF CLINICAL SPECIMENS FROM THE POINT OF COLLECTION TO THE TESTING SITE. , URINE ANALYSIS STRIP 4S (GLUCOSE/ PROTEIN/PH/ SPECIFIC GRAVITY)(BIOSCI® TRUE-DETECT URINE STRIP 4S (GLUCOSE/ PROTEIN/PH/ SPECIFIC GRAVITY))-URINE ANALYSIS STRIP 4S (GLUCOSE/ PROTEIN/PH/SPECIFIC GRAVITY)FOR THE SEMI-QUANTITATIVE DETERMINATION OF GLUCOSE/ PROTEIN/PH/SPECIFIC GRAVITY IN HUMAN URINE.,BIOSCI TRUE-DETECT CHIKUNGUNYA ANTIBODIES (IGM) RAPID TEST DEVICE (BIOSCI TRUE-DETECT CHIKUNGUNYA ANTIBODY (IGM) TEST)-BIOSCI TRUE-DETECT CHIKUNGUNYA ANTIBODY (IGM) TEST IS A RAPID LATERAL FLOW THROUGH IMMUNOCHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF CHIKUNGUNYA ANTIBODIES (IGM) IN HUMAN WHOLE BLOOD/ SERUM/ PLASMA.,BIOSCI TRUE-DETECT CHIKUNGUNYA ANTIBODIES (IGM & IGG) RAPID TEST DEVICE(BIOSCI TRUE-DETECT CHIKUNGUNYA ANTIBODY (IGM & IGG) TEST)-BIOSCI TRUE-DETECT CHIKUNGUNYA ANTIBODY (IGM & IGG) TEST IS A RAPID LATERAL FLOW THROUGH IMMUNOCHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF CHIKUNGUNYA ANTIBODIES (IGM & IGG) IN HUMAN WHOLE BLOOD/ SERUM/ PLASMA.,HUMAN CHORIONIC GONADOTROPIN(HCG) TEST REAGENTS AND KITS(BIOSCI TRUE-DETECT HUMAN CHORIONIC GONADOTROPIN (HCG) TEST)-A HUMAN CHORIONIC GONADOTROPIN (HCG) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE PRELIMINARY SELF TESTING OF HCG IN URINE,H. PYLORI ANTIBODIES(IGM, IGG & IGA) TEST REAGENT AND KITS(BIOSCI TRUE -DETECT H. PYLORI ANTIBODIES(IGM, IGG & IGA) TEST)-H.PYLORI ANTIBODY TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF H.PYLORI ANTIBODY IN BLOOD/BODY FLUIDS-SERUM, PLASMA & WHOLE BLOOD,URINE ANALYSIS STRIP 2P (GLUCOSE/ PROTEIN)(BIOSCI® TRUE-DETECT URINE STRIP 2P (GLUCOSE/ PROTEIN))-URINE ANALYSIS STRIP 2P (GLUCOSE/ PROTEIN) FOR THE SEMI-QUANTITATIVE DETERMINATION OF GLUCOSE & PROTEIN IN HUMAN URINE.,LUTEINIZING HORMONE (LH) TEST REAGENT AND KIT(BIOSCI TRUE -DETECT LUTEINIZING HORMONE(LH) TEST)-A LUTEINIZING HORMONE (LH) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE PRELIMINARY SELF-TESTING OF LUTEINIZING HORMONE (LH) IN URINE

2964	MFG/IVD/2020/000156	1.License Holder Name: ROBONIK INDIA PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:MALARIA TEST MULTIPACK(GAZELLE)-GAZELLE™ MALARIA IS AN IN VITRO DIAGNOSTIC TEST INTENDED FOR THE QUALITATIVE DETECTION OF MALARIA. IT USES THE MALARIA TEST MULTIPACK, INCLUDING CARTRIDGES. THE TEST TARGETS HEMOZOIN, A PARAMAGNETIC BY-PRODUCT OF ALL MALARIA PARASITE SPECIES INFECTING HUMANS (P. FALCIPARUM, P. VIVAX, P. OVALE, P. MALARIAE, AND P. KNOWLESI). THE TEST IS FOR PROFESSIONAL USE IN A LAB SETTING AND REQUIRES HUMAN WHOLE BLOOD.
2965	MFG/IVD/2020/000157	1.License Holder Name: CUTTING EDGE MEDICAL DEVICES PVT. LTD. 2.Approving Authority: MADHYA PRADESH 3.Device Name(Brand Name)-Intended Use:URINE MICROPROTEIN REAGENT KIT(SCINTIGLO)-TO ESTIMATE PROTEINS IN URINE IN MICRO QUANTITIES STARTING FROM 2 MG/100 ML OF URINE
2966	MFG/IVD/2020/000158	1.License Holder Name: AXIVA SICHEM BIOTECH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:SPIN COLUMN VIRAL RNA EXTRACTION KIT(AXIBIO)-FAST AN EASY ISOLATION METHOD FOR THE EXTRACTION AND PURIFICATION OF NUCLEIC ACID (RNA) IN SAMPLES.
2967	MFG/IVD/2020/000159	1.License Holder Name: M/S. JEEV DIAGNOSTICS PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:D-DIMER TEST KIT(IDENTI D-DIMER TEST KIT)-PARTICLE ENHANCED IMMUNOTURBIDIMETRY FOR QUANTITATIVE IN VITRO DETERMINATION OF D-DIMER IN PLASMA ON PHOTOMETRIC SYSTEMS DETERMINATION OF THE D-DIMER CONCENTRATION BY PHOTOMETRIC MEASUREMENT OF ANTIGEN-ANTIBODY-REACTION BETWEEN ANTIBODIES AGAINST D-DIMER BOUND TO PARTICLES AND D-DIMER PRESENT IN THE SAMPLE,SPIN COLUMN RNA EXTRACTION KIT(IDENTI RNA EXTRACTION KIT - SPIN COLUMN)-THE KIT IS INTENDED FOR LYSIS OF ORAL/NASAL SWAB CELLS IN VIRAL TRANSPORT MEDIUM, RELEASE OF VIRAL RNA FROM CELLS, BINDING OF RNA TO SILICA SPIN COLUMN AND ELUTION FROM THE COLUMN. THE RNA CAN BE USED FOR DOWNSTREAM APPLICATIONS LIKE RT-PCR

2968	MFG/IVD/2020/000160	1.License Holder Name: UNIWORTH LABORATORY 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use: LYSE(UNILYSE - 2100 PLUS)-A BLOOD CELL DILUENT IS A MEDICAL DEVICE USED TO DILUTE BLOOD FOR FURTHER TESTING, SUCH AS COMPLETE BLOOD COUNT (CBC),RINSE (UNIRINSE - 1)-AT THE END OF EACH CYCLE RINSING OF ALL THE TUBINGS IS REQUIRE IN ORDER TO PREVENT THE CARRY FORWARD OF THE PREVIOUS SAMPLE.,RINSE(UNIRINSE - 2)-A BLOOD CELL DILUENT IS A MEDICAL DEVICE USED TO DILUTE BLOOD FOR FURTHER TESTING, SUCH AS COMPLETE BLOOD COUNT (CBC),LYSE(UNILYSE -SY- 2100)-LYSE ALL THE RED BLOOD CELLS, AND RELEASE THE HAEMOGLOBIN COMPOUND, WHICH IS MEASURE. AND WBC ARE COUNTED.,DILUENT(UNITON DILUENT - 4)-A BLOOD CELL DILUENT IS A MEDICAL DEVICE USED TO DILUTE BLOOD FOR FURTHERTESTING, SUCH AS COMPLETE BLOOD COUNT(CBC) ., DILUENT(UNITON DILUENT - 2)-DILUTES THE BLOOD & KEEP THE MORPHOLOGY OF RBC / WBC & PLATELETS INTACT.,DILUENT (UNITON DILUENT - 5)-A BLOOD CELL DILUENT IS A MEDICAL DEVICE USED TO DILUTE BLOOD FOR FURTHER TESTING, SUCH AS COMPLETE BLOOD COUNT (CBC),LYSE(UNILYSE - 530/620)-LYSE ALL THE RED BLOOD CELLS, AND RELEASE THE HAEMOGLOBIN COMPOUND, WHICH IS MEASURE. AND WBC ARE COUNTED.,LYSE(UNILYSE - 2100 PLUS)-A BLOOD CELL DILUENT IS A MEDICAL DEVICE USED TO DILUTE BLOOD FOR FURTHER TESTING, SUCH AS COMPLETE BLOOD COUNT (CBC) ,LYSE (UNILYSE - MAA + / 2800)-LYSE ALL THE RED BLOOD CELLS, AND RELEASE THE HAEMOGLOBIN COMPOUND, WHICH IS MEASURE. AND WBC ARE COUNTED., LYSE(UNILYSE - 2300 PLUS)-A BLOOD CELL DILUENT IS A MEDICAL DEVICE USED TO DILUTE BLOOD FOR FURTHER TESTING, SUCH AS COMPLETE BLOOD COUNT (CBC),DILUENT(UNITON DILUENT - 1)-DILUTES THE BLOOD & KEEP THE MORPHOLOGY OF RBC / WBC & PLATELETS INTACT.,LYSE (UNILYSE - 1800/3000 +)-LYSE ALL THE RED BLOOD CELLS, AND RELEASE THE HAEMOGLOBIN COMPOUND, WHICH IS MEASURE. AND WBC ARE COUNTED.,BASOPHIL LYSE(UNILYSE - BASO)-LYSE ALL THE RED BLOOD CELLS, AND RELEASE THE HAEMOGLOBIN COMPOUND, WHICH IS MEASURE. AND WBC ARE COUNTED.,LYSE(UNILYSE - NH/60)-LYSE ALL THE RED BLOOD CELLS, AND RELEASE THE HAEMOGLOBIN COMPOUND, WHICH IS MEASURE. AND WBC ARE COUNTED.

2969	MFG/IVD/2020/000161	1.License Holder Name: ADVY CHEMICAL PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:COVID -19 IGG/IGM RAPID ANTIBODY TEST FOR DETECTION OF IGG AND IGM ANTIBODIES IN HUMAN SERUM/PLASMA/WHOLE BLOOD(EZDX)-EZDX COVID-19 ANTIBODY DETECTION RAPID KIT IS A RAPID AND QUALITATIVE IMMUNE-CHROMATOGRAPHIC IN VITRO ASSAY FOR THE DIFFERENTIAL DETECTION OF IGM & IGG ANTIBODIES TO COVID-19 VIRUS IN HUMAN SERUM, PLASMA/WHOLE BLOOD SAMPLES OBTAINED FROM PATIENT WITH SIGNS AND SYMPTOMS OF RESPIRATORY INFECTION. IT IS DESIGNED FOR QUALITATIVE DETECTION OF IMMUNOGLOBULIN G AND IMMUNOGLOBULIN M ANTIBODY OF NOVEL CORONAVIRUS (COVID-19) IN HUMAN BLOOD. THE TEST IS INTENDED FOR PROFESSIONAL AND LABORATORY USE., COVID-19 RAPID ANTIGEN TEST FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIGEN FROM NASOPHARYNGEAL SWAB SPECIMEN(EZDX)-EZDXTM COVID 19 RAPID ANTIGEN TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIGENS TO SARS-COV-2 PRESENT IN HUMAN NASOPHARYNGEAL SWAB SPECIMEN. THIS TEST IS FOR ADMINISTRATION BY HEALTHCARE WORKERS AND LABS ONLY, AS AN AID TO EARLY DIAGNOSIS OF SARS-COV-2 INFECTION IN PATIENT WITH CLINICAL SYMPTOMS WITH SARS-COV-2 INFECTION. IT PROVIDES ONLY AN INITIAL SCREENING TEST RESULT. THE RESULT OF THIS TEST SHOULD NOT BE THE SOLE BASIS FOR THE DIAGNOSIS; CONFIRMATORY TESTING IS REQUIRED.

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2970	MFG/IVD/2020/000162	1.License Holder Name: VANGUARD DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:TYPHOID AG/ AB COMBO TEST(TYPHOID AG/ AB COMBO TEST)-THE TYPHOID COMBO ANTIGEN & ANTIBODY DETECTION CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF TYPHOID ANTIGEN AND ANTIBODIES IN HUMAN SERUM AND PLASMA. ,DIPAS-VDX COVID 19 IGG ELISA TEST KIT(DIPCOVAN DIPAS-VDX COVID-19 LGG ANTIBODY(MICROWELL ELISA DETECTION KIT))-DIPAS-VDX COVID 19 LGG ELISA TEST IS INTENDED TO BE USED FOR THE IN-VITRO, QUALITATIVE DETECTION OF LGG ANTIBODIES TO SARS-COV-2 IN HUMAN SERUM OR PLASMA.,DENGUE COMBO NS1/IGG/IGM (ANTIGEN & ANTIBODY DETECTION RAPID CARD TEST)(DENGUE COMBO NS1/IGG/IGM (ANTIGEN & ANTIBODY DETECTION RAPID CARD TEST))-THE DENGUE COMBO NS1/IGG/IGM ANTIGEN & ANTIBODY DETECTION CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF DENGUE VIRUS IN HUMAN SERUM AND PLASMA. ,TROPONIN-I(RAPID CARD TEST)(TROPONIN-I(RAPID CARD TEST))-THE TROPONIN-I CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF TROPONIN-I IN HUMAN SERUM/PLASMA AND WHOLE BLOOD.,MALARIA PAN (ANTIGEN DETECTION CARD TEST)(MALARIA PAN (ANTIGEN DETECTION CARD TEST))-THE MALARIA PAN ANTIGEN CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF MALARIA ANTIGEN IN HUMAN BLOOD. ,MALARIA PF/PV (ANTIGEN DETECTION CARD TEST)(MALARIA PF/PV (ANTIGEN DETECTION CARD TEST))-THE MALARIA PF/PV ANTIGEN CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF MALARIAL PLASMODIUM FALCIPARUM & PLASMODIUM VIVAX IN HUMAN BLOOD. ,STREP-A, ANTIGEN DETECTION TEST(STREP-A, ANTIGEN DETECTION TEST)-THE STREP-A ANTIGEN CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF STREP-A ANTIGEN IN HUMAN THROAT SWAB SPECIMENS. ,TYPHOID ANTIGEN DETECTION TEST (TYPHOID ANTIGEN DETECTION TEST)-THE TYPHOID ANTIGEN CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF TYPHOID ANTIGEN IN HUMAN SERUM AND PLASMA AND FECES. ,ANTI STREPTOLYSIN-O (ASO) TEST(ANTI STREPTOLYSIN-O (ASO) TEST)-THE ANTISTREPTOLYSIN “O” (ASO) LATEX TEST IS A LATEX AGGLUTINATION ASSAY FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETECTION OF ANTISTREPTOLYSIN “O” ANTIBODIES (ASO) IN HUMAN SERUM AND PLASMA. , C-REACTIVE PROTEIN (CRP) TEST(C-REACTIVE PROTEIN

	(CRP) TEST)-THE C - REACTIVE PROTEIN (CRP) LATEX TEST IS A LATEX AGGLUTINATION ASSAY FOR THE QUALITATIVE AND SEMI-QUANTITATIVE DETECTION OF C - REACTIVE PROTEIN (CRP) IN HUMAN SERUM. ,MALARIA PF/PAN (ANTIGEN DETECTION CARD TEST) (MALARIA PF/PAN (ANTIGEN DETECTION CARD TEST))-THE MALARIA PF/PAN ANTIGEN CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF MALARIAL ANTIGEN IN HUMAN BLOOD. ,H.PYLORI ANTIGEN DETECTION TEST(H. PYLORI ANTIGEN DETECTION TEST)-THE H. PYLORI ANTIGEN CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HELICOBACTER PYLORI ANTIGEN IN HUMAN FECAL. ,DENGUE NS1-AG MICROWELL ELISA(DENGUE NS1-AG MICROWELL ELISA)-THE DENGUE NS1 ANTIGEN MICROWELL ELISA IS AN IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN SERUM AND PLASMA.,STREP-B, ANTIGEN DETECTION TEST(STREP-B, ANTIGEN DETECTION TEST)-THE STREP-B ANTIGEN CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF STREP-B ANTIGEN IN HUMAN THROAT SWAB SPECIMENS. ,ROTAVIRUS ANTIGEN DETECTION TEST (ROTAVIRUS ANTIGEN DETECTION TEST)-THE ROTAVIRUS ANTIGEN CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ROTAVIRUS ANTIGEN IN HUMAN FECAL. ,DENGUE NS1 (ANTIGEN DETECTION CARD TEST)(DENGUE NS1 (ANTIGEN DETECTION CARD TEST))-THE DENGUE NS1 ANTIGEN CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF DENGUE NS1 VIRUS IN HUMAN SERUM AND PLASMA.

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2971	MFG/IVD/2020/000163	1.License Holder Name: M/S ALLIED BIOTECHNOLOGY INDIA PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM KIT(ABI)-VIRAL TRANSPORT MEDIUM KIT IS INTENDED FOR THE TRANSPORTATION OF VIRAL SAMPLES IN ASEPTIC CONDITION., SGPT/ALT TEST KIT(ALLCARE)-THIS REAGENT KIT IS INTENDED FOR "IN VITRO" QUANTITATIVE DETERMINATION OF SGPT-(ALT) ACTIVITY IN SERUM/ PLASMA.,TOTAL PROTEIN TEST KIT(ALLCARE)-FOR THE PHOTOMETRIC DETERMINATION OF TOTAL PROTEIN ACCORDING TO THE BIURET METHOD IN SERUM, HEPARIN-PLASMA OR EDTA-PLASMA,CHLORIDE REAGENT TEST KIT(ALLCARE)-CHLORIDE REAGENT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF CHLORIDE IN HUMAN SERUM OR PLASMA, ASAT/GOT TEST KIT(ALLCARE)-PHOTOMETRIC DETERMINATION OF ASAT/GOT IN THE SAMPLE METHOD IN SERUM, HEPARIN-PLASMA OR EDTA-PLASMA.,ADENOSINE DEAMINASE (ADA) REAGENT TEST KIT (ALLCARE)-ADENOSINE DEAMINASE (ADA) REAGENT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF ADENOSINE DEAMINASEIN HUMAN SERUM OR PLASMA,BILIRUBIN TEST KIT (ALLCARE)-FOR PHOTOMETRIC DETERMINATION OF BILIRUBIN USING BROMOCRESOL GREEN METHOD IN SERUM, HEPARIN-PLASMA OR EDTA-PLASMA,URIC ACID TEST KIT(ALLCARE)-FOR PHOTOMETRIC DETERMINATION OF URIC ACID USING ENZYMATIC URICASE/PEROXIDASE METHOD,ALAT/GPT TEST KIT(ALLCARE)-FOR PHOTOMETRIC DETERMINATION OF ALAT/GPT USING THE RATE OF NADH CONSUMPTION IS MEASURED PHOTOMETRICALLY AND IS DIRECTLY PROPORTIONAL TO THE ASAT CONCENTRATION IN THE SAMPLE METHOD IN SERUM, HEPARIN-PLASMA OR EDTA-PLASMA, ALBUMIN TEST KIT(ALLCARE)-PHOTOMETRIC DETERMINATION OF ALAT/GPT IN SERUM, HEPARIN-PLASMA OR EDTA-PLASMA,GLUCOSE TEST KIT(ALLCARE)-FOR PHOTOMETRIC DETERMINATION OF GLUCOSE USING ENZYMATIC (GOD/POD) METHOD IN SERUM/PLASMA,BILIRUBIN TOTAL TEST KIT(ALLCARE)-FOR PHOTOMETRIC DETERMINATION OF BILIRUBIN USING BROMOCRESOL GREEN METHOD IN SERUM, HEPARIN-PLASMA OR EDTA-PLASMA, MAGNESIUM REAGENT TEST KIT(ALLCARE)-MAGNESIUM REAGENT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM OR PLASMA AND URINE. ,LDL CHOLESTEROL DIRECT TEST KIT(ALLCARE)-LDL-CHOLESTEROL ASSAY IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL IN HUMAN SERUM OR PLASMA,UREA UV TEST KIT(ALLCARE)-FOR PHOTOMETRIC DETERMINATION OF UREA USING ENZYMATIC URICASE/PEROXIDASE METHOD,ALPHA AMYLASE TEST KIT

		(ALLCARE)-PHOTOMETRIC IN VITRO DETERMINATION OF -AMYLASE ACCORDING TO THE DIRECT SUBSTRATE METHOD IN SERUM/PLASMA/ URINE.,ALKALINE PHOSPHATASE TEST KIT (ALLCARE)-QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM,POTASSIUM TEST KIT(ALLCARE)-POTASSIUM REAGENT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF POTASSIUM IN HUMAN SERUM OR PLASMA AND URINE. ,HDL CHOLESTEROL DIRECT TEST KIT(ALLCARE)-INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL IN HUMAN SERUM OR PLASMA.,LDH TEST KIT(ALLCARE)-LACTATE DEHYDROGENASE REAGENT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE IN HUMAN SERUM OR PLASMA,UREA BERTHELOT TEST KIT(ALLCARE)-FOR PHOTOMETRIC DETERMINATION OF UREA USING ENZYMATIC URICASE/PEROXIDASE METHOD IN SERUM/PLASMA/URINE,SGOT/AST TEST KIT(ALLCARE)-THIS REAGENT KIT IS INTENDED FOR "IN VITRO" QUANTITATIVE DETERMINATION OF SGPT-(ALT) ACTIVITY IN SERUM/ PLASMA.
2972	MFG/IVD/2020/000164	1.License Holder Name: MOLBIO DIAGNOSTICS PVT. LTD. 2.Approving Authority: SUB ZONAL GOA 3.Device Name(Brand Name)-Intended Use:REAL TIME DUPLEX PCR TEST FOR COVID-19(TRUEMIX™ COVID-19)-TRUEMIX™ COVID-19 IS A LYOPHILISED, READY-TO-USE, OPEN FORMAT, DUPLEX REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT PCR) TEST FOR THE QUALITATIVE DETECTION OF SARS COV-2 RNA IN HUMAN OROPHARYNGEAL AND NASOPHARYNGEAL SWABS AND AIDS IN THE DIAGNOSIS OF COVID-19. THE TEST DETECTS THE E AND ORF1A GENES OF THE VIRUS. TRUEMIX™ COVID-19 RUNS ON STANDARD REAL TIME PCR ANALYZERS.
2973	MFG/IVD/2020/000165	1.License Holder Name: MNP MEDITECH PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:RAPID IMMUNOCHROMATOGRAPHY TEST FOR PREGNANCY(SURE IT)-HUMAN CHORIONIC GONADOTROPIN IS A HORMONE PRODUCED BY THE PLACENTA SHORTLY AFTER IMPLANTATION. SINCE HCG IS PRESENT IN THE URINE OF PREGNANT WOMEN, IT IS AN EXCELLENT MARKER FOR CONFIRMING PREGNANCY.

2974	MFG/IVD/2020/000166	1.License Holder Name: NEODX BIOTECH LABS PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:RT-PCR COVID 19 KIT (COVIDX DETECT SARS-COV - 2 RT-PCR DETECTION KIT)-TO QUALITATIVELY DIAGNOSE SARS-COV-2 IN HUMAN RESPIRATORY SAMPLES BY RT-PCR METHOD.,RT-PCR COVID 19 KIT(COVIDX ASSURE SARS-COV - 2 RT-PCR DETECTION KIT)-TO QUALITATIVELY DIAGNOSE SARS -COV-2 IN HUMAN RESPIRATORY SAMPLES BY RT-PCR METHOD.
2975	MFG/IVD/2020/000167	1.License Holder Name: EPYGEN BIOTECH PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:ONE-STEP MULTIPLEX RT-PCR KIT(GENOCOV)-GENOCOV SARS-COV-2 RT-PCR KIT IS A REAL-TIME RT-PCR (REVERSE-TRANSCRIPTASE) TEST INTENDED FOR THE QUALITATIVE DETECTION OF E AND RDRP GENE FROM SEVERE ACUTE RESPIRATORY SYNDROME-RELATED CORONAVIRUS 2 (SARS-COV-2) IN THE HUMAN NASOPHARYNGEAL SWAB, ANTERIOR NASAL SWAB, AND MID-TURBINATE NASAL SWAB SPECIMENS FROM INDIVIDUALS SUSPECTED OF 2019-NCOV BY THEIR HEALTHCARE PROVIDER.

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2976	MFG/IVD/2020/000168	1.License Holder Name: UMIKOM HEALTHCARE INDIA LLP 2.Approving Authority: CHHATTISGARH 3.Device Name(Brand Name)-Intended Use:GAMMA GLUTAMYL/TRANSFERASE TESTING KIT-INTENDED FOR ESTIMATION OF THE ENZYME GAMMA GLUTAMYL TRANSFERASE GGT IN SERUM, PLASMA.,FERRITIN TEST KIT-INTENDED FOR ESTIMATION OF FERRITIN IN SERUM, PLASMA.,BILIRUBIN TOTAL AND DIRECT TEST KIT-INTENDED FOR ESTIMATION OF BILIRUBIN (TOTAL AND DIRECT) IN SERUM/PLASMA,ALKALINE PHOSPHATASE TEST KIT-INTENDED FOR ESTIMATION OF ALKALINE PHOSPHATASE OR ITS ISOENZYMES., POTASSIUM TEST KIT-INTENDED FOR THE ESTIMATION OF POTASSIUM IN SERUM, PLASMA / URINE,GLYCOSYLATED HEMOGLOBIN TEST KIT-INTENDED FOR ESTIMATION OF GLYCOSYLATED HEMOGLOBIN OR ITS VARIANTS INCLUDING A1A, A1B, A1C IN BLOOD,GLUCOSE TEST KIT-INTENDED FOR THE ESTIMATION OF GLUCOSE IN BLOOD, PLASMA, BODY FLUIDS.,LDL CHOLESTEROL TEST KIT-INTENDED FOR ESTIMATION OF LDL CHOLESTEROL IN SERUM, PLASMA,CREATINE KINASE TEST KIT-INTENDED FOR ESTIMATION OF ENZYME CREATINE PHOSPHOKINASE OR ITS ISOENZYMES IN SERUM, PLASMA,HEMOGLOBIN TEST KIT-INTENDED FOR ESTIMATION OF HEMOGLOBIN IN BLOOD,CREATININE TEST KIT-INTENDED FOR ESTIMATION OF CREATININE IN SERUM, PLASMA AND URINE.,AMYLASE TEST KIT-INTENDED FOR ESTIMATION OF ENZYME AMYLASE IN SERUM, SALIVA OR URINE,CALCIUM TEST KIT-INTENDED FOR ESTIMATION OF TOTAL CALCIUM IN SERUM, CHLORIDE TEST KIT-INTENDED FOR ESTIMATION OF CHLORIDE IN PLASMA, SERUM, SWEAT/URINE,ALBUMIN TEST KIT-INTENDED TO BE USED FOR ESTIMATION OF ALBUMIN IN SERUM/PLASMA, CHOLESTEROL TOTAL TEST KIT-INTENDED FOR ESTIMATION OF CHOLESTEROL IN SERUM OR PLASMA,IRON TEST KIT-INTENDED FOR ESTIMATION OF IRON IN SERUM/ PLASMA,KITS FOR ESTIMATION OF PARAMETERS OF URINE-INTENDED FOR ESTIMATION OF ASCORBIC ACID/ BILIRUBIN /BLOOD IN THE URINE /BLOOD CELLS/GLUCOSE/ KETONE / LEUKOCYTE PEROXIDASE / SPECIFIC PEROXIDASE / SPECIFIC GRAVITY/UROBILINOGEN NITRITE / PH /PROTEIN /NITRITE /ANALYTES TEST REAGENTS/ ALBUMIN & OTHER MEDICAL DEVICES INTENDED FOR THE URINARY ANALYTES TEST PRELIMINARY ESTIMATION OF DIAGNOSTIC REAGENTS /STRIPS/KITS MARKERS IN URINE.,OTHER CLINICAL CHEMISTRY TEST KIT (ADENOSINE DEAMINASE)-INTENDED FOR QUANTITATIVE MEASUREMENT OF ADENOSINE DEAMINASE IN SERUM, PLASMA,HDL CHOLESTEROL TEST KIT-INTENDED FOR ESTIMATIO OF HDL CHOLESTEROL IN SERUM, PLASMA,BLOOD CELL DILUENTS-INTENDED TO DILUTE BLOOD FOR FURTHER TESTING FOR CBC,URIC ACID TEST KIT-

		INTENDED FOR THE ESTIMATION OF URIC ACID IN SERUM/ PLASMA / URINE,LIPASE TEST KITS-A LIPASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF LIPASE IN SERUM / PLASMA,LACTATE DEHYDROGENASE TEST KIT-INTENDED FOR THE ESTIMATION OF ENZYME LACTATE DEHYDROGENASE AND ITS ISOENZYMES IN SERUM / PLASMA,MICRO PROTEIN TEST KIT-INTENDED FOR THE ESTIMATION OF MICRO-PROTEINS INCLUDING MICRO-ALBUMIN IN URINE,RINSE/DETERGETN/CLEANERS KIT-INTENDED FOR CLEANING VARIOUS PARTS OF HEMATOLOGY ANALYZERS LIKE PROBES, NEEDLES, BATHS, TUBING ETC.,IRON BINDING CAPACITY TEST KIT-INTENDED FOR ESTIMATION OF IRON BINDING CAPACITY IN SERUM, PLASMA,UREA (BUN) TESTING KIT-INTENDED FOR THE ESTIMATION OF UREA/BLOOD UREA NITROGEN (BUN) IN PLASMA/ SERUM / URINE.,SODIUM TEST REAGENTS-INTENDED FOR THE ESTIMATION OF SODIUM IN SERUM/ PLASMA / URINE.,ASPARTATE AMINO TRANSFERASE AST/SGOT TEST KIT-INTENDED FOR THE ESTIMATION OF THE ENZYME ASPARTATE AMINO TRANSFERASE (AST/SGOT) IN SERUM / PLASMA.,ALANINE AMINO TRANSFERASE (ALT/SGPT) TEST KIT-INTENDED FOR THE ESTIMATION OF ENZYME ALANINE AMINO TRANSFERASE (ALT/SGPT) IN SERUM / PLASMA.,PROTEIN (FRACTIONATION) TEST KIT-INTENDED FOR THE ESTIMATION OF PROTEIN FRACTIONS IN BLOOD, URINE, CEREBROSPINAL FLUID / OTHER BODY FLUIDS.,PHOSPHORUS TESTING KIT-INTENDED FOR THE ESTIMATION OF INORGANIC PHOSPHORUS IN SERUM, PLASMA / URINE.,LYSE KITS FOR DIFFERENTIAL COUNTS-INTENDED FOR LYSING OF CELLS FOR THE ESTIMATION OF COMPLETE BLOOD COUNT(CBC),TOTAL PROTEIN TEST KIT-INTENDED FOR THE ESTIMATION OF TOTAL PROTEIN(S) IN SERUM / PLASMA.,TRIGLYCERIDES TEST KIT-INTENDED FOR THE ESTIMATION OF TRIGLYCERIDES IN SERUM / PLASMA,OTHER CLINICAL CHEMISTRY TEST KIT (SICKLE CELL SOLUBILITY TEST)-INTENDED FOR QUANTITATIVE MEASUREMENT OF SICKLE CELL ANEMIA IN SERUM, PLASMA ,ACID PHOSPHATASE TEST KIT-USED FOR ESTIMATION OF ACID PHOSPHATASE IN SERUM OR PLASMA
2977	MFG/IVD/2021/000001	1.License Holder Name: GENEBIO HEALTHCARE PVT LTD 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM-THE DEVICES IS ENVISIONED FOR COLLECTION, TRANSPORTATION AND PRESERVATION OF SPECIMENS CONTAINING VIRUSES, MYCOPLASMA,UREAPLASMA AND CHLAMYDIA, FROM THE COLLECTION SITE TO THE RESEARCH CENTRES, DIAGNOSTIC CENTRES AND LABORATORIES..

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2978	MFG/IVD/2021/000002	1.License Holder Name: VANGUARD DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: SOUTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:CHIKUNGUNYA IGG/IGM ANTIBODY (ANTIBODY DETECTION CARD TEST)(VDX CHIKUNGUNYA IGG/IGM ANTIBODY (ANTIBODY DETECTION CARD TEST))-THE CHIKUNGUNYA IGG/IGM ANTIBODY CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR DETECTION OF CHIKUNGUNYA IN HUMAN SERUM AND PLASMA,CLEAN CELL 5P1-S (VDX CLEAN CELL 5P1-S)-CLEANCELL 5P1-S IS USED FOR PERIODIC CLEANING THE TUBES AND BATHS IN SYSMEX 5 PART HEMATOLOGY ANALYZERS.,DILUENT-P(VDX DILUENT-P)-DILUENT-P IS USED FOR DILUTING THE BLOOD CELLS IN PROKAN 3 PART HEMATOLOGY ANALYZERS.,MICROPROTEIN(VDX MICROPROTEIN)-MICROPROTEIN KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF MICROPROTEIN IN HUMAN URINE WITH THE HELP OF BIOCHEMISTRY ANALYZER.,AMMONIA(VDX AMMONIA)-AMMONIA KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF AMMONIA IN HUMAN SERUM WITH THE HELP OF BIOCHEMISTRY ANALYZER.,VITAMIN D MICROWELL ELISA(VDX VITAMIN D MICROWELL ELISA)-THE VITAMIN D MICROWELL ELISA IS AN IMMUNOASSAY FOR THE QUANTITATIVE DETECTION OF VITAMIN D IN HUMAN SERUM AND PLASMA.,DENGUE IGM ANTIBODY MICROWELL ELISA(VDX DENGUE IGM ANTIBODY MICROWELL ELISA)-THE DENGUE IGM ANTIBODY MICROWELL ELISA IS AN IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM AND PLASMA, SULFOLYSE-5P1-S(VDX SULFOLYSE-5P1-S)-SULFOLYSE-5P1-S IS USED FOR LYSING THE BLOOD CELLS IN SYSMEX 5 PART HEMATOLOGY ANALYZERS.,CLENZ- C/CLEANER-CD(VDX CLENZ-C/CLEANER-CD)-CLENZ-C/CLEANER-CD IS USED FOR PERIODIC CLEANING THE TUBES AND BATHS IN DYMIND 3 PART HEM ANALYZERS,LYSE(VDX LYSE)-LYSE IS USED FOR LYSING THE BLOOD CELLS IN MINDRAY 3 PART HEMATOLOGY ANALYZERS.,LYSE-D CELL (VDX LYSE-D CELL)-LYSE-D CELL IS USED FOR LYSING THE BLOOD CELLS IN DIAGON 3 PART HEMATOLOGY ANALYZERS.,ZINC(VDX ZINC)-ZINC KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF ZINC IN HUMAN SERUM WITH THE HELP OF BIOCHEMISTRY ANALYZER.,UREA UV(VDX UREA UV)-UREA UV KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF UREA UV IN HUMAN SERUM WITH THE HELP OF BIOCHEMISTRY ANALYZER.,HOMOCYSTEINE(VDX HOMOCYSTEINE)-HOMOCYSTEINE KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF HOMOCYSTEINE IN HUMAN SERUM WITH THE HELP OF BIOCHEMISTRY ANALYZER.,

	G6PDH KIT(VDX G6PDH KIT)-G6PDH KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF G6PDH IN HUMAN BLOOD WITH THE HELP OF BIOCHEMISTRY ANALYZER.,CYMET- IIIRD DIFF R/ LYSE-R(VDX CYMET- IIIRD DIFF R/ LYSE-R)-CYMET-IIIRD DIFF R/ LYSE-R IS USED FOR LYSING THE BLOOD CELLS IN RAYTO 3 PART HEMATOLOGY ANALYZERS.,TOTAL PROTEIN(VDX TOTAL PROTEIN)-TOTAL PROTEIN KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF TOTAL PROTEIN IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER.,EZ CLEANER-M(VDX EZ CLEANER-M)-EZ CLEANER-M IS USED FOR CLEANING THE TUBES AND BATHS BEFORE SHUTDOWN IN MINDRAY 3 PART H ANALYZERS.,CLEANER-P(VDX CLEANER-P)-CLEANER-P IS USED FOR CLEANING THE BLOOD CELLS IN PROKAN 3 PART HEMATOLOGY ANALYZERS.,DILUENT-IIIRD DIFF R/DILUENT-R(VDX DILUENT-IIIRD DIFF R/DILUENT-R)-DILUENT-IIIRD DIFF R/DILUENT-R IS USED FOR DILUTING THE BLOOD CELLS IN RAYTO 3 PART HEMATOLOGY ANALYSER.,DETECTOTERGER /CLEANER-R(VDX DETECTOTERGER /CLEANER-R)-DETECTOTERGE-R /CLEANER-R IS USED FOR CLEANING THE BLOOD CELLS IN RAYTO 3 PART HEMATOLOGY ANALYZERS.,SODIUM(VDX SODIUM)-SODIUM KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF SODIUM IN HUMAN SERUM WITH THE HELP OF BIOCHEMISTRY ANALYZER.,ALKALINE PHOSPHATASE (VDX ALKALINE PHOSPHATASE)-ALKALINE PHOSPHATASE KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER.,DILUTING FLUID/SALINE(VDX DILUTING FLUID/SALINE)-DILUTING FLUID/SALINE IS USED FOR DILUTING THE BLOOD CELLS IN AUTOMATED ANALYZERS.,JAPANEASE ENCEPHALITIS VIRUS IGG/IGM ANTIBODY (ANTIBODY DETECTION CARD TEST)(VDX JAPANEASE ENCEPHALITIS VIRUS IGG/IGM ANTIBODY (ANTIBODY DETECTION CARD TEST))-THE JAPANEASE ENCEPHALITIS VIRUS IGG/IGM ANTIBODY CARD TEST IS A RAPID CHROMATOGRAPHIC IMMNOASSAY FOR THE QUALITATIVE DETECTION OF JAPANEASE ENCEPHALITIS VIRUS IN HUMAN SERUM AND PLASMA,HEMOGLOBIN REAGENT(VDX HEMOGLOBIN REAGENT)-HEMOGLOBIN REAGENT KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF HEMOGLOBIN REAGENT IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER., CREATINE KINASE MB(VDX CREATINE KINASE MB)-CREATINE KINASE MB KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF CREATINE KINASE MB IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER.,CELL

	CLEAN/CELL CLEAN 1,2,3(VDX CELL CLEAN/CELL CLEAN 1,2,3)-CELL CLEAN IS USED FOR PERIODIC CLEANING THE TUBES OF BIOCHEMISTRY ANALYZERS.,CHLORIDE(VDX CHLORIDE)-CHLORIDE KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF CHLORIDE IN HUMAN SERUM WITH THE HELP OF BIOCHEMISTRY ANALYZER.,POTASSIUM(VDX POTASSIUM)-POTASSIUM KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF POTASSIUM IN HUMAN SERUM WITH THE HELP OF BIOCHEMISTRY ANALYZER.,TYPHI IGM (ANTIBODY DETECTION CARD TEST)(VDX TYPHI IGM (ANTIBODY DETECTION CARD TEST))-THE TYPHI IGM CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO TYPHI IGM IN HUMAN SERUM AND PLASMA.,FERRITIN(VDX FERRITIN)-FERRITIN KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF FERRITIN IN HUMAN SERUM WITH THE HELP OF BIOCHEMISTRY ANALYZER., DETERGENT-U(VDX DETERGENT-U)-DETERGENT-U IS USED FOR CLEANING THE BLOOD CELLS IN URINT 3 PART HEMATOLOGY ANALYZERS,HDL CHOLESTEROL(VDX HDL CHOLESTEROL)-HDL CHOLESTEROL KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF HDL CHOLESTEROL IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER., DILUENT-U(VDX DILUENT-U)-DILUENT-U IS USED FOR DILUTING THE BLOOD CELLS IN URINT 3 PART HEMATOLOGY ANALYZERS.,PROBE CLEANER/HARD CLEANER(VDX PROBE CLEANER/HARD CLEANER)-PROBE CLEANER/HARD CLEANER IS USED FOR PERIODIC CLEANING THE TUBES AND BATHS IN ANALYZERS.,RINSE/CLEANER- A(VDX RINSE/CLEANER- A)-RINSE/CLEANER- A IS USED FOR RINSING THE BLOOD CELLS IN ABX 3 PART HEMATOLOGY ANALYZER.,FILARIASIS IGG/IGM ANTIBODY (ANTIBODY DETECTION CARD TEST)(VDX FILARIASIS IGG/IGM ANTIBODY (ANTIBODY DETECTION CARD TEST))-THE FILARIASIS IGG/IGM ANTIBODY CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF FILARIASIS IGG/IGM ANTIBODIES IN HUMAN SERUM AND PLASMA OR BLOOD,CELL WASHING REAGENT(VDX CELL WASHING REAGENT)-CELL WASHING REAGENT IS USED FOR WASHING THE CELLS IN FLOW CYTOMETER ANALYZER,CLEANSER-5P1-M(VDX CLEANSER-5P1-M)-CLEANSER-5P1-M IS USED FOR CLEANING THE BLOOD CELLS IN MINDRAY 5 PART HEMATOLOGY ANALYZER.,GAMMA GT(VDX GAMMA GT)-GAMMA GT KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF GAMMA GT IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER,DILUENT/SHEATH FLUID(VDX DILUENT/SHEATH FLUID)-DILUENT/SHEATH FLUID IS USED FOR

	DILUTING THE BLOOD CELLS IN AUTOMATED ANALYZERS., LEPTOSPIROSIS IGG/IGM ANTIBODY (ANTIBODY DETECTION CARD TEST)(VDX LEPTOSPIROSIS IGG/IGM ANTIBODY (ANTIBODY DETECTION CARD TEST))-THE LEPTOSPIROSIS IGG/IGM ANTIBODY CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF LEPTOSPIROSIS IGG/IGM ANTIBODIES IN HUMAN SERUM AND PLASMA.,RINSE- NK/CLEANER-NK(VDX RINSE- NK/CLEANER-NK)-RINSE-NK/CLEANER-NK IS USED FOR CLEANING THE BLOOD CELLS IN NIHON KOHDEN 3 PART HEMATOLOGY ANALYSER.,URIC ACID(VDX URIC ACID)-URIC ACID KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF URIC ACID IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER., CHEMISTRY CONTROL NORMAL(VDX CHEMISTRY CONTROL NORMAL) -CHEMISTRY CONTROL-NORMAL IS USED FOR THE IN-VITRO QUALITY CHECK FOR BIOCHEMISTRY KIT/REAGENT THE HELP OF BIOCHEMISTRY ANALYZER.,LEISHMANIASIS ANTIBODY (ANTIBODY DETECTION CARD TEST)(VDX LEISHMANIASIS ANTIBODY (ANTIBODY DETECTION CARD TEST))-THE LEISHMANIASIS ANTIBODY CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF LEISHMANIASIS ANTIBODIES IN HUMAN SERUM AND PLASMA.,ZIKA VIRUS IGG/IGM ANTIBODY (ANTIBODY DETECTION CARD TEST)(VDX ZIKA VIRUS IGG/IGM ANTIBODY (ANTIBODY DETECTION CARD TEST))-THE ZIKA VIRUS IGG/IGM ANTIBODY CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ZIKA VIRUS IGG/IGM ANTIBODIES IN HUMAN SERUM AND PLASMA OR BLOOD., LEO I LYSE- 5P1-M(VDX LEO I LYSE- 5P1-M)-LEO I LYSE-5P1-M IS USED FOR LYSING THE BLOOD CELLS IN MINDRAY 5 PART HEMATOLOGY ANALYZERS.,DILUENT(VDX DILUENT)-DILUENT IS USED FOR DILUTING THE BLOOD CELLS IN 3 PART HEMATOLOGY ANALYZERS., DILUENT-A(VDX DILUENT-A)-DILUENT-A IS USED FOR DILUTING THE BLOOD CELLS IN ABX 3 PART HEMATOLOGY ANALYZERS.,RINSE-M (VDX RINSE-M)-RINSE-M IS USED FOR RINSING THE BLOOD CELLS IN MINDRAY 3 PART HEMATOLOGY ANALYZERS,PROBE CLEANSER-5P (VDX PROBE CLEANSER-5P)-PROBE CLEANSER-5P IS USED FOR PERIODIC CLEANING THE TUBES AND BATHS IN MINDRAY 5 PART HEMATOLOGY ANALYSER,CLEANER/CLEANSER/CLEANING REAGENT (VDX CLEANER/CLEANSER/CLEANING REAGENT)- CLEANER/CLEANSER/CLEANING REAGENT IS USED FOR PERIODIC CLEANING OF THE TUBES IN ANALYSER.,TOTAL IRON/TIBC/UIBC(VDX TOTAL IRON/TIBC/UIBC)-TOTAL IRON/TIBC/UIBC KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF TOTAL IRON/TIBC/UIBC IN HUMAN SERUM WITH THE HELP OF

	BIOCHEMISTRY ANALYZER.,LYSE-C/LYSE-CD(VDX LYSE-C/LYSE-CD) -LYSE-C/LYSE-CD IS USED FOR LYSING THE BLOOD CELLS IN 3 PART HEMATOLOGY ANALYZERS.,DILUENT-C/DILUENT-CD(VDX DILUENT-C/DILUENT-CD)-DILUENT-C/DILUENT-CD IS USED FOR DILUTING THE BLOOD CELLS IN 3 PART HEMATOLOGY ANALYZERS.,CLEANER-S (VDX CLEANER-S)-CLEANER-S IS USED FOR PERIODIC CLEANING THE TUBES AND BATHS IN SYSMEX 3 PART HEMATOLOGY ANALYSER., HEMATOLOGY CONTROLS NORMAL(VDX HEMATOLOGY CONTROLS NORMAL)-HEMATOLOGY CONTROLS NORMAL (N) USED FOR QUALITY CONTROL FOR DIFFERENTIAL COUNT AND OTHER PARAMETERS OF COMPLETE BLOOD COUNT AS ABNORMAL HEMATOLOGY PARAMETERS.,PROBE CLEANER-M(VDX PROBE CLEANER-M)-PROBE CLEANER-M IS USED FOR PERIODIC CLEANING THE TUBES AND BATHS IN MINDRAY 3 PART HEMAT ANALYZERS.,CELL RINSING REAGENT(VDX CELL RINSING REAGENT)-CELL RINSING REAGENT IS USED FOR RINSING THE BLOOD CELLS IN FLOW CYTOMETER ANALYZER,ALBUMIN(VDX ALBUMIN)-ALBUMIN KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF ALBUMIN IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER.,DILUENT-M(VDX DILUENT-M)-DILUENT-M IS A DILUTING REAGENT FOR DILUTING THE BLOOD CELLS INSIDE THE AUTOMATED HEMATOLOGY ANALYZER.,STROMALYSE-II 5P1-S(VDX STROMALYSE-II 5P1-S)-STROMALYSE-II 5P1-S IS USED FOR LYSING THE BLOOD CELLS IN SYSMEX 5 PART HEMATOLOGY ANALYZERS.,CHOLINE ESTERASE REAGENT(VDX CHOLINE ESTERASE REAGENT)-CHOLINE ESTERASE REAGENT KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF CHOLINE ESTERASE REAGENT IN HUMAN SERUM WITH THE HELP OF BIOCHEMISTRY ANALYZER., HEMATOLOGY CONTROLS ABNORMAL(VDX HEMATOLOGY CONTROLS ABNORMAL)-HEMATOLOGY CONTROLS ABNORMAL (L/H) USED FOR QUALITY CONTROL FOR DIFFERENTIAL COUNT AND OTHER PARAMETERS OF COMPLETE BLOOD COUNT AS ABNORMAL HEMATOLOGY PARAMETERS.,LYSE-M(VDX LYSE-M)-LYSE-M IS USED FOR LYSING THE BLOOD CELLS IN MINDRAY 3 PART HEMATOLOGY ANALYZERS.,PREGNANCY RAPID CARD TEST(VDX PREGNANCY RAPID CARD TEST)-THE PREGNANCY RAPID CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HUMAN CHORIONIC GONADOTROPIN IN URINE.,PROBE CLEANER-U(VDX PROBE CLEANER-U)-PROBE CLEANER-U IS USED FOR PERIODIC CLEANING THE TUBES AND BATHS IN URIT 3 PART HEMATOLOGY ANALYZERS.,CREATININE(VDX CREATININE)-CREATININE KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER,SHUTTING DOWN

	REAGENTS(VDX SHUTTING DOWN REAGENTS)-SHUTTING DOWN REAGENTS IS USED FOR PERIODIC CLEANING THE TUBES AND BATHS IN FLOW CYTOMETER,CREATINE KINASE CK-NAC(VDX CREATINE KINASE CK-NAC)-CREATINE KINASE CK-NAC KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF CREATINE KINASE CK-NAC IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER,URINE STRIPS(VDX URINE STRIPS)-THE URINE STRIPS TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HUMAN GLUCOSE, PROTEIN, KETONE, PH, SPECIFIC GRAVITY, BILIRUBIN, URIBILINOGEN, NITRITE, LEUKOCYTE, NITRITE,PROTEIN,BLOOD IN URINE,VITAMIN D TOTAL MICROWELL ELISA(VDX VITAMIN D TOTAL MICROWELL ELISA)-THE VITAMIN D TOTAL MICROWELL ELISA IS AN IMMUNOASSAY FOR THE QUANTITATIVE DETECTION OF VIRUS IN HUMAN SERUM AND PLASMA.,LYTIC-U(VDX LYTIC-U)-LYTIC-U IS USED FOR LYSING THE BLOOD CELLS IN URIT 3 PART HEMATOLOGY ANALYZERS.,LYSE-A (VDX LYSE-A)-LYSE-A IS USED FOR LYSING THE BLOOD CELLS IN ABX 3 PART HEMATOLOGY ANALYZERS,LIPASE(VDX LIPASE)-LIPASE KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF LIPASE IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER.,LYSE-NK(VDX LYSE-NK)-LYSE-NK IS USED FOR LYSING THE BLOOD CELLS IN NIHON KOHDEN 3 PART HEMATOLOGY ANALYZERS.,SGPT(VDX SGPT)-SGPT KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF SGPT IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER.,RBC LYSING REAGENT(VDX RBC LYSING REAGENT)-RBC LYSING REAGENT IS USED FOR LYSING THE RED BLOOD CELLS IN FLOW CYTOMETER ANALYZER .,DILUENT- D/I/G/XP/HEMAT(VDX DILUENT-D/I/G/XP/HEMAT)-DILUENT-D/I/G/XP/HEMAT IS USED FOR DILUTING THE BLOOD CELLS IN 3 PART HEMATOLOGY ANALYZERS,AMYLASE (VDX AMYLASE)-AMYLASE KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF AMYLASE IN HUMAN SERUM WITH THE HELP OF BIOCHEMISTRY ANALYZER., BICARBONATE/CO2(VDX BICARBONATE/CO2)-BICARBONATE/CO2 KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF BICARBONATE/CO2 IN HUMAN BLOOD WITH THE HELP OF BIOCHEMISTRY ANALYZER.,DENGUE IGG/IGM (ANTIBODY DETECTION CARD TEST)(VDX DENGUE IGG/IGM (ANTIBODY DETECTION CARD TEST))-THE DENGUE IGG/IGM CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGG/IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM AND PLASMA.,STROMALYSEI 5P1-S(VDX STROMALYSEI 5P1-S)-STROMALYSE-I 5P1-S IS USED FOR LYSING THE

	BLOOD CELLS IN SYSMEX 5 PART HEMATOLOGY ANALYZER, DILUENT-D CELL(VDX DILUENT-D CELL)-DILUENT-D CELL IS USED FOR DILUTING THE BLOOD CELLS IN DIAGON 3 PART HEMATOLOGY ANALYZERS.,PROCLEAN-R(VDX PROCLEAN-R)-PROCLEAN-R IS USED FOR PERIODIC CLEANING THE TUBES AND BATHS IN RAYTO 3 PART HEMATOLOGY ANALYZER.,CHEMISTRY CALIBRATOR(VDX CHEMISTRY CALIBRATOR)-CHEMISTRY CALIBRATOR IS USED FOR THE IN-VITRO QUALITY CHECK FOR BIOCHEMISTRY KIT/REAGENT WITH THE HELP OF BIOCHEMISTRY ANALYZER.,LDL CHOLESTEROL (VDX LDL CHOLESTEROL)-LDL CHOLESTEROL KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF LDL CHOLESTEROL IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER.,CHEMISTRY CONTROL-ABNORMAL(VDX CHEMISTRY CONTROL-ABNORMAL)-CHEMISTRY CONTROL-ABNORMAL IS USED FOR THE IN-VITRO QUALITY CHECK FOR BIOCHEMISTRY KIT/REAGENT WITH THE HELP OF BIOCHEMISTRY ANALYZER.,S. TYPHI IGG/IGM (ANTIBODY DETECTION CARD TEST) (VDX S. TYPHI IGG/IGM (ANTIBODY DETECTION CARD TEST))-THE S. TYPHI IGG/IGM CARD TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGG/IGM ANTIBODIES TO S. TYPHI IN HUMAN SERUM AND PLASMA,DILUENT PACK-5P1-S(VDX DILUENT PACK-5P1-S)-DILUENT PACK-5P1-S IS USED FOR DILUTING THE BLOOD CELLS IN SYSMEX 5 PART HEMATOLOGY ANALYZER.,TRIGLYCERIDE(VDX TRIGLYCERIDE)-TRIGLYCERIDE KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF TRIGLYCERIDE IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER., LYSE- D/I/G/XP/HEMAT(VDX LYSE- D/I/G/XP/HEMAT)-LYSE-D/I/G/XP/HEMAT IS USED FOR LYSING THE BLOOD CELLS IN 3 PART HEMATOLOGY ANALYZERS,GLYCOHEMOGLOBIN/HBA1C REAGENT (VDX GLYCOHEMOGLOBIN/HBA1C REAGENT)-GLYCOHEMOGLOBIN/HBA1C REAGENT KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF GLYCOHEMOGLOBIN/HBA1C REAGENT IN HUMAN BLOOD WITH THE HELP OF BIOCHEMISTRY ANALYZER.,CELL FIXING REAGENT(VDX CELL FIXING REAGENT)-CELL FIXING REAGENT IS USED FOR FIXING THE CELLS.,LH LYSE5P1-M(VDX LH LYSE5P1-M)-LH LYSE-5P1-M IS USED FOR LYSING THE BLOOD CELLS IN MINDRAY 5 PART HEMATOLOGY ANALYZERS.,LYSE-S(VDX LYSE-S)-LYSE-S IS USED FOR LYSING THE BLOOD CELLS IN SYSMEX 3 PART HEMATOLOGY ANALYZERS.,LEO II LYSE-5P1-M(VDX LEO II LYSE-5P1-M)-LEO II LYSE-5P1-M IS USED FOR LYSING THE BLOOD CELLS IN MINDRAY 5 PART HEMATOLOGY ANALYZERS,DILUENT-5P1 M(VDX DILUENT-5P1 M)-DILUENT-5P1M IS USED FOR DILUTING THE BLOOD CELLS IN

	MINDRAY 5 PART HEMATOLOGY ANALYZERS.,DILUENT-S(VDX DILUENT-S)-DILUENT-S IS USED FOR DILUTING THE BLOOD CELLS IN SYSMEX 3 PART HEMATOLOGY ANALYZERS.,UREA BERTHELOT(VDX UREA BERTHELOT)-UREA BERTHELOT KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF UREA IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER., GLUCOSE(VDX GLUCOSE)-GLUCOSE KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF GLUCOSE IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER,DILUENT-NK(VDX DILUENT-NK)-DILUENT-NK IS USED FOR DILUTING THE BLOOD CELLS IN NIHON KOHDEN 3 PART HEMATOLOGY ANALYZER.,LYSE-P(VDX LYSE-P)-LYSE-P IS USED FOR LYSING THE BLOOD CELLS IN PROKAN 3 PART HEMATOLOGY ANALYZERS.,RINSE/DETERGENT(VDX RINSE/DETERGENT)-RINSE/DETERGENT IS USED FOR RINSING THE BLOOD CELLS IN MINDRAY 3 PART HEMATOLOGY ANALYZERS.,BILIRUBIN T&D(VDX BILIRUBIN T&D)-BILIRUBIN T&D KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF BILIRUBIN T&D IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER.,ACID PHOSPHATASE(VDX ACID PHOSPHATASE)-ACID PHOSPHATASE KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF ACID PHOSPHATASE IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER., SGOT(VDX SGOT)-SGOT KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF SGOT IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER., CHOLESTEROL(VDX CHOLESTEROL)-CHOLESTEROL KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF CHOLESTEROL I HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER,CALCIUM(VDX CALCIUM)-CALCIUM KIT IS USED FOR THE IN-VITRO QUANTITATIVE DETERMINATION/ESTIMATION OF CALCIUM IN HUMAN SERUM/PLASMA WITH THE HELP OF BIOCHEMISTRY ANALYZER.

2979	MFG/IVD/2021/000003	1.License Holder Name: UNICARE BIOMEDICAL 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:DILUENT-ESTIMATION OF TOTAL BLOOD COUNT IN WHOLE BLOOD,CHOLESTEROL TEST KIT-ESTIMATION OF CHOLESTEROL IN PLASMA OR SERUM,ALKALINE PHOSPHATASE TEST KIT-ESTIMATION OF ALKALINE PHOSPHATASE IN SERUM OR PLASMA,E Z CLEANER-CLEANING OF COUNTING CHAMBER OF BLOOD CELL COUNTER,RINSE/ CLEANER-CLEANING OF COUNTING CHAMBER AND FLUIDIC PATH OF BLOOD CELL COUNTER, CALCIUM (ARSENAZO) TEST KIT-ESTIMATION OF CALCIUM IN SERUM., LYSE-ESTIMATION OF HEMOGLOBIN AND WBC COUNT IN WHOLE BLOOD USING BLOOD CELL COUNTER.,TRIGLYCERIDES TEST KIT-ESTIMATION OF TRIGLYCERIDES IN SERUM OR PLASMA,BILIRUBIN (TOTAL & DIRECT) TEST KIT-ESTIMATION OF BILIRUBIN IN SERUM OR PLASMA,UREA TEST KIT-ESTIMATION OF UREA IN SERUM OR PLASMA,PROBE CLEANER-CLEANING OF COUNTING CHAMBER OF BLOOD CELL COUNTER,CREATININE TEST KIT-ESTIMATION OF CREATININE IN SERUM OR PLASMA,HDL CHOLESTEROL (DIRECT) TEST KIT-ESTIMATION OF HDL CHOLESTEROL IN SERUM,GLUCOSE TEST KIT-FOR ESTIMATION OF GLUCOSE IN BLOOD OR SERUM, ALT/SGPT TEST KIT-ESTIMATION OF SGPT IN PLASMA OR SERUM, AST/SGOT TEST KIT-ESTIMATION OF SGOT IN PLASMA OR SERUM, URIC ACID TEST KIT-ESTIMATION OF URIC ACID IN PLASMA OR SERUM

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2980	MFG/IVD/2021/000004	1.License Holder Name: OSCAR MEDICARE PVT. LTD. 2.Approving Authority: SOUTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:KALA AZAR TEST (CARD/CASSETTE)(KALA AZAR TEST (CARD/CASSETTE))-THE OSCAR KALA AZAR (CARD / CASSETTE) IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF ANTIBODIES TO VISCERAL LEISHMANIASIS (VL), MEMBERS OF L. DONOVANI, IN HUMAN SERUM SPECIMENS. FOR PROFESSIONAL USE ONLY.,OVULATION TEST (STRIP / DIPSTICK)(OVULATION (LH DETECTTION) TEST)-OVULATION (STRIP / DIPSTICK) IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF LH (LUTEINIZING HORMONE), A MARKER FOR OVULATION, IN URINE SPECIMENS. FOR PROFESSIONAL USE ONLY., DENGUE ANTIBODY TEST (IGM/IGG)(DENGUE ANTIBODY TEST)-DENGUE ANTIBODY TEST (IGM/IGG) IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNOCHROMATOGRAPHY ON A MEMBRANE, FOR SIMULTANEOUS AND DIFFERENTIAL DETECTION OF DENGUE SPECIFIC ANTIBODY (IGM/IGG) IN HUMAN SERUM / PLASMA FOR DIAGNOSIS OF DENGUE INFECTION . FOR PROFESSIONAL USE ONLY.,PREGNANCY TEST (MIDSTREAM TEST)(PREGSTREAM (MIDSTREAM TEST))-PREGNANCY TEST (MIDSTREAM TEST) IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG), A MARKER FOR PREGNANCY, IN URINE SPECIMENS. FOR PROFESSIONAL USE ONLY,PREGNANCY TEST (STRIP / DIPSTICK)(PREGNANCY TEST (STRIP / DIPSTICK))-PREGNANCY TEST (STRIP / DIPSTICK) IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG), A MARKER FOR PREGNANCY, IN URINE SPECIMENS. FOR PROFESSIONAL USE ONLY., H.PYLORI TEST(H.PYLORI TEST)-OSCAR H. PYLORI TEST IS A RAPID, QUALITATIVE, SANDWICH IMMUNOASSAY FOR SIMULTANEOUS DETECTION OF TOTAL ANTIBODIES (IGM / IGG / IGA) TO H. PYLORI IN HUMAN SERUM / PLASMA.,CHIKUNGUNYA TEST (IGM/IGG DETECTION TEST)(CHIKUNGUNYA TEST (IGM/IGG DETECTION TEST))-CHIKUNGUNYA TEST IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNE-CHROMATOGRAPHY ON A MEMBRANE, FOR SIMULTANEOUS AND DIFFERENTIAL DETECTION OF CHIKUNGUNYA SPECIFIC ANTIBODY (IGM/IGG) IN HUMAN SERUM / PLASMA FOR DIAGNOSIS OF CHIKUNGUNYA INFECTION.,TYPHOID ANTIBODY TEST (IGM/IGG)(TYPHOID ANTIBODY TEST (IGM/IGG))-TYPHOID IGM / IGG TEST DEVICE IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNOCHROMATOGRAPHY ON A MEMBRANE FOR DIFFERENTIAL DETECTION OF IGM AND IGG

		ANTIBODIES TO SALMONELLA TYPHI (S. TYPHI) IN HUMAN SERUM OR PLASMA. FOR PROFESSIONAL USE ONLY,OVULATION TEST (MIDSTREAM TEST)(OVULATION (LH DETECTTION) TEST)-OVULATION TEST (MIDSTREAM) IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAYS FOR THE DETERMINATION OF LUTEINIZING HORMONE (LH), A MARKER FOR OVULATION, IN URINE SPECIMENS. FOR PROFESSIONAL USE ONLY,OVULATION TEST (CARD / CASSETTE)(OVULATION (LH DETECTTION) TEST)-OVULATION TEST (CARD / CASSETTE) IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAYS FOR THE DETERMINATION OF LUTEINIZING HORMONE (LH), A MARKER FOR OVULATION, IN URINE SPECIMENS. FOR PROFESSIONAL USE ONLY,PREGNANCY TEST (CARD / CASSETTE)(PREGNANCY TEST (CARD / CASSETTE))-PREGNANCY TEST (CARD / CASSETTE) IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG), A MARKER FOR PREGNANCY, IN URINE SPECIMENS. FOR PROFESSIONAL USE ONLY,KALA AZAR TEST (STRIP/DIPSTICK)(KALA AZAR TEST (STRIP/DIPSTICK))-THE OSCAR KALA AZAR (STRIP / DIPSTICK) IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF ANTIBODIES TO VISCERAL LEISHMANIASIS (VL), MEMBERS OF L. DONOVANI, IN HUMAN SERUM SPECIMENS. FOR PROFESSIONAL USE ONLY.
2981	MFG/IVD/2021/000005	1.License Holder Name: SCI CELLSOLUTIONS LLP 2.Approving Authority: SOUTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use::VIRAL TRANSPORT MEDIUM KIT (VTM)(RAPISURE)-:FOR THE DETECTION OF SARS-COV-2 RNA (COVID-19) FROM HUMAN CLINICAL SPECIMEN
2982	MFG/IVD/2021/000006	1.License Holder Name: AB DIAGNOPATH MFG PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use: COVID-19 RT-PCR KIT (INNODETECT)-THE INNODETECTTM COVID RT-PCRKIT ASSAY IS AN IN VITRO NUCLEIC ACID AMPLIFICATION TEST FOR THE QUALITATIVE DETECTION OF SARS-COV-2 RNA IN NASOPHARYNGEAL/ OROPHARYNGEAL SWAB AND SALIVA SAMPLES . THE TEST IS INTENDED FOR USE AS AN AID IN THE CONFIRMATORY DIAGNOSIS OF COVID-19 INFECTION. THIS RT-PCR KIT IS INTENDED FOR USE BY QUALIFIED CLINICAL LABORATORY PERSONNEL SPECIFICALLY INSTRUCTED AND TRAINED IN THE TECHNIQUES OF REAL-TIME PCR AND IN VITRO DIAGNOSTIC PROCEDURES.

2983	MFG/IVD/2021/000007	1.License Holder Name: GCC BIOTECH INDIA PRIVATE LIMITED 2.Approving Authority: WEST BENGAL 3.Device Name(Brand Name)-Intended Use:DIAGSURE VTM KIT (WITH TWO NYLON SWAB)(DIAGSURE)-DIAGSURETM VTM KIT (WITH TWO NYLON SWAB) SAMPLE COLLECTION AND TRANSPORT KIT IS A SPECIALLY DESIGNED TRANSPORT SYSTEM TO COLLECT AND TRANSPORT VIRUSES IN AN ACTIVE FORM TO THE LABORATORY FOR ISOLATION/IDENTIFICATION. WITH ITS ENHANCED FORMULATION IT ENSURES THE VIABILITY AND THE VIRULENCE OF THE VIRAL SAMPLE. IT IS ALSO SUPPLEMENTED WITH CRYOPROTECTANT PROTEIN FOR MAINTAINING VIRUS VIABILITY. IT HAS ANTIMICROBIAL AGENTS INCORPORATED TO MINIMIZE COMMENSAL BACTERIAL AND FUNGAL CONTAMINATION. THE MEDIUM IS ISOTONIC AND NON-TOXIC TO HOST CELLS. IT HAS BUFFERS TO CONTROL THE PH. PHENOL RED IS USED AS A PH INDICATOR IN THIS KIT. THE SUCCESS OF THE DIAGNOSIS OF SARS-COV-2 (2019- NCOV) DURING THE COVID-19 OUTBREAK DEPENDS LARGELY ON THE QUALITY OF THE SPECIMEN AND THE CONDITIONS UNDER WHICH THE SPECIMEN IS TRANSPORTED AND STORED BEFORE BEING PROCESSED IN THE LABORATORY. DIAGSURE VTM KIT (WITH NYLON SWAB) ALLOWS THE SAFE TRANSFER OF THE SAMPLES FOR FURTHER RESEARCH, INCLUDING CONVENTIONAL CELL CULTURE METHODS, DIAGNOSTIC TESTS, AND MOLECULAR BIOLOGY TECHNIQUES.
2984	MFG/IVD/2021/000008	1.License Holder Name: VOXTUR BIO LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:LH OVULATION TEST (VOXPRESS AND OTHER BRAND)-A LUTEINIZING HORMONE (LH) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE PRELIMINARY SELF TESTING OF LUTEINIZING HORMONE (LH) IN URINE/BODY FLUIDS.

2985	MFG/IVD/2021/000009	1.License Holder Name: SIDAK LIFECARE PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:DENGUE NS1 RAPID TEST KIT(CARD/STRIP)-FOR DETECTION OF DENGUE,TOXOPLASMA GONDII RAPID TEST DEVICE/KIT-FOR DETECTION OF TOXOPLASMA GONDII, TROPONIN-L RAPID TEST KIT/DEVICE-FOR DIAGNOSIS OF ACUTE MYOCARDIAL INFARCTION (AMI),MALARIA PF/PAN RAPID TEST KIT (CARD/STRIP)-FOR DETECTION OF MALARIA,MALARIA AG RAPID TEST KIT (CARD/STRIP)-FOR DETECTION OF MALARIA,DENGUE COMBO TEST KIT-FOR DETECTION OF DENGUE BOTH IGG/IGM AND NS1,RPR SYPHILIS SCREENING TEST KIT/DEVICE-FOR DETECTION OF SYPHILIS IN HUMAN BLOOD/PLASMA,SYPHILIS RAPID TEST DEVICE/KITS (CARD/STRIP)-FOR DETECTION OF SYPHILIS IN HUMAN WHOLE BLOOD/PLASMA,WIDAL ANTIGEN RAPID TEST KIT-DETECTION OF TYPHOID,C-REACTIVE PROTEIN (CRP TURBI LATEX) TEST KIT-DETECTION OF C-REACTIVE PROTEIN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA,HIV TEST DEVICE/KITS-FOR DETECTION OF TRANSMISSIBLE HIV IN BLOOD/BODY FLUIDS.,HCV TEST DEVICE/KIT(HCV CARD)-FOR DETECTION OF HCV IN BLOOD/BODY FLUIDS,MALARIA PF/PV RAPID TEST KIT (CARD/STRIP)-FOR DETECTION OF MALARIA,LEPTOSPIRA IGG/IGM RAPID TEST DEVICE/KIT-FOR DETECTION OF LEPTOSPIRA IN HUMAN SERUM/PLASMA,DENGUE LGG/LGM TEST KIT (CARD/STRIP)-FOR DETECTION OF DENGUE,C-REACTIVE PROTEIN (CRP LATEX) ANTIGEN TEST KIT-DETECTION OF C-REACTIVE PROTEIN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA,HBSAG TEST DEVICE/KIT(HEPATITIS STRIP AND CARD KIT)-FOR DETECTION OF HBSAG IN BLOOD/BODY FLUIDS,WIDAL (O&H) RAPID TEST KIT-FOR DETECTION OF TYPHOID

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2986	MFG/IVD/2021/000010	1.License Holder Name: HINDUSTAN SYRINGES & MEDICAL DEVICES LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTION TUBE - CTAD [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - SOL. A (ACD) [EVACUATED TUBE] (VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - ESR (4NC) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - CITRATE (4NC) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - SILICON COAT (Z) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - GLUCOSE (FX) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - CITRATE - B.CIT. (9NC) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS

	BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - GEL [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - SODIUM FLUORIDE/EDTA K2 (FE) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - EDTA K3 (K3E) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - LITHIUM HEPARIN (LH) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - EDTA K3 (K3E) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - LITHIUM HEPARIN (LH) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - CITRATE - B.CIT.(9NC) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - SODIUM

	HEPARIN (NH) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - CTAD [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - GLUCOSE (FX) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - CLOT ACC., NO ADD.+BCA (CAT) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - SOL. B (ACD) [EVACUATED TUBE] (VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - GEL + BCA (CAT) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - NO ADDITIVE (Z) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - CLOT ACC., NO ADD.+BCA (CAT) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION

	NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - GEL [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - SILICON COAT (Z) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - NO ADDITIVE (Z) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - SODIUM FLUORIDE/EDTA K3 (FE) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - ESR (4NC) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - GEL + BCA (CAT) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - SODIUM FLUORIDE/EDTA K2 (FE) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT

		AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - EDTA K2 (K2E) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - EDTA K2 (K2E) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - SODIUM FLUORIDE/EDTA K3 (FE) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - SODIUM HEPARIN (NH) [EVACUATED TUBE](VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLES AND HOLDERS, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.
2987	MFG/IVD/2021/000011	1.License Holder Name: INVITROGEN BIOSERVICES INDIA PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:COVID-19 RT-PCR KIT (APPLIED BIOSYSTEMS COVIPATH)-COVIPATH™ COVID-19 RT-PCR KIT CONTAINS THE REAGENTS AND CONTROLS FOR A REAL-TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM SARS-COV-2 IN NASOPHARYNGEAL SWAB, NASOPHARYNGEAL ASPIRATE, AND BRONCHOALVEOLAR LAVAGE (BAL) SPECIMENS FROM INDIVIDUALS SUSPECTED OF COVID-19.

2988	MFG/IVD/2021/000012	1.License Holder Name: ALCHEM DIAGNOSTICS 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:COVID-19 VIRAL RNA EXTRACTION SPIN COLUMN KIT(BIOPRO)-THROUGH EXTENSIVE RESEARCH COVID-19 RNA EXTRACTION SPIN COLUMN KIT HAS BEEN SPECIFICALLY DEVELOPED FOR COVID VIRAL EXTRACTION WITH THE USE OF CARRIER RNA FOR CAPTURING VIRAL RNA

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

2989	MFG/IVD/2021/000013	1.License Holder Name: AFFIGENIX BIOSOLUTIONS PVT LTD., 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:ASPARTATE AMINOTRANSAMINASE (AST/SGOT) REAGENT KIT - TRIS BUFFER WITHOUT P5P METHOD(AFFI CC PLUS ASPARTATE AMINOTRANSAMINASE (AST/SGOT) REAGENT KIT - TRIS BUFFER WITHOUT P5P METHOD)-QUANTITATIVE DETERMINATION OF AST / SGOT IN SERUM / PLASMA,UREA KIT - GLDH METHOD(AFFI CC PLUS UREA KIT - GLDH METHOD)-QUANTITATIVE DETERMINATION OF UREA IN SERUM/PLASMA,-AMYLASE TEST REAGENT PNP - MALTOTRIOSIDE SUBSTRATE METHOD(AFFI CC PLUS -AMYLASE KIT PNP - MALTOTRIOSIDE SUBSTRATE METHOD)-QUANTITATIVE DETERMINATION OF AMYLASE IN SERUM / PLASMA,PHOSPHORUS KIT - PHOSPHOMOLYBDATE UV METHOD(AFFI CC PLUS PHOSPHORUS KIT - PHOSPHOMOLYBDATE UV METHOD)-QUANTITATIVE DETERMINATION OF PHOSPHORUS IN SERUM/PLASMA,LACTATE DEHYDROGENASE (LDH) TEST KIT - P TO L METHOD(AFFI CC-PLUS LACTATE DEHYDROGENASE (LDH) TEST KIT - P TO L METHOD)-QUANTITATIVE DETERMINATION OF LDH IN SERUM/PLASMA,CALCIUM REAGENT KIT -ARSENAZO III METHOD (AFFI CC PLUS CALCIUM REAGENT KIT -ARSENAZO III METHOD)-QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM / PLASMA, ALBUMIN REAGENT KIT - BCG METHOD(AFFI CC PLUS ALBUMIN REAGENT KIT - BCG METHOD)-QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM / PLASMA BY BCG METHOD,GAMMA-GT (GGT) REAGENT KIT - KINETIC IFCC METHOD(AFFI CC PLUS GAMMA-GT (GGT) REAGENT KIT - KINETIC IFCC METHOD)-QUANTITATIVE DETERMINATION OF GAMMA GT ACTIVITY IN SERUM / PLASMA., CREATINE KINASE-MB (CK-MB) REAGENT KIT - IMMUNOINHIBITION METHOD(AFFI CC PLUS CREATINE KINASE-MB (CK-MB) REAGENT KIT IMMUNOINHIBITION METHOD)-QUANTITATIVE DETERMINATION OF CREATINE KINASE- MB IN SERUM/PLASMA,ALKALINE PHOSPHATASE (ALP) REAGENT KIT - KINETIC IFCC METHOD(AFFI CC PLUS ALKALINE PHOSPHATASE (ALP) REAGENT KIT - KINETIC IFCC METHOD)-QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN SERUM / PLASMA.,MAGNESIUM TEST REAGENT - XYLIDYL BLUE METHOD(AFFI CC PLUS MAGNESIUM KIT - XYLIDYL BLUE METHOD)-QUANTITATIVE DETERMINATION OF MAGNESIUM IN SERUM/PLASMA, TRIGLYCERIDES KIT - GPO/PAP METHOD(AFFI CC PLUS TRIGLYCERIDES KIT - GPO/PAP METHOD)-QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN SERUM/PLASMA BY GPO/PAP METHOD,CHOLESTEROL REAGENT KIT - (CHOD/PAP) METHOD(AFFI CC PLUS CHOLESTEROL REAGENT KIT - (CHOD/PAP) METHOD)-QUANTITATIVE DETERMINATION OF CHOLESTEROL IN

		SERUM/PLASMA,CREATINE KINASE (CK-NAC) REAGENT KIT - IFCC METHOD(AFFI CC PLUS CREATINE KINASE (CK-NAC) REAGENT KIT - IFCC METHOD)-QUANTITATIVE DETERMINATION OF [N-ACETYL-CYSTEIN-(NAC)-ACTIVATED CREATINE KINASE IN SERUM/PLASMA, GLUCOSE REAGENT KIT - GOD/POD METHOD(AFFI CC PLUS GLUCOSE REAGENT KIT - GOD/POD METHOD)-QUANTITATIVE DETERMINATION OF GLUCOSE IN SERUM/PLASMA,BILIRUBIN TOTAL REAGENT KIT - DIAZOTIZED WITH SULFANILIC ACID METHOD(AFFI CC PLUS BILIRUBIN TOTAL REAGENT KIT - DIAZOTIZED WITH SULFANILIC ACID METHOD)-QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN SERUM / PLASMA.,TOTAL PROTEIN KIT - BIURET METHOD(AFFI CC PLUS TOTAL PROTEIN KIT - BIURET METHOD)-QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM/PLASMA BIURET METHOD,URIC ACID KIT - URICASE PEROXIDASE/AOX METHOD(AFFI CC PLUS URIC ACID KIT - URICASE PEROXIDASE/AOX METHOD)-QUANTITATIVE DETERMINATION OF URIC ACID IN SERUM/PLASMA BY URICASE PEROXIDASE/AOX METHOD,BILIRUBIN DIRECT REAGENT KIT - DIAZOTIZED WITH SULPHANIC ACID METHOD (AFFI CC PLUS BILIRUBIN DIRECT REAGENT KIT - DIAZOTIZED WITH SULPHANIC ACID METHOD)-QUANTITATIVE DETERMINATION OF BILIRUBIN DIRECT IN SERUM / PLASMA,CREATININE REAGENT KIT - ALKALINE PICRATE METHOD(AFFI CC PLUS CREATININE REAGENT KIT - ALKALINE PICRATE METHOD)-QUANTITATIVE DETERMINATION OF CREATININE IN SERUM/PLASMA,HDL CHOLESTEROL REAGENT - DIRECT PRECIPITATION METHOD(AFFI CC PLUS HDL CHOLESTEROL REAGENT KIT - DIRECT PRECIPITATION METHOD)-QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN SERUM / PLASMA, ALANINE AMINO TRANSAMINASE (ALT/SGPT) REAGENT KIT - TRIS BUFFER WITHOUT P5P METHOD(AFFI CC PLUS ALANINE AMINO TRANSAMINASE (ALT/SGPT) REAGENT KIT - TRIS BUFFER WITHOUT P5P METHOD)-QUANTITATIVE DETERMINATION OF ALANINE AMINO TRANSAMINASE (ALT/SGPT) IN SERUM/PLASMA BY TRIS BUFFER WITHOUT P5P METHOD
2990	MFG/IVD/2021/000014	1.License Holder Name: LIVGEN BIOTECHNOLOGIES 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIA KIT(LIVGEN)-LIVGEN VIRAL TRANSPORT MEDIUM(VTM) KIT IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMA OR UREAPLASMA FROM THE COLLECTION SITE TO THE TESTING LABORATORY

2991	MFG/IVD/2021/000015	1.License Holder Name: EDGE PHARMA PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:COVID-19 ANTIBODY DETECTION TEST(EDGEXPRESS - COVID-19 ANTIBODY DETECTION TEST)-EDGEXPRESS IS BASED ON THE IMMUNO-CHROMATOGRAPHIC TECHNIQUE INTENDED FOR RAPID QUALITATIVE AND DIFFERENTIAL DETECTION OF COVID-19 IGM AND IGG ANTIBODIES IN HUMAN BLOOD, PLASMA, AND SERUM. THIS TEST KIT IS INTENDED TO BE USED BY PROFESSIONALS ONLY. THIS TEST PROVIDES PRELIMINARY RESULTS.,UNCUT SHEETS FOR COVID-19 ANTIBODY DETECTION TEST (EDGEXPRESS)-THE UNCUT SHEET FOR COVID 19 RAPID ANTIBODY TEST IS BASED ON THE IMMUNO-CHROMATOGRAPHIC TECHNIQUE INTENDED FOR RAPID QUALITATIVE AND DIFFERENTIAL DETECTION OF COVID-19 IGM AND IGG ANTIBODIES IN HUMAN BLOOD, PLASMA, AND SERUM.
2992	MFG/IVD/2021/000016	1.License Holder Name: LABNOVA HEALTHCARE AND DIAGNOSTICS PRODUCTS 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:LYSE(LABMIN - LYSE)-HEMATOLOGY ANALYZER LYSE REAGENT WHICH IS USED FOR THE LYSIS OF THE BLOOD.,ELETROLYTE REAGENT(LABYLYTE ELECTROLYTE REAGENT)-ELECTROLYTE ANALYZER REAGENT (CLINICAL CHEMISTRY REAGENTS) WHICH ARE USEFUL FOR THE ESTIMATION OF THE ELECTROLYTES IN THE BLOOD, PLASMA, SERUM AND SWEAT/ URINE.,DILUENT(LABMIN - DILUENT)-HEMATOLOGY ANALYZER DILUENT REAGENT WHICH IS USEFUL FOR THE DILUTE OF THE BLOOD.,RINSE(LABMIN - RINSE)-IT IS USEFUL FOR THE HEMATOLOGY ANALYZER CLEANING REAGENT

2993	MFG/IVD/2021/000017	1.License Holder Name: AGD BIOMEDICALS P LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:MAGNESIUM-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF MAGNESIUM LEVELS IN SERUM AND PLASMA.,LACTATE DEHYDROGENASE-P (LDH-P)-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF LDH P LEVELS IN SERUM AND PLASMA.,LDL CHOLESTEROL-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF LDL - CHOLESTEROL LEVELS IN SERUM AND PLASMA.,LIPASE-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF LIPASE LEVELS IN SERUM AND PLASMA.,HDL CHOLESTEROL-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF HIGH DENSITY LIPOPROTEIN HDL-CHOLESTEROL LEVELS IN SERUM AND PLASMA,SODIUM-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF SODIUM LEVELS IN SERUM AND PLASMA.,UREA BERTHELOT-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF UREA (BERTHELOT) LEVELS IN SERUM AND PLASMA.,UREA UV-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF UREA LEVELS IN SERUM AND PLASMA.,ADENOSINE DEAMINASE (ADA)-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ADA LEVELS IN SERUM AND PLASMA.,ALKALINE PHOSPHATASE MONO-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE LEVELS IN SERUM AND PLASMA.,BILIRUBIN DIRECT-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF BILIRUBIN DIRECT LEVELS IN SERUM AND PLASMA.,ALKALINE PHOSPHATASE-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE LEVELS IN SERUM AND PLASMA.,CREATINE KINASE-MB (CK-MB)-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CK MB LEVELS IN SERUM AND PLASMA.,CREATINE KINASE-NAC (CK-NAC)-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CK NAC LEVELS IN SERUM AND PLASMA.,PHOSPHOROUS-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF PHOSPHORUS LEVELS IN SERUM AND PLASMA.,CHLORIDE-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CHLORIDE LEVELS IN SERUM AND PLASMA.,AMYLASE-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF AMYLASE LEVELS IN SERUM AND URINE.,CALIBRATING SOLUTION FOR ELECTROLYTE ANALYZER (ISEPAK / TURBOLYTE ISEPAK / ISEPAK-ER)-CLINICAL CHEMISTRY TEST REAGENTS/KITS (ISEPAK) INTENDED FOR THE ESTIMATION OF SODIUM, POTASSIUM, CHLORIDE, CALCIUM ANALYTES/ PARAMETERS (OTHER THAN LISTED DEVICES UNDER MDR) IN SERUM/ PLASMA/ URINE OR OTHER BODY FLUIDS,CHOLESTEROL (TOTAL) TEST

	REAGENTS / KITS(NA)-A CHOLESTEROL (TOTAL) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHOLESTEROL IN SERUM OR PLASMA.,UREA NED-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF UREA NED LEVELS IN SERUM AND PLASMA.,CREATININE TEST REAGENTS / KITS(NA)-A CREATININE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CREATININE IN SERUM, PLASMA / URINE.,CALCIUM TEST REAGENTS / KITS(NA)-A CALCIUM TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TOTAL CALCIUM IN SERUM.,CREATININE TEST REAGENTS / KITS(NA)-A CREATININE MONO TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CREATININE IN SERUM, PLASMA / URINE.,ALBUMIN TEST REAGENT / KIT(NA)-AN ALBUMIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALBUMIN IN SERUM/PLASMA,DILUTION SOLUTION URINE(URINE DILUENT / TURBOLYTE URINE DILUENT / URINE DILUENT-ER)-CLINICAL CHEMISTRY TEST REAGENTS INTENDED FOR DILUTION FOR URINE FOR ESTIMATION OF ELECTROLYTES IN SERUM IN SERUM/ PLASMA/ URINE OR OTHER BODY FLUIDS,URIC ACID TEST REAGENTS / KITS(NA)-A URIC ACID TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF URIC ACID IN SERUM / PLASMA / URINE.,BILIRUBIN T AND D SINGLE-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF BILIRUBIN TOTAL AND DIRECT LEVELS IN SERUM AND PLASMA.,REAGENT FOR CLEANING & MAINTENANCE OF ELECTROLYTE ANALYZER(DEPROTEINIZER / TURBOLYTE DEPROTEINIZER / DEPROTEINIZER-ER)-DEPROTEINIZER IS INTENDED FOR USE ONLY IN THE ELECTROLYTE ANALYZER.,TOTAL PROTEIN TEST REAGENTS / KITS(NA)-A TOTAL PROTEIN TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TOTAL PROTEIN(S) IN SERUM / PLASMA,BILIRUBIN TOTAL TEST REAGENTS / KITS(NA)-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF BILIRUBIN TOTAL LEVELS IN SERUM.,BILIRUBIN (TOTAL / DIRECT) TEST REAGENTS / KITS(NA)-A BILIRUBIN (TOTAL AND DIRECT) TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF BILIRUBIN (TOTAL AND DIRECT) IN SERUM/PLASMA.,ASPARTATE AMINO TRANSFERASE (AST /SGOT) TEST REAGENTS / KITS(NA)-AN ASPARTATE AMINO TRANSFERASE (AST/SGOT) TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF THE ENZYME ASPARTATE AMINO TRANSFERASE (AST/SGOT) IN SERUM / PLASMA,GLUCOSE TEST REAGENTS / KITS (NA)-A GLUCOSE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF GLUCOSE IN BLOOD/PLASMA/ BODY FLUIDS.,REAGENT FOR FILLING OF ELECTRODES(IFS / TURBOLYTE IFS / IFS-ER)-REAGENT FOR FILLING OF ELECTRODES (IFS) IS

		REAGENT INTENDED FOR FILLING OF ELECTRODES USED IN VARIOUS TESTING KITS FOR MEASUREMENT OF NA+,K+,CL-,CA++ ETC., ALANINE AMINO TRANSFERASE (ALT/SGPT) TEST REAGENTS / KITS (NA)-AN ALANINE AMINO TRANSFERASE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME ALANINE AMINO TRANSFERASE (ALT/SGPT) IN SERUM / PLASMA., REAGENTS FOR CONFORMING ACCURACY OF THE ELECTROLYTE ANALYZER(ISE-TRITROL / TURBOLYTE ISE-TRITROL / ISE TRITROL -ER)-TRITROL ISE IS USED FOR CONFIRMING THE ACCURACY OF THE ELECTROLYTE ANALYZER THAT MEASURES NA+, K+, CL-, CA++ & LI+, TRIGLYCERIDES TEST REAGENTS / KITS(NA)-A TRIGLYCERIDE TEST REAGENT/KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TRIGLYCERIDES IN SERUM / PLASMA.,REAGENTS FOR CONFORMING ACCURACY OF THE ELECTROLYTE ANALYZER(ISE-TRITROL COMBOPAK / TURBOLYTE ISE-TRITROL COMBOPAK / ISE-TRITROL COMBOPAK-ER)-TRITROL ISE COMBO IS USED FOR CONFIRMING THE ACCURACY OF THE ELECTROLYTE ANALYZER THAT MEASURES NA+ ,K+,CL-,CA++ & LI+,POTASSIUM-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF POTASSIUM LEVELS IN SERUM AND PLASMA.,GAMMA GT-IT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF GGT LEVELS IN SERUM AND PLASMA.
2994	MFG/IVD/2021/000018	1.License Holder Name: SAVI RAPID DIAGNOSTICS COMPANY 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:URINE MULTIPARAMETER STRIPS(URISIGN)-QUALITATIVE TESTING OF ALBUMIN, GIUCOSE, PROTEIN, UROBILINOGEN, BILLRUBIN, SPECIFIC GRAVITY, PH, KETONE, BLOOD, NITRATE, LEUCOCYTES, ASCORBIC ACID, CREATININE AND CALCIUM.,HCG (PREGNANCY TEST) RAPID TEST (SAVISIGN)-QUALITATIVE TESTING OF HCG (PREGNANCY TEST) IN HUMAN SPECIMEN.
2995	MFG/IVD/2021/000019	1.License Holder Name: PROMEA THERAPEUTICS PRIVATE LIMITED 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:COVID 19 IGG ELISA (PROLISA)-PROLISA COVID-19 IGG ELISA IS AN IN VITRO ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF HUMAN ANTI-COVID-19 IGG ANTIBODY IN HUMAN SERUM AND PLASMA.

2996	MFG/IVD/2021/000020	1.License Holder Name: ADVY CHEMICAL PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:DENGUE COMBO (AG +AB) RAPID DENGUE NS1 ANTIGEN & DENGUE IGM/IGG ANTIBODY DETECTION TEST(EZDX)-DENGUE COMBO (AG+AB) IS A RAPID QUALITATIVE IMMUNE CHROMATOGRAPHIC TEST FOR THE DETECTION OF DENGUE NS1 ANTIGEN & DIFFERENTIAL DETECTION OF IGM & IGG ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM/PLASMA/WHOLE BLOOD. THIS TEST IS FOR IN VITRO DIAGNOSTIC USE ONLY AND IS INTENDED AS AN AID IN THE EARLIER DIAGNOSIS OF DENGUE INFECTION & PRESUMPTIVE DIAGNOSIS BETWEEN PRIMARY AND SECONDARY DENGUE INFECTION.,MALARIA PV/PF RAPID MALARIA AG DETECTION TEST (DETECTION OF PV (PLDH) AND PF (HRP-II) ANTIGEN)(EZDX)-MALARIA PV/PF TEST IS A RAPID IN-VITRO IMMUNO-CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF MALARIA INFECTION IN HUMAN BLOOD SAMPLE INDICATING DIFFERENTIAL DIAGNOSIS BETWEEN P. FALCIPARUM, HRP-II (PLASMODIUM FALCIPARUM, HISTIDINE RICH PROTEIN II) AND PLASMODIUM VIVAX SPECIES (P. VIVAX, PLDH). THE TEST IS INTENDED FOR PRIMARY SCREENING OF MALARIA INFECTION IN SYMPTOMATIC PATIENTS OF ALL AGE GROUPS. THE TEST IS INTENDED FOR PROFESSIONAL USE AND MUST BE USED BY A TRAINED PERSONNEL.,DENGUE NS1 ANTIGEN RAPID DENGUE NS1 ANTIGEN DETECTION TEST(EZDX)-DENGUE NS1 ANTIGEN IS A QUALITATIVE RAPID TEST FOR THE DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN SERUM/ PLASMA/ WHOLE BLOOD. THIS TEST IS FOR DIAGNOSTIC USE ONLY IN ACUTE DENGUE INFECTION.THIS TEST IS INTENDED FOR PROFESSIONAL USE AND MUST BE USED BY TRAINED PERSONNEL.,MALARIA PF RAPID MALARIA AG DETECTION TEST (DETECTION OF PF (HRP-II) ANTIGEN)(ADVDX)-MALARIA PF TEST KIT IS AN IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF MALARIA INFECTION CAUSED BY PLASMODIUM FALCIPARUM PARASITES IN HUMAN. IT DETECTS HRP-II (HISTIDINE RICH PROTEIN-II) ANTIGEN OF PLASMODIUM FALCIPARUM IN WHOLE BLOOD SPECIMENS. IT DOES NOT ASSESS PARASITE DENSITIES. THE TEST MUST BE PERFORMED BY TRAINED PROFESSIONAL USER AND NOT BY LAY USERS., MALARIA PAN RAPID MALARIA AG DETECTION TEST (DETECTION OF PAN (PLDH) ANTIGEN(EZDX)-MALARIA PAN IS A RAPID QUALITATIVE CHROMATOGRAPHIC IMMUNOASSAY FOR THE DETECTION OF MALARIA INFECTION IN HUMAN BLOOD SAMPLE INDICATING PLASMODIUM SPECIES (PAN, PLDH) (P. FALCIPARUM P. VIVAX, P. OVALE AND P. MALARIAE). THE TEST IS INTENDED FOR PRIMARY

	SCREENING OF MALARIA INFECTION IN SYMPTOMATIC PATIENTS OF ALL AGE GROUPS. THE TEST IS INTENDED FOR PROFESSIONAL USE AND MUST BE USED BY A TRAINED PERSONNEL.,MALARIA PAN/PF RAPID TEST DETECTION KIT (DETECTION OF PAN (PLDH) AND PF (HRP-II) ANTIGEN)(EZDX)-MALARIA PAN/PF IS A RAPID IN-VITRO IMMUNO-CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF MALARIA INFECTION IN HUMAN BLOOD SAMPLE INDICATING DIFFERENTIAL DIAGNOSIS BETWEEN P. FALCIPARUM, HRP-II (PLASMODIUM FALCIPARUM, HISTIDINE-RICH PROTEIN II) AND OTHER PLASMODIUM SPECIES (PAN, PLDH) (P. VIVAX, P. OVALE AND P. MALARIAE). THE TEST IS INTENDED FOR PRIMARY SCREENING OF MALARIA INFECTION IN SYMPTOMATIC PATIENTS OF ALL AGE GROUPS. THE TEST IS INTENDED FOR PROFESSIONAL USE AND MUST BE USED BY A TRAINED PERSONNEL., SYPHILIS ANTIBODY RAPID CARD TEST(EZDX)-" THE SYPHILIS ANTIBODY RAPID CARD TESTIS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF TP ANTIBODIES (IGG AND IGM) IN WHOLE BLOOD , SERUM OR PLASMA. THE TEST MUST BE PERFORMED BY TRAINED PROFESSIONAL USER AND NOT BY LAY USERS. IT IS FOR IN-VITRO DIAGNOSTIC USE ONLY. IT PROVIDES ONLY AN INITIAL SCREENING TEST INDICATING THE PRESENCE OF TP ANTIBODIES IN THE SPECIMEN AND SHOULD NOT BE USED AS THE SOLE CRITERIA FOR THE DIAGNOSIS OF TP INFECTION. ",TROPONIN I RAPID CTNI DETECTION TEST (EZDX)-"THE TROPONIN IRAPID CTNI DETECTION TEST IS A RAPID IMMUNO-CHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF CARDIAC TROPONIN I (CTNI) IN HUMAN WHOLE BLOOD , SERUM OR PLASMA AS AN AID IN THE DIAGNOSIS OF ACUTE MYCARDIAL INFARCTION IN EMERGENCY ROOM, CRITICAL CARE, POINT-OF-CARE, AND HOSPITAL SETTINGS. THE TEST MUST BE PERFORMED BY TRAINED PROFESSIONAL USER AND NOT BY LAY USERS. IT IS FOR IN-VITRO DIAGNOSTIC USE ONLY.,MALARIA PAN/SYPHILIS COMBO RAPID TEST(EZDX)-"THE MALARIA PAN/SYPHILIS COMBO RAPID TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF FOUR KINDS OF CIRCULATING ANTIGENS TO P.FALCIPARUM (P.F), P. VIVAX (P. V), P.OVALE (P. O), P. MALARIAE (P. M) AND SYPHILIS ANTIBODIES (IGG AND IGM) TO TREPONEMA PALLIDUM (TP) IN WHOLE BLOOD. IT IS FOR PROFESSIONAL USE IN IN-VITRO DIAGNOSTICS ONLY. THE TEST MUST BE PERFORMED BY TRAINED PROFESSIONAL USER AND NOT BY LAY USERS. IT IS FOR IN-VITRO DIAGNOSTIC USE ONLY.

2997	MFG/IVD/2021/000021	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: SUB ZONAL GOA 3.Device Name(Brand Name)-Intended Use:ANTI-B (MONOCLONAL) (ERYCLONE ANTI-B (MONOCLONAL))-ERYCLONE ANTI-B IS A MURINE MONOCLONAL IGM REAGENT USED FOR ABO FORWARD GROUPING BY SLIDE AND TUBE TEST METHOD AND IS 100% SPECIFIC TO B ANTIGENS.,ABO/RHO(D) FORWARD AND REVERSE GROUPING CARD WITH SUBGROUPING(MATRIX OCTOPLUS FORWARD AND REVERSE GROUPING CARD WITH SUBGROUPING)-MATRIX OCTOPLUS FORWARD AND REVERSE GROUPING CARD WITH SUB GROUPING FACILITATES THE FORWARD AND REVERSE GROUPING, ANTI-A 1 AND ANTI-H LECTIN FOR SUB GROUPING ALONG WITH A CONTROL MICROTUBE ON SINGLE CARD.,ANTI-A (MONOCLONAL)(ERYCLONE ANTI-A (MONOCLONAL))-ERYCLONE ANTI-A IS A MURINE MONOCLONAL IGM REAGENT USED FOR ABO FORWARD GROUPING BY SLIDE AND TUBE TEST METHOD AND IS 100% SPECIFIC TO A1, A2 AND AX ANTIGENS.,ANTI HUMAN GLOBULIN(ERYCLONE ANTI HUMAN GLOBULIN)-ERYCLONE AHG, IS USED FOR COMPATIBILITY TESTING, ANTIBODY DETECTION, ANTIBODY IDENTIFICATION, UMBILICAL CORD RED BLOOD TESTING AND U DETECTION OF D VARIANTS OF HUMAN RED BLOOD CELL ANTIGEN D (RHO).,ANTI-K (KELL) MONOCLONAL (ERYCLONE ANTI-K (KELL))-ERYCLONE ANTI-K REAGENT CAN BE USED TO DETECT THE PRESENCE OF K ANTIGEN ON RED BLOOD CELLS FOR PHENOTYPING AND BLOOD TRANSFUSION PURPOSE., ABO/RHO(D) FORWARD GROUPING CONFIRMATION CARD(MATRIX ABO/RHO(D) FORWARD GROUPING CONFIRMATION CARD)-MATRIX ABO & RHO (D) FORWARD GROUPING CARD IS USED FOR DETECTING THE FORWARD GROUP AND TYPE OF HUMAN BLOOD ACCORDING TO THE ABO / RHO (D) SYSTEM,ANTI-D IGM (MONOCLONAL)(ERYCLONE ANTI-D IGM)-ERYCLONE ANTI D (IGM) CONSISTS OF BLOOD GROUPING REAGENT FOR SLIDE AND MODIFIED TUBE TESTS. THE REAGENT IS MURINE MONOCLONAL IGM FOR RHO (D) TYPING., NEUTRAL GEL CARD(MATRIX NEUTRAL GEL CARD)-MATRIX NEUTRAL GEL CARD IS USED FOR SALINE AND ENZYME PHASE TESTS INCLUDING ANTIBODY SCREENING, ANTIBODY IDENTIFICATION, COMPATIBILITY TESTING AND ABO REVERSE GROUPING. CONTAINS NEUTRAL GEL.,FORWARD AND REVERSE GROUPING CARD WITH AUTOCONTROL(MATRIX FORWARD AND REVERSE GROUPING CARD WITH AUTOCONTROL)-MATRIX ABO / RHO (D) FORWARD AND REVERSE GROUPING CARD WITH AUTOCONTROL IS USED FOR DETERMINATION OF ABO AND RHO (D) BLOOD GROUP SYSTEMS AND REVERSE GROUPING FOR CONFIRMATION OF ABO GROUPING. CONTAINS MONOCLONAL ANTI-A, ANTI-B AND ANTI-D (VI-).,DIRECT ANTIGLOBULIN TEST CARD(MATRIX DIRECT ANTIGLOBULIN TEST

	CARD)-MATRIX DIRECT ANTIGLOBULIN TEST CARD IS FOR DETECTION AND DIFFERENTIATION OF IGG AND C3D ACTIVITY FOR DAT POSITIVE SAMPLES IN WHOLE BLOOD SPECIMEN.,BLOOD GROUPING CARD FOR ABO FORWARD GROUPING WITH AUTOCONTROL(ERYCARD ABO)-ERYCARD ABO IS A BLOOD GROUPING CARD FOR ABO FORWARD GROUPING WITH AUTOCONTROL. IT CAN BE USED FOR DONOR'S BLOOD GROUP SCREENING IN OUTDOOR CAMPS AS WELL AS IN BLOOD BANKS., FORWARD GROUPING CARD WITH ANTI D(VI+)(MATRIX FORWARD GROUPING CARD WITH ANTI D(VI+))-ACCORDING TO ABO BLOOD GROUP SYSTEM, HUMAN RED BLOOD CELL ANTIGEN CAN BE DIVIDED INTO FOUR GROUPSA,B,AB AND O DEPENDING ON THE PRESENCE OR ABSENCE OF CORRESPONDING ANTIGENS ON THE RED BLOOD CELLS.,ABO/RHOD/AHG NEONATE GROUP CARD(MATRIX ABO/RHOD/AHG NEONATE GROUP CARD)-MATRIX ABO/RHO (D) /AHG NEONATE GROUP CARD IS USED FOR THE DETERMINATION OF ABO AND RHO (D) STATUS AND DIRECT COOMBS TEST OF NEONATES. CONTAINS MONOCLONAL ANTI-A, ANTI-B, ANTI-A,B ANTI-D (VI-) AND POLYSPECIFIC COOMBS.,ABO SUBGROUPING CARD ANTI A1(MATRIX ABO SUBGROUPING CARD ANTI A1)-MATRIX ABO SUBGROUPING CARD ANTI-A1 IS FOR THE CONFIRMATION OF A1 SUBGROUP OF A IN WHOLE BLOOD SPECIMEN. IT IS QUALITATIVE, SCREENING TEST USED FOR IN VITRO DIAGNOSTICS ONLY.,AHG COOMBS TEST CARD(MATRIX AHG COOMBS TEST CARD)-MATRIX AHG (COOMBS) TEST CARD IS USED FOR DIRECT COOMBS TEST (DAT) AND INDIRECT COOMBS TESTS (IAT) INCLUDING ANTIBODY SCREENING, ANTIBODY IDENTIFICATION AND COMPATIBILITY TESTING. CONTAINS POLYSPECIFIC COOMBS REAGENT,FORWARD GROUPING AND CROSSMATCH CARD(MATRIX FORWARD GROUPING AND CROSSMATCH CARD)-MATRIX FORWARD GROUPING AND CROSSMATCH CARD IS USED FOR CONFIRMATION OF ABO AND RHO (D) BLOOD GROUP SYSTEMS FOR BOTH PATIENT AND DONOR, ABO AND RHO (D) COMPATIBILITY TESTING, MAJOR CROSSMATCH IN COOMBS AND ENZYME PHASE ALONG WITH COOMBS PHASE AUTOCONTROL FOR THE PATIENT,BLOOD GROUPING CARD FOR ABO/RHOD FORWARD GROUPING WITH AUTOCONTROL(ERYCARD 2.0)-ERYCARD 2.0 BLOOD GROUPING CARD FOR ABO/RHO(D) FORWARD GROUPING WITH AUTOCONTROL CAN BE USED AS BED SIDE TESTING FOR PATIENT AND DONOR'S BLOOD UNIT PRIOR TO TRANSFUSION. ERYCARD 2.0 CAN ALSO BE USED FOR DONOR'S BLOOD GROUP SCREENING IN OUTDOOR CAMPS AS WELL AS IN BLOOD BANKS.,AHG (COOMBS) TEST CARD(MATRIX OCTOPLUS AHG (COOMBS) TEST CARD)-MATRIX OCTOPLUS AHG (COOMBS) TEST CARD IS SUITABLE FOR DIRECT COOMBS TEST, INDIRECT COOMBS

	TEST INCLUDING COMPATIBILITY TESTING ,ANTIBODY SCREENING AND ANTIBODY IDENTIFICATION. .,COOMBS ANTI IGG CARD(MATRIX COOMBS ANTI IGG CARD)-MATRIX COOMBS ANTI-IGG CARD CAN BE USED IN WEAK D TESTING, ANTIBODY SCREENING, ANTIBODY IDENTIFICATION, DIRECT AND INDIRECT ANTIGLOBULIN TEST (DAT, IAT) AND COMPATIBILITY TESTING.,ABO/RHO(D) FORWARD AND REVERSE GROUPING CARD (MATRIX OCTOPLUS COMPLETE GROUPING CARD)-MATRIX OCTOPLUS COMPLETE GROUPING CARD FACILITATES THE FORWARD AND REVERSE GROUPING ALONG WITH A CONTROL MICROTUBE ON A SINGLE CARD.,ANTI D IGG(ERYCLONE ANTI D IGG)-ERYCLONE ANTI-D (IGG) IS A MONOCLONAL IGG REAGENT FOR RHO (D) TYPING USED FOR RHO (D) TYPING REAGENT FOR SLIDE AND TUBE TESTS AND IS 100% SPECIFIC TO RHO(D) ANTIGEN IN WHOLE BLOOD SPECIMENS.,RH PHENOTYPE CARD WITH ANTI-K(MATRIX RH PHENOTYPE CARD WITH ANTI-K)-MATRIX RH PHENOTYPE CARD WITH ANTI-K FACILITATES THE DETERMINATION OF RH PHENOTYPES ALONG WITH K ANTIGEN OF KELL SYSTEM., BOVINE SERUM ALBUMIN 22% SOLUTION(ERYBANK BOVINE SERUM ALBUMIN)-BOVINE SERUM ALBUMIN IS MAINLY USED TO ENHANCE THE REACTIVITY OF BLOOD GROUPING AND TYPING ANTIBODIES IN DIRECT AGGLUTINATION TESTS.,ANTI-A,B (MONOCLONAL) (ERYCLONE ANTI-A,B (MONOCLONAL))-ERYCLONE ANTI- A,B IS A MURINE MONOCLONAL IGM REAGENT USED FOR ABO FORWARD GROUPING BY SLIDE AND TUBE TEST METHOD AND IS 100% SPECIFIC TO A & B ANTIGENS.,ANTI-A1 LECTIN(ERYBANK ANTI A-1 LECTIN)-ERYBANK ANTI-A1 LECTIN IS A READY TO USE PURIFIED EXTRACT OF DOLICHOS BIFLORUS SEEDS TO DIFFERENTIATE A1 RED CELLS FROM A2 RED CELLS.,ANTI-D IGG+IGM (MONOCLONAL)(RHOFINAL ANTI-D IGG+IGM)-RHOFINAL ANTI-D (IGG+IGM) (RHO) A READY TO USE REAGENT, BLEND OF MONOCLONAL ANTIBODIES HAVING THE CAPABILITY OF RECOGNIZING RHO (D) U TYPING AND D TESTING EPITOPES OF HUMAN RED BLOOD CELL ANTIGENS AND CONFIRMATION OF RHO (D) PHENOTYPES BY SLIDE AND TUBE TESTS, ABO SUBGROUPING CARD ANTI H(MATRIX ABO SUBGROUPING CARD ANTI H)-MATRIX ABO SUBGROUPING CARD ANTI-H IS FOR DETECTION OF H ANTIGEN ON RED CELLS IN WHOLE BLOOD SPECIMEN. IT IS QUALITATIVE, SCREENING TEST USED FOR IN VITRO DIAGNOSTICS ONLY,ANTI H LECTIN(ERYBANK ANTI H LECTIN)-ERYBANK ANTI-H LECTIN, ULEX EUROPAEUS LECTIN REAGENT USED FOR RECOGNITION OF THE H ANTIGEN ON HUMAN RED BLOOD CELLS. IT IS USEFUL, ESPECIALLY FOR ASSESSING THE H SECRETOR STATUS OF GROUP 'O' INDIVIDUALS AND ALSO IN DIFFERENTIAL GROUPING OF A SUBGROUP ALONG WITH ANTI- INT A LECTIN.,FORWARD GROUPING DAT CARD (MATRIX FORWARD GROUPING DAT CARD)-

		MATRIX FORWARD GROUPING DAT CARD IS FOR DETECTION OF ABO AND RHO (D) BLOOD GROUP SYSTEMS USING TWO DIFFERENT CLONES OF ANTI-D IN SEPARATE MICROTUBES AND DIRECT COOMBS TEST (DAT) IN WHOLE BLOOD SPECIMEN.,FIBRINOGEN DETERMINATION TEST (QUANTITATIVE)(FIBROQUANT)-FIBROQUANT IS A REAGENT USED FOR THE QUANTITATIVE ESTIMATION OF FIBRINOGEN IN PLASMA.,CROSS LINKED FIBRIN DEGRADATION PRODUCT(XL-FDP)-LATEX AGGLUTINATION SLIDE TEST FOR QUALITATIVE AND SEMIQUANTITATIVE DETECTION OF CROSS LINKED FIBRIN DEGRADATION PRODUCTS IN HUMAN PLASMA., THROMBIN TIME TEST(FIBROSCREEN)-FIBROSCREEN IS USED FOR THE QUALITATIVE ESTIMATION OF FIBRINOGEN IN PLASMA.,ANTI HUMAN IGG (MONOSPECIFIC COOMBS SERUM)(ERYBANK ANTI HUMAN IGG)-ERYBANK ANTI-HUMAN IGG MONOSPECIFIC COOMBS REAGENT FOR DIRECT AND INDIRECT ANTIGLOBULIN TEST.
2998	MFG/IVD/2021/000022	1.License Holder Name: S D FINE- CHEM LIMITED 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:SOLUBILITY TEST KIT-DETECTION OF SICKLE CELL ANEMIA
2999	MFG/IVD/2021/000023	1.License Holder Name: S D FINE- CHEM LIMITED 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:ALKALINE PAPER ELECTROPHORESIS KIT(ALKALINE PAPER ELECTROPHORESIS KIT)-CLINICAL CHEMISTRY TEST REAGENT /KIT INTENDED FOR THE ESTIMATION OF ANALYTES/ PARAMETERS IN THE BLOOD
3000	MFG/IVD/2021/000024	1.License Holder Name: STRUMED SOLUTIONS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:COVID 19 RAPID ANTIGEN TEST(INSTAXPLOR)-THIS TEST IS RECOMMENDED FOR ADMINISTRATION BY QUALIFIED HEALTHCARE WORKERS AND CERTIFIED LABORATORIES ONLY, AS AN AID FOR RAPID DIFFERENTIAL DIAGNOSIS OF SARS-COV-2 INFECTION IN PATIENTS WITH THE ASSOCIATED CLINICAL SYMPTOMS. THIS PRODUCT PROVIDES ONLY A PRELIMINARY TEST RESULT. THE INTERPRETATION OF THE RESULTS SHOULD BE DONE BY TRAINED HEALTH PROFESSIONALS AND CANNOT BE THE SOLE BASIS FOR THE DIAGNOSIS OF SARS-COV-2 INFECTION; NEGATIVE RESULTS SHOULD BE ASCERTAINED USING CONFIRMATORY TESTS SUCH AS RT-PCR (REVERSE TRANSCRIPTION - POLYMERASE CHAIN REACTION).

3001	MFG/IVD/2021/000025	1.License Holder Name: IMMUNOSCIENCE INDIA PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:RAPID TEST FOR DETECTION OF COVID-19 ANTIGEN-DEVICE & COMPONENTS (IMMUNOQUICK)-IT IS A RAPID LATERAL FLOW IMMUNOASSAY FOR DETECTION OF COVID-19 ANTIGEN IN NASOPHARYNGEAL SWAB SPECIMENS. IT IS A QUALITATIVE TEST AND FOR HEALTHCARE PROFESSIONAL USE ONLY.,RAPID TEST FOR DETECTION OF NOVEL CORONAVIRUS (COVID-19) IGG ANTIBODIES-DEVICE & COMPONENTS (IMMUNOQUICK)-IT IS RAPID, QUALITATIVE, IMMUNOCHROMATOGRAPHIC TEST FOR DETECTION OF IGG ANTIBODIES TO COVID-19 IN HUMAN SERUM/PLASMA/WHOLE BLOOD. THIS TEST IS FOR HEALTHCARE PROFESSIONAL USE ONLY.
3002	MFG/IVD/2021/000026	1.License Holder Name: TRANSCIENCE INNOVATIVE TECHNOLOGIES 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:COVID-19 MULTIPLEX REAL TIME PCR DETECTION KIT(TRUESCREEN)-TURESCREEN COVID-19 REAL-TIME MULTIPLEX PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM 2019-NCOV IN UPPER AND LOWER RESPIRATORY TRACT ASPIRATE AND NASOPHARNGEAL WASH BY REVERSE TRANSCRIPTASE REAL TIME PCR METHOD

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3003	MFG/IVD/2021/000027	1.License Holder Name: DIAGNOCURE INDIA 2.Approving Authority: SUB ZONAL BADDI 3.Device Name(Brand Name)-Intended Use:HCV AB RAPID TEST DEVICE(XAMIN)-HCV AB RAPID TEST IS A DOUBLE ANTIGEN LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTI-HEPATITIS C VIRUS ANTIBODIES (IGG, IGM, IGA) IN HUMAN SERUM OR PLASMA.,SYPHILIS AB RAPID TEST DEVICE (XAMIN)-SYPHILIS AB RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES INCLUDING IGG, IGM, AND IGA TO TREPONEMA PALLIDUM (TP) IN HUMAN SERUM OR PLASMA.,HIV ½ TRILINE AB RAPID TEST DEVICE(XAMIN)-HIV RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HIV 1 & 2 ANTIBODY IN HUMAN SERUM, PLASMA AND WHOLE BLOOD. IT IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV).,HIV/SYPHILIS AB COMBO RAPID TEST DEVICE(XAMIN)-HIV/SYPHILIS AB COMBO RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES TO HIV-1, HIV-2 AND TREPONEMA PALLIDUM (TP) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD,MALARIA PF AG RAPID TEST DEVICE(XAMIN)-MALARIA PF ANTIGEN IS A RAPID, QUALITATIVE TEST FOR THE DETECTION OF PRESENCE OF PLASMODIUM FALCIPARUM SPECIFIC PROTEIN HRP-II (HISTIDINE-RICH PROTEIN II) BOTH IN THE SEXUAL AND ASEXUAL FORMS OF PARASITE. THE DIAGNOCURE MALARIA AG IS SUITABLE FOR THE DETECTION OF MALARIA INFECTION IN A BLOOD SAMPLE, INDICATING PRESENCE OR ABSENCE OF PLASMODIUM FALCIPARUM AND EXTENSIVELY DIAGNOSIS OF PLASMODIUM FALCIPARUM., DENGUE DAY1 NS1 AG RAPID TEST DEVICE(XAMIN)-DENGUE DAY1 RAPID TEST IS AN IMMUNOCHROMATOGRAPHIC STRIP ASSAY FOR THE QUALITATIVE DETECTION OF NON-STRUCTURAL PROTEIN 1 (NS1) IN HUMAN SERUM, AND SERVES AS AN AID IN THE DIAGNOSIS OF EARLY DENGUE INFECTIONS. THIS TEST WILL AID IN THE RAPID DIAGNOSIS OF DENGUE VIRUS IN HUMAN SERUM EVEN PRIOR TO THE PRESENCE OF IGM OR IGG ANTIBODIES.,DENGUE DUO (AG +AB) RAPID TEST DEVICE(XAMIN)-THE DENGUE DUO KIT IS A RAPID, AN IN-VITRO IMMUNOCHROMATOGRAPHIC, ONE STEP ASSAY DESIGNED TO DETECT BOTH DENGUE VIRUS NS1 ANTIGEN AND ANTIBODIES TO DENGUE VIRUS (DENGUE IGG/IGM) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD,MALARIA PF/PV AG RAPID TEST DEVICE(XAMIN)-THE MALARIA P.F/P.V TEST IS A RAPID, QUALITATIVE AND DIFFERENTIAL TEST FOR THE DETECTION OF ANTIBODIES TO PLASMODIUM FALCIPARUM / PLASMODIUM VIVAX IN HUMAN WHOLE BLOOD.,

	MALARIA PF/PAN AG RAPID TEST DEVICE(XAMIN)-THE MALARIA P.F /PAN RAPID TEST CASSETTE (WHOLE BLOOD) IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF FOUR KINDS OF CIRCULATING PLASMODIUM FALCIPARUM(P. FALCIPARUM (P.F.), P. VIVAX (P.V.), P. OVALE (P.O.), AND P. MALARIAE (P.M.) IN WHOLE BLOOD.,HBSAG RAPID TEST DEVICE(XAMIN)-HBSAG RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN SERUM OR PLASMA AT A LEVEL EQUAL TO 0.5 NG/ML. IT IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH HEPATITIS B VIRUS (HBV),XAMIN COVID-19 AG RAPID TEST DEVICE(XAMIN COVID-19 AG RAPID TEST DEVICE)-XAMIN COVID-19 AG TEST IS USED FOR IN VITRO QUALITATIVE DETECTION OF THE ANTIGEN OF NOVEL CORONAVIRUS IN HUMAN NASOPHARYNX.,XAMIN COVID-19 IGG RAPID TEST DEVICE(XAMIN COVID-19 IGG RAPID TEST DEVICE)-THE SARS-COV-2 IGG ANTIBODY RAPID TEST IS USED TO QUALITATIVELY DETECT IGG ANTIBODIES OF CORONAVIRUS DISEASE-19 IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THIS DEVICE IS INTENDED TO BE USED BY PROFESSIONALS AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH 2019 CORONA VIRUS. ANY REACTIVE SPECIMEN WITH THE SARS-COV-2 IGG ANTIBODY RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S).

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3004	MFG/IVD/2021/000028	1.License Holder Name: TRIVITRON HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:COVIDSURE MULTIPLEX REALTIME RT-PCR KIT(COVIDSURE MULTIPLEX REALTIME RT-PCR KIT)-THE COVIDSURE MULTIPLEX REALTIME RT-PCR KIT, IS AN OPEN PLATFORM, QUALITATIVE, RT-PCR TEST, INTENDED TO BE USED FOR IN VITRO DETECTION OF SARS-COV-2 (COVID-19) IN RESPIRATORY SPECIMENS (NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, OROPHARYNGEAL WASH, SPUTUM, ENDOTRACHEAL ASPIRATE, BRONCHOALVEOLAR LAVAGE ETC.) OF SUSPECTED CASES OF COVID-19 DISEASE.,COVIDSURE PRO MULTIPLEX RT PCR KIT (COVIDSURE PRO MULTIPLEX RT PCR KIT)-COVIDSURE PRO MULTIPLEX RT PCR KIT IS DEVELOPED FOR THE RAPID DETECTION OF COVIDSURE PRO VIRAL INFECTION BY SIMULTANEOUS TARGETING OF THREE MAJOR GENES ORF 1AB, ENVELOPE (E), AND NUCLEOCAPSID (N). THE KIT ALSO INCLUDES AN INTERNAL CONTROL TO INSURE SUCCESSFUL EXTRACTION AND AMPLIFICATION OF VIRAL RNA.,RNA EXTRACTION KIT(RNASURE RNA EXTRACTION KIT)-RNASURE CORONA VIRUS (SARS-COV-2) RNA EXTRACTION KIT IS INTENDED FOR MOLECULAR BIOLOGY APPLICATIONS. ALL DUE CARE AND ATTENTION SHOULD BE EXERCISED IN THE HANDLING OF THE PRODUCTS.
3005	MFG/IVD/2021/000029	1.License Holder Name: BIOSYSTEMS DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:VIRAL NUCLEIC ACID EXTRACTION KIT(CONCEPTA VIRAL NUCLEIC ACID EXTRACTION KIT)-IT IS INTENDED TO USE FOR EXTRACTION OF VIRAL NUCLEIC ACID FROM CLINICAL SAMPLE.

3006	MFG/IVD/2021/000030	1.License Holder Name: SENSA CORE MEDICAL INSTRUMENTATION PVT. LTD. 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:ARTERIAL BLOOD GAS ANALYSER REAGENT PACK(ST-200 CC, HDC LYTE PLUS, NULYTE POCT, APL ABGE, ICULYTIC-BGE)-ARTERIAL BLOOD GAS ANALYSER IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF SODIUM, POTASSIUM, IONIZED CALCIUM, GLUCOSE, LACTATE, LITHIUM, PH, CHLORIDE, PCO2, PO2, HCT, HB, HCO3, BE, BE-B, BE-ECF, TCO2, AG_NA, AG_K, SO2, O2CT, SBC IN WHOLE BLOOD, ELECTROLYTES IN SERUM/PLASMA/CSF AND DILUTED URINE. THESE REAGENT PACKS ARE USED WITH ARTERIAL BLOOD GAS ANALYZER INSTRUMENTS MANUFACTURED BY SENSACORE AND ARE INTENDED FOR CLINICAL LABORATORY USE ONLY.
3007	MFG/IVD/2021/000031	1.License Holder Name: YASHRAJ BIOTECHNOLOGY LTD., 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:HIV 1 P24 CONTROL-IN-VITRO DIAGNOSIS OF HIV INFECTION
3008	MFG/IVD/2021/000032	1.License Holder Name: ADITYA CLINICAL SYSTEMS 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:HEMOGLOBIN MICROCUVETTE (REAGENT FREE SPECIMEN RECEPTICLE)(DOLPHIN HEMOGLOBIN MICROCUVETTES)-DOLPHIN HEMOGLOBIN MICROCUVETTES IS USED WITH DOLPHIN HEMOGLOBIN METER TO MEASURE HEMOGLOBIN.
3009	MFG/IVD/2021/000033	1.License Holder Name: LORVEN BIOLOGICS PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM KIT(LORVEN)-THE LORVEN VIRAL TRANSPORT MEDIUM (VTM) IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS OR UREA PLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY.

3010	MFG/IVD/2021/000034	1.License Holder Name: MOREPEN LABORATORIES LTD. 2.Approving Authority: SUB ZONAL BADDI 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE METER (DR. MOREPEN GLUCOONE)-MEASUREMENT OF GLUCOSE IN CAPILLARY WHOLE BLOOD.,BLOOD GLUCOSE MONITORING SYSTEM-THIS APG-01 BLOOD GLUCOSE MONITOR IS INTENDED FOR THE QUANTITATIVEMEASUREMENT OF THE CONCENTRATION OF GLUCOSE IN CAPILLARY WHOLEBLOOD FROM FI NGERTIP, PALM AND FOREARM BY DIABETIC PATIENTS ORHEALTHCARE PROFESSIONALS AS AN AID IN THE MANAGEMENT OF DIABETES. ITIS INTENDED FOR USE OUTSIDE OF THE BODY (IN VITRO DIAGNOSTIC USE) ANDNOT FOR DIAGNOSIS OF OR SCREENING FOR DIABETES, NOR FOR USE ON NEONATESOR ARTERIAL BLOOD. THE ALTERNATIVE SITE TESTING (PALM AND FOREARM) INTHIS SYSTEM CAN ONLY BE USED DURING STEADY-STATE BLOOD GLUCOSECONDITIONS
3011	MFG/IVD/2021/000035	1.License Holder Name: SVASHMI GENOTECH PVT LTD. 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:STELLENCE COVID 19 RT Q PCR KIT(TEST -A- LYSE)-STELLENCE COVID-19 RT-QPCR KIT IS USED FOR THE QUALITATIVE DETECTION OF A NOVEL CORONAVIRUS IN SUSPECTED TEST SPECIMENS FROM UPPER RESPIRATORY TRACT SPECIMENS (NASOPHARYNGEAL EXTRACTS, DEEP COUGH SPUTUM, ETC.) AND LOWER RESPIRATORY TRACT SPECIMENS (ALVEOLI IRRIGATION FLUID, ETC.) BY REAL TIME PCR SYSTEMS. THIS TEST IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF COVID 19 IN COMBINATION WITH CLINICAL AND EPIDEMIOLOGICAL RISK FACTORS. RNA IS EXTRACTED FROM RESPIRATORY SPECIMENS, AMPLIFIED USING RT-PCR AND DETECTED USING FLUORESCENT REPORTER DYE PROBES SPECIFIC FOR COVID 19.
3012	MFG/IVD/2021/000037	1.License Holder Name: GENOME DIAGNOSTICS PVT LTD, 2.Approving Authority: SUB ZONAL BADDI 3.Device Name(Brand Name)-Intended Use:VIRAL RNA EXTRACTION MINI KIT(GENO SEN'S® VIRAL RNA EXTRACTION MINI KIT)-VIRAL RNA EXTRACTION MINI KITS INTENDED TO BE USED FOR ISOLATION OF VIRAL RNA FROM A WIDE VARIETY OF VIRUSES.,COVID-19 REAL TIME PCR KIT(GENO-SEN'S NCOV-2019 (RG) REAL TIME PCR REAGENTS KIT)-IT IS INTENDED FOR DETECTION OF COVID-19 VIRUS RNA BY REAL TIME PCR METHOD FROM EXTRACTED RNA OF PATIENT SAMPLES.

3013	MFG/IVD/2021/000038	1.License Holder Name: PRIMORDIA LIFESCIENCES PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:RNA EXTRACTION KIT (PRIME RAPID RNA EXTRACTION KIT)-THE KIT IS USED FOR THE EXTRACTION OF VIRAL RNA FROM NASAL/THROAT SWABS

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3014	MFG/IVD/2021/000039	1.License Holder Name: TOSOH INDIA PVT. LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:PROLACTIN HORMONE (PRL) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENSE, VITAMIN B-12 (B12) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,ANTI-THYROID PEROXIDASE (ANTI-TPO) TRACER(ACCULITE)-THE ANTI-THYROIDPEROXIDASE (ANTI-TPO) TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF ANTI-THYROIDPEROXIDASE (ANTI-TPO) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,CORTISOL ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),C-PEPTIDE CALIBRATOR SET (ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND C-PEPTIDE USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),THYROID (TT3+TT4+TSH) VAST CLIA KIT (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE; TOTAL TRIIODOTHYRONINE; THYROID STIMULATING HORMONE CONCENTRATION FOR A COMPREHENSIVE THYROID STATUS OF A HUMAN SERUM OR PLASMA SAMPLE BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,TESTOSTERONE ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,CREATINE KINASE (CK-MB) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING CREATININE KINASE (MB-ISOFORM) CONCENTRATIONS IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,INSULIN ENZYME CONJUGATE REAGENT (ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),IMMUNOGLOBULIN E (IGE) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, UNCONJUGATED ESTRIOL (U-E3) CALIBRATOR SET(ACCULITE)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE ESTRIOL USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,FREE TESTOSTERONE ELISA KIT (ACCUBIND)-FOR THE QUANTITATIVE MEASUREMENT OF FREE

	TESTOSTERONE IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,CORTISOL CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND CORTISOL USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),BETA HUMAN CHORIONIC GONADOTROPIN (HCG) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CHORIONIC GONADOTROPIN (HCG) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,TESTOSTERONE CALIBRATOR SET(ACCULITE)-THE TESTOSTERONE CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE TESTOSTERONE USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD, PROGESTERONE ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),FREE TRIIODOTHYRONINE (FT3) CLIA KIT (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),ANTI-THYROID PEROXIDASE (ANTI-TPO) CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND ANTI-THYROIDPEROXIDASE (ANTI-TPO) USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),FREE TESTOSTERONE CALIBRATOR SET(ACCUBIND)-THE FREE TESTOSTERONE CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND FREE TESTOSTERONE USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),PROGESTERONE ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) CALIBRATOR SET (ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) USING MICROPLATE ENZYME IMMUNOASSAY (ELISA), HUMAN GROWTH HORMONE (HGH) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF GROWTH HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,THYROTROPIN (TSH) CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND THYROTROPIN (TSH) USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),ANTI-DOUBLE STRANDED DNA (DSDNA) SCREEN ELISA KIT(AUTOBIND)-FOR THE QUANTITATIVE MEASUREMENT OF IGG, IGM AND IGA CLASS AUTOANTIBODIES AGAINST DOUBLE-STRANDED DNA IN HUMAN

	SERUM OR PLASMA BY AN INDIRECT SOLID PHASE ENZYME IMMUNOASSAY (ELISA),ANTI-CARDIOLIPIN IGG/IGM ELISA KIT (AUTOBIND)-FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN IN HUMAN SERUM OR PLASMA BY AN INDIRECT SOLID PHASE ENZYME IMMUNOASSAY (ELISA).,PROGESTERONE CALIBRATOR SET (ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND PROGESTERONE USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),FOLLICLE STIMULATING HORMONE (FSH) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,TESTOSTERONE CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,INSULIN ELISA KIT (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF INSULIN LEVELS IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,UNCONJUGATED ESTRIOL (U-E3) TRACER(ACCULITE) -FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF FREE (UNCONJUGATED) ESTRIOL (U-E3) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,FREE THYROXINE (FT4) TRACER (ACCULITE)-THE FREE THYROXINE (FT4) TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,FREE THYROID (FT3+FT4+TSH) COMBI CALIBRATOR SET (ACCUBIND)-THE FREE THYROID (FT3+FT4+TSH) COMBI CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND FREE THYROID (FT3+FT4+TSH) VAST KIT FOR PARAMETERS SUCH AS FT3, FT4 & TSH USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),FREE TESTOSTERONE CALIBRATOR SET(ACCULITE)-THE FREE TESTOSTERONE CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE FREE TESTOSTERONE USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,FOLLICLE STIMULATING HORMONE (FSH) TRACER (ACCULITE)-THE FOLLITROPIN (FSH) TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF FOLLITROPIN (FSH) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,INSULIN/C-PEPTIDE VAST ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF INSULIN OR C-PEPTIDE CONCENTRATION

	LEVELS IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, COLORIMETRIC,ANTI-MULLERIAN HORMONE (AMH) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF AMH CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, COLORIMETRIC, PROGESTERONE CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,PROGESTERONE TRACER(ACCULITE)-THE PROGESTERONE TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF PROGESTERONE IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD.,TOTAL THYROXINE (TT4) ELISA KIT (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,FREE TRIIODOTHYRONINE (FT3) TRACER(ACCULITE)-THE FREE TRI-IODOTHYRONINE (FT3) TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF FREE TRI-IODOTHYRONINE (FT3) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,FREE TESTOSTERONE TRACER (ACCULITE)-THE FREE TESTOSTERONE TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,FREE THYROID (FT3+FT4+TSH) COMBI CALIBRATOR SET(ACCULITE)-THE FREE THYROID (FT3+FT4+TSH) COMBI CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE FREE THYROID (FT3+FT4+TSH) VAST KIT FOR FT3, FT4 & TSH USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,IMMUNOGLOBULIN E (IGE) CALIBRATOR SET(ACCULITE)-THE IMMUNOGLOBULIN E (IGE) CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE IMMUNOGLOBULIN E (IGE) USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,TOTAL THYROXINE (TT4) ENZYME CONJUGATE REAGENT (ACCUBIND)-THE THYROXINE (T4) ENZYME CONJUGATE IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),FREE TESTOSTERONE ENZYME CONJUGATE REAGENT(ACCUBIND)-THE FREE TESTOSTERONE ENZYME CONJUGATE IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE IN HUMAN SERUM BY A MICROPLATE ENZYME

	IMMUNOASSAY (ELISA),PROLACTIN HORMONE (PRL) TRACER (ACCULITE)-THE PROLACTIN (PRL) TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,CREATINE KINASE (CK-MB) CALIBRATOR SET(ACCULITE)-THE CK-MB CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE CREATININE KINASE (MB-ISOFORM) USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE M,LUTEINIZING HORMONE (LH) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,CORTISOL CLIA KIT (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL CORTISOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE, INSULIN/C-PEPTIDE VAST CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF INSULIN OR C-PEPTIDE LEVELS IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,INSULIN TRACER(ACCULITE)-THE INSULIN TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD.,UNCONJUGATED ESTRIOL (U-E3) CALIBRATOR SET (ACCUBIND)-THE ESTRIOL CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND ESTRIOL USING MICROPLATE ENZYME IMMUNOASSAY (ELISA)., CREATINE KINASE (CK-MB) TRACER(ACCULITE)-THE CREATINE KINASE (CK-MB) TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF CREATININE KINASE (MB-ISOFORM) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,FREE TRIIODOTHYRONINE (FT3) ENZYME CONJUGATE REAGENT (ACCUBIND)-THE FREE TRI-IODOTHYRONINE (FT3) ENZYME CONJUGATE IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF FREE TRI-IODOTHYRONINE (FT3) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),UNCONJUGATED ESTRIOL (U-E3) ENZYME CONJUGATE REAGENT(ACCUBIND)-THE U-ESTRIOL ENZYME CONJUGATE IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF UNCONJUGATED ESTRIOL IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA).,FERTILITY (HCG+LH+FSH+PRL) VAST CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF HCG, FSH, LH, AND PRLS

	CONCENTRATION IN HUMAN SERUM AND PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,THYROID (TT3+TT4+TSH) COMBI CALIBRATOR SET(ACCUBIND)-THE THYROID (T3+T4+TSH) COMBI CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND THYROID (T3+T4+TSH) COMBI VAST KIT FOR PARAMETERS SUCH AS T3, T4 & TSH USING MICROPLATE ENZYME IMMUNOASSAY (ELISA)., TESTOSTERONE TRACER(ACCULITE)-THE TESTOSTERONE TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD.,IMMUNOGLOBULIN E (IGE) CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND IMMUNOGLOBULIN E (IGE) USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),INSULIN CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF INSULIN CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE ASSAY, ANTI-THYROGLOBULIN (ANTI-TG) CALIBRATOR SET(ACCULITE)-THE ANTI-THYROGLOBULIN (ANTI-TG) CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE ANTI-THYROGLOBULIN (ANTI-TG) USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD.,CORTISOL CALIBRATOR SET(ACCULITE)-THE CORTISOL CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE CORTISOL USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,THYROID (TT3+TT4+TSH) COMBI CALIBRATOR SET(ACCULITE)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE THYROID COMBI (T3+T4+TSH) VAST KIT FOR PARAMETERS SUCH AS T3, T4 & TSH MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,THYROTROPIN (TSH) ELISA KIT (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF THYROTROPIN CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,ANTI-CYCLIC CITRULLINATED PEPTIDES HIGH SENSITIVE (CCP HS) ELISA KIT (AUTOBIND)-FOR THE QUANTITATIVE DETERMINATION OF CONCENTRATION OF IGG CLASS OF ANTIBODIES AGAINST CYCLIC CITRULLINATED PEPTIDES (CCP) IN HUMAN SERUM OR PLASMA, TOTAL TRIIODOTHYRONINE (TT3) TRACER(ACCULITE)-THE TRI-IODOTHYRONINE (T3) TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF TRI-IODOTHYRONINE (T3) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,FREE TRIIODOTHYRONINE (FT3) ELISA KIT(ACCUBIND)-FOR THE

	QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,LUTEINIZING HORMONE (LH) TRACER(ACCULITE)-THE LUTROPIN (LH) TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF LUTROPIN (LH) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD.,THYROTROPIN (TSH) TRACER (ACCULITE)-THE THYROTROPIN (TSH) TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF THYROTROPIN (TSH) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,ANTI-THYROID PEROXIDASE (ANTI-TPO) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF THYROID PEROXIDASE (TPO) AUTOANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENSE,ESTRADIOL (E2) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,TOTAL THYROXINE (TT4) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),FREE THYROXINE (FT4) ENZYME CONJUGATE REAGENT(ACCUBIND)-THE FREE THYROXINE (FT4) ENZYME CONJUGATE IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA)., ANTI-THYROID PEROXIDASE (ANTI-TPO) CALIBRATOR SET (ACCULITE)-THE ANTI-THYROIDPEROXIDASE (ANTI-TPO) CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE ANTI-THYROIDPEROXIDASE (ANTI-TPO) USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD.,TESTOSTERONE ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF TESTOSTERONE IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA), FERTILITY (HCG+LH+FSH+PRL) VAST ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF HCG, PRL, LH AND FSH CONCENTRATION IN HUMAN SERUM AND PLASMA BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY (ELISA),FERTILITY (HCG+LH+FSH+PRL) COMBI CALIBRATOR SET(ACCUBIND)-THE FERTILITY (LH+FSH+PRL+HCG) COMBI CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND FERTILITY (LH+FSH+PRL+HCG) VAST KIT FOR PARAMETERS SUCH AS LH, FSH, PRL & HCG USING

	MICROPLATE ENZYME IMMUNOASSAY (ELISA), DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) CLIA KIT (ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE CONCENTRATION (DHEA-$) IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,THYROTROPIN (TSH) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF THYROTROPIN (TSH) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),VITAMIN B-12 (B12) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF VITAMIN B12 CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,PROLACTIN HORMONE (PRL) ELISA KIT (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF PROLACTIN HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,HUMAN GROWTH HORMONE (HGH) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF GROWTH HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,ANTI TISSUE TRANSGLUTAMINASE IGA ELISA KIT(AUTOBIND)-FOR THE QUANTITATIVE MEASUREMENT OF IGA CLASS AUTOANTIBODIES AGAINST TISSUE TRANSGLUTAMINASE (TTG) IN HUMAN SERUM OR PLASMA BY AN INDIRECT SOLID PHASE ENZYME IMMUNOASSAY (ELISA),C-PEPTIDE CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING C-PEPTIDE CONCENTRATIONS IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,FOLLICLE STIMULATING HORMONE (FSH) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY (ELISA), ANTI-THYROGLOBULIN (ANTI-TG) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) AUTOANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,IMMUNOGLOBULIN E (IGE) TRACER (ACCULITE)-THE IMMUNOGLOBULIN E (IGE) TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,CORTISOL ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL CORTISOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, UNCONJUGATED ESTRIOL (U-E3) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF UNCONJUGATED (FREE) ESTRIOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE

	ENZYME IMMUNOASSAY, COLORIMETRIC,HUMAN GROWTH HORMONE (HGH) ENZYME CONJUGATE REAGENT(ACCUBIND)-THE HUMAN GROWTH HORMONE (HGH) ENZYME CONJUGATE IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF HUMAN GROWTH HORMONE (HGH) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA), ESTRADIOL (E2) CALIBRATOR SET(ACCULITE)-THE ESTRADIOL CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE ESTRADIOL USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,BETA HUMAN CHORIONIC GONADOTROPIN (HCG) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF CHORIONIC GONADOTROPIN (HCG) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),BETA HUMAN CHORIONIC GONADOTROPIN (HCG) TRACER (ACCULITE)-THE CHORIONIC GONADOTROPIN (HCG) TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF CHORIONIC GONADOTROPIN (HCG) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,FERTILITY (HCG+LH+FSH+PRL) COMBI CALIBRATOR SET(ACCULITE)-THE FERTILITY (LH+FSH+PRL+HCG) COMBI CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE FERTILITY (LH+FSH+PRL+HCG) VAST KIT FOR PARAMETERS SUCH AS LH, FSH, PRL & HCG USING MICROPLATE ENZYME IMMUNOASSAY (ELISA).,ESTRADIOL (E2) TRACER(ACCULITE)-THE ESTRADIOL TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD.,TESTOSTERONE CALIBRATOR SET (ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND TESTOSTERONE USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),TOTAL THYROXINE (TT4) TRACER (ACCULITE)-THE THYROXINE (T4) TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF THYROXINE (T4) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,ESTRADIOL (E2) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF ESTRADIOL IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),CORTISOL TRACER(ACCULITE)-THE CORTISOL TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF CORTISOL IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,

	CHEMILUMINESCENCE METHOD.,DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,PROGESTERONE CALIBRATOR SET (ACCULITE)-THE PROGESTERONE CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE PROGESTERONE USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,C-PEPTIDE TRACER (ACCULITE)-THE C-PEPTIDE TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,HUMAN GROWTH HORMONE (HGH) TRACER(ACCULITE)-THE HUMAN GROWTH HORMONE (HGH) TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF HUMAN GROWTH HORMONE (HGH) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,IMMUNOGLOBULIN E (IGE) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE, THYROID (TT3+TT4+TSH) VAST ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL THYROXINE; TOTAL TRIIODOTHYRONINE; THYROTROPIN CONCENTRATION FOR A COMPREHENSIVE THYROID STATUS OF A HUMAN SERUM OR PLASMA SAMPLE BY A MICROPLATE ENZYME IMMUNOASSAY, COLORIMETRIC, ANA DETECT ELISA KIT(AUTOBIND)-FOR THE QUALITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST SS-A-52 (RO-52), SS-A-60 (RO-60), SS-B (LA), RNP/SM, RNP-70, RNP-A, RNP-C, SM-BB, SM-D, SM-E, SM-F, SM-G, SCL-70, JO-1, DSDNA, SSDNA, POLYNUCLEOSOMES, MONONUCLEOSOMES, HISTONE COMPLEX, HISTONE H1, HISTONE H2A, HISTONE H2B, HISTONE 3, HISTONE H4, PM-SCL-100 AND CENTROMERE B IN HUMAN SERUM OR PLASMA SAMPLES,HUMAN GROWTH HORMONE (HGH) CALIBRATOR SET (ACCULITE)-THE GROWTH HORMONE (HGH) CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE GROWTH HORMONE (HGH) USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,INSULIN CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND INSULIN USING MICROPLATE ENZYME IMMUNOASSAY (ELISA), INSULIN/C-PEPTIDE COMBI CALIBRATOR SET(ACCULITE)-THE C-PEPTIDE & INSULIN CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE C-

	PEPTIDE & INSULIN VAST KIT FOR PARAMETERS SUCH AS INSULIN & C-PEPTIDE USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,BETA HUMAN CHORIONIC GONADOTROPIN (HCG) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CHORIONIC GONADOTROPIN CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENSE,LUTEINIZING HORMONE (LH) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE (LH) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA).,UNCONJUGATED ESTRIOL (U-E3) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE (UNCONJUGATED) ESTRIOL (U-E3) CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY,CREATINE KINASE (CK-MB) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING CREATININE KINASE (MB-ISOFORM) CONCENTRATIONS IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE, MASTER CLIA KIT (N.G)(ACCULITE)-THE KIT CONTAINS THE COMMON COMPONENTS LIKE STREPTAVIDIN COATED MICROPLATE, WASH BUFFER, SIGNAL REAGENT A & SIGNAL REAGENT B FOR IN VITRO DIAGNOSTIC USE WITH ANALYTE SPECIFIC ACCULITE TRACER REAGENT & ACCULITE CALIBRATOR SET FOR THE QUANTITATIVE DETERMINATION OF VARIOUS ANALYTE'S CONCENTRATION IN HUMAN SERUM OR PLASMA BY A CHEMILUMINESCENCE IMMUNOASSAY. THE ACCULITE MASTER KIT ALONE CANNOT PRODUCE ANY RESULT. ACCULITE MASTER KIT CAN ONLY WORK IN CONJUNCTION WITH ANALYTE SPECIFIC ACCULITE TRACER REAGENTS & ACCULITE CALIBRATOR SET,LUTEINIZING HORMONE (LH) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF LUTEINIZING HORMONE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) TRACER(ACCULITE)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF DHEA-S ANTIBODIES IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,ANTI-THYROGLOBULIN (ANTI-TG) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) AUTOANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,25-OH VITAMIN D TOTAL (VIT D-DIRECT) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY ,TOTAL TRIIODOTHYRONINE (TT3) ENZYME CONJUGATE REAGENT

	(ACCUBIND)-THE TRI-IODOTHYRONINE (T3) ENZYME CONJUGATE IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF TRI-IODOTHYRONINE (T3) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA).,THYROTROPIN (TSH) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF THYROTROPIN CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,ANTI-THYROGLOBULIN (ANTI-TG) CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND ANTI-THYROGLOBULIN (ANTI-TG) USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),ANTI-THYROID PEROXIDASE (ANTI-TPO) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF ANTI-THYROIDPEROXIDASE (ANTI-TPO) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),ANTI-THYROGLOBULIN (ANTI-TG) TRACER(ACCULITE)-THE ANTI-THYROGLOBULIN (ANTI-TG) TRACER IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF ANTI-THYROGLOBULIN (ANTI-TG) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,FREE TESTOSTERONE CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,ANTI-MULLERIAN HORMONE (AMH) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF ANTI-MULLERIAN HORMONE (AMH) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE ASSAY,INSULIN/C-PEPTIDE COMBI CALIBRATOR SET(ACCUBIND)-THE C-PEPTIDE & INSULIN CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND C-PEPTIDE & INSULIN USING MICROPLATE ENZYME IMMUNOASSAY (ELISA).,C-PEPTIDE ELISA KIT (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING C-PEPTIDE CONCENTRATIONS IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,ESTRADIOL (E2) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF ESTRADIOL CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,UNIVERSAL ELISA KIT (N.G) (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CONCENTRATION OF VARIOUS TEST ANALYTES IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,TOTAL TRIIODOTHYRONINE (TT3) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE

	CHEMILUMINESCENCE IMMUNOASSAY (CLIA),ANTI-THYROID PEROXIDASE (ANTI-TPO) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF THYROID PEROXIDASE (TPO) AUTOANTIBODIES IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,FREE THYROXINE (FT4) CLIA KIT(ACCULITE) -FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE CHEMILUMINESCENCE IMMUNOASSAY (CLIA),IMMUNOGLOBULIN E (IGE) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E (IGE) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),ANTI-PHOSPHOLIPID SCREEN IGG/IGM ELISA KIT(ACCUBIND)-FOR SCREENING THE PRESENCE OF IGG AND IGM CLASS AUTOANTIBODIES AGAINST CARDIOLIPIN, PHOSPHATIDYL SERINE, PHOSPHATIDYL INOSITOL, PHOSPHATIDIC ACID AND BETA-2-GLYCOPROTEIN I IN HUMAN SERUM OR PLASMA BY AN ENZYME IMMUNOASSAY (ELISA),FREE THYROID (FT3+FT4+TSH) VAST CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE; FREE TRIIODOTHYRONINE; THYROID STIMULATING HORMONE CONCENTRATION FOR A COMPREHENSIVE THYROID STATUS OF A HUMAN SERUM OR PLASMA SAMPLE BY A MICROPLATE ENZYME IMMUNOASSAY (CLIA),ANTI-THYROGLOBULIN (ANTI-TG) ENZYME CONJUGATE REAGENT (ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF ANTI-THYROGLOBULIN (ANTI-TG) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),CREATINE KINASE (CK-MB) ENZYME CONJUGATE REAGENT (ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF CREATININE KINASE (MB-ISOFORM) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),ESTRADIOL (E2) CALIBRATOR SET (ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND ESTRADIOL USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),FOLLICLE STIMULATING HORMONE (FSH) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF FOLLITROPIN (FSH) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),HUMAN GROWTH HORMONE (HGH) CALIBRATOR SET(ACCUBIND)-THE ACCUBIND GROWTH HORMONE (HGH) CALIBRATOR SET IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND GROWTH HORMONE USING MICROPLATE ENZYME IMMUNOASSAY (ELISA), DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE

	ONLY FOR QUANTITATIVE DETERMINATION OF DHEA-S IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),C-PEPTIDE ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),PROLACTIN HORMONE (PRL) ENZYME CONJUGATE REAGENT(ACCUBIND)-THE PROLACTIN (PRL) ENZYME CONJUGATE IS INTENDED FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF PROLACTIN (PRL) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA), DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) CALIBRATOR SET (ACCULITE)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,FREE THYROXINE (FT4) CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND FREE T4 USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),TOTAL TRIIODOTHYRONINE (TT3) ELISA KIT (ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL TRIIODOTHYRONINE CONCENTRATION IN HUMAN SERUM OR PLASMA BY A MICROPLATE ENZYME IMMUNOASSAY,FREE THYROXINE (FT4) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,25-OH VITAMIN D TOTAL (VIT D-DIRECT) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF 25-OH VITAMIN D CONCENTRATION IN HUMAN SERUM BY CHEMILUMINESCENCE IMMUNOASSAY (CLIA),FREE THYROID (FT3+FT4+TSH) VAST ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE THYROXINE; FREE TRIIODOTHYRONINE; THYROID STIMULATING HORMONE CONCENTRATION FOR A COMPREHENSIVE THYROID STATUS OF A HUMAN SERUM OR PLASMA SAMPLE BY A MICROPLATE ENZYME IMMUNOASSAY,CREATINE KINASE (CK-MB) CALIBRATOR SET (ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND CREATININE KINASE (MB-ISOFORM) USING MICROPLATE ENZYME IMMUNOASSAY (ELISA)

3015	MFG/IVD/2021/000040	1.License Holder Name: OSCAR MEDICARE PVT. LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:HBS AG RAPID TEST KIT (CARD / DEVICE)(HBS AG RAPID TEST KIT (CARD / DEVICE))-OSCAR HBSAG TEST IS A ONE-STEP RAPID, QUALITATIVE, SANDWICH IMMUNOASSAY. IT IS USED FOR THE DETECTION OF HEPATITIS B SURFACE ANTIGEN IN HUMAN SERUM/PLASMA SPECIMEN. FOR PROFESSIONAL USE ONLY.,CORONA IGG ANTIBODY DETECTION TEST (OSKIT)-CORONA IGG ANTIBODY DETECTION TEST IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNOCHROMATOGRAPHY ON A MEMBRANE FOR QUALITATIVE DETECTION OF CORONA VIRUS SPECIFIC IGG ANTIBODY IN HUMAN SERUM / PLASMA / WHOLE BLOOD. FOR PROFESSIONAL USE ONLY., HIV RAPID TEST(HIV RAPID TEST)-OSCAR HIV RAPID TEST IS A RAPID, QUALITATIVE, SANDWICH IMMUNOASSAY FOR SIMULTANEOUS AND DIFFERENTIAL DETECTION OF TOTAL ANTIBODIES (IGM / IGG / IGA) TO HIV-1 AND HIV-2 IN HUMAN SERUM / PLASMA/ WHOLE BLOOD. , CORONA ANTIGEN TEST(CORONA ANTIGEN TEST)-OSCAR CORONA ANTIGEN TEST IS A ONE-STEP RAPID, QUALITATIVE, SANDWICH IMMUNOASSAY. IT IS USED FOR THE DETECTION OF N ANTIGEN OF CORONA VIRUS IN HUMAN NASAL SWAB SPECIMEN. FOR PROFESSIONAL USE ONLY,SYPHILIS CARD/DEVICE TEST(SYPHILIS CARD/DEVICE TEST)-OSCAR SYPHILIS TEST IS A RAPID IMMUNE-CHROMATOGRAPHIC ASSAY INTENDED TO BE USED FOR QUALITATIVE DETECTION OF ANTIBODIES (IGG/ IGM/ IGA) TO TREPONEMA PALLIDUM (TP) A MARKER FOR DIAGNOSIS OF SYPHILIS IN HUMAN SERUM / PLASMA/ WHOLE BLOOD.,HCV RAPID TEST(HCV RAPID TEST)-OSCAR HCV TEST IS A RAPID IMMUNE-CHROMATOGRAPHIC ASSAY INTENDED TO BE USED FOR QUALITATIVE DETECTION OF ANTIBODIES TO HEPATITIS C VIRUS (HCV) IN HUMAN SERUM / PLASMA / WHOLE BLOOD.

3016	MFG/IVD/2021/000041	1.License Holder Name: BIOSCI HEALTH CARE 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:MALARIA ANTIGEN (PF/PAN) RAPID TEST DEVICE(BIOSCI TRUE-DETECT MALARIA ANTIGEN (PF/PAN) TEST)-MALARIA ANTIGEN (PF/PAN) RAPID TEST DEVICE IS A RAPID LATERAL FLOW THROUGH IMMUNOCHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF TWO KINDS OF CIRCULATING ANTIGENS OF PLASMODIUM FALCIPARUM (PF) SPECIFIC HISTIDINE RICH PROTEIN 2 & PLASMODIUM SPECIES (PLASMODIUM FALCIPARUM ,VIVEX , MALARIAE & OVALE) , IN HUMAN WHOLE BLOOD,DENGUE VIRUS NS1 ANTIGEN RAPID TEST DEVICE(BIOSCI TRUE-DETECT DENGUE VIRUS NS1 ANTIGEN TEST)-DENGUE VIRUS NS1 ANTIGEN RAPID TEST DEVICE IS A RAPID LATERAL FLOW THROUGH IMMUNOCHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN SERUM/ PLASMA/ WHOLE BLOOD,MALARIA ANTIGEN (PV/PF) RAPID TEST DEVICE(BIOSCI TRUE-DETECT MALARIA ANTIGEN (PV/PF) TEST)-MALARIA ANTIGEN (PV/PF) RAPID TEST DEVICE IS A RAPID LATERAL FLOW THROUGH IMMUNOCHROMATOGRAPHIC TEST FOR THE QUALITATIVE DETECTION OF TWO KINDS OF CIRCULATING ANTIGENS OF PLASMODIUM. VIVAX (PV) AND PLASMODIUM FALCIPARUM (PF) & IN HUMAN WHOLE BLOOD
3017	MFG/IVD/2021/000042	1.License Holder Name: BIOFOOTPRINTS HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:COVID-19 AG TEST (MYTEST COVID-19 AG)-RAPID IMMUNO-CHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF TEST FOR SARS-COV-2 SPECIFIC AG PRESENT IN HUMAN NASOPHARYNGEAL SPECIMEN

3018	MFG/IVD/2021/000043	1.License Holder Name: IMMUNOSCIENCE INDIA PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:RAPID SYPHILIS ANTIBODY TEST-DEVICE(CHECK-IT)- RAPID SYPHILIS ANTIBODY TEST (DEVICE) IS AN IMMUNOASSAY FOR THE RAPID AND VISUAL DETECTION OF ANTIBODIES TO TREPONEMA PALLIDUM IN HUMAN SERUM OR PLASMA OR WHOLE BLOOD TO AID IN THE DIAGNOSIS OF SYPHILIS.,RAPID TEST FOR DETECTION OF HBSAG- DEVICE AND COMPONENTS(CHECK-IT)-"RAPID TEST FOR DETECTION OF HBSAG (DEVICE)" IS AN IMMUNOASSAY FOR THE RAPID AND VISUAL DETECTION OF HEPATITIS B SURFACE ANTIGEN IN HUMAN SERUM/ PLASMA/WHOLE BLOOD FOR THE DIAGNOSIS OF HEPATITIS B VIRUS INFECTION.,RAPID TEST FOR DETECTION OF ANTIBODIES TO HIV 1 AND HIV 2- DEVICE AND COMPONENTS.(CHECK-IT)-"RAPID TEST FOR DETECTION OF ANTIBODIES TO HIV 1 AND HIV 2 (DEVICE)" IS AN IMMUNOASSAY FOR THE RAPID AND VISUAL DETECTION OF ANTIBODIES TO HIV 1 AND HIV 2 IN HUMAN SERUM/PLASMA/WHOLE BLOOD FOR THE DIAGNOSIS OF HUMAN IMMUNODEFICIENCY VIRUS INFECTION (HIV).,RAPID MALARIA PF (HRP 2)/PAN (PLDH) ANTIGEN TEST -DEVICE & COMPONENTS(CHECK-IT)-FOR DIAGNOSIS OF MALARIA,RAPID TEST FOR DETECTION OF ANTIBODIES TO HCV-DEVICE AND COMPONENTS.(CHECK-IT)-RAPID TEST FOR DETECTION OF ANTIBODIES TO HCV (DEVICE) IS AN IMMUNOASSAY FOR THE RAPID AND VISUAL DETECTION OF ANTIBODIES TO HCV IN HUMAN SERUM/ PLASMA/WHOLE BLOOD FOR THE DIAGNOSIS OF HEPATITIS C VIRUS INFECTION.
3019	MFG/IVD/2021/000044	1.License Holder Name: BIOGENOMICS LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:REAL TIME RT-PCR KIT FOR DETECTION OF COVID-19(BIOCOV-ID-ERN)-BIOCOV-ID-ERN REAL-TIME RT-PCR DETECTION KIT BY BIOGENOMICS LIMITED IS DESIGNED TO DETECT THE PRESENCE OF SARS-COV-2 CORONAVIRUS IN RESPIRATORY SPECIMENS AND SERUM SAMPLE. THE KIT IS DESIGNED AS PER RECOMMENDED WHO STANDARD GUIDELINES

3020	MFG/IVD/2021/000045	1.License Holder Name: DENOVO BIOLABS PVT LTD 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM (VTM) KIT(DEQUANTO VTM KIT)-DEQUANTO VTM IS INTENDED FOR THE COLLECTION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES FROM THE COLLECTION SITE TO THE TESTING LABORATORY
3021	MFG/IVD/2021/000046	1.License Holder Name: MEDZOME LIFE SCIENCEZ PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BADDI 3.Device Name(Brand Name)-Intended Use:COVID-19 RAPID ANTIGEN DETECTION KIT(FUTURECARE COVID-19 ANTIGEN RAPID TEST)-FUTURECARE COVID-19 ANTIGEN RAPID TEST IS A MEDICAL DEVICE INTENDED FOR THE DETECTION OF ANTIGEN RELEASED BY SARS-COV-2 IN NASAL/NASOPHARYNGEAL FLUIDS.
3022	MFG/IVD/2021/000047	1.License Holder Name: PATHSHODH HEALTHCARE PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:COVID-19 TOTAL ANTIBODY (IGM+IGG) TEST STRIPS(ANUPATH)-IN-VITRO DIAGNOSTIC OF COVID-19 ANTIBODIES: IGM AND IGG.

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3023	MFG/IVD/2021/000048	1.License Holder Name: HORIBA INDIA PVT. LTD. 2.Approving Authority: NAGPUR DIVISION 3.Device Name(Brand Name)-Intended Use:ABX LYSEBIO 0.4L(ABX LYSEBIO 0.4L)-ABX LYSEBIO IS A LYSING SOLUTION AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) AND FOR HEMOGLOBIN DETERMINATION ON HORIBA MEDICAL BLOOD CELL COUNTERS. ,ABX MINIDIL LMG 20L(ABX MINIDIL LMG 20L)-ABX MINIDIL LMG IS A BUFFERED ISOTONIC SOLUTION AND DESIGNED FOR THE DETERMINATION OF BLOOD CELLS COUNTING, AND THE MEASUREMENT OF HEMATOCRIT ON HORIBA MEDICAL BLOOD CELL COUNTERS. ,MINILYSEBIO 0.4L(MINILYSEBIO 0.4L)-MINILYSEBIO IS A LYSING SOLUTION AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) AND FOR HEMOGLOBIN DETERMINATION ON HORIBA MEDICAL BLOOD CELL COUNTERS. ,ABX BASOLYSE II 1L(ABX BASOLYSE II 1L)-ABX BASOLYSE II IS A LYSING SOLUTION INTENDED FOR IN VITRO DIAGNOSTIC USE AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) FOR LEUCOCYTES (WBC) COUNTING AND DIFFERENTIATION ON HORIBA MEDICAL BLOOD CELL COUNTERS. ,ABX LYSEBIO 1L(ABX LYSEBIO 1L)-ABX LYSEBIO IS A LYSING SOLUTION AND DESIGNED FOR LYSING ERYTHROCYTES (RBC) AND FOR HEMOGLOBIN DETERMINATION ON HORIBA MEDICAL BLOOD CELL COUNTERS. ,ABX CLEANER 1L(ABX CLEANER 1L)-ABX CLEANER IS AN ENZYMATIC SOLUTION WITH PROTEOLYTIC ACTION FOR THE CLEANING OF HORIBA MEDICAL BLOOD CELL COUNTERS. ,ABX MINIDIL LMG 10L (ABX MINIDIL LMG 10L)-ABX MINIDIL LMG IS A BUFFERED ISOTONIC SOLUTION AND DESIGNED FOR THE DETERMINATION OF BLOOD CELLS COUNTING, AND THE MEASUREMENT OF HEMATOCRIT ON HORIBA MEDICAL BLOOD CELL COUNTERS. ,ABX DILUENT 20L(ABX DILUENT 20L)-ABX DILUENT IS A BUFFERED ISOTONIC SOLUTION AND DESIGNED FOR SHEATHING AND DILUTING LEUCOCYTES (WBC), AND FOR THE DETERMINATION AND DIFFERENTIATION OF BLOOD CELLS, AND THE MEASUREMENT OF HEMATOCRIT ON HORIBA MEDICAL BLOOD CELL COUNTERS.

3024	MFG/IVD/2021/000049	1.License Holder Name: PROMEA THERAPEUTICS PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:SGPT TESTING KIT-THE INTENDED USE OF THE KIT IS TO DETECT THE CONCENTRATION OF SERUM GLUTAMIC PYRUVIC TRANSAMINASE LEVELS IN THE BODY AND NOT DIAGNOSE ANY DISORDERS OR DISEASES.,PHOSPHORUS TESTING KIT-THE INTENDED USE OF THE KIT IS TO DETECT THE CONCENTRATION OF PHOSPHOROUS IN THE BODY AND NOT DIAGNOSE ANY DISORDERS OR DISEASES.,ALKALINE PHOSPHATASE TESTING KIT-THE REAGENT IS USED TO DETECT THE CONCENTRATION OF ALP LEVELS IN THE SERUM/PLASMA, BUT NOT TO DIAGNOSE ANY SPECIFIC DISORDER, CONDITION OR RISK FACTOR.,SGOT TESTING KIT(NIL)-THE INTENDED USE OF THE KIT IS TO DETECT THE CONCENTRATION OF SERUM GLUTAMIC OXALOACETATE TRANSAMINASE LEVELS IN HUMAN SERUM OR PLASMA.,LDL TESTING KIT(NIL)-THE INTENDED USE OF THE KIT IS TO DETERMINE THE CONCENTRATION OF LOW-DENSITY LIPOPROTEIN LEVELS IN HUMAN SERUM OR PLASMA.,CHOLESTEROL TESTING KIT-THE INTENDED USE OF THE KIT IS TO SOLELY MONITOR THE LEVEL OF CHOLESTEROL AND NOT DIAGNOSE ANY DISORDERS OR DISEASES.,GLUCOSE TESTING KIT-THE REAGENT IS USED TO DETECT THE CONCENTRATION OF GLUCOSE LEVELS AND NOT TO DIAGNOSE ANY SPECIFIC DISORDER, CONDITIONS OR RISK FACTOR., TRIGLYCERIDES TESTING KIT-THE KIT IS USED TO DETECT THE TRIGLYCERIDE LEVELS IN THE SERUM/PLASMA AND NOT A DIAGNOSTIC DEVICE FOR A SPECIFIC DISORDER, CONDITION, OR RISK FACTOR.,TOTAL PROTEIN TESTING KIT-THE INTENDED USE OF THE KIT IS TO DETECT THE CONCENTRATION OF TOTAL PROTEIN IN THE BODY AND NOT DIAGNOSE ANY DISORDERS OR DISEASES.,CK-NAC TESTING KIT(NIL)-THE INTENDED USE OF THE KIT IS TO SOLELY MONITOR THE LEVEL OF CK-NAC AND NOT DIAGNOSE ANY DISORDERS OR DISEASES.,LDH TESTING KIT-THE INTENDED USE OF THE KIT IS TO DETECT THE CONCENTRATION OF LACTATE DEHYDROGENASE LEVELS IN THE PLASMA/SERUM SAMPLE AND NOT DIAGNOSE ANY DISORDERS OR DISEASES.,CK- MB TESTING KIT(NIL)-THE INTENDED USE OF THE KIT IS TO SOLELY MONITOR THE LEVEL OF CK-MB AND NOT DIAGNOSE ANY DISORDERS OR DISEASES., CHLORIDE TESTING KIT(NIL)-THE INTENDED USE OF THE KIT IS TO SOLELY MONITOR THE LEVEL OF CHLORIDE AND NOT DIAGNOSE ANY DISORDERS OR DISEASES.,HDL TESTING KIT-THE KIT IS USED TO DETECT THE HDL LEVELS IN SERUM SAMPLE AND DOES NOT DIAGNOSE A SPECIFIC DISORDER, CONDITION OR RISK FACTOR., CREATININE TESTING KIT-THE REAGENT IS USED TO DETECT THE CONCENTRATION OF CREATININE LEVELS AND NOT DIAGNOSE ANY

		SPECIFIC DISORDER, CONDITION OR RISK FACTOR.,URIC ACID TESTING KIT(NIL)-THE INTENDED USE OF THE KIT IS TO SOLELY DETECT THE LEVEL OF URIC ACID CONCENTRATION IN HUMAN SERUM OR PLASMA.
3025	MFG/IVD/2021/000050	1.License Holder Name: YUVRAJ BIOBIZ INCUBATOR INDIA PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:COVID19 AG TEST(YBIO)-COVID19 AG TEST IS A RAPID QUALITATIVE IMMUNOASSAY, USED FOR DETECTION OF SARS-COV-2 ANTIGEN IN HUMAN NASOPHARYNGEAL SPECIMENS. THIS TEST IS VERY SENSITIVE AND RAPID. RESULTS ARE INTERPRETED IN LESS THAN 20 MIN.
3026	MFG/IVD/2021/000051	1.License Holder Name: ABBES BIOTECH 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:COVID 19 VIRAL RNA EXTRACTION SPIN COLUMN MINIPREP KIT(ABIGEN COVID 19 VIRAL RNA EXTRACTION SPIN COLUMN MINIPREP KIT)-INDENTED USE COVID-19 VIRAL RNA EXTRACTION SPIN COLUMN MINI PREP KIT IS INTENDED FOR EXTRACTION AND PURIFICATION OF THE VIRAL TOTAL RNA FOR MOLECULAR BIOLOGY APPLICATIONS SUCH AS RT PCR AND QPCR.

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3027	MFG/IVD/2021/000052	1.License Holder Name: RECOMBIGEN LABORATORIES PVT LTD 2.Approving Authority: NORTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:HCG (HUMAN CHORIONIC GONADOTROPIN TEST) SERUM/PLASMA/URINE(CLEAR & SURE)-THE PROPOSED IVD PRODUCT IS A “HCG (HUMAN CHORIONIC GONADOTROPIN TEST) IN PLASTIC CASSETTE FORMAT”. IT IS INTENDED FOR QUALITATIVE DETECTION OF HCG (HUMAN CHORIONIC GONADOTROPIN TEST) IN HUMAN SERUM, PLASMA AND WHOLE BLOOD SAMPLE.,MALE FERTILITY TEST KIT(CLEAR & SURE)-THE MALE FERTILITY TEST IS A QUICK, RELIABLE, TEST FOR THE DETECTION OF SUB FERTILE OR LOW SPERM COUNT. THIS TEST IS INTENDED FOR THE USE WITH SPERM CHECK FERTILITY SOLUTION., RAPID FSH (MENOPAUSE) TEST - SERUM/ PLASMA/ URINE(CLEAR & SURE)-THE PROPOSED IVD PRODUCT IS A “RAPID FSH (MENOPAUSE) TEST" IN PLASTIC CASSETTE FORMAT”. IT IS INTENDED FOR QUALITATIVE DETECTION OF RAPID FSH (MENOPAUSE) TEST IN HUMAN SERUM, PLASMA AND WHOLE BLOOD SAMPLE.,ANTI-OVARY ANTIBODIES TEST REAGENT/ KIT(CLEAR & SURE)-ANTI OVARY ANTIBODIES TEST REAGENTS/ KITS IS A MEDICAL DEVICE FOR THE SCREENING OF AUTO ANTIBODIES TO OVARIAN. ANTIGENS IN HUMAN SPECIMEN.,RAPID LUTEINIZING HORMONE (LH) TEST – SERUM/ PLASMA/ URINE(CLEAR & SURE)-THE PROPOSED IVD PRODUCT IS A “RAPID LUTEINIZING HORMONE (LH) TEST IN PLASTIC CASSETTE FORMAT”. IT IS INTENDED FOR QUALITATIVE DETECTION OF RAPID LUTEINIZING HORMONE (LH) TEST IN HUMAN SERUM, PLASMA AND WHOLE BLOOD SAMPLE.
3028	MFG/IVD/2021/000053	1.License Holder Name: DIA SURE IMMUNODIAGNOSTIC LLP 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:RAPID ANTIGEN TEST FOR NOVEL CORONA VIRUS (NCOVID-19)(DSI COVID-19 AG RAPID TEST)-DSI COVID-19 AG RAPID TEST IS AN IN VITRO DIAGNOSTIC TEST FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS ANTIGENS IN NASOPHARYNGEAL SWAB, USING THE RAPID IMMUNO-CHROMATOGRAPHIC METHOD.

3029	MFG/IVD/2021/000054	1.License Holder Name: WRIG NANOSYSTEMS PRIVATE LIMITED 2.Approving Authority: BILASPUR,SHIMLA,KINNAUR ,SOLAN(OTHER THAN BBN) 3.Device Name(Brand Name)-Intended Use:HEMOGLOBIN TEST STRIPS(TRUEHB)-THE TRUEHB HEMOGLOBIN MONITORING KIT IS INTENDED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF HEMOGLOBIN IN FRESH CAPILLARY WHOLE BLOOD SAMPLES TAKEN FROM THE FOREARM, UPPER ARM, HAND, THIGH, CALF, OR FINGERS. THE TRUEHB HEMOGLOBIN MONITORING KIT IS INTENDED FOR USE OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) BY HEALTHCARE PROFESSIONALS AND BY END-USERS AT HOME. TRUEHB HEMOMETER IS USED WITH GENUINE TRUEHB STRIPS TO MEASURE HEMOGLOBIN IN THE BLOOD.
3030	MFG/IVD/2021/000055	1.License Holder Name: M/S RAPHA DIAGNOSTICS PVT. LTD., 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:D-DIMER TURBILATEX (SECURE)-SECURE D-DIMER IS THE DIAGNOSTIC REAGENT FOR QUANTITATIVE IN VITRO DETERMINATION OF D-DIMER IN PLASMA ON PHOTOMETRIC SYSTEMS. THIS PRODUCT IS USED FOR IN VITRO DIAGNOSIS BY PROFESSIONALS.,CRP TURBILATEX(SECURE)-SECURE CRP TURBILATEX IS A REAGENT KIT FOR QUANTITATIVE TURBIDIMETRIC DETECTION OF C - REACTIVE PROTEIN (CRP) IN HUMAN SERUM BASED ON TURBIDIMETRIC METHOD . THIS PRODUCT IS USED FOR IN VITRO DIAGNOSIS BY PROFESSIONALS.,CRP LATEX KIT(RAPHA SERO)-RAPHA SERO CRP LATEX REAGENT IS A SLIDE AGGLUTINATION TEST FOR THE QUALITATIVE AND SEMI QUANTITATIVE DETECTION OF C - REACTIVE PROTEIN (CRP) IN HUMAN SERUM. RAPHA SERO CRP LATEX IS A SLIDE AGGLUTINATION TEST IS FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.

3031	MFG/IVD/2021/000056	1.License Holder Name: OSBRO PHARMACEUTICAL PRIVATE LIMITED. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:UNIVERSAL SAMPLE PRE-TREATMENT PACK FOR NON MTB SAMPLES(TRUEPREP® AUTO UNIVERSAL SAMPLE PRE-TREATMENT PACK)-TRUEPREP® AUTO UNIVERSAL SAMPLE PRE-TREATMENT PACK IS USED TO PRE-TREAT THE SAMPLES BEFORE PROCEEDING FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE, UNIVERSAL SAMPLE PRE-TREATMENT PACK FOR NON MTB SAMPLES (NA)-TRUEPREP® AUTO UNIVERSAL SAMPLE PRE-TREATMENT PACK IS USED TO PRE-TREAT THE SAMPLES BEFORE PROCEEDING FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE
3032	MFG/IVD/2021/000057	1.License Holder Name: RECOMBIGEN LABORATORIES PVT LTD 2.Approving Authority: NORTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:H. PYLORI ANTIBODY RAPID TEST KIT(GENERIC)-THE H. PYLORI ANTIBODY RAPID TEST KIT (SERUM/PLASMA/WHOLE BLOOD) IS A RAPID VISUAL IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC IGM, IGG AND IGA ANTIBODIES TO HELICOBACTER PYLORI IN HUMAN SERUM, PLASMA OR WHOLE BLOOD SPECIMENS. THIS KIT IS INTENDED FOR USE AS AN AID IN THE DIAGNOSIS OF H. PYLORI INFECTION.

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3033	MFG/IVD/2021/000058	1.License Holder Name: PRECISION BIOMED PVT. LTD. 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:DIAGNOSTICS TEST REAGENT KITS FOR SODIUM-A SODIUM TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF SODIUM IN SERUM/PLASMA,DIAGNOSTICS TEST REAGENT/ KITS FOR AST/SGOT-AN ASPARTATE AMINO TRANSFERASE (ALT/SGOT) TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME ASPARTATE AMINO TRANSFERASE (AST/SGOT) IN SERUM / PLASMA,DIAGNOSTICS TEST REAGENT/KITS FOR CALCIUM-A CALCIUM ARS TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TOTAL CALCIUM IN SERUM OR PLASMA, DIAGNOSTICS TEST REAGENT /KITS FOR CREATININE (JAFFE METHOD)-A CREATININE TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CREATININE IN SERUM, PLASMA/URINE,DIAGNOSTICS TEST REAGENT/KITS FOR ALKALINE PHOSPHATASE-AN ALKALINE PHOSPHATASE TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALKALINE PHOSPHATASE IN SERUM / PLASMA,DIAGNOSTICS TEST REAGENT/ KITS FOR ALT/SGPT-AN ALANINE AMINO TRANSFERASE (ALT/SGPT) TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ENZYME ALANINE AMINO TRANSFERASE (ALT/SGPT) IN SERUM / PLASMA,DIAGNOSTICS TEST REAGENT/ KITS FOR BILIRUBIN-AN BILIRUBIN (TOTAL AND DIRECT) TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF BILIRUBIN (TOTAL AND DIRECT) IN SERUM / PLASMA,DIAGNOSTICS TEST REAGENT KITS FOR CRP-CRP TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF C-REACTIVE PROTEIN IN SERUM AND OTHER BODY FLUIDS,DIAGNOSTICS TEST REAGENT/ KITS FOR UREA-A UREA BERTHELOT TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF UREA (BUN) IN SERUM/PLASMA/URINE,DIAGNOSTICS TEST REAGENT KITS FOR POTASSIUM-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF POTASSIUM IN HUMAN SERUM.,DIAGNOSTICS TEST REAGENT KITS FOR ADENOSINE DEAMINASE (ADA)-AN ADENOSINE DEAMINASE (ADA)TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ADENOSINE DEAMINASE IN SERUM / PLASMA, DIAGNOSTICS TEST REAGENT/ KITS FOR URIC ACID-A URIC ACID TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF URIC ACID IN SERUM/PLASMA/URINE,DIAGNOSTICS TEST REAGENT KITS FOR RF – RHEUMATOID FACTOR -RF IMMUNOLOGICAL TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE THE SCREENING OF RF IN HUMAN SPECIMENS, DIAGNOSTICS TEST REAGENT/ KITS FOR UREA (UV)-A UREA UV TEST

	REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF UREA (BUN) IN SERUM/PLASMA/URINE,DIAGNOSTICS TEST REAGENT/KITS FOR TRIGLYCERIDES-A TRIGLYCERIDES TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TRIGLYCERIDES IN SERUM/PLASMA,DIAGNOSTICS TEST REAGENT/KITS FOR GLUCOSE-A GLUCOSE TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF GLUCOSE IN PLASMA/BODY FLUIDS,DIAGNOSTICS TEST REAGENT/ KITS FOR ALPHA AMYLASE-AN AMYLASE TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF THE ENZYME AMYLASE IN SERUM / PLASMA,DIAGNOSTICS TEST REAGENT/ KITS FOR CHOLESTEROL-A CHOLESTEROL (TOTAL) TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF CHOLESTEROL IN SERUM OR PLASMA,DIAGNOSTICS TEST REAGENT/ KITS FOR TOTAL PROTEIN-A TOTAL PROTEIN TEST REAGENT/ KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF TOTAL PROTEIN IN SERUM/PLASMA,DIAGNOSTICS TEST REAGENT/ KITS FOR ALBUMIN-AN ALBUMIN TEST REAGENT / KIT IS A MEDICAL DEVICE INTENDED FOR THE ESTIMATION OF ALBUMIN IN SERUM/PLASMA

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3034	MFG/IVD/2021/000060	1.License Holder Name: POCT SERVICES PRIVATE LIMITED 2.Approving Authority: NORTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:ALT/GPT (Q-LINE)-Q-LINE® ALT/GPT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC ETERMINATION OF ALKANINE AMINOTRANSFERASE (ALT) IN HUMAN SERUM. ,LDL CHOLESTEROL (DIRECT)(Q-LINE)-THE Q-LINE™ LDL-CHOLESTEROL REAGENT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL IN HUMAN SERUM OR PLASMA. THE REAGENT CAN ASSIST IN THE DIAGNOSIS AND TREATMENT OF PATIENTS AT RISK FOR DEVELOPING CORONARY HEART DISEASE. , AST/GOT (Q-LINE)-Q-LINE™ AST/GOT SL IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ASPARTATE AMINOTRANSFERASE (AST), IN HUMAN SERUM. ,CRP LATEX(Q-LINE)-Q-LINE BRAND IS A QUANTITATIVE MEASUREMENT OF CRP (C-REACTIVE PROTEIN). ,URIC ACID MONO (Q-LINE)-Q-LINE™ URIC ACID MONO SL IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC ETERMINATION OF URIC ACID IN HUMAN SAMPLES OF SERUM, PLASMA AND URINE. ,VITAMIN - D(Q-LINE)-THE Q-LINE 25-OH VITAMIN D ASSAY IS INTENDED FOR USE IN CLINICAL LABORATORIES FOR THE QUANTITATIVE DETERMINATION OF TOTAL 25-OH VITAMIN D IN HUMAN SERUM AND PLASMA ON AUTOMATED CHEMISTRY ANALYZER. MEASUREMENT OF 25-HYDROXY VITAMIN D (25-OH VITAMIN D) IS FOR THE ASSESSMENT OF VITAMIN D SUFFICIENCY. FOR IN VITRO DIAGNOSTIC USE ONLY. ,CK NAC SL(Q-LINE)-Q-LINE BRAND CK-NAC IN INTENDED FOR IVD QUANTITATIVE DETERMINATION OF HUMAN APOLIPOROTEIN . ,LDH-P (Q-LINE)-Q-LINE® CLINICAL SYSTEMS LDH-P SL IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF LACTATE DEHYDROGENASE (LDH) IN HUMAN SERUM AND PLASMA. ,AMYLASE (Q-LINE)-Q-LINE™ AMYLASE SL IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ?-AMYLASE, IN HUMAN SERUM AND PLASMA. ,HBA1C DIRECT (Q-LINE)-Q-LINE® HBA1C DIRECT KIT IS INTENDED FOR IN-VITRO QUANTITATIVE DETERMINATION OF PLATINUM% HBA1C (HEMOGLOBIN FRACTION) IN HUMAN WHOLE BLOOD. PERCENT HBA1C MEASUREMENTS ARE USED FOR MONITORING LONG TERM GLYCEMIC CONTROL IN DIABETIC PATIENTS. ,CYSTATIN C ASSAY(Q-LINE)-Q-LINE™ CYSTATIN C ASSAY IS INTENDED FOR QUANTITATIVE DETERMINATION OF CYSTATIN C IN HUMAN SERUM AND PLASMA FOR BETTER KIDNEY FUNCTIONING. , GLUCOSE PAP(Q-LINE)-Q-LINE™ GLUCOSE PAP IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC ETERMINATION OF GLUCOSE IN HUMAN SAMPLES OF SERUM, PLASMA AND URINE. ,ASO TURBILATEX (Q-LINE)-Q-LINE® ASO TURBILATEX REAGENT IS INTENDED FOR IN

	VITRO QUANTITATIVE DETERMINATION OF ASO IN HUMAN SERUM. , UREA UV(Q-LINE)-Q-LINE™ UREA UV IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC ETERMINATION OF URIC ACID IN HUMAN SAMPLES OF SERUM, PLASMA AND URINE. ,BILIRUBIN (T & D) 4+1(Q-LINE)-"FOR TOTAL BILIRUBIN: Q-LINE BILIRUBIN TOTAL IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM AND PLASMA ON ADULTS AND CHILDREN OVER 10 DAYS. FOR DIRECT BILIRUBIN: Q-LINE BILIRUBIN DIRECT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM AND PLASMA. " ,FERRITIN KIT(Q-LINE)-Q-LINE BRAND IS A QUANTITATIVE MEASUREMENT OF FERRITIN. , GAMMA-GT PLUS(Q-LINE)-Q-LINE™ GAMMA-GT PLUS SL IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF GAMMA-GLUTAMYLTRANSFERASE (-GT), IN HUMAN SERUM AND PLASMA. ,APOLIPOPROTEIN B(Q-LINE)-Q-LINE BRAND APO B IN INTENDED FOR IVD QUANTITATIVE DETERMINATION OF HUMAN APOLIPOROTEIN B (APO B). ,GLYCATED SERUM PROTEIN ASSAY(Q-LINE)-Q-LINE™ GLYCATED SERUM ASSAY IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA. ,LIPASE(Q-LINE)-"Q-LINE™ LIPASE SL IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF LIPASE IN HUMAN SERUM AND PLASMA. ,LIPO PROTEIN (A) : LP(A)(Q-LINE)-"Q-LINE™ LP(A) IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA. , HDL CHOLESTEROL (DIRECT)(Q-LINE)-THE Q-LINE™ HDL-CHOLESTEROL REAGENT IS INTENDED FOR THE IN VITRO QUANTITATIVE DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL IN HUMAN SERUM OR PLASMA. THE REAGENT CAN ASSIST IN THE DIAGNOSIS AND TREATMENT OF PATIENTS AT RISK FOR DEVELOPING CORONARY HEART DISEASE. ,ALBUMIN (Q-LINE)-Q-LINE™ ALBUMIN IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ALBUMIN IN HUMAN SERUM. , APOLIPOPROTEIN A1(Q-LINE)-Q-LINE BRAND APO A1 IN INTENDED FOR IVD QUANTITATIVE DETERMINATION OF HUMAN APOLIPOROTEIN A1 (APO A1). ,CHOLESTEROL(Q-LINE)-"Q-LINE™ CHOLESTEROL SL IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA " ,IRON(Q-LINE)-Q-LINE™ IRON IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA. ,CALCIUM ARSENAZO (Q-LINE)-Q-LINE CALCIUM ARSENAZO REAGENT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC

	DETERMINATION OF TOTAL CALCIUM IN HUMAN SAMPLES OF SERUM, PLASMA & URINE. ,CRP TURBILATEX(Q-LINE)-Q-LINE® CRP TURBI LATEX REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF CREACTIVE PROTEIN (CRP) IN HUMAN SERUM. , CREATININE PAP(Q-LINE)-Q-LINE™ CREATININE PAP IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CREATININE IN HUMAN SAMPLE SERUM ,PLASMA & URINE. , HOMOCYSTEINE(Q-LINE)-Q-LINE® CLINICAL SYSTEMS ENZYMATIC HOMOCYSTEINE IS INTENDED FOR THE PLATINUM QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF TOTAL L-HOMOCYSTEINE IN SERUM OR PLASMA .THE ASSAY CAN ASSIST IN DIAGNOSIS AND TREATMENT OF PATIENTS SUSPECTED OF HAVING HYPERHOMOCYSTEINEMIA AND HOMOCYSTINURIA. PATIENTS WHO ARE TAKING METHOTREXATE, CARBAMAZEPINE, PHENYTOIN, NITROUS OXIDE, ANTICONVULSANTS, OR 6-AZURIDINE TRIACETATE MAY HAVE HIGHER LEVELS OF HCY DUE TOMETABOLIC INTERFERENCE WITH HCY METABOLISM. ,ALP (IFCC)(Q-LINE)-Q-LINE® ALP (IFCC) SL IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC ETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM. ,CK-MB SL(Q-LINE)-Q-LINE BRAND CK-MB IN INTENDED FOR IVD QUANTITATIVE DETERMINATION OF HUMAN APOLIPOROTEIN . , BILIRUBIN TOTAL 4+1 (Q-LINE)-FOR TOTAL BILIRUBIN: Q-LINE BILIRUBIN TOTAL IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM AND PLASMA ON ADULTS AND CHILDREN OVER 10 DAYS. , ASO LATEX (Q-LINE)-Q-LINE BRAND IS A QUANTITATIVE MEASUREMENT OF ASO (ANTI-STREPTOLYSIN O). ,RF LATEX(Q-LINE)-Q-LINE BRAND IS A QUANTITATIVE MEASUREMENT OF RHEUMATOID FACTORS (RF). ,TIBC(Q-LINE)-Q-LINE™ TOTAL IRON-BINDING CAPACITY (TIBC) IS INTENDED TO CORRESPOND MAXIMUM AMOUNT OF IRON THAT PLASMA PROTEINS CAN BIND. IT IS THEREFORE AN INDIRECT WAY OF MEASURING TRANSFERRIN LEVELS, PROTEIN WHICH TRANSPORTS IRON IN PLASMA. ,CHLORIDE(Q-LINE)-Q-LINE™ CHLORIDE IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CHLORIDE IN HUMAN SERUM & PLASMA. ,CREATININE JAFFE(Q-LINE)-Q-LINE™ CREATININE JAFFE IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CREATININE IN HUMAN SERUM & PLASMA. , HIGH-SENSITIVITY C-REACTIVE PROTEIN (HS-CRP)(Q-LINE)-THE Q-LINE™ HS-CRP TEST KIT IS FOR THE IN VITRO QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN VENOUS WHOLE BLOOD ON SMART ANALYZERS. MEASUREMENT OF CRP IS OF USE FOR THE DETECTION AND EVALUATION OF INFLAMMATORY DISORDERS AND ASSOCIATED DISEASES, INFECTION AND TISSUE

		INJURY. FOR IN VITRO DIAGNOSTIC USE ONLY. ,ALP (DEA) (Q-LINE)-Q-LINE™ ALP(DEL) IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ALKALINE IN HUMAN SERUM. ,TRIG MONO(Q-LINE)-Q-LINE™ TRIG MONO IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC ETERMINATION OF TRIGLYCERIDES MONO IN HUMAN SAMPLES OF SERUM, PLASMA AND URINE. ,ADENOSINE DEAMINASE ASSAY (ADA) (Q-LINE)-Q-LINE™ ADENOSINE DEAMINASE ASSAY (ADA) IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF ADA ACTIVITY IN HUMAN SAMPLES OF SERUM & PLASMA. ,LACTATE(Q-LINE)-Q-LINE™ LACTATE IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF CHOLESTEROL IN HUMAN SERUM AND PLASMA. ,PHOSPHORUS(Q-LINE)-Q-LINE™ PHOPHORUS IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF INORGANIC PHOSPHORUS IN HUMAN SERUM & PLASMA. ,TOTAL PROTEIN PLUS (Q-LINE)-Q-LINE™ TOTAL PROTEIN PLUS IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM AND PLASMA. ,MAGNESIUM XYLIDYL (Q-LINE)-"Q-LINE™ CLINICAL SYSTEMS MAGNESIUM XYLIDYL IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF MAGNESIUM IN HUMAN SERUM AND PLASMA." ,BILIRUBIN DIRECT 4+1 (Q-LINE)-FOR DIRECT BILIRUBIN: Q-LINE BILIRUBIN DIRECT IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM AND PLASMA. ,RF TURBILATEX(Q-LINE)-"Q-LINE™ RF TURBI IS INTENDED FOR THE QUANTITATIVE IN VITRO DIAGNOSTIC DETERMINATION OF RHEUMATOID FACTORS (RF) IN HUMAN SERUM AND PLASMA.
3035	MFG/IVD/2021/000061	1.License Holder Name: SANCARA MD PRIVATE LIMITED 2.Approving Authority: PUNJAB 3.Device Name(Brand Name)-Intended Use:HEMOGLOBIN TEST REAGENTS/KITS-HEMOGLOBIN TEST REAGENTS/KITS IS A MEDICAL DEVICE INTENDED FOR PRELIMINARY TESTING OF HEMOGLOBIN LEVEL IN BLOOD/BODY FLUIDS.,HUMAN CHORIONIC GONADOTROPIN (HCG) TEST REAGENTS/KITS-HCG IS INTENDED FOR THE QUALITATIVE DETECTION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN URINE AS AN AID IN THE DIAGNOSIS OF PREGNANCY. , BLOOD GLUCOSE TEST STRIP/KIT-BLOOD GLUCOSE TEST STRIP IS FOR QUANTITATIVELY MEASURING THE GLUCOSE LEVEL IN BLOOD.

3036	MFG/IVD/2021/000062	1.License Holder Name: MYLAB DISCOVERY SOLUTIONS PVT. LTD. LONAVLA 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:EXTRACTION OF RNA/DNA FROM CELL FREE BODY FLUIDS (SILICA MEMBRANE BASED)(MAVERICK NUCLEIC ACID EXTRACTION KIT)-EXTRACTION OF RNA/DNA FROM CELL FREE BODY FLUIDS,EXTRACTION OF DNA FROM BLOOD AND RELATED BODY FLUIDS (SILICA MEMBRANE BASED)(MAVERICK BLOOD NUCLEIC ACID EXTRACTION KIT)-EXTRACTION OF DNA FROM BLOOD AND RELATED BODY FLUIDS
3037	MFG/IVD/2021/000063	1.License Holder Name: STANDARD ANALYTICAL LABORATORY (ND) PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:RAPISPIN RNA ISOLATION KIT(RAPIDEX)-RAPISPIN RNA ISOLATION KIT IS INTENDED FOR MOLECULAR APPLICATIONS.,VIRAL RNA ISOLATION KIT RAPIVRIK (COVID-19/SARS-COV-2)(RAPIDEX)-RAPIVRIK CORONAVIRUS (SARSCOV2) VIRAL RNA ISOLATION KIT IS INTENDED FOR MOLECULAR APPLICATIONS.

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3038	MFG/IVD/2021/000064	1.License Holder Name: MOLBIO DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:SAMPLE PRE-TREATMENT PACK FOR MTB SAMPLES(TRUEPREP® AUTO MTB SAMPLE PRETREATMENT PACK)-TRUEPREP® AUTO MTB SAMPLE PRE-TREATMENT PACK IS USED TO LIQUEFY AND PRETREAT THE PULMONARY AND EPTB SPECIMEN BEFORE PROCEEDING FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP® AUTO TRUEPREP® /AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND AUTO/AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE ,MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF SWAB SPECIMEN FOR TRUEPREP® AUTO(TRUEPREP® AUTO TRANSPORT MEDIUM FOR SWAB SPECIMEN PACK)-TRUEPREP® AUTO TRANSPORT MEDIUM FOR SWAB SPECIMEN PACK IS INTENDED FOR USE WITH CLINICIAN-COLLECTED ENDOCERVICAL, VAGINAL, ANORECTAL, NASAL AND THROAT SWAB SPECIMENS. THE TRANSPORT MEDIA IS USED AS A MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF VARIOUS TYPES OF SWABS SPECIMENS BEFORE PROCEEDING FOR PRE-TREATMENT USING LYSIS BUFFER, EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP® AUTO/AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP® AUTO/AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE. ,CONTROL KIT FOR TRUENAT™ CHIP-BASED MICRO PCR TESTS: HAV, HEV, RABIES, LTS, NIPAH AND MALARIA PV/PF (TRUENAT™ POSITIVE CONTROL KIT - PANEL IV)-TRUENAT™ POSITIVE CONTROL KIT - PANEL IV IS A SET OF POSITIVE AND NEGATIVE CONTROL FOR VALIDATING THE PERFORMANCE OF TRUENAT™ CHIP BASED MICRO PCR TESTS - HAV, HEV, RABIES, LTS, NIPAH AND MALARIA PV/PF AS WELL AS TRUELAB® REAL TIME MICRO PCR ANALYZERS.,SAMPLE PREPARATION KIT FOR NUCLEIC ACID EXTRACTION ON TRUEPREP® AUTO(TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT)-TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT WORKS WITH TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE AND IS USED FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS FROM A WIDE RANGE OF BIOLOGICAL SPECIMENS , CONTROL KIT FOR TRUENAT™ CHIP-BASED MICRO PCR TESTS: CT, NG, TRICH, HPV-HR, GBS AND SALMONELLA(TRUENAT™ POSITIVE CONTROL KIT - PANEL III)-TRUENAT™ POSITIVE CONTROL KIT - PANEL III IS A SET OF POSITIVE AND NEGATIVE CONTROL FOR VALIDATING THE PERFORMANCE OF TRUENAT™ CHIP BASED MICRO PCR TESTS - CT, NG, TRICH, HPV-HR, GBS AND SALMONELLA AS WELL AS TRUELAB® REAL TIME MICRO PCR ANALYZERS.,UNIVERSAL

		SAMPLE PRE-TREATMENT PACK FOR NON MTB SAMPLES (TRUEPREP® AUTO UNIVERSAL SAMPLE PRE-TREATMENT PACK)-TRUEPREP® AUTO UNIVERSAL SAMPLE PRE-TREATMENT PACK IS USED TO PRE-TREAT THE SAMPLES SUCH AS WHOLE BLOOD/ SERUM/PLASMA/URINE/STOOL/SWAB SPECIMENS/OTHER BODY FLUIDS BEFORE PROCEEDING FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP® AUTO/AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP® AUTO/AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE.,CONTROL KIT FOR TRUENAT™ CHIP-BASED MICRO PCR TESTS: HBV, HCV, HIV-1, HLA-B27, DENGUE, CHIKUNGUNYA AND INFLUENZA A/B(TRUENAT™ POSITIVE CONTROL KIT - PANEL II)-TRUENAT™ POSITIVE CONTROL KIT - PANEL II IS A SET OF POSITIVE AND NEGATIVE CONTROL FOR VALIDATING THE PERFORMANCE OF TRUENAT™ CHIP BASED MICRO PCR TESTS - HBV, HCV, HIV-1, HLA-B27, DENGUE, CHIKUNGUNYA AND INFLUENZA A/B AS WELL AS TRUELAB® REAL TIME MICRO PCR ANALYZERS.,CHIP-BASED REAL TIME PCR TEST FOR HLA-B27 (TRUENAT™ HLA-B27)-TRUENAT™ HLA-B27 IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE QUALITATIVE DETECTION OF HLAB27 IN HUMAN BLOOD SPECIMEN AND AIDS IN THE DIAGNOSIS OF HLA-B27 TYPING. TRUENAT™ HLA-B27 RUNS ON THE TRUELAB® REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.,SAMPLE PREPARATION KIT FOR NUCLEIC ACID EXTRACTION ON TRUEPREP® AUTO V2(TRUEPREP® AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT)-TRUEPREP® AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT WORKS WITH TRUEPREP® AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE AND IS USED FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS FROM A WIDE RANGE OF BIOLOGICAL SPECIMENS , CONTROL KIT FOR TRUENAT™ CHIP-BASED MICRO PCR TESTS: MTB, MTB PLUS, MTB-RIF DX, BETA COV, SARS COV-2, COVID-19 AND H1N1 (TRUENAT™ POSITIVE CONTROL KIT - PANEL I)-TRUENAT™ POSITIVE CONTROL KIT - PANEL I IS A SET OF POSITIVE AND NEGATIVE CONTROL FOR VALIDATING THE PERFORMANCE OF TRUENAT™ CHIP BASED MICRO PCR TESTS - MTB, MTB PLUS, MTB-RIF DX, BETA COV, SARS COV-2, COVID-19 AND H1N1 AS WELL AS TRUELAB® REAL TIME MICRO PCR ANALYZERS.
3039	MFG/IVD/2021/000065	1.License Holder Name: DNA XPERTS PRIVATE LIMITED 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:COVID19 PCR KIT(XPERT COVIDO-19 - FAST RT-PCR KIT)-FOR DIAGNOSIS OF COVID19 RNA USING REAL TIME PCR METHOD

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3040	MFG/IVD/2021/000066	1.License Holder Name: CML BIOTECH PRIVATE LTD 2.Approving Authority: KERALA 3.Device Name(Brand Name)-Intended Use:POLYESTER SWAB WITH PLASTIC STICK IN PP TUBE(MICROZO)-FOR COLLECTION AND TRANSPORT OF MICROBIOLOGICAL SPECIMENS,NYLON FLOCCULATED NASOPHARYNGEAL (NASAL) SWAB WITH BREAKABLE PLASTIC STICK IN PP TUBE(MICROZO)-FOR COLLECTION AND TRANSPORT OF MICROBIOLOGICAL SPECIMENS,UNIVERSAL TRANSPORT SYSTEM [UNIVERSAL TRANSPORT MEDIUM KIT-3ML WITH 2 SWABS (ONE THROAT AND ONE NASAL SWAB)](MICROZO)-UNIVERSAL TRANSPORT SYSTEM [UNIVERSAL TRANSPORT MEDIUM KIT-3ML WITH 2 SWABS (ONE THROAT AND ONE NASAL SWAB)] IS INTENDED FOR THE COLLECTION, TRANSPORT AND MAINTENANCE OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS AND UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. FOR PROFESSIONAL DIAGNOSTIC USE ONLY,VIRAL TRANSPORT SYSTEM (VIRAL TRANSPORT MEDIUM KIT-3ML WITH ONE THROAT SWAB)(MICROZO)-VIRAL TRANSPORT SYSTEM (VIRAL TRANSPORT MEDIUM KIT-3ML WITH ONE THROAT SWAB) IS INTENDED FOR SPECIMEN COLLECTION, TRANSPORT AND PRESERVATION OF MANY BACTERIAL AND VIRAL SPECIES INCLUDING COVID -19 VIRUS (SARS COV 2). FOR PROFESSIONAL DIAGNOSTIC USE ONLY,NYLON FLOCCULATED OROPHARYNGEAL (THROAT) SWAB WITH BREAKABLE PLASTIC STICK IN PP TUBE (MICROZO)-FOR COLLECTION AND TRANSPORT OF MICROBIOLOGICAL SPECIMENS,UNIVERSAL TRANSPORT SYSTEM (UNIVERSAL TRANSPORT MEDIUM KIT-3ML WITH ONE THROAT SWAB) (MICROZO)-UNIVERSAL TRANSPORT SYSTEM (UNIVERSAL TRANSPORT MEDIUM KIT-3ML WITH ONE THROAT SWAB) IS INTENDED FOR THE COLLECTION, TRANSPORT AND MAINTENANCE OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS AND UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. FOR PROFESSIONAL DIAGNOSTIC USE ONLY,POLYESTER SWAB WITH PLASTIC STICK(MICROZO)-FOR COLLECTION AND TRANSPORT OF MICROBIOLOGICAL SPECIMENS COMBINED PACK OF NYLON FLOCCULATED OROPHARYNGEAL (THROAT) SWAB WITH BREAKABLE PLASTIC STICK & NASOPHARYNGEAL (NASAL) SWAB WITH BREAKABLE PLASTIC STICK (MICROZO)-FOE COLLECTION AND TRANSPORT OF MICROBIOLOGICAL SPECIMENS,VIRAL TRANSPORT SYSTEM (VIRAL TRANSPORT MEDIUM KIT-3ML WITH ONE NASAL SWAB(MICROZO)-VIRAL TRANSPORT SYSTEM (VIRAL TRANSPORT MEDIUM KIT-3ML WITH ONE NASAL SWAB) IS INTENDED FOR SPECIMEN COLLECTION, TRANSPORT AND PRESERVATION OF MANY BACTERIAL AND VIRAL

	SPECIES INCLUDING COVID -19 VIRUS (SARS COV 2). FOR PROFESSIONAL DIAGNOSTIC USE ONLY,VIRAL TRANSPORT SYSTEM [VIRAL TRANSPORT MEDIUM KIT-3ML WITH 2 SWABS (ONE THROAT AND ONE NASAL SWAB)](MICROZO)-VIRAL TRANSPORT SYSTEM [VIRAL TRANSPORT MEDIUM KIT-3ML WITH 2 SWABS (ONE THROAT AND ONE NASAL SWAB)] IS INTENDED FOR SPECIMEN COLLECTION, TRANSPORT AND PRESERVATION OF MANY BACTERIAL AND VIRAL SPECIES INCLUDING COVID -19 VIRUS (SARS COV 2). FOR PROFESSIONAL DIAGNOSTIC USE ONLY,UNIVERSAL TRANSPORT MEDIUM-3ML(MICROZO)-UNIVERSAL TRANSPORT MEDIUM-3ML IS INTENDED FOR THE COLLECTION, TRANSPORT AND MAINTENANCE OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS AND UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. FOR PROFESSIONAL DIAGNOSTIC USE ONLY,NYLON FLOCCULATED OROPHARYNGEAL (THROAT) SWAB WITH BREAKABLE PLASTIC STICK(MICROZO)-FOR COLLECTION AND TRANSPORT OF MICROBIOLOGICAL SPECIMENS,UNIVERSAL TRANSPORT SYSTEM (UNIVERSAL TRANSPORT MEDIUM KIT-3ML WITH ONE NASAL SWAB)(MICROZO)-UNIVERSAL TRANSPORT SYSTEM (UNIVERSAL TRANSPORT MEDIUM KIT-3ML WITH ONE NASAL SWAB) IS INTENDED FOR THE COLLECTION, TRANSPORT AND MAINTENANCE OF CLINICAL SPECIMENS CONTAINING VIRUSES, CHLAMYDIAE, MYCOPLASMAS AND UREAPLASMAS FROM THE COLLECTION SITE TO THE TESTING LABORATORY. FOR PROFESSIONAL DIAGNOSTIC USE ONLY,NYLON FLOCCULATED NASOPHARYNGEAL(NASAL) SWAB WITH BREAKABLE PLASTIC STICK (MICROZO)-FOR COLLECTION & TRANSPORT OF MICROBIOLOGICAL SPECIMEN,VIRAL TRANSPORT MEDIUM(MICROZO)-VIRAL TRANSPORT MEDIUM (VTM) IS INTENDED FOR SPECIMEN COLLECTION, TRANSPORT AND PRESERVATION OF MANY BACTERIAL AND VIRAL SPECIES INCLUDING COVID -19 VIRUS (SARS COV 2). FOR PROFESSIONAL DIAGNOSTIC USE ONLY

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3041	MFG/IVD/2021/000067	1.License Holder Name: BIOFOOTPRINTS HEALTHCARE PVT. LTD. 2.Approving Authority: WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:ONE STEP DENGUE ANTIBODY DETECTION TEST(MYTEST® DENGUE IGG/IGM)-SCREENING TEST FOR DENGUE IGG AND IGM ANTIBODIES IN HUMAN SERUM/PLASMA OR WHOLE BLOOD SAMPLE IN ORDER TO DETECT DENGUE INFECTION.,ONE STEP S. TYPHI IGM ANTIBODY DETECTION TEST(MYTEST® SALMONELLA TYPHI IGM)-SCREENING TEST FOR SALMONELLA TYPHI IGM ANTIBODIES IN HUMAN SERUM/PLASMA OR WHOLE BLOOD SAMPLE IN ORDER TO DETECT SALMONELLA TYPHI INFECTION.,ONE STEP SALMONELLA TYPHI IGG/IGM ANTIBODY DETECTION TEST(MYTEST® SALMONELLA TYPHI IGG/IGM)-SCREENING TEST FOR SALMONELLA TYPHI IGG AND IGM ANTIBODIES IN HUMAN SERUM/PLASMA OR WHOLE BLOOD SAMPLE IN ORDER TO DETECT SALMONELLA TYPHI INFECTION.,ONE STEP FILARIASIS ANTIBODY DETECTION TEST(MYTEST® FILARIASIS AB)-SCREENING TEST FOR FILARIA IGG AND IGM ANTIBODIES IN HUMAN SERUM/PLASMA OR WHOLE BLOOD SAMPLE IN ORDER TO DETECT FILARIASIS.,ONE STEP CHIKUNGUNYA IGM(MYTEST® CHIKUNGUNYA IGM)-SCREENING TEST FOR CHIKUNGUNYA IGM ANTIBODIES IN HUMAN SERUM/PLASMA OR WHOLE BLOOD SAMPLE IN ORDER TO DETECT CHIKUNGUNYA INFECTION.,ONE STEP HCG DETECTION TEST (MYTEST® HCG PREGNANCY CARD)-SCREENING TEST FOR HUMAN CHORIONIC GONADOTROPIN IN HUMAN URINE SAMPLE IN ORDER TO DETECT PREGNANCY.,ONE STEP SCRUB TYPHUS ANTIBODY DETECTION TEST(MYTEST® SCRUB TYPHUS AB)-SCREENING TEST FOR ORIENTIA TSUTSUGAMUSHI IGG AND IGM ANTIBODIES IN HUMAN SERUM/PLASMA OR WHOLE BLOOD SAMPLE IN ORDER TO DETECT SCRUB TYPHUS.,ONE STEP HELICOBACTER PYLORI ANTIBODIES DETECTION TEST(MYTEST® H. PYLORI AB)-SCREENING TEST FOR HELICOBACTER PYLORI ANTIGEN IN HUMAN FECES SAMPLE IN ORDER TO DETECT PEPTIC ULCER.,ONE STEP LEPTOSPIRA ANTIBODY DETECTION TEST(MYTEST® LEPTOSPIRA IGG/IGM)-SCREENING TEST FOR LEPTOSPIRA IGG AND IGM ANTIBODIES IN HUMAN SERUM/PLASMA OR WHOLE BLOOD SAMPLE IN ORDER TO DETECT LEPTOSPIROSIS.,ONE STEP JAPANESE ENCEPHALITIS VIRUS ANTIBODIES DETECTION TEST(MYTEST® JEV IGM)-SCREENING TEST FOR DETECTION OF JAPANESE ENCEPHALITIS VIRUS IGM ANTIBODIES IN HUMAN SERUM, PLASMA OR BLOOD SAMPLE FOR AID IN DIAGNOSIS OF PRIMARY INFECTION OF JE VIRUS.,ONE STEP LEISHMANIA ANTIBODY DETECTION TEST(MYTEST® LEISHMANIA AB) -SCREENING TEST FOR LEISHMANIA IGG AND IGM ANTIBODIES IN HUMAN SERUM/PLASMA OR WHOLE BLOOD SAMPLE IN ORDER TO DETECT LEISHMANIASIS.

3042	MFG/IVD/2021/000068	1.License Holder Name: PATHKITS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:RNA EXTRACTION KIT(PK RAPID VIRAL RNA EXTRACTION KIT)-VIRAL RNA EXTRACTION KIT IS FOR THE EXTRACTION,ENRICHMENT AND PURIFICATION OF NUCLEIC ACID(RNA) IN SAMPLES.IT PROCEEDS PRODUCTS ARE FOR CLINICAL IN VITRO DIAGNOSTICS FOR MEDICAL PROFESSIONALS.,RNA EXTRACTION KIT(PK MAGNETIC VIRAL RNA EXTRACTION KIT)-VIRAL RNA EXTRACTION KIT (MAGNETIC BEADS METHOD) IS FOR EXTRACTION, ENRICHMENT AND PURIFICATION OF NUCLEIC ACID (RNA) IN SAMPLES],COVID-19 AG RAPID TEST(PATHKITS SIMPLE COVID-19 AG RAPID KIT)-THE SIMPLE COVID-19 AG RAPID TEST IS A LATERAL FLOW IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SARS-COV-2 NUCLEOCAPSID ANTIGENS IN NASAL AND NASOPHARYNGEAL (NP) SWAB SPECIMENS FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER WITHIN THE FIRST FIVE DAYS OF THE ONSET OF SYMPTOMS. IT IS INTENDED FOR THE IDENTIFICATION OF INFECTION WITH SARS-COV-2, IN THE HUMAN BODY.
3043	MFG/IVD/2021/000069	1.License Holder Name: PATHKITS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:VIRAL LYSIS TRANSPORT MEDIA KIT(PK VIRAL LYSIS TRANSPORT MEDIA KIT)-PK VIRAL LYSIS TRANSPORT MEDIUM IS A SPECIALLY FORMULATED MEDIUM FOR COLLECTION AND TRANSPORT OF VIRUSES. IT IS DESIGNED TO MAINTAIN THE OPTIMUM VIABILITY AND VIRULENCE OF THE VIRAL SAMPLE.,VIRAL TRANSPORT MEDIA KIT(PK VIRAL TRANSPORT MEDIA KIT)-PK VIRAL TRANSPORT MEDIUM IS A SPECIALLY FORMULATED MEDIUM FOR COLLECTION AND TRANSPORT OF VIRUSES. IT IS DESIGNED TO MAINTAIN THE OPTIMUM VIABILITY AND VIRULENCE OF THE VIRAL SAMPLE.,UNIVERSAL TRANSPORT MEDIA KIT(PK UNIVERSAL TRANSPORT MEDIA KIT)-PK UNIVERSAL TRANSPORT MEDIUM IS A SPECIALLY FORMULATED MEDIUM FOR COLLECTION AND TRANSPORT OF VIRUSES. IT IS DESIGNED TO MAINTAIN THE OPTIMUM VIABILITY AND VIRULENCE OF THE VIRAL SAMPLE.

3044	MFG/IVD/2021/000070	1.License Holder Name: M/S MYLAB DISCOVERY SOLUTIONS PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:COVID-19 ANTIGEN LATERAL FLOW TEST DEVICE OTC HOME TEST(COVISELF TM)-THE COVISELF™ COVID-19 ANTIGEN LATERAL FLOW TEST (OTC HOME TEST) IS AN IN VITRO IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF NUCLEOCAPSID PROTEIN ANTIGEN FROM SARS-COV-2 IN DIRECT NASAL SWAB SPECIMENS DIRECTLY FROM INDIVIDUALS WITH OR WITHOUT SYMPTOMS OR OTHER EPIDEMIOLOGICAL REASONS TO SUSPECT COVID-19. THIS TEST IS AUTHORIZED FOR NONPRESCRIPTION HOME USE WITH SELF-COLLECTED NASAL SWAB SPECIMENS FROM INDIVIDUALS AGED 18 YEARS AND OLDER OR WITH ADULT-COLLECTED NASAL SWAB SAMPLES FROM INDIVIDUALS AGED 2 YEARS OR OLDER.

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3045	MFG/IVD/2021/000071	1.License Holder Name: MOLBIO DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: SUB ZONAL GOA 3.Device Name(Brand Name)-Intended Use:CHIP-BASED REAL TIME PCR TEST FOR CHLAMYDIA TRACHOMATIS(TRUENAT® CT)-TRUENAT® CT IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMIQUANTITATIVE DETECTION OF CHLAMYDIA TRACHOMATIS IN FEMALE ENDOCERVICAL AND VAGINAL SWAB SPECIMENS, MALE URETHRAL SWAB SPECIMEN AND MALE AND FEMALE URINE SPECIMEN. IT AIDS IN THE DIAGNOSIS OF SYMPTOMATIC OR ASYMPTOMATIC INFECTION WITH CHLAMYDIA TRACHOMATIS. TRUENAT® CT RUNS ON THE TRUELAB® REAL TIME MICRO PCR ANALYZERS. ,CHIP-BASED REAL TIME PCR TEST FOR RIFAMPICIN RESISTANT MYCOBACTERIUM TUBERCULOSIS (TRUENAT® MTB-RIF DX)-TRUENAT™ MTB-RIF DX IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE DETECTION OF RIFAMPICIN RESISTANCE IN MYCOBACTERIUM TUBERCULOSIS (MTB) IN TRUENAT™ MTB/MTB PLUS POSITIVE HUMAN SPECIMEN AND AIDS IN THE DIAGNOSIS OF MDR-TB. THIS TEST DETECTS THE PRESENCE OF MAJOR MUTATIONS (SNPS) IN THE MTB GENOME THAT ARE KNOWN TO CAUSE RESISTANCE TO RIFAMPICIN. TRUENAT™ MTB-RIF DX RUNS ON THE TRUELAB® REAL TIME QUANTITATIVE MICRO PCR ANALYZERS. THIS IS A FOLLOW ON TEST, TO BE PERFORMED ONLY ON THE EXTRACTED DNA FROM TRUENAT™ MTB/MTB PLUS POSITIVE SAMPLE. ,CHIP-BASED REAL TIME PCR TEST FOR MYCOBACTERIUM TUBERCULOSIS (TRUENAT® MTB PLUS)-TRUENAT® MTB PLUS IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE SEMIQUANTITATIVE DETECTION AND DIAGNOSIS OF MYCOBACTERIUM TUBERCULOSIS (MTB) IN HUMAN PULMONARY (SPUTUM/NON-SPUTUM) AND EPTB SPECIMEN AND AIDS IN THE DIAGNOSIS OF INFECTION WITH MTB. ,CHIP-BASED REAL TIME PCR TEST FOR MYCOBACTERIUM TUBERCULOSIS (TRUENAT® MTB)-TRUENAT® MTB IS A CHIP-BASED REAL TIME POLYMERASE CHAIN REACTION (PCR) TEST FOR THE QUANTITATIVE DETECTION AND DIAGNOSIS OF MYCOBACTERIUM TUBERCULOSIS (MTB) IN HUMAN PULMONARY AND EPTB SPECIMEN AND AIDS IN THE DIAGNOSIS OF INFECTION WITH MTB. ,CHIP-BASED REAL TIME PCR TEST FOR HEPATITIS C VIRUS (TRUENAT® HCV)-TRUENAT® HCV IS A CHIP-BASED REAL TIME REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) TEST FOR THE QUANTITATIVE DETECTION OF HEPATITIS C VIRUS (HCV) RNA IN HUMAN PLASMA, SERUM AND WHOLE BLOOD SAMPLES. TRUENAT® HCV AIDS IN THE DIAGNOSIS AND CONFIRMATION OF HCV INFECTION (IN CONJUNCTION WITH HCV ANTIBODY TEST) AND IN ESTIMATION OF VIRAL LOAD. IT IS NOT

		INTENDED AS A BLOOD DONOR SCREENING TEST. TRUENAT® HCV RUNS ON THE TRUELAB® REAL TIME MICRO PCR ANALYZERS. ,CHIP BASED REAL TIME DUPLEX PCR TEST FOR COVID-19(TRUENAT® COVID-19)-TRUENAT® COVID-19 IS A CHIP-BASED REAL TIME DUPLEX REVERSE TRANSCRIPTION POLYMERASE CHAIN REACTION (RT PCR) TEST FOR THE SEMI QUANTITATIVE DETECTION OF SARS COV-2 RNA IN HUMAN OROPHARYNGEAL AND NASOPHARYNGEAL SWAB SPECIMEN AND AIDS IN DETECTION AND CONFIRMATION OF SARS COV-2 INFECTION AND DIAGNOSIS OF COVID-19. THE TEST DETECTS THE E AND ORF1A GENES OF THE VIRUS. TRUENAT® COVID-19 RUNS ON TRUELAB® REAL TIME QUANTITATIVE MICRO PCR ANALYZERS.
3046	MFG/IVD/2021/000072	1.License Holder Name: MEDLEY PHARMACEUTICALS LTD 2.Approving Authority: JAMMU AND KASHMIR 3.Device Name(Brand Name)-Intended Use:SURGICAL DRESSING(HB SPRAY)-WOUND HEALING ULCER DRESSINGS
3047	MFG/IVD/2021/000073	1.License Holder Name: DIABETOMICS MEDICAL (P) LTD 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:SARS-COV-2 ANTIBODY TEST(COVABSCREEN / COVAB)-THE COVABSCREENTM SARS-COV-2 AB TEST IS A LATERAL FLOW IMMUNOASSAY INTENDED FOR QUALITATIVE DETECTION OF TOTAL ANTIBODIES (IGG+IGM+IGA) TO SARS-COV-2 IN ORAL FLUID SPECIMEN (GINGIVAL CREVICULAR FLUID, GCF)
3048	MFG/IVD/2021/000074	1.License Holder Name: AJAY BIO-TECH (INDIA) LTD 2.Approving Authority: BILASPUR,SHIMLA,KINNAUR ,SOLAN(OTHER THAN BBN) 3.Device Name(Brand Name)-Intended Use:MOLECULAR TRANSPORT MEDIUM(VIROTRAP)-VIROTRAP MOLECULAR TRANSPORT MEDIUM (MTM) SPECIALLY DESIGNED FOR HEALTHCARE WORKERS FOR MOLECULAR TESTING PERMITTING PATHOGENIC SAMPLES TO BE COLLECTED, TRANSPORTED, AND PROCESSED SAFELY AND EFFICIENTLY FOR THE MOLECULAR TESTING IN THE SARS-COV-2 PANDEMIC SITUATIONS.

3049	MFG/IVD/2021/000075	1.License Holder Name: KAYNES TECHNOLOGY INDIA PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:GLUCOMETER(BEATO CURV GLUCOMETER (USB C))-THE BEATO CURV USB TYPE-C GLUCOMETER IS INTENDED FOR USE IN THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN HUMAN WHOLE BLOOD TAKEN FROM THE FINGERTIP (CAPILLARY) OR FROM THE VEIN (VENOUS). IT IS INTENDED TO BE USED BY PEOPLE WITH DIABETES AT HOME OR CLINICAL SITE AS AN AID IN MONITORING THE EFFECTIVENESS OF THEIR DIABETES CONTROL PROGRAMS. THE BEATO CURV USB TYPE-C GLUCOMETER IS FOR IN VITRO DIAGNOSTIC USE ONLY. THE BEATO CURV USB TYPE-C GLUCOMETER IS NOT INTENDED FOR THE DIAGNOSIS OF, OR SCREENING FOR DIABETES. IT IS NOT INTENDED FOR USE ON NEONATES. THE BLOOD GLUCOSE TEST STRIP IS USED WITH THE BLOOD GLUCOSE METER IN THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN HUMAN WHOLE BLOOD TAKEN FROM THE FINGERTIP (CAPILLARY) OR FROM THE VEIN (VENOUS).
3050	MFG/IVD/2021/000076	1.License Holder Name: SANMINA-SCI INDIA PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE METERS (EXPORTS ONLY)-BLOOD GLUCOSE METERS ARE INTENDED TO BE USED FOR QUANTITATIVE BLOOD GLUCOSE TESTS IN FRESH CAPILLARY BLOOD FROM THE FINGER, PALM, FOREARM AND UPPER ARM AS A AIDE IN MONITORING THE EFFECTIVENESS OF GLUCOSE CONTROL. IT IS SUITABLE FOR SELF-TESTING AND FOR PROFESSIONAL USE.,BLOOD GLUCOSE METERS (EXPORTS ONLY)-BLOOD GLUCOSE METERS ARE INTENDED TO BE USED FOR QUANTITATIVE BLOOD GLUCOSE TESTS IN FRESH CAPILLARY BLOOD FROM THE FINGER, PALM, FOREARM AND UPPER ARM AS A AIDE IN MONITORING THE EFFECTIVENESS OF GLUCOSE CONTROL. IT IS SUITABLE FOR SELF-TESTING AND FOR PROFESSIONAL USE.,BLOOD GLUCOSE METERS (DOMESTIC & EXPORTS)-BLOOD GLUCOSE METERS ARE INTENDED TO BE USED FOR QUANTITATIVE BLOOD GLUCOSE TESTS IN FRESH CAPILLARY BLOOD FROM THE FINGER, PALM, FOREARM AND UPPER ARM AS A AIDE IN MONITORING THE EFFECTIVENESS OF GLUCOSE CONTROL. IT IS SUITABLE FOR SELF-TESTING AND FOR PROFESSIONAL USE.

3051	MFG/IVD/2021/000077	1.License Holder Name: OSBRO PHARMACEUTICAL PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:UNIVERSAL SAMPLE PRE-TREATMENT PACK FOR NON MTB SAMPLES(TRUEPREP® AUTO UNIVERSAL SAMPLE PRE-TREATMENT PACK)-TRUEPREP® AUTO UNIVERSAL SAMPLE PRE-TREATMENT PACK IS USED TO PRE-TREAT THE SAMPLES SUCH AS WHOLE BLOOD/ SERUM/PLASMA/URINE/STOOL/SWAB SPECIMENS/OTHER BODY FLUIDS BEFORE PROCEEDING FOR EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP® AUTO/AUTO V2 UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE.

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3052	MFG/IVD/2021/000078	1.License Holder Name: TOSOH INDIA PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:THYROGLOBULIN (TG) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),TOTAL PROSTATE SPECIFIC ANTIGEN (TPSA) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF PROSTATE SPECIFIC ANTIGEN (TPSA) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),CANCER ANTIGEN 19-9 (CA 19-9) CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND CANCER ANTIGEN 19-9 (CA 19-9) USING MICROPLATE ENZYME IMMUNOASSAY (ELISA), CANCER ANTIGEN 15-3 (CA 15-3) ENZYME CONJUGATE REAGENT (ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF CA-15.3 IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),MYOGLOBIN ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA), TOTAL PROSTATE SPECIFIC ANTIGEN (TPSA) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROSTATE SPECIFIC ANTIGEN (TPSA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,CANCER ANTIGEN 15-3 (CA 15-3) CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND CA-15.3 USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),TROPONIN I (CTNL) CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND TROPONIN-I (CTNL) USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),TOTAL PROSTATE SPECIFIC ANTIGEN (TPSA) CALIBRATOR SET(ACCULITE)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE PROSTATE SPECIFIC ANTIGEN (TPSA) USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,TOTAL PROSTATE SPECIFIC ANTIGEN (TPSA) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROSTATE SPECIFIC ANTIGEN (TPSA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE, CANCER ANTIGEN 125 (CA-125) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 125 (CA-125) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,ALPHA FETO PROTEIN (AFP) ELISA KIT(ACCUBIND)-

	FOR THE QUANTITATIVE DETERMINATION OF ALPHA-FETOPROTEIN (AFP) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,FREE PROSTATE SPECIFIC ANTIGEN (FPSA) CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND FREE PROSTATE SPECIFIC ANTIGEN (FPSA) USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),CARCINOEMBRYONIC ANTIGEN (CEA) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY,FREE PROSTATE SPECIFIC ANTIGEN (FPSA) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (FPSA) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,FERRITIN ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF FERRITIN IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA), THYROGLOBULIN (TG) CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND THYROGLOBULIN (TG) USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),THYROGLOBULIN (TG) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF THYROGLOBULIN (TG) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,CANCER ANTIGEN 15-3 (CA 15-3) CALIBRATOR SET (ACCULITE)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCULITE CA-15.3 USING MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,TROPONIN I (CTNL) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING TROPONIN-I CONCENTRATIONS IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,CANCER ANTIGEN 15-3 (CA 15-3) TRACER(ACCULITE)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF CA-15.3 IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,ALPHA FETO PROTEIN (AFP) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF ALPHA FETO PROTEIN (AFP) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA), TROPONIN I (CTNL) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF TROPONIN-I (CTNL) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),ALPHA FETO PROTEIN (AFP) CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND ALPHA FETO PROTEIN (AFP) USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),

	MYOGLOBIN ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING MYOGLOBIN CONCENTRATIONS IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,CANCER ANTIGEN 15-3 (CA 15-3) CLIA KIT(ACCULITE)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 15-3 (CA 15-3) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE,CARCINOEMBRYONIC ANTIGEN (CEA) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF CARCINOEMBRYONIC ANTIGEN (CEA) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),FERRITIN CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND FERRITIN USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),CANCER ANTIGEN 125 (CA-125) CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND CANCER ANTIGEN 125 (CA-125) USING MICROPLATE ENZYME IMMUNOASSAY (ELISA), CARCINOEMBRYONIC ANTIGEN (CEA) CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND CARCINOEMBRYONIC ANTIGEN (CEA) USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),CANCER ANTIGEN 19-9 (CA 19-9) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN 19-9 (CA 19-9) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY,MYOGLOBIN CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND MYOGLOBIN USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),CANCER ANTIGEN 15-3 (CA 15-3) ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CANCER ANTIGEN (CA 15-3) CONCENTRATION IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY, FERRITIN ELISA KIT(ACCUBIND)-FOR THE QUANTITATIVE DETERMINATION OF CIRCULATING FERRITIN CONCENTRATIONS IN HUMAN SERUM BY A MICROPLATE IMMUNOENZYMOMETRIC ASSAY, TOTAL PROSTATE SPECIFIC ANTIGEN (TPSA) TRACER (ACCULITE)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF PROSTATE SPECIFIC ANTIGEN (TPSA) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY, CHEMILUMINESCENCE METHOD,TOTAL PROSTATE SPECIFIC ANTIGEN (TPSA) CALIBRATOR SET(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR THE CALIBRATION OF ACCUBIND PROSTATE SPECIFIC ANTIGEN (TPSA) USING MICROPLATE ENZYME IMMUNOASSAY (ELISA),CANCER ANTIGEN 19-9 (CA 19-9) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF CA-19.9 IN HUMAN SERUM BY A

	MICROPLATE ENZYME IMMUNOASSAY (ELISA),FREE PROSTATE SPECIFIC ANTIGEN (FPSA) ENZYME CONJUGATE REAGENT (ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF FREE PROSTATE SPECIFIC ANTIGEN (FPSA) IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA),CANCER ANTIGEN 125 (CA-125) ENZYME CONJUGATE REAGENT(ACCUBIND)-FOR IN-VITRO DIAGNOSTIC USE ONLY FOR QUANTITATIVE DETERMINATION OF CA-125 IN HUMAN SERUM BY A MICROPLATE ENZYME IMMUNOASSAY (ELISA)

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3053	MFG/IVD/2021/000079	1.License Holder Name: OSCAR MEDICARE PVT. LTD. 2.Approving Authority: UTTARAKHAND 3.Device Name(Brand Name)-Intended Use:OVULATION TEST-MIDSTREAM(OVASTREAM)-LH MIDSTREAM / OVASTREAM TEST IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAYS FOR THE DETERMINATION OF LUTEINIZING HORMONE (LH), A MARKER FOR OVULATION, IN URINE SPECIMENS. FOR PROFESSIONAL USE ONLY., KALA AZAR TEST-STRIP / DIPSTICK (KALA AZAR TEST-STRIP / DIPSTICK)-THE OSCAR KALA AZAR TEST (STRIP / DIPSTICK) IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAYS FOR THE DETERMINATION OF ANTIBODIES TO VISCERAL LEISHMANIASIS (VL), MEMBERS OF L. DONOVANI, IN HUMAN SERUM SPECIMENS. FOR PROFESSIONAL USE ONLY.,TYPHOID ANTIBODY TEST (IGM/IGG) (TYPHOID ANTIBODY TEST (IGM/IGG))-TYPHOID IGM / IGG TEST DEVICE IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNOCHROMATOGRAPHY ON A MEMBRANE FOR DIFFERENTIAL DETECTION OF IGM AND IGG ANTIBODIES TO SALMONELLA TYPHI (S. TYPHI) IN HUMAN SERUM OR PLASMA. FOR PROFESSIONAL USE ONLY.,DENGUE ANTIBODY TEST (IGM/IGG) (DENGUE ANTIBODY TEST (IGM/IGG))-DENGUE ANTIBODY TEST (IGM/IGG) IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNOCHROMATOGRAPHY ON A MEMBRANE, FOR SIMULTANEOUS AND DIFFERENTIAL DETECTION OF DENGUE SPECIFIC ANTIBODY (IGM/IGG) IN HUMAN SERUM / PLASMA FOR DIAGNOSIS OF DENGUE INFECTION. FOR PROFESSIONAL USE ONLY., OVULATION TEST-STRIP / DIPSTICK (OVULATION TEST-STRIP / DIPSTICK)-LH TEST (STRIP / DIPSTICK) IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAYS FOR THE DETERMINATION OF LH (LUTEINIZING HORMONE), A MARKER FOR OVULATION, IN URINE SPECIMENS. FOR PROFESSIONAL USE ONLY.,CHIKUNGUNYA TEST (IGM/IGG) (CHIKUNGUNYA TEST (IGM/IGG))-CHIKUNGUNYA TEST IS AN IN VITRO DIAGNOSTIC RAPID TEST BASED ON THE PRINCIPLE OF IMMUNOCHROMATOGRAPHY ON A MEMBRANE, FOR SIMULTANEOUS AND DIFFERENTIAL DETECTION OF CHIKUNGUNYA SPECIFIC ANTIBODY (IGM/IGG) IN HUMAN SERUM / PLASMA FOR DIAGNOSIS OF CHIKUNGUNYA INFECTION. FOR PROFESSIONAL USE ONLY, PREGNANCY TEST-STRIP / DIPSTICK (PREGNANCY TEST-STRIP / DIPSTICK)- HCG TEST (STRIP /DIPSTICK) IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAY FOR THE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG), A MARKER FOR PREGNANCY, IN URINE SPECIMENS. FOR PROFESSIONAL USE ONLY. . , OVULATION TEST- CARD / CASSETTE(OVULATION TEST- CARD / CASSETTE)-LH TEST (CARD / CASSETTE) IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAYS FOR THE DETERMINATION OF

		LUTEINIZING HORMONE (LH), A MARKER FOR OVULATION, IN URINE SPECIMENS. FOR PROFESSIONAL USE ONLY,PREGNANCY TEST-CARD / CASSETTE(PREGSIGN)-PREGNANCY TEST (CARD / CASSETTE) IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAYS FOR THE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG), A MARKER FOR PREGNANCY, IN URINE SPECIMENS. FOR PROFESSIONAL USE ONLY,HCG TEST-MIDSTREAM(PREGSTREAM HCG)-HCG MIDSTREAM TEST / PREGSTREAM IS A DEVICE FOR THE RAPID, QUALITATIVE AND VISUAL DETECTION OF HCG IN THE HUMAN URINE. THIS TEST CAN BE USED BY SELF AT HOME OR AT CLINIC. PRESENCE OF HCG IN URINE INDICATES EARLY STAGE OF PREGNANCY AND ALLOWS TO CONSULT WITH THE DOCTOR / GYNECOLOGIST FOR THE MANAGEMENT OF PREGNANCY AND PRECAUTIONS TO BE TAKEN DURING THE STAGE OF PREGNANCY,H. PYLORI TEST (H.PYLORI TEST)-OSCAR H. PYLORI TEST IS A RAPID, QUALITATIVE, SANDWICH IMMUNOASSAY FOR SIMULTANEOUS DETECTION OF TOTAL ANTIBODIES (IGM / IGG / IGA) TO H. PYLORI IN HUMAN SERUM / PLASMA. FOR PROFESSIONAL USE ONLY.,KALA AZAR TEST- CARD / CASSETTE(KALA AZAR TEST- CARD / CASSETTE) -THE OSCAR KALA AZAR TEST (CARD / DEVICE) IS A RAPID, QUALITATIVE, TWO SITE SANDWICH IMMUNOASSAYS FOR THE DETERMINATION OF ANTIBODIES TO VISCERAL LEISHMANIASIS (VL), MEMBERS OF L. DONOVANI, IN HUMAN SERUM SPECIMENS. FOR PROFESSIONAL USE ONLY.
3054	MFG/IVD/2021/000080	1.License Holder Name: DHITI DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: UTTARAKHAND 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM KIT(VIRAL TRANSPORT MEDIUM KIT)-USED FOR COLLECTION & TRANSPORTATION OF SPECIMENS CONTAINING VIRUSES SUCH AS SARS COV2,SWINE FLU,
3055	MFG/IVD/2021/000081	1.License Holder Name: CHIMERA BIOTECH PRIVATE LIMITED 2.Approving Authority: SOUTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIA (CHIMERA)-THE KIT IS USED FOR COLLECTION AND TRANSPORTATION OF CLINICAL SPECIMEN FOR RECOVERY OF VIRUS. THIS IN-VITRO DIAGNOSTIC DEVICE IS A NON-HAZARDOUS TRANSPORT MEDIA CLEAR LIQUID SOLUTION.

3056	MFG/IVD/2021/000082	1.License Holder Name: AVIENCE BIOMEDICALS PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:COVID 19 RT PCR ASSAY (AVIENBIO)-THE SARS-COV-2 RNA QUALITATIVE RT-PCR" IS A REAL-TIME RT-PCR TEST INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEIC ACID FROM THE SARS-COV-2 IN NASOPHARYNGEAL OR OROPHARYNGEAL SWABS, SPUTUM, TRACHEAL ASPIRATES, AND BRONCHOALVEOLAR LAVAGE COLLECTED FROM PATIENTS SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. IT IS MEANT FOR THE DETECTION OF SARS-COV-2 RNA. THE SARS-COV-2 RNA IS GENERALLY DETECTABLE IN RESPIRATORY SPECIMENS DURING THE ACUTE PHASE OF INFECTION.
3057	MFG/IVD/2021/000083	1.License Holder Name: MATRIX LABS PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:DENGUE NS1 ELISA KIT (LISAZURE)-THE DENGUE NS1 ELISA TEST IS AN ENZYME-LINKED IMMUNOSORBENT ASSAY DESIGNED FOR THE QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN (DEN1, 2, 3, 4) IN HUMAN SERUM OR PLASMA. THE TEST KIT IS INTENDED FOR PROFESSIONAL USE ONLY.

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3058	MFG/MD/2018/000002	1.License Holder Name: ROBONIK (INDIA) PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:RHEUMATOID FACTOR (RF) TEST KIT (RHEUMATOID FACTOR (RF) TEST KIT)-FOR DETERMINATION OF RF IN SERUM PLASMA OR BODY FLUID.,CALCIUM CHLORIDE SOLUTION(CALCIUM CHLORIDE SOLUTION)-USED AS FIBRIN CLOT FORMATION IN DETERMINATION OF APTT,STRIPS FOR DETERMINATION OF GLUCOSE & PROTEIN IN URINE(URICHA GP)-DETERMINATION OF GLUCOSE AND PROTEIN IN URINE ,DILUENT (DILUENT)-ESTIMATION OF COMPLETE BLOOD COUNT IN BLOOD, MICRO PROTEIN TEST KIT (MICRO PROTEIN TEST KIT)-ESTIMATION OF MICRO PROTEIN IN SERUM OR PLASMA.,URIC ACID TEST KIT(URIC ACID TEST KIT)-ESTIMATION OF URIC ACID IN PLASMA, SERUM,UREA (GLDH -UV KINATIC) TEST KIT(UREA (GLDH -UV KINATIC) TEST KIT)-ESTIMATION OF UREA IN SERUM OR PLASMA.,UREA (MOD. BERTHELOT) TEST KIT(UREA (MOD. BERTHELOT) TEST KIT)-ESTIMATION OF UREA IN SERUM OR PLASMA.,TRIGLYCERIDES TEST KIT(TRIGLYCERIDES TEST KIT)-ESTIMATION OF TRIGLYCERIDES IN SERUM OR PLASMA,TOTAL PROTEIN TEST KIT(TOTAL PROTEIN TEST KIT)-ESTIMATION OF TOTAL PROTEIN IN SERUM/ PLASMA,ALT/SGPT TEST KIT(ALT/SGPT TEST KIT)-ESTIMATION OF SERUM GPT IN SERUM OR PLASMA,AST/SGOT TEST KIT(AST/SGOT TEST KIT)-ESTIMATION OF SGOT ENZYME IN SERUM/ PLASMA,PHOSPHORUS (INORGANIC) TEST KIT(PHOSPHORUS (INORGANIC) TEST KIT)-ESTIMATION OF PHOSPHORUS IN SERUM OR PLASMA.,HEMOGLOBIN TEST KIT (HEMOGLOBIN TEST KIT)-FOR ESTIMATION OF HEMOGLOBIN IN BLOOD,HBA1C TEST KIT(HBA1C TEST KIT)-ESTIMATION OF HBA1C IN SERUM, PLASMA.,GLUCOSE TEST KIT(GLUCOSE TEST KIT)-ESTIMATION OF GLUCOSE IN SERUM, PLASMA,GAMMA GT TEST KIT (GAMMA GT TEST KIT)-ESTIMATION OF GAMMA GT IN SERUM, PLAMA , CREATININE TEST KIT(CREATININE TEST KIT)-ESTIMATION OF CREATININE IN SERUM , PLASMA.,LDL CHOLESTROL (DIRECT) TEST KIT(LDL CHOLESTROL (DIRECT) TEST KIT)-ESTIMATION OF LDL CHOLESTEROL IN SERUM OR PLASMA,HDL CHOLESTEROL (DIRECT) TEST KIT(HDL CHOLESTEROL (DIRECT) TEST KIT)-ESTIMATION OF HDL CHOLESTEROL IN PLASMA OR SERUM.,HDL CHOLESTEROL (PRECIPITANT) TEST KITS(HDL CHOLESTEROL (PRECIPITANT) TEST KITS)-ESTIMATION OF HDL CHOLESTEROL BY PRECIPITATION METHOD IN SERUM OR PLASMA,TOTAL CHOLESTEROL TEST KIT (TOTAL CHOLESTEROL TEST KIT)-ESTIMATION OF TOTAL CHOLESTEROL IN PLASMA OR SERUM.,CHLORIDE TEST KIT(CHLORIDE TEST KIT)-ESTIMATION OF CHLORIDE IN PLASMA OR SERUM,CALCIUM (ARSENAZO) TEST KIT(CALCIUM (ARSENAZO) TEST KIT)-ESTIMATION OF CALCIUM IN PLASMA OR SERUM,CALCIUM (OCPC) TEST KIT

		(CALCIUM (OCPC) TEST KIT)-ESTIMATION OF CALCIUM IN PLASMA OR RESUM,BILIRUBIN (TOTAL & DIRECT) TEST KIT(BILIRUBIN (TOTAL & DIRECT) TEST KIT)-ESTIMATION OF BILIRUBIN TOTAL AND DIRECT IN SERUM AND PLASMA,BILIRUBIN TOTAL TEST KIT(BILIRUBIN TOTAL TEST KIT)-ESTIMATION OF BILIRUBIN IN SERUM OR PLASMA, AMYLASE TEST KIT(AMYLASE TEST KIT)-ESTIMATION OF ENZYME AMYLASE IN SERUM OR PLASMA.,ALKALINE PHOSPHATASE TEST KIT (ALKALINE PHOSPHATASE TEST KIT)-ESTIMATION OF ALKALINE PHOSPHATASE IN SERUM, PLASMA.,ALBUMIN TEST KIT(ALBUMIN TEST KIT)- IN VITRO DETERMINATION OF CONCENTRATION OF ALBUMIN IN SERUM, PLASMA,E Z CLEANER(E Z CLEANER)-FOR CLEANING OF COUNTING CHAMBER IN BLOOD CELL COUNTER,RINSE (RINSE)-FOR RINSING OF COUNTING CHAMBER AND OTHER TUBINGS IN BLOOD CELL COUNTER,LYSE(LYSE)-FOR ESTIMATION OF HEMOGLOBIN AND DIFFERENTIAL COUNT OF WBC ON BLOOD CELL COUNTER ,STRIPS FOR DETERMINATION OF GLUCOSE AND KETONE IN URINE(URICHA GK)-DETRMINATION OF GLUCOSE AND KETONE IN URINE,STRIPS FOR DETERMINATION OF GLUCOSE, PROTEIN, KETONE, BLOOD, BILIRUBIN,UROBILINOGEN, NITRITE, LEUCOCYTES, PH AND SPECIFIC GRAVITY IN URINE (URICHA -10)-DETERMINATION OF GLUCOSE, PROTEIN, KETONE, BLOOD, BILIRUBIN, UROBILINOGEN, NITRITE, LEUCOCYTES, PH AND SPECIFIC GRAVITY IN URINE
3059	MFG/MD/2018/000003	1.License Holder Name: CHINTAKUNTA MEDI EQUIPMENTS 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:HYPODERMIC DISPOSABLE SYRINGES(STERILIFE)-HOSPITAS AND MEDICAL LABS ETC.

3060	MFG/MD/2018/000004	1.License Holder Name: M/S. CYRO HEALTHCARE PVT. LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:POLY (UREA- URETHANE) POLYMER (HUMAN USE)-POLY RURCA-URETHANE] POLYMER IN ORGANIC SOLVENTS IS TOCOVER INTACT SKIN OR MINOR CUTS, SCRAPES, STING, BURNS AND IRRITATIONS OF THE SKIN TO HELP KEEP THEM CLEAN UND DRY AND HELP PROTECT THEM FROM INFECTION.,POLY (UREA- URETHANE) POLYMER (VETERINARY USE)-POLY [UREA-URETHANE) POLYMER IN ORGANIC SOLVENTS IS FOR USE ON COMPANION ANIMALS, INCLUDING DOGS, CATS, AND HORSES. FOR USE ON INTACT SKIN, PAWS OR HOOVES, OR TO TREAT CUTS, BITES, SCRAPES, HOTSPOTS, BUMS OR OTHER IRRITATIONS AND ABRASIONS, OR FOR USE ALTER MINOR SURGERIES TO KEEP WOUNDS CLEAN AND DRY.,POLY (UREA- URETHANE) POLYMER (NAIL CARE)-POLY [UREA-URETHANE] POLYMER IN ORGANIC SOLVENTS IS INDICATED FOR MANAGING SIGNS AND SYMPTOMS OF NAIL DYSTROPHY, I.E., NAIL SPLITTING AND NAIL FRAGILITY, FOR INTACT OR DAMAGED NAILS. POLY [UREA-URETHANE] POLYMER IN ORGANIC SOLVENTS COATS AND ADHERES TO THE NAIL SURFACE PREVENTING DIRECT ABRASION AND FRICTION ON THE NAIL SURFACE WHILE ALSO PROVIDING PROTECTION AGAINST THE EFFECTS OF MOISTURE.

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3061	MFG/MD/2018/000005	1.License Holder Name: SD BIOSENSOR HEALTHCARE PVT. LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ONE STEP RAPID TEST FOR DETECTION OF HEPATITIS B SURFACE ANTIGEN(STANDARD Q HBSAG, ULTRA HBSAG)-IT IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) PRESENT IN SERUM OR PLASMA., STANDARD Q ULTRA-DOT HCV-IT IS A VISUAL, RAPID, SENSITIVE AND ACCURATE IMMUNOASSAY TO DETECT ANTIBODIES AGAINST HCV IN HUMAN SERUM OR PLASMA,ONE STEP RAPID TEST FOR DETECTION OF HIV 1 & 2 ANTIBODIES(STANDARD Q HIV 1/2 AB, ULTRA HIV 1/2 AB) -IT IS A RAPID, QUALITATIVE IMMUNOASSAY TO DETECT CIRCULATING ANTIBODIES AGAINST HIV IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,STANDARD Q ULTRA-DOT HIV-IT IS A VISUAL, RAPID, SENSITIVE AND ACCURATE IMMUNOASSAY TO DETECT CIRCULATING ANTIBODIES AGAINST HIV IN HUMAN SERUM OR PLASMA.,IGRA ELISA KIT FOR DETECTION OF MYCOBACTERIUM TUBERCULOSIS(STANDARD E TB FERON ELISA, ULTRA TB FERON ELISA)-DETECTION OF INTERFERON-GAMMA (IFN-) BY ENZYME-LINKED IMMUNOSORBENT ASSAY (ELISA) IS USED TO IDENTIFY IN VITRO RESPONSES TO THOSE RECOMBINANT TB ANTIGENS THAT ARE ASSOCIATED WITH MYCOBACTERIUM TUBERCULOSIS INFECTION ,ULTRA HBSAG(NA)-ULTRA HBSAG TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) PRESENT IN SERUM OR PLASMA. ,ONE STEP RAPID TEST FOR DETECTION OF HEPATITIS C ANTIBODIES(STANDARD Q HCV AB, ULTRA HCV AB)-IT IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES TO HCV PRESENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,ULTRA BAR(NA)-IT IS USED FOR THE DETECTION OF BARBITURATE IN URINE. ,ONE STEP MALARIA P. F/PAN ANTIGEN RAPID TEST(STANDARD Q MALARIA PF/PAN AG, ULTRA MALARIA PF/PAN AG)-IT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DIFFERENTIAL DETECTION BETWEEN PLASMODIUM FALCIPARUM HISTIDINE-RICH-PROTEIN –II (HRP-II) AND PLASMODIUM SPECIES (PLASMODIUM FALCIPARUM, P VIVAX, P. OVALE AND P. MALARIAE) LACTATE DEHYDROGENASE (PLDH) IN HUMAN WHOLE BLOOD.,ULTRA AMP(NA)-IT IS USED FOR THE DETECTION OF AMPHETAMINE IN URINE.,ONE STEP MALARIA P.F/P.V ANTIGEN RAPID TEST(STANDARD Q MALARIA PF/P.V AG, ULTRA MALARIA PF/P.V AG)-IT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DIFFERENTIAL DETECTION BETWEEN PLASMODIUM FALCIPARUM HISTIDINE-RICH PROTEIN-II (HRP-II) AND PLDH (PLASMODIUM LACTATE DEHYDROGENASE) SPECIFIC TO

	PLASMODIUM VIVAX IN HUMAN WHOLE BLOOD. ,ONE STEP RAPID TEST KIT FOR DETECTION OF HIV 1 & 2 / SYPHILIS AB(STANDARD Q HIV/SYPHILIS COMBO, ULTRA HIV /SYPHILIS COMBO)-IT IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES SPECIFIC TO HIV-1 INCLUDING SUBTYPE 0, HIV-2 AND SYPHILIS (TREPONEMA PALLIDUM) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS FOR IN VITRO DIAGNOSTIC USE AND INTENDED AS AN AID TO DETECT ANTIBODIES TO HIV-1 /2 AND SYPHILIS IN INDIVIDUALS AT RISK FOR HIV-1/2 AND SYPHILIS INFECTION.,STANDARD Q COVID-19 IGM/IGG COMBO(NA)-IT IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES TO SARS-COV-2 PRESENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,ONE STEP RAPID TEST KIT FOR DETECTION OF HIV 1&2 AB(STANDARD Q HIV 1/2 AB 4-LINE , ULTRA HIV 1/2 AB 4-LINE)-IT IS A RAPID, QUALITATIVE IMMUNOASSAY TO DETECT CIRCULATING ANTIBODIES TO ALL ISO-TYPES OF HIV IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST IS FOR IN VITRO DIAGNOSTIC USE AND IS INTENDED AS AN AID TO EARLY DIAGNOSIS OF HIV INFECTION. THIS IS INTENDED FOR PROFESSIONAL USE, ONLY FOR AN INITIAL SCREENING TEST., STANDARD Q COVID-19 IGM/IGG DUO(NA)-STANDARD Q COVID-19 IGM/IGG DUO TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES TO COVID-19 PRESENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD , ONE STEP RAPID TEST KIT FOR DETECTION OF SYPHILIS AB (STANDARD Q SYPHILIS AB, ULTRA SYPHILIS AB)-IT IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTI-SYPHILIS FROM HUMAN SERUM, PLASMA OR WHOLE BLOOD. THIS TEST IS FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE AND INTENDED AS AN AID TO EARLY DIAGNOSIS OF SYPHILIS INFECTION.,STANDARD Q COVID -19 AG(NA)-STANDARD COVID-19 AG TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIGENS TO COVID-19 PRESENT IN HUMAN NASOPHARYNX AND OROPHARYNX , STANDARD M NCOV REAL TIME DETECTION KIT(NA)-STANDARD M NCOV REAL-TIME DETECTION KIT IS USED FOR IDENTIFICATION AND DETECTION OF NOVEL CORONAVIRUS (2019-NCOV) OR 1 AB (RDRP) GENE AND E GENE IN HUMAN NASOPHARYNGEAL SWAB, OROPHARYNGEAL SWAB, AND SPUTUM SPECIMENS USING REVERSE TRANSCRIPTION (RT) REAL-TIME PCR.,STANDARD F COVID-19 AG FIA (NA)-STANDARD F COVID-19 AG FIA IS THE FLUORESCENT IMMUNOASSAY TO DETECT COVID-19 INFECTION IN HUMAN NASOPHARYNGEAL SWAB SPECIMEN, IDENTIFYING EXISTENCE OF COVID-19 VIRAL NUCLEOPROTEIN ANTIGENS

3062	MFG/MD/2018/000006	1.License Holder Name: TAPAS BIOCARE 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P-USED AS SURGICAL DRESSING
3063	MFG/MD/2018/000008	1.License Holder Name: WOCKHARDT LIMITED 2.Approving Authority: DAMAN AND DIU 3.Device Name(Brand Name)-Intended Use:MEDICATION INJECTOR (GLYCIPEN, MYPEN II, GLARITUS PEN ROYALE, MYPEN, WOSULIN PEN ROYALE AND WOZULIM PEN ROYALE,)-A SUBCUTANEOUS INJECTION IS A METHOD OF ADMINISTERING MEDICATION
3064	MFG/MD/2018/000011	1.License Holder Name: RELYSIS MEDICAL DEVICES LIMITED 2.Approving Authority: CDSCO 3.Device Name(Brand Name)-Intended Use:DRUG ELUTING CORONARY STENT(EVRONIX)-THIS STENT IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF "DE NOVO" LESIONS IN NATIVE CORONARY ARTERIES.IT IS INDICATED FOR TREATMENT OF ABRUBT OR THREATENED CLOSURE IN PATIENTS WITH FAILED INTERVENTIONAL THERAPHY.THE TREATED LESION LENGTH SHOULD BE LESS THAN THE NOMINAL STENT LENGTH (08 TO 44 MM) WITH REFERENCE VESSEL DIAMETER MORE THAN 2.25 OR LESS THAN 5.00 MM.,POST DILATATION CATHETER(HISCO - NC)-POST-DILATION CATHETER IS A DOUBLE LUMEN CORONARY CATHETER DESIGNED ON A RAPID EXCHANGE PLATFORM WITH A BALLOON AND IT IS USED TO OPEN UP BLOCKED CORONARY ARTERIES ALLOWING BLOOD TO CIRCULATE UNOBSTRUCTED TO THE HEART MUSCLE.,PRE- DILATATION CATHETER(LAXO - SC)-PRE-DILATATION CATHETER IS A DOUBLE LUMEN CORONARY CATHETER ON A RAPID EXCHANGE PLATFORM WITH A BALLOON AND IT IS USED TO OPEN UP BLOCKED CORONARY ARTERIES,ALLOWING BLOOD TO CIRCULATE UNOBSTRUCTED TO THE HEART MUSCLE.

3065	MFG/MD/2018/000012	1.License Holder Name: BIORAD MEDISYS PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:TIBIAL EXTENSION ROD (GENUIN)-TOTAL MODULAR KNEE REPLACEMENT,TIBIAL TRAY (OURO)-ORTHOPEDIC IMPLANT SURGERY,TIBIAL TRAY(GENIUS)-TOTAL MODULAR KNEE REPLACEMENT,FEMORAL COMPONENT (OURO)-ORTHOPEDIC IMPLANT SURGERY,BIPOLAR HEAD(INDUS)-TOTAL HIP PROSTHESIS,CERVICAL PLATE(SOLACE)-SPINE IMPLANT SURGERY,FEMORAL HEAD(SIGNATURE)-TOTAL HIP REPLACEMENT, CERVICAL CAGE (WISDOM)-SPINE IMPLANT SURGERY ,FEMORAL COMPONENT(GENIUS)-TOTAL MODULAR KNEE REPLACEMENT, BALLOON HYDROPHILIC CATHETER-PTCA AND PTA (VESPREP, BFF, AMF, CITATION, ARION, ADIOS, PEGASUS)-PTCA: THE PTCA CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY INCLUDING IN-STENT RESTENOSIS, POST STENT DILATATION, OR BYPASS GRAFT FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. PTA: THE PTA CATHETER IS INTENDED TO DILATE STENOSIS IN THE ILIAC, FEMORAL, ILIO-FEMORAL, POPLITEAL, INFRA-POPLITEAL, AND RENAL ARTERIES AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THIS DEVICE IS ALSO RECOMMENDED FOR POST DILATATION OF BALLOON EXPANDABLE STENTS AND SELF-EXPANDING STENTS. ,ACETABULAR CUP(AVATAR)-TOTAL HIP REPLACEMENT,STERILE POLYPROPYLENE MESH(INDOVASIVE)-IT IS IMPLANTABLE MIDURETHRAL SUPPORT SLING SYSTEM INDICATED FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE (SUI) DEVICE.,SMP FEMORAL STEM(INDUS)-PARTIAL HIP PROSTHESIS (SMP),FEMORAL COMPONENT (GENIUS)-TOTAL MODULAR KNEE REPLACEMENT,ALL POLY TIBIA COMPONENT(GENIUS)-TOTAL MODULAR KNEE REPLACEMENT,TIBIAL TRAY (GENIUS)-TOTAL MODULAR KNEE REPLACEMENT,FEMORAL HEAD(INDUS)-TOTAL HIP REPLACEMENT,PTCA GUIDEWIRE(CHASE/INDOVASIVE)-INTENDED FOR INTERVENTIONAL CARDIOLOGY PROCEDURES.,ALL POLY TIBIAL COMPONENT(GENIUS)-TOTAL MODULAR KNEE REPLACEMENT, LUMBAR CAGE LORDOTIC(WISDOM)-SPINE IMPLANT SURGERY,TIBIAL INSERT(GENIUS)-TOTAL MODULAR KNEE REPLACEMENT,LUMBAR CAGE PARALLEL (WISDOM)-SPINE IMPLANT SURGERY ,ACETABULAR CUP(INDUS)-TOTAL HIP REPLACEMENT,ROD SMOOTH(PI-LOK)-SPINE IMPLANT SURGERY ,SCREW PLUG(SIGNATURE)-TOTAL HIP REPLACEMENT,CONNECTING ROD(PI-LOK)-SPINE IMPLANT SURGERY,UNCEMENTED HIP STEM(SIGNATURE)-TOTAL HIP REPLACEMENT,CERVICAL REVISION SCREW(SOLACE)-SPINE

	IMPLANT SURGERY,TIBIAL EXTENSION ROD(INDUS)-TOTAL KNEE PROSTHESIS,CERVICAL SCREW (SOLACE)-SPINE IMPLANT SURGERY , AVATAR CEMENTED COLLARLESS STEM WITH PLAIN CENTRALIZER AND WINGED CENTRALIZER (AVATAR)-TOTAL HIP REPLACEMENT, NUT & BOLT(ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,SMP FEMORAL HEAD(INDUS)-PARTIAL HIP PROSTHESIS (SMP),HIP & SHOLDER FIXETION PROSTHESIS(ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,BIPOLAR HEAD(AVATAR)-TOTAL HIP REPLACEMENT,FEMORAL METAL HEAD(AVATAR NX)-ORTHOPEDIC IMPLANT SURGERY,TIBIAL EXTENSION ROD(GENIUS)-TOTAL MODULAR KNEE REPLACEMENT,TIBIAL TRAY (GOLD)(OURO)-ORTHOPEDIC IMPLANT SURGERY,REVISION STEM(INDUS)-TOTAL HIP PROSTHESIS,FEMORAL COMPONENT (GOLD)(OURO)-ORTHOPEDIC IMPLANT SURGERY,PATELLAR COMPONENT(INDUS)-TOTAL KNEE PROSTHESIS,GUIDE PIN(ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,TIBIAL INSERT(GENUIN)-TOTAL MODULAR KNEE REPLACEMENT,LOCKING SYSTEM (ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,FEMORAL COMPONENT(GENUIN)-TOTAL MODULAR KNEE REPLACEMENT,INTRAMEDULLARY NAILS (ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY, INTRAMEDULLARY PLUG(AVATAR)-TOTAL HIP REPLACEMENT,BONE PLATE(ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY, UNCEMENTED STEM(INDUS)-TOTAL HIP PROSTHESIS,A.O. TYPE CLAMP & FOR HUMERUS/ TIBIA/FEMUR(ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,CERAMIC FEMORAL HEAD (SIGNATURE)-TOTAL HIP REPLACEMENT,A.O. TYPE CLAMP FOR RADIUS / ULNA / METACARPLAE(ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,TIBIAL TRAY(GENUIN)-TOTAL MODULAR KNEE REPLACEMENT,MENDIBAL SCREW(ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,BIPOLAR HEAD(SIGNATURE)-TOTAL HIP REPLACEMENT,LOCKING SYSTEM(ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,ACETABULAR LINER(SIGNATURE)-TOTAL HIP REPLACEMENT,BONE SCREW(ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,FEMORAL COMPONENT(INDUS)-TOTAL KNEE PROSTHESIS, MANDIBLE PLATES 1.5/2.0/2.5MM(ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,UNCEMENTED ACETABULAR CUP(SIGNATURE)-TOTAL HIP REPLACEMENT,EXTERNAL FIXETOR (ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,CEMENTED STEM(INDUS)-TOTAL HIP PROSTHESIS,PINS – SCREWS(ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,BONE SCREW(SIGNATURE)-TOTAL HIP REPLACEMENT,MANDIBLE PLATES 1.5/2.0/2.5MM(ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,ALL POLY TIBIAL COMPONENT (GENUIN)-TOTAL MODULAR KNEE REPLACEMENT,CR FEMORAL COMPONENT(GENIUS)-ORTHOPEDIC IMPLANT SURGERY,PATELLA

	(GENUIN)-TOTAL MODULAR KNEE REPLACEMENT,SPANNER (ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,CEMENTED CUP (INDUS)-TOTAL HIP PROSTHESIS,INTERLOCKING BOLT & FRAGMENT SCREWS (ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,TIBIAL COMPONENT(INDUS)-TOTAL KNEE PROSTHESIS,SPINE FIXETION IMPLANTS(ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY, PATELLA(GENIUS)-TOTAL MODULAR KNEE REPLACEMENT, UNCEMENTED COATED STEM (COATED WITH HYDROXYAPATITE I.E HA COATED)(AVATAR NX)-ORTHOPEDIC IMPLANT SURGERY,TRISTAR STEM(INDUS)-TOTAL HIP PROSTHESIS,WIRES - STAPLES (ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,FEMORAL METAL HEAD(AVATAR)-TOTAL HIP REPLACEMENT,ILIZAROW RING FIXETOR (ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,BIPOLAR HEAD (AVATAR /SIGNATURE/ INDUS/ AVATAR NX & AVATAR NXT)-HIP REPLACEMENT IS ALSO A PARTIAL HIP REPLACEMENT IS A SURGICAL PROCEDURE WHERE ONLY THE FEMORAL HEAD (THE BALL) OF THE DAMAGED HIP JOINT IS REPLACED. THE ACETABULUM (THE SOCKET) IS NOT REPLACED. BY CONTRAST, IN TOTAL HIP REPLACEMENT, THE ACETABULUM IS REPLACED WITH A PROSTHETIC.,CR TIBIAL INSERT (GENIUS)-ORTHOPEDIC IMPLANT SURGERY,REVISION STEM(INDUS)-LONG REVISION FEMORAL STEM FOR REVISION HIP ARTHROPLASTY IS REQUIRED WHEN EXTENSIVE BONE LOSS IS FOUND IN THE PROXIMAL FEMUR AND PRIMARY PROSTHESIS STARTS LOOSENING. IT IS INTENDED TO ACHIEVE AXIAL & ROTATIONAL MECHANICAL STABILITY. LONG REVISION FEMORAL STEM IS REQUIRED IN THE FOLLOWING CLINICAL INDICATIONS: DEGENERATIVE JOINT DISEASE (NIDJD) INFLAMMATORY JOINT DISEASE (IJD) RHEUMATOID ARTHRITIS AVASCULAR NECROSIS OSTEOARTHRITIS PROXIMAL BONE DEFECTS BONE FRACTURE FAILED PREVIOUS SURGERY WHERE PAIN DEFORMITY DIS-FUNCTION PERSIST POST TRAUMATIC ARTHRITIS REVISION OF PREVIOUSLY FAILED HIP ARTHROPLASTY INSTABILITY,LOCKING SYSTEM(ORTHOVASIVE)-ORTHOPEDIC IMPLANT SURGERY,ACETABULAR CUP(AVATAR NX)-AVATAR NX PROSTHESIS ARE REQUIRED WHEN THE HIP JOINT IS WORN OR DAMAGED SO THE MOBILITY IS REDUCED. AVATAR NX TOTAL/PARTIAL HIP REPLACEMENT IS USED TO TREAT POINT FAILURE DUE TO OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS AND CERTAIN HIP FRACTURES.,PROXIMAL COATED STEM(SIGNATURE)-PROSTHESIS ARE REQUIRED WHEN THE HIP JOINT IS WORN OR DAMAGED SO THE MOBILITY IS REDUCED. TOTAL/PARTIAL HIP REPLACEMENT IS USED TO TREAT POINT FAILURE DUE TO SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA, AVASCULAR NECROSIS

	OF THE FEMORAL HEAD, ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK, FAILED PREVIOUS HIP SURGERY (INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY AND/OR TOTAL ARTHROPLASTY), AND CERTAIN CASES OF ANKYLOSIS.,DUAL MOBILITY POLY INSERT(SIGNATURE)-DUAL MOBILITY SYSTEM IS INTENDED FOR USE IN THE FOLLOWING INDICATIONS: 1.NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE, INCLUDING OSTEOARTHRITIS & AVASCULAR NECROSIS. 2.RHEUMATOID ARTHRITIS 3.CORRECTION OF FUNCTIONAL DEFORMITY 4.REVISION OF PREVIOUSLY FAILED TOTAL HIP ARTHROPLASTY. 5.PATIENTS AT INCREASED RISK OF DISLOCATION. 6.DEVELOPMENTAL DYSPLASIA OF THE HIP (DDH),DUAL MOBILITY CUP(SIGNATURE)-DUAL MOBILITY SYSTEM IS INTENDED FOR USE IN THE FOLLOWING INDICATIONS: 1. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE, INCLUDING OSTEOARTHRITIS & AVASCULAR NECROSIS. 2.RHEUMATOID ARTHRITIS 3.CORRECTION OF FUNCTIONAL DEFORMITY 4.REVISION OF PREVIOUSLY FAILED TOTAL HIP ARTHROPLASTY. 5.PATIENTS AT INCREASED RISK OF DISLOCATION. 6.DEVELOPMENTAL DYSPLASIA OF THE HIP (DDH),DUAL MOBILITY HEAD(SIGNATURE)-DUAL MOBILITY SYSTEM IS INTENDED FOR USE IN THE FOLLOWING INDICATIONS: 1.NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE, INCLUDING OSTEOARTHRITIS & AVASCULAR NECROSIS. 2. RHEUMATOID ARTHRITIS 3.CORRECTION OF FUNCTIONAL DEFORMITY 4.REVISION OF PREVIOUSLY FAILED TOTAL HIP ARTHROPLASTY. 5.PATIENTS AT INCREASED RISK OF DISLOCATION. 6.DEVELOPMENTAL DYSPLASIA OF THE HIP (DDH),FEMORAL METAL HEAD(AVATAR NX)-AVATAR NX PROSTHESIS ARE REQUIRED WHEN THE HIP JOINT IS WORN OR DAMAGED SO THE MOBILITY IS REDUCED. AVATAR NX TOTAL/PARTIAL HIP REPLACEMENT IS USED TO TREAT POINT FAILURE DUE TO OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS AND CERTAIN HIP FRACTURES.,TIBIAL INSERT(GENIUS)-CANDIDATES FOR TOTAL KNEE REPLACEMENT INCLUDING PATIENTS WITH FOLLOWING CONDITIONS 1.SEVERE KNEE PAIN 2.DISABLED JOINT RESULTING FROM OSTEOARTHRITIS/LOSS OF MOBILITY 3.POST TRAUMATIC ARTHRITIS FAILED PREVIOUS IMPLANT,FEMORAL METAL HEAD(AVATAR NX)-AVATAR NX PROSTHESIS ARE REQUIRED WHEN THE HIP JOINT IS WORN OR DAMAGED SO THE MOBILITY IS REDUCED. AVATAR NX TOTAL/PARTIAL HIP REPLACEMENT IS USED TO TREAT POINT FAILURE DUE TO OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS AND CERTAIN HIP FRACTURES.,DUAL MOBILITY LINER(SIGNATURE)-DUAL MOBILITY SYSTEM IS INTENDED FOR USE IN THE FOLLOWING INDICATIONS: 1.NON-INFLAMMATORY

	DEGENERATIVE JOINT DISEASE, INCLUDING OSTEOARTHRITIS & AVASCULAR NECROSIS. 2.RHEUMATOID ARTHRITIS 3.CORRECTION OF FUNCTIONAL DEFORMITY 4.REVISION OF PREVIOUSLY FAILED TOTAL HIP ARTHROPLASTY. 5.PATIENTS AT INCREASED RISK OF DISLOCATION. 6.DEVELOPMENTAL DYSPLASIA OF THE HIP (DDH), CEMENTED STEM(AVATAR NXT)-AVATAR NXT PROSTHESIS ARE REQUIRED WHEN THE HIP JOINT IS WORN OR DAMAGED SO THE MOBILITY IS REDUCED. AVATAR NXT TOTAL/PARTIAL HIP REPLACEMENT IS USED TO TREAT POINT FAILURE DUE TO OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS AND CERTAIN HIP FRACTURES.,HEMOCLIP(INDOVASIVE)-THE HEMOCLIP IS INDICATED FOR ENDOSCOPIC CLIP PLACEMENT WITHIN THE GASTROINTESTINAL TRACT FOR THE PURPOSE OF: 1. ENDOSCOPIC MARKING 2. HEMOSTASIS FOR A) MUCOSAL/SUB-MUCOSAL DEFECTS 3CM B) BLEEDING ULCERS C) ARTERIES 2MM D) POLYPS 1.5CM IN DIAMETER E) DIVERTICULA IN THE COLON 3. ANCHORING TO AFFIX JEJUNAL FEEDING TUBES TO THE WALL OF THE SMALL BOWEL 4. AS A SUPPLEMENTARY METHOD, CLOSURE FOR GI TRACT LUMINAL PERFORATIONS 20MM THAT CAN BE TREATED CONSERVATIVELY.,URETERAL STENTS(INDOVASIVE)-URETERAL STENT IS USED FOR STENTING THE URETHRA AFTER HYPOSPADIAS OR EPISPADIAS REPAIR,FEMORAL COMPONENT (OURO CR)-CANDIDATES FOR TOTAL KNEE REPLACEMENT INCLUDING PATIENTS WITH FOLLOWING CONDITIONS 1.SEVERE KNEE PAIN 2.DISABLED JOINT RESULTING FROM OSTEOARTHRITIS/LOSS OF MOBILITY 3.POST TRAUMATIC ARTHRITIS FAILED PREVIOUS IMPLANT,ESOPHAGEAL DILATOR(INDOVASIVE)-ESOPHAGEAL DILATOR IS INTENDED FOR USE IN ADULT AND ADOLESCENT POPULATIONS TO ENDOSCOPICALLY DILATE STRICTURES OF THE ESOPHAGUS.,MINI BONE PLATE SYSTEM (1 MM)(PRESCA, PRESCIO , KRANEO, CRANIMAX, STERNFLEX , STERNAGRIP)-IT IS INTENDED FOR USE IN ORAL AND MAXILLOFACIAL SURGERY, MANDIBLE TRAUMA, MANDIBLE RECONSTRUCTION AND ORTHOGNATHIC SURGERY,BONE SCREW(AVATAR NX)-AVATAR NX PROSTHESIS ARE REQUIRED WHEN THE HIP JOINT IS WORN OR DAMAGED SO THE MOBILITY IS REDUCED. AVATAR NX TOTAL/PARTIAL HIP REPLACEMENT IS USED TO TREAT POINT FAILURE DUE TO OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS AND CERTAIN HIP FRACTURES.,HINGE KNEE (GENIUS ROTACON)-HINGE KNEE TKR PROSTHESIS IS INDICATED FOR SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS AND/OR MODERATE TO SEVERE KNEE INSTABILITY,SIGNIFICANT BONE LOSS, LIGAMENT DEFICIENCIES CAUSED BY: NEOPLASMS ,TRAUMA, RHEUMATOID ARTHRITIS,OSTEOARTHRITIS,TRAUMATIC ARTHRITIS POLYARTHRITIS, POST-TRAUMATIC ARTHRITIS,COLLAGEN

	DISORDERS,AVASCULAR NECROSIS OF THE FEMORAL CONDYLE, VARUS/VALGUS/FLEXION DEFORMITIES.,ACETABULAR LINER (AVATAR NX)-AVATAR NX PROSTHESIS ARE REQUIRED WHEN THE HIP JOINT IS WORN OR DAMAGED SO THE MOBILITY IS REDUCED. AVATAR NX TOTAL/PARTIAL HIP REPLACEMENT IS USED TO TREAT POINT FAILURE DUE TO OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS AND CERTAIN HIP FRACTURES.,FLOWER CENTRALISER(AVATAR)-HIP REPLACEMENT IS ALSO A PARTIAL HIP REPLACEMENT IS A SURGICAL PROCEDURE WHERE ONLY THE FEMORAL HEAD (THE BALL) OF THE DAMAGED HIP JOINT IS REPLACED. THE ACETABULUM (THE SOCKET) IS NOT REPLACED. BY CONTRAST, IN TOTAL HIP REPLACEMENT, THE ACETABULUM IS REPLACED WITH A PROSTHETIC.,BILIARY STENT (PLASTIC/METAL)(INDOVASIVE)-BILIARY PANCREATIC STENT IS THE TYPE OF STENTS USED TO DRAIN THE BILE DUCTS.,DOUBLE J CATHETERS/DOUBLE J STENT(INDOVASIVE)-DOUBLE J STENT IS USED FOR INTERNAL DRAINAGE FROM KIDNEY TO BLADDER., REVISION KNEE(GENIUS EVOCON)-TO REDUCE OR RELIEVE PAIN AND RESTORE FUNCTION AND MOTION TO THE KNEE JOINT. TOTAL KNEE REPLACEMENT IS INDICATED FOR PATIENTS WITH SEVER KNEE PAIN AND DISABILITY DUE TO RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, PRIMARY AND SECONDARY TRAUMATIC ARTHRITIS, POLYARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS OF THE FEMORAL CONDYLE OR PSEUDOGOUT, POSTTRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATTEKKECTOMY, MODERATE VALGUS VARUS OR FLEXION DEFORMITIES,SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, KNEE FRACTURES UNTREATABLE BY OTHER METHODS, REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT .,MULTI BAND LIGATOR/ MULTI BAND LIGATOR AND SET(INDOVASIVE)-MULTIBAND LIGATOR IS USED TO ENDOSCOPICALLY LIGATE ESOPHAGEAL VARICES AT OR ABOVE THE GASTROESOPHAGEAL JUNCTION OR TO LIGATE INTERNAL HEMORRHOIDS.,MULTIHOLE ACETABULAR CUP (SIGNATURE)-TOTAL HIP REPLACEMENT PROSTHESIS ARE REQUIRED WHEN THE HIP JOINT IS WORN OR DAMAGED SO THE MOBILITY IS REDUCED. TOTAL HIP REPLACEMENT IS USED TO TREAT POINT FAILURE DUE TO OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS AND CERTAIN HIP FRACTURES.,ACETABULAR LINER NEUTRAL(AVATAR NX)-AVATAR NX PROSTHESIS ARE REQUIRED WHEN THE HIP JOINT IS WORN OR DAMAGED SO THE MOBILITY IS REDUCED. AVATAR NX TOTAL/PARTIAL HIP REPLACEMENT IS USED TO TREAT POINT FAILURE DUE TO OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS

	AND CERTAIN HIP FRACTURES.,LONG REVISION STEM(SIGNATURE)-LONG REVISION FEMORAL STEM FOR REVISION HIP ARTHROPLASTY IS REQUIRED WHEN EXTENSIVE BONE LOSS IS FOUND IN THE PROXIMAL FEMUR AND PRIMARY PROSTHESIS STARTS LOOSENING. IT IS INTENDED TO ACHIEVE AXIAL & ROTATIONAL MECHANICAL STABILITY. LONG REVISION FEMORAL STEM IS REQUIRED IN THE FOLLOWING CLINICAL INDICATIONS: RHEUMATOID ARTHRITIS AVASCULAR NECROSIS OSTEOARTHRITIS PROXIMAL BONE DEFECTS BONE FRACTURE FAILED PREVIOUS SURGERY WHERE PAIN DEFORMITY DIS-FUNCTION PERSIST POST TRAUMATIC ARTHRITIS REVISION OF PREVIOUSLY FAILED HIP ARTHROPLASTY INSTABILITY,ACETABULAR CUP SCREW PLUG(AVATAR NX)-AVATAR NX PROSTHESIS ARE REQUIRED WHEN THE HIP JOINT IS WORN OR DAMAGED SO THE MOBILITY IS REDUCED. AVATAR NX TOTAL/PARTIAL HIP REPLACEMENT IS USED TO TREAT POINT FAILURE DUE TO OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS AND CERTAIN HIP FRACTURES.,REVISION KNEE(GENIUS EVOCON)-B.TO REDUCE OR RELIEVE PAIN AND RESTORE FUNCTION AND MOTION TO THE KNEE JOINT. TOTAL KNEE REPLACEMENT IS INDICATED FOR PATIENTS WITH SEVER KNEE PAIN AND DISABILITY DUE TO RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, PRIMARY AND SECONDARY TRAUMATIC ARTHRITIS, POLYARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS OF THE FEMORAL CONDYLE OR PSEUDOGOUT, POSTTRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATTEKKECTOMY, MODERATE VALGUS VARUS OR FLEXION DEFORMITIES,SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, KNEE FRACTURES UNTREATABLE BY OTHER METHODS, REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT .,PEG KIT (PERCUTANEOUS ENDOSCOPIC GASTROSTOMY)(INDOVASIVE)-IT IS A SOFT PLASTIC TUBE THAT IS PUT INTO THE STOMACH THROUGH THE SKIN, USED THE PATIENT FOR DECOMPRESSION,TIBIAL INSERT(GENIUS / GENUIN)-CANDIDATES FOR TOTAL KNEE REPLACEMENT INCLUDING PATIENTS WITH FOLLOWING CONDITIONS 1.SEVERE KNEE PAIN 2. DISABLED JOINT RESULTING FROM OSTEOARTHRITIS/LOSS OF MOBILITY 3.POST TRAUMATIC ARTHRITIS FAILED PREVIOUS IMPLANT,MID - BONE PLATE SYSTEM (1.5MM)(PRESCA, PRESCIO , KRANEO, CRANIMAX, STERNFLEX , STERNAGRIP)-IT IS INTENDED FOR USE IN ORAL AND MAXILLOFACIAL SURGERY, MANDIBLE TRAUMA, MANDIBLE RECONSTRUCTION AND ORTHOGNATHIC SURGERY,ALL POLY TIBIAL COMPONENT(GENIUS / GENUIN)-CANDIDATES FOR TOTAL KNEE REPLACEMENT INCLUDING PATIENTS WITH FOLLOWING CONDITIONS 1.SEVERE KNEE PAIN 2.DISABLED JOINT RESULTING

	FROM OSTEOARTHRITIS/LOSS OF MOBILITY 3.POST TRAUMATIC ARTHRITIS FAILED PREVIOUS IMPLANT,MAXI - MANDIBLE RECONSTRUCTION SYSTEM (2.5MM)(PRESCA, PRESCIO , KRANEO, CRANIMAX, STERNFLEX , STERNAGRIP)-IT IS INTENDED FOR USE IN ORAL AND MAXILLOFACIAL SURGERY, MANDIBLE TRAUMA, MANDIBLE RECONSTRUCTION AND ORTHOGNATHIC SURGERY, ACETABULAR CUP CENTRE SCREW PLUG(AVATAR NX)-AVATAR NX PROSTHESIS ARE REQUIRED WHEN THE HIP JOINT IS WORN OR DAMAGED SO THE MOBILITY IS REDUCED. AVATAR NX TOTAL/PARTIAL HIP REPLACEMENT IS USED TO TREAT POINT FAILURE DUE TO OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS AND CERTAIN HIP FRACTURES.,MICRO BONE PLATE/ SCREW/MESH SYSTEM(PRESCA, PRESCIO , KRANEO, CRANIMAX, STERNFLEX , STERNAGRIP)-IT IS INTENDED FOR USE IN ORAL AND MAXILLOFACIAL SURGERY, MANDIBLE TRAUMA, MANDIBLE RECONSTRUCTION, CARDIAC SURGERY/ ORTHOGNATHIC SURGERY AND STERNAL CLOSURE,ESOPHAGEAL METAL STENT (INDOVASIVE)-THE ESOPHAGEAL STENT IS INTENDED FOR RE-ESTABLISHING LUMINAL PATENCY IN ESOPHAGEAL STRICTURES CAUSED BY INTRINSIC AND/OR EXTRINSIC MALIGNANT TUMORS., STANDARD TIBIAL INSERT(GENIUS CR)-CANDIDATES FOR TOTAL KNEE REPLACEMENT INCLUDING PATIENTS WITH FOLLOWING CONDITIONS 1.SEVERE KNEE PAIN 2.DISABLED JOINT RESULTING FROM OSTEOARTHRITIS/LOSS OF MOBILITY 3.POST TRAUMATIC ARTHRITIS FAILED PREVIOUS IMPLANT,REVISION KNEE(GENIUS EVOCON)-TO REDUCE OR RELIEVE PAIN AND RESTORE FUNCTION AND MOTION TO THE KNEE JOINT. TOTAL KNEE REPLACEMENT IS INDICATED FOR PATIENTS WITH SEVER KNEE PAIN AND DISABILITY DUE TO RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, PRIMARY AND SECONDARY TRAUMATIC ARTHRITIS, POLYARTHRITIS, COLLAGEN DISORDERS, AVASCULAR NECROSIS OF THE FEMORAL CONDYLE OR PSEUDOGOUT, POSTTRAUMATIC LOSS OF JOINT CONFIGURATION, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATTEKKECTOMY, MODERATE VALGUS VARUS OR FLEXION DEFORMITIES,SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, KNEE FRACTURES UNTREATABLE BY OTHER METHODS, REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT.,MAXI - MANDIBLE RECONSTRUCTION SYSTEM (2MM)(PRESCA, PRESCIO , KRANEO, CRANIMAX, STERNFLEX , STERNAGRIP)-IT IS INTENDED FOR USE IN ORAL AND MAXILLOFACIAL SURGERY, MANDIBLE TRAUMA, MANDIBLE RECONSTRUCTION AND ORTHOGNATHIC SURGERY,HINGE KNEE(GENIUS ROTACON)-HINGE KNEE TKR PROSTHESIS IS INDICATED FOR SALVAGE OF PREVIOUSLY FAILED SURGICAL

	ATTEMPTS AND/OR MODERATE TO SEVERE KNEE INSTABILITY, SIGNIFICANT BONE LOSS,LIGAMENT DEFICIENCIES CAUSED BY: NEOPLASMS ,TRAUMA,RHEUMATOID ARTHRITIS,OSTEOARTHRITIS, TRAUMATIC ARTHRITIS POLYARTHRITIS, POST-TRAUMATIC ARTHRITIS,COLLAGEN DISORDERS,AVASCULAR NECROSIS OF THE FEMORAL CONDYLE,VARUS/VALGUS/FLEXION DEFORMITIES., URETHRAL STENT/ CATHETER(INDOVASIVE)-URETHRAL STENT IS USED FOR STENTING THE URETHRA AFTER HYPOSPADIAS OR EPISPADIAS REPAIR,UNCEMENTED COATED STEM (FULLY/PROXIMAL)(AVATAR NX / SIGNATURE)-AVATAR NX PROSTHESIS ARE REQUIRED WHEN THE HIP JOINT IS WORN OR DAMAGED SO THE MOBILITY IS REDUCED. AVATAR NX TOTAL/PARTIAL HIP REPLACEMENT IS USED TO TREAT POINT FAILURE DUE TO OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS AND CERTAIN HIP FRACTURES,HINGE KNEE (GENIUS ROTACON)-HINGE KNEE TKR PROSTHESIS IS INDICATED FOR SALVAGE OF PREVIOUSLY FAILED SURGICAL ATTEMPTS AND/OR MODERATE TO SEVERE KNEE INSTABILITY,SIGNIFICANT BONE LOSS, LIGAMENT DEFICIENCIES CAUSED BY: NEOPLASMS ,TRAUMA, RHEUMATOID ARTHRITIS,OSTEOARTHRITIS,TRAUMATIC ARTHRITIS POLYARTHRITIS, POST-TRAUMATIC ARTHRITIS,COLLAGEN DISORDERS,AVASCULAR NECROSIS OF THE FEMORAL CONDYLE, VARUS/VALGUS/FLEXION DEFORMITIES

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3066	MFG/MD/2018/000015	1.License Holder Name: AUSTRALIAN ORTHOPAEDIC INDIA PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:SUTURE -THE SUTURE STRANDS ATTACHED TO THE NEEDLE IS PASSED THROUGH THE SOFT TISSUE OF SHOULDER OR KNEE JOINT. THE NEEDLE IS THEN DISPOSED OFF.,CORTICAL SUSPENSION LOOP-THE METAL PLATE WITH OZ LOOP IS SUSPENDED OVER THE CORTICAL BONE WHICH PROVIDES A SUSPENSORY FIXATION FOR THE GRAFT WHICH IS PASSED THROUGH THE TUNNEL IN THE BONE OF KNEE JOINT.OZ LOOP IS INTENDED FOR USE IN THE FIXATION OF LIGAMENTS & TENDONS IN PATIENTS REQUIRING LIGAMENT OR TENDON REPAIR., ANCHOR -THE ANCHOR IS INSERTED INTO THE PREDRILLED HOLE IN THE BONE OF THE SHOULDER OR KNEE JOINT WITH THE HELP OF INSERTER HANDLE. THE HANDLE IS DISPOSED OFF AFTER INSERTION. THE SUTURE STRANDS ARE PASSED THROUGH THE SOFT TISSUE TO ANCHOR IT TO THE BONE AT INSERTION SITE. IT IS ORTHOPEDIC IMPLANT USED FOR ATTACHMENT OF SOFT TISSUE TO BONE. , INTERFERENCE SCREW-THE GRAFT IS EARLIER PASSED THROUGH THE TUNNEL DRILLED IN THE BONE OF THE KNEE JOINT. THE INTERFERENCE SCREW IS PASSED THROUGH THE SAME TUNNEL BESIDES THE GRAFT SO AS TO FIX THE GRAFT TO THE BONE. OZ SCREW IS INTENDED FOR USE IN THE FIXATION OF LIGAMENTS & TENDONS IN PATIENTS REQUIRING LIGAMENT OR TENDON REPAIR.
3067	MFG/MD/2018/000016	1.License Holder Name: J J IMPLANTS 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT (GENESIS)-IT IS SURGICAL COMPONENT THAT INTERFACES WITH THE BONE OF THE JAW OR SKULL TO SUPPORT A DENTAL PROSTHESIS SUCH AS CROWN, BRIDGE, DENTURE, FACIAL PROSTHESIS OR TO ACT AS AN ORTHODONTIC ANCHOR.

3068	MFG/MD/2018/000017	1.License Holder Name: ANGSTROM BIOTECH PVT. LTD. 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIA KIT (VTM KIT)(ANG VTM)-THIS KIT IS SPECIALLY FOR COLLECTION & TRANSPORT OF SAMPLES OF VIRUSES AND IS DESIGNED TO MAINTAIN OPTIMUM VIABILITY AND VIRULENCE OF VIRAL SAMPLES., UREA (BUN) TEST REAGENT/KIT(UREA GLDH)- ESTIMATION OF UREA/BLOOD UREA NITROGEN (BUN) IN PLASMA/ SERUM / URINE., UREA (BUN) TEST REAGENT/KIT-ESTIMATION OF UREA/BLOOD UREA NITROGEN (BUN) IN PLASMA/ SERUM / URINE.,GAMMA GLUTAMYLTRANSFERASE(GGT) AND ISOENZYMES TEST REAGENT/KIT-ESTIMATION OF THE ENZYME GAMMA GLUTAMYL TRANSFERASE (GGT) IN SERUM / PLASMA. ,GLUCOSE TEST REAGENT/KIT-ESTIMATION OF GLUCOSE IN BLOOD/PLASMA/ BODY FLUIDS.,CHOLESTEROL TEST REAGENT/KIT-ESTIMATION OF CHOLESTEROL IN BLOOD /BODY FLUIDS,AMYLASE TEST REAGENT/KIT-ESTIMATION OF THE ENZYME AMYLASE IN SERUM, SALIVA / URINE,PHOSPHORUS (INORGANIC)TEST REAGENT/KIT-ESTIMATION OF INORGANIC PHOSPHORUS IN SERUM PLASMA / URINE,CHLORIDE TEST REAGENT/KIT-ESTIMATION OF CHLORIDE IN PLASMA SERUM, SWEAT /URINE.,CALCIUM TEST REAGENT/KIT-ESTIMATION OF TOTAL CALCIUM IN SERUM.,ALKALINE PHOSPHATASE ORISOENZYMES TEST REAGENT/KIT-ESTIMATION OF ALKALINE PHOSPHATASE OR ITS ISOENZYMES IN SERUM/PLASMA., ALBUMIN TEST REAGENT/KIT- ESTIMATION OF ALBUMIN IN SERUM/PLASMA. ,LIPASE TEST REAGENT/KIT- ESTIMATION OF LIPASE IN SERUM / PLASMA.,TOTAL PROTEIN TEST REAGENT/KIT-ESTIMATION OF TOTAL PROTEIN(S) IN SERUM/ PLASMA. , GLYCOSYLATED HEMOGLOBIN OR ITS VARIANTS TEST REAGENT/KIT (GLYCOHEMOGLOBIN)- ESTIMATION OF GLYCOSYLATED HEMOGLOBIN OR ITS VARIANTS INCLUDING A1A, A1B, AND A1C IN BLOOD,TSH TEST REAGENT/KIT- ESTIMATION OF TSH IN BLOOD/BODY FLUIDS.,LIPOPROTEIN TEST REAGENT/KIT-ESTIMATION OF LIPOPROTEINS IN SERUM /PLASMA.,TOTAL / FREE THYROXINE(T4) TEST REAGENT/KIT- ESTIMATION OF TOTAL / FREE THYROXINE (T4)IN BLOOD/BODYFLUIDS,TOTAL /FREETRIIODOTHYRONINE (T3)TEST REAGENT/KIT- ESTIMATION OF TOTAL /FREE TRIIODOTHYRONINE (T3) IN BLOOD/BODY FLUIDS., CHOLINESTERASE TESTR EAGENT/KIT- ESTIMATION OF CHOLINESTERAL IN SERUM /PLASMA.,MICRO-PROTEIN TEST REAGENT/KIT(MICRO ALBUMIN)-ESTIMATION OF MICRO-PROTEINS INCLUDING MICRO-ALBUMIN IN URINE. ,LDL CHOLESTEROL TEST REAGENT/KIT(LDL C DIRECT)- ESTIMATION OF LDL CHOLESTEROL IN SERUM/PLASMA.,ACID PHOSPHATASE (TOTAL OR PROSTATIC) TEST

	REAGENT/KIT(PHOSPHATE DH)- ESTIMATION OF ACID PHOSPHATASE IN SERUM/PLASMA.,GLUCOSE-6-PHOSPHATE DEHYDROGENASE(G6PD) AND ITS ISOENZYMES TEST REAGENT/KIT-TO DETECT ESTIMATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE OR ITS ISOENZYMES IN SERUM / PLASMA., GLUCOSE TEST REAGENT/KIT-ESTIMATION OF GLUCOSE IN BLOOD/PLASMA/ BODY FLUIDS,LACTATE DEHYDROGENASEAND ITS ISOENZYMES TESTREAGENT/KIT(LDH P-L)-ESTIMATION OF ENZYME LACTATE DEHYDROGENASE AND ITS ISOENZYMES IN SERUM / PLASMA. ,LACTATE DEHYDROGENASEAND ITS ISOENZYMES TESTREAGENT/KIT(LDH L-P)-ESTIMATION OF ENZYME LACTATE DEHYDROGENASE AND ITS ISOENZYMES IN SERUM / PLASMA. , ALANINE AMINOTRANSFERASE(ALT/SGPT) TESTREAGENT/KIT(SGPT) -ESTIMATION OFENZYME ALANINE AMINOTRANSFERASE (ALT/SGPT) IN SERUM /PLASMA.,ASPARTATE AMINOTRANSFERASE(AST/SGOT) TESTREAGENT/KIT(SGOT)-ESTIMATION OF THE ENZYME ASPARTATE AMINO TRANSFERASE (AST/SGOT) IN SERUM / PLASMA.,CREATINE KINASE AND ITSISOENZYMESTESTREAGENTS/KIT(CK-MB)-ESTIMATION OF THE ENZYME CREATINE PHOSPHOKINASE OR ITS ISOENZYMES IN SERUM / PLASMA.,CREATINE KINASE AND ITSISOENZYMESTESTREAGENTS/KIT(CK-NAC)-TO ESTIMATE THE ENZYME CREATINE PHOSPHOKINASE OR ITS ISOENZYMES IN SERUM / PLASMA.,URIC ACID TESTREAGENT/KIT- ESTIMATION OF URIC ACID IN SERUM/PLASMA / URINE.,CREATININE TEST REAGENT/KIT - ESTIMATION OF CREATININE IN SERUM, PLASMA / URINE.,A HDL CHOLESTEROL TEST REAGENT/KIT -ESTIMATE OF HDL CHOLESTEROL IN SERUM/PLASMA,RHEUMATOID FACTOR (RF) IMMUNOLOGICAL TEST REAGENTS/KIT-SCREENING OF RHEUMATOID FACTOR IN HUMAN SPECIMENS ,HEMOGLOBIN TEST REAGENT/KIT-ESTIMATION OF HEMOGLOBIN IN BLOOD.,HUMAN CHORIONIC GONADOTROPIN (HCG) TEST REAGENT/KIT(PREGNANCY STRIP AND CARD KIT)-TO DETECT PREGNANCY BY CHECKING PRESENCE OF HCG IN URINE.,HDL CHOLESTEROL TEST REAGENT/KIT (HDL C DIRECT)-ESTIMATION OF HDL CHOLESTEROL IN SERUM/PLASMA,IRON TEST REAGENT/KIT-FOR THE ESTIMATION OF IRON IN SERUM /PLASMA., PROTEIN (FRACTIONATION) TEST REAGENT/KIT (REAGENT STRIP FOR URINE ANALYSIS GLUCOSE)-THE ESTIMATION OF PROTEIN FRACTIONS IN BLOOD, URINE, CEREBROSPINAL FLUID / OTHER BODY FLUIDS.,GLUCOSE TEST REAGENT/KIT(REAGENT STRIP FOR URINE ANALYSIS GLUCOSE)-ESTIMATION OF GLUCOSE IN BLOOD/PLASMA/ BODY FLUIDS,ALANINE AMINO TRANSFERASE (ALT/SGPT) TEST REAGENT/KIT (SGPT LS)-FOR THE ESTIMATION OF ENZYME ALANINE AMINO TRANSFERASE (ALT/SGPT) IN SERUM /PLASMA.,ASPARTATE AMINO TRANSFERASE (AST/SGOT) TEST REAGENT/KIT (SGOT LS)-

	FOR THE ESTIMATION OF THE ENZYME ASPARTATE AMINO TRANSFERASE (AST/SGOT) IN SERUM / PLASMA.,URIC ACID TEST REAGENT/KIT- ESTIMATION OF URIC ACID IN SERUM/PLASMA / URINE.,TRIGLYCERIDES TEST REAGENT/KIT(TRIGLYCERIDES LS)- ESTIMATION OF TRIGLYCERIDES IN SERUM / PLASMA.,MAGNESIUM TEST REAGENT/KIT- ESTIMATION OF MAGNESIUM LEVELS IN SERUM / PLASMA.,POTASSIUM TEST REAGENT/KIT- ESTIMATION OF POTASSIUM IN SERUM PLASMA / URINE.,SODIUM TEST REAGENT/KIT- ESTIMATION OF SODIUM IN SERUM/ PLASMA / URINE.,ALANINE AMINO TRANSFERASE (ALT/SGPT) TEST REAGENTS/KITS (SGPT DNHP)-FOR THE ESTIMATION OF ENZYME ALANINE AMINO TRANSFERASE (ALT/SGPT) IN SERUM /PLASMA.,ASPARTATE AMINO TRANSFERASE (AST/SGOT) TEST REAGENT/KIT (SGOT DNPH)-FOR THE ESTIMATION OF THE ENZYME ASPARTATE AMINO TRANSFERASE (AST/SGOT) IN SERUM / PLASMA.,GLUCOSE-6-PHOSPHATE DEHYDROGENASE(G6PD) AND ITS ISOENZYMES TEST REAGENT/KIT (GLUCOSE LS)-ESTIMATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE OR ITS ISOENZYMES IN SERUM / PLASMA.,HDL CHOLESTEROL TEST REAGENT/KIT (CHOLESTEROL LS WITH HDL)- FOR THE ESTIMATION OF HDL CHOLESTEROL IN SERUM / PLASMA., CALCIUM TEST REAGENT/KIT(CALCIUM ARSENAZO)- ESTIMATION OF TOTAL CALCIUM IN SERUM.,BILIRUBIN (TOTAL AND DIRECT) TEST REAGENT/KIT- ESTIMATION OF BILIRUBIN (TOTAL AND DIRECT) IN SERUM/PLASMA.,GLUCOSE-6-PHOSPHATE DEHYDROGENASE (G6PD) AND ITS ISOENZYMES TEST REAGENT/KIT (GLUCOSE-6-PHOSPHATE DYE)-ESTIMATION OF GLUCOSE-6-PHOSPHATE DEHYDROGENASE OR ITS ISOENZYMES IN SERUM / PLASMA.

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3069	MFG/MD/2018/000018	1.License Holder Name: CARTEL HEALTHCARE PVT LTD 2.Approving Authority: CHHATTISGARH 3.Device Name(Brand Name)-Intended Use:PERFUSION SET FOR SINGLE USE(BIO-SAFE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VAIN.,MEASURED VOLUME IV SET(BIO-SAFE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,BLOOD ADMINISTRATION KIT(BIO-SAFE)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.,SINGLE LUMEN HYPODERMIC NEEDLE(BIO-SAFE)-A HYPODERMIC SINGLE LUMEN NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN., DISPOSABLE HYPODERMIC SYRINGE(BIO-SAFE)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.
3070	MFG/MD/2018/000019	1.License Holder Name: CEVA POLCHEM PRIVATE LIMITED 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE,ALKYL DIMETHYL ETHYL BENZYL AMMONIUM CHLORIDE,ORTHOPTHALALDEHYDE(AQUINA STAR)-USE IN POULTRY

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3071	MFG/MD/2018/000020	1.License Holder Name: MERIL LIFE SCIENCES PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:SINUS BALLOON CATHETER SYSTEM(MESIRE PRO)-IT IS INTENDED TO DILATE SINUS OSTIA AND SPACES WITHIN THE PARANASAL SINUS CAVITIES FOR DIAGNOSTIC AND THERAPEUTIC PROCEDURES.,EUSTACHIAN TUBE GUIDE CATHETER(MYCS GUIDE)-IT IS INTENDED TO PROVIDE A MEANS TO ACCESS THE EUSTACHIAN TUBE.,EUSTACHIAN TUBE BALLOON DILATATION CATHETER(MYCS BALLOON CATHETER)-IT IS INTENDED TO DILATE THE EUSTACHIAN TUBE FOR TREATMENT OF PERSISTENT EUSTACHIAN TUBE DYSFUNCTION IN ADULTS AGED 22 AND OLDER.,AIRWAY BALLOON CATHETER(METIC)-IT IS USED TO SAFELY DILATE AIRWAY STRICTURES SUCH AS IN THE TRACHEA AND UPPER BRONCHI WITH MINIMAL MUCOSAL TRAUMA,SINUS BALLOON CATHETER(MESIRE SINUS BALLOON CATHETER)-TO DILATE SINUS OSTIA AND SPACES WITHIN THE PARANASAL SINUS CAVITIES FOR DIAGNOSTIC AND THERAPEUTIC PROCEDURES.,SINUS GUIDE CATHETER(MESIRE GUIDE)-TO PROVIDE A ACCESS PATH TO SINUS OSTIUM FOR BALLOON CATHETER.,SINUS LIGHT WIRE(MESIRE ILLUMINUS)-FOR GUIDING THE CATHETER INTO RIGHT SINUS OSTIUM, BALLOON SINUS DILATATION SYSTEM(MESIRE SPHENOID SINUS KIT)-SINUS BALLOON CATHETER IS INDICATED TO DILATE SINUS OSTIA AND SPACES WITHIN THE PARANASAL SINUS CAVITIES FOR DIAGNOSTIC AND THERAPEUTIC PROCEDURES. SINUS GUIDE CATHETER IS INDICATED TO PROVIDE A ACCESS PATH TO SINUS OSTIUM FOR BALLOON CATHETER. SINUS LIGHT WIRE IS INDICATED FOR GUIDING THE CATHETER INTO RIGHT SINUS OSTIUM.,BALLOON SINUS DILATATION SYSTEM(MESIRE FRONTAL SINUS KIT)-SINUS BALLOON CATHETER IS INDICATED TO DILATE SINUS OSTIA AND SPACES WITHIN THE PARANASAL SINUS CAVITIES FOR DIAGNOSTIC AND THERAPEUTIC PROCEDURES. SINUS GUIDE CATHETER IS INDICATED TO PROVIDE A ACCESS PATH TO SINUS OSTIUM FOR BALLOON CATHETER. SINUS LIGHT WIRE IS INDICATED FOR GUIDING THE CATHETER INTO RIGHT SINUS OSTIUM.,BALLOON SINUS DILATATION SYSTEM(MESIRE MAXILLARY SINUS KIT)-SINUS BALLOON CATHETER IS INDICATED TO DILATE SINUS OSTIA AND SPACES WITHIN THE PARANASAL SINUS CAVITIES FOR DIAGNOSTIC AND THERAPEUTIC PROCEDURES. SINUS GUIDE CATHETER IS INDICATED TO PROVIDE A ACCESS PATH TO SINUS OSTIUM FOR BALLOON CATHETER. SINUS LIGHT WIRE IS INDICATED FOR GUIDING THE CATHETER INTO RIGHT SINUS OSTIUM.

3072	MFG/MD/2018/000022	1.License Holder Name: MERIL DIAGNOSTICS PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:RF (RHEUMATOID FACTOR) KIT(CLINIQUANT (3RD BRAND) AND AUTOQUANT (4TH BRAND))-IT IS USED FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR (RF) CONCENTRATION IN SERUM BY LATEX TURBIDIMETRY.,GLUCOSE KIT(CLINIQUANT-FSR (1ST BRAND), MARANATHA (2ND BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF GLUCOSE CONCENTRATION IN HUMAN SERUM OR PLASMA.,ASO KIT(CLINIQUANT (3RD BRAND) AND AUTOQUANT (4TH BRAND))-IT IS USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN ANTISTREPTOLYSIN O (ASO) CONCENTRATION IN SERUM BY LATEX TURBIDIMETRY.,ALKALINE PHOSPHATASE KI(CLINIQUANT-FSR (1ST BRAND), AUTOQUANT (2ND BRAND), ARIQUANT-MR (ALP) (3RD BRAND), ARIQUANT-ER (ALP) (4TH BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERU,D-DIMER KIT(CLINIQUANT (3RD BRAND) AND AUTOQUANT (4TH BRAND))-IT IS USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN D-DIMER (DDM) CONCENTRATION IN SERUM BY LATEX TURBIDIMETRY.,CLEANZER KIT(AUTOQUANT)-THIS REAGENT IS TO BE USED FOR MAINTENANCE AND CLEANING OF AUTOQUANT 100 / 100 AMARA / 200I /200 EXCELUS / 400I AUTOMATED CLINICAL CHEMISTRY ANALYZER.,FERRITIN KIT(AUTOQUANT (1ST BRAND), CLINIQUANT-FSR (2ND BRAND) AND PROVISO (3RD BRAND))-IT IS INTENDED FOR QUANTITATIVE DETERMINATION OF FERRITIN CONCENTRATION IN SERUM BY LATEX TURBIDIMETRY.,CLEANSER (C) (CELQUANT 3S)-THIS REAGENT IS TO BE USED FOR MAINTENANCE AND CLEANING CELQUANT 3S– HEMATOLOGY ANALYZERS.,VIRAL TRANSPORT MEDIUM KIT(MERIL)-THIS KIT IS USED FOR COLLECTION, TRANSPORTATION AND PRESERVATION OF HUMAN NASOPHARYNGEAL OR OROPHARYNGEAL VIRUS SAMPLES FROM THE COLLECTION SITE TO THE TESTING LABORATORY.,IGM KIT (PROVISO)-THIS PRODUCT IS FOR USE ON "PROVISO" - SPECIFIC PROTEIN ANALYZER FOR THE QUANTITATIVE DETERMINATION OF HUMAN IGM IN SERUM.,BIOCAL KIT-BIOCAL IS INTENDED FOR USE IN THE CALIBRATION OF QUANTITATIVE METHODS ON MERIL CLINICAL CHEMISTRY ANALYZERS.,IGG KIT(PROVISO)-THIS PRODUCT IS FOR USE ON "PROVISO" - SPECIFIC PROTEIN ANALYZER FOR THE QUANTITATIVE DETERMINATION OF HUMAN IGG IN SERUM.,BIOPATH KIT-BIOPATH IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE ACCURACY AND PRECISION FOR THE QUANTITATIVE TEST.,IGA KIT(PROVISO)-THIS PRODUCT IS FOR USE ON "PROVISO" - SPECIFIC PROTEIN ANALYZER FOR THE

	QUANTITATIVE DETERMINATION OF HUMAN IGA IN SERUM.,BIONORM KIT-BIONORM IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE ACCURACY AND PRECISION FOR THE QUANTITATIVE TEST.,HBA1C REAGENT KIT(AUTOQUANT (1ST BRAND), CLINIQUANT-FSR (2ND BRAND), ARIQUANT-ER (HBA1C) (3RD BRAND))-THIS REAGENT IS INTENDED FOR IN VITRO QUANTITATIVE DETERMINATION OF % HBA1C IN HUMAN BLOOD - LATEX ENHANCED IMMUNOTURBIDIMETRY -READY TO USE STABLE LIQUID REAGENTS - MULTIPOINT CALIBRATION- DIRECT RESULT (% HBA1C) FROM ANALYZER -NO NEED TO MEASURE TOTAL HB ON AUTOQUANT 100 / 100 AMARA / 200I / 200 EXCELUS / 400I / 400 SUPREMUS / 400 AUTOMATED CLINICAL CHEMISTRY ANALYZER.,ENZYMATIC CREATININE KIT(AUTOQUANT)-IT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM, PLASMA OR URINE BY ENZYMATIC CREATININE ON AUTOQUANT 100 / 100 AMARA / 200I / 200 EXCELUS AUTOMATED CLINICAL CHEMISTRY ANALYZER,HBA1C REAGENT KIT(GLUQUANT A1C)-IT IS INTENDED FOR THE PERCENT DETERMINATION OF HBA1C IN HUMAN WHOLE BLOOD USING ION EXCHANGE HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC).,ANTIBACTERIAL CLEANING LIQUID (AUTOQUANT)-THIS REAGENT IS TO BE USED FOR MAINTENANCE AND CLEANING OF AUTOQUANT 400 AUTOMATED CLINICAL CHEMISTRY ANALYSER.,APO B KIT(PROVISO)-IT IS USED FOR ON “PROVISO” – SPECIFIC PROTEIN ANALYZER FOR THE QUANTITATIVE DETERMINATION OF HUMAN APO B IN SERUM.,APO A1 KIT(PROVISO)-IT IS USED FOR ON “PROVISO” – SPECIFIC PROTEIN ANALYZER FOR THE QUANTITATIVE DETERMINATION OF HUMAN APO A1 IN SERUM.,ALKALINE DETERGENT(AUTOQUANT)-THIS REAGENT IS TO BE USED FOR MAINTENANCE AND CLEANING OF AUTOQUANT 400 AUTOMATED CLINICAL CHEMISTRY ANALYSER.,ALBUMIN KIT (AUTOQUANT (1ST BRAND), ARIQUANT-MR (ALB) (2ND BRAND), ARIQUANT-ER (ALB) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALBUMIN CONCENTRATION IN HUMAN SERUM OR PLASMA.,GLUCOSE KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (GLU) (2ND BRAND), ARIQUANT-ER (GLU) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF GLUCOSE CONCENTRATION IN HUMAN SERUM OR PLASMA.,CHOLESTEROL KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (CHO) (2ND BRAND), ARIQUANT-ER (CHO) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CHOLESTEROL CONCENTRATION IN HUMAN SERUM OR PLASMA.,AMYLASE KIT(CLINIQUANT-FSR (1ST BRAND), AUTOQUANT (2ND BRAND), ARIQUANT-MR (AMY) (3RD BRAND), ARIQUANT-ER (AMY) (4TH BRAND))-THIS REAGENT IS INTENDED FOR

	QUANTITATIVE DETERMINATION OF AMYLASE IN HUMAN SERUM, CYSTATIN C KIT(NEPHELOQUANT(FIRST BRAND), PROVISO(SECOND BRAND))-IT IS USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN CYSTATIN C (CYSC) IN SERUM OR URINE.,RF (RHEUMATOID FACTOR) KIT(NEPHELOQUANT(FIRST BRAND), PROVISO(SECOND BRAND))-IT IS USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN RHEUMATOID FACTOR {RF) IN SERUM BY PARTICLE-ENHANCED IMMUNOTURBIDIMETRY.,ASO KIT(NEPHELOQUANT(FIRST BRAND), PROVISO (SECOND BARND))-IT IS USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN ANTISTREPTOLYSIN 0 (ASO) IN SERUM.,MICRO ALBUMIN KIT(NEPHELOQUANT(FIRST BRAND), PROVISO(SECOND BRAND))-IT IS USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN MICROALBUMIN (MALB) IN URINE.,D-DIMER KIT(NEPHELOQUANT(FIRST BRAND), PROVISO(SECOND BRAND))-IT IS USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN D-DIMER (DDM) IN PLASMA BY LATEX PARTICLE-ENHANCED IMMUNOTURBIDIMETRY ASSAY.,HBALC (HEMOGLOBIN A1C) KIT (NEPHELOQUANT(FIRST BRAND), PROVISO(SECOND BRAND))-IT IS USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN HAEMOGLOBIN ALE {HBALC) IN WHOLE BLOOD BY LATEX PARTICLE IMMUNOTURBIDIMETRIC ASSAY.,C4 (COMPLEMENT 4) KIT (NEPHELOQUANT(FIRST BRAND), PROVISO(SECOND BRAND))-IT IS USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN COMPLEMENT C4 (C4) IN SERUM BY IMMUNOTURBIDIMETRY.,C3 (COMPLEMENT 3) KIT(NEPHELOQUANT(FIRST BRAND), PROVISO (SECOND BRAND))-IT IS USED FOR THE QUANTITATIVE DETERMINATION OF HUMAN COMPLEMENT C3 (C3) IN SERUM BY IMMUNOTURBIDIMETRY.,REAGENT FOR ELECTROLYTE ANALYZER (QUANTILYTE)-IN VITRO TEST FOR THE QUANTITATIVE DETERMINATION OF ELECTROLYTE CONCENTRATION IN HUMAN SERUM, PLASMA AND DILUTED URINE.,ONE STEP RAPID TEST FOR DETECTION OF HCG IN HUMAN URINE(MERISCREEN HCG DIPSTICK)-IT IS A RAPID IMMUNE-CHROMATOGRAPHIC DIPSTICK FOR QUALITATIVE DETECTION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN HUMAN URINE TO AID IN THE EARLY DETECTION OF PREGNANCY.,THYROGLOBULIN ELISA(MERILISA)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF THYROGLOBULIN CONCENTRATION IN HUMAN SERUM. THYROGLOBULIN KIT IS INTENDED FOR LABORATORY USE ONLY.,HUMAN GROWTH HORMONE (HGH)(MERILISA)-HGH ELISA KIT IS A DIRECT SOLID PHASE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE MEASUREMENT OF GROWTH HORMONE IN HUMAN SERUM OR PLASMA. HGH ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,25OH VITAMIN D ELISA(MERILISA I)-IMMUNOENZYMATIC

	COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF 25OH VITAMIN D CONCENTRATION IN HUMAN SERUM OR PLASMA. 25OH VITAMIN D KIT IS INTENDED FOR LABORATORY USE ONLY.,TSH ELISA (MERILISA I (1ST BRAND) MAKESURE (2ND BRAND))-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH, THYROTROPIN) CONCENTRATION IN HUMAN SERUM. TSH ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,T4 ELISA(MERILISA I (1ST BRAND) MAKESURE (2ND BRAND))-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T4) CONCENTRATION IN HUMAN SERUM. T4 KIT IS INTENDED FOR LABORATORY USE ONLY.,T3 ELISA(MERILISA I (1ST BRAND) MAKESURE (2ND BRAND))-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) CONCENTRATION IN HUMAN SERUM. T3 KIT IS INTENDED FOR LABORATORY USE ONLY.,CELL CLEANER (ARIQUANT-ER)-THIS REAGENT IS USED TO RINSE ERMA (3PDA) - HEMATOLOGY ANALYZERS BETWEEN MEASUREMENTS AND CLEANING.,LYSE(ARIQUANT-ABX)-THIS REAGENT IS USED BY HORIBA ABX (3PDA) -HEMATOLOGY ANALYZER, RED BLOOD CELL HEMOLYSING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTES COUNT, MONO CELL, GRANULOCYTE COUNT., CLEANER(ARIQUANT-ABX)-THIS REAGENT IS USED TO RINSE HORIBA ABX (3PDA) - HEMATOLOGY ANALYZERS BETWEEN MEASUREMENTS AND CLEANING,DILUENT(ARIQUANT-ER)-THIS REAGENT IS USED BY ERMA (3PDA) - HEMATOLOGY ANALYZER AS A WHOLE BLOOD SAMPLE DILUTING REAGENT.,DILUENT(ARIQUANT-ABX)-THIS REAGENT IS USED BY HORIBA ABX (3PDA) - HEMATOLOGY ANALYZER AS A WHOLE BLOOD SAMPLE DILUTING REAGENT.,LYSE (ARIQUANT-ER)-THIS REAGENT IS USED BY ERMA (3PDA) HEMATOLOGY ANALYZER, RED BLOOD CELL HEMOLYSING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTES COUNT, MID CELL, GRANULOCYTE COUNT.,MAGNESIUM KIT (AUTOQUANT (1ST BRAND), ARIQUANT-MR (MG) (2ND BRAND), ARIQUANT-ER (MG) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF MAGNESIUM CONCENTRATION IN HUMAN SERUM OR PLASMA AND URINE.,GAMMA GT KIT(CLINIQUANT-FSR (1ST BRAND), AUTOQUANT (2ND BRAND), ARIQUANT-MR (GGT) (3RD BRAND), ARIQUANT-ER (GGT) (4TH BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE ANALYSIS OF GGT IN HUMAN SERUM., CALCIUM (A) KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (CAL) (2ND BRAND), ARIQUANT-ER (CAL) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CALCIUM CONCENTRATION IN HUMAN SERUM OR PLASMA AND URINE.,

	BILIRUBIN (TOTAL & DIRECT) KIT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF TOTAL AND DIRECT BILIRUBIN IN HUMAN SERUM OR PLASMA.,PHOSPHORUS KIT (CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF PHOSPHORUS CONCENTRATION IN HUMAN SERUM OR PLASMA.,CHLORIDE KIT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CHLORIDE CONCENTRATION IN HUMAN SERUM OR PLASMA.,CALCIUM KIT (CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CALCIUM CONCENTRATION IN HUMAN SERUM OR PLASMA AND URINE.,CALCIUM (OCPC) KIT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CALCIUM CONCENTRATION IN HUMAN SERUM OR PLASMA.,LIPASE KIT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE ANALYSIS OF PANCREATIC LIPASE IN HUMAN SERUM.,CREATINE KINASE KIT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CREATININE KINASE (CK) LEVEL IN HUMAN SERUM.,CK-MB KIT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CREATINE KINASE LEVEL IN HUMAN SERUM,ONE STEP TEST FOR MALARIA PF/PV AB(MERISCREEN MALARIA PF/PV AB (1ST BRAND), MERISCREEN MALARIA NIU AB (2ND BRAND))-IT IS IMMUNOCHROMATOGRAPHIC RAPID TEST FOR THE QUALITATIVE DETECTION OF ANTIBODIES OF ALL ISOTYPES (IGG, IGM, IGA) SPECIFIC TO PLASMODIUM FALCIPARUM AND PLASMODIUM VIVAX AT THE SAME TIME IN HUMAN SERUM, PLASMA OR WHOLE BLOOD., HEMATOLOGY CONTROLS(CELQUANT)-IT IS USED FOR MONITORING OR EVALUATING TEST RESULT ACCURACY OF 5-PART HEMATOLOGY ANALYZER,ONE STEP TEST FOR HCG (UNCUT SHEET)-UNCUT SHEET IS USED FOR FURTHER MANUFACTURING USE AND FINISHED PRODUCT IS USED FOR QUALITATIVE DETECTION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN HUMAN URINE TO AID IN THE EARLY DETECTION OF PREGNANCY.,ONE STEP TEST FOR MALARIA PF/PV AB (UNCUT SHEET)- IT IS IMMUNOCHROMATOGRAPHIC RAPID TEST FOR THE QUALITATIVE DETECTION OF ANTIBODIES OF ALL ISOTYPES (IGG, IGM, IGA) SPECIFIC TO PLASMODIUM FALCIPARUM AND PLASMODIUM VIVAX AT THE SAME TIME IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,ONE STEP TEST FOR HCG(ONE STEP TEST FOR HCG (ON GENERIC NAME), MERISCREEN HCG (1ST BRAND), E-ZEE CHECK (2ND BRAND), PREGIOS (3RD BRAND), SURYA TRUST PREGNANCY TEST CARD (4TH BRAND), LYDIA E-ZEE CHECK (5TH BRAND), I-CAN ONE STEP PREGNANCY TEST DEVICE (6TH BRAND), PREGIOS ADVANCE (7TH BRAND), MARANATHA (8TH BRAND), NISHCHAY (9TH BRAND),CARENT (10TH BRAND))-MERISCREEN HCG

	IS A RAPID IMMUNOCHROMATOGRAPHIC TEST DEVICE FOR QUALITATIVE DETECTION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN HUMAN URINE TO AID IN THE EARLY DETECTION OF PREGNANCY.,BLOOD GLUCOSE TEST STRIPS (GLUCOSE DEHYDROGENASE)-IT IS TO BE USED ONLY WITH EXIMO GLUCOMETER BY PEOPLE WITH DIABETES AT HOME OR BY HEALTHCARE PROFESSIONALS FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN CAPILLARY WHOLE BLOOD FROM THE FINGER, FOREARM, AND PALM. IT IS ALSO USED AS AN AID IN MONITORING THE EFFECTIVENESS OF DIABETES CONTROL PROGRAMS.,BLOOD GLUCOSE TEST STRIPS(EXIMO)-IT IS TO BE USED ONLY WITH EXIMO GLUCOMETER BY PEOPLE WITH DIABETES AT HOME OR BY HEALTHCARE PROFESSIONALS FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN CAPILLARY WHOLE BLOOD FROM THE FINGER, FOREARM, AND PALM. IT IS ALSO USED AS AN AID IN MONITORING THE EFFECTIVENESS OF DIABETES CONTROL PROGRAMS.,BLOOD GLUCOSE TEST STRIPS (GLUCOSE OXIDASE)-IT IS TO BE USED ONLY WITH CREDO GLUCOMETER BY PEOPLE WITH DIABETES AT HOME OR BY HEALTHCARE PROFESSIONALS FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN CAPILLARY WHOLE BLOOD FROM THE FINGER, FOREARM AND PALM. IT IS ALSO USED AS AN AID IN MONITORING THE EFFECTIVENESS OF DIABETES CONTROL PROGRAMS.,BLOOD GLUCOSE TEST STRIPS(MERICHECK (1ST BRAND), CREDO (2ND BRAND))-IT IS TO BE USED ONLY WITH CREDO GLUCOMETER BY PEOPLE WITH DIABETES AT HOME OR BY HEALTHCARE PROFESSIONALS FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE IN CAPILLARY WHOLE BLOOD FROM THE FINGER, FOREARM AND PALM. IT IS ALSO USED AS AN AID IN MONITORING THE EFFECTIVENESS OF DIABETES CONTROL PROGRAMS.,TSH ELISA(MERILISA I)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF THYROID-STIMULATING HORMONE (TSH, THYROTROPIN) CONCENTRATION IN HUMAN SERUM. TSH ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,URIC ACID KIT(CLINIQUANT-FSR (1ST BRAND), MARANATHA (2ND BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF URIC ACID CONCENTRATION IN HUMAN SERUM OR PLASMA AND URINE.,T4 ELISA(MERILISA I)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T4) CONCENTRATION IN HUMAN SERUM. T4 KIT IS INTENDED FOR LABORATORY USE ONLY.,T3 ELISA(MERILISA I)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF TRIIODOTHYRONINE (T3) CONCENTRATION IN HUMAN SERUM. T3 KIT IS INTENDED FOR LABORATORY USE ONLY.,ANTI-TPO CLIA(LUMIQUANT)-USED FOR

	THE QUANTITATIVE DETERMINATION OF ANTI-TPO (ANTI-THYROID PEROXIDASE) IN HUMAN SERUM.,ANTI-TG CLIA(LUMIQUANT)-USED FOR THE QUANTITATIVE DETERMINATION OF ANTI-TG (ANTI-THYROGLOBULIN) IN HUMAN SERUM.,FT4-CLIA(LUMIQUANT)-USED FOR THE QUANTITATIVE DETERMINATION OF FT4 (FREE THYROXINE) IN HUMAN SERUM.,FT3-CLIA(LUMIQUANT)-USED FOR THE QUANTITATIVE DETERMINATION OF FT3 (FREE TRIIODOTHYRONINE) IN HUMAN SERUM.,TSH-CLIA(LUMIQUANT)-USED FOR THE QUANTITATIVE DETERMINATION OF TSH (THYROID STIMULATING HORMONE) IN HUMAN SERUM.,T4-CLIA(LUMIQUANT)-USED FOR THE QUANTITATIVE DETERMINATION OF T4 (THYROXINE) IN HUMAN SERUM.,T3-CLIA(LUMIQUANT)-USED FOR THE QUANTITATIVE DETERMINATION OF T3 (TRIIODOTHYRONINE) IN HUMAN SERUM., HCG-CLIA(LUMIQUANT)-USED FOR QUANTITATIVE DETERMINATION OF -HCG (- HUMAN CHORIONIC GONADOTROPIN) IN HUMAN SERUM .,URIC ACID KIT(CLINIQUANT-FDR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF URIC ACID CONCENTRATION IN HUMAN SERUM OR PLASMA AND URINE., INSULIN-CLIA(LUMIQUANT)-USED FOR THE QUANTITATIVE DETERMINATION OF INSULIN CONCENTRATION IN HUMAN SERUM,C-PEPTIDE(LUMIQUANT)-USED FOR THE QUANTITATIVE DETERMINATION OF INSULIN CONCENTRATION IN HUMAN SERUM., ESTRADIOL-CLIA(LUMIQUANT)-USED FOR THE QUANTITATIVE DETERMINATION OF E2 (ESTRADIOL) CONCENTRATION IN HUMAN SERUM.,TESTOSTERONE-CLIA(LUMIQUANT)-USED FOR THE QUANTITATIVE DETERMINATION OF TESTOSTERONE CONCENTRATION IN HUMAN SERUM,PROGESTERONE-CLIA (LUMIQUANT)-USED FOR THE QUANTITATIVE DETERMINATION OF PRG (PROGESTERONE) CONCENTRATION IN HUMAN SERUM., PROLACTIN-CLIA(LUMIQUANT)-USED FOR QUANTITATIVE DETERMINATION OF PRL (PROLACTIN) CONCENTRATION IN HUMAN SERUM.,FSH-CLIA(LUMIQUANT)-USED FOR QUANTITATIVE DETERMINATION OF FSH (FOLLICLE STIMULATING HARMONE) CONCENTRATION IN HUMAN SERUM.,LH-CLIA(LUMIQUANT)-USED FOR QUANTITATIVE DETERMINATION OF LH (LUTEINIZING HORMONE) CONCENTRATION IN HUMAN SERUM.,25OH VITAMIN D ELISA (MERILISA)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF 25OH VITAMIN D CONCENTRATION IN HUMAN SERUM OR PLASMA. 25OH VITAMIN D KIT IS INTENDED FOR LABORATORY USE ONLY.,FT4 ELISA(MERILISA)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE THYROXINE (FT4) CONCENTRATION IN HUMAN SERUM OR PLASMA. FT4 KIT IS INTENDED FOR LABORATORY USE ONLY.,FT3 ELISA(MERILISA)-IMMUNOENZYMATIC

	COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE TRIIODOTHYRONINE (FT3) CONCENTRATION IN HUMAN SERUM AND PLASMA. FT3 KIT IS INTENDED FOR LABORATORY USE ONLY., FERRITIN ELISA(MERILISA)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FERRITIN CONCENTRATION IN HUMAN SERUM OR PLASMA. FERRITIN KIT IS INTENDED FOR LABORATORY USE ONLY.,TOTAL IGE ELISA(MERILISA) -IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF IGE CONCENTRATION IN HUMAN SERUM OR PLASMA. IGE KIT IS INTENDED FOR LABORATORY USE ONLY.,ANTI-PR3 (CANCA) ELISA(MERILISA)-ANTI-PR3 (CANCA) IS AN INDIRECT SOLID PHASE ENZYME IMMUNOASSAY (ELISA) FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST PROTEINASE 3 (PR3) IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF CERTAIN AUTOIMMUNE VASCULITIDES SUCH AS WEGENER 'S GRANULOMATOSIS. ANTI -PR3 (CANCA) KIT IS INTENDED FOR LABORATORY USE ONLY,ANTI-MPO (PANCA) ELISA (MERILISA)-ANTI-MPO (PANCA) KIT IS AN INDIRECT SOLID PHASE ENZYME IMMUNOASSAY (ELISA) FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTOANTIBODIES AGAINST MYELOPEROXIDASE (MPO) IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF CERTAIN AUTOIMMUNE VASCULITITES SUCH AS WEGENER'S GRANULOMATOSIS ANTI - MPO (PANCA) KIT IS INTENDED FOR LABORATORY USE ONLY. ,ANTI-CCP (CYCLIC CITRULLINATED PEPTIDE) ELISA(MERILISA)-ANTI CCP KIT IS AN IMMUNOENZYMATIC TEST (ELISA), INTENDED FOR THE QUANTITATIVE DETERMINATION OF IGG CLASS ANTIBODIES DIRECTED AGAINST CYCLIC CITRULLINATED PEPTIDES, PRESENT IN HUMAN SERUM OR PLASMA. ANTI CCP KIT IS INTENDED FOR LABORATORY USE ONLY. ,ANTI-TPO ELISA(MERILISA)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF ANTI-TPO CONCENTRATION IN HUMAN SERUM OR PLASMA. ANTI TPO KIT IS INTENDED FOR LABORATORY USE ONLY.,ANTI-TG ELISA(MERILISA)- INDIRECT IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF ANTI-TG CONCENTRATION IN HUMAN SERUM OR PLASMA. ANTI TG ELISA KIT IS INTENDED FOR LABORATORY USE ONLY,ANTI CARDIOLIPIN SCREEN(MERILISA)-MERIL ANTI CARDIOLIPIN SCREEN IS AN INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGG OR IGM CLASS AUTO-ANTIBODIES DIRECTED AGAINST CARDIOLIPIN-2-GLYCOPROTEIN COMPLEX IN HUMAN SERUM OR PLASMA.,ANTI CARDIOLIPIN IGM

	(MERILISA)-ANTI CARDIOLIPIN IGM IS AN INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGM CLASS AUTOANTIBODIES DIRECTED AGAINST CARDIOLIPINA-2-GLYCOPROTEIN COMPLEX IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF INCREASED RISK OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERITEMATOSUS (SLE) OR SIMILAR DISORDERS. ANTI CARDIOLIPIN IGM KIT IS INTENDED FOR LABORATORY USE ONLY,ANTI CARDIOLIPIN IGG(MERILISA)-ANTI CARDIOLIPIN IGG KIT IS AN INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS AUTO-ANTIBODIES DIRECTED AGAINST CARDIOLIPINA-2- GLYCOPROTEIN COMPLEX IN HUMAN SERUM OR PLASMA. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF INCREASED RISK OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERITEMATOSUS (SLE) OR SIMILAR DISORDERS. ANTI CARDIOLIPIN IGG KIT IS INTENDED FOR LABORATORY USE ONLY., ANTI DSDNA IGG(MERILISA)-ANTI DSDNA IGG KIT IS AN INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) DESIGNED FOR THE QUANTITATIVE MEASUREMENT OF IGG CLASS ANTIBODIES DIRECTED AGAINST DSDNA IN HUMAN SERUM OR PLASMA. ANTI DSDNA IGG IS INTENDED FOR LABORATORY USE ONLY.,ANTI PHOSPHOLIPID SCREEN(MERILISA)-ANTI PHOSPHOLIPID SCREEN IS AN INDIRECT SOLID PHASE IMMUNOASSAY KIT FOR THE QUANTITATIVE MEASUREMENT OF IGG AND IGM CLASS AUTO-ANTIBODIES DIRECTED AGAINST 2- GLYCOPROTEIN MEDIATED ANIONIC PHOSPHOLIPIDS IN HUMAN SERUM OR PLASMA, INCLUDING CARDIOLIPIN, PHOSPHATIDYL SERINE, PHOSPHATIDYL INOSITOL, PHOSPHATIDIC ACID, PHOSPHATIDYL CHOLINE, LYSO-PHOSPHATIDYL CHOLINE, PHOSPHATIDYL ETHANOLAMINE. THE ASSAY IS INTENDED FOR IN VITRO DIAGNOSTIC USE ONLY AS AN AID IN THE DIAGNOSIS OF INCREASED RISK OF THROMBOSIS IN PATIENTS WITH SYSTEMIC LUPUS ERITEMATOSUS (SLE) OR SIMILAR DISORDERS. ANTI PHOSPHOLIPID SCREEN KIT IS INTENDED FOR LABORATORY USE ONLY,ANA SCREEN(MERILISA)-ANA SCREEN KIT IS AN INDIRECT SOLID PHASE ENZYME IMMUNOMETRIC ASSAY (ELISA) DESIGNED FOR SEMIQUANTITATIVE MEASUREMENT OF IGG ANTIBODIES DIRECTED AGAINST SM (SMITH), RNP/SM, SCL-70, SS-A (RO) (52KDA E 60KDA), SS-B (LA), JO1, U1-SMRNP, CENP-B, DSDNA, AND HISTONES IN HUMAN SERUM OR PLASMA. ANA SCREEN KIT IS INTENDED FOR LABORATORY USE ONLY,FREE ESTRIOL ELISA (MERILISA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE ESTRIOL CONCENTRATION IN HUMAN SERUM OR PLASMA. FREE ESTRIOL KIT

	IS INTENDED FOR LABORATORY USE ONLY.,CORTISOL ELISA (MERILISA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF CORTISOL CONCENTRATION IN HUMAN SERUM OR PLASMA. ,17OH PROGESTERONE ELISA(MERILISA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF 17OH PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. 17OH PROGESTERONE KIT IS INTENDED FOR LABORATORY USE ONLY,C-PEPTIDE ELISA(MERILISA)-C-PEPTIDE KIT IS A DIRECT SOLID PHASE ENZYME IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF C-PEPTIDE IN HUMAN SERUM OR PLASMA. C-PEPTIDE KIT IS INTENDED FOR LABORATORY USE ONLY., INSULIN ELISA(MERILISA)-INSULIN ELISA KIT IS A DIRECT SOLID PHASE ENZYME IMMUNOASSAY FOR QUANTITATIVE DETERMINATION OF INSULIN IN HUMAN SERUM OR PLASMA. INSULIN KIT IS INTENDED FOR LABORATORY USE ONLY.,DHEA-S ELISA(MERILISA)-COMPETITIVE IMMUNE ENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF DEHYDROEPIANDROSTERONE SULFATE (DHEA-S) CONCENTRATION IN HUMAN SERUM OR PLASMA. DHEA-S KIT IS INTENDED FOR LABORATORY USE ONLY ,FREE TESTOSTERONE ELISA(MERILISA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF FREE TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. SECOND GENERATION KIT FREE TESTOSTERONE ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,ß HCG ELISA(MERILISA)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF -HCG CONCENTRATION IN HUMAN SERUM OR PLASMA. -HCG KIT IS INTENDED FOR LABORATORY USE ONLY., PROLACTIN ELISA(MERILISA)-IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF PROLACTIN CONCENTRATION IN HUMAN SERUM. PROLACTIN ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,FSH ELISA(MERILISA)-MERIL FSH ELISA KIT IS A DIRECT SOLID PHASE IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF FOLLICLE STIMULATING HORMONE (FSH) IN HUMAN SERUM OR PLASMA. FSH KIT IS INTENDED FOR LABORATORY USE ONLY.,LH ELISA(MERILISA)-LH ELISA KIT IS A SOLID PHASE ENZYME IMMUNOASSAY FOR THE QUANTITATIVE DETERMINATION OF THE LUTEINIZING HORMONE (LH) CONCENTRATION IN HUMAN SERUM OR PLASMA. LH ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,PROGESTERONE ELISA (MERILISA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF PROGESTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. PROGESTERONE ELISA KIT IS INTENDED FOR LABORATORY USE ONLY., ESTRADIOL

	ELISA(MERILISA)-COMPETITIVE IMMUNOENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF ESTRADIOL CONCENTRATION IN HUMAN SERUM OR PLASMA. ESTRADIOL ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,TESTOSTERONE ELISA(MERILISA)-COMPETITIVE IMMUNE ENZYMATIC COLORIMETRIC METHOD FOR QUANTITATIVE DETERMINATION OF TOTAL TESTOSTERONE CONCENTRATION IN HUMAN SERUM OR PLASMA. TESTOSTERONE ELISA KIT IS INTENDED FOR LABORATORY USE ONLY.,ONE STEP TEST FOR DENGUE IGG/IGM (UNCUT SHEET)-UNCUT SHEET IS USED FOR FURTHER MANUFACTURING AND FINISHED PRODUCT IS USED FOR DIAGNOSIS OF DENGUE INFECTION AND QUALITATIVE DETECTION OF IGG / IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM OR PLASMA.,ONE STEP TEST FOR DENGUE IGG/IGM(MERISCREEN DENGUE IGG/IGM (1ST BRAND), RAPIDSURE DENGUE IGG/IGM (2ND BRAND),VIVASCREEN (3RD BRAND) DENTRIX (4TH BRAND))-T IS USED FOR DIAGNOSIS OF DENGUE INFECTION AND QUALITATIVE DETECTION OF IGG / IGM ANTIBODIES TO DENGUE VIRUS IN HUMAN SERUM OR PLASMA.,PROBE CLEANER(ARIQUANT SYS)-THIS REAGENT IS USED FOR MAINTAINANCE AND CLEANING OF SYSMEX (3PDA) HEMATOLOGY ANALYZERS.,CLEANZER(CELQUANT 3 PRIME)-THIS REAGENT IS USED FOR MAINTAINANCE AND CLEANING OF CELQUANT 3 (3PDA) HEMATOLOGY ANALYZERS.,CLEANING SOLUTION(ARIQUANT NK)-THIS REAGENT IS USED FOR MAINTENANCE AND CLEANING OF NK (3PDA) HEMATOLOGY ANALYZERS.,RINSE(MERILINE-BC3 (1ST BRAND), ARIQUANT-MR (2ND BRAND))-THIS REAGENT IS USED TO RINSE BC3 HEMATOLOGY ANALYZER AND MINDRAY 3000 PLUS -HEMATOLOGY ANALYZERS BETWEEN MEASUREMENT AND CLEANING.,DILUENT(MERILINE-BC3 (1ST BRAND), ARIQUANT-MR (2ND BRAND))-THIS REAGENT IS USED BY BC3 HEMATOLOGY ANALYSER AND MIDRAY (3PDA) HEMATOLOGY ANALYZER AS A WHOLE BLOOD SAMPLE DILUTING REAGENT.,LYSE(MERILINE-BC3 (1ST BRAND), ARIQUANT-MR (2ND BRAND))-THIS REAGENT IS USED BY BC3-HEMATOLOGY ANALYZER AND MIDRAY (3PDA) HEMATOLOGY ANALYZER ,RED BLOOD CELL HEMOLYSING AGENT FOR THE ASSAY OF WBC ,LYMPHOCYTES,MID CELLS, GRANULOCYTE COUNTS.,LYSE(MERILINE-WH (1ST BRAND), ARIQUANT-SYS (2ND BRAND), CELQUANT 3 PRIME (3RD BRAND))-THIS REAGENT IS USED BY CELQUANT 3 PRIME(3PDA)HEMATOLOGY ANALYZER AND SYSMEX(3PDA) HEMATOLOGY ANALYZER, RED BLOOD CELL HEMOLYSING REAGENT FOR THE ASSAY OF WHITEBLOOD CELL COUNT, LYMPHOCYTES COUNT, MID CELL, GRANULOCYTE COUNT,WBC TRI-MODAL SIZE DISTRIBUTION ANALYSIS AND HEMOGLOBIN LEVEL MEASUREMENT.,DILUENT (MERILINE-SYS (1ST BRAND), ARIQUANT-SYS (2ND BRAND),

	CELQUANT 3 PRIME (3RD BRAND))-THIS REAGENT IS USED BY HEMATOLOGY ANALYZER AS A WHOLE BLOOD SAMPLE DILUTING REAGENT,RINSE(MERILINE-NK (1ST BRAND), ARIQUANT-NK (2ND BRAND))-THIS REAGENT IS USED TO RINSE NK -HEMATOLOGY ANALYZERS BETWEEN MEASUREMENTS AND CLEANING.,LYSE (MERILINE-NK (1ST BRAND), ARIQUANT-NK (2ND BRAND))-THIS REAGENT IS USED BY NIHON KOHDEN(3PDA) HEMATOLOGY ANALYZER, RED BLOOD CELL HEMOLYSING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTES COUNT, MID CELL,NEUTROPHIL CELL COUNT.,DILUENT(MERILINE-NK (1ST BRAND), ARIQUANT-NK (2ND BRAND))-THIS REAGENT IS USED BY NK (3PDA) HEMATOLOGY ANALYZER AS A WHOLE BLOOD SAMPLE DILUTING REAGENT,LYSE-FDO(CELQUANT 5)-THIS REAGENT IS USED BY CELQUANT 5-HEMATOLOGY ANALYZER.FOR THE DISSOLUTION OF RED BLOOD CELLS, DYE OF CELL CONTENT DETECTION OF LYMPHOCYTES,MONOCYTE,EOSINOPHIL AND NEUTROPHIL.,LYSE-FDT(CELQUANT 5)-THIS REAGENT IS USED BY CELQUANT 5-HEMATOLOGY ANALYZER.FOR THE DISSOLUTION OF RED BLOOD CELLS, DYE OF CELL CONTENT DETECTION OF LYMPHOCYTES, MONOCYTE,EOSINOPHIL AND NEUTROPHIL.,DETERGENT(CELQUANT 5)-THIS REAGENT IS USED FOR MAINTENANCE AND CLEANING OF CELQUANT 5 -HEMATOLOGY ANALYZERS.,LYSE-SLS(CELQUANT 5)-THIS REAGENT IS USED BY CELQUANT 5 -HEMATOLOGY ANALYZER . DISSOLVE RED BLOOD CELLS, COUNT WHITE BLOOD CELLS, BASOPHILS AND TEST HEMOGLOBIN CONTENT.,DILUENT(CELQUANT 5)-THIS REAGENT IS USED BY CELEUANT 5 - HEMATOLOGY ANALYZER AS A WHOLE BLOOD SAMPLE DILUTING REAGENT.,RINSE (CELQUANT 3 ASPIRE (1ST BRAND), CELQUANT 360 (2ND BRAND))-THIS REAGENT IS USED TO RINSE CELQUANT 360 (3PDA) -HEMATOLOGY ANALYZERS BETWEEN MEASUREMENTS AND CLEANING.,LYSE(CELQUANT 3 ASPIRE (1ST BRAND), CELQUANT 360 (2ND BRAND))-THIS REAGENT IS USED BY CELQUANT 360(3PDA) – HEMATOLOGY ANALYZER, RED BLOOD CELL HEMOLYSING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTES COUNT, MID CELL, NEUT COUNT,DILUENT(CELQUANT 3 ASPIRE (1ST BRAND), CELQUANT 360 (2ND BRAND))-THIS REAGENT IS USED BY CELQUANT 360 (3PDA) – HEMATOLOGY ANALYZER AS A WHOLE BLOOD SAMPLE DILUTING REAGENT.,CLEANSER(CELQUANT 3S)-THIS REAGENT IS USED BY CELQUANT 3S (3PDA) HEMATOLOGY ANALYZER, RED BLOOD CELL HEMOLYSING REAGENT FOR THE ASSAY OF, WHITE BLOOD CELL COUNT, LYMPHOCYTES COUNT, MID CELL,NEUTROPHIL CELL COUNT.,LYSE(CELQUANT 3S)-THIS REAGENT IS USED BY CELQUANT 3S (3PDA) HEMATOLOGY ANALYZER, RED BLOOD CELL HEMOLYSING REAGENT FOR THE ASSAY OF, WHITE

	BLOOD CELL COUNT, LYMPHOCYTES COUNT, MID CELL,NEUTROPHIL CELL COUNT.,DILUENT(CELQUANT 3S)-THIS REAGENT IS USED BY CELQUANT 3S (3PDA) HEMATOLOGY ANALYZER AS A WHOLE BLOOD SAMPLE DILUTING REAGENT,LYSE KIT(CELQUANT 3)-THIS REAGENT IS USED BY CELQUANT 3 – HEMATOLOGY ANALYZER RED BLOOD CELL HEMOLYSING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTES COUNT, MID CELL, GRANULOCYTE COUNT. , DILUENT(CELQUANT 3)-THIS REAGENT IS USED BY CELQUANT 3 – HEMATOLOGY ANALYZER AS A WHOLE BLOOD SAMPLE DILUTING REAGENT.,RINSE(CELQUANT 3I)-THIS REAGENT IS USED TO RINSE CELQUANT 3I – HEMATOLOGY ANALYZERS BETWEEN MEASUREMENTS AND CLEANING.,LYSE(CELQUANT 3I)-THIS REAGENT IS USED BY CELQUANT 3I – HEMATOLOGY ANALYZER RED BLOOD CELL HEMOLYSING REAGENT FOR THE ASSAY OF WHITE BLOOD CELL COUNT, LYMPHOCYTES COUNT, MID CELL, GRANULOCYTE COUNT., DILUENT(CELQUANT 3I)-THIS REAGENT IS USED BY CELQUANR 3I - HEMATOLOGY ANALYZER AS A WHOLE BLOOD SAMPLE DILUTING REAGENT.,RINSE(CELQUANT 3)-THIS REAGENT IS USED TO RINSE CELQUANT 3 – HEMATOLOGY ANALYZERS BETWEEN MEASUREMENTS AND CLEANING.,PROBE CLEANER(CELQUANT 3 (1ST BRAND), CELQUANT 3I (2ND BRAND))-THIS REAGENT IS USED FOR MAINTENANCE AND CLEANING OF CELQUANT 3 – HEMATOLOGY ANALYZERS,ENZ CLEANER(CELQUANT 3 (1ST BRAND), CELQUANT 3I (2ND BRAND))-THIS REAGENT IS TO BE USED FOR MAINTENANCE AND CLEANING CELQUANT 3 – HEMATOLOGY ANALYZERS.,MICRO ALBUMIN KIT(CLINIQUANT-TIA (1ST BRAND), AUTOQUANT (2ND BRAND), ARIQUANT-MR (3RD BRAND), ARIQUANT-ER (4TH BRAND))-MICRO ALBUMIN KIT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF MICRO ALBUMIN IN HUMAN URINE BY TURBIDIMETRIC IMMUNOASSAY.,CRP KIT(CLINIQUANT-TIA (1ST BRAND), AUTOQUANT (2ND BRAND), ARIQUANT-MR (3RD BRAND), ARIQUANT-ER (4TH BRAND))-IT IS INTENDED FOR THE QUANTITATIVE DETERMINATION OF C - REACTIVE PROTEIN IN HUMAN SERUM BY TURBIDIMETRIC IMMUNOASSAY.,LDL CHOLESTEROL (DIRECT) KIT (AUTOQUANT (1ST BRAND), ARIQUANT-MR (LDL) (2ND BRAND), ARIQUANT-ER (LDL) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LOW-DENSITY LIPOPROTEIN CHOLESTEROL (LDLC) CONCENTRATION IN HUMAN SERUM OR PLASMA.,CREATININE KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (CRE) (2ND BRAND), ARIQUANT-ER (CRE) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CREATININE CONCENTRATION IN HUMAN SERUM OR PLASMA OR URINE.,TOTAL PROTEIN KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (TP) (2ND BRAND), ARIQUANT-ER (TP) (3RD BRAND))-THIS

	REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF PROTEIN CONCENTRATION IN HUMAN SERUM OR PLASMA., MICROPROTEIN KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (MPRO) (2ND BRAND), ARIQUANT-ER (MPRO) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF PROTEIN CONCENTRATION IN HUMAN URINE AND CSF.,UREA (BUN) KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (URE) (2ND BRAND), ARIQUANT-ER (URE) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF UREA (BUN) CONCENTRATION IN HUMAN SERUM AND URINE.,URIC ACID KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (UA) (2ND BRAND), ARIQUANT-ER (UA) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF URIC ACID CONCENTRATION IN HUMAN SERUM OR PLASMA AND URINE.,BILIRUBIN DIRECT KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (DBIL) (2ND BRAND), ARIQUANT-ER (DBIL) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF BILIRUBIN DIRECT CONCENTRATION IN HUMAN SERUM OR PLASMA., BILIRUBIN TOTAL KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (TBIL) (2ND BRAND), ARIQUANT-ER (TBIL) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN CONCENTRATION IN HUMAN SERUM OR PLASMA., HDL CHOLESTEROL (DIRECT) KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (HDL) (2ND BRAND), ARIQUANT-ER (HDL) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL (HDLC) CONCENTRATION IN HUMAN SERUM OR PLASMA., TRIGLYCERIDE KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (TG) (2ND BRAND), ARIQUANT-ER (TG) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF TRIGLYCERIDE CONCENTRATION IN HUMAN SERUM OR PLASMA.,PHOSPHOROUS KIT (AUTOQUANT (1ST BRAND), ARIQUANT-MR (PHO) (2ND BRAND), ARIQUANT-ER (PHO) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF PHOSPHORUS CONCENTRATION IN HUMAN SERUM OR PLASMA.,CHLORIDE KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (CHL) (2ND BRAND), ARIQUANT-ER (CHL) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CHLORIDE CONCENTRATION IN HUMAN SERUM OR PLASMA.,SGPT KIT(CLINIQUANT-FSR (1ST BRAND), AUTOQUANT (2ND BRAND), ARIQUANT-MR (SGPT) (3RD BRAND), ARIQUANT-ER (SGPT) (4TH BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF SGPT/ALT LEVEL IN HUMAN SERUM.,LIPASE KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (LIP) (2ND BRAND), ARIQUANT-ER (LIP) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE ANALYSIS OF PANCREATIC LIPASE IN

	HUMAN SERUM.,CK-MB KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (CK-MB) (2ND BRAND), ARIQUANT-ER (CK-MB) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CREATINE KINASE LEVEL IN HUMAN SERUM.,SGOT KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (SGOT) (2ND BRAND), ARIQUANT-ER (SGOT) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF SGOT LEVEL IN HUMAN SERUM., CREATINE KINASE KIT(AUTOQUANT (1ST BRAND), ARIQUANT-MR (CK) (2ND BRAND), ARIQUANT-ER (CK) (3RD BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CREATININE KINASE (CK) LEVEL IN HUMAN SERUM.,BIOCAL KIT(MERILINE-FDR)-BIOCAL IS INTENDED FOR USE IN THE CALIBRATION OF QUANTITATIVE METHODS ON MERIL CLINICAL CHEMISTRY ANALYZERS.,BIOPATH KIT(MERILINE-FDR)-BIOPATH IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE ACCURACY AND PRECISION FOR THE QUANTITATIVE TEST., BIONORM KIT(MERILINE-FDR)-BIONORM IS INTENDED FOR USE AS AN ASSAYED QUALITY CONTROL SERUM TO MONITOR THE ACCURACY AND PRECISION FOR THE QUANTITATIVE TEST.,UREA (BUN) KIT (CLINIQUANT-FDR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF UREA (BUN) CONCENTRATION IN HUMAN SERUM AND URINE.,GLUCOSE KIT(CLINIQUANT-FDR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF GLUCOSE CONCENTRATION IN HUMAN SERUM OR PLASMA.,TRIGLYCERIDE KIT (CLINIQUANT-FDR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF TRIGLYCERIDE CONCENTRATION IN HUMAN SERUM OR PLASMA.,CHOLESTEROL KIT(CLINIQUANT-FDR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CHOLESTEROL CONCENTRATION IN HUMAN SERUM OR PLASMA, CREATINE KINASE KIT(CLINIQUANT-FDR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CREATININE KINASE (CK) LEVEL IN HUMAN SERUM.,CK-MB KIT(CLINIQUANT-FDR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CREATINE KINASE LEVEL IN HUMAN SERUM.,ALKALINE PHOSPHATASE KIT(CLINIQUANT-FDR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM.,GAMMA GT (GLUPA) KIT(CLINIQUANT-FDR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE ANALYSIS OF GGT IN HUMAN SERUM.,LDH-P KIT(CLINIQUANT-FDR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LDH LEVEL IN HUMAN SERUM,AMYLASE KIT(CLINIQUANT-FDR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF AMYLASE IN HUMAN SERUM,SGOT KIT(CLINIQUANT-FDR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF SGOT LEVEL IN

	HUMAN SERUM.,SGPT KIT(CLINIQUANT-FDR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF SGPT/ALT LEVEL IN HUMAN SERUM.,CELL WASH KIT(CLINIQUANT-FSR (1ST BRAND NAME), ARIQUANT-ER(CW) (2ND BRAND NAME))-THIS SOLUTION IS INTENDED FOR CLEANING MICROFLOW CELLS AND CUVETTES OF MERILYZER CLINIQUANT. ,TOTAL PROTEIN KIT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF PROTEIN CONCENTRATION IN HUMAN SERUM OR PLASMA., MICROPROTEIN KIT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF PROTEIN CONCENTRATION IN HUMAN URINE AND CSF.,LDL DIRECT REAGENT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LOW DENSITY LIPOPROTEIN CHOLESTEROL (LDL-C) CONCENTRATION IN HUMAN SERUM OR PLASMA.,HDL-CHOLESTEROL KIT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL CONCENTRATION IN HUMAN SERUM OR PLASMA.,TRIGLYCERIDE KIT (CLINIQUANT-FSR (1ST BRAND), MARANATHA (2ND BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF TRIGLYCERIDE CONCENTRATION IN HUMAN SERUM OR PLASMA., ENZYME IMMUNOASSAY FOR THE DETECTION OF DENGUE IGG ANTIBODIES(MERILISA DENGUE LGG)-IT IS AN ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO DENGUE IGG IN HUMAN SERUM OR PLASMA BY HEALTHCARE PROFESSIONAL.,BILIRUBIN DIRECT KIT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF BILIRUBIN DIRECT CONCENTRATION IN HUMAN SERUM OR PLASMA.,HDL DIRECT REAGENT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF HIGH DENSITY LIPOPROTEIN CHOLESTEROL (HDL-C) CONCENTRATION IN HUMAN SERUM OR PLASMA.,ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO DENGUE IGM IN HUMAN SERUM OR PLASMA(MERILISA DENGUE LGM)-IT IS AN ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO DENGUE IGM IN HUMAN SERUM OR PLASMA BY HEALTHCARE PROFESSIONAL.,SGOT KIT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF SGOT LEVEL IN HUMAN SERUM.,UREA (BUN) KIT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF UREA (BUN) CONCENTRATION IN HUMAN SERUM AND URINE., BILIRUBIN TOTAL KIT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN CONCENTRATION IN HUMAN SERUM OR PLASMA.,CREATININE KIT (CLINIQUANT-FSR (1ST BRAND), MARANATHA (2ND BRAND))-THIS

	REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CREATININE CONCENTRATION IN HUMAN SERUM OR PLASMA OR URINE.,CHOLESTEROL KIT(CLINIQUANT-FSR (1ST BRAND), MARANATHA (2ND BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF CHOLESTEROL CONCENTRATION IN HUMAN SERUM OR PLASMA.,ALBUMIN KIT(CLINIQUANT-FSR)-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF ALBUMIN CONCENTRATION IN HUMAN SERUM OR PLASMA. THIS ASSAY KIT IS COVERED UNDER FLUID STABLE REAGENTS (FSR) USED WITH SEMI-AUTOMATED BIOCHEMISTRY ANALYZER. ,LDH-P KIT (CLINIQUANT-FSR (1ST BRAND), AUTOQUANT (2ND BRAND), ARIQUANT-MR (LDH) (3RD BRAND), ARIQUANT-ER (LDH) (4TH BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF LDH LEVEL IN HUMAN SERUM

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3073	MFG/MD/2018/000023	1.License Holder Name: SIEMENS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:MULTI CALIBRATOR (AUTOPAK®)-MULTI CALIBRATOR IS A MULTI-PARAMETRIC CALIBRATOR FOR IN VITRO DIAGNOSTICS USE IN THE CALIBRATION OF QUANTITATIVE AUTOPAK® CLINICAL SYSTEMS METHODS,URIC ACID -LIQUID STABLE(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF URIC ACID IN SERUM OR PLASMA BY ENZYMATIC METHOD USING CLINICAL CHEMISTRY ANALYZER,TOTAL BILIRUBIN VANADATE(AUTOPAK®)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,URIC ACID(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF URIC ACID IN SERUM , PLASMA OR URINE USING CLINICAL CHEMISTRY ANALYZER.,ALKALINE PHOSPHATASE AMP(AUTOPAK®)-FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY IN HUMAN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZERS.,UREA (AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF UREA IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER ,TOTAL PROTEIN MONO(AUTOPAK®)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZERS.,UIBC FERENE(AUTOPAK®)-FOR IN VITRO DIAGNOSTIC USE IN QUANTITATIVE DETERMINATION OF UNSATURATED IRON BINDING CAPACITY (UIBC) IN HUMAN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,MAGNESIUM(AUTOPAK®)-FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZERS., TRIGLYCERIDES-LIQUID STABLE(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF TRIGLYCERIDE IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,GLUCOSE HEXO(AUTOPAK®)-FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZERS.,TRIGLYCERIDES (AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF TRIGLYCERIDE IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,CALCIUM ARS(AUTOPAK®)-FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN HUMAN SERUM USING CLINICAL CHEMISTRY ANALYZERS.,TOTAL PROTEIN (AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF GPT (ALT) ACTIVITY IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,ADA CALIBRATOR (AUTOPAK®)-ADA CALIBRATOR IS INTENDED TO BE USED FOR

	CALIBRATION OF ADA ASSAY KIT.,REAGENT STRIPS FOR URINALYSIS- PROTEIN, GLUCOSE(URISTIX®)-DIAGNOSIS OF TOXEMIA OF PREGNANCY, GLOMERULONEPHRITIS, NEPHRITIS, DIABETES MELLITUS ETC.,LDH LIQUID STABLE(AUTOPAK®)-LDH LIQUID STABLE ASSAY KITS IS FOR IN VITRO DIAGNOSTICS USE IN THE QUANTITATIVE DETERMINATIONS OF LACTATE DEHYDROGENASE (LDH) ACTIVITY IN HUMAN SERUM AND PLASMA SAMPLE.,REAGENT STRIP FOR URINALYSIS-UROBILINOGEN, PROTEIN, PH, BLOOD, SPECIFIC GRAVITY, KETONE, BILIRUBIN, GLUCOSE(MULTISTIX® SG)-DIAGNOSIS OF DIABETES MELLITUS, JAUNDICE, HEPATITIS, TOXEMIA OF PREGNANCY, GLOMERULONEPHRITIS, NEPHRITIS, ACIDOS, ALKALOSIS, CIRRHOSIS, PYELNEPHRITIS, RENAL CARCINOMA ETC ARDENAL INSUFFICIENCY HEPATIC DISEASES AND DIABETES INSIPIDUS,ANTI-STREPTOLYSIN O (AUTOPAK®)-ANTI-STREPTOLYSIN O(ASO) ASSAY KITS IS FOR IN VITRO DIAGNOSTICS USE IN THE QUANTITATIVE DETERMINATIONS OF STREPTOLYSIN O IN SERUM SAMPLE,REAGENT STRIPS FOR URINALYSIS – LEUKOCYTES, NITRATE, UROBILINOGEN, PROTEIN, PH, BLOOD, SPECIFIC GRAVITY, KETONE, BILIRUBIN, GLUCOSE (MULTISTIX® 10SG)-REAGENT TRIPS FOR URINALYSIS FOR TESTING PROTEIN, BLOOD, LEUKOCYTES, NITRITE, GLUCOSE, KETONE, PH, SPECIFIC GRAVITY, BILIRUBIN & UROBILINOGEN,CRP CALIBRATOR (AUTOPAK®)-CRP CALIBRATOR IS INTENDED TO BE USED FOR CALIBRATION OF CRP ASSAY KIT.,SGPT (ALT)(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF GPT (ALT) ACTIVITY IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,C-REACTIVE PROTEIN(AUTOPAK®)-C-REACTIVE PROTEIN (CRP) ASSAY KITS IS FOR IN VITRO DIAGNOSTICS USE IN THE QUANTITATIVE DETERMINATIONS OF C-REACTIVE PROTEIN IN SERUM OR PLASMA SAMPLE.,SGOT (AST)(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF GOT (AST) ACTIVITY IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,ASO CALIBRATOR(AUTOPAK®)-ASO CALIBRATOR IS INTENDED TO BE USED FOR CALIBRATION OF ASO ASSAY KIT.,LIQUID TRIGLYCERIDES(AUTOPAK®)-FOR IN VITRO QUANTITIATIVE DETERMINATION OF TRIGLYCERIDE IN SERUMS OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,ADENOSINE DEAMINASE (AUTOPAK®)-ADENOSINE DEAMINASE (ADA) ASSAY KITS IS FOR IN VITRO DIAGNOSTICS USE IN THE QUANTITATIVE DETERMINATIONS OF ADENOSINE DEAMINASE ACTIVITY IN SERUM, PLASMA, PLEURAL FLUID AND CEREBROSPINAL FLUID SAMPLE,LIQUID DIRECT LDL (AUTOPAK®)-FOR IN VITRO QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IN SERUM OR PLASMA,LIPASE(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN THE QUANTITATIVE DETERMINATION OF

	LIPASE IN SERUM OR PLASMA SAMPLE.,LIQUID DIRECT HDL (AUTOPAK®)-FOR IN VITRO QUANTITIATIVE DETERMINATION OF HDL CHOLESTEROL IN SERUM.,RHEUMATOID FACTOR(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTORS (RF) IN SERUM OR PLASMA SAMPLE.,LIQUID CHOLESTEROL(AUTOPAK®)-FOR IN VITRO QUANTITATIVE DETERMINATION OF CHOLESTEROL IN SERUMS OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,IRON(AUTOPAK®)-FOR THE QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZERS.,LDH(AUTOPAK®) -FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF LACTATE DEHYDROGENASE ACTIVITY IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER ,TOTAL PROTEIN(AUTOPAK) -FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZERS.,INORGANIC PHOSPHORUS(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF INORGANIC PHOSPHORUS IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,CREATININE ENZ(AUTOPAK®)-FOR IN VITRO DIAGNOSTIC USE IN THE QUANTITATIVE MEASUREMENT OF CREATININE CONCENTRATION IN HUMAN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,HDL-CHOLESTEROL -LIQUID STABLE(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF HDL-C IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,ADA CONTROL-1(AUTOPAK) -ADA CONTROL-1 IS USED FOR QUALITY CONTROL PROCEDURES IN EXAMINING THE ACCURACY OF QUANTITATIVE ADENOSINE DEAMINASE ASSAYS.,HDL- CHOLESTEROL(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF HDL-CHOLESTEROL (HIGH DENSITY LIPOPROTEIN CHOLESTEROL) IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,AUTO-CAL(AUTOPAK)-AUTO-CAL IS A MULTI-PARAMETRIC CALIBRATOR FOR IN VITRO DIAGNOSTICS USE IN THE CALIBRATION OF QUANTITATIVE AUTOPAK CLINICAL SYSTEMS METHODS,GLUCOSE (TABLET FORMAT)(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF GLUCOSE IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,GLUCOSE(AUTOPAK)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF GLUCOSE IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,GGTP-LIQUID STABLE(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF GGTP ACTIVITY IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,REAGENT STRIPS FOR URINALYSIS- PROTEIN, GLUCOSE (URISTIX® - LONG)-DIAGNOSIS OF TOXEMIA OF PREGNANCY,

	GLOMERULONEPHRITIS, NEPHRITIS, DIABETES MELLITUS ETC., CREATININE(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF CREATINE IN SERUM, PLASMA OR URINE USING CLINICAL CHEMISTRY ANALYZER.,ADA CONTROL-2 (AUTOPAK)-ADA CONTROL-2 IS USED FOR QUALITY CONTROL PROCEDURES IN EXAMINING THE ACCURACY OF QUANTITATIVE ADENOSINE DEAMINASE ASSAYS.,CK-MB(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF TOTAL CK-MB IN SERUM USING CLINICAL CHEMISTRY ANALYZER .,DIRECT BILIRUBIN VANADATE(AUTOPAK®)-FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,CK(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF CREATINE KINASE ACTIVITY IN SERUM USING CLINICAL CHEMISTRY ANALYZER ,CHOLINESTERASE(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF ACETYL CHOLINESTERASE IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER ,CHOLESTEROL-LIQUID STABLE(AUTOPAK®) -FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF CHOLESTEROL IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,CHOLESTEROL(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF CHOLESTEROL IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER .,CHLORIDE(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF CHLORIDE IN SERUM, PLASMA OR URINE USING CLINICAL CHEMISTRY ANALYZER.,CALCIUM-CYANIDE FREE(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER .,CALCIUM(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,BUN-LIQUID STABLE(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF UREA NITROGEN IN SERUM OR PLASMA BY ENZYMATIC METHOD USING CLINICAL CHEMISTRY ANALYZER.,BUN(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF UREA NITROGEN IN SERUM OR PLASMA BY ANALYTICAL METHOD USING CLINICAL CHEMISTRY ANALYZER .,BILIRUBIN (TOTAL+DIRECT) (AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF TOTAL AND DIRECT BILIRUBIN IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,AMYLASE-LIQUID STABLE(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF ALPHA AMYLASE ACTIVITY IN SERUM , PLASMA OR URINE USING CLINICAL CHEMISTRY ANALYZER.,

	ALKALINE PHOSPHATASE(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER, ALBUMIN(AUTOPAK®)-FOR IN VITRO DIAGNOSTICS USE IN QUANTITATIVE DETERMINATION OF ALBUMIN IN SERUM OR PLASMA USING CLINICAL CHEMISTRY ANALYZER.,ACID PHOSPHATASE (AUTOPAK®)-DIAGNOSIS OF LIVER, BONE DISEASE & DESTRUCTION OF PLATELETS ETC,REAGENT STRIP FOR URINALYSIS- GLUCLOSE , KETONE(KETO-DIASTIX®)-DIAGNOSIS OF DIABETES MELLITUS (UNCONTROLLED DIABETES) ,REAGENT STRIP FOR URINALYSIS- GLUCOSE(DIASTIX®)-DIAGNOSIS OF DIABETES MELLITUS, A DISEASE WHICH PROVES FATAL IF NOT MANAGED PROPERLY,REAGENT STRIPS FOR URINALYSIS – CREATININE ,ALBUMIN(CLINITEK® MICROALBUMIN 2)-CLINITEK MICROALBUMIN 2 ARE PLASTIC STRIPS CONTAINING 2 REAGENT PADS THAT TESTS ALBUMIN & CREATININE IN URINE,REAGENT STRIPS FOR URINALYSIS – CREATININE, ALBUMIN (MICROALBUSTIX®)-MICROABLUSTIX REAGENT STRIPS ARE FIRM PLASTIC STRIPS THAT CONTAINS 02 REAGENT AREAS THAT TESTS ALBUMIN & CREATININE IN URINE,REAGENT STRIPS FOR URINALYSIS – GLUCOSE,PROTEIN, PH, SPECIFIC GRAVITY(COMBISTIX® SG)-DIAGNOSIS OF DIABETES INSIPIDUS, DIABETES MELLITUS, TOXEMIA OF PREGNANCY, NEPHRITIS, ACIDOSIS, ALKALOSIS, ADRENAL DISORDERS AND HEPATIC DISEASES,HDL-CALIBRATOR(AUTOPAK®)-HDL-CALIBRATOR IS INTENDED TO BE USED FOR CALIBRATION OF HDL ASSAY KIT.,LDL-CALIBRATOR(AUTOPAK®)-LDL-CALIBRATOR IS INTENDED TO BE USED FOR CALIBRATION OF LDL ASSAY KIT.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3074	MFG/MD/2018/000024	1.License Holder Name: M/S. MERIL ENDO SURGERY PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE STAPLES (PINS) FOR DISPOSABLE ENDO CUTTER STAPLER(MIRUS™ DISPOSABLE ENDO CUTTER STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY. , STERILE STAPLES (PINS) FOR DISPOSABLE CURVED CUTTER STAPLER(MIRUS™ DISPOSABLE CURVED CUTTER STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,STERILE STAPLES (PINS) FOR DISPOSABLE LINEAR CUTTER STAPLER(MIRUS™ DISPOSABLE LINEAR CUTTER STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY, STERILE STAPLES (PINS) FOR DISPOSABLE HEMORRHOIDS STAPLER (MIRUS™ DISPOSABLE HEMORRHOIDS STAPLER 3 ROWS)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY. ,STERILE STAPLES (PINS) FOR DISPOSABLE HEMORRHOIDS STAPLER(MIRUS™ DISPOSABLE HEMORRHOIDS STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY. ,STERILE STAPLES (PINS) FOR DISPOSABLE LINEAR STAPLER(MIRUS™ DISPOSABLE LINEAR STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,STERILE STAPLES (PINS) FOR DISPOSABLE CIRCULAR STAPLERS(MIRUS™ DISPOSABLE CIRCULAR STAPLER 3 ROWS)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY. ,STERILE STAPLES (PINS) FOR DISPOSABLE CIRCULAR STAPLER(MIRUS™ DISPOSABLE CIRCULAR STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,DISPOSABLE SKIN STAPLER (MIRUS™ STERILE DISPOSABLE SKIN STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,STERILISED UMBILICAL COTTON TAPE(MERIL - UMBILICAL COTTON TAPE™)-MERIL - UMBILICAL COTTON TAPE™ IS USED TO TIE OFF THE UMBILICAL CORD.,BONEWAX(MERIL-

		BONEWAX™)-MERIL - BONEWAX™ IS INTENDED TO AID IN THE CONTROL OF BLEEDING IN BONE INJURIES.
3075	MFG/MD/2018/000025	1.License Holder Name: WIRKSAM PHARMA PRIVATE LIMITED 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:URINE BAG-A CLOSED URINARY DRAINAGE SYSTEM CONSISTS OF A CATHETER INSERTED INTO THE URINARY BLADDER AND CONNECTED VIA TUBING TO A DRAINAGE BAG,THREE WAY STOP COCK-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,MICRO DRIP INFUSION SET (INFUSION SET FOR SINGLE USE) (IS 12655-4)-AN MICRO DRIP INFUSION SET IS USED TO ADMINISTER IV FLUIDS AND DRUGS INTO THE CIRCULATION SYSTEM OF PAEDIATRIC PATIENTS, OFFERING CONSISTENT DELIVERY WITH GRAVITY FEED.,MEASURED VOLUME ADMINISTRATION SET (BURETTE INFUSION SET FOR SINGLE USE (ISO 8536-4,5; IS 12655-4)-IT IS USED FOR THE ADMINISTRATION OF IV FLUIDS FROM A MEASURED VOLUME BURETTE INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE., INFUSION SET FOR SINGLE USE WITH Y CONNECTOR [IS 12655-4]-AN INFUSION SET IS USED TO ADMINISTER INTRAVENOUS FLUID AND DRUGS INTO THE CIRCULATING SYSTEM WITH PRECISION AND CONSISTENT DELIVERY.,I.V. INFUSION SET (INFUSION SET FOR SINGLE USE) [IS 12655-4]-AN INFUSION SET IS USED TO ADMINISTER INTRAVENOUS FLUID AND DRUGS INTO THE CIRCULATING SYSTEM WITH PRECISION AND CONSISTENT DELIVERY.,BLOOD TRANSFUSION SET (TRANSFUSION SET FOR SINGLE USE) [IS 9824-3]-TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN

3076	MFG/MD/2018/000026	1.License Holder Name: MEDORAH MEDITEK PVT LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:POLYPECTOMY SNARE (ALFIOS)-POLYPECTOMY SNARE IS INDICATED TO USE FOR POLYPECTOMY, REMOVING AND DISSECTING THE POLYPS FROM GI TRACT.,STONE EXTRACTION BALLOON(CAPTOR)-IT IS USED FOR DILATING THE SPHINCTER MUSCLE AND REMOVES THE STONE FROM THE COMMON BILE DUCT. IT IS INTENDED TO EXTRACT STONES TREATED BY ENDOSCOPIC SPHINCTEROTOMY.,STENT INTRODUCER SET/ STENT PUSHER(MEDORAH)-IT IS USED FOR DELIVERING THE BILIARY DRAINAGE CATHETERS USED FOR THE DRAINAGE OF THE OBSTRUCTED BILIARY SYSTEM DUE TO BENIGN OR MALIGNANT TUMORS. THIS DEVICE PROVIDES SUPPORT FOR DEVICE ADVANCEMENT TO ITS INTENDED LOCATION WITHIN THE ANATOMY., PERCUTANEOUS ENDOSCOPIC GASTROSTOMY(PEG) KIT(MEDORAH)-IT IS INDICATED FOR ENTERAL NUTRITION DIRECTLY INTO THE STOMACH IN BOTH PEDIATRIC AND ADULT PATIENTS WHO ARE UNABLE TO CONSUME NUTRITION BY CONVENTIONAL MEANS., NEEDLE KNIFE(MEDORAH)-IT IS USED FOR ACCESSING THE COMMON BILE DUCT WHEN STANDARD METHODS FOR CANNULATION HAVE BEEN EXHAUSTED AND FOR INCISION OF PAPILLA OF VATER PRIOR TO ERCP. THE TRIPLE LUMEN DESIGN FACILITATES CANNULATION AFTER INCISION WITHOUT REQUIRING THAT THE CATHETER BE EXCHANGED.,ENDOSCOPIC NEEDLE(PIVOT)-USED TO SAMPLE TARGETED SUBMUCOSAL GASTROINTESTINAL LESIONS THROUGH THE ACCESSORY CHANNEL OF AN ULTRASOUND ENDOSCOPE.,PTCA KIT(MEDORAH)-IT IS INTENDED TO USE AS ACCESSORIES AND FOR PTCA PROCEDURES.,BILIARY STONE RETRIEVAL BASKET(MEDORAH)-IT IS INTENDED TO EXTRACT STONES IN AN ANTEGRADE FASHION THROUGH AN AMPULLARY ORIFICE PREVIOUSLY TREATED BY ENDOSCOPIC SPHINCTEROROMY OR LESS COMMONLY WITH BALLOON DILATION.,SCLEROTHERAPY NEEDLE(MEDORAH)-THESE ARE DESIGNED TO BE USED TO PROVIDE ACCESS FOR INJECTION THERAPY APPLICATIONS AND MAY ALSO BE USED FOR POLYPECTOMY AND ENDOSCOPIC MUCOSAL RESECTION(EMR), MANIFOLDS(MEDORAH)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT/PORTS FOR ADMINISTRATION OF A SOLUTION.,ANGIOGRAPHIC NEEDLE (MEDORAH)-IT HAS A UNIQUE HUB DESIGN WITH AN ERGONOMIC FEEL AND BLACK TRIANGLE INDICATOR TO ORIENT THE BEVEL.,Y CONNECTOR(MEDORAH)-IT IS INTENDED TO BE USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC.,BALLOON DILATOR(MEDORAH)-SOFT CATHETER WITH AN INFLATABLE BALLOON AT ITS TIP WHICH IS USED DURING A

	CATHERIZATION PROCEDURE TO ENLARGE A NARROW OPENING OR PASSAGE WITHIN THE BODY.,FOREIGN BODY REMOVAL NET (FORENET)-ENDOSCOPIC FORCEPS ARE INTENDED TO BE USED TO GRASP TISSUE, RETRIEVE FOREIGN BODIES AND REMOVE TISSUES FROM WITHIN THE GASTROINTESTINAL TRACT.,ENDOSCOPIC FORCEPS(MEDORAH)-IT IS INTENDED TO BE USED TO GRASP TISSUE , RETRIEVE FOREIGN BODIES AND REMOVE TISSUES FROM WITHIN THE GI TRACT.,SPHINCTEROTOME(MEDORAH)-THIS DEVICE IS BEING USED TO PERFORM TRANSENDOSCOPIC CANNULATION OF THE BILIARY SYSTEM AND SPHINCTEROTOMY OF THE PAPILLA.,BAND LIGATOR/ENDOSCOPIC LIGATION DEVICE(MEDORAH)-IT IS INTENDED TO USE FOR PROXIMAL AND DISTAL LIGATION OF VESSELS DURING ENDOSCOPIC VESSEL HARVESTING PROCEDURES.,ERCP GUIDEWIRE (JAQUAR)-IT IS USED TO DIRECT A CATHETER TO THE DESIRED ANATOMICAL LOCATION DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURES.THIS WIRE IS USED TO GAIN ACCESS TO THE BILIARY SYSTEM. IT IS ALSO USED TO LEAD ACCESSORIES IN ORDER TO PERFORM BILIARY/ LIVER PROCEDURES LIKE ERCP.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3077	MFG/MD/2018/000027	1.License Holder Name: M/S. MERIL ENDO SURGERY PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ABSORBABLE POLY (P-DIOXANONE) KNOTLESS SUTURE(PINION™ PDO KNOTLESS SUTURE)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,ABSORBABLE POLY (P-DIOXANONE) SURGICAL SUTURE ANTIBACTERIAL WITH CHLORHEXIDINE COATED SUTURE(FILAXYN™ C+/ASPIRON POLYDIOXANONE C+)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,ABSORBABLE STERILIZED SURGICAL POLY (GLYCOLIDE/L-LACTIDE) SUTURE ANTIBACTERIAL WITH TRICLOSAN COATED SUTURE(MITSU™ AB / ASPIRON POLYGLACTIN 910 AB / MITSU AB™ CAS)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,ABSORBABLE POLY (P-DIOXANONE) SURGICAL SUTUREANTIBACTERIAL WITH TRICLOSAN COATED SUTURE(FILAXYN™ AB/ ASPIRON POLYDIOXANONE AB)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, ABSORBABLE POLY (GLYCOLIDE-CO-CAPROLACTONE) SURGICAL SUTURE (FILAPRON™ / ASPIRON POLYGLECAPRONE 25 / REDICAPRONE / FILAPRON™ CAS)-FILAPRON™ CAS SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION WHERE AN ABSORBABLE MATERIAL IS INDICATED.,ABSORBABLE STERILIZED SURGICAL POLYGLYCOLIC ACID SUTURE ANTIBACTERIAL WITH CHLORHEXIDINE COATED SUTURE(MEGASORB™ PLUS / ASPIRON POLYGLYCOLIC ACID PLUS)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,ABSORBABLE POLY(GLYCOLIDE-CO-CAPROLACTONE) SURGICAL SUTURE U.S.P ANTIBACTERIAL WITH TRICLOSAN COATED SUTURE(FILAPRON™ AB/ ASPIRON POLYGLECAPRON 25 AB)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, ABSORBABLE STERILIZED SURGICAL POLYGLYCOLIC ACID SUTURE ANTIBACTERIAL WITH TRICLOSAN COATED SUTURE(MEGASORB™ PLUS / MEGASORB™ T+/ASPIRON POLYGLYCOLIC ACID T+)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,LEVONORGESTREL 20MICROGRAMS/24 HOURS HORMONAL INTRAUTERINE SYSTEM (FIONA™ U.S.P/ IFORIUS™ U.S.P /CHARLIZE U.S.P/ SABATICA™ U.S.P)-INTENDED FOR CONTRACEPTION. IT CAN ALSO BE USED IN IDIOPATHIC MENORRHAGIA AND PROTECTION FROM ENDOMETRIAL HYPERPLASIA DURING ESTROGEN REPLACEMENT THERAPY., ABSORBABLE STERILIZED SURGICAL POLY(GLYCOLIDE/L-LACTIDE)

	SUTURE ANTIBACTERIAL WITH CHLORHEXIDINE COATED SUTURE (MITSU™ C+/ ASPIRON POLYGLACTIN 910 C+)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,LEVONORGESTREL 20MICROGRAMS/24 HOURS HORMONAL INTRAUTERINE SYSTEM(FIONA™/IFORIUS™ /CHARLIZE / SABATICA™)-INTENDED FOR CONTRACEPTION. IT CAN ALSO BE USED IN IDIOPATHIC MENORRHAGIA AND PROTECTION FROM ENDOMETRIAL HYPERPLASIA DURING ESTROGEN REPLACEMENT THERAPY.,CU 250 STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICE(MERITE™ CU 250)-INDICATED FOR INTRAUTERINE CONTRACEPTION,ABSORBABLE STERILIZED SURGICAL CATGUT CHROMIC SUTURE U.S.P(MERISOFT CHROMIC™ / ASPIRON CATGUT CHROMIC / REDIGUT CHROMIC™ / MERISOFT CHROMIC™ REEL / MERISOFT CHROMIC™ CAS/REDIGUT® CHROMIC PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,ABSORBABLE POLY (P-DIOXANONE) SURGICAL SUTURE U. S.P.(REDIDIOX® PRO (ADDITIONAL BRAND NAME OF FILAXYN™))-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,NON-ABSORBABLE POLY (ETHYLENE TEREPHTHALATE) SURGICAL SUTURE U.S.P.(MERICRON XL™ / ASPIRON POLYESTER / REDIBOND™, MERICRON XL™ REEL, MERICRON XL™ CAS/REDIBOND® PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION., STERILE ABSORBABLE POLY (LACTIDE-CO-GLYCOLIDE) MESH FIXATION DEVICE(PROFOUND™ A)-INTENDED FOR THE FIXATION OF SURGICAL MESH TO TISSUE DURING OPEN OR LAPAROSCOPIC SURGICAL PROCEDURES, SUCH AS HERNIA REPAIR.,STERILE STAPLES (PINS) FOR DISPOSABLE LINEAR CUTTER STAPLER(MIRUS™ DISPOSABLE LINEAR CUTTER STAPLER)-MIRUS™ LINEAR CUTTER AND RELOAD HAVE APPLICATION IN GASTROINTESTINAL, GYNECOLOGIC, THORACIC, AND PEDIATRIC SURGERY FOR TRANSECTION, RESECTION, AND/OR CREATION OF ANASTOMOSES AND CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIALS.,NON-ABSORBABLE STERILISED SURGICAL POLYPROPYLENE SOFT MESH(FILAPROP™ MESH SOFT/ASPIRON POLY PROPYLENE SOFT MESH)-INTENDED FOR USE IN HERNIA REPAIR, ABDOMINAL WALL REPAIR AND OTHER FASCIAL SURGICAL INTERVENTION PROCEDURES.,STERILE STAPLES (PINS) FOR DISPOSABLE CIRCULAR STAPLER(MIRUS™ DISPOSABLE CIRCULAR STAPLER)-MIRUS CIRCULAR STAPLER HAS APPLICATION THROUGHOUT THE ALIMENTARY TRACT FOR END TO END, END TO SIDE AND SIDE TO SIDE ANASTOMOSES.,NON-ABSORBABLE STERILISED SURGICAL MACROPOROUS POLYPROPYLENE MESH (MERIGROW™ MESH)-INTENDED FOR USE IN HERNIA REPAIR,

	ABDOMINAL WALL REPAIR AND OTHER FASCIAL SURGICAL INTERVENTION PROCEDURES.,STERILE STAPLES (PINS) FOR DISPOSABLE CURVED CUTTER STAPLER (MIRUS™ DISPOSABLE CURVED CUTTER STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY., DUAL SIDE MESH FOR INTRA-PERITONIAL PLACEMENT(CONTACTO™ MESH)-INTENDED FOR USE IN HERNIA REPAIR, ABDOMINAL WALL REPAIR AND OTHER FASCIAL SURGICAL INTERVENTION PROCEDURES,BONEWAX(MERIL-BONEWAX™)-MERIL - BONEWAX™ IS INTENDED TO AID IN THE CONTROL OF BLEEDING IN BONE INJURIES., LEVONORGESTREL 20MICROGRAMS/24 HOURS HORMONAL INTRAUTERINE SYSTEM(ERINNA™ U.S.P. / EMIRELLE™ U.S.P.)-INTENDED FOR CONTRACEPTION. IT CAN ALSO BE USED IN IDIOPATHIC MENORRHAGIA AND PROTECTION FROM ENDOMETRIAL HYPERPLASIA DURING ESTROGEN REPLACEMENT THERAPY., ABSORBABLE POLY (P-DIOXANONE) SURGICAL SUTURE ANTIBACTERIAL WITH CHLORHEXIDINE COATED SUTURE(FILAXYN™ C+/ASPIRON POLYDIOXANONE C+)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, PARTIALLY ABSORBABLE STERILISED MONOFILAMENT KNITTED TISSUE RECONSTRUCTION PROSTHESIS MESH(ABSOMESH™)-INTENDED FOR USE IN HERNIA REPAIR, ABDOMINAL WALL REPAIR AND OTHER FASCIAL SURGICAL INTERVENTION PROCEDURES,NON ABSORBABLE POLYVINYLIDENE FLUORIDE SURGICAL SUTURE U.S.P (FILADENE™)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,PARTIALLY ABSORBABLE SURGICAL TISSUE SEPARATING DUAL LAYER MESH(MERINEUM™ MESH)-INTENDED FOR USE IN HERNIA REPAIR, ABDOMINAL WALL REPAIR AND OTHER FASCIAL SURGICAL INTERVENTION PROCEDURES,STERILE STAPLES (PINS) FOR DISPOSABLE LINEAR STAPLER(MIRUS™ DISPOSABLE LINEAR STAPLER)-MIRUS™ LINEAR STAPLER AND RELOAD HAS APPLICATIONS IN ABDOMINAL, GYNECOLOGICAL, PEDIATRIC AND THORACIC SURGICAL PROCEDURES FOR RESECTION OR TRANSECTION OF TISSUE AND CREATION OF ANASTOMOSIS, INCLUDING OCCLUSION OF THE LEFT ATRIAL APPENDAGE IN OPEN PROCEDURES. THEY MAY BE USED FOR TRANSECTION AND RESECTION OF PANCREAS.,NON-ABSORBABLE STERILISED HYDROPHILIC 3-DIMENSIONAL MESH(MERICRON 3D™ MESH)-INTENDED FOR USE IN HERNIA REPAIR, ABDOMINAL WALL REPAIR AND OTHER FASCIAL SURGICAL INTERVENTION PROCEDURES.,ABSORBABLE STERILIZED SURGICAL POLYGLYCOLIC ACID SUTURE ANTIBACTERIAL WITH CHLORHEXIDINE COATED SUTURE(MEGASORB™ PLUS / ASPIRON POLYGLYCOLIC ACID PLUS)-

	THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,STERILE NON - ABSORBABLE TITANIUM MESH FIXATION DEVICE(PROFOUND™ N)-INTENDED FOR THE FIXATION OF SURGICAL MESH TO TISSUE DURING OPEN OR LAPAROSCOPIC SURGICAL PROCEDURES, SUCH AS HERNIA REPAIR., NATURAL NON-ABSORBABLE SILK SURGICAL SUTURE U.S.P. (FILASILK™ / ASPIRON SILK BLACK/ REDISILK™ / FILASILK™ CAS/REDISILK® PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,CU 375 SLEEK STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICES (MERITE™ CU 375 SLEEK)-INDICATED FOR INTRAUTERINE CONTRACEPTION,POWERED ENDOSCOPIC LINEAR CUTTER (MIRUS™ POWERED ENDOCUTTER)-THE MIRUS POWERED ENDOCUTTER IS INTENDED FOR TRANSECTION, RESCETION, AND/OR CREATION OF ANASTOMOSES. THE INSTRUMENTS HAVE APPLICATION IN MULTIPLE MINIMALLY INVASIVE GENERAL, GYNECOLOGIC, UROLOGIC, THORACIC, AND PEDIATRIC PROCEDURES. THEY CAN BE USED WITH STAPLE LINE OR TISSUE BUTTRESSING MATERIALS. THE INSTRUMENTS MAY ALSO BE USED FOR TRANSECTION AND RESECTION OF LIVER PANRENCHYMA (HEPATIC VASCULAR AND BILIARY STRUCTRES), PANCREAS,KIDNEY AND SPLEEN.,NON-ABSORBABLE POLY(ETHYLENE TEREPHTHALATE) SURGICAL SUTURE U.S.P WITH PTFE PLEDGET(MERICRON™ XL P)-NON ABSORBABLE PLEDGETED SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION INCLUDING CARDIOVASCULAR SURGERY, NEUROLOGICAL AND OPHTHALMIC PROCEDURES.,DISPOSABLE ENDOSCOPIC TROCAR (XPRESS™ / MONIK™ / ELIRO™)-THE DISPOSABLE ENDOSCOPIC TROCAR HAS APPLICATIONS IN ABDOMINAL, THORACIC AND GYNECOLOGIC MINIMALLY INVASIVE SURGICAL PROCEDURES TO ESTABLISH A PATH OF ENTRY FOR ENDOSCOPIC INSTRUMENTS. THE TROCAR MAY BE USED WITH OR WITHOUT VISUALIZATION FOR PRIMARY AND SECONDARY INSERTIONS.,NATURAL NON-ABSORBABLE SILK SURGICAL SUTURE U.S.P.(FILASILK™ REEL / ASPIRON SILK BLACK REEL)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,STERILE STAPLES (PINS) FOR DISPOSABLE HEMORRHOIDS STAPLER(MIRUS™ DISPOSABLE HEMORRHOIDS STAPLER 3 ROWS)-MIRUS HEMORRHOIDAL CIRCULAR STAPLER HAS APPLICATION THROUGHOUT THE ANAL CANAL TO PERFORM SURGICAL TREATMENT OF HEMORRHOIDAL DISEASE.,LEVONORGESTREL 20MICROGRAMS/24 HOURS HORMONAL INTRAUTERINE SYSTEM (ERINNA™ / EMIRELLE™)-INTENDED FOR CONTRACEPTION. IT CAN ALSO BE USED IN IDIOPATHIC MENORRHAGIA AND PROTECTION

	FROM ENDOMETRIAL HYPERPLASIA DURING ESTROGEN REPLACEMENT THERAPY.,STERILE STAPLES (PINS) FOR DISPOSABLE ENDO CUTTER STAPLER(MIRUS™ DISPOSABLE ENDO CUTTER STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,ABSORBABLE POLYGLYCOLIC ACID SURGICAL SUTURE U.S.P.(MEGASORB™ / ASPIRON POLYGLYCOLIC ACID / REDISORB™ / MEGASORB™ REEL / MEGASORB™ CAS)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,DISPOSABLE SKIN STAPLER(MIRUS™ STERILE DISPOSABLE SKIN STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,ABSORBABLE STERILIZED SURGICAL CATGUT PLAIN SUTURE U.S.P(REDIGUT® PLAIN PRO (ADDITIONAL BRAND NAME OF MERISOFT PLAIN™))-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION., STERILE STAPLES (PINS) FOR DISPOSABLE CIRCULAR STAPLERS (MIRUS™ DISPOSABLE CIRCULAR STAPLER 3 ROWS)-MIRUS CIRCULAR STAPLER HAS APPLICATION THROUGHOUT THE ALIMENTARY TRACT FOR END TO END, END TO SIDE AND SIDE TO SIDE ANASTOMOSES.,ABSORBABLE POLY(GLYCOLIDE/L-LACTIDE) SURGICAL SUTURE U.S.P.(REDICRYL® - FAST PRO (ADDITIONAL BRAND NAME OF MITSU FST™))-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION., ABSORBABLE STERILIZED SURGICAL POLY(GLYCOLIDE/L-LACTIDE) SUTURE ANTIBACTERIAL WITH TRICLOSAN COATED SUTURE (MITSU™ AB / ASPIRON POLYGLACTIN 910 AB / MITSU AB™ CAS)-MITSU AB™ CAS IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION EXCEPT FOR OPHTHALMIC, CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE POLYGLYCOLIC ACID SURGICAL SUTURE U.S.P.(MEGASORB RAPID™ / ASPIRON POLYGLYCOLIC ACID RAPID / REDISORB - FAST™)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,ABSORBABLE STERILIZED SURGICAL POLY(GLYCOLIDE/L-LACTIDE) SUTURE ANTIBACTERIAL WITH CHLORHEXIDINE COATED SUTURE(MITSU™ C+/ ASPIRON POLYGLACTIN 910 C+)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, ABSORBABLE POLY(GLYCOLIDE/L-LACTIDE) SURGICAL SUTURE U.S. P.(MITSU FST™ / MABEL FST™ / ASPIRON POLYGLACTIN 910 FST/ REDICRYL - FAST™)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,NATURAL NON-ABSORBABLE SILK SURGICAL SUTURE U.S.P.(FILASILK™ REEL /

	ASPIRON SILK BLACK REEL)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, ABSORBABLE POLY(GLYCOLIDE-CO-CAPROLACTONE) SURGICAL SUTURE U.S.P(FILAPRON™ / ASPIRON POLYGLECAPRONE 25 / REDICAPRONE™)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,ABSORBABLE POLY (GLYCOLIDE/L-LACTIDE) SURGICAL SUTURE U.S.P.(MITSU FST™ / MABEL FST™ / ASPIRON POLYGLACTIN 910 FST/ REDICRYL - FAST™/REDICRYL® - FAST PRO/ / MITSU FST™ CAS)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,ABSORBABLE POLY(GLYCOLIDE/L-LACTIDE) SURGICAL SUTURE U.S.P(MITSU™ / MABEL™ / ASPIRON POLYGLACTIN 910 / REDICRYL™ / MITSU™ REEL/ MITSU™ CAS)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, ABSORBABLE STERILIZED SURGICAL CATGUT CHROMIC SUTURE U.S. P. (PRE-KNOTTED LOOP LIGATURE FOR ENDO SURGERY)(FILATWINE) -FILATWINE SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,ABSORBABLE POLY (P-DIOXANONE) SURGICAL SUTURE.(FILAXYN™ / ASPIRON POLYDIOXANONE / REDIDIOX™)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,NON-ABSORBABLE POLY(ETHYLENE TEREPHTHALATE) SURGICAL SUTURE U.S.P WITH PTFE PLEDGET(MERICRON™ XL P)-NON ABSORBABLE PLEDGETED SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION INCLUDING CARDIOVASCULAR SURGERY, NEUROLOGICAL AND OPHTHALMIC PROCEDURES.,ABSORBABLE POLY (P-DIOXANONE) KNOTLESS SUTURE(PINION™ PDO KNOTLESS SUTURE)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,ABSORBABLE POLY (P-DIOXANONE) SURGICAL SUTURE (FILAXYN™ / ASPIRON POLYDIOXANONE / REDIDIOX / FILAXYN™ CAS)-FILAXYN™ CAS SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION INCLUDING USE IN OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY USEFUL WHERE AN ABSORBABLE SUTURE WITH PROLONGED WOUND SUPPORT (UP TO 42 DAYS) IS REQUIRED.,NON-ABSORBABLE POLYPROPYLENE SURGICAL SUTURE U.S.P.(FILAPROP™ / ASPIRON POLYPROPYLENE BLUE / REDILENE™ / FILAPROP™ REEL/ FILAPROP™ CAS)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,NON-ABSORBABLE POLYAMIDE SURGICAL SUTURE U.S.P(FILAMIDE™ / ASPIRON POLYAMIDE BLACK / REDILON™, FILAMIDE™ – B / FILAMIDE™ REEL & FILAMIDE™ CAS/REDILON® PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,

	ABSORBABLE STERILIZED SURGICAL CATGUT PLAIN SUTURE U.S.P (MERISOFT PLAIN™ / ASPIRON CATGUT PLAIN / REDIGUT PLAIN™ / MERISOFT PLAIN™ REEL / MERISOFT PLAIN™ CAS)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,NON ABSORBABLE POLYTETRAFLUOROETHYLENE SURGICAL SUTURE(RI-CORD)-THE RI CORD SUTURE IS INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN CARDIOVASCULAR SURGERY AND DURA MATER REPAIR. IT IS RECOMMENDED FOR USE WHERE REDUCED SUTURE LINE BLEEDING DURING CARDIOVASCULAR ANASTOMOTIC PROCEDURES IS DESIRED.,NATURAL NON-ABSORBABLE SILK SURGICAL SUTURE U.S.P.(FILASILK™ / ASPIRON SILK BLACK/ REDISILK™ / FILASILK™ CAS)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,ABSORBABLE POLY (P-DIOXANONE) SURGICAL SUTURE ANTIBACTERIAL WITH TRICLOSAN COATED SUTURE(FILAXYN™ AB/ ASPIRON POLYDIOXANONE AB)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,ABSORBABLE STERILIZED SURGICAL CATGUT CHROMIC SUTURE U.S.P(MERISOFT CHROMIC™ / ASPIRON CATGUT CHROMIC / REDIGUT CHROMIC™ / MERISOFT CHROMIC™ REEL / MERISOFT CHROMIC™ CAS)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,STERILE STAPLES (PINS) FOR DISPOSABLE HEMORRHOIDS STAPLER(MIRUS™ DISPOSABLE HEMORRHOIDS STAPLER)-MIRUS HEMORRHOIDAL CIRCULAR STAPLER HAS APPLICATION THROUGHOUT THE ANAL CANAL TO PERFORM SURGICAL TREATMENT OF HEMORRHOIDAL DISEASE.,LEVONORGESTREL 20MICROGRAMS/24 HOURS HORMONAL INTRAUTERINE SYSTEM (FIONA™)-INTENDED FOR CONTRACEPTION. IT CAN ALSO BE USED IN IDIOPATHIC MENORRHAGIA AND PROTECTION FROM ENDOMETRIAL HYPERPLASIA DURING ESTROGEN REPLACEMENT THERAPY., ABSORBABLE POLYGLYCOLIC ACID SURGICAL SUTURE U.S.P. (MEGASORB RAPID™ / ASPIRON POLYGLYCOLIC ACID RAPID / REDISORB - FAST™/REDISORB® - FAST PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,NON-ABSORBABLE POLYAMIDE SURGICAL SUTURE U.S.P (FILAMIDE™ / ASPIRON POLYAMIDE BLACK / REDILON™, FILAMIDE™ – B / FILAMIDE™ REEL & FILAMIDE™ CAS)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION., ABSORBABLE POLY(GYLCOLIDE/L-LACTIDE) SURGICAL SUTURE U.S.P(REDISORB® PRO)-REDISORB® PRO SUTURE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES, BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE

	STERILIZED SURGICAL CATGUT CHROMIC SUTURE U.S.P(REDIGUT® CHROMIC PRO (ADDITIONAL BRAND NAME OF MERISOFT CHROMIC™))-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,CU 375 STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICE(MERITE CU 375 / KHUSHI CU 375 / PRIMA CU 375 / INTIMA CU 375 / TIUP A CU 375 / FREEDOM5 CU 375 / URVASHI 375 STANDARD)-THE CU 375 INTRAUTERINE DEVICE (IUD) IS A FORM OF BIRTH CONTROL CONSISTING OF A SHAPED FRAME COMPRISING TWO WINGS JOINED TO UPRIGHT STEM, BRIEFLY DESCRIBED AS A 'U'-SHAPED DEVICE, CONTAINING COPPER IS INSERTED INTO THE UTERUS. IUDS ARE A FORM OF LONG-ACTING REVERSIBLE CONTRACEPTION, WHICH IS THE MOST EFFECTIVE TYPE OF REVERSIBLE BIRTH CONTROL. MERITETM CU 375 IS INDICATED FOR INTRAUTERINE CONTRACEPTION FOR UP TO 5 YEARS,NON-ABSORBABLE POLY(ETHYLENE TEREPHTHALATE) SURGICAL SUTURE U.S.P.(MERICRON XL™ / ASPIRON POLYESTER / REDIBOND™, MERICRON XL™ REEL, MERICRON XL™ CAS)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION., ABSORBABLE STERILIZED SURGICAL POLYGLYCOLIC ACID SUTURE ANTIBACTERIAL WITH TRICLOSAN COATED SUTURE(MEGASORB™ PLUS / MEGASORB™ T+/ASPIRON POLYGLYCOLIC ACID T+)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,NON-ABSORBABLE POLYAMIDE SURGICAL SUTURE U.S.P(REDILON® PRO (ADDITIONAL BRAND NAME OF FILAMIDE™))-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,ABSORBABLE POLYGLYCOLIC ACID SURGICAL SUTURE U.S.P.(MEGASORB™ / ASPIRON POLYGLYCOLIC ACID / REDISORB™ / MEGASORB™ REEL / MEGASORB™ CAS/REDISORB® PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,NON ABSORBABLE STAINLESS STEEL SURGICAL SUTURE U.S.P (MERISTEEL™ / ASPIRON STAINLESS STEEL)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,ABSORBABLE STERILIZED SURGICAL POLY(GLYCOLIDE/L-LACTIDE) SUTURE (MITSU FST™ / MABEL FST™/ ASPIRON POLYGLACTIN 910 FST / REDICRYL - FAST™ / REDICRYL® FAST PRO / MITSU FST™ CAS)-MITSU FST™ CAS SUTURE IS USED WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND ALSO WHERE THE RAPID ABSORPTION OF THE SUTURE IS DESIRABLE. THE RAPID ABSORPTION PROFILE IS PARTICULARLY USEFUL FOR APPLICATIONS SUCH AS SKIN CLOSURE INCLUDING EPISIOTOMY REPAIR, PAEDIATRIC SURGERY, CLOSURE OF ORAL MUCOSA AND ALSO IN OPHTHALMIC SURGERY FOR CONJUNCTIVAS SUTURES., ABSORBABLE POLYGLYCOLIC ACID- POLY(GLYCOLIDE-CO-

	CAPROLACTONE) KNOTLESS SUTURE(PINION™ PGA-PCL KNOTLESS SUTURE)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,ABSORBABLE POLY (GLYCOLIDE/L-LACTIDE) SURGICAL SUTURE U.S.P(MITSU™ / MABEL™ / ASPIRON POLYGLACTIN 910 / REDICRYL™ / MITSU™ REEL/ MITSU™ CAS/REDISORB® PRO/REDICRYL® PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, NON ABSORBABLE POLYVINYLIDENE FLUORIDE SURGICAL SUTURE U.S.P(FILADENE™)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,NON-ABSORBABLE POLYPROPYLENE SURGICAL SUTURE U.S.P. WITH PTFE PLEDGET (FILAPROP™ P)-NON ABSORBABLE PLEDGETED SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION INCLUDING CARDIOVASCULAR SURGERY, NEUROLOGICAL AND OPHTHALMIC PROCEDURES.,CU 375 STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICE(MERITE™ CU 375 / KHUSHI™ CU 375 / INTIMA™ CU 375 / TIUP™ A CU 375 / FREEDOM5™ CU 375/PRIMA™ CU 375)-INDICATED FOR INTRAUTERINE CONTRACEPTION.,ABSORBABLE POLYGLYCOLIC ACID- POLY(GLYCOLIDE-CO-CAPROLACTONE) KNOTLESS SUTURE (PINION™ PGA-PCL KNOTLESS SUTURE)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, CU T 380 A STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICES (MERITE™ CU T 380 A /KHUSHI™ CU T 380 A / PRIMA™ CU T 380A / ENOVA™ CU T 380A /TIUP™ CU T 380A)-INDICATED FOR INTRAUTERINE CONTRACEPTION.,ABSORBABLE POLY (P-DIOXANONE) SURGICAL SUTURE(FILAXYN™ / ASPIRON POLYDIOXANONE / REDIDIOX™/REDIDIOX® PRO / FILAXYN™ CAS)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,NATURAL NON-ABSORBABLE SILK SURGICAL SUTURE U.S.P.(REDISILK® PRO (ADDITIONAL BRAND NAME OF FILASILK™))-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION., ABSORBABLE STERILIZED SURGICAL CATGUT PLAIN SUTURE U.S.P (MERISOFT PLAIN™ / ASPIRON CATGUT PLAIN / REDIGUT PLAIN™ / MERISOFT PLAIN™ REEL / MERISOFT PLAIN™ CAS/REDIGUT® PLAIN PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,CU 250 SLEEK STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICES(MERITE™ CU 250 SLEEK / U-KARE® CU 250 SLEEK)-INDICATED FOR INTRAUTERINE CONTRACEPTION,NON-ABSORBABLE PTFE (POLYTETRAFLUOROETHYLENE) PLEDGETS(MERIL PLEDGET / FILAPLEDGE)-PLEDGETS ARE INTENDED FOR USE TO SECURE AND SUPPORT SUTURE PLACEMENT.,ABSORBABLE POLY(GLYCOLIDE-CO-

	CAPROLACTONE) SURGICAL SUTURE U.S.P ANTIBACTERIAL WITH CHLORHEXIDINE COATED SUTURE(FILAPRON™ C+/ ASPIRON POLYGLECAPRON 25 C+)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,NON ABSORBABLE STAINLESS STEEL SURGICAL SUTURE U.S.P (MERISTEEL™ / ASPIRON STAINLESS STEEL)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,NON-ABSORBABLE POLY(ETHYLENE TEREPHTHALATE) SURGICAL SUTURE U.S.P.(REDIBOND® PRO (ADDITIONAL BRAND NAME OF MERICRON XL™))-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION., ABSORBABLE POLY(GLYCOLIDE-CO-CAPROLACTONE) SURGICAL SUTURE U.S.P ANTIBACTERIAL WITH CHLORHEXIDINE COATED SUTURE(FILAPRON™ C+/ ASPIRON POLYGLECAPRON 25 C+)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,ABSORBABLE POLY(GLYCOLIDE-CO-CAPROLACTONE) SURGICAL SUTURE U.S.P(REDICAPRONE® PRO (ADDITIONAL BRAND NAME OF FILAPRON™))-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,ABSORBABLE POLY(GLYCOLIDE-CO-CAPROLACTONE) SURGICAL SUTURE U.S.P(FILAPRON™ / ASPIRON POLYGLECAPRONE 25 / REDICAPRONE™/REDICAPRONE® PRO / FILAPRON™ CAS)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,ABSORBABLE POLY(GLYCOLIDE/L-LACTIDE) SURGICAL SUTURE U.S.P(REDICRYL® PRO (ADDITIONAL BRAND NAME OF MITSU™))-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,NON-ABSORBABLE POLYPROPYLENE SURGICAL SUTURE U.S.P. (FILAPROP™ / ASPIRON POLYPROPYLENE BLUE / REDILENE™ / FILAPROP™ REEL/ FILAPROP™ CAS/REDILENE® PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,CU T 380 A STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICES(MERITE™ CU T 380 A /KHUSHI™ CU T 380 A / PRIMA™ CU T 380A / ENOVA™ CU T 380A /TIUP™ CU T 380A/ FREEDOM10 CU T 380 A)-INDICATED FOR INTRAUTERINE CONTRACEPTION.,NON ABSORBABLE POLYTETRAFLUOROETHYLENE SURGICAL SUTURE(RI-CORD)-THE RI CORD SUTURE IS INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN CARDIOVASCULAR SURGERY AND DURA MATER REPAIR. IT IS RECOMMENDED FOR USE WHERE REDUCED SUTURE LINE BLEEDING DURING CARDIOVASCULAR ANASTOMOTIC PROCEDURES IS DESIRED.,NON-ABSORBABLE POLYPROPYLENE SURGICAL SUTURE U.S.P. (REDILENE® PRO (ADDITIONAL BRAND NAME OF FILAPROP™))-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE

	APPROXIMATION AND LIGATION.,LEVONORGESTREL 20MICROGRAMS/24 HOURS HORMONAL INTRAUTERINE SYSTEM (FIONA™ U.S.P/IFORIUS™ U.S.P/CHARLIZE U.S.P)-INTENDED FOR CONTRACEPTION. IT CAN ALSO BE USED IN IDIOPATHIC MENORRHAGIA AND PROTECTION FROM ENDOMETRIAL HYPERPLASIA DURING ESTROGEN REPLACEMENT THERAPY., LEVONORGESTREL 20MICROGRAMS/24 HOURS HORMONAL INTRAUTERINE SYSTEM(FIONA™ U.S.P.)-INTENDED FOR CONTRACEPTION. IT CAN ALSO BE USED IN IDIOPATHIC MENORRHAGIA AND PROTECTION FROM ENDOMETRIAL HYPERPLASIA DURING ESTROGEN REPLACEMENT THERAPY., LEVONORGESTREL 20MICROGRAMS/24 HOURS HORMONAL INTRAUTERINE SYSTEM(ERINNA™ U.S.P. / EMIRELLE™ U.S.P. /CHARLIZE U.S.P.)-INTENDED FOR CONTRACEPTION. IT CAN ALSO BE USED IN IDIOPATHIC MENORRHAGIA AND PROTECTION FROM ENDOMETRIAL HYPERPLASIA DURING ESTROGEN REPLACEMENT THERAPY.,ABSORBABLE POLYGLYCOLIC ACID SURGICAL SUTURE U. S.P.(REDISORB® - FAST PRO (ADDITIONAL BRAND NAME OF MEGASORB RAPID™))-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,LEVONOGESTEREL 20MICROGRAM /24 HOURS HORMONAL INTRAUTERINE SYSTEM (FIONA™ U.S.P./IFORIUS™ U.S.P.)-INTENDED FOR CONTRACEPTION. IT CAN ALSO BE USED IN IDIOPATHIC MENORRHAGIA AND PROTECTION FROM ENDOMETRIAL HYPERPLASIA DURING ESTROGEN REPLACEMENT THERAPY.,ABSORBABLE POLY(GLYCOLIDE-CO-CAPROLACTONE) SURGICAL SUTURE U.S.P ANTIBACTERIAL WITH TRICLOSAN COATED SUTURE(FILAPRON™ AB/ ASPIRON POLYGLECAPRON 25 AB)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, LEVONORGESTREL 20MICROGRAMS/24 HOURS HORMONAL INTRAUTERINE SYSTEM(ERINNA™ / EMIRELLE™ /CHARLIZE)-INTENDED FOR CONTRACEPTION. IT CAN ALSO BE USED IN IDIOPATHIC MENORRHAGIA AND PROTECTION FROM ENDOMETRIAL HYPERPLASIA DURING ESTROGEN REPLACEMENT THERAPY., ABSORBABLE POLYGLYCOLIC ACID SURGICAL SUTURE U.S.P. (REDISORB® PRO (ADDITIONAL BRAND NAME OF MEGASORB™))-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,NON-ABSORBABLE PRE-SHAPED POLYPROPYLENE MESH(FILAPROP™ 3D MESH)-INTENDED FOR USE FOR THE REPAIR OF HERNIAS OR OTHER FACIAL DEFECTS THAT REQUIRES THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT. , ABSORBABLE STERILIZED SURGICAL POLY(GLYCOLIDE/L-LACTIDE) SUTURE ANTIBACTERIAL WITH TRICLOSAN COATED SUTURE(MITSU™

	AB / ASPIRON POLYGLACTIN 910 AB)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, LEVONORGESTREL 20MICROGRAMS/24 HOURS HORMONAL INTRAUTERINE SYSTEM(FIONA™/IFORIUS™ /CHARLIZE)-INTENDED FOR CONTRACEPTION. IT CAN ALSO BE USED IN IDIOPATHIC MENORRHAGIA AND PROTECTION FROM ENDOMETRIAL HYPERPLASIA DURING ESTROGEN REPLACEMENT THERAPY.,NON-ABSORBABLE STERILISED SURGICAL POLYPROPYLENE MESH (FILAPROP™ MESH/ASPIRON POLY PROPYLENE MESH)-INTENDED FOR USE IN HERNIA REPAIR, ABDOMINAL WALL REPAIR AND OTHER FASCIAL SURGICAL INTERVENTION PROCEDURES., LEVONORGESTREL 20MICROGRAMS/24 HOURS HORMONAL INTRAUTERINE SYSTEM(FIONA™/IFORIUS™)-INTENDED FOR CONTRACEPTION. IT CAN ALSO BE USED IN IDIOPATHIC MENORRHAGIA AND PROTECTION FROM ENDOMETRIAL HYPERPLASIA DURING ESTROGEN REPLACEMENT THERAPY.,NON-ABSORBABLE POLYPROPYLENE SURGICAL SUTURE U.S.P. WITH PTFE PLEDGET(FILAPROP™ P)-NON ABSORBABLE PLEDGETED SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION INCLUDING CARDIOVASCULAR SURGERY, NEUROLOGICAL AND OPHTHALMIC PROCEDURES.,LIGATING CLIP (MIRUS™)-LIGATING CLIP IS INTENDED TO SECURELY GRIP THE VESSEL OR TISSUE TO PROVIDE COMPLETE OCCLUSION ATRAUMATICALLY.,POLYMER LIGATING CLIP(MYCLIP™)-LIGATING CLIP IS INTENDED TO SECURELY GRIP THE VESSEL OR TISSUE TO PROVIDE COMPLETE OCCLUSION ATRAUMATICALLY.,TOPICAL SKIN ADHESIVE(MERIFIX™)-INTENDED FOR CLOSURE OF SURGICAL INCISIONS,ABSORBABLE STERILIZED SURGICAL CATGUT CHROMIC SUTURE U.S.P. (PRE-KNOTTED LOOP LIGATURE FOR ENDO SURGERY) (FILATWINE)-FILATWINE SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION., SURGICAL ADHESIVE(BIOAID™)-INTENDED FOR CLOSURE OF SURGICAL INCISIONS,TOPICAL SKIN ADHESIVE(MERIGLU™)-INTENDED FOR CLOSURE OF SURGICAL INCISIONS,NON-ABSORBABLE PTFE (POLYTETRAFLUOROETHYLENE) PLEDGETS (MERIL PLEDGET / FILAPLEDGE)-PLEDGETS ARE INTENDED FOR USE TO SECURE AND SUPPORT SUTURE PLACEMENT.,ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE U.S.P.) (MERIZELLE™ FIBER)-AN ABSORBABLE HEMOSTATIC AGENT OR DRESSING IS A DEVICE INTENDED TO PRODUCE HAEMOSTATIS BY ACCELERATING THE CLOTTING PROCESS OF BLOOD,ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE U.S.P.) (MERIZELLE™ STANDARD)-AN ABSORBABLE HEMOSTATIC AGENT OR DRESSING IS A DEVICE INTENDED TO PRODUCE HAEMOSTATIS BY

	ACCELERATING THE CLOTTING PROCESS OF BLOOD.,ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE U.S.P.) (MERIZELLE™ WOVEN)-AN ABSORBABLE HEMOSTATIC AGENT OR DRESSING IS A DEVICE INTENDED TO PRODUCE HAEMOSTATIS BY ACCELERATING THE CLOTTING PROCESS OF BLOOD.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3078	MFG/MD/2018/000028	1.License Holder Name: MERIL LIFE SCIENCES PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BIODEGRADABLE POLYMER BASED SIROLIMUS ELUTING CORONARY STENT SYSTEM (DRUG ELUTING CORONARY STENT)(PREVADE (10TH BRAND NAME))-FOR CYLINDRICAL SIZES: IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESIONS (LENGTH 44MM) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 MM TO 4.50 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES. FOR TAPERED SIZES: IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESIONS (LENGTH 56MM) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM TO 4.50 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES.,BARE METAL AORTIC STENT (LITTLE ANGELS)-THE DEVICE IS INDICATED FOR IMPLANTATION IN THE NATIVE AND/OR RECURRENT COARCTATION OF THE AORTA ON PATIENTS WITH THE FOLLOWING CLINICAL CONDITIONS: • STENOSIS OF THE AORTA RESULTING IN SIGNIFICANT ANATOMIC NARROWING AS DETERMINED BY ANGIOGRAPHY OR NON-INVASIVE IMAGING, I.E. ECHOCARDIOGRAPHY, MAGNETIC RESONANCE IMAGING (MRI), CT SCAN; • STENOSIS OF THE AORTA RESULTING IN HEMODYNAMIC ALTERATIONS, RESULTING IN SYSTOLIC PRESSURE GRADIENT, SYSTEMIC HYPERTENSION OR ALTERED LEFT VENTRICULAR FUNCTION; • STENOSIS OF THE AORTA WHERE BALLOON ANGIOPLASTY IS INEFFECTIVE OR CONTRAINDICATED; • STENOSIS DIAMETER GRATER THAN 20 PERCENTAGE OF THE ADJACENT VESSEL DIAMETER,RAPID EXCHANGE PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY BALLOON DILATATION CATHETER(KULANI SC (4TH BRAND NAME))-IT IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. IT IS ALSO INDICATED FOR POSTDELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS,COVERED BARE METAL AORTIC STENT (LITTLE ANGELS)-THE DEVICE IS INDICATED FOR IMPLANTATION IN THE NATIVE AND/OR RECURRENT COARCTATION OF THE AORTA ON PATIENTS WITH THE FOLLOWING CLINICAL CONDITIONS: • STENOSIS OF THE AORTA RESULTING IN SIGNIFICANT

	ANATOMIC NARROWING AS DETERMINED BY ANGIOGRAPHY OR NON-INVASIVE IMAGING, I.E. ECHOCARDIOGRAPHY, MAGNETIC RESONANCE IMAGING (MRI), CT SCAN; • STENOSIS OF THE AORTA RESULTING IN HEMODYNAMIC ALTERATIONS, RESULTING IN SYSTOLIC PRESSURE GRADIENT, SYSTEMIC HYPERTENSION OR ALTERED LEFT VENTRICULAR FUNCTION; • STENOSIS OF THE AORTA WHERE BALLOON ANGIOPLASTY IS INEFFECTIVE OR CONTRAINDICATED; • STENOSIS DIAMETER LESS THAN 20 PERCENTAGE OF THE ADJACENT VESSEL DIAMETER. STENOSIS THAT WOULD PRESENT INCREASED RISK OF VASCULAR DAMAGE OR DISRUPTION; OR ANEURYSM ASSOCIATED WITH COARCTATION OF THE AORTA. ,50M EVEROLIMUS ELUTING CORONARY STENT SYSTEM(PEREMO (2ND BRAND NAME))-CYLINDRICAL MODEL: IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESIONS (LENGTH 44MM) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 MM TO 4.50 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES.; TAPER MODEL: IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC SCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESIONS (LENGTH 56MM) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM TO 4.50 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES.,COVERED BARE METAL AORTIC STENT SYSTEM(LITTLE ANGELS)-THE DEVICE IS INDICATED FOR IMPLANTATION IN THE NATIVE AND/OR RECURRENT COARCTATION OF THE AORTA ON PATIENTS WITH THE FOLLOWING CLINICAL CONDITIONS: • STENOSIS OF THE AORTA RESULTING IN SIGNIFICANT ANATOMIC NARROWING AS DETERMINED BY ANGIOGRAPHY OR NON-INVASIVE IMAGING, I.E. ECHOCARDIOGRAPHY, MAGNETIC RESONANCE IMAGING (MRI), CT SCAN; • STENOSIS OF THE AORTA RESULTING IN HEMODYNAMIC ALTERATIONS, RESULTING IN SYSTOLIC PRESSURE GRADIENT, SYSTEMIC HYPERTENSION OR ALTERED LEFT VENTRICULAR FUNCTION; • STENOSIS OF THE AORTA WHERE BALLOON ANGIOPLASTY IS INEFFECTIVE OR CONTRAINDICATED; • STENOSIS DIAMETER LESS THAN 20 PERCENTAGE OF THE ADJACENT VESSEL DIAMETER. STENOSIS THAT WOULD PRESENT INCREASED RISK OF VASCULAR DAMAGE OR DISRUPTION; OR ANEURYSM ASSOCIATED WITH COARCTATION OF THE AORTA. ,RAPID EXCHANGE PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY BALLOON DILATATION CATHETER(KULANI NC (3RD BRAND NAME))-

	IT IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. IT IS ALSO INDICATED FOR POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS.,SIROLIMUS ELUTING BIORESORBABLE PERIPHERAL SCAFFOLD SYSTEM(CREDENCE BTK)-FOR CYLINDRICAL MODELS: IT IS INDICATED FOR IMPROVING PERIPHERAL LUMINAL DIAMETER IN PATIENTS WITH CRITICAL LIMB ISCHEMIA DISEASE DUE TO DE NOVO LESIONS (LENGTH LESS THAN OR EQUAL TO 44 MM) IN BELOW THE KNEE ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM TO 4.50 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). FOR TAPERED MODELS:IT IS INDICATED FOR IMPROVING PERIPHERAL LUMINAL DIAMETER IN PATIENTS WITH CRITICAL LIMB ISCHEMIA DISEASE DUE TO DE NOVO LESIONS (LENGTH LESS THAN OR EQUAL TO 56 MM) IN BELOW THE KNEE ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM TO 3.50 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA).,TRANSCATHETER HEART VALVE SYSTEM(MYVAL (1ST BRAND), MYVAL INCEPTION (2ND BRAND), MYVAL INTEGRA (3RD BRAND), MYVAL GENESIS (4TH BRAND), MYVAL ETERNIS (5TH BRAND), MYVAL PULMO (6TH BRAND), MYVAL PRO (7TH BRAND), MYVAL NEO (8TH BRAND), MAVIS(9TH BRAND), ETERNIS(10TH BRAND), MERINEUM(11TH BRAND))-1. TRANSCATHETER HEART VALVE: TRANSCATHETER HEART VALVE (THV) AND ACCESSORIES ARE INDICATED FOR RELIEF OF AORTIC STENOSIS IN PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO SEVERE NATIVE CALCIFIC AORTIC STENOSIS AS JUDGED BY A HEART TEAM (INCLUDING A CARDIAC SURGEON) AND IN PATIENTS WHO ARE AT RISK FOR OPEN HEART SURGICAL THERAPY (SOCIETY OF THORACIC SURGEONS OPERATIVE RISK SCORE OF GREATER OR EQUAL TO 4 PERCENT RISK OF MORTALITY AT 30 DAYS). 2. TRANSCATHETER HEART VALVE DELIVERY SYSTEM IS INDICATED FOR IMPLANTATION OF THE TRANSCATHETER HEART VALVE BY BALLOON EXPANSION; 3. BALLOON DILATATION CATHETER IS INDICATED FOR PRE-DILATATION OF NATIVE STENOTIC CARDIAC VALVE PRIOR TO THE IMPLANTATION OF TRANS-CATHETER HEART VALVE; 4. INTRODUCER SET IS INTENDED TO BE INSERTED IN THE VASCULATURE TO PROVIDE A CONDUIT FOR THE INSERTION OF ENDOVASCULAR DEVICES WHILE MINIMIZING BLOOD LOSS ASSOCIATED WITH SUCH INSERTIONS; 5. TRANSCATHETER HEART VALVE CRIMPING TOOL (STERILE) IS INTENDED FOR CRIMPING OF TRANSCATHETER HEART VALVE FOR IMPLANTATION; OR 6. TRANSCATHETER HEART VALVE CRIMPING TOOL (NON-STERILE) INTENDED FOR CRIMPING OF TRANSCATHETER HEART VALVE FOR

	IMPLANTATION;,PERICARDIAL BIOPROSTHESIS(DAFODIL™ (1ST BRAND), DAFODIL NEO (2ND BRAND), FLOMERO (3RD BRAND), FREESIA (4TH BRAND))-PERICARDIAL BIOPROSTHESIS (AORTIC)- IT IS INDICATED FOR USE IN PATIENTS WHOSE AORTIC VALVULAR DISEASE IS SUFFICIENTLY ADVANCED TO WARRANT REPLACEMENT OF THEIR NATURAL VALVE WITH A PROSTHETIC ONE. IT IS ALSO INTENDED FOR USE IN PATIENTS WITH A PREVIOUSLY IMPLANTED AORTIC VALVE PROSTHESIS WHICH IS NO LONGER FUNCTIONING ADEQUATELY AND REQUIRES REPLACEMENT. IN THE LATTER CASE, THE PREVIOUSLY IMPLANTED PROSTHESIS IS SURGICALLY EXCISED AND REPLACED BY THE REPLACEMENT PROSTHESIS; PERICARDIAL BIOPROSTHESIS (MITRAL)- IT IS INDICATED FOR USE IN PATIENTS WHOSE MITRAL VALVULAR DISEASE IS SUFFICIENTLY ADVANCED TO WARRANT REPLACEMENT OF THEIR NATURAL VALVE WITH A PROSTHETIC ONE. IT IS ALSO INTENDED FOR USE IN PATIENTS WITH A PREVIOUSLY IMPLANTED MITRAL VALVE PROSTHESIS WHICH IS NO LONGER FUNCTIONING ADEQUATELY AND REQUIRES REPLACEMENT. IN THE LATTER CASE, THE PREVIOUSLY IMPLANTED PROSTHESIS IS SURGICALLY EXCISED AND REPLACED BY THE REPLACEMENT PROSTHESIS;,THROMBUS ASPIRATION CATHETER(EKISU)-IT IS INDICATED FOR THE REMOVAL OF FRESH, SOFT EMBOLI AND THROMBI FROM VESSELS IN THE CORONARY AND PERIPHERAL SYSTEM. THE STERILE ASPIRATION CATHETER IS NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE.,BARE METAL AORTIC STENT SYSTEM(LITTLE ANGELS)-THE DEVICE IS INDICATED FOR IMPLANTATION IN THE NATIVE AND/OR RECURRENT COARCTATION OF THE AORTA ON PATIENTS WITH THE FOLLOWING CLINICAL CONDITIONS: • STENOSIS OF THE AORTA RESULTING IN SIGNIFICANT ANATOMIC NARROWING AS DETERMINED BY ANGIOGRAPHY OR NON-INVASIVE IMAGING, I.E. ECHOCARDIOGRAPHY, MAGNETIC RESONANCE IMAGING (MRI), CT SCAN; • STENOSIS OF THE AORTA RESULTING IN HEMODYNAMIC ALTERATIONS, RESULTING IN SYSTOLIC PRESSURE GRADIENT, SYSTEMIC HYPERTENSION OR ALTERED LEFT VENTRICULAR FUNCTION; • STENOSIS OF THE AORTA WHERE BALLOON ANGIOPLASTY IS INEFFECTIVE OR CONTRAINDICATED; • STENOSIS DIAMETER GRATER THAN 20 PERCENTAGE OF THE ADJACENT VESSEL DIAMETER., BIODEGRADABLE POLYMER BASED SIROLIMUS ELUTING CORONARY STENT SYSTEM(DRUG ELUTING CORONARY STENT SYSTEM)(BIOM ME 4O)-IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN THE FOLLOWING: • PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO NATIVE CORONARY ARTERY LESIONS. • FOR RESTORING CORONARY FLOW IN PATIENTS EXPERIENCING ACUTE MYOCARDIAL INFARCTION WHO

	PRESENT WITHIN 12 HOURS OF SYMPTOM ONSET. • FOR THE TREATMENT OF PATIENTS WITH CONCOMITANT DIABETES, ACUTE CORONARY SYNDROME, DUAL VESSEL LESIONS (TWO LESIONS IN TWO DIFFERENT EPICARDIAL VESSELS), LESIONS RESIDING WITHIN SMALL CORONARY VESSELS; LESIONS WHERE TREATMENT RESULTS IN THE JAILING OF SIDE BRANCHES (LESIONS WITH A SIDE BRANCH LESS THAN 2 MM IN DIAMETER OR AN OSTIAL STENOSIS LESS THAN 50 PERCENT); FOR THE TREATMENT OF ELDERLY PATIENTS (AGE GREATER THAN OR EQUAL TO 65), AND FOR TREATMENT OF BOTH MEN AND WOMEN. • FOR THE TREATMENT OF PATIENTS PRESENTING WITH IN-STENT RESTENOSIS IN CORONARY ARTERY LESIONS; CHRONIC TOTAL OCCLUDED CORONARY ARTERY LESIONS (DEFINED AS CORONARY ARTERY LESIONS WITH TIMI FLOW 0 AND LASTING LONGER THAN 3 MONTHS); AND CORONARY ARTERY BIFURCATION LESIONS. IN ALL CASES; FOR LINEAR MODELS THE TREATED LESION LENGTH SHOULD BE LESS THAN OR EQUAL TO 44MM WITH REFERENCE VESSEL DIAMETER OF 2.00 MM TO 4.50 MM. FOR TAPERED MODELS THE TREATED LESION LENGTH SHOULD BE LESS THAN OR EQUAL TO 56MM WITH REFERENCE VESSEL DIAMETER OF 2.25 MM TO 3.50 MM.,PTFE COVERED STENT GRAFT(MERISKIN)-IT IS INDICATED FOR USE IN THE TREATMENT OF FREE PERFORATION, SAPHENOUS VEIN BYPASS GRAFTS AND OTHER COMPATIBLE INDICATIONS LIKE IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESIONS (LENGTHS 44 MM) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.0 MM TO 4.5 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES.,TRANSCATHETER HEART VALVE SYSTEM(MYVAL (1ST BRAND), MYVAL INCEPTION (2ND BRAND), MYVAL INTEGRA (3RD BRAND), MYVAL GENESIS (4TH BRAND), MYVAL ETERNIS (5TH BRAND), MYVAL PULMO (6TH BRAND), MYVAL PRO (7TH BRAND), MYVAL NEO (8TH BRAND);)-1. TRANSCATHETER HEART VALVE SYSTEM AND ACCESSORIES ARE INDICATED FOR RELIEF OF AORTIC STENOSIS IN PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO SEVERE NATIVE CALCIFIC AORTIC STENOSIS AND FOR PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO FAILURE (STENOSED, INSUFFICIENT, OR COMBINED) OF A SURGICAL AORTIC VALVE, MITRAL VALVE AND TRICUSPID BIOPROSTHETIC. TRANSCATHETER HEART VALVE (THV) SYSTEM AND ACCESSORIES ARE ALSO INDICATED TO TREAT HEART DISEASE DUE TO FAILURE OF NATIVE BICUSPID AORTIC AND PULMONIC VALVE FOR PATIENTS WHO ARE AT RISK OF OPEN SURGICAL THERAPY; 2. TRANSCATHETER HEART VALVE DELIVERY SYSTEM IS INDICATED FOR IMPLANTATION OF THE

	TRANSCATHETER HEART VALVE BY BALLOON EXPANSION; 3. BALLOON DILATATION CATHETER IS INDICATED FOR PRE-DILATATION OF NATIVE STENOTIC CARDIAC VALVE PRIOR TO THE IMPLANTATION OF TRANS-CATHETER HEART VALVE; 4. INTRODUCER SET IS INTENDED TO BE INSERTED IN THE VASCULATURE TO PROVIDE A CONDUIT FOR THE INSERTION OF ENDOVASCULAR DEVICES WHILE MINIMIZING BLOOD LOSS ASSOCIATED WITH SUCH INSERTIONS; 5. TRANSCATHETER HEART VALVE CRIMPING TOOL (STERILE) IS INTENDED FOR CRIMPING OF TRANSCATHETER HEART VALVE FOR IMPLANTATION; OR 6. TRANSCATHETER HEART VALVE CRIMPING TOOL (NON-STERILE) INTENDED FOR CRIMPING OF TRANSCATHETER HEART VALVE FOR IMPLANTATION;,COBALT CHROMIUN EMBOLIC PROTECTION STENT SYSTEM(NEXGEN PROTECT)-IT IS INDICATED FOR IMPROVING LUMINAL DIAMETER IN VESSELS WITH REFERENCE DIAMETER FROM 2.0 TO 4.5 MM HAVING LESION LENGTH 44 MM AND PROVIDING EMBOLIC PROTECTION IN SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESION IN A NATIVE CORONARY ARTERIES. IT IS ALSO INDICATED FOR ELECTIVE IMPLANTATION AND IN THE TREATMENT OF ACUTE OR THREATENED CLOSURE ASSOCIATED WITH A CORONARY INTERVENTION FOR SAPHENOUS VEIN GRAFT AND IN PATIENTS UNDERGOING PRIMARY PCI (PERCUTANEOUS CORONARY INTERVENTION) FOR STEMI (ST- ELEVATION MYOCARDIAL INFARCTION).,LIQUID EMBOLIC SYSTEM(MENOX)-IT IS INDICATED FOR PRESURGICAL EMBOLIZATION OF BRAIN ARTERIOVENOUS MALFORMATION (BAVM).,50M SIROLIMUS ELUTING CORONARY STENT SYSTEM(BIOMIME MIRAGE)-CYLINDRICAL MODEL: IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESIONS (LENGTH 44MM) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 MM TO 4.50 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES.; TAPER MODEL: IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESIONS (LENGTH 56MM) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM TO 4.50 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES.,RAPID EXCHANGE PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY BALLOON DILATATION CATHETER(MOZEC NC (FIRST BRAND NAME), LINEAGE NC (SECOND BRAND NAME))-IT IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION

	OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. IT IS ALSO INDICATED FOR POSTDELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS.,COBALT CHROMIUM CORONARY STENT SYSTEM(OSUM)-IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENT WITH SYMPTOMATIC ISCHEMIC HEART DISEASE IN DE NOVO CORONARY ARTERY LESION IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.5 MM TO 4.5 MM AND LESION LENGTH 36 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) & STENTING PROCEDURES. ,RAPID EXCHANGE PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY BALLOON DILATATION CATHETER(XPEDIENT(FIRST BRAND), MOZEC (SECOND BRAND), LINEAGE (THIRD BRAND))-IT IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. IT IS ALSO INDICATED FOR POSTDELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS., ANGIO KIT(PROEM)-IT IS USED TO FACILITATE THE CATHETER TO ENTER THROUGH A HEMOSTATIC VALVE WHICH DOES NOT ALLOW THE BLOOD TO FLOW IN TO THE REVERSE DIRECTION BUT ALLOWS THE CATHETER TO PASS INTO THE BLOOD VESSEL.,POLYVINYL ALCOHOL (PVA) FOAM EMBOLIZATION PARTICLES (EMBOX)-IT IS INTENDED FOR EMBOLIZATION OF THE BLOOD SUPPLY TO HYPERVASCULAR TUMORS AND ARTERIOVENOUS MALFORMATIONS, INCLUDING USE IN INTRACRANIAL EMBOLIZATION. ,PERICARDIUM COVERED STENT GRAFT SYSTEM(MERIGRAF)-IT IS INDICATED FOR IMMEDIATE AND COMPLETE EXCLUSION OF ANEURYSMS, EMERGENCY CASES FOLLOWING RUPTURE OF ARTERIES, IN CASE OF SVG AND IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESIONS (LENGTHS 36 MM) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.5 MM TO 4.0 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES.,INTRACRANIAL ANEURYSM FLOW DIVERTER SYSTEM (SILKROUTE)-THE INTRACRANIAL ANEURYSM FLOW DIVERTER SYSTEM IS INDICATED FOR THE ENDOVASCULAR TREATMENT OF ADULTS (22 YEARS OF AGE OR OLDER) WITH LARGE OR GIANT WIDE-NECKED INTRACRANIAL ANEURYSMS (LAS) IN THE INTERNAL CAROTID ARTERY FROM THE PETROUS TO THE SUPERIOR HYPOPHYSEAL SEGMENTS.,PTCA & PTA GUIDEWIRE (FINESSE)-IT IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETER DURING PERCUTANEOUS TRANSLUMINAL

	CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). THIS GUIDEWIRE MAY ALSO BE USED WITH COMPATIBLE STENT DEVICES DURING THERAPEUTIC PROCEDURES. ,DRUG ELUTING RX PTCA BALLOON DILATATION CATHETER(MOZEC DEB)-THE MOZEC™ DEB PACLITAXEL ELUTING RX PTCA BALLOON DILATATION CATHETER IS USED FOR THE CORONARY NATIVE ARTERIES. IT IS INDICATED FOR THE DILATATION OF STENOTIC PORTIONS ALSO INCLUDING TOTAL OCCLUSIONS, AMI PATIENTS, AND IT CAN BE USED ALSO FOR THE POST DILATATION OF STENTS,RAPID EXCHANGE PERCUTENEOUS TRANSLUMINAL CORONARY ANGIOPLASTY BALLOON DILATATION CATHETER (NON-STERILE)(MOZEC PLUS)-NON STERILE DEVICE IS USED FOR FURTHER MANUFACTURING I.E. IN-HOUSE CAPTIVE CONSUMPTION AND SELLING TO LICENSED MANUFACTURER(S).STERILE DEVICE IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. THE MOZEC PLUS RX PTCA BALLOON DILATATION CATHETER IS ALSO INDICATED FOR POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS ,RAPID EXCHANGE PERCUTENEOUS TRANSLUMINAL CORONARY ANGIOPLASTY BALLOON DILATATION CATHETER (STERILE)(MOZEC PLUS)-THE MOZEC PLUS RX PTCA BALLOON DILATATION CATHETER IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. THE MOZEC PLUS RX PTCA BALLOON DILATATION CATHETER IS ALSO INDICATED FOR POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS, STAINLESS STEEL CORONARY STENT SYSTEM(CRYPTON)-IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE IN DE NOVO CORONARY ARTERY LESION IN NATIVE CORONARY ARTERIES WITH REFERENCE VESSEL DIAMETER OF 2.50 MM TO 4.50 MM AND A LESION LENGTH 36 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) & STENTING PROCEDURES., EVEROLIMUS ELUTING CORONARY STENT SYSTEM(EVERMINE)-FOR CYLINDRICAL MODELS: IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESIONS (LENGTH 44MM) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 MM TO 4.50 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES. FOR TAPER MODEL: IT IS INDICATED FOR IMPROVING CORONARY LUMINAL

	DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESIONS (LENGTH 56MM) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM TO 4.50 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES., INTRACORONARY SHUNT(NAUTICA)-IT IS INTENDED TO BE USED IN YIELDING BLOODLESS OPERATIVE FIELD DURING VESSEL ANASTOMOSIS PROCEDURE BY TEMPORARILY THROTTLING THE BLOOD FLOW TOWARDS A DISTAL BY-PASS ROUTE FROM ANASTOMOTIC SITE IN THE VESSEL. THE SHUNT IS REMOVED JUST PRIOR TO THE FINAL SUTURING OF THE VESSEL.,PATENT DUCTUS ARTERIOSUS OCCLUDER DELIVERY SYSTEM(LOTUS (FIRST BRAND), FLORET (SECOND BRAND))-IT IS DESIGNED SPECIFICALLY TO FACILITATE ATTACHMENT, LOADING, DELIVERY AND DEPLOYMENT OF PATENT DUCTUS ARTERIOSUS OCCLUDER,MUSCULAR VENTRICULAR SEPTAL DEFECT OCCLUDER DELIVERY SYSTEM(LOTUS (FIRST BRAND), FLORET (SECOND BRAND))-IT IS DESIGNED SPECIFICALLY TO FACILITATE ATTACHMENT, LOADING, DELIVERY AND DEPLOYMENT OF MUSCULAR VENTRICULAR SEPTAL DEFECT OCCLUDER,VENTRICULAR SEPTAL DEFECT OCCLUDER DELIVERY SYSTEM(LOTUS (FIRST BRAND), FLORET (SECOND BRAND))-IT IS DESIGNED SPECIFICALLY TO FACILITATE ATTACHMENT, LOADING, DELIVERY AND DEPLOYMENT OF VENTRICULAR SEPTAL DEFECT OCCLUDER,ATRIAL SEPTAL DEFECT OCCLUDER DELIVERY SYSTEM (LOTUS (FIRST BRAND), FLORET (SECOND BRAND))-IT IS DESIGNED SPECIFICALLY TO FACILITATE ATTACHMENT, LOADING, DELIVERY AND DEPLOYMENT OF ATRIAL SEPTAL DEFECT OCCLUDER.,PATENT DUCTUS ARTERIOSUS OCCLUDER(LOTUS (FIRST BRAND), FLORET (SECOND BRAND))-IT IS PERCUTANEOUS, TRANSCATHETER DEVICE ESPECIALLY DESIGNED FOR CLOSURE OF NORMALLY LOCATED PATENT DUCTUS ARTERIOSUS INDEPENDENT OF SHAPT OR SIZE. TREATMENT IS FEASIBLE IN THE VERY YOUNG PEDIATRIC POPULATION.,MUSCULAR VENTRICULAR SEPTAL DEFECT OCCLUDER (LOTUS (FIRST BRAND), FLORET (SECOND BRAND))-IT IS A PERCUTANEOUS, TRANSCATHETER, OCCLUSION DEVICE INTENDED OF HEMODYNAMICALLY SIGNIFICANT MUSCULAR VENTRICULAR SEPTAL DEFECTS (MVSD)PERIMEMBRANOUS AND MUSCULAR VENTRICULAR SEPTAL DEFECTS (MVSD). SHUNTS WILL BE CONSIDERED HEMODYNAMICALLY SIGNIFICANT IN PATIENTS WITH THE EVIDENCE OF LEFT VENTRICULAR AND/OR LEFT ATRIAL ENLARGEMENT FOR BODY SURFACE AREA AS DOCUMENTED BY TRANSTHORACIC ECHOCARDIOGRAPHY. ,VENTRICULAR SEPTAL DEFECT OCCLUDER(LOTUS (FIRST BRAND), FLORET (SECOND

	BRAND))-IT IS A PERCUTANEOUS, TRANSCATHETER, OCCLUSION DEVICE INTENDED OF HEMODYNAMICALLY SIGNIFICANT PERIMEMBRANOUS VENTRICULAR SEPTAL DEFECTS (VSD). SHUNTS WILL BE CONSIDERED HEMODYNAMICALLY SIGNIFICANT IN PATIENTS WITH THE EVIDENCE OF LEFT VENTRICULAR AND/OR LEFT ATRIAL ENLARGEMENT FOR BODY SURFACE AREA AS DOCUMENTED BY TRANSTHORACIC ECHOCARDIOGRAPHY.,ATRIAL SEPTAL DEFECT OCCLUDER(LOTUS (FIRST BRAND), FLORET (SECOND BRAND))-IT IS A PERCUTANEOUS, TRANSCATHETER, CLOSURE DEVICE INTENDED FOR OCCLUSION OF ATRIAL SEPTAL DEFECTS IN SECUNDUM POSITION OR PATIENT WHO HAVE UNDERGONE A FENESTRATED FONTAN PROCEDURE AND WHO NOW HAVE TO CLOSE THE FENESTRATION.,SELF-EXPANDING NITINOL PERIPHERAL STENT SYSTEM(ATTUNE BMS (FIRST BRAND), PROMESA BMS (SECOND BRAND))-IT IS INTENDED FOR USE IN THE TREATMENT OF ATHEROSCLEROTIC DISEASES OF PERIPHERAL ARTERIES WITH REFERENCE VESSEL DIAMETER OF 3.00 MM TO 4.00MM FOR BTK AND 7.00 TO 10.00MM FOR ILIAC/SUB-CLAVIAN, BILIARY ARTERY AND 5.00 MM TO 7.00 MM FOR SFA AND 7.00 TO 9.00 MM (CYLINDRICAL STENT), 8.00-6.00, 10.00-7.00 MM (TAPERED STENT) FOR CAROTID ARTERY IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) AND STENTING PROCEDURES.,SIROLIMUS ELUTING CORONARY SIDE BRANCH STENT SYSTEM(BIOMIME BRANCH)-IT IS INTENDED FOR IMPROVING THE CORONARY LUMINAL DIAMETER OF THE SIDE BRANCH OF DE NOVO BIFURCATION LESIONS IN-STENT RESTENOTIC LESIONS IN NATIVE CORONARY ARTERIES WITH REFERENCE DIAMETERS RANGING FROM 2.5 MM TO 3.5 MM IN THE SIDE BRANCH AND 2.5 MM TO 4.0 MM IN THE MAIN VESSEL. THE DEVICE IS INTENDED FOR USE IN CONJUNCTION WITH BALLOON EXPANDABLE CORONARY STENTS (BARE METAL AND DRUG ELUTING) IN THE MAIN BRANCH.,LIQUID EMBOLIC SYSTEM(MENOX)-IT IS INDICATED FOR PRESURGICAL EMBOLIZATION OF BRAIN ARTERIOVENOUS MALFORMATION (BAVM).,INTRA AORTIC BALLOON CATHETER KIT (MYOSIST)-THE INTRA-AORTIC BALLOON CATHETER AND ACCESSORIES ARE USED TO PROVIDE COUNTER PULSATION THERAPY IN THE AORTA, WHEREBY BALLOON INFLATION DURING DIASTOLE AND DEFLATION DURING SYSTOLE INCREASES BLOOD SUPPLY TO THE HEART MUSCLE AND DECREASES THE WORK OF THE LEFT VENTRICLE.,VASCULAR CLOSURE DEVICE(OBTURA)-THE OBTURA VASCULAR CLOSURE DEVICE IS INDICATED FOR FEMORAL ARTERY PUNCTURE SITE CLOSURE, REDUCING TIMES TO HEMOSTASIS AND AMBULATION IN PATIENTS WHO HAVE UNDERGONE DIAGNOSTIC OR INTERVENTIONAL CATHETERIZATION PROCEDURES USING A STANDARD 6F OR 7 F INTRODUCER SHEATH

	FOR 6 F OBTURA VCD AND 8F OR 9F INTRODUCER SHEATH WITH 8 F OBTURA VCD. ,PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON DILATATION CATHETER(NON STERILE)(MOZEC PTA)-NON STERILE DEVICE IS USED FOR FURTHER MANUFACTURING I.E. IN-HOUSE CAPTIVE CONSUMPTION AND SELLING TO LICENSED MANUFACTURER(S).STERILE DEVICE IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN PATIENT WITH OBSTRUCTIVE DISEASE OF PERIPHERAL ARTERIES WITH REFERENCE DIAMETER EQUAL OR LARGER THAN SELECTED BALLOON SIZE. THIS DEVICE IS INDICATED FOR STENTING PROCEDURE, POST DILATATION OF BALLOON-EXPANDABLE AND SELF-EXPANDING STENTS IN THE PERIPHERAL VASCULATURE. , PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON DILATATION CATHETER(MOZEC PTA)-ITIS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN PATIENT WITH OBSTRUCTIVE DISEASE OF CAROTID, ILIAC, FEMORAL, POPLITEAL, INFRA-POPLITEAL AND RENAL ARTERIES WITH REFERENCE DIAMETER EQUAL OR LARGER THAN SELECTED BALLOON SIZES. THIS DEVICE IS ALSO INDICATED FOR POST DILATION OF BALLOON-EXPANDABLE AND SELF-EXPANDING STENTS IN THE PERIPHERAL VASCULATURE. ,TRANSCATHETER HEART VALVE SYSTEM(MYVAL)-1.MYVAL - TRANSCATHETER HEART VALVE: THE MYVAL - TRANSCATHETER HEART VALVE (THV) SYSTEM AND ACCESSORIES ARE INDICATED FOR RELIEF OF AORTIC STENOSIS IN PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO SEVERE NATIVE CALCIFIC AORTIC STENOSIS AS JUDGED BY A HEART TEAM (INCLUDING A CARDIAC SURGEON) AND IN PATIENTS WHO ARE AT HIGHER RISK FOR OPEN HEART SURGICAL THERAPY (SOCIETY OF THORACIC SURGEONS OPERATIVE RISK SCORE OF GREATER OR EQUAL TO 4 PERCENTAGE OR AT A GREATER OR EQUAL TO 15 PERCENTAGE RISK OF MORTALITY AT 30 DAYS); 2. NAVIGATOR - TRANSCATHETER HEART VALVE DELIVERY SYSTEM IS INDICATED FOR DELIVERY OF THE TRANSCATHETER HEART VALVE; 3. MAMMOTH - BALLOON DILATATION CATHETER IS INDICATED FOR DILATATION OF NATIVE STENOTIC CARDIAC VALVES. IT IS ALSO INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF PERIPHERAL VESSELS AND AORTA. FURTHER, IT IS INDICATED FOR STENTING PROCEDURE AND PRE/POST-DELIVERY EXPANSION OF STENTS. 4. PYTHON (1ST BRAND), PYTHON 2 (2ND BRAND), PYTHON NEO (3RD BRAND) - INTRODUCER SET IS INTENDED TO BE INSERTED IN THE VASCULATURE TO PROVIDE A CONDUIT FOR THE INSERTION OF ENDOVASCULAR DEVICES WHILE MINIMIZING BLOOD LOSS ASSOCIATED WITH SUCH INSERTIONS; 5. VAL-DE-CRIMP (1ST BRAND), VAL-DE-CRIMP NEO (2ND BRAND), CROCODIAL NEO (3RD BRAND) -

	TRANSCATHETER HEART VALVE CRIMPING TOOL (STERILE) IS INTENDED FOR CRIMPING OF MYVAL-TRANSCATHETER HEART VALVE FOR IMPLANTATION; OR CROCODIAL - TRANSCATHETER HEART VALVE CRIMPING TOOL (NON-STERILE) INTENDED FOR CRIMPING OF TRANSCATHETER HEART VALVE FOR IMPLANTATION., THROMBUS ASPIRATION CATHETER(NON STERILE)(ASPIRON)-NON STERILE DEVICE IS USED FOR FURTHER MANUFACTURING I.E. IN-HOUSE CAPTIVE CONSUMPTION AND SELLING TO LICENSED MANUFACTURER(S). THE STERILE ASPIRON - ASPIRATION CATHETER IS INDICATED FOR THE REMOVAL OF FRESH, SOFT EMBOLI AND THROMBI FROM VESSELS IN THE CORONARY AND PERIPHERAL SYSTEM. THE STERILE ASPIRON - ASPIRATION CATHETER IS NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE.,THROMBUS ASPIRATION CATHETER (ASPIRON)-THE STERILE ASPIRON - ASPIRATION CATHETER IS INDICATED FOR THE REMOVAL OF FRESH, SOFT EMBOLI AND THROMBI FROM VESSELS IN THE CORONARY AND PERIPHERAL SYSTEM. THE STERILE ASPIRON - ASPIRATION CATHETER IS NOT INTENDED FOR USE IN THE CEREBRAL VASCULATURE.,PACLITAXEL ELUTING PTA BALLOON CATHETER (MOZEC PEB PTA(FIRST BRAND), PAXIMUS(SECOND BRAND))-DEVICE IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) IN PATIENTS WITH OBSTRUCTIVE DISEASE OF PERIPHERAL ARTERIES FOR THE TREATMENT OF IN-STENT RESTENOSIS OR DE NOVO PERIPHERAL LESIONS WITH REFERENCE DIAMETER EQUAL OR LARGER THAN SELECTED BALLOON SIZE. THE DEVICE IS ALSO INDICATED FOR PRE AND POST-DILATATION OF STENTS IN THE PERIPHERAL VASCULAR.,SIROLIMUS ELUTING RX PTCA BALLOON DILATATION CATHETER(MOZEC SEB(FIRST BRAND NAME), SIRORX (SECOND BRAND NAME))-IT IS USED FOR CORONARY NATIVE ARTERIES. IT IS INDICATED FOR THE DILATATION OF STENOTIC PORTIONS ALSO INCLUDING TOTAL OCCLUSIONS, AMI PATIENTS, AND IT CAN BE USED ALSO FOR THE POST DILATATION OF STENTS., RAPID EXCHANGE PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY BALLOON DILATATION CATHETER(NON STERILE) (MOZEC NC (FIRST BRAND NAME), LINEAGE NC (SECOND BRAND NAME)-NON STERILE DEVICE IS USED FOR FURTHER MANUFACTURING I.E. IN-HOUSE CAPTIVE CONSUMPTION AND SELLING TO LICENSED MANUFACTURER(S).IT IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. IT IS ALSO INDICATED FOR POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS., RAPID EXCHANGE PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY BALLOON DILATATION CATHETER(MOZEC NC (FIRST

	BRAND NAME), LINEAGE NC (SECOND BRAND NAME))-IT IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. IT IS ALSO INDICATED FOR POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS.,RAPID EXCHANGE PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY BALLOON DILATATION CATHETER (NON STERILE)(XPEDIENT(FIRST BRAND), MOZEC (SECOND BRAND), LINEAGE (THIRD BRAND))-NON STERILE DEVICE IS USED FOR FURTHER MANUFACTURING I.E. IN-HOUSE CAPTIVE CONSUMPTION AND SELLING TO LICENSED MANUFACTURER(S). THE STERILE DEVICE IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. THE STERILE DEVICE IS ALSO INDICATED FOR POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS.,RAPID EXCHANGE PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY BALLOON DILATATION CATHETER (STERILE) (XPEDIENT(FIRST BRAND), MOZEC (SECOND BRAND), LINEAGE (THIRD BRAND))-IT IS INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. IT IS ALSO INDICATED FOR POST-DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS.,BALLOON EXPANDABLE PERIPHERAL STENT SYSTEM(MYRA BMS (FIRST BRAND), CREDENCE BMS (SECOND BRAND))-IT IS INTENDED FOR USE IN THE TREATMENT OF ATHEROSCLEROTIC DISEASES OF PERIPHERAL ARTERIES BELOW THE AORTIC ARCH, WITH REFERENCE VESSEL DIAMETER OF 2.00 MM TO 5.00 MM FOR BTK AND INFRAPOPLITEAL ARTERIES AND 3.00 MM TO 10.MM FOR ILIAC / SUB-CLAVIAN AND FOR OTHER PROTECTED PERIPHERAL ARTERIES IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) AND STENTING PROCEDURES., BALLOON EXPANDABLE RENAL & BILIARY STENT SYSTEM(COGENT BMS(FIRST BRAND) ,MELANGE BMS (SECOND BRAND))-IT IS INTENDED FOR USE IN PATIENTS WITH ATHEROSCLEROTIC DISEASE OF THE RENAL ARTERIES FOLLOWING SUB-OPTIMAL PERCUTENEOUS TRANSLUMINAL RENAL ANGIOPLASTY (PTRA) OF A DE NOVO OR RESTENOTIC ATHEROSCLEROTIC LESION & FOR PALLIATION OR MALIGNANT NEOPLASMS IN THE BILIARY TREE, WITH REFERENCE VESSEL DIAMETER OF 4.00 MM TO 8.00 MM IN PATIENTS ELIGIBLE FOR PERCUTENEOUS TRANSLUMINAL ANGIOPLASTY (PTA) AND STENTING PROCEDURES,SIROLIMUS ELUTING BIORESORBABLE VASCULAR SCAFFOLD SYSTEM(NON STERILE)-NON STERILE DEVICE IS USED FOR FURTHER MANUFACTURING I.E. IN-HOUSE CAPTIVE

	CONSUMPTION AND SELLING TO LICENSED MANUFACTURER(S). STERILE DEVICE IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO LESION IN NATIVE CORONARY ARTERIES IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY(PTCA) AND SCAFFOLDING PROCEDURES. THE SCAFFOLD WILL EVENTUALLY RESORB AND POTENTIALLY FACILITATE NORMALIZATION OF VESSEL FUNCTION IN PATIENTS., SIROLIMUS ELUTING BIORESORBABLE VASCULAR SCAFFOLD SYSTEM(MERES100 (FIRST BRAND NAME), MERES100 LINEAGE (SECOND BRAND NAME), MERES LINEAGE(THIRD BRAND NAME), MERES MORPH (FOURTH BRAND NAME), RESOMORPH (FIFTH BRAND NAME))-IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO LESION IN NATIVE CORONARY ARTERIES IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY(PTCA) AND SCAFFOLDING PROCEDURES. THE SCAFFOLD WILL EVENTUALLY RESORB AND POTENTIALLY FACILITATE NORMALIZATION OF VESSEL FUNCTION IN PATIENTS., COBALT CHROMIUM CORONARY STENT SYSTEM(NEXGEN(FIRST BRAND), EPITOME (SECOND BRAND))-CYLINDRICAL MODELS: IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE IN DE NOVO CORONARY ARTERY LESION IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 MM TO 4.5 MM AND A LESION LENGTH 44 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES. TAPERED MODEL: IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE IN DE NOVO CORONARY ARTERY LESION IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM TO 4.5 MM AND A LESION LENGTH 56 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES.,50M EVEROLIMUS ELUTING CORONARY STENT SYSTEM(EVERMINE50)-CYLINDRICAL MODEL: IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESIONS (LENGTH 44MM) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 MM TO 4.50 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES.; TAPER MODEL: IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC

	ISCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESIONS (LENGTH 56MM) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM TO 4.50 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES., BIODEGRADABLE POLYMER BASED SIROLIMUS ELUTING CORONARY STENT SYSTEM(DRUG ELUTING CORONARY STENT SYSTEM)(BIOMIME (FIRST BRAND), METAFOR (SECOND BRAND), BIOMIME AURA (THIRD BRAND), BIOMIME MORPH (FOURTH BRAND), PROFICIENT (FIFTH BRAND), METAFLEX (SIXTH BRAND), MABEL (SEVENTH BRAND) , BIOMIME LINEAGE (EIGHTH BRAND))-CYLINDRICAL MODEL: IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESIONS (LENGTH 44MM) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 MM TO 4.50 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES.; TAPER MODEL: IT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DE NOVO & IN-STENT RESTENOTIC LESIONS (LENGTH 56MM) IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.25 MM TO 4.50 MM IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND STENTING PROCEDURES., TRANSCATHETER HEART VALVE SYSTEM(MYVAL)-1.MYVAL - TRANSCATHETER HEART VALVE: THE MYVAL- TRANSCATHETER HEART VALVE (THV) SYSTEM AND ACCESSORIES ARE INDICATED FOR RELIEF OF AORTIC STENOSIS IN PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO SEVERE NATIVE CALCIFIC AORTIC STENOSIS AS JUDGED BY A HEART TEAM (INCLUDING A CARDIAC SURGEON) AND IN PATIENTS WHO ARE AT HIGH RISK FOR OPEN HEART SURGICAL THERAPY (SOCIETY OF THORACIC SURGEONS OPERATIVE RISK SCORE OF GREATER OR EQUAL TO 4 PERCENTAGE OR AT A GREATER OR EQUAL TO 15 PERCENTAGE RISK OF MORTALITY AT 30 DAYS). 2. NAVIGATOR - TRANSCATHETER HEART VALVE DELIVERY SYSTEM IS INDICATED FOR DELIVERY OF THE TRANSCATHETER HEART VALVE 3. THE MAMMOTH-BALLOON DILATATION CATHETER IS INDICATED FOR DILATATION OF NATIVE STENOTIC CARDIAC VALVES. IT IS ALSO INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF PERIPHERAL VESSELS AND AORTA. FURTHER, IT IS INDICATED FOR STENTING PROCEDURE AND PRE/POST-DELIVERY EXPANSION OF STENTS. 4. PYTHON - INTRODUCER SET IS INTENDED TO BE INSERTED IN THE VASCULATURE TO PROVIDE A CONDUIT FOR THE INSERTION OF ENDOVASCULAR DEVICES WHILE

	MINIMIZING BLOOD LOSS ASSOCIATED WITH SUCH INSERTIONS. 5. CRIMPER VAL-DE-CRIMP TRANSCATHETER HEART VALVE CRIMPING TOOL (STERILE) IS INTENDED FOR CRIMPING OF MYVAL-TRANSCATHETER HEART VALVE FOR IMPLANTATION. CROCODIAL TRANSCATHETER HEART VALVE CRIMPING TOOL (NON-STERILE) INTENDED FOR CRIMPING OF MYVAL - TRANSCATHETER HEART VALVE FOR IMPLANTATION.,BALLOON DILATATION CATHETER (MAMMOTH)-IT IS INDICATED FOR DILATATION OF NATIVE STENOTIC CARDIAC VALVES. IT IS ALSO INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF PERIPHERAL VESSELS AND AORTA. FURTHER, IT IS INDICATED FOR STENTING PROCEDURE AND PRE/POST-DELIVERY EXPANSION OF STENTS.,BALLOON DILATATION CATHETER (NON STERILE)(MAMMOTH)-NON STERILE DEVICE IS USED FOR FURTHER MANUFACTURING USE. THE STERILE DEVICE IS INDICATED FOR DILATATION OF NATIVE STENOTIC CARDIAC VALVES. IT IS ALSO INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF PERIPHERAL VESSELS AND AORTA. FURTHER, IT IS INDICATED FOR STENTING PROCEDURE AND PRE/POST-DELIVERY EXPANSION OF STENTS.,MECHANICAL BI-LEAFLET HEART VALVE (MILTONIA)-IT IS INDICATED FOR THE REPLACEMENT OF DISEASED, DAMAGED, OR MALFUNCTIONING NATIVE OR PROSTHETIC AORTIC OR MITRAL VALVES.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3079	MFG/MD/2018/000029	1.License Holder Name: MERIL DIAGNOSTICS PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BLOOD GLUCOSE MONITORING SYSTEM(EXIMO)-THE EXIMO BLOOD GLUCOSE MONITORING SYSTEM IS ADVISED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE (SUGAR) IN FRESH CAPILLARY WHOLE BLOOD. THE EXIMO BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED FOR USE OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) BY DIABETIC PEOPLE AT HOME AND BY HEALTHCARE PROFESSIONALS IN A CLINICAL ENVIRONMENT; AS AN AID TO MONITOR THE EFFECTIVENESS OF DIABETES CONTROL. PLEASE NOTE THAT, IT SHOULD NOT BE USED FOR THE DIAGNOSIS OF DIABETES OR FOR TESTING NEWBORNS.,GENERIC NAME: ONE STEP TEST FOR MALARIA PF / PV AG (UNCUT SHEET)-THE ONE STEP TEST FOR MALARIA PF / PV AG (UNCUT SHEET) IS USED IN FURTHER MANUFACTURING OF ONE STEP TEST FOR MALARIA PF / PV AG (RAPID TEST DEVICE). IT IS AN IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF INFECTION WITH PLASMODIUM PARASITES CAUSING MALARIA IN HUMAN WHOLE BLOOD SPECIMENS.,BLOOD GLUCOSE MONITORING SYSTEM(CREDO)-THE CREDO BLOOD GLUCOSE MONITORING SYSTEM IS ADVISED TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF GLUCOSE (SUGAR) IN FRESH CAPILLARY WHOLE BLOOD. THE CREDO BLOOD GLUCOSE MONITORING SYSTEM IS INTENDED FOR USE OUTSIDE THE BODY (IN VITRO DIAGNOSTIC USE) BY DIABETIC PEOPLE AT HOME OR BY HEALTHCARE PROFESSIONALS IN A CLINICAL ENVIRONMENT AS AN AID TO MONITOR THE EFFECTIVENESS OF DIABETES CONTROL. PLEASE NOTE THAT, IT SHOULD NOT BE USED FOR THE DIAGNOSIS OF DIABETES OR FOR TESTING NEWBORNS.,ONE STEP TEST FOR MALARIA PF / PV AG (MERISCREEN MALARIA PF / PV AG (1ST BRAND NAME), MERISCREEN MONO MALARIA PF / PV AG (2ND BRAND NAME))-IT IS AN IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF INFECTION WITH PLASMODIUM PARASITES CAUSING MALARIA IN HUMAN WHOLE BLOOD SPECIMENS.,COVID-19 IGG/IGM RAPID TEST (EXPORT ONLY) (MERIL)-THE DIAGNOSTIC KIT (COLLOIDAL GOLD) FOR IGG/IGM ANTIBODY TO SARS-COV-2 IS A RAPID IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES (IGG AND IGM) TO SARS-COV-2 VIRUS IN WHOLE BLOOD / SERUM / PLASMA.,ONE STEP TEST FOR MALARIA PF HRP-II AG (UNCUT SHEET)-THE ONE STEP TEST FOR MALARIA PF HRP-II AG (UNCUT SHEET) IS USED IN FURTHER MANUFACTURING OF ONE STEP TEST FOR MALARIA PF HRP-II AG

	(RAPID TEST DEVICE). IT IS AN IN-VITRO DIAGNOSTIC IMMUNE-CHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF INFECTION WITH PLASMODIUM PARASITES CAUSING MALARIA IN HUMAN WHOLE BLOOD SPECIMENS.,ANTI-SARS COV-2 HUMAN IGG ELISA(COVID KAVACH - MERILISA)-SARS COV-2 HUMAN IGG ELISA KIT IS INTENDED FOR QUALITATIVE DETECTION OF IGG ANTIBODIES IN SERUM/PLASMA OF PATIENTS PRESENTING CLINICAL SIGNS AND SYMPTOMS CONSISTENT WITH SARS COV-2 INFECTION.,ONE STEP TEST FOR MALARIA PF HRP-II AG (MERISCREEN MALARIA PF HRP-II AG (1ST BRAND NAME), MERISCREEN MONO MALARIA PF HRP-II AG (2ND BRAND NAME))-IT IS AN IN-VITRO DIAGNOSTIC IMMUNE-CHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF INFECTION WITH PLASMODIUM PARASITES CAUSING MALARIA IN HUMAN WHOLE BLOOD SPECIMENS.,COVID-19 ONE-STEP RT-PCR KIT (MERIL)-THIS KIT IS DESIGNED TO DETECT COVID-19 USING REAL TIME PCR. THE RESULTS CAN BE USED TO ASSIST DIAGNOSIS OF PATIENTS WITH COVID-19 INFECTION, AND PROVIDE MOLECULAR DIAGNOSTIC BASIS FOR INFECTED PATIENTS. THE TEST RESULTS OF THIS KIT ARE FOR CLINICAL REFERENCE ONLY AND SHOULD NOT BE USED AS THE ONLY STANDARD FOR CLINICAL DIAGNOSIS. IT IS RECOMMENDED TO CONDUCT A COMPREHENSIVE ANALYSIS BY COMBINING THE TEST RESULTS WITH PATIENTS' SYMPTOMS AND OTHER LABORATORY TESTS. ,ONE STEP TEST FOR MALARIA PF / PAN AG (UNCUT SHEET)-THE ONE STEP TEST FOR MALARIA PF / PAN AG (UNCUT SHEET) IS USED IN FURTHER MANUFACTURING OF ONE STEP TEST FOR MALARIA PF / PAN AG (RAPID TEST DEVICE). IT IS AN IN-VITRO DIAGNOSTIC IMMUNE-CHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF INFECTION WITH PLASMODIUM PARASITES CAUSING MALARIA IN HUMAN WHOLE BLOOD SPECIMENS.,COVID-19 IGG/IGM RAPID TEST(MERIL)-THE DIAGNOSTIC KIT COLLOIDAL GOLD FOR IGG/IGM ANTIBODY TO SARSCOV- 2 IS A RAPID IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES (IGG AND IGM) TO SARS-COV-2 VIRUS IN WHOLE BLOOD /SERUM / PLASMA.,ONE STEP TEST FOR MALARIA PF / PAN AG (MERISCREEN MALARIA PF / PAN AG (1ST BRAND), MERISCREEN MONO MALARIA PF / PAN AG (2ND BRAND))- IT IS AN IN-VITRO DIAGNOSTIC IMMUNECHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF INFECTION WITH PLASMODIUM PARASITES CAUSING MALARIA IN HUMAN WHOLE BLOOD SPECIMENS.,ONE STEP TEST FOR DENGUE NS1 AG(DENTRIX DENGUE NS1 (4TH BRAND))-IT IS A RAPID IMMUNO-CHROMATOGRAPHIC ASSAY FOR THE DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA BY HEALTHCARE PROFESSIONALS. THE ASSAY IS USED AS A RAPID TEST FOR ACUTE

	DENGUE VIRAL INFECTION.,ONE STEP TEST FOR MALARIA PLDH AG (UNCUT SHEET)-THE ONE STEP TEST FOR MALARIA PLDH AG (UNCUT SHEET) IS USED IN FURTHER MANUFACTURING OF ONE STEP TEST FOR MALARIA PLDH AG (RAPID TEST DEVICE). IT IS AN IN-VITRO DIAGNOSTIC IMMUNO-CHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF INFECTION WITH PLASMODIUM PARASITES CAUSING MALARIA IN HUMAN WHOLE BLOOD SPECIMENS.,COMBO (ANTI - A, ANTI - B, ANTI - D (IGM)) (MONOCLONAL IGM)(MERISERA (FIRST BRAND NAME), MARANATHA (SECOND BRAND NAME))-THESE REAGENTS ARE INTENDED FOR IN-VITRO DETERMINATION OF ABO GROUP AND RH TYPING OF HUMAN RED BLOOD CELL ANTIGENS.,ONE STEP TEST FOR MALARIA PLDH AG (MERISCREEN MALARIA PLDH AG)-IT IS AN IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF INFECTION WITH PLASMODIUM PARASITES CAUSING MALARIA IN HUMAN WHOLE BLOOD SPECIMENS.,ANTI - A (MONOCLONAL IGM)(MERISERA (FIRST BRAND NAME), MARANATHA (SECOND BRAND NAME))-ANTI-A (MONOCLONAL IGM) REAGENT IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS, BLOOD BANKS AND IS A QUALITATIVE, IN-VITRO DIAGNOSTIC ANTI-SERA FOR THE RECOGNITION OF A ANTIGEN ON HUMAN RED BLOOD CELLS BY THE SLIDE AND TUBE METHOD.,APTT FSR-ELLAGIC ACID (CLOTQUANT)-IT IS USED FOR THE DETERMINATION OF THE ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) ASSAY AND MONITOR THE CLINICAL FUNCTION OF COAGULATION AND FIBRINOLYSIS.,ANTI - D (MONOCLONAL IGM)(MERISERA (FIRST BRAND NAME), MARANATHA (SECOND BRAND NAME))-ANTI-D (MONOCLONAL IGM) REAGENT IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS, BLOOD BANKS AND IS A QUALITATIVE, IN-VITRO DIAGNOSTIC ANTI-SERA FOR THE RECOGNITION OF RHO(D) ANTIGEN ON HUMAN RED BLOOD CELLS BY THE SLIDE AND TUBE METHOD.,PROTHROMBIN TIME (PT) FSR (CLOTQUANT)-IT IS USED FOR THE DETERMINATION OF PROTHROMBIN TIME AND MONITOR THE CLINICAL FUNCTION OF COAGULATION AND FIBRINOLYSIS.,ANTI - B (MONOCLONAL IGM) (MERISERA (FIRST BRAND NAME), MARANATHA (SECOND BRAND NAME))-ANTI-B (MONOCLONAL IGM) REAGENT IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS, BLOOD BANKS AND IS A QUALITATIVE, IN-VITRO DIAGNOSTIC ANTI-SERA FOR THE RECOGNITION OF B ANTIGEN ON HUMAN RED BLOOD CELLS BY THE SLIDE AND TUBE METHOD.,CACL2(CLOTQUANT)- IT USED FOR MONITORING THE CLINICAL FUNCTION OF COAGULATION AND FIBRINOLYSIS.,COMBO (ANTI - A, ANTI - B, ANTI - D (IGM)) (MONOCLONAL IGM)(PROSERA (3RD BRAND))-THESE REAGENTS ARE

	INTENDED FOR IN-VITRO DETERMINATION OF ABO GROUP AND RH TYPING OF HUMAN RED BLOOD CELL ANTIGENS.,CA 19-9 CLIA (LUMIQUANT)-MICROPLATE BASED CLIA (CHEMILUMINESCENCE IMMUNOASSAY) FOR THE QUANTITATIVE DETERMINATION OF CA 19-9 (CARBOHYDRATE ANTIGEN 19-9) CONCENTRATION IN HUMAN SERUM.,ANTI-D (MONOCLONAL IGM)(PROSERA (3RD BRAND))-ANTI-D (MONOCLONAL IGM) REAGENT IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS, BLOOD BANKS AND IS A QUALITATIVE, IN-VITRO DIAGNOSTIC ANTI-SERA FOR THE RECOGNITION OF RHO(D) ANTIGEN ON HUMAN RED BLOOD CELLS BY THE SLIDE AND TUBE METHOD.,CA 125 CLIA(LUMIQUANT)-MICROPLATE BASED CLIA (CHEMILUMINESCENCE IMMUNOASSAY) FOR THE QUANTITATIVE DETERMINATION OF CA 125 (CANCER ANTIGEN 125) CONCENTRATION IN HUMAN SERUM ,ANTI-B (MONOCLONAL IGM)(PROSERA (3RD BRAND))-ANTI-B (MONOCLONAL IGM) REAGENT IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS, BLOOD BANKS AND IS A QUALITATIVE, IN-VITRO DIAGNOSTIC ANTI-SERA FOR THE RECOGNITION OF B ANTIGEN ON HUMAN RED BLOOD CELLS BY THE SLIDE AND TUBE METHOD.,AFP-CLIA(LUMIQUANT)-MICROPLATE BASED CLIA (CHEMILUMINESCENCE IMMUNOASSAY) FOR THE QUANTITATIVE DETERMINATION OF AFP (ALPHA-FETOPROTEIN) IN HUMAN SERUM.,ANTI-A (MONOCLONAL IGM)(PROSERA (3RD BRAND))-ANTI-A (MONOCLONAL IGM) REAGENT IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS, BLOOD BANKS AND IS A QUALITATIVE, IN-VITRO DIAGNOSTIC ANTI-SERA FOR THE RECOGNITION OF A ANTIGEN ON HUMAN RED BLOOD CELLS BY THE SLIDE AND TUBE METHOD.,CEA CLIA(LUMIQUANT)-MICROPLATE BASED CLIA (CHEMILUMINESCENCE IMMUNOASSAY) FOR THE QUANTITATIVE DETERMINATION OF CEA (CARCINOEMBRYONIC ANTIGEN) CONCENTRATION IN HUMAN SERUM.,ENZYME IMMUNOASSAY FOR DETECTION OF HBSAG IN HUMAN SERUM OR PLASMA(PROLISA (3RD BRAND))-IT IS ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF HEPATITIS B SURFACE ANTIGEN IN HUMAN SERUM OR PLASMA BY HEALTHCARE PROFESSIONAL.,CA 15-3 CLIA(LUMIQUANT)-MICROPLATE BASED CLIA (CHEMILUMINESCENCE IMMUNOASSAY) FOR THE QUANTITATIVE DETERMINATION OF CA 15-3 (CANCER ANTIGEN 15-3) CONCENTRATION IN HUMAN SERUM ,ONE STEP TEST FOR DENGUE AB (LGG/LGM) + NS 1 AG COMBO(DENTRIX DENGUE ONSET DUO (6TH BRAND))-IT IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE SIMULTANEOUS DETECTION OF DENGUE NS1 ANTIGEN & DENGUE ANTIBODIES IN HUMAN SERUM OR PLASMA. THE ASSAY IS USED AS A SCREENING TEST FOR ACUTE DENGUE VIRAL INFECTION.,CEA-ELISA (MERILISA)-

	MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUANTITATIVE DETERMINATION OF CEA (CARCINOEMBRYONIC ANTIGEN) IN HUMAN SERUM,ENZYME IMMUNOASSAY FOR THE DETECTION OF ANTIBODIES TO HEPATITIS C VIRUS IN HUMAN SERUM OR PLASMA(PROLISA (3RD BRAND))-IT IS ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO HEPATITIS C VIRUS IN HUMAN SERUM OR PLASMA BY HEALTHCARE PROFESSIONAL.,AFP-ELISA (MERILISA)-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUANTITATIVE DETERMINATION OF AFP (APHA-FETOPROTEIN) IN HUMAN SERUM,ONE STEP TEST FOR DENGUE AB (LGG/LGM) + NS 1 AG COMBO(VIVASCREEN DENGUE DUO NS1 + IGG/IGM (5TH BRAND))-IT IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE SIMULTANEOUS DETECTION OF DENGUE NS1 ANTIGEN & DENGUE ANTIBODIES IN HUMAN SERUM OR PLASMA. THE ASSAY IS USED AS A SCREENING TEST FOR ACUTE DENGUE VIRAL INFECTION.,ONE STEP RAPID TEST FOR DETECTION OF ANTI-HIV IN HUMAN SERUM / PLASMA / WHOLE BLOOD (UNCUT SHEET)-THE ONE STEP TEST FOR DETECTION OF ANTI-HIV IN HUMAN SERUM/PLASMA/WHOLE BLOOD (UNCUT SHEET) IS USED IN FURTHER MANUFACTURING OF ONE STEP TEST FOR OF ANTI-HIV IN HUMAN SERUM/PLASMA/WHOLE BLOOD (RAPID TEST DEVICE). IT IS AN IN-VITRO DIAGNOSTIC IMMUNECHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF INFECTION WITH HIV CAUSING AIDS IN HUMAN WHOLE BLOOD/ SERUM/ PLASMA SPECIMENS.,ONE STEP TEST FOR DENGUE NS1 AG(VIVASCREEN DENGUE NS1 (3RD BRAND))-IT IS A RAPID IMMUNO-CHROMATOGRAPHIC ASSAY FOR THE DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA BY HEALTHCARE PROFESSIONALS. THE ASSAY IS USED AS A RAPID TEST FOR ACUTE DENGUE VIRAL INFECTION.,COMBO (ANTI - A, ANTI - B, ANTI - D (IGM)) (MONOCLONAL IGM)(MERISERA)- THESE REAGENTS ARE INTENDED FOR IN-VITRO DETERMINATION OF ABO GROUP AND ·RH TYPING OF HUMAN RED BLOOD CELL ANTIGENS. ASSAY METHOD: SLIDE METHOD & TUBE METHOD,CRP (C-REACTIVE PROTEIN) KIT (PROVISO (2ND BRAND))-THIS PRODUCT IS USED ON PROVISO SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF HUMAN C-REACTIVE PROTEIN (CRP) IN SERUM BY LATEX-ENHANCED IMMUNONEPHELOMETRIC. FOR IN VITRO DIAGNOSTIC USE ONLY.,ANTI - AB (MONOCLONAL IGM) (MERISERA)-ANTI-AB (MONOCLONAL' LGM) REAGENT IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS, BLOOD BANKS AND IS A ·QUALITATIVE, IN-VITRO DIAGNOSTIC ANTI-SERA FOR THE RECOGNITION OF A OR B OR AB ANTIGEN ON HUMAN RED BLOOD CELLS BY·THE SLIDE AND TUBE METHOD. ,HIV + SYPHILIS ANTIBODY

	TEST(MERISCREEN VIROBACT HIV + SYPHILIS AB (FIRST BRAND NAME), RETROBACT (SECOND BRAND NAME))-IT IS A QUALITATIVE, SCREENING, IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHY ASSAY FOR DETECTION OF ANTIBODIES SPECIFIC TO TREPONEMA PALLIDUM BACTERIA (THE CAUSATIVE AGENT OF SYPHILIS) AND/OR HIV-1 AND HIV-2 IN HUMAN SERUM, PLASMA AND WHOLE BLOOD., ANTI - D (MONOCLONAL IGM) (MERISERA)-ANTI-D(MONOCLONAL IGM) REAGENT IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS, BLOOD BANKS AND IS A QUALITATIVE, IN-VITRO DIAGNOSTIC ANTI-SERA FOR THE RECOGNITION OF RHO(D) ANTIGEN ON HUMAN RED BLOOD CELLS BY THE SLIDE AND TUBE METHOD., ENZYME IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) AND TYPE 2 (HIV-2) IN HUMAN SERUM OR PLASMA(PROLISA (3RD BRAND))-IT IS ENZYME IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) AND TYPE 2 (HIV-2) IN HUMAN SERUM OR PLASMA BY HEALTHCARE PROFESSIONAL.,ANTI - B (MONOCLONAL IGM)(MERISERA)-ANTI-B (MONOCLONAL IGM) REAGENT IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS, BLOOD BANKS AND IS A QUALITATIVE, IN-VITRO DIAGNOSTIC ANTI-SERA FOR THE RECOGNITION OF B ANTIGEN ON HUMAN RED BLOOD CELLS BY THE SLIDE AND TUBE METHOD.,RNA EXTRACTION KIT(MERIL)-IT IS USED TO ISOLATE THE NUCLEIC ACID (RNA) FROM VIRUS IN BIOFLUID AND TRANSPORT MEDIA SAMPLES FOR CLINICAL IN-VITRO DIAGNOSTICS APPLICATIONS.,ANTI - A (MONOCLONAL IGM)(MERISERA)- ANTI-A (MONOCLONAL IGM) REAGENT IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS, BLOOD BANKS AND IS A QUALITATIVE, IN-VITRO DIAGNOSTIC ANTI-SERA FOR THE RECOGNITION OF A ANTIGEN ON HUMAN RED BLOOD CELLS BY THE SLIDE AND TUBE METHOD.,C-REACTIVE PROTEIN (CRP) KIT (CLINIQUANT (3RD BRAND) AND AUTOQUANT (4TH BRAND))-THIS REAGENT IS INTENDED FOR QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM BY LATEX TUBIDIMETRY.,ONE STEP RAPID TEST FOR DETECTION OF ANTI-HIV IN HUMAN SERUM / PLASMA / WHOLE BLOOD(MERISCREEN HIV 1-2 WB (1ST BRAND NAME), MERISCREEN MONO HIV 1-2 WB (2ND BRAND NAME))-IT IS A QUALITATIVE, SCREENING, IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHY ASSAY FOR DETECTION OF ANTIBODIES SPECIFIC TO HIV-1 AND HIV-2 IN HUMAN SERUM, PLASMA AND WHOLE BLOOD.,RNA ISOLATION KIT (GARGLE BASED)(MERIL)-THIS KIT IS USED TO ISOLATE THE NUCLEIC ACID (RNA) MATERIAL FROM GARGLE SAMPLE OF SUSPECTED COVID-19 PATIENTS. IT'S INTENDED

	FOR IN-VITRO DIAGNOSTICS LABORATORY AND PROFESSIONAL USE ONLY.,ENZYME IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) AND TYPE 2 (HIV-2) IN HUMAN SERUM OR PLASMA(MERILISA HIV GEN 4 (1ST BRAND NAME), MAKESURE (2ND BRAND NAME))-IT IS ENZYME IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION OF HIV P24 ANTIGEN AND ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) AND TYPE 2 (HIV-2) IN HUMAN SERUM OR PLASMA BY HEALTHCARE PROFESSIONAL.,COVID-19 ANTIGEN DETECTION TEST (FIA)(MERIL)-THIS KIT IS USED FOR IN VITRO QUALITATIVE DETECTION OF SARSCOV-2 ANTIGEN. THIS KIT IS A LATERAL FLOW IMMNUNOFLUORESCENT SANDWICH ASSAY THAT IS USED WITH THE IMMNUNOFLUORESCENT ANALYZER INTENDED FOR THE QUALITATIVE DETECTION OF THE NUCLEOCAPSID PROTEIN ANTIGEN FROM 2019-NCOV IN NASOPHARYNGEAL (NP) AND NASAL (NS) SWAB SPECIMENS DIRECTLY OR AFTER THE SWABS HAVE BEEN ADDED TO VIRAL TRANSPORT MEDIA FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. THIS TEST IS ONLY FOR CLINICAL LABORATORY USE OR FOR IMMEDIATE INSPECTION BY MEDICAL PERSONNEL, NOT FOR HOME TESTING, AND CANNOT BE USED AS THE BASIS FOR THE DIAGNOSIS AND EXCLUSION OF PNEUMONIA CAUSED BY NEW CORONA VIRUS INFECTION, AND IS NOT SUITABLE FOR SCREENING BY THE GENERAL POPULATION., ENZYME IMMUNOASSAY FOR THE DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) AND TYPE 2 (HIV-2) IN HUMAN SERUM OR PLASMA(MERILISA HIV 1-2 GEN 3)-IT IS ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) AND TYPE 2 (HIV-2) IN HUMAN SERUM OR PLASMA BY HEALTHCARE PROFESSIONAL.,COVID-19 ANTIGEN DETECTION TEST(EVO (2ND BRAND))-COVID-19 ANTIGEN DETECTION TEST IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY KIT FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIGEN IN NASOPHARYNGEAL SWAB FROM HUMAN.,ONE STEP TEST FOR HBSAG (UNCUT SHEET)-THE ONE STEP TEST FOR HBSAG (UNCUT SHEET) IS USED IN FURTHER MANUFACTURING OF ONE STEP TEST FOR HBSAG (RAPID TEST DEVICE). IT IS A RAPID, QUALITATIVE, SAND-WITCH IMMUNOASSAY FOR THE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) A MARKER FOR HEPATITIS B INFECTION IN HUMAN SERUM OR PLASMA BY TRAINED COMPETENT PERSON.,EXTRACTION FREE DRY SWAB TEST(MERIL)-THIS KIT IS USED TO ISOLATE THE NUCLEIC ACID (RNA) FROM DRY SWAB SAMPLES FOR CLINICAL IN-VITRO DIAGNOSTICS APPLICATIONS.,ONE STEP TEST FOR HBSAG(MERISCREEN HBSAG

	(1ST BRAND NAME), NEXGEN HBSAG (2ND BRAND NAME))-IT IS A RAPID, QUALITATIVE, SAND-WITCH IMMUNOASSAY FOR THE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) A MARKER FOR HEPATITIS B INFECTION IN HUMAN SERUM OR PLASMA BY TRAINED COMPETENT PERSON.,RNA EXTRACTION KIT (MAGNETIC BEAD)(MERIL)-IT IS USED TO ISOLATE THE NUCLEIC ACID (RNA) FROM VIRUS AND EASY TO LYSE BACTERIA IN BIOFLUID AND TRANSPORT MEDIA SAMPLES FOR CLINICAL IN-VITRO DIAGNOSTICS APPLICATIONS.,ENZYME IMMUNOASSAY FOR DETECTION OF HBSAG IN HUMAN SERUM OR PLASMA(MERILISA HBSAG (1ST BRAND), MAKESURE (2ND BRAND))-IT IS ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF HEPATITIS B SURFACE ANTIGEN IN HUMAN SERUM OR PLASMA BY HEALTHCARE PROFESSIONAL., COVID-19 ANTIGEN SELF TEST(COVIFIND)-IT IS A IN-VITRO DIAGNOSTICS IMMUNOCHROMATOGRAPHIC RAPID ASSAY KIT FOR THE QUALITATIVE DETECTION OF SARS-COV-2 SPECIFIC ANTIGEN IN NASAL SWAB SPECIMENS FROM SYMPTOMATIC & ASYMPTOMATIC INDIVIDUALS. THIS TEST IS AUTHORIZED AND INTENDED FOR NON-PRESCRIPTION HOME USE AS SELF TEST WITH THE SELF COLLECTED NASAL SPECIMENS FROM INDIVIDUALS AGED 18 YEARS OR OLDER AND WITH ADULT COLLECTED NASAL SPECIMENS FROM INDIVIDUALS AGED 2 YEARS OR OLDER. THIS TEST IS INTENDED TO BE USED AS AN AID IN THE DIAGNOSIS OF SARS-COV-2 INFECTION. A POSITIVE TEST RESULT SHOULD BE CONSIDERED AS A TRUE POSITIVE AND DOES NOT NEED RECONFIRMATION BY RT-PCR TEST. NEGATIVE RESULTS MUST BE COMBINED WITH CLINICAL OBSERVATIONS, PATIENT HISTORY AND EPIDEMIOLOGICAL INFORMATION. SYMPTOMATIC INDIVIDUALS IDENTIFIED NEGATIVE BY RAPID ANTIGEN TEST (RAT) SHOULD BE LINKED WITH RT-PCR TEST FACILITY AND SUBSEQUENTLY GET TESTED BY RT-PCR TO RULE OUT COVID-19 INFECTION. IN THE MEANTIME, SUCH INDIVIDUAL WILL BE URGED TO FOLLOW HOME ISOLATION AND TREATMENT AS A NEGATIVE REPORT ON RAT MAY NOT BE TRUE NEGATIVE IN SOME CASES.,ENZYME IMMUNOASSAY FOR THE DETECTION OF ANTIBODIES TO HEPATITIS C VIRUS IN HUMAN SERUM OR PLASMA(MERILISA HCV (1ST BRAND NAME), MAKESURE (2ND BRAND NAME))-IT IS ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO HEPATITIS C VIRUS IN HUMAN SERUM OR PLASMA BY HEALTHCARE PROFESSIONAL.,COVID-19 NEUTRALIZING ANTIBODY RAPID TEST(MERISCREEN (1ST BRAND), EVO (2ND BRAND),ABFIND (3RD BRAND))-COVID-19 NEUTRALIZING ANTIBODY RAPID TEST IS A QUALITATIVE IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHY ASSAY, THIS TEST IS DESIGNED FOR USE TO DETECT THE CIRCULATING SARS-COV-2 NEUTRALIZING ANTIBODIES IN SERUM,

	PLASMA AND WHOLE BLOOD. THIS TEST IS INTENDED FOR USE IN ANY LABORATORY & NON-LABORATORY SETTING TO CHECK IMMUNE RESPONSE IN SUBJECTS POST COVID-19 VACCINATION & OR INFECTION WITH THE SARS-COV-2 INITIATES BY THE HEALTHCARE PROFESSIONAL AND INDIVIDUAL'S WITH SELF COLLECTED SPECIMEN. , ONE STEP RAPID TEST FOR SYPHILIS (UNCUT SHEET)-THE UNCUT SHEET FOR ONE STEP RAPID TEST FOR SYPHILISG (UNCUT SHEET) IS USED IN FURTHER MANUFACTURING USE ONLY, MERISCREEN SYPHILINE IS A SINGLE TEST DEVICE FOR THE QUALITATIVE DETECTION OF DEVICE ANTIBODIES (IGM, IGG & IGA) IN HUMAN SERUM/PLASMA/WHOLE BLOOD SAMPLES BY HEALTHCARE PROFESSIONALS.,COVID-19 NEUTRALIZING ANTIBODY RAPID TEST (UNCUT SHEET)-MERISCREEN COVID-19 NEUTRALIZING ANTIBODY RAPID TEST (UNCUT SHEET) IS USED IN FURTHER MANUFACTURING. IT IS A QUALITATIVE IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHY ASSAY, THIS TEST IS DESIGNED FOR USE TO DETECT THE CIRCULATING SARS-COV-2 NEUTRALIZING ANTIBODIES IN SERUM, PLASMA AND WHOLE BLOOD. THIS TEST IS INTENDED FOR USE IN ANY LABORATORY & NON-LABORATORY SETTING TO CHECK IMMUNE RESPONSE IN SUBJECTS POST COVID-19 VACCINATION & OR INFECTION WITH THE SARS-COV-2 INITIATES BY THE HEALTHCARE PROFESSIONAL AND INDIVIDUAL'S WITH SELF COLLECTED SPECIMEN. ,ONE STEP RAPID TEST FOR SYPHILIS (MERISCREEN SYPHILINE)-MERISCREEN SYPHILINE IS A SINGLE TEST DEVICE FOR THE QUALITATIVE DETECTION OF DEVICE ANTIBODIES (IGM, IGG & IGA) IN HUMAN SERUM/PLASMA/WHOLE BLOOD SAMPLES BY HEALTHCARE PROFESSIONALS.,COVID-19 NEUTRALIZING ANTIBODY RAPID TEST(MERISCREEN (1ST BRAND), EVO (2ND BRAND))-COVID-19 NEUTRALIZING ANTIBODY RAPID TEST CAN DETECT CIRCULATING SARS-COV-2 NEUTRALIZING ANTIBODIES THAT BLOCK THE INTERACTION BETWEEN THE RECEPTOR BINDING DOMAIN OF THE VIRAL SPIKE GLYCOPROTEIN (RBD) WITH THE ACE2 CELL SURFACE RECEPTOR IN SERUM, PLASMA AND WHOLE BLOOD. THIS TEST IS ONLY PROVIDED FOR USE BY CLINICAL LABORATORIES OR TO HEALTHCARE WORKERS FOR POINT-OF-CARE TESTING, AND NOT FOR AT HOME TESTING.,ONE STEP TEST FOR DEN_GUE AB (LGG/LGM) + NS 1 AG COMBO (UNCUT SHEET)-UNCUT SHEET IS USED FOR FURTHER MANUFACTURING AND FINISHED PRODUCT IS IT IS USED FOR DIAGNOSIS OF DENGUE INFECTION AND QUALITATIVE DETECTION OF LGG / LGM ANTIBODIES & NSL ANTIGEN TO DENGUE VIRUS IN HUMAN SERUM OR PLASMA.,COVID-19 ANTIGEN DETECTION TEST (UNCUT SHEET)-COVID-19 ANTIGEN DETECTION TEST (UNCUT SHEET) IS USED IN FURTHER MANUFACTURING OF COVID-19 ANTIGEN DETECTION TEST. IT IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY

	KIT FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIGEN IN NASOPHARYNGEAL SWAB FROM HUMAN.,ONE STEP TEST FOR DENGUE NS1 AG (UNCUT SHEET)-UNCUT SHEET IS USED FOR FURTHER MANUFACTURING AND FINISHED PRODUCT IS A RAPID IMMUNO-CHROMATOGRAPHIC ASSAY FOR THE DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA BY HEALTHCARE PROFESSIONALS. THE ASSAY IS USED AS A RAPID TEST FOR ACUTE DENGUE VIRAL INFECTION.,COVID-19 IGG/IGM RAPID TEST(EVO (2ND BRAND))-THE DIAGNOSTIC KIT COLLOIDAL GOLD FOR IGG/IGM ANTIBODY TO SARSCOV- 2 IS A RAPID IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF ANTIBODIES (IGG AND IGM) TO SARS-COV-2 VIRUS IN WHOLE BLOOD/ SERUM / PLASMA.,ONE STEP TEST FOR DENGUE AB (LGG/LGM) + NS 1 AG COMBO(MERISCREEN DENGUE AB (IGG / IGM) + NS1 AG COMBO (1ST BRAND),MERISCREEN FIRST (1ST) DAY DENGUE (2ND BRAND), MERISCREEN DENGUE ONSET (3RD BRAND), RAPIDSURE DANGUE DUO NS1+ IGG/IGM (4TH BRAND))-IT IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR THE SIMULTANEOUS DETECTION OF DENGUE NS1 ANTIGEN & DENGUE ANTIBODIES IN HUMAN SERUM OR PLASMA. THE ASSAY IS USED AS A SCREENING TEST FOR ACUTE DENGUE VIRAL INFECTION.,COVID-19 NEUTRALIZING ANTIBODY ELISA TEST(MERILISA)-COVID - 19 NEUTRALIZING ANTIBODY DETECTION KIT IS A BLOCKING ENZYME-LINKED IMMUNOSORBENT ASSAY INTENDED FOR QUALITATIVE DIRECT DETECTION OF TOTAL NEUTRALIZING ANTIBODIES TO COVID-19 IN HUMAN SERUM AND PLASMA.,ONE STEP TEST FOR DENGUE NS1 AG(MERISCREEN DENGUE NS1 AG (1ST BRAND), REPDISURE DENGUE NS1(2ND BRAND))-IT IS A RAPID IMMUNO-CHROMATOGRAPHIC ASSAY FOR THE DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN WHOLE BLOOD, SERUM OR PLASMA BY HEALTHCARE PROFESSIONALS. THE ASSAY IS USED AS A RAPID TEST FOR ACUTE DENGUE VIRAL INFECTION.,COVID-19 ANTIGEN DETECTION TEST (MERISCREEN PLUS)-COVID-19 ANTIGEN DETECTION TEST IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY KIT FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIGEN IN NASOPHARYNGEAL SWAB FROM HUMAN.,CRP (C-REACTIVE PROTEIN) KIT(NEPHELOQUANT)-THIS PRODUCT IS USED ON NEPHELOQUANT SPECIFIC PROTEIN ANALYZER FOR QUANTITATIVE DETERMINATION OF HUMAN C-REACTIVE PROTEIN (CRP) IN SERUM BY LATEX-ENHANCED IMMUNONEPHELOMETRIC. FOR IN VITRO DIAGNOSTIC USE ONLY., ONE-STEP COVID-19 RT-PCR KIT (LYOPHILIZED) (TARGET ORF1AB AND N GENES)(MERIL)-THIS KIT IS INTENDED TO IN VITRO QUALITATIVELY DETECT THE ORF1AB AND N GENES OF 2019-NCOV IN THE THROAT SWAB AND NASOPHARYNGEAL SWAB SAMPLES

	COLLECTED FROM CASES AND CLUSTERED CASES SUSPECTED WITH NOVEL CORONA VIRUS–INFECTED PNEUMONIA AND OTHERS REQUIRED FOR THE DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS OF NOVEL CORONA VIRUS INFECTION,COAGULATION CONTROL - ABNORMAL(CLOTQUANT)-THE PRODUCT IS INTENDED FOR INTRA-LABORATORY QUALITY CONTROL PURPOSES ONLY ON MERILYZER CLOTQUANT 2 & 4 ANALYZERS.,ONE-STEP COVID-19 RT-PCR KIT (LYOPHILIZED) (TARGET ORF1AB, E AND N GENES)(MERIL)-THIS KIT IS INTENDED TO IN VITRO QUALITATIVELY DETECT THE ORF1AB, E AND N GENES OF 2019-NCOV IN THE THROAT SWAB AND NASOPHARYNGEAL SWAB SAMPLES COLLECTED FROM CASES AND CLUSTERED CASES SUSPECTED WITH NOVEL CORONA VIRUS–INFECTED PNEUMONIA AND OTHERS REQUIRED FOR THE DIAGNOSIS OR DIFFERENTIAL DIAGNOSIS OF NOVEL CORONA VIRUS INFECTION., COAGULATION CONTROL - NORMAL(CLOTQUANT)-THE PRODUCT IS INTENDED FOR INTRA-LABORATORY QUALITY CONTROL PURPOSES ONLY ON MERILYZER CLOTQUANT 2 & 4 ANALYZERS. ,COVID-19 ANTIGEN DETECTION TEST KIT(MERISCREEN)-COVID-19 ANTIGEN DETECTION TEST IS A RAPID IMMUNOCHROMATOGRAPHIC ASSAY KIT FOR THE QUALITATIVE DETECTION OF SARS-COV-2 ANTIGEN IN NASOPHARYNGEAL SWAB FROM HUMAN.,FIBRINOGEN (FIB) WITH IBS & CALIBRATION PLASMA-FSR(CLOTQUANT)-THIS REAGENT KIT IS INTENDED FOR USE ON OPTICAL COAGULATION ANALYZER MERILYZER CLOTQUANT 2 OR 4 AND PROVIDES REAGENT FOR IN-VITRO DETERMINATION OF THE FIBRINOGEN (FIB) ASSAY TO MONITOR THE CLINICAL FUNCTION OF COAGULATION AND FIBRINOLYSIS,PROTHROMBIN TIME (PT) FDR(CLOTQUANT)-THIS REAGENT KIT IS INTENDED FOR USE ON OPTICAL COAGULATION ANALYZER MERILYZER CLOTQUANT 2 OR 4 AND PROVIDES REAGENTS FOR INVITRO DETERMINATION OF PROTHROMBIN TIME (PT) ASSAY AND MONITOR THE CLINICAL FUNCTION OF COAGULATION AND FIBRINOLYSIS. ,FIBRINOGEN (FIB) WITH IBS & CALIBRATION PLASMA-FDR(CLOTQUANT)-THIS REAGENT KIT IS INTENDED FOR USE ON OPTICAL COAGULATION ANALYZER MERILYZER CLOTQUANT 2 OR 4 AND PROVIDES REAGENT FOR IN-VITRO DETERMINATION OF THE FIBRINOGEN (FIB) ASSAY TO MONITOR THE CLINICAL FUNCTION OF COAGULATION AND FIBRINOLYSIS.,THROMBIN TIME - FDR(CLOTQUANT)-THIS REAGENT KIT IS INTENDED FOR USE ON OPTICAL COAGULATION ANALYZER MERILYZER CLOTQUANT 2 OR 4 AND PROVIDES REAGENT FOR INVITRO DETERMINATION OF THE THROMBIN TIME (TT) ASSAY TO MONITOR THE CLINICAL FUNCTION OF COAGULATION AND FIBRINOLYSIS.,ANTI-D MONOCLONAL (IGG+IGM)(MERISERA)-IT IS INTENDED TO USE AS A REAGENT FOR THE DETECTION OF THE 'D'

	ANTIGEN PRESENT ON HUMAN RED BLOOD CELL.,ANTI-H LECTIN (MERISERA)- IT IS USED TO DEMONSTRATE THE PRESENCE OF H ANTIGEN ON RED BLOOD CELLS AND IN ASSESSING THE H SECRETOR STATUS OF GROUP 'O' INDIVIDUALS.,ANTI-A1 LECTIN(MERISERA)- IT IS USED FOR THE DETECTION OF THE A1 ANTIGEN ON RED BLOOD CELLS. ,RAPID TEST FOR DETECTION OF ANTIBODIES TO HIV IN HUMAN SERUM/PLASMA(4-DOT HIV 1-2 (1ST BRAND NAME), QAUDRO HIV 1-2 AB (2ND BRAND NAME))-IT IS A SINGLE USE, RAPID, FLOW-THROUGH IN-VITRO QUALITATIVE ASSAY FOR THE DETECTION OF ANTIBODIES TO HIV-1 AND HIV-2 IN HUMAN SERUM, PLASMA SPECIMENS.,RAPID TEST FOR DIFFERENTIAL DETECTION OF ANTIBODIES TO HIV-1 & HIV-2 IN HUMAN SERUM/PLASMA(MERI-DOT HIV 1-2 (1ST BRAND NAME), TREDRO HIV 1-2 AB (2ND BRAND NAME))-IT IS A SINGLE USE, RAPID, FLOW-THROUGH IN-VITRO QUALITATIVE ASSAY FOR THE DETECTION OF ANTIBODIES TO HIV-1 AND HIV-2 IN HUMAN SERUM, PLASMA SPECIMENS.,RAPID TEST FOR DETECTION OF ANTIBODIES TO HEPATITIS C IN HUMAN SERUM/PLASMA(MERI-DOT HCV (1ST BRAND NAME), TREDRO HCV AB (2ND BRAND NAME))-IT IS A SINGLE USE RAPID TEST, FLOW THROUGH IN-VITRO QUALITATIVE ASSAY FOR THE DETECTION OF ANTIBODIES TO HCV IN HUMAN SERUM/PLASMA SPECIMENS.,ELISA TEST FOR DETECTION OF DENGUE NS1 AG IN HUMAN SERUM/PLASMA(MERILISA I DENGUE NS1 AG)- MERILISA I DENGUE NS1 AG IS INTENDED TO BE USED FOR IN VITRO QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN SERUM OR PLASMA AND IS USED AS A SCREENING TEST FOR TESTING OF COLLECTED BLOOD SAMPLES SUSPECTED FOR DENGUE. THE KIT DETECTS ALL FOUR SUB-TYPES; DEN1, DEN2, DEN3 AND DEN4 OF DENGUE VIRUS.,ELISA KIT FOR MALARIA PAN AG (PLDH)(MERILISA MALARIA PAN AG)- IT IS AN IN-VITRO ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF MALARIA PLASMODIUM SPP. PLDH (PLASMODIUM LACTATE DEHYDROGENASE) IN HUMAN WHOLE BLOOD SPECIMENS,ONE STEP TEST FOR MALARIA PF/PV/PAN AG (UNCUT SHEET)-ONE STEP TEST FOR MALARIA PF/PV/PAN AG (UNCUT SHEET) IS USED IN FURTHER MANUFACTURING OF ONE STEP TEST FOR MALARIA PF/PV/PAN AG (RAPID TEST DEVICE). IT IS AN IN VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF INFECTIONS WITH PLASMODIUM PARASITES CAUSING MALARIA IN HUMAN WHOLE BLOOD SPECIMENS. ,ONE STEP TEST FOR MALARIA PF/PV/PAN AG(MERISCREEN MALARIA PF/PV/PAN AG (1ST BRAND NAME), MERISCREEN MONO MALARIA PF/PV/PAN AG (2ND BRAND NAME))-IT IS AN IN VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF INFECTIONS WITH PLASMODIUM PARASITES CAUSING MALARIA IN HUMAN WHOLE

	BLOOD SPECIMENS. ,ONE STEP TEST FOR MALARIA PAN AG (UNCUT SHEET)-ONE STEP TEST FOR MALARIA PAN AG (UNCUT SHEET) IS USED IN FURTHER MANUFACTURING OF ONE STEP TEST FOR MALARIA PAN AG (RAPID TEST DEVICE). IT IS AN IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF INFECTION WITH PLASMODIUM PARASITE CAUSING MALARIA IN HUMAN WHOLE BLOOD SPECIMENS. , ONE STEP TEST FOR MALARIA PAN AG(MERISCREEN MALARIA PAN AG)-IT IS AN IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF INFECTION WITH PLASMODIUM PARASITE CAUSING MALARIA IN HUMAN WHOLE BLOOD SPECIMENS.,TOXOPLASMA IGM ELISA(MERILISA)-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUALITATIVE DETECTION OF ANTI-TOXO IGM (LGG ANTIBODIES TO TOXOPLASMA GONDII) IN HUMAN SERUM OR PLASMA,(EDTA,HEPARIN AND SODIUM CITRATE). ,TOXOPLASMA IGG ELISA(MERILISA)-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUALITATIVE DETECTION OF ANTI-TOXO IGG (IGG ANTIBODIES TO TOXOPLASMA GONDII) IN HUMAN SERUM OR PLASMA.(EDTA,HEPARIN AND SODIUM CITRATE)., RUBELLA IGM ELISA(MERILISA)-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUALITATIVE DETECTION OFANTI-RUBELLA IGM(LGM ANTIBODIES TO RUBELL) IN HUMAN SERUM OR PLASMA (EDTA,HEPARIN AND SODIUM CITRATE). , RUBELLA IGG ELISA(MERILISA)-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUALITATIVE DETECTION OF ANTI-RUBELLA IGG (IGG ANTIBODIES TO RUBELLA) IN HUMAN SERUM OR PLASMA(EDTA, HEPARIN AND SODIUM CITRATE). , CMV IGM ELISA(MERILISA)-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUALITATIVE DETECTION OF ANTI-CMVIGM (IGM ANTIBODIES TO CYTOMEGALOVIRUS) IN HUMAN SERUM OR PLASMA(EDTA, HEPARIN AND SODIUM CITRATE).,CMV IGG ELISA(MERILISA)-MICROPLATE BASED ELISA (ENZYME LINKED IMMUNOSORBENT ASSAY) FOR THE QUALITATIVE DETECTION OF ANTI-CMV IGG(IGG ANTIBODIES TO CYTOMEGALOVIRUS) IN HUMAN SERUM OR PLASMA(EDTA, HEPARIN AND SODIUM CITRATE).,HSV-2 IGM ELISA(MERILISA)-IT IS INTENDED FOR THE QUALITATIVE DETECTION OF LGM ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE 2 IN HUMAN SERUM OR PLASMA. ,HSV-1 IGM ELISA(MERILISA)-IT IS INTENDED FOR THE QUALITATIVE DETECTION OF LGM ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE I IN HUMAN SERUM OR PLASMA. ,HSV-2 IGG ELISA(MERILISA)-IT IS INTENDED FOR THE QUALITATIVE DETECTION OF LGG ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE 2 IN HUMAN SERUM OR PLASMA.,HSV-1 IGG

	ELISA(MERILISA)-IT IS INTENDED FOR THE QUALITATIVE DETECTION OF LGG ANTIBODIES TO HERPES SIMPLEX VIRUS TYPE I IN HUMAN SERUM OR PLASMA.,ONE STEP RAPID TEST FOR HCV (UNCUT SHEET)-ONE STEP RAPID TEST FOR HCV (UNCUT SHEET) IS USED IN FURTHER MANUFACTURING OF ONE STEP RAPID TEST FOR HCV (RAPID TEST DEVICE). IT IS A SINGLE TEST DEVICE FOR THE QUALITATIVE DETECTION OF HCV ANTIBODIES (IGM, IGG & IGA) IN HUMAN SERUM / PLASMA / WHOLE BLOOD SAMPLES BY HEALTHCARE PROFESSIONALS.,ONE STEP RAPID TEST FOR HCV(MERISCREEN HCV) -IT IS A SINGLE TEST DEVICE FOR THE QUALITATIVE DETECTION OF HCV ANTIBODIES (IGM, IGG & IGA) IN HUMAN SERUM / PLASMA / WHOLE BLOOD SAMPLES BY HEALTHCARE PROFESSIONALS., THROMBIN TIME - FSR(CLOTQUANT)-THIS REAGENT KIT IS INTENDED FOR USE ON OPTICAL COAGULATION ANALYZER MERILYZER CLOTQUANT 2 OR 4 AND PROVIDES REAGENT FOR INVITRO DETERMINATION OF THE THROMBIN TIME (TT) ASSAY TO MONITOR THE CLINICAL FUNCTION OF COAGULATION AND FIBRINOLYSIS,HIV + SYPHILIS ANTIBODY TEST(MERISCREEN VIROBACT HIV + SYPHILIS AB)-IT IS A QUALITATIVE, SCREENING, IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHY ASSAY FOR DETECTION OF ANTIBODIES SPECIFIC TO TREPONEMA PALLIDUM BACTERIA (THE CAUSATIVE AGENT OF SYPHILIS) AND/OR HIV-1 AND HIV-2 IN HUMAN SERUM, PLASMA AND WHOLE BLOOD.,ONE STEP ANTI-HIV 1/2 TEST (MERISCREEN HIV 1-2 AB)-IT IS A QUALITATIVE, SCREENING, IN-VITRO DIAGNOSTIC IMMUNOCHROMATOGRAPHY ASSAY FOR DETECTION OF ANTIBODIES SPECIFIC TO HIV-1 AND HIV-2 IN HUMAN SERUM OR PLASMA.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3080	MFG/MD/2018/000030	1.License Holder Name: PETERS SURGICAL INDIA (P) LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:NON-ABSORBABLE SURGICAL SUTURE(STERISTEEL)-INDICATED FOR USE IN CARDIO THORACIC SURGERY(STERNUM CLOSURE) AND ORTHOPAEDIC SURGERY.,NON-ABSORBABLE SURGICAL SUTURE(STERILENE)-INDICATED FOR APPLICATION WHERE SURGICAL PRACTICE REQUIRES THE USE OF NON-ABSORBABLE SUTURE MATERIAL, PARTICULARLY IN CARDIOVASCULAR SURGERY, WHERE THE LOW THROMBOGENIC PROPERTIES OF STERILENE HAS A POSITIVE INFLUENCE ON WOUND HEALING.,NON-ABSORBABLE SURGICAL SUTURE(STERILON)-INDICATED FOR APPLICATION WHERE IT IS A SURGICAL PRACTICE TO EMPLOY NON-ABSORBABLE SUTURE ,NON-ABSORBABLE SURGICAL SUTURE(STERISIL)-STERISIL IS INDICATED FOR APPLICATION IN G.I. TRACT, GENERAL CLOSURE, SKIN, PLASTIC, OPHTHALMIC, NEURO AND CARDIOVASCULAR SURGERY.,NON-ABSORBABLE SURGICAL SUTURE(STERIPOL)-INDICATED FOR THE FIELDS OF APPLICATION WHERE IT IS A SURGICAL PRACTICE TO EMPLOY NON-ABSORBABLE SUTURE.,NON-ABSORBABLE SURGICAL SUTURE(STERIBON)-INDICATED FOR FIELDS OF APPLICATION WHERE IT IS SURGICAL PRACTICE TO EMPLOY NON-ABSORBABLE SUTURE MATERIAL,SYNTHETIC ABSORBABLE SURGICAL SUTURE(STERICRYL) -INDICATED FOR USE IN GASTROINTESTINAL ANASTOMISIS, UROLOGY, PEDIATRIC SURGERY AND PLASTIC SURGERY. IT IS NOT INDICATE FOR CARDIOVASCULAR AND NEUROLOGICAL TISSUE APPROXIMATION.,SYNTHETIC ABSORBABLE SURGICAL SUTURE (POLYCOL-FAST)-POLYCOL-FAST SUTURES ARE INDICATED FOR USE IN SHORT TERM WOUND SUUPORT,SYNTHETIC ABSORBABLE SURGICAL SUTURE(MONOCOL)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PEDIATRIC CARDIOVASCULAR TISSUE, IN MICRO SURGERY AND IN OPHTHALMIC SURGERY. MONOCOL IS PARTICULARLY USEFUL WHERE EXTENDED WOUND SUPPORT (UPTO 6 WEEKS) IS DESIRABLE,NON-ABSORBABLE SURGICAL SUTURE(ACIER)-INDICATED FOR USE IN CARDIO THORACIC SURGERY(STERNUM CLOSURE) AND ORTHOPAEDIC SURGERY.,NON-ABSORBABLE SURGICAL SUTURE(CARDIOLENE)-INDICATED FOR THE FIELDS OF APPLICATION WHERE IT IS A SURGICAL PRACTICE TO EMPLOY NON-ABSORBABLE SUTURE, ABSORBABLE SURGICAL SUTURE(CATGUT CHROMIC)-INDICATED FOR APPLICATION WHERE IT IS A SURGICAL PRACTICE TO EMPLOY ABSORBABLE SUTURE MATERIAL. CATGUT CHROMIC IS USED IN GENERAL SOFT TISSUE APPROXIMATION OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES.,NON-ABSORBABLE SURGICAL SUTURE(PREMIO)-INDICATED FOR THE FIELDS OF APPLICATION

		WHERE IT IS A SURGICAL PRACTICE TO EMPLOY NON-ABSORBABLE SUTURE.,ABSORBABLE SURGICAL SUTURE(CATGUT PLAIN)-THIS PRODUCT MAY HAVE DIFFERENT VARIANTS, SIZES, WITH AND WITHOUT NEEDLES BUT THE PRODUCT COMPOSITION, INTENDED USE AND MANUFACTURING PROCESS ARE SAME,NON-ABSORBABLE SURGICAL SUTURE(CARDIOXYL)-INDICATED FOR FIELDS OF APPLICATION WHERE IT IS SURGICAL PRACTICE TO EMPLOY NON-ABSORBABLE SUTURE MATERIAL,NON-ABSORBABLE SURGICAL SUTURE(CARDIONYL)-INDICATED FOR APPLICATION WHERE IT IS A SURGICAL PRACTICE TO EMPLOY NON-ABSORBABLE SUTURE,NON-ABSORBABLE SURGICAL SUTURE(COROLENE)-INDICATED FOR APPLICATION WHERE SURGICAL PRACTICE REQUIRES THE USE OF NON-ABSORBABLE SUTURE MATERIAL, PARTICULARLY IN CARDIOVASCULAR SURGERY, WHERE THE LOW THROMBOGENIC PROPERTIES OF STERILENE HAS A POSITIVE INFLUENCE ON WOUND HEALING.,SYNTHETIC ABSORBABLE SURGICAL SUTURE(OPTIME)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, PERINEAL REPAIR AND SKIN CLOSURE.,SYNTHETIC ABSORBABLE SURGICAL SUTURE(POLYCOL)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, DEVICE ARE USED FOR SKIN CLOSURE PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA.,SYNTHETIC ABSORBABLE SURGICAL SUTURE(I-COL)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, PERINEAL REPAIR AND SKIN CLOSURE.,SYNTHETIC ABSORBABLE SURGICAL SUTURE(I-COL-FAST)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. PERINEAL REPAIR AND SKIN CLOSURE.
3081	MFG/MD/2018/000031	1.License Holder Name: PLASMA BIOTAL INDIA PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:HYDROXY APPATITE (HA), TITANIUM SPRAY COATING -COATING HELPS IN OSTEOGENISIS.

3082	MFG/MD/2018/000032	1.License Holder Name: POLY MEDICURE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:FLOCKED SWAB-TO COLLECT AND TRANSPORT VIRUSES IN AN ACTIVE FORM TO THE LABORATORY FOR ISOLATION.,STOP COCK WITH/WITHOUT EXTENSION TUBE-THE PRODUCT IS USED TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM. THE THREE WAY STOP COCK FAMILY IS TO PROVIDE ACCESS INTO IV CANNULA SYSTEM FOR ADMINISTRATION OF TWO FLUIDS OR DRUGS AT A TIME.,VIAL ACCESS SPIKE (VIAL ADAPTER) (CHIRAPLUS)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL.,FOLEYS BALOON CATHETERS-THE PRODUCT IS USED FOR DRAINAGE, CLEANING, HAEMOSTATIC AND MEDICINE INJECTION FOR THE URINARY SYSTEM OF THE PATIENTS.,VIAL ACCESS SPIKE (VIAL ADAPTER) (KRUUSE SAFEVET SPIKE)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL. ,I.V. INFUSION SET-THE INFUSION SETS ARE USED ONLY FOR GRAVITY FEED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER OR CANNULA. THE IV SET IS DESIGNED TO ADMINISTER INFUSION FLUID THROUGH GRAVITY METHOD.,VIAL ACCESS SPIKE (VIAL ADAPTER)(WITHDRAWAL CANNULA)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL. ,MANIFOLD-PRODUCT IS USED TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM. MANIFOLDS ARE USED IN ANGIOPLASTY PROCEDURES IN WHICH FLUIDS ARE ADMINISTERED UNDER PRESSURE.,VIAL ADAPTER (VIAL ACCESS SPIKE)(TRANSFER SPIKE)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL. ,INTRAVENOUS CANNULA-IV CANNULA IS INSERTED INTO A VEIN, MAINLY FOR THE ADMINISTRATION OF INTRAVENOUS FLUIDS, WITHDRAWAL OF BLOOD SAMPLES AND TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING. SAFETY IV CANNULA IS USED TO DELIVER IV FLUIDS AND MEDICINES IN TO CIRCULATING SYSTEM AND IT ALSO PROVIDING SAFETY FROM THE ACCIDENTAL NEEDLE STICK INJURIES.,VIAL ACCESS SPIKE (VIAL ADAPTER)(KD-SPIKE)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL. ,SAFETY ARTERIAL CANNULA-INTENDED USE FOR INSERTION INTO

	PERIPHERAL ARTERIES, FOR THE DETERMINATION OF BLOOD GAS ESTIMATIONS OR MONITORING BLOOD PRESSURE. ARTERIAL LINES ARE ROUTINELY USED IN CRITICAL CARE AREAS FOR MONITORING ARTERIAL BLOOD PRESSURE OR SERIAL BLOOD GAS MEASUREMENTS. THE PRODUCT HAS INTEGRATED PASSIVE SAFETY FEATURES TO COVER THE NEEDLE AFTER USE TO PREVENT THE ACCIDENTAL NEEDLE PRICK INJURIES.,VIAL ACCESS SPIKE (VIAL ADAPTER) (MULTI DOSE VIAL ADAPTER)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL.,BLOOD COLLECTION NEEDLE-INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD., VIAL ACCESS SPIKE (VIAL ADAPTER) (PICA-SPIKE)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL.,TRACHEOSTOMY TUBE-TRACHEOSTOMY IS A SURGICAL PROCEDURE THAT IS USUALLY DONE IN THE OPERATING ROOM UNDER GENERAL ANESTHESIA. A TRACHEOTOMY IS AN INCISION INTO THE TRACHEA (WINDPIPE) THAT FORMS A TEMPORARY OR PERMANENT OPENING WHICH IS CALLED A TRACHEOSTOMY. A TUBE IS INSERTED THROUGH THE OPENING TO ALLOW PASSAGE OF AIR AND REMOVAL OF SECRETIONS. INSTEAD OF BREATHING THROUGH THE NOSE AND MOUTH, THE CHILD WILL NOW BREATHE THROUGH THE TRACHEOSTOMY TUBE. ,VIAL ACCESS SPIKE (VIAL ADAPTER)(POLYSPIKE V PLUS)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL. , VIAL ACCESS SPIKE(POLYSPIKE)-THE PRODUCT IS USED TO STEADY REPEATED WITHDRAWALS & INJECTION. THE PRODUCT IS DESIGNED TO BE USED TO TRANSFER MEDICATION FROM A VIAL TO A SYRINGE AND FROM SYRINGE TO VIAL.,MANIFOLDS WITH/WITHOUT EXTENSION LINE(UNIFOLD)-PRODUCT IS USED TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM. MANIFOLDS ARE USED IN ANGIOPLASTY PROCEDURES IN WHICH FLUIDS ARE ADMINISTERED UNDER PRESSURE., ENDOTRACHEAL TUBE-•THE TRACHEAL TUBES ARE USED FOR PERFORMING RESPIRATION FOR PATIENTS CONNECTED WITH RESPIRATORY SYSTEM DURING OPERATION OR WHO LOOSE ACTIVE BREATHABILITY. •AN ENDOTRACHEAL TUBE (ALSO CALLED AN ET TUBE OR ETT) IS USED IN GENERAL ANESTHESIA, INTENSIVE CARE AND EMERGENCY MEDICINE FOR AIRWAY MANAGEMENT AND MECHANICAL VENTILATION.,SCALP VEIN SET(POLYMED SCALP VEIN SET)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE

	TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD. ,A. V. FISTULA NEEDLE-THE PRODUCT IS USED TO DELIVER BLOOD INTO HUMAN CIRCULATING SYSTEM. FISTULA NEEDLE IS USED TO CONNECT BLOOD LINES TO THE BLOOD VESSEL THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT VIA AN INTERNAL FISTULA.,SPINAL NEEDLE(SENSIMEDICAL SPINAL NEEDLE)-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM.,I.V. FLOW REGULATOR(POLY FLOW)-FLOW REGULATOR IS USED TO DELIVER ACCURATE VOLUME OF IV FLUID AND MEDICINES INTO HUMAN CIRCULATION SYSTEM. IT IS INTENDED FOR SINGLE USE. THE DEVICE IS INTENDED TO BE USED FOR ALL PATIENTS.,ENDOTRACHEAL TUBE (VITROMED ENDOTRACHEAL TUBE)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS. ,BLOOD LINE SET-THE BLOOD LINE SET CONSISTS OF ARTERIAL AND VENOUS LINES USED DURING HEMODIALYSIS AND ATTACHED WITH AV FISTULA AND HEMODIALYSIS MACHINE, DISPOSABLE AUTO DISABLE SYRINGE(UNOVAC)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,BLOOD LINE SET(HAEMOLINE)-THE BLOOD LINE SET CONSISTS OF ARTERIAL AND VENOUS LINES USED DURING HEMODIALYSIS AND ATTACHED WITH AV FISTULA AND HEMODIALYSIS MACHINE. ,A. V. FISTULA NEEDLE (EXELINT A. V. FISTULA)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT ,I.V. CANNULA WITHOUT INJECTION PORT & WITH SMALL WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., DISPOSABLE AUTO DISABLE SYRINGE-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT(PETIT-FLO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,DISPOSABLE AUTO DISABLE SYRINGE(UNOVAC)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,I.V. CANNULA WITH INJECTION PORT & WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , DISPOSABLE AUTO DISABLE SYRINGE-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,SAFETY I.V. CANNULA WITH WINGS & WITHOUT INJECTION PORT (POLYCAN SAFETY, POLYWIN PLUS SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO

	PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,ARTERIAL BLOOD COLLECTION SYRINGE-ARTERIAL BLOOD COLLECTION SYRINGE IS USED TO COLLECT BLOOD BY MANUAL ASPIRATION FOR BLOOD GAS ANALYSIS.,SAFETY I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK(POLYCATH SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., SPINAL NEEDLE(VITROMED SPINAL NEEDLE)-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM. ,SAFETY HUBER NEEDLE-A SUBCUTANEOUS INJECTION IS A METHOD OF ADMINISTERING MEDICATION.,SPINAL NEEDLE(EXELINT SPINAL NEEDLE)-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM.,BLOOD COLLECTION NEEDLE(HAEMOFLASH)-INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD,DISPOSABLE AUTO DISABLE SYRINGE(POLYUNO)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SPINAL NEEDLE(HEUER SPINAL NEEDLE)-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM.,I.V. CANNULA WITHOUT INJECTION PORT & WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., ENDOTRACHEAL TUBES (EXELINT TRACHEAL TUBE)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS. ,I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK(POLYCATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,VIAL ACCESS SPIKE (VIAL ADAPTER)(DICOSPIKE)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL. ,SPINAL NEEDLE(POLYMED SPINAL NEEDLE)-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF

	CONTRAST MEDIUM,SAFETY FISTULA CANNULA(POLYSAFE PROTEKT)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT.,SAFETY I.V. CANNULA WITHOUT INJECTION PORT & WINGS FOR QIUCK FLASHBACK(POLYWIN SAFETY ADVA, POLYCAN SAFETY ADVA, POLYPEN SAFETY ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SPINAL NEEDLE(NEEDLE FOR SPINAL ANESTHESIA SHARPENING TYPE OF QUINCKE, PREMIUM, "ANGEL CARE")-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM, THREE WAY STOP COCK (POLYWAY, POLYWAY PRO, POLYWAY-CLICK, POLYWAY PRO-CLICK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,INSULIN SYRINGE-USED TO INJECT INSULIN FOR THE TREATMENT OF DIABETES.,VIRAL TRANSPORT KIT (VIRAL TRANSPORT MEDIUM & SWAB STICK)-TO COLLECT AND TRANSPORT VIRUSES IN AN ACTIVE FORM TO THE LABORATORY FOR ISOLATION . TO MAINTAIN THE VIABILITY AND VIRULENCE OF THE VIRAL SAMPLE, INSULIN SYRINGE(POLYMED INSULIN SYRINGE)-USED TO INJECT INSULIN FOR THE TREATMENT OF DIABETES. ,SAFETY I.V. CANNULA WITH INJECTION PORT QIUCK FLASHBACK(POLYSAFETY ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,RECTAL CATHETER (POLYMED RECTAL CATHETER)-IT IS INSERTED INTO THE RECTUM IN ORDER TO RELIEVE FLATULENCE WHICH HAS BEEN CHRONIC AND WHICH HAS NOT BEEN ALLEVIATED BY OTHER METHODS. ,I.V. CANNULA (NOUVOFLEX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,SPINAL NEEDLE-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM, EXTENSION LINE (LOW PRESSURE & HIGH PRESSURE LINE)(POLYMED EXTENSION LINE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION,SAFETY I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK FOR QIUCK FLASHBACK(POLYCATH SAFETY ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE

	THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY I.V. CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS(POLYON SAFETY, POLYWIN SAFETY, POLYPEN SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,MID LINE CATHETER-CATHETERS CAN BE PLACED IN VEINS IN THE NECK (INTERNAL JUGULAR VEIN), CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN),EXTENSION LINE (LOW PRESSURE & HIGH PRESSURE LINE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,HIGH PRESSURE VACUUM DRAINAGE BOTTLE WITH EXTENSION TUBE (ULTRAVAK SET)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,NASAL OXYGEN CANNULA(POLYMED NASAL OXYGEN CANNULA)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP. ,IRRIGATION SET(POLYMED IRRIGATION SET)-INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS. ,VIRAL LYSIS TRANSPORT MEDIUM (VLTM) KITS-FOR THE COLLECTION, INACTIVATION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES AND BACTERIA FROM THE COLLECTION SITE TO THE TESTING LABORATORY.,I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK FOR QIUCK FLASHBACK(POLYCATH ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY ARTERIAL CANNULA (ART-CAN)-INSERTED INTO AN ARTERY, COMMONLY THE RADIAL ARTERY, AND IS USED DURING MAJOR OPERATIONS AND IN CRITICAL CARE AREAS TO MEASURE BEAT-TO-BEAT BLOOD PRESSURE AND TO DRAW REPEATED BLOOD SAMPLES. ,I V CANNULA WITH EXTENSION TUBE (CLOSED I V CATHETER/CANNULA WITH / WITHOUT SAFETY)(NOUVO SAFETY SET)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT INJECTION PORT & WITH SMALL WINGS(POLYNEO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY I.V. CANNULA (NOUVO

	PROTEKT)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I V FLOW REGULATOR EXTENSION SET(POLYFLO NOVO)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. ,SAFETY I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS(POLYSAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY ARTERIAL CANNULA (ART-CAN SAFETY)-INSERTED INTO AN ARTERY, COMMONLY THE RADIAL ARTERY, AND IS USED DURING MAJOR OPERATIONS AND IN CRITICAL CARE AREAS TO MEASURE BEAT-TO-BEAT BLOOD PRESSURE AND TO DRAW REPEATED BLOOD SAMPLES. ,I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT(POLYCAN, POLYNEO, NEONOVO, POLYWIN PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,MID LINE CATHETER KIT-CATHETERS CAN BE PLACED IN VEINS IN THE NECK (INTERNAL JUGULAR VEIN), CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN), DISINFECTING PORT-IT IS A SINGLE USE, STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE.,MINI MID LINES-OVER THE NEEDLE (POLYLEAD OVER THE NEEDLE)-CATHETERS CAN BE PLACED IN VEINS IN THE NECK (INTERNAL JUGULAR VEIN),CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN),MINI MID LINES-OVER THE WIRE-CATHETERS CAN BE PLACED IN VEINS IN THE NECK (INTERNAL JUGULAR VEIN),CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN),MINI MID LINES-OVER THE WIRE(POLYLEAD OVER THE WIRE)-CATHETERS CAN BE PLACED IN VEINS IN THE NECK (INTERNAL JUGULAR VEIN),CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN),MINI MID LINES-OVER THE NEEDLE -CATHETERS CAN BE PLACED IN VEINS IN THE NECK (INTERNAL JUGULAR VEIN),CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN), , DISINFECTING PORT (POLYSWAB)-IT IS A SINGLE USE, STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE.,I.V. CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS(POLYON, POLYWIN, POLYPEN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS(POLYFLEX)-

	THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., SAFETY I.V. CANNULA WITH SPRING (POLYSHIELD)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,THREE WAY STOP COCK WITH EXTENSION TUBE (POLYWAY WITH EXTENSION TUBE, POLYWAY PRO WITH EXTENSION TUBE, POLYWAY-CLICK WITH EXTENSION TUBE, POLYWAY PRO-CLICK WITH EXTENSION TUBE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,HAEMODIALYSIS CATHETER KIT (HAEMOCENT)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT.,SAFETY A. V. FISTULA NEEDLE (POLY PROTEKT)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT ,I V CANNULA WITH QUICK FLASH BACK (POLYNEO ADVA, NEONOVO ADVA, POLYWIN ADVA, POLYFLEX ADVA, POLYFLON ADVA, POLYCAN ADVA, POLYPEN ADVA, POLYWIN PLUS ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INJECTION PORT & WINGS(POLYFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,HAEMODIALYSIS CATHETER KIT-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT.,HIGH PRESSURE VACUUM DRAINAGE BOTTLE WITH EXTENSION TUBE -A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,HUBER NEEDLE-A SUBCUTANEOUS INJECTION IS A METHOD OF ADMINISTERING MEDICATION.,RECTAL CATHETER -IT IS INSERTED INTO THE RECTUM IN ORDER TO RELIEVE FLATULENCE WHICH HAS BEEN CHRONIC AND WHICH HAS NOT BEEN ALLEVIATED BY OTHER METHODS. ,I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF

		VASCULAR ACCESS DEVICES.
3083	MFG/MD/2018/000033	1.License Holder Name: S M HEALTH CARE PRODUCTS PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:CATHETER(INNOWIZ)-USED TO ADMINISTER MEDICATION OR FLUIDS, OBTAIN BLOOD FOR TESTS AND DIRECTLY OBTAIN CARDIOVASCULAR MEASUREMENTS., CATHETER(INNOWIZ)-USED FOR DIAGNOSTIC/DRAINAGE TO OPEN A BLOCKED DUCT.,CATHETER (INNOWIZ)-USED DURING DIALYSIS FOR DRAINAGE AND GIVING BACK BLOOD/DIALYSIS FLUID AFTER FILTRATION.,CATHETER(INNOWIZ)-USED FOR DIAGNOSTIC, TREATMENT AND DRAINAGE PURPOSE.,CATHETER (INNOWIZ)-USED FOR DIAGNOSTIC, TREATMENT AND DRAINAGE PURPOSE.,CATHETER (INNOWIZ)-USED FOR DIAGNOSTIC/ TREATMENT AND DRAINAGE PURPOSE.
3084	MFG/MD/2018/000034	1.License Holder Name: FRISCH MEDICAL DEVICES LLP 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:INTRODUCER SHEATH -RADIAL(STEER-R)-THE INTRODUCER SHEATH IS USED DURING ANGIOPLASTY PROCEDURES TO PROVIDE A PATHWAY THROUGH WHICH A PTCA GUIDING CATHETER MAY BE PERCUATNEOUSLY INTRODUCED INTO THE VASCULATURE OR VARIOUS DEVICES INTO VEIN OR ARTERIES WHILE MAINTAINING HEMOSTASIS FOR A VARIETY OF DIAGNOSTIC AND THERAPEUTIC PROCEDURE.,INTRODUCER SHEATH -FEMORAL(STEER-F)-THE INTRODUCER SHEATH IS USED DURING ANGIOPLASTY PROCEDURES TO PROVIDE A PATHWAY THROUGH WHICH A PTCA GUIDING CATHETER MAY BE PERCUATNEOUSLY INTRODUCED INTO THE VASCULATURE OR VARIOUS DEVICES INTO VEIN OR ARTERIES WHILE MAINTAINING HEMOSTASIS FOR A VARIETY OF DIAGNOSTIC AND THERAPEUTIC PROCEDURE.

3085	MFG/MD/2018/000035	1.License Holder Name: RECOMBIGEN LABORATORIES PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:MALARIA ANTIGEN TEST DEVICE(RECOMBIGEN)-THIS IS A RAPID, IN VITRO, QUALITATIVE LATERAL FLOW IMMUNOASSAY FOR THE DETECTION OF MALARIA ANTIGEN SPECIFIC PROTEIN IN WHOLE BLOOD SAMPLES. THE TEST MAY BE USED FOR THE FOLLOW UP OF ANTI-MALARIAL THERAPY IN WHOLE BLOOD SAMPLES,CRP (C-REACTIVE PROTEIN) TEST (RECOMBIGEN)-CRP LATEX SLIDE TEST IS A LATEX AGGLUTINATION TEST FOR QUALITATIVE AND SEMI QUANTITATIVE IN VITRO DETERMINATION OF C-REACTIVE PROTEIN (CRP) IN HUMAN SERUM, TYPHOID ANTIGEN TEST DEVICE(RECOMBIGEN)-THIS IS A RAPID, IN VITRO, QUALITATIVE LATERAL FLOW IMMUNOASSAY FOR THE DETECTION OF S.TYPHI AND PARATYPHI ANTIGENS IN HUMAN SERUM OR STOOL SAMPLES,TROPONIN I TEST DEVICE(RECOMBIGEN) -THIS IS A RAPID, IN VITRO, QUALITATIVE LATERAL FLOW IMMUNOASSAY FOR THE DETECTION OF CARDIAC TROPONIN I (CTNI) IN HUMAN WHOLE BLOOD/SERUM/PLASMA SPECIMENS AS AN AID IN THE DIAGNOSIS OF MYOCARDIAL INFARCTION,SYPHILIS (TP) TEST DEVICE(RECOMBIGEN)-THIS IS A RAPID, IN VITRO, QUALITATIVE LATERAL FLOW IMMUNOASSAY FOR THE DETECTION OF ANTIBODIES TO TREPONEMA PALLIDUM IN SERUM, PLASMA AND WHOLE BLOOD SAMPLES

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3086	MFG/MD/2018/000036	1.License Holder Name: SD BIOSENSOR HEALTHCARE PVT. LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ULTRA HIV 1/2 AB(NA)-IT IS A RAPID QUALITATIVE IMMUNOASSAY TO DETECT CIRCULATING ANTIBODIES AGAINST HIV IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,ULTRA MALARIA P.F AG(NA)-IT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF PLASMODIUM FALCIPARUM HISTIDINE RICH PROTEIN-II (HRP-II) IN HUMAN WHOLE BLOOD.,ULTRA MALARIA P.F/P.V AG(NA)-IT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DIFFERENTIAL DETECTION BETWEEN PLASMODIUN FALCIPARUM HISTIDINE RICH PROTEIN - II (HRP-II) AND PLDH (PLASMODIUM LACTATE DEHYDROGENASE) SPECIFIC TO PLASMODIUM VIVAX IN HUMAN WHOLE BLOOD.,ULTRA HCV AB(NA)-IT IS RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF SPECIFIC ANTIBODIES TO HCV PRESENT IN HUMAN SERUM, PLASMA OR WHOLE BLOOD.,ULTRA MALARIA PF/PAN AG(NA)-IT IS AN IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DIFFERENTIAL DETECTION BETWEEN PLASMODIUN FALCIPARUM HISTIDINE RICH PROTEIN - II (HRP-II) AND PLDH (PLASMODIUM SPECIES P. FALCIPARUM, P. VIVAX, P. OVALE & P. MALARIAE) LACTATE DEHYDROGENASE (PLDH) IN HUMAN WHOLE BLOOD.
3087	MFG/MD/2018/000037	1.License Holder Name: VITTHU MAULI CHEMICAL AND GASES 2.Approving Authority: AMRAVATI DIVISION 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON IP-SERGICAL DRESSING

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3088	MFG/MD/2018/000038	1.License Holder Name: DOLPHIN LIFESCIENCE INDIA LLP 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:HEMOSTASIS Y CONNECTOR KIT(Y SATIS)-Y-CONNECTOR: IT PROVIDES A MEAN FOR INSERTING GUIDE WIRES OR CATHETERS DEEP INTO THE VASCULATURE, AND POSITIONING AND LOCKING THEM INTO A DESIRED PLACE. THE SIDE ACCESS LUMEN ALLOWS PRESSURE MONITORING AND PERFUSION. METALLIC INSERTION TOOL (BLUNT INTRODUCER): IT IS AN ACCESSORY DESIGN TO FACILITATE THE INTRODUCTION OF GUIDEWIRES (UP TO 0.018") USED IN CONJUNCTION WITH INTERVENTIONAL DEVICES DURING VASCULAR INTERVENTIONAL PROCEDURES. TORQUER: IT IS DESIGN TO FACILITATE STEERING OF 0.010" TO 0.014" GUIDEWIRES IN SIDE THE VASCULATURE. ,TRANS RADIAL BAND(CRANK)-TRANS RADIAL BAND IS PRINCIPALLY USED FOR THE COMPRESSION HAEMOSTASIS AFTER PERCUTANEOUS ARTERIAL INTERVENTIONAL OPERATION. THIS PRODUCT CAN APPLY MECHANICAL PRESSURE AT THE VESSEL PUNCTURE SITE IN PLACE OF ARTIFICIAL HAND COMPRESSION HEMOSTASIS SO AS TO MAKE THE PATIENTS MORE COMFORTABLE AND REDUCE THE WORKLOAD OF MEDICAL STAFF.
3089	MFG/MD/2018/000039	1.License Holder Name: TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:PROTEUS OX19 KIT FOR WEIL FELIX TEST(PROGEN OX19 KIT)-DIAGNOSIS OF RICKETTSIAL INFECTION AND DIFFERENTIAL DIAGNOSIS IN PATIENTS WITH FEBRILE FEVER
3090	MFG/MD/2018/000040	1.License Holder Name: HARSORIA HEALTHCARE PVT LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:IV CANNULA WITH INJECTION PORT(HEALFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS AND OR/BLOOD COMPONENTS,OR TO FACILIATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV CNNULA WITHOUT INJECTION PORT. (HEALCATH)-THE IV CANNULA IS PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS AND OR/ BLOOD COMPONENTS,OR TO FACILIATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.

3091	MFG/MD/2018/000041	1.License Holder Name: NULIFE 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:HUMAN CHORIONIC GONADOTROPIN (HCG) TEST KITS-THE PREGNANCY ONE STEP RAPID TEST CASSETTE IS A RAPID, ONE STEP TEST FOR THE QUALITATIVE DETECTION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN URINE, AS AN AID FOR THE EARLY DETECTION OF PREGNANCY. THE TEST IS INTENDED FOR IN VITRO DIAGNOSTIC SELF-TESTING.
3092	MFG/MD/2018/000042	1.License Holder Name: ZYWIE PHARMACEUTICALS PVT LTD 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:SURGICAL DRESSING COTTON-SURGICAL DRESSING
3093	MFG/MD/2018/000043	1.License Holder Name: NIPRO MEDICAL (INDIA) PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:3-WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS(SHINRAI)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF FLUID AND PRESSURE MONITORING, EXTENSION SETS(SHINRAI)-EXTENSION SET ARE SINGLE USE DEVICE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION, INTRAVENOUS CANNULA (SHINRAI)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND /OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.
3094	MFG/MD/2018/000044	1.License Holder Name: M/S GANDHI TRADERS 2.Approving Authority: BIHAR 3.Device Name(Brand Name)-Intended Use:CREPE BANDAGE-CREPE BANDAGES ARE SUITABLE FOR USE WRIST AND ANKLE INJURIES, KNEE JOINT PAIN, AND AROUND THE ELBOW AND ARM.,ROLLED BANDAGE-ROLLED BANDAGE IS USED FOR DIFFERENT TYPES OF CUTS, INJURIES, WOUNDS ETC.,ABSORBENT GAUZE-DRESSING FOR USE TO CLEAN WOUND OR APPLY MEDICATION. IT CAN ALSO BE USED TO COVER A MINOR WOUND.

3095	MFG/MD/2018/000045	1.License Holder Name: ROMSONS JUNIORS INDIA 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use: STERILE TRANSFUSION SET, FOR SINGLE USE ONLY, GRAVITY FEED. (BLOOD ADMINISTRATION SET) (RMS® BLOOD ADMINISTRAION SET)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER. , STERILE BURETTE INFUSION SET FOR SINGLE USE ONLY, GRAVITY FEED. (FOR BLOOD TRANSFUSION)(BURETTA® FOR BLOOD)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE INFUSION SET, SINGLE USE ONLY. GRAVITY FEED(INTRA KIT™ (I.V INFUSION KIT))-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. ,STERILE HYPODERMIC SYRINGE WITH NEEDLE FOR SINGLE USE ONLY(ROMO LOK®)-INTEND TO INJECT FLUID INTO OR WITHDRAW FLUID FROM THE BODY ,STERILE HYPODERMIC SYRINGE WITHOUT NEEDLE FOR SINGLE USE ONLY (ROMO JET™)-INTEND TO INJECT FLUID INTO OR WITHDRAW FLUID FROM THE BODY,STERILE HYPODERMIC SYRINGE WITH NEEDLE, FOR SINGLE USE ONLY(ROMO JET™)-INTEND TO INJECT FLUID INTO OR WITHDRAW FLUID FROM THE BODY ,ISOPROPYL RUBBING ALCOHOL AS PER USP (SURGICAL DRESSING)(ISOPROPYL RUBBING ALCOHOL (ALCOHOL SWAB))-IT IS SINGLE USE, STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE ,ISOPROPYL RUBBING ALCOHOL AS PER USP (SURGICAL DRESSING)(ALCO SWAB)-IT IS SINGLE USE, STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE , STERILE BURETTE INFUSION SET FOR SINGLE USE ONLY, GRAVITY FEED.(VOLUFIX®-(150ML))-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH VASCULAR ACCESS DEVICE , STERILE BURETTE INFUSION SET FOR SINGLE USE ONLY, GRAVITY FEED.(STERILE DISPOSABLE PERFUSION SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH VASCULAR ACCESS DEVICE , STERILE VENTED INFUSION SET, FOR SINGLE USE ONLY. GRAVITY FEED.(STERIFLO™ PLUS)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. ,STERILE HYPODERMIC SYRINGE WITHOUT NEEDLE FOR SINGLE USE ONLY(INJECTA™)-INTEND TO INJECT FLUID INTO OR WITHDRAW FLUID FROM THE BODY

	,STERILE HYPODERMIC SYRINGE WITH NEEDLE FOR SINGLE USE ONLY(INJECTA™)-INTEND TO INJECT FLUID INTO OR WITHDRAW FLUID FROM THE BODY , STERILE TRANSFUSION SET, FOR SINGLE USE ONLY, GRAVITY FEED, (WITH LEUCOCYTE REDUCTION FILTER)(LEUCODEP)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED , STERILE INFUSION SET, FOR SINGLE USE ONLY, GRAVITY FEED. (ACCESSORY OF IV INFUSION SET WITH ROTATING TYPE PRECISION FLOW CONTROLLER.)(ROTA FLO)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE INFUSION SET, FOR SINGLE USE ONLY, GRAVITY FEED. (IV INFUSION SET WITH ROTATING TYPE PRECISION FLOW CONTROLLER.)(DIAL FLOW)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE INFUSION SET, FOR SINGLE USE ONLY, GRAVITY FEED. (IV INFUSION SET WITH ROTATING TYPE PRECISION FLOW CONTROLLER.)(ROMOTROL®)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE VENTED INFUSION SET, FOR SINGLE USE ONLY.(WITH 0.2 MICRON FILTER, DEHP FREE.)(MICROGUARD® STD.)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE BURETTE INFUSION SET FOR SINGLE USE ONLY, GRAVITY FEED.(VOLUMETRIC® PLUS)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASULAR SYSTEM THROUGH A VASCULAR ACCESSS DEVICE. , STERILE BURETTE INFUSION SET FOR SINGLE USE ONLY, GRAVITY FEED.(VOLUFIX® PLUS)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASULAR SYSTEM THROUGH A VASCULAR ACCESSS DEVICE. , STERILE ACCESSORY OF INFUSION SET FOR SINGLE USE ONLY(T- CONNECTOR EXTENSION LINE)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE ACCESSORY OF INFUSION SET FOR SINGLE USE ONLY(END EXTENSION.)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE ACCESSORY OF INFUSION SET FOR SINGLE USE ONLY(Y- TYPE EXTENSION TUBE)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE ACCESSORY OF INFUSION SET FOR SINGLE USE ONLY(EXTENSION

	TUBE)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE VENTED INFUSION SET, FOR SINGLE USE ONLY. GRAVITY FEED.(STANDARD GIVING SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE INFUSION SET, FOR SINGLE USE ONLY. GRAVITY FEED.(PREMIUM GIVING SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE VENTED INFUSION SET, FOR SINGLE USE ONLY. GRAVITY FEED.(PAEDIATRIC GIVING SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE VENTED INFUSION SET, FOR SINGLE USE ONLY. GRAVITY FEED.(SOLU FLO™)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. ,STERILE VENTED INFUSION SET, FOR SINGLE USE ONLY. GRAVITY FEED(VENE SET™)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN, STERILE VENTED INFUSION SET, FOR SINGLE USE ONLY. GRAVITY FEED.(STERI FLO™)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE VENTED INFUSION SET, FOR SINGLE USE ONLY . GRAVITY FEED (WITH AIR EMBOLISM PREVENTION FILTER.) (INTRA FLOW -AS)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE VENTED INFUSION SET, FOR SINGLE USE ONLY. GRAVITY FEED.(INTRA FLOW)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. ,STERILEBLOOD TAKNG SET FOR SINGLE USE ONLY(BLOOD TAKING SET)-IT IS USED TO WITHDRAW/ COLLECTING THE BLOOD FROM A BODY THROUGH A NEEDLE, STERILE TRANSFUSION SET, FOR SINGLE USE ONLY, GRAVITY FEED. (PLASMA, BLOOD AND SALINE GIVING SET.) (SET PLASMA, (BLOOD & SALINE GIVING SET))-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER. , STERILE TRANSFUSION SET, FOR SINGLE USE ONLY, GRAVITY FEED. (VENTED BLOOD ADMINISTRATION SET) (VENTRA FIX™ PLUS)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER. , STERILE TRANSFUSION SET, FOR SINGLE USE ONLY, GRAVITY FEED. (BLOOD ADMINISTRATION KIT) (BEE TEE KIT, (BLOOD

	TRANSFUSION KIT),)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER. , STERILE TRANSFUSION SET, FOR SINGLE USE ONLY, GRAVITY FEED. (BLOOD ADMINISTRATION SET) (VENTRA FIX™)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER. , STERILE INFUSION SET FOR SINGLE USE ONLY. GRAVITY FEED(MICRO INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE INFUSION SET FOR SINGLE USE ONLY. GRAVITY FEED(INFLOW INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE INFUSION SET FOR SINGLE USE ONLY. GRAVITY FEED(REGULAR FLUID INFUSION SET®)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE VENTED INFUSION SET, FOR SINGLE USE ONLY. GRAVITY FEED (WITH 0.2 MICRON FILTER, DEHP FREE.)(MICROGUARD®)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE VENTED INFUSION SET FOR SINGLE USE ONLY. GRAVITY FEED(ROMO FLOW®)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE VENTED INFUSION SET, FOR SINGLE USE ONLY. GRAVITY FEED.(TRANS FLOW®)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE VENTED INFUSION SET FOR SINGLE USE ONLY. GRAVITY FEED (WITH OR WITHOUT NEEDLE)(MICROPERF®)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE VENTED INFUSION SET FOR SINGLE USE ONLY . GRAVITY FEED (WITH NEEDLE) (RMS® VENTED INFUSION SET WITH NEEDLE)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE VENTED INFUSION SET FOR SINGLE USE ONLY, GRAVITY FEED. (WITHOUT NEEDLE)(RMS® VENTED INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN. , STERILE INFUSION SET FOR SINGLE USE ONLY, GRAVITY FEED. (WITH OR WITHOUT NEEDLE)(RMS® INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR

		CATHETER INSERTED IN TO VEIN. , STERILE BURETTE INFUSION SET FOR SINGLE USE ONLY, GRAVITY FEED.(VOLUMETRIC SET®)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASULAR SYSTEM THROUGH A VASCULAR ACCESSS DEVICE. , STERILE BURETTE INFUSION SET FOR SINGLE USE ONLY, GRAVITY FEED.(VOLUFIX®)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASULAR SYSTEM THROUGH A VASCULAR ACCESSS DEVICE. , STERILE BURETTE INFUSION SET FOR SINGLE USE ONLY, GRAVITY FEED.(BURETTA®)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASULAR SYSTEM THROUGH A VASCULAR ACCESSS DEVICE. , STERILE BURETTE INFUSION SET FOR SINGLE USE ONLY, GRAVITY FEED.(PEDIA DRIP® PLUS)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASULAR SYSTEM THROUGH A VASCULAR ACCESSS DEVICE. , STERILE BURETTE INFUSION SET FOR SINGLE USE ONLY, GRAVITY FEED.(PEDIA DRIP®)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASULAR SYSTEM THROUGH A VASCULAR ACCESSS DEVICE. ,STERILE HYPODERMIC NEEDLE FOR SINGLE USE ONLY (DISPOSABLE NEEDLE)-A HYPODERMIC SINGLE LUMEN NEEDLE IS DEVICE INTENDED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, PARTS OF BODY BELOW THE SURFACE OF SKIN. ,STERILE HYPODERMIC SYRINGE WITHOUT NEEDLE FOR SINGLE USE ONLY (ROMO LOK®)-INTEND TO INJECT FLUID INTO OR WITHDRAW FLUID FROM THE BODY
3096	MFG/MD/2018/000046	1.License Holder Name: ZENITH SURGICARE 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.-SURGICAL DRESSING: IT SERVES AS A MECHANICAL PROTECTION TO WOUNDS AND INJURED AREA; TO ABSORB BLOOD, MUCUS, OR PUS; IT IS USED IN THE DRESSING OF WOUNDS. AT HOME IT IS USED FOR FIRST AID.

3097	MFG/MD/2018/000047	1.License Holder Name: ACHIEVER HEALTH CARE PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:PLASTER OF PARIS BANDAGE-SURGICAL DRESSINGS,GAUZE BANDAGE / ROLLER BANDAGE-SURGICAL DRESSINGS,ABDOMINAL PAD-SURGICAL DRESSINGS ,COMBINE DRESSING-SURGICAL DRESSINGS ,ELASTIC ADHESIVE BANDAGE-SURGICAL DRESSINGS,W.O.W BANDAGE-SURGICAL DRESSINGS,COTTON CREPE BANDAGE-SURGICAL DRESSINGS
3098	MFG/MD/2018/000048	1.License Holder Name: OMEX MEDICAL TECHNOLOGY 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:INTRAVENOUS CANNULA-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITHOUT AIRVENT-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE INFUSION SET WITHOUT AIRVENT-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. , STERILE DISPOSABLE INFUSION SET WITH AIRVENT-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3099	MFG/MD/2018/000049	1.License Holder Name: OPHTHALMIC MARKETING & SERVICES PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:HYDROPHOBIC FOLDABLE INTRAOCULAR LENS(VISION+™)-INTRAOCULAR LENS (IOL) LENS IMPLANTED IN THE EYE USED TO TREAT CATARACTS OR MYOPIA,HYDROPHILIC FOLDABLE INTRAOCULAR LENS (CLEARVIEW™)-INTRAOCULAR LENS (IOL) LENS IMPLANTED IN THE EYE USED TO TREAT CATARACTS OR MYOPIA,HYDROPHILIC FOLDABLE INTRAOCULAR LENS(CLEARVIEW™)-INTRAOCULAR LENS (IOL) LENS IMPLANTED IN THE EYE USED TO TREAT CATARACTS OR MYOPIA,PMMA INTRAOCULAR LENS(SHARPVIEW®)-INTRAOCULAR LENS (IOL) LENS IMPLANTED IN THE EYE USED TO TREAT CATARACTS OR MYOPIA,PMMA INTRAOCULAR LENS(SHARPVIEW®)-INTRAOCULAR LENS (IOL) LENS IMPLANTED IN THE EYE USED TO TREAT CATARACTS OR MYOPIA,PMMA INTRAOCULAR LENS (SHARPVIEW®)-INTRAOCULAR LENS (IOL) LENS IMPLANTED IN THE EYE USED TO TREAT CATARACTS OR MYOPIA
3100	MFG/MD/2018/000050	1.License Holder Name: KSHEMA MEDICAL SYSTEMS 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:ABSORBANT COTTON(K MEDIKOT)-PRODUCT IS BASICALLY ABSORBENT COTTON. USEFUL IN ABSORBANCY AND OTHER WOUND CLEANING PROCESS ETC
3101	MFG/MD/2018/000051	1.License Holder Name: RAJDHANI SURGICALS LLP 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL IP-TO BE USED FOR MEDICAL AND COSMETIC PURPOSES.
3102	MFG/MD/2018/000052	1.License Holder Name: SHIV SHAKTI ENTERPRISES 2.Approving Authority: BIHAR 3.Device Name(Brand Name)-Intended Use:ROLLED BANDAGE, ABSORBENT GAUZE , COTTON CREPE BANDAGE B.P.-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB.

3103	MFG/MD/2018/000054	1.License Holder Name: HARSORIA HEALTHCARE PVT LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:3 WAY STOP COCK WITH EXTENSION LINE(VIGGO CONNECT ULTRA)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,BT SET WITH FLOW REGULATOR (TRANSFIX)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO PATIENT 'S VASCULAR SYSTEM THROUGH A NEEDLE/ CATHETER INSERTED A VEIN.,EXTENSION LINE -2 WAY/3WAY(VIGGO-2WAY & VIGGO-3WAY)-S PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS., AV FISTULA NEEDLE(VIGGOLINK)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLE WHEN DIALYSIS IS CARRIED OUT.,BLOOD TRANSFUSION SET(HEMOCONTROL)-TRANSFUSION SET USED TO ADMINISTER BLOOD/DRUGS TO THE PATIENT'S VASCULAR SYSTEM THROUGH NEEDLE/CATHETER INSERTED INTO A VEIN. ,3 WAY STOP COCK WITH/WITHOUT EXTENSION TUBE.(VIGGOWAY)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,EXTENSION LINE(VIGGO-1-WAY)-EXTENSION LINE ARE STERILE MEDICAL DEVICE USE FOR SINGLE USE ONLY.THEY ARE INTENDED TO USED AS A PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATION FOR MEDICAL APPLICATIONS.,EXTENSION TUBE(VIGGO CONNECT)-EXTENSIONS SET ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO USED AS PART OF A SYSTEM FOR INFUSION OF FLUID/MEDICATIONS IN MEDICAL APPLICATION.,EXTENSION LINE (VIGGO CONNECT-S)-EXTENSION LINE ARE STERILE DEVICE FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS A PART OF A SYSTEM FOR THE INFUSION OF FLUID/MEDICATIONS IN MEDICAL APPLICATIONS.,IV CANNULA WITH/WITHOUT INJECTION PORT (VIGGOFLON,VIGGOVEIN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND /OR BLOOD COMPONENTS,OR TO FACILIATE THE PLACEMENT OF VASCULAR ACESS VALVE.,IV CANNULA WITH CATHETER WITHOUT PORT/VALVE AND WITHOUT WINGS.(VIGGOCANN)-THE IV CANNULA IS PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND /OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENTS OF VASCULAR ACCESS DEVICE.,SAFETY IV CANNULA WITH/WITHOUT INJECTION PORT AND WITH WINGS/SMALI/ WINGS.(VIGGOFLON-S , VIGGOVEIN-S)-THE IV CANNULA IA PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUID/DRUGS AND /OR BLOOD COMPONENTS,OR TO FACILITATE THE VASCULAR ACCESS DEVICE.,HEMODIALYSIS

		CATHETER KIT ,DOUBLE LUMEN(VIGGOCATH)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT.,INTRVENOUS INFUSION SET(FLEXICONTROL)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,FLOW REGULATOR(VIGGOFLO)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTANT DELIVERY.,IV SET WITH FLOW REGULATOR(CONTROFIX) -TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE/ CATHETER INSERTED INTO VEIN.
3104	MFG/MD/2018/000055	1.License Holder Name: KULKARNI WEAVING MILLS PRIVATE LIMITED 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:COTTON CREPE BANDAGE-COTTON CREPE BANDAGE IS USED IN THE TREATMENT OF SPRAINS, AND STRAINS AND IN OTHER CONDITIONS IN WHICH LIGHT SUPPORT IS REQUIRED. IT MAY BE USED FOR THIS PURPOSE IN CONJUNCTION WITH OTHER SURGICAL APPLIANCES. IT IS ALSO USED FOR CORRECTIONAL PURPOSE.,ROLLED LENO BANDAGE-ROLLER BANDAGE CAN BE USED IN WOUND CARE FOR CLEANING OR COVERING THE WOUND OR BANDAGING THE WOUND AREA OR PLASTIC PACKAGING.,GAUZE SWAB-GAUZE SWABS CAN BE USED IN WOUND CARE FOR CLEANING THE WOUND, APPLYING MEDICINE OVER THE WOUND, COVERING THE WOUND OR BANDAGING THE WOUND AREA.,GAMJEE ROLL/PAD-GAMJEE PAD/ROLL CAN BE USED IN WOUND CARE FOR COVERING THE WOUND, APPLYING MEDICINE OVER THE WOUND OR BANDAGING THE WOUND AREA.,SPONGE/MOP-SPONGES/MOPS ARE USED IN WOUND CARE OR DURING A SURGERY TO ABSORB THE BODY FLUIDS AND TO CLEAN THE WOUND/SURGERY AREA.,ABSORBENT COTTON GAUZE-USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES ETC.,BECAUSE OF HIGH FLUID ABSORBENCY POWER
3105	MFG/MD/2018/000056	1.License Holder Name: DEGANIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:PTCA DILATION CATHETER-THE CATHETER IS PLACED IN THE OPENING OR OSTIUM OF ONE THE CORONARY ARTERIES.,PTCA DILATION CATHETER (MAYA)-THE CATHETER IS PLACED IN THE OPENING OR OSTIUM OF ONE THE CORONARY ARTERIES.,PTCA DILATION CATHETER(VEGA)-THE CATHETER IS PLACED IN THE OPENING OR OSTIUM OF ONE THE CORONARY ARTERIES

3106	MFG/MD/2018/000057	1.License Holder Name: DATT MEDIPRODUCTS PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:DRESSING PACK (SOFTPACK DRESSING KIT)-PACK FOR SMALL SURGICAL PROCEDURE,WOUND DRESSING(GAMJEE ROLL)-A DRESSING ROLL FOR THE ABSORPTION OF DISCHARGES FROM WOUND,WOUND DRESSING(SOFTPAD)-A DRESSING PAD FOR THE ABSORPTION OF DISCHARGES FROM WOUND,GAUZE SWAB(VELSWAB)-A GAUZE SWAB FOR THE ABSORPTION OF DISCHARGES FROM WOUND,WOUND DRESSING(GAMJEE PAD)-A DRESSING PAD FOR ABSORPTION OF DISCHARGES FROM WOUND,GAUZE SWAB(SOFTSWAB)-A GAUZE SWAB FOR THE ABSORPTION OF DISCHARGES FROM WOUND, ABDOMINAL PAD(SOFTLAPS)-A GAUZE PAD FOR THE ABSORPTION OF DISCHARGES FROM ABDOMINAL WOUND,ADHESIVE DRESSING (VELFIX EASY)-DRESSING FOR CANNULA FIXATION,ADHESIVE DRESSING(VELFIX T)-DRESSING FOR CANNULA FIXATION

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3107	MFG/MD/2018/000058	1.License Holder Name: BIORAD MEDISYS PVT LTD 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:ARTERIAL CATHETER-INTENDED TO BE USED IN CONJUNCTION WITH STEERABLE GUIDEWIRES IN ORDER TO ACCESS DISCRETE REGIONS OF THE CORONARY AND PERIPHERAL ARTERIAL VASCULATURE. (HYDROPHILIC COATING, OFFERS EXTRA LUBRICITY, REDUCING FRICTION DRASTICALLY AND ENABLING SMOOTH MANIPULATION)., VESSEL DIALATOR FOR PERCUTANEOUS CATHETERIZATION-A VESSEL DILATOR FOR PERCUTANEOUS CATHETERIZATION IS A DEVICE WHICH IS PLACED OVER THE GUIDE WIRE TO ENLARGE THE OPENING IN THE VESSEL, AND WHICH IS THEN REMOVED BEFORE SLIDING THE CATHETER OVER THE GUIDE WIRE.(THINNER SHEATH LAYER IMPROVES SHEATH-TO-DILATOR TRANSITION, ASSURING LESS PUNCTURE RESISTANCE),FORCEPS, ENDOSCOPIC-USED TO CUT AND COAGULATE THE PROSTATE GLAND DURING TRANS-URETHRAL RESECTIONS OF THE PROSTATE (TURP).,GASTRO-UROLOGY NEEDLE -INTRODUCER NEEDLE IS DESIGNED FOR PERCUTANEOUS ACCESS., ASPIRATION AND INJECTION NEEDLE-THE BIOPSY NEEDLES ARE USED TO EXTRACT THE TISSUE OF THE PATIENT FOR BIOPSY., HAEMODIALYSIS CATHETER-USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT, NEPHROSTOMY CATHETER -USED FOR NEPHROSTOMY DRAINAGE., FOLEY CATHETER-USED FOR NEPHROSTOMY DRAINAGE., SCLEROTHERAPY NEEDLE/ CATHETER-SCLEROTHERAPHY NEEDLES ARE USED FOR INJECTION OF SCELEROTHERAPATIC SOLUTION IN TO ESOPHAGEAL VARICES. ALSO USED FOR INJECTION OF APPROPRIATE VASOCONSTRICTION/MEDICATION AGENT INTO THE GASTROINTESTINAL TRACT.,NEPHROSTOMY CATHETER -THIS DEVICE IS USED FOR THE TEMPORARY DRAINAGE BY DIRECT PUNCTURE THOUGH THE SKIN INTO THE KIDNEY FOR THE DISTAL OBSTRUCTION. USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE ,URETHRAL CATHETER -USED FOR TEMPORARY INTERNAL DRAINAGE FROM THE URETERO PELVIC JUNCTION TO THE BLADDER FOLLOWING INCISION OF STRICTURE.,NEPHROSTOMY CATHETER -USED FOR EXTERNAL DRAINAGE OF VISCOUS LIQUIDS FROM RENAL PELVIS OR BLADDER, FOR PCN & SUPRAPUBIC PROCEDURES RESPECTIVELY., NEPHROSTOMY CATHETER -THIS DEVICE IS USED FOR THE TEMPORARY DRAINAGE BY DIRECT PUNCTURE THOUGH THE SKIN INTO THE KIDNEY FOR THE DISTAL OBSTRUCTION. USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE.,NEPHROSTOMY CATHETER -THIS DEVICE IS USED FOR THE TEMPORARY DRAINAGE BY DIRECT PUNCTURE

	THOUGH THE SKIN INTO THE KIDNEY FOR THE DISTAL OBSTRUCTION. USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE.,NEPHROSTOMY CATHETER -THIS DEVICE IS USED FOR THE TEMPORARY DRAINAGE BY DIRECT PUNCTURE THOUGH THE SKIN INTO THE KIDNEY FOR THE DISTAL OBSTRUCTION. USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE.,GASTRO-UROLOGY NEEDLE -IT IS USED FOR PERCUTANEOUS NEPHROSTOMY FOR INITIAL PUNCTURE AND ALL OTHER PERCUTANEOUS. ,PLATES, CLIPERS SCREWS (PI-LOK)-SPINE IMPLANT SURGERY. ,PLATES, CLIPERS SCREWS (PI-LOK)-SPINE IMPLANT SURGERY.,PLATES, CLIPERS SCREWS (PI-LOK)-SPINE IMPLANT SURGERY,PLATES, CLIPERS SCREWS (PI-LOK)-SPINE IMPLANT SURGERY,GASTRO-UROLOGY NEEDLE -USED FOR PERCUTANEOUS NEPHROSTOMY PROCEDURES, CYTOLOGICAL BIOPSIES, NEEDLE-ASPIRATIONS, THORACENTESIS EXPLORATORY PUNCTURES, TO INJECT CONTRAST DYES.,VESSEL DIALATOR FOR PERCUTANEOUS CATHETERIZATION -URETERAL ACCESS SHEATH USED TO ESTABLISH A CONDUIT DURING ENDOSCOPIC UROLOGICAL PROCEDURES FACILITATING THE PASSAGE OF ENDOSCOPES AND OTHER INSTRUMENTS INTO THE URINARY TRACT. THE WORKING CHANNEL PROTECTS THE URETER DURING REPEATED INSTRUMENT EXCHANGES. THE SHEATH ALSO PROTECTS DELICATE INSTRUMENTS AND SMALLER FLEXIBLE SCOPES FROM DAMAGE. ,VESSEL DIALATOR FOR PERCUTANEOUS CATHETERIZATION -IT IS A DILATOR USED FOR URETERAL DILATION PRIOR TO URETERAL STONE MANIPULATION OR URETEROSCOPY, AS WELL AS DILATION OF THE INTRAMURAL URETER & URINARY TRACT. ALSO USED FOR WIDENING THE URETERAL STRICTURE. ,VESSEL DIALATOR FOR PERCUTANEOUS CATHETERIZATION -NEPHROSTOMY BALLOON DILATOR USED FOR DILATING THE NEPHROSTOMY TRACK AND FOR THE PLACEMENT OF THE WORKING SHEATH.,SUPRAPUBIC CATHETER -CYSTO CATHETER OFFERS A SIMPLIFIED SYSTEM FOR BLADDER DRAINAGE BY SUPRAPUBIC PLACEMENT.,HAEMODIALYSIS CATHETER-USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT.,IN-VITRO FERTILIZATION/ EMBRYO TRANSFER CATHETER-THE IUI CATHETER IS DESIGNED AS POTENTIALLY EFFECTIVE TREATMENT OF ALL CAUSES IN WOMEN FOR ARTIFICIAL INTRA UTERINE INSEMINATION PURPOSE.,RADIOGRAPHIC (NON VASCULAR) CATHETER-USED FOR PERCUTANEOUS DRAINAGE APPLICATIONS OF BILIARY AND ABSCESS.,GASTROINTESTINAL TUBE-USED TO DELIVER NUTRITION IN TO THE SMALL BOWEL., FEEDING TUBE-THE MEDICAL DEVICE, JEJUNAL FEEDING TUBE IS USED WHEN PATIENTS REQUIRE FEEDING PAST THE STOMACH DIRECTLY INTO THE JEJUNUM & IT IS USED TO ENHANCE THE

	ABSORPTION OF NUTRIENTS AND MINIMIZE THE RISKS OF GASTRIC FEEDING INCLUDING GASTRIC REFLUX AND ASPIRATION., OESOPHAGEAL BLAKEMORE TUBE-IT IS USED FOR BILIARY DUCT DRAINAGE THROUGH NASAL PASSAGE& ALSO FOR TREATMENT OF STRICTURES IN THE DUCTILE SYSTEM. IT INCLUDES A NASAL TRANSFER TUBE AND A CONNECTING TUBE WHICH FACILITATE EASY & SAFE IRRIGATION AND DRAINAGE.,CHOLANGIOGRAPHY CATHETER-DRAINAGE CATHETER IS THE TYPE OF STENTS USED TO DRAIN THE BILE DUCTS.,UPPER URINARY TRACT CATHETER -THE DUAL LUMEN CATHETER IS USED FOR DRAINAGE OF URINE, CONTRAST INJECTION, URETERAL DILATION & PLACEMENT OF SAFETY GUIDE WIRE.,VESSEL DIALATOR FOR PERCUTANEOUS CATHETERIZATION -USED TO DILATE THE INTRAMURAL TUNNEL AND URETERAL IN ONE STEP.,UPPER URINARY TRACT CATHETER -USED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY THROUGH THE KIDNEY., UPPER URINARY TRACT CATHETER-USED FOR EXTERNAL URETHRAL DRAINAGE AND FOR RETROGRADE PYELOGRAM AND NAVIGATION OF THE TORTUOUS URETER THOUGHT THE URETHRA.,SUPRAPUBIC CATHETER-A SUPRAPUBIC CATHETER IS USED TO DRAIN URINE FROM THE BLADDER WHEN YOU CANNOT URINATE. THIS TYPE OF CATHETER IS USED IF YOU AREN'T ABLE TO USE A CATHETER THAT IS INSERTED INTO THE URETHRA. THIS IS MAINLY USED IN CASES WHERE THE THICK/VISCOUS LIQUIDS HAS TO BE DRAINED., NEPHROSTOMY CATHETER-RE-ENTRY MALECOT CATHETER IS USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE (INTERNAL AND EXTERNAL DRAINAGE).

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3108	MFG/MD/2018/000059	1.License Holder Name: BREATHE HEALTHCARE 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:FISTULA NEEDLE(NIL)-TO CONNECT THEBLOOD LINES WITH THE BLOOD VESSEL THROUGH NEEDLES WHEN DIALYSIS CARRIED OUT. A FISTULA NEEDLE SET ARE INDICATED FOR USE IN CONJUNCTION WITH A CONNECTOR OF HAEMODIALYSIS BLOOD TUBING SET. FISTULA IS USED TO CONNECT BLOOD LINES TO THE BLOOD VESSELS THROUGH NEEDLE WHEN DIALYSIS IS CARRIED OUT VIA AN INTERNAL FISTULA. ,SINGLE NEEDLE HAEMODIALYSIS CATHETER(NIL)-: A CATHETER USED FOR HAEMODIALYSIS TO ACCESS BLOOD FROM PATIENT TO HAEMODIALYSIS MACHINE AND MACHINE TO PATIENT THROUGH A SINGLE NEEDLE OR SINGLE LUMEN CATHETER.,ANAESTHETIC CONDUCTION NEEDLE(NIL)-AN ANAESTHETIC CONDUCTION NEEDLE IS A DEVICE USED TO INJECT LOCAL ANAESTHETICS IN TO A PATIENT TO PROVIDE REGIONAL ANAESTHESIA. ,I.V.FLOW REGULATOR(NIL)-: AN I.V SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY . I.V FLOW REGULATOR IS USED FOR THE FLOW CONTROL OF I.V FLUIDS DURING INFUSION OR TRANSFUSION. FLOW REGULATOR SETS REGULATES THE FLOW OF I.V FLUIDS FROM A INFUSION SET INTO A I.V CATHETER. ,MANIFOLDS (NIL)-: INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT/PORTS FOR ADMINISTRATION OF A SOLUTION. MANIFOLDS IS USED FOR FLUID FLOW DIRECTIONAL CONTRO AND FOR PROVIDING ACCESS PORT/PORTS FOR ADMINISTRATION OF A SOLUTION WHERE FLUIDS ARE ADMINISTRATED UNDER PRESSURE. ,MULTIPLE LUMEN CATHETER (NIL)-: A CATHETER INTENDED TO BE USE FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD AND MULTIPLE I.V. SOLUTIONS OR DRUGS. ,ORTHOPEDIC IMPLANTS(NIL)- 1.3 INTENDED USE : ORTHOPEDIC IMPLANTS INTENDED TO BE USE FOR REPAIRING AND PROVIDE SUPPORT OR STRENGTH TO THE BREAKAGE BONES BY IMPLANTING INSIDE THE HUMAN BODY. ,HAEMODILYSIS CATHETER (NIL)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT. ,THORACIC DRAINAGE CATHETER-THORACIC DRAINAGE CATHETER ARE MOST SUITABLE FOR POST OPERATIVE DRAINAGE AFTER CARDIO-THORACIC AND THORACIC SURGERY,AORTIC ROOT CANNULA-AORTIC ROOT CANNULAE ARE INTENDED FOR USE DURING CARDIO PULMONARY BYPASS FOR ANTEGRADE DELIVERY OF CARDIOPLEGIA SOLUTIONS AND VENTING OF THE HEART. THE CANNULA MAY ALSO BE USED TO ASPIRATE AIR FROM THE AORTA AT THE CONCLUSION OF THE CARDIAC PROCEDURE,FEMORAL CANNULA- FEMORAL CANNULAS ARE INTENDED FOR CONNECTION TO AN

	EXTRACORPOREAL CIRCULATION OF THE FEMORAL BLOOD VESSELS,VENOUS CANNULA-THIS CANNULA IS INTENDED FOR USE IN VENOUS DRAINAGE VIA THE RIGHT ATRIUM AND INFERIOR VENA CAVA SIMULTANEOUSLY DURING CARDIOPULMONARY BYPASS SURGERY,THREE WAY STOP COCK -3-WAY FLOW (FROM INLET TO OUTLET, INLET TO SIDE-PORT OR SIDE PORT TO OUTLET) BY USE OF THE HANDLE ON THE TOP OF THE STOPCOCK TO OPEN AND CLOSE LINES.THE DEVICE CAN ALSO BE USED TO REDUCE TO LINES DOWN TO ONE, FOR DRUGS/DRUG INFUSION PURPOSES AND FOR THE ATTACHMENT OF EXTENSION LINES,ARTERIAL CANNULA-AN ARTERIAL CANNULA IS INSERTED INTO AN ARTERY, COMMONLY THE RADIAL ARTERY, AND IS USED DURING MAJOR OPERATIONS AND IN CRITICAL CARE AREAS TO MEASURE BEAT-TO-BEAT BLOOD PRESSURE AND TO DRAW REPEATED BLOOD SAMPLES, ENDOTRACHEAL TUBE(BRETRACH)-AN ENDOTRACHEAL TUBE IS USED IN GENERAL ANAESTHESIA, INTENSIVE CARE AND EMERGENCY MEDICINE FOR AIRWAY MANAGEMENT AND MECHANICAL VENTILATION. THE TUBE IS INSERTED INTO A PATIENT'S TRACHEA THROUGH THE PATIENT'S NOSE OR MOUTH IN ORDER TO ENSURE THAT THE AIRWAY IS NOT CLOSED OFF AND THAT AIR IS ABLE TO REACH THE LUNGS.,YANKAUER SUCTION SET(BREYAN)-THE YANKAUER SUCTION SETS TO BE USE TO SUCK INFECTED BLOOD OR SECRETION FROM THE OPERATIVE SITE,BLOOD TUBING SET FOR HAEMODIALYSIS(BRE HAEMOLINE)-HEMODIALYSIS BLOOD TUBING SET WITH ATTACHED PRIMING SET AND TRANSDUCER PROTECTORS IS A SINGLE USE, DISPOSABLE ARTERIAL AND VENOUS BLOODLINE SET INTENDED TO PROVIDE EXTRACORPOREAL ACCESS DURING HEMODIALYSIS. THE SET IS INTENDED FOR USE WITH A PRESCRIBED HEMODIALYZER,DISPOSABLE PERFUSION SET(BREFUSION SET)-PERFUSION SET IS USED TO ADMINISTER BLOOD/DRUG TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,EXTENSION LINE SET-INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS / MEDICATIONS IN MEDICAL APPLICATIONS,SUBCLAVIN CATHETER(NIL)-A CATHETER INTENDED TO BE USE FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD AND MULTIPLE I.V. SOLUTIONS OR DRUGS THROUGH NECK (INTERNAL JUGULAR VEIN), CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN). ,NASOPHARYNGEAL CATHETER(NIL)-A CATHETER PASSES THROUGH THE NARES AND ADVANCED TO THE DEPTH OF THE NASOPHARYNX TO REMOVE AIR CHOKE OR OBSTRUCTION / A RESUSCITATOR.

3109	MFG/MD/2018/000061	1.License Holder Name: INDO SURGICAL 2.Approving Authority: BIHAR 3.Device Name(Brand Name)-Intended Use:PLASTER OF PARIS I.P.-PLASTER IS WIDELY USED AS A SUPPORT FOR BROKEN BONES; A BANDAGE IMPREGNATED WITH PLASTER IS MOISTENED AND THEN WRAPPED AROUND THE DAMAGED LIMB, SETTING INTO A CLOSE-FITTING YET EASILY REMOVED TUBE, KNOWN AS AN ORTHOPEDIC CAST. ALSO USED IN PREPARATION FOR RADIOTHERAPY WHEN FABRICATING INDIVIDUALIZED IMMOBILIZATION SHELLS FOR PATIENTS. PLASTER BANDAGES ARE USED TO CONSTRUCT AN IMPRESSION OF A PATIENT'S HEAD AND NECK, AND LIQUID PLASTER IS USED TO FILL THE IMPRESSION AND PRODUCE A PLASTER BUST. , ROLLED BANDAGE, ABSORBENT GAUZE , COTTON CREPE BANDAGE B.P.(POPULAR)-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB.

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3110	MFG/MD/2018/000062	1.License Holder Name: SURGIMEDIK HEALTHCARE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ELLICK BLADDER EVACUATOR-ELLICK BLADDER EVACUATOR USED FOR BLADDER WASH DURING TURP. TUR-VAC BLADDER EVACUATOR IS INTENDED TO USE FOR EVACUATING IRRIGATION SOLUTIONS, BLOOD CLOTS, TISSUE COLLECTION AND/OR TRAINING FUNCTIONS DURING PROSTATE SURGERY OR BLADDER SURGERY.,BITE-O-BITE BLOCK-BITE-O-BITE BLOCK USED FOR GENERAL GASTROENTEROLOGY EXAM,EGD & ERCP THERAPY,TRANSESOPHAGEAL. ECHOCARDIOGRAPHY.,BIO VALVE-USED FOR MINIMIZE LEAKAGE AND BACK FLOW OF FLUID AND OTHER BIO MATERIAL FROM THE ENDOSCOPE.,INFLATION GAUGE & DEVICE-USED WITH BALLOON DILATION CATHETERS TO MONITOR INFLATION PRESSURE.,MEATAL DILATOR-USED FOR DILATION OF PENILE URETHRAL MEATUS.,STONE EXTRACTION BALLOON-USED FOR REMOVAL OF BILIARY STONES AND TO FACILITATE THE INJECTION OF CONTRAST MEDIUM WHILE OCCLUDING THE DUCT WITH THE BALLOON. ,FALLOPIAN TUBE RECANALISATION-USED FOR FALLOPIAN TUBE RECANALIZATION UNDER RADIOLOGICAL FLUOROSCOPIC CONTROL.,AMPLATZ SHEATH-AMPLATZ SHEATH USED TO MAINTAIN PREVIOUSLY EASTABLISHED NEPHROSTOMY TRACT.,NASO BILIARY DRAINAGE CATHETER-NASO BILIARY DRAINAGE CATHETER USED FOR TEMPORARY DRAINAGE OF THE BILIARY DUCT THROUGH THE USE OF AN INDWELLING CATHETER.,POLYPECTOMY & RETRIEVAL SNARE-POLYSNARE POLYPECTOMY SNARES ARE USED FOR THE ENDOSCOPIC EXCISION OF POLYPECTOMY IN CONJUNCTION WITH AN ELECTRO-SURGICAL UNIT. NON-DIATHERMIC RETRIEVAL SNARE IS USED TO RETRIEVE FOREIGN OBJECTS FROM THE UPPER G.I. TRACT.,IRRIGATION SYRINGE-ASEPTO BULB IRRIGATION SYRINGE USED FOR IRRIGATION OF FLUIDS IN THE BODY SPECIFICALLY FOR BLADDER WASH. TOOMEY SYRINGE IS USED FOR REMOVING DEBRIS DURING ENDOSURGICAL RESECTION AND CLOTS FROM THE BLADDER. ,STENT REMOVER & SNARE-THE STENT REMOVER & SNARE USED FOR REMOVING STENTS THROUGH EITHER RIGID OR FLEXIBLE CYSTOSCOPY. ,INJECTION NEEDLE-INJECTION NEEDLE USED FOR INJECTION INTO URETHRA, BLADDER NECK AND THE BLADDER WALL UNDER CYSTOSCOPIC VISION.,SCLEROTHERAPY NEEDLE-SCLEROTHERAPY NEEDLE & SJ USED FOR INJECTION INTO AND AROUND BLEEDING VESSELS INCLUDING VARICES.,PUNCTURE NEEDLES-INITIAL PUNCTURE NEEDLE IS USED FOR PERCUTANEOUS NEPHROSTOMY AND ALL OTHER PERCUTANEOUS APPLICATIONS WHERE A 0.035” GUIDEWIRE IS TO BE USED. CHIBA NEEDLE IS USED FOR PERCUTANEOUS CHOLANGIOGRAPHY, CYTOLOGICAL BIOPSY

	AND ROUTINE PERCUTANEOUS PROCEDURE.,BALLOON DILATOR-THE URETRACK URETERAL BALLOON DILATORS ARE RECOMMENDED FOR THE DILATATION OF THE URINARY TRACK. THE NEPHROTRACK BALLOONS ARE RECOMMENDED FOR DILATATION OF THE NEPHROSTOMY TRACK.,ASPIRATION NEEDLE-ASPIRATION NEEDLE USED FOR LAPAROSCOPIC OR ULTRASOUND GUIDED TRANSVAGINAL ASPIRATION.,PERCUTANEOUS TRANSHEPATIC CHOLAGIOGRAPHY DRAINAGE CATHETER-USED TO PERFORM CHOLANGIOGRAPHY AND FOR INTERNAL / EXTERNAL BILE DUCT DRAINAGE,ENDOPYELOTOMY STENT-THE ENDOPYELOTOMY STENT IS USED FOR TEMPORARY INTERNAL DRAINAGE FROM URETEROPELVIC JUNCTION TO BLADDER FOLLOWING INCISION OF A STRICTURE.,TUMOR STENT-SUPER STRONG TUMOR STENT IS USED FOR TEMOPRARY AS WELL AS FOR PALLIATIVE TREATMENTS OF INTERNAL URINARY DRAINAGE WHEN TUMORS ARE PRESENT IN URETERAL TRACT.,URETERAL STENTS-THE URETERAL STENT IS INTENDED TO TEMPORARILY FACILITATE DRAINAGE OF URINE FROM KIDNEY TO BLADDER BY TRAINED PHYSICIAN. THE URINARY DIVERSION STENT [MONO-J] USED FOR INTEROPERATIVE PLACEMENT TO STENT THE URETER DURING PERCUTANEOUS, ENDOSCOPY OR OPERATIVE PROCEDURES,MECHANICAL LITHOTRIPTER-USED FOR MECHANICALLY CRUSH STONES IN THE BILIARY DUCT WHEN OTHER METHODS OF ENDOSCOPIC RETRIEVAL HAS FAILED.,MALE INCONTINENCE DEVICE-USED FOR TO PREVENT ACCIDENTAL URINE LEAKAGE. ,IRRIGATION DEVICE-USED FOR TEMPORARY INTERNAL DRAINAGE FROM THE URETEROPELVIC JUNCTION TO THE BLADDER.,DRAINAGE BAG CONNECTOR-USED FOR DRAINAGE OF FLUID.,U-FLEX URETERAL ACCESS SHEATH-URETERAL ACCESS SHEATH USED TO ESTABLISH CONTINUOUS WORKING CHANNEL THEREBY REDUCING URETERAL TRAUMA DURING MULTIPLE INSTRUMENTS.,SMALL BOWEL ENEMA CATHETER-SMALL BOWEL ENEMA CATHETER IS USED FOR DOUBLE CONTRAST DISPLAY OF SMALL INTESTINE.,CERVICAL OS DILATOR-USED FOR GENTLE DILATATION OF THE CERVICAL CANAL.,CERVICAL SPATULA AYRE'S WITH CYTOBRUSH-USED FOR CERVICAL CELLS SAMPLING., TRACKFINDER BULB IRRIGATOR-TRACKFINDER BULB IRRIGATOR IS USED FOR CONTINUOUS AND BOLUS IRRIGATION DURING ENDOSCOPIC SURGERIES.,ENDOMETRIAL BIOPSY CATHETER-EMBC ENDOMETRIAL BIOPSY CATHETER: USED TO OBTAIN HISTOLOGICAL TISSUE BIOPSY AND EXTRACT SAMPLE OF UTERINE MENSTRUAL CONTENT. EZ VAC ENDOMETRIAL BIOPSY SAMPLER: USED FOR OBTAINING CLEARLY DIFFERENTIATED ENDOMETRIAL TISSUE WITH SUPERIOR ADEQUACY AND PAINLESS PROCEDURE. ,GUIDEWIRE-GUIDEWIRE: FOR PERCUTANEOUS ENTRY INTO VESSEL USING THE

	SELDINGER TECHNIQUE OR FOR ENDOSCOPIC ACCESS. SUPREMO NITINOL HYDROPHILIC GUIDEWIRE USED FOR ACCESS URETER DURING ROUTINE AND DIFFICULT CASES.,VITRIFICATION STRAW-SURGIMEDIK V-STRIP IS INTENDED FOR CRYOPRESERVATION AND USED IN VITRIFICATION PROCEDURE TO HOLD AND MAINTAIN HUMAN 4-8 CELL AND BLASTOCYST STAGE EMBRYOS. SURGIMEDIK V-LOCK IS INTENDED FOR CRYOPRESERVATION AND USED IN VITRIFICATION PROCEDURE TO HOLD AND MAINTAIN HUMAN 1-CELL STAGE EMBRYOS.,STONE BASKET & EXTRACTORS-THE STONE BASKET HAS BEEN DESIGNED FOR ENDOSCOPIC MANIPULATION, DISLODGING, ENGAGING AND REMOVAL OF RENAL, URETERAL STONE OR BILIARY STONES. U-PERC NITINOL STONE BASKET IS USED FOR STONE EXTRACTION DURING PCNL. THE THREE PRONG GRASPING FORCEPS IS DESIGNED FOR ENDOSCOPIC MANIPULATION, DISLODGING, ENGAGING AND REMOVAL OF RENAL, URETERAL STONES. MULTIWIRE STONE EXTRACTOR IS USED FOR ENDOSCOPIC REMOVAL OF STONES AND FOREIGN BODIES. ,INTRODUCER NEEDLE-INTRODUCER NEEDLE IS USED AS PERCUTANEOUS ENTRY TO INTRODUCE GUIDEWIRE,OVUM PICKUP NEEDLE-SINGLE LUMEN OVUM PICKUP NEEDLE USED FOR LAPAROSCOPIC OR ULTRASOUND GUIDED TRANSVAGINAL HARVESTING OF OOCYTE FROM FOLLICLES. DOUBLE LUMEN OVUM PICKUP NEEDLE USED FOR LAPAROSCOPIC OR ULTRASOUND GUIDED TRANSVAGINAL HARVESTING OF OOCYTE FROM FOLLICLES ALONG WITH FLUSHING OF FOLLICLES. ,INTRA UTERINE INSEMINATION CATHETER-USED TO INSEMINATE WASHED SPERMATOZOA INTO THE UTERINE CAVITY.,URETERAL CATHETER-URETERAL CATHETER USED FOR DRAINAGE OF URINE FROM THE URETER AND IT ALSO ALLOWS THE DELIVERY OF CONTRAST MEDIA., SUPRAPUBIC-SUPRAPUBIC DRAINAGE CATHETER USED FOR PERCUTANEOUS BLADDER DRAINAGE.,NASO JEJUNAL FEEDING TUBE-USED TO PROVIDE SHORT TERM ENTERAL ACCESS FOR DELIVERY OF MEDICATION OR NUTRITION TO SMALL BOWEL, HYSTERO SONO SALPINGOGRAPHY CATHETER-HSG CATHETER IS USED FOR INJECTION OF CONTRAST MEDIA INTO THE UTERINE CAVITY TO EVALUATE PATENCY OF THE FALLOPIAN TUBES., RETRIEVAL FORCEPS-NON-DIATHERMIA RETRIEVAL FORCEPS IS USED TO RETRIEVE FOREIGN OBJECTS FROM THE UPPER G.I. TRACT, GASTROSTOMY TUBE-USED FOR PERCUTANEOUS ENDOSCOPIC PLACEMENT TO PROVIDE ENTERAL ACCESS FOR THE DELIVERY OF NUTRITION, MEDICATION, GASTRIC DRAINAGE OR DECOMPRESSION., EMBRYO TRANSFER CATHETER-EMBRYO TRANSFER CATHETER IS AN ASSISTED REPRODUCTION CATHETER USED IN IVF PROCEDURE TO INTRODUCE EMBRYO(S) INTO THE FEMALE BODY,DRAINAGE CATHETER AND SETS-DRAINAGE CATHETERS ARE DESIGNED FOR

	DRAINAGE OF KIDNEY (NEPHROSTOMY), ABSCESSES AND CYST EITHER USING: • SELDINGER TECHNIQUE • DIRECT PUNCTURE TECHNIQUE RE-ENTRY MALECOT CATHETER USED FOR INTERNAL AS WELL AS EXTERNAL DRAINAGE WITH COMBINATION OF NEPHROSTOMY CATHETER WITH STENT.,DILATORS AND SETS-URETERAL DILATOR: USED FOR STEP BY STEP DILATATION OF THE INTRAMURAL AND URETER AND / OR FOR STONE MANIPULATION. NOTTINGHAM ONE STEP DILATOR: ONE STEP DILATATION FOR THE INTRAMURAL PORTION AND URETER AMPLATZ RENAL DILATOR SET: USED FOR PROGRESSIVE DILATATION FOR TRACT PRIOR TO PERCUTANEOUS KIDNEY STONE REMOVAL RENAL DILATOR: USED FOR DILATATION OF RENAL TRACT.,BREAST LOCALIZATION NEEDLE-BREAST LOCALIZATION NEEDLE USED FOR PRE-SURGERY LOCALIZATION OF BREAST NON-PALPABLE LESIONS.,BONE MARROW BIOPSY NEEDLE-USED FOR THE PUNCTURE AND TO RECOVER RELIABLE BONE MARROW SAMPLES FOR HISTOLOGICAL EXTRACTION OF TISSUE FROM THE AREA OF PELVIC BONE FOR DIAGNOSIS.,BIOPSY NEEDLE-AUTOCORE BIOPSY NEEDLE USED FOR PERFORMING SOFT TISSUE BIOPSY. SPEEDO (AUTOMATIC) BIOPSY NEEDLE USED FOR SOFT TISSUE BIOSPY. PRONTO COAX SEMI-AUTO BIOPSY NEEDLE USED FOR PERFORMING CORE BIOPSY OF TISSUES. ULTRACORE BIOPSY NEEDLE USED FOR PERFORMING CORE BIOPSIES OF SOFT TISSUES.,BAND MULTIPLE LIGATOR-SURGIBAND MULTIPLE LIGATOR USED TO LIGATE OESOPHAGEAL VARICES AT AND ABOVE GASTROESOPHAGEAL JUNCTION

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3111	MFG/MD/2018/000063	1.License Holder Name: MERIL HEALTHCARE PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:TOTAL HIP REPLACEMENT SYSTEM(TRENT)-THE HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN HIP ARTHROPLASTY TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENT WHO SHOULD BE SKELETALLY MATURE TO RECEIVE A HIP REPLACEMENT.,REVISION KNEE COMPONENTS (STEMMED TIBIAL COMPONENTS & PCK COMPONENTS)(DESTIKNEE)-THE NON-STERILE KNEE COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”.,REVISION KNEE COMPONENTS (STEMMED TIBIAL COMPONENTS & PCK COMPONENTS)(FREEDOM)-THE DESTIKNEETM STEMMED TIBIAL AND PCK COMPONENTS ARE DESIGNED TO BE USED WITH DESTIKNEETM-TOTAL KNEE SYSTEM AND IS INDICATED FOR THE FOLLOWING: • SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY.,HIP ACETABULAR SYSTEM(LATITUD TRIAD)-THE NON-STERILE HIP COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”.,HIP REPLACEMENT SYSTEM (LIBERTAS)-HIP ACETABULAR SYSTEM IS INTENDED FOR USE IN HIP ARTHROPLASTY TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED ACETABULAR ARTICULATION IN PATIENT WHO SHOULD BE SKELETALLY MATURE TO RECEIVE ACETABULAR REPLACEMENT.,TOTAL KNEE SYSTEM(OPULENT)-THE NON-STERILE KNEE COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”.,TOTAL KNEE SYSTEM (UNI KNEE) (DESTIKNEE)-THE NON-STERILE UNI KNEE COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”. THE STERILE PARTIAL REPLACEMENT OF THE ARTICULATION OF THE ARTICULATING SURFACE OF THE KNEE WHEN ONLY ONE SIDE OF THE JOINT IS AFFECTED DUE TO COMPARTMENTAL PRIMARY DEGENERATIVE OR POST -TRAUMATIC DEGENERATIVE DISEASE, PREVIOUS TIBIAL CONDYLE OR PLEATEAU FRACTURES, DEFORMITY OR REVISION OF PREVIOUS ARTHROPLASTY.,TOTAL HIP REPLACEMENT SYSTEM

	(REVISION HIP SYSTEM)(LATITUD)-THE NON-STERILE HIP COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”.,TOTAL KNEE SYSTEM(FREEDOM)-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS,TOTAL HIP REPLACEMENT SYSTEM(LATITUD)-THE NON-STERILE HIP COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”.,HIP REPLACEMENT SYSTEM (LIBERTAS)-THE HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENT WHO SHOULD BE SKELETALLY MATURE TO RECEIVE A HIP REPLACEMENT.,TOTAL KNEE SYSTEM (UNI KNEE) (DESTIKNEE)-THE NON-STERILE KNEE COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”.,TOTAL KNEE SYSTEM (UNI KNEE)(DESTIKNEE)-PARTIAL REPLACEMENT OF THE ARTICULATION OF THE ARTICULATING SURFACE OF THE KNEE WHEN ONLY ONE SIDE OF THE JOINT IS AFFECTED DUE TO COMPARTMENTAL PRIMARY DEGENERATIVE OR POST -TRAUMATIC DEGENERATIVE DISEASE, PREVIOUS TIBIAL CONDYLE OR PLEATEAU FRACTURES, DEFORMITY OR REVISION OF PREVIOUS ARTHROPLASTY.,TOTAL HIP REPLACEMENT SYSTEM(VITELON)-THE NON-STERILE HIP COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”.,TOTAL HIP REPLACEMENT SYSTEM(LATITUD)-THE HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENT WHO SHOULD BE SKELETALLY MATURE TO RECEIVE A HIP REPLACEMENT.,TOTAL HIP REPLACEMENT SYSTEM(TRENT)-THE NON-STERILE HIP COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”.,TOTAL KNEE SYSTEM(OPULENT)-[OPULENT – TOTAL KNEE SYSTEM: THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL

	DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLA FEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS]; [OPULENT – TOTAL KNEE SYSTEM(UNIKNEE): PARTIAL REPLACEMENT OF THE ARTICULATION OF THE ARTICULATING SURFACE OF THE KNEE WHEN ONLY ONE SIDE OF THE JOINT IS AFFECTED DUE TO COMPARTMENTAL PRIMARY DEGENERATIVE OR POST -TRAUMATIC DEGENERATIVE DISEASE, PREVIOUS TIBIAL CONDYLE OR PLEATEAU FRACTURES, DEFORMITY OR REVISION OF PREVIOUS ARTHROPLASTY.]; [OPULENT- STEMMED TIBIAL COMPONENTS: THE OPULENT STEMMED TIBIAL COMPONENTS ARE DESIGNED TO BE USED WITH OPULENT TOTAL KNEE SYSTEM, AND IS INDICATED FOR THE FOLLOWING: • SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY.]; OPULENT - PCK COMPONENTS: THE OPULENT-PCK (POSTERIOR CONSTRAINT KNEE) COMPONENTS ARE TO BE USED WITH THE STEMMED TIBIAL COMPONENTS AND AS A PART OF THE OPULENT- TOTAL KNEE SYSTEM, AND IS INDICATED FOR THE FOLLOWING: • SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY.],TOTAL KNEE SYSTEM(VITELON)-THE NON-STERILE KNEE COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”.,TOTAL KNEE SYSTEM(OPULENT)- THE NON-STERILE KNEE COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”. ,TOTAL KNEE SYSTEM(DESTIKNEE – MOBILE BEARING KNEE SYSTEM)-THE NON-

	STERILE KNEE COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”.,TOTAL HIP REPLACEMENT SYSTEM (LATITUD)-THE NON-STERILE HIP COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”. THE STERILE HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENT WHO SHOULD BE SKELETALLY MATURE TO RECEIVE A HIP REPLACEMENT.,TOTAL KNEE SYSTEM(DESTIKNEE)-THE NON-STERILE KNEE COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”.,TOTAL KNEE SYSTEM(MACLES)-THE NON-STERILE KNEE COMPONENTS ARE USED “FOR FURTHER MANUFACTURING USE ONLY”.,TOTAL KNEE SYSTEM - CEMENTLESS TIBIAL BASE PLATE (EVOLVE - CEMENTLESS TIBIAL BASE PLATE (ADDITIONAL BRAND NAME OF DESTIKNEE))-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS REVISION KNEE COMPONENTS (STEMMED TIBIAL COMPONENTS)- STEMMED TIBIAL BASE PLATE(EVOLVE - STEMMED TIBIAL BASE PLATE (ADDITIONAL BRAND NAME OF DESTIKNEE))-STEMMED TIBIAL COMPONENTS ARE DESIGNED TO BE USED WITH TOTAL KNEE SYSTEM, AND IS INDICATED FOR THE FOLLOWING: • SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY.,REVISION KNEE COMPONENTS (STEMMED TIBIAL COMPONENTS)- STEMMED TIBIAL BASE PLATE(EVOLVE - STEMMED TIBIAL BASE PLATE (ADDITIONAL BRAND NAME OF DESTIKNEE))- STEMMED TIBIAL COMPONENTS ARE DESIGNED TO BE USED WITH TOTAL KNEE SYSTEM, AND IS INDICATED FOR THE FOLLOWING: •

	SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY.,TOTAL KNEE SYSTEM - CEMENTLESS TIBIAL BASE PLATE(EVOLVE - CEMENTLESS TIBIAL BASE PLATE (ADDITIONAL BRAND NAME OF DESTIKNEE))-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS,REVISION KNEE COMPONENTS (STEMMED TIBIAL COMPONENTS)- REVISION TIBIAL BASE PLATE(EVOLVE - REVISION TIBIAL BASE PLATE (ADDITIONAL BRAND NAME OF DESTIKNEE))- STEMMED TIBIAL COMPONENTS ARE DESIGNED TO BE USED WITH TOTAL KNEE SYSTEM, AND IS INDICATED FOR THE FOLLOWING: • SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY.,TOTAL KNEE SYSTEM - CEMENTLESS TIBIAL BASE PLATE(EVOLVE - CEMENTLESS TIBIAL BASE PLATE (ADDITIONAL BRAND NAME OF DESTIKNEE))-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC

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	DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS,TOTAL KNEE SYSTEM - ALL POLY PATELLA (EVOLVE - ALL POLY PATELLA (ADDITIONAL BRAND NAME OF DESTIKNEE))-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS TOTAL KNEE SYSTEM - ALL POLY PATELLA(EVOLVE - ALL POLY PATELLA (ADDITIONAL BRAND NAME OF DESTIKNEE))-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS,TOTAL KNEE SYSTEM-TIBIAL ARTICULAR SURFACE [LINER METAL BACKED]CR & PS(EVOLVE - TIBIAL ARTICULAR SURFACE [LINER METAL BACKED]CR & PS (ADDITIONAL BRAND NAME OF DESTIKNEE))-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS TOTAL KNEE SYSTEM-TIBIAL ARTICULAR SURFACE [LINER METAL

	BACKED]CR & PS(EVOLVE - TIBIAL ARTICULAR SURFACE [LINER METAL BACKED]CR & PS (ADDITIONAL BRAND NAME OF DESTIKNEE)) -THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS TOTAL KNEE SYSTEM- TIBIAL BASE PLATE(EVOLVE - TIBIAL BASE PLATE (ADDITIONAL BRAND NAME OF DESTIKNEE))-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS,TOTAL KNEE SYSTEM- TIBIAL BASE PLATE(EVOLVE - TIBIAL BASE PLATE (ADDITIONAL BRAND NAME OF DESTIKNEE))-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS TOTAL KNEE SYSTEM- FEMORAL CR & PS (LEFT & RIGHT)(EVOLVE - FEMORAL CR & PS (LEFT & RIGHT) (ADDITIONAL BRAND NAME OF DESTIKNEE))-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY

	WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS TOTAL KNEE SYSTEM - CEMENTLESS FEMORAL CR & PS (LEFT &RIGHT)(EVOLVE - CEMENTLESS FEMORAL CR & PS (LEFT &RIGHT) (ADDITIONAL BRAND NAME OF DESTIKNEE))-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS,TOTAL KNEE SYSTEM - CEMENTLESS FEMORAL CR & PS (LEFT &RIGHT)(EVOLVE - CEMENTLESS FEMORAL CR & PS (LEFT &RIGHT) (ADDITIONAL BRAND NAME OF DESTIKNEE))-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS,REVISION KNEE COMPONENTS (PCK COMPONENTS) - FEMORAL AUGMENTS (POSTERIOR AND DISTAL)(EVOLVE - FEMORAL AUGMENTS (POSTERIOR AND DISTAL) (ADDITIONAL BRAND NAME OF DESTIKNEE))-PCK COMPONENTS ARE DESIGNED TO BE USED WITH TOTAL KNEE SYSTEM, AND IS INDICATED FOR THE FOLLOWING: • SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY., REVISION KNEE COMPONENTS (PCK COMPONENTS)- TIBIAL LINER/

	TIBIAL ARTICULAR SURFACE(EVOLVE - TIBIAL LINER/ TIBIAL ARTICULAR SURFACE (ADDITIONAL BRAND NAME OF DESTIKNEE))-PCK COMPONENTS ARE DESIGNED TO BE USED WITH TOTAL KNEE SYSTEM, AND IS INDICATED FOR THE FOLLOWING: • SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY.,REVISION KNEE COMPONENTS (PCK COMPONENTS)- TIBIAL LINER/ TIBIAL ARTICULAR SURFACE(EVOLVE - TIBIAL LINER/ TIBIAL ARTICULAR SURFACE (ADDITIONAL BRAND NAME OF DESTIKNEE))-PCK COMPONENTS ARE DESIGNED TO BE USED WITH TOTAL KNEE SYSTEM, AND IS INDICATED FOR THE FOLLOWING: • SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY., REVISION KNEE COMPONENTS (PCK COMPONENTS)- STEMMED FEMORAL COMPONENT(EVOLVE - STEMMED FEMORAL COMPONENT (ADDITIONAL BRAND NAME OF DESTIKNEE))-PCK COMPONENTS ARE DESIGNED TO BE USED WITH TOTAL KNEE SYSTEM, AND IS INDICATED FOR THE FOLLOWING: • SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE

	INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY.,TOTAL KNEE SYSTEM - CEMENTLESS FEMORAL CR & PS (LEFT &RIGHT)(EVOLVE - CEMENTLESS FEMORAL CR & PS (LEFT &RIGHT) (ADDITIONAL BRAND NAME OF DESTIKNEE))-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS,REVISION KNEE COMPONENTS (STEMMED TIBIAL COMPONENTS)- OFFSET JUNCTION(EVOLVE - OFFSET JUNCTION (ADDITIONAL BRAND NAME OF DESTIKNEE))-STEMMED TIBIAL COMPONENTS ARE DESIGNED TO BE USED WITH TOTAL KNEE SYSTEM, AND IS INDICATED FOR THE FOLLOWING: • SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY.,REVISION KNEE COMPONENTS (STEMMED TIBIAL COMPONENTS)- STEM EXTENSION(EVOLVE - STEM EXTENSION (ADDITIONAL BRAND NAME OF DESTIKNEE))-STEMMED TIBIAL COMPONENTS ARE DESIGNED TO BE USED WITH TOTAL KNEE SYSTEM, AND IS INDICATED FOR THE FOLLOWING: • SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY.,REVISION KNEE COMPONENTS (STEMMED TIBIAL

	COMPONENTS)- REVISION STEM EXTENSION(EVOLVE - REVISION STEM EXTENSION (ADDITIONAL BRAND NAME OF DESTIKNEE))- STEMMED TIBIAL COMPONENTS ARE DESIGNED TO BE USED WITH TOTAL KNEE SYSTEM, AND IS INDICATED FOR THE FOLLOWING: • SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY.,NON-STERILE SPINAL IMPLANTS (PRIMO)-THIS SYSTEM IS INTENDED FOR POSTERIOR, NON-CERVICAL SPINE FIXATION.,NON-STERILE SPINAL IMPLANTS(CLINCH 5.5)-THIS SYSTEM IS INTENDED FOR POSTERIOR, NON-CERVICAL FIXATION., NON-STERILE SPINAL IMPLANTS(KEDGE)-THIS SYSTEM IS INDICATED FOR INTERVERTEBRAL BODY FUSION IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) OF THE CERVICAL & LUMBAR SPINE.,NON-STERILE SPINAL IMPLANTS(MYEL 3.2)-THIS SYSTEM IS INTENDED FOR POSTERIOR CERVICAL SPINAL FIXATION.,NON-STERILE SPINAL IMPLANTS(LINT)-THIS IS A VERTEBRAL BODY REPLACEMENT DEVICE FOR THE CERVICAL, THORACIC AND LUMBAR SPINE.,NON-STERILE SPINAL IMPLANTS (INFIX 5.5)-THIS SYSTEM IS INTENDED FOR ANTERIOR, NON-CERVICAL SPINE FIXATION.,NON-STERILE SPINAL IMPLANTS(CLINCH 4.75)-THIS SYSTEM IS INTENDED FOR POSTERIOR, NON-CERVICAL SPINE FIXATION.,NON-STERILE SPINAL IMPLANTS(MERILOCK)-THIS SYSTEM IS INTENDED FOR ANTERIOR INTERBODY SCREW FIXATION OF THE CERVICAL SPINE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3112	MFG/MD/2018/000063	1.License Holder Name: MERIL HEALTHCARE PVT. LTD. ,GROUND & FIRST FLOOR, SURVEY NO.173/4 AND FIRST FLOOR, H1-H3, MERIL PARK, SURVEY NO. 135/2/B & 174/2, MUKTANAND MARG, CHALA, VAPI-396191 GUJARAT, INDIA. ,VALSAD GUJARAT ,396191 ,INDIA 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:HIP ACETABULAR SYSTEM(LATITUD TRIAD)-STERILE HIP ACETABULAR SYSTEM IS INTENDED FOR USE IN HIP ARTHROPLASTY TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED ACETABULAR ARTICULATION IN PATIENT WHO SHOULD BE SKELETALLY MATURE TO RECEIVE ACETABULAR REPLACEMENT., TOTAL HIP REPLACEMENT SYSTEM(VITELON)-THE HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENT WHO SHOULD BE SKELETALLY MATURE TO RECEIVE A HIP REPLACEMENT.,TOTAL HIP REPLACEMENT SYSTEM(TRENT)-THE HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENT WHO SHOULD BE SKELETALLY MATURE TO RECEIVE A HIP REPLACEMENT.,TOTAL HIP REPLACEMENT SYSTEM(LATITUD)-THE HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENT WHO SHOULD BE SKELETALLY MATURE TO RECEIVE A HIP REPLACEMENT.,TOTAL HIP REPLACEMENT SYSTEM (REVISION HIP SYSTEM)(LATITUD)-THE HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENT WHO SHOULD BE SKELETALLY MATURE TO RECEIVE A HIP REPLACEMENT.,TOTAL KNEE SYSTEM (MACLES)-STERILE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLA FEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS TOTAL KNEE SYSTEM(OPULENT)-THE TOTAL KNEE SYSTEM IS

	INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLA FEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS,TOTAL KNEE SYSTEM(VITELON)-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS,TOTAL KNEE SYSTEM(DESTIKNEE – MOBILE BEARING KNEE SYSTEM)-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS TOTAL KNEE SYSTEM(DESTIKNEE)-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS,REVISION KNEE COMPONENTS (STEMMED TIBIAL COMPONENTS & PCK COMPONENTS)(DESTIKNEE)-THE DESTIKNEETM STEMMED TIBIAL COMPONENTS ARE DESIGNED TO BE USED WITH DESTIKNEETM-TOTAL KNEE SYSTEM, AND IS INDICATED FOR THE

	FOLLOWING: • SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY.,TOTAL KNEE SYSTEM(DESTIKNEE)-PARTIAL REPLACEMENT OF THE ARTICULATION OF THE ARTICULATING SURFACE OF THE KNEE WHEN ONLY ONE SIDE OF THE JOINT IS AFFECTED DUE TO COMPARTMENTAL PRIMARY DEGENERATIVE OR POST -TRAUMATIC DEGENERATIVE DISEASE, PREVIOUS TIBIAL CONDYLE OR PLEATEAU FRACTURES, DEFORMITY OR REVISION OF PREVIOUS ARTHROPLASTY.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3113	MFG/MD/2018/000064	1.License Holder Name: PREMIER MEDICAL CORPORATION PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:MALARIA AG. P.F. / P.V. CARD TEST(FIRST RESPONSE®)-FIRST RESPONSE® MALARIA AG. P.F. / P.V. CARD TESTS INTENDED TO BE PERFORMED BY TRAINED USERS (IN EITHER LABORATORY OR POINT OF CARE SETTINGS) AS QUALITATIVE SCREENING IN VITRO DIAGNOSTIC TEST FOR DETECTION OF P. FALCIPARUM AND P. VIVAX. THE TEST IS INTENDED TO BE USED WITH HUMAN WHOLE BLOOD SPECIMENS (CAPILLARY OR VENOUS BLOOD). VENOUS BLOOD WITH THE ANTI-COAGULANTS HEPARIN, EDTA OR SODIUM CITRATE DO NOT AFFECT THE TEST RESULTS. THE TEST IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT.,HIV 1-2.O CARD TEST (VERSION 2.0) (FIRST RESPONSE)-FIRST RESPONSE® HIV 1-2.O CARD TEST IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS AND IS A QUALITATIVE, SCREENING, IN VITRO DIAGNOSTIC TEST FOR DETECTION OF ANTIBODIES OF ALL CLASSES SPECIFIC TO HIV-1 (INCLUDING GROUP O) AND HIV-2 IN HUMAN SERUM, PLASMA OR VENOUS AND CAPILLARY BLOOD. THE TEST KIT IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. REACTIVE SAMPLES SHOULD BE CONFIRMED BY SUPPLEMENTAL TESTING., SYPHILIS ANTI-TP CARD TEST(FIRST RESPONSE®)-FIRST RESPONSE® SYPHILIS ANTI-TP CARD TEST IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS AND TRAINED USERS. IT IS A RAPID, QUALITATIVE, SCREENING, IN VITRO DIAGNOSTIC TEST FOR DETECTION OF ANTIBODIES OF ALL CLASSES SPECIFIC TO TREPONEMA PALLIDUM IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST KIT IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. REACTIVE SPECIMENS SHOULD BE CONFIRMED BY ELISA OR TPHA.,HIV 1+2/ SYPHILIS COMBO CARD TEST(FIRST RESPONSE®)-FIRST RESPONSE® HIV 1+2 / SYPHILIS COMBO CARD TEST IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS AND TRAINED USER. IT IS A RAPID, QUALITATIVE SCREENING, IN VITRO DIAGNOSTIC TEST FOR THE DETECTION OF ANTIBODIES (IGG & IGM) SPECIFIC TO HIV (TYPE 1 & 2) AND TREPONEMA PALLIDUM IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST KIT IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. REACTIVE SPECIMENS SHOULD BE CONFIRMED FURTHER WITH ELISA, WESTERN BLOT OR TPHA.,HBSAG CARD TEST(FIRST RESPONSE®)-FIRST RESPONSE® HBSAG CARD TEST IS A CHROMATOGRAPHIC IMMUNOASSAY FOR QUALITATIVE DETECTION OF THE HEPATITIS B SURFACE ANTIGEN IN

	SERUM/PLASMA/WHOLE BLOOD (VENOUS & CAPILLARY BLOOD) SPECIMENS. IT IS INTENDED FOR USE IN MEDICAL INSTITUTION AS A AID FOR DIAGNOSIS AND MANAGEMENT OF PATIENTS RELATED TO THE INFECTION WITH HEPATITIS B AS WELL AS FOR PRIMARY SCREENING OF BLOOD FROM VOLUNTEER DONORS ON THE SPOT., COVID-19 IGG/IGM CARD TEST(SURE STATUS®)-"SURE STATUS® COVID-19 IGG/IGM CARD TEST IS A CHROMATOGRAPHIC IMMUNOASSAY FOR QUALITATIVE DETECTION OF THE COVID-19 IGG AND/OR IGM ANTIBODY IN SERUM/PLASMA/WHOLE BLOOD (VENOUS & CAPILLARY BLOOD) SPECIMENS. IT IS INTENDED FOR USE IN MEDICAL INSTITUTION AS A AID FOR DIAGNOSIS AND MANAGEMENT OF PATIENTS RELATED TO THE INFECTION WITH COVID-19 AS WELL AS FOR PRIMARY SCREENING OF BLOOD FROM VOLUNTEER DONORS ON THE SPOT." ,MALARIA ANTIGEN P. FALCIPARUM (HRP2) CARD TEST(FIRST RESPONSE®)-FIRST RESPONSE® MALARIA ANTIGEN P. FALCIPARUM (HRP2) CARD TEST IS INTENDED TO BE PERFORMED BY TRAINED USERS (IN EITHER LABORATORY OR POINT OF CARE SETTINGS) AS QUALITATIVE SCREENING IN VITRO DIAGNOSTIC TEST FOR DETECTION OF P. FALCIPARUM SPECIFIC HRP2 ANTIGENS. THE TEST IS INTENDED FOR USE WITH HUMAN WHOLE BLOOD SPECIMENS (CAPILLARY OR VENOUS BLOOD). VENOUS BLOOD WITH THE ANTI-COAGULANTS HEPARIN, EDTA OR CITRATE DO NOT AFFECT THE TEST RESULTS. THE TEST IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT.,COVID-19 ANTIGEN CARD TEST(SURE STATUS®)-SURE STATUS® COVID-19 ANTIGEN CARD TEST IS A LATERAL FLOW IMMUNOCHROMATOGRAPHIC ASSAY FOR QUALITATIVE DETECTION OF NUCLEOCAPSID PROTEIN ANTIGEN FROM SARS-COV-2 IN NASOPHARYNGEAL (NP) SWAB SPECIMENS DIRECTLY COLLECTED FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. SURE STATUS® COVID-19 ANTIGEN CARD TEST IS FOR IN VITRO DIAGNOSTIC USE AND INTENDED AS AN AID TO DETECTION OF NUCLEOCAPSID PROTEIN ANTIGEN IN PATIENT WITH CLINICAL SYMPTOMS OF SARS-COV-2 INFECTION. IT PROVIDES ONLY AN INITIAL SCREENING TEST RESULTS AND MORE SPECIFIC ALTERNATIVE DIAGNOSIS METHOD SHOULD BE PERFORMED IN ORDER TO OBTAIN THE CONFIRMATION OF SARS-COV-2 INFECTIONS. THE TEST IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. TEST IS DESIGNED TO BE PERFORMED BY LABORATORY PROFESSIONALS/TRAINED USERS ONLY.,MALARIA AG. PLDH/HRP2 COMBO CARD TEST(FIRST RESPONSE®)-FIRST RESPONSE® MALARIA AG. PLDH/HRP2 COMBO CARD TEST IS INTENDED TO BE PERFORMED BY TRAINED USERS (IN EITHER LABORATORY OR POINT OF CARE SETTINGS) AS QUALITATIVE SCREENING TEST FOR DETECTION OF P.FALCIPARUM,

	P. VIVAX, P. OVALE AND P. MALARIAE. THE TEST IS INTENDED FOR USE WITH WHOLE BLOOD SPECIMENS (CAPILLARY OR VENOUS BLOOD). VENOUS BLOOD WITH THE ANTI-COAGULANTS HEPARIN, EDTA OR CITRATE DO NOT AFFECT THE TEST RESULTS. THE TEST IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT.,COVID-19 ANTIGEN CARD TEST (HOME TEST)(SURE STATUS®)-SURE STATUS® COVID-19 ANTIGEN CARD (HOME TEST) IS A SINGLE USE, LATERAL FLOW IMMUNOASSAY INTENDED FOR THE QUALITATIVE DETECTION OF NUCLEOCAPSID PROTEIN ANTIGEN FROM SARS-COV-2. THIS TEST IS INTENDED FOR HOME USE WITH SELF-COLLECTED OBSERVED DIRECT ANTERIOR NASAL SWAB SAMPLES FROM INDIVIDUALS AGED 15 YEARS OR OLDER WHO ARE SUSPECTED OF COVID-19. ADULT COLLECTED NASAL SWAB SAMPLES FROM INDIVIDUALS AGED 2-15 YEARS WHO ARE SUSPECTED OF COVID-19. SURE STATUS® COVID-19 ANTIGEN CARD (HOME TEST) DOES NOT DIFFERENTIATE BETWEEN SARS-COV AND SARS-COV-2. RESULTS ARE FOR THE IDENTIFICATION OF SARS-COV-2 NUCLEOCAPSID PROTEIN ANTIGEN. ANTIGEN IS GENERALLY DETECTABLE IN ANTERIOR NASAL SWABS DURING THE ACUTE PHASE OF INFECTION. POSITIVE RESULTS INDICATE THE PRESENCE OF VIRAL ANTIGENS, BUT CLINICAL CORRELATION WITH PATIENT HISTORY AND OTHER DIAGNOSTIC INFORMATION IS NECESSARY TO DETERMINE INFECTION STATUS. NEGATIVE RESULTS SHOULD BE TREATED AS PRESUMPTIVE AND CONFIRMATION WITH A MOLECULAR ASSAY, IF NECESSARY, FOR PATIENT MANAGEMENT, MAY BE PERFORMED. NEGATIVE RESULTS DO NOT RULE OUT SARSCOV-2 INFECTION AND SHOULD NOT BE USED AS THE SOLE BASIS FOR TREATMENT OR PATIENT MANAGEMENT DECISIONS INCLUDING INFECTION CONTROL DECISIONS. NEGATIVE RESULTS SHOULD BE CONSIDERED IN THE CONTEXT OF A PATIENT'S RECENT EXPOSURES, HISTORY AND THE PRESENCE OF CLINICAL SIGNS AND SYMPTOMS CONSISTENT WITH COVID-19. INDIVIDUALS WHO TEST NEGATIVE AND CONTINUE TO EXPERIENCE COVID-LIKE SYMPTOMS SHOULD SEEK FOLLOW UP CARE FROM THEIR HEALTHCARE PROVIDER.,HCV CARD TEST(FIRST RESPONSE®)-FIRST RESPONSE® HCV CARD TEST IS A CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF THE ANTIBODIES AGAINST HEPATITIS C VIRUS (HCV AB) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD SPECIMENS. IT IS INTENDED TO BE PERFORMED BY TRAINED USERS (IN EITHER LABORATORY OR POINT OF CARE SETTINGS) AS AN AID FOR DIAGNOSIS AND MANAGEMENT OF PATIENTS RELATED TO INFECTION WITH HEPATITIS C AS WELL FOR PRIMARY SCREENING OF BLOOD FROM VOLUNTEER DONORS ON THE SPOT. THE TEST KIT IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL

	INSTRUMENT. REACTIVE SAMPLES SHOULD BE CONFIRMED BY SUPPLEMENTAL TESTING.,COVID-19 ANTIGEN CARD TEST (NC/PC) (SURE STATUS®)-SURE STATUS® COVID-19 ANTIGEN CARD TEST IS A LATERAL FLOW IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF NUCLEOCAPSID PROTEIN ANTIGEN FROM SARS-COV-2 IN NASOPHARYNGEAL (NP) SWAB SPECIMENS DIRECTLY COLLECTED FROM INDIVIDUALS WHO ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. SURE STATUS® COVID-19 ANTIGEN CARD TEST IS FOR IN VITRO DIAGNOSTIC USE AND INTENDED AS AN AID TO THE DETECTION OF NUCLEOCAPSID PROTEIN ANTIGEN IN A PATIENT WITH CLINICAL SYMPTOMS OF SARS-COV-2 INFECTION. IT PROVIDES ONLY INITIAL SCREENING TEST RESULTS AND A MORE SPECIFIC ALTERNATIVE DIAGNOSIS METHOD SHOULD BE PERFORMED TO OBTAIN THE CONFIRMATION OF SARS-COV-2 INFECTIONS. THE TEST IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. THE TEST IS DESIGNED TO BE PERFORMED BY LABORATORY PROFESSIONALS/TRAINED USERS ONLY. THE PRODUCT CAN BE USED IN A CLINICAL SETUP AND POINT OF CARE SITES THAT MEETS THE REQUIREMENTS STATED IN THESE INSTRUCTIONS FOR USE OR LOCAL REGULATIONS.,HIV 1+2/HCV COMBO CARD TEST(FIRST RESPONSE®)-FIRST RESPONSE® HIV 1+2/ HCV COMBO CARD TEST IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS AND IS A RAPID, QUALITATIVE, SCREENING, IN VITRO DIAGNOSTIC TEST FOR DETECTION OF ANTIBODIES OF SPECIFIC TO HIV (TYPE 1 & 2) AND HEPATITIS C VIRUS (HCV AB) IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. THE TEST KIT IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. REACTIVE SAMPLES SHOULD BE CONFIRMED FURTHER WITH CONFIRMATORY TESTS LIKE ELISA, WESTERN BLOT.,HIV-1 RAPID RECENCY CARD TEST (FOR EXPORT ONLY)(SURE STATUS®)-SURE STATUS® HIV-1 RAPID RECENCY CARD TEST IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS AND IT IS A QUALITATIVE SCREENING IN VITRO DIAGNOSTIC TEST FOR DETECTION OF ANTIBODIES OF ALL CLASSES, SPECIFIC TO HIV-1 (INCLUDING GROUP O) AND R-IDR-M (RECOMBINANT IMMUNO-DOMINANT REGION) IN HUMAN SERUM, PLASMA, OR WHOLE BLOOD. THE TEST KIT IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. REACTIVE SAMPLES SHOULD BE CONFIRMED BY ELISA OR WESTERN BLOT.,COVID-19 ANTIGEN CARD TEST (NASAL SWAB) FOR EXPORT ONLY(SURE STATUS®)-SURE STATUS® COVID-19 ANTIGEN CARD TEST IS A LATERAL FLOW IMMUNOCHROMATOGRAPHIC ASSAY FOR QUALITATIVE DETECTION OF NUCLEOCAPSID PROTEIN ANTIGEN FROM SARS-COV-2 IN NASAL SWAB SPECIMENS DIRECTLY COLLECTED FROM INDIVIDUALS WHO

		ARE SUSPECTED OF COVID-19 BY THEIR HEALTHCARE PROVIDER. SURE STATUS® COVID-19 ANTIGEN CARD TEST IS FOR IN VITRO DIAGNOSTIC USE AND INTENDED AS AN AID TO DETECTION OF NUCLEOCAPSID PROTEIN ANTIGEN IN PATIENT WITH CLINICAL SYMPTOMS OF SARS-COV-2 INFECTION. IT PROVIDES ONLY AN INITIAL SCREENING TEST RESULTS AND MORE SPECIFIC ALTERNATIVE DIAGNOSIS METHOD SHOULD BE PERFORMED IN ORDER TO OBTAIN THE CONFIRMATION OF SARS-COV-2 INFECTIONS. THE TEST IS NOT AUTOMATED AND DOES NOT REQUIRE ANY ADDITIONAL INSTRUMENT. TEST IS DESIGNED TO BE PERFORMED BY LABORATORY PROFESSIONALS/TRAINED USERS ONLY.
3114	MFG/MD/2018/000067	1.License Holder Name: ROBONIK (INDIA) PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:ANTI STREPTOLYSIN O (ASO) TEST KIT(ANTI STREPTOLYSIN O (ASO) TEST KIT)-QUANTITATIVE DETRMINATION OF ANTI STREPTOLYSIN O IN SERUM, C- REACTIVE PROTEIN (CRP) TEST KIT(C- REACTIVE PROTEIN (CRP) TEST KIT)-FOR ESTIMATION OF C REACTIVE PROTEIN IN PLASMA / BODY FLUID.,ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) TEST KIT(ACTIVATED PARTIAL THROMBOPLASTIN TIME (APTT) TEST KIT)-FOR ESTIMATION OF ACTIVATED PARTIAL THROMBOPLASTINTIME IN PLASMA/ BODY FLUID.,PT (PROTHROMBIN TIME) TEST KIT(PT (PROTHROMBIN TIME) TEST KIT)-USED FOR ESTIMATION OF PROTHROMBIN TIME IN PLASMA/BODY FLUID

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3115	MFG/MD/2018/000068	1.License Holder Name: MEDIPLUS (INDIA) LIMILED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:I.V CANNULA WITH INJECTION VALVE WITH WINGS(ADVASAFE)-THE I.V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS AND/OR BLOOD COMPONENT , OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE.,3 WAY STOP COCK-AS AN ACCESSORY TO PERFUSION SET(ANGELTOUCH, HEUER)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF A SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS(MEDIX BRASIL)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF A SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS(PLUSWAY, UYDUMED, TPK, NEOTEC, EUROMED, BEYBI, MEDNET, WINFLON, COSMOMED, SINOMEDIC, MEDIPLUS, CM CEGAMED, ITALIANA MEDICAZIONE, CPK, ADVANTIVE, INTRA SPECIAL, BIOLENA, KNOWMEDICAL, EXTRACOCK, ALFASAFE, ALLPRO.)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF A SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,SAFETY I.V CANNULA WITHOUT INJECTION VALVE WITHOUT WINGS(MEDIX BRASIL)-THE SAFETY I.V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENT, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE.,3 WAY STOP COCK WITH EXTENSION TUBE(PLUSWAYET, TPK, NEOTEC, EUROMED, WINFLON, COSMOMED, SINOMEDIC, MEDIPLUS, ITALIANA MEDICAZIONE, CPK, ALLPRO.)-3 WAY STOP COCK WITH EXTENSION TUBE ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATIONS IN MEDICAL APPLICATIONS,3-WAY STOP COCK WITH EXTENSION TUBE (PLUSFLEX)-WAY STOP COCK WITH EXTENSION TUBE ARE A STERILE DEVICE FOR SINGLE-USE ONLY. THEY ARE INTENDED TO BE USED AS A PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIOND, EXTENSION TUBE(PLUSET)-EXTENSION TUBE ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATIONS IN MEDICAL APPLICATIONS ,3 WAY STOP COCK (GREENLIFE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF A SOLUTION WITHDRAWAL OF FLUID AND PRESSURE MONITORING,I.V. CANNULA WITHOUT INJECTION PORT AND WITHOUT

	WINGS(DYNAFLO, DYNAMICS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION VALVE WITH WINGS (CORNER PURE)-THE I.V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE,I.V. CANNULA WITH WINGS & PORT(NEOTEC)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT INJECTION PORT & WINGS(PLUSFLEX)-THE I.V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE.,I.V. CANNULA WITH SAFETY FEATURE WITH WINGS & PORT(NEOTEC SAFETY 3)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V CANNULA WITHOUT INJECTION VALVE WITHOUT WINGS(MEDIX BRASIL , DISPROMED)-THE I.V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENT, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE.,3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS(BRP, CAREPLUS, EASYFLOW)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF A SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,I.V. CANNULA WITH INJECTION VALVE WITH WINGS(CARESET)-THE I.V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE,I.V. CANNULA WITH WINGS & INJECTION VALVE (CAREPLUS)-THE I V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION FLUIDS, DRUG AND / OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE,I. V. CANNULA WITH WINGS & INJECTION PORT-THE I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE,I.V. CANNULA WITHOUT INJECTION VALVE & WITHOUT WINGS(COSMOMED)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV. CANNULA WITH LUER LOCK & INJECTION PORT(CP)-THE I.V CANNULA IS A PASSIVE DEVICE TO

	PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE,I.V. CATHETER WITH WINGS & PORT(B.P)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT INJECTION PORT & WINGS(PLUSWIN ALPHA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH WINGS AND PORT(SUPREME)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT INJECTION VALVE &WINGS(PLUSCAN ALPHA, PLUSCATH, WINFLON, FARCOCATH, PLUSPEN, ALFASAFE, MADHOS, TKL, LAVET, RELI, PLUSPRO, MED-E-CATH+, CEGAMED, DIPROMED,CHEMIL.)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INTEGRATED 3- WAY STOP COCK(TRICATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH LUER LOCK WING AND WITHOUT INJECTION PORT.(ANGELTOUCH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH LUER LOCK WING AND INJECTION PORT(ANGELTOUCH, DISPOTOUCH.)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CATHETER WITH INJECTION PORT(VYGONULE V)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INJECTION VALVE WITH WINGS(PLUSFLON, PLUSVEIN, ULTRAFLON, STERILO 4, TPK, FARCOCATH, VINMED, MEDNET, SHAHEEN, I.V.CATH, WINFLON, SINOMEDIC, GREENLIFE, BIOFLOKAGE BUDGET, VITASTA, CHEMIL, BIOFLOKAGE, EXTRAFLON, PANACAN.)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT WINGS & PORT(NEOTEC-1)-THE IV CANNULA IS A

	PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH WINGS, WITHOUT INJECTION PORT(HEMOVAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INJECTION PORT WITH WINGS(ALPHA FLOW)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH WINGS & INJECTION VALVE (DO DO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH WINGS & INJECTION PORT (MEDICINEA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INJECTION PORT &WING(CATHYFLO, PROVY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITHOUT INJECTION VALVE WITH WINGS(PLUSCAN SAFE, PLUSNEO SAFE, PLUSCLIP.)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INJECTION PORT, PTFE CATHETER AND LUER LOCK(PROMED)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION VALVE, WINGS AND LOCK(UNICUT)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH WINGS, WITH INJECTION PORT (HEMOFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT INJECTION PORT WITH SMALL WINGS(ALPHA FLOW +PLUS +)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY I.V. CANNULA WITH WINGS, WITH INJECTION PORT.(VENIFLON SAFE)-THE IV CANNULA IS A

	PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY I.V. CANNULA WITH WINGS AND INJECTION PORT.(ANGELTOUCH)-THE I V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION FLUIDS, DRUG AND / OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE,I.V. CANNULA WITH INJECTION VALVE (ASDRUG, JIMIT, COSMOMED, PARSLIFE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT INJECTION PORT & WITH WINGS(PROCAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CATHETER WITH INJECTION VALVE (VANKATH.DE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITHOUT WINGS, WITHOUT INJECTION PORT(HEMOCATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH CATHETER & INJECTION VALVE(NEXTECH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH WINGS & WITHOUT PORT (NEOTEC-1W)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY I.V. CANNULA WITH INJECTION VALVE &WINGS(PLUSFLON SAFE, PLUSVEIN SAFE, PLUSCLIP SAFE, WINFLON, COSMOMED, SINOMEDIC, PANACAN, CHEMIL.)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY I.V. CANNULA WITHOUT INJECTION VALVE & WINGS(PLUSKI SAFE 1)-THE I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE.,I.V. CANNULA WITHOUT INJECTION VALVE & WITH WING(BRP)-THE I V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION FLUIDS, DRUG AND / OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE,I.V. CANNULA WITH CATHETER & INJECTION VALVE

	(HEALFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , SAFETY I.V. CANNULA WITHOUT INJECTION VALVE & WINGS (PLUSCAN ALPHA SAFE, PLUSCLIP ALPHA SAFE, INJEX CATH SAFETY, NEOTEC-1 SAFETY, LA VITA, UNIDIX, CEGAMED, DIPROMED,CHEMIL.)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,3 WAY STOP COCK WITH EXTENSION TUBE(GREENLIFE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF A SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS(ANDINO, PLUSFLEX, PLUSCARE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF A SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,SAFETY I.V. CANNULA WITH INJECTION VALVE &WINGS(CAREPLUS)-THE I V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION FLUIDS, DRUG AND / OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE,I.V. CANNULA WITH/WITHOUT INJECTION VALVE & WINGS(ALLPRO)-THE I.V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE.,I.V. CANNULA WITH INJECTION VALVE WITH WINGS(ECOMED, SAVACARE)-THE I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE.,I.V. CANNULA WITHOUT INJECTION VALVE & WITH WINGS(ECOMED)-THE I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE.,SAFETY I.V. CANNULA WITH INJECTION VALVE WITH WINGS(PLUSKI SAFE 2)-THE I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE.,3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS(JK MEDIRISE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF A SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,I.V. CANNULA WITH INJECTION VALVE WITH WINGS(BRP)-THE I V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION FLUIDS, DRUG AND / OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF

	VASCULAR ACCESS DEVICE,3 WAY STOP COCK WITH EXTENSION TUBE(BARCAT, DISPROMED)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATIONS IN MEDICAL APPLICATIONS,I.V. CANNULA WITH INJECTION VALVE WITH WINGS (PLUSFLEX, PLUSCARE)-THE I V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION FLUIDS, DRUG AND / OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE,3 WAY STOP COCK (TKL,BARCAT, DISPROMED, CEGAMED, DIPROMED,CHEMIL, SUPREME)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF A SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,I.V. CANNULA WITHOUT INJECTION PORT WITH WINGS(PLUSWIN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH LUER LOCK &WITHOUT WING AND INJECTION PORT (ANGELTOUCH.)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITHOUT INJECTION VALVE & WITH WINGS (PLUSCAN, PLUSNEO, SYMCATH, FARCOCATH.) -THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., SAFETY I.V. CANNULA WITH INJECTION VALVE &WINGS(SAFETY I.V. CANNULA WITH INJECTION VALVE & WINGS)-THE I V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION FLUIDS, DRUG AND / OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE,SAFETY I.V. CANNULA WITH INJECTION PORT WITH WINGS.(KNOW-VEN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH WINGS & INJECTION VALVE(UYDUMED)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.

3116	MFG/MD/2018/000069	1.License Holder Name: ROMSONS MEDICONS 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:NASAL OXYGEN CATHETER(OXY SET)-SINGLE USE DEVICE INTENDED FOR DELIVERING OXYGEN FOR INHALING WHEREVER SMALL AMOUNTS OF SUPPLEMENTAL OXYGEN ARE REQUIRED, WITHOUT RIGID CONTROL OF RESPIRATION, SUCH AS IN OXYGEN THERAPY., UMBILICAL OCCLUSION DEVICE (KLIK CLAMP)-UMBILICAL CORD CLAMP INTENDED USE IS TO CLAMP OVER THE NEWBORN INFANTS UMBILICAL CORD AT DELIVERY AND PREVENT BLOOD LOSS AS THE CORD DRIES AND SHRINKS AFTER THE BIRTH.
3117	MFG/MD/2018/000070	1.License Holder Name: MEDICON 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON-SURGICAL DRESSING
3118	MFG/MD/2018/000071	1.License Holder Name: GOYAL BROTHER SURGICALS 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:COTTON BANDAGE (ROLLED BANDAGE) [SCHEDULE F(II)](-)-BANDAGES A SURGICAL DRESSING CAN HAVE A NUMBER OF PURPOSES, DEPENDING ON THE TYPE, SEVERITY AND POSITION OF THE WOUND, ALTHOUGH ALL PURPOSES ARE FOCUSED TOWARDS PROMOTING RECOVERY AND PROTECTING FROM FURTHER HARM.,COTTON BANDAGE (ROLLED BANDAGE) [SCHEDULE F(II)](-)-COTTON BANDAGE A DRESSING CAN HAVE A NUMBER OF PURPOSES, DEPENDING ON THE TYPE, SEVERITY AND POSITION OF THE WOUND, ALTHOUGH ALL PURPOSES ARE FOCUSED TOWARDS PROMOTING RECOVERY AND PROTECTING FROM FURTHER HARM.

3119	MFG/MD/2018/000072	1.License Holder Name: NH HEALTHCARE ,6-4-170, SEIE KATTEDAN, BABU REDDY NAGAR, KATTEDAN(V). ,RANGA REDDY TELANGANA , 500077 ,INDIA 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:ABSORBENT ZIG ZIG COTTON ROLL(MEDCOT)-SURGICAL COTTON OR COTTON WOOL AND MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC. BECAUSE OF ITS PROPERTY OF HIGH FLUID ABSORBENCY, IT IS BETTER KNOWN AMONG MASSES AS ABSORBENT COTTON.,COTTON BALLS (MEDCOT)-AS SURGICAL COTTON OR COTTON WOOL AND MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC. BECAUSE OF ITS PROPERTY OF HIGH FLUID ABSORBENCY, IT IS BETTER KNOWN AMONG MASSES AS ABSORBENT COTTON,SURGICAL ABSORBENT COTTON ROLL(MEDCOT)-SURGICAL COTTON OR COTTON WOOL AND MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC. BECAUSE OF ITS PROPERTY OF HIGH FLUID ABSORBENCY, IT IS BETTER KNOWN AMONG MASSES AS ABSORBENT COTTON.
3120	MFG/MD/2018/000073	1.License Holder Name: VRK LIFESCIENCES PVT LTD 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:IV CANNULA FIXATOR (IVFIXOR)-IV CANNULA FIXATOR IS HELPFUL FOR FIXING IV CANNULA,ELASTIC ADHESIVE BANDAGE(VPLAST)-IT IS USUALLY USED TO WRAP SOFT TISSUE INJURIES TO PROVIDE COMPRESSION AND SUPPORT
3121	MFG/MD/2018/000074	1.License Holder Name: MRK HEALTH CARE PVT. LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:INTRAVENOUS CANNULA (NULIFE, NUTEC,DIVINEMED)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS(NULIFE, NUTEC)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF A SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING

3122	MFG/MD/2018/000075	1.License Holder Name: MEDORAH MEDITEK PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:HEMOCLIPS(MEDORAH)-MEDORAH® HEMOCLIPS ARE INTENDED TO USE FOR ENDOSCOPIC CLIP PLACEMENT WITHIN THE GASTROINTESTINAL TRACT FOR THE PURPOSE OF ENDOSCOPIC MARKING, HEMOSTASIS FOR MUCOSAL/SUB MUCOSAL DEFECTS LESS THAN 3 CM IN THE UPPER GI TRACT, BLEEDING ULCERS, ARTERIES LESS THAN 2 MM AND POLYPS LESS THAN 1.5 CM IN DIAMETER IN THE GI TRACT.,TRACHEAL STENT (JAVASTENT)-IT IS INTENDED TO BE IMPLANTED TO RESTORE THE STRUCTURE AND/OR FUNCTION OF THE TRACHEA OR TRACHEALBRONCHIAL TREE.,DUODENAL STENTS(JAVASTENT)-DUODENAL STENT IS INDICATED FOR THE PALLIATIVE TREATMENT OF GASTRODUODENAL OBSTRUCTIONS.,COLONIC STENT (JAVASTENT)-A COLONIC STENT IS A FLEXIBLE, HOLLOW TUBE DESIGNED TO KEEP A SEGMENT OF THE COLON (LARGE BOWEL) OPEN WHEN IT HAS BECOME BLOCKED(OBSTRUCTED). THIS BLOCKAGE IS COMMONLY CAUSED BY A TUMOUR INSIDE THE BOWEL OR BY OUTSIDE PRESSURE ON THE BOWEL WALL.,PANCREATIC STENT(MEDORAH)-PANCREATIC DUCT STENTS ARE OFTEN PLACED IN PATIENTS WHO HAVE CHRONIC PANCREATITIS.,ESOPHAGEAL STENTS(JAVASTENT)-AN ESOPHAGEAL STENT IS A STENT (TUBE) PLACED IN THE OESOPHAGUS TO KEEP A BLOCKED AREA OPEN SO THE PATIENT CAN SWALLOW SOFT FOOD AND LIQUIDS.,BILIARY STENTS-BILIARY STENTS PROVIDE BILE DRAINAGE FROM THE GALLBLADDER, PANCREAS AND BILE DUCTS TO THE DUODENUM IN CONDITIONS SUCHAS ASCENDING CHOLANGITIS DUE TO OBSTRUCTING GALLSTONES.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MANDAVIYA BHAVAN MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3123	MFG/MD/2018/000076	1.License Holder Name: BIORAD MEDISYS PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:PERMANENT DIALYSIS CATHETER SET(INDOVASIVE)-USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT,MONO J STENT (INDOVASIVE)-USED FOR TEMPORARY INTERNAL DRAINAGE FROM THE URETROPELVIC JUNCTION TO THE BLADDER. ALSO USED FOR PRE AND/OR POST MANIPULATION OF THE URETER IN ORDER TO ALLOW THE KIDNEY TO DRAIN,CENTRAL VENOUS CATHETERIZATION SET(INDOVASIVE)-USE TO GIVE MEDICINE, FLUIDS, NUTRIENTS OR BLOOD PRODUCTS. ,URETHRAL CATHETER (INDOVASIVE)-USED FOR STENTING THE URETHRA AFTER HYPOSPADIAS OR EPISPADIAS REPAIR AND TO PROVIDE POSTOPERATIVE DRAINAGE OF THE BLADDER. POSTOPERATIVE DRAINAGE OF THE BLADDER. ,DOUBLE J SHAPE CATHETER (INDOVASIVE)-DOUBLE J STENT IS USED FOR INTERNAL DRAINAGE FROM KIDNEY TO BLADDER. ,BILIARY PANCREATIC STENT (INDOVASIVE)-DRAINAGE CATHETER IS THE TYPE OF STENTS USED TO DRAIN THE BILE DUCTS.,ENDOPYELOYOMY STENT CATHETER (INDOVASIVE)-ENDOPYELOTOMY STENT IS USED FOR INTERNAL DRAINAGE FROM KIDNEY TO BLADDER FOR ANY IRREGULAR PYLEM STRUCTURE.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3124	MFG/MD/2018/000077	1.License Holder Name: CHETAN MEDITECH PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ARTHROSCOPY IMPLANTS-FIXATION BUTTON WITH LOOP(BIOTEK, ONBUTTON CL, SYNPLE BUTTON CL, LIGABUTTON CL, BUTTONFIX, LIGABUTTON AL, AC-FIX -I, PIVOTFIX-I, ARTHROVIMS, AC-FIX II KIT, PIVOTFIX II KIT, AC-FIX III, PIVOTFIX III, AK FR KIT, AK FR KIT II, WT-FIX KIT, F-FIX KIT, BIOPF,BIO-PF II, BTLOOP-AC, BUTTONFIX-W, BUTTONFIX-F)-FOR ARTHROSCOPIC FIXATION OF BONE & SOFT TISSUE IN THE JOINTS , SPINE IMPLANTS(BIOTEK, XENCAGE, XEN-TC, XEN-PC, XENCAGE-PL)-FOR TREATMENT OF DEGENERATIVE DISC DISEASE, TRAUMA FRACTURE OR DISLOCATION, DEFORMITY, TUMOR, STENOSIS, PSEUDOARTHROSIS AND PREVIOUS FAILED FUSION,ARTHROSCOPY IMPLANTS-LIGAMENT ANCHORS(BIOTEK, ARTHROVIMS, MICRO-VIM , MICRO-VIM II, NANO-VIM, NANO-VIM II, MINI-VIM, MINI-VIM II, VIMFIX LRT, RC-LOC LRT, VIMFIX BT, VIMFIX PKT, VIMFIX PKT III, MICRO-FIX, MICRO-FIX II, ARTHROVIMS ANCHOR MICROTI, BIO-VIM, BIO-VIM II, ARTHROVIMS ANCHOR MINITI, SUPER-VIM, SUPER-VIM III, SUPER-VIM L, SUPER-VIM T, SUPER-VIM LT, SUPER-VIM IIIT, SUPER-BIO, SUPER-BIO III, SUPER-BIO L, SUPER-VIM II T, ARTHROVIMS ANCHOR TI, VIMFIX, VIMFIX-T, VIMFIX-T III, RC-LOC, RC-LOC T, RC-LOC T III, MINI-VIM T)-FOR ARTHROSCOPIC FIXATION OF BONE & SOFT TISSUE IN THE JOINTS ,INTRAMEDULLARY NAILS(BIOTEK, PAT)-FRACTURES OF HUMERAL, FEMORAL & TIBIAL,ARTHROSCOPY IMPLANTS-LIGAMENT ANCHORS(BIOTEK, MICRO-FIX PK, MICRO-FIX II PK, MICRO-VIM PK, MICRO-VIM II PK, NANO-VIM PK, NANO -VIM PK II, ARTHROVIMS ANCHOR MICROPK, MINI-VIM PK, MINI-VIM II PK, MINI-VIM PKT, MINI-VIM II PKT, ARTHROVIMS ANCHOR MINIPK, VIMFIX PK, VIMFIX PK III , VIMFIX PKT, VIMFIX PKT III, RC-LOC PK, RC-LOC PK II, ARTHROVIMS ANCHOR PK, VIMFIX-LRP, VIMFIX-LRT, VIMFIX-BT, RC-LOC LRP, RC-LOC LRT, NANO VIM-KT, NANO VIM KT II, ARTHROVIMS ANCHOR LRP, ARTHROVIMS ANCHOR LRT, ARTHROVIMS ANCHOR BT, ARTHROVIMS,, BIO-VIM, BIO-VIM II)-FOR ARTHROSCOPIC FIXATION OF BONE & SOFT TISSUE IN THE JOINTS ,WIRE, PIN, WASHER(BIOTEK)-FOR TEMPORARY AND DEFINITIVE FIXATION OF BONE FRACTURES, ARTHROSCOPY IMPLANTS-FIBER WIRE AND FIBER TAPE(BIOTEK, BIOFIBER, BIOFIBER-PH, OSTEOFIBER, ORTHOFIBER, ARTHROFIBER, BIOCINCH, BIOCINCH-AI2, BIOCINCH-AI3, BIOCINCH-AI5, FIBERCINCH, BIOCINCH-20, BIOCINCH-II, BIOCINCH-10, ARTHROVIMS, BIOLOOP-I, BIOLOOP-II, FIBERKNOT, FIBERKNOT-T, FIBERKNOT-T II, FIBERKNOT-I, FIBERKNOT-II, FIBERKNOT-III, KNOTFIX, KNOTFIX-T, SOFTPORT, SOFTPORT-T, BIOLOOP-NB, ARTHROVIMS SOFT ANCHOR)-FOR ARTHROSCOPIC FIXATION OF BONE & SOFT TISSUE IN THE JOINTS ,

	BONE SCREWS(BIOTEK)-FOR PLATE FIXATION FOR BONE FRACTURES,ARTHROSCOPY IMPLANTS-SCREW, BUTTON, WASHER (BIOTEK, AC-FIX, PIVOT-FIX, ONBUTTON, ONBUTTON-EX, SYNPLE BUTTON, BT-FIX, WT-FIX, F-FIX,MR-FIX, AK-FIX, SOFTFIX, SYNPLE SCREW TI, LIGATEK TI, SOFTFIX-BT, LIGATEK-BT, TIBIAL POST, SOFTFIX-TP, SYNPLE, STAYFIX, STAYFIX-MINI, STAYFIX-T, SUTUREFIX, SUTUREFIX-LOC, SUTUREFIX-T, SMARTFIX, BIDDU, BIDDUAD, BIOFIX,BIO-T, BIO-F, BIOFIX-DF, BIOFIX-W, BIOFIX-NP, BIO LATARJET-P, BIO LATARJET, LCS-LATARJET, BIDDU-LPH, BIOFIX)-FOR ARTHROSCOPIC FIXATION OF BONE & SOFT TISSUE IN THE JOINTS ,BONE PLATES(BIOTEK, BIO-HP, BIDDU, BIO-LATARJET)-FOR STABILIZATION AND FIXATION OF BONE FRAGMENTS IN FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF BONES,ARTHROSCOPY IMPLANTS-FIXATION BUTTON WITH LOOP (BIOTEK, ONBUTTON CL, SYNPLE BUTTON CL, LIGABUTTON CL, BUTTONFIX, BUTTONFIX-NB, LIGABUTTON AL, BTLOOP-AC, BUTTONFIX-W, BUTTONFIX-F, AC-FIX -I, PIVOTFIX-I, AC-FIX II KIT, PIVOTFIX II KIT , ARTHROVIMS, AC-FIX III, PIVOTFIX III , AK FR KIT , AK FR KIT II, WT-FIX KIT , F-FIX KIT)-FOR ARTHROSCOPIC FIXATION OF BONE & SOFT TISSUE IN THE JOINTS ,PROSTHESIS(BIOTEK, URSA, URSA-TIG, TEXX, TEXX-21, OSKAR, OSKAR-II)-INDICATED FOR ARTHROPLASTY PROCEDURE FOR PATIENTS WITH OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, FRACTURES, BONE TUMORS, CORRECTION OF FUNCTIONAL DEFORMITY, SEVERE TRAUMA RECONSTRUCTION, ARTHROSCOPY IMPLANTS-SCREW, BUTTON, WASHER(BIOTEK, SOFTFIX-PK, SYNPLE SCREW PK, LIGATEK PK, ARTHROVIMS, SOFTFIX-BT, TIBIAL POST, SOFTFIX-TP, SYNPLE, AC-FIX, PIVOT-FIX, ONBUTTON, ONBUTTON-EX, SYNPLE BUTTON, BT-FIX, WT-FIX, F-FIX, MR-FIX, AK-FIX, STAYFIX, STAYFIX-MINI, STAYFIX-T, SUTUREFIX, SUTUREFIX-LOC, SUTUREFIX-T, SMARTFIX, BIDDU, BIDDU AD, BIOFIX, BIO-T, BIO-F, BIOFIX-DF, BIOFIX-W, BIOFIX-NP, BIO LATARJET-P, BIO LATARJET, LCS-LATARJET, BIDDU-LPH, BIOFIX)-FOR ARTHROSCOPIC FIXATION OF BONE & SOFT TISSUE IN THE JOINTS,PROSTHESIS (BIOTEK, URSA, URSA-TIG,TEXX, TEXX-21)-INDICATED FOR ARTHROPLASTY PROCEDURE FOR PATIENTS WITH OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, FRACTURES, BONE TUMORS, CORRECTION OF FUNCTIONAL DEFORMITY, SEVERE TRAUMA RECONSTRUCTION, ARTHROSCOPY IMPLANTS- BIOABSORBABLE LIGAMENT ANCHOR (BIOTEK, ARTHROVIMS BR ANCHOR, BIO-VIM, BIO-VIM LRP, BIO-VIM LRT)-THESE DEVICES ARE INTENDED TO REATTACH SOFT TISSUE TO BONE IN ORTHOPEADIC SURGICAL PROCEDURES IN SHOULDER. THE SYSTEM MAY BE USED IN EITHER ARTHROSCOPIC OR OPEN

	SURGICAL PROCEDURES. AFTER THE SUTURE IS ANCHORED TO THE BONE, IT MAY BE USED TO REATTACH SOFT TISSUE, SUCH AS LIGAMENTS, TENDONS, OR JOINT CAPSULES TO THE BONE. THE SUTURE ANCHOR SYSTEM THEREBY STABILIZES THE DAMAGED SOFT TISSUE, IN CONJUNCTION WITH APPROPRIATE POSTOPERATIVE IMMOBILIZATION THROUGHOUT THE HEALING PERIOD.,SPINE IMPLANTS(BIOTEK, XEN-PLUS, XEN-ACP, XENICA-ACP, CAGELOC, XENCAGE, XEN-TC, XEN-PC, XENCAGE-PL, XEN-M)-FOR TREATMENT OF DEGENERATIVE DISC DISEASE, TRAUMA FRACTURE OR DISLOCATION, DEFORMITY, TUMOR, STENOSIS, PSEUDOARTHROSIS AND PREVIOUS FAILED FUSION,ARTHROSCOPY IMPLANTS-BIOABSORBABLE LIGAMENT ANCHOR (BIOTEK, ARTHROVIMS BR ANCHOR, BIO-VIM, BIO-VIM LRP, BIO-VIM LRT)-THESE DEVICES ARE INTENDED TO REATTACH SOFT TISSUE TO BONE IN ORTHOPEADIC SURGICAL PROCEDURES IN SHOULDER. THE SYSTEM MAY BE USED IN EITHER ARTHROSCOPIC OR OPEN SURGICAL PROCEDURES. AFTER THE SUTURE IS ANCHORED TO THE BONE, IT MAY BE USED TO REATTACH SOFT TISSUE, SUCH AS LIGAMENTS, TENDONS, OR JOINT CAPSULES TO THE BONE. THE SUTURE ANCHOR SYSTEM THEREBY STABILIZES THE DAMAGED SOFT TISSUE, IN CONJUNCTION WITH APPROPRIATE POSTOPERATIVE IMMOBILIZATION THROUGHOUT THE HEALING PERIOD.,INTRAMEDULLARY NAILS(BIOTEK, PAT)-FRACTURES OF HUMERAL, FEMORAL & TIBIAL,WIRE, PIN, WASHER (BIOTEK)-FOR TEMPORARY AND DEFINITIVE FIXATION OF BONE FRACTURES,BONE SCREWS(BIOTEK)-FOR PLATE FIXATION FOR BONE FRACTURES,BONE PLATES(BIOTEK, BIO-HP, BIO-PC, BIO-PH, BIOFIX, ARTHROVIMS, BIO-T, BIO-F, BIDDU, BIO-LATARJET)-FOR STABILIZATION AND FIXATION OF BONE FRAGMENTS IN FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF BONES,SPINE IMPLANTS(BIOTEK, XENCAGE, XEN-TC, XEN-PC, XENCAGE-PL)-FOR TREATMENT OF DEGENERATIVE DISC DISEASE, TRAUMA FRACTURE OR DISLOCATION, DEFORMITY, TUMOR, STENOSIS, PSEUDOARTHROSIS AND PREVIOUS FAILED FUSION, PROSTHESIS(BIOTEK, URSA, URSA-TIG, TEXX, TEXX-21, OSKAR, OSKAR-HP, OSKAR-II)-INDICATED FOR ARTHROPLASTY PROCEDURE FOR PATIENTS WITH OSTEOARTHRITIS, RHEUMATOID ARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, FRACTURES, BONE TUMORS, CORRECTION OF FUNCTIONAL DEFORMITY, SEVERE TRAUMA RECONSTRUCTION,WIRE, PIN, WASHER(BIOTEK)-FOR TEMPORARY AND DEFINITIVE FIXATION OF BONE FRACTURES,BONE SCREWS(BIOTEK)-FOR PLATE FIXATION FOR BONE FRACTURES, INTRAMEDULLARY NAILS(BIOTEK, PAT)-FRACTURES OF HUMERAL, FEMORAL & TIBIAL,BONE PLATES(BIOTEK, BIO-HP, BIO-PC, BIO-PH, BIOFIX, ARTHROVIMS, BIO-T, BIO-F, BIDDU, BIO-LATARJET)-FOR

	STABILIZATION AND FIXATION OF BONE FRAGMENTS IN FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF BONES,ARTHROSCOPY IMPLANTS-LIGAMENT ANCHORS(BIOTEK, ARTHROVIMS, MICRO-VIM , MICRO-VIM II, NANO-VIM, NANO-VIM II, MINI-VIM, MINI-VIM II, BIO-VIM, BIO-VIM II, SUPER-VIM, SUPER-VIM III, SUPER-VIM L, SUPER-VIM T, SUPER-VIM LT, SUPER-VIM IIIT, SUPER-BIO, SUPER-BIO III, SUPER BIO L, MINI-VIM T, MINI-VIM, VIM-FIX LRT, RC-LOC LRT, VIM-FIX BT, VIM-FIX T, VIM-FIX T III, VIM-FIX PKT, VIM-FIX PKT III, RC-LOC T, RC-LOC T III)-FOR ARTHROSCOPIC FIXATION OF BONE & SOFT TISSUE IN THE JOINTS,ARTHROSCOPY IMPLANTS-FIBER WIRE AND FIBER TAPE(BIOTEK, BIOFIBER, BIOFIBER-PH, BIOCINCH, BIOCINCH-AI2, BIOCINCH-AI3, BIOCINCH-AI5, ARTHROVIMS, BIOLOOP-I, BIOLOOP-II, FIBERKNOT, FIBERKNOT-T, KNOTFIX, KNOTFIX-T, SOFTPORT, SOFTPORT-T, BIOLOOP-NB)-FOR ARTHROSCOPIC FIXATION OF BONE & SOFT TISSUE IN THE JOINTS, ARTHROSCOPY IMPLANTS-FIXATION BUTTON WITH LOOP(BIOTEK, ONBUTTON CL, SYNPLE BUTTON CL, LIGABUTTON CL,BUTTONFIX, BUTTONFIX-NB, LIGABUTTON AL, AC-FIX -I, PIVOTFIX-I, AC-FIX II KIT, PIVOTFIX II KIT , ARTHROVIMS, AC-FIX III, PIVOTFIX III , AK FR KIT , AK FR KIT II, WT-FIX KIT , F-FIX KIT)-FOR ARTHROSCOPIC FIXATION OF BONE & SOFT TISSUE IN THE JOINTS,ARTHROSCOPY IMPLANTS-SCREW, BUTTON, WASHER(BIOTEK, SOFTFIX, SYNPLE SCREW TI, LIGATEK TI, SOFTFIX-BT, LIGATEK-BT, ARTHROVIMS, TIBIAL POST, SYNPLE, STAYFIX, BIO-LATARJET, LCS-LATARJET, SUTUREFIX, SUTUREFIX-LOC, SUTUREFIX-F, SUTUREFIX-T, AC-FIX, PIVOT-FIX, BT-FIX, WT-FIX, F-FIX, MR-FIX, AK-FIX, ONBUTTON , SYNPLE BUTTON)-FOR ARTHROSCOPIC FIXATION OF BONE & SOFT TISSUE IN THE JOINTS,SPINE IMPLANTS(BIOTEK, XEN-PLUS, XEN-ACP, XENICA-ACP, CAGELOC, XENCAGE, XEN-TC, XEN-PC, XENCAGE-PL, XEN-M)-FOR TREATMENT OF DEGENERATIVE DISC DISEASE, TRAUMA FRACTURE OR DISLOCATION, DEFORMITY, TUMOR, STENOSIS, PSEUDOARTHROSIS AND PREVIOUS FAILED FUSION,ARTHROSCOPY IMPLANTS-LIGAMENT ANCHORS(BIOTEK, ARTHROVIMS, MINI-VIM PK, MINI-VIM II PK, MICRO-VIM PK, MICRO-VIM II PK, NANO-VIM PK, NANO -VIM PK II, BIO-VIM, BIO-VIM II, MINI-VIM PKT, MINI-VIM II PKT, VIM-FIX LRP, RC-LOC LRP, VIM-FIX BT, VIM-FIX PK, VIM-FIX PK III, RC-LOC PK, RC-LOC PK II, VIM-FIX PKT, VIM-FIX PKT III)-FOR ARTHROSCOPIC FIXATION OF BONE & SOFT TISSUE IN THE JOINTS,ARTHROSCOPY IMPLANTS-FIXATION BUTTON WITH LOOP(BIOTEK, ONBUTTON CL, SYNPLE BUTTON CL, LIGABUTTON CL, BUTTONFIX, LIGABUTTON AL, AC-FIX -I, PIVOTFIX-I, ARTHROVIMS,AC-FIX II KIT, PIVOTFIX II KIT, AC-FIX III, PIVOTFIX III, AK FR KIT, AK FR KIT II, WT-FIX KIT, F-FIX KIT, BIO-PF,BIO-PF II)-FOR ARTHROSCOPIC FIXATION OF BONE & SOFT TISSUE IN THE JOINTS,ARTHROSCOPY IMPLANTS- SCREW, BUTTON, WASHER

		(BIOTEK, SOFTFIX-PK, SYNPLE SCREW PK, LIGATEK PK, ARTHROVIMS, SOFTFIX-BT, TIBIAL POST, SOFTFIX-TP, SYNPLE, SUTUREFIX, SUTUREFIX-LOC, SUTUREFIX-F, SUTUREFIX-T, AC-FIX, PIVOT-FIX, BT-FIX, WT-FIX, F-FIX, MR-FIX, AK-FIX, ONBUTTON , SYNPLE BUTTON)-FOR ARTHROSCOPIC FIXATION OF BONE & SOFT TISSUE IN THE JOINTS,INTRAMEDULLARY NAILS(BIOTEK, PAT)-FRACTURES OF HUMERAL, FEMORAL & TIBIAL,BONE SCREWS(BIOTEK)-FOR PLATE FIXATION FOR BONE FRACTURES,BONE PLATES(BIOTEK, BIO-HP, BIDDU, BIO-LATARJET)-FOR STABILIZATION AND FIXATION OF BONE FRAGMENTS IN FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF BONES,WIRE, PIN, WASHER(BIOTEK)-FOR TEMPORARY AND DEFINITIVE FIXATION OF BONE FRACTURES
3125	MFG/MD/2018/000078	1.License Holder Name: MJS LATEX PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:PLAIN/DOTTED/RIBBED, FLAVORED,COLORED LUBRICATED LATEX BASED CONDOMS -FOR PREVENTION OF STI/ FAMILY PLANNING
3126	MFG/MD/2018/000079	1.License Holder Name: NEBULA SURGICAL PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATE(NEBULA)-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURES IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREWS TO PROPERLY ALIGN THE FRACTURED BONE.,BONE SCREW(NEBULA)-BONE SCREWS ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR ALONG WITH BONE PLATES OR INTERLOCKING NAILS. , CERVICAL IMPLANTS(NEBULA)-CERVICAL IMPLANTS ARE USED IN CERVICAL SPINAL CODE FRACTURES IN ANTERIOR CERVICAL SPINE AND POSTERIOR CERVICAL SPINE. ,SPINE IMPLANTS(NEBULA)-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE. ,ENDOPROSTHESIS(NEBULA)-ENDO PROSTHESIS ARE SPECIALLY USED IN FEMUR NECK FRACTURE. WHEN FEMUR BONE HEAD IS DAMAGED OR FRACTURED. ,IM NAILS(NEBULA)-INTRAMEDULLARY NAILING IS COMMONLY USED TO FIX THE LONG BONE FRACTURES.,PINS AND WIRES(NEBULA)-PINS AND WIRES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS AND WIRE SUPPORT FIX THE BONE PLATES.

3127	MFG/MD/2018/000080	1.License Holder Name: BONE LIFE SURGICALS 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATES(OSSEIN)-BONE PLATES SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE WIRES(OSSEIN)-BONE WIRES SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,SPINAL IMPLANTS (OSSEIN)-SPINAL IMPLANTS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE SCREWS(OSSEIN)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PINS(OSSEIN)-BONE PINS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE NAILS(OSSEIN)-BONE PLATES SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3128	MFG/MD/2018/000081	1.License Holder Name: MARK ORTHO CARE PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATE - SS(MARK)-THE BONE PLATING SYSTEM IS INTENDED FOR ESSENTIALLY NON-LOAD BEARING STABILIZATION AND FIXATION OF BONE FRAGMENTS IN FRESH FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF SMALL BONES OF THE HAND, FOOT, WRIST, ANKLE, HUMERUS, SCAPULA, FINGER, TOE, PELVIS AND CRANIOMAXILLOFACIAL SKELETON.,BONE SCREW - SS(MARK)-INDICATIONS :- THE BONE SCREW SYSTEM IS INTENDED FOR ESSENTIALLY NON-LOAD BEARING STABILIZATION AND FIXATION OF BONE FRAGMENTS IN FRESH FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF SMALL BONES OF THE HAND, FOOT, WRIST, ANKLE, HUMERUS, SCAPULA, FINGER, TOE, PELVIS AND CRANIOMAXILLOFACIAL SKELETON.,HIP REPLACEMENT SYSTEM - STEM -(MARK)-HIP SYSTEM IS INTENDED FOR CURE OR RECONSTRUCTION REPLACEMENT OF OF DAMAGED JOINT BONE OF HIP.,ARTHROSCOPIC IMPLANT - PEEK(MARK)-THE ARTHROSPIC SYSTEM IS INTENDED FOR ESSENTIALLY CURE OF LIGAMENTS FRAGMENTS IN FRESH FRACTURES,OR INJURYS, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION,NAIL - TITANIUM(MARK)-THE BONE NAILING SYSTEM IS INTENDED FOR ESSENTIALLY NON-LOAD BEARING STABILIZATION AND FIXATION OF BONE FRAGMENTS IN FRESH FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF SMALL BONES OF THE HAND, FOOT, WRIST, ANKLE, HUMERUS,,MAXILO FACIAL IMPLANT - TITANIUM(MARK)-:- MAXILLOFACIAL SYSTEM IS INTENDED FOR CURE OR RECONSTRUCTION OF DAMAGED OR FRACTURED BONE OF MAXILLOFACIAL PART.,ARTHROSCOPIC IMPLANT - TITANIUM(MARK)-THE ARTHROSPIC SYSTEM IS INTENDED FOR ESSENTIALLY CURE OF LIGAMENTS FRAGMENTS IN FRESH FRACTURES,OR INJURYS, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION,HIP REPLACEMENT SYSTEM - FEMORAL HEAD(MARK)-HIP SYSTEM IS INTENDED FOR CURE OR RECONSTRUCTION REPLACEMENT OF OF DAMAGED JOINT BONE OF HIP JOINT,HIP REPLACEMENT SYSTEM - ACETABULER CUP(MARK)-HIP SYSTEM IS INTENDED FOR CURE OR RECONSTRUCTION REPLACEMENT OF OF DAMAGED JOINT BONE OF HIP JOINT.,SHOULDER REPLACEMENT SYSTEM - HEAD(MARK)-SHOULDER REPLACEMENT ARE INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED SHOULDER JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS.,SHOULDER REPLACEMENT SYSTEM - NECK(MARK)-

	SHOULDER REPLACEMENT ARE INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED SHOULDER JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS.,ELBOW REPLACEMENT SYSTEM - ULNA COMPONENT (MARK)-AN ELBOW JOINT METAL/POLYMER CONSTRAINED CEMENTED PROSTHESIS IS A DEVICE INTENDED TO BE IMPLANTED TO REPLACE AN ELBOW JOINT.,SPINE IMPLANT - PEEK(MARK)-THE SPINE SYSTEM IS INTENDED FOR ESSENTIALLY STABILIZATION AND FIXATION OF SPINE FRAGMENTS IN FRESH FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF VERTEBRAL COLLUM.,SPINE IMPLANT - TITANIUM(MARK)-:- THE SPINE SYSTEM IS INTENDED FOR ESSENTIALLY STABILIZATION AND FIXATION OF SPINE FRAGMENTS IN FRESH FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF VERTEBRAL COLLUM., BONE SCREW - TITANIUM(MARK)-INDICATIONS :- THE BONE SCREW SYSTEM IS INTENDED FOR ESSENTIALLY NON-LOAD BEARING STABILIZATION AND FIXATION OF BONE FRAGMENTS IN FRESH FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF SMALL BONES OF THE HAND, FOOT, WRIST, ANKLE, HUMERUS, SCAPULA, FINGER, TOE, PELVIS AND CRANIOMAXILLOFACIAL SKELETON.,BONE PLATE - TITANIUM(MARK)-THE BONE PLATING SYSTEM IS INTENDED FOR ESSENTIALLY NON-LOAD BEARING STABILIZATION AND FIXATION OF BONE FRAGMENTS IN FRESH FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF SMALL BONES OF THE HAND, FOOT, WRIST, ANKLE, HUMERUS, SCAPULA, FINGER, TOE, PELVIS AND CRANIOMAXILLOFACIAL SKELETON.,ARTHROSCOPIC IMPLANT - SS (MARK)-THE ARTHROSPIC SYSTEM IS INTENDED FOR ESSENTIALLY CURE OF LIGAMENTS FRAGMENTS IN FRESH FRACTURES,OR INJURYS, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION,MAXILO FACIAL IMPLANT - SS(MARK)-MAXILLOFACIAL SYSTEM IS INTENDED FOR CURE OR RECONSTRUCTION OF DAMAGED OR FRACTURED BONE OF MAXILLOFACIAL PART.,ELBOW REPLACEMENT SYSTEM - HUMERAL COMPONENT(MARK)-AN ELBOW JOINT METAL/POLYMER CONSTRAINED CEMENTED PROSTHESIS IS A DEVICE INTENDED TO BE IMPLANTED TO REPLACE AN ELBOW JOINT.,SHOULDER REPLACEMENT SYSTEM - STEM(MARK)-THE SHOULDER SYSTEM IS INTENDED FOR REPLACE DAMAGED BONE OF SHOULDER,SPINE IMPLANT - SS(MARK)-:- THE SPINE SYSTEM IS INTENDED FOR ESSENTIALLY STABILIZATION AND FIXATION OF SPINE FRAGMENTS IN FRESH FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF VERTEBRAL COLLUM.,NAIL - SS(MARK)-THE

		BONE NAILING SYSTEM IS INTENDED FOR ESSENTIALLY NON-LOAD BEARING STABILIZATION AND FIXATION OF BONE FRAGMENTS IN FRESH FRACTURES, REVISION PROCEDURES, JOINT FUSION AND RECONSTRUCTION OF SMALL BONES OF THE HAND, FOOT, WRIST, ANKLE, HUMERUS,
3129	MFG/MD/2018/000082	1.License Holder Name: HOSPI LINE EQUIPMENTS PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:STENT (UROLOGY/BILLIARY/PANCREATIC) (HOSPILINE)-THE URETERAL STENT IS INTENDED TO PROVIDE DRAINAGE FROM THE KIDNEY TO THE BLADDER, SERVING AS AN INTERNAL INDWELLING CATHETER. IN THE CASE OF STONE OBSTRUCTION IN URETER. THIS STENT PROVIDE THE BYPASS TRACK FOR URINE FLOW FROM KIDNEYTO BLADDER. THE BILLIARY STENTS ARE INDICATED FOR USE IN THE PALLIATIVE TREATMENT OF BILIARY STRICTURES PRODUCED BY MALIGNANT NEOPLASMS. IT IS REQUIRED TO BYPASS THE BILE JUICE FROM GALLBLADDER TO INTESTINE WHEN THERE IS BLOCKAGE BECAUSE OF STONE IN BILLIARY TRACK.,WIRE (SELF EXPENDABLE METAL STENT)(HOSPILINE)-THE VAST MAJORITY OF SEMS ARE USED TO ALLEVIATE SYMPTOMS CAUSED BY CANCERS OF THE GASTROINTESTINAL TRACT THAT OBSTRUCT THE INTERIOR OF THE TUBE-LIKE (OR LUMINAL) STRUCTURES OF THE BOWEL — NAMELY THE ESOPHAGUS, DUODENUM, COMMON BILE DUCT AND COLON. SEMS ARE DESIGNED TO BE PERMANENT AND, AS A RESULT, ARE OFTEN USED WHEN THE CANCER IS AT AN ADVANCED STAGE AND CANNOT BE REMOVED BY SURGERY.
3130	MFG/MD/2018/000083	1.License Holder Name: NAV JEEVAN SURGICAL INDUSTRIES 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:ROLLED BANDAGE-EXTERNAL DRESSING FOR SMALL BURN AND WOUND,GAUZE-FOR ABSORBTION OF EXUDATE AND MICROENVIROMENT OF WOUND, DRESSING PAD-: EXTERNAL DRESSING FOR SMALL BURN AND WOUND,ABSORBENT COTTON WOOL IP-CLEANING OF EXUDATES AND COSMETIC PURPOSES,GAMZI ROLL-ABSOURBTION OF EXCUDATE AND MICROENVIROMENT OF WOUND

3131	MFG/MD/2018/000084	1.License Holder Name: AMKAY PRODUCTS PRIVATE LIMITED 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:STERILE DRAPES(AMKAY) -IT IS USED DURING VARIOUS SURGERIES.,UMBILICAL OCCLUSION DEVICE(AMKAY)-IT IS USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEW BORN INFANT.,ALCOHOL SWAB(AMKAY)-IT IS A SINGLE USE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLES ACCESS SITES PRIOR TO USE
3132	MFG/MD/2018/000085	1.License Holder Name: FRISCH MEDICAL DEVICES LLP 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:BLUNT INTRODUCER DEVICE(TURBO)-HAEMOSTASIS Y-CONNECTOR KIT PROVIDES A MEAN FOR INSERTING GUIDE WIRES OR CATHETERS DEEP INTO THE VASCULATURE, AND POSITIONING AND LOCKING THEM INTO A DESIRED PLACE. HAEMOSTASIS Y-CONNECTOR INCLUDES A STRAIGHT AND A SIDE ACCESS LUMEN. THE HEMOSTASIS VALVE LOCATED AT THE PROXIMAL END OF THE STRAIGHT LUMEN CAN BE OPENED OR CLOSED BY OPERATION OF THE PUSH-PULL BUTTON. THE DISTAL END HAS A ROTATING MALE LUER LOCK. THE SIDE ACCESS LUMEN ALLOWS PRESSURE MONITORING AND PERFUSION. THE TORQUER DEVICE PROVIDED WITH COPPER CYLINDER TO PROTECT THE GUIDE WIRE COATING AND GRIP THE GUIDE WIRE. THE BLUNT INTRODUCER DEVICE ACTS AS A MEDIUM TO PASS GUIDE WIRE THROUGH THE Y CONNECTOR.,PUNCTURE NEEDLE(INVENT)-PUNCTURE NEEDLE ARE USED WITH THE INTRODUCER SYSTEM FOR INTRODUCTION AND PLACEMENT OF A GUIDEWIRE.,PRESSURE LINE (RESIST)-PRESSURE MONITORING TUBING IS INTENDED TO PROVIDE CHANNEL FOR FLUID AND MEDICINE IN INTERVENTIONAL OPERATION .,CONTROL SYRINGE(ASSURE)-CONTROL SYRINGE IS AN ACCESSORY DESIGN TO FACILITATE THE INJECTION OF DIE OR ANY OTHER FLUID MATERIAL USED IN CONJUNCTION WITH INTERVENTIONAL DEVICES DURING VASCULAR INTERVENTIONAL PROCEDURES.,3-WAY STOPCOCK(DELTA)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING

3133	MFG/MD/2018/000086	1.License Holder Name: STERIMED MEDICAL DEVICES PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:FOLEY CATHETER (FOLEY BALLOON CATHETER 3 WAY)(EASYFLOW)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS (NO BRAND NAME)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,FOLEY CATHETER (FOLEY BALLOON CATHETER 2 WAY)(EASYFLOW)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,TRACHEOSTOMY TUBE / TRACHEAL TUBE (TRACHEOSTOMY TUBE CATHETERS, CUFFED)(NO BRAND NAME)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,FOLEY CATHETER / FOLEY BALLOON CATHETER (3 WAY- 100 % SILICONE)(EASYFLOW)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,EXTENSION SETS (EXTENSION LINE WITH OR WITHOUT 3 WAY STOP COCK)(NO BRAND NAME)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,FOLEY CATHETER (FOLEY BALLOON CATHETER 3 WAY)(CORECATH)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,TRACHEAL (ENDOTRACHEAL) TUBES / (ENDOTRACHEAL TUBES CATHETERS, PLAIN)(NO BRAND NAME)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,FOLEY CATHETER (FOLEY BALLOON CATHETER 2 WAY)(CORECATH-HF)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,NASAL OXYGEN (NASAL OXYGEN CANNULA)(NO BRAND NAME)-INTENDED FOR DELIVERING OXYGEN FOR INHALING SMALL AMOUNT OF SUPPLEMENT,FOLEY CATHETER (FOLEY BALLOON CATHETER 2 WAY)(FOLCATH-HF)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,TRACHEAL (ENDOTRACHEAL) TUBES /

	(ENDOTRACHEAL TUBES CATHETERS, CUFFED)(NO BRAND NAME)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,TRACHEOBRONCHIAL SUCTION CATHETERS (SUCTION CATHETERS)(CORTISLIFE)-CLEANING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILLATION.,TRACHEOSTOMY TUBE / TRACHEAL TUBE (TRACHEOSTOMY TUBE CATHETERS, PLAIN) (NO BRAND NAME)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,FOLEY CATHETER (FOLEY BALLOON CATHETER 2 WAY)(FOLCATH)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., PRESSURE MONITORING LINE(NO BRAND NAME)-IT IS USED FOR HIGH PRESSURE MONITORING AND CONNECTION BETWEEN SYRINGE AND INFUSION PUMP.,FOLEY CATHETER (FOLEY BALLOON CATHETER 2 WAY)(CORECATH)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,CLOSED SUCTION SYSTEM(NO BRAND NAME)-IT IS INTENDED FOR ENDOTRACHEAL SUCTIONING TO PROVIDE A PATIENT AIRWAY BY REMOVING EXCESS FLUIDS, SECRETIONS, EXUDATES AND TRANSUDATE THROUGH THE ARTIFICIAL AIRWAY.,FOLEY CATHETER (FOLEY BALLOON CATHETER 3 WAY)(FOLCATH)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,INFANT MUCUS EXTRACTOR(NO BRAND NAME)-IT IS USED FOR ASPIRATION OF SECRETION FROM OROPHARYNX IN NEWLY BORN BABY.,FOLEY CATHETER (FOLEY BALLOON CATHETER 3 WAY)(CORECATH-HF)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETER (FOLEY BALLOON CATHETER 100 % SILICONE-2 WAY)(MEGACARE)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETER (FOLEY BALLOON CATHETER 3 WAY) (FOLCATH-HF)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETER (FOLEY BALLOON CATHETER 100 % SILICONE-3 WAY) (MEGACARE)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE

	URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETER / FOLEY BALLOON CATHETER (2 WAY- 100 % SILICONE) (EASYFLOW)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,INFANT MUCUS EXTRACTOR(MEGACARE)-INFANT MUCUS EXTRACTOR IS USED FOR ASPIRATION OF SECRETION FROM OROPHARYNX IN NEWLY BORN BABY.,NELATON CATHETERS(NO BRAND)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,ABDOMINAL DRAINAGE KIT(NO BRAND NAME)-THE PRODUCT IS USED FOR ABDOMINAL DRAINAGE SURGERY.,FOLEY CATHETER / FOLEY BALLOON CATHETER (2 WAY-100 % SILICONE)(NO BRAND NAME)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,UMBILICAL OCCLUSION DEVICE (UMBILICAL CORD CLAMP/UMBILICAL TAPE)(NO BRAND NAME)-THESE DEVICES MAY BE A CLIP, TIE, TAPE OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,NASAL OXYGEN CATHETER (OXYGEN CATHETERS)(NO BRAND)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY., FOLEY CATHETER (FOLEY BALLOON CATHETER 2 WAY)(HEUER)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETER / FOLEY BALLOON CATHETER (3 WAY-100 % SILICONE)(NO BRAND NAME)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,NASOGASTRIC TUBE/RYLES TUBE (RYLES TUBES CATHETERS)(STERI-LENE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,FOLEY CATHETER (FOLEY BALLOON CATHETER 3 WAY)(MEGACARE)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,LEVINE TUBE (LEVIN / STOMACH TUBES CATHETERS)(NO BRAND)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,URETHRAL CATHETER / LOTUS CATHETER(NO BRAND NAME)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER

	THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETER / FOLEY BALLOON CATHETER (2 WAY, SILICONISED)(NO BRAND NAME)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,TRACHEOSTOMY TUBE / TRACHEAL TUBE (TRACHEOSTOMY TUBE CATHETERS)(MEGACARE)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,SUCTION TIP AND CATHETER (YANKAUR SUCTION SET CATHETER)(NO BRAND)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,TRACHEOSTOMY TUBE / TRACHEAL TUBE / TRACHEOSTOMY TUBE CUFFED (FENESTRATED)(NO BRAND NAME)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,TRACHEOSTOMY TUBE / TRACHEAL TUBE (TRACHEOSTOMY TUBE CATHETERS)(NO BRAND)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,TRACHEOBRONCHIAL SUCTION CATHETER / SUCTION CATHETER (THUMB CONTROL)(NO BRAND NAME)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,UPPER URINARY TRACT CATHETER (URETERIC CATHETERS)(NO BRAND)-THE CATHETER TO THE BLADDER AND SUBSEQUENTLY TO THE UPPER URINARY TRACT.,TRACHEOSTOMY TUBE / TRACHEAL TUBE / TRACHEOSTOMY TUBE CUFFED (REINFORCED)(NO BRAND)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,TRACHEAL (ENDOTRACHEAL) TUBE (ENDOTRACHEAL TUBES CATHETERS)(MEGACARE)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., CONTINUOUS IRRIGATION CATHETER (THORACIC DRAINAGE CATHETERS)(MEGACARE)-INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS.,TRACHEOSTOMY TUBE / TRACHEAL TUBE / TRACHEOSTOMY TUBE CUFFED (WITH SUBGLOTTIC SUCTION LINE) (NO BRAND NAME)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,URETHRAL CATHETER / MALECOT CATHETER(NO BRAND NAME)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., TRACHEAL (ENDOTRACHEAL) TUBE / ENDOTRACHEAL TUBE PLAIN

	(REINFORCED)(NO BRAND NAME)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., FOLEY CATHETER (FOLEY BALLOON CATHETER 3 WAY)(MEDI-NORM) -A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETER (FOLEY BALLOON CATHETER)(NORTA)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,TRACHEAL (ENDOTRACHEAL) TUBE / ENDOTRACHEAL TUBE CUFFED (WITH SUBGLOTTIC SUCTION)(NO BRAND NAME)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS,LEVINE TUBE (LEVIN / STOMACH TUBES CATHETERS)(MEGACARE)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS., NASOGASTRIC TUBE/ RYLES TUBE (RYLES TUBES CATHETERS)(NO BRAND)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,CLOSED WOUND DRAINAGE TUBE OR SYSTEM (STERIVAC, CLOSED WOUND SUCTION UNIT CATHETERS)(NO BRAND)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,FOLEY CATHETER (FOLEY BALLOON CATHETER 2 WAY, 100 % SILICONE)(SUPERCARE)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FEEDING TUBE (INFANT FEEDING TUBES CATHETERS)(MEGACARE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING., MALE EXTERNAL CATHETERS (NOT CLASSIFIED UNDER MDR 2017) (MEGACARE)-AN EXTERNAL CATHETER USED FOR URINE IN-CONTINENCY.,GASTRIC, COLONIC, ETC.) IRRIGATION AND ASPIRATION CATHETER (SALEM SUMP TUBES CATHETERS)(NO BRAND)-USED FOR INSTILLING FLUID INTO, WITHDRAWING FLUIDS FROM, SPLINTING, OR SUPPRESSING BLEEDING OF THE ALIMENTARY TRACT.,FEEDING TUBE (INFANT FEEDING TUBES CATHETERS)(NO BRAND)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,GASTRIC, COLONIC,

	ETC.) IRRIGATION AND ASPIRATION CATHETER (SALEM SUMP TUBES CATHETERS)(MEGACARE)-USED FOR INSTILLING FLUID INTO, WITHDRAWING FLUIDS FROM, SPLINTING, OR SUPPRESSING BLEEDING OF THE ALIMENTARY TRACT.,FOLEY CATHETER / FOLEY BALLOON CATHETER (3 WAY, SILICONE ELASTOMER COATED)(NO BRAND NAME)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., CONTINUOUS IRRIGATION CATHETER (THORACIC TROCAR CATHETER)(NO BRAND)-INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS.,FOLEY CATHETER (FOLEY BALLOON CATHETER 2 WAY) (SUPERCARE)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., SUCTION TIP AND CATHETER (YANKAUR SUCTION SET CATHETER) (MEGACARE)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., URETHRAL CATHETER(MEGACARE)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,UMBILICAL OCCLUSION DEVICE (UMBILICAL COTTON TAPE)(N.A.)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT. ,FOLEY CATHETER (FOLEY BALLOON CATHETER 3 WAY)(HEUER)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETER / FOLEY BALLOON CATHETER (3 WAY-100 % SILICONE)(HEUER)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,NASAL OXYGEN CATHETER (OXYGEN CATHETERS) (MEGACARE)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY.,FOLEY CATHETER (FOLEY BALLOON CATHETER 2 WAY)(NO BRAND)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., TRACHEAL (ENDOTRACHEAL) TUBE / ENDOTRACHEAL TUBE CUFFED (PREFORMED/RAE TUBES, SOUTH ORAL/NASAL)(NO BRAND NAME)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE

	TRACHEA, JUST BELOW THE VOCAL CORDS.,RECTAL CATHETERS(NO BRAND)-RECTUM IN ORDER TO RELIEVE FLATULENCE WHICH HAS BEEN CHRONIC AND WHICH HAS NOT BEEN ALLEVIATED BY OTHER METHODS.,FOLEY CATHETER (FOLEY BALLOON CATHETER 100% SILICONE)(NO BRAND)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., TRACHEOBRONCHIAL SUCTION CATHETER (SUCTION CATHETERS) (NO BRAND)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,MALE EXTERNAL CATHETER (NOT CLASSIFIED UNDER MDR 2017)(NO BRAND)-AN EXTERNAL CATHETER USED FOR URINE IN-CONTINENCY.,FOLEY CATHETER / FOLEY BALLOON CATHETER (3 WAY, SILICONISED)(NO BRAND NAME)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,UMBILICAL ARTERY CATHETER (UMBILICAL CATHETER)(NO BRAND)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS.,NELATON CATHETER(MEGACARE)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,URETHRAL CATHETER(NO BRAND)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,CONTINUOUS IRRIGATION CATHETER (THORACIC DRAINAGE CATHETERS)(NO BRAND)-INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS.,CLOSED WOUND DRAINAGE TUBE OR SYSTEM (REDON DRAINAGE CATHETERS)(MEGACARE)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,CLOSED WOUND DRAINAGE TUBE OR SYSTEM (REDON DRAINAGE CATHETERS)(NO BRAND)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS., NASOGASTRIC TUBE/ RYLES TUBE (RYLES TUBES CATHETERS) (MEGACARE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED

	FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES., KEHR'S "T" TUBES CATHETERS (NOT CLASSIFIED UNDER MDR 2017) (NO BRAND)-USED FOR SHORT TERM POST OPERATIVE DRAINAGE OF COMMON BILE DUCT.,TRACHEAL (ENDOTRACHEAL) TUBE / ENDOTRACHEAL TUBE CUFFED (REINFORCED)(NO BRAND NAME)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,TRACHEAL (ENDOTRACHEAL) TUBE ENDOTRACHEAL TUBE CUFFED (PREFORMED/RAE TUBES, SOUTH ORAL/NASAL)(NO BRAND NAME)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,FOLEY CATHETER / FOLEY BALLOON CATHETER (2 WAY-100 % SILICONE)(HEUER)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,TRACHEAL (ENDOTRACHEAL) TUBE / ENDOTRACHEAL TUBE PLAIN (PREFORMED/RAE TUBES, SOUTH ORAL/NASAL)(NO BRAND NAME)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,TRACHEOBRONCHIAL SUCTION CATHETER / SUCTION CATHETER (NORMAL)(NO BRAND NAME)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,CLOSED WOUND DRAINAGE TUBE OR SYSTEM (STERIVAC, CLOSED WOUND SUCTION UNIT CATHETERS)(MEGACARE)-USED FOR CLOSE WOUND DRAINAGE UNDER NEGATIVE PRESSURE WITH THE OPTION TO USE ONE CATHETER OR TWO CATHETERS SIMULTANEOUSLY.,TRACHEAL (ENDOTRACHEAL) TUBE (ENDOTRACHEAL TUBE CUFFED) (STERITRACH)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,FOLEY CATHETER (FOLEY BALLOON CATHETER 3 WAY, 100 % SILICONE) (SUPERCARE)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETER (FOLEY BALLOON CATHETER 3 WAY)(SUPERCARE)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,TRACHEOSTOMY TUBE / TRACHEAL TUBE / TRACHEOSTOMY TUBE CUFFED (WITH INNER CANNULA)(NO BRAND)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR

	VENTILATION.,TRACHEAL (ENDOTRACHEAL) TUBE (ENDOTRACHEAL TUBES CATHETERS)(NO BRAND)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., TRACHEOBRONCHIAL SUCTION CATHETER / SUCTION CATHETER (FINGER TIP)(NO BRAND NAME)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,TRACHEAL (ENDOTRACHEAL) TUBE / ENDOTRACHEAL TUBE PLAIN (PREFORMED/RAE TUBES, NORTH ORAL / NASAL)(NO BRAND NAME)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,FOLEY CATHETER / FOLEY BALLOON CATHETER (2 WAY, SILICONE ELASTOMER COATED)(NO BRAND NAME)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETER (FOLEY BALLOON CATHETER 2 WAY)(MEDI-NORM)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETER (FOLEY BALLOON CATHETER 3 WAY)(NO BRAND)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,KEHR'S "T" TUBES CATHETERS (NOT CLASSIFIED UNDER MDR 2017)(MEGACARE)-USED FOR SHORT TERM POST OPERATIVE DRAINAGE OF COMMON BILE DUCT.,UPPER URINARY TRACT CATHETER (URETERIC CATHETERS) (MEGACARE)-THE CATHETER TO THE BLADDER AND SUBSEQUENTLY TO THE UPPER URINARY TRACT.,TRACHEAL (ENDOTRACHEAL) TUBE / (ENDOTRACHEAL TUBE PLAIN, SILICONISED)(NO BRAND)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,TRACHEOBRONCHIAL SUCTION CATHETER SUCTION CATHETERS(MEGACARE)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,RECTAL CATHETERS (MEGACARE) -RECTUM IN ORDER TO RELIEVE FLATULENCE WHICH HAS BEEN CHRONIC AND WHICH HAS NOT BEEN ALLEVIATED BY OTHER METHODS.,CONTINUOUS IRRIGATION CATHETER (THORACIC TROCAR CATHETERS)(MEGACARE)-INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS.,FOLEY CATHETER (FOLEY BALLOON CATHETER 2 WAY) (MEGACARE)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR

	INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., UMBILICAL ARTERY CATHETER (UMBILICAL CATHETERS) (MEGACARE)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS.

3134	MFG/MD/2018/000087	1.License Holder Name: ILIFE MEDICAL DEVICES 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:EXTENSION TUBE-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS., INTRAVENOUS CATHETER WITH WINGS & WITH PORT(ONEFLON, ONEPLUS, VANOCATHE, ONEFLOW, SOFTCATHE, STER-X, NANOCATHE)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE.,THREE WAY STOP COCK WITH EXTENSION TUBE-THREE-WAY STOPCOCK WITH EXTENSION TUBE HAS BEEN DESIGNED FOR THE INFUSION THERAPY CONTAINS 3-WAY STOPCOCK AT ONE END & MALE STOPPER THREADED CONNECTION AT OTHER END., INTRAVENOUS CATHETER WITH WINGS & WITHOUT PORT(ONECAN)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE.,I.V. SET-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,INTRAVENOUS CATHETER WITH SUTURABLE WINGS & PORT(ONEFLOW, SOFTCATHE, STER-X, VANOCATHE)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE.,THREE WAY STOP COCK-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,INTRAVENOUS CATHETER WITH SMALL WINGS & WITHOUT PORT(NANOCATHE, VANOCATHE)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE.,B.T.SET-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INTRAVENOUS CATHETER WITHOUT WINGS & WITHOUT PORT(ONEON)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE.,INTRAVENOUS CATHETER WITHOUT WINGS & WITHOUT PORT(ONEPEN, PERICAN NEO)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOOD STREAM OR FOR

	DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE. , EXTENSION SETS (THREE WAY STOP COCK WITH EXTENSION TUBE-RED,BLUE AND WHITE HANDLE)(AJS,MEDIWISE,NEOWAY,ALKHOFAR)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. , THREE WAY STOP COCK WITH EXTENSION TUBE (ANGELTOUCH, ALKHOFAR, AJS, VANOSAFE, FEP CATH, SAFECATHE, TRI-M, UNIMED, VANOSUN, LIFEFLON, NEOWAY, MEDIWISE)-THREE WAY STOP COCK WITH EXTENSION TUBE HAS BEEN DESIGNED FOR THE INFUSION THERAPY CONTAINS THREE WAY STOP COCK AT ONE END & MALE STOPPER THREADED CONNECTION AT OTHER END.,INTRAVENOUS CANNULA(ANGELTOUCH, DISPOTOUCH)-THE IV CANNULA /CATHETER IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND /OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,EXTENSION TUBE (AJS, VANOSAFE, FEP CATH, SAFECATHE, TRI-M, UNIMED, VANOSUN, LIFEFLON, MEDIWISE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENTED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICINES IN MEDICAL APPLICATIONS. ,INTRAVENOUS CANNULA(ELEFLON,MARTA,FIRST CARE,FLEBOCATH,DISPOTOUCH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THREE WAY STOP COCK(ANGELTOUCH, ALKHOFAR, AJS, VANOSAFE, FEP CATH, SAFECATHE, TRI-M, UNIMED, VANOSUN, LIFEFLON, MEDIWISE, NEOWAY)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL & FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWL OF FLUID & PRESSURE MONITORING. ,INTRAVENOUS CANNULA(ONE PEN, VOMFLON,PERICAN,AJS,AXIOM)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INTRAVENOUS CATHETER WITH WINGS & WITH PORT(ANGELTOUCH, PERICAN, ELEFLON, ALKHOFAR, AJS, VANOSAFE, FEP CATH, SAFECATHE, SUTURECATH, TRI-M, UNIMED, VANOSUN, VOMFLON, LIFEFLON)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATION OR NUTRIENTS DIRECTLY INTO THE BLOOD STREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE. , 3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS (RED,BLUE AND WHITE HANDLE)(AJS,MEDIWISE, NEOWAY,ALKHOFAR,ANGELTOUCH)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND

	PRESSURE MONITORING.,B. T. SET(ONEFLON)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., HEPARIN CAP(ONEFLON)-YELLOW STOPPER/HEPARIN CAP IS AN INTERMITTENT INTRAVENOUS DEVICE FOR THE ADMINISTRATION OF HEPARIN AND ASSURANCE OF HIGH HYGIENE. IT DOES NOT REQUIRE A CONTINUOUS FLOW OF FLUIDS IN INTRAVENOUS LINE.,THREE WAY STOP COCK WITH EXTENSION TUBE(SOFTCATHE)-THREE-WAY STOPCOCK WITH EXTENSION TUBE HAS BEEN DESIGNED FOR THE INFUSION THERAPY CONTAINS 3-WAY STOPCOCK AT ONE END & MALE STOPPER THREADED CONNECTION AT OTHER END., INTRAVENOUS CATHETER(ONEFLON)-THE IV CANNULA /CATHETER IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND /OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. SAFETY CLIP HAS BEEN PROVIDED TO ACTUATE SAFETY FUNCTION. ,THREE WAY STOP COCK (ONEFLON)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, EXTENSION SETS (EXTENSION TUBE)(AJS)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,THREE WAY STOP COCK(ONEPLUS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, THREE WAY STOP COCK(DISPOTOUCH)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,EXTENSION TUBE(NANOCATHE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS., INTRAVENOUS CANNULA(SUPERLIFE)-THE IV CANNULA /CATHETER IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND /OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,B. T. SET(VANOCATHE) -TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INTRAVENOUS CANNULA(LIFEFLOW,LIFEMED, ALKHOFAR,ANGELTOUCH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THREE WAY STOP COCK(STER-X)-IT IS INDICATED

	FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,THREE WAY STOP COCK (SUPERLIFE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,THREE WAY STOP COCK(ONEFLOW)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,INTRAVENOUS CANNULA(MP MEDPLAST)-THE IV CANNULA /CATHETER IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS AND /OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , THREE WAY STOP COCK WITH EXTENSION TUBE(NANOCATHE)-THREE-WAY STOPCOCK WITH EXTENSION TUBE HAS BEEN DESIGNED FOR THE INFUSION THERAPY CONTAINS 3-WAY STOPCOCK AT ONE END & MALE STOPPER THREADED CONNECTION AT OTHER END., THREE WAY STOP COCK(NANOCATHE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,THREE'WAY STOP COCK(ANGELTOUCH)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,B. T. SET (ONEFLOW)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,EXTENSION TUBE (ONEFLOW)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS., I. V. SET(ONEFLOW)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,THREE WAY STOP COCK WITH EXTENSION TUBE(ONEFLOW)-THREE-WAY STOPCOCK WITH EXTENSION TUBE HAS BEEN DESIGNED FOR THE INFUSION THERAPY CONTAINS 3-WAY STOPCOCK AT ONE END & MALE STOPPER THREADED CONNECTION AT OTHER END., EXTENSION TUBE(STER-X)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS,I. V. SET(STER-X)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,B. T. SET(STER-X)-TRANSFUSION SET IS USED TO ADMINISTER

	BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,THREE WAY STOP COCK WITH EXTENSION TUBE(STER-X)-THREE-WAY STOPCOCK WITH EXTENSION TUBE HAS BEEN DESIGNED FOR THE INFUSION THERAPY CONTAINS 3-WAY STOPCOCK AT ONE END & MALE STOPPER THREADED CONNECTION AT OTHER END.,I. V. SET(ONEPLUS)-:IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,EXTENSION TUBE(ONEPLUS)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS,B. T. SET(ONEPLUS)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,THREE WAY STOP COCK WITH EXTENSION TUBE(ONEPLUS)-THREE-WAY STOPCOCK WITH EXTENSION TUBE HAS BEEN DESIGNED FOR THE INFUSION THERAPY CONTAINS 3-WAY STOPCOCK AT ONE END & MALE STOPPER THREADED CONNECTION AT OTHER END.,EXTENSION TUBE (VANOCATHE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,THREE WAY STOP COCK WITH EXTENSION TUBE (VANOCATHE)-THREE-WAY STOPCOCK WITH EXTENSION TUBE HAS BEEN DESIGNED FOR THE INFUSION THERAPY CONTAINS 3-WAY STOPCOCK AT ONE END & MALE STOPPER THREADED CONNECTION AT OTHER END.,I. V. SET(VANOCATHE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,THREE WAY STOP COCK(VANOCATHE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,B. T. SET(NANOCATHE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,THREE WAY STOP COCK WITH EXTENSION TUBE (ONEFLON)-THREE-WAY STOPCOCK WITH EXTENSION TUBE HAS BEEN DESIGNED FOR THE INFUSION THERAPY CONTAINS 3-WAY STOPCOCK AT ONE END & MALE STOPPER THREADED CONNECTION AT OTHER END.,B. T. SET(SOFTCATHE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,I. V. SET (NANOCATHE)-:IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM

		THROUGH A VASCULAR ACCESS DEVICE.,THREE WAY STOP COCK (SOFTCATHE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING .,I. V. SET(ONEFLON)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,EXTENSION TUBE(SOFTCATHE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED/TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS,EXTENSION TUBE (ONEFLON)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS., I. V. SET(SOFTCATHE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.
3135	MFG/MD/2018/000088	1.License Holder Name: REEVAX PHARMA PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:WOUND CLOSURE DEVICE (XION, GESIKA, DESIDRAPE,VETCRYL,OPTIKA, TRUSEAL AND TOPOCRYL)-WOUND CLOSURE DEVICE IS INDICATED FOR SOFT TISSUE APPROXIMATION. TOPICAL APPLICATION TO HOLD CLOSED EASILY APPROXIMATED SKIN EDGES OF MINIMUM-TENSION WOUNDS FROM CLEAN SURGICAL INCISIONS AND SIMPLE, THOROUGHLY CLEANSED, TRAUMA-INDUCED LACERATIONS.
3136	MFG/MD/2018/000089	1.License Holder Name: LEELAVATHY MEDICAL DEVICES COMPANY 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:STERILE TWO WAY SILICONE FOLEY CATHETER-STERILE TWO WAY SILICONE FOLEY CATHETER IS A URINARY CATHETER INTENDED FOR BEING INTRODUCED THROUGH THE URETHRA IN ORDER TO PROVIDE DRAINAGE OF THE BLADDER. THE PRODUCT IS INTENDED FOR SINGLE USE ONLY.

3137	MFG/MD/2018/000090	1.License Holder Name: ADAPTIVE OCULAR SCIENCES PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:HYDROPHYLIC ACRYLIC LENSES(ADTEC)-THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING SUCCESSFUL CATARACTOUS LENS EXTRACTION WITH A VERIFIED ABSENCE OF RADIAL TEARS PERFORMED BY AN OPHTHALMOLOGIST DURING CAPSULOTOMY. ADTEC IOLS ARE INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN PERSONS 55 YEARS OF AGE OR OLDER IN WHOM THE CATARACTOUS LENS HAS BEEN REMOVED BY PHACO EMULSIFICATION CATARACT EXTRACTION,HYDROPHOBIC ACRYLIC LENSES(ALPRO)-THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING SUCCESSFUL CATARACTOUS LENS EXTRACTION WITH A VERIFIED ABSENCE OF RADIAL TEARS PERFORMED BY AN OPHTHALMOLOGIST DURING CAPSULOTOMY. ALPRO IOLS ARE INDICATED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN PERSONS 55 YEARS OF AGE OR OLDER IN WHOM THE CATARACTOUS LENS HAS BEEN REMOVED BY PHACO EMULSIFICATION CATARACT EXTRACTION
3138	MFG/MD/2018/000091	1.License Holder Name: U. S. DIAGNOSTICS 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:AGGLUTINATION SERA REAGENT OF HCG FOR DETECTION OF PREGNANCY(NEW BABY)-QUICK IMMUNO-ASSAY TEST KIT FOR DETECTION OF HCG IN URINE FOR DETERMINATION OF PREGNANCY

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3139	MFG/MD/2018/000092	1.License Holder Name: S M HEALTH CARE PRODUCTS PVT LTD 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:ENDOSCOPIC LIGATION DEVICE(INNOWIZ)-IT IS USED FOR PROXIMAL AND DISTAL LIGATION OF VESSELS DURING ENDOSCOPIC VESSEL HARVESTING PROCEDURES.,TUBING SET(INNOWIZ)-USED DURING THE PROCEDURE OF HEMODIALYSIS, RENAL REPLACEMENT THERAPY AND FOR BLOOD TRANSFUSION AND SPECIALIZED USAGES AS PER THE MANUFACTURER OF THE MACHINE.,BILIARY STONE RETRIEVAL BASKET(INNOWIZ)-INTEND TO EXTRACT STONES IN AN ANTEGRADE FASHION THROUGH AN AMPULLARY ORIFICE PREVIOUSLY TREATED BY ENDOSCOPIC SPHINCTEROTOMY OR LESS COMMONLY WITH BALLOON DILATION.,GUIDE WIRE(INNOWIZ)-USED FOR DIRECTING THE CATHETER FOR REQUIRED SITE.,URETHRAL CATHETER/NELATON CATHETER/FOLEY CATHETER(INNOWIZ)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETHRA, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,NEEDLE(INNOWIZ)-USED FOR GUIDING / INITIATING THE DIAGNOSTIC/ INITIATING THE PROCEDURE.

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3140	MFG/MD/2018/000093	1.License Holder Name: HARSORIA HEALTHCARE PVT LTD UNIT-2 2.Approving Authority: SOLAN(BBN) 3.Device Name(Brand Name)-Intended Use:I.V. CANNULA (INPHARVEN, FORTUNE MEDICAL)-I.V. CANNULA IS A PASSIVE DEVICES TO PROVIDE FOR INFUSION OF FLUIDS, DRUGS ,AND/OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,A.V.FISTULA NEEDLE(HARSORIA)-TO CONNECT BLOOD LINE WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT ,THREE WAY STOP COCK (ADRIAMED)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, THREE WAY STOP COCK(HARSORIA)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,I.V.CANNULA(HEALFLON)-THE I.V. CANNULA IS A PASSIVE DEVICES TO PROVIDE TO FOR INFUSION OF FLUIDS, DRUGS , AND/OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,VESSEL DIALATOR FOR PRECUTANEOUS CATHETERIZATION(HARSORIA)-A VESSEL DIALATOR FOR PERCUTANEOUS CATHERTERIZATION IS A DEVICE WHICH IS PLACED OVER THE GUIDE WIRE TO ENLARGE THE OPENING IN THE VESSEL, AND WHICH IS THEN REMOVED BEFORE SLIDING THE CATHETER OVER THE GUIDE WIRE ,I.V. FLOW REGULATOR(HARSORIA) -AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY,EXTENSION TUBE(HARSORIA)- EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUID/MEDICATIONS IN MEDICAL APPLICATION ,HEMODIALYSIS CATHETER(HARSORIA)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT

3141	MFG/MD/2018/000098	1.License Holder Name: DEGANIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:SILICONE FOLEY CATHETER THREE WAY SUPRAPUBIC(SAYCO)-DRAINAGE OF URINE, ROUND, HUBLESS BLAKE™ SILICONE DRAIN. REORDER # 2227, 2229, 2231, 2232 & 2233.-DRAINS FOR EJECTION OF PUS / WASTES FROM WOUND. DRAINS ARE OF DIFFERENT SIZE AND SHAPE. TROCAR IS FOR PIERCING THE BODY TO DRAW THE DRAIN THROUGH WOUND ., FOLEY CATHETER(AQUARIUS MEDICAL)-DRAINAGE OF URINE,BLAKE CARDIO CONNECTOR REORDER # BCC1-1:1, BCC2-2:1 BCC3-3:1-ATTACHED TO END OF DRAIN PIPE FOR MULTIPLE CONNECTIONS. THE PORT OF CONNECTIONS MAY BE FOR MEDICATION PORT, SUCTION BULB PORT / INJECTION OF STERILE WATER FOR WASHING OF WOUND .,FOLEY CATHETER(DE ROYAL)-DRAINAGE OF URINE,FLAT ,FLUTED BLAKE™ SILICONE DRAIN KIT + J-VAC RESERVOIR + ADAPTER . REF # 2205, 2207, 2213 & 2238-DRAINS FOR EJECTION OF PUS / WASTES FROM WOUND. DRAINS ARE OF DIFFERENT SIZE AND SHAPE. KIT CONTAINS SUCTION BULB FOR SUCTION OF PUS ETC. ADAPTER IS USED TO CONNECT SUCTION BULB WITH DRAIN PIPES., SILICONE FOLEY CATHETER THREE WAY IRRIGATION(ENTRACARE)-DRAINAGE OF URINE,FLAT ,FLUTED BLAKE™ SILICONE DRAIN. REORDER # 2210, 2211, 2213 & 2214-DRAINS FOR EJECTION OF PUS / WASTES FROM WOUND. DRAINS ARE OF DIFFERENT SIZE AND SHAPE, FOLEY CATHETER(CARDINAL HEALTH)-DRAINAGE OF URINE,STERILE MERCIER THREE WAY IRRIGATION / FOLEY CATHETER BLUE LINE FOR SINGLE USE ONLY.-DRAINAGE OF URINE,SILICONE FOLEY CATHETER THREE WAY IRRIGATION(UNOMED AUSTRALIA)-DRAINAGE OF URINE, J-VAC™ DRAIN ADAPTER REORDER # 2209, 2298 & 2199-ADAPTER IS USED TO CONNECT SUCTION BULB WITH DRAIN PIPES.,FOLEY CATHETER(AMEVISA SUMINISTROS CLINICOS)-DRAINAGE OF URINE, DUFOUR THREE WAY IRRIGATION / FOLEY CATHETER BLUE LINE FOR SINGLE USE ONLY(BIOMETRIX)-DRAINAGE OF URINE,SILICONE FOLEY CATHETER THREE WAY MERCIER(PROMEPLA)-DRAINAGE OF URINE, STERILE THREE WAY IRRIGATION CATHETER BLUE LINE FOR SINGLE USE ONLY-DRAINAGE OF URINE,SILICONE FOLEY CATHETER THREE WAY NELATON(PROMEPLA)-DRAINAGE OF URINE,STERILE CAUVELAIRE THREE WAY IRRIGATION / FOLEY CATHETER BLUE LINE FOR SINGLE USE ONLY.-DRAINAGE OF URINE,GASTROSTOMY TUBE CATHETERS(BIOMETRIX)-A TUBE INSERTED THROUGH THE ABDOMEN THAT DELIVERS NUTRITION DIRECTLY TO THE STOMACH,MERCIER THREE WAY IRRIGATION / FOLEY CATHETER BLUE LINE FOR SINGLE USE ONLY(BIOMETRIX)-DRAINAGE OF URINE,FOLEY CATHETER (HALTIJA GROUP)-DRAINAGE OF URINE,STERILE DUFOUR THREE WAY IRRIGATION / FOLEY CATHETER BLUE LINE FOR SINGLE USE

	ONLY.-DRAINAGE OF URINE,GASTROSTOMY TUBE CATHETERS (MEDICINA)-A TUBE INSERTED THROUGH THE ABDOMEN THAT DELIVERS NUTRITION DIRECTLY TO THE STOMACH,CAUVELAIRE THREE WAY IRRIGATION / FOLEY CATHETER BLUE LINE FOR SINGLE USE ONLY(BIOMETRIX)-DRAINAGE OF URINE,FOLEY CATHETER(C R BARD)-DRAINAGE OF URINE,THREE WAY IRRIGATION / FOLEY CATHETER BLUE TIP FOR SINGLE USE ONLY(BIOMETRIX)-DRAINAGE OF URINE,FOLEY CATHETER(MEDLINE)-DRAINAGE OF URINE,STERILE SOFT FOLEY LIGHT BLUE LINE UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY.(PFM)-DRAINAGE OF URINE,GASTROSTOMY TUBE CATHETERS(DANUMED)-A TUBE INSERTED THROUGH THE ABDOMEN THAT DELIVERS NUTRITION DIRECTLY TO THE STOMACH,STERILE SILICONE GASTROSTOMY TUBE CATHETER 2 WAY WITH EN FIT FOR SINGLE USE ONLY.(NESTLE DEUTCH)-DRAINAGE OF URINE, GASTROSTOMY TUBE CATHETERS(DYNAREX)-A TUBE INSERTED THROUGH THE ABDOMEN THAT DELIVERS NUTRITION DIRECTLY TO THE STOMACH,MERCIER THREE WAY BLUE LINE IRRIGATION CATHETER FOR SINGLE USE ONLY.(UROTECH)-DRAINAGE OF URINE, GASTROSTOMY TUBE CATHETERS(DEGANIA)-A TUBE INSERTED THROUGH THE ABDOMEN THAT DELIVERS NUTRITION DIRECTLY TO THE STOMACH,STERILE RECTAL SILICONE CATHETER FOR SINGLE USE ONLY-DRAINAGE OF URINE,FOLEY CATHETER(MEDLINE)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER WITH BALLOON, TWO WAY FUNNEL, FOR SINGLE USE ONLY .-DRAINAGE OF URINE,GASTROSTOMY TUBE CATHETERS(VESCO)-A TUBE INSERTED THROUGH THE ABDOMEN THAT DELIVERS NUTRITION DIRECTLY TO THE STOMACH,SILICONE UROLOGICAL FOLEY NELATON CATHETER FOR SINGLE USE ONLY.-DRAINAGE OF URINE,SILICONE FOLEY CATHETER THREE WAY IRRIGATION(WOLFE TORY MED)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.-DRAINAGE OF URINE,FOLEY CATHETER(CARDINAL)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY TEMPERATURE SENSOR CATHETER, 3 WAY, FOR SINGLE USE ONLY-DRAINAGE OF URINE,GASTROSTOMY TUBE CATHETERS(MEDLINE)-A TUBE INSERTED THROUGH THE ABDOMEN THAT DELIVERS NUTRITION DIRECTLY TO THE STOMACH,SILICONE UROLOGICAL FOLEY NELATON CATHETER FOR SINGLE USE ONLY-DRAINAGE OF URINE, SILICONE FOLEY CATHETER THREE WAY DUFOUR(PROMEPLA)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER, WITH BALLOON, 3 WAY FOR IRRIGATION & DRAINAGE, SINGLE USE.-DRAINAGE OF URINE,SILICONE FOLEY CATHETER THREE WAY COUVELAIRE(PROMEPLA)-DRAINAGE OF URINE,SILICONE UROLOGICAL (FEMALE) FOLEY CATHETER, 2 WAY FUNNEL, FOR SINGLE USE ONLY.-DRAINAGE OF URINE,FOLEY CATHETER(COVIDIEN

	)-DRAINAGE OF URINE,SILICON UROLOGICAL (FOLEY) THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY.-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER LSP DARK BLUE LINE(URONOVIS 100%)-DRAINAGE OF URINE,SILICONE FOLEY CATHETER WITH BALLOON, TWO WAY FUNNEL AND NELATON TIP, FOR SINGLE USE ONLY-DRAINAGE OF URINE,SILICONE FOLEY CATHETER THREE WAY SUPRA SIL(TYCO)-DRAINAGE OF URINE, SILICONE UROLOGICAL FOLEY THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY.-DRAINAGE OF URINE,SILICONE FOLEY CATHETER THREE WAY DUFOUR(DANUMED)-DRAINAGE OF URINE,SILICONE FOLEY CATHETER WITH BALLOON, TWO WAY FUNNEL AND NELATON TIP, FOR SINGLE USE ONLY-DRAINAGE OF URINE,SILICONE FOLEY CATHETER THREE WAY IRRIGATION (UNOMEDICAL SDN. BHD.)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER, 2 WAY FOR SINGLE USE ONLY.-DRAINAGE OF URINE,GASTROSTOMY TUBE CATHETERS(MEDILIME)-A TUBE INSERTED THROUGH THE ABDOMEN THAT DELIVERS NUTRITION DIRECTLY TO THE STOMACH,STERILE/ NON STERILE G TUBE CATHETER FOR SINGLE USE ONLY(NUTRICIA/FLOCARE)-DRAINAGE OF URINE,STERILE/ NON STERILE SILICONE UROLOGICAL FOLEY CATHETER WITH TIEMANN TIP FOR SINGLE USE ONLY(BARD)-DRAINAGE OF URINE,STERILE/ NON STERILE SILICONE UROLOGICAL FOLEY CATHETER TWO WAY FOR SINGLE USE ONLY(BARD)-DRAINAGE OF URINE,STERILE/ NON STERILE SILICONE UROLOGICAL FOLEY CATHETER TWO WAY FOR SINGLE USE ONLY(ISZA HOSPITAL)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER, PAEDIATRIC, 2 WAY, FOR SINGLE USE ONLY-DRAINAGE OF URINE, STERILE SOFT FOLEY NATURAL BLUE LINE UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY(PFM)-DRAINAGE OF URINE, UROLOGICAL (FOLEY) THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY-DRAINAGE OF URINE & TEMP. SENSING OF BODY PART,STERILE SUPRAPUBIC 420 SOFT UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY.(PFM)-DRAINAGE OF URINE, STERILE SUPRAPUBIC BLUE LINE UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY.(PFM)-DRAINAGE OF URINE,NON STERILE SOFT FOLEY NATURAL BLUE LINE UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY.(PFM)-DRAINAGE OF URINE,NON STERILE SILICONE SP PIG TAIL BBM UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY.(B BRAUN)-DRAINAGE OF URINE,NON STERILE SILICONE STRAIGHT CYST INTEGRAL CONSIGN UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY.(B BRAUN)-DRAINAGE OF URINE,STERILE RECTAL SILICONE CATHETER FOR SINGLE USE ONLY.(HOSPIMED (65MM))-PASSAGE OF STOOL,STERILE SILICONE GASTROSTOMY TUBE CATHETER WITH EN FIT 2- WAYS FOR SINGLE USE ONLY.(NESTLE

	HEALTH SCIENCE)-FEEDING/ MEDICATION TUBE,STERILE SILICONE GASTROSTOMY TUBE CATHETERS 2- WAY WITH EN FIT FOR SINGLE USE ONLY.(NUTRICIA NV)-FEEDING/ MEDICATION TUBE,NON STERILE NEPHROSTOMY BBM NATURAL UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY.(B BRAUN)-DRAINAGE OF MEDICAL DEVICE, ROUND, HUBLESS BLAKE™ SILICONE DRAIN. REORDER # 2226, 2228, 2230 & 2234-DRAINS FOR EJECTION OF PUS / WASTES FROM WOUND. DRAINS ARE OF DIFFERENT SIZE AND SHAPE,STERILE THREE WAY IRRIGATION / FOLEY CATHETER BLUE LINE FOR SINGLE USE ONLY.(AQUARIUS)-DRAINAGE OF URINE,FLAT ,FLUTED BLAKE™ SILICONE DRAIN + TROCAR (STIFF OR BENDABLE). REORDER # 2212, 2215, 2216 & 2217-DRAINS FOR EJECTION OF PUS / WASTES FROM WOUND. DRAINS ARE OF DIFFERENT SIZE AND SHAPE. TROCAR IS FOR PIERCING THE BODY TO DRAW THE DRAIN THROUGH WOUND , ROUND, HUBLESS BLAKE™ SILICONE DRAINS KIT + TROCAR (STIFF OR BENDABLE) + J-VAC RESERVOIR + ADAPTER. REF # 2268-DRAINS FOR EJECTION OF PUS / WASTES FROM WOUND. DRAINS ARE OF DIFFERENT SIZE AND SHAPE. KIT CONTAINS SUCTION BULB FOR SUCTION OF PUS ETC. ADAPTER IS USED TO CONNECT SUCTION BULB WITH DRAIN PIPES.,SILICONE UROLOGICAL FOLEY CATHETER WITH BALLOON, TWO WAY FUNNEL, FOR SINGLE USE ONLY.(MEDLINE)-DRAINAGE OF URINE,SILICONE UROLOGY FOLEY CATHETERS FOR SINGLE USE ONLY(CR BARD)-DRAINAGE OF URINE,MERCIER THREE WAY IRRIGATION / FOLEY CATHETER WHITE LINE FOR SINGLE USE ONLY(ROCAMED)-DRAINAGE OF MEDICAL DEVICE,STERILE THREE WAY IRRIGATION / FOLEY CATHETER BLUE TIP FOR SINGLE USE ONLY(MEDLINE)-DRAINAGE OF URINE,DUFOUR THREE WAY IRRIGATION / FOLEY CATHETER WHITE LINE FOR SINGLE USE ONLY. (ROCAMED)-DRAINAGE OF URINE,THREE WAY IRRIGATION / FOLEY CATHETER WHITE LINE FOR SINGLE USE ONLY(ROCAMED)-DRAINAGE OF URINE,CAUVELAIRE THREE WAY IRRIGATION / FOLEY CATHETER WHITE LINE FOR SINGLE USE ONLY(ROCAMED)-DRAINAGE OF URINE, STERILE THREE WAY IRRIGATION / FOLEY CATHETER WHITE LINE FOR SINGLE USE ONLY.(RUSCH TELEFLEX)-DRAINAGE OF URINE, TIEMANN IRRIGATION / FOLEY CATHETER FOR SINGLE USE ONLY. (UROVISION)-DRAINAGE OF URINE,STERILE CAUVELAIRE THREE WAY WHITE LINE IRRIGATION / FOLEY CATHETER FOR SINGLE USE ONLY (RUSCH TELEFLEX)-DRAINAGE OF URINE,MERCIER TWO WAY BLUE / GREEN LINE IRRIGATION / FOLEY CATHETER FOR SINGLE USE ONLY. (UROVISION)-DRAINAGE OF URINE,MERCIER THREE WAY BLUE / GREEN LINE IRRIGATION / FOLEY CATHETER FOR SINGLE USE ONLY (UROVISION)-DRAINAGE OF URINE,STERILE MERCIER THREE WAY WHITE LINE IRRIGATION / FOLEY CATHETER FOR SINGLE USE ONLY (RUSCH TELEFLEX)-DRAINAGE OF URINE,STERILE DUFOUR THREE

	WAY WHITE LINE IRRIGATION / FOLEY CATHETER FOR SINGLE USE ONLY(RUSCH TELEFLEX)-DRAINAGE OF URINE,THREE WAY BLUE / GREEN LINE IRRIGATION / FOLEY CATHETER BLUE LINE FOR SINGLE USE ONLY(UROVISION)-DRAINAGE OF URINE,STERILE CAUVELAIRE THREE WAY WHITE LINE IRRIGATION / FOLEY CATHETER FOR SINGLE USE ONLY(UROVISION)-DRAINAGE OF URINE,STERILE MERCIER THREE WAY WHITE LINE IRRIGATION / FOLEY CATHETER FOR SINGLE USE ONLY(UROVISION)-DRAINAGE OF URINE,STERILE DUFOUR THREE WAY WHITE LINE IRRIGATION / FOLEY CATHETER FOR SINGLE USE ONLY(UROVISION)-DRAINAGE OF URINE,STERILE MERCIER THREE WAY IRRIGATION / FOLEY CATHETER BLUE LINE FOR SINGLE USE ONLY(AQUARIUS)-DRAINAGE OF URINE,J-VAC™ RESERVIOR (BULB SUCTION) 100CC REF #2160-RESERVOIR IS USED FOR SUCTION OF PUS FROM WOUND WITH THE AID OF DRAIN TUBE.,CAUVELAIRE THREE WAY BLUE / GREEN LINE IRRIGATION CATHETER FOR SINGLE USE ONLY.(UROVISION)-DRAINAGE OF URINE,CAUVELAIRE TWO WAY BLUE / GREEN LINE IRRIGATION CATHETER FOR SINGLE USE ONLY. (UROVISION)-DRAINAGE OF URINE,STERILE DOVER COUNCILL TWO WAY IRRIGATION CATHETER FOR SINGLE USE ONLY.(DOVER COVIDIEN USA)-DRAINAGE OF URINE,DUFOUR THREE WAY BLUE / GREEN LINE IRRIGATION CATHETER FOR SINGLE USE ONLY (UROVISION)-DRAINAGE OF URINE,DUFOUR TWO WAY BLUE / GREEN LINE IRRIGATION / FOLEY CATHETER FOR SINGLE USE ONLY. (UROVISION)-DRAINAGE OF URINE,DOVER COUNCILL TWO WAY IRRIGATION CATHETER FOR SINGLE USE ONLY(DOVER COVIDIEN USA)-DRAINAGE OF URINE,IRRIGATION / FOLEY CATHETER BLUE LINE FOR SINGLE USE ONLY.(UROVISION)-DRAINAGE OF URINE, THREE WAY BLUE LINE IRRIGATION CATHETER FOR SINGLE USE ONLY.(UROTECH)-DRAINAGE OF URINE,COUVELAIRE THREE WAY BLUE LINE IRRIGATION CATHETER FOR SINGLE USE ONLY(UROTECH) -DRAINAGE OF URINE,STERILE DUFOUR THREE WAY BLUE LINE IRRIGATION CATHETER FOR SINGLE USE ONLY(URIMED CATH B|BRAUN)-DRAINAGE OF URINE,DUFOUR THREE WAY BLUE LINE IRRIGATION CATHETER FOR SINGLE USE ONLY(UROTECH)-DRAINAGE OF URINE,STERILE DOVER BLUE LINE IRRIGATION CATHETER FOR SINGLE USE ONLY.(DOVER COVIDIEN USA)-DRAINAGE OF URINE, STERILE DUFOUR THREE WAY IRRIGATION / FOLEY CATHETER BLUE LINE FOR SINGLE USE ONLY(AQUARIUS)-DRAINAGE OF URINE, STERILE CAUVELAIRE THREE WAY IRRIGATION / FOLEY CATHETER BLUE LINE FOR SINGLE USE ONLY(AQUARIUS)-DRAINAGE OF URINE, STERILE DOVER TWO L. WAY BLUE LINE IRRIGATION CATHETER FOR SINGLE USE ONLY.(DOVER COVIDIEN USA)-DRAINAGE OF URINE, SILICON UROLOGICAL (FOLEY) THREE WAY THERMISTOR SENSOR CATHETER SINGLE USE ONLY.(ABLEXAN CORPORATION)-DRAINAGE

	OF URINE & TEMP. SENSING OF BODY PART,SILICONE GASTROSTOMY TUBE CATHETER FOR SINGLE USE ONLY-DRAINAGE OF URINE, UROLOGY FOLEY CATHETER -2 WAY COUNCILL TIP WITH WHITE LINE FOR SINGLE USE ONLY-DRAINAGE OF URINE,UROLOGICAL INCONTINENCE FEMALE FOLEY CATHETER FOR SINGLE USE ONLY -DRAINAGE OF URINE,SILICONE RECTAL CATHETER FOR SINGLE USE ONLY-DRAINAGE OF STOOL,UROLOGICAL INCONTINENCE MALE FOLEY CATHETER FOR SINGLE USE ONLY.-DRAINAGE OF URINE, STERILE LSP BLUE LINE UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY.(PFM)-DRAINAGE OF URINE,SILICONE GASTROSTOMY TUBE CATHETERS FOR SINGLE USE ONLY(NUTRICIA NV)-FEEDING /MEDICATION TUBE,STERILE SUPRAPUBIC BLUE LINE UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY.(PFM)-DRAINAGE OF URINE, SILICONE UROLOGICAL (FOLEY) THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY-DRAINAGE OF URINE,STERILE/ NON STERILE SILICONE COUNCIL UROLOGY FOLEY CATHETER 2-WAY FOR SINGLE USE ONLY.(DOVER COVIDIEN USA)-DRAINAGE OF URINE,NON STERILE SILICONE, IRRIGATION UROLOGY FOLEY CATHETER GOLD TIP WITH FOR SINGLE USE ONLY.(COVIDIEN KENMEX)-DRAINAGE OF URINE,UROLOGICAL FOLEY CATHETER, WITH BALLOON 2 WAY, TIEMANN TIP, FOR SINGLE USE ONLY-DRAINAGE OF URINE,STERILE/ NON STERILE SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY(BARD)-DRAINAGE OF URINE, STERILE/ NON STERILE SILICONE UROLOGICAL FOLEY CATHETER TWO WAY FOR SINGLE USE ONLY(ISZA HOSPITAL)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(SIR)-DRAINAGE OF URINE,STERILE LSP BLUE LINE UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY.(PFM)-DRAINAGE OF URINE, STERILE SILICONE UROLOGY IRRIGATION FOLEY CATHETER LIGHT BLUE FOR SINGLE USE ONLY.(DOVER COVIDIEN USA)-DRAINAGE OF URINE,STERILE DUFOUR 3 WAY BLUE LINE UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY.(B BRAUN)-DRAINAGE OF URINE, NON STERILE SILICONE SUPRAPUBIC BBM UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY(B BRAUN)-DRAINAGE OF URINE, SILICONE UROLOGY FOLEY CATHETERS FOR SINGLE USE ONLY(PFM)-DRAINAGE OF URINE,SILICONE UROLOGY FOLEY CATHETERS FOR SINGLE USE ONLY(B BRAUN)-DRAINAGE OF URINE,SILICONE GASTROSTOMY TUBE CATHETERS FOR SINGLE USE ONLY(NUTRICIA NV)-FEEDING /MEDICATION TUBE,SILICONE UROLOGY FOLEY CATHETERS FOR SINGLE USE ONLY(DOVER COVIDIEN USA)-DRAINAGE OF URINE,SILICONE GASTROSTOMY TUBE CATHETERS FOR SINGLE USE ONLY(NUTRICIA NV)-FEEDING /MEDICATION TUBE, SILICONE UROLOGY FOLEY CATHETERS FOR SINGLE USE ONLY (DOVER COVIDIEN USA)-DRAINAGE OF URINE,SILICONE UROLOGICAL

	FOLEY CATHETER FOR SINGLE USE ONLY.(HUIKESHOVEN)-DRAINAGE OF URINE,SILICONE UROLOGY FOLEY CATHETERS FOR SINGLE USE ONLY(DOVER COVIDIEN)-DRAINAGE OF URINE,SILICONE UROLOGY FOLEY CATHETERS FOR SINGLE USE ONLY(DOVER COVIDIEN USA)-DRAINAGE OF URINE,SILICONE UROLOGY FOLEY CATHETERS FOR SINGLE USE ONLY(COVIDIEN KENMEX)-DRAINAGE OF URINE,SILICONE UROLOGY FOLEY CATHETERS FOR SINGLE USE ONLY(COVIDIEN KENMEX)-DRAINAGE OF URINE,STERILE SILICONE GASTROSTOMY TUBE CATHETERS 2 WAY NATURAL FOR SINGLE USE ONLY(NUTRICIA NV)-FEEDING /MEDICATION TUBE,UROLOGICAL INCONTINENCE MALE CATHETER FOR SINGLE USE ONLY.(OPTICON)-DRAINAGE OF URINE,STERILE DUFOUR 3 WAY BLUE LINE UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY(B BRAUN)-DRAINAGE OF URINE,SILICONE UROLOGY FOLEY CATHETERS FOR SINGLE USE ONLY(COVIDIEN KENMEX)-DRAINAGE OF URINE,SILICONE UROLOGY FOLEY CATHETERS FOR SINGLE USE ONLY(CR BARD)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER WITH BALLOON, TWO WAY FUNNEL, FOR SINGLE USE ONLY.(INWAY)-DRAINAGE OF URINE,UROLOGICAL (FOLEY) THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY.(COVIDIEN/DSL)-DRAINAGE OF URINE & TEMP. SENSING OF BODY PART.,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(ITALMEDIA)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(JOIN MEDICAL SRO)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(PAT COAKLEY)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(PORGES)-DRAINAGE OF URINE, STERILE RECTAL SILICONE CATHETER FOR SINGLE USE ONLY. (HOSPIMED (65MM))-DRAINAGE OF STOOL,STERILE RECTAL SILICONE CATHETER FOR SINGLE USE ONLY.(B. BRAUN)-PASSAGE OF STOOL, SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY. (ICET)-DRAINAGE OF URINE,SILICONE UROLOGY FOLEY CATHETERS FOR SINGLE USE ONLY(B BRAUN)-DRAINAGE OF URINE,SILICONE UROLOGY FOLEY CATHETERS FOR SINGLE USE ONLY(COVIDIEN KENMEX)-DRAINAGE OF URINE,STERILE LSP 330 BLUE LINE UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY.(PFM)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(UNOMEDICAL AUSTRALIA)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(EMIL PHARMA)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER WITH BALLOON, TWO WAY FUNNEL, FOR SINGLE USE ONLY.(SILSTAR SCHWARZ PHARMA)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER WITH BALLOON, TWO WAY FUNNEL, FOR SINGLE USE ONLY.(BLUE STAR/SCHWARZ PHARMA)-DRAINAGE

	OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(COVALON)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY(SOLOTION MEDICAL CARE) -DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER WITH BALLOON, TWO WAY FUNNEL, FOR SINGLE USE ONLY.(SILSTAR SCHWARZ PHARMA)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(UROVISION (220MM 270MM))-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY(UNOMEDICAL MALAYSIA)- DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(EZEM/AVAIL)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY NELATON CATHETER FOR SINGLE USE ONLY. (AMEVISA SUMINISTROS CLINICOS)-DRAINAGE OF URINE,STERILE/ NON STERILE SILICONE G TUBE / ENFIT CATHETER TWO WAY FOR SINGLE USE ONLY(ISZA HOSPITAL)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(UROKINK)- DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(TOP (ENTRA CARE))-DRAINAGE OF URINE, SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY. (UROVISION)-DRAINAGE OF URINE,UROLOGICAL INCONTINENCE FEMALE CATHETER FOR SINGLE USE ONLY.(OPTICON)-DRAINAGE OF URINE,SILICONE UROLOGICAL (FOLEY) THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY.(CURITY / TYCO HEALTHCARE (DE))-DRAINAGE OF URINE,SILICONE UROLOGICAL (FOLEY) THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY.(DEGANIA/DEGANIA SILICONE)-DRAINAGE OF URINE, SILICONE UROLOGICAL (FOLEY) THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY.(DEGANIA/DEGANIA SILICONE)- DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(RUSCH MALAYSIA)-DRAINAGE OF URINE, SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY (EURO-MEDICAL)-DRAINAGE OF URINE,UROLOGICAL (FOLEY) THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY. (CURITY / TYCO HEALTHCARE (DE))-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY.(CURITY / TYCO HEALTHCARE (DE))- DRAINAGE OF URINE,SILICONE UROLOGICAL (FOLEY) THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY. (DEGANIA/DEGANIA SILICONE)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY.(DE-ROYAL)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY.(NON LOGO/DE-ROYAL IND)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY THREE WAY THERMISTOR

	SENSOR CATHETER FOR SINGLE USE ONLY.(DE-ROYAL)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY.(DE-ROYAL)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY NELATON CATHETER FOR SINGLE USE ONLY.(URONOVIS / (UI/UL))-DRAINAGE OF URINE, SILICONE UROLOGICAL FOLEY THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY(DE-ROYAL)-DRAINAGE OF URINE, SILICONE UROLOGICAL FOLEY THREE WAY THERMISTOR SENSOR CATHETER FOR SINGLE USE ONLY.(NON LOGO/DE-ROYAL IND)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(SECUR DRAIN)-DRAINAGE OF URINE.,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY. (KSB/MEDICOPLAST)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(ALPO)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(URONOVIS)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(MPI/MEDICOPLAST)-DRAINAGE OF URINE.,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY(UROTECH)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY (DAHLHAUSEN / MEDIZIN)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(MEDLINE®)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY(ADHE - ELE / DSE)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETERS FOR SINGLE USE ONLY(DOVER / TYCO)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY(DEGANIA/DEGANIA SILICONE)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY (RUSCH)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY(NORTA BSN) -DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(AQUARIUS)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(SECURMED)-DRAINAGE OF URINE.,SILICONE UROLOGICAL FOLEY CATHETER FOR SINGLE USE ONLY.(HOYER)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY TEMPERATURE SENSOR CATHETER, 3 WAY, FOR SINGLE USE ONLY(DOVER COVIDIEN)-DRAINAGE OF URINE,SILICONE FOLEY CATHETER WITH BALLOON, TWO WAY FUNNEL AND TIEMANN TIP, FOR SINGLE USE ONLY(URIMED® / B BRAUN)-DRAINAGE OF URINE,SILICONE FOLEY CATHETER WITH BALLOON, THREE WAY FUNNEL AND DUFOUR TIP, FOR SINGLE USE ONLY(URIMED® / B BRAUN)-DRAINAGE OF URINE,SILICONE FOLEY CATHETER WITH BALLOON, TWO WAY FUNNEL AND NELATON TIP, FOR SINGLE USE ONLY(URIMED® / B BRAUN)-DRAINAGE OF URINE,STERILE DUFOUR 3

		WAY BLUE LINE UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY. (B BRAUN)-DRAINAGE OF URINE,UROLOGICAL FOLEY CATHETER, WITH BALLOON 2 WAY, TIEMANN TIP, SINGLE USE, FOR SINGLE USE ONLY(DOVER COVIDIEN)-DRAINAGE OF URINE,NON STERILE SILICONE, UROLOGY FOLEY CATHETER -2 WAY COUNCIL WITH WHITE LINE FOR SINGLE USE ONLY.(CR BARD)-DRAINAGE OF URINE,STERILE SILICONE GASTROSTOMY TUBE CATHETER 2 WAY FOR SINGLE USE ONLY.(NESTLE DEUTCH)-FEEDING /MEDICATION TUBE,STERILE DUFOUR 3 WAY BLUE LINE UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY.(B BRAUN)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER, WITH BALLOON, 3 WAY FOR IRRIGATION & DRAINAGE, SINGLE USE.(DOVER COVIDIEN)-DRAINAGE OF URINE, STERILE DUFOUR 3 WAY BLUE LINE UROLOGY FOLEY CATHETER FOR SINGLE USE ONLY.(B BRAUN)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER, 2 WAY FOR SINGLE USE ONLY. (DOVER COVIDIEN)-DRAINAGE OF URINE,SILICONE UROLOGICAL (FEMALE) FOLEY CATHETER, 2 WAY FUNNEL, FOR SINGLE USE ONLY (DOVER COVIDIEN)-DRAINAGE OF URINE,SILICONE UROLOGICAL FOLEY CATHETER, PAEDIATRIC, 2 WAY, FOR SINGLE USE ONLY (DOVER COVIDIEN)-DRAINAGE OF URINE,SILICONE FOLEY CATHETER WITH BALLOON, THREE WAY FUNNEL AND DUFOUR TIP, FOR SINGLE USE ONLY-DRAINAGE OF URINE
3142	MFG/MD/2018/000099	1.License Holder Name: M/S.LAXMI GAUZE BANDAGE & TEXTILES 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:ROLLER BANDAGE-KEEP THE ROLLED PART OF THE BANDAGE ABOVE THE INJURY AND THE UNROLLED PART BELOW THE INJURY. BEGIN BY WRAPPING TWICE AROUND THE INJURY TO HOLD THE END IN PLACE. SECURE THE END OF THE BANDAGE IN PLACE WITH A TURN OF THE BANDAGE. WRAP THE BANDAGE AROUND THE BODY PART UNTIL THE DRESSING IS COMPLETELY COVERED AND THE BANDAGE EXTENDS SEVERAL INCHES BEYOND THE DRESSING,BANDAGE-KEEP THE ROLLED PART OF THE BANDAGE ABOVE THE INJURY AND THE UNROLLED PART BELOW THE INJURY. BEGIN BY WRAPPING TWICE AROUND THE INJURY TO HOLD THE END IN PLACE. SECURE THE END OF THE BANDAGE IN PLACE WITH A TURN OF THE BANDAGE. WRAP THE BANDAGE AROUND THE BODY PART UNTIL THE DRESSING IS COMPLETELY COVERED AND THE BANDAGE EXTENDS SEVERAL INCHES BEYOND THE DRESSING.

3143	MFG/MD/2018/000100	1.License Holder Name: DCL DENCARE INDIA PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE GRAFT(OSSOPRE)-INTENDED TO FILL AUGMENT,OR RECONSTRUCT PERIODONTAL OR BONY DEFECTS OF THE ORAL AND MAXILLOFACIAL REGION.,BONE CEMENT(OSSCHEM)-INTENDED FOR USE IN ARTHROPLASTIC PROCEDURE OF THE HIP, KNEE, AND OTHER JOINTS FOR THE FIXATION OF POLYMER OR METALLIC PROSTHETIC IMPLANTS TO LIVING BONE,ORTHOPAEDIC IMPLANT(XCEM ORTHO)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT,DENTAL IMPLANT(XCEM IMPLANT)-A DENTAL IMPLANT IS A SURGICAL COMPONENT THE INTERFACES WITH THE BONE OF THE JAW OR SKULL TO SUPPORT A DENTAL PROSTHESIS SUCH AS CROWN BRIDGE, DENTURE, FACIAL PROSTHESIS OR TO ACT AS AN ORTHODONTIC ANCHOR.
3144	MFG/MD/2018/000101	1.License Holder Name: MIV THERAPEUTICS (INDIA) PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:PRE-DILATATION BALLOON CATHETER (PTA)(DIRECT-X PTA 0.014''/0.018"/0.035" OTW PRE-DILATATION BALLOON CATHETER)-PTA PRE DILATATION CATHETER IS INTENDED FOR DILATATION OF LESIONS IN THE ILIAC, FEMORAL, POPLITEAL, INFRAPOPLITEAL, AND RENAL ARTERIES), PRE-DILATATION BALLOON CATHETER (PTA)(DIRECT-X PTA 0.014" RX PRE-DILATATION BALLOON CATHETER)-DIRECT-X PTA 0.014" RX PRE-DILATATION BALLOON CATHETER
3145	MFG/MD/2018/000103	1.License Holder Name: SHAILI ENDOSCOPY 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ESOPHAGEAL METAL STENT(NA)-ESOPHAGEAL METAL STENT USED TO TREAT TRACHEA ESOPHAGEAL FISTULAS AND EXPANSION TREATMENT OF THE ESOPHAGEAL STENOSIS CAUSED BY ESOPHAGEAL CARCINOMA, CHEMICAL INJURIES, CARDIAC CARCINOMA, ANASTOMATIC STENOSIS, AND OTHER TRAUMAS, WHICH ARE SURGICAL CONTRAINDICATED.,BILIARY STENT(NA)-BILIARY STENT IS USED TO DRAIN BILE FROM OBSTRUCTED BILIARY DUCT.,BILIARY METAL STENT(NA)-BILIARY METAL STENT IS USED FOR STENOSIS OR OBSTRUCTED BILIARY TRACT CAUSED BY BENIGN OR MALIGNANT CHANGES.

3146	MFG/MD/2018/000104	1.License Holder Name: ROMSONS SCIENTIFIC & SURGICAL PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:SNUGGERS SET(NIL)-DESIGNED FOR PUTTING PURSE-STRING SUTURES DURING CABG (CORONARY ARTERY BYPASS GRAFTING) SURGERY,GUIDEWIRE STRAIGHT AND J TIP (NA)-GUIDEWIRES ARE USED TO GUIDE CATHETER PRODUCTS TO A DESIRED TREATMENT LOCATION WITHIN THE BODY. THEY ARE TYPICALLY INSERTED INTO PATIENTS THROUGH A SMALL INCISION IN THE GROIN AND THEN MANEUVERED THROUGH ARTERIES AND VESSELS TO THE AREA OF VASCULAR DISEASE.,TRACHEOSTOMY TUBE(ROMSONS PERCUTANEOUS TRACHEOSTOMY KIT, ROMO-SOFT CUFF–DF)-INTENDED FOR PERCUTANEOUS DILATIONAL TRACHEOSTOMY FOR MANAGEMENT OF THE AIRWAY AND VENTILATION.,ANTIMICROBIAL COATED CENTRAL VENOUS CATHETER – KIT(CVC- ANTIBAC)-ADMINISTRATION OF SHORT/LONG TERM INTRAVENOUS THERAPY/PARENTERAL NUTRITION, FOR MONITORING OF CENTRAL VENOUS PRESSURE, FOR INTERMITTENT BLOOD SAMPLING. THE CVC – ANTIBAC CATHETER CONTAINS AN ANTIMICROBIAL AGENT WHICH MAY DESTROY OR INHIBIT THE GROWTH OF MICROORGANISMS ON BOTH THE INNER AND OUTER SURFACES OF THE CATHETER. THE ANTIMICROBIAL AGENT IS INTENDED TO REDUCE THE POSSIBILITY THAT THE CATHETER MAY BECOME MICROBIALLY COMPROMISED. THE ANTIMICROBIAL AGENT IS NOT INTENDED TO BE USED AS A TREATMENT FOR EXISTING INFECTIONS,TRACHEOSTOMY TUBE (ROMSONS PERCUTANEOUS TRACHEOSTOMY KIT, ROMO-SOFT CUFF–WDF)-INTENDED FOR PERCUTANEOUS DILATIONAL TRACHEOSTOMY FOR MANAGEMENT OF THE AIRWAY AND VENTILATION.,CENTRAL VENOUS CATHETER KIT(CENTRO)-ADMINISTRATION OF SHORT/LONG TERM INTRAVENOUS THERAPY/PARENTERAL NUTRITION, FOR MONITORING OF CENTRAL VENOUS PRESSURE, FOR INTERMITTENT BLOOD SAMPLING, CORRUGATED DRAINAGE SHEET(NIL)-IT IS DESIGNED FOR EFFICIENT MULTICHANNEL WOUND DRAINAGE ESPECIALLY WHERE AIRTIGHT CLOSURE OF WOUND IS NOT POSSIBLE.,CARDIOPLEGIA CANNULA (NIL)-CARDIOPLEGIA CANNULA IS USED TO DELIVER CARDIOPLEGIC SOLUTION DURING CARDIAC SURGERY.,ANTEGRADE CORONARY PERFUSION CANNULA(ACP CANNULA)-INTENDED TO BE CONNECTED TO THE CARDIOPLEGIA LINE IN ORDER TO INFUSE CARDIOPLEGIC SOLUTION,LEFT VENTRICULAR SUMP VENT CATHETER(ROMO VENTE) -ROMO VENTE USED DURING CARDIAC SURGERY FOR DECOMPRESSION OF THE LEFT VENTRICLE OF THE HEART TO PREVENT OVER-DISTENTION AND SUBSEQUENT TISSUE DAMAGE.

3147	MFG/MD/2019/000001	1.License Holder Name: MOI COTTON CARE INDUSTRIES 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.(NA)-SURGICAL DRESSING ; IT IS INTENDED TO SERVE AS MECHANICAL PROTECTION TO WOUNDS AND INJURED AREA ; TO ABSORB BLOOD, MUCUS OR PUS; USED IN THE DRESSING OF WOUNDS. IT IS USED FOR FIRST AID ALSO.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3148	MFG/MD/2019/000002	1.License Holder Name: LIFECARE SURGICALS 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:IV CANNULA(VSTAR DISPO IV CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND BLOOD COMPONENT OR TO FACILITATE THE PLACEMENT OF PERFUSION SET OR VASCULAR ACESS DEVICE. ,COTTON GAUGE AND BANDAGES (VSTAR DISPO COTTON GAUGE AND BANDAGE)-ADHESIVE BANDAGES, GAUGES BANDAGES , PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT BANDAGES,HYPODERMIC NEEDLE (VSTAR DISPO HYPODERMIC NEEDLE)-USED TO INJECT FLUIDS OR MEDICINES IN TO PATIENTS BODY DURING TREATMENT,TRADITIONAL HYPODERMIC SINGLE USE SYRINGE(VSTAR DISPO TRADITIONAL HYPODERMIC SINGLE USE SYRINGE)-INTENDED TO INJECT FLUIDS IN TO OR WITHDRAW FLUIDS FROM THE BODY,BLOOD ADMINISTRATION SET(VSTAR DISPO BLOOD ADMINISTRATION SET)-IT IS USED TO ADMINISTRATION OF BLOOD FROM A CONTAINER TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED, INFUSION SET MICRO DRIPPER(VSTAR DISPO INFUSION SET MICRO DRIPPER)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF SMALL VOLUMES FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE , INFUSION SET NON VENTED(VSTAR DISPO INFUSION SET NON VENTED)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,INFUSION SET REGULAR (VSTAR DISPO INFUSION SET REGULAR)-IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,AUTO-DISABLED (AD)IMMUNIZATION SYRINGES(VSTAR DISPO AUTO-DISABLED (AD)IMMUNIZATION SYRINGES)-INTENDED TO INJECT FLUIDS IN TO OR WITHDRAW FLUIDS FROM THE BODY, INFUSION SET VENTED(VSTAR DISPO INFUSION SET VENTED)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS IN TO PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO A VEIN

3149	MFG/MD/2019/000003	1.License Holder Name: MIRACLUS ORTHOTECH PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATES. (MIRACLUS)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY.PLATES ARE OF DIFFERENT TYPES WHICH USED IN DIFFERENT PARTS OF HUMAN BODY E.G. ONE THIRD TUBULAR PLATES ARE GENERALLY USED IN FOREARM BONES ALONG WITH CORTICAL & CANCELLOUS SCREWS, SMALL T – PLATES ARE GENERALLY USED IN LOWER END OF FOREARM BONE, MINI STRAIGHT PLATES ARE USED IN PHALANGEAL FRACTURES, AND MINI T & L PLATES ARE USED IN FRACTURES OF THE DISTAL OR PROXIMAL ENDS OF PHALANGES.,SPINAL IMPLANTS (MIRACLUS)-SPINAL IMPLANTS ARE USED IN THE SURGICAL PROCEDURES RELATED TO THE SPINAL INJURIES AND SPINAL DISEASES.,BONE PLATES(MIRACLUS)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PLATES ARE OF DIFFERENT TYPES WHICH USED IN DIFFERENT PARTS OF HUMAN BODY E.G. ONE THIRD TUBULAR PLATES ARE GENERALLY USED IN FOREARM BONES ALONG WITH CORTICAL & CANCELLOUS SCREWS, SMALL T – PLATES ARE GENERALLY USED IN LOWER END OF FOREARM BONE, MINI STRAIGHT PLATES ARE USED IN PHALANGEAL FRACTURES, AND MINI T & L PLATES ARE USED IN FRACTURES OF THE DISTAL OR PROXIMAL ENDS OF PHALANGES., BONE SCREWS(MIRACLUS)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. SCREWS ARE OF DIFFERENT TYPES E.G. CORTICAL SCREWS, CANCELLOUS SCREWS, CANCELLOUS CANNULATED SCREWS, MALLEOLAR SCREWS, LOCKING BOLT, LAG (DHS/DCS) SCREWS, SHERMAN SCREWS, STEFFEE SCREWS, SHAFT SCREWS, PLUG SCREWS.,SPINAL IMPLANTS (MIRACLUS)-SPINAL IMPLANTS ARE USED IN THE SURGICAL PROCEDURES RELATED TO THE SPINAL INJURIES AND SPINAL DISEASES,BONE PLATES(MIRACLUS)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PLATES ARE OF DIFFERENT TYPES WHICH USED IN DIFFERENT PARTS OF HUMAN BODY E.G. ONE THIRD TUBULAR PLATES ARE GENERALLY USED IN FOREARM BONES ALONG WITH CORTICAL & CANCELLOUS SCREWS, SMALL T – PLATES ARE GENERALLY USED IN LOWER END OF FOREARM BONE, MINI STRAIGHT PLATES ARE USED IN PHALANGEAL FRACTURES, AND MINI T & L PLATES ARE USED IN FRACTURES OF THE DISTAL OR PROXIMAL ENDS OF PHALANGES., NAILS(MIRACLUS)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY.NAILS ARE OF DIFFERENT TYPES WHICH USED IN TIBIA, FEMUR AND HUMOROUS

		BONES MAINLY.,NAILS(MIRACLUS)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. NAILS ARE OF DIFFERENT TYPES WHICH USED IN TIBIA, FEMUR AND HUMOROUS BONES MAINLY.,BONE SCREWS(MIRACLUS)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY.SCREWS ARE OF DIFFERENT TYPES E.G. CORTICAL SCREWS, CANCELLOUS SCREWS, CANCELLOUS CANNULATED SCREWS,MALLEOLAR SCREWS, LOCKING BOLT, LAG (DHS/DCS) SCREWS, SHERMAN SCREWS, STEFFEE SCREWS, SHAFT SCREWS, PLUG SCREWS.,SPINAL IMPLANTS(MIRACLUS)-SPINAL IMPLANTS ARE USED IN THE SURGICAL PROCEDURES RELATED TO THE SPINAL INJURIES AND SPINAL DISEASES.,SPINAL IMPLANTS (MIRACLUS)-SPINAL IMPLANTS ARE USED IN THE SURGICAL PROCEDURES RELATED TO THE SPINAL INJURIES AND SPINAL DISEASES.,BONE PLATES(MIRACLUS)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PLATES ARE OF DIFFERENT TYPES WHICH USED IN DIFFERENT PARTS OF HUMAN BODY E.G. ONE THIRD TUBULAR PLATES ARE GENERALLY USED IN FOREARM BONES ALONG WITH CORTICAL & CANCELLOUS SCREWS, SMALL T – PLATES ARE GENERALLY USED IN LOWER END OF FOREARM BONE, MINI STRAIGHT PLATES ARE USED IN PHALANGEAL FRACTURES, AND MINI T & L PLATES ARE USED IN FRACTURES OF THE DISTAL OR PROXIMAL ENDS OF PHALANGES., BONE SCREW(MIRACLUS)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY.SCREWS ARE OF DIFFERENT TYPES E.G. CORTICAL SCREWS, CANCELLOUS SCREWS, CANCELLOUS CANNULATED SCREWS,MALLEOLAR SCREWS, LOCKING BOLT, LAG (DHS/DCS) SCREWS, SHERMAN SCREWS, STEFFEE SCREWS, SHAFT SCREWS,PLUG SCREWS.,BONE SCREWS (MIRACLUS)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. SCREWS ARE OF DIFFERENT TYPES E.G. CORTICAL SCREWS, CANCELLOUS SCREWS, CANCELLOUS CANNULATED SCREWS, MALLEOLAR SCREWS, LOCKING BOLT, LAG (DHS/DCS) SCREWS, SHERMAN SCREWS, STEFFEE SCREWS, SHAFT SCREWS, PLUG SCREWS.
3150	MFG/MD/2019/000004	1.License Holder Name: POPULAR UNITED LABORATORIES 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:ALCOHOL SWABS-TO CLEAN & DISINFECT THE SKIN BEFORE ADMINISTERING THE INJECTABLES IN THE HUMAN BODY

3151	MFG/MD/2019/000006	1.License Holder Name: WOMCO LABORATORIES PVT. LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:INFUSION SET(I TYPE / EASY FLOW)-TO ADMINISTER DRUG TO PATIENT VASCULAR SYSTEM THROUGH NEEDLE OR CATHETER INSERTED IN TO THE VEIN,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITH OR WITH OUT NEEDLE (DISCARD IT)-TO INJECT FLUID INTO OR WITHDRAW FLUID FROM THE BODY, SCALP VEIN SET(EASY FLOW)-INTENDED TO BE USED FOR INSERTION TO THE PATIENTS THROUGH VASCULAR SYSTEM (SINGLE USE ONLY) AS AN-DWELLING DEVICE TO ADMINISTER FLUID INTRAVENOUSLY OR SAMPLE BLOOD,INTRAVENOUS INFUSION SET (MICRO DRIP PEDIATRIC)-TO ADMINISTER DRUG TO PATIENTS THROUGH VASCULAR SYSTEM BY NEEDLE OR CATHETER IN TO VEIN, BLOOD TRANSFUSION SET(G TYPE)-TO ADMINISTER BLOOD AND PRODUCTS TO PATIENT VASCULAR SYSTEM THROUGH NEEDLE OR CATHETER INSERTED IN TO THE VEIN,THREE WAY STOP COCK (BI-VALVE CONNECTION)(EASY FLOW)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUIDS OR PRESSURE MONITORING.

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3152	MFG/MD/2019/000007	1.License Holder Name: S.H.PITKAR ORTHOTOOLS PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:WIRE(PITKAR)-THE APPARATUS, WHICH WAS DEVELOPED IN THE EARLY 1950S IN THE WORLD MARKET, WAS DESIGNED WITH THE FOLLOWING GOALS IN MIND: I.ANATOMICAL REDUCTION OF BONY INJURIES. II.HIGH STABILITY OF THE BONE FRACTURE SEGMENTS. III.PRESERVATION OF INJURED LIMB FUNCTION. IV.EARLY MOBILIZATION OF THE PATIENT.,PINS(PITKAR)-I.ANATOMICAL REDUCTION OF BONY INJURIES. II.HIGH STABILITY OF THE BONE FRACTURE SEGMENTS. III. PRESERVATION OF INJURED LIMB FUNCTION. IV.EARLY MOBILIZATION OF THE PATIENT.,SOLAR MODULAR HIP SYSTEM (PITKAR)-HIP COMPONENTS ARE INDICATED FOR INDIVIDUALS UNDERGOING PRIMARY AND REVISION SURGERY WHERE OTHER TREATMENTS OR DEVICES HAVE FAILED IN REHABILITATING HIPS DAMAGED AS A RESULT OF TRAUMA OR NONINFLAMMATORY DEGENERATIVE JOINT DISEASE OR ANY OF ITS COMPOSITE DIAGNOSES OF OSTEOARTHRITIS, AVASCULAR NECROSIS, TRAUMATIC ARTHRITIS, SLIPPED CAPITAL EPIPHYSIS, FUSED HIP, FRACTURE OF THE PELVIS, AND DIASTROPHIC VARIANT. HIP COMPONENTS ARE ALSO INDICATED FOR INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING RHEUMATOID ARTHRITIS, ARTHRITIS SECONDARY TO A VARIETY OF DISEASES AND ANOMALIES, AND CONGENITAL DYSPLASIA; TREATMENTS OF NONUNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT THAT ARE UNMANAGEABLE USING OTHER TECHNIQUES; ENDLOPROSTHESIS, FEMORAL OSTEOTOMY, OR GIRDLE STONE RESECTION; FRACTURE-DISLOCATION OF THE HIP; AND CORRECTION OF DEFORMITY. ,ENDOBUTTON(PITKAR)-THE ENDOBUTTON FIXATION DEVICES ARE USED FOR FIXATION OF TENDONS AND LIGAMENTS DURING ORTHOPEDIC RECONSTRUCTION PROCEDURES SUCH AS ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION AND ACROMIOCLAVICULAR JOINT SEPARATIONS DUE TO CORACOCLAVICULAR LIGAMENT DISRUPTIONS.,ARTHROSCOPY SYSTEM(PITKAR)-THE INTERFERENCE SCREWS ARE INTENDED TO BE USED FOR THE FIXATION OF TENDON OR BONE-TO-BONE (BTB) GRAFTS IN THE RECONSTRUCTION SURGERY OF THE ACL OR PCL THE SCREWS ARE USED TO SECURE THE GRAFT INTO THE CORTICAL BONE OF THE TIBIA OR THE FEMUR. CUFFGRIP-T SUTURE ANCHOR PROVIDE A TAPERED BODY THAT IS MATED TO THE DILATOR TO REDUCE INSERTION TORQUE, THEREBY HELPING TO MINIMIZE ANCHOR BREAKAGE. SUTURE EYELETS ARE LOCATED DEEPER IN THE

	ANCHOR BODY TO REDUCE SUTURE EYELET FAILURE UNDER CYCLIC LOADING. CUFFGRIP-T SUTURE ANCHOR PROVIDE SECURE FIXATION WITH A WIDE RANGE OF SIZES TO MATCH VARIOUS APPLICATIONS AND BONE QUALITIES. ANCHOR CORES ARE MATCHED TO THE DRILL SIZE TO FACILITATE INSERTION WHILE MAXIMIZING FIXATION STRENGTH. THE SHOULDER ANCHORS ARE INTENDED TO BE USED FOR THE FIXATION OF TENDON GRAFTS IN THE REPAIR OR RECONSTRUCTION SURGERY OF THE ROTATOR CUFF. THE SCREWS ARE USED TO SECURE THE GRAFT INTO THE CORTICAL BONE OF THE HUMERUS. ,HIP PROSTHESIS(PITKAR)-INTENDED TO BE IMPLANTED TO REPLACE THE ARTICULATING SURFACE OF THE HIP WHILE PRESERVING THE FEMORAL HEAD AND NECK,ARTHROSCOPY SYSTEM(PITKAR)-THE USE OF FLEXSTUD, FLEXHOOK AND FLEXLOOP IS INTENDED TO BE USED FOR FIXATION OF TENDON OR BONE-TO-BONE(BTB) GRAFTS IN THE RECONSTRUCTION SURGERY OF THE ACL OR PCL. IT USED TO SECURE THE GRAFTS TO THE SURFACE OF THE COTICAL BONE OF THE TIBIA. ,BONE PLATES(PITKAR)-THE USE OF METALLIC SURGICAL IMPLANTS PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION & HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANTS ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.,CAGES(PITKAR)-IT IS INDICATED FOR USE WITH AUTOGENOUS BONE GRAFT IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTIGUOUS SPINAL LEVELS,PEDICLE SCREW SPINAL SYSTEM(PITKAR)-IT IS USED TO INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS,BONE SCREWS(PITKAR)-THE USE OF METALLIC SURGICAL IMPLANTS PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION & HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANTS ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING. , INTERVERTEBRAL BODY FUSION DEVICE(PITKAR)-THE DEVICE IS INSERTED INTO THE INTERVERTEBRAL BODY SAPCE OF THE CERVICAL OR LUMBOSACRAL SPINE AND IS INTENDED FOR INTERVERTEBRAL BODY FUSION,INTRAMEDULLARY LOCKING NAILS (PITKAR)-THE USE OF METALLIC SURGICAL IMPLANTS PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION & HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANTS ARE INTENDED AS

		AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.,CERVICAL ARTIFICIAL DISC(PITKAR)-CERVICAL ARTIFICIAL DISC IS INDICATED FOR RECONSTRUCTION OF THE DISC
3153	MFG/MD/2019/000008	1.License Holder Name: PURPLE MEDICAL SOLUTIONS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM(FIREHAWK I-RAPAMYCIN TARGET ELUTING CORONARY STENT & FIREHAWK IN-RAPAMYCIN TARGET ELUTING CORONARY STENT)-THE RAPAMYCIN TARGET ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC HEART DISEASE DUE TO DE NOVO NATIVE CORONARY ARTERY LESIONS LENGTH 60 MM WITH REFERENCE VESSEL DIAMETERS OF 2.25 TO 4.0 MM

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3154	MFG/MD/2019/000008	1.License Holder Name: PURPLE MEDICAL SOLUTIONS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:NC PTCA POST DILATATION BALLOON CATHETER(ZOOMEX RX NC PTCA POST DILATATION BALLOON CATHETER)-NC POST DILATATION CATHETER IS INTENDED FOR USE TO STENOTIC PORTION OF CORONARY ARTERY OR A CORONARY BYPASS, TO IMPROVE MYOCARDIAL PERFUSION / DILATATION OF A STENT AFTER IMPLANTATION DILATATION OF STENOTIC PORTION OF ARTERY/STENT AFTER IMPLANTATION ,PRE-DILATATION BALLOON CATHETER(DIRECT-X RX PTCA PRE-DILATATION BALLOON CATHETER)-THE PTCA PRE DILATATION CATHETER IS INTENDED FOR USE IN PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES AND WHO ARE REGARDED AS BEING CANDIDATES FOR MYOCARDIAL REVASCULARIZATION. DILATATION OF STENOTIC PORTION OF CORONARY ARTERY,HYDROXYAPATITE COBALT CHROMIUM CORONARY STENT SYSTEM(VESTACOR CORONARY STENT SYSTEM)-PRODUCT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE IN DE NOVO CORONARY ARTERY LESION IN NATIVE CORONARY ARTERIES IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). , BIODEGRADABLE POLYMER BASED EVEROLIMUS ELUTING CORONARY STENT SYSTEM(I-SYNC EVEROLIMUS ELUTING CORONARY STENT SYSTEM)-PRODUCT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE IN DE NOVO CORONARY ARTERY LESION IN NATIVE CORONARY ARTERIES IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). ,CTO PTCA PRE-DILATATION BALLOON CATHETER(FAST TECH RX CTO PTCA PRE-DILATATION BALLOON CATHETER)-CTO PRE DILATATION CATHETER IS INTENDED FOR USE TO DILATE THE DISEASED SEGMENTS(S) IN CORONARY ARTERY OR A CORONARY BYPASS, TO IMPROVE MYOCARDIAL PERFUSION. DILATATION OF STENOTIC PORTION OF ARTERY,STAINLESS STEEL CORONARY STENT SYSTEM(GENX STAINLESS STEEL CORONARY STENT SYSTEM, LOTUS STAINLESS STEEL CORONARY STENT SYSTEM)-PRODUCT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE IN DE NOVO CORONARY ARTERY LESION IN NATIVE CORONARY ARTERIES IN PATIENTS ELIGIBLE FOR PERCUTANEOUS

	TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA).,COBALT CHROMIUM CORONARY STENT SYSTEM(GENX CRCO CORONARY STENT SYSTEM, PROTEA COBALT CHROMIUM CORONARY STENT SYSTEM, P-ROMO COBALT CHROMIUM CORONARY STENT SYSTEM, XPRO COBALT CHROMIUM CORONARY STENT SYSTEM, X-STENT COBALT CHROMIUM CORONARY STENT SYSTEM)-PRODUCT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE IN DE NOVO CORONARY ARTERY LESION IN NATIVE CORONARY ARTERIES IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). ,ASPIRATION CATHETER (X-CHANGE ASPIRATION CATHETER)-INDICATED FOR USE IN THE CENTRAL & PERIPHERAL CIRCULATION SYSTEM INCLUDING SAPHENOUS VEIN GRAFT, TO CONTAIN & ASPIRATE EMBOLIC MATERIAL (THROMBUS/DEBRIS) WHILE PERFORMING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) OR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) AND/OR STENTING PROCEDURE,BIODEGRADABLE POLYMER BASED SIROLIMUS ELUTING CORONARY STENT SYSTEM(GENXSYNC SIROLIMUS ELUTING CORONARY STENT SYSTEM, GENXSYNC PLUS SIROLIMUS ELUTING CORONARY STENT SYSTEM TREAT SIROLIMUS ELUTING CORONARY STENT SYSTEM, BREED SIROLIMUS ELUTING CORONARY STENT SYSTEM, E-NOVATE SIROLIMUS ELUTING CORONARY STENT SYSTEM, FLEXIBITE SIROLIMUS ELUTING CORONARY STENT SYSTEM, GENPLUS SIROLIMUS ELUTING CORONARY STENT SYSTEM, YALIMUS SIROLIMUS ELUTING CORONARY STENT SYSTEM)-PRODUCT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE IN DE NOVO CORONARY ARTERY LESION IN NATIVE CORONARY ARTERIES IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA).,POLYMER FREE HYDROXYAPATITE COATED SIROLIMUS ELUTING CORONARY STENT SYSTEM(VESTASYNC SIROLIMUS ELUTING CORONARY STENT SYSTEM)-PRODUCT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE IN DE NOVO CORONARY ARTERY LESION IN NATIVE CORONARY ARTERIES IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA).

3155	MFG/MD/2019/000009	1.License Holder Name: KAUSHIK ORTHOPAEDIC PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ORTHOPAEDIC IMPLANT (KAUSHIK)-AN ORTHOPEDIC IMPLANT IS A MEDICAL DEVICE MANUFACTURED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE.

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3156	MFG/MD/2019/000010	1.License Holder Name: M/S BOARD OF RADIATION & ISOTOPE TECHNOLOGY 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT COVER SCREW(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE.,BONE SCREW- CAP SCREW FOR SOL T TIBIA NAIL (PITKAR)-END CAP SECURELY LOCK THE MOST PROXIMAL OBLIQUE LOCKING SCREW TO CREAT A FIXED ANGLE CONSTRUCT & USED AS A NAIL EXTENSION & PREVENT THE INGROWTH OF TISSUE AND FACILITATE NAIL EXTRACTION ,BONE SCREW- HIP BOLT(PITKAR)-THE USE OF METALLIC SURGICAL IMPLANTS PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION & HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANTS ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.,ENDOBUTTON(PITKAR)-USE:THE ENDOBUTTON FIXATION DEVICES ARE USED FOR FIXATION OF TENDONS AND LIGAMENTS DURING ORTHOPEDIC RECONSTRUCTION PROCEDURES SUCH AS ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION AND ACROMIOCLAVICULAR JOINT SEPARATIONS DUE TO CORACOCLAVICULAR LIGAMENT DISRUPTIONS ,ORTHODONTIC SCREW(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE.,DENTAL ANCHORAGE SCREW (WITH HOLE)(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE.,SLIM ABUTMENT(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE.,BONE SCREW- PFNA II BLADE (PITKAR)-COMPACTION OF CANCELLOUS BONE I.E. PFNA-II BLADE COMPACTS THE CANCELLOUS BONE PROVIDING ADDITIONAL ANCHORING, WHICH IS ESPECIALLY IMPORTANT IN OSTEOPOROTIC BONE,BONE SCREW- INTERFERENCE SCREW(PITKAR)-THE USE OF METALLIC SURGICAL IMPLANTS PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION & HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANTS ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.,BONE SCREW- HIP PIN (PITKAR)-THE USE OF METALLIC SURGICAL IMPLANTS PROVIDES THE

	ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION & HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANTS ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.,BONE SCREW- INTERLOCKING SCREW(PITKAR)-THE USE OF METALLIC SURGICAL IMPLANTS PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION & HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANTS ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.,BONE SCREW- YT SCREW(PITKAR)-THE USE OF METALLIC SURGICAL IMPLANTS PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION & HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANTS ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.,BONE SCREW- CAP SCREW FOR SOL T FEMUR NAIL(PITKAR) -END CAP SECURELY LOCK THE MOST PROXIMAL OBLIQUE LOCKING SCREW TO CREAT A FIXED ANGLE CONSTRUCT & USED AS A NAIL EXTENSION. END CAP PREVENT THE INGROWTH OF TISSUE AND FACILITATE NAIL EXTRACTION.,DENTAL IMPLANT(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE.,ABUTMENT SCREW (PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE., STRAIGHT ABUTMENT(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE.,ABUTMENT(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE.,PFNA II NAIL(PITKAR)-1. SUBTROCHANTERIC FRACTURES 2. PERTROCHANTERIC FRACTURES ASSOCIATED WITH SHAFT FRACTURES 3. PATHOLOGICAL FRACTURES (INCLUDING PROPHYLACTIC USE) IN BOTH TROCHANTERIC AND DIAPHYSAL AREAS 4. NONUNION AND MALUNION,BONE SCREW- CERVICAL SCREW(PITKAR)-TO BE USED IN TANDEM WITH INTRAMEDULLARY LOCKING NAIL IN INTERTROCHANTERIC REGION CLASS OF MEDICAL DEVICE,YT NAIL (PITKAR)-1. SUBTROCHANTERIC FRACTURES 2. PERTROCHANTERIC FRACTURES ASSOCIATED WITH SHAFT FRACTURES 3. PATHOLOGICAL FRACTURES (INCLUDING PROPHYLACTIC USE) IN

	BOTH TROCHANTERIC AND DIAPHYSAL AREAS 4. NONUNION AND MALUNION,BONE SCREW- CAP SCREW FOR YT NAIL(PITKAR)-END CAP SECURELY LOCK THE MOST PROXIMAL OBLIQUE LOCKING SCREW TO CREAT A FIXED ANGLE CONSTRUCT & USED AS A NAIL EXTENSION & PREVENT THE INGROWTH OF TISSUE AND FACILITATE NAIL EXTRACTION,BONE SCREW- CAP FOR SOL T PFD NAIL(PITKAR)-END CAP SECURELY LOCK THE MOST PROXIMAL OBLIQUE LOCKING SCREW TO CREAT A FIXED ANGLE CONSTRUCT & USED AS A NAIL EXTENSION & PREVENT THE INGROWTH OF TISSUE AND FACILITATE NAIL EXTRACTION,SOL T FEMUR NAIL(PITKAR)-1. ALL CLOSED & OPEN FEMORAL SHAFT FRACTURES 2. SUBTROCHANTERIC FRACTURES 3. SHAFT FRACTURES IN COMBINATION WITH FEMORAL NECK OR 4. PERTROCHANTERIC FRACTURES. 5. PSEUDOARTHROSIS OR DELAYED UNION,SOL T TIBIA NAIL(PITKAR)-1.METAPHYSEAL AND CERTAIN INTRAARTICULAR FRACTURES OF THE TIBIAL HEAD AND THE PILON TIBIALE: 41-A2/A3, 2.ALL SHAFT FRACTURES 43-A1/A2/A3,SOL T PFD NAIL(PITKAR)-1. HIGH SUB TROCHANTRIC FRACTURES OF FEMUR,PLIF CAGES(PITKAR)-IT IS INDICATED FOR USE WITH AUTOGENOUS BONE GRAFT IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTIGUOUS SPINAL LEVELS

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3157	MFG/MD/2019/000010	1.License Holder Name: S.H.PITKAR ORTHOTOOLS PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:TAPERED THREADED PINS (PITKAR)- 1.FRACTURE FIXATION (OPEN AND CLOSED) 2. PSEUDOARTHROSES OF LONG BONES (BOTH CONGENITAL AND ACQUIRED). 3.LIMB LENGTHENING BY EPIPHYSIS OR METAPHYSEAL DISTRACTION. 4.CORRECTION OF BONY OR SOFT TISSUE DEFORMITIES. 5.CORRECTION OF BONY OR SOFT TISSUE DEFECTS., BIPOLAR PROSTHESIS(PITKAR)-1.ACUTE FEMORAL NECK FRACTURE. 2.NON-UNION OF FEMORAL HEAD AND NECK FRACTURE. 3. AVASCULAR NECROSIS OF THE FEMORAL HEAD. 4.OSTEO, RHEUMATOID AND POST-TRAUMATIC ARTHRITICS OF THE HIP WITH MINIMAL ACETABULAR INVOLVEMENT OR DISTORTION. ,THOMPSON PROSTHESIS(PITKAR)-1.ACUTE FEMORAL NECK FRACTURE. 2.NON-UNION OF FEMORAL HEAD AND NECK FRACTURE. 3.AVASCULAR NECROSIS OF THE FEMORAL HEAD. 4.OSTEO, RHEUMATOID AND POST-TRAUMATIC ARTHRITICS OF THE HIP WITH MINIMAL ACETABULAR INVOLVEMENT OR DISTORTION.,AUSTIN MOORE PROSTHESIS(PITKAR)-1.ACUTE FEMORAL NECK FRACTURE. 2.NON-UNION OF FEMORAL HEAD AND NECK FRACTURE. 3.AVASCULAR NECROSIS OF THE FEMORAL HEAD. 4.OSTEO, RHEUMATOID AND POST-TRAUMATIC ARTHRITICS OF THE HIP WITH MINIMAL ACETABULAR INVOLVEMENT OR DISTORTION.
3158	MFG/MD/2019/000011	1.License Holder Name: MERIL HEALTHCARE PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:INTRAMEDULLARY NAILS (ACCURA/CLAVO/DHUM/KET)-TRAUMA IMPLANTS ARE USED FOR THE SURGICAL TREATMENT OF FRACTURES, DEFORMITIES, AND TUMOUR DISEASES OF LONG BONES, SUCH AS THOSE OF THE ARMS AND LEGS.,BONE SCREWS(FIXION/MBOSS/DHUM/KET)-TRAUMA IMPLANTS ARE USED FOR THE SURGICAL TREATMENT OF FRACTURES, DEFORMITIES, AND TUMOUR DISEASES OF LONG BONES, SUCH AS THOSE OF THE ARMS AND LEGS.,BONE PLATES (ARTIS/ARMAR/DHUM/KET)-TRAUMA IMPLANTS ARE USED FOR THE SURGICAL TREATMENT OF FRACTURES, DEFORMITIES, AND TUMOUR DISEASES OF LONG BONES, SUCH AS THOSE OF THE ARMS AND LEGS.,INTRAMEDULLARY NAILS(ACCURA/CLAVO/DHUM/KET)-TRAUMA IMPLANTS ARE USED FOR THE SURGICAL TREATMENT OF FRACTURES, DEFORMITIES, AND TUMOUR DISEASES OF LONG BONES, SUCH AS THOSE OF THE ARMS AND LEGS.

3159	MFG/MD/2019/000012	1.License Holder Name: GLOWTRONICS PRIVATE LIMITED 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:ENDOSCOPIC ULTRASOUND NEEDLE-THIS DEVICE IS USED TO SAMPLE TARGETED SUB-MUCOSAL & EXTRAMURAL GASTROINTESTINAL LESIONS THROUGH THE ACCESSORY CHANNEL OF AN ULTRASOUND ENDOSCOPE,DISPOSABLE PERFUSION SETS(CHEMO PERFUSION SET 2020 , CHEMO PERFUSION SET 2025 , CHEMO PERFUSION SET 2220 , CHEMO PERFUSION SET 2225)-IT IS USED FOR USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,FORCEPS , ENDOSCOPIC-USED TO COLLECT TISSUE, OR FOREIGN BODY RETRIEVAL, FROM GASTROINTESTINAL TRACT USING AN ENDOSCOPE.,MULTIPLE BAND LIGATOR-IT IS USED FOR THE ENDOSCOPE LIGATION OF ESOPHAGEAL VARICES AND ANORECTAL HEMORRHOIDS
3160	MFG/MD/2019/000013	1.License Holder Name: SHREE SURGICAL 2.Approving Authority: WEST BENGAL 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON-MEDICAL PURPOSES IN HOSPITALS, NURSHING HOMES, DISPENSARIES AND TO PRODUCE DRESSING MATERIALS ETC.
3161	MFG/MD/2019/000014	1.License Holder Name: SGREMEDIAL HEALTHCARE PVT LTD 2.Approving Authority: NAGPUR DIVISION 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC SYRINGES(SAFEGUARD)-INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUID FROM BODY
3162	MFG/MD/2019/000015	1.License Holder Name: M/S. RAUNAK ENTERPRISES 2.Approving Authority: BIHAR 3.Device Name(Brand Name)-Intended Use:ROLLED BANDAGE, ABSORBENT GAUZE, COTTON CREPE BANDAGE B.P.-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB.

3163	MFG/MD/2019/000016	1.License Holder Name: SAKSHAM LIFE 2.Approving Authority: BIHAR 3.Device Name(Brand Name)-Intended Use:STERILE HYPODERMIC SINGLE USE SYRINGE(DOCTOR PLUS)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUID FROM THE BODY,SINGLE LUMEN HYPODERMIC NEEDLE(DOCTOR PLUS)-A HYPODERMIC SINGLE LUMEN NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN,DISPOSABLE PERFUSION SETS(DOCTOR PLUS)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.

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3164	MFG/MD/2019/000017	1.License Holder Name: GLOBAL OPHTHALMIC PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use: INTRAOCULAR LENS (OPTIOL)-THE INTRAOCULAR LENSES ARE INTENDED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS,INTRAOCULAR LENS(GLOWVISION)-THE INTRAOCULAR LENSES ARE INTENDED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS., INTRAOCULAR LENS(CATRACURE)-THE INTRAOCULAR LENSES ARE INTENDED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS,INTRAOCULAR LENS(FLEXIOL PHOBIC)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS INDICATED FOR THE VISUAL CORRECTION OF APAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG.,INTRAOCULAR LENS-THE MULTIFOCAL INTRAOCULAR LENSES ARE INDICATE FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION AND WHO DESIRE NEAR, INTERMEDIATE, AND DISTANCE VISION WITH INCREASED SPECTACLE INDEPENDENCE. THE INTRAOCULAR LENSES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG.,INTRAOCULAR LENS-TORIC ACRYLIC IOLS ARE INDICATED FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM OF ONE DIOPTER OR GREATER, WITH OR WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION. THE DEVICE IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,INTRAOCULAR LENS-THE MULTIFOCAL INTRAOCULAR LENSES ARE INDICATE FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION AND WHO DESIRE NEAR, INTERMEDIATE, AND DISTANCE VISION WITH INCREASED SPECTACLE INDEPENDENCE. THE INTRAOCULAR LENSES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG., INTRAOCULAR LENS(HYPHOFLEX)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG., INTRAOCULAR LENS(OPTIOL FOLD)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS

	BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG, INTRAOCULAR LENS(OPTITECHNICS)-THE INTRAOCULAR LENSES ARE INTENDED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS, INTRAOCULAR LENS(OPTIOL BRIGHTA)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG., INTRAOCULAR LENS(IRISHGLOW)-THE INTRAOCULAR LENSES ARE INTENDED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS, INTRAOCULAR LENS(CFRANCE FOLD)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG, INTRAOCULAR LENS(HEMAFOLD)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG, INTRAOCULAR LENS(IOVUE)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG., INTRAOCULAR LENS(EUROFOLD)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG,INTRAOCULAR LENS (PROXYLENZ)-THE INTRAOCULAR LENSES ARE INTENDED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS, INTRAOCULAR LENS(IOVUE ASPHERIC OPTICS)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG., INTRAOCULAR LENS(HYPHOVUE)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE

	LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG,INTRAOCULAR LENS(GLOWFOLD)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG., INTRAOCULAR LENS(IOVUE)-THE INTRAOCULAR LENSES ARE INTENDED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS, INTRAOCULAR LENS(CATRALENS)-THE INTRAOCULAR LENSES ARE INTENDED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS,INTRAOCULAR LENS-THE INTRAOCULAR LENSES ARE INTENDED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS,INTRAOCULAR LENS(GLOWEDGE)-THE INTRAOCULAR LENSES ARE INTENDED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS,INTRAOCULAR LENS (ACCURAVUE)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG., INTRAOCULAR LENS(CFRANCELENZ)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG, INTRAOCULAR LENS(OPTIOL ENVU)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG., INTRAOCULAR LENS(FLEXIOL AO)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG.,INTRAOCULAR LENS-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG., INTRAOCULAR LENS(FLEXIOL)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY

	EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG, INTRAOCULAR LENS-THE MULTIFOCAL INTRAOCULAR LENSES ARE INDICATE FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION AND WHO DESIRE NEAR, INTERMEDIATE, AND DISTANCE VISION WITH INCREASED SPECTACLE INDEPENDENCE. THE INTRAOCULAR LENSES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG., INTRAOCULAR LENS(ASPROLENZ)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG.,INTRAOCULAR LENS(FLEXIOL PHOBIC)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES INDICATED FOR THE VISUAL CORRECTION OF APHAKIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION. THE LENS IS INTENDED THROUGH SMALL INCISION TO BE PLACED IN THE CAPSULAR BAG,INTRAOCULAR LENS-THE MULTIFOCAL INTRAOCULAR LENSES ARE INDICATE FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA IN WHOM A CATARACTOUS LENS HAS BEEN REMOVED BY PHACOEMULSIFICATION AND WHO DESIRE NEAR, INTERMEDIATE, AND DISTANCE VISION WITH INCREASED SPECTACLE INDEPENDENCE. THE INTRAOCULAR LENSES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG.,INTRAOCULAR LENS(OPTIOL GOLD)-THE INTRAOCULAR LENSES ARE INTENDED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3165	MFG/MD/2019/000018	1.License Holder Name: AABHA CONTRACEPTIVES PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:MALE LATEX CONDOM (CHARI CHARI PLAIN STRAWBERRY FLAVOR LUBRICATED CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,CONDOMS-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS.ALSO USED FOR SEXUAL PLEASURE. MALE LATEX CONDOM(CHARI CHARI DOTTED STRAWBERRY FLAVOR LUBRICATED CONDOM)-THIS NATURAL RUBBER LATEX MALE CONDOM IS USED FOR CONTRACEPTION AND FOR PROPHYLACTIC PURPOSES. (TO HELP PREVENT PREGNANCY AND THE TRANSMISSION OF SEXUALLY TRANSMITTED DISEASES).,CONDOMS-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS. ALSO USED FOR SEXUAL PLEASURE.,MALE LATEX CONDOM(CHARI CHARI MULTITEXTURE (RIB-CONTOUR-DOT) BANANA FLAVORED CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(KEF LUBRICATED CHOCOLATE FLAVOR DOTTED CONDOM)-THIS NATURAL RUBBER LATEX MALE CONDOM IS USED FOR CONTRACEPTION AND FOR PROPHYLACTIC PURPOSES. (TO HELP PREVENT PREGNANCY AND THE TRANSMISSION OF SEXUALLY TRANSMITTED DISEASES).,MALE LATEX CONDOM(CHARI CHARI MULTITEXTURE (RIB-CONTOUR-DOT) CHOCOLATE FLAVOR LUBRICATED CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(KEF LUBRICATED STRAWBERRY FLAVOR DOTTED CONDOM)-THIS NATURAL RUBBER LATEX MALE CONDOM IS USED FOR CONTRACEPTION AND FOR PROPHYLACTIC PURPOSES. (TO HELP PREVENT PREGNANCY AND THE TRANSMISSION OF SEXUALLY TRANSMITTED DISEASES).,MALE LATEX CONDOM(CHARI CHARI DOTTED (EXTRA TIME) WITH BENZOCAINE)-THIS NATURAL RUBBER LATEX MALE CONDOM IS USED FOR CONTRACEPTION AND FOR PROPHYLACTIC PURPOSES. (TO HELP PREVENT PREGNANCY AND THE TRANSMISSION OF SEXUALLY TRANSMITTED DISEASES).,MALE LATEX CONDOM(KEF LUBRICATED DOTTED CONDOM)-THIS NATURAL RUBBER LATEX MALE CONDOM IS USED FOR CONTRACEPTION AND FOR PROPHYLACTIC PURPOSES. (TO HELP PREVENT PREGNANCY AND THE TRANSMISSION OF SEXUALLY TRANSMITTED DISEASES)..

	MALE LATEX CONDOM(CHARI CHARI MULTITEXTURE (RIB-CONTOUR-DOT) STRAWBERRY FLAVOR LUBRICATED CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(STRONG CHOCOLATE FLAVORED DOTTED CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(CHARI CHARI DOTTED CHOCOLATE FLAVOR LUBRICATED CONDOM)-THIS NATURAL RUBBER LATEX MALE CONDOM IS USED FOR CONTRACEPTION AND FOR PROPHYLACTIC PURPOSES. (TO HELP PREVENT PREGNANCY AND THE TRANSMISSION OF SEXUALLY TRANSMITTED DISEASES).,MALE LATEX CONDOM(STRONG JASMINE FLAVORED DOTTED CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(CHARI CHARI PLAIN CHOCOLATE FLAVOR LUBRICATED CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(STRONG STRAWBERRY FLAVORED PLAIN CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(CHARI CHARI MULTITEXTURE (RIB-CONTOUR-DOT) EXTRA TIME LUBRICATED CONDOM WITH BENZOCAINE 4.5%)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(STRONG PINEAPPLE FLAVORED DOTTED CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(CHARI CHARI DOTTED BANANA FLAVOR LUBRICATED CONDOM)-THIS NATURAL RUBBER LATEX MALE CONDOM IS USED FOR CONTRACEPTION AND FOR PROPHYLACTIC PURPOSES. (TO HELP PREVENT PREGNANCY AND THE TRANSMISSION OF SEXUALLY TRANSMITTED DISEASES).,MALE LATEX CONDOM(STRONG BANANA FLAVORED DOTTED CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(LOVE PLUS+ ULTRA THIN (PLAIN) CONDOM)-THIS CONDOM IS MADE OF NATURAL RUBBER LATEX SHEATH, WHICH COMPLETELY COVERS THE PENIS WITH A CLOSELY FITTED MEMBRANE. THIS CONDOM IS

	ALMOST CYLINDRICAL SHAPE IN LENGTH AND INCLUDES A RESERVOIR TEAT. THE SURFACE OF THE CONDOM IS SMOOTH OR TEXTURED (DOTTED OR RIBBED), TRANSLUCENT AND MAY OR MAY NOT BE LUBRICATED WITH SILICONE OIL. ,MALE LATEX CONDOM (STRONG PINEAPPLE FLAVORED PLAIN CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(LOVE PLUS+ MULTITEXTURE (DOT-RIB-CONTOUR) CHOCOLATE FLAVOURED.)-THIS CONDOM IS MADE OF NATURAL RUBBER LATEX SHEATH, WHICH COMPLETELY COVERS THE PENIS WITH A CLOSELY FITTED MEMBRANE. THIS CONDOM IS ALMOST CYLINDRICAL SHAPE IN LENGTH AND INCLUDES A RESERVOIR TEAT. THE SURFACE OF THE CONDOM IS SMOOTH OR TEXTURED (DOTTED OR RIBBED), TRANSLUCENT AND MAY OR MAY NOT BE LUBRICATED WITH SILICONE OIL. ,MALE LATEX CONDOM (STRONG CHOCOLATE FLAVORED PLAIN CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(LOVE PLUS+ DOTTED (1600 DOTTED WITH BENZOCAINE 4.5%))-THIS CONDOM IS MADE OF NATURAL RUBBER LATEX SHEATH, WHICH COMPLETELY COVERS THE PENIS WITH A CLOSELY FITTED MEMBRANE. THIS CONDOM IS ALMOST CYLINDRICAL SHAPE IN LENGTH AND INCLUDES A RESERVOIR TEAT. THE SURFACE OF THE CONDOM IS SMOOTH OR TEXTURED (DOTTED OR RIBBED), TRANSLUCENT AND MAY OR MAY NOT BE LUBRICATED WITH SILICONE OIL. THE LUBRICANT BENZOCAINE 4.5% ON THE CONDOM HELPS IN TEMPORALLY PROLONGING THE TIME UNTIL EJACULATION.,MALE LATEX CONDOM(STRONG STRAWBERRY FLAVORED DOTTED CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(CHARI CHARI PLAIN LUBRICATED EXTRA TIME CONDOM WITH BENZOCAINE 4.5%)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(STRONG BANANA FLAVORED PLAIN CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(LOVE PLUS+ DOTTED (SUPER DOTTED WITH BENZOCAINE 4.5%))-THIS CONDOM IS MADE OF NATURAL RUBBER LATEX SHEATH, WHICH COMPLETELY COVERS THE PENIS WITH A CLOSELY FITTED MEMBRANE. THIS CONDOM IS ALMOST CYLINDRICAL SHAPE IN LENGTH AND INCLUDES A RESERVOIR TEAT. THE SURFACE OF THE CONDOM IS SMOOTH OR

		TEXTURED (DOTTED OR RIBBED), TRANSLUCENT AND MAY OR MAY NOT BE LUBRICATED WITH SILICONE OIL. THE LUBRICANT BENZOCAINE 4.5% ON THE CONDOM HELPS IN TEMPORALLY PROLONGING THE TIME UNTIL EJACULATION.,MALE LATEX CONDOM (STRONG JASMINE FLAVORED PLAIN CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(CHARI CHARI PLAIN BANANA FLAVOR LUBRICATED CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(BANG BANG DOTTED CONDOM WITH STRAWBERRY FLAVOUR)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(LOVE PLUS+ MULTITEXTURE (DOT-RIB-CONTOUR) STRAWBERRY FLAVOURED.)-THIS CONDOM IS MADE OF NATURAL RUBBER LATEX SHEATH, WHICH COMPLETELY COVERS THE PENIS WITH A CLOSELY FITTED MEMBRANE. THIS CONDOM IS ALMOST CYLINDRICAL SHAPE IN LENGTH AND INCLUDES A RESERVOIR TEAT. THE SURFACE OF THE CONDOM IS SMOOTH OR TEXTURED (DOTTED OR RIBBED), TRANSLUCENT AND MAY OR MAY NOT BE LUBRICATED WITH SILICONE OIL. ,MALE LATEX CONDOM(BANG BANG DOTTED CONDOM WITH CHOCOLATE FLAVOUR)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.,MALE LATEX CONDOM(BANG BANG PLAIN CONDOM WITH SILICONE OIL)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE. ,MALE LATEX CONDOM(GALAMOR DOTTED LUBRICATED CONDOM)-CONTRACEPTION AND/OR PREVENTION AGAINST “SEXUALLY TRANSMITTED DISEASES (STD’S)” INCLUDING HIV/AIDS; UNDER SPECIFIED CONDITIONS OF USE.
3166	MFG/MD/2019/000019	1.License Holder Name: DOLPHIN LIFESCIENCE INDIA LLP 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:BALLOON INFLATION DEVICE(GALACTIC)-INFLATION DEVICE IS USED DURING ANGIOPLASTY PROCEDURES TO INFLATE THE BALLOON CATHETER, CONTROL PRESSURE AND DEFLATE THE BALLOON CATHETER.

3167	MFG/MD/2019/000020	1.License Holder Name: DOLPHIN LIFESCIENCE INDIA LLP 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:PRESSURE MONITORING LINE(SMART LINE)-P M LINE ARE INTENDED TO BE USED IN FLUID MANAGEMENT AND/OR INVASIVE PRESSURE MONITORING SYSTEMS.
3168	MFG/MD/2019/000021	1.License Holder Name: DOLPHIN LIFESCIENCE INDIA LLP 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:MANIFOLD(MULTIVERSE)-MANIFOLD IS AN ACCESSORY DESIGN TO FACILITATE THE DIRECTIONAL CONTROL OF FLUID MATERIAL USED IN CONJUNCTION WITH INTERVENTIONAL DEVICES DURING VASCULAR INTERVENTIONAL PROCEDURES.
3169	MFG/MD/2019/000023	1.License Holder Name: DOLPHIN LIFESCIENCE INDIA LLP 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:CONTROL SYRINGE (MATIS)-CONTROL DEVICE (12 ML) IS AN ACCESSORY DESIGN TO FACILITATE THE INJECTION OF DIE OR ANY OTHER FLUID MATERIAL USED IN CONJUNCTION WITH INTERVENTIONAL DEVICES DURING VASCULAR INTERVENTIONAL PROCEDURES.
3170	MFG/MD/2019/000024	1.License Holder Name: DOLPHIN LIFESCIENCE INDIA LLP 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ADVANCE GUIDEWIRE INTRODUCER (OSTIUM)-ADVANCE GUIDE WIRE INTRODUCER IS AN ACCESSORY TO PUNCTURE THE FEMORAL ARTERY FOR INTRODUCING THE GUIDEWIRE WITHIN THE BODY DURING ANGIOPLASTY.
3171	MFG/MD/2019/000025	1.License Holder Name: DOLPHIN LIFESCIENCE INDIA LLP 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:GUIDING CATHETER (ELIEZER)-THE PRODUCT IS DISPOSABLE MEDICAL DEVICE, WHICH IS INTENDED FOR INJECT OR INPUT THE SUBSTANCE OR/AND LIQUID, MAINLY USED TO INJECT CONTRAST MEDIUM, DRUG AND EMBOLIC MATERIAL .

3172	MFG/MD/2019/000029	1.License Holder Name: S3V VASCULAR TECHNOLOGIES PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER(3V AGILE)-CENTRAL VENOUS CATHETERS ARE INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE, SAMPLING OF BLOOD, AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE INTRA-VENOUS SOLUTIONS OR DRUGS. THE INDICATIONS OF USE INCLUDE THE FOLLOWING: • RAPID FLUID ADMINISTRATION • ADMINISTRATION OF IV FLUIDS REQUIRING DILUTION WITHIN THE CENTRAL CIRCULATION TO AVOID VASCULAR DAMAGE. • ADMINISTRATION OF VASO-ACTIVE AND/OR INCOMPATIBLE DRUGS. • FREQUENT BLOOD SAMPLING (IN PATIENTS WITHOUT AN ARTERIAL LINE) AND/OR BLOOD ADMINISTRATION THERAPIES. • CENTRAL VENOUS PRESSURE MONITORING FOR ASSESSMENT OF INTRAVASCULAR FLUID STATUS. • MEASUREMENT OF OXYGEN SATURATION LEVELS IN BLOOD RETURNING TO THE HEART. • MONITORING AND ACCESS FOR EITHER PRE- OR POST- PULMONARY ARTERY CATHETER INSERTION., ASPIRATION CATHETER(3V XTRA)-INDICATED FOR USE IN THE CENTRAL AND PERIPHERAL CIRCULATIOTORY SYSTEM, INCLUDING SAPHENOUS VEIN GRAFTS TO CONTAIN AND ASPIRATE EMBOLIC MATERIAL (THROMBUS/DEBRIS) WHILE PERFORMING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY AND/OR STENTING PROCEDURES.,SIROLIMUS ELUTING STAINLESS STEEL (NICKEL FREE) STENT SYSTEM(3V SIRONIX)-INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO AND IN-STENT RESTENOTIC LESIONS IN NATIVE CORONARY ARTERIES, COBALT CHROMIUM CORONARY STENT SYSTEM(3V KROME, 3V PRIME)-NDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO STENOTIC LESIONS IN NATIVE CORONARY ARTERIES,ANGIOPLASTY PTCA BALLOON CATHETER (3V PAULO NC, AMADEUS SUPERCROSS SLEEK NC)-TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES, SIROLIMUS DRUG ELUTING STENT SYSTEM(3V NEIL, 3V ASTRA)-INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO AND IN-STENT RESTENOTIC LESIONS IN NATIVE CORONARY ARTERIES,PACLITAXEL ELUTING PTCA BALLOON CATHETER(3V PAULO PLUS)-THE 3V PAULO PLUS PTCA CATHETER IS COATED WITH PACLITAXEL, A HIGHLY LIPOPHILIC DRUG, WHICH PROVIDES AN ANTI-PROLIFERATIVE TREATMENT IN CORONARY ARTERIES IMPROVING MYOCARDIAL PERFUSION. THE 3V PAULO PLUS IS

		INTENDED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES AND IN THE MANAGEMENT OF IN-STENT RESTENOSIS.,STAINLESS STEEL (NICKEL FREE) CORONARY STENT SYSTEM(3V STENIX)-INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DENOVO LESIONS IN NATIVE CORONARY ARTERIES ,PTA DILATATION CATHETER(3V ORION)-THE DEVICE IS INDICATED IMPROVING PERIPHERAL LUMINAL DIAMETER IN PATIENTS WITH STENOSIS OF THE CAROTID, VERTEBRAL, SUB-CLAVIAN, VISCERAL, RENAL, INFERIOR MEMBER'S ARTERIES USING EITHER DILATATION OR STENTING / POST STENTING TECHNIQUES,ANGIOPLASTY PTCA BALLOON CATHETER (3V PAULO, AMADEUS SUPERCROSS SLEEK)-TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES,STENT DELIVERY DEVICE(3V PAULO SDD)-TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES,RAPAMYCIN ELUTING CORONARY STENT IMPLANTATION SYSTEM(3V SIRIS)-INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO AND IN-STENT RESTENOTIC LESIONS IN NATIVE CORONARY ARTERIES
3173	MFG/MD/2019/000030	1.License Holder Name: NANO THERAPEUTICS PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ENDOSCOPIC ASPIRATION NEEDLE(QUANTACORE HD)-IT IS INTENDED TO BE USED WITH ENDOBRONCHIAL ULTRASOUND ENDOSCOPES FOR ULTRASOUND-GUIDED FINE NEEDLE ASPIRATION (FNA) OF THE SUBMUCOSAL AND EXTRAMURAL LESIONS, MEDIASTINAL MASSES, LYMPH NODES AND INTRAPERITONEAL MASSES OF THE TRACHEOBRONCHIAL TREE AND GASTROINTESTINAL TRACT.

3174	MFG/MD/2019/000031	1.License Holder Name: NANO THERAPEUTICS PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:GUIDE SHEATH(CONVOY)-THE CONVOY GUIDE SHEATH KIT IS INTENDED TO USE AS AN EXTENDED WORKING CHANNEL, TO IDENTIFY LESIONS AND TO INCREASE THE DIAGNOSTIC YIELD OF PERIPHERAL LESIONS. IT MEANT TO BE USED WITH AN ENDOSCOPE TO COLLECT CELL OR TISSUE SPECIMEN FROM THE RESPIRATORY ORGAN.
3175	MFG/MD/2019/000032	1.License Holder Name: IMPERIAL MEDCARE PRIVATE LIMITED 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:COTTON GAUZE - LAP SPONGES(ABOSPONGE)-USED FOR CLEANING OF EXUDATES/CUTS/ABRASIONS,ADHESIVE TAPE - PAPER TAPE-USED FOR HOLD THE DRESSING,DRESSING PAD(COMBIPAD)-USED WHERE HIGH ABSORBENCY IS REQUIRED TO MANAGE HEAVY EXUDATES. WORK AS A SECONDARY DRESSING,COTTON GAUZE -SWABS (ABOSWAB)-USED AS A DRESSING FOR CUTS/ABRASIONS,PRESSURE BANDAGE – COMPRESSION BANDAGE -SUPPORT BANDAGE IN SPRAINS & STRAINS CASES ,GAUZE BANDAGE-FOR SUPPORTING OF DRESSING ,ADHESIVE BANDAGE - ELASTIC ADHESIVE BANDAGE (TENSOCLING)-USED FOR COMPRESSION AND ALSO FOR HOLD DRESSING,ADHESIVE TAPE -FIXING ROLL(FIXOFIX)-USED FOR HOLD THE DRESSING
3176	MFG/MD/2019/000033	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS(N/A)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF A SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,SAFETY IV CANNULA(N/A)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV CANNULA(N/A)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.

3177	MFG/MD/2019/000034	1.License Holder Name: BECTON DICKINSON INDIA PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC NEEDLE(BD ULTRA-FINE PEN NEEDLES)-THE BD PEN NEEDLE IS INTENDED FOR USE WITH PEN INJECTOR DEVICES FOR THE SUBCUTANEOUS INJECTION OF DRUGS.,I.V.CANNULA(BD VENFLON)-IT IS A STERILE, SINGLE USE DEVICE DESIGNED FOR THE PARENTERAL ADMINISTRATION OF PHARMACEUTICALS.,PEN NEEDLES(BD ULTRA-FINE PEN NEEDLES EASYFLOW TECHNOLOGY PENTA POINT COMFORT)-PARENTERAL ADMINISTRATION OF A DRUG (INSULIN) FROM A CARTRIDGE CONTAINED IN A DRUG (INSULIN) PEN INJECTOR,I.V.CANNULA(BD VENFLON I)-IT IS A STERILE, SINGLE USE DEVICE DESIGNED FOR THE PARENTERAL ADMINISTRATION OF PHARMACEUTICALS.,I.V.CANNULA(BD VENFLON PRO IV CANNULA)-IT IS INTENDED TO GAIN ACCESS TO PERIPHERAL VEINS OF THE PATIENT'S BLOOD SYSTEM FOR REHYDRATION, PARENTERAL NUTRITION, MEDICATION DELIVERY, BLOOD TRANSFUSION, AND MONITORING PURPOSES.,DISPOSABLE HYPODERMIC SYRINGES WITH NEEDLES, REUSE PREVENTION SYRINGES(BD EMERALD PRO)-IT IS INTENDED FOR INJECTION AND/OR ASPIRATION OF LIQUIDS/FLUIDS (BIOLOGICAL FLUIDS BLOOD, ETC. AND/OR MEDICAMENTS), DISPOSABLE HYPODERMIC SYRINGES(BD DISCARDIT II SYRINGES)-IT IS INTENDED FOR INJECTION AND/OR ASPIRATION OF LIQUIDS/FLUIDS (BIOLOGICAL FLUIDS BLOOD, ETC. AND/OR MEDICAMENTS).,DISPOSABLE HYPODERMIC SYRINGES WITH NEEDLES, STERILE HYPODERMIC SYRINGE FOR SINGLE USE, FOR RE-USE PREVENTION(BD SOLOMED)-IT IS INTENDED FOR INJECTION AND/OR ASPIRATION OF LIQUIDS/FLUIDS (BIOLOGICAL FLUIDS BLOOD, ETC. AND/OR MEDICAMENTS),DISPOSABLE HYPODERMIC SYRINGES, STERILE HYPODERMIC SYRINGE FOR SINGLE USE, FOR RE-USE PREVENTION(BD SOLOMED)-IT IS INTENDED FOR INJECTION AND/OR ASPIRATION OF LIQUIDS/FLUIDS (BIOLOGICAL FLUIDS BLOOD, ETC. AND/OR MEDICAMENTS),DISPOSABLE HYPODERMIC SYRINGES WITH NEEDLES(BD DISCARDIT II SYRINGES)-IT IS INTENDED FOR INJECTION AND/OR ASPIRATION OF LIQUIDS/FLUIDS (BIOLOGICAL FLUIDS BLOOD, ETC. AND/OR MEDICAMENTS), DISPOSABLE HYPODERMIC SYRINGES, REUSE PREVENTION SYRINGES(BD EMERALD PRO)-IT IS INTENDED FOR INJECTION AND/OR ASPIRATION OF LIQUIDS/FLUIDS (BIOLOGICAL FLUIDS BLOOD, ETC. AND/OR MEDICAMENTS),DISPOSABLE HYPODERMIC SYRINGES WITH NEEDLES(BD EMERALD)-IT IS INTENDED FOR INJECTION AND/OR ASPIRATION OF LIQUIDS/FLUIDS (BIOLOGICAL FLUIDS BLOOD, ETC. AND/OR MEDICAMENTS),AUTO DISABLE SYRINGES(BD AUTO DISABLE SYRINGES)-IT IS INTENDED FOR

		INJECTION AND/OR ASPIRATION OF LIQUIDS/FLUIDS (BIOLOGICAL FLUIDS BLOOD, ETC. AND/OR MEDICAMENTS),DISPOSABLE HYPODERMIC SYRINGES(BD EMERALD)-IT IS INTENDED FOR INJECTION AND/OR ASPIRATION OF LIQUIDS/FLUIDS (BIOLOGICAL FLUIDS BLOOD, ETC. AND/OR MEDICAMENTS)
3178	MFG/MD/2019/000035	1.License Holder Name: CURITEX MEDICAL PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ABSORBENT GAUZE, AS PER DRUGS ACT, SCHEDULE F(II), (IS 758)-INTENDED FOR DRESSING SURFACE WOUNDS AND ABSORBING SMALL AMOUNTS OF BODY FLUIDS, OR EXUDATE, FROM A PATIENT'S BODY SURFACE., ABSORBENT COTTON WOOL IP, (IS 16468)-INTENDED FOR DRESSING SURFACE WOUNDS AND ABSORBING SMALL AMOUNTS OF BODY FLUIDS, OR EXUDATE, FROM A PATIENT'S BODY SURFACE.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3179	MFG/MD/2019/000036	1.License Holder Name: SOMNATH ORTHO CARE PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATES SS316L (SOMAT/TECH-MED/LOYAL/AZTECH/AZMED/RK-MEDICARE)-THE USE OF BONE PLATE PROVIDE THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION AND HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANT ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.,BONE NAILS SS316L(SOMAT/TECH-MED/LOYAL/AZTECH/AZMED/RK-MEDICARE)-THE USE OF BONE NAIL PROVIDE THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION AND HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANT ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.,BONE PLATES TITANIUM(SOMAT/TECH-MED/LOYAL/AZTECH/AZMED/RK-MEDICARE)-THE USE OF BONE PLATE PROVIDE THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION AND HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANT ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.,ACCETUBULAR CUP SS316L AND UHMWPE(SOMAT/TECH-MED/LOYAL/AZTECH/AZMED/RK-MEDICARE)-THE USE OF ACCETUBULAR CUP PROVIDE THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION AND HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANT ARE INTENDED AS AIDS TO NORMAL HEALING, FEMORAL STEM TITANIUM(SOMAT/TECH-MED/LOYAL/AZTECH/AZMED/RK-MEDICARE)-THE USE OF FEMORAL STEM PROVIDE THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION AND HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANT ARE INTENDED AS AIDS TO NORMAL HEALING,BONE SCREWS SS316L(SOMAT/TECH-MED/LOYAL/AZTECH/AZMED/RK-MEDICARE)-THE USE OF BONE SCREWS PROVIDE THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION AND HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANT ARE INTENDED AS

	AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.,BONE SCREWS TITANIUM (SOMAT/TECH-MED/LOYAL/AZTECH/AZMED/RK-MEDICARE)-THE INTENDED USE OF BONE SCREWS PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION AND HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THIS IMPLANT ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.,FEMORAL STEM SS316L (SOMAT/TECH-MED/LOYAL/AZTECH/AZMED/RK-MEDICARE)-THE USE OF FEMORAL STEM PROVIDE THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION AND HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANT ARE INTENDED AS AIDS TO NORMAL HEALING,BONE NAILS TITANIUM (SOMAT/TECH-MED/LOYAL/AZTECH/AZMED/RK-MEDICARE)-THE USE OF BONE NAIL PROVIDE THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION AND HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANT ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.,ACCETUBULAR CUP TITANIUM AND UHMWPE(SOMAT/TECH-MED/LOYAL/AZTECH/AZMED/RK-MEDICARE)-THE USE OF ACCETUBULAR CUP PROVIDE THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION AND HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANT ARE INTENDED AS AIDS TO NORMAL HEALING

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3180	MFG/MD/2019/000037	1.License Holder Name: MAIS INDIA MEDICAL DEVICES PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:I.V. CANNULA(ONE PLUS 1)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/ OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA(GOLDMED)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/ OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA(ICARE CLASSIC, ICARE PREMIUM & ICARE SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/ OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT WINGS & WITHOUT INJECTION PORT, I.V. CANNULA WITHOUT INJECTION PORT & WINGS AND SAFETY I.V. CANNULA WITH INJECTION PORT & WINGS (PRECISION CARE, MAISPEN & MAISFLEX SAFE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/ OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,EXTENSION SETS (NIL)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,ENDOTRACHEAL TUBE (WITH OR WITHOUT CUFFED)(N/A)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,I.V. CANNULA(CARESS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/ OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,FLUID DELIVERY TUBING(MAIS HIGH PRESSURE EXTENSION LINE)-TUBE USED TO DELIVER FLUID IN BODY.,YANKAUER HANDLE WITH CONNECTING TUBE (YANKUR SUCTION SET.)-YANKAUER HANDLE WITH CONNECTING TUBE IS INTENDED FOR THE USE OF SUCTIONING BODY FLUID IN COMBINATION WITH SUCTION APPARATUS DURING OPERATION ON THORACIC CAVITY OR ABDOMINAL CAVITY.,FOLEY BALLOON CATHETER (FOLEDRAIN, UROSILICO)-THE FOLEY BALLOON CATHETERS ARE USED TO DRAIN URINE FROM THE BLADDER INTO URINE BAG. ,I.V. ADMINISTRATION SET(I.V. SET (NON-STERILE BULK PACK), MAISFUSION SET, GENERIC NAME, SMMP PRIMEFUSION, CHEMFUSION SET, I.V. SET WITH FLOW REGULATOR (GENERIC NAME), MASITROL (I.V. SET WITH FLOW REGULATOR), SINOMEDIC.)-IV INFUSION SET IS USED TO ADMINISTRATE THE FLUIDS FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM, THROUGH A

	NEEDLE OR CATHETER INSERTED INTO A VEIN UNDER GRAVITY FEED AND MEDICAL APPLICATION IN ORDER TO ENSURE THEIR COMPATIBILITY FOR INFUSION SOLUTION.,I.V. FLOW REGULATOR (MAISFLOW, FLOW REGULATOR)-THE I.V. FLOW REGULATOR EXTENSION SET IS A MEDICAL DEVICE THAT INCORPORATED BETWEEN INFUSION LINE AND INDWELLING VENIPUNCTURE DEVICE BY A MALE AND A FEMALE LUER LOCK CONNECTOR TO REGULATE THE FLOW OF IV FLUIDS THROUGH FLOW REGULATOR.,EXTENSION LINE / FLUID DELIVERY TUBE (LOW OR HIGH PRESSURE) (EXTENSION TUBE (NON-STERILE BULK PACK), MAIS EX LINE, GENERIC NAME, SINOMEDIC.)-EXTENSION LINE / FLUID DELIVERY TUBE IS A DEVICE TO BE INCORPORATED BETWEEN INFUSION LINE AND THE INDWELLING VENIPUNCTURE DEVICE TO MINIMIZE DISTURBANCE AT CANNULATION/INSERTION SITES BY TAKING THE MOVEMENT OF AWAY FROM CANCELLATION/INSERTION SITE. LUER LOCK AND THREADED FEMALE PORTS ARE PROVIDED TO FACILITATE SAFE AND SURE CONNECTION TO THE LUERS.,3-WAY STOP COCK (WITH OR WITHOUT EXTENSION TUBE) (THREE WAY STOP COCK (NON-STERILE BULK PACK), MAISWAY, MI WAY, SMMP, GENERIC NAME, ATPL, RTM, MEDDEW, DEMOTEK, SINOMEDIC, THREE WAY STOP COCK WITH EXTENSION LINE (NON-STERILE BULK PACK), MAISWAY EXTN., SMMP, GENERIC NAME, SINOMEDIC,)-THE STOP COCK / STOP COCK MANIFOLD IS A DEVICE TO BE INCORPORATED BETWEEN INFUSION LINE AND INDWELLING VENIPUNCTURE DEVICE TO DELIVER ADDITIONAL FLUID TO THE HUMAN CIRCULATORY SYSTEM. ADMINISTRATE THE FLUIDS FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM.,TRACHEOSTOMY TUBE (WITH OR WITHOUT CUFFED)(TRACHEOSTOMY TUBE)-THE DEVICE TRACHEOSTOMY TUBES ARE INTENDED TO PROVIDE TRACHEAL ACCESS FOR AIRWAY MANAGEMENT OF TRACHEOSTOMNIZED PATIENTS.,TWIN BORE NASAL OXYGEN SET (OXY-PRONG)-TWIN BORE NASAL OXYGEN SET IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP., ENDOTRACHEAL TUBE (WITH OR WITHOUT CUFFED)(ENDOTRACHEAL TUBE)-THE ENDOTRACHEAL TUBE IS INTENDED FOR ORAL OR NASAL INTUBATION AND FOR AIRWAY MANAGEMENT,MEASURED VOLUME SET (M.V. SET)(BURETTE SET (NON-BULKSTERILE PACK), MAISVOL BURETTE SET, SMMP, GENERIC NAME, BURROPET, MAISVOL-PRO, SINOMEDIC.)-MEASURED VOLUME BURETTE FLUID INFUSION SET IS USED TO ADMINISTRATE THE FLUIDS FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM, THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN UNDER GRAVITY FEED AND MEDICAL APPLICATION IN ORDER TO ENSURE THEIR COMPATIBILITY FOR INFUSION SOLUTION.,BLOOD TRANSFUSION SET (B.T. SET)(GENERIC

	NAME, SINOMEDIC.)-BLOOD ADMINISTRATION SET IS USED TO ADMINISTER BLOOD FROM A CONTAINER (PLASTIC BAG OR GLASS BOTTLE) TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,I.V. CANNULA (WITH OR WITHOUT SAFETY FEATURE)(MAISFLON, MAISFLON INSTANT FLASH BACK, I.V. CANNULA (NON-STERILE BULK PACK), MAISFLON PLUS, MAISFLON PREMIUM, MAISFLEX, MAISCAN, MAISNEO, MASICATH, MAISWIN, MAISSAFE, SMMP, PRO-SURJ, SAFEZONE, MEDDEW, GENERIC NAME, HEALLIFE, MEDIPURE, SURGIALPHA, MEDIPRIME, SINOMEDIA, RTM, TEFLO, HEALTHESE, LIBERTON, DEMOTEK, INTRACURE, INTRAVENO, MAISFLON PRO, MEDIINJECTO, MEDIPRICK, SURGIVENO, MAISFLEX ORDERED BY UNICUT, PRO-SURJ (LABEL CHANGED), UFLON, UNEW, XIVA YOUR PARTNERS IN HEALTH CARE, NEOTEF, INTRAVENO SAFE, MAISWIN SAFE.)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES. THE SAFETY FEATURES PROTECTS THE HEALTHCARE PROFESSIONAL FROM THE NEEDLE STICK INJURY.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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3181	MFG/MD/2019/000038	1.License Holder Name: M/S. MERIL ENDO SURGERY PVT. LTD. 2.Approving Authority: DAMAN AND DIU 3.Device Name(Brand Name)-Intended Use:STERILE STAPLES (PINS) FOR DISPOSABLE ENDO CUTTER STAPLER(MIRUS™ DISPOSABLE ENDO CUTTER STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY., STERILE STAPLES (PINS) FOR DISPOSABLE CURVED CUTTER STAPLER(MIRUS™ DISPOSABLE CURVED CUTTER STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,STERILE STAPLES (PINS) FOR DISPOSABLE LINEAR CUTTER STAPLER(MIRUS™ DISPOSABLE LINEAR CUTTER STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY, STERILE STAPLES (PINS) FOR DISPOSABLE HEMORRHOIDS STAPLER (MIRUS™ DISPOSABLE HEMORRHOIDS STAPLER 3 ROWS)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,STERILE STAPLES (PINS) FOR DISPOSABLE HEMORRHOIDS STAPLER(MIRUS™ DISPOSABLE HEMORRHOIDS STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,STERILE STAPLES (PINS) FOR DISPOSABLE LINEAR STAPLER(MIRUS™ DISPOSABLE LINEAR STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,STERILE STAPLES (PINS) FOR DISPOSABLE CIRCULAR STAPLERS(MIRUS™ DISPOSABLE CIRCULAR STAPLER 3 ROWS)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,STERILE STAPLES (PINS) FOR DISPOSABLE CIRCULAR STAPLER(MIRUS™ DISPOSABLE CIRCULAR STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,DISPOSABLE SKIN STAPLER (MIRUS™ STERILE DISPOSABLE SKIN STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.

3182	MFG/MD/2019/000039	1.License Holder Name: BLUE NEEM MEDICAL DEVICES PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:GUIDEWIRES STAINLESS STEEL-USED TO GAIN ACCESS TO DESIRED ANATOMICAL LOCATION AND TO ASSIST IN PLACEMENT OF MEDICAL DEVICES DURING DIAGNOSTIC, INTERVENTIONAL, PTCA, PTA PROCEDURES ETC..., URETHRAL STENT-USED FOR STENTING THE URETHRA AFTER HYPOSPEDIAS OR EPISPEDIAS REPAIR AND TO PROVIDE POST-OPERATIVE DRAINAGE OF THE BLADDER,HEAMODIALYSIS CATHETER & SET-A HEAMODIALYSIS CATHETER IS A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT, A HEMODIALYSIS CATHETER IS USED FOR ACCESS OR VASCULAR ACCESS TO REACH THE BLOOD FOR HEMODIALYSIS.,MONO J STENT-USED FOR TEMPORARY DRAINAGE AND IRRIGATION OF URINE FROM THE KIDNEY,CENTRAL VENOUS CATHETER & SET-THE CENTRAL VENOUS CATHETERS ARE INTENDED FOR VASCULAR ACCESS INFUSION AND WITHDRAWAL OF BLOOD, BLOOD PRODUCTS, AND FLUIDS, CENTRAL VENOUS BLOOD SAMPLING AND INTERMITTENT DRUG INFUSION, FOR PERCUTANEOUS PLACEMENT OF A TUBE FOR DRAINAGE OF ASCITES & PLEURAL EFFUSIONS.,ENDOPYELOTOMY STENT-USED FOR INTERNAL DRAINAGE FROM URETERO PELVIC JUNCTION TO THE BLADDER FOLLOWING INCISION OF A STRICTURE,GUIDEWIRES NITINOL-USED TO GAIN ACCESS TO DESIRED ANATOMICAL LOCATION AND TO ASSIST IN PLACEMENT OF MEDICAL DEVICES DURING DIAGNOSTIC, INTERVENTIONAL, PTCA, PTA PROCEDURES ETC...,TUMOR STENT-USED FOR TEMPORARY OR PALLIATIVE TREATMENT OF URETER IN PATIENTS WITH EXTRINSIC URETERAL OBSTRUCTIONS,URETERAL STENT & SET(P FLEX STENT / BLUTHANE) -USED FOR INTERNAL DRAINAGE OF URINE FROM KIDNEY TO THE BLADDER,URETERAL STENT-USED FOR TEMPORARY INTERNAL DRAINAGE OF URINE FROM KIDNEY TO THE BLADDER,BILIARY STENTS-BILIARY STENTS ARE USED TO DRAIN BILE FROM OBSTRUCTED BILIARY DUCT
3183	MFG/MD/2019/000040	1.License Holder Name: CARE MED SURGIICAL COTTON 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS

3184	MFG/MD/2019/000041	1.License Holder Name: BLUE NEEM MEDICAL DEVICES PRIVATE LIMITED 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:INITIAL PUNCTURE NEEDLES-USED FOR GAINING ACCESS FOR PERCUTANEOUS NEPHROSTOMY PROCEDURE,URETERAL CATHETER CLOSED END-USED FOR DRAINAGE, RETROGRADE PYELOGRAM, ATRAUMATIC ENTRY OF URETERAL ORIFICE,DISCOGRAPHY KIT-THE DISCOGRAPHY KIT IS INDICATED FOR THE DISCOGRAPHY PROCEDURE,PCN CATHETER WITH SUTURE-USED FOR PERCUTANEOUS PLACEMENT OF A PIGTAIL CATHETER IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE,PERCUTANEOUS ACCESS SET-USED FOR SINGLE PUNCTURE PERCUTANEOUS ACCESS TO FACILITATE PLACEMENT OF 0.035 INCH DIAMETER GUIDE WIRE FOR INTERVENTIONAL RADIOLOGY PROCEDURES,PCN CATHETER WITH NEEDLE-USED FOR PERCUTANEOUS PLACEMENT OF A PIGTAIL CATHETER IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE,SCLEROTHERAPY INJECTION NEEDLE-THIS DEVICE IS USED FOR ENDOSCOPIC INJECTION INTO GASTROINTESTINAL MUCOSA,INTERNAL EXTERNAL DRAINAGE CATHETER-USED FOR TRANS HEPATIC BILIARY DRAINAGE,BIOPSY GUN-USED TO OBTAIN HISTOLOGICAL CORE SAMPLES FROM SOFT TISSUES AND ORGANS,CI CATHETER MALE-USED TO DRAIN URINE FROM BLADDER,CHIBA NEEDLES-USED FOR RENAL FINE ASPIRATION FOR CYTOLOGICAL STUDY,NEPHROSTOMY CATHETER SET-USED FOR PERCUTANEOUS PLACEMENT OF A CATHETER IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE,TROCAR NEEDLE WITH SHEATH-USED FOR PERCUTANEOUS ACCESS,INITIAL PUNCTURE NEEDLE-USED FOR GAINING ACCESS FOR PERCUTANEOUS NEPHROSTOMY PROCEDURE,SPINE PERCUTANEOUS ACCESS SET-USED FOR DILATION OF A PERCUTANEOUS TRACT AND SETUP OF A WORKING CHANNEL FOR ACCESS,IUI CATHETER-IUI CATHETERS ARE USED FOR ARTIFICIAL INSEMINATION,CHIBA NEEDLE-USED FOR RENAL FINE ASPIRATION FOR CYTOLOGICAL STUDY,SCLEROTHERAPY INJECTION NEEDLE-THIS DEVICE IS USED FOR ENDOSCOPIC INJECTION INTO GASTROINTESTINAL MUCOSA,RE-ENTRY MALECOT CATHETER-USED FOR RENAL DRAINAGE,MALECOT CATHETER-USED FOR PERCUTANEOUS PLACEMENT OF A MALECOT CATHETER IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE,PTBD CATHETER-PTBD CATHETERS ARE USED FOR TRANS HEPATIC BILIARY DRAINAGE,URETERAL CATHETER CONE TIP-USED FOR DRAINAGE, RETROGRADE PYELOGRAM, ATRAUMATIC ENTRY OF URETERAL ORIFICE,BILIARY DUCT DRAINAGE CATHETER-USED FOR TRANS HEPATIC BILIARY DRAINAGE,EXTERNAL INTERNAL CATHETER-USED FOR TRANS HEPATIC BILIARY DRAINAGE,DUAL LUMEN CATHETER-

	USED FOR DRAINAGE, RETROGRADE PYELOGRAM, ATRAUMATIC ENTRY OF URETERAL ORIFICE,SUPRAPUBIC CATHETER-USED TO PROVIDE BLADDER DRAINAGE BY PERCUTANEOUS PLACEMENT OF A MALECOT CATHETER,ABCESS DRAINAGE CATHETER-USED FOR ABSCESS DRAINAGE,PCN CATHETER-USED FOR PERCUTANEOUS PLACEMENT OF A PIGTAIL CATHETER IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE,NBDC CATHETER-NASO BILIARY DRAINAGE CATHETERS ARE USED FOR BILIARY DUCT DRAINAGE THROUGH NASAL PASSAGE AND TREATMENT OF STRICTURES IN THE DUCTILE SYSTEM,BIOPSY GUN-USED TO OBTAIN HISTOLOGICAL CORE SAMPLES FROM SOFT TISSUES AND ORGANS,URETERAL BALLOON CATHETER-URETERAL BALLOON DILATORS ARE USED TO EXERT RADIAL FORCE TO DILATE NARROW URETERAL SEGMENTS, GUIDEWIRE-USED PRIMARILY TO ESTABLISH A TRACT AND ASSIST IN THE PLACEMENT OF A SURGICAL DEVICE DURING UROLOGY PROCEDURES,GRASPING FORCEPS-USED TO REMOVE THE STONES AND RETRIEVAL OF FOREIGN OBJECT UNDER DIRECT VISION, URETHRAL DILATORS-USED FOR URETHRAL DILATION,NEGATIVE PRESSURE WOUND THERAPY POLYURETHANE FOAM KIT-TO BE USED AS NEGATIVE PRESSURE WOUND THERAPY DRAINAGE ALONG WITH A SUCTION PUMP,CI CATHETER FEMALE-USED TO DRAIN URINE FROM BLADDER,TROCAR NEEDLE WITH SHEATH-USED FOR PERCUTANEOUS ACCESS,FEMALE URETHRAL DILATOR-USED FOR SELF-DILATION OF URETHRA,AMPLATZ SHEATH-USED AS A WORKING CHANNEL TO MAINTAIN A PREVIOUSLY ESTABLISHED NEPHROSTOMY TRACT,URETERAL DILATORS-USED FOR DILATION OF THE URETER PRIOR TO URETEROSCOPY OR STONE MANIPULATION, DISCOGRAPHY KIT-THE DISCOGRAPHY KIT IS INDICATED FOR THE DISCOGRAPHY PROCEDURE,SUPRAPUBIC DRAINAGE CATHETER SET-USED TO PROVIDE BLADDER DRAINAGE BY PERCUTANEOUS PLACEMENT OF A CATHETER,PERCUTANEOUS ACCESS SET-USED FOR SINGLE PUNCTURE PERCUTANEOUS ACCESS TO FACILITATE PLACEMENT OF 0.035 INCH DIAMETER GUIDE WIRE FOR INTERVENTIONAL RADIOLOGY PROCEDURES,BILBAO DOTTER-BILBAO DOTTERS ARE USED FOR ENTEROCLYSIS PROCEDURE, TO INFUSE CONTRAST MEDIUM TO THE DISTAL DUODENAL LOOP OR THE PROXIMAL JEJUNUM TO PERFORM RADIOGRAPHIC STUDIES OF SMALL BOWEL,URETERAL CATHETER OPEN END-USED FOR DRAINAGE, RETROGRADE PYELOGRAM, ATRAUMATIC ENTRY OF URETERAL ORIFICE,JEJUNAL FEEDING TUBE-JEJUNAL FEEDING TUBE IS USED TO PROVIDE SHORT DURATION INTERNAL ACCESS TO SMALL BOWEL THROUGH ORAL CAVITY/MOUTH FOR DELIVERY OF NUTRITION OR MEDICATION,PTA BALLOON DILATOR-USED FOR TRANSLUMINAL DILATION,MEATAL DILATOR-USED BY ADULTS FOR

	SELF-DILATION OF THE URETHRAL MEATUS AND ADULT ASSISTED DILATION OF URETHRAL MEATUS FOR PAEDIATRIC PATIENTS,SCREW DILATOR-USED FOR FASCIAL DILATION IN ONE STEP,PEEL AWAY INTRODUCERS WITH DILATORS-USED FOR DILATION & INTRODUCTION OF SHEATH FOR CREATING ACCESS FOR TRANSLUMINAL ACCESS,URETHRAL SELF DILATOR-USED FOR MALE SELF-DILATION OF URETHRA,ONE STEP URETERAL DILATOR-USED FOR ONE STEP DILATION OF THE URETER PRIOR TO URETEROSCOPY OR STONE MANIPULATION,URETERAL BALLOON DILATOR-USED FOR DIALATION OF NARROW URETERAL SEGMENTS,PCNL 4 STEP DILATORS-USED FOR 4 STEP DILATION OF KIDNEY DURING PCNL PROCEDURES,FASCIAL DILATORS-USED FOR FASCIAL DILATION, RENAL DILATORS WITH AMPLATZ SHEATH-USED FOR DILATION OF A PERCUTANEOUS TRACT AND SETUP OF A WORKING CHANNEL INTO THE KIDNEY FOR REMOVAL OF STONES,STONE BASKET-USED FOR STONE MANIPULATION AND REMOVAL IN THE URINARY TRACT, URETERAL ACCESS SHEATH-USED TO ESTABLISH A CONDUIT DURING ENDOSCOPIC UROLOGICAL PROCEDURES, FACILITATING THE PASSAGE OF ENDOSCOPES AND OTHER INSTRUMENTS INTO THE URINARY TRACT,NEPHROSTOMY TRACK BALLOON DILATOR-USED FOR DILATION OF PERCUTANEOUS TRACT FOR NEPHROSTOMY PROCEDURE,AMPLATZ RENAL DILATION SET-USED FOR DILATION OF A PERCUTANEOUS TRACT AND SETUP OF A WORKING CHANNEL INTO THE KIDNEY FOR REMOVAL OF STONES

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3185	MFG/MD/2019/000042	1.License Holder Name: DOLPHIN LIFESCIENCE INDIA LLP 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:INTRODUCER SHEATH (ASTERIA)-THE INTRODUCER SHEATH IS USED DURING ANGIOPLASTY PROCEDURES TO PROVIDE A PATHWAY THROUGH WHICH A PTCA GUIDING CATHETER MAY BE PERCUATNEOUSLY INTRODUCED INTO THE VASCULATURE OR VARIOUS DEVICES INTO VEIN OR ARTERIES WHILE MAINTAINING HEMOSTASIS FOR A VARIETY OF DIAGNOSTIC AND THERAPEUTIC PROCEDURE.,PTCA CUSTOM KIT(SYMEOM)-PTCA CUSTOM KIT IS INTENDED TO USE DIFFERENT ACCESSORIES SPECIFIED KIT FOR USE DURING PTCA AND ANGIOGRAPHY PROCEDURE FOR FLUID AND PRESSURE MANAGEMENT OF THE PROCEDURE. THE KITS ARE MULTIPURPOSE AND EACH DEVICE HAS SPECIFIC USE DURING PROCEDURE.,PTCA GUIDEWIRE(MARINER)-MARINER PTCA GUIDEWIRES ARE STEERABLE GUIDEWIRES THAT ARE USED DURING THE PERCUTANEOUS CORONARY INTERVENTION (PCI) TO REACH A LESION OR VESSEL SEGMENT BY SERVING AS A GUIDING FOR OTHER DIAGNOSTIC OR INTERVENTIONAL DEVICES IN THE CORONARY AND PERIPHERAL VASCULATURE.,ANGIOGRAPHIC GUIDE WIRE(EXPLORER)-GUIDE WIRE IS DESIGNED FOR PERCUTANEOUS VESSEL ENTRY USING SELDINGER TECHNIQUE TO FACILITATE THE SUBSEQUENT INTRODUCTION OF AN INTRAVASCULAR DEVICE DURING INVASIVE CARDIOLOGY PROCESS. THE GUIDE WIRE IS MANUFACTURED FROM STAINLESS STEEL WHICH COULD BE COATED WITH PTFE SILICONE OR NOT.
3186	MFG/MD/2019/000043	1.License Holder Name: LEVRAM LIFESCIENCES PVT. LTD. 2.Approving Authority: DADRA AND NAGAR HAVELI 3.Device Name(Brand Name)-Intended Use:HYPODERMIC NEEDLE(VN (LEVRAM))-BLOOD COLLECTION

3187	MFG/MD/2019/000044	1.License Holder Name: INVENT BIOMED PRIVATE LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:3 WAY STOP COCK & 2 PORT / 3 PORT / 4 PORT MANIFOLD(FLEXIPORT)-STOP COCKS • STOP COCKS ARE INTENDED FOR USE AS A VALVE THAT REGULATES THE FLOW OF FLUID THROUGH A PIPE; A FAUCET. IT IS MAINLY USED FOR FLOW AND FLUID MANAGEMENT DEVICE WITH PRINCIPAL USE FOR CONTROLLING FLUIDS /CHANGE IN DIRECTION OF FLUIDS/STOPPING OF FLOW/FLUIDS .STOP COCKS ARE ANGIOGRAPHIC ACCESSORY INTENDED FOR USE AS A FLOW CONTROL KNOBS AN ON/OFF DEVICE FOR ANGIOGRAPHY AND VARIOUS SURGICAL APPLICATIONS AT HIGH PRESSURE OPERATIONS. MANIFOLDS • MANIFOLDS ARE INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT(S) FOR ADMINISTRATION OF SOLUTIONS. TYPICAL USES INCLUDE PRESSURE MONITORING, INTRAVENOUS FLUID ADMINISTRATION AND TRANSFUSION.,CONTROL SYRINGE (CONTROL DEVICE)-CONTROL DEVICE (CONTROL SYRINGE 2ML,3ML, 5ML,10ML,12ML,20ML &25 ML) IS PRECISELY DESIGNED FOR USE DURING PERCUTANEOUS TRANSLUMINAL CORONARYANGIOPLASTY (PTCA) ANY OTHER INTRAVASCULAR THERAPEUTIC PROCEDURES THAT USED FOR MEASUREMENT AND DISCHARGE OF FLUID (SALINE/ CONTRAST)INTO THE BODY.,PRESSURE MONITORING LINE(EASY FLOW)- PRESSURE MONITORING LINE : PRESSURE MONITORING LINE IS PRECISELY DESIGNED FOR USE DURING PTCA AND ANY OTHER INTRAVASCULAR THERAPEUTIC PROCEDURES THAT NEED TO MONITOR PRESSURE OF ANY FLUID OR BLOOD.,TRANS RADIAL COMPRESSION DEVICE AND ANGIO CLOSURE FEMO SEAL PAD (COMPRESS TR / COMPRESS FC)-TR BAND : THIS PRODUCT IS AN AUXILIARY DEVICE USED FOR THE COMPRESSION OF REDIAL ARTERY AFTER TRANS RADIAL INTERVENTIONAL PROCEDURE. FEMO SEAL PAD : IT IS PRESSURE ASSISTED DEVICES ARE TO ASSIST FOR MAINTAINING HEMOSTASIS . THE DEVICE IS ALSO INDICATED IN THE REDUCTION OF ACTIVE COMPRESSION TIME IN FEMORAL ARTERY CANNULATION FOLLOWING DIAGNOSIS AND INTERVENTIONAL PROCEDURE.,PTCA CUSTOM KIT(ANGITRIX)-PTCA CUSTOM KIT IS DESIGNED ACCESSORIES SPECIFIED KIT FOR USE DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND ANGIOGRAPHY PROCEDURE FOR FLUID AND PRESSURE MANAGEMENT OF THE PROCEDURE. THE KITS ARE MULTIPURPOSE AND EACH DEVICE HAS SPECIFIC USE DURING PROCEDURE. , BALLOON INFLATION DEVICE (STAR/NOVA/COMFORT/INTEGRA/GALAXY)-BALLOON INFLATION DEVICE IS PRECISELY DESIGN FOR USE DURING PTCA AND ANY OTHER INTRAVASCULAR THERAPEUTICS THAT UTILIZE A BALLOON

	CATHETER AND PRESSURE MONITORING.,HEMOSTASIS Y CONNECTOR WITH BLUNT INTRODUCER, TORQUER, ADVANCED GUIDE WIRE INTRODUCER 18G,20G,21G AND SIDE ARM WITH STOPCOCK(PERFORMER)-Y-CONNECTOR: (PUSH CLICK TYPE, PUSH PULL TYPE, SCREW TYPE) • Y CONNECTOR INTENDS TO PROVIDE TWO TUNNELS INTO THE BLOOD VESSEL; THIS CAN INTRODUCE THE CONTRAST MEDIUM AND GUIDE WIRE OR CATHETERS DURING THE INTERVENTIONAL SURGERY. Y CONNECTOR VALVE INTENDS TO PREVENT BLOOD LOST.• IT PROVIDES A MEAN FOR INSERTING GUIDE WIRES OR CATHETERS DEEP INTO THE VASCULATURE, AND POSITIONING AND LOCKING THEM INTO A DESIRED PLACE. Y-CONNECTOR INCLUDES A STRAIGHT AND A SIDE ACCESS LUMEN. THE HEMOSTASIS VALVE LOCATED AT THE PROXIMAL END OF THE STRAIGHT LUMEN CAN BE OPENED OR CLOSED BY OPERATION OF THE PUSH-CLICK BUTTON. THE DISTAL END HAS A ROTATING MALE LUER LOCK. THE SIDE ACCESS LUMEN ALLOWS PRESSURE MONITORING AND PERFUSION. BLUNT INTRODUCER (INSERTION TOOL): IT IS AN ACCESSORY DESIGN TO FACILITATE THE INTRODUCTION OF GUIDE WIRES (UP TO 0.018”) USED IN CONJUNCTION WITH INTERVENTIONAL DEVICES DURING VASCULAR INTERVENTIONAL PROCEDURES. BLUNT INTRODUCER INSERTS THE VALVE OF Y CONNECTOR, MAKING A TUNNEL FOR GUIDE WIRE TO GET THROUGH AND PROTECTING GUIDE WIRE TIP TORQUER : TORQUER HOLD GUIDEWIRE AND MAKES TORQUE GUIDEWIRE MOVE EASILY . IT IS DESIGN TO FACILATE STERING OF0.010'' GUIDEWIRE INSIDE THE VASCULATURE. ADVANCE GUIDE WIRE INTRODUCER: ADVANCE GUIDE WIRE INTRODUCER IS AN ACCESSORY TO PUNCTURE THE FEMORAL ARTERY FOR INTRODUCING THE GUIDE WIRE WITHIN THE BODY DURING ANGIOPLASTY.

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3188	MFG/MD/2019/000046	1.License Holder Name: ARHTRON IMPLANTS PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATE(ARTHRON)-BONE PLATE ARE USED FOR TREATMENT OF SURGICAL FRACTURE TO RECONSTRUCT THE ANATOMY AND RESTORE THE FUNCTION OF PARTICULAR BONE.,WIRE AND PIN(ARTHRON)-WIRE ARE USED TO HOLD SMALL BONE FRACTURE. PIN ARE USED WITH EXTERNAL FIXATOR TO SUPPORT BONE FRACTURE.,BONE SCREW(ARTHRON)-BONE SCREWS ARE USED IN TRAUMATOLOGY AND ORTHOPAEDICS FOR OSTHEOSYNTHESIS, FIXATION OF BONE PLATES TO THE BONE AND FOR NAIL LOCKING.,BONE SCREW(ARTHRON)-BONE SCREWS ARE USED IN TRAUMATOLOGY AND ORTHOPAEDICS FOR OSTHEOSYNTHESIS, FIXATION OF BONE PLATES TO THE BONE AND FOR NAIL LOCKING.,BONE NAIL(ARTHRON)-AN INTERLOCKING NAIL IS A NAIL PLACED WITHIN THE MEDULLARY CAVITY OF A LONG BONE SECURED IN POSITION BY PROXIMAL AND DISTAL TRANSFIXING SCREWS TO PROVIDE AXIAL, BENDING AND TORSIONAL STABILITY. THEY ARE BEST SUITED FOR DIAPHYSEAL FRACTURES AND PARTICULARLY USEFUL IN CASES WITH EXTENSIVE COMMINUTION.,SPINE(ARTHRON)-SPINE IMPLANTS ARE USED TO SUPPORT, REPLACE COLLAPSED, DAMAGED OR UNSTABLE VERTEBRAL BODIES DUE TO ANY SORT OF TRAUMA OR TUMOR.,BONE PLATE(ARTHRON)-BONE PLATE ARE USED FOR TREATMENT OF SURGICAL FRACTURE TO RECONSTRUCT THE ANATOMY AND RESTORE THE FUNCTION OF PARTICULAR BONE.,BONE NAIL(ARTHRON)-AN INTERLOCKING NAIL IS A NAIL PLACED WITHIN THE MEDULLARY CAVITY OF A LONG BONE SECURED IN POSITION BY PROXIMAL AND DISTAL TRANSFIXING SCREWS TO PROVIDE AXIAL, BENDING AND TORSIONAL STABILITY. THEY ARE BEST SUITED FOR DIAPHYSEAL FRACTURES AND PARTICULARLY USEFUL IN CASES WITH EXTENSIVE COMMINUTION.

3189	MFG/MD/2019/000047	1.License Holder Name: TTK HEALTHCARE LIMITED (PROTECTIVE DEVICES DIVISION) 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:NATURAL RUBBER LATEX MALE CONDOMS (FOR EXPORT PURPOSE)(BLUE / GOLD)-TO AVOID UN WANTED PREGNANCY AND PREVENTION OF TRANSMISSION OF SEXUALLY TRANSMITTED INFECTIONS (STI),NATURAL RUBBER LATEX MALE CONDOMS(HOT PINK)-TO AVOID UNWANTED PREGNANCY AND PREVENTION OF TRANSMISSION OF SEXUALLY TRANSMITTED INFECTIONS (STI),NATURAL RUBBER LATEX MALE CONDOMS(NO LOGO)-TO AVOID UN WANTED PREGNANCY AND PREVENTION OF TRANSMISSION OF SEXUALLY TRANSMITTED INFECTIONS (STI),1. NATURAL RUBBER LATEX MALE CONDOMS (FOR BOTH DOMESTIC AND EXPORT)(NIRODH, DELUXE NIRODH, AASHA NIRODH, MASTI, SKORE, DUREX, KOHINOOR, DUREX KOHINOOR, BULK UNTESTED / TESTED CONDOMS, BULK FOILED GENERIC CONDOMS, JEITO, DOM, UNFPA, CONTEX, CHOICE, CONDOMIZE, DOCTISSIMO, MASIBAMBISANE, SUSTAIN NATURAL, INTIMY, MORE A MORE, ETOS, KURIDVAT,. RING SAFE N SURE, TRUST, PRUDENCE, DELIGHT, ULINZI)-TO AVOID UNWANTED PREGNANCY AND PREVENTION OF TRANSMISSION OF SEXUALLY TRANSMITTED INFECTIONS (STI)., NATURAL RUBBER LATEX MALE CONDOMS(FOR EXPORT - PRUDENCE BLACK/YELLOW)-TO AVOID UNWANTED PREGNANCY AND PREVENTION OF TRANSMISSION OF SEXUALLY TRANSMITTED INFECTIONS (STI),NATURAL RUBBER LATEX MALE CONDOMS WITH 5% BENZOCAINE AS DESENSITIZIER (CREAM/SOLUTION) FOR BOTH DOMESTIC AND EXPORT(SKORE, DUREX, DOM, MASTI, KOHINOOR, DUREX KOHINOOR, TRUST, PRUDENCE, DELIGHT, ULINZI, JEITO)-THE MALE LATEX CONDOM LUBRICATED WITH BENZOCAINE 5% IS INTENDED TO BE USED FOR CONTRACEPTIVE AND PROPHYLACTIC PURPOSES. ADDITIONALLY, THE LUBRICANT ON THE CONDOM HELPS IN TEMPORARILY PROLONGING THE TIME UNTIL EJACULATION., RUBBER LATEX MALE CONDOMS(FOR EXPORT - SICO)-TO AVOID UNWANTED PREGNANCY AND PREVENTION OF TRANSMISSION OF SEXUALLY TRANSMITTED INFECTIONS (STI),NATURAL RUBBER LATEX MALE CONDOMS - FOR EXPORT PURPOSE(VIBE)-TO AVOID UNWANTED PREGNANCY AND PREVENTION OF TRANSMISSION OF SEXUALLY TRANSMITTED INFECTIONS (STI),RUBBER LATEX MALE CONDOMS(FOR EXPORT - PROTEC NATURAL)-TO AVOID UN WANTED PREGNANCY AND PREVENTION OF TRANSMISSION OF SEXUALLY TRANSMITTED INFECTIONS (STI)

3190	MFG/MD/2019/000048	1.License Holder Name: JIND SURGICALS 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.-MEDICAL ABSORBENT(FIBRE BANDAGE),BANDAGE, GAUZE (JIND SURGICAL BANDAGE, GAUZE)-USED TO HOLD IN PLACE DRESSING/COMPRESSES TO COVER AND ISOLATE A WOUND.

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3191	MFG/MD/2019/000049	1.License Holder Name: DR. SURGICAL 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:EMBOLACTOMY CATHETER(DR SURGICAL)-ARTERIAL EMBOLACTOMY CATHETER SIMPLE RAPID REMOVAL OF SOFT, FRESH EMBOLI FROM THE ARTERIAL SYSTEM.,ARTERIAL CATHETER(DR. SURGICAL)-THE SELDINGER TECHNIQUE IS USED FOR ANGIOGRAPHY, INSERTION OF CHEST DRAINS AND CENTRAL VENOUS CATHETERS, INSERTION OF PEG TUBES USING THE PUSH TECHNIQUE, INSERTION OF THE LEADS FOR AN ARTIFICIAL PACEMAKER OR IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR, AND NUMEROUS OTHER INTERVENTIONAL MEDICAL PROCEDURES.,CUSTOM PACK(DR SURGICAL)-THE HEART LUNG PACK IS A PART OF AN EXTRACORPOREAL SYSTEM. IT IS USED EXCLUSIVELY IN COMBINATION WITH HEART LUNG MACHINE AND OTHER DEVICES OF THE SYSTEM, SUCH AS OXYGENATOR, BCD. THE SET IS USED EXCLUSIVELY FOR TRANSPORTATION OF BLOOD AND OTHER LIQUID BETWEEN THE PATIENT AND EXTRACORPOREAL SYSTEM. THIS SET IS NOT A STANDARD PRODUCT. IT IS ASSEMBLED ACCORDING TO THE CUSTOMERS SPECIFICATIONS, E.T.O AND PYROGEN FREE.,PRE- ONE WAY CHECK VALVE(DR. SURGICAL)-THE TRANSPARENT BODY FACILITATES PRIMING OPERATIONS AND RECOVERY OF THE SOLUTION CONTAINED IN THE FILTER. CHECK THAT THE PACKAGE IS WELL SEALED AND WITHOUT ANY DAMAGE. ONE-WAY VALVE COMPONENTS ARE USED TO CREATE A UNIDIRECTIONAL FLOW IN A DEVICE. THEY ARE IN FACT ELASTOMERIC SEALING ELEMENTS THAT ALLOW FORWARD FLOW AND PREVENT BACKFLOW.,THERMODILUTION CATHETER(DR SURGICAL)-IN ADDITION TO PAOP MONITORING.THE STANDARD PA THERMODILUTION CATHETERS MONITOR CVP, PROVIDE INTERMITTENT CARDIAC OUTPUT MEASUREMENTS.ALLOW FOR VENOUS AND MIXED VENOUS BLOOD SAMPLING AND HAVE OPTIONAL VENTRICULAR PACING CAPABILITY.THESE CATHETERS ARE ALSO AVAILABLE IN A TORQUE LINE FOR ENHANCED MANUEUVERABILITY. THE STANDARD PA THERMODILUTION CATHETERS ARE PART OF A COMPLETE LINE OF PA CATHETERSOFFERED WITH NO NATURAL RUBBER LATEX COMPONENTS IN ORDER TO REDUCE THE RISK OF PATIENT LATEX ALLERGY OF HYPER SENSTIVITY WITHOUT COMPROMISING PERFORMANCE.,INTRODUCER SHEATH MULIN(DR. SURGICAL)-A PERCUTANEOUS INTRODUCER IS USED TO FACILITATE PLACING A CATHETER THROUGH THE SKIN INTO A VEIN OR ARTERY. PERCUTANEOUS INTRODUCERS ARE RECOMMENDED FOR INITIAL PERCUTANEOUS INTRODUCTION OR THE EXCHANGE OF INTRAVASCULAR DEVICES. THE CATHETER INTRODUCER SHEATH IS

	INDICATED FOR USE INPATIENTS REQUIRING ACCESS OF THE VENOUS SYSTEM OR TO FACILITATE CATHETER INSERTION.,GUIDE EXTENSION CATHETER(DR SURGICAL)-GUIDE LINER CATHETERS ARE INTENDED TO BE USED IN CONJUNCTION WITH GUIDE CATHETERS TO ACCESS DISCRETE REGIONS OF THE PERIPHERAL VASCULATURE, AND TO FACILITATE PLACEMENT OF INTERVENTIONAL DEVICES., CUSTOMIZED ANGIO KIT(DR. SURGICAL)-THE ANGIO KITS ARE INDICATED FOR ENDOVASCULAR COAGULATION OF THE GREAT SAPHENOUS VEIN (GSV) IN PATIENTS WITH SUPERFICIAL VEIN REFLUX, FOR THE TREATMENT OF VARICOSE VEINS AND VARICOSITIES ASSOCIATED WITH SUPERFICIAL REFLUX OF THE GREAT SAPHENOUS VEIN (GSV), AND FOR THE TREATMENT OF INCOMPETENCE AND REFLUX OF SUPERFICIAL VEINS OF THE LOWER EXTREMITY. THIS PRODUCT SHOULD BE USED ONLY WITH LASERS CLEARED FOR USE IN THE TREATMENT OF VARICOSE VEINS, VARICOSITIES WITH SUPERFICIAL REFLUX OF THE GSV, AND IN THE TREATMENT OF INCOMPETENT REFLUXING VEINS IN THE SUPERFICIAL VENOUS SYSTEM IN THE LOWER LIMBS.,MICRO CATHETER (DR SURGICAL)-MICRO-CATHETERS, ALTHOUGH A BROAD TERM, IS OFTEN USED TO DESCRIBE THIN WALL, SMALL DIAMETER CATHETERS AND DELIVERY DEVICES USED IN MINIMALLY INVASIVE APPLICATIONS. THESE SMALL CATHETERS ARE IDEAL FOR NAVIGATING THE VAST NETWORK OF TINY VEINS FOUND WITHIN THE BODY.,ARTERIAL FILTER(DR. SURGICAL)-THE AFFINITY FUSION OXYGENATOR WITH INTEGRATED ARTERIAL FILTER AND BALANCE BIOSURFACE IS INTENDED TO BE USED IN AN EXTRACORPOREAL PERFUSION CIRCUIT TO OXYGENATE AND REMOVE CARBON DIOXIDE FROM THE BLOOD AND TO COOL OR WARM THE BLOOD DURING ROUTINE CARDIOPULMONARY BYPASS PROCEDURES UP TO 6 HOURS IN DURATION. THE AFFINITY FUSION OXYGENATOR WITH INTEGRATED ARTERIAL FILTER AND BALANCE BIOSURFACE IS DESIGNED TO FILTER FROM THE -CIRCUIT MICROEMBOLI LARGER THAN THE SPECIFIED MICRON SIZE FOR PERIODS UP TO SIX HOURS DURING CARDIOPULMONARY BYPASS SURGERY.,DISPOSABLE SHUNT(DR SURGICAL)-DISPOSABLE CORONARY SHUNT IS USED IN OFF-PUMP CORONARY ARTERY BYPASS GRAFTING OPERATIONS TO INSURE THAT THERE WOULD BE ENOUGH BLOOD FLOW TO THE DISTANT PART OF THE HEART.,GUIDE WIRE SS UNCOATED(CARRY)-GUIDEWIRE FACILITATES PLACEMENT OF A CATHETER DURING DIAGNOSTIC OR INTERVENTIONAL PERIPHERAL INTRAVASCULAR PROCEDURES INCLUDING BUT NOT LIMITED TO RENAL INTERVENTION. THE WIRE CAN BE TORQUED TO FACILITATE NAVIGATION THROUGH THE VASCULATURE. GUIDEWIRE FACILITATES PLACEMENT OF A CATHETER DURING DIAGNOSTIC OR

	INTERVENTIONAL PERIPHERAL INTRAVASCULAR PROCEDURES INCLUDING BUT NOT LIMITED TO RENAL INTERVENTION. THE WIRE CAN BE TORQUED TO FACILITATE NAVIGATION THROUGH THE VASCULATURE.,CENTRAL VENOUS CATHETER(DR SURGICAL)-CVC IS MANUFACTURED WITH MEDICAL GRADE, FLEXIBLE POLYURETHANE. A PRESSURE INJECTABLE CVC MAY VARY FROM 2 TO 4 NON COMMUNICATING LUMENS. THE CATHETERS HAS A SOFT BLUE FLEX TIP THAT IS MORE PLIABLE THAN THE CATHETER BODY. LUMENS ARE CONNECTED TO SEPARATE COLOUR CODED EXTENSION LINES WHICH HAVE HUBS ON THE END THAT ARE STANDARD LUER LOCK. CENTIMETER MARKING REFERENCED FROM THE TIP THAT ARE PLACED ALONG THE OF INDWELLING CATHETER BODY TO FACILITATE PROPER POSITIONING. THE KIT COMPONENTS ASSIST THE CLINICAL IN MAINTAINING MAXIMAL STERILE BARRIER PRECAUTIONS.,DISPOSABLE ANGIO CLOSURE PAD(DR. SURGICAL)-PATIENTS WITH CORONARY ARTERY DISEASES WHO NEED FEMORAL ARTERY PUNCTURE. THIS PRODUCT MUST BE USED BEFORE EXPIRY DATE. THIS PRODUCT CAN ONLY BE USED ONCE AND REUSING IS NOT PERMITTED. THE DEVICE SHOULD BE USED IMMEDIATELY AFTER OPENING THE PACKAGE AND DISPOSED OF SAFELY AND PROPERLY AFTER USE. ANGIO-CLOSURE PAD AND TR BAND ARE THE BUFFER MATERIALS TO STOP BLEEDING IN GROIN AND WRIST AFTER ANGIOMA OPERATION. THE PARTICAL APPLICATION PATIENTS WITH CLOSURE PAD CAN GET OFF BED TWO HOURS LATER.STRIP LENGTH CAN BE AJUSTED FOR PATIENT COMFORT.,GUIDING CATHETER(DR SURGICAL)-THE GUIDE CATHETER PROVIDES SUPPORT FOR DEVICE ADVANCEMENT.,RADIAL BAND(DR. SURGICAL)-THE RADIAL DEVICE IS A 26-CM LONG, SELF-ADHESIVE WRISTBAND DESIGNED TO ASSIST HEMOSTASIS OF THE RADIAL ARTERY AFTER A CATHETERIZATION PROCEDURE AND IS NOT MADE WITH NATURAL RUBBER LATEX. THE BAND DELIVERS ADJUSTABLE COMPRESSION OF THE RADIAL PUNCTURE SITE WITH AN INFLATABLE BULB AND STANDARD LUER VALVE FOR EASY INFLATION AND DEFLATION WITH ANY STANDARD LUER SYRINGE.,PA CATHETER(DR SURGICAL)-THE CATHETER CAN ALSO BE USED FOR AORTIC ANGIOGRAPHIC IN THE PAEDIATRIC POPULATION. THE INDICATIONS FOR USE OF THIS CATHETER COULD INCLUDE TRANSPOSITION OF THE GREAT VESSELS OR TETRA LOGY OF FALLOT AMONG OTHERS.,SNUGGER SET(DR. SURGICAL)-SUGGNER SET THERAPY IS USED TO DELIVER MEDICATIONS ALONG THE RESPIRATORY TRACT AND IS INDICATED TO VARIOUS RESPIRATORY PROBLEMS AND DISEASES SUCH AS:. • BRONCHO-SPASMS • CHEST TIGHTNESS • EXCESSIVE AND THICK MUCUS SECRETIONS • RESPIRATORY CONGESTIONS • PNEUMONIA,VASCULAR SNARE(DR SURGICAL)-A VASCULAR SNARE IS A ENDOVASCULAR DEVICE THAT

	IS USED TO REMOVE FOREIGN BODIES FROM INSIDE ARTERIES AND VEINS. THE SNARE CONSISTS OF SEVERAL RADIO PAQUE LOOPS OF WIRE INSIDE A CATHETER, WHICH WHEN EXTENDED FLOWER OUT, AND WHICH COLLAPSE WHEN WITHDRAWN INTO THE CATHETER., NITINOL GUIDE WIRE(CARRY)-GUIDEWIRE FACILITATES PLACEMENT OF A CATHETER DURING DIAGNOSTIC OR INTERVENTIONAL PERIPHERAL INTRAVASCULAR PROCEDURES INCLUDING BUT NOT LIMITED TO RENAL INTERVENTION. THE WIRE CAN BE TORQUED TO FACILITATE NAVIGATION THROUGH THE VASCULATURE. NITINOL WIRE, USED BY ITSELF OR BRAIDED WITH STAINLESS STEEL, HELPS INCREASE FLEXIBILITY AND ALLOWS THE WIRE TO SPRING BACK INTO SHAPE AFTER NAVIGATING A TORTUOUS VESSEL SEGMENT. GUIDE WIRES USUALLY HAVE A FLOPPY TIP AND A STIFF BODY TO ENABLE EASY TIP NAVIGATION, WITH GOOD PUSHABILITY OFFERED BY THE STIFFER SECTION OF THE WIRE.,PTCA BALLOON CATHETER (DR SURGICAL)-PTCA BALLOON CATHETER IS INDICATED FOR BALLOON DIALATION OF THE STENTOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,HYDROPHILIC GUIDE WIRE (CARRY)-GUIDEWIRE FACILITATES PLACEMENT OF A CATHETER DURING DIAGNOSTIC OR INTERVENTIONAL PERIPHERAL INTRAVASCULAR PROCEDURES INCLUDING BUT NOT LIMITED TO RENAL INTERVENTION. THE WIRE CAN BE TORQUED TO FACILITATE NAVIGATION THROUGH THE VASCULATURE. ALL HI-TORQUE GUIDE WIRES ARE INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA).,VENTRICULAR CATHETER KIT (DR SURGICAL)-THE VENTRICULAR ASSIST SYSTEM IS INDICATED FOR USE AS A BRIDGE TO CARDIAC TRANSPLANTATION IN PATIENTS WHO ARE AT RISK OF DEATH FROM REFRACTORY END STAGE LEFT VENTRICULAR HEART FAILURE. THE SYSTEM IS DESIGNED FOR IN HOSPITAL AND OUT OF HOSPITAL SETTINGS. INCLUDING TRANSPORTATION VIA FIXED WING AIRCRAFT OR HELICOPTER., DIAGNOSTIC CATHETER(DR. SURGICAL)-THE POLARIS X STEERABLE DIAGNOSTIC CATHETER IS INTENDED FOR TEMPORARY USE IN ELECTROPHYSIOLOGY STUDIES FOR INTRACARDIAC STIMULATION (PACKING) AND/OR RECORDING OF ELECTRICAL POTENTIALS. EXCESSIVE BENDING OR KINKING OF THE CATHETER SHAFT MAY DAMAGE INTERNAL WIRES, MANUAL PREBENDING OF THE DISTAL CURVE CAN DAMAGE THE STEERING MECHANISM AND /OR ELECTRICAL WIRE AND MAY CAUSE PATIENT INJURY. BEFORE USING INSPECT FOR PHYSICAL DAMAGE INCLUDING ELECTRICAL INSULATION ON THE CABLES AND THE CATHETER SHAFT. REPLACE

	DAMAGED EQUIPMENT. CORONERY ANGIOGRAPHY IS A DIAGNOSTIC PROCEDURE THAT ALLOWS VISUALIZATION OF THE CORONARY VESSELS. FLUOROSCOPY IS USED TO VISUALIZE THE LUMENS OF THE ARTERIES AS A 2-D PROJECTION. SHOULD THESE ARTERIES SHOW NARROWING OR BLOCKAGE, THEN TECHNIQUES EXIST TO OPEN THESE ARTERIES. PERCUTANEOUS CORONARY INTERVENTION IS A BLANKET TERM THAT INVOLVES THE USE OF MECHANICAL STENTS, BALLOONS, ETC TO INCREASE BLOOD FLOW TO PREVIOUSLY BLOCKED (OR OCCLUDED) VESSELS.,KHYPHOPLASTY AND VERBTROPLASTY KIT(DR SURGICAL)-VERTEBROPLASTY IS A PROCEDURE IN WHICH ACRYCLIC CEMENT IS INJECTED INTO A FRACTURED AND COLLAPSED VERTEBRA (SPINAL BONE) IN ORDER TO STRENGTHEN THE BONE AND DECREASED PAIN FROM THE FRACTURE. IN KHYPHOPLASTY, A BALLOON IS INSERTED INTO A FRACTURED AND COMPRESSED VERTEBRA AND INFLATED, AFTER WHICH ACRYLIC CEMENT IS INJECTED INTO THE RESULTING CAVITY, KHYPHOPLASTY IS DESIGNED TO RELEIVE PAIN AND IMPROVE SPINAL DEFOMITIES ASSOCIATED WITH VERTEBRAL COMPRESSION FRACTURE.,PTFE GUIDE WIRE(CARRY)-GUIDEWIRE FACILITATES PLACEMENT OF A CATHETER DURING DIAGNOSTIC OR INTERVENTIONAL PERIPHERAL INTRAVASCULAR PROCEDURES INCLUDING BUT NOT LIMITED TO RENAL INTERVENTION. THE WIRE CAN BE TORQUED TO FACILITATE NAVIGATION THROUGH THE VASCULATURE. ALL HI-TORQUE GUIDE WIRES ARE INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA)., INTRODUCER RADIAL SHEATH(DR. SURGICAL)-A PERCUTANEOUS INTRODUCER IS USED TO FACILITATE PLACING A CATHETER THROUGH THE SKIN INTO A VEIN OR ARTERY. PERCUTANEOUS INTRODUCERS ARE RECOMMENDED FOR INITIAL PERCUTANEOUS INTRODUCTION OR THE EXCHANGE OF INTRAVASCULAR DEVICES. THE CATHETER INTRODUCER SHEATH IS INDICATED FOR USE INPATIENTS REQUIRING ACCESS OF THE VENOUS SYSTEM OR TO FACILITATE CATHETER INSERTION,CUSTOMIZED PTCA KIT(DR. SURGICAL)-THE PTCA KIT ARE INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY IN THE PERIPHERAL VASCULATURE, INCLUDING ILIAC, FEMORAL, POPLITEAL, INFRA-POPLITEAL, RENAL, AND FOR THE TREATMENT OF OBSTRUCTIVE LESIONS OF NATIVE OR SYNTHETIC ARTERIOVENOUS DIALYSIS FISTULAE. THESE DEVICES ARE ALSO INDICATED FOR POST-DILATATION OF BALLOON EXPANDABLE AND SELF-EXPANDING STENTS IN THE PERIPHERAL VASCULATURE. THE BALLOON DILATATION CATHETER (ONLY) IS ALSO INDICATED FOR THE CAROTID ARTERIES. WHEN YOUR

		CLINICAL NEEDS ARE UNIQUE, DR. SURGICAL CAN CUSTOMIZE ANPTCA KIT TO MEET YOUR SPECIFIC REQUIREMENTS. DR SURGICAL CAN ASSIST IN COMBINING ANY COMPONENTS INTO A SINGLE KIT.. PTCA GUIDE WIRE(CARRY)-GUIDEWIRE FACILITATES PLACEMENT OF A CATHETER DURING DIAGNOSTIC OR INTERVENTIONAL PERIPHERAL INTRAVASCULAR PROCEDURES INCLUDING BUT NOT LIMITED TO RENAL INTERVENTION. THE WIRE CAN BE TORQUED TO FACILITATE NAVIGATION THROUGH THE VASCULATURE. ALL HI-TORQUE GUIDE WIRES ARE INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA).,ZEBRA GUIDE WIRE(CARRY)-GUIDEWIRE FACILITATES PLACEMENT OF A CATHETER DURING DIAGNOSTIC OR INTERVENTIONAL PERIPHERAL INTRAVASCULAR PROCEDURES INCLUDING BUT NOT LIMITED TO RENAL INTERVENTION. THE WIRE CAN BE TORQUED TO FACILITATE NAVIGATION THROUGH THE VASCULATURE. THE ZEBRA GUIDE WIRE IS WIDELY USED IN ENDOSCOPIC SURGERY.,INTRODUCER FEMORAL SHEATH(DR. SURGICAL)-A PERCUTANEOUS INTRODUCER IS USED TO FACILITATE PLACING A CATHETER THROUGH THE SKIN INTO A VEIN OR ARTERY. PERCUTANEOUS INTRODUCERS ARE RECOMMENDED FOR INITIAL PERCUTANEOUS INTRODUCTION OR THE EXCHANGE OF INTRAVASCULAR DEVICES. THE CATHETER INTRODUCER SHEATH IS INDICATED FOR USE INPATIENTS REQUIRING ACCESS OF THE VENOUS SYSTEM OR TO FACILITATE CATHETER INSERTION.
3192	MFG/MD/2019/000050	1.License Holder Name: TTK HEALTHCARE LIMITED - HEART VALVE DIVISION 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:RIGID TILTING DISC HEART VALVE SUBSTITUTE(TTK CHITRA HEART VALVE)-REPLACEMENT OF DISEASED NATURAL HEART VALVE OR FOR THE REPLACEMENT OF AN IMPLANTED MALFUNCTIONING HEART VALVE PROSTHESIS

3193	MFG/MD/2019/000051	1.License Holder Name: ARIETTE HEALTH CARE & DIAGNOSTICS 2.Approving Authority: EAST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:EPIDURAL ANAESTHESIA KIT -DELIVERY OF ANESTHETICS,RYLES TUBE / NASOGASTRIC TUBE-TO FEED THE FOOD AND MEDICINE TO THE STOMACH THE THROUGH NOSE,FOLEY BALLOON CATHETER – 2 WAY & 3 WAY (SILICONE) (ARIETTE-FOLEY BALLOON CATHETER – 2 WAY & 3 WAY (SILICONE))-FOR DRAINAGE OF URINE,NELATON CATHETER / URETHRAL CATHETER -FOR SHORT TERM BLADDER CATHERISATION,CLOSED WOUND DRAINAGE TUBE OR SYSTEM WITH NEGATIVE SUCTION-TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND,TRACHEAL (ENDOTRACHEAL) TUBE (PLAIN, CUFFED, REINFORCED, SOUTH POLE, NORTH POLE) -FOR ESTABLISHING AND MAINTAINING PATIENT AIRWAY,FOLEY BALLOON CATHETER – 2 WAY & 3 WAY (LATEX RUBBER) (ARIETTE-FOLEY BALLOON CATHETER – 2 WAY & 3 WAY (LATEX RUBBER))-FOR DRAINAGE OF URINE,TRACHEOSTOMY TUBE/TRACHEAL TUBE (WITH PLAIN & CUFF) -TO PROVIDE AN AIRWAY AND TO REMOVE SECRETION FROM LUNGS.,SUCTION CATHETER -TO REMOVE MUCUS, PUS, OR ASPIRATED MATERIALS FROM AIRWAYS
3194	MFG/MD/2019/000052	1.License Holder Name: SPECTRA VISION 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:FOLDABLE HYDROPHOBIC INTRAOCULAR LENS (STERILE)-INTRAOCULAR LENS IS INTENDED TO USE AS AN IMPLANT FOR REPLACEMENT OF CATARACT LENS FOR VISUAL CORRECTION OF APHAKIA IN CATARACT PATIENT ABOVE 18 YEARS.,FOLDABLE HYDROPHILIC ACRYLIC INTRAOCULAR LENS (STERILE)-INTRAOCULAR LENS IS INTENDED TO USE AS AN IMPLANT FOR REPLACEMENT OF CATARACT LENS FOR VISUAL CORRECTION OF APHAKIA IN CATARACT PATIENT ABOVE 18 YEARS.,SINGLE PIECE PMMA INTRAOCULAR LENS (STERILE)-INTRAOCULAR LENS IS INTENDED TO USE AS AN IMPLANT FOR REPLACEMENT OF CATARACT LENS FOR VISUAL CORRECTION OF APHAKIA IN CATARACT PATIENT ABOVE 18 YEARS.

3195	MFG/MD/2019/000054	1.License Holder Name: SHAGUN CARES INC. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:KNEE REPLACEMENT SYSTEM -KNEE REPLACEMENT SYSTEM IS USED TO CURE DEFORMITIES AND FRACTURES OF KNEE ,SHOULDER REPLACEMENT SYSTEM -SHOULDER REPLACEMENT SYSTEM IS USED TO CURE DEFORMITIES OR FRACTURE IN SHOULDER AREA,HIP REPLACEMENT SYSTEM-HIP PROSTHESIS SYSTEM IS USED TO CURE DEFORMITIES IN PROXIMAL PART OF FEMUR AND ACETABULUM AREA,BONE NAILS-BONE NAILS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS,ELBOW REPLACEMENT SYSTEM -ELBOW REPLACEMENT SYSTEM IS USED TO CURE DEFORMITIES AND FRACTURES IN ELBOW PARTS,BONE PINS & WIRES-BONE PINS & WIRES SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,ARTHROSCOPY IMPLANTS-ARTHROSCOPIC IMPLANTS SET IS INTENDED TO BE USED FOR THE FIXATION OF SOFT TISSUE FIXATION OR ANCHORAGE.,BONE SCREWS-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,SPINAL IMPLANTS SYSTEM-SPINAL IMPLANTS SET IS INTENDED TO BE USED FOR THE FIXATION OF SPINE DEFORMITIES OR FRACTURES ,,BONE PLATES-BONE PLATES SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.
3196	MFG/MD/2019/000055	1.License Holder Name: ROSHANI REVOLUTIONARIES 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL IP(ROSHANI)-FOR SURGICAL DRESSING

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3197	MFG/MD/2019/000056	1.License Holder Name: SURETEX PROPHYLACTICS (INDIA) PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:SYNTHETIC POLYISOPRENE MALE CONDOMS-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX CONDOMS-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,SYNTHETIC POLYISOPRENE MALE CONDOMS-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS(BRAND NAMES MENTIONED UNDER MODEL NO.)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS,NATURAL RUBBER LATEX MALE CONDOMS(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,SYNTHETIC POLYISOPRENE MALE CONDOMS(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS(AS MENTIONED IN MODELS)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS(AS MENTIONED IN MODELS)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS(BRAND NAMES MENTIONED UNDER MODEL NO.)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS(AS MENTIONED IN MODELS)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY & SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS(BRAND NAMES MENTIONED UNDER MODEL NO.)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,SYNTHETIC POLYISOPRENE MALE CONDOMS(AS MENTIONED IN MODELS)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,SYNTHETIC POLYISOPRENE MALE CONDOMS(BRAND NAMES MENTIONED UNDER MODEL NO.)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,SYNTHETIC POLYISOPRENE MALE CONDOMS(AS

	MENTIONED IN MODELS)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS(AS MENTIONED IN MODELS)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS(AS MENTIONED IN MODELS)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS(AS MENTIONED IN MODELS)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS -AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS,SYNTHETIC POLYISOPRENE MALE CONDOMS-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.

3198	MFG/MD/2019/000057	1.License Holder Name: KAMAL ENCON INDUSTRIES LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:EVEROLIMUS ELUTING CORONARY STENT SYSTEM(TRACKPRO & TRACKPLUS)-EVEROLIMUS ELUTING CORONARY STENT SYSTEM IS INTENDED FOR USE IN THE PATIENT ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). EVEROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO LESIONS OF LENGTH 48 MM IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 TO 4.50 MM.,SIROLIMUS ELUTING CORONARY STENT SYSTEM (TRACKFLEX (TM UNDER PROCESS) & STENOFLEX (TM UNDER PROCESS))-SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INTENDED FOR USE IN THE PATIENT ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO LESIONS OF LENGTH 40 MM IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 TO 4.50 MM AND THOSE WHO ARE ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA)., SIROLIMUS ELUTING CORONARY STENT SYSTEM(STENOPRO & STENOPLUS)-SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INTENDED FOR USE IN THE PATIENT ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO LESIONS OF LENGTH 40 MM IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 TO 4.50 MM.,EVEROLIMUS ELUTING CORONARY STENT SYSTEM(EVEROSHINE (TM UNDER PROCESS) & TRACKMASTER (TM UNDER PROCESS))-EVEROLIMUS ELUTING CORONARY STENT SYSTEM IS INTENDED FOR USE IN THE PATIENT ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). EVEROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO LESIONS OF LENGTH 40 MM IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 TO 4.50 MM AND THOSE WHO ARE ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA).,DENTAL IMPLANTS & PROSTHESIS(I-FIX SLIM, I-FIX PRO, I-FIX C1, I-FIX ONE & I-FIX K)-DENTAL IMPLANTS INTENDED TO BE USED IN THE UPPER OR LOWER JAW BONE FOR ANCHORING

		OR SUPPORTING TOOTH REPLACEMENT TO RESTORE CHEWING FUNCTION AND AESTHETIC ORAL REHABILITATION OF EDENTULOUS AND PARTIALLY DENTATE PATIENTS.,EVEROLIMUS ELUTING CORONARY STENT SYSTEM(ETERNIA SELECT (TM UNDER PROCESS), ETERNIA IGNIS (TM UNDER PROCESS), ETERNIA NEXA (TM UNDER PROCESS) & ETERNIA BRIO (TM UNDER PROCESS))-EVEROLIMUS ELUTING CORONARY STENT SYSTEM IS INTENDED FOR USE IN THE PATIENT ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). EVEROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO LESIONS OF LENGTH 40 MM IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 TO 4.50 MM AND THOSE WHO ARE ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA)., SIROLIMUS ELUTING CORONARY STENT SYSTEM(SIROFLEX PLUS (TM UNDER PROCESS), SIROFLEX CURVE (TM UNDER PROCESS), INSIGNIA NEO (TM UNDER PROCESS) & INSIGNIA NEXUS (TM UNDER PROCESS).) -SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INTENDED FOR USE IN THE PATIENT ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO LESIONS OF LENGTH 40 MM IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 TO 4.50 MM AND THOSE WHO ARE ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA)., DENTAL IMPLANTS WITH ABUTMENTS & PROSTHESIS(IFIX, MULTIFIX, SFIX, CFIX)-DENTAL IMPLANTS ARE INTENDED FOR SURGICAL PLACEMENT IN THE UPPER OR LOWER JAW TO PROVIDE A MEANS FOR PROSTHETIC ATTACHMENT IN SINGLE TOOTH RESTORATIONS AND IN PARTIALLY OR FULLY EDENTULOUS SPANS WITH MULTIPLE SINGLE TEETH UTILIZING DELAYED LOADING, OR AS A TERMINAL OR INTERMEDIARY ABUTMENT FOR FIXED OR REMOVABLE BRIDGEWORK, AND TO RETAIN OVERDENTURES.
3199	MFG/MD/2019/000058	1.License Holder Name: DOBERSUN PRODUCTS PVT. LTD. 2.Approving Authority: KERALA 3.Device Name(Brand Name)-Intended Use:CASTING TAPE (NOVACAST)-FOR MOST ORTHOPEDIC CAST APPLICATIONS IN WHICH RIGID IMMOBILIZATION IS REQUIRED INCLUDING FRESH OR UNSTABLE FRACTURE

3200	MFG/MD/2019/000059	1.License Holder Name: OMEX MEDICAL TECHNOLOGY 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:SUPRAPUBIC CATHETERISATION SET(NIL)-USED FOR INTERNAL TEMPORARY SUPRAPUBIC URINARY DIVERSIONS AND DRAINAGE,STERILE DISPOSABLE TRANS-URETHRAL RESECTION SET-TRANSURETHRAL RESECTION SET IS USED FOR PERFUSION OF BLADDER CLEANING SOLUTION.,STERILE DISPOSABLE FOLEY BALLOON CATHETER (INFECTION STOP)(NIL)-IT IS USED TO ASSIST PEOPLE WHO CANNOT URINATE ON THEIR OWN. A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,MICRO POROUS PAPER TAPE-MICRO POROUS PAPER TAPE IS USED TO DRESS WOUNDS AND SECURE MEDICAL TUBING.,STERILE DISPOSABLE NASOPHARYNGEAL CATHETER-NASOPHARYNGEAL CATHETER IS USED IN BRONCHIOLITIS TO TREAT HYPOXIA.,GAUZE BANDAGE / ROLLER BANDAGE-GAUZE BANDAGE / ROLLER BANDAGE IS USED FOR ALMOST ANY BANDAGE APPLICATION., STERILE DISPOSABLE EPIDURAL CATHETER-EPIDURAL CATHETER IS USED IN PATIENTS REHABILITATING FROM CANCER OR IN THOSE WITH PROLONGED PAIN AFTER MAJOR CHEST SURGERY.,STERILE DISPOSABLE INSULIN SYRINGE WITH OR WITHOUT NEEDLE-INSULIN SYRINGE IS MOST COMMONLY USED FOR SUBCUTANEOUS INJECTION OF INSULIN.,STERILE DISPOSABLE UNDER WATER SEAL DRAINAGE BAG-UNDER WATER SEAL DRAINAGE BAG IS USED TO RESTORE PROPER AIR PRESSURE TO THE LUNGS, RE-INFLATE A COLLAPSED LUNG AS WELL AS REMOVE BLOOD AND OTHER FLUIDS.,STERILE DISPOSABLE HYPODERMIC SYRINGE WITH OR WITHOUT NEEDLE-HYPODERMIC SYRINGE IS MOST COMMONLY USED FOR INJECT/INFUSE OR WITHDRAW FLUIDS.,STERILE DISPOSABLE TRACHEOSTOMY TUBE WITH / WITHOUT CUFF-TRACHEOSTOMY TUBE ARE INTENDED FOR USE IN PROVIDING DIRECT TRACHEAL ACCESS FOR AIR WAY MANAGEMENT.,ABSORBENT COTTON WOOL - ABSORBENT COTTON WOOL IS USED FOR CLEANING & SWABBING VARIOUS TYPES OF WOUNDS,STERILE DISPOSABLE BLOOD COLLECTING NEEDLE-BLOOD COLLECTING NEEDLE IS MOST COMMONLY USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD.,STERILE DRAPE-SURGICAL DRAPES ARE USED TO PROTECT THE PATIENT, CLINICIANS, AND EQUIPMENT DURING VARIOUS SURGERIES.,STERILE DISPOSABLE SURGICAL GLOVES POWDERED / POWDER FREE-STERILE SURGICAL GLOVES IS WORN ON THE EXAMINER'S HAND TO PREVENT CONTAMINATION BETWEEN PATIENT AND EXAMINER.,CANNULA FIXATOR-CANNULA FIXATOR IS USED TO FIX THE IV CANNULA.,STERILE DISPOSABLE

	SILICONE FOLEY BALLOON CATHETER-SILICONE FOLEY BALLOON CATHETER IS USED TO ASSIST PEOPLE WHO CANNOT URINATE ON THEIR OWN.,STERILE DISPOSABLE SPINAL NEEDLE-SPINAL NEEDLE IS MOST COMMONLY USED FOR SURGERIES BELOW THE UMBILICUS AS WELL AS FOR POSTOPERATIVE ANALGESIA.,ADHESIVE TAPE-ADHESIVE TAPE IS USED IN MEDICINE AND FIRST AID TO HOLD A BANDAGE OR OTHER DRESSING ONTO A WOUND.,STERILE DISPOSABLE GUIDE WIRE-GUIDE WIRE IS MOST COMMONLY USED AS A GUIDE FOR PLACEMENT OF A LARGER DEVICE OR PROSTHESIS, SUCH AS A CATHETER OR INTRAMEDULLARY PIN.,STERILE DISPOSABLE CORRUGATED DRAINAGE SHEET-CORRUGATED DRAINAGE SHEET IS USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND.,STERILE ABSORBENT GAUZE SWAB-ABSORBENT GAUZE SWAB IS USED FOR PROTECTING SURGICAL INJURIES OR WOUND.,COTTON CREPE BANDAGE-COTTON CREPE BANDAGE IS USED TO TREAT SPRAINS AND STRAINS, TO HELP CORRECT FRACTURES AND OTHER BONE PROBLEMS IN ORTHOPEDICS.,STERILE DISPOSABLE SURGICAL STAPLE-SURGICAL STAPLE IS MOST COMMONLY USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF THE BOWELS OR LUNGS,STERILE DISPOSABLE PRESSURE MONITORING LINE-PRESSURE MONITORING LINE IS USED FOR EXTENDING MEDICAL TUBING AND PRESSURE MONITORING.,ELASTIC ADHESIVE BANDAGE-ELASTIC ADHESIVE BANDAGE IS USED IN POST-OPERATION DRESSING APPLICATIONS.,STERILE DISPOSABLE PERITONEAL DIALYSIS SET-PERITONEAL DIALYSIS SET IS USED TO ADMINISTER DIALYSIS SOLUTION INTO THE PERITONEAL CAVITY., STERILE ARTERIOVENOUS FISTULA NEEDLE-ARTERIOVENOUS FISTULA NEEDLE IS USED TO CONNECT BLOOD LINES OF THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT THROUGH AN INTERNAL FISTULA.,STERILE DISPOSABLE HYPODERMIC NEEDLE-HYPODERMIC NEEDLE IS MOST COMMONLY USED FOR RAPID DELIVERY OF LIQUID.,STERILE DISPOSABLE BONE MARROW BIOPSY NEEDLE-BONE MARROW BIOPSY NEEDLE IS MOST COMMONLY USED TO ALLOW THE COLLECTION OF A SOLID CORE (A CYLINDRICAL SAMPLE) OF MARROW.,PLASTER OF PARIS BANDAGE-PLASTER OF PARIS BANDAGE IS USED MAKE PLASTER CASTS TO IMMOBILIZE BROKEN BONES.,STERILE DISPOSABLE HAEMODIALYSIS CATHETER KIT-HAEMODIALYSIS CATHETER KIT IS USED FOR EXCHANGING BLOOD TO AND FROM A HAEMODIALYSIS MACHINE AND A PATIENT.,STERILE DISPOSABLE BIOPSY NEEDLE-BIOPSY NEEDLE IS MOST COMMONLY USED FOR SOFT TISSUE AND TUMOUR BIOPSY OF SUCH ORGANS AS THE LIVER, SPLEEN, KIDNEY, PROSTATE, LUNG, BREAST, AND LYMPH NODES.,STERILE COMBINE

		DRESSING PAD-COMBINE DRESSING PAD IS USED FOR PROTECTING SURGICAL INJURIES OR WOUND.,STERILE DISPOSABLE EPIDURAL NEEDLE-EPIDURAL NEEDLE IS INTENDED FOR THE TRANSIENT DELIVERY OF ANESTHETICS TO PROVIDE NEURAXIAL ANESTHESIA OR TO FACILITATE PLACEMENT OF AN EPIDURAL CATHETER.,STERILE PARAFFIN DRESSING-PARAFFIN DRESSING IS USED FOR COVERING WOUNDS SUCH AS MINOR BURNS, LACERATIONS, ABRASIONS, GRAFT SITES AND LEG ULCERS.,STERILE CHLOROHEXADINE GAUZE DRESSING-CHLORHEXIDINE GAUZE DRESSING IS USED BURNS, CUTS & BEDSORES.,ORTHOPAEDIC BANDAGE-ORTHOPEDIC BANDAGE IS USED PRIOR TO THE APPLICATION OF POP BANDAGE & FIBER GLASS CASTING TAPE.
3201	MFG/MD/2019/000060	1.License Holder Name: OMNI LENS PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:PMMA INTRA OCULAR LENS(OMNI, INTRA,C-THRU, INNOVA,INNOVA PLUS,BIOL,TECHNO INSTRUMENT LENS.)-INTRA OCULAR LENS IS USED FOR REPLACING NATURAL EYE LENS IN THE OPHTHALMIC REGION BY SURGICAL INCISION IN THE EYE,HYDROPHILIC ACRYLIC FOLDABLE IOL(OMNI, INTRA,C-THRU, INNOVA,INNOVA PLUS,BIOL,TECHNO INSTRUMENT LENS,.AQUAFOLD,GENNEXT, REVIVE, AXIS)-INTRA OCULAR LENS IS USED FOR REPLACING NATURAL EYE LENS IN THE OPHTHALMIC REGION BY SURGICAL INCISION IN THE EYE,HYDROPHOBIC ACRYLIC FOLDABLE IOL(OMNI, INTRA,C-THRU, INNOVA,INNOVA PLUS,BIOL, TECHNO INSTRUMENT LENS,.ACRIVUE,GENNEXT, REVIVE, AXIS)-INTRA OCULAR LENS IS USED FOR REPLACING NATURAL EYE LENS IN THE OPHTHALMIC REGION BY SURGICAL INCISION IN THE EYE

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3202	MFG/MD/2019/000061	1.License Holder Name: SMIT MEDIMED PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATE(SMPL)-THE BONE PLATE IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, TIBIA, FIBULA, FEMORAL. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS. THIS SYSTEM CAN BE USED FOR VENTRAL, DORSAL OR ORTHOGONAL APPLICATIONS.,SPINAL SYSTEM(SMPL)-THE SMPL SPINAL SYSTEM IS INTENDED TO HELP PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS, AS AN ADJUNCT TO FUSION OF THE CERVICAL, THORACIC, LUMBAR, AND/OR SACRAL SPINE. THE SMPL SPINAL SYSTEM CONSISTS OF CAGES THAT ARE TO BE RIGIDLY LOCKED FOR GETTING THE BETTER RESULT.,TOTAL SHOULDER & ELBOW SYSTEM(SMPL)-THE TOTAL SHOULDER AND ELBOW SYSTEM ARE USED IN CASE OF NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS, RHEUMATOID ARTHRITIS, REVISION WHERE OTHER DEVICES HAVE FAILED, CORRECTION OF FUNCTIONAL DEFORMITY, ONCOLOGY APPLICATION INCLUDING BONE LOSS DUE TO TUMOUR RESECTION., TOTAL JOINTS SYSTEM/ KNEE REPLACEMENT SYSTEM (FIX/MOBILE/REVISION SYSTEM AND TUMOR SYSTEM)(SMPL)-INTENDED USE / INDICATIONS: TOTAL KNEE REPLACEMENT IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. CANDIDATES FOR TOTAL KNEE REPLACEMENT INCLUDE ELDERLY PATIENTS WITH SEVERELY PAINFUL AND/OR SEVERELY DISABLED JOINT RESULTING FROM RHEUMATOID ARTHRITIS; OSTEOARTHRITIS; KNEE ANKYLOSIS; OTHER KNEE DISEASES WHICH ADAPT TO KNEE REPLACEMENT,TOTAL JOINT SYSTEM/HIP SYSTEM(SMPL)-INTENDED USE: TOTAL HIP JOINT SYSTEM USED IN HIP REPLACEMENT BONE SURGERY FOR HUMAN BODY, TO REPLACE THE DISEASED HIP JOINTS AND TO ABRIDGE THE DISCOMFORT AND PAIN. POOR HEALING AFTER FRACTURE OF FEMORAL HEAD (NECK); NECROSIS OF FEMORAL HEAD; OSTEOARTHRITIS; ACETABULAR DYSPLASIA; OTHER SURGERY FAILURES (E.G. FAILURE OF ARTHROPLASTY, DOUBLE CUPS, JOINT INSTRUMENTATION, PARTIAL HIP OR TOTAL HIP REPLACEMENT);

	OTHER SITUATIONS THAT REQUIRE JOINT REPLACEMENT.,SPINAL FIXATION SYSTEM(SMPL)-THE SMPL SPINAL SYSTEM IS INTENDED TO HELP PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS AS AN ADJUNCT TO FUSION OF THE CERVICAL, THORACIC, LUMBAR, AND/OR SACRAL SPINE .THE SMPL SPINAL SYSTEM CONSISTS OF A VARIETY OF SHAPES AND SIZES OF RODS, SCREW, TRANSVERSE LINK AS WELL AS CAGES AND CERVICAL IMPLANTS AND ARE TO BE RIGIDLY LOCKED FOR GETTING BETTER RESULT. SCREW IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF SPINAL BONES, AND FOR SCOLIOSIS,INTRAMEDULLARY NAILS(SMPL)-THE INTRAMEDULLARY NAIL IS INTENDED FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF THE HUMERUS, TIBIA, FIBULA, FEMORAL BONES. THE I.M.NAIL IS HAVING BETTER STRENGTH WITH GOOD BONE HEALING CAPACITY. DIFFERENT SIZES ARE AVAILABLE WITH DIFFERENT DESIGN FOR BETTER ALIGNMENT OF THE FRACTURE, BONE SCREW(SMPL)-THE BONE SCREW IS INTENDED TO USE FOR INTERNAL FIXATION OF BONE FRACTURES AND RECONSTRUCTION OF BONES, THERE ARE SEVERAL TYPES OF SCREW LIKE LOCKING HEAD SCREW, GENERAL CORTICAL SCREW OR LEG SCREW OF DHS (DYNAMIC HIP SCREW) ARE USED FOR FIXING OF BONE PLATE, NAIL, DHS PLATE, LOCKING PLATES WHICH IS USED FOR OSTEOTOMY PATIENTS EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS. THIS SYSTEM CAN BE USED FOR VENTRAL, DORSAL OR ORTHOGONAL APPLICATIONS.

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3203	MFG/MD/2019/000062	1.License Holder Name: PASECA HEALTHCARE LLP 2.Approving Authority: NORTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:TRANSPARENT FILM DRESSING(NA)-KIND OF CELLS (E.G. MACROPHAGE, NEUTROPHILE GRANULOCYTE) ARE ACTIVATED IN THE MOIST ENVIRONMENT, AND OTHER MICROORGANISMS IN THE WOUND COULD BE KILLED.,NON WOVEN DRESSING WITH ABSORBENT PAD(NA)-ACCELERATE THE AUTO-DEBRIDEMENT HELP THE GENERATION OF GRANULATION AND EPIDERMIS. REDUCE THE PRESSURE, FRICTION AND SHEARING FORCE TO THE AND IMPROVE THE BLOOD SUPPLY.,TRANSPARENT FILM DRESSING WITH ABSORBENT PAD(NA)-KIND OF CELLS (E.G. MACROPHAGE, NEUTROPHILE GRANULOCYTE) ARE ACTIVATED IN THE MOIST ENVIRONMENT, AND OTHER MICROORGANISMS IN THE WOUND COULD BE KILLED.,CALCIUM ALGINATE DRESSING(NA)-PROTECT THE WOUND FROM MICROBIAL INVASION. KEEP WOUND AREA WARM AND MOIST. ,TRANSPARENT FILM DRESSING WITH SILVER PAD(NA)-KIND OF CELLS (E.G. MACROPHAGE, NEUTROPHILE GRANULOCYTE) ARE ACTIVATED IN THE MOIST ENVIRONMENT, AND OTHER MICROORGANISMS IN THE WOUND COULD BE KILLED.
3204	MFG/MD/2019/000063	1.License Holder Name: ZIBON SURGITECH 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:INTERLOCKING NAIL (ZIBON)-BONE SURGERY,BONE SCREW(ZIBON)-BONE SURGERY, WIRES & PINS(ZIBON)-BONE SURGERY,LOCKING SCREW(ZIBON)-BONE SURGERY,BONE PLATE(ZIBON)-BONE SURGERY,LOCKING PLATE(ZIBON)-BONE SURGERY,SPINAL IMPLANTS(ZIBON)-BONE SURGERY

3205	MFG/MD/2019/000064	1.License Holder Name: PLASMA BIOTAL INDIA PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:UNCEMENTED STEM(FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)(SIGNATURE)-TOTAL HIP REPLACEMENT,CERVICAL SCREW (FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)(SOLACE)-SPINE IMPLANT SURGERY,CEMENTED STEM(FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)(AVATAR)-TOTAL HIP REPLACEMENT,TLIF CAGE(FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)-ORTHOPEDIC IMPLANT SURGERY,CERVICAL REVISION SCREW (FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)(SOLACE)-SPINE IMPLANT SURGERY,FEMORAL COMPONENT(FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)(GENUIN)-TOTAL KNEE REPLACEMENT,ECO CAGE(FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)-ORTHOPEDIC IMPLANT SURGERY,LUMBAR CAGE LORDOTIC (FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)(WISDOM)-SPINE IMPLANT SURGERY, TIBIAL TRAY(FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)(GENUIN)-TOTAL MODULAR KNEE REPLACEMENT,CERVICAL SQUARE CAGE(FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)-ORTHOPEDIC IMPLANT SURGERY,TIBIAL TRAY(FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)(GENIUS)-TOTAL MODULAR KNEE RPLACEMENT,PLIF CAGE(FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)-ORTHOPEDIC IMPLANT SURGERY,FEMORAL COMPONENT(FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)(GENIUS)-TOTAL MODULAR KNEE REPLACEMENT,CERVICAL CAGE(FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY) (WISDOM)-SPINE IMPLANT SURGERY,KIDNEY CAGE (BANANA CAGE) (FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)-ORTHOPEDIC IMPLANT SURGERY,EXPANDABLE CAGE(FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)-ORTHOPEDIC IMPLANT SURGERY,UNCEMENTED ACETABULAR CUP (FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)(SIGNATURE)-TOTAL HIP REPLACEMENT,LUMBAR CAGE PARALLEL(FOR HYDROXY APPATITE (HA) & TITANIUM SPRAY COATING PROCESS ONLY)(WISDOM)-SPINE IMPLANT SURGERY

3206	MFG/MD/2019/000065	1.License Holder Name: ANKIT HATHAKARGA VASTRA UTPADAK SAHAKARI SAMITI LTD. 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:GAUZE (ABSORBENT COTTON GAUZE) [AS PER SCHEDULE F(II)](NIL)-THE COTTON GAUZE ARE USED FOR DRESSING OF WOUNDS. THEY MAY BE USED TO FILL UP THE WOUND ALONG WITH MEDICATION AND TO COVER IT UP. THESE MAY BE CUT INTO REQUIRED SHAPE AND SIZE TO BE USED FOR DRESSING AND MAY BE REQUIRED TO BE STERILIZED BEFORE USE.,COTTON BANDAGE (ROLLED BANDAGE) [AS PER SCHEDULE F (II)](NA)-THE COTTON BANDAGES ARE USED TO BIND, WRAP OR AS A SUPPORTIVE MATERIAL FOR WOUNDS, CUTS, BURNS AND IN DRESSING FOR WOUND HEALING PROCESS AND PROTECTING FROM FURTHER HARM.
3207	MFG/MD/2019/000066	1.License Holder Name: NASCO SURGITECH 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATE TI(NASCO)-ORTHOPAEDIC SURGERY,BONE PLATE SS316L(NASCO)-ORTHOPAEDIC SURGERY,LOCKING PLATE LVM(NASCO)-ORTHOPAEDIC SURGERY,WIRES & PINS LVM(NASCO)-ORTHOPAEDIC SURGERY,INTERLOCKING NAIL LVM(NASCO)-ORTHOPAEDIC SURGERY,BONE PLATE LVM(NASCO)-ORTHOPAEDIC SURGERY,WIRES & PINS TI(NASCO)-ORTHOPAEDIC SURGERY,BONE SCREWS LVM (NASCO)-ORTHOPAEDIC SURGERY,INTERLOCKING NAIL SS316L (NASCO)-ORTHOPAEDIC SURGERY,BONE SCREWS SS316L(NASCO)-ORTHOPAEDIC SURGERY,BONE SCREWS TI(NASCO)-ORTHOPAEDIC SURGERY,LOCKING PLATE SS316L(NASCO)-ORTHOPAEDIC SURGERY, LOCKING PLATE TI(NASCO)-ORTHOPAEDIC SURGERY,WIRES & PINS SS316L(NASCO)-ORTHOPAEDIC SURGERY,INTERLOCKING NAIL TI (NASCO)-ORTHOPAEDIC SURGERY
3208	MFG/MD/2019/000067	1.License Holder Name: A V PROCESSOR PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:GAMMA RADIATION TREATMENT OF THE PRODUCT(NA)-NA,GAMMA RADIATION TREATMENT OF THE PRODUCT(NA)-NA

3209	MFG/MD/2019/000068	1.License Holder Name: AEGIS LIFESCIENCES 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ABSORBABLE GELATIN SPONGE(SURGISPON, UNISPONGE, STELLIGEL, BIOSPONGE, MEDISPONGE, HEMOGEL, SURGISGEL, FLOSPONG, SMI-SPON, GEL-SPONGE, MEDISPON, CLINISPON, I-SPONGE, MERIFEIM, BLOXANG, GELASPIN, TOP DENT DENTOSTAN, DSI SPONGE, HYGITECH, CLINIX, CHIRUSPONGE, MERIFOAM, R & S, KENTDENTAL, IDSPONGE, DENTOSPON, KARESPON, EVOSPON, SURGISENZ, HEMOSPON, PERISPONGE)-SURGISPON CAN BE EFFECTIVELY USED IN VARIOUS SURGERIES FOR HAEMOSTASIS, WHEN CONTROL OF CAPILLARY, VENOUS AND ARTERIOLAR BLEEDING BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS INEFFECTIVE OR IMPRACTICAL.
3210	MFG/MD/2019/000070	1.License Holder Name: MIL LABORATORIES PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:WOUND DRESSINGS-INDICATED FOR ACUTE AND CHRONIC WOUNDS CONDITIONS. ACUTE WOUND CONDITIONS LIKE- ABRASIONS, LACERATIONS, CUTS, SKIN TEARS AND POST-OPERATIVE WOUNDS. CHRONIC WOUND CONDITIONS LIKE- PRESSURE ULCERS, DIABETIC FOOT ULCERS, VENOUS LEG ULCERS, AND BURNS (IST AND II ND DEGREE BURNS) AND ALSO DONOR SITE WOUNDS

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3211	MFG/MD/2019/000071	1.License Holder Name: PRIME MEDICA PROMOTION PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ELASTIC ADHESIVE BANDAGE BP(PRIME PLAST)-SPRAIN, STRAIN, DISLOCATION, PAINFUL JOINTS, POST-OPERATIVE CONDITIONS, SPORTS MISHAPS, SUPPORT BANDAGING FOR OTHER GENERAL SURGICAL & ORTHOPAEDIC USE,PLASTER OF PARIS BANDAGE(-)-FUNCTIONAL IMMOBILIZATION IN FRACTURES, STRAINS & SPRAINS, TO MAKE SLABS / SPLINT FOR SUPPORT, POST-OPERATIVE IMMOBILIZATION, ELASTIC ADHESIVE BANDAGE BP(NIL)-SPRAIN, STRAIN, DISLOCATION, PAINFUL JOINTS, POST-OPERATIVE CONDITIONS, SPORTS MISHAPS, SUPPORT BANDAGING FOR OTHER GENERAL SURGICAL & ORTHOPAEDIC USE,COTTON CREPE BANDAGE BP(NIL)-SPRAIN, STRAIN, DILOCATION, PAINFUL JOINT, POST-OPERATIVE CONDITIONS, SPORTS MISHAPS, SUPPORT BANDAGING FOR OTHER GENERAL SURGICAL AND ORTHOPAEDIC USE.,COTTON CREPE BANDAGE BP(PRIME CREPE)-SPRAIN, STRAIN, DISLOCATION, PAINFUL JOINTS, POST-OPERATIVE CONDITIONS, SPORTS MISHAPS, SUPPORT BANDAGING FOR OTHER GENERAL SURGICAL & ORTHOPAEIC USE,PLATER OF PARIS BANDAGE SPLINT (NIL)-FUNCTIONAL IMMOBILIZATION IN FRACTURES, STRAINS & SPRAINS, TO MAKE SLABS / SPLINT FOR SUPPORT, POST-OPERATIVE IMMOBILIZATION,PLASTER OF PARIS BANDAGE(PRIME POP PREMIUM)-FUNCTIONAL IMMOBILIZATION IN FRACTURES, STRAINS & SPRAINS, TO MAKE SLABS / SPLINT FOR SUPPORT, POST-OPERATIVE IMMOBILIZATION,PLASTER OF PARIS BANDAGE SPLINT (PRIME POP SPLINT)-FUNCTIONAL IMMOBILIZATION IN FRACTURES, STRAINS & SPRAINS, TO MAKE SLABS / SPLINT FOR SUPPORT, POST-OPERATIVE IMMOBILIZATION,ELASTIC ADHESIVE BANDAGE BP(PRIME FIX)-SPRAIN, STRAIN, DISLOCATION, PAINFUL JOINTS, POST-OPERATIVE CONDITIONS, SPORTS MISHAPS, SUPPORT BANDAGING FOR OTHER GENERAL SURGICAL & ORTHOPAEDIC USE

3212	MFG/MD/2019/000072	1.License Holder Name: SHAILI ENDOSCOPY 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:MONOPOLAR PROBE(NA)-MONOPOLAR PROBE USED FOR MONOPOLAR CUTTING /COAGULATION THROUGH ENDOSCOPE.,ESO GASTRIC BALLOON DEFLATION DEVICE(NA)-ESO GASTRIC BALLOON DEFLATION DEVICE USED TO DEFLATE PREVIOUSLY PLACED ESOPHAGEAL GASTRIC BALLOON,GUIDING CATHETER(NA)-GUIDING CATHETER IS USED TO PLACE BILIARY STENT ENDOSCOPICALLY.,FOREIGN BODY RETRIEVAL HOOD(NA)-USED TO RETRIEVE SHARP OBJECTS THROUGH THE SCOPE AND TO PREVENT ESOPHAGUS TARE,BILIARY BALLOON DILATOR(NA)-BILIARY BALLOON DILATOR USED TO DILATE PAPILLA OR BILIARY STRICTURES THROUGH THE SCOPE., BILIARY DILATOR(NA)-BILIARY DILATOR USED TO DILATE PAPILLA OR BILIARY STRICTURES THROUGH THE SCOPE.,SPHINCTEROTOME (NA)-SPHINCTEROTOME IS USED FOR ENDOSCOPIC CANNULATION OF BILIARY DUCTAL SYSTEM AND SPHINCTEROTOMY.,MEMORY BASKET(NA)-MEMORY BASKET USED TO RETRIEVE FOREIGN BODY / STONE FROM GI TRACT THROUGH THE SCOPE,STONE BASKET(NA)-STONE BASKET INDICATED FOR THE MANIPULATION AND REMOVAL/RETRIEVAL OF STONES FROM URINARY TRACT.,STONE GRASPER(NA)-STONE GRASPERUSED TO FACILITATE ENDOSCOPIC MANIPULATION/ REMOVAL OF STONES &CAN ALSO BE USED FOR REMOVING STENTS FROM URINARY TRACT.,WIRE GUIDED STONE EXTRACTION BALLOON(NA)-WIRE GUIDED STONE EXTRACTION BALLOON USED FOR ENDOSCOPIC EXTRACTION OF BILIARY STONES., SCLEROTHERAPY NEEDLE(NA)-SCLEROTHERAPY NEEDLE IS USED FOR ENDOSCOPIC INJECTION INTO ESOPHAGEAL VARICES ABOVE OG JUNCTION. SCLEROTHERAPY NEEDLE IS USED FOR ENDOSCOPIC INJECTION TO INTRODUCE A SCLEROSING AGENT OF VASOCONSTRICTOR INTO SELECTED SIDES TO CONTROL ACTUAL OR POTENTIAL BLEEDING LESIONS. THE INJECTION OF SALINE TO AID IN ENDOSCOPIC MUCOSAL RESECTION (EMR), POLYPECTOMY PROCEDURES AND TO CONTROL NON-VARICEAL HAEMORRHAGE., ERCP CANNULA(NA)-ERCP CANNULA USED ENDOSCOPICALLY TO OPACIFY THE BILIARY DUCT WITH RADIOPAQUE CONTRAST MATERIAL FOR FLUOROSCOPIC VIEW.,ENDOLITHOTRIPTOR ASSEMBLY(NA)-ENDOLITHOTRIPTOR ASSEMBLY USED FOR PURPOSE OF C.B.D STONE RETRIEVAL THROUGH THE SCOPE AND FOR LITHOTRIPSY TO CRUSH STONE IN BILIARY DUCT.,ASPIRATION NEEDLE(NA)-USED FOR ENDOSCOPIC ASPIRATION FROM LUNGS AND BRONCHILE,COURNUAL CANNULATION SET(NA)-SELECTIVE CATHETERIZATION/CANNULATION OF THE FALLOPIAN TUBES FOR INJECTION OF DYE OR CONTRAST MEDIUM IN ORDER TO EVALUATE

	PROXIMAL TUBAL OCCLUSION AND/OR PATENCY UNDER FLUOROSCOPY OR HYSTEROSCOPY/LAPAROSCOPY.,SINGLE ACTION STENT INTRODUCER SYSTEM(NA)-SINGLE ACTION STENT INTRODUCER SYSTEM USED FOR ENDOSCOPICALLY BILIARY STENT PLACEMENT TO REDUCE TIME AND EASIER STENT PLACEMENT., SUCTION COAGULATION PROBE(NA)-SUCTION COAGULATION PROBE IS USED FOR SUCTION AND COAGULATION DURING ENDOSCOPIC MUCOSAL.,MANUAL LITHOTRIPTOR(NA)-MANUAL LITHOTRIPTORUSEDFOR CBD STONE LITHOTRIPSY,EUS BALLOON (NA)-EUS BALLOON USED TO ACOUSTIC COUPLING OF THE ULTRASONIC TRANSDUCER TO THE GASTROINTESTINAL WALL REQUIRES APPLICATION OF FLUID AS INTERFACE BETWEEN THE TRANSDUCER AND THE WALL. THIS IS ACHIEVED BY EUS BALLOON., EUS NEEDLE(NA)-USED FOR ASPIRATION BIOPSY TO DIAGNOSE AND STAGE G.I. LESIONS, THE TIP PROVIDES SAMPLING BY EMPLOYING ULTRASOUND TECHNOLOGY TO GUIDE THE NEEDLE.,SPRAY PROBE (NA)-SPRAY PROBE IS USED TO SPRAY DYEING.,BALLOON INFLATION DEVICE(NA)-IT IS USED FOR INFLATION AND DEFLATION OF THE DILATION BALLOON,ESOPHAGEAL BALLOON DILATOR(NA)-ESOPHAGEAL BALLOON DILATOR USED TO DILATE ESOPHAGEAL STRICTURES OVER PREVIOUSLY PLACED WIRE GUIDE THROUGH THE ENDOSCOPE.,STENT PUSHER(NA)-STENT PUSHER IS USED ENDOSCOPICALLY FOR BILIARY STENT PLACEMENT.,NASO JEJUNAL FEEDING TUBE(NA)-NASO JEJUNAL FEEDING TUBES ARE FREQUENTLY USED FOR LONG-TERM ENTERAL NUTRITION.,SPRING TIP STEEL GUIDE WIRE(NA)-SPRING TIP STEEL GUIDE WIRE USED TO GUIDE ESOPHAGEAL DILATORS FOR DILATATION.,FOREIGN BODY HOLDER(NA)-FOREIGN BODY HOLDER USED TO REMOVE FOREIGN BODY FROM G.I. TRACT.,NITINOL BLACK WIRE(NA)-NITINOL BLACK WIRE USED TO GAIN ACCESS THROUGH DIFFICULT BILIARY AND PANCREATIC STRICTURES AND TO FACILITATE EXCHANGE OF COMPATIBLE WIRE GUIDED ACCESSORIES TO DESIRED BILIARY OR PANCREATIC DUCTS. ,ACHALASIA BALLOON DILATOR(NA)-ACHALASIA BALLOON DILATOR USED FOR DILATION OF THE LOWER ESOPHAGEAL SPHINCTER IN PATIENT WITH ACHALASIA.,HYDRA NEG GUIDE WIRE(NA)-HYDRA NEG GUIDE WIRE USED TO GAIN ACCESS THROUGH DIFFICULT BILIARY AND PANCREATIC STRICTURES AND TO FACILITATE EXCHANGE OF COMPATIBLE WIRE GUIDED ACCESSORIES TO DESIRED BILIARY OR PANCREATIC DUCTS.,NASO BILIARY DRAINAGE CATHETER(NA)-NASO BILIARY DRAINAGE CATHETER USED TO DRAIN THE BILE FROM OBSTRUCTED BILIARY DUCT THROUGH NASO.,NEG GUIDE WIRE(NA)-NEG GUIDE WIRE USED TO GAIN ACCESS THROUGH DIFFICULT BILIARY AND PANCREATIC STRICTURES AND TO FACILITATE EXCHANGE OF COMPATIBLE WIRE

		GUIDED ACCESSORIES TO DESIRED BILIARY OR PANCREATICDUCTS., BIOPSY FORCEP(NA)-BIOPSY FORCEPS IS USED ENDOSCOPICALLY TO OBTAIN MUCOSAL TISSUE SAMPLES FROM GASTROINTESTINAL TRACT FOR MICROSCOPIC HISTOPATHOLOGICAL EXAMINATION., RETRIEVAL BASKET(NA)-RETRIEVAL BASKET USED TO RETRIEVE FOREIGN BODIES AND C.B.D STONES ENDOSCOPICALLY., POLYPECTOMY SNARE(NA)-POLYPECTOMY SNARE USED FOR ENDOSCOPIC EXCISION OF POLYPS USING MONOPOLAR ELECTROSURGICAL UNIT AND USED FOR RETRIEVAL OF FOREIGN BODY FROM G.I. TRACT ENDOSCOPICALLY.,NEEDLE KNIFE(NA)-NEEDLE KNIFE IS USED FOR PRECUTPAPILLOTOMY.,CYTOLOGY BRUSH(NA)-CYTOLOGY BRUSH IS USED TO COLLECT CELLS FROM THE UPPER AND LOWER GASTROINTESTINAL TRACTS FOR HISTOPATHOLOGICAL TESTING.,REPLACEMENT PEG TUBE(NA)-PEG REPLACEMENT TUBE USED AS A REPLACEMENT GASTROSTOMY TUBE THROUGH AN ESTABLISHED GASTROSTOMY TREATMENT., ENDOSCISSOR(NA)-ENDOSCISSOR IS USED TO CUT AND COAGULATE DURING ENDOSCOPIC MUCOSAL RESECTION.,PEG KIT(NA)-PEG KIT USED FOR PERCUTANEOUS ENDOSCOPIC GASTROSTOMY PLACEMENT TO PROVIDE ENTERAL NUTRITION TO PATIENT REQUIRING NUTRITIONAL SUPPORT.,ENDOLITHOTRIPTOR HANDLE (NA)-ENDOLITHOTRIPTOR HANDLE INDICATED FOR USE IN ELECTIVE CASES TO PERFORM TRANSENDOSCOPIC LITHOTRIPSY IN THE COMMON BILE DUCT. THIS DEVICE SHOULD BE USED FOR MECHANICAL CRUSHING OF LARGE BILIARY STONES WHERE EITHER BASKET OR BALLOON REMOVAL IS EITHER BEEN UNSUCCESSFUL OR IS CONTRAINDICATED.
3213	MFG/MD/2019/000073	1.License Holder Name: KILITCH HEALTHCARE INDIA LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:POVIDONE-IODINE SOLUTION IP 5 % W/V (SWABSTICK)-DISINFECTING & SURGICAL SITE PREPARATION PRIOR TO OPERATION

3214	MFG/MD/2019/000074	1.License Holder Name: SHAILI ENDOSCOPY 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:NEPHROSTOMY PROBE (NA)-TO APPLY LITHOTRIPSY TO BREAK STONE FROM URINARY TRACT.,NEPHROSTOMY BASKET(NA)-NEPHROSTOMY BASKET USED TO INDICATED FOR THE MANIPULATION AND REMOVAL/RETRIEVAL FROM URINARY TRACT.,STIFF GUIDE WIRE(NA)-STIFF GUIDE WIRE USED TO GAIN ACCESS ENDOSCOPICALLY THROUGH THE DIFFICULT STRICTURES.,NITINOL BLACK WIRE(NA)-NITINOL BLACK WIRE USED TO GAIN ACCESS THROUGH DIFFICULT UROLOGICAL STRICTURES. TO FACILITATE EXCHANGE OF COMPATIBLE WIRE GUIDED ACCESSORIES.,HYDRA NEG COMBO GUIDE WIRE(NA)-HYDRA NEG COMBO GUIDE WIRE USED TO GAIN ACCESS UROLOGY TRACT FOR ACCESS AND EXCHANGE OF ACCESSORIES.,HYDRA NEG GUIDE WIRE (NA)-HYDRA NEG GUIDE WIRE USED TO ACCESS UROLOGYTRACT FOR ACCESS AND EXCHANGE OF ACCESSORIES IN URINARY TRACT.,NEG GUIDE WIRE(NA)-NEG GUIDE WIRE USED TOGAINACCESS UROLOGY TRACT FOR ACCESS AND EXCHANGE OF ACCESSORIES.,HOT BIOPSY FORCEP(NA)-HOT BIOPSY FORCEPS ISUSED ENDOSCOPICALLY TO OBTAIN MUCOSAL TISSUE SAMPLES FROM GASTROINTESTINAL TRACT FOR MICROSCOPIC HISTOPATHOLOGICAL EXAMINATION. MONOPOLAR ELECTROSURGICAL UNIT CAN BE USE TO CAUTERIZE THE TISSUE WHEN BLEEDING OCCURS DURING TISSUE SAMPLING. ESO GASTRIC BALLOON RETRIEVAL DEVICE(NA)-ESO GASTRIC BALLOON RETRIEVAL DEVICE USED FOR RETRIEVAL OF ESOPHAGEAL GASTRIC BALLOON.,CYSTOSTOME(NA)-CYSTOSTOME IS USED TO ELECTRO SURGICALLY CANNULATE THE TRANSGASTRIC OR TRANSDUODENAL WALL AND INTO A PANCREATIC PSEUDO CYST THAT IS VISIBLY BULGING INTO THE GASTROINTESTINAL TRACT., ENDOCLIP APPLICATOR(NA)-USED TO DELIVER CLIPS FOR ENDOCLIP.,ESOPHAGEAL DILATOR(NA)-ESOPHAGEAL DILATOR USED TO DILATE ESOPHAGEAL STRICTURES OVER PREVIOUSLY PLACED WIRE GUIDE.,3 STAGE BALLOON DILATOR(NA)-3 STAGE BALLOON DILATOR USED TO DILATE STRICTURES OF THE GASTROINTESTINAL TRACT INCLUDING STRICTURES OF THE ESOPHAGUS/ COLONIC/ BILIARY THROUGH THE SCOPE.,STIFF GUIDE WIRE(NA)-STIFF GUIDE WIRE USED TO GAIN ACCESS ENDOSCOPICALLY/ PERCUTANEOUS THROUGH THE DIFFICULT STRICTURES.,SUPER STIFF HYDRA NEG GUIDE WIRE(NA)-SUPER STIFF HYDRA NEG GUIDE WIRE USED TO GAIN ACCESS THROUGH DIFFICULT BILIARY AND PANCREATIC STRICTURES WITH THIN DIAMETER BUT ADEQUATE STIFFNESS .TO FACILITATE EXCHANGE OF COMPATIBLE WIRE GUIDED ACCESSORIES TO THE DESIRED BILIARY OR PANCREATICDUCTS.,HYDRA NEG COMBO GUIDE WIRE(NA)-HYDRA NEG COMBO GUIDE WIRE USED

	TOGAINACCESS THROUGH DIFFICULT BILIARY AND PANCREATIC STRICTURES AND TO FACILITATEEXCHANGE OF COMPATIBLE WIRE GUIDED ACCESSORIESTO DESIRED BILIARY OR PANCREATIC DUCTS., CHOLEDOCHO BASKET(NA)-CHOLEDOCHO BASKET USED TO REMOVAL OF BILE DUCT STONE THROUGH CHOLEDOCHO SCOPE FROM G.I TRACT.,PANCREATIC BASKET(NA)-PANCREATIC BASKET USED TO REMOVAL OF STONE FROM PANCREATIC DUCT.,LITHO BASKET- TTS(NA)-LITHO BASKET- TTS USED FOR PURPOSE OF CBD STONE RETRIEVAL/LITHOTRIPSY OF STONE IN BILE DUCT THROUGH THE SCOPE,HOOK KNIFE WITH FLUSH(NA)-HOOK KNIFE WITH FLUSH IS USED FOR SMOOTH INCISION AND CUTTING AND CAN BE FLUSHED IF REQUIRE DURING EMR AND ESD ENDOSCOPY PROCEDURE,FLEXI KNIFE(NA)-FLEXI KNIFE IS USED FOR SMOOTH INCISION AND CUTTING DURING EMR AND ESD ENDOSCOPY PROCEDURE,HOOK KNIFE(NA)-HOOK KNIFE IS USED FOR SMOOTH INCISION AND CUTTING DURING EMR AND ESD ENDOSCOPY PROCEDURE,BALL TIP KNIFE(NA)-BALL TIP KNIFE USED FOR SMOOTH INCISION AND CUTTING DURING EMR AND ENDOSCOPY PROCEDURE.,LOOP BASKET (NA)-FOR ENDOSCOPIC RETRIEVAL OF FOREIGN BODIES FROM G.I TRACT & TO RETRIEVE POLYP THROUGH COLONO SCOPE.,MULTI BAND LIGATOR(NA)-MULTI BAND LIGATOR USED FOR ENDOSCOPIC LIGATION OF ESOPHAGEAL VARICES AT OR ABOVE GASTRO ESOPHAGEAL JUNCTION AND COLONIC VARICES.

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3215	MFG/MD/2019/000075	1.License Holder Name: INNVOL MEDICAL INDIA LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:ANTICOAGULANT CITRATE DEXTROSE SOLUTION A USP-ANTICOAGULANT CITRATE DEXTROSE SOLUTION, SOLUTION A, USP. (ACD-A), IS INTENDED FOR USE AS AN ANTICOAGULANT IN THE EXTRACORPOREAL BLOOD PROCESSING WITH AUTOLOGOUS PRP SYSTEMS IN PRODUCTION OF PLATELET RICH PLASMA (PRP). ,ANTICOAGULANT CITRATE DEXTROSE SOLUTION IP-TO BE USED WITH APHERESIS PROCEDURES, BLOOD COLLECTION BAG - CPDA-1 IP-BLOOD BAG SYSTEMS FOR COLLECTION OF BLOOD AND BLOOD PRODUCTS INTENDED TO BE USED CLINICALLY FOR COLLECTION, STORAGE AND TRANSFUSION OF HUMAN WHOLE BLOOD AND STORAGE AND TRANSFUSION OF BLOOD COMPONENTS.,BLOOD COLLECTION BAG - CPD/SAGM IP-BLOOD BAG SYSTEMS FOR COLLECTION OF BLOOD AND BLOOD PRODUCTS INTENDED TO BE USED CLINICALLY FOR COLLECTION, STORAGE AND TRANSFUSION OF HUMAN WHOLE BLOOD AND STORAGE AND TRANSFUSION OF BLOOD COMPONENTS.,BLOOD COLLECTION BAG - CPD USP-BLOOD BAG SYSTEMS FOR COLLECTION OF BLOOD AND BLOOD PRODUCTS INTENDED TO BE USED CLINICALLY FOR COLLECTION, STORAGE AND TRANSFUSION OF HUMAN WHOLE BLOOD AND STORAGE AND TRANSFUSION OF BLOOD COMPONENTS.,BLOOD COLLECTION BAG - CPD/SAGM USP-BLOOD BAG SYSTEMS FOR COLLECTION OF BLOOD AND BLOOD PRODUCTS INTENDED TO BE USED CLINICALLY FOR COLLECTION, STORAGE AND TRANSFUSION OF HUMAN WHOLE BLOOD AND STORAGE AND TRANSFUSION OF BLOOD COMPONENTS.,BLOOD COLLECTION BAG - CPD IP-BLOOD BAG SYSTEMS FOR COLLECTION OF BLOOD AND BLOOD PRODUCTS INTENDED TO BE USED CLINICALLY FOR COLLECTION, STORAGE AND TRANSFUSION OF HUMAN WHOLE BLOOD AND STORAGE AND TRANSFUSION OF BLOOD COMPONENTS., BLOOD COLLECTION BAG - CPDA-1 USP-BLOOD BAG SYSTEMS FOR COLLECTION OF BLOOD AND BLOOD PRODUCTS INTENDED TO BE USED CLINICALLY FOR COLLECTION, STORAGE AND TRANSFUSION OF HUMAN WHOLE BLOOD AND STORAGE AND TRANSFUSION OF BLOOD COMPONENTS.

3216	MFG/MD/2019/000076	1.License Holder Name: SAFEGUARD CONTRACEPTIVES PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:SURELIFE MALE NATURAL DOTTED STRAWBERRY FLAVOURED LUBRICATED CONDOM-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION.,SURELIFE MALE NATURAL DOTTED CHOCOLATE FLAVOURED LUBRICATED CONDOM-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION.,SURELIFE MALE NATURAL DOTTED BANANA FLAVOURED LUBRICATED CONDOM-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION.,SURELIFE MALE NATURAL DOTTED PINEAPPLE FLAVOURED LUBRICATED CONDOM-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION.,SURELIFE MALE NATURAL DOTTED PINEAPPLE FLAVOURED LUBRICATED CONDOM-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION.,SURELIFE MALE NATURAL DOTTED BANANA FLAVOURED LUBRICATED CONDOM-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION.,SURELIFE MALE NATURAL DOTTED CHOCOLATE FLAVOURED LUBRICATED CONDOM-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION.,SURELIFE MALE NATURAL DOTTED STRAWBERRY FLAVOURED LUBRICATED CONDOM-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION.,SURELIFE MALE NATURAL DOTTED CHOCOLATE FLAVOURED LUBRICATED CONDOM-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION.,SURELIFE NATURAL DOTTED PINEAPPLE FLAVOURED LUBRICATED CONDOM-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION.,SURELIFE NATURAL DOTTED BANANA FLAVOURED

	LUBRICATED CONDOM-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION., SURELIFE MALE NATURAL DOTTED STRAWBERRY FLAVOURED LUBRICATED CONDOM-NATURAL RUBBER LATEX CONDOMS ARE INTENDED TO ACT AS A METHOD OF CONTRACEPTION AND PREVENT THE TRANSMISSION OF SEXUALLY TRANSMITTED INFECTION.

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3217	MFG/MD/2019/000077	1.License Holder Name: RECOMBIGEN LABORATORIES PVT. LTD 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:RINSE REAGENT KIT (RECOMBIGEN)-THIS KIT IS DESIGNED FOR HEALTH SERVICES LABORATORIES FORCLEANING MICRO FLOW-THROUGH CELLS AND CUVETTES OF SEMI-AUTOMATEDCLINICAL CHEMISTRY ANALYZERS. THE MIXTURE IS INTENDED FOR PROFESSIONAL USE.,CALCIUM REAGENT TEST KIT(RECOMBIGEN)-THIS KIT IS DESIGNED FOR HEALTH SERVICES LABORATORIES FOR DETERMINATION OF CALCIUM IN HUMAN SERUM/PLASMA AND URINE SAMPLES. THE MIXTURE IS INTENDED FOR PROFESSIONAL USE,LYSE REAGENT KIT (RECOMBIGEN)-LYSE REAGENT IS A GENERAL PURPOSE REAGENT USED TOLYSE RED BLOOD CELLS FROM ANY BIOLOGICAL FLUIDS AND, IN PARTICULAR, TO LYSE ERYTHROCYTES FROM WHOLE BLOOD.,RAPID PLASMA REAGIN (RPR) TEST KIT(RECOMBIGEN)-THE RPR CARBON REAGENT IS A STABILIZED SUSPENSION OF CHOLESTEROL CRYSTALS COATED BY CARDIOLIPIN LECITHIN ADDED TO ADJUST THE SENSITIVITY AND CHARCOAL PARTICLES TO IMPROVE THE READING OF THE REACTION. THE REAGENTS ACT AS ANTIGEN AGAINST ANTIBODIES PRESENTS IN PERSONS SUFFERING FROM SYPHILIS. THESE ANTIBODIES ARE CALLED “ REAGINS”. , BLOOD CELL DILUENT KIT(RECOMBIGEN)-THIS KIT IS DESIGNED FOR HEALTH SERVICES LABORATORIES FOR SUSPENSION AND PRESERVATION OF HUMAN RED BLOOD CELLS FOR USE IN IN VITRO IMMUNOHEMATOLOGY TESTS. THE MIXTURE IS INTENDED FOR PROFESSIONAL USE.,GLUCOSE-6-PHOSPHATE DEHYDROGENASE REAGENT TEST KIT(RECOMBIGEN)-THIS KIT IS DESIGNED FOR HEALTH SERVICES LABORATORIES FOR DETERMINATION OFGLUCOSE-6-PHOSPHATE DEHYDROGENASE IN HUMAN WHOLE BLOOD SAMPLES. THE MIXTURE IS INTENDED FOR PROFESSIONAL USE.,LEPTOSPIRA ANTIBODYTEST KIT(RECOMBIGEN)-LATERAL FLOW IMMUNOASSAY FOR THE SIMULTANEOUS DETECTION OF LEPTOSPIRAIGM/IGG ANTIBODY IN HUMAN SERUM/PLASMA/WHOLE BLOOD SAMPLES.,CHIKUNGUNYA ANTIBODY TEST KIT(RECOMBIGEN) -THE CHIKUNGUNYAIGM RAPID TEST IS A LATERAL FLOW CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF IGM ANTI-CHIKUNGUNYA VIRUS CHIK IN HUMAN SERUM, PLASMA OR WHOLE BLOOD. IT IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH CHIK. ANY REACTIVE SPECIMEN WITH THE CHIKUNGUNYAIGM RAPID TEST MUST BE CONFIRMED WITH ALTERNATIVE TESTING METHOD(S) AND CLINICAL FINDINGS.

3218	MFG/MD/2019/000078	1.License Holder Name: HOSPI LINE EQUIPMENTS PVT. LTD. 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:ENDOSCOPY MUCOSAL RESSECTION CATHETER (HOSPILINE)-A SNARE IS A SELF-CONTAINED METAL RING THAT IS OPENED OVER THE POLYP AND THEN CLOSED ENTRAPPING POLYP TISSUE FOR RESECTION BY CLOSING THE RING. BEFORE PULLING THE SNARE OUT OF THE SCOPE, THE POLYP SHOULD BE BROUGHT TO THE SIX O'CLOCK POSITION. ONCE THE POLYP IS CAPTURED IN THE SNARE, THE SNARE PLASTIC SHEATH SHOULD BE ADVANCED MOVING THE POLYP AWAY FROM THE SCOPE TIP IF ELECTROCAUTERY IS TO BE USED TO AVOID ELECTRICAL DAMAGE TO THE SCOPE. WHEN SNARING A PEDUNCULATED POLYP, THE SNARE SHOULD BE PLACED ABOUT HALF WAY UP THE STALK, SO THAT AFTER CUTTING, A STALK REMNANT IS LEFT WHICH CAN BE GRABBED OR CLIPPED IF HEMORRHAGE OCCURS. THE POLYP IS PULLED AWAY FROM ITS BASE INTO THE LUMEN TENTING THE COLON WALL TO AVOID BURNING THE ADJACENT DEEP COLON LAYERS. NEEDLE-KNIFE SPHINCTEROTOMY OR NEEDLE-KNIFE PAPILLOTOMY IS A CUTTING METHOD THAT USES A STRAIGHT, FINE, WIRE-TYPE NEEDLE, REFERRED TO AS A NEEDLE KNIFE, TO INCISE THE PAPILLA AS WELL AS THE OVERLYING AND DEEPER TISSUES, OPENING THE SPHINCTER ITSELF. THE NEEDLE KNIFE UTILIZES ELECTROCAUTERY TO AID IN CUTTING. THE PURPOSE OF NEEDLE KNIFE SPHINCTEROTOMY IS TO CUT INTO THE SPHINCTER AREA AND FACILITATE ENTRY INTO EITHER THE COMMON BILE DUCT OR PANCREATIC DUCT. DIRECT NEEDLE-KNIFE ENTRY AND RELEASE OF THE STONE IS A MUCH-PREFERRED METHOD THAT IS USED BY MANY ENDOSCOPISTS.,URETHRAL/URETIC CATHETER(HOSPILINE)-ONE OF THE MOST COMMON TYPES IS THE URETIC OR URINARY CATHETER, WHICH IS USED TO DRAIN URINE FROM THE URINARY BLADDER OF A MAN OR WOMAN.DRAINAGE OF URINE FROM THE KIDNEY.,BILLIARY STONE RETRIEVAL BASKET(HOSPILINE)-BILLIARY STONE RETREIVAL BASKETS AND BALLOON ARE USUALLY USED FOR THE REMOVAL OF COMMON BILE DUCT STONES. BASKETS ARE GENERALLY USED FOR STONE EXTRACTION, BUT BALLOON EXTRACTION CATHETERS ARE ALSO USED FOR THIS PURPOSE, ESPECIALLY TO REMOVE SMALL STONES AND BILIARY TRACK. 1. AFTER ENDOSCOPIC SPHINCTEROTOMY, REMOVE THE WIRE GUIDE WITH THE SPHINCTEROTOME BUT BEGINNERS CAN LEAVE THE WIRE GUIDE IN THE BILE DUCT. 2. CAPTURING THE STONE THE MOST BASIC TECHNIQUE OF CAPTURING A STONE WITH A STANDARD 4-WIRE BASKET IS TO ADVANCE THE CATHETER UNTIL UPSTREAM OF THE STONE, THEN PULL THE CATHETER BACK SLOWLY AFTER OPENING THE BASKET. STONE CAPTURE IS ACCOMPLISHED,SCLEROTHERAPY

	NEEDLE /CATHETER(HOSPILINE)-INDICATIONS FOR ENDOSCOPY TO INTRODUCE A SCLEROSING AGENT OR VASOCONSTRICTOR INTO SELECTED SITES TO CONTROL ACTUAL OR POTENTIAL BLEEDING LESIONS IN THE DIGESTIVE SYSTEM; AND THE INJECTION OF SALINE TO AID IN ENDOSCOPIC MUCOSAL RESECTION (EMR), POLYPECTOMY PROCEDURES AND TO CONTROL NON-VARICEAL HEMORRHAGE, PERCUTANEOUS NEPHROSTOMY DRAINAGE CATHETER(HOSPILINE)-PERCUTANEOUS NEPHROSTOMY SET: USED FOR EXTERNAL URINE DRAINAGE FROM THE RENAL PELVIS. NEPHROSTOMY IS PERFORMED WHENEVER A BLOCKAGE KEEPS URINE FROM PASSING FROM THE KIDNEYS, THROUGH THE URETER AND INTO THE URINARY BLADDER. WITHOUT ANOTHER WAY FOR URINE TO DRAIN, PRESSURE WOULD RISE WITHIN THE URINARY SYSTEM AND THE KIDNEYS WOULD BE DAMAGED.,OESOPHAGEAL SENGSTAKEN TUBE(HOSPILINE)-IT IS USED IN LIKE THREATENING UPPER GI BLEED FROM RUPTURED OESOPHOGEAL/GASTRIC VARICES WHEN TRADITIONAL TREATMENT WITH BAND LIGATON OR GLUE INJECTION HAS FAILED OR ARE NOT AVAILABLE. THIS IS ONLY TEMPORARY METHOD TO BUY TIME FOR MORE DEFINITIVE PROCEDURES TO STOP THE BLEEDING.,GASTRO-ENTEROSTOMY TUBE(HOSPILINE)-PATIENTS WHO ARE UNABLE TO MOVE FOOD FROM THEIR MOUTH TO THEIR STOMACH ARE THE ONES WHO COMMONLY NEED PEG TUBE PLACEMENT. THIS INCLUDES THOSE WITH NEUROLOGIC DISORDERS SUCH AS STROKE, CEREBRAL PALSY, BRAIN INJURY, AMYOTROPHIC LATERAL SCLEROSIS, AND IMPAIRED SWALLOWING. IN ADDITION, PATIENTS WHO HAVE TRAUMA, CANCER, OR RECENT SURGERY OF THE UPPER GASTROINTESTINAL OR THE RESPIRATORY TRACT MAY REQUIRE THIS PROCEDURE TO MAINTAIN NUTRITION INTAKE.,FORCEPS ENDOSCOPIC(HOSPILINE)-FOR REMOVING THE FOREIGN BODY THESE FORCEP ARE PASSES THROUGH THE ENDOSCOPE AND GRIP OVER THE FOREIGN BODY AND REMOVE IT. FOR DIFFERENCE TYPE OF FOREIGN BODY ENDOSCOPIST HAS TO DECIDE WHICH DESIGN/TYPE OF FOREIGN BODY REMOVING FORCEP HAS TO USE. FOR MARBEL/DENTURE TYPE OF FOREIGN BODIES, NET SNARE HAS TO USE, FOR BONE PCS. 2/3/4 PRONGS ARE REQUIRED AND FOR COIN RAT TEETH/ALLIGATOR FORCEP REQUIRED. IF DOCTOR FOUND ANY POLYPS OR TUMORS DURING ENDOSCOPY OR OTHER COLORECTAL EXAM, AND THEY ARE TOO BIG TO BE REMOVED ON THE SPOT, THEN DOCTOR WILL PASS THE BIOPSY THROUGH THE CHANNEL OF THE ENDOSCOPE, WILL TAKE SMALL SAMPLES OF THE TISSUE AND TEST IT FOR CANCER BEFORE ORDERING ANOTHER TEST. THE TISSUE IS GENERALLY EXAMINED UNDER A MICROSCOPE BY A PATHOLOGIST, AND CAN ALSO BE ANALYZED CHEMICALLY.SAME PROCESS WILL BE USED FOR THE BRUSH BIOPSY.,ENDOSCOPIC LIGATION DEVICE

		(HOSPILINE)-BAND LIGATOR SET UNDER DIRECT VISUALIZATION THROUGH AN ENDOSCOPE, ELASTIC BANDS ARE APPLIED TO ESOPHAGEAL OR GASTRIC VARICES. WHEN VARICES ARE BLEEDING, THIS PROCEDURE PROVIDES A MEANS OF HEMORRHAGE CONTROL. WHEN VARICES ARE NOT BLEEDING, LIGATION THERAPY MAY BE PERFORMED FOR THERAPEUTIC PREVENTION OF FUTURE HEMORRHAGE VIA VARICEAL ABLATION.,ASPIRATION AND INJECTION NEEDLE(HOSPILINE)-THE STANDARD TBNA TECHNIQUE USES 21-GAUGE CYTOLOGY NEEDLES OR 19-GAUGE HISTOLOGY NEEDLES TOGETHER WITH A FLEXIBLE BRONCHOVIDEOSCOPE. TO LOCALISE THE MASS OR NODE TO BE ASPIRATED THE BRONCHOSCOPIST USES CHEST RADIOGRAPHS AND CT SCAN. THE NEEDLE IS THEN ADVANCED TO THE SAMPLING AREA AND MOVED OUT OF THE SHEATH. THE TARGET TISSUE IS PIERCED WITH THE NEEDLE AND ASPIRATION IS STARTED. AFTER ASPIRATION, THE NEEDLE IS FULLY RETRACTED INTO THE SHEATH AND WITHDRAWN THROUGH THE WORKING CHANNEL.
3219	MFG/MD/2019/000079	1.License Holder Name: MRK HEALTH CARE PVT. LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:INTRAVENOUS CANNULA (PARTNERS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3220	MFG/MD/2019/000080	1.License Holder Name: WELLMED INTERNATIONAL INDUSTRIES PVT. LTD. 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:TRANSFER SPIKE-IT IS INDICATED TO ALLOW MULTIPLE NEEDLE LESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIALS.,I.V. CANNULA WITH WINGS & WITHOUT INJECTION PORT FOR NEONATES-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA WITHOUT WINGS & INJECTION PORT-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,A.V. FISTULA NEEDLE-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT.,I.V. CANNULA WITH WINGS & 3 WAY-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,UMBILICAL CORD CLAMP-THESE DEVICE (CLIP) IS USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,I.V. CANNULA WITH WINGS & WITHOUT INJECTION PORT-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA SAFETY WITHOUT WINGS & INJECTION PORT (SAFETY FEATURE WITH NEEDLE BEVEL ENCLOSURE)-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,STOP COCK- THREE WAY STOP COCK- STANDARD-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING., I.V. CANNULA SAFETY WITH WINGS & WITHOUT INJECTION PORT (SAFETY FEATURE WITH NEEDLE BEVEL ENCLOSURE)-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA WITH WINGS & WITHOUT INJECTION PORT-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA SAFETY WITH SUTURABLE WINGS & FLIP TYPE INJECTION PORT (SAFETY FEATURE WITH NEEDLE BEVEL ENCLOSURE)-I.V. CANNULA IS A PASSIVE DEVICE TO

	PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,ENDOTRACHEAL TUBE WITH CUFF-THE PRODUCT IS USED TO KEEP THE RESPIRATORY TRACT OPEN DURING ANESTHESIA,I.V. CANNULA SAFETY WITHOUT WINGS & INJECTION PORT (SAFETY FEATURE WITH COMPLETE NEEDLE ENCLOSURE)-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,STOP COCK-THREE WAY STOP COCK HIGH PRESSURE- STANDARD-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,SUCTION CATHETER- THUMB CONTROL-SUCTION CATHETER IS USED TO PROVIDE ACCESS TO RESPIRATORY TRACT TO REMOVE SECRETION WITH MAXIMUM COMFORT TO THE PATIENT.,Y - CONNECTOR (AN ACCESSORY TO PERFUSION SET)-IT CAN BE USED TO CONNECT TO A PERFUSION SET OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC.,MEASURED VOLUME I.V. SET-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,I.V. CANNULA WITHOUT WINGS & INJECTION PORT-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THORACIC DRAINAGE CATHETER STRAIGHT-THORACIC DRAINAGE CATHETER - IS USED TO PROVIDE FOR POST OPERATIVE DRAINAGE FROM THE CHEST AFTER CARDIO THORACIC AND THORACIC SURGERY., THORACIC DRAINAGE CATHETER WITH TROCAR-THORACIC DRAINAGE CATHETER - IS USED TO PROVIDE FOR POST OPERATIVE DRAINAGE FROM THE CHEST AFTER CARDIO THORACIC AND THORACIC SURGERY.,I.V. CANNULA SAFETY WITHOUT WINGS & INJECTION PORT (SAFETY FEATURE WITH NEEDLE BEVEL ENCLOSURE)-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES, RYLES TUBE-THE PRODUCT IS USED TO PROVIDE ACCESS TO NASO-GASTRIC TRACT FOR INTRODUCTION OF NUTRITION AND ASPIRATION OF INTESTINAL SECRETION.,STOP COCK- THREE WAY STOP COCK WITH EXTENSION LINE- LIPID RESISTANT-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,STOP COCK- THREE WAY STOP COCK CLICK TYPE- STANDARD-IT IS INDICATED FOR FLUID FLOW

	DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,STOP COCK- THREE WAY STOP COCK CLICK TYPE- LIPID RESISTANT-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,LEVINS TUBE-USED FOR ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,STOP COCK- TWO WAY STOP COCK-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,STOP COCK- THREE WAY STOP COCK WITH EXTENSION LINE- STANDARD-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,SUCTION CATHETER- FINGER TIP COCNTROL-SUCTION CATHETER IS USED TO PROVIDE ACCESS TO RESPIRATORY TRACT TO REMOVE SECRETION WITH MAXIMUM COMFORT TO THE PATIENT.,CLOSED WOUND DRAINAGE SET-CLOSE WOUND DRAINAGE SET IS USED TO PROVIDE FOR DRAINAGE OF BLOOD AND SERUM ETC. FROM OPERATIVE WOUNDS IN CLOSED SYSTEM UNDER NEGATIVE PRESSURE. THE BELLOW IS COLLAPSED AND RELEASED TO GENERATE PRESSURE AND START SUCTION. THE CLOSED SYSTEM PREVENTS INFECTIONS, THORACIC DRAINAGE CATHETER- CURVED-THORACIC DRAINAGE CATHETER - IS USED TO PROVIDE FOR POST OPERATIVE DRAINAGE FROM THE CHEST AFTER CARDIO THORACIC AND THORACIC SURGERY.,I.V. CANNULA WITHOUT WINGS & INJECTION PORT-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,INFANT FEEDING TUBE-INFANT FEEDING TUBE IS USED TO PROVIDE FEEDING TO NEONATES AND INFANTS.,REDON DRAIN-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,SUCTION CATHETER- PLAIN-SUCTION CATHETER IS USED TO PROVIDE ACCESS TO RESPIRATORY TRACT TO REMOVE SECRETION WITH MAXIMUM COMFORT TO THE PATIENT,I.V. CANNULA SAFETY WITHOUT WINGS & INJECTION PORT (SAFETY FEATURE WITH NEEDLE BEVEL ENCLOSURE)-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA SAFETY WITH WINGS & INJECTION PORT (SAFETY FEATURE WITH NEEDLE

	BEVEL ENCLOSURE)-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA WITH SUTURABLE WINGS & FLIP TYPE INJECTION PORT-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH WINGS & INJECTION PORT-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA SAFETY WITH WINGS & WITHOUT INJECTION PORT FOR NEONATES (SAFETY FEATURE WITH NEEDLE BEVEL ENCLOSURE)-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,NELATON CATHETER-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,STOP COCK- THREE WAY STOP COCK- LIPID RESISTANT-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,NASAL OXYGEN CATHETER-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIR FLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,ENDOTRACHEAL TUBE WITHOUT CUFF-THE PRODUCT IS USED TO KEEP THE RESPIRATORY TRACT OPEN DURING ANESTHESIA,I V FLOW REGULATOR-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,I.V. CANNULA WITHOUT WINGS & INJECTION PORT-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA WITHOUT WINGS & INJECTION PORT-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA WITHOUT WINGS & INJECTION PORT-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES, EXTENSION TUBE / LINE-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS A PART OF A SYSTEM FOR THE INFUSION OF FLUIDS / MEDICATIONS IN MEDICAL APPLICATIONS.,I.V. CANNULA WITH WINGS & WITHOUT INJECTION

	PORT WITH HOLDER FOR NEONATES-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,FOLEY CATHETER-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,I.V. CANNULA WITH WINGS & INJECTION PORT-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA SAFETY WITH SUTURABLE WINGS & FLIP TYPE INJECTION PORT (SAFETY FEATURE WITH NEEDLE BEVEL ENCLOSURE)-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA WITH WINGS & WITHOUT INJECTION PORT FOR NEONATES-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,STOP COCK- THREE WAY STOP COCK HIGH PRESSURE- LIPID RESISTANT-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,I.V. CANNULA WITH SUTURABLE WINGS & FLIP TYPE INJECTION PORT-I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,PERFUSION SETS FOR SINGLE USE-TRANSFUSION SET IS USED TO ADMINISTER BLOOD / DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.

3221	MFG/MD/2019/000081	1.License Holder Name: LA-MED HEALTHCARE PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:IV INFUSION SET(DRIPPY NV PRO)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER OR CANNULAE., UMBILICAL CORD CLAMP(LA-MED)-UMBILICAL CORD CLAMP IS USED FOR CLAMPING THE UMBILICAL CORD IMMEDIATELY AFTER BIRTH., EXTENSION TUBING(BI-CONNECT PRO, TRI-CONNECT PRO, DIDACTIC) -EXTENSION TUBE ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATION IN MEDICAL APPLICATIONS., HEMODIALYSIS KIT (CATHETER)(LA-MED/DYLAX-LM)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT HEMODIALYSIS KIT IS USED FOR SHORT TERM VASCULAR ACCESS FOR DIALYSIS OR APHERESIS. HEMODIALYSIS KIT IS USUALLY USED TO BUILD A TEMPORARY BLOOD CONNECTION BETWEEN THE PATIENT AND THE DIALYSIS MACHINE FOR ACUTE AND SHORT-TERM DIALYSIS.,THREE WAY STOP COCK(ENDURE)-LT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWN OF FLUIDS AND PRESSURE MONITORING, EXTENSION TUBING(LINK/LINK XT/LINK PM/LINK 3XT/LINK CT/ UNI CONNECT/BI CONNECT/TRI CONNECT/LINK PM PRO/LINK 3XT PRO)- EXTENSION TUBE ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATION IN MEDICAL APPLICATIONS., LNFANT FEEDING TUBE(ENDURE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO STOMACH THROUGH MOUTH OR NOSE TO SUPPLY NUTRITION. INFANT FEEDING TUBE IS USED FOR THE NUTRITIONAL FEEDING OF NEONATAL AND PEDIATRIC NUTRITIONAL SUPPLEMENTS.,YANKAUR SUCTION SET(LA-MED/YANKAUR SUCTION SET PRO)-YANKAUR SUCTION SET ARE USED FOR THE SUCTION FROM THORACIC CAVITY OR/ AND OPERATION SITE DURING SURGICAL PROCEDURE.,SUCTION CATHETER(ENDURE)-THE SUCTION CATHETER HAS BEEN DESIGNED FOR REMOVAL OF SECRETION FROM MOUTH, TRACHEA AND BRONCHIAL TUBE USED IN THE RESPIRATORY TRACT,TWIN BORE NASAL OXYGEN SET(TWIN O2 SET)- THE TWIN BORE NASAL OXYGEN SET IS USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASE AIR FLOW TO A PATIENT OR PERSON WHO HAVE A PRESCRIPTION FOR OXYGEN THERAPY.,LV INFUSION SET(ENDURE)-THE LNFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER OR

	CANNULAE.,LEVIN'S TUBE(LA-MED)-LEVIN'S TUBE IS USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENT AND ADMINISTRATION OF TUBE FEEDING AND MEDICATIONS.,LV CANNULA(TEFLO, NEOTEF)-THE LV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES LT IS A DEVICE THROUGH WHICH FLUID IS INTRODUCED OR WITHDRAWN FROM HUMAN CIRCULATION SYSTEM, THROUGH A CATHETER,REDON DRAIN CATHETER(LA-MED)-THE TUBE IS USED TO REMOVE PUS, BLOOD OR OTHER FLUID FROM A WOUND. THE REDON DRAIN CATHETER HAS BEEN DESIGNED FOR POST-OPERATIVE DRAINAGE.,IV CANNULA(ENDURE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. IT IS A DEVICE THROUGH WHICH FLUID IS INTRODUCED OR WITHDRAWN FROM HUMAN CIRCULATION SYSTEM, THROUGH A CATHETER.,MANIFOLD(LA-MED)-INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND PROVIDING ACCESS PORT/PORTS FOR ADMINISTRATION OF A SOLUTION. ,BLOOD TRANSFUSION SET(ENDURE)-BLOOD TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN BLOOD TRANSFUSION SET IS USED IN DELIVERING MEASURED AND REGULATED BLOOD TO PATIENT,MEASURED VOLUME BURETTE SET(LA-MED/DRIPPY PAEDIA/DRIPPY PAEDIA PRO)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUID FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. MEASURE VOLUME SET IS USED IN DELIVERING MEASURED AND REGULATED INTRAVENOUS SOLUTION TO GENERALLY PEDIATRIC PATIENT BUT CAN BE USED SPECIFICALLY IN PATIENTS WHERE DOSAGE IS VERY CRITICAL.,STOMACH TUBE(ENDURE)-STOMACH TUBE IS USED FOR THE NUTRITIONAL FEEDING OF NUTRITIONAL SUPPLEMENTS. LT IS A MEDICAL DEVICE USED TO PROVIDE NUTRITION TO PATIENTS WHO CANNOT OBTAIN NUTRITION BY MOUTH, ARE UNABLE TO SWALLOW SAFELY, OR NEED NUTRITIONAL SUPPLEMENTATION.,INFANT FEEDING TUBE(LA-MED/INFANTY/INFANT FEEDING TUBE PRO)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO STOMACH THROUGH MOUTH OR NOSE TO SUPPLY NUTRITION. INFANT FEEDING TUBE IS USED FOR THE NUTRITIONAL FEEDING OF NEONATAL AND PEDIATRIC NUTRITIONAL SUPPLEMENTS.,UMBILICAL CORD CLAMP(ENDURE)-UMBILICAL CORD CLAMP IS USED FOR CLAMPING THE UMBILICAL CORD IMMEDIATELY AFTER BIRTH.,NELATON CATHETER(LA-MED/NELTO)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR

	INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER. THE LA-MED NELATON CATHETER HAS BEEN DESIGNED FOR SHORT TERM BLADDER CATHETERIZATION THROUGH URETHRA IN MALES AND FEMALES.,TWIN BORE NASAL OXYGEN SET(TWIN O2 SET PRO)-THE TWIN BORE NASAL OXYGEN SET IS USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASE AIR FLOW TO A PATIENT OR PERSON WHO HAVE A PRESCRIPTION FOR OXYGEN THERAPY.,IV INFUSION SET(LA-MED/DRIPPY/ONCO GUARD/ONCO GUARD PLUS/DRIPPY ULTRA/TRANSFIX IV/ENDURE ONCO SET PLUS/NICHE)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER OR CANNULAE.,MEASURED VOLUME BURETTE SET(ENDURE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUID FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. MEASURE VOLUME SET IS USED IN DELIVERING MEASURED AND REGULATED INTRAVENOUS SOLUTION TO GENERALLY PEDIATRIC PATIENT BUT CAN BE USED SPECIFICALLY IN PATIENTS WHERE DOSAGE IS VERY CRITICAL., SUCTION CATHETER(LA-MED/OROCATH/SUCTION CATHETER PRO)-THE SUCTION CATHETER HAS BEEN DESIGNED FOR REMOVAL OF SECRETION FROM MOUTH, TRACHEA AND BRONCHIAL TUBE USED IN THE RESPIRATORY TRACT.,EXTENSION TUBE(ENDURE)-EXTENSION TUBE ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATION IN MEDICAL APPLICATIONS.,BLOOD TRANSFUSION SET(LA-MED/TRANSFIX BT)-BLOOD TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. BLOOD TRANSFUSION SET IS USED IN DELIVERING MEASURED AND REGULATED BLOOD TO PATIENT.,ENDOTRACHEAL TUBE PLAIN/RE-INFORCED(ENDURE)-AN ENDOTRACHEAL TUBE IS USED IN GENERAL ANESTHESIA, INTENSIVE CARE AND EMERGENCY MEDICINE FOR AIRWAY MANAGEMENT AND MECHANICAL VENTILATION.,THORACIC DRAINAGE CATHETER(LA-MED)-THE THORACIC DRAINAGE TUBE IS USED TO REMOVE PUS, BLOOD OR OTHER FLUID FROM A WOUND., SALEM SUMP TUBE(ENDURE)-PASSAGE OF TUBE BY MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUME OF LIQUID SALEM SUMP TUBE IS USED TO PREVENT THE ACCUMULATION OF GASTRIC SECRETIONS AND AIR,RYLE'S TUBE(LA-MED/RYLO/RYLE'S TUBE PRO/ENDURE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,

	CLOSED WOUND SUCTION SET(VAC SET PRO, KIDI VAC SET PRO)-THE DEVICE IS USED TO REMOVE PUS, BLOOD OR OTHER FLUID FROM A WOUND.,FLOW REGULATOR/IV FLOW REGULATOR(FLOW REG/FLOW REGULATOR PRO)-IT IS AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. INTENDED TO USE TO CONTROL PRECISELY THE FLOW OF INFUSION FLUID UP TO 300 ML/ HR.,BLOOD TRANSFUSION SET(BT SET PRO)-BLOOD TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. BLOOD TRANSFUSION SET IS USED IN DELIVERING MEASURED AND REGULATED BLOOD TO PATIENT.,FOLEY BALLOON CATHETER(LA-MED/U CATH/FOLEY BALLOON CATHETER PRO)-FOLEY CATHETERS ARE USED FOR THE EXTRACTION AND COLLECTION OF URINE FROM THE PATIENTS SUFFERING FROM URINARY TRACT PROBLEMS.,LEVIN'S TUBE(ENDURE)-LEVIN'S TUBE IS USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENT AND ADMINISTRATION OF TUBE FEEDING AND MEDICATIONS.,STOMACH TUBE(LA-MED)-STOMACH TUBE IS USED FOR THE NUTRITIONAL FEEDING OF NUTRITIONAL SUPPLEMENTS. IT IS A MEDICAL DEVICE USED TO PROVIDE NUTRITION TO PATIENTS WHO CANNOT OBTAIN NUTRITION BY MOUTH, ARE UNABLE TO SWALLOW SAFELY, OR NEED NUTRITIONAL SUPPLEMENTATION., THORACIC DRAINAGE CATHETER(ENDURE)-THE THORACIC DRAINAGE TUBE IS USED TO REMOVE PUS, BLOOD OR OTHER FLUID FROM A WOUND.,CLOSED WOUND SUCTION SET(VAC SET/SILICO DRAIN)-THE DEVICE IS USED TO REMOVE PUS, BLOOD OR OTHER FLUID FROM A WOUND.,IV CANNULA(QUALI+CATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. IT IS A DEVICE THROUGH WHICH FLUID IS INTRODUCED OR WITHDRAWN FROM HUMAN CIRCULATION SYSTEM, THROUGH A CATHETER.,MUCUS EXTRACTOR(LA-MED)-INTENDED TO USED FOR CLEARING THE AIRWAYS OF MUCUS TO IMPROVE OXYGENATION AND VENTILATION. MUCUS EXTRACTOR IS USED FOR COLLECTION OF MUCUS FROM PATIENTS.,IV CANNULA(ALPHA-FLOW)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,ENDOTRACHEAL TUBE PLAIN/RE-INFORCED(LA-MED)-AN ENDOTRACHEAL TUBE IS USED IN GENERAL ANESTHESIA, INTENSIVE CARE AND EMERGENCY MEDICINE FOR AIRWAY MANAGEMENT AND MECHANICAL VENTILATION.,RYLE'S TUBE/NASOGASTRIC TUBE(ENDURE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE

	NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,FOLEY BALLOON CATHETER(ENDURE)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY. FOLEY CATHETERS ARE USED FOR THE EXTRACTION AND COLLECTION OF URINE FROM THE PATIENTS SUFFERING FROM URINARY TRACT PROBLEMS.,FEMALE/URETHRAL CATHETER(LA-MED)-THE LA-MED FEMALE CATHETER HAS BEEN DESIGNED FOR SHORT TERM BLADDER CATHETERIZATION THROUGH URETHRA IN FEMALES.,HYPODERMIC NEEDLES(LA-MED)-A HYPODERMIC SINGLE LUMEN NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.,SALEM SUMP TUBE(LA-MED)-PASSAGE OF TUBE BY MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUME OF LIQUID. SALEM SUMP TUBE IS USED TO PREVENT THE ACCUMULATION OF GASTRIC SECRETIONS AND AIR.,THREE WAY STOP COCK(LA-MED/LINK/LINK LR/LINK-3KLR/3-WAY STOP COCK PRO/GALENA/NICHE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWN OF FLUIDS AND PRESSURE MONITORING.,IV CANNULA(LA-MED/PRIMAFLON/IV FLON/NOVOCATH/CANNATECH/PRIMAFLO/PRIMAFLO PRO/IV FLON PRO/PRIMACAN ALPHA/PRIMAPEN/IV NEO ALPHA/PRIMA NEO ALPHA/IZZY/IV NEO/IV CAN/PRIMACAN/PRIMANEO/PRIMACATH/PRIMASAFE/SYLON/JAPF LON/GALENA/ISOMED/BEROMED/BEROCAN/IV CATH/MEDITEX/NICHE/VERNULE/VM CATHETER)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. IT IS A DEVICE THROUGH WHICH FLUID IS INTRODUCED OR WITHDRAWN FROM HUMAN CIRCULATION SYSTEM, THROUGH A CATHETER

3222	MFG/MD/2019/000084	1.License Holder Name: LIFE O LINE TECHNOLOGIST 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ANETHESIA MASK / CUSION MASK(LIFE-O-MED)-INTENDED FOR THE ADMINISTRATION OF A GAS MIXTURE COMING THROUGH DEVICES FOR ARTIFICIAL VENTILATION ,ENDOTRACHEAL TUBE(LIFE-O-MED)-THE ENDOTRACHEAL TUBES ARE INTENDED FOR AIRWAY MANAGEMENT BY NASAL OR ORAL INTUBATION OF THE TRACHEA. THEY ARE INTENDED FOR USE ON ADULT AND PEDIATRIC PATIENTS,SCALPEL BLADE DISPOSABLE(LIFE-O-MED)-INTENDED FOR USE AS A CUTTING DEVICE DURING SURGICAL, PATHOLOGY AND MINOR MEDICAL PROCEDURES. IT IS INTENDED TO AID IN THE PROTECTION AGAINST ACCIDENTAL INJURIES DURING LOADING. PASSING, AND DISPOSAL , SPINAL NEEDLE(LIFE-O-MED)-SPINAL NEEDLES WITH OR WITHOUT INTRODUCER ARE INTENDED FOR THE INJECTION OF LOCAL ANESTHETICS INTO THE SUBARACHNOID SPACE TO PROVIDE SPINAL ANESTHESIA FOR PAIN MANAGEMENT OR TO FACILITATE CSF SAMPLE COLLECTION FOR DIAGNOSTIC PURPOSES (LUMBAR PUNCTURE). THE NEEDLES ARE INTENDED FOR USE IN ANY TARGET POPULATION WITH CONSIDERATION GIVEN TO THE ANATOMY OF THE PATIENT.,OXYGENATOR WITH TUBE(LIFE-O-MED)-USED TO EXCHANGE GASES BETWEEN BLOOD AND A GASEOUS ENVIRONMENT TO SATISFY THE GAS EXCHANGE NEEDS OF A PATIENT DURING CARDIOPULMONARY BYPASS SURGERY FOR PERIODS UP TO 6 HOURS.,URINE COLLECTING BAG WITH MEASURED VOLUME METER (LIFE-O-MED)-URINARY CATHERTISATION TREATMENT FOR URINE COLLECTING BAG WITH MEASURED VOLUME METER,B.PAPE / C.PAPE MASK(LIFE-O-MED)-BI-LEVEL POSITIVE AIRWAY PRESSURE (BIPAP) THERAPY IS OFTEN USED IN THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD). COPD IS AN UMBRELLA TERM FOR LUNG AND RESPIRATORY DISEASES THAT MAKE BREATHING DIFFICULT.,SKIN STAPLER(LIFE-O-MED)-STEPLERS ARE USE TO CLOSE BOTH INTERNAL AND SKIN WOUNDS. SKIN STAPLER ARE USUALLY APPLIED USING A DISPOSABLE STAPLER AND REMOVED WITH A SPECIALIZED STAPLE REMOVER,BORN MARROW JAMSHEDI NEEDLE(LIFE-O-MED)-INTENDED TO OBTAIN BONE MARROW ASPIRATE AND CORE BIOPSY SAMPLES FROM BONE AND/ORBONE MARROW. ,BLOOD LINE TUBING SET (DIALYSIS TUBING)(LIFE-O-MED)-HEMODIALYSIS BLOOD TUBING WITH ATTACHED PRIMING SET AND TRASDUCER PROTECTORES IS A SINGAL USE DISPOSABLE ARTERIAL AND VENUS BLOODLINE SET INTENDED TO PROVIDE EXTRACORPORAL ACCES DURING HEMODIALYSIS.,CLOSE SUCTION SET(LIFE-O-MED)-INTENDED FOR ENDOTRACHEAL / TRACHEOSTOMY SUCTION OF ADULT AND

	PEDIATRIC INTUBATED PATIENTS (INCLUDING NEONATES). ,BLOOD TRANSFUSION SET (B.T. SET)(LIFE-O-MED)-BLOOD TRANSFUSION SET IS USED TO ADMINISTER BLOOD FROM A CONTAINER (PLASTIC BAG OR GLASS BOTTLE) TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,ASPIRATION NEEDLE (LIFE-O-MED)-USED FOR ASPIRATION OF BONE MARROW OR AUTOLOGOUS BLOOD BY USE OF A STANDARD SYRINGE. ,URETHRAL CATHETER(LIFE-O-MED)-IT IS USED FOR PROLONGED URINARY DRAINAGE, FOR SINGLE USE ONLY,SILICON CAP (SUCTION SET)(LIFE-O-MED)-THE SUCTION AND IRRIGATION SET IS INTENDED FOR USE IN LAPAROSCOPIC GYNAECOLOGIC, GENERAL, THORACIC AND UROLOGY PROCEDURES TO PROVIDE SUCTION AND IRRIGATION FUNCTIONS TO HELP FLUSH BLOOD AND TISSUE DEBRIS FROM THE OPERATIVE SITE DURING LAPAROSCOPY TO AID VISUALIZATION., HIGH PRESSURE MONITORING LINE(LIFE-O-MED)-CHANNELING A FLUID INTRAVENOUS INFUSION TREATMENT,URINE BAG(LIFE-O-MED) -URINE COLLECTION BAGS ARE ATTACHED TO THE END OF THE CATHETER TO COLLECT URINE AS IT FLOWS FROM THE BLADDER. FOLEY CATHETER (LIFE-O-MED)-IT IS USED FOR PROLONGED URINARY DRAINAGE,MULTIFLOW VENTURY MASK(LIFE-O-MED)-INTENDED TO PROVIDE CONTINUOUS OR INTERMITTENT VENTILATORY SUPPORT FOR THE CARE OF INDIVIDUALS WHO REQUIRE MECHANICAL VENTILATION WITH OR WITHOUT AIR/OXYGEN BLENDING.,ICD BAG(LIFE-O-MED)-THE ICD BAG PROVIDES UNDER WATER SEAL DRAINAGE SYSTEM. IT IS USED FOR THE COLLECTION OF FLUID OR TO DRAIN AIR FROM THE THORACIC CAVITY. 1000 ML CAPACITY BAG GRADUATED AT 50 ML SPECIALLY MOLDED HANDLE WITH PROVISION TO HANG THE BAG 100 CMS LONG TUBE HAS CONNECTOR TO CONNECT TO THE ICD TUBE. THE SOFT AND KINK RESISTANT TUBE HAS BLOCKER WHICH CAN BE USED TO BLOCK THE TUBE WHILE EMPTYING THE BAG.IT IS USE WHEN CARDIOVASCULAR SURGERY ,BVF HME FILTER(LIFE-O-MED)-USED FOR HUMIDIFICATION AND BACTERIAL/VIRAL FILTRATION DURING ANESTHESIA AND VENTILATOR CARE.,SUCTION CATHETER(LIFE-O-MED)-SUCTION CATHETERS, INCLUDING CLOSED SUCTION CATHETERS, MADE OF FLEXIBLE MATERIALS AND INTENDED FOR USE IN SUCTIONING OF THE RESPIRATORY TRACT.,HIGH CONCENTRATION MASK(LIFE-O-MED)-HIGH CONCENTRATION MASKS INTENDED FOR ADMINISTRATION OF OXYGEN. THEY ARE EQUIPPED WITH A RESERVOIR BAG ALLOWING AN ADEQUATE AMOUNT OF OXYGEN TO BE AVAILABLE TO MEET UNPREDICTABLE BREATHING PATTERNS AND TIDAL VOLUMES.,GUDAL AIRWAYS(LIFE-O-MED)-AN OROPHARYNGEAL AIRWAY IS A MEDICAL DEVICE CALLED AN AIRWAY ADJUNCT USED TO MAINTAIN OR OPEN A PATIENT'S

	AIRWAY,SINGLE DIAL VENTURY MASK(LIFE-O-MED)-INTENDED FOR DELIVERING SUPPLEMENTAL OXYGEN AND MONITORING EXHALED CARBON DIOXIDE IN NON-INTUBATED SPONTANEOUSLY BREATHING PATIENTS. STANDARD OXYGEN TUBING AND TWO FEMALE LUER PORTS FOR GAS SAMPLE LINE ATTACHMENT ARE INCLUDED.,MUCUS EXTRUCTOR(LIFE-O-MED)-MUCUS EXTRACTOR USED FOR ASPIRATION OF SECRETION FROM THE OROPHARYNX IN NEW BORN BABIES TO ENSURE FREE RESPIRATION OR TO OBTAIN MUCUS SPECIMEN FOR MICROBIOLOGICAL EXAMINATION.,VENTILATOR CIRCUIT - PLAIN(LIFE-O-MED)-DURING EXPIRATION, THE GASES IN THE PATIENT'S LUNGS EMPTY INTO THE BELLOWS, MAKING THE BELLOWS RISE UP. THE RISING BELLOWS PUSHES OUT THE “USED UP” DRIVING GAS (OXYGEN) THROUGH VENTILATOR CONTROLLER INTO THE ATMOSPHERE. VENTILATOR CIRCUIT IS A MEDICAL DEVICE USED TO DELIVER OXYGEN, REMOVE CARBON DIOXIDE, AND DELIVER INHALATIONAL ANAESTHETIC AGENTS TO A PATIENT.,CORD CLAMP (LIFE-O-MED)-THE UMBILICAL CORD CLAMP IS USED FOR THE CLAMPING OF THE UMBILICAL CORD TO PREVENT BLEEDING FROM THE CORD CLAMP STUMP AFTER THE CORD HARD BEEN CUT., VENTILATOR CIRCUIT - SWT(LIFE-O-MED)-PROVIDES CONTINUOUS OR INTERMITTENT VENTILATORY SUPPORT FOR PATIENTS WEIGHING MORE THAN 5KG (11 ILB) WHO REQUIRE MECHANICAL VENTILATION., EXTENSION LINE WITH 3 WAY STOP COCK(LIFE-O-MED)-LOW PRESSURE EXTENSION LINES USED TO REDUCE MOVEMENT AT CANNULATION SITE,THEREBY REDUCING MECHANICAL IRRITATION & REDUCES CHANCE OF INFECTION. KINK RESISTANT TUBING WITH MALE LUER LOCK AT ONE END AND 3 WAY STOP COCK AT THE OTHER END FOR SAFE & SECURE CONNECTION.,BAINS CIRCUIT(LIFE-O-MED)-A BREATHING SYSTEM OR BREATHING CIRCUIT IS A MEDICAL DEVICE USED TO DELIVER OXYGEN, REMOVE CARBON DIOXIDE, AND DELIVER INHALATIONAL ANAESTHETIC AGENTS TO A PATIENT. , RYLE'S TUBE(LIFE-O-MED)-RYLE'S TUBES CAN BE USED TO REMOVE AIR AND LIQUIDS FROM THE STOMACH(DECOMPRESSION) BY CONNECTION TO INTERMITTENT SUCTION UNITS AND AS TEMPORARY FEEDING TUBES; THEY ARE USED FREQUENTLY FOR VERY ILL OR COMATOSE PATIENTS. ... A TUBE THAT IS INSERTED THROUGH THE NOSE,DOWN THE THROAT AND ESOPHAGUS, AND INTO THE STOMACH.,HME FILTER(LIFE-O-MED)-USED FOR HUMIDIFICATION AND BACTERIAL/VIRAL FILTRATION DURING ANESTHESIA AND VENTILATOR CARE.,DIAL FLOW REGULATOR(LIFE-O-MED)-CONTROLLER IS INTENDED FOR USE IN THE INTRAVASCULAR INFUSION OF FLUIDS TO BE DELIVERED TO THE PATIENT IN A PRECISE MANNER FOR NO LONGER THAN 72 HOURS., DILATOR(LIFE-O-MED)-INTENDED FOR TISSUE DILATION AND

	STIMULATION OF PERIPHERAL NERVES INCLUDING SPINAL NERVE ROOTS FOR LOCATION AND IDENTIFICATION DURING SPINAL SURGERY. ,THORACIC CATHETER/CHEST DRAINAGE CATHETER(LIFE-O-MED)-THE CATHETER IS MAINLY INTENDED FOR EVACUATING AIR AND/OR LIQUIDS FROM THE CHEST CAVITY,OXYGEN MASK WITH TUBING(LIFE-O-MED)-INTENDED TO DELIVER SUPPLEMENTAL OXYGEN TO PATIENTS AND MONITOR BREATHING BY SAMPLING EXHALED CARBON DIOXIDE.,FEEDING TUBE(LIFE-O-MED)-FEEDING TUBE IS INTENDED FOR NASOGASTRIC OR OROGASTRIC DELIVERY OF VARIOUS TYPES OF LIQUID NUTRITIONAL MEDIA THROUGH THE GASTRO INTESTINAL TRACT OF NEONATAL AND SMALL PEDIATRIC PATIENTS,AND IS NOT INTENDED FOR USE BEYOND 30 DAYS.,BVF FILTER(LIFE-O-MED)-USED FOR HUMIDIFICATION AND BACTERIAL/VIRAL FILTRATION DURING ANESTHESIA AND VENTILATOR CARE.,INTRAVENOUS INFUSION SET (I.V. SET)(LIFE-O-MED)-INFUSION SETS ARE INTENDED FO R USE IN PARENTERAL, ETERNAL AND EPIDURAL THERAPIES AND THE ADMINISTRATION OF FLUIDS, MEDICATIONS, NUTRITIONAL FLUIDS, SAFETY FEATURES ON THESE DEVICES AID IN PREVENTION OF NEEDLE-STICK INJURIES. INDICATIONS FOR USE MAY INCLUDE HOSPITAL AND OTHER MEDICAL SETTINGS, AMBULATORY AND HOME USE.,RESUSCITATOR (SILICON) / AMBU BAG(LIFE-O-MED)-INTENDED FOR MANUAL PULMONARY RESUSCITATION AND EMERGENCY RESPIRATORY SUPPORT. FOR USE BY CPR-TRAINED PERSONNEL ONLY, IN HOSPITAL AND PRE-HOSPITAL SETTINGS ,PCN CATHETER(LIFE-O-MED)-THE PRECANCEROUS NEPHROSTOMY (PCN) CATHETER WITH NEEDLE IS USED IN SAME CASES AS THE PCN CATHETER. IT CAN HOWEVER DIRECTLY PUNCTURE THROUGH THE SKIN IN TO THE KIDNEY THE NEEDLE IS MADE OF STAINLESS STEEL.,TRANSPARENT FILM DRESSINGS(LIFE-O-MED)-" CHG CHLORHEXIDINE GLUCONATE I. V. SECUREMENT DRESSING CAN BE USED TO COVER AND PROTECT CATHETER SITES AND TO SECURE DEVICES TO SKIN. COMMON APPLICATIONS INCLUDE SECURING AND COVERING I.V. CATHETERS, OTHER INTRAVASCULAR CATHETERS AND PERCUTANEOUS DEVICES. " ,PIGTAIL CATHETER(LIFE-O-MED)-IT IS INTENDED FOR USE IN ENGIOGRAPHIC PROCEDURES IT DELIVERS RADIO OPAQUE MEDIA AND THERAPEUTIC AGENTS TO SELECTED SITES IN THE VASCULAR SYSTEM,COLOSTOMY BAG(LIFE-O-MED)-INTENDED TO REST THE PATIENT'S COLON IN THE CASE OF A TEMPORARY PROCEDURE, OR TO ACT AS AN ARTIFICIAL OUTLET FOR THE BOWEL WHEN THE SURGERY IS INTENDED AS PERMANENT. ,TRANSDUCER PROTECTOR (LIFE-O-MED)-TRANSDUCER PROTECTORS ARE USED IN HEMODIALYSIS BLOOD LINES TO KEEP THE BLOOD SIDE OF THE CIRCUIT SEPARATED FROM THE MACHINE SIDE, AND TO PREVENT

	CONTAMINATION OF THE MACHINE BY THE BLOOD FLOWING THROUGH THE CIRCUIT.TRANSDUCER PROTECTORS LET AIR PASS WHILE PREVENTING THE BLOOD FROM PASSING THROUGH.,B.P. METER(LIFE-O-MED)-"INTENDED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES AND PULSE RATE OF AN ADULT INDIVIDUAL BY USING A NON-INVASIVE TECHNIQUE IN WHICH AN INFLATABLE CUFF IS WRAPPED AROUND THE WRIST. THE CUFF CIRCUMFERENCE IS LIMITED TO L4CM-25CM.",CODAN SET(LIFE-O-MED)-HYDROPHOBIC END CAP FOR UNIVERSAL USE; REDUCES RISK OF BACTERIAL OR PARTICULATE CONTAMINATION; SAFE AND LEAK FREE PRIMING OF SETS; BACTERIA-FREE, DRIP-FREE,HYPODERMIC SYRINGE WITH NEEDLE & W/O NEEDLE(LIFE-O-MED)-INTENDED TO BE USED FOR MEDICAL PURPOSES TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,HEMODIALYSIS CATHETER KIT (LIFE-O-MED)-HEMODIALYSIS CATHETER IS INDICATED FOR USE IN ATTAINING LONG-TERM VASCULAR ACCESS FOR HEMODIALYSIS . IT MAY BE INSERTED PERCUTANEOUSLY AND IS PRIMARILY PLACED IN THE INTERNAL JUGULAR VEIN OF AN ADULT PATIENT. THIS CATHETER IS INDICATED FOR > 30 DAYS LONG TERM PLACEMENT. THE CATHETER INSERTED ON THE PIGTAIL CATHETER CAN BE USED TO STRAIGHTEN THE CATHETER TIP FOR EASIER INSERTION INTO THE SHEATH.,3 BALL SPIROMETER(LIFE-O-MED)-INTENDED AS AN INSPIRATORY DEEP BREATHING POSITIVE EXERCISER. INTENDED FOR SINGLE-PATIENT, MULTI-USE IN A HOSPITAL OR HOME CARE SETTING. ,NEPHROSTOMY CATHETER KIT(LIFE-O-MED)-IT IS INTENDED FOR USE IN ANGIOGRAPHIC PROCEDURES. IT DELIVERS RADIOPAQUE MEDIA AND THERAPEUTIC AGENTS TO SELECTED SITES IN THE VASCULAR SYSTEM.,PAPER TAPE(LIFE-O-MED)-INTENDED FOR HEALTHCARE PROFESSIONALS ONLY. ,YANKUR SUCTION SET (LIFE-O-MED)-YANKUR SUCTION SET IS INTENDED FOR SUCTION OF THE BODY FLUID IN COMBINATION WITH ASPIRATOR DURING OPERATION ON THORACIC CAVITY OR ABDOMINAL CAVITY., LARYNGEAL MASK AIRWAYS (L.M.A)(LIFE-O-MED)-INDICATED FOR USE VIA A RIGID OR SEMI-RIGID ENDOSCOPE WITH A STRAIGHT WORKING CHANNEL, FOR THE FRAGMENTATION OF URINARY TRACT (I.E. KIDNEY, URETER AND BLADDER) STONES. ,BIOPSY GUN(LIFE-O-MED)-THE CORE NEEDLE BIOPSY DEVICES IS INTENDED FOR USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS LIVER KIDNEY BREAST PROSTATE SPLEEN.,VENTILATOR CIRCUIT - DWT(LIFE-O-MED)-INTENDED FOR NEONATAL AND INFANT PATIENTS IN PROFESSIONAL HEALTHCARE ENVIRONMENTS AS A CONDUIT FOR RESPIRATORY GAS BETWEEN A PATIENT AND A VENTILATOR OR INFANT FLOW GENERATOR (FOR SINGLE LIMB CONFIGURATION) AND INCLUDE HEATED WIRE(S) FOR USE WITH THE HUDSON RCI NEPTUNE

	HEATED HUMIDIFIER.,INTRODUCER NEEDLE(LIFE-O-MED)-ACCESSING A BLOOD VESSEL FOR PLACEMENT OF A GUIDE WIRE INTO CIRCULATORY SYSTEM,TRANSURETHRAL OF THE PROSTATE (TUR) SET(LIFE-O-MED)-USED FOR ENDOSCOPIC IRRIGATION DURING TRANS-URETHRAL RESECTION OF PROSTATE GLAND. ,INTRAVENOUS CANNULA (I.V. CANNULA)(LIFE-O-MED)-IT IS INSERTED INTO AN ARTERY COMMONLY THE REDIAL ARTERY AND IS USED DURING MAJOR OPERATIONS AND IN CRITICAL CARE AREAS TO MEASURE BEAT TO BEAT BLOOD PRESSURE AND TO DRAW REPEATED BLOOD SAMPLE.,NASAL CANNULA(LIFE-O-MED)-THE NASAL CANNULA (NC) IS A DEVICE USED TO DELIVER SUPPLEMENTALOXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,MEASURED VOLUME SET(LIFE-O-MED)-MEASURED VOLUME SET INDICATED FOR INTRAVENOUS, INTRA-ARTERIAL, ENTERAL, SUBCUTANEOUS AND EPIDURAL INFUSION OF MEDICATIONS OR FLUIDS REQUIRING CONTINUOUS DELIVERY AT CONTROLLED INFUSION RATES. IT IS ALSO INTENDED TO PROVIDE CONTINUOUS INFUSION OF A LOCAL ANESTHETIC DIRECTLY INTO THE INTRAOPERATIVE SITE FOR POSTOPERATIVE PAIN MANAGEMENT,IV CANNULA FIXATOR(LIFE-O-MED)-INTENDED TO PREVENT ACCIDENTAL DISPLACEMENT OF INTRAVENOUS CATHETERS AFTER PROPER ESTABLISHMENT OF INFUSION LINE ACCESS. ,FOGATI CATHETER(LIFE-O-MED)-IT IS INTENDED TO BE USED FOR TEMPORARY OCCLUSION IN THE PERIPHERAL VASCULAR SYSTEM.,TRACHEOTOMY TUBE(LIFE-O-MED)-THE DEVICE IS INTENDED TO BE USED TO PROVIDE AND ARTIFICIAL AIRWAY IN ORDER TO PROVIDE ACCESS TO THE PATIENT'S AIRWAY FOR AIRWAY MANAGEMENT. WHEN INSERTED IN A TRACHEOTOMY STOMA, THE DEVICE IS SECURED IN PLACE WITH A NECK STRAP AROUND THE PATIENT'S NECK WHICH IS ATTACHED TO AN INTEGRAL NECK PLATE. THEREBY PROVIDING FOR A SECURE ARTIFICIAL AIRWAY FOR SPONTANEOUS BREATHING OR DIRECT HOOK-UP TO VENTILATION OR ANESTHESIA EQUIPMENT. ,A V FISTULA NEEDLE(LIFE-O-MED)-USE FOR TEMPORARY CANNULATION FOR VASCULAR ACCESS FOR EXTRACORPOREAL BLOOD TREATMENT. THIS DEVICE IS INTENDED TO SINGLE USE ONLY AND IS FOR TEMPORARY CATHETERIZATION LESS THAN 30 DAYS. THE SAFETY FEATURE (FOLDABLE WING AND WING EATER) AIDS IN PREVENTION OF NEEDLESTICK INJURY WHEN REMOVING AND DISCARDING NEEDLE AFTER DIALYSIS SESSION., VENTILATOR KIT(LIFE-O-MED)-FOR THE CONTINUOUS OR INTERMITTENT MECHANICAL VENTILATORY SUPPORT OF PATIENTS WEIGHING AT LEAST 5 KG WHO REQUIRE MECHANICAL VENTILATION. THE VENTILATOR IS A RESTRICTED MEDICAL DEVICE INTENDED FOR USE BY QUALIFIED, TRAINED PERSONNEL UNDER THE DIRECTION OF

	A PHYSICIAN. ,EPIDURAL CATHETER KIT(LIFE-O-MED)-THE EPIDURAL CATHETER KIT IS USE UP TO 72 HOURS THE PROPOSED FLAT ANESTHESIA CONDUCTION FILTER IS SUBSTANTIALLY EQUIVALENT TO THE PREDICATE DEVICES WITH RESPECT TO INDICATIONS FOR USE.,NASOPHARYNGEAL AIRWAYS(LIFE-O-MED)-AN OROPHARYNGEAL AIRWAY (ORAL AIRWAY, OPA) IS AN AIRWAY ADJUNCT USED TO MAINTAIN OR OPEN THE AIRWAY BY STOPPING THE TONGUE FROM COVERING THE EPIGLOTTIS. IN THIS POSITION, THE TONGUE MAY PREVENT AN INDIVIDUAL FROM BREATHING. , SURGICAL GLOVES (EXAMINATION GLOVES)(LIFE-O-MED)-THE EXAMINATION GLOVES IS A DISPOSABLE DEVICES USE FOR MEDICAL AND DENTAL PURPOSE THAT IS WORN ON THE EXAMINER'S HAND TO PREVENT CONTAMINATION BETWEEN PATIENT AND EXAMINER., NEBULIZER MASK(LIFE-O-MED)-IT IS DEVICE USED TO ADMINISTER MEDICATIONS IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDERS,BOUGIE(LIFE-O-MED)-IT IS INTENDED FOR USE AS A CUTTING DEVICE DURING SURGICAL, PATHOLOGY AND MINOR MEDICAL PROCEDURES. IT IS INTENDED TO AID IN THE PROTECTION AGAINST ACCIDENTAL INJURIES DURING LOADING, PASSING, AND DISPOSAL.,TRACHEOTOMY TUBE(LIFE-O-MED)-THE DEVICE IS INTENDED TO BE USED TO PROVIDE AND ARTIFICIAL AIRWAY IN ORDER TO PROVIDE ACCESS TO THE PATIENT'S AIRWAY FOR AIRWAY MANAGEMENT.,CLOSE SUCTION SET (MINI VAC SET)(LIFE-O-MED)-IT IS DESIGNED TO CORRECT TO THE ENDOTRACHEAL TUBE OR TRACHEOTOMY TUBE OF THE PATIENT AND REMAINS IN PLACE UP TO 48 HOURS MUST BE RELAPSE AFTER 24 HOURS WHILE THE ANGLED CONNECTOR (ELBOW) MAY BE REPLACED.,REINFORCED ENDOTRACHEAL TUBE (CUFFED)(LIFE-O-MED)-THE REINFORCED ENDOTRACHEAL TUBES ARE INTENDED FOR AIRWAY MANAGEMENT BY NASAL OR ORAL INTUBATION OF THE TRACHEA. THEY ARE INTENDED FOR USE ON ADULT AND PEDIATRIC PATIENTS,MOUNT CATHETER(LIFE-O-MED)-IT IS CONNECTED BETWEEN THE PATIENT AND THE BREATHING SYSTEMS THE MOUNT CATHETER WITH DOUBLE SWIVEL CONNECTOR AND FLEXIBLE TUBING PROVIDE MOBILITY AND FLEXIBILITY TO THE PATIENT END OF THE CIRCUIT. THE CATHETER MOUNT IS USED AS AN INTERMEDIARY CONNECTION BETWEEN THE PATIENT AND THE BREATHING SYSTEM.,ABDOMINAL DRAINAGE CATHETER AND KIT(LIFE-O-MED)-IT IS USE IN POST OPERATIVE DRAINAGE FROM ABDOMINAL AREAS,SINGLE LUMEN DIALYSIS KIT (LIFE-O-MED)-IT IS INDICATED FOR USE IN ATTAINING SHORT-TERM OR LONGTERM VASCULAR ACCESS FOR HEMODIALYSIS, HEMOPERFUSION OR APHERESIS THERAPY. ACCESS IS ATTAINED VIA THE INTERNAL JUGULAR VEIN, EXTERNAL JUGULAR VEIN, SUBCLAVIAN VEIN, OR FEMORAL VEIN.,FEMORAL CATHETER(LIFE-O-

	MED)-IT IS USE TO DRAIN CENTRAL VENOUS BLOOD VIA THE FEMORAL VEIN DURING EXTRA CORPOREAL PROCEDURES FOR UP TO SIX HOURS.,GUIDE WIRE(LIFE-O-MED)-GUIDE WIRES THAT ARE USED FOR THE INTRODUCTION AND PLASMENT OF DIGNOSTIC AND PLACEMENT OF DIGNOSTIC OR INTERVENTIONAL DEVICES IN THE CORONARY AND PERIPLERAL VASCULATURE AND MANY BE USED TO REACH AND CROSS A TARGET LESION.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3223	MFG/MD/2019/000085	1.License Holder Name: PEHCHAN PHARMACEUTICALS AND SURGICALS LLP 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE NAIL (SEINSER/ACTOSE/ROOTSURE/JOIBIS)-BONE NAILS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMURS, FEMORAL SHAFT, TIBIA AND HUMOROUS.,BONE NAIL(SEINSER/ACTOSE/ROOTSURE/JOIBIS)-BONE IM NAILS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMURS, FEMORAL SHAFT, TIBIA AND HUMOROUS.,PINS & WIRES(SEINSER/ACTOSE/ROOTSURE/JOIBIS)-WIRES & PINS ARE INDICATED FOR USE IN FIXATION OF BONE FRACTURES, FOR BONE RECONSTRUCTION, FOR SKELETAL TRACTION IN ALIGNMENT OF LONG BONE FRACTURED SEGMENTS, AND AS GUIDE PINS & WIRES FOR INSERTION OF IMPLANTS AND THE PROTECTION OF FISSURES.,PINS & WIRES (SEINSER/ACTOSE/ROOTSURE/JOIBIS)-WIRES & PINS ARE INDICATED FOR USE IN FIXATION OF BONE FRACTURES, FOR BONE RECONSTRUCTION, FOR SKELETAL TRACTION IN ALIGNMENT OF LONG BONE FRACTURED SEGMENTS, AND AS GUIDE PINS & WIRES FOR INSERTION OF IMPLANTS AND THE PROTECTION OF FISSURES., SPINAL IMPLANTS(SEINSER/ACTOSE/ROOTSURE/JOIBIS)-SPINAL SYSTEM CONSISTS OF A VARIETY OF SHAPES AND SIZES OF RODS, SCREW, TRANSVERSE LINK AS WELL AS CAGES AND CERVICAL IMPLANTS. SCREW IS INTENDED FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF SPINAL BONES, AND FOR SCOLIOSIS. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS.,SPINAL IMPLANT(SEINSER/ACTOSE/ROOTSURE/JOIBIS)-SPINAL SYSTEM CONSISTS OF A VARIETY OF SHAPES AND SIZES OF RODS, SCREW, TRANSVERSE LINK AS WELL AS CAGES AND CERVICAL IMPLANTS. SCREW IS INTENDED FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF SPINAL BONES, AND FOR SCOLIOSIS. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS.,BONE SCREW (SEINSER/ACTOSE/ROOTSURE/JOIBIS)-THE BONE SCREW IS INTENDED FOR INTERNAL FIXATION OF FRACTURES AND

	RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, DISTAL, TIBIA, FIBULA, HAND AND FOOT IN ADULTS AND FOR LONG BONES IN ADOLESCENTS IN WHOM THE GROWTH PLATES ARE FUSED. IT CAN BE USED WITH OR WITHOUT THE PLATES.,BONE SCREW (SEINSER/ACTOSE/ROOTSURE/JOIBIS)-THE BONE SCREW IS INTENDED FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, DISTAL, TIBIA, FIBULA, HAND AND FOOT IN ADULTS AND FOR LONG BONES IN ADOLESCENTS IN WHOM THE GROWTH PLATES ARE FUSED. IT CAN BE USED WITH OR WITHOUT THE PLATES.,BONE PLATE (SEINSER/ACTOSE/ROOTSURE/JOIBIS)-THE BONE PLATE IS INTENDED FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, DISTAL, TIBIA, FIBULA, HAND AND FOOT IN ADULTS AND FOR LONG BONES IN ADOLESCENTS IN WHOM THE GROWTH PLATES ARE FUSED,BONE PLATE(SEINSER/ACTOSE/ROOTSURE/JOIBIS)-THE BONE PLATE IS INTENDED FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, DISTAL, TIBIA, FIBULA, HAND AND FOOT IN ADULTS AND FOR LONG BONES IN ADOLESCENTS IN WHOM THE GROWTH PLATES ARE FUSED

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3224	MFG/MD/2019/000086	1.License Holder Name: POLY MEDICURE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:SAFETY I V CANNULA WITH 3 WAY STOP COCK (TRO-VENSITE 3+ SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA - THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES, SAFETY ARTERIAL CANNULA (KD-ARTERIA SAFETY)-INSERTED INTO AN ARTERY, COMMONLY THE RADIAL ARTERY, AND IS USED DURING MAJOR OPERATIONS AND IN CRITICAL CARE AREAS TO MEASURE BEAT-TO-BEAT BLOOD PRESSURE AND TO DRAW REPEATED BLOOD SAMPLES. ,IV CANNULA WITH EXTENSION TUBE-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA WITH INJECTION PORT & WINGS(ULTRA IP)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT FOR QUICK FLASHBACK(POLYCAN SAFETY ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA (POLYFLON-PRO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITHOUT INJECTION PORT & WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITHOUT INJECTION PORT & WITH SMALL WINGS (NEONOVO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., SAFETY I.V. CANNULA (Q-FLOW SAFETY I.V. CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA (SENSIMEDICAL I.V. CANNULA CATETER INTRAVENOSO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE

	THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS FOR QUICK FLASHBACK(POLYFLEX ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,MINI MID LINES-OVER THE WIRE (POLYLEAD OVER THE WIRE)-CATHETERS CAN BE PLACED IN VEINS IN THE NECK (INTERNAL JUGULAR VEIN),CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN),I.V. CANNULA WITHOUT INJECTION PORT & WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,IV CANNULA WITHOUT PORT& WITHOUT WINGS (VITROPEN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITHOUT PORT & WITHOUT WINGS FOR QUICK FLASHBACK(POLYPEN ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., SAFETY IV CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS (SENTRAWIN SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITHOUT INJECTION PORT & WINGS FOR QUICK FLASHBACK(POLYWIN SAFETY ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT INJECTION PORT & WITH SMALL WINGS FOR QUICK FLASHBACK(NEONOVO ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT INJECTION PORT & WINGS FOR QUICK FLASHBACK(POLYON ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS(EUROMIX CATETER I.V. SIN PUERTO Y SIN ALAS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITHOUT INJECTION PORT & WINGS FOR QUICK FLASHBACK(POLYWIN ADVA)-THE IV CANNULA IS A

	PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT INJECTION PORT WITHOUT WINGS(TRO-VENSITE SAFETY PEN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK FOR QUICK FLASHBACK (POLYCATH ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V CANNULA WITHOUT INJECTION PORT.(SENTRACAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITH EXTENSION TUBE-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,IV CANNULA WITHOUT INJECTION PORT AND WITHOUT WINGS(IDEALCARE I.V. CATHETER WITHOUT PORT AND WITHOUT WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA (POLYWIN PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV CANNULA WITH SMALL WING & WITHOUT INJECTION PORT(EASY-CATH W NEO FEP)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH WINGS, WITHOUT INJECTION PORT FOR QUICK FLASHBACK(POLYCAN ADVA) -THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., SAFETY I.V. CANNULA (NUOVOWIN SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA -THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA WITH INJECTION PORT & WINGS(INTRAVENOUS (IV) CANNULA WITH

	INJECTION PORT, PREMIUM, PUR, “ALEXPHARM”)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA (RAMYFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV CANNULA WITH INJECTION PORT AND WINGS (IDEALCARE I.V. CATHETER WITH INJECTION VALVE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CANNULA WITHOUT INJECTION PORT & WITH WINGS(SENTRACAN SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITH EXTENSION TUBE(NOUVO SAFETY SET)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT(NEO VENOPIC 1)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITHOUT INJECTION PORT AND WITH SMALL WINGS(POLYNEO PLUS) -THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., SAFETY IV CANNULA WITH PORT & WITH WINGS WITH BLOOD CONTROL VALVE(POLYSAFETY - BC)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS FOR QUICK FLASHBACK (POLY SAFETY ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INJECTION PORT & WINGS (ELITE HOLDINGS I.V. CANNULA WITH INJECTION PORT & WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF

	FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,ARTERIAL CANNULA WITH OR WITHOUT SAFETY FEATURE-INSERTED INTO AN ARTERY, COMMONLY THE RADIAL ARTERY, AND IS USED DURING MAJOR OPERATIONS AND IN CRITICAL CARE AREAS TO MEASURE BEAT-TO-BEAT BLOOD PRESSURE AND TO DRAW REPEATED BLOOD SAMPLES. ,I.V. CANNULA WITH INJECTION PORT(TRO-VENSITE SAFETY PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT, SNAPFIT CAP & SUTURABLE WNGS. (SAFETY I.V.CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT(CHIRAFLEX I.V. CANNULA WITHOUT INJECTION PORT)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , SAFETY IV CANNULA WITH FLEXIBLE WINGS(POLYCAN PLUS SAFETY) -THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV CANNULA WITH 3-WAY STOP COCK(SENTRACATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,ARTERIAL CANNULA (ART-CAN)-INSERTED INTO AN ARTERY, COMMONLY THE RADIAL ARTERY, AND IS USED DURING MAJOR OPERATIONS AND IN CRITICAL CARE AREAS TO MEASURE BEAT-TO-BEAT BLOOD PRESSURE AND TO DRAW REPEATED BLOOD SAMPLES. ,SAFETY IV CANNULA WITH WINGS AND WITHOUT INJECTION PORT(SENTRACAN SAFE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INTEGRATED 3-WAY STOP COCK.-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,SAFETY IV CANNULA WITH INJECTION PORT, SNAP FIT CAP & SUTURABLE WINGS(SENTRAFLEX SAFE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE

	WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,MINI MID LINES-OVER THE WIRE-CATHETERS CAN BE PLACED IN VEINS IN THE NECK (INTERNAL JUGULAR VEIN),CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN),SAFETY I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK FOR QUICK FLASHBACK(POLYCATH SAFETY ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS (NEO VENOPIC 2)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITHOUT INJECTION PORT & WITH SMALL WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY IV CANNULA WITH INJECTION PORT & SUTURABLE WINGS(SENTRAFLEX SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT & WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH WINGS & WITHOUT INJECTION PORT(POLYCAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY I.V. CANNULA WITHOUT INJECTION PORT & WINGS FOR QUICK FLASHBACK(POLYPEN SAFETY ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH WINGS & WITHOUT INJECTION PORT (INTRAVENOUS (IV) CANNULA WITHOUT INJECTION PORT, “ALEXPHARM”)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH FLEXIBLE WINGS (POLYCAN PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INTEGRATED 3-WAY STOP

	COCK.(TRO-VENOCATH 3+)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INJECTION PORT & WINGS(JACTERMAC I.V. CANNULA WITH INJECTION PORT & WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITH EXTENSION TUBE(Q-FLOW SAFETY CLOSED I.V. CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,CLOSE WOUND SUCTION UNIT(POLYVAC SET)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS. ,HIGH PRESSURE VACUUM DRAINAGE BOTTLE WITH EXTENSION TUBE (SAFETY-VAC)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,I.V. CANNULA WITHOUT INJECTION PORT (TRO-VENOCATH 2 SINE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA (SANVIFLON PREMIUM)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITH WING WITHOUT PORT (BODYCAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITH INJECTION PORT AND WINGS(KD-FIX QUICK)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA (POLYFLEX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SPINAL NEEDLE-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM,

	SAFETY I.V. CANNULA (NUOVOFLEX SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,BLOOD COLLECTION NEEDLE-"INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD. ",IV CANNULA WITH INJECTION PORT AND WITH WINGS(IDEALCARE I.V. CATHETER WITH INJECTION VALVE (QUICK FLESH BACK))-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA (SANVIFLON SAFE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,MINI MID LINES OVER THE NEEDLE (POLYLEAD OVER THE NEEDLE)-CATHETERS CAN BE PLACED IN VEINS IN THE NECK (INTERNAL JUGULAR VEIN),CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN), ,SAFETY I.V. CANNULA WITHOUT PORT & WITH SUTURABLE WINGS(POLYWIN-PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV CANNULA WITH INJECTION PORT AND WINGS(IDEALCARE I.V. CATHETER WITH INJECTION PORT AND WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,HAEMODIALYSIS CATHETER KIT(HAEMOCENT)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT.,IV CANNULA (CATETER PERIFERICO IV DESCARPACK)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,INFUSION SET WITH THREE WAY STOP COCK -INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,IV CANNULA WITH QUICK FLASH BACK (ADVA DISPOSITIVO SEGURANCA CATETER PARA INFUSAO INTRAVENOSA DE USO PERIFERICO SOBRE AGULHA COM DISPOSITIVO DE SEGURANCA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,VIAL ACCESS SPIKE (VIAL ADAPTER)(CHIRAPLUS) -THE PRODUCT IS USED TO STEADY REPEATED WITHDRAWALS & INJECTION. THE PRODUCT IS DESIGNED TO BE USED TO TRANSFER MEDICATION FROM A VIAL TO A SYRINGE AND FROM SYRINGE TO

	VIAL.,I. V. CANNULA(MOP-VASCUFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,THREE WAY STOPCOCK WITH EXTENSION TUBE-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING., I.V. CANNULA WITH INJECTION PORT & WINGS(INTRAVENOUS (IV) CANNULA WITH INJECTION PORT, SUPER PREMIUM, PUR QUICK FLASHBACK, “ALEXPHARM”)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY IV CANNULA WITH INJECTION PORT, SNAPFIT CAP & SUTURABLE WINGS(KD-FIX SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT INJECTION PORT & WINGS(POLYWIN - 2)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,VIAL ACCESS SPIKE (VIAL ADAPTER)(POLYSPIKE)-THE PRODUCT IS USED TO STEADY REPEATED WITHDRAWALS & INJECTION. THE PRODUCT IS DESIGNED TO BE USED TO TRANSFER MEDICATION FROM A VIAL TO A SYRINGE AND FROM SYRINGE TO VIAL.,I.V. CANNULA WITHOUT INJECTION PORT AND WITHOUT WINGS(HEUER I.V. CANNULA WITHOUT INJECTION PORT AND WITHOUT WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,THREE WAY STOP COCK -IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,IV CANNULA WITH SMALL WING & WITHOUT PORT (SENTRANEO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CANNULA WITH WINGS & WITHOUT INJECTION PORT(KD-FIX MONO SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I. V. CANNULA (REMEDI FLASHBACK I. V. CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT

	OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA(POLYMED I.V. CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES, SAFETY I.V. CANNULA WITHOUT INJECTION PORT & WINGS (CHIRAFLEX WIN SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CANNULA WITHOUT PORT & WINGS WITH BLOOD CONTROL VALVE(POLYSAFETY - BC)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV CANNULA (LABOR IMPORT CATHETER DE SEGURANCA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA (SANVIFLON SAFE ECO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT(POLYCAN IP)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV CANNULA WITH INJECTION PORT AND WINGS.(KD-FIX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS(TRO-VENOCATH NOVO PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , SAFETY I.V. CANNULA(KD FIX SAFETY SOLOPEN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT INJECTION PORT AND WITHOUT WINGS(TRO-VENSITE SAFETY SINE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA (SANVIFLON PREMIUM S)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA (LIFEN I.V. CANNULA)-

	THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , ENDOTRACHEAL TUBE-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS ,I.V. CANNULA WITHOUT INJECTION PORT & WINGS(I.V. PLACEMENT UNIT WITHOUT FIXATION WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA (SANVIFLON N)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITHOUT INJECTION PORT & WITH SMALL WINGS(POLYNEO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA(KD FIX SOLOPEN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY IV CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS(EASY-PEN SAFETY FEP)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,FOLEY BALLOON CATHETER (POLYMED FOLEY BALLOON CATHETER)-THE PRODUCT IS USED FOR DRAINAGE, CLEANING, HAEMOSTATIC AND MEDICINE INJECTION FOR THE URINARY SYSTEM OF THE PATIENTS.,SAFETY IV CANNULA (POLY GUARD)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , SAFETY IV CANNULA WITH INJECTION PORT(POLYSAFETY PRO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I V CANNULA (NOUVOFLEX ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,INFUSION SET WITH THREE WAY STOP COCK (POLYFUSION SET WITH THREE WAY STOP COCK)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,I.V. CANNULA (POLYPEN - 2)-THE IV CANNULA IS A PASSIVE DEVICE TO

	PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,EXTENSION LINE HIGH PRESSURE STRAIGHT - PVC FREE(POLYMED HIGH PRESSURE EXTENSION LINE STRAIGHT-PVC FREE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION O FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,IV CANNULA WITH INTEGRATED THREE WAY STOP COCK(VITROCATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA (SANVIFLON PREMIUM N)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV CANNULA WITHOUT PORT & WITH SMALL WINGS (VITRONEO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. INFUSION SET (DISPOSABLE PERFUSION SET)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,I.V. CANNULA WITHOUT INJECTION PORT, SNAP FIT CAP & SUTURABLE WINGS(HEUER I.V. CANNULA WITHOUT INJECTION PORT, SNAP FIT CAP & SUTURABLE WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,HIGH PRESSURE VACUUM DRAINAGE BOTTLE WITH EXTENSION TUBE (ULTRAVAK SET)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,SAFETY IV CANNULA WITH INJECTION PORT & WINGS(EASY-PORT SAFETY PUR)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,HIGH PRESSURE VACUUM DRAINAGE BOTTLE WITH EXTENSION TUBE-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,IV CANNULA WITHOUT PORT & WITH SMALL WINGS(VITROPEDIA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,EXTENSION LINE (LOW PRESSURE & HIGH PRESSURE LINE)-EXTENSION SETS ARE STERILE

	DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION O FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,I.V. CANNULA WITHOUT INJECTION PORT & WINGS(KRUUSE SAFEVET PENCIL STYLE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,EXTENSION LINE (HIGH PRESSURE COILED - PVC FREE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION O FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,SAFETY IV CANNULA WITH INJECTION PORT & WINGS (EASY-PORT SAFETY FEP)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,EXTENSION LINE (HIGH PRESSURE STRAIGHT - PVC FREE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION O FLUIDS/MEDICATIONS IN MEDICAL APPLICATION., SAFETY IV CANNULA WITHOUT INJECTION PORT& WITHOUT WINGS (EASY-PEN SAFETY PUR)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,BLOOD COLLECTION NEEDLE(HAEMOFLASH)-INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD. ,ENDOTRACHEAL TUBE (VITROMED)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS. , EXTENSION LINE (HIGH PRESSURE COILED - PVC FREE)(POLYMED HIGH PRESSURE EXTENSION LINE COILED-PVC FREE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION O FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,IV CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS(EASY-PEN FEP)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SPINAL NEEDLE (HEUER SPINAL NEEDLE)-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM,IV CANNULA WITH WING & WITHOUT INJECTION PORT(EASY-CATH W PUR)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SPINAL NEEDLE(VITROMED)-USED

	FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM, SAFETY IV CANNULA WITH WING & WITHOUT INJECTION PORT(EASY-CATH W SAFETY PUR)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,EXTENSION LINE (LOW PRESSURE & HIGH PRESSURE LINE)(POLYMED EXTENSION TUBE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION O FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,I V CANNULA WITH EXTENSION TUBE(KRUUSE SAFEVET IV COMBI SET)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SPINAL NEEDLE (POLYMED SPINAL NEEDLE)-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM,IV CANNULA WITH INJECTION PORT & WINGS(VITROFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA (SANVIFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CANNULA WITH WING & WITHOUT INJECTION PORT(EASY-CATH W SAFETY FEP)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITH WINGS WITHOUT INJECTION PORT(KD-FIX MONO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV CANNULA WITH INJECTION PORT & WINGS(EASY-PORT FEP)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,MANIFOLD -PRODUCT IS USED TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM. MANIFOLDS ARE USED IN ANGIOPLASTY PROCEDURES IN WHICH FLUIDS ARE ADMINISTERED UNDER PRESSURE,I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT (HEUER I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE

	THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CANNULA(POLY GUARD BC)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS(EASY-CATH SAFETY PUR)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CANNULA (SENSIMEDICAL CATETER PERIFERICO DE SEGURIDAD)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV CANNULA WITH INJECTION PORT(KRUUSE SAFEVET INFUVEIN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS(POLY SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., SAFETY IV CANNULA(SENTRA NEO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITHOUT INJECTION PORT & WINGS(POLYWIN SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,PERIPHERAL I.V. CATHETER WITH PORT WINGS(SF VENOX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,ENDOTRACHEAL TUBE(POLYMED ENDOTRACHEAL TUBE)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,IV CANNULA (EXEFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , SAFETY IV CANNULA WITHOUT INJECTION PORT AND WINGS(KD-FIX SAFETY SOLO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY I.V. CANNULA WITHOUT INJECTION PORT &

	WINGS(POLYWIN – 2 SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITH SPRING (POLYSHIELD) -THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH WINGS, WITHOUT INJECTION PORT(TRO-VENOCATH NOVO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I V CANNULA WITH EXTENSION TUBE (KD-FIX SAFESET)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I V CANNULA WITHOUT INJECTION PORT. (TRO-VENOCATH NEO PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,THREE WAY STOPCOCK WITH EXTENSION LINE(UNIWAYS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,I.V. CANNULA WITH EXTENSION TUBE (TRO VENOCATH FLEX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT & WINGS (P & Q DISPOSABLE I.V. CANNULA WITH INJECTION PORT & WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA (EXEWIN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA (SEBIS I.V. CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT, SNAPFIT CAP & SUTURABLE WINGS(TRO-VENOCATH PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITHOUT INJECTION PORT AND WINGS(KD-FIX QUICK SOLO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF

	FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,HAEMODIALYSIS CATHETER KIT(EXELINT HAEMODIALYSIS CATHETER KIT)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT. ,SAFETY I.V. CANNULA WITH WINGS, WITHOUT INJECTION PORT(POLYCAN SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , HAEMODIALYSIS CATHETER KIT(HAEMOCENT PRO)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT.,VIAL ACCESS SPIKE (VIAL ADAPTER)-THE PRODUCT IS USED TO STEADY REPEATED WITHDRAWALS & INJECTION. THE PRODUCT IS DESIGNED TO BE USED TO TRANSFER MEDICATION FROM A VIAL TO A SYRINGE AND FROM SYRINGE TO VIAL.,IV CANNULA(CATETER PARA INFUSAO INTRAVENOSA DE USO PERIFERICO SOBRE AGULHA COM DISPOSITIVO DE SEGURANCA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,FOLEY BALLOON CATHETERS-THE PRODUCT IS USED FOR DRAINAGE, CLEANING, HAEMOSTATIC AND MEDICINE INJECTION FOR THE URINARY SYSTEM OF THE PATIENTS.,I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS (CHIRAFLEX I.V. CANNULA WITH PORT SNAPFIT CAP & SUTURABLE WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SCALP VEIN SET-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD. ,IV CANNULA WITH QUICK FLASH BACK (ADVA CATETER PARA INFUSAO INTRAVENOSA DE USO PERIFERICO SOBRE AGULHA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,HAEMODIALYSIS CATHETER KIT-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT. ,I.V. CANNULA WITH INJECTION PORT WINGS(MEDMAX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITH WINGS WITHOUT INJECTION PORT(KD-FIX QUICK MONO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD

	COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT INJECTION PORT & WINGS (POLYON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA (SANVIFLON S)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS(VENOPIC 2 SMARTSAFE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA (POLYCAN IP)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA (NUOVOFLEX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SPINAL NEEDLE(SENSIMEDICAL)-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM,I.V. CANNULA WITHOUT INJECTION PORT AND WITH SMALLER WINGS(HEUER I.V. CANNULA WITHOUT INJECTION PORT AND WITH SMALLER WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,THREE WAY STOPCOCK WITH EXTENSION TUBE(POLYMED THREE WAY STOPCOCK WITH EXTENSION TUBE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, IV CANNULA WITH INJECTION PORT & WINGS(EASY-PORT PUR)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITHOUT INJECTION PORT & WINGS(POLYPEN SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., ENDOTRACHEAL TUBE(EXELINT ENDOTRACHEAL TUBE)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS. ,I V CANNULA WITH 4 WAY STOP COCK

	(POLYCATH ADVA (PORT))-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,SAFETY I.V CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS(HEUER SAFETY I V CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , SPINAL NEEDLE(EXELINT)-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM,I.V. CANNULA(VIAPEN VET)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITHOUT INJECTION PORT AND WINGS(KD-FIX SOLO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT(TRO-VENOCATH 2 RAPID FLASH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , THREE WAY STOP COCK(POLYWAY, POLYWAY-PRO)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,IV CANNULA WITHOUT INJECTION PORT & WINGS(VITRO ON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,VIAL ACCESS SPIKE (VIAL ADAPTER) (ASIDSPIKE)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL.,I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK(HEUER I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITHOUT INJECTION PORT & WITH SUTURABLE WINGS FOR QIUCK FLASHBACK (POLYWIN PLUS SAFETY ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY PERIPHERAL I.V. CATHETER WITH PORT SNAPFIT CAP AND WINGS(SF VENOX)-THE IV CANNULA IS

	A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I V CANNULA(PETIT FLO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., SAFETY ARTERIAL CANNULA (ART-CAN SAFETY)-INSERTED INTO AN ARTERY, COMMONLY THE RADIAL ARTERY, AND IS USED DURING MAJOR OPERATIONS AND IN CRITICAL CARE AREAS TO MEASURE BEAT-TO-BEAT BLOOD PRESSURE AND TO DRAW REPEATED BLOOD SAMPLES. ,SAFETY I.V. CANNULA (SANVIFLON SAFE S)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV CANNULA WITH SMALL WING & WITHOUT PORT(SENTRANOVO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CANNULA WITHOUT INJECTION PORT& WINGS (VITROWIN SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,HIGH PRESSURE VACUUM DRAINAGE BOTTLE WITH/WITHOUT EXTENSION TUBE-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,SAFETY SCALP VEIN SET-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD., SAFETY IV CANNULA WITHOUT PORT WITHOUT WINGS(SENTRAPEN SAFE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , SAFETY I.V. CANNULA (SANVIFLON SAFE N)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,MINI MID LINES OVER THE NEEDLE - CATHETERS CAN BE PLACED IN VEINS IN THE NECK (INTERNAL JUGULAR VEIN),CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN), SAFETY IV CATHETER WITH SPRING WITH BLOOD CONTROL (POLYSHIELD-BC ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT & WINGS

	(BEROCAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , MID LINE CATHETERS (HEALTH-MID)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE . ,IV CANNULA (KRUUSE SAFEVET VENOCAN MINI)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CATHETER(POLYGUARD+ ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS(EASY-CATH FEP)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,MINI MID LINES OVER THE NEEDLE CATHETER (POLYLEAD OVER THE NEEDLE CATHETER)-CATHETERS CAN BE PLACED IN VEINS IN THE NECK (INTERNAL JUGULAR VEIN),CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN).,SAFETY IV CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS(EASY-CATH SAFETY FEP)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I. V. CANNULA (INTRAVENOUS (IV) CANNULA WITH INJECTION PORT, STANDARD, "ANGEL CARE")-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT & WINGS(TRO-VENOCATH 2 PLUS RAPID FLASH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT & WINGS(KILANI I V CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT & WINGS(POLYFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CATHETER(POLYGUARD) -THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO

	FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA(HOSPITECH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CANNULA WITHOUT PORT& WITHOUT WINGS (VITROPEN SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITHOUT PORT AND WITHOUT WINGS (VITROWIN-SAFE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,PERIPHERALLY INSERTED CENTRAL CATHETER (PICC)-INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD, AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTIONS OR DRUGS.,IV CANNULA WITH PORT & SUTURABLE WINGS(VITROFLEX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY IV CATHETER WITH SPRING (POLYSHIELD ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS(EASY-CATH PUR)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY IV CATHETER-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I V CANNULA WITH PORT & WITH WINGS(TRO-VENOCATH Y FLEX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CATHETER WITH SPRING WITH BLOOD CONTROL(POLYSHIELD BC)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CANNULA WITH INJECTION PORT(VITROSAFE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I V CANNULA WITH INJECTION PORT & WINGS (SPRUKFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE

	FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS (CHIRAFLEX FLEX SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CATHETER WITH SPRING (POLYSHIELD)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,DOG CATHETER -A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY. ,SAFETY I.V. CANNULA(ALFASAFE CATHETER INTRAVENOSO DE SEGURIDAD)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,GASTROSCOPIC FLUSHING CATHETER(FIONAVET)-INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS. ,SAFETY IV CATHETER WITH BLOOD CONTROL (POLYGUARD BC)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,ENDOSCOPE FLUSHING CATHETER(FIONAVET)-INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS.,I.V. CANNULA WITH INJECTION PORT & WINGS(NARFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,GASTROSCOPIC FLUSHING CATHETER-INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS. ,I.V. CANNULA WITH WINGS & WITHOUT INJECTION PORT(POLYCAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,VIAL ACCESS SPIKE (VIAL ADAPTER)(POLYSPIKE PLUS)-THE PRODUCT IS USED TO STEADY REPEATED WITHDRAWALS & INJECTION. THE PRODUCT IS DESIGNED TO BE USED TO TRANSFER MEDICATION FROM A VIAL TO A SYRINGE AND FROM SYRINGE TO VIAL.,I.V. CANNULA WITH WINGS &

	WITHOUT INJECTION PORT(POLYWIN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,ENDOSCOPE FLUSHING CATHETER-INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS.,SAFETY I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK (POLYCATH SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT & WINGS(LYDIAFLON PRO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,VIAL ACCESS SPIKE (VIAL ADAPTER)(WITHDRAWAL CANNULA)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL. , IV CANNULA(JELCO SERIVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA (PERIPHERAL IV CATHETER)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT & WINGS(SFM IV CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I V CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS FOR QUICK FLASH BACK (CANNULA INFUSION VENOPORT PLUS DISPOSABLE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,CAT CATHETER-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,VIAL ACCESS SPIKE (VIAL ADAPTER)(KD-SPIKE)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL. ,I. V. CANNULA WITHOUT INJECTION PORT & WINGS(TRO-VENOCATH 2 SINE RAPID FLASH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR

	ACCESS DEVICES. ,SAFETY I V CANNULA WITH EXTENSION TUBE(U-FLEX PLUS PERIPHERAL VENOUS CANNULA WITH SECURITY SYSTEM, 2 LUER LOCK CONNECTORS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITHOUT INJECTION PORT WITH WINGS(TRO-VENSITE SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I V CANNULA WITH EXTENSION TUBE(U-FLEX PLUS PERIPHERAL VENOUS CANNULA WITH SECURITY SYSTEM, 1NEEDLELESS LUER LOCK CONNECTOR)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , I.V. CANNULA WITH INJECTION PORT & WINGS(HEUER I.V. CANNULA WITH INJECTION PORT & WINGS) -THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA (EASY FLOW)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITHOUT INJECTION PORT & WINGS (CHIRAFLEX WIN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT(NARCAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT(CHIRAFLEX CAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I V CANNULA WITH EXTENSION TUBE(U-FLEX PLUS PERIPHERAL VENOUS CANNULA WITH SECURITY SYSTEM, 2 NEEDLELESS LUER LOCK CONNECTORS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITH WINGS WITHOUT INJECTION PORT(VITROCAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,MID LINE CATHETERS -A CATHETER THAT IS

	INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE . ,IV CANNULA WITHOUT INJECTION PORT& WINGS (VITROWIN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CATHETER WITH BLOOD CONTROL(POLYGUARD-BC ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT(VENOPIC 1 SMARTSAFE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY IV CANNULA WITH WINGS WITHOUT INJECTION PORT(VITROCAN SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INJECTION PORT & WINGS(SUMITEX® CATETER PARE VENOCLISIS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CATHETER(POLYGUARD+)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY ARTERIAL CANNULA(TRO-ARTEROCATH SAFETY)-INSERTED INTO AN ARTERY, COMMONLY THE RADIAL ARTERY, AND IS USED DURING MAJOR OPERATIONS AND IN CRITICAL CARE AREAS TO MEASURE BEAT-TO-BEAT BLOOD PRESSURE AND TO DRAW REPEATED BLOOD SAMPLES. ,GUIDE WIRE-THE GUIDE CATHETER PROVIDES SUPPORT FOR DEVICE ADVANCEMENT . ,I.V. CANNULA WITHOUT INJECTION PORT WITH WINGS(TRO-VENOCATH NEO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,VIAL ACCESS SPIKE (VIAL ADAPTER)(POLYSPIKE V PLUS)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL. ,IV CANNULA (CATETER PARA INFUSAO INTRAVENOSA DE USO PERIFERICO SOBRE AGULHA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I. V. CANNULA

	WITH INJECTION PORT & WINGS (MASTER)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITHOUT INJECTION PORT & WINGS(TRO-VENOCATH SINE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CANNULA WITH PORT & WITH WINGS WITH BLOOD CONTROL VALVE(POLYSAFETY – BC PORT) -THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITH WING & WITHOUT INJECTION PORT(EASY-CATH W FEP)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,MINI MID LINES OVER THE NEEDLE CATHETER -CATHETERS CAN BE PLACED IN VEINS IN THE NECK (INTERNAL JUGULAR VEIN),CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN),I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT(POLYCAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SAFETY IV CANNULA WITH PORT & SUTURABLE WINGS(VITROFLEX SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITH INJECTION PORT & WINGS(MOP-VASUFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I V CANNULA WITH EXTENSION TUBE(U-FLEX PLUS PERIPHERAL VENOUS CANNULA WITH SECURITY SYSTEM, 1 LUER LOCK CONNECTOR)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH WINGS, WITHOUT INJECTION PORT(TRO-VENOCATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CANNULA WITH INTEGRATED THREE WAY STOP COCK(VITROCATH SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA (NOKAST I.V.

	CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , SAFETY IV CANNULA WITHOUT INJECTION PORT & WITH WINGS WITH QUICK FLASHBACK (SENTRACAN SAFETY ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITHOUT INJECTION PORT & WINGS(TRO-VENOCATH NOVO SINE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., SAFETY IV CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS WITH QUICK FLASHBACK (SENTRAWIN SAFETY ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA (BLUER IV CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,MINI MIDLINES CATHETER (PERIPHERAL CATHETER)-CATHETERS CAN BE PLACED IN VEINS IN THE NECK (INTERNAL JUGULAR VEIN),CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN). ,ARTERIAL CANNULA(TRO-ARTEROCATH)-INSERTED INTO AN ARTERY, COMMONLY THE RADIAL ARTERY, AND IS USED DURING MAJOR OPERATIONS AND IN CRITICAL CARE AREAS TO MEASURE BEAT-TO-BEAT BLOOD PRESSURE AND TO DRAW REPEATED BLOOD SAMPLES. ,I. V. CANNULA (INTRAVENOUS (IV) CANNULA WITH INJECTION PORT,PREMIUM,PUR, "ANGEL CARE")-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT(TRO-VENOCATH 2)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY ARTERIAL CANNULA (CHIRAFLEX SAFETY ARTERIAL CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS(IVIVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA

	(SOFT PACK IV CATHETER)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS (TRO-VENOSITE SAFETY PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,VIAL ACCESS SPIKE (VIAL ADAPTER)(DICOSPIKE)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL. ,IV CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS(EASY-PEN PUR)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , TRACHEOSTOMY TUBE-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION ,I.V. CANNULA WITH INJECTION PORT & WINGS(HEUER I.V. CANNULA WITH INJECTION PORT & WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY IV CANNULA WITH INJECTION PORT & SUTURABLE WINGS WITH QUICK FLASHBACK (SENTRAFLEX SAFETY ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA (NOUVO WIN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,DOG URINARY CATHETER (CURAVET DOG URINARY CATHETER)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA ANDBLADDER OR POST ERIORLY VIA THE KIDNEY. ,I.V. CANNULA WITHOUT INJECTION PORT & WINGS(TRO-VENOCATH PEN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,ENDOSCOPE FLUSHING CATHETER (EQUIVET)-INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS. ,IV CANNULA (CATETER PERIFERICO IV COM DISPOSITIVO DE SEGURANCA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD

	COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,MINI MIDLINES CATHETER (PERIPHERAL CATHETER)(POLYLEAD)-CATHETERS CAN BE PLACED IN VEINS IN THE NECK (INTERNAL JUGULAR VEIN),CHEST (SUBCLAVIAN VEIN OR AUXILIARY VEIN). ,CLOSE WOUND SUCTION UNIT(NEOVAC SET)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS. ,I. V. CANNULA (INTRAVENOUS (IV) CANNULA WITH INJECTION PORT, SUPER PREMIUM,PUR QUICK FLASHBACK, "ANGEL CARE")-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT(CHIRAFLEX CAN SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,DOG URINARY CATHETER -A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA ANDBLADDER OR POST ERIORLY VIA THE KIDNEY. ,I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT (HEUER I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA PLUS WITH INJECTION VALVE & RADIOPAQUE CATHETER (HOSPITECH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT & WINGS(I.V. PLACEMENT UNIT WITH PORT & WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA(ALFASAFE CATETER INTRAVENOSO) -THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,VIAL ACCESS SPIKE (VIAL ADAPTER)(KRUUSE SAFEVET SPIKE)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL.,SAFETY I.V. CANNULA (PANACAN SAFETY I.V. CANNULA WITH WINGS AND PORT)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF

	VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS (TRO-VENOSITE SAFETY NONO PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK(TRO-VENOFLOW 3 PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS (CHIRAFLEX I.V. CANNULA SAFETY WITH PORT SNAPFIT CAP & SUTURABLE WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS(CHIRAFLEX I.V. CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA (NOUVO FLEX ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I V CANNULA WITH EXTENSION TUBE (CLOSED SYSTEM)(ADVA PLUS CATETER DE SEGURANÇA INTROVENOSO (I.V) DE USO PERIFÉRICO SOBRE AGULHA SISTEMA FECHADO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I V CANNULA (PETIT FLO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., SPINAL NEEDLE (NEEDLE FOR SPINAL ANESTHESIA SHARPENING TYPE OF QUINCKE, PREMIUM, “ALEXPHARM”)-AN ANAESTHESIA CONDUCTION NEEDLE IS A DEVICE USED TO INJECT LOCAL ANAESTHETICS INTO A PATIENT TO PROVIDE REGIONAL ANAESTHESIA ,PERIPHERAL I.V. CATHETER WITH PORT SNAPFIT CAP AND WINGS(SF VENOX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,ARTERIAL CANNULA (KD-ARTERIA)-INSERTED INTO AN ARTERY, COMMONLY THE RADIAL ARTERY, AND IS USED DURING MAJOR OPERATIONS AND IN CRITICAL CARE AREAS TO MEASURE BEAT-TO-BEAT BLOOD PRESSURE AND TO DRAW

	REPEATED BLOOD SAMPLES. ,I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS (CHIRAFLEX FLEX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I V CANNULA (EQUINE IV CATHETER)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK(POLYCATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V.CANNULA(ESKAMED)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS(TRO-VENOCATH 2 PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I V CANNULA WITH INJECTION PORT. (ACTI-FINE I V CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,CLOSE WOUND SUCTION UNIT(NOVOVAC SET)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS. ,SAFETY I V CANNULA(NOUVO PROTEKT)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I. V. CANNULA (MOP-VASCUPUR)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA (EXEFLEX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITH INJECTION PORT (IVENA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , SAFETY IV CANNULA(SENTRA NEO PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT

	OF VASCULAR ACCESS DEVICES. ,IV CANNULA (LABOR IMPORT CATETER PARA INFUSAO INTRAVENOSA FEP)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,VIAL ACCESS SPIKE (VIAL ADAPTER) (MULTI DOSE VIAL ADAPTER)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL.,VIAL ACCESS SPIKE (VIAL ADAPTER) (PICA-SPIKE)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLELESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL., IV CANNULA WITH PORT & SUTURABLE WINGS (SENTRAFLEX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,SAFETY I.V. CANNULA (PANACAN SAFETY I.V. CANNULA WITH WINGS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT & WINGS(RAMYFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT INJECTION PORT & WINGS(POLYWIN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITHOUT INJECTION PORT AND WITH SMALL WINGS FOR QUICK FLASHBACK(POLYNEO ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V. CANNULA WITH INJECTION PORT & WINGS(INTRAVENOUS (IV) CANNULA WITH INJECTION PORT, STANDARD “ALEXPHARM”)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT & WINGS FOR QUICK FLASHBACK(POLYFLON ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITHOUT INJECTION PORT & WINGS(POLYPEN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV CANNULA WITH INJECTION PORT

		& WINGS(SENTRAFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS(POLYFLEX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.
3225	MFG/MD/2019/000087	1.License Holder Name: TTK HEALTHCARE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:NATURAL RUBBER LATEX MALE CONDOMS(SKORE)-TO AVOID UN WANTED PREGNANCY AND PREVENTION OF TRANSMISSION OF SEXUALLY TRANSMITTED INFECTIONS (STI)

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3226	MFG/MD/2019/000088	1.License Holder Name: INVENT BIOMED PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:CO-CR STENT DELIVERY SYSTEM(NANO-CHROM)-THE NANO-CHROMTM IS INTENDED FOR USE IN PATIENTS ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA),PTCA GUIDEWIRE(MARATHON / MARATHONCTO+)-MARATHON / MARATHONCTO+ PTCA GUIDEWIRES ARE INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). THE MARATHONCTO+ PTCA GUIDE WIRE IS NOT TO BE USED IN THE CEREBRAL BLOOD VESSELS., ANGIOGRAPHY GUIDEWIRE(GUIDER)-GUIDEWIRE IS DESIGNED FOR PERCUTANEOUS VESSEL ENTRY USING SELDINGER TECHNIQUE TO FACILITATE THE SUBSQUENT INTRODUCTION OF AN INTRAVASCULAR DEVICE DURING INVASIVE CARDIOLOGY PROCESS., SIROLIMUS ELUTING CORONARY STENT SYSTEM(NOVA MATRIX)-THE STENT IS INTENDED FOR USE AS AN AJUNCT TO CORONARY INTERVENTIONS,SIROLIMUS ELUTING CORONARY STENT SYSTEM (NOVA VIDA CHROME)-THE STENT IS INTENDED FOR USE AS AN AJUNCT TO CORONARY INTERVENTIONS,INTRODUCER SHEATH (PROACCESS/ PROACCESS R)-THE SHEATH INTRODUCER IS A PERCUTANEOUS INTRODUCER FOR USE WITH PTCA GUIDING CATHETER AND ANY OTHER INTRAVASCUALR THERAPEUTIC PROCEDURES.,RAPID EXCHANGE PTCA DILATION CATHETER (INVENTO)-THE INVENTOTM RAPID EXCHANGE PTCA DILATION CATHETER IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO CORONARY ARTERY LESIONS WITH A REFERNACE VESSEL DIAMETER RANGING FROM 1.25 MM TO 4.0 MM AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER.

3227	MFG/MD/2019/000089	1.License Holder Name: SHARMA ORTHO SYSTEM PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:PROSTHESIS, TOTAL KNEE REPLACEMENT (STERILE) {XLPE}(SHARMA, ENTICE)-TOTAL KNEE REPLACEMENT (TKR) IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TKR MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TKR OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM AGAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. TKR IS INDICATED FOR A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR A FAILED PREVIOUS IMPLANT.,PROSTHESIS, TOTAL KNEE REPLACEMENT (STERILE) {UHMWPE}(SHARMA, ENTICE)-TOTAL KNEE REPLACEMENT (TKR) IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TKR MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TKR OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM AGAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. TKR IS INDICATED FOR A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR A FAILED PREVIOUS IMPLANT.,HIP PROSTHESIS, TOTAL HIP REPLACEMENT (STERILE) {COCR}(SHARMA, FINER, CREST, DUPLUS, SPIRE, TENACIOUS)-TOTAL HIP REPLACEMENT (UN-CEMENTED) IS INTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESSFIT (CEMENTLESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE

	COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A). NON INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B). CORRECTION OF FUNCTIONAL DEFORMITY. C). TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D). REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,PROSTHESIS, TOTAL KNEE REPLACEMENT (STERILE) {TITANIUM ALLOY (ISO 5832-3)}(SHARMA, ENTICE)-TOTAL KNEE REPLACEMENT (TKR) IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TKR MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TKR OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM AGAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. TKR IS INDICATED FOR A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR A FAILED PREVIOUS IMPLANT.,ORAL MAXILLOFACIAL IMPLANTS (STERILE & NON-STERILE) {TITANIUM ALLOY (ISO 5832-3)}(SHARMA, ELEGANT)-ORAL-MAXILLOFACIAL IMPLANTS ARE INDICATED FOR USE IN FRACTURE FIXATION, MANDIBULAR RECONSTRUCTION AND SURGERY INVOLVING OSTEOTOMIES, ORTHOGNATHIC RECONSTRUCTION OR SURGERY, SURGERY RELATED TO DENTO-FACIAL OR FACIAL CAVITY AND TRAUMA DUE TO IT. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING.,PROSTHESIS, TOTAL KNEE REPLACEMENT (STERILE) {SS316L}(SHARMA, ENTICE)-TOTAL KNEE REPLACEMENT (TKR) IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TKR MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TKR OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED

	DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM AGAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. TKR IS INDICATED FOR A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR A FAILED PREVIOUS IMPLANT.,INTERLOCKING NAILS, LOCKING BOLTS & ACCESSORIES (STERILE & NON-STERILE) {SS(ISO 5832-1)}(SHARMA, ELEGANT)-INDICATIONS FOR INTERLOCKING NAILS INCLUDE SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNIONS; AND BONE LENGTHENING/SHORTENING. FEMORAL INTERLOCKING NAILS INCLUDE THE INDICATION FOR PROXIMAL, MIDDLE AND DISTAL THIRD FEMORAL SHAFT FRACTURES. TIBIAL INTERLOCKING NAILS ALSO INCLUDE THE SAME INDICATIONS FOR TIBIAL SHAFT FRACTURES. HUMERAL INTERLOCKING NAILS ARE INDICATED FOR HUMERAL SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNIONS, PROXIMAL, MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES; HUMERUS RECONSTRUCTION, FOLLOWING TUMOR RESECTION AND GRAFTING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. R/U INTERLOCKING NAILS ARE INDICATED FOR RADIAL AND ULNAR SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; PROXIMAL MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES. INTERLOCKING RECONSTRUCTION NAILS ARE INDICATED FOR THE FOLLOWING: SUBTROCHANTERIC FRACTURES WITH LESSER TROCHANTERIC INVOLVEMENT; IPSILATERAL FEMORAL SHAFT/NECK FRACTURES; SEVERELY COMMINUTED SHAFT FRACTURES; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; BONE SHORTENING/LENGTHENING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. RETROGRADE NAILS ARE INDICATED FOR SHAFT FRACTURES INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; BONE LENGTHENING/SHORTENING; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; FRACTURES IN OSTEOPOROTIC BONE; SEVERELY COMMINUTED SHAFT FRACTURES; PATHOLOGIC FRACTURES, PSEUDOARTHROSIS, FAILED OSTEOSYNTHESIS; CLOSED SUPRACONDYLAR FRACTURES; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. ADDITIONAL INDICATIONS

	FOR RETROGRADE NAILS INCLUDE: SEVERELY COMMINUTED SUPRACONDYLAR FRACTURES WITH OR WITHOUT DIFFICULT INTRAARTICULAR EXTENSION, FRACTURES THAT REQUIRE OPENING THE KNEE JOINT TO STABILIZE THE FEMORAL CONDYLAR SEGMENT. K-NAIL IS INDICATED FOR TIBIA, FEMUR AND HUMREUS SHAFT FRACTURE. GAM NAIL IS INDICATED FOR SUBTROCHANTERIC FRACTURE. ELASTIC NAIL (FLEXIBLE NAIL) IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ENDER'S NAIL IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ANKLE ARTHODESIS NAIL IS INDICATED FOR FOOT AND ANKLE FRACTURE. D-IMSC LOCKED NAIL IS INDICATED FOR SUPRACONDYLAR FRACTURE. INTERLOCKING NAIL CAP, NAIL PLUG SAFETY STAR DRIVE (GAM NAIL CAP), INTERLOCKING GUIDE WIRE-SIMPLE AND INTERLOCKING GUIDE WIRE-OLIVE TIP (BALL TIP) ARE INDICATED FOR NAIL AND BONE FIXATION.,INTERLOCKING NAILS, LOCKING BOLTS & ACCESSORIES (STERILE & NON-STERILE) {TITANIUM ALLOY (ISO 5832-3)}(SHARMA, ELEGANT)-INDICATIONS FOR INTERLOCKING NAILS INCLUDE SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNIONS; AND BONE LENGTHENING/SHORTENING. FEMORAL INTERLOCKING NAILS INCLUDE THE INDICATION FOR PROXIMAL, MIDDLE AND DISTAL THIRD FEMORAL SHAFT FRACTURES. TIBIAL INTERLOCKING NAILS ALSO INCLUDE THE SAME INDICATIONS FOR TIBIAL SHAFT FRACTURES. HUMERAL INTERLOCKING NAILS ARE INDICATED FOR HUMERAL SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNIONS, PROXIMAL, MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES; HUMERUS RECONSTRUCTION, FOLLOWING TUMOR RESECTION AND GRAFTING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. R/U INTERLOCKING NAILS ARE INDICATED FOR RADIAL AND ULNAR SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; PROXIMAL MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES. INTERLOCKING RECONSTRUCTION NAILS ARE INDICATED FOR THE FOLLOWING: SUBTROCHANTERIC FRACTURES WITH LESSER TROCHANTERIC INVOLVEMENT; IPSILATERAL FEMORAL SHAFT/NECK FRACTURES; SEVERELY COMMINUTED SHAFT FRACTURES; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; BONE SHORTENING/LENGTHENING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. RETROGRADE NAILS ARE INDICATED FOR SHAFT FRACTURES INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND

	SEGMENTAL FRACTURES; NONUNION AND MALUNION; BONE LENGTHENING/SHORTENING; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; FRACTURES IN OSTEOPOROTIC BONE; SEVERELY COMMINUTED SHAFT FRACTURES; PATHOLOGIC FRACTURES, PSEUDOARTHROSIS, FAILED OSTEOSYNTHESIS; CLOSED SUPRACONDYLAR FRACTURES; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. ADDITIONAL INDICATIONS FOR RETROGRADE NAILS INCLUDE: SEVERELY COMMINUTED SUPRACONDYLAR FRACTURES WITH OR WITHOUT DIFFICULT INTRAARTICULAR EXTENSION, FRACTURES THAT REQUIRE OPENING THE KNEE JOINT TO STABILIZE THE FEMORAL CONDYLAR SEGMENT. K-NAIL IS INDICATED FOR TIBIA, FEMUR AND HUMREUS SHAFT FRACTURE. GAM NAIL IS INDICATED FOR SUBTROCHANTERIC FRACTURE. ELASTIC NAIL (FLEXIBLE NAIL) IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ENDER'S NAIL IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ANKLE ARTHODESIS NAIL IS INDICATED FOR FOOT AND ANKLE FRACTURE. D-IMSC LOCKED NAIL IS INDICATED FOR SUPRACONDYLAR FRACTURE. INTERLOCKING NAIL CAP, NAIL PLUG SAFETY STAR DRIVE (GAM NAIL CAP), INTERLOCKING GUIDE WIRE-SIMPLE AND INTERLOCKING GUIDE WIRE-OLIVE TIP (BALL TIP) ARE INDICATED FOR NAIL AND BONE FIXATION.,PROSTHESIS, TOTAL KNEE REPLACEMENT (STERILE) {COCR}(SHARMA, ENTICE)-TOTAL KNEE REPLACEMENT (TKR) IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TKR MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TKR OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM AGAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. TKR IS INDICATED FOR A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR A FAILED PREVIOUS IMPLANT.,HIP PROSTHESIS, TOTAL HIP REPLACEMENT (STERILE) {SS(ISO 5832-9)}(SHARMA, FINER, CREST, DUPLUS, SPIRE, TENACIOUS)-TOTAL HIP REPLACEMENT (UN-CEMENTED) IS INTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESSFIT (CEMENTLESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE

	DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A). NON INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B). CORRECTION OF FUNCTIONAL DEFORMITY. C). TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D). REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,HIP PROSTHESIS, TOTAL HIP REPLACEMENT (STERILE) {XLPE}(SHARMA, FINER, CREST, DUPLUS, SPIRE, TENACIOUS)-TOTAL HIP REPLACEMENT (UN-CEMENTED) IS INTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESSFIT (CEMENTLESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A). NON INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B). CORRECTION OF FUNCTIONAL DEFORMITY. C). TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D). REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,SPINAL IMPLANTS (STERILE) {PEEK} (SHARMA, CORE)-SPINAL IMPLANTS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THORACIC, LUMBAR, AND SACRAL SPINE: FRACTURE, DISLOCATION, FAILED PREVIOUS FUSION (PSEUDOARTHROSIS), SPINAL STENOSIS, DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, SPINAL DEFORMATIONS SUCH AS SCOLIOSIS OR KYPHOSIS AND LOSS OF STABILITY DUE TO TUMORS. SPINAL IMPLANTS ARE INTENDED TO BE USED AS A TEMPORARY CONSTRUCT THAT ASSISTS NORMAL HEALING AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES. THEY ARE INTENDED TO STABILIZE THE SPINAL OPERATIVE SITE DURING

	FUSION PROCEDURES AND SHOULD BE REMOVED AFTER FUSION. BONE PLATE & BONE SCREW (STERILE & NON-STERILE) {SS316L}. (SHARMA, ELEGANT)-PLATES ARE INDICATED FOR USE IN FIXATION OF VARIOUS FRACTURED BONES BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING. SHARMA ORTHO SYSTEM PVT. LTD. IMPLANTS AND ACCESSORIES ARE INTENDED FOR USE IN INTERNAL FIXATION OF BONES AFFECTED BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. SCREWS ALONG WITH PLATES, NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC, SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE OF SO MANY DIFFERENT TYPES E.G. (LOCKED SCREWS, LOCKING BOLTS ETC.), INTERLOCKING NAILS, LOCKING BOLTS & ACCESSORIES (STERILE & NON-STERILE) {SS316L}(SHARMA, ELEGANT)-INDICATIONS FOR INTERLOCKING NAILS INCLUDE SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNIONS; AND BONE LENGTHENING/SHORTENING. FEMORAL INTERLOCKING NAILS INCLUDE THE INDICATION FOR PROXIMAL, MIDDLE AND DISTAL THIRD FEMORAL SHAFT FRACTURES. TIBIAL INTERLOCKING NAILS ALSO INCLUDE THE SAME INDICATIONS FOR TIBIAL SHAFT FRACTURES. HUMERAL INTERLOCKING NAILS ARE INDICATED FOR HUMERAL SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNIONS, PROXIMAL, MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES; HUMERUS RECONSTRUCTION, FOLLOWING TUMOR RESECTION AND GRAFTING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. R/U INTERLOCKING NAILS ARE INDICATED FOR RADIAL AND ULNAR SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; PROXIMAL MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES. INTERLOCKING RECONSTRUCTION NAILS ARE INDICATED FOR THE FOLLOWING: SUBTROCHANTERIC FRACTURES WITH LESSER TROCHANTERIC INVOLVEMENT; IPSILATERAL FEMORAL SHAFT/NECK FRACTURES; SEVERELY COMMINUTED SHAFT FRACTURES; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; BONE SHORTENING/LENGTHENING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. RETROGRADE NAILS ARE INDICATED FOR SHAFT FRACTURES INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; BONE

	LENGTHENING/SHORTENING; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; FRACTURES IN OSTEOPOROTIC BONE; SEVERELY COMMINUTED SHAFT FRACTURES; PATHOLOGIC FRACTURES, PSEUDOARTHROSIS, FAILED OSTEOSYNTHESIS; CLOSED SUPRACONDYLAR FRACTURES; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. ADDITIONAL INDICATIONS FOR RETROGRADE NAILS INCLUDE: SEVERELY COMMINUTED SUPRACONDYLAR FRACTURES WITH OR WITHOUT DIFFICULT INTRAARTICULAR EXTENSION, FRACTURES THAT REQUIRE OPENING THE KNEE JOINT TO STABILIZE THE FEMORAL CONDYLAR SEGMENT. K-NAIL IS INDICATED FOR TIBIA, FEMUR AND HUMREUS SHAFT FRACTURE. GAM NAIL IS INDICATED FOR SUBTROCHANTERIC FRACTURE. ELASTIC NAIL (FLEXIBLE NAIL) IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ENDER'S NAIL IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ANKLE ARTHODESIS NAIL IS INDICATED FOR FOOT AND ANKLE FRACTURE. D-IMSC LOCKED NAIL IS INDICATED FOR SUPRACONDYLAR FRACTURE. INTERLOCKING NAIL CAP, NAIL PLUG SAFETY STAR DRIVE (GAM NAIL CAP), INTERLOCKING GUIDE WIRE-SIMPLE AND INTERLOCKING GUIDE WIRE-OLIVE TIP (BALL TIP) ARE INDICATED FOR NAIL AND BONE FIXATION.,SPINAL IMPLANTS (STERILE & NON-STERILE) {SS (ISO 5832-1)}(SHARMA, CORE)-SPINAL IMPLANTS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THORACIC, LUMBAR, AND SACRAL SPINE: FRACTURE, DISLOCATION, FAILED PREVIOUS FUSION (PSEUDOARTHROSIS), SPINAL STENOSIS, DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, SPINAL DEFORMATIONS SUCH AS SCOLIOSIS OR KYPHOSIS AND LOSS OF STABILITY DUE TO TUMORS. SPINAL IMPLANTS ARE INTENDED TO BE USED AS A TEMPORARY CONSTRUCT THAT ASSISTS NORMAL HEALING AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES. THEY ARE INTENDED TO STABILIZE THE SPINAL OPERATIVE SITE DURING FUSION PROCEDURES AND SHOULD BE REMOVED AFTER FUSION.,BONE PLATE & BONE SCREW (STERILE & NON-STERILE) {SS(ISO 5832-1)}..(SHARMA, ELEGANT)-PLATES ARE INDICATED FOR USE IN FIXATION OF VARIOUS FRACTURED BONES BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING. SHARMA ORTHO SYSTEM PVT. LTD. IMPLANTS AND ACCESSORIES ARE INTENDED FOR USE IN INTERNAL FIXATION OF BONES AFFECTED BY TRAUMA OR FOR

	RECONSTRUCTION OR ARTHRODESIS. SCREWS ALONG WITH PLATES, NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC, SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE OF SO MANY DIFFERENT TYPES E.G. (LOCKED SCREWS, LOCKING BOLTS ETC.), BONE PLATE & BONE SCREW (STERILE & NON-STERILE) {TITANIUM ALLOY (ISO 5832-3)}..(SHARMA, ELEGANT)-PLATES ARE INDICATED FOR USE IN FIXATION OF VARIOUS FRACTURED BONES BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING. SHARMA ORTHO SYSTEM PVT. LTD. IMPLANTS AND ACCESSORIES ARE INTENDED FOR USE IN INTERNAL FIXATION OF BONES AFFECTED BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. SCREWS ALONG WITH PLATES, NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC, SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE OF SO MANY DIFFERENT TYPES E.G. (LOCKED SCREWS, LOCKING BOLTS ETC.), BONE PLATE & BONE SCREW (STERILE & NON-STERILE) {SS316L}.. (SHARMA, ELEGANT)-PLATES ARE INDICATED FOR USE IN FIXATION OF VARIOUS FRACTURED BONES BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING. SHARMA ORTHO SYSTEM PVT. LTD. IMPLANTS AND ACCESSORIES ARE INTENDED FOR USE IN INTERNAL FIXATION OF BONES AFFECTED BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. SCREWS ALONG WITH PLATES, NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC, SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE OF SO MANY DIFFERENT TYPES E.G. (LOCKED SCREWS, LOCKING BOLTS ETC.), BONE PLATE & BONE SCREW (STERILE & NON-STERILE) {TITANIUM ALLOY (ISO 5832-3)}.(SHARMA, ELEGANT)-PLATES ARE INDICATED FOR USE IN FIXATION OF VARIOUS FRACTURED BONES BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING. SHARMA ORTHO SYSTEM PVT. LTD. IMPLANTS AND ACCESSORIES ARE INTENDED FOR USE IN INTERNAL FIXATION OF BONES AFFECTED BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. SCREWS ALONG WITH PLATES, NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC, SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE OF SO MANY DIFFERENT TYPES E.G. (LOCKED SCREWS, LOCKING BOLTS ETC.), ORAL MAXILLOFACIAL IMPLANTS (STERILE & NON-STERILE) {SS(ISO 5832-1)}(SHARMA, ELEGANT)-ORAL-MAXILLOFACIAL IMPLANTS ARE INDICATED FOR USE IN FRACTURE FIXATION, MANDIBULAR RECONSTRUCTION AND SURGERY INVOLVING OSTEOTOMIES,

	ORTHOGNATHIC RECONSTRUCTION OR SURGERY, SURGERY RELATED TO DENTO-FACIAL OR FACIAL CAVITY AND TRAUMA DUE TO IT. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING.,ARTHROSCOPY IMPLANTS, PINS AND WIRES (STERILE & NON-STERILE) {TITANIUM ALLOY (ISO 5832-3)}(SHARMA)-INDICATIONS FOR PINS AND WIRES INCLUDE FIXATION OF BONE FRACTURES, BONE RECONSTRUCTIONS, AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS AND IMPLANTED THROUGH THE SKIN FOR TRACTION APPLIED TO THE SKELETAL SYSTEM. ARTHROSCOPY IMPLANTS ARE INTENDED FOR USE IN FIXATION OF SEMITENDINOUS AND/OR GRACILE TENDON GRAFTS. ACL/PCL SCREW IS INTENDED FOR USE IN ANTERIOR/POSTERIOR CRUCIATE LIGAMENT (ACL/PCL) RECONSTRUCTION PROCEDURES. ACL/PCL SCREW IS INDICATED FOR FIXATION OF BONE-PATELLAR TENDON-BONE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION, FIXATION OF THE SOFT TISSUE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION AND RECONSTRUCTION OF POSTERIOR CRUCIATE LIGAMENT (PCL)., HIP PROSTHESIS, TOTAL HIP REPLACEMENT (STERILE) {CERAMIC (ISO 6474)}(SHARMA, FINER, CREST, DUPLUS, SPIRE, TENACIOUS)-TOTAL HIP REPLACEMENT (UN-CEMENTED) IS INTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESS FIT (CEMENTLESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A). NON INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B). CORRECTION OF FUNCTIONAL DEFORMITY. C). TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D). REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED., ORAL MAXILLOFACIAL IMPLANTS (STERILE & NON-STERILE) {SS316L}(SHARMA, ELEGANT)-ORAL-MAXILLOFACIAL IMPLANTS ARE INDICATED FOR USE IN FRACTURE FIXATION, MANDIBULAR RECONSTRUCTION AND SURGERY INVOLVING OSTEOTOMIES, ORTHOGNATHIC RECONSTRUCTION OR SURGERY, SURGERY RELATED TO DENTO-FACIAL OR FACIAL CAVITY AND TRAUMA DUE

	TO IT. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING.,ARTHROSCOPY IMPLANTS, PINS AND WIRES (STERILE & NON-STERILE) {SS(ISO 5832-1)}(SHARMA)-INDICATIONS FOR PINS AND WIRES INCLUDE FIXATION OF BONE FRACTURES, BONE RECONSTRUCTIONS, AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS AND IMPLANTED THROUGH THE SKIN FOR TRACTION APPLIED TO THE SKELETAL SYSTEM. ARTHROSCOPY IMPLANTS ARE INTENDED FOR USE IN FIXATION OF SEMITENDINOUS AND/OR GRACILE TENDON GRAFTS. ACL/PCL SCREW IS INTENDED FOR USE IN ANTERIOR/POSTERIOR CRUCIATE LIGAMENT (ACL/PCL) RECONSTRUCTION PROCEDURES. ACL/PCL SCREW IS INDICATED FOR FIXATION OF BONE-PATELLAR TENDON- BONE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION, FIXATION OF THE SOFT TISSUE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION AND RECONSTRUCTION OF POSTERIOR CRUCIATE LIGAMENT (PCL).,HIP PROSTHESIS, TOTAL HIP REPLACEMENT (STERILE) {UHMWPE} (SHARMA, FINER, CREST, DUPLUS, SPIRE, TENACIOUS)-TOTAL HIP REPLACEMENT (UN-CEMENTED) IS INTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESSFIT (CEMENTLESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A). NON INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B). CORRECTION OF FUNCTIONAL DEFORMITY. C). TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D). REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,ARTHROSCOPY IMPLANTS, PINS AND WIRES (STERILE & NON-STERILE) {SS316L}(SHARMA)-INDICATIONS FOR PINS AND WIRES INCLUDE FIXATION OF BONE FRACTURES, BONE RECONSTRUCTIONS, AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS AND IMPLANTED THROUGH THE SKIN FOR TRACTION APPLIED TO THE SKELETAL SYSTEM. ARTHROSCOPY IMPLANTS ARE INTENDED FOR USE IN FIXATION OF SEMITENDINOUS AND/OR GRACILE TENDON GRAFTS. ACL/PCL SCREW IS INTENDED FOR USE IN ANTERIOR/POSTERIOR CRUCIATE

	LIGAMENT (ACL/PCL) RECONSTRUCTION PROCEDURES. ACL/PCL SCREW IS INDICATED FOR FIXATION OF BONE-PATELLAR TENDON-BONE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION, FIXATION OF THE SOFT TISSUE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION AND RECONSTRUCTION OF POSTERIOR CRUCIATE LIGAMENT (PCL)., HIP PROSTHESIS, TOTAL HIP REPLACEMENT (STERILE) {SS316L} (SHARMA, FINER, CREST, DUPLUS, SPIRE, TENACIOUS)-TOTAL HIP REPLACEMENT (UN-CEMENTED) IS INTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESSFIT (CEMENTLESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A). NON INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B). CORRECTION OF FUNCTIONAL DEFORMITY. C). TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D). REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,HIP PROSTHESIS, TOTAL HIP REPLACEMENT (STERILE) {PMMA}(SHARMA, FINER, CREST, DUPLUS, SPIRE, TENACIOUS)-TOTAL HIP REPLACEMENT (UN-CEMENTED) IS INTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESSFIT (CEMENTLESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A). NON INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B). CORRECTION OF FUNCTIONAL DEFORMITY. C). TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D). REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,PROSTHESIS, TOTAL KNEE REPLACEMENT (STERILE) {SS(ISO-5832-1)}(SHARMA, ENTICE)-TOTAL KNEE

	REPLACEMENT (TKR) IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TKR MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TKR OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM AGAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. TKR IS INDICATED FOR A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR A FAILED PREVIOUS IMPLANT.,HIP PROSTHESIS, TOTAL HIP REPLACEMENT (STERILE) {TITANIUM ALLOY (ISO 5832-3)} (SHARMA, FINER, CREST, DUPLUS, SPIRE, TENACIOUS)-TOTAL HIP REPLACEMENT (UN-CEMENTED) IS INTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESSFIT (CEMENTLESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A). NON INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B). CORRECTION OF FUNCTIONAL DEFORMITY. C). TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D). REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,HIP PROSTHESIS, TOTAL HIP REPLACEMENT (STERILE) {SS(ISO 5832-1)}(SHARMA, FINER, CREST, DUPLUS, SPIRE, TENACIOUS)-TOTAL HIP REPLACEMENT (UN-CEMENTED) IS INTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESSFIT (CEMENTLESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A). NON INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC

	ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B). CORRECTION OF FUNCTIONAL DEFORMITY. C). TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D). REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,BONE PLATE & BONE SCREW (STERILE & NON-STERILE) {SS(ISO 5832-1)}.(SHARMA, ELEGANT)-PLATES ARE INDICATED FOR USE IN FIXATION OF VARIOUS FRACTURED BONES BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING. SHARMA ORTHO SYSTEM PVT. LTD. IMPLANTS AND ACCESSORIES ARE INTENDED FOR USE IN INTERNAL FIXATION OF BONES AFFECTED BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. SCREWS ALONG WITH PLATES, NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC, SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE OF SO MANY DIFFERENT TYPES E. G. (LOCKED SCREWS, LOCKING BOLTS ETC.),SPINAL IMPLANTS (STERILE & NON-STERILE) {TITANIUM ALLOY (ISO 5832-3)}(SHARMA, CORE)-SPINAL IMPLANTS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THORACIC, LUMBAR, AND SACRAL SPINE: FRACTURE, DISLOCATION, FAILED PREVIOUS FUSION (PSEUDOARTHROSIS), SPINAL STENOSIS, DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, SPINAL DEFORMATIONS SUCH AS SCOLIOSIS OR KYPHOSIS AND LOSS OF STABILITY DUE TO TUMORS. SPINAL IMPLANTS ARE INTENDED TO BE USED AS A TEMPORARY CONSTRUCT THAT ASSISTS NORMAL HEALING AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES. THEY ARE INTENDED TO STABILIZE THE SPINAL OPERATIVE SITE DURING FUSION PROCEDURES AND SHOULD BE REMOVED AFTER FUSION.,ARTHROSCOPY IMPLANTS, PINS AND WIRES (STERILE) {PEEK} (SHARMA)-INDICATIONS FOR PINS AND WIRES INCLUDE FIXATION OF BONE FRACTURES, BONE RECONSTRUCTIONS, AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS AND IMPLANTED THROUGH THE SKIN FOR TRACTION APPLIED TO THE SKELETAL SYSTEM. ARTHROSCOPY IMPLANTS ARE INTENDED FOR USE IN FIXATION OF SEMITENDINOUS AND/OR GRACILE TENDON GRAFTS. ACL/PCL SCREW IS INTENDED FOR USE IN ANTERIOR/POSTERIOR CRUCIATE LIGAMENT (ACL/PCL) RECONSTRUCTION PROCEDURES. ACL/PCL

	SCREW IS INDICATED FOR FIXATION OF BONE-PATELLAR TENDON-BONE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION, FIXATION OF THE SOFT TISSUE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION AND RECONSTRUCTION OF POSTERIOR CRUCIATE LIGAMENT (PCL).

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3228	MFG/MD/2019/000090	1.License Holder Name: ANGIPLAST PRIVATE LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE SINGLE USE EXTENSION SET(1.GENERIC, 2. SOLCARE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,STERILE DISPOSABLE SINGLE USE DOUBLE SWIVEL MOUNT (CATHETER T MOUNT)(OKJO)-THE STERILE DOUBLE SWIVEL MOUNT WHICH IS AN INSTRUMENT USED IN ANESTHESIOLOGY,STERILE DISPOSABLE SINGLE USE SYRINGE 10ML WITH / WITHOUT NEEDLE(1.GENERIC,2 ANGELTOUCH, 3.DISPOTOUCH,4.SANBAO)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE DISPOSABLE SINGLE USE HME FILTER / BV FILTER(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-IT IS USED IN MECHANICALLY VENTILATED PATIENTS INTENDED TO HELP FORM PREVENTING COMPLICATIONS DUE DRYING OF THE RESPIRATORY MUCOSA.,STERILE DISPOSABLE SINGLE USE SYRINGE 50ML WITH/WITHOUT NEEDLE(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH,4.SANBAO)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE DISPOSABLE SINGLE USE REDON DRAIN CATHETER(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-REDON DRAIN CATHETER IS A FLEXIBLE PVC TUBE WITH 45-55 EYE HOLES AT THE DISTAL END USED AS A SURGICAL DRAIN, TO PREVENT BUILD UP OF FLUID IN A SURGICAL SITE. , STERILE DISPOSABLE PAEDIATRIC(MICRODRIP) INFUSION SET WITHOUT AIRVENT(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SINGLE USE GUEDEL AIRWAY(1. GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-IT IS SUITABLE FOR MAINTAINING AN UNOBSTRUCTED OROPHARYNGEAL AIRWAY DURING GENERAL ANESTHESIA AND IN UNCONSCIOUS PATIENTS., STERILE DISPOSABLE SINGLE USE NASAL OXYGEN CANNULA(1. GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THE NASAL OXYGEN CANNULA IS USED FOR EASY APPLICATION AND EFFICIENT ADMINISTRATION OF OXYGEN FOR GREATER COMFORT OF PATIENT., STERILE DISPOSABLE SINGLE USE IV CANNULA WITH LUER LOCK AND WITHOUT WINGS, INJECTION PORT(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THE IV CANNULAE IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS DRUGS AND OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE,STERILE DISPOSABLE INFUSION SET WITH NEEDLE FREE INJECTION SITE WITHOUT AIRVENT(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS

	TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SINGLE USE IV CANNULA WITH LUER LOCK, WINGS AND WITHOUT INJECTION PORT(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS DRUGS AND OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE SINGLE USE TUR SET / Y JUNTION SET(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THE STERILE T.U.R. SET IS USED FOR CONTINUOUS IRRIGATION DURING TRANS-URETHRAL RESECTION OF PROSTATE GLAND.,STERILE DISPOSABLE SINGLE USE UMBILICAL CORD CLAMP (1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-STERILE DISPOSABLE SINGLE USE UMBILICAL CORD CLAMP IS INTENDED TO REPLACE THE LIGATURE USED FOR TYING THE FOETAL UMBILICAL CORD FOLLOWING DELIVERY.,STERILE DISPOSABLE INFUSION SET WITH NEEDLE FREE INJECTION SITE WITH AIRVENT(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SINGLE USE SUCTION CATHETER WITH THUMB CONTROLLER(OKJO)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,STERILE DISPOSABLE SINGLE USE SILICON FOLEY BALLON CATHETER (2WAY/3WAY)(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,:STERILE DISPOSABLE SINGLE USE RYLE'S TUBE(OKJO)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES, STERILE DISPOSABLE SINGLE USE THORACIC CATHETER WITH TROCAR(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THE STERILE THORACIC CATHETER WITH TROCAR SUITABLE FOR QUICK NON OPERATIVE PLUERAL AND AND CHEST DRAINAGE FOR THE RELIEF OF CHEST CONDITION SUCH AS TENSION, PNEUMOTHORAX.,IV EXTENSION SET / PRESSURE MONITORING LINE(OKJO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,STERILE DISPOSABLE INFUSION SET WITHOUT AIRVENT(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH, 4.RED BULB)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH AIRVENT(OKJO)-IT

	IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE MEASURED VOLUME INFUSION SET WITH/WITHOUT AIRVENT(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH,4.EXOCARE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE SINGLE USE INFANT MUCUS EXTRACTOR WITH FILTER(OKJO)-MUCUS EXTRACTOR IS USED TO EXTRACT MUCUS FROM INFANT,STERILE DISPOSABLE SINGLE USE CORRUGATED DRAINAGE SHEET(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-IT IS USED FOR EFFICIENT DRAINAGE DURING OPERATION AND WOUND TREATMENT,STERILE DISPOSABLE SINGLE USE THORACIC CATHETER WITH TROCAR(OKJO)-THE STERILE THORACIC CATHETER WITH TROCAR SUITABLE FOR QUICK NON OPERATIVE PLUERAL AND AND CHEST DRAINAGE FOR THE RELIEF OF CHEST CONDITION SUCH AS TENSION, PNEUMOTHORAX.,STERILE DISPOSABLE SINGLE USE FOLEY BALLOON CATHETER (2WAY/3 WAY)(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE DISPOSABLE SINGLE USE ENDOTRACHEAL TUBE (CUFFED)(OKJO)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,STERILE DISPOSABLE SINGLE USE SYRINGE 5ML WITH / WITHOUT NEEDLE(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH,4. SANBAO)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE DISPOSABLE SINGLE USE MALE EXTERNAL CATHTER (SMALL, MEDIUM, LARGE, EXTRA LARGE)(OKJO)-THE STERILE MALE EXTERNAL CATHETER IS USED IN MALE PATIENT FOR URINE INCONTINENCE FOR DAY AND NIGHT.,STERILE DISPOSABLE INFUSION SET - NON VENTED(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SINGLE USE IV CANNULA WITH LUER LOCK, WINGS AND INJECTION PORT(OKJO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS DRUGS AND OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE., MINIBORE EXTENSION SET(1.GENERIC, 2. MERIT)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,STERILE

	DISPOSABLE SINGLE USE CLOSED WOUND SUCTION UNIT(OKJO)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND,STERILE DISPOSABLE INFUSION SET WITH AIRVENT FOR PACLITAXEL(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH,4.EXOCARE)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SINGLE USE UMBILICAL CORD CLAMP(OKJO)-STERILE DISPOSABLE SINGLE USE UMBILICAL CORD CLAMP IS INTENDED TO REPLACE THE LIGATURE USED FOR TYING THE FOETAL UMBILICAL CORD FOLLOWING DELIVERY.,STERILE DISPOSABLE SINGLE USE THORACIC CATHETER(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THE STERILE THORACIC CATHETER SUITABLE FOR POST OPERATIVE DRAINAGE AFTER CARDIO THORACIC AND THORACIC SURGERY, STERILE DISPOSABLE SINGLE USE NASOPHARYNGEAL AIRWAY (OKJO)-A CATHETER (FOR ADULTS) PASSED THROUGH THE NARES AND ADVANCED TO THE DEPTH OF THE NASOPHARYNX TO REMOVE AIR CHOKE OR OBSTRUCTION.,STERILE DISPOSABLE MEASURED VOLUME TRANSFUSION SET WITH/WITHOUT AIRVENT(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SINGLE USE LARYNGEAL MASK AIRWAY(OKJO)-THE STERILE LARYNGEAL MASK IS A MEDICAL DEVICE USED TO KEEP A PATIENT'S AIRWAY OPEN DURING ANESTHESIA OR UNCONSCIOUSNESS., STERILE DISPOSABLE PAEDIATRIC(MICRODRIP) INFUSION SET WITH AIRVENT(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., STERILE DISPOSABLE SINGLE USE SYRINGE(OKJO)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY., STERILE DISPOSABLE SINGLE USE SCALP VEIN SET(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD,STERILE DISPOSABLE SINGLE USE YANKAUER SUCTION SET(OKJO)-THE STERILE VACUUM SUCTION SET IS USED FOR GENERAL SUCTION PURPOSES. IT IS USED FOR REMOVAL THE SECRETION OR IRRIGATION FLUID DURING OPERATION OF DELIVERY FROM THE HUMAN BODY.,STERILE DISPOSABLE SINGLE USE TRACHEOSTOMY TUBE (CUFFED)(1. GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL

	CORDS.,STERILE DISPOSABLE SINGLE USE FOLEY BALLOON CATHETER (2WAY/3 WAY)(OKJO)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER.,STERILE DISPOSABLE SINGLE USE EXTENSION SET WITH THREE WAY STOPCOCK(1.GENERIC, 2. ANGELTOUCH, 3.DISPOTOUCH, 4.EXOCARE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS / MEDICATIONS IN MEDICAL APPLICATIONS,STERILE DISPOSABLE MEASURED VOLUME INFUSION SET WITH/WITHOUT AIRVENT(OKJO)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,IV ADMINISTRATION INFUSION SET WITH AIRVENT(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH,4.MERIT)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SINGLE USE 3 WAY STOPCOCK (OKJO)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING., STERILE DISPOSABLE SINGLE USE 1ML INSULINE SYRINGE(1.GENERIC, 2. ANGELTOUCH, 3.DISPOTOUCH,4.SANBAO)-IT IS USED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE DISPOSABLE INFUSION SET WITH AIRVENT(OKJO)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,IV EXTENSION SET / PRESSURE MONITORING LINE(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH,4.KENAFLEXX)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,STERILE DISPOSABLE SINGLE USE SILICON FOLEY BALLON CATHETER (2WAY/3WAY)(OKJO)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER.,IV ADMINISTRATION SET WITH/WITHOUT EXTENSION SET(1.GENERIC,2. KENAFLEXX)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE SINGLE USE TRACHEOSTOMY TUBE (CUFFED)(OKJO)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH AIRVENT(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH,4. RED BULB,5.SANBAO)-IT IS USED TO

	ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., STERILE DISPOSABLE SINGLE USE DEODENAL RYLE'S TUBE(1. GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,STERILE DISPOSABLE SINGLE USE A.V. FISTULA NEEDLE(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT.,STERILE DISPOSABLE SINGLE USE IV EXTENSION SET(1.GENERIC, 2. DYNAREX)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITHOUT AIRVENT(1. GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH,4. RED BULB,5.SANBAO)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SINGLE USE NASAL OXYGEN CATHETER / OXYGEN CONNECTING TUBE(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY NEED OF RESPIRATORY HELP.,STERILE DISPOSABLE SINGLE USE LEVIN'S TUBE(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,STERILE DISPOSABLE SINGLE USE EXTENSION TUBE(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH,5.BIRSET)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS., STERILE DISPOSABLE SINGLE USE MINIVAC SET(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH,4. RED BULB)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS,STERILE DISPOSABLE MEASURED VOLUME INFUSION BURETTE SET WITH / WITHOUT AIRVENT(1. GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE SINGLE USE INFANT MUCUS EXTRACTOR WITH FILTER(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-MUCUS EXTRACTOR IS USED TO EXTRACT MUCUS FROM INFANT,INFUSION SET WITH AIRVENT WITH PRECISION FLOW

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	CONTROLLER DIAL TYPE(1.GENERIC, 2. ASCO)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE SINGLE USE INFANT FEEDING TUBE(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING, STERILE DISPOSABLE SINGLE USE CLOSED WOUND SUCTION UNIT(1. GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH, 4.RED BULB)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS,STERILE DISPOSABLE SINGLE USE IV ADMINISTRATION SET(1.GENERIC,2.DYNAREX)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SINGLE USE STOMACH TUBE(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID., STERILE DISPOSABLE SINGLE USE 3 WAY STOPCOCK(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,STERILE DISPOSABLE SINGLE USE ENDOTRACHEAL TUBE (REINFORCED)-PLAIN(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., STERILE DISPOSABLE SINGLE USE SUCTION CATHETER WITH THUMB CONTROLLER(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,IV ADMINISTRATION INFUSION SET(1.GENERIC,2. MERIT)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SINGLE USE HAEMODIALYSIS BLOOD TUBING SET (DIALYSIS BLOOD LINE)(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT.,STERILE DISPOSABLE IV SOLUTION ADMINISTRATION SET WITH/WITHOUT AIRVENT(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH,4.EXOCARE,5.SANBAO)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., IV SET WITH AIRVENT(1.GENERIC,2.CHEMOTAXEL)-TRANSFUSION SET

	IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH AIRVENT(QATAR PHARMA)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET VENTED(1.GENERIC, 2. ANGELTOUCH, 3. DISPOTOUCH)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SINGLE USE UMBILICAL CATHETER(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS.,STERILE DISPOSABLE SINGLE USE TRACHEOSTOMY TUBE (PLAIN)(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., STERILE DISPOSABLE SINGLE USE ENDOTRACHEAL TUBE (CUFFED)(1. GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,STERILE DISPOSABLE SINGLE USE ENDOTRACHEAL TUBE (REINFORCED)-CUFFED(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,STERILE DISPOSABLE SINGLE USE IV CANNULA WITH WINGS AND INJECTION PORT(1. GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS DRUGS AND OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE SINGLE USE ENDOTRACHEAL TUBE (PLAIN)(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., STERILE DISPOSABLE SINGLE USE NELATON / URETHRAL CATHETER (1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY,STERILE DISPOSABLE SINGLE USE RYLE'S TUBE(1. GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH

	THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES,STERILE DISPOSABLE SINGLE USE URETHRAL INDWELLING DOUBLE PIGTAIL STENT SET(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THE STERILE URECATH STENT SET IS USED FOR TEMPORARY INTERNAL DRAINAGE FROM THE URETROPELVIC JUNCTION TO THE BLADDER.,STERILE DISPOSABLE SINGLE USE PERITONEAL DIALYSIS CATHTER KIT(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THE STERILE PERITONEAL DIALYSIS CATHETER KIT IS A MEDICAL DEVICE USED FOR THE PATIENT WITH SEVERE CHRONIC KIDNEY DISEASE,STERILE DISPOSABLE SINGLE USE RECTAL CATHETER(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH) -IT IS INSERTED INTO THE RECTUM IN ORDER TO RELIEVE FLATULENCE WHICH HAS BEEN CHRONIC AND WHICH HAS NOT BEEN ALLEVIATED BY OTHER METHODS.,STERILE DISPOSABLE SINGLE USE SYRINGE 2ML WITH/WITHOUT NEEDLE(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH,4.SANBAO)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE DISPOSABLE SINGLE USE DOUBLE SWIVEL MOUNT (CATHETER T MOUNT)(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THE STERILE DOUBLE SWIVEL MOUNT WHICH IS AN INSTRUMENT USED IN ANESTHESIOLOGY, STERILE DISPOSABLE SINGLE USE KARMAN CANNULA WITH OR WITHOUT ADAPTOR(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)- THE STERILE KARMAN CANNULA IS USED FOR ASEPTIC MEDICAL TERMINATION OF PREGNANCY.,STERILE DISPOSABLE SINGLE USE MALE EXTERNAL CATHTER (SMALL, MEDIUM, LARGE, EXTRA LARGE) (1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THE STERILE MALE EXTERNAL CATHETER IS USED IN MALE PATIENT FOR URINE INCONTINENCE FOR DAY AND NIGHT.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIRVENT WITH PRECISION FLOW CONTROLLER DIAL TYPE(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH)- TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SINGLE USE YANKAUER SUCTION SET (VACCUM SUCTION SET)(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THE STERILE VACUUM SUCTION SET IS USED FOR GENERAL SUCTION PURPOSES. IT IS USED FOR REMOVAL THE SECRETION OR IRRIGATION FLUID DURING OPERATION OF DELIVERY FROM THE HUMAN BODY.,STERILE DISPOSABLE SINGLE USE SAFTEY CANNULA(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS DRUGS AND OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE SINGLE USE SYRINGE 3ML WITH / WITHOUT NEEDLE(1.GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH,4.SANBAO)-INTEND TO INJECT FLUIDS

	INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE DISPOSABLE SINGLE USE SUCTION CATHETER(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,STERILE DISPOSABLE INFUSION SET WITH AIRVENT(1. GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH, 4.RED BULB)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SINGLE USE SILICON WOUND SUCTION UNIT(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,STERILE DISPOSABLE SINGLE USE NASOPHARYNGEAL AIRWAY(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-A CATHETER (FOR ADULTS) PASSED THROUGH THE NARES AND ADVANCED TO THE DEPTH OF THE NASOPHARYNX TO REMOVE AIR CHOKE OR OBSTRUCTION.,STERILE DISPOSABLE SINGLE USE SYRINGE 20ML WITH / WITHOUT NEEDLE(1. GENERIC,2. ANGELTOUCH, 3.DISPOTOUCH,4.SANBAO)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY., STERILE DISPOSABLE SINGLE USE INFANT MUCUS EXTRACTOR(1. GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-MUCUS EXTRACTOR IS USED TO EXTRACT MUCUS FROM INFANT,STERILE DISPOSABLE SINGLE USE ABDOMINAL DRAIN KIT(1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THIS DEVICE IS USED FOR REMOVING ABDOMINAL FLUID FROM HUMAN BODY.,STERILE DISPOSABLE SINGLE USE PERCUTANEOUS PIGTAIL NEPHROSTOMY CATHETER SET(1.GENERIC, 2. ANGELTOUCH, 3. DISPOTOUCH)-A NEPHROSTOMY IS A TUBE THAT' S USED TO DRAIN URINE FROM A KIDNEY INTO A BAG OUTSIDE THE BODY.,STERILE DISPOSABLE SINGLE USE LARYNGEAL MASK AIRWAY (1.GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THE STERILE LARYNGEAL MASK IS A MEDICAL DEVICE USED TO KEEP A PATIENT'S AIRWAY OPEN DURING ANAESTHESIA OR UNCONSCIOUSNESS., STERILE DISPOSABLE SINGLE USE PERITONEAL DIALYSIS SET(1. GENERIC,2. ANGELTOUCH, 3. DISPOTOUCH)-THAT ALLOWS DIALYSIS FLUID TO ENTER THE ABDOMINAL CAVITY, DWELL INSIDE FOR A WHILE AND THEN DRAIN BACK OUT AGAIN.

3229	MFG/MD/2019/000091	1.License Holder Name: HINDUSTAN SYRINGES & MEDICAL DEVICES LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:INTRA VENOUS CANNULA (KITKATH+, CATHY , CATHULA, CATHY+ , CATHULA+, CLIP®VEN, CLIP®NEO, CLIP®PORTED, CLIP® WINGED)-INTRAVENUS /INTRAVASCULAR ACCESS FOR SHORT TERM PERIPHERAL CANNULATION,SINGLE USE SYRINGE(DISPOJEKT)-INJECTION / ASPIRATION / ADMINISTRATION OF FLUIDS,PEN NEEDLE(DISPOVAN)-PEN NEEDLES TO BE USED WITH INSULIN INJECTOR FOR INJECTING INSULIN TO PATIENT WITH DIABETES,SINGLE USE SYRINGE (DISPOVAN, UNOLOK, KOJAK AND PERFEKTUM)-INJECTION / ASPIRATION / ADMINISTRATION OF FLUIDS.

3230	MFG/MD/2019/000092	1.License Holder Name: TULSI ORTHO 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATE(TULSI ORTHO, ARISE)-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURES IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREWS TO PROPERLY ALIGN THE FRACTURED BONE,PINS AND WIRES(TULSI ORTHO, ARISE)-PINS AND WIRES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS AND WIRE SUPPORT FIX THE BONE PLATES.,MAXILLOFACIAL IMPLANT(TULSI ORTHO, ARISE)-MAXILLOFACIAL IMPLANTS ARE USED IN MAXILLOFACIAL FRACTURES,SPINAL IMPLANT(TULSI ORTHO, ARISE)-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE,BONE PLATE(TULSI ORTHO, ARISE)-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURES IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREWS TO PROPERLY ALIGN THE FRACTURED BONE,BONE SCREW(TULSI ORTHO, ARISE)-BONE SCREW IS USED TO FIXING FRACTURE. WITH THE HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES,BONE NAIL(TULSI ORTHO, ARISE)-BONE NAILS ARE USED IN HUMERUS BONE, TIBIA BONE, FEMUR BONE, WHERE FOUND THE FRACTURES IN PROXIMAL AND DISTAL AREA. ALL TYPES OF BONE NAILS ARE USED INSIDE THE BONE AND ITS PASS THROUGH FRACTURES AND HOLD THE FRACTURES WITH THE HELP OF BONE SCREWS. AND ITS MINIMAL INSERTION SURGERY., BONE SCREW(TULSI ORTHO, ARISE)-BONE SCREW IS USED TO FIXING FRACTURE. WITH THE HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES,BONE NAIL (TULSI ORTHO, ARISE)-BONE NAILS ARE USED IN HUMERUS BONE, TIBIA BONE, FEMUR BONE, WHERE FOUND THE FRACTURES IN PROXIMAL AND DISTAL AREA. ALL TYPES OF BONE NAILS ARE USED INSIDE THE BONE AND ITS PASS THROUGH FRACTURES AND HOLD THE FRACTURES WITH THE HELP OF BONE SCREWS. AND ITS MINIMAL INSERTION SURGERY.,TOTAL HIP REPLACEMENT SYSTEM(TULSI ORTHO, ARISE)-TOTAL HIP REPLACEMENT SYSTEM ARE USED IN PROXIMAL FEMUR BONE FRACTURES, WHERE IS FEMUR PROXIMAL AREA ARE FRACTURED BADLY, THE SURGEON REMOVED PROXIMAL AREA AND THEY FIXED ENDO PROSTHESIS AND FIX WITH FEMUR DISTAL PART.,PINS AND WIRES(TULSI ORTHO, ARISE)-PINS AND WIRES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS AND WIRE SUPPORT FIX THE BONE PLATES.

3231	MFG/MD/2019/000093	1.License Holder Name: PIVOT FABRIQUE 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANTS(PIVOT FABRIQUE)-DENTAL IMPLANTS ARE TINY TITANIUM SCREWS THAT ARE SURGICALLY PLACED IN THE JAWBONE. THESE IMPLANTS ARE MEANT TO ACT AS REPLACEMENT TOOTH ROOTS

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3232	MFG/MD/2019/000094	1.License Holder Name: EAGLE OPTICS PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:CAPSULAR TENSION RING / ENDO CAPSULAR RING / CTR-CAPSULAR TENSION RINGS (CTR) ARE IMPLANTED IN HUMAN EYE PRIOR TO THE IOL IMPLANT DURING THE CATARACT SURGERY FOR EXPANSION & STABILIZATION OF THE CAPSULAR BAG TO FACILITATE IOL IMPLANTATION & MAINTAINING EXCELLENT IOL CENTRATION.,CAPSULAR TENSION RING / ENDO CAPSULAR RING / CTR(INTRAOPTICS)-CAPSULAR TENSION RINGS (CTR) ARE IMPLANTED IN HUMAN EYE PRIOR TO THE IOL IMPLANT DURING THE CATARACT SURGERY FOR EXPANSION & STABILIZATION OF THE CAPSULAR BAG TO FACILITATE IOL IMPLANTATION & MAINTAINING EXCELLENT IOL CENTRATION.,CAPSULAR TENSION RING / ENDO CAPSULAR RING / CTR(TEXEL)-CAPSULAR TENSION RINGS (CTR) ARE IMPLANTED IN HUMAN EYE PRIOR TO THE IOL IMPLANT DURING THE CATARACT SURGERY FOR EXPANSION & STABILIZATION OF THE CAPSULAR BAG TO FACILITATE IOL IMPLANTATION & MAINTAINING EXCELLENT IOL CENTRATION.,PMMA IOL(EPOCH)-INTRAOCULAR LENSES (IOL) ARE IMPLANTED IN HUMAN EYE AS A REPLACEMENT OF HUMAN CRYSTALLINE LENS IN CATARACT SURGERY.,HYDROPHILIC ACRYLIC IOL / FOLDABLE IOL (INTRAOPTICS)-INTRAOCULAR LENSES (IOL) ARE IMPLANTED IN HUMAN EYE AS A REPLACEMENT OF HUMAN CRYSTALLINE LENS IN CATARACT SURGERY,HYDROPHILIC ACRYLIC IOL / FOLDABLE IOL (INTRAOPTICS)-INTRAOCULAR LENSES (IOL) ARE IMPLANTED IN HUMAN EYE AS A REPLACEMENT OF HUMAN CRYSTALLINE LENS IN CATARACT SURGERY.,PMMA IOL(INTRAOPTICS)-INTRAOCULAR LENSES (IOL) ARE IMPLANTED IN HUMAN EYE AS A REPLACEMENT OF HUMAN CRYSTALLINE LENS IN CATARACT SURGERY.,HYDROPHILIC ACRYLIC IOL / FOLDABLE IOL-INTRAOCULAR LENSES (IOL) ARE IMPLANTED IN HUMAN EYE AS A REPLACEMENT OF HUMAN CRYSTALLINE LENS IN CATARACT SURGERY.,PMMA IOL-INTRAOCULAR LENSES (IOL) ARE IMPLANTED IN HUMAN EYE AS A REPLACEMENT OF HUMAN CRYSTALLINE LENS IN CATARACT SURGERY.,HYDROPHILIC ACRYLIC IOL / FOLDABLE IOL(TEXEL SOFT)-INTRAOCULAR LENSES (IOL) ARE IMPLANTED IN HUMAN EYE AS A REPLACEMENT OF HUMAN CRYSTALLINE LENS IN CATARACT SURGERY,HYDROPHILIC ACRYLIC IOL / FOLDABLE IOL(TEXEL SOFT)-INTRAOCULAR LENSES (IOL) ARE IMPLANTED IN HUMAN EYE AS A REPLACEMENT OF HUMAN CRYSTALLINE LENS IN CATARACT SURGERY,PMMA IOL(TEXEL)-INTRAOCULAR LENSES (IOL) ARE IMPLANTED IN HUMAN EYE AS A REPLACEMENT OF HUMAN CRYSTALLINE LENS IN CATARACT SURGERY.

3233	MFG/MD/2019/000095	1.License Holder Name: A V PROCESSOR PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NON-ABSORBABLE SURGICAL BONE WAX FOR GAMMA STERILIZATION PURPOSE ONLY (CENTIIWAX)-BONE WAX IS A WAXY SUBSTANCE USED TO HELP MECHANICALLY CONTROL BLEEDING FROM BONE SURFACES DURING SURGICAL PROCEDURES.,ABSORBABLE HEMOSTAT OXIDIZED REGENRATED CELLULOSE USP FOR GAMMA STERILIZATION PURPOSE ONLY-ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS, AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE.

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3234	MFG/MD/2019/000096	1.License Holder Name: HLL LIFECARE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION, PVC BLOODBAGS(HL HAEMOPACK, DONATO, COLBA, IDA, UPS FLEX, DONOPACK)-STORAGE OF WHOLE BLOOD AND COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION, PVC BLOODBAGS(HL HAEMOPACK, DONATO, COLBA, IDA, UPS FLEX, DONOPACK)-STORAGE OF WHOLE BLOOD AND ITS COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATEDEXTROSE SOLUTION-PVC BLOODBAGS(HL HAEMOPACK, DONATO, COLBA, IDA, UPS FLEX, DONOPACK)-STORAGE OF WHOLE BLOOD AND ITS COMPONENTS., ANTICOAGULANT CITRATE DEXTROSE SOLUTION B-PVC BLOODBAGS (HL HAEMOPACK, DONATO, COLBA, IDA, UPS FLEX, DONOPACK)-STORAGE OF WHOLE BLOOD AND ITS COMPONENTS.,SODIUM CHLORIDE ADENINE GLUCOSE MANNITOL-2(SAGM-2 ADDITIVE SOLUTION)PVC TRANSFER BAGS(HL HAEMOPACK, DONATO, COLBA, IDA, UPS FLEX, DONOPACK)-STORAGE OF WHOLE BLOOD AND ITS COMPONENTS.,SODIUM CHLORIDE ADENINE GLUCOSE MANNITOL (SAGM ADDITIVE SOLUTION)PVC TRANSFER BAGS(HL HAEMOPACK, DONATO, COLBA, IDA, UPS FLEX, DONOPACK)-STORAGE OF WHOLE BLOOD AND ITS COMPONENTS.,ANTICOAGULANT CITRATE DEXTROSE SOLUTION A-.PVC BLOODBAGS(HL HAEMOPACK, DONATO, COLBA, IDA, UPS FLEX, DONOPACK)-STORAGE OF WHOLE BLOOD AND COMPONENTS,SODIUM CHLORIDE ADENINE GLUCOSE MANNITOL-1(SAGM-1ADDITIVE SOLUTION) IN PVC TRANSFER BAGS (HL HAEMOPACK, DONATO, COLBA, IDA, UPS FLEX, DONOPACK)-STORAGE OF WHOLE BLOOD AND ITS COMPONENTS.,PLASTIC COLLAPSIBLE CONTAINERS FOR HUMAN BLOOD AND BLOOD COMPONENTS(HL HAEMOPACK, DONATO, COLBA, IDA, UPS FLEX, DONOPACK)-1. COLLECTION, TRANSPORT, STORAGE AND ADMINISTRATION OF WHOLE HUMAN BLOOD. 2. SEPARATION, STORAGE, TRANSPORT AND ADMINISTRATION OF BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION-1 (CPDA-1)(HL HAEMOPACK, DONATO, COLBA, IDA, UPS FLEX, DONOPACK, EUROMED, PROTEK)-FOR COLLECTION, PRESERVATION, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF WHOLE BLOOD AND ITS COMPONENTS. FOR COLLECTION, PRESERVATION, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF RED BLOOD CELLS.

3235	MFG/MD/2019/000097	1.License Holder Name: ADARSH SURGICAL 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATE(AS)-BONE PLATE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURE, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PLATES(AS)-BONE PLATE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURE, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE SCREWS(AS)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE. ,BONE WIRE(AS)-BONE WIRE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURE, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,SPINAL IMPLANTS(AS)-SPINAL IMPLANTS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE,BONE NAILS(AS)-BONE NAILS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURE, FUSION OF JOINT OR TISSUE FIXATION OR ANCHORAGE.,BONE WIRE(AS)-BONE WIRE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURE, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,SPINAL IMPLANT(AS)-SPINAL IMPLANT SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURE, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PIN(AS)-BONE PIN SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURE, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PINS(AS)-BONE PINS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE NAILS(AS)-BONE NAILS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURE, FUSION OF JOINT OR TISSUE FIXATION OR ANCHORAGE.,BONE SCREW(AS)-BONE SCREW SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURE, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.
3236	MFG/MD/2019/000098	1.License Holder Name: ROMSONS INTERNATIONAL UNIT-II 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:CONNECTING TUBE-FOR SUCTION DURING SURGERY

3237	MFG/MD/2019/000099	1.License Holder Name: MEDII HEAL SOLUTIIONS 2.Approving Authority: NAGPUR DIVISION 3.Device Name(Brand Name)-Intended Use:ELASTIC ADHESIVE BANDAGE-IT IS USED FOR STRAPPING - ANKLE , HAND , KNEE , WRIST . IT IS ALSO USED FOR HOLDING SURGICAL WOUND DRESSINGS IN PLACE ,ROLLER BANDAGE-IT IS USED TO COVER WOUNDS , TO KEEP DRESSINGS IN PLACE , TO APPLY PRESSURE OVER BLEEDING SITE , TO SUPPORT MEDICAL DEVICE SUCH AS SPLINTS .,CANNULA FIXATOR-IT IS USED TO HOLD INTRAVENOUS CANNULA IN PLACE OVER THE SKIN SURFACE,ELASTIC CREPE BANDAGE-ELASTIC CREPE BANDAGE IS USED TO TREAT MUSCLE SPRAINS AND STRAINS BY REDUCING BLOOD FLOW TO A PARTICULAR AREA BY APPLICATION OF EVEN STABLE PRESSURE . USED IN VARICOSE VEINS .,GAMJEE ROLL-IT IS APPLIED OVER DRESSINGS TO HOLD THE BANDAGING POINT ,GAUZE SWAB-USED FOR WOUND DRESSING , PADDING , PROTECTION , ABSORPTION OF BODILY FLUIDS,CAST PAD-THE CAST PAD IS USED FOR CUSHIONING UNDER THE SYNTHETIC / PLASTER OF PARIS BANDAGE ,GAUZE MOPS / SPONGES-GAUZE MOPS / SPONGES ARE USED FOR SOAKING / ABSORBING BODILY FLUIDS .
3238	MFG/MD/2019/000100	1.License Holder Name: MITRA INDUSTRIES PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:TRACHEOBRONCHIAL STENTS(BRAVO)-FOR PALLIATIVE TREATMENT OF TRACHEOBRONCHIAL TRACT'S OBSTRUCTION ETC.,ESOPHAGEAL STENTS(BRAVO)-FOR PALLIATIVE TREATMENT OF GASTROINTESTINAL TRACT BY PROVIDING MECHANICAL STRENGTH TO THESE BODY PARTS.,URETHRAL STENTS(HONTO)-FOR PALLIATIVE TREATMENT OF URETHRAL DUCT'S OBSTRUCTION CAUSED BY MALIGNANT TUMOR ETC.,PYLORIC/DUODENAL STENTS (HONTO)-FOR PALLIATIVE TREATMENT OF PYLORIC/DUODENAL OBSTRUCTION CAUSED BY TUMORS ETC.,BILIARY STENTS(HONTO)-FOR PALLIATIVE TREATMENT OF BILE DUCT OBSTRUCTION.,COLO-RECTAL STENTS(HONTO)-FOR PALLIATIVE TREATMENT OF COLO-RECTAL TRACT.,PANCREATIC STENTS(HONTO)-FOR PALLIATIVE TREATMENT OF PANCREATIC DUCT'S OBSTRUCTION ETC.

3239	MFG/MD/2019/000101	1.License Holder Name: EKTA SURGICAL 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE SCREW(EKTA)-BONE SCREW IS USED FIXING FRACTURE WITH THE HELP OF BONE SCREW, BONE PLATE FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES.,BONE SCREW(EKTA)-BONE SCREW IS USED FIXING FRACTURE WITH THE HELP OF BONE SCREW, BONE PLATE FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES.,BONE PLATE (EKTA)-BONE PLATE IS AN ORTHOPAEDIC IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURES IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREWS TO PROPERLY ALIGN THE FRACTURE BONE.,BONE PLATE(EKTA)-BONE PLATE IS AN ORTHOPAEDIC IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURES IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREWS TO PROPERLY ALIGN THE FRACTURE BONE.
3240	MFG/MD/2019/000102	1.License Holder Name: GAMMA AGRO MEDICAL PROCESSINGS PVT. LTD 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:ALCOHOL PREPARATION PADS-SKIN CLEANSER BEFORE INJECTION
3241	MFG/MD/2019/000103	1.License Holder Name: FLEXUS SURGICALS PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:CORN-CAPS(HI-AID)-FOR REMOVAL OF CORNS AND CALLUSES,MICROPOROUS NON-WOVEN PAPER TAPE(HI-AID)-FOR USED AS DRESSING MATERIAL,FIRST AID BANDAGE(HI-AID)-FOR FIRST AID DRESSING USED IN MINOR CUTS AND GRAZES AND BURNS,BELLADONA PLASTER(HI-AID)-FOR USED IN PAIN ,MUMPS & MUSCLE STIFNESS,ADHESIVE TAPE(HI-AID)-FOR SURGICAL DRESSING MATERIAL

3242	MFG/MD/2019/000104	1.License Holder Name: ANONDITA HEALTHCARE 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:NATURAL RUBBER LATEX CONDOM (DOTTED WITH DRUG BENZOCAINE)(COBRA EXTRA TIME CONDOM)-IT IS USED FOR CONTRACEPTION AND FOR PROPHYLACTIC PURPOSE TO HELP REDUCE THE RISK OF PREGNANCY AND TRANSMISSION OF SEXUALLY TRANSMITTED DISEASES (STDS).,NATURAL RUBBER LATEX CONDOM- FEMALE(MID NIGHT, COBRA PREMIUM)-INTENDED USE OF NATURAL RUBBER LATEX CONDOM IS TO REDUCE THE RISK OF TRANSMISSION OF HIV (AIDS) & MANY OTHER SEXUAL TRANSMITTED INFECTIONS (STI).IT IS FOR SINGLE USE ONLY.IT ENHANCES OR EXTENDS THE TIMING AND INTIMACY OF INTIMATE MOMENTS.IT PREVENT PREMATURE EJACULATION,NATURAL RUBBER LATEX MALE CONDOM (MULTI TEXTURED)(AM PM)-INTENDED USE OF NATURAL RUBBER LATEX CONDOM IS TO REDUCE THE RISK OF TRANSMISSION OF HIV (AIDS) & MANY OTHER SEXUAL TRANSMITTED INFECTIONS (STI).IT IS ALSO USED AS CONTRACEPTIVE FOR PREVENTION OF PREGNANCY. IT IS FOR SINGLE USE ONLY.,NATURAL RUBBER LATEX MALE CONDOM (LOVE TIME, COBRA, ENJOY, MID NIGHT, VIGORE, VIGI FORCE, FORCE, NIGHT KING, TAMANNA, MORE FUN, EKLAMHA, BARKHAT, MELT-ME, COBRA PREMIUM, NIRODH, ASHA, STYLE, THRIL, DELUX NIRODH, MITHUN, DELUCA. STROKE, MAGIC MOMENT, PLAY NIGHT, RED NIGHT, FEELS, GOOD FEEL, 6XE, LUV CHOICE, VICOGRA, FUNKEY, MENCOUR, LOVE FORCE)-INTENDED USE OF NATURAL RUBBER LATEX CONDOM IS TO REDUCE THE RISK OF TRANSMISSION OF HIV (AIDS) & MANY OTHER SEXUAL TRANSMITTED INFECTIONS (STI).IT IS ALSO USED AS CONTRACEPTIVE FOR PREVENTION OF PREGNANCY. IT IS FOR SINGLE USE ONLY.,NATURAL RUBBER LATEX MALE CONDOM (PLAIN) (WARNIGHT)-INTENDED USE OF NATURAL RUBBER LATEX CONDOM IS TO REDUCE THE RISK OF TRANSMISSION OF HIV (AIDS) & MANY OTHER SEXUAL TRANSMITTED INFECTIONS (STI).IT IS ALSO USED AS CONTRACEPTIVE FOR PREVENTION OF PREGNANCY. IT IS FOR SINGLE USE ONLY.,NATURAL RUBBER LATEX MALE CONDOM (MULTI TEXTURED)(DARK HORSE)-INTENDED USE OF NATURAL RUBBER LATEX CONDOM IS TO REDUCE THE RISK OF TRANSMISSION OF HIV (AIDS) & MANY OTHER SEXUAL TRANSMITTED INFECTIONS (STI).IT IS ALSO USED AS CONTRACEPTIVE FORPREVENTION OF PREGNANCY. IT IS FOR SINGLE USE ONLY.,NATURAL RUBBER LATEX MALE CONDOM (MULTI TEXTURED)(MAGIC SHOT)-INTENDED USE OF NATURAL RUBBER LATEX CONDOM IS TO REDUCE THE RISK OF TRANSMISSION OF HIV (AIDS) & MANY OTHER SEXUAL TRANSMITTED INFECTIONS (STI).IT IS ALSO USED AS CONTRACEPTIVE FOR PREVENTION OF PREGNANCY. IT IS FOR SINGLE USE ONLY.,NATURAL RUBBER LATEX

	MALE CONDOM (DOTTED WITH DRUG BENZOCAINE, (4.5% W/W)) (ENJOY, MID NIGHT, VIGORE, FORCE, NIGHT KING, COBRA PREMIUM, PLAY NIGHT, RED NIGHT, FEELS, GOOD FEEL, LUV CHOICE, VICOGRA, FUNKEY, MENCOUR, LOVE FORCE)-IT IS USED FOR CONTRACEPTION AND FOR PROPHYLACTIC PURPOSE TO HELP TO REDUCE THE RISK OF PREGNANCY AND TRANSMISSION OF SEXUALLY TRANSMITTED DISEASES.,NATURAL RUBBER LATEX MALE CONDOM (DOTTED) (MANJOY)-INTENDED USE OF NATURAL RUBBER LATEX CONDOM IS TO REDUCE THE RISK OF TRANSMISSION OF HIV (AIDS) & MANY OTHER SEXUAL TRANSMITTED INFECTIONS (STI).IT IS ALSO USED AS CONTRACEPTIVE FOR PREVENTION OF PREGNANCY. IT IS FOR SINGLE USE ONLY.,NATURAL RUBBER LATEX MALE CONDOM (DOTTED)(WARNIGHT)-INTENDED USE OF NATURAL RUBBER LATEX CONDOM IS TO REDUCE THE RISK OF TRANSMISSION OF HIV (AIDS) & MANY OTHER SEXUAL TRANSMITTED INFECTIONS (STI).IT IS ALSO USED AS CONTRACEPTIVE FOR PREVENTION OF PREGNANCY. IT IS FOR SINGLE USE ONLY.,NATURAL RUBBER LATEX MALE CONDOM (MULTI TEXTURED)(MANJOY)-INTENDED USE OF NATURAL RUBBER LATEX CONDOM IS TO REDUCE THE RISK OF TRANSMISSION OF HIV (AIDS) & MANY OTHER SEXUAL TRANSMITTED INFECTIONS (STI).IT IS ALSO USED AS CONTRACEPTIVE FOR PREVENTION OF PREGNANCY. IT IS FOR SINGLE USE ONLY.,NATURAL RUBBER LATEX MALE CONDOM (MULTI-TEXTURED WITH DRUG BENZOCAINE, (4.5% W/W)) (6XE FUN)-IT IS USED FOR CONTRACEPTION AND FOR PROPHYLACTIC PURPOSE TO HELP TO REDUCE THE RISK OF PREGNANCY AND TRANSMISSION OF SEXUALLY TRANSMITTED DISEASES.,NATURAL RUBBER LATEX MALE CONDOM (MULTI TEXTURED)(WARNIGHT)-INTENDED USE OF NATURAL RUBBER LATEX CONDOM IS TO REDUCE THE RISK OF TRANSMISSION OF HIV (AIDS) & MANY OTHER SEXUAL TRANSMITTED INFECTIONS (STI).IT IS ALSO USED AS CONTRACEPTIVE FOR PREVENTION OF PREGNANCY. IT IS FOR SINGLE USE ONLY.,NATURAL RUBBER LATEX MALE CONDOM (DOTTED)(M-FORCE)-INTENDED USE OF NATURAL RUBBER LATEX CONDOM IS TO REDUCE THE RISK OF TRANSMISSION OF HIV (AIDS) & MANY OTHER SEXUAL TRANSMITTED INFECTIONS (STI).IT IS ALSO USED AS CONTRACEPTIVE FOR PREVENTION OF PREGNANCY. IT IS FOR SINGLE USE ONLY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO BY THE CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3243	MFG/MD/2019/000105	1.License Holder Name: INNVOL MEDICAL INDIA LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION (CPD SOLUTION) IP (JMS-BLOOD COLLECTION BAG- CPD)-BLOOD BAG SYSTEMS FOR COLLECTION OF BLOOD AND BLOOD PRODUCTS INTENDED TO BE USED CLINICALLY FOR COLLECTION, STORAGE AND TRANSFUSION OF HUMAN WHOLE BLOOD AND STORAGE AND TRANSFUSION OF BLOOD COMPONENTS,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION (CPD SOLUTION) IP(JMS-BLOOD COLLECTION BAG- CPD)-BLOOD BAG SYSTEMS FOR COLLECTION OF BLOOD AND BLOOD PRODUCTS INTENDED TO BE USED CLINICALLY FOR COLLECTION, STORAGE AND TRANSFUSION OF HUMAN WHOLE BLOOD AND STORAGE AND TRANSFUSION OF BLOOD COMPONENTS, SODIUM CHLORIDE ADENINE GLUCOSE MANNITOL SOLUTION (SAGM SOLUTION)(JMS-BLOOD COLLECTION BAG- CPD-SAGM)-BLOOD BAG SYSTEMS FOR COLLECTION OF BLOOD AND BLOOD PRODUCTS INTENDED TO BE USED CLINICALLY FOR COLLECTION, STORAGE AND TRANSFUSION OF HUMAN WHOLE BLOOD AND STORAGE AND TRANSFUSION OF BLOOD COMPONENTS,SODIUM CHLORIDE ADENINE GLUCOSE MANNITOL SOLUTION (SAGM SOLUTION)(JMS-BLOOD COLLECTION BAG- CPD-SAGM)-BLOOD BAG SYSTEMS FOR COLLECTION OF BLOOD AND BLOOD PRODUCTS INTENDED TO BE USED CLINICALLY FOR COLLECTION, STORAGE AND TRANSFUSION OF HUMAN WHOLE BLOOD AND STORAGE AND TRANSFUSION OF BLOOD COMPONENTS,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION (CPDA SOLUTION) IP(JMS-BLOOD COLLECTION BAG- CPDA-1)-BLOOD BAG SYSTEMS FOR COLLECTION OF BLOOD AND BLOOD PRODUCTS INTENDED TO BE USED CLINICALLY FOR COLLECTION, STORAGE AND TRANSFUSION OF HUMAN WHOLE BLOOD AND STORAGE AND TRANSFUSION OF BLOOD COMPONENTS

3244	MFG/MD/2019/000106	1.License Holder Name: M/S DISPOSAFE HEALTH AND LIFE CARE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:FISTULA NEEDLE (A.V FISTULA NEEDLES)(NIL)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT.,INTRAVENOUS CANNULA(CEGAMED)- THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS, AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,EXTENSION SETS (EXTENSION TUBE) -HIGH PRESSURE AND LOW PRESSURE(NIL)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,INTRAVENOUS CANNULA(3 WAY CATH,ADVA-TEC,KARMAN-CATH,MASTER FIX, MASTER PEN)- THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,INTRAVENOUS CANNULA(FEEL FLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INTRAVENOUS CANNULA(MASTER-VET, MASTER CATH,MASTER FLO,OCEAN FLON,Q-FLASH)- THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,INTRAVENOUS CANNULA(ANGEL TOUCH,DOLPHIN,AJS,JAYZEE,MEDICATETER)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV FLOW REGULATOR(DISPOSABLE INTRAVENOUS SET WITH FLOW REGULATOR)(MULTI+PLUS)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY., NELATON CATHETER(NIL)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,SCALP VEIN SET(MEDECO)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENTS VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,FOLEY CATHETER (FOLEY BALLOON CATHETER)-ONE WAY, TWO WAY AND THREE WAY-ADULT AND PAEDIATRIC(NIL)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,

	INTRAVENOUS CANNULA(RAMYFLON,RAMYFLON-S,VY CAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,BLOOD COLLECTING NEEDLE (BLOOD COLLECTION NEEDLE)(NIL)-INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD.,IV FLOW REGULATOR(DISPOSABLE INTRAVENOUS SET WITH FLOW REGULATOR)(LIFE CARE)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,TRANSFUSION SETS FOR SINGLE USE (DISPOSABLE BLOOD TRANSFUSION SET)-VENTED/NON-VENTED (NIL)-TRANSFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,IV FLOW REGULATOR(FLOW REGULATOR AS AN ACCESSORY OF INFUSION SET)(LIFECARE)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,SUCTION TIP AND CATHETER (YANKAUER SET)(DISPOYANKAUER, IGNITE PLUS)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,EXTENSION SETS(THREE WAY STOPCOCK WITH EXTENSION TUBE-RED,BLUE AND WHITE HANDLE)(MULTI+PLUS)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,FOLEY CATHETER (FOLEY BALLOON CATHETER)-ONE WAY, TWO WAY AND THREE WAY-ADULT AND PAEDIATRIC (DISPO-FOLEYS)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., HYPODERMIC SYRINGE FOR SINGE USE(DISPOJECT)-INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY., FEEDING TUBE (INFANT FEEDING SET)(NIL)-A FEEDING TUBE IS A DEVICE THATS INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. ITS USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,INTRAVENOUS CANNULA(SAFE-LIFE,WAY CATH, FAXIFLON)- THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , INTRAVENOUS CANNULA(EMSIG,METAFLON,YILKAL,VEINTO,HEUER)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV CANNULA(NEOTEC-1)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD

	COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SUCTION TIP AND CATHETER (YANKAUER SET) (NIL)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., EXTENSION SETS(EXTENSION TUBE)-HIGH PRESSURE AND LOW PRESSURE(MULTI+PLUS)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,IV FLOW REGULATOR (FLOW REGULATOR AS AN ACCESSORY OF INFUSION SET)(IGNITE PLUS)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,PERFUSION SETS FOR SINGLE USE (DISPOSABLE INTRAVENOUS SET)-VENTED/NON VENTED (MULTI+PLUS)-PERFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,EXTENSION SETS (EXTENSION TUBE) -HIGH PRESSURE AND LOW PRESSURE(DISPOEX, CATH TEC,LEADCARE,PERIFLOW,PLASMED,NERVETEC,WINNER, MEDECO,TOPDESC,HEXACARE,HE,FRESCO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,THREE WAY STOPCOCK AS AN ACCESSORY TO PERFUSION SETS-RED,BLUE AND WHITE HANDLE(MULTI+PLUS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING,EXTENSION SETS (THREE WAY STOPCOCK WITH EXTENSION TUBE-RED,BLUE AND WHITE HANDLE)(NIL)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,I.V INFUSION SET-VENTED/ NON-VENTED(FEEL FLON)-PERFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,I IV FLOW REGULATOR (DISPOSABLE INTRAVENOUS SET WITH FLOW REGULATOR)(NIL)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,THREE WAY STOPCOCK AS AN ACCESSORY TO PERFUSION SETS-RED, BLUE AND WHITE HANDLE(VERONA)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,INTRAVENOUS CANNULA(NIL)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE

	THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INTRAVENOUS CANNULA(MEDEREN)- THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,PERFUSION SETS FOR SINGLE USE(DISPOSABLE INTRAVENOUS SET)-VENTED/NON VENTED,(NIL)-PERFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., INTRAVENOUS CANNULA(CANNORAL)- THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS, AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,PERFUSION SETS FOR SINGLE USE (DISPOSABLE INTRAVENOUS SET)-VENTED/NON VENTED(DISPOSET, DISPODRIP,TKL,TALGE,BECARE,ALL PRO,PERIFLOW,3MED,NERVETEC, WINNER)-PERFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,UMBILICAL OCCLUSION DEVICE (UMBILICAL CORD CLAMP)(IDL)-THESE DEVICES MAY BE A CLIP,TIE, TAPE OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT. ,NASAL OXYGEN CATHETER (TWIN BORE NASAL OXYGEN CATHETER)-ADULT, PAEDIATRIC & NEONATAL(MASTERFLON)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,FOLEY BALLOON CATHETER- ONE WAY, TWO WAY AND THREE WAY-ADULT AND PAEDIATRIC(BECT)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY. ,INTRAVENOUS CANNULA(DISPON,DISPOSAFE,DISPOCATH, TRIWAYCATH,DISPONEO,DISPOWAY, DISPOWING,LEADCARE, PENCATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., THREE WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS-RED, BLUE AND WHITE HANDLE(BECT)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,INTRAVENOUS CANNULA(NIRVANA, PRECISION,GOLDEN+,Q-FLON,SHILOHCATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS, AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INTRAVENOUS CANNULA(VERONA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO

	FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , SPINAL NEEDLES(NIL)-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM.,SURGICAL DRESSING (I.V FIXATOR)(MASTER FLON)-DRESSING AEROSOL,NON-ADHERENT, DRESSING,PERIODONTAL,KIT,DRESSING PAD,DRESSING./I.V FIXATOR USED FOR FIXING IV CANNULA/CATHETER FOR SECUREMENT.,SINGLE NEEDLE HEMODIALYSIS CATHETER/BLOOD LINES (HEMODIALYSIS BLOOD TUBING SET)(NIL)-THE SINGLE-NEEDLE DIALYSIS,IN WHICH CASE ONLY ONE CANNULA OR A SINGLE-LUMEN CATHETER IS USED TO ACCESS THE BLOOD.,INTRAVENOUS CANNULA(BECT)- THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,UMBILICAL OCCLUSION DEVICE (UMBILICAL CORD CLAMP)(IGNITE PLUS)-THESE DEVICES MAY BE A CLIP,TIE, TAPE OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,INTRAVENOUS CANNULA(MED-ONE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INTRAVENOUS CANNULA(BERIKA,REBONEL,QUIP,VEINFIX,VENFIC)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INTRAVENOUS CANNULA(GLOMED,CANOCARE)- THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,PERITONEAL DIALYSIS CATHETER(NIL) -THAT ALLOWS DIALYSIS FLUID TO ENTER THE ABDOMINAL CAVITY, DWELL INSIDE FOR A WHILE, AND THEN DRAIN BACK OUT AGAIN., FEEDING TUBE(IDL)-A FEEDING TUBE IS A DEVICE THATS INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. ITS USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,BLOOD COLLECTING NEEDLE (BLOOD COLLECTION SET)(NIL)-INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD.,THREE WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS- RED, BLUE AND WHITE HANDLE (DISPOWAY)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING., SINGLE NEEDLE HEMODIALYSIS CATHETER/BLOOD LINES (HEMODIALYSIS BLOOD TUBING SET)(DISPOSAFE)-THE SINGLE-NEEDLE DIALYSIS,IN WHICH CASE ONLY ONE CANNULA OR A SINGLE-

	LUMEN CATHETER IS USED TO ACCESS THE BLOOD.,FOLEY BALLOON CATHETER- ONE WAY, TWO WAY AND THREE WAY-ADULT AND PAEDIATRIC(LIFECARE)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,THREE WAY STOPCOCK AS AN ACCESSORY TO PERFUSION SETS-RED,BLUE AND WHITE HANDLE(NIL)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,TRACHEAL(ENDOTRACHEAL)TUBE(MASTER FLON)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,UMBILICAL OCCLUSION DEVICE (UMBILICAL CORD CLAMP)(DISPO-CLAMP,HEXACARE,ALLIED) -THESE DEVICES MAY BE A CLIP,TIE, TAPE OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS(VITASTA)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,MEASURED VOLUME IV SET(NIL)- IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,EXTENSION SETS (THREE WAY STOP COCK WITH EXTENSION TUBE)(VITASTA)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,IV FLOW REGULATOR (FLOW REGULATOR AS AN ACCESSORY OF INFUSION SET)(NIL)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,NELATON CATHETER (MASTER FLON)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., EXTENSION SETS (EXTENSION TUBE)-HIGH PRESSURE AND LOW PRESSURE(BIO-FLOW,PRIMA,NOKAST,LIFEN,SINOMEDIC,QY,ANGEL TOUCH,AJS,NATASO,BROMED,FLASH FLON,ALLIED)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,INTRAVENOUS CANNULA(SURGITECH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INTRAVENOUS CANNULA(ELVACATH,VENFIC SW®,

	VENFIC WP®,ALL PRO,PERIFLOW)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,DISPOSABLE INTRAVENOUS SET (MASTER FLON, VITASTA)-PERFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,NASAL OXYGEN CATHETER (TWIN BORE NASAL OXYGEN CATHETER TUBE)(IGNITE PLUS)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,INTRAVENOUS CANNULA(DESCARPACK)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SPINAL NEEDLES (DISPOSAFE)-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUIDS,DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM.,DISPOSABLE INTRAVENOUS SET (I.V INFUSION SET-VENTED/NON VENTED)(NIRVANA)-PERFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., HAEMODIALYSIS CATHETER (DISPOSAFE)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT.,EXTENSION SETS (EXTENSION TUBE)(VITASTA)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. , BLOOD COLLECTING NEEDLE (BLOOD COLLECTION SET)(DISPOSAFE) -INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD.,TRANSFUSION SETS FOR SINGLE USE(DISPOSABLE BLOOD TRANSFUSION SET)(MASTER FLON, VITASTA)-TRANSFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INTRAVENOUS CANNULA(VYGONULE(V),BIOVALVE SAFE,CADIFLO,ACCUFIX, CADIFLOW-NEO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., FOLEY CATHETER (FOLEY BALLOON CATHETER)(MASTER FLON)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,PERITONEAL DIALYSIS CATHETER(DISPOSAFE)-THAT ALLOWS DIALYSIS FLUID TO ENTER THE ABDOMINAL CAVITY,DWELL INSIDE FOR A WHILE, AND THEN DRAIN BACK OUT AGAIN.,SCALP VEIN SET(MASTER FLON)- INTENDED

	TO BE USED FOR INSERTION INTO THE PATIENTS VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,NELATON CATHETER(DISPOSAFE)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,MEASURED VOLUME IV SET(MASTER FLON, VITASTA)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,TRACHEOBRONCHIAL SUCTION CATHETER (MUCUS EXTRACTOR)(DISPOSAFE)-CLEANING THE AIRWAYS OF MUCUS,PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,INTRAVENOUS CANNULA(MASTER FLON,VITASTA,LAURA-CATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,EXTENSION SETS (EXTENSION TUBE)(DISPO-MULTI)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. , THREE WAY STOPCOCK(DESCARPACK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,FOLEY BALLOON CATHETER-ONE WAY,TWO WAY AND THREE WAY(NEOVAC)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,INTRAVENOUS CANNULA(DISPOFLON,SOFT MED)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,EXTENSION SETS (THREE WAY STOP COCK WITH EXTENSION TUBE)-BLUE,WHITE AND RED HANDLE(IGNITE PLUS)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,SUCTION TIP AND CATHETER (YANKAUER SET) (DISPOSAFE,ALLPRO,CATH TEC,LEADCARE,MEDECO, BROMED)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., INTRAVENOUS CANNULA(SP FLON PRIME)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS, AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SCALP VEIN SET(DISPOSCALP)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENTS

	VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD., TRACHEAL (ENDOTRACHEAL) TUBE-PLAIN AND CUFFED(DISPOSAFE, MEDECO)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,INTRAVENOUS CANNULA (SP FLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., PERFUSION SETS FOR SINGLE USE (I.V. INFUSION SET)-VENTED/NON-VENTED(SOM)-PERFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,TRANSFUSION SETS FOR SINGLE USE(BLOOD TRANSFUSION SET)-VENTED/NON-VENTED (SOM)-TRANSFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,SURGICAL DRESSING (I.V. FIXATOR)(DISPOFIX)-DRESSING,AEROSOL,NON ADHERENT, DRESSING,PERIODONTAL,KIT,DRESSING PAD DRESSING./I.V FIXATOR USED FOR FIXING IV CANNULA/CATHETER FOR SECUREMENT, INTRAVENOUS CANNULA(KAR-SET)- THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,INTRAVENOUS CANNULA(SOM)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,NASAL OXYGEN CATHETER (TWIN BORE NASAL OXYGEN CATHETER)-ADULT, PAEDIATRIC & NEONATAL(NASAL-SAFE,IGNITE PLUS)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,THREE WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS-BLUE, WHITE AND RED HANDLE(IGNITE PLUS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,INTRAVENOUS CANNULA(DISPOSAFE , DISPOSAFE , DISPOWAY , DISPOWAY ,DISPOSAFE TELE, DISPOSAFE ANN,DISPOINTRO,DISPOACTIVE,SAFE FLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,FEEDING TUBE (INFANT FEEDING SET)(DISPOSAFE FEEDY)-A FEEDING TUBE IS A DEVICE THATS INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. ITS USED TO SUPPLY NUTRITION WHEN YOU HAVE

	TROUBLE EATING., NELATON CATHETER(DISPOSAFE NELTO)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,INTRAVENOUS CANNULA(NERVETEC, WINNER,CATH TEC,MEDECO,BPI)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THREE WAY STOPCOCK AS AN ACCESSORY TO PERFUSION SETS-RED,BLUE AND WHITE HANDLE (DISPOFLEX,TKL,TALGE,BECARE,3A+, ALL PRO,PERIFLOW,PLASMED, 3MED,NERVETEC,WINNER,CATH TEC,LEADCARE,MEDECO,IPD LIFECARE,TOPDESC)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING., EXTENSION SETS(THREE WAY STOPCOCK WITH EXTENSION TUBE-RED,BLUE AND WHITE HANDLE)(PERIFLOW,PLASMED,3 MED, NERVETEC,WINNER,MEDECO,IPD LIFECARE,TOPDESC,HEXACARE,HE, FRESCO,BIO-FLOW,PRIMA,NOKAST,LIFEN)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,EXTENSION SETS (THREE WAY STOPCOCK WITH EXTENSION TUBE-RED,BLUE AND WHITE HANDLE)(SINOMEDIC,QY,ANGEL TOUCH,AJS,JAYZEE,NATASO, CK-PLUS,QUALIMAXX,CIRUGIA PERUANA,BROMED,FLASH FLON, RAMYPLUS,ALLIED)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,INTRAVENOUS CANNULA(NEOTEC,ALPHA FLOW, LIFETECH,QUALIMAXX,CIRUGIA PERUANA,LAURA-CATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THREE WAY STOPCOCK AS AN ACCESSORY TO PERFUSION SETS-RED,BLUE AND WHITE HANDLE(UWAY,ALPHA,MEDTAP,LIFE TECH,QUALIMAXX, CIRUGIA PERUANA,BROMED,FLASH FLON,RAMYFLEX,ALLIED)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,SCALP VEIN SET(DISPOSAFE,CATH TEC,LEADCARE,IDL)- INTENDED TO BE USED FOR INSERTION INTO THE PATIENTS VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,THREE WAY STOPCOCK AS AN ACCESSORY TO PERFUSION SETS-RED, BLUE AND WHITE HANDLE (NATASO,BERIKA,REBONEL,PHIDCARE,NET,MANAFLO,CK-FLEX,SIDA

	WAY,HICO,VY TAP,HEUER,GALENA,CADIFLO-TRIO,MORTON,NEOTEC)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,LEVINE TUBE (NIL)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,SUCTION TIP AND CATHETER (SUCTION CATHETER)-SUCTION PLAIN,WITH FINGER TIP CONTROL AND WITH THUMB CONTROL (NIL)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,I V FLOW REGULATOR (DISPOSABLE INTRAVENOUS SET WITH FLOW REGULATOR)(DISPOFLOW,DISPOSET,DISPODRIP)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,INTRAVENOUS CANNULA(UNIQUE-IN,AQ-CATH,MANAFLO,CK-FLON,CK-SAFE,CK-NEO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS, AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THREE WAY STOPCOCK-RED, BLUE AND WHITE HANDLE(LIFECARE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,IV CANNULA(LIFECARE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INTRAVENOUS CANNULA(MECYFLON,MEDISAFE,FRESCO,BIO-FLOW,PRIMA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THREE WAY STOPCOCK AS AN ACCESSORY TO PERFUSION SETS-RED,BLUE AND WHITE HANDLE(SAKAMED)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,INTRAVENOUS CANNULA(BROMED,FLASH FLON,REMYFLON,REMYFLON-S,FARCOCATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS, AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,EXTENSION SETS(THREE WAY STOPCOCK WITH EXTENSION TUBE-RED,BLUE AND WHITE HANDLE) (SAKAMED)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. , TRACHEAL (ENDOTRACHEAL) TUBE-PLAIN AND CUFFED(OPSET)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN

	INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,THREE WAY STOPCOCK AS AN ACCESSORY TO PERFUSION SETS-RED,BLUE AND WHITE HANDLE(HEXACARE,HE,FRESCO,BIO-FLOW,PRIMA,NOKAST,LIFEN, OPSET,SINOMEDIC,QY,ANGEL TOUCH,DOLPHIN,AJS,JAYZEE, MYMEDIC,IDL)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING., UMBLICAL ARTERY CATHETER (UMBLICAL CATHETER)(NIL)-UMBLICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE A SOURCE OF ARTERIAL BLOOD SAMPLING ,AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS.,MEASURED VOLUME IV SET(DISPOSAFE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,EXTENSION SETS (EXTENSION TUBE)-HIGH PRESSURE AND LOW PRESSURE(SAKAMED)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,TRANSFUSION SETS FOR SINGLE USE(DISPOSABLE BLOOD TRANSFUSION SET)-VENTED/NON-VENTED(DISPOSAFE,SAKAMED)-TRANSFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., FOLEY CATHETER (FOLEY BALLOON CATHETER)-ONE WAY, TWO WAY AND THREE WAY-ADULT AND PAEDIATRIC(DISPOSAFE,SAKAMED, OPSET,BROMED,GALENA)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,DISPOSABLE HYPODERMIC NEEDLES(ONE PRICK)-A SUBCUTANEOUS INJECTION IS A METHOD OF ADMINISTERING MEDICATION.,INTRAVENOUS CANNULA(DISPOSAFE,PILOT,SAKAMED) -THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., SUCTION TIP AND CATHETER (SUCTION CATHETER)-SUCTION PLAIN, WITH FINGER TIP CONTROL AND WITH THUMB CONTROL (SAKAMED)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,CLOSED WOUND DRAINAGE SYSTEM (CLOSED WOUND SUCTION SET)(SAFE VAC,ALL PRO,PERIFLOW,CATH TEC,LEADCARE,BROMED, FLASH FLON)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND.THEY ARE COMMONLY PLACED

	BY SURGEONS OR INTERVENTIONAL RADIOLOGIST.,INTRAVENOUS CANNULA(TKL,TALGE,BECARE,3A+,E-CARE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS, AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INTRAVENOUS CANNULA(MYMEDIC, UMA FLOW,LYDIAFLON-PRO,IDL,NATASO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS, AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INTRAVENOUS CANNULA(LIFE-SURG,CRITICAN,CRITIFLON,CRITINAN,HE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS, AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,NASAL OXYGEN CATHETER (TWIN BORE NASAL OXYGEN CATHETER)-ADULT,PAEDIATRIC & NEONATAL (NIL)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,TRANSFUSION SETS FOR SINGLE USE (DISPOSABLE BLOOD TRANSFUSION SET)-VENTED/NON-VENTED (DISPOFUSION,SAFE B.T,ALL PRO,3MED,NERVETEC,WINNER,CATH TEC,LEADCARE,MEDECO,IPD LIFECARE,SHILOHSET,IDL,FLASH FLON, ALLIED)-TRANSFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INTRAVENOUS CANNULA (GALENA,ECM,AG-CATH,VASO-CATH ADVANTIVE,VAGON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,IV FLOW REGULATOR (FLOW REGULATOR AS AN ACCESSORY OF INFUSION SET)(MULTI+PLUS)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,FEEDING TUBE (INFANT FEEDING SET)(DISPOSAFE,ALL PRO,MEDECO,IDL)-A FEEDING TUBE IS A DEVICE THATS INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. ITS USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,IV FLOW REGULATOR (FLOW REGULATOR AS AN ACCESSORY OF INFUSION SET)(DISPO FLOW, PERIFLOW,CATH TEC,LEADCARE)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,MEASURED VOLUME IV SET(DISPO M.V, DISPOVOLVE,TKL,TALGE,BECARE,3A+,ALL PRO,3MED,NERVETEC, WINNER,CATH TEC,LEADCARE,IPD LIFECARE,SHILOHSET,IDL, QUALIMAXX,CIRUGIA PERUANA,FLASH FLON,ALLIED,MEDROP)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,CLOSED WOUND DRAINAGE SYSTEM

	(CLOSED WOUND SUCTION SET)(NIL)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGIST.,CONTINOUS IRRIGATION CATHETER (IRRIGATION SET) -WITH SINGLE AND DUAL SPIKE(DISPOSAFE)-INTENDED TO BE USED TO INTRODUCE FLUIDS IN TO BODY CAVITIES OTHER THAN BLOOD VESSELS,DRAIN FLUIDS FROM BODY CAVITIES,OR EVALUATED CERTAIN PHYSIOLOGIC CONDITIONS.,RYLES TUBE(NIL)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE.IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,INTRAVENOUS CANNULA(HICO,UFLON,UCAN ALPHA,UNEW,ARTICARE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,TRACHEAL (ENDOTRACHEAL) TUBE-PLAIN AND CUFFED(NIL)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,CLOSED WOUND DRAINAGE SYSTEM (REDON DRAIN TUBE)(DISPOSAFE)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS,BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,INTRAVENOUS CANNULA(IPD LIFECARE,FAB,FAB CATH,TOPDESC,HEXACARE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SCALP VEIN SET(NIL)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENTS VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,SUCTION TIP AND CATHETER (SUCTION CATHETER)-SUCTION PLAIN,WITH FINGER TIP CONTROL AND WITH THUMB CONTROL (SUCTION-CARE,ALL PRO, CATH TEC,LEADCARE,MEDECO,BROMED,FLASH FLON)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,LEVINE TUBE (DISPOSAFE,ALL PRO)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,HYPODERMIC SYRINGE FOR SINGE USE (DISPOINJECT,IDL,ALL PRO,LEADCARE)-INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,INTRAVENOUS CANNULA(NOKAST,LIFEN,OPSET,SINOMEDIC,QY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,PERFUSION SETS FOR

	SINGLE USE(DISPOSABLE INTRAVENOUS SET)-VENTED/NON-VENTED(CATH TEC,LEADCARE,MEDESET,IPD LIFECARE,SHILOHSET, IDL,QUALIMAXX,CIRUGIA PERUANA,FLASH FLON,ALLIED)-PERFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,UMBILICAL OCCLUSION DEVICE (UMBILICAL CORD CLAMP)(NEOVAC)-THESE DEVICES MAY BE A CLIP,TIE, TAPE OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,INTRAVENOUS CANNULA (ALLIED,ONE PRICK,NUFIX,MEDIPLUS,KOVAX,DISPOSAFE,HEALFLON) -THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,FLOW DIRECTED CATHETER(PRESSURE MONITORING LINE)-HIGH PRESSURE(NIL)-USED FOR VENOUS SAMPLING AND PRESSURE MONITORING.,TRACHEOSTOMY TUBE/TRACHEAL TUBE-PLAIN AND CUFFED(DISPOSAFE)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,FISTULA NEEDLE (A.V FISTULA NEEDLES)(DISPOSAFE)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT.,PERFUSION SETS FOR SINGLE USE(DISPOSABLE INTRAVENOUS SET)-VENTED/NON VENTED (DISPOSAFE,SAKAMED)-PERFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,CLOSED WOUND DRAINAGE SYSTEM (THORACIC CATHETER SET)-STRAIGHT, ANGLED, TROCAR(DISPOSAFE,MEDECO,ALL PRO)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND.THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGIST.,UMBILICAL OCCLUSION DEVICE (UMBILICAL CORD CLAMP)(NIL)-THESE DEVICES MAY BE A CLIP,TIE, TAPE OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,CLOSED WOUND DRAINAGE TUBE (REDON DRAIN TUBE)(NIL)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND.THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGIST.,UMBILICAL ARTERY CATHETER (UMBILICAL CATHETER)(DISPOSAFE)-UMBLICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE A SOURCE OF ARTERIAL BLOOD SAMPLING ,AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS.,HAEMODIALYSIS CATHETER (NIL)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS

	MACHINE FROM THE PATIENT.,RYLES TUBE(RYLES-CARE,ALL PRO, CATH TEC,LEADCARE,MEDECO,BROMED)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE.IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,FLOW DIRECTED CATHETER (PRESSURE MONITORING LINE) -HIGH PRESSURE(DISPO HP,PERIFLOW)-USED FOR VENOUS SAMPLING AND PRESSURE MONITORING., TRACHEOSTOMY TUBE/TRACHEAL TUBE-PLAIN AND CUFFED(NIL)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,HYPODERMIC SYRINGE FOR SINGE USE(NIL)-INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,NASAL OXYGEN CATHETER (TWIN BORE NASAL OXYGEN CATHETER)-ADULT,PAEDIATRIC & NEONATAL (NASAL-SAFE)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,INTRAVENOUS CANNULA(PHIDCARE,Q-FLON,NET-FLON,NET-CAN,NET-ON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INTRAVENOUS CANNULA(SAMIN, PLASMED,INJEX CATH,INJEX CATH SAFETY,3 MED)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INTRAVENOUS CANNULA(HE-FLON,MATRONA,INNOCATH,SIDAFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS,AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,CLOSED WOUND DRAINAGE SYSTEM (THORACIC CATHETER SET)-STRAIGHT, ANGLED, TROCAR(NIL)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND.THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGIST.,BLOOD COLLECTING NEEDLE (BLOOD COLLECTION NEEDLE)(DISPOSAFE)-INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD.,DISPOSABLE HYPODERMIC NEEDLES(NIL)-A SUBCUTANEOUS INJECTION IS A METHOD OF ADMINISTERING MEDICATION.,FOLEY CATHETER (FOLEY BALLOON CATHETER)-ONE WAY, TWO WAY AND THREE WAY-ADULT AND PAEDIATRIC(DISPOFOLEY,ALL PRO,CATH TEC,LEAD CARE,MEDECO, IDL,FLASH FLON,NIRVANA)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,CONTINOUS IRRIGATION CATHETER (IRRIGATION SET)-WITH SINGLE AND DUAL SPIKE(NIL)-INTENDED TO BE USED TO INTRODUCE

		FLUIDS IN TO BODY CAVITIES OTHER THAN BLOOD VESSELS,DRAIN FLUIDS FROM BODY CAVITIES,OR EVALUATED CERTAIN PHYSIOLOGIC CONDITIONS.,NASAL OXYGEN CATHETER (OXYGEN CATHETER)(DISPOSAFE,MEDECO)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,DISPOSABLE HYPODERMIC NEEDLES(DISPO PRICK,ALL PRO,CATH TEC,LEADCARE,IDL)-A SUBCUTANEOUS INJECTION IS A METHOD OF ADMINISTERING MEDICATION.,EXTENSION SETS(THREE WAY STOPCOCK WITH EXTENSION TUBE-RED,BLUE AND WHITE HANDLE)(DISPOPLUS, DISPOFLEX,CATH TEC,LEADCARE,LIFECARE,TKL,TALGE,BECARE,3A+, ALL PRO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.
3245	MFG/MD/2019/000108	1.License Holder Name: M N SURGICAL 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:ABSORBENT GAUZE CLOTH-DRESSING AND CLEANING PURPOSES,GAMJEE ROLL / GAMJEE PAD-DRESSING AND CLEANING PURPOSES,WARD GAUZE / THEATRE GAUZE / CARDIAC GAUZE-THIN LOOSELY WOVEN CLOTH USED FOR DRESSINGS AND SWABS,ROLLER BANDAGE-A BANDAGE IS A PIECE OF MATERIAL USED EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS A DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT THE MOVEMENT OF A PART OF THE BODY. WHEN USED WITH A DRESSING, THE DRESSING IS APPLIED DIRECTLY ON A WOUND, AND A BANDAGE USED TO HOLD THE DRESSING IN PLACE. OTHER BANDAGES ARE USED WITHOUT DRESSINGS,,RADIO OPAQUE GAUZE-DRESSING AND CLEANING PURPOSES,PLEDGETS-DRESSING AND CLEANING PURPOSE,COTTON SWAB-GENTLE CLEANING PURPOSES,TRACHEOSTOMY GAUZE-CLEANING AND DRESSING PURPOSES,ABDOMINAL SPONGES-ABDOMINAL SPONGES ARE USED FOR DRESSING AND CLEANING PURPOSES DURING SURGERIES..
3246	MFG/MD/2019/000109	1.License Holder Name: MICTROTROL STERILISATION SERVICES PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT (GENESIS)-IT IS SURGICAL COMPONENT THAT INTERFACES WITH THE BONE OF THE JAW OR SKULL TO SUPPORT A DENTAL PROSTHESIS SUCH AS CROWN, BRIDGE, DENTURE, FACIAL PROSTHESIS OR TO ACT AS AN ORTHODONTIC ANCHOR.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3247	MFG/MD/2019/000110	1.License Holder Name: SAHAJANAND LASER TECHNOLOGY LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:COBALT CHROMIUM EVEROLIMUS ELUTING CORONARY STENT SYSTEM(EVERPRO, EVERPRIME, EVERTRACE)-FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO OR RESTENOTIC LESIONS., COBALT CHROMIUM PERIPHERAL STENT SYSTEM(ZEPHYR , REJUVANT)-FOR THE TREATMENT OF DE NOVO OR RESTENOTIC ATHEROSCLEROTIC LESIONS IN PERIPHERAL ARTERIES ,RENAL ARTERIES, PALLIATION IN MALIGNANT STRUCTURE IN BILIARY TREE., PTCA BALLOON CATHETER(VECTOR, TRACKER, VECTOR AXIAL, TANGENT, VECTOR PROJECTION, VECTOR NC , NECTOR)-PTCA BALLOON CATHETER IS INTENDED TO BE USED FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) FOR THE PURPOSE OF IMPROVING MYOCARDIAL BLOOD OW IN THE LOCALIZED STENOTIC LESIONS OF CORONARY ARTERIES.,STAINLESS STEEL RAPAMYCIN (SIROLIMUS) ELUTING CORONARY STENT (EASYRAP , PROSECTOR , MOVYRAP , TWINRAP)-INTENDED FOR IMPROVING CORONARY LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES,COBALT CHROMIUM BARE METAL CORONARY STENT(FLEXYSTAR, PASSAGER, HEXAPRO, STEPPER)-INTENDED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO OR RESTENOTIC LESIONS.,COBALT CHROMIUM CORONARY STENT WITH DELIVERY SYSTEM(FLEXYSTAR, PASSAGER, HEXAPRO, STEPPER)-FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO OR RESTENOTIC LESIONS,COBALT CHROMIUM RAPAMYCIN (SIROLIMUS) ELUTING CORONARY STENT(FLEXYRAP, RAPID-R, RELEASER, NEOHEXA, NEOHEXA+, PATHNDER, GRADIATOR, BIFAR)-INTENDED FOR IMPROVING CORONARY LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES., COBALT CHROMIUM RAPAMYCIN (SIROLIMUS) ELUTING CORONARY STENT WITH DELIVERY SYSTEM(FLEXYRAP, RAPID-R, RELEASER, NEOHEXA, NEOHEXA+, PATHFINDER, GRADIATOR, BIFAR)-IMPROVING CORONARY LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES.,STAINLESS STEEL BARE METAL CORONARY STENT. (EASYFLEX , SECTOR , MOVYSTAR , TWINFLEX)-INTENDED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH

		SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO OR RESTENOTIC LESIONS.,STAINLESS STEEL RAPAMYCIN (SIROLIMUS) ELUTING CORONARY STENT WITH DELIVERY SYSTEM (EASYRAP , PROSECTOR , MOVYRAP , TWINRAP)-IMPROVING CORONARY LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES,COBALT CHROMIUM PERIPHERAL STENT(ZEPHYR , REJUVANT)-INTENDED FOR THE TREATMENT OF DE NOVO OR RESTENOTIC ATHEROSCLEROTIC LESIONS IN PERIPHERAL ARTERIES ,RENAL ARTERIES, PALLIATION IN MALIGNANT STRUCTURE IN BILIARY TREE.,STAINLESS STEEL CORONARY STENT WITH DELIVERY SYSTEM.(EASYFLEX , SECTOR , MOVYSTAR , TWINFLEX)-FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO OR RESTENOTIC LESIONS
3248	MFG/MD/2019/000110	1.License Holder Name: SAHAJANAND LASER TECHNOLOGY LIMITED (SLTL MEDICAL) 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:PTCA BALLOON CATHETER(RIPPER, VECTOR PRO, IMPELLER, WAIVE)-PTCA BALLOON CATHETER IS INTENDED TO BE USED FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) FOR THE PURPOSE OF IMPROVING MYOCARDIAL BLOOD FLOW IN THE LOCALIZED STENOTIC LESIONS OF CORONARY ARTERIES.,COBALT CHROMIUM RAPAMYCIN (SIROLIMUS) ELUTING CORONARY STENT WITH DELIVERY SYSTEM(FLEXYRAP+, RAYFLEX, RAPAFLEX)-IMPROVING CORONARY LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES.

3249	MFG/MD/2019/000111	1.License Holder Name: SB SALES 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:NEEDLE FREE CONNECTOR(PURE LINK)-THE SINGLE-NEEDLE DIALYSIS, IN WHICH CASE ONLY ONE CANNULA OR A SINGLE LUMEN CATHETER IS USED TO ACCESS THE BLOOD.,MEASURED VOLUME SET(INDO-BURETTE, SB SALES)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,VIAL ADAPTOR(-)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLESS ACCESSES TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUID FROM THE VIAL.,TRANSFUSION OR PERFUSION SET FOR SINGLE USE(SB SALES, INDO-FUSION, PURE LINK)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., SECUREMENT DEVICE(SECURA)-IT IS INDICATED FOR SHORT OR LONG TERM SECUREMENT OF PERCUTANEOUS INDWELLING CATHETERS OR TUBES FOR INTRAVENOUS USE TO THE ACCESS SITE BY MEANS OF A SUBCUTANEOUS ANCHOR. ,I V SET WITH FLOW REGULATOR(SB SALES, PURE LINK, INDO-FUSION)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,DISINFECTANTS(IV-CAP, I-PURE, PURA, SB SALES, GERM-FREE)-AN AGENT THAT DESTROYS PATHOGENIC AND OTHER KINDS OF MICROORGANISMS BY CHEMICAL OR PHYSICAL MEANS. A DISINFECTANT DESTROYS MOST RECOGNIZED PATHOGENIC MICROORGANISMS, BUT NOT NECESSARILY ALL MICROBIAL FORMS, SUCH AS BACTERIAL SPORES. IT IS INTENDED TO DISINFECT A MEDICAL DEVICE,EXTENSION SETS(PURE LINK, SB SALES)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATIONS IN MEDICAL APPLICATIONS., FOLEY CATHETER(SB SALES, INDO-CATH)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETHRA, EITHER THROUGH THE URETHRA AND BLADDER OR POST CATHETER PRIORY VIA THE KIDNEY,PENIS WEARABLE URINAL(SB SALES, RELIEF)-A NON-STERILE, EXTERNALLY-WORN, URINE DRAINAGE DEVICE INTENDED TO BE WORN OVER THE PENIS OF AN INCONTINENT MALE PATIENT TO CHANNEL URINE, VIA A TUBE, INTO A COLLECTION BAG. IT CONSISTS OF A URINARY INCONTINENCE PENIS ATTACHMENT (E.G., SHEATH OR ADHESIVE PORT), TUBING, AND A WEARABLE URINE COLLECTION BAG

3250	MFG/MD/2019/000112	1.License Holder Name: PLASMA BIOTAL INDIA PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:UNCEMENTED PROSTHESIS (STEM) - FOR HYDROXY APPETITE(HA) COATING ONLY. (ADLER LEGEND)-REPLACEMENT OF JOINTS
3251	MFG/MD/2019/000113	1.License Holder Name: ASIAN HEALTH CARE 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:ROLLER BANDAGE / ROLLER GAUZE-CLEANING AND DRESSING PURPOSE,COTTON BALL/ROLL-GENTLE CLEANING PURPOSE,DIALYSIS DRESSING KIT-CLEANING AND DRESSING PURPOSE DURING DIALYSIS.,GAMJEE ROLL / PAD-CLEANING AND DRESSING PURPOSES,ABSORBENT GAUZE SWABS-DRESSING AND CLEANING PURPOSE,RADIO OPAQUE GAUZE-CLEANING AND DRESSING PURPOSE,WARD GAUZE / THEATRE GAUZE-CLEANING AND DRESSING PURPOSE, TRACHEOSTOMY GAUZE-CLEANING AND DRESSING PURPOSE, PLEDGETS-CLEANING AND DRESSING PURPOSES,ABDOMINAL SPONGES-CLEANING AND DRESSING PURPOSE
3252	MFG/MD/2019/000114	1.License Holder Name: ATLAS SURGICAL 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATES(ATLAS / BONEFIX / TERRA / ATLAS ORTHO)-BONE PLATES SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE WIRES(ATLAS / BONEFIX / TERRA / ATLAS ORTHO)-BONE WIRES SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,SPINAL IMPLANTS (ATLAS / BONEFIX / TERRA / ATLAS ORTHO)-SPINAL IMPLANTS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE,BONE NAILS(ATLAS / BONEFIX / TERRA / ATLAS ORTHO)-BONE NAILS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PINS (ATLAS / BONEFIX / TERRA / ATLAS ORTHO)-BONE PINS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE,BONE SCREWS(ATLAS / BONEFIX / TERRA / ATLAS ORTHO)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE

3253	MFG/MD/2019/000115	1.License Holder Name: PRECISION GUIDETECH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:CATHETER GUIDE WIRE (NIL)-IT IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA). THE PTCA GUIDE WIRES ARE NOT TO BE USED IN THE CEREBRAL BLOOD VESSEL.,ANGIOGRAPHIC GUIDE WIRE(NIL)-IT DELIVERS RADIO OPAQUE MEDIA AND THERAPEUTIC AGENTS TO SELECTED SITES IN THE VASCULAR SYSTEM. IT IS ALSO USED TO LEAD A CATHETER INTO THE TARGET SITE.

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3254	MFG/MD/2019/000116	1.License Holder Name: MITRA INDUSTRIES PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BLOOD BAG 250 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER USP. (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, TRANSPORT AND ADMINISTRATION OF BLOOD. FOR STORAGE OF BLOOD UP TO 35 DAYS.,BLOOD BAG 400 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER IP(MITRA)-FOR COLLECTION, STORAGE, TRANSPORT AND ADMINISTRATION OF BLOOD. FOR STORAGE OF BLOOD UP TO 35 DAYS.,BLOOD BAG 500 ML CONTAINING ANTICOAGULANT CPD AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION II (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT.,BLOOD BAG 400 ML CONTAINING ANTICOAGULANT CPD SOLUTION AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION III WITH IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD , RBC AND/ OR PLATELETS(MITRA)-FOR COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTE (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT,BLOOD BAG 100 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER USP. (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, TRANSPORT AND ADMINISTRATION OF BLOOD. FOR STORAGE OF BLOOD UP TO 35 DAYS.,BLOOD BAG 400 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER USP & IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD, RBC AND/ OR PLATELETS (FOR EXPORT ONLY)(MITRA)-FOR COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTE (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT,BLOOD BAG 500 ML CONTAINING ANTICOAGULANT CPD AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION II WITH IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD, RBC AND/OR PLATELETS(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTES (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS; PLATELETS UP TO 5 DAYS & PLASMA AS PER REQUIREMENT.,BLOOD BAG 400 ML

	CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER USP (FOR EXPORT ONLY)(MITRA)-FOR COLLECTION, STORAGE, TRANSPORT AND ADMINISTRATION OF BLOOD. FOR STORAGE OF BLOOD UP TO 35 DAYS,BLOOD BAG 350 ML CONTAINING ANTICOAGULANT CPD AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION III (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT., BLOOD BAG 400 ML CONTAINING ANTICOAGULANT CPD SOLUTION AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION III(MITRA)-FOR COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT,BLOOD BAG 500 ML CONTAINING ANTICOAGULANT CPD AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION III (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT.,BLOOD BAG 400 ML CONTAINING ANTICOAGULANT CPD SOLUTION AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION III (FOR EXPORT ONLY) (MITRA)-FOR COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT,BLOOD BAG 350 ML CONTAINING ANTICOAGULANT CPD AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION II (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT.,BLOOD BAG 400 ML CONTAINING ANTICOAGULANT CPD SOLUTION AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION III WITH IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD , RBC AND/ OR PLATELETS (FOR EXPORT ONLY)(MITRA)-FOR COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTE (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT,BLOOD BAG 450 ML CONTAINING ANTICOAGULANT CPD AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION II (FOR EXPORT ONLY)(MITRA)-

	FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT.,BLOOD BAG 400 ML CONTAINING ANTICOAGULANT CPD SOLUTION AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION II (FOR EXPORT ONLY) (MITRA)-FOR COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT,BLOOD BAG 450 ML CONTAINING ANTICOAGULANT CPD AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION III (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT.,BLOOD BAG 400 ML CONTAINING ANTICOAGULANT CPD SOLUTION AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION II WITH IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD , RBC AND/ OR PLATELETS (FOR EXPORT ONLY)(MITRA)-FOR COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTE (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT,TRANSFER BAGS (WITHOUT ANTICOAGULANT AND PRESERVATIVE SOLUTION)(MITRA) -FOR THE STORAGE AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS.,BLOOD BAG 400 ML CONTAINING ANTICOAGULANT CPD SOLUTION AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION II (MITRA)-FOR COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT,LABSIDE FILTER. FILTER WITH EMPTY TRANSFER BAG FOR LABSIDE LEUKODEPLETION FOR WHOLE BLOOD/ RBC/ PLATELETS(MITRA)-FOR THE LEUKODEPLETION, STORAGE, TRANSPORT AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. ,BLOOD BAG 400 ML CONTAINING ANTICOAGULANT CPD SOLUTION AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION II WITH IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD , RBC AND/ OR PLATELETS(MITRA)-FOR COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTE (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS,

	PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT ,BLOOD BAG 450 ML CONTAINING ANTICOAGULANT CPD AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION III WITH IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD, RBC AND/OR PLATELETS. (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION, AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTES (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS; PLATELETS UP TO 5 DAYS & PLASMA AS PER REQUIREMENT.,BLOOD BAG 400 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER IP & IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD, RBC AND/ OR PLATELETS(MITRA)-FOR COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTE (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT,BLOOD BAG 100 ML, CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER IP.(MITRA)-FOR THE COLLECTION, STORAGE, TRANSPORT AND ADMINISTRATION OF BLOOD. FOR STORAGE OF BLOOD UP TO 35 DAYS.,BLOOD BAG 500 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER USP.(FOR EXPORT ONLY) (MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. FOR STORAGE OF BLOOD/RBC UP TO 35 DAYS, PLATELETS FOR 5 DAYS & PLASMA.,BLOOD BAG 450 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER USP (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. FOR STORAGE OF BLOOD/RBC UP TO 35 DAYS, PLATELETS FOR 5 DAYS & PLASMA.,BLOOD BAG 350 ML CONTAINING ANTICOAGULANT CPD AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION II WITH IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD, RBC AND/OR PLATELETS. (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION, AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTES (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS; PLATELETS UP TO 5 DAYS & PLASMA AS PER REQUIREMENT.,BLOOD BAG 450 ML CONTAINING ANTICOAGULANT CPD AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION III(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT.,BLOOD BAG 450 ML CONTAINING

	ANTICOAGULANT CPD AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION II(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT., ACD BLOOD BAG 500 ML CONTAINING ANTICOAGULANT ACD-A SOLUTION AS PER IP(MITRA)-FOR USE ONLY WITH THE CYTAPHERESIS/APHERESIS DEVICES. THE SOLUTION IS USED DURING APHERESIS TO PREVENT PLATELET ACTIVATION AND COAGULATION AS BLOOD MOVES THROUGHOUT THE TUBING SET IN AN APHERESIS MACHINE. IT IS NOT INTENDED FOR DIRECT INTRAVENOUS INFUSION.,BLOOD BAG 350 ML CONTAINING ANTICOAGULANT CPD AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION II(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT., BLOOD BAG 350 ML CONTAINING ANTICOAGULANT CPD AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION III(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT.,BLOOD BAG 500 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER IP(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. FOR STORAGE OF BLOOD/RBC UP TO 35 DAYS, PLATELETS FOR 5 DAYS & PLASMA.,BLOOD BAG 450 ML CONTAINING ANTICOAGULANT CPD AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION I(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT., BLOOD BAG 350 ML CONTAINING ANTICOAGULANT CPD AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION I(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. STORAGE OF SAGM MIXED RBC UP TO 42 DAYS, PLATELETS UP TO 5 DAYS, PLASMA AS PER REQUIREMENT.,BLOOD BAG 450 ML CONTAINING ANTICOAGULANT CPD AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION II WITH IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD, RBC AND/OR PLATELETS. (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION, AND ADMINISTRATION AFTER REMOVAL

	OF LEUCOCYTES (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS; PLATELETS UP TO 5 DAYS & PLASMA AS PER REQUIREMENT.,BLOOD BAG 350 ML CONTAINING ANTICOAGULANT CPD AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION II WITH IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD, RBC AND/OR PLATELETS(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION, AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTES (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS; PLATELETS UP TO 5 DAYS & PLASMA AS PER REQUIREMENT.,BLOOD BAG 500 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER USP & IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD, RBC AND/OR PLATELETS (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION, AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTES (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 35 DAYS; PLATELETS UP TO 5 DAYS & PLASMA AS PER REQUIREMENT.,BLOOD BAG 450 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER IP.(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. FOR STORAGE OF BLOOD/RBC UP TO 35 DAYS, PLATELETS FOR 5 DAYS & PLASMA.,BLOOD BAG 350 ML CONTAINING ANTICOAGULANT CPD AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION III WITH IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD, RBC AND/OR PLATELETS. (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION, AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTES (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS; PLATELETS UP TO 5 DAYS & PLASMA AS PER REQUIREMENT.,BLOOD BAG 250 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER IP(MITRA)-FOR THE COLLECTION, STORAGE, TRANSPORT AND ADMINISTRATION OF BLOOD. FOR STORAGE OF BLOOD UP TO 35 DAYS.,BLOOD BAG 350 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER IP(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. FOR STORAGE OF BLOOD/RBC UP TO 35 DAYS, PLATELETS FOR 5 DAYS & PLASMA.,BLOOD BAG (AUTOLOGOUS) 450 ML CONTAINING ANTICOAGULANT ACD-A SOLUTION AS PER IP.(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. FOR HAEMODILUTION USES

	ALSO.,BLOOD BAG (AUTOLOGOUS) 350 ML CONTAINING ANTICOAGULANT ACD-A SOLUTION AS PER IP.(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. FOR HAEMODILUTION USES ALSO,BLOOD BAG 350 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER USP & IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD, RBC AND/OR PLATELETS. (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION, AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTES (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 35 DAYS; PLATELETS UP TO 5 DAYS & PLASMA AS PER REQUIREMENT.,BLOOD BAG 450 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER USP & IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD, RBC AND/OR PLATELETS (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION, AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTES (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 35 DAYS; PLATELETS UP TO 5 DAYS & PLASMA AS PER REQUIREMENT.,BLOOD BAG 450 ML CONTAINING ANTICOAGULANT CPD AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION II WITH IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD, RBC AND/OR PLATELETS(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION, AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTES (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS; PLATELETS UP TO 5 DAYS & PLASMA AS PER REQUIREMENT.,BLOOD BAG 500 ML CONTAINING ANTICOAGULANT CPD AS PER USP & RBC PRESERVATIVE (SAGM) SOLUTION II WITH IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD, RBC AND/OR PLATELETS. (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION, AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTES (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS; PLATELETS UP TO 5 DAYS & PLASMA AS PER REQUIREMENT.,BLOOD BAG 350 ML CONTAINING ANTICOAGULANT CPDA SOLUTION AS PER USP. (FOR EXPORT ONLY)(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS. FOR STORAGE OF BLOOD/RBC UP TO 35 DAYS, PLATELETS FOR 5 DAYS & PLASMA.,BLOOD BAG 350 ML CONTAINING ANTICOAGULANT CPD AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION III WITH IN-LINE LEUKODEPLETION FILTERS FOR

	WHOLE BLOOD, RBC AND/OR PLATELETS(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION, AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTES (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS; PLATELETS UP TO 5 DAYS & PLASMA AS PER REQUIREMENT.,BLOOD BAG 450 ML CONTAINING ANTICOAGULANT CPD AS PER IP & RBC PRESERVATIVE (SAGM) SOLUTION III WITH IN-LINE LEUKODEPLETION FILTERS FOR WHOLE BLOOD, RBC AND/OR PLATELETS(MITRA)-FOR THE COLLECTION, STORAGE, PROCESSING, TRANSPORT, SEPARATION, AND ADMINISTRATION AFTER REMOVAL OF LEUCOCYTES (LEUKODEPLETION) FROM BLOOD AND BLOOD COMPONENTS. STORAGE OF LEUCODEPLETED RBC UP TO 42 DAYS; PLATELETS UP TO 5 DAYS & PLASMA AS PER REQUIREMENT.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3255	MFG/MD/2019/000117	1.License Holder Name: R.K. ENTERPRISES 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:NAILS(NOT APPLICABLE)-NAILS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE., BONE SCREW(NOT APPLICABLE)-BONE SCREWS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,WIRE AND PINS(NOT APPLICABLE)-WIRE AND PINS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE SCREW(NOT APPLICABLE)-BONE SCREWS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE., WIRE AND PINS(NOT APPLICABLE)-WIRE AND PINS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE PLATE(NOT APPLICABLE)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE PLATE(NOT APPLICABLE)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE., NAILS(NOT APPLICABLE)-NAILS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,SPINAL IMPLANTS(NOT APPLICABLE)-SPINAL IMPLANTS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,SPINAL IMPLANTS(NOT APPLICABLE)-SPINAL IMPLANTS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3256	MFG/MD/2019/000118	1.License Holder Name: S.H.PITKAR ORTHOTOOLS PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:BONE SCREW- CAP FOR SOL T PFD NAIL(PITKAR)-END CAP SECURELY LOCK THE MOST PROXIMAL OBLIQUE LOCKING SCREW TO CREAT A FIXED ANGLE CONSTRUCT & USED AS A NAIL EXTENSION & PREVENT THE INGROWTH OF TISSUE AND FACILITATE NAIL EXTRACTION,PFNA II NAIL (PITKAR)-1.SUBTROCHANTERIC FRACTURES 2. PERTROCHANTERIC FRACTURES ASSOCIATED WITH SHAFT FRACTURES 3.PATHOLOGICAL FRACTURES (INCLUDING PROPHYLACTIC USE) IN BOTH TROCHANTERIC AND DIAPHYSAL AREAS 4.NONUNION AND MALUNION,SOL T TIBIA NAIL(PITKAR)-1. METAPHYSEAL AND CERTAIN INTRAARTIC-ULAR FRACTURES OF THE TIBIAL HEAD AND THE PILON TIBIALE: 41-A2/A3, 2.ALL SHAFT FRACTURES 43-A1/A2/A3 ,SOL T PFD NAIL(PITKAR)-1. HIGH SUB TROCHANTRIC FRACTURES OF FEMUR,BONE SCREW- PFNA II BLADE (PITKAR)-COMPACTION OF CANCELLOUS BONE I.E. PFNA-II BLADE COMPACTS THE CANCELLOUS BONE PROVIDING ADDITIONAL ANCHORING, WHICH IS ESPECIALLY IMPORTANT IN OSTEOPOROTIC BONE ,BONE SCREW- HIP BOLT(PITKAR)-THE USE OF METALLIC SURGICAL IMPLANTS PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION & HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANTS ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING. ,BONE SCREW- CAP SCREW FOR SOL T TIBIA NAIL(PITKAR)-END CAP SECURELY LOCK THE MOST PROXIMAL OBLIQUE LOCKING SCREW TO CREAT A FIXED ANGLE CONSTRUCT & USED AS A NAIL EXTENSION & PREVENT THE INGROWTH OF TISSUE AND FACILITATE NAIL EXTRACTION,BONE SCREW- CERVICAL SCREW(PITKAR)-TO BE USED IN TANDEM WITH INTRAMEDULLARY LOCKING NAIL IN INTERTROCHANTERIC REGION,SOL T FEMUR NAIL(PITKAR)-1.ALL CLOSED & OPEN FEMORAL SHAFT FRACTURES 2.SUBTROCHANTERIC FRACTURES 3.SHAFT FRACTURES IN COMBINATION WITH FEMORAL NECK OR 4.PERTROCHANTERIC FRACTURES. 5.PSEUDOARTHROSIS OR DELAYED UNION,YT NAIL(PITKAR)- 1.SUBTROCHANTERIC FRACTURES 2.PERTROCHANTERIC FRACTURES ASSOCIATED WITH SHAFT FRACTURES 3.PATHOLOGICAL FRACTURES (INCLUDING PROPHYLACTIC USE) IN BOTH TROCHANTERIC AND DIAPHYSAL AREAS 4.NONUNION AND MALUNION,BONE SCREW- YT SCREW (PITKAR)-THE USE OF METALLIC SURGICAL IMPLANTS PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION &

	HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANTS ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING. ,BONE SCREW- INTERLOCKING SCREW(PITKAR)-THE USE OF METALLIC SURGICAL IMPLANTS PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION & HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANTS ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.,BONE SCREW- CAP SCREW FOR SOL T FEMUR NAIL(PITKAR) -END CAP SECURELY LOCK THE MOST PROXIMAL OBLIQUE LOCKING SCREW TO CREAT A FIXED ANGLE CONSTRUCT & USED AS A NAIL EXTENSION & PREVENT THE INGROWTH OF TISSUE AND FACILITATE NAIL EXTRACTION,BONE SCREW- CAP SCREW FOR YT NAIL(PITKAR)- END CAP SECURELY LOCK THE MOST PROXIMAL OBLIQUE LOCKING SCREW TO CREAT A FIXED ANGLE CONSTRUCT & USED AS A NAIL EXTENSION & PREVENT THE INGROWTH OF TISSUE AND FACILITATE NAIL EXTRACTION,BONE SCREW- INTERFERENCE SCREW(PITKAR)- THE USE OF METALLIC SURGICAL IMPLANTS PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION & HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANTS ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING. ,BONE SCREW- HIP PIN (PITKAR)-THE USE OF METALLIC SURGICAL IMPLANTS PROVIDES THE ORTHOPAEDIC SURGEON A MEANS OF ACCURATE BONE FIXATION & HELPS GENERALLY IN THE MANAGEMENT OF FRACTURES AND RECONSTRUCTIVE SURGERY. THESE IMPLANTS ARE INTENDED AS AIDS TO NORMAL HEALING BUT ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES OR BEAR WEIGHT OF THE BODY IN THE PRESENCE OF INCOMPLETE BONE HEALING.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3257	MFG/MD/2019/000119	1.License Holder Name: AGROSURG IRRADIATORS INDIA PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:CO-60 GAMMA IRRADIATION FACILITY(AGROSURG)-FOR TREATING MEDICAL DEVICES WITH CO-60 GAMMA RAYS,CO-60 GAMMA IRRADIATION FACILITY(AGROSURG)-FOR TREATING MEDICAL DEVICES WITH CO-60 GAMMA RAYS
3258	MFG/MD/2019/000120	1.License Holder Name: KAMAL ENCON INDUSTRIES LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANTS WITH ABUTMENTS & PROSTHESIS(IFIX (TM UNDER PROCESS), MULTIFIX (TM UNDER PROCESS), SFIX (TM UNDER PROCESS), CFIX (TM UNDER PROCESS))-:DENTAL IMPLANTS ARE INTENDED FOR SURGICAL PLACEMENT IN THE UPPER OR LOWER JAW TO PROVIDE A MEANS FOR PROSTHETIC ATTACHMENT IN SINGLE TOOTH RESTORATIONS AND IN PARTIALLY OR FULLY EDENTULOUS SPANS WITH MULTIPLE SINGLE TEETH UTILIZING DELAYED LOADING, OR AS A TERMINAL OR INTERMEDIARY ABUTMENT FOR FIXED OR REMOVABLE BRIDGEWORK, AND TO RETAIN OVERDENTURES.
3259	MFG/MD/2019/000121	1.License Holder Name: AEGIS LIFE SCIENCES 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:HAEMOSTATIC GELATIN SPONGE(KARESPON)-IT CAN BE EFFECTIVELY USED IN VARIOUS SURGERIES LIKE DENTAL SURGERY, MALIGNANCY, ABDOMINAL SURGERY, ORTHOPAEDIC SURGERY, NEURO SURGERY, GENITO-URINARY SURGERY, ANORECTAL SURGERY, GYNAECOLOGICAL SURGERY, OTO-LARYNGOLOGICAL SURGERY ETC FOR HAEMOSTASIS, WHEN CONTROL OF CAPILLARY, VENOUS AND ARTERIOLAR BLEEDING BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS INEFFECTIVE OR IMPRACTICAL.

3260	MFG/MD/2019/000122	1.License Holder Name: UTESHIYA MEDICARE PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE SCREW(UTESHIYA)-BONE SCREWS CAN BE USED ALONE OR COMBINED WITH BONE PLATES TO TREAT VARIOUS FRACTURES OF LIMBS AND IRREGULAR BONE.,BONE PLATES(UTESHIYA)-BONE PLATES CAN BE COMBINED WITH BONE SCREWS TO TREAT VARIOUS BONE FRACTURES, INCLUDING LARGE BONE (CLAVICLE, SCAPULA, PELVIS, HUMERUS, ULNA, RADIUS, FEMUR, TIBIA, AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, AND PHALANGES).,ARTHROSCOPY IMPLANTS(UTESHIYA, STATIV, VIP LOCK, CEPTRE, HELYSIS, INFILOOP, PROLOOP-ULTRA, PROLOOP-MINI, PROLOOP-XL)-THE ARTHROSCOPY IMPLANTS ARE SMALLER THAN TRADITIONAL INSTRUMENTS. SURGEONS VIEW THE JOINT AREA ON A VIDEO MONITOR, AND CAN DIAGNOSE AND REPAIR TORN JOINT TISSUE, SUCH AS LIGAMENTS. IT IS TECHNICALLY POSSIBLE TO DO AN ARTHROSCOPIC EXAMINATION OF ALMOST EVERY JOINT, BUT IS MOST COMMONLY USED FOR THE KNEE, SHOULDER, ELBOW, WRIST, ANKLE, FOOT, AND HIP.,WIRE AND PINS(UTESHIYA)-WIRE AND PINS ARE USED FOR FIXATION OF DIAPHYSEAL AND METAPHYSEAL FRACTURE AND IRREGULAR BONE FRACTURE IN COMBINATION WITH EXTERNAL FIXATORS,ENDOPROSTHESIS(UTESHIYA)-ENDOPROSTHESIS ARE INTENDED TO RESTORE THE NORMAL FUNCTIONS OF THE MISSING BODY PART,SPINE IMPLANTS (CERVICAL,THORACIC & LUMBER)(UTESHIYA)-THE CERVICAL AND LUMBER SPINE IMPLANTS IS USED FOR THE INTERNAL FIXATION OF POSTERIOR CERVICAL AND THORACOLUMBAR SPINE FRACTURES. CERVICAL AND LUMBER SPINE IMPLANTS IS DESIGNED AND MANUFACTURED IN ACCORDANCE WITH THE ANATOMIC FEATURE OF HUMAN SPINE. IT IS COMPOSED OF CORTEX SCREWS AND PLATES, WHICH ARE APPLICABLE FOR DIFFERENT SEGMENTS OF POSTERIOR SPINE FIXATION.,NAIL(UTESHIYA)-IM NAILS ARE INTENDED TO BE IMPLANTED INTO THE MEDULLARY CANAL OF LIMBS FOR ALIGNMENT, STABILIZATION, FIXATION OF FRACTURES CAUSED BY TRAUMA OR DISEASES.

3261	MFG/MD/2019/000123	1.License Holder Name: AV PROCESSORS PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:ABSORBABLE GELATIN SPONGE(NA)-ABSORBABLE GELATIN SPONGE MAY BE APPLIED TO BLEEDING SURFACE IN AMOUNTS,SUFFICIENT TO COVER THE AREA. IT RAPIDLY CONTROLS CAPILLARY AND VENOUS BLEEDING, FORMING A STABLE ADHERENT COAGULUM. IT CAN ALSO BE USED IN SURGERY OF THE LARGER VESSELS UPON APPLICATION OF THE PROPER SURGICAL TECHNIQUES.,ABSORBABLE GELATIN SPONGE (NA)-ABSORBABLE GELATIN SPONGE MAY BE APPLIED TO BLEEDING SURFACE IN AMOUNTS,SUFFICIENT TO COVER THE AREA.IT RAPIDLY CONTROLS CAPILLARY AND VENOUS BLEEDING,FORMING A STABLE ADHERENT COAGULUM. IT CAN ALSO BE USED IN SURGERY OF THE LARGER VESSELS UPON APPLICATION OF THE PROPER SURGICAL TECHNIQUES.

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3262	MFG/MD/2019/000124	1.License Holder Name: STAYMAXX MEDICAL PVT. LTD. 2.Approving Authority: SUB ZONAL BADDI 3.Device Name(Brand Name)-Intended Use:BONE PINS & WIRES (STAYMAXX)-PINS & WIRES ARE THE MOST COMMONLY USED ORTHOPAEDIC IMPLANTS. ONE OF THE MAJOR ADVANTAGES OF PINS & WIRES IS THEIR RELATIVELY LOW COST AND LIMITED EQUIPMENT REQUIREMENTS FOR SURGICAL APPLICATION. THEY ARE APPLICABLE TO A RELATIVELY SMALL NUMBER OF FRACTURE SITUATIONS WHEN USED ON THEIR OWN. PINS & WIRES ARE OF VARYING LENGTHS AND ALSO VARY IN THE END CONSTRUCTION. THE MOST COMMON POINTED ENDS ARE A THREE-SIDED TROCAR TIP OR A TWO SIDED CHISEL WITH THE FORMER BEING BETTER SUITED TO PENETRATING CORTICAL BONE & LATER ABLE TO BE BRACED AGAINST THE ENDOSTEAL SURFACE OF THE BONE'S CORTEX OR APPLICABLE TO LODGING IN CANCELLOUS BONE.,BONE SCREWS (STAYMAXX)-ORTHOPAEDIC BONE SCREWS ARE TITANIUM OR STAINLESS STEEL SCREWS THAT ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF THE BONES. THE MATERIAL OF THE BONE SCREWS IS HIGHLY NON-REACTIVE, THUS THESE SCREWS DO NOT CAUSE ANY CORROSIVE OR ALLERGIC REACTIONS INSIDE THE BODY. THEY CAN REMAIN IN YOUR BODY FOR AN ENTIRE LIFE PERIOD WITHOUT CAUSING ANY HARM TO YOUR BONES OR ANY OTHER PHYSICAL DAMAGE.,BONE PLATES(STAYMAXX)-A BONE PLATE IS A THIN METAL IMPLANT WITH DIFFERENT THICKNESS IS USED TO IMMOBILIZE BROKEN BONE SEGMENTS IN A PARTICULAR FRACTURE SITE. THE PLATE IS FIXED WITH SCREWS TO PROPERLY ALIGN & MAINTAIN ANATOMY OF THE BONE & IS THE AID IN A HEALING PROCESS WHICH OCCURS NATURALLY IN THE BODY. BONE PLATES ARE OFTEN APPLIED TO FRACTURES WHICH CANNOT BE HEALED WITH CAST & NEED FIXATION TO REGAIN THE NATURAL ANATOMY OF THE BONE. BONE PLATES ARE OFTEN APPLIED TO THE FRACTURES OCCURING IN ANY PART OF THE HUMAN SKELETON IN THE MAXIMUM RANGE OF POSSIBILITY. MOSTLY THE BONE PLATES ARE MADE OF STAINLESS STEEL & TITANIUM ALLOYS.,BONE NAILS(STAYMAXX)-AN INTERLOCKING NAIL IS A SURGICAL ROD INSERTED INTO THE INTRAMEDULLARY CANAL TO ACT AS AN IMMOBILIZATION DEVICE TO HOLD THE TWO ENDS OF A FRACTURED LONG BONE IN POSITION. THESE METAL RODS FORCED INTO MEDULLARY CAVITY OF LONG, WEIGHT-BEARING BONES (E.G. FEMUR, TIBIA), WHICH ALLOWS AMBULATION WITHIN WEEKS RATHER THAN MONTHS. INTERLOCKING NAILS HAVE A CLOVERLEAF APPEARANCE ON CROSS-SECTION AND ARE MADE OF STAINLESS STEEL AND TITANIUM, WHICH HAS A LOWER RATE OF MECHANICAL FAILURE & IMPROVED BIO-

	COMPATIBILITY.,PEDICAL SCREWS(STAYMAXX)-THESE SCREWS ARE USED TO CORRECT DEFORMITY, AND/OR TREAT TRAUMA. SIMILAR TO OTHER BONE SCREWS, PEDICLE SCREWS MAY BE USED IN INSTRUMENTATION PROCEDURES TO AFFIX RODS AND PLATES TO THE SPINE. THE SCREWS MAY ALSO BE USED TO IMMOBILIZE PART OF THE SPINE TO ASSIST FUSION BY HOLDING BONY STRUCTURES TOGETHER.

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3263	MFG/MD/2019/000125	1.License Holder Name: POLY MEDICURE LIMITED 2.Approving Authority: UTTARAKHAND 3.Device Name(Brand Name)-Intended Use:THREE WAY STOP COCK WITH EXTENSION TUBE(POLYMED THREE WAY STOP COCK WITH EXTENSION TUBE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,CLOSED WOUND SUCTION UNIT(WILTEX DRENO PARA SUCCAO SISTEMA FECHADO DRENAGEM CONTINUO)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS. ,BLOOD ADMINISTRATION SET WITH AIRVENT(HAEMOFUSOR SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,CLOSED WOUND SUCTION UNIT(WILTEX DRENO PARA SUCCAO SISTEMA FECHADO DE DRENAGEM COM VALVULA ANTI- REFLUXO)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,BLOOD ADMINISTRATION SET-TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INTRAVENOUS FLUID INFUSION SET WITH AIRVENT & THREEWAY STOP COCK(POLYFUSION VENTED SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,NON VENTED I.V. INFUSION SET(POLYFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,EXTENSION LINE (HIGH PRESSURE /LOW PRESSURE) (POLYMED EXTENSION LINE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,THREE WAY STOP COCK WITH EXTENSION TUBE-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,UMBILICAL CATHETER(PU FEED)-UMBILICAL CATHETER IS USED TO PROVIDE ACCESS TO THE STOMACH FOR DRAINAGE. THE PRODUCT CAN ALSO BE USED WITH VENOUS OR ARTERIAL ROUTES FOR INFUSION, TRANSFUSION, ADMINISTRATION OF MEDICATION, BLOOD SAMPLING, PRESSURE MEASUREMENT.,EXTENSION TUBE (HIGH PRESSURE /LOW PRESSURE)(POLYMED EXTENSION TUBE)-"EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE

	USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS." ,THORACIC DRAINAGE CATHETER (STRAIGHT/ANGLED) WITH & WITHOUT TROCAR (ULTRACATH NOVO-STRAIGHT, ULTRACATH NOVO - ANGLED, ULTRACATH NOVO - TROCAR)-THE PRODUCT IS USED FOR POST OPERATIVE DRAINAGE AFTER CARDIO-THORACIC AND THORACIC SURGERY. THE PRODUCT IS DESIGNED FOR USED IN THORACIC SURGERY AND ESPECIALLY IN HEART SURGERY POSTOPERATIVELY OR AFTER A TRAUMATISM IN THE THORAX IN ORDER TO REMOVE BLOOD, SECRETIONS AND AIR WHICH ACCUMULATE IN THE THORAX GENERATING ACUTE CARDIO RESPIRATORY INSUFFICIENCY AND SOMETIMES EVEN DEATH., VENTED I.V. INFUSION SET(POLYFUSION VENTED SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., OXYGEN CATHETER-THE PRODUCT OXYGEN CATHETER IS USED TO PROVIDE OXYGEN FOR RESPIRATION WITH MAXIMUM COMFORT TO THE PATIENT. ,I.V. INFUSION SET WITH AIRVENT(NOVOFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,NELATON CATHETER-THE PRODUCT NELATON CATHETER IS USED TO PROVIDE ACCESS TO THE BLADDER CATHETERIZATION THROUGH URETHRA IN CASE OF URINARY RETENTION ESPECIALLY IN MALES. ,IV CANNULA (POLYCAN IP)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITHOUT INJECTION PORT WITH WINGS(POLYCAN)-IV CANNULA COMMONLY KNOWN AS INTRAVENOUS CANNULA/CATHETER IS INSERTED INTO A VEIN, MAINLY FOR THE ADMINISTRATION OF INTRAVENOUS FLUIDS, WITHDRAWAL OF BLOOD SAMPLES AND TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING.,BLOOD TRANSFUSION SET-TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,IV CANNULA WITH INJECTION PORT AND WINGS(POLYFLON, VITROFLON, ULTRA I.P.)-IV CANNULA COMMONLY KNOWN AS INTRAVENOUS CANNULA/CATHETER IS INSERTED INTO A VEIN, MAINLY FOR THE ADMINISTRATION OF INTRAVENOUS FLUIDS, WITHDRAWAL OF BLOOD SAMPLES AND TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING.,MEASURED VOLUME FLUID ADMINISTRATION SET(POLYVOL BURETTE SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A

	VASCULAR ACCESS DEVICE. ,SUCTION CATHETER-THE PRODUCT SUCTION CATHETER IS USED TO PROVIDE ACCESS TO RESPIRATORY TRACT TO REMOVE SECRETION WITH MAXIMUM COMFORT TO THE PATIENT. ,THREE WAY STOP COCK(POLYWAY, POLYWAY PRO)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,RYLE'S TUBE-RYLES TUBE IS DESIGNED TO PROVIDE ACCESS TO NASOGASTRIC TRACT FOR INTRODUCTION OF NUTRITION AND ASPIRATION OF INTESTINAL SECRETION. ,THREE WAY STOP COCK-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,INFANT FEEDING TUBE (POLYFEED, NOVOFEED,)-INFANT FEEDING TUBE IS USED TO PROVIDE FEEDING TO NEONATES AND INFANTS. THESE TUBES ARE USED TO PROVIDE FEEDINGS AND MEDICATIONS INTO THE STOMACH UNTIL THE BABY CAN TAKE FOOD BY MOUTH. ,BLOOD TRANSFUSION SET(TRANSVOL SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,IV CANNULA WITHOUT INJECTION PORT AND WITHOUT WINGS(POLYWIN)-IV CANNULA COMMONLY KNOWN AS INTRAVENOUS CANNULA/CATHETER IS INSERTED INTO A VEIN, MAINLY FOR THE ADMINISTRATION OF INTRAVENOUS FLUIDS, WITHDRAWAL OF BLOOD SAMPLES AND TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING.,EXTENSION TUBE (HIGH PRESSURE /LOW PRESSURE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,NASAL OXYGEN CANNULA(NASOCATH)-NASAL OXYGEN CATHETER IS USED TO PROVIDE OXYGEN FOR RESPIRATION WITH MAXIMUM COMFORT TO THE PATIENT. ,IV INFUSION SET (SENSIMEDICAL)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,CLOSED WOUND SUCTION UNIT(POLYVAC SET, NEOVAC SET, NOVOVAC SET)-THE PRODUCT IS USED FOR CLOSED WOUND DRAINAGE OR COLLECTION OF FLUID FROM SURGICAL WOUND UNDER NEGATIVE PRESSURE THROUGH A COLLECTION TUBE AND COLLECTION DEVICE (BELLOW) WITH AN OPTION TO OPERATE ONE OR TWO CATHETERS SIMULTANEOUSLY. ,MICRO VENTED INFUSION SET(MICROFUSION PLUS, MICROFUSION VENTED SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,BLOOD COLLECTION SET -INTENDED TO BE USE FOR INSERTION INTO THE

	PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD. ,BLOOD LINE SET (HAEM-O-LINE)-THE SINGLE-NEEDLE DIALYSIS, IN WHICH CASE ONLY ONE CANNULA OR A SINGLE-LUMEN CATHETER IS USED TO ACCESS THE BLOOD,THREE WAY STOP COCK WITH EXTENSION TUBE(LLAVES DE PASO DE TRES VIAS CON TUBO DE EXTENSION DE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,MICRODRIP INFUSION SET NON VENTED (MICROFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,I.V. FLOW REGULATOR EXTENSION SET(POLYFLO NOVO)-"AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY." ,I.V. FLOW REGULATOR EXTENSION SET-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,NON VENTED I.V. INFUSION SET-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,VENTED I.V. INFUSION SET-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,IV INFUSION SET WITH 0.2 MICRON IN LINE FILTER AND PRIMING FILTER (WITH AIRVENT)(ONCOFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,I.V. FLOW REGULATOR EXTENSION SET(POLYFLOW NOVO, POLYFLO)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. ,MICRODRIP INFUSION SET NON VENTED-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,CLOSED WOUND SUCTION UNIT-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS. ,IV CANNULA WITH INJECTION PORT AND WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITHOUT INJECTION PORT & WITH WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , SCALP VEIN SET WITH/WITHOUT SAFETY-INTENDED TO BE USE FOR

	INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,IV CANNULA WITH INJECTION PORT -THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,IV CANNULA WITH LUER LOCK & INJECTION PORT - THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , SCALP VEIN SET(BUTTERFLY WINGED INFUSION SET)-INTENDED TO BE USE FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,MICRODRIP INFUSION SET WITH AIRVENT-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,NON VENTED WINGED I.V. INFUSION SET(POLYFUSION - W)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.

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3264	MFG/MD/2019/000126	1.License Holder Name: MJ SURGICAL 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ARTHROSCOPY IMPLANTS (COMBINATION OF PEEK WITH UHMWPE)(MJ SURGICAL)-ABC,BONE SCREW (STAINLESS STEEL)(MJ SURGICAL)-MJ SURGICAL BONE SCREWS WHEN USED IN COMBINATION WITH PLATES ARE INTENDED FOR FIXATION OF VARIOUS FRACTURES, OSTEOTOMIES, MALUNIONS, ARTHRODESIS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL.,SPINAL IMPLANTS (TITANIUM)(MJ SURGICAL)-SPINAL IMPLANTS ARE USED IN SPINE CODE FRACTURES IN THORACIC SPINE AND LUMBER SPINE. ALL THE SPINE IMPLANTS LIKE ANTERIOR CERVICAL PLATE AND SCREW, MONOAXIAL SCREWS AND HOOKS WITH SPINAL RODS, POLYAXIAL SCREWS WITH SPINAL RODS, DRUMMER'S WIRE, HART SHELL AND HARRINGTON ROD & HOOKS ARE USED TO FIX THE SPINE BONE FRACTURES.,BONE NAIL (STAINLESS STEEL)(MJ SURGICAL)-THE MJ SURGICAL'S TIBIAL NAIL SYSTEM IS INTENDED TO STABILIZE FRACTURES OF THE PROXIMAL AND DISTAL TIBIA AND THE TIBIAL SHAFT; OPEN AND CLOSED TIBIAL SHAFT FRACTURES; CERTAIN PRE- AND POST-ISTHMIC FRACTURES; AND TIBIAL MALUNIONS AND NON-UNIONS. THE TIBIAL NAILS CAN BE OF INTERLOCKING TIBIAL NAIL, CANNULATED TIBIAL NAIL AND DISTAL TIP DISTAL LOCKING TIBIAL NAIL TYPES.,SPINAL IMPLANTS (PEEK)(MJ SURGICAL)-SPINAL IMPLANTS ARE USED IN SPINE CODE FRACTURES IN THORACIC SPINE AND LUMBER SPINE. SPINE IMPLANTS LIKE CERVICAL CAGE, OLIF CAGE, ALIF CAGE, LORDOTIC PLIF CAGE, TLIF CAGE, PLIF CAGE ARE USED TO FIX THE SPINE BONE FRACTURES.,BONE PLATE (TITANIUM) (MJ SURGICAL)-MJ SURGICAL'S BONE PLATES ARE INTENDED FOR FIXATION OF FRACTURES, OSTEOTOMIES, MALUNION, ARTHRODESIS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL. MJ SURGICAL'S BONE PLATES ARE PROVIDED IN NON-STERILE PACKAGE.,SPINAL IMPLANTS (STAINLESS STEEL)(MJ SURGICAL)-SPINAL IMPLANTS ARE USED IN SPINE CODE FRACTURES IN THORACIC SPINE AND LUMBER SPINE. ALL THE SPINE IMPLANTS LIKE ANTERIOR CERVICAL PLATE AND SCREW, MONOAXIAL SCREWS AND HOOKS WITH SPINAL RODS, POLYAXIAL SCREWS WITH SPINAL RODS, DRUMMER'S WIRE, HART SHELL AND HARRINGTON ROD & HOOKS

	ARE USED TO FIX THE SPINE BONE FRACTURES.,COMPLETE HIP JOINT SYSTEM (STAINLESS STEEL)(MJ SURGICAL)-COMPLETE HIP JOINT SYSTEM IS A ONE PIECE, HEMI-HIP REPLACEMENT COMPONENT. IT IS INTENDED FOR FEMORAL HEAD/NECK FRACTURES, ASEPTIC NECROSIS OF FEMORAL HEAD & OSTEO – RHEUMATOID, POST TRAUMATIC ARTHITIS OF THE HIP.,BONE NAIL (TITANIUM)(MJ SURGICAL)-THE MJ SURGICAL'S TIBIAL NAIL SYSTEM IS INTENDED TO STABILIZE FRACTURES OF THE PROXIMAL AND DISTAL TIBIA AND THE TIBIAL SHAFT; OPEN AND CLOSED TIBIAL SHAFT FRACTURES; CERTAIN PRE- AND POST-ISTHMIC FRACTURES; AND TIBIAL MALUNIONS AND NON-UNIONS. THE TIBIAL NAILS CAN BE OF INTERLOCKING TIBIAL NAIL, CANNULATED TIBIAL NAIL AND DISTAL TIP DISTAL LOCKING TIBIAL NAIL TYPES.,BONE SCREW (TITANIUM) (MJ SURGICAL)-MJ SURGICAL BONE SCREWS WHEN USED IN COMBINATION WITH PLATES ARE INTENDED FOR FIXATION OF VARIOUS FRACTURES, OSTEOTOMIES, MALUNIONS, ARTHRODESIS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL., BONE PLATE (STAINLESS STEEL)(MJ SURGICAL)-MJ SURGICAL'S BONE PLATES ARE INTENDED FOR FIXATION OF FRACTURES, OSTEOTOMIES, MALUNION, ARTHRODESIS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL. MJ SURGICAL'S BONE PLATES ARE PROVIDED IN NON-STERILE PACKAGE.,PINS AND WIRES (STAINLESS STEEL)(MJ SURGICAL)-STEINMAN PIN ARE GENERALLY USED IN TIBIA & FEMUR BONES ALONG WITH STEINMANN PIN HOLDER. KIRSCHNER WIRES ARE USED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION. INTENDED USE OF THESE WIRES IS IN PATELLA, OLECRANON, AND MALLEOLAR & HAND FRACTURES.,ARTHROSCOPY IMPLANTS (COMBINATION OF TITANIUM WITH UHMWPE)(MJ SURGICAL)-ABC

3265	MFG/MD/2019/000127	1.License Holder Name: M/S.LAXMI GAUZE BANDAGE & TEXTILES 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:ABSORBENT GAUZE CLOTH-KEEP THE ROLLED PART OF THE BANDAGE ABOVE THE INJURY AND THE UNROLLED PART BELOW THE INJURY. BEGIN BY WRAPPING TWICE AROUND THE INJURY TO HOLD THE END IN PLACE. SECURE THE END OF THE BANDAGE IN PLACE WITH A TURN OF THE BANDAGE. WRAP THE BANDAGE AROUND THE BODY PART UNTIL THE DRESSING IS COMPLETELY COVERED AND THE BANDAGE EXTENDS SEVERAL INCHES BEYOND THE DRESSING. THE GAUZE IS PURE 100% COTTON FABRIC, BLEACHED TO ENSURE SUPERIOR PURITY AND ABSORBENCY. THE PRODUCT HAS NO FLUORESCENCE. IT IS USED WIDELY IN MEDICAL CIRCLE AND OTHER AREAS.

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3266	MFG/MD/2019/000128	1.License Holder Name: ESSITY OPERATIONS GOA LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:MEDICATED DRESSING (HANSAPLAST® WASHPROOF)-READY TO USE MEDICATED DRESSING FOR TREATMENT OF MINOR WOUNDS AND CUTS,PLASTER OF PARIS BANDAGE B.P. "88"(RAPIDUR®)--IMMOBILISATION OF ALL TYPES OF BONE FRACTURES - FOR CORRECTION & PREVENTION OF DEFORMITIES - HELP TO HEAL SOFT TISSUE INJURIES,MEDICATED DRESSING(HANSAPLAST®)-READY TO USE MEDICATED DRESSING (AS FIRST AID DRESSING) FOR TREATMENT OF MINOR WOUNDS AND CUTS,PLASTER OF PARIS BANDAGE B.P. "88"(GYPSONA®)--IMMOBILISATION OF ALL TYPES OF BONE FRACTURES - FOR CORRECTION & PREVENTION OF DEFORMITIES - HELP TO HEAL SOFT TISSUE INJURIES,ADHESIVE TAPE U.S.P(HANSAPLAST® TAPE)-FIXATION OF DRESSINGS, SECURING OF CATHETERS, PROBES, CANNULAE, TRACTION AND RIGID STRAPPING.,ADHESIVE TAPE U.S.P (LEUKOPLAST®)-FIXATION OF DRESSINGS, SECURING OF CATHETERS, PROBES, CANNULAE, TRACTION AND RIGID STRAPPING., PLASTER OF PARIS BANDAGE(GYPSONA® S)--IMMOBILISATION OF ALL TYPES OF BONE FRACTURES - FOR CORRECTION & PREVENTION OF DEFORMITIES - HELP TO HEAL SOFT TISSUE INJURIES,FIRST AID DRESSING(HANSAPLAST® SILVERHEALING™ WASHPROOF)-READY TO USE FIRST AID DRESSINGS FOR COVERING SUPERFICIAL, EVERYDAY WOUNDS, I.E. MINOR CUTS, ABRASIONS AND LACERATIONS.,MEDICATED DRESSING(HANSAPLAST®)-READY TO USE MEDICATED DRESSING (AS FIRST AID DRESSING) FOR TREATMENT OF MINOR WOUNDS AND CUTS,FIRST AID DRESSING (HANSAPLAST® SILVERHEALING™ X'TRA PROTECT)-READY TO USE FIRST AID DRESSINGS FOR COVERING SUPERFICIAL, EVERYDAY WOUNDS, I.E. MINOR CUTS, ABRASIONS AND LACERATIONS, MEDICATED DRESSING(HANSAPLAST® WASHPROOF)-READY TO USE MEDICATED DRESSING FOR TREATMENT OF MINOR WOUNDS AND CUTS

3267	MFG/MD/2019/000129	1.License Holder Name: PCM ORTHO PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:SPINAL IMPLANTS(NOT APPLICABLE)-SPINAL IMPLANTS ARE USUALLY USED TO FACILITATE FUSION, CORRECT DEFORMITIES & STABILIZE & STRENGTHEN THE SPINE.,WIRE AND PINS(NOT APPLICABLE)-PINS & WIRES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE SCREW (NOT APPLICABLE)-BONE SCREWS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE PLATE(NOT APPLICABLE)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE., WIRE AND PINS(NOT APPLICABLE)-PINS & WIRES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE SCREW(NOT APPLICABLE)-BONE SCREWS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE PLATE(NOT APPLICABLE)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE., NAILS(NOT APPLICABLE)-NAILS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,SPINAL IMPLANTS(NOT APPLICABLE)-SPINAL IMPLANTS ARE USUALLY USED TO FACILITATE FUSION, CORRECT DEFORMITIES & STABILIZE & STRENGTHEN THE SPINE., NAILS(NOT APPLICABLE)-NAILS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.

3268	MFG/MD/2019/000131	1.License Holder Name: SAMAY SURGICAL 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE NAILS(SAMAY)-INTRAMEDULLARY NAILING IS COMMONLY USED TO FIX THE LONG BONE FRACTURES.,LOCKING SCREW(SAMAY)-LOCKING SCREW SERVE AS A SUPPORT FOR IMPLANT ON BONE.,BONE SCREW(SAMAY) -BONE SCREW ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVES AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR ALONG WITH BONE PLATES OR INTERLOCKING NAILS,BONE PLATES(SAMAY)-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURES IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH SCREW TO PROPERLY ALIGN THE FRACTURED BONE, SPINAL IMPLANT(SAMAY)-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,LOCKING PLATES(SAMAY)-LOCKING PLATES ARE USED SURGERY TOHOLD FRACTURES IN PLACE TO ALLOW BONE HEALING.,PINS AND WIRES(SAMAY)-PINS AND WIRES ARE USED IN MAXIMUM BONE FRACTURES SURGERY TO MAKE INSERTION IN THE BONE AND THRIUGH PINS AND WIRE SUPPORTFIX ABOVE PLATES

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3269	MFG/MD/2019/000132	1.License Holder Name: LIFE O LINE TECHNOLOGIST 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:DISPOSABLE ELECTROSURGICAL CAUTERY PENCIL(LIFE-O-MED)-THE PENCIL CAN BE USED DURING ELECTROSURGICAL PROCEDURES FOR BOTH CUTTING AND COAGULATION. DEVICE DESCRIPTION: EIECTRCSURGERY CAN BE USED TO ACCOMPLISH ANY ONE OF THREE FUNCTIONS IN THE SURGICAL ENVIRONMENT: INCISE, DESICCATE, OR COAGULATE. THIS IS A SINGLE USE, DISPOSABLE DEVICE.,DOUBLE LUMEN DIALYSIS KIT : JUGULAR / STRAIGHT(LIFE-O-MED)-THE INTENDED USE OF THE SHORT-TERM DIALYSIS CATHETER ATTAINING TEMPORARY/SHORT- TERM (LESS THAN 30 DAYS) VASCULAR ACCESS FOR DIALYSIS,CVC CATHETER (CENTRAL VENUS CATHETER) - S.L. / D.L. / T.L.(LIFE-O-MED)-CENTRAL VENOUS CATHETER IS A POLYURETHANE THAN C.V.C WITH IS INTENDED TO INSERT IT TO THE PATIENT'S VASCULAR SYSTEM FOR SHORT TERM USE. (LESS THEN 30 DAYS) TO SAMPLE BLOOD MONITOR BLOOD PRESSURE OR ADMINISTER FLUID INTRAVENOUSLY.,D.J. STANT(LIFE-O-MED)-D.J STENT IS INTENDED TO FACILITATED THE TEMPORARY INTERNAL DRAINAGE OF URINE FROM THE KIDNEY TO THE BLADDER VIA PLACEMENT ENDOSCOPICALLY BY A TRAINED PHYSICIAN., TRIPLE LUMEN DIALYSIS KIT(LIFE-O-MED)-THE THIRD LUMEN IS COMPLETELY INDEPENDENT FROM THE TWO DIALYSIS LUMENS AND IS INDICATED FOR POWER INJECTION OF CONTRAST MEDIA CENTRAL VENOUS PRESSURE MONITORING AND CAN BE USED FOR BLOOD DRAWS AND FLUID OR MEDICATION DELIVERY WITHOUT THE NEED FOR A SEPARATE ACCESS.
3270	MFG/MD/2019/000133	1.License Holder Name: UNIVERSAL MEDITECH 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.(I CURE)-THE ABSORBENT COTTON ARE USED TO BIND, WRAP OR AS A SUPPORTIVE MATERIAL FOR WOUNDS, CUTS,BURNS AND IN DRESSING FOR WOUND HEALING PROCESS.

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3271	MFG/MD/2019/000134	1.License Holder Name: BIO-MED HEALTHCARE PRODUCTS PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:3- WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS WITH OR WITHOUT EXTENSION TUBE(IDA, ABZ, BONEC, HEALTH)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF FLUID AND PRESSURE MONITORING.,BLOOD LINE SETS FOR HAEMODIALYSIS(BIO-MED, GENERIC NAME)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT.,INTRAVENOUS CANNULA WITH OR WITHOUT SAFETY FEATURE(IVENY, MEDROP, HEALTH, EPIC-HEIGHT, QI ,ONEFLON , 4K ,TEFLO, BONEC, ABZ-FLON, Y-CANNULA ,SA-MED , STARFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND / OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,TRANSFUSION OR PERFUSION SETS FOR SINGLE USE(BIO-MED, MR. INJECT, AG CATH, GENERIC NAME)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,BLOOD LINE SETS FOR HAEMODIALYSIS (SHINRAI)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT.,I.V. FLOW REGULATOR(BIO-MED, AGARY, GENERIC NAME)-AN I.V. SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY,CLOSED WOUND DRAINAGE TUBE OR SYSTEM (BIO-VAC SET)-CLOSED WOUND DRAINAGE SYSTEM WITH TRANSPARENT SPRING BELLOW SUITABLE FOR DRAINAGE UNDER NEGATIVE PRESSURE POST OPERATIVELY WITH THE OPTIONS TO OPERATE ONE OR TWO CATHETERS SIMULTANEOUSLY., INTRAVENOUS CANNULA WITH OR WITHOUT SAFETY FEATURE(BIO-FLON, BIO-CAN, BIO-ON, NEO-KATH, MAXIMA, SOLIDOR, BEL-FLON, EURO-FLON, EURO-CAN, VENAX-2, VENAX-1, GREN-FLON, VAGON + , NOVAFLON, NET-FLON, NET-CAN, SWAN MEDICARE, ROMED, KAY-FLON, HOLDEN, MORNINGSIDE, VASOCATH, DEMOTEK, BIO-NEO, BIO-SIS, MEDECO, FARCOCATH, HM HEALTHCARE, MEDICARE, IRISMED, RE-FLON, CANNATECH, BEX, HELMFLON®, HELMFLON®+, HELMSYTE®, IGLACATH, AGARY, AMBI-FLON, AMBI-ON, AMBI-CAN, AMBI-KATH, INDO-FLON, INDOPLAS, IVECATH, KKAREMAX, MEDIN, MEDICANN, VM FLON, BARAFLON, HARMED, ANGELTOUCH, HE-FLON, NEOTECH, HALF, SIDA-FLON, MAXIMA, VASOCATH ADVENTIVE, BIO-PEN, MICROMED-FLON, FACTOR B, GENERIC NAME, PRECISION CARE, NEOVAC, VEINFIX, BIO-MED, PLUS-MED, CADIFLO, UNION, ROSEMED, HEUER, MEDI-LIFE, VAGON , SAFEMED, LIFECARE, MEDIPLAST, NULIFE, UNIMED, IE MEDICAL, ASCO, SIDRA, JRZ, DISPOTOUCH,

	SANBAO, DODO, AG-CATH, VITALCARE, RITEMED, MANAFLO. IDA, EURO-FLOW, EURO-FLOW -1, JUFLON, MEDIPLUS, HEALCATH, NEWLIFE, MAB, T-CARE, LIGASURE, MAYEDON, BIOSAFE, POLNET, PLASMED, BIO CATH, BEGOTEK, JE MED, ADVASAFE, EASY-VEIN, I-INSTA, I-CURE, EASY CATH , EASY CATH PLUS, ACCURE, NET-ON, OPTIMA, MR. INJECT, MEDFLOW, INFUSAFE, LIFE FLOW, K (PEN TYPE), CURJECT, X-FLON.)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND / OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,3- WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS WITH OR WITHOUT EXTENSION TUNE(BIO-MED, SAFE- WAYS, MEDICARE, HEUER, ALFA, FARMABAN, DEMOTEK, NOVAFLEX, PLASMED, INDOPLAS, INDO-FLON, MEDISCIENCE, ROMED, SOLIDOR, MAXIMA, REBONEL, NET, MANAFLO, MANASAFE, HARMED, AG CATH, DODO, VITALCARE, RITEMED, GENERIC NAME JUCATH, BIOSAFE, 4K, PLUS-MED, MR. INJECT, OPTIMA, HE, ACCURE, EURO-FLOW)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF FLUID AND PRESSURE MONITORING.,EXTENSION SETS(BIO-MED, MEDICARE, HEUER, ALFA, FARMABAN, DEMOTEK, SOLIDOR, MAXIMA, REBONEL, NET, MANAFLO, HARMED, AG CATH, VITALCARE, RITEMED, MANASAFE, GENERIC NAME. JUCATH, BIOSAFE, MR. INJECT, OPTIMA, ACCURE)-EXTENSION SET ARE SINGLE USE DEVICE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3272	MFG/MD/2019/000135	1.License Holder Name: HARSORIA HEALTHCARE PVT LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:SAFETY I.V.CANNULA (HENRY SCHEIN)-THE I.V. CANNULA IS A PASSIVE DEVICES TO PROVIDE TO FOR INFUSION OF FLUIDS, DRUGS , AND/OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,ENDOTRACHEAL TUBE (TRACHEAL TUBE)(GENERIC NAME, HARSORIA, VIGGO)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS ,I.V. CANNULA(VIGGOFLON, VEROTRUE)-THE I.V. CANNULA IS A PASSIVE DEVICES TO PROVIDE TO FOR INFUSION OF FLUIDS, DRUGS ,AND/OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,A.V.FISTULA NEEDLE SET(GENERIC NAME, HARSORIA, JCM MED, NEOTEC, REIN, ELITE- HARSORIA, ELI-FLOW, NEXTECH)-TO CONNECT BLOOD LINE WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT , SAFETY I.V.CANNULA(CURA SLIDE, CURA SAFE, TRUSAFE 1, TRUSAFE 2)-THE I.V. CANNULA IS A PASSIVE DEVICES TO PROVIDE TO FOR INFUSION OF FLUIDS, DRUGS , AND/OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,I.V. CANNULA(GENERIC NAME, HEALFLON, HEALVAN, HEALCATH, CANUSOFT, INFLO, SENSECURE, HEALFLON PLUS, HEALCATH PLUS, JCM MED, JCM MED IV SAFE, NEOTEC, NEOTEC-1, NEOTEC-1W, VENOFIX, VIVON, VIVON CATH, MEDCATETER, VASOCATH, TEFLO, NEOTEF, VEINCATH, MEDIN+, PAEDIFIX, INTRAFIX, INFLO PLUS, EASYFIX, NEOFIX, JCM MED SV CONCEPT, HARSON, NEXTECH, SOFTMED, NERVTEC, GLOBAL CARE, TRUFLON, HEALFLON INSTA, HEALFLON INSTA PLUS, TRUFLON INSTA, TRUFLON NEO, SHAHEENFLON, MEDSOURCE, GLOMED, PERIPHERAL IV CATHETER SELECT)-THE I.V. CANNULA IS A PASSIVE DEVICES TO PROVIDE TO FOR INFUSION OF FLUIDS, DRUGS , AND/OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES, NASAL OXYGEN CATHETER/CANNULA(GENERIC, HARSORIA, VIGGO , MEDSOURCE, NASO-TWIN SET)-THE NASAL OXYGEN CATHETER/CANNULA IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,SAFETY I.V.CANNULA(GENERIC NAME, HEALCATH AUTOSAF, MEDIN, NEOTEC, CANUVEIN, UNOFLON, UNIQUE-IN, HEALFLON SAFETY, HEALVAN SAFETY, HEALCATH SAFETY, QUICKSAFE, NEXTECH SAFETY, SAFNULE, CLEAR SAFE SAFETY, USAFE, CLEAR SAFE COMFORT, TRUE SAFE, CARESS SAFETY, SURESITE IV AUTO, SURESITE IV SLIDE, ESKAMED, BULLPUP, BIOCIV, JCM-MED, NUSAF, PUR SAFETY R, PUR SAFETY S, PERIPHERAL IV

	CATHETER SAFETY)-THE I.V. CANNULA IS A PASSIVE DEVICES TO PROVIDE TO FOR INFUSION OF FLUIDS, DRUGS , AND/OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,SAFETY I.V.CANNULA(JELCO TRUESAFE)-THE I.V. CANNULA IS A PASSIVE DEVICES TO PROVIDE TO FOR INFUSION OF FLUIDS, DRUGS , AND/OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,INTRAVENOUS INFUSION SET (IV SET)(GENERIC NAME, HARSORIA, HARSORIA PREMIUM, HARSORIA NV PRO, HARSORIA ECO, MEDSOURCE)-: IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,HAEMODIALYSIS CATHETER KIT TRIPLE LUMEN(MECCA, HARSORIA,)-A CATHETER USED FOR EXCHANGING THE BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT,EXTENSION TUBE/LINE /SET(GENERIC NAME, HARSORIA, NEOTEC)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUID/MEDICATIONS IN MEDICAL APPLICATION ,I.V. CANNULA(FARCOCATHE, TOPSN)-THE I.V. CANNULA IS A PASSIVE DEVICES TO PROVIDE TO FOR INFUSION OF FLUIDS, DRUGS ,AND/OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,THREE WAY STOP COCK(GENERIC NAME, HARSORIA, MEDSOURCE, NEOTEC, SENSECURE, MEDIMAX, NEXTECH, QUALICARE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,HAEMODIALYSIS CATHETER DOUBLE LUMEN(MECCA, HARSORIA,)-:A CATHETER USED FOR EXCHANGING THE BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT,I.V.FLOW REGULATOR(GENERIC NAME, HARSORIA, NEOTEC, CANUSOFT, NEXTECH)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY, HAEMODIALYSIS CATHETER KIT SINGLE LUMEN(MECCA, HARSORIA,)-A CATHETER USED FOR EXCHANGING THE BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT,I.V. CANNULA (VANOCATHE)-THE I.V. CANNULA IS A PASSIVE DEVICES TO PROVIDE TO FOR INFUSION OF FLUIDS, DRUGS , AND/OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES, I.V. CANNULA(FARCOCATH)-THE I.V. CANNULA IS A PASSIVE DEVICES TO PROVIDE TO FOR INFUSION OF FLUIDS, DRUGS , AND/OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,HAEMODIALYSIS CATHETER KIT(GENERIC NAME, ELITE HARSORIA, SEMILLAS)-A CATHETER USED FOR EXCHANGING THE BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE

		PATIENT
3273	MFG/MD/2019/000136	1.License Holder Name: GIAPLUS MEDICAL PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:SPINAL IMPLANTS (GIAPLUS)-SPINAL IMPLANTS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE WIRES(GIAPLUS)-BONE WIRES SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE NAILS(GIAPLUS)-BONE NAILS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE SCREWS(GIAPLUS)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PIN(GIAPLUS)-BONE PIN SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE WIRE(GIAPLUS)-BONE WIRE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,SPINAL IMPLANT(GIAPLUS)-SPINAL IMPLANT SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PLATES(GIAPLUS)-BONE PLATES SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PINS(GIAPLUS)-BONE PINS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE NAILS(GIAPLUS)-BONE NAILS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE SCREWS(GIAPLUS)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PLATE(GIAPLUS)-BONE PLATE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.

3274	MFG/MD/2019/000137	1.License Holder Name: GENIUS ORTHO PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ARTHROSCOPIC IMPLANTS(GENIUS)-ARTHROSCOPIC IMPLANTS ARE USED IN ARTHROSCOPIC SURGERY IN THE KNEE, SMALL JOINTS, SHOULDER AND HIP AND SERVE AS INVASIVE AND SURGICALLY-INVASIVE TREATMENTS AND SURGICAL INTERVENTIONS.,MAXILLOFACIAL IMPLANTS(GENIUS)-MAXILLOFACIAL IMPLANTS ARE USED IN MAXILLOFACIAL FRACTURES.,LOCKING IMPLANTS(GENIUS)-LOCKING IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., BONE SCREW(GENIUS)-BONE SCREW IS USED TO FIXING FRACTURE. WITH THE HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES,FIXATOR & ELIZARO(GENIUS)-FIXATOR AND ELIZARO ARE INTENDED FOR TEMPORARY FIXATION AND INTRA- AND POSTOPERATIVE TREATMENT OF OPEN AND CLOSED FRACTURES AND ELECTIVE ORTHOPEDIC INTERVENTIONS., LOCKING IMPLANTS(GENIUS)-LOCKING IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,BONE PLATE(GENIUS)-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURES IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREWS TO PROPERLY ALIGN THE FRACTURED BONE.,BONE NAIL(GENIUS)-BONE NAILS ARE USED IN HUMERUS BONE, TIBIA BONE, FEMUR BONE, WHERE FOUND THE FRACTURES IN PROXIMAL AND DISTAL AREA. ALL TYPES OF BONE NAILS ARE USED INSIDE THE BONE AND ITS PASS THROUGH FRACTURES AND HOLD THE FRACTURES WITH THE HELP OF BONE SCREWS. AND ITS MINIMAL INSERTION SURGERY.,WIRES AND PINS(GENIUS)-PINS AND WIRES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS AND WIRES SUPPORT FIX THE BONE PLATES, BONE SCREWS, IM NAILS, SPINE IMPLANTS ETC. ALL PINS AND WIRES ARE NOT PERMANENTLY USED IN SURGERY.,BONE SCREWS(GENIUS)-BONE SCREW IS USED TO FIXING FRACTURE. WITH THE HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES,BONE PLATE (GENIUS)-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURES IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREWS TO PROPERLY ALIGN THE FRACTURED BONE.,WIRES AND PINS(GENIUS)-PINS AND WIRES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS AND WIRES SUPPORT FIX THE BONE PLATES, BONE SCREWS, IM NAILS, SPINE IMPLANTS ETC. ALL

		PINS AND WIRES ARE NOT PERMANENTLY USED IN SURGERY., MAXILLOFACIAL IMPLANTS(GENIUS)-MAXILLOFACIAL IMPLANTS ARE USED IN MAXILLOFACIAL FRACTURES.,BONE NAIL(GENIUS)-BONE NAILS ARE USED IN HUMERUS BONE, TIBIA BONE, FEMUR BONE, WHERE FOUND THE FRACTURES IN PROXIMAL AND DISTAL AREA. ALL TYPES OF BONE NAILS ARE USED INSIDE THE BONE AND ITS PASS THROUGH FRACTURES AND HOLD THE FRACTURES WITH THE HELP OF BONE SCREWS. AND ITS MINIMAL INSERTION SURGERY., ARTHROSCOPIC IMPLANTS(GENIUS)-ARTHROSCOPIC IMPLANTS ARE USED IN ARTHROSCOPIC SURGERY IN THE KNEE, SMALL JOINTS, SHOULDER AND HIP AND SERVE AS INVASIVE AND SURGICALLY-INVASIVE TREATMENTS AND SURGICAL INTERVENTIONS.
3275	MFG/MD/2019/000138	1.License Holder Name: BROWNDOVE HEALTHCARE PVT LTD 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:HAEMODIALYSIS CATHETER(DIALYNE)-IT IS USED FOR EXCHANGING BLOOD TO AND FROM A HAEMODIALYSIS MACHINE AND PATIENT.,AV FISTULA NEEDLE SET(BROWNDOVE PRISTINE 15G, 16G, 17G)-IT IS INDICATED IN THE VEIN PUNCTURE FOR THE HEMODIALYSIS TREATMENT.,COTTON GRUDGES AND BANDAGES(EMERALD ON OFF KIT)-EMERALD ON-OFF KIT IS A SINGLE USE STERILE MEDICAL DEVICE.IT PLAYS A IMPORTANT ROLE IN DRESSING OF THE BODY PART OF THE PATIENT DURING HAEMODIALYSIS. THE ACCESSORIES OF THE ON-OFF KIT DIRECTY CONTACT WITH THE SKIN, USED TO STOP BLEEDING FROM MINOR PUNCTURES SUCH AS INJECTIONS OR VENEPUNCTURE AND FOR CLEANSING AND COVERING OR DRESSING THE PARTS OF THE PATIENT.,BLOOD TUBING SET FOR HAEMODIALYSIS(BROWNDOVE CURUM)-INTENDED TO SERVE AS A CONDUCT THROUGH WHICH BLOOD IS TAKE FROM THE PATIENT, DELIVERED TO THE HAEMODIALYSER AND RETURNED TO THE PATIENT DURING HAEMODIALYSIS THERAPY. THE DEVICE IS INTENDED TO BE USED FOR PATIENTS SUFFERING FROM RENAL DISEASE ONLY.

3276	MFG/MD/2019/000139	1.License Holder Name: HEALTHIUM MEDTECH PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:ABSORBABLE SURGICAL NEEDLED SUTURE (SYNTHETIC) KNOTLESS TISSUE-CLOSURE DEVICE MONOFILAMENT POLIGLECAPRONE 25(TRUBARB, TRULOCK, TRUQUICK)-POLIGLECAPRONE 25 KNOTLESS TISSUE-CLOSURE DEVICE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE THE USE OF ABSORBABLE SUTURES IS APPROPRIATE., ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) STERILISED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910(H-SYNTH)-POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL NEEDLED SUTURE (SYNTHETIC) KNOTLESS TISSUE-CLOSURE DEVICE MONOFILAMENT POLYDIOXANONE(TRUBARB, TRULOCK, TRUQUICK)-POLYDIOXANONE KNOTLESS TISSUE-CLOSURE DEVICE COMPRISED OF DYED PDO IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE USE OF ABSORBABLE SUTURES IS APPROPRIATE.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID(IGLYDE, RITEMED PGA,GEYCOL, POLYGLYCOLIC ACID, PGA RESORBA,SABAGLYDE, ADVAMED-PGA, LINX-PGA)-POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE-POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) STERILIZED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910 FAST(VETSUTURE FASTPGLA, NOÉCARE FASTPGLA, NOÉDENTAL FASTPGLA,ISYNTH FAST, RITEMED PGLA FAST, POLYGLACTIN FAST,U-SYNTH FAST,FLYSORB, ADVAMED PGLA FAST, LINX RPGLA)-FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO THE RAPID ABSORPTION PROFILE, FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. FAST ABSORBABLE

	POLYGLACTIN 910 SUTURE IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES.,STERILE BONEWAX 2.5GM(TRUWAX, CERA PERA HUESO, D-TEK BONEWAX, Q-CLOSETM BONEWAX, ALPHA BONEWAX, LINX X-WAX)-BONEWAX MAY BE USED FOR THE CONTROL OF BLEEDING FROM BONE SURFACES., NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE(SURGISUT-TRULENE, N-CARE POLYPROPYLENE)-POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL SUTURE MONOFILAMENT NYLON WITHOUT NEEDLE(TRULON, NYLON MONOFILAMENTONEGRA)-NYLON SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,STERILE POLYPROPYLENE MESH(Q-CLOSE MESH, ADVAMED-POLYPROPYLENE MESH, LINX REGULAR MESH,LINX LIGHT MESH, DTEK MESH, KOLLSUT MESH, SPERILENE MESH, DEMELENE MESH)-POLYPROPYLENE MESH USED FOR THE REPAIR OF HERNIA.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE COATED POLYESTER WITHOUT NEEDLE-POLYESTER SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., HERNIA KIT CONTAINS (POLYPROPYLENE MESH, MONOFILAMENT POLYPROPYLENE SUTURE, POLYGLYCOLIC ACID SUTURE)(TRULENE, TRUGLYDE, TRULENE MESH)-1. POLYPROPYLENE MESH USED FOR THE REPAIR OF HERNIA. 2. POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES. 3. POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITH NEEDLE - PLAIN(TRUGUT, BROPLAIN, CATGUT SIMPLE, REDIGUT PLAIN, U-GUT)-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25(SURGISUT-MONOGLYDE, N-CARE MONOGLYDE)-MONOFILAMENT POLIGLECAPRONE 25 SUTURES

	ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) MONOFILAMENT POLY DI OXANONE(PD SYNTH, BROCRYL MONOFILAMENT, PDX, POLYDIOXANONE, REDIDOX, Q-CLOSE PD SYNTH, ALPHA-PDO, LINX PDO)-MONOFILAMENT –POLY DI OXANONE SUTURE, MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN OPHTHALMIC SURGERY. MONOFILAMENT –POLY DI OXANONE SUTURE SUTURES IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE., STERILE POLYPROPYLENE MESH(SURGISUT- TRULENE MESH)-POLYPROPYLENE MESH IS USED FOR THE REPAIR OF HERNIA, ENDOSCOPIC PROCEDURES,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) COATED POLYGLACTIN 910-POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES.,SUTURING KIT CONTAINS (POLYGLYCOLIC ACID SUTURE, MONOFILAMENT NYLON SUTURE) (TRUGLYDE, TRULON)-1. POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES. 2. NYLON SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) COATED POLYGLACTIN 910(TRUSYNTH)-POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID FAST(RITEMED PGA FAST,GEYCOL FAST, POLYGLYCOLIC ACID FAST,U-GLYDE FAST,PGA RESOQUICK, SABASORB RAPID, LINX RPGA, ADVAMED-PGA FAST)-FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT-TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION WOULD

	BE BENEFICIAL. DUE TO THE ABSORPTION PROFILE FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. TRUGLYDE FAST IS NOT INTENDED FOR USE IN OPHTHALMIC SURGERY CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES., ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) STERILIZED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910(TRUSYNTH, BROCRYL 910, POLIGLACTINA 910, REDICRYL, Q-CLOSE SYNTH, ALPHA-CYRIL, LINX VIPRONE 910, POGAL 910)-POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID FAST(SURGISUT- TRUGLYDE FAST, N-CARE PGA FAST)-FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT-TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION WOULD BE BENEFICIAL. DUE TO THE ABSORPTION PROFILE FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. TRUGLYDE FAST IS NOT INTENDED FOR USE IN OPHTHALMIC SURGERY CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL COATED POLYESTER WITHOUT NEEDLE (TRUBOND, POLIESTER)-POLYESTER SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., HERNIA KIT CONTAINS (POLYPROPYLENE MESH, MONOFILAMENT POLYPROPYLENE SUTURE, POLYGLACTIN 910 SUTURE, MONOFILAMENT NYLON SUTURE)(TRULENE, TRUSYNTH, TRULON, TRULENE MESH)-1. POLYPROPYLENE MESH USED FOR THE REPAIR OF HERNIA. 2. POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES. 3. POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES. 4. NYLON SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,STERILE OXIDIZED REGENERATED CELLULOSE SURGICAL

	DRESSING(TRUSTAT, CLINICEL)-ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS, AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE.,STERILE OXIDIZED REGENERATED CELLULOSE SURGICAL DRESSINGS(-)-ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS, AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE.,STERILE BONEWAX-TRUWAX MAY BE USED FOR THE CONTROL OF BLEEDING FROM BONE SURFACES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE COATED POLYESTER(SURGISUT-TRUBOND, N-CARE POLYESTER)-POLYESTER SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25-MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,SUTURING KIT CONTAINS (POLYGLYCOLIC ACID SUTURE, MONOFILAMENT POLIGLECAPRONE 25 SUTURE)(TRUGLYDE, MONOGLYDE)-1. POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES. 2. MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,ABSORBABLE SURGICAL SUTURE STERILIZED SURGICAL SUTURE (SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25-MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,STERILE BONEWAX 2.5GM(EQUIWAX, DEMELENE WAX, LINXWAX, BONEWAXBW25, CERA PARA HUESOL)-BONEWAX MAY BE USED FOR THE CONTROL OF BLEEDING FROM BONE SURFACES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT 316 LVM STAINLESS STEEL WIRE(TRUSTEEL, ACERO, REDISTEEL, Q-CLOSE

	STEEL, ALPHA-STEEL, LINX STEEL)-STEEL SURGICAL SUTURE IS INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, ORTHOPEDIC PROCEDURES INCLUDING CERCILAGE & TENDON REPAIR AND ALSO IN STERNUM CLOSURE.,SUTURING KIT CONTAINS (POLYGLACTIN 910 SUTURE, MONOFILAMENT POLIGLECAPRONE 25 SUTURE, MONOFILAMENT POLYDIOXANONE SUTURE)(TRUSYNTH, MONOGLYDE, PD SYNTH)-1. POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES. 2. MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY. 3. MONOFILAMENT –POLY DI OXANONE SUTURE MONOFILAMENT SYNTHETIC ABSORBABLE SUTURE IS PREPARED FROM THE POLYESTER, POLY (P-DIOXANONE). THE EMPIRICAL FORMULA OF THE POLYMER IS (C4H603)X. POLYDIOXANONE POLYMER HAS BEEN FOUND TO BE NON ANTIGENIC, NON PYROGENIC AND ELICITS ONLY A SLIGHT TISSUE REACTION DURING ABSORPTION. IT IS COLORED VIOLET, DYED WITH D&C VIOLET. MONOFILAMENT –POLY DI OXANONE SUTURE COMPLY WITH USP REQUIREMENTS, EXCEPT FOR DIAMETER.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT 316 LVM STAINLESS STEEL WIRE-STEEL SURGICAL SUTURE IS INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, ORTHOPEDIC PROCEDURES INCLUDING CERCILAGE & TENDON REPAIR AND ALSO IN STERNUM CLOSURE., ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITH NEEDLE CHROMIC(H-GUT)-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE MONOFILAMENT NYLON WITHOUT NEEDLE-NYLON SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., SUTURING KIT CONTAINS (ANTIBACTERIAL WITH TRICLOSAN SUTURE, CATGUT CHROMIC SUTURE, MONOFILAMENT NYLON SUTURE)(TRUGUT, TRULON, TRUSYNTH PLUS)-1. TRUSYNTH PLUS ANTIBACTENAL SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION EXCEPT FOR OPHTHALMIC, CARDIOVASCULAR AND NEUROLOGICAL TISSUES. 2. CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE

	APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES. 3. NYLON SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,STERILE OXIDIZED REGENERATED CELLULOSE SURGICAL DRESSING-ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS, AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE.,SUTURING KIT CONTAINS (POLYGLYCOLIC ACID SUTURE, MONOFILAMENT POLIGLECAPRONE 25 SUTURE)(TRUGLYDE, MONOGLYDE)-1. POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES. 2. MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY. 2.,NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL SUTURE WITHOUT NEEDLE BLACK BRAIDED SILK-SILK SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., HERNIA KIT CONTAINS (POLYPROPYLENE MESH, MONOFILAMENT POLYPROPYLENE SUTURE, POLYGLYCOLIC ACID SUTURE)(TRULENE, TRUGLYDE, TRULENE MESH)-1. POLYPROPYLENE MESH USED FOR THE REPAIR OF HERNIA. 2. POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES. 3. POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) STERILISED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910-POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITH NEEDLE - PLAIN(SURGISUT- TRUGUT PLAIN)-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR

	LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) POLY(HEXA FLUROPROPYLENE-VINYLIDENE FLUORIDE)-POLY(HEXA FLUROPROPYLENE-VDF) SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT 316 LVM STAINLESS STEEL WIRE(SURGISUT- TRUSTEEL, N-CARE STEEL)-STAINLESS STEEL SURGICAL SUTURE IS INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, ORTHOPEDIC PROCEDURES INCLUDING CERCILAGE & TENDON REPAIR AND ALSO IN STERNUM CLOSURE.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) STERILIZED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910 FAST-FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO THE RAPID ABSORPTION PROFILE, FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES.,STERILE OXIDIZED REGENERATED CELLULOSE SURGICAL DRESSING(SURGISUT- CLINICEL)-ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS, AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) MONOFILAMENT POLYDIOXANONE-MONOFILAMENT – POLY DI OXANONE SUTURE, MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN OPHTHALMIC SURGERY. MONOFILAMENT –POLY DI OXANONE SUTURE SUTURES IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) BRAIDED &

	COATED POLYGLYCOLIC ACID(H-GLYDE)-POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE COATED POLYESTER (TRUBOND, BROPOLYESTER, BOND, POLIESTER, REDIBOND, Q-CLOSE BOND, ALPHA-BOND, LINX X-BOND)-POLYESTER SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,LIGATING CLIPS(Q TIE, TRUTIE)-LIGATING CLIPS HAVE APPLICATIONS FOR USE ON TUBULAR STRUCTURES OR VESSELS WHERE EVER METAL LIGATING CLIPS ARE INDICATED. THE TISSUE BEING LIGATED SHOULD BE CONSISTENT WITH THE SIZE OF THE LIGATING CLIPS,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT NYLON-NYLON SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., SUTURING KIT CONTAINS(POLYGLACTIN 910 SUTURE, MONOFILAMENT POLIGLECAPRONE 25 SUTURE)(TRUSYNTH MONOGLYDE)-1. POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES. 2. MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) STERILIZED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910 FAST(TRUSYNTH FAST, REDICRYL FAST, Q-CLOSE SYNTH FAST, ALPHA-CYRIL FAST, LINX RAPID VIPRONE 910 FAST)-FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO THE RAPID ABSORPTION PROFILE, FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES.,SUTURING KIT CONTAINS (POLYGLYCOLIC ACID SUTURE, MONOFILAMENT NYLON SUTURE) (TRUGLYDE, TRULON)-1. POLYGLYCOLIC ACID SUTURE IS INDICATED

	FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES. 2. NYLON SUTURE IS A NON ABSORBABLE, STERILE, SURGICAL SUTURE, COMPOSED OF LONG CHAIN-ALIPHATIC POLYMERS, NYON 6 AND NYLON 6.6. THE MONOFILAMENT POLYAMIDE SUTURES ATTACHED NEEDLES ARE AVAILABLE IN BLACK AND BLUE, COLORS DYED WITH FDA APPROVED DYES. POLYAMIDE 6.6 IS FORMED BY POLYCONDENSATION OF HEXAMETHYLENE DIAMINE AND ADIPIC ACID. POLYAMIDE 6 IS FORMED BY POLYMERISATION OF EPSILON CAPROLACTUM. BLUE NYLON SUTURES IS DYED WITH A BLUE PIGMENT, COLOUR INDEX NO.69800 AND BLACK NYLON SUTURE IS DYED WITH HAEMATIN HCK, COLOUR INDEX NO. 75290. NYLON SUTURE MEETS ALL THE REQUIREMENTS, ESTABLISHED BY THE UNITED STATES PHARMACOPEIA FOR NON ABSORBABLE SURGICAL SUTURE.,ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITHOUT NEEDLE - CHROMIC(TRUGUT, BROCHROMIC, CATGUT CROMADO)-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES., SUTURING KIT CONTAINS (POLYGLACTIN 910 SUTURE , MONOFILAMENT POLIGLECAPRONE 25 SUTURE SN 3326 , CATGUT CHROMIC SUTURE)(TRUSYNTH, MONOGLYDE, TRUGUT)-1. POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES. 2. MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY. 3. CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP ANTIBACTERIAL WITH TRICLOSAN STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) COATED POLYGLACTIN 910-POLYGLACTIN 910 ANTIBACTERIAL SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION EXCEPT FOR OPHTHALMIC, CARDIOVASCULAR AND NEUROLOGICAL TISSUES., HERNIA KIT CONTAINS (POLYPROPYLENE MESH, MONOFILAMENT POLYPROPYLENE SUTURE, MONOFILAMENT POLIGLECAPRONE 25 SUTURE)(TRULENE, MONOGLYDE, TRULENE MESH)-1. POLYPROPYLENE MESH USED FOR THE REPAIR OF HERNIA. 2.

	POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES. 3. MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE-ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE IS INDICATED FOR USE IN APPROXIMATION AND/OR LIGATION OF SOFT TISSUE, INCLUDING THE USE IN CARDIOVASCULAR SURGERIES AND THE USE OF ALLOGRAFT TISSUE FOR ORTHOPEDIC PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE COATED POLYESTER(VETSUTURE BOND, NOÉCARE BOND, NOÉDENTAL BOND,RITEMED POLYESTER, KEYCRON, U- BOND,POLYTEK,HMS POLYESTER, SABAGUARD, ADVAMED POLYESTER, LINX BOND)-POLYESTER SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) ULTRA HIGH MOLECULAR WEIGHT(CLINI FIBRE)-CLINI FIBRE IS INDICATED FOR USE IN APPROXIMATION AND/OR LIGATION OF SOFT TISSUE, INCLUDING THE USE IN CARDIOVASCULAR SURGERIES AND THE USE OF ALLOGRAFT TISSUE FOR ORTHOPEDIC PROCEDURES.,HERNIA KIT CONTAINS (POLYPROPYLENE MESH, MONOFILAMENT POLYPROPYLENE SUTURE, POLYGLYCOLIC ACID SUTURE, MONOFILAMENT NYLON SUTURE)(TRULENE, TRUGLYDE, TRULON, TRULENE MESH)-1. POLYPROPYLENE MESH USED FOR THE REPAIR OF HERNIA. 2. POLYPROPYLENE SUTURE IS A NON ABSORBABLE, STERILE, SURGICAL SUTURE, COMPOSED OF POLYPROPYLENE, A SYNTHETIC LINEAR POLYOLEFIN. THE MOLECULAR FORMULA IS (C3H6) N. POLYPROPYLENE SUTURE IS COLORED BLUE WITH PHTHALOCYANINE COPPER BLUE, COLOR INDEX NO.74160, AND U.S. F.D.A.APPROVED DYE. POLYPROPYLENE SUTURE IS MONOFILAMENT AND IT IS UNCOATED. POLYPROPYLENE SUTURE MEETS ALL THE REQUIREMENTS AS PER UNITED STATES PHARMACOPEIA FOR NON ABSORBABLE SURGICAL SUTURE. 3. POLYGLYCOLIC ACID SUTURE IS AN ABSORBABLE, STERILE, SYNTHETIC SURGICAL SUTURE, COMPOSED OF HOMOPOLYMERS OF GLYCOLIDE(100%). POLYGLYCOLIC ACID SUTURE IS COLORED VIOLET WITH D & C VIOLET NO.2, CONFORMING TO U.S.CODE OF FEDERAL REGULATIONS. POLYGLYCOLIC ACID SUTURE IS AVAILABLE UNDYED ALSO. FOR

	ADDED LUBRICATION AND SMOOTHNESS, POLYGLYCOLIC ACID SUTURE IS COATED WITH UNIQUE COMBINATION OF POLYCAPROLACTONE AND CALCIUM STEARATE. POLYGLYCOLIC ACID SUTURE MEETS ALL THE REQUIREMENTS AS PER UNITED STATES P.HARMACOPEIA FOR ABSORBABLE SURGICAL SUTURE (SYNTHETIC) 4. NYLON SUTURE IS A NON ABSORBABLE, STERILE, SURGICAL SUTURE, COMPOSED OF LONG CHAIN-ALIPHATIC POLYMERS, NYON 6 AND NYLON 6.6. THE MONOFILAMENT POLYAMIDE SUTURES ATTACHED NEEDLES ARE AVAILABLE IN BLACK AND BLUE, COLORS DYED WITH FDA APPROVED DYES. POLYAMIDE 6.6 IS FORMED BY POLYCONDENSATION OF HEXAMETHYLENE DIAMINE AND ADIPIC ACID. POLYAMIDE 6 IS FORMED BY POLYMERISATION OF EPSILON CAPROLACTUM. BLUE NYLON SUTURES IS DYED WITH A BLUE PIGMENT, COLOUR INDEX NO. 69800 AND BLACK NYLON SUTURE IS DYED WITH HAEMATIN HCK, COLOUR INDEX NO. 75290. NYLON SUTURE MEETS ALL THE REQUIREMENTS, ESTABLISHED BY THE UNITED STATES PHARMACOPEIA FOR NON ABSORBABLE SURGICAL SUTURE., ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID FAST(TRUGLYDE FAST, BROCRYL RAPID, FAST PGA, REDISORB FAST, Q-CLOSE GLYDE FAST, ALPHA-SORB FAST, LINX RAPID VIPRONE, POGAL FAST)-FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT-TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION WOULD BE BENEFICIAL. DUE TO THE ABSORPTION PROFILE FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. FAST ABSORBABLE POLYGLYCOLIC ACID IS NOT INTENDED FOR USE IN OPHTHALMIC SURGERY CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES. NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE(VETSUTURE LENE, NOÉCARE LENE, NOÉDENTAL LENE,RITEMED POLYPROPYLENE, LINX PROLINE, KEYLENE, POLYPROPYLENE,MOPYLEN,SABAPOL, ADVAMED POLYPROPYLENE, LINX PROLINE)-POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITH NEEDLE - PLAIN-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN

	CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,SUTURING KIT CONTAINS (POLYGLACTIN 910 SUTURE , MONOFILAMENT POLIGLECAPRONE 25 SUTURE)(TRUSYNTH, MONOGLYDE)-1. POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES. 2. MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID(TRUGLYDE, ACIDO POLIGLICOLICO)-POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITH NEEDLE - CHROMIC (SURGISUT- TRUGUT CHROMIC)-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE(TRULENE, ALAN LENE, BROPROPYLENE, LENE, PROPYL CUT, POLIPROPILENO, REDILENE, Q-CLOSE POLYP, ALPHA-LENE, LINX CARDIOPILENE, U-LENE)-POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., SUTURING KIT CONTAINS (POLYGLYCOLIC ACID SUTURE, MONOFILAMENT NYLON SUTURE)(TRUGLYDE, TRULON)-1. POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES. 2. NYLON SUTURE IS A NON ABSORBABLE, STERILE, SURGICAL SUTURE, COMPOSED OF LONG CHAIN-ALIPHATIC POLYMERS, NYON 6 AND NYLON 6.6. THE MONOFILAMENT POLYAMIDE SUTURES ATTACHED NEEDLES ARE AVAILABLE IN BLACK AND BLUE, COLORS DYED WITH FDA APPROVED DYES. POLYAMIDE 6.6 IS FORMED BY POLYCONDENSATION OF HEXAMETHYLENE DIAMINE AND ADIPIC ACID. POLYAMIDE 6 IS FORMED BY POLYMERISATION OF EPSILON CAPROLACTUM. BLUE NYLON SUTURES IS DYED WITH A BLUE PIGMENT, COLOUR INDEX NO.69800 AND BLACK NYLON SUTURE IS

	DYED WITH HAEMATIN HCK, COLOUR INDEX NO. 75290. NYLON SUTURE MEETS ALL THE REQUIREMENTS, ESTABLISHED BY THE UNITED STATES PHARMACOPEIA FOR NON ABSORBABLE SURGICAL SUTURE.,ABSORBABLE SURGICAL SUTURE USP ANTIBACTERIAL WITH TRICLOSAN STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) COATED POLYGLACTIN 910(TRUSYNTH PLUS)-TRUSYNTH PLUS ANTIBACTERIAL SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION EXCEPT FOR OPHTHALMIC, CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE BLACK BRAIDED SILK(SURGISUT-TRUSILK, N-CARE SILK)-SILK SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) POLY(HEXA FLUROPROPYLENE-VINYLIDENE FLUORIDE)(TRUVYL)-POLY(HEXA FLUROPROPYLENE-VDF) SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) STERILIZED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910 (SURGISUT- TRUSYNTH, N-CARE POLYGLACTIN 910)-POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID-POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES., HERNIA KIT CONTAINS (POLYPROPYLENE MESH, MONOFILAMENT POLYPROPYLENE SUTURE, POLYGLACTIN 910 SUTURE, BLACK BRAIDED SILK SUTURE)(TRULENE, TRUSYNTH, TRUSILK, TRULENE MESH)-1. POLYPROPYLENE MESH USED FOR THE REPAIR OF HERNIA. 2. POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES. 3. POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES. 4. SILK SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING

	USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE STERILIZED SURGICAL SUTURE (SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25 (MONOGLYDE, POGAL MONO, POLIGLECAPRONE 25)-MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) STERILIZED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910 FAST(SURGISUT- TRUSYNTH FAST, N-CARE POLYGLACTIN 910 FAST)-FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO THE RAPID ABSORPTION PROFILE, FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES., ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID FAST-FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT-TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION WOULD BE BENEFICIAL. DUE TO THE ABSORPTION PROFILE FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS NOT INTENDED FOR USE IN OPHTHALMIC SURGERY CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES.,ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) STERILISED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910(VETSUTURE PGLA, NOÉCARE PGLA, NOÉDENTAL PGLA, ISYNTH, RITEMED PGLA, GEY910, POLYGLACTIN,U-SYNTH, ADVAMED PGLA, LINX PGLA)-POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES., NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE WITHOUT NEEDLE BLACK BRAIDED SILK(TRUSILK, SEDA NEGRA)-SILK SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,

	ABSORBABLE SURGICAL NEEDLED-SUTURE (SYNTHETIC) KNOTLESS TISSUE-CLOSURE DEVICE MONOFILAMENT POLYDIAXANONE(Q CLOSE BARBED SUTURES, RESORBA BARBED SUTURE, PDX BARB, LINX BARBED, IM-BARBED)-POLYDIAXANONE KNOTLESS TISSUE-CLOSURE DEVICE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE USE OF POLYDIAXANONE ABSORBABLE SUTURE IS APPROPRIATE.,ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITH NEEDLE - CHROMIC-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE(RESORBA®OTZZ-CORD) -ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE SUTURE IS INDICATED FOR USE IN APPROXIMATION AND/OR LIGATION OF SOFT TISSUE, INCLUDING THE USE IN CARDIOVASCULAR SURGERIES AND THE USE OF ALLOGRAFT TISSUE FOR ORTHOPEDIC PROCEDURES., ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITHOUT NEEDLE - PLAIN-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES., ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) MONOFILAMENT POLYDIOXANONE (SURGISUT- PDSYNTH, N-CARE PD SYNTH)-MONOFILAMENT –POLY DI OXANONE SUTURE, MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN OPHTHALMIC SURGERY. MONOFILAMENT –POLY DI OXANONE SUTURE SUTURES IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE., ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25(MONOGLYDE , BROCRYL MONO FAST, PGC, POLIGLECAPRONE 25, REDICAPRONE 25, Q-CLOSE MONO, ALPHA-MONO, LINX MONOPRONE)-MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT 316 LVM STAINLESS STEEL WIRE(ADVAMED STEEL

	SUTURE)-STEEL SURGICAL SUTURE IS INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, ORTHOPEDIC PROCEDURES INCLUDING CERCILAGE & TENDON REPAIR AND ALSO IN STERNUM CLOSURE.,STERILE POLYPROPYLENE MESH(TRULENE MESH, ALPHA-LENE MESH, LINX MESH)-TRULENE MESH IS USED FOR THE REPAIR OF HERNIA, ENDOSCOPIC PROCEDURES.,ABSORBABLE SURGICAL SUTURE USP ANTIBACTERIAL WITH TRICLOSAN STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) COATED POLYGLACTIN 910(SURGISUT- TRUSYNTH PLUS)-TRUSYNTH PLUS ANTIBACTERIAL SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) BRAIDED AND COATED POLYGLYCOLICACID FAST-FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT-TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION WOULD BE BENEFICIAL. DUE TO THE ABSORPTION PROFILE FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. TRUGLYDE FAST IS NOT INTENDED FOR USE IN OPHTHALMIC SURGERY CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES.,STERILE BONEWAX 2.5GM(IM-WAX, LINX WAX)-BONEWAX MAY BE USED FOR THE CONTROL OF BLEEDING FROM BONE SURFACES.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID FAST(TRUGLYDE FAST)-FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT-TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION WOULD BE BENEFICIAL. DUE TO THE ABSORPTION PROFILE FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. TRUGLYDE FAST IS NOT INTENDED FOR USE IN OPHTHALMIC SURGERY CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES.,STERILE POLYPROPYLENE MESH(B LENE MESH, HMLENE MESH, IM-LENEMESH, LINX LAPRO MESH, RESORBA MESH)-POLYPROPYLENE MESH USED FOR THE REPAIR OF HERNIA.,ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITHOUT NEEDLE - CHROMIC-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR

	AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITH NEEDLE - PLAIN(TRUVET CATGUT PLAIN, TRUDENT CATGUT PLAIN, ECATGUT, ALPHAGUT)-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITHOUT NEEDLE - PLAIN (TRUGUT, BROPLAIN, CATGUT SIMPLE)-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITH NEEDLE - CHROMIC.(TRUVET CATGUT CHROMIC, TRUDENT CATGUT CHROMIC, ECHROMIC, ALPHAGUT)-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) BRAIDED & COATED POLYGLYCOLIC ACID-POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT 316 LVM STAINLESS STEEL WIRE(B STEEL, HMSTEEL)-STEEL SURGICAL SUTURE IS INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, ORTHOPEDIC PROCEDURES INCLUDING CERCILAGE & TENDON REPAIR AND ALSO IN STERNUM CLOSURE.,NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL NEEDLED SUTURE BLACK BRAIDED SILK-SILK SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE COATED POLYESTER(SUPOLENE, SUPOLENE CV, B BOND, HMBOND, TRUVET POLYESTER, TRUDENT POLYESTER, IM-BOND, ALPHABOND, ELYESTER, UNODENT POLYESTER)-POLYESTER SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE STERILIZED SURGICAL SUTURE (SYNTHETIC) MONOFILAMENT POLY DI OXANONE(PD SYNTH, POLY DI OXANONE)-MONOFILAMENT –POLY DI OXANONE SUTURE, MONOFILAMENT

	SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN OPHTHALMIC SURGERY. MONOFILAMENT –POLY DI OXANONE SUTURE SUTURES IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID FAST(HMGLYDE FAST, TRUVET POLYGLYCOLIC ACID FAST, TRUDENT POLYGLYCOLIC ACID FAST, IM-GLYDE FAST, ESORB PLUS, UNODENT PGA FAST)-FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT-TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION WOULD BE BENEFICIAL. DUE TO THE ABSORPTION PROFILE FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. POLYGLYCOLIC ACID FAST IS NOT INTENDED FOR USE IN OPHTHALMIC SURGERY CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT NYLON(TRULON, NYLAMID, ALAN LON, BRONYLON, NYLON, NYLON MONOFILAMENTONEGRA, REDILON, Q-CLOSE NYLON, LINX NYLON, U-LON, ALPHA-LON)-NYLON SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,STERILE OXIDIZED REGENERATED CELLULOSE SURGICAL DRESSINGS(LINX CELL, Q CLOSE STAT, CLINICEL, Q CLOSE CEL)-ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS, AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE.,ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITH NEEDLE - CHROMIC(TRUGUT, BROCHROMIC, CATGUT CROMADO, REDIGUT CHROMIC, U-GUT)-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL NEEDLED SUTURE BLACK BRAIDED SILK (TRUVET SILK, TRUDENT SILK, IM-SILK, ALPHASILK, ESILK, UNODENT SILK)-SILK SUTURE IS INDICATED FOR USE IN SOFT TISSUE

	APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID(TRUGLYDE, POGAL, ALAN GLYDE, EICKFIL, BROCRYL PGA, PGA, POGAL FAST, ACIDO POLIGLICOLICO, REDISORB, Q-CLOSE GLYDE, ALPHA-SORB, LINX VIPRONE, ANNCRYL, U-GLYDE)-POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) MONOFILAMENT POLYDIOXANONE(U-PDSYNTH, B PD SYNTH, HMPDSYNTH, TRUVET POLYDIOXANONE, TRUDENT POLYDIOXANONE, IM-PDS, EXANONE, UNODENT PDO)-MONOFILAMENT POLY DI OXANONE SUTURE, MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN OPHTHALMIC SURGERY. MONOFILAMENT –POLY DI OXANONE SUTURE SUTURES IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE BLACK BRAIDED SILK (TRUSILK, ALAN SILK, BROSILK, SEDA NEGRA, REDISILK, Q-CLOSE SILK, ALPHA-SILK, LINX SILK, U-SILK, SILKCUT)-SILK SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT NYLON(B LON, HMLON, TRUVET NYLON, TRUDENT NYLON, IM-LON, ALPHALON, ELYAMIDE, UNODENT NYLON)-NYLON SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE COATED POLYESTER-POLYESTER SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE(MOPYLEN CV, B LENE, HMLENE, TRUVET POLYPROPYLENE,TRUDENT POLYPROPYLENE, IM-LENE, ALPHALENE, EPYLENE, UNODENT POLYPROPYLENE)-

	POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., ABSORBABLE SURGICAL SUTURE STERILIZED SURGICAL SUTURE (SYNTHETIC) MONOFILAMENT POLYDIOXANONE-MONOFILAMENT –POLY DI OXANONE SUTURE, MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN OPHTHALMIC SURGERY. MONOFILAMENT –POLY DI OXANONE SUTURE SUTURES IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) BRAIDED & COATED POLYGLYCOLIC ACID(B GLYDE, HMGLYDE, TRUVET POLYGLYCOLIC ACID, TRUDENT POLYGLYCOLIC ACID, IM-GLYDE, ESORB, UNODENT PGA)-POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES., ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) MONOFILAMENT POLYDIOXANONE-MONOFILAMENT –POLY DI OXANONE SUTURE, MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN OPHTHALMIC SURGERY. MONOFILAMENT –POLY DI OXANONE SUTURE SUTURES IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) STERILIZED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910 FAST(HMSYNTH FAST, TRUVET POLYGLACTIN FAST, TRUDENT POLYGLACTIN FAST, FLYSORB FAST, IM-SYNTH FAST, ALPHACRYL FAST, ECRYL PLUS, UNODENT PGLA FAST)-FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO THE RAPID ABSORPTION PROFILE, FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS

	ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE CATGUT CHROMIC-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25(U-MONOGLYDE, B-ONOGLYDE, HMCRYL, TRUVET POLIGLECAPRONE, TRUDENT POLIGLECAPRONE, IM-MONO, ECAPRONE, UNODENT PGCL)-MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE CATGUT PLAIN-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES. , ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) STERILIZED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910(B SYNTH, HMSYNTH, TRUVET POLYGLACTIN, TRUDENT POLYGLACTIN, FLYSORB, IM-SYNTH, ALPHA CRYIL, ECRYL, UNODENT PGLA)-POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP ANTIBACTERIAL WITH TRICLOSAN STERILIZED SURGICAL SUTURE (SYNTHETIC) COATED POLYGLACTIN 910-POLYGLACTIN 910 ANTIBACTERIAL SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION EXCEPT FOR OPHTHALMIC, CARDIOVASCULAR AND NEUROLOGICAL TISSUES., STERILE OXIDIZED REGENERATED CELLULOSE SURGICAL DRESSING (CLINICEL)-ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS, AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE MONOFILAMENT 316 LVM STAINLESS STEEL WIRE-STAINLESS STEEL SURGICAL SUTURE IS INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, ORTHOPEDIC PROCEDURES INCLUDING CERCILAGE & TENDON REPAIR AND ALSO IN STERNUM CLOSURE.,ABSORBABLE SURGICAL SUTURE USP STERILIZED

	SURGICAL NEEDLED SUTURE (SYNTHETIC) MONOFILAMENT POLY DI OXANONE(VETSUTURE PDX, NOÉCARE PDX,NOÉDENTAL PDX, RITEMED POLYDIOXONONE,PDO RESORBA,SABAGLYDE PLUS, ADVAMED-PD)-MONOFILAMENT POLY DI OXANONE SUTURE, MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN OPHTHALMIC SURGERY. MONOFILAMENT –POLY DI OXANONE SUTURE SUTURES IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE.,NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL NEEDLED SUTURE BLACK BRAIDED SILK (MARV-SILK, PISILK, GLYSILK)-SILK SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) BRAIDED & COATED POLYGLYCOLIC ACID(SURGISUT- TRUGLYDE, N-CARE PGA)-POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) POLY(HEXA FLUROPROPYLENE-VINYLIDENE FLUORIDE)-POLY(HEXA FLUROPROPYLENE-VDF) SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT NYLON (SURGISUT- TRULON, N-CARE NYLON)-NYLON SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL SUTURE BLACK BRAIDED SILK-SILK SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,SUTURING KIT CONTAINS (POLYGLACTIN 910 SUTURE, MONOFILAMENT POLIGLECAPRONE)(TRUSYNTH, MONOGLYDE)-1. POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES. 2. MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR

	USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) BRAIDED & COATED POLYGLYCOLIC ACID-POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES. , HERNIA KIT CONTAINS (POLYPROPYLENE MESH, MONOFILAMENT POLYPROPYLENE SUTURE, MONOFILAMENT POLIGLECAPRONE 25 SUTURE)(TRULENE, MONOGLYDE, TRULENE MESH)-1. MESH-POLYPROPYLENE MESH USED FOR THE REPAIR OF HERNIA. 2. MONOFILAMENT POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES. 3. MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE COATED POLYESTER-POLYESTER SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT NYLON(VETSUTURE NYLON, NOÉCARE NYLON, NOÉDENTAL NYLON, RITEMED NYLON,KEYLON, MONOMYD,HMS NYLON, ADVAMED NYLON)-NYLON SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) KNOTLESS TISSUE-CLOSURE DEVICE MONOFILAMENT POLIGLECAPRONE 25(TRUBARB, TRULOCK, TRUQUICK)-POLIGLECAPRONE 25 KNOTLESS TISSUE-CLOSURE DEVICE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE THE USE OF ABSORBABLE SUTURES IS APPROPRIATE.,SUTURING KIT CONTAINS (POLYGLYCOLIC ACID SUTURE, MONOFILAMENT POLIGLECAPRONE 25 SUTURE)(TRUGLYDE, MONOGLYDE)-1. POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES. 2. MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC

	SURGERY.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE(SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25-MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,HERNIA KIT CONTAINS (POLYPROPYLENE MESH, MONOFILAMENT POLYPROPYLENE SUTURE, POLYGLYCOLIC ACID SUTURE, MONOFILAMENT NYLON SUTURE)(TRULENE, TRUGLYDE, TRULON, TRULENE MESH)-1. POLYPROPYLENE MESH USED FOR THE REPAIR OF HERNIA. 2. POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES. 3. POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES. 4. NYLON SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) STERILIZED SURGICAL SUTURE COATED POLYGLACTIN 910-POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES. ,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25(VETSUTURE PGC, NOÉCARE PGC, NOÉDENTAL PGC,RITEMED POLIGLECAPRONE, GEYCRYL, POLIGLECAPRONE 25, FLYSORB MONO, ADVAMED POLIGLECAPRONE, LINX-MONO)-MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE-CLINI FIBRE IS INDICATED FOR USE IN APPROXIMATION AND/OR LIGATION OF SOFT TISSUE, INCLUDING THE USE IN CARDIOVASCULAR SURGERIES AND THE USE OF ALLOGRAFT TISSUE FOR ORTHOPEDIC PROCEDURES.,SUTURING KIT CONTAINS (POLYGLACTIN 910 SUTURE, MONOFILAMENT POLIGLECAPRONE 25 SUTURE)(TRUSYNTH MONOGLYDE)-1. POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR

	AND NEUROLOGICAL TISSUES. 2. MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL SUTURE MONOFILAMENT POLYPROPYLENE-: POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES, STERILE BONEWAX 2.5GM(SURGISUT- TRUWAX)-BONEWAX MAY BE USED FOR THE CONTROL OF BLEEDING FROM BONE SURFACES., ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE(SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID FAST-FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT-TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION WOULD BE BENEFICIAL. DUE TO THE ABSORPTION PROFILE FAST ABSORBABLE POLYGLYCOLIC ACID SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. TRUGLYDE FAST IS NOT INTENDED FOR USE IN OPHTHALMIC SURGERY CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES. SUTURING KIT CONTAINS (POLYGLACTIN 910 SUTURE , MONOFILAMENT POLIGLECAPRONE 25 SUTURE ,MONOFILAMENT POLYDIOXANONE SUTURE(TRUSYNTH, MONOGLYDE, PD SYNTH)-1. POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES. 2. MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY. 3. MONOFILAMENT –POLY DI OXANONE SUTURE, MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN OPHTHALMIC SURGERY. MONOFILAMENT –POLY DI OXANONE SUTURE SUTURES IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) KNOTLESS TISSUE-CLOSURE DEVICE MONOFILAMENT POLYDIOXANONE(TRUBARB, TRULOCK, TRUQUICK)- POLYDIOXANONE KNOTLESS TISSUE-CLOSURE DEVICE COMPRISED

	OF DYED PDO IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE USE OF ABSORBABLE SUTURES IS APPROPRIATE.,HERNIA KIT CONTAINS (POLYPROPYLENE MESH, MONOFILAMENT POLYPROPYLENE SUTURE, MONOFILAMENT POLIGLECAPRONE 25 SUTURE)(TRULENE, MONOGLYDE, TRULENE MESH)-1. POLYPROPYLENE MESH USED FOR THE REPAIR OF HERNIA. 2. POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES. 3. MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE(CLINIFIBRE TAPE, SIRONIX)- ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE IS INDICATED FOR USE IN APPROXIMATION AND/OR LIGATION OF SOFT TISSUE, INCLUDING THE USE IN CARDIOVASCULAR SURGERIES AND THE USE OF ALLOGRAFT TISSUE FOR ORTHOPEDIC PROCEDURES , SUTURING KIT CONTAINS (POLYGLACTIN 910 SUTURE, MONOFILAMENT POLYPROPYLENE SUTURE SN 843, MONOFILAMENT POLIGLECAPRONE 25 SUTURE)(TRUSYNTH, TRULENE, MONOGLYDE) -1. POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES. 2. POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES. 3. MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE COATED POLYESTER(MARV-BOND, PIBOND, TRUBOND TAPE, TRUBOND FOR CV)-POLYESTER SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL NEEDLED SUTURE BLACK BRAIDED SILK (VETSUTURE SILK, NOÉCARE SILK, NOÉDENTAL SILK,ISILK, RITEMED SILK, KEYSILK, SILK,SETA, SEIDE, ADVAMED SILK)-SILK SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,STERILE BONEWAX 2.5GM(MARV-

	BONEWAX, PIMAIN)-TRUWAX MAY BE USED FOR THE CONTROL OF BLEEDING FROM BONE SURFACES.,ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITH NEEDLE CHROMIC (LINX X CHOME)-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT 316 LVM STAINLESS STEEL WIRE(TITAN WIRE, TITAN DOUBLE WIRE)-STEEL SURGICAL SUTURE IS INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, ORTHOPEDIC PROCEDURES INCLUDING CERCILAGE & TENDON REPAIR AND ALSO IN STERNUM CLOSURE.,SUTURING KIT CONTAINS (POLYGLYCOLIC ACID SUTURE, BLACK BRAIDED SILK SUTURE)(TRUGLYDE, TRUSILK)-1. POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES. 2. SILK SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT 316 LVM STAINLESS STEEL WIRE (MARV-STEEL, PISTEEL)-STEEL SURGICAL SUTURE IS INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, ORTHOPEDIC PROCEDURES INCLUDING CERCILAGE & TENDON REPAIR AND ALSO IN STERNUM CLOSURE.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) MONOFILAMENT POLYDIOXANONE(MARV-PDO, PIPDS)-MONOFILAMENT –POLY DI OXANONE SUTURE, MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN OPHTHALMIC SURGERY. MONOFILAMENT –POLY DI OXANONE SUTURE SUTURES IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT NYLON(MARV-NYLON, PILON, GLYLON)-NYLON SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., STERILE POLYPROPYLENE MESH(MARV-LENE MESH, PIMESH, TRULENE MESH)-TRULENE MESH IS USED FOR THE REPAIR OF HERNIA, ENDOSCOPIC PROCEDURES.,ABSORBABLE SURGICAL

	SUTURE (SYNTHETIC) STERILIZED SURGICAL SUTURE COATED POLYGLACTIN 910 FAST-:FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO THE RAPID ABSORPTION PROFILE, FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES,NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE(MARV-LENE, PILENE, GLYLENE, TRULENE FOR CV)-POLYPROPYLENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL NEEDLED SUTURE (SYNTHETIC) KNOTLESS TISSUE-CLOSURE DEVICE MONOFILAMENT POLIGLECAPRONE 25(TRUBARB, TRULOCK, TRUQUICK)-POLIGLECAPRONE 25 KNOTLESS TISSUE-CLOSURE DEVICE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE THE USE OF ABSORBABLE SUTURES IS APPROPRIATE.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25(MARV-MONO, PICAP, MONOFYL)-MONOFILAMENT POLIGLECAPRONE 25 SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,ABSORBABLE SURGICAL NEEDLED SUTURE (SYNTHETIC) KNOTLESS TISSUE-CLOSURE DEVICE MONOFILAMENT POLYDIOXANONE(TRUBARB, TRULOCK, TRUQUICK)-POLYDIOXANONE KNOTLESS TISSUE-CLOSURE DEVICE COMPRISED OF DYED PDO IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE USE OF ABSORBABLE SUTURES IS APPROPRIATE.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) BRAIDED & COATED POLYGLYCOLIC ACID(MARV-SORB, PIGLYCOLIC)-POLYGLYCOLIC ACID SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITH AND WITHOUT NEEDLE-CHROMIC(MARV-GUT, PIGUT, TRULOOP)-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES

	BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) STERILIZED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910 FAST (MARV-CRYIL FAST, PICRYL FAST)-FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO THE RAPID ABSORPTION PROFILE, FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. FAST ABSORBABLE POLYGLACTIN 910 SUTURE IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES.,TEMPORARY CARDIAC PACING WIRE(TRUPACE)-TRUPACE IS INDICATED FOR USE IN TEMPORARY CARDIAC PACING OR MONITORING PROCEDURE FOLLOWING OPEN-HEART SURGERY AND IS USED IN COMBINATION WITH A PACING UNIT.,ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITH NEEDLE - PLAIN(MARV-GUT, PIGUT) -CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) STERILISED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910(MARV-CRYIL, PICRYL, GLYCRYL)-POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP ANTIBACTERIAL WITH TRICLOSAN STERILIZED SURGICAL NEEDLED SUTURE(SYNTHETIC) COATED POLYGLACTIN 910(TRUSYNTH PLUS NEO, U-SYNTH PLUS NEO)-POLYGLACTIN 910 ANTIBACTERIAL SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION EXCEPT FOR OPHTHALMIC, CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,STERILE OXIDIZED REGENERATED CELLULOSE SURGICAL DRESSING(LINX CEL)-ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS, AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE.,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE MONOFILAMENT NYLON(POLYAMIDE)-NYLON SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND

	NEUROLOGICAL TISSUES.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3277	MFG/MD/2019/000140	1.License Holder Name: GESCO HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:POSTERIOR OCCIPITAL CERVICO - THORACIC FIXATION(POSTERIOR OCCIPITAL CERVICO - THORACIC FIXATION)-INTENDED FOR THE FIXATION AND THE STABILIZATION OF THE OCCIPITAL CERVICAL AND THORACIC SPINE IN INSTABILITY DEGENERATION TRAUMA RECONSTRUCTION, CERVICAL ANTERIOR PLATE - DISTRACTABLE(CERVICAL ANTERIOR DISTRACTABLE PLATE (CRESCO))-FIXATION AND STABILIZATION OF THE CERVICAL SPINE; THE CERVICAL PLATE SYSTEM IS INTENDED FOR ANTERIOR SCREW FIXATION OF THE CERVICAL SPINE PARTICULARLY TO CORRECT THE FIXATION OF CERVICAL SPINAL DEFORMITIES THOUGH FUSION,ATLANTO AXIAL SYSTEM(GAAS - GOEL ATLANTO AXIAL SYSTEM)-FIXATION OF THE ATLANTO AXIAL JUNCTION C1 / C2 FIXATION,GOEL FACET PROSTHESIS(GFS- GOEL FACET PROSTHESIS)-FACET REPLACEMENT PROSTHESIS,PEDICLE SCREW SYSTEM(GSGM - GANGA SPINAL GROWTH MODULATOR)-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION ,VERTEBRAL BODY CAGE POSTERIOR - TLIF INTERBODY CAGE(BEAN CAGE)-THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE THORACIC AND LUMBAR SPINE. TLIF,PEDICLE SCREW SYSTEM (PASS POSTERIOR AND ANTERIOR SPINAL SYSTEM)-PEDICLE SCREW SYSTEM IS PRIMARILY USED FOR THE CORRECTION AND FIXATION OF DEGENERATIVE DISORDERS, DEFORMITIES AND TRAUMA INDICATIONS IN NON-CERVICAL SPINE.,EXPANDABLE CAGE (EXPA CAGE)-SPINAL DISC SPACE REPLACEMENT - CERVICAL / DORSAL / LUMBAR ,VERTEBRAL DISC CAGE ANTERIOR (RECAGE - DORSO LUMBAR)-THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE NON-CERVICAL SPINE. ,HUMERAL INTRAMEDULLARY NAIL(HALDER HUMERAL NAIL)-HUMERAL INTRAMEDULLARY NAILING SYSTEM IS USED FOR SURGICAL FIXATION OF FRACTURES IN THE HUMERUS, TROCHANTERIC FEMUR INTRAMEDULLARY NAIL(HALIFAX NAIL (INTRACAPSULAR NAIL))-HALIFAX INTERMEDULLARY NAILING SYSTEM IS USED FOR SURGICAL FIXATION OF FRACTURES IN THE FEMUR. THIS IS PRIMARILY USED FOR INTERTROCHANTERIC, SUBTROCHANTERIC, BASAL AND INTACAPULAR FRACTURES., INTERSPINOUS PROCESS SYSTEM(INTERSPINOUS PROCESS)-SPINAL DISC CAGE - LUMBAR; THE INTERVERTEBRAL CAGE IS USED TO

	REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE THORACIC AND LUMBAR SPINE.,MINIMALLY INVASIVE SPINAL SYSTEM (MAGNUM PLUS - MINIMAL INVASIVE SPINAL SYSTEM)-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION ,INTERBODY CAGE - EXPANDABLE (CRESCO - EXPANDABLE INTERBODY CAGE)-SPINAL DISC CAGE; THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF SPINE.,CERVICAL ANTERIOR PLATING SYSTEM(CERVICAL ANTERIOR PLATE - LP)-FIXATION AND STABILIZATION OF THE CERVICAL SPINE,VERTEBRAL DISC CAGE ANTERIOR(FUZER - CERVICAL THREADED FUSION CAGE)-THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE CERVICAL SPINE. ,LAMINOPLASTY IMPLANT (LAMINOFIX - LAMINOPLASTY IMPLANT)-FIXATION AND STABILISATION OF THE CERVICAL SPINE ,WIRES-FIXATION AND STABILIZATION WITH WIRING AND CABLE; WIRES ARE INDICATED FOR USE INFIXATION OF BONE FRACTURES, FOR BONE RECONSTRUCTION, FOR SKELETAL TRACTION INALIGNMENT OF BONE AND SPINE FRACTURED SEGMENTS, AND AS GUIDE PINS & WIRES FOR INSERTION OF OTHER IMPLANTS.,FACET STABILIZATION SYSTEM(FACET LINK SYSTEM - FACET STABILIZATION SYSTEM)-FIXATION AND STABILIZATION OF THE FACETS; THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE THORACIC AND LUMBAR SPINE. , SACROLITIC FIXATION SYSTEM(SACROLITIC FIXATION SYSTEM)-FIXATION AND THE STABILIZATION OF THE SACRUM,INTERBODY CAGE - LATERAL LUMBAR(LLIF CAGE - LATERAL LUMBAR INTERBODY CAGE)-SPINAL DISC CAGE - LUMBAR; THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE THORACIC AND LUMBAR SPINE. ,PLATES -GENERAL ORTHO IMPLANT FOR ALL TRAUMA AND DEGENERATION OF BONE BONE PLATES AND BONE SCREWS ARE INTENDED TO TREAT FRACTURES OF VARIOUS BONES, INCLUDING THE CLAVICLE PELVIS, SCAPULA, LONG BONE (SUCH AS HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND, SMALL BONES. ,SCREWS-GENERAL ORTHO IMPLANT FOR ALL TRAUMA AND DEGENERATION OF BONE; BONE PLATES AND BONE SCREWS ARE INTENDED TO TREAT FRACTURES OF VARIOUS BONES, INCLUDING THE CLAVICLE PELVIS, SCAPULA,

	LONG BONE (SUCH AS HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND, SMALL BONES.,INTERBODY CAGE - LUMBAR (ALIF - ANTERIOR LUMBAR INTERBODY FUSION CAGE)-SPINAL DISC CAGE - LUMBAR; THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE THORACIC AND LUMBAR SPINE.,VERTEBRAL BODY ANTERIOR SPACERS(ETHAN - CERVICAL ANTERIOR SPACER)-SPINE VERTEBRAL BODY REPLACEMENT CERVICAL,INTERBODY CAGE (DLIF - DIRECT LATERAL INTERBODY CAGE)-SPINAL DISC CAGE - LUMBAR; THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE THORACIC AND LUMBAR SPINE. , INTERBODY CAGE (BEAN CAGE ULTRA)-SPINAL DISC CAGE - LUMBAR; THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE THORACIC AND LUMBAR SPINE.,TROCHANTERIC FEMUR INTRAMEDULLARY NAIL (HALIFAX NAIL (TROCHANTERIC / INTERTROCHANTERIC NAIL))-HALIFAX INTERMEDULLARY NAILING SYSTEM IS USED FOR SURGICAL FIXATION OF FRACTURES IN THE FEMUR. THIS IS PRIMARILY USED FOR INTERTROCHANTERIC, SUBTROCHANTERIC, BASAL AND INTACAPULAR FRACTURES. ,TROCHANTERIC FEMUR INTRAMEDULLARY NAIL(HALIFAX NAIL (TROCHANTERIC / INTERTROCHANTERIC NAIL))-HALIFAX INTERMEDULLARY NAILING SYSTEM IS USED FOR SURGICAL FIXATION OF FRACTURES IN THE FEMUR. THIS IS PRIMARILY USED FOR INTERTROCHANTERIC, SUBTROCHANTERIC, BASAL AND INTACAPULAR FRACTURES., HUMERAL INTRAMEDULLARY NAIL(HALDER HUMERAL NAIL)-HUMERAL INTRAMEDULLARY NAILING SYSTEM IS USED FOR SURGICAL FIXATION OF FRACTURES IN THE HUMERUS,FEMORAL INTRAMEDULLARY NAIL(HALDER FEMORAL NAIL)-INTERMEDULLARY NAILING SYSTEM IS USED FOR SURGICAL FICATION OF FRACTURES IN THE FEMUR,POSTERIOR SPINAL IMPLANTS -NTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION ,TROCHANTERIC FEMUR INTRAMEDULLARY NAIL(HALIFAX NAIL (INTRACAPSULAR NAIL))-HALIFAX INTERMEDULLARY NAILING SYSTEM IS USED FOR SURGICAL FIXATION OF FRACTURES IN THE FEMUR. THIS IS PRIMARILY USED FOR INTERTROCHANTERIC, SUBTROCHANTERIC, BASAL AND INTACAPULAR FRACTURES.,FEMORAL INTRAMEDULLARY NAIL (HALDER FEMORAL NAIL)-INTERMEDULLARY NAILING SYSTEM IS USED FOR SURGICAL FICATION OF FRACTURES IN THE FEMUR,

	IMPLANTS FOR KNEE, ELBOW, HAND, CRANIAL-CUSTOM IMPLANTS , CRANIAL & MAXILLO FACIAL / PLASTIC / RECOSTRUCTIVE / HAND SURGERY IMPLANTS(INFIGO - CMF - CRANIAL & MAXILLO FACIAL / PLASTIC / RECOSTRUCTIVE / HAND SURGERY IMPLANTS)-FIXATION IN TRAUMA CRANIOPLASTY DEPRESSED FRACTURE OF THE SKULL / FACE / ORAL AND MAXILLO FACIAL; THE SYSTEM IS USED FOR REPAIR AND RECONSTRUCTION OF TRAUMA OF THE CRANIAL MAXILLO FACIAL (CMF) REGION,MINIMALLY INVASIVE SPINAL SYSTEM(MAGNUM - MINIMAL INVASIVE SPINAL SYSTEM)-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION ,DISTRACTABLE ANTERIOR SPACER WITH HOLDING DEVICE (DAS ULTRA-DISTRACTABLE ANTERIOR SPACER WITH SCREW)-DAS IS INTENDED TO BE USED AS A VERTEBRAL BODY REPLCACEMENT DURING CORPECTOMY AND STABILIZATION OF THE SPINE. ,INTERBODY CAGE (BULLCAGE INTER BODY CAGE)-SPINAL DISC CAGE - LUMBAR; THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE THORACIC AND LUMBAR SPINE. ,ANTERIOR SPINAL IMPLANTS - INTENDED FOR ANTERIOR STABILIZATION AND FIXATION OF THE SPINE ,INTERBODY CAGE(PLIF CAGE)-SPINAL DISC CAGE - LUMBAR; THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE THORACIC AND LUMBAR SPINE.,PEDICLE SCREW SYSTEM(RIGID PEDICLE SCREW SYSTEM)-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION ,PEDICLE SCREW SYSTEM (UNO PLUS PEDICLE SCREW SYSTEM)-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION ,PEDICLE SCREW SYSTEM(UNO LOCK PEDICLE SCREW SYSTEM)-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION ,PEDICLE SCREW SYSTEM (UNO PLUS PEDICLE SCREW SYSTEM)-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION , FENESTRATED PEDICLE SCREW SYSTEM(RIGID FEN -FENESTRATED PEDICLE SYSTEM AND CANNULA)-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION ,PEDICLE SCREW SYSTEM(RIGID OSTEO - HA COATED PEDICLE SCREW SYSTEM)

	-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION ,POSTERIOR AND ANTERIOR C1 / C2 IMPLANTS(POSTERIOR / ANTERIOR C1/ C2 IMPLANTS)-FIXATION AND STABILIZATION OF THE CERVICAL SPINE,FENESTRATED PEDICLE SCREW SYSTEM AND CANNULA(ALPHA FEN - FENESTRATED PEDICLE SYSTEM AND CANNULA)-STABILIZATION OF THE SPINE - DORSO LUMBAR,PEDICLE SCREW SYSTEM(ALPHA OSTEO - HA COATED PEDICLE SCREW SYSTEM)-STABILIZATION OF THE SPINE - DORSO LUMBAR. PEDICLE SCREW SYSTEM IS PRIMARILY USED FOR THE CORRECTION AND FIXATION OF DEGENERATIVE DISORDERS, DEFORMITIES AND TRAUMA INDICATIONS IN NON-CERVICAL SPINE. , MICRO SCREWS FOR CRANIAL ORAL MAXILLO FACIAL-FIXATION IN TRAUMA CRANIOPLASTY DEPRESSED FRACTURE OF THE SKULL / FACE / ORAL AND MAXILLO FACIAL ,INTERBODY CAGE(OCTACAGE - DORSO LUMBAR)-THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE DORSO LUMBAR SPINE. ,DISTRACTABLE ANTERIOR SPACER(DAS - LUMBAR)-DAS IS INTENDED TO BE USED AS A VERTEBRAL BODY REPLCACEMENT DURING CORPECTOMY AND STABILIZATION OF THE SPINE. ,ANTERIOR DISC CAGE WITH SCREWS(C-FIX - ANTERIOR DISC CAGE WITH SCREW)-THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE CERVICAL SPINE. ,GOEL FACET SPACER(GFS- GOEL FACET SPACER)-FACET REPLACEMENT CAGE ,ANTERIOR DISC CAGE WITH SCREW(C-FIX - PLUS - ANTERIOR DISC CAGE WITH SCREW)-THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE CERVICAL SPINE.,VERTEBRAL DISC CAGE - ANTERIOR / POSTERIOR (FUZER - DORSO / LUMBAR THREADED FUSION CAGE)-THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE THORACIC AND LUMBAR SPINE. ,MICRO SCREWS FOR CRANIAL ORAL MAXILLO FACIAL-FIXATION IN TRAUMA CRANIOPLASTY DEPRESSED FRACTURE OF THE SKULL / FACE / ORAL AND MAXILLO FACIAL, PEDICLE SCREW SYSTEM(DENIQUE PEDICLE SCREW SYSTEM)-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION ,ATLANTO AXIAL PROSTHESIS (GOEL ATLANTO AXIAL PROSTHESIS)-FIXATION OF THE ATLANTO AXIAL JUNCTION C1 / C2 ,WIRES-WIRES ARE INDICATED FOR USE

	INFIXATION OF BONE FRACTURES, FOR BONE RECONSTRUCTION, FOR SKELETAL TRACTION INALIGNMENT OF BONE AND SPINE FRACTURED SEGMENTS, AND AS GUIDE PINS & WIRES FOR INSERTION OF OTHER IMPLANTS.,INTERBODY CAGE(OCTACAGE - CERVICAL)-SPINAL DISC CAGE - CERVICAL. THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE CERVICAL SPINE. ,MICRO PLATES FOR CRANIAL ORAL MAXILLO FACIAL-FIXATION IN TRAUMA CRANIOPLASTY DEPRESSED FRACTURE OF THE SKULL / FACE / ORAL AND MAXILLO FACIAL, MICRO PLATES FOR CRANIAL ORAL & MAXILLO FACIAL-FIXATION IN TRAUMA CRANIOPLASTY DEPRESSED FRACTURE OF THE SKULL / FACE / ORAL AND MAXILLO FACIAL ,WIRES -WIRES ARE INDICATED FOR USE INFIXATION OF BONE FRACTURES, FOR BONE RECONSTRUCTION, FOR SKELETAL TRACTION INALIGNMENT OF BONE AND SPINE FRACTURED SEGMENTS, AND AS GUIDE PINS & WIRES FOR INSERTION OF OTHER IMPLANTS.,RECTANGLE SPINAL (REPOFIX - CERVICAL AND DORSO LUMBAR)-STABILIZATION IN TRAUMA WITH WIRING ,CRANIO-VERTEBRAL JUNCTION LOOP(CVJ LOOP - CRANIO VERTEBRAL JUNCTION LOOP)-FOR FIXING THE CRANIO VERTEBRAL JUNCTION,PEDICLE SCREW SYSTEM(K-FIXATOR MULTI-SEGMENTAL INTERNAL FIXATOR)-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION ,PEDICLE SCREW SYSTEM(UNO LOCK PEDICLE SCREW SYSTEM)-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION ,CERVICAL ANTERIOR PLATING SYSTEM(CAPS CERVICAL ANTERIOR PLATING SYSTEM)-FIXATION AND STABILIZATION OF THE CERVICAL INSTABILITY AND DECOMPRESSION, PEDICLE SCREW SYSTEM(CYGNET - PEDIATRIC SCOLIOSIS CORRECTION AND FIXATION SYSTEM)-INTENDED FOR STABILIZATION / FIXATION OF THE PEDIATRIC DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION,BONE PLATES -GENERAL ORTHO IMPLANT FOR ALL TRAUMA AND DEGENERATION OF BONE ,INTERBODY CAGE (TLIF INTERBODY CAGE)-SPINAL DISC CAGE - LUMBAR; THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE THORACIC AND LUMBAR SPINE.,PEDICLE SCREW SYSTEM (ALPHA - PASS POSTERIOR AND ANTERIOR SPINAL SYSTEM)-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION ,BONE SCREWS -GENERAL

	ORTHO IMPLANT FOR ALL TRAUMA AND DEGENERATION OF BONE , IMPLANTS FOR KNEE, ELBOW, HAND, CRANIAL-CUSTOM IMPLANTS , CANNULATED ODONTOID FIXATION SYSTEM(COFS - CANNULATED ODONTOID FIXATION SYSTEM)-FIXATION OF THE ATLANTA AXIAL JUNCTION / C1/C2 FIXATION,CERVICAL ANTERIOR PLATING SYSTEM (K-CER CERVICAL ANTERIOR PLATING SYSTEM)-FIXATION AND STABILIZATION OF THE CERVICAL INSTABILITY AND DECOMPRESSION; THE CERVICAL PLATE SYSTEM IS INTENDED FOR ANTERIOR SCREW FIXATION OF THE CERVICAL SPINE PARTICULARLY TO CORRECT THE FIXATION OF CERVICAL SPINAL DEFORMITIES THOUGH FUSION,THORACIC LUMBAR PLATE WITH SCREW-FIXATION OF THE THORACIC / LUMBAR SPINE,PEDICLE SCREW SYSTEM(ALPHA PLUS - PASS POSTERIOR AND ANTERIOR SPINAL SYSTEM)-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION,PEDICLE SCREW SYSTEM(PASS POSTERIOR AND ANTERIOR SPINAL SYSTEM)-INTENDED FOR STABILIZATION / FIXATION OF THE DORSAL / LUMBAR / SACRAL SPINE IN TRAUMA / DEGENERATION / SCOLIOSIS AND LYSTHESIS REDUCTION , POSTERIOR OCCIPITAL CERVICO - THORACIC FIXATION (RELIANT / RELIANT PLUS - POSTERIOR OCCIPITAL CERVICO - THORACIC FIXATION SYSTEM)-INTENDED FOR THE FIXATION AND THE STABILIZATION OF THE OCCIPITAL CERVICAL AND THORACIC SPINE IN INSTABILITY DEGENERATION TRAUMA RECONSTRUCTION , RECTANGLE SPINAL(RAVI'S RECTANGLE)-STABILIZATION IN TRAUMA ,NAILS-GENERAL ORTHO IMPLANT FOR ALL TRAUMA AND DEGENERATION OF BONE IN ADULT BONE AND PAEDIATRICS NAILING SYSTEM IS USED FOR THE SURGICAL FIXATION OF FRACTURES IN LONG BONES;,BONE PLATES -GENERAL ORTHO IMPLANT FOR ALL TRAUMA AND DEGENERATION OF BONE , VERTEBRAL BODY ANTERIOR SPACERS (ETHAN - DORSO LUMBAR ANTERIOR SPACER)-SPINE VERTEBRAL BODY REPLACEMENT DORSO LUMBAR,BONE SCREWS -GENERAL ORTHO IMPLANT FOR ALL TRAUMA AND DEGENERATION OF BONE ,CERVICAL DISC(C-DISC-CERVICAL DISC)-SPINAL DISC SPACE REPLACEMENT - CERVICAL, VERTEBRAL DISC CAGE ANTERIOR(RECAGE - CERVICAL)-THE INTERVERTEBRAL CAGE IS USED TO REPLACE THE INTERVERTEBRAL DISCS AND TO FUSE ADJACENT VERTEBRAL BODIES FOR REDUCTION AND STABILIZATION OF THE CERVICAL SPINE. ,FACET CAGE SYSTEM (DYNAMIC FACET CAGE)-STABILIZATION OF THE FACETS ,WIRES-FIXATION AND STABILIZATION WITH WIRING AND CABLE; WIRES ARE INDICATED FOR USE INFIXATION OF BONE FRACTURES, FOR BONE RECONSTRUCTION, FOR SKELETAL TRACTION INALIGNMENT OF BONE AND SPINE FRACTURED SEGMENTS, AND AS GUIDE PINS &

		WIRES FOR INSERTION OF OTHER IMPLANTS.,LUMBAR DISC (L-DISC LUMBAR DISC)-SPINAL DISC SPACE REPLACEMENT - DORSO LUMBAR ,TIBIAL NAIL(HALDER TIBIAL NAIL)-TIBIAL INTERMEDULLARY NAILING SYSTEM IS USED FOR SURGICAL FICATION OF FRACTURES IN THE TIBIA,TIBIAL INTRAMEDULLARY NAIL(HALDER TIBIAL NAIL)-TIBIAL INTERMEDULLARY NAILING SYSTEM IS USED FOR SURGICAL FICATION OF FRACTURES IN THE TIBIA,FACET CAGE SYSTEM (STATIC FACET CAGE)-STABILIZATION OF THE FACETS,NAILS-GENERAL ORTHO IMPLANT FOR ALL TRAUMA AND DEGENERATION OF BONE IN ADULT BONE AND PAEDIATRICS NAILING SYSTEM IS USED FOR THE SURGICAL FIXATION OF FRACTURES IN LONG BONES;,CERVICAL ANTERIOR PLATING SYSTEM(CAPS PLUS CERVICAL ANTERIOR PLATING SYSTEM)-FIXATION AND STABILIZATION OF THE CERVICAL INSTABILITY AND DECOMPRESSION,CERVICAL ANTERIOR PLATING SYSTEM(CERLOCK - CERVICAL ANTERIOR PLATING SYSTEM)-STABILIZATION OF THE CERVICAL SPINE; THE CERVICAL PLATE SYSTEM IS INTENDED FOR ANTERIOR SCREW FIXATION OF THE CERVICAL SPINE PARTICULARLY TO CORRECT THE FIXATION OF CERVICAL SPINAL DEFORMITIES THOUGH FUSION,DISTRACTABLE ANTERIOR SPACER (DAS - CERVICAL)-DAS IS INTENDED TO BE USED AS A VERTEBRAL BODY REPLCACEMENT DURING CORPECTOMY AND STABILIZATION OF THE SPINE.
3278	MFG/MD/2019/000141	1.License Holder Name: AACURE SURGICARE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:COTTON GAUZE CLOTH-IT IS USED FOR MEDICAL DRESSING.,BANDAGE CLOTH (WITH STARCH)-IT IS USED FOR MEDICAL DRESSING.,COTTON BANDAGES: (HANDLOOM GAUZE ROLL)-IT IS USED TO TAKE CARE OF DIFFERENT TYPES OF CUTS, INJURIES, ABRASIONS ON SKIN.,CREPE BANDAGES (AACUCREPE)-IT IS USED AS A GENTLE SUPPORT AND COMPRESSION BANDAGE TO HELP REDUCE PAIN AND MAINTAIN STABILITY IN SPRAINS AND STRAINS
3279	MFG/MD/2019/000142	1.License Holder Name: MOHAN HEALTH CARE 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ALCOHOL SWABS (DISPOCANN)-IT IS A SINGLE USE,STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE..

3280	MFG/MD/2019/000143	1.License Holder Name: RELISYS MEDICAL DEVICES LIMITED 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:POST-DILATATION CATHETER-POST-DILATATION CATHETER IS A DOUBLE LUMEN CORONARY CATHETER DESIGNED ON A RAPID EXCHANGE PLATFORM WITH A BALLOON & IT IS USED TO OPEN UP BLOCKED CORONARY ARTERIES, ALLOWING BLOOD TO CIRCULATE UNOBSTRUCTED TO THE HEART MUSCLE.,PRE-DILATATION CATHETER-PRE-DILATATION CATHETER IS A DOUBLE LUMEN CORONARY CATHETER DESIGNED ON A RAPID EXCHANGE PLATFORM WITH A BALLOON & IT IS USED TO OPEN UP BLOCKED CORONARY ARTERIES, ALLOWING BLOOD TO CIRCULATE UNOBSTRUCTED TO THE HEART MUSCLE.,EVEROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM(REIVAS EPITOME)-THE EVEROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM STENT IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF “DE NOVO” LESIONS IN NATIVE CORONARY ARTERIES. IT IS ALSO INDICATED FOR TREATMENT OF ABRUPT OR THREATENED CLOSURE IN PATIENTS WITH FAILED INTERVENTIONAL THERAPY. THE TREATED LESIONS LENGTH SHOULD BE LESS THAN THE NOMINAL STENT LENGTH (08 TO 44MM) WITH REFERENCE VESSEL DIAMETERS 2.25 OR 5.00MM. ,SIROLIMUS ELUTING CORONARY STENT SYSTEM(REIVAS)-THE SIROLIMUS ELUTING CORONARY STENT SYSTEM STENT IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF “DE NOVO” LESIONS IN NATIVE CORONARY ARTERIES. IT IS ALSO INDICATED FOR TREATMENT OF ABRUPT OR THREATENED CLOSURE IN PATIENTS WITH FAILED INTERVENTIONAL THERAPY. THE TREATED LESIONS LENGTH SHOULD BE LESS THAN THE NOMINAL STENT LENGTH (10 TO 40MM) WITH REFERENCE VESSEL DIAMETERS 2.25 OR 4.00MM.

3281	MFG/MD/2019/000144	1.License Holder Name: RELIFE ORTHO 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:INTRAMEDULLARY NAIL (ABUMAC MEDICAL/ARTHRO LIFE/REFIX/RELIFE/ZEALMAX ORTHO/AYAD)-INTRAMEDULLARY NAILS ARE USED IN HUMERUS BONE, TIBIA BONE, FEMUR BONE, WHERE FOUND THE FRACTURES IN PROXIMAL AND DISTAL AREA. ALL TYPES OF INTRAMEDULLARY NAILS ARE USED INSIDE THE BONE AND ITS PASS THROUGH FRACTURES AND HOLD THE FRACTURES WITH THE HELP OF BONE SCREWS. AND ITS MINIMAL INSERTION SURGERY.,MAXILLOFACIAL IMPLANT(RELIFEORTHO)-MAXILLOFACIAL IMPLANTS ARE USED IN MAXILLOFACIAL FRACTURES.,SPINAL IMPLANT(ABUMAC MEDICAL/ARTHRO LIFE/REFIX/RELIFE/ZEALMAX ORTHO/AYAD)-SPINAL IMPLANTS ARE USED IN SPINE CODE FRACTURES IN THORACIC SPINE AND LUMBER SPINE. ALL THE SPINE IMPLANTS LIKE PEDICLE SCREW, HOOKS, RODS, STAPLES AND CONNECTORS ARE USED TO FIX THE SPINE BONE FRACTURES.,SPINAL IMPLANT (RELIFEORTHO)-SPINAL IMPLANTS ARE USED IN SPINE CODE FRACTURES IN THORACIC SPINE AND LUMBER SPINE. ALL THE SPINE IMPLANTS LIKE PEDICLE SCREW, HOOKS, RODS, STAPLES AND CONNECTORS ARE USED TO FIX THE SPINE BONE FRACTURES.,BONE SCREW(ABUMAC MEDICAL/ARTHRO LIFE/REFIX/RELIFE/ZEALMAX ORTHO/AYAD)-BONE SCREW IS USED TO FIXING FRACTURE. WITH THE HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES.,PINS/WIRES(RELIFEORTHO)-PINS & WIRES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS & WIRES SUPPORT FIX THE BONE PLATES, BONE SCREWS, IM NAILS, SPINE IMPLANTS ETC. ALL PINS & WIRES ARE NOT PERMANENTLY USED IN SURGERY., MAXILLOFACIAL IMPLANT(ABUMAC MEDICAL/ARTHRO LIFE/REFIX/RELIFE/ZEALMAX ORTHO/AYAD)-MAXILLOFACIAL IMPLANTS ARE USED IN MAXILLOFACIAL FRACTURES., INTRAMEDULLARY NAIL(RELIFEORTHO)-INTRAMEDULLARY NAILS ARE USED IN HUMERUS BONE, TIBIA BONE, FEMUR BONE, WHERE FOUND THE FRACTURES IN PROXIMAL AND DISTAL AREA. ALL TYPES OF INTRAMEDULLARY NAILS ARE USED INSIDE THE BONE AND ITS PASS THROUGH FRACTURES AND HOLD THE FRACTURES WITH THE HELP OF BONE SCREWS. AND ITS MINIMAL INSERTION SURGERY., PROSTHESIS IMPLANT(ABUMAC MEDICAL/ARTHRO LIFE/REFIX/RELIFE/ZEALMAX ORTHO/AYAD)-PROSTHESIS IMPLANT ARE USED IN PROXIMAL FEMUR BONE FRACTURES, WHERE IS FEMUR PROXIMAL AREA ARE FRACTURED BADLY, THE SURGEON REMOVED PROXIMAL AREA AND THEY FIXED ENDO PROSTHESIS AND FIX WITH

		FEMUR DISTAL PART.,BONE SCREW(RELIFEORTHO)-BONE SCREW IS USED TO FIXING FRACTURE. WITH THE HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES., PINS/WIRES(ABUMAC MEDICAL/ARTHRO LIFE/REFIX/RELIFE/ZEALMAX ORTHO/AYAD)-PINS & WIRES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS & WIRES SUPPORT FIX THE BONE PLATES, BONE SCREWS, IM NAILS, SPINE IMPLANTS ETC. ALL PINS & WIRES ARE NOT PERMANENTLY USED IN SURGERY.,BONE PLATE (RELIFEORTHO)-BONE PLATES IS USED TO FIXING FRACTURE. WITH HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES.,BONE PLATE(ABUMAC MEDICAL/ARTHRO LIFE/REFIX/RELIFE/ZEALMAX ORTHO/AYAD)-BONE PLATES IS USED TO FIXING FRACTURE. WITH HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES.,PROSTHESIS IMPLANT(RELIFEORTHO)-PROSTHESIS IMPLANT ARE USED IN PROXIMAL FEMUR BONE FRACTURES, WHERE IS FEMUR PROXIMAL AREA ARE FRACTURED BADLY, THE SURGEON REMOVED PROXIMAL AREA AND THEY FIXED ENDO PROSTHESIS AND FIX WITH FEMUR DISTAL PART.
3282	MFG/MD/2019/000145	1.License Holder Name: M/S HAMPTON INDUSTRIES 2.Approving Authority: CHHATTISGARH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL(HAMPTON)-SURGICAL DRESSINGS USED IN WOUNDS
3283	MFG/MD/2019/000146	1.License Holder Name: MEDIVAC SURGCAL PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:I.V.INFUSION SET WITH & WITHOUT AIR VENT, M.V. INFUSION SET WITH & WITHOUT AIR VENT, BLOOD ADMINISTRATION SET WITH & WITHOUT AIR VENT, EXTENSION SET, HYPODERMIC NEEDLE , SYRINGES AND I.V. CANNULA-THE USE OF THE PRODUCT IS RESTRICTED TO A QUALIFIED DOCTOR OR A PARAMEDIC.

3284	MFG/MD/2019/000147	1.License Holder Name: POLY MEDICURE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:UNDER WATER SEAL DRAINAGE SYSTEM(POLYSEAL)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS. ,I.V. CANNULA WITHOUT INJECTION PORT & WITH SMALL WINGS(NEONOVO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,I.V. CANNULATION KIT-PRODUCT IS USED TO FIX AND STABILIZE I.V. CATHETERS., I V INFUSION SET (IDEALCARE MICRODRIP PRECISION SOLUTION ADMINISTRATION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,NELATON CATHETER (NELATON CATHETER "ANGEL CARE")-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY. ,RYLE'S TUBE (POLYMED RYLE'S TUBE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,HIGH PRESSURE VACUUM DRAINAGE BOTTLE WITH EXTENSION TUBE (SAFETY-VAC)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,I V INFUSION SET (POLYFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. , THREE WAY STOP COCK THREE WAY STOP COCK WITH/WITHOUT EXTENSION LINEWITH/WITHOUT EXTENSION LINE(NEOWAYS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,VIAL ACCESS SPIKE (VIAL ADAPTER)(CHIRAPLUS)-THE PRODUCT IS USED TO STEADY REPEATED WITHDRAWALS & INJECTION. THE PRODUCT IS DESIGNED TO BE USED TO TRANSFER MEDICATION FROM A VIAL TO A SYRINGE AND FROM SYRINGE TO VIAL.,THREE WAY STOP COCK (ESKAMED THREE WAY STOP COCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,I.V. CANNULA WITHOUT INJECTION PORT & WINGS(POLYPEN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD

	COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,HIGH PRESSURE VACUUM DRAINAGE BOTTLE WITH EXTENSION TUBE (ULTRAVAK SET)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,THORACIC CATHETER WITH & WITHOUT TROCAR-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,T-TYPE EXTENSION SET-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,STOMACH TUBE (POLYMED STOMACH TUBE)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID., HIGH PRESSURE VACUUM DRAINAGE BOTTLE WITH EXTENSION TUBE -A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,I V INFUSION SET WITH EXTENSION LINE (LOW PRESSURE & HIGH PRESSURE LINE) (EVERCARE INLINE- MONOSET,1-WAY)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,EXTENSION TUBE (EXTENSION TUBE OF HIGH PRESSURE"ANGEL CARE")-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,STOMACH TUBE (ACTI-FINE STOMACH FEEDING TUBE)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID.,FOLEY BALLOON CATHETER (FOLEY CATHETER "ANGEL CARE")-IT HAS A BALLOON AT THE DISTAL END, WHICH IS INFLATED WITH STERILE WATER OR SALINE TO PREVENT THE CATHETER FROM SLIPPING OUT OF THE BLADDER , I V INFUSION SET (CHIRAPLUS-P DEHP FREE WITH AUTO AIR STOP AND PRIMING FILTER)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,UNDER WATER SEAL DRAINAGE SYSTEM-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,I.V. CANNULA WITH INJECTION PORT & WINGS FOR QUICK FLASHBACK(POLYFLON ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF

	FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,UMBILICAL CORD CLAMP (UMBILICAL CORD CLAMP "ALEXPHARM")-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT. , OXYGEN CATHETER (POLYMED OXYGEN CATHETER)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,INFANT FEEDING TUBE(FEEDING CATHETER "ANGEL CARE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING ,SCALP VEIN SET(MED8 EASY-VEN SET SAFETY)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD., SURGICAL DRESSING (ADHESIVE BANDAGE)(I.V. DRESSING FOR FIXING CANNULA" ANGEL CARE")-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,CLOSE WOUND DRAINAGE SET-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS. ,GUEDEL AIRWAY -IT IS A MEDICAL DEVICE INSERTED THROUGH THE NOSE OR MOUTH AND USED OCCASIONALLY IN THE MANAGEMENT OF UPPER GASTROINTESTINAL HEMORRHAGE DUE UPPER GASTROINTESTINAL HEMORRHAGE DUE ,SCALP VEIN SET(POLYMED SCALP VEIN SET)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD., THREE WAY STOP COCK(3-WAY STOP COCK WITH ROTARY CLICK, "ANGEL CARE")-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , SAFETY SCALP VEIN SET(POLYMED SAFETY SCALP VEIN SET)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD., IRRIGATION SET -INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS. , ENDOTRACHEAL TUBE(POLYMED ENDOTRACHEAL TUBE)-INSERTS THE TUBE WITH THE HELP OF ALARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,STOMACH TUBE (STOMACH PROBE

	"ANGEL CARE")-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID. , LEVIN'S TUBE-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS. ,DISPOSABLE SYRINGE(POLYJECT)-THE SYRINGE IS INTENDED TO BE USED FOR MEDICAL PURPOSES TO INJECT FLUID INTO OR WITHDRAW FLUID FROM BODY.,I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS(POLYFLEX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , SUCTION CATHETER (SUCTION CATHETER "ANGEL CARE)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING. ,SUCTION CATHETER (HEUER SUCTION CATHETER)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,THREE WAY STOP COCK(SENSIMEDICAL LLAVE 4 VIAS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , UMBILICAL CATHETER (CATETER UMBILICAL EM PVC)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS ,I V INFUSION SET (KRUUSE SAFEVET INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,SURGICAL DRESSING (ADHESIVE BANDAGE)/IV FIXATOR)(NOVOGUARD)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,EXTENSION TUBE(EXTENSION TUBE OF LOW PRESSURE "ANGEL CARE")-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THREE WAY STOP COCK(EUROMIX LLAVE DE TRES VIAS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,THREE WAY STOP COCK(KD-

	FLEX PLUS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , ABDOMINAL DRAINAGE SET -USED TO PROVIDE CONNECTION TO A DRAINAGE BAG,MEASURED VOLUME DISPOSABLE PERFUSION SET (POLYVOL BURETTE SET (PAEDIATRIC))-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,CVP MANOMETER-INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD, AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTIONS OR DRUGS. , NEEDLELESS SWABABLE ACCESS SITE (NEEDLE FREE CONNECTOR) (SWABABLE NEEDLELESS ACCESS SITE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,UNDER WATER SEAL DRAINAGE SYSTEM(POLYDRAIN SET)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,FEMALE CATHETER(POLYMED FEMALE CATHETER)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY., FEEDING BAG -A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING ,I.V. CANNULA WITHOUT INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,DISPOSABLE SYRINGE-THE SYRINGE IS INTENDED TO BE USED FOR MEDICAL PURPOSES TO INJECT FLUID INTO OR WITHDRAW FLUID FROM BODY. ,PERITONEAL DIALYSIS CATHETER KIT-THAT ALLOWS DIALYSIS FLUID TO ENTER THE ABDOMINAL CAVITY, DWELL INSIDE FOR A WHILE, AND THEN DRAIN BACK OUT AGAIN ,THREE WAY STOP COCK (SENSIMEDICAL LLAVE 3 VIAS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , I V INFUSION SET (TRO- SOLUSET PLUS)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,UMBILICAL CORD CLAMP (UMBILICAL CORD CLAMP "ANGEL CARE")-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL

	CORD OF A NEWBORN INFANT. ,I V INFUSION SET WITH MICRO DRIP AND FLOW REGULATOR (POLYTROL MICRO SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,THREE WAY STOP COCK LIPID RESISTANT (INFUSION CRANE 3 WAY LIPID RESISTANT)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THREE WAY STOP COCK LIPID RESISTANT 45 DEGREE(INFUSION CRANE 3 WAY LIPID RESISTANT WITH CLICK FUNCTION)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,I.V. CANNULA WITH INTEGRATED 3- WAY STOP COCK (POLYCATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THREE WAY STOP COCK(INFUSION CRANE 3 WAY)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,UMBILICAL CATHETER (CATETER UMBILICAL EM POLIURETANO)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS ,DISPOSABLE HYPODERMIC SYRINGE-THE SYRINGE IS INTENDED TO BE USED FOR MEDICAL PURPOSES TO INJECT FLUID INTO OR WITHDRAW FLUID FROM BODY.,THREE WAY STOP COCK WITH EXTENSION TUBE(KRUUSE THREE WAY STOP COCK WITH EXTENSION TUBE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, SAFETY BLOOD COLLECTION SET (NUOVO SAFE)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD. ,I V INFUSION SET WITH THREE WAY STOP COCK (EVERCARE INLINE- GRAVITY SET, VENTED, 3-WAY STOP COCK)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,THREE WAY STOP

	COCK 45 DEGREE(INFUSION CRANE 3 WAY WITH CLICK FUNCTION)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. , I V INFUSION SET (IDEALCARE INTRAVENOUS ADMINISTRATION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,EXTENSION SET(COVETRUS T-CONNECTOR)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS., THREE WAY STOP COCK WITH EXTENSION TUBE(UNIWAYS THREE WAY STOPCOCK WITH EXTENSION TUBE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,THREE WAY STOPCOCK WITH EXTENSION TUBE(LLAVES DE PASO DE TRES VIAS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,I.V. CANNULA WITH 3-WAY STOP COCK (TRO-VENSITE 3+SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,NEBULIZER MASK -NEBULIZER MASK IS A DRUG DELIVERY DEVICE USED TO ADMINISTER MEDICATION IN THE FORM OF A MIST INHALED INTO THE LUNGS.,THREE WAY STOP COCK (TORNEIRINHA 03 VIAS LUER SLIP)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,THREE WAY STOP COCK(EVERCARE IN LINE 3-WAY STOPCOCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , I V INFUSION SET(UNI'PERF PERFUSEUR AVEC ROBINET + AIGUILLE)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,THREE WAY STOP COCK(LLAVES DE PASO DE TRES VIAS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,THREE WAY STOP COCK(TORNEIRA 3 VIAS DESCARPACK LUER LOCK RESISTENTE A LIPIDIOS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,

	THREE WAY STOP COCK(LLAVE DE 3 VIAS RESISTENTE A LIPIDOS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,I V INFUSION SET WITH AUTO STOP & PRIMING FILTER (AUTOFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,EXTENSION SET (MICRO POLYSYTE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,THORACIC CATHETER WITH AND WITHOUT TROCAR-CURVED (REDAX THORACIC CATHETER RIGHT ANGLED)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,THREE WAY STOP COCK(BEVER STOPCOCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , I V INFUSION SET (POLYUSION-W SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,THREE WAY STOP COCK (MULTIGATE THREE WAY STOP COCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,SUCTION CATHETER WITH FINGER TIP CONTROL CONNECTOR (ACTI-FINE® SUCTION CATHETER 3)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,THREE WAY STOP COCK LIPID RESISTANT 45 DEGREE WITH EXTENSION TUBE(POLYWAY PRO-CLICK WITH EXTENSION TUBE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,I.V. CANNULA WITHOUT INJECTION PORT AND WITH SMALL WINGS FOR QUICK FLASHBACK (POLYNEO ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,THREE WAY STOP COCK 45 DEGREE(POLYWAY-CLICK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, EXTENSION LINE (LOW PRESSURE & HIGH PRESSURE)(UNILINE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY

	ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION. ,BLOOD LINE SET (HAEM-O-LINE)-THE SINGLE-NEEDLE DIALYSIS, IN WHICH CASE ONLY ONE CANNULA OR A SINGLE- LUMEN CATHETER IS USED TO ACCESS THE BLOOD ,THREE WAY STOP COCK WITH EXTENSION TUBE (TRO-VENOFLOW 3 + EXTENSOR)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,BLOOD ADMINISTRATION SET (TRANSFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,THREE WAY STOP COCK (EXEWAY)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,I V INFUSION SET(NOVOFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STOMACH TUBE - PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID. ,I V INFUSION SET (POLYFUSION SET WITH THREE WAY STOP COCK)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,NELATON CATHETER (POLYMED NELATON CATHETER)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY. ,THREE WAY STOP COCK 45 DEGREE WITH EXTENSION TUBE(POLYWAY CLICK WITH EXTENSION TUBE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING., THORACIC CATHETER WITH & WITHOUT TROCAR-CURVED-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS. ,THREE WAY STOPCOCK WITH EXTENSION TUBE-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , I.V. CANNULA WITHOUT INJECTION PORT & WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,UMBILICAL CORD CLAMP (VASO CLAMP)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR

	OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,THORACIC CATHETER WITHOUT TROCAR (HEUER THORACIC CATHETER WITHOUT TROCAR)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,EXTENSION SET (MICRO POLYSYTE PLUS- DUO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,I.V. CANNULA WITH INJECTION PORT & WITH SMALLER WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,TRANSFUSION PUMP SET-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,NASAL OXYGEN CANNULA (POLYMED NASOCATH)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,THREE WAY STOPCOCK WITH EXTENSION TUBE(POLYMED THREE WAY STOPCOCK WITH EXTENSION TUBE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,I.V. CANNULA WITHOUT INJECTION PORT & WINGS FOR QUICK FLASHBACK (POLYON ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,MUCUS EXTRACTOR WITH /WITHOUT BACTERIAL BARRIER FILTER -CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION. ,I V INFUSION SET WITH THREE WAY STOP COCK (EVERCARE INLINE- GRAVITY SET, NON-VENTED, 3-WAY STOP COCK)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,I. V. FLOW REGULATOR EXTENSION SET(POLY FLO)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY., THREE WAY STOP COCK(TORNEIRA 3 VIAS DESCARPACK LUER LOCK) -IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,A. V. FISTULA NEEDLE WITH AND WITHOUT SAFETY -TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT. ,THREE WAY STOP COCK(LIFEN THREE WAY STOP

	COCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,I V INFUSION SET (POLYMED INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,I V INFUSION SET WITH THREE WAY STOP COCK & PRIMING FILTER (ULTRAFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,I. V. FLOW REGULATOR EXTENSION SET(POLY FLO NOVO)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. ,I.V. CANNULA WITHOUT INJECTION PORT & WINGS FOR QUICK FLASHBACK (POLYWIN ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,EXTENSION SET (SAFE CONEKT- PENTA)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,I.V. CANNULA WITHOUT INJECTION PORT & WINGS (POLYON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , EXTENSION SET (POLYSYTE – MONO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,NELATON CATHETER-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY. ,EXTENSION SET(BAG SPIKE ADAPTER)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS., I.V. CANNULA WITH INJECTION PORT & WINGS-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,A. V. FISTULA NEEDLE (POLYMED A. V. FISTULA NEEDLE)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT., SAFETY I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS FOR QUICK FLASHBACK(POLYSAFETY ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO

	FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , UMBILICAL CORD CLAMP -THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT. ,I.V. CANNULA WITHOUT INJECTION PORT & WITH SMALL WINGS FOR QUICK FLASHBACK (NEONOVO ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,EXTENSION SET (MICRO POLYSYTE - MONO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,IV CANNULA WITHOUT PORT & WITHOUT WINGS FOR QUICK FLASHBACK (POLYPEN ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,EXTENSION SET (MICRO POLYSYTE - TRIO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,I.V. CANNULA WITHOUT INJECTION PORT & WITH SMALL WINGS (POLYNEO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , EXTENSION SET (SAFE CONEKT- TRIO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,THREE WAY STOP COCK LIPID RESISTANT (CHIRAWAY PRO)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,EXTENSION SET (MICRO POLYSYTE - DUO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS FOR QUICK FLASHBACK (POLYFLEX ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,EXTENSION SET (SAFE CONEKT PLUS-MONO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,I.V. CANNULA WITHOUT INJECTION PORT & WITH

	SMALL WINGS FOR QUICK FLASHBACK(NEONOVO ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,EXTENSION SET (SAFE CONEKT PLUS-TRIO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,MEASURED VOLUME DISPOSABLE PERFUSION SET (POLYPEDIA)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,EXTENSION SET (MICRO POLYSYTE PLUS- TRIO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,EXTENSION LINE (LOW PRESSURE)(TRO-EXTENSOR LP)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION., EXTENSION SET (SAFE CONEKT PLUS-DUO)- EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,A. V. FISTULA NEEDLE (TRO-HAEMOCAN)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT ,EXTENSION SET (SAFE CONEKT- DUO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,BLOOD COLLECTION NEEDLE-INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD. , EXTENSION SET (SAFE CONEKT- MONO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,THREE WAY STOP COCK(TRO-VENOFLOW 3 BR)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,INSULIN SYRINGES (POLYMED INSULIN SYRINGE)-USED TO INJECT INSULIN FOR THE TREATMENT OF DIABETES.,A. V. FISTULA NEEDLE (EXELINT)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT ,I V INFUSION SET -TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,

	MEASURED VOLUME DISPOSABLE PERFUSION SET(POLYVOL PRO)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,SAFETY A. V. FISTULA NEEDLE (POLY PROTEKT)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT.,I V INFUSION SET(UNI'PERF PERFUSEUR AVEC SITE D'INJECTION + AIGUILLE)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,EXTENSION LINE (LOW PRESSURE & HIGH PRESSURE LINE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION O FLUIDS/MEDICATIONS IN MEDICAL APPLICATION., MEASURED VOLUME DISPOSABLE PERFUSION SET(EXEVOL)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,I V INFUSION SET (POLYMED MICROFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,I V INFUSION SET(EVERCARE INLINE- GRAVITY SET, NON-VENTED)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,EXTENSION SET (POLYSYTE – DUO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,I V INFUSION SET(EVERCARE INLINE- GRAVITY SET, VENTED)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,EXTENSION SET (MICRO POLYSYTE PLUS-PENTA)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS., INFANT FEEDING TUBE -A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING , MEASURED VOLUME DISPOSABLE PERFUSION SET(POLYVOL BURETTE SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,MEASURED VOLUME DISPOSABLE PERFUSION SET(TRO-MICROSET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,MEASURED VOLUME DISPOSABLE PERFUSION SET(BURETTE

	SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,I V INFUSION SET(UNI'PERF PERFUSEUR AVEC ROBINET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,MEASURED VOLUME DISPOSABLE PERFUSION SET-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,I V INFUSION SET(KRUUSE SPIRAL INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,I. V. FLOW REGULATOR EXTENSION SET-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. ,THREE WAY STOP COCK(KD-FLEX)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,EXTENSION LINE (LOW PRESSURE & HIGH PRESSURE LINE)(POLYMED EXTENSION LINE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION O FLUIDS/MEDICATIONS IN MEDICAL APPLICATION., MICRO I V INFUSION SET WITH MICRO DRIP (KRUUSE MICROFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,INSULIN SYRINGES -USED TO INJECT INSULIN FOR THE TREATMENT OF DIABETES. ,BLOOD COLLECTION NEEDLE(HAEMOFLASH)-INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD. , EXTENSION SET (POLYSYTE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,SURGICAL DRESSING (ADHESIVE BANDAGE)/IV FIXATOR-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,THREE WAY STOP COCK LIPID RESISTANT 45 DEGREE (POLYWAY PRO-CLICK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,I V INFUSION SET(WDT CURAVET BOVINE INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,EXTENSION SET (POLYSYTE – TRIO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE

	ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS., THREE WAY STOP COCK(TORNEIRINHA 03 VIAS LUER LOCK-RESISTENTE A LIPIDIOS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,THREE WAY STOP COCK(MCM LLAVE DE TRES VIAS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, EXTENSION LINE (HIGH PRESSURE)(TRO-EXTENSOR HP)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,INFANT FEEDING TUBE (NOVOFEED TUBE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING . THREE WAY STOP COCK(TORNEIRA DE TRES VIAS LUER LOCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,EXTENSION SET (MICRO POLYSYTE PLUS - MONO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,THORACIC CATHETER WITH AND WITHOUT TROCAR (REDAX THORACIC CATHETER STRAIGHT, REDAX TROCAR CATHETER)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,THREE WAY STOP COCK(POLYWAY)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,RECTAL CATHETER (POLYMED RECTAL CATHETER)-IT IS INSERTED INTO THE RECTUM IN ORDER TO RELIEVE FLATULENCE WHICH HAS BEEN CHRONIC AND WHICH HAS NOT BEEN ALLEVIATED BY OTHER METHODS.,BLOOD ADMINISTRATION SET WITH AIRVENT AND PRIMING FILTER (POLYMED HAEMOFUSOR SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,THREE WAY STOP COCK (IDEALCARE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,THREE WAY STOP COCK-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR

	PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,THREE WAY STOP COCK(ACTI-FINE 3-WAY STOPCOCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,BLOOD ADMINISTRATION SET WITHOUT AIRVENT(POLYMED TRANSVOL SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., MEASURED VOLUME DISPOSABLE PERFUSION SET(TRO-MICROSET PLUS)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,EXTENSION SET (MICRO POLYSYTE PLUS-QUARTA)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK (INSTACAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THREE WAY STOP COCK LIPID RESISTANT (POLYWAY PRO)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , I.V. CANNULA WITHOUT INJECTION PORT & WINGS(POLYWIN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,INSULIN SYRINGES (KILANI INSULIN SYRINGES)-USED TO INJECT INSULIN FOR THE TREATMENT OF DIABETES.,THREE WAY STOP COCK(TORNEIRA 3 VIAS DESCARPACK LUER SLIP)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , I V INFUSION SET (SENSIMEDICAL EQUIPO PARA VENOCLISIS MICROGOTERO (IV SET MACRO WITH AIRVENT, 60 DROPS))-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,THORACIC CATHETER WITH & WITHOUT TROCAR (FREE LIFE THORAX DRAINAGE, GERADE)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,THREE WAY STOP COCK(NOUVO CLICK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF

	SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,T-TYPE EXTENSION SET(KRUUSE T-CONNECTOR)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,THREE WAY STOP COCK(VITROMED)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , YANKAUR SUCTION SET WITH TUBE & HANDLE (POLYSUCTION SET)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,THREE WAY STOP COCK (MED8 EASY WAY BLUE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,UMBILICAL CATHETER (ACTI-FINE® UMBILICAL CATHETER)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS .,RECTAL CATHETER (MEDPROT RECTAL CATHETER)-IT IS INSERTED INTO THE RECTUM IN ORDER TO RELIEVE FLATULENCE WHICH HAS BEEN CHRONIC AND WHICH HAS NOT BEEN ALLEVIATED BY OTHER METHODS. ,THORACIC CATHETER WITH & WITHOUT TROCAR (FREE LIFE THORAX DRAINAGE, GEBOGEN)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,I V INFUSION SET (ULTRAFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. , YANKAUR SUCTION SET WITH TUBE & HANDLE -SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING. ,THREE WAY STOPCOCK WITH EXTENSION TUBE(VITROMED)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,UMBILICAL CATHETER (PU FEED)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS .,THREE WAY STOP COCK (MED8 EASY WAY WHITE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION

	OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , UMBILICAL CATHETER (HEUER UMBILICAL CATHETER)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS .,EXTENSION LINE (LOW PRESSURE & HIGH PRESSURE LINE)(MED8 EASY-XTEND PVC FREE (STRAIGHT))-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,CLOSE WOUND DRAINAGE SET(SERODRAIN SOFFIETTO 600 ML PER DRENAGGIO)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,INSULIN SYRINGES (HEUER INSULIN SYRINGES)-USED TO INJECT INSULIN FOR THE TREATMENT OF DIABETES. ,UMBILICAL CATHETER (POLYMED UMBILICAL CATHETER)-"UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS " ,THREE WAY STOPCOCK WITH EXTENSION TUBE(ANDINO THREE WAY STOP COCK WITH EXTENSION TUBE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,I V INFUSION SET (ONCOFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,HEAT AND MOISTURE EXCHANGE FILTER (POLYMED HME FILTER)-IT IS INTENDED TO USE FOR AIRWAY MANAGEMENT BY ANAESTHESIA/RESPIRATORY CARE DEPARTMENT.,I.V. CANNULA WITH INJECTION PORT & WINGS(POLYFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , I V INFUSION SET (MULTIGATE GRAVITY INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STOMACH TUBE(KRUUSE STOMACH TUBE)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID., THREE WAY STOP COCK(VITROWAY)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT

	FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,SUCTION CATHETER (TRO-SUCOCATH, TRO-SUCOCATH PLUS, TRO-SUCOCATH TC PLUS)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,THREE WAY STOP COCK (MED8 EASY WAY-XTEND)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , THORACIC CATHETER WITH & WITHOUT TROCAR (DAHLHASUSEN THORACIC CATHETER)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,I. V. FLOW REGULATOR EXTENSION SET(HEUER FLOW REGULATOR)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. ,SAFETY I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK(TRO VENOCATH 3+SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,NEEDLE FREE CONNECTOR(KRUUSE SAFEVET INJECTION SITE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,STOMACH TUBE (HEUER STOMACH TUBE)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID.,VIRAL TRANSPORT KIT (VIRAL TRANSPORT MEDIUM & SWAB STICK)-TO COLLECT AND TRANSPORT VIRUSES IN AN ACTIVE FORM TO THE LABORATORY FOR ISOLATION . TO MAINTAIN THE VIABILITY AND VIRULENCE OF THE VIRAL SAMPLE, STOMACH TUBE(EQUIVET GASTROSCOPE FLUSHING CATHETER)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID.,EXTENSION SET (POLYSYTE-MDVA WITH CLAVE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,THREE WAY STOP COCK(CHIRAWAY)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,THREE WAY STOP COCK(HEUER THREE WAY STOP COCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID

	AND PRESSURE MONITORING ,LEVIN'S TUBE(HEUER LEVIN'S TUBE)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS., EXTENSION LINE (LOW PRESSURE & HIGH PRESSURE LINE)(MED8 EASY XTEND HIGH)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,SAFETY I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK(SENTRACAN PLUS SAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,EXTENSION LINE (LOW PRESSURE & HIGH PRESSURE LINE)(HEUER EXTENSION TUBE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,SAFETY SCALP VEIN SET(HEUER SAFETY SCALP VEIN SET)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,SUCTION CATHETER (MEDPROT SUCTION CATHETER)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING. ,I V INFUSION SET (PHOTOFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,I V INFUSION SET (POLYTROL MICRO SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,SCALP VEIN SET(PD SCALP VEIN SET SAFETY NEEDLE SHIELD)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD., BLOOD ADMINISTRATION SET (TRANSFUSION SET)(HEUER BLOOD ADMINISTRATION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,RECTAL CATHETER -IT IS INSERTED INTO THE RECTUM IN ORDER TO RELIEVE FLATULENCE WHICH HAS BEEN CHRONIC AND WHICH HAS NOT BEEN ALLEVIATED BY OTHER METHODS. ,I V INFUSION SET (AUTOFUSION PROTEKT)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,REDON DRAINAGE TUBE(KD-DRAIN)-USED TO PROVIDE CONNECTION TO A DRAINAGE BAG.,STOMACH TUBE (MEDPROT STOMACH TUBE)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE

	DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID. , SAFETY SCALP VEIN SET (TRO-VENOSET SAFETY, TRO-VENOSET SAFETY BR)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,THREE WAY STOPCOCK WITH EXTENSION TUBE (NOUVO CLICK EXT)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,FEMALE CATHETER-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY. ,THREE WAY STOP COCK(POINT MEDICAL THREE WAY STOP COCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,INFANT FEEDING TUBE (HEUER INFANT FEEDING TUBE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,EXTENSION SET (MICRO VITROSYTE - DUO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS., THREE WAY STOP COCK (HEUER THREE WAY STOP COCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,THREE WAY STOPCOCK WITH EXTENSION TUBE(KELMER THREE WAY STOP COCK WITH EXTENSION TUBE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,INFANT FEEDING TUBE(POLYFEED TUBE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING,I V INFUSION SET (AUTOFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,RYLE'S TUBE (EQUIVET ENDOSCOPE FLUSHING CATHETER)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES., EXTENSION SET (MICRO VITROSYTE - TRIO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE

	USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,SUCTION CATHETER WITH THUMB CONTROL CONNECTOR (ACTI-FINE® SUCTION CATHETER 2)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,THREE WAY STOPCOCK WITH EXTENSION TUBE (VITROWAY)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,OXYGEN CATHETER -IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP. ,EXTENSION LINE (LOW PRESSURE & HIGH PRESSURE LINE)(MINIMUM VOLUME EXTENSION SET)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION., NELATON CATHETER(HEUER NELATON CATHETER)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,MEASURED VOLUME DISPOSABLE PERFUSION SET(MED8 EASY VOL)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT (POLYCAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. , MEASURED VOLUME DISPOSABLE PERFUSION SET(MINIFLON MEASURED VOLUME SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,NELATON CATHETER(EQUIVET UTERUS FLUSHING TUBE)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,THREE WAY STOPCOCK WITH EXTENSION TUBE(LLAVE DE 3 VIAS CON EXTENSION DE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,THORACIC CATHETER WITH & WITHOUT TROCAR (POLYMED ULTRA CATH NOVO) -A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS. ,EXTENSION SET (POLYSYTE ACCESS-MULTI CAP WITH CLAVE)-EXTENSION SETS ARE

	STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,LEVIN'S TUBE (POLYMED LEVIN'S TUBE)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,HEAT AND MOISTURE EXCHANGE FILTER (POLYMED HME FILTER)-IT IS INTENDED TO USE FOR AIRWAY MANAGEMENT BY ANAESTHESIA/RESPIRATORY CARE DEPARTMENT.,I.V. CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS -THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., MEASURED VOLUME DISPOSABLE PERFUSION SET(SENSIMEDICAL BURETA EQUIPO DE VOLUMENES MEDIDIS (BURETTE SET))-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,LEVIN'S TUBE(ACTI-FINE LEVIN FEEDING TUBE)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,THREE WAY STOPCOCK WITH EXTENSION TUBE (HEUER THREE WAY STOP COCK WITH EXTENSION TUBE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,NELATON CATHETER (ACTI-FINE® NELATON CATHETER)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,I V INFUSION SET (MINIFLON I.V. MICRO INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,FEEDING TUBE (KRUUSE FEEDING TUBE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING., I V INFUSION SET (HEUER I.V. INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,SAFETY BLOOD COLLECTION SET -INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD. ,EXTENSION SET (MICRO VITROSYTE - MONO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,

	THREE WAY STOP COCK(TORNEIRINHA 03 VIAS LUER LOCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,EXTENSION SET (POLYSYTE -MICRO VENT WITH CLAVE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,THREE WAY STOP COCK(TORNEIRA DE TRES VIAS LUER SLIP)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,EXTENSION SET (BIFUSE EXTENSION SET)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS., RYLE'S TUBE (HEUER RYLE'S TUBE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,EXTENSION SET(SAFE CONEKT-QUADRO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS., EXTENSION LINE (LOW PRESSURE & HIGH PRESSURE)(TRO-EXTENSOR HP + T-CONNECTOR)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,EXTENSION LINE (LOW PRESSURE & HIGH PRESSURE LINE)(MED8 EASY-XTEND PVC FREE (COILED))-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,RYLE' S TUBE -IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES. ,NEEDLE FREE CONNECTOR(SAFE CONEKT STANDALONE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,FEMALE CATHETER(ACTI-FINE® FEMALE CATHETER)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,I. V. FLOW REGULATOR EXTENSION SET(MED8 EASY-FLO XTEND WHITE)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. ,THORACIC

	CATHETER WITH TROCAR (HEUER THORACIC CATHETER WITH TROCAR)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,I V INFUSION SET (MINIFLON I.V. MACRO INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. , SUCTION CATHETER -SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING. ,BLOOD ADMINISTRATION SET (TRANSFUSION SET) (MINIFLON BLOOD ADMINISTRATION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,SUCTION CATHETER (POLYMED SUCTION CATHETER)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING. ,MEASURED VOLUME DISPOSABLE PERFUSION SET(HEUER BURETTE SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,THREE WAY STOP COCK(TRO-VENOFLOW 3)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,THREE WAY STOP COCK(MED8 EASY WAY RED)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , ENDOTRACHEAL TUBE-INSERTS THE TUBE WITH THE HELP OF ALARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS. ,VIRAL LYSIS TRANSPORT MEDIUM (VLTM) KITS-FOR THE COLLECTION, INACTIVATION AND TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES AND BACTERIA FROM THE COLLECTION SITE TO THE TESTING LABORATORY.,PERITONEAL DIALYSIS CATHETER KIT(POLYMED PERITONEAL DIALYSIS CATHETER KIT)-THAT ALLOWS DIALYSIS FLUID TO ENTER THE ABDOMINAL CAVITY, DWELL INSIDE FOR A WHILE, AND THEN DRAIN BACK OUT AGAIN., I V INFUSION SET (SENSIMEDICAL EQUIPO PARA VENOCLISIS NORMOGOTERO (IV SET MACRO WITH AIRVENT, 20 DROPS))-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,I. V. FLOW REGULATOR EXTENSION SET (UNIFLOW)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. ,THREE WAY STOPCOCK WITH EXTENSION TUBE(SENSIMEDICAL LLAVE CON TUBO

	DE EXTENSION 3 VIAS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,SAFETY I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS(POLYSAFETY)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,THREE WAY STOP COCK(SENSIMEDICAL LLAVE DE 3 VIAS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,NASAL OXYGEN CANNULA (HEUER NASAL OXYGEN CANNULA)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP. ,BLOOD ADMINISTRATION SET (TRANSFUSION SET)(HEUER BLOOD TRANSFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,THREE WAY STOP COCK(NOKAST THREE WAY STOP COCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, THREE WAY STOP COCK (MED8 EASY WAY – PRO BLUE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,UMBILICAL CATHETER -"UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS " ,THREE WAY STOP COCK (SENSIMEDICAL LLAVE CON TUBO DE EXTENSION 4 VIAS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,THREE WAY STOP COCK LIPID RESISTANT(TRO-VENOFLOW3 LIPID RESISTANT)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,THREE WAY STOP COCK(SENSIMEDICAL LLAVE DE 4 VIAS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,INFANT FEEDING TUBE(TRO-NUTRICATH PAED)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED

	INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING. ,INFANT FEEDING TUBE (ACTI-FINE INFANT FEEDING TUBE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,THREE WAY STOP COCK (KRUUSE THREE WAY STOP COCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, SCALP VEIN SET-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD. ,THREE WAY STOP COCK(UNIWAYS THREE WAY STOP COCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , NASAL OXYGEN CANNULA-"IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP. " ,THORACIC CATHETER WITHOUT TROCAR-CURVED(HEUER THORACIC CATHETER WITHOUT TROCAR-CURVED)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,FEEDING TUBE -A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING , FOLEY BALLOON CATHETER (POLYMED FOLEY BALLOON CATHETER) -IT HAS A BALLOON AT THE DISTAL END, WHICH IS INFLATED WITH STERILE WATER OR SALINE TO PREVENT THE CATHETER FROM SLIPPING OUT OF THE BLADDER.,FOLEY BALLOON CATHETER -IT HAS A BALLOON AT THE DISTAL END, WHICH IS INFLATED WITH STERILE WATER OR SALINE TO PREVENT THE CATHETER FROM SLIPPING OUT OF THE BLADDER. ,VIAL ADAPTER (VIAL ACCESS SPIKE)(POLYSPIKE)-IT IS INDICATED TO ALLOW MULTIPLE NEEDLE-LESS ACCESS TO INJECTION MEDICATION VIALS FOR TRANSFER OR WITHDRAWAL OF FLUIDS FROM THE VIAL. ,I.V. CANNULA (POLYWIN PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,RECTAL CATHETER (ACTI-FINE® RECTAL CATHETER)-IT IS INSERTED INTO THE RECTUM IN ORDER TO RELIEVE FLATULENCE WHICH HAS BEEN CHRONIC AND WHICH HAS NOT BEEN ALLEVIATED BY OTHER METHODS.,THORACIC DRAINAGE CATHETER WITH TROCAR (ACTI-FINE TROCAR THORAX DRAIN)-A SURGICAL DRAIN IS A TUBE USED

	TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,I V INFUSION SET(KD-DRIP)-TRANSFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,CLOSE WOUND DRAINAGE SET(POLYVAC SET, NOVOVAC SET, NEOVAC SET)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,SUCTION CATHETER (TRO- ASPICAT- A, TRO- ASPICAT- B, TRO- ASPICAT- C)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., THORACIC CATHETER WITH TROCAR-CURVED (HEUER THORACIC CATHETER WITH TROCAR-CURVED)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,THREE WAY STOP COCK (TORNEIRA 3 VIAS LUER SLIP)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,RECTAL CATHETER (HEUER RECTAL CATHETER)-IT IS INSERTED INTO THE RECTUM IN ORDER TO RELIEVE FLATULENCE WHICH HAS BEEN CHRONIC AND WHICH HAS NOT BEEN ALLEVIATED BY OTHER METHODS.,I.V. CANNULA WITH WINGS, WITHOUT INJECTION PORT FOR QUICK FLASHBACK (POLYCAN ADVA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,BLOOD TRANSFUSION SET (FIONAVET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,RYLE'S TUBE(TRO-NUTRICATH)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,CLOSE WOUND DRAINAGE SET(HEUER CLOSE WOUND SUCTION UNIT)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.

3285	MFG/MD/2019/000148	1.License Holder Name: RAMAN & WEIL PVT.LTD. 2.Approving Authority: DAMAN AND DIU 3.Device Name(Brand Name)-Intended Use:GLUTARALDEHYDE & 1.6 DIHYDROXY - 2.5 DIOXAHEXANE(KOHRSOLIN TH)-IT IS PURE DISINFECTANTS FOR POULTRY AND LIVESTOCK,PROPYLENE GLYCOL IP -SODIUM BENZOATE IP - SODIUM SAKICYLATE IP -SODIUM LAURYL SULPHATE (BAKTOLIN 5.5)-IT IS HYGENIC NON SOAP CLEANSER , THE SKIN REMAINS SMOOTH AND WELL NOURISHED, BAKTOLIN 5.5 IS A PH OF SAME TO NEUTRAL SKIN,ETHANOL SKIN PROTECTORS (STERILLIUM GEL)-IT IS PURE HAND IN RUB DISINFECTANT GEL AND SKIN PROTECTOR GEL.,CHLORIHEXDINE GLUCONATE SOLUTION IP EQUIVALENT TO CHLORIHEXDINE GLUCONATE(BACTOSCRUB)-CHLORHEXIDINE GLUCONATE SOLUTION CLEANSING SOLUTION DO NOT MIX WITH WATER & OTHER DISINFECTANT.IT IS PINK COLOR SOLUTION, WITH FRESH SMELL. IT IS HAND DISINFECTANTS.,IT IS A COMBO PACK OF STERILLIUM GEL HAND SANITISER +, STERISKIN, STERISMART(STERI 360 KIT)-IT IS A COMBI PACK OF THREE PRODUCT STERILLIUM GEL HAND SANITISER +, STERISKIN, STERISMART. AS STERILLIUM GEL HAND SANITISER + IS DISINFECTANT , STERISKIN IS HYGIENIC HAND WASH AND STERISMART IS SURFACE DISINFECTANT.,BENZYALKONIUM CHLORIDE. DODECYLBISPROPYLENE TRIAMINE (MIKROBAC FORTE)-STANDARD DILUTION FOR NON CRITICAL AREA AND CRITICAL AREA USE 0.5% AND 2%SOLUTION RESPECTIVELY. THE STANDARD RECOMMENDED CONCENTRATION IS 1.5 %,PROPYLENE GLYCOL IP -SODIUM BENZOATE IP - SODIUM SAKICYLATE IP -SODIUM LAURYL SULPHATE (STERISKIN)- IT IS HYGIENIC SOAP CLEANSER. THE SKIN REMAIN SMOOTH AND WELL NOURISHED. STERISKIN HAVING A PH NEUTRAL TO SKIN. ,GLUTARALDEHYDE -2.45 % (GLUTIHYDE 2.45%)-INSTRUMENT & SCOPE DISINFECTANT ALONG WITH ACTIVATOR. ADD THE ACTIVATOR AS PER INSTRUCTION ON LABEL.,ETHYLENEDIOXY DIMENTHANOL & GLUTARALDEHYDE (BACILLOCID EXTRA)-IT IS USED FOR DISINFECTANT THE SURGICAL EQUIPMENT AND SURFACE OF THE EQUIPMENT.,CHLORIHEXDINE GLUCONATE SOLUTION IP , CITRIMIDE IP , ISOPROPYLE ALCOHOL(ACEPTIK H.C)-CHLORHEXIDINE, CETRIMIDE & ISOPROPYL ALCOHOL ANTISEPTIC LIQUID. USE AS PER DILUTION MENTIONED IN LABEL., GLUTARALDEHYDE & 1.6 DIHYDROXY - 2.5 DIOXAHEXANE(KORSOLEX RAPID)-IT IS USE TO DISINFECTANT THE SURGICAL EQUIPMENT,PEG – 40 HYDROGENATED CASTER OIL PEG -150 DISTERATE GLYCERINE PENTHENOL. PEG -7 GLYCERYL COCONATE DIDECYLDIAMMONIUM CHLORIDES SODIUM CITRATE ,ALLANTOIN(STELLISEPT MED)-STELLISEPT MED HAS REPLENISHING PROPERTIES AND A BROAD SPECTRUM OF ANTISEPTIC EFFECT.ANTISEPTIC WHOLE BODY

	WASHING IN CASE OF MRSA/ORSA,ETHANOL , 2- PROPANOL , 1-PROPANOL (STERISMART)-IT IS USED FOR SURFACE DISINFECTANT, ISO-PROPANOL , BENZYLALKONIUM CHLORIDE (CUTASEPT F)-IT IS USED FOR PRE AND POST INCISION OF SKIN. IT IS USED FOR PREPPING & DRESSING OF SKIN.,2-PROPANOL ,1-PROPANOL, MECETRONIUM ETHYL SULPHATE(STERILLIUM CLEAR)-IT IS PURE HAND IN RUB DISINFECTANT,ISO-PROPANOL , BENZYLALKONIUM CHLORIDE (CUTASEPT)-IT IS A SKIN DISINFECTANTS FOR PREPPING AND POST CLOSURE OF SKIN .,ETHANOL SKIN PROTECTORS (STERILLIUM GEL HAND SANITISER +)-IT IS RUB- IN HAND DISINFECTANT ,ETHANOL , 2- PROPANOL , 1-PROPANOL (BACILLOL-25)-BACILLOL-25 USED FOR SURFACE AND EQUIPMENTS DISINFECTANTS. IT IS ALDEHYDE FREE DISINFECTANTS, FOR INSTANT DISINFECTION WITH IN 25 SEC.,GLUTARALDEHYDE -2 % (GLUTIHYDE 2%)-INSTRUMENT & SCOPE DISINFECTANT ALONG WITH ACTIVATOR. ADD THE ACTIVATOR AS PER INSTRUCTION ON LABEL.,2- PROPANOL, 1-PROPANOL, MECETRONIUM ETHYL SULPHATE (STERILLIUM)-100 % PURE RUB-IN HAND DISINFECTANT. DO NOT MIX WITH WATER & OTHER DISINFECTANT.IT IS LIGHT BLUE COLOR SOLUTION, WITH FRESH ALCOHOLIC SMELL. ,DODECYBISPROPYLENE TRIAMINE , DIDECYLDIMETHYL AMMONIUM CHLORIDE (KORSOLEX PLUS)-IT IS USED FOR SURFACE MOPPING , FOGGING DISINFECTION AND INSTRUMENT/ ENDOSCOPE DISINFECTION.,DIDECYL- DIMETHYL-AMMONIUM CHLORIDE (SOKRENA - WS)-SOKRENA WS IS A SAFE WATER SANITIZER USED IN POLUTRY, HATCHERY, DAIRY, FOOD PROCESSING PLANTS.,2- PROPANOL - 1-PROPANOL ,. ETHYL-HEXADECYL DIMETHYL AMMONIUM ETHYLE SULPHATE , (MECETRONIUM ETHYL SULPHATE)(BACTORUB BLUE)-100 % PURE RUB-IN HAND DISINFECTANT. DO NOT MIX WITH WATER & OTHER DISINFECTANT.IT IS LIGHT BLUE IN COLOUR. ,1,6 DIHYDROXY -2, 5 DIOXAHEXANE (GLUTARALDEHYDE , BENZYLALKONIUM CHLORIDE , ALKYLL UREA DERIVATIVES (BACILLOCID SPECIAL)-100 % PURE SURFACE & EQUIPMENT DISINFECTANT- CONCENTRATE. USE AS PER DILUTION MENTIONED ON LABEL.DO NOT MIX WITH OTHER DISINFECTANT ,CHLORIHEXDINE GLUCONATE SOLUTION IP EQUIVALENT TO CHLORIHEXDINE GLUCONATE , ETHYL ALCOHOL IP (BACTORUB)-100 % PURE HAND DISINFECTANT. DO NOT MIX WITH WATER & OTHER DISINFECTANT.IT IS LIGHT PINK COLOR SOLUTION, WITH PLEASANT SMELL ,DIDECYL- DIMETHYL- AMMONIUM CHLORIDE (SOKRENA)-100 % PURE SURFACE & EQUIPMENT DISINFECTANT-CONCENTRATE. USE AS PER DILUTION MENTIONED ON LABEL.DO NOT MIX WITH OTHER DISINFECTANT. ,CHLORHEXIDINE GLUCONATE AND ALCOHOL DISINFECTANT(BACCIRUB)-IT IS A PINK COLOR HAND RUB SKIN DISINFECTANT . IT IS USED FOR HYGIENIC HAND AND

	SURGICAL HAND DISINFECTION.,DIDECYLDIMETHYL AMMONIUM CHLORIDE (BACILLO FLOOR)-USE FRESHLY DILUTED 0.1% SOLUTION .,ETHANOL ,2- PROPANOL ,1-PROPANOL (WETTASK WITH BACILLOL 25)-WIDE USAGE FOR INSTANT DISINFECTION ON WATER SENSITIVE SURFACES SPECIALLY ON FREQUENT HAND CONTACT SURFACES., CHLORIHEXDINE GLUCONATE SOLUTION IP , CITRIMIDE IP , ISOPROPYLE ALCOHOL (ACEPTIK L.A)-CHLORHEXIDINE, CETRIMIDE & ISOPROPYL ALCOHOL ANTISEPTIC LIQUID. USE AS PER DILUTION MENTIONED IN LABEL, HAVING LIGHT YELLOW & LIME FRAGRANCE.

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3286	MFG/MD/2019/000149	1.License Holder Name: MEDITECH DEVICES PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use::I.U.I CANNULA-THE IUI CANNULA IS DESIGNED AS POTENTIALLY EFFECTIVE TREATMENT OF ALL CAUSES IN WOMEN FOR INTRA UTERINE INSEMINATION PURPOSE,BONE MARROW BIOPSY NEEDLE(MARDEX , OXYFLOW)-FOR BONE MARROW BIOPSY & APIRATION ,H.M.E - BACTERIAL, VIRAL FILTER -HEAT AND MOISTURE EXCHANGERS AND BREATHING SYSTEM FILTERS ARE INTENDED TO REPLACE THE NORMAL WARMING, HUMIDIFYING AND FILTERING FUNCTIONS OF THE UPPER AIRWAYS,WING HUBER NEEDLE(TARGET , SECURE)-WING HUBER NEEDLE DESIGNED TO BE INTRODUCED INTO A SILICONE SEPTUM OF A SUBCUTANEOUSLY PLACE IMPLANTED PORT FOR INFUSION OF MEDICATIONS , I.V. FLUIDS , PARENTERAL NUTRITION SOLUTIONS , BLOOD PRODUCTS AND FOR THE WITHDRAWAL OF BLOOD SAMPLES. THE NON-CORING NEEDLE IS DESIGNED NOT TO CORE THE SILICONE SEPTUM.,BALLOON DILATION CATHETER -INTENDED USE IT IS A DILATOR USED FOR URETERAL DILATION PRIOR TO URETERAL STONE MANIPULATION OR URETEROSCOPY, AS WELL AS DILATION OF THE INTRAMURAL URETER & URINARY TRACT. ALSO USED FOR WIDENING THE URETERAL STRICTURE.,SKIN STAPLER(MAXIMA , OXYFLOW)-INTENDED TO SEW THE SKIN IN SURGICAL OPERATION.,PICC CATHETER-:PERIPHERALLY INSERTED CATHETER(PICC)KIT IS APPLICABLE AS FOLLOWS: 1. MONITORING OF CVP 2. ADMINISTRATION OF MULTIPLE IV SOLUTION OF DRUG OR CHEMOTHERAPY 3.BLOOD SAMPLING.,BIOPSY NEEDLE (MEDI CORE , MEDPLUS , MEDI CUT ,SOFT CORE)-FOR TAKING THE BIOPSY OF INTERNAL ORGAN,SCALP VEIN SET-THIS PRODUCT IS USED IN ROUTINE BLOOD COLLECTION PROCEDURES AND/OR THE SHORT-TERM INFU-SION OF INTRAVENOUS FLUIDS. THE WINGED NEEDLE IS DESIGNED WITH A SAFETY SHIELD, WHICH CAN BE ACTIVATED TO COVER THE NEEDLE IMMEDIATELY FOLLOWING BLOOD COLLECTION/INFUSION TO AID IN THE PROTECTION AGAINST ACCIDENTAL NEEDLESTICK INJURY. THE PRODUCT IS TO BE USED BY APPRO-PRIATELY TRAINED HEALTHCARE PROFESSIONALS ONLY IN ACCORDANCE WITH THESE INSTRUCTIONS.,DILATORS (MARDEX,)-FOR PERCUTANEOUS DILATION ,BIOPSY FORCEP-BIOPSY FORCEPS ARE DESIGNED FOR INSERTION THROUGH AN APPROPRIATE SIZED ENDOSCOPY FOR USE CHANNEL FOR REMOVAL AND HISTOLOGICAL SAMPLING OF TISSUE. BIOPSY FORCEPS ARE INTENDED FOR REMOVAL OF POLYPS AND/OR TISSUE WITHIN THE GASTROINTESTINAL TRACT,METALLIC GUIDE WIRE (STRIPE, SLIDE , HYDRA STRIPE)-FOR ENDOSCOPY & FOR PERCUTANEOUS PROCEDURE ,FEEDING TUBE (ALL TYPE- NASAL, ORAL , GASTRIC)-

	THIS PRODUCT IS INTENDED FOR USE PATIENTS TO PROVIDE NUTRITION VIA NASAL OR ORAL GASTRIC PLACEMENT ,(OPEN OR VAI ENDOSCOPY),CHIBA NEEDLE(MEDI SHARP, OXYFLOW)-FOR PERCUTANEOUS CHOLANGIOGRAPHY, CYTOLOGY BIOPSY AND ROUTINE PERCUTANEOUS APPLICATIONS,DRAINAGE CATHETER (BILIARY, SUPRAPUBIC, NEPHROSTOMY , THORACIC)-DRAINAGE CATHETERS ARE USED IN THE REMOVAL AND TREATMENT OF FLUID BUILD-UP THROUGHOUT THE HUMAN BODY. THESE CATHETERS CAN BE PLACED IN MULTIPLE LOCATIONS, AND ARE USED IN THE EXTRACTION OF FLUIDS FROM ABSCESSES, CYSTS, PSEUDOCYSTS, PNEUMOTHORACES, HEMATOMAS, BILOMAS, AND URINOMAS,PICC CATHETER(TRAGET, MARDEX , VAS POWER, FAST PICC)-USE:: PERIPHERALLY INSERTED CATHETER(PICC)KIT IS APPLICABLE AS FOLLOWS: 1. MONITORING OF CVP 2. ADMINISTRATION OF MULTIPLE IV SOLUTION OF DRUG OR CHEMOTHERAPY 3.BLOOD SAMPLING, INTRA - VENOUS CANNULA -INFUSION OF I V SOLUTIONS • INTERMITTENT INTRAVENOUS DRUGS ADMINISTRATION • TO MAINTAIN HYDRATION AND/OR CORRECT DEHYDRATION IF PATIENT IS UNABLE TO TAKE SUFFICIENT VOLUME OF ORAL FLUID,MUTIPLE LUMEN CVP CATHETER KIT (SINGLE, DOUBLE , TRIPLE)(DURA FLOW , EXL FLOW , MAXIMA , OXYFLOW)-INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTIONS OR DRUGS.,STONE RETRIEVAL BASKET -IT IS USED FOR THE REMOVAL OR RETRIEVAL OF URETERAL STONES FROM THE BLADDER, RENAL PELVIS AND URETER AND RETRIEVAL OF FOREIGN OBJECTS., HEMODIALYSIS CATHETER (SINGLE, DOUBLE , TRIPLE)(DURA FLOW , EXL FLOW , MAXIMA , OXYFLOW)-ITS IS USED FOR DOING HEMODIALYSIS,INFUSION /PERFUSION SET -THE INFUSION SET /BLOOD TRAFUSION IS A SINGLE-USE, STERILE, BLOOD COLLECTION NEEDLE BONDED TO A FLEXIBLE TUBING WITH A LUER CONNECTOR. THE BLOOD COLLECTION/INFUSION SET IS USED FOR BLOOD COLLECTION AND/OR THE SHORT-TERM INFUSION OF INTRAVENOUS FLUIDS,TRACHEOSTOMY TUBE-A TRACHEOSTOMY IS PERFORMED FOR SEVERAL REASONS, ALL INVOLVING RESTRICTED AIRWAYS. IT MAY BE DONE DURING AN EMERGENCY WHEN YOUR AIRWAY IS BLOCKED. OR IT COULD BE USED WHEN A DISEASE OR OTHER PROBLEM MAKES NORMAL BREATHING IMPOSSIBLE., ENDOTRACHEAL TUBE-AIR WAY,SPINAL NEEDLE-FOR ANESTHESIA, NEPHROSTOMY CATHETER (PIGTAIL AND MALECOTE TYPE)-TO DRAIN URINE FROM THE BODY,A. V. FISTULA NEEDLE-FOR HEMODIALYSIS,NASAL OXYGEN CATHETER - USED TO DELIVER SUPPLEMENTAL OXYGEN FROM OXYGEN SUPPLY OR BOTTLE TO PATIENT ,WING HUBER NEEDLE-USE TO GIVE INFUSION &

	MEDICATION ,INTRODUCER NEEDLE-TO PUNCTURE VEIN FOR CATHETER INSERTION, BLOOD WITHDRAWAL.,DOUBLE J CATHETER-FOR STONE REMOVING AND EASY PASSAGE OF URINE,FOLEYS CATHETER-DRAINAGE FROM KIDNEY.,EPIDURAL CATHETER KIT-AN EPIDURAL CATHETER IS A VERY FINE PLASTIC CATHETER (TUBE) THAT IS PLACED THROUGH THE SKIN INTO THE EPIDURAL SPACE IN YOUR SPINE. THIS TEMPORARY CATHETER IS LEFT IN PLACE FOR A DEFINED PERIOD OF TIME; NORMALLY LESS THAN TWO WEEKS. THE CATHETER ALLOWS ACCESS TO THE EPIDURAL SPACE TO INJECT MEDICATION SUCH AS LOCAL ANESTHETICS AND/OR NARCOTICS FOR RELIEF OF PAIN.,HEMODIALYSIS BLOODLINE TUBING SET -FOR HEMODAILYSIS PROCEDURE ,3-WAY STOP COCK WITH / WITHOUT EXTENSION TUBING-TO ADMINISTRATION DRUGS OR ADDITIONAL LINES,EPIDURAL NEEDLE-TO PUNCTURE EPIDURAL FOR ANESTHESIA,SKIN STAPLER-TO CLOSE ANY KIND OF WOUNDS, SUCTION CATHETER-TO REMOVE BODILY SECREATION FROM THE BODY.,URETERAL CATHETER-USED FOR DRAINAGE AND RETROGRADE PYELOGRAM,DILATORS-FOR VESSEL DILATORS FOR PERCUTENOUS CATHETERIZATION,SCLEROTHERAPHY NEEDLE-FOR TAKING BIOPSY BY ENDOSCOPY,Y CONNECTOR KIT-FOR PERFUSION SET OR CATHETER TO INSERT CONTRAST MEDIA,LIGATION CLIPS-FOR CLOSING THE ALL TYPE OF WOUND ,,MANIFOLD-INTENDED FOR FLUID FLOW DIRECTIONAL CONTROL,IV FLOW CONNECTOR-IV SYSTEM AND ADMINISTERATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY,CODON SET -FOR INFUSION,CHIBA NEEDLE-FOR PERCUTANEOUS CHOLANGIOGRAPHY, CYTOLOGY BIOPSY AND ROUTINE PERCUTANEOUS APPLICATIONS,COAXIAL NEEDLE-FOR GUIDING BIOPSY NEEDLE,INITIAL PUNCTURE NEEDLE-USED FOR PERCUTANEOUS NEPHROSTOMY FOR ALL PROCEDURE, PRESSURE MONITORING TUBING -KIT-FOR MEASURING ARTERIAL PRESSURE,MUTIPLE LUMEN CVP CATHETER KIT (SINGLE, DOUBLE , TRIPLE) -INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTIONS OR DRUGS.,PERITONEAL DIALYSIS CATHETER-FOR DIALYSIS,ARTERIAL CATHETER-FOR ARTERIAL INFUSION OF DRUGS,CENTRAL VENOUS PORT . (CVP)-INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTIONS OR DRUGS.,BONE MARROW BIOPSY NEEDLE-FOR BONE MARROW BIOPSY,HEMODIALYSIS CATHETER (SINGLE, DOUBLE , TRIPLE)-ITS IS USED FOR DOING HEMODIALYSIS,BIOPSY NEEDLE-FOR BIOPSY OF SOFT TISSUE

3287	MFG/MD/2019/000150	1.License Holder Name: GHANSHYAM COTTON AND SURGICAL UDYOG 2.Approving Authority: BIHAR 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.-MEDICAL PURPOSES, SURGICAL OPERATIONS AND SANITARY PURPOSES.,COTTON CREPE BANDAGE B.P.-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB., ABSORBENT GAUZE-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB.,ROLLED BANDAGE-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB
3288	MFG/MD/2019/000151	1.License Holder Name: PS SURGICAL PVT LTD 2.Approving Authority: CHHATTISGARH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL IP(PS-COT)-USED FOR OPERATION
3289	MFG/MD/2019/000152	1.License Holder Name: GAMMA AGRO MEDICAL PROCESSING PVT LTD 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:ABSORBENT DRESSING PAD-ABSORBENT DRESSING PAD IS MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC. BECAUSE OF ITS PROPERTY OF HIGH FLUID ABSORBENCY, IT IS BETTER KNOWN AMONG MASSES

3290	MFG/MD/2019/000153	1.License Holder Name: SKYLABZ 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:ANGIOGRAPHIC NEEDLE (PUNCTURE NEEDLE)(INSET NEEDLE)-THE INSET NEEDLE IS A SINGLE USE STERILE DEVICE INTENDED FOR PROVIDEING A PUNCTURE SITE IN A BLOOD VESSELS FOR THE INTRODUCTION OF VASCULAR ACCESS DEVICES.,EXTENSION SET (PRESSURE MONITORING LINE) (PASCAL LINE)-THE PASCAL LINE OR THE EXTENSION SET ARE SINGLE USE STERILE DEVICES THAT ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS / MEDICATIONS IN MEDICAL APPLICATIONS.,INFLATION DEVICE / INFLATION DEVICE KIT (TRIGGER DEVICE)-THE TRIGGER DEVICE IS USED TO INFLATE THE BALLOON OR STENT BY CREATING POSITIVE PRESSURE DURING ANGIOPLASTY.,MANIFOLDS(THOR)-THOR IS A SINGLE USE STERILE DEVFICE AND INTENDED FOR FLUID FLOW DIRECTIONAL CONTROL AND PROVIDING ACCESS PORTS FOR ADMINISTRATION OF SOLUTIONS.,Y CONNECTOR SET(YKON SET)-:THE Y- CONNECTOR SET IS INTENDED TO BE USED TO CONNECT TO PERFUSION SET OR CATHETER FOR INFUSION OF CONTRAST MEDIA, ETC.,,Y CONNECTOR SET(YKON SET)-THE Y- CONNECTOR SET IS INTENDED TO BE USED TO CONNECT TO A PERFUSION SET OR CATHETER FOR INFUSION OF CONTRAST MEDIA, ETC.,

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3291	MFG/MD/2019/000154	1.License Holder Name: TATANAGAR HEALTHCARE PVT. LTD. 2.Approving Authority: JHARKHAND 3.Device Name(Brand Name)-Intended Use:CANNULA FIXATOR(SELFI & HOSPICARE)-FOR PROVIDING BREATHABLE AND QUICK FIXATION OF IV CANNULA AND OTHER INTRAMUSCULAR CATHETERS AND PER CUTANEOUS DEVICES TO THE SKIN.,CREPE BANDAGE(SELFI & HOSPICARE)-AN ELASTIC BANDAGE IS A "STRETCHABLE BANDAGE USED TO CREATE LOCALIZED PRESSURE". ELASTIC BANDAGES ARE COMMONLY USED TO TREAT MUSCLE SPRAINS AND STRAINS BY REDUCING THE FLOW OF BLOOD TO A PARTICULAR AREA BY THE APPLICATION OF EVEN STABLE PRESSURE WHICH CAN RESTRICT SWELLING AT THE PLACE OF INJURY,UMBILICAL CORD CLAMP(SELFI & HOSPICARE)-THIS DEVICE IS A CLIP USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT. , PERFUSION SETS(SELFI & HOSPICARE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,SCALP VEIN SET(SELFI & HOSPICARE)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.
3292	MFG/MD/2019/000155	1.License Holder Name: M/S PLASMA BIOTAL INDIA PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:TAPERED HALF PIN WITH HYDROXY APETITE COATING(PITKAR)-HA COATED TAPERED HALF PINS ARE INTENDED FOR USE IN EXTERNAL FIXATION FOR THE TREATMENT OF BONE CONDITIONS INCLUDING LIMB LENGTHENING, CORRECTIVE OSTEOTOMIES, ARTHRODESIS, FRACTURE FIXATION, ACUTE OR GRADUAL MULTIPLANER CORRECTION AND OTHER BONE CONDITIONS AMENABLE TO TREATMENT BY USE OF THE EXTERNAL FIXATION MODALITY.

3293	MFG/MD/2019/000156	1.License Holder Name: STERISAFE HEALTH SOLUTIONS 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:STERILE HYPODERMIC SYRINGES FOR SINGLE USE WITH OR WITHOUT NEEDLE ATTACHED [IS 10258], [ISO 7886-1], [IS 12050](STERILIFE, STERISAFE PRO, STERIVAN)-THE SYRINGES ARE USED FOR GIVING INJECTION DOSAGE TO THE PATIENTS. INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUID FROM THE BODY.,STERILE HYPODERMIC NEEDLE FOR SINGLE USE [IS 10654](SAFETYVAN)-A HYPODERMIC SINGLE LUMEN NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN,STERILE HYPODERMIC NEEDLE FOR SINGLE USE [IS 10654] [ISO 7864](STERILIFE , STERISAFE PRO , STERIVAN)-A HYPODERMIC SINGLE LUMEN NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN. THE NEEDLES ARE USED FOR GIVING VACCINES AND OTHER INJECTION DOSAGE TO THE PATIENTS.,STERILE HYPODERMIC SYRINGES FOR SINGLE USE [IS 10258] [ISO 7886-1](SAFETYVAN)-INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUID FROM THE BODY,INFUSION SETS FOR SINGLE USE [IS 12655-4] [ISO 8536-4](SAFETYVAN)-INFUSION SET IS USED TO ADMINISTER FLUIDS AND DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3294	MFG/MD/2019/000157	1.License Holder Name: MULTIMEDICS 2.Approving Authority: SUB ZONAL BADDI 3.Device Name(Brand Name)-Intended Use:NON ABSORBABLE SURGICAL SUTURE U.S.P.(PEARSILK, SILKFIL.)-NON- ABSORBABLE SUTURES FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,BIODEGRADABLE POLYMER BASED EVEROLIMUS ELUTING CORONARY STENT SYSTEM(M'SURE-EVRO, ELIMINATOR.)-A CORONARY STENT IS A TUBE-SHAPED DEVICE PLACED IN THE CORONARY ARTERIES THAT SUPPLY BLOOD TO THE HEART, TO KEEP THE ARTERIES OPEN IN THE TREATMENT OF CORONARY HEART DISEASE.,CHROMIUM COBALT CORONARY STENT SYSTEM(M'SURE-CR, MYSTENT-CR, MASTERSTENT-CR, STREAM-CR, TAPPER-CR, ELIMINATE-CR,)-A CORONARY STENT IS A TUBE-SHAPED DEVICE PLACED IN THE CORONARY ARTERIES THAT SUPPLY BLOOD TO THE HEART, TO KEEP THE ARTERIES OPEN IN THE TREATMENT OF CORONARY HEART DISEASE.,STAINLESS STEEL CORONARY STENT SYSTEM(M'SURE, MYSTENT, MASTERSTENT, STREAM, TAPPER, ELIMINATE-S,)-A CORONARY STENT IS A TUBE-SHAPED DEVICE PLACED IN THE CORONARY ARTERIES THAT SUPPLY BLOOD TO THE HEART, TO KEEP THE ARTERIES OPEN IN THE TREATMENT OF CORONARY HEART DISEASE.,BIODEGRADABLE POLYMER BASED SIROLIMUS ELUTING CORONARY STENT SYSTEM(M'SURE-S, MYSTENT-S, MASTERSTENT-S, STREAM-S, TAPPER-S, ELIMINATE-R, E-MAGIC PLUS)-A CORONARY STENT IS A TUBE-SHAPED DEVICE PLACED IN THE CORONARY ARTERIES THAT SUPPLY BLOOD TO THE HEART, TO KEEP THE ARTERIES OPEN IN THE TREATMENT OF CORONARY HEART DISEASE.,NON ABSORBABLE SURGICAL SUTURE U.S.P(BARBLIN, LINEFIL)-NON- ABSORBABLE SUTURES FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.

3295	MFG/MD/2019/000158	1.License Holder Name: RELISYS MEDICAL DEVICES LIMITED 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:PRE DILATATION CATHETER-PRE-DILATATION CATHETER IS A MINIMALLY INVASIVE PROCEDURE TO OPEN UP BLOCKED CORONARY ARTERIES, ALLOWING BLOOD TO CIRCULATE UNOBSTRUCTED TO THE HEART MUSCLE.,POST DILATATION CATHETER-1. BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS, FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. 2. BALLOON DILATATION OF A CORONARY ARTERY OCCLUSION, FOR THE PURPOSE OF RESTORING CORONARY FLOW IN PATIENTS WITH ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION. 3. BALLOON DILATATION OF A STENT AFTER IMPLANTATION , SIROLIMUS ELUTING CORONARY STENT SYSTEM-THE SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES. SIROLIMUS ELUTING CORONARY STENT SYSTEM IS ALSO INDICATED FOR TREATMENT OF ABRUPT OF THREATENED CLOSURE IN PATIENTS WITH FAILED INTERVENTIONAL THERAPY. THE DRUG COATING IS INTENDED TO INHIBIT RESTENOSIS.
3296	MFG/MD/2019/000159	1.License Holder Name: FRISCH MEDICAL DEVICES PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:INTRODUCER SHEATH - RADIAL(STEER-R)-THE INTRODUCER SHEATH IS USED DURING ANGIOPLASTY PROCEDURES TO PROVIDE A PATHWAY THROUGH WHICH A PTCA GUIDING CATHETER MAY BE PERCUATNEOUSLY INTRODUCED INTO THE VASCULATURE OR VARIOUS DEVICES INTO VEIN OR ARTERIES WHILE MAINTAINING HEMOSTASIS FOR A VARIETY OF DIAGNOSTIC AND THERAPEUTIC PROCEDURE.,INTRODUCER SHEATH -FEMORAL(STEER-F)-THE INTRODUCER SHEATH IS USED DURING ANGIOPLASTY PROCEDURES TO PROVIDE A PATHWAY THROUGH WHICH A PTCA GUIDING CATHETER MAY BE PERCUATNEOUSLY INTRODUCED INTO THE VASCULATURE OR VARIOUS DEVICES INTO VEIN OR ARTERIES WHILE MAINTAINING HEMOSTASIS FOR A VARIETY OF DIAGNOSTIC AND THERAPEUTIC PROCEDURE.

3297	MFG/MD/2019/000160	1.License Holder Name: SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:SYNTHETIC ABSORBABLE SURGICAL SUTURE USP(I-COL FAST)-INTENDED FOR USE IN GENERAL SIFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE RAPID ABSORPTION OF SUTURE WOULD BE BENEFICIAL. PERINEAL REPAIR AND SKIN CLOSURE., ABSORBABLE SURGICAL SUTURE(CATGUT PLAIN)-INDICATED FOR APPLICATION WHERE IT IS A SURGICAL PRACTICES TO EMPLOY ABSORBABLE SUTURE MATERIAL.,NON ABSORBABLE SURGICAL SUTURE(STERISIL)-STERISIL IS INDICATED FOR APPLICATION IN GI TRACT, GENERAL CLOSURE, SKIN, PLASTIC OPHTHALMIC, NEURO AND CARDIOVASCULAR SURGERY.,NON ABSORBABLE SURGICAL SUTURE(STERIBON)-INDICATED FOR FILELDS OF APPLICATION WHERE IT IS SURGICAL PRACTICE TO EMPLOY NON ABSORBABLE SUTURE MATERIAL.,NON ABSORBABLE SURGICAL SUTURE (STERILON)-INDICATED FOR APPLICATION WHERE IT IS A SURGICAL PRACTICES TO EMPLOY NON ABSORBABLE SUTURE.,ABSORBABLE SURGICAL SUTURE(CATGUT CHROMIC)-INDICATED FOR APPLICATION WHERE IT IS A SURGICAL PRACTICES TO EMPLOY A ABSORBABLE SUTURE MATERIAL.
3298	MFG/MD/2019/000161	1.License Holder Name: KAUSHIK ORTHOPAEDIC PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ORTHOPAEDIC IMPLANTS (GPC, ORTHOSON, D&D)-AN ORTHOPEDIC IMPLANT IS A MEDICAL DEVICE MANUFACTURED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE
3299	MFG/MD/2019/000162	1.License Holder Name: BIOPORE SURGICALS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:CRANIO MAXILLO FACIAL IMPLANTS(BIOPORE)-INTERNAL PROSTHETIC REPLACEMENT FOR RECONSTRUCTION AND AESTHETIC USE

3300	MFG/MD/2019/000163	1.License Holder Name: RECOMBIGEN LABORATORIES PRIVATE LIMITED 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:PRE-INJECTION SWAB (ALCOHOL SWAB)-THE ALCOHOL SWAB IS A SINGLE USE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE.
3301	MFG/MD/2019/000165	1.License Holder Name: SIDDHARTH SURGICALS 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS
3302	MFG/MD/2019/000166	1.License Holder Name: VISHAL HEALTH CARE PRODUCTS PVT.LTD 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:GAUZE PAD-A COVERED WOUND HEALS FASTER THAN AN UNCOVERED ONE. GAUZE PADS ARE DESIGNED TO PROTECT MINOR CUTS, SCRAPES AND BURNS. IT IS MADE OF 100% COTTON TO ENSURE SUPERIOR ABSORBENCY .THESE 12-PLY GAUZE PADS ARE INDIVIDUALLY-WRAPPED STERILE GAUZE PADS DESIGNED TO WICK AWAY FLUID FROM WOUNDS TO HELP KEEP THEM CLEAN. GAUZE PAD IS USED A MEDICAL DRESSING .THESE NON-ADHESIVE GAUZE PADS ARE ESSENTIAL FIRST AID SUPPLIES , EYE PAD-EYE PAD IS A COMBINE DRESSING PAD CUT APPROPRIATELY TO FACILITATE THE SHAPE OF THE EYE. IT IS A STERILE COMBINE DRESSING PAD OR COMPRESS APPLIED TO COVER AND PROTECT SURGICAL SITES IN OPHTHALMIC SURGERIES AND PROMOTES HEALING,COMBINE DRESSING PAD-COMBINE DRESSING PAD IS A STERILE PAD OR COMPRESS APPLIED TO A WOUND TO PROMOTE HEALING AND PROTECT THE WOUND FROM FURTHER HARM. COMBINE DRESSING PAD IS DESIGNED TO BE IN EXTERNAL CONTACT WITH THE WOUND,ABSORBENT COTTON WOOL IP-ABSORBENT COTTON MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC. BECAUSE OF ITS PROPERTY OF HIGH FLUID ABSORBENCY.

3303	MFG/MD/2019/000167	1.License Holder Name: VIRCHOW BIOTECH PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:DISPOSABLE PEN DEVICE-WITHOUT HYPODERMIC NEEDLE FOR PTH CARTRIDGE INJECTION(+)-DISPOSABLE PEN DEVICE-WITHOUT HYPODERMIC NEEDLE FOR PTH CARTRIDGE INJECTION IS USED FOR SUBCUTANEOUS ADMINISTRATION OF RECOMBINANT HUMAN PARA THYROID HORMONE INJECTION.
3304	MFG/MD/2019/000168	1.License Holder Name: SPECTRUM MEDTECH PVT. LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:GUIDING CATHETER (SPENDID)-THE GUIDE CATHETER PROVIDES SUPPORT FOR DEVICE ADVANCEMENT,MANIFOLD(MULTIWAY)-INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT / PORTS FOR ADMINISTRATION OF A SOLUTION,ANGIOGRAPHY NEEDLE, HAIR TRANSPLANT NEEDLE, AND BLUNT INTRODUCER(ACCURATE, SAVA, ASSIST)-ANGIOGRAPHIC NEEDLE HAS A UNIQUE HUB DESIGN WITH AN ERGONOMIC FEEL AND A BLACK TRIANGLE INDICATOR TO ORIENT THE BEVEL,CONTROL DEVICE(EXACT)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY
3305	MFG/MD/2019/000169	1.License Holder Name: AGROSURG IRRADIATORS (INDIA) PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:POLYVINYL ALCOHOL (PVA) FOAM EMBOLIZATION PARTICLES(EMBOX)-IT IS INTENDED FOR EMBOLIZATION OF THE BLOOD SUPPLY TO HYPERVASCULAR TUMORS AND ARTERIOVENOUS MALFORMATIONS, INCLUDING USE IN INTRACRANIAL EMBOLIZATION.,VASCULAR CLOSURE DEVICE (OBTURA)-THE OBTURA - VASCULAR CLOSURE DEVICE IS INDICATED FOR FEMORAL ARTERY PUNCTURE SITE CLOSURE, REDUCING TIMES TO HEMOSTASIS AND AMBULATION IN PATIENTS WHO HAVE UNDERGONE DIAGNOSTIC OR INTERVENTIONAL CATHETERIZATION PROCEDURES USING A STANDARD 6F OR 7F INTRODUCER SHEATH WITH 6F OBTURA - VASCULAR CLOSURE DEVICE AND 8F OR 9F INTRODUCER SHEATH WITH 8F OBTURA - VASCULAR CLOSURE DEVICE.

3306	MFG/MD/2019/000170	1.License Holder Name: TERUMO PENPOL PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP/IP/EP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - PENTA BAG(TERUMO BCT REVEOS® LR EXT)-FOR THE PROCESSING OF BLOOD OR BLOOD COMPONENTS.,EMPTY BLOOD TRANSFER BAG - DOUBLE BAG(TERUMO PENPOL)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP/IP/EP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - PENTA BAG (TERUMO BCT REVEOS® NLR)-FOR THE PROCESSING OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP IN PRIMARY BAG & SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP/IP/EP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG – QUADRUPLE BAG WITH INLINE LEUKOCYTE FILTER(TERUMO BCT REVEOS® LR)-FOR THE PROCESSING OF BLOOD OR BLOOD COMPONENTS.,EMPTY BLOOD TRANSFER BAG - DOUBLE BAG (TERUMO)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION IP - TRIPLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP - SINGLE BAG(TERUMO PENPOL)-FOR COLLECTION AND PROCESSING OF 250ML CORD BLOOD, ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG – QUADRUPLE BAG WITH INLINE LEUKOCYTE FILTER(TERUMO BCT REVEOS® LR)-FOR THE PROCESSING OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG (TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,EMPTY BLOOD TRANSFER BAG - SINGLE BAG

	(TERUMO PENPOL)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,SALINE ADENINE GLUCOSE MANNITOL, SAGM (SAG-M) SOLUTION IP/BP/EP/USP - SINGLE BAG(TERUMO)-FOR PRESERVATION AND STORAGE OF RED BLOOD CELLS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,SALINE ADENINE GLUCOSE MANNITOL, SAGM - 2 (OPTISOL) (SAG-M - 2) SOLUTION IP/BP/EP/USP - SINGLE BAG(TERUMO)-FOR PRESERVATION AND STORAGE OF RED BLOOD CELLS.,EMPTY BLOOD TRANSFER BAG WITH INLINE LEUKOCYTE FILTER - SINGLE BAG(TERUMO)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP 21ML IN PRIMARY BAG AND 14ML IN DIVERSION POUCH - SINGLE BAG (TERUMO PENPOL)-FOR COLLECTION AND PROCESSING OF 250ML CORD BLOOD,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP - DOUBLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP - TRIPLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO) -FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION BP/USP IN PRIMARY BAG & SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION USP/BP/EP - SINGLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP - DOUBLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP - DOUBLE BAG(TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP - SINGLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD.,ANTICOAGULANT CITRATE

	PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP - SINGLE BAG (TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP - TRIPLE BAG(TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP - SINGLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION IP/BP/EP/USP - SINGLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION USP/BP/EP - DOUBLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP 21ML IN PRIMARY BAG AND 14ML IN DIVERSION POUCH - SINGLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION USP/BP/EP - PENTA BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,EMPTY BLOOD TRANSFER BAG - QUADRUPLE BAG(TERUMO)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP 21ML IN PRIMARY BAG AND 14ML IN DIVERSION POUCH - SINGLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION USP/BP/EP - QUADRUPLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION USP/BP/EP - TRIPLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,EMPTY BLOOD TRANSFER BAG - SINGLE BAG (TERUMO)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD

	COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION BP/USP IN PRIMARY BAG & SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP - TRIPLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION BP/USP/EP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - PENTA BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION BP/USP/EP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG (TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG (TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,EMPTY BLOOD TRANSFER BAG - TRIPLE BAG(TERUMO)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP - SINGLE BAG(TERUMO PENPOL)-FOR COLLECTION AND PROCESSING OF 150 ML CORD BLOOD, ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., EMPTY BLOOD TRANSFER BAG WITH INLINE LEUKOCYTE FILTER - SINGLE BAG(TERUMO PENPOL)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,EMPTY BLOOD TRANSFER BAG WITH INLINE LEUKOCYTE FILTER - SINGLE BAG(TERUMO IMUFLEX)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION BP/USP IN PRIMARY BAG & SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG (TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG -

	QUADRUPLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP/BP (SOLUTION A) - SINGLE BAG(TERUMO) -FOR APHAERESIS PURPOSE,ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP/BP (SOLUTION B) - SINGLE BAG(TERUMO)-FOR APHAERESIS PURPOSE,EMPTY BLOOD TRANSFER BAG - PENTA BAG (TERUMO)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION BP/USP/EP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,EMPTY BLOOD TRANSFER BAG - SINGLE BAG(TERUMO TERUFLEX)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,EMPTY BLOOD TRANSFER BAG - TRIPLE BAG(TERUMO PENPOL)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG (TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG (TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,EMPTY BLOOD TRANSFER BAG - QUADRUPLE BAG(TERUMO PENPOL)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION USP/BP - SINGLE BAG(TERUMO)-FOR COLLECTION AND PROCESSING OF 150 ML CORD BLOOD,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION IP - PENTA BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP 21ML IN PRIMARY BAG AND 14ML IN DIVERSION POUCH - SINGLE BAG(TERUMO)-FOR

	COLLECTION AND PROCESSING OF 250ML CORD BLOOD, ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - PENTA BAG WITH INLINE LEUKOCYTE FILTER(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - PENTA BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG (TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE DEXTROSE SOLUTION IP (SOLUTION A) - SINGLE BAG (TERUMO PENPOL)-FOR APHAERESIS PURPOSE,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - PENTA BAG WITH INLINE LEUKOCYTE FILTER(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG WITH INLINE LEUKOCYTE FILTER(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE

	SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO) -FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,EMPTY BLOOD TRANSFER BAG - PENTA BAG (TERUMO PENPOL)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG WITH INLINE LEUKOCYTE FILTER - PENTA BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG WITH INLINE LEUKOCYTE FILTER - QUADRUPLE BAG (TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG WITH INLINE LEUKOCYTE FILTER(TERUMO)- FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION BP/USP IN PRIMARY BAG & SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG(TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - PENTA BAG (TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG(TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP - SINGLE BAG(TERUMO)-FOR COLLECTION AND PROCESSING OF 250ML CORD BLOOD,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP - SINGLE BAG (TERUMO TERUFLEX)-FOR COLLECTION AND PROCESSING OF 250ML CORD BLOOD,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL)

	(SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG (TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION IP - QUADRUPLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG WITH INLINE LEUKOCYTE FILTER - TRIPLE BAG (TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG (TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP IN PRIMARY BAG & SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION IP/BP/EP/USP - SINGLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG WITH INLINE LEUKOCYTE FILTER - TRIPLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF

	BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION USP - PENTA BAG (TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE DEXTROSE SOLUTION IP (SOLUTION B) - SINGLE BAG (TERUMO PENPOL)-FOR APHAERESIS PURPOSE,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG(TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - PENTA BAG WITH INLINE LEUKOCYTE FILTER(TERUMO IMUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG(TERUMO) -FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION USP - QUADRUPLE BAG(TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION USP - DOUBLE BAG(TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION USP - TRIPLE BAG(TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG (TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP 21ML IN PRIMARY BAG AND 14ML IN DIVERSION POUCH - SINGLE BAG (TERUMO TERUFLEX)-FOR COLLECTION AND PROCESSING OF 250ML CORD BLOOD,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION USP - SINGLE BAG(TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD

	COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG WITH INLINE LEUKOCYTE FILTER(TERUMO IMUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION IP - SINGLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION IP - DOUBLE BAG(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - PENTA BAG WITH INLINE LEUKOCYTE FILTER(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG WITH INLINE LEUKOCYTE FILTER - QUADRUPLE BAG(TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG WITH INLINE LEUKOCYTE FILTER - PENTA BAG (TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG (TERUMO)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION BP/USP IN PRIMARY BAG & SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - TRIPLE BAG (TERUMO TERUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG WITH INLINE LEUKOCYTE FILTER(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., EMPTY BLOOD TRANSFER BAG - QUADRUPLE BAG(TERUMO TERUFLEX)-FOR PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM - 2 (OPTISOL) (SAG-M - 2) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE

		BAG WITH INLINE LEUKOCYTE FILTER(TERUMO IMUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - PENTA BAG WITH INLINE LEUKOCYTE FILTER(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS., ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - PENTA BAG WITH INLINE LEUKOCYTE FILTER(TERUMO IMUFLEX)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.,ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION IP/BP/EP/USP IN PRIMARY BAG AND SAGM (SAG-M) ADDITIVE SOLUTION IN SATELLITE BAG - QUADRUPLE BAG WITH INLINE LEUKOCYTE FILTER(TERUMO PENPOL)-FOR THE COLLECTION, PROCESSING AND STORAGE OF BLOOD OR BLOOD COMPONENTS.
3307	MFG/MD/2019/000171	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT. LTD. 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:GAMMA/ ETHYLENE OXIDE STERILISATION OF CLASS D PRODUCTS-GAMMA/ ETHYLENE OXIDE STERILISATION OF PRODUCTS FALLING UNDER CLASS D. INTENDED USE OF THE PRODUCTS WOULD BE AS DECIDED BY THE MEDICAL DEVICE MANUFACTURER.,GAMMA/ ETHYLENE OXIDE STERILISATION OF CLASS C PRODUCTS-GAMMA/ ETHYLENE OXIDE STERILISATION OF PRODUCTS FALLING UNDER CLASS C. INTENDED USE OF THE PRODUCTS WOULD BE AS DECIDED BY THE MEDICAL DEVICE MANUFACTURER.

3308	MFG/MD/2019/000172	1.License Holder Name: DELITE SURGICAL 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE HIGH PRESSURE MONITORING LINE FOR SINGLE USE ONLY(PERFECT) -EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS THE PART OF THE SYSTEM OF INFUSION OF FLUID/MEDICATION IN THE MEDICAL APPLICATION, STERILE DISPOSABLE INFUSION SET WITH AIR VENT BIS 12655 (PERFECT)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,DISPOSABLE STERILE DIAL FLOW REGULATOR WITH OR WITHOUT INFUSION SET FOR SINGLE USE ONLY(PERFECT)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655(DRIP FLOW /PERFECT/SAFE-T/DRIP FLOW JMS /DRIP FLOW BD //NINU CARE /I BLUE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE ENDOTRACHEAL TUBE FOR SINGLE USE ONLY(PERFECT)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITHOUT AIR VENT BIS 9824(DRIP FLOW)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED., STERILE TRACHEOBRONCHIAL YANKAUR SUCTION CATHETER FOR SINGLE USE ONLY(DRIPFLOW)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE ,STERILE DISPOSABLE THREE WAY STOP COCK AN ACCESSORY TO PERFUSION SETS(PERFECT/DRIP FLOW)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUIDS AND PRESSURE MONITORING. ,STERILE DISPOSABLE CLOSED WOUND SUCTION SET FOR SINGLE USE ONLY(PERFECT)-EXTRACT PUS FROM THE WOUND OF A HUMAN BODY,STERILE DISPOSABLE EXTENSION LINE(- - -)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS THE PART OF THE SYSTEM OF INFUSION OF FLUID/MEDICATION IN THE MEDICAL APPLICATION. ,STERILE DISPOSABLE MICRO DRIP INFUSION SET WITHOUT AIR VENT BIS 12655(PERFECT/DRIP FLOW /)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE MEASURED VOLUME INFUSION

	SET WITHOUT AIR VENT BIS 12655(FLOW)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3309	MFG/MD/2019/000173	1.License Holder Name: ORTHO MAX MANUFACTURING COMPANY PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:HIP REPLACEMENT SYSTEM (MODULAR BIPOLAR HEAD)(ORTHO MAX)-HEMIARTHROPLASTY IN PARTIAL HIP SURGERY. NOT INTENDED FOR TOTAL HIP REPLACEMENT,HIP REPLACEMENT SYSTEM (FEMORAL HEAD)(ORTHO MAX)-HEMIARTHROPLASTY IN PARTIAL HIP SURGERY, HIP REPLACEMENT SYSTEM (FEMORAL STEM)(ORTHO MAX)-ARTHROPLASTY IN HIP REPLACEMENT SURGERY,BONE PLATES (ORTHO MAX)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PLATES ARE OF DIFFERENT TYPES WHICH USED IN DIFFERENT PARTS OF HUMAN BODY E.G. ONE THIRD TUBULAR PLATES ARE GENERALLY USED IN FOREARM BONES ALONG WITH CORTICAL & CANCELLOUS SCREWS, MINI BONE PLATES, SMALL T –PLATES ARE GENERALLY USED IN LOWER END OF FOREARM BONE, MINI STRAIGHT PLATES ARE USED IN PHALANGEAL FRACTURES, MINI T & L PLATES ARE USED IN FRACTURES OF THE DISTAL OR PROXIMAL ENDS OF PHALANGES AND MAXILLOFACIAL SURGERY,PINS/WIRES(ORTHO MAX)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. WIRES ARE OF DIFFERENT TYPES WHICH USED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENT. WIRES ARE MAINLY INDICATED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION IN ORTHOPEDIC& MAXILLOFACIAL SURGERY,SPINAL IMPLANTS(ORTHO MAX)-USED TO CORRECT DEFORMITY OR FRACTURE FIXATION IN SPINAL SURGERY, BONE PLATES(ORTHO MAX)-THESE IMPLANTS ARE USED IN THE HUMAN JAW TO CORRECT THE DEFORMITY OF JAW IN ANKYLOSIS OR ARTHRITIC PATIENTS BY REPLACING THE CONDYLAR HEAD,HIP REPLACEMENT SYSTEM(FEMORAL STEM WITH HEAD)(ORTHO MAX)-HEMIARTHROPLASTY IN PARTIAL HIP SURGERY AND SHOULDER ARTHROPLASTY. NOT INTENDED FOR TOTAL HIP OR SHOULDER REPLACEMENT,HIP REPLACEMENT SYSTEM (ACETABULAR CUP-CEMENTED)(ORTHO MAX)-HIP REPLACEMENT ARTHROPLASTY SURGERY,NAILS(ORTHO MAX)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. NAILS ARE OF DIFFERENT TYPES WHICH USED IN TIBIA, FEMUR AND HUMERUS BONES MAINLY.,HIP REPLACEMENT SYSTEM (CENTRALIZER)(ORTHO MAX)-HIP REPLACEMENT ARTHROPLASTY SURGERY,PINS/WIRES(ORTHO MAX)-WIRE : THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. WIRES ARE OF DIFFERENT TYPES WHICH USED IN

	FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENT. WIRES ARE MAINLY INDICATED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION IN ORTHOPEDIC & MAXILLOFACIAL SURGERY PINS : THIS IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PINS ARE OF DIFFERENT TYPES WHICH GENERALLY USED WITH EXTERNAL FIXATOR IMPLANTS IN TIBIA, FEMUR & FOREARM BONES IN ORTHOPEDIC SURGERY,HIP REPLACEMENT SYSTEM (ACETABULAR BONE SCREWS)(ORTHO MAX)-HIP REPLACEMENT ARTHROPLASTY SURGERY,BONE PLATES(ORTHO MAX)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PLATES ARE OF DIFFERENT TYPES WHICH USED IN DIFFERENT PARTS OF HUMAN BODY E.G. ONE THIRD TUBULAR PLATES ARE GENERALLY USED IN FOREARM BONES ALONG WITH CORTICAL & CANCELLOUS SCREWS, MINI BONE PLATES, SMALL T –PLATES ARE GENERALLY USED IN LOWER END OF FOREARM BONE, MINI STRAIGHT PLATES ARE USED IN PHALANGEAL FRACTURES, MINI T & L PLATES ARE USED IN FRACTURES OF THE DISTAL OR PROXIMAL ENDS OF PHALANGES AND MAXILLOFACIAL SURGERY,HIP REPLACEMENT SYSTEM (CEMENT RESTRICTOR)(ORTHO MAX)-HIP REPLACEMENT ARTHROPLASTY SURGERY,SPINAL IMPLANTS(ORTHO MAX)-USED TO CORRECT DEFORMITY OR FRACTURE FIXATION IN SPINAL SURGERY, HIP REPLACEMENT SYSTEM (FEMORAL HEAD)(ORTHO MAX)-ARTHROPLASTY IN HIP REPLACEMENT SURGERY,SPINAL IMPLANTS (ORTHO MAX)-USED TO CORRECT DEFORMITY OR FRACTURE FIXATION IN SPINAL SURGERY,JOINT REPLACEMENT SYSTEM (TMJ FOSSA)(ORTHO MAX)-FOR DEFORMITY CORRECTION OF GLENOID FOSSA IN TMJ ANKYLOSIS SURGERY,BONE SCREWS(ORTHO MAX)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. SCREWS ARE OF DIFFERENT TYPES EG. MINI BONE SCREWS, CORTICAL SCREWS, CANCELLOUS SCREWS, CANCELLOUS CANNULATED SCREWS, MALLEOLAR SCREWS, LOCKING BOLT, LAG (DHS/DCS) SCREWS, SPINAL SCREWS, SHAFT SCREWS USED IN ORTHOPEDIC AND MAXILLOFACIAL SURGERY,HIP REPLACEMENT SYSTEM (FEMORAL STEM)(ORTHO MAX)-ARTHROPLASTY IN HIP REPLACEMENT SURGERY,HIP REPLACEMENT SYSTEM (FEMORAL STEM)(ORTHO MAX)-HEMIARTHROPLASTY IN PARTIAL HIP SURGERY,HIP REPLACEMENT SYSTEM (ACETABULAR LINER)(ORTHO MAX)-HIP REPLACEMENT ARTHROPLASTY SURGERY, BONE SCREWS(ORTHO MAX)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. SCREWS ARE OF DIFFERENT TYPES EG. MINI BONE SCREWS, CORTICAL SCREWS, CANCELLOUS SCREWS, CANCELLOUS CANNULATED SCREWS, MALLEOLAR SCREWS, LOCKING BOLT, LAG (DHS/DCS)

	SCREWS, SPINAL SCREWS, SHAFT SCREWS USED IN ORTHOPEDIC AND MAXILLOFACIAL SURGERY,HIP REPLACEMENT SYSTEM (FEMORAL STEM WITH HEAD)(ORTHO MAX)-HEMIARTHROPLASTY IN PARTIAL HIP SURGERY. NOT INTENDED FOR TOTAL HIP OR SHOULDER REPLACEMENT,HIP REPLACEMENT SYSTEM (FEMORAL STEM)(ORTHO MAX)-HEMIARTHROPLASTY IN PARTIAL HIP SURGERY, HIP REPLACEMENT SYSTEM (BIPOLAR HIP PROSTHESIS)(ORTHO MAX)-HEMIARTHROPLASTY IN HIP SURGERY. NOT INTENDED FOR TOTAL HIP REPLACEMENT,HIP REPLACEMENT SYSTEM (FEMORAL STEM)(ORTHO MAX)-HEMIARTHROPLASTY IN PARTIAL HIP SURGERY, NAILS(ORTHO MAX)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. NAILS ARE OF DIFFERENT TYPES WHICH USED IN TIBIA, FEMUR AND HUMERUS BONES MAINLY.,HIP REPLACEMENT SYSTEM (FEMORAL HEAD) (ORTHO MAX)-HEMIARTHROPLASTY IN PARTIAL HIP SURGERY,BONE SCREWS(ORTHO MAX)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. SCREWS ARE OF DIFFERENT TYPES EG. MINI BONE SCREWS, CORTICAL SCREWS, CANCELLOUS SCREWS, CANCELLOUS CANNULATED SCREWS, MALLEOLAR SCREWS, LOCKING BOLT, LAG (DHS/DCS) SCREWS, SPINAL SCREWS, SHAFT SCREWS USED IN ORTHOPEDIC AND MAXILLOFACIAL SURGERY,HIP REPLACEMENT SYSTEM(FEMORAL STEM WITH HEAD)(ORTHO MAX)-HEMIARTHROPLASTY IN PARTIAL HIP SURGERY. NOT INTENDED FOR TOTAL HIP OR SHOULDER REPLACEMENT,NAILS(ORTHO MAX)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. NAILS ARE OF DIFFERENT TYPES WHICH USED IN TIBIA, FEMUR AND HUMERUS BONES MAINLY.,PINS/WIRES(ORTHO MAX)-WIRE : THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. WIRES ARE OF DIFFERENT TYPES WHICH USED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENT. WIRES ARE MAINLY INDICATED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION IN ORTHOPEDIC & MAXILLOFACIAL SURGERY PINS : THIS IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PINS ARE OF DIFFERENT TYPES WHICH GENERALLY USED WITH EXTERNAL FIXATOR IMPLANTS IN TIBIA, FEMUR & FOREARM BONES IN ORTHOPEDIC SURGERY,BONE PLATES(ORTHO MAX)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PLATES ARE OF DIFFERENT TYPES WHICH USED IN DIFFERENT PARTS OF HUMAN BODY E.G. ONE THIRD TUBULAR PLATES ARE GENERALLY USED IN FOREARM BONES ALONG WITH CORTICAL & CANCELLOUS SCREWS, MINI BONE PLATES, SMALL T –PLATES ARE GENERALLY USED IN LOWER END OF

	FOREARM BONE, MINI STRAIGHT PLATES ARE USED IN PHALANGEAL FRACTURES, MINI T & L PLATES ARE USED IN FRACTURES OF THE DISTAL OR PROXIMAL ENDS OF PHALANGES AND MAXILLOFACIAL SURGERY,PINS/WIRES(ORTHO MAX)-WIRE : THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. WIRES ARE OF DIFFERENT TYPES WHICH USED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENT. WIRES ARE MAINLY INDICATED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION IN ORTHOPEDIC & MAXILLOFACIAL SURGERY PINS : THIS IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PINS ARE OF DIFFERENT TYPES WHICH GENERALLY USED WITH EXTERNAL FIXATOR IMPLANTS IN TIBIA, FEMUR & FOREARM BONES IN ORTHOPEDIC SURGERY,HIP REPLACEMENT SYSTEM (FEMORAL HEAD)(ORTHO MAX)-HEMIARTHROPLASTY IN PARTIAL HIP SURGERY

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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3310	MFG/MD/2019/000174	1.License Holder Name: ADVANCED MEDTECH SOLUTIONS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:STERILIZED SURGICAL SUTURE KIT(ADVAKIT - C-SECTION KIT)-1. ADVACRYL: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS & MICRO-SURGERY FOR VESSELS LESS THAN 2 MM DIAMETER, BUT NOT FOR CARDIOVASCULAR TISSUES. 2. ADVAMRYL: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN OPHTHALMIC SURGERY, MICRO SURGERY, CARDIOVASCULAR & NEUROLOGICAL TISSUES. 3. ADVAPD: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION INCLUDING USE IN OPHTHALMIC SURGERY AND PAEDIATRIC CARDIOVASCULAR TISSUE WHERE GROWTH IS EXPECTED TO OCCUR BUT NOT FOR USE IN ADULT CARDIOVASCULAR TISSUES, PERIPHERAL NERVE ANASTOMOSIS & MICRO SURGERY. 4. ADVACAT CHROMIC: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC PROCEDURES.,NON-ABSORBABLE SURGICAL SUTURE U.S.P. BRAIDED COATED POLYESTER WHITE / GREEN STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE(SUPERBOND)-IT IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR AND OPHTHALMIC., STERILIZED SURGICAL SUTURE KIT(ADVAKIT - ORTHO KIT)-1. ADVACRYL: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS & MICRO-SURGERY FOR VESSELS LESS THAN 2 MM DIAMETER, BUT NOT FOR CARDIOVASCULAR TISSUES. 2. ADVALON: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC PROCEDURE.,NON-ABSORBABLE SURGICAL SUTURE U.S.P. MONOFILAMENT POLYAMIDE BLACK STERILISED SURGICAL SUTURE WITHOUT NEEDLE(SUPERLON)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC PROCEDURE., STERILIZED SURGICAL SUTURE KIT(ADVAKIT - GYNAE KIT)-1. ADVACRYL: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS & MICRO-SURGERY FOR VESSELS LESS THAN 2 MM DIAMETER, BUT NOT FOR CARDIOVASCULAR TISSUES. 2. ADVAMRYL: INDICATED FOR

	USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN OPHTHALMIC SURGERY, MICRO SURGERY, CARDIOVASCULAR & NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC) BRAIDED COATED POLYGLACTIN 910 UNDYED STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE(SUPERCRYL)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS & MICRO SURGERY FOR VESSELS LESS THAN 2 MM DIAMETER, BUT NOT FOR CARDIOVASCULAR TISSUES.,PTCA BALLOON CATHETER (SEMI COMPLIANT)(ADVA GLIDE (1ST BRAND NAME), CLEVER (2ND BRAND NAME))-THE CLINICAL DATA PRESENTLY AVAILABLE INDICATES THAT THE LUMINAL DIAMETER OF A CORONARY ARTERY AT THE SITE OF CERTAIN TYPES OF STENOTIC LESIONS CAN BE INCREASED BY BALLOON DILATATION AND THAT PTCA IS A SAFE AND EFFICACIOUS PROCEDURE FOR REDUCTION OF SOME FORMS OF ATHEROSCLEROTIC CORONARY ARTERY DISEASE (SEE INDICATIONS). INDICATIONS: PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CAN BE INDICATED BY THE PHYSICIAN IN PATIENTS WITH SIGNIFICANT CORONARY ARTERY DISEASE WHO ARE ACCEPTABLE CANDIDATES FOR CORONARY ARTERY BYPASS GRAFT SURGERY AND WHO MEET ONE OF THE FOLLOWING SELECTION CRITERIA: 1. ATHEROSCLEROTIC CORONARY ARTERY DISEASE THAT IS ACCESSIBLE WITH A DILATATION CATHETER. 2. CORONARY ARTERY DISEASE OF THE NATIVE CORONARY ARTERIES AND/OR CORONARY ARTERY BYPASS GRAFTS OF SOME PATIENTS WHO HAVE PREVIOUSLY UNDERGONE CORONARY ARTERY BYPASS GRAFT SURGERY AND WHO HAVE RECURRENCE OF SYMPTOMS AND (A) PROGRESSION OF DISEASE OR (B) STENOSIS AND CLOSURE OF THE GRAFTS.,ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC) BRAIDED COATED POLYGLACTIN 910 VIOLET STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE(SUPERCRYL)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS & MICRO SURGERY FOR VESSELS LESS THAN 2 MM DIAMETER, BUT NOT FOR CARDIOVASCULAR TISSUES.,NON-ABSORBABLE SURGICAL SUTURE U.S.P. MONOFILAMENT POLYPROPYLENE BLUE STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE WITH PLEDGETS (ADVALENE - WITH PLEDGETS)-ADVALENE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS, CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES.,STERILIZED SURGICAL SUTURE & MESH KIT(ADVAKIT -

	HERNIA KIT)-ADVAMESH: INTENDED FOR USE IN HERNIA REPAIR, CHEST WALL RECONSTRUCTION, TRAUMATIC OR SURGICAL WOUNDS AND OTHER FASCIAL SURGICAL INTERVENTION PROCEDURES REQUIRING REINFORCEMENT WITH A NON-ABSORBABLE SUPPORTIVE MATERIAL. ADVAMRYL: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN OPHTHALMIC SURGERY, MICRO-SURGERY, CARDIOVASCULAR & NEUROLOGICAL TISSUES. ADVACRYL: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS & MICRO-SURGERY FOR VESSELS LESS THAN 2 MM DIAMETER, BUT NOT FOR CARDIOVASCULAR TISSUES. ADVALENE: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS, CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES.,ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC) ANTIBACTERIAL WITH TRICLOSAN BRAIDED COATED POLYGLACTIN 910 VIOLET STERILIZED SURGICAL SUTURE WITH AND WITHOUT NEEDLE(ADVACRYL PLUS)-ADVACRYL PLUS ANTIBACTERIAL SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, EXCEPT FOR OPHTHALMIC, CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,NON-ABSORBABLE SURGICAL SUTURE U.S.P. MONOFILAMENT POLYAMIDE BLACK STERILISED SURGICAL NEEDLED SUTURE(SUPERLON)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC PROCEDURE., ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC) ANTIBACTERIAL WITH TRICLOSAN BRAIDED COATED POLYGLACTIN 910 UNDYED STERILIZED SURGICAL SUTURE WITH AND WITHOUT NEEDLE(ADVACRYL PLUS)-ADVACRYL PLUS ANTIBACTERIAL SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, EXCEPT FOR OPHTHALMIC, CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE U.S.P. CATGUT - CHROMIC STERILISED SURGICAL NEEDLED SUTURE(SUPERGUT)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES.,PTCA BALLOON CATHETER (NON COMPLIANT)(NC ADVA GLIDE (1ST BRAND NAME), NC CLEVER (2ND BRAND NAME))-THE CLINICAL DATA PRESENTLY AVAILABLE INDICATES THAT THE LUMINAL DIAMETER OF A CORONARY ARTERY AT THE SITE OF CERTAIN TYPES OF STENOTIC LESIONS CAN BE INCREASED BY BALLOON DILATATION AND THAT PTCA IS A SAFE AND EFFICACIOUS PROCEDURE FOR REDUCTION OF SOME FORMS OF

	ATHEROSCLEROTIC CORONARY ARTERY DISEASE (SEE INDICATIONS). INDICATIONS: PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CAN BE INDICATED BY THE PHYSICIAN IN PATIENTS WITH SIGNIFICANT CORONARY ARTERY DISEASE WHO ARE ACCEPTABLE CANDIDATES FOR CORONARY ARTERY BYPASS GRAFT SURGERY AND WHO MEET ONE OF THE FOLLOWING SELECTION CRITERIA: 1. ATHEROSCLEROTIC CORONARY ARTERY DISEASE THAT IS ACCESSIBLE WITH A DILATATION CATHETER. 2. CORONARY ARTERY DISEASE OF THE NATIVE CORONARY ARTERIES AND/OR CORONARY ARTERY BYPASS GRAFTS OF SOME PATIENTS WHO HAVE PREVIOUSLY UNDERGONE CORONARY ARTERY BYPASS GRAFT SURGERY AND WHO HAVE RECURRENCE OF SYMPTOMS AND (A) PROGRESSION OF DISEASE OR (B) STENOSIS AND CLOSURE OF THE GRAFTS.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) MONOFILAMENT POLYDIOXANONE VIOLET STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE (SUPERPD)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION INCLUDING USE IN OPHTHALMIC SURGERY AND PAEDIATRIC CARDIOVASCULAR TISSUE WHERE GROWTH IS EXPECTED TO OCCUR BUT NOT FOR USE IN ADULT CARDIOVASCULAR TISSUES, PERIPHERAL NERVE ANASTOMOSIS & MICRO SURGERY.,PTCA BALLOON CATHETER (SEMI COMPLIANT) (ADVA ONE (1ST BRAND NAME), CONIC ONE (2ND BRAND NAME))-THE CLINICAL DATA PRESENTLY AVAILABLE INDICATES THAT THE LUMINAL DIAMETER OF A CORONARY ARTERY AT THE SITE OF CERTAIN TYPES OF STENOTIC LESIONS CAN BE INCREASED BY BALLOON DILATATION AND THAT PTCA IS A SAFE AND EFFICACIOUS PROCEDURE FOR REDUCTION OF SOME FORMS OF ATHEROSCLEROTIC CORONARY ARTERY DISEASE (SEE INDICATIONS). INDICATIONS: PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CAN BE INDICATED BY THE PHYSICIAN IN PATIENTS WITH SIGNIFICANT CORONARY ARTERY DISEASE WHO ARE ACCEPTABLE CANDIDATES FOR CORONARY ARTERY BYPASS GRAFT SURGERY AND WHO MEET ONE OF THE FOLLOWING SELECTION CRITERIA: 1. ATHEROSCLEROTIC CORONARY ARTERY DISEASE THAT IS ACCESSIBLE WITH A DILATATION CATHETER. 2. CORONARY ARTERY DISEASE OF THE NATIVE CORONARY ARTERIES AND/OR CORONARY ARTERY BYPASS GRAFTS OF SOME PATIENTS WHO HAVE PREVIOUSLY UNDERGONE CORONARY ARTERY BYPASS GRAFT SURGERY AND WHO HAVE RECURRENCE OF SYMPTOMS AND (A) PROGRESSION OF DISEASE OR (B) STENOSIS AND CLOSURE OF THE GRAFTS.,ABSORBABLE SURGICAL SUTURE U.S.P. CATGUT - PLAIN STERILISED SURGICAL NEEDLED SUTURE(SUPERGUT)-INDICATED FOR USE IN GENERAL

	SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES.,BONE WAX(ADVAWAX)-ADVAWAX IS INDICATED FOR USE IN THE CONTROL OF BLEEDING FROM BONE SURFACES.,NON-ABSORBABLE SURGICAL SUTURE U.S.P. BRAIDED SILK BLACK STERILISED SURGICAL SUTURE WITHOUT NEEDLE (SUPERSYL)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,NON-ABSORBABLE SURGICAL SUTURE U.S.P. BRAIDED COATED POLYESTER WHITE / GREEN STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE WITH PLEDGETS(ADVABOND - WITH PLEDGETS)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) BRAIDED COATED POLYGLACTIN 910 DYED / UNDYED STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE (SUPERCRYL RAPID)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO ITS ABSORPTION PROFILE RAPID SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PAEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. IT IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES.,STERILIZED SURGICAL SUTURE & MESH KIT(ADVAKIT - HERNIA KIT)-ADVAMESH: INTENDED FOR USE IN HERNIA REPAIR, CHEST WALL RECONSTRUCTION, TRAUMATIC OR SURGICAL WOUNDS AND OTHER FASCIAL SURGICAL INTERVENTION PROCEDURES REQUIRING REINFORCEMENT WITH A NON-ABSORBABLE SUPPORTIVE MATERIAL. ADVAMRYL: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN OPHTHALMIC SURGERY, MICRO SURGERY, CARDIOVASCULAR & NEUROLOGICAL TISSUES. ADVALENE: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS, CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES., ABSORBABLE SURGICAL SUTURE U.S.P. CATGUT - CHROMIC STERILISED SURGICAL SUTURE WITHOUT NEEDLE(SUPERGUT)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES., NON-ABSORBABLE STERILE SURGICAL POLYTETRAFLUOROETHYLENE PLEDGETS(ADVAPLEDGET)-ADVAPLEDGET IS INDICATED FOR USE IN CARDIOVASCULAR TISSUE. PLEDGETS ARE USED TO MECHANICALLY SECURE AND SUPPORT

	SUTURES IN FRAGILE TISSUE AND ORGAN PARENCHYMAS, WHEN A NON-ABSORBABLE SUTURE IS INDICATED. THESE ARE USED AS BUTTRESSES UNDER SUTURES WHEN THERE IS A POSSIBILITY OF SUTURES TEARING THROUGH THE TISSUE.,ABSORBABLE SURGICAL SUTURE U.S.P. CATGUT - PLAIN STERILISED SURGICAL SUTURE WITHOUT NEEDLE(SUPERGUT)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES.,NON ABSORBABLE SYNTHETIC MONOFILAMENT KNITTED POLYPROPYLENE UNDYED STERILISED SURGICAL MESH(ADVAMESH)-ADVAMESH IS INTENDED FOR USE IN HERNIA REPAIR, CHEST WALL RECONSTRUCTION, TRAUMATIC OR SURGICAL WOUNDS AND OTHER FASCIAL SURGICAL INTERVENTION PROCEDURES REQUIRING REINFORCEMENT WITH A NON-ABSORBABLE SUPPORTIVE MATERIAL.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25 VIOLET STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE (SUPERMRYL)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN OPHTHALMIC SURGERY, MICRO SURGERY, CARDIOVASCULAR & NEUROLOGICAL TISSUES.,STERILIZED SURGICAL SUTURE & MESH KIT (ADVAKIT - HERNIA KIT)-ADVAMESH: INTENDED FOR USE IN HERNIA REPAIR, CHEST WALL RECONSTRUCTION, TRAUMATIC OR SURGICAL WOUNDS AND OTHER FASCIAL SURGICAL INTERVENTION PROCEDURES REQUIRING REINFORCEMENT WITH A NON-ABSORBABLE SUPPORTIVE MATERIAL. ADVALENE: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS, CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES. ADVACRYL: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS & MICRO-SURGERY FOR VESSELS LESS THAN 2 MM DIAMETER, BUT NOT FOR CARDIOVASCULAR TISSUES. & ADVALON: INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC PROCEDURE.,NON-ABSORBABLE SURGICAL SUTURE U.S.P. MONOFILAMENT POLYPROPYLENE BLUE STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE (SUPERLENE)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS, CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES.,NON-ABSORBABLE SURGICAL SUTURE U.S.P. BRAIDED SILK BLACK STERILISED SURGICAL NEEDLED SUTURE(SUPERSYL)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR

	LIGATION INCLUDING USE IN OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25 UNDYED STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE(SUPERMRYL)- INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN OPHTHALMIC SURGERY, MICRO SURGERY, CARDIOVASCULAR & NEUROLOGICAL TISSUES.

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3311	MFG/MD/2019/000174	1.License Holder Name: ADVANCED MEDTECH SOLUTIONS PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:NON-ABSORBABLE SURGICAL SUTURE U.S.P. MONOFILAMENT STAINLESS STEEL 316 LVM STERILIZED SURGICAL SUTURE WITH AND WITHOUT NEEDLE (ADVASTEEL)-ADVASTEEL STAINLESS STEEL SUTURES ARE INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, INTESTINAL ANASTOMOSIS, HERNIA REPAIR, STERNAL CLOSURE AND FOR CERTAIN ORTHOPAEDIC PROCEDURES INCLUDING CERCLAGE OR TENDON REPAIR.,NON-ABSORBABLE SURGICAL SUTURE U.S.P. BRAIDED SILK BLACK STERILISED SURGICAL NEEDLED SUTURE (ADVASYL)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,NON-ABSORBABLE SURGICAL SUTURE U.S.P. BRAIDED SILK BLACK STERILISED SURGICAL SUTURE WITHOUT NEEDLE(ADVASYL)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC) BRAIDED COATED POLYGLACTIN 910 VIOLET STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE(ADVACRYL)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS & MICRO SURGERY FOR VESSELS LESS THAN 2 MM DIAMETER, BUT NOT FOR CARDIOVASCULAR TISSUES.,NON-ABSORBABLE SURGICAL SUTURE U.S.P. MONOFILAMENT POLYPROPYLENE BLUE STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE(ADVALENE)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS, CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES.,ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC) BRAIDED COATED POLYGLACTIN 910 UNDYED STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE(ADVACRYL)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS & MICRO SURGERY FOR VESSELS LESS THAN 2 MM DIAMETER, BUT NOT FOR CARDIOVASCULAR TISSUES.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25 UNDYED STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE (ADVAMRYL)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN OPHTHALMIC SURGERY, MICRO SURGERY, CARDIOVASCULAR & NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE U.S.P.

	CATGUT - CHROMIC STERILISED SURGICAL SUTURE WITHOUT NEEDLE(1. ADVACAT & 2. QUALGUT)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25 VIOLET STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE (ADVAMRYL)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN OPHTHALMIC SURGERY, MICRO SURGERY, CARDIOVASCULAR & NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE U.S.P. CATGUT - PLAIN STERILISED SURGICAL SUTURE WITHOUT NEEDLE(1. ADVACAT & 2. QUALGUT)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES.,ABSORBABLE SURGICAL SUTURE U.S.P. CATGUT - PLAIN STERILISED SURGICAL NEEDLED SUTURE(1. ADVACAT & 2. QUALGUT)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES.,NON-ABSORBABLE SURGICAL SUTURE U.S.P. BRAIDED COATED POLYESTER WHITE / GREEN STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE(ADVABOND)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,NON-ABSORBABLE SURGICAL SUTURE U.S.P. MONOFILAMENT POLYAMIDE BLACK STERILISED SURGICAL SUTURE WITHOUT NEEDLE(ADVALON)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC PROCEDURE., ABSORBABLE SURGICAL SUTURE (SYNTHETIC) BRAIDED COATED POLYGLACTIN 910 DYED / UNDYED STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE(ADVACRYL RAPID)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO ITS ABSORPTION PROFILE RAPID SUTURE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PAEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. IT IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES.,ABSORBABLE SURGICAL SUTURE U.S.P. CATGUT - CHROMIC STERILISED SURGICAL NEEDLED SUTURE(1. ADVACAT & 2. QUALGUT)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) MONOFILAMENT POLYDIOXANONE VIOLET STERILISED SURGICAL SUTURE WITH & WITHOUT NEEDLE(ADVAPD)-INDICATED

	FOR USE IN GENERAL SOFT TISSUE APPROXIMATION INCLUDING USE IN OPHTHALMIC SURGERY AND PAEDIATRIC CARDIOVASCULAR TISSUE WHERE GROWTH IS EXPECTED TO OCCUR BUT NOT FOR USE IN ADULT CARDIOVASCULAR TISSUES, PERIPHERAL NERVE ANASTOMOSIS & MICRO SURGERY.,NON-ABSORBABLE SURGICAL SUTURE U.S.P. MONOFILAMENT POLYAMIDE BLACK STERILISED SURGICAL NEEDLED SUTURE(ADVALON)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC PROCEDURE.

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3312	MFG/MD/2019/000175	1.License Holder Name: VITROMED HEALTHCARE 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:HAEMODIALYSIS CATHETER (BLOOD LINE)(BLOOD LINE SET)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT,UMBILICAL ARTERY CATHETER (UMBILICAL CATHETER)(UMBILICAL CATHETER)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS.,NEBULIZER MASK(-)-IT IS USED FOR THE DEEP MEDICATION INTO THE LUNGS WHEN PATIENT IS SUFFERING FROM ASTHMA OR OTHER LUNGS RELATED PROBLEMS AND DRUG DELIVERY DEVICE USED TO ADMINISTER MEDICATION IN THE FORM OF A MIST INHALED INTO THE LUNGS.,UMBILICAL CORD CLAMP (UMBILICAL OCCLUSION DEVICE)(VASO CLAMP (UMBILICAL CORD CLAMP))-UMBILICAL CORD CLAMP IS A STERILE OCCLUSION DEVICE (CLIP) DESIGN TO COMPRESS THE UMBILICAL CORD. THE DEVICE IS USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEW BORN INFANTS.,INFUSION SETS FOR SINGLE USE, GRAVITY FEED [IS 12655-4] [ISO 8536-4](P & Q INFUSION SET WITH /WITHOUT AIR-VENT)-INFUSION SET IS USED ADMINISTER I.V. FLUIDS AND DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,FEEDING TUBE (INFANT FEEDING TUBE) (INFANT FEEDING TUBE)-INFANT FEEDING TUBE IS USED TO PROVIDE FEEDING TO NEONATES AND INFANTS. IT IS A SMALL, SOFT, PLASTIC TUBE PLACED THROUGH THE NOSE OR MOUTH INTO THE STOMACH., OXYGEN CATHETERS(OXYGEN CATHETERS)-OXYGEN CATHETER IS USED FOR ADMINISTRATION OF OXYGEN THROUGH THE NASO PHARYNX FOR RESPIRATION IN PATIENTS IN NEED OF RESPIRATORY HELP.,STERILE SINGLE USE INTRAVASCULAR CATHETERS (ISO 10555-1 & 5) SAFETY I.V CANNULA WITH DEHP FREE EXTENSION TUBE AND WING(SAFETY I.V CANNULA WITH DEHP FREE EXTENSION TUBE AND WING (CLOSED SYSTEM IV CATHETER WITH WING)))-SAFETY I.V CANNULA WITH PU EXTENSION TUBE AND WING WITH SAFETY FEATURE USE INJECTION FOR ADMINISTRATION OF INTRAVENOUS FLUID , WITHDRAWAL OF BLOOD SAMPLES AND TO DELIVER INTRAVENOUS FLUID AND MEDICINE INTO HUMAN CIRCULATING SYSTEM , THE PRODUCT HAS INTEGRATED PASSIVE SAFETY FEATURE TO COVER THE NEEDLE AFTER USE TO PREVENT THE ACCIDENTAL NEEDLE PRICK INJURIES .,FEMALE URETHRAL CATHETER(FEMALE CATHETER)-FEMALE CATHETER IS USED TO PROVIDE ACCESS TO THE BLADDER THROUGH URETHRA IN CASE OF URINARY RETENTION IN

	FEMALES. THE FEMALE CATHETER HAS NO BALLOON ON ITS TIP AND IS FOR SHORT TERM USE.,ESOPHAGEAL OBTURATOR (GUEDEL AIRWAYS) (GUEDEL AIRWAYS)-THE PRODUCT IS USED TO MAINTAIN AN UNOBSTRUCTED OROPHARYNGEAL AIRWAY AND IT PREVENTS BITING OF TONGUE AND AIRWAY OCCLUSION,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] (I. V. CANNULA WITHOUT INJECTION PORT & WITH SMALL WINGS)(VITROPEDIA)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,FEEDING BAG(FEEDING BAG)-THE FEEDING BAG IS USED FOR CONVIENT FEEDING OF NUTRITION THROUGH NASOGASTRIC TUBE TO THE PATIENT.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I. V. CANNULA WITH INJECTION PORT, SNAP FIT CAP & SUTURABLE WINGS(VITROFLEX (I. V. CANNULA WITH INJECTION PORT, SNAP FIT CAP & SUTURABLE WINGS))-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., YANKAUR SUCTION SET (YANKAUR HANDLE)(YANKAUR HANDLE (STANDARD / CROWN TIP))-YANKAUR SUCTION SET (YANKAUR HANDLE) IS A SURGICAL DRAIN, USED TO REMOVE PUS, BLOOD OR OTHERS FLUID FROM WOUND. IT IS COMMONLY PLACED BY SURGEONS AND USED FOR PRE/ POST OPERATIVE REMOVAL OF SECRETION, BLOOD AND POSTOPERATIVE FLUID AFTER SURGERY., THORACIC DRAINAGE CATHETER (STRAIGHT / CURVED; WITH AND WITHOUT TROCAR)(THORACIC DRAINAGE CATHETER (STRAIGHT / CURVED; WITH AND WITHOUT TROCAR))-THORACIC DRAINAGE CATHETER IS A SURGICAL DRAIN USED FOR POST OPERATIVE DRAINAGE AFTER CARDIO-THORACIC AND THORACIC SURGERY; IN ORDER TO REMOVE BLOOD, SECRETIONS AND AIR WHICH ACCUMULATE IN THE THORAX GENERATING ACUTE CARDIO RESPIRATORY INSUFFICIENCY AND SOMETIMES EVEN DEATH., MULTIPLE LUMEN CATHETER (CVP MANOMETER)(CVP MANOMETER) -IT IS USED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTIONS OR DRUGS.,INFUSION SET FOR SINGLE USE (MICRO INFUSION SET) [IS 12655-4] [ISO 8536-4](MICRO INFUSION SET WITH / WITHOUT AIR-VENT)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,MUCUS EXTRACTOR (TRACHEOBRONCHIAL SUCTION CATHETER)(EUROMIX EXTRACTOR DE MUCUS)-MUCUS EXTRACTOR IS USED FOR ASPIRATION OF

	SECRETION FROM ORO-PHARYNX ENSURING FREE RESPIRATION AND CONVENIENT FOR SAFE TRANSPORT OF ASPIRATE FOR EXAMINATION. IT CLEARS THE AIRWAYS OF MUCUS AND ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION., YANKAUR SUCTION SET(YANKAUR SUCTION SET)-"YANKAUR SUCTION SET IS A SURGICAL DRAIN TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. IT IS COMMONLY PLACED BY SURGEONS AND USED FOR PRE/POST OPERATIVE REMOVAL OF SECRETION, BLOOD & POSTOPERATIVE FLUIDS AFTER SURGERY. ", YANKAUR SUCTION SET (SUCTION TUBE)(SUCTION TUBE (FOR WASTE FLUID))-YANKAUR SUCTION SET (SUCTION TUBE) IS A SURGICAL DRAIN, USED TO REMOVE PUS, BLOOD OR OTHERS FLUID FROM WOUND. IT IS COMMONLY PLACED BY SURGEONS AND USED FOR PRE/ POST OPERATIVE REMOVAL OF SECRETION, BLOOD AND POSTOPERATIVE FLUID AFTER SURGERY.,MUCUS EXTRACTOR (TRACHEOBRONCHIAL SUCTION CATHETER)(MUCUS EXTRACTOR)-"MUCUS EXTRACTOR IS USED FOR ASPIRATION OF SECRETION FROM OROPHARYNX ENSURING FREE RESPIRATION AND CONVENIENT FOR SAFE TRANSPORT OF ASPIRATE FOR EXAMINATION. " IT CLEARS THE AIRWAYS OF MUCUS AND ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILLATION.,UMBILICAL CORD CLAMP (UMBILICAL OCCLUSION DEVICE)(EUROMIX CLAMP UMBILICAL)-UMBILICAL CORD CLAMP IS A STERILE OCCLUSION DEVICE (CLIP) DESIGN TO COMPRESS THE UMBILICAL CORD. THE DEVICE IS USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEW BORN INFANTS.,THREE WAY STOP- COCKS (AS AN ACCESSORY OF PERFUSION SETS)(VITROWAY THREEWAY STOP COCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,DIALYSATE TUBING AND CONNECTOR (PERITONEAL DIALYSIS TRANSFUSION SET) (PERITONEAL DIALYSIS TRANSFUSION SET)-A TUBING CONNECTOR ADAPTED FOR PERITONEAL DIALYSIS CONNECTIONS BETWEEN TUBING SETS AND CONTAINERS OF DIALYSATE. THE DEVICE IS USED TO ALLOW SOLUTION TO FLOW INTO AND OUT OF THE PERITONEAL CAVITY. WHEN THE DIALYSIS SOLUTION IS IN THE PERITONEAL CAVITY, IT WILL REMOVE EXTRA FLUID AND WASTE PRODUCTS FROM THE BODY. PERITONEAL DIALYSIS WILL REPLACE THE LIFE SUSTAINING FUNCTION OF YOUR KIDNEYS THAT ARE NO LONGER WORKING. IN THIS METHOD BLOOD IS PURIFIED USING THE ARTIFICIAL KIDNEY APPARATUS VIA FILTRATION THROUGH AN ARTIFICIAL SEMI PERMEABLE MEMBRANE,TRANSFUSION SETS FOR SINGLE USE [IS 9824] [ENISO 1135-4](TRANSFUSION SETS WITH OR WITHOUT AIR VENT)-"TRANSFUSION SET IS USED ADMINISTER

	BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ",REDON DRAINAGE TUBE WITH TROCAR(REDON DRAINAGE TUBE WITH TROCAR)-IT IS A SURGICAL DRAIN USE TO PROVIDE CONNECTION A DRAINAGE BAG TO DRAIN SECRETION , BLOOD AND PUS FROM WOUNDS AFTER SURGERY.,I.V. FLOW REGULATOR (AS AN ACCESSORY OF INFUSION SET)(FLOW REGULATOR)-AN I V SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. ", CONTINUOUS IRRIGATION CATHETER(IRRIGATION SET ONE WAY / TWO WAY / FOUR WAY)-IRRIGATION SET USED TO INTRODUCE FLUID INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUID$ FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS.,INFUSION SET FOR SINGLE USE WITH FLOW REGULATOR(IV SET WITH FLOW REGULATOR WITH/ WITHOUT AIR VENT AND WITH/WITHOUT MIRODRIP)-"AN I V SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. ",THREEWAY STOP COCK WITH EXTENSION LINE AS AN ACCESSORIES OF IV CANNULA / CATHETER / PERFUSION SET(THREEWAY STOP COCK WITH EXTENSION LINE AS AN ACCESSORIES OF IV CANNULA / CATHETER / PERFUSION SET)-THREEWAY STOP COCK WITH EXTENSION LINE AS AN ACCESSORIES OF IV CANNULA / CATHETER / PERFUSION SET. THE THREEWAY STOP COCK WITH EXTENSION LINE IS DESIGNED TO PROVIDE EXCESS INFUSION OF FLUID / MEDICATION IN THE MEDICAL APPLICATION . THREEWAY IS A INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL.,EXTENSION LINE AS AN ACCESSORY OF INFUSION SET [ISO 8536-9](EXTENSION LINE AS AN ACCESSORY OF INFUSION SET)-THESE ARE STERILE SINGLE USE DEVICES INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION. CAN BE USED TO CONNECT A PERFUSION SET OR CATHETER FOR INFUSION. USED TO CONNECT THE INFUSION SITE AND THE SOURCE OF INFUSION (I.E. TO CONNECT THE IV CANNULA OR THREE WAY STOP COCK AND IV SET) TO EXTENDED THE PATH BETWEEN INFUSION SITE & SOURCE OF INFUSION.,FLOW REGULATOR AS A ACCESSORIES OF INFUSION SET (I V FLOW REGULATOR) (FLOW REGULATOR AS A ACCESSORIES OF INFUSION SET)-FLOW REGULATOR IS USED TO DELIVER ACCURATE VOLUME OF IV FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM. AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I V CANNULA WITH WINGS WITHOUT INJECTION PORT(VITROCAN)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO

	FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES, INFUSION SETS FOR SINGLE USE (WITH AIRVENT) [IS 12655-4] [ISO 8536-4](ESKAMED INFUSION SET (WITH SAFETY DOUBLE DRIP CHAMBER))-INFUSION SET IS USED ADMINISTER FLUIDS /DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] SAFETY I. V. CANNULA WITH PTFE CATHETER AND INJECTION PORT(VITRO-SAFE)-SAFETY IV CANNULA IS USED TO PROVIDE ACCESS IN TO THE PERIPHERAL VASCULAR SYSTEM FOR THE ADMINISTRATION OF FLUIDS AND DRUGS AND FOR WITHDRAWAL OF BLOOD. THE PRODUCT HAS INTEGRATED PASSIVE SAFETY FEATURES TO COVER THE NEEDLE AFTER USE TO PREVENT THE ACCIDENTAL NEEDLE PRICK INJURIES.,LEVINS TUBE(LEVINS TUBE)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,A.V FISTULA NEEDLE(A.V FISTULA NEEDLE)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT.,SUCTION CATHETERS [ISO 8836](SUCTION CATHETERS)-SUCTION CATHETERS (FEATURING A PLAIN, TIP OR A THUMB CONTROL) IS USED TO PROVIDE ACCESS TO RESPIRATORY TRACT FOR SUCTIONING SECRETION WITH PRECISION AND MAXIMUM COMFORT TO THE PATIENT. ,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] (I. V. CANNULA WITHOUT PORT & WITHOUT WINGS)(VITROPEN)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INFUSION SET FOR SINGLE USE [IS 12655-4] [ISO 8536-4](I.V. INFUSION SET WITH / WITHOUT AIRVENT)-"INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.",INFUSION SET FOR SINGLE USE (BURETTE TYPE) [IS 12655-4] [ISO 8536-4&5](BURETTE SET (MEASURED VOLUME FLUID ADMINSTRATION SET))-INFUSION SET BURETTE TYPE IS USED ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] (I. V. CANNULA WITHOUT INJECTION PORT AND WINGS) (LABOR IMPORT CATHETER PARA INFUSA INTRAVENOSA)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] (I. V. CANNULA

	WITH WINGS AND INJECTION PORT)(P & Q DISPOSABLE IV CANNULA WITH WING AND INJECTION PORT)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] SAFETY I. V. CANNULA WITH INTEGRATED 3-WAY STOP COCK (VITROCATH-SAFE (SAFETY IV CANNULA WITH INTEGRATED THREE WAY STOP COCK))-SAFETY IV CANNULA IS USED TO PROVIDE ACCESS IN TO THE PERIPHERAL VASCULAR SYSTEM FOR THE ADMINISTRATION OF FLUIDS AND DRUGS AND FOR WITHDRAWAL OF BLOOD. THE PRODUCT HAS INTEGRATED PASSIVE SAFETY FEATURES TO COVER THE NEEDLE AFTER USE TO PREVENT THE ACCIDENTAL NEEDLE PRICK INJURIES.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] SAFETY I. V. CANNULA, WITHOUT PORT WITHOUT WINGS(VITROWIN-SAFE (SAFETY IV CANNULA WITHOUT PORT ,WITHOUT WINGS))-SAFETY IV CANNULA IS USED TO PROVIDE ACCESS IN TO THE PERIPHERAL VASCULAR SYSTEM FOR THE ADMINISTRATION OF FLUIDS AND DRUGS AND FOR WITHDRAWAL OF BLOOD. THE PRODUCT HAS INTEGRATED PASSIVE SAFETY FEATURES TO COVER THE NEEDLE AFTER USE TO PREVENT THE ACCIDENTAL NEEDLE PRICK INJURIES.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I. V. CANNULA WITHOUT INJECTION PORT & WINGS(VITROON)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I. V. CANNULA WITHOUT INJECTION PORT & WITH SMALL WINGS(VITRONEO)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I V CANNULA WITH INTEGRATED THREE WAY STOP COCK (VITROCATH)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., CLOSED WOUND DRAINAGE SET(VITROVAC (CLOSED WOUND SUCTION UNIT))-IT IS SURGICAL DRAIN USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. CLOSED WOUND SUCTION UNIT IS USED IN SURGICAL SPECIALTIES MANY OF WHICH EMPLOY NEGATIVE PRESSURE WOUND THERAPY TO VARYING DEGREES

	AGAINST CHALLENGING WOUNDS.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] SAFETY I. V. CANNULA WITH WINGS, WITHOUT PORT(VITROCAN-SAFE (SAFETY IV CANNULA WITH WINGS WITHOUT PORT))-SAFETY IV CANNULA IS USED TO PROVIDE ACCESS IN TO THE PERIPHERAL VASCULAR SYSTEM FOR THE ADMINISTRATION OF FLUIDS AND DRUGS AND FOR WITHDRAWAL OF BLOOD. THE PRODUCT HAS INTEGRATED PASSIVE SAFETY FEATURES TO COVER THE NEEDLE AFTER USE TO PREVENT THE ACCIDENTAL NEEDLE PRICK INJURIES.,TRANSFUSION SETS FOR SINGLE USE [IS 9824-3] [ISO 1135-4](P & Q BLOOD TRANSFUSION SET WITH/WITHOUT AIR-VENT)-TRANSFUSION SET IS USED ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,REDON DRAINAGE TUBE(REDON DRAINAGE TUBE)-IT IS A SURGICAL DRAIN USED TO PROVIDE CONNECTION TO A DRAINAGE BAG TO DRAIN SECRETIONS, BLOOD AND PUS FROM WOUNDS AFTER SURGERY.,RECTAL CATHETERS (RECTAL CATHETERS)-RECTAL CATHETER IS USED FOR INSERTING INTO THE RECTUM IN ORDER TO RELIEVE FLATULENCE UNRESPONSIVE TO ACTIVITY OR MEDICATIONS AND ALSO TO DISCHARGE THE WASTE.,NASAL OXYGEN CANNULA / CATHETER (NASAL OXYGEN CANNULA /CATHETER)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,UNDER WATER SEAL DRAINAGE BOTTLE(UNDER WATER SEAL DRAINAGE BOTTLE)-UNDER WATER SEAL DRAINAGE SYSTEM (BAG / BOTTLE) IS A SURGICAL DRAIN USED FOR COLLECTION OF DRAINAGE FLUID FROM THORACIC CAVITY. IT IS SUITABLE FOR PLEURAL DRAINAGE IN CONJUNCTION WITH CHEST DRAINAGE CATHETERS IN CARDIO-THORACIC PROCEDURES. THE PRODUCT IS USED BY MEDICALLY TRAINED PERSONNEL WATER SEAL DRAINAGE SYSTEM IS A CLOSED CHEST DRAINAGE SYSTEM USED TO ALLOW AIR AND FLUID TO ESCAPE FROM THE PLURAL SPACE WITH EACH EXHALATION AND TO PREVENT THEIR RETURN FLOW WITH EACH INHALATION. WATER SEAL MEANS THAT THE WATER IN THE BOTTLE SEALS OFF THE ATMOSPHERIC AIR THUS PREVENTS THE ENTERING OF AIR OR FLUID BACK INTO THE PLEURAL SPACE ",FOLEY CATHETER(FOLEY BALLOON CATHETER)-A LONG, SMALL GAUGE STERILE CATHETER USED FOR INSERTION INTO THE BLADDER THROUGH URETHRA TO DRAIN URINE. IT IS HELD IN PLACE WITH A BALLOON AT THE END., TUR SET (TRANSURETHRAL RESECTION)(TUR SET)-TUR SET IS A CONTINUOUS IRRIGATION CATHETER USED FOR ENDOSCOPIC IRRIGATION DURING TRANS URETHRAL RESECTION OF PROSTATE GLAND. IT IS ALSO INDICATED FOR USE IN SUCH PROCEDURES AS CYSTOSCOPY AND TRANS URETHRAL-RESECTION AS A MEANS OF

	CONTINUOUS BLADDER IRRIGATION. ,STOMACH TUBE(STOMACH TUBE)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID.,UMBILICAL CORD CLAMP (UMBILICAL OCCLUSION DEVICE)(UMBILICAL CORD CLAMP)-UMBILICAL CORD CLAMP IS A STERILE OCCLUSIN DEVICE (CLIP) DESIGNED TO COMPRESS THE UMBILICAL CORD. THE DEVICE IS USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,PERITONEAL DIALYSIS SET(PERITONEAL DIALYSIS SET)-PERITONEAL DIALYSIS CATHETER KIT IS USED TO ALLOW DIALYSIS FLUID TO FLOW INTO AND OUT OF THE PERITONEAL CAVITY. IT HELPS TO REMOVE EXTRA FLUID AND WASTE PRODUCTS FROM THE BODY.,STERILE SINGLE USE SCALP VEIN INFUSION SET [IS 16097](SCALP VEIN SET)-SCALP VEIN SET IS INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD. ",IV SET FLOW REGULATOR (AS AN ACCESSORY OF INFUSION SET)(IV SET WITH/ WITHOUT AIR VENT AND WITH/WITHOUT MIRODRIP AND FLOW REGULATOR)-"AN I V SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. ",ENDOTRACHEAL TUBE (PLAIN & CUFFED) [IS / ISO 5361](ENDOTRACHEAL TUBE (PLAIN & CUFFED))-ENDOTRACHEAL TUBE IS A CATHETER THAT IS INSERTED INTO THE TRACHEA FOR THE PRIMARY PURPOSE OF ESTABLISHING AND MAINTAINING A PATENT AIRWAY AND TO ENSURE RESPIRATION IN PATIENTS CONNECTED WITH RESPIRATORY SYSTEM DURING OPERATION OR WHO LOOSE ACTIVE BREATH ABILITY. ,ABDOMINAL DRAINAGE SET(ABDOMINAL DRAINAGE SET)-IT IS A SURGICAL DRAIN USED TO DRAIN OUT AND COLLECT FLUID FROM A SPACE OF THE BODY. A CUT IS MADE IN THE SKIN AND THE CATHETER IS PASSED THROUGH INTO THE SPACE TO ALLOW THE FLUID TO FLOW OUT INTO COLLECTION BAG.,UNDER WATER SEAL DRAINAGE BAG(UNDER WATER SEAL DRAINAGE BAG)-UNDER WATER SEAL DRAINAGE SYSTEM IS A SURGICAL DRAIN USED FOR COLLECTION OF DRAINAGE FLUID FROM THORACIC CAVITY. IT IS SUITABLE FOR PLEURAL DRAINAGE IN CONJUNCTION WITH CHEST DRAINAGE CATHETERS IN CARDIO-THORACIC PROCEDURES. IT IS A CLOSED CHEST DRAINAGE SYSTEM USED TO ALLOW AIR AND FLUID TO ESCAPE FROM THE PLURAL SPACE WITH EACH EXHALATION AND TO PREVENT THEIR RETURN FLOW WITH EACH INHALATION.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 1055-1 AND 5] I V CANNULA WITH INJECTION PORT AND WING(VITROFLON)-"THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD /BLOOD COMPONENTS, OR FOR WITHDRAWL OF BLOOD SAMPLES OR

	TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES . ", INFANT FEEDING TUBE(INFANT FEEDING TUBE)-INFANT FEEDING TUBE IS USED TO PROVIDE FEEDING TO NEONATES AND INFANTS. IT IS A SMALL, SOFT, PLASTIC TUBE PLACED THROUGH THE NOSE OR MOUTH INTO THE STOMACH. ,TRANSFUSION SET FOR SINGLE USE [IS 9824 -3; ISO 1135-4](BLOOD ADMINISTRATION SET WITH / WITHOUT AIR-VENT)-"TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,RYLES TUBE (NASOGASTRIC TUBE)(RYLES TUBE)-IT IS A NASO-GASTRIC TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT MAY ALSO BE USED FOR ASPIRATION OF INTESTINAL SECRETIONS., TRACHEOSTOMY TUBE, PLAIN & CUFFED [IS / ISO 5366-1] (TRACHEOSTOMY TUBE PLAIN / CUFFED)-TRACHEOSTOMY TUBE IS A BREATHING TUBE INSERTED INTO THE TRACHEA (THROUGH A CUT IN THE NECK) TO RELIEVE AIRWAY OBSTRUCTION, FACILITATE MECHANICAL VENTILATION OR THE REMOVAL OF TRACHEAL SECRETIONS. ,HIGH PRESSURE VACUUM DRAINAGE BOTTLE(HIGH PRESSURE VACUUM DRAINAGE BOTTLE)-HIGH PRESSURE VACUUM DRAINAGE BOTTLE IS A SURGICAL DRAIN USED FOR COLLECTION OF FLUID FROM SURGICAL WOUND UNDER NEGATIVE PRESSURE THROUGH A COLLECTION TUBE AND COLLECTION DEVICE (BOTTLE). THE VACUUM GUARANTEES AN EFFICIENT AND CONSTANT EVACUATION OF EXUDATES WITHOUT RISK OF INTERNAL HEMORRHAGING. ",STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] SAFETY I. V. CANNULA WITH SNAP FIT CAP, SUTURABLE WINGS(VITRO-SAFE (SAFETY IV CANNULA WITH SNAPFIT CAP WINGS SUTURABLE WINGS))-SAFETY IV CANNULA IS USED TO PROVIDE ACCESS IN TO THE PERIPHERAL VASCULAR SYSTEM FOR THE ADMINISTRATION OF FLUIDS AND DRUGS AND FOR WITHDRAWAL OF BLOOD. THE PRODUCT HAS INTEGRATED PASSIVE SAFETY FEATURES TO COVER THE NEEDLE AFTER USE TO PREVENT THE ACCIDENTAL NEEDLE PRICK INJURIES.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] SAFETY I. V. CANNULA, WITHOUT PORT AND WINGS(VITROPEN-SAFE (SAFETY IV CANNULA WITHOUT PORT & WINGS))-SAFETY IV CANNULA IS USED TO PROVIDE ACCESS IN TO THE PERIPHERAL VASCULAR SYSTEM FOR THE ADMINISTRATION OF FLUIDS AND DRUGS AND FOR WITHDRAWAL OF BLOOD. THE PRODUCT HAS INTEGRATED PASSIVE SAFETY FEATURES TO COVER THE NEEDLE AFTER USE TO PREVENT THE ACCIDENTAL NEEDLE PRICK INJURIES.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I. V. CANNULA WITHOUT INJECTION PORT &WINGS(VITROWIN)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR

		BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,NELATON CATHETERS (URETHRAL)(NELATON CATHETERS) -NELATON CATHETER IS USED TO PROVIDE ACCESS TO THE BLADDER THROUGH URETHRA IN CASE OF URINARY RETENTION ESPECIALLY IN MALES. THE NELATON CATHETER HAS NO BALLOON ON ITS TIP.
3313	MFG/MD/2019/000176	1.License Holder Name: FOCUZ INTERNATIONAL 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:NON ALCOHOL ANTISPTIC WIPES(NEO WIPES)-THESE READY TO USE WIPES ARE FOR RAPID DISINFECTION AND CLEANING OF MEDICAL DEVICE AND MEDICAL EQUIPMENT. NEOWIPES ARE WIDELY USED TO CLEAN THE MEDICAL DEVICE AND MEDICAL EQUIPMENT BEFORE THEY UNDERGO THE STERILIZATION PROCESS. THEY CAN ALSO BE USED FOR CLEANSING OF HUMAN AND/OR ANIMAL SKIN WHERE ALCOHOL IS INADVISABLE, MULTIBAND LIGATOR(FOCUZ BAND (TM UNDER PROCESS))-THE MULTIBAND LIGATOR IS USED VIA ENDOSCOPE TO LEGATE ESOPHAGEAL VARIES AT AND ABOVE THE GASTRO- ESOPHAGEAL JUNCTION. THE MULTIBAND LIGATOR IS SUPPLIED NON-STERILE AND IS INTENDED FOR SINGLE USE ONLY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3314	MFG/MD/2019/000177	1.License Holder Name: FOCUZ INTERNATIONAL 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STONE RETRIEVAL BALLOON(ASTEROID BALLOON)-STONE RETRIEVAL BALLOON ARE INDICATED FOR USE ENDOSCOPICALLY TO REMOVE STONES FROM THE BILIARY SYSTEM.,SCLEROTHERAPY NEEDLE-• SCLEROTHERAPY NEEDLE - PLUG NEEDLETM FOR ESOPHAGEAL VARICES INVOLVES INJECTING A STRONG AND IRRITATING SOLUTION (A SCLEROSANT) INTO THE VEINS AND/OR THE AREA BESIDE THE DISTENDED VEIN. SCLEROSANT INJECTED DIRECTLY INTO THE VEIN CAUSES BLOOD CLOTS TO FORM AND STOPS THE BLEEDING, WHILE SCLEROSANT INJECTED INTO THE AREA BESIDE THE DISTENDED VEIN STOPS THE BLEEDING BY THICKENING AND SWELLING THE VEIN TO COMPRESS THE BLOOD VESSEL. SCLEROTHERAPY NEEDLE PLUG NEEDLETM USED TO INJECT SCLEROSING AGENT IN AND AROUND THE BLEEDING ULCER. • IT CAN BE USED TO INJECT SCLEROSING AGENT IN THE BLEEDING ESOPHAGEAL AND GASTRIC VARICES AS WELL AS BLEEDING ULCER.,GUIDE WIRE-GUIDE WIRE IS INTENDED TO FACILITATE THE PLACEMENT BILIARY STENT (PTFE MATERIAL) IN OBSTRUCTING BILIARY SYSTEM VIA FLEXIBLE ENDOSCOPE AND PLACEMENT OF URETERIC STENT (PU AND PTFE MATERIAL) IN OBSTRUCTING URINARY SYSTEM VIA FLEXIBLE ENDOSCOPE.
3315	MFG/MD/2019/000178	1.License Holder Name: FUTURA SURGICARE PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:MONOFILAMENT KNITTED POLYPROPYLENE MESH STERILIZED(DOLPHIN MESH)-DOLPHIN MESH IS SUITABLE FOR USE IN GENERAL SOFT TISSUE SUPPORT. IT IS MAINLY USED IN HERNIA REPAIR.

3316	MFG/MD/2019/000179	1.License Holder Name: M/S GLOBAL MEDIKIT LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:EPIDURAL MINI PACK (ENDURE)-EPIDURAL ANAESTHESIA FOR FAST AND RELIABLE ANAESTHESIA DURING SURGERY. IF NECESSARY, ANAESTHESIA CAN BE EXTENDED AND PROLONGED DURING SURGERY. ANALGESIA IS POSSIBLE AT ANY TIME AFTER SURGERY,CENTRAL VENOUS CATHETER(AVAN, GLOCENT, MEDICENT, ACENT-1, ACENT-2, ACENT-3, CENTUM UNO, CENTUM DUO, CENTUM TRIO)-CENTRAL VENOUS CATHETER IS AN INTRAVASCULAR CATHETER, DESIGNED FOR INTRODUCTION INTO, OR WITHDRAWAL OF LIQUID FROM, THE CENTRAL VENOUS SYSTEM AND/OR FOR PRESSURE OR OTHER MEASUREMENTS,CENTRAL VENOUS CATHETER(ENDURE)-CATHETERISATION OF THE SUPERIOR VENA CAVA USING THE SELDINGER TECHNIQUE FOR LONG-TERM INFUSION THERAPY OR PARENTERAL NUTRITION, FOR ADMINISTRATION OF HIGHLY OSMOLAR OR VERY VEIN-IRRITATING SOLUTIONS, FOR CONTINUOUS OR INTERMITTENT MONITORING OF THE CENTRAL VENOUS PRESSURE, FOR BLOOD SAMPLING, OR WHEN PERIPHERAL VENOUS PUNCTURE IS NOT POSSIBLE IN STATE OF SHOCK, IN PATIENTS WITH INJURED EXTREMITIES OR NO DETECTABLE PERIPHERAL VEINS.,EPIDURAL KIT(ALEXPHARM, EPIDURAL MINI PACK)-SET FOR CONTINUOUS EPIDURAL ANAESTHESIA WITH TUOHY NEEDLE, EPIDURAL TUBING AND FLAT FILTER. THE DEVICE IS USED TO DELIVER ANESTHETIC OR PAIN KILLING DRUGS TO THE NERVES THAT CONVEY PAIN.,PERCUTANEOUS INTRODUCER SHEATH SET (FAVIA, INTRODUCER SET)-INTRODUCERS ARE INTENDED TO BE INSERTED PERCUTANEOUSLY INTO A VESSEL TO FACILITATE THE ENTIRE ENVIRONMENT PROCEDURE

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3317	MFG/MD/2019/000180	1.License Holder Name: SHREE HARI SURGICAL 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE SCREWS.(BONE SCREWS)-BONE SCREWS INTENDED FOR USE IN INTERNAL FIXATION OF BONES AFFECTED BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. SCREWS ALONG WITH PLATES, NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC, SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE OF SO MANY DIFFERENT TYPES E. G. (LOCKED SCREWS, LOCKING BOLTS ETC.).,BONE SCREWS..(BONE SCREWS)-BONE SCREWS INTENDED FOR USE IN INTERNAL FIXATION OF BONES AFFECTED BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. SCREWS ALONG WITH PLATES, NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC, SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE OF SO MANY DIFFERENT TYPES E. G. (LOCKED SCREWS, LOCKING BOLTS ETC.).,BONE PLATES...(BONE PLATES)-BONE PLATES INTENDED TO BE ATTACHED TO FRACTURED LONG BONE FRAGMENT WITH SCREW TO BRIDGE AND STABILIZE THE FRACTURE GAP, AND SHIELD THE SITE FROM STRESS AS THE BONE HEALS. IT MAY ALSO BE USED TO TEMPORARILY AUGMENT BONE FOLLOWING A LENGTHENING PROCEDURE, OR FOR ARTHRODESIS., BONE SCREWS...(BONE SCREWS)-BONE SCREWS INTENDED FOR USE IN INTERNAL FIXATION OF BONES AFFECTED BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. SCREWS ALONG WITH PLATES, NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC, SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE OF SO MANY DIFFERENT TYPES E.G. (LOCKED SCREWS, LOCKING BOLTS ETC.)., BONE PLATES.(BONE PLATES)-BONE PLATES INTENDED TO BE ATTACHED TO FRACTURED LONG BONE FRAGMENT WITH SCREW TO BRIDGE AND STABILIZE THE FRACTURE GAP, AND SHIELD THE SITE FROM STRESS AS THE BONE HEALS. IT MAY ALSO BE USED TO TEMPORARILY AUGMENT BONE FOLLOWING A LENGTHENING PROCEDURE, OR FOR ARTHRODESIS.,BONE PLATES..(BONE PLATES)-BONE PLATES INTENDED TO BE ATTACHED TO FRACTURED LONG BONE FRAGMENT WITH SCREW TO BRIDGE AND STABILIZE THE FRACTURE GAP, AND SHIELD THE SITE FROM STRESS AS THE BONE HEALS. IT MAY ALSO BE USED TO TEMPORARILY AUGMENT BONE FOLLOWING A LENGTHENING PROCEDURE, OR FOR ARTHRODESIS., BONE NAILS (INTRAMEDULLARY NAILS)..(BONE NAILS (INTRAMEDULLARY NAILS))-INDICATIONS FOR INTERLOCKING NAILS INCLUDE SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL-UNIONS; AND BONE LENGTHENING/SHORTENING. FEMORAL INTERLOCKING NAILS INCLUDE THE INDICATION FOR PROXIMAL, MIDDLE AND DISTAL

	THIRD FEMORAL SHAFT FRACTURES. TIBIAL INTERLOCKING NAILS ALSO INCLUDE THE SAME INDICATIONS FOR TIBIAL SHAFT FRACTURES. HUMERAL INTERLOCKING NAILS ARE INDICATED FOR HUMERAL SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL-UNIONS, PROXIMAL, MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES; HUMERUS RECONSTRUCTION, FOLLOWING TUMOR RESECTION AND GRAFTING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. R/U INTERLOCKING NAILS ARE INDICATED FOR RADIAL AND ULNAR SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; PROXIMAL MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES. INTERLOCKING RECONSTRUCTION NAILS ARE INDICATED FOR THE FOLLOWING: SUBTROCHANTERIC FRACTURES WITH LESSER TROCHANTERIC INVOLVEMENT; IPSILATERAL FEMORAL SHAFT/NECK FRACTURES; SEVERELY COMMINUTED SHAFT FRACTURES; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; BONE SHORTENING/LENGTHENING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. RETROGRADE NAILS ARE INDICATED FOR SHAFT FRACTURES INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; BONE LENGTHENING/SHORTENING; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; FRACTURES IN OSTEOPOROTIC BONE; SEVERELY COMMINUTED SHAFT FRACTURES; PATHOLOGIC FRACTURES, PSEUDOARTHROSIS, FAILED OSTEOSYNTHESIS; CLOSED SUPRACONDYLAR FRACTURES; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. ADDITIONAL INDICATIONS FOR RETROGRADE NAILS INCLUDE: SEVERELY COMMINUTED SUPRACONDYLAR FRACTURES WITH OR WITHOUT DIFFICULT INTRA-ARTICULAR EXTENSION, FRACTURES THAT REQUIRE OPENING THE KNEE JOINT TO STABILIZE THE FEMORAL CONDYLAR SEGMENT. K-NAIL IS INDICATED FOR TIBIA, FEMUR AND HUMREUS SHAFT FRACTURE. GAM NAIL IS INDICATED FOR SUBTROCHANTERIC FRACTURE. ELASTIC NAIL (FLEXIBLE NAIL) IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ENDER'S NAIL IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ANKLE ARTHODESIS NAIL IS INDICATED FOR FOOT AND ANKLE FRACTURE. D-IMSC LOCKED NAIL IS INDICATED FOR SUPRACONDYLAR FRACTURE. INTERLOCKING NAIL CAP, NAIL PLUG SAFETY STAR DRIVE (GAM NAIL CAP), INTERLOCKING GUIDE WIRE-SIMPLE AND INTERLOCKING GUIDE WIRE-OLIVE TIP (BALL TIP) ARE INDICATED

	FOR NAIL AND BONE FIXATION.,SPINAL IMPLANTS..(SPINAL IMPLANTS)-SPINAL IMPLANTS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THORACIC, LUMBAR, AND SACRAL SPINE: FRACTURE, DISLOCATION, FAILED PREVIOUS FUSION (PSEUDOARTHROSIS), SPINAL STENOSIS, DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, SPINAL DEFORMATIONS SUCH AS SCOLIOSIS OR KYPHOSIS AND LOSS OF STABILITY DUE TO TUMORS. SPINAL IMPLANTS ARE INTENDED TO BE USED AS A TEMPORARY CONSTRUCT THAT ASSISTS NORMAL HEALING AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES. THEY ARE INTENDED TO STABILIZE THE SPINAL OPERATIVE SITE DURING FUSION PROCEDURES AND SHOULD BE REMOVED AFTER FUSION. THE IMPLANET SPINE SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION OF THE THORACIC, LUMBAR AND/OR SACRAL SPINE. THE IMPLANET SPINE SYSTEM IS INTENDED FOR POSTERIOR, NON-CERVICAL PEDICLE AND NON-PEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, SPINAL DEFORMITIES (I.E., SCOLIOSIS, KYPHOSIS AND/OR LORDOSIS), TUMOR, PSEUDARTHROSIS, OR REVISION OF A FAILED FUSION ATTEMPT.,ARTHROSCOPY IMPLANTS...(ARTHROSCOPY IMPLANTS)-ARTHROSCOPY IMPLANTS ARE INTENDED FOR USE IN FIXATION OF SEMITENDINOUS AND/OR GRACILE TENDON GRAFTS. ACL/PCL SCREW IS INTENDED FOR USE IN ANTERIOR/POSTERIOR CRUCIATE LIGAMENT (ACL/PCL) RECONSTRUCTION PROCEDURES. ACL/PCL SCREW IS INDICATED FOR FIXATION OF BONE-PATELLAR TENDON- BONE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION, FIXATION OF THE SOFT TISSUE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION AND RECONSTRUCTION OF POSTERIOR CRUCIATE LIGAMENT (PCL). THE ARTHROSCOPE IS INTENDED TO BE USED AS AN ENDOSCOPE IN ARTHROSCOPIC PROCEDURES PERFORMED ON THE KNEE, SHOULDER, HIP, WRIST (CARPEL TUNNEL SYNDROME), TEMPORAL MANDIBULAR JOINT, ANKLE, ELBOW, AND FEET (PLANTAR FASCIA RELEASE) TO VIEW THE SURGICAL SITE.,

	ARTHROSCOPY IMPLANTS..(ARTHROSCOPY IMPLANTS)-ARTHROSCOPY IMPLANTS ARE INTENDED FOR USE IN FIXATION OF SEMITENDINOUS AND/OR GRACILE TENDON GRAFTS. ACL/PCL SCREW IS INTENDED FOR USE IN ANTERIOR/POSTERIOR CRUCIATE LIGAMENT (ACL/PCL) RECONSTRUCTION PROCEDURES. ACL/PCL SCREW IS INDICATED FOR FIXATION OF BONE-PATELLAR TENDON-BONE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION, FIXATION OF THE SOFT TISSUE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION AND RECONSTRUCTION OF POSTERIOR CRUCIATE LIGAMENT (PCL). THE ARTHROSCOPE IS INTENDED TO BE USED AS AN ENDOSCOPE IN ARTHROSCOPIC PROCEDURES PERFORMED ON THE KNEE, SHOULDER, HIP, WRIST (CARPEL TUNNEL SYNDROME), TEMPORAL MANDIBULAR JOINT, ANKLE, ELBOW, AND FEET (PLANTAR FASCIA RELEASE) TO VIEW THE SURGICAL SITE.,SPINAL IMPLANTS...(SPINAL IMPLANTS)-SPINAL IMPLANTS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THORACIC, LUMBAR, AND SACRAL SPINE: FRACTURE, DISLOCATION, FAILED PREVIOUS FUSION (PSEUDOARTHROSIS), SPINAL STENOSIS, DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, SPINAL DEFORMATIONS SUCH AS SCOLIOSIS OR KYPHOSIS AND LOSS OF STABILITY DUE TO TUMORS. SPINAL IMPLANTS ARE INTENDED TO BE USED AS A TEMPORARY CONSTRUCT THAT ASSISTS NORMAL HEALING AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES. THEY ARE INTENDED TO STABILIZE THE SPINAL OPERATIVE SITE DURING FUSION PROCEDURES AND SHOULD BE REMOVED AFTER FUSION. THE IMPLANET SPINE SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION OF THE THORACIC, LUMBAR AND/OR SACRAL SPINE. THE IMPLANET SPINE SYSTEM IS INTENDED FOR POSTERIOR, NON-CERVICAL PEDICLE AND NON-PEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, SPINAL DEFORMITIES (I.E., SCOLIOSIS, KYPHOSIS AND/OR LORDOSIS), TUMOR, PSEUDARTHROSIS, OR REVISION OF A FAILED FUSION ATTEMPT.,BONE NAILS (INTRAMEDULLARY NAILS)...(BONE

	NAILS (INTRAMEDULLARY NAILS))-INDICATIONS FOR INTERLOCKING NAILS INCLUDE SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL-UNIONS; AND BONE LENGTHENING/SHORTENING. FEMORAL INTERLOCKING NAILS INCLUDE THE INDICATION FOR PROXIMAL, MIDDLE AND DISTAL THIRD FEMORAL SHAFT FRACTURES. TIBIAL INTERLOCKING NAILS ALSO INCLUDE THE SAME INDICATIONS FOR TIBIAL SHAFT FRACTURES. HUMERAL INTERLOCKING NAILS ARE INDICATED FOR HUMERAL SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL-UNIONS, PROXIMAL, MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES; HUMERUS RECONSTRUCTION, FOLLOWING TUMOR RESECTION AND GRAFTING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. R/U INTERLOCKING NAILS ARE INDICATED FOR RADIAL AND ULNAR SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; PROXIMAL MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES. INTERLOCKING RECONSTRUCTION NAILS ARE INDICATED FOR THE FOLLOWING: SUBTROCHANTERIC FRACTURES WITH LESSER TROCHANTERIC INVOLVEMENT; IPSILATERAL FEMORAL SHAFT/NECK FRACTURES; SEVERELY COMMINUTED SHAFT FRACTURES; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; BONE SHORTENING/LENGTHENING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. RETROGRADE NAILS ARE INDICATED FOR SHAFT FRACTURES INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; BONE LENGTHENING/SHORTENING; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; FRACTURES IN OSTEOPOROTIC BONE; SEVERELY COMMINUTED SHAFT FRACTURES; PATHOLOGIC FRACTURES, PSEUDOARTHROSIS, FAILED OSTEOSYNTHESIS; CLOSED SUPRACONDYLAR FRACTURES; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. ADDITIONAL INDICATIONS FOR RETROGRADE NAILS INCLUDE: SEVERELY COMMINUTED SUPRACONDYLAR FRACTURES WITH OR WITHOUT DIFFICULT INTRA-ARTICULAR EXTENSION, FRACTURES THAT REQUIRE OPENING THE KNEE JOINT TO STABILIZE THE FEMORAL CONDYLAR SEGMENT. K-NAIL IS INDICATED FOR TIBIA, FEMUR AND HUMREUS SHAFT FRACTURE. GAM NAIL IS INDICATED FOR SUBTROCHANTERIC FRACTURE. ELASTIC NAIL (FLEXIBLE NAIL) IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ENDER'S NAIL IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ANKLE

	ARTHODESIS NAIL IS INDICATED FOR FOOT AND ANKLE FRACTURE. D-IMSC LOCKED NAIL IS INDICATED FOR SUPRACONDYLAR FRACTURE. INTERLOCKING NAIL CAP, NAIL PLUG SAFETY STAR DRIVE (GAM NAIL CAP), INTERLOCKING GUIDE WIRE-SIMPLE AND INTERLOCKING GUIDE WIRE-OLIVE TIP (BALL TIP) ARE INDICATED FOR NAIL AND BONE FIXATION.,BONE WIRES, PINS & STAPLES...(BONE WIRES, PINS & STAPLES)-INDICATIONS FOR PINS AND WIRES INCLUDE FIXATION OF BONE FRACTURES, BONE RECONSTRUCTIONS, AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS AND IMPLANTED THROUGH THE SKIN FOR TRACTION APPLIED TO THE SKELETAL SYSTEM. WIRES ARE USED IN THE FIXATION OF FRACTURES IN WHICH LOADING IS MINIMAL. WIRES ARE EASIER TO BEND, SO, ARE SUPPLEMENTED WITH OTHER IMMOBILIZATION DEVICES WHERE NECESSARY. PIN OR WIRE FIXATION IS MOSTLY USED FOR FRACTURES OF THE PHALANGES, METACARPALS, METATARSALS, PROXIMAL HUMERUS AND DISTAL HUMERUS. PINS ARE USED IN FIXATION OF FRACTURES WHERE MINIMAL BONE AND SOFT TISSUE DAMAGE ARE INVOLVED. PINS PROVIDE PROVISIONAL FIXATION LEAVING ROOM FOR ADDITIONAL HARDWARE PLACEMENT. THE PROVISIONAL FIXATION IS PLANNED TO AVOID FAULTY PERMANENT FIXATION. DEPENDING ON THE DIAMETER, PINS MAY ALSO BE USED AS GUIDEWIRES FOR CANNULATED SCREW FIXATION. STAPLES ARE USED FOR FRAGMENT FIXATION, WHERE INTER-FRAGMENTAL SCREW FIXATION IS DIFFICULT. THESE ARE AN EFFECTIVE INTERNAL FIXATION METHOD AND ARE WIDELY USED IN FOOT AND ANKLE SURGERY. THE STAPLES ARE ALSO USED IN FIXATION OF SOFT TISSUES TO BONE.,BONE WIRES, PINS & STAPLES. (BONE WIRES, PINS & STAPLES)-INDICATIONS FOR PINS AND WIRES INCLUDE FIXATION OF BONE FRACTURES, BONE RECONSTRUCTIONS, AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS AND IMPLANTED THROUGH THE SKIN FOR TRACTION APPLIED TO THE SKELETAL SYSTEM. WIRES ARE USED IN THE FIXATION OF FRACTURES IN WHICH LOADING IS MINIMAL. WIRES ARE EASIER TO BEND, SO, ARE SUPPLEMENTED WITH OTHER IMMOBILIZATION DEVICES WHERE NECESSARY. PIN OR WIRE FIXATION IS MOSTLY USED FOR FRACTURES OF THE PHALANGES, METACARPALS, METATARSALS, PROXIMAL HUMERUS AND DISTAL HUMERUS. PINS ARE USED IN FIXATION OF FRACTURES WHERE MINIMAL BONE AND SOFT TISSUE DAMAGE ARE INVOLVED. PINS PROVIDE PROVISIONAL FIXATION LEAVING ROOM FOR ADDITIONAL HARDWARE PLACEMENT. THE PROVISIONAL FIXATION IS PLANNED TO AVOID FAULTY PERMANENT FIXATION. DEPENDING ON THE DIAMETER, PINS MAY ALSO BE USED AS GUIDEWIRES FOR CANNULATED SCREW FIXATION. STAPLES ARE USED FOR FRAGMENT FIXATION, WHERE INTER-

	FRAGMENTAL SCREW FIXATION IS DIFFICULT. THESE ARE AN EFFECTIVE INTERNAL FIXATION METHOD AND ARE WIDELY USED IN FOOT AND ANKLE SURGERY. THE STAPLES ARE ALSO USED IN FIXATION OF SOFT TISSUES TO BONE. WIRES ARE USED IN THE FIXATION OF FRACTURES IN WHICH LOADING IS MINIMAL. WIRES ARE EASIER TO BEND, SO, ARE SUPPLEMENTED WITH OTHER IMMOBILIZATION DEVICES WHERE NECESSARY. PIN OR WIRE FIXATION IS MOSTLY USED FOR FRACTURES OF THE PHALANGES, METACARPALS, METATARSALS, PROXIMAL HUMERUS AND DISTAL HUMERUS. PINS ARE USED IN FIXATION OF FRACTURES WHERE MINIMAL BONE AND SOFT TISSUE DAMAGE ARE INVOLVED. PINS PROVIDE PROVISIONAL FIXATION LEAVING ROOM FOR ADDITIONAL HARDWARE PLACEMENT. THE PROVISIONAL FIXATION IS PLANNED TO AVOID FAULTY PERMANENT FIXATION. DEPENDING ON THE DIAMETER, PINS MAY ALSO BE USED AS GUIDEWIRES FOR CANNULATED SCREW FIXATION. STAPLES ARE USED FOR FRAGMENT FIXATION, WHERE INTER-FRAGMENTAL SCREW FIXATION IS DIFFICULT. THESE ARE AN EFFECTIVE INTERNAL FIXATION METHOD AND ARE WIDELY USED IN FOOT AND ANKLE SURGERY. THE STAPLES ARE ALSO USED IN FIXATION OF SOFT TISSUES TO BONE.,BONE NAILS (INTRAMEDULLARY NAILS)(BONE NAILS (INTRAMEDULLARY NAILS))- INDICATIONS FOR INTERLOCKING NAILS INCLUDE SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL-UNIONS; AND BONE LENGTHENING/SHORTENING. FEMORAL INTERLOCKING NAILS INCLUDE THE INDICATION FOR PROXIMAL, MIDDLE AND DISTAL THIRD FEMORAL SHAFT FRACTURES. TIBIAL INTERLOCKING NAILS ALSO INCLUDE THE SAME INDICATIONS FOR TIBIAL SHAFT FRACTURES. HUMERAL INTERLOCKING NAILS ARE INDICATED FOR HUMERAL SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL-UNIONS, PROXIMAL, MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES; HUMERUS RECONSTRUCTION, FOLLOWING TUMOR RESECTION AND GRAFTING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. R/U INTERLOCKING NAILS ARE INDICATED FOR RADIAL AND ULNAR SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; PROXIMAL MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES. INTERLOCKING RECONSTRUCTION NAILS ARE INDICATED FOR THE FOLLOWING: SUBTROCHANTERIC FRACTURES WITH LESSER TROCHANTERIC INVOLVEMENT; IPSILATERAL FEMORAL SHAFT/NECK FRACTURES; SEVERELY COMMINUTED SHAFT

	FRACTURES; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; BONE SHORTENING/LENGTHENING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. RETROGRADE NAILS ARE INDICATED FOR SHAFT FRACTURES INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; BONE LENGTHENING/SHORTENING; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; FRACTURES IN OSTEOPOROTIC BONE; SEVERELY COMMINUTED SHAFT FRACTURES; PATHOLOGIC FRACTURES, PSEUDOARTHROSIS, FAILED OSTEOSYNTHESIS; CLOSED SUPRACONDYLAR FRACTURES; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. ADDITIONAL INDICATIONS FOR RETROGRADE NAILS INCLUDE: SEVERELY COMMINUTED SUPRACONDYLAR FRACTURES WITH OR WITHOUT DIFFICULT INTRA-ARTICULAR EXTENSION, FRACTURES THAT REQUIRE OPENING THE KNEE JOINT TO STABILIZE THE FEMORAL CONDYLAR SEGMENT. K-NAIL IS INDICATED FOR TIBIA, FEMUR AND HUMREUS SHAFT FRACTURE. GAM NAIL IS INDICATED FOR SUBTROCHANTERIC FRACTURE. ELASTIC NAIL (FLEXIBLE NAIL) IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ENDER'S NAIL IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ANKLE ARTHODESIS NAIL IS INDICATED FOR FOOT AND ANKLE FRACTURE. D-IMSC LOCKED NAIL IS INDICATED FOR SUPRACONDYLAR FRACTURE. INTERLOCKING NAIL CAP, NAIL PLUG SAFETY STAR DRIVE (GAM NAIL CAP), INTERLOCKING GUIDE WIRE-SIMPLE AND INTERLOCKING GUIDE WIRE-OLIVE TIP (BALL TIP) ARE INDICATED FOR NAIL AND BONE FIXATION.,BONE WIRES, PINS & STAPLES..(BONE WIRES, PINS & STAPLES)-INDICATIONS FOR PINS AND WIRES INCLUDE FIXATION OF BONE FRACTURES, BONE RECONSTRUCTIONS, AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS AND IMPLANTED THROUGH THE SKIN FOR TRACTION APPLIED TO THE SKELETAL SYSTEM. WIRES ARE USED IN THE FIXATION OF FRACTURES IN WHICH LOADING IS MINIMAL. WIRES ARE EASIER TO BEND, SO, ARE SUPPLEMENTED WITH OTHER IMMOBILIZATION DEVICES WHERE NECESSARY. PIN OR WIRE FIXATION IS MOSTLY USED FOR FRACTURES OF THE PHALANGES, METACARPALS, METATARSALS, PROXIMAL HUMERUS AND DISTAL HUMERUS. PINS ARE USED IN FIXATION OF FRACTURES WHERE MINIMAL BONE AND SOFT TISSUE DAMAGE ARE INVOLVED. PINS PROVIDE PROVISIONAL FIXATION LEAVING ROOM FOR ADDITIONAL HARDWARE PLACEMENT. THE PROVISIONAL FIXATION IS PLANNED TO AVOID FAULTY PERMANENT FIXATION. DEPENDING ON THE DIAMETER, PINS MAY ALSO BE USED AS GUIDEWIRES FOR CANNULATED SCREW FIXATION. STAPLES ARE USED FOR FRAGMENT FIXATION, WHERE INTER-

	FRAGMENTAL SCREW FIXATION IS DIFFICULT. THESE ARE AN EFFECTIVE INTERNAL FIXATION METHOD AND ARE WIDELY USED IN FOOT AND ANKLE SURGERY. THE STAPLES ARE ALSO USED IN FIXATION OF SOFT TISSUES TO BONE.

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3318	MFG/MD/2019/000181	1.License Holder Name: GLOBAL ORTHOSYS 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATE(NIL)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. BONE PLATES ARE GENERALLY FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,SPINAL IMPLANT(NIL)-SPINAL IMPLANTS ARE USED IN THE SURGICAL PROCEDURES RELATED TO THE SPINAL INJURIES AND SPINAL DISEASES.,BONE PLATE(NIL)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. BONE PLATES ARE GENERALLY FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE WIRE AND PINS(NIL)-THE WIRES AND PINS ARE USED FOR TEMPORARY DEFINITIVE FIXATION IF THE FRACTURE FRAGMENTS ARE SMALL DURING SOME OPERATIONS. AFTER DEFINITIVE FIXATION THEY ARE THEN REMOVED.,BONE WIRE AND PINS(NIL)-THE WIRES AND PINS ARE USED FOR TEMPORARY DEFINITIVE FIXATION IF THE FRACTURE FRAGMENTS ARE SMALL DURING SOME OPERATIONS. AFTER DEFINITIVE FIXATION THEY ARE THEN REMOVED.,BONE SCREW(NIL)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. SCREWS ARE OF DIFFERENT TYPES E.G. CORTI CAL SCREWS, CANCELLOUS SCREWS, CANCELLOUS CANNULATED SCREWS, MALLEOLAR SCREWS, LOCKING BOLT, LAG (DHS/DCS) SCREWS, SHERMAN SCREWS, STEFFEE SCREWS, SHAFT SCREWS, PLUG SCREWS.,SPINAL IMPLANT(NIL)-SPINAL IMPLANTS ARE USED IN THE SURGICAL PROCEDURES RELATED TO THE SPINAL INJURIES AND SPINAL DISEASES.,BONE NAIL(NIL)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. NAILS ARE OF DIFFERENT TYPES WHICH USED IN TIBIA, FEMUR AND HUMOROUS BONES MAINLY.,BONE SCREW(NIL)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. SCREWS ARE OF DIFFERENT TYPES E.G. CORTI CAL SCREWS, CANCELLOUS SCREWS, CANCELLOUS CANNULATED SCREWS, MALLEOLAR SCREWS, LOCKING BOLT, LAG (DHS/DCS) SCREWS, SHERMAN SCREWS, STEFFEE SCREWS, SHAFT SCREWS, PLUG SCREWS.,BONE NAIL(NIL)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. NAILS ARE OF DIFFERENT TYPES WHICH USED IN TIBIA, FEMUR AND HUMOROUS BONES MAINLY.

3319	MFG/MD/2019/000182	1.License Holder Name: M/S MAGNAMED DEVICES 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:AV FISTULA NEEDLE(NIL)-AN AV FISTULA IS AN ABNORMAL CONNECTION OR PASSAGEWAY BETWEEN AN ARTERY AND A VEIN FOR HEMODIALYSIS TREATMENT
3320	MFG/MD/2019/000183	1.License Holder Name: AGROSURG IRRADIATORS INDIA PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:ALCOHOL SWABS-IT IS A SINGLE USE, STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE.
3321	MFG/MD/2019/000184	1.License Holder Name: PREGNA INTERNATIONAL LIMITED 2.Approving Authority: DAMAN AND DIU 3.Device Name(Brand Name)-Intended Use:CRYOTHERAPY DEVICE (CRYOPOP)-CRYOTHERAPY DEVICE IS USED FOR TREATMENT OF PRECANCEROUS CERVICAL LESIONS AND PREVENTATION OF CERVICAL CANCER.,DISPOSABLE UTERINE SOUND(ESA)-TO MEASURE DEPTH OF UTERUS.

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3322	MFG/MD/2019/000185	1.License Holder Name: SHRI RAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: NORTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:ABSORBENT LINT; SPECIFICATIONS: I.P. (NIL)-USEFUL FOR THE TOPICAL APPLICATION OF MEDICATION,HANDLOOM COTTON BANDAGE CLOTH/ROLLED BANDAGES; SPECIFICATIONS: SCHEDULE F-(II) AND IS:863(NIL)-USED TO HOLD DRESSINGS IN PLACE,DISPOSABLE DELIVERY KIT(NIL)-USED FOR CONDUCTING A CLEAN DELIVERY,HANDLOOM COTTON GAUZE ABSORBENT(SWAB); SPECIFICATIONS: SCHEDULE F-(II) AND IS:758(NIL)-USED FOR CLEANING, DRYING AND DRESSING WOUND$, TRIANGULAR BANDAGE; SPECIFICATIONS: MADE FROM BANDAGE CLOTH AS PER SCHEDULE F-(II), MADE FROM BANDAGE CLOTH AS PER IS:863, MADE FROM BANDAGE CLOTH AS PER B.P.C. 1963 AND AS PER JSS:6510-02(NIL)-USED FOR MAKING SLINGS,ABSORBENT COTTON RIBBON GAUZE; SPECIFICATIONS: MADE FROM GAUZE CLOTH AS PER SCHEDULE F-(II), MADE FROM GAUZE CLOTH AS PER IS:758, MADE FROM GAUZE CLOTH AS PER B.P.C. 1963 AND AS PER JSS:6510-01(NIL)-USED FOR CLEANING, DRYING AND DRESSING WOUNDS,COTTON CREPE BANDAGES / CREPE BANDAGE; SPECIFICATIONS: B.P. 88, B.P.C 1973 AND IS: 4605(NIL)-USED FOR DRESSING OF VARICOSE VEINS, WEAK ANKLES, LEGS AND KNEES AND WRISTS IN CASE OF SPRAINS AND OTHER CONDITIONS IN WHICH LIGHT SUPPORT IS REQUIRED,HANDLOOM COTTON CLOTH/CUT BANDAGE FOR PLASTER OF PARIS BANDAGE; SPECIFICATIONS: SCHEDULE F-(II)(NIL)-USED TO IMMOBILIZE JOINT OR LIMB FRACTURE,STARCH BANDAGE FOR P.O.P.; SPECIFICATIONS: IS:6237 (VARIETY NO. 1)(NIL)-USED TO IMMOBILIZE JOINT OR LIMB FRACTURE,ABDOMINAL SPONGE; SPECIFICATIONS: MADE FROM GAUZE CLOTH AS PER SCHEDULE F-(II), MADE FROM GAUZE CLOTH AS PER IS:758, MADE FROM GAUZE CLOTH AS PER B.P. AND AS PER JSS:6510-08(NIL)-USED FOR CLEANING, DRYING AND DRESSING WOUNDS,COMBINED DRESSING (X-RAY DETECTABLE ABSORBENT COTTON & VISCOSE GAUZE B.P.)(NIL)-USED AS SECONDARY DRESSING, PADDING OR PROTECTION FOR MAJOR WOUNDS., OPERATION THEATRE PACK (O.T. PACK)(NIL)-USED AT THE TIME OF SURGERY

3323	MFG/MD/2019/000186	1.License Holder Name: BHARTI TEXTILES 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:HANDLOOM COTTON BANDAGE CLOTH/ROLLED BANDAGES/OPEN WOVE BANDAGE/CUT BANDAGES; SPECIFICATIONS: SCHEDULE F-(II) AND IS:863(NIL)-USED TO HOLD DRESSINGS IN PLACE,HANDLOOM COTTON GAUZE ABSORBENT / UNMEDICATED GAUZE; SPECIFICATIONS: SCHEDULE F-(II) AND IS:758(NIL)-USED FOR CLEANING, DRYING AND DRESSING WOUNDS,HANDLOOM COTTON CLOTH / CUT BANDAGES FOR PLASTER OF PARIS BANDAGE; SPECIFICATIONS: SCHEDULE F-(II)(NIL) -USED TO IMMOBILIZE JOINT OR LIMB FRACTURE,TRIANGULAR BANDAGE; SPECIFICATIONS: MADE FROM BANDAGE CLOTH AS PER SCHEDULE F-(II), MADE FROM BANDAGE CLOTH AS PER IS:863, MADE FROM BANDAGE CLOTH AS PER B.P.C. 1963 AND AS PER JSS:6510-02 (NIL)-USED FOR MAKING SLINGS,ABDOMINAL SPONGE; SPECIFICATIONS: MADE FROM GAUZE CLOTH AS PER SCHEDULE F-(II), MADE FROM GAUZE CLOTH AS PER IS:758, MADE FROM GAUZE CLOTH AS PER B.P. AND AS PER JSS:6510-08(NIL)-USED FOR CLEANING, DRYING AND DRESSING WOUNDS,ABSORBENT COTTON RIBBON GAUZE; SPECIFICATIONS: MADE FROM GAUZE CLOTH AS PER SCHEDULE F-(II), MADE FROM GAUZE CLOTH AS PER IS:758, MADE FROM GAUZE CLOTH AS PER B.P.C. 1963 AND AS PER JSS:6510-01 (NIL)-USED FOR CLEANING, DRYING AND DRESSING WOUNDS,STARCH BANDAGE FOR P.O.P.; SPECIFICATIONS: IS:6237 (VARIETY NO. 1)(NIL)-USED TO IMMOBILIZE JOINT OR LIMB FRACTURE,COTTON CREPE BANDAGES / CREPE BANDAGE; SPECIFICATIONS: B.P. 88, B.P.C 1973 AND IS:4605(NIL)-USED FOR DRESSING OF VARICOSE VEINS, WEAK ANKLES, LEGS AND KNEES AND WRISTS IN CASE OF SPRAINS AND OTHER CONDITIONS IN WHICH LIGHT SUPPORT IS REQUIRED, COMBINED DRESSING (X RAY DETECTABLE ABSORBENT COTTON & VISCOSE GAUZE B.P.)(NIL)-USED AS SECONDARY DRESSING, PADDING OR PROTECTION FOR MAJOR WOUNDS.,ABSORBENT LINT; SPECIFICATIONS: I.P.(NIL)-USEFUL FOR THE TOPICAL APPLICATION OF MEDICATION

3324	MFG/MD/2019/000187	1.License Holder Name: AEGIS LIFESCIENCES PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ABSORBABLE GELATIN SPONGE(SURGISPON®, MEDISPONGE, UNISPONGE, BLOXANG, GEL-SPONGE, HEMOGEL, HEMOSPONGE, PERISPONGE, SURGIGEL, TOP DENT DENTOSTAN, EVOSPON, CLINIX, HYGITECH, R&S, KENTDENTAL, OCTOCOLOGEN, TOPISPON, SURGISENZ, MVG, SCHMIDT, ILION DENTAL, GELASPON, KDM, PROCLINIC, BESTDENT, STELLIGEL, BIOSPONGE, FLOSPONG, SMI-SPON, MEDISPON, CLINISPON, I-SPONGE, MERIFEIM, DSI SPONGE, CHIRUSPONGE, MERIFOAM, IDSPONGE, DENTOSPON, KARESPON, HEMOSPON, ALPHA-SPON)-ABSORBABLE HAEMOSTATIC GELATIN SPONGE CAN BE EFFECTIVELY USED IN VARIOUS SURGERIES FOR HAEMOSTASIS, WHEN CONTROL OF CAPILLARY, VENOUS AND ARTERIOLAR BLEEDING BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS INEFFECTIVE OR IMPRACTICAL.,ABSORBABLE GELATIN SPONGE WITH COLLOIDAL SILVER(DENTOSPON)-THE SPONGE IS USED IN THE TREATMENT OF ALVEOLI AND WOUND CAVITIES, E.G. AFTER EXTRACTIONS, CYSTECTOMIES, CYSTOSTOMIES, APICAL AMPUTATIONS, MAXILLARY SINUS PERFORATIONS, FOLLOWING SURGICAL REMOVAL OF TUMOURS OR RETAINED TEETH; FOR THE PREVENTION OF SECONDARY CAVITY FORMATION; PROPHYLAXIS OF WOUND INFECTIONS; SECONDARY HAEMORRHAGE PROPHYLAXIS; AS A DRESSING AFTER GINGIVECTOMY AND IN PERIODONTOPATHIES., OXIDIZED REGENERATED CELLULOSE HAEMOSTAT(SURGI-ORC)-OXIDIZED REGENERATED CELLULOSE HAEMOSTAT IS DESIGNED TO ARREST CAPILLARY BLEEDING AND BLEEDING FROM PARENCHYMATOUS ORGANS AND RESECTION AREAS AT SURGICAL INTERVENTIONS. IT SHALL BE USED TO STOP BLEEDING WHEN OTHER HAEMOSTATIC PROCEDURES ARE INEFFECTIVE OR IMPRACTICAL. IT IS SUITABLE FOR USE IN GENERAL SURGERY AND DIGESTIVE SURGERY, NEUROSURGERY (ESPECIALLY CEREBRAL OPERATIONS), PLASTIC SURGERY, ORTHOPAEDIC, GYNAECOLOGY, UROLOGY, STOMATOLOGY, TRAUMATOLOGY, AND MANY OTHER BRANCHES OF SURGERY. OXIDIZED REGENERATED CELLULOSE HAEMOSTAT CAN BE APPLIED INTO CAVITIES (AFTER EXTIRPATION OF TUMOURS) AS WELL AS ENDOSCOPIC INTERVENTIONS OR DENTAL PRAXIS.

3325	MFG/MD/2019/000188	1.License Holder Name: BHAGYASHRI SURGICALS 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:ABSORBENT GAUZE SWAB SCH F-II-GAUZE SWABS ARE TYPICALLY USED IN FIRST RESPONSE TO INJURIES, THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR CLEANING, PACKAGING, SCRUBBING, COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND. CLOSELY WOVEN GAUZE IS BEST FOR EXTRA STRENGTH OR GREATER PROTECTION, WHILE OPEN OR LOOSE WEAVE IS BETTER FOR ABSORBENCY OR DRAINAGE,ROLLED GAUZE SCH F-II-ROLLED GAUZE ARE TYPICALLY USED IN FIRST RESPONSE TO INJURIES, THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR PACKAGING,COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND. CLOSELY WOVEN GAUZE IS BEST FOR EXTRA STRENGTH OR GREATER PROTECTION, WHILE OPEN OR LOOSE WEAVE IS BETTER FOR ABSORBENCY OR DRAINAGE.,ABSORBENT COTTON BALLS I.P.-COTTON BALL ARE TYPICALLY USED IN FIRST RESPONSE TO INJURIES, THEY ARE MADE FROM ABSORBENT COTTON THIS MAKES THEM IDEAL FOR CLEANING, SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND,BANDAGE CLOTH, ROLLED BANDAGE (AS PER SCH F-II)-BANDAGE CLOTH ARE TYPICALLY USED IN FIRST RESPONSE TO INJURIES, THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR CLEANING, PACKAGING, SCRUBBING, COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND. CLOSELY WOVEN GAUZE IS BEST FOR EXTRA STRENGTH OR GREATER PROTECTION, WHILE OPEN OR LOOSE WEAVE IS BETTER FOR ABSORBENCY OR DRAINAGE.,COTTON ABSORBENT GAUZE (GAMJEE PAD, GAMJEE ROLL) SCH F-II-GAMJEE PAD/GAMJEE ROLL, ARE TYPICALLY USED IN FIRST RESPONSE TO INJURIES, THEY ARE COMBINED DRESSING PADS MADE FROM ABSORBENT COTTON WHICH IS WRAPPED IN GAUZE CLOTH AND THIS MAKES THEM IDEAL FOR PACKAGING, WRAPPING,COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND,ABSORBENT GAUZE (AS PER SCH F-II)-WOUND DRESSING AND BLOOD ABSORPTION, COTTON ABSORBENT ABDOMINAL PAD SCH F-II-COTTON ABSORBENT ABDOMINAL PADS ARE MAINLY USED DURING SURGERIES. THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND

	EXUDATES FLUID FROM A WOUND. ,X-RAY DETECTABLE ABDOMINAL PAD B.P.-X RAY DETECTABLE ABDOMINAL PADS ARE MAINLY USED DURING SURGERIES. THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND. X RAY THREAD MAKE THEM EASIER TO TRACE INSIDE THE BODY. ,X-RAY DETECTABLE GAUZE SWAB B.P.-X RAY DETECTABLE GAUZE SWABS, ARE USED IN FIRST RESPONSE TO INJURIES, THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDES FLUID FROM A WOUND. X RAY DETECTABLE GAUZE SWABS ARE ALSO USED DURING VARIOUS SURGERIES,X RAY THREAD MAKE THEM EASIER TO TRACE INSIDE THE BODY. ,KITS-KITS ARE EMERGENCY CARE GIVEN IMMEDIATELY TO AN INJURED PERSON. THE PURPOSE OF KIT FOR E.G. FIRST AID KIT IS TO MINIMIZE INJURY AND FUTURE DISABILITY. IN SERIOUS CASES, FIRST AID MAY BE NECESSARY TO KEEP THE VICTIM ALIVE. THE VARIOUS GAUZES, DRESSINGS AND BANDAGES FOUND IN KITS HAVE DIFFERENT USES. THESE DRESSINGS ARE USED FOR MINOR CUTS AND SKIN INJURIES. SOME KITS SUCH AS PICC HICKMAN ARE USED IN SPECIAL SURGICAL PROCEDURE DURING TREATMENT OF CANCER.

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3326	MFG/MD/2019/000189	1.License Holder Name: RAMAN & WEIL PVT.LTD,UNIT -3 2.Approving Authority: DAMAN AND DIU 3.Device Name(Brand Name)-Intended Use:GLUTARALDEHYDE -2 % (GLUTARALDEHYDE SOLUTION -2 %)-INSTRUMENT & SCOPE DISINFECTANT ALONG WITH ACTIVATOR. ADD THE ACTIVATOR AS PER INSTRUCTION ON LABEL.,GLUTARALDEHYDE & 1.6 DIHYDROXY - 2.5 DIOXAHEXANE(KOHRSOLIN TH)-THIS IS PURE DISINFECTANT FOR POULTRY AND LIVESTOCK,GLUTARALDEHYDE -2.45 % (GLUTIHYDE 2.45%)-INSTRUMENT & SCOPE DISINFECTANT ALONG WITH ACTIVATOR , ADD THE ACTIVATOR AS PER LABEL INSTRUCTION, DIDECYL- DIMETHYL- AMMONIUM CHLORIDE (SOKRENA)-100 % PURE SURFACE & EQUIPMENT DISINFECTANT - CONCENTRATE. USE AS PER DILUTION MENTIONED ON LABEL . DO NOT MIX WITH OTHER DISINFECTANT,GLUTARALDEHYDE & 1.6 DIHYDROXY - 2.5 DIOXAHEXANE(KORSOLEX RAPID)-THE INTENT USE FOR DISINFECTANT THE SURGICAL INSTRUMENT.,1,6 DIHYDROXY -2, 5 DIOXAHEXANE (GLUTARALDEHYDE , BENZYLALKONIUM CHLORIDE , ALKYLL UREA DERIVATIVES (BACILLOCID SPECIAL)-100 % PURE SURFACE & EQUIPMENT DISINFECTANT CONCENTRATE. USE AS PER DILUTION MENTIONED ON LABEL. DO NOT MIX WITH OTHER DISINFECTANT.,2 PROPANOL, 1 PROPANOL MECETRONIUM ETHYL SULPHATE(STERILLIUM CLEAR)-IT IS PURE HAND IN RUB DISINFECTANT. ,2-PROPANOL ,1-PROPANOL,MECETRONIUM ETHYL SULPHATE(STERILLIUM)-100 % PURE RUB IN HAND DISINFECTANT. DO NOT MIX WITH WATER & OTHER DISINFECTANT. IT IS LIGHT BLUE COLOR SOLUTION , WITH FRESH ALCOHOLIC SMELL.,2- PROPANOL - 1-PROPANOL ,. ETHYL- HEXADECYL DIMETHYL AMMONIUM ETHYLE SULPHATE , (MECETRONIUM ETHYL SULPHATE)(BACTORUB BLUE) -100 % PURE RUB - IN HAND DISINFECTANT . DO NOT MIX WITH WATER AND OTHER DISINFECTANT. IT IS LIGHT BLUE IN COLOUR.,ISO-PROPANOL , BENZYLALKONIUM CHLORIDE (CUTASEPT)-IT IS A SKIN DISINFECTANTS FOR PREPPING AND POST CLOSURE OF SKIN, CHLORIHEXDINE GLUCONATE SOLUTION IP EQUIVALENT TO CHLORIHEXDINE GLUCONATE , ETHYL ALCOHOL IP (BACTOSCRUB)-CHLORHEXIDINE GLUCONATE ANTISEPTIC SOLUTION . DO NOT MIX WITH OTHER ANTISEPTIC SOLUTION , IT IS PINK IN COLOUR WITH FRESH SMELL.,DIDECYLDIMETHYL AMMONIUM CHLORIDE(SOKRENA - WS)-IT IS ALDEHYDE FREE WATER SANITIZER USED FOR POULTRY, LIVESTOCK AND AQUACULTURE. USE DILUTION AS PER MENTION ON LABEL.,CHLORIHEXIDINE GLUCONATE SOLUTION IP, CITRIMIDE IP, ISOPROPYLE ALCOHOL(BACTORUB)-100 % PURE HAND DISINFECTANT . DO NOT MIX WITH WATER AND OTHER DISINFECTANT. IT IS LIGHT PINK IN COLOUR SOLUTION WITH PLEASANT FRAGRANCE.,CHLORIHEXDINE GLUCONATE SOLUTION IP ,

	CITRIMIDE IP , ISOPROPYLE ALCOHOL(ACEPTIK L.A)-IT IS AN ANTISEPTIC SOLUTION,ETHANOL , 2- PROPANOL , 1-PROPANOL (WETTASK WITH BACILLOL 25)-WIDE USAGE FOR INSTANT DISINFECTION ON WATER SENSITIVE SURFACE SPECIALLY ON FREQUENT HAND CONTACT SURFACE SPECIALLY ON FREQUENT HAND CONTACT SURFACES,DODECYBISPROPYLENE TRIAMINE , DIDECYLDIMETHYL AMMONIUM CHLORIDE (KORSOLEX PLUS)-IT IS USED FOR SURFACE MOPPING , FOGGING DISINFECTION AND INSTRUMENT / ENDOSCOPE DISINFECTION,PEG – 40 HYDROGENATED CASTER OIL PEG -150 DISTERATE GLYCERINE PENTHENOL. PEG -7 GLYCERYL COCONATE DIDECYLDIAMMONIUM CHLORIDES SODIUM CITRATE ,ALLANTOIN(STELLISEPT MED)-STELLISEPT MED HAS REPLENISHING PROPERTIES AND A BROAD SPECTRUM OF ANTISEPTIC EFFECT. ANTISEPTIC WHOLE BODY WASHING IN CASE OF MRSA/ORSA,PROPYLENE GLYCOL IP -SODIUM BENZOATE IP - SODIUM SALICYLATE IP -SODIUM LAURYL SULPHATE (BAKTOLIN 5.5) -IT IS HYGIENIC NON SOAP CLEANSER. THE SKIN REMAINS SMOOTH AND WELL NOURISHED. BAKTOLIN 5.5 IS A PH OF SAME TO NEUTRAL SKIN.,BENZYALKONIUM CHLORIDE. DODECYLBISPROPYLENE TRIAMINE (MIKROBAC FORTE)-STANDARD DILUTION FOR NON CRITICAL AREA AND CRITICAL AREA USE 0.5% AND 2% SOLUTION RESPECTIVELY . THE STANDARD RECOMMENDED CONCENTRATION IS 1.5%,2 PROPANOL, 1 PROPANOL MECETRONIUM ETHYL SULPHATE (STERILLIUM GEL)-IT IS PURE HAND IN RUB DISINFECTANT,ETHANOL , 2- PROPANOL , 1-PROPANOL (BACILLOL-25)-BACILLOL - 25 USED FOR SURFACE AND EQUIPMENT DISINFECTANT . IT IS ALDEHYDE FREE DISINFECTANT FOR INSTANT DISINFECTION WITH IN 25 SECOND.,GLUTARALDEHYDE -2 % (GLUTIHYDE 2%)-INSTRUMENT & SCOPE DISINFECTANT ALONG WITH ACTIVATOR. ADD THE ACTIVATOR AS PER LABEL INSTRUCTION.,DIDECYL- DIMETHYL-AMMONIUM CHLORIDE (BACILLO FLOOR)-USE FRESHLY DILUTED 0.1% SOLUTION,ETHYLENEDIOXY DIMENTHANOL & GLUTARALDEHYDE (BACILLOCID EXTRA)-IT IS USED FOR DISINFECTANT THE SURGICAL EQUIPMENT AS WELL AS SURFACE OF EQUIPMENT.,ISO-PROPANOL , BENZYLALKONIUM CHLORIDE (CUTASEPT F)-IT IS USED FOR PRE & POST INCISION OF SKIN. IT IS USED FOR PREPPING AND DRESSING OF SKIN.,CHLORIHEXDINE GLUCONATE SOLUTION IP , CITRIMIDE IP , ISOPROPYLE ALCOHOL (ACEPTIK H.C)-IT IS AN ANTISEPTIC SOLUTION

3327	MFG/MD/2019/000190	1.License Holder Name: SANMED HEALTHCARE PVT. LTD. 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:SOLUTION OF DODECYL BIS PROPYLENE TRIAMINE AND DIDECYL DIMETHYL AMMONIUM CHLORIDE(STRUMEN ALDEHYDE FREE)-ALDEHYDE FREE HIGH LEVEL DISINFECTANT FOR REPROCESSING HEAT SENSITIVE REUSABLE SEMI-CRITICAL MEDICAL DEVICES, FOR WHICH STERILIZATION IS NOT FEASIBLE. (ENDOSCOPE ETC.),SOLUTION OF GLUTARALDEHYDE WITH ACTIVATOR(STRUMEN G 2%)-HIGH LEVEL DISINFECTANT FOR INSTRUMENTS, ENDOSCOPES AND ANESTHESIA ACCESSORIES, SOLUTION OF PERACEITC ACID AND HYDROGEN PEROXIDE(STRUMEN HYPA100)-CLEANING, DISINFECTING, STERILIZING DIALYZER / BLOODLINE FOR REUSE. DISINFECTING AND EFFECTIVELY CLEANING BIO-FILM AND CALCIUM PRECIPITATE TO REDUCE HAEMODIALYSIS MACHINE BREAK DOWN,PERACETIC ACID SOLUTION(STRUMEN PAA 750)-INSTRUMENT DISINFECTANT,SOLUTION OF PERACETIC ACID AND HYDROGEN PEROXIDE(STRUMEN HYPA)-CLEANING, DISINFECTING, STERILIZING DIALYZER / BLOODLINE FOR REUSE. DISINFECTING AND EFFECTIVELY CLEANING BIO-FILM AND CALCIUM PRECIPITATE TO REDUCE HAEMODIALYSIS MACHINE BREAK DOWN. , ENZYMATIC COMPLEX(STRUMEN MULTIZYME)-MULTI-ENZYME INSTRUMENT CLEANER FOR PRE-SOAKING OF SURGICAL INSTRUMENTS AND MEDICAL DEVICES INCLUDING ENDOSCOPES, SOLUTION OF ETHANOL , ISOPROPYL ALCOHOL AND N-PROPANOL (FACEIN SPRAY)-RAPID DISINFECTION OF CRITICAL AREAS LIKE OTS IN BETWEEN SURGERIES, ICU, NICU, MEDICAL LABORATORIES ETC. PHARMACEUTICAL STERILE SECTIONS, ESPECIALLY ON PACKAGING MACHINES,SOLUTION OF CHLORHEXIDINE GLUCONATE, CETRIMIDE AND ISOPROPYL ALCOHOL (DEZSEP HC)-CLEANSING AND DISINFECTING CATHETERS, RUBBER APPLIANCES ETC.,SOLUTION OF GLUTARALDEHYDE WITH ACTIVATOR(STRUMEN G 2.45%)-HIGH LEVEL DISINFECTANT FOR INSTRUMENTS, ENDOSCOPES AND ANESTHESIA ACCESSORIES,SOLUTION OF ORTHOPHTHALDEHYDE (STRUMEN OPA)-HIGH LEVEL DISINFECTANT FOR REPROCESSING HEAT SENSITIVE REUSABLE SEMI-CRITICAL MEDICAL DEVICES, FOR WHICH STERILIZATION IS NOT FEASIBLE.,CRITIC ACID(STRUMEN TRI ACID)-IT IS USED FOR CHEMO-THERMAL DISINFECTION OF HEMODIALYSIS MACHINES WITH RECIRCULATION. CAN BE USED IN ANY DIALYSIS MACHINE. IT IS USED FOR DESCALING & DECALCIFICATION OF HEMODIALYSIS MACHINES ,SODIUM PERBORATE MONOHYDRATE(STRUMEN SP)-FOR STERILIZING SURGICAL , MEDICAL & DENTAL INSTRUMENTS,SOLUTION OF GLUTARALDEHYDE(STRUMEN RAPID)-IT IS IDEAL FOR DISINFECTION AND STERILIZATION OF RIGID AND FLEXIBLE ENDOSCOPES,

	INSTRUMENTS MADE OF RUBBER, PLASTIC, METAL, PORCELAIN AND GLASS. AND ALSO DIAMOND CUTTING BARS, ROOT CANAL AND HAND SET INSTRUMENTS. SUITABLE FOR IMMERSION BATCH, CIRCULATION PROCESS AND ULTRASONIC BATH. ,HYDROGEN PEROXIDE SOLUTION (STRUMEN HP)-FOR HIGH LEVEL DISINFECTION OF SURGICAL AND MEDICAL INSTRUMENTS INCLUDING ENDOSCOPES

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3328	MFG/MD/2019/000191	1.License Holder Name: OM SURGICALS INDUSTRIES 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:DENTAL COTTON ROLL DRESSING(N/A)-ADHESIVE BANDAGES,GAUGE BANDAGES,PRESSURE BANDAGES,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES ,OT KIT(N/A)-DRESSING AEROSOL, NON-ADHERENT DRESSING PERIODONTAL, KIT, DRESSING PAD, DRESSING, CATHETERIZATION KIT(N/A)-DRESSING AEROSOL, NON-ADHERENT DRESSING PERIODONTAL, KIT, DRESSING PAD, DRESSING,NON WOVEN STERILE IV DRESSING(N/A)-ADHESIVE BANDAGES,GAUGE BANDAGES,PRESSURE BANDAGES,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES. ,SUSPENSION BANDAGE(N/A)-ADHESIVE BANDAGES,GAUGE BANDAGES,PRESSURE BANDAGES, TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES, ABSORBENT LINT CLOTH(ABSORBENT CELLULOSE SHEET)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBRE) BANDAGES., POVIDONE IODINE EXTERNAL APPLICATION(N/A)-AN AGENT DESTROYS PATHOGENIC AND OTHER KIND OF MICROORGANISM BY CHEMICAL OR PHYSICAL MEANS. A DISINFECTANT DESTROYS MOST RECOGNIZED PATHOGENIC MICROORGANISM FORMS,SUCH AS BACTERIAL SPORES.IT IS INTENDED TO DISINFECT A MEDICAL DEVICE. ,HAND SANITIZER (N/A)-HAND SANITIZER IS VERY IMPORTANT FOR OUR HEALTH BECAUSE IF AT A PLACE WATER IS NOT THERE YOU CAN USE HAND SANITIZER BUT OUT MADE HAND SANITIZER CONTAIN HARD CHEMICALS WHICH ARE NOT AT ALL NICE FOR OUR HEALTH. ,ALCOHOL SWAB(N/A)-IT IS A SINGLE USE, STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLES ACCESS SITE PRIOR TO USE. ,CAST PADDING FOR PLASTER OF PARIS (N/A)-A PROSTHETIC AND ORTHOTIC ACCESSORY, INTENDED FOR MEDICAL PURPOSE TO SUPPORT,PROTECT,OR AID IN THE USE OF A CAST,ORTHOSIS (BRACE),OR PROSTHESIS.,ABSORBENT GAUZE CLOTH(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBRE) BANDAGES. ,WHITE PHENYL(N/A)-AN AGENT DESTROY PATHOGENIC AND OTHER KIND OF MICROORGANISM BY CHEMICAL OR PHYSICAL MEAN.A DISINFECTANT DESTROY MOST RECOGNIZED PATHOGENIC MICROORGANISM BUT NOT NECESSARILY ALL MICROBIAL FORMS, SUCH AS BACTERIAL SPORES.IT IS INTENDED TO DISINFECTANT A MEDICAL DEVICE.,BLOOD TRANSFUSION SET(N/A)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN.,FIRST AID KIT(N/A)-DRESSING AEROSOL, NON-

	ADHERENT DRESSING PERIODONTAL, KIT, DRESSING PAD, DRESSING, HIV KIT(N/A)-DRESSING AEROSOL, NON ADHERENT DRESSING, PERIODONTAL,KIT,DRESSING PAD,DRESSING,DIALYSIS KIT(N/A)-DRESSING AEROSOL, NON-ADHERENT DRESSING PERIODONTAL, KIT, DRESSING PAD, DRESSING,PERSONNEL PROTECTION KIT(N/A)-DRESSING AEROSOL, NON-ADHERENT DRESSING PERIODONTAL, KIT, DRESSING PAD, DRESSING,DRESSING KIT(N/A)-DRESSING AEROSOL, NON ADHERENT DRESSING, PERIODONTAL,KIT,DRESSING PAD, DRESSING,GAUZE RIBBON DRESSING(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES ,ROLLED BANDAGE(WOW BANDAGE)-ADHESIVE BANDAGES,GAUGE BANDAGES,PRESSURE BANDAGES,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES ,ELASTIC CREPE BANDAGE(WOVEN CONFORMING RETENTION BANDAGE,COTTON CREPE BANDAGE BP,COTTON CREPE BANDAGE BPC,SHORT STRETCH COMPRESSION BANDAGE,SHORT STRETCH BANDAGE FOR MODERATE COMPRESSION,WOVEN CONFORMING COHESIVE BANDAGE,WOVEN COHESIVE MODERATE COMPRESSION BANDAGE,NON WOVEN COHESIVE MODERATE COMPRESSION BANDAGE,SHORTS STRETCH COHESIVE COMPRESSION BANDAGE)-ADHESIVE BANDAGES,GAUGE BANDAGES, PRESSURE BANDAGES,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES,GAUZE SWAB BP(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT BANDAGES,CHLORHEXIDINE GAUZE DRESSING BP(N/A)-ADHESIVE BANDAGES,GAUGE BANDAGES,PRESSURE BANDAGES,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES ,INFUSION SET(N/A)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN. ,EYE PAD(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES ,GAMJEE ROLL DRESSING(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES,PLASTER OF PARIS BANDAGE BP(N/A)- ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBRE) BANDAGES . ,COMBINE COOLING & COMPRESSION(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT BANDAGES ,DELIVERY KIT(N/A)-DRESSING AEROSOL, NON-ADHERENT DRESSING PERIODONTAL, KIT, DRESSING PAD, DRESSING,OBSTETRICAL KIT (N/A)-DRESSING AEROSOL, NON-ADHERENT DRESSING PERIODONTAL, KIT, DRESSING PAD, DRESSING,GYANE KIT(N/A)-

	DRESSING AEROSOL, NON-ADHERENT DRESSING PERIODONTAL, KIT, DRESSING PAD, DRESSING,UMBILICAL CORD CLAMP(N/A)-THESE DEVICES MAY BE A CLIP, TIE, TAPE OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSEL IN THE UMBILICAL OF A NEW BORN INFANT.,CORN CAP(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES ,TRIANGULAR BANDAGE(N/A)-ADHESIVE BANDAGES,GAUGE BANDAGES,PRESSURE BANDAGES,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES,BLACK PHENYL(N/A)-BLACK PHENYL IS A POWERFUL DISINFECTANT AND GERMICIDE. IT IS A BLACK COLOR LIQUID WHICH IS USED FOR CLEANING SURFACE AT HOME, BUSINESS AND EVERYWHERE. VERY USEFUL DURING RAINY SEASON OR MONSOON SEASON. ,NITRILE GLOVES (N/A)- NITRILE EXAMINATION GLOVES ARE SUITABLE IN WORK ENVIRONMENTS WHERE THERE IS POSSIBLE CONTACT WITH BODILY FLUIDS, MICROORGANISMS, AND CHEMICALS. ,COMBINE DRESSING(N/A)-DRESSING AEROSOL, NON-ADHERENT DRESSING, PERIODONTAL, KIT, DRESSING PAD, DRESSING.,ABSORBENT GAUZE ROLL(N/A)-ADHESIVE BANDAGES,GAUGE BANDAGES,PRESSURE BANDAGES,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES ,NON WOVEN DRESSING WITH NON ADHERENT PAD(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBRE) BANDAGES , SYNTHETIC CASTING TAPE(N/A)-A PROSTHETIC AND ORTHOTIC ACCESSORY, INTENDED FOR MEDICAL PURPOSE TO SUPPORT, PROTECT, OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE),OR PROSTHESIS. ,PARAFFIN GAUZE DRESSING BP(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBRE) BANDAGES. ,COTTON STOCKINETTE(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES. ,TRANSPARENT PERFORATED SURGICAL PE TAPE(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT BANDAGES ,MICROPOROUS TAPE(MICROPOROUS HYPOALLERGENIC PAPER TAPE)-ADHESIVE BANDAGES,GAUGE BANDAGES,PRESSURE BANDAGES,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES ,HYPOALLERGENIC & LATEX FREE SILK LIKE TAPE(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT BANDAGES ,T-SHAPED BANDAGE(N/A)-ADHESIVE BANDAGES,GAUGE BANDAGES,PRESSURE BANDAGES,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES ,EYE PAD WITH ADHESIVE BORDER(N/A)-DRESSING AEROSOL, NON ADHERENT DRESSING ,PERIODONTAL, KIT, DRESSING

	PAD, DRESSING,HYPOALLERGENIC AND LATEX FREE SURGICAL PAPER TAPE(N/A)-ADHESIVE BANDAGE,GAUZE BANDAGE,PRESSURE BANDAGE,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES.,ADHESIVE TAPE USP(ADHESIVE TAPE USP (FABRIC BASE),ADHESIVE TAPE)-ADHESIVE BANDAGES,GAUGE BANDAGES, PRESSURE BANDAGES,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES,MEDICATED DRESSING (BAND-AID)(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBRE) BANDAGES. , ELASTIC ADHESIVE BANDAGE BP(N/A)-ADHESIVE BANDAGES,GAUGE BANDAGES,PRESSURE BANDAGES,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES ,TEARABLE SPORTS TAPE HYPOALLERGENIC(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES ,ABSORBENT BANDAGE CLOTH(N/A)-ADHESIVE BANDAGES,GAUGE BANDAGES,PRESSURE BANDAGES,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES ,IV CANNULA FIXTATOR(N/A)-ADHESIVE BANDAGES,GAUGE BANDAGES,PRESSURE BANDAGE,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES.,SURGICAL GLOVES(N/A)-SURGICAL GLOVES ARE USES IN VARIOUS HOSPITAL ACTIVITIES DURING OPERATION, DRESSING TO AVOID THE CONTAMINATION/INFECTION TO PATIENT AS WELL AS USER,BELLADONNA PLASTER(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICATED ABSORBENT (FIBER) BANDAGES. ,ABSORBENT COTTON WOOL IP(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT BANDAGES ,SHELL DRESSING(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES,TRANSPARENT FILM DRESSING WITH NON ADHERENT PAD(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,URINE COLLECTION BAG(N/A)-THE STERILE URINE BAG IS TO FIT ANY TYPE INDWELLING URINE CATHETER FOR COLLECTING URINE FROM THE PATIENT.,ABSORBENT CELLULOSE SHEET(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBRE) BANDAGES. ,LATEX EXAMINATION GLOVES(N/A)-USES IN HOSPITAL DURING EXAMINATION OF PATIENTS.,TRANSPARENT STERILE IV DRESSING(N/A)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT BANDAGES

3329	MFG/MD/2019/000192	1.License Holder Name: MECCA INDUSTRIES 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ENDOTRACHEAL TUBE (MECCA)-INSERT THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF TRACHEA, JUST BELOW THE VOCAL CORD.,NEEDLE FREE CONNECTOR(MECCA)-TO BE USED FOR THE DELIVERY AND OR ASPIRATION OF FLUIDS FROM AN IV CATHETER.,HEMODIALYSIS CATHETER(MECCA)-A CATHETER IS USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT., CHEST DRAINAGE CATHETER WITH TROCAR(MECCA)-A TROCAR IS MADE UP OF AN OBTURATOR (WHICH MAY BE A METAL OR PLASTIC SHARPENED OR NON-BLADED TIP), A CANNULA (BASICALLY A HOLLOW TUBE), AND A SEAL. THE TROCAR FUNCTIONS AS A PORTAL FOR THE SUBSEQUENT PLACEMENT OF OTHERS INSTRUMENTS, SUCH AS GRASPERS, SCISSORS, STAPLERS, ETC. IT IS ALSO INTENDED TO REMOVE AIR OR FLUID FOR THE PLEURAL SPACE IN A CLOSED, ONE WAY FASHION.,PERITONIAL DIALYSIS CATHETER(MECCA)-THAT ALLOWS DIALYSIS FLUID TO ENTER THE ABDOMINAL CAVITY, DWELL INSIDE FOR A WHILE, AND THEN DRAIN BACK OUT AGAIN., ANGIOGRAPHIC NEEDLE(MECCA)-ANGIOGRAPHIC NEEDLES HAVE A UNIQUE HUB DESIGN WITH AN ERGONOMIC FEEL AND A BLACK TRIANGLE INDICATOR TO ORIENT THE BEVEL. ,INTRAVENOUS CANNULA(MECCA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS DRUGS, AND OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,I.V FLOW REGULATOR(MECCA)-AN I.V. SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,THREE WAY STOP COCK(MECCA)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,URINARY DRAINAGE UNIT(MECCA)-A CLOSED URINARY DRAINAGE SYSTEMS CONSISTS OF A CATHETER INSERTED INTO THE URINARY BLADDER AND CONNECTED VIA TUBING TO A DRAINAGE BAG. ,CORONARY ARTERY CANNULA(MECCA)-CANNULATION TECHNIQUE FOR LEFT SIDE CORONARY ARTERY SURGERY.,FOLEY CATHETER(MECCA)-A LONG, SMALL GUAGE CATHETER DESIGNED FOR INSERTION DIRECTLY INSERTED INTO THE URETER, EITHER THROUGH THE URETHRA AND BLADDER AND POST PRIORY VIA THE KIDNEY. FOLEY CATHETER IS USED A ROUTINE MEDICAL PROCEDURE THAT FACILITATES DIRECT DRAINAGE OF THE URINARY BLADDER INTO AN ATTACHED URINE COLLECTION BAG OR CONTAINER. IT CONSISTS IN THE INSERTION OF A CATHETER INTO A PATIENT'S BLADDER. ,

	NELATON CATHETER(MECCA)-A LONG,SMALL GUAGE CATHETER DESIGNED FOR INSERTION DIRECTLY INSERTED INTO THE URETER, EITHER THROUGH THE URETHRA AND BLADDER AND POST PRIORY VIA THE KIDNEY.,MULTIPLE LUMEN CATHETER(MECCA)-INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP) SAMPLING BLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTIONS OR DRUGS.,INTRAMUSCULAR PRESSURE MONITORING CATHETER(MECCA)-A MODIFIED FIBRE OPTIC TRANSDUCER-TIPPED CATHETER SYSTEM FOR MEASURING INTRAMUSCULAR PRESSURE DURING EXERCISE WAS DETERMINED.,CLOSED WOUND DRAINAGE TUBE OR SYSTEM(MECCA)-INTENDED FOR EVACUATION OF BIOLOGICAL FLUID FROM WOUND OR BODY CAVITY DURING SURGICAL PROCEDURE OR IN WOUND CARE MANAGEMENT.,SUCTION TIP & CATHETER(MECCA)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,MANIFOLDS(MECCA)-INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT/PORTS FOR ADMINISTRATION OF A SOLUTIONS,TRACHEOSTOMY TUBE (MECCA)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION., TRACHEOBRONCHIAL SUCTION CATHETER(MECCA)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,SINGLE NEEDLE HAEMODIALYSIS CATHETER/BLOOD LINES(MECCA)-A CATHETER IS USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE BY USING ONLY ONE CANNULA OR SINGLE NEEDLE.,HME FILTER(MECCA) -THIS DEVICE IS INTENDED TO USE FOR AIRWAY MANAGEMENT BY ANAESTHESIA/RESPIRATORY CARE DEPARTMENT.,CHEST DRAINAGE CATHETER(MECCA)-A TROCAR IS MADE UP OF AN OBTURATOR (WHICH MAY BE A METAL OR PLASTIC SHARPENED OR NON-BLADED TIP), A CANNULA (BASICALLY A HOLLOW TUBE), AND A SEAL. THE TROCAR FUNCTIONS AS A PORTAL FOR THE SUBSEQUENT PLACEMENT OF OTHERS INSTRUMENTS, SUCH AS GRASPERS, SCISSORS, STAPLERS, ETC. IT IS ALSO INTENDED TO REMOVE AIR OR FLUID FOR THE PLEURAL SPACE IN A CLOSED, ONE WAY FASHION., ANGIOGRAPHIC CATHETER(MECCA)-DESIGNED TO PROVIDE A PATHWAY FOR DELIVERING CONTRAST MEDIA TO SELECTED SITES IN THE DEVICE VASCULAR SYSTEM INCLUDING THE CAROTID ARTERIES., ARTERIAL CANNULA(MECCA)-INSERTED INTO AN ARTERY, COMMONLY THE RADIAL ARTERY, AND IS USED DURING MAJOR OPERATIONS AND IN CRITICAL CARE AREAS TO MEASURE BEAT-TO-BEAT BLOOD PRESSURE AND TO DRAW REPEATED BLOOD SAMPLES., LEVINE TUBE(MECCA)-THIS DEVICE IS USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF

	TUBE FEEDINGS OR MEDICATIONS.,FEEDING TUBE(MECCA)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S IS USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,Y CONNECTOR AS AN ACCESSORY TO PERFUSION SETS(MECCA)-IT CAN BE USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC.,VENOUS CANNULA(MECCA)-IT IS INTENDED FOR USE AS A SINGLE CANNULA FOR BOTH VENOUS DRAINAGE AND REINFUSION OF BLOOD VIA AN INTERNAL JUGULAR VEIN DURING EXTRACORPOREAL LIFE SUPPORT PROCEDURES.,URETHROGRAPHIC MALE CATHETER(MECCA)-A CATHETER USED TO PASS INTO A MAN'S BLADDER.,SPINAL NEEDLE(MECCA)-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANAESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM. ,NASAL OXYGEN CATHETER(MECCA)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP. ,TONSIL SUCTION TUBE (MECCA)-USED TO SUCK OUT STONES IN TONSILS.,VENTRICULAR CANNULA(MECCA)-FOR USE IN NEUROSURGICAL PROCEDURES. IT IS SPECIALLY DESIGNED TO PENETRATE DELICATE BRAIN TISSUE AND GIVE CONTINUED ACCESS TO BRAIN'S VENTRICULAR SYSTEM., NASOGASTRIC TUBE/ RYLES TUBE(MECCA)-IT IS SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,FISTULA NEEDLE(MECCA)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT.,HEART-LUNG BYPASS UNIT TUBE(MECCA) -A TUBE WILL BE PLACED IN YOUR HEART TO DRAIN BLOOD TO THE MACHINE.,EXTENSION SETS(MECCA)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATIONS IN MEDICAL APPLICATIONS.,NASOPHARYNGEAL CATHETER(MECCA)-A CATHETER (FOR ADULTS) PASSED THROUGH THE NARES AND ADVANCED TO THE DEPTH OF THE NASOPHARYNX TO REMOVE AIR CHOKE OR OBSTRUCTION. RESUSCITATOR,URETHRAL CATHETER (MECCA)-A LONG, SMALL GUAGE CATHETER DESIGNED FOR INSERTION DIRECTLY INSERTED INTO THE URETER, EITHER THROUGH THE URETHRA AND BLADDER AND POST PRIORY VIA THE KIDNEY. URETHRAL CATHETER IS USED A ROUTINE MEDICAL PROCEDURE THAT FACILITATES DIRECT DRAINAGE OF THE URINARY BLADDER INTO AN ATTACHED URINE COLLECTION BAG OR CONTAINER. IT CONSISTS IN THE INSERTION OF A CATHETER INTO A PATIENT'S BLADDER

3330	MFG/MD/2019/000193	1.License Holder Name: MED PLUS INDIA 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE SCREW(MPI)-THE BONE SCREW IS INTENDED TO USE FOR INTERNAL FIXATION OF BONE FRACTURES AND RECONSTRUCTION OF BONES, THERE ARE SEVERAL TYPES OF SCREW LIKE LOCKING HEAD SCREW, GENERAL CORTICAL SCREW OR LEG SCREW OF DHS (DYNAMIC HIP SCREW) ARE USED FOR FIXING OF BONE PLATE, NAIL, DHS PLATE, LOCKING PLATES WHICH IS USED FOR OSTEOTOMY PATIENTS EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS.,BONE PLATE(MPI)-THE BONE PLATE IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, TIBIA, FIBULA, FEMORAL. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS. THIS SYSTEM CAN BE USED FOR VENTRAL, DORSAL OR ORTHOGONAL APPLICATIONS,SPINAL SYSTEM(MPI)-THE MPI SPINAL SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS, AS AN ADJUNCT TO FUSION OF THE CERVICAL, THORACIC, LUMBAR, AND/OR SACRAL SPINE. THE MPI SPINAL SYSTEM CONSISTS OF CAGES THAT ARE TO BE RIGIDLY LOCKED FOR GETTING BETTER RESULT.,AUSTIN MOORE ENDOPROTHESIS(MPI)-ONE PIECE ENDOPROTHESIS REPLACEMENT COMPONENT, WHICH IS INTENDED FOR CEMENTED USE ONLY, FEMORAL HEAD AND NECK FRACTURE ASEPTIC NEUROSIS OF FEMORAL HEAD OSTEO, RHEUMATOID, POST TRAUMATIC ARTHRITIS OF HIP WITH MINIMAL ACCETABULAR INVOLVEMENT.,INTRAMEDULLARY NAILS(MPI)-THE INTRAMEDULLARY NAIL IS INTENDED FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF THE HUMERUS, TIBIA, FIBULA, FEMORAL BONES. THE I.M.NAIL IS HAVING BETTER STRENGTH WITH GOOD BONE HEALING CAPACITY. DIFFERENT SIZES ARE AVAILABLE WITH DIFFERENT DESIGN FOR BETTER ALIGNMENT OF THE FRACTURE.,MAXILLOFACIAL IMPLANT(MPI)-THE MAXILLOFACIAL IMPLANTS ARE INTENDED TO BE USED AS RECONSTRUCTION OF THE MAXILLOFACIAL SKELETON.

3331	MFG/MD/2019/000194	1.License Holder Name: RESCQTEC SUTURES PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:POLYGLACTIN-910 COATED AND BRAIDED ABSORBABLE SURGICAL SYNTHETIC SUTURE USP(MEDCRYL)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,MONOFILAMENT POLYPROPYLENE NON ABSORBABLE SURGICAL MESH(MEDLENE-MESH)-POLYPROPYLENE MESH USE FOR THE HERNIA REPAIR AND OTHER FACIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT.,MONOFILAMENT POLYPROPYLENE NON-ABSORBABLE SURGICAL SUTURE USP(MEDLENE)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,BLACK BRAIDED SILK NON- ABSORBABLE SURGICAL SUTURE-MEDSILK IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LEGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., CATGUT CHROMIC/PLIAN ABSORBABLE SURGICAL SUTURE USP (MEDGUT)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,POLYGLACTIN-910 FAST ABSORBABLE COATED AND BRAIDED SYNTHETIC SUTURE USP (MEDCRYL-FAST)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,MONOFILAMENT POLIGLECAPRONE25 ABSORBABLE SYNTHETIC SUTURE USP (MEDCRYL-MONO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,POLYGLYCOLIC ACID COATED AND BRAIDED ABSORBABLE SURGICAL SYNTHETIC SUTURE USP(MEDISORB)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,POLYGLACTIN-910 ANTIBACTERIAL TRICLOSAN COATED AND BRAIDED ABSORBABLE SURGICAL SYNTHETIC SUTURE USP(MEDCRYL-AB)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,MONOFILAMENT POLYAMIDE NON-ABSORBABLE SURGICAL SUTURE USP(MEDLON)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,COATED AND BRAIDED POLYESTER NON-ABSORBABLE SURGICAL SUTURE USP(MEDBOND)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,MONOFILAMENT POLYDIOXANONE ABSORBABLE SURGICAL SYNTHETIC SUTURE USP (MEDSYNTH)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.

3332	MFG/MD/2019/000195	1.License Holder Name: SURGILIFE MEDICAL DEVICES PVT. LTD. 2.Approving Authority: EAST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:STERILE DRAPES (LIFEMED)-IT IS INTENDED FOR USE DURING VARIOUS SURGERIES. STERILE DRAPES ARE THE BARRIER TO CREATE & MAINTAIN A STERILE FIELD, TO PREVENT CONTACT WITH UNPREPARED SURFACES & TO MAINTAIN THE STERILITY OF ENVIRONMENTAL SURFACES, EQUIPMENT & THE PATIENT SURROUNDINGS. , CATHETERS(LIFEMED)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERT DIRECTLY IN A URETER, EITHER THROUGH THE URETER AND BLADDER OR POSTERIOR VIA KIDNEY ,COTTON GRUDGES, GAUZE & BANDAGES(LIFEMED)-A STRIP OF FABRIC USED ESPECIALLY TO COVER, DRESS, AND BIND UP WOUNDS AND A FLEXIBLE STRIP OR BAND USED TO COVER, STRENGTHEN, OR COMPRESS SOMETHING ,THERMOMETER(LIFEMED)-A DIGITAL THERMOMETER IS A DEVICE USED TO MEASURE THE BODY TEMPERATURE OF A PATIENT BY MEANS OF A TRANSDUCER COUPLED WITH AN ELECTRIC SIGNAL AMPLIFICATION, CONDITIONING, AND DISPLAY UNIT. ,DISINFECTANTS(LIFEMED)-11) AN AGENT THAT DESTROYS PATHOGENIC & OTHER KINDS OF MICRO ORGANISMS BY CHEMICAL OR PHYSICAL MEANS. A DISINFECTANT DESTROYED MOST RECOGNIZED PATHOGENIC MICRO ORGANISMS, BUT NOT NECESSARILY ALL MICROBIAL FORMS ,SUCH AS BACTERIAL SPORES. ,UMBILICAL OCCLUSION DEVICE(LIFEMED)-THESE DEVICES MAY BE A CLIP ,TIE, TAPE OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEW BORN INFANT. , SURGICAL DRESSINGS(LIFEMED)-NON ADHERENT DRESSINGS DO NOT STICK ON WOUNDS ,THEY CAN BE PLACED DIRECTLY ON THE WOUND NONSTICK WOUND DRESSINGS PREVENT SKIN MACERATION & MANAGE WOUNDS WITH DRY TO HEAVY EXUDATES. MULTILAYER CONSTRUCTION REDUCES FRICTION, ELIMINATES FRAYED EDGES, LOOSE THREADS & LINTING.COMPATIBLE WITH MOST TOPICAL AGENTS, LIQUIDS & CREAMS. THESE WOUND DRESSINGS ABSORBS BLOOD, CAN BE USED FOR SWABBING ,CLEANING ,WET, DRY ON CLEAN OR CONTAMINATED WOUNDS. WATER RESISTANT DRESSING., BLOOD COLLECTING NEEDLE(LIFEMED)-INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD. ,SURGICAL DRESSINGS(LIFEMED)-A DRESSING CAN HAVE A NUMBER OF PURPOSES, DEPENDING ON THE TYPE, SEVERITY AND POSITION OF THE WOUND, ALTHOUGH ALL PURPOSES ARE FOCUSED TOWARDS PROMOTING RECOVERY AND PROTECTING FROM FURTHER HARM. ,ALCOHOL SWAB(LIFEMED)-IT IS A SINGLE USE STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING & ALLOWING DRYING & WILL DISINFECT NEEDLESS

	ACCESS SITES PRIOR TO USE.,AUTO DISABLE SYRINGE FOR SINGLE USE(LIFEMED)-INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,WOUND CLOSURE DEVICE(LIFEMED)-WOUND CLOSURE DEVICES ARE INDICATED FOR SOFT TISSUE DRAINAGE

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3333	MFG/MD/2019/000196	1.License Holder Name: DKSORTHO & SHARMA PHARMACEUTICAL PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:TOTAL SHOULDER REPLACEMENT- GLENOID(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-PRODUCT IS INDICATED FOR USE IN SHOULDERARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED SHOULDER FUNCTION IN SKELETALLY MATURE PATIENTS WITH ENOUGH AND SATISFACTORY BONE STOCK TO SUPPORT THE PROSTHESIS WITH THE FOLLOWING CONDITIONS: A. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND A VASCULAR NECROSIS. B. RHEUMATOID ARTHRITIS. C. REVISION WHERE OTHER DEVICES OR TREATMENTS HAVE FAILED. D. CORRECTION OF FUNCTIONAL DEFORMITY. E. FRACTURES OF THE PROXIMAL HUMERUS, WHERE OTHER METHODS OF TREATMENT ARE DEEMED INADEQUATE. F. DIFFICULT CLINICAL MANAGEMENT PROBLEMS, INCLUDING CUFF ARTHROPATHY, WHERE OTHER METHODS OF TREATMENT MAYNOT BE SUITABLE OR MAY BE INADEQUATE.,BONE NAILS(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-INDICATIONS FOR INTERLOCKING NAILS INCLUDE SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL- UNIONS; AND BONE LENGTHENING/SHORTENING. FEMORAL INTERLOCKING NAILS INCLUDE THE INDICATION FOR PROXIMAL, MIDDLE AND DISTAL THIRD FEMORAL SHAFT FRACTURES. TIBIAL INTERLOCKING NAILS ALSO INCLUDE THE SAME INDICATIONS FOR TIBIAL SHAFT FRACTURES.,TOTAL HIP REPLACEMENT - FEMORAL HEAD(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES, FINER)-TOTAL HIP REPLACEMENT (UN-CEMENTED) ISINTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESS FIT (CEMENT LESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B. CORRECTION OF FUNCTIONAL DEFORMITY. C. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D. REVISION PROCEDURES WHERE OTHER

	TREATMENT OR DEVICES HAVE FAILED.,TOTAL HIP REPLACEMENT - ACETABULAR CUP(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES, FINER)-TOTAL HIP REPLACEMENT (UN-CEMENTED) ISINTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESS FIT (CEMENT LESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B. CORRECTION OF FUNCTIONAL DEFORMITY. C. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,TOTAL HIP REPLACEMENT - FEMORAL HEAD(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES, FINER)-TOTAL HIP REPLACEMENT (UN-CEMENTED) ISINTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESS FIT (CEMENT LESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B. CORRECTION OF FUNCTIONAL DEFORMITY. C. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,TOTAL HIP REPLACEMENT - ACETABULAR CUP(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES, FINER)-TOTAL HIP REPLACEMENT (UN-CEMENTED) ISINTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESS FIT (CEMENT LESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS.

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	PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THORACIC, LUMBAR, AND SACRAL SPINE: FRACTURE, DISLOCATION, FAILED PREVIOUS FUSION (PSEUDOARTHROSIS), SPINAL STENOSIS, DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, SPINAL DEFORMATIONS SUCH AS SCOLIOSIS OR KYPHOSIS AND LOSS OF STABILITY DUE TO TUMORS. SPINAL IMPLANTS ARE INTENDED TO BE USED AS A TEMPORARY CONSTRUCT THAT ASSISTS NORMAL HEALING AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES. THEY ARE INTENDED TO STABILIZE THE SPINAL OPERATIVE SITE DURING FUSION PROCEDURES AND SHOULD BE REMOVED AFTER FUSION.,TOTAL HIP REPLACEMENT - FEMORAL HEAD(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES, FINER)-TOTAL HIP REPLACEMENT (UN-CEMENTED) ISINTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESS FIT (CEMENT LESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B. CORRECTION OF FUNCTIONAL DEFORMITY. C. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,TOTAL HIP REPLACEMENT - FEMORAL HEAD(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES, FINER)-TOTAL HIP REPLACEMENT (UN-CEMENTED) IS INTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESS FIT (CEMENT LESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B. CORRECTION OF FUNCTIONAL DEFORMITY. C. TREATMENT OF NON-UNION, FEMORAL NECK

	FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,BONE SCREWS(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-SCREWS (BONE SCREW, LOCKED SCREWS, LOCKING BOLTS) ALONG WITH PLATES, NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC, SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE USED EITHER TO FASTEN PLATES, INTERLOCKING NAILS OR SIMILAR DEVICES ONTO BONES OR, AS LAG SCREWS, TO HOLD BONE FRAGMENTS TOGETHER AFFECTED BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. SCREW IS INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE. WASHERS MAY BE USED WITH THE SCREWS IN CERTAIN APPLICATIONS.,BONE SCREWS(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-SCREWS (BONE SCREW, LOCKED SCREWS, LOCKING BOLTS) ALONG WITH PLATES, NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC, SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE USED EITHER TO FASTEN PLATES, INTERLOCKING NAILS OR SIMILAR DEVICES ONTO BONES, OR, AS LAG SCREWS, TO HOLD BONE FRAGMENTS TOGETHER AFFECTED BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. SCREW IS INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE. WASHERS MAY BE USED WITH THE SCREWS IN CERTAIN APPLICATIONS.,BONE PINS & WIRES(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-INDICATIONS FOR PINS AND WIRES INCLUDE FIXATION OF BONE FRACTURES, BONE RECONSTRUCTIONS, AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS AND IMPLANTED THROUGH THE SKIN FOR TRACTION APPLIED TO THE SKELETAL SYSTEM.,SPINAL IMPLANTS(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-SPINAL IMPLANTS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THORACIC, LUMBAR, AND SACRAL SPINE: FRACTURE, DISLOCATION, FAILED PREVIOUS FUSION (PSEUDOARTHROSIS), SPINAL STENOSIS, DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, SPINAL DEFORMATIONS SUCH AS SCOLIOSIS OR KYPHOSIS AND LOSS OF STABILITY DUE TO TUMORS. SPINAL IMPLANTS ARE INTENDED TO BE USED AS A TEMPORARY

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO IN CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

	CONSTRUCT THAT ASSISTS NORMAL HEALING AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES. THEY ARE INTENDED TO STABILIZE THE SPINAL OPERATIVE SITE DURING FUSION PROCEDURES AND SHOULD BE REMOVED AFTER FUSION.,TOTAL KNEE REPLACEMENT - FEMORAL & TIBIAL COMPONENT (SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-TOTAL KNEE REPLACEMENT (TKR) IS INTENDEDTO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION INPATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TKR MAY BE CONSIDERED FOR YOUNGERPATIENTSIF, INTHE OPINION OFTHESURGEON,ANUNEQUIVOCAL INDICATIONFORTKROUTWEIGHS THERISKS ASSOCIATEDWITH THEAGEOFTHEPATIENT, ANDIF LIMITEDDEMANDS REGARDINGACTIVITY ANDKNEE JOINT LOADING CANBEASSURED. THIS INCLUDES SEVERELYCRIPPLEDPATIENTSWITH MULTIPLEJOINT INVOLVEMENT FORWHOMAGAININKNEE MOBILITYMAYLEADTOANEXPECTATION OF SIGNIFICANT IMPROVEMENT INTHEQUALITYOF THEIRLIVES. TKRISINDICATED FORASEVERELY PAINFUL AND/ORDISABLED JOINTFROM OSTEOARTHRITIS,POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS ORAFAILEDPREVIOUS IMPLANT.,BONE PINS & WIRE (SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-INDICATIONS FOR PINS AND WIRES INCLUDE FIXATION OF BONE FRACTURES, BONE RECONSTRUCTIONS, AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS AND IMPLANTED THROUGH THE SKIN FOR TRACTION APPLIED TO THE SKELETAL SYSTEM.,TOTAL KNEE REPLACEMENT - TIBIAL & FEMORAL COMPONENT(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-TOTAL KNEE REPLACEMENT (TKR) IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION INPATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TKR MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TKR OUTWEIGHS THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM AGAIN IN KNEE MOBILITY MAY LEAD TO AN EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. TKR IS INDICATED FOR A SEVERELY PAINFUL AND/OR DISABLED JOINT FROM OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR A FAILED PREVIOUS IMPLANT.,BONE NAILS(SHARMA,

	SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-INDICATIONS FOR INTERLOCKING NAILS INCLUDE SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL- UNIONS; AND BONE LENGTHENING/SHORTENING. FEMORAL INTERLOCKING NAILS INCLUDE THE INDICATION FOR PROXIMAL, MIDDLE AND DISTAL THIRD FEMORAL SHAFT FRACTURES. TIBIAL INTERLOCKING NAILS ALSO INCLUDE THE SAME INDICATIONS FOR TIBIAL SHAFT FRACTURES.,BONE PLATES(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-PLATES ARE INDICATED FOR USE IN FIXATION OFVARIOUS FRACTURED BONES BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING.,TOTAL KNEE REPLACEMENT - TIBIAL & FEMORAL COMPONENT(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-TOTAL KNEE REPLACEMENT (TKR) IS INTENDEDTO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION INPATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TKR MAY BE CONSIDERED FOR YOUNGERPATIENTSIF, IN THE OPINION OFTHESURGEON,ANUNEQUIVOCAL INDICATIONFORTKROUTWEIGHS THERISKS ASSOCIATEDWITH THEAGEOFTHEPATIENT, ANDIF LIMITEDDEMANDS REGARDINGACTIVITY ANDKNEE JOINT LOADING CANBEASSURED. THIS INCLUDES SEVERELYCRIPPLEDPATIENTSWITH MULTIPLEJOINT INVOLVEMENT FORWHOMAGAININKNEE MOBILITYMAYLEADTOANEXPECTATION OF SIGNIFICANT IMPROVEMENT INTHEQUALITYOF THEIRLIVES. TKRISINDICATED FORASEVERELY PAINFUL AND/ORDISABLED JOINTFROM OSTEOARTHRITIS,POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS ORAFAILEDPREVIOUS IMPLANT.,BONE PLATES(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-PLATES ARE INDICATED FOR USE IN FIXATION OFVARIOUS FRACTURED BONES BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING., TOTAL KNEE REPLACEMENT - PATELLAR & TIBIAL TRAY COMPONENT (SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-TOTAL KNEE REPLACEMENT (TKR) IS INTENDEDTO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION INPATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TKR MAY BE CONSIDERED FOR YOUNGERPATIENTSIF, IN THE OPINION OFTHESURGEON,ANUNEQUIVOCAL

	INDICATIONFORTKROUTWEIGHS THERISKS ASSOCIATEDWITH THEAGEOFTHEPATIENT, ANDIF LIMITEDDEMANDS REGARDINGACTIVITY ANDKNEE JOINT LOADING CANBEASSURED. THIS INCLUDES SEVERELYCRIPPLEDPATIENTSWITH MULTIPLEJOINT INVOLVEMENT FORWHOMAGAININKNEE MOBILITYMAYLEADTOANEXPECTATION OF SIGNIFICANT IMPROVEMENT INTHEQUALITYOF THEIRLIVES. TKRISINDICATED FORASEVERELY PAINFUL AND/ORDISABLED JOINTFROM OSTEOARTHRITIS,POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS ORAFAILEDPREVIOUS IMPLANT.,TOTAL HIP REPLACEMENT - FEMORAL STEM(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES, FINER)-TOTAL HIP REPLACEMENT (UN-CEMENTED) ISINTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESS FIT (CEMENT LESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B. CORRECTION OF FUNCTIONAL DEFORMITY. C. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,TOTAL HIP REPLACEMENT - FEMORAL STEM(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES, FINER)-TOTAL HIP REPLACEMENT (UN-CEMENTED) ISINTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESS FIT (CEMENT LESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B. CORRECTION OF FUNCTIONAL DEFORMITY. C. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER

	TECHNIQUES. D. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,BONE NAILS(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-INDICATIONS FOR INTERLOCKING NAILS INCLUDE SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL- UNIONS; AND BONE LENGTHENING/SHORTENING. FEMORAL INTERLOCKING NAILS INCLUDE THE INDICATION FOR PROXIMAL, MIDDLE AND DISTAL THIRD FEMORAL SHAFT FRACTURES. TIBIAL INTERLOCKING NAILS ALSO INCLUDE THE SAME INDICATIONS FOR TIBIAL SHAFT FRACTURES.,TOTAL SHOULDER REPLACEMENT - HUMERAL STEM WITH HEAD(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-PRODUCT IS INDICATED FOR USE IN SHOULDERARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED SHOULDER FUNCTION IN SKELETALLY MATURE PATIENTS WITH ENOUGH AND SATISFACTORY BONE STOCK TO SUPPORT THE PROSTHESIS WITH THE FOLLOWING CONDITIONS: A. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND A VASCULAR NECROSIS. B. RHEUMATOID ARTHRITIS. C. REVISION WHERE OTHER DEVICES OR TREATMENTS HAVE FAILED. D. CORRECTION OF FUNCTIONAL DEFORMITY. E. FRACTURES OF THE PROXIMAL HUMERUS, WHERE OTHER METHODS OF TREATMENT ARE DEEMED INADEQUATE. F. DIFFICULT CLINICAL MANAGEMENT PROBLEMS, INCLUDING CUFF ARTHROPATHY, WHERE OTHER METHODS OF TREATMENT MAYNOT BE SUITABLE OR MAY BE INADEQUATE.,TOTAL SHOULDER REPLACEMENT - HUMERAL STEM WITH HEAD(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-PRODUCT IS INDICATED FOR USE IN SHOULDERARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED SHOULDER FUNCTION IN SKELETALLY MATURE PATIENTS WITH ENOUGH AND SATISFACTORY BONE STOCK TO SUPPORT THE PROSTHESIS WITH THE FOLLOWING CONDITIONS: A. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND A VASCULAR NECROSIS. B. RHEUMATOID ARTHRITIS. C. REVISION WHERE OTHER DEVICES OR TREATMENTS HAVE FAILED. D. CORRECTION OF FUNCTIONAL DEFORMITY. E. FRACTURES OF THE PROXIMAL HUMERUS, WHERE OTHER METHODS OF TREATMENT ARE DEEMED INADEQUATE. F. DIFFICULT CLINICAL MANAGEMENT PROBLEMS, INCLUDING CUFF ARTHROPATHY, WHERE OTHER METHODS OF TREATMENT MAYNOT BE SUITABLE OR MAY BE INADEQUATE.,ORAL MAXILLOFACIAL IMPLANTS(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-ORAL-MAXILLOFACIAL IMPLANTS ARE INDICATED FOR USE IN FRACTURE FIXATION, MANDIBULAR RECONSTRUCTION AND SURGERY INVOLVING OSTEOTOMIES, ORTHOGNATHIC RECONSTRUCTION OR SURGERY.

	SURGERY RELATED TO DENTO-FACIAL OR FACIAL CAVITY AND TRAUMA DUE TO IT. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING.,TOTAL HIP REPLACEMENT - ACETABULAR CUP (SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES, FINER)-TOTAL HIP REPLACEMENT (UN-CEMENTED) ISINTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESS FIT (CEMENT LESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B. CORRECTION OF FUNCTIONAL DEFORMITY. C. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,TOTAL HIP REPLACEMENT - ACETABULAR CUP(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES, FINER)-TOTAL HIP REPLACEMENT (UN-CEMENTED) IS INTENDED FOR USE IN THE TOTAL HIP ARTHROPLASTY AND IS INTENDED FOR PRESS FIT (CEMENT LESS) USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SIT AND SUPPORT THE COMPONENTS. TOTAL HIP REPLACEMENT IS INDICATED IN THE FOLLOWING CONDITIONS. A. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AND AVASCULAR NECROSIS. B. CORRECTION OF FUNCTIONAL DEFORMITY. C. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE, AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE BY OTHER TECHNIQUES. D. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,TOTAL KNEE REPLACEMENT - TIBIAL & FEMORAL COMPONENT(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-TOTAL KNEE REPLACEMENT (TKR) IS INTENDEDTO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION INPATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE

		TO SEAT AND SUPPORT THE COMPONENTS. TKR MAY BE CONSIDERED FOR YOUNGERPATIENTSIF, IN THE OPINION OFTHESURGEON,ANUNEQUIVOCAL INDICATIONFORTKROUTWEIGHS THERISKS ASSOCIATEDWITH THEAGEOFTHEPATIENT, ANDIF LIMITEDDEMANDS REGARDINGACTIVITY ANDKNEE JOINT LOADING CANBEASSURED.THIS INCLUDES SEVERELYCRIPPLEDPATIENTSWITH MULTIPLEJOINT INVOLVEMENT FORWHOMAGAININKNEE MOBILITYMAYLEADTOANEXPECTATION OF SIGNIFICANT IMPROVEMENT INTHEQUALITYOF THEIRLIVES. TKRISINDICATED FORASEVERELY PAINFUL AND/ORDISABLED JOINTFROM OSTEOARTHRITIS,POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS ORAFAILEDPREVIOUS IMPLANT.,BONE SCREWS(SHARMA, SPCPL, DKSORTHO, DKSORTHO MEDICAL DEVICES)-SCREWS (BONE SCREW, LOCKED SCREWS, LOCKING BOLTS) ALONG WITH PLATES NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC, SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE USED EITHER TO FASTEN PLATES, INTERLOCKING NAILS OR SIMILAR DEVICES ONTO BONES, OR, AS LAG SCREWS, TO HOLD BONE FRAGMENTS TOGETHER AFFECTED BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. SCREW IS INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE. WASHERS MAY BE USED WITH THE SCREWS IN CERTAIN APPLICATIONS.
3334	MFG/MD/2019/000197	1.License Holder Name: SEWAGRAM SURGICAL PRODUCTS 2.Approving Authority: NAGPUR DIVISION 3.Device Name(Brand Name)-Intended Use:BANDAGE CLOTH F-II (SEWAGRAM)-FOR EXTERNAL USE ONLY-USED IN SURGICAL DRESSINGS,ABSORBANT GAUZE CLOTH F-II(SEWAGRAM)-FOR EXTERNAL USE ONLY-USED IN SURGICAL DRESSINGS,ROLLED BANDAGE CLOTH F-II(SEWAGRAM)-FOR EXTERNAL USE ONLY-USED IN SURGICAL DRESSINGS

3335	MFG/MD/2019/000198	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT. LTD. 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:DELIVERY SYSTEM / LENS DELIVERY SYSTEM / DS / LDS- DELIVERY SYSTEM (DS) IS INTENDED TO BE USED TO PROGRESSIVELY FOLD / COMPRESS AND INSERT THE FOLDABLE IOL DURING CATARACT SURGERY. ,DELIVERY SYSTEM / LENS DELIVERY SYSTEM / DS / LDS(TEXEL SOFT)- DELIVERY SYSTEM (DS) IS INTENDED TO BE USED TO PROGRESSIVELY FOLD / COMPRESS AND INSERT THE FOLDABLE IOL DURING CATARACT SURGERY. ,DELIVERY SYSTEM / LENS DELIVERY SYSTEM / DS / LDS (INTRAOPTICS SOFT)- DELIVERY SYSTEM (DS) IS INTENDED TO BE USED TO PROGRESSIVELY FOLD / COMPRESS AND INSERT THE FOLDABLE IOL DURING CATARACT SURGERY. ,PMMA IOL- INTRAOCULAR LENSES (IOL) ARE IMPLANTED IN HUMAN EYE AS A REPLACEMENT OF HUMAN CRYSTALLINE LENS IN CATARACT SURGERY.,PMMA IOL(TEXEL)- INTRAOCULAR LENSES (IOL) ARE IMPLANTED IN HUMAN EYE AS A REPLACEMENT OF HUMAN CRYSTALLINE LENS IN CATARACT SURGERY.,PMMA IOL (INTRAOPTICS)- INTRAOCULAR LENSES (IOL) ARE IMPLANTED IN HUMAN EYE AS A REPLACEMENT OF HUMAN CRYSTALLINE LENS IN CATARACT SURGERY.,CAPSULAR TENSION RING / ENDO CAPSULAR RING / CTR-CAPSULAR TENSION RINGS (CTR) ARE IMPLANTED IN HUMAN EYE PRIOR TO THE IOL IMPLANT DURING THE CATARACT SURGERY FOR EXPANSION & STABILIZATION OF THE CAPSULAR BAG TO FACILITATE IOL IMPLANTATION & MAINTAINING EXCELLENT IOL CENTRATION. .,CAPSULAR TENSION RING / ENDO CAPSULAR RING / CTR(TEXEL)-CAPSULAR TENSION RINGS (CTR) ARE IMPLANTED IN HUMAN EYE PRIOR TO THE IOL IMPLANT DURING THE CATARACT SURGERY FOR EXPANSION & STABILIZATION OF THE CAPSULAR BAG TO FACILITATE IOL IMPLANTATION & MAINTAINING EXCELLENT IOL CENTRATION. ,PMMA IOL(EPOCH)-INTRAOCULAR LENSES (IOL) ARE IMPLANTED IN HUMAN EYE AS A REPLACEMENT OF HUMAN CRYSTALLINE LENS IN CATARACT SURGERY. ,CAPSULAR TENSION RING / ENDO CAPSULAR RING / CTR(INTRAOPTICS)-CAPSULAR TENSION RINGS (CTR) ARE IMPLANTED IN HUMAN EYE PRIOR TO THE IOL IMPLANT DURING THE CATARACT SURGERY FOR EXPANSION & STABILIZATION OF THE CAPSULAR BAG TO FACILITATE IOL IMPLANTATION & MAINTAINING EXCELLENT IOL CENTRATION.

3336	MFG/MD/2019/000199	1.License Holder Name: POLY MEDICURE LIMITED 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTION TUBE - WITH ACDA (EVACUATED TUBE)(HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE-K2EDTA (EVACUATED TUBE)(HAEMOCHEK, LABOR IMPORT K2EDTA, GT- VACUUM TUBO PARA COLETA DE SANGUE A VACUO EDTA K2)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - WITH SODIUM FLUORIDE, K3EDTA (EVACUATED TUBE)(HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - SERUM WITH CLOT ACTIVATOR (EVACUATED TUBE)(HAEMOCHEK, LABOR IMPORT SILICONIZADO, VACUPLAST COLLECT, FARMA VISION SILICONIZADO LINE ATIVADOR DE COAGULO, GT- VACUUM TUBO PARA COLETA DE SANGUE A VACUO PRO COAGULACAO)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - FOR SERUM, WITHOUT CLOT ACTIVATOR (EVACUATED TUBE) (HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - SODIUM CITRATE 4NC (NON EVACUATED TUBE)(NOVAC)-THE PRODUCTS ARE USED FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - FOR SERUM, WITH GEL (EVACUATED TUBE)(HAEMOCHEK, FARMA VISION GEL, LABOR IMPORT GEL, GT. VACUUM)-THE PRODUCTS ARE USED TOGETHER

	WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE- CPDA (EVACUATED TUBE)(HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - WITH SODIUM CITRATE 4NC (EVACUATED TUBE)(HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE- SODIUM HEPARIN TUBE (EVACUATED TUBE)(HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - WITH SODIUM HEPARIN (EVACUATED TUBE)(HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE- ACDA (EVACUATED TUBE)(HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY, BLOOD COLLECTION TUBE - K3EDTA (EVACUATED TUBE)(LABOR IMPORT K3EDTA, FARMA VISION K3EDTA, GT- VACUUM K3EDTA, "VACUPLAST COLLECT LINE K3EDTA)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY., BLOOD COLLECTION TUBE- SODIUM FLUORIDE NA2EDTA (EVACUATED TUBE)(HAEMOCHEK, LABOR IMPORT FLUORETO, FARMA VISION FLUORETO, VACUPLAST COLLECT LINE FLUORETO DE SODIO, GT- VACUUM TUBO PARA COLETA DE SANGUE A VACUO

	FLUORETO DE SODIO)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - WITH LITHIUM HEPARIN (EVACUATED TUBE)(HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - K3EDTA (EVACUATED TUBE)(HAEMOCHEK, LABOR IMPORT K3EDTA, FARMA VISION K3EDTA, VACUPLAST COLLECT LINE EDTA K3)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - WITH K3EDTA (EVACUATED TUBE)(HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE -SODIUM CITRATE 9NC (EVACUATED TUBE)(HAEMOCHEK, LABOR IMPORT 3.2% CITRATO, FARMA VISION 3.2% CITRATO, VACUPLAST COLLECT LINE CITRARO DE SODIO, GT- VACUUM TUBO PARA COLETA DE SANGUE A VACUO 3.2% CITRATO)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,RYLES TUBE (NASOGASTRIC TUBE) -IT IS A NASO-GASTRIC TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT MAY ALSO BE USED FOR ASPIRATION OF INTESTINAL SECRETIONS. , INFUSION SET FOR SINGLE USE [IS 12655-4] [ISO 8536-4] (AUTOFUSION SET (I V INFUSION SET))-INFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,BLOOD COLLECTION TUBE - WITH LITHIUM HEPARIN (EVACUATED TUBE)(GT VACUUM TUBO PARA COLETA DE SANGUE A VACUO HEPARINA LITIO) -THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT

	AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE-SODIUM FLUORIDE K3EDTA (EVACUATED TUBE)(HAEMOCHEK, LABOR IMPORT FLUORETO)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - WITH K2EDTA (EVACUATED TUBE)(LABOR IMPORT K2EDTA, GT- VACUUM TUBO PARA COLETA DE SANGUE A VACUO EDTA K2)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE-LITHIUM HEPARIN TUBE (EVACUATED TUBE)(HAEMOCHEK, GT-VACUUM TUBO PARA COLETA DE SANGUE A VACUO HEPARINA LITIO) -THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - WITH SODIUM CITRATE 9NC (EVACUATED TUBE)(LABOR IMPORT 3.2% CITRATO, FARMA VISION 3.2% CITRATO, VACUPLAST COLLECT LINE CITRARO DE SODIO, "GT- VACUUM TUBO PARA COLETA DE SANGUE A VACUO 3.2% CITRATO)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE -SODIUM CITRATE 4NC (EVACUATED TUBE)(HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,ALCOHOL SWAB (70% IPA) (POLYPREP)-IT IS A SINGLE USE, STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE. ,BLOOD COLLECTION TUBE- SERUM WITH CLOT ACTIVATOR (NON EVACUATED TUBE)(NOVAC)-THE PRODUCTS ARE USED FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD

	COLLECTION TUBE - WITH SODIUM CITRATE 9NC (EVACUATED TUBE) (HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE -SERUM GEL (EVACUATED TUBE)(HAEMOCHEK, FARMA VISION GEL, LABOR IMPORT GEL, GT- VACUUM TUBO PARA COLETA DE SANGUE A VACUO GEL E CLOT)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY., BLOOD COLLECTION TUBE - SODIUM FLUORIDE, NA2EDTA (EVACUATED TUBE)(LABOR IMPORT FLUORETO, FARMA VISION FLUORETO, VACUPLAST COLLECT LINE FLUORETO DE SODIO, "GT VACUUM TUBO PARA COLETA DE SANGUE A VACUO FLUORETO DE SODIO)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE -SERUM GEL (NON EVACUATED TUBE)(NOVAC)-THE PRODUCTS ARE USED FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY, INFANT FEEDING TUBE (POLYFEED TUBE)-INFANT FEEDING TUBE IS USED TO PROVIDE FEEDING TO NEONATES AND INFANTS. IT IS A SMALL, SOFT TUBE. PLACED THROUGH THE NOSE OR MOUTH IN TO STOMACH. ,BLOOD COLLECTION TUBE - SODIUM FLUORIDE + NA2EDTA (GLUCOSE ESTIMATION TUBE) (NON EVACUATED TUBE) "(NOVAC)-THE PRODUCTS ARE USED FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,TRANSFUSION SET FOR SINGLE USE (IS:9824-3)(ISO:1135-4) DISPOSABLE BLOOD ADMINISTRATION SET WITH AIR VENT (BLOOD ADMINISTRATION SET) (IDEALCARE)-TRANSFUSION SET IS USED ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,BLOOD COLLECTION TUBE -SERUM WITHOUT CLOT ACTIVATOR (NON EVACUATED TUBE)(NOVAC)-THE PRODUCTS ARE USED FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,

	ALCOHOL SWAB (70% IPA)-IT IS A SINGLE USE, STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE. ,BLOOD COLLECTION TUBE - SODIUM FLUORIDE K3EDTA (GLUCOSE ESTIMATION TUBE) (NON EVACUATED TUBE) (NOVAC)-THE PRODUCTS ARE USED FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,INFUSION SET FOR SINGLE USE (IS; 12655-4)(ISO: 8536-4 &5) (BURETTE SET WITH Y –SITE, ROTATING LUER CONNECTOR)-USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,SUCTION CATHETER [ISO 8836](TENDER TIP (OPEN SUCTION CATHETER))-SUCTION CATHETERS (FEATURING A PLAIN, TIP OR A THUMB CONTROL) IS USED TO PROVIDE ACCESS TO RESPIRATORY TRACT FOR SUCTIONING SECRETION WITH PRECISION AND MAXIMUM COMFORT TO THE PATIENT.,BLOOD COLLECTION TUBE - FOR SERUM, WITH CLOT ACTIVATOR (EVACUATED TUBE)(LABOR IMPORT SILICONIZADO, VACUPLAST COLLECT, GT- VACUUM, FARMA VISION SILICONIZADO LINE ATIVADOR DE COAGULO)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,EXTENSION LINE AS AN ACCESSORY OF INFUSION SET [ISO 8536-9](DISPOSABLE EXTENSION SET)-THESE ARE STERILE SINGLE USE DEVICES INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION. CAN BE USED TO CONNECT A PERFUSION SET OR CATHETER FOR INFUSION. USED TO CONNECT THE INFUSION SITE AND THE SOURCE OF INFUSION (I.E. TO CONNECT THE IV CANNULA OR THREE WAY STOP COCK AND IV SET) TO EXTENDED THE PATH BETWEEN INFUSION SITE & SOURCE OF INFUSION.,BLOOD COLLECTION TUBE - SODIUM FLUORIDE, K3EDTA (EVACUATED TUBE) (LABOR IMPORT FLUORETO)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE - SODIUM CITRATE 9NC (NON EVACUATED TUBE) (NOVAC)-THE PRODUCTS ARE USED FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE

	BLOOD IN THE CLINICAL LABORATORY,INFUSION SET FOR SINGLE USE (IS; 12655-4)(ISO: 8536-4) (I.V. FLUID INFUSION SET) (AUTOFUSION)-USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,BLOOD COLLECTION TUBE - K2EDTA (NON EVACUATED TUBE)(NOVAC)-THE PRODUCTS ARE USED FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,LEVIN'S TUBE-LEVIN'S TUBE IS USE FOR GASTRO-INTESTINAL FEEDING AND ASPIRATION OF INTESTINAL SECRETIONS. LEVIN'S TUBE IS A TUBE THAT IS INSERTED THROUGH THE NOSE IN TO UPPER ALIMENTARY CANAL.,BLOOD COLLECTION TUBE - SODIUM HEPARIN (NON EVACUATED TUBE)(NOVAC)-THE PRODUCTS ARE USED FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - WITH SODIUM FLUORIDE, NA2EDTA (EVACUATED TUBE) (HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE -LITHIUM HEPARIN (NON EVACUATED TUBE)(NOVAC)-THE PRODUCTS ARE USED FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - K2EDTA (EVACUATED TUBE)(HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY.,BLOOD COLLECTION TUBE-SERUM WITHOUT CLOT ACTIVATOR (EVACUATED TUBE) (HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,INFUSION SET FOR SINGLE USE, GRAVITY FEED [ISO 8536-4](TRO-SOLUSET)-THE INFUSION SETS ARE USED ONLY FOR GRAVITY FEED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER OR CANNULA.,INFUSION SET FOR SINGLE USE [IS 12655-4] [ISO 8536-4](DISPOSABLE

	INFUSION SET)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,3-WAY STOP COCK WITH EXTENSION LINE (ISO:8536-9) (3-WAY CONNECTOR WITH EXTENSION TUBING)-INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,INFUSION SET FOR SINGLE USE (WITH AIR VENTED SPIKE) [IS 12655-4] [ISO 8536-4] (BLUE DOT)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,BLOOD COLLECTION TUBE - WITH CPDA (EVACUATED TUBE)(HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY., BLOOD COLLECTION TUBE - K3EDTA (NON EVACUATED TUBE) (NOVAC)-THE PRODUCTS ARE USED FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,BLOOD COLLECTION TUBE - FOR SERUM, WITH CLOT ACTIVATOR (EVACUATED TUBE) (HAEMOCHEK)-THE PRODUCTS ARE USED TOGETHER WITH BLOOD COLLECTION HOLDERS AND NEEDLES, AS A SYSTEM FOR THE COLLECTION OF VENOUS BLOOD. THE TUBES ARE USED TO COLLECT, TRANSPORT AND PROCESS BLOOD FOR TESTING SERUM, PLASMA OR WHOLE BLOOD IN THE CLINICAL LABORATORY,NELATON CATHETER (URETHRAL)(NELATON CATHETER)-NELATON CATHETER IS USED TO PROVIDE ACCESS TO THE BLADDER THROUGH URETHRA IN CASE OF URINARY RETENTION ESPECIALLY IN MALES. THE NELATON CATHETER HAS NO BALLOON ON ITS TIP.,INFUSION SET FOR SINGLE USE (IS; 12655-4)(ISO: 8536-4) (I.V. FLUID INFUSION SET)-USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT' S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE., INFUSION SET FOR SINGLE USE (WITH MICRO DRIP AND FLOW REGULATOR) [IS 12655-4] [ISO 8536-4](POLYTROL SET (INTRAVENOUS INFUSION SET))-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,SUCTION TUBE-SUCTION SET IS USED FOR PRE-OPERATIVE REMOVAL OF SECRETION, BLOOD & POSTOPERATIVE FLUIDS AFTER SURGERY., THREE WAY STOP COCK (AS AN ACCESSORY OF PERFUSION SET) (POLYWAY, POLYWAY PRO, THREE WAY STOP COCK (POLYMEDICURE))-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL

	CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, INFUSION SET FOR SINGLE USE [IS 12655-4] [ISO:8536-4] (AUTOFUSION SET (I V INFUSION SET))-INFUSION SET IS USED ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,NASAL OXYGEN CANNULA/CATHETER(NASOCATH)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,INFUSION SET FOR SINGLE USE (WITH AIR VENT) IS 12655-4; ISO 8536-4(IDEALCARE INTRAVENOUS ADMINISTRATION SET WITH AIRVENT)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER OR CANNULA.,EXTENSION LINE AS AN ACCESSORY OF INFUSION SET [ISO 8536-9](POLY SYTE MONO, POLY SYTE DUO, POLY SYTE TRIO, MICRO POLY SYTE-MONO, MICRO POLY SYTE DUO, MICRO POLY SYTE DUO, MICRO POLY SYTE TRIO, MICRO POLY SYTE TRIO (LUER))-THESE ARE STERILE SINGLE USE DEVICES INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION. IT CAN BE USED TO CONNECT A PERFUSION SET OR CATHETER FOR INFUSION. USED TO CONNECT THE INFUSION SITE AND THE SOURCE OF INFUSION., ENDOTRACHEAL TUBE (PLAIN AND CUFFED) [IS/ISO 5361] (ENDOTRACHEAL TUBE (PLAIN/CUFFED))-ENDOTRACHEAL TUBE IS A CATHETER THAT IS INSERTED INTO THE TRACHEA FOR THE PRIMARY PURPOSE OF ESTABLISHING AND MAINTAINING A PATIENT AIR WAY AND TO ENSURE RESPIRATION IN PATIENTS CONNECTED WITH RESPIRATORY SYSTEM DURING OPERATION OR WHO LOOSE ACTIVE BREATH ABILITY., FOLEY CATHETER(FOLEY BALLOON CATHETER)-A LONG, SMALL GAUGE STERILE CATHETER USED FOR INSERTION INTO THE BLADDER THROUGH URETHRA TO DRAIN URINE. IT IS HELD IN PLACED WITH A BALLOON AT THE END.,THREE WAY STOP COCK WITH EXTENSION LINE (AS AN ACCESSORY OF PERFUSION SET)(POLYWAY WITH EXTENSION TUBE.)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] IV CANNULA WITH INJECTION PORT AND WINGS(POLYFLON)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD/BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., UMBILICAL ARTERY CATHETER(UMBILICAL CATHETER)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE

	ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS., LEVINS TUBE(LEVINS TUBE)-LEVIN'S TUBE IS USED FOR GASTRO-INTESTINAL FEEDING AND ASPIRATION OF INTESTINAL SECRETIONS. LEVIN'S TUBE IS A TUBE THAT IS INSERTED THROUGH THE NOSE INTO THE UPPER ALIMENTARY CANAL.,INFUSION SET FOR SINGLE USE [IS 12655-4] [ISO 8536-4](POLYFUSION SET WITH THREE WAY STOP COCK (IV SET))-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I.V. CANNULA WITH WINGS WITHOUT INJECTION PORT(POLYCAN)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD/BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THORACIC DRAINAGE CATHETER (STRAIGHT/CURVED; WITH AND WITHOUT TROCAR)(ULTRACATH NOVO)-THORACIC DRAINAGE CATHETER IS A SURGICAL DRAIN USED FOR POST OPERATIVE DRAINAGE AFTER CARDIO-THORACIC AND THORACIC SURGERY; IN ORDER TO REMOVE BLOOD, SECRETIONS AND AIR WHICH ACCUMULATE IN THE THORAX GENERATING ACUTE CARDIO RESPIRATORY INSUFFICIENCY AND SOMETIMES EVEN DEATH., INFUSION SET FOR SINGLE USE (WITH OR WITHOUT AIR VENT) [IS 12655-4] [ISO 8536-4](MICROFUSION SET (IV SET), POLYFUSION-W SET (IV SET))-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,CLOSE WOUND DRAINAGE SET(POLYVAC, NOVOVAC, NEOVAC)-IT IS SURGICAL DRAIN USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. CLOSED WOUND SUCTION UNIT IS USED IN SURGICAL SPECIALITIES, MANY OF WHICH EMPLOY NEGATIVE PRESSURE WOUND THERAPY TO VERIFY DEGREES AGAINST CHALLENGING WOUNDS.,TRANSFUSION SET FOR SINGLE USE (WITH OR WITHOUT AIR VENT) [IS 9824-3] [ISO 1135-4](BLOOD TRANSFUSION (B.T.) SET, TRANSVOL SET)-TRANSFUSION SET IS USED ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INFUSION SET FOR SINGLE USE [IS 12655-4] [ISO 8536-4](EUROSET 60 INFUSION SET MICRODRIP CHAMBER 60 DROPS/ML, EUROSET 20 INFUSION SET (WITH AIR VENT SPIKE AND FLOW REGULATOR))-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,RECTAL CATHETER(RECTAL CATHETER)-RECTAL CATHETER IS USED FOR INSERTING INTO THE RECTUM IN ORDER TO RELIEVE FLATULENCE

	UNRESPONSIVE TO ACTIVITY OR MEDICATIONS AND ALSO TO DISCHARGE THE WASTE.,INFUSION SET FOR SINGLE USE (BURETTE TYPE) [IS 12655-4] [ISO 8536-4&5](BURETTE SET MEASURED VOLUME FLUID ADMINISTRATION SET, POLYVOL BURETTE SET, POLYVOL PRO, SENSIMEDICAL BURETA EQUIPE DE VOLUMENES MEDIDIS(BURETTE SET 100 ML, 150 ML))-INFUSION SET BURETTE TYPE IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN, STERILE SINGLE USE SCALP VEIN INFUSION SET [IS 16097] (SCALP VEIN SET)-SCALP VEIN SET IS INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,FEMALE URETHRAL CATHETER(FEMALE CATHETER)-FEMALE CATHETER IS USED TO PROVIDE ACCESS TO THE BLADDER THROUGH URETHRA IN CASE OF URINARY RETENTION IN FEMALES. THE FEMALE CATHETER HAS NO BALLOON ON ITS TIP AND IS FOR SHORT TERM USE.,I.V. FLOW REGULATOR (AS AN ACCESSORY OF INFUSION SET)(POLY FLO, POLY FLO NOVO)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY,PERITONEAL DIALYSIS SET(PERITONEAL DIALYSIS SET)-PERITONEAL DIALYSIS CATHETER KIT IS USED TO ALLOW DIALYSIS FLUID TO FLOW INTO AND OUT OF THE PERITONEAL CAVITY. IT HELPS TO REMOVE EXTRA FLUID AND WASTE PRODUCTS FROM THE BODY.,EXTENSION LINE AS AN ACCESSORY OF INFUSION SET [ISO 8536-9](EXTENSION TUBE)-THESE ARE STERILE SINGLE USE DEVICES INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION. IT CAN BE USED TO CONNECT A PERFUSION SET OR CATHETER FOR INFUSION. USED TO CONNECT THE INFUSION SITE AND THE SOURCE OF INFUSION.,THREE WAY STOP COCK WITH EXTENSION LINE (AS AN ACCESSORY OF PERFUSION SET)(DISPOSABLE EXTENSION SET (XTEN-R30, XTEN-R10, XTEN-R50, XTEN-R15, XTEN-R100 , XTEN-R75))-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I.V. CANNULA WITHOUT INJECTION PORT & WINGS(POLYWIN, POLYON, POLYPEN)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., STOMACH TUBE(STOMACH TUBE)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUIDS.

	EXTENSION LINE AS AN ACCESSORY OF INFUSION SET [ISO 8536-9] (HIGH PRESSURE EXTENSION TUBE, EUROSET EXTENSION SET)-THESE ARE STERILE SINGLE USE DEVICES INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION. IT CAN BE USED TO CONNECT A PERFUSION SET OR CATHETER FOR INFUSION. USED TO CONNECT THE INFUSION SITE AND THE SOURCE OF INFUSION.,INFUSION SET FOR SINGLE USE [IS 12655-4] [ISO 8536-4](DISPOSABLE INFUSION SET(INFU-R3, INFU-R6, INFU-R1, INFU-R3X, INFU-1, INFU-1X ,INFU-1Y, INFU-YR3, INFU-RY2))-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INFANT FEEDING TUBE(POLYFEED, NOVOFEED)-INFANT FEEDING TUBE IS USED TO PROVIDE FEEDING TO NEONATES AND INFANTS. IT IS A SMALL, SOFT, PLASTIC TUBE PLACED THROUGH THE NOSE OR MOUTH INTO THE STOMACH.,INFUSION SET FOR SINGLE USE [IS 12655-4] [ISO 8536-4](SENSIMEDICAL EQUIPO PARA VENOCLISIS NORMOGOTERO(IV SET MACRO WITH AIR VENT), SENSIMEDICAL EQUIPO PARA VENOCLISIS MICROGOTERO (IV SET MICRO WITH AIR VENT))-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I.V. CANNULA WITH INJECTION PORT SNAPFIT CAP & SUTURABLE WINGS. (POLYSAFETY)-SAFETY IV CANNULA IS USED TO PROVIDE ACCESS INTO THE PERIPHERAL VASCULAR SYSTEM FOR THE ADMINISTRATION OF FLUIDS AND DRUGS AND FOR WITHDRAWAL OF BLOOD. THE PRODUCT HAS INTEGRATED PASSIVE SAFETY FEATURES TO COVER THE NEEDLE AFTER USE TO PREVENT THE ACCIDENTAL NEEDLE PRICK INJURIES.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I.V. CANNULA WITHOUT INJECTION PORT & WITH SMALL WINGS(POLYNEO)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD/BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I.V. CANNULA WITH INTEGRATED THREE WAY STOP COCK(POLYCATH)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD/BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INFUSION SET FOR SINGLE USE [IS 12655-4] [ISO 8536-4](ONCOFUSION SET (IV SET), NOVOFUSION SET (INTRAVENOUS INFUSION SET), POLYFUSION SET (INTRAVENOUS INFUSION SET),(WITH AIR VENTED SPIKE))-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR

		SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] (IV CANNULA WITH EXTENSION TUBE)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., OXYGEN CATHETER(OXYGEN CATHETER)-OXYGEN CATHETER IS USED FOR ADMINISTRATION OF OXYGEN THROUGH THE NASO PHARYNX FOR RESPIRATION IN PATIENTS IN NEED OF RESPIRATORY HELP.,SUCTION CATHETER [ISO 8836](SUCTION CATHETER)-SUCTION CATHETERS (FEATURING A PLAIN, FINGER TIP OR A THUMB CONTROL) IS USED TO PROVIDE ACCESS TO RESPIRATORY TRACT FOR SUCTIONING SECRETIONS WITH PRECISION AND MAXIMUM COMFORT TO THE PATIENT., RYLES TUBE (NASOGASTRIC TUBE)(RYLE'S TUBE)-IT IS A NASO-GASTRIC TUBE THAT CARRIES FOOD AND MEDICINES TO THE STOMACH THROUGH THE NOSE. IT MAY ALSO BE USED FOR ASPIRATION OF INTESTINAL SECRETIONS.
3337	MFG/MD/2019/000200	1.License Holder Name: DISPOSAFE HEALTH AND LIFE CARE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:INTRAVENOUS CANNULA (VYGONULEV,BIOVALVE SAFE,VYCAN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS, AND/OR BLOOD COMPONENTS,OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. ,THREE WAY STOPCOCK AS AN ACCESSORY TO PERFUSION SETS-RED,BLUE AND WHITE HANDLE (VYTAP)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING.

3338	MFG/MD/2019/000201	1.License Holder Name: NEWTECH MEDICAL DEVICES 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:DRUG ELUTING STENT (COHERENT, COMICAL, MEDSURE, AMPLE, AURICLE, QUAINT)-DRUG ELUTING STENT IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS INCLUDING THOSE WITH DIABETES MELITUS., BARE METAL STENT(CROSS STENT, GNEW, GSHINE)-BARE METAL STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETERS IN PATIENTS, INCLUDING THOSE WITH DIABETES MELLITUS, WITH SYMPTOMATIC ISCHEMIC HEART DISEASE ,STABLE ANGINA ,UNSTABLE ANGINA, NON –ST ELEVATION DOCUMENTED DUE TO ARTHERSCLEROTIC LESIONS IN NATIVE CORONARY ARTERIES., DRUG ELUTING STENT(EVRONEW, EVROCROSS, EVROSURE, EVROPLUS,)-EVEROLIMUS CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINA DIAMETERS IN PATIENTS, INCLUDING THOSE WITH DIABETES, MELLITUS, WITH SYMPTOMATIC ISCHEMIC HEART DISEASE, STABLE ANGINA, UNSTABLE ANGINA, NON-ST ELEVATION DOCUMENTED DUE TO ARTHERSCLEROTIC LESIONS IN NATIVE CORONARY ARTERIES
3339	MFG/MD/2019/000202	1.License Holder Name: PROMPT TRADING COMPANY 2.Approving Authority: KERALA 3.Device Name(Brand Name)-Intended Use:GAUZE FOR DRESSING (PTC GAUZE SWAB)-IT IS USED MEDICAL WOUND DRESSINGS AND SURGICAL WOUND DRESSINGS. IT IS USED FOR CLINICAL AND HOSPITAL PURPOSE.,ABSORBENT COTTON GAUZE(PTC GAUZE ABSORBENT)-IT IS USED MEDICAL WOUND DRESSINGS AND SURGICAL WOUND DRESSINGS. IT IS USED FOR CLINICAL AND HOSPITAL PURPOSE.,DRESSING PAD(PTC COMBINE DRESSING PAD)-TO SECURE WOUND, IMMOBILIZATION INJURED BODY PARTS, PROVIDE PRESSURE TO STOP BLEEDING.,ABSORBENT GAUZE WITH COTTON PAD WITH X-RAY DETECTABLE THREAD(PTC ABDOMINAL SPONGE)-IT IS USED MEDICAL WOUND DRESSINGS AND SURGICAL WOUND DRESSINGS. IT IS USED FOR CLINICAL AND HOSPITAL PURPOSE.

3340	MFG/MD/2019/000203	1.License Holder Name: M/S LIFELONG MEDITECH PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITH NEEDLE(CARESS)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,STERILE HYPODERMIC SAFETY NEEDLE FOR SINGLE USE(LIFELONG, DESCARPACK)-A HYPODERMIC SINGLE LUMEN NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITHOUT NEEDLE(CARESS)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITHOUT NEEDLE(SAFEWAY, LIFELONG,LIFELONG MATRIX,LIFELONG PREMIUM, DESCARPACK,MEDICARE,LE ROY,MEDIC-O-PLANET,SF, SF MEDICAL PRODUCTS GMBH,NOVAMED,EUROMIX,DISPROMED,BREMEN, DARLING,SKB,BRILLMED)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE HYPODERMIC NEEDLES FOR SINGLE USE(TOPSAL)-ADMINISTRATIONS OF INJECTIONS OR MEDICINAL FLUIDS INTRAMUSCULAR AND INTRAVENOUS, HYPODERMIC SYRINGE FOR SINGLE USE (BULK PACK ONLY)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY., STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITHOUT NEEDLE (TOPSAL)-ADMINISTRATIONS OF INJECTIONS OR MEDICINAL FLUIDS INTRAMUSCULAR AND INTRAVENOUS,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITH NEEDLE(VOGT MEDICAL (VM))-ADMINISTRATIONS OF INJECTIONS OR MEDICINAL FLUIDS INTRA MUSCULAR AND INTRA VENOUS. ,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITH NEEDLE(TOPSAL)-ADMINISTRATIONS OF INJECTIONS OR MEDICINAL FLUIDS INTRAMUSCULAR AND INTRAVENOUS,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITH NEEDLE(BRITTANIA)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITHOUT NEEDLE(BRITTANIA)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITH NEEDLE(VOGT MEDICAL (VM))-ADMINISTRATIONS OF INJECTIONS OR MEDICINAL FLUIDS INTRA MUSCULAR AND INTRA VENOUS. ,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITH NEEDLE(VOGT MEDICAL (VM))-ADMINISTRATIONS OF INJECTIONS OR MEDICINAL FLUIDS INTRA MUSCULAR AND INTRA VENOUS. ,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITH NEEDLE(SAFEWAY, LIFELONG,LIFELONG MATRIX,LIFELONG PREMIUM,DESCARPACK, MEDICARE,LE ROY,MEDIC-O-PLANET,ALL MAGIC,SF, SF MEDICAL PRODUCTS GMBH,NOVAMED,EUROMIX,DISPROMED,BREMEN,

	DARLING,SKB,BRILLMED)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITH NEEDLE(BRITTANIA)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,STERILE INFUSION SETS FOR SINGLE USE WITH LATEX BULB(SAFEWAY, LIFELONG, DESCARPACK, MEDIC-O-PLANET, ALL MAGIC, BRILLMED)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITHOUT NEEDLE(SF TRIO)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE HYPODERMIC SAFETY SYRINGE (CLIP TYPE) FOR SINGLE USE WITHOUT NEEDLE(SAFEWAY, LIFELONG, LIFELONG SHIELDPRO,DESCARPACK,MEDIC-O-PLANET, CARESS SAFETY,BRILLMED)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE SINGLE USE SYRINGES, WITH OR WITHOUT NEEDLE FOR INSULIN. (LIFELONG PREMIUM AND LIFELONG MATRIX)-PRODUCT IS INTENDED TO SUBCUTANEOUS INJECT THE DESIRED DOSE OF INSULIN.,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITH NEEDLE(MCM)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITH NEEDLE(SF TRIO)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE HYPODERMIC NEEDLES FOR SINGLE USE (MCM)-ADMINISTRATIONS OF INJECTIONS OR MEDICINAL FLUIDS INTRAMUSCULAR AND INTRAVENOUS,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITHOUT NEEDLE(MCM)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,STERILE CATHETER TIP SYRINGE(SAFEWAY, LIFELONG MATRIX, LIFELONG PREMIUM,)-INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS., STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITHOUT NEEDLE (BRITTANIA)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE HYPODERMIC NEEDLES FOR SINGLE USE (SAFEWAY, LIFELONG,DESCARPACK,LE ROY,MEDIC-O-PLANET, NOVAMED,EUROMIX,DISPROMED,BREMEN,DARLING,BRILLMED)-A HYPODERMIC SINGLE LUMEN NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.,CATHETER TIP SYRINGE (BULK PACK ONLY)-INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS,STERILE HYPODERMIC SAFETY SYRINGE (CLIP TYPE) FOR SINGLE USE WITH NEEDLE(SAFEWAY, LIFELONG, LIFELONG

	SHIELDPRO,DESCARPACK,MEDIC-O-PLANET,CARESS SAFETY,SF, SF MEDICAL PRODUCTS GMBH,BRILLMED)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,NEEDLE RETRACTABLE SAFETY SYRINGE(SAFEWAY CLICKZIP , LIFELONG CLICKZIP, CARESS SAFETY , IRASAFETY , SF, SF MEDICAL PRODUCTS GMBH, BRILLMED)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE INFUSION SETS FOR SINGLE USE WITHOUT LATEX BULB(SAFEWAY, LIFELONG, DESCARPACK, MEDIC-O-PLANET, ALL MAGIC, BRILLMED)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3341	MFG/MD/2019/000204	1.License Holder Name: SCEPTRE MEDICAL DEVICES PVT LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC NEEDLE / BIOPSY NEEDLE KIT / BIOPSY GUN(REIN, JETFLOW, JETLITE)-A SET OF NEUROSURGICAL INSTRUMENT DESIGNED TO ALLOW MULTIPLE BIOPSIES FROM ONE OR MORE TARGETS IN ONE TRAJECTORY ,CATHETERS / MULTIPLE LUMEN CATHETER(CADON)-INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTION OR DRUGS,IV CANNULA / TRANSDUCER PROTECTOR AS AN ACCESSORIES FOR BLOOD TUBING SET / HEMODIAYSIS CANNULA (REIN, JETFLOW, JETLITE, OXYFLOW)-ALLOWING THE ARTERIAL BLOOD TO FLOW TO THE DIALYZER AND THE DIALYZED BLOOD TO RETURN FROM THE DIALYZER TO THE CIRCULATION THROUGH THE CANNULA IN THE VEIN,CATHETERS / MULTIPLE LUMEN CATHETER(ONEFLON,ONE PLUS)-INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLINGBLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTION OR DRUGS,CATHETERS / DOUBLE & TRIPLE LUMEN(REIN CATH, REIN, JETFLOW, JETLITE & OXYFLOW)-CATHETER USE FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FORM THE PATIENT,CATHETER /DOUBLE & TRIPLE LUMEN (ENA CATH)-CATHETER USE FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FORM THE PATIENT ,CATHETERS / MULTIPLE LUMEN CATHETER / CVC KIT (SHORT TERM)(DYSON & GMKEY)-INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTION OR DRUGS,IV CANNULA / TRANSDUCER PROTECTOR AS AN ACCESSORIES FOR BLOOD TUBING SET / HEMODIALYSIS CANNULA(SUNFLO)-ALLOWING THE ARTERIAL BLOOD TO FLOW TO THE DIALYZER AND THE DIALYZED BLOOD TO RETURN FROM THE DIALYZER TO THE CIRCULATION THROUGH THE CANNULA IN THE VEIN,CATHETERS INTRAMUSCULAR PRESSURE MONITORING CATHETER / PRESSURE MONITORING LINE(REIN, JETFLOW, JETLITE, OXYFLOW)-A MODIFIED FIBRE OPTIC TRANSDUCER -TIPPED CATHETER SYSTEM FOR MEASURING INTRAMUSCULAR PRESSURE DURING EXERCISE WAS DETERMINED, CATHETERS INTRAMUSCULAR PRESSURE MONITORING CATHETER / PRESSURE MONITORING LINE(ONEFLON,ONE PLUS)-A MODIFIED FIBRE OPTIC TRANSDUCER -TIPPED CATHETER SYYTEM FOR MEASURING INTRAMUSCULAR PRESSURE DURING EXERCISE WAS DETERMINED,DISPOSABLE HYPODERMIC NEEDLE / ASPIRATION AND INJECTION NEEDLE (REIN, JETFLOW, JETLITE)-A THIN NEEDLE IS INSERTED INTO AN AREA OF ABNORMAL-APPEARING TISSUEOR

	BODY FLUID. AS WITH OTHER TYPE OF BIOPSIES , THE SAMPLE COLLECTED DURING FINE NEEDLE ASPIRATION CAN HELP MAKE A DIAGNOSIS OR RULE OUT CONDITION SUCH AS CANCER.,CATHETER /DOUBLE & TRIPLE LUMEN(SUNFLO)-CATHETER USE FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FORM THE PATIENT,A.V FISTULA NEEDLE(REIN, JETFLOW, JETLITE, OXYFLOW)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLE WHEN THE DIALYSIS IS CARRIED OUT,CATHERS / SINGLE NEEDLE/ LUMEN CATHETER(FLOCATH)-THE SINGLE-NEEDLE DIALYSIS , IN WHICH CASE ONLY ONE CANNULA OR A SINGLE-LUMEN CATHETER IS USED TO ACCESS THE BLOOD,DISPOSABLE PERFUSION SET / 3 WAY STOP COCK(REIN, JETFLOW, JETLITE)-:IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAW OF FLUID AND PRESSURE MONITORING.,CATHERS / SINGLE NEEDLE/ LUMEN CATHETER(SUNFLO)-THE SINGLE-NEEDLE DIALYSIS , IN WHICH CASE ONLY ONE CANNULA OR A SINGLE-LUMEN CATHETER IS USED TO ACCESS THE BLOOD,CATHETERS / SINGLE NEEDLE/ LUMEN CATHETER(REIN CATH , REIN , JETFLOW, JETLITE & OXYFLOW)-THE SINGLE-NEEDLE DIALYSIS , IN WHICH CASE ONLY ONE CANNULA OR A SINGLE LUMEN CATHETER IS USED TO ACCESS THE BLOOD., CATHETERS / MULTIPLE LUMEN CATHETER(SUNFLO)-INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTION OR DRUGS,DISPOSABLE HYPODERMIC NEEDLE / BONE MARROW NEEDLE(REIN, JETFLOW, JETLITE,)-NEEDLE INSERTED IN BONE MARROW TO COLLECT SAMPLE,CATHERS / SINGLE NEEDLE/ LUMEN CATHETER(ELICATH)-THE SINGLE-NEEDLE DIALYSIS , IN WHICH CASE ONLY ONE CANNULA OR A SINGLE-LUMEN CATHETER IS USED TO ACCESS THE BLOOD ,BLOOD COLLECTION NEEDLE/WITH WING / MYSAFTEY ARMOUR / MYSAFTEY ARMOUR SERO(BLOOD COLLECTION NEEDLE)-INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD, CATHERS / SINGLE NEEDLE/ LUMEN CATHETER(NEPHROTEQ)-THE SINGLE-NEEDLE DIALYSIS , IN WHICH CASE ONLY ONE CANNULA OR A SINGLE-LUMEN CATHETER IS USED TO ACCESS THE BLOOD, DISPOSABLE PERFUSION SETS / EXTENSION SET / 3 WAY STOP COCK WITH EXTENSION SETS(REIN, JETFLOW, JETLITE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,CATHERS / SINGLE NEEDLE/ LUMEN CATHETER(ENA CATH)-THE SINGLE-NEEDLE DIALYSIS , IN WHICH CASE ONLY ONE CANNULA OR A SINGLE-LUMEN CATHETER IS USED TO ACCESS THE BLOOD,CATHETER /URINARY

	DRAINAGE UNIT / SILKY GOLD FOLEY BALLOON CATHETER (SILICONISED) (REIN , JETFLOW & JETLITE)-A CLOSED URINARY DRAINAGE SYETEM CONSISTS OF A CATHETER INSERTED INTO THE URINARY BLADDER AND CONNECTED VIA TUBING TO A DRAINAGE BAG.,CATHETER /DOUBLE & TRIPLE LUMEN(ELICATH)-CATHETER USE FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FORM THE PATIENT ,DISPOSABLE PERFUSION SETS /MEASURED VOLUME IV SET / IV SET(REIN, JETFLOW, JETLITE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,A.V FISTULA NEEDLE(ONEFLON,ONE PLUS)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLE WHEN THE DIALYSIS IS CARRIED OUT,CATHETER /SINGLE / DOUBLE & TRIPLE LUMEN(ERILITE)-CATHETER USE FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FORM THE PATIENT,AV FISTULA NEEDLE(ELI FLOW)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLE WHEN THE DIALYSIS IS CARRIED OUT,CATHETERS / PERITONEAL DIALYSIS CATHETER(REIN CATH, REIN , JETFLOW, JETLITE & OXFLOW)-THAT ALLOWS DILAYSIS FLUIDS TO ENTER THE ABDOMINAL CAVITY , DWELL INSIDE FOR A WHILE, AND THEN DRAIN BACK OUT AGAIN, CATHETER /DOUBLE & TRIPLE LUMEN(FLOCATH)-CATHETER USE FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FORM THE PATIENT,CATHETERS / GUIDING CATHETER / GUIDEWIRE WITH ADVANCER(REIN CATH , REIN, JETFLOW, JETLITE)-THE GUIDE CATHETER PROVIDES SUPPORT FOR DEVICE ADVANCEMENT.,CATHETER /DOUBLE & TRIPLE LUMEN(NEPHROTEQ) -CATHETER USE FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FORM THE PATIENT,DISPOSABLE PERFUSION SET /TRANSFUSION OR PERFUSION SETS FOR SINGLE USE / B.T SET(REIN, JETFLOW, JETLITE)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN, CATHETER /DOUBLE & TRIPLE LUMEN(VD-SAFE)-CATHETER USE FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FORM THE PATIENT ,DISPOSABLE HYPODERMIC SYRINGE(REIN, JETFLOW, JETLITE)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,IV CANNULA / TRANSDUCER PROTECTOR AS AN ACCESSORIES FOR BLOOD TUBING SET / HEMODIALYSIS CANNULA(ONEFLON,ONE PLUS)-ALLOWING THE ARTERIAL BLOOD TO FLOW TO THE DIALYZER AND THE DIALYZED BLOOD TO RETURN FROM THE DIALYZER TO THE CIRCULATION THROUGH THE CANNULA IN THE VEIN,HD TUBING SET / BLOOD TUBING SET(REIN, JETFLOW, JETLITE, OXYFLOW)-ALLOWING THE ARTERIAL BLOOD TO FLOW TO

		THE DIALYZER AND THE DIALYZED BLOOD TO RETURN FROM THE DIALYZER TO THE CIRCULATION THROUGH THE CANNULA IN THE VEIN,CATHETER /DOUBLE & TRIPLE LUMEN(ONEFLON,ONE PLUS)-CATHETER USE FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FORM THE PATIENT,CATHETERS / MULTIPLE LUMEN CATHETER(REIN CATH , REIN , JETFLOW , JETLITE & OXYFLOW)-INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTION OR DRUGS,CATHERS / SINGLE NEEDLE/ LUMEN CATHETER(ONEFLON,ONE PLUS)-THE SINGLE-NEEDLE DIALYSIS , IN WHICH CASE ONLY ONE CANNULA OR A SINGLE-LUMEN CATHETER IS USED TO ACCESS THE BLOOD,BLOOD COLLECTION NEEDLE KIT(MYSAFETY ARMOUR/MYSAFETY ARMOUR (SERO)/ MYSAFETY (SURE))-INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD (SR.NO. 171),BLOOD COLLECTION NEEDLE KIT (MYSAFETY ARMOUR (WITH WINGS) / MYSAFETY (SURE WITH WINGS)) -INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD (SR.NO. 171)
3342	MFG/MD/2019/000205	1.License Holder Name: TRANSCATH MEDICAL DEVICES PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:VESSEL DILATOR FOR PERCUTANEOUS CATHETERISATION-A VESSEL DILATOR FOR PERCUTAENEOUS CATHETERIZATION IS A DEVICE WHICH IS PLACED OVER THE GUIDE WIRE TO ENLARGE OPENING IN THE VESSEL, AND WHICH IS THEN REMOVED BEFORE SLIDING THE CATHETER OVER THE GUIDE WIRE.,VESSEL DILATOR FOR PERCUTANEOUS CATHETERIZATION-A VESSEL DILATOR FOR PERCUTANEOUS CATHETERIZATION IS A CLASS B DEVICE WHICH IS PLACED OVER THE GUIDE WIRE TO ENLARGE OPENING IN THE VESSEL, AND WHICH IS THEN REMOVED BEFORE SLIDING THE CATHETER OVER THE GUIDE WIRE.,HEMODIALYSIS CATHETER KIT CONTAINING HAEMODIALYSIS CATHETER, GUIDEWIRE, VESSEL DILATOR, INTRODUCER NEEDLE AND FIXING WING.-IT IS USED FOR EXCHANGING BLOOD TO AND FROM HAEMODIALYSIS MACHINE AND THE PATIENT.

3343	MFG/MD/2019/000207	1.License Holder Name: KOHINOOR PRODUCTS 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ABSORBENT GAUZE CLOTH(KOHINOOR)-IT IS USED FOR MEDICAL DRESSINGS,EYE PAD (KOHINOOR)-FOR EYE DRESSING,TRIANGULAR BANDAGES (KOHINOOR)-TO SUPPORT AN INJURED FOREARM.,X-RAY DETECTABLE ABDOMINAL PAD(KOHINOOR)-ABSORB BLOOD DURING OPERATION.,BANDAGE CLOTH (WITH STARCH)(KOHINOOR)-IT IS USED TO SUPPORT THE MEDICAL DRESSINGS MATERIAL.,GAMJEE ROLL(KOHINOOR)-PRIMARY SUPPORT FOR POP,ROLLED GAUZE (WITH STARCH)(KOHINOOR)-IT IS ONLY USED TO SUPPORT THE SURGICAL DRESSINGS MATERIAL.,CHLORHEXIDINE GAUZE DRESSING (KOHINOOR)-WOUND AND BURN DRESSING,ROLLED BANDAGE (WITH STARCH)(KOHINOOR)-IT IS ONLY USED TO SUPPORT THE SURGICAL DRESSINGS MATERIAL.,COTTON BUDS(KOHINOOR)-USED FOR CLEANING WOUNDS AND FOR PADDING AND PROTECTION,CREPE BANDAGES(KOHINOOR)-IT IS USED TO PROVIDE GENTLE SUPPORT AND COMPRESSION TO HELP REDUCE PAIN AND MAINTAIN STABILITY IN SPRAINS AND STRAINS. ,P.O.P. BANDAGE(KOHINOOR)-TO RIGIDLY PROTECT AN INJURED BONE OR JOINT.,ADHESIVE TAPE (KOHINOOR)-TO SUPPORT DRESSING.,ELASTIC ADHESIVE BANDAGE (KOHINOOR)-ANKLE, KNEE, HAND & WRIST TAPING. SUPPORT FOR JOINT SPRAINS,GAUZE SWAB(KOHINOOR)-WOUND DRESSING., ELASTIC ADHESIVE BANDAGE I. V. CANNULA FIXATOR(KOHINOOR)-TO FIX IV CANNULA,PARAFFIN GAUZE DRESSING(KOHINOOR)-WOUND AND BURN DRESSING,COMBINE OPERATION SURGICAL PAD (KOHINOOR)-WOUND DRESSING.,ABSORBENT COTTON RIBBON GAUZE(KOHINOOR)-USED AS A LONG SPONGE TO CONTROL BLEEDING DURING THE PRO-STATIC SURGERIES

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3344	MFG/MD/2019/000210	1.License Holder Name: KILITCH DRUGS INDIA LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:N-BUTYLCYANOACRYLATE (STERILE TISSUE ADHESIVE)(C-SEAL 0.50 ML)-USED IN TOPICAL APPLICATION TO HOLD CLOSED EASILY APPROXIMATED SKIN EDGES OF WOUNDS FROM SURGICAL INCISIONS INCLUDING PUNCTURES FROM MINIMALLY INVASIVE SURGERY & SIMPLE TRAUMA INCLUDING LACERATIONS .,N-BUTYLCYANOACRYLATE (STERILE TISSUE ADHESIVE)(C-SEAL 0.25 ML)-USED IN TOPICAL APPLICATIONS TO HOLD CLOSED EASILY APPROXIMATED SKIN EDGES OF WOUNDS FROM, SURGICAL INCISIONS INCLUDING PUNCTURES FROM MINIMALLY INVASIVE SURGERY AND SIMPLE TRAUMA INCLUDING LACERATIONS.,N-BUTYLCYANOACRYLATE (STERILE TISSUE ADHESIVE)(C-SEAL 0.15 ML)-USED IN TOPICAL APPLICATIONS TO HOLD CLOSED EASILY APPROXIMATED SKIN EDGES OF WOUNDS FROM, SURGICAL INCISIONS INCLUDING PUNCTURES FROM MINIMALLY INVASIVE SURGERY AND SIMPLE TRAUMA INCLUDING LACERATIONS.

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3345	MFG/MD/2019/000212	1.License Holder Name: PYRRA SUTURES PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:STERILISED NON ABSORBABLE SURGICAL NEEDLED SUTURE U.S.P. POLYPROPYLENE (PYLENE)-PYLENE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIO VASCULAR, OPHTHALMIC AND NEUROLOGICAL SURGERY., STERILISED NON ABSORBABLE SURGICAL NEEDLED SUTURE U.S.P. POLYESTER(PYBOND)-PYBOND IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIO VASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,STERILISED NON ABSORBABLE SURGICAL NEEDLED SUTURE U.S.P. POLYAMIDE(PYLON)-PYLON IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC, AND NEUROLOGICAL SURGERY.,STERILISED ABSORBABLE SURGICAL NEEDLED SUTURE U.S.P. POLIGLECAPRONE 25(PYCRYL MONO)-PYCRYL MONO SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION. BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPTHALMIC SURGERY.,STERILISED ABSORBABLE SURGICAL NEEDLED SUTURE U. S.P. POLYGLACTIN 910(PYCRYL 910)-PYCRYL 910 IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES.,STERILISED ABSORBABLE SURGICAL NEEDLED SUTURE U.S.P. POLYGLYCOLIC ACID(PYCRYL)-PYCRYL IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES.,STERILISED ABSORBABLE SURGICAL NEEDLED SUTURE U.S.P. POLYDIOXANONE(PYCRYL PDS)-PYCRYL PDS, MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN OPHTHALMIC SURGERY. PYCRYL PDS SUTURES IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE,STERILISED ABSORBABLE SURGICAL NEEDLED SUTURE U.S.P. POLYGLYCOLIC ACID 100%(PYCRYL SPEED)-PYCRYL SPEED IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT-TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION WOULD BE BENEFICIAL. DUE TO THE

		RAPID ABSORPTION PROFILE PYCRYL SPEED IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. PYCRYL SPEED IS NOT INTENDED FOR USE IN OPHTHALMIC SURGERY CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES.
3346	MFG/MD/2019/000213	1.License Holder Name: BIOREGEN TECHNOLOGIES 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:COLLAGEN PARTICLES-COLLAGEN PARTICLES ARE USED FOR THE MANAGEMENT OF DEEP WOUNDS, STAB WOUNDS AND OTHER DEEP CUT WOUNDS. , COLLAGEN DRY SHEET-COLLAGEN DRY SHEETS CAN BE USED AS A BURN / WOUND DRESSING MATERIAL IT CAN ALSO BE USED FOR THE MANAGEMENT OF (I) DIABETIC ULCERS, (II) LEPROSY ULCERS, (III) NON-HEALING ULCERS,COLLAGEN WET SHEET-BURN / WOUND DRESSING MATERIAL. THIS MATERIAL CAN ALSO BE USED FOR THE MANAGEMENT OF DIABETIC ULCERS, LEPROSY ULCERS AND NON HEALING WOUNDS

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3347	MFG/MD/2019/000214	1.License Holder Name: TTK HEALTHCARE LIMITED (ORTHO DIVISION) 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:TOTAL HIP REPLACEMENT SYSTEM(ALTIUS)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT BONE TO SEAT AND SUPPORT THE COMPONENTS.,TOTAL HIP REPLACEMENT SYSTEM(TOTAL HIP REPLACEMENT SYSTEM (CEMENTED) – ALTIUS¸ PARTIAL HIP REPLACEMENT SYSTEM (CEMENTED) – ALTIUS, TOTAL HIP REPLACEMENT SYSTEM (UNCEMENTED) – TRANSITION)-TOTAL HIP REPLACEMENT SYSTEM (CEMENTED AND UNCEMENTED): TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT BONE TO SEAT AND SUPPORT THE COMPONENTS. PARTIAL HIP REPLACEMENT SYSTEM (CEMENTED): THIS HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN HEMI-ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM.,HIP REPLACEMENT SYSTEM (ALTIUS)-TOTAL HIP REPLACEMENT SYSTEM: TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT BONE TO SEAT AND SUPPORT THE COMPONENTS. PARTIAL HIP REPLACEMENT SYSTEM : THIS PARTIAL HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN HEMI-ARTHROPLASTY WHERE THERE IS EVIDENCE OF A SATISFACTORY NATURAL ACETABULUM AND SUFFICIENT FEMORAL BONE TO SEAT AND SUPPORT THE FEMORAL STEM. ,TOTAL KNEE REPLACEMENT SYSTEM(ALTIUS)-MODEL NAME: A.BUECHEL-PAPPAS HIGH FLEX TOTAL KNEE REPLACEMENT SYSTEM, B. BUECHEL-PAPPAS HIGH FLEX TOTAL KNEE REPLACEMENT SYSTEM – MARK IV - TOTAL KNEE REPLACEMENT SYSTEM IS INTENDED TO PROVIDE PRIMARY OR REVISION OPTIONS TO THE SURGEONS TO REDUCE OR ELIMINATE PAIN, RESTORE MOTION, AND/OR CORRECT DEFORMITY. MODEL NAME : C. BUECHEL-PAPPAS REVISION KNEE REPLACEMENT SYSTEM-I. CO-CR MOBILE BEARING REVISION KNEE – CEMENTED - THIS BUECHEL-PAPPAS (BP) REVISION KNEE REPLACEMENT SYSTEM IS INTENDED TO PROVIDE PRIMARY OR REVISION OPTIONS TO THE SURGEON TO CORRECT SEVERE DEFORMITY AND/OR REDUCE OR ELIMINATE PAIN, RESTORE MOTION, AND/OR CORRECTION OF PREVIOUSLY FAILED JOINT REPLACEMENT PROCEDURES, IN CASE WHERE ADDITIONAL COMPONENT STABILIZATION BY MEANS OF A

	STEM IS REQUIRED. II. CO-CR HINGE KNEE – CEMENTED AND III. TITANIUM HINGE KNEE – CEMENTED-THIS BUECHEL-PAPPAS REVISION KNEE REPLACEMENT SYSTEM IS INTENDED TO PROVIDE PRIMARY OR REVISION OPTIONS TO THE SURGEON TO CORRECT SEVERE DEFORMITY AND/OR REDUCE OR ELIMINATE PAIN, RESTORE MOTION, AND/OR CORRECTION OF PREVIOUSLY FAILED JOINT REPLACEMENT PROCEDURES IN THE ABSENCE OF VIABLE COLLATERAL LIGAMENTS.,TOTAL HIP REPLACEMENT SYSTEM (ALTIUS)-TOTAL HIP REPLACEMENT SYSTEM (CEMENTED): TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT BONE TO SEAT AND SUPPORT THE COMPONENTS.,TOTAL HIP REPLACEMENT SYSTEM (TOTAL HIP REPLACEMENT SYSTEM (UNCEMENTED) – TRANSITION)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT BONE TO SEAT AND SUPPORT THE COMPONENTS.,TOTAL KNEE REPLACEMENT SYSTEM(ALTIUS)-THIS BUECHEL-PAPPAS REVISION KNEE REPLACEMENT SYSTEM IS INTENDED TO PROVIDE PRIMARY OR REVISION OPTIONS TO THE SURGEON TO CORRECT SEVERE DEFORMITY AND/OR REDUCE OR ELIMINATE PAIN, RESTORE MOTION, AND/OR CORRECTION OF PREVIOUSLY FAILED JOINT REPLACEMENT PROCEDURES IN THE ABSENCE OF VIABLE COLLATERAL LIGAMENTS.

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3348	MFG/MD/2019/000215	1.License Holder Name: EXCELLENT HI- CARE PVT LTD ., 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:INTRAOCULAR LENS (ASTIC TORIC, MAC -TORIC)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(ASTIC TORIC, MAC -TORIC)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA -PHAKIC MF)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA ,INTRAOCULAR LENS(OPTIMA LENS I-PURE, MAC LENS , HOSMED, I-LENS, I-MAX)-PMMA INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(ASTIG TORIC -VUE,MAC TORIC PLUS, I PURE -TORIC)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA EDGE, MAC EDGE, I-PURE EDGE, I-EDGE SERIES, OPTIMA GOLD, MAC GOLD, I-PURE YELLOW, I-EDGE SERIES, I-MAX GOLD)-PMMA INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA , INTRAOCULAR LENS(OPTIMA FOLD ,MAC FOLD, I-PURE FOLD, HOSMED, AKRITI FOLD, I-MAX FOLD)-HYDROPHILIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(ASTIG TORIC -VUE,MAC TORIC PLUS, I PURE -TORIC)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(NIL)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF

	PATIENTS SUFFERING FROM APHAKIA ,INTRAOCULAR LENS(OPTIMA VUE, OPTIMA VUE PLUS , MAC PHOB)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(ASTIGTORIC-VUE, TRIFOCAL-EF, MAC TRIFOCAL-TORIC)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(OPTIMA FOLD ,MAC FOLD, I-PURE FOLD, HOSMED, AKRITI FOLD)-HYDROPHILIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA ,INTRAOCULAR LENS(OPTIMA VUE -TRI, OPTIMA VUE -TRIFOCAL-EF, MAC DIFF-TRI PLUS, I-PURE TRIFOCAL)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA CLEAR, MAC CLEAR, I-PURE FOLD, I-CLEAR SERIES, I-MAX,OPTIMA TRU, MAC TRU, I-PURE GOLD, I-CLEAR SERIES, I-MAX GOLD)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA-CLAW,MAC-CLAW,I-MAX)-PMMA INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(ASTIC TORIC, MAC -TORIC)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(OPTIMA BINARY, MAC DIFF, I-PURE MF)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS (ASTIGTORIC-VUE, TRIFOCAL-EF, MAC TRIFOCAL-TORIC)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA

	LENS , I-PURE, MAC LENS , HOSMED, I-LENS, I-MAX)-PMMA INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA , INTRAOCULAR LENS(ASTIGTORIC-VUE, TRIFOCAL-EF, MAC TRIFOCAL-TORIC)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(ASTIC TORIC-BINARY, ASTIG TORIC-TRIFOCAL -EF)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA BINARY PLUS, MAC-DIFF PLUS)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(OPTIMA LENS , I-MAX)-PMMA INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA ,INTRAOCULAR LENS(ASTIG TORIC-VUE BINARY)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(NIL)-PMMA INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(ASTIC TORIC-BINARY, ASTIG TORIC-TRIFOCAL -EF)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(OPTIMA VUE -TRI, OPTIMA VUE -TRIFOCAL-EF, MAC DIFF-TRI PLUS, I-PURE TRIFOCAL)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(OPTIMA DIFF-TRI, OPTIMA -BINARY TRIFOCAL EF, MAC DIFF -TRI, I-PURE TF)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,

	INTRAOCULAR LENS(ASTIC TORIC, MAC -TORIC)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA VUE, OPTIMA VUE PLUS, MAC PHOB, I-PURE PHOB, I-PHOB, I -MAXI PHOB, I-MAXI PHOB PLUS)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA.,INTRAOCULAR LENS(ASTIG TORIC -VUE,MAC TORIC PLUS, I PURE -TORIC)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(ASTIG TORIC-VUE BINARY)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(ASTIG TORIC -VUE,MAC TORIC PLUS, I PURE -TORIC)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(NIL)-PMMA INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA ,INTRAOCULAR LENS(OPTIMA BINARY PLUS)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA BINARY PLUS, MAC-DIFF PLUS)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(OPTIMA FOLD ,MAC FOLD, I-PURE FOLD, HOSMED, AKRITI FOLD, I-MAX FOLD)-HYDROPHILIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(OPTIMA FOLD , HOSMED, AKRITI FOLD,)-HYDROPHILIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING

	FROM APHAKIA ,INTRAOCULAR LENS(OPTIMA -PHAKIC TORIC)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA DIFF-TRI, OPTIMA -BINARY TRIFOCAL EF, MAC DIFF -TRI, I-PURE TF)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA.,INTRAOCULAR LENS(OPTIMA DIFF-TRI, OPTIMA -BINARY TRIFOCAL EF)- HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(ASTIG TORIC-VUE BINARY)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA BINARY, MAC DIFF, I-PURE MF)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA.,INTRAOCULAR LENS(OPTIMA VUE -TRI, OPTIMA VUE -TRIFOCAL-EF, MAC DIFF-TRI PLUS, I-PURE TRIFOCAL)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA BINARY, MAC DIFF, I-PURE MF)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(NIL)-HYDROPHILIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA BINARY PLUS)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA VUE, OPTIMA VUE PLUS , MAC PHOB)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,

	INTRAOCULAR LENS(OPTIMA EDGE, MAC EDGE, I-PURE EDGE, I-EDGE SERIES, OPTIMA GOLD, MAC GOLD, I-PURE YELLOW, I-EDGE SERIES, I-MAX GOLD)-PMMA INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA ,INTRAOCULAR LENS(OPTIMA DIFF-TRI, OPTIMA -BINARY TRIFOCAL EF, MAC DIFF -TRI, I-PURE TF)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA.,INTRAOCULAR LENS(OPTIMA CLEAR, MAC CLEAR, I-PURE FOLD, I-CLEAR SERIES, I-MAX,OPTIMA TRU, MAC TRU, I-PURE GOLD, I-CLEAR SERIES, I-MAX GOLD)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(ASTIG TORIC-VUE BINARY)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA CLEAR, MAC CLEAR, I-PURE FOLD, I-CLEAR SERIES,OPTIMA TRU,)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA , INTRAOCULAR LENS(OPTIMA FOLD ,MAC FOLD, I-PURE FOLD, HOSMED, AKRITI FOLD, I-MAX FOLD)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA , INTRAOCULAR LENS(OPTIMA BINARY, MAC DIFF, I-PURE MF)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(ASTIC TORIC-BINARY, ASTIG TORIC-TRIFOCAL -EF)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(OPTIMA LENS , I-PURE, MAC LENS , HOSMED, I-LENS, I-MAX)-PMMA INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(OPTIMA -PHAKIC LENS, MAC-

	RIPCL)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS (ASTIGTORIC-VUE, TRIFOCAL-EF, MAC TRIFOCAL-TORIC)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA,INTRAOCULAR LENS(ASTIC TORIC-BINARY, ASTIG TORIC-TRIFOCAL -EF)-HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA, INTRAOCULAR LENS(OPTIMA VUE -TRI, OPTIMA VUE -TRIFOCAL-EF, MAC DIFF-TRI PLUS, I-PURE TRIFOCAL)-HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3349	MFG/MD/2019/000217	1.License Holder Name: SPECTRUM MEDTECH PVT. LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ANGIOGRAPHIC CATHETER (SPLENDID, DISCOVER)-DESIGNED TO PROVIDE A PATHWAY FOR DELIVERING CONTRAST MEDIA TO SELECTED SITES IN THE DEVICE VASCULAR SYSTEM INCLUDING THE CAROTID ARTERIES. ,LARYNGEAL MASK AIRWAY(ADLISC)-THE LMA (LARYNGEAL MASK AIRWAY) IS INDICATED FOR USE IN ACHIEVING AND MAINTAINING CONTROL OF THE AIRWAY DURING ROUTINE ANAESTHETIC PROCEDURES IN FASTED PATIENTS USING EITHER SPONTANEOUS OR POSITIVE PRESSURE VENTILATION (PPV). IT IS ALSO INDICATED FOR SECURING THE IMMEDIATE AIRWAY IN KNOWN OR UNEXPECTED DIFFICULT AIRWAY SITUATIONS. WHEN USED IN A DIFFICULT AIRWAY PATIENT, THE RISK OF REGURGITATION AND ASPIRATION MUST BE WEIGHED AGAINST THE POTENTIAL BENEFIT OF ESTABLISHING AN AIRWAY. IT IS BEST SUITED FOR USE IN ELECTIVE SURGICAL PROCEDURES WHERE TRACHEAL INTUBATION IS NOT NECESSARY., SUCTION TIP AND CATHETER (ADLISC)-SUCTION CATHETER FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING. ,STERILE DISPOSABLE SKIN STAPLER FOR SINGLE USE ONLY(ADLISC)-SKIN STAPLER IS INTENDED TO BE APPLIED TO CLOSE LACERATIONS ON THE OUTER LAYER OF THE DERMIS.,TRACHEOSTOMY TUBE(ADLISC)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,STERILE DISPOSABLE 3-WAY STOP COCK FOR SINGLE USE ONLY(DIVERT/DIVERT PLUS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,ENDOTRACHEAL TUBE(ADLISC)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,ANESTHESIA MASK (ADLISC)-IT IS INTENDED TO USE AIRWAY MANAGEMENT BY ANAESTHESIA/ RESPIRATORY CARE DETERMENT,SCALP VEIN SET (ADLISC)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT VASCULAR SYSTEM AS AN IN DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD. ,SUCTION CATHETER(ADLISC)-CLEARING THE AIRWAY OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGEN TION AND VENTILATION.,OXYGEN MASK(ADLISC)-IT IS INTENDED TO USE AIRWAY MANAGEMENT BY ANAESTHESIA/ RESPIRATORY CARE DETERMENT,CPAP MASK/ BI-LEVEL MASK (ADLISC)-IT IS INTENDED TO USE AIRWAY MANAGEMENT BY ANAESTHESIA/ RESPIRATORY CARE DETERMENT,SPINAL NEEDLE(ADLISC)-DISPOSABLE SPINAL

		ANESTHESIA NEEDLE IS INTENDED TO BE USED FOR INJECTION OF LOCAL ANESTHETIC AGENT INTO THE SUBARACHNOID CAVITY FOR PAIN MANAGEMENT,BREATHING CIRCUIT (ADLISC)-IT IS INTENDED TO USE AIRWAY MANAGEMENT BY ANAESTHESIA/ RESPIRATORY CARE DETERMENT,MEASURED VOLUME IV SET(INFUSION SET/ BLOOD TRANSFUSION SET) (IV/BT SET)-IT IS INTENDED USE IN THE ADMINISTRATION OF FLUIDS FORM A CONTAINER INTO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,BREATHING FILTERS(ADLISC)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,NASAL CANNULA(ADLISC)-IT IS INTENDED TO USE AIRWAY MANAGEMENT BY ANAESTHESIA/ RESPIRATORY CARE DETERMENT, NASOPHARYNGEAL AIRWAY(ADLISC)-A CATHETER PASSED THROUGH THE NARES AND ADVANCED TO THE DEPTH OF THE NASOPHARYNX TO REMOVE AIR CHOKE OR OBSTRUCTION. ARESUSCITATOR.,NEBULIZER MASK(ADLISC)-IT IS INTENDED TO USE AIRWAY MANAGEMENT BY ANAESTHESIA/ RESPIRATORY CARE DETERMENT,EXTENSION SET(CLEARWAY , CLEARFLOW)-ENTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,FOLEY BALLOON CATHETER(ADLISC)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,Y-CONNECTOR (FABULOUS, EASY PASS)-IT CAN USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC.
3350	MFG/MD/2019/000218	1.License Holder Name: BOARD OF RADIATION AND ISOTOPE TECHNOLOGY 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:ALCOHOL SWABS-IT IS A SINGLE USE, STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE.

3351	MFG/MD/2019/000219	1.License Holder Name: HARSORIA HEALTHCARE PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER KIT(VIGGO CVC)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS CATHETERS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.

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3352	MFG/MD/2019/000220	1.License Holder Name: FREEDOM OPHTHALMIC PVT LTD. 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:IRIS CLAW INTRA OCULAR LENS(ALPHA IRIS CLAW)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,HYDROPHILIC ACRYLIC POSTERIOR CHAMBER SINGLE PIECE 360 SQUARE EDGE FOLDABLE INTRAOCULAR LENS -FOR IMPLANTATION IN THE POSTERIOR CHAMBER OF THE EYE AFTER CATARACT REMOVAL,YELLOW HYDROPHILIC ACRYLIC POSTERIOR CHAMBER TORIC ASPHERIC SQUARE EDGE SINGLE PIECE FOLDABLE INTAOCULAR LENS(ALPHA)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,YELLOW PMMA POSTERIOR CHAMBER SINGLE PIECE 360 SQUARE EDGE INTRAOCULAR LENS -FOR IMPLANTATION IN THE POSTERIOR CHAMBER OF THE EYE AFTER CATARACT REMOVAL,HYDROPHOBIC ACRYLIC POSTERIOR CHAMBER MULTIFOCAL DDIFFRACTIVE- REFFRACTIVE ASPHERIC SQUARE EDGE SINGLE PIECE FOLDABLE INTRAOCULAR LENS(ALPHA)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,HYDROPHILIC ACRYLIC POSTERIOR CHAMBER SINGLE PIECE FOLDABLE INTRAOCULAR LENS-FOR IMPLANTATION IN THE POSTERIOR CHAMBER OF THE EYE AFTER CATARACT REMOVAL,HYDROPHILIC ACRYLIC POSTERIOR CHAMBER SINGLE PIECE FOLDABLE INTRAOCULAR LENS(ALPHA LENS)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,PMMA POSTERIOR CHAMBER

	SINGLE PIECE INTRAOCULAR LENS -FOR IMPLANTATION IN THE POSTERIOR CHAMBER OF THE EYE AFTER CATARACT REMOVAL, PMMA POSTERIOR CHAMBER SINGLE PIECE 360 SQUARE EDGE INTRAOCULAR LENS(ALPHA)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,YELLOW HYDROPHOBIC ACRYLIC ASPHERIC FOLDABLE 360 SQUARE EDGE INTRAOCULAR LENSES-FOR IMPLANTATION IN THE POSTERIOR CHAMBER OF THE EYE AFTER CATARACT REMOVAL,HYDROPHILIC ACRYLIC POSTERIOR CHAMBER TORIC ASPHERIC SQUARE EDGE SINGLE PIECE FOLDABLE INTAOCULAR LENS(ALPHA)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,YELLOW HYDROPHOBIC ACRYLIC ASPHERIC FOLDABLE INTRAOCULAR LENSES-FOR IMPLANTATION IN THE POSTERIOR CHAMBER OF THE EYE AFTER CATARACT REMOVAL,HYDROPHILIC ACRYLIC POSTERIOR CHAMBER MULTIFOCAL DIFFRACTIVE -REFFRACTIVE ASPHERIC SQUARE EDGES SINGLE PIECE FOLDABLE INTRAOCULAR LENS(ALPHA LENS)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,HYDROPHILIC ACRYLIC POSTERIOR CHAMBER SINGLE PIECE 360 SQUARE EDGE ASPHERIC FOLDABLE INTRAOCULAR LENS-FOR IMPLANTATION IN THE POSTERIOR CHAMBER OF THE EYE AFTER CATARACT REMOVAL, PMMA ANTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENS (ALPHA)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,PMMA ANTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENS-FOR IMPLANTATION IN THE ANTERIOR CHAMBER OF THE EYE

	AFTER CATARACT REMOVAL,YELLOW HYDROPHILIC ACRYLIC POSTERIOR CHAMBER MULTIFOCAL TORIC ASPHERIC SQUARE EDGE SINGLE PIECE FOLDABLE INTAOCULAR LENS(ALPHA)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,YELLOW HYDROPHILIC ACRYLIC POSTERIOR CHAMBER SINGLE PIECE 360 SQUARE EDGE FOLDABLE INTRAOCULAR LENS-FOR IMPLANTATION IN THE POSTERIOR CHAMBER OF THE EYE AFTER CATARACT REMOVAL,YELLOW HYDROPHILIC ACRYLIC POSTERIOR CHAMBER MULTIFOCAL DIFFRACTIVE- REFFRACTIVE ASPHERIC SQUARE EDGESINGLE PIECE FOLDABLE INTRAOCULAR LENS(ALPHA)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,HYDROPHOBIC ACRYLIC ASPHERIC FOLDABLE INTRAOCULAR LENSES-FOR IMPLANTATION IN THE POSTERIOR CHAMBER OF THE EYE AFTER CATARACT REMOVAL,PMMA POSTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENS(ALPHA)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,YELLOW HYDROPHILIC ACRYLIC POSTERIOR CHAMBER SINGLE PIECE 360 SQUARE EDGE ASPHERIC FOLDABLE INTRAOCULAR LENS -FOR IMPLANTATION IN THE POSTERIOR CHAMBER OF THE EYE AFTER CATARACT REMOVAL, HYDROPHOBIC ACRYLIC POSTERIOR CHAMBER MULTIFOCAL TORIC ASPHERIC SQUARE EDGE SINGLE PIECE FOLDABLE INTAOCULAR LENS(ALPHA)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,HYDROPHOBIC ACRYLIC ASPHERIC FOLDABLE 360 SQUARE EDGE INTRAOCULAR LENSES-FOR IMPLANTATION IN THE

	POSTERIOR CHAMBER OF THE EYE AFTER CATARACT REMOVAL, HYDROPHILIC ACRYLIC POSTERIOR CHAMBER MULTIFOCAL TORIC ASPHERIC SQUARE EDGE SINGLE PIECE FOLDABLE INTAOCULAR LENS(ALPHA)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,YELLOW HYDROPHOBIC ACRYLIC POSTERIOR CHAMBER TORIC ASPHERIC SQUARE EDGE SINGLE PIECE FOLDABLE INTAOCULAR LENS(ALPHA)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,HYDROPHOBIC ACRYLIC POSTERIOR CHAMBER TORIC ASPHERIC SQUARE EDGE SINGLE PIECE FOLDABLE INTAOCULAR LENS(ALPHA)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.,YELLOW HYDROPHOBIC ACRYLIC POSTERIOR CHAMBER MULTIFOCAL TORIC ASPHERIC SQUARE EDGE SINGLE PIECE FOLDABLE INTAOCULAR LENS(ALPHA)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS., YELLOW HYDROPHOBIC ACRYLIC POSTERIOR CHAMBER MULTIFOCAL DIFFRACTIVE- REFFRACTIVE ASPHERIC SQUARE EDGE SINGLE PIECE FOLDABLE INTRAOCULAR LENS(ALPHA)-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRA CAPSULAR EXTRACTION METHODS.

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3353	MFG/MD/2019/000221	1.License Holder Name: DATT MEDIPRODUCTS PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ADHESIVE DRESSING (SURGICAL TAPE)(VELPORE, VELPORE WITH DISPENSOR, MINIPORE, VELSILK, VELPORE-T, VELSOFT - FR)-ADHESIVE TAPES ARE INTENDED FOR HOLDING OR ADHESION ON THE INTACT SKIN SUCH AS DRESSING FIXATION, SECURING TUBING, CANNULA, CATHETERS, AND OTHER DRESSINGS.,ADHESIVE DRESSING(VELFIX I.V. KIT-III)-IV CANNULIZATION DRESSING KIT (TOURNIQUET IS USED TO FASTEN ARM OR LEG AT THE TIME OF CANNULIZATION).,COTTON CREPE BANDAGE(TRIPLE CROSS PREMIUM, CREPESAN LITE, NABALAN VERBAND, ELVIC, VIC, AJAY CREPE, VELSOFT BLUE)-A COTTON BANDAGE IS PRIMARILY INTENDED TO BE USED FOR RELIEF FROM MUSCLE STRAINS AND JOINT PAINS. IT ALSO USED AS SECONDARY DRESSING FOR WOUNDS.,ADHESIVE DRESSING (SURGICAL TAPE) (VELSOFIX)-ADHESIVE TAPES ARE INTENDED FOR HOLDING OR ADHESION ON THE INTACT SKIN SUCH AS DRESSING FIXATION, SECURING TUBING, CANNULA, CATHETERS, AND OTHER DRESSINGS., ELASTIC ADHESIVE BANDAGE(VELSOFT ADHESIVE, VELSOFT COHESIVE, VELSOFT PLUS, VELFORM, VELCOOL)-ADHESIVE BANDAGE WITH SUPERIOR STRETCH. USEFUL TO SECURE PRIMARY DRESSINGS.,COTTON GAUZE & BANDAGES(VEL-2, VEL-3, VELFOUR – A, VELFOUR-B, VELFOUR-A PLUS, VELFOUR-B PLUS, VELFOUR-C)-MULTI-LAYER BANDAGING SYSTEM FOR TREATING VENOUS LEG ULCERS & ASSOCIATED CONDITIONS.,CASTING TAPES/SPLINT ROLLS (VELROLL PLUS)-SYNTHETIC CAST PADDING PROVIDES PADDING AROUND THE BONY STRUCTURE.,ELASTIC ADHESIVE BANDAGE (DOCTOR'S CHOICE, VELSOFT COMPRESSION TAPE, VELPORE-Z, COKOMP, RUDALASTIK, VELFORM COHESIVE, RUDASPORT)-ADHESIVE BANDAGE WITH SUPERIOR STRETCH. USEFUL TO SECURE PRIMARY DRESSINGS.,ADHESIVE DRESSING(VELFIX EASY + PAD, VELFIX-T+PAD, VELFIX-T FILM, VELFIX EDGE, VELSOFT FR-T, RUDAFILM, VELFIX EDGE-S)-TRANSPARENT FILM / NON-WOVEN IV DRESSING OR WOUND DRESSING WITH ABSORBENT PAD (TO ABSORB EXUDATE, FLUIDS) OR WITHOUT ABSORBENT PAD.,COMPRESSION BANDAGE(VELSOFT-E, VELSOFT-I, VELSOFT-H, CREPESAN -E, FLEXOCREPE, VELSPAN, DMP CREPE, NOBADUR, NOBASTRETCH KRAFTIG, NOBASTRETCH ULTRA, NOBASTRETCH FEIN, NOBA EXTENSIONSVERBAND, TENSOLASTIC, VELSOLASTIC)-COMPRESSION BANDAGE PRIMARILY INTENDED TO BE USED FOR RELIEF FROM MUSCLE STRAINS AND JOINT PAINS,GAUZE SWABS WITH X-RAY THREAD AND WITHOUT X-RAY THREAD(TONSIL GAUZE, PEANUT GAUZE, GAUZE TAIL, RIBBON GAUZE, ANESTHETIC GAUZE, NASAL PACK, ROBATIC GAUZE, CARDIAC SWAB, GAUZE THAN, PETTIES

	GAUZE, COTTON BALL, SOFTSWAB-HA, SOFTSWAB-H, SOFTLAPS-PW) -INTENDED FOR CLEANING A WOUND AND ABSORBING BLOOD AND EXUDATE FLUIDS FROM A WOUND, SURGICAL PROCEDURES AND DIFFERENT INJURIES,COTTON CREPE BANDAGE(VELCARE LYMPHEDEMA KIT- ARM, VELCARE LYMPHEDEMA KIT- LEG)-A SET OF BANDAGE FOR EDEMA MANAGEMENT.,ADHESIVE DRESSING(VELFIX I. V., VELFIX-T, VELFIX-EASY, VEL-DRESS)-TRANSPARENT FILM / NON-WOVEN IV DRESSING OR WOUND DRESSING WITH ABSORBENT PAD (TO ABSORB EXUDATE, FLUIDS) OR WITHOUT ABSORBENT PAD., ELASTIC TUBULAR BANDAGE(VELNET)-A STOCKINETTE THAT PROTECTS SKIN FROM FRICTION UNDER PLASTER/ FIBERGLASS BANDAGE.,COTTON GAUZE & BANDAGES(VELFOUR)-MULTI-LAYER BANDAGING SYSTEM FOR TREATING VENOUS LEG ULCERS & ASSOCIATED CONDITIONS.,GAUZE SWABS WITH X-RAY THREAD AND WITHOUT X-RAY THREAD(SOFTSWAB, VELSWAB, SOFTLAPS)-INTENDED FOR CLEANING A WOUND AND ABSORBING BLOOD AND EXUDATE FLUIDS FROM A WOUND, SURGICAL PROCEDURES AND DIFFERENT INJURIES.,CASTING TAPES/SPLINT ROLLS(VELPOP)-FOR IMMOBILIZATION TO PROTECT LIMBS WITH BROKEN BONES.,GAUZE SWABS(SMART GAUZE, LAPAROTOMY SPONGE, PROPAX, FIVEX, KOMPRESSEN, MULLKOMPRESSEN, SWABX, GAUZE BALLS, MULLTUPFER, DRESSING FIELD COMPRESSED, DRESSING SHELL COMPRESSED, DRESSING FIRST AID, VELNEXT DRESSING)-INTENDED FOR CLEANING A WOUND AND ABSORBING BLOOD AND EXUDATE FLUIDS FROM A WOUND.,DRESSING PACK(SOFTPACK (RENAL DIALYSIS ON/OFF PACK))-A SURGICAL DRESSING KIT FOR RENAL DIALYSIS PROCEDURE.,DRESSING PACK(SOFTPACK DRESSING KIT)-CLEANING OF WOUNDS OR INJURY SITE.,CASTING TAPES/SPLINT ROLLS(VELROLL)-SYNTHETIC CAST PADDING PROVIDES PADDING AROUND THE BONY STRUCTURE.,CREPE BANDAGE(VEL2#2)-MEDIUM COMPRESSION BANDAGE PRIMARILY INTENDED TO BE USED FOR RELIEF FROM MUSCLE STRAINS AND JOINT PAINS,ADHESIVE DRESSING (SURGICAL TAPE)(VELPORE-S, VELPORE PRO, RUDAPOR, DOCTOR'S CHOICE SURGICAL TAPE, DOQTAR, RUDASILK, RUDAFIX)-ADHESIVE TAPES ARE INTENDED FOR HOLDING OR ADHESION ON THE INTACT SKIN SUCH AS DRESSING FIXATION, SECURING TUBING, CANNULA, CATHETERS, AND OTHER DRESSINGS.,COTTON GAUZE & BANDAGES(VELCARE LYMPHEDEMA KIT)-A SET OF BANDAGE FOR EDEMA MANAGEMENT.,ADHESIVE DRESSING(VELFIX PICC/CVC SECUREMENT KIT)-THE DRESSING IS USED TO SECURE AND TIE PICC/CVC CANNULA OR CATHETER ON THE BODY AND ELIMINATE THE RISK OF DISLODGEMENT,COMPRESSION BANDAGE(VELSOFT-V)-HIGH COMPRESSION BANDAGE PRIMARILY INTENDED TO BE USED FOR RELIEF FROM MUSCLE STRAINS AND JOINT PAINS,COTTON

	CREPE BANDAGE(SOFT CREPE, TENSOCREPE LITE, TENSOCREPE LITE+, ELASTOLITE, ELASTOCREPE, COTOCREPE, SAVIC, MEDICREPE, NOBALAN, IDEAL BINDE, NOBA IDEAL, IDEALAST, TRIPLE CROSS CREPE BANDAGE, ELASTOFORM, NOBA CREPE, MEDIK, M-CREPE, VELSOFT, VELKOMP, E-FORM, VELFOAM C)-A COTTON BANDAGE IS PRIMARILY INTENDED TO BE USED FOR RELIEF FROM MUSCLE STRAINS AND JOINT PAINS. IT ALSO USED AS SECONDARY DRESSING FOR WOUNDS.,DRESSING PACK(GAMJEE ROLL, GAMJEE PAD, SOFTPAD, SOFTPAD (EYE PAD))-A DRESSING FOR THE ABSORPTION OF DISCHARGES FROM THE WOUND SITE.,ADHESIVE DRESSING (VELFIX IV KIT)-IV CANNULIZATION DRESSING KIT (TOURNIQUET IS USED TO FASTEN ARM OR LEG AT THE TIME OF CANNULIZATION)., COTTON GAUZE & BANDAGES(GAUZE ROLLS, EP-17, EP-20)-FOR FURTHER PRODUCT MANUFACTURING, THE ROLL MAY BE PROCESSED TO PRODUCE SWABS, GAUZE BANDAGES, AND POP BANDAGES.

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3354	MFG/MD/2019/000222	1.License Holder Name: AGROSURG IRRADIATORS (INDIA) PVT. LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:STERILE STAPLES (PINS) FOR DISPOSABLE CIRCULAR STAPLER(MIRUS™ DISPOSABLE CIRCULAR STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY., DISPOSABLE SKIN STAPLER(MIRUS™ STERILE DISPOSABLE SKIN STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,STERILE STAPLES (PINS) FOR DISPOSABLE CIRCULAR STAPLERS(MIRUS™ DISPOSABLE CIRCULAR STAPLER 3 ROWS)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY., STERILISED UMBILICAL COTTON TAPE(MERIL - UMBILICAL COTTON TAPE™)-UMBILICAL COTTON TAPE™ IS USED TO TIE OFF THE UMBILICAL CORD,STERILE STAPLES (PINS) FOR DISPOSABLE LINEAR STAPLER(MIRUS™ DISPOSABLE LINEAR STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,STERILE STAPLES (PINS) FOR DISPOSABLE CURVED CUTTER STAPLER(MIRUS™ DISPOSABLE CURVED CUTTER STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,STERILE STAPLES (PINS) FOR DISPOSABLE LINEAR CUTTER STAPLER(MIRUS™ DISPOSABLE LINEAR CUTTER STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY,STERILE STAPLES (PINS) FOR DISPOSABLE HEMORRHOIDS STAPLER(MIRUS™ DISPOSABLE HEMORRHOIDS STAPLER 3 ROWS)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,STERILE STAPLES (PINS) FOR DISPOSABLE HEMORRHOIDS STAPLER(MIRUS™ DISPOSABLE HEMORRHOIDS STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,STERILE STAPLES (PINS) FOR DISPOSABLE ENDO CUTTER STAPLER(MIRUS™ DISPOSABLE ENDO CUTTER STAPLER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.,BONEWAX(MERIL-BONEWAX™)-

		MERIL - BONEWAX™ IS INTENDED TO AID IN THE CONTROL OF BLEEDING IN BONE INJURIES.
3355	MFG/MD/2019/000223	1.License Holder Name: UNITED COTTON 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.-ABSORBENT COTTON IS USED TO PRODUCE DRESSING MATERIAL, PADDING FOR ITEMS OF CLOTHING, QUILTS ETC.
3356	MFG/MD/2019/000224	1.License Holder Name: BASIC HEALTHCARE PRODUCTS PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BADDI 3.Device Name(Brand Name)-Intended Use:BONE PLATE(B-SAF)-RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,BONE WIRE/ PINS(B-SAF)-RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,BONE SCREW(B-SAF)-RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,BONE NAIL(B-SAF)-RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,HEMI PROSTHESIS(B-SAF)-RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,SYNTHETIC BONE GRAFT.(B-OSTIN)-CANCELLOUS BONE VOID FILLER

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3357	MFG/MD/2019/000225	1.License Holder Name: AUROLAB 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:HYDROPHOBIC ASPHERIC ACRYLIC FOLDABLE IOL(AUROVUE VIVID)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY,HYDROPHILIC ACRYLIC FOLDABLE IOL, HYDROPHILIC ASPHERIC FOLDABLE IOL,(----------)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY, HYDROPHOBIC ACRYLIC FOLDABLE IOL(AUROVUE VIVID)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY,PMMA INTRAOCULAR LENS(---------)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY,YELLOW HYDROPHOBIC FOLDABLE ACRYLIC INTRAOCULAR LENS(AUROVUE EV GOLD, ECO-FLEX PRELOADED)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY,YELLOW HYDROPHILIC FOLDABLE POLY HYDROXY ETHYL METHACRYLATE INTRAOCULAR LENS(AUROFLEX –EV GOLD)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY, HYDROPHILIC FOLDABLE POLY HYDROXY ETHYL METHACRYLATE INTRAOCULAR LENS(AUROFLEX, AUROFLEX-EV,AUROFOLD, MICROFOLD,AUROFLEX TORIC, I-VISION, FOCUS-HYDROPHILIC FOLDABLE LENS,AUROBIL, VISIFOLD,VISIFLEX-EV, 863 UV, 860UV , HYDRO –FLEX PLUS, VISIFLEX-SQ)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY,POLY METHYL METHACRYLATE INTRAOCULAR LENS(AUROLENS, AUROLENS-EV, TRUEDGE, AUROLENS-CM, AUROLENS TORIC, FOCUS-PMMA LENS, FLUORIOL, HEPARIOL, VISILENS)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY,HYDROPHOBIC FOLDABLE ACRYLIC INTRAOCULAR LENS(AUROVUE, AUROVUE-EV AUROVUE-EV TORIC, AUROVUE DFINE, VISISOFT)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY,HYDROPHOBIC ACRYLIC FOLDABLE IOL, HYDROPHOBIC ASPHERIC ACRYLIC FOLDABLE IOL(----------)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY

3358	MFG/MD/2019/000226	1.License Holder Name: HLL LIFECARE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:MALE LATEX CONDOMS (LUBRICATED MALE LATEX CONDOMS,MOODS REGULAR,SHARE DELAY,SHARE RIBBED,SHARE THIN,SHARE DOTTED,RAKSHAK,JOSH, NIRODH,DELUXE NIRODH,NIRODH ASHA,USTAD)-WHEN USED CORRECTLY EVERY TIME YOU HAVE SEX, CONDOMS GREATLY REDUCE THE RISK OF UNINTENDED PREGNANCY, HIV/AIDS AND SOME OTHER SEXUALLY TRANSMITTED INFECTIONS.,FEMALE LATEX CONDOMS(FC2 FEMALE CONDOMS,VELVET, V.A.W.O.W,FEMALE LATEX CONDOMS,MOODS VELVET, CONDON FEMENINO)-WHEN USED CORRECTLY EVERY TIME YOU HAVE SEX, CONDOMS GREATLY REDUCE THE RISK OF UNINTENDED PREGNANCY, HIV/AIDS AND SOME OTHER SEXUALLY TRANSMITTED INFECTIONS.

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3359	MFG/MD/2019/000227	1.License Holder Name: TRANSLUMINA THERAPEUTICS LLP 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:SIROLIMUS ELUTING CORONARY STENT SYSTEM(YUKON CHOICE SWIFT)-SIROLIMUS ELUTING CORONARY STENT SYSTEM USED FOR TREATMENT OF: • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO DISCRETE DE NOVO OR RESTENOSIS LESION IN NATIVE CORONARY ARTERY. • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO CULPRIT LESION IN SAPHENOUS VEIN GRAFT. • TREATMENT OF CORONARY LESION IN PATIENTS UNDERGOING PRIMARY OR RESCUE PCI FOR ACUTE ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI) • TREATMENT OF CORONARY LESION HAVING ATHERO THROMBOTIC APPEARANCE IN PATIENTS WITH NON-ST- ELEVATION ACUTE CORONARY SYNDROMES (UNSTABLE ANGINA AND NON-ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION),SEMI COMPLIANT PTCA BALLOON CATHETER(YUKON SC PRIME)-HE YUKON SC PRIME BALLOON CATHETER IS INTENDED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES.,GUIDEWIRE(TRANS WIRE-PRIME)-GUIDEWIRE IS A STEERABLE GUIDEWIRE THAT ARE USED FOR THE INTRODUCTION AND PLACEMENT OF DIAGNOSTIC OR INTERVENTIONAL DEVICES IN THE CORONARY AND PERIPHERAL VASCULATURE AND MAY BE USED TO REACH AND CROSS A TARGET LESION. GUIDEWIRE ARE USED TO FACILITATE THE SUBSTITUTION OF ONE DIAGNOSTIC OR INTERVENTIONAL DEVICE FOR ANOTHER.,NON COMPLIANT PTCA BALLOON CATHETER(YUKON NC PRIME)-BALLOON DILATION OF THE STENOTIC PORTION OF A NATIVE CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL REPERFUSION AND ALSO USED FOR POST-DILATION OF STENTS.,SIROLIMUS ELUTING CORONARY STENT SYSTEM(YUKON CHOICE PC)-SIROLIMUS ELUTING CORONARY STENT SYSTEM USED FOR TREATMENT OF: • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO DISCRETE DE NOVO OR RESTENOSIS LESION IN NATIVE CORONARY ARTERY. • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO CULPRIT LESION IN SAPHENOUS VEIN GRAFT. • TREATMENT OF CORONARY LESION IN PATIENTS UNDERGOING PRIMARY OR RESCUE PCI FOR ACUTE ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI) • TREATMENT OF CORONARY LESION HAVING ATHERO THROMBOTIC APPEARANCE IN PATIENTS WITH NON-ST-ELEVATION ACUTE CORONARY SYNDROMES (UNSTABLE ANGINA AND NON-ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION),POLYMER FREE EVEROLIMUS ELUTING CORONARY STENT SYSTEM(ISAR 4EVER)-

	POLYMER FREE EVEROLIMUS ELUTING CORONARY STENT SYSTEM USED FOR TREATMENT OF: • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO DISCRETE DE NOVO OR RESTENOSIS LESION IN NATIVE CORONARY ARTERY. • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO CULPRIT LESION IN SAPHENOUS VEIN GRAFT. • TREATMENT OF CORONARY LESION IN PATIENTS UNDERGOING PRIMARY OR RESCUE PCI FOR ACUTE ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI) • TREATMENT OF CORONARY LESION HAVING ATHERO THROMBOTIC APPEARANCE IN PATIENTS WITH NON-ST- ELEVATION ACUTE CORONARY SYNDROMES (UNSTABLE ANGINA AND NON-ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION),SIROLIMUS ELUTING CORONARY STENT SYSTEM(YUKON CHOICE FLEX)-SIROLIMUS ELUTING CORONARY STENT SYSTEM USED FOR TREATMENT OF: •SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO DISCRETE DE NOVO OR RESTENOSIS LESION IN NATIVE CORONARY ARTERY. •SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO CULPRIT LESION IN SAPHENOUS VEIN GRAFT. •TREATMENT OF CORONARY LESION IN PATIENTS UNDERGOING PRIMARY OR RESCUE PCI FOR ACUTE ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI) •TREATMENT OF CORONARY LESION HAVING ATHERO THROMBOTIC APPEARANCE IN PATIENTS WITH NON-ST- ELEVATION ACUTE CORONARY SYNDROMES (UNSTABLE ANGINA AND NON-ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION),NON COMPLIANT PTCA BALLOON CATHETER(YUKON NC)-BALLOON DILATION OF THE STENOTIC PORTION OF A NATIVE CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL REPERFUSION AND ALSO USED FOR POST-DILATION OF STENTS., SIROLIMUS ELUTING CORONARY STENT SYSTEM(YUKON CHOICE PC ELITE)-SIROLIMUS ELUTING CORONARY STENT SYSTEM USED FOR TREATMENT OF: • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO DISCRETE DE NOVO OR RESTENOSIS LESION IN NATIVE CORONARY ARTERY. • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO CULPRIT LESION IN SAPHENOUS VEIN GRAFT. • TREATMENT OF CORONARY LESION IN PATIENTS UNDERGOING PRIMARY OR RESCUE PCI FOR ACUTE ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI) • TREATMENT OF CORONARY LESION HAVING ATHERO THROMBOTIC APPEARANCE IN PATIENTS WITH NON-ST-ELEVATION ACUTE CORONARY SYNDROMES (UNSTABLE ANGINA AND NON-ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION), POLYMER FREE SIROLIMUS ELUTING CORONARY STENT SYSTEM (VIVO ISAR)-VIVO ISAR-POLYMER FREE SIROLIMUS ELUTING CORONARY STENT SYSTEM USED FOR TREATMENT OF: - SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO DISCRETE DE

	NOVO OR RESTENOSIS LESION IN NATIVE CORONARY ARTERY. - SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO CULPRIT LESION IN SAPHENOUS VEIN GRAFT. - TREATMENT OF CORONARY LESION IN PATIENTS UNDERGOING PRIMARY OR RESCUE PCI FOR ACUTE ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI) TREATMENT OF CORONARY LESION HAVING ATHERO THROMBOTIC APPEARANCE IN PATIENTS WITH NON ST-ELEVATION ACUTE CORONARY SYNDROMES (UNSTABLE ANGINA AND NON ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION),INTRODUCER SHEATH SET (TRANS-INTRO)-INTRODUCER SET FOR SINGLE USE IS MAINLY USED TO PENETRATE INTO ARTERY AT THE BEGINNING OF THE INTERVENTION OPERATION AND THEN INTRODUCE THE GUIDEWIRE INTO THE LEAD BLOOD VESSEL IN THE INTERVENTION OPERATION. THE INTRODUCER SHEATH IS INDICATED FOR USE IN ARTERIAL AND VENOUS PROCEDURES REQUIRING PERCUTANEOUS INTRODUCTION OF INTRAVASCULAR DEVICES.,NON-COMPLIANT PTCA BALLOON CATHETER(ENERGY NC)-BALLOON DILATION OF THE STENOTIC PORTION OF A NATIVE CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL REPERFUSION AND ALSO USED FOR POST-DILATION OF STENTS., SIROLIMUS ELUTING CORONARY STENT SYSTEM(RACER CC)-SIROLIMUS ELUTING CORONARY STENT SYSTEM USED FOR TREATMENT OF: • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO DISCRETE DE NOVO OR RESTENOSIS LESION IN NATIVE CORONARY ARTERY. • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO CULPRIT LESION IN SAPHENOUS VEIN GRAFT. • TREATMENT OF CORONARY LESION IN PATIENTS UNDERGOING PRIMARY OR RESCUE PCI FOR ACUTE ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI) • TREATMENT OF CORONARY LESION HAVING ATHERO THROMBOTIC APPEARANCE IN PATIENTS WITH NON-ST-ELEVATION ACUTE CORONARY SYNDROMES (UNSTABLE ANGINA AND NON-ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION), GUIDING CATHETER(AGILE)-THE AGILE-GUIDING CATHETER IS DESIGNED TO PROVIDE A PATHWAY THROUGH WHICH THERAPEUTIC AND DIAGNOSTIC DEVICES ARE INTRODUCED. THE AGILE-GUIDING CATHETER IS INTENDED TO BE USED IN THE CORONARY VASCULAR SYSTEM,GUIDEWIRE(TRANS-WIRE)-GUIDEWIRE IS A STEERABLE GUIDEWIRE THAT ARE USED FOR THE INTRODUCTION AND PLACEMENT OF DIAGNOSTIC OR INTERVENTIONAL DEVICES IN THE CORONARY AND PERIPHERAL VASCULATURE AND MAY BE USED TO REACH AND CROSS A TARGET LESION. GUIDEWIRE ARE USED TO FACILITATE THE SUBSTITUTION OF ONE DIAGNOSTIC OR INTERVENTIONAL DEVICE FOR ANOTHER.,SIROLIMUS ELUTING CORONARY STENT SYSTEM(RACER PC)-SIROLIMUS ELUTING

	CORONARY STENT SYSTEM USED FOR TREATMENT OF: • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO DISCRETE DE NOVO OR RESTENOSIS LESION IN NATIVE CORONARY ARTERY. • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO CULPRIT LESION IN SAPHENOUS VEIN GRAFT. • TREATMENT OF CORONARY LESION IN PATIENTS UNDERGOING PRIMARY OR RESCUE PCI FOR ACUTE ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI) •TREATMENT OF CORONARY LESION HAVING ATHERO THROMBOTIC APPEARANCE IN PATIENTS WITH NON-ST- ELEVATION ACUTE CORONARY SYNDROMES (UNSTABLE ANGINA AND NON-ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION),SIROLIMUS ELUTING CORONARY STENT SYSTEM(ULTIMA PC)-SIROLIMUS ELUTING CORONARY STENT SYSTEM USED FOR TREATMENT OF: • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO DISCRETE DE NOVO OR RESTENOSIS LESION IN NATIVE CORONARY ARTERY. • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO CULPRIT LESION IN SAPHENOUS VEIN GRAFT. • TREATMENT OF CORONARY LESION IN PATIENTS UNDERGOING PRIMARY OR RESCUE PCI FOR ACUTE ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI) • TREATMENT OF CORONARY LESION HAVING ATHERO THROMBOTIC APPEARANCE IN PATIENTS WITH NON-ST- ELEVATION ACUTE CORONARY SYNDROMES (UNSTABLE ANGINA AND NON-ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION),SIROLIMUS ELUTING CORONARY STENT SYSTEM(YUKON CHOICE PC PLUS)-SIROLIMUS ELUTING CORONARY STENT SYSTEM USED FOR TREATMENT OF: • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO DISCRETE DE NOVO OR RESTENOSIS LESION IN NATIVE CORONARY ARTERY. • SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO CULPRIT LESION IN SAPHENOUS VEIN GRAFT. • TREATMENT OF CORONARY LESION IN PATIENTS UNDERGOING PRIMARY OR RESCUE PCI FOR ACUTE ST SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI) • TREATMENT OF CORONARY LESION HAVING ATHERO THROMBOTIC APPEARANCE IN PATIENTS WITH NON-ST- ELEVATION ACUTE CORONARY SYNDROMES (UNSTABLE ANGINA AND NON-ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION), ASPIRATION CATHETER(TRANS- ASPIRATOR)-THE TRANS ASPIRATOR IS INDICATED FOR USE IN THE CENTRAL AND PERIPHERAL CIRCULATORY SYSTEM, INCLUDING SAPHENOUS VEIN GRAFT TO CONTAIN AND ASPIRATE EMBOLIC MATERIAL (THROMBUS/DEBRIS) WHILE PERFORMING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY, PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) AND / OR STENTING PROCEDURE.,GUIDEWIRE(TRANS-HYDRO WIRE)-GUIDEWIRE IS A STEERABLE GUIDEWIRE THAT ARE USED FOR THE INTRODUCTION

		AND PLACEMENT OF DIAGNOSTIC OR INTERVENTIONAL DEVICES IN THE CORONARY AND PERIPHERAL VASCULATURE AND MAY BE USED TO REACH AND CROSS A TARGET LESION. GUIDEWIRE ARE USED TO FACILITATE THE SUBSTITUTION OF ONE DIAGNOSTIC OR INTERVENTIONAL DEVICE FOR ANOTHER., ANGIOGRAPHIC/DIAGNOSTIC CATHETER(TRANS-ANGIO)-THE ANGIOGRAPHIC CATHETER IS BRAIDED CARDIOVASCULAR CATHETER DESIGNED TO DELIVER CONTRAST MEDIUM INTO SELECTED BLOOD VESSELS DURING AN ANGIOGRAPHIC PROCEDURE TO FACILITATE THE VISUALIZATION OF THE VASCULAR SYSTEM OF A TARGET AREA. ANGIOGRAPHIC CATHETERS ARE DESIGNED TO DELIVER RADIOPAQUE CONTRAST MEDIUM TO SELECTED SITES IN THE VASCULAR SYSTEM.,SEMI-COMPLIANT PTCA BALLOON CATHETER(RAPID)-DEVICE IS INTENDED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES.,BARE METAL STENT SYSTEM(FLAXON)-FLAXON-STENT SYSTEM IS INDICATED FOR INTRALUMINAL CHRONIC PLACEMENT IN STENOSED CORONARY ARTERY OR AORTO-CORONARY BYPASS GRAFTS OR THE TIBIAL ANTERIOR AND POSTERIOR ARTERY OF THE LOWER LIMB WITH A MAXIMUM LESION LENGTH OF 48 MM, IN ORDER TO OBTAIN VESSEL PATENCY FOLLOWING ACUTE OR SUBACUTE ARTERY OBSTRUCTION. IT IS ALSO INDICATED IN RESTENOSIS OR ARTERIAL DISSECTION AFTER PTCA PROCEDURES.
3360	MFG/MD/2019/000228	1.License Holder Name: FUTURA SURGICARE PVT LTD 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:APPLICATOR FOR LIGATION CLIPS.(APPLIGRIP & OTHER OEM BRANDS.)-IT IS INTENDED TO PLACE THE LIGATION CLIP THROUGH BODY ORIFICE ON A TUBULAR STRUCTURE.,STAPLE REMOVER.(DOLPHIN REMOVER & OTHER OEM BRANDS.)-IT IS INTENDED TO REMOVE THE SURGICAL SKIN STAPLES FROM THE INTACT HEALED SKIN.,MICROPOROUS ADHESIVE PAPER TAPE.(DOLPHIN TAPE & OTHER OEM BRANDS.)-IT IS INTENDED TO BE PLACED ON THE INTACT SKIN OF THE PATIENT AS A HOLDING DEVICE TO HOLD/ PASTE OTHER SURGICAL DRESSINGS IN PLACE. IT IS NOT INTENDED TO COME IN CONTACT WITH BLOOD OR BREACHED SKIN.

3361	MFG/MD/2019/000229	1.License Holder Name: SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT(PIVOT IMPLANT)-DENTAL IMPLANTS ARE TINY TITANIUM SCREWS THAT ARE SURGICALLY PLACED IN THE JAW BONE. THESE IMPLANTS ARE MEANT TO ACT AS REPLACEMENT TOOTH ROOTS.

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3362	MFG/MD/2019/000230	1.License Holder Name: LOTUS SURGICAL PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BRAIDED COATED SILK SYNTHETIC NON- ABSORBABLE SUTURE(PREMISUT SILK (FOR EXPORT ONLY))-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,TETRALOGY OF FALLOT KIT (TOF KIT)-INTENDED USED FOR SURGICAL DRESSING AND CONTROL BLOOD LOSS DURING TETRALOGY OF FALLOT DEFECT REPAIR OR TREATMENT SURGERY. TETRALOGY OF FALLOT IS A COMBINATION OF FOUR HEART DEFECTS THAT RESULT IN OXYGEN-POOR BLOOD FLOWING OUT OF THE HEART AND INTO THE BODY. THIS CAN CAUSE CYANOSIS — THE MEDICAL TERM FOR TURNING BLUE BECAUSE OF DEFICIENT OXYGEN IN THE BLOOD.,BRAIDED COATED POLYESTER SYNTHETIC NON- ABSORBABLE SUTURE(PREMISUT POLYESTER (FOR EXPORT ONLY))-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,MONOFILAMENT POLYPROPYLENE SYNTHETIC NON- ABSORBABLE SUTURE (POLYPROP)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,BRAIDED COATED SHORT TERM POLY (GLYCOLIDE-L-LACTIDE)/POLYGLACTIN-910 SYNTHETIC ABSORBABLE SUTURE(PREMISUT PGLAR (FOR EXPORT ONLY))-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL.,VASCULAR EMBELACTOMY KIT(VASCULAR EMBELACTOMY KIT)-INTENDED USED FOR SURGICAL DRESSING AND CONTROL BLOOD LOSS DURING VASCULAR EMBELACTOMY SURGERY. VASCULAR EMBELACTOMY IS A EMERGENCY SURGICAL PROCEDURE THAT INVOLVES SURGICAL REMOVAL OF EMBOLI WHICH ARE BLOCKING BLOOD CIRCULATION.,MONOFILAMENT POLYPROPYLENE MESH(PROLIPRO (FOR EXPORT AND DOMESTIC))-POLYPROPYLENE MESH USED FOR ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISIONAL, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS. USED IN BOTH COELIOSCOPY AND LAPAROTOMY.,MONOFILAMENT KNITTED POLYPROPYLENE MESH(PROLUS ECO MESH)-POLYPROPYLENE MESH USED FOR ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISIONAL, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS. USED IN BOTH COELIOSCOPY AND LAPAROTOMY.,BRAIDED COATED SHORT TERM POLY (GLYCOLIDE-L-LACTIDE)/POLYGLACTIN-910 SYNTHETIC ABSORBABLE SUTURE(SYLAS SWIFT 910 (FOR EXPORT AND DOMESTIC))-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL.,MONOFILAMENT POLYPROPYLENE MESH

	(FREEDOM VM)-FREEDOM VM (POLYPROPYLENE MESH)- TRANS OBTURATOR SLING SYSTEM IS INTENDED FOR THE PLACEMENT OF A SUB-URETHRAL MESH FOR THE TREATMENT OF FEMALE STRESS INCONTINENCE (SUI) RESULTING FROM URETHRAL HYPER MOBILITY AND / OR INTRINSIC SPHINCTER DEFICIENCY.,BRAIDED COATED POLY (GLYCOLIDE-L-LACTIDE)/POLYGLACTIN-910 SYNTHETIC ABSORBABLE SUTURE(PREMISUT PGLA (FOR EXPORT ONLY))-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,BRAIDED COATED POLY (GLYCOLIDE-L-LACTIDE) /POLYGLACTIN-910 SYNTHETIC ABSORBABLE SUTURE(RENACRYL)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,BRAIDED COATED POLYGLYCOLIC ACID SYNTHETIC ABSORBABLE SUTURE(PREMISUT PGA (FOR EXPORT ONLY))-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION AND/OR LIGATION.,POLY(GLYOCOLIDE-CO-CAPROLACTONE) & POLYPROPYLENE PARTIALLY ABSORBABLE LIGHT WEIGHT MESH FOR HERNIA REPAIR(PRO-AB MESH)-PRO-AB IS A POLYPROPYLENE AND POLY (GLYCOLIDE CO-CAPROLACTONE) COMPOSITE MESH IS USED FOR THE REPAIR OF HERNIA OR OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITIONAL OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT.,BRAIDED COATED SHORT TERM POLYGLYCOLIC ACID SYNTHETIC ABSORBABLE SUTURE(PREMISUT PGAR (FOR EXPORT ONLY))-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL.,CHROMIC AND PLAIN CATGUT ABSORBABLE SURGICAL SUTURE (COLLAGEN) (LOGUT)-LOGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC SURGERY AND IN OPHTHALMIC PROCEDURES.,BRAIDED COATED SILK SYNTHETIC NON- ABSORBABLE SUTURE(SILKRIL (FOR EXPORT AND DOMESTIC))-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,ULTRA-LIGHT WEIGHT POLYPROPYLENE MESH(PROLUS ULTRA LITE MESH)-POLYPROPYLENE MESH IS USED FOR ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISION, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS. USED IN BOTH COELIOSCOPY AND LAPAROTOMY.,MONOFILAMENT POLYPROPYLENE MESH (PREMISUT POLYPROPYLENE MESH (FOR EXPORT ONLY))-POLYPROPYLENE MESH USED FOR ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISIONAL, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS. USED IN BOTH COELIOSCOPY AND LAPAROTOMY.,MONOFILAMENT 316L STAINLESS STEEL SYNTHETIC NON- ABSORBABLE SUTURE(STELUS)-INDICATED FOR

	USE IN ABDOMINAL WOUND CLOSURE, HERNIA REPAIR, STERNA CLOSURE AND ORTHOPEDIC PROCEDURES INCLUDING CERCLAGE AND TENDON REPAIR.,MONOFILAMENT 316L STAINLESS STEEL SYNTHETIC NON- ABSORBABLE SUTURE(PREMISUT STEEL (FOR EXPORT ONLY))-INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, HERNIA REPAIR, STERNA CLOSURE AND ORTHOPEDIC PROCEDURES INCLUDING CERCLAGE AND TENDON REPAIR.,LIGHT WEIGHT MONOFILAMENT POLYPROPYLENE MESH(PROLUS LITE MESH)-POLYPROPYLENE MESH USED FOR ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISIONAL, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS. USED IN BOTH COELIOSCOPY AND LAPAROTOMY.,SYNTHETIC NON- ABSORBABLE SUTURE MONOFILAMENT POLYPROPYLENE(PROLIPRO (FOR EXPORT AND DOMESTIC))-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,MONOFILAMENT POLYAMIDE SYNTHETIC NON- ABSORBABLE SUTURE(NYLUS)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION., MONOFILAMENT POLY (P-DIOXANONE) SYNTHETIC ABSORBABLE SUTURE(PREMISUT PDO (FOR EXPORT ONLY))-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION IN MICROSURGERY AND IN OPHTHALMIC SURGERY.,CESAREAN SECTION KIT(LCS KIT)-INTENDED FOR USED TO HELP SURGICAL DRESSING AND HEAL FROM SURGERY AND ACQUIRE OVERALL WELL BEING.,MONOFILAMENT POLYPROPYLENE SYNTHETIC NON- ABSORBABLE SUTURE (PREMISUT POLYPROPYLENE (FOR EXPORT ONLY))-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION., MONOFILAMENT POLYAMIDE SYNTHETIC NON- ABSORBABLE SUTURE(NYLON)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.,CHROMIC AND PLAIN CATGUT ABSORBABLE SURGICAL SUTURE (COLLAGEN)(PREMISUT CATGUT (FOR EXPORT ONLY))-PREMISUT CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC SURGERY AND IN OPHTHALMIC PROCEDURES., MONOFILAMENT POLYPROPYLENE MESH(PROLUS MESH)-POLYPROPYLENE MESH USED FOR ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISIONAL, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS. USED IN BOTH COELIOSCOPY AND LAPAROTOMY.,MONOFILAMENT POLY (GLYCOLIDE-CO-CAPROLACTONE)/ POLYGLECAPRONE-25 SYNTHETIC ABSORBABLE SUTURE(PREMISUT PGCL (FOR EXPORT ONLY))-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,, POLYESTER & POLYURETHANE COMPOSITE DUAL-SIDE 3D MESH FOR INTRA-PERITONEAL PLACEMENT(PRO-VISC 3D MESH)-PRO- VISC 3D – IS A STERILE POLYESTER AND POLYURETHANE DUAL SIDE MESH IS

	USED FOR THE INTRA-PERITONEAL PLACEMENT. TREATMENT FOR VENTRAL AND UMBILICAL HERNIAS.,BRAIDED COATED POLY (GLYCOLIDE-L-LACTIDE)/POLYGLACTIN-910 SYNTHETIC ABSORBABLE SUTURE(SYLAS 910 (FOR EXPORT AND DOMESTIC))-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,POLYTETRAFLUOROETHYLENE (PTFE) INTRA-CARDIAC PATCH(PLEDGETS)-PTFE PLEDGETS USED IN VARIOUS APPLICATIONS FOR GENERAL, VASCULAR AND CARDIAC SURGERY. PLEDGETS ARE USED AS BUTTRESSES UNDER SUTURES WHEN THERE IS A POSSIBILITY OF SUTURES TEARING THROUGH TISSUE. PTFE PLEDGETS ARE INDICATED FOR THE PURPOSES OF TISSUE APPROXIMATION, RETRACTION, AND AS A TEMPORARY OR PERMANENT LIGATURE.,MONOFILAMENT POLYAMIDE SYNTHETIC NON- ABSORBABLE SUTURE(PREMISUT NYLON (FOR EXPORT ONLY)) -INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.,ABDOMINAL HYSTERECTOMY KIT(LAH KIT)-INTENDED FOR USED TO HELP SURGICAL DRESSING AND HEAL FROM SURGERY AND ACQUIRE OVERALL WELL BEING.,MONOFILAMENT POLY (GLYCOLIDE-CO-CAPROLACTONE)/ POLYGLECAPRONE-25 SYNTHETIC ABSORBABLE SUTURE(PGC30)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION., BYLATORAL FEMORAL BYPASS SURGERY KIT(BYLATORAL FEMORAL BYPASS SURGERY KIT)-INTENDED USED FOR SURGICAL DRESSING AND CONTROL BLOOD LOSS DURING BYLATORAL FEMORAL BYPASS SURGERY. BYLATORAL FEMORAL BYPASS SURGERY IS A PROCEDURE USED TO TREAT FEMORAL ARTERY DISEASE. IT IS PERFORMED TO BYPASS THE BLOCKED PORTION OF MAIN ARTERY IN THE LEG USING A PIECE OF ANOTHER BLOOD VESSEL., MONOFILAMENT POLYPROPYLENE SYNTHETIC NON- ABSORBABLE SUTURE(PROLIN-R)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,HERNIA KIT(HERNIA KIT)-INTENDED USED FOR SURGICAL DRESSING AND ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISIONAL, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS.,CHROMIC AND PLAIN CATGUT ABSORBABLE SURGICAL SUTURE (COLLAGEN)(CATGUT-R)-CATGUT-R SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC SURGERY AND IN OPHTHALMIC PROCEDURES.,KNEE ARTHROPLASTY KIT(KNEE ARTHROPLASTY KIT)-INTENDED USED FOR SURGICAL DRESSING AND CONTROL BLOOD LOSS DURING KNEE ARTHROPLASTY. KNEE ARTHROPLASTY, IS A SURGICAL PROCEDURE IN WHICH PARTS OF THE KNEE JOINT OR THE WEIGHT-BEARING SURFACES ARE REPLACED WITH ARTIFICIAL PARTS S A SURGICAL PROCEDURE TO RELIEVE PAIN AND DISABILITY.,STERILE BONE WAX(BONE WAX)-

	LOTUS BONE WAX IS A STERILE MIXTURE OF BEESWAX AND ISOPROPYL PALMITATE, A WAX-SOFTENING AGENT, USED TO HELP CONTROL BLEEDING FROM BONE SURFACES.,BRAIDED COATED SILK SYNTHETIC NON- ABSORBABLE SUTURE(SILK –R)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION., POLYESTER & POLYURETHANE COMPOSITE DUAL MESH FOR INTRA-PERITONEAL PLACEMENT(PRO–VISC MESH)-INTENDED TO USED FOR THE INTRA-PERITONEAL PLACEMENT. TREATMENT FOR VENTRAL AND UMBILICAL HERNIAS.,PAEDIATRIC KIT 5 YEAR(PAEDIATRIC KIT 5 YEAR)-INTENDED USED FOR SURGICAL DRESSING AND CONTROL BLOOD LOSS DURING GENERAL SURGERY OF PAEDIATRIC PATIENTS OF BELOW AGE 5 YEARS.,TITANIUM HAEMOSTATIC CLIP(HEMOSEC)-THE HEMOSEC TITANIUM CLIP IS USED TO OCCLUDE VESSELS. WITH ITS HERRINGBONE SHAPE IT CAN ENCOMPASS THE ENTIRE VESSEL TO BE LIGATED. THE MICRO GEOMETRY OF THE CLIPS INNER SURFACE PROVIDES FOR EXCELLENT GRIP ON THE VESSEL. THIS CLIP MAY BE USED FOR ALL SURGICAL PROCEDURE REQUIRING HAEMOSTATIC OR RADIOGRAPHIC MARKING. CLIP SIZE IS TO BE CHOSEN BY THE USER IN RELATION TO THE INTENDED PROCEDURE TO ENSURE THAT THE WHOLE OF THE TISSUE TO BE LIGATED IS CONTAINED WITHIN THE CLIP.,BRAIDED COATED SILK SYNTHETIC NON- ABSORBABLE SUTURE(SILKUS (REEL))-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION., BRAIDED COATED SHORT TERM POLYGLYCOLIC ACID SYNTHETIC ABSORBABLE SUTURE(PGA15)-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL.,MONOFILAMENT POLYPROPYLENE SYNTHETIC NON- ABSORBABLE SUTURE(PROLUS)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION., MONOFILAMENT POLY (P-DIOXANONE) SYNTHETIC ABSORBABLE SUTURE(MASS)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION IN MICROSURGERY AND IN OPHTHALMIC SURGERY., BRAIDED COATED POLYGLYCOLIC ACID SYNTHETIC ABSORBABLE SUTURE(PGA30)-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION AND/OR LIGATION.,BRAIDED COATED SHORT TERM POLYGLYCOLIC ACID SYNTHETIC ABSORBABLE SUTURE(SOLUS SWIFT)-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL., BRAIDED COATED SHORT TERM POLY (GLYCOLIDE-L-LACTIDE) /POLYGLACTIN-910 SYNTHETIC ABSORBABLE SUTURE(SOLUS SWIFT -910)-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE

	RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL., MONOFILAMENT POLY (GLYCOLIDE-CO-CAPROLACTONE)/ POLYGLECAPRONE-25 SYNTHETIC ABSORBABLE SUTURE (MONOLUS)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,,BRAIDED COATED POLYGLYCOLIC ACID SYNTHETIC ABSORBABLE SUTURE(SOLUS)-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION AND/OR LIGATION.,BRAIDED COATED POLY (GLYCOLIDE-L-LACTIDE) /POLYGLACTIN-910 SYNTHETIC ABSORBABLE SUTURE(SOLUS-910)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,BRAIDED COATED SILK SYNTHETIC NON-ABSORBABLE SUTURE(SILKUS)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,BRAIDED COATED POLYESTER SYNTHETIC NON- ABSORBABLE SUTURE(POLYESTER)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,ABSORBABLE HEMOSTAT FOR SURGICAL USE (OXIDIZED REGENERATED CELLULOSE)(HEMOLUS)-INTERNAL USE, WHOLLY ABSORBABLE, FOR THE CONTROL OF BLEEDING DURING AND AFTER SURGERY, FOR THE GENERAL POPULATION AND FOR THOSE ON ANTICOAGULATION MEDICATION. ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS, AND SMALL ARTERIAL HEMORRHAGE WHEN SURGICAL HEMOSTASIS IS INADEQUATE OR IMPRACTICAL.,LIVER TRANSPLANT KIT(LIVER TRANSPLANT KIT)-INTENDED USED FOR SURGICAL DRESSING AND CONTROL BLOOD LOSS DURING LIVER TRANSPLANT SURGERY, IS A TYPE OF SURGERY THAT IMPROVE THE QUALITY OF LIFE AS WELL AS LONGEVITY IN PATIENTS WITH DECOMPENSATED CHRONIC LIVER DISEASE.,ATRIAL SEPTAL DEFECT / VENTRICULAR SEPTAL DEFECT KIT(ASD/VSD KIT)-INTENDED USED FOR SURGICAL DRESSING AND CONTROL BLOOD LOSS DURING ATRIAL SEPTAL DEFECT / VENTRICULAR SEPTAL DEFECT REPAIR SURGERY, IS A TYPE OF SURGERY THAT CLOSING A LARGE VSD/ASD BY OPEN-HEART SURGERY USUALLY DONE IN INFANCY OR CHILDHOOD EVEN IN PATIENTS WITH FEW SYMPTOMS, TO PREVENT COMPLICATIONS LATER.,RENAL TRANSPLANT KIT (RENAL TRANSPLANT KIT)-INTENDED USED FOR SURGICAL DRESSING AND CONTROL BLOOD LOSS DURING RENAL TRANSPLANT SURGERY. RENAL REPLACEMENT THERAPY (RRT) IS THAT TYPE OF SURGERY WHICH INCLUDES HEMODIALYSIS, PERITONEAL DIALYSIS, AND TRANSPLANTATION. TRANSPLANTATION IS CONSIDERED TO BE THE BEST OPTION OF RRT FOR THE PATIENT BOTH FOR QUALITY OF LIFE AND COST-EFFECTIVENESS.,MONOFILAMENT POLYESTER NON ABSORBABLE MESH(ESTERLUS MESH)-POLYESTER MESH IS USED

	FOR ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISION, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS. USED IN BOTH COELIOSCOPY AND LAPAROTOMY.,AORTIC VALVE REPLACEMENT KIT(AVR KIT)-INTENDED USED FOR SURGICAL DRESSING AND CONTROL BLOOD LOSS DURING AORTIC VALVE REPAIR OR REPLACEMENT SURGERY, IS A TYPE OF SURGERY THAT OFFERS EXCELLENT VALVE FUNCTION AND WORKS IN COORDINATION WITH THE ENTIRE CIRCULATORY SYSTEM TO PROTECT EACH PART FROM DAMAGE.,MONOFILAMENT POLY (P-DIOXANONE) SYNTHETIC ABSORBABLE SUTURE(PDX60)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION IN MICROSURGERY AND IN OPHTHALMIC SURGERY.,CORONARY ARTERY BYPASS GRAFTING KIT(CABG KITS)-INTENDED USED FOR SURGICAL DRESSING AND CONTROL BLOOD LOSS DURING CORONARY ARTERY BYPASS GRAFTING (CABG) SURGERY, IS A TYPE OF SURGERY THAT IMPROVES BLOOD FLOW TO THE HEART. IT'S USED FOR PEOPLE WHO HAVE SEVERE CORONARY HEART DISEASE., BRAIDED COATED POLYESTER SYNTHETIC NON- ABSORBABLE SUTURE(ESTERLUS)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,MITRAL VALVE REPLACEMENT KIT(MVR KIT)-INTENDED USED FOR SURGICAL DRESSING AND CONTROL BLOOD LOSS DURING MITRAL VALVE REPAIR OR REPLACEMENT SURGERY, IS A TYPE OF SURGERY THAT OFFERS EXCELLENT VALVE FUNCTION AND WORKS IN COORDINATION WITH THE ENTIRE CIRCULATORY SYSTEM TO PROTECT EACH PART FROM DAMAGE.,LUNG RESECTION KIT(LUNG RESECTION KIT)-INTENDED USED FOR SURGICAL DRESSING AND CONTROL BLOOD LOSS DURING LUNG RESECTION SURGERY. LUNG RESECTION IS A SURGICAL PROCEDURE THAT INVOLVES THE REMOVAL OF TISSUE FROM WITHIN THE LUNGS.THE LUNG RESECTION PROCEDURE IS PERFORMED FOR REMOVAL OF SUSPECTED CANCEROUS TUMOR, WITHIN A LUNG OR IF THE LUNG IS SEVERELY DAMAGED, FOLLOWING AN INJURY TO THE CHEST.,THORASIC DECORTICATION KIT(THORASIC DECORTICATION KIT)-INTENDED USED FOR SURGICAL DRESSING AND CONTROL BLOOD LOSS DURING THORASIC DECORTICATION SURGERY. DECORTICATION IS A SURGICAL PROCEDURE THAT REMOVES A RESTRICTIVE LAYER OF FIBROUS TISSUE OVERLYING THE LUNG, CHEST WALL, AND DIAPHRAGM.

3363	MFG/MD/2019/000231	1.License Holder Name: SUBHAM SURGICAL COTTON INDUSTRIES 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P(ABSORBENT COTTON WOOL)-THE ABSORBENT COTTON ARE USED FOR APPLING MEDICATION TO,OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS
3364	MFG/MD/2020/000001	1.License Holder Name: AGROSURG IRRADIATORS INDIA PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:CO-60 GAMMA IRRADIATION FACILITY(AGROSURG)-FOR TREATING MEDICAL DEVICES WITH CO-60 GAMMA RAYS,CO-60 GAMMA IRRADIATION FACILITY(AGROSURG)-FOR IRRADIATING MEDICAL DEVICES WITH CO-60 GAMMA RAYS

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3365	MFG/MD/2020/000003	1.License Holder Name: CENTENIAL SURGICAL SUTURE LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:ABSORBABLE HEMOSTAT OXIDISED REGENRATED CELLULOSE USP(CENTCEL)-ABSORBABLE HEMOSTAT, STERILISED OXIDIZED REGENERATED CELLULOSE (ORC) USP IS USED TO STOP CAPILLARY AND VENOUS BLEEDING. ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF VENOUS, CAPILLARY AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE INEFFECTIVE OR IMPRACTICAL. ABSORBABLE HEMOSTAT, STERILISED OXIDIZED REGENERATED CELLULOSE (ORC) USP CAN BE CUT TO SIZE FOR USE IN ENDOSCOPIC PROCEDURES AND APPLICATION IN CONTAMINATED ENVIRONMENT IS NOT SUITABLE.,NON ABSORBABLE EXPANDED POLYTETRAFLUOROETHYLENE [EPTFE] PLEDGETS / BUTTRESS, SOFT / HARD(CENTIPLED)-AN INTRA-CARDIAC PATCH OR PLEDGET MADE OF POLYPROPYLENE, POLYETHYLENE TEREPHTHALATE, OR POLYTETRAFLUROETHYLENE IS A FABRIC DEVICE PLACED IN THE HEART THAT IS USED TO REPAIR SEPTAL DEFECTS, FOR PATCH GRAFTING, TO REPAIR TISSUE, AND TO BUTTRESS SUTURES., ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC) BRAIDED, COATED POLYGLACTIN 910 VIOLET / UNDYED STERILISED SURGICAL SUTURE WITH / WITHOUT NEEDLE(CENTISORB RAPID)-CENTISORB RAPID BRAIDED, COATED POLY(GLYCOLIDE-CO-LACTIDE) 910 (POLYGLACTIN 910) , VIOLET / UNDYED SUTURE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURES WOULD BE BENEFICIAL. DUE TO ITS ABSORPTION PROFILE BRAIDED, COATED POLY(GLYCOLIDE-CO-LACTIDE) 910 (POLYGLACTIN 910) SUTURE IS USEFUL SKIN CLOSURE, PARTICULARLY IN PAEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. CENTISORB RAPID BRAIDED, COATED POLY(GLYCOLIDE-CO-LACTIDE) 910 (POLYGLACTIN 910) SUTURE IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY AS CONJUNCTIVAL SUTURES. CENTISORB RAPID SHOULD NOT BE USED WHERE LONG TERM WOUND SUPPORT IS REQUIRED AND SHOULD BE USED FOR SKIN CLOSURE AND ORAL MUCOSA.,ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC), BRAIDED, COATED POLYGLYCOLIC ACID (PGA) VIOLET / UNDYED STERILISED SURGICAL SUTURE WITH / WITHOUT NEEDLE (CENTICRYL)-CENTICRYL SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION, INCLUDING USE IN ESPECIALLY GENERAL SURGERY, SKIN CLOSURE,

	GASTROINTESTINAL SURGERY, GYNAECOLOGY, OBSTETRICS, PLASTIC SURGERY, UROLOGY, MICRO SURGERY FOR VESSELS LESS THAN 2 MM DIAMETER, OPHTHALMIC SURGERY AND ORTHOPAEDICS SURGERY. THE SAFETY AND EFFECTIVENESS IN CARDIOVASCULAR TISSUE HAVE NOT BEEN ESTABLISHED.,ABSORBABLE SURGICAL CATGUT CHROMIC SUTURE U.S.P. (NATURAL) STERILISED SURGICAL SUTURE WITH / WITHOUT NEEDLE(CENTENIAL - CATGUT CHROMIC)-CATGUT CHROMIC IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND / OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES.,TEMPORARY CARDIAC PACING WIRE [ELECTRODE] MULTIFILAMENT 316L STAINLESS STEEL COATED WITH BLUE / WHITE / ORANGE POLYETHYLENE(CENTIPACE)-A CARDIAC CATHETER CONTAINING ONE OR MORE ELECTRODES; IT MAY BE USED TO PACE THE HEART OR TO DELIVER HIGH ENERGY SHOCKS., ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC) BRAIDED, COATED POLYGLACTIN 910 VIOLET / UNDYED ANTIBACTERIAL WITH TRICLOSAN STERILISED SURGICAL SUTURE WITH / WITHOUT NEEDLE (CENTISORB TRI-PLUS®)-CENTISORB TRI-PLUS® ANTIBACTERIAL (POLYGLACTIN 910), BRAIDED, COATED WITH TRICLOSAN SYNTHETIC ABSORBABLE STERILE SURGICAL SUTURE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION EXCEPT FOR NEUROLOGICAL, OPHTHALMIC AND CARDIOVASCULAR TISSUES.,STERILISED SURGICAL BONE WAX(CENTIIWAX)-TO STOP BLEEDING AT BONES IN ORTHOPAEDICS AND TRAUMATOLOGY, THORACIC SURGERY, DENTAL, ORAL JAW SURGERY, NEUROSURGERY.,ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC) MONOFILAMENT, POLY(GLYCOLIDE-CO-CAPROLACTONE) PGCL VIOLET / UNDYED STERILISED SURGICAL SUTURE WITH / WITHOUT NEEDLE(CENTISYNTH®)-CENTISYNTH® POLY(GLYCOLIDE-CO-CAPROLACTONE) (PGCL) STERILISED ABSORBABLE SURGICAL NEEDLED SUTURE ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION, WHERE AN ABSORBABLE SUTURE MATERIAL IS INDICATED. THE SAFETY AND EFFECTIVENESS OF CENTISYNTH® POLY(GLYCOLIDE-CO-CAPROLACTONE) (PGCL) STERILISED ABSORBABLE SURGICAL NEEDLED SUTURE HAS NOT BEEN ESTABLISHED IN NEURAL TISSUE, CARDIOVASCULAR, MICROSURGERY AND OPHTHALMIC SURGERY., ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC) BRAIDED, COATED POLYGLYCOLIC ACID (PGA) VIOLET / UNDYED STERILISED SURGICAL SUTURE WITH / WITHOUT NEEDLE(CENTICRYL RAPID)-CENTICRYL RAPID BRAIDED, COATED POLYGLYCOLIC ACID (PGA) STERILISED ABSORBABLE SYNTHETIC SURGICAL NEEDLED SUTURE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE

	RAPID ABSORPTION OF THE SUTURE IS REQUIRED AND INTENDED FOR EFFECTIVE SHORT TERM WOUND SUPPORT OF 12 DAYS. THIS SUTURE IS INDICATED FOR THE CLOSURE OF SKIN AND MUCOSA, VASCULAR SURGERY, CLOSURE OF SKIN WOUNDS, PAEDIATRIC SURGERY, CIRCUMCISION, SCALP, OPHTHALMIC SURGERY-CONJUNCTIVAL, EPISIOTOMY REPAIR, ORAL MUCOSA, OUTPATIENT CLINIC & FOR EMERGENCY ROOM PATIENTS. CENTICRYL RAPID SHOULD NOT BE USED WHERE LONG TERM WOUND SUPPORT IS REQUIRED AND SHOULD BE USED ONLY FOR SKIN AND MUCOSA. THE SAFETY AND EFFECTIVENESS OF CENTICRYL RAPID SUTURES IN CARDIOVASCULAR TISSUE HAVE NOT BEEN ESTABLISHED., ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC) MONOFILAMENT POLYDIOXANONE [PDO] VIOLET / UNDYED STERILISED SURGICAL SUTURE WITH / WITHOUT NEEDLE (MONOSYNTH®)-MONOSYNTH® SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION, INCLUDING USE IN PAEDIATRIC CARDIOVASCULAR TISSUES, IN MICROSURGERY AND OPHTHALMIC SURGERY. MONOSYNTH® SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO 6 WEEKS) IS DESIRABLE.,ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC) BRAIDED, COATED POLYGLACTIN 910 VIOLET / UNDYED STERILISED SURGICAL SUTURE WITH / WITHOUT NEEDLE (CENTISORB®)-CENTISORB® ~ POLYGLACTIN 910, (90%)GLYCOLIDE AND (10%)L-LACTIDE, [GLACOMER91], BRAIDED, COATED SUTURES VIOLET / UNDYED ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND / OR LIGATION, INCLUDING USE IN VASCULAR SURGERY, OPHTALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER. THE SAFETY AND EFFECTIVENESS OF CENTISORB® SUTURES IN CARDIAC TISSUE HAVE NOT BEEN ESTABLISHED.,NON ABSORBABLE SURGICAL SUTURE U.S.P. MONOFILAMENT POLYAMIDE, BLACK / UNDYED / BLUE STERILISED SURGICAL SUTURE WITH / WITHOUT NEEDLE(CENTLON)-CENTLON SUTURE IS A MONOFILAMENT, SYNTHETIC NON-ABSORBABLE, STERILE SURGICAL NEEDLED / NON NEEDLED SUTURE COMPOSED OF POLYAMIDE 6 OR 6.6 ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, SKIN CLOSURE AND / OR LIGATION, INCLUDING USE IN CARDIOVASCULAR TISSUE CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P. BRAIDED, SILICONE COATED, POLYESTER, GREEN / WHITE, UNDYED STERILISED SURGICAL SUTURE WITH / WITHOUT NEEDLE(CENTIBOND®)-CENTIBOND® SUTURE IS BRAIDED, SILICONE COATED POLYESTER, SYNTHETIC NON-ABSORBABLE, STERILE

	SURGICAL NEEDLED / NON NEEDLED SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION, INCLUDING USE IN CARDIOVASCULAR TISSUE CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P. BRAIDED, COATED SILK, BLACK / BLUE / VIRGIN STERILISED SURGICAL SUTURE WITH / WITHOUT NEEDLE (CENTISILK)-CENTISILK SUTURE IS A NON ABSORBABLE STERILE SURGICAL NEEDLED / NON NEEDLED SUTURE ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P. MONOFILAMENT STAINLESS STEEL, 316L STERILISED SURGICAL SUTURE WITH NEEDLE(CENTSTEEL®)-CENTSTEEL® STERILISED, STAINLESS STEEL SURGICAL SUTURE IS A NON-ABSORBABLE, COMPOSED OF 316L STAINLESS STEEL, A CORROSION RESISTANT STEEL MONOFILAMENT SUTURE IS INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE SURGERY, ORTHOPAEDIC PROCEDURES (INCLUDING CERCIAGE AND TENDON REPAIR), HERNIA REPAIR SURGERY AND STERNAL CLOSURE. IT IS DESIGNED TO REMAIN IN THE PATIENT.,NON-ABSORBABLE MONOFILAMENT POLYPROPYLENE MESH, UNDYED, KNITTED, SYNTHETIC(CENTILENE MESH)-INDICATED TO REINFORCE SOFT TISSUE WHERE WEAKNESS EXISTS, I.E., REPAIR OF HERNIAS AND CHEST WALL DEFECTS.,NON ABSORBABLE SURGICAL SUTURE U.S.P. MONOFILAMENT POLYPROPYLENE, BLUE / UNDYED STERILISED SURGICAL SUTURE WITH NEEDLE(CENTILENE®)-CENTILENE® MONOFILAMENT POLYPROPYLENE, BLUE / UNDYED, NON ABSORBABLE SURGICAL SUTURE, U.S.P. (SYNTHETIC), STERILISED SURGICAL NEEDLED SUTURE ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND / OR LIGATION, INCLUDING USE IN CARDIOVASCULAR TISSUE CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P. MONOFILAMENT POLYVINYLIDENE FLUORIDE (PVDF), BLUE / UNDYED STERILISED SURGICAL SUTURE WITH NEEDLE (CENTIDENE)-CENTIDENE MONOFILAMENT POLYVINYLIDENE FLUORIDE (PVDF), BLUE / UNDYED, NON ABSORBABLE SURGICAL SUTURE, U.S.P. (SYNTHETIC), STERILISED SURGICAL NEEDLED SUTURE ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND / OR LIGATION, INCLUDING USE IN CARDIOVASCULAR TISSUE CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.

3366	MFG/MD/2020/000004	1.License Holder Name: AKSHAT BIO-MEDICALS(P) LTD. 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:BLOOD CELL DILUENTS (NA)-A BLOOD CELL DILUENT IS A MEDICAL DEVICE USED TO DILUTE BLOOD FOR FURTHER TESTING, SUCH AS COMPLETE BLOOD COUNT (CBC),DETERGENT(NA)-A DETERGENT REAGENT IS A MEDICAL DEVICE USED FOR CLEANING VARIOUS PARTS OF HEMATOLOGY ANALYZERS LIKE PROBES, NEEDLES,BATHS, TUBING ETC,LYSE REAGENTS(NA)-A LYSE REAGENT/KIT IS A MEDICAL DEVICE USED FOR LYSING OF CELLS FOR THE ESTIMATION OF COMPLETE BLOOD COUNT(CBC).

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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3367	MFG/MD/2020/000005	1.License Holder Name: RON & BAKER 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:GLUTARALDEHYDE, 15.2 GRM ,1-6- DIHYDROXY2-5-DIOXAHEXANE.19.7 GRM,RUST INHIBITORS. 4%-DISINFECTANT FOR MEDICAL INSTRUMENTS. EXCELLENT MATERIAL COMPATIBILITY WITH HEAT-RESISTANT AND HEAT-SENSITIVE INSTRUMENTS AND SUITABLE FOR ALL .,DIDECYL DIMETHYL AMMONIUM CHLORIDE,N-ALKYLDIMETHYL BENZYLAMMONIUM CHLORIDE SOLUTION(NIL)-AN AGENT THAT DESTROYS PATHOGENIC AND OTHER KIND OF MICROORGANISM BY CHEMICAL OR PHYSICAL MEANS.A DISINFECTANT DESTROYS MOST RECOGNIZED PATHOGENIC MICROORGANISMS,BUT NOT NECESSARILY ALL MICROBIAL FORMS,SUCH AS BACTERIAL SPORES. IT IS INTENDED TO DISINFECTANT A MEDICAL DEVICE., DODECYLBISPROPYLENETRIAMINE9.2GRM DIDECYL DIMETHYL AMMONIUM CHLORIDE 13.0GRM-AS A CHEMICAL DISINFECTANT FOR DISINFECTION OF NONLIVING SURFACES,SODIUM PERBORATE MONOHYDRATE POWDER (40%-60%)(NIL)-AN AGENT THAT DESTROYS PATHOGENIC AND OTHER KIND OF MICROORGANISM BY CHEMICAL OR PHYSICAL MEANS.A DISINFECTANT DESTROYS MOST RECOGNIZED PATHOGENIC MICROORGANISMS,BUT NOT NECESSARILY ALL MICROBIAL FORMS,SUCH AS BACTERIAL SPORES. IT IS INTENDED TO DISINFECTANT A MEDICAL DEVICE.,POLYMERIC BIGUANIDE HYDROCHLORIDE, 10% W/W ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE& DIDECYL DIMETHYL AMMONIUM CHLORIDE 10% W/W-DISINFECTANTS ARE DIFFERENT FROM OTHER ANTIMICROBIAL AGENTS SUCH AS ANTIBIOTICS, WHICH DESTROY MICROORGANISMS WITHIN THE BODY, AND ANTISEPTICS, WHICH DESTROY MICROORGANISMS ON LIVING TISSUE.,21% CITRIC ACID SOLUTION(NIL)-AN AGENT THAT DESTROYS PATHOGENIC AND OTHER KIND OF MICROORGANISM BY CHEMICAL OR PHYSICAL MEANS.A DISINFECTANT DESTROYS MOST RECOGNIZED PATHOGENIC MICROORGANISMS,BUT NOT NECESSARILY ALL MICROBIAL FORMS,SUCH AS BACTERIAL SPORES.IT IS INTENDED TO DISINFECTANT A MEDICAL DEVICE.,1- PROPANOL 30G ,2- PROPANOL 45G DIDECYL DIMETHYL AMMONIUM CHLORIDE 0.5.G N- ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE 0.5G POLY-HEXAMETHYLENE BIGUANIDE HYDRO-CHLORIDE 0.5G-USED AS AS A CHEMICAL DISINFECTANT FOR DISINFECTION OF NONLIVING SURFACES.,ORTHO- PHTHALDEHYDE SOLUTION(NIL)-AN AGENT THAT DESTROYS PATHOGENIC AND OTHER KIND OF MICROORGANISM BY CHEMICAL OR PHYSICAL MEANS.A DISINFECTANT DESTROYS MOST RECOGNIZED PATHOGENIC MICROORGANISMS,BUT NOT NECESSARILY ALL MICROBIAL FORMS,

	SUCH AS BACTERIAL SPORES.IT IS INTENDED TO DISINFECTANT A MEDICAL DEVICE.,1-PROPANOL-30G ,2- PROPANOL 45G DIDECYL DIMETHYL AMMONIUM CHLORIDE 0.2G N- ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE 0.2G-DISINFECTANTS ARE DIFFERENT FROM OTHER ANTIMICROBIAL AGENTS SUCH AS ANTIBIOTICS, WHICH DESTROY MICROORGANISMS WITHIN THE BODY, AND ANTISEPTICS, WHICH DESTROY MICROORGANISMS ON LIVING TISSUE. ... DISINFECTANTS ARE FREQUENTLY USED IN HOSPITALS, DENTAL SURGERIES, KITCHENS, AND BATHROOMS TO KILL INFECTIOUS ORGANISMS.,2%W/VPOLY HEXA METHYLENE BIGUANIDE HYDROCHLORIDE,2% DIDECYL DIMETHYL AMMONIUM CHLORIDE+ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE15%, DODECYLAMINE AND SULPHAMIC ACID5%W/V(NIL)-AN AGENT THAT DESTROYS PATHOGENIC AND OTHER KIND OF MICROORGANISM BY CHEMICAL OR PHYSICAL MEANS.A DISINFECTANT DESTROYS MOST RECOGNIZED PATHOGENIC MICROORGANISMS,BUT NOT NECESSARILY ALL MICROBIAL FORMS,SUCH AS BACTERIAL SPORES. IT IS INTENDED TO DISINFECTANT A MEDICAL DEVICE.,OCTYLDECYL DIMETHYL AMMONIUM CHLORIDE 6.510, DIOTCYL DIMETHYL AMMONIUM CHLORIDE 2.604, DIDECYL DIMETHYL AMMONIUM CHLORIDE 3.906, ALKYL C 14 50 C12, 40 C16, 10 DIMETHYL BENZYL AMMONIUM CHLORIDE(NA)-IS AN ANTISEPTIC/DISINFECTANT THAT IS USED IN MANY BIOCIDAL APPLICATIONS. ... THEY ARE BROAD SPECTRUM BACTERICIDAL AND FUNGICIDAL AND CAN BE USED AS DISINFECTANT CLEANER FOR LINEN, RECOMMENDED FOR USE IN HOSPITALS, HOTELS AND INDUSTRIES.,ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE SOLUTION FOR SURFACE DISINFECTANT(NIL)-AN AGENT THAT DESTROYS PATHOGENIC AND OTHER KIND OF MICROORGANISM BY CHEMICAL OR PHYSICAL MEANS.A DISINFECTANT DESTROYS MOST RECOGNIZED PATHOGENIC MICROORGANISMS,BUT NOT NECESSARILY ALL MICROBIAL FORMS, SUCH AS BACTERIAL SPORES.IT IS INTENDED TO DISINFECTANT A MEDICAL DEVICE.,1,6DIHYDROXIDE.2-5 DIOXAHEXANE 11.2GRM GLUTRALDEHYDE, 5.0GRM BENZALKONIUMCHOLRIDE IP 5.0 GRM ALKYL UREA, DERIVATE, 3.0 GRM-USED FOR CHEMICAL INSTRUMENT & SURFACE AND ENVIRONMENTAL DISINFECTANT., GLUTARALDEHYDE SOLUTION FOR INSTRUMENT DISINFECTANT 2.45% W/V(NIL)-AN AGENT THAT DESTROYS PATHOGENIC AND OTHER KIND OF MICROORGANISM BY CHEMICAL OR PHYSICAL MEANS.A DISINFECTANT DESTROYS MOST RECOGNIZED PATHOGENIC MICROORGANISMS,BUT NOT NECESSARILY ALL MICROBIAL FORMS,SUCH AS BACTERIAL SPORES.IT IS INTENDED TO DISINFECTANT A MEDICAL DEVICE.,SODIUM HYPOCHLORITE,SODIUM LAURYL ETHER SULPHATE,LAURYL AMINE OXIDE,SODIUM

		HYDROXIDE FOR SURFACE AND BATHROOM CLEANER DISINFECTANT (NIL)-AN AGENT THAT DESTROYS PATHOGENIC AND OTHER KIND OF MICROORGANISM BY CHEMICAL OR PHYSICAL MEANS.A DISINFECTANT DESTROYS MOST RECOGNIZED PATHOGENIC MICROORGANISMS,BUT NOT NECESSARILY ALL MICROBIAL FORMS, SUCH AS BACTERIAL SPORES.IT IS INTENDED TO DISINFECTANT A MEDICAL DEVICE.,ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE, ALKYL DIMETHY ETHYL BENZYL AMMONIUM CHLORIDE SOLUTION (NIL)-AN AGENT THAT DESTROYS PATHOGENIC AND OTHER KIND OF MICROORGANISM BY CHEMICAL OR PHYSICAL MEANS.A DISINFECTANT DESTROYS MOST RECOGNIZED PATHOGENIC MICROORGANISMS,BUT NOT NECESSARILY ALL MICROBIAL FORMS, SUCH AS BACTERIAL SPORES.IT IS INTENDED TO DISINFECTANT A MEDICAL DEVICE.,GLUTARALDEHUDE SOLUTION FOR INSTRUMENT DISINFECTANT 2%W/V(NIL)-AN AGENT THAT DESTROYS PATHOGENIC AND OTHER KIND OF MICROORGANISM BY CHEMICAL OR PHYSICAL MEANS.A DISINFECTANT DESTROYS MOST RECOGNIZED PATHOGENIC MICROORGANISMS,BUT NOT NECESSARILY ALL MICROBIAL FORMS,SUCH AS BACTERIAL SPORES. IT IS INTENDED TO DISINFECTANT A MEDICAL DEVICE.,8-POTASSIUM PEROXYMONOSULPHATE(NIL)-AN AGENT THAT DESTROYS PATHOGENIC AND OTHER KIND OF MICROORGANISM BY CHEMICAL OR PHYSICAL MEANS.A DISINFECTANT DESTROYS MOST RECOGNIZED PATHOGENIC MICROORGANISMS,BUT NOT NECESSARILY ALL MICROBIAL FORMS,SUCH AS BACTERIAL SPORES. IT IS INTENDED TO DISINFECTANT A MEDICAL DEVICE.,HYDROGEN PEROXIDE SILVER NITRATE IP ,DISINFECTANT(NIL)-AN AGENT THAT DESTROYS PATHOGENIC AND OTHER KIND OF MICROORGANISM BY CHEMICAL OR PHYSICAL MEANS.A DISINFECTANT DESTROYS MOST RECOGNIZED PATHOGENIC MICROORGANISMS,BUT NOT NECESSARILY ALL MICROBIAL FORMS,SUCH AS BACTERIAL SPORES. IT IS INTENDED TO DISINFECTANT A MEDICAL DEVICE.
3368	MFG/MD/2020/000006	1.License Holder Name: M/S.SRI VENKATESWARA SURGICAL COTTON 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P-ABSORBENT COTTON WOOL I.P - MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC. BECAUSE OF ITS PROPERTY OF HIGH FLUID ABSORBENCY, IT IS BETTER KNOWN AMONG MASSES AS ABSORBENT COTTON.

3369	MFG/MD/2020/000007	1.License Holder Name: HOLLISTER MEDICAL INDIA PVT LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:INTERMITTENT CATHETER WITHOUT BLISTER PACK(NA)-TO DRAIN URINE FROM THE BLADDER (SUB ASSEMBLY),INTERMITTENT CATHETER COUDE(APOGEE PLUS)-DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,URINE COLLECTION BAG COMBINATION PACK(HOLLISTER)-A PRIMARY LEG BAG COLLECTS AND CONTAINS URINE. THE EXTENSION TUBING DIVERTS URINE TO URINARY COLLECTION BAGS. THE STRAPS SECURE A URINARY LEG BAG TO LEG. THESE ACCESSORY PRODUCTS ARE INDIVIDUALS WITH URINARY INCONTINENCE OR A URINARY STOMA,INTERMITTENT CATHETER TIEMANN/ COUDE(ADVANCE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG, URINE COLLECTION BAG(HOLLISTER)-A PRIMARY LEG BAG COLLECTS AND CONTAINS URINE,INTERMITTENT CATHETER STRAIGHT(NA)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,EXTENSION TUBING WITH CONNECTOR (STERILE)-FOR URINE COLLECTION BAG(HOLLISTER)-THE EXTENSION TUBING DIVERTS URINE TO URINARY COLLECTION BAGS,STOMA IRRIGATOR DRAIN(HOLLISTER)-ROUTINE IRRIGATION TO REGULATE EMPTYING OF THE BOWEL; REUSABLE AFTER CLEANING WITH WATER, EXTENSION TUBING WITH CONNECTOR (NON STERILE)- FOR URINE COLLECTION BAG(HOLLISTER)-THE EXTENSION TUBING DIVERTS URINE TO URINARY COLLECTION BAGS,INTERMITTENT CATHETER TIEMANN/ COUDE(NA)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,URINE COLLECTION BAG- NIGHT DRAINAGE COLLECTOR(HOLLISTER)-URINARY NIGHT DRAINAGE BAG COLLECTS AND CONTAINS URINE FOR INDIVIDUALS WITH URINARY INCONTINENCE.,COUDE TAPER TIP CATHETER/ INTERMITTENT CATHETER COUDE(APOGEE IC)-TO DRAIN URINE FROM THE BLADDER,STRAP FOR URINE COLLECTION BAG(HOLLISTER)-THE STRAPS SECURE A URINARY LEG BAG TO LEG. THESE ACCESSORY PRODUCTS ARE INDIVIDUALS,INTERMITTENT CATHETER TIEMANN/ COUDE(NA)-TO DRAIN URINE FROM THE BLADDER,INTERMITTENT CATHETER(APOGEE)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,INTERMITTENT CATHETER KIT TIEMANN/ COUDE (CONTAINING 1 PAIR GLOVES, 1 WATER PROOF UNDERPAD, 3 SWAB STICK (BZK), IFU(ADVANCE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,PRE-LUBRICATED URINARY CATHETERISATION SYSTEM, TIEMANN(NA)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,URINARY CATHETERIZATION SYSTEM (CONTAINS GLOVES, UNDERPAD, GAUZE, PVP SWAB STICKS (3)/ INTERMITTENT CATHETER KIT (CONTAINS GLOVES, UNDERPAD, GAUZE, PVP SWAB STICKS (3)(APOGEE PLUS)-TO DRAIN URINE FROM

	THE BLADDER IN TO COLLECTION BAG,INTERMITTENT CATHETER STRAIGHT WITH KIT (CONTAINING 1 PAIR GLOVES, 1 WATER PROOF UNDERPAD, 3 SWAB STICK (BZK), IFU(NA)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,STOMA CONE WITH CONNECTOR(HOLLISTER)-ROUTINE IRRIGATION TO REGULATE EMPTYING OF THE BOWEL; REUSABLE AFTER CLEANING WITH WATER,INTERMITTENT CATHETER STRAIGHT WITH KIT (CONTAINING 1 PAIR GLOVES, 1 WATER PROOF UNDERPAD, 3 SWAB STICK (BZK), IFU (ADVANCE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,INFYNA CHIC LINER SUB ASSEMBLY (BULK PACK) (NA)-COMPONENT FOR URINARY CATHETER,PRE-LUBRICATED URINARY CATHETERISATION SYSTEM, NELATON(NA)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,INTERMITTENT CATHETER NELATON/ STRAIGHT(ADVANCE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,DRAINABLE IRRIGATOR SLEEVE(HOLLISTER)-ROUTINE IRRIGATION TO REGULATE EMPTYING OF THE BOWEL; REUSABLE AFTER CLEANING WITH WATER,COUDE TAPPER TIP CATHETER/ INTERMITTENT CATHETER COUDE(APOGEE)-TO DRAIN URINE FROM THE BLADDER,INTERMITTENT CATHETERURINARY CATHETERIZATION SYSTEM/ INTERMITTENT CATHETER(NA)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,IRRIGATIONS-STARTER-SET(HOLLISTER)-ROUTINE IRRIGATION TO REGULATE EMPTYING OF THE BOWEL; REUSABLE AFTER CLEANING WITH WATER,COUDE TAPPER TIP CATHETER/ INTERMITTENT CATHETER COUDE(NA)-TO DRAIN URINE FROM THE BLADDER,CATHETER INSERTION KIT(NA)-TO FACILITATE CATHETERIZATION,PRE-LUBRICATED URINARY CATHETERISATION SYSTEM, TIEMANN(INSTANTCATH PROTECT)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,CATHETER INSERTION KIT (APOGEE)-TO FACILITATE CATHETERIZATION,INTERMITTENT CATHETER, NELATON(ADVANCE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,INTERMITTENT CATHETER(NA)-TO DRAIN URINE FROM BLADDER,INTERMITTENT CATHETER STRAIGHT (ADVANCE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,INTERMITTENT CATHETER TIEMANN/ COUDE (ADVANCE)-TO DRAIN URINE FROM THE BLADDER,PRE-LUBRICATED CATHETER(INSTANTCATH)-TO DRAIN URINE FROM THE BLADDER, IRRIGATIONS-KIT(HOLLISTER)-ROUTINE IRRIGATION TO REGULATE EMPTYING OF THE BOWEL; REUSABLE AFTER CLEANING WITH WATER,STOMA IRRIGATOR SLEEVE(HOLLISTER)-ROUTINE IRRIGATION TO REGULATE EMPTYING OF THE BOWEL; REUSABLE AFTER CLEANING WITH WATER,INTERMITTENT CATHETER WITHOUT BLISTER PACK(NA)-TO DRAIN URINE FROM THE BLADDER (SUB ASSEMBLY),STOMA CONE IRRIGATOR KIT(HOLLISTER)-ROUTINE

	IRRIGATION TO REGULATE EMPTYING OF THE BOWEL; REUSABLE AFTER CLEANING WITH WATER,INTERMITTENT CATHETER COUDE (APOGEE IC)-TO DRAIN URINE FROM THE BLADDER,URINARY CATHETERIZATION SYSTEM (CONTAINS GLOVES, UNDERPAD, GAUZE, PVP SWAB STICKS (3)/ INTERMITTENT CATHETER KIT (CONTAINS GLOVES, UNDERPAD, GAUZE, PVP SWAB STICKS (3)(NA)-TO DRAIN URINE FROM BLADDER IN TO COLLECTION BAG,INTERMITTENT CATHETER STRAIGHT(NA)-TO DRAIN URINE FROM THE BLADDER, INTERMITTENT CATHETER(APOGEE)-TO DRAIN URINE FROM THE BLADDER,INTERMITTENT CATHETER STRAIGHT(ADVANCE)-TO DRAIN URINE FROM THE BLADDER,INTERMITTENT CATHETER NELATON(NA)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG, INTERMITTENT CATHETER(APOGEE IC)-TO DRAIN URINE FROM THE BLADDER,PRE-LUBRICATED URINARY CATHETERISATION SYSTEM, NELATON(INSTANTCATH PROTECT)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,PRE-LUBRICATED CATHETER(NA)-TO DRAIN URINE FROM THE BLADDER,INTERMITTENT CATHETER NELATON/ STRAIGHT(NA)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,INTERMITTENT CATHETER KIT, COUDE (CONTAINS GLOVES, UNDERPAD, GAUZE, PVP SWAB STICKS (3) (APOGEE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3370	MFG/MD/2020/000008	1.License Holder Name: M/S GLOBAL MEDIKIT LIMITED 2.Approving Authority: UTTARAKHAND 3.Device Name(Brand Name)-Intended Use:I.V CATHETER(MAICATH, GOGAFLON,ONE PLUS,ALPHA-FLOW)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,MEASURED VOLUME FLUID INFUSION SET(ENDURE)-INTRAVENOUS FLUID INFUSION SET TO INFUSE DRUGS / FLUIDS FROM OV SOLUTION BAGS TO IV CATHETERS IN USE.,THREE WAY STOP COCK(NA)-THREE WAY STOP COCK IS A DEVICE TO BE INCORPORATED BETWEEN INFUSION LINE AND INDWELLING VENIPUNCTURE DEVICE TO DELIVER ADDITIONAL FLUID TO THE HUMAN CIRCULATORY SYSTEM,NELATON CATHETER(ENDURE)-THE NELATON CATHETERS ARE USED FOR BLADDER CATHETERIZATION FOR DRAINAGE PURPOSE,DISPOSABLE BLOOD TRANSFUSION SET (NA)-THIS DEVICE IS INTENDED TO BE USED TO ADMINISTER THE BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., NEBULIZER KIT(ENDURE)-IT IS DESIGNED TO INCREASE EFFICIENCY SO PATIENTS GET THEIR MUCH-NEEDED MEDICATION DEEP INTO THEIR LUNGS. THEY ADMINISTER MEDICATION IN THE FORM OF A MIST THAT'S INHALED INTO THE LUNGS AND IS USED IN CONDITIONS LIKE ASTHMA, CYSTIC FIBROSIS AND OTHER RESPIRATORY ILLNESS., I.V CATHETER(MEDLIFE)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES., BLOOD TRANSFUSION SET(ENDURE,CUREJECT)-THIS DEVICE IS INTENDED TO BE USED TO ADMINISTER THE BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,I.V CANNULA WITH INJECTION PORT AND WINGS(ONE PLUS)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,YANKAUER HANDLE(ENDURE , MEDROP)-THE YANKAUER HANDLES WITH CONNECTING TUBE IS CONNECTED WITH RESPIRATORY SYSTEM TO PERFORM SUCTION OF THE BODY FLUID WHEN PERFORM OPERATION ON THORACIC CAVITY OR ABDOMINAL CAVITY.,THREE WAY STOP COCK(NA)-THREE WAY STOP COCK IS A DEVICE TO BE INCORPORATED BETWEEN INFUSION LINE AND INDWELLING VENIPUNCTURE DEVICE TO DELIVER ADDITIONAL FLUID TO THE HUMAN CIRCULATORY SYSTEM,MUCUS EXTRACTOR(GLOEX, MEDIEX,MUCOCATH)-MUCUS EXTRACTOR IS A DEVICE USED TO EXTRACT MUCUS FROM THE MOUTH & NOSE OF NEW BORN BABY. I.V CATHETER(TEFLO, NEOTEF ,NEOTEF)-I.V. CATHETER IS A DEVICE FOR

	ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,THORACIC CATHETER(ENDURE, GLOCIC, MEDICIC)-THORACIC CATHETERS ARE PRIMARILY INTENDED FOR DRAINAGE OF AIR OR FLUID FROM THE PLEURAL CAVITY AFTER CARDIO-THORACIC AND THORACIC SURGERY.,ENDOTRACHEAL TUBE(NUBENO)-THE DEVICE DESIGNED TO BE INSERTED INTO THE TRACHEA THROUGH THE ORAL/NASAL CAVITY TO SECURE THE AIRWAY AND MAINTAIN THE GAS EXCHANGE IN THE LUNGS.,I.V CATHETER(DISPOTOUCH, SANBAO, ENDURE,MEDROP)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,I.V CATHETER(ADVANCE-CATH,ONE PLUS)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,SPINAL NEEDLE(ENDURE,MAXIMA,EUROVEINS)-SPINAL NEEDLE IS USED TO INJECT LOCAL ANAESTHETICS IN ORDER TO PROVIDE REGIONAL ANESTHESIA.,I.V CATHETER(ONEVAC, ABOVCAN,ABOVAL ALPHA,ABOVCATH)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES,THREE WAY STOP COCK(ENDURE,GLOFLEX)-THREE WAY STOP COCK IS A DEVICE TO BE INCORPORATED BETWEEN INFUSION LINE AND INDWELLING VENIPUNCTURE DEVICE TO DELIVER ADDITIONAL FLUID TO THE HUMAN CIRCULATORY SYSTEM,I.V CATHETER(CATHUCENT, ANGIOPROX)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,EXTENSION SETS(ENDURE,NICHE,MEDIFLEXO, GLOFLEXO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS., I.V CATHETER WITH INJECTION VALVE AND WITH WINGS(NA)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,I.V INFUSION SET(ENDURE, MEDIDIAL,MEDIMIC ALPHA)-INTRAVENOUS FLUID INFUSION SET TO INFUSE DRUGS / FLUIDS FROM OV SOLUTION BAGS TO IV CATHETERS IN USE.,I.V CATHETER(HEFLON, MEDPLUS,MEDIVEN)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,INFANT FEEDING TUBE(ENDURE)-THE INFANT FEEDING TUBES ARE USED TO CONVEY NOURISH SUBSTANCE TO NEONATES AND PEDIATRICS THROUGH INSERTION FROM NASAL

	CAVITY TO THE STOMACH.,SAFETY I.V CATHETER WITH INJECTION VALVE AND WINGS(ANINA SAFETY)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,TWIN BORE NASAL OXYGEN SET(ENDURE , MEDROP)-TWIN BORE NASAL OXYGEN SET IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,SPINAL NEEDLE(GALENA, ANINA, ABOVAL)-SPINAL NEEDLE IS USED TO INJECT LOCAL ANAESTHETICS IN ORDER TO PROVIDE REGIONAL ANESTHESIA.,OXYGEN MASK (ENDURE)-TRANSPARENT OXYGEN MASK WITH TUBING MEANT TO ADMINISTER OXYGEN TO PATIENTS.,MICRO DRIP DISPOSABLE INFUSION SET WITH BUILT IN BACTERIA BARRIER AIRVENT(GLOMIC ALPHA)-INTRAVENOUS FLUID INFUSION SET TO INFUSE DRUGS / FLUIDS FROM OV SOLUTION BAGS TO IV CATHETERS IN USE., INJECTION STOPPER(N/A)-FUNCTIONS AS A MALE LUER CAP WITH ADDITIONAL FEATURE OF INJECTION SITE TO INJECT THE MEDICINE THROUGH HYPODERMIC NEEDLE,THREE WAY STOP COCK(GALENA, ANINA, ABOVAL)-THREE WAY STOP COCK IS A DEVICE TO BE INCORPORATED BETWEEN INFUSION LINE AND INDWELLING VENIPUNCTURE DEVICE TO DELIVER ADDITIONAL FLUID TO THE HUMAN CIRCULATORY SYSTEM,WOUND SUCTION DRAINAGE SYSTEM (ENDURE)-IT IS A PORTABLE SUCTION DRAINAGE SYSTEM UNIT FOR CONTINUOUS POST OPERATIVE DRAINAGE OF INTERNAL HEMORRHAGE AND EXUDATE. BY UTILIZING THE VACUUM FORCE OF DEPRESSED BELLOW, THE DRAIN LIQUID IS SUCKED OUT THROUGH DRAIN.,SAFETY I.V. CATHETER WITH INJECTION VALVE AND WINGS (GLOFLON SAFETY -1)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES., SUCTION CATHETER(ENDURE)-THE SUCTION CATHETER IS USED FOR REMOVAL OF SECRETION FROM MOUTH OROPHARYNX TRACHEA AND BRONCHIAL TUBE,EXTENSION TUBING WITH 3- WAY STOP COCK (ANINA, ABOVAL)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS,FOLEY'S CATHETER-THE FOLEY CATHETER (LATEX AND SILICONE) ARE USED TO DRAIN URINE FROM THE BLADDER INTO URINE BAG. LATEX CATHETERS ARE USED ON PATIENTS WHICH ARE NON-ALLERGIC TO LATEX AND ARE MEANT FOR SHORT TERM USE. WHEREAS, SILICONE CATHETERS ARE MEANT FOR LONG TERM USE AND CAN BE USED ON ANY TYPE OF PATIENTS.,I.V CATHETER (ABOVAL,ABOVAL SAFETY ,MEDIFLON SAFETY,GLOFLON SAFETY)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY

	SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,THREE WAY STOP COCK-THREE WAY STOP COCK IS A DEVICE TO BE INCORPORATED BETWEEN INFUSION LINE AND INDWELLING VENIPUNCTURE DEVICE TO DELIVER ADDITIONAL FLUID TO THE HUMAN CIRCULATORY SYSTEM, SPINAL NEEDLE(NUBENO)-SPINAL NEEDLE IS USED TO INJECT LOCAL ANAESTHETICS IN ORDER TO PROVIDE REGIONAL ANESTHESIA.,I.V. CATHETER-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,I.V CATHETER(PROMAK)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,EXTENSION SETS-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,I.V CATHETER(NEOTEC ,GLOFLON)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,NEBULIZER KIT-IT IS DESIGNED TO INCREASE EFFICIENCY SO PATIENTS GET THEIR MUCH-NEEDED MEDICATION DEEP INTO THEIR LUNGS. THEY ADMINISTER MEDICATION IN THE FORM OF A MIST THAT'S INHALED INTO THE LUNGS AND IS USED IN CONDITIONS LIKE ASTHMA, CYSTIC FIBROSIS AND OTHER RESPIRATORY ILLNESS.,I.V CATHETER(TOPSN, TEEBA)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,STOP COCK MANIFOLD-MANIFOLD USED FOR INFUSING MULTIPLE DRUGS THERAPIES TO THE PATENT SIMULTANEOUSLY,I.V CATHETER(KAYFLON, DIVINEMED, SPRUKFLON)-I.V. CATHETER IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND / OR WITHDRAWAL OF BLOOD SAMPLES.,BLOOD TRANSFUSION SET-THIS DEVICE IS INTENDED TO BE USED TO ADMINISTER THE BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,SPINAL NEEDLE(TOPMEDCO,TEEBA)-SPINAL NEEDLE IS USED TO INJECT LOCAL ANAESTHETICS IN ORDER TO PROVIDE REGIONAL ANESTHESIA. ,NELATON CATHETER-THE NELATON CATHETERS ARE USED FOR BLADDER CATHETERIZATION FOR DRAINAGE PURPOSE,ENDOTRACHEAL TUBE-THE DEVICE DESIGNED TO BE INSERTED INTO THE TRACHEA THROUGH THE ORAL/NASAL CAVITY TO SECURE THE AIRWAY AND MAINTAIN THE GAS EXCHANGE IN THE LUNGS.,OXYGEN MASK-TRANSPARENT OXYGEN MASK WITH

	TUBING MEANT TO ADMINISTER OXYGEN TO PATIENTS.,MEASURE VOLUME BURETTE FLUID INFUSION SET-INTRAVENOUS FLUID INFUSION SET TO INFUSE DRUGS / FLUIDS FROM OV SOLUTION BAGS TO IV CATHETERS IN USE.,WOUND SUCTION DRAINAGE SYSTEM-IT IS A PORTABLE SUCTION DRAINAGE SYSTEM UNIT FOR CONTINUOUS POST OPERATIVE DRAINAGE OF INTERNAL HEMORRHAGE AND EXUDATE. BY UTILIZING THE VACUUM FORCE OF DEPRESSED BELLOW, THE DRAIN LIQUID IS SUCKED OUT THROUGH DRAIN.,A.V FISTULA NEEDLE-AV FISTULA NEEDLE SET IS USED DURING THE DIALYSIS TO CONNECT THE BLOOD LINES TO THE BLOOD VESSELS, INJECTION STOPPER-FUNCTIONS AS A MALE LUER CAP WITH ADDITIONAL FEATURE OF INJECTION SITE TO INJECT THE MEDICINE THROUGH HYPODERMIC NEEDLE,I.V CANNULA FIXING TAPE-CANNULA FIXING TAPE IS USED TO FIX THE IV CANNULA WITH THE BODY OUTER SURFACE BY ADHESIVE WHEN IV CANNULA IN USE., SUCTION CATHETER-THE SUCTION CATHETER IS USED FOR REMOVAL OF SECRETION FROM MOUTH OROPHARYNX TRACHEA AND BRONCHIAL TUBE,THORACIC CATHETER-THORACIC CATHETERS ARE PRIMARILY INTENDED FOR DRAINAGE OF AIR OR FLUID FROM THE PLEURAL CAVITY AFTER CARDIO-THORACIC AND THORACIC SURGERY.,MUCUS EXTRACTOR-MUCUS EXTRACTOR IS A DEVICE USED TO EXTRACT MUCUS FROM THE MOUTH & NOSE OF NEW BORN BABY.,RYLE'S TUBE-RYLES TUBES ARE USED FOR NASO GASTRIC INTRODUCTION FOR NUTRITION AND ASPIRATION OF INTESTINAL SECRETION-IN GASTROENTEROLOGY,INFANT FEEDING TUBE-THE INFANT FEEDING TUBES ARE USED TO CONVEY NOURISH SUBSTANCE TO NEONATES AND PEDIATRICS THROUGH INSERTION FROM NASAL CAVITY TO THE STOMACH.,I.V. INFUSION SET-INTRAVENOUS FLUID INFUSION SET TO INFUSE DRUGS / FLUIDS FROM OV SOLUTION BAGS TO IV CATHETERS IN USE.,TWIN BORE NASAL OXYGEN SET-TWIN BORE NASAL OXYGEN SET IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,HAEMODIALYSIS KIT-THE DEVICE IS USED FOR SHORT-TERM VASCULAR ACCESS TO PROVIDE HAEMODIALYSIS TO PATIENTS.,YANKAUER HANDLE-THE YANKAUER HANDLES WITH CONNECTING TUBE IS CONNECTED WITH RESPIRATORY SYSTEM TO PERFORM SUCTION OF THE BODY FLUID WHEN PERFORM OPERATION ON THORACIC CAVITY OR ABDOMINAL CAVITY.,SPINAL NEEDLE-SPINAL NEEDLE IS USED TO INJECT LOCAL ANAESTHETICS IN ORDER TO PROVIDE REGIONAL ANESTHESIA.,I.V FLOW REGULATOR-THE I.V. FLOW REGULATOR EXTENSION SET IS A MEDICAL DEVICE USED TO REGULATE THE FLOW OF IV FLUIDS.

3371	MFG/MD/2020/000009	1.License Holder Name: BUYWEL HEALTHCARE PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:3 WAY STOPCOCK AS AN ACCESSORY TO PERFUSION SETS(NIL)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,MEASURED VOLUME I.V.SET FOR SINGLE USE(NIL)- IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S. VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,I.V.FLOW REGULATOR(NIL)-AN I.V SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY . I.V FLOW REGULATOR I.V.SET WITH FLOW REGULATOR IS USED FOR THE FLOW CONTROL OF I.V FLUIDS DURING INFUSION OR TRANSFUSION. FLOW REGULATOR SETS REGULATES THE FLOW OF I.V FLUIDS FROM A INFUSION SET INTO A I.V CATHETER.,EXTENSION SETS(NIL)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. IT CAN BE USED TO CONNECT A PERFUSION SET OR CATHETER.,TRANSFUSION OR PERFUSION SETS FOR SINGLE USE(NIL)-TRANSFUSION SETS OR PERFUSION SETS IS USED TO ADMINISTER BLOOD / DRUG /INFUSION SOLUTION TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO A VEIN.,RYLES TUBE/ NASOGASTRIC TUBE(NIL)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDING OR FOR GIVING A PERSON EXTRA COLORIES. ,BLOOD LINES/ SINGLE NEEDLE HAEMODIALYSIS CATHETER(NIL)-THE SINGLE NEEDLE DISLYSIS, IN WHICH CASE ONLY ONE CANNULA OR A SINGLE LUMEN CATHETER IS USED TO ACCESS THE BLOOD.,CARD CLAMP (NIL)-SUITABLE FOR CLAMPING THE UMBILICAL CORD OF NEW BORN BABY, IMMEDIATELY AFTER BIRTH. PROVIDED WITH GROOVES ALL ALONG THE LENGTH TO PREVENT THE SLIPPING OF UMBILICAL CORD AND RETAIN IT IN THE SAME POSITION.

3372	MFG/MD/2020/000010	1.License Holder Name: FREEDOM OPTHALMICPVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:PMMA POSTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENS -AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,HYDROPHOBIC ACRYLIC ASPHERIC FOLDABLE 360 SQUARE EDGE INTRAOCULAR LENSES -AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,YELLOW HYDROPHOBIC ACRYLIC ASPHERIC FOLDABLE 360 SQUARE EDGE INTRAOCULAR LENSES-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,PMMA POSTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENS -AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,PMMA POSTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENS -AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,HYDROPHOBIC ACRYLIC ASPHERIC FOLDABLE 360 SQUARE EDGE INTRAOCULAR LENSES -AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF

	PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,PMMA ANTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENS -AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,YELLOW HYDROPHOBIC ACRYLIC ASPHERIC FOLDABLE 360 SQUARE EDGE INTRAOCULAR LENSES -AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,YELLOW HYDROPHILIC ACRYLIC POSTERIOR CHAMBER SINGLE PIECE SQUARE EDGE ASPHERIC FOLDABLE INTRAOCULAR LENS-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,HYDROPHILIC ACRYLIC POSTERIOR CHAMBER SINGLE PIECE FOLDABLE INTRAOCULAR LENS -AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS, HYDROPHILIC ACRYLIC POSTERIOR CHAMBER SINGLE PIECE SQUARE EDGE ASPHERIC FOLDABLE INTRAOCULAR LENS-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,PMMA POSTERIOR CHAMBER SINGLE PIECE 360° SQUARE EDGE INTRAOCULAR LENS -AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF

	THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,PMMA POSTERIOR CHAMBER SINGLE PIECE 360° SQUARE EDGE INTRAOCULAR LENS -AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,PMMA POSTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENS -AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,YELLOW HYDROPHILIC ACRYLIC POSTERIOR CHAMBER SINGLE PIECE SQUARE EDGE FOLDABLE INTRAOCULAR LENS -AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,HYDROPHILIC ACRYLIC POSTERIOR CHAMBER SINGLE PIECE SQUARE EDGE ASPHERIC FOLDABLE INTRAOCULAR LENS-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,HYDROPHILIC ACRYLIC POSTERIOR CHAMBER SINGLE PIECE FOLDABLE INTRAOCULAR LENS -AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS,PMMA POSTERIOR CHAMBER SINGLE PIECE INTRAOCULAR LENS-AN ULTRAVIOLET BLOCKING INTRAOCULAR LENSES ARE INTENDED FOR THE USE IN PRIMARY IMPLANTATION, AT THE DISCRETION OF THE

		SURGEON, FOR THE VISUAL CORRECTION OF PATIENTS SUFFERING FROM APHAKIA. WHERE A MONOCULAR, MATURE, CONGENITAL, OCCUPATIONAL, TRAUMATIC CATARACT LENS HAS BEEN REMOVED BY EXTRACAPSULAR EXTRACTION METHODS
3373	MFG/MD/2020/000011	1.License Holder Name: ANGEL LIFE SCIENCCE 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ABSORBABLE HAEMOSTATIC GELATIN SPONGE(ANGISPONGE, STERISPON, TRUSPONGE, PREVASPONGE, STELLI GEL, ANGIPLAST, ANGIFOAM, ANGIPAD)-ANGISPONGE CAN BE EFFECTIVELY USED IN VARIOUS SURGERIES FOR HAEMOSTASIS, WHEN CONTROL OF CAPILLARY, VENOUS AND ARTERIOLAR BLEEDING BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS INEFFECTIVE OR IMPRACTICAL. ANGISPONGE MAY BE USED DRY OR SATURATED WITH PHYSIOLOGICAL SALT SOLUTION. CUT TO THE DESIRED SIZE, A PIECE OF ANGISPONGE, EITHER DRY OR SATURATED WITH STERILE, ISOTONIC SODIUM CHLORIDE SOLUTION (STERILE SALINE), CAN BE APPLIED WITH LIGHT PRESSURE DIRECTLY TO THE BLEEDING SITE. WHEN APPLIED DRY, A SINGLE PIECE OF ANGISPONGE SHOULD BE MANUALLY APPLIED TO THE BLEEDING SITE, AND HELD IN PLACE WITH MODERATE PRESSURE UNTIL HAEMOSTATIC RESULTS

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3374	MFG/MD/2020/000012	1.License Holder Name: JOHNSON & JOHNSON PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NON ABSORBABLE SURGICAL SUTURE U.S.P.(ETHICON*)-THIS SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPTHALMIC AND NEUROSURGICAL PROCEDURES.,CORONARY ARTERY BYPASS GRAFT (ETHICON* CABG B KIT)-SURGICAL PROCEDURES RELATED TO CORONARY ARTERY BYPASS,NON ABSORBABLE SURGICAL SUTURE U.S.P.(ETHICON*)-SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROSURGICAL PROCEDURES.,CORONARY ARTERY BYPASS GRAFT(ETHICON* CABG (M) KIT)-SURGICAL PROCEDURES RELATED TO CORONARY ARTERY BYPASS.,ABSORBABLE SURGICAL SUTURE U.S.P. (SYNTHETIC) (VICRYL*)-VICRYL SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER., CORONARY ARTERY BYPASS GRAFT(ETHICON* CABG AB OFF PUMP KIT)-SURGICAL PROCEDURES RELATED TO CORONARY ARTERY BYPASS.,NON ABSORBABLE SURGICAL SUTURE U. S. P.(ETHISTEEL*)-INDENDED FOR USE IN ABDOMINAL WOUND CLOSURE, HERNIA REPAIR, STERNAL CLOSURE AND ORTHOPEDIC PROCEDURES INCLUDING CERCLAGE AND TENDON REPAIR.,CORONARY ARTERY BYPASS GRAFT(ETHICON* CABG AB ON PUMP KIT)-SURGICAL PROCEDURES RELATED TO CORONARY ARTERY BYPASS.,HERNIA KIT (SIMTRUS* HERNIA KIT)-SURGICAL PROCEDURES RELARED TO HERNIA SURGERY,HERNIA KIT(ETHICON* HERNIA KIT HK-2)-SURGICAL PROCEDURES RELATED TO HERNIA SURGERY,CORONARY ARTERY BYPASS GRAFT(ETHICON* CABG KIT)-SURGICAL PROCEDURES RELARED TO CORONARY ARTERY BYPASS.,C-SECTION KIT(SIMTRUS* C-SECTION KIT)-SURGICAL PROCEDURES RELATED TO C-SECTION SURGERY.,HERNIA KIT(ETHICON* HS KIT HS-1)-SURGICAL PROCEDURES RELATED TO HERNIA SURGERY.,CAESAR-BAS KIT (ETHICON* CAESAR-BAS KIT)-SURGICAL PROCEDURES RELATED TO C-SECTION SURGERY.,NON-STERILE NON-ABSORBABLE SURGICAL SUTURE U.S.P. (BLACK BRAIDED SILK)(ETHICON*)-BLACK BRAIDED SILK (NON-STERILE) SUTURE IS INDICATED FOR USE IN LIGATION, DRAIN FIXATION AND RETRACTION PURPOSE.,CAESAR KIT(ETHICON* CAESAR* KIT)-SURGICAL PROCEDURES RELATED TO C-SECTION SURGERY.,NONABSORBABLE SYNTHETIC SURGICAL MESH (PROLENE* (POLYPROPYLENE) HERNIA SYSTEM)-THE PROLENE*

	(POLYPROPYLENE) HERNIA SYSTEM IS INDICATED FOR THE REPAIR OF INGUINAL (DIRECT & INDIRECT) AND ABDOMINAL WALL HERNIA DEFECTS.,ABHY-ADV KIT(ETHICON* ABHY-ADV KIT)-SURGICAL PROCEDURES RELATED TO ABDOMINAL HYSTERECTOMY SECTION, ABHY-BAS KIT(ETHICON* ABHY-BAS KIT)-SURGICAL PROCEDURES RELARED TO ABDOMINAL HYSTERECTOMY SECTION,CAESAR-ADV KIT(ETHICON* CAESAR-ADV KIT)-SURGICAL PROCEDURES RELATED TO C-SECTION SURGERY.,STERILISED POLYESTER FIBRE TAPE (MERSILENE*)-MERSILENE* TAPE IS INDICATED FOR CIRCULAR SUTURE OF THE CERVIX. NON-NEEDLED TAPES ARE USED AS RETRACTION AND/OR FIXING TAPE DURING SURGERY.,NON ABSORBABLE SURGICAL SUTURE U.S.P.(MERSILENE*)-MERSILENE SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC, AND EUROLOGICAL PROCEDURES, AND ALSO FOR THE FIXATION OF SOFT TISSUE TO BONE TISSUE., ABHY KIT(ETHICON*ABHY* KIT)-SURGICAL PROCEDURES RELARED TO ABDOMINAL HYSTERECTOMY SECTION,NON ABSORBABLE SURGICAL SUTURE U. S. P.(MERSILK* / ETHICON*)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROSURGICAL PROCEDURES.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC)(MONOCRYL*)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION WHERE AN ABSORBABLE MATERIAL IS INDICATED.,HERNIA KIT(SIMTRUS* HERNIA KIT)-SURGICAL PROCEDURES RELARED TO HERNIA SURGERY,NON ABSORBABLE SURGICAL SUTURE U. S. P.(PROLENE*)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPTHALMIC AND NEUROSURGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U. S. P.(ETHIBOND* EXCEL)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROSURGICAL PROCEDURES.,C-SECTION KIT(SIMTRUS* C-SECTION KIT)-SURGICAL PROCEDURES RELATED TO C-SECTION SURGERY.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC)(PDS* II)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PAEDIATRIC CARDIOVASCULAR TISSUE , IN MICROSURGERY AND IN OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC)(VICRYL* RAPIDE)-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS

	REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO ITS ABSORPTION PROFILE VICRYL RAPIDE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PAEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. VICRYL RAPIDE IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES.,ETHICON* HERNIA KIT(ETHICON* HERNIA KIT)-SURGICAL PROCEDURES RELATED TO HERNIA SURGERY.,ABSORBABLE SURGICAL SUTURE U. S. P. (SYNTHETIC)(VICRYL*)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER.,NON ABSORBABLE SURGICAL SUTURE U. S. P.(ETHILON*)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPTHALMIC AND NEUROSURGICAL PROCEDURES.,ABSORBABLE SURGICAL SUTURE U. S. P. (SYNTHETIC)(VICRYL* PLUS)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,NONABSORBABLE SYNTHETIC SURGICAL MESH(PROLENE* MESH)-THIS MESH MAY BE USED FOR THE REPAIR OF HERNIA AND OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT. IT CAN BE USED IN ENDOSCOPIC PROCEDURE.

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3375	MFG/MD/2020/000013	1.License Holder Name: M/S S.K.TRADING CO 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655(JVS/JMS)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655(- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(JVS)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH AIR VENT BIS 9824 FOR SINGLE USE ONLY (- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITHOUT AIR VENT BIS 9824(- -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH AIR VENT BIS 9824 FOR SINGLE USE ONLY (JVS)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.,STERILE DISPOSABLE INFUSION SET WITH AIR VENT BIS 12655(- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN
3376	MFG/MD/2020/000015	1.License Holder Name: LOTUS SURGICAL PVT LTD 2.Approving Authority: UTTARAKHAND 3.Device Name(Brand Name)-Intended Use:SKIN STAPLER,PROSEC CIRCULAR STAPLER,PROSEC HEMORRHOIDAL STAPLER,UMBILICAL COTTON TAPE(PROSEC)-FOR SKIN CLOSURE OF WOUNDS, INCISIONS OR LACERATIONS OF THE EPIDERMIS. ,APPLICABLE TO THE END-TO-END AND END-TO-SIDE ANASTOMOSIS FOR ARCHENTERIC TISSUES IN ESOPHAGUS, STOMACH, INTESTINAL TRACT, ETC.,APPLICABLE TO THE SELECTIVE MUCOSAL INCISION ON THE DENTATE LINE.TO TIE OFF THE UMBILICAL CORDS OF NEWBORN INFANTS

3377	MFG/MD/2020/000016	1.License Holder Name: DENEX INTERNATIONAL 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:TRACHEOBRONCHIAL SUCTION CATHETER (MUCUS EXTRACTOR)(DENEX)-MUCUS EXTRACTOR IS USED FOR ASPIRATION OF SECRETION FROM OROPHARYNX IN NEWLY BORN BABIES AND TO ENSURE FREE RESPIRATION AND ALSO SUITABLE FOR OBTAINING MUCUS SPECIMEN FOR MICRO BIOLOGICAL EXAMINATION.,INFANT FEEDING TUBE(DENEX)-AN INFANT FEEDING TUBE IS USED FOR NEONATAL AND PAEDIATRIC NUTRITIONAL FEEDING. IT IS A SMALL, SOFT, PLASTIC TUBE PLACED THROUGH THE NOSE OR MOUTH INTO THE STOMACH.,CONNECTORS STRAIGHT WITHOUT LUER LOCK, STRAIGHT WITH LUERLOCK (HEPARIN CAP)(DENEX)-CONNECTORS CAN BE USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA OR FLUID ETC. ,CORRUGATED DRAINAGE SHEET(DENEX)-IT IS AN EFFICIENT MULTI CHANNEL WOUND DRAINAGE SYSTEM SPECIALLY WHERE AIR TIGHT CLOSURE OF WOUND IS NOT POSSIBLE,CATHETER MOUNT(DENEX)-CATHETER MOUNTS ARE ADAPTORS THAT CONNECT THE TRACHEAL TUBE TO THE END OF THE ANAESTHETIC BREATHING SYSTEM. VARIOUS CONNECTORS FIT BETWEEN THE DISTAL END AND THE TRACHEAL TUBE.,MTP CANNULA (KARMAN CANNULA)(DENEX)-THE MTP CANNULA OR KARMAN CANNULA IS A SOFT, FLEXIBLE CANNULA (OR CURETTE) WHICH IS CLAIMED TO REDUCE THE RISK OF PERFORATING THE UTERUS DURING VACUUM ASPIRATION. IT IS ALSO USED BY PHYSICIANS SOMETIMES IN EARLY INDUCED SURGICAL ABORTION, IN TREATMENT OF INCOMPLETE ABORTION (MEDICAL TERMINATION OF PREGNANCY I.E. MTP) , AND IN ENDOMETRIAL BIOPSY AND ALSO IN "MENSTRUAL REGULATION" AND VACUUM ASPIRATION PROCEDURES.,NELATON CATHETER/ URETHRAL CATHETER(DENEX)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO THE URETER THROUGH THE URETHRA AND BLADDER AND POST PRIORY VIA THE KIDNEY IN CASE OF URINARY RETENTION.,SUCTION CATHETER WITH THUMB CONTROL, SUCTION CATHETER WITH Y-CONNECTOR, SUCTION CATHETER WITH PLAIN ADAPTOR [ISO 8836](DENEX)-A SUCTION CATHETER IS USED TO REMOVE MUCUS AND OTHER SECRETIONS FROM THE UPPER AIRWAY, TRACHEA, AND MAIN BRONCHI WITH PRECISION AND MAXIMUM COMFORT TO THE PATIENT.,THREE WAY STOPCOCK ,THREE WAY STOPCOCK WITH EXTENSION TUBE(DXFLON, DXCAN, VASOFLO, ZICATH, ATLAS, PEDICAN, BABYCAN, AZIVAC)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,STERILE SINGLE USE INTRAVASCULAR

	CATHETERS [ISO 10555-1 AND 5] IV CANNULA WITH WINGS WITH PORT, IV CANNULA WITHOUT WINGS WITHOUT PORT, IV CANNULA WITH WINGS WITHOUT PORT, SAFETY IV CANNULA(DXFLON, DXCAN, VASOFLO, ZICATH, ATLAS, PEDICAN, BABYCAN, AZIVAC)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD/BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,MALE CATHETER (URETHRAL CATHETER)(DENEX)-MALE CATHETER/CONDOM CATHETERS ARE USED BY MEN WITH INCONTINENCE. THERE IS NO TUBE PLACED INSIDE THE PENIS. INSTEAD, A CONDOM-LIKE DEVICE IS PLACED OVER THE PENIS. A TUBE LEADS FROM THIS DEVICE TO A DRAINAGE BAG. THE CONDOM CATHETER MUST BE CHANGED EVERY DAY.,ADULT FEEDING TUBE / RYLE'S TUBE / NASOGASTRIC TUBE/ STOMACH TUBE / LEVIN'S TUBE(DENEX)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID. IT MAY ALSO BE USED FOR ASPIRATION OF INTESTINAL SECRETIONS.,REDON DRAIN CATHETER(DENEX)-THE REDON DRAINAGE IS AN INNER SUCTION DRAINAGE, WHICH IS LEFT IN THE TEMPORARY RULE AFTER MAJOR SURGERY IN THE OPERATING AREA AND WOUND FLUID (BLOOD AND SEROUS FLUID) IS DERIVED OUTSIDE. DEPENDING ON THE WOUND SECRETION ,THE DRAIN IS REMOVED AFTER ABOUT 48 TO 72 HOURS.,RECTAL CATHETER (DENEX)-RECTAL CATHETER IS USED FOR INSERTING INTO THE RECTUM IN ORDER TO RELIEVE FLATULENCE UNRESPONSIVE TO ACTIVITY OR MEDICATIONS AND ALSO TO DISCHARGE THE WASTE., UMBILICAL ARTERY CATHETER (UMBILICAL CATHETER)(DENEX)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS.,CLAVE CONNECTOR (NEEDLE FREE CONNECTOR)(DENEX)-CLAVE CONNECTOR (NEEDLE FREE CONNECTORS) IS INTENDED FOR USE AS AN ACCESSORY TO AN INTRAVASCULAR CATHETER PLACED IN THE VEIN OR ARTERY. THE DEVICE MAY BE USED FOR THE ADMINISTRATION OF BLOOD AND FLUIDS TO PATIENTS. ,EXTENSION LINE (EXTENSION TUBE) [ISO 8536-9](DENEX)-IT IS A STERILE SINGLE USE DEVICE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION. IT CAN BE USED TO CONNECT THE INFUSION SITE AND THE SOURCE OF INFUSION., MANIFOLDS(DENEX)-MANIFOLDS IS MEANT FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT/PORTS

	FOR ADMINISTRATION OF A SOLUTION.,URINE COLLECTION BAGS (DENEX)-THIS DEVICE IS USED IN UROLOGY PROCEDURES FOR THE COLLECTION OF URINE FROM THE PATIENTS FOR DIAGNOSTIC AND/ OR TREATMENT PURPOSES.,PRESSURE MONITORING LINE(DENEX)-IT IS USED TO ASSESS THE LEFT VENTRICULAR END-DIASTOLIC PRESSURE INDIRECTLY AND TO OBTAIN ACCURATE CENTRAL VASCULAR PRESSURES IN THE CONDITION OF LOW CARDIAC OUTPUT.,ENDOTRACHEAL TUBE PLAIN / CUFFED [IS 12504-1] [ISO 5361](DENEX)-IT IS MEANT FOR INSERTION INTO THE TRACHEA THROUGH THE MOUTH OR NOSE TO MAINTAIN AN UNOBSTRUCTED PASSAGEWAY ESPECIALLY TO DELIVER OXYGEN OR ANESTHESIA TO THE LUNGS.,CLOSED WOUND DRAINAGE SET(DENEX)-INTENDED FOR EVACUATION OF BIOLOGICAL FLUID FROM WOUND OR BODY CAVITY DURING SURGICAL PROCEDURE OR IN WOUND CARE MANAGEMENT.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3378	MFG/MD/2020/000017	1.License Holder Name: BEACON DIAGNOSTICS PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:CYSTATIN C CALIBRATOR (ULTIMA CYSTATIN C CALIBRATOR SET)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,CYSTATIN C TEST KIT(CYSTATIN C SYSTEM PACK)-QUANTITATIVE TURBIDIMETRIC TEST FOR THE MEASUREMENT OF CYSTATIN C IN SERUM OR PLASMA,ADA CONTROL (ULTIMA ADA CONTROL SET)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,HDL DIRECT TEST KIT(HDL DIRECT SYSTEM PACK)-QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN SERUM/PLASMA,DIRECT HBA1C(DIRECT HBA1C ENZYMATIC TEST KIT) -FOR USE IN THE QUANTITATIVE DETERMINATION OF HBA1C IH HUMAN WHOLE BLOOD SAMPLE ,RF TURBILATEX TEST KIT(RF TURBILATEX SYSTEM PACK)-QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR IN SERUM,HAPTOGLOBIN(HAPTOGLOBIN TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF HAPTOGLOBIN IN HUMAN SERUM OR PLASMA.,CRP TURBILATEX TEST KIT(CRP TURBILATEX SYSTEM PACK)-QUANTITATIVE DETREMINATION OF C REACTIVE PROTEIN IN SERUM,ETHANOL (ETHANOL SYSTEM PACK)-FOR QUANTITATIVE DETERMINATION OF ETHANOL IN HUMAN SERUM OR PLASMA ,UREA UV TEST KIT(UREA UV SYSTEM PACK)-QUANTITATIVE DETERMINATION OF UREA IN SERUM/PLASMA AND URINE,IGA(IMMUNOGLOBULIN A (IGA) TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A IN HUMAN SERUM OR PLASMA ,LDL DIRECT TEST KIT(LDL DIRECT SYSTEM PACK)-QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IN SERUM/PLASMA, POTASSIUM(ENZYMATIC POTASSIUM SYSTEM PACK)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF POTASSIUM IN SERUM , TRIGLYCERIDES TEST KIT(TRIGLYCERIDES SYSTEM PACK)-QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN SERUM/PLASMA,IGA(IMMUNOGLOBULIN A (IGA) SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN A IN HUMAN SERUM OR PLASMA ,URIC ACID TEST KIT(URIC ACID SYSTEM PACK)-QUANTITATIVE DETERMINATION OF URIC ACID IN SERUM/PLASMA AND URINE,CKNAC / CKMB COMBIPACK(LIQUIZYME CK-NAC / CK-MB COMBIPACK)-FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE /CK -MB IN HUMAN SERUM OR PLASMA.,H.PYLORI ANTIBODY TEST KIT(H.PYLORI ANTIBODY RAPID IMMUNOCHROMATOGRAPHIC TEST)-FOR THE DETECTION OF ANTIBODIES TO HELICOBACTER PYLORI IN HUMAN SERUM OR PLASMA.,URINE ANALYZERS(ULTIMA URINE ANALYZER)-IT IS USED TO DETECT AND QUANTIFY A NUMBER OF ANALYTES INCLUDING

	BILIRUBIN, PROTEIN, GLUCOSE AND RED BLOOD CELLS IN URINE , GAMMA GT TEST KIT(GAMMA GT SYSTEM PACK)-QUANTITATIVE DETERMINATION OF GAMMA GT IN SERUM/PLASMA,LACTATE (LIQUIZYME LACTATE)-FOR THE QUANTITATIVE DETERMINATION OF LACTATE IN HUMAN PLASMA.,VITAMIN D TEST KIT(VITAMIN D SYSTEM PACK)-QUALITATIVE DETERMINATION OF TOTAL 25-OH VITAMIN D IN HUMAN WHOLE BLOOD,IRON(IRON SYSTYEM PACK)-FOR QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM OR HEPARINIZED PLASMA. ,STAINED SALMONELLA ANTIGEN SET WITH POSITIVE AND NEGATIVE CONTROL(STAINED SALMONELLA ANTIGEN SET WITH POSITIVE AND NEGATIVE CONTROL)-FOR THE DETECTION OF SALMONELLA TYPHI, PARA TYPHI ANTIBODIES IN HUMAN SERUM , 1- ACID GLYCOPROTEIN(1- ACID GLYCOPROTEIN SYSTEM PACK)-FOR QUANTITATIVE DETERMINATION OF 1-ACID GLYCOPROTEIN IN HUMAN SERUM OR PLASMA,MAGNESIUM TEST KIT(MAGNESIUM SYSTEM PACK)-QUANTITATIVE DETERMINATION OF MAGNESIUM IN SERUM,TRANSFERRIN (TRANSFERRIN SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF TRANSFERRIN IN HUMAN SERUM OR PLASMA. ,SLE KIT(SLE)-FOR QUALITATIVE DETECTION OF ANTIBODIES TO DSDNA AND HISTONES,ALKALINE PHOSPHATASE (ALKALINE PHOSPHATASE SYSTEM PACK (DEA METHOD))-FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR PLASMA. ,SALMONELLA 6 ANTIGEN KIT WITH CONTROLS(SALMONELLA 6 ANTIGEN SLIDE AND TUBE TEST KIT WITH CONTROLS)-FOR THE DETECTION OF SALMONELLA TYPHI, PARA TYPHI ANTIBODIES IN HUMAN SERUM ,TOTAL BILE ACIDS CALIBRATOR(ULTIMA TOTAL BILE ACIDS CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,CK NAC TEST KIT(CK NAC SYSTEM PACK)-QUANTITATIVE DETERMINATION OF CREATINE KINASE ACTIVITY IN SERUM,HBDH(HBDH SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF - HYDROXYBUTYRATE DEHYDROGENASE(HBDH) IN HUMAN SERUM OR PLASMA. , APOLIPOPROTEIN B TEST KIT(APOLIPOPROTEIN B SYSTEM PACK)-FOR THE MEASUREMENT OF APOLIPOPROTEIN B IN HUMAN SERUM OR PLASMA,TOTAL BILIRUBIN (J & G)(LIQUIZYME TOTAL BILIRUBIN (J & G METHOD))-FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM. ,HBA1C TEST KIT(HBA1C SYSTEM PACK) -QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C IN HUMAN BLOOD,MALARIA PF DEVICE(ULTIMA MALARIA PF DEVICE)-QUALITATIVE DETERMINATION OF P.FALCIPARUM SPECIFIC HISTIDINE RICH PROTEIN -2(PF.HRP- 2)FROM HUMAN WHOLE BLOOD SAMPLES. ,OX 19 KIT WITH CONTROLS(PROTEUS OX 19 KIT WITH CONTROLS)-FOR THE DETECTION OF RICKETTSIAL ANTIBODIES IN

	HUMAN SERUM,CHOLINESTERASE(CHOLINESTERASE SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF CHOLINESTERASE IN HUMAN SERUM AND PLASMA.,BRUCELLA MELITENSIS KIT(BRUCELLA MELITENSIS SLIDE AND TUBE TEST KIT)-FOR DETECTION OF SPECIFIC ANTIBODIES TO BRUCELLA ABORTUS AND BRUCELLA MELITENSIS IN HUMAN SERUM,ASO CONTROL(ULTIMA ASO CONTROL (LOW))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,CALCIUM TEST KIT(CALCIUM SYSTEM PACK)-QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM,FERRITIN CONTROL(ULTIMA FERRITIN CONTROL) -USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS , AMYLASE TEST KIT(AMYLASE SYSTEM PACK)-QUANTITATIVE DETERMINATION OF AMYLASE IN SERUM/PLASMA/URINE,CK-NAC CONTROL(ULTIMA CK-NAC CONTROL LEVEL 2)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS,NEGATIVE CONTROL KIT (NEGATIVE CONTROL)-TO BE USED AS NEGATIVE CONTROL IN THE DETERMINATION OF STAINED SALMONELLA ANTIGEN, RPR, BRUCELLA, PROTEOUS VULGARIS AND OX 19,PROCALCITONIN CALUBRATOR(ULTIMA UPROCALCITONIN CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARACTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,BILIRUBIN TEST KIT (BILIRUBIN SYSTEM PACK)-QUANTITATIVE DETERMINATION OF TOTAL AND DIRECT BILIRUBIN IN SERUM,ADA CONTROL(ULTIMA ADA CONTROL (LOW))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,ALBUMIN TEST KIT(ALBUMIN SYSTEM PACK)-QUANTITATIVE DETERMINATION OF ALBUMIN IN SERUM/PLASMA, ADA CONTROL(ULTIMA ADA CONTROL (HIGH))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,SGPT TEST KIT(SGPT SYSTEM PACK)-QUANTITATIVE DETERMINATION OF SGPT (ALT) ACTIVITY IN SERUM,PREALBUMIN(PREALBUMIN SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF PREALBUMIN IN HUMAN SERUM OR PLASMA.,INFECTIOUS MONONUCLEOSIS KIT(INFECTIOUS MONONUCLEOSIS RAPID SLIDE HAEMAGGLUTINATION TEST)-FOR THE QUALITATIVE DETECTION OF INFECTIOUS MONONUCLEOSIS HETEROPHILE ANTIBODIES IN SERUM,TRANSFERRIN(TRANSFERRIN TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF TRANSFERRIN IN HUMAN SERUM OR PLASMA. ,LDH TEST KIT(LDH SYSTEM PACK)-QUANTITATIVE DETERMINATION OF LDH IN SERUM/PLASMA,CK-NAC CONTROL(ULTIMA CK-NAC CONTROL SET)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS , CREATININE TEST KIT(CREATININE SYSTEM PACK)-QUANTITATIVE DETERMINATION OF CREATININE IN SERUM/URINE,IGG (IMMUNOGLOBULIN G (IGG) TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G IN HUMAN SERUM OR PLASMA ,ADA TEST KIT(ADA SYSTEM PACK)-QUANTITATIVE

	DETERMINATION OF ADA (ADENOSINE DEAMINASE) IN SERUM, PLASMA, PLEURAL FLUID, CSF, PERICARDIAL FLUID, ASCITIC FLUID, DIRECT BILIRUBIN(J & G)(LIQUIZYME DIRECT BILIRUBIN (J & G METHOD))-FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM. ,AMMONIA TEST KIT(AMMONIA SYSTEM PACK)-QUANTITATIVE DETERMINATION OF AMMONIA IN PLASMA, FLOW CELL CLEANER(ULTIMA FLOW CELL CLEANER)- USED FOR CLENING MICRO FLOW-THROUGH CELLS AND CUVETTS IN SEMI AUTO ANALYZER. ,SALMONELLA 8 ANTIGEN KIT WITH CONTROLS (SALMONELLA 8 ANTIGEN SLIDE AND TUBE TEST KIT WITH CONTROLS)-FOR THE DETECTION OF SALMONELLA TYPHI, PARA TYPHI ANTIBODIES IN HUMAN SERUM,GLUCOSE HEXOKINASE (GLUCOSE HEXOKINASE SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM OR PLASMA. , LIPASE TEST KIT(LIPASE SYSTEM PACK)-QUANTITATIVE DETERMINATION OF LIPASE IN SERUM/PLASMA,MICROALBUMIN CONTROL(ULTIMA MICROALBUMIN CONTROL)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,BILIRUBIN TEST KIT (BILIRUBIN (VANADATE OXIDASE METHOD))-QUANTITATIVE DETERMINATION OF TOTAL AND DIRECT BILIRUBIN IN SERUM,CRP CONTROL(ULTIMA CRP CONTROL (HIGH))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,SGOT TEST KIT(SGOT SYSTEM PACK)-QUANTITATIVE DETERMINATION OF SGOT (AST) ACTIVITY IN SERUM,MYOGLOBIN CALIBRATOR (ULTIMA MYOGLOBIN CALIBRATOR SET)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,HOMOCYSTEINE TEST KIT(HOMOCYSTEINE SYSTEM PACK)-QUANTITATIVE DETERMINATION OF HOMOCYSTEINE IN HUMAN SERUM AND PLASMA,CERULOPLASMIN(CERULOPLASMIN TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF CERULOPLASMIN IN HUMAN SERUM OR PLASMA.,CK MB TEST KIT(CK MB SYSTEM PACK)-QUANTITATIVE DETERMINATION OF CK MB LEVELS IN SERUM,HDL PRECIPITATING REAGEMT(LIQUIZYME HDL PRECIPITATING REAGENT)-FOR THE QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM OR PLASMA. ,GLUCOSE TEST KIT(GLUCOSE SYSTEM PACK)-QUANTITATIVE DETERMINATION OF GLUCOSE IN SERUM/PLASMA OR URINE,COMPLEMENT C4 (COMPLEMENT C4 TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT C 4 IN HUMAN SERUM OR PLASMA ,ASO TURBILATEX TEST KIT(ASO TURBILATEX SYSTEM PACK)-QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN -O IN SERUM,MYOGLOBIN(MYOGLOBIN SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM ON PLASMA. ,INORGANIC PHOSPHOROUS TEST KIT(INORGANIC

	PHOSPHOROUS SYSTEM PACK)-QUANTITATIVE DETERMINATION OF PHOSPHOROUS IN SERUM,PLASMA AND URINE,5 PART CELL COUNTER(ULTIMA 5 PART CELL COUNTER)-FOR THE QUANTITATIVE DETERMINATION OF RBC, WBC AND PLATELETS ,CHOLESTEROL TEST KIT(CHOLESTEROL SYSTEM PACK)-QUANTITATIVE DETERMINATION OF CHOLESTEROL IN SERUM/PLASMA,ELECTROLYTE REFERENCE SOLUTION(ULTIMA ELECTROLYTE REFERENCE SOLUTION)-FOR CALIBRATION PURPOSE ,ALKALINE PHOSPHATASE TEST KIT (ALKALINE PHOSPHATASE SYSTEM PACK)-QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN SERUM/PLASMA, DIRECT HBA1C(DIRECT HBA1C ENZYMATIC SYSTEM PACK)-FOR USE IN THE QUANTITATIVE DETERMINATION OF HBA1C IH HUMAN WHOLE BLOOD SAMPLE ,APOLIPOPROTEIN A-1 TEST KIT(APOLIPOPROTEIN A SYSTEM PACK)-FOR THE MEASUREMENT OF APOLIPOPROTEIN A IN HUMAN SERUM OR PLASMA,PROCALCITONIN(PROCALCITONIN SYSTEM PACK)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PROCALCITONIN IN SERUM OR PLASMA ,TOTALPROTEIN TEST KIT (TOTALPROTEIN SYSTEM PACK)-QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN SERUM/PLASMA,HAPTOGLOBIN(HAPTOGLOBIN SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF HAPTOGLOBIN IN HUMAN SERUM OR PLASMA.,URIC ACID TEST KIT (URIC ACID TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM,PLASMA AND URINE.,AMMONIA (LIQUIZYME AMMONIA SINGLE REAGENT)-FOR THE QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN PLASMA. ,MICROALBUMIN TURBILATEX TEST KIT(MICROALBUMIN TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF MICROALBUMIN IN HUMAN URINE.,CK -MB CONTROL(ULTIMA CK-MB CONTROL LEVEL 1)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS,FEBRILE S. PARATYPHI A(H) ANTIGEN(FEBRILE S. PARATYPHI A(H) ANTIGEN (WIDAL TUBE METHOD))-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN RESPONSE TO THE STIMULATION BY SPECIFIC ANTIGEN OF SALMONELLA (GROUP),CYSTATIN C CONTROL(ULTIMA CYSTATIN C CONTROL (LOW))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,RINSE-MR(ULTIMA RINSE- MDR)-RINSE FOR MINDRAY 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,ZINC(ZINC SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF ZINC IN HUMAN SERUM OR PLASMA,RINSE(RINSE)-RINSE (FOR ALL 3-PART DIFFERENTIAL BLOOD CELL COUNTER) ,PROTEIN CONTROL(ULTIMA PROTEIN CONTROL)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,POSITIVE CONTROL FOR WIDAL TEST(WIDAL POSITIVE CONTROL)-FOR THE PURPOSE OF PERFORMANCE VALIDATION OF WIDAL TEST KIT,IGE(IMMUNOGLOBULIN E (IGE) TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF

	IMMUNOGLOBULIN E IN HUMAN SERUM OR PLASMA ,ZINC TEST KIT (LIQUIZYME ZINC (COLORIMETRIC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF ZINC IN SERUM.,STAINED SALMONELLA ANTIGEN SET(STAINED SALMONELLA ANTIGEN SET WITH CONTROLS (SLIDE & TUBE METHOD))-FOR THE DETECTION OF SALMONELLA TYPHI O ,SALMONELLA TYPHI H ANTIBODIES IN HUMAN SERUM ,LYPHOZYME URIC ACID TEST KIT(LYPHOZYME URIC ACID (URICASE/POD METHOD))-FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM,PLASMA AND URINE.,DIRECT BILIRUBIN(DMSO)(LIQUIZYME DIRECT BILIRUBIN (DMSO METHOD))-FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM. ,CLEANER-ERM(ULTIMA CLEANER - ERM)-CLEANER FOR ERMA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,TOTAL BILE ACID(LIQUIZYME TOTAL BILE ACIDS)-FOR QUANTITATIVE DETERMINATION OF TOTAL BILE ACIDS IN HUMAN SERUM OR PLASMA,DILUENT - ERM(ULTIMA DILUENT - ERM)-DILUENT FOR ERMA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, COMPLEMENT C3(COMPLEMENT C3 TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT C 3 IN HUMAN SERUM OR PLASMA ,POSITIVE CONTROL KAHN/VDRL(POSITIVE CONTROL)-FOR THE PURPOSE OF PERFORMANCE VALIDATION OF VDRL TEST KIT,FULLY AUTO BIOCHEMISTRY ANALYZERS(ULTIMA FULLY AUTO BIOCHEMISTRY ANLYZER-200)-DEVICES WHICH ARE USED TO MEASURE THE CONCENTRATION OF CHEMICALS IN A BIOLOGICAL PROCESS ,HBA1C DIRECT (WITHOUT CALIBRATOR) TEST KIT(HBA1C DIRECT WITHOUT CALIBRATOR (LATEX TURBIDIMETRIC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN BLOOD.,ETHANOL CALIBRATOR (ULTIMA ETHANOL CALIBRATOR SET)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,G.O.T TEST KIT(SGOT TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF AST/GOT (ASPARTATE AMINOTRANSFERASE) IN HUMAN SERUM.,LDL DIRECT(LDL DIRECT SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IN HUMAN SERUM OR PLASMA.,LYPHOZYME ALKALINE PHOSPHATASE TEST KIT(LYPHOZYME ALKALINE PHOSPHATASE (AMP OPTIMIZED IFCC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR HEPARIN PLASMA,CRP CONTROL(ULTIMA CRP CONTROL (LOW))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,HBA1C CONTROL SET(HBA1C CONTROL)-FOR THE VALIDATION OF PERFORMANCE OF HBA1C REAGENT.,LP (A) CONTROL(ULTIMA LP (A) CONTROL)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,URITRACE -5P(URITRACE -5

	P)-FOR GLUCOSE,PROTEIN,PH,BLOOD & KETONE ANALYSIS FROM URINE.,HDL CALIBRATOR(ULTIMA HDL CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,BICARBONATE TEST KIT(LIQUIZYME BICARBONATE (PEPC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF CARBON DIOXIDE IN HUMAN SERUM OR HEPARINIZED PLASMA.,CK -MB CONTROL(ULTIMA CK-MB CONTROL SET)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS , STAINED SALMONELLA ANTIGEN SET(STAINED SALMONELLA ANTIGEN (WIDAL SLIDE & TUBE METHOD))-FOR THE DETECTION OF SALMONELLA TYPHI, PARA TYPHI ANTIBODIES IN HUMAN SERUM, FERRITIN CALIBRATOR(ULTIMA FERRITIN CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,CREATININE TEST KIT (LIQUIZYME CREATININE (ENZYMATIC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM OR URINE.,CYSTATIN C CONTROL(ULTIMA CYSTATIN C CONTROL (HIGH))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS , BIOCHEMISTRY CONTROL NORM & PATH(BEACON CONTROL NORM & PATH (BIOCHEMISTRY))-CONTROL TO BE USED IN INTERNAL QUALITY CONTROL SCHEMES, TO MONITOR THE PRECISION., ANTITHROMBIN III(ANTITHROMBIN III TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF ANTITHROMBIN III IN HUMAN SERUM OR PLASMA ,NEGATIVE CONTROL KAHN/VDRL(NEGATIVE CONTROL)-FOR THE PURPOSE OF PERFORMANCE VALIDATION OF VDRL TEST KIT,MYOGLOBIN(LIQUIZYME MYOGLOBIN)-FOR THE QUANTITATIVE DETERMINATION OF MYOGLOBIN IN HUMAN SERUM ON PLASMA. ,ALBUMIN TEST KIT(LIQUIZYME ALBUMIN (BCG METHOD))-FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM OR PLASMA.,ASO/CRP/RF CONTROL(ULTIMA ASO/CRP/RF CONTROL (HIGH))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,FEBRILE S. PARATYPHI B(H) ANTIGEN (FEBRILE S. PARATYPHI B(H) ANTIGEN (WIDAL TUBE METHOD))-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN RESPONSE TO THE STIMULATION BY SPECIFIC ANTIGEN OF SALMONELLA (GROUP), COAGULATION ANALYZERS(SEROCLOT)-SEMI-AUTOMATED MECHANICAL CLOT DETECTION SYSTEM DESIGNED FOR THE DETERMINATION OF PT, APTT, FIBRINOGEN CONCENTRATIONS , BIOCHEMISTRY CONTROL NORM(BEACON CONTROL NORM (BIOCHEMISTRY))-CONTROL TO BE USED IN INTERNAL QUALITY CONTROL SCHEMES, TO MONITOR THE PRECISION.,PROCALCITONIN(PROCALCITONIN TURBILATEX)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF PROCALCITONIN IN SERUM OR PLASMA , SALMONELLA HIGH TITRE ANTISERA(SALMONELLA HIGH TITRE

	ANTISERA)-TO VALIDATE THE SPECIFICITY OF THE SALMONELLA ANTIGEN,1-ANTITRYPSIN(1-ANTITRYPSIN SYSTEM PACK)-FOR QUANTITATIVE DETERMINATION OF 1 -ANTITRIPSIN IN HUMAN SERUM OR PLASMA,FEBRILE S. TYPHI O ANTIGEN(FEBRILE S. TYPHI O ANTIGEN (WIDAL TUBE METHOD))-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN RESPONSE TO THE STIMULATION BY SPECIFIC ANTIGEN OF SALMONELLA (GROUP),HDL/LDL COMBIPACK (LIQUIZYME HDL / LDL COMBIPACK)-FOR THE QUANTITATIVE DETERMINATION OF HDL/LDL CHOLESTEROL IN HUMAN SERUM OR PLASMA.,STAINED SALMONELLA ANTIGEN SET(STAINED SALMONELLA ANTIGEN (WIDAL SLIDE & TUBE METHOD))-FOR THE DETECTION OF SALMONELLA TYPHI, PARA TYPHI ANTIBODIES IN HUMAN SERUM,LDL CALIBRATOR(ULTIMA LDL CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,ASO TURBILATEX TEST KIT (ASO TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF ANTISTREPTOLYSIN -O ACTIVITY IN HUMAN SERUM.,ELECTROLYTE CONTROL(ULTIMA ELECTROLYTE CONTROL SET)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,HBA1C DIRECT WITH CALIBRATOR TEST KIT(HBA1C DIRECT WITH CALIBRATOR (LATEX TURBIDIMETRIC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN BLOOD.,ELECTROLYTE FLUSH CLEANER(ULTIMA ELECTROLYTE FLUSH CLEANER)-FOR CLEANING THE FLUID PATH ON THE ELECTROLYTE ANALYZER ,G6PD QUALITATIVE TEST KIT(G6PD (QUALITATIVE METHOD))-FOR THE QUALITATIVE DETERMINATION OF G6PDH DEFICIENCY IN RED BLOOD CELLS.,ELECTROLYTE EZ CLEANER(ULTIMA ELECTROLYTE EZ CLEANER)-TO CLEAN THE SAMPLE PATH,STAINED SALMINELLA ANTIGEN S.TYPHI 'H'(STAINED SALMINELLA ANTIGEN S.TYPHI 'H' (WIDAL SLIDE & TUBE METHOD))-FOR THE DETECTION OF SALMONELLA TYPHI, PARA TYPHI ANTIBODIES IN HUMAN SERUM,LP (A)(LP (A) SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF LP (A) IN HUMAN SERUM OR PLASMA. ,G.G.T.P TEST KIT(GAMMA GT TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF GGT IN HUMAN SERUM OR PLASMA.,WASH CONCENTRATE(ULTIMA WASH CONCENTRATE)- USED FOR CLEANING CUVETTES IN FULLY AUTOMATED ANALYZER. ,FEBRILE ANTIGEN SET(FEBRILE ANTIGEN (WIDAL TUBE METHOD))-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN RESPONSE TO THE STIMULATION BY SPECIFIC ANTIGEN OF SALMONELLA (GROUP),ETHANOL CONTROL(ULTIMA ETHANOL CONTROL SET)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,FEBRILE S. TYPHI H ANTIGEN(FEBRILE S. TYPHI H ANTIGEN (WIDAL TUBE METHOD))-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN RESPONSE TO THE STIMULATION BY SPECIFIC ANTIGEN

	OF SALMONELLA (GROUP),COLORIMETER(OCTA-1 COLORIMETER)-INSTRUMENT INTENDED TO MEASURE LIGHT EMITTED, TRANSMITTED, ABSORBED, OR REFLECTED UNDER CONTROLLED CONDITIONS , BILIRUBIN TEST KIT(LIQUIZYME BILIRUBIN (DMSO METHOD))-FOR THE QUANTITATIVE DETERMINATION OF BILIRUBIN IN HUMAN SERUM.,ELECTROLYTE STANDARD B(ULTIMA ELECTROLYTE STANDARD B)-TO PROVIDE CALIBRATION POINT FOR NA+, K+, CA++, CL-, LI+ ,DILUENT - URT(ULTIMA DILUENT - URT)-DILUENT FOR URIT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,URINARY PROTEIN (URINARY PROTEIN SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF URINARY AND CSF PROTEIN .,CK – MB (NAC ACT.) TEST KIT(LIQUIZYME CK – MB (IMMUNOINHIBITION METHOD))-FOR THE QUANTITATIVE DETERMINATION OF CK-MB LEVELS IN SERUM OR PLASMA.,SODIUM(LIQUIZYME ENZYMATIC SODIUM)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF SODIUM IN SERUM , BIOCHEMISTRY CONTROL PATH(BEACON CONTROL PATH (BIOCHEMISTRY))-CONTROL TO BE USED IN INTERNAL QUALITY CONTROL SCHEMES, TO MONITOR THE PRECISION.,IGE (IMMUNOGLOBULIN E (IG E) SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN E IN HUMAN SERUM OR PLASMA ,FEBRILE ANTIGEN SET(FEBRILE ANTIGEN (WIDAL TUBE METHOD))-FOR DETECTION OF SPECIFIC ANTIBODIES PRESENT IN RESPONSE TO THE STIMULATION BY SPECIFIC ANTIGEN OF SALMONELLA (GROUP),HDL DIRECT(HDL DIRECT SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM OR PLASMA.,ZINC TEST KIT(ZINC TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF ZINC IN SERUM.,LP (A)(LP (A) TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF LP (A) IN HUMAN SERUM OR PLASMA. ,LYPHOZYME SGPT TEST KIT (LYPHOZYME SGPT (IFCC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF ALT/GPT (ALANINE AMINOTRANSFERASE) IN HUMAN SERUM.,STAINED SALMONELLA ANTIGEN SET(STAINED SALMONELLA ANTIGEN SET WITH CONTROLS (SLIDE & TUBE METHOD))-FOR THE DETECTION OF SALMONELLA TYPHI O , SALMONELLA TYPHI H ANTIBODIES IN HUMAN SERUM,BONAVERA COUNT LYSE(ULTIMA LYSE BCT)-LYSE FOR BONAVERA COUNT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,APOLIPOPROTEIN E (APOLIPOPROTEIN E SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPRETEIN E IN HUMAN SERUM OR PLASMA ,BIOCHEMISTRY MULTICALIBRATOR(BEACON MULTICALIBRATOR (BIOCHEMISTRY))-FOR THE PURPOSE OF CALIBRATING BIOCHEMISTRY REAGENT IN SEMI AUTOMATED AND FULLY AUTOMATED BIOCHEMISTRY ANALYZER,COMPLEMENT C4 (COMPLEMENT C4 SYSTEM PACK)-FOR THE QUANTITATIVE

	DETERMINATION OF COMPLEMENT C 4 IN HUMAN SERUM OR PLASMA ,NEGATIVE CONTROL FOR WIDAL TEST(WIDAL NEGATIVE CONTROL)-FOR THE PURPOSE OF PERFORMANCE VALIDATION OF WIDAL TEST KIT,SODIUM(ENZYMATIC SODIUM SYSTEM PACK)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF SODIUM IN SERUM , CLEANER(CLEANER)-CLEANER (FOR ALL 3-PART DIFFERENTIAL BLOOD CELL COUNTER) ,HOMOCYSTEIN CONTROL(ULTIMA HOMOCYSTEIN CONTROL)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,STAINED SALMONELLA ANTIGEN S. PARATYPHI C(O)(STAINED SALMONELLA ANTIGEN S.PARATYPHI C(O) (WIDAL SLIDE & TUBE METHOD))-FOR THE DETECTION OF SALMONELLA TYPHI, PARA TYPHI ANTIBODIES IN HUMAN SERUM, HDL / LDL CALIBRATOR(ULTIMA HDL/LDL CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,STRONG CLEANER-NK (ULTIMA STRONG CLEANER - NKH)-STRONG CLEANER FOR NIHON KOHDEN 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,FERRITIN (FERRITIN SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION FERRITIN HUMAN SERUM OR PLASMA. ,STAINED SALMONELLA ANTIGEN SET(STAINED SALMONELLA ANTIGEN (WIDAL SLIDE & TUBE METHOD))-FOR THE DETECTION OF SALMONELLA TYPHI, PARA TYPHI ANTIBODIES IN HUMAN SERUM,FULLY AUTO BIOCHEMISTRY ANALYZERS(ULTIMA FULLY AUTO BIOCHEMISTRY ANLYZER-400)-DEVICES WHICH ARE USED TO MEASURE THE CONCENTRATION OF CHEMICALS IN A BIOLOGICAL PROCESS ,RF ANTIGEN(RF LATEX ANTIGEN)-FOR THE QUALITATIVE DETERMINATION OF RHEUMATOID FACTOR IN HUMAN SERUM.,LACTATE(LACTATE SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF LACTATE IN HUMAN PLASMA.,HBA1C CALIBRATOR SET(HBA1C CALIBRATOR)-FOR THE PURPOSE OF CALIBRATING HBA1C TEST KIT IN SEMI AUTOMATED AND FULLY AUTOMATED BIOCHEMISTRY ANALYZER,ASO CONTROL(ULTIMA ASO CONTROL(HIGH))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,BONAVERA COUNT RINSE(ULTIMA RINSE BCT)-RINSE BONAVERA COUNT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,POTASSIUM(LIQUIZYME ENZYMATIC POTASSIUM)-FOR THE QUANTITATIVE IN VITRO DETERMINATION OF POTASSIUM IN SERUM ,HEMOGLOBIN TEST KIT(HEMOGLOBIN (DRABKIN'S METHOD))-FOR QUANTITATIVE DETERMINATION OF HEMOGLOBIN IN HUMAN VENOUS OR CAPILLARY BLOOD.,HBDH(LIQUIZYME HBDH)-FOR THE QUANTITATIVE DETERMINATION OF - HYDROXYBUTYRATE DEHYDROGENASE(HBDH) IN HUMAN SERUM OR PLASMA. ,CRP TURBILATEX TEST KIT(CRP TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM., HOMOCYSTEIN CALIBRATOR(ULTIMA HOMOCYSTEIN CALIBRATOR)-

	DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,AMYLASE TEST KIT (AMYLASE TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF ALPHA-AMYLASE IN HUMAN SERUM ,PLASMA AND URINE.,CRP CALIBRATOR(ULTIMA CRP CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,FIELD STAIN B REAGENT(FIELD STAIN B)-FOR THE RAPID DEMONSTRATION OF MALARIA PARASITES IN THICK AND THIN BLOOD SMEARS.,RF CALIBRATOR(ULTIMA RF CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,CK (NAC ACT.) TEST KIT(LIQUIZYME CREATINE KINASE (OPTIMIZED IFCC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE IN HUMAN SERUM OR PLASMA.,IGE CONTROL(ULTIMA IGE CONTROL)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,CEDAR WOOD OIL(CEDAR WOOD OIL)-FOR MICROSCOPIC EXAMINATION OF PREPARED SAMPLES WITH AS MUCH DETAIL AS POSSIBLE.,PROTEIN CALIBRATOR(ULTIMA PROTEIN CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,CMG STANDARD(CMG STANDARD)-FOR QUANTITATIVE DETERMINATION OF HEMOGLOBIN IN HUMAN VENOUS OR CAPILLARY BLOOD.,BILIRUBIN CALIBRATOR(ULTIMA BILIRUBIN CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,FIELD STAIN A REAGENT(FIELD STAIN A)-FOR THE RAPID DEMONSTRATION OF MALARIA PARASITES IN THICK AND THIN BLOOD SMEARS.,CYSTATIN C CONTROL(ULTIMA CYSTATIN C CONTROL SET)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,TOTAL PROTEIN TEST KIT(TOTAL PROTEIN TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA.,ASO CALIBRATOR(ULTIMA ASO CALIBRATOTR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,UREA TEST KIT(LIQUIZYME UREA (NED METHOD))-FOR THE QUANTITATIVE DETERMINATION OF UREA IN SERUM,PLASMA AND URINE.,CK-NAC CONTROL(ULTIMA CK-NAC CONTROL LEVEL 1)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,LYPHOZYME UREA (UV) TEST KIT(LYPHOZYME UREA (UV GLDH METHOD))-FOR THE QUANTITATIVE DETERMINATION OF UREA IN SERUM,PLASMA AND URINE.,ANTITHROMBIN III (ANTITHROMBIN III SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF ANTITHROMBIN III IN HUMAN SERUM OR PLASMA ,LYPHOZYME UREA KIT(LYPHOZYME UREA (BERTHELOT METHOD))-FOR THE QUANTITATIVE DETERMINATION OF UREA IN

	SERUM,PLASMA AND URINE.,APOLIPOPROTEIN CALIBRATOR(ULTIMA APOLIPOPROTEIN CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,URITRACE -2GP(URITRACE -2GP)-FOR GLUCOSE, PROTEIN ANALYSIS FROM URINE.,MICROALBUMIN CALIBRATOR(ULTIMA MICROALBUMIN CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,BILIRUBIN KIT(LIQUIZYME BILIRUBIN (MOD. JENDRASSIK & GROF'S METHOD))-FOR THE QUANTITATIVE DETERMINATION OF BILIRUBIN IN HUMAN SERUM.,ELECTROLYTE ANALYZERS(ULTIMA ELECTROLYTE ANALYZER)-THE ELECTROLYTE ANALYZERS IS A DEVICE FOR MEASURING THE ELECTROLYTES IN THE HUMAN BODY. ,URIC ACID TEST KIT(LIQUIZYME URIC ACID (URICASE / POD METHOD))-FOR THE QUANTITATIVE DETERMINATION OF URIC ACID IN HUMAN SERUM,PLASMA AND URINE., CERULOPLASMIN(CERULOPLASMIN SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF CERULOPLASMIN IN HUMAN SERUM OR PLASMA.,TRIGLYCERIDES TEST KIT(TRIGLYCERIDES TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM OR PLASMA.,SEMI AUTO BIOCHEMISTRY ANALYZERS (ULTIMA SEMI AUTO BIOCHEMISTRY ANALYZER)-DEVICES WHICH ARE USED TO MEASURE THE CONCENTRATION OF CHEMICALS IN A BIOLOGICAL PROCESS ,URITRACE- GK(URITRACE- GK)-FOR GLUCOSE AND KETONE ANALYSIS FROM URINE.,LYSE(ULTIMA 5 PART LYSE)-FOR THE PURPOSE OF LYSING RED BLOOD CELL,RELEASING HEMOGLOBIN AND PRESERVES THE INTEGRITY OF WBC NUCLEUS, IRON & TIBC TEST KIT(IRON & TIBC)-FOR QUANTITATIVE DETERMINATION OGF IRON AND TOTAL IRON BINDING CAPACITY IN HUMAN SERUM OR HEPARINIZED PLASMA.,CHOLINESTERASE (LIQUIZYME CHOLINESTERASE)-FOR THE QUANTITATIVE DETERMINATION OF CHOLINESTERASE IN HUMAN SERUM AND PLASMA.,UREA (UV) TEST KIT(LIQUIZYME UREA (UV GLDH METHOD))-FOR THE QUANTITATIVE DETERMINATION OF UREA IN SERUM, PLASMA AND URINE.,ASO/CRP/RF CONTROL(ULTIMA ASO/CRP/RF CONTROL (LOW))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,CHLORIDE TEST KIT(LIQUIZYME CHLORIDE (COLORIMETRIC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF CHLORIDE IN SERUM.,IGE CALIBRATOR(ULTIMA IGE CALIBRATOR) -DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,LYPHOZYME TRIGLYCERIDES TEST KIT(LYPHOZYME TRIGLYCERIDES (GPO/POD METHOD))-FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM OR PLASMA.,COLORIMETER (OCTA-1 PLUS COLORIMETER)-INSTRUMENT INTENDED TO MEASURE

	LIGHT EMITTED, TRANSMITTED, ABSORBED, OR REFLECTED UNDER CONTROLLED CONDITIONS ,GAMMA GT TEST KIT(LIQUIZYME GAMMA GT (SASZ METHOD))-FOR THE QUANTITATIVE DETERMINATION OF GGT IN HUMAN SERUM OR PLASMA.,3 PART CELL COUNTER(ULTIMA 3 PART CELL COUNTER)-FOR THE QUANTITATIVE DETERMINATION OF RBC, WBC AND PLATELETS ,LYPHOZYME GLUCOSE TEST KIT (LYPHOZYME GLUCOSE (GOD/POD METHOD))-FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM AND PLASMA (PREFERABLY SODIUM FLUORIDE).,APOLIPOPROTEIN CIII (APOLIPOPROTEIN CIII SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPRETEIN C III IN HUMAN SERUM OR PLASMA ,BILIRUBIN TEST KIT (MANUAL)(BILIRUBIN TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF BILIRUBIN IN HUMAN SERUM.,CK -MB CONTROL(ULTIMA CK-MB CONTROL LEVEL 2)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS,CRP ANTIGEN (CRP LATEX ANTIGEN)-FOR THE QUALITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM., TOTAL BILIRUBIN (DMSO) (LIQUIZYME TOTAL BILIRUBIN (DMSO METHOD))-FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM. ,UREA BUN TEST KIT(UREA BUN)-FOR THE QUANTITATIVE DETERMINATION OF UREA IN SERUM,PLASMA AND URINE.,GLUCOSE HEXOKINASE(LIQUIZYME GLUCOSE HEXOKINASE)-FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM OR PLASMA. ,LIPASE TEST KIT(LIPASE TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF LIPASE IN HUMAN SERUM OR PLASMA.,APOLIPOPROTEIN CONTROL(ULTIMA APOLIPOPROTEIN CONTROL)-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,SGPT TEST KIT(LIQUIZYME SGPT (IFCC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF ALT/GPT (ALANINE AMINOTRANSFERASE) IN HUMAN SERUM.,LP (A) CALIBRATOR(ULTIMA LP (A) CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,MAGNESIUM TEST KIT(LIQUIZYME MAGNESIUM (XB METHOD))-FOR THE QUANTITATIVE DETERMINATION OF MAGNESIUM IN HUMAN SERUM OR PLASMA.,APOLIPOPROTEIN CII(APOLIPOPROTEIN CII SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF APOLIPOPRETEIN C II IN HUMAN SERUM OR PLASMA ,ANTI S. TYPHI O (ANTI S. TYPHI O)-TO VALIDATE THE SPECIFICITY OF THE SALMONELLA ANTIGEN,AMMONIA(AMMONIA SINGLE REAGENT SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN PLASMA. ,CREATININE SINGLE REAGENT KIT (LIQUIZYE CREATININE SINGLE REAGENT (MODIFIED JAFFE'S METHOD))-FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM OR URINE.,DIRECT BILIRUBIN(DIRECT BILIRUBIN

	SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF DIRECT BILIRUBIN IN HUMAN SERUM.,C.P.K TEST KIT(CREATINE KINASE TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF CREATINE KINASE IN HUMAN SERUM OR PLASMA.,IGG(IMMUNOGLOBULIN G (IGG) SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN G IN HUMAN SERUM OR PLASMA ,CLEANER-DIA (ULTIMA CLEANER - DIA)-CLEANER FOR DIATRON 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,FULLY AUTO BIOCHEMISTRY ANALYZERS(ULTIMA FULLY AUTO BIOCHEMISTRY ANALYZER-120)-DEVICES WHICH ARE USED TO MEASURE THE CONCENTRATION OF CHEMICALS IN A BIOLOGICAL PROCESS ,TIBC TEST KIT(LIQUIZYME TIBC)-FOR MEASURING THE TOTAL IRON BINDING CAPACITY IN HUMAN.,IGM(IMMUNOGLOBULIN M (IGM) SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M IN HUMAN SERUM OR PLASMA,ALBUMIN TEST KIT(ALBUMIN TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF ALBUMIN IN HUMAN SERUM OR PLASMA.,IGM(IMMUNOGLOBULIN M (IGM) TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF IMMUNOGLOBULIN M IN HUMAN SERUM OR PLASMA,LYPHOZYME SGOT TEST KIT(LYPHOZYME SGOT (IFCC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF AST/GOT (ASPARTATE AMINOTRANSFERASE) IN HUMAN SERUM., TOTAL BILIRUBIN(TOTAL BILIRUBIN SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL BILIRUBIN IN HUMAN SERUM.,LDH TEST KIT(LDH TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF LDH IN HUMAN SERUM OR PLASMA.,CKMB CALIBRATOR(ULTIMA CKMB CALIBRATOR)-DEVICE WITH KNOWN QUANTITATIVE CHARECTERISTICS USED TO CALIBRATE MEASUREMENT PROCEDURE ,CLEANER-NK(ULTIMA CLEANER - NKH)-CLEANER FOR NIHON KOHDEN 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,DILUENT (ULTIMA 5 PART DILUENT)-ISOTONIC SOLUTION FOR DILUTING CELLS AND FOR PRESERVING INTEGRITY AND VOLUME OF CELLS. ,RHEUMATOID FACTOR TEST KIT(RF LATEX (SLIDE AGGLUTINATION METHOD))-FOR THE QUALITATIVE DETERMINATION OF RHEUMATOID FACTOR IN HUMAN SERUM.,RF CONTROL(ULTIMA RF CONTROL(HIGH))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,URITRACE-10P(URITRACE-10P)-FOR LEUCOCYTES, NITRITE,UROBILINOGEN,PROTEIN , PH, BLOOD,SG,KETONE, BILIRUBIN, GLUCOSE ANALYSIS FROM URINE.,RF CONTROL(ULTIMA RF CONTROL (LOW))-USED TO MONITOR PERFORMANCE WITHIN DESIRED LIMITS ,HDL CHOLESTEROL TEST KIT(HDL CHOLESTEROL TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM OR PLASMA.,URINARY PROTEIN (LIQUIZYME URINARY PROTEIN)-FOR THE QUANTITATIVE DETERMINATION OF TOTAL URINARY AND CSF PROTEIN . ,CALCIUM

	TEST KIT(CALCIUM TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM.,DETERGENT(ULTIMA 5 PART DETERGENT)-FOR THE PURPOSE OF MAINTAINING CLEANLINESS OF TUBINGS . ,CALCIUM TEST KIT(LIQUIZYME CALCIUM (ARSENAZO III METHOD))-FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM.,COMPLEMENT C3(COMPLEMENT C3 SYSTEM PACK)-FOR THE QUANTITATIVE DETERMINATION OF COMPLEMENT C 3 IN HUMAN SERUM OR PLASMA,IRON TEST KIT(LIQUIZYME IRON (CHROMAZUROL METHOD))-FOR QUANTITATIVE DETERMINATION OF IRON IN HUMAN SERUM OR HEPARINIZED PLASMA.,SHEATH(ULTIMA 5 PART SHEATH) -FOR THE PURPOSE OF UNIFORM FLOW OF CELLS ,DILUENT-MDC (ULTIMA DILUENT - MDC)-DILUENT FOR MDC(AL SYSTEMEO) 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,COPPER(LIQUIZYME COPPER)-FOR THE QUANTITATIVE DETERMINATION OF COPPER IN SERUM . ,HDL CHOLESTEROL DIRECT REAGENT TEST KIT(LIQUIZYME DIRECT HDL CHOLESTEROL (PEGME METHOD))-FOR THE QUANTITATIVE DETERMINATION OF HDL CHOLESTEROL IN HUMAN SERUM OR PLASMA.,TOTAL BILE ACIDS(TOTAL BILE ACIDS SYSTEM PACK)-FOR QUANTITATIVE DETERMINATION OF TOTAL BILE ACIDS IN HUMAN SERUM OR PLASMA,LDH TEST KIT(LIQUIZYME LDH (L -> P KINETIC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF LDH IN HUMAN SERUM OR PLASMA.,FERRITIN (FERRITIN TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION FERRITIN HUMAN SERUM OR PLASMA. ,ACID PHOSPHATASE REAGENT(ACID PHOSPHATASE)-FOR QUANTITATIVE DETERMINATION OF ACID PHOSPHATASE (ACP) IN HUMAN SERUM.,ELECTROLYTE STANDARD A(ULTIMA ELECTROLYTE STANDARD A)-TO PROVIDE CALIBRATION POINT FOR NA+, K+, CA++, CL-, LI+,CRP TEST KIT(CRP LATEX (SLIDE AGGLUTINATION METHOD))-FOR THE QUALITATIVE DETERMINATION OF C-REACTIVE PROTEIN IN HUMAN SERUM.,LYSE-DIA(ULTIMA LYSE - DIA)-LYSE FOR DIATRON 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,LDL CHOLESTEROL TEST KIT(LDL CHOLESTEROL TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IN HUMAN SERUM OR PLASMA.,RINSE-URT(ULTIMA RINSE - URT)-RINSE FOR URIT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,ASO TEST KIT(ASO LATEX (SLIDE AGGLUTINATION METHOD))-FOR THE QUALITATIVE DETERMINATION OF ANTISTREPTOLYSIN -O ACTIVITY IN HUMAN SERUM.,STAINED SALMONELLA ANTIGEN S.PARATYPHI A(H)(STAINED SALMONELLA ANTIGEN S.PARATYPHI A(H) (WIDAL SLIDE & TUBE METHOD))-FOR THE DETECTION OF SALMONELLA TYPHI, PARA TYPHI ANTIBODIES IN HUMAN SERUM,GLUCOSE TEST KIT(GLUCOSE TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM AND PLASMA (PREFERABLY SODIUM FLUORIDE).,BENDICT'S QUALITATIVE

	REAGENT(BENDICT'S QUALITATIVE REAGENT)-TO DETECT THE PRESENCE OF REDUCING SUGAR.,ADENOSINE DEAMINASE TEST KIT (LIQUIZYME ADENOSINE DEAMINASE (PNP-XOD METHOD))-FOR THE QUANTITATIVE DETERMINATION OF ADENOSINE DEAMINASE(ADA) IN HUMAN SERUM,PLASMA, PLEURAL FLUID,CSF, PERICARDIAL FLUID AND ASCITIC FLUID.,HBA1C TEST KIT(HBA1C TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF HEMOGLOBIN A1C (HBA1C) IN HUMAN BLOOD.,AMMONIA TEST KIT(LIQUIZYME AMMONIA (KINETIC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF AMMONIA IN HUMAN PLASMA.,URITRACE-4P(URITRACE-4P)-FOR GLUCOSE, PROTEIN PH, SG ANALYSIS FROM URINE.,DILUENT - MR(ULTIMA DILUENT - MDR)-DILUENT FOR MINDRAY 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,RF TURBILATEX TEST KIT(RF TURBILATEX)-FOR THE QUANTITATIVE DETERMINATION OF RHEUMATOID FACTOR IN HUMAN SERUM.,HBA1C CALIBRATOR SET(HBA1C CALIBRATOR)-FOR THE PURPOSE OF CALIBRATING HBA1C TEST KIT IN SEMI AUTOMATED AND FULLY AUTOMATED BIOCHEMISTRY ANALYZER , ASO ANTIGEN(ASO LATEX ANTIGEN)-FOR THE QUALITATIVE DETERMINATION OF ANTISTREPTOLYSIN -O ACTIVITY IN HUMAN SERUM.,STAINED SALMONELLA ANTIGEN S.TYPHI 'O'(STAINED SALMONELLA ANTIGEN S.TYPHI 'O' (WIDAL SLIDE & TUBE METHOD))-FOR THE DETECTION OF SALMONELLA TYPHI, PARA TYPHI ANTIBODIES IN HUMAN SERUM,STAINED SALMONELLA ANTIGEN S. PARATYPHI B(O)(STAINED SALMONELLA ANTIGEN S.PARATYPHI B(O) (WIDAL SLIDE & TUBE METHOD))-FOR THE DETECTION OF SALMONELLA TYPHI, PARA TYPHI ANTIBODIES IN HUMAN SERUM, SODIUM TEST KIT(LIQUIZYME SODIUM (COLORIMETRIC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF SODIUM IN SERUM., LYSE-ERM(ULTIMA LYSE - ERM)-LYSE FOR ERMA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,ANTI S.PARATYPHI A(H)(ANTI S.PARATYPHI A(H))-TO VALIDATE THE SPECIFICITY OF THE SALMONELLA ANTIGEN,LDL CHOLESTEROL DIRECT REAGENT TEST KIT(LIQUIZYME DIRECT LDL CHOLESTEROL (DETERGENT METHOD))-FOR THE QUANTITATIVE DETERMINATION OF LDL CHOLESTEROL IN HUMAN SERUM OR PLASMA.,BRUCELLA ABORTUS ANTIGEN (PLAIN) (BRUCELLA ABORTUS ANTIGEN)-FOR QUALITATIVE DETERMINATION OF FEBRILE ANTIBODIES IN HUMAN SERUM.,GLUCOSE TEST KIT (LIQUIZYME GLUCOSE (GOD/POD METHOD))-FOR THE QUANTITATIVE DETERMINATION OF GLUCOSE IN HUMAN SERUM AND PLASMA (PREFERABLY SODIUM FLUORIDE).,CREATININE TEST KIT (CREATININE SYSTEM PACK (ENZYMATIC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM OR URINE.,STAINED SALMONELLA ANTIGEN S.PARATYPHI C(H) (STAINED SALMONELLA ANTIGEN S.PARATYPHI C(H) (WIDAL SLIDE &

	TUBE METHOD))-FOR THE DETECTION OF SALMONELLA TYPHI, PARA TYPHI ANTIBODIES IN HUMAN SERUM,LYSE-MR(ULTIMA LYSE - MDR)-LYSE FOR MINDRAY 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, DILUENT - HRB(ULTIMA DILUENT - HRB)-DILUENT FOR HORIBA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CLEANER-HRB(ULTIMA CLEANER- HRB)-CLEANER FOR HORIBA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,LYSE-SWL(ULTIMA LYSE - SWL)-LYSE FOR SWELAB 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,BONAVERA COUNT DILUENT(ULTIMA DILUENT BCT)-DILUENT FOR BONAVERA COUNT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,BOVINE ALBUMIN 20%, 22%,30 % SOLUTION(BOVINE ALBUMIN 20%, 22%,30 % SOLUTION)-QUALITATIVE PROCEDURE FOR ANTIGEN -ANTIBODIES INTERACTION ENHANCEMENT,CELL CLEANER-M60(ULTIMA CLEANER - M60)-CLEANER FOR ABX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,ANTI S.PARATYPHI B(O)(ANTI S.PARATYPHI B(O))-TO VALIDATE THE SPECIFICITY OF THE SALMONELLA ANTIGEN, IMMERSION OIL(IMMERSION OIL)-FOR MICROSCOPIC EXAMINATION OF PREPARED SAMPLES WITH AS MUCH DETAIL AS POSSIBLE., DILUENT-MED(ULTIMA DILUENT - MED)-DILUENT FOR MEDONIC 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,ADA CALIBRATOR(ADA CALIBRATOR)-FOR THE PURPOSE OF CALIBRATING LIQUIZYME ADENOSINE DEAMINASE KIT IN SEMI AUTOMATED AND FULLY AUTOMATED BIOCHEMISTRY ANALYZER,EZ-MR(ULTIMA EZ-MDR)-CLEANER FOR MINDRAY 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,LYSE-M60(ULTIMA LYSE - M60)-LYSE FOR ABX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,DILUENT-SWL(ULTIMA DILUENT - SWL)-DILUENT FOR SWELAB 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,DILUENT - SY(ULTIMA DILUENT - SYS)-DILUENT FOR SYSMEX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, AMYLASE KIT(LIQUIZYME AMYLASE (CNPG3 METHOD))-FOR THE QUANTITATIVE DETERMINATION OF ALPHA-AMYLASE IN HUMAN SERUM ,PLASMA AND URINE.,URITRACE-11P (URITRACE-11P)-FOR MICROALBUMIN, LEUCOCYTES, NITRITE, UROBILINOGEN,PROTEIN ,PH,BLOOD, SG,KETONE, BILIRUBIN, GLUCOSE ANALYSIS FROM URINE.,LYSE-NK(ULTIMA LYSE - NKH)-LYSE FOR NIHON KOHDEN 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CHOLESTEROL TEST KIT(CHOLESTEROL TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA.,CLEANER-URT(ULTIMA CLEANER - URT)-CLEANER FOR URIT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS, ALKALINE PHOSPHATASE (SINGLE) REAGENT TEST KIT(LIQUIZYME ALKALINE PHOSPHATASE SINGLE REAGENT (AMP OPTIMIZED IFCC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR PLASMA,LYSE-MED(ULTIMA

	LYSE - MED)-LYSE FOR MEDONIC 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,LYSE-URT(ULTIMA LYSE - URT)-LYSE FOR URIT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,LIPASE TEST KIT(LIQUIZYME LIPASE (METHYL RESORUFIN METHOD))-FOR THE QUANTITATIVE DETERMINATION OF LIPASE IN HUMAN SERUM OR PLASMA.,STAINED SALMONELLA ANTIGEN S.PARATYPHI B(H)(STAINED SALMONELLA ANTIGEN S.PARATYPHI B(H) (WIDAL SLIDE & TUBE METHOD))-FOR THE DETECTION OF SALMONELLA TYPHI, PARA TYPHI ANTIBODIES IN HUMAN SERUM,URITRACE- G(URITRACE- G)-FOR GLUCOSE ANALYSIS FROM URINE.,RINSE-ERM(ULTIMA RINSE- ERM)-RINSE FOR ERMA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CREATININE KIT (LIQUIZYME CREATININE (ALKALINE PICRATE METHOD))-FOR THE QUANTITATIVE DETERMINATION OF CREATININE IN HUMAN SERUM OR URINE.,SGOT TEST KIT(LIQUIZYME SGOT (IFCC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF AST/GOT (ASPARTATE AMINOTRANSFERASE) IN HUMAN SERUM.,TYPHOID (IGM/IGG) TEST KIT(TYPHOID (IGM/IGG))-FOR QUALITATIVE DETECTION AND DIFFERENTIATION OF IGG/IGM ANTIBODIES OF S.TYPHI AND S. PARATYPHI IN HUMAN SERUM OR PLASMA.,CHLORIDE TEST KIT (CHLORIDE TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF CHLORIDE IN SERUM.,TRIGLYCERIDES TEST KIT(LIQUIZYME TRIGLYCERIDES (GPO/POD METHOD))-FOR THE QUANTITATIVE DETERMINATION OF TRIGLYCERIDES IN HUMAN SERUM OR PLASMA., CHOLESTEROL TEST KIT(LYPHOZYME CHOLESTEROL (CHOD-POD METHOD))-FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA.,PROBE CLEANER-MR (ULTIMA PROBE CLEANER - MDR)-PROBE CLEANER FOR MINDRAY 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,LYSE-SY(ULTIMA LYSE - SYS)-LYSE FOR SYSMEX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,POTASSIUM TEST KIT(LIQUIZYME POTASSIUM (COLORIMETRIC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF POTASSIUM IN SERUM.,TOTAL PROTEIN TEST KIT(LIQUIZYME TOTAL PROTEIN (BIURET METHOD))-FOR THE QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN HUMAN SERUM OR PLASMA., DILUENT - M60(ULTIMA DILUENT - M60)-DILUENT FOR ABX 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CALCIUM KIT(LIQUIZYME CALCIUM (OCPC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF CALCIUM IN SERUM.,ANTI S.TYPHI H(ANTI S.TYPHI H)-TO VALIDATE THE SPECIFICITY OF THE SALMONELLA ANTIGEN,ANTI S. PARATYPHI C(O)(ANTI S.PARATYPHI C(O))-TO VALIDATE THE SPECIFICITY OF THE SALMONELLA ANTIGEN,DILUENT - NK(ULTIMA DILUENT - NKH)-DILUENT FOR NIHON KOHDEN 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,CELL CLEANER-SY(ULTIMA CLEANER - SYS)-CLEANER FOR SYSMEX 3-PART DIFFERENTIAL BLOOD CELL

	COUNTERS,DILUENT-DIA(ULTIMA DILUENT - DIA)-DILUENT FOR DIATRON 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,LYSE-HRB (ULTIMA LYSE - HRB)-LYSE FOR HORIBA 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,DILUENT(DILUENT)-DILUENT (FOR ALL 3-PART DIFFERENTIAL BLOOD CELL COUNTER) ,INORGANIC PHOSPHORUS TEST KIT(LIQUIZYME INORGANIC PHOSPHORUS (MOLYBDATE UV METHOD))-FOR THE QUANTITATIVE DETERMINATION OF PHOSPHOROUS IN HUMAN SERUM,PLASMA AND URINE.,INORGANIC PHOSPHORUS TEST KIT(INORGANIC PHOSPHORUS TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF PHOSPHOROUS IN HUMAN SERUM,PLASMA AND URINE., AMYLASE TEST KIT(LIQUIZYME AMYLASE (DIRECT SUBSTRATE METHOD))-FOR THE QUANTITATIVE DETERMINATION OF ALPHA-AMYLASE IN HUMAN SERUM ,PLASMA AND URINE.,STAINED SALMONELLA ANTIGEN S.PARATYPHI A(O)(STAINED SALMONELLA ANTIGEN S.PARATYPHI A(O) (WIDAL SLIDE & TUBE METHOD))-FOR THE DETECTION OF SALMONELLA TYPHI, PARA TYPHI ANTIBODIES IN HUMAN SERUM,LYSE(LYSE)-LYSE (FOR ALL 3-PART DIFFERENTIAL BLOOD CELL COUNTER) ,ALKALINE PHOSPHATASE TEST KIT (LIQUIZYME ALKALINE PHOSPHATASE (AMP OPTIMIZED IFCC METHOD))-FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR PLASMA,BONAVERA COUNT EZ (ULTIMA COUNT EZ)-CLEANER BONAVERA COUNT 3-PART DIFFERENTIAL BLOOD CELL COUNTERS,ANTI S.PARATYPHI A(O)(ANTI S.PARATYPHI A(O))-TO VALIDATE THE SPECIFICITY OF THE SALMONELLA ANTIGEN,ALKALINE PHOSPHATASE TEST KIT (ALKALINE PHOSPHATASE TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF ALKALINE PHOSPHATASE IN HUMAN SERUM OR PLASMA,MICROPROTEIN TEST KIT(LIQUIZYME MICROPROTEIN (PYROGALLOL RED METHOD))-FOR QUANTITATIVE DETERMINATION OF TOTAL PROTEIN IN URINE.,URITRACE-8P(URITRACE-8P)-FOR GLUCOSE,PROTEIN,PH,BLOOD ,KETONE,SG,BILIRUBIN,UROBILINOGEN ANALYSIS FROM URINE.,G.P.T TEST KIT(SGPT TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF ALT/GPT (ALANINE AMINOTRANSFERASE) IN HUMAN SERUM.,ANTI S.PARATYPHI B(H) (ANTI S.PARATYPHI B(H))-TO VALIDATE THE SPECIFICITY OF THE SALMONELLA ANTIGEN,UREA TEST KIT(UREA TEST KIT)-FOR THE QUANTITATIVE DETERMINATION OF UREA IN SERUM,PLASMA AND URINE.,LIQUIZYME UREA KIT(LIQUIZYME UREA (BERTHELOT METHOD))-FOR THE QUANTITATIVE DETERMINATION OF UREA IN SERUM,PLASMA AND URINE.,CHOLESTEROL TEST KIT(LIQUIZYME CHOLESTEROL (CHOD/POD METHOD))-FOR THE QUANTITATIVE DETERMINATION OF CHOLESTEROL IN HUMAN SERUM OR PLASMA., ANTI S.PARATYPHI C(H)(ANTI S.PARATYPHI C(H))-TO VALIDATE THE

	SPECIFICITY OF THE SALMONELLA ANTIGEN,VITAMIN D TSET KIT (BVITA-D)-QUALITATIVE DETERMINATION OF TOTAL 25-OH VITAMIN D IN HUMAN WHOLE BLOOD

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3379	MFG/MD/2020/000018	1.License Holder Name: RIBBEL INTERNATIONAL 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:CLOSED WOUND SUCTION UNIT(RIBBEL)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS., INTRAVENOUS CANNULA(RIBBEL I.V. CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,FOLEY CATHETEER (SILICONE)(ANGELTOUCH)-FOLEY CATHETER IS USED TO TREAT URINE PROBLEMS. A FOLEY CATHETER IS A THIN STERILE TUBE INSERTED INTO THE BLADDER TO DRAIN URINE.,SPINAL NEEDLES (RIBBEL SPINAL NEEDLE)-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM.,LEVIN'S TUBE(RIBBEL)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,URINARY DRAINAGE UNIT(RIBBEL URINE BAG)-A CLOSED URINARY DRAINAGE SYSTEM CONSISTS OF A CATHETER INSERTED INTO THE URINARY BLADDER AND CONNECTED VIA TUBING TO A DRAINAGE BAG. ,FLOW REGULATOR LINE(RIBBEL)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY., FOLEY CATHETEER(SILICONE)(RIBBEL FOLEY CATHETER)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,PRESSURE MONITORING LINE (RIBBEL)-USED FOR MULTIPURPOSE EXTENSION LINE SUITABLE FOR ANGIOGRAPHY, ARTERIOGRAPHY, C.V.P. MEASUREMENT ETC.,I.V. SET (PERFUSION SET)(RIBBEL I.V. SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,SUCTION CATHETER (RIBBEL)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING. ,MEASURED VOLUME IV SET(RIBBEL MV SET)-:IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STOMACH TUBE (RIBBEL)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID. ,BLOOD TRANSFUSION SET (TRANSFUSION SET)(RIBBEL B.T.SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,THREE -

	WAY EXTENSION LINE (RIBBEL)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,NEEDLE FREE CONNECTORS (RIBBEL)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. , MUCUS EXTRACTOR(RIBBEL)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION. ,AV FISTULA NEEDLE(RIBBEL)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT.,YANKUR SUCTION HANDLE (RIBBEL)-YANKUR USED TO CLEAR OPERATIVE SITES DURING SURGICAL PROCEDURES AND ITS SUCTIONED VOLUME COUNTED AS BLOOD LOSS DURING SURGERY. ,TRACHEOSTOMY TUBE (RIBBEL)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,FOLEY CATHETER(SILKY GOLD)- FOLEY CATHETER IS USED TO TREAT URINE PROBLEMS. A FOLEY CATHETER IS A THIN, STERILE TUBE INSERTED INTO THE BLADDER TO DRAIN URINE. ,ENDOTRACHEAL TUBE(RIBBEL)-INSERTS THE TUBE WITH THE HELP OF ALARYNGOSCOPE, AN INSTRUMENT TTHAT PERMITS TO SEE THE UPPER PORTION OF THEN TRACHEA, JUST BELOW THE VOCAL CORDS. ,INFANT FEEDING TUBE (RIBBEL)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,NELATON CATHETER (RIBBEL)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST PRIORLY VIA THE KIDNEY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3380	MFG/MD/2020/000019	1.License Holder Name: LARS MEDICARE PVT LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:INFUSION SET WITH Y SITE(ROMED HOLLAND)-INTRAVENOUS INFUSION SETS ARE INTENDED FOR ADMINISTRATION OF INTRAVENOUS FLUIDS/LIQUIDS AND/OR DRUGS/MEDICINE INTO HUMAN CIRCULATORY SYSTEM WHEN AN EXTENDED PATH IS REQUIRED FOR ADMINISTRATION. INFUSION SETS ARE SINGLE USE, STERILE DEVICES USED TO ADMINISTER. THEY ARE USED IN BETWEEN CONTAINERS OF INFUSION SOLUTION & INTRAVENOUS EQUIPMENT.,THREE WAY STOPCOCK(MEDWAY,ROBINETE,TROJCESTNY)-3-WAY STOPCOCKS ARE INTENDED FOR DISPOSABLE USE FOR CONNECTION OF ONE OR TWO INFUSION OR TRANSFUSION SETS WITH INTRAVENOUS NEEDLE, FOR CONNECTION OF TWO BLOOD CONSERVES OR FOR CONNECTION OF TWO DIFFERENT SETS TERMINATED WITH NEGATIVE CONNECTOR AND GRADUAL CONNECTOR. TERMINATION OF THE TUBE ON BOTH ENDS WITH LUER LOCK CONNECTORS ALLOWS SAFE CONNECTION TO STANDARD SYRINGE FOR INEAR DOSER AND TO INTRAVENOUS OR INTRA-ARTERIAL CATHETER. THE 3-WAY STOPCOCK IS TO PROVIDE AN ALTERNATIVE CHANNEL FOR INTRODUCTION OF MEDICINE TO THE PATIENT.,TWIN BORE NASAL CATHETER-A NASAL OXYGEN CATHETER IS A DEVICE INTENDED TO BE INSERTED THROUGH A PATIENT'S NOSTRIL TO ADMINISTER OXYGEN, INTRAVENOUS INFUSION SETS(ELEKTRO,HB,MED VEIN SET,ROMED HOLLAND)-INTRAVENOUS INFUSION SETS ARE INTENDED FOR ADMINISTRATION OF INTRAVENOUS FLUIDS/LIQUIDS AND/OR DRUGS/MEDICINE INTO HUMAN CIRCULATORY SYSTEM WHEN AN EXTENDED PATH IS REQUIRED FOR ADMINISTRATION. INFUSION SETS ARE SINGLE USE, STERILE DEVICES USED TO ADMINISTER. THEY ARE USED IN BETWEEN CONTAINERS OF INFUSION SOLUTION & INTRAVENOUS EQUIPMENT. ,I.V.CANNULA (TRIDENT,MEDIVAC, CANOCARE,FERMEDIES,LYDIAFLON PRO)-I.V.CANNULA IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND/OR WITHDRAWAL OF BLOOD SAMPLES,BLOOD TRANSFUSION SET(ELEKTRO,HB)-BLOOD TRANSFUSION SETS ARE INTENDED FOR TRANSFUSION OF BLOOD AND BLOOD COMPONNETS. BLOOD IS TRANSFUSED EITHER AS WHOLE BLOOD (WITH ALL ITS PARTS) OR, MORE OFTEN, AS INDIVIDUAL PARTS. THE INDIVIDUAL PARTS INCLUDE RED BLOOD CELLS, PLATELETS, CLOTTING FACTORS, AND PLASMA. BLOOD TRANSFUSION SETS ARE USED IN BETWEEN CONTAINERS OF BLOOD AND BLOOD COMPONENTS AND INTRAVENOUS EQUIPMENT., INTRAVENOUS INFUSION SET(TRIPLE-D,EPIC HEIGHT)-INTENDED USE INTRAVENOUS INFUSION SETS ARE INTENDED FOR ADMINISTRATION

	OF INTRAVENOUS FLUIDS/LIQUIDS AND/OR DRUGS/MEDICINE INTO HUMAN CIRCULATORY SYSTEM WHEN AN EXTENDED PATH IS REQUIRED FOR ADMINISTRATION. INFUSION SETS ARE SINGLE USE, STERILE DEVICES USED TO ADMINISTER. THEY ARE USED IN BETWEEN CONTAINERS OF INFUSION SOLUTION & INTRAVENOUS EQUIPMENT. ,A.V. FISTULA NEEDLE(PROFIST)-A.V FISTULA(ARTERIAL VENOUS FISTULA) SET IS A PART DIALYSIS EQUIPMENT. THEY ARE SINGLE USE, STERILE DEVICES INTENDED TO SERVE AS A CONDUIT FOR BLOOD BETWEEN BLOOD VESSEL OF THE PATIENT AND THE DIALYSIS FILTER. THE DEVICES COMPRISES AN ULTRA SHARP HOLLOW NEEDLE. WHICH IS MOUNTED ON A HUB THAT PASSES INTO A SMOOTH KINK RESISTANT TUBE. AT THE OTHER END OF THE TUBE THERE IS A UNIVERSAL FEMALE LUER THAT IS USED TO CONNECT DEVICE WITH THE OTHER PART OF THE DIALYSIS.,NEBULIZER MASK-IS A DEVICE THAT IS USE FOR BREATHING TREATMENTS.IT CHANGES LIQUID MEDICINE INTO A MIST. THIS MIST GOES INTO THE PATIENT'S LUNGS WHEN INHALED (BREATHED IN),SPINAL NEEDLE(GENERIC NAME)-SPINAL PUNCTURE AND INJECTION OF LIQUID DRUGS INTO THE SUBARACHNOID SPACE,3-WAY STOP COCK(ROMED)-3-WAY STOPCOCKS ARE INTENDED FOR DISPOSABLE USE FOR CONNECTION OF ONE OR TWO INFUSION OR TRANSFUSION SETS WITH INTRAVENOUS NEEDLE, FOR CONNECTION OF TWO BLOOD CONSERVES OR FOR CONNECTION OF TWO DIFFERENT SETS TERMINATED WITH NEGATIVE CONNECTOR AND GRADUAL CONNECTOR,MEASURED VOLUME SETS(GENERIC NAME)-MEASURED VOLUME INFUSION SETS ARE SINGLE USE, STERILE DEVICES WITH A CYLINDRICAL GRADUATED CONTAINER CALLED BURETTE USED TO ADMINISTER MEASURED VOLUME OF INTRAVENOUS FLUIDS/LIQUIDS AND/OR DRUGS/MEDICINE INTO HUMAN CIRCULATORY SYSTEM. THE BURETTE IS USED TO PREPARE COCKTAILS OF DRUGS AND PHYSIOLOGICAL LIQUIDS FOR INFUSION. IT CAN ALSO BE USED FOR ENTERAL OR PARENTERAL FEEDINGS ESPECIALLY IN PEDIATRIC WARD. IT IS USED IN BETWEEN CONTAINERS OF INFUSION SOLUTION & INTRAVENOUS EQUIPMENT. ,EXTENSION TUBE(TRIPLE-D)-EXTENSION TUBES ARE INTENDED FOR DISPOSABLE USE FOR CONNECTION OF ONE OR TWO INFUSION OR TRANSFUSION SETS WITH INTRAVENOUS NEEDLE, FOR CONNECTION OF TWO BLOOD CONSERVES OR FOR CONNECTION OF TWO DIFFERENT SETS TERMINATED WITH NEGATIVE CONNECTOR AND GRADUAL CONNECTOR. THEY ARE ALSO USED AS UNIVERSAL TUBES FOR LABORATORY AND CLINICAL PRACTICE.,EXTENSION TUBE(MEDEXT)-EXTENSION TUBES ARE INTENDED FOR DISPOSABLE USE FOR CONNECTION OF ONE OR TWO INFUSION OR TRANSFUSION SETS WITH INTRAVENOUS NEEDLE, FOR CONNECTION OF TWO BLOOD

	CONSERVES OR FOR CONNECTION OF TWO DIFFERENT SETS TERMINATED WITH NEGATIVE CONNECTOR AND GRADUAL CONNECTOR. THEY ARE ALSO USED AS UNIVERSAL TUBES FOR LABORATORY AND CLINICAL PRACTICE.,3WAY STOPCOCK(TRIPLE-D) -3-WAY STOPCOCKS ARE INTENDED FOR DISPOSABLE USE FOR CONNECTION OF ONE OR TWO INFUSION OR TRANSFUSION SETS WITH INTRAVENOUS NEEDLE, FOR CONNECTION OF TWO BLOOD CONSERVES OR FOR CONNECTION OF TWO DIFFERENT SETS TERMINATED WITH NEGATIVE CONNECTOR AND GRADUAL CONNECTOR. TERMINATION OF THE TUBE ON BOTH ENDS WITH LUER LOCK CONNECTORS ALLOWS SAFE CONNECTION TO STANDARD SYRINGE FOR INEAR DOSER AND TO INTRAVENOUS OR INTRA-ARTERIAL CATHETER. ,I..V .FLOW REGULATOR(GENERIC NAME)-I.V. FLOWREGULATOR ARE ITHER PART OF I.V.TUBING OR ADDED ON. THESE ARE DEVICES DESIGNED TO REGULATE THE FLOW OF LIQUID MANUAL INSTEAD OF USING THE ROLLER CLAMP ON THE I.V.TUBING., MEASURED VOLUME SET(TRIPLE-D)-MEASURED VOLUME INFUSION SETS ARE SINGLE USE, STERILE DEVICES WITH A CYLINDRICAL GRADUATED CONTAINER CALLED BURETTE USED TO ADMINISTER MEASURED VOLUME OF INTRAVENOUS FLUIDS/LIQUIDS AND/OR DRUGS/MEDICINE INTO HUMAN CIRCULATORY SYSTEM. THE BURETTE IS USED TO PREPARE COCKTAILS OF DRUGS AND PHYSIOLOGICAL LIQUIDS FOR INFUSION. IT CAN ALSO BE USED FOR ENTERAL OR PARENTERAL FEEDINGS ESPECIALLY IN PEDIATRIC WARD. IT IS USED IN BETWEEN CONTAINERS OF INFUSION SOLUTION & INTRAVENOUS EQUIPMENT. ,THREE WAY STOPCOCK(GENERIC NAME,PROWAY,SKY-CATH,NOKAST,NOVACATH,DEXAL,LIFEN,SENSI MEDICAL,FESCO,CUSTOMMED,HINIKO,LIFEMED,PRINTEX)-3-WAY STOPCOCKS ARE INTENDED FOR DISPOSABLE USE FOR CONNECTION OF ONE OR TWO INFUSION OR TRANSFUSION SETS WITH INTRAVENOUS NEEDLE, FOR CONNECTION OF TWO BLOOD CONSERVES OR FOR CONNECTION OF TWO DIFFERENT SETS TERMINATED WITH NEGATIVE CONNECTOR AND GRADUAL CONNECTOR. TERMINATION OF THE TUBE ON BOTH ENDS WITH LUER LOCK CONNECTORS ALLOWS SAFE CONNECTION TO STANDARD SYRINGE FOR LINEAR DOSER AND TO INTRAVENOUS OR INTRA-ARTERIAL CATHETER. THE 3-WAY STOPCOCK IS TO PROVIDE AN ALTERNATIVE CHANNEL FOR INTRODUCTION OF MEDICINE TO THE PATIENT.,I.V.CANNULA(ADVA SAFE,B-CAT 2,B-CAT,B-CAT(SAFETY IV CANNULA)FUA UCGE MEDICAL,CAN CARE SAFE ,GEZIRA)-INTENDED USE OF I.V. CANNULA : THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES . I.V. CANNULA COMPRISES OF A SHORT FLEXIBLE

	PLASTIC TUBE (THE CATHETER), WHICH IS INSERTED INTO A VEIN OVER A HOLLOW INTRODUCER NEEDLE, AFTER WHICH THE NEEDLE IS WITHDRAWN FROM VEIN AND TUBE REMAINS INSERTED IN TO HUMAN CIRCULATORY SYSTEM.,BLOOD TRANSFUSION SETS (GENERIC NAME)-BLOOD TRANSFUSION SETS ARE INTENDED FOR TRANSFUSION OF BLOOD AND BLOOD COMPONNETS. BLOOD IS TRANSFUSED EITHER AS WHOLE BLOOD (WITH ALL ITS PARTS) OR, MORE OFTEN, AS INDIVIDUAL PARTS. THE INDIVIDUAL PARTS INCLUDE RED BLOOD CELLS, PLATELETS, CLOTTING FACTORS, AND PLASMA. BLOOD TRANSFUSION SETS ARE USED IN BETWEEN CONTAINERS OF BLOOD AND BLOOD COMPONENTS AND INTRAVENOUS EQUIPMENT.,BLOOD ADMINISTRATION SET(ROMED HOLLAND)-BLOOD TRANSFUSION SETS ARE INTENDED FOR TRANSFUSION OF BLOOD AND BLOOD COMPONENTS. BLOOD IS TRANSFUSED EITHER AS WHOLE BLOOD (WITH ALL ITS PARTS) OR, MORE OFTEN, AS INDIVIDUAL PARTS. THE INDIVIDUAL PARTS INCLUDE RED BLOOD CELLS, PLATELETS, CLOTTING FACTORS, AND PLASMA. BLOOD TRANSFUSION SETS ARE USED IN BETWEEN CONTAINERS OF BLOOD AND BLOOD COMPONENTS AND INTRAVENOUS EQUIPMENT,THREE WAY WITH EXTENSION TUBE (MEDWAYEXT)-EXTENSION TUBES ARE INTENDED FOR DISPOSABLE USE FOR CONNECTION OF ONE OR TWO INFUSION OR TRANSFUSION SETS WITH INTRAVENOUS NEEDLE, FOR CONNECTION OF TWO BLOOD CONSERVES OR FOR CONNECTION OF TWO DIFFERENT SETS TERMINATED WITH NEGATIVE CONNECTOR AND GRADUAL CONNECTOR. THEY ARE ALSO USED AS UNIVERSAL TUBES FOR LABORATORY AND CLINICAL PRACTICE.,HYPODERMIC SYRINGES WITH NEEDLE(--)-THE DISPOSABLE SYRINGE IS MAINLY APPLIED TO CLINICAL INTRAMUSCULAR INJECTION, BLOOD DRAWING AND LIQUID COMPOUNDING IN MEDICAL INSTITUTIONS.,I.V.CANNULA (SAFE-CATH,SAFE-INJECT,ELEFLON,HB,MEDVEIN,TEFLO,VET VEIN ALPHA, VET VEIN FLASH,VET VEIN SAFE ALPHA,ROMED (SAFETY I.V CATHETER),ROMED HOLLAND (I.V CATHETER),NEOTEF,KARDIOLINE, NEOJET PLUS,TOPSN,TEEBA,HEALTHEASE(I.V.CATHETER))-I.V. CANNULA IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND/OR WITHDRAWAL OF BLOOD SAMPLES,THREE WAY WITH EXTENSION TUB(LENFLOW)-EXTENSION TUBES ARE INTENDED FOR DISPOSABLE USE FOR CONNECTION OF ONE OR TWO INFUSION OR TRANSFUSION SETS WITH INTRAVENOUS NEEDLE, FOR CONNECTION OF TWO BLOOD CONSERVES OR FOR CONNECTION OF TWO DIFFERENT SETS TERMINATED WITH NEGATIVE CONNECTOR AND GRADUAL CONNECTOR.,INTRAVENOUS INFUSION SETS (GENERIC NAME)-INTRAVENOUS INFUSION SETS ARE INTENDED FOR ADMINISTRATION

		OF INTRAVENOUS FLUIDS/LIQUIDS AND/OR DRUGS/MEDICINE INTO HUMAN CIRCULATORY SYSTEM WHEN AN EXTENDED PATH IS REQUIRED FOR ADMINISTRATION. INFUSION SETS ARE SINGLE USE, STERILE DEVICES USED TO ADMINISTER. THEY ARE USED IN BETWEEN CONTAINERS OF INFUSION SOLUTION & INTRAVENOUS EQUIPMENT. ,OXYGEN MASK (-)-FOR OXYGEN SUPPLY TO THE PATIENTS,THREE WAY WITH EXTENSION TUBE(PROWAYEXT,FESCO, PRINTEX)-EXTENSION TUBES ARE INTENDED FOR DISPOSABLE USE FOR CONNECTION OF ONE OR TWO INFUSION OR TRANSFUSION SETS WITH INTRAVENOUS NEEDLE, FOR CONNECTION OF TWO BLOOD CONSERVES OR FOR CONNECTION OF TWO DIFFERENT SETS TERMINATED WITH NEGATIVE CONNECTOR AND GRADUAL CONNECTOR. THEY ARE ALSO USED AS UNIVERSAL TUBES FOR LABORATORY AND CLINICAL PRACTICE.,I.V.CANNULA(PROVEIN, PROVEIN ALPHA,PROVEIN BETA,PROVEIN NEO,PROPEN,BIOVALVE SAFE,BEROCAN,KNOW-VEN,VYGONULE V,B.P.CANNULA,PROVEIN SAFE,PROVEIN SAFE ALPHA,PROVEIN SAFE BETA,CAN-CARE,UBI-ONE (SAFETY),UBI-ONE,CUSTOMMED,NOVACATH,BERICA,BP SAFETY, DISPOTUCH,CAPVEIN,ANGELTOUCH,ANGELTOUCH,DEXAL, SENSIMEDICAL,FESCO,LAVET,LAVITA,SUMITEX,I.V.CATHETER, NOKAST,KILANI,SYNEFLON,TKL,U-MEC,SKY-CATH,HINIKO,LIFEMED, EASYCAN,LIFEN,NEOJET,BIOVEIN,SUNNY,FIXOFLON,I.V.CANNULA (GENERIC NAME))-I.V.CANNULA IS A DEVICE FOR ACCESS TO THE HUMAN CIRCULATORY SYSTEM FOR INTRODUCTION OF FLUIDS OR MEDICAMENT AND/OR WITHDRAWAL OF BLOOD SAMPLES, EXTENSION TUBE(PROEXT)-EXTENSION TUBES ARE INTENDED FOR DISPOSABLE USE FOR CONNECTION OF ONE OR TWO INFUSION OR TRANSFUSION SETS WITH INTRAVENOUS NEEDLE, FOR CONNECTION OF TWO BLOOD CONSERVES OR FOR CONNECTION OF TWO DIFFERENT SETS TERMINATED WITH NEGATIVE CONNECTOR AND GRADUAL CONNECTOR. THEY ARE ALSO USED AS UNIVERSAL TUBES FOR LABORATORY AND CLINICAL PRACTICE.
3381	MFG/MD/2020/000020	1.License Holder Name: DELITE SURGICAL 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655(SARGEN)-TRANSFUSION SET IS USED TO ADMINISTER INTEND TO INJECT FLUID INTO OR WITHDRAW FLUID FROM THE BODY.

3382	MFG/MD/2020/000021	1.License Holder Name: SPECTRUM MEDTECH PVT. LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:BLOOD COLLECTING NEEDLE(ACCURATE)-EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION VENOUS BLOOD.
3383	MFG/MD/2020/000022	1.License Holder Name: ADITYA SURGICAL COTTON 2.Approving Authority: AMRAVATI DIVISION 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.(ADITYA SURGICAL COTTON)-USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC
3384	MFG/MD/2020/000023	1.License Holder Name: UP PHARMACEUTICALS 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPODERMIC SYRINGE WITH NEEDLE BIS 10258 (ONE PRICK)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY, DISPOSABLE HYPODERMIC SYRINGE WITH NEEDLE BIS 10258(ONE-PRICK)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,DISPOSABLE HYPODERMIC SYRINGE BIS 10258(- - -)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,DISPOSABLE HYPODERMIC SYRINGE WITH NEEDLE BIS 10258 (NIL, ONE-PRICK, ONE-SYRIN)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,DISPOSABLE HYPODERMIC SYRINGE WITH NEEDLE BIS 10258(- - -)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,DISPOSABLE HYPODERMIC SYRINGE WITH NEEDLE BIS 10258(ONE-SYRIN)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY, DISPOSABLE HYPODERMIC SYRINGE WITH NEEDLE BIS 10258 (AMEGHAJECT)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,DISPOSABLE HYPODERMIC SYRINGE BIS 10258(NIL, ONE-PRICK, ONE-SYRIN)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,DISPOSABLE HYPODERMIC SYRINGE BIS 10258(AMEGHAJECT)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY

3385	MFG/MD/2020/000024	1.License Holder Name: VITROMED HEALTHCARE 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:ESOPHAGEAL OBTURATOR (GUEDEL AIRWAYS) (GUEDEL AIRWAYS)-THE PRODUCT IS USED TO MAINTAIN AN UNOBSTRUCTED OROPHARYNGEAL AIRWAY AND IT PREVENTS BITING OF TONGUE AND AIRWAY OCCLUSION,TRANFUSION SET FOR SINGLE USE (BLOOD TRANSFUSION SET WITH / WITHOUT AIRVENT(IS 9824-3, ISO 1135-4)(-)-TRANSFUSION SET IS USED ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,UMBILICAL CORD CLAMP (UMBILICAL OCCLUSION DEVICE)(VASO CLAMP (UMBILICAL CORD CLAMP))-UMBILICAL CORD CLAMP IS A STERILE OCCLUSION DEVICE (CLIP) DESIGN TO COMPRESS THE UMBILICAL CORD. THE DEVICE IS USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEW BORN INFANTS,INFUSION SET FOR SINGLE USE (WITH AIRVENT/ NON-VENT & AUTOSHUT VALVE) (IS12655-4. ISO 8536-4)(-)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., DIALYSATE TUBING AND CONNECTOR (PERITONEAL DIALYSIS TRANSFUSION SET)(PERITONEAL DIALYSIS TRANSFUSION SET)-A TUBING CONNECTOR ADAPTED FOR PERITONEAL DIALYSIS CONNECTIONS BETWEEN TUBING SETS AND CONTAINERS OF DIALYSATE. THE DEVICE IS USED TO ALLOW SOLUTION TO FLOW INTO AND OUT OF THE PERITONEAL CAVITY. WHEN THE DIALYSIS SOLUTION IS IN THE PERITONEAL CAVITY, IT WILL REMOVE EXTRA FLUID AND WASTE PRODUCTS FROM THE BODY. PERITONEAL DIALYSIS WILL REPLACE THE LIFE SUSTAINING FUNCTION OF YOUR KIDNEYS THAT ARE NO LONGER WORKING. IN THIS METHOD BLOOD IS PURIFIED USING THE ARTIFICIAL KIDNEY APPARATUS VIA FILTRATION THROUGH AN ARTIFICIAL SEMI PERMEABLE MEMBRANE, NEBULIZER MASK(-)-IT IS USED FOR THE DEEP MEDICATION INTO THE LUNGS WHEN PATIENT IS SUFFERING FROM ASTHMA OR OTHER LUNGS RELATED PROBLEMS AND DRUG DELIVERY DEVICE USED TO ADMINISTER MEDICATION IN THE FORM OF A MIST INHALED INTO THE LUNGS.,YANKAUR SUCTION SET(UNI'VAC (YANKAUR SUCTION SET))-YANKAUR SUCTION SET IS A SURGICAL DRAIN TUBE USED TO REMOVE PUS , BLOOD OR OTHER FLUIDS FROM A WOUND .IT IS COMMONLY PLACED BY SURGEONS AND USED FOR PRE /POST OPERATIVE REMOVAL OF SECRETION, BLOOD & POSTOPERATIVE FLUIDS AFTER SURGERY ,INFUSION SET FOR SINGLE USE (WITH OR WITHOUT AIRVENT) (IS 12655-4. ISO 8536-4)(-)-INFUSION SET IS USED ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,

	YANKAUR SUCTION SET (SUCTION TUBE (FOR WASTE FLUID))-YANKAUR SUCTION SET (SUCTION TUBE) IS A SURGICAL DRAIN, USED TO REMOVE PUS, BLOOD OR OTHERS FLUID FROM WOUND. IT IS COMMONLY PLACED BY SURGEONS AND USED FOR PRE/ POST OPERATIVE REMOVAL OF SECRETION, BLOOD AND POSTOPERATIVE FLUID AFTER SURGERY.,INFUSION SET FOR SINGLE USE (WITH FILTER STOP) (IS 12655-4. ISO 8536-4)(-)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,FISTULA NEEDLE (AV FISTULA NEEDLE IS A STERILE)(FISTULA NEEDLE (AV FISTULA NEEDLE IS A STERILE))-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT .THE PRODUCT IS USED TO DELIVER BLOOD INTO HUMAN CIRCULATING SYSTEM. FISTULA NEEDLE IS USED TO CONNECT BLOOD LINES TO THE BLOOD VESSEL THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT VIA AN INTERNAL FISTULA. ,INFUSION SET FOR SINGLE USE (MICRO INFUSION SET) [IS 12655-4] [ISO 8536-4](MICRO INFUSION SET WITH/ WITHOUT AIRVENT)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,VIRAL TRANSPORT KIT (VIRAL TRANSPORT MEDIUM & SWAB STICK)(NIL)-TO COLLECT AND TRANSPORT CLINICAL SAMPLES OF VIRUSES IN AN ACTIVE FORM TO THE LABORATORY FOR ISOLATION, MAINTAINING THE VIABILITY AND VIRULENCE OF THE VIRAL SAMPLES.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I. V. CANNULA WITHOUT INJECTION PORT & WINGS(VITROON)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,YANKAUR SUCTION SET (YANKAUR HANDLE)(YANKAUR HANDLE (STANDARD / CROWN TIP))-YANKAUR SUCTION SET (YANKAUR HANDLE) IS A SURGICAL DRAIN, USED TO REMOVE PUS, BLOOD OR OTHERS FLUID FROM WOUND. IT IS COMMONLY PLACED BY SURGEONS AND USED FOR PRE/ POST OPERATIVE REMOVAL OF SECRETION, BLOOD AND POSTOPERATIVE FLUID AFTER SURGERY., ABDOMINAL DRAINAGE SET(ABDOMINAL DRAINAGE SET)-IT IS A SURGICAL DRAIN USED TO DRAIN OUT AND COLLECT FLUID FROM A SPACE OF THE BODY. A CUT IS MADE IN THE SKIN AND THE CATHETER IS PASSED THROUGH INTO THE SPACE TO ALLOW THE FLUID TO FLOW OUT INTO COLLECTION BAG.,FEEDING BAG (FEEDING BAG)-THE FEEDING BAG IS USED TO FOR CONVENIENT FEEDING OF NUTRITION THROUGH NASO-GASTRIC TUBE TO THE PATIENT. , STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] (I. V. CANNULA WITHOUT PORT & WITHOUT WINGS)(VITROPEN)-

	THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,STERILE SINGLE USE INTRAMUSCULAR CATHETERS (ISO 10555-1 & 5) SAFETY I.V CANNULA WITH DEHP FREE EXTENSION TUBE AND WING(SAFETY I.V CANNULA WITH DEHP FREE EXTENSION TUBE AND WING (CLOSED SYSTEM IV CATHETER WITH WING)))-SAFETY I.V CANNULA WITH PU EXTENSION TUBE AND WING WITH SAFETY FEATURE USE INJECTION FOR ADMINISTRATION OF INTRAVENOUS FLUID , WITHDRAWAL OF BLOOD SAMPLES AND TO DELIVER INTRAVENOUS FLUID AND MEDICINE INTO HUMAN CIRCULATING SYSTEM , THE PRODUCT HAS INTEGRATED PASSIVE SAFETY FEATURE TO COVER THE NEEDLE AFTER USE TO PREVENT THE ACCIDENTAL NEEDLE PRICK INJURIES .,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] SAFETY I. V. CANNULA WITH PTFE CATHETER AND INJECTION PORT (VITRO-SAFE)-SAFETY IV CANNULA IS USED TO PROVIDE ACCESS IN TO THE PERIPHERAL VASCULAR SYSTEM FOR THE ADMINISTRATION OF FLUIDS AND DRUGS AND FOR WITHDRAWAL OF BLOOD. THE PRODUCT HAS INTEGRATED PASSIVE SAFETY FEATURES TO COVER THE NEEDLE AFTER USE TO PREVENT THE ACCIDENTAL NEEDLE PRICK INJURIES.,MULTI-LUMEN CATHETER (CVP MANOMETER) (CVP MANOMETER)-:IT IS USED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTIONS OR DRUGS.,INFUSION SET FOR SINGLE USE (BURETTE TYPE) [IS 12655-4] [ISO 8536-4&5] (BURETTE SET (MEASURED VOLUME FLUID ADMINISTRATION SET))-INFUSION SET BURETTE TYPE IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,FLOW REGULATOR AS A ACCESSORIES OF INFUSION SET (I V FLOW REGULATOR) (FLOW REGULATOR AS A ACCESSORIES OF INFUSION SET)-FLOW REGULATOR IS USED TO DELIVER ACCURATE VOLUME OF IV FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM.AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. , EXTENSION LINE AS AN ACCESSORY OF INFUSION SET [ISO 8536-9] (EXTENSION LINE AS AN ACCESSORY OF INFUSION SET)-THESE ARE STERILE SINGLE USE DEVICES INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION. CAN BE USED TO CONNECT A PERFUSION SET OR CATHETER FOR INFUSION. USED TO CONNECT THE INFUSION SITE AND THE SOURCE OF INFUSION (I.E. TO CONNECT THE IV CANNULA OR THREE WAY STOP COCK AND IV SET) TO EXTENDED THE PATH BETWEEN INFUSION SITE & SOURCE OF INFUSION.,CONTENTIOUS

	IRRIGATION CATHETER (IRRIGATION SET ONE WAY / TWO WAY / FOUR WAY)-IRRIGATION SET USED TO INTRODUCE FLUID INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS.,A V FISTULA NEEDLE(A V FISTULA NEEDLE)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT.,THREEWAY STOP COCK WITH EXTENSION LINE AS AN ACCESSORIES OF IV CANNULA / CATHETER / PERFUSION SET (THREEWAY STOP COCK WITH EXTENSION LINE AS AN ACCESSORIES OF IV CANNULA / CATHETER / PERFUSION SET)-THE PRODUCT IS USED TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM. THE THREE WAY STOP COCK WITH EXTENSION LINE IS DESIGNED TO PROVIDE ACCESS INTO THE INFUSION OF FLUID / MEDICATION IN THE MEDICAL APPLICATION. THREE WAY IS A INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL. ,RYLES TUBE (NASOGASTRIC TUBE)(RYLES TUBE)-IT IS A NASO-GASTRIC TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT MAY ALSO BE USED FOR ASPIRATION OF INTESTINAL SECRETIONS.,STERILE IV CANNULA WITH WINGS AND INJECTION PORT(P & Q DISPOSABLE IV CANNULA WITH WING AND INJECTION PORT)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,STERILE PERFUSION SET FOR SINGLE USE (STERILE INFUSION SET GRAVITY FEED)(P & Q INFUSION SET WITHOUT AIR-VENT)-INFUSION SET IS USED ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,CLOSED WOUND DRAINAGE SET(VITROVAC (CLOSED WOUND SUCTION UNIT))-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,INFANT FEEDING TUBE(INFANT FEEDING TUBE)-INFANT FEEDING TUBE IS USED TO PROVIDE FEEDING TO NEONATES AND INFANTS. IT IS A SMALL, SOFT, PLASTIC TUBE PLACED THROUGH THE NOSE OR MOUTH INTO THE STOMACH.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I. V. CANNULA WITHOUT INJECTION PORT & WINGS(VITROWIN)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,YANKAUR SUCTION SET(YANKAUR SUCTION SET)-YANKAUR SUCTION SET IS A SURGICAL DRAIN TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. IT IS COMMONLY PLACED BY SURGEONS AND USED FOR PRE/POST

	OPERATIVE REMOVAL OF SECRETION, BLOOD & POSTOPERATIVE FLUIDS AFTER SURGERY. ",NELATON CATHETERS (URETHRAL) (NELATON CATHETERS)-NELATON CATHETER IS USED TO PROVIDE ACCESS TO THE BLADDER THROUGH URETHRA IN CASE OF URINARY RETENTION ESPECIALLY IN MALES. THE NELATON CATHETER HAS NO BALLOON ON ITS TIP.,CLOSED WOUND DRAINAGE SET(CLOSED WOUND SUCTION UNIT)-IT IS SURGICAL DRAIN USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. CLOSED WOUND SUCTION UNIT IS USED IN SURGICAL SPECIALTIES MANY OF WHICH EMPLOY NEGATIVE PRESSURE WOUND THERAPY TO VARYING DEGREES AGAINST CHALLENGING WOUNDS.,HIGH PRESSURE VACUUM DRAINAGE BOTTLE(HIGH PRESSURE VACUUM DRAINAGE BOTTLE)-HIGH PRESSURE VACUUM DRAINAGE BOTTLE IS A SURGICAL DRAIN USED FOR COLLECTION OF FLUID FROM SURGICAL WOUND UNDER NEGATIVE PRESSURE THROUGH A COLLECTION TUBE AND COLLECTION DEVICE (BOTTLE). THE VACUUM GUARANTEES AN EFFICIENT AND CONSTANT EVACUATION OF EXUDATES WITHOUT RISK OF INTERNAL HEMORRHAGING. ,INFUSION SET FOR SINGLE USE [IS 12655-4] [ISO 8536-4](ESKAMED INFUSION SET (SAFETY DOUBLE DRIP CHAMBER))-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,REDON DRAINAGE TUBE(REDON DRAINAGE TUBE)-IT IS A SURGICAL DRAIN USED TO PROVIDE CONNECTION TO A DRAINAGE BAG TO DRAIN SECRETIONS, BLOOD AND PUS FROM WOUNDS AFTER SURGERY.,FOLEY CATHETER(FOLEY BALLOON CATHETER)-A LONG, SMALL GAUGE STERILE CATHETER USED FOR INSERTION INTO THE BLADDER THROUGH URETHRA TO DRAIN URINE. IT IS HELD IN PLACE WITH A BALLOON AT THE END,UMBILICAL CORD CLAMP (UMBILICAL OCCLUSION DEVICE) (UMBILICAL CORD CLAMP)-UMBILICAL CORD CLAMP IS A STERILE OCCLUSION DEVICE (CLIP) DESIGNED TO COMPRESS THE UMBILICAL CORD. THE DEVICE IS USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,ENDOTRACHEAL TUBE PLAIN / CUFFED [IS 12504-1] [ISO 5361](ENDOTRACHEAL TUBE (PLAIN/CUFFED))-IT IS MEANT FOR INSERTION INTO THE TRACHEA THROUGH THE MOUTH OR NOSE TO MAINTAIN AN UNOBSTRUCTED PASSAGEWAY ESPECIALLY TO DELIVER OXYGEN OR ANESTHESIA TO THE LUNGS.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I V CANNULA WITH WINGS WITHOUT INJECTION PORT(VITROCAN)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,UMBILICAL ARTERY CATHETER(UMBILICAL CATHETER)-UMBILICAL ARTERY

	CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS.,MUCUS EXTRACTOR (TRACHEOBRONCHIAL SUCTION CATHETER)(MUCUS EXTRACTOR)-MUCUS EXTRACTOR IS USED FOR ASPIRATION OF SECRETION FROM OROPHARYNX ENSURING FREE RESPIRATION AND CONVENIENT FOR SAFE TRANSPORT OF ASPIRATE FOR EXAMINATION. IT CLEARS THE AIRWAYS OF MUCUS AND ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILLATION.,FEMALE URETHRAL CATHETER(FEMALE CATHETERS) -FEMALE CATHETER IS USED TO PROVIDE ACCESS TO THE BLADDER THROUGH URETHRA IN CASE OF URINARY RETENTION IN FEMALES. THE FEMALE CATHETER HAS NO BALLOON ON ITS TIP AND IS FOR SHORT TERM USE.,STOMACH TUBE(STOMACH TUBE)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID.,SCALP VEIN SET(SCALP VEIN SET)- SCALP VEIN SET IS MEANT FOR ADMINISTRATION OF INTRAVENOUS FLUIDS, WITHDRAWAL OF BLOOD SAMPLES AND TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING. , STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I. V. CANNULA WITHOUT INJECTION PORT & WITH SMALL WINGS (VITRONEO)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THREE WAY STOP- COCK (AS AN ACCESSORY OF PERFUSION SETS)(THREE WAY STOP COCK AS AN ACCESSORY OF I.V. CANNULA/CATHETER/PERFUSION SET)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,THORACIC DRAINAGE CATHETER (STRAIGHT / CURVED)(THORACIC DRAINAGE CATHETER (STRAIGHT / CURVED))-THORACIC DRAINAGE CATHETER IS A SURGICAL DRAIN USED FOR POST OPERATIVE DRAINAGE AFTER CARDIO-THORACIC AND THORACIC SURGERY; IN ORDER TO REMOVE BLOOD, SECRETIONS AND AIR WHICH ACCUMULATE IN THE THORAX GENERATING ACUTE CARDIO RESPIRATORY INSUFFICIENCY AND SOMETIMES EVEN DEATH.,LEVINS TUBE(LEVINS TUBE)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,I.V. FLOW REGULATOR(FLOW REGULATOR AS AN ACCESSORY OF INFUSION SET)-AN I V SYSTEM AND ADMINISTRATION DEVICE OFFERING

	PRECISION CARE AND CONSISTENT DELIVERY.,INFUSION SET FOR SINGLE USE [IS 12655-4] [ISO 8536-4](IV INFUSION SET WITH FLOW REGULATOR AND WITH/WITHOUT AIRVENT)-INFUSION SET IS USED ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 1055-1 AND 5] I V CANNULA WITH INJECTION PORT AND WING(VITROFLON)-"THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD /BLOOD COMPONENTS, OR FOR WITHDRAWL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES . ", UNDER WATER SEAL DRAINAGE BAG/ BOTTLE(UNDER WATER SEAL DRAINAGE BAG/ BOTTLE)-UNDER WATER SEAL DRAINAGE SYSTEM IS A SURGICAL DRAIN USED FOR COLLECTION OF DRAINAGE FLUID FROM THORACIC CAVITY. IT IS SUITABLE FOR PLEURAL DRAINAGE IN CONJUNCTION WITH CHEST DRAINAGE CATHETERS IN CARDIO-THORACIC PROCEDURES. IT IS A CLOSED CHEST DRAINAGE SYSTEM USED TO ALLOW AIR AND FLUID TO ESCAPE FROM THE PLURAL SPACE WITH EACH EXHALATION AND TO PREVENT THEIR RETURN FLOW WITH EACH INHALATION.,TUR SET (TRANSURETHRAL RESECTION)(TUR SET)-TUR SET IS A CONTINUOUS IRRIGATION CATHETER USED FOR ENDOSCOPIC IRRIGATION DURING TRANS URETHRAL RESECTION OF PROSTATE GLAND. IT IS ALSO INDICATED FOR USE IN SUCH PROCEDURES AS CYSTOSCOPY AND TRANS URETHRAL-RESECTION AS A MEANS OF CONTINUOUS BLADDER IRRIGATION.,INTRAVASCULAR CATHETERS – STERILE AND SINGLE -USE CATHETER(VITRO-SAFE (SAFETY IV CANNULA WITH SNAPFIT CAP WINGS SUTURABLE WINGS))-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES ,HAEMODIALYSIS CATHETER (BLOOD LINE) (BLOOD LINE SET)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT,INTRAVASCULAR CATHETERS – STERILE AND SINGLE -USE CATHETER(VITROPEN-SAFE (SAFETY IV CANNULA WITHOUT PORT & WINGS))-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES . , STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] (I. V. CANNULA WITHOUT INJECTION PORT & WITH SMALL WINGS) (VITROPEDIA)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., INTRAVASCULAR CATHETERS – STERILE AND SINGLE -USE

	CATHETER(VITROCATH-SAFE (SAFETY IV CANNULA WITH INTEGRATED THREE WAY STOP COCK))-THE IV CANNULA IS A PASSIVE DEVICE SAFETY CLIP TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES ,PERITONEAL DIALYSIS SET(PERITONEAL DIALYSIS SET)-PERITONEAL DIALYSIS CATHETER KIT IS USED TO ALLOW DIALYSIS FLUID TO FLOW INTO AND OUT OF THE PERITONEAL CAVITY. IT HELPS TO REMOVE EXTRA FLUID AND WASTE PRODUCTS FROM THE BODY.,NASAL OXYGEN CANNULA / CATHETER(NASAL OXYGEN CANNULA /CATHETER)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,TRANSFUSION SET FOR SINGLE USE [IS 9824-3, ISO 1135-4] (BLOOD ADMINISTRATION SET WITH / WITHOUT AIR-VENT)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I V CANNULA WITH INTEGRATED THREE WAY STOP COCK(VITROCATH)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., BLOOD TRANSFUSION SET (FOR SINGLE USE ONLY (DISPOSABLE PERFUSION SETS)(P & Q BLOOD TRANSFUSION SET WITHOUT AIR-VENT)-TRANSFUSION SET IS USED ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INTRAVASCULAR CATHETERS – STERILE AND SINGLE -USE CATHETER(VITROWIN-SAFE (SAFETY IV CANNULA WITHOUT PORT ,WITHOUT WINGS)-THE IV CANNULA WITH SAFETY CLIP IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,IV CANNULA WITHOUT INJECTION PORT & WITHOUT WINGS (LABOR IMPORT CATHETER PARA INFUSA INTRAVENOSA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES ,THORACIC DRAINAGE CATHETER WITH TROCAR(THORACIC DRAINAGE CATHETER WITH TROCAR)-THORACIC DRAINAGE CATHETER IS A SURGICAL DRAIN USED FOR POST OPERATIVE DRAINAGE AFTER CARDIO-THORACIC AND THORACIC SURGERY; IN ORDER TO REMOVE BLOOD, SECRETIONS AND AIR WHICH ACCUMULATE IN THE THORAX GENERATING ACUTE CARDIO RESPIRATORY INSUFFICIENCY AND SOMETIMES EVEN DEATH.,INTRAVASCULAR CATHETERS – STERILE AND SINGLE -USE

		CATHETER(VITROCAN-SAFE (SAFETY IV CANNULA WITH WINGS WITHOUT PORT))-THE IV CANNULA WITH SAFETY CLIP IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES . ,STERILE SINGLE USE INTRAVASCULAR CATHETERS [ISO 10555-1 AND 5] I. V. CANNULA WITH INJECTION PORT, SNAP FIT CAP & SUTURABLE WINGS(VITROFLEX)-THE IV CANNULA IS USED TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD OR BLOOD COMPONENTS, OR FOR WITHDRAWAL OF BLOOD SAMPLES OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,OXYGEN CATHETERS (OXYGEN CATHETERS)-OXYGEN CATHETER IS USED FOR ADMINISTRATION OF OXYGEN THROUGH THE NASO PHARYNX FOR RESPIRATION IN PATIENTS IN NEED OF RESPIRATORY HELP.,SUCTION CATHETERS [ISO 8836](SUCTION CATHETERS)-SUCTION CATHETERS (FEATURING A PLAIN, TIP OR A THUMB CONTROL) IS USED TO PROVIDE ACCESS TO RESPIRATORY TRACT FOR SUCTIONING SECRETION WITH PRECISION AND MAXIMUM COMFORT TO THE PATIENT.,RECTAL CATHETERS(RECTAL CATHETERS)-RECTAL CATHETER IS USED FOR INSERTING INTO THE RECTUM IN ORDER TO RELIEVE FLATULENCE UNRESPONSIVE TO ACTIVITY OR MEDICATIONS AND ALSO TO DISCHARGE THE WASTE.
3386	MFG/MD/2020/000027	1.License Holder Name: LEVRAM LIFESCIENCES PVT. LTD. 2.Approving Authority: DADRA AND NAGAR HAVELI 3.Device Name(Brand Name)-Intended Use:PLATELET RICH PLASMA (PRP) TUBE(VPRP)-INTENDED USE IS PREPARATION OF AUTOLOGOUS PLATELET RICH PLASMA OR OTHER PLASMA DERIVATIVES.
3387	MFG/MD/2020/000028	1.License Holder Name: LEVRAM LIFESCIENCES PVT. LTD. 2.Approving Authority: DADRA AND NAGAR HAVELI 3.Device Name(Brand Name)-Intended Use:HYPODERMIC NEEDLE (BENESPHERA)-IT IS USED FOR BLOOD COLLECTION.
3388	MFG/MD/2020/000029	1.License Holder Name: LA-MED HEALTHCARE PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER KIT(LA-MED/CERATO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING OF ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.

3389	MFG/MD/2020/000030	1.License Holder Name: XYSTER DEVICES PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:CATHETER - ACCESS SHEATH(XYSTER)-INTENDED TO USE IN ANTIGRADE ENDOSCOPE PROCEDURES WHERE FLEXIBLE UROSCOPE IS EASILY PASSED IN TO THE URETER WITH OUT DAMAGING THE TRACK AS WELL AS ENDOSCOPE.,CATHETER - TRU-CUT BIOPSY(XYSTER)-THE NEEDLE IS COMMONLY USED FOR PER CUTANEOUS BIOPSY OF LYMPH NODES, LIVER, KIDNEY, ETC. ,CATHETER - D J STENT(XYSTER)-USED AS TEMPORARY DRAINAGE TUBE TO DRAIN FLUID INTERNALLY FROM KIDNEY TO BLADDER,CATHETER - NEEDLES (IPN) INITIAL PUNCTURE NEEDLE(XYSTER)-INTENDED TO USE FOR PERCUTANIOUS NEPHROSTOMY CYST PUNCTURE,CATHETER - SPDC (SUPRAPUBIC DRAINAGE SET)(XYSTER)-INTENDED TO DILATE THE BLOCKED FLUID FROM KIDNEY / BLADDER WITH ONE STEP INSERTION OF FOLEY BALLOON CATHETER THROUGH LDPE PEEL OFF SHEATH.,CATHETER - URETHRAL DILATOR(XYSTER)-USED FOR DILATION OF THE URETHRA TILL KIDNEY PRIOR TO URETROSCOPY PROCEDURES.,CATHETER - URETERAL CATHETER(XYSTER)-TEMPORARY DRAINAGE FROM RETROGRADE / ANTIGRADE PYELOGRAM,CATHETER - DILATORS (PCN) FASCIAL(XYSTER)-USED FOR STEP DILATING OF THE TRACK TO KIDNEY,CATHETERS – MALECOT / MALECOT TROCAR(XYSTER)-TEMPORARY DRAINAGE FROM BLADDER AND KIDNEY BY PERCUTANIOUS PROCEDURES,CATHETER - URS (RIGID FORCEPS) (XYSTER)-INTENDED TO USE WITH RIGID ENDOSCOPE PROCEDURES., CATHETER - PERK BASKET (RIGID)(XYSTER)-USED FOR EXTRACTION OF STONES AND FOREIGN OBJECTS IN THE KIDNEY AND BLADDER, CATHETER - STONE CONE(XYSTER)-INTENDED TO USED IN THE URETER OR AT THE PELVIC JUNCTION OF THE KIDNEY TO STOP THE FRAGMENTED STONES PARTICLES IN LITHO CLAST PROCEDURES , CATHETER - RETRIEVALS - STONE BASKET (XYSTER)-USED TO MANIPULATE AND REMOVAL OF STONES IN KIDNEY , URETER AND BLADDER,CATHETER - URETERAL DILATOR(XYSTER)-USED FOR DILATION OF THE URETER PRIOR TO URETROSCOPY PROCEDURES., CATHETER - SHEATH (AMPLATZ)(XYSTER)-USED FOR INTRODUCING ENDOSCOPE THROUGH RETROGRADE PROCEDURES,CATHETERS – PIGTAIL / PIGTAL TROCAR(XYSTER)-TEMPORARY DRAINAGE FROM BLADDER / KIDNEY BY PER-CUTANEOUS PROCEDURES,CATHETER - CHIBA NEEDLE(XYSTER)-INTENDED TO USE TO PUNCTURE PRIOR TO INSERTION OF GUIDE WIRES IN TO KIDNEY / BLADDER

3390	MFG/MD/2020/000031	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ETHYLENE OXIDE STERILISATION OF CLASS A & B PRODUCTS-INTENDED USE SHALL BE AS PER THE MEDICAL DEVICES FALLING UNDER CLASS A & B PRODUCTS
3391	MFG/MD/2020/000032	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:GAMMA/ ETHYLENE OXIDE STERILISATION OF CLASS A PRODUCTS-GAMMA/ ETHYLENE OXIDE STERILISATION OF PRODUCTS FALLING UNDER CLASS A. INTENDED USE OF THE PRODUCTS WOULD BE AS DECIDED BY THE MEDICAL DEVICE MANUFACTURER.,GAMMA/ ETHYLENE OXIDE STERILISATION OF CLASS B PRODUCTS-GAMMA/ ETHYLENE OXIDE STERILISATION OF PRODUCTS FALLING UNDER CLASS B. INTENDED USE OF THE PRODUCTS WOULD BE AS DECIDED BY THE MEDICAL DEVICE MANUFACTURER.

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3392	MFG/MD/2020/000033	1.License Holder Name: STERILOOK PHARMA 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON I.P. (STERILE)-ABSORBENT COTTON MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC. BECAUSE OF ITS PROPERTY OF HIGH FLUID ABSORBENCY.,ABDOMINAL SWAB-ABDOMINAL MOPS ARE USED AFTER BEING STERILIZED DURING THE COURSE OF SURGERY TO MOP THE EXCESS BLEEDING. IN OTHER WORDS TO ELIMINATE THE BACTERIAL ATTACK DURING SURGICAL PROCESS.,BANDAGE CLOTH SCH.F (II) (STERILE)-BANDAGE CLOTH IS CONVERTED OVER THE ROLLING AND CUTTING MACHINES TO THERE ARE DIFFERENT METHODS OF APPLYING ROLL BANDAGES; CIRCULAR,SPIRAL, REVERSE-SPIRAL ANDRECURRENTFOLD. THE CIRCULAR-TURN BANDAGE IS USED TO SECURE A DRESSING OR TO COVER A CONFINED AREA OF AN EXTREMITY.,ABSORBENT GAUZE IP & SCH II WITH X RAY THREAD (STERILE)-A COVERED WOUND HEALS FASTER THAN AN UNCOVERED ONE. GAUZE PADS ARE DESIGNED TO PROTECT MINOR CUTS, SCRAPES AND BURNS. IT IS MADE OF 100% COTTON TO ENSURE SUPERIOR ABSORBENCY .THESE 12-PLY GAUZE PADS ARE INDIVIDUALLY-WRAPPED STERILE GAUZE PADS DESIGNED TO WICK AWAY FLUID FROM WOUNDS TO HELP KEEP THEM CLEAN. GAUZE PAD IS USED A MEDICAL DRESSING .THESE NON-ADHESIVE GAUZE PADS ARE ESSENTIAL FIRST AID SUPPLIES.,BURNS PAD - DRESSING PAD-COMBINE DRESSING PAD IS A STERILE PAD OR COMPRESS APPLIED TO A WOUND TO PROMOTE HEALING AND PROTECT THE WOUND FROM FURTHER HARM. COMBINE DRESSING PAD IS DESIGNED TO BE IN EXTERNAL CONTACT WITH THE WOUND, STERILE DRESSING PAD AND EYE PAD - ABSORBENT COTTON I.P & ABSORBENT GAUZE-STERILE ABSORBENT DRESSINGS PADS ARE ABSORBENT PADS FOR SINGLE USE.THEY ARE APPLIED TO WOUNDS WITH ABUNDANT SECRETION.THE CORE IS OF 100% BLEACHED ABSORBENT COTTON WRAPPED IN BLEACHED GAUZE.,STERILE UMBILICAL POLYSTER TAPE OF SCH-F(III)-THIS PRODUCT IS STERILE AND UTILIZED TO TIE ACROSS DRESSING AND TRACHEOTOMY TUBES.,STERILE UMBILICAL COTTON TAPE OF SCH-F(III)-THIS IS A STERILE COTTON TAPE FOR TYING OFF UMBILICAL CORD STUMP DURING CAUTERIZATION.,ABDOMINAL SWAB STERILE-ABDOMINAL MOPS ARE USED AFTER BEING STERILIZED DURING THE COURSE OF SURGERY TO MOP THE EXCESS BLEEDING. IN OTHER WORDS TO ELIMINATE THE BACTERIAL ATTACK DURING SURGICAL PROCESS., ABSORBENT GAUZE SCH-F (II) (STERILE)-A COVERED WOUND HEALS FASTER THAN AN UNCOVERED ONE. GAUZE PADS ARE DESIGNED TO PROTECT MINOR CUTS, SCRAPES AND BURNS. IT IS

		MADE OF 100% COTTON TO ENSURE SUPERIOR ABSORBENCY .THESE PLY GAUZE PADS ARE INDIVIDUALLY-WRAPPED STERILE GAUZE PADS DESIGNED TO WICK AWAY FLUID FROM WOUNDS TO HELP KEEP THEM CLEAN. GAUZE PAD IS USED A MEDICAL DRESSING ., MATERNITY KIT STERILE-GAUZE IS USED TOGETHER WITH COTTON WHILE DRAINING AND DRY BLOOD OF THE MOTHER AFTER BIRTH. DUE TO THE NATURE OF COTTON IT MAY LEAVE PARTICLES IN THE MOTHER'S BODY WHICH IS HARMFUL AND TO PREVENT IT FROM HAPPENING GAUZE IS WRAPPED AROUND EACH PIECE OF COTTON BEFORE USAGE,INFUSION SET AS PER ISI-STERILE ITEM, USED FOR PARENTERAL ADMINISTRATION OF INJECTABLE PREPARATIONS., STERILE DISPOSABLE DELIVERY KIT-ABSORBENT COTTON MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC. BECAUSE OF ITS PROPERTY OF HIGH FLUID ABSORBENCY. A COVERED WOUND HEALS FASTER THAN AN UNCOVERED ONE. GAUZE PADS ARE DESIGNED TO PROTECT MINOR CUTS, SCRAPES AND BURNS. IT IS MADE OF 100% COTTON TO ENSURE SUPERIOR ABSORBENCY .THESE 12-PLY GAUZE PADS ARE INDIVIDUALLY-WRAPPED STERILE GAUZE PADS DESIGNED TO WICK AWAY FLUID FROM WOUNDS TO HELP KEEP THEM CLEAN. GAUZE PAD IS USED A MEDICAL DRESSING .THESE NON-ADHESIVE GAUZE PADS ARE ESSENTIAL FIRST AID SUPPLIES,ROLLED BANDAGE SCH- II STERILE-ROLLER BANDAGE : IS ALSO KNOWN AS SURGICAL CLOTH OR/ COTTON MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC. IT IS BETTER KNOWN AMONG MASSES BANDAGE & ROLLER BANDAGE THERE ARE DIFFERENT METHODS OF APPLYING ROLL BANDAGES; CIRCULAR,SPIRAL, REVERSE-SPIRAL AND RECURRENT FOLD.,DIALYSIS KIT-HIGH FLUID ABSORBENCY POWER
3393	MFG/MD/2020/000034	1.License Holder Name: HI-TECH MEDICARE DEVICES PVT. LTD. 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:I.V. CANNULA(HI-FLON, NEO-HIFLON)-I.V. CANNULA: IT IS A DEVICE THROUGH WHICH INTRA VENOUS BODY FLUIDS ARE INTRODUCED IN TO THE HUMAN CIRCULATION SYSTEM, THROUGH A CATHETER WITH THE HELP OF A HOLLOW INTRODUCER NEEDLE WHICH IS PLACED INSIDE THE CATHETER. NEEDLE IS WITHDRAWN ONCE IT PLACES THE CATHETER IN TO THE HUMAN VEIN.

3394	MFG/MD/2020/000035	1.License Holder Name: MAPELEAF HEALTH CARE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ELASTIC ADHESIVE BANDAGE(MAPELPLAST)- USED FOR MAINTAINING DRESSING IN ITS POSITION AFTER OPERATION, FRACTURED OF MANDIBLE RIBS, CLAVICLE A FINGERS, VARICOSE & CHRONIC ULCERS, SPRAINS & JOINTS INJURIES, SUPERFICIAL THROMBOPHLEBITIS ETC, ABSORBENT GAMJEE ROLL- USED TO DRESS INFECTED WOUNDS, GAUZE BANDAGE- USED FOR DRESSING WOUNDS WHERE OTHER FABRICS MIGHT STICK TO THE BURN OR LACERATION, CANNULA FIXATOR(MAPELFIX)- USED IN SURGERY TO HOLD TUBE INSERTED INTO THE BODY TO ADMINISTER MEDICATION, DRAIN OFF FLUID, OR INTRODUCE A SURGICAL INSTRUMENT, COTTON CRAPE BANDAGE (MAPELCREPE)-USED AS A COMPRESSION BANDAGE FOR ALL CHRONIC LEG CONDITIONS, VARICOSE VEINS AND THEIR AFTER-CARE AS A PRESSURE DRESSING FOR BURNS,FOR SKIN GRAFTS AND WHEREVER ELASTIC SUPPORTS IS REQUIRED FOR TREATMENT FOR STRAINS, AND SIMILAR CONDITIONS,GAUZE SWABS-USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, APPLYING ANTISEPTIC AND MUCH MORE. IT IS ESPECIALLY USEFUL FOR DRESSING WOUNDS WHERE OTHER FABRICS MIGHT STICK TO THE BURN OR LACERATION. ,PLASTER OF PARIS (POP) BANDAGE- USED TO CREATE A RESISTANT CASTS FOR BROKEN LIMB, ABSORBENT COTTON WOOL-USED IN SURGICAL DRESSING AND PERSONAL HYGIENE, ORTHOPAEDIC BANDAGE (COTTON SOFT ROLL)(MAPELSOFT)- USED IN APPLICATIONS RELATED TO ORTHOPEDIC SURGERY, SURGICAL PAPER TAPE(MAPELPOR)- USED TO SECURE BANDAGE OR DRESSING ADHESION ON SKIN , DOCTOR TAPE-USED TO HOLD A BANDAGE OR DRESSING ONTO A WOUND

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3395	MFG/MD/2020/000036	1.License Holder Name: BIPSON SURGICAL PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ORTHO ROLL CAST PADDING (SOFT ROLL)(BIPSON)-A PROSTHETIC AND ORTHOTIC ACCESSORY, INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT, OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE), OR PROSTHESIS.,ABSORBENT GAUZE AS PER SCHEDULE F (II)(BIPSON)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE.,GAUZE SWAB B.P.(BIPSON)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE., DISPOSABLE DELIVERY KIT WITH GLOVES STERILISED BY ETO (BIPSON)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE., BANDAGE CLOTH [ROLLED](BIPSON)-A PROSTHETIC AND ORTHOTIC ACCESSORY, INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT, OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE), OR PROSTHESIS.,BANDAGE CLOTH AS PER SCHEDULE F (II)(BIPSON)-A PROSTHETIC AND ORTHOTIC ACCESSORY, INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT, OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE), OR PROSTHESIS.,X RAY DETECTABLE ABDOMINAL PAD - STERILE(BIPSON)-IT IS INTENDED FOR THE USE DURING VARIOUS SURGERIES.,COMBINE DRESSING SURGICAL PAD STERILISED BY ETO(BIPSON)-A PROSTHETIC AND ORTHOTIC ACCESSORY, INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT, OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE), OR PROSTHESIS.,GAMJEE ROLL (BIPSON)-ADHESIVE BENDAGES. GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.

3396	MFG/MD/2020/000037	1.License Holder Name: M/S FUSION TUBE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (DR CROWN)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE INFANT FEEDING TUBE SIZE-FG-4/FG-5/FG-6/FG-7/FG-8/FG-9/FG-10/FG-12 FOR SINGLE USE ONLY (- - -)-A FEEDING TUBE IS A DEVICE THAT IS INSERTED INTO THE STOMACH THROUGH THE ABDOMEN. IT IS USED TO SUPPLY NUTRITION WHEN THERE IS A TROUBLE IN EATING. ,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(SOLOWIN)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE URETHRAL CATHETER (PLAIN & THUMB CONTROL) SIZE : FG 6,8,10,12, 14, 16,18 FOR SINGLE USE ONLY (- - -)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETHRA, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(UNIDRIP)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE FOLEY'S BALLOON CATHETER SIZE : FR 8/10/12/14/16/18/20/22/24 FOR SINGLE USE ONLY (- - -)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETHRA, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(DISPO PRO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE CLOSED WOUND DRAINAGE SET SIZE : FG 10,12,14,16 FOR SINGLE USE ONLY (- - -)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY THE SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(SPS)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS

	12655 FOR SINGLE USE ONLY(LIFE-LINE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITHOUT AIR VENT BIS 9824(- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(MEDIVEIN)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE RYLE'S TUBE SIZE-FG-6/FG-8/ FG-10/FG-12/FG-14 /FG-16/FG-18/ FG-20/FG-22/FG-24 FOR SINGLE USE ONLY (- - -)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH NOSE. IT CAN BE USED OF ALL FEEDING FOR GIVING A PERSON EXTRA CALORIES. ,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(IMD)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE NELATON CATHETER SIZE-FG-8/ FG-10/FG-12/FG-14/FR-16/FG-18/ FG-20/FG-22/FG-24 (- - -)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTIONDIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(YAVADRIP ECO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(FUSION FIRST)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN

3397	MFG/MD/2020/000038	1.License Holder Name: P. H. HEALTHCARE PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE HYPODERMIC SYRINGE WITH NEEDLES FOR SINGLE USE(PARAS , PARASAFE, LAVET, LAVITA, TKL, DISPOJECT, DC.INDJECT, NUMBER ONE, PRIME,EVRON.)-THE DEVICE IS USED FOR HYPODERMIC INJECTION.,STERILE HYPODERMIC AUTO DISABLE SYRINGE WITH NEEDLE(PARAS, PARASAFE)-THE DEVICE IS USED FOR HYPODERMIC INJECTION, MUSCLE AND INTRAVENOUS INJECTION AND INJECT THE MEDICAMENT INSIDE THE HUMAN BODY.,STERILE HYPODERMIC SYRINGE WITHOUT NEEDLE FOR SINGLE USE(PARAS , PARASAFE, LAVET, LAVITA, TKL, DISPOJECT, DC.INDJECT, NUMBER ONE, PRIME, EVRON.)-THE DEVICE IS USED FOR HYPODERMIC INJECTION,,STERILE HYPODERMIC SAFETY SYRINGE WITH NEEDLE(PARAS, PARASAFE)-THE DEVICE IS USED FOR HYPODERMIC INJECTION, MUSCLE AND INTRAVENOUS INJECTION AND INJECT THE MEDICAMENT INSIDE THE HUMAN BODY.,STERILE DISPOSABLE HYPODERMIC NEEDLE FOR SINGLE USE(PARAS , PARASAFE, LAVET, LAVITA, TKL, DISPOJECT, DC. INDJECT, NUMBER ONE, PRIME, EVRON.)-THE DEVICE IS USED FOR HYPODERMIC INJECTION.,STERILE HYPODERMIC AUTO DISABLE SYRINGE WITHOUT NEEDLE(PARAS, PARASAFE)-THE DEVICE IS USED FOR HYPODERMIC INJECTION, MUSCLE AND INTRAVENOUS INJECTION AND INJECT THE MEDICAMENT INSIDE THE HUMAN BODY., STERILE DISPOSABLE SYRINGE FOR INSULIN (PARAS , PARASAFE, LAVET, LAVITA, TKL, DISPOJECT, DC.INDJECT, NUMBER ONE, PRIME, EVRON.)-THE DEVICE IS USED FOR HYPODERMIC INJECTION.,STERILE HYPODERMIC SAFETY SYRINGE WITHOUT NEEDLE(PARAS, PARASAFE)-THE DEVICE IS USED FOR HYPODERMIC INJECTION, MUSCLE AND INTRAVENOUS INJECTION AND INJECT THE MEDICAMENT INSIDE THE HUMAN BODY.

3398	MFG/MD/2020/000039	1.License Holder Name: ECON LIFE SCIENCE PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE INFUSION SET WITH AIR VENT BIS 12655(ECON LIFE /LIFE FLOW/UMAFLO/IVILIS-NEO/IM-LIFE/IVILIS BETA)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN., STERILE TRACHEOBRONCHIAL MUCUS EXTRACTOR CATHETER FOR SINGLE USE ONLY(ECON LIFE MUCUS EXTRACTOR)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824FOR SINGLE USE ONLY (LIFE FLOW)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ECON LIFE MEASURED VOLUME INFUSION SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE ,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ECON LIFE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE SCALP VEIN SET FOR SINGLE USE ONLY (FOR EXPORT ONLY)(ECON LIFE)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD., STERILE DISPOSABLE INFUSION SET WITH AND WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (FOR EXPORT ONLY)(ZENITH PLUS) -THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE UMBILICAL OCCLUSION DEVICE FOR SINGLE USE ONLY(ECON LIFE CORD CLAMP)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ECONLIFE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. CLASS OF MEDICAL ,STERILE SCALP VEIN SET FOR SINGLE USE ONLY(ECON LIFE)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-

	DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.

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3399	MFG/MD/2020/000040	1.License Holder Name: NOVO BRICKS HEALTH CARE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY (- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(HEALTH PLUSE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN ,STERILE DISPOSABLE MICRO DRIP INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (- -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE MICRO DRIP INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (FOR EXPORT ONLY)(NOXIVENT)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (FOR EXPORT ONLY)(NOXIVENT / HEALTH PLUSE) -TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE INFUSION SET WITH AIR VENT BIS 12655 FOR SINGLE USE ONLY (- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(NOXIVEN)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN ,STERILE DISPOSABLE MEASURED VOLUME INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(- - -)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(NOXIVEN) -IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH

		AIR VENT BIS 9824 FOR SINGLE USE ONLY (- -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.,STERILE DISPOSABLE MICRO DRIP INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(NOXIVEN)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE MEASURED VOLUME INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (NOXIVEN)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE MEASURED VOLUME INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (FOR EXPORT ONLY)(NOXIVENT)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY (FOR EXPORT ONLY)(NOXIVENT)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.
3400	MFG/MD/2020/000041	1.License Holder Name: DEVON INNOVATIONS PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:FEMORAL COMPONENT-HA COATING AND HEAD-FEMORAL COMPONENT-USE IN TOTAL OR PARTIAL HIP ORTHOPLASTY IN PRIMARY OR REVISION SURGERY. HEAD- HIP IMPLANT

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

3401	MFG/MD/2020/000042	1.License Holder Name: BOMBAY ORTHO INDUSTRIES 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE SCREW (TITANIUM) (CURE HEALTH CARE/OSTEON/PARTH/BIOMED)-BONE SCREW IS USED TO FIXING FRACTURE. WITH THE HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES. , HIP REPLACEMENT SYSTEM (TITANIUM)(BOMBAY ORTHO/AVDHOOT) -HIP REPLACEMENT SYSTEM ARE USED IN PROXIMAL FEMUR BONE FRACTURES, WHERE IS FEMUR PROXIMAL AREA ARE FRACTURED BADLY, THE SURGEON REMOVED PROXIMAL AREA AND THEY FIXED ENDO PROSTHESIS AND FIX WITH FEMUR DISTAL PART.,SPINAL IMPLANTS (SS)(CURE HEALTH CARE/OSTEON/PARTH/BIOMED)-SPINAL IMPLANTS ARE USED IN SPINE CODE FRACTURES IN THORACIC SPINE AND LUMBER SPINE. ALL THE SPINE IMPLANTS LIKE PEDICLE SCREW, HOOKS, RODS, STAPLES AND CONNECTORS ARE USED TO FIX THE SPINE BONE FRACTURES.,INTERLOCKING NAIL (SS) (BOMBAY ORTHO/AVDHOOT)-INTERLOCKING NAILS ARE USED IN HUMERUS BONE, TIBIA BONE, FEMUR BONE, WHERE FOUND THE FRACTURES IN PROXIMAL AND DISTAL AREA. ALL TYPES OF INTERLOCKING NAILS ARE USED INSIDE THE BONE AND ITS PASS THROUGH FRACTURES AND HOLD THE FRACTURES WITH THE HELP OF BONE SCREWS. AND ITS MINIMAL INSERTION SURGERY.,HIP REPLACEMENT SYSTEM (TITANIUM)(CURE HEALTH CARE/OSTEON/PARTH/BIOMED)-HIP REPLACEMENT SYSTEM ARE USED IN PROXIMAL FEMUR BONE FRACTURES, WHERE IS FEMUR PROXIMAL AREA ARE FRACTURED BADLY, THE SURGEON REMOVED PROXIMAL AREA AND THEY FIXED ENDO PROSTHESIS AND FIX WITH FEMUR DISTAL PART. ,HIP REPLACEMENT SYSTEM (SS)(BOMBAY ORTHO/AVDHOOT)-HIP REPLACEMENT SYSTEM ARE USED IN PROXIMAL FEMUR BONE FRACTURES, WHERE IS FEMUR PROXIMAL AREA ARE FRACTURED BADLY, THE SURGEON REMOVED PROXIMAL AREA AND THEY FIXED ENDO PROSTHESIS AND FIX WITH FEMUR DISTAL PART.,BONE PLATE (SS)(CURE HEALTH CARE/OSTEON/PARTH/BIOMED)-BONE PLATES IS USED TO FIXING FRACTURE. WITH HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES.,BONE SCREW (SS) (BOMBAY ORTHO/AVDHOOT)-BONE SCREW IS USED TO FIXING FRACTURE. WITH THE HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES.,PINS & WIRES (SS) (CURE HEALTH CARE/OSTEON/PARTH/BIOMED)-PINS & WIRES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS & WIRES SUPPORT FIX THE BONE PLATES, BONE SCREWS, IM NAILS, SPINE IMPLANTS ETC.

	ALL PINS & WIRES ARE NOT PERMANENTLY USED IN SURGERY.,PINS & WIRES (TITANIUM)(BOMBAY ORTHO/AVDHOOT)-PINS & WIRES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS & WIRES SUPPORT FIX THE BONE PLATES, BONE SCREWS, IM NAILS, SPINE IMPLANTS ETC. ALL PINS & WIRES ARE NOT PERMANENTLY USED IN SURGERY.,INTERLOCKING NAIL (TITANIUM) (CURE HEALTH CARE/OSTEON/PARTH/BIOMED)-INTERLOCKING NAILS ARE USED IN HUMERUS BONE, TIBIA BONE, FEMUR BONE, WHERE FOUND THE FRACTURES IN PROXIMAL AND DISTAL AREA. ALL TYPES OF INTERLOCKING NAILS ARE USED INSIDE THE BONE AND ITS PASS THROUGH FRACTURES AND HOLD THE FRACTURES WITH THE HELP OF BONE SCREWS. AND ITS MINIMAL INSERTION SURGERY. ,INTERLOCKING NAIL (TITANIUM)(BOMBAY ORTHO/AVDHOOT)-INTERLOCKING NAILS ARE USED IN HUMERUS BONE, TIBIA BONE, FEMUR BONE, WHERE FOUND THE FRACTURES IN PROXIMAL AND DISTAL AREA. ALL TYPES OF INTERLOCKING NAILS ARE USED INSIDE THE BONE AND ITS PASS THROUGH FRACTURES AND HOLD THE FRACTURES WITH THE HELP OF BONE SCREWS. AND ITS MINIMAL INSERTION SURGERY.,HIP REPLACEMENT SYSTEM (S$) (CURE HEALTH CARE/OSTEON/PARTH/BIOMED)-HIP REPLACEMENT SYSTEM ARE USED IN PROXIMAL FEMUR BONE FRACTURES, WHERE IS FEMUR PROXIMAL AREA ARE FRACTURED BADLY, THE SURGEON REMOVED PROXIMAL AREA AND THEY FIXED ENDO PROSTHESIS AND FIX WITH FEMUR DISTAL PART. ,PINS & WIRES (SS)(BOMBAY ORTHO/AVDHOOT)-PINS & WIRES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS & WIRES SUPPORT FIX THE BONE PLATES, BONE SCREWS, IM NAILS, SPINE IMPLANTS ETC. ALL PINS & WIRES ARE NOT PERMANENTLY USED IN SURGERY.,BONE SCREW (SS)(CURE HEALTH CARE/OSTEON/PARTH/BIOMED)-BONE SCREW IS USED TO FIXING FRACTURE. WITH THE HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES. ,SPINAL IMPLANTS (SS)(BOMBAY ORTHO/AVDHOOT)-SPINAL IMPLANTS ARE USED IN SPINE CODE FRACTURES IN THORACIC SPINE AND LUMBER SPINE. ALL THE SPINE IMPLANTS LIKE PEDICLE SCREW, HOOKS, RODS, STAPLES AND CONNECTORS ARE USED TO FIX THE SPINE BONE FRACTURES.,SPINAL IMPLANTS (TITANIUM)(CURE HEALTH CARE/OSTEON/PARTH/BIOMED)-SPINAL IMPLANTS ARE USED IN SPINE CODE FRACTURES IN THORACIC SPINE AND LUMBER SPINE. ALL THE SPINE IMPLANTS LIKE PEDICLE SCREW, HOOKS, RODS, STAPLES AND CONNECTORS ARE USED TO FIX THE SPINE BONE FRACTURES.,BONE PLATE (SS)(BOMBAY ORTHO/AVDHOOT)-BONE PLATES IS USED TO FIXING FRACTURE. WITH HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE

	FRACTURES.,BONE PLATE (TITANIUM)(CURE HEALTH CARE/OSTEON/PARTH/BIOMED)-BONE PLATES IS USED TO FIXING FRACTURE. WITH HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES.,BONE PLATE (TITANIUM)(BOMBAY ORTHO/AVDHOOT)-BONE PLATES IS USED TO FIXING FRACTURE. WITH HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES., INTERLOCKING NAIL (SS)(CURE HEALTH CARE/OSTEON/PARTH/BIOMED)-INTERLOCKING NAILS ARE USED IN HUMERUS BONE, TIBIA BONE, FEMUR BONE, WHERE FOUND THE FRACTURES IN PROXIMAL AND DISTAL AREA. ALL TYPES OF INTERLOCKING NAILS ARE USED INSIDE THE BONE AND ITS PASS THROUGH FRACTURES AND HOLD THE FRACTURES WITH THE HELP OF BONE SCREWS. AND ITS MINIMAL INSERTION SURGERY. ,SPINAL IMPLANTS (TITANIUM)(BOMBAY ORTHO/AVDHOOT)-SPINAL IMPLANTS ARE USED IN SPINE CODE FRACTURES IN THORACIC SPINE AND LUMBER SPINE. ALL THE SPINE IMPLANTS LIKE PEDICLE SCREW, HOOKS, RODS, STAPLES AND CONNECTORS ARE USED TO FIX THE SPINE BONE FRACTURES.,PINS & WIRES (TITANIUM) (CURE HEALTH CARE/OSTEON/PARTH/BIOMED)-PINS & WIRES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS & WIRES SUPPORT FIX THE BONE PLATES, BONE SCREWS, IM NAILS, SPINE IMPLANTS ETC. ALL PINS & WIRES ARE NOT PERMANENTLY USED IN SURGERY. ,BONE SCREW (TITANIUM)(BOMBAY ORTHO/AVDHOOT)-BONE SCREW IS USED TO FIXING FRACTURE. WITH THE HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3402	MFG/MD/2020/000043	1.License Holder Name: PRAGATI SURGITECH 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE WIRE AND PINS (ORION, PRAGATI)-THE WIRES AND PINS ARE USED FOR TEMPORARY DEFINITIVE FIXATION IF THE FRACTURE FRAGMENTS ARE SMALL DURING SOME OPERATIONS. AFTER DEFINITIVE FIXATION THEY ARE THEN REMOVED.,BONE WIRE AND PINS(ORION, PRAGATI)-THE WIRES AND PINS ARE USED FOR TEMPORARY DEFINITIVE FIXATION IF THE FRACTURE FRAGMENTS ARE SMALL DURING SOME OPERATIONS. AFTER DEFINITIVE FIXATION THEY ARE THEN REMOVED.,BONE PLATE (ORION, PRAGATI)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. BONE PLATES ARE GENERALLY FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,SPINAL IMPLANT(ORION, PRAGATI)-SPINAL IMPLANTS ARE USED IN THE SURGICAL PROCEDURES RELATED TO THE SPINAL INJURIES AND SPINAL DISEASES.,BONE NAIL(ORION, PRAGATI)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. NAILS ARE OF DIFFERENT TYPES WHICH USED IN TIBIA, FEMUR AND HUMOROUS BONES MAINLY.,BONE SCREW(ORION, PRAGATI)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. SCREWS ARE OF DIFFERENT TYPES E.G. CORTI CAL SCREWS, CANCELLOUS SCREWS, CANCELLOUS CANNULATED SCREWS, MALLEOLAR SCREWS, LOCKING BOLT, LAG (DHS/DCS) SCREWS, SHERMAN SCREWS, STEFFEE SCREWS, SHAFT SCREWS, PLUG SCREWS,BONE PLATE (ORION, PRAGATI)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. BONE PLATES ARE GENERALLY FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE SCREW (ORION, PRAGATI)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. SCREWS ARE OF DIFFERENT TYPES E.G. CORTI CAL SCREWS, CANCELLOUS SCREWS, CANCELLOUS CANNULATED SCREWS, MALLEOLAR SCREWS, LOCKING BOLT, LAG (DHS/DCS) SCREWS, SHERMAN SCREWS, STEFFEE SCREWS, SHAFT SCREWS, PLUG SCREWS.,BONE NAIL(ORION, PRAGATI)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. NAILS ARE OF DIFFERENT TYPES WHICH USED IN TIBIA, FEMUR AND HUMOROUS BONES MAINLY. ,SPINAL IMPLANT(ORION, PRAGATI)-SPINAL IMPLANTS ARE USED IN THE SURGICAL PROCEDURES RELATED TO

	THE SPINAL INJURIES AND SPINAL DISEASES.

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3403	MFG/MD/2020/000044	1.License Holder Name: BIO-TECH VISION CARE PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS(EYECRYL PLUS NATURAL HD)-THE REPLACEMENT OF HUMAN NATURAL LENS TO ACHIEVE CORRECTION OF APHAKIA IN ADULT PATIENTS AND REPLACEMENT IN CAPSULAR BAG.,HYDROPHOBIC TRIFOCAL DIFFRACTIVE TORIC FOLDABLE INTRAOCULAR LENS(EYECRYL TRI ACTV TORIC)-THE EYECRYL TRI ACTV TORIC REFRACTIVE - DIFFRACTIVE TRIFOCAL TORIC IOL IS INTENDED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM, SECONDARY TO REMOVAL OF A CATARACTOUS LENS IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA, WHO WISH NEAR, INTERMEDIATE AND DISTANCE VISION WITH DECREASED DEPENDENCY ON SPECTACLES AND REDUCTION OF RESIDUAL REFRACTIVE CYLINDER. THE LENS IS INTENDED TO BE PLACED IN THE CAPSULAR BAG.,HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS (EYECRYL ACTV TORIC)-TO IMPLANT IN CAPSULAR BAG OF EYE FOR VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENT WITH OR WITHOUT PRESBYOPIA, WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCY FOR DISTANCE AND NEAR VISION. ,HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS WITH DELIVERY SYSTEM(EYECRYL ACTV TORIC)-TO IMPLANT IN CAPSULAR BAG OF EYE FOR VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENT WITH OR WITHOUT PRESBYOPIA, WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCY FOR DISTANCE VISION., HYDORPHILIC ACRYLIC FOLDABLE PHAKIC TORIC INTRAOCULAR LENS WITH DELIVERY SYSTEM(EYECRYL PHAKIC TORIC)-EYECRYL PHAKIC TORIC IOLS ARE INDICATED IN PHAKIC ADULTS FOR THE CORRECTION OR REDUCTION OF MODERATE TO HIGH MYOPIA WITH CO-EXISTING ASTIGMATISM.,HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENS WITH HYDROPHOBIC SURFACE (EYECRYL PLUS, EYECRYL PLUS CLEAR)-IT IS THE REPLACEMENT OF THE HUMAN NATURAL LENS TO ACHIEVE CORRECTION OF APHAKIA IN ADULT PATIENTS AND REPLACEMENT IN THE CAPSULAR BAG., HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS IN PRELOADED DELIVERY SYSTEM(EYECRYL-SERT)-TO IMPLANT IN CAPSULAR BAG OF EYE FOR VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENTS WITH OR

	WITHOUT PRESBYOPIA, WHO DESIRE IMPROVED UNCORRECTED DISTANCE AND NEAR VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTRAL INDEPENDENCY FOR DISTANCE AND NEAR VISION.,PMMA INTRAOCULAR LENS-SURGICAL CORRECTION OF THE APHAKIA AFTER INTRA OR EXTRA CAPSULAR EXTRACTION OF THE LENS.,HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS(EYECRYL TORIC)-TO IMPLANT IN CAPSULAR BAG OF EYE FOR VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENT WITH OR WITHOUT PRESBYOPIA, WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCY FOR DISTANCE VISION., HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS WITH DELIVERY SYSTEM(EYECRYL TORIC)-TO IMPLANT IN CAPSULAR BAG OF EYE FOR VISUAL CORRECTION OF APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM IN ADULT PATIENT WITH OR WITHOUT PRESBYOPIA, WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCY FOR DISTANCE VISION., HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS(EYECRYL TRI ACTV)-IT IS INTENDED FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA SECOND TO REMOVAL OF A CATARACTOUS LENS IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA, WHO WISH NEAR, INTERMEDIATE AND DISTANCE VISION WITH DECREASED DEPENDENCY ON SPECTACLES., HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS WITH DELIVERY SYSTEM(EYECRYL PLUS)-THE REPLACEMENT OF HUMAN NATURAL LENS TO ACHIEVE CORRECTION OF APHAKIA IN ADULT PATIENTS AND REPLACEMENT IN CAPSULAR BAG.,PHAKIC ASPHERIC HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENS WITH DELIVERY SYSTEM(EYECRYL PHAKIC)-IT IS THE REPLACEMENT OF THE HUMAN NATURAL LENS TO ACHIEVE CORRECTION OF NEARSIGHTEDNESS IN PHAKIC ADULT PATIENTS.,HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS WITH PRELOADED DELIVERY SYSTEM(EYECRYL-SERT)-IT IS INDICATED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS IN CAPSULAR BAG TO ACHIEVE CORRECTION OF APHAKIA IN PATIENTS AND IN ORDER TO GUARANTEE AN EXCELLENT VISUAL CORRECTION FURTHER TO EXTRACTION OF THE CRYSTALLINE LENS.,PHAKIC ASPHERIC HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENS WITH DELIVERY SYSTEM(EYECRYL PHAKIC)-IT IS THE REPLACEMENT OF THE HUMAN NATURAL LENS TO ACHIEVE CORRECTION OF APHAKIA IN ADULT PATIENT AND REPLACEMENT IN THE CAPCULAR BAG. IT IS USED TO CORRECT NEARSIGHTEDNESS.,DIFFRACTIVE

		NATURAL YELLOW HYDROPHOBIC ASPHERIC MULTIFOCAL ACRYLIC FOLDABLE INTRAOCULAR LENS(EYECRYL ACTV, EYECRYL ACTV +3)-PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA. TO REMOVAL OF A CATARACTOUS LENS IN ADULT PATIENTS WITH AND WITHOUT PRESBYOPIA, WHO WITH NEAR, INTERMEDIATE AND DISTANCE VISION WITH DECREASED DEPENDENCY ON SPECTACLES.,HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENS(EYECRYL)-IT IS THE REPLACEMENT OF THE HUMAN NATURAL LENS TO ACHIEVE CORRECTION OF APHAKIA AND REPLACEMENT IN THE CAPSULAR BAG.,HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS WITH DELIVERY SYSTEM(EYECRYL PLUS NATURAL HD)-THE EYECRYL PLUS NATURAL HD ASPHERIC INTRAOCULAR LENSES ARE INDICATED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS IN CAPSULAR BAG TO ACHIEVE CORRECTION OF APHAKIA IN PATIENTS AND IN ORDER TO GUARANTEE AN EXCELLENT VISUAL CORRECTION FURTHER TO EXTRACTION OF THE CRYSTALLINE LENS.,HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENS WITH DELIVERY SYSTEM(EYECRYL PLUS)-IT IS THE REPLACEMENT OF THE HUMAN NATURAL LENS TO ACHIEVE CORRECTION OF APHAKIA AND REPLACEMENT IN THE CAPSULAR BAG.
3404	MFG/MD/2020/000045	1.License Holder Name: MIL LABORATORIES PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ABSORBABLE GELATIN SPONGE USP(GELOSTAT, GELOSTAT FA,GELOSTAT FILM)-ABSORBABLE GELATIN HEMOSTATS IS INDICATED IN WIDE RANGE OF SURGERIES LIKE- GASTROINTESTINAL, DENTAL, ORTHOPEDIC, GYNAECOLOGICAL, OTOLARYNGOLOGICAL, GENTIOURINARY, NEUROSURGERY, ANORECTAL SURGERY, PARTIAL NEPHROTOMY, ENT SURGERY, PLASTIC SURGERY, VASCULAR SURGERY, HYESTROTOMY.

3405	MFG/MD/2020/000046	1.License Holder Name: BUYWEL HEALTHCARE PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:3 WAY STOPCOCK AS AN ACCESSORY TO PERFUSION SETS(NIL)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAL OF FLUID AND PRESSURE MONITORING. ,RYLES TUBE/NASOGASTRIC TUBE(NIL)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDING OR FOR GIVING A PERSON EXTRA COLORIES. ,BLOOD LINES/ SINGLE NEEDLE HAEMODIALYSIS CATHETER(NIL)-THE SINGLE NEEDLE DISLYSIS, IN WHICH CASE ONLY ONE CANNULA OR A SINGLE LUMEN CATHETER IS USED TO ACCESS THE BLOOD. ,EXTENSION SETS(NIL)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY.THEY ARE INTENTED TO BE USED AS PART OF A SYSTEM FOR INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPPLICATIONS.,CORD CLAMP (NIL)-SUITABLE FOR CLAMPING THE UMBILICAL CORD OF NEW BORN BABY, IMMEDIATELY AFTER BIRTH. PROVIDED WITH GROOVES ALL ALONG THE LENGTH TO PREVENT THE SLIPPING OF UMBILICAL CORD AND RETAIN IT IN THE SAME POSITION. ,MEASURED VOLUME I.V.SET FOR SINGLE USE(NIL)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT' S. VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,I.V. FLOW REGULATOR(NIL)-AN I.V SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTANT DELIVERY. I.V FLOW REGULATOR I.V.SET WITH FLOW REGULATOR IS USED FOR THE FLOW CONTROL OF I.V FLUIDS DURING INFUSION OR TRANSFUSION. FLOW REGULATOR SETS REGULATES THE FLOW OF I.V . FLUIDS FROM A INFUSION SET INTO A I.V CATHETER ,TRANSFUSION OR PERFUSION SETS FOR SINGLE USE (NIL)-1) INFUSION SET (WITH AIRVENT & NON VENTED) FOR SINGLE USE 2) INFUSION SET (MICRO WITH AIRVENT & MICRO NON VENTED) FOR SINGLE USE 3) INFUSION SET (PREMIUM WITH AIRVENT & PREMIUM NON VENTED) FOR SINGLE USE 4) BLOOD TRANSFUSION SET (WITH AIRVENT & NON VENTED) FOR SINGLE USE 5) INFUSION SET WITH 0.2 MICRONS IN LINE FILTER WITH AIR VENT FOR SINGLE USE 6) INFUSION SET NON –DEHP(VENTE& NON VENTED) FOR SINGLE USE

3406	MFG/MD/2020/000047	1.License Holder Name: SYSKO ASIA HEALTHCARES PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:THREE WAY STOPCOCK AS AN ACCESSORY TO PERFUSION SETS-RED,BLUE AND WHITE HANDLE(SYSKO)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MONITORING., 3-WAY STOP COCK WITH EXTENSION TUBE (SYSKO)-3-WAY STOP COCK WITH EXTENSION TUBE IS TO BE USED WITH ANY OF THE VARIOUS INFUSION OR TRANSFUSION DEVICES IN ORDER TO ALLOW FOR ATTACHMENT WITH ANY SPECIAL OR GENERAL PURPOSE MEDICAL DEVICE, IN ORDER TO IMPROVE EASE OF USE ALSO TO PROVIDE AN ALTERNATIVE CHANNEL FOR INTRODUCTION OF MEDICINE TO THE PATIENT,RYLES TUBE(SYSKO)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE.IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,NELATON CATHETER/URETHRAL CATHETER/FEMALE CATHETER(SYSKO)-THE NELATON & FEMALE CATHETERS & URETHRAL HAVE BEEN DESIGNED FOR SHORT TERM BLADDER CATHETERIZATION THROUGH URETHRA IN MALES. THIS PRODUCT IS MANUFACTURED FROM NON-TOXIC, NON-IRRITANT PVC. UNIVERSAL FUNNEL SHAPE CONNECTOR FOR EASY CONNECTING TO URINE BAG. NELATON CATHETERS ARE GENERALLY USED IN MALE PATIENTS WHILE FEMALE CATHETERS ARE USED IN FEMALE PATIENTS,FEEDING TUBE(INFANT FEEDING SET) (SYSKO)-A FEEDING TUBE IS A DEVICE THATS INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. ITS USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,MUCOUS EXTRACTOR (SYSKO)-MUCOUS EXTRACTOR IS USED FOR COLLECTION OF MUCUS FROM PATIENTS. THE PRODUCT IS STERILIZED USING EO (ETHYLENE OXIDE) GAS AND PYROGEN-FREE, SUCTION TIP AND CATHETER(SUCTION CATHETER)-SUCTION PLAIN, WITH FINGER TIP CONTROL AND WITH THUMB CONTROL(SYSKO)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., EXTENSION TUBE (SYSKO)-EXTENSION TUBE TO CONNECTION AND EXTENSION INFUSION OR TRANSFUSION SETS FOR ADMINISTRATION LIQUIDS OR BLOOD INTO THE CIRCULATION SYSTEM BY USING OF INTRAVENOUS CATHETER AND CANNULA,TRANSFUSION SETS FOR SINGLE USE(BLOOD TRANSFUSION SET)-VENTED/NON VENTED (SYSKO)-TRANSFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,I.V FLOW REGULATOR (SYSKO)-FLOW REGULATOR LINE IS AN INFUSION ACCESSORY WITH

	REQUIRED CONNECTORS AT ITS END TO HELP IT GET CONNECTED IN AN INFUSION CIRCUIT. IT IS USED TO CONTROL PRECISELY THE FLOW OF INFUSION FLUID UP TO 250 ML/ HR. IT HAS CIRCULAR SCALE WITH GRADUATIONS FOR SETTING A DESIRED FLOW RATE. THIS CAN BE FITTED WITH A Y- INJECTION SITE FOR EXTRA MEDICATIONS,CLOSED WOUND DRAINAGE SYSTEM(CLOSED WOUND SUCTION SET)(SYSKO)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND.THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGIST.,NEBULIZER MASK (SYSKO)-THE NEBULIZER COMPRESSOR SYSTEM IS INTENDED TO PROVIDE AIR TO THE PNEUMATIC NEBULIZER IN ORDER TO AEROSOLIZE MEDICATIONS FOR INHALATION BY THE PATIENT FOR RESPIRATORY DISORDERS. THE SYSTEM IS DESIGNED FOR USE WITH PEDIATRIC (DEFINED BY THE PRESCRIBED MEDICATION) AND ADULT PATIENTS IN THE HOME, HOSPITAL, AND SUB-ACUTE SETTINGS, SUCTION TIP AND CATHETER(YANKAUER SET)(SYSKO)-SUCTION CATHETERS(YANKAUER SET)FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., ENDOTRACHEAL TUBE (SYSKO)-THE DEVICE IS INTENDED FOR ORAL OR NASAL INTUBATIONS OR FOR AIRWAY MANAGEMENT. THE TRACHEAL TUBES ARE MADE FROM, MEDICAL GRADE PVC WITH A CONNECTOR AND VALVE. THE TRACHEAL TUBES MAY BE CUFFED OR UN-CUFFED AND ARE FOR NASAL OR ORAL USE,CLOSED WOUND DRAINAGE SYSTEM(THORACIC CATHETER SET)-STRAIGHT,ANGLED, TROCAR(SYSKO)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND.THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGIST.,ABDOMINAL DRAIN KIT (SYSKO)-ABDOMINAL DRAIN KIT IS USED FOR POST OPERATIVE ABDOMINAL DRAINAGE. IT IS ALSO USED FOR CHEST AND ABDOMINAL DRAINAGE OPERATION. THE NORMAL TYPE OF THIS DISPOSABLE OPERATION KIT INCLUDES THE FITTINGS AS BELOW. SOFT & SMOOTH CATHETER WITH LARGE A TRAUMATIC EYES FOR EFFICIENT DRAINAGE RADIO- OPAQUE LINE ON CATHETERS SPECIALLY DESIGNED HANDLE HOLDS TUBE UP RIGHT AND FACILITATES CARRYING ,(PERFUSION SETS FOR SINGLE USE)I.V INFUSION SET-VENTED/NON VENTED(SYSKO)-PERFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,MEASURED VOLUME IV SET(SYSKO)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,NASAL OXYGEN CATHETER(TWIN BORE NASAL OXYGEN CATHETER)-ADULT,PAEDIATRIC AND NEONATAL(SYSKO)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED

		AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.
3407	MFG/MD/2020/000048	1.License Holder Name: M/S SPECTRUM MED TECH PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:MANIFOLD(UNIWAY)-INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND PROVIDING ACCESS PORT/PORTS FOR ADMINISTRATION OF A SOLUTION.,EXTENSION SET(CLEARFLOW)-EXTENSION SET S ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR INFUSION OF FLUIDS/ MEDICATION IN MEDICAL APPLICATION.,GUIDE CATHETER(TRAVERSE)-THE GUIDE CATHETER PROVIDE SUPPORT FOR DEVICE ADVANCEMENT,Y-CONNECTOR (EASY PASS)-IT CAN USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION TO CONTRAST MEDIA ETC.,CONTROL DEVICE(PRECISE)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,ANGIO KIT(CUSTOMIZED PACK)-ANGIO KIT IS INTENDED TO USE DIFFERENT ACCESSORIES SPECIFIED KIT FOR USE DURING PTCA PROCEDURE.THE KIT IS MULTIPURPOSE AND EACH DEVICE HAS SPECIFIC USE DURING PROCEDURE., ANGIOGRAPHY NEEDLE, BLUNT INTRODUCER(PRIME)-ANGIOGRAPHIC NEEDLE HAS A UNIQUE HUB DESIGN WITH AN ERGONOMIC FEEL AND A BLACK TRIANGLE INDICATOR TO ORIENT THE BEVEL.,ANGIOGRAPHIC CATHETER (TRAVERSE)-DESIGNED TO PROVIDE A PATHWAY FOR DELIVERING CONTRAST MEDIA TO SELECTED SITES IN THE DEVICE VASCULAR SYSTEM INCLUDING THE CAROTID ARTERIES. ,BALLOON INFLATION DEVICE(MAC-20)-INFLATION DEVICE IS USED DURING ANGIOPLASTY PROCEDURE TO INFLATE AND DEFLATE THE BALLOON CATHETER ALSO CONTROL THE PRESSURE OF BALLOON CATHETER.
3408	MFG/MD/2020/000049	1.License Holder Name: HLL LIFECARE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:NON LUBRICATED MALE LATEX CONDOM-WHEN USED CORRECTLY EVERY TIME YOU HAVE SEX, CONDOMS GREATLY REDUCE THE RISK OF UNINTENDED PREGNANCY, HIV/AIDS AND SOME OTHER SEXUALLY TRANSMITTED INFECTIONS.

3409	MFG/MD/2020/000050	1.License Holder Name: MATRIX MEDITEC PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ARTHROSCOPY IMPLANTS-IN ARTHROSCOPY SURGERY, A SMALL FIBER OPTIC TELESCOPE (ARTHROSCOPE) IS INSERTED INTO A JOINT. IN ORDER TO VISUALIZE THE STRUCTURE WITHIN THAT JOINT, A FLUID IS INSERTED INTO THE JOINT TO DISTEND IT. WITH OUR IMPLANTS, WE ASSURE SAFETY AND REPRODUCIBILITY IN TECHNICALLY DEMANDING SURGICAL PROCEDURES. OUR DEVICES ARE DESIGNED FOR GRAFT HARVESTING, CRUCIATE AND MENISCAL RECONSTRUCTION AND REPAIR SYSTEMS, TUNNEL PREPARATION, IMPLANTS AS WELL AS MENISCAL ASSOCIATED ACCESSORIES.,BONE PLATES-ORTHOPEDIC IMPLANTS ARE INTENDED TO BE USED FOR THE INTERNAL FIXATION OF BONE FRACTURES AND BONE RECONSTRUCTION. THE USE OF PLATE IS INDICATED: - WHEN ANATOMICAL ALIGNMENT MUST BE RESTORED ACCURATELY. - WHERE THE USE OF SCREWS ALONE IS INADEQUATE. - WHEN LOAD SHARING MAY BE ACHIEVED WITH CONFIDENCE. IF THIS CANNOT BE GUARANTEED, THEN A BONE GRAFT MAY BE ADDED AT THE SITE OF ANY DEFICIT. THE AREAS OF THE BODY WHERE THE CONDITIONS DESCRIBED ABOVE ARISE COMMONLY ARE: - AROUND JOINTS – FAILURE TO RESTORE A JOINT SURFACE TO ITS NORMAL SHAPE MAY LEAD TO OSTEOARTHRITIS BECAUSE OF UNEVEN WEAR OF THE JOINT SURFACES. - IN THE BONE OF THE FOREARM WHICH ROTATES ABOUT EACH OTHER. - ON THE PELVIS ESPECIALLY AROUND THE ACETABULUM - ON THE FACE AND JAW.,PINS, WIRES, WASHERS & SPACERS-PINS: PINS ARE USED IN FIXATION OF FRACTURES WHERE MINIMAL BONE AND SOFT TISSUE DAMAGE ARE INVOLVED. PINS PROVIDE PROVISIONAL FIXATION LEAVING ROOM FOR ADDITIONAL HARDWARE PLACEMENT. THE PROVISIONAL FIXATION IS PLANNED TO AVOID FAULTY PERMANENT FIXATION. DEPENDING ON THE DIAMETER, PINS MAY ALSO BE USED AS GUIDEWIRES FOR CANNULATED SCREW FIXATION. WIRES: WIRES ARE USED IN THE FIXATION OF FRACTURES IN WHICH LOADING IS MINIMAL. WIRES ARE EASIER TO BEND, SO, ARE SUPPLEMENTED WITH OTHER IMMOBILIZATION DEVICES WHERE NECESSARY. PIN OR WIRE FIXATION IS MOSTLY USED FOR FRACTURES OF THE PHALANGES, METACARPALS, METATARSALS, PROXIMAL HUMERUS AND DISTAL HUMERUS. WASHERS: WASHERS ARE TO FUNCTION WITH SCREWS TO PREVENT THE SCREW HEAD FROM BREAKING THROUGH THE CORTEX OF THE BONE BY PROVIDING ADDITIONAL SURFACE AREA DURING SCREW PLACEMENT. SPACERS: TO REDUCE THE PLATE-TO-BONE CONTACT TO A MINIMUM, SCREW A SPACER IN THE PLATE BEFORE

	POSITIONING THE PLATE. THE SPACER ENSURES THAT A DISTANCE OF 2 MM WILL BE MAINTAINED BETWEEN THE PLATES AND THE BONE WHEN THE SCREWS ARE LATER INSERTED. THE SPACER CAN BE REMOVED AFTER SETTING THE LOCKING SCREWS.,INTRAMEDULLARY NAILS (IM NAILS)-THE INTRAMEDULLARY NAIL SYSTEM IS INTENDED FOR SURGICAL MANAGEMENT OF FEMORAL AND TIBIAL FRACTURES INCLUDING OPEN AND CLOSED FRACTURES, PSEUDARTHROSIS AND CORRECTION OSTEOTOMY, PATHOLOGIC FRACTURES, IMPENDING PATHOLOGIC FRACTURES, TUMOR RESECTIONS, NONUNIONS AND MALUNIONS. THE HIP NAILS MAY BE USED FOR BASILAR NECK, SUBTROCHANTERIC AND INTERTROCHANTERIC FRACTURES. THE FEMORAL NAILS MAY BE USED FOR FRACTURES OF THE FEMUR BELOW THE HIP JOINT INCLUDING IPSILATERAL FEMUR FRACTURES, FRACTURES PROXIMAL TO A TOTAL KNEE ARTHROPLASTY AND SUPRACONDYLAR FRACTURES, INCLUDING THOSE WITH INTRAARTICULAR EXTENSION.,PINS, WIRES, WASHERS & SPACERS-PINS: PINS ARE USED IN FIXATION OF FRACTURES WHERE MINIMAL BONE AND SOFT TISSUE DAMAGE ARE INVOLVED. PINS PROVIDE PROVISIONAL FIXATION LEAVING ROOM FOR ADDITIONAL HARDWARE PLACEMENT. THE PROVISIONAL FIXATION IS PLANNED TO AVOID FAULTY PERMANENT FIXATION. DEPENDING ON THE DIAMETER, PINS MAY ALSO BE USED AS GUIDEWIRES FOR CANNULATED SCREW FIXATION. WIRES: WIRES ARE USED IN THE FIXATION OF FRACTURES IN WHICH LOADING IS MINIMAL. WIRES ARE EASIER TO BEND, SO, ARE SUPPLEMENTED WITH OTHER IMMOBILIZATION DEVICES WHERE NECESSARY. PIN OR WIRE FIXATION IS MOSTLY USED FOR FRACTURES OF THE PHALANGES, METACARPALS, METATARSALS, PROXIMAL HUMERUS AND DISTAL HUMERUS. WASHERS: WASHERS ARE TO FUNCTION WITH SCREWS TO PREVENT THE SCREW HEAD FROM BREAKING THROUGH THE CORTEX OF THE BONE BY PROVIDING ADDITIONAL SURFACE AREA DURING SCREW PLACEMENT. SPACERS: TO REDUCE THE PLATE-TO-BONE CONTACT TO A MINIMUM, SCREW A SPACER IN THE PLATE BEFORE POSITIONING THE PLATE. THE SPACER ENSURES THAT A DISTANCE OF 2 MM WILL BE MAINTAINED BETWEEN THE PLATES AND THE BONE WHEN THE SCREWS ARE LATER INSERTED. THE SPACER CAN BE REMOVED AFTER SETTING THE LOCKING SCREWS.,SPINAL IMPLANTS-SPINAL IMPLANTS ARE BASICALLY INDICATED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THORACIC, LUMBAR, AND SACRAL SPINE: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE

	DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION.,BONE PLATES-ORTHOPEDIC IMPLANTS ARE INTENDED TO BE USED FOR THE INTERNAL FIXATION OF BONE FRACTURES AND BONE RECONSTRUCTION. THE USE OF PLATE IS INDICATED: - WHEN ANATOMICAL ALIGNMENT MUST BE RESTORED ACCURATELY. - WHERE THE USE OF SCREWS ALONE IS INADEQUATE. - WHEN LOAD SHARING MAY BE ACHIEVED WITH CONFIDENCE. IF THIS CANNOT BE GUARANTEED, THEN A BONE GRAFT MAY BE ADDED AT THE SITE OF ANY DEFICIT. THE AREAS OF THE BODY WHERE THE CONDITIONS DESCRIBED ABOVE ARISE COMMONLY ARE: - AROUND JOINTS – FAILURE TO RESTORE A JOINT SURFACE TO ITS NORMAL SHAPE MAY LEAD TO OSTEOARTHRITIS BECAUSE OF UNEVEN WEAR OF THE JOINT SURFACES. - IN THE BONE OF THE FOREARM WHICH ROTATES ABOUT EACH OTHER. - ON THE PELVIS ESPECIALLY AROUND THE ACETABULUM - ON THE FACE AND JAW.,INTRAMEDULLARY NAILS (IM NAILS)-THE INTRAMEDULLARY NAIL SYSTEM IS INTENDED FOR SURGICAL MANAGEMENT OF FEMORAL AND TIBIAL FRACTURES INCLUDING OPEN AND CLOSED FRACTURES, PSEUDARTHROSIS AND CORRECTION OSTEOTOMY, PATHOLOGIC FRACTURES, IMPENDING PATHOLOGIC FRACTURES, TUMOR RESECTIONS, NONUNIONS AND MALUNIONS. THE HIP NAILS MAY BE USED FOR BASILAR NECK, SUBTROCHANTERIC AND INTERTROCHANTERIC FRACTURES. THE FEMORAL NAILS MAY BE USED FOR FRACTURES OF THE FEMUR BELOW THE HIP JOINT INCLUDING IPSILATERAL FEMUR FRACTURES, FRACTURES PROXIMAL TO A TOTAL KNEE ARTHROPLASTY AND SUPRACONDYLAR FRACTURES, INCLUDING THOSE WITH INTRAARTICULAR EXTENSION.,ARTHROSCOPY IMPLANTS-IN ARTHROSCOPY SURGERY, A SMALL FIBER OPTIC TELESCOPE (ARTHROSCOPE) IS INSERTED INTO A JOINT. IN ORDER TO VISUALIZE THE STRUCTURE WITHIN THAT JOINT, A FLUID IS INSERTED INTO THE JOINT TO DISTEND IT. WITH OUR IMPLANTS, WE ASSURE SAFETY AND REPRODUCIBILITY IN TECHNICALLY DEMANDING SURGICAL PROCEDURES. OUR DEVICES ARE DESIGNED FOR GRAFT HARVESTING, CRUCIATE AND MENISCAL RECONSTRUCTION AND REPAIR SYSTEMS, TUNNEL PREPARATION, IMPLANTS AS WELL AS MENISCAL ASSOCIATED ACCESSORIES.,MAXILLOFACIAL IMPLANTS-ORTHOPEDIC IMPLANTS ARE INTENDED TO BE USED FOR THE INTERNAL FIXATION OF BONE FRACTURES AND BONE RECONSTRUCTION. MAXILLOFACIAL SYSTEM ARE IMPLANTABLE BONE PLATES AND BONE SCREWS FOR ORAL AND MAXILLOFACIAL PROCEDURES INCLUDING FRACTURES, OSTEOTOMNIES,

	ORTHOGNATHIC, RECONSTRUCTIVE PROCEDURES AND REVISIONS PROCEDURES WHEN OTHER TREATMENTS OF DEVICES HAVE FAILED. SURGICAL LOCATIONS FOR DEVICE PLACEMENT INCLUDE FRACTURE AND RECONSTRUCTION SITES IN THE MANDIBLE, MAXILLA, ZYCOMNATIC BONE AND ORBITAL SOCKET.,SPINAL IMPLANTS-SPINAL IMPLANTS ARE BASICALLY INDICATED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THORACIC, LUMBAR, AND SACRAL SPINE: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION.,MAXILLOFACIAL IMPLANTS-ORTHOPEDIC IMPLANTS ARE INTENDED TO BE USED FOR THE INTERNAL FIXATION OF BONE FRACTURES AND BONE RECONSTRUCTION. MAXILLOFACIAL SYSTEM ARE IMPLANTABLE BONE PLATES AND BONE SCREWS FOR ORAL AND MAXILLOFACIAL PROCEDURES INCLUDING FRACTURES, OSTEOTOMNIES, ORTHOGNATHIC, RECONSTRUCTIVE PROCEDURES AND REVISIONS PROCEDURES WHEN OTHER TREATMENTS OF DEVICES HAVE FAILED. SURGICAL LOCATIONS FOR DEVICE PLACEMENT INCLUDE FRACTURE AND RECONSTRUCTION SITES IN THE MANDIBLE, MAXILLA, ZYCOMNATIC BONE AND ORBITAL SOCKET.,BONE SCREWS-ORTHOPEDIC IMPLANTS ARE INTENDED TO BE USED FOR THE INTERNAL FIXATION OF BONE FRACTURES AND BONE RECONSTRUCTION. BONE SCREWS ARE INTENDED FOR LONG AND SMALL BONE FRACTURE FIXATION. METALLIC BONE SCREWS ARE INTERNAL SUPPORT, WHICH TEMPORARILY ALIGN THE FRACTURE UNTIL BONY FUSION OCCURS.,BONE SCREWS-ORTHOPEDIC IMPLANTS ARE INTENDED TO BE USED FOR THE INTERNAL FIXATION OF BONE FRACTURES AND BONE RECONSTRUCTION. BONE SCREWS ARE INTENDED FOR LONG AND SMALL BONE FRACTURE FIXATION. METALLIC BONE SCREWS ARE INTERNAL SUPPORT, WHICH TEMPORARILY ALIGN THE FRACTURE UNTIL BONY FUSION OCCURS.

3410	MFG/MD/2020/000051	1.License Holder Name: M/S. MERIL ENDO SURGERY PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:POLYMER LIGATING CLIP (MYCLIP™)-LIGATING CLIP IS INTENDED TO SECURELY GRIP THE VESSEL OR TISSUE TO PROVIDE COMPLETE OCCLUSION ATRAUMATICALLY.,LIGATING CLIP(MIRUS™)-LIGATING CLIP IS INTENDED TO SECURELY GRIP THE VESSEL OR TISSUE TO PROVIDE COMPLETE OCCLUSION ATRAUMATICALLY.,CU 250 SLEEK STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICES(MERITE™ CU 250 SLEEK / U-KARE® CU 250 SLEEK)-INDICATED FOR INTRAUTERINE CONTRACEPTION,CU 375 SLEEK STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICES(MERITE™ CU 375 SLEEK)-INDICATED FOR INTRAUTERINE CONTRACEPTION,CU 250 STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICE(MERITE™ CU 250)-INDICATED FOR INTRAUTERINE CONTRACEPTION,CU T 380 A STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICES(MERITE™ CU T 380 A /KHUSHI™ CU T 380 A / PRIMA™ CU T 380A / ENOVA™ CU T 380A /TIUP™ CU T 380A)-INDICATED FOR INTRAUTERINE CONTRACEPTION.,CU 375 STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICE(MERITE™ CU 375 / KHUSHI™ CU 375 / INTIMA™ CU 375 / TIUP™ A CU 375 / FREEDOM5™ CU 375/PRIMA™ CU 375)-INDICATED FOR INTRAUTERINE CONTRACEPTION

3411	MFG/MD/2020/000052	1.License Holder Name: PARSHWA CORPORATION 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATES-BONE PLATE ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE., BONE SCREW-BONE SCREW IS INTENDED FOR FIXATION OF FRACTURES, OSTEOTOMIES, AND NON-UNIONS OF THE CLAVICLE, SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, TIBIA, AND FIBULA, INCLUDING PERIARTICULAR AND INTRAARTICULAR FRACTURES.,BONE PLATE-BONE PLATE ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,SPINE IMPLANTS-A SPINE IMPLANT IS A MEDICAL DEVICE MANUFACTURED TO REPLACE A MISSING JOINT OR SPINE BONE OR TO SUPPORT A DAMAGED SPINE BONE.,SPINE IMPLANTS- A SPINE IMPLANT IS A MEDICAL DEVICE MANUFACTURED TO REPLACE A MISSING JOINT OR SPINE BONE OR TO SUPPORT A DAMAGED SPINE BONE.
3412	MFG/MD/2020/000053	1.License Holder Name: ACTION MEDICAL MARKETING PVT.LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:INTRAOCULAR LENS HYDROPHILIC FOLDABLE(HYDROPHILEX)-REPLACEMENT OF CATARACT AFFECTED NATURAL LENS,INTRAOCULAR LENS HYDROPHILIC FOLDABLE(UFOLD)-REPLACEMENT OF CATARACT AFFECTED NATURAL LENS,INTRAOCULAR LENS PMMA (POLY METHYL METHA ACRYLATE)(3D)-REPLACEMENT OF CATARACT AFFECTED NATURAL LENS,INTRAOCULAR LENS HYDROPHOBIC FOLDABLE(ACTIONFOLD)-REPLACEMENT OF CATARACT AFFECTED NATURAL LENS,INTRAOCULAR LENS PMMA (POLY METHYL METHA ACRYLATE)(ENVISION)-REPLACEMENT OF CATARACT AFFECTED NATURAL LENS

3413	MFG/MD/2020/000054	1.License Holder Name: GEN WORLD MEDICAL DEVICES 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:THREE WAY EXTENSION (GWMD)-THREE WAY STOP COCK WITH EXTENSION LINE IS INTENDED TO BE USED AS A PART OF SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATIONS IN MEDICAL APPLICATION.,PM O LINE(GWMD)-SUITABLE FOR HIGH PRESSURE MONITORING AND FOR CONNECTION BETWEEN SYRINGE INFUSION PUMP AND PATIENT. ,ARTERIAL FILTER WITH BYPASS LOOP(GWMD)-USED IN CARDIOPULMONARY BYPASS TO REMOVE BLOCKAGES ORIGINATION IN THE PERFUSION CIRCUIT., HEART LUNG PACK(GWMD)-SURGICAL PROCEDURE REQUIRING EXTRA CORPOREAL SUPPORT FOR PERIOD UPTO SIX HOURS.
3414	MFG/MD/2020/000055	1.License Holder Name: AMAR SURGICARE PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ABSORBENT GAUZE SWAB (- - -)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,PU FOAM / POLYURETHANES FOAM(- - -)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,ABSORBENT GAUZE CLOTH (SCH F(II)(- - -)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES. ,COTTON GAMJEE ROLL(- - -)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES., ABDOMINAL PAD WITH X-RAY DETECTABLE THREAD(GAUZE TOUCH)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.
3415	MFG/MD/2020/000056	1.License Holder Name: SPECTRUM MEDTECH PVT. LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ANGIO KIT(CUSTOMIZED PACK)-ANGIO KIT IS INTENDED TO USE DIFFERENT ACCESSORIES SPECIFIED KIT FOR USE DURING PTCA PROCEDURE. THE KIT IS MULTIPURPOSE AND EACH DEVICE HAS SPECIFIC USE DURING PROCEDURE.,BALLOON INFLATION DEVICE (EMINENCE, MAC-20)-INFLATION DEVICE IS USED DURING ANGIOPLASTY PROCEDURE TO INFLATE AND DEFLATE THE BALLOON CATHETER ALSO CONTROL THE PRESSURE OF BALLOON CATHETER.

3416	MFG/MD/2020/000057	1.License Holder Name: M/S ST. STONE MEDICAL DEVICES PRIVATE LIMITED 2.Approving Authority: MANIPUR 3.Device Name(Brand Name)-Intended Use:EPIDURAL NEEDLE & KIT (MERCURY+)-INTENDED FOR TRANSIENT DELIVERY OF ANASTHETICS TO PROVIDE REGIONAL ANESTHESIA OR TO FACILITATE PLACEMENT OF AN EPIDURAL CATHETER,HEMODIALYSIS CATHETER(SHINECATH / PLATICATH)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENTS, PERFUSION SET (IV SET)(STARSET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., PRESSURE MONITORING LINE(STARKIT)-THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUID/MEDICATIONS IN MEDICAL APPLICATION,HEMODIALYSIS CATHETER KIT(PLATINUM PLUS)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENTS,AV FISTULA NEEDLE(STARFIST)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT,INTRODUCER NEEDLE(MERCURY+)-ANGIOGRAPHIC NEEDLE HAS A UNIQUE HUB DESIGN WITH AN ERGONOMIC FEEL AND A BLACK TRIANGLE INDICATOR TO ORIENT THE BEVEL. ,BIOPSY NEEDLE(MERCURY +)-THE GROWTH SAMPLE IS SUCTIONED OUT THROUGH A NEEDLE OR CUT OUT USING A SURGICAL PROCEDURE,CONTROL SYRINGE(STARKIT)-USED FOR EITHER LAPAROSCOPIC ASPIRATION OR INJECTION ,EXTENSION LINE (STARKIT)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, UROLOGY CATHETER(UROSTAR)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY,BLOODLINE(STARLINE)-INTEND USE ARE DISPOSABLE BLOODLINES INTENDED TO PROVIDE EXTRACORPOREAL ACCESS TO THE PATIENT’S BLOOD DURING HEMODIALYSIS THERAPY.,HIGH PRESSURE LINE(STARKIT)-THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUID/MEDICATIONS IN MEDICAL APPLICATION,SPINAL NEEDLE (MERCURY+)-THE PROPOSED DEVICES ARE INTENDED FOR THE INJECTION OF MEDICATIONS INTO OR THE WITHDRAWAL OF BODY FLUIDS FROM PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN,MANIFOLD (STARKIT)-INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT /PORTS FOR ADMINISTRATION OF A SOLUTION.

3417	MFG/MD/2020/000058	1.License Holder Name: MEDTECH LIFE PVT. LTD. 2.Approving Authority: DAMAN AND DIU 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITOR(NOVACHECK®)-THE BLOOD PRESSURE MONITOR IS FOR USE BY MEDICAL PROFESSIONALS, OPERATOR OR AT HOME AND IS A NON-INVASIVE BLOOD PRESSURE MEASUREMENT SYSTEM INTENDED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES AND PULSE RATE OF AN ADULT INDIVIDUAL BY USING A NON-INVASIVE TECHNIQUE IN WHICH AN INFLATABLE CUFF IS WRAPPED AROUND THE ARM.,DIGITAL THERMOMETER-THE DEVICE IS USED FOR MEASUREMENT OF BODY TEMPERATURE.
3418	MFG/MD/2020/000059	1.License Holder Name: MIL LABORATORIES PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ABSORBABLE HEMOSTAT FOR SURGICAL DRESSINGS(NEMIGEN)-NEMIGEN IS INDICATED FOR HEALING OF WOUNDS OF DIFFERENT ETIOLOGIES LIKE- VENOUS LEG ULCERS, ARTERIAL ULCERS, PRESSURE ULCERS, DIABETIC FOOT ULCERS, AND BURNS
3419	MFG/MD/2020/000060	1.License Holder Name: SHRIRAM INSTITUTE OF INDUSTRIAL RESEARCH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ORTHOPAEDIC IMPLANT (KAUSHIK)-AN ORTHOPEDIC IMPLANT IS A MEDICAL DEVICE MANUFACTURED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE.
3420	MFG/MD/2020/000061	1.License Holder Name: SHRI RAM INSTITUTE FOR THE INDUSTRIAL RESEARCH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:DENTAL IMPLANT(XCEM IMPLANT)-A DENTAL IMPLANT IS A SURGICAL COMPONENT THE INTERFACES WITH THE BONE OF THE JAW OR SKULL TO SUPPORT A DENTAL PROSTHESIS SUCH AS CROWN BRIDGE, DENTURE, FACIAL PROSTHESIS OR TO ACT AS AN ORTHODONTIC ANCHOR

3421	MFG/MD/2020/000062	1.License Holder Name: A V PROCESSORS PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NON ABSORBABLE SURGICAL SUTURE U.S.P.(ETHIBOND* EXCEL)-ETHIBOND* EXCEL SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROSURGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P. (ETHICON*)-SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROSURGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P. (MERSILENE*)-MERSILENE* SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC, AND EUROLOGICAL PROCEDURES, AND ALSO FOR THE FIXATION OF SOFT TISSUE TO BONE TISSUE.,NON ABSORBABLE SURGICAL SUTURE U.S. P.(ETHICON*)-THIS SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPTHALMIC AND NEUROSURGICAL PROCEDURES,NON ABSORBABLE SURGICAL SUTURE U.S.P. (ETHISTEEL*)-STAINLESS STEEL SUTURES ARE FOR USE IN ABDOMINAL WOUND CLOSURE, HERNIA REPAIR, STERNAL CLOSURE AND ORTHOPEDIC PROCEDURES INCLUDING CERCLAGE AND TENDON REPAIR.,STERILISED POLYESTER FIBRE TAPE(MERSILENE*)-MERSILENE* TAPE IS INDICATED FOR CIRCULAR SUTURE OF THE CERVIX. NON-NEEDLED TAPES ARE USED AS RETRACTION AND/OR FIXING TAPE DURING SURGERY.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC)(VICRYL* RAPIDE)-VICRYL* RAPIDE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO ITS ABSORPTION PROFILE VICRYL* RAPIDE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PAEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. VICRYL* RAPIDE IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES.,NON ABSORBABLE SURGICAL SUTURE U.S. P.(ETHILON*)-ETHILON* SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPTHALMIC AND NEUROSURGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P. (MERSILK*/ETHICON*)-SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,

		INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROSURGICAL PROCEDURES.
3422	MFG/MD/2020/000063	1.License Holder Name: SCEPTRE MEDICAL DEVICES PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER(REIN, JETFLOW, JETLITE)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS , BLOOD SAMPLING, CENTRAL VENOUS CATHETER, PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA,INTRODUCER SHEATH(REIN, JETFLOW, JETLITE)-INTENDED TO PROVIDE EASIER ACCESS TO THE FEMORAL, POPLITEAL AND INFRAPOPLITEAL ARTERIES, HEMODIALYSIS CATHETER (LONG TERM)(REIN, JETFLOW , JETLITE)-A DIALYSIS CATHETER IS A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT.THE DIALYSIS CATHETER CONTAINS TWO LUMENS : VENOUS ARTERIAL

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3423	MFG/MD/2020/000064	1.License Holder Name: ISCON SURGICALS LIMITED 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:STERILE HYPODERMIC AUTO DISABLE SYRINGE FOR SINGLE USE [ISO 7886-3:2005] (PRICON)-INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY AND FOR VACCINATION,STERILE HYPODERMIC SYRING WITH ATTACHED NEEDLE, FOR SINGLE USE(BENESPHERA)-HYPODERMIC SYRINGE IS USED WITH HYPODERMIC NEEDLE TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY.,INFUSION SET FOR SINGLE USE (INFUSION EQUIPMENT FOR MEDICAL USE) [IS 12655 (PART-4):2003, ISO 8536-4](PRICON)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE HYPODERMIC NEEDLE FOR SINGLE USE(WINJECT)-HYPODERMIC NEEDLE IS USED WITH HYPODERMIC SYRINGE TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY,STERILE HYPODERMIC SYRINGE FOR SINGLE USE [IS 10258:2002](PRICON)-INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,STERILE HYPODERMIC SYRINGE WITH ATTACHED NEEDLE FOR SINGLE USE (CROWN)-HYPODERMIC SYRINGE IS USED WITH HYPODERMIC NEEDLE TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY.,SPINAL NEEDLE FOR SINGLE USE [JIS T 3308:2006, IN HOUSE SPECIFICATION](PRICON)-SPINAL NEEDLES ARE USED TO INJECT ANALGESIA AND/OR ANAESTHETIC DIRECTLY INTO THE CSF USUALLY AT A POINT BELOW THE SECOND LUMBAR VERTEBRA.,STERILE HYPODERMIC SYRING FOR SINGLE USE (CROWN)-HYPODERMIC SYRINGE IS USED WITH HYPODERMIC NEEDLE TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY,SCALP VEIN (WINGED NEEDLE) INFUSION SET [ISO 8536-4:2004](PRICON)-SCALP VEIN SET IS INTENDED TO BE USED FOR INSERTION INTO THE PATIENTS VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD., STERILE HYPODERMIC SYRINGE FOR SINGLE USE(WINJECT)-HYPODERMIC SYRINGE IS USED WITH HYPODERMIC NEEDLE TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY,STERILE HYPODERMIC NEEDLE FOR SINGLE USE [IS 10654:2002](PRICON)-INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY WITH HELP OF DISPOSABLE SYRINGE,STERILE HYPODERMIC NEEDLE FOR SINGLE USE(CROWN)-HYPODERMIC NEEDLE IS USED WITH HYPODERMIC SYRINGE TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY,STERILE HYPODERMIC SYRINGE WITH

	NEEDLE ATTACH FOR SINGLE USE [IS 12050:1996](PRICON)-INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,SPINAL ANESTHESIA NEEDLE (ONE PLUS)-SPINAL NEEDLE IS USED WITH A SYRINGE TO INJECT ANESTHESIA MEDICINE BY SPINAL ROUTE,STERILE HYPODERMIC MULTI SAMPLE BLOOD COLLECTING NEEDLES FOR DINGLE USE [IS 10654] [ISO 13485](PRICON)-MULTI-SAMPLE BLOOD COLLECTION NEEDLES PERMIT SEVERAL SAMPLES TO BE TAKEN WITH A SINGLE PUNCTURE. SHARP, SMOOTH EDGES HELP REDUCE PAIN UPON PENETRATION, AND PROVIDE EASY CONNECTION TO RUBBER STOPPERS.,STERILE HYPODERMIC NEEDLE FOR SINGLE USE(BENESPHERA)-HYPODERMIC NEEDLE IS USED WITH HYPODERMIC SYRINGE TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY.,STERILE HYPODERMIC SYRINGE FOR SINGLE USE - AUTO DISABLE SYRINGES FOR FIXED DOSE IMMUNIZATION [IS 10258-3], [ISO 7886-3](PRICON)-SYRINGES WITH AUTO DISABLE IS A RE-USE PREVENTION FEATURE CAN MEASURE FLEXIBLE DOSING AMOUNTS, HAVE REMOVABLE NEEDLES AND A FEATURE THAT BLOCKS THE SYRINGE FROM BEING USED A SECOND TIME. THESE ARE IDEAL FOR FIXED DOSE IMMUNIZATION.,STERILE HYPODERMIC NEEDLE FOR SINGLE USE(CUSAFE)-HYPODERMIC NEEDLE IS USED WITH HYPODERMIC SYRINGE TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY.,STERILE HYPODERMIC SYRINGES FOR SINGLE USE WITH RE-USE PREVENTION FEATURE [IS 10258-3 ; ISO 7886-4](PRISAFE)-RE-USE PREVENTION FEATURE INCLUDES SYRINGES THAT CAN MEASURE FLEXIBLE DOSING AMOUNTS, AND BLOCKS THE SYRINGE FROM BEING USED A SECOND TIME.,INFUSION SETS FOR SINGLE USE (MICRO DRIP SET) - VENTED OR NON-VENTED [IS 12655-4](PRICON)-INFUSION OF MEDICATION, ADMINISTRATION OF DRUG SOLUTIONS/ FLUIDS, NUTRITIONAL FLUIDS ETC. FOR PAEDIATRIC USE.,STERILE HYPODERMIC SYRINGES FOR SINGLE USE-AUTO DISABLE SYRINGES FOR FIXED DOSE IMMUNIZATION [IS 10258-3 ; ISO 7886-3](PRISAFE)-AUTO DISABLE SYRINGES ARE USED TO INJECT A FIXED DOSE OF LIQUID INTO BODY TISSUES, WITH RE-USE PRETENSION FEATURE.,STERILE SINGLE USE SYRINGE, WITH OR WITHOUT NEEDLE , FOR INSULIN [IS 12227; ISO 8537](PRISAFE)-HYPODERMIC SYRINGES ARE USED WITH HYPODERMIC NEEDLES TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY.,INFUSION SETS FOR SINGLE USE, GRAVITY FEED (VENTED, NON-VENTED) [IS 12655-4 ; ISO 8536-4](PRISAFE)-INFUSION SET IS INDENTED FOR ADMINISTRATION OF SALINE SOLUTION OR OR OTHER IV FLUIDS, MEDICINE TO A PATIENT / UNCONSCIOUS PATIENT THROUGH INTRAVENOUS ROUTE.,STERILE HYPODERMIC SYRINGE WITH NEEDLE ATTACHED FOR SINGLE USE [IS

		12050; ISO 7886] (PRISAFE)-HYPODERMIC SYRINGE IS USED WITH HYPODERMIC NEEDLE TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY.,SPINAL ANESTHESIA NEEDLE [IS 7350](PRISAFE)-THESE NEEDLES ARE USED TO ADMINISTER SPINAL ANESTHETICS.,STERILE HYPODERMIC NEEDLES FOR SINGLE USE [IS 10654 ; ISO 7864](PRISAFE)-HYPODERMIC NEEDLES ARE USED WITH HYPODERMIC SYRINGE TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY.,STERILE SCALP VEIN SET (WINGED NEEDLE) [IS 16097] (PRISAFE)-SCALP VEIN SET IS INTENDED FOR CONNECTING TO A INFUSION SET FOR ADMINISTRATION OF INFUSION /MEDICATION WITH EASY HANDLING.,STERILE SINGLE-USE SYRINGE, WITH OR WITHOUT NEEDLE FOR INSULIN(PRICON)-INSULIN SYRINGES ARE USED WITH HYPODERMIC NEEDLES TO ADMINISTRATION OF SUBCUTANEOUS INJECTION OF INSULIN INTO BODY TISSUES FOR DIABETES MANAGEMENT,SPINAL ANESTHESIA NEEDLE [IS 7350](-)-PRICON SPINAL NEEDLE IS A SINGLE USE DISPOSABLE CANNULA INTENDED FOR THE INJECTION OF FLUID INTO OR ASPIRATION OF FLUID FROM THE BODY. SPINAL NEEDLES ARE USED FOR SINGLE SHOT SPINAL ANESTHESIA AND FOR LUMBAR PUNCTURE FOR DIAGNOSTIC PURPOSE.,STERILE HYPODERMIC SYRINGE WITH NEEDLE ATTACHED FOR SINGLE USE(PRICON)-HYPODERMIC SYRINGE IS USED WITH HYPODERMIC NEEDLE TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY., STERILE HYPODERMIC SYRINGE WITH NEEDLE ATTACHED FOR SINGLE USE [IS 12050](PRICON)-HYPODERMIC SYRINGE IS USED WITH HYPODERMIC NEEDLE TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY.,INFUSION SETS FOR SINGLE USE-GRAVITY FEED -VENTED, NON-VENTED [IS 12655-4] [ISO 8536-4](PRICON)-INFUSION OF MEDICATION, ADMINISTRATION OF DRUG SOLUTIONS/ FLUIDS, NUTRITIONAL FLUIDS ETC.,STERILE HYPODERMIC SYRINGE FOR SINGLE USE [IS 10258; ISO 7886-1] (PRISAFE)-HYPODERMIC SYRINGE IS USED WITH HYPODERMIC NEEDLE TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY.
3424	MFG/MD/2020/000066	1.License Holder Name: SJD SURGICOT PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.-MEDICAL ABSORBENT (FIBRE BANDAGES)

3425	MFG/MD/2020/000067	1.License Holder Name: SPECTRUM MED TECH PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ANGIOGRAPHY NEEDLE AND BLUNT INTRODUCER-ANGIOGRAPHIC NEEDLE HAS A UNIQUE HUB DESIGN WITH AN ERGONOMIC FEEL AND A BLACK. TRIANGLE INDICATOR TO ORIENT THE BEVEL. ,MANIFOLD-INDICATED FOR FLUID FLOW DIRECTION CONTROL AND FOR PROVIDING ACCESS PORT/PORTS FOR ADMINISTRATION OF A SOLUTION. ,CONTROL DEVICE -INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FORM THE BODY. ,ANGIOGRAPHIC CATHETER -DESIGNED TO PROVIDE PATHWAY FOR DELIVERING CONTRAST MEDIA TO SELECTED SITES IN THE DEVICE VASCULAR SYSTEM INCLUDING THE CAROTID ARTERIES. ,Y- CONNECTOR -IT CAN USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC.,ANGIO KIT-ANGIO KIT IS INTENDED TO USE DIFFERENT ACCESSORIES SPECIFIED KIT FOR USE DURING PTCA PROCEDURE. THE KIT IS MULTIPURPOSE AND EACH DEVICE HAS SPECIFIC USE DURING PROCEDURE. ,BALLOON INFLATION DEVICE -INFLATION DEVICE IS USED DURING ANGIOPLASTY PROCEDURE TO INFLATE AND DEFLATE THE BALLOON CATHETER ALSO CONTROL THE PRESSURE OF BALLOON CATHETER.,GUIDING CATHETER -THE GUIDE CATHETER PROVIDE SUPPORT FOR DEVICE ADVANCEMENT. ,EXTENSION SET -ENTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATION IN MEDICAL APPLICATION.
3426	MFG/MD/2020/000068	1.License Holder Name: MIL LABORATORIES PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:HYDROFIBER DRESSING, HYDROFIBER DRESSING WITH SILVER, COLLAGEN WOUND MATRIX, SEMIPERMEABLE WATERPROOF TRANSPARENT DRESSING WITH SILVER, HEMOSTATIC PRESSURE BANDAGES, NASAL DRESSING (NA)-INDICATED FOR ACUTE AND CHRONIC WOUNDS CONDITIONS. IN ACUTE WOUND CONDITIONS LIKE ABRASIONS, LACERATIONS, CUTS, SKIN TEARS AND POST-OPERATIVE INCISIONS/WOUNDS. CHRONIC WOUND CONDITIONS LIKE- PRESSURE ULCERS, DIABETIC FOOT ULCERS, VENOUS LEG ULCERS, BURNS (IST & IIND DEGREE), DONOR SITE WOUNDS. ALSO INDICATED AS PRESSURE BANDAGES FOR ARTERIAL AND VENOUS BLEEDING, BLEEDING FROM DIALYSIS CATHETER SITE, POST- TREATMENT.

3427	MFG/MD/2020/000069	1.License Holder Name: MIL LABORATORIES PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:DRY COLLAGEN SHEET, GAUZE FABRIC IMPREGNATED WITH COLLAGEN, STERILE COLLAGEN PARTICLES, AMORPHOUS HYDROGEL WOUND DRESSING CONFORMABLE(NA)-DRY COLLAGEN SHEET, GAUZE PAD IMPREGNATED WITH COLLAGEN & STERILE COLLAGEN PARTICLES ARE INDICATED AS IDEAL FOR NON-INFECTIVE 2ND DEGREE BURNS, SUPERFICIAL & DEEP DERMAL BURNS, FOR 3RD DEGREE BURNS AS A TEMPORARY COVER, TRAUMATIC LOSS OF SKIN COVER, TEMPORARY LOSS OF SKIN COVER, SKIN DONOR SITES. AMORPHOUS HYDROGEL WOUND DRESSING CONFORMABLE IS INDICATED FOR USE IN OPEN WOUNDS LIKE PRESSURE SORES, SURGICAL WOUNDS HEALING BY SECONDARY INTENTION AND MALIGNANT WOUNDS. IT IS ESPECIALLY USEFUL FOR THE PACKING OF DEEP CAVITY WOUNDS TO PREVENT PREMATURE CLOSURE. IT CAN BE USED ON INFECTED WOUNDS UNDER MEDICAL SUPERVISION. ,TRANSPARENT FILM , TRANSPARENT FILM WITH ABSORBENT PAD , NON-WOVEN ABSORBENT PAD , HYLOGEL GAUZE PAD IMPREGNATE, STERILE HYDROCOLLOID, CALCIUM ALGINATE,ANTIMICROBIAL WOUND DRESSING, GLUTRALDEHYDE SOL.(NEMIDERM,NEMIDERM-ABS, NEMIDERM- ABS LAPAROSCOPY PACK, NEMIPORE, HYLOGEL TULLE, NEMISORB, CALGISORB, NEMIPORE-PHMB, GLUTRAMIL, HYDROPHILIC FOAM DRESSING, HYDROPHILIC FOAM DRESSING WITH SILVER, CALCIUM ALGINATE DRESSING WITH ANTIMICROBIAL SILVER, HYALURONIC ACID IMPREGANETD TULLE DRESSING)-SURGICAL DRESSINGS INTENDED TO BE USED FOR - ACUTE WOUND CONDITIONS LIKE ABRASIONS, LACERATIONS, POST-OPERATIVE WOUNDS , MINOR BURNS, SCALDS, CUTS. CHRONIC WOUND CONDITIONS LIKE- EXUDING/NON-EXUDING INFECTED WOUND CONDITIONS LIKE PRESSURE ULCERS , VENOUS LEG ULCERS (ARTERIAL/VENOUS), DIABETIC FOOT ULCER, BURNS (IST AND IIND DEGREE). ALSO INDICATED FOR DONOR SITE SKIN GRAFTS. DISINFECTANTS USED FOR THE HIGH LEVEL DISINFECTION OF LENS INSTRUMENTS LIKE ENDOSCOPE, BRONCHOSCOPE & COLONOSCOPE.,GLUTARALDEHYDE SOLUTION (NA)-GLUTARALDEHYDE SOLUTION IS USED FOR DISINFECTION OF THERMOSTABLE & THERMOLABILE INSTRUMENTS LIKE ENDOSCOPES (FLEXIBLE & RIGID), LAPAROSCOPES, ANESTHESIA AND DENTAL INSTRUMENTS. ,MEDICATED COLLAGEN SHEET (NA)-MEDICATED COLLAGEN SHEET CAN BE INDICATED IN- 1. SECOND DEGREE/ SUPERFICIAL BURNS 2. INFECTED WOUNDS 3. DIABETIC FOOT ULCERS 4. VENOUS/VASCULAR ULCERS 5. PRESSURE (SHALLOW) ULCERS 6. SURGICAL WOUNDS ETC.

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3428	MFG/MD/2020/000070	1.License Holder Name: DZIRE SURGICAL INDIA PRIVATE LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON (DZICOTT)-ABSORBENT COTTON ROLLS ARE USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES ETC., GAUZE SWAB(DZISWAB)-GAUZE SWAB USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, APPLYING ANTISEPTIC AND MUCH MORE. IT IS ESPECIALLY USEFUL FOR DRESSING WOUNDS WHERE OTHER FABRICS MIGHT STICK TO THE BURN OR LACERATION. STERILE GAUZE SWAB SHOULD BE USED FOR ANY APPLICATION TO AN OPEN WOUND.,GAMJEE ROLL-GAMJEE HIGHLY ABSORBENT PADDING IS USED FOR WOUND DRESSING, SUPPORT, PADDING, PROTECTION AND INSULATION.FOR SWABBING AND CLEANING WOUNDS,FOR DRESSING LOW EXUDATES WOUNDS ,COMBINE DRESSING(DZIPAD)-COMBINE DRESSINGS ARE SUITABLE FOR USE, EITHER IN DIRECT CONTACT FOR MEDIUM TO HEAVILY EXUDING WOUNDS, OR AS A SECONDARY DRESSING.,CREPE BANDAGE (DZICREPE)-ELASTIC BANDAGES ARE COMMONLY USED TO TREAT MUSCLE SPRAINS AND STRAINS BY REDUCING THE FLOW OF BLOOD TO A PARTICULAR AREA BY THE APPLICATION OF EVEN STABLE PRESSURE WHICH CAN RESTRICT SWELLING AT THE PLACE OF INJURY. ELASTIC BANDAGES ARE ALSO USED TO TREAT BONE FRACTURES.,GAUZE CLOTH-SURGICAL GAUZE CLOTH IS EXTENSIVELY USED IN HOSPITALS FOR WIPING, PADDING, DRESSING ETC. DURING THE PROCESS OF SURGERY.,ELASTIC ADHESIVE BANDAGE(DZIPLAST)-ADHESIVE BANDAGE USED AS A RELIEVING AND STRETCH COMPRESSION BANDAGE.,ABDOMINAL MOP(DZIMOP)-ABDOMINAL MOPS ARE USED IN HOSPITALS, NURSING HOMES AND OTHER MEDICAL SECTORS.,ABDOMINAL MOP(DZIMOP)-ABDOMINAL MOPS ARE USED IN HOSPITALS, NURSING HOMES AND OTHER MEDICAL SECTORS.,GAMJEE ROLL-GAMJEE HIGHLY ABSORBENT PADDING IS USED FOR WOUND DRESSING, SUPPORT, PADDING, PROTECTION AND INSULATION.FOR SWABBING AND CLEANING WOUNDS,FOR DRESSING LOW EXUDATES WOUNDS,GAUZE SWAB (DZISWAB)-GAUZE SWAB USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, APPLYING ANTISEPTIC AND MUCH MORE. IT IS ESPECIALLY USEFUL FOR DRESSING WOUNDS WHERE OTHER FABRICS MIGHT STICK TO THE BURN OR LACERATION. STERILE GAUZE SWAB SHOULD BE USED FOR ANY APPLICATION TO AN OPEN WOUND.,SOFT ROLL-SOFT ROLL IS A CAST PADDING, WHICH IS BASICALLY USED IN APPLICATION RELATED TO SURGERY AND OPERATING.,BANDAGE ROLL-BANDAGE ROLL IS EXTENSIVELY USED IN HOSPITALS FOR WIPING, PADDING, DRESSING ETC. DURING THE PROCESS OF SURGERY.,MICROPORUS TAPE(DZIPORE)-MICROPORUS

	SURGICAL PAPER TAPE IS THE NON-STERILE SINGLE USE TAPE HAS HYPOALLERGENIC ADHESIVE USED TO HOLD BANDAGE AND OTHER DRESSINGS ONTO A SKIN.,I.V CANNULA FIXATOR(DZIFIX)-IV CANNULA FIXATOR IS USED FOR PROVIDING BREATHABLE AND QUICK FIXATION DRESSING TO SECURE IV CANNULA AND OTHER INTRAMUSCULAR CATHETERS AND PER CUTANEOUS DEVICES TO THE SKIN.,PARAFFIN GAUZE(DZIFFIN)-PARAFFIN GAUZE ARE USED FOR PRIMARY WOUND TREATMENT FOR BURNS, SKIN GRAFTS, ULCERS & OTHER INJURIES.

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3429	MFG/MD/2020/000071	1.License Holder Name: SKY INDUSTRIES ,P.NO.75 TO 80, GANRAJ NAGAR, TUPPA, NANDED ,NANDED MAHARASHTRA ,431603 ,INDIA 2.Approving Authority: AURANGABAD DIVISION 3.Device Name(Brand Name)-Intended Use:GAUZE SWAB-GAUZE SWAB ARE USED TO PLACE OVER A WOUND BEFORE TAPING, STRAPPING OR BANDAGING UP OR CAN BE SOAKED IN ANTISEPTIC LIQUID AND USED TO WIPE OVER HARD SURFACES. GAUZE SWABS ARE A USEFUL UTILITY PRODUCT IN A KIT AND CAN BE USED FOR PADDING, PROTECTION, BLOOD SPILL WOUND DRESSING, APPLYING ANTISEPTIC AND MUCH MORE IS USED AS SURGICAL DRESSING MATERIAL FOR EXTERNAL USE IN HOSPITALS.,COTTON CREPE BANDAGE-PRESSURE BANDAGES, TRACTION BANDAGES, USED AS A COMPRESSION BANDAGE FOR ALL CHRONIC LEG CONDITION AS PRESSURE DRESSING.,ORTHOPEDIC , REHABILITATION & SPORTS INJURIES.USED FOR THE TREATMENT OF SPRAINS, ACHES, DISLOCATION, PAINFUL JOINTS, VARICOSE VEINS, CRAMPS, SKIN GRAFTING, POST OPERATIVE CONDITIONS & MUSCLES STRAIN USED AS SURGICAL DRESSING MATERIAL FOR EXTERNAL USE IN HOSPITALS.,COTTON BANDAGE CLOTH AS PER SCH. F-II OF DRUGS AND COSMETICS ACT 1940 -USED AS SURGICAL DRESSING MATERIAL FOR EXTERNAL USE ONLY IN HOSPITALS AND USE IS AS PRESSURE BANDAGE, TRACTION BANDAGES, COVERING EXTERNALLY SUPPORTING PLASTER,ABSORBENT COTTON WOOL-ABSORBENT COTTON WOOL IS USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BLOOD FLUIDS USED AS SURGICAL DRESSING MATERIAL FOR EXTERNAL USE IN HOSPITALS., ABSORBENT GAUZE CLOTH-USED AS SURGICAL DRESSING MATERIAL. USED AS PRESSURE GAUZE,TRACTION GAUZE, COVERING EXTERNALLY ,COTTON GAMJEE PAD-COTTON GAMJEE PAD IS USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BLOOD FLUIDS USED AS SURGICAL DRESSING MATERIAL FOR EXTERNAL USE IN HOSPITALS.,COTTON ROLLED BANDAGE-PRESSURE BANDAGES, TRACTION BANDAGES, USED AS DRESSING MATERIAL FOR EXTERNAL USE IN HOSPITALS.,EYE PAD-EYE PAD IS USED AS SURGICAL DRESSING MATERIAL FOR EXTERNAL USE FOR EYE CARE IN HOSPITALS.,SURGICAL DRESSING PAD-SURGICAL DRESSING PAD IS USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BLOOD FLUIDS USED AS SURGICAL DRESSING MATERIAL FOR EXTERNAL USE IN HOSPITALS.

3430	MFG/MD/2020/000072	1.License Holder Name: VENTURA ADHESIVE COATINGS PVT LTD 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:I V CANNULA FIXATION PATCH.(KANFIX)-IV CANNULA FIXATOR TAPE IS USED FOR PROVIDING BREATHABLE AND QUICK FIXATION DRESSING TO SECURE IV CANNULA AND OTHER INTRAMUSCULAR CATHETERS AND PERCUTANEOUS DEVICES TO THE SKIN.,ADHESIVE TAPE U.S.P. (VENTOPLAST)-ADHESIVE TAPE USP IS A TYPE OF PRESSURE-SENSITIVE ADHESIVE TAPE USED IN SECURE DRESSING MATERIALS TO SKIN. IT IS NOT INTENDED TO COME IN CONTACT WITH BLOOD. IT IS BREATHABLE AND REDUCES THE RISK OF SKIN MACERATION. THE APPLICATIONS OF THE ADHESIVE TAPE USP ARE MAINLY FOR FIXATION OF DRESSINGS ON NORMAL SKIN SECURING OF TUBES, CATHETERS, PROBES, CANNULAE.,SURGICAL ADHESIVE MICROPOROUS PAPER TAPE(VENTOPORE)-SURGICAL ADHESIVE MICROPOROUS PAPER TAPE OR MICROPOROUS SURGICAL PAPER TAPE IS THE NON-STERILE SINGLE-USE TAPE THAT HAS HYPOALLERGENIC ADHESIVE. THE DEVICE IS INDICATED TO BE USED ON A PATIENT OF THE SURGICAL ADHESIVE MICROPOROUS PAPER TAPE INCLUDE FIXATION OF DRESSING, TUBING, OSTEOMY POUCHES IN POST-SURGICAL CARE. THE DEVICE IS INDICATED TO BE USED ONLY BY A QUALIFIED SURGEON, NURSES, MIDWIVES AND ANY QUALIFIED MEDICAL PRACTITIONERS,ELASTIC ADHESIVE BANDAGE B.P.(VENTOPLAST)-ELASTIC ADHESIVE BANDAGE B.P. IS USED FOR SUPPORT STRAPPING FRACTURES, MUSCLE INJURIES, ELBOWS, KNEES, SHOULDERS ESPECIALLY REQUIRING ELASTICITY. IT IS ALSO USED FOR CORRECTIONAL PURPOSES. ELASTIC ADHESIVE BANDAGE (EAB) OFFERS FIRM DIRECTIONAL SUPPORT FOR STRAINS, SPRAINS, AND MINOR INJURIES. THE ELASTICATED BANDAGE IS USED FOR SHORT-TERM SUPPORT TO WEAK JOINTS, PARTICULARLY ANKLES AND KNEES. IT IS ALSO USED AS A RELIEVING AND STRETCH COMPRESSION BANDAGE. THE ELASTIC ADHESIVE BANDAGE PROVIDES COMPRESSION SUPPORT FOR JOINTS DURING HIGH-STRESS SPORT ACTIVITY. THE ADHESIVE ELASTIC BANDAGES HELP TO MINIMIZE SWELLING AND PROVIDE ADDITIONAL SUPPORT AS AN OVERWRAP.,CREPE BANDAGE B.P.(VENTOCREPE)-CREPE BANDAGEB.P. IS USED IN THE TREATMENT OF SPRAINS, AND STRAINS AND IN OTHER CONDITIONS IN WHICH LIGHT SUPPORT IS REQUIRED. IT MAY BE USED FOR THIS PURPOSE IN CONJUNCTION WITH OTHER SURGICAL APPLIANCES. IT IS ALSO USED FOR THE CORRECTIONAL PURPOSE. • INTENDED TO CREATE LOCALIZED PRESSURE. • TO TREAT MUSCLE SPRAINS AND STRAINS BY REDUCING THE FLOW OF BLOOD TO A PARTICULAR AREA BY THE APPLICATION OF EVEN STABLE PRESSURE THIS CAN RESTRICT SWELLING AT THE PLACE OF

		INJURY. • TO TREAT BONE FRACTURES.
3431	MFG/MD/2020/000073	1.License Holder Name: STRAUSS BURG STERILES 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:STERILE GAUZE PAD - CONTAINS : - ABSORBENT GAUZE OF SCHEDULE F (II)-A COVERED WOUND HEALS FASTER THAN AN UNCOVERED ONE. GAUZE PADS ARE DESIGNED TO PROTECT MINOR CUTS, SCRAPES AND BURNS. IT IS MADE OF 100% COTTON TO ENSURE SUPERIOR ABSORBENCY .THESE 12-PLY GAUZE PADS ARE INDIVIDUALLY-WRAPPED STERILE GAUZE PADS DESIGNED TO WICK AWAY FLUID FROM WOUNDS TO HELP KEEP THEM CLEAN. GAUZE PAD IS USED A MEDICAL DRESSING .THESE NON-ADHESIVE GAUZE PADS ARE ESSENTIAL FIRST AID SUPPLIES., STERILE EYE PAD - CONTAINS : ABSORBENT COTTON WITH GAUZE OF SCHEDULE F (II)-EYE PAD IS A COMBINE DRESSING PAD CUT APPROPRIATELY TO FACILITATE THE SHAPE OF THE EYE. IT IS A STERILE COMBINE DRESSING PAD OR COMPRESS APPLIED TO COVER AND PROTECT SURGICAL SITES IN OPHTHALMIC SURGERIES AND PROMOTES HEALING.,STERILE DRESSING PAD - CONTAINS : ABSORBENT COTTON WOOL & ABSORBENT GAUZE OF SCHEDULE F (II) - I.P-A DRESSING IS A STERILE PAD OR COMPRESS APPLIED TO A WOUND TO PROMOTE HEALING AND PROTECT THE WOUND FROM FURTHER HARM. A DRESSING IS DESIGNED TO BE IN DIRECT CONTACT WITH THE WOUND, AS DISTINGUISHED FROM A BANDAGE, WHICH IS MOST OFTEN USED TO HOLD A DRESSING IN PLACE., STERILE CANNUAL FIXATOR - CONTAINS ELASTIC ADHESIVE BANDAGE BP-A CANNULA FIXATION DEVICE IS AN ESSENTIAL ACCESSORY IN SUCH CASES.OUR CANNULA FIXATION IS A STERILE ADHESIVE DRESSING WITH A PAD AT THE POINT OF INJECTION FOR THE RELIABLE CANNULA FIXATION. THE MANUFACTURING PROCESS OF CANNULA FIXATOR CONSISTS OF AN ELASTIC ADHESIVE BANDAGE WHICH PREVENTS THE PAD FROM ADHERING AT THE POINT OF INJECTION.

3432	MFG/MD/2020/000074	1.License Holder Name: SHREE JEE INDUSTRIES 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:OPEN WOVE BANDAGE-IT IS USED TO COVER THE WOUNDS TO PREVENT IT FROM DUST AND BACTERIA,COMBINED DRESSING PAD-THESE ARE IDEAL FOR HANDLING HEAVY DRAINAGE, PROMOTING HEALING AND KEEPING THE WOUND DRY FOR OPTIMAL COMFORT AND RELIEF,ABDOMINAL PAD-FOR THE ABSORPTION OF DISCHARGES FROM ABDOMINAL WOUND,ABSORBENT COTTON GAUZE RIBBON-USED IN DRESSINGS, GAUZE SWAB-FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, APPLYING ANTISEPTIC,ELASTIC ADHESIVE BANDAGE (OSMOPLAST)-IT IS USUALLY USED TO WRAP SOFT TISSUE INJURIES TO PROVIDE COMPRESSION AND SUPPORT,COTTON BANDAGE CLOTH-TO SUPPORT THE DRAPING.,CREPE BANDAGE-FOR THE REDUCES SWELLING, SECURES WOUND DRESSING, SUPPORTS STRAINS AND SPRAINS,ABSORBENT GAUZE CLOTH-FOR CLEAN THE WOUND,IV CANNULA FIXATOR-IV CANNULA FIXATOR IS HELPFUL FOR FIXING IV CANNULA,GAMJEE ROLL-FOR THE CLEANING AND DRYING PURPOSE
3433	MFG/MD/2020/000075	1.License Holder Name: RECOMBIGEN LABORATORIES PVT. LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:INFLUENZA-B ANTIGEN (RECOMBIGEN)-THE INFLUENZA B ANTIGEN TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF INFLUENZA B ANTIGENS IN NASAL SWAB SPECIMENS. IT IS INTENDED TO AID IN THE RAPID DIAGNOSIS OF INFLUENZA B VIRAL INFECTIONS.,INFLUENZA-A ANTIGEN(RECOMBIGEN)-THE INFLUENZA A ANTIGEN TEST IS A RAPID CHROMATOGRAPHIC IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF INFLUENZA A ANTIGENS IN NASAL SWAB SPECIMENS. IT IS INTENDED TO AID IN THE RAPID DIAGNOSIS OF INFLUENZA A VIRAL INFECTIONS.,DENGUE NS1 ANTIGEN(RECOMBIGEN)-THE PROPOSED IVD PRODUCT IS A “RAPID DENGUE NS1 ANTIGEN DETECTION KIT IN PLASTIC CASSETTE FORMAT”. IT IS INTENDED FOR QUALITATIVE DETECTION OF DENGUE NS1 ANTIGEN IN HUMAN SERUM, PLASMA AND WHOLE BLOOD SAMPLE.

3434	MFG/MD/2020/000076	1.License Holder Name: CONVEX LATEX PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NATURAL RUBBER LATEX DOTTED MALE CONDOMS(GENERIC)-MECHANICAL CONTRACEPTIVE, NATURAL RUBBER LATEX MALE CONDOM(SHIELD DOTTED CONDOM) -USED FOR SINGLE TIME. MALE CONTRACEPTIVE.,NATURAL RUBBER LATEX MULTITEXTURE MALE CONDOM(GENERIC)-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX MALE CONDOM(MY LOVE PLAIN CONDOM (FOR EXPORT))-MECHANICAL CONTRACEPTIVE, NATURAL RUBBER LATEX MALE CONDOMS(GENERIC)-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX MALE CONDOM (MY LOVE DOTTED CONDOM (FOR EXPORT))-MECHANICAL CONTRACEPTIVE, NATURAL RUBBER LATEX DOTTED MALE CONDOM(GENERIC)-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX MALE CONDOM(MY LOVE LONG LAST PLAIN CONDOM (FOR EXPORT))-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX MULTITEXTURE MALE CONDOMS(GENERIC)-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX MALE CONDOM(MY LOVE MULTITEXTURE CONDOM (FOR EXPORT))-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX ALOEVERA DOTTED MALE CONDOM(GENERIC)-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX MALE CONDOM(MY LOVE ULTRA THIN PLAIN CONDOM (FOR EXPORT))-MECHANICAL CONTRACETIVE,NATURAL RUBBER LATEX DOTTED MALE CONDOMS (EXVIAGRA (FOR EXPORT))-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX MALE CONDOMS(HEALTHY CONDOMS (FOR EXPORT))-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX DOTTED MALE CONDOM (LOVER (FOR EXPORT))-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX PLAIN (SMOOTH) MALE CONDOMS(GENERIC)-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX MALE CONDOMS(GENERIC)-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX MALE CONDOMS(HEALTHY CONDOMS (FOR EXPORT)) -MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX DOTTED MALE CONDOM(GENERIC)-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX DOTTED MALE CONDOMS(GENERIC)-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX MALE CONDOM (DOTTED) ALOEVERA(GENERIC)-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX SMOOTH MALE CONDOMS (ULTRA THIN)(GENERIC)-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX MULTITEXTURE MALE CONDOMS(GENERIC)-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX MALE CONDOMS (GENERIC)-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX MULTITEXTURE MALE CONDOMS(GENERIC)-MECHANICAL

		CONTRACEPTIVE,NATURAL RUBBER LATEX ALOEVERA MULTITEXTURE MALE CONDOMS(GENERIC)-MECHANICAL CONTRACEPTIVE,NATURAL RUBBER LATEX PLAIN (SMOOTH) MALE CONDOMS(GENERIC)-MECHANICAL CONTRACEPTIVE
3435	MFG/MD/2020/000077	1.License Holder Name: M/S MICROTROL STERILIZATION SERVICES PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:COLLAGEN PARTICLES-COLLAGEN PARTICLES IS USED FOR THE MANAGEMENT OF DEEP WOUNDS / ALL TYPE OF WOUNDS INCLUDING BURN WOUNDS, COLLAGEN WET SHEET-WET COLLAGEN SHEET IS USED FOR MANAGEMENT OF BURN WOUNDS / ALL TYPES OF WOUNDS, COLLAGEN DRY SHEET-DRY COLLAGEN SHEET IS USED FOR MANAGEMENT OF ALL TYPES OF WOUNDS INCLUDING BURN WOUNDS

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3436	MFG/MD/2020/000078	1.License Holder Name: KRENILA ORTHO 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:SPINAL IMPLANTS (KRENILA)-• THE KRENILA SPINE SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM .INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE FOR USE IN SKELETALLY MATURE PATIENTS. IT IS AN INSTRUMENT SET DESIGNED FOR INSERTION OF CANNULATED KRENILA PEDICLE SCREWS AND RODS THROUGH A PERCUTANEOUS OR MINI-OPEN MUSCLE SPARING APPROACH. THE KRENILA PERFORATED SCREWS ARE AN ADDITION TO THE KRENILA SYSTEM, A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. KRENILA PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID KRENILA SCREWS AND WITH KIRSCHNER WIRE GUIDANCE AS KRENILA CANNULATED SCREWS INCLUDING A MINIMALLY INVASIVE APPROACH WITH KRENILA. KRENILA PERFORATED SCREWS DIRECT VERTECEM V+ THROUGH LATERAL PERFORATIONS TO AUGMENT THE PEDICLE SCREW IN THE VERTEBRAL BODY. AUGMENTATION OF PEDICLE SCREWS WITH CEMENT INCREASES PEDICLE SCREW ANCHORING IN VERTEBRAL BONE, ESPECIALLY IN CASES OF DIMINISHED BONE QUALITY,BONE SCREW-BONE SCREW IS INTENDED FOR IMPLANTATION INTO PREPARED BONE DURING ORTHOPAEDIC SURGERY WHEN THE SURGEON DETERMINES THE NEED FOR ADDITIONAL FIXATION: BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE. BONE SCREW IS INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,SPINAL IMPLANTS(KRENILA)-THE KRENILA SPINE SYSTEM IS A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM .INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE FOR USE IN SKELETALLY MATURE PATIENTS. IT IS AN INSTRUMENT SET DESIGNED FOR INSERTION OF CANNULATED KRENILA PEDICLE SCREWS AND RODS THROUGH A PERCUTANEOUS OR MINI-OPEN MUSCLE SPARING APPROACH. THE KRENILA PERFORATED SCREWS ARE AN ADDITION TO THE KRENILA SYSTEM, A POSTERIOR PEDICLE SCREW AND HOOK FIXATION SYSTEM INTENDED TO PROVIDE PRECISE AND SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. KRENILA PERFORATED PEDICLE SCREWS MAY BE INSERTED TRADITIONALLY AS SOLID KRENILA

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	INTRA MEDULLARY NAILS ARE USED INSIDE THE BONE AND ITS PASS THROUGH FRACTURES AND HOLD THE FRACTURES WITH THE HELP OF BONE SCREWS. AND ITS MINIMAL INSERTION SURGERY INTRA-MEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS. ANKLE FUSION NAILS ARE INTENDED FOR TIBIOTALOCALCANEAL ARTHRODESIS. TEN AND STEN NAILS ARE USED AS SINGLE IMPLANT OR IN PAIRS FOR ELASTIC STABLE INTRA-MEDULLARY FIXATION (ESIN). OLECRANON OSTEOTOMY NAILS ARE INTENDED FOR FIXATION OF SIMPLE FRACTURES AND OSTEOTOMIES OF THE OLECRANON,BONE PLATE LOCKING(KRENILA)-BONE PLATES IS USED TO FIXING FRACTURE. WITH HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES. PLATE IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS,BONE PLATE LOCKING(KRENILA)-BONE PLATES IS USED TO FIXING FRACTURE. WITH HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES. PLATE IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS,BONE PLATE FOR 3.5MM SCREW(KRENILA)-BONE PLATES IS USED TO FIXING FRACTURE. WITH HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES. PLATE IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS, BONE PLATE FOR 4.5MM SCREW(KRENILA)-BONE PLATES IS USED TO FIXING FRACTURE. WITH HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES. PLATE IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS, BONE PLATE FOR 3.5MM SCREW(KRENILA)-BONE PLATES IS USED TO FIXING FRACTURE. WITH HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES. PLATE IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS, PINS WIRES STAPLES(KRENILA)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. THESE ARE OF DIFFERENT TYPES WHICH USED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENT. THOSE ARE MAINLY INDICATED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION

3437	MFG/MD/2020/000079	1.License Holder Name: BONE LIFE SURGICALS 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE WIRES(EMT)-BONE WIRES SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE,BONE PINS(EMT)-BONE PINS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE,BONE NAILS(EMT)-BONE NAIL IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PLATES(EMT)-BONE PLATES SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE SCREWS(EMT)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE,SPINAL IMPLANTS(EMT)-SPINAL IMPLANTS ARE USED TO TREAT THE SPINAL DISORDERS ,TO CORRECT DEFORMITIES FACILITATE FUSION, STABILIZE AND STRENGTHEN THE SPINE

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3438	MFG/MD/2020/000080	1.License Holder Name: GREENS SURGICALS (P) LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:HIP REPLACEMENT STEM WITH HEAD -TITANIUM(GREENS)-TOTAL HIP ARTHROPLASTY (THA) IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. THIS IS INDICATED: THIS IS INDICATED FOR A SEVERELY PAINFUL AND/ OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AVASCULAR NECROSIS OF THE FEMORAL HEAD; ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK; FAILED PREVIOUS HIP SURGERY; AND CERTAIN CASES OF ANKYLOSIS.,BONE PLATE -STAINLESS STEEL (GREENS)-GREEN'S BONE PLATES ARE INTENDED FOR FIXATION OF FRACTURES, OSTEOTOMIES, MALUNION, ARTHRODESIS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL. GREEN'S BONE PLATES ARE PROVIDED IN NON-STERILE PACKAGE., KNEE REPLACEMENT SYSTEM PATELLA -UHMWPE(GREENS)-GREENS SURGICALS' CEMENTLESS FIXED BEARING KNEE: INTENDED USE: TOTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL KNEE REPLACEMENT OUTWEIGH THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. INDICATIONS: GREENS SURGICALS' CEMENTLESS CR FEMORAL COMPONENTS ARE INTENDED FOR CEMENTLESS USE WITHIN THE GREENS SURGICALS' TOTAL KNEE REPLACEMENT SYSTEM. CANDIDATES FOR TOTAL KNEE REPLACEMENT INCLUDES PATIENTS WITH SEVERELY PAINFUL AND/ OR SEVERELY DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, OR A FAILED PREVIOUS IMPLANT (PROVIDED THAT ADEQUATE BONE

	IS PRESENT). GREENS SURGICALS' CEMENTLESS ROTATING PLATFORM(RP) KNEE: INDICATION FOR USE WITHOUT CEMENT THE POROUS COATED GREENS SURGICALS' ROTATING PLATFORM TIBIAL BASE IS INDICATED FOR CEMENTLESS USE WITHIN THE GREENS SURGICALS' TOTAL KNEE REPLACEMENT.IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR RECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSIS OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE CR RP DEVICE CONFIGURATION INDICATED FOR USE IN KNEES WHOSE POSTERIOR CRUCIATE LIGAMENT IS INTACT, ABSENT OR IN SUCH CONDITION AS TO JUSTIFY ITS SACRIFICE. CR= CRUCIATE RETAINING, RP= ROTATING PLATFORM GREENS SURGICALS' FIXED BEARING KNEE INTENDED USE: TOTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL KNEE REPLACEMENT OUTWEIGH THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. INDICATIONS: CANDIDATES FOR TOTAL KNEE REPLACEMENT INCLUDES PATIENTS WITH SEVERELY PAINFUL AND/ OR SEVERELY DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR A FAILED PREVIOUS IMPLANT. GREENS SURGICALS' KNEE SYSTEM –ROTATING PLATFORM INTENDED USE: TOTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL KNEE REPLACEMENT OUTWEIGH THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN

	IN KNEE MOBILITY MAY LEAD TO EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. INDICATIONS: THE ROTATING PLATFORM TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASE OS OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE ROTATING PLATFORM PROSTHESIS IS INDICATED FOR PRIMARY TOTAL KNEE ARTHROPLASTY OR THE REVISION OF FAILED KNEE PROSTHESIS.,HIP REPLACEMENT ACETABULUM CUP - TITANIUM + UHMWPE(GREENS)-TOTAL HIP ARTHROPLASTY (THA) IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. THIS IS INDICATED: THIS IS INDICATED FOR A SEVERELY PAINFUL AND/ OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AVASCULAR NECROSIS OF THE FEMORAL HEAD; ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK; FAILED PREVIOUS HIP SURGERY; AND CERTAIN CASES OF ANKYLOSIS.,HIP REPLACEMENT ACETABULUM CUP - STAINLESS STEEL + UHMWPE(GREENS)-TOTAL HIP ARTHROPLASTY (THA) IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. THIS IS INDICATED: THIS IS INDICATED FOR A SEVERELY PAINFUL AND/ OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AVASCULAR NECROSIS OF THE FEMORAL HEAD; ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK; FAILED PREVIOUS HIP SURGERY; AND CERTAIN CASES OF ANKYLOSIS.,PINS, WIRES & STAPLES -STAINLESS STEEL (GREENS)- KIRSCHNER WIRE INTENDED USE / APPLICATION: KIRSCHNER WIRES ARE USED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION. INTENDED USE OF THESE WIRES IS IN PATELLA, OLECRANON, AND MALLEOLAR & HAND FRACTURES. STEINMAN PIN INTENDED USE / APPLICATION: STEINMAN PIN ARE GENERALLY USED IN TIBIA & FEMUR BONES ALONG WITH STEINMANN PIN HOLDER. CENTARLLY THREADED STEINMAN PIN (DENHAM PIN) INTENDED USE / APPLICATION: INTENDED USES OF DENHAM PINS ARE TO STABILISE FRACTURES OF TIBIA & FEMUR BONES ALONG WITH STEINMANN PIN HOLDER. KNOWEL PIN INTENDED USE / APPLICATION: KNOWEL PINS ARE INSERTED PARALLEL TO THE EXIS OF THE FEMORAL NECK CIRCLAGE WIRE WITH LOOP INTENDED USE / APPLICATION: USES OF CIRLAGE WIRE ARE MAINLY INDICATED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENT. THESE INCLUDE

	FRACTURES OF PATELLA AND THE OLECRANON. DRUMMER'S WIRE INTENDED USE / APPLICATION: THESE WIRES ARE GENERALLY USED IN SPINE FRACTURES ALONGWITH HART SHELLS. SCHANZ PIN – TROCAR POINTS INTENDED USE / APPLICATION: SCHANZ PIN ARE GENERALLY USED WITH EXTERNAL FIXATOR DEVICES IN TIBIA, FEMUR & FOREARM BONES. GENERALLY SCHANZ PINS ARE USED IN OPEN WOUND FRACTURES. CONNECING ROD INTENDED USE / APPLICATION: USED TO CONNECT FIXATOR CLAMPS,KNEE REPLACEMENT SYSTEM FEMORAL BONE-STAINLESS STEEL(GREENS) -GREENS SURGICALS' CEMENTLESS FIXED BEARING KNEE: INTENDED USE: TOTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL KNEE REPLACEMENT OUTWEIGH THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. INDICATIONS: GREENS SURGICALS' CEMENTLESS CR FEMORAL COMPONENTS ARE INTENDED FOR CEMENTLESS USE WITHIN THE GREENS SURGICALS' TOTAL KNEE REPLACEMENT SYSTEM. CANDIDATES FOR TOTAL KNEE REPLACEMENT INCLUDES PATIENTS WITH SEVERELY PAINFUL AND/ OR SEVERELY DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, OR A FAILED PREVIOUS IMPLANT (PROVIDED THAT ADEQUATE BONE IS PRESENT). GREENS SURGICALS' CEMENTLESS ROTATING PLATFORM(RP) KNEE: INDICATION FOR USE WITHOUT CEMENT THE POROUS COATED GREENS SURGICALS' ROTATING PLATFORM TIBIAL BASE IS INDICATED FOR CEMENTLESS USE WITHIN THE GREENS SURGICALS' TOTAL KNEE REPLACEMENT.IN SKELETALLY MATURE INDIVIDUALS UNDERGOING PRIMARY SURGERY FOR RECONSTRUCTING KNEES DAMAGED AS A RESULT OF NONINFLAMMATORY DEGENERATIVE JOINT DISEASE (NIDJD) OR EITHER OF ITS COMPOSITE DIAGNOSIS OF OSTEOARTHRITIS AND POST-TRAUMATIC ARTHRITIS PATHOLOGIES. THE CR RP DEVICE CONFIGURATION INDICATED FOR USE IN KNEES WHOSE POSTERIOR CRUCIATE LIGAMENT IS INTACT, ABSENT OR IN SUCH CONDITION AS TO JUSTIFY ITS SACRIFICE. CR= CRUCIATE RETAINING, RP= ROTATING PLATFORM GREENS SURGICALS' FIXED BEARING KNEE

	INTENDED USE: TOTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL KNEE REPLACEMENT OUTWEIGH THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. INDICATIONS: CANDIDATES FOR TOTAL KNEE REPLACEMENT INCLUDES PATIENTS WITH SEVERELY PAINFUL AND/ OR SEVERELY DISABLED JOINT RESULTING FROM OSTEOARTHRITIS, POST-TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR A FAILED PREVIOUS IMPLANT. GREENS SURGICALS' KNEE SYSTEM –ROTATING PLATFORM INTENDED USE: TOTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL KNEE REPLACEMENT OUTWEIGH THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. INDICATIONS: THE ROTATING PLATFORM TOTAL KNEE SYSTEM IS INDICATED FOR CEMENTED USE IN CASE OS OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS. THE ROTATING PLATFORM PROSTHESIS IS INDICATED FOR PRIMARY TOTAL KNEE ARTHROPLASTY OR THE REVISION OF FAILED KNEE PROSTHESIS.,SPINAL IMPLANT -TITANIUM(GREENS)-ANTERIOR CERVICAL PLATE AND SCREW:THE ANTERIOR CERVICAL PLATE SYSTEM IS INDICATED FOR STABILIZATION OF THE CERVICAL SPINE FROM C2 TO C7 EMPLOYING SCREW FIXATION AT THE ANTERIOR FACE OF THE VERTEBRAL BODIES. SPECIFIC CLINICAL INDICATIONS FOR ANTERIOR PLATING INCLUDE: INSTABILITY CAUSED BY TRAUMA; INSTABILITY ASSOCIATED WITH CORRECTION OF CERVICAL LORDOSIS AND KYPHOSIS DEFORMITY; INSTABILITY

	ASSOCIATED WITH PSEUDOARTHOSIS AS A RESULT OF PREVIOUSLY FAILED CERVICAL SPINE SURGERY;INSTABILITY ASSOCIATED WITH SINGLE OR MULTIPLE LEVEL CORPECTOMY IN ADVANCED DEGENERATIVE DISC DISEASE, SPINAL CANAL STENOSIS AND CERVICAL MYELOPATHY MONOAXIAL SCREWS AND HOOKS WITH SPINAL RODS: THE MONOAXIAL SCREWS AND HOOK SYSTEM ARE INTENDED FOR USE A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1 THROUGH S2) OR POSTERIOR HOOK FIXATION SYSTEM (T1 THROUGH L5) OR AS AN ANTEROLATERAL FIXATION SYSTEM (T8 THROUGH L5). THESE DEVICES ARE INTENDED FOR ALL THE BELOW: DEGENERATIVE DISC DISEASE, SPONDYLOLISTHESIS, TRAUMA, DEFORMITIES OR CURVATURES, STENOSIS, PSEUDOARTHROSIS AND FAILED PREVIOUS FUSION. POLYAXIAL SCREWS WITH SPINAL RODS: THE POLYAXIAL SCREW AND ROD SYSTEM ARE INTENDED FOR PROVIDING SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. DRUMMER'S WIRE: INTENDED USE / APPLICATION: THESE WIRES ARE GENERALLY USED IN SPINE FRACTURES ALONG WITH HART SHELLS. HART SHELL: INTENDED USE / APPLICATION: HART SHALL ARE GENERALLY USED IN SPINE FRACTURES ALONG WITH DRUMMER'S WIRES. HARRINGTON ROD & HOOKS: INTENDED USE / APPLICATION: HARRINGTON RODS ARE USED IN SPINAL SURGERY. HARRINGTON ROD IS USED ALONG WITH HARRINGTON HOOKS IN SPINAL FRACTURES.,HIP PROSTHESIS FEMORAL STEM -TITANIUM(GREENS)-• ORTHOPAEDIC IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. THESE IMPLANTS ARE IMPLANTED BY TRAINED QUALIFIED SURGEONS DURING OPERATION. HIP PROSTHESES ARE MEANT FOR ONLY HIP JOINTS FRACTURES.,KNEE REPLACEMENT SYSTEM FEMORAL BONE -TITANIUM(GREENS)-GREENS SURGICALS' CEMENTLESS FIXED BEARING KNEE: INTENDED USE: TOTAL KNEE ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCED PAIN BY REPLACING THE DAMAGED KNEE JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. TOTAL KNEE REPLACEMENT MAY BE CONSIDERED FOR YOUNGER PATIENTS IF, IN THE OPINION OF THE SURGEON, AN UNEQUIVOCAL INDICATION FOR TOTAL KNEE REPLACEMENT OUTWEIGH THE RISKS ASSOCIATED WITH THE AGE OF THE PATIENT, AND IF LIMITED DEMANDS REGARDING ACTIVITY AND KNEE JOINT LOADING CAN BE ASSURED. THIS INCLUDES SEVERELY CRIPPLED PATIENTS WITH MULTIPLE JOINT INVOLVEMENT FOR WHOM A GAIN IN KNEE MOBILITY MAY LEAD TO EXPECTATION OF SIGNIFICANT IMPROVEMENT IN THE QUALITY OF THEIR LIVES. INDICATIONS: GREENS SURGICALS' CEMENTLESS CR FEMORAL COMPONENTS ARE

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	INCLUDE: INSTABILITY CAUSED BY TRAUMA; INSTABILITY ASSOCIATED WITH CORRECTION OF CERVICAL LORDOSIS AND KYPHOSIS DEFORMITY; INSTABILITY ASSOCIATED WITH PSEUDOARTHOSIS AS A RESULT OF PREVIOUSLY FAILED CERVICAL SPINE SURGERY;INSTABILITY ASSOCIATED WITH SINGLE OR MULTIPLE LEVEL CORPECTOMY IN ADVANCED DEGENERATIVE DISC DISEASE, SPINAL CANAL STENOSIS AND CERVICAL MYELOPATHY MONOAXIAL SCREWS AND HOOKS WITH SPINAL RODS: THE MONOAXIAL SCREWS AND HOOK SYSTEM ARE INTENDED FOR USE A POSTERIOR PEDICLE SCREW FIXATION SYSTEM (T1 THROUGH S2) OR POSTERIOR HOOK FIXATION SYSTEM (T1 THROUGH L5) OR AS AN ANTEROLATERAL FIXATION SYSTEM (T8 THROUGH L5). THESE DEVICES ARE INTENDED FOR ALL THE BELOW: DEGENERATIVE DISC DISEASE, SPONDYLOLISTHESIS, TRAUMA, DEFORMITIES OR CURVATURES, STENOSIS, PSEUDOARTHROSIS AND FAILED PREVIOUS FUSION. POLYAXIAL SCREWS WITH SPINAL RODS: THE POLYAXIAL SCREW AND ROD SYSTEM ARE INTENDED FOR PROVIDING SEGMENTAL STABILIZATION OF THE SPINE IN SKELETALLY MATURE PATIENTS. DRUMMER'S WIRE: INTENDED USE / APPLICATION: THESE WIRES ARE GENERALLY USED IN SPINE FRACTURES ALONG WITH HART SHELLS. HART SHELL: INTENDED USE / APPLICATION: HART SHALL ARE GENERALLY USED IN SPINE FRACTURES ALONG WITH DRUMMER'S WIRES. HARRINGTON ROD & HOOKS: INTENDED USE / APPLICATION: HARRINGTON RODS ARE USED IN SPINAL SURGERY. HARRINGTON ROD IS USED ALONG WITH HARRINGTON HOOKS IN SPINAL FRACTURES.,BONE SCREWS AND WASHERS -STAINLESS STEEL(GREENS)-GREENS BONE SCREWS WHEN USED IN COMBINATION WITH PLATES ARE INTENDED FOR FIXATION OF VARIOUS FRACTURES, OSTEOTOMIES, MALUNIONS, ARTHRODESIS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL. THE GREENS BONE WASHER ARE INTENDED TO PREVENT A SCREW HEAD FROM BREAKING THROUGH THE CORTEX OF THE BONE BY DISTRIBUTING THE FORCES/LOAD OVER A LARGE AREA WHEN USED FOR FRACTURE FIXATION OF LARGE BONE AND BONE FRAGMENTS., INTRAMEDULLARY NAIL -TITANIUM(GREENS)-TIBIAL NAILS: THE GREENS TIBIAL NAIL SYSTEM IS INTENDED TO STABILIZE FRACTURES OF THE PROXIMAL AND DISTAL TIBIA AND THE TIBIAL SHAFT; OPEN AND CLOSED TIBIAL SHAFT FRACTURES; CERTAIN PRE- AND POST-ISTHMIC FRACTURES; AND TIBIAL MALUNIONS AND NON-UNIONS. THE TIBIAL NAILS CAN BE OF INTERLOCKING TIBIAL NAIL, CANNULATED TIBIAL NAIL AND DISTAL TIP DISTAL LOCKING TIBIAL

	NAIL TYPES. UNREAMED FEMORAL NAILS: THE GREENS RETROGRADE/ANTEGRADE FEMORAL NAIL SYSTEM IS INTENDED TO STABILIZE FRACTURES OF THE DISTAL FEMUR AND THE FEMORAL SHAFT, INCLUDING SUPRACONDYLAR FRACTURES, INCLUDING THOSE WITH INTRA-ARTICULAR EXTENSION; IPSILATERAL HIP/SHAFT FRACTURES; IPSILATERAL FEMUR/TIBIA FRACTURES; FEMORAL FRACTURES IN MULTIPLE TRAUMA PATIENTS; FRACTURES PROXIMAL TO TOTAL KNEE ARTHROPLASTY; FRACTURES DISTAL TO A HIP IMPLANT; FRACTURES IN THE MORBIDLY OBESE; FRACTURES IN OSTEOPOROTIC BONE, IMPENDING PATHOLOGIC FRACTURES; AND MALUNIONS AND NONUNIONS. UNIVERSAL FEMORAL NAILS: THE GREENSFEMORAL NAIL IS INDICATED FOR USE IN A VARIETY OF FEMORAL FRACTURES SUCH AS COMMINUTED FRACTURES, SEGMENTAL FRACTURES, FRACTURES WITH BONE LOSS, PROXIMAL AND DISTAL FRACTURES, NONUNIONS, SUBTROCHANTERIC FRACTURES, INTERTROCHANTERIC FRACTURES. SUPRACONDYLAR NAILS: THE GREENSSUPRACONDYLAR INTRAMEDULLARY NAILS ARE INTENDED FOR USE IN FIXATION OF VARIOUS TYPES OF FRACTURES OF SUPRACONDYLAR OR DISTAL REGION OF THE FEMUR AS WELL AS FOR PROXIMAL FRACTURES IN CONJUNCTION WITH SUPRACONDYLAR FRACTURES. PROXIMAL FEMORAL NAIL, PROXIMAL FEMORAL NAIL-LONG: THE GREENSPROXIMAL FEMORAL NAIL IS INTENDED TO TREAT STABLE AND UNSTABLE PROXIMAL FEMORAL FRACTURES INCLUDING PERTROCHANTERIC FRACTURES, INTERTROCHANTERIC FRACTURES, HIGH SUBTROCHANTERIC FRACTURES. CANNULATED HUMERAL NAILS: THE GREENSCANNULATED HUMERAL NAIL SYSTEM IS INTENDED TO AID IN THE ALIGNMENT AND STABILIZATION OF HUMERAL FRACTURES TO INCLUDE DIAPHYSEAL FRACTURES OF THE HUMERAL SHAFT, FRACTURES OF THE PROXIMAL HUMERUS, PROXIMAL HUMERAL FRACTURES WITH DIAPHYSEAL EXTENSION, IMPENDING PATHOLOGIC FRACTURES & MALUNIONS AND NONUNIONS. UNREAMED HUMERAL NAILS: THE GREENSUNREAMED HUMERAL NAILS ARE INDICATED FOR THE TREATMENT OF FRACTURES OF PROXIMAL HUMERUS. RECON NAILS: THE GREENS RECON NAIL SYSTEM IS A FRACTURE FIXATION DEVICE COMPRISED OF RECONSTRUCTION NAILS AND THE RELATED ACCESSORIES SUCH AS WASHERS, LOCKING SCREWS, SET SCREWS, END CAPS, AND LAG SCREWS. THE DEVICES ARE INTENDED TO PROVIDE STRONG AND STABLE INTERNAL FRACTURE FIXATION WITH MINIMAL SOFT TISSUE IRRITATION OF THE TIBIA AND FEMUR. THIS DEVICE IS UTILIZED AS AN AID TO HEALING, NOT AS A SUBSTITUTE FOR NORMAL INTACT BONE AND TISSUE. GAMMA NAIL THE GREENS GAMMA NAIL IS INDICATED FOR USE IN FIXATION OF FEMORAL FRACTURES

	OCCURRING FROM THE BASE OF THE FEMORAL NECK EXTENDING DISTALLY TO A POINT PROXIMAL TO INTERCONDYLAR NOTCH. FRACTURE TYPES INCLUDE BASILAR NECK, INTERTROCHANTERIC SUBTROCHANTERIC FRACTURES AND FEMORAL SHAFT FRACTURES. ELASTIC NAILS: THE GREENS ELASTIC INTRAMEDULLARY NAIL SYSTEM IS INDICATED FOR FIXATION OF DIAPHYSEAL FRACTURES WHERE THE CANAL IS NARROW OR FLEXIBILITY OF THEIMPLANT IS IMPORTANT. THIS INCLUDES UPPER EXTREMITY FRACTURES IN ALL PATIENTS AND LOWER EXTREMITY FRACTURES IN PEDIATRIC OR SMALL-STATURE PATIENTS. THIS SYSTEM IS ALSO INTENDED TO TREAT METAPHYSEAL AND EPIPHYSEAL FRACTURES, SUCH AS RADIAL NECK FRACTURES AND IS INTENDED FOR FIXATION OF SMALL LONG BONES, SUCH AS CARPAL AND TARSAL BONES.,BONE PLATE -TITANIUM(GREENS)-GREEN'S BONE PLATES ARE INTENDED FOR FIXATION OF FRACTURES, OSTEOTOMIES, MALUNION, ARTHRODESIS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL. GREEN'S BONE PLATES ARE PROVIDED IN NON-STERILE PACKAGE.,HIP REPLACEMENT STEM WITH HEAD –STAINLESS STEEL (GREENS)-TOTAL HIP ARTHROPLASTY (THA) IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS. THIS IS INDICATED: THIS IS INDICATED FOR A SEVERELY PAINFUL AND/ OR DISABLED JOINT FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, RHEUMATOID ARTHRITIS OR CONGENITAL HIP DYSPLASIA; AVASCULAR NECROSIS OF THE FEMORAL HEAD; ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK; FAILED PREVIOUS HIP SURGERY; AND CERTAIN CASES OF ANKYLOSIS.,BONE SCREWS AND WASHERS - TITANIUM(GREENS)-GREENS BONE SCREWS WHEN USED IN COMBINATION WITH PLATES ARE INTENDED FOR FIXATION OF VARIOUS FRACTURES, OSTEOTOMIES, MALUNIONS, ARTHRODESIS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL. THE GREENS BONE WASHER ARE INTENDED TO PREVENT A SCREW HEAD FROM BREAKING THROUGH THE CORTEX OF THE BONE BY DISTRIBUTING THE FORCES/LOAD OVER A LARGE AREA WHEN USED FOR FRACTURE FIXATION OF LARGE BONE AND BONE FRAGMENTS., INTRAMEDULLARY NAIL -STAINLESS STEEL(GREENS)-TIBIAL NAILS:

	THE GREENS TIBIAL NAIL SYSTEM IS INTENDED TO STABILIZE FRACTURES OF THE PROXIMAL AND DISTAL TIBIA AND THE TIBIAL SHAFT; OPEN AND CLOSED TIBIAL SHAFT FRACTURES; CERTAIN PRE- AND POST-ISTHMIC FRACTURES; AND TIBIAL MALUNIONS AND NON-UNIONS. THE TIBIAL NAILS CAN BE OF INTERLOCKING TIBIAL NAIL, CANNULATED TIBIAL NAIL AND DISTAL TIP DISTAL LOCKING TIBIAL NAIL TYPES. UNREAMED FEMORAL NAILS: THE GREENS RETROGRADE/ANTEGRADE FEMORAL NAIL SYSTEM IS INTENDED TO STABILIZE FRACTURES OF THE DISTAL FEMUR AND THE FEMORAL SHAFT, INCLUDING SUPRACONDYLAR FRACTURES, INCLUDING THOSE WITH INTRA-ARTICULAR EXTENSION; IPSILATERAL HIP/SHAFT FRACTURES; IPSILATERAL FEMUR/TIBIA FRACTURES; FEMORAL FRACTURES IN MULTIPLE TRAUMA PATIENTS; FRACTURES PROXIMAL TO TOTAL KNEE ARTHROPLASTY; FRACTURES DISTAL TO A HIP IMPLANT; FRACTURES IN THE MORBIDLY OBESE; FRACTURES IN OSTEOPOROTIC BONE, IMPENDING PATHOLOGIC FRACTURES; AND MALUNIONS AND NONUNIONS. UNIVERSAL FEMORAL NAILS: THE GREENSFEMORAL NAIL IS INDICATED FOR USE IN A VARIETY OF FEMORAL FRACTURES SUCH AS COMMINUTED FRACTURES, SEGMENTAL FRACTURES, FRACTURES WITH BONE LOSS, PROXIMAL AND DISTAL FRACTURES, NONUNIONS, SUBTROCHANTERIC FRACTURES, INTERTROCHANTERIC FRACTURES. SUPRACONDYLAR NAILS: THE GREENSSUPRACONDYLAR INTRAMEDULLARY NAILS ARE INTENDED FOR USE IN FIXATION OF VARIOUS TYPES OF FRACTURES OF SUPRACONDYLAR OR DISTAL REGION OF THE FEMUR AS WELL AS FOR PROXIMAL FRACTURES IN CONJUNCTION WITH SUPRACONDYLAR FRACTURES. PROXIMAL FEMORAL NAIL, PROXIMAL FEMORAL NAIL-LONG: THE GREENSPROXIMAL FEMORAL NAIL IS INTENDED TO TREAT STABLE AND UNSTABLE PROXIMAL FEMORAL FRACTURES INCLUDING PERTROCHANTERIC FRACTURES, INTERTROCHANTERIC FRACTURES, HIGH SUBTROCHANTERIC FRACTURES. CANNULATED HUMERAL NAILS: THE GREENSCANNULATED HUMERAL NAIL SYSTEM IS INTENDED TO AID IN THE ALIGNMENT AND STABILIZATION OF HUMERAL FRACTURES TO INCLUDE DIAPHYSEAL FRACTURES OF THE HUMERAL SHAFT, FRACTURES OF THE PROXIMAL HUMERUS, PROXIMAL HUMERAL FRACTURES WITH DIAPHYSEAL EXTENSION, IMPENDING PATHOLOGIC FRACTURES & MALUNIONS AND NONUNIONS. UNREAMED HUMERAL NAILS: THE GREENSUNREAMED HUMERAL NAILS ARE INDICATED FOR THE TREATMENT OF FRACTURES OF PROXIMAL HUMERUS. RECON NAILS: THE GREENS RECON NAIL SYSTEM IS A FRACTURE FIXATION DEVICE COMPRISED OF RECONSTRUCTION NAILS AND THE RELATED ACCESSORIES SUCH AS WASHERS, LOCKING SCREWS, SET SCREWS, END CAPS, AND LAG

	SCREWS. THE DEVICES ARE INTENDED TO PROVIDE STRONG AND STABLE INTERNAL FRACTURE FIXATION WITH MINIMAL SOFT TISSUE IRRITATION OF THE TIBIA AND FEMUR. THIS DEVICE IS UTILIZED AS AN AID TO HEALING, NOT AS A SUBSTITUTE FOR NORMAL INTACT BONE AND TISSUE. GAMMA NAIL THE GREENS GAMMA NAIL IS INDICATED FOR USE IN FIXATION OF FEMORAL FRACTURES OCCURRING FROM THE BASE OF THE FEMORAL NECK EXTENDING DISTALLY TO A POINT PROXIMAL TO INTERCONDYLAR NOTCH. FRACTURE TYPES INCLUDE BASILAR NECK, INTERTROCHANTERIC SUBTROCHANTERIC FRACTURES AND FEMORAL SHAFT FRACTURES. ELASTIC NAILS: THE GREENS ELASTIC INTRAMEDULLARY NAIL SYSTEM IS INDICATED FOR FIXATION OF DIAPHYSEAL FRACTURES WHERE THE CANAL IS NARROW OR FLEXIBILITY OF THEIMPLANT IS IMPORTANT. THIS INCLUDES UPPER EXTREMITY FRACTURES IN ALL PATIENTS AND LOWER EXTREMITY FRACTURES IN PEDIATRIC OR SMALL-STATURE PATIENTS. THIS SYSTEM IS ALSO INTENDED TO TREAT METAPHYSEAL AND EPIPHYSEAL FRACTURES, SUCH AS RADIAL NECK FRACTURES AND IS INTENDED FOR FIXATION OF SMALL LONG BONES, SUCH AS CARPAL AND TARSAL BONES.

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3439	MFG/MD/2020/000081	1.License Holder Name: BIPSON SURGICAL PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:X RAY DETECTABLE ABDOMINAL PAD(BIPSON)-IT IS INTENDED FOR THE USE DURING VARIOUS SURGERIES.,COMBINE DRESSING SURGICAL PAD(BIPSON)-A PROSTHETIC AND ORTHOTIC ACCESSORY, INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT, OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE), OR PROSTHESIS.,COTTON CREPE BANDAGE - B.P. (BIPSON)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,ELASTIC ADHESIVE BANDAGE(BIPSON)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,X- RAY DETECTABLE GAUZE SWAB – B.P.(BIPSON)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,ABSORBENT COTTON RIBBON GAUZE – B.P.(BIPSON)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,GAUZE SWAB – B.P.(BIPSON)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES., ABSORBENT GAUZE (ROLLED) – SCH. F(II)(BIPSON)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.

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3440	MFG/MD/2020/000082	1.License Holder Name: BIPSON SURGICAL PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE CHLORHEXIDINE GAUZE DRESSING – B.P.(BIPSON)-DRESSING-GEL, DRESSING-PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE.,STERILE PARAFFIN GAUZE DRESSING - B.P.(BIPSON)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE.,STERILE GAMJEE ROLL(BIPSON)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. ,STERILE DRESSING FIELD COMPRESSED(BIPSON)-DRESSING-GEL, DRESSING-PERMEABLE, MOISTURE DRESSING,TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. ,STERILE COMBINE DRESSING SURGICAL PAD(BIPSON)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING,TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. ,STERILE UMBILICAL COTTON TAPE – SCH. F(III)(BIPSON)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. ,STERILE POVIDONE IODINE NON ADHERENT DRESSING(BIPSON)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING,TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE.,STERILE X -RAY DETECTABLE GAUZE SWAB – B.P.(BIPSON)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING,TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE.,STERILE ABSORBENT COTTON RIBBON GAUZE – B.P.(BIPSON)-DRESSING-GEL, DRESSING-PERMEABLE, MOISTURE DRESSING,TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE.,STERILE DRESSING SHELL COMPRESSED (BIPSON)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING,TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. ,STERILE EYE PAD – B.P. FOR SINGLE USE ONLY(BIPSON)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE.

3441	MFG/MD/2020/000083	1.License Holder Name: A.V.PROCESSOR PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NAILS(OCCPL)-1. UNDISPLACED STABLE CLOSED FRACTURE 2. SIGNIFICANT COMORBIDITIES (EXCESSIVE RISK OF SURGERY AND ANESTHESIA) 3. REDUCIBLE DEFORMITY JUDGED TO BE STABLE IN A SUITABLE CAST, HIP PROSTHESIS(OCCPL)-1. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS; 2. RHEUMATOID ARTHRITIS; 3. CORRECTION OF FUNCTIONAL DEFORMITY; 4. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT,UNMANAGEABLE USING OTHER TECHNIQUES; AND 5. REVISION PROCEDURES WHERE OTHER TREATMENT OR DEVICES HAVE FAILED.,BONE PLATES (OCCPL)-1 REPAIR OF BONE FRACTURE BY OSTEOSYNTHESIS 2 FIXATION OF BONE FRAGMENTS IN BONE GRAFTING 3 FIXATION OF BONE FRAGMENTS IN OSTEOTOMY 4 FIXATION OF BONE FRAGMENTS IN RECONSTRUCTIVE PROCEDURES 5 FIXATION OF LIGAMENTS OR SOFT TISSUES,WIRE & PINS(OCCPL)-WIRE & PINS ARE USED MAINLY FOR TRACTION THROUGH THE FEMUR, THE TIBIA (PROXIMAL OR DISTAL END), OR THE CALCIS. INTRAMEDULLARY PINNING WITH A SINGLE STEINMANN PIN MAY BE INDICATED IN FRACTURES THROUGHOUT THE LENGTH OF A LONG BONE. IT IS BEST FOR TRANSVERSE AND SHORT OBLIQUE FRACTURES OF THE MIDDLE THIRD OF LONG BONES. IT CAN BE APPLIED IN CONJUNCTION WITH CERCLAGE AND HEMICERCLAGE WIRING, WHICH WILL EXTEND ITS INDICATIONS CONSIDERABLY. SINGLE OR MULTIPLE STEINMANN PINS TOGETHER WITH CERCLAGE AND HEMICERCLAGE WIRING MAY BE ADAPTED FOR ALL TYPES OF FRACTURE FIXATION.,BONE SCREWS (OCCPL)-1 REPAIR OF BONE FRACTURE BY OSTEOSYNTHESIS 2 FIXATION OF BONE FRAGMENTS IN BONE GRAFTING 3 FIXATION OF BONE FRAGMENTS IN OSTEOTOMY 4 FIXATION OF BONE FRAGMENTS IN RECONSTRUCTIVE PROCEDURES 5 FIXATION OF LIGAMENTS OR SOFT TISSUES,SPINAL IMPLANT(OCCPL)-1. DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES) 2. SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); 3. SPINAL STENOSIS; CURVATURES (I. E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); 4. TUMOR; PSEUDOARTHROSIS; AND 5. FAILED PREVIOUS FUSION.

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3442	MFG/MD/2020/000084	1.License Holder Name: EUCARE PHARMACEUTICALS PRIVATE LIMITED. 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use: STERILE MEDICATED COLLAGEN PARTICLES (FISH ORIGIN)(COLLBOND-AB)-STERILE MEDICATED COLLAGEN PARTICLES IS INDICATED FOR INFECTED EXUDING ACUTE (TRAUMA WOUNDS & SURGICAL WOUNDS) & CHRONIC (DIABETIC FOOT ULCERS, LEG ULCERS, PRESSURE ULCERS) WOUNDS.,STERILE SYNTHETIC HYDROXYAPATITE AND BETA-TRICALCIUM PHOSPHATE BONE GRAFT COMPOSITE(SYBOGRAF PLUS)-STERILE SYNTHETIC HYDROXYAPATITE & BETA-TRICALCIUM PHOSPHATE BONE GRAFT IS INDICATED AS HYDROXYAPATITE & BETA-TRICALCIUM PHOSPHATE COMBINATION GRAFT MATERIAL FOR BONE REGENERATION PROCEDURES IN DENTAL SURGERIES., STERILE ABSORBABLE GELATIN SPONGE-USP / IP(GELBOND-B)-STERILE ABSORBABLE GELATIN SPONGE – USP / IP IS INDICATED FOR CONTROL OF BLEEDING WHEN HEMOSTASIS IS NOT ACHIEVABLE OR IMPRACTICAL WITH OTHER CONVENTIONAL HEMOSTATIC PROCEDURES.,STERILE POROUS COLLAGEN SHEETS IN DRY FORM (KOLLAGEN-D; HELISORB SHEET; BAVILON SHEET; URGOREGENERATE SHEET)-• STERILE POROUS COLLAGEN SHEETS IN DRY FORM IS INDICATED FOR EXUDING NON-INFECTED SECOND-DEGREE BURNS • INDICATED AS A PRE-GRAFT PREPARATION MATRIX FOR NON-INFECTED LARGE SURFACE AREA WOUNDS OF ALL ORIGINS,STERILE COLLAGEN DEVICES (BIOLOGICAL SKIN DRESSINGS – BOVINE ORIGIN)(COLLBOND SHEET, COLLBOND-M SHEET)-1. STERILE COLLAGEN SHEETS (BIOLOGICAL SKIN DRESSING) INDICATED AS A BIOLOGICAL DRESSING FOR NON-INFECTED SECOND-DEGREE BURNS. 2. STERILE COLLAGEN SHEETS IN MESHED FORM (BIOLOGICAL SKIN DRESSING) INDICATED AS A BIOLOGICAL DRESSING FOR EXUDING NON-INFECTED SECOND-DEGREE BURNS. 3. . STERILE COLLAGEN SHEETS IN DRY FORM (BIOLOGICAL SKIN DRESSING) INDICATED AS A DRY BIOLOGICAL DRESSING FOR NON-INFECTED SECOND-DEGREE BURNS,STERILE ABSORBABLE GELATIN SPONGE-USP / IP(GELSPON; SCROFALON-B)-STERILE ABSORBABLE GELATIN SPONGE – USP / IP IS INDICATED FOR CONTROL OF BLEEDING WHEN HEMOSTASIS IS NOT ACHIEVABLE OR IMPRACTICAL WITH OTHER CONVENTIONAL HEMOSTATIC PROCEDURES., STERILE ABSORBABLE GELATIN SPONGEUSP/IP ((PORCINE ORIGIN) (GELBOND)-STERILE ABSORBABLE GELATIN SPONGE - IP/USP (PORCINE ORIGIN) IS INDICATED FOR CONTROL OF BLEEDING WHEN HEMOSTASIS IS NOT ACHIEVABLE OR IMPRACTICAL WITH OTHER CONVENTIONAL HEMOSTATIC PROCEDURES.,STERILE MEDICATED

	COLLAGEN PARTICLES (FISH ORIGIN)(BIOFIL-AB PARTICLES; COMUPIMET, UNIFIL-D)-STERILE MEDICATED COLLAGEN PARTICLES IS INDICATED FOR INFECTED EXUDING ACUTE (TRAUMA WOUNDS & SURGICAL WOUNDS) & CHRONIC (DIABETIC FOOT ULCERS, LEG ULCERS, PRESSURE ULCERS) WOUNDS.,STERILE COLLAGEN PARTICLES(COLLBOND)-INDICATED FOR NON-INFECTED EXUDING ACUTE (TRAUMA WOUNDS & SURGICAL WOUNDS) & CHRONIC (DIABETIC FOOT ULCERS, LEG ULCERS, PRESSURE ULCERS) WOUNDS.,STERILE ABSORBABLE COLLAGEN SPONGE - HAEMOSTATIC(HELISORB)-STERILE ABSORBABLE COLLAGEN SPONGE - HAEMOSTATIC IS INDICATED FOR CONTROL OF BLEEDING WHEN HEMOSTASIS IS NOT ACHIEVABLE OR IMPRACTICAL WITH OTHER CONVENTIONAL HEMOSTATIC PROCEDURES.,STERILE SYNTHETIC HYDROXYAPATITE BONE GRAFT(COREGRAFT)-STERILE SYNTHETIC HYDROXYAPATITE BONE GRAFT IS INDICATED AS A HYDROXYAPATITE GRAFT MATERIAL FOR BONE REGENERATION PROCEDURES IN DENTAL SURGERIES,STERILE COLLAGEN SPONGE (KOLSPON; BIOFIL SPONGE; URGOREGENERATE SPONGE)-STERILE COLLAGEN SPONGE INDICATED FOR NON-INFECTED CAVITATED (TUNNELED & UNDERMINED) EXUDING ACUTE (TRAUMA WOUNDS, SURGICAL WOUNDS) & CHRONIC (DIABETIC FOOT ULCERS, LEG ULCERS, PRESSURE ULCERS) WOUNDS., STERILE COLLAGEN PERIODONTAL MEMBRANE(COLLBOND-GTR)-INDICATED FOR GUIDED TISSUE REGENERATION IN PERIODONTAL AND IMPLANT PROCEDURES.,STERILE COLLAGEN ABSORBENT DRESSING (DONORDRES)-STERILE COLLAGEN ABSORBENT DRESSING IS INDICATED AS A D RESSING FOR RAW DONOR SITE WOUNDS.,STERILE COLLAGEN PERIODONTAL MEMBRANE(PERIOCOL-GTR, HELISORB-GTR)-STERILE COLLAGEN PERIODONTAL MEMBRANE IS INDICATED FOR GUIDED TISSUE REGENERATION IN PERIODONTAL AND IMPLANT PROCEDURES.,STERILE COLLAGEN SHEETS IN DRY FORM (FISH ORIGIN) (BIOLOGICAL SKIN DRESSING)(NEUSKIN-F; URGOREGENERATE FILM)-STERILE COLLAGEN SHEETS IN DRY FORM (FISH ORIGIN) IS INDICATED AS SCAFFOLD FOR EPIDERMAL GRAFTS DURING CELL TRANSPLANT THERAPY IN VITILIGO SURGERIES., STERILE COLLAGEN DEVICES (BIOLOGICAL SKIN DRESSINGS – BOVINE ORIGIN)(KOLLAGEN, BIODRES ; EFFICOL - W, KOLLAGEN-M, BIODRES-M; EFFICOL-M, KOLLAGEN DRY, NEUSKIN; EFFICOL)-1. STERILE COLLAGEN SHEETS (BIOLOGICAL SKIN DRESSING) INDICATED AS A BIOLOGICAL DRESSING FOR NON-INFECTED SECOND-DEGREE BURNS. 2. STERILE COLLAGEN SHEETS IN MESHED FORM (BIOLOGICAL SKIN DRESSING) INDICATED AS A BIOLOGICAL DRESSING FOR EXUDING NON-INFECTED SECOND-DEGREE BURNS. 3. . STERILE COLLAGEN SHEETS IN DRY FORM (BIOLOGICAL SKIN

		DRESSING) INDICATED AS A DRY BIOLOGICAL DRESSING FOR NON-INFECTED SECOND-DEGREE BURNS,STERILE SYNTHETIC HYDROXYAPATITE BONE GRAFT(SYBOGRAF)-STERILE SYNTHETIC HYDROXYAPATITE BONE GRAFT IS INDICATED AS A HYDROXYAPATITE GRAFT MATERIAL FOR BONE REGENERATION PROCEDURES IN DENTAL SURGERIES.,STERILE SYNTHETIC BETA-TRICALCIUM PHOSPHATE BONE GRAFT(SYBOGRAF-T)-STERILE SYNTHETIC BETA-TRICALCIUM PHOSPHATE BONE GRAFT IS INDICATED AS A BETA TRICALCIUM PHOSPHATE GRAFT MATERIAL FOR BONE REGENERATION PROCEDURES IN DENTAL SURGERIES., STERILE COLLAGEN PARTICLES(BIOFIL PARTICLES; HELISORB PARTICLES ; URGOREGENERATE PARTICLES; BAVILON PARTICLES ; BIOCOLLAZ PARTICLES, UNIFIL)-STERILE COLLAGEN PARTICLES IS INDICATED FOR NON-INFECTED EXUDING ACUTE (TRAUMA WOUNDS & SURGICAL WOUNDS) & CHRONIC (DIABETIC FOOT ULCERS, LEG ULCERS, PRESSURE ULCERS) WOUNDS.,STERILE ABSORBABLE GELATIN SPONGE-USP/IP ((PORCINE ORIGIN)(GELSPON-P; SCROFALON; EQUISPON; MEDISPONGE; URGOSPON; GALENASPON)-STERILE ABSORBABLE GELATIN SPONGE - USP/IP (PORCINE ORIGIN) IS INDICATED FOR CONTROL OF BLEEDING WHEN HEMOSTASIS IS NOT ACHIEVABLE OR IMPRACTICAL WITH OTHER CONVENTIONAL HEMOSTATIC PROCEDURES.
3443	MFG/MD/2020/000085	1.License Holder Name: DOVE MEDITECH 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.(NIL)-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS,ABSORBENT COTTON WOOL B.P.(NIL)-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS

3444	MFG/MD/2020/000086	1.License Holder Name: RELISYS MEDICAL DEVICES LIMITED 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:EVEROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM(PRISTINE / PRISTINE+ / ACE / BESTIE / BRILLIANT / PRISTINE FLEX / PRISTINE NEO / ETERNIA SELECT / ETERNIA NEXA)-THE RELISYS EVEROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES. EVEROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM IS ALSO INDICATED FOR TREATMENT OF ABRUPT OF THREATENED CLOSURE IN PATIENTS WITH FAILED INTERVENTIONAL THERAPY. THE DRUG COATING IS INTENDED TO INHIBIT RESTENOSIS.,STAINLESS STEEL BARE METAL STENT-STAINLESS STEEL BARE METAL STENT IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES. IT IS ALSO INDICATED FOR TREATMENT OF ABRUPT OF THREATENED CLOSURE IN PATIENTS WITH FAILED INTERVENTIONAL THERAPY., EVEROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM(ETERNIA, ETERNIA BRIO)-THE RELISYS EVEROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES. EVEROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM IS ALSO INDICATED FOR TREATMENT OF ABRUPT OF THREATENED CLOSURE IN PATIENTS WITH FAILED INTERVENTIONAL THERAPY. THE DRUG COATING IS INTENDED TO INHIBIT RESTENOSIS.,COBALT CHROMIUM CORONARY BARE METAL STENT-COBALT CHROMIUM CORONARY BARE METAL STENT IS INDICATED FOR PERCUTANEOUS CORONARY INTERVENTION (PCI) I.E. IMPROVING LUMINAL DIAMETER AND REDUCING RE-STENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES. PCI ALSO KNOWN AS CORONARY ANGIOPLASTY. IT IS ALSO INDICATED FOR TREATMENT OF ABRUPT OF THREATENED CLOSURE IN PATIENTS WITH FAILED INTERVENTIONAL THERAPY, SIROLIMUS ELUTING CORONARY STENT SYSTEM(SIROFLEX, SIROFLEX PLUS)-THE RELISYS SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES. SIROLIMUS ELUTING CORONARY STENT SYSTEM IS ALSO INDICATED FOR TREATMENT OF ABRUPT OF THREATENED CLOSURE IN PATIENTS WITH FAILED INTERVENTIONAL THERAPY. THE DRUG COATING IS INTENDED TO

	INHIBIT RESTENOSIS.,SIROLIMUS ELUTING CORONARY STENT SYSTEM(RELEASE-R, PREMIER, PREMIER+, BEST, INSIGNIA NEO, PARAMOUNT, PERFECT, PREMIER FLEX, PREMIER NEO AND SLENDER) -THE RELISYS SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES. SIROLIMUS ELUTING CORONARY STENT SYSTEM IS ALSO INDICATED FOR TREATMENT OF ABRUPT OF THREATENED CLOSURE IN PATIENTS WITH FAILED INTERVENTIONAL THERAPY. THE DRUG COATING IS INTENDED TO INHIBIT RESTENOSIS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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3445	MFG/MD/2020/000087	1.License Holder Name: UNISYS ORTHO. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:PINS & WIRES(UNISYS, EMT, AO-G,APEX)-WIRE AND PINS ARE USED FOR FIXATION OF DIAPHYSEAL AND METAPHYSEAL FRACTURE AND IRREGULAR BONE FRACTURE IN COMBINATION WITH EXTERNAL FIXATORS.,BONE SCREW(UNISYS, EMT, AO-G,APEX)-BONE CREWS ARE USED FOR FIXATION OF DIAPHYSEAL AND METAPHYSEAL FRACTURE AND IRREGULAR BONE FRACTURE IN COMBINATION WITH EXTERNAL FIXATORS.,BONE PLATES(UNISYS, EMT, AO-G,APEX)-BONE PLATES ARE USED FOR FIXATION OF DIAPHYSEAL AND METAPHYSEAL FRACTURE AND IRREGULAR BONE FRACTURE IN COMBINATION WITH EXTERNAL FIXATORS.,ARTHROSCOPY IMPLANTS(UNISYS, EMT, AO-G, APEX)-THE ARTHROSCOPY IMPLANTS ARE SMALLER THAN TRADITIONAL INSTRUMENTS. SURGEONS VIEW THE JOINT AREA ON A VIDEO MONITOR, AND CAN DIAGNOSE AND REPAIR TORN JOINT TISSUE, SUCH AS LIGAMENTS. IT IS TECHNICALLY POSSIBLE TO DO AN ARTHROSCOPIC EXAMINATION OF ALMOST EVERY JOINT, BUT IS MOST COMMONLY USED FOR THE KNEE, SHOULDER, ELBOW, WRIST, ANKLE, FOOT, AND HIP.,SPINAL IMPLANTS(UNISYS, MASADA,EMT, AO-G,APEX)-SPINAL IMPLANTS IS USED FOR THE INTERNAL FIXATION OF ANTERIOR, POSTERIOR CERVICAL, LUMBER AND THORACOLUMBAR SPINE FRACTURES.,MAXILLOFACIAL IMPLANTS (UNISYS, EMT, AO-G,APEX, M-FIX)-MAXILLOFACIAL IMPLANTS ARE USED FOR FIXATION OF MAXILOFACIAL FRACTURE AND IRREGULAR BONE FRACTURE IN COMBINATION FOR INTERNAL FIXATIONS., INTRAMEDULLARY NAILS(UNISYS, EMT, AO-G,APEX)-INTRAMEDULLARY NAILS ARE INTENDED TO BE IMPLANTED INTO THE MEDULLARY CANAL OF LIMBS FOR ALIGNMENT, STABILIZATION, FIXATION OF FRACTURES CAUSED BY TRAUMA OR DISEASES., STERNUM IMPLANTS(UNISYS, APEX, INNVOLOCK)-STERNUM IMPLANTS ARE USED FOR FIXATION OF STERNUM BONE FRACTURE IN COMBINATION WITH CROSS DRIVE SCREWS.,CRANIAL IMPLANTS (UNISYS, APEX, AO-G, C-FIX)-CRANIAL IMPLANTS ARE USED FOR FIXATION OF CRANIAL BONE OR SKULL BONE DIAPHYSEAL AND METAPHYSEAL FRACTURE AND IRREGULAR BONE FRACTURE IN COMBINATION WITH INTERNAL FIXATIONS.

3446	MFG/MD/2020/000088	1.License Holder Name: ANGSTROM BIOTECH PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:TYPHOID ANTIGENS TEST REAGENT AND KIT(ANGCARD)-ESTIMATION OF TYPHOID ANTIGENS/ANTIBODY IN BLOOD/BODY FLUIDS.,HBV TEST REAGENT/KIT(HEPATITIS STRIP AND CARD KIT)(ANGCARD)-FOR THE DETECTION OF HBV IN BLOOD/BODY FLUIDS,C- REACTIVE PROTEIN (CRP)TEST REAGENTS/KIT(ANGCARD)-ESTIMATION OF C -REACTIVE PROTEIN (CRP) IN SERUM AND OTHER BODY FLUIDS,MALARIA ANTIGEN TEST REAGENT AND KIT(MALARIA STRIP AND CARD) (ANGCARD)-DETECTION OF MALARIA ANTIGEN IN BLOOD/BODY FLUIDS.,LEPTOSPIRA ANTIGEN TEST REAGENT AND KIT(ANGCARD)-DETECTION OF LEPTOSPIRA ANTIGEN IN BLOOD/BODY FLUIDS, SYPHILIS SCREENING REAGENT/KIT(SYPHILIS CARD)(ANGCARD)-ESTIMATION OF SYPHILIS IN BLOOD/BODY FLUIDS.,TYPHOID ANTIGENS TEST REAGENT AND KIT(WIDAL TEST KIT)(ANGCARD)-ESTIMATION OF TYPHOID ANTIGENS/ANTIBODY IN BLOOD/BODY FLUIDS.,FILARIASIS ANTIGEN TEST REAGENT AND KIT(ANGCARD)-DETECTION OF FILARIASIS ANTIGEN/ ANTIBODY IN BLOOD/BODY FLUIDS,A TROPONIN TEST REAGENT/KIT (TROPONIN I CARD) (ANGCARD)-ESTIMATION OF TROPONIN T, I AND ITS VARIANTS IN BLOOD/BODY FLUIDS,HLA TEST REAGENT/KIT (BLOOD GROUPING AND TESTING SERA)(ANGCARD)-FOR BLOOD GROUPING OR TISSUE TYPING,HCV TEST REAGENT/KIT(HCV CARD)(ANGCARD)-DETECTION OF HCV IN BLOOD/BODY FLUIDS.,DENGUE VIRUS ANTIGEN TEST REAGENT AND KIT(DENGUE STRIP AND CARD)(ANGCARD)-DETECTION OF DENGUE VIRUS ANTIGEN IN BLOOD/BODY FLUIDS., CHIKUNGUNYA ANTIGEN TEST REAGENT AND KIT(ANGCARD)-ESTIMATION OF CHIKUNGUNYA ANTIGEN/ANTIBODY OF IN BLOOD/BODY FLUIDS.,HIV TEST REAGENTS/KITS (HIV ½ CARD) (ANGCARD)-DETECTION OF TRANSMISSIBLE HIV IN BLOOD/BODY FLUIDS.,TOXOPLASMA GONDII TEST REAGENT/KIT (TOXO IGG/IGM CARD TEST KIT)(ANGCARD)-TO THE DETECTION OF TOXOPLASMA GONDII IN SERUM/BODY FLUIDS.,SYPHILIS SCREENING REAGENT/KIT (RAPID PLASMA REAGIN RPR)(ANGCARD)-ESTIMATION OF SYPHILIS IN BLOOD/BODY FLUIDS.

3447	MFG/MD/2020/000089	1.License Holder Name: M/S VEDIC MEDIFLOW DEVICE PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:I.V FLOW REGULATOR (VMD)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. ,DISPOSABLE BLOOD ADMINISTRATION SET(VMD)-USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED,CORD CLAMP(VMD)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT, DISPOSABLE PERFUSION SET/ INFUSION SET(VMD)-USED TO ADMINISTER BLOOD/DRUG TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN., ENDOTRACHEAL TUBE(VMD)-INSERT THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., DISPOSABLE MEASURED VOLUME INFUSION SET(VMD)-USED TO ADMINISTER FLUID FROM A CONTAINER INTO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN.,CHEST DRAINAGE CATHETER(VMD)-CLEARING THE AIRWAYS OF MUCUS, PUS OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,FLOW DIRECTED CATHETER(VMD)-USED FOR VENOUS SAMPLING AND PRESSURE MONITORING.,THREE WAY STOP COCK(VMD)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION , WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,SCALP VEIN SET(VMD)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT’S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD,HAEMODIALYSIS CATHETER(VMD)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT. , DIALYSIS SET(VMD)-DIALYSIS SET IS A TUBING THAT USE TO CONNECT CATHETER TO BAG OF DIALYSIS SOLUTION,MUCUS EXTRACTOR(VMD)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,I.V CANNULA(VMD)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/ OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,CONNECTING TUBE(VMD)-USED TO PROVIDE CONNECTION TO A DRAINAGE BAG.,DIALYSIS KIT(VMD)-IT IS USED TO PREVENT INFECTION DURING DIALYSIS OR CLEANING PURPOSE,URETERAL DOUBLE J-STENT(VMD)-DOUBLE J STENT IS USED FOR INTERNAL DRAINAGE FROM KIDNEY TO BLADDER.,CLOSED

		SUCTION SYSYTEM(VMD)-IT IS INTENDED FOR ENDOTRACHEAL SUCTIONING TO PROVIDE A PATIENT AIRWAY BY REMOVING EXCESS FLUID, SECRETIONS, EXUDATES AND TRANSUDATE THROUGH THE ARTIFICIAL AIRWAY,FOLEY CATHETER(VMD)-A LONG SMALL GAUGE CATHETER DESIGN FOR INSERTION DIRECTLY INTO URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY,RYLE'S TUBE(VMD)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,SPINAL NEEDLE(VMD)-AN ANAESTHESIA CONDUCTION NEEDLE IS A DEVICE USED TO INJECT LOCAL ANAESTHETICS INTO PATIENTS TO PROVIDE REGIONAL ANAESTHESIA,FEEDING TUBE (VMD)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE IN EATING
3448	MFG/MD/2020/000090	1.License Holder Name: EUCARE PHARMACEUTICALS PRIVATE LIMITED. 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:STERILE HYDROCOLLOID WOUND DRESSING WITH FOAM PADDING(HYCOLOID PLUS)-STERILE HYDROCOLLOID WOUND DRESSING WITH FOAM PADDING IS INDICATED AS AN OCCLUSIVE DRESSING FOR ACUTE & CHRONIC WOUNDS,STERILE HYDROPHILIC FOAM DRESSING(HYDREZ)-HYDROPHILIC FOAM DRESSING IS INDICATED FOR MANAGEMENT OF MODERATE TO SEVERELY EXUDING (LEAKING) WOUNDS TO CREATE NON-EXUDING AND MOIST WOUNDS SUITABLE FOR HEALING., SILICONE GEL SHEET(LYSIL; URGOSCAR SHEET, EUSIL)-INDICATED FOR MANAGEMENT OF RAISED HYPERTROPHIC AND KELOID SCARS, SILICONE GEL(LYSIL GEL; URGOSCAR GEL, EUSIL GEL)-INDICATED FOR MANAGEMENT OF RAISED HYPERTROPHIC AND KELOID SCARS, STERILE HYDROCOLLOID WOUND DRESSING(HYCOLOID)-INDICATED AS AN OCCLUSIVE DRESSING FOR ACUTE & CHRONIC WOUNDS

3449	MFG/MD/2020/000091	1.License Holder Name: AUSTEOFIX SURGICAL PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE SCREW, WASHER, END CAP-SS(AUSTEOFIX)-BONE SCREWS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR BONE RECONSTRUCTION.,BONE SCREW, WASHER, END CAP-TI(AUSTEOFIX)-BONE SCREWS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR BONE RECONSTRUCTION.,BONE PLATE-TI(AUSTEOFIX)-BONE PLATE IMPLANTS ARE INTENDED FOR FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS,BONE NAIL-TI(AUSTEOFIX)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS,ORTHOPAEDIC PINS AND WIRE-SS(AUSTEOFIX)-THESE IMPLANTS ARE USED IN FIXATION OF BONE FRACTURES, BONE RECONSTRUCTION, SKELETAL TRACTION, ALIGNMENT OF LONG BONE FRACTURED SEGMENTS, TEMPORARY FIXATION, INTRAMEDULLARY FIXATION OF ULNA & CLAVICLE. THESE ARE ALSO USED AS GUIDE PINS & WIRES FOR INSERTION OF IMPLANTS.,SPINAL IMPLANT-TI(AUSTEOFIX)-THESE IMPLANTS ARE INTENDED TO BE USED AS A TEMPORARY OR PERMANENT POSTERIOR, NON-CERVICAL IMPLANT TO CORRECT SPINAL DISORDERS AND PROVIDE STABILIZATION OF THE SPINE TO PERMIT THE BIOLOGICAL PROCESS OF SPINAL FUSIONS TO OCCUR.,BONE NAIL-SS(AUSTEOFIX)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS, ORTHOPAEDIC MAXILLOFACIAL IMPLANTS-TI(AUSTEOFIX)-ORTHOPAEDIC MAXILLOFACIAL IMPLANTS ARE USED IN MANAGEMENT OF MAXILLOFACIAL TRAUMA, CORRECTION OF DENTOFACIAL DEFORMITIES, RECONSTRUCTION OF JAWS AFTER ABLATIVE SURGERY AND RESTORATION OF LOST STOMATOGNATHIC APPARATUS.,BONE PLATE-SS(AUSTEOFIX)-BONE PLATE IMPLANTS ARE INTENDED FOR FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.

3450	MFG/MD/2020/000092	1.License Holder Name: PENTA LATEX LLP(UNIT-II) 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:MALE LATEX CONDOM (MANFORCE CONDOMS)-PROPERLY USED CONDOMS AID IN PREVENTION OF PREGNANCY AND CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES .,MALE LATEX CONDOM(MANFORCE XTASY CONDOMS (HAZELNUT))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES.,MALE LATEX CONDOM(MANFORCE CONDOMS)-PROPERLY USED CONDOMS AID IN PREVENTION OF PREGNANCY AND CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES .,MALE LATEX CONDOM(MANFORCE EPIC CONDOMS (HOT DOTS))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM(MANFORCE XTASY CONDOMS (BUTTERSCOTCH))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES,MALE LATEX CONDOM(MANFORCE XOTIC CONDOMS (CHOCOLATE))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES.,MALE LATEX CONDOM(MANFORCE XTASY CONDOMS (BLACK GRAPES))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES.,MALE LATEX CONDOM (MANFORCE EPIC CONDOMS (DESIRE))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES.

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3451	MFG/MD/2020/000093	1.License Holder Name: ENDOSYS HEALTHCARE INDIA PVT. LTD. 2.Approving Authority: GREATER MUMBAI DIVISION 3.Device Name(Brand Name)-Intended Use:SUTURE GRASPER PILOT GUIDE-SUTURE GRASPER PILOT GUIDE IS USED DURING LAPAROSCOPIC PROCEDURES TO PASS SUTURE GRASPER DEVICE TO CLOSE THE TROCAR PORT SITE COMPLETELY AND SECURELY. , TROCAR SYSTEM-TROCAR SYSTEM IS USED FOR CREATING A PATH FOR PASSING TELESCOPE, SECONDARY INSTRUMENTS & DEVICES IN PATIENT'S BODY TO PERFORM VARIOUS MINIMAL INVASIVE SURGERIES. ,SKIN HOOKS-SKIN HOOKS ARE WIDELY USED ALONG WITH RETRACTORS RINGS FOR RETRACTION OF SOFT OR HARD TISSUES / STRUCTURES WITH FLEXIBILITY TO GIVE OPTIMAL EXPOSURE, ENHANCED VISIBILITY AND UN-OBSTRUCTIVE ACCESS DURING VAGINAL AND RECTAL PROLAPSE SURGERY, URETHROPLASTY ETC.,LAP ASPIRATION NEEDLE-THE LAP ASPIRATION DEVICE IS USED FOR ASPIRATION OF FLUIDS FROM THE ABDOMINAL CAVITY OR ABDOMINAL ORGANS DURING LAPAROSCOPIC PROCEDURES. ,VERESS NEEDLE-THE VERESS NEEDLE USED TO CREATE PNUEMOPERITONEUM DURING MINIMALLY INVASIVE / ACCESS SURGERIES LIKE LAPAROSCOPY, GYNECOLOGY , UROLOGY SURGERIES.,MULTIPURPOSE SUTURE PASSER / GRASPER - THE MULTIPURPOSE SUTURE PASSER/GRASPER IS USED FOR TROCAR SITE CLOSURE, TEMPORARILY REPOSITION OF ANATOMIC STRUCTURES DURING MINIMALLY INVASIVE / ACCESS SURGERIES, TACKING HERNIA MESH IN POSITION PRIOR TO FINAL PLACEMENT, PERCUTANEOUS SUTURING, LIGATING ABDOMINAL WALL BLEEDERS.

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3452	MFG/MD/2020/000094	1.License Holder Name: SMB MEDICAL DEVICES PVT LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:CU 250 IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,TUBAL RING(SMB)-CONTRACEPTION IN WOMEN,COPPER T 380A (TCU 380A) IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,NON ABSORBABLE SURGICAL BRAIDED SILK SUTURE WITH NEEDLE(SMB)-WOUND CLOSURE,TCU 380AG IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,CU 375 IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,NON ABSORBABLE SURGICAL BRAIDED POLYESTER SUTURE WITH NEEDLE(SMB)-WOUND CLOSURE,NON ABSORBABLE SURGICAL POLYAMIDE MONOFILAMENT SUTURE WITH NEEDLE(SMB)-WOUND CLOSURE,COPPER T 380A (TCU 380A) IUD WITH SAFE LOAD AND PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE
3453	MFG/MD/2020/000095	1.License Holder Name: MICRO HEALTH CARE 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:BONE NAIL(MICRO HEALTH CARE)-BONE NAILS ARE USED IN HUMERUS BONE, TIBIA BONE, FEMUR BONE, WHERE FOUND THE FRACTURES IN PROXIMAL AND DISTAL AREA. ALL TYPES OF BONE NAILS ARE USED INSIDE THE BONE AND ITS PASS THROUGH FRACTURES AND HOLD THE FRACTURES WITH THE HELP OF BONE SCREWS. AND ITS MINIMAL INSERTION SURGERY.,BONE HIP PROSTHESIS(MICRO HEALTH CARE)-BONE HIP PROSTHESIS ARE USED IN PROXIMAL FEMUR BONE FRACTURES, WHERE IS FEMUR PROXIMAL AREA ARE FRACTURED BADLY, THE SURGEON REMOVED PROXIMAL AREA AND THEY FIXED ENDO PROSTHESIS AND FIX WITH FEMUR DISTAL PART.,BONE PLATE (MICRO HEALTH CARE)-BONE PLATES IS USED TO FIXING FRACTURE. WITH HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES.,BONE SCREW(MICRO HEALTH CARE)-BONE SCREW IS USED TO FIXING FRACTURE. WITH THE HELP OF BONE SCREW, BONE PLATES FIX OUTSIDE OF THE BONE AND ITS HOLD THE FRACTURES.

3454	MFG/MD/2020/000097	1.License Holder Name: STERILE WORLD TECHNOLOGOIES LLP. 2.Approving Authority: AURANGABAD DIVISION 3.Device Name(Brand Name)-Intended Use:ANGIOGRAPHIC CATHETER(LIFER)-A DIAGNOSTIC CATHETER IS INTENDED FOR USE IN ANGIOGRAPHIC PROCEDURES. DESIGNATED TO PROVIDE A PATHWAY FOR DELIVERING CONTRAST MEDIA TO SELECTED SITES IN THE DEVICE VASCULAR SYSTEM INCLUDING THE CAROTID ARTERIES.
3455	MFG/MD/2020/000099	1.License Holder Name: HEAL PLUS 2.Approving Authority: CHHATTISGARH 3.Device Name(Brand Name)-Intended Use:BANDAGE(HEAL PLUS SURGICALS)-BANDAGE NON-STERILE FOR SINGLE USE APPLIED OVER ABSORBENT COTTON ,BANDAGE(HEAL PLUS SURGICALS)-BANDAGE NON-STERILE FOR SINGLE USE APPLIED OVER ABSORBENT COTTON
3456	MFG/MD/2020/000100	1.License Holder Name: HINDCARE SURGICALS 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.(HINDCARE SURGICALS)-MEDICAL ABSORBENT (FIBER BANDAGES)

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3457	MFG/MD/2020/000101	1.License Holder Name: ROMSONS SCIENTIFIC & SURGICAL PVT LTD 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:IV CANNULA FIXATOR (SOFLENE)-FIXATOR IS HELPFUL FOR FIXING. I.V. CANNULA,URINARY DRAINAGE UNIT(UROKIT)-A CLOSED URINARY DRAINAGE SYSTEM CONSISTS OF A CATHETER INSERTED INTO THE URINARY BLADDER AND CONNECTED VIA TUBING TO A DRAINAGE BAG.,WOUND ABSORBENT PAD(STERISORB)-WOUND AND BURN DRESSINGS., SUCTION TUBE WITH CONNECTORS- AN ACCESSORY OF CATHETER (NIL)-ACCESSORIES OF A CATHETER INTENDED FOR SUCTION OF SURGICAL IRRIGATION FLUID BLOOD & DEBRIS,NON-WOVEN ADHESIVE TAPE(STERI FLEX)-DRESSING PERMEABLE,RYLES TUBE(RYLE'S TUBE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES., ADHESIVE WOUND PAD(STERIKEN)-DRESSING PERMEABLE, URETHRAL CATHETER (ROMSONS, URETERIC CATHETER OPEN TIP)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA ANDBLADDER OR POST ERIORLY VIA THE KIDNEY.,INTRAVENOUS CANNULA(FARCOCATH)-"THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.",FOLEY CATHETER(REDAX, FOLEY BALLOON CATHETER -2 WAY ADULT)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,NASAL OXYGEN CATHETER(OXY SET)-"IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.", TRACHEOSTOMY TUBE PLAIN(NIL)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,STERILE DRAPES(ROMO DRAPE)-IT IS INTENDED FOR USE DURING VARIOUS SURGERIES.,SUCTION CATHETER(ROMSONS SUCTION CATHETER)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,NON WOVEN IV CANNULA FIXATOR WITH PAD(VEIN GUARD)-FIXATOR IS HELPFUL FOR FIXING. I.V. CANNULA,SUCTION TUBE WITH CONNECTORS- AN ACCESSORY OF CATHETER (REDAX, YANKAUR SUCTION SET)-ACCESSORIES OF A CATHETER INTENDED FOR SUCTION OF SURGICAL IRRIGATION FLUID BLOOD & DEBRIS , TRANSPARENT IV CANNULA FIXATOR(INTRA SHIELD)-FIXATOR IS HELPFUL FOR FIXING. I.V. CANNULA.,SUCTION CATHETER(GELATO)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB

	CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,CREPE BANDAGE(KREPEX)-COTTON CREPE BANDAGE FOR THE REDUCES SWELLING SECURES WOUND DRESSING SUPPORTS STRAINS AND SPRAINS,MALE EXTERNAL CATHETER (REDAX, EXTERNAL CATHETER)-IT IS USED FOR URINE INCONTINENCE IN MALE PATIENT., MICRO POROUS ADHESIVE PAPER TAPE(KENPORE)-DRESSING PERMEABLE,SUCTION CATHETER(REDAX, SUCTION CATHETER – PLAIN)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., INTRAVENOUS CANNULA(NEOTEC)-"THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.",FOLEY CATHETER(REDAX, FOLEY BALLOON CATHETER-2 WAY PAEDIATRIC)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,THORACIC DRAINAGE CATHETER(SILICONE FLEXOCATH)-`INTENDED FOR POST-OPERATIVE PLEURAL DRAINAGE.,NELATON CATHETER (FEMALE)(NEL CATH)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA ANDBLADDER OR POST ERIORLY VIA THE KIDNEY.,ENDOTRACHEAL TUBE- CUFFED WITH SUCTION PORT(SUCCOR)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., GASTRO- ENTEROSTOMY TUBE(GASTROLENE)-TUBE IS PLACED THROUGH THE ABDOMINAL WALL INTO THE STOMACH AND THEN THROUGH THE DUODENUM INTO THE JEJUNUM.,UNDER WATER SEAL DRAINAGE SYSTEM(ROMO-SEAL PRO)-USED FOR QUICK OPERATIVE PLEURAL AND CHEST DRAINAGE.,THORACIC DRAINAGE CATHETER (TROCATH)-INTENDED FOR POST OPERATIVE PLEURAL DRAINAGE, BLOOD PRESSURE MONITORING DEVICES-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES, THORACIC DRAINAGE CATHETER(ROMSONS FLEXO CATH – RIGHT ANGLE)-INTENDED FOR POST OPERATIVE PLEURAL DRAINAGE, INTRAVENOUS CANNULA(INTRA CATH-2)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND / OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THORACIC DRAINAGE CATHETER (FLEXO CATH)-INTENDED FOR POST OPERATIVE PLEURAL DRAINAGE,BLOOD PRESSURE MONITORING DEVICE(BPX)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES,FOLEY CATHETER(FOLEY TRAC)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER,

	EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,DIGITAL THERMOMETER--IT IS A DEVICE USED TO MEASURE BODY TEMPERATURE.,FOLEY CATHETER(UROLENE)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA ANDBLADDER OR POST ERIORLY VIA THE KIDNEY.,EPIDURAL CATHETER KIT(EPIKIT SFT)-EPIDURAL CATHETER IS A VERY THIN, FLEXIBLE TUBE THAT IS IMPLANTED INTO SPINE.,SUCTION CATHETER (CEE TEE CATH)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,INTRAVENOUS CANNULA(VENESAFE PLUS)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,INTRAVENOUS CANNULA(VENESAFE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,FOLEY CATHETER(REDAX, FOLEY BALLOON CATHETER -3 WAY ADULT)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA ANDBLADDER OR POST ERIORLY VIA THE KIDNEY.,CONNECTING TUBE CONDUCTIVE (NIL)-USED TO PROVIDE CONNECTION TO A DRAINAGE BAG.,SUCTION CATHETER(ROMSONS SUCKATH)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., ASPIRATION CATHETER – OROPHARYNGEAL CATHETER(MUCUS TRAP)-INTENDED FOR ASPIRATION OF SECRETION FORM THE OROPHARYNX OF NEWLY BORN BABIES OR DEVICE INTENDED FOR USE WITH BRONCHOSCOPE FOR AIRWAYS MANAGEMENT.,UNDER WATER SEAL DRAINAGE SYSTEM(NIL)-USED FOR QUICK OPERATIVE PLEURAL AND CHEST DRAINAGE.,INTRAVENOUS CANNULA(NEO CATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES, TRACHEOSTOMY TUBE(ROMSONS PERCUTANEOUS TRACHEOSTOMY KIT, ROMO-SOFT CUFF – WDF)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,NASOGASTRIC TUBE KIT (ROMO-NGK)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,CONNECTING TUBE WITH INTEGRAL FUNNEL ENDS(NIL)-USED TO PROVIDE CONNECTION TO A DRAINAGE BAG.,CLOSED WOUND DRAINAGE SYSTEM(ROMSONS MINI VAC SET)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS,

	BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS, ASPIRATION CATHETER –AIRWAYS CATHETER(LARYNGEAL MASK AIRWAY-DL)-INTENDED FOR ASPIRATION OF SECRETION FORM THE OROPHARYNX OF NEWLY BORN BABIES OR DEVICE INTENDED FOR USE WITH BRONCHOSCOPE FOR AIRWAYS MANAGEMENT.,UMBLICAL ARTERY CATHETER(NIL)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS.,THORACIC DRAINAGE CATHETER(CHEST DRAINAGE CATHETER)-INTENDED FOR POST OPERATIVE PLEURAL DRAINAGE.,TRACHEOBRONCHIAL SUCTION CATHETER KIT -RIGHT (NIL)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,NELATON CATHETER (NEL CATH)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,FOLEY CATHETER(SILKO CATH)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,THORACIC DRAINAGE CATHETER(REDAX, CHEST DRAINAGE CATHETER - STRAIGHT)-INTENDED FOR POST OPERATIVE PLEURAL DRAINAGE. ,FEEDING TUBE(INFANT FEEDING TUBE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING., SUPRAPUBIC CATHETER(NIL)-A SUPRAPUBIC CATHETER IS A THIN, STERILE TUBE USED TO DRAIN URINE FROM BLADDER.,UNDER WATER SEAL DRAINAGE SYSTEM (ROMO SEAL)-USED FOR QUICK OPERATIVE PLEURAL AND CHEST DRAINAGE.,RYLES TUBE(ROMOLENE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,RYLES TUBE(REDAX, RYLE'S TUBE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES., SUCTION CATHETER(REDAX, SUCTION CATHETER -THUMB CONTROL) -SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., TRACHEOSTOMY TUBE(ROMSONS PERCUTANEOUS TRACHEOSTOMY KIT, ROMO-SOFT CUFF–DF)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,SUPRAPUBIC CATHETER(SUPRA CATH)-A

	SUPRAPUBIC CATHETER IS A THIN, STERILE TUBE USED TO DRAIN URINE FROM BLADDER.,ASPIRATION CATHETER –AIRWAYS CATHETER(ROMSONS LARYNGEAL MASK AIRWAYS- EXCELL)-INTENDED FOR ASPIRATION OF SECRETION FORM THE OROPHARYNX OF NEWLY BORN BABIES OR DEVICE INTENDED FOR USE WITH BRONCHOSCOPE FOR AIRWAYS MANAGEMENT.,ASPIRATION CATHETER –AIRWAYS CATHETER(NIL)-INTENDED FOR ASPIRATION OF SECRETION FORM THE OROPHARYNX OF NEWLY BORN BABIES OR DEVICE INTENDED FOR USE WITH BRONCHOSCOPE FOR AIRWAYS MANAGEMENT.,INTRAVENOUS CANNULA(VENEPORT)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,INTRAVENOUS CANNULA(MICRON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,CONNECTING TUBE WITH MOLDED CONNECTORS (NIL)-USED TO PROVIDE CONNECTION TO A DRAINAGE BAG., INTRAVENOUS CANNULA(NEO CARE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,FEEDING TUBE(FEEDY)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,INTRAVENOUS CANNULA(TRIFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,URETHRAL CATHETER(UROSIS)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA ANDBLADDER OR POST ERIORLY VIA THE KIDNEY.,CLOSED WOUND DRAINAGE SYSTEM(ROMO VAC SET)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,SUCTION TIP AND CATHETER(NIL)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,SCALP VEIN SET- SAFETY (NIL)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,SUCTION TUBE WITH CONNECTORS- AN ACCESSORY OF CATHETER (VACCU SUCK)-ACCESSORIES OF A CATHETER INTENDED FOR SUCTION OF SURGICAL IRRIGATION FLUID BLOOD & DEBRIS ,SUCTION CATHETER(ROMSONS SUCTION CATHETER – TC)-

	SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., ABDOMINAL DRAINAGE TUBE(NIL)-INTENDED FOR POST-OPERATIVE ABDOMINAL DRAINAGE.,SCALP VEIN SET(NIL)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,TRACHEOSTOMY TUBE CUFFED (NIL)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION., ENDOTRACHEAL TUBE- CUFFED WITH SUCTION PORT (NIL)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,INTRAVENOUS CANNULA(VENNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,INTRAVENOUS CANNULA(VEIN CATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,LEVINE TUBE(NIL)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,THORACIC DRAINAGE CATHETER KIT (NIL)-INTENDED FOR POST OPERATIVE PLEURAL DRAINAGE, THORACIC DRAINAGE CATHETER(REDAX, CHEST DRAINAGE CATHETER - ANGLED)-INTENDED FOR POST OPERATIVE PLEURAL DRAINAGE,NELATON CATHETER(INTEGRA)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA ANDBLADDER OR POST ERIORLY VIA THE KIDNEY.,CLOSED SUCTION SYSTEM(NIL)-IT IS INTENDED FOR ENDOTRACHEAL SUCTIONING TO PROVIDE A PATIENT AIRWAY BY REMOVING EXCESS FLUIDS, SECRETIONS, EXUDATES AND TRANSUDATE THROUGH THE ARTIFICIAL AIRWAY.,GUEDEL AIRWAYS (REDAX, GUEDEL AIRWAYS)-VENTILATION DEVICE INSERTED THROUGH THE MOUTH TO PROVIDE A PATIENT (UNOBSTRUCTED) AIRWAY DURING GENERAL ANAESTHESIA.,CATHETER-LEFT VENTRICULAR SUMP VENT CATHETER(ROMO VENTE)-LEFT VENTRICULAR SUMP VENT CATHETER IS USED IN CARDIO THORACIC SURGERY. ,INTRAVENOUS CANNULA(ROMSONS NEXAA NEO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,: INTRAVENOUS CANNULA(INTRAFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR

	ACCESS DEVICES .,TRACHEOBRONCHIAL SUCTION CATHETER KIT LEFT (NIL)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,SUCTION TIP AND CATHETER(ROMSONS SUCTION CATHETER FLOWER TIP)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., INTRAVENOUS CANNULA(NIL)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,THORACIC DRAINAGE CATHETER(THORAXEAL)-INTENDED FOR POST-OPERATIVE PLEURAL DRAINAGE,FEEDING BAG(FEE BAG)-ENTERAL FEEDING BAG SET INTEGRATED WITH BAG AND TUBING SETS.,ASPIRATION CATHETER –AIRWAYS CATHETER (ROMSONS LARYNGEAL MASK AIRWAYS-SILKEN)-INTENDED FOR ASPIRATION OF SECRETION FORM THE OROPHARYNX OF NEWLY BORN BABIES OR DEVICE INTENDED FOR USE WITH BRONCHOSCOPE FOR AIRWAYS MANAGEMENT.,THORACIC DRAINAGE CATHETER (TROCAR CATHETER)-INTENDED FOR POST OPERATIVE PLEURAL DRAINAGE,CATHETERS- ANTE GRADE CORONARY PERFUSION CANNULA (ACP CANNULA)-DEVICE IS USED CARDIAC SURGICAL PROCEDURES DURING THE CPB/ CABG SURGERY FOR ADMINISTRATION OF CARDIOPLEGIA SOLUTION. ,KARMAN CANNULA (NIL)-USED FOR VACUUM ASPIRATION OF UTERUS IN CASE OF INCOMPLETE ABORTION.,INTRAVENOUS CANNULA(INTRA CATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES,FOLEY CATHETER(ROMSONS LOTUS CATH)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,EPIDURAL CATHETER(EPI CATH)-EPIDURAL CATHETER IS A VERY THIN, FLEXIBLE TUBE THAT IS IMPLANTED INTO SPINE,FEEDING TUBE(REDAX, INFANT FEEDING TUBE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,EPIDURAL CATHETER KIT(ROMSONS EPI KIT)-EPIDURAL CATHETER IS A VERY THIN, FLEXIBLE TUBE THAT IS IMPLANTED INTO SPINE.,THORACIC DRAINAGE CATHETER(ROMSONS SILICONE FLEXO CATH-ANGLED)-INTENDED FOR POST OPERATIVE PLEURAL DRAINAGE,EPIDURAL CATHETER(NIL)-EPIDURAL CATHETER IS A VERY THIN, FLEXIBLE TUBE THAT IS IMPLANTED INTO SPINE.,ENDOTRACHEAL TUBE CUFFED (NIL)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL

	CORDS.,FOLEY CATHETER(URO CATH)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA ANDBLADDER OR POST ERIORLY VIA THE KIDNEY.,TRACHEOSTOMY TUBE KIT (NIL)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,CLOSED WOUND DRAINAGE SYSTEM(NIL) -A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,GUEDEL AIRWAYS (NIL)-VENTILATION DEVICE INSERTED THROUGH THE MOUTH TO PROVIDE A PATIENT (UNOBSTRUCTED) AIRWAY DURING GENERAL ANESTHESIA.,MALE EXTERNAL CATHETER(MALE CATH)-IT IS USED FOR URINE INCONTINENCE IN MALE PATIENT,FOLEY CATHETER(NIL)- A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,PERITONEAL DIALYSIS CATHETER(NIL)-THAT ALLOWS DIALYSIS FLUID TO ENTER THE ABDOMINAL CAVITY, DWELL INSIDE FOR A WHILE, AND THEN DRAIN BACK OUT AGAIN.,GASTRO- ENTEROSTOMY TUBE(NIL)-TUBE IS PLACED THROUGH THE ABDOMINAL WALL INTO THE STOMACH AND THEN THROUGH THE DUODENUM INTO THE JEJUNUM, NASOPHARYNGEAL CATHETER(ROMSONS, NASOPHARYNGEAL AIRWAYS)-A CATHETER (FOR ADULTS) PASSED THROUGH THE NARES AND ADVANCED TO THE DEPTH OF THE NASOPHARYNX TO REMOVE AIR CHOKE OR OBSTRUCTION. A RESUSCITATOR.,THORACIC DRAINAGE CATHETER(NIL)-INTENDED FOR POST OPERATIVE PLEURAL DRAINAGE,INTRAVENOUS CANNULA(ROMSONS INVENTA)- THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., SUCTION TUBE WITH CONNECTORS- AN ACCESSORY OF CATHETER (ROMSONS SUCTION EXTENSION LINE)-ACCESSORIES OF A CATHETER INTENDED FOR SUCTION OF SURGICAL IRRIGATION FLUID BLOOD & DEBRIS ,SUCTION TUBE WITH CONNECTORS- AN ACCESSORY OF CATHETER(CONNECTA)-ACCESSORIES OF A CATHETER INTENDED FOR SUCTION OF SURGICAL IRRIGATION FLUID BLOOD & DEBRIS,GASTRO- ENTEROSTOMY TUBE(ROMSONS, GASTROLENE PUR)-TUBE IS PLACED THROUGH THE ABDOMINAL WALL INTO THE STOMACH AND THEN THROUGH THE DUODENUM INTO THE JEJUNUM.,CARDIOPLEGIA CANNULA(ROMSONS, CARDIOPLEGIA CANNULA)-INDICATED FOR USE IN THE EXTRA CORPOREAL CIRCUIT DURING CARDIO PULMONARY BYPASS SURGERY PROCEDURE.,FEEDING BAG(FEEDING BAG)-ENTERAL FEEDING BAG SET INTEGRATED WITH BAG AND TUBING SETS.,

	ENDOTRACHEAL TUBE PLAIN(NIL)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,PERITONEAL DIALYSIS TRANSFUSION SET(NIL)-INTENDED FOR ADMINISTRATION OF DIALYSIS SOLUTIONS DURING PERITONEAL DIALYSIS PROCEDURES.,ENDOTRACHEAL TUBE -RE-INFORCED-CUFFED(NIL)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,FOLEY CATHETER(URO-CATH 3 WAY)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,ABDOMINAL DRAINAGE TUBE(ROMO ADK)-LNTENDED FOR POST-OPERATIVE ABDOMINAL DRAINAGE.,ABDOMINAL DRAINAGE TUBE(ROMSONS SUMP SUCTION SET)-INTENDED FOR POST-OPERATIVE ABDOMINAL DRAINAGE.,INTRAVENOUS CANNULA (ROMSONS INTRA VEIN-I)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,INTRAVENOUS CANNULA(NEOCATH2)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,ASPIRATION CATHETER – OROPHARYNGEAL CATHETER(MUCUS EXTRACTOR)-INTENDED FOR ASPIRATION OF SECRETION FORM THE OROPHARYNX OF NEWLY BORN BABIES OR DEVICE INTENDED FOR USE WITH BRONCHOSCOPE FOR AIRWAYS MANAGEMENT.,INTRAVENOUS CANNULA(ROMSONS INTRA VEIN-P)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,INTRAVENOUS CANNULA(REDAX INTRA VEIN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES ., MIST BLOWER(ROMSONS MISTAIR)-SURGICAL MIST BLOWER FOR BETTER VISIBILITY DURING SURGERIES INVOLVING ANASTOMOSIS., GASTRIC, IRRIGATION AND ASPIRATION CATHETER(SALEM TUBE)-USED FOR INSTILLING FLUIDS INTO, WITHDRAWING FLUIDS FROM, SPLINTING, OR SUPPRESSING BLEEDING OF THE ALIMENTARY TRACT.,SUCTION CATHETER(GELATO PLAIN)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,SUCTION TUBE WITH CONNECTORS-AN ACCESSORY OF CATHETER (ROMSONS ECO SUCK)-ACCESSORIES OF A CATHETER INTENDED FOR SUCTION OF SURGICAL IRRIGATION

	FLUID BLOOD & DEBRIS ,MALE EXTERNAL CATHETER (SIL CATH)-IT IS USED FOR URINE INCONTINENCE IN MALE PATIENT,THORACIC DRAINAGE CATHETER(CHEST DRAINAGE CATHETER)-INTENDED FOR POST OPERATIVE PLEURAL DRAINAGE.,INTRAVENOUS CANNULA (ROMSONS NEXAA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,URETHRAL CATHETER (ROMSONS, URETERIC CATHETER CLOSED TIP)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,TRACHEOSTOMY TUBE(ROMSONS SIL TRACHEOSTOMY TUBE (CUFFED))-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,EPIDURAL CATHETER KIT (NIL)-EPIDURAL CATHETER IS A VERY THIN, FLEXIBLE TUBE THAT IS IMPLANTED INTO SPINE., URETHRAL CATHETER(NIL)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA ANDBLADDER OR POST ERIORLY VIA THE KIDNEY.,KEHR'S "T" TUBE(NIL)-INTENDED FOR POST-OPERATIVE COMMON BILE DUCT DRAINAGE.,CLOSED WOUND DRAINAGE TUBE (NIL)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,DOUBLE "J" STENT (OPEN & CLOSE END)(URO TRAC)-INTENDED FOR SHORT TERM / LONG TERM URINE DRAINAGE FROM THE URETERO PELVIC JUNCTION TO THE URINARY BLADDER.,CLOSED WOUND DRAINAGE SYSTEM(FLAT DRAINAGE SET)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,2 - WAY ANTIMICROBIAL COATED FOLEY BALLOON CATHETER (NIL)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA ANDBLADDER OR POST ERIORLY VIA THE KIDNEY.,KIT – DOUBLE "J" STENT, PUSHER,GUIDE- WIRE & CATH CLAMP(OPEN & CLOSE END)(ROMSONS URO TRAC KIT)-INTENDED FOR SHORT TERM / LONG TERM URINE DRAINAGE FROM THE URETERO PELVIC JUNCTION TO THE URINARY BLADDER.

3458	MFG/MD/2020/000102	1.License Holder Name: AXIO BIOSOLUTIONS PRIVATE LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:CHITOSAN WOUND DRESSING(MAXIOCEL)-CHITOSAN WOUND DRESSING IS INTENDED TO BE USED FOR THE EXUDATING WOUND MANAGEMENT.,CHITOSAN HAEMOSTATIC DRESSING-CHITOSAN HAEMOSTATIC DRESSING IS A STERILE, SINGLE USE, NON- ABSORBABLE HAEMOSTATIC DRESSING INTENDED TO BE USED FOR TEMPORARY CONTROL OF BLEEDING WOUNDS.
3459	MFG/MD/2020/000103	1.License Holder Name: GIRNAR PRODUCTS PVT. LTD. 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:GAUGE BANDAGE-COVER WOUNDS,COTTON BANDAGE-COVER WOUND
3460	MFG/MD/2020/000104	1.License Holder Name: SECURE MEDICAL DEVICES PRIVATE LIMITED 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:FOLEY CATHETER-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO THE URETER, EITHER THROUGH A URETHRA OR BLADDER.,TRANSFUSION SET FOR SINGLE USE-TRANFUSION SET IS USED TO ADMINISTER FLUIDS OR DRUGS TO A PATIENT'S VASCULAR SYSTEM FROM A CONTAINER THROUGH A CATHETER OR NEEDLE INSERTED INTO A VEIN,SURGICAL DRESSING-NON-ADHERENT AND ABSORBENT COTTON DRESSING PAD WITHOUT AND DRUG IN IT, USED TO IN SURGICAL DRESSING OF SIMPLE WOUNDS.,MEASURED VOLUME I V SET-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. IT IS INTENDED FOR PAEDIATRIC INTRA-VENOUS USE ONLY.,I V CANNULA-THE I V CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE.,BLOOD ADMINISTRATION SET-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED DIRECTLY INTO THE VEIN

3461	MFG/MD/2020/000105	1.License Holder Name: AMAR SURGICARE PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE ABSORBENT GAUZE SWAB BP FOR SINGLE USE ONLY(GAUZE TOUCH)-:DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE.,STERILE PU DRESSING KIT FOR SINGLE USE ONLY(GAUZE TOUCH)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,STERILE DIALYSIS KIT (GAUZE TOUCH)-DIALYSIS KIT IS INTENDED TO USE FOR THE DIALYSIS PURPOSE FOR THE CLEANING OF THE BLOOD.,ROLLED BANDAGE SCH F(II)(GAUZE TOUCH)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES., X -RAY DETECTABLE GAUZE SWAB – B.P. (GAUZE TOUCH)-:DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING,TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. ,STERILE COMBINE DRESSING PAD FOR SINGLE USE ONLY(GAUZE TOUCH)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,BANDAGE CLOTH SCH F(II)(GAUZE TOUCH)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,: STERILE X -RAY DETECTABLE GAUZE SWAB – B.P. (GAUZE TOUCH)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. ,COTTON GAMJEE ROLL(GAUZE TOUCH)-ADHESIVE BENDAGES. GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,ELASTIC ADHESIVE BANDAGE (GAUZE TOUCH)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES,ABDOMINAL PAD WITH X-RAY DETECTABLE THREAD(GAUZE TOUCH)-IT IS INTENDED FOR THE USE DURING VARIOUS SURGERIES.,:STERILE EYE PAD – B.P. FOR SINGLE USE ONLY (GAUZE TOUCH)-:DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. , COTTON CREPE BANDAGE(GAUZE TOUCH)-:ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.

3462	MFG/MD/2020/000106	1.License Holder Name: SURVEY NO. 25/1 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF SWAB SPECIMEN FOR TRUEPREP® AUTO-TRUEPREP® AUTO TRANSPORT MEDIUM FOR SWAB SPECIMEN PACK IS USED AS A MEDIUM FOR COLLECTION, DECONTAMINATION AND TRANSPORT OF VARIOUS TYPES OF SWAB SPECIMENS BEFORE PROCEEDING FOR PRE-TREATMENT USING LYSIS BUFFER, EXTRACTION AND PURIFICATION OF NUCLEIC ACIDS USING TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP KIT AND TRUEPREP® AUTO UNIVERSAL CARTRIDGE BASED SAMPLE PREP DEVICE.

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3463	MFG/MD/2020/000107	1.License Holder Name: MEDICARE HYGIENE LTD, 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:COMBINATION PACK (COMBI KIT) PACKING OF ORTHOPAEDIC CASTING TAPE (ARTICAST) ALONG WITH RIBBED COTTON STOCKINETTE BP 1988, CAST PADDING (ORTHO ROLL CAST PADDING ARTIFLEX) AND A PAIR OF GLOVES (ARTICAST PROMOPACK)-PROVIDES RIGID EXTERNAL IMMOBILIZATION FOR FRACTURES AND OTHER ORTHOPEDIC INDICATIONS. THE PRODUCT CAN BE USED FOR CASTING REQUIREMENTS EXCEPT WHEN OEDEMA IS PRESENT OR LIKELY TO OCCUR. VALVING THE CAST MAY BE NECESSARY TO ACCOMMODATE SWOLLEN TISSUE.,ABSORBENT GAUZE B.P (ABSORBENT GAUZE ROLL)(MEDICA)-FOR WOUND DRESSING ABSORB EXUDATES USED IN CONTAMINATED EXUDING WOUND LIKE CAVITY WOUND & FISTULAS., ORTHO ROLL CAST PADING(ARTIFLEX)-EXTENSIVELY USED FOR FOR PROTECTION OF BONES FROM ELEVATION OR PROJECTION, THESE PADS REDUCES THE CHANCES OF SKIN MACERATION AND ACTS AS A CUSHION BETWEEN CAST AND SKIN. CHARACTERISTIC: HIGHLY COMFORTABLE. PROTECTS BONY PROMINENCES,COMBINE (OPERATION) SURGICAL PAD CONTAINS ABSORBENT COTTON WOOL I.P WRAPPED IN ABSORBENT GAUZE SCHFII/ABS GAUZE B.P.. OR NON WOVEN FABRIC(MEDICA, MEDIPAD)-THIS IS USED TO PROTECT WOUNDS AFTER INITIAL BLEEDING CONTROL BY DIRECT PRESSURE. DO NOT USE IT FOR SURGICAL OPEN WOUNDS,GAUZE SWAB / X-RAY DETECTABLE GAUZE SWAB (STD. AS PER B.P. 1993)(MEDISWAB, MEDICA)-GAUZE SWAB ARE USED TO PLACE OVER A WOUND BEFORE TAPING, STRAPPING OR BANDAGING UP OR CAN BE SOAKED IN ANTISEPTIC LIQUID AND USED TO WIPE OVER WOUND SITES. GAUZE SWABS ARE USEFUL CAN BE USED FOR PADDING, PROTECTION, BLOOD SPILL WOUND DRESSING, APPLYING ANTISEPTIC AND USE IN SURGERY TO ABSORB BLOOD & EXUDATES ETC.,ABSORBENT COTTON RIBBON GAUZE (STD. AS PER B.P. 1993)(MEDIRIBON, MEDICA)-FOR WOUND DRESSING ABSORB EXUDATES USED IN CONTAMINATED EXUDING WOUND LIKE CAVITY WOUND & FISTULAS., GAMJEE ROLL(MEDICA)-GAMJEE ROLL ARE USED TO PLACE OVER A WOUND BEFORE TAPING, STRAPPING OR BANDAGING UP OR CAN BE SOAKED IN ANTISEPTIC LIQUID AND USED TO WIPE OVER WOUND SITES. GAMJEE ROLL ARE USEFUL CAN BE USED FOR PADDING, PROTECTION, BLOOD SPILL WOUND DRESSING, APPLYING ANTISEPTIC AND USE IN SURGERY TO ABSORB BLOOD & EXUDATES ETC,COTTON CREPE BANDAGE (WHITE)(MEDICA)-CREPE BANDAGE USED FOR COMPRESSION BANDAGE FOR LIGHTER APPLICATION, ORTHO ROLL CAST PADING(MEDICA, MEDISOFT)-EXTENSIVELY USED FOR FOR PROTECTION OF BONES FROM ELEVATION OR PROJECTION,

	THESE PADS REDUCES THE CHANCES OF SKIN MACERATION AND ACTS AS A CUSHION BETWEEN CAST AND SKIN. CHARACTERISTIC: HIGHLY COMFORTABLE. PROTECTS BONY PROMINENCES,STRETCH BANDAGE (SYNTHETIC)(MEDICA, MEDISTRETCH)-STRETCH BANDAGES USED FOR COMPRESSION BANDAGE FOR LIGHTER APPLICATION,ABSORBENT COTTON WOOL IP COTTON BALL(MEDICA) -COTTON WOOL OR COTTON BALL ARE USED TO PLACE OVER A WOUND BEFORE TAPING, STRAPPING OR BANDAGING UP OR CAN BE SOAKED IN ANTISEPTIC LIQUID AND USED TO WIPE OVER WOUND SITES. COTTON WOOL OR COTTON BALL ARE USEFUL CAN BE USED FOR PADDING, PROTECTION, BLOOD SPILL WOUND DRESSING, APPLYING ANTISEPTIC AND USE IN SURGERY TO ABSORB BLOOD & EXUDATES ETC.,ABSORBENT GAUZE USP (ABSORBENT GAUZE ROLL) (MEDICA)-FOR WOUND DRESSING ABSORB EXUDATES USED IN CONTAMINATED EXUDING WOUND LIKE CAVITY WOUND & FISTULAS. FOR ABSORB EXUDATES,GAUZE SWAB / X-RAY DETECTABLE GAUZE SWAB (STD. AS PER B.P. 1993)(MEDISWAB, MEDICA)-GAUZE SWAB ARE USED TO PLACE OVER A WOUND BEFORE TAPING, STRAPPING OR BANDAGING UP OR CAN BE SOAKED IN ANTISEPTIC LIQUID AND USED TO WIPE OVER WOUND SITES. GAUZE SWABS ARE USEFUL CAN BE USED FOR PADDING, PROTECTION, BLOOD SPILL WOUND DRESSING, APPLYING ANTISEPTIC AND USE IN SURGERY TO ABSORB BLOOD & EXUDATES ETC.,ELASTIC ADHESIVE BANDAGES (STD. AS PER B.P. 1993)./ ELASTIC ADHESIVE BANDAGE (STD. AS PER B.P 1993) CANNULA FIXATURE(MEDICA, MEDIPLAST, CANFIX)-USED FOR MAINTAINING /HOLDING DRESSING IN ITS POSITION AFTER OPERATION, FRACTURED OF MANDIBLE RIBS, CLADE A FINGERS AND CHRONIC ULCERS, SPRAINS & JOINTS INJURIES ETC. FOR EXTERNAL USE ONLY,ROLLED BANDAGE SCHFII(MEDICA)-USE DRESSING FOR WOUNDS AND ALSO IN ORTHOPEDIC USES,PARAFFIN GAUZE DRESSING (STD. AS PER B.P. 1993)(MEDIFIN, MEDICA)-THE DRESSING IS USED AS A PRIMARY WOUND CONTACT LAYER AND THE PARAFFIN IS PRESENT TO REDUCE THE ADHERENCE OF THE PRODUCT TO THE SURFACE OF A GRANULATING WOUND,ABSORBENT GAUZE ROLL SCH. FII(MEDICA)-USE DRESSING FOR WOUNDS AND ALSO IN ORTHOPAEDIC USES,PERMEABLE NONWOVEN SYNTHETIC ADHESIVE TAPE (STD. AS PER B.P. 1993)(M'PORE, MEDICA)-USED DIRECTLY ON SKIN TO HOLD WOUND BANDAGES OR OTHER FIRST AID OR MEDICAL APPLIANCES IN PLACE.,ABDOMINAL PAD . / X-RAY DETECTABLE ABDOMINAL PAD (STD. AS PER B.P. 1993)(MEDICA, MEDIMOP)- ABDOMINAL PAD USED USE IN ABDOMINAL SURGERY FOR ABSORB BLEEDING & EXUDATES, ALSO USED AS PADDING FOR PRESSURE POINTS AND ANYWHERE HIGH ABSORBENCY IS NEEDED.,ADHESIVE TAPE (STD. AS PER U.S.P. 2013)(MEDICA. MEDITAPE)-TO SECURE

	DRESSING MATERIALS TO THE SKIN. .. ADHESIVE TAPE U.S.P. IS OFTEN USED FOR DRESSING PURPOSES IN CASE OF A WOUND OR CUT ALSO.,EYE PAD (STD. AS PER B.P. 1993)(MEDICA)-THIS IS USED TO PROTECT WOUNDS AFTER INITIAL BLEEDING CONTROL BY DIRECT PRESSURE. DO NOT USE IT FOR SURGICAL OPEN WOUNDS, CHLORHEXIDENE GAUZE DRESSING (STD. AS PER B.P. 1993)(MEDICA. CHLODIN)-INTENDED FOR USE AS A WOUND CONTACT LAYER FOR WOUNDS SUCH AS: MINOR BURNS AND SCALDS. LACERATIONS, ABRASIONS AND OTHER SKIN LOSS WOUNDS. DONOR AND RECIPIENT GRAFT SITES. CHLORHEXIDINE GAUZE DRESSING IS CONTAINING PARAFFIN & CHLORHEXIDINE ACETATE, WHICH PREVENTS THE MOISTURE LOSS FROM THE INJURED SKIN, ACT AS BARRIER BETWEEN WOUND & SECONDARY DRESSING; IT HELPS IN STOPPAGE OF DEHYDRATION OF INJURED SKIN & WOUND SITES. ALL KIND OF SKIN DAMAGES IN WHICH HUMID MEDIUM IS FAVOURABLE. APPLICATION ON BURNS, , SCALDS, CUTS, SKIN LOSS WOUNDS, COTTON CREPE BANDAGE)STD. AS PER B.P. 1993)(MEDICA, MEDICREPE)-CREPE BANDAGE USED FOR COMPRESSION BANDAGE FOR ALL CHRONIC LEG CONDITION VARICOSE VEINS AND THERE AFTER CARE AS A PRESSURE DRESSING FOR BURNS, FOR SKIN GRAFT & WHENEVER ELASTIC SUPPORT IS REQUIRED FOR TREATMENT OF SPRAIN & SIMILAR CONDITIONS,ROLLED BANDAGE SCHFII(MEDICA)-USE DRESSING FOR WOUNDS AND ALSO IN ORTHOPEDIC USES,GAUZE CLOTH SCH.FII (T SHAPED / TRIANGULAR) (MEDICA, MEDISCOPE)-USE DRESSING FOR WOUNDS AND ALSO IN ORTHOPAEDIC USES,PERMEABLE NONWOVEN SYNTHETIC ADHESIVE TAPE (STD. AS PER B.P. 1988)(M'PORE, MEDICA)-USED DIRECTLY ON SKIN TO HOLD WOUND BANDAGES OR OTHER FIRST AID OR MEDICAL APPLIANCES IN PLACE.

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3464	MFG/MD/2020/000108	1.License Holder Name: HI-TECH HOSPITAL & HEALTHCARE CORPORATION LIMITED 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:TRANSFUSION SETS FOR SINGLE USE-TO PROVIDE FLUID THERAPY AND TO ADMINISTER MEDICINES AND BLOOD PRODUCTS,STERILE HYPODERMIC SYRINGES FOR SINGLE USE-USED IN CLINICAL MEDICINE TO ADMINISTER INJECTIONS, INFUSE INTRAVENOUS THERAPY INTO THE BLOODSTREAM, AND DRAW/MEASURE LIQUIDS,AUTO-DISABLE (AD) SYRINGES FOR IMMUNIZATION-USED IN CLINICAL MEDICINE TO ADMINISTER INJECTIONS, INFUSE INTRAVENOUS THERAPY INTO THE BLOODSTREAM, AND DRAW/MEASURE LIQUIDS,INSULIN SYRINGES-USED FOR INJECTION OF INSULIN FLUIDS,SYRINGES WITH RE-USE PREVENTION FEATURE-USED IN CLINICAL MEDICINE TO ADMINISTER INJECTIONS, INFUSE INTRAVENOUS THERAPY INTO THE BLOODSTREAM, AND DRAW/MEASURE LIQUIDS,STERILE HYPODERMIC SYRINGES FOR SINGLE USE-USED IN CLINICAL MEDICINE TO ADMINISTER INJECTIONS, INFUSE INTRAVENOUS THERAPY INTO THE BLOODSTREAM, AND DRAW/MEASURE LIQUIDS, SINGLE LUMEN HYPODERMIC NEEDLE-USED AS AN ATTACHMENT TO SYRINGES TO ADMINISTER INJECTIONS, INFUSE INTRAVENOUS THERAPY INTO THE BLOODSTREAM, AND DRAW/MEASURE LIQUIDS

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3465	MFG/MD/2020/000109	1.License Holder Name: UNISUR LIFECARE PVT.LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:MONOFILAMENT POLYPROPYLENE MESH(N-CARE POLYPROPYLENE MESH, POLY MESH, MDB-LENE MESH)-MONOFILAMENT POLYPROPYLENE MESH IS USED FOR THE REPAIR OF HERNIA, UTERO-VAGINAL PROLAPSE AND OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT. IT CAN BE USED IN ENDOSCOPIC PROCEDURES., BRAIDED AND COATED POLYGLYCOLIC ACID(MARFLOW -GLYDE)-BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS., MONOFILAMENT POLYAMIDE (LIVLON, N-CARE NYLON, MDB-LON)-MONOFILAMENT POLYAMIDE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION., MONOFILAMENT POLYGLECAPRONE 25(MARFLOW –GLYDE MONO)-MONOFILAMENT POLYGLECAPRONE 25 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, WHERE AN ABSORBABLE MATERIAL IS INDICATED, BRAIDED AND COATED POLYESTER (N-CARE POLYESTER, MDB-BOND)-BRAIDED AND COATED POLYESTER SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,BRAIDED AND COATED POLYESTER (ADVAMED-POLYESTER)-BRAIDED AND COATED POLYESTER SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION,BRAIDED AND COATED POLYGLYCOLIC ACID(N-CARE PGA, UNILOOP-PGA, MDB-GLYDE)-BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,CATGUT PLAIN(UNIGUT PLAIN)-CATGUT PLAIN SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES,STERILE BONEWAX (N-CARE BONEWAX, MDB-WAX)-STERILE BONE WAX IS USED TO CONTROL LOCAL BLEEDING FROM BONE SURFACES. IT IS COMMONLY USED IN PATIENTS UNDERGOING ORTHOPAEDIC SURGICAL PROCEDURES., FAST ABSORBABLE BRAIDED AND COATED POLYGLACTIN 910(I SYNTH FAST)- BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR

	VESSELS.,MONOFILAMENT STAINLESS STEEL 316LVM(N-CARE STEEL, MDB-STEEL)-MONOFILAMENT STAINLESS STEEL SUTURES ARE INTENDED FOR USE IN CLOSURE OF STERNUM, ORTHOPAEDICS, ABDOMINAL WALL CLOSURE & HERNIA REPAIR,MONOFILAMENT POLYPROPYLENE MESH (LINX-MESH)-MONOFILAMENT POLYPROPYLENE MESH IS USED FOR THE REPAIR OF HERNIA, UTERO-VAGINAL PROLAPSE AND OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT. IT CAN BE USED IN ENDOSCOPIC PROCEDURES. ,MONOFILAMENT POLYPROPYLENE(N-CARE POLYPROPYLENE, MDB-LENE)-MONOFILAMENT POLYPROPYLENE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION., MONOFILAMENT POLYPROPYLENE MESH (ALPHALENE-MESH)-MONOFILAMENT POLYPROPYLENE MESH IS USED FOR THE REPAIR OF HERNIA, UTERO-VAGINAL PROLAPSE AND OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT. IT CAN BE USED IN ENDOSCOPIC PROCEDURES. ,MONOFILAMENT POLYGLECAPRONE 25(N-CARE MONO, MDB-MONO)-MONOFILAMENT POLYGLECAPRONE 25 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, WHERE AN ABSORBABLE MATERIAL IS INDICATED.,FAST ABSORBABLE BRAIDED AND COATED POLYGLYCOLIC ACID(ALPHA-SORB FAST)-BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,BRAIDED AND COATED POLYGLACTIN 910(N-CARE PGLA, UNILOOP-PGLA, LIVCRYL, MDB-GLACTIN 910)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,FAST ABSORBABLE BRAIDED AND COATED POLYGLACTIN 910(ADVAMED-PGLA FAST)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,MONOFILAMENT POLYDIOXANONE (UNILOOP-PDS, N-CARE PDS, MDB-PDS)-MONOFILAMENT POLYDIOXANONE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PAEDIATRIC CARDIOVASCULAR TISSUE, IN MICROSURGERY, AND IN OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY

	USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE WITH EXTENDED WOUND SUPPORT (UPTO SIX WEEKS) IS DESIRABLE. ,MONOFILAMENT POLYAMIDE (UNILON)-MONOFILAMENT POLYAMIDE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.,CATGUT PLAIN(N-CARE GUT PLAIN, MDB-GUT PLAIN)- CATGUT PLAIN SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES,CATGUT PLAIN(I GUT PLAIN)-CATGUT PLAIN SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES,FAST ABSORBABLE BRAIDED AND COATED POLYGLYCOLIC ACID(N-CARE PGA FAST, MDB-GLYDE FAST)-BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,MONOFILAMENT POLYPROPYLENE (MARFLOW-LENE)-MONOFILAMENT POLYPROPYLENE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.,FAST ABSORBABLE BRAIDED AND COATED POLYGLACTIN 910(N-CARE PGLA FAST, MDB-GLACTIN 910 FAST)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,FAST ABSORBABLE BRAIDED AND COATED POLYGLACTIN 910(M-SYNTH FAST)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,BLACK BRAIDED SILK (LIVSILK, N-CARE SILK, MDB-SILK)-BLACK BRAIDED SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,FAST ABSORBABLE BRAIDED AND COATED POLYGLYCOLIC ACID(M-GLYDE FAST)- BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,CATGUT CHROMIC (UNILOOP-CATGUT, N-CARE GUT CHROMIC, MDB-GUT CHROMIC)- CATGUT CHROMIC SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES, MONOFILAMENT POLYPROPYLENE (ADVAMED-POLYPROPYLENE)-MONOFILAMENT POLYPROPYLENE SUTURE IS INDICATED FOR USE IN

	GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.,HERNIA KIT FOR HERNIA REPAIR (UNISUR HERNIA KIT)-HERNIA KIT INTENDED FOR USE IN DIFFERENT TYPES OF HERNIA SURGERIES.,FAST ABSORBABLE BRAIDED AND COATED POLYGLACTIN 910(ALPHA-CRYIL FAST)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,OBSTETRICAL KIT(UNISUR OB KIT)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION AND ALSO THIS SPECIFIC KITS ARE DEVELOPED FOR THE OBSTETRIC AND GYNECOLOGY SURGERIES ,CATGUT CHROMIC (I GUT CHROMIC)-CATGUT CHROMIC SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES,CHLORHEXIDINE COATED POLYGLACTIN 910(UNISYNTH PLUS ; VIPRONE 910 PLUS ; ADVAMED-PGLA PLUS ; N-CARE PGLA PLUS ; M-SYNTH PLUS ; M-CRYL PLUS ; MEDCRYL PLUS ; I SYNTH PLUS)-ANTIBACTERIAL CHLORHEXIDINE COATED POLYGLACTIN 910 SUTURE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, EXCEPT FOR OPHTHALMIC, CARDIOVASCULAR AND NEUROLOGICAL TISSUES., FAST ABSORBABLE BRAIDED AND COATED POLYGLACTIN 910 (MEDICRYIL FAST)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,TRICLOSAN COATED POLYGLACTIN 910(UNISYNTH PRO ; VIPRONE 910 PRO ; ADVAMED-PGLA PRO ; N-CARE PGLA PRO ; M-SYNTH PRO ; M-CRYL PRO ; MEDCRYL PRO ; I SYNTH PRO)-ANTIBACTERIAL TRICLOSAN COATED POLYGLACTIN 910 SUTURE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, EXCEPT FOR OPHTHALMIC, CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,MONOFILAMENT POLYPROPYLENE MESH (UNILENE MESH)-MONOFILAMENT POLYPROPYLENE MESH IS USED FOR THE REPAIR OF HERNIA, UTERO-VAGINAL PROLAPSE AND OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT. IT CAN BE USED IN ENDOSCOPIC PROCEDURES. ,BRAIDED AND COATED POLYGLYCOLIC ACID (ALPHA-SORB)-BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,MONOFILAMENT POLYGLECAPRONE

	25(M-MONO)-MONOFILAMENT POLYGLECAPRONE 25 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, WHERE AN ABSORBABLE MATERIAL IS INDICATED.,BLACK BRAIDED SILK (I SILK)-BLACK BRAIDED SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,FAST ABSORBABLE BRAIDED AND COATED POLYGLACTIN 910(UNISYNTH FAST)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,BRAIDED AND COATED POLYESTER (M-BOND)-BRAIDED AND COATED POLYESTER SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,MONOFILAMENT POLYDIOXANONE (ALPHA-PDO)-MONOFILAMENT POLYDIOXANONE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PAEDIATRIC CARDIOVASCULAR TISSUE, IN MICROSURGERY, AND IN OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE WITH EXTENDED WOUND SUPPORT (UPTO SIX WEEKS) IS DESIRABLE. ,BRAIDED AND COATED POLYGLACTIN 910 (I SYNTH)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,MONOFILAMENT POLYDIOXANONE (ADVAMED-PD)-MONOFILAMENT POLYDIOXANONE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PAEDIATRIC CARDIOVASCULAR TISSUE, IN MICROSURGERY, AND IN OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE WITH EXTENDED WOUND SUPPORT (UPTO SIX WEEKS) IS DESIRABLE. ,MONOFILAMENT POLYAMIDE (I LON)-MONOFILAMENT POLYAMIDE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.,CATGUT PLAIN(M- GUT PLAIN)-CATGUT PLAIN SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES,FAST ABSORBABLE BRAIDED AND COATED POLYGLACTIN 910(MARFLOW –SYNTH FAST)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,MONOFILAMENT POLYPROPYLENE MESH (M-LENE MESH)-MONOFILAMENT

	POLYPROPYLENE MESH IS USED FOR THE REPAIR OF HERNIA, UTERO-VAGINAL PROLAPSE AND OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT. IT CAN BE USED IN ENDOSCOPIC PROCEDURES. ,CATGUT CHROMIC (ALPHA-GUT)- CATGUT CHROMIC SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURESV,MONOFILAMENT POLYPROPYLENE MESH (ADVAMED – POLYPROPYLENE MESH)-MONOFILAMENT POLYPROPYLENE MESH IS USED FOR THE REPAIR OF HERNIA, UTERO-VAGINAL PROLAPSE AND OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT. IT CAN BE USED IN ENDOSCOPIC PROCEDURES. ,BRAIDED AND COATED POLYESTER (UNIBOND)-BRAIDED AND COATED POLYESTER SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,MONOFILAMENT STAINLESS STEEL 316LVM(M-STEEL)-MONOFILAMENT STAINLESS STEEL SUTURES ARE INTENDED FOR USE IN CLOSURE OF STERNUM, ORTHOPAEDICS, ABDOMINAL WALL CLOSURE & HERNIA REPAIR,BLACK BRAIDED SILK (ADVAMED-SILK)-BLACK BRAIDED SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION., BONEWAX(MARFLOW -WAX)-STERILE BONE WAX IS USED TO CONTROL LOCAL BLEEDING FROM BONE SURFACES. IT IS COMMONLY USED IN PATIENTS UNDERGOING ORTHOPAEDIC SURGICAL PROCEDURES.,BLACK BRAIDED SILK (ALPHA- SILK)-BLACK BRAIDED SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,FAST ABSORBABLE BRAIDED AND COATED POLYGLACTIN 910(RAPID VIPRONE 910)- BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,BRAIDED AND COATED POLYESTER (X BOND)-BRAIDED AND COATED POLYESTER SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,BRAIDED AND COATED POLYGLACTIN 910(MEDICRYIL)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,CATGUT CHROMIC (M- GUT CHROMIC)-CATGUT CHROMIC SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES,CATGUT PLAIN(LINX GUT PLAIN)-

	CATGUT PLAIN SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES,BLACK BRAIDED SILK(UNISIL)-BLACK BRAIDED SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION,MONOFILAMENT STAINLESS STEEL 316LVM(X-STEEL)-MONOFILAMENT STAINLESS STEEL SUTURES ARE INTENDED FOR USE IN CLOSURE OF STERNUM, ORTHOPAEDICS, ABDOMINAL WALL CLOSURE & HERNIA REPAIR, MONOFILAMENT POLYPROPYLENE MESH (I LENE MESH)-MONOFILAMENT POLYPROPYLENE MESH IS USED FOR THE REPAIR OF HERNIA, UTERO-VAGINAL PROLAPSE AND OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT. IT CAN BE USED IN ENDOSCOPIC PROCEDURES. ,BRAIDED AND COATED POLYESTER (I BOND)-BRAIDED AND COATED POLYESTER SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,BONEWAX(M- WAX)-STERILE BONE WAX IS USED TO CONTROL LOCAL BLEEDING FROM BONE SURFACES. IT IS COMMONLY USED IN PATIENTS UNDERGOING ORTHOPAEDIC SURGICAL PROCEDURES.,BLACK BRAIDED SILK (LINX SILK)-BLACK BRAIDED SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,FAST ABSORBABLE BRAIDED AND COATED POLYGLYCOLIC ACID(UNIGLYDE FAST)-BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,MONOFILAMENT POLYPROPYLENE (UNILENE)-MONOFILAMENT POLYPROPYLENE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.,FAST ABSORBABLE BRAIDED AND COATED POLYGLYCOLIC ACID(ADVAMED-PGA FAST)- BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,BONEWAX (HAEMOWAX)-STERILE BONE WAX IS USED TO CONTROL LOCAL BLEEDING FROM BONE SURFACES. IT IS COMMONLY USED IN PATIENTS UNDERGOING ORTHOPAEDIC SURGICAL PROCEDURES., BONEWAX(ALPHA – WAX)-STERILE BONE WAX IS USED TO CONTROL LOCAL BLEEDING FROM BONE SURFACES. IT IS COMMONLY USED IN PATIENTS UNDERGOING ORTHOPAEDIC SURGICAL PROCEDURES., MONOFILAMENT STAINLESS STEEL 316LVM(ADVAMED STEEL)-MONOFILAMENT STAINLESS STEEL SUTURES ARE INTENDED FOR USE IN CLOSURE OF STERNUM, ORTHOPAEDICS, ABDOMINAL WALL

	CLOSURE & HERNIA REPAIR,MONOFILAMENT STAINLESS STEEL 316LVM(ALPHA – STEEL)-MONOFILAMENT STAINLESS STEEL SUTURES ARE INTENDED FOR USE IN CLOSURE OF STERNUM, ORTHOPAEDICS, ABDOMINAL WALL CLOSURE & HERNIA REPAIR, MONOFILAMENT POLYPROPYLENE(M-LENE)-MONOFILAMENT POLYPROPYLENE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.,BRAIDED AND COATED POLYESTER (ALPHA-BOND)-BRAIDED AND COATED POLYESTER SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION,CATGUT PLAIN(ADVAMED-GUT PLAIN)-CATGUT PLAIN SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES,MONOFILAMENT POLYGLECAPRONE 25(ADVAMED-POLIGLECAPRONE)-MONOFILAMENT POLYGLECAPRONE 25 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, WHERE AN ABSORBABLE MATERIAL IS INDICATED., MONOFILAMENT POLYAMIDE (MARFLOW –NYLON)-MONOFILAMENT POLYAMIDE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.,MONOFILAMENT POLYGLECAPRONE 25(I GLYDE MONO)- MONOFILAMENT POLYGLECAPRONE 25 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, WHERE AN ABSORBABLE MATERIAL IS INDICATED.,MONOFILAMENT POLYAMIDE (ADVAMED-NYLON)-MONOFILAMENT POLYAMIDE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.,MONOFILAMENT POLYAMIDE (M-LON)-MONOFILAMENT POLYAMIDE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION., MONOFILAMENT POLYAMIDE (LINX NYLON)-MONOFILAMENT POLYAMIDE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION,BRAIDED AND COATED POLYGLYCOLIC ACID (M-GLYDE)-BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,FAST ABSORBABLE BRAIDED AND COATED POLYGLYCOLIC ACID(MARFLOW –GLYDE FAST)-BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,MONOFILAMENT STAINLESS STEEL 316LVM(MARFLOW-STEEL)-MONOFILAMENT STAINLESS STEEL SUTURES ARE INTENDED FOR USE IN CLOSURE OF

	STERNUM, ORTHOPAEDICS, ABDOMINAL WALL CLOSURE & HERNIA REPAIR,CATGUT CHROMIC (MARFLOW –GUT CHROMIC)-CATGUT CHROMIC SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES,BRAIDED AND COATED POLYESTER (MARFLOW-BOND)-BRAIDED AND COATED POLYESTER SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,MONOFILAMENT POLYGLECAPRONE 25(ALPHA-MONO) -MONOFILAMENT POLYGLECAPRONE 25 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, WHERE AN ABSORBABLE MATERIAL IS INDICATED.,FAST ABSORBABLE BRAIDED AND COATED POLYGLYCOLIC ACID(I GLYDE FAST)- BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,BLACK BRAIDED SILK (MARFLOW -SILK)-BLACK BRAIDED SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,MONOFILAMENT POLYDIOXANONE (I SYNTH PD)-MONOFILAMENT POLYDIOXANONE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PAEDIATRIC CARDIOVASCULAR TISSUE, IN MICROSURGERY, AND IN OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE WITH EXTENDED WOUND SUPPORT (UPTO SIX WEEKS) IS DESIRABLE. ,BRAIDED AND COATED POLYGLACTIN 910 (ALPHA-CRYIL)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,BONEWAX(I WAX)-STERILE BONE WAX IS USED TO CONTROL LOCAL BLEEDING FROM BONE SURFACES. IT IS COMMONLY USED IN PATIENTS UNDERGOING ORTHOPAEDIC SURGICAL PROCEDURES.,FAST ABSORBABLE BRAIDED AND COATED POLYGLACTIN 910(M-CRYL FAST)-BRAIDED AND COATED POLYGLACTIN 910 IS A SYNTHETIC, ABSORBABLE, STERILE SUTURE, COMPOSED OF THE CO-POLYMER, POLYGLACTIN 910, MADE FROM 90% GLYCOLIDE AND 10% LACTIDE. ,CATGUT PLAIN(ALPHA-GUT PLAIN)-CATGUT PLAIN SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES,MONOFILAMENT POLYAMIDE (ALPHA-LON)-MONOFILAMENT POLYAMIDE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.,CATGUT CHROMIC (ADVAMED-GUT CHROMIC)-

	CATGUT CHROMIC SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES,MONOFILAMENT STAINLESS STEEL 316LVM(MONOSTEEL)-MONOFILAMENT STAINLESS STEEL SUTURES ARE INTENDED FOR USE IN CLOSURE OF STERNUM, ORTHOPAEDICS, ABDOMINAL WALL CLOSURE & HERNIA REPAIR,MONOFILAMENT POLYDIOXANONE (MARFLOW –SYNTH PDS)-MONOFILAMENT POLYDIOXANONE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PAEDIATRIC CARDIOVASCULAR TISSUE, IN MICROSURGERY, AND IN OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE WITH EXTENDED WOUND SUPPORT (UPTO SIX WEEKS) IS DESIRABLE. , MONOFILAMENT POLYPROPYLENE MESH (MARFLOW-LENE MESH)-MONOFILAMENT POLYPROPYLENE MESH IS USED FOR THE REPAIR OF HERNIA, UTERO-VAGINAL PROLAPSE AND OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT. IT CAN BE USED IN ENDOSCOPIC PROCEDURES. ,MONOFILAMENT POLYDIOXANONE (M-PDS)-MONOFILAMENT POLYDIOXANONE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PAEDIATRIC CARDIOVASCULAR TISSUE, IN MICROSURGERY, AND IN OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE WITH EXTENDED WOUND SUPPORT (UPTO SIX WEEKS) IS DESIRABLE. ,CATGUT CHROMIC(UNIGUT CHROMIC)-CATGUT CHROMIC SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES,CATGUT CHROMIC(LINX GUT CHROMIC)-CATGUT CHROMIC SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES,BLACK BRAIDED SILK (M-SILK)-BLACK BRAIDED SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,BRAIDED AND COATED POLYGLACTIN 910(M-CRYL)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,BRAIDED AND COATED POLYGLACTIN 910(UNISYNTH)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS,BRAIDED AND COATED POLYGLACTIN

	910(ADVAMED-PGLA)- BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,BRAIDED AND COATED POLYGLACTIN 910(M-SYNTH)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,BRAIDED AND COATED POLYGLYCOLIC ACID (ADVAMED-PGA)-BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,MONOFILAMENT POLYDIOXANONE (LINX - PDO)-MONOFILAMENT POLYDIOXANONE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PAEDIATRIC CARDIOVASCULAR TISSUE, IN MICROSURGERY, AND IN OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE WITH EXTENDED WOUND SUPPORT (UPTO SIX WEEKS) IS DESIRABLE. ,MONOFILAMENT POLYPROPYLENE (I LENE)-MONOFILAMENT POLYPROPYLENE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION., BRAIDED AND COATED POLYGLYCOLIC ACID (UNIGLYDE)- BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,MONOFILAMENT POLYDIOXANONE (UNISYNTH PDS)-MONOFILAMENT POLYDIOXANONE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PAEDIATRIC CARDIOVASCULAR TISSUE, IN MICROSURGERY, AND IN OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE WITH EXTENDED WOUND SUPPORT (UPTO SIX WEEKS) IS DESIRABLE. ,BRAIDED AND COATED POLYGLYCOLIC ACID(VIPRONE)-BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,CATGUT PLAIN(MARFLOW –GUT C PLAIN)-CATGUT PLAIN SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES,BONEWAX(ADVAMED

	– WAX)-STERILE BONE WAX IS USED TO CONTROL LOCAL BLEEDING FROM BONE SURFACES. IT IS COMMONLY USED IN PATIENTS UNDERGOING ORTHOPAEDIC SURGICAL PROCEDURES., MONOFILAMENT POLYPROPYLENE (ALPHA-LENE)-MONOFILAMENT POLYPROPYLENE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION,MONOFILAMENT POLYGLECAPRONE 25(UNIGLYDE MONO)-MONOFILAMENT POLYGLECAPRONE 25 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, WHERE AN ABSORBABLE MATERIAL IS INDICATED.,MONOFILAMENT POLYGLECAPRONE 25(MONOPRONE)- MONOFILAMENT POLYGLECAPRONE 25 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, WHERE AN ABSORBABLE MATERIAL IS INDICATED.,BONEWAX (X-WAX)-STERILE BONE WAX IS USED TO CONTROL LOCAL BLEEDING FROM BONE SURFACES. IT IS COMMONLY USED IN PATIENTS UNDERGOING ORTHOPAEDIC SURGICAL PROCEDURES.,FAST ABSORBABLE BRAIDED AND COATED POLYGLYCOLIC ACID(RAPID VIPRONE)-BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS., MONOFILAMENT STAINLESS STEEL 316LVM(I STEEL)-MONOFILAMENT STAINLESS STEEL SUTURES ARE INTENDED FOR USE IN CLOSURE OF STERNUM, ORTHOPAEDICS, ABDOMINAL WALL CLOSURE & HERNIA REPAIR,MONOFILAMENT POLYPROPYLENE (CARDIOPILENE)-MONOFILAMENT POLYPROPYLENE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION,BRAIDED AND COATED POLYGLYCOLIC ACID (I GLYDE) -BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS,BRAIDED AND COATED POLYGLACTIN 910(VIPRONE 910)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,BRAIDED AND COATED POLYGLACTIN 910(MARFLOW –SYNTH)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.

3466	MFG/MD/2020/000110	1.License Holder Name: TMDPL 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA
3467	MFG/MD/2020/000111	1.License Holder Name: VASCULAR CONCEPTS LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:SIROLIMUS ELUTING STENT SYSTEM - COBALT CHROMIUM DEGRADABLE MATRIX (PRONOVA XR - SIROLIMUS ELUTING STENT SYSTEM - COBALT CHROMIUM DEGRADABLE MATRIX)-THE PRONOVA XR CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.5MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT)AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT., SIROLIMUS ELUTING STENT SYSTEM - COBALT CHROMIUM(PRONOVA - SIROLIMUS ELUTING STENT SYSTEM - COBALT CHROMIUM)-THE PRONOVA CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT.,SIROLIMUS ELUTING STENT SYSTEM- STAINLESS STEEL (PRONOVA SS - SIROLIMUS ELUTING STENT SYSTEM- STAINLESS STEEL)-THE PRONOVA SS CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.5MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT.

3468	MFG/MD/2020/000112	1.License Holder Name: SEASONS MEDICARE PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:READY TO USE STERILE SURGICAL DRESSING(I- PAD)-PREVENTION OF INJECTION BY LIMITING EXPOSURE TO DIRT AND GERMS IN CASE OF MINOR CUTS, ABRASIONS AND BLISTERS.,DRESSING FIELD COMPRESSED-GAUZE PAD ATTACHED TO A BANDAGE FOR WRAPPING AROUND A WOUND, AND A SAFETY PIN TO SECURE IT ONCE USED.,ABSORBENT DRESSING PAD-PREVENTION OF INJECTION BY LIMITING EXPOSURE TO DIRT AND GERMS IN CASE OF MINOR CUTS, ABRASIONS AND BLISTERS., STERILE DRESSING SHELL (COMPRESSED)-GAUZE PAD ATTACHED TO A BANDAGE FOR WRAPPING AROUND A WOUND, AND A SAFETY PIN TO SECURE IT ONCE USED.,READY TO USE STERILE SURGICAL DRESSING(STERIPAD)-PREVENTION OF INJECTION BY LIMITING EXPOSURE TO DIRT AND GERMS IN CASE OF MINOR CUTS, ABRASIONS AND BLISTERS.,BANDAGE CLOTH-PREVENTION OF INJECTION BY LIMITING EXPOSURE TO DIRT AND GERMS IN CASE OF MINOR CUTS, ABRASIONS AND BLISTERS.,INFUSION SET (IV SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,BLOOD TRANSFUSION SET-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,ABSORBENT COTTON (STERILISED) (STERILCOT)-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS,ABSORBENT GAUZE-PREVENTION OF INJECTION BY LIMITING EXPOSURE TO DIRT AND GERMS IN CASE OF MINOR CUTS, ABRASIONS AND BLISTERS., ABSORBENT COTTON (STERILISED)-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS,ABSORBENT GAUZE(STERIGAUZE)-PREVENTION OF INJECTION BY LIMITING EXPOSURE TO DIRT AND GERMS IN CASE OF MINOR CUTS, ABRASIONS AND BLISTERS.,CLOTH FOR MANUFACTURE OF PLASTER OF PARIS BANDAGES-PLASTER CASTS TO IMMOBILIZE BROKEN BONES WHILE THEY HEAL, THOUGH MANY MODERN ORTHOPEDIC CASTS.,ABSORBENT ABDOMINAL SWAB-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS,STERILE ROLLER BANDAGE SCH F-PREVENTION OF INJECTION BY LIMITING EXPOSURE TO DIRT AND GERMS IN CASE OF MINOR CUTS, ABRASIONS AND BLISTERS, ABSORBENT GAUZE SWAB-PREVENTION OF INJECTION BY LIMITING EXPOSURE TO DIRT AND GERMS IN CASE OF MINOR CUTS, ABRASIONS AND BLISTERS.,DRESSING FIRST AID UNMEDICATED STERILE-A DRESSING IS A STERILE PAD OR COMPRESS APPLIED TO A

	WOUND TO PROMOTE HEALING AND PROTECT THE WOUND FROM FURTHER HARM

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3469	MFG/MD/2020/000113	1.License Holder Name: SURETECH MEDICAL INC 2.Approving Authority: GREATER MUMBAI DIVISION 3.Device Name(Brand Name)-Intended Use:DILATORS(SURETECH)-FOR DILATION OF VESSELS,BREAST LOCALIZATION NEEDLE (SURETECH)-USED TO HELP THE SURGEON IN LOCALIZING AND REMOVING THE LESSON AFTER IT HAS BEEN RECOGNIZED AND IDENTIFIED THROUGH BIOPSY,BONE MARROW BIOPSY NEEDLE (SURETECH)-INTENDED USE FOR THE POSTERIOR ILIAC CREST BIOPSY TECHNIQUE,Y-CONNECTOR KIT PUSH PULL/ PUSH CLICK/ SCREW TYPE(SURETECH)-IT CAN BE USED TO CONNECT TO PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA AND INSERTION OF CATHETERS AND BALLOONS ETC.,TRANSDUCER PROTECTOR(SURETECH)-TRANSDUCER PROTECTOR ARE USED IN HEMODIALYSIS BLOOD LINE TO KEEP THE BLOOD SIDE OF THE CIRCUIT SEPERATED FROMTHE MACHINE SIDE, AND TO PREVENT CONTAMINATION OF THE MACHINE BY BLOOD FLOWING THROUGH THE CIRCUIT,FISTULA NEEDLE(SURETECH)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSEL THROUGH NEEDLE WHEN DIALYSIS IS CARRIED OUT.,DISCOGRAPHY NEEDLE(SURETECH)-A THIN NEEDLE IN INSERTED IN TO AN AREA OF ABNORMAL APPEARINGTISSUE OR BODY FLUID .,DOUBLE J STENT(SURETECH)-USED FOR INSTILLING FLUIDS INTO WITHDRAWING FLUIDS FROM SPLINTING OR SUPPRESSING BLEEDING OF THE ALIMENTARY TRACT. ,BONE MARROW ASPIRATION NEEDLE(SURETECH)-FOR ASPIRATION, PUNCTURE SHEATH(SURETECH)-FOR INSERTION OF SS WIRE TO THE BODY.,GUIDING/ DIAGNOSTIC CATHETER(SURETECH)-A GUIDING CATHETER IS INTENDED TO ACCESS THE CORONARY VENOUS SYSTEM AND MAY BE USED AS A DUAL CATHETER ASSEMBLY,PTCA BALLOON CATHETER(SURETECH)-PTCA CATHETER WITH AN INFLATABLE BALLOON AT ITS TIP IS USED DURING A CAUTERIZATION PROCEDURE TO ENLARGE A NARROW OPENING OR PASSAGE WITHIN THE BODY.,BLADDER EVACULATOR BOTTLE(SURETECH)-BLADDER EVACULATOR BOTTLE IS INTENDED TO BE USED FOR EVACUATING IRRIGATION SOLUTIONS, BLOOD CLOTS, TISSUE COLLECTION AND STRAINING FUNCTION DIRING PROSTATE SURGERY OR BLADDER SURGERY,HEMODIALYSIS CATHETER KIT(SURETECH)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE CATHETER FROM THE PATIENT,EPIDURAL NEEDLE (SURETECH)-INTENDED FOR TRANSIENT DELIVERY OF ANASTHESICS TO PROVIDE REGIONAL ANESTHESIA OR TO FACILATE PLACEMENT OF AN EPIDURAL CATHETER.,BLOOD TUBING SET(SURETECH)-BLOOD TUBING SET HAS BEEN SPECIALLY DESIGNED FOR THE PATIENT TO CONNECT WITH EXTERNAL SYSTEM WHICH EXTRACTS PATIENTS BLOOD TO THE DIALYZER AND THEN RETURNS PATIENTS BLOOD

	FROM THE DIALYZER,MANIFOLD(SURETECH)-INDICATED FOR FLUID FLOW DIRECTION CONTROL AND PROVIDING ACCESS PORT/PORTS FOR ADMINISTRATION OF A SOLUTION,BIOPSY NEEDLE/ CORE BIOPSY NEEDLE/ BIOPSY GUN(AUTO/SEMI AUTOMATIC)(SURETECH)-A SET OF NEUROSURGICAL INSTRUMENTS DESIGN TO ALLOW MULTIPLE BIOPSIES FROM ONE OR MORE TARGETS IN ONE TRAJECTORY. BIOPSY GUN IS INTENDED USE IN OBTAINING BIOPSIES FROM SOFT TISSUES SUCH AS LIVER, KIDNEY, BREAST, AND VARIOUS SOFT TISSUE TUMORS,RADIAL COMPRESSION BAND(SURETECH)-TR BAND ASSIST IN MAINTAINING RADIAL ARTERY PATENCY AT THE TIME OF HOMEOSTASIS IN ORDER TO PREVENT FUTURE RADIAL ARTERY OCCLUSION.,HYPODERMIC NEEDLE (ROUND TIP NEEDLE) (SURETECH)-NEEDLES HAVE ULTRA THIN WALL PERMITTING RAPID AND EFFICIENT DRUG DELIVERY ,INFLATION DEVICE(SURETECH)-SYRINGE IS USED TO INFLATE AND DEFLATE BALLOON ANGIOPLASTY CATHETERS OR THER INTERVENTIONAL DEVICES AND TO MEASURE THE PRESSURE AND TIME OF INFLATION WITHIN THE BALLOON DURING PROCEDURE.,CHIBA NEEDLE(SURETECH)-IT CAN BE USED TO INJECT DRUGS AGENTS , AS WELL AS FOR LINE-NEEDLE ASPIRATION BIOPSY,MALECOT / SUPRAPUBIC CATHETER WITH NEEDLE(SURETECH)-A SUPRAPUBIC CATHETERS IS A THIN, STERILE TUBE USED TO DRAIN URINE FROM BLADDER.,PTMC / BMV BALLOON CATHETER KIT(SURETECH)-USES A THIN FLEXIBLE TUBE (CATHETER) THAT IS INSERTED THROUGH AN ARTERY IN THE GROIN OR ARM AND THREADED INTO THE HEART.,URETERAL ACCESS SHEATH (SURETECH)-USED TO BE INTRODUCED IN TO URETER TO FUNCTION AS DILATOR AND TO ESTABLISH A CONDUIT DURING ENDOSCOPIC UROLOGICAL PROCEDURE FACILITATING THE PASSAGE OF ENDOSCOPES AND OTHER INSTRUMENTS INTO THE URINARY TRACT,IV SET FLOW REGULATOR(SURETECH)-FOR THE FLOW RATE CONTROLOF IV FLUID DURING INFUSION ,INITIAL PUNCURE NEEDLE (SURETECH)-USED BY UROLOGIST FOR PCNL PROCEDURE, ASPIRATION NEEDLE(SURETECH)-USED FOR EITHER LAPAROSCOPIC ASPIRATION HYPODERMIC OR INJECTION NEEDLE.,TRANSEPTAL NEEDLE-THE TRANSEPTAL PUNCTURE PERMIT A DIRECT ROUTH TO THE LA VIA THE INTRA-ATRIAL SEPTUM AND SYSTEMIC VENOUS SYSTEM,PRESSURE MONITORING LINE(SURETECH)-SUITED FOR HIGH PRESSURE MONITORING AND FOR CONNECTON BETWEEN SYRINGE INFUSION PUMP AND PATIENT.,3 WAY STOP COCK WITH EXTENSION LINE(SURETECH)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION , WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,ASPIRATION CATHETER (SURETECH)-USED FOR INSTILLING INTO ,WITHDRAWING FLUID FROM

		SPLINTING OR SUPPRESING BLEEDING OF THE ALIMENTARY TRACT., RADIO FREQUENCY NEEDLE(SURETECH)-A THIN NEEDLE IS INSERTED IT AN AREA OF ABNORMAL APPEARING TISSUE OR BODY FLUID.AS WITH OTHER TYPE OF BIOPSIES THE SAMPLE COLLECTED DURING FINE NEEDLE ASPIRATION CAN HELP MAKE A DIAGNOSIS OR RULE OUT CONDITION SUCH AS CANCER,INTRODUCER NEEDLE(SURETECH) -A NEEDLE IS USED TO PUNCTURE THE SITE TO REACH THE VESSEL DIRECTLY IN ONE SHOT. USUALLY IS BETTER PRACTITIONER IN TO THE CORRECT VESSEL BY MAINTAING CORRECT ANGLE.,PCN TROCAR / PIGTAIL CATHETER WITH NEEDLE(SURETECH)-USED FOR TEMPORARY OR PERMAM=NENT DRAINAGE & IRRIGATION OF URINE FROM THE KIDNEY BY DIRECT PUNCTURE ,IN THE PRESENCE OF DISTAL OBSTRUCTION.,URETRIC CATHETER(SURETECH)-USED FOR DRAINAGE AS WELL AS RETROGRADE PYELOGRAM BY OPEN END TIP .IT IS PLACED OVER A GUIDE WIRE FOR NEGOTIATION TO TORTUOUS URETER.
3470	MFG/MD/2020/000114	1.License Holder Name: LAXMI DHANIRAM INDUSTRIES 2.Approving Authority: NAGPUR DIVISION 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL IP-ABSORBENT COTTON WOOL FIBER FOR GENERAL AND SURGICAL USE
3471	MFG/MD/2020/000115	1.License Holder Name: KALYX INDIA HEALTHCARE (P) LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:HIP JOINT METAL/CERAMIC/ POLYMER SEMI CONSTRAINED CEMENTED OR NON POROUS UNCEMENTED PROSTHESIS(PLUS FIT)-INTEBDED TO BE IMPLANTED TO REPLACE A HIP JOINT
3472	MFG/MD/2020/000116	1.License Holder Name: ORIGIN DIAGNOSTICS AND RESEARCH 2.Approving Authority: KERALA 3.Device Name(Brand Name)-Intended Use:NASOPHARYNGEAL AND OROPHARYNGEAL SWABS(ORIGIN CHITRA ENMESH)-SPECIMEN COLLECTION FROM NASOPHARYNGEAL AND OROPHARYNGEAL REGIONS FOR VARIOUS APPLICATIONS.

3473	MFG/MD/2020/000117	1.License Holder Name: BONE LIFE SURGICALS 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE SCREWS(SIGNOR)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE.,BONE PLATES(SIGNOR)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE.,BONE PLATES(SIGNOR)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE.,SPINAL IMPLANTS(SIGNOR)-A SINGLE MEDICAL DEVICE IS A MEDICAL DEVICE SOLD AS A DISTINCT PACKAGED ENTITY. IT MAY BE SOLD IN A RANGE OF PACKAGE SIZES. IT IS INDICATED FOR USE WITH AUTOGENOUS BONE GRAFT IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE ("DDD") AT ONE OR TWO CONTIGUOUS SPINAL LEVELS.,BONE PIN (SIGNOR)-A SINGLE MEDICAL DEVICE IS A MEDICAL DEVICE SOLD AS A DISTINCT PACKAGED ENTITY. IT MAY BE SOLD IN A RANGE OF PACKAGE SIZES. IT MAY BE USED FOR FIXATION OF BONE FRACTURES, FOR BONE RECONSTRUCTIONS, AS A GUIDE PIN FOR INSERTION OF OTHER IMPLANTS, OR IT MAY BE IMPLANTED THROUGH THE SKIN SO THAT A PULLING FORCE (TRACTION) MAY BE APPLIED TO THE SKELETAL SYSTEM.,SPINAL IMPLANTS(SIGNOR)-IT IS INDICATED FOR USE WITH AUTOGENOUS BONE GRAFT IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE ("DDD") AT ONE OR TWO CONTIGUOUS SPINAL LEVELS.,BONE NAILS (SIGNOR)-INTENDED TO BE IMPLANTED INTO THE MEDULLARY (BONE MARROW) CANAL OF LONG BONES FOR THE FIXATION OF FRACTURES.,BONE WIRE(SIGNOR)-STABILIZATION OF THE FRACTURED BONY PARTS BY DIRECT FIXATION TO ONE ANOTHER WITH SURGICAL WIRES.,BONE SCREWS(SIGNOR)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE.,BONE PIN(SIGNOR)-IT MAY BE USED FOR FIXATION OF BONE FRACTURES, FOR BONE RECONSTRUCTIONS, AS A GUIDE PIN FOR INSERTION OF OTHER IMPLANTS, OR IT MAY BE IMPLANTED THROUGH THE SKIN SO THAT A PULLING FORCE (TRACTION) MAY BE APPLIED TO THE SKELETAL SYSTEM.,BONE NAILS(SIGNOR)-INTENDED TO BE IMPLANTED INTO THE MEDULLARY (BONE MARROW) CANAL OF LONG BONES FOR THE FIXATION OF FRACTURES.,BONE WIRE(SIGNOR)-STABILIZATION OF THE FRACTURED BONY PARTS BY DIRECT FIXATION TO ONE ANOTHER WITH SURGICAL WIRES.

3474	MFG/MD/2020/000118	1.License Holder Name: RELISYS MEDICAL DEVICES LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:GUIDING CATHETER (AMBER, OPAL, RELIGUIDE, RELITRAC, RELICATH, BOULEVARD)-GUIDING CATHETERS ARE DESIGNED TO BE USED FOR INTRAVASCULAR INTRODUCTION OF INTERVENTIONAL DEVICES INTO THE VASCULATURE.,ANGIOGRAPHIC DIAGNOSTIC CATHETER (ANANTH / CORAL / TOPAZ / ONYX / EMERALD / QUARTZ)-• ANGIOGRAPHIC DIAGNOSTIC CATHETERS DELIVERS RADIOPAQUE FLUIDS TO THE SPECIFIC ARTERIES IN THE CARDIOVASCULAR SYSTEM. • THIS SERVES THE PURPOSE OF DIFFERENTIATING THE VESSEL FROM THE SURROUNDING ANATOMY DURING DIAGNOSTIC IMAGING PROCEDURES.,ANGIOGRAPHIC DIAGNOSTIC CATHETER (ANANTH / CORAL / TOPAZ / ONYX / EMERALD / QUARTZ)-• ANGIOGRAPHIC DIAGNOSTIC CATHETERS DELIVERS RADIOPAQUE FLUIDS TO THE SPECIFIC ARTERIES IN THE VASCULAR SYSTEM. • THIS SERVES THE PURPOSE OF DIFFERENTIATING THE VESSEL FROM THE SURROUNDING ANATOMY DURING DIAGNOSTIC IMAGING PROCEDURES.,GUIDE EXTENSION CATHETER(MUTUAL, DEEPACCESS, ACCESSGUIDE, PROTRACT, PRORROGA)-THE RELISYS GUIDE EXTENSION CATHETER IS INTENDED TO BE USED IN CONJUNCTION WITH GUIDE CATHETERS TO ACCESS DISCRETE REGIONS OF THE CORONARY USE AND/OR PERIPHERAL VASCULATURE, AND TO FACILITATE PLACEMENT OF GUIDE WIRES AND OTHER INTERVENTIONAL DEVICES.,MANIFOLD-MANIFOLD IS A KIND OF TRANSFUSION DEVICE, T SHAPE WITH AN “OFF” RIGHT HANDLE, CAN CONTROL THE DIRECTION OF FLOW OF FLUID, WITH THE HIGH PRESSURE OF 500PSI, THIS MANIFOLD GENERALLY USED AS AN IMPORTANT ACCESSORY DURING THE PROCESS OF ANGIOGRAPHY OPERATION OR INTERVENTIONAL OPERATION. IT WILL BE INNOCUOUS DISPOSED IMMEDIATELY AFTER SINGLE USE., INTRODUCER NEEDLE-INTRODUCER NEEDLE IS MAINLY INDICATED FOR PUNCTURE AND GUIDING IN INVASIVE SURGERY. WHEN COMBINED WITH OTHER MEDICAL DEVICES IT CAN BE DIRECT PAIN POINTS AND ELIMINATE THE PAIN OF PATIENTS.,HEMOSTASIS VALVE SET / Y-CONNECTOR-HEMOSTASIS VALVE SET IS INTENDED FOR INTERVENTIONAL EFFECT ON INTRAVASCULAR AND CHECK THE GUIDEWIRE OR AS THE DIAGNOSIS INSTRUMENT, AND USED IN A VARIETY OF PERCUTANEOUS MEDICAL PROCEDURES THAT REQUIRE THE INSERTION OF A CATHETER OR OTHER INSTRUMENTS AND DEVICES INTO PATIENT'S BODY. IT ALSO MINIMISES BLOOD LOSS AND FACILITATES MINIMAL INVASION IN CATHETER BASED MEDICAL PROCEDURES.

3475	MFG/MD/2020/000119	1.License Holder Name: MALLELIL INDUSTRIES PVT. LTD 2.Approving Authority: KERALA 3.Device Name(Brand Name)-Intended Use:NASOPHARYNGEAL AND OROPHARYNGEAL FLOCKED SWABS(CHITRA EMBED)-COLLECTION OF THE SPECIMEN FROM NASOPHARYNGEAL AND OROPHARYNGEAL REGIONS FOR VARIOUS APPLICATIONS.
3476	MFG/MD/2020/000120	1.License Holder Name: SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:PRE-FILLED SYRINGE 0.9% SODIUM CHLORIDE (0.9% NACL)-THE PREFILLED SYRINGES - NORMAL SALINE FLUSH SYRINGES ARE INTENDED TO BE USED ONLY FOR THE FLUSHING OF INDWELLING VASCULAR ACCESS DEVICES AND INTENDED FOR USE IN MAINTAINING PATENCY OF VASCULAR ACCESS DEVICES (VAD'S).,PRE-FILLED SYRINGE 0.9% SODIUM CHLORIDE (0.9% NACL)(POLYFLUSH SYRINGE 0.9% SODIUM CHLORIDE (0.9% NACL))-THE PREFILLED SYRINGES - NORMAL SALINE FLUSH SYRINGES ARE INTENDED TO BE USED ONLY FOR THE FLUSHING OF INDWELLING VASCULAR ACCESS DEVICES AND INTENDED FOR USE IN MAINTAINING PATENCY OF VASCULAR ACCESS DEVICES (VAD'S).

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3477	MFG/MD/2020/000121	1.License Holder Name: BIORAD MEDISYS PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:ENDOPYELOTOMY STENT / URETHRAL TUMOR CATHETER (NIL)-ENDOPYELOTOMY STENT / URETHRAL TUMOR CATHETER IS USED FOR INTERNAL DRAINAGE FROM KIDNEY TO BLADDER FOR ANY IRREGULAR PYLEM STRUCTURE.,CENTRAL VENOUS CATHETER SET(INDOCATH-CV)-CENTRAL VENOUS CATHETERS ARE INTENDED TO BE USED FOR CENTRAL VENOUS ACCESS IN PATIENTS FOR TOTAL PARENTERAL NUTRITION (T.P.N.), INFUSION OF I.V. LIQUIDS / BLOOD PRODUCTS / DRUGS AND FOR REPEATED WITHDRAWAL OF BLOOD SAMPLES. , TURP LOOP / TURP ELECTRODE(NIL)-TURP LOOP IS USED TO ABLATE/ COAGULATE/ VAPORIZE THE TISSUES OF PROSTATE GLAND DURING TRANS-URETHRAL RESECTIONS OF THE PROSTATE (TURP).,BILIARY DRAINAGE CATHETER / BILIARY PANCREATIC STENT (NIL)-BILIARY DRAINAGE CATHETER IS THE USED TO DRAIN THE BILE DUCTS.,DOUBLE J SHAPE STENT / URETERAL STENT / DOUBLE J STENT(RELEEZ)-DOUBLE J STENT / URETERAL STENT / DOUBLE J SHAPE STENT IS USED FOR INTERNAL DRAINAGE FROM KIDNEY TO BLADDER.,PERCUTANEOUS TRANSHEPATIC BILIARY DRAINAGE CATHETER (PTBD CATHETER)(NIL)-PERCUTAENOUS TRANSHEPATIC BILIARY DRAINAGE CATHETER IS USED FOR TRANSHEPATIC BILIARY DRAINAGE OF THE BILIARY DUCT THROUGH THE USE OF AN INDWELLING CATHETER. ,MONO J STENT (NIL)-MONO J STENT IS USED FOR EXTERNAL DRAINAGE FROM KIDNEY THROUGH URETHRA., PERMANENT DIALYSIS CATHETER / LONG TERM HEMODIALYSIS CATHETER(INDOCATH-HD)-PERMANENT DIALYSIS CATHETER / LONG TERM HEMODIALYSIS CATHETER IS INDICATED FOR USE IN ATTAINING LONG TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS.,AQUA INCONTINENCE SLING(AQUA)-AQUA INCONTINENECE SLING IS IMPLANTABLE MID URETHRAL SUPPORT SLING SYSTEM INDICATED FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE (SUI) DEVICE.

3478	MFG/MD/2020/000122	1.License Holder Name: I.Q.MEDITECH PVT LTD 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:STERILE TRANSFUSION SET (I.V.SET) FOR SINGLE USE(IM-LIFE)-IV (INTRAVENOUS) SETS ARE USED FOR PARENTERAL THERAPY THAT DELIVERS LIQUID SUBSTANCES DIRECTLY IN TO VEIN THROUGH A NEEDLE OR CATHETER INSERTED IN TO A VEIN. AN INJECTION CAN BE GIVEN THROUGH THE IV SET FOR WHICH IV SET HAVING AN INJECTION SITE., STERILE HYPODERMIC SYRINGES FOR SINGLE USE(IM-LIFE)-HYPODERMIC SINGLE USE SYRINGES ARE USED INJECT MEDICAMENT IN THE HUMAN AND ANIMAL BODIES AND IT ALSO USED FOR THE VACCINATION OF THE KIDS. IT IS USED FOR THE INTRA MUSCULAR AND INTRA VENOUS IMMEDIATELY AFTER FILING OF THE MEDICAMENTS IN THE SYRINGES. HYPODERMIC SINGLE USE SYRINGES ARE USED TO WITHDRAW FLUIDS FROM BODY.

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3479	MFG/MD/2020/000124	1.License Holder Name: ALPHA THERAPEUTICS PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(GREENLIFE HEALTHCARE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., ADHESIVE TAPE NON WOVEN SUPPORT AS PER B.P. 1988 /MICROPORE TAP(NANOPORE)-DRESSING AEROSOL, NON-ADHERENT, DRESSING, PERIODONTAL, KIT, DRESSING PAD, DRESSING.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(MICRO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,DISPOSABLE STERILE DIAL FLOW REGULATOR WITH OR WITHOUT INFUSION SET FOR SINGLE USE ONLY(ACCUFLUX IV)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(PARENT'S)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(ATPL BT)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 (FOR EXPORT ONLY)(SKY SAFE BT)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT' VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ATPL NANO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(NEOLINE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE UMBILICAL OCCLUSION DEVICE FOR SINGLE USE ONLY(CLAMPY)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE DISPOSABLE INTRA VENOUS CANNULAE FOR SINGLE USE ONLY(TEFLO)-THE IV

	CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,NON STERILE I.V. CANNULA FIXATOR FOR SINGLE USE ONLY(TEFLOFIX)-DRESSING AEROSOL, NON-ADHERENT, DRESSING, PERIODONTAL, KIT, DRESSING PAD, DRESSING.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(ATPL BT GEM)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(NEODRIP)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(BMS)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SCALP VEIN SET FOR SINGLE USE ONLY(VENOLOK)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY(ATPL MX)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION.,STERILE INFANT FEEDING TUBE FOR SINGLE USE ONLY(ATPL FT)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING, STERILE URETHRAL/ NELATON CATHETER (PLAIN & THUMB CONTROL) FOR SINGLE USE ONLY(ATPL U-CATH)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE DISPOSABLE THREE WAY STOP COCK WITH/WITHOUT EXTENSION TUBE FOR SINGLE USE ONLY (ATPL XT)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(GREEN CROSS)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., STERILE URETHRAL/ NELATON CATHETER (PLAIN & THUMB CONTROL) FOR SINGLE USE ONLY(ATPL NELATON)-A LONG SMALL

	GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY,STERILE DISPOSABLE SCALP VEIN SET FOR SINGLE USE ONLY(ATPL VEIN)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(HARSORIA BT SELECT)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ZENITH)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ATPL MICRO VENT)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ATPL MICRO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ATPL GLOW)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ATPL GEM)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(TEFLOMED)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(CAREBARDIA)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(FIRSTCARE IV)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR

	SINGLE (ATPL ORA)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ATPL ECO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ATPL VENT)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ATPL CROSS)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(HARSORIA PREMIUM)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(HARSORIA ECO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(HARSORIA NV PRO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY (ATPL SUCC)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ATPL SOUL)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., STERILE DISPOSABLE NASOGASTRIC/RYLE'S TUBE FOR SINGLE USE ONLY(ATPL RT)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES., DISPOSABLE STERILE DIAL FLOW REGULATOR WITH OR WITHOUT INFUSION SET FOR SINGLE USE ONLY(ACCUFLUX)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(HARSORIA NEO)-IT IS INTENDED FOR USE IN THE

	ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE HIGH PRESSURE MONITORING LINE FOR SINGLE USE ONLY(ATPL HPM)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,STERILE DISPOSABLE THREE WAY STOP COCK WITH/WITHOUT EXTENSION TUBE FOR SINGLE USE ONLY (ATPL)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING., STERILE DISPOSABLE UMBILICAL OCCLUSION DEVICE FOR SINGLE USE ONLY(CLAMPY-R)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(ATPL BT VENT)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INTRA VENOUS CANNULAE FOR SINGLE USE ONLY (NEOTEF)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ZENITH)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.

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3480	MFG/MD/2020/000125	1.License Holder Name: KMS MANUFACTURING COMPANY 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:ORTHOPAEDIC CASTING SPLINT(-)-A PROSTHETIC &ORTHOTIC ACCESSORY , INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT OR AID IN THE USE OF A CAST,ORTHOSIS(BRACE) OR PROSTHESIS,MICRO POROUS SURGICAL TRANSPARENT TAPE (-)-ALLOWS FREE PASSAGE OF AIR & MOISTURE .THUS PREVENTS MOISTURE ACCUMULATION ON THE SKIN TRANSPARENT : MAKES IT QUICK AND EASY TO SECURE CATHETERS AND INSPECT THE WOUND VISIBLY AND MONITOR FOR EASY SIGN OF COMPLICATIONS. WATERPROOF : ALLOWS BATHING, SHOWERING AND SWIMMING. ,THEATER INCISE DRAPES ANTIMICROBIAL(-)-TO PREVENT CROSS CONTAMINATION & FOREIGN PARTICLES DURING ALL TYPES OF MEDICAL PROCEDURE (SURGERY).,SKIN BARRIER MICROPOROUS SURGICAL TAPE(-)-FIXATION OF PRIMARY DRESSING, SKIN BARRIER MICROPOROUS SURGICAL TAPE(-)-FIXATION OF PRIMARY DRESSING,MICRO POROUS SURGICAL SILK TAPE (TAFFETA) (-)-USED FOR MANY DIFFERENT APPLICATIONS SUCH AS SECURING BULKY DRESSINGS, TUBING AND SMALL SPLINTS.,NONWOVEN ADHESIVE DRESSING WITH PAD(-)-1. PRIMARY AND SECONDARY CARE OF LOW TO MODERATE EXUDING WOUND. 2. FIXATION OF I.V CATHETERS 3. POST-OPERATIVE DRESSINGS TO PROTECT CLEAN CLOSED WOUND,TRANSPARENT ADHESIVE DRESSING WITHOUT PAD (-)-1. PRIMARY AND SECONDARY CARE OF LOW TO MODERATE EXUDING WOUND. 2. FIXATION OF I.V CATHETERS 3. POST-OPERATIVE DRESSINGS TO PROTECT CLEAN CLOSED WOUNDS. , MICRO POROUS SURGICAL TRANSPARENT TAPE(-)-ALLOWS FREE PASSAGE OF AIR & MOISTURE .THUS PREVENTS MOISTURE ACCUMULATION ON THE SKIN TRANSPARENT : MAKES IT QUICK AND EASY TO SECURE CATHETERS AND INSPECT THE WOUND VISIBLY AND MONITOR FOR EASY SIGN OF COMPLICATIONS. WATERPROOF : ALLOWS BATHING, SHOWERING AND SWIMMING.,SOFT SILICON SKIN BARRIER MICROPROUS SURGICAL TAPE(-)-SECURING DRESSINGS ON DAMP OR DRY SKIN,TAPING FRAGILE OR AT RISK SKIN,ANCHORING TUBING AND OTHER DEVICES,WHERE REPEATED TAPING IS REQUIRED,ORTHOPAEDIC CASTING TAPE(-)- A PROSTHETIC & ORTHOTIC ACCESSORY , INTENDED FOR MEDICAL PURPOSE TO SUPPORT,PROTECT OR AID IN USE OF A CAST,ORTHOSIS (BRACE), OR PROSTHESIS,ADHESIVE TAPE USP(STICKING PLASTER)(-)-FIXATION OF PRIMARY DRESSING,THEATER INCISE DRAPE PLAIN(-)-TO PREVENT CROSS CONTAMINATION & FOREIGN PARTICLES DURING ALL TYPES OF MEDICAL PROCEDURE (SURGERY).,ELASTIC ADHESIVE BANDAGE(-)-FOR SUPPORT STRAPPING FRACTURES, ELBOWS, KNEES, SHOULDERS SPECIALLY REQUIRING ELASTICITY. IT IS ALSO

		USED FOR CORRECTIONAL PURPOSES. EXCELLENT AS PRESSURE DRESSING, PROVIDES ADEQUATE COMPRESSION AND BETTER MOBILITY.,ANTIMICROBIAL MICROPOROUS SURGICAL TAPE(-)-FIXATION PRIMARY DRESSING,MICRO POROUS SURGICAL SILK TAPE (TAFFETA)(-)-USED FOR MANY DIFFERENT APPLICATIONS SUCH AS SECURING BULKY DRESSINGS, TUBING AND SMALL SPLINTS., COHESIVE BANDAGE(-)-SUPPORT COHESIVE BANDAGE ARE DESIGNED FOR FIXING DRESSINGS AND IMMOBILIZATION SPLINTS ON DIFFERENT PARTS OF THE BODY. THEY ARE ALSO USED AS PROTECTIVE BANDAGES.,TRANSPARENT ADHESIVE DRESSING WITH PAD(-)-1. PRIMARY AND SECONDARY CARE OF LOW TO MODERATE EXUDING WOUND. 2. FIXATION OF I.V CATHETERS 3. POST-OPERATIVE DRESSINGS TO PROTECT CLEAN CLOSED WOUNDS, MICROPOROUS SURGICAL FOAM TAPE(-)-TO FIX A PRIMARY DRESSING,HYDROCOLLOID ADHESIVE DRESSING WITH PAD(-)-HYDROCOLLOID DRESSING IS USED TO TREAT UN INFECTED WOUNDS & BURN.,CLOTH BASED HYPOALLERGENIC ADHESIVE TAPES(-)-THIS IS USE TO FIXATION OF PRIMARY DRESSING,HYDROCOLLOID ADHESIVE DRESSING WITHOUT PAD(-)-HYDROCOLLOID DRESSING IS USED TO TREAT UN INFECTED WOUNDS & BURN.
3481	MFG/MD/2020/000126	1.License Holder Name: A V PROCESSOR PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:GAMMA RADIATION TREATMENT OF THE PRODUCT(NA)-NA,GAMMA RADIATION TREATMENT OF THE PRODUCT(NA)-NA

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3482	MFG/MD/2020/000127	1.License Holder Name: SIRMAXO CHEMICALS PVT.LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:TRIPLE ENZYMATIC CLEANER.(SANI3ZYME.)-SANI3ZYME IS A TRIPLE ENZYMATIC CLEANER AND IT IS USED FOR PRE-CLEANING OF SURGICAL INSTRUMENTS AND MEDICAL DEVICES BEFORE THE LATTER IS STERILIZED OR DISINFECTED.,COPROPYLENEDIAMINE-1,5 BIS GUANIDINIUM ACETATE + PHENOXYPROPANOL+ BENZALKONIUM CHLORIDE SOLUTION.(SANIDEX AF)-ALDEHYDE FREE DISINFECTANT AND CLEANER FOR MEDICAL INSTRUMENTS.,ENZYMATIC CLEANER.(SANIZYME.)-PR-CLEANING OF MEDICAL DEVICES BEFORE THE LATTER IS STERILIZED OR UNDERGOES END-POINT DISINFECTION., ACTIVATED GLUTARALDEHYDE SOLUTION (GLUTARALDEHYDE 2.45%)(SANIDEX C)-HIGH LEVEL INSTRUMENT DISINFECTANT,TEST STRIPS(SANIDEX OPA SOLUTION TEST STRIPS)-SANIDEX OPA SOLUTION TEST STRIPS ARE USED FOR DETECTING MINIMUM EFFECTIVE CONCENTRATION [MEC] OF SANIDEX OPA SOLUTION., ORTHO-PHTHALALDEHYDE 0.6 % SOLUTION(SANIDEX OPA PLUS)-SANIDEX OPA PLUS SOLUTION IS USED FOR THE HIGH LEVEL DISINFECTION OF HEAT-SENSITIVE AND REUSABLE SEMI-CRITICAL MEDICAL DEVICES AND INSTRUMENTS.,MULTI ENZYMATIC CLEANSER (SANIZYME X)-SANIZYME X IS A MULTI ENZYMATIC CLEANSER AND ITS USE FOR PRE-SOAKING AND CLEANING OF REUSABLE MEDICAL INSTRUMENT AND DEVICES.,GLUTARALDEHYDE 2% SOLUTION.(SANIDEX EXTRA)-HIGH LEVEL DISINFECTANT FOR INSTRUMENTS AND ENDOSCOPES.,POLYMERIC BIGUANIDE HYDROCHLORIDE +QUATERNARY AMMONIUM COMPOUNDS SOLUTION.(SANIHIGENE.)-SANIHIGENE IS A HIGH LEVEL SURFACE AND AERIAL DISINFECTANT. EFFECTIVE DISINFECTANT FOR CRITICAL AND NON CRITICAL AREAS, SPILL MANAGEMENT, FOGGING AND LINEN.,ACTIVATED GLUTARALDEHYDE SOLUTION(GLUTARALDEHYDE 2%)(SANIDEX)-HIGH LEVEL INSTRUMENT DISINFECTANT,ORTHO-PHTHALALDEHYDE 0.55% SOLUTION(SANIDEX OPA)-HIGH LEVEL INSTRUMENT DISINFECTANT,DIDECYL DIMETHYL AMMONIUM CHLORIDE+ POLYMERIC BIGUANIDE HYDROCHLORIDE SOLUTION(SANIOS)-CLEANING AND PRE-DISINFECTION OF MEDICAL INSTRUMENTS., SODIUM PERBORATE MONOHYDARTE 50 % POWDER MIX.(SANISCOPE.)-SANISCOPE IS AN INSTRUMENT STERILANT USEFUL FOR STERILIZATION OF CRITICAL AND SEMI-CRITICAL MEDICAL DEVICES FOR WHICH AUTOCLAVING IS NOT POSSIBLE.

3483	MFG/MD/2020/000128	1.License Holder Name: SIRMAXO CHEMICALS PVT. LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:POLYMERIC BIGUANIDE HYDROCHLORIDE +QUATERNARY AMMONIUM COMPOUNDS SOLUTION.(SANIHIGENE.)-SANIHIGENE IS A HIGH LEVEL SURFACE & AERIAL DISINFECTANT .EFFECTIVE DISINFECTANT FOR CRITICAL AND NON-CRITICAL AREAS, SPILL MANAGEMENT, FOGGING & LINEN., GLUTARALDEHYDE 2% SOLUTION(SANIDEX EXTRA)-SANIDEX EXTRA SOLUTION CAN BE USED AS A DISINFECTANT FOR MEDICAL DEVICES, INSTRUMENTS & ENDOSCOPES.,COCOPROPYLENEDIAMINE-1,5 BIS-GUANIDIUMACETATE+ PHENOXYPROPANOL+ BENZALKONIUM CHLORIDE SOLUTION.(SANIDEX AF)-ALDEHYDE FREE DISINFECTANT AND CLEANER FOR MEDICAL INSTRUMENTS.,ACTIVATED GLUTARALDEHYDE SOLUTION (GLUTARALDEHYDE 2.45%)(SANIDEX C)-HIGH LEVEL INSTRUMENT DISINFECTANT,DIDECYL DIMETHYL AMMONIUM CHLORIDE + POLYMERIC BIGUANIDE HYDROCHLORIDE SOLUTION.(SANIOS)-CLEANING AND PRE-DISINFECTION OF MEDICAL INSTRUMENTS.,ORTHO-PHTHALALDEHYDE 0.6% SOLUTION.(SANIDEX OPA PLUS)-HIGH LEVEL INSTRUMENT DISINFECTANT,ORTHO-PHTHALALDEHYDE 0.55% SOLUTION(SANIDEX OPA)-HIGH LEVEL INSTRUMENT DISINFECTANT,ACTIVATED GLUTARALDEHYDE SOLUTION (GLUATARALDEHYDE 2%)(SANIDEX)-HIGH LEVEL INSTRUMENT DISINFECTANT
3484	MFG/MD/2020/000129	1.License Holder Name: KALYX INDIA HEALTHCARE (P) LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:KNEE JOINT PATELLOFEMEROTIBIAL POLYMER / METAL / METAL CONSTRAINED CEMENTED PROSTHESIS(SWIFT)-INTENDED TO BE IMPLANTED TO REPLACE A KNEE JOINT
3485	MFG/MD/2020/000130	1.License Holder Name: SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:GAMMA RADIATION TREATMENT OF THE PRODUCT(NA)-NA,GAMMA RADIATION TREATMENT OF THE PRODUCT(NA)-NA

3486	MFG/MD/2020/000131	1.License Holder Name: UTESHIYA MEDICARE PVT. LTD., 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ARTHROSCOPY IMPLANTS(UTESHIYA,STATIV, VIP LOK, CEPTRE, HELYSIS, INFILOOP, PROLOOP - ULTRA, PROLOOP - MINI, PROLOOP - XL)-THE ARTHROSCOPY IMPLANTS ARE SMALLER THAN TRADITIONAL INSTRUMENTS. SURGEONS VIEW THE JOINT AREA ON A VIDEO MONITOR, AND CAN DIAGNOSE AND REPAIR TORN JOINT TISSUE, SUCH AS LIGAMENTS. IT IS POSSIBLE TO DO AN ARTHROSCOPIC EXAMINATION OF ALMOST EVERY JOINT, BUT IS MOST COMMONLY USED FOR THE KNEE, SHOULDER, ELBOW, WRIST, ANKLE, FOOT, AND HIP.
3487	MFG/MD/2020/000132	1.License Holder Name: MICROTROL STERILIZATION SERVICES PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:STERILISED UMBILICAL TAPE SCH.F(III)-UMBILICAL COTTON TAPE IS USED TO TIE THE UMBILICAL CARD OF THE NEW BORN INFANT WHEN IT IS SEPARATED FROM THE MOTHER DURING DELIVERY.,STERILE BONEWAX(TRUWAX) -TRUWAX MAY BE USED FOR THE CONTROL OF BLEEDING FROM BONE SURFACES.,ABSORBABLE SURGICAL SUTURE USP CATGUT PLAIN(REDIGUT PLAIN)-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP CATGUT CHROMIC-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP CATGUT CHROMIC (REDIGUT CHROMIC)-CATGUT SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,STERILE OXIDIZED REGENERATED CELLULOSE SURGICAL DRESSING (OXIDIZED REGENERATED CELLULOSE USP)-ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS, AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE.

3488	MFG/MD/2020/000133	1.License Holder Name: MICROTROL STERILIZATION SERVICES PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:URETERAL STENT-USED FOR TEMPORARY INTERNAL DRAINAGE OF URINE FROM KIDNEY TO THE BLADDER,BILIARY STENTS-BILIARY STENTS ARE USED TO DRAIN BILE FROM OBSTRUCTED BILIARY DUCT,URETHRAL STENT-USED FOR STENTING THE URETHRA AFTER HYPOSPEDIAS OR EPISPEDIAS REPAIR AND TO PROVIDE POST-OPERATIVE DRAINAGE OF THE BLADDER,ENDOPYELOTOMY STENT-USED FOR INTERNAL DRAINAGE FROM URETERO PELVIC JUNCTION TO THE BLADDER FOLLOWING INCISION OF A STRICTURE,TUMOR STENT-USED FOR TEMPORARY OR PALLIATIVE TREATMENT OF URETER IN PATIENTS WITH EXTRINSIC URETERAL OBSTRUCTIONS,MONO J STENT-USED FOR TEMPORARY DRAINAGE AND IRRIGATION OF URINE FROM THE KIDNEY
3489	MFG/MD/2020/000134	1.License Holder Name: INTESSENCE SOLUTIONS PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:ENDOSSEOUS DENTAL IMPLANT(REFIRM)-REFIRM DENTAL IMPLANTS ARE PLACED ENDOSSEOUSLY IN MANDIBLE OR MAXILLA AS A SUBSTITUTE FOR TOOTH TO ANCHOR A SINGLE OR MULTIPLE TEETH PROSTHESIS, IN CASE OF EDENTULISM OR TOOTH LOSS.
3490	MFG/MD/2020/000135	1.License Holder Name: A V PROCESSORS PVT LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NON ABSORBABLE SURGICAL SUTURES USP(DAFILON)-DAFILON SUTURE MATERIALS ARE USED PRIMARILY FOR ADAPTATION OF THE WOUND EDGES TO RENDER POSSIBLE AN UNDISTURBED WOUND HEALING,NON ABSORBABLE SURGICAL SUTURES USP(SILKAM)-SILKAM IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION AND/OR LIGATION OF THE WOUND EDGES TO RENDER POSSIBLE AN UNDISTURBED WOUND HEALING

3491	MFG/MD/2020/000136	1.License Holder Name: FUTURA SURGICARE PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:MONOFILAMENT POLYPROPYLENE WITH NEEDLE(NETLENE)-A NETLENE SUTURE IS SUITABLE FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,BLACK BRAIDED SILK WITH NEEDLE-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION IN ALL SURGICAL PROCEDURES EXCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,BONEWAX-GENERAL ORTHOPEDICS, CRANIOMAXILLOFACIAL AND CARDIO-THORACIC SURGERY FOR STERNAL CLOSURE,MONOFILAMENT POLYAMIDE-INDICATED FOR CLOSING SKIN SUB CUTICULAR LAYERS. ITS HIGH DEGREE OF ELASTICITY CONTRIBUTES TO ITS GREAT STRENGTH IN THE FINE SIZES, ENABLING THE PLASTIC SURGEONS, THE MICRO SURGEONS & THE OPHTHALMOLOGISTS TO TIE SECURE KNOTS.,MONOFILAMENT POLYPROPYLENE STERILISED SURGICAL SUTURE(NETLENE)-A NETLENE SUTURE IS SUITABLE FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,MONOFILAMENT POLYAMIDE WITH NEEDLE-INDICATED FOR CLOSING SKIN SUB CUTICULAR LAYERS. ITS HIGH DEGREE OF ELASTICITY CONTRIBUTES TO ITS GREAT STRENGTH IN THE FINE SIZES, ENABLING THE PLASTIC SURGEONS, THE MICRO SURGEONS & THE OPHTHALMOLOGISTS TO TIE SECURE KNOTS., STAINLESS STEEL STERILIZED SURGICAL NEEDLED SUTURE-STAINLESS STEEL SUTURES ARE INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, INTESTINAL ANASTOMOSIS, HERNIA REPAIR, STERNAL CLOSURE AND ALSO FOR CERTAIN ORTHOPEDIC PROCEDURES (CERCLAGE OR TENDON REPAIR).,MONOFILAMENT POLYAMIDE(NETPLAST)-NETPLAST IS SUITABLE FOR CLOSING SKIN SUB CUTICULAR LAYERS. ITS HIGH DEGREE OF ELASTICITY CONTRIBUTES TO ITS GREAT STRENGTH IN THE FINE SIZES, ENABLING THE PLASTIC SURGEONS, THE MICRO SURGEONS & THE OPHTHALMOLOGISTS TO TIE SECURE KNOTS.,MONOFILAMENT POLYPROPYLENE WITH NEEDLE-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,BLACK BRAIDED SILK-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION IN ALL SURGICAL PROCEDURES EXCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,BLACK BRAIDED SILK WITH NEEDLE(NETSILK)-NETSILK IS INDICATED FOR USE IN

	GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION IN ALL SURGICAL PROCEDURES EXCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,BLACK BRAIDED SILK(NETSILK)-NETSILK IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION IN ALL SURGICAL PROCEDURES EXCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES,POLYGLACTIN 910 STERILIZED SURGICAL SUTURE (SYNTHETIC)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER. THE SAFETY AND EFFECTIVENESS OF POLYGLACTIN 910 SUTURES IN CARDIOVASCULAR TISSUE HAVE NOT BEEN ESTABLISHED., POLIGLECAPRONE 25 STERILIZED SURGICAL NEEDLED SUTURE-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY,POLYDIOXANONE STERILISED SURGICAL NEEDLED SUTURE-POLYDIOXANONE MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN PEDIATRIC CARDIOVASCULAR TISSUE WHERE GROWTH IS EXPECTED TO OCCUR, AND OPHTHALMIC SURGERY. POLYDIOXANONE SUTURE IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE., POLYGLYCOLIC ACID STERILISED SURGICAL SUTURE (SYNTHETIC)(NETSORB)-NETSORB SUTURES ARE INDICATED FOR USE IN GENERAL, SOFT TISSUE INCLUDING USE IN OPHTHALMIC. BUT NOT FOR USE IN CARDIO VASCULAR & NEUROLOGICAL TISSUES. IF THERE IS ANY LOCALIZED INFLAMMATION, ITCHING OR ANY SORT OF ALLERGY OF A PARTICULAR PATIENT THEN THE USAGE OF THIS PRODUCT SHOULD BE STOPPED AND MEDICAL ADVICE SHOULD BE TAKEN IMMEDIATELY,POLYGLYCOLIC ACID STERILISED SURGICAL NEEDLED SUTURE (SYNTHETIC)(NETSORB)-NETSORB SUTURES ARE INDICATED FOR USE IN GENERAL, SOFT TISSUE INCLUDING USE IN OPHTHALMIC. BUT NOT FOR USE IN CARDIO VASCULAR & NEUROLOGICAL TISSUES. IF THERE IS ANY LOCALIZED INFLAMMATION, ITCHING OR ANY SORT OF ALLERGY OF A PARTICULAR PATIENT THEN THE USAGE OF THIS PRODUCT SHOULD BE STOPPED AND MEDICAL ADVICE SHOULD BE TAKEN IMMEDIATELY.,STERILISED SURGICAL SUTURE (CATGUT CHROMIC)-FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR

	LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES., POLIGLECAPRONE 25 STERILISED SURGICAL SUTURE-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,POLYDIOXANONE STERILIZED SURGICAL NEEDLED SUTURE-POLYDIOXANONE MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN PEDIATRIC CARDIOVASCULAR TISSUE WHERE GROWTH IS EXPECTED TO OCCUR, AND OPHTHALMIC SURGERY. POLYDIOXANONE SUTURE IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE., POLYGLYCOLIC ACID STERILISED SURGICAL SUTURE (SYNTHETIC)-INDICATED FOR USE IN GENERAL, SOFT TISSUE INCLUDING USE IN OPHTHALMIC. BUT NOT FOR USE IN CARDIO VASCULAR & NEUROLOGICAL TISSUES. IF THERE IS ANY LOCALIZED INFLAMMATION, ITCHING OR ANY SORT OF ALLERGY OF A PARTICULAR PATIENT THEN THE USAGE OF THIS PRODUCT SHOULD BE STOPPED AND MEDICAL ADVICE SHOULD BE TAKEN IMMEDIATELY.,POLYGLACTIN 910 STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER. THE SAFETY AND EFFECTIVENESS OF POLYGLACTIN 910 SUTURES IN CARDIOVASCULAR TISSUE HAVE NOT BEEN ESTABLISHED., POLYGLACTIN 910 STERILIZED SURGICAL NEEDLED SUTURE [SYNTHETIC]-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER. THE SAFETY AND EFFECTIVENESS OF POLYGLACTIN 910 SUTURES IN CARDIOVASCULAR TISSUE HAVE NOT BEEN ESTABLISHED., POLYGLACTIN 910 STERILIZED SURGICAL SUTURE (SYNTHETIC) (NETCRYL)-NETCRYL SUTURES IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER. THE SAFETY AND EFFECTIVENESS OF NETCRYL SUTURES IN CARDIOVASCULAR TISSUE HAVE NOT BEEN ESTABLISHED., POLIGLECAPRONE 25 STERILIZED SURGICAL NEEDLED SUTURE

	(NETCRYL MONO)-NETCRYL MONO SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,POLYGLACTIN 910 STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC)(NETCRYL) -NETCRYL SUTURES IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER. THE SAFETY AND EFFECTIVENESS OF NETCRYL SUTURES IN CARDIOVASCULAR TISSUE HAVE NOT BEEN ESTABLISHED.,STERILE DISPOSABLE SKIN STAPLER-SKIN STAPLER ARE INTENDED TO BE USED FOR SKIN CLOSURE OF WOUNDS, INCISIONS OR LACERATIONS OF THE EPIDERMIS.,STERILISED SURGICAL NEEDLED SUTURE (CATGUT CHROMIC)-FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES.,STERILISED SURGICAL SUTURE (CATGUT PLAIN)-FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,MONOFILAMENT POLYPROPYLENE STERILISED SURGICAL SUTURE-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,STERILISED SURGICAL NEEDLED SUTURE (CATGUT PLAIN)-FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,MONOFILAMENT POLYAMIDE WITH NEEDLE(NETPLAST)-NETPLAST IS SUITABLE FOR CLOSING SKIN SUB CUTICULAR LAYERS. ITS HIGH DEGREE OF ELASTICITY CONTRIBUTES TO ITS GREAT STRENGTH IN THE FINE SIZES, ENABLING THE PLASTIC SURGEONS, THE MICRO SURGEONS & THE OPHTHALMOLOGISTS TO TIE SECURE KNOTS.,STERILISED SURGICAL NEEDLED SUTURE (CATGUT CHROMIC) (NETGUT)-NETGUT IS FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES.,COATED POLYESTER WITH NEEDLE (NETBOND)-NETBOND SUTURES ARE AN EXCELLENT CHOICE FOR CARDIOVASCULAR AND OPHTHALMIC SURGERY. IF THERE IS ANY LOCALIZED INFLAMMATION, ITCHING OR ANY SORT OF ALLERGY OF A PARTICULAR PATIENT THEN THE USAGE OF THIS PRODUCT SHOULD BE STOPPED AND MEDICAL ADVICE SHOULD BE TAKEN IMMEDIATELY.,COATED POLYESTER WITH NEEDLE-EXCELLENT CHOICE FOR CARDIOVASCULAR AND OPHTHALMIC SURGERY. IF THERE IS ANY LOCALIZED INFLAMMATION, ITCHING OR ANY SORT OF ALLERGY OF A PARTICULAR PATIENT THEN THE USAGE OF THIS PRODUCT SHOULD BE STOPPED AND MEDICAL ADVICE SHOULD BE TAKEN IMMEDIATELY.,POLYGLYCOLIC ACID STERILISED SURGICAL

	NEEDLED SUTURE (SYNTHETIC)-INDICATED FOR USE IN GENERAL, SOFT TISSUE INCLUDING USE IN OPHTHALMIC. BUT NOT FOR USE IN CARDIO VASCULAR & NEUROLOGICAL TISSUES. IF THERE IS ANY LOCALIZED INFLAMMATION, ITCHING OR ANY SORT OF ALLERGY OF A PARTICULAR PATIENT THEN THE USAGE OF THIS PRODUCT SHOULD BE STOPPED AND MEDICAL ADVICE SHOULD BE TAKEN IMMEDIATELY.,STERILISED SURGICAL SUTURE (CATGUT PLAIN) (NETGUT)-NETGUT IS FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,STERILISED SURGICAL NEEDLED SUTURE (CATGUT PLAIN)(NETGUT)-NETGUT IS FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION., POLYDIOXANONE STERILIZED SURGICAL NEEDLED SUTURE (NETSYNTH)-POLYDIOXANONE MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN PEDIATRIC CARDIOVASCULAR TISSUE WHERE GROWTH IS EXPECTED TO OCCUR, AND OPHTHALMIC SURGERY. POLYDIOXANONE SUTURE IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE., ANTIBACTERIAL POLYGLACTIN 910 STERILISED SURGICAL NEEDLED SUTURE-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, EXCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER., STERILISED SURGICAL SUTURE (CATGUT CHROMIC)(NETGUT)-NETGUT IS FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES., STAINLESS STEEL STERILIZED SURGICAL NEEDLED SUTURE (NETSTEEL)-STAINLESS STEEL SUTURES ARE INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, INTESTINAL ANASTOMOSIS, HERNIA REPAIR, STERNAL CLOSURE AND ALSO FOR CERTAIN ORTHOPEDIC PROCEDURES (CERCLAGE OR TENDON REPAIR).

3492	MFG/MD/2020/000136	1.License Holder Name: FUTURA SURGICARE PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:MONOFILAMENT POLYDIOXANONE BARBED SUTURE, ABSORBABLE SURGICAL SUTURE. ANTIBACTERIAL WITH TRICLOSAN.(VFIX AB)-THE DEVICE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE THE USE OF ABSORBABLE SUTURES IS APPROPRIATE.,MONOFILAMENT POLIGLECAPRONE 25 SUTURE, ABSORBABLE SURGICAL SUTURE, ANTIBACTERIAL WITH TRICLOSAN.(NETCRYL MONO AB)-POLIGLECAPRONE 25 ANTIBACTERIAL SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY., POLYPROPYLENE MESH COATED WITH TITANIUM DIOXIDE. NON ABSORBABLE SURGICAL MESH.(TITANIA MESH)-IT IS INTENDED FOR SUPPORTING WEAK TISSUES LIKE CHEST WALL DEFECT, HERNIA ETC., COMPOSITE MESH COMPOSED OF POLYPROPYLENE AND LOW DENSITY POLYETHYLENE. NON ABSORBABLE.(NETPRO MESH)-COMPOSITE MESH IS INDICATED FOR USE IN THE RECONSTRUCTION OF SOFT TISSUE DEFICIENCIES, SUCH AS FOR THE REPAIR OF HERNIAS AND CHEST WALL DEFECTS.,BLACK BRAIDED SILK SUTURE. NON ABSORBABLE SURGICAL SUTURE.(NETSILK)-SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION IN ALL SURGICAL PROCEDURES EXCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,COATED AND BRAIDED POLYGLACTIN 910, SUTURE, ABSORBABLE SURGICAL SUTURE. ANTIBACTERIAL WITH CHLORHEXIDINE.(NETCRYL CS)-POLYGLACTIN 910 NEEDLED WITH CHLORHEXIDINE SUTURE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/ OR LIGATION ACROSS SUITABLE SURGERY TYPES.,MONOFILAMENT POLYDIOXANONE SUTURE, ABSORBABLE SURGICAL SUTURE. ANTIBACTERIAL WITH TRICLOSAN. (NETSYNTH AB)-IT IS INTENDED FOR SOFT TISSUE APPROXIMATION AFTER A SURGICAL PROCEDURE,POLYMER LIGATION CLIPS, NON ABSORBABLE.(NETCLIP)-POLYMER LIGATING CLIPS ARE INTENDED FOR USE IN OPEN AND LAPAROSCOPIC CASE APPLICATION PROCEDURES INVOLVING LIGATION OF VESSELS OR TISSUE STRUCTURES. SURGEONS SHOULD APPLY THE APPROPRIATE SIZE CLIP FOR THE SIZE OF THE VESSEL OR TISSUE STRUCTURE TO BE LIGATED SUCH THAT THE CLIP COMPLETELY ENCOMPASSES THE VESSEL OR TISSUE STRUCTURE.,MONOFILAMENT POLYDIOXANONE BARBED SUTURE, ABSORBABLE SURGICAL SUTURE.(VFIX)-IT IS INTENDED FOR TISSUE APPROXIMATION WITHOUT THE USAGE OF KNOTS.,OXIDIZED REGENERATED CELLULOSE. HEMOSTAT.

	(HEMONET)-THE PRODUCT IS INTENDED TO PROMOTE CLOTTING DURING SURGERY. IT IS USED IN VARIOUS SURGERIES LIKE LAPAROSCOPIC PARTIAL NEPHRECTOMY, GALLBLADDER BED AND IN MINOR SPLENIC INJURY, TO CONTROL HEMORRHAGE FROM AN EDEMATOUS, FRAGILE MUCOSA AND SKIN EDGE AT THE PERIPHERAL SURFACE OF THE STOMA.,MONOFILAMENT KNITTED POLYPROPYLENE MESH.(NETLENE MESH.)-IT IS SUITABLE FOR USE IN GENERAL SOFT TISSUE SUPPORT. IT IS MAINLY USED IN HERNIA REPAIR.,ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE WITH POLYESTER SUTURE, NON ABSORBABLE SURGICAL SUTURE. (ULTRANET FIBER)-IT IS INTENDED FOR TISSUE APPROXIMATION., MONOFILAMENT POLIGLECAPRONE 25 BARBED SUTURE, ABSORBABLE SURGICAL SUTURE. ANTIBACTERIAL WITH TRICLOSAN. (NETCRYL MONO BARB AB)-IT IS INTENDED FOR SOFT TISSUE APPROXIMATION WITHOUT THE USAGE OF KNOTS.,MONOFILAMENT POLYTETRAFLUOROETHYLENE SUTURE, NON ABSORBABLE SURGICAL SUTURE.(NETPTFE & NETFENE)-POLYTETRA FLUORO ETHYLENE IS SUITABLE FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,TITANIUM LIGATION CLIPS, NON ABSORBABLE(LIGANET)-TITANIUM LIGATING CLIPS ARE INTENDED FOR USE IN CARDIOVASCULAR AND GENERAL SURGERY APPLICATIONS PROCEDURES INVOLVING LIGATION OF VESSELS OR TISSUE STRUCTURES. SURGEONS SHOULD APPLY THE APPROPRIATE SIZE CLIP FOR THE SIZE OF THE VESSEL OR TISSUE STRUCTURE TO BE LIGATED SUCH THAT THE CLIP COMPLETELY ENCOMPASSES THE VESSEL OR TISSUE STRUCTURE.,POLYPROPYLENE BARBED SUTURE, NON ABSORBABLE SURGICAL SUTURE.(NETLENE BARB)-IT IS INTENDED FOR TISSUE APPROXIMATION WITHOUT THE USAGE OF KNOTS.,STERILE REUSABLE SKIN STAPLER(NETMATE)-SKIN STAPLERS ARE INTENDED TO BE USED FOR SKIN CLOSURE OF WOUNDS, INCISIONS OR LACERATIONS OF THE EPIDERMIS.,SURGICAL SKIN STAPLER CARTRIDGE(NETMATE CARTRIDGE.)-SKIN STAPLER CARTRIDGE IS USED FOR SKIN CLOSURE.,SURGICAL KITS.-INTEND TO COMPLETE A SURGICAL PROCEDURE BY USING VARIOUS COMPONENTS IN THE KIT.,MONOFILAMENT POLIGLECAPRONE 25 BARBED SUTURE, ABSORBABLE SURGICAL SUTURE.(NETCRYL MONO BARB)-IT IS INTENDED FOR TISSUE APPROXIMATION WITHOUT THE USAGE OF KNOTS.,COMPOSITE POLYMER MESH, COMPOSED OF POLYMER AND SILICONE, NON ABSORBABLE.(NETSIL MESH)-IT IS INTENDED FOR SUPPORTING WEAK TISSUES LIKE CHEST WALL DEFECT, HERNIA ETC.,COMPOSITE MESH COMPOSED OF POLYPROPYLENE AND POLYTETRA FLUORO ETHYLENE. NON ABSORBABLE.(NETPTFE MESH)-COMPOSITE MESH IS INDICATED FOR USE IN THE RECONSTRUCTION OF SOFT TISSUE DEFICIENCIES, SUCH

		AS FOR THE REPAIR OF HERNIAS AND CHEST WALL DEFECTS., PARTIALLY ABSORBABLE MESH, COMPOSED OF POLYPROPYLENE AND POLIGLECAPRONE 25(NETSOLVE MESH)-PARTIALLY ABSORBABLE MESH IS INDICATED FOR RECONSTRUCTION OF HERNIAS OR OTHER ABDOMINAL WALL DEFICIENCIES, AS WELL AS FOR REINFORCEMENT OF SOFT TISSUES WHERE WEAKNESS EXISTS., COMPOSITE MESH COMPOSED OF POLYESTER AND LOW DENSITY POLYETHYLENE. NON ABSORBABLE.(NETEX MESH)-IT IS INTENDED FOR SUPPORTING WEAK TISSUES LIKE CHEST WALL DEFECT, HERNIA ETC.
3493	MFG/MD/2020/000137	1.License Holder Name: KALYX INDIA HEALTHCARE (P) LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:HIP JOINT METAL/CERAMIC/ POLYMER SEMI CONSTRAINED CEMENTED OR NON POROUS UNCEMENTED PROSTHESIS(C2)-INTENDED TO BE IMPLANTED TO REPLACE A HIP JOINT

CENTRAL DRUG STANDARD CONTROL ORGANISATION
CDSCO CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3494	MFG/MD/2020/000138	1.License Holder Name: AMIGO SURGICARE PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE SINGLE USE ENDOTRACHEAL TUBE(NASAL/ORAL)(CUFF/UNCUFFED) [FOR EXPORT ONLY](AMIGO)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN. ,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY[FOR EXPORT ONLY](AMIGO)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE SINGLE USE INTRAVENOUS CANNULA (- - -)-THE IV CANNULA IS A PASSIVE DEVICE TO INTRAVENOUS PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY [FOR EXPORT ONLY](AMIGO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SCALP VEIN SET FOR SINGLE USE ONLY (- - -)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM SCALP VEIN SET AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,STERILE DISPOSABLE RYLES TUBE WITH X-RAY OPAQUE TUBE FOR SINGLE USE ONLY [FOR EXPORT ONLY](AMIGO)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITHOUT AIR VENT BIS 9824FOR SINGLE USE ONLY (- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED., STERILE DISPOSABLE INFANT FEEDING TUBE WITH X-RAY OPAQUE TUBE FOR SINGLE USE ONLY [FOR EXPORT ONLY](AMIGO)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING ,STERILE DISPOSABLE MICRO DRIP INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A

	PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN. ,STERILE DISPOSABLE SINGLE USE INTRAVENOUS CANNULA(IV CANNULA) FOR SINGLE USE ONLY. [FOR EXPORT ONLY](AMIGO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES ,STERILE DISPOSABLE SCALP VEIN SET FOR SINGLE USE ONLY(AMIGO)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM SCALP VEIN SET AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD. ,STERILE DISPOSABLE SINGLE USE FOLEY'S BALLOON CATHETER [FOR EXPORT ONLY](AMIGO)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE DISPOSABLE INFUSION SET WITH OR WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(AMIGO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY [FOR EXPORT ONLY](AMIGO)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,STERILE URETHRAL/ NELATON CATHETER (PLAIN & THUMB CONTROL) FOR SINGLE USE ONLY (AMIGO)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY. , STERILE DISPOSABLE SCALP VEIN SET FOR SINGLE USE [FOR EXPORT ONLY](AMIGO)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD ,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (AMIGO)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY [FOR EXPORT ONLY](AMIGO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN.,STERILE UMBILICAL OCCLUSION DEVICE FOR SINGLE USE ONLY (AMIGO CORD CLAMP)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE THREE WAY STOP COCK WITH EXTENSION TUBE FOR SINGLE USE

	(AMIGO)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, STERILE UMBLICAL ARTERY CATHETER FOR SINGLE USE ONLY (AMIGO)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS,STERIIE DISPOSABLE HIGH PRESSURE MONITORING LINE FOR SINGLE USE ONLY(AMIGO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY (AMIGO)-:SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING. , STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY(AMIGO MUCUS EXTRACTOR)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH OR WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(AMIGO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,:STERILE DISPOSABLE INTRA VENOUS CANNULAE FOR SINGLE USE ONLY (RONAK'S)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES , STERILE DISPOSABLE MICRO DRIP INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(AMIGO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN. ,STERILE DISPOSABLE CHEST DRAINAGE CATHETER FOR SINGLE USE ONLY (AMIGO)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA.,STERILE DISPOSABLE YANKUR SUCTION SET FOR SINGLE USE ONLY(AMIGO)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION.,DISPOSABIE STERILE DIAL FLOW REGULATOR WITH OR WITHOUT INFUSION SET FOR SINGLE USE ONLY(AMIGO)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,CATHETER STERILE DISPOSABLE SINGLE USE CLOSED WOUND SUCTION UNIT(AMIGO)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS

	FROM A WOUND. THEY ARE COMMONLY PLACED BY THE SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,:STERILE INFANT FEEDING TUBE FOR SINGLE USE ONLY(AMIGO)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,STERILE DISPOSABLE INTRA VENOUS CANNULAE FOR SINGLE USE ONLY (AMIGO)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES . ,CATHETER STERILE DISPOSABLE SINGLE USE FOLEY'S BALLOON CATHETER FOR SINGLE USE ONLY (AMIGO)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,CATHETER STERILE DISPOSABLE SINGLE USE ENDOTRACHEAL TUBE(NASAL/ORAL)(CUFF/UNCUFFED) (AMIGO)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA.,STERILE DISPOSABLE NASOGASTRIC/RYLE'S TUBE FOR SINGLE USE ONLY(AMIGO)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES. ,STERILE THREE WAY STOP COCK FOR SINGLE USE (AMIGO)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING

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3495	MFG/MD/2020/000139	1.License Holder Name: FREEDOM OPTHALMIC PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:POLY METHYL METHACRYLATE INTRAOCULAR LENS(FREEDOM LENS, FREEDOM GOLD, FREEDOM POWER, FREEDOM EDGE, FREEDOM IRIS, VIS TRILL, CLAR IOL, USIOL)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY.,YELLOW HYDROPHILIC ACRYLIC POSTERIOR CHAMBER SINGLE PIECE 360°SQUARE EDGE ASPHERIC FOLDABLE INTRAOCULAR LENS(FREEDOM ELITE, FREEDOM MULTIFOCAL, FREEDOM TORIC, FREEDOM TRIFLEX, FREEDOM SULCO, VIS TRILL, CLAR IOL)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY.,YELLOW PMMA POSTERIOR CHAMBER SINGLE PIECE SQUARE EDGE INTRAOCULAR LENS(FREEDOM GOLD, VIS TRILL, CLAR IOL)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY., YELLOW HYDROPHOBIC ACRYLIC ASPHERIC FOLDABLE INTRAOCULAR LENS(FREEDOM ZEN, FREEDOM ZEN+, FREEDOM MULTIFOCAL, FREEDOM TORIC, FREEDOM TRIFOCAL, FREEDOM SULCO, VIS TRILL, CLAR IOL)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY.,HYDROPHOBIC ACRYLIC ASPHERIC FOLDABLE INTRAOCULAR LENS(FREEDOM ACE, FREEDOM ACE+, FREEDOM MULTIFOCAL, FREEDOM TORIC, FREEDOM TRIFLEX, FREEDOM SULCO, VIS TRILL, CLAR IOL)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY.,ICL - HYDROPHILLIC IOLS (IMPLANTABLE COLLAMER LENS)(FREEDOM ICL)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY.,HYDROPHILIC ACRYLIC POSTERIOR CHAMBER SINGLE PIECE FOLDABLE INTRAOCULAR LENS(FREEDOM FOLD, FREEDOM FOCUS, FREEDOM ICON, FREEDOM MULTIFOCAL, FREEDOM TORIC, FREEDOM TRIFLEX, FREEDOM SULCO, VIS TRILL, CLAR IOL, USIOL)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY.,YELLOW HYDROPHOBIC ACRYLIC SPHERIC FOLDABLE INTRAOCULAR LENS (FREEDOM ARCY, FREEDOM ARCY+)-THE INTRAOCULAR LENSES MANUFACTURED BY FREEDOM OPTHALMIC PVT. LTD. ARE INTENDED FOR THE REPLACEMENT OF THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF THE APHAKIA. THE IOL IS INTENDED FOR PRIMARY OR SECONDARY IMPLANTATION IN THE POSTERIOR CHAMBER/ ANTERIOR CHAMBER IN PATIENTS WHERE A CHARACTER LENS HAS BEEN REMOVED BY SURGICAL PROCEDURE., HYDROPHOBIC ACRYLIC SPHERIC FOLDABLE INTRAOCULAR LENS (FREEDOM ARC, FREEDOM ARC+)-THE INTRAOCULAR LENSES MANUFACTURED BY FREEDOM OPTHALMIC PVT. LTD. ARE INTENDED FOR THE RE PLACEMENT OF THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF THE APHAKIA. THE IOL ARE INTENDED FOR

		PRIMARY OR SECONDARY IMPLANTATION IN THE POSTERIOR CHAMBER/ ANTERIOR CHAMBER IN PATIENTS WHERE A CHARACTER LENS HAS BEEN REMOVED BY SURGICAL PROCEDURE.
3496	MFG/MD/2020/000140	1.License Holder Name: MICROTROL STERILIZATION SERVICES (P) LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ETHYLENE OXIDE STERILIZATION OF URINARY CATHETERIZATION SYSTEM (CONTAINS GLOVES, UNDERPAD, GAUZE, PVP SWAB STICKS (3)/ INTERMITTENT CATHETER KIT (CONTAINS GLOVES, UNDERPAD, GAUZE, PVP SWAB STICKS (3)(APOGEE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,ETHYLENE OXIDE STERILIZATION OF COUDE TAPER TIP CATHETER/ INTERMITTENT CATHETER COUDE(APOGEE IC) -TO DRAIN URINE FROM THE BLADDER,ETHYLENE OXIDE STERILIZATION OF CATHETER INSERTION KIT(APOGEE)-TO FACILITATE CATHETERIZATION,ETHYLENE OXIDE STERILIZATION OF INTERMITTENT CATHETER COUDE(APOGEE PLUS)-DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,ETHYLENE OXIDE STERILIZATION OF INTERMITTENT CATHETER(APOGEE IC)-TO DRAIN URINE FROM THE BLADDER,ETHYLENE OXIDE STERILIZATION OF PRE-LUBRICATED URINARY CATHETERISATION SYSTEM, NELATON (INSTANTCATH PROTECT)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,ETHYLENE OXIDE STERILIZATION OF INTERMITTENT CATHETER KIT, COUDE (CONTAINS GLOVES, UNDERPAD, GAUZE, PVP SWAB STICKS (3)(APOGEE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,ETHYLENE OXIDE STERILIZATION OF COUDE TAPPER TIP CATHETER/ INTERMITTENT CATHETER COUDE(APOGEE)-TO DRAIN URINE FROM THE BLADDER, ETHYLENE OXIDE STERILIZATION OF INTERMITTENT CATHETER COUDE(APOGEE IC)-TO DRAIN URINE FROM THE BLADDER,ETHYLENE OXIDE STERILIZATION OF INTERMITTENT CATHETER(APOGEE)-TO DRAIN URINE FROM THE BLADDER,ETHYLENE OXIDE STERILIZATION OF PRE-LUBRICATED URINARY CATHETERISATION SYSTEM, TIEMANN (INSTANTCATH PROTECT)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,ETHYLENE OXIDE STERILIZATION OF INTERMITTENT CATHETER(APOGEE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG

3497	MFG/MD/2020/000141	1.License Holder Name: MICROTROL STERILIZATION SERVICES (P) LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ETHYLENE OXIDE STERILIZATION OF INTERMITTENT CATHETER KIT, COUDE (CONTAINS GLOVES, UNDERPAD, GAUZE, PVP SWAB STICKS (3)(APOGEE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG, ETHYLENE OXIDE STERILIZATION OF INTERMITTENT CATHETER (APOGEE)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,GAMMA STERILIZATION OF INTERMITTENT CATHETER TIEMANN/ COUDE(ADVANCE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,ETHYLENE OXIDE STERILIZATION OF INTERMITTENT CATHETER COUDE(APOGEE IC)-TO DRAIN URINE FROM THE BLADDER,ETHYLENE OXIDE STERILIZATION OF INTERMITTENT CATHETER COUDE(APOGEE PLUS)-DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,GAMMA STERILIZATION OF PRE-LUBRICATED CATHETER(INSTANTCATH)-TO DRAIN URINE FROM THE BLADDER,GAMMA STERILIZATION OF INTERMITTENT CATHETER KIT TIEMANN/ COUDE (CONTAINING 1 PAIR GLOVES, 1 WATER PROOF UNDERPAD, 3 SWAB STICK (BZK), IFU(ADVANCE PLUS) -TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG, ETHYLENE OXIDE STERILIZATION OF PRE-LUBRICATED URINARY CATHETERISATION SYSTEM, TIEMANN(INSTANTCATH PROTECT)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,GAMMA STERILIZATION OF INTERMITTENT CATHETER NELATON/ STRAIGHT (ADVANCE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,GAMMA STERILIZATION OF INTERMITTENT CATHETER STRAIGHT WITH KIT (CONTAINING 1 PAIR GLOVES, 1 WATER PROOF UNDERPAD, 3 SWAB STICK (BZK), IFU(ADVANCE PLUS) -TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG, GAMMA STERILIZATION OF INTERMITTENT CATHETER STRAIGHT (ADVANCE)-TO DRAIN URINE FROM THE BLADDER,GAMMA STERILIZATION OF INTERMITTENT CATHETER TIEMANN/ COUDE (ADVANCE)-TO DRAIN URINE FROM THE BLADDER,ETHYLENE OXIDE STERILIZATION OF URINARY CATHETERIZATION SYSTEM (CONTAINS GLOVES, UNDERPAD, GAUZE, PVP SWAB STICKS (3)/ INTERMITTENT CATHETER KIT (CONTAINS GLOVES, UNDERPAD, GAUZE, PVP SWAB STICKS (3)(APOGEE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,GAMMA STERILIZATION OF INTERMITTENT CATHETER, NELATON(ADVANCE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,ETHYLENE OXIDE STERILIZATION OF CATHETER INSERTION KIT(APOGEE)-TO FACILITATE CATHETERIZATION,ETHYLENE OXIDE STERILIZATION OF INTERMITTENT CATHETER(APOGEE)-TO DRAIN URINE FROM THE

		BLADDER,ETHYLENE OXIDE STERILIZATION OF INTERMITTENT CATHETER(APOGEE IC)-TO DRAIN URINE FROM THE BLADDER, GAMMA STERILIZATION OF INTERMITTENT CATHETER STRAIGHT (ADVANCE PLUS)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,ETHYLENE OXIDE STERILIZATION OF COUDE TAPER TIP CATHETER/ INTERMITTENT CATHETER COUDE(APOGEE IC) -TO DRAIN URINE FROM THE BLADDER,ETHYLENE OXIDE STERILIZATION OF PRE-LUBRICATED URINARY CATHETERISATION SYSTEM, NELATON(INSTANTCATH PROTECT)-TO DRAIN URINE FROM THE BLADDER IN TO COLLECTION BAG,ETHYLENE OXIDE STERILIZATION OF COUDE TAPPER TIP CATHETER/ INTERMITTENT CATHETER COUDE(APOGEE)-TO DRAIN URINE FROM THE BLADDER
3498	MFG/MD/2020/000142	1.License Holder Name: BHARAT SURGICAL INDUSTRIES 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.(NIL)-MEDICAL ABSORBENT (COTTON FIBER), SURGICAL DRESSINGS

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3499	MFG/MD/2020/000143	1.License Holder Name: RAYMOND CONSUMER PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NATURAL RUBBER LATEX MALE CONDOMS.(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS.(KAMASUTRA)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS.(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS.(KAMASUTRA)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS WITH 4.5% W/W BENZOCAINE AS DESENSITIZER(NIL)-THE MALE LATEX CONDOM LUBRICATED WITH BENZOCAINE 4.5% W/W IS INTENDED TO BE USED FOR CONTRACEPTIVE AND PROPHYLACTIC PURPOSES. ADDITIONALLY, THE LUBRICANT ON THE CONDOM HELPS IN TEMPORARILY PROLONGING THE TIME UNTIL EJACULATION,: NATURAL RUBBER LATEX MALE CONDOMS.(KAMASUTRA)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS WITH 4.5% W/W BENZOCAINE AS DESENSITIZER (KAMASUTRA)-THE MALE LATEX CONDOM LUBRICATED WITH BENZOCAINE 4.5% W/W IS INTENDED TO BE USED FOR CONTRACEPTIVE AND PROPHYLACTIC PURPOSES. ADDITIONALLY, THE LUBRICANT ON THE CONDOM HELPS IN TEMPORARILY PROLONGING THE TIME UNTIL EJACULATION.,NATURAL RUBBER LATEX MALE CONDOMS WITH VIBRATING RING(KAMASUTRA)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS ALONG WITH VIBRATION FOR PLEASURE.

3500	MFG/MD/2020/000144	1.License Holder Name: FIBROHEAL WOUNDCARE PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:SURGICAL DRESSING (SILK BASED) D-FIBROHEAL-(SHEET ADHESIVE, AG SHEET ADHESIVE, FOAM ADHESIVE, AG FOAM ADHESIVE, SUTURE DRESS, SCARLITE, WOUND AID, SILKPLAST, WOUND NET & MICROGRAS)(D- FIBROHEAL)-IT USE IN COVERING OF BOTH INFECTED AND NON-INFECTED WOUNDS SUCH AS SURGICAL SITES, BURN, SKIN GRAFTS, SKIN ULCER ETC. IT CAN BE USED IN ANY OTHER TYPE OF WOUNDS OR ON PATIENTS AFTER SURGERY AS REQUIRED BY SURGEONS,SURGICAL DRESSINGS (SILK BASED) (D-FIBROHEAL SPRINKLING POWDER, D-FIBROHEAL AG SPRINKLING POWDER ,D- FIBROHEAL PARTICLES, D-FIBROHEAL AG PARTICLES)(D- FIBROHEAL)-IT USE IN COVERING OF BOTH INFECTED AND NON-INFECTED WOUNDS SUCH AS BURN, SKIN GRAFTS AND SKIN ULCER ETC, FOR PATIENTS AFTER SURGERY AS REQUIRED BY SURGEONS EVEN IN ANY OTHER TYPE OF WOUNDS, SURGICAL DRESSINGS (SILK BASED) (D-FIBROHEAL SPRINKLING POWDER, D- FIBROHEAL AG SPRINKLING POWDER ,D- FIBROHEAL PARTICLES, D- FIBROHEAL AG PARTICLES)(D- FIBROHEAL)-IT USE IN COVERING OF BOTH INFECTED AND NON-INFECTED WOUNDS SUCH AS BURN, SKIN GRAFTS AND SKIN ULCER ETC, FOR PATIENTS AFTER SURGERY AS REQUIRED BY SURGEONS EVEN IN ANY OTHER TYPE OF WOUNDS,SURGICAL DRESSINGDRESSINGS (SILK BASED) (D-FIBROHEAL, D-FIBROHEAL AG, D-FIBROHEAL MESHED, D-FIBROHEAL AG MESHED D-FIBROHEAL FOAM, D-FIBROHEAL AG FOAM)(D-FIBROHEAL)-IT USE IN COVERING OF BOTH INFECTED AND NON-INFECTED WOUNDS SUCH AS BURN, SKIN GRAFTS AND SKIN ULCER ETC, FOR PATIENTS AFTER SURGERY AS REQUIRED BY SURGEONS.

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3501	MFG/MD/2020/000145	1.License Holder Name: PANCHAL MEDITECH PVT.LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:INTER-LOCKING NAIL (PMPL)-IF THE MEDULLARY CANAL IS DEFORMED (E.G. PRIOR FRACTURE, OR DEVELOPMENTAL ABNORMALITY). SEVERE BACTERIAL CONTAMINATION OR INFECTION. DYNAMICALLY LOCKED AND NO LOCKED MODES OF INTRAMEDULLARY NAILING SHOULD NOT BE USED IN THE STABILIZATION OF SPIRAL AND OBLIQUE FRACTURES OF THE TIBIAL SHAFT.,FEMORAL STEM (STAINLESS STEEL)(PMPL)-XXX,WIRES AND PINS(PMPL)-A WIRE IS PASSED THROUGH THE SKIN THEN TRANSVERSELY THROUGH THE BONE AND OUT THE OTHER SIDE OF THE LIMB. THE WIRE IS THEN ATTACHED TO SOME FORM OF TRACTION SO THAT THE PULL IS APPLIED DIRECTLY TO BONE. IN TRACTION OF THE FEMUR FOR EXAMPLE, THE PROTRUDING ENDS OF THE WIRE ARE FIXED TO THE LEGS OF A HORSESHOE SHAPED FRAME WHICH MAINTAINS TENSION IN THE WIRE WHILE THE CROOK OF THE HORSESHOE IS ATTACHED VIA LINE AND PULLEYS TO WEIGHTS WHICH MAINTAIN THE TRACTION.,BONE PLATES(PMPL)-IT IS USED IN OSTEOPENIC BONE, SHORT BONE FRAGMENTS AND MULTIFRAGMENT FRACTURES. THIS IS IMPLANT OF CHOICE FOR FOREARM FRACTURES AND MAY BE ALSO USED FOR DISTAL HUMERAL FRACTURES AND THE CLAVICLE.,BONE PLATES (PMPL)-IT IS USED IN OSTEOPENIC BONE, SHORT BONE FRAGMENTS AND MULTIFRAGMENT FRACTURES. THIS IS IMPLANT OF CHOICE FOR FOREARM FRACTURES AND MAY BE ALSO USED FOR DISTAL HUMERAL FRACTURES AND THE CLAVICLE.,SPINAL IMPLANT(PMPL)-XX,SPINAL IMPLANT(PMPL)-XXX,BONE SCREW(PMPL)-PARTIALLY THREADED BONE SCREWS ARE OFTEN USED AS LAG SCREWS FOR METAPHYSICAL FRACTURES. IT IS INTENDED FOR USE IN THE DCU PORTION OF THE COMBI HOLES IN THE PLATE SHAFT OR IN ROUND LOCKING HOLES. IT IS MAINLY USED IN TIBIAL CONDYLAR FRACTURE AND SMALL FRAGMENT FIXATION IN CANCELLOUS BONE., ARTHROSCOPY IMPLANTS - SCREW, BUTTON, WASHER(PMPL)-XX, INTER-LOCKING NAIL(PMPL)-IF THE MEDULLARY CANAL IS DEFORMED (E.G. PRIOR FRACTURE, OR DEVELOPMENTAL ABNORMALITY). SEVERE BACTERIAL CONTAMINATION OR INFECTION. DYNAMICALLY LOCKED AND NO LOCKED MODES OF INTRAMEDULLARY NAILING SHOULD NOT BE USED IN THE STABILIZATION OF SPIRAL AND OBLIQUE FRACTURES OF THE TIBIAL SHAFT.,BONE SCREWS(PMPL)-BONE SCREWS ARE INTENDED FOR FIXATION OF FRACTURES, OSTEOTOMIES AND NON-UNIONS OF THE CLAVICLE, SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, TIBIA, CALANEOUS, FEMUR AND FIBULA.,WIRES AND PINS(PMPL)-A

		WIRE IS PASSED THROUGH THE SKIN THEN TRANSVERSELY THROUGH THE BONE AND OUT THE OTHER SIDE OF THE LIMB. THE WIRE IS THEN ATTACHED TO SOME FORM OF TRACTION SO THAT THE PULL IS APPLIED DIRECTLY TO BONE. IN TRACTION OF THE FEMUR FOR EXAMPLE, THE PROTRUDING ENDS OF THE WIRE ARE FIXED TO THE LEGS OF A HORSESHOE SHAPED FRAME WHICH MAINTAINS TENSION IN THE WIRE WHILE THE CROOK OF THE HORSESHOE IS ATTACHED VIA LINE AND PULLEYS TO WEIGHTS WHICH MAINTAIN THE TRACTION.
3502	MFG/MD/2020/000146	1.License Holder Name: DYNAMIC TECHNO MEDICALS PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:SEMIPERMEABLE WATERPROOF PLASTIC WOUND DRESSING WITH SILVER(STERIZONE) -SEMIPERMEABLE WATERPROOF PLASTIC WOUND DRESSING WITH SILVER IS INTENDED TO BE USED AS ANTIMICROBIAL DRESSINGS FOR POST-OPERATIVE WOUNDS, ABRASIONS, LACERATIONS AND MINOR CUTS.
3503	MFG/MD/2020/000147	1.License Holder Name: BIO-MED PVT. LTD. 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM(BM-VTM)-BIO-MED VIRUS TRANSPORT MEDIUM (BM-VTMTM) KIT FOR COLLECTION & TRANSPORT OF CLINICAL SPECIMENS CONTAINING VIRUSES.

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3504	MFG/MD/2020/000149	1.License Holder Name: MEHTA SURGICARE PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ADHESIVE TAPE U.S.P. (MEHTAPLAST)-DRESSING USE,MICROPOROUS SURGICAL TAPE (MEHTAPORE)-DRESSING USE,BELLADONNA ADHESIVE PLASTER (PERFORATED)(MEHTA'S BELLADONNA PLASTER)-DRESSING FOR PAIN RELIEF,MEDICATED PAD(MEDISTRIP)-DRESSING USE,ELASTIC ADHESIVE BANDAGE(MEDIFIX)-DRESSING USE,CAPSICUM PLASTER (PERFORATED)(MEHTA'S CAPSICUM PLASTER)-DRESSING FOR PAIN RELIEF,PLASTER(MONSON'S AMERICAN POROUS PLASTER)-DRESSING FOR PAIN RELIEF,COTTON CREPE BANDAGE (D'PAINCREPE)-DRESSING USE,ADHESIVE PLASTER(RADIPLAST)-DRESSING USE,MEDICATED PAD(MEHTA'S MEDISTRIP)-DRESSING USE,ELASTIC ADHESIVE BANDAGE-DRESSING USE,ADHESIVE TAPE U.S.P.-DRESSING USE,ADHESIVE PLASTER(MEDIFIX)-DRESSING USE, COTTON CREPE BANDAGE(MEHTA'S COTTON CREPE)-DRESSING USE, MEDICATED FIRST AID DRESSING-DRESSING USE,ADHESIVE PLASTER-DRESSING USE
3505	MFG/MD/2020/000150	1.License Holder Name: KRIYA MEDICAL TECHNOLOGIES PVT LTD 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM KIT 2(KRIVIDA SAFE VIRAL TRANSPORT KIT 2)-FOR COLLECTION AND TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING VIRUSES FOR NASOPHARYNGEAL & OROPHARYNGEAL SAMPLING FROM COLLECTION CENTER TO LABORATORY AND MAIN LABORATORY,VIRAL TRANSPORT MEDIUM KIT 1(KRIVIDA SAFE VIRAL TRANSPORT KIT 1)-FOR COLLECTION AND TRANSPORTATION OF CLINICAL SPECIMENS CONTAINING VIRUSES FOR NASAL AND NASOPHARYNGEAL SAMPLING FROM COLLECTION CENTER TO LABORATORY AND MAIN LABORATORY
3506	MFG/MD/2020/000151	1.License Holder Name: SERENE TEXTILES 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:SURGICAL COTTON (MEDICOT)-SURGICAL DRESSING

3507	MFG/MD/2020/000152	1.License Holder Name: PREGNA INTERNATIONAL LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:COPPER T 380 A (T CU 380A)(LANA T T CU 380A, PREGNA T CU 380 A, PREGNA MODEL T CU 380 A, TRUST T CU 380 A, LYDIA T CU 380 A, INTERPHARMA MODEL T CU 380A, INTERPHARMA PREGNA MODEL T CU 380 A, SECURIT T IUD MODEL T CU 380 A, VEVINA T CU 380 A, MYCHOICE IUD MODEL T CU 380 A, ALTHEA T CU 380 A, LONGACT T CU 380 A, PREGNA+ T-KARE MODEL T CU 380 A, PREGNA+ T CU 380 A, ANDALAN T CU 380 A, PREGNA+ MODEL T CU 380 A, OK IUCD T CU 380 A, LYDIA COPPER T CU 380 A, HEER T CU 380 A, HEER T CU 380 A PLUS, PREGNA T-CARE T CU 380 A,FREEDOM 10 COPPER T 380 A, OPSET MODEL T CU 380 A, TRUST COPPER T CU 380 A, LONGACT T CU 380 A, ANDALAN CLASSIC CU 380 DISPOSITIVO INTRAUTERINO, NEW CHOICE MODEL T CU 380 A, NEW CHOICE MODEL T CU 380 A, EASY CARE T CU 380 A, PREGNA EASYCARE CU 380 A, KHUSHI MODEL COPPER T 380 A, ELENORA + T CU 380 A, PROTEC T CU 380 A, LANA T PLUS T CU 380 A)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,CU 380 AG WITH LOADER(SILVERLINE CU 380 AG WITH LOADER)-INTRAUTERINE CONTRACEPTIVE DEVICE, CU 380 AG OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER T 380 A WITH SAFELOAD (T CU 380 A WITH SAFELOAD)(PREGNA MODEL T CU 380 A WITH SAFELOAD, SAFELOAD T CU 380 A, ALTHEA T CU 380 A WITH SAFELOAD, ANDALAN SAFELOAD T CU 380 A, HEER T CU 380 A WITH SAFELOAD, LYDIA T CU 380 A SAFELOAD, PREGNA FEMININ SAFELOAD T CU 380 A, FREEDOM 10 COPPER T 380 A WITH SAFELOAD, TRUST T CU 380 A SAFELOAD, ANDALAN CLASSIC CU 380 DISPOSITIVO INTRAUTERINO SAFELOAD, EASY CARE T CU 380 A, ALZEE SAFELOAD T CU 380 A, PROTECT 10 T CU 380 A WITH SAFELOAD, PREGNA EASYCARE CU 380 A, ELENORA SAFELOAD T CU 380 A, LANA TS T CU 380 A WITH SAFELOAD)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,MINI CU 380 WITH LOADER(COPPER Y MINI CU 380 WITH LOADER)-INTRAUTERINE CONTRACEPTIVE DEVICE, MINI CU 380 OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 250 (CU 250)(PREGNA MODEL CU 250, U-KARE MODEL CU 250, INARA MODEL CU 250, LIBERTA MODEL CU 250, ANDALAN COMFORT CU 250 DISPOSITIVO INTRAUTERINO, LYDIA CU 250, FREEDOM 3 MODEL CU 250, CLARA CU 250)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,CU 375 SLEEK(CU 375 SLEEK WITH DISPOSABLE UTERINE SOUND, INARA CU 375 SLEEK WITH DISPOSABLE UTERINE SOUND)-INTRAUTERINE CONTRACEPTIVE DEVICE, CU 375 SLEEK OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,

	COPPER 380 (CU 380)(COPPER Y CU 380, LYDIA COPPER Y 380 IUD, HEER COPPER Y CU 380, EASY CARE CU 380, TRUST COPPER Y CU 380)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER T 380 A (T CU 380A)(ETHERENA T CU 380A IUD KIT (ETHERENA T CU 380A IUD, STERILE HAND GLOVES, PREGNANCY TEST STRIP, DISPOSABLE UTERINE SOUND, VAGINAL SPECULUM, UNDER PAD, COTTON SWAB))-ETHERENA T CU 380A IUD OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 375 SLEEK (POSTPARTUM)(PREGNA CU 375 SLEEK WITH LONG INSERTER, INARA CU 375 SLEEK WITH LONG INSERTER, PREGNA POSTPARTUM IUD CU 375 SLEEK)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,CU 200 AG(SILVERLINE CU 200 AG WITH DISPOSABLE UTERINE SOUND)-INTRAUTERINE CONTRACEPTIVE DEVICE, CU 200 AG OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,CU 380 AG(SILVERLINE CU 380 AG WITH DISPOSABLE UTERINE SOUND)-IT OFFERS COMPLETE PROTECTION AGAINST PREGNANCY.,CU 380 WITH CROSSGLIDE INSERTER(YANAE CU 380 WITH CROSSGLIDE INSERTER)-INTRAUTERINE CONTRACEPTIVE DEVICE, CU 380 OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,TUBAL RING(TUBAL RING)-IT IS USED FOR FEMALE STERILIZATION.,CU 250(CU 250 WITH DISPOSABLE UTERINE SOUND, INARA CU 250 WITH DISPOSABLE UTERINE SOUND)-INTRAUTERINE CONTRACEPTIVE DEVICE, CU 250 OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,T CU 380 A (COPPER T 380 A)(ETHERENA T CU 380 A WITH DISPOSABLE UTERINE SOUND, ANDALAN CLASSIC FASTLOAD CU 380 DISPOSITIVO INTRAUTERINO)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,CU 250 SLEEK(CU 250 SLEEK WITH DISPOSABLE UTERINE SOUND, INARA CU 250 SLEEK WITH DISPOSABLE UTERINE SOUND)-INTRAUTERINE CONTRACEPTIVE DEVICE, CU 250 SLEEK OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,CU 250 SLEEK(PREGNA MODEL CU 250 SLEEK, U-KARE SLEEK CU 250, LYDIA CU 250 SLEEK, INARA MODEL CU 250 SLEEK)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 250 (CU 250) (INARA CU 250 IUD KIT (INARA CU 250 IUD, STERILE HAND GLOVES, PREGNANCY TEST STRIP, DISPOSABLE UTERINE SOUND, VAGINAL SPECULUM, UNDER PAD, COTTON SWAB))-CU 250 IUD OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,T CU 380 A (COPPER T 380 A) (ETHERENA T CU 380 A)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,MINI CU 380 AG WITH LOADER(SILVERLINE MINI CU 380 AG WITH LOADER)-INTRAUTERINE CONTRACEPTIVE DEVICE, MINI CU 380 AG OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER T 380 A (POSTPARTUM)(POSTPRTUM

	IUD CU T 380 A, ANDALAN POST-PARTUS T CU 380 A, LYDIA POSTPARTUM COPPER T 380 A, POSTPARTUM IUD T CU 380 A, ALEZE POST-PARTUM IUD T CU 380 A, PREGNA PP IUD T CU 380 A, FREEDOM 10 POSTPARTUM IUD COPPER T 380 A, ANDALAN CLASSIC POS-PARTO CU 380 DISPOSITIVO INTRAUTERINO, ANDALAN POSTPARTUM T CU 380 A)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 250 SLEEK (CU 250 SLEEK)(INARA CU 250 SLEEK IUD KIT (INARA CU 250 SLEEK IUD, STERILE HAND GLOVES, PREGNANCY TEST STRIP, DISPOSABLE UTERINE SOUND, VAGINAL SPECULUM, UNDER PAD, COTTON SWAB))-CU 250 SLEEK IUD OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,MINI CU 380 AG(SILVERLINE MINI CU 380 AG, ANDALAN SILVERFLEX MINI CU 380 AG, SILVERCARE MINI CU 380 AG)-INTRAUTERINE CONTRACEPTIVE DEVICE,CU 380 WITH LOADER (COPPER Y CU 380 WITH LOADER)-INTRAUTERINE CONTRACEPTIVE DEVICE, CU 380 OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 375 (CU 375)(PREGNA MODEL CU 375, U-KARE MODEL CU 375, INARA MODEL CU 375, ALTHEA CU 375, OK CU 375, LIBERTA MODEL CU 375, B-SURE MULTICHOICE MODEL CU 375, OPSET MODEL CU 375, INARA ESTANDAR CU 375, KHUSHI MODEL CU 375, PROTECT 5 CU 375, ANDALAN COMFORT CU 375 DISPOSITIVO INTRAUTERINO, U-CARE CU 375, CU 375, PREGNA CU 375, U-CARE ESTANDAR CU 375, FREEDOM 5 MODEL CU 375, CUPRALUNA OMEGA CU 375, ELENORA CU 375, LANA U CU 375)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 375 (CU 375)(INARA CU 375 IUD KIT (INARA CU 375 IUD, STERILE HAND GLOVES, PREGNANCY TEST STRIP, DISPOSABLE UTERINE SOUND, VAGINAL SPECULUM, UNDER PAD, COTTON SWAB))-CU 375 IUD OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY., COPPER 200 AG (CU 200 AG)(PREGNA CU 200 AG, SILVERLINE CU 200 AG, ANDALAN SILVERLINE CU 200 AG, SILVERLINE 200, HEER CU 200 AG, ANDALAN SILVERFLEX CU 200 AG DISPOSITIVO INTRAUTERINO, PREGNA MODEL CU 250)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 375 SLEEK (CU 375 SLEEK)(INARA CU 375 SLEEK IUD KIT (INARA CU 375 SLEEK IUD, STERILE HAND GLOVES, PREGNANCY TEST STRIP, DISPOSABLE UTERINE SOUND, VAGINAL SPECULUM, UNDER PAD, COTTON SWAB))-CU 375 SLEEK OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 380 AG (CU 380 AG)(PREGNA CU 380 AG, SILVERLINE CU 380 AG, ANDALAN SILVERLINE CU 380 AG, SILVERLINE 380, FEMININ SILVER CU 380 AG, SILVERCARE CU 380 AG, TRUST PLUS SILVERLINE CU 380 AG, OPSET CU 380 AG, ANDALAN SILVERFLEX CU 380 AG DISPOSITIVO INTRAUTERINO, CUPRALUNA SILVER CU 380 AG, ELENORA SILVERLINE CU 380 AG,

		PREGNA MODEL CU 380 AG, LANA V CU 380 AG AND STERLING CU 380 AG)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,MINI CU 380 WITH CROSSGLIDE INSERTER(YANAE MINI CU 380 WITH CROSSGLIDE INSERTER)-INTRAUTERINE CONTRACEPTIVE DEVICE, MINI CU 380 OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 375 (POSTPARTUM) (PREGNA CU 375 WITH LONG INSERTER, INARA CU 375 WITH LONG INSERTER, POSPARTUM IUD CU 375, FREEDOM 5 POSTPARTUM CU 375, PREGNA PP IUD CU 375)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,CU 375(CU 375 WITH DISPOSABLE UTERINE SOUND, INARA CU 375 WITH DISPOSABLE UTERINE SOUND)-INTRAUTERINE CONTRACEPTIVE DEVICE, CU 375 OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY., COPPER 380 MINI (CU 380 MINI)(COPPER Y MINI CU 380)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER T 380 A (T CU 380A)(IUD KIT (COTTON GUAGE, STERILE HAND GLOVES, PREGNANCY TEST STRIP, DISPOSABLE UTERINE SOUND, VAGINAL SPECULUM))-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 375 SLEEK (CU 375 SLEEK)(PREGNA MODEL CU 375 SLEEK, INARA MODEL CU 375 SLEEK, ANDALAN CU 375 SLEEK, U-KARE SLEEK MODEL CU 375 SLEEK, HEER CU 375 SLEEK, LYDIA CU 375 SLEEK, SAKHI MODEL CU 375 SLEEK, TRUST CU 375 SLEEK, INARA CORTO CU 375, ANDALAN CONFORT MINI CU 375 DISPOSITIVO INTRAUTERINO, U-CARE CORTO CU 375, CU 375 SLEEK, FREEDOM 5 SLEEK MODEL CU 375, ELENORA CU 375 SLEEK, LANA M MINI CU 375) -IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.
3508	MFG/MD/2020/000153	1.License Holder Name: M/S SRI LEKHA INDUSTRIES 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:BANDAGE CLOTH-BANDAGES ARE USED EXTENSIVELY IN HEALTH CARE INSTITUTIONS AND HOME . THE USES OF BANDAGES RANGE FROM SIMPLE DRESSING OF SUPERFICIAL WOUNDS TO HOLDING TOGETHER FRACTURED BONES OR BODY PARTS FOR REHABILITATION AND RECOVERY.,ABSORBENT GAUZE CLOTH -GAUZE CAN BE USED FOR CLEANSING, PACKING, SCRUBBING, COVERING, AND SECURING IN A VARIETY OF WOUNDS. CLOSELY WOVEN GAUZE IS BEST FOR EXTRA STRENGTH OR GREATER PROTECTION, WHILE OPEN OR LOOSE WEAVE IS BETTER FOR ABSORBENCY OR DRAINAGE.

3509	MFG/MD/2020/000154	1.License Holder Name: M/S KRISHNA SAI SURGICAL BANDAGE 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:ABSORBENT GAUZE CLOTH -GAUZE CAN BE USED FOR CLEANSING, PACKING, SCRUBBING, COVERING, AND SECURING IN A VARIETY OF WOUNDS. CLOSELY WOVEN GAUZE IS BEST FOR EXTRA STRENGTH OR GREATER PROTECTION, WHILE OPEN OR LOOSE WEAVE IS BETTER FOR ABSORBENCY OR DRAINAGE. ,ROLLED BANDAGE-BANDAGES ARE USED EXTENSIVELY IN HEALTH CARE INSTITUTIONS AND HOME . THE USES OF BANDAGES RANGE FROM SIMPLE DRESSING OF SUPERFICIAL WOUNDS TO HOLDING TOGETHER FRACTURED BONES OR BODY PARTS FOR REHABILITATION AND RECOVERY.,BANDAGE CLOTH-BANDAGES ARE USED EXTENSIVELY IN HEALTH CARE INSTITUTIONS AND HOME . THE USES OF BANDAGES RANGE FROM SIMPLE DRESSING OF SUPERFICIAL WOUNDS TO HOLDING TOGETHER FRACTURED BONES OR BODY PARTS FOR REHABILITATION AND RECOVERY.
3510	MFG/MD/2020/000155	1.License Holder Name: M/S. SRI LAXMI INDUSTRY 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:BANDAGE CLOTH-BANDAGES ARE USED EXTENSIVELY IN HEALTH CARE INSTITUTIONS AND HOME . THE USES OF BANDAGES RANGE FROM SIMPLE DRESSING OF SUPERFICIAL WOUNDS TO HOLDING TOGETHER FRACTURED BONES OR BODY PARTS FOR REHABILITATION AND RECOVERY.,ABSORBENT COTTON GAUZE-GAUZE CAN BE USED FOR CLEANSING, PACKING, SCRUBBING, COVERING, AND SECURING IN A VARIETY OF WOUNDS. CLOSELY WOVEN GAUZE IS BEST FOR EXTRA STRENGTH OR GREATER PROTECTION, WHILE OPEN OR LOOSE WEAVE IS BETTER FOR ABSORBENCY OR DRAINAGE.

3511	MFG/MD/2020/000156	1.License Holder Name: A V PROCESSORS PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NON ABSORBABLE SURGICAL SUTURE U.S.P.(ETHICON*)-ETHICON* SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROSURGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P.(MERSILK*)-MERSILK* SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROSURGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P. (ETHICON*)-ETHICON* IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROSURGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P. (ETHICON*)-ETHICON* SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPTHALMIC AND NEUROSURGICAL PROCEDURES,NON ABSORBABLE SURGICAL SUTURE U.S.P. (ETHILON*)-ETHILON SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPTHALMIC AND NEUROSURGICAL PROCEDURES

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3512	MFG/MD/2020/000157	1.License Holder Name: R K SURGICALS 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:ROLLED BANDAGE-GAUZE ROLLED BANDAGES ARE VERY COMMON AND VERY VERSATILE THIN WOVEN AND BREATHABLE FABRIC BANDAGES THAN CAN BE USED TO SECURE A DRESSING IN PLACE , OR MAY BE PLACED DIRECTLY OVER A WOUND TO KEEP IT CLEAN WHILE ALLOWING AIR TO PENETRATE TO IMPROVE HEALING PROCESS., ABSORBENT COTTON WOOL-COTTON WOOL ARE MAINLY USED FOR MEDICAL PURPOSE IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME FOR FIRST AID ETC… APART FROM MEDICAL PURPOSES ABSORBENT COTTON IS ALSO USED FOR MAKING CONVENTIONAL TYPE OF SANITARY NAPKINS OR PADS.,CREPE BANDAGE-THE MEDIUM WEIGH CREPE BANDAGE IS SUITABLE FOR USE AS DRESSING RETENTION. THE HEAVY WEIGHT CREPE BANDAGE IS SUITABLE FOR USE A SUPPORT FOR SPRAINS AND STRAINS IN JOINT AND MUSCLES. IT ALSO WORKS AS A MODERATE COMPRESSION BANDAGE FOR KNEE SWELLING ANKLE SWELLING AND OTHER RELEVANT INJURIES

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3513	MFG/MD/2020/000158	1.License Holder Name: HINDUSTAN SYRINGES & MEDICAL DEVICES LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:SCALP VEIN SET(SCALP VAN, UNOLOK, UNOLOK+, VAKU 8, VAKU 8 +)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD,SCALP VEIN SET(SCALP VAN, UNOLOK AND UNOLOK+)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY,BLOOD COLLECTION TUBE(VAKU-8)-SINGLE USE BLOOD COLLECTION TUBES TO BE USED WITH BLOOD COLLECTION NEEDLE FOR SPECIMEN BLOOD COLLECTION.,3 WAY STOP COCK, LIPID RESISTANT, AS AN ACCESSORY TO PERFUSION SETS (DISPOWAY)-IT IS TO BE USED FOR INTRAVENOUS BLOOD TRANSFUSION OR THE TRANSFUSION OF BLOOD DERIVATIVES AND INFUSION OF NUTRITIVE OR MEDICINAL FLUIDS. IT CAN ALSO BE USED FOR INFUSION OF MORE THAN ONE FLUID AT A SINGLE TIME.,3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS (DISPOWAY)-IT IS TO BE USED FOR INTRAVENOUS BLOOD TRANSFUSION OR THE TRANSFUSION OF BLOOD DERIVATIVES AND INFUSION OF NUTRITIVE OR MEDICINAL FLUIDS. IT CAN ALSO BE USED FOR INFUSION OF MORE THAN ONE FLUID AT A SINGLE TIME.
3514	MFG/MD/2020/000159	1.License Holder Name: MICROTROL STERILIZATION SERVICES PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:STERILE OXIDISED REGENERATED CELLULOSE USP ABSORBABLE HEMOSTAT(TRUSTAT, PURIFIED RAYON IP, CLINICEL)-ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE) IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS, AND SMALL ARTERIAL HEMORRHAGE WHEN LIGATION OR OTHER CONVENTIONAL METHODS OF CONTROL ARE IMPRACTICAL OR INEFFECTIVE.,STERILE BONEWAX(TRUWAX)-STERILE BONEWAX MAY BE USED FOR THE CONTROL OF BLEEDING FROM BONE SURFACES.

3515	MFG/MD/2020/000160	1.License Holder Name: MICROMEC SURGICALS CORPORATION 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:OPHTHALMIC CYSTOTOME CANNULA(-)-CYSTOTOME CANNULA IS INTENDED TO PUNCTURE THE ANTERIOR CAPSULE, AND AN INITIAL CUT IN THE ANTERIOR CAPSULE. IT GIVES EASIER ACCESS TO ALL AREAS OF THE ANTERIOR CAPSULE & REDUCES THE CHANCE OF TOUCHING CORNEAL ENDOTHELIUM.,OPHTHALMIC CYSTOTOME CANNULA (IV CANNULA)(-)-CYSTOTOME CANNULA IS INTENDED TO PUNCTURE THE ANTERIOR CAPSULAR, AND AN INITIAL CUT IN THE ANTERIOR CAPSULE OF EYE. IT GIVES EASIER ACCESS TO ALL AREAS OF THE ANTERIOR CAPSULE AND REDUCES THE CHANCE OF TOUCHING CORNEAL ENDOTHELIUM.
3516	MFG/MD/2020/000161	1.License Holder Name: ECON LIFE SCIENCE PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655(ECON LIFE /LIFE/FLOW/UMAFLO/IVILIS-NEO/IM-LIFE/IVILIS BETA)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN

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3517	MFG/MD/2020/000162	1.License Holder Name: AGROSURG IRRADIATORS (INDIA) PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:BONEWAX (FOR GAMMA STERILIZATION)(MERIL-BONEWAX™)-MERIL - BONEWAX™ IS INTENDED TO AID IN THE CONTROL OF BLEEDING IN BONE INJURIES., ABSORBABLE POLYGLYCOLIC ACID SURGICAL SUTURE U.S.P. (FOR GAMMA STERILIZATION)(MEGASORB RAPID™ / ASPIRON POLYGLYCOLIC ACID RAPID / REDISORB - FAST™/REDISORB® - FAST PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,NON-ABSORBABLE POLYAMIDE SURGICAL SUTURE U.S.P (FOR GAMMA STERILIZATION)(FILAMIDE™ / ASPIRON POLYAMIDE BLACK/ REDILON™/ FILAMIDE™ – B / FILAMIDE™ REEL /FILAMIDE™ CAS/REDILON® PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,LIGATING CLIP (FOR GAMMA STERILIZATION)(MIRUS™)-LIGATING CLIP IS INTENDED TO SECURELY GRIP THE VESSEL OR TISSUE TO PROVIDE COMPLETE OCCLUSION ATRAUMATICALLY., NON-ABSORBABLE STERILISED HYDROPHILIC 3-DIMENSIONAL MESH (FOR GAMMA STERILIZATION)(MERICRON 3D™ MESH)-INTENDED FOR USE IN HERNIA REPAIR, ABDOMINAL WALL REPAIR AND OTHER FASCIAL SURGICAL INTERVENTION PROCEDURES.,CU 375 SLEEK STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICES (FOR GAMMA STERILIZATION)(MERITE™ CU 375 SLEEK)-INDICATED FOR INTRAUTERINE CONTRACEPTION,CU T 380 A STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICES (FOR GAMMA STERILIZATION)(MERITE™ CU T 380 A /KHUSHI™ CU T 380 A / PRIMA™ CU T 380A / ENOVA™ CU T 380A / TIUP™ CU T 380A/FREEDOM10 CU T 380 A)-INDICATED FOR INTRAUTERINE CONTRACEPTION.,NON-ABSORBABLE POLY(ETHYLENE TEREPHTHALATE) SURGICAL SUTURE U.S.P. (FOR GAMMA STERILIZATION)(MERICRON XL™ / ASPIRON POLYESTER / REDIBOND™/MERICRON XL™ REEL/ MERICRON XL™ CAS/REDIBOND® PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION., ABSORBABLE STERILIZED SURGICAL CATGUT CHROMIC SUTURE U.S. P. (PRE-KNOTTED LOOP LIGATURE FOR ENDO SURGERY) (FOR GAMMA STERILIZATION)(FILATWINE)-FILATWINE SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,NATURAL NON-ABSORBABLE SILK SURGICAL SUTURE U.S.P. (FOR GAMMA STERILIZATION)(FILASILK™ / ASPIRON SILK BLACK/ REDISILK™ / FILASILK™ CAS/REDISILK® PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,SURGICAL ADHESIVE (FOR GAMMA

	STERILIZATION)(BIOAID™)-INTENDED FOR CLOSURE OF SURGICAL INCISIONS,CU 250 STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICE (FOR GAMMA STERILIZATION)(MERITE™ CU 250)-INDICATED FOR INTRAUTERINE CONTRACEPTION,ABSORBABLE POLY (GLYCOLIDE/L-LACTIDE) SURGICAL SUTURE U.S.P. (FOR GAMMA STERILIZATION)(MITSU FST™ / MABEL FST™ / ASPIRON POLYGLACTIN 910 FST/ REDICRYL - FAST™/REDICRYL® - FAST PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,ABSORBABLE STERILIZED SURGICAL CATGUT PLAIN SUTURE U.S.P (FOR GAMMA STERILIZATION)(MERISOFT PLAIN™ / ASPIRON CATGUT PLAIN / REDIGUT PLAIN™ / MERISOFT PLAIN™ REEL / MERISOFT PLAIN™ CAS/REDIGUT® PLAIN PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, ABSORBABLE HEMOSTAT (OXIDIZED REGENERATED CELLULOSE U.S. P.) (FOR GAMMA STERILIZATION)(MERIZELLE™ STANDARD/MERIZELLE™ FIBER/MERIZELLE™ WOVEN)-AN ABSORBABLE HEMOSTATIC AGENT OR DRESSING IS A DEVICE INTENDED TO PRODUCE HAEMOSTATIS BY ACCELERATING THE CLOTTING PROCESS OF BLOOD.,CU 375 STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICE (FOR GAMMA STERILIZATION)(MERITE™ CU 375 / KHUSHI™ CU 375 / INTIMA™ CU 375 / TIUP™ A CU 375 / FREEDOM5™ CU 375/ PRIMA™ CU 375)-INDICATED FOR INTRAUTERINE CONTRACEPTION.,DUAL SIDE MESH FOR INTRA-PERITONIAL PLACEMENT (FOR GAMMA STERILIZATION)(CONTACTO™ MESH)-INTENDED FOR USE IN HERNIA REPAIR, ABDOMINAL WALL REPAIR AND OTHER FASCIAL SURGICAL INTERVENTION PROCEDURES,CU 250 SLEEK STERILIZED INTRAUTERINE CONTRACEPTIVE DEVICES (FOR GAMMA STERILIZATION)(MERITE™ CU 250 SLEEK / U-KARE® CU 250 SLEEK)-INDICATED FOR INTRAUTERINE CONTRACEPTION,NON ABSORBABLE STAINLESS STEEL SURGICAL SUTURE U.S.P (FOR GAMMA STERILIZATION) (MERISTEEL™ / ASPIRON STAINLESS STEEL)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,ABSORBABLE STERILIZED SURGICAL CATGUT CHROMIC SUTURE U.S.P (FOR GAMMA STERILIZATION)(MERISOFT CHROMIC™ / ASPIRON CATGUT CHROMIC / REDIGUT CHROMIC™ / MERISOFT CHROMIC™ REEL / MERISOFT CHROMIC™ CAS/REDIGUT® CHROMIC PRO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,PARTIALLY ABSORBABLE SURGICAL TISSUE SEPARATING DUAL LAYER MESH (FOR GAMMA STERILIZATION)(MERINEUM™ MESH)-INTENDED FOR USE IN HERNIA REPAIR, ABDOMINAL WALL REPAIR AND OTHER FASCIAL SURGICAL INTERVENTION PROCEDURES

3518	MFG/MD/2020/000163	1.License Holder Name: CAREGROUP SIGHT SOLUTION PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:SINGLE PIECE PMMA INTRAOCULAR LENS (STERILE)-THE DEVICE IS INTENDED TO USE FOR REPLACEMENT OF CATARACTOUS LENS FOR VISUAL CORRECTION OF APHAKIA IN CATARACT PATIENT,FOLDABLE HYDROPHILIC ACRYLIC INTRAOCULAR LENS (STERILE)-THE DEVICE IS INTENDED TO USE AS AN IMPLANT FOR REPLACEMENT OF CATARACT LENS FOR VISUAL CORRECTION OF APHAKIA IN CATARACT PATIENT.,FOLDABLE HYDROPHOBIC INTRAOCULAR LENS (STERILE)-THE DEVICE IS INTENDED TO USE FOR REPLACEMENT OF CATARACTOUS LENS FOR VISUAL CORRECTION OF APHAKIA IN CATARACT PATIENT,FOLDABLE HYDROPHILIC ACRYLIC INTRAOCULAR LENS (STERILE)-THE DEVICE IS INTENDED TO USE FOR REFRACTIVE CORRECTION IN PHAKIC PATIENTS FOR THE TREATMENT OF MYOPIA OR HYPEROPIA WITH PRESBYOPIA AND ASTIGMATISM.,SINGLE PIECE PMMA INTRAOCULAR LENS (STERILE)-PHAKIC IOL IS INTEDED TO USE FOR SURGICAL CORRECTION OF REFRACTIVE ERROR IN PHAKIC EYE.

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3519	MFG/MD/2020/000164	1.License Holder Name: DOSTAN SURGICAL ENGG. WORKS 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE NAIL (SS 316 L)-BONE NAILS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PLATES (SS 316 L)-BONE PLATE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PIN AND WIRE (SS 316 L)-BONE WIRE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE SCREWS (SS 316 L)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE SCREWS (TITANIUM)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PLATES (TITANIUM)( )-BONE PLATE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE,BONE NAIL (TITANIUM)( )-BONE NAILS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE,BONE PIN AND WIRE (TITANIUM)( )-BONE PIN AND WIRE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.

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3520	MFG/MD/2020/000165	1.License Holder Name: CARDIOMAC INDIA PRIVATE LIMITED 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:PTCA BALLOON CATHETER (SEMI COMPLAINT AND NON COMPLAINT)(SPALNO)-INTENDED FOR USE IN PERCUTANEOUS TRANS- LUMINAL ANGIOPLASTY OF RENAL, TIBIAL, POPLITEAL, FEMORAL AND PERONEAL ARTERIES .,PRESSURE MONITORING LINE(PROCONNEKT)-PRESSURE MONITORING LINE IS SMALL BORE HIGH PRESSURE EXTENSION LINE SUITABLE FOR ANGIOGRAPHY ,C.V.P MEASUREMENT, SUITABLE FOR HIGH PRESSURE MONITORING AND CONNECTION BETWEEN SYRINGE INFUSION PUMP AND PATIENT., PTCA Y-CONNECTOR KIT(PROCONNEKT)-IT CAN BE USED TO CONNECT TO PERFUSION SET OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC,HYPODERMIC NEEDLE(SYFTER)-A HYPODERMIC NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS IN TO OR WITHDRAW FLUIDS FROM PART OF BODY BELOW THE SURFACE OF SKIN .,GUIDING CATHETER(PROCTRA)-THE GUIDE CATHETER PROVIDES SUPPORT FOR DEVICE ADVANCEMENT., DIALYZER / HEMOFILTER(AVRO)-THE DIALYZER IS DESIGNED AS A FILTER MEMBRANE FOR SINGLE USE IN CHRONIC HEMODIALYSIS. COMMONLY USED IN ACUTE OR CHRONIC RENAL FAILURE FOR REMOVAL OF DRUGS OR OTHER TOXIC SUBSTANCES ACCUMULATED OF THE BODY.,ANGIOGRAPHIC / DIAGNOSTIC CATHETER(PROCTRA)-IT IS DESIGNED TO PROVIDE A PATHWAY FOR DELIVERING CONTRAST MEDIA TO SELECTED SITES IN THE VASCULAR SYSTEM INCLUDING THE CAROTID ARTERIES.,FISTULA NEEDLE(SYFTER)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT .,INFLATION DEVICE (PROCTUS)-INFLATION DEVICE USE AS AN ACCESSORY OF BALLOON DIALATION CATHETER DURING INTERVENTIONAL PROCEDURES. THE INFLATION DEVICE IS DESIGNED TO BE USED TO INFLATE/DEFLATE BALLOON CATHETERS AS WELL AS TO MONITOR PRESSURE WITHIN THE BALLOON.,LIGATION DEVICE(PROCONNEKT)-IT IS USED FOR PROXIMAL AND DISTAL LIGATION OF VESSEL DURING ENDOSCOPIC VESSEL HARVESTING PROCEDURES.TISSUE CLAMP IS SUITABLE FOR THE SIZE OF BLOOD VESSELS AND TISSUE STRUCTURE. ,BIOPSY NEEDLES KIT(SYFTER)- A SET OF NEUROSURGICAL INSTRUMENTS DESIGNED TO ALLOW MULTIPLE BIOPSIES FROM ONE OR MORE TARGETS IN ONE TRAJECTORY. ,HEMODIALYSIS CATHETER(AVRO)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT.,HEMODIALYSIS BLOOD TUBING SET(AVRO)-THE BLOOD TUBING SETS ARE DISPOSABLE BLOODLINES, INTENDED TO TRANSFER BLOOD FROM PATIENTS' VASCULAR SYSTEM TO THE HEMODIALYZER THROUGH AN ARTERIAL

	TUBING, AND FROM THE HEMODIALYZER TO THE PATIENT VASCULAR SYSTEM VIA VENOUS TUBING. IT IS FOR SINGLE USE ONLY.,SURGICAL STAPLES(SYFTER)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY. ,3-WAY STOP COCK WITH EXTENSION LINE / EXTENSION SET(PROCTUS)-IT IS INTENDED TO BE USED AS A PART OF SYSTEM FOR INFUSION OF FLUID/MEDICATION IN THE VASCULAR SYSTEM. IT IS USED AS AN ACCESSORY OF DISPOSABLE PERFUSION SET.,ASPIRATION CATHETER(PROCTUS)-USED FOR INSTILLING FLUIDS INTO, WITHDRAWING FLUIDS FROM, SPLINTING, OR SUPPRESSING BLEEDING OF THE ALIMENTARY TRACT.,ANGIO KIT/PTCA KIT (PROCONNEKT)-ANGIO KIT ACCESSORIES USED DURING THE ANGIOGRAPHIC/PTCA PROCEDURES TO DIAGNOSTIC/TREAT CARDIAC BLOCKAGES. INTRODUCER NEEDLE USED TO GAIN VASCULAR ACCESS FOR THE PLACEMENT OF GUIDE WIRE .GUIDE WIRE USED TO INSERT GUIDING CATHETER . ,MANIFOLD (PROCONNEKT)-IT IS INTENDED FOR PROVIDING MULTIPLE PORTS FOR ADMINISTRATION OF SOLUTION WITH DIRECTIONAL CONTROL., HEART LUNG PACK (HEART LUNG BYPASS UNIT TUBE)(PROCTRA)-A TUBE INTENDED TO DRAIN BLOOD FROM HEART TO THE MACHINE DURING CARDIAC SURGERY.

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3521	MFG/MD/2020/000166	1.License Holder Name: SHRIRAM INSTITUTE OF INDUSTRIAL RESEARCH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:NON ABSORBABLE SURGICAL SUTURE U.S.P.(ETHICON*)-ETHICON* IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROSURGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P.(ETHICON*)-:ETHICON* SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROSURGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P.(MERSILK*)-MERSILK* SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROSURGICAL PROCEDURES,NON ABSORBABLE SURGICAL SUTURE U.S.P.(ETHILON*)-ETHILON* SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPTHALMIC AND NEUROSURGICAL PROCEDURES,NON ABSORBABLE SURGICAL SUTURE U.S.P.(ETHICON*)-ETHICON* SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPTHALMIC AND NEUROSURGICAL PROCEDURES.

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3522	MFG/MD/2020/000167	1.License Holder Name: DATT MEDIPRODUCTS PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:HAEMOSTATIC SPONGE (VELSEAL, VELSEAL - C)-USE AS A TOPICAL DRESSING FOR EMERGENCY USE IN CASE OF SEVERE BLEEDING WOUNDS SUCH ACCIDENTS, TRAUMA CASES, DEEP ARTERIAL WOUND, VENOUS PUNCTURES. FOR EXTERNAL USE ONLY.,WOUND DRESSING (ANTI-MICROBIAL)(SILVEL)-NANOCRYSTALLINE SILVER COATED ANTIMICROBIAL BARRIER DRESSING INTENDED FOR- PARTIAL-THICKNESS BURNS, PRESSURE ULCERS, DIABETIC FOOT ULCERS, SURGICAL WOUNDS, VENOUS LEG ULCERS.,HAEMOSTATIC SPONGE (VELSEAL-T)-USE AS A TOPICAL DRESSING FOR EMERGENCY USE IN CASE OF SEVERE BLEEDING WOUNDS SUCH ACCIDENTS, TRAUMA CASES, DEEP ARTERIAL WOUND, VENOUS PUNCTURES, POST ANGIOGRAPHY/ANGIOPLASTY AND PATIENTS WITH HAEMOPHILIA. FOR EXTERNAL USE ONLY.,HAEMOSTATIC SPONGE(VELNEZ)-THE FRAGMENTABLE VELNEZ IS INTENDED TO BE USED IN THE NASAL/SINUS CAVITY OF SURGERY OR TRAUMA PATIENTS. IT ACTS AS A SPACE OCCUPYING DRESSING, PREVENTS ADHESION BY SEPARATING THE COMPROMISED MUCOSAL SURFACES. AND ALSO HELPS IN HEALING AND ACHIEVING HAEMOSTASIS. LIKEWISE, CAN BE USED IN EAR CAVITY FOR SIMILAR PURPOSE.

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3523	MFG/MD/2020/000168	1.License Holder Name: MITRA INDUSTRIES PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:COLONOSCOPE DISTAL ATTACHMENT(ENDOPASS)-INTENDED USE OF COLONOSCOPE DISTAL ATTACHMENT IS IN COLONOSCOPIES, WHICH WHEN FIXED ON THE DISTAL END OF COLONOSCOPE DURING THE PROCEDURE WILL RADIALLY AND LONGITUDINALLY OPEN THE FOLDS OF THE COLON TO PROVIDE BETTER VISIBILITY SO THAT THE ADENOMAS AND POLYPS CAN BE IDENTIFIED , THEREBY MINIMIZING THE MISSING RATE OF ADENOMAS AND POLYPS DURING COLONOSCOPY,GAUZE-THE GAUZE IS USED AS A DRESSING PAD FOR COVERING OF PERITONEAL CATHETER EXIT SITE (THE PLACE FROM WHERE THE PERITONEAL DIALYSIS CATHETER COMES OUT OF SKIN) WHICH IS ALREADY HEALED.,TRANSBRONCHIAL NEEDLE ASPIRATION (TBNA) (ENDOSHOT)-TRANS BRONCHIAL NEEDLE ASPIRATION (TBNA) IS USED FOR DIAGNOSIS AND STAGING OF BRONCHIAL DISEASES INCLUDING MEDIASTINAL OF PERIPHERAL OF PERIPHERAL PATHOLOGIES, SUBCARINAL AND PARABRONCHIAL NODES AND PARENCHYMA ABNORMALITIES,START UP KIT(MITRA)-START UP KIT CONTAINING STERILE GAUZE AND OTHER NON-DRUGS ITEMS (FACE MASK, COTTON BELT TO HOLD TRANSFER SET, COTTON TOWEL, PLASTIC TRAYS & JAR) IS USED DURING THE PERITONEAL DIALYSIS THERAPY/EXCHANGES BY KIDNEY FAILURE PATIENTS,INJECTOR NEEDLE(ENDOINJECT)-THE INJECTION NEEDLE IS DESIGNED TO BE USED IN ENDOSCOPY FOR THE INJECTION OF LIQUID MEDIA. IT IS USED FOR SALINE ASSISTED POLYPECTOMY, TO ESOPHAGEAL VARICES, ULCERS AND TATTOORING,EMPTY STERILE EFFLUENT TRANSFER BAGS WITH OR WITHOUT CONNECTING TUBE AND COUPLER/CONNECTOR.(MITRA)-EMPTY STERILE EFFLUENT TRANSFER BAGS WITH OR WITHOUT CONNECTING TUBE AND COUPLER/CONNECTOR IS USED FOR DRAINAGE OF CONSUMED CAPD SOLUTION AFTER COMPLETION OF DWELL PERIOD IN PERITONEAL DIALYSIS THERAPY.,TRANSFER SET CHANGE KIT(MITRA)-TRANSFER SET CHANGE KIT CONTAINING STERILE GAUZE AND OTHER NON-DRUGS ITEMS (FACE MASK, PLASTIC GALLIPOT TRAYS, PLASTIC FORCEPS, PAPER TOWEL AND PLASTIC DRAPES) IS USED FOR REPLACEMENT OF TRANSFER SET IN PERITONEAL DIALYSIS THERAPY.,CAPD DRESSING PACK(MITRA)-CAPD DRESSING PACK CONTAINING STERILE GAUZE AND OTHER NON DRUGS ITEM (PLASTIC GALLIPOT TRAY, EAR BUD, PAPER TOWEL AND PLASTIC SHEET / DRAPE) IS USED FOR ROUTINE DRESSING OF EXIT SITE OF PERITONEAL DIALYSIS CATHETER IN PERITONEAL DIALYSIS THERAPY.,TITANIUM ADAPTER(MITRA)-TITANIUM ADAPTER IS INTENDED TO SECURE EXIT SITE END OF THE PERITONEAL DIALYSIS

	CATHETER TO THE TRANSFER SET USED DURING PERITONEAL DIALYSIS THERAPY.,CAPD DRESSING KIT(MITRA)-CAPD DRESSING KIT CONTAINING STERILE GAUZE AND OTHER NON-DRUGS ITEMS (PLASTIC GALLIPOT TRAY, EAR BUD, PAPER TOWEL, TISSUE PAPER, LIQUID SOAP & DISPENSOR AND PLASTIC SHEET/DRAPE) IS USED FOR ROUTINE DRESSING & DISINFECTION OF THE EXIT-SITE OF PERITONEAL DIALYSIS CATHETER IN PERITONEAL DIALYSIS THERAPY.,TRANSFER SET CAP WITH SPONGE OF POVIDONE IODINE SOLUTION(MITRA)-TRANSFER SET CAP IS INTENDED FOR DISINFECTION OF THE TIP OF TRANSFER SET (MEDICAL DEVICE) AND PROTECTION FROM THE CONTAMINATION IN EXTERNAL ENVIRONMENT BY ENCLOSING IT.,TRANSFER SET(MITRA)-TRANSFER SET IS INTENDED TO USE AS TUBING CONNECTOR/EXTENSION BETWEEN THE PERITONEUM CATHETER/TITANIUM ADAPTER AND THE PERITONEAL DIALYSIS SOLUTION BAG. IT IS USED FOR CHANNELING AND CONTROLLING OF FLOW OF PERITONEAL DIALYSIS SOLUTION TO THE PERITONEUM CATHETER OF PATIENT.

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3524	MFG/MD/2020/000169	1.License Holder Name: B.D SURGICAL INDUSTRIES 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ORTHOPAEDIC SCREWS (BDS)-ORTHOPEDIC SURGEONS USE VARIATIONS OF SCREWS IMPLANTS TO REPAIR AND STABILIZE BONES. FACTORS SUCH AS THE LOCATION OF THE INJURY THE TYPE OF INJURY AND THE TYPE OF BONE THAT WILL BE ANCHORING THE SCREWS IMPLANTS DETERMINE THE TYPE USED. SCREWS IMPLANTS ARE USED ALONE OR IN CONJUNCTION WITH SCREW, PLATE OR OTHER ORTHOPEDIC HARDWARE OR DEVICES. THEY MAY BE USED TEMPORARILY AND THEN REMOVED OR LEFT IN PLACE INDEFINITELY.,ORTHOPAEDIC PLATES(BDS)-ORTHOPEDIC SURGEONS USE VARIATIONS OF PLATES IMPLANTS TO REPAIR AND STABILIZE BONES. FACTORS SUCH AS THE LOCATION OF THE INJURY, THE TYPE OF INJURY AND THE TYPE OF BONE THAT WILL BE ANCHORING THE PLATES IMPLANTS DETERMINE THE TYPE USED. PLATES IMPLANTS ARE USED ALONE OR IN CONJUNCTION WITH SCREW, PLATE OR OTHER ORTHOPEDIC HARDWARE OR DEVICES. THEY MAY BE USED TEMPORARILY AND THEN REMOVED OR LEFT IN PLACE INDEFINITELY.,ORTHOPAEDIC SPINAL SCREWS(BDS)-ORTHOPEDIC SURGEONS USE VARIATIONS OF SPINAL IMPLANTS TO REPAIR AND STABILIZE BONES. FACTORS SUCH AS THE LOCATION OF THE INJURY, THE TYPE OF INJURY AND THE TYPE OF BONE THAT WILL BE ANCHORING THE SPINAL IMPLANTS DETERMINE THE TYPE USED. SPINAL IMPLANTS ARE USED ALONE OR IN CONJUNCTION WITH SCREW, PLATE OR OTHER ORTHOPEDIC HARDWARE OR DEVICES. THEY MAY BE USED TEMPORARILY AND THEN REMOVED OR LEFT IN PLACE INDEFINITELY.,ORTHOPAEDIC WIRE(BDS)-ORTHOPEDIC SURGEONS USE VARIATIONS OF WIRES IMPLANTS TO REPAIR AND STABILIZE BONES. FACTORS SUCH AS THE LOCATION OF THE INJURY, THE TYPE OF INJURY AND THE TYPE OF BONE THAT WILL BE ANCHORING THE WIRES IMPLANTS DETERMINE THE TYPE USED. WIRES IMPLANTS ARE USED ALONE OR IN CONJUNCTION WITH SCREW, PLATE OR OTHER ORTHOPEDIC HARDWARE OR DEVICES. THEY MAY BE USED TEMPORARILY AND THEN REMOVED OR LEFT IN PLACE INDEFINITELY.,ORTHOPAEDIC PINS(BDS)-ORTHOPEDIC SURGEONS USE VARIATIONS OF PINS IMPLANTS TO REPAIR AND STABILIZE BONES. FACTORS SUCH AS THE LOCATION OF THE INJURY, THE TYPE OF INJURY AND THE TYPE OF BONE THAT WILL BE ANCHORING THE PINS IMPLANTS DETERMINE THE TYPE USED. PINS IMPLANTS ARE USED ALONE OR IN CONJUNCTION WITH SCREW, PLATE OR OTHER ORTHOPEDIC HARDWARE OR DEVICES. THEY MAY BE USED TEMPORARILY AND THEN REMOVED OR LEFT IN PLACE INDEFINITELY.,ORTHOPAEDIC NAIL(BDS)-ORTHOPEDIC SURGEONS

	USE VARIATIONS OF NAILS IMPLANTS TO REPAIR AND STABILIZE BONES. FACTORS SUCH AS THE LOCATION OF THE INJURY, THE TYPE OF INJURY AND THE TYPE OF BONE THAT WILL BE ANCHORING THE NAILS IMPLANTS DETERMINE THE TYPE USED. NAILS IMPLANTS ARE USED ALONE OR IN CONJUNCTION WITH SCREW, PLATE OR OTHER ORTHOPEDIC HARDWARE OR DEVICES. THEY MAY BE USED TEMPORARILY AND THEN REMOVED OR LEFT IN PLACE INDEFINITELY.

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3525	MFG/MD/2020/000170	1.License Holder Name: ORTHO LIFE SYSTEMS 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ORTHOPAEDIC ENDOPROSTHESIS-ORTHOPAEDIC ENDOPROSTHESIS ARE USED IN HUMAN BODY TO REPLACEMENT OF DEFECTIVE BONES/ TUMORS. ORTHOPAEDIC BONE PINS-ORTHOPAEDIC IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. THESE IMPLANTS ARE IMPLANTED BY TRAINED QUALIFIED SURGEONS DURING OPERATION. SUPRA CONDYLAR NAIL IS PRIMARILY INDICATED FOR COMMINUTED FRACTURES OF THE SUPRA CONDYLAR REGION OF THE FEMUR WHICH EXTENDS INTO THE ARTICULAR SURFACE. SECONDARY INDICATIONS INCLUDE POTHOLOGIC FRACTURES, MALUNIOUS, FAILED DISTAL FEMORAL OSTEOSYNTHESIS AND DISTAL FRACTURES IN OSTEOPOROTIC PATIENTS.,ORTHOPAEDIC BONE PLATES-ORTHOPAEDIC IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. THESE IMPLANTS ARE IMPLANTED BY TRAINED QUALIFIED SURGEONS DURING OPERATION. - ONE THIRD TUBULAR PLATES ARE GENERALLY USED IN FOREARM BONES ALONG WITH CORTI CAL & CANCELLOUS SCREWS. - SMALL T-PLATE ARE GENERALLY USED IN LOWER END OF FOREARM BONE. - HOOK PLATES ARE USED IN PROXIMAL PART OF RADIUS BONE WITH 4.0MM CANCELLOUS & 3.5MM CORTICAL SCREWS.,ORTHOPAEDIC BONE SCREWS-ORTHOPAEDIC IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. THESE IMPLANTS ARE IMPLANTED BY TRAINED QUALIFIED SURGEONS DURING OPERATION. 1.5MM, 2.0MM & 2.7MM DIA SCREWS ARE USED IN SMALL SIZE BONES AND ALSO IN THE METAPHYSEAL AND EPIPHYSEAL AREAS. 3.5MM DIA SCREWS ARE MAINLY USED IN THE DIAPHYSIS. 4.5 MM DIA SCREWS ARE USUALLY USED IN THE DIAPHYSIS OF LARGE BONES,ORTHOPAEDIC BONE SPINAL IMPLANTS-ORTHOPAEDIC BONE SPINAL IMPLANTS ARE USED TO REPLACE DISK BETWEEN ADJACENT VERTEBRAE,ORTHOPAEDIC BONE NAILS-ORTHOPAEDIC IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. THESE IMPLANTS ARE IMPLANTED BY TRAINED QUALIFIED SURGEONS DURING OPERATION. KUNTSCHERS NAIL ARE GENERALLY USED IN TIBIA & FEMUR BONES. SMALL DIAMETER NAILS CAN BE USE IN HUMERUS BONES ALSO.

3526	MFG/MD/2020/000171	1.License Holder Name: EXCELLENT HI- CARE PVT LTD ., 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS(BIO FLEX)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY,PMMA INTRAOCULAR LENS(BIO FLEX)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY,HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENS (BIO FLEX)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY
3527	MFG/MD/2020/000172	1.License Holder Name: SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:HAEMOSTATIC PATCH (VELNEZ)-THE FRAGMENTABLE VELNEZ IS INTENDED TO BE USED IN THE NASAL/SINUS CAVITY OF SURGERY OR TRAUMA PATIENTS. IT ACTS AS A SPACE-OCCUPYING DRESSING, PREVENTS ADHESION BY SEPARATING THE COMPROMISED MUCOSAL SURFACES. AND ALSO HELPS IN HEALING AND ACHIEVING HEMOSTASIS. LIKEWISE, CAN BE USED IN EAR CAVITY FOR A SIMILAR PURPOSE.,HAEMOSTATIC PATCH (WITH THROMBIN)(VELSEAL-T)-USE AS A TOPICAL DRESSING FOR EMERGENCY USE IN CASE OF SEVERE BLEEDING WOUNDS SUCH AS AS-ACCIDENTS, TRAUMA CASES, DEEP ARTERIAL WOUND, VENOUS PUNCTURES, POST ANGIOGRAPHY/ANGIOPLASTY AND PATIENTS WITH HEMOPHILIA. FOR EXTERNAL USE ONLY.,HAEMOSTATIC PATCH (VELSEAL, VELSEAL - C)-USE AS A TOPICAL DRESSING FOR EMERGENCY USE IN CASE OF SEVERE BLEEDING WOUNDS SUCH AS - ACCIDENTS, TRAUMA CASES, DEEP ARTERIAL WOUND, VENOUS PUNCTURES. FOR EXTERNAL USE ONLY.,SURGICAL DRESSINGS (SILVEL)-NANOCRYSTALLINE SILVER COATED ANTIMICROBIAL BARRIER DRESSING INTENDED FOR- PARTIAL-THICKNESS BURNS, PRESSURE ULCERS, DIABETIC FOOT ULCERS, SURGICAL WOUNDS, VENOUS LEG ULCERS.,NEGATIVE PRESSURE WOUND THERAPY KIT (VELNEXT FOAM DRESSING KIT)-THIS DRESSING KIT IS INTENDED TO BE USED WITH VELNEXT NPWT TO REMOVE WOUND EXUDATES/FLUIDS, INFECTIOUS MATERIALS, AND TISSUE DEBRIS FROM WOUND BED WHICH MAY PROMOTE WOUND HEALING.

3528	MFG/MD/2020/000175	1.License Holder Name: DATT MEDIPRODUCTS PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:NEGATIVE PRESSURE WOUND THERAPY KIT(VELNEXT FOAM DRESSING KIT)-THIS DRESSING KIT IS INTENDED TO BE USED WITH VELNEXT NPWT TO REMOVE WOUND EXUDATES/FLUIDS, INFECTIOUS MATERIALS AND TISSUE DEBRIS FROM WOUND BED WHICH MAY PROMOTE WOUND HEALING.
3529	MFG/MD/2020/000176	1.License Holder Name: DYNAMIC TECHNO MEDICALS PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:HRDROPHILIC FOAM SILVER PAD (NON ADHESIVE)-FOR THE MANAGEMENT OF MINIMALLY EXUDING, NON- EXUDING PARTIAL THICKNESS OPEN WOUNDS
3530	MFG/MD/2020/000177	1.License Holder Name: ANGEL LIFE SCIENCE 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ABSORBABLE GELATIN SPONGE USP(STERISPON, TRUSPONGE)-GELATIN SPONGE CAN BE EFFECTIVELY USED IN VARIOUS SURGERIES FOR HAEMOSTASIS, WHEN CONTROL OF CAPILLARY, VENOUS AND ARTERIOLAR BLEEDING BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS INEFFECTIVE OR IMPRACTICAL.

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3531	MFG/MD/2020/000178	1.License Holder Name: YOGESHWAR IMPLANTS (I) PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:BONE SCREWS(NA)-THE YIPL SCREWS (SOLID AND CANNULATED) ARE AVAILABLE WITH DIFFERENT TYPES OF SCREW THREAD, FOR CORTICAL OR CANCELLOUS BONE. THE SCREWS DESIGNED FOR CORTICAL BONE HAVE AN INCREASED CORE DIAMETER AND ARE MACHINED-TOOLED WITH A DOUBLE LEAD THREAD FOR FAST INSERTION. CANNULATED SCREWS CAN BE PLACED WITH HIGH PRECISION – NO PREDRILLING IS REQUIRED AS THEY ARE SELF-DRILLING AND SELF-TAPPING.,HEMI-ENDOPROSTHESIS(NA)-THE YIPL HEMI ENDOPROSTHESIS ARE INTENDED TO BE USED BY QUALIFIED AND TRAINED ORTHOPAEDIC SURGEONS TO CARRY OUT A PARTIAL OR 'HEMI' REPLACEMENT OF THE FEMORAL HEAD OF THE HIP JOINT IN CASES INVOLVING DEGENERATIVE OR TRAUMATIC CHANGES TO THE FEMORAL HEAD, WHERE THERE IS X-RAY EVIDENCE OF A SATISFACTORY ACETABULUM AND SUFFICIENT BONE IN THE FEMORAL NECK TO SEAT THE PROSTHESIS WITH OR WITHOUT BONE CEMENT. THESE DEVICES ARE MEANT TO BEAR LOAD WHILE IN USE AND ARE SUBJECTED TO VARIOUS MECHANICAL FORCES. THE EXTENT TO WHICH THE DEVICE WOULD WITHSTAND THESE FORCES IS LIMITED BY THE OPERATING SURGEON ACHIEVING APPROPRIATE RESTORATION OF HIP BIOMECHANICS AND PERIARTICULAR SOFT TISSUES.,BONE NAILS & WIRES(NA)-THE YIPL NAILS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMURS, FEMORAL SHAFT, TIBIA AND HUMERUS. THE YIPL WIRES ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. WIRES ARE OF DIFFERENT TYPES WHICH USED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENT. WIRES ARE MAINLY INDICATED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION.,BONE PLATES(NA)-THE YIPL PLATES (NEUTRALIZATION PLATE, BUTTRESS PLATE, DYNAMIC COMPRESSION PLATE & BRIDGING PLATE) ARE AVAILABLE WITH DIFFERENT TYPES OF DESIGNS, FOR DIFFERENT BONE FRACTURES. BONE PLATE SYSTEM PROVIDES FIXATION FOR FRACTURES, FUSIONS OR OSTEOTOMIES FOR THE CLAVICLE, HUMERUS, RADIUS, ULNA, METACARPAL, METATARSAL MALLEOLUS, TIBIA & FIBULA.

3532	MFG/MD/2020/000179	1.License Holder Name: UNIVERSAL SURGICAL COMPANY 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:GAUZE (ABSORBENT GAUZE)(NA)-THE ABSORBENT GAUZE ARE USED TO CLEANING, DRYING AND DRESSING WOUNDS A MEDICAL TREATMENT ALSO USED TO SUPPORTIVE MATERIAL FOR DRESSING ETC .GAUZE IS PERFECT FOR DELIVERING ANTISEPTICS TO INJURIES, MOISTURE REMOVAL FROM WOUNDS BEFORE THE EXERTION OF A DRESSING,COTTON BANDAGE (ROLLED BANDAGE) (NA)-THE COTTON BANDAGES ARE USED TO BIND, WRAP OR AS A SUPPORTIVE MATERIAL FOR WOUNDS, CUTS, BURNS AND IN DRESSING FOR WOUND HEALING PROCESS

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3533	MFG/MD/2020/000180	1.License Holder Name: WELCO LIFECARE PRIVATE LIMITED 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:NASO GASTRIC TUBE/RYLES TUBE-IT IS SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES., URETHRAL CATHETER-A LONG,SMALL GUAGE CATHETER DESIGNED FOR INSERTION DIRECTLY INSERTED INTO THE URETER, EITHER THROUGH THE URETHRA AND BLADDER AND POST PRIORY VIA THE KIDNEY.,TRACHEOTOMY TUBE/TRACHEAL TUBE-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,ANGIOGRAPHIC NEEDLE-ANGIOGRAPHIC NEEDLES HAS A UNIQUE HUB DESIGN WITH AN ERGONOMIC FEEL AND A BLACK TRIANGLE INDICATOR TO ORIENT THE BEVEL., TRANSFUSION SET FOR SINGLE USE-TRANSFUSION SETS IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,Y CONNECTOR AS AN ACCESSORY TO PERFUSION SETS-IT CAN BE USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC.,FOLEY CATHETER-A LONG, SMALL GUAGE CATHETER DESIGNED FOR INSERTION DIRECTLY INSERTED INTO THE URETER, EITHER THROUGH THE URETHRA AND BLADDER AND POST PRIORY VIA THE KIDNEY.,ENDOTRACHEAL TUBE-INSERT THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF TRACHEA, JUST BELOW THE VOCAL CORD.,VENTRICULAR CANNULA-FOR USE IN NEUROSURGICAL PROCEDURES. IT IS SPECIALLY DESIGNED TO PENETRATE DELICATE BRAIN TISSUE AND GIVE CONTINUED ACCESS TO BRAIN'S VENTRICULAR SYSTEM.,SUCTION CATHETER-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., FEEDING TUBE-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S IS USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,INTRAMUSCULAR PRESSURE MONITORING CATHETER-A MODIFIED FIBRE OPTIC TRANSDUCER-TIPPED CATHETER SYSTEM FOR MEASURING INTRAMUSCULAR PRESSURE DURING EXERCISE WAS DETERMINED., VENOUS CANNULA-IT IS INTENDED FOR USE AS A SINGLE CANNULA FOR BOTH VENOUS DRAINAGE AND REINFUSION OF BLOOD VIA AN INTERNAL JUGULAR VEIN DURING EXTRACORPOREAL LIFE SUPPORT PROCEDURES.,ANGIOGRAPHIC CATHETER-DESIGNED TO PROVIDE A PATHWAY FOR DELIVERING CONTRAST MEDIA TO SELECTED SITES IN THE DEVICE VASCULAR SYSTEM INCLUDING THE CAROTID ARTERIES., INTRAVENOUS CANNULA-THE IV CANNULA IS A PASSIVE DEVICE TO

	PROVIDE FOR THE INFUSION OF FLUIDS DRUGS, AND OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,MANIFOLDS-INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT/PORTS FOR ADMINISTRATION OF A SOLUTION.,PERITONEAL DIALYSIS CATHETER-THAT ALLOWS DIALYSIS FLUID TO ENTER THE ABDOMINAL CAVITY, DWELL INSIDE FOR A WHILE, AND THEN DRAIN BACK OUT AGAIN.,MULTIPLE LUMEN CATHETER-INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP) SAMPLING BLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTIONS OR DRUGS.,HEMODIALYSIS CATHETER-A CATHETER IS USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT.,3WAY STOPCOCK AS AN ACCESSORY TO PERFUSION SETS-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING., BIOPSY KIT-INVOLVING SAMPLING OF CELLS OR TISSUES FOR EXAMINATION,EXTENSION SETS-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,HEART LUNG BYPASS UNIT TUBE-A TUBE WILL BE PLACED IN YOUR HEART TO DRAIN BLOOD TO THE MACHINE.,CORONARY ARTERY CANNULA-CANNULATION TECHNIQUE FOR LEFT SIDE CORONARY ARTERY SURGEORY.,ARTERIAL CANNULA-INSERTED INTO AN ARTERY, COMMONLY THE RADIAL ARTERY, AND IS USED DURING MAJOR OPERATIONS AND IN CRITICAL CARE AREAS TO MEASURE BEAT-TO-BEAT BLOOD PRESSURE AND TO DRAW REPEATED BLOOD SAMPLES.,NELATON CATHETER-A LONG, SMALL GUAGE CATHETER DESIGNED FOR INSERTION DIRECTLY INSERTED INTO THE URETER, EITHER THROUGH THE URETHRA AND BLADDER AND POST PRIORY VIA THE KIDNEY.,URINARY DRAINAGE UNIT-A CLOSED URINARY DRAINAGE SYSTEM CONSISTS OF A CATHETER INSERTED INTO THE URINARY BLADDER AND CONNECTED VIA TUBING TO A DRAINAGE BAG.,MEASURED VOLUME IV SET-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSSTEM THROUGH A VASCULAR ACCESS DEVICE,URETHROGRAPHIC MALE CATHETER-A CATHETER USED TO PASS INTO A MAN'S BLADDER.,CLOSED WOUND DRAINAGE SYSTEM-INTENDED FOR EVACUATION OF BIOLOGICAL FLUID FROM WOUND OR BODY CAVITY DURING SURGICAL PROCEDURE OR IN WOUND CARE MANAGEMENT.

3534	MFG/MD/2020/000181	1.License Holder Name: CHOWDHURY SURGICAL DRESSING COMPANY 2.Approving Authority: BIHAR 3.Device Name(Brand Name)-Intended Use:A HANDLOOM SURGICAL BANDAGE (ROLLED BANDAGE / BANDAGE CLOTH) (TRISHUL)-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB, COTTON CREPE BANDAGE B.P(TRISHUL)-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB.,ABSORBENT GAUZE (MAA LAXMI)-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB.

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3535	MFG/MD/2020/000182	1.License Holder Name: POLY MEDICURE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:QUADRUPLE LUMEN CENTRAL VENOUS CATHETER KIT (POLYCENT QUATTRO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,SINGLE LUMEN CENTRAL VENOUS CATHETER-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,SINGLE LUMEN CENTRAL VENOUS CATHETER KIT (POLYCENT MONO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,QUADRUPLE LUMEN CENTRAL VENOUS CATHETER KIT(POLYMED)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,DOUBLE LUMEN CENTRAL VENOUS CATHETER KIT (NOVOCENT-N DUO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA. ,TRIPLE LUMEN CENTRAL VENOUS CATHETER-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,QUADRUPLE LUMEN CENTRAL VENOUS CATHETER KIT (NOVOCENT-N QUATTRO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA. ,QUADRUPLE LUMEN CENTRAL VENOUS CATHETER KIT(NOVOCENT PRO QUATTRO) -IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,DOUBLE LUMEN CENTRAL VENOUS CATHETER KIT(POLYCENT DUO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,SINGLE LUMEN CENTRAL VENOUS CATHETER KIT(TRO-CENTRAKIT-1 CVC BR)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,TRIPLE LUMEN CENTRAL VENOUS CATHETER KIT(NOVOCENT-N TRIO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD

	SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA. ,TRIPLE LUMEN CENTRAL VENOUS CATHETER KIT(TRO-CENTRAKIT-3 CVC BR)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,TRIPLE LUMEN CENTRAL VENOUS CATHETER KIT(POLYCENT TRIO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,DOUBLE LUMEN CENTRAL VENOUS CATHETER KIT(ISO – CATH DOUBLE CENTRAL VENOUS CATHETER KIT)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,SINGLE LUMEN CENTRAL VENOUS CATHETER KIT(NOVOCENT-N MONO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA. ,TRIPLE LUMEN CENTRAL VENOUS CATHETER KIT(ISO – CATH TRIPLE CENTRAL VENOUS CATHETER KIT)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,QUADRUPLE LUMEN CENTRAL VENOUS CATHETER-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,QUADRUPLE LUMEN CENTRAL VENOUS CATHETER KIT(KD-QUADROSOFT)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,TRIPLE LUMEN CENTRAL VENOUS CATHETER KIT(NOVOCENT TRIO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,QUADRUPLE LUMEN CENTRAL VENOUS CATHETER KIT(NOVOCENT PRO PROTEKT- QUATTRO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,SINGLE LUMEN CENTRAL VENOUS CATHETER KIT(VITROMED)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,TRIPLE LUMEN CENTRAL VENOUS CATHETER KIT(EXEVENT-TRIO)-IT IS INDICATED FOR USE IN

	PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,DOUBLE LUMEN CENTRAL VENOUS CATHETER KIT(KD-DUOSOFT)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,TRIPLE LUMEN CENTRAL VENOUS CATHETER KIT (NOVOCENT PRO TRIO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,SINGLE LUMEN CENTRAL VENOUS CATHETER KIT (KD-MONOSOFT)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,TRIPLE LUMEN CENTRAL VENOUS CATHETER KIT(VITROMED)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,QUADRUPLE LUMEN CENTRAL VENOUS CATHETER KIT(NOVOCENT QUATTRO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,DOUBLE LUMEN CENTRAL VENOUS CATHETER KIT(POLYMED)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,SINGLE LUMEN CENTRAL VENOUS CATHETER KIT(TRO-CENTRAKIT-1 CVC)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,TRIPLE LUMEN CENTRAL VENOUS CATHETER KIT(POLYMED)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,DOUBLE LUMEN CENTRAL VENOUS CATHETER KIT (EXEVENT-DUO)-A CENTRAL VENOUS CATHETER IS A LONG, THIN, FLEXIBLE TUBE USED TO GIVE MEDICINES, FLUIDS, NUTRIENTS OR BLOOD PRODUCTS. A CATHETER IS OFTEN INSERTED IN THE ARM OR CHEST THROUGH THE SKIN INTO A LARGE VEIN. THE CATHETER IS THREADED THROUGH THIS VEIN UNTIL IT REACHES A LARGE VEIN NEAR THE HEART.,TRIPLE LUMEN CENTRAL VENOUS CATHETER KIT (NOVOCENT NEO TRIO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,SINGLE LUMEN CENTRAL VENOUS CATHETER KIT

	(EXEVENT-MONO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA,DOUBLE LUMEN CENTRAL VENOUS CATHETER KIT(NOVOCENT NEO DUO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,DOUBLE LUMEN CENTRAL VENOUS CATHETER KIT (VITROMED)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,SINGLE LUMEN CENTRAL VENOUS CATHETER KIT(NOVOCENT MONO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,DOUBLE LUMEN CENTRAL VENOUS CATHETER KIT (NOVOCENT DUO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,DOUBLE LUMEN CENTRAL VENOUS CATHETER KIT (NOVOCENT PRO DUO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,DOUBLE LUMEN CENTRAL VENOUS CATHETER KIT (TRO-CENTRAKIT-2 CVC BR)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,SINGLE LUMEN CENTRAL VENOUS CATHETER KIT-A CENTRAL VENOUS CATHETER IS A LONG, THIN, FLEXIBLE TUBE USED TO GIVE MEDICINES, FLUIDS, NUTRIENTS OR BLOOD PRODUCTS. A CATHETER IS OFTEN INSERTED IN THE ARM OR CHEST THROUGH THE SKIN INTO A LARGE VEIN. THE CATHETER IS THREADED THROUGH THIS VEIN UNTIL IT REACHES A LARGE VEIN NEAR THE HEART.,DOUBLE LUMEN CENTRAL VENOUS CATHETER-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,QUADRUPLE LUMEN CENTRAL VENOUS CATHETER KIT-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,TRIPLE LUMEN CENTRAL VENOUS CATHETER KIT-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST

	MEDIA.,DOUBLE LUMEN CENTRAL VENOUS CATHETER KIT(TRO-CENTRAKIT-2 CVC)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,TRIPLE LUMEN CENTRAL VENOUS CATHETER KIT (KD-TRIOSOFT)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,SINGLE LUMEN CENTRAL VENOUS CATHETER KIT(NOVOCENT PRO MONO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,SINGLE LUMEN CENTRAL VENOUS CATHETER KIT(NOVOCENT NEO MONO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,SINGLE LUMEN CENTRAL VENOUS CATHETER KIT(POLYMED)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,TRIPLE LUMEN CENTRAL VENOUS CATHETER KIT(NOVOCENT PRO PROTEKT- TRIO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,DOUBLE LUMEN CENTRAL VENOUS CATHETER KIT-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,SINGLE LUMEN CENTRAL VENOUS CATHETER KIT(NOVOCENT PRO PROTEKT- MONO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,QUADRUPLE LUMEN CENTRAL VENOUS CATHETER KIT(VITROMED)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,TRIPLE LUMEN CENTRAL VENOUS CATHETER KIT(TRO-CENTRAKIT-3 CVC)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,DOUBLE LUMEN CENTRAL VENOUS CATHETER KIT(NOVOCENT PRO PROTEKT- DUO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.

3536	MFG/MD/2020/000183	1.License Holder Name: POLY MEDICURE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:RNA EXTRACTION KITS-RNA EXTRACTION KIT IS INTENDED FOR MOLECULAR BIOLOGY APPLICATIONS. THIS PRODUCT IS NOT INTENDED FOR THE DIAGNOSIS, PREVENTION, OR TREATMENT OF A DISEASE.,PRE-FILLED SYRINGE 0.9% SODIUM CHLORIDE (0.9% NACL)-THE PREFILLED SYRINGES - NORMAL SALINE FLUSH SYRINGES ARE INTENDED TO BE USED ONLY FOR THE FLUSHING OF INDWELLING VASCULAR ACCESS DEVICES AND INTENDED FOR USE IN MAINTAINING PATENCY OF VASCULAR ACCESS DEVICES (VAD'S). ,RNA EXTRACTION KITS (POLYMED VIRAL RNA EXTRACTION KIT)-VIRAL RNA EXTRACTION KIT IS INTENDED FOR MOLECULAR BIOLOGY APPLICATIONS. THIS PRODUCT IS NOT INTENDED FOR THE DIAGNOSIS, PREVENTION, OR TREATMENT OF A DISEASE.,PRE-FILLED SYRINGE 0.9% SODIUM CHLORIDE (0.9% NACL)(POLYFLUSH SYRINGE 0.9% SODIUM CHLORIDE (0.9% NACL))-THE PREFILLED SYRINGES - NORMAL SALINE FLUSH SYRINGES ARE INTENDED TO BE USED ONLY FOR THE FLUSHING OF INDWELLING VASCULAR ACCESS DEVICES AND INTENDED FOR USE IN MAINTAINING PATENCY OF VASCULAR ACCESS DEVICES (VAD'S).,POLYMED Q 2019 NCOV RT PCR KIT-POLYMED Q 2019 NCOV RT PCR KIT IS THE ONE-STEP REVERSE TRANSCRIPTION REAL-TIME PCR KIT DESIGNED TO DETECT NOVEL CORONA VIRUS (NCOV-2019) QUALITATIVELY THROUGH REVERSE TRANSCRIPTION REACTION AND REAL-TIME POLYMERASE CHAIN REACTION FROM NASOPHARYNGEAL AND OROPHARYNGEAL.

CENTRAL DRUG STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

3537	MFG/MD/2020/000184	1.License Holder Name: BETAMED EXIM PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ORTHOPAEDIC BONE WIRES (TITANIUM)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,ORTHOPAEDIC BONE SCREWS (SS 316L)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,SPINAL IMPLANTS (SS316LVM)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,MAXILLOFACIAL IMPLANTS (SS 316L)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,ORTHOPAEDIC HIP IMPLANT (SS 316L)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,ORTHOPAEDIC BONE SCREWS (TITANIUM) (BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN, ORTHOPAEDIC BONE SCREWS (SS316LVM)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,ORTHOPAEDIC HIP IMPLANT (UHMWPE)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,ARTHOSCOPY IMPLANTS (PEEK)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,ARTHOSCOPY IMPLANTS (TITANIUM)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,ARTHOSCOPY IMPLANTS (SS 316L)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,MAXILLOFACIAL IMPLANTS (SS316LVM)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,MAXILLOFACIAL IMPLANTS (TITANIUM)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,SPINAL IMPLANTS (TITANIUM)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,SPINAL IMPLANTS (SS 316L)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,ORTHOPAEDIC NAILING SYSTEM (SS316LVM)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,ORTHOPAEDIC BONE WIRES (SS316LVM)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,ORTHOPAEDIC BONE WIRES (SS 316L)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,ORTHOPAEDIC PLATING SYSTEM (SS316LVM) (BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN, ORTHOPAEDIC PLATING SYSTEM (TITANIUM)(BETAMED, BETA, ALTIS) -USED TO FIX BROKEN BONES OF HUMAN,ORTHOPAEDIC PLATING SYSTEM (SS 316L)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,ORTHOPAEDIC HIP IMPLANT (TITANIUM) (BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN, STAPLES(BETAMED, BETA, ALTIS)-STAPLES ARE USED FOR SKIN CLOSURE OF THE EPIDERMIS.,ORTHOPAEDIC HIP IMPLANT (SS316LVM)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,ORTHOPAEDIC NAILING SYSTEM (SS 316L)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN,ORTHOPAEDIC NAILING SYSTEM (TITANIUM)(BETAMED, BETA, ALTIS)-USED TO FIX BROKEN BONES OF HUMAN

3538	MFG/MD/2020/000185	1.License Holder Name: DYNAMIC TECHNO MEDICALS PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:HRDROPHILIC FOAM SILVER PAD 10-MANAGEMENT OF MODERATELY EXUDING NON-EXUDING PARTIAL TO FULL THICKNESS OPEN WOUNDS

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3539	MFG/MD/2020/000186	1.License Holder Name: SIGMA SURGICAL PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:SPINE IMPLANTS (SORATH, SORATH ORTHO)-THE SPINAL IMPLANT SYSTEM IS INTENDED TO PROMOTE FUSION OF THE CERVICAL AND THORACIC SPINE (CI-T3) FOR THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC AS CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; SPINAL STENOSIS; TRAUMA(FRACTURE/DISLOCATION); FAILED PREVIOUS FUSION; AND/OR TUMORS. THE HOOKS AND RODS ARE ALSO INTENDED TO PROVIDE STABILIZATION TO PROMOTE FUSION FOLLOWING REDUCTION OF FRACTURE/DISLOCATION OR TRAUMA IN THE CERVICAL/UPPER THORACIC (CI -T3) SPINE. THE USES OF MULTIAXIL SCREWS (PLOY AXIAL)/ CONNECTORS ARE LIMITED TO PLACEMENT IN TI -T3 VERTEBRAE FOR TREATING THORACIC CONDITIONS ONLY. SCREWS ARE NOT INTENDED TO BE PLACED IN THE CERVICAL SPINE. TITANIUM RODS ARE PROVIDED IN VARIOUS LENGTHS AND ARE USED TO CONNECT PEDICLE SCREWS (MONO & PLOY AXIAL) AND CREATE A RIGID STRUCTURE.,INTERLOCKING NAIL (SORATH, SORATH ORTHO)-INTRAMEDULLARY NAILS IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMURS, FEMORAL SHAFT, TIBIA AND HUMERUS.,BONE PLATE(SORATH, SORATH ORTHO)-THE BONE PLATE IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, TIBIA, FIBULA, FEMORAL. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA- ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS.,BONE PLATE(SORATH, SORATH ORTHO)-THE BONE PLATE IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, TIBIA, FIBULA, FEMORAL. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA- ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS., INTERLOCKING NAIL(SORATH, SORATH ORTHO)-INTRAMEDULLARY NAILS IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS

	ANATOMICAL REGIONS SUCH AS PROXIMAL FEMURS, FEMORAL SHAFT, TIBIA AND HUMERUS.,WIRES AND PINS(SORATH, SORATH ORTHO)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. WIRES ARE OF DIFFERENT TYPES WHICH USED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENT. WIRES ARE MAINLY INDICATED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION. THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PINS ARE OF DIFFERENT TYPES WHICH GENERALLY USED WITH EXTERNAL FIXATOR IMPLANTS IN TIBIA, FEMUR & FOREARM BONES.,BONE SCREW(SORATH, SORATH ORTHO)-THE BONE SCREW IS INTENDED TO USE FOR INTERNAL FIXATION OF BONE FRACTURES AND RECONSTRUCTION OF BONES, THERE ARE SEVERAL TYPES OF SCREW LIKE LOCKING HEAD SCREW, GENERAL CORTICAL SCREW OR FEMUR HEAD BONE SCREW ARE USED FOR FIXING OF FEMUR HEAD COMPRESSION PLATE, LOCKING PLATES WHICH IS USED FOR OSTEOTOMY PATIENTS EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS.,WIRES AND PINS(SORATH, SORATH ORTHO)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. WIRES ARE OF DIFFERENT TYPES WHICH USED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENT. WIRES ARE MAINLY INDICATED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION. THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PINS ARE OF DIFFERENT TYPES WHICH GENERALLY USED WITH EXTERNAL FIXATOR IMPLANTS IN TIBIA, FEMUR & FOREARM BONES.,BONE PLATE(SORATH, SORATH ORTHO)-THE BONE PLATE IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, TIBIA, FIBULA, FEMORAL. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA- ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS.,BONE SCREW(SORATH, SORATH ORTHO)-THE BONE SCREW IS INTENDED TO USE FOR INTERNAL FIXATION OF BONE FRACTURES AND RECONSTRUCTION OF BONES, THERE ARE SEVERAL TYPES OF SCREW LIKE LOCKING HEAD SCREW, GENERAL CORTICAL SCREW OR FEMUR HEAD BONE SCREW ARE USED FOR FIXING OF FEMUR HEAD COMPRESSION PLATE, LOCKING PLATES WHICH IS USED FOR OSTEOTOMY PATIENTS EXAMPLES OF THESE INTERNAL

		FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS.,BONE SCREW(SORATH, SORATH ORTHO)-THE BONE SCREW IS INTENDED TO USE FOR INTERNAL FIXATION OF BONE FRACTURES AND RECONSTRUCTION OF BONES, THERE ARE SEVERAL TYPES OF SCREW LIKE LOCKING HEAD SCREW, GENERAL CORTICAL SCREW OR FEMUR HEAD BONE SCREW ARE USED FOR FIXING OF FEMUR HEAD COMPRESSION PLATE, LOCKING PLATES WHICH IS USED FOR OSTEOTOMY PATIENTS EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS.,WIRES AND PINS(SORATH, SORATH ORTHO)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. WIRES ARE OF DIFFERENT TYPES WHICH USED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENT. WIRES ARE MAINLY INDICATED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION. THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PINS ARE OF DIFFERENT TYPES WHICH GENERALLY USED WITH EXTERNAL FIXATOR IMPLANTS IN TIBIA, FEMUR & FOREARM BONES.,INTERLOCKING NAIL(SORATH, SORATH ORTHO)-INTRAMEDULLARY NAILS IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMURS, FEMORAL SHAFT, TIBIA AND HUMERUS.
3540	MFG/MD/2020/000186	1.License Holder Name: SIGMA SURGICAL PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:INTERLOCKING NAIL-BONE SURGERY,WIRES & PINS-BONE SURGERY,BONE SCREW-BONE SURGERY,SPINE IMPLANTS-BONE SURGERY,BONE SCREW-BONE SURGERY,INTERLOCKING NAIL-BONE SURGERY,BONE PLATE-BONE SURGERY,WIRES AND PINS-BONE SURGERY,INTERLOCKING NAIL-BONE SURGERY,BONE PLATE-BONE SURGERY,BONE SCREW-BONE SURGERY,BONE PLATE-BONE SURGERY,WIRES AND PINS-BONE SURGERY

3541	MFG/MD/2020/000187	1.License Holder Name: DYNAMIC TECHNO MEDICALS PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:SILVER WOUND DRESSING-INTENDED TO BE USED AS A PRIMARY DRESSING FOR WOUNDS, ABRASIONS AND LACERATIONS.

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3542	MFG/MD/2020/000188	1.License Holder Name: AIRWAYS SURGICALS PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE SILICON FOLEY BALOON CATHTER (2 WAY / 3 WAY) FOR SINGLE USE ONLY(AIRWAYS)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STER ILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(AIRWAYS)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN, DISPOSABLE STERILE MULTIPLE LUMEN CATHTER FOR SINGLE USE ONLY(AIRWAYS CVP MANOMETER)-INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP), SAMPLING BLOOD, AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTIONS OR DRUGS ,STERILE THREE WAY STOP COCK AS AN ACCESSORY TO THE PERFUSION SET FOR SINGLE USE ONLY(AIRWAYS)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,STERILE DISPOSABLE ENDOTRACHEAL TUBE FOR SINGLE USE ONLY(AIROLINE)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,STERILE SKIN STAPLER FOR SINGLE USE ONLY(AIRWAYS)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN SURGICAL DRESSINGS IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY. ,STERILE DISPOSABLE NASOPHARYNGEAL CATHETER FOR SINGLE USE ONLY(AIRWAYS)-A CATHETER (FOR ADULTS) PASSED THROUGH THE NARES AND ADVANCED TO THE DEPTH OF THE NASOPHARYNX TO REMOVE AIR CHOKE OR OBSTRUCTION. AR ESUSCITATOR. ,STERILE PRESSURE MONITORING LINE FOR SINGLE USE ONLY(AIRWAYS)-P M LINE ARE INTENDED TO BE USED IN FLUID MANAGEMENT AND/OR INVASIVE PRESSURE MONITORING SYSTEMS.,DIGITAL THERMOMETER-MEASURE HUMAN BODY TEMPERATURE TO CHECK FEVER,STERILE ENDOTRACHEAL TUBE WITH/WITHOUT CUFF(AIRWAYS)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS. ,STERILE DISPOSABLE ENDOTRACHEAL TUBE FOR SINGLE USE ONLY(NEO ET)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., STERILE DISPOSABLE SILICON FOLEY BALOON CATHTER (2 WAY / 3

	WAY) FOR SINGLE USE ONLY(AIRWAYS)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE TRACHEOBRONCHIAL YANKAUR SUCTION CATHETER FOR SINGLE USE ONLY(AIROSUCK)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,STERILE CLOSED WOUND SUCTION UNIT FOR SINGLE USE ONLY(AIROCARE)-EXTRACT PUS FROM THE WOUND OF A HUMAN BODY,STERILE NASAL OXYGEN CATHETER FOR SINGLE USE ONLY(AIROPRONG)-IT IS A DEVICE DELIVER SUPPLEMENTAL INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP. ,STERILE TRACHEOBRONCHIAL YANKAUR SUCTION CATHETER FOR SINGLE USE ONLY(NEOYANK)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING,STERILE DISPOSABLE SILICON FOLEY BALOON CATHTER (2 WAY / 3 WAY) FOR SINGLE USE ONLY(NEON)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE DISPOSABLE SILICON FOLEY BALOON CATHTER (2 WAY / 3 WAY) FOR SINGLE USE ONLY(NEON)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE NASAL OXYGEN CATHETER FOR SINGLE USE ONLY(NEOTWIN)-IT IS A DEVICE DELIVER SUPPLEMENTAL INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP. ,DISPOSABLE EXTENSION TUBE WITH/WITHOUT THREE WAY STOP COCK FOR SINGLE USE ONLY(NEOWAY)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,DISPOSABLE EXTENSION TUBE WITH/WITHOUT THREE WAY STOP COCK FOR SINGLE USE ONLY(AIROEX)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING., DISPOSABLE STERILE DIAL FLOW REGULATOR WITH OR WITHOUT INFUSION SET FOR SINGLE USE ONLY (AIROFLOW)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,BP INSTRUMENT-TO MEASURE HUMAN BODY BLOOD PRESSURE,DISPOSABLE EXTENSION TUBE WITH/WITHOUT THREE WAY STOP COCK FOR SINGLE USE ONLY (NEOEX)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.

3543	MFG/MD/2020/000189	1.License Holder Name: SHRI GURUKRUPA SURGICAL 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE INFUSION SET(GENERIC, BLESSING, SAYFT-NV, CAREWELL, LIFE, MAHAVEER, DOCTOR GRIP)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT"S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE MEASURED VOLUME INFUSION SET WITH/WITHOUT AIR VENT BIS 12655(BLESSIMG MEASURED VOLUME SET)-IT IS INTEDED TO USE THE ADMINISTRATION OF FLUIDS FROMA CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,STERILE DISPOSABLE BLOOD ADMINISTRATION SET (GENERIC, DOCTOR SUPER DELUXE)-TRANSFUSION SET SPECIALLY DESIGNED FOR BLOOD AND BLOOD COMPONENTS. SPECIALLY DESIGNED ROLLER CLAMP FOR BETTER FLOW CONTROL AND PRECISE ADJUSTMENT OF INFUSION RATE. SUPERIOR QUALITY FOR SELF-SEALING. ,STERILE DISPOSABLE MICRO DRIP INTRAVENOUS INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (CAREWELL MICRODRIP INFUSION SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (BLESSING MEASURED VOLUME SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,STERILE DISPOSABLE MICRO DRIP INFUSION SET WITH/WITHOUT AIR VENT BIS 12655(CAREWELL MICRO DRIP SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT’S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.

3544	MFG/MD/2020/000190	1.License Holder Name: BHAGWATI MEDICARE DEVICES 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE EXTENSIONAL LINE AS A ACCESSORY TO THE PERFUSION SET FOR SINGLE USE ONLY(FLO-ON/QUIP/VITAL CARE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATIONS IN THE MEDICAL APPLICATION.,STERILE INFANT FEEDING TUBE FOR SINGLE USE ONLY(SYMON'S)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING, STERILE CLOSED WOUND DRAINAGE SET SIZE : FG 10,12,14,16 FOR SINGLE USE ONLY(FLO-ON/QUIP/VITAL CARE)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY THE SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,STERILE DISPOSABLE RYLE'S TUBE FOR SINGLE USE ONLY(FLO-ON)-10. INTENDED USE :IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES. ,STERILE DISPOSABLE MEASURED VOLUME INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(FLO-ON/QUIP/VITAL CARE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE Y-CONNECTOR FOR SINGLE USE ONLY(SYMON'S)-IT CAN USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC.,STERILE DISPOSABLE FLOW REGULATOR FOR SINGLE USE ONLY (FLOW-ON/QUIP/VITAL-CARE)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY., STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY(FLO-ON CHEST DRAINAGE CATHTHER)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(FLOW-ON/QUIP/VITAL CARE)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.,STERILE DISPOSABLE UMBILICAL OCCLUSION DEVICE FOR SINGLE USE ONLY (FLO-ON CORD CLAMP)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE INTRAVENOUS MANIFOLD FOR SINGLE USE ONLY(FLO-ON/QUIP/VITAL CARE)-INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR

	PROVIDING ACCESS PORT/PORTS FOR ADMINISTRATION OF THE SOLUTION. ,STERILE NELATON CATHETER (PLAIN & THUMB CONTROL) FOR SINGLE USE ONLY(SYMON'S)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(- -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY(SYMON;S INFANT MUCUS EXTRACTOR)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION,STERILE URETHRAL CATHETER (PLAIN & THUMB CONTROL) SIZE : FG 6,8,10,12, 14, 16,18 FOR SINGLE USE ONLY (FLO-ON/QUIP/VITAL-CARE)-A LONG, SMALL GAUGE CATHETER DESIGNED F OR INSERTION DIRECTLY INTO A URETHRA, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY(FLO-ON)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(FLO-ON/QUIP, VITAL CARE STERILE DISPOSABLE INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE NELATON CATHETER (PLAIN & THUMB CONTROL) FOR SINGLE USE ONLY(FLO-ON)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED., STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY(SYMON'S CHEST DRAINAGE CATHTHER)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING,STERILE THREE WAY STOP COCK AS A ACCESSORY TO THE PERFUSION SET FOR SINGLE USE ONLY(FLO-ON/QUIP/VITAL CARE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF THE SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,STERILE DISPOSABLE Y-CONNECTOR FOR SINGLE USE ONLY(FLO-ON)-:IT CAN USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA

	ETC.,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY(FLO-ON INFANT MUCUS EXTRACTOR)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION,STERILE INFANT FEEDING TUBE FOR SINGLE USE ONLY(FLO-ON)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING, STERILE DISPOSABLE UMBILICAL OCCLUSION DEVICE FOR SINGLE USE ONLY(SYMON'S CORD CLAMP)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE DISPOSABLE ENDOTRACHEAL TUBE FOR SINGLE USE ONLY(SYMON;S)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION. ,STERILE DISPOSABLE RYLE'S TUBE FOR SINGLE USE ONLY(SYMON'S)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,STERILE DISPOSABLE YANKAUR SUCTION SET FOR SINGLE USE ONLY(SYMON'S)-:CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION,STERILE DISPOSABLE ENDOTRACHEAL TUBE FOR SINGLE USE ONLY(FLO-ON)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION. ,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY (SYMON'S)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION.,STERILE DISPOSABLE YANKAUR SUCTION SET FOR SINGLE USE ONLY(FLO-ON)-:CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3545	MFG/MD/2020/000191	1.License Holder Name: SHREE UMIYA SURGICAL PVT. LTD. UNIT-II 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:PERITONEAL DIALYSIS SET(MEDIPLUS)-IT IS USED IN DIALYSIS SOLUTION FOR CHRONIC RENAL FAILURE TREATMENT.,URETHRAL CATHETER(MEDIPLUS)-USED FOR SHORT-TERM BLADDER CATHETERIZATION THROUGH URETHRA.,LEVIN'S TUBE(MEDIPLUS)-IT IS USED TO DRAIN GASTRIC CONTENTS, DECOMPRESS THE STOMACH OR DUODENUM, OBTAIN A SPECIMEN OF THE GASTRIC CONTENTS AND ADMINISTER MEDICINE, LIQUIDS AND/OR ENTERAL FEEDING.,DISPOSABLE NEEDLE (MEDIPLUS)-USED WITH SYRINGES INJECTING MEDICINE.,KARMAN CANNULA(MEDIPLUS)-IT IS USED FOR ASEPTIC MENSTRUAL TERMINATION OF PREGNANCY.,SCALP VEIN SET(MEDIPLUS)-SCALP VEIN SET INTENDED TO BE USED FOR INSERTION INTO A PATIENT'S VASCULAR SYSTEM (FOR SINGLE USE) AS AN INDWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD. SECONDLY, IT IS DESIGNED WITH AN ACTIVE SHARP FEATURE THAT REQUIRES PHYSICAL ACTION BY THE CLINICIAN TO PREVENT NEEDLE STICK INCIDENTS.,THREE WAY STOPCOCK WITH EXTENSION TUBE(MEDIPLUS)-IT FACILITATE MULTIPLE LINES THROUGH SINGLE IV ACCESS & HAS EXTENSION TUBE CONNECTED TO IT,CHEST DRAINAGE CATHETER (ALL TYPE)(MEDIPLUS)-A CHEST TUBE IS A HOLLOW, FLEXIBLE TUBE PLACED INTO THE CHEST. IT ACTS AS A DRAIN. CHEST TUBES DRAIN BLOOD, FLUID, OR AIR FROM AROUND YOUR LUNGS, HEART, OR ESOPHAGUS. THE TUBE AROUND YOUR LUNG IS PLACED BETWEEN YOUR RIBS AND INTO THE SPACE BETWEEN THE INNER LINING AND THE OUTER LINING OF YOUR CHEST CAVITY. THIS IS CALLED THE PLEURAL SPACE. IT IS DONE TO ALLOW YOUR LUNGS TO FULLY EXPAND.,INFANT FEEDING TUBE(MEDIPLUS)-SUITABLE FOR NEONATES & PEDIATRIC NUTRITIONAL FEEDING, YANKAUR SUCTION SET(MEDIPLUS)-SINGLE USE YANKAUR SUCTION SET IT INTENDED FOR SUCTION OF BODY FLUID IN COMBINATION WITH ASPIRATOR DURING OPERATION ON THORACIC CAVITY OR ABDOMINAL CAVITY.,BLOOD TUBING SET(MEDIPLUS)-THIS TUBE IS HELPS TO TRANSFER BLOOD TO PATIENT BODY,CATHETER MOUNT (MEDIPLUS)-USED TO CONNECT ET TUBE TO BREATHING CIRCUIT, TO MINIMIZE THE JERKS,RYLE'S TUBE(MEDIPLUS)-DECOMPRESSION OF STOMACH BY SUCTION OR ASPIRATION OF GASTRIC CONTENTS. SHORT-TERM ADMINISTRATION OF TERM TUBE FEEDING, LAVAGE FLUID AND MEDICATIONS.,CVP MANOMETER(MEDIPLUS)-A CENTRAL VENOUS PRESSURE (CVP) MANOMETER SET IS USED TO EITHER CONTINUOUSLY OR INTERMITTENTLY MEASURE CENTRAL VENOUS PRESSURE.,FOLEY BALLOON CATHETER (ALL TYPE)(MEDIPLUS)-USED TO PROVIDE CONTINUOUS BLADDER IRRIGATION OF FLUIDS

	AND DRAINAGE OF URINE FROM THE URINARY TRACT. URINARY TRACT ACCESS IS GENERALLY ACCOMPLISHED BY INSERTION OF THE CATHETER THROUGH THE URETHRA AND INTO THE BLADDER. BUT MAY ALSO BE ACCOMPLISHED BY SUPRAPUBIC PLACEMENT OR BY NEPHROSTOMY.,LP PINAL NEEDLE (ALL TYPE)(MEDIPLUS)-THE PENCAN SPINAL NEEDLES WITH OR WITHOUT INTRODUCER ARE INTENDED FOR THE INJECTION OF LOCAL ANESTHETICS INTO THE SUBARACHNOID SPACE TO PROVIDE SPINAL ANESTHESIA FOR PAIN MANAGEMENT OR TO FACILITATE CSF SAMPLE COLLECTION FOR DIAGNOSTIC PURPOSES (LUMBAR PUNCTURE).,NASAL OXYGEN CATHETER(MEDIPLUS)-USE FOR EFFICIENT ADMINISTRATION OF OXYGEN, THIS IS CONNECTED TO PIPELINE.,EXTENSION TUBE (MEDIPLUS)-USE FOR CONNECTION OF ONE OR TWO INFUSION OR TRANSFUSION SETS WITH EACH OTHER.,THREE WAY STOPCOCK (MEDIPLUS)-USED FOR SIMULTANEOUS AND CONTINUOUS INFUSION OF TWO FLUIDS TO CONNECT STANDARD 6% LUER DEVICE AND CONTROL FLOW DIRECTION.,IV CANNULA (ALL TYPE)(MEDIPLUS)-AN IV IS A SMALL PLASTIC TUBE, INSERTED INTO A VEIN, USUALLY IN YOUR HAND OR ARM. AN IV IS USED TO: PROVIDE FLUIDS WHEN YOU ARE DEHYDRATED OR CAN'T DRINK GIVE A BLOOD TRANSFUSION ADMINISTER MEDICATIONS DIRECTLY INTO YOUR BLOODSTREAM. SOME DRUGS WORK BETTER THIS WAY.,SUCTION CATHETER (ALL TYPE)(MEDIPLUS)-FOR REMOVAL OF SECRETION FROM TRACHEA AND BRONCHIAL REGION.,NELATON CATHETER(MEDIPLUS)-NELATON CATHETERS ARE INTENDED TO BE USED TO PROVIDE AN INTERMITTENT PATHWAY FOR SHORT TERM DRAINAGE OF FLUIDS FROM THE BLADDER.,BLOOD TRANSFUSION SET (MEDIPLUS)-USED FOR INFUSION OF BLOOD IN THE BODY PASS THROUGH VEIN PUNCTURE. ,FEMALE CATHETER(MEDIPLUS)- FEMALE CATHETERS ARE INTENDED TO BE USED TO PROVIDE AN INTERMITTENT PATHWAY FOR SHORT TERM DRAINAGE OF FLUIDS FROM THE BLADDER.,INSULIN SYRINGE (MEDIPLUS)-IT IS USED TO INJECT INSULIN IN BODY. ,AV FISTULA NEEDLE(MEDIPLUS)-USE FOR TEMPORARY CANNULATION FOR VASCULAR ACCESS FOR EXTRACORPOREAL BLOOD TREATMENT. THIS DEVICE IS INTENDED TO SINGLE USE ONLY AND IS FOR TEMPORARY CATHETERIZATION LESS THAN 30 DAYS. THE SAFETY FEATURE (FOLDABLE WING AND WING EATER) AIDS IN PREVENTION OF NEEDLE STICK INJURY WHEN REMOVING AND DISCARDING NEEDLE AFTER DIALYSIS SESSION., MALE EXTERNAL CATHETER(MEDIPLUS)-IT IS USE FOR URINE INCONTINENCE FOR DAY AND NIGHT USE IN A MALE PATIENT & IS CONNECTED TO URINE BAG,ABDOMINAL DRAIN KIT(MEDIPLUS)-INTENDED FOR THE USE IN POST-OPERATIVE DRAINAGES FROM ABDOMINAL AREAS.,SUCTION CATHETER CLOSED SYSTEM

	(MEDIPLUS)-USED TO MAINITAIN VENTILATION AND OXYGEN THERAPY WHILE SUCTIONING IN MECHANICALLY VENTILATED PATIENTS.,STAPLER REMOVER(MEDIPLUS)-OUR DESIGNED REMOVER FOR SKIN STAPLER IS SPECIALLY USED FOR THE REMOVING OF SKIN STAPLES WITH THE FEATURE EASY STRUCTURE AND NOVEL APPEARANCE.,IV CANNULA FIXATOR(MEDIPLUS)-U SHAPED DESIGN TO SECURE THE I. V. CANNULA IN PLACE.,INJECTION STOPPER (MEDIPLUS)-USED WITH I V CANNULA TO STOP FLUID FROM FLOWING,PERITONEAL TRANSFUSION DIALYSIS KIT(MEDIPLUS)-ITS USED FOR DIALYSIS FAILURE TREATMENT. ,PRESSURE MONITORING LINE(MEDIPLUS)-FOR HIGH PRESSURE MONITORING & FOR CONNECTION BETWEEN SYRINGE INFUSION PUMP & PATIENT.,INFANT MUCUS EXTRACTOR(MEDIPLUS)-USED FOR ASPIRATION OF SECRETION FROM OROPHARYNX IN NEWLY BORN BABIES AND TO ENSURE FREE RESPIRATION,ENDOTRACHEAL TUBE (ALL TYPE) (MEDIPLUS)-ENDOTRACHEAL TUBE IS USED IN GENERAL ANAESTHESIA, INTENSIVE CARE AND EMERGENCY MEDICINE FOR AIRWAY MANAGEMENT AND MECHANICAL VENTILATION. THE TUBE IS INSERTED INTO A PATIENT'S TRACHEA THROUGH THE PATIENT'S NOSE OR MOUTH IN ORDER TO ENSURE THAT THE AIRWAY IS NOT CLOSED OFF AND THAT AIR IS ABLE TO REACH THE LUNGS., UMBILICAL CORD CLAMP(MEDIPLUS)-UMBILICAL CORD CLAMP INTENDED USE IS TO CLAMP OVER THE NEWBORN INFANTS UMBILICAL CORD AT DELIVERY AND PREVENT BLOOD LOSS AS THE CORD DRIED AND SHRINKS AFTER THE BIRTH.,BREATHING FILTER (MEDIPLUS)-BREATHING SYSTEM FILTER MUST BE USED FOR EACH PATIENT DURING ANESTHESIA INTENDED TO PROTECT A PATIENT FROM INHALING INFECTIVE AND HAZARDOUS PARTICLE,INFUSION SET(MEDIPLUS)-USED FOR INFUSION OF LIQUID IN THE BODY PASS THROUGH VEIN PUNCTURE.,TRACHEOSTOMY TUBE(MEDIPLUS)-USED TO MAINTAIN A PATENT AIRWAY THROUGH TRACHEOSTOMY AND MECHANICALLY VENTILATE PATIENTS.,IV FLOW REGULATOR (MEDIPLUS)-PRECISE FLOW RATE CONTROL OF I.V. FLUIDS WITH RANGE OF 5 TO 25ML /HR, IT IS USED WITH IV SET.,UMBILICAL CATHETER(MEDIPLUS)-USED FOR INTERMITTENT OR CONTINUOUS ACCESS TO THE UMBILICAL ARTERY OR VEIN OF NEW BORN OR PREMATURE INFANTS TO ADMINISTER FLUID & TRANSFUSION,REDON DRAIN CATHETER(MEDIPLUS)-THE CROSS PERFORATED DRAIN ARE SUITABLE FOR USE WITH HIGH VACCUM WOUND DRAINAGE SYSTEM FOR POST-OPERATIVE WOUND DRAINAGE (IN MEDICAL DRAINAGE REFER TO THE SYSTEMIC WITHDRAWAL OF INCREASE OR DISEASED FLUID, GASES AND DISCHARGES TO RE-ESTABLISH NORMAL CONDITION),STOMACH TUBE(MEDIPLUS)-STOMACH TUBE SPECIALLY DESIGNED FOR NASO-GASTRIC INTRODUCTION FOR NUTRITIONAL

	PURPOSES AND ASPIRATION OF INTESTINAL SECRETIONS.,BONE MARROW BIOPSY NEEDLE(MEDIPLUS)-DEVICES ARE MANUAL, STERILE, DISPOSABLE NEEDLES INTENDED TO OBTAIN BONE MARROW ASPIRATE AND CORE BIOPSY SAMPLES FROM BONE AND/OR BONE MARROW.,SKIN STAPLER(MEDIPLUS)-SKIN STAPLER IS INTENDED TO BE USED FOR SKIN CLOSURE OF WOUNDS, INCISIONS OR LACERATIONS OF THE EPIDERMIS.,EPIDURAL CATHETER (MEDIPLUS)-THE CATHETER ALLOWS ACCESS TO THE EPIDURAL SPACE TO INJECT MEDICATION SUCH AS LOCAL ANESTHETICS AND/OR NARCOTICS FOR RELIEF OF PAIN.,NASOGASTRIC TUBE (MEDIPLUS)-A NASOGASTRIC TUBE (NG TUBE) IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE.,BIOPSY NEEDLE(MEDIPLUS)-MEDI- CUT BIOPSY NEEDLES ARE DESIGNED FOR MANUAL CAPTURE OF HIGH-QUALITY TISSUE SAMPLES WITH MINIMAL TRAUMA TO PATIENT.,DOUBLE J STENTS (ALL TYPE)(MEDIPLUS)-A THIN, HOLLOW TUBE PLACED INSIDE THE URETER DURING SURGERY TO ENSURE DRAINAGE OF URINE FROM THE KIDNEY INTO THE BLADDER. J SHAPED CURLS ARE PRESENT AT BOTH ENDS TO HOLD THE TUBE IN PLACE AND PREVENT MIGRATION., EPIDURAL NEEDLE (ALL TYPE)(MEDIPLUS)-IT'S AN INJECTION THAT GOES INTO YOUR “EPIDURAL SPACE,” WHICH IS RIGHT OUTSIDE OF THE MEMBRANE THAT PROTECTS YOUR SPINAL CORD.,MEASURED VOLUME BURETTE SET(MEDIPLUS)-MEASURED VOLUME BURETTE SET WITH A WELL-MARKED DRIP CHAMBER FOR PRECISE FLUID ADMINISTRATION,DISPOSABLE SYRINGE (ALL TYPE)(MEDIPLUS)-IT IS USED BY A DOCTOR TO INJECT THE MEDICINE THROUGH INTRAVENOUS OR INTRA MUSCULAR VEIN FOR TREATMENT OF DISEASE.,MULTIPLE LUMEN CATHETER (ALL TYPE)(MEDIPLUS)-MULTIPLE LUMEN IS A POLYURETHANELUMENS CATHETER WHICH IS INTENDED TO INSERT INTO THE PATIENT'S VASCULAR SYSTEM FOR SHORT TERM USE (LESS THAN 30 DAYS) TO SAMPLE BLOOD, MONITOR BLOOD PRESSURE, OR ADMINISTER FLUIDS INTRAVENOUSLY. ,HAEMODIALYSIS CATHETER (ALL TYPE) (MEDIPLUS)-HEMODIALYSIS IS A TREATMENT USED WHEN YOUR KIDNEYS FAIL (STAGE 5 KIDNEY DISEASE) AND CAN NO LONGER CLEAN YOUR BLOOD AND REMOVE EXTRA FLUID FROM YOUR BODY. A HEMODIALYSIS ACCESS OR VASCULAR ACCESS IS A WAY TO REACH YOUR BLOOD FOR HEMODIALYSIS. ,RECTAL CATHETER (MEDIPLUS)-FOR INTRODUCTION OF ENEMA SOLUTION INTO RECTUM TO RELEASE/ASPIRE RECTAL FLUID.,CLOSE WOUND SUCTION UNIT (MEDIPLUS)-USED DURING SURGERY BY DOCTOR FOR CLOSED WOUND DRAINAGE UNDER NEGATIVE PRESSURE POST OPERATIVELY WITH OPTION TO USE ONE CATHETER OR TWO CATHETERS SIMULTANEOUSLY,TUR SET(MEDIPLUS)-USED IN IRRIGATION DURING

	TRANS URETHRAL RESECTION OF PROSTATE GLAND

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3546	MFG/MD/2020/000193	1.License Holder Name: V R ORTHO 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE NAIL.(NA)-INDICATIONS FOR INTERLOCKING NAILS INCLUDE SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL-UNIONS; AND BONE LENGTHENING/SHORTENING. FEMORAL INTERLOCKING NAILS INCLUDE THE INDICATION FOR PROXIMAL, MIDDLE AND DISTAL THIRD FEMORAL SHAFT FRACTURES. TIBIAL INTERLOCKING NAILS ALSO INCLUDE THE SAME INDICATIONS FOR TIBIAL SHAFT FRACTURES. HUMERAL INTERLOCKING NAILS ARE INDICATED FOR HUMERAL SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL-UNIONS, PROXIMAL, MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES; HUMERUS RECONSTRUCTION, FOLLOWING TUMOR RESECTION AND GRAFTING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. R/U INTERLOCKING NAILS ARE INDICATED FOR RADIAL AND ULNAR SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; PROXIMAL MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES. INTERLOCKING RECONSTRUCTION NAILS ARE INDICATED FOR THE FOLLOWING: SUBTROCHANTERIC FRACTURES WITH LESSER TROCHANTERIC INVOLVEMENT; IPSILATERAL FEMORAL SHAFT/NECK FRACTURES; SEVERELY COMMINUTED SHAFT FRACTURES; FEMUR RECONSTRUCTION FOLLOWING TUMO RESECTION AND GRAFTING; BONE SHORTENING/LENGTHENING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. RETROGRADE NAILS ARE INDICATED FOR SHAFT FRACTURES INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; BONE LENGTHENING/SHORTENING; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; FRACTURES IN OSTEOPOROTIC BONE; SEVERELY COMMINUTED SHAFT FRACTURES; PATHOLOGIC FRACTURES, PSEUDOARTHROSIS, FAILED OSTEOSYNTHESIS; CLOSED SUPRACONDYLAR FRACTURES; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. ADDITIONAL INDICATIONS FOR RETROGRADE NAILS INCLUDE: SEVERELY COMMINUTED SUPRACONDYLAR FRACTURES WITH OR WITHOUT DIFFICULT INTRA-ARTICULAR EXTENSION, FRACTURES THAT REQUIRE OPENING THE KNEE JOINT TO STABILIZE THE FEMORAL CONDYLAR SEGMENT. K-NAIL IS INDICATED FOR TIBIA, FEMUR AND HUMREUS SHAFT

	FRACTURE. GAM NAIL IS INDICATED FOR SUBTROCHANTERIC FRACTURE. ELASTIC NAIL (FLEXIBLE NAIL) IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ENDER'S NAIL IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ANKLE ARTHODESIS NAIL IS INDICATED FOR FOOT AND ANKLE FRACTURE. D-IMSC LOCKED NAIL IS INDICATED FOR SUPRACONDYLAR FRACTURE. INTERLOCKING NAIL CAP, NAIL PLUG SAFETY STAR DRIVE (GAM NAIL CAP), INTERLOCKING GUIDE WIRE-SIMPLE AND INTERLOCKING GUIDE WIRE-OLIVE TIP (BALL TIP) ARE INDICATED FOR NAIL AND BONE FIXATION.,BONE PLATES.(NA)-BONE PLATES INTENDED TO BE ATTACHED TO FRACTURED LONG BONE FRAGMENT WITH SCREW TO BRIDGE AND STABILIZE THE FRACTURE GAP, AND SHIELD THE SITE FROM STRESS AS THE BONE HEALS. IT MAY ALSO BE USED TO TEMPORARILY AUGMENT BONE FOLLOWING A LENGTHENING PROCEDURE, OR FOR ARTHRODESIS.,BONE PLATES.. (NA)-BONE PLATES INTENDED TO BE ATTACHED TO FRACTURED LONG BONE FRAGMENT WITH SCREW TO BRIDGE AND STABILIZE THE FRACTURE GAP, AND SHIELD THE SITE FROM STRESS AS THE BONE HEALS. IT MAY ALSO BE USED TO TEMPORARILY AUGMENT BONE FOLLOWING A LENGTHENING PROCEDURE, OR FOR ARTHRODESIS., BONE SCREW..(NA)-BONE SCREWS INTENDED FOR USE IN INTERNAL FIXATION OF BONES AFFECTED BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. SCREWS ALONG WITH PLATES, NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC, SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE OF SO MANY DIFFERENT TYPES E.G. (LOCKED SCREWS, LOCKING BOLTS ETC.)., BONE NAIL..(NA)-INDICATIONS FOR INTERLOCKING NAILS INCLUDE SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL-UNIONS; AND BONE LENGTHENING/SHORTENING. FEMORAL INTERLOCKING NAILS INCLUDE THE INDICATION FOR PROXIMAL, MIDDLE AND DISTAL THIRD FEMORAL SHAFT FRACTURES. TIBIAL INTERLOCKING NAILS ALSO INCLUDE THE SAME INDICATIONS FOR TIBIAL SHAFT FRACTURES. HUMERAL INTERLOCKING NAILS ARE INDICATED FOR HUMERAL SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL-UNIONS, PROXIMAL, MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES; HUMERUS RECONSTRUCTION, FOLLOWING TUMOR RESECTION AND GRAFTING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. R/U INTERLOCKING NAILS ARE INDICATED FOR RADIAL AND ULNAR SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; PROXIMAL MIDDLE AND

	DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES. INTERLOCKING RECONSTRUCTION NAILS ARE INDICATED FOR THE FOLLOWING: SUBTROCHANTERIC FRACTURES WITH LESSER TROCHANTERIC INVOLVEMENT; IPSILATERAL FEMORAL SHAFT/NECK FRACTURES; SEVERELY COMMINUTED SHAFT FRACTURES; FEMUR RECONSTRUCTION FOLLOWING TUMO RESECTION AND GRAFTING; BONE SHORTENING/LENGTHENING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. RETROGRADE NAILS ARE INDICATED FOR SHAFT FRACTURES INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; BONE LENGTHENING/SHORTENING; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; FRACTURES IN OSTEOPOROTIC BONE; SEVERELY COMMINUTED SHAFT FRACTURES; PATHOLOGIC FRACTURES, PSEUDOARTHROSIS, FAILED OSTEOSYNTHESIS; CLOSED SUPRACONDYLAR FRACTURES; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. ADDITIONAL INDICATIONS FOR RETROGRADE NAILS INCLUDE: SEVERELY COMMINUTED SUPRACONDYLAR FRACTURES WITH OR WITHOUT DIFFICULT INTRA-ARTICULAR EXTENSION, FRACTURES THAT REQUIRE OPENING THE KNEE JOINT TO STABILIZE THE FEMORAL CONDYLAR SEGMENT. K-NAIL IS INDICATED FOR TIBIA, FEMUR AND HUMREUS SHAFT FRACTURE. GAM NAIL IS INDICATED FOR SUBTROCHANTERIC FRACTURE. ELASTIC NAIL (FLEXIBLE NAIL) IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ENDER'S NAIL IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ANKLE ARTHODESIS NAIL IS INDICATED FOR FOOT AND ANKLE FRACTURE. D-IMSC LOCKED NAIL IS INDICATED FOR SUPRACONDYLAR FRACTURE. INTERLOCKING NAIL CAP, NAIL PLUG SAFETY STAR DRIVE (GAM NAIL CAP), INTERLOCKING GUIDE WIRE-SIMPLE AND INTERLOCKING GUIDE WIRE-OLIVE TIP (BALL TIP) ARE INDICATED FOR NAIL AND BONE FIXATION.,BONE SCREW.(NA)-BONE SCREWS INTENDED FOR USE IN INTERNAL FIXATION OF BONES AFFECTED BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. SCREWS ALONG WITH PLATES, NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC, SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE OF SO MANY DIFFERENT TYPES E.G. (LOCKED SCREWS, LOCKING BOLTS ETC.).

3547	MFG/MD/2020/000194	1.License Holder Name: PROMINENCE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use: COTTON CREPE BANDAGE B.P.-COTTON CREPE BANDAGE IS USED IN THE TREATMENT OF SPRAINS, AND STRAINS AND IN OTHER CONDITIONS IN WHICH LIGHT SUPPORT IS REQUIRED. IT MAY BE USED FOR THIS PURPOSE IN CONJUNCTION WITH OTHER SURGICAL APPLIANCES. IT IS ALSO USED FOR CORRECTIONAL PURPOSE.,PERFORATED TRANSPARENT SURGICAL TAPE (PERMEABLE PLASTIC SYNTHETIC ADHESIVE TAPE B.P.)-FOR SECURING BULKY DRESSINGS & DEVICES., TRANSPARENT IV DRESSING-FOR SECURING IV CANNULA IN CASES WHERE LONG TERM USE IS REQUIRED. THE TRANSPARENT PU FILM OF WHICH THIS DRESSING IS MADE OF, ALLOWS REGULAR INSPECTION OF THE CANNULA INSERTION SITE FOR SIGNS OF INFECTION OR PHLEBITIS.,ADHESIVE NON-WOVEN DRESSING TAPE (PERMEABLE NON WOVEN SYNTHETIC ADHESIVE TAPE B. P.)-TO SECURE ANY KIND OF SURGICAL & DRESSING MATERIAL ON FRAGILE SKIN..,PLASTER OF PARIS BANDAGE-FOR IMMOBILIZATION OF ALL TYPES OF SIMPLE & COMPOUND FRACTURES, FOR TREATMENT OF DISLOCATION OF HIP, OTHER ORTHOPAEDIC FRACTURES, SPLIT, SOFT TISSUE INJURIES, SPINAL TUBERCULOSIS & TRAUMA, FOR BONE, JOINT CORRECTION & PREVENTION OF DEFORMITIES,ELASTIC ADHESIVE BANDAGE IV DRESSING (ELASTIC ADHESIVE BANDAGE BP) -IT IS USED TO PROVIDE BREATHABLE AND AGGRESSIVE FIXATION OF DRESSING TO SECURE IV CANNULA AND OTHER INTRAMUSCULAR CATHETERS AND PER CUTANEOUS DEVICES TO THE SKIN., MICROPOROUS NON-WOVEN SURGICAL TAPE (PERMEABLE NON-WOVEN SYNTHETIC ADHESIVE TAPE BP)-USED TO SECURE DRESSING MATERIALS TO SKIN ESPECIALLY RECOMMENDED FOR BABIES AND ELDERLY PATIENTS WITH FRAGILE OF DRY SKIN, AND FOR PATIENTS UNDERGOING RADIATION TREATMENTS.,ELASTIC ADHESIVE BANDAGE B.P.-IDEAL BANDAGE FOR SUPPORT STRAPPING FRACTURES, MUSCLES INJURIES, ELBOWS, KNEES, SHOULDERS SPECIALLY REQUIRING ELASTICITY. IT IS ALSO USED FOR CORRECTIONAL PURPOSES.,CORN CAP-CORN CAP IS USED FOR EFFECTIVE TREATMENT OF CORNS.,ORTHOPAEDIC CAST PADDING-IT IS USED IN PROVIDING CUSHION (LINER) UNDER THE SYNTHETIC CAST OR PLASTER OF PARIS BANDAGE.,BELLADONNA PLASTER-FOR THE RELIEF OF ACHES AND PAINS, SUCH AS - MUSCULAR TENSION AND STRAIN, STIFF NECK AND ACHING SHOULDERS, SCIATICA, LUMBAGO, RHEUMATISM, BACKACHE,KINESIOLOGY TAPE-KINESIOLOGY TAPE PROVIDES DRAMATIC PAIN RELIEF FROM SEVERAL SPRAINS AND INJURIES. USERS WILL SEE INSTANT IMPROVEMENT IN PERFORMANCE IN PHYSICAL ACTIVITIES WITH

		ADDED SUPPORT AND BLOOD FLOW.,FIRST AID PLASTER (MEDICATED DRESSING)-IT IS USED IN PROVIDING FIRST PROTECTION TO SUPERFICIAL INJURIES, MINOR CUTS AND BRUISES, EXUDATES ABSORPTION,IV DRESSING-FOR PROVIDING BREATHABLE AND QUICK FIXATION DRESSING TO SECURE IV CANNULA AND OTHER INTRAMUSCULAR CATHETERS AND PER CUTANEOUS DEVICES TO THE SKIN.,CAPSICUM PLASTER-CAPSICUM PLASTER IS A PAIN RELIEF PATCH FOR EXTERNAL USE; IT CONTAINS EXTRACT OF CAPSICUM WHICH IS EFFECTIVE IN RELIEVING RHEUMATISM, ALSO EFFECTIVE FOR MUSCULAR FATIGUE, LUMBAGO, BACK PAIN AND STIFF SHOULDERS.,ADHESIVE TAPE USP (ZINC OXIDE PLASTER)-TO SECURE DRESSING MATERIAL TO SKIN
3548	MFG/MD/2020/000196	1.License Holder Name: OSSEOUS SURGICALS 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ARTHROSCOPY IMPLANTS(- - -)-THE ARTHROSCOPY IMPLANTS ARE SMALLER THAN TRADITIONAL INSTRUMENTS. SURGEONS VIEW THE JOINT AREA ON A VIDEO MONITOR, AND CAN DIAGNOSE AND REPAIR TORN JOINT TISSUE, SUCH AS LIGAMENTS. IT IS TECHNICALLY POSSIBLE TO DO AN ARTHROSCOPIC EXAMINATION OF ALMOST EVERY JOINT, BUT IS MOST COMMONLY USED FOR THE KNEE, SHOULDER, ELBOW, WRIST, ANKLE, FOOT, AND HIP. CLASS OF MEDICAL DEVICE,SPINE IMPLANTS (CERVICAL,THORACIC & LUMBER)(- - -)-SPINE IMPLANTS (CERVICAL, THORACIC & LUMBER) IS USED FOR THE SPINE FRACTURE,BONE SCREW(- - -)-TO JOIN TWO BROKEN BONES,NAIL(- - -)-TO FIX TWO BROKEN BONES,WIRE AND PINS(- - -)-TO JOIN TWO BROKEN BONES, ARTHROSCOPY IMPLANTS(- - -)-THE ARTHROSCOPY IMPLANTS ARE SMALLER THAN TRADITIONAL INSTRUMENTS. SURGEONS VIEW THE JOINT AREA ON A VIDEO MONITOR, AND CAN DIAGNOSE AND REPAIR TORN JOINT TISSUE, SUCH AS LIGAMENTS. IT IS TECHNICALLY POSSIBLE TO DO AN ARTHROSCOPIC EXAMINATION OF ALMOST EVERY JOINT, BUT IS MOST COMMONLY USED FOR THE KNEE, SHOULDER, ELBOW, WRIST, ANKLE, FOOT, AND HIP. CLASS OF MEDICAL DEVICE,BONE PLATES(- -)-TO JOIN THE TWO BROKEN BONES,NAIL(---)-TO FIX THE TWO BROKEN BONES,BONE SCREW(- - -)-TO JOIN TWO BROKEN BONES,WIRE AND PINS(- - -)-TO JOIN THE TWO BROKEN BONES,SPINE IMPLANTS (CERVICAL,THORACIC & LUMBER)(- -)-SPINE IMPLANTS (CERVICAL,THORACIC & LUMBER) IS USED FOR THE SPINE INJURY ,BONE PLATES(- - -)-TO JOIN THE TWO BROKEN BONES

3549	MFG/MD/2020/000197	1.License Holder Name: LIFE ORTHO CARE 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ACETABULAR CUP (ACETALIFE LINER)-ANY DISEASE OF THE HIP JOINT CAUSED BY DEGENERATION OR CONGENITAL DISORDERS, INFLAMMATORY OR POST-TRAUMATIC AFFECTION, CONSEQUENCES OF PREVIOUS INTERVENTIONS, TOTAL HIP REPLACEMENT & OSTEOTOMY. • FEMORAL HEAD NECROSIS. • RHEUMATOID ARTHRITIS. • TREATMENT OF FEMORAL NECK FRACTURES. • TREATMENT OF TROCHANTERIC FRACTURES OF HIP. • OSTEOARTHRITIS. • OSTEONECROSIS. • HIP DYSPLASIA.,MULLER STEM(MULIFE)-ANY DISEASE OF THE HIP JOINT CAUSED BY DEGENERATION OR CONGENITAL DISORDERS, INFLAMMATORY OR POST-TRAUMATIC AFFECTION, CONSEQUENCES OF PREVIOUS INTERVENTIONS, TOTAL HIP REPLACEMENT & OSTEOTOMY. • FEMORAL HEAD NECROSIS. • RHEUMATOID ARTHRITIS. • TREATMENT OF FEMORAL NECK FRACTURES. • TREATMENT OF TROCHANTERIC FRACTURES OF HIP. • OSTEOARTHRITIS. • OSTEONECROSIS. • HIP DYSPLASIA., FENESTRATED BIPOLAR(LIFE FENESTRATED BIPOLAR)-ANY DISEASE OF THE HIP JOINT CAUSED BY DEGENERATION OR CONGENITAL DISORDERS, INFLAMMATORY OR POST-TRAUMATIC AFFECTION, CONSEQUENCES OF PREVIOUS INTERVENTIONS, TOTAL HIP REPLACEMENT & OSTEOTOMY. • FEMORAL HEAD NECROSIS. • RHEUMATOID ARTHRITIS. • TREATMENT OF FEMORAL NECK FRACTURES. • TREATMENT OF TROCHANTERIC FRACTURES OF HIP. • OSTEOARTHRITIS. • OSTEONECROSIS. • HIP DYSPLASIA,CPT STEM (LIFE BI - TAPER STEM)-ANY DISEASE OF THE HIP JOINT CAUSED BY DEGENERATION OR CONGENITAL DISORDERS, INFLAMMATORY OR POST-TRAUMATIC AFFECTION, CONSEQUENCES OF PREVIOUS INTERVENTIONS, TOTAL HIP REPLACEMENT & OSTEOTOMY. • FEMORAL HEAD NECROSIS. • RHEUMATOID ARTHRITIS. • TREATMENT OF FEMORAL NECK FRACTURES. • TREATMENT OF TROCHANTERIC FRACTURES OF HIP. • OSTEOARTHRITIS. • OSTEONECROSIS. • HIP DYSPLASIA.,FIXED NECK BIPOLAR(LIFE BIPOLAR)-ANY DISEASE OF THE HIP JOINT CAUSED BY DEGENERATION OR CONGENITAL DISORDERS, INFLAMMATORY OR POST-TRAUMATIC AFFECTION, CONSEQUENCES OF PREVIOUS INTERVENTIONS, TOTAL HIP REPLACEMENT & OSTEOTOMY. • FEMORAL HEAD NECROSIS. • RHEUMATOID ARTHRITIS. • TREATMENT OF FEMORAL NECK FRACTURES. • TREATMENT OF TROCHANTERIC FRACTURES OF HIP. • OSTEOARTHRITIS. • OSTEONECROSIS. • HIP DYSPLASIA. ,MODULAR STEM(MODULIFE)-ANY DISEASE OF THE HIP JOINT CAUSED BY DEGENERATION OR CONGENITAL DISORDERS, INFLAMMATORY OR

		POST-TRAUMATIC AFFECTION, CONSEQUENCES OF PREVIOUS INTERVENTIONS, TOTAL HIP REPLACEMENT & OSTEOTOMY. • FEMORAL HEAD NECROSIS. • RHEUMATOID ARTHRITIS. • TREATMENT OF FEMORAL NECK FRACTURES. • TREATMENT OF TROCHANTERIC FRACTURES OF HIP. • OSTEOARTHRITIS. • OSTEONECROSIS. • HIP DYSPLASIA.,INTERNAL HEAD(LIFE INTERNAL HEAD)-ANY DISEASE OF THE HIP JOINT CAUSED BY DEGENERATION OR CONGENITAL DISORDERS, INFLAMMATORY OR POST-TRAUMATIC AFFECTION, CONSEQUENCES OF PREVIOUS INTERVENTIONS, TOTAL HIP REPLACEMENT & OSTEOTOMY. • FEMORAL HEAD NECROSIS. • RHEUMATOID ARTHRITIS. • TREATMENT OF FEMORAL NECK FRACTURES. • TREATMENT OF TROCHANTERIC FRACTURES OF HIP. • OSTEOARTHRITIS. • OSTEONECROSIS. • HIP DYSPLASIA.,FEMORAL CEMENT RESTRICTOR(LIFE POLYCURB)-ANY DISEASE OF THE HIP JOINT CAUSED BY DEGENERATION OR CONGENITAL DISORDERS, INFLAMMATORY OR POST-TRAUMATIC AFFECTION, CONSEQUENCES OF PREVIOUS INTERVENTIONS, TOTAL HIP REPLACEMENT & OSTEOTOMY. • FEMORAL HEAD NECROSIS. • RHEUMATOID ARTHRITIS. • TREATMENT OF FEMORAL NECK FRACTURES. • TREATMENT OF TROCHANTERIC FRACTURES OF HIP. • OSTEOARTHRITIS. • OSTEONECROSIS. • HIP DYSPLASIA.,MODULAR CUP(MODULIFE CUP)-ANY DISEASE OF THE HIP JOINT CAUSED BY DEGENERATION OR CONGENITAL DISORDERS, INFLAMMATORY OR POST-TRAUMATIC AFFECTION, CONSEQUENCES OF PREVIOUS INTERVENTIONS, TOTAL HIP REPLACEMENT & OSTEOTOMY. • FEMORAL HEAD NECROSIS. • RHEUMATOID ARTHRITIS. • TREATMENT OF FEMORAL NECK FRACTURES. • TREATMENT OF TROCHANTERIC FRACTURES OF HIP. • OSTEOARTHRITIS. • OSTEONECROSIS. • HIP DYSPLASIA.
3550	MFG/MD/2020/000198	1.License Holder Name: LAXMI HEALTH CARE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:COTTON CREPE BANDAGE (PERFECT CARE)-USED AS A COMPRESSION BANDAGE FOR ALL CHRONIC LEG CONDITIONS, VARICOSE VEINS AND THEIR AFTER-CARE AS A PRESSURE DRESSING FOR BURNS, FOR SKIN GRAFTS AND WHEREVER ELASTIC SUPPORTS IS REQUIRED FOR TREATMENT FOR STRAINS, AND SIMILAR CONDITIONS

3551	MFG/MD/2020/000199	1.License Holder Name: VAIBHAVI ENTERPRISES 2.Approving Authority: AURANGABAD DIVISION 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL IP (COTTON ROLL)(COTTONY)-USED FOR MEDICAL PURPOSES/SURGICAL DRESSINGS IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST-AID),ABSORBENT COTTON WOOL IP (ZIG-ZAG)(COTTONY)-USED FOR MEDICAL PURPOSES/SURGICAL DRESSINGS IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST-AID)

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3552	MFG/MD/2020/000200	1.License Holder Name: FUTURA SURGICARE PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:ABSORBABLE SURGICAL SUTURE POLYGLYCOLIC ACID STERILIZED SURGICAL SUTURE (SYNTHETIC)(PETCRYL AND OTHER OEM BRANDS.)-POLYGLYCOLIC ACID SUTURE ARE INDICATED FOR USE IN GENERAL, SOFT TISSUE INCLUDING USE IN OPHTHALMIC. BUT NOT FOR USE IN CARDIO VASCULAR & NEUROLOGICAL TISSUES. THIS SUTURE BEING ABSORBABLE SHOULD NOT BE USED WHERE EXTENDED APPROXIMATION OF TISSUE IS REQUIRED.,MONOFILAMENT POLYAMIDE, NON ABSORBABLE SURGICAL SUTURE.(LINEX AND OTHER OEM BRANDS.)-IT IS INTENDED FOR TISSUE APPROXIMATION AND LIGATION.,ABSORBABLE STERILIZED SURGICAL POLYGLYCOLIC ACID SUTURE ANTIBACTERIAL WITH TRICLOSAN COATED SUTURE (PETCRYL AB AND OTHER OEM BRANDS.)-COATED & BRAIDED POLYGLYCOLIC ACID SUTURE ANTIBACTERIAL WITH TRICLOSAN. ARE INDICATED FOR USE IN GENERAL AND SOFT TISSUE APPROXIMATION. BUT NON FOR USE IN CARDIO VASCULAR, OPHTHALMIC & NEUROLOGICAL TISSUES. THIS SUTURE BEING ABSORBABLE SHOULD NOT BE USED WHERE EXTENDED APPROXIMATION OF TISSUE IS REQUIRED.,COATED AND BRAIDED POLYGLACTIN 910, SUTURE, ABSORBABLE SURGICAL SUTURE. ANTIBACTERIAL WITH CHLORHEXIDINE.(PETCRYL CS AND OTHER OEM BRANDS.)-POLYGLACTIN 910 NEEDLED WITH CHLORHEXIDINE SUTURE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/ OR LIGATION ACROSS SUITABLE SURGERY TYPES.,MONOFILAMENT POLYDIOXANONE SUTURE, ABSORBABLE SURGICAL SUTURE. ANTIBACTERIAL WITH TRICLOSAN.-IT IS INTENDED FOR SOFT TISSUE APPROXIMATION AFTER A SURGICAL PROCEDURE.,COATED AND BRAIDED POLYESTER, NON ABSORBABLE SURGICAL SUTURE.(PROCARE AND OTHER OEM BRANDS.)-IT IS INTENDED FOR TISSUE APPROXIMATION AND LIGATION.,POLYMER LIGATION CLIPS, NON ABSORBABLE.(POLYLOC & OTHER OEM BRANDS.)-POLYMER LIGATING CLIPS ARE INTENDED FOR USE IN OPEN AND LAPAROSCOPIC CASE APPLICATION PROCEDURES INVOLVING LIGATION OF VESSELS OR TISSUE STRUCTURES. SURGEONS SHOULD APPLY THE APPROPRIATE SIZE CLIP FOR THE SIZE OF THE VESSEL OR TISSUE STRUCTURE TO BE LIGATED SUCH THAT THE CLIP COMPLETELY ENCOMPASSES THE VESSEL OR TISSUE STRUCTURE.,ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE WITH POLYESTER SUTURE, NON ABSORBABLE SURGICAL SUTURE.-IT IS INTENDED FOR TISSUE APPROXIMATION.,SURGICAL SKIN STAPLER.(DURAMATE, DERMAMATE, DERMAMATE ECO AND OTHER OEM BRANDS.)-SKIN STAPLER HAS THE APPLICATION IN SKIN

	CLOSURE.,TITANIUM LIGATION CLIPS, NON ABSORBABLE-TITANIUM LIGATING CLIPS ARE INTENDED FOR USE IN CARDIOVASCULAR AND GENERAL SURGERY APPLICATIONS PROCEDURES INVOLVING LIGATION OF VESSELS OR TISSUE STRUCTURES. SURGEONS SHOULD APPLY THE APPROPRIATE SIZE CLIP FOR THE SIZE OF THE VESSEL OR TISSUE STRUCTURE TO BE LIGATED SUCH THAT THE CLIP COMPLETELY ENCOMPASSES THE VESSEL OR TISSUE STRUCTURE., CATGUT CHROMIC, ABSORBABLE SURGICAL SUTURE.-CATGUT CHROMIC SUTURE IS SUITABLE FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN GENERAL CLOSURE, OPHTHALMIC, ORTHOPAEDICS, OBSTETRICS/GYNAECOLOGY , GASTROINTESTINAL TRACT SURGERY.,COATED AND BRAIDED POLYGLACTIN 910, SUTURE, ABSORBABLE SURGICAL SUTURE.(PETCRYL 910, PETCRYL 910 FAST & OTHER OEM BRANDS.)-POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,CATGUT PLAIN, ABSORBABLE SURGICAL SUTURE. (PROGUT & OTHER OEM BRANDS.)-CATGUT PLAIN SUTURE IS SUITABLE FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN GENERAL CLOSURE, OPHTHALMIC, ORTHOPAEDICS, OBSTETRICS/GYNAECOLOGY , GASTROINTESTINAL TRACT SURGERY.,MONOFILAMENT POLYTETRAFLUOROETHYLENE SUTURE, NON ABSORBABLE SURGICAL SUTURE.(TEFLENE AND OTHER OEM BRANDS.)-POLYTETRA FLUORO ETHYLENE IS SUITABLE FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,COMPOSITE MESH COMPOSED OF POLYPROPYLENE AND LOW DENSITY POLYETHYLENE. NON ABSORBABLE.(DUOLENE MESH AND OTHER OEM BRANDS.)-COMPOSITE MESH IS INDICATED FOR USE IN THE RECONSTRUCTION OF SOFT TISSUE DEFICIENCIES, SUCH AS FOR THE REPAIR OF HERNIAS AND CHEST WALL DEFECTS.,BLACK BRAIDED SILK. NON ABSORBABLE SURGICAL SUTURE.(SUTURA & OTHER OEM BRANDS.)-SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION IN ALL SURGICAL PROCEDURES EXCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,CATGUT CHROMIC, ABSORBABLE SURGICAL SUTURE.(PROGUT & OTHER OEM BRANDS.)-CATGUT CHROMIC SUTURE IS SUITABLE FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN GENERAL CLOSURE, OPHTHALMIC, ORTHOPAEDICS, OBSTETRICS/GYNAECOLOGY , GASTROINTESTINAL TRACT SURGERY.,OXIDIZED REGENERATED CELLULOSE. HEMOSTAT. (HEMOSTAX, INSEAL AND OTHER OEM BRANDS.)-THE PRODUCT IS INTENDED TO PROMOTE CLOTTING DURING SURGERY. IT IS USED IN

	VARIOUS SURGERIES LIKE LAPAROSCOPIC PARTIAL NEPHRECTOMY, GALLBLADDER BED AND IN MINOR SPLENIC INJURY, TO CONTROL HEMORRHAGE FROM AN EDEMATOUS, FRAGILE MUCOSA AND SKIN EDGE AT THE PERIPHERAL SURFACE OF THE STOMA.,MONOFILAMENT POLIGLECAPRONE 25, ABSORBABLE SURGICAL SUTURE.(PETCRYL MONO AND OTHER OEM BRANDS.)-IT IS INTENDED FOR TISSUE APPROXIMATION AND LIGATION.,PARTIALLY ABSORBABLE MESH, COMPOSED OF POLYPROPYLENE AND POLIGLECAPRONE 25. (MONOSOLVE MESH AND OTHER OEM BRANDS.)-PARTIALLY ABSORBABLE MESH IS INDICATED FOR RECONSTRUCTION OF HERNIAS OR OTHER ABDOMINAL WALL DEFICIENCIES, AS WELL AS FOR REINFORCEMENT OF SOFT TISSUES WHERE WEAKNESS EXISTS., COATED AND BRAIDED POLYGLACTIN 910, SUTURE, ABSORBABLE SURGICAL SUTURE. ANTIBACTERIAL WITH TRICLOSAN.(PETCRYL PLUS & OTHER OEM BRANDS.)-PETCRYL® PLUS SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,COATED AND BRAIDED POLYGLYCOLIC ACID, ABSORBABLE SURGICAL SUTURE.(PETCRYL AND OTHER OEM BRANDS.)-POLYGLYCOLIC ACID SUTURE ARE INDICATED FOR USE IN GENERAL, SOFT TISSUE INCLUDING USE IN OPHTHALMIC. BUT NOT FOR USE IN CARDIO VASCULAR & NEUROLOGICAL TISSUES. THIS SUTURE BEING ABSORBABLE SHOULD NOT BE USED WHERE EXTENDED APPROXIMATION OF TISSUE IS REQUIRED., MONOFILAMENT POLIGLECAPRONE 25 SUTURE, ABSORBABLE SURGICAL SUTURE, ANTIBACTERIAL WITH TRICLOSAN.(MONOPLUS & OTHER OEM BRANDS)-POLIGLECAPRONE 25 ANTIBACTERIAL SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,COMPOSITE POLYMER MESH, COMPOSED OF POLYMER AND SILICONE, NON ABSORBABLE.-IT IS INTENDED FOR SUPPORTING WEAK TISSUES LIKE CHEST WALL DEFECT, HERNIA ETC., COMPOSITE MESH COMPOSED OF POLYPROPYLENE AND POLYTETRA FLUORO ETHYLENE. NON ABSORBABLE.-COMPOSITE MESH IS INDICATED FOR USE IN THE RECONSTRUCTION OF SOFT TISSUE DEFICIENCIES, SUCH AS FOR THE REPAIR OF HERNIAS AND CHEST WALL DEFECTS.,COATED AND BRAIDED POLYGLACTIN 910, SUTURE, ABSORBABLE SURGICAL SUTURE. ANTIBACTERIAL WITH CHLORHEXIDINE.-POLYGLACTIN 910 NEEDLED WITH CHLORHEXIDINE SUTURE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/ OR LIGATION ACROSS SUITABLE SURGERY TYPES.,CATGUT PLAIN, ABSORBABLE SURGICAL SUTURE.-CATGUT PLAIN SUTURE IS SUITABLE FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN GENERAL

	CLOSURE, OPHTHALMIC, ORTHOPAEDICS, OBSTETRICS/GYNAECOLOGY , GASTROINTESTINAL TRACT SURGERY.,MONOFILAMENT POLIGLECAPRONE 25 BARBED SUTURE, ABSORBABLE SURGICAL SUTURE.-IT IS INTENDED FOR TISSUE APPROXIMATION WITHOUT THE USAGE OF KNOTS.,COMPOSITE POLYMER MESH, COMPOSED OF POLYMER AND SILICONE, NON ABSORBABLE.(SILENE MESH AND OTHER OEM BRANDS.)-IT IS INTENDED FOR SUPPORTING WEAK TISSUES LIKE CHEST WALL DEFECT, HERNIA ETC.,MONOFILAMENT POLYDIOXANONE SUTURE, ABSORBABLE SURGICAL SUTURE. ANTIBACTERIAL WITH TRICLOSAN. (DURACRYL-PLUS AND OTHER OEM BRANDS.)-IT IS INTENDED FOR SOFT TISSUE APPROXIMATION AFTER A SURGICAL PROCEDURE., SURGICAL SKIN STAPLER CARTRIDGE.-SKIN STAPLER CARTRIDGE IS USED FOR SKIN CLOSURE.,MONOFILAMENT STAINLESS STEEL, NON ABSORBABLE SURGICAL SUTURE.(ALL OEM BRANDS.)-IT IS INTENDED FOR TISSUE APPROXIMATION AFTER A SURGICAL PROCEDURE.,POLYPROPYLENE MESH COATED WITH TITANIUM DIOXIDE. NON ABSORBABLE SURGICAL MESH.(TIOLENE MESH AND OTHER OEM BRANDS.)-IT IS INTENDED FOR SUPPORTING WEAK TISSUES LIKE CHEST WALL DEFECT, HERNIA ETC.,COMPOSITE MESH COMPOSED OF POLYPROPYLENE AND POLYTETRA FLUORO ETHYLENE. NON ABSORBABLE.(TEFLENE MESH AND OTHER OEM BRANDS.)-COMPOSITE MESH IS INDICATED FOR USE IN THE RECONSTRUCTION OF SOFT TISSUE DEFICIENCIES, SUCH AS FOR THE REPAIR OF HERNIAS AND CHEST WALL DEFECTS.,OXIDIZED REGENERATED CELLULOSE. HEMOSTAT.-THE PRODUCT IS INTENDED TO PROMOTE CLOTTING DURING SURGERY. IT IS USED IN VARIOUS SURGERIES LIKE LAPAROSCOPIC PARTIAL NEPHRECTOMY, GALLBLADDER BED AND IN MINOR SPLENIC INJURY, TO CONTROL HEMORRHAGE FROM AN EDEMATOUS, FRAGILE MUCOSA AND SKIN EDGE AT THE PERIPHERAL SURFACE OF THE STOMA.,MONOFILAMENT POLYDIOXANONE BARBED SUTURE, ABSORBABLE SURGICAL SUTURE.-IT IS INTENDED FOR TISSUE APPROXIMATION., MONOFILAMENT POLIGLECAPRONE 25 SUTURE, ABSORBABLE SURGICAL SUTURE, STERILE. ANTIBACTERIAL WITH TRICLOSAN.-POLIGLECAPRONE 25 ANTIBACTERIAL SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY., MONOFILAMENT POLYDIOXANONE, ABSORBABLE SURGICAL SUTURE.-IT IS INTENDED FOR TISSUE APPROXIMATION AND LIGATION.,MONOFILAMENT STAINLESS STEEL, NON ABSORBABLE SURGICAL SUTURE.-IT IS INTENDED FOR TISSUE APPROXIMATION AFTER A SURGICAL PROCEDURE.,SURGICAL SKIN STAPLER.-SKIN

	STAPLER HAS THE APPLICATION IN SKIN CLOSURE.,BONE WAX.-BONE WAX IS INDICATED FOR USE IN THE CONTROL OF BLEEDING FROM BONE SURFACES. BONE WAX ACHIEVES LOCAL HEMOSTASIS OF BONE BY ACTING AS A MECHANICAL (TAMPONADE) BARRIER. IT DOES NOT ACT BIOCHEMICALLY AND IS NONABSORBABLE.,COATED AND BRAIDED POLYESTER, NON ABSORBABLE SURGICAL SUTURE.-IT IS INTENDED FOR TISSUE APPROXIMATION AND LIGATION., MONOFILAMENT POLYPROPYLENE, NON ABSORBABLE SURGICAL SUTURE.-IT IS INTENDED FOR TISSUE APPROXIMATION AND LIGATION.,MONOFILAMENT POLYAMIDE, NON ABSORBABLE SURGICAL SUTURE.-IT IS INTENDED FOR TISSUE APPROXIMATION AND LIGATION.,MONOFILAMENT POLIGLECAPRONE 25, ABSORBABLE SURGICAL SUTURE.-IT IS INTENDED FOR TISSUE APPROXIMATION AND LIGATION.,PARTIALLY ABSORBABLE MESH, COMPOSED OF POLYPROPYLENE AND POLIGLECAPRONE 25.-PARTIALLY ABSORBABLE MESH IS INDICATED FOR RECONSTRUCTION OF HERNIAS OR OTHER ABDOMINAL WALL DEFICIENCIES, AS WELL AS FOR REINFORCEMENT OF SOFT TISSUES WHERE WEAKNESS EXISTS., TITANIUM LIGATION CLIPS, NON ABSORBABLE(TILOC & OTHER OEM BRANDS)-TITANIUM LIGATING CLIPS ARE INTENDED FOR USE IN CARDIOVASCULAR AND GENERAL SURGERY APPLICATIONS PROCEDURES INVOLVING LIGATION OF VESSELS OR TISSUE STRUCTURES. SURGEONS SHOULD APPLY THE APPROPRIATE SIZE CLIP FOR THE SIZE OF THE VESSEL OR TISSUE STRUCTURE TO BE LIGATED SUCH THAT THE CLIP COMPLETELY ENCOMPASSES THE VESSEL OR TISSUE STRUCTURE.,COATED AND BRAIDED POLYGLYCOLIC ACID, ABSORBABLE SURGICAL SUTURE.-POLYGLYCOLIC ACID SUTURE ARE INDICATED FOR USE IN GENERAL, SOFT TISSUE INCLUDING USE IN OPHTHALMIC. BUT NOT FOR USE IN CARDIO VASCULAR & NEUROLOGICAL TISSUES. THIS SUTURE BEING ABSORBABLE SHOULD NOT BE USED WHERE EXTENDED APPROXIMATION OF TISSUE IS REQUIRED.,COMPOSITE MESH COMPOSED OF POLYESTER AND LOW DENSITY POLYETHYLENE. NON ABSORBABLE.(ULTRALENE MESH AND OTHER OEM BRANDS.)-IT IS INTENDED FOR SUPPORTING WEAK TISSUES LIKE CHEST WALL DEFECT, HERNIA ETC.,SURGICAL SKIN STAPLER CARTRIDGE. (DURAMATE-C & OTHER OEM BRANDS)-SKIN STAPLER CARTRIDGE IS USED FOR SKIN CLOSURE.,MONOFILAMENT POLYDIOXANONE BARBED SUTURE, ABSORBABLE SURGICAL SUTURE. ANTIBACTERIAL WITH TRICLOSAN.(DURABARB-PLUS AND OTHER OEM BRANDS.)-THE DEVICE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE THE USE OF ABSORBABLE SUTURES IS APPROPRIATE., MONOFILAMENT POLYDIOXANONE, ABSORBABLE SURGICAL SUTURE.(DURACRYL AND OTHER OEM BRANDS.)-IT IS INTENDED FOR

	TISSUE APPROXIMATION AND LIGATION.,COMPOSITE MESH COMPOSED OF POLYESTER AND LOW DENSITY POLYETHYLENE. NON ABSORBABLE.-IT IS INTENDED FOR SUPPORTING WEAK TISSUES LIKE CHEST WALL DEFECT, HERNIA ETC.,MONOFILAMENT POLYPROPYLENE, NON ABSORBABLE SURGICAL SUTURE. (DURACARE AND OTHER OEM BRANDS.)-IT IS INTENDED FOR TISSUE APPROXIMATION AND LIGATION.,MONOFILAMENT POLIGLECAPRONE 25 BARBED SUTURE, ABSORBABLE SURGICAL SUTURE. ANTIBACTERIAL WITH TRICLOSAN.(MONOBARB-PLUS AND OTHER OEM BRANDS.)-IT IS INTENDED FOR SOFT TISSUE APPROXIMATION WITHOUT THE USAGE OF KNOTS.,POLYMER LIGATION CLIPS, NON ABSORBABLE.-POLYMER LIGATING CLIPS ARE INTENDED FOR USE IN OPEN AND LAPAROSCOPIC CASE APPLICATION PROCEDURES INVOLVING LIGATION OF VESSELS OR TISSUE STRUCTURES. SURGEONS SHOULD APPLY THE APPROPRIATE SIZE CLIP FOR THE SIZE OF THE VESSEL OR TISSUE STRUCTURE TO BE LIGATED SUCH THAT THE CLIP COMPLETELY ENCOMPASSES THE VESSEL OR TISSUE STRUCTURE.,MONOFILAMENT POLYDIOXANONE BARBED SUTURE, ABSORBABLE SURGICAL SUTURE.(DURABARB AND OTHER OEM BRANDS.)-IT IS INTENDED FOR TISSUE APPROXIMATION WITHOUT THE USAGE OF KNOTS.,BONE WAX.(WAXOCARE AND OTHER OEM BRANDS.)-BONE WAX IS INDICATED FOR USE IN THE CONTROL OF BLEEDING FROM BONE SURFACES. BONE WAX ACHIEVES LOCAL HEMOSTASIS OF BONE BY ACTING AS A MECHANICAL (TAMPONADE) BARRIER. IT DOES NOT ACT BIOCHEMICALLY AND IS NONABSORBABLE.,MONOFILAMENT POLIGLECAPRONE 25 BARBED SUTURE, ABSORBABLE SURGICAL SUTURE.(MONOBARB AND OTHER OEM BRANDS.)-IT IS INTENDED FOR TISSUE APPROXIMATION WITHOUT THE USAGE OF KNOTS.,COMPOSITE MESH COMPOSED OF POLYPROPYLENE AND LOW DENSITY POLYETHYLENE. NON ABSORBABLE.-COMPOSITE MESH IS INDICATED FOR USE IN THE RECONSTRUCTION OF SOFT TISSUE DEFICIENCIES, SUCH AS FOR THE REPAIR OF HERNIAS AND CHEST WALL DEFECTS.,POLYPROPYLENE MESH COATED WITH TITANIUM DIOXIDE. NON ABSORBABLE SURGICAL MESH.-IT IS INTENDED FOR SUPPORTING WEAK TISSUES LIKE CHEST WALL DEFECT, HERNIA ETC.,MONOFILAMENT POLYTETRAFLUOROETHYLENE SUTURE, NON ABSORBABLE SURGICAL SUTURE.-POLYTETRA FLUORO ETHYLENE IS SUITABLE FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,COATED AND BRAIDED POLYGLACTIN 910, SUTURE, ABSORBABLE SURGICAL SUTURE.-POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,BLACK BRAIDED SILK. NON ABSORBABLE SURGICAL SUTURE.-SILK SUTURE IS INDICATED FOR USE IN GENERAL

	SOFT TISSUE APPROXIMATION AND/OR LIGATION IN ALL SURGICAL PROCEDURES EXCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,POLYPROPYLENE BARBED SUTURE, NON ABSORBABLE SURGICAL SUTURE.(POLYBARB AND OTHER OEM BRANDS.)-IT IS INTENDED FOR TISSUE APPROXIMATION WITHOUT THE USAGE OF KNOTS.,ULTRA HIGH MOLECULAR WEIGHT POLYETHYLENE WITH POLYESTER SUTURE, NON ABSORBABLE SURGICAL SUTURE.(ULTRASUT AND OTHER OEM BRANDS.)-IT IS INTENDED FOR TISSUE APPROXIMATION.

3553	MFG/MD/2020/000201	1.License Holder Name: GPC MEDICAL LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ARTHROPLASTY IMPLANTS(GPC-HIPHEAL ARTHROPLASTY IMPLANTS / ARTHROPLASTY IMPLANTS)-ARTHROPLASTY IMPLANTS ARE USED FOR HIP REPLACEMENT SURGERY,LOCKING HEAD BONE SCREWS (GPC-FIXLOCK / LOCKING HEAD BONE SCREWS)-BONE SCREWS ARE USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE., ARTHROSCOPY(GPC ARTHROSCOPY / ARTHROSCOPY)-ARTHROSCOPY ARE USED FOR KNEE SURGERY,BONE PLATES(GPC BONE PLATES / BONE PLATES)-THE BONE PLATES ARE THE DEVICES, USED TO FASTEN THE BONES FOR THE PURPOSE OF FIXATION OF FRACTURED BONES.,STAPLES(GPC STAPLES / STAPLES)-STAPLES ARE INDICATED FOR FIXATION OF ARTHRODESIS, OSTEOTOMIES AND FRACTURES IN HAND OR FOOT SURGERY,INTRAMEDULLARY INTERLOCKING NAILS(GPC-INTRAHEAL INTRAMEDULLARY INTERLOCKING NAILS / INTRAMEDULLARY INTERLOCKING NAILS)-INTRAMEDULLARY INTERLOCKING NAILS ARE USED TO TREAT FRACTURES OF LONG BONES OF THE BODY.,WIRES(GPC WIRES / WIRES)-WIRES ARE MAINLY INDICATED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENTS.,SPINAL IMPLANTS(GPC SPINEHEAL - SPINAL IMPLANTS / SPINAL IMPLANTS)-SPINAL IMPLANTS ARE THE MOST COMMONLY USED FOR THE PURPOSE OF VERTEBRAL FIXATION WITH THE AIM OF REDUCING VERTEBRAL MOBILITY AND THUS AVOIDING POSSIBLE DAMAGE TO THE SPINAL CORD AND/OR SPINAL ROOTS.,BONE SCREWS(GPC BONE SCREWS / BONE SCREWS)-BONE SCREWS ARE USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,LOCKING BONE PLATES (GPC-FIXLOCK BONE PLATES / LOCKING BONE PLATES)-THE BONE PLATES ARE THE DEVICES, USED TO FASTEN THE BONES FOR THE PURPOSE OF FIXATION OF FRACTURED BONES.,PINS(GPC PINS / PINS)-PINS ARE USED TO STABILIZE THE FRACTURES OF BONES

3554	MFG/MD/2020/000202	1.License Holder Name: KOSDRUG PVT. LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:INTRODUCER SHEATH (EZEE IN)-INTENDED TO PROVIDE EASIER ACCESS TO THE FEMORAL, RADIAL POPLITEAL AND INFRAPOPLITEAL ARTERIES,CATH LAB KIT (EZEE CATH)-CARDIAC CATHETERIZATION IS A GENERAL TERM FOR A GROUP OF PROCEDURES THAT ARE PERFORMED USING THIS METHOD, SUCH AS CORONARY ANGIOGRAPHY AND LEFT VENTRICLE ANGIOGRAPHY.,BLOOD CARDIOPLEGIA DELIVERY SYSTEM(EZEE PERF C)-INDICATED FOR USE IN THE EXTRA CORPOREAL CIRCUIT DURING CARDIO PULMONARY BYPASS SURGERY PROCEDURE., CENTRAL VENOUS CATHETER - TRIPLE LUMEN(EZEE CATHE)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,CORONARY ARTERY OSTIAL CANNULA(EZEE OSCAN)-CANNULATION TECHNIQUE FOR LEFT-SIDED CORONARY ARTERY SURGERY.,PTCA KIT(EZEE CATH)-CARDIAC CATHETERIZATION IS A GENERAL TERM FOR A GROUP OF PROCEDURES THAT ARE PERFORMED USING THIS METHOD, SUCH AS CORONARY ANGIOGRAPHY AND LEFT VENTRICLE, VENOUS CANNULA(EZEE VENCAN)-IT IS INTENDED FOR USE AS A SINGLE CANNULA FOR BOTH VENOUS DRAINAGE AND REINFUSION OF BLOOD VIA AN INTERNAL JUGULAR VEIN DURING EXTRACORPOREAL LIFE SUPPORT PROCEDURES.,CENTRAL VENOUS CATHETER - DOUBLE LUMEN(EZEE CATHE)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,ANGIOGRAPHIC GUIDE WIRE(EZEE GUIDE)-IT DELIVERS RADIO OPAQUE MEDIA AND THERAPEUTIC AGENTS TO SELECTED SITES IN THE VASCULAR SYSTEM. IT IS ALSO USED TO LEAD A GUIDE WIRE OR A CATHETER INTO THE TARGET SITE.,ANGIO KIT(EZEE CATH)-CARDIAC CATHETERIZATION IS A GENERAL TERM FOR A GROUP OF PROCEDURES THAT ARE PERFORMED USING THIS METHOD, SUCH AS CORONARY ANGIOGRAPHY AND LEFT VENTRICLE ANGIOGRAPHY., HAEMODIALYZER(EZEE DIALYZER)-A HEMODIALYZER IS A FLUID REMOVAL DEVICE USED DURING CARDIO BYPASS SURGERY. THE DEVICE IS INSERTED INTO THE EXTRACORPEAL CIRCUIT WHERE IT ACTS TO CONTROL HEMODILUTION, MAINTAIN HEMATOCRIT LEVELS AND REDUCE THE NEED FOR ADDITIONAL BLOOD PRODUCTS DURING AND AFTER SURGERY.,CENTRAL VENOUS CATHETER - SINGLE LUMEN (EZEE CATHE)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST

	MEDIA.,HAEMOCONCENTRATOR SET / HEMOFILTER(EZEE FILTRATE)-A HEMOCONCENTRATOR IS A FLUID REMOVAL DEVICE USED DURING CARDIO BYPASS SURGERY. THE DEVICE IS INSERTED INTO THE EXTRACORPEAL CIRCUIT WHERE IT ACTS TO CONTROL HEMODILUTION, MAINTAIN HEMATOCRIT LEVELS AND REDUCE THE NEED FOR ADDITIONAL BLOOD PRODUCTS DURING AND AFTER SURGERY.,ELECTRODE RECORDING PROBE CATHETER(EZEE PACE)-A CARDIAC CATHETER CONTAINING ONE OR MORE ELECTRODES: IT MAY BE USED TO PACE THE HEART OR TO DELIVER HIGH ENERGY SHOCKS,AORTIC PERFUSION CANNULA(EZEE AORTACAN)-AORTIC PERFUSION CANNULA'S ARE STERILE MEDICAL DEVICES DEDICATED TO DELIVER OXYGENATED BLOOD TO ARTERIAL VASCULATURE DURING CARDIAC SURGERY.,CARDIAC THERMODILUTION CATHETER (EZEE WEDGE)-A CATHETER USED IN THERMODILUTION FOR INTRODUCTION OF THE COLD LIQUID INDICATOR INTO THE CARDIOVASCULAR SYSTEM OR FOR THE ASSESSMENT OF A PATIENT'S HEMODYNAMIC CONDITION THROUGH SIMULTANEOUS RIGHT ATRIAL, RIGHT VENTICULAR AND PULMONARY ARTERYOR WEDGE PRESSURE MONITORING, CARDIAC OUTPUT DETERMINATION, AND FOR INFUSING SOLUTIONS,PERFUSION SYSTEM / HEART LUNG PACK(EZEE PERF-H)-INDICATED FOR USE IN THE EXTRA CORPOREAL CIRCUIT DURING CARDIO PULMONARY BYPASS SURGERY PROCEDURE.,EMBOLECTOMY CATHETER(EZEE EMBO)-EMBOLECTOMY CATHETERS ARE STERILE MEDICAL DEVICES DEDICATED FOR REMOVAL OF FRESH ARTERIAL EMBOLISM. CATHETER IS NON-TOXIC, PYROGEN FREE, VISIBLE UNDER FLUOROSCOPY,PRESSURE TRANSDUCER CATHETER KIT(EZEE DOME) -IT IS INTENDED TO CONVERT THE HEMODYNAMIC WAVEFORM FROM THE PATIENT'S CATHETER, THROUGH THE DISPOSABLE PRESSURE TRANSDUCER WITH INTEGRATED PRESSURE SENSOR, INTO ELECTRICAL SIGNALS WHICH CAN BE DISPLAYED USING SEPARATE MONITORING EQUIPMENT.,AORTIC ROOT CANNULA(EZEE ROOTCAN)-CANNULATION TECHNIQUE FOR LEFT-SIDED CORONARY ARTERY SURGERY.,VESSEL CANNULA(EZEE VESCAN)-USES DURING CARDIO THORACIC AND VASCULAR SURGERY,LEFT VENTRICULAR VENT CATHETER(EZEE VENT)-USES DURING CARDIO THORACIC AND VASCULAR SURGERY

3555	MFG/MD/2020/000203	1.License Holder Name: PERFECT MEDICARE PRODUCTS 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE SCREW(PERFECT)-DESIGNED AND MADE FOR TRAUMA AND RECONSTRUCTIVE SURGERY TO PROVIDE TEMPORARY INTERNAL FIXATION TO THE FRACTURE UNTIL BONY FUSION OCCURS. ,BONE SCREW(PERFECT)-DESIGNED AND MADE FOR TRAUMA AND RECONSTRUCTIVE SURGERY TO PROVIDE TEMPORARY INTERNAL FIXATION TO THE FRACTURE UNTIL BONY FUSION OCCURS. ,BONE PLATES(PERFECT)-DESIGNED AND MADE FOR TRAUMA AND RECONSTRUCTIVE SURGERY TO PROVIDE TEMPORARY INTERNAL FIXATION TO THE FRACTURE UNTIL BONY FUSION OCCURS. ,INTRA-MEDULLARY NAIL (PERFECT)-DESIGNED AND MADE FOR TRAUMA AND RECONSTRUCTIVE SURGERY TO PROVIDE TEMPORARY INTERNAL FIXATION TO THE FRACTURE UNTIL BONY FUSION OCCURS. ,SPINAL IMPLANTS(PERFECT)-DESIGNED AND MADE FOR TRAUMA AND RECONSTRUCTIVE SURGERY TO PROVIDE TEMPORARY INTERNAL FIXATION TO THE FRACTURE UNTIL BONY FUSION OCCURS. ,SPINAL IMPLANTS(PERFECT)-DESIGNED AND MADE FOR TRAUMA AND RECONSTRUCTIVE SURGERY TO PROVIDE TEMPORARY INTERNAL FIXATION TO THE FRACTURE UNTIL BONY FUSION OCCURS. ,INTRA-MEDULLARY NAIL(PERFECT)-DESIGNED AND MADE FOR TRAUMA AND RECONSTRUCTIVE SURGERY TO PROVIDE TEMPORARY INTERNAL FIXATION TO THE FRACTURE UNTIL BONY FUSION OCCURS. ,BONE PLATES(PERFECT)-DESIGNED AND MADE FOR TRAUMA AND RECONSTRUCTIVE SURGERY TO PROVIDE TEMPORARY INTERNAL FIXATION TO THE FRACTURE UNTIL BONY FUSION OCCURS
3556	MFG/MD/2020/000204	1.License Holder Name: ALFA SURGICALS PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL IP(NIL)-MEDICAL ABSORBENT, HOSPITAL DRESSING

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3557	MFG/MD/2020/000205	1.License Holder Name: METADESIGN SOLUTIONS PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:VIRAL TRANSPORT MEDIUM(PATHKITS)-FOR SAMPLE COLLECTION AND TRANSPORTATION OF VIRUSES LIKE COVID-19,VIRAL LYSIS TRANSPORT MEDIUM(PATHKITS)-FORMULATED MEDIUM FOR COLLECTION AND TRANSPORT OF VIRUSES.,MOLECULAR TRANSPORT MEDIUM KIT(MDS MOLECULAR TRANSPORT MEDIUM KIT)-IT IS A SPECIALLY FORMULATED MEDIUM FOR COLLECTION AND TRANSPORT OF VIRUSES. IT IS DESIGNED TO LYSE AS WELL AS MAINTAIN OPTIMUM CONDITIONS FOR THE TRANSPORT OF THE VIRAL SAMPLE.,UNIVERSAL TRANSPORT MEDIUM KIT(MDS UNIVERSAL TRANSPORT MEDIUM KIT)-IT IS A SPECIALLY FORMULATED MEDIUM FOR COLLECTION AND TRANSPORT OF VIRUSES. IT IS DESIGNED TO MAINTAIN THE OPTIMUM VIABILITY AND VIRULENCE OF THE VIRAL SAMPLE.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3558	MFG/MD/2020/000206	1.License Holder Name: SHREE BHAGWATI SURGICAL 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE INFUSION SET WITH AIR VENT BIS 12655(- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN. , STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 (MEDICARE DISPOSABLE IV SET WITHOUT AIR VENT)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH AIR VENT BIS 9824(- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655(JMS DISPOSABLE IV SET WITHOUT AIR VENT)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN.,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655(- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN. ,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655(4 M DISPOSABLE IV SET WITHOUT AIR VENT)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN.,STERILE DISPOSABLE MEASURED VOLUME SET WITHOUT AIR VENT BIS 12655 (- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN. ,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITHOUT AIR VENT BIS 9824(- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.

3559	MFG/MD/2020/000207	1.License Holder Name: BIO-MED HEALTHCARE PRODUCTS PVT. LTD. 2.Approving Authority: UTTARAKHAND 3.Device Name(Brand Name)-Intended Use:TRANSFUSION OR PERFUSION SETS FOR SINGLE USE (B.T.SET)(BIO-MED, ANARMED, MEDILIFE, NET, RITEMED, HEALTH, JUCATH, T CARE, MAB, M&V, BLOOD ADMINISTRATION SET (GENERIC NAME))-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., INSULIN SYRINGES (LTN)-USE TO INJECT INSULIN FOR THE TREATMENT OF DIABETES,MEASURED VOLUME IV SET (BURETTE SET) (NET, KINGS, SIDRA, HM HEALTHCARE, JUCATH, VITALCARE, AGARY, IPD LIFECARE, MAB, BIO-DRIP SET, M&V, MEASURED VOLUME ADMINISTRATION SET (GENERIC NAME))-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,TRANSFUSION OR PERFUSION SETS FOR SINGLE USE (B.T. SET)(BEGOTEK)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OF CATHETER INSERTED INTO A VEIN.,INSULIN SYRINGE(MR. INJECT, PROCARE, HE, HM HEALTHCARE, PROTEK, NET, ANGELTOUCH, HEALTH, EUROVEIN, JUCATH, SANBAO,MEDIPLUS, TECHMED, VENSOR-ND,ANGIPLAST,MEDICARE, MEDROP, JK MEDIRISE, INSULIN SYRINGE (GENERIC NAME))-USE TO INJECT INSULIN FOR THE TREATMENT OF DIABETES,TRANSFUSION OR PERFUSION SETS FOR SINGLE USE (I.V. SET)(BEGOTEK)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OF CATHETER INSERTED INTO A VEIN., TRANSFUSION OR PERFUSION SETS FOR SINGLE USE (I.V.SET)(BIO-MED, ROMED, LIFELINE, ANARMED, DODO FUSION, MEDILIFE, SIDRA, NET, RITEMED(INFUSION SET), KAYSUN, KINGS, IPD LIFECARE, HEALTH, TOP CARE, JUCATH,DEAMED, KAREMAX, MAB, M&V, INFUSION SET (GENERIC NAME))-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE HYPODERMIC SYRINGES FOR SINGLE USE(VACCI-INJECT)-INTEND TO INJECT FLUIDS INTO OR WITHOUT FLUIDS FROM THE BODY, INTRAVENOUS CANNULA (WITH OR WITHOUT SAFETY FEATURES) (BIO-FLON, BIO-CAN, BIO-ON, BIO-NEO, MAXIMA, BIO-MED, GENERIC NAME)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND / OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., DISPOSABLE HYPODERMIC NEEDLES (2MM)-A HYPODERMIC SINGLE LUMAN NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM PARTS OF THE BODY BELOW THE SURFACE

		OF THE SKIN.,STERILE HYPODERMIC SYRINGES FOR SINGLE USE(MR. INJECT,PROCARE, MEDICARE, DEMOTEK, HEMC, ANARMED ,HARMED, ANGELTOUCH,K(KRAPE), MEDILIFE, TRONN, RITEMED,DJECT,NET, KAYSUN,G-TRONN, HEALTH, HOMED, TOP CARE, JUCATH,MEDROP, DEAMED, SANBAO,BIO-STAR, VENSOR-ND, VENSOR, EUROVEIN, ATLAS, MAB, JK MEDIRISE, DISPOSABLE HYPODERMIC SYRINGES(GENERIC NAME))-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE HYPODERMIC SYRINGES FOR SINGLE USE(PACINJECT, NCARE)-INTEND TO INJECT FLUIDS INTO OR WITHOUT FLUIDS FROM THE BODY,DISPOSABLE HYPODERMIC NEEDLES(MR. INJECT, NET, TRONN, SCOPE PLUS, RITEMED, JRZ+, JUCATH,MEDROP,DEAMED, MAB, DISPOSABLE HYPODERMIC NEEDLE (GENERIC NAME))-A HYPODURMIC SINGLE LUMAN NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDSINTO, OR WITHDRAW FLUIDS FROM ,PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.
3560	MFG/MD/2020/000208	1.License Holder Name: ADVY CHEMICAL PVT. LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:RAPID DIPSTICK TEST FOR DETECTION OF IGFBP-1 AS INDICATOR OF PREMATURE RUPTURE OF AMNIOTIC FLUID MEMBRANE(EZDX ACTIM PROM)-THE RAPID DIPSTICK TEST FOR DETECTION OF IGFBP-1 AS INDICATOR OF PREMATURE RUPTURE OF AMNIOTIC FLUID MEMBRANE IS A VISUALLY INTERPRETED, QUALITATIVE IMMUNOCHROMATOGRAPHIC DIPSTICK TEST FOR DETECTION OF AMNIOTIC FLUID IN VAGINAL SECRETIONS DURING PREGNANCY. ACTIM PROM DETECTS IGFBP-1, WHICH IS A MAJOR PROTEIN IN AMNIOTIC FLUID AND A MARKER OF THE AMNIOTIC FLUID IN A VAGINAL SAMPLE. THE TEST IS INTENDED FOR PROFESSIONAL USE TO HELP DIAGNOSE THE RUPTURE OF FETAL MEMBRANES (ROM) IN PREGNANT WOMEN. ,RAPID DIPSTICK TEST FOR DETECTION OF PHIGFBP-1 IN CERVICAL SECRETION AS PRE-TERM BIRTH RISK FACTOR(EZDX ACTIM PARTUS)-ACTIM PARTUS IS A VISUALLY INTERPRETED, QUALITATIVE IMMUNOCHROMATOGRAPHIC DIPSTICK TEST FOR DETECTING THE PRESENCE OF PHOSPHORYLATED IGFBP-1 (INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN-1) IN CERVICAL SECRETIONS DURING PREGNANCY. THE TEST IS INTENDED FOR PROFESSIONAL USE TO HELP PREDICT THE RISK OF PRETERM OR IMMINENT DELIVERY WHEN FETAL MEMBRANES ARE INTACT. A NEGATIVE TEST RESULT IS A CLEAR INDICATION THAT THE PATIENT WILL NOT DELIVER WITHIN 7-14 DAYS

3561	MFG/MD/2020/000209	1.License Holder Name: SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: NORTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:GAUZE SWABS WITH X-RAY THREAD AND WITHOUT X-RAY THREAD(SOFTSWAB, SOFTLAP$)-INTENDED FOR CLEANING A WOUND AND ABSORBING BLOOD AND EXUDATE FLUIDS FROM A WOUND, SURGICAL PROCEDURES AND DIFFERENT INJURIES.,DRESSING PACK(GAMJEE ROLL, GAMJEE PAD, SOFTPAD (EYE PAD))-A DRESSING FOR THE ABSORPTION OF DISCHARGES FROM THE WOUND SITE.,GAUZE SWABS(SMART GAUZE) -INTENDED FOR CLEANING A WOUND AND ABSORBING BLOOD AND EXUDATE FLUIDS FROM A WOUND.,ADHESIVE DRESSING(VELFIX-T)-TRANSPARENT FILM / NON-WOVEN IV DRESSING OR WOUND DRESSING WITH ABSORBENT PAD (TO ABSORB EXUDATE, FLUIDS) OR WITHOUT ABSORBENT PAD.
3562	MFG/MD/2020/000210	1.License Holder Name: HLL LIFECARE LIMITED (A GOVT. OF INDIA ENTERPRISE) 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:MALE LATEX CONDOMS (DELUXE NIRODH, RAKSHAK, SAWAN, THRILL, USTAD, BLISS, NIRODH, DELUXE, JOSH, MOODS)-INTENDED USE OF HLL CONDOM IS TO REDUCE THE RISK OF TRANSMISSION OF SEXUALLY TRANSMITTED INFECTIONS AND TO PREVENT PREGNANCY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3563	MFG/MD/2020/000211	1.License Holder Name: HINDUSTAN SURGICAL 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 (HMS)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN.,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655(- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN.,STERILE DISPOSABLE INFUSION SET WITH AIR VENT BIS 12655 (- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN., STERILE DISPOSABLE MEASURED VOLUME SET WITHOUT AIR VENT BIS 12655(- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN.,STERILE DISPOSABLE MEASURED VOLUME SET WITHOUT AIR VENT BIS 12655 (- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITHOUT AIR VENT BIS 9824(- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 (HICARE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN.,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 (STERIVEIN)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN.,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 (SAFEX)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN.,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 (DISPOCARE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO VEIN.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH AIR VENT BIS 9824 (- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.

3564	MFG/MD/2020/000212	1.License Holder Name: ONYX MEDICALS PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE PIN-IT MAY BE USED FOR FIXATION OF BONE FRACTURES, FOR BONE RECONSTRUCTIONS, AS A GUIDE PIN FOR INSERTION OF OTHER IMPLANTS, OR IT MAY BE IMPLANTED THROUGH THE SKIN SO THAT A PULLING FORCE (TRACTION) MAY BE APPLIED TO THE SKELETAL SYSTEM.,BONE NAILS/INTRAMEDULLARY FIXATION ROD-INTENDED TO BE IMPLANTED INTO THE MEDULLARY (BONE MARROW) CANAL OF LONG BONES FOR THE FIXATION OF FRACTURES.,BONE WIRE/INTRA OSSEOUS FIXATION WIRE-THE PACKAGE SIZE IS AS PER THE DIMENSION OF THE MEDICAL DEVICE. STABILIZATION OF THE FRACTURED BONY PARTS BY DIRECT FIXATION TO ONE ANOTHER WITH SURGICAL WIRES.,BONE PIN-A SINGLE MEDICAL DEVICE IS A MEDICAL DEVICE SOLD AS A DISTINCT PACKAGED ENTITY. IT MAY BE SOLD IN A RANGE OF PACKAGE SIZES. IT MAY BE USED FOR FIXATION OF BONE FRACTURES, FOR BONE RECONSTRUCTIONS, AS A GUIDE PIN FOR INSERTION OF OTHER IMPLANTS, OR IT MAY BE IMPLANTED THROUGH THE SKIN SO THAT A PULLING FORCE (TRACTION) MAY BE APPLIED TO THE SKELETAL SYSTEM.,BONE PLATES-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE.,PEDICLE SCREW SPINAL SYSTEM-IT IS USED TO INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS.,BONE SCREWS-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE.,SPINAL IMPLANTS-IT IS INDICATED FOR USE WITH AUTOGENOUS BONE GRAFT IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE ("DDD") AT ONE OR TWO CONTIGUOUS SPINAL LEVELS.,BONE GRAFTING MATERIAL-INTENDED TO FILL, AUGMENT, OR RECONSTRUCT PERIODONTAL OR BONY DEFECTS OF THE ORAL AND MAXILLOFACIAL REGION.,BONE NAILS/INTRAMEDULLARY FIXATION ROD-INTENDED TO BE IMPLANTED INTO THE MEDULLARY (BONE MARROW) CANAL OF LONG BONES FOR THE FIXATION OF FRACTURES.,BONE SCREWS-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE.,BONE PLATES-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE.

3565	MFG/MD/2020/000213	1.License Holder Name: KOSDRUG PVT. LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:OESOPHAGEAL SENGSTAKEN TUBE-IT IS USED ONLY IN EMERGENCIES WHERE BLEEDING FROM PRESUMED VARICES IS IMPOSSIBLE TO CONTROL WITH MEDICATION ALONE,SUPRAPUBIC CATHETER(EZEE SUPRA)-A SUPRAPUBIC CATHETER IS A THIN, STERILE TUBE USED TO DRAIN URINE FROM BLADDER.,NASO GASTRIC TUBE/ RYLES TUBE(EZEE RYLO)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,BLOOD ADMINISTRATION KITS(EZEE TRANSFUSION)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN, OESOPHAGEAL BLACKMORE TUBE-IT IS A MEDICAL DEVICE INSERTED THROUGH THE NOSE OR MOUTH AND USED OCCASIONALLY IN THE MANAGEMENT OF UPPER GASTROINTESTINAL HEMORRHAGE DUE TO OESOPHAGEAL VARICES.,3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS (EZEE WAY)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, Y CONNECTOR AS AN ACCESSORY FOR PERFUSION SETS (EZEE CONNECT)-IT CAN BE USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC.,CLOSED SUCTION SYSTEM(EZEE CLOSED SUCTION)-IT IS INTENDED FOR ENDOTRACHEAL SUCTIONING TO PROVIDE A PATIENT AIRWAY BY REMOVING EXCESS FLUIDS, SECRETIONS, EXUDATES AND TRANSUDATE THROUGH THE ARTIFICIAL AIRWAY.,MANIFOLDS(EZEE FOLD)-INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESSPORT/PORTS FOR ADMINISTRATION OF A SOLUTION,BALLOON TYPE CATHETER(EZEE DILATION)-SOFT" CATHETER WITH AN INFLATABLE "BALLOON" AT ITS TIP WHICH IS USED DURING A CATHETERIZATION PROCEDURE TO ENLARGE A NARROW OPENING OR PASSAGE WITHIN THE BODY.,ANGIOGRAPHIC CATHETER(EZEE DETECT)-DESIGNED TO PROVIDE A PATHWAY FOR DELIVERING CONTRAST MEDIA TO SELECTED SITES IN THE DEVICE VASCULAR SYSTEM INCLUDING THE CAROTID ARTERIES.,URETHRAL CATHETER/ NELATON CATHETER/ FOLEY CATHETER(EZEE FOLEY)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,UMBILICAL ARTERY CATHETER(EZEE CLAMP)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND

	ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS,FEEDING TUBE(EZEE FEED)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,CLOSED WOUND DRAINAGE TUBE OR SYSTEM(EZEE VAC)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,TRACHEOSTOMY TUBE / TRACHEAL TUBE(EZEE TRACHEA)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,CARDIOTOMY RESERVOIR(EZEE RESERVOIR)-IT IS INTENDED FOR USE DURING CARDIO THORACIC AND VASCULAR SURGERY,VACCUM SUCTION SET(EZEE YANK)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,NEPHROSTOMY CATHETER(EZEE NEPHCATH)-A NEPHROSTOMY IS A TUBE THAT'S USED TO DRAIN URINE FROM A KIDNEY INTO A BAG OUTSIDE THE BODY.,PERITONEAL DIALYSIS CATHETER(EZEE DIALCATH)-THAT ALLOWS DIALYSIS FLUID TO ENTER THE ABDOMINAL CAVITY, DWELL INSIDE FOR A WHILE, AND THEN DRAIN BACK OUT AGAIN,CATHETER MOUNT(EZEE MOUNT)-ANESTHESIA,I.V. CANNULA(EZEE FLEX)-.V. CANNULA USES TO PUT MEDICINES OR FLUIDS STRAIGHT INTO BLOODSTREAM. IT CAN SOMETIMES BE USED TO TAKE BLOOD SAMPLES DURING TESTS AND INVESTIGATIONS.,HAEMODIALYSIS BLOOD TUBING SET(EZEE HEMO CHECK)-USES FOR HEMODIALYSIS,NEEDLE FREE INFUSION SET (EZEE INJECT)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM ,INFUSION SET WITH PRIMING FILTER(EZEE GUARD)-INFUSION SET WITH 0.2 MICRON IN-LINE FILTER PREVENTS PARTICLE, AIR, BACTERIA & FUNGI PASSING INTO THE VENOUS SYSTEM HYDROPHOBIC PRIMING FILTER CAP PREVENTS FLUID LEAKAGE ,SUCTION TIP AND CATHETER(EZEE SUCTION)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., IV FLOW REGULATOR(EZEE FLOW)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY,URINARY DRAINAGE UNIT / PENILE SHEATH (EZEE DOM)-A CLOSED URINARY DRAINAGE SYSTEM CONSISTS OF A CATHETER INSERTED INTO THE URINARY BLADDER AND CONNECTED VIA TUBING TO A DRAINAGE BAG,FISTULA NEEDLE(EZEE FIST)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT,INTER COASTAL

	DRAINAGE CATHETER (EZEE DRAIN)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,MEASURED VOLUME IV SET(EZEE DRIP)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE ,CONNECTING TUBE AND LOOPS(EZEE LINE)-USED TO PROVIDE CONNECTION TO A DRAINAGE BAG., BONEMARROW NEEDLE(EZEE CORE)-NEEDLE INSERTED IN BONE MARROW TO COLLECT SAMPLE,ANGIOGRAPHIC NEEDLE-ANGIOGRAPHIC NEEDLE HAS A UNIQUE HUB DESIGN WITH AN ERGONOMIC FEEL AND A BLACK TRIANGLE INDICATOR TO ORIENT THE BEVEL.,MUCCUS EXTRACTOR(EZEE EXTRACT)-FOR MUCUS SUCTION,ENDOTRACHEAL TUBE(EZEE INTUBATE)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE,AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,CHEST DRAINAGE BOTTLE(EZEE SEAL)-IT INCLUDES A PLACE FOR DRAINAGE TO COLLECT AND A ONE-WAY VALVE THAT PREVENTS AIR OR FLUID FROM RETURNING TO THE CHEST. BOTH THE ONE AND TWO-BOTTLE CHEST DRAINAGE SYSTEMS RELY ON GRAVITY TO CREATE A PRESSURE GRADIENT BY WHICH AIR AND FLUID LEAVE THE CHEST.,PRESSURE MONITORING LINE(EZEE P- LINE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATIONSIN MEDICAL APPLICATIONS. ,HAEMODIALYSIS CATHETER(EZEE HEMO)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT.,EPIDURAL CATHETER (EZEE EPIDURA)-EPIDURAL CATHETER IS A VERY THIN, FLEXIBLE TUBE THAT IS IMPLANTED INTO SPINE.,NASAL OXYGEN CANNULA (EZEE PRONG)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,MISTER BLOWER (EZEE MIST)-DEVICE OFFERS ADVANCED FLUID/GAS MIXING TECHNOLOGY TO CREATE A CONSISTENT, PREDICTABLE BLOOD CLEARING MIST. THE MALLEABLE SHAFT AND ON/OFF CONTROL ON THE HAND PIECE MAKE IT AN EXCELLENT CHOICE FOR FACILITATING A BLOODLESS FIELD,GUIDING CATHETER(EZEE GUIDE)-THE GUIDE CATHETER PROVIDES SUPPORT FOR DEVICE ADVANCEMENT ,EXTENSION SETS / PERFUSION ADAPTORS (EZEE E- LINE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATIONSIN MEDICAL APPLICATIONS. ,INFUSION SET(EZEE INFUSE)-IT IS USED TO ADMINISTER FLUID FROM A CONTAINER TO A

		PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,TUR SET(EZEE TUR)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN
3566	MFG/MD/2020/000214	1.License Holder Name: SECURE SURGICAL 2.Approving Authority: UTTARAKHAND 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL (SECURE SURGICAL)-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3567	MFG/MD/2020/000215	1.License Holder Name: DR. SURGICAL 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:VESSEL CANNULA (FEMORAL AORTIC)(DR SURGICAL)-THE VARIOUS CANNULA USED IN SURGERY ARE IMPORTANT TO THE PERFUSIONIST. THESE CANNULA LINK THE PERFUSION CIRCUIT WITH THE PATIENT. THE CANNULAE OF THE PERFUSION INCLUDES RETROGRADE CANNULA IN ADDITION, THERE ARE LEFT VENTRICLE VENTS ,PULMONARY ARTERY VENTS AND AORTIC ROOT VENTS.,SURGICAL DRAPE (DR SURGICAL)-SURGICAL DRAPE IS INTENDED FOR SINGLE USE TO BE USED AS A PROTECTIVE PATIENT COVERING, SUCH AS TO ISOLATE A SITE ON A SURGICAL INCISION FROM MICROBIAL AND OTHER CONTAMINATION., BURETTE INFUSION SET(DR SURGICAL)-THE SET IS USED IN MEDICAL, HOSPITALS ,CLINIC ,ICU UNITS ETC. OWING TO ITS SEVERAL FUTURE LIKE NON TOXIC AND ECO FRIENDLY ,THIS SET IS HIGHLY ACCLAIMED IN MARKET .,HIGH PRESSURE MANIFOLD(DR SURGICAL)-THE PRODUCT IS USED AS A PRESSURE ACCESSORY WITH AN OPERATIONAL FUNCTIONS AND HAVING AN IDENTIFICABLE PRESSURE BEARING HOUSING .THE PRODUCT IS NOT INTENDED SPECIFICALLY FOR USE IN DIRECT CONTACT WITH CENTRAL NERVOUS SYSTEM .,LEFT HEART CATHETER (VENT LINE)(DR SURGICAL)-THE CATHETER IS THEN MOVED THROUGH THE AORTIC VALVE INTO THE LEFT SIDE OF YOUR HEART. THE PRESSURE IS MEASURED IN THE HEART IN THIS POSITION. OTHER PROCEDURES , CAN ALSO BE DONE AT THIS TIME .THE MOST LEFT HEART CATHERIZATION PROCEDURES ARE NOW PERFORMED VIA A PERCUTANEOUS APPROACH FROM THE FEMORAL , RADIAL , BRACHIAL OR AXILLARY ARTERY RIGHT HEART CATHERIZATION IS COMMONLY PERFORMED VIA A PERCUTANEOUS APPROACH FROM THE FEMORAL ,INTERNAL JUGULAR OR SUBCLAVIAN VEIN.,GUIDING CATHETER(DR SURGICAL)-THE GUIDE CATHETER PROVIDES SUPPORT FOR DEVICE ADVANCEMENT.,DILATION CATHETER (DR SURGICAL)-DILATION CATHETER IS INDICATED FOR BALLOON DIALATION OF THE STENTOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,CLOSED SUCTION CATHETER(DR SURGICAL)-IS USE TO REDUCE POST OPERATIVE EDEMA AND HEMATOMA FORMATION , DECREASE THE POSSIBILITY OF INFECTION AND MINIMIZE THE CHANCE OF EXTERNAL CONTAMINATION OF SURGICAL SITE.,BONE MARROW BIOPSY NEEDLE(DR SURGICAL)-A SINGLE NEEDLE SINGLE SITE TECHNIQUE FOR BONE MARROW ASPIRATION AND CORE BIOPSY HAS BEEN COMPARED WITH A TWO NEEDLE TECHNIQUE IN ADDITION TWO SINGLE NEEDLE TECHNIQUE WERE COMPARED ASPIRATING IMMEDIATELY AFTER PENETRATING

	THE CORTEX OR ALTERNATIVELY, ASPIRATING AFTER THE NEEDLE WITHOUT THE STYLET HAS BEEN ADVANCED 20-25MM.THE TWO NEEDLE TECHNIQUE WAS FOUND TO BE SUPERIOR TO EITHER OF THE SINGLE NEEDLE TECHNIQUES ,WHICH OFTEN RESULTED IN A BIOPSY SPECIMEN THAT WAS DENUDED OF BONE MARROW CELLS.,EPIDURAL ANESTHESIA CATHETER KIT (DR SURGICAL)-IT MUST BE PERFORMED BY APPROPRIATELY TRAINED PERSONAL USING THE PROPER EQUIPMENT. CAUTIONS DURING CATHETER USE. DO NOT PULL THE CATHETER FROM EPIDURAL NEEDLE SINCE THIS CAN CAUSE CATHETER TO RUPTURE AND ALSO DO NOT PULL THE CATHETER WHEN RETRACTING THE EPIDURAL NEEDLE. ,PRE BYPASS FILTER (DR SURGICAL)-FILTERATION OF CARDIOPULMONARY BYPASS (CPB) PRIMING FLUID BEFORE CONNECTION OF THE CIRCUIT TO THE PATIENT WAS FIRST ACCOMPLISHED BY ARTERIAL LINE FILTERATION. WHEN DEDICATED PRE BYPASS FILTERS WITH SMALLER PORE SIZE BECOME AVAILABLE,A LARGE NUMBER OF PARTICLES COULD BE FOUND ON THE FILTERS SUFRFACE., ASPIRATION CATHETER(DR SURGICAL)-THROMBOSIS OCCURS WHEN CLOTS FORM AND OBSTRUCT THE BLOOD VESSELS. IF THIS OCCURS IN A PATIENTS ARTERIES , ITS CALLED ARTERIAL THROMBUS. WHEN BLOW IS INTERRUPTED , THE HEART MUSCLE IS DEPRIVED OF OXYGEN .PROLONGED OXYGEN DEPRIVATION CAN LEAD TO DEATH OF THE HEART MUSCLES . THE PRIMARY PURPOSE IS ONLY TO REMOVE THROMBUS.,HEMOFILTER/HEMO CONCENTRATOR/DIALYSER (DR SURGICAL)-IT IS USED AS EXTERNALLY COMMUNICATING DEVICE, USED FOR CONTACTING CIRCULATING BLOOD. THE PRODUCT IS NOT INTENDED SPECIFICALLY FOR USE IN DIRECT CONTACT WITH CENTRAL NERVOUS SYSTEM.,PRESSURE MONITORING LINE AND HIGH PRESSURE MONITORING LINE(DR SURGICAL)-HIGH PRESSURE LINE ARE USED IN ANGIO PROCEDURES FOR TRANSFER OF FLUID /BLOOD/MEDICINES AT HIGHER PRESSURE.,RETROGRADE CANNULA (DR SURGICAL)-THE VARIOUS CANNULA USED IN SURGERY ARE IMPORTANT TO THE PERFUSIONIST. THESE CANNULA LINK THE PERFUSION CIRCUIT WITH THE PATIENT. THE CANNULAE OF THE PERFUSION INCLUDES RETROGRADE CANNULA IN ADDITION, THERE ARE LEFT VENTRICLE VENTS ,PULMONARY ARTERY VENTS AND AORTIC ROOT VENTS .,HEMODIALYSIS BLOOD TUBING(DR SURGICAL) -IT IS USED AS EXTERNALLY COMMUNICATING DEVICE , USED FOR CONTACTING CIRCULATING BLOOD. THE PRODUCT IS NOT INTENDED SPECIFICALLY FOR USE IN DIRECT CONTACT WITH CENTRAL NERVOUS SYSTEM.,INFLATION DEVICE(DR SURGICAL)-INFLATION DEVICE IS USED TO DELIVER MEDICATION/FLUID AT MEASURED PRESSURE.THE PRODUCT IS NOT INTENDED SPECIFICALLY FOR USE

	IN DIRECT CONTACT WITH CENTRAL NERVOUS SYSTEM.,INTRODUCER NEEDLE(DR SURGICAL)-DEVICE DESCRIPTIONS AN INTRODUCER NEEDLE CONSISTING OF A 0.018 IN GUIDE WIRE ,A RADIOPAQUE COAXIAL MICRO-INTRODUCER AND A 18G AND 21 G ECHOGENIC INTRODUCER NEEDLE .INDICATIONS FOR USE THE COAXIAL MICRO-INTRODUCER NEEDLE NEEDLE IS INDICATED PERCUTANEOUS INTRODUCTION OF UP TO A 0.038 IN. GUIDE WIRE OR CATHETER INTO THE VASCULAR SYSTEM THROUGH AN INITIAL PRESSURE OF 21 G INTRODUCER .,SURGICAL GOWN(DR SURGICAL)-SURGICAL GOWN ARE INTENDED FOR SINGLE USE TO BE USED AS A PROTECTIVE PATIENT COVERING, SUCH AS TO ISOLATE A SITE ON A SURGICAL INCISION FROM MICROBIAL AND OTHER CONTAMINATION.,SUCTION SET (DR SURGICAL)-THE PRIMARY PURPOSE OF THE HAND HELD SUCTION SET IS TO PROVIDE FINE SUCTION AT THE ANASTOMOSIS SITE .THESE PRODUCTS FEATURES COMFORTABLE HANDGRIPS WITH A VACUUM CONTROL PORT BUILT INTO THE HAND TO ALLOW MORE CONTROL OVER THE SUCTION .ADDITIONAL FEATURES INCLUDE A MALLEABLE ,PVC/STAINLESS STEEL SHAFT, WHICH CAN BE SHAPED TO MEET THE DISTINCT ANGLE REQUIRED AND ARE AVAILABLE WITH OR WITHOUT A SOFT TIP. ,DISPOSABLE PRESSURE TRANSDUCER KIT (DR SURGICAL)-A DISPOSABLE PRESSURE TRANSDUCER (DPT) IS INDICATED FOR PRESSURE SENSING DURING CLINICAL INVASIVE PROCEDURES WITHOUT INTERFERING WITH PATIENTS BLOOD FLOW OR BLOOD PRESSURE. THE SENSOR IS IN FLUID COMMUNICATION WITH DIFFERENT BODY FLUIDS.,ARTERIAL VENOUS TUBING(DR SURGICAL)-IT IS USED AS EXTERNALLY COMMUNICATING DEVICE. USED FOR CONTACTING BLOOD CIRCULATIONS. THE PROCEDURE IS NOT INTENDED TO USE DIRECT CONTACT WITH CENTRAL NERVOUS SYSTEM.,STRAIGHT /Y/T CONNECTOR(DR SURGICAL)-IT IS USED TO JOIN THE A V LINE TO TUBING.,ARTERIAL PERFUSION CANNULA(DR SURGICAL)-THE VARIOUS CANNULA USED IN SURGERY ARE IMPORTANT TO THE PERFUSIONIST. THESE CANNULA LINK THE PERFUSION CIRCUIT WITH THE PATIENT. THE CANNULAE OF THE PERFUSION INCLUDES RETROGRADE CANNULA IN ADDITION, THERE ARE LEFT VENTRICLE VENTS ,PULMONARY ARTERY VENTS AND AORTIC ROOT VENTS,TEMPORARY PACING LEAD(DR SURGICAL)-THE TEMPORARY PACING LEAD, A SMALL CATHETER WITH TWO ELECTRODES, IS PLACED IN THE RIGHT VENTRICLE OF THE HEART THROUGH A VEIN IN THE GROIN OR NECK .THE LEAD IS THEN CONNECTED TO AN EXTERNAL PACEMAKER ALLOWING A PHYSICIAN TO MONITOR AND CONTROL A PATIENT'S HEART RATE OF SEVERAL DAYS. ,ANGIO SYRINGE(DR SURGICAL)-THE ANGIOGRAPHIC SYRINGE IS INDICATED FOR USE DURING ANGIOGRAPHY PROCEDURE AS A CONNECTING LINE FOR THE INJECTION OF LIQUID, SUCH AS

	RADIOPAQUE DYE, SALINE, OR OTHER DIAGONOSTIC FLUIDS. ,BLOOD CARDIOPLEGIA DELIVERY SYSTEM (DR SURGICAL)-CARDIOPLEGIA PLAYS A CRTICAL ROLE KEEPING THE HEART PROTECTED AND ARRESTED DURING CARDIOPULMONARY BYPASS BY MAINTAINING A DESIRED RATIO OF BLOOD CARDIOPLEGIA SOLUTIONS AT A PRESCRIBED TEMPERATURE.,AROTIC ROOT CARDIOPLEGIA CANNULA(DR SURGICAL)-THE VARIOUS CANNULA USED IN SURGERY ARE IMPORTANT TO THE PERFUSIONIST. THESE CANNULA LINK THE PERFUSION CIRCUIT WITH THE PATIENT. THE CANNULA OF THE PERFUSION INCLUDES RETROGRADE CANNULA IN ADDITION, THERE ARE LEFT VENTRICLE VENTS ,PULMONARY ARTERY VENTS AND AORTIC ROOT VENTS,SUCTION CATHETER(DR SURGICAL)-INABILITY TO EXPECTORATE SPUTUM/SALIVA/ASPIRATE FROM THE BACK OF THE MOUTH / THROAT, THE PRESENCE OF WHICH IS CAUSING AN OBSTRUCTION OR DISCOMFORT. THE INSERTION OF A SUCTION CATHETER INTO THE MOUTH IN ORDER TO REMOVE SPUTUM, SALIVA, ASPIRATE. ,HIGH PRESSURE CONTROL SYRINGE(DR SURGICAL)-IT IS USED TO REMOVE AIR OR FLUID FROM PLURAL CAVITY .THE FLUID CAN BE DIRTY BLOOD, PLUS OR A PLEURAL EFFUSION. THE FLUID COLLECTED IN A BAG /BOTTLE WITH PROPER SEALING TO PREVENT AIR ENTERING THE PLEURAL /CHEST CAVITY. THE PRODUCT IS NOT INTENDED SPECIFICALLY FOR USE IN DIRECT CONTACT WITH CENTRAL NERVOUS SYSTEM. ,VENOUS CANNULA(DR SURGICAL)-THE VARIOUS CANNULA USED IN SURGERY ARE IMPORTANT TO THE PERFUSIONIST. THESE CANNULA LINK THE PERFUSION CIRCUIT WITH THE PATIENT. THE CANNULAE OF THE PERFUSION INCLUDES RETROGRADE CANNULA IN ADDITION, THERE ARE LEFT VENTRICLE VENTS ,PULMONARY ARTERY VENTS AND AORTIC ROOT VENTS,MIST BLOWER (DR SURGICAL)-THE THREE WAY CONNECTOR IS ATTACHED TO THE INTRODUCER SHEATH AWAY FROM THE TAPERED SIDE .THE INFUSION SET AND THE TUBING IS ATTACHED TO THE OTHER TWO LIMBS OF THE THREE WAY .THE INFUSION SET IS ATTACHED TO A PRESSURE BAG CONTAINING STERILE ISOTONIC SALINE AND THE TUBING ATTACHED TO AN OXYGEN SOURCE. THE FLOW OF OXYGEN AND AND SALINE CAN BE EASILY REGULATED FOR OPTIMAL MIXING OF GAS AND SALINE .

3568	MFG/MD/2020/000216	1.License Holder Name: AGROSURG IRRADIATORS (INDIA) PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:TOTAL HIP REPLACEMENT SYSTEM (REVISION HIP SYSTEM) (FOR GAMMA STERILIZATION) (LATITUD)-THE HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENT WHO SHOULD BE SKELETALLY MATURE TO RECEIVE A HIP REPLACEMENT.,HIP ACETABULAR SYSTEM (FOR GAMMA STERILIZATION)(LATITUD TRIAD)-THE HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENT WHO SHOULD BE SKELETALLY MATURE TO RECEIVE A HIP REPLACEMENT.,TOTAL HIP REPLACEMENT SYSTEM (FOR GAMMA STERILIZATION)(TRENT)-THE HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENT WHO SHOULD BE SKELETALLY MATURE TO RECEIVE A HIP REPLACEMENT.,TOTAL KNEE SYSTEM (FOR GAMMA STERILIZATION) (OPULENT)-THE TOTAL KNEE SYSTEM IS INDICATED FOR REPLACEMENT OF TOTAL KNEE OR KNEE COMPONENTS FOR PATIENTS WITH SEVERE KNEE PAIN AND DISABILITY DUE TO: • PAINFUL DEGENERATIVE KNEE JOINT DISEASE CAUSED BY: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. • CORRECTION OF FUNCTIONAL DEFORMITIES. • POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLA FEMORAL EROSION, DYSFUNCTION OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS TOTAL HIP REPLACEMENT SYSTEM (FOR GAMMA STERILIZATION) (LATITUD)-THE HIP REPLACEMENT SYSTEM IS INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENT WHO SHOULD BE SKELETALLY MATURE TO RECEIVE A HIP REPLACEMENT.,REVISION KNEE COMPONENTS (STEMMED TIBIAL COMPONENTS & PCK COMPONENTS) (FOR GAMMA STERILIZATION)(DESTIKNEE)-THE DESTIKNEE STEMMED TIBIAL COMPONENTS/PCK COMPONENTS ARE DESIGNED TO BE USED WITH DESTIKNEE-TOTAL KNEE SYSTEM, AND IS INDICATED FOR THE FOLLOWING: • SEVERE KNEE JOINT PAIN, LOSS OF MOBILITY, AND DISABILITY DUE TO: RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, TRAUMATIC ARTHRITIS, POLYARTHRITIS. •CORRECTION OF

	FUNCTIONAL DEFORMITIES. POST-TRAUMATIC LOSS OF KNEE JOINT CONTOUR, PARTICULARLY WHEN THERE IS PATELLOFEMORAL EROSION, DYSFUNCTION, AND/OR PRIOR PATELLECTOMY. • MODERATE VALGUS, VARUS, OR FLEXION TRAUMA. • KNEE FRACTURES UNTREATABLE BY OTHER METHODS • REVISION SURGERY WHERE SUFFICIENT BONE STOCK AND SOFT TISSUE INTEGRITY ARE PRESENT THESE COMPONENTS ARE INTENDED FOR CEMENTED USE ONLY. THIS DEVICE IS FOR SINGLE USE ONLY.

3569	MFG/MD/2020/000217	1.License Holder Name: MICROTROL STERILIZATION SERVICES PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:KITS-KITS ARE EMERGENCY CARE GIVEN IMMEDIATELY TO AN INJURED PERSON. THE PURPOSE OF KIT FOR E.G. FIRST AID KIT IS TO MINIMIZE INJURY AND FUTURE DISABILITY. IN SERIOUS CASES, FIRST AID MAY BE NECESSARY TO KEEP THE VICTIM ALIVE. THE VARIOUS GAUZES, DRESSINGS AND BANDAGES FOUND IN KITS HAVE DIFFERENT USES. THESE DRESSINGS ARE USED FOR MINOR CUTS AND SKIN INJURIES. SOME KITS SUCH AS PICC HICKMAN ARE USED IN SPECIAL SURGICAL PROCEDURE DURING TREATMENT OF CANCER.,COTTON ABSORBENT ABDOMINAL PAD SCH F-II-COTTON ABSORBENT ABDOMINAL PADS ARE MAINLY USED DURING SURGERIES. THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND. , COTTON ABSORBENT GAUZE (GAMJEE PAD, GAMJEE ROLL) SCH F-II-GAMJEE PAD/GAMJEE ROLL, ARE TYPICALLY USED IN FIRST RESPONSE TO INJURIES, THEY ARE COMBINED DRESSING PADS MADE FROM ABSORBENT COTTON WHICH IS WRAPPED IN CAUZE CLOTH AND THIS MAKES THEM IDEAL FOR PACKAGING, WRAPPING, COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND, ABSORBENT COTTON BALLS I.P.-COTTON BALL ARE TYPICALLY USED IN FIRST RESPONSE TO INJURIES, THEY ARE MADE FROM ABSORBENT COTTON THIS MAKES THEM IDEAL FOR CLEANING, SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND,X-RAY DETECTABLE GAUZE SWAB B.P-X RAY DETECTABLE GAUZE SWABS, ARE USED IN LIRST RESPONSE TO INJURIES, THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDES FLUID FROM A WOUND. X RAY DETECTABLE GAUZE SWABS ARE ALSO USED DURING VARIOUS SURGERIES, X RAY THREAD MAKE THEM EASIER TO TRACE INSIDE THE BODY.,X-RAY DETECTABLE ABDOMINAL PAD B.P.-X RAY DETECTABLE ABDOMINAL PADS ARE MAINLY USED DURING SURGERIES. THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND. X RAY THREAD MAKE THEM EASIER TO TRACE INSIDE THE BODY,: ABSORBENT GAUZE SWAB SCH F-II-GAUZE SWABS ARE TYPICALLY USED IN FIRST RESPONSE TO INJURIES, THEY ARE MADE FROM

		SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR CLEANING, PACKAGING, SCRUBBING, COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND. CLOSELY WOVEN GAUZE IS BEST FOR EXTRA STRENGTH OR GREATER PROTECTION, WHILE OPEN OR LOOSE WEAVE IS BETTER FOR ABSORBENCY OR DRAINAGE
3570	MFG/MD/2020/000218	1.License Holder Name: INJECTA LIFE SCIENCE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:INFUSION SET REGULAR-TRANSFUSION SET REGULAR IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,SCALP VEIN SET-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD. , MUCUS EXTRACTOR-MUCUS EXTRACTOR IS INTENDED USED FOR ASPIRATION OF SECRETION FROM THE OROPHARYNX IN NEW BORN BABIES TO ENSURE FREE RESPIRATION OR TO OBTAIN MUCUS SPECIMEN FOR MICROBIOLOGICAL EXAMINATION.,INFUSION SET PREMIUM-TRANSFUSION SET PREMIUM IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,BLOOD TRANSFUSION SET-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD, URETHRAL CATHETER-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY. , FEEDING TUBE-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING. USED TO PROVIDE SHORT TERM ENTERAL ACCESS FOR DELIVERY OF MEDICATION OR NUTRITION TO SMALL BOWEL THROUGH CHANNEL OF ENDOSCOPE., CORD CLAMP-THIS IS USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.

3571	MFG/MD/2020/000219	1.License Holder Name: SCEPTRE MEDICAL INDIA PVT LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:PERACETIC ACID & HYDROGEN PEROXIDE DISINFECTANT LIQUID(MDT PLUS)-FOR CLEANING OF MEDICAL DEVICES,DIDECYLDIMETHYLAMMONIUM CHLORIDE N- ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE SOLUTION(SCEPTOSHEILD DS (W))-FOR CLEANING OF MEDICAL DEVICES,BIS (3-AMINOPROPYL DODECYLAMIN, DIDECYLDIMETYL AMMONIUM CHLORIDE SOLUTION(RHEOSEPT ID PLUS)-FOR CLEANING OF MEDICAL DEVICES,HYDROGEN PEROXIDE SOLUTION (100 VOL)(GUARD 360)-FOR CLEANING OF MEDICAL DEVICES, GLUTARALDEHYDE SOLUTION (SCEPTOGUARD - PLUS)-FOR CLEANING OF MEDICAL DEVICES,ETHANOL (DENATURED WITH 1% DEP) 2 - PROPANOL ,1- PROPANOL TOPICAL SPRAY(SCEPTOGUARD - W)-WET WIPES FOR CLEANING OF MEDICAL DEVICES,CITRIC ACID ANHYDRATE (48% TO 52%)(KLOR KLEEN B)-FOR CLEANING OF MEDICAL DEVICES,ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE SOLUTION(SEPTOSHIELD - ECO)-FOR CLEANING OF MEDICAL DEVICES,CITRIC ACID SOLUTION DISINFECTANT 21%W/V(KLOR KLEEN)-FOR CLEANING OF MEDICAL DEVICES,ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE 5% + NONYL PHENOLETHOXIDE 6% +INERT INGREDIENT 89%(SCEPTOSHIELD - 5)-FOR CLEANING OF MEDICAL DEVICES,ISO PROPYL RUBBING ALCOHOL IP SOLUTION FOR WET WIPES (KLOR CLEAN (W))-FOR CLEANING OF MEDICAL DEVICES, DIDECYLDIMETHYL AMMONIUM CHLORIDE ,BENZYL C- 12-16 ALKLDIMETYHL CHLORIDE ,N - (3- AMINOPROPYL) -N - DODECYPROPANE -1,3 DIAMINE SOLUTION(RHEOSEPT FD PLUS)-FOR CLEANING OF MEDICAL DEVICES,1, 6 DIHYDROXY 2-5 DIOHEXANE GLUTERALDEHYDE BENZYL ALKONIUM CHLORIDE, ALKYL UREA DERIVATIVE SOLUTION(SCEPTO KLEEN ULTRA)-FOR CLEANING OF MEDICAL DEVICES,ORTHO-PHTHALALDEHYDE SOLUTION (SCEPTODEX OPA)-FOR CLEANING OF MEDICAL DEVICES,ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE SOLUTION SURFACE DISINFECTANT(SCEPTOSHEILD - 1)-FOR CLEANING OF MEDICAL DEVICES,DIDECYLDIMETHYL AMMONIUM CHLORIDE N-ALKYL DIMETHYL BENZYLAMMONIUMCHLORIDE SOLUTION DISINFECTION (SCEPTOSHEILD -DS)-FOR CLEANING OF MEDICAL DEVICES, GLUTARALDEHYDE SOLUTION(SCEPTODEX)-FOR CLEANING OF MEDICAL DEVICES,PERACETIC ACID & HYDROGEN PEROXIDE DISINFECTANT LIQUID(REIN PLUS)-FOR CLEANING OF MEDICAL DEVICES,ETHANOL (DENATURED WITH 1% DEP) 2 - PROPANOL ,1- PROPANOL TOPICAL SPRAY(SCEPTOGUARD)-FOR CLEANING OF MEDICAL DEVICES,HYDROGEN PEROXIDE,SILVER NITRATE IP SOLUTION(GUARD 360 PLUS)-FOR CLEANING OF MEDICAL DEVICES,

		ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE SOLUTION DISINFECTANT FOR WET WIPES (WITH PROPORTIONAL RATIO 1:32) (SCEPTOSHEILD 1 (W))-FOR CLEANING OF MEDICAL DEVICES, PERACITIC ACID & HYDROGEN PEROXIDE DISINFECTION SOLUTION (OXY ACTIVE)-FOR CLEANING OF MEDICAL DEVICES,SODIUM HYPOCHLORITE ,SODIUM LAURYL ETHER SULPHATE , LAURYL AMINE OXIDE , SODIUM HYDROXIDE SOLUTION(SEPTOPIC)-FOR CLEANING OF MEDICAL DEVICES
3572	MFG/MD/2020/000220	1.License Holder Name: ONYX MEDICALS PVT. LTD. CARE OF SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE GRAFTING MATERIAL(BIOSYN®)-INTENDED TO FILL, AUGMENT, OR RECONSTRUCT PERIODONTAL OR BONY DEFECTS OF THE ORAL AND MAXILLOFACIAL REGION.
3573	MFG/MD/2020/000221	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:SURGICAL DRESSING (SILK BASED) D-FIBROHEAL-(SHEET ADHESIVE, AG SHEET ADHESIVE, FOAM ADHESIVE, AG FOAM ADHESIVE, SUTURE DRESS, SCARLITE, WOUND AID, SILKPLAST, WOUND NET & MICROGRAS)(D- FIBROHEAL)-IT USE IN COVERING OF BOTH INFECTED AND NON-INFECTED WOUNDS SUCH AS SURGICAL SITES,BURN, SKIN GRAFTS, SKIN ULCER ETC. IT CAN BE USED IN ANY OTHER TYPE OF WOUNDS OR ON PATIENTS AFTER SURGERY AS REQUIRED BY SURGEONS,SURGICAL DRESSING (SILK BASED) (D-FIBROHEAL, D-FIBROHEAL AG, D-FIBROHEALMESHED, D-FIBROHEAL AG MESHED D-FIBROHEAL FOAM, D-FIBROHEAL AG FOAM)(D-FIBROHEAL)-IT USE IN COVERING OF BOTH INFECTED AND NON-INFECTED WOUNDS SUCH AS BURN, SKIN GRAFTS AND SKIN ULCER ETC, FOR PATIENTS AFTER SURGERY AS REQUIRED BY SURGEONS,SURGICAL DRESSINGS (SILK BASED) (D-FIBROHEAL SPRINKLING POWDER, D- FIBROHEAL AG SPRINKLING POWDER ,D- FIBROHEAL PARTICLES, D- FIBROHEAL AG PARTICLES) (D- FIBROHEAL)-T USE IN COVERING OF BOTH INFECTED AND NON-INFECTED WOUNDS SUCH AS BURN, SKIN GRAFTS AND SKIN ULCER ETC, FOR PATIENTS AFTER SURGERY AS REQUIRED BY SURGEONS EVEN IN ANY OTHER TYPE OF WOUNDS

3574	MFG/MD/2020/000222	1.License Holder Name: TULIP SURGICALS 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:ROLLED BANDAGE-MEDICAL PURPOSE USE IN CUTS, WOUNDS, DRESSING, SUPPORT, ABSORBENT COTTON WOOL I.P.-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS,ORTHO- ROLL (ABSORBENT COTTON WOOL IP)-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS , AND ALSO TO SUPPORT,CREPE BANDAGE-FOR SUPPORT AND LIMITING MOVEMENT IN SPRAINS AND STRAIN IN JOINTS AND MUSCLES,ZINC OXIDE SURGICAL ADHESIVE TAPE / ZINC OXIDE SELF-ADHESIVE PLASTER / ZINC OXIDE PLASTER-IT IS USEFUL FOR EXTERNAL WOUNDS, PARTICULARLY USEFUL FOR SKIN AND SOFT TISSUE INJURIES. ZINC OXIDE INCLUDED IN WOUND DRESSINGS, SPEEDS UP WOUND HEALING. ,PAPER ADHESIVE TAPE/PAPER ADHESIVE PLASTER/NON WOVEN ADHESIVE TAPE/SURGICAL TAPE/ADHESIVE TAPE/NON WOVEN SUPPORT (GENTLEPORE)-TO SUPPORT/ HOLD OR FIX OTHER MEDICAL DEVICE, SURGICAL DRESSING,GAUZE SWABS-MEDICAL PURPOSE, WOUND CARE, FOR SURGERY, ABSORBING OF BODY FLUID,ADHESIVE TAPE/SELF ADHESIVE PLASTER-TO SUPPORT/ FIX OR HOLD OTHER DEVICE,ELASTIC ADHESIVE BANDAGE/ZINC OXIDE ELASTIC ADHESIVE BANDAGE-SUPPORT, HOLD OR FIX OTHER DEVICE,GAUZE SWABS (WITH X- RAY THREAD)-AS SURGICAL DRESSING, WOUND CARE, SURGERY, ABSORPTION OF BODY FLUID,ELASTIC SURGICAL ADHESIVE TAPE / ELASTIC ADHESIVE PLASTER/ ZINC OXIDE ELASTIC ADHESIVE PLASTER / ZINC OXIDE- ELASTIC SELF- ADHESIVE PLASTER-AS SURGICAL DRESSING /TO SUPPORT/ HOLD OR FIX OTHER DEVICES,GAUZE-SURGICAL DRESSING, FOR ABSORBING BODY FLUID, APPLYING MEDICAMENTS,PAPER ADHESIVE TAPE / PAPER ADHESIVE PLASTER / NON WOVEN ADHESIVE TAPE/ SURGICAL TAPE/ NON-WOVEN SUPPORT-TO HOLD A BANDAGE OR OTHER DRESSING ONTO A WOUND. TO SUPPORT/ HOLD OTHER MEDICAL DEVICE. IT CAN BE REMOVED EASILY WITHOUT DAMAGING THE SKIN.

3575	MFG/MD/2020/000223	1.License Holder Name: BIORAD MEDISYS PVT LTD 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:FILIFORM URETHRAL SELF DILATOR(NIL)-FILIFORM URETHRAL SELF DILATOR IS USED FOR TRAVERSING AND DILATING URETHRAL STRICTURES. THE FILIFORM TIP REPLACES THE NEED FOR SEPARATE FILIFORM AND FLOWERS TO DILATE THE URETHRA.,IP (INITIAL PUNCTURE) NEEDLE(NIL)-IP NEEDLE IS USED FOR INITIAL PUNCTURE FOR ALL PERCUTANEOUS APPLICATIONS.,GUIDEWIRE(NIL)-GUIDE WIRE IS INTENDED TO FACILITATE THE PLACEMENT OF ENDO-UROLOGICAL INSTRUMENTS DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURES. USED FOR GAINING ACCESS AND NAVIGATING TORTUOUS URINARY TRACT., BIOPSY NEEDLE / BIOPSY GUN(NIL)-THE BIOPSY NEEDLE IS USED FOR TAKING THE TISSUE OF THE PATIENT FOR BIOPSY. INVOLVES REMOVING SOME CELLS EITHER SURGICALLY OR IN A LESS INVASIVE PROCEDURE INVOLVING A HOLLOW NEEDLE FROM A SUSPICIOUS AREA WITHIN THE BODY OR EXAMINING THEM UNDER A MICROSCOPE FOR DIAGNOSIS. ALSO USED FOR RENAL BIOPSIES.,INTRAUTERINE INSEMINATION CATHETER (IUI CATHETER / IUI CATHETER CANNULA) (NIL)-THE IUI CATHETER IS DESIGNED AS POTENTIALLY EFFECTIVE TREATMENT OF ALL CAUSES IN WOMEN FOR INTRA UTERINE INSEMINATION.,BILIARY PUSHER(NIL)-BILIARY PUSHER IS USED TO INTRODUCE BILIARY STENT IN BILIARY TRACT,NASAL BILIARY DRAINAGE CATHETER (NBDC)(NIL)-NASAL BILIARY DRAINAGE CATHETER (NBDC) USED FOR BILIARY DUCT DRAINAGE THROUGH NASAL PASSAGE AND TREATMENT OF STRICTURES IN THE DUCTILE SYSTEM.,HEMODIALYSIS CATHETER(INDOCATH-HD)-HEMODIALYSIS CATHETER IS INDICATED FOR USE IN ATTAINING SHORT-TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS.,PERK (PCNL) BASKET(RETRIVO)-PERK BASKET EXTRACTOR IS DESIGNED TO PROVIDE RAPID ATRAUMATIC STONE EXTRACTION DURING PERCUTANEOUS NEPHROLITHOTOMY (PCNL). PERK BASKETS ARE USED FOR KIDNEY STONE REMOVAL.,Y-CONNECTOR(NIL)-Y-CONNECTOR IS USED TO SIMPLIFY REDUCE BLOOD LOSS DURING PERCUTANEOUS PROCEDURES BY PROVIDING A SEAL AROUND GUIDE WIRE & OTHER DEVICES. UNIQUE SEAL TECHNOLOGY PROVIDES PROTECTION DURING INTERVENTIONS.,URS FORCEPS (RETRIVO)-URS FORCEPS IS USED FOR GRASPING, MANIPULATING AND EXTRACTING CALCULI FROM URETERAL AND RENAL PELVIS., ENDOMETRIAL TUBE(NIL)-ENDOMETRIAL TUBE IS USED TO OBTAIN HISTOLOGICAL TISSUES BIOPSY & EXTRACT SAMPLE OF UTERINE MENSTRUAL CONTENT,SCELEROTHERAPY NEEDLE (INJECTOR / VARICES)(NIL)-SCLEROTHERAPY NEEDLE (VARICES) IS USED FOR INJECTION OF SCELEROTHERAPATIC SOLUTION INTO ESOPHAGEAL

	VARICES.,SUPRAPUBIC CATHETER(NIL)-SUPRAPUBIC CATHETER IS USED TO DRAIN URINE FROM THE BLADDER WHEN ONE CANNOT URINATE.,MEATAL DILATOR(NIL)-MEATAL DILATOR IS USED FOR SELF DILATION OF PENILE URETHRAL MEATUS. STRETCHING OF THE URETHRA OR THE URETHRAL OPENING FOR NARROWING RESULTING IN A POOR URINARY SYSTEM.,URINE BAG CONNECTOR(NIL)-URINE BAG CONNECTOR IS USED TO CONNECT BETWEEN THE CATHETERS / DILATORS, OR ANY OTHER DRAINAGE DEVICES TO URINE BAG.,PCN CATHETER / NEPHROSTOMY CATHETER(NIL)-PCN CATHETER / NEPHROSTOMY CATHETER IS USED FOR THE TEMPORARY DRAINAGE BY DIRECT PUNCTURE THOUGH THE SKIN INTO THE KIDNEY FOR THE DISTAL OBSTRUCTION. USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE.,DUAL LUMEN CATHETER(NIL)-THE DUAL LUMEN CATHETER IS USED FOR DRAINAGE OF URINE, CONTRAST INJECTION, URETERAL DILATION & PLACEMENT OF SAFETY GUIDEWIRE,STONE BASKET(RETRIVO)-STONE BASKET IS USED TO RETRIEVE STONES OR TO RESTRAINT STONE MIGRATION FROM OR WITHIN THE URINARY SYSTEM.,RE-ENTRY MALECOT CATHETER(NIL)-RE-ENTRY MALECOT CATHETER IS USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE (INTERNAL AND EXTERNAL DRAINAGE).,URETERAL DILATOR(NIL)-URETERAL DILATOR & SET ARE THE SET OF DILATORS USED FOR DILATATION OF THE URETER PRIOR TO URETERORENOSCOPY AND ALSO FOR SEQUENTIAL DILATATION OF THE INTRAMURAL TUNNEL AND URETHRA AND / OR STONE MANIPULATION.,URETHRAL DILATOR(NIL)-URETHRAL DILATORS ARE THE SET OF DILATORS USED FOR DILATATION OF THE URETHRA.,FASCIAL DILATOR(NIL)-FASCIAL DILATOR IS USED FOR DILATATION OF PERCUTANEOUS TRACK OVER THE GUIDEWIRE FOR FASCIAL DILATION.,STONE COLLECTOR(NIL)-STONE COLLECTOR IS USED TO COLLECT THE STONES PRESENT IN THE URINE,CHIBA NEEDLE(NIL)-CHIBA NEEDLE IS USED FOR PERCUTANEOUS NEPHROSTOMY PROCEDURES, CYTOLOGICAL BIOPSIES, NEEDLE-ASPIRATIONS, THORACENTESIS EXPLORATORY PUNCTURES, TO INJECT CONTRAST DYES.,SCELEROTHERAPY NEEDLE (VARICES)(NIL)-SCLEROTHERAPY NEEDLE (VARICES) IS USED FOR INJECTION OF SCELEROTHERAPATIC SOLUTION INTO ESOPHAGEAL VARICES.,AMPLATZ DILATOR (DILATRON)-AMPLATZ DILATOR & SET IS A DEVICE USED TO DILATE THE NEPHROSTOMY TRACT.,URETERAL BALLOON DILATOR(NIL)-URETERAL BALLOON DILATOR IS USED FOR URETERAL DILATION PRIOR TO URETERAL STONE MANIPULATION OR URETEROSCOPY, AS WELL AS DILATION OF THE INTRAMURAL URETER & URINARY TRACT. ALSO USED FOR WIDENING THE URETERAL STRICTURE.,TRANSDUCER PROTECTOR(NIL)-TRANSDUCER PROTECTOR IS USED FOR

	HEMODIALYSIS BLOOD LINES TO KEEP THE BLOOD SIDE OF CIRCUIT SEPARATE FROM THE MACHINE SIDE.,PENILE CLAMP(NIL)-PENILE CLAMP KNOWN ALSO AS A CUNNINGHAM CLAMP IS WORN EXTERNALLY TO CONTROL INCONTINENCE IN MEN. THIS CLAMP HELP PATIENTS MANAGE URINE LEAKAGE.,URS FORCEPS(RETRIVO)-URS FORCEPS IS USED FOR GRASPING, MANIPULATING AND EXTRACTING CALCULI FROM URETERAL AND RENAL PELVIS. ,PCN CATHETER / NEPHROSTOMY CATHETER(NIL)-PCN CATHETER / NEPHROSTOMY CATHETER IS USED FOR THE TEMPORARY DRAINAGE BY DIRECT PUNCTURE THOUGH THE SKIN INTO THE KIDNEY FOR THE DISTAL OBSTRUCTION. USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE ,MALECOT CATHETER(NIL)-MALECOT CATHETER IS USED FOR EXTERNAL DRAINAGE OF VISCOUS LIQUIDS FROM RENAL PELVIS OR BLADDER, FOR PCN & SUPRAPUBIC PROCEDURES RESPECTIVELY.,URETHRAL STENT(NIL)-URETHRAL STENT IS USED FOR STENTING THE URETHRA AFTER HYPOSPADIAS OR EPISPADIAS REPAIR,URETERAL ACCESS SHEATH / BRAIDED SHAFT CATHETER(UROX)-URETERAL ACCESS SHEATH / BRAIDED SHAFT CATHETER PROVIDES URETERAL DILATION AND WORKING CHANNEL FOR THE INTRODUCTION OF URETEROSCOPES AND DEVICES DURING URETEROSCOPIC PROCEDURES.,URETERAL CATHETER(NIL)-URETERAL CATHETER IS USED FOR EXTERNAL URETERAL DRAINAGE AND FOR RETROGRADE PYELOGRAM AND NAVIGATION OF THE TORTUOUS URETER THROUGH THE URETHRA.,BILBAO DOTTER(NIL)-BILBAO DOTTER IS USED THROUGH THE CHANNEL OF ENDOSCOPE TO PROVIDE SHORT DURATION INTERNAL ACCESS FOR DELIVERY OF NUTRITION OR MEDICATION TO THE SMALL BOWEL.,CYSTO CATHETER(NIL)-CYSTO CATHETER OFFERS A SIMPLIFIED SYSTEM FOR BLADDER DRAINAGE BY SUPRAPUBIC PLACEMENT,EVACUATOR(NIL)-EVACUATOR IS USED FOR REMOVAL/COLLECTION OF TISSUE SECTIONS DURING TRANSURETHRAL RESECTION OF THE PROSTATE (TURP).,INFLATION DEVICE(NIL)-INFLATION DEVICE IS A HIGH PRESSURE SYRINGE BARREL, ERGONOMIC PISTON HANDLE, AND A GAUGE USED TO MONITOR THE INFLATION AND DEFLATION OF BALLOON CATHETERS WHEN CONNECTED TO URETERAL BALLOON CATHETERS, THE INFLATION DEVICE MAY BE REFERRED TO AS THE BALLOON INFLATION DEVICE.,PATH FINDER / IRRIGATION PUMP(NIL)-PATH FINDER/ IRRIGATION PUMP IS USED FOR CONTROLLED UROLOGIC IRRIGATION SYSTEM,PERK (PCNL) BASKET(RETRIVO)-PERK BASKET EXTRACTOR IS DESIGNED TO PROVIDE RAPID ATRAUMATIC STONE EXTRACTION DURING PERCUTANEOUS NEPHROLITHOTOMY (PCNL). PERK BASKETS ARE USED FOR KIDNEY STONE REMOVAL,AMPLATZ DILATOR SET (MINI PERC)(DILATRON)-AMPLATZ DILATOR (MINI

	PERC) IS A DEVICE USED TO DILATE THE NEPHROSTOMY TRACT IN PEDIATRIC.,GUIDEWIRE(NIL)-GUIDE WIRE IS INTENDED TO FACILITATE THE PLACEMENT OF ENDO-UROLOGICAL INSTRUMENTS DURING DIAGNOSTIC OR INTERVENTIONAL PROCEDURES. USED FOR GAIN ING ACCESS AND NAVIGATING TORTUOUS URINARY TRACT.,JEJUNAL FEEDING TUBE(NIL)-JEJUNAL FEEDING TUBE IS USED THROUGH THE CHANNEL OF THE ENDOSCOPE TO PROVIDE SHORT DURATION INTERNAL ACCESS FOR DELIVERY OF NUTRITION OR MEDICATION TO THE SMALL BOWEL.,INTRAUTERINE INSEMINATION CATHETER (IUI CATHETER / IUI CATHETER CANNULA)(NIL)-THE IUI CATHETER IS DESIGNED AS POTENTIALLY EFFECTIVE TREATMENT OF ALL CAUSES IN WOMEN FOR INTRA UTERINE INSEMINATION.,NOTTINGHAM ONE STEP DILATOR(NIL)-NOTTINGHAM ONE STEP DILATOR IS USED TO DILATE THE INTRAMURAL TUNNEL AND URETER IN ONE STEP,FOLEYS CATHETER(NIL)-FOLEYS CATHETER IS INTENDED FOR USE IN PROVIDING CONTINUOUS BLADDER IRRIGATION OF FLUIDS AND /OR DRAINAGE OF URINE FROM THE URINARY TRACT. URINARY TRACT ACCESS IS GENERALLY ACCOMPLISHED BY INSERTION OF THE CATHETER THROUGH THE URETHRA AND INTO THE BLADDER.,STONE BASKET(RETRIVO)-STONE BASKET IS USED TO RETRIEVE STONES OR TO RESTRAINT STONE MIGRATION FROM OR WITHIN THE URINARY SYSTEM.,INTRODUCER NEEDLE (NIL)-INTRODUCER NEEDLE IS USED FOR THE PLACEMENT OF A GUIDEWIRE, INTRODUCER NEEDLE IS DESIGNED FOR PERCUTANEOUS ACCESS,S-CURVE URETHRAL DILATOR(NIL)-S - CURVE URETERAL DILATOR IS USED FOR DILATION OF MALE URETHRAL STRICTURES & VESICAL NECK CONTRACTURES. IT SUPPORTS THE NATURAL CURVATURE OF THE MALE URETHRA, SCREW DILATOR(NIL)-SCREW DILATOR IS USED FOR ONE STEP DILATION. THIS CAN BE USED INSTEAD OF SEQUENTIAL DILATION OR FASCIAL DILATION.,AMPLATZ SHEATH(DILATRON)-AMPLATZ SHEATH IS USED TO ALLOW SMOOTH PASSAGE OF SURGICAL INSTRUMENTS INTO THE NEPHROSTOMY TRACT.,NEPHROSTOMY BALLOON DILATOR(NIL)-NEPHROSTOMY BALLOON DILATOR USED FOR DILATING THE NEPHROSTOMY TRACK AND FOR THE PLACEMENT OF THE WORKING SHEATH.,GASTRO BASKET(NIL)-GASTRO BASKET IS USED FOR THE ENDOSCOPIC REMOVAL OF BILIARY STONES AND FOREIGN BODIES.,MEATAL DILATOR(NIL)-MEATAL DILATOR IS USED FOR SELF DILATION OF PENILE URETHRAL MEATUS. STRETCHING OF THE URETHRA OR THE URETHRAL OPENING FOR NARROWING RESULTING IN A POOR URINARY SYSTEM,FILIFORM URETHRAL SELF DILATOR (NIL)-FILIFORM URETHRAL SELF DILATOR IS USED FOR TRAVERSING AND DILATING URETHRAL STRICTURES. THE FILIFORM TIP REPLACES THE NEED FOR SEPARATE FILIFORM AND FLOWERS TO DILATE THE URETHRA,NASAL BILIARY DRAINAGE CATHETER (NBDC)

		(NIL)-NASAL BILIARY DRAINAGE CATHETER (NBDC) USED FOR BILIARY DUCT DRAINAGE THROUGH NASAL PASSAGE AND TREATMENT OF STRICTURES IN THE DUCTILE SYSTEM
3576	MFG/MD/2020/000224	1.License Holder Name: SUNWAYS INOR MEDICAL DEVICES PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:STAPLES(INOR / INOR XL / SWI / SUNWAYS INOR)-IMPLANT FOR BODY USED TO FIX FRACTURE, BONE PLATE(INOR / INOR XL / SWI / SUNWAYS INOR)-IMPLANT FOR BODY USED TO FIX FRACTURE,PIN AND WIRES(INOR / INOR XL / SWI / SUNWAYS INOR)-IMPLANT FOR BODY USED TO FIX FRACTURE,HIP SYSTEM(INOR / INOR XL / SWI / SUNWAYS INOR)-THE DEVICE IS INTENDED TO BE IMPLANTED TO REPLACE WHOLE OR PART OF HIP JOINT,BONE SCREW(INOR / INOR XL / SWI / SUNWAYS INOR)-IMPLANT FOR BODY USED TO FIX FRACTURE,INTRA MEDULLARY (IM) NAIL(INOR / INOR XL / SWI / SUNWAYS INOR)-IMPLANT FOR BODY USED TO FIX FRACTURE,BONE SCREW(INOR / INOR XL / SWI / SUNWAYS INOR)-IMPLANT FOR BODY USED TO FIX FRACTURE, ENDCAPS(INOR / INOR XL / SWI / SUNWAYS INOR)-IMPLANT FOR BODY USED TO FIX FRACTURE,TOTAL KNEE SYSTEM(INOR / INOR XL / SWI / SUNWAYS INOR)-THE DEVICE IS INTENDED TO BE IMPLANTED TO REPLACE WHOLE OR PART OF KNEE JOINT,WASHER(INOR / INOR XL / SWI / SUNWAYS INOR)-IMPLANT FOR BODY USED TO FIX FRACTURE
3577	MFG/MD/2020/000225	1.License Holder Name: ALTUS SURGICAL PRIVATE LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL IP-MEDICAL / SURGICAL DRESSING

3578	MFG/MD/2020/000226	1.License Holder Name: AGROSURG IRRADIATORS (INDIA) PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:COPPER 200 AG (CU 200 AG)(PREGNA CU 200 AG, SILVERLINE CU 200 AG, ANDALAN SILVERLINE CU 200 AG, SILVERLINE 200, HEER CU 200 AG, ANDALAN SILVERFLEX CU 200 AG DISPOSITIVO INTRAUTERINO, PREGNA MODEL CU 250)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,T CU 380 A (COPPER T 380 A)(ETHERENA T CU 380 A)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 380 MINI (CU 380 MINI)(COPPER Y MINI CU 380)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER T 380 A WITH SAFELOAD (T CU 380 A WITH SAFELOAD)(PREGNA MODEL T CU 380 A WITH SAFELOAD, SAFELOAD T CU 380 A, ALTHEA T CU 380 A WITH SAFELOAD, ANDALAN SAFELOAD T CU 380 A, HEER T CU 380 A WITH SAFELOAD, LYDIA T CU 380 A SAFELOAD, PREGNA FEMININ SAFELOAD T CU 380 A, FREEDOM 10 COPPER T 380 A WITH SAFELOAD, TRUST T CU 380 A SAFELOAD, ANDALAN CLASSIC CU 380 DISPOSITIVO INTRAUTERINO SAFELOAD, EASY CARE T CU 380 A, ALZEE SAFELOAD T CU 380 A, PROTECT 10 T CU 380 A WITH SAFELOAD, PREGNA EASYCARE CU 380 A, ELENORA SAFELOAD T CU 380 A, LANA TS T CU 380 A WITH SAFELOAD)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY., COPPER T 380 A (POSTPARTUM)(POSTPRTUM IUD CU T 380 A, ANDALAN POST-PARTUS T CU 380 A, LYDIA POSTPARTUM COPPER T 380 A, POSTPARTUM IUD T CU 380 A, ALEZE POSTPARTUM IUD T CU 380 A, PREGNA PP IUD T CU 380 A, FREEDOM 10 POSTPARTUM IUD COPPER T 380 A, ANDALAN CLASSIC POS-PARTO CU 380 DISPOSITIVO INTRAUTERINO, ANDALAN POSTPARTUM T CU 380 A)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY., COPPER T 380 A (T CU 380A)(LANA T T CU 380A, INTERPHARMA MODEL T CU 380A, PREGNA T CU 380 A, INTERPHARMA PREGNA MODEL T CU 380 A, PREGNA MODEL T CU 380 A, SECURIT T IUD MODEL T CU 380 A, TRUST T CU 380 A, VEVINA T CU 380 A, LYDIA T CU 380 A, MYCHOICE IUD MODEL T CU 380 A, NEW CHOICE MODEL CU 380 A, ALTHEA T CU 380 A, NEW CHOICE MODEL T CU 380 A, LONGACT T CU 380 A, PREGNA EASYCARE CU 380 A, PREGNA+ T-KARE MODEL T CU 380 A, EASY CARE T CU 380 A, PREGNA+ T CU 380 A, KHUSHI MODEL COPPER T 380 A, ANDALAN T CU 380 A, ELENORA + T CU 380 A, PREGNA+ MODEL T CU 380 A, PROTEC T CU 380 A, LANA T PLUS T CU 380 A.OK IUCD T CU 380 A, FREEDOM 10 COPPER T 380 A, LYDIA COPPER T CU 380 A, OPSET MODEL T CU 380 A, HEER T CU 380 A, TRUST COPPER T CU 380 A, HEER T CU 380 A PLUS, LONGACT T CU 380 A, PREGNA T-CARE T CU 380 A,ANDALAN

	CLASSIC CU 380 DISPOSITIVO INTRAUTERINO,)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,CU 380 AG (SILVERLINE CU 380 AG WITH DISPOSABLE UTERINE SOUND)-IT OFFERS COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 375 SLEEK (CU 375 SLEEK)(PREGNA MODEL CU 375 SLEEK, INARA MODEL CU 375 SLEEK, ANDALAN CU 375 SLEEK, U-KARE SLEEK MODEL CU 375 SLEEK, HEER CU 375 SLEEK, LYDIA CU 375 SLEEK, SAKHI MODEL CU 375 SLEEK, TRUST CU 375 SLEEK, INARA CORTO CU 375, ANDALAN CONFORT MINI CU 375 DISPOSITIVO INTRAUTERINO, U-CARE CORTO CU 375, CU 375 SLEEK, FREEDOM 5 SLEEK MODEL CU 375, ELENORA CU 375 SLEEK, LANA M MINI CU 375)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 375 SLEEK (POSTPARTUM)(PREGNA CU 375 SLEEK WITH LONG INSERTER, INARA CU 375 SLEEK WITH LONG INSERTER, PREGNA POSTPARTUM IUD CU 375 SLEEK)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 250 (CU 250)(PREGNA MODEL CU 250, U-KARE MODEL CU 250, INARA MODEL CU 250, LIBERTA MODEL CU 250, ANDALAN COMFORT CU 250 DISPOSITIVO INTRAUTERINO, LYDIA CU 250, FREEDOM 3 MODEL CU 250, CLARA CU 250)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,T CU 380 A (COPPER T 380 A)(ETHERENA T CU 380 A WITH DISPOSABLE UTERINE SOUND, ANDALAN CLASSIC FASTLOAD CU 380 DISPOSITIVO INTRAUTERINO)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 380 (CU 380)(COPPER Y CU 380, LYDIA COPPER Y 380 IUD, HEER COPPER Y CU 380, EASY CARE CU 380, TRUST COPPER Y CU 380)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 380 AG (CU 380 AG)(PREGNA CU 380 AG, SILVERLINE CU 380 AG, ANDALAN SILVERLINE CU 380 AG, SILVERLINE 380, FEMININ SILVER CU 380 AG, SILVERCARE CU 380 AG, TRUST PLUS SILVERLINE CU 380 AG, OPSET CU 380 AG, ANDALAN SILVERFLEX CU 380 AG DISPOSITIVO INTRAUTERINO, CUPRALUNA SILVER CU 380 AG, ELENORA SILVERLINE CU 380 AG, PREGNA MODEL CU 380 AG, LANA V CU 380 AG.)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,COPPER 375 (CU 375)(PREGNA MODEL CU 375, U-KARE MODEL CU 375, INARA MODEL CU 375, ALTHEA CU 375, OK CU 375, LIBERTA MODEL CU 375, B-SURE MULTICHOICE MODEL CU 375, OPSET MODEL CU 375, INARA ESTANDAR CU 375, KHUSHI MODEL CU 375, PROTECT 5 CU 375, ANDALAN COMFORT CU 375 DISPOSITIVO INTRAUTERINO, U-CARE CU 375, CU 375, PREGNA CU 375, U-CARE ESTANDAR CU 375, FREEDOM 5 MODEL CU 375, CUPRALUNA OMEGA CU 375, ELENORA CU 375, LANA U CU 375)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,TUBAL RING(TUBAL RING)-IT IS USED FOR FEMALE STERILIZATION.,COPPER 375

		(POSTPARTUM)(PREGNA CU 375 WITH LONG INSERTER, INARA CU 375 WITH LONG INSERTER, POSPARTUM IUD CU 375, FREEDOM 5 POSTPARTUM CU 375, PREGNA PP IUD CU 375)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,MINI CU 380 AG (SILVERLINE MINI CU 380 AG, ANDALAN SILVERFLEX MINI CU 380 AG, SILVERCARE MINI CU 380 AG)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.,CU 250 SLEEK(PREGNA MODEL CU 250 SLEEK, U-KARE SLEEK CU 250, LYDIA CU 250 SLEEK, INARA MODEL CU 250 SLEEK)-IT OFFERS ALMOST COMPLETE PROTECTION AGAINST PREGNANCY.
3579	MFG/MD/2020/000227	1.License Holder Name: VASMED HEALTH SCIENCES PVT. LTD. 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:PTCA GUIDEWIRE(ASTRA PTCA GUIDEWIRE)-VASMED GUIDE WIRES ARE INTENDED TO FACILITATE THE PLACEMENT OF BALLOON DILATATION CATHETERS DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA), INCLUDING USE IN CROSSING OR ASSISTING IN CROSSING DE NOVO CORONARY CHRONIC TOTAL OCCLUSIONS (CTO).

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO CDSCO
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3580	MFG/MD/2020/000228	1.License Holder Name: ENVISION SCIENTIFIC PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:SIROLIMUS COATED PTA BALLOON CATHETER(MAGIC TOUCH - AVF)-MAGIC TOUCH - AVF DEVICE IS A DRUG COATED BALLOON CATHETER WHICH IS INTENDED FOR USE IN THE PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA), AFTER PRE-DILATATION, FOR TREATMENT OF STENOTIC LESIONS OF DYSFUNCTIONAL NATIVE ARTERIOVENOUS DIALYSIS FISTULAE AND GRAFT THAT ARE 3.00 MM TO 12.00 MM IN DIAMETER AND UP TO 95 MM IN LESION LENGTH.,SIROLIMUS COATED BALLOON CATHETER(MAGIC TOUCH, DEVOIR, VANQUISHER, MAGIC TOUCH - SCB)-SIROLIMUS COATED BALLOON CATHETER IS INDICATED FOR TREATMENT OF CORONARY ARTERY DISEASE BY PERFORMING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY, AFTER APPROPRIATE LESION PREPARATION. SIROLIMUS COATED BALLOON CATHETER IS THEREFORE INDICATED TO DILATE THE DISEASED SEGMENT(S) IN CORONARY ARTERY BY DELIVERING DRUG IN CORONARY ARTERY OR GRAFT WITH LESION LENGTHS OF 6.00 MM TO 36.00 MM AND REFERENCE VESSEL DIAMETER FROM 1.50 MM TO 4.00 MM.,SIROLIMUS COATED PTA BALLOON CATHETER(XTREME TOUCH NEO, MAGIC TOUCH PTA)-XTREME TOUCH NEO (0.014”, 0.018” & 0.035”) SIROLIMUS COATED BALLOON CATHETERS (OTW & RX) IS INDICATED FOR TREATMENT OF PATIENTS WITH STENOTIC OR OBSTRUCTIVE VASCULAR LESIONS (LENGTH 200 MM) IN THE LOWER EXTREMITIES FOR THE PURPOSE OF IMPROVING LIMB PERFUSION AND DECREASING THE INCIDENCE OF RESTENOSIS IN NATIVE FEMOROPOPLITEAL ARTERIES HAVING REFERENCE VESSEL DIAMETERS OF 1.50 MM TO 12.0 MM.,PTCA DILATATION CATHETER (MASTERY)-THE MASTERY CATHETER IS INTENDED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. THE MASTERY PTCA CATHETER IS THEREFORE INDICATED TO DILATE THE DISEASED SEGMENT(S) IN A CORONARY ARTERY OR A CORONARY BYPASS, TO IMPROVE MYOCARDIAL PERFUSION.,SIROLIMUS BASED BIFURCATION STENT SYSTEM(NILE SIR, BIFUR)-IT IS INDICATED FOR IMPROVING CORONARY ARTERY LUMINAL DIAMETER, WHILE SIMULTANEOUSLY MAINTAINING SIDE BRANCH ACCESS IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO LESIONS (LENGTH 18 MM) IN NATIVE CORONARY ARTERIES INVOLVING A MAJOR BRANCH WITH A MAIN BRANCH REFERENCE VESSEL DIAMETER OF 2.50 TO 3.50 MM AND WITH A SIDE BRANCH REFERENCE VESSEL DIAMETER OF 2.00 TO 3.00 MM.,SIROLIMUS

	ELUTING CORONARY STENT SYSTEM(ABLUMINUS, MITIGATOR, NOSTRUM, AMAZONIA-SIR, IHTDESTINY®BD, AGILE, MINORIS, SERPENTIS, CROCUS, ABLUMINUS DES+, FUTURE, FUSION, ABLUMINUS – DM, ABLUMINUS - AMI, ABRAX COCR)-THE SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR TREATMENT OF PATIENTS WITH STENOSIS IN CORONARY ARTERIES. IT IS INDICATED FOR IMPROVING AND MAINTAINING THE CORONARY LUMINAL DIAMETER IN PATIENTS. THE SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED TO TREAT CORONARY ARTERY DISEASE IN PATIENTS WITH DIABETES MELLITUS AND LESION IN CORONARY ARTERY WITH DIFFUSED PROLIFERATIVE DISEASE. THE SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR TREATMENT OF SYMPTOMATIC ISCHEMIC DISEASE WITH DIABETES MELLITUS DUE TO LESIONS OF LENGTH 52 MM IN NATIVE CORONARY ARTERIES WITH A REFERENCE DIAMETER FROM 2.25MM TO 5.00MM.,SIROLIMUS BASED NANO CARRIER ELUTING STENT SYSTEM(FOCUS NP, ABLUMINUS NP, CYNOSURE)-SIROLIMUS BASED NANO CARRIER ELUTING STENT SYSTEM IS INTENDED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. RECOGNIZED USE OF INTRACORONARY STENTS CURRENTLY INCLUDES BUT IS NOT LIMITED TO THE TREATMENT OF DE NOVO OR RESTENOTIC LESIONS IN NATIVE CORONARY ARTERIES AND IN DE NOVO LESIONS OF SAPHENOUS VEIN GRAFTS. SIROLIMUS BASED NANO CARRIER ELUTING STENT SYSTEM IS AVAILABLE FOR INTRACORONARY IMPLANTATION FOR INNER VESSEL DIAMETERS OF 2.25 TO 4.00 MM., PTCA DILATATION CATHETER(SWIMMER, SWIMMER NC, SWIMMER CTO)-THE PTCA DILATATION CATHETER IS INTENDED FOR USE IN TREATMENT OF PATIENT WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO PATHOLOGICAL CONDITIONS OF ONE OR MORE CORONARY ARTERIES. THE PTCA DILATATION CATHETER IS THEREFORE INDICATED TO DILATE THE DISEASED SEGMENT(S) IN A CORONARY ARTERY OR A CORONARY BYPASS, TO IMPROVE MYOCARDIAL PERFUSION. THE PTCA DILATATION CATHETER IS INDICATED FOR PATIENTS WITH FOLLOWING CRITERIA: PATIENT MUST BE JUDGED TO BE ACCEPTABLE CANDIDATE FOR CORONARY BYPASS SURGERY. PATIENTS WITH SINGLE VESSEL ATHEROSCLEROTIC LESION (S), NONCALCIFIED, SUBTOTAL AND ACCESSIBLE TO DILATATION WITH GUIDEWIRE AND CATHETER. CERTAIN MULTIVESSEL DISEASED PATIENT MAY ALSO BE CANDIDATES FOR THIS PROCEDURE. CERTAIN PATIENTS, WHO HAVE UNDERGONE PREVIOUS CORONARY BYPASS SURGERY WITH RECURRENCE OF SYMPTOMS AND PROGRESSION OF THE DISEASE IN

		THE CORONARY ARTERY, OR STENOSIS AND CLOSURE OF THE GRAFTS, MAY ALSO BE CANDIDATES.
3581	MFG/MD/2020/000229	1.License Holder Name: GAYATRI INDUSTRIES 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:GAUZE ROLL -IT IS USED IN MEDICAL DRESSINGS,ABSORBENT GAUZE CLOTH-IT IS USED FOR MEDICAL DRESSINGS,ROLLED BANDAGE-IT IS USED TO SUPPORT THE MEDICAL DRESSINGS MATERIAL,BANDAGE CLOTH-IT IS USED TO SUPPORT THE MEDICAL DRESSINGS MATERIAL,COTTON CREPE BANDAGES-IT IS USED TO PROVIDE GENTLE SUPPORT AND COMPRESSION TO HELP REDUCE PAIN AND MAINTAIN STABILITY IN SPRAINS AND STRAINS

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3582	MFG/MD/2020/000230	1.License Holder Name: AI OPTICS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:ACRYLIC FOLDABLE INTRAOCULAR LENS (EXPORT & DOMESTIC)(RIL TORIC)-THE RIL TORIC LENS IS INDICATED FOR THE CORRECTION OF MYOPIA (NEARSIGHTEDNESS) AND HYPEROPIA (FARSIGHTEDNESS) WITH ASTIGMATISM IN THE PHAKIC ADULTS.,POSTERIOR CHAMBER INTRAOCULAR LENS (EXPORT & DOMESTIC)(SUPRAPHOB INFOCUS)-IT IS INDICATED FOR THE REPLACEMENT OF THE HUMAN NATURAL LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULTS PATIENTS FOLLOWING CATARACT SURGERY. THE LENS IS INTENDED FOR PLACEMENT IN THE CAPSULAR BAG. IT IS INDICATED IN MONOCULAR CATARACT, MATURE CATARACT, OCCUPATIONAL CATARACT, TRAUMATIC CATARACT AND CONGENITAL CATARACT., ACRYLIC FOLDABLE INTRAOCULAR LENS WITH DISPOSABLE INJECTOR SYSTEM (EXPORT & DOMESTIC)(RIL TORIC)-THE RIL TORIC LENS IS INDICATED FOR THE CORRECTION OF MYOPIA (NEARSIGHTEDNESS) AND HYPEROPIA (FARSIGHTEDNESS) WITH ASTIGMATISM IN THE PHAKIC ADULTS.,FOLDABLE HYDROPHILIC ACRYLIC INTRAOCULAR LENS (EXPORT & DOMESTIC)(REFRACTIVE IMPLANTABLE LENS)-IT IS INDICATED FOR THE CORRECTION OF MYOPIA TO ACHIEVE VISUAL CORRECTION OF MYOPIA IN THE PHAKIC ADULTS.,FOLDABLE INTRAOCULAR LENS WITH DISPOSABLE INJECTOR SYSTEM (EXPORT AND DOMESTIC)(CM-T FLEX)-INTRAOCULAR LENSES ARE OPTICAL IMPLANTS FOR THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA. IT IS INDICATED IN MONOCULAR CATARACT, MATURE CATARACT, CONGENITAL CATARACT, OCCUPATIONAL CATARACT AND TRAUMATIC CATARACT.,FOLDABLE HYDROPHILIC ACRYLIC INTRAOCULAR LENS WITH DISPOSABLE INJECTOR SYSTEM (EXPORT & DOMESTIC)(REFRACTIVE IMPLANTABLE LENS)-IT IS INDICATED FOR THE CORRECTION OF MYOPIA TO ACHIEVE VISUAL CORRECTION OF MYOPIA IN THE PHAKIC ADULTS.,FOLDABLE INTRAOCULAR LENS (EXPORT AND DOMESTIC)(CM-T FLEX)-INTRAOCULAR LENSES ARE OPTICAL IMPLANTS FOR THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA. IT IS INDICATED IN MONOCULAR CATARACT, MATURE CATARACT, CONGENITAL CATARACT, OCCUPATIONAL CATARACT AND TRAUMATIC CATARACT.,ASPHERIC FOLDABLE POSTERIOR CHAMBER INTRAOCULAR LENS WITH DISPOSABLE INJECTOR SYSTEM (EXPORT AND DOMESTIC)(NASPRO INFOCUS)-IT IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN THE PATIENTS OF AGE FORTY YEARS OR OLDER. THESE LENSES ARE

	INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,FOLDABLE INTRAOCULAR LENS WITH DISPOSABLE INJECTOR SYSTEM (EXPORT AND DOMESTIC- FOR VETERINARY USE ONLY)(VETFOLD)-INTRAOCULAR LENSES ARE OPTICAL IMPLANTS FOR THE ANIMAL CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA. IT IS INDICATED IN MONOCULAR CATARACT, MATURE CATARACT, CONGENITAL CATARACT, OCCUPATIONAL CATARACT AND TRAUMATIC CATARACT.,ASPHERIC FOLDABLE POSTERIOR CHAMBER INTRAOCULAR LENS (EXPORT AND DOMESTIC)(NASPRO INFOCUS)-IT IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN THE PATIENTS OF AGE FORTY YEARS OR OLDER. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,FOLDABLE INTRAOCULAR LENS (EXPORT AND DOMESTIC- FOR VETERINARY USE ONLY)(VETFOLD)-INTRAOCULAR LENSES ARE OPTICAL IMPLANTS FOR THE ANIMAL CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA. IT IS INDICATED IN MONOCULAR CATARACT, MATURE CATARACT, CONGENITAL CATARACT, OCCUPATIONAL CATARACT AND TRAUMATIC CATARACT.,FOLDABLE HYDROPHOBIC ACRYLIC INTRAOCULAR LENS WITH DISPOSABLE PRELOADED SYSTEM (EXPORT & DOMESTIC)(SUPRAPHOB TORIC)-IT IS INTENDED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG OF THE EYE FOR VISUAL CORRECTION O APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM SECONDARY TO REMOVAL OF A CATARACTOUS LENS IN ADULTS PATIENTS WITH OR WITHOUT PRESBYOPIA, WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE VISION.,FOLDABLE HYDROPHOBIC ACRYLIC INTRAOCULAR LENS (EXPORT & DOMESTIC)(SUPRAPHOB TORIC)-IT IS INTENDED FOR PRIMARY IMPLANTATION IN THE CAPSULAR BAG OF THE EYE FOR VISUAL CORRECTION O APHAKIA AND PRE-EXISTING CORNEAL ASTIGMATISM SECONDARY TO REMOVAL OF A CATARACTOUS LENS IN ADULTS PATIENTS WITH OR WITHOUT PRESBYOPIA, WHO DESIRE IMPROVED UNCORRECTED DISTANCE VISION, REDUCTION OF RESIDUAL REFRACTIVE CYLINDER AND INCREASED SPECTACLE INDEPENDENCE FOR DISTANCE VISION., FOLDABLE INTRAOCULAR LENS WITH DISPOSABLE INJECTOR SYSTEM (EXPORT AND DOMESTIC)(ACRYFOLD)-INTRAOCULAR LENS ARE OPTICAL IMPLANTS FOR THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA. IT IS INDICATED IN MONOCULAR CATARACT, MATURE CATARACT, CONGENITAL CATARACT, OCCUPATIONAL CATARACT AND TRAUMATIC CATARACT.,FOLDABLE HYDROPHILIC ACRYLIC INTRAOCULAR LENS WITH DISPOSABLE INJECTOR SYSTEM (EXPORT & DOMESTIC)(MULTI DIFF)-IT IS

	INDICATED FOR THE REPLACEMENT OF HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,ASPHERIC FOLDABLE INTRAOCULAR LENS WITH DISPOSABLE INJECTOR SYSTEM (EXPORT & DOMESTIC)(NASPRO BBY)-IT IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN SIXTY YEARS OF AGE AND OLDER PATIENTS FOLLOWING SURGERY. THESE LENSES ARE INTENDED FOR PLACEMENT IN CAPSULAR BAG.,ASPHERIC FOLDABLE INTRAOCULAR LENS (EXPORT & DOMESTIC)(NASPRO BBY)-IT IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN SIXTY YEARS OF AGE AND OLDER PATIENTS FOLLOWING SURGERY. THESE LENSES ARE INTENDED FOR PLACEMENT IN CAPSULAR BAG.,POSTERIOR CHAMBER INTRAOCULAR LENS WITH PRELOADED DISPOSABLE INJECTOR SYSTEM (EXPORT & DOMESTIC) (SUPRAPHOB INFOCUS)-IT IS INDICATED FOR THE REPLACEMENT OF THE HUMAN NATURAL LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULTS PATIENTS FOLLOWING CATARACT SURGERY. THE LENS IS INTENDED FOR PLACEMENT IN THE CAPSULAR BAG. IT IS INDICATED IN MONOCULAR CATARACT, MATURE CATARACT, OCCUPATIONAL CATARACT, TRAUMATIC CATARACT AND CONGENITAL CATARACT.,HYDROPHILIC TRIFOCAL FOLDABLE INTRAOCULAR LENS WITH DISPOSABLE INJECTOR SYSTEM (EXPORT & DOMESTIC)(MULTIDIFF TRIFIT)-IT IS INDICATED FOR THE REPLACEMENT OF HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,FOLDABLE HYDROPHILIC ACRYLIC INTRAOCULAR LENS (EXPORT & DOMESTIC)(MULTI DIFF)-IT IS INDICATED FOR THE REPLACEMENT OF HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,ASPHERIC FOLDABLE INTRAOCULAR LENS (EXPORT & DOMESTIC)(NASPRO)-IT IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN THE PATIENTS OF AGE FORTY YEARS OR OLDER. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,FOLDABLE HYDROPHILIC ACRYLIC INTRAOCULAR LENS (EXPORT & DOMESTIC) (REFRACTIVE IMPLANTABLE LENS)-IT IS INDICATED FOR THE CORRECTION OF MYOPIA TO ACHIEVE VISUAL CORRECTION OF MYOPIA IN THE PHAKIC ADULTS.,FOLDABLE INTRAOCULAR LENS (EXPORT AND DOMESTIC)(ACRYFOLD)-INTRAOCULAR LENS ARE OPTICAL IMPLANTS FOR THE HUMAN CRYSTALLINE LENS IN THE VISUAL CORRECTION OF APHAKIA. IT IS INDICATED IN MONOCULAR CATARACT, MATURE CATARACT, CONGENITAL CATARACT, OCCUPATIONAL CATARACT AND TRAUMATIC CATARACT.,

		HYDROPHILIC TRIFOCAL FOLDABLE INTRAOCULAR LENS (EXPORT & DOMESTIC)(MULTIDIFF TRIFIT)-IT IS INDICATED FOR THE REPLACEMENT OF HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS (EXPORT & DOMESTIC)(SUPRAPHOB REGEN)-IT IS INTENDED FOR REPLACEMENT OF HUMAN LENS IN VISUAL CORRECTION OF APHAKIA. THE LENSES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG ONLY.,ASPHERIC FOLDABLE INTRAOCULAR LENS WITH DISPOSABLE INJECTOR SYSTEM (EXPORT & DOMESTIC) (NASPRO)-IT IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN THE PATIENTS OF AGE FORTY YEARS OR OLDER. THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS WITH DISPOSABLE PRELOADED INJECTOR SYSTEM (EXPORT & DOMESTIC)(SUPRAPHOB REGEN)-IT IS INTENDED FOR REPLACEMENT OF HUMAN LENS IN VISUAL CORRECTION OF APHAKIA. THE LENSES ARE INTENDED TO BE PLACED IN THE CAPSULAR BAG ONLY.,FOLDABLE HYDROPHILIC ACRYLIC INTRAOCULAR LENS WITH DISPOSABLE INJECTOR SYSTEM (EXPORT & DOMESTIC)(REFRACTIVE IMPLANTABLE LENS)-IT IS INDICATED FOR THE CORRECTION OF MYOPIA TO ACHIEVE VISUAL CORRECTION OF MYOPIA IN THE PHAKIC ADULTS.
3583	MFG/MD/2020/000231	1.License Holder Name: ATLUS HYGIENIC PRODUCTS PRIVATE LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL IP-MEDICAL / SURGICAL DRESSING
3584	MFG/MD/2020/000232	1.License Holder Name: R R INDUSTRIES 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL-ABSORBENT COTTON ALSO KNOWN AS SURGICAL COTTON IS USED MAINLY FOR MEDICAL PURPOSES. THERE IS AN INCREASING DEMAND FOR THIS ITEM IN INDIA AND HAS GOOD MARKET POSSIBILITIES. ABSORBENT COTTON OR MEDICAL COTTON IS USED BY DOCTOR, DENTISTS, AND INDUSTRIAL SAFETY ORGANIZATIONS IN HOSPITALS AND FOR INDIVIDUALS FOR FIRST AID AND HOME KITS.

3585	MFG/MD/2020/000233	1.License Holder Name: CARENOW MEDICAL PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:WOUND DRESSING (THERUPTOR BARRIER DRESSING)-THERUPTOR IS A STERILE BARRIER WOUND DRESSING INTENDED FOR USE AS A PRIMARY DRESSING FOR EXUDING WOUNDS, TO SECURE AND PREVENT MOVEMENT OF A PRIMARY DRESSING, TO MANAGE THE MICROENVIRONMENT OF A WOUND THAT BREACHED DERMIS AND AS A WOUND PACKING.
3586	MFG/MD/2020/000234	1.License Holder Name: SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:NON ABSORBABLE SURGICAL SUTURES USP(SILKAM)-SILKAM IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION AND/OR LIGATION OF THE WOUND EDGES TO RENDER POSSIBLE AN UNDISTURBED WOUND HEALING., NON ABSORBABLE SURGICAL SUTURES USP(DAFILON)-DAFILON SUTURE MATERIALS ARE USED PRIMARILY FOR ADAPTATION OF THE WOUND EDGES TO RENDER POSSIBLE AN UNDISTURBED WOUND HEALING.

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3587	MFG/MD/2020/000235	1.License Holder Name: ENVISION SCIENTIFIC PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:SIROLIMUS ELUTING CORONARY STENT SYSTEM(ABLUMINUS(FIRST BRAND), MITIGATOR (SECOND BRAND), NOSTRUM (THIRD BRAND), AMAZONIA-SIR (FOURTH BRAND), IHTDESTINY®BD(FIFTH BRAND), AGILE(SIXTH BRAND), MINORIS(SEVENTH BRAND), SERPENTIS(EIGHTH BRAND), CROCUS(NINTH BRAND), ABLUMINUS DES+(TENTH BRAND), FUTURE (ELEVENTH BRAND), FUSION(TWELVETH BRAND), ABLUMINUS – DM (THIRTEENTH BRAND), ABLUMINUS – AMI (FOURTEENTH BRAND) & ABRAX COCR(FIFTEENTH BRAND))-THE SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING LUMINAL DIAMETER IN PATIENTS WITH DIABETES MELLITUS, ACUTE MYOCARDIAL INFARCTION, SYMPTOMATIC HEART DISEASE, STABLE ANGINA, UNSTABLE ANGINA OR DOCUMENTED SILENT ISCHEMIA DUE TO ATHEROSCLEROTIC LESIONS IN NATIVE CORONARY ARTERIES WITH REFERENCE VESSEL DIAMETER 2.25MM TO 4.00MM AND LESIONS OF LESIONS OF LENGTH 40 MM.,SIROLIMUS COATED PTA BALLOON CATHETER(MAGIC TOUCH - AVF)-MAGIC TOUCH - AVF DEVICE IS A DRUG COATED BALLOON CATHETER WHICH IS INTENDED FOR USE IN THE PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA), AFTER PRE-DILATATION, FOR TREATMENT OF STENOTIC LESIONS OF DYSFUNCTIONAL NATIVE ARTERIOVENOUS DIALYSIS FISTULAE AND GRAFT THAT ARE 3.00 MM TO 12.00 MM IN DIAMETER AND UP TO 95 MM IN LESION LENGTH.,SIROLIMUS COATED BALLOON CATHETER(MAGIC TOUCH(FIRST BRAND), DEVOIR(SECOND BRAND), VANQUISHER(THIRD BRAND) & MAGIC TOUCH- SCB(FOURTH BRAND)) -SIROLIMUS COATED BALLOON CATHETER IS INDICATED FOR TREATMENT OF CORONARY ARTERY DISEASE BY PERFORMING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY, AFTER APPROPRIATE LESION PREPARATION. SIROLIMUS COATED BALLOON CATHETER IS THEREFORE INDICATED TO DILATE THE DISEASED SEGMENT(S) IN CORONARY ARTERY BY DELIVERING DRUG IN CORONARY ARTERY OR GRAFT WITH LESION LENGTHS OF 6.00 MM TO 36.00 MM AND REFERENCE VESSEL DIAMETER FROM 1.50 MM TO 4.00 MM. THE DEVICE IS INTENDED FOR USE IN FOLLOWING CONDITIONS: • PATIENTS WITH DE-NOVO LESION; • PATIENTS WITH INSTENT RESTENOSIS OF PREVIOUS STENT IMPLANTATION; • PATIENTS WITH DISEASE IN SMALL VESSELS WHERE STENT IMPLANTATION IS EITHER NOT FEASIBLE OR INVOLVING HIGHER RISK OF RESTENOSIS; • PATIENTS WITH BIFURCATION LESIONS WHERE SIDE BRANCH STENT TREATMENT INCREASES RISKS OF DISSECTION, RESTENOSIS AND A BALLOON CATHETER TREATMENT IS

	RECOMMENDED.,SIROLIMUS BASED NANO CARRIER ELUTING STENT SYSTEM(FOCUS NP (FIRST BRAND), CYNOSURE(SECOND BRAND) & ABLUMINUS NP(THIRD BRAND))-SIROLIMUS BASED NANO CARRIER ELUTING STENT SYSTEM IS INTENDED FOR USE IN THE TREATMENT OF PATIENTS WITH CLINICAL SYMPTOMS OF MYOCARDIAL ISCHEMIA RELATED TO THE PATHOLOGICAL CONDITION OF ONE OR MORE CORONARY ARTERIES. RECOGNIZED USE OF INTRACORONARY STENTS CURRENTLY INCLUDES BUT IS NOT LIMITED TO THE TREATMENT OF DE NOVO OR RESTENOTIC LESIONS IN NATIVE CORONARY ARTERIES AND IN DE NOVO LESIONS OF SAPHENOUS VEIN GRAFTS. THE SIROLIMUS BASED NANO CARRIER ELUTING STENT SYSTEM IS AVAILABLE FOR INTRACORONARY IMPLANTATION FOR INNER VESSEL DIAMETERS OF 2.25 TO 4.00 MM,SIROLIMUS COATED PTA BALLOON CATHETER(XTREME TOUCH NEO(FIRST BRAND), MAGIC TOUCH PTA(SECOND BRAND))-SIROLIMUS COATED PTA BALLOON CATHETER IS SINGLE USABLE, INVASIVE, NON IMPLANTABLE DEVICE INTENDED TO USE FOR TREATMENT OF DE NOVO, RESTENOTIC LESIONS IN LOWER EXTREMITY VASCULAR DISEASE (ILIAC, FEMORAL, ILIACFEMORAL, POPLITEAL, INFRA POPLITEAL) AND RENAL ARTERIES.

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3588	MFG/MD/2020/000236	1.License Holder Name: NANO THERAPEUTICS PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:EVEROLIMUS ELUTING CORONARY STENT SYSTEM(ETERNIA, EVERLITE, EVERMAX, CRUZON, ENCRUSO, ETERNIA NEXA, ETERNIA SELECT, ETERNIA BRIO)-EVEROLIMUS ELUTING CORONARY STENT SYSTEM (EECS) IS INTENDED FOR USE IN THE PATIENT ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). EVEROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO LESIONS AND IN-STENT RESTENOTIC LESION OF LENGTH 52 MM IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 TO 4.50 MM.,SIROLIMUS ELUTING CORONARY STENT SYSTEM (SUPERIA, DELIGHT, NOVUS, SIROMOUNT, SIROFLEX, SIROCOR, SESPRO, SIROFLEX PLUS)-SIROLIMUS ELUTING CORONARY STENT SYSTEM (SECS) IS INTENDED FOR USE IN THE PATIENT ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO LESIONS AND IN-STENT RESTENOTIC LESION OF LENGTH 52 MM IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 TO 4.50 MM.,COBALT CHROMIUM CORONARY STENT SYSTEM (FLEXIA, CORNET , CURO, COREAL, AMBEAL)-COBALT CHROMIUM CORONARY STENT SYSTEM (CCCS) IS INTENDED FOR USE IN THE PATIENT ELIGIBLE FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA). COBALT CHROMIUM CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC DISEASE DUE TO DISCRETE DE NOVO LESIONS AND IN-STENT RESTENOTIC LESION OF LENGTH 52 MM IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 TO 4.50 MM.

3589	MFG/MD/2020/000237	1.License Holder Name: SHRIRAM INSTITUTE OF INDUSTRIAL RESEARCH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:STERILISED POLYESTER FIBRE TAPE(MERSILENE*)-MERSILENE* TAPE IS INDICATED FOR CIRCULAR SUTURE OF THE CERVIX. NON-NEEDLED TAPES ARE USED AS RETRACTION AND/OR FIXING TAPE DURING SURGERY.,NON ABSORBABLE SURGICAL SUTURE U.S.P.(MERSILK*/ETHICON*)-SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROSURGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P. (ETHIBOND* EXCEL)-ETHIBOND SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROSURGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P.(ETHILON*)-ETHILON SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPTHALMIC AND NEUROSURGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P.(ETHISTEEL*)-STAINLESS STEEL SUTURES ARE FOR USE IN ABDOMINAL WOUND CLOSURE, HERNIA REPAIR, STERNAL CLOSURE AND ORTHOPEDIC PROCEDURES INCLUDING CERCLAGE AND TENDON REPAIR.,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) (VICRYL* RAPIDE)-VICRYL* RAPIDE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO ITS ABSORPTION PROFILE VICRYL* RAPIDE IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PAEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. VICRYL* RAPIDE IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P.(MERSILENE*)-MERSILENE SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC, AND EUROLOGICAL PROCEDURES, AND ALSO FOR THE FIXATION OF SOFT TISSUE TO BONE TISSUE.

3590	MFG/MD/2020/000238	1.License Holder Name: SURU INTERNATIONAL PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:STERILE CENTRAL VENOUS CATHETER / KIT(NOVOCENT MONO, NOVOCENT DUO, NOVOCENT TRIO)-CENTRAL VENOUS CATHETER / KIT CONSISTS OF A CENTRAL VENOUS CATHETER & ACCESSORIES, INTENDED FOR TRANSIENT TO SHORT TERM APPLICATION INTO THE CENTRAL VENOUS CIRCULATORY SYSTEM TO ADMINISTER CONTINUOUS/ INTERMITTENT INTRAVENOUS THERAPY, TO MONITOR CENTRAL VENOUS PRESSURE AND TO CONDUCT BLOOD SAMPLING AS & WHEN REQUIRED,STERILE CENTRAL VENOUS CATHETER / KIT(SURU CENOCATH)-CENTRAL VENOUS CATHETER / KIT CONSISTS OF A CENTRAL VENOUS CATHETER & ACCESSORIES, INTENDED FOR TRANSIENT TO SHORT TERM APPLICATION INTO THE CENTRAL VENOUS CIRCULATORY SYSTEM TO ADMINISTER CONTINUOUS/ INTERMITTENT INTRAVENOUS THERAPY, TO MONITOR CENTRAL VENOUS PRESSURE AND TO CONDUCT BLOOD SAMPLING AS & WHEN REQUIRED,STERILE ABSORBABLE GELATIN SPONGE USP(SURU)-GELATIN SPONGE IS USED IN SURGICAL PROCEDURES AS A HAEMOSTATIC DEVICE,STERILE SYNTHETIC ABSORBABLE POLYGLYCOLIC ACID (PGA) SUTURE WITH / WITHOUT NEEDLE USP (SURUCRYL)-IT IS USED IN GENERAL CLOSURE, OPHTHALMIC, ORTHOPAEDICS, OBSTETRICS / GYNAECOLOGY AND GASTROINTESTINAL TRACT SURGERY,STERILE INTRODUCER SHEATH / SET(SURU)-THE INTRODUCER SHEATH SPECIFICALLY DESIGNED AND INTENDED FOR SMOOTH ATRAUMATIC RADIAL ACCESS TO MINIMIZE THE RISK OF SCARRING AND DAMAGE.,STERILE SYNTHETIC ABSORBABLE MONOFILAMENT POLYDIOXANONE SUTURE WITH / WITHOUT NEEDLE USP(SURUSYNTH)-MONOFILAMENT POLYDIOXANONE SUTURE ARE INTENDED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION.,STERILE POLYPROPYLENE MESH (SURUMESH, GLUMESH, GLYMESH, ISOFAM, SURGIMESH)-THE INDENTED USE OF STERILE SURGICAL MESH IS TO REPAIR THE HERNIA AND OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT.,STERILE SYNTHETIC ABSORBABLE POLYGLACTIN 910 SUTURE WITH / WITHOUT NEEDLE USP(SURUCRYL 910)-POLYGLACTIN 910 SUTURES ARE INDICATED FOR SOFT TISSUE APPROXIMATION AND LIGATION, EXCELLENT CHOICE FOR CATARACT AND STRABISMUS SURGERY,STERILE URETERAL STENT SET / DOUBLE J STENT SET / DOUBLE J STENT KIT(SURU)-URETERAL STENT SET / DJ STENT / KIT ARE USED FOR TEMPORARY INTERNAL DRAINAGE FROM URETEROPELVIC JUNCTION TO THE BLADDER,

	STERILE MONOFILAMENT POLYAMIDE NYLON SUTURE WITH / WITHOUT NEEDLE USP(SURULON)-MONOFILAMENT POLYAMIDE NYLON SUTURES INTENDED FOR USE IN SOFT-TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC SURGERY, OPHTHALMIC PROCEDURE BUT NOT IN CARDIOVASCULAR AND NEUROLOGICAL SURGICAL PROCEDURES.,STERILE MONOFILAMENT POLYPROPYLENE SUTURE WITH / WITHOUT NEEDLE USP(SURULENE)-MONOFILAMENT POLYPROPYLENE SUTURES INTENDED TO BE USED IN GENERAL SOFT TISSUE APPROXIMATION AND / OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT IN NEUROLOGICAL & CARDIOVASCULAR SURGERIES, STERILE BONE WAX(SURUWAX)-IT IS USED TO CONTROL BLEEDING FROM SURFACES OF INJURED BONES DURING BONE REPAIR SURGERY. BARRIER TO CONTROL BLEEDING FROM BONE INJURY., SYNTHETIC ABSORBABLE MONOFILAMENT POLIGLECAPRONE 25 SUTURE WITH / WITHOUT NEEDLE USP(SURUGLYDE)-MONOFILAMENT POLIGLECAPRONE SUTURE ARE INTENDED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION. ,STERILE PRESSURE TRANSDUCER KIT(SURU)-DISPOSABLE BLOOD PRESSURE TRANSDUCER & ACCESSORIES ARE KINDS OF ARTERIOVENOUS PRESSURE MONITORING SYSTEM, WITH CHARACTERISTICS OF THE CONTINUOUS AND DYNAMIC MONITORING ARTERIOVENOUS PRESSURE, GREATLY SATISFY THE CLINICAL DEMAND OF MEDICAL STAFF,STERILE BLACK BRAIDED SILK SUTURE WITH / WITHOUT NEEDLE USP(SURUSIL)-BLACK BRAIDED SILK SUTURES ARE SUITABLE FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR USE IN OPHTHALMIC BUT NOT IN NEUROLOGICAL AND CARDIOVASCULAR SURGERIES.,STERILE FEMALE URINARY INCONTINENCE SET / SLING(SURU)-THE DEVICE IS MEANT FOR TREATING STRESS URINARY INCONTINENCE (SUI) RESULTING FROM URETHRAL HYPERMOBILITY AND/OR INTRINSIC SPHINCTER DEFICIENCY IN WOMEN.,STERILE COATED / BRAIDED POLYESTER SUTURE WITH / WITHOUT NEEDLE USP(SURUPOL)-POLYESTER SUTURES INTENDED TO BE USED IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURE BUT NOT TO BE USED IN CARDIOVASCULAR AND NEUROLOGICAL SURGERIES.

3591	MFG/MD/2020/000239	1.License Holder Name: RAYMOND CONSUMER CARE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NATURAL RUBBER LATEX MALE CONDOMS WITH 4.5% W/W BENZOCAINE AS DESENSITIZER. (NIL)- THE MALE LATEX CONDOM LUBRICATED WITH BENZOCAINE 4.5% W/W IS INTENDED TO BE USED FOR CONTRACEPTIVE AND PROPHYLACTIC PURPOSES. ADDITIONALLY, THE LUBRICANT ON THE CONDOM HELPS IN TEMPORARILY PROLONGING THE TIME UNTIL EJACULATION.,NATURAL RUBBER LATEX MALE CONDOMS.(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS.(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS.(KAMASUTRA)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS WITH 4.5% W/W BENZOCAINE AS DESENSITIZER (KAMASUTRA)-THE MALE LATEX CONDOM LUBRICATED WITH BENZOCAINE 4.5% W/W IS INTENDED TO BE USED FOR CONTRACEPTIVE AND PROPHYLACTIC PURPOSES. ADDITIONALLY, THE LUBRICANT ON THE CONDOM HELPS IN TEMPORARILY PROLONGING THE TIME UNTIL EJACULATION.,NATURAL RUBBER LATEX MALE CONDOMS.(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS WITH VIBRATING RING(KAMASUTRA)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS ALONG WITH VIBRATION FOR PLEASURE.,NATURAL RUBBER LATEX MALE CONDOMS.(KAMASUTRA)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS. (KAMASUTRA)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,NATURAL RUBBER LATEX MALE CONDOMS WITH 4.5% W/W BENZOCAINE AS DESENSITIZER(NIL)-THE MALE LATEX CONDOM LUBRICATED WITH BENZOCAINE 4.5% W/W IS INTENDED TO BE USED FOR CONTRACEPTIVE AND PROPHYLACTIC PURPOSES. ADDITIONALLY, THE LUBRICANT ON THE CONDOM HELPS IN TEMPORARILY PROLONGING THE TIME UNTIL EJACULATION

3592	MFG/MD/2020/000240	1.License Holder Name: BASSIL SCIENTIFIC PVT. LTD. 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:PERCUTANEOUS NEPHROSTOMY CATHATER(PCN) WITH TROCAR,WITH LOCKING MECHANISM,(PIGTAIL&MALECOT)(NIL)-USED FOR TEMPORARY PERCUTANEOUS DRAINAGE OF BLADDER AND ABSCESS,FASCIAL DILATOR(NIL)-DILATION OF FASCIA,FASCIAL DILATOR SET (NIL)-USED TO DILATE FASCIA,INITIAL PUNCTURE NEEDLE(NIL)-INITIAL PUNCTURE OF FASCIA,PERCUTANEOUS NEPHROSTOMY CATHATER SET,PIGTAIL&MALECOT(NIL)-PERCUTANEOUS DRAINAGE OF URINE FROM KIDNEY, BLADDER,NEPHROSTOMY CATHETERS - PCN AND MALECOT(NIL)-USED FOR PERCUTANEOUS PLACEMENT OF CATHETER IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE, MULTI PURPOSE DRAINAGE CATHATER SET PIGTAIL, MALECOT&STRAIGHT(NIL)-FOR PERCUTANEOUS DRAINAGE IN VARIOUS DRAINAGE APPLICATION IN NEPHROSTOMY, BILIARY AND ABCESS,FORCEPS(NIL)-REMOVAL OF STONE FRAGMENT AND FOREIGN PARTICLES ,MULTI PURPOSE DRAINAGE CATHATER PIGTAIL, MALECOT & STRAIGHT, WITH TROCAR, WITH LOCKING MECHANISM(NIL)-FOR PERCUTANEOUS DRAINAGE IN VARIOUS DRAINAGE APPLICATIONS IN NEPHROSTOMY, BILIARY AND ABCESS, FORCEPS(NIL)-REMOVAL OF STONE FRAGMENT AND FOREIGN PARTICLES
3593	MFG/MD/2020/000241	1.License Holder Name: DYNAMIC TECHNO MEDICALS PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:SILICONE HYDROPHILIC FOAM DRESSING-MANAGEMENT OF MODERATE TO HEAVILY EXUDING PARTIAL TO FULL THICKNESS WOUNDS.,HYDROPHILIC FOAM SILVER PAD (NON-ADHESIVE)(AGFIX TR)-FOR DRESSING AROUND THE CATHETER AT THE TRACHEOSTOMY SITE,SUPER ABSORBENT HYDROPHILIC FOAM SILVER PAD-FOR THE MANAGEMENT OF HEAVILY EXUDING NON-EXUDING PARTIAL THICKNESS OPEN WOUNDS

3594	MFG/MD/2020/000242	1.License Holder Name: BIOLIFE MEDICAL PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION AS PER IP AND ADDITIVE SOLUTION SAGM-2(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION AS PER USP AND ADDITIVE SOLUTION SAGM-2 (FOR EXPORT ONLY)(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,UMBILICAL CORD BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION USP (FOR EXPORT ONLY)(NA)-UMBILICAL CORD BLOOD BAG SYSTEM, CONTAINING ANTICOAGULANT SOLUTION AS PER BAG CAPACITY IS USED FOR COLLECTION, STORAGE, PROCESS, TRANSPORT OF UMBILICAL CORD BLOOD IN CLOSED AND STERILE CONDITIONS.,TRANSFER BAG AS PER USP (FOR EXPORT ONLY)(NA)-STERILE TRANSFER BLOOD BAG IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,UMBILICAL CORD BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION IP(NA)-UMBILICAL CORD BLOOD BAG SYSTEM, CONTAINING ANTICOAGULANT SOLUTION AS PER BAG CAPACITY IS USED FOR COLLECTION, STORAGE, PROCESS, TRANSPORT OF UMBILICAL CORD BLOOD IN CLOSED AND STERILE CONDITIONS.,TRANSFER BAG AS PER IP(NA)-STERILE MEDICAL DEVICE TRANSFER BLOOD BAG IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,BLOOD BAG WITH ANTICOAGULANT CPD (CITRATE PHOSPHATE DEXTROSE) SOLUTION AS PER IP AND ADDITIVE SOLUTION SAGM(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION (CPDA /CPDA-1 SOLUTION) AS PER USP (FOR EXPORT ONLY)(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,BLOOD

	BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION (CPD SOLUTION) AS PER IP(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION (CPD SOLUTION) USP (FOR EXPORT ONLY)(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION (CPDA/CPDA-1 SOLUTION) AS PER IP(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,BLOOD BAG WITH ANTICOAGULANT CPD (CITRATE PHOSPHATE DEXTROSE) SOLUTION AS PER USP AND ADDITIVE SOLUTION SAGM (FOR EXPORT ONLY)(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.

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3595	MFG/MD/2020/000243	1.License Holder Name: FRISCH MEDICAL DEVICES PVT. LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:PRESSURE LINE(RESIST)-PRESSURE MONITORING TUBING IS INTENDED TO PROVIDE CHANNEL FOR FLUID AND MEDICINE IN INTERVENTIONAL OPERATION ., CONTROL SYRINGE(ASSURE)-CONTROL SYRINGE IS AN ACCESSORY DESIGN TO FACILITATE THE INJECTION OF DIE OR ANY OTHER FLUID MATERIAL USED IN CONJUNCTION WITH INTERVENTIONAL DEVICES DURING VASCULAR INTERVENTIONAL PROCEDURES.,PUNCTURE NEEDLE(INVENT)-:PUNCTURE NEEDLE ARE USED WITH THE INTRODUCER SYSTEM FOR INTRODUCTION AND PLACEMENT OF A GUIDEWIRE.,BLUNT INTRODUCER DEVICE(TURBO)-HAEMOSTASIS Y-CONNECTOR KIT PROVIDES A MEAN FOR INSERTING GUIDE WIRES OR CATHETERS DEEP INTO THE VASCULATURE, AND POSITIONING AND LOCKING THEM INTO A DESIRED PLACE. HAEMOSTASIS YCONNECTOR INCLUDES A STRAIGHT AND A SIDE ACCESS LUMEN. THE HEMOSTASIS VALVE LOCATED AT THE PROXIMAL END OF THE STRAIGHT LUMEN CAN BE OPENED OR CLOSED BY OPERATION OF THE PUSH-PULL BUTTON. THE DISTAL END HAS A ROTATING MALE LUER LOCK. THE SIDE ACCESS LUMEN ALLOWS PRESSURE MONITORING AND PERFUSION. THE TORQUER DEVICE PROVIDED WITH COPPER CYLINDER TO PROTECT THE GUIDE WIRE COATING AND GRIP THE GUIDE WIRE. THE BLUNT INTRODUCER DEVICE ACTS AS A MEDIUM TO PASS GUIDE WIRE THROUGH THE Y CONNECTOR.,3-WAY STOPCOCK(DELTA)-:IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING

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3596	MFG/MD/2020/000244	1.License Holder Name: LIFE GUARD PHARMA PVT LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use::PERACETIC ACID AND HYDROGEN PEROXIDE DISINFECTANT POWDER(NIL)-THE PRODUCT IS INTENDED FOR DISINFECTION OF MEDICAL DEVICE., DODECYLDIPROPYLENETRIAMINE, TRIALKYLETHOXYAMMONIUMPROPIONATE SOLUTION.(NIL)-:THE PRODUCT IS INTENDED FOR DISINFECTION OF MEDICAL DEVICE., POTASSIUM MONO PERSULPHATE, POTASSIUM HYDROGEN SULPHATE POTASSIUM SULPHATE, SODIUM CHLORIDE DISINFECTANT POWDER(NIL)-THE PRODUCT IS INTENDED FOR DISINFECTION OF MEDICAL DEVICE., PERACETIC ACID AND HYDROGEN PEROXIDE DISINFECTANT LIQUID(NIL)-THE PRODUCT IS INTENDED FOR DISINFECTION OF MEDICAL DEVICE.,CITRIC ACID SOLUTION 21%W/V(NIL)-THE PRODUCT IS INTENDED FOR DISINFECTION OF MEDICAL DEVICES.,SODIUM PERBORATE MONOHYDRATE 50% W/W DISINFECTANT POWDER(NIL)-THE PRODUCT IS INTENDED FOR DISINFECTION OF MEDICAL DEVICE., PERACETIC ACID AND HYDROGEN PEROXIDE DISINFECTANT LIQUID (NIL)-THE PRODUCT IS INTENDED FOR DISINFECTION OF MEDICAL DEVICE.

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3597	MFG/MD/2020/000245	1.License Holder Name: TRINITY HEALTH CARE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITHOUT AIR VENT BIS 9824(- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED., STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY(STERISOL)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655(- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE INFANT FEEDING TUBE FOR SINGLE USE ONLY(STERISOL)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING CLASS OF MEDICAL ,STERILE DISPOSABLE MEASURED VOLUME SET WITHOUT AIR VENT BIS 12655(- - -)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT’S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE NASOGASTRIC/RYLE’S TUBE FOR SINGLE USE ONLY 1(STERISOL)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH AIR VENT BIS 9824(- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED., STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY(STERISOL MUCUS EXTRACTOR)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION.,STERILE DISPOSABLE INFUSION SET WITH AIR VENT BIS 12655(- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE MICRO DRIP INFUSION SET WITH/WITHOUT AIR VENT BIS 12655(TRINITY)-:IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT’S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.

3598	MFG/MD/2020/000246	1.License Holder Name: EXCELLENT HI-CARE PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:INTRAOCULAR LENS (MICROVISION)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY,INTRAOCULAR LENS(MAC FOLD)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY,INTRAOCULAR LENS (MICRO FOLD)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3599	MFG/MD/2020/000247	1.License Holder Name: GRIPORTHO SURGICALS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:PINS & WIRES(GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-PINS, WIRES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE PLATES(GSPL , GRIPORTHO)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE PLATES(GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,SPINE IMPLANTS(GSPL , GRIPORTHO)-SPINE IMPLANT IS A MEDICAL DEVICE MANUFACTURED TO REPLACE A MISSING JOINT OR SPINE BONE OR TO SUPPORT A DAMAGED SPINE BONE,ARTHROSCOPY(GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-ARTHROSCOPES ARE INDICATED FOR USE IN ARTHROSCOPIC PROCEDURES (SUCH AS THE KNEE, SHOULDER, HIP, ANKLE, ELBOW) TO PROVIDE VISUALIZATION DURING SURGERY.,BONE PLATES(GSPL , GRIPORTHO)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,HIP IMPLANTS(GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-HIP IMPLANTS ARE MEDICAL DEVICES INTENDED TO RESTORE MOBILITY AND RELIEVE PAIN USUALLY ASSOCIATED WITH ARTHRITIS AND OTHER HIP DISEASES OR INJURIES.,NAILS(GSPL , GRIPORTHO)-NAILS ARE USUALLY USED FOR THE FRACTURE OF LONG BONES LIKE THE FEMUR, HUMERUS, TIBIA ETC.,BONE PLATES(GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE PLATES(GSPL , GRIPORTHO)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,HIP IMPLANTS(GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-HIP IMPLANTS ARE MEDICAL DEVICES INTENDED TO RESTORE MOBILITY AND RELIEVE PAIN USUALLY ASSOCIATED WITH ARTHRITIS AND OTHER HIP DISEASES OR INJURIES.,NAILS(GSPL , GRIPORTHO)-NAILS ARE USUALLY USED

	FOR THE FRACTURE OF LONG BONES LIKE THE FEMUR, HUMERUS, TIBIA ETC.,PINS & WIRES(GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-PINS, WIRES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE SCREW(GSPL , GRIPORTHO)-BONE SCREWS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE., BONE PLATES(GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE., BONE PLATES(GSPL , GRIPORTHO)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,SPINAL IMPLANTS (GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-SPINE IMPLANT IS A MEDICAL DEVICE MANUFACTURED TO REPLACE A MISSING JOINT OR SPINE BONE OR TO SUPPORT A DAMAGED SPINE BONE, PINS & WIRES(GSPL , GRIPORTHO)-PINS, WIRES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,ARTHROSCOPY(GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-ARTHROSCOPES ARE INDICATED FOR USE IN ARTHROSCOPIC PROCEDURES (SUCH AS THE KNEE, SHOULDER, HIP, ANKLE, ELBOW) TO PROVIDE VISUALIZATION DURING SURGERY.,BONE SCREW(GSPL , GRIPORTHO)-BONE SCREWS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE PLATES(GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE., INTRAMEDULLARY NAILS(GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-NAILS ARE USUALLY USED FOR THE FRACTURE OF LONG BONES LIKE THE FEMUR, HUMERUS, TIBIA ETC.,BONE SCREW(GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-BONE SCREWS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE SCREW (GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-BONE SCREWS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY,

		ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE., INTRAMEDULLARY NAILS(GSPL, GRIPORTHO, GRIPORTHO PRIME, GRIPHOLD)-NAILS ARE USUALLY USED FOR THE FRACTURE OF LONG BONES LIKE THE FEMUR, HUMERUS, TIBIA ETC.
3600	MFG/MD/2020/000248	1.License Holder Name: MEDIASHA TECHNOLOGIES PRIVATE LIMITED 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:SPLINT(FRACTOAID)-TO IMMOBILIZE AND/ OR SUPPORT OR STABILIZE THE MOVEMENT OF FRACTURED LIMB FOR 3-4 HOURS.
3601	MFG/MD/2020/000250	1.License Holder Name: IMAZ SURGICALS 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL(NIL)-COTTON WOOL ARE MAINLY USED FOR MEDICAL PURPOSE IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME FOR FIRST AID ETC… APART FROM MEDICAL PURPOSES ABSORBENT COTTON IS ALSO USED FOR MAKING CONVENTIONAL TYPE OF SANITARY NAPKINS OR PADS.,GAUZE SWAB-GAUZE SWAB ARE USED TO PLACE OVER A WOUND BEFORE TAPING, STRAPPING OR BANDAGING UP OR CAN BE SOAKED IN ANTISEPTIC LIQUID AND USED TO WIPE OVER HARD SURFACES. GAUZE SWABS ARE A USEFUL UTILITY PRODUCT IN A KIT AND CAN BE USED FOR PADDING, PROTECTION, BLOOD SPILL WOUND DRESSING, APPLYING ANTISEPTIC AND MUCH MORE.,RIBBON GAUZE-RIBBON GAUZE IS INTENDED TO BE USED FOR SHORT-TERM WOUND CARE DURING INVASIVE SURGERY AND FOR THE TAMPONAGE OF WOUND CAVITIES AND FISTULOUS TRACTS.,ABSORBENT GAUZE-FINE-MESH COTTON GAUZE IS OFTEN USED FOR PACKING, SUCH AS IN A NORMAL SALINE WET-TO-MOIST DRESSING, WHEREAS COARSE-MESH COTTON GAUZE, SUCH AS A NORMAL SALINE WET-TO-DRY DRESSING, IS USED FOR NONSELECTIVE DEBRIDING.

3602	MFG/MD/2020/000251	1.License Holder Name: WILSON TAPES PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:COMBINE DRESSING - STERILE-COMBINE DRESSING-STERILE IS A DEVICE INTENDED USED FOR HANDLING HEAVY DRAINAGE, PROMOTING HEALING AND KEEPING THE WOUND DRY FOR OPTIMAL COMFORT AND RELIEF. IT IS ESPECIALLY USEFUL FOR DRESSING WOUNDS WHERE OTHER FABRICS MIGHT STICK TO THE BURN OR LACERATION.,EYE PAD - STERILE-EYE PAD IS A DEVICE INTENDED USED TO COVER THE EYES FOR PROTECTION AFTER THE OPERATION.,ELASTIC ADHESIVE BANDAGE-IDEAL BANDAGE FOR SUPPORT STRAPPING FRACTURES, MUSCLES INJURIES, ELBOWS, KNEES, SHOULDERS SPECIALLY REQUIRING ELASTICITY.,ADHESIVE TAPE-A MEDICAL ADHESIVE TAPE IS A DEVICE INTENDED FOR MEDICAL PURPOSES THAT COATED ON ONE SIDE WITH AN ADHESIVE, THE DEVICE IS USED TO COVER AND PROTECT WOUNDS, TO HOLD TOGETHER THE SKIN EDGES OF A WOUND, TO SUPPORT AN INJURED PART OF THE BODY, OR TO SECURE OBJECTS TO THE SKIN.,PARAFFIN GAUZE DRESSING B.P. STERILE-PARAFFIN GAUZE DRESSING B.P. IS A DEVICE INTENDED USED FOR MEDICAL PURPOSE THAT CONSIST OF STERILE PAD APPLIED TO A WOUND TO PROMOTE HEALING AND PROTECT THE WOUND FROM FURTHER HARM. A DRESSING IS DESIGNED TO BE IN DIRECT CONTACT WITH THE WOUND, AS DISTINGUISHED FROM A BANDAGE, WHICH IS MOST OFTEN USED TO HOLD A DRESSING IN PLACE.,BELLADONNA PLASTER-BELLADONNA PLASTER IS A DEVICE INTENDED USED TO STIMULATE BLOOD FLOW TO RELIEVE ACHES AND PAINS. IDEALLY USE FOR THE MUSCULAR TENSION AND STRAIN, STIFF NECK AND ACHING SHOULDERS, RHEUMATISM AND BACK ACHE.,MICROPOROUS SURGICAL TAPES-MICROPOROUS SURGICAL TAPE IS A DEVICE INTENDED FOR MEDICAL PURPOSES THAT COATED ON ONE SIDE WITH AN ADHESIVE, THE DEVICE IS USED TO COVER AND PROTECT WOUNDS, TO HOLD TOGETHER THE SKIN EDGES OF A WOUND, TO SUPPORT AN INJURED PART OF THE BODY, OR TO SECURE OBJECTS TO THE SKIN.,PLASTER OF PARIS BANDAGE-PLASTER OF PARIS BANDAGE IS A DEVICE INTENDED FOR IMMOBILIZATION OF ALL TYPES OF SIMPLE & COMPOUND FRACTURES, FOR TREATMENT OF DISLOCATION OF HIP, OTHER ORTHOPAEDIC FRACTURES, SPLIT, SOFT TISSUE INJURIES, SPINAL TUBERCULOSIS & TRAUMA AND FOR BONE, JOINT CORRECTION & PREVENTION OF DEFORMITIES.,GAUZE SWAB STERILE ABSORBENT-GAUZE SWABS ARE A USEFUL UTILITY PRODUCT IN A KIT CAN BE USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, APPLYING ANTISEPTIC AND MUCH MORE. IT IS ESPECIALLY USEFUL FOR DRESSING WOUNDS WHERE OTHER FABRICS MIGHT STICK TO

	THE BURN OR LACERATION. STERILE GAUZE SWAB SHOULD BE USED FOR ANY APPLICATION TO AN OPEN WOUND,GAMJEE ROLL-THESE BANDAGE ROLL, GAMJEE ROLL ARE HIGHLY ABSORBENT COTTON ARE AVAILABLE IN LOW ADHERENT GAUZE COVER AND IS APPLIED OVER DRESSING TO PROVIDE LOW ADHERENT WOUND INTERFACE. GENERALLY USED FOR PRIMARY WOUND DRESSINGS OR IS APPLIED OVER A DRESSING, THESE BANDAGE ROLL ALLOW LOW ADHERENT WOUND INTERFACE. THESE BANDAGE ROLL HAVE EXCELLENT ABSORBENCY, WHICH PROMOTES HEALING HEALING AND ALSO PROTECTS THE WOUND.,ORTHO CAST PADDING-ORTHO CAST PADDING IS A DEVICE INTENDED TO USE AS A CUSHION BETWEEN SKIN AND CAST OF PLASTER OF PARIS FOR TREATMENT OF DISLOCATION OF HIP, OTHER ORTHOPAEDIC FRACTURES, SPLIT, SOFT TISSUE INJURIES, SPINAL TUBERCULOSIS & TRAUMA AND FOR BONE, JOINT CORRECTION & PREVENTION OF DEFORMITIES.,COTTON CREPE BANDAGE-COTTON CREPE BANDAGEIS A DEVICE INTENDED FOR STABILIZING JOINTS, TENDONS AND LIGAMENTS DURING VIGOROUS EXERCISE. FIRMLY WRAP AROUND THE ANKLE, WRIST, OR ANY OTHER HIGHLY-USED JOINT TO PREVENT INJURY CAUSED BY MUSCLE STRESS AND FATIGUE.,MEDICATED DRESSING-MEDICATED DRESSING IS A DEVICE INTENDED USED TO PROTECT A WOUND, PREVENT INFECTION AND ALLOW HEALING. ALSO USED AS FIRST AID TO REDUCE THE RISK OF INFECTION IN MINOR CUTS, SCRAPES, AND BURNS.,STERILIZED GAUZE SWAB ABDOMINAL WITH X-RAY DETECTABLE THREAD-STERILIZED GAZE SWAB ABDOMINAL WITH X-RAY DETECTABLE THREAD IS A DEVICE INTENDED USED FOR ABSORBING BLOOD WHILE SURGERY AND AVOID BLOOD SPILL

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3603	MFG/MD/2020/000252	1.License Holder Name: M/S RESCQTEC SUTURES PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:MONOFILAMENT POLYPROPYLENE BLUE NONABSORBABLE SURGICAL SUTURE USP (AQLENE)-POLYPROPYLENE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES, MONOFILAMENT POLYPROPYLENE BLUE NON- ABSORBABLE SURGICAL SUTURE USP(AQPROP)-AQPROP IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION OR LIGATION INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., MONOFILAMENT KNITTED POLYPROPYLENE TISSUE RECONSTRUCTION PROSTHESIS NONABSORBABLE STERILE SURGICAL MESH(QLENE , QLENE E-TEP , POLENE)-POLYPROPYLENE MESH USE FOR THE HERNIA REPAIR AND OTHER FACIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT., BRAIDED AND COATED POLYGLACTIN -910 UNDYED FAST ABSORBABLE SURGICAL SYNTHETIC SUTURE USP(NCRYL FAST)-NCRYL FAST IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION,MONOFILAMENT POLYAMIDE (BLACK & BLUE) NONABSORBABLE SURGICAL SUTURE U.S.P.(AQLON) -NYLON IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES,MONOFILAMENT POLYAMIDE (BLACK & BLUE) NON-ABSORBABLE SURGICAL SUTURE USP(N LON)-N LON IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., BRAIDED AND COATED POLYGLACTIN -910 UNDYED FAST ABSORBABLE SURGICAL SYNTHETIC SUTURE USP(AQFAST)-BRAIDED AND COATED POLYGLACTIN -910 UNDYED FAST IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION , BRAIDED & COATED POLYGLACTIN 910 UNDYED FAST ABSORBABLE ABSORBABLE SURGICAL SYNTHETIC SUTURE USP.(POLYSOLVE FAST)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, AND LIGATION.,MONOFILAMENT POLYDIOXANONE VIOLET ABSORBABLE SURGICAL SYNTHETIC SUTURE(AQPDSYN)-MONOFILAMENT POLYDIOXANONE VIOLET ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN OPHTHALMIC SURGERY.,POLYGLACTIN-910, BRAIDED AND COATED, ANTIBACTERIAL TRICLOSAN VIOLET ABSORBABLE SURGICAL SYNTHETIC SUTURE USP.(POLYSOLVE +)-POLYSOLVE + IS INTENDED

	FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, GENERAL CLOSURE, OPHTHALMIC, ORTHOPAEDICS, OBSTETRICS/GYNAECOLOGY AND GASTROINTESTINAL TRACT SURGERY.,MONOFILAMENT POLIGLECAPRONE 25 UNDYED ABSORBABLE SURGICAL SYNTHETIC SUTURE(AQMONO)-MONOFILAMENT POLIGLECAPRONE 25 UNDYED SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY,POLYESTER COATED AND BRAIDED (GREEN & WHITE) NON-ABSORBABLE SURGICAL SUTURE USP(AQBOND)-AQBOND IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION OR LIGATION INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., CATGUT CHROMIC/PLAIN ABSORBABLE SURGICAL SUTURE USP (AQGUT)-CATGUT IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES,MONOFILAMENT POLYDIOXANONE VIOLET ABSORBABLE SURGICAL SYNTHETIC SUTURE(PD SOLVE)-PD SOLVE ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN OPHTHALMIC SURGERY, BRAIDED AND COATED POLYGLACTIN - 910 VIOLET ABSORBABLE SURGICAL SYNTHETIC SUTURE USP(AQSOLVE)-BRAIDED & COATED POLYGLACTIN 910 VIOLET IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION. GENERAL CLOSURE, OPHTHALMIC, ORTHOPAEDICS, OBSTETRICS/GYNAECOLOGY AND GASTROINTESTINAL TRACT SURGERY,BLACK BRAIDED SILK NON-ABSORBABLE SURGICAL SUTURE USP(N-SILK)-BLACK BRAIDED SILK IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES,BRAIDED AND COATED POLYGLACTIN 910 VIOLET ABSORBABLE SURGICAL SYNTHETIC SUTURE USP (POLYSOLVE 910)-POLYSOLVE 910 IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, GENERAL CLOSURE, OPHTHALMIC, ORTHOPAEDICS, OBSTETRICS/GYNAECOLOGY AND GASTROINTESTINAL TRACT SURGERY.,MONOFILAMENT POLYAMIDE (BLACK & BLUE) NON-ABSORBABLE SURGICAL SUTURE USP(QLON)-NYLON IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES,POLYESTER COATED AND BRAIDED (GREEN & WHITE) NON- ABSORBABLE SURGICAL SUTURE USP(N BOND)-N BOND IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION OR LIGATION INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND

	NEUROLOGICAL TISSUES.,MONOFILAMENT POLYPROPYLENE BLUE NON-ABSORBABLE SURGICAL SUTURE USP(QLENE)-POLYPROPYLENE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., BLACK BRAIDED SILK NON ABSORBABLE SURGICAL SUTURE USP (AQSILK)-AQSILK IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION OR LIGATION INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., CATGUT CHROMIC/PLAIN ABSORBABLE SURGICAL SUTURE USP (QGUT)-CATGUT IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,CATGUT CHROMIC/PLAIN ABSORBABLE SURGICAL SUTURE USP(N GUT)-N GUT IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES., POLYGLACTIN 910 BRAIDED & COATED WITH ANTIBACTERIAL TRICLOSAN VIOLET ABSORBABLE SURGICAL SYNTHETIC SUTURE USP(N CRYL PLUS)-N CRYL PLUS IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, GENERAL CLOSURE, OPHTHALMIC, ORTHOPAEDICS, OBSTETRICS/GYNAECOLOGY AND GASTROINTESTINAL TRACT SURGERY.,BRAIDED AND COATED POLYGLACTIN - 910 VIOLET ABSORBABLE SURGICAL SYNTHETIC SUTURE USP(NCRYL)-NCRYL IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION. GENERAL CLOSURE, OPHTHALMIC, ORTHOPAEDICS, OBSTETRICS/GYNAECOLOGY AND GASTROINTESTINAL TRACT SURGERY,MONOFILAMENT POLYPROPYLENE BLUE NON- ABSORBABLE SURGICAL SUTURE USP (POLENE)-POLENE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION OR LIGATION INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., MONOFILAMENT POLIGLECAPRONE 25 UNDYED ABSORBABLE SURGICAL SYNTHETIC SUTURE(MONOPOLLY)-MONOPOLLY SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY., MONOFILAMENT POLIGLECAPRONE 25 UNDYED ABSORBABLE SURGICAL SYNTHETIC SUTURE(MONO NEP)-MONO NEP SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,BRAIDED & COATED POLYGLYCOLIC ACID VIOLET ABSORBABLE SURGICAL

		SYNTHETIC SUTURE USP(POLYSOLVE)-POLYSOLVE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION, GENERAL CLOSURE, OPHTHALMIC, ORTHOPAEDICS, OBSTETRICS/GYNAECOLOGY AND GASTROINTESTINAL TRACT SURGERY.,MONOFILAMENT POLYDIOXANONE VIOLET ABSORBABLE SURGICAL SYNTHETIC SUTURE(PD NEP)-PD NEP ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN OPHTHALMIC SURGERY.
3604	MFG/MD/2020/000253	1.License Holder Name: APAR INDUSTRIES LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:E BEAM STERILIZATION-NOT APPLICABLE
3605	MFG/MD/2020/000254	1.License Holder Name: NAV DURGA INDUSTRIES 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.-MEDICAL ABSORBENT (FIBRE BANDAGES)
3606	MFG/MD/2020/000255	1.License Holder Name: LIFESOL MEDICAL INDIA PRIVATE LIMITED 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:NON WOVEN SURGICAL DRESSINGS-THESE DRESSINGS ARE INTENDED TO BE APPLIED OVER I.V. INJECTION SITES, INFUSION SITES, CLEAN SKIN, OR WOUNDS. THESE DRESSINGS PROVIDE A BARRIER AGAINST MICROBIAL AND OTHER ENVIRONMENTAL CONTAMINANTS.,INFUSION SET-STERILE INFUSION SET SINGLE USE ARE INTENDED FOR HUMAN BODY VEIN INFUSION USE UNDER GRAVITY FEED.,TRANSPARENT SURGICAL DRESSINGS-THESE DRESSINGS ARE INTENDED TO BE APPLIED OVER I.V. INJECTION SITES, INFUSION SITES, CLEAN SKIN, OR WOUNDS. THESE DRESSINGS PROVIDE A BARRIER AGAINST MICROBIAL AND OTHER ENVIRONMENTAL CONTAMINANTS.

3607	MFG/MD/2020/000256	1.License Holder Name: SAP & PAP 2.Approving Authority: CENTRAL DRUGS STANDARD CONTROL ORGANIZATION(EAST ZONE) 3.Device Name(Brand Name)-Intended Use:HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENS(OCUSAP)-FOR REPLACING NATURAL HUMAN LENS DURING CATARACT SURGERY,HYDROPHOBIC ACRYLIC FOLDABLE INTRAOCULAR LENS(OCUPAP)-FOR REPLACING NATURAL HUMAN LENS DURING CATARACT SURGERY,PMMA INTRAOCULAR LENS(OCUSET)-INTRAOCULAR LENSES FOR REPLACING NATURAL HUMAN LENS DURING CATARACT SURGERY. CAPSULAR TENSION RING FOR SUPPORTING DEVICE DURING CATARACT SURGERY

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3608	MFG/MD/2020/000257	1.License Holder Name: SAHAJANAND MEDICAL TECHNOLOGIES PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:PTCA BALLOON CATHETER(1. WILMA 2. FINCH & 3.PIPIT)-FOR FURTHER MANUFACTURING USE ONLY,COBALT CHROMIUM CORONARY STENT SYSTEM(1.FLEXINNIUM, 2. FINAE)-THE CORONARY STENT SYSTEM ARE INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN THE FOLLOWING: A. PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO OR RESTENOTIC NATIVE CORONARY ARTERY LESIONS WITH REFERENCE VESSEL DIAMETERS RANGING FROM 2.0 MM TO 4.5 MM. B. PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO LESIONS IN SAPHENOUS VEIN BYPASS GRAFTS WITH REFERENCE VESSEL DIAMETERS RANGING FROM 2.0 MM TO 4.5 MM. C. RESTORING CORONARY FLOW IN PATIENTS EXPERIENCING ACUTE MYOCARDIAL INFARCTION, AS CONFIRMED BY ST SEGMENT ELEVATION OR ANGIOGRAPHIC FINDINGS, WHO PRESENT WITHIN 12 HOURS OF SYMPTOM ONSET WITH NATIVE CORONARY ARTERY LESIONS WITH A REFERENCE VESSEL DIAMETER OF 2.0 MM TO 4.5 MM.,PTCA BALLOON DILATATION CATHETER (NC- NON COMPLIANT)((1.WILMA-NC, 2. FINCH-NC & 3. PIPIT-NC))-FOR BALLOON DILATION OF A STENOTIC PORTION OF A CORONARY ARTERY IN PATIENTS EVIDENCING CORONARY ISCHEMIA FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION. IT IS ALSO INDICATED FOR POST DELIVERY EXPANSION OF BALLOON EXPANDABLE STENTS., BALLOON EXPANDABLE COBALT CHROMIUM RENAL AND BILIARY STENT SYSTEM(RENOFIT)-THE COBALT CHROMIUM RENAL AND BILIARY STENT SYSTEM IS INTENDED TO OPEN LUMEN RESTRICTIONS IN THE BILIARY TREE, RENAL ARTERIES AND PROTECTED PERIPHERAL ARTERIES.,PACLITAXEL DRUG COATED PTA BALLOON ((1. PERIPHERICS))-THE PACLITAXEL DRUG COATED PTA BALLOON CATHETER IS INDICATED FOR PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY, AFTER APPROPRIATE VESSEL PREPARATION, OF DE NOVO OR RESTENOTIC LESIONS UP TO 200 MM IN LENGTH IN NATIVE INFRAPOPLITEAL ARTERIES AND POPLITEAL ARTERIES (SUPERFICIAL FEMORAL) WITH REFERENCE VESSEL DIAMETERS OF 2-12 MM.,EVEROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM(1. TETRILIMUS, 2. SMT EVEROFLEX GRACE, 3. SMT EVEROFLEX NEVO, 4. EVERO EXPLORER, 5. EVEROFLEX DESTINY, 6. TETRILIMUS INFINITY, 7. TETRILIMUS ADVANCED, 8. TETRILIMUS GLORY)-THE EVEROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN

	PATIENTS WITH SYMPTOMATIC CORONARY ARTERY DISEASE DUE TO ARTERY LESIONS WITH A REFERENCE VESSEL DIAMETER FROM 2.00 MM TO 4.50 MM.,SIROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM((1. TETRIFLEX, 2. DESTINY, 3. QUINTILLION, 4. CENTILLION, 5. SUPRAFLEX STAR, 6. SUPRAFLEX CRUZ, 7. SUPRALIMUS GRACE, 8. SUPRALIMUS NEVO, 9. SUPRA EXPLORER & 10. SUPRAFLEX INFINITY))-THE SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE-NOVO STENOTIC LESIONS AND IN-STENT RESTENOTIC LESIONS IN NATIVE CORONARY ARTERIES WITH A REFERENCE VESSEL DIAMETER OF 2.00 MM TO 4.50 MM.,SIROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM(1.SUPRAFLEX, 2. FLEXILIMUS, 3. PROTOLIMUS, 4. VACTAFLEX, 5. SUPRALIMUS-FLEX, 6. FLEXILIMUS PLUS, 7. PROTOLIMUS PLUS, 8. VACTAFLEX PLUS, 9. SUPRALIMUS FLEX PLUS, 10. AIMA PLUS, 11. ABRAX COCR)-THE SIROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR TREATMENT OF CORONARY ARTERY LESIONS WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.00 MM TO 4.50 MM.,PTCA BALLOON DILATATION CATHETER (SC-SEMI COMPLIANT)((1.WILMA-SC, 2. FINCH-SC & 3. PIPIT-SC))-FOR BALLOON DILATION OF A STENOTIC PORTION OF A CORONARY ARTERY IN PATIENTS EVIDENCING CORONARY ISCHEMIA FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION., EVEROLIMUS ELUTING COBALT CHROMIUM CORONARY STENT SYSTEM (EES-1)((1. EVEROFLEX))-THE EVEROLIMUS ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR TREATMENT OF CORONARY ARTERY LESIONS WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.00 MM TO 4.50 MM.

3609	MFG/MD/2020/000258	1.License Holder Name: SURU INTERNATIONAL PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:STERILE STONE BASKET / STONE EXTRACTOR / STONE GRASPER(SURU)-THE STONE RETRIEVAL BASKET IS INTENDED TO BE USED DURING UROLOGICAL PROCEDURES TO ENDOSCOPICALLY GRASP, TRANSURETHRAL MANIPULATION AND EXTRACTION OF URINARY CALCULI (STONES) AND OTHER FOREIGN OBJECTS IN THE URETER, BLADDER OR URETHRA.,STERILE EPIDURAL NEEDLE(SURUEPIN)-EPIDURAL NEEDLE IS INTENDED FOR THE TRANSIENT DELIVERY OF ANESTHETICS IN EPIDURAL SPACE PRIOR TO SPINAL CORD TO PROVIDE EPIDURAL ANESTHESIA OR TO FACILITATE PLACEMENT OF AN EPIDURAL CATHETER,STERILE COLOSTOMY BAG / KIT(SURU)-COLOSTOMY BAG / KIT INTENDED TO ATTACHES TO THE STOMA TO COLLECT THE WASTE.,STERILE BLOOD TRANSFUSION SET / BLOOD GIVING SET / TRANSFUSION SET(SURU, INSTAFUSE, MCVEIN)-THE PRODUCT IS INTENDED TO USE FOR TRANSFUSION OF BLOOD AND ITS COMPONENTS INTO HUMAN PERIPHERAL CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER AND CANNULA.,STERILE STAPLE REMOVER(SURUREM, RAXSTAP, NEWMED, POLNET)-THE REMOVER IS USED TO REMOVE THE STAPLE FIXED ON THE SKIN ONCE THE WOUND IS HEALED,STERILE BURETTE SET (PAEDIATRIC DRIP SET / MEASURED VOLUME FLUID ADMINISTRATION SET(SURUVOL, ULTRAMED, INSTAVOLS)-THE PRODUCT IS USED TO ADMINISTER INTRAVENOUS FLUID ANDMEDICINES INTO HUMAN CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER OR CANNULAE.,STERILE NELATON CATHETER / URETHRAL CATHETER(SURU)-THE DEVICE IS USED TO PROVIDE ACCESS TO THE BLADDER CATHETERIZATION THROUGH URETHRA IN CASE OF URINARY RETENTION.,STERILE NEEDLELESS CONNECTOR WITH OR WITHOUT TUBE / LUER LOCK (SURU)-THE DEVICE IS DESIGNED TO BE USED IN CONJUNCTION WITH AN INTRAVASCULAR CANNULA FOR ITS LONG TERM CLOSURE., STERILE PERITONEAL DIALYSIS CATHETER KIT / TRANSFUSION SET (SURU)-THE PERITONEAL DIALYSIS CATHETER KIT IS USED TO ALLOW SOLUTION TO FLOW INTO AND OUT OF THE PERITONEAL CAVITY AND THE PERITONEAL DIALYSIS TRANSFUSION SET IS USED TO ALLOW SOLUTION TO FLOW INTO AND OUT OF THE PERITONEAL CAVITY.,STERILE ABDOMINAL DRAIN CATHETER / SET(SURU)-INTENDED TO PASSIVELY DRAIN OUT AND COLLECT A FLUID FROM ABDOMINAL SPACE OF THE BODY.,STERILE EXTENSION LINE / EXTENSION TUBE / PRESSURE MONITORING LINE(SURU)-DEVICE INTENDED TO CONNECT THE INFUSION SITE AND THE SOURCE OF INFUSION TO EXTEND THE PATH BY MEANS OF MAKING CONNECTION WITH 6% LUER CONNECTORS.,STERILE NEBULIZER MASK /

	NEBULIZER MOUTH PIECE KIT(SURU)-NEBULIZER MASK IS USED FOR THE DEEP MEDICATION INTO THE LUNGS WHEN PATIENT IS SUFFERING FROM ASTHMA OR OTHER LUNGS RELATED PROBLEMS., STERILE STYLET (OBTURATOR / MANDRIN)(SURU)-THE DEVICE IS USED IN CONJUNCTION WITH AN INTRAVENOUS CANNULA/CATHETER FOR ITS LONG-TERM CLOSURE. THE DEVICE WHICH CLOSES OR STOPS AN OPENING IS CALLED OBTURATOR., STERILE MALE EXTERNAL CATHETER(SURUXCATH)-MALE EXTERNAL CATHETER IS SPECIALLY DESIGNED FOR URINE INCONTINENCE FOR DAY AND NIGHT USE IN MALE PATIENTS.,STERILE OXYGEN MASK (OXYGEN FACE MASK) / OXYGEN RECOVERY "T" KIT(SURU-O2-MASK, SURU)-OXYGEN MASKS ARE USED TO TRANSFER BREATHING OXYGEN GAS FROM A STORAGE TANK TO THE LUNGS.,STERILE SPIKE (SURUSPIKE)-THE PRODUCT IS USED TO TRANSFER MEDICATION FROM VIAL TO SYRINGE AND VICE-VERSA.,STERILE I V FLOW REGULATOR WITH / WITHOUT EXTENSION SET(SURUFLOW)-DEVICE INTENDED TO CONNECT THE INFUSION SITE AND THE SOURCE OF INFUSION (GRAVITY SOURCE ONLY) TO EXTEND THE PATH AND DELIVERING ACCURATE VOLUME OF IV FLUID OR MEDICINES BY MEANS OF ADJUSTING PRESCRIBED FLOW RATE ON THE REGULATOR.,STERILE ENDOTRACHEAL TUBE / TRACHEAL TUBE KIT (SURUNTREK, CAREON)-THE TUBES ARE USED FOR PERFORMING RESPIRATION FOR PATIENTS CONNECTED WITH RESPIRATORY SYSTEM DURING OPERATION OR WHO LOOSE ACTIVE BREATH ABILITY.,STERILE EPIDURAL CATHETER / EPIDURAL SET / KIT / PACK (SURU)-EPIDURAL CATHETER / SET / KIT ARE USED TO PROVIDE, VIA PERCUTANEOUS ADMINISTRATION, CONTINUOUS AND/OR INTERMITTENT INFUSION OF LOCAL ANESTHETICS AND ANALGESICS IN THE EPIDURAL SPACE PRIOR TO SPINAL CORD.,STERILE INTRA COSTAL DRAINAGE BAG / WATER SEALED DRAINAGE BAG(SURU)-INTENDED TO PASSIVELY DRAIN OUT AND COLLECT A FLUID FROM PLEURAL SPACE OF THE BODY.,STERILE SCALP VEIN BUTTERFLY SET (SAFETY WINGED INFUSION SET)(SURU)-INTENDED TO USE FOR BLOOD COLLECTION AND/OR THE SHORT-TERM INFUSION OF INTRAVENOUS FLUIDS. ALSO INTENDED FOR SCALP VEINS ACCESS IN SMALL CHILDREN AND INFANTS.,STERILE URINE DRAINAGE BAG / URINE COLLECTION BAG(SURU, SURU-BABY BAG, SURU-LEG BAG, SURU URIMETER, SURU-UBAG)-THE PRODUCT IS DESIGNED TO COLLECT URINE FROM A PATIENT IN SHORT OR LONG TERM. IT IS CONNECTED TO A FOLEY'S OR NELATON CATHETER FOR COLLECTION OF URINE.,STERILE NASO BILIARY DRAINAGE CATHETER / SET (NBDC)(SURU)-USED FOR BILIARY DUCT DRAINAGE THROUGH NASAL PASSAGE AND TREATMENT OF STRICTURES IN THE DUCTILE SYSTEM,STERILE ANGIOGRAPHY KIT(SURU)-KIT IS USED IN

	FIELD OF INTERVENTIONAL MEDICINE AND DIALYSIS.,STERILE CVP MANOMETER(SURU CVP)-THE CVP MANOMETERS ARE USED FOR CONTINUOUS OR INTERMITTENT MONITORING OF CENTRAL VENOUS PRESSURE DURING INFUSION.,STERILE ADULT FEEDING TUBE / STOMACH TUBE / NASOGASTRIC TUBE(SURU)-FEEDING TUBES ARE USED FOR FEEDING THROUGH GASTRO-INTESTINAL FEEDING OR THROUGH NASOGASTRIC TRACT FOR INTRODUCTION OF NUTRITION AND ASPIRATION OF INTESTINAL SECRETIONS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,STERILE BREATHING SYSTEM (BREATHING CIRCUITS) / VENTILATOR CIRCUIT KIT(SURUVENT, SURUVENT SOLO, SURUVENT DUO, SURU)-THE PRODUCT IS USED FOR CONNECTION BETWEEN ENDOTRACHEAL TUBE AND BREATHING CIRCUITS.,STERILE SUPRA PUBIC DRAINAGE CATHETER / SET(SURU)-USED FOR PERCUTANEOUS PLACEMENT OF A MALECOT CATHETER IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE.,STERILE A. V. FISTULA NEEDLE (ARTERIAL VENOUS FISTULA NEEDLE)(SURU)-THE PRODUCT IS USED TO DELIVER BLOOD INTO HUMAN CIRCULATING SYSTEM. FISTULA NEEDLE IS USED TO CONNECT BLOOD LINES TO THE BLOOD VESSEL THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT VIA AN INTERNAL FISTULA.,STERILE FLUSHING TUBE (ENDOSCOPIC, GASTROSCOPE, UTERUS)(SURU)-IT ENSURES AN EASY AND SECURE COUPLING OF FLUSHING TUBE AND FLUSHING LIQUID.,STERILE CHEST DRAINAGE BOTTLE (UNDER WATER SEALED DRAINAGE SYSTEM)(SURUDRAIN)-CHEST DRAINAGE BOTTLE (UNDER WATER SEAL DRAINAGE SYSTEM IS USED TO DRAIN THE FLUID FROM BODY COLLECTED DUE TO VARIOUS REASONS LIKE LARGER PLEURAL EFFUSIONS, POST OPERATIVE DRAINAGE ETC FROM A PATIENT.,STERILE FOLEY BALLOON CATHETER (LATEX, SILICONISED / SILICON COATED)(SURUCATH, CORONET)-FOLEY BALLOON CATHETER/ FOLEY URINARY CATHETER IS INTENDED TO DRAIN THE URINARY BLADDER THROUGH URETHRAL ORIFICE., STERILE VENTURI MASK / KIT / VENTURI VALVE MASK KIT(SURU)-VENTURI MASK SET / KIT IS USED TO EASY ADJUSTABLE, VARIABLE VENTURI SYSTEM ENSURES FIXED & ACCURATE CONCENTRATION OF OXYGEN BEING ADMINISTERED TO THE PATIENT.,STERILE TWIN BORE NASAL OXYGEN SET (NASAL OXYGEN CATHETER)(SURU-O-TUBE)-TWIN BORE NASAL OXYGEN SET INTENDED TO BE USED DISTRIBUTION SMALL AMOUNTS OF SUPPLEMENTAL OXYGEN THROUGH SOFT TWIN PRONG NASAL TIPS.,STERILE CORRUGATED DRAINAGE SHEET(SURU)-THE MULTI CHANNEL CORRUGATED DRAINAGE SHEET IS DESIGNED TO INTEND FOR EFFICIENT OPEN PASSIVE DRAINAGE WHERE AIRTIGHT CLOSURE OF WOUND IS NOT POSSIBLE OR IN SITUATIONS WHERE WOUND MUST BE KEPT OPEN., STERILE GUEDEL AIRWAYS / NASOPHARYNGEAL AIRWAYS(SURU)-

	THE PRODUCT IS USED TO MAINTAIN AN UNOBSTRUCTED OROPHARYNGEAL / NASOPHARYNGEAL AIRWAY.,STERILE CLOSE WOUND SUCTION DRAINAGE UNIT / HIGH PRESSURE VACUUM DRAINAGE BOTTLE(SURUVAC SET, SURUVAC PRO, SURU, APEXMED)-THE PRODUCT IS USED FOR CLOSED WOUND DRAINAGE OR COLLECTION OF FLUID FROM SURGICAL WOUND UNDER NEGATIVE PRESSURE THROUGH A COLLECTION TUBE AND COLLECTION DEVICE (BELLOW) WITH AN OPTION TO OPERATE ONE OR TWO CATHETERS SIMULTANEOUSLY.,STERILE HAEMODIALYSIS CATHETER / KIT(SURU HAEMOCATH, SURU HAEMOKIT)-HAEMODIALYSIS CATHETERS ARE SINGLE LUMEN OR MULTIPLE LUMEN, THAT PROVIDES TEMPORARY VASCULAR ACCESS FOR HAEMODIALYSIS UNTIL A PERMANENT ACCESS IS AVAILABLE OR UNTIL ANOTHER TYPE OF DIALYSIS THERAPY IS SUBSTITUTED.,STERILE FEMALE CATHETER(SURU)-THE DEVICE IS USED TO PROVIDE ACCESS TO THE BLADDER CATHETERIZATION THROUGH URETHRA IN CASE OF URINARY RETENTION.,STERILE FOLEY BALLOON CATHETER (100% SILICON) / ALL SILICON FOLEY BALLOON CATHETER(SURUCATH PRO, RAXCATH)-FOLEY BALLOON CATHETER/ FOLEY URINARY CATHETER IS INTENDED TO DRAIN THE URINARY BLADDER THROUGH URETHRAL ORIFICE.,STERILE KEHR'S "T" TUBE(SURU)-KEHR'S T TUBE IS USED FOR SHORT TERM POST OPERATIVE DRAINAGE OF COMMON BILE DUCT.,STERILE OXYGEN CATHETER (NASAL OXYGEN CATHETER) (SURU)-OXYGEN CATHETER IS USED TO PROVIDE OXYGEN FOR RESPIRATION WITH MAXIMUM COMFORT TO THE PATIENT.,STERILE GUIDING CATHETER (GUIDEWIRE)(SURU)-SOFT FLEXIBLE J-TIP GUIDE WIRE PREVENTS THE VESSEL PERFORATION AND ALSO PROVIDES GOOD TORQUE TO ENSURE FIRM INSERTION.,STERILE DOG CATHETER / TUBE(SURU)-USED TO DRAIN URINE FROM DOG,STERILE TRACHEOSTOMY TUBE(SURU)-THE TRACHEOSTOMY TUBE IS USED IN GENERAL ANAESTHESIA, INTENSIVE CARE AND EMERGENCY MEDICINE FOR AIRWAY MANAGEMENT AND MECHANICAL VENTILATION. THE TUBE IS INSERTED INTO A PATIENT'S TRACHEA THROUGH AN INCISION IN THE TRACHEA (THE WINDPIPE)., RESPIRATORY EXERCISER(SURUREX SOLO, SURUREX TRIO)-HELPS PATIENT TO RECOVER THE NORMAL RESPIRATORY AFTER A CHEST OR ABDOMINAL SURGERY,STERILE ENTERAL FEEDING BAG(SURU)-ENTERAL FEEDING BAG IS USED FOR GASTRO-INTESTINAL FEEDING. BAG NEED TO BE CONNECTED TO THE NASOGASTRIC TUBE FOR EASY FEEDING TO THE PATIENT.,STERILE CAT CATHETER / TUBE(SURU)-USED TO DRAIN URINE FROM CAT,STERILE SYRINGES (SAFETY SYRINGE / SINGLE USE SYRINGE / AUTO DISABLE SYRINGE / INSULIN SYRINGE) WITH / WITHOUT NEEDLE(SURU)-DISPOSABLE SYRINGES WITH/WITHOUT NEEDLE IS INTENDED FOR INJECTING THE FLUIDS

	INTO OR WITHDRAWING FLUIDS FROM THE BODY. INTENDED FOR SINGLE USE ONLY.,STERILE THREE WAY STOPCOCK WITH OR WITHOUT EXTENSION LINE(SURUWAY, SURUWAY PRO, SURUWAY PLUS, SURUWAY HP, ZURGEON, APEXMED)-THE PRODUCT IS USED TO DELIVER TWO INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM AT A TIME.,STERILE STAPLER / SKIN STAPLER (SURUSTAP, RAXSTAP, SURGI-CARE, NEWMED, POLSTAP, SLANEY)-SKIN STAPLER IS A DISPOSABLE SURGICAL SKIN STAPLER WHICH IS INTENDED TO BE USED FOR CLOSURE OF SKIN WOUND IN A WIDE VARIETY OF SURGICAL PROCEDURES INCLUDING ABDOMINAL, GYNECOLOGICAL, ORTHOPEDIC, AND THORACIC SURGERY.,STERILE THORACIC CATHETER WITH / WITHOUT TROCAR (CHEST DRAINAGE CATHETER / PLEURAL CATHETER)(SURUCATH ULTRA, UNIMEX, APEXMED, SURGI-CARE)-THORACIC DRAINAGE CATHETERS ARE INSERTED THROUGH THE THORAX TO REMOVE AIR AND FLUIDS FROM THE PLEURAL SPACE AND TO REESTABLISH NORMAL INTRAPLEURAL AND INTRAPULMONIC PRESSURES. THEY ARE SUITABLE FOR EFFECTIVE DRAINAGE AFTER CARDIO-THORACIC & THORACIC SURGERY.,STERILE SALEM SUMP TUBE / IRRIGATION TUBE(SURU)-THE DUAL FLOW TYPE PRODUCT IS DESIGNED TO PREVENT THE ACCUMULATION OF GASTRIC SECRETIONS & AIR, THUS ALLOWING DECOMPRESSION OF THE STOMACH BY CONTINUOUS ASPIRATION WITHOUT TRAUMA TO THE GASTRIC MUCOSA.,STERILE REDON DRAIN CATHETER(SURU)-REDON DRAINAGE TUBE IS USED FOR CLOSE WOUND DRAINAGE OR COLLECTION OF FLUID FROM SURGICAL WOUND UNDER NEGATIVE PRESSURE.,STERILE T.U.R. SET (TRANS URETHRAL RESECTION(SURU)-THE Y- SHAPED TUR SET IS USED FOR ENDOSCOPIC IRRIGATION DURING TRANS URETHRAL RESECTION OF PROSTATE GLAND. THE PRODUCT IS INTENDED FOR THE INFUSION OF FLUIDS TO EVACUATE THE BLADDER.,STERILE NEPHROSTOMY DRAINAGE CATHETER / SET (PCN DRAINAGE CATHETER / SET)(SURU)-INTENDED TO USE FOR PERCUTANEOUS PLACEMENT OF A CATHETER IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE.,STERILE IRRIGATION SET(SURU)-IRRIGATION SET IS USED FOR TRANSFER OF IRRIGATION SOLUTION FOR RINSE THE TARGET HUMAN TISSUE OR CAVITY. IT IS ONLY INTENDED TO BE CONNECTED WITH THE SPIKE TO A STERILE IRRIGATION SOLUTION BAG, E.G. NACL 0,9%. ALL THE APPLICATIONS HAVE A COMMON OBJECTIVE I.E. CARRY OUT WASHING AND/OR CLEANING THROUGH THE IRRIGATION TUBE CONNECTED TO A FINAL MEDICAL DEVICE DIRECTLY ON CONTACT WITH PATIENT BODY., STERILE L P SPINAL NEEDLE(SURUSPIN, ROMED, NEWMED)-LP SPINAL NEEDLE IS INTENDED FOR INJECTION OF LOCAL ANESTHETICS INTO THE SUBARACHNOID SPACE TO PROVIDE

	REGIONAL ANESTHESIA FOR PAIN MANAGEMENT OR TO FACILITATE CSF SAMPLE COLLECTION FOR DIAGNOSTIC PURPOSES., RESUSCITATOR(SURU)-A RESUSCITATOR IS A DEVICE USING POSITIVE PRESSURE TO INFLATE THE LUNGS OF AN UNCONSCIOUS PERSON WHO IS NOT BREATHING, IN ORDER TO KEEP THEM OXYGENATED AND ALIVE.,STERILE SPECIALITY NEEDLE(SURU, CREEDMED)-NEEDLES ARE USED IN VARIOUS PROCEDURES NAMELY PERCUTANEOUS NEPHROSTOMY PROCEDURE, DENTAL PROCEDURE, FOR BIOPSIES, FOR BONE MARROW SPECIMEN, SUCTION FLUID AND CERUMEN FROM EAR, FOR TRANSIENT DELIVERY OF ANESTHETICS TO PROVIDE LOCAL ANESTHESIA, HYPODERMIC NEEDLES ARE USED WITH LUER SYRINGE FOR ASPIRATION & INJECTION OF FLUIDS FOR MEDICAL PURPOSES.,STERILE RECTAL CATHETER(SURU)-RECTAL CATHETER IS USED FOR INTRODUCTION OF ENEMA SOLUTION INTO RECTUM,STERILE SUCTION CATHETER / SUCTION TUBE / YANKAUR SUCTION SET / CLOSED SUCTION SYSTEM(SURU, CAREON)-THE PRODUCT IS USED TO PROVIDE ACCESS TO RESPIRATORY TRACT TO REMOVE SECRETION WITH MAXIMUM COMFORT TO THE PATIENT., STERILE INFANT FEEDING TUBE(SURU)-INFANT FEEDING TUBE IS USED TO PROVIDE FEEDING TO NEONATES AND INFANTS. THESE TUBES ARE USED TO PROVIDE FEEDINGS AND MEDICATIONS INTO THE STOMACH UNTIL THE BABY CAN TAKE FOOD BY MOUTH.,STERILE UMBILICAL CORD CLAMP(SURU)-THE PRODUCT IS USED TO CLAMP THE UMBILICAL CORD IMMEDIATELY AFTER THE BIRTH OF A CHILD., STERILE I V CANNULA / I V CATHETER / INTRA VENOUS CATHETER (SURUNEO, SURUFLON, SURUCAN, SURUCAN PLUS, SURUFLON PRO, SURUON, SURUON PRO, SURUPEN, SURUINTRA, FLEXICAN, FLEXICATH, INSTAFLON, SUPER FLOW, CUREX, ROMEDFLON, GOSH, APROMED, TG MED, CAREPLUS, INSTANEO, SURUFLON INSTA, FLEXICATH VISION, SURUFLON SAFE, TROGE)-IV CANNULA COMMONLY IS USED TO DELIVER INTRAVENOUS FLUIDS, WITHDRAWAL OF BLOOD SAMPLES AND MEDICINES INTO HUMAN CIRCULATING SYSTEM,STERILE INFANT MUCUS EXTRACTOR(SURU)-INFANT MUCUS EXTRACTOR IS DESIGNED FOR ASPIRATION OF SECRETION FROM OROPHARYNX ENSURING FREE RESPIRATION AND CONVENIENT FOR SAFE TRANSPORT OF ASPIRATE FOR EXAMINATION.,STERILE UMBILICAL CATHETER(SURU)-INTENDED FOR INTERMITTENT OR CONTINUOUS ACCESS TO THE UMBILICAL VESSELS OF NEW BORN OR PRE-MATURE INFANTS, SUITABLE FOR MONITORING BLOOD PRESSURE, WITHDRAWAL OF BLOOD FOR SAMPLING WITHOUT REPEATED NEEDLE PRICKS, INTRA VENOUS INFUSION AND EXCHANGE TRANSFUSION.,STERILE INFUSION SET (ADULT / PAEDIATRIC)(SURU, SURULINE, SURULINE PRO, MCDRIP, INSTAFLOW, SURU INFU-NOAIR)-THE INFUSION SET(S) INTENDED TO

	USE FOR ADMINISTRATION OF INTRAVENOUS FLUID AND MEDICINES BY MEANS OF GRAVITY FEED INTO HUMAN CIRCULATING SYSTEM USING INTRAVENOUS CATHETER OR CANNULA.,STERILE FLEXIBLE CATHETER MOUNT(SURU)-THE PRODUCT IS USED FOR CONNECTION BETWEEN ENDOTRACHEAL TUBE AND BREATHING CIRCUITS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3610	MFG/MD/2020/000259	1.License Holder Name: LIFELINE SYSTEMS PVT. LTD. 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:CVP MENOMETER (LIFELINE)- A CENTRAL VENOUS PRESSURE (CVP) MANOMETER SET IS USED TO EITHER CONTINUOUSLY OR INTERMITTENTLY MEASURE CENTRAL VENOUS PRESSURE. THIS DEVICE IS NORMALLY USED IN ICUS AND SURGERY WARDS TO MONITOR AND CONTROL THE HEMODYNAMIC STATE OF PATIENTS BY MEASUREMENT OF THE CENTRAL VENOUS PRESSURE THROUGH A GRADUATED COLUMN WHERE MEASUREMENTS ARE IN CENTIMETRES OF WATER. ,RIGID SUCTION DEVICE/SUCKERS(LIFELINE)-THE SUCTION DEVICES CONSISTS OF SPECIAL STAINLESS STEEL TUBE WITH A RIBBED / MINI TIP AND IRGONOMICALLY FORMED HANDLE.THE SUCTION DEVICES USED IN MEDICAL PROCEDURES. IT IS TYPICALLY A FIRM PLASTIC SUCTION TIP AND SS TUBE WITH A LARGE OPENING SURROUNDED BY A BULBOUS HEAD AND IS DESIGNED TO ALLOW EFFECTIVE SUCTION WITHOUT DAMAGING SURROUNDING TISSUE. THIS TOOL IS USED TO SUCTION OROPHARYNGEAL SECRETIONS IN ORDER TO PREVENT ASPIRATION. ,AV TUBING(LIFELINE)-NON-TOXIC MEDICAL GRADE. P. V.C. TUBING. VENTED PROTECTIVE CAPS ARE PROVIDED AT TUBING ENDS. AVAILABLE IN VARIABLE LENGTHS AS PER CUSTOMERS SPECIFICATION. E.T.O. STERILE AND PYROGEN FREE,CENTRAL VENOUS CATHETER(LIFELINE)-INTENDED FOR MONITORING CENTRAL VENOUS PRESSURE (CVP) SAMPLING BLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTIONS OR DRUGS,ENDOTRACHEAL TUBE(LIFELINE)-AN ENDOTRACHEAL TUBE IS A FLEXIBLE PLASTIC TUBE THAT IS PLACED THROUGH THE MOUTH INTO THE TRACHEA (WINDPIPE) TO HELP A PATIENT BREATHE. THE ENDOTRACHEAL TUBE IS THEN CONNECTED TO A VENTILATOR, WHICH DELIVERS OXYGEN TO THE LUNGS. THE PROCESS OF INSERTING THE TUBE IS CALLED ENDOTRACHEAL INTUBATION. , YANKEUR SUCTION SET(LIFELINE)-YANKEUR SUCTION SET IS SUITABLE FOR CONVENIENT REMOVAL OF SECRETION, BLOOD AND DEBRIS ETC PER OPERATIVELY YANKEUR IS A SUCTION SET PURPOSIVE FOR THE REMOVAL OF BLOOD AND FLUIDS DURING SURGERY. YANKEUR SUCTION SET IS USED FOR GENERAL SUCTION PURPOSES. IT HAS A RIGID TRANSPARENT SUCTION HANDLE AVAILABLE WITH BULB/PLAIN OPEN TIP. IT IS OBTAINABLE WITH AND WITHOUT CONTROL VENTS ,INFANT FEEDING TUBE(LIFELINE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S IS USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING,HEART LUNGS BYPASS UNIT TUBE(LIFELINE)-A TUBE WILL BE PLACED IN YOUR HEART TO DRAIN BLOOD TO THE MACHINE,RYLES TUBE(LIFELINE)-INTENDED USE TO

	FEEDING OF LIQUID FOOD IN ADULTS BY DIRECTLY INSERTED INTO THE THROAT OR BY INSERTED TRACHEAL CATHETER FOR ANESTHESIA. ,CLOSED WOUND DRAINAGE SET(LIFELINE LINE)-CLOSED WOUND DRAINAGE TUBE OR SYSTEM INTENDED FOR EVACUATION OF BIOLOGICAL FLUID FROM WOUND OR BODY CAVITY DURING SURGICAL PROCEDURE OR IN WOUND CARE MANAGEMENT. , SPINAL NEEDLE(LIFELINE)-THIS DEVICE IS USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM. ,SUCTION CATHETER WITH/WITHOUT CONTROL VALVE(LIFELINE)-A SUCTION CATHETER IS A MEDICAL DEVICE USED TO EXTRACT BODILY SECRETIONS, SUCH AS MUCUS OR SALIVA FROM THE UPPER AIRWAY. A SUCTION CATHETER CONNECTS TO A SUCTION MACHINE OR COLLECTION CANISTER,MALE CATHETER(LIFELINE)-MALE CATHETER/CONDOM CATHETERS ARE USED BY MEN WITH INCONTINENCE. THERE IS NO TUBE PLACED INSIDE THE PENIS. INSTEAD, A CONDOM-LIKE DEVICE IS PLACED OVER THE PENIS. A TUBE LEADS FROM THIS DEVICE TO A DRAINAGE BAG. THE CONDOM CATHETER MUST BE CHANGED EVERY DAY. MALE CATHETERS ARE USED TO DRAIN THE BLADDER. YOUR HEALTH CARE PROVIDER MAY RECOMMEND THAT YOU USE A CATHETER IF YOU HAVE: • URINARY INCONTINENCE (LEAKING URINE OR BEING UNABLE TO CONTROL WHEN YOU URINATE) • URINARY RETENTION (BEING UNABLE TO EMPTY YOUR BLADDER WHEN YOU NEED TO) • SURGERY ON THE PROSTATE OR GENITALS • OTHER MEDICAL CONDITIONS SUCH AS MULTIPLE SCLEROSIS, SPINAL CORD INJURY, OR DEMENTIA MALE CATHETERS COME IN MANY SIZES, MATERIALS (LATEX, SILICONE) DEVICE DESCRIPTION: MALE CATHETER/CONDOM CATHETERS ARE USED BY MEN WITH INCONTINENCE. THERE IS NO TUBE PLACED INSIDE THE PENIS. INSTEAD, A CONDOM-LIKE DEVICE IS PLACED OVER THE PENIS. A TUBE LEADS FROM THIS DEVICE TO A DRAINAGE BAG. THE CONDOM CATHETER MUST BE CHANGED EVERY DAY. , URINE COLLECTION BAG/UROMEASURE(LIFELINE)-THIS DEVICE IS USED IN UROLOGY PROCEDURES FOR THE COLLECTION OF URINE FROM THE PATIENTS FOR DIAGNOSTIC AND/ OR TREATMENT PURPOSES. URINE COLLECTION BAG IS IS A BAG USED TO COLLECT URINE FROM URETHRA OF THE PATIENT THROUGH CATHETER. , URETHRAL CATHETER(LIFELINE)-URETHRAL CATHETER A LONG, SMALL GUAGE CATHETER DESIGNED FOR INSERTION DIRECTLY INSERTED INTO THE URETER, EITHER THROUGH THE URETHRA AND BLADDER AND POST PRIORY VIA THE KIDNEY. URETHRAL CATHETER IS USED A ROUTINE MEDICAL PROCEDURE THAT FACILITATES DIRECT DRAINAGE OF THE URINARY BLADDER INTO AN ATTACHED URINE COLLECTION BAG OR CONTAINER. IT CONSISTS IN THE INSERTION OF

	A CATHETER INTO A PATIENT'S BLADDER. ,IV CANNULAE(LIFELINE)-INTRAVENOUS CATHETER: THIS DEVICE IS USED FOR INFUSION THERAPY FOR INFUSING INTO HUMAN BODY, INTRAVENOUS FLUIDS SUCH AS GLUCOSE, SALINE SOLUTIONS OR BLOOD. THIS DEVICE IS TO BE CONNECTED WITH I.V. SET FOR THE INFUSION OF FLUIDS INTO THE HUMAN BODY. THIS PRODUCT IS HAVING DIFFERENT GAUGES FROM 14G, 16G, 17G, 18G, 20G, 22G, 24G AND 26G. ANY INTERMITTENT DRUG TO BE ADMINISTERED CAN BE ADMINISTERED THROUGH PORT OF IV CANNULA WHICH COMPRISES OF ONE WAY VALVE THAT OPENS AND CLOSES WITH THE PRESSURE OF MEDICINE BEING ADMINISTERED.THE PTFE/FEP TUBING ALONG WITH THE NEEDLE IS INSERTED INTO HUMAN BODY VEIN BY PERFORMING VENIPUNCTURE. THE NEEDLE ACTS AS A GUIDE FOR THE PTFE/FEP TUBING. AFTER INSERTION NEEDLE IS TAKEN OUT OF THE BODY WHILE THE PTFE/FEP TUBE STAYS IN. POUCH OR BOTTLE CONTAINING THE BODY FLUIDS IS CONNECTED TO THE HUB USING AN I.V. SET. ANY MEDICINE TO BE INJECTED CAN BE GIVEN THROUGH THE INJECTION PORT HAVING ONE WAY VALVE WHICH DOES NOT LET THE FLUIDS COME BACK (CATHETER OF 24G I.E. FOR NEONATES ALSO COMES WITHOUT THE INJECTION PORT). AFTER THE WHOLE FLUID IS INFUSED IN TO THE HUMAN BODY, THE BOTTLE WITH THE I.V. SET IS REMOVED AND THE CATHETER REMAINS IN THE BODY, IF REQUIRED. PTFE/FEP TUBING CAN REMAIN INSIDE THE BODY FOR UP TO 96 HOURS. THE DEVICE IS STERILE AND STERILANT IS ETHYLENE OXIDE GAS. THE DEVICE IS MEANT FOR SINGLE USE. THE DEVICE DOES NOT CONTAIN DRUG BIOLOGICAL PRODUCT AS COMPONENT. ,MTP CANNULAE(LIFELINE)-THE MTP CANNULA OR KARMAN CANNULA IS A SOFT, FLEXIBLE CANNULA (OR CURETTE) WHICH IS CLAIMED TO REDUCE THE RISK OF PERFORATING THE UTERUS DURING VACUUM ASPIRATION. IT IS ALSO USED BY PHYSICIANS SOMETIMES IN EARLY INDUCED SURGICAL ABORTION, IN TREATMENT OF INCOMPLETE ABORTION (MEDICAL TERMINATION OF PREGNANCY I.E. MTP) , AND IN ENDOMETRIAL BIOPSY AND ALSO IN "MENSTRUAL REGULATION" VACUUM ASPIRATION PROCEDURES. ,HEMOCONCENTRATOR (LIFELINE)-HEMOCONCENTRATOR IS INTENDED FOR USE AS AN ULTRAFILTRATION SYSTEM TO REMOVE EXCESS FLUID DURING AND/OR FOLLOWING CARDIOPULMONARY BYPASS PROCEDURES WHERE ACUTE HEMODILUTION IS EMPLOYED,BLOOD CARDIOPLEGIA DELIVERY SYSTEM(LIFELINE)-INTENDED USE FOR SURFACE MODIFIED BLOOD CARDIOPLEGIA SYSTEM IS INTENDED TO MIX, COOL, WARM AND DELIVER OXYGENATED BLOOD AND CARDIOPLEGIA SOLUTION FOR PERIODS OF UP TO SIX HOURS. THE DEVICE ALSO ALLOWS MONITORING OF TEMPERATURE AND PRESSURE TRAPS BUBBLES AND REMOVES AIR, BLOOD AND

	CARDIOPLEGIC SOLUTION ARE DELIVERED TO THE PATIENT BY A SINGLE 100% OCCLUSIVE ROLLER PUMP THROUGH THE EXTENSION LINE AND APPROPRIATE CANNULA. ,ARTERIAL LINE FILTER (LIFELINE)-ARTERIAL LINE FILTERS (ALFS) ARE ARGUABLY THE MOST IMPORTANT COMPONENT IN THE CARDIOPULMONARY BYPASS CIRCUIT TO PROTECT THE PATIENT FROM GASEOUS MACRO-AND MICRO-EMBOLI (GME) ORIGINATING IN THE PERFUSION CIRCUIT. THE ARTERIAL FILTER COMBINES EASY HANDLING, EFFECTIVE ELIMINATION OF GAS EMBOLI, FAT EMBOLI AND AGGREGATES COMPOSED OF PLATELETS, RED BLOOD CELLS AND OTHER DEBRIS. FILTER BASED ON COMPLETELY NEW CONSTRUCTION PRINCIPLE INCREASES THE EFFICIENCY AND BRINGS MAXIMUM SAFETY TO THE PATIENT. FILTRATION MEMBRANE 40 MICRON. ,FOLEY BALLOON CATHETER(LIFELINE)-FOLEY CATHETER A LONG, SMALL GUAGE CATHETER DESIGNED FOR INSERTION DIRECTLY INSERTED INTO THEURETER, EITHER THROUGH THE URETHRA AND BLADDER AND POST PRIORY VIA THE KIDNEY. FOLEY CATHETER IS FLEXIBLE TUBE WHICH A CLINICIAN PASSES THROUGH THE URETHRA AND INTO THE BLADDER TO DRAIN URINE. IT IS THE MOST COMMON TYPE OF INDWELLING URINARY CATHETER. ,PRESSURE MONITORING KIT/LINE (LIFELINE)-A MODIFIED FIBRE OPTIC TRANSDUCER-TIPPED CATHETER SYSTEMS FOR MEASURING INTRAMUSCULAR PRESSURE DURING EXERCISE WAS DETERMINED. ,MV SET(LIFELINE)-MEASURED VOLUME INFUSION SETS ARE SINGLE USE, STERILE DEVICES WITH A CYLINDRICAL GRADUATED CONTAINER CALLED BURETTE USED TO ADMINISTER MEASURED VOLUME OF INTRAVENOUS FLUIDS/LIQUIDS AND/OR DRUGS/MEDICINE INTO HUMAN CIRCULATORY SYSTEM. THE BURETTE IS USED TO PREPARE COCKTAILS OF DRUGS AND PHYSIOLOGICAL LIQUIDS FOR INFUSION. IT CAN ALSO BE USED FOR ENTERAL OR PARENTERAL FEEDINGS ESPECIALLY IN PEDIATRIC WARD. IT IS USED IN BETWEEN CONTAINERS OF INFUSION SOLUTION & INTRAVENOUS EQUIPMENT.,PERITONEAL DIALYSIS CATHETER/SET (LIFELINE)-PERITONEAL DIALYSIS CATHETER THAT ALLOWS DIALYSIS FLUID TO ENTER THE ABDOMINAL CAVITY. DWELL INSIDE FOR A WHILE, AND THEN DRAIN BACK OUT AGAIN. ,NELATON CATHETER(LIFELINE)-A LONG, SMALL GUAGE CATHETER DESIGNED FOR INSERTION DIRECTLY INSERTED INTO THE URETER, EITHER THROUGH THE URETHRA AND BLADDER AND POST PRIORY VIA THE KIDNEY. NELATON CATHETER IS USED FOR DRAINAGE THE URINE FROM THE BLADDER THROUGH URETHRAL. ,CHEST DRAINAGE CATHETER(LIFELINE)-CHEST DRAINAGE CATHETER USED WHEN A PATIENT HAS A PNEUMOTHORAX OR HEMOTHORAX, WHICH IS AIR OR BLOOD IN THE PLEURAL SPACE (THE SPACE BETWEEN THE LUNG AND THE CHEST WALL). THIS CONDITION DOES NOT ALLOW THE

	LUNG TO INFLATE, WHICH CAN BE FATAL IF NOT TREATED. IN A SITUATION LIKE THIS, A CHEST TUBE IS INSERTED TO PROVIDE DRAINAGE FROM THE PLEURAL SPACE. IT IS DESIGNED TO MINIMIZE BRUISING TO THE PLEURA AND THE CHEST WALL DURING INSERTION. ,3-WAY STOP COCK WITH/WITH OUT EXTENSION LINE(LIFELINE)-THREE WAY STOPCOCK / EXTENSION LINE IS A DEVICE INTENDED TO BE USED FOR EXTENDING THE LINES AND ALSO CHANNELIZING THE FLOW OF FLUIDS OR MEDICAMENTS FROM MORE THAN ONE LINE THROUGH IV CANNULA OR ANY OTHER SUCH DEVICE. TAP WITH 2 FEMALE LUER PORTS AND A MALE LUER LOCK. THE 3 PORTS ARE CAPPED. COLOURED STUDS ARE PROVIDED AND CAN BE ATTACHED FOR COLOUR CODING PURPOSES. OFTEN TAPS ARE BLUE OR RED TO INDICATE VENOUS OR ARTERIAL USE RESPECTIVELY. SOME STOPCOCKS HAVE EXTENSION TUBING ALREADY CONNECTED. , CHEST DRAINAGE CATHETR WITH TROCAR(LIFELINE)-A TROCAR IS MADE UP OF AN OBTURATOR (WHICH MAY BE A METAL OR PLASTIC SHARPENED OR NON-BLADED TIP), A CANNULA (BASICALLY A HOLLOW TUBE), AND A SEAL. THE TROCAR FUNCTIONS AS A PORTAL FOR THE SUBSEQUENT PLACEMENT OF OTHERS INSTRUMENTS, SUCH AS GRASPERS, SCISSORS, STAPLERS, ETC. IT IS ALSO INTENDED TO REMOVE AIR OR FLUID FOR THE PLEURAL SPACE IN A CLOSED, ONE WAY FASHION. ,CARDIOPLEGIA ADAPTOR(LIFELINE)-CARDIOPLEGIA ADAPTERS CONNECT TO THE ARC OR VESSEL CANNULAE AND ARE INTENDED FOR THE DELIVERY OF CARDIOPLEGIA SOLUTION OR VENTING THE HEART DURING CARDIOPULMONARY BYPASS. ADAPTERS CAN BE USED TO CONNECT MULTIPLE CARDIOPLEGIA CANNULAE AND/OR VEIN GRAFT CANNULAE TO A SINGLE INLET SOURCE, SWITCH BETWEEN ANTEGRADE AND RETROGRADE DELIVERY OF CARDIOPLEGIA AND PROVIDE THE OPTION FOR ATTACHING A VENT LINE TO THE CARDIOPLEGIA CANNULAE. , ABDOMINAL DRAINAGE KIT(LIFELINE)-ABDOMINAL DRAINAGE KITS ARE USED IN THE POST-OPERATIVE STAGE TO ENABLE DRAINAGE OF EXCESSIVE FLUIDS FROM THE PERITONEAL CAVITY. THEY ARE USED, FOR EXAMPLE, IN PARACENTESIS PROCEDURES FOR DRAINING ABDOMINAL ASCITES. THE PRODUCT IS INTENDED FOR USE BY MEDICAL PRACTITIONERS,HEMODIALYSIS CATHETER(LIFELINE)-HEMODIALYSIS CATHETER A CATHETER IS USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT,IV SET(LIFELINE)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER OR CANNULAE.,CHEST DRAINAGE BOTTLE(LIFELINE)-• CHEST DRAINAGE BOTTLE IS A SINGLE USE DISPOSABLE UNIT WHICH IS DESIGNED TO FORWARD THE COLLECTED DRAINAGE INTO A COLLECTION

	CHAMBER BY THE LIQUID STATIC SUCTION EFFECTS.,MUCUS EXTRACTOR(LIFELINE)-FOR ASPIRATION OF SECRETION FROM OR PHARYNX IN NEWLY BORN BABIES AND TO ENSURE FREE RESPIRATION. ALSO SUITABLE FOR OBTAINING MUCUS SPECIMEN FOR MICRO BIOLOGICAL EXAMINATION.,BLOOD TRANSFUSION SET (LIFELINE)-BLOOD TRANSFUSION SET IS USED IN DELIVERING MEASURED AND REGULATED BLOOD TO PATIENT. BLOOD TRANSFUSION SET IS MADE OF CYLINDRICAL DRIP CHAMBER WITH / WITHOUT VENT PROVIDED WITH FILTER FOR USE WITH BLOOD BAG OR BLOOD BOTTLE RESPECTIVELY. IT HAS EFFICIENT ROLLER CONTROLLER FOR ACCURATE ADJUSTMENT OF TRANSFUSION RATE AND HAS LATEX FLUSH VALVE BALL FOR EXTRA MEDICATION.,TUR SET(LIFELINE)-TUR SET IRRIGATION SET IS A Y- SHAPED SET USED FOR ENDOSCOPIC IRRIGATION DURING TRANS URETHERAL RESECTION OF PROSTATE GLAND. IT IS MANUFACTURED FROM NON-TOXIC, NON-IRRITANT MEDICAL GRADE PVC MATERIAL. THE THUMB OPERATED CLAMPS, HELPS QUICK AND SMOOTH CHANGE OF BOTTLES. ,CORRUGATED DRAIN SHEET(LIFELINE)-MULTI CHANNEL DRAINAGE SYSTEM FOR EFFICIENT DRAINAGE DURING OPERATION DEVICE DESCRIPTION PROVIDED WITH X-RAY OPAQUE LINE EXTRA SOFT SUPER SMOOTH PVC CORRUGATED SHEET FOR WOUND DRAINAGE SIZES AVAILABLE : 250 MM X 25 MM, 400 MM X 25 MM , CONNECTOR(LIFELINE)-MADE FROM NON-TOXIC MEDICAL GRADE P. C. AND USE WITH HEART LUNG PACK DURING HEART SURGERY .IT CAN BE USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC. ,GUEDEL AIRWAY(LIFELINE)-THE GUEDEL AIRWAY IS A OROPHARYNGEAL TUBE USED TO PROP OPEN THE UPPER AIRWAYS. DUE TO HIS FORM, THE CORRECTLY USED GUEDEL AIRWAY PREVENTS THAT THE TONGUE OF A PATIENT CAN DROP BACK AND THEREFORE BLOCK THE AIRWAY. IT DOES NOT OFFER PROTECTION FROM ASPIRATION. THE USE OF A SUCTION CATHETER IS HOWEVER POSSIBLE. FURTHERMORE, THE GUEDEL AIRWAY CAN BE USED FOR TRACHEAL TUBE FIXATION. FOR THIS USE, THE GUEDEL AIRWAY ALSO FUNCTIONS AS BITE BLOCK TO PREVENT AN OCCLUSION OF THE TRACHEAL TUBE CAUSED BY THE PATIENT'S TEETH.,CARDIOPLEGIA CONNECTOR(LIFELINE)-MADE FROM NON-TOXIC MEDICAL GRADE P.C. AND USE WITH HEART LUNG PACK DURING HEART SURGERY .IT CAN BE USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC. ,UMBILICAL CATHETER(LIFELINE)-AN UMBILICAL IS INSERTED INTO ONE OF THE TWO ARTERIES OR THE VEIN OF THE UMBILICAL CORD.

3611	MFG/MD/2020/000260	1.License Holder Name: SAFE SURGICAL INDUSTRIES 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:BANDAGE CLOTH/BLEACHED BANDAGE CLOTH/ROLLED BANDAGE/OPEN WOVE BANDAGE/COTTON BANDAGE CLOTH (CUT OR UNCUT)(SAFE)-USE FOR SURGICAL DRESSING, GENERAL PURPOSE OR USE FOR PROVIDING SUPPORT/COMPRESSION ON WOUNDS.,ABSORBENT COTTON WOOL I.P. (UNSTERILIZED) ABSORBENT COTTON WOOL B.P. (UNSTERILIZED) (FOR EXPORT)(SAFE)-CAN BE USE FOR SURGICAL & GENERAL PURPOSE.,GAUZE/UNMEDICATED GAUZE/ABSORBENT COTTON GAUZE (UNSTERILIZED)(SAFE)-SURGICAL DRESSING ON WOUNDS OR GENERAL PURPOSE
3612	MFG/MD/2020/000261	1.License Holder Name: JHUNJHUNU BUNKAR SAHAKARI SAMITI LTD. 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:GAUZE (ABSORBENT GAUZE)(HANDLOOM ABSORBENT GAUZE)-THE ABSORBENT GAUZE ARE USED TO CLEANING, DRYING AND DRESSING WOUNDS A MEDICAL TREATMENT ALSO USED TO SUPPORTIVE MATERIAL FOR DRESSING ETC .GAUZE IS PERFECT FOR DELIVERING ANTISEPTICS TO INJURIES, MOISTURE REMOVAL FROM WOUNDS BEFORE THE EXERTION OF A DRESSING .,COTTON BANDAGE (ROLLED BANDAGE) (HANDLOOM ROLLED BANDAGE /BANDAGE CLOTH)-THE COTTON BANDAGES ARE USED TO BIND, WRAP OR AS A SUPPORTIVE MATERIAL FOR WOUNDS ,CUTS, BURNS AND IN DRESSING FOR WOUND HEALING PROCESS

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3613	MFG/MD/2020/000262	1.License Holder Name: SHALIMAR HEALTH CARE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(OCEARCARE B.T. SET)-:IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED.,STERILE DISPOSABLE INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(OCEANCARE INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN ,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(- - -)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (STERIVAN INFUSION SET)-:THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY(- - -)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION. ,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(OCEANCARE M V SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT' S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY (- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED., STERILE DISPOSABLE NASOGASTRIC/RYLE'S TUBE FOR SINGLE USE ONLY(- - -)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.

3614	MFG/MD/2020/000263	1.License Holder Name: MEDTECH DEVICES 2.Approving Authority: SOUTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:MANIFOLD(TOPFLOW)-MANIFOLD IS INTENDED FOR CONNECTION BETWEEN THE DEVICES, SUCH LIKE INJECTION SYRINGE , ANGIOGRAPHIC CATHETER, DRIP SET TO THE BOTTLE DELIVERING CONTRAST AGENT OR SALINE FLUSH, OR PRESSURE MONITORING SYSTEM, ETC. EACH FLUID CHANNEL CAN BE INDEPENDENTLY CONTROLLED BY SWITCH.,PTCA /ANGIO KIT(TOPFLOW)-ANGIO & PTCA KITS ARE USED IN CARDIOLOGY (ANGIOPLASTY AND ANGIOGRAPHY),HYPODERMIC NEEDLES(TOPFLOW)-AN INTRODUCER NEEDLE IS A HOLLOW NEEDLE COMMONLY USED WITH A SYRINGE TO INJECT SUBSTANCES INTO THE BODY OR EXTRACT FLUID FROM IT.,HEMODIALYSIS CATHETER KIT-THE 15.5FR HEMO STREAM CHRONIC DIALYSIS CATHETER IS DESIGNED FOR CHRONIC HEMODIALYSIS & APHERESIS.,A. V. FISTULA NEEDLE(TOPFLOW)-AV FISTULA NEEDLE PROTECTOR IS INDICATED FOR USE AS A VASCULAR ACCESS DEVICE FOR HEMODIALYSIS., HEMODIALYSIS CATHETER-THE LONG TERM HEMODIALYSIS CATHETER IS INDICATED FOR USE IN ATTAINING SHORT TERM OR LONG TERM VASCULAR ACCESS FOR HEMODIALYSIS, HEMOPERFUSION OR APHERESIS THERAPY VIA THE JUGULAR OR SUBCLAVIAN VEIN
3615	MFG/MD/2020/000264	1.License Holder Name: IMAZ SURGICALS 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL-ABSORBENT COTTON WOOL IS MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC. ... APART FROM MEDICAL PURPOSES ABSORBENT COTTON IS ALSO USED FOR MAKING CONVENTIONAL TYPE OF SANITARY NAPKINS OR PADS.
3616	MFG/MD/2020/000265	1.License Holder Name: IMAZ SURGICALS 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:ROLLED BANDAGE-ROLLED BANDAGES ARE VERY COMMON AND VERY VERSATILE THIN WOVEN AND BREATHABLE FABRIC BANDAGES THAT CAN BE USED TO SECURE A DRESSING IN PLACE, OR MAY BE PLACED DIRECTLY OVER A WOUND TO KEEP IT CLEAN WHILE ALLOWING AIR TO PENETRATE TO IMPROVE HEALING PROCESS.

3617	MFG/MD/2020/000266	1.License Holder Name: PENTA LATEX LLP 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:MALE LATEX CONDOM (SHAPKA CONDOM ULTRA THIN)-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM(EXPORT SALE)(I TEX)-CONDOMS AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING STI/STD,MALE LATEX CONDOM(MANFORCE EPIC CONDOMS (HIGH))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM (DOMESTIC SALE)(MASTER STROKE)-CONDOMS AID IN PREVENTION OF PREGNANCY & ALSO CAN AID IN REDUCING THE REDUCING THE RISK OF SPREADING STI.,MALE LATEX CONDOM (MANFORCE EPIC CONDOMS (PASSION))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES.,MALE LATEX CONDOM (DOMESTIC SALE)(MAX FORCE,)-CONDOMS AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING STIS.,MALE LATEX CONDOM(MANFORCE EPIC CONDOMS (HOT DOTS))-: PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES,MALE LATEX CONDOM (DOMESTIC SALE)(PLAY SAFE,)-CONDOMS AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING STI.,MALE LATEX CONDOM(MANFORCE EPIC CONDOMS (LOVE BITE))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM(DOMESTIC SALE)(RIDER PLUS,)-CONDOMS AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING STI.,MALE LATEX CONDOM(SHAPKA CONDOM CLASSIC PLAIN)-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM (MANFORCE CONDOMS (IGNITE))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM(NEW MANFORCE CONDOMS LITCHI (1740 DOTS),)-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM(MANFORCE EPIC CONDOMS (BARE))-: PROPERLY USED CONDOM AID IN PREVENTION

	OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM(MANFORCE XTASY CONDOMS (BUTTERSCOTCH))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM(EXPORT SALE) (TRUST STUDDED CONDOMS)-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM(MANFORCE XOTIC CONDOMS (STRAWBERRY))-: PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM(MANFORCE EPIC CONDOMS (MAXGASM))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM(MANFORCE XTASY CONDOMS (HAZELNUT))-: PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM(MANFORCE XOTIC CONDOMS (CHOCOLATE))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM(MANFORCE XTASY CONDOMS (BLACK GRAPES))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES. ,MALE LATEX CONDOM(MANFORCE EPIC CONDOMS (PLEASURE))-PROPERLY USED CONDOM AID IN PREVENTION OF PREGNANCY & CAN ALSO AID IN REDUCING THE RISK OF SPREADING SEXUALLY TRANSMITTED DISEASES.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3618	MFG/MD/2020/000267	1.License Holder Name: KPM HEALTHCARE 2.Approving Authority: WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:STERILE SPIRAL EXTENSION LINE "FOR SINGLE USE ONLY"(KPM HEALTHCARE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATIONS IN MEDICAL APPLICATIONS., MULTI LUMEN CATHETER(KPM HEALTHCARE)-INTENDED FOR MOINTORING CENTRAL VENOUS PRESSURE ,SAMPLING BLOOD SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTIONS OR DRUGS.,STERILE EXTENSION LINE WITH THREE WAY STOPCOCK "FOR SINGLE USE ONLY"(KPM HEALTHCARE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,RYLES TUBE(KPM HEALTHCARE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE .IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,STERILE EXTENSION LINE "FOR SINGLE USE ONLY"(KPM HEALTHCARE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATIONS IN MEDICAL APPLICATIONS.,NASAL OXYGEN CATHETER(KPM HEALTHCARE)-IT IS A DEVICE USED TO DELIVER SUPPLEEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,STERILE TWO WAY EXTENSION LINE WITH NEEDLE FREE VALVE" FOR SINGLE USE ONLY" (KPM HEALTHCARE)-IT IS USED FOR THE DELIVERY AND OR ASPIRATION OF FLUID.,INTRAVENOUS CANNULA(KPM HEALTHCARE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS OR TO FACILIATE THE PLACEMENT OF VASCULAR ACCESS DEVICES., STERILE BLOOD TRANSFUSION SETS "FOR SINGLE USE ONLY"(KPM HEALTHCARE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INFANT FEEDING TUBE(KPM HEALTHCARE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. ITS USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING . STERILE MEASURED VOLUME SET/BURETTE SET "FOR SINGLE USE ONLY"(KPM HEALTHCARE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,CLOSED SUCTION SYSTEM(KPM HEALTHCARE)-IT IS INTENDED FOR ENDOTRACHEAL SUCTIONING TO PROVIDE A PATIENT

	AIRWAY BY REMOVING EXCESS FLUID, SECRETION, EXUDATES AND TRANSUDATE THROUGH THE ARTIFICIAL AIRWAY.USED FOR ORAL INTUBATION ONLY INTENDED FOR AIRWAY MANAGEMENT. MADE OF CLEAR POLYVINYL CHLORIDE (PVC).,STERILE ONE WAY EXTENSION LINE WITH NEEDLE FREE VALVE "FOR SINGLE USE ONLY"(KPM HEALTHCARE)-IT IS USED FOR THE DELIVERY AND OR ASPIRATION OF FLUID.,SUCTION TIP AND CATHETER(KPM HEALTHCARE)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,STERILE THREE WAY EXTENSION LINE WITH NEEDLE FREE VALVE "FOR SINGLE USE ONLY" (KPM HEALTHCARE)-IT IS USED FOR THE DELIVERY AND OR ASPIRATION OF FLUID.,EPIDURAL CATHETER(KPM HEALTHCARE)-EPIDURAL CATHETER IS A VERY THIN ,FLEXIBLE TUBE THAT IS IMPLANTED INTO SPINE.,STERILE I V SET WITH FLOW REGULATOR' FOR SINGLE USE ONLY"(KPM HEALTHCARE)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,HAEMODIALYSIS CATHETER(KPM HEALTHCARE)-A CATHETER USED FOR EXCHANGE BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT.,STERILE I. V SET "FOR SINGLE USE ONLY" (KPM HEALTHCARE)-IT IS USED TO PROVIDE FLUID THERAPY TO ADMINISTER MEDICINES AND BLOOD PRODUCTS.,FOLYS BALLOON CATHETER(KPM HEALTHCARE)-"SOFT" CATHETER WITH AN INFLATABLE "BALLOON " AT ITS TIP WHICH IS USED DURING A CATHETERIZATION PROCEDURE TO ENLARGE A NARROW OPENING OR PASSAGE WITHIN THE BODY,VIAL ADAPTOR (KPM HEALTHCARE)-IT IS INTENDED FOR ENDOTRACHEAL SUCTIONING TO PROVIDE A PATIENT AIRWAY BY REMOVING EXCESS FLUID, SECRETION, EXUDATES AND TRANSUDATE THROUGH THE ARTIFICIAL AIRWAY.USED FOR ORAL INTUBATION ONLY INTENDED FOR AIRWAY MANAGEMENT. MADE OF CLEAR POLYVINYL CHLORIDE (PVC).,BIOPSY NEEDLE KIT(KPM HEALTHCARE)-A SET OF NEUROSURGICAL INSTRUMENTS DESIGNED TO ALLOW MULTIPLE BIOPSIES FROM ONE OR MORE TARGETS IN ONE TRAJECTORY., EPIDURAL NEEDLE(KPM HEALTHCARE)-INTENDED FOR TRANSIENT DELIVERY OF ANASTHETICS TO PROVIDE REGIONAL ANESTHESIA OR TO FACILITATE PLACEMENT OF AN EPIDURAL CATHETER, URETHRAL/NELATON CATHETER(KPM HEALTHCARE)-A LONG, SMALL GUAGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,WOUND DRAINAGE SYSTEM(KPM HEALTHCARE)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS. BLOOD OR OTHER FLUIDS FROM A WOUND.THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS., FISTULA NEEDLE(KPM HEALTHCARE)-TO CONNECT BLOOD LINES

	WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT,ENDOTRACHEAL TUBE(KPM HEALTHCARE)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA JUST BELOW THE VOCAL CODE,ARTERIAL CATHETER(KPM HEALTHCARE)-IT IS INTENDED TO BE USED IN CONJUNCTION WITH STEERABLE GUIDEWIRES IN ORDER TO ACCESS DISCRETE REGIONS OF THE CORONARY AND PERIPHERAL ARTERIAL VASCULATURE.,3 WAY STOPCOCK(KPM HEALTHCARE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION,WITHDRAWAL OF FLUID AND PRESSURE MOINTORING,ANGIOGRAPHIC CATHETER(KPM HEALTHCARE)-ANGIOGRAPHIC NEEDLE HAS A UNIQUE HUB DESIGN WITH AN ERONOMIC FEEL AND A BLACK TRIANGLE INDICATOR TO ORIENT THE BEVEL

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3619	MFG/MD/2020/000269	1.License Holder Name: BIORAD MEDISYS PVT LTD 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:URETHRAL STENT / URETHRAL CATHETER(INDOVASIVE)-URETHRAL STENT IS USED FOR STENTING THE URETHRA AFTER HYPOSPADIAS OR EPISPADIAS REPAIR,URETHRAL DILATOR / SUPRAPUBIC, NON-DISPOSABLE CANNULA(INDOVASIVE)-URETHRAL DILATORS ARE THE SET OF DILATORS USED FOR DILATATION OF THE URETHRA.,LOOP BASKET / BILIARY STONE RETRIEVAL BASKET(INDOVASIVE)-THIS DEVICE IS INTENDED FOR USE IN ENDOSCOPIC RETRIEVAL OF FOREIGN OBJECTS, FOOD BOLUS, TISSUE FRAGMENTS AND EXCISED TISSUE SUCH AS POLYPS.,GUIDEWIRE/ GUIDING CATHETER (GASTROENTEROLOGY & UROLOGY)(INDOVASIVE)-GASTRO/URO GUIDE WIRES ARE INTENDED FOR USE IN GASTROENTEROLOGICAL PROCEDURES TO FACILITATE THE PLACEMENT OF VARIOUS GASTROENTEROLOGICAL INSTRUMENTS SUCH AS CATHETER/STENTS/DILATORS ETC AND TO FACILITATE THE PLACEMENT OF ENDOUROLOGICAL INSTRUMENTS DURING DIAGNOSTIC OR TREATMENT PROCEDURES.,S-CURVE URETHRAL DILATOR / SUPRAPUBIC, NON-DISPOSABLE CANNULA(INDOVASIVE)-S - CURVE URETERAL DILATOR IS USED FOR DILATION OF MALE URETHRAL STRICTURES & VESICAL NECK CONTRACTURES. IT SUPPORTS THE NATURAL CURVATURE OF THE MALE URETHRA, AMPLATZ DILATOR SET (MINI PERC) / STRAIGHT CATHETER (DILATRON, INDOVASIVE)-AMPLATZ DILATOR (MINI PERC) IS A DEVICE USED TO DILATE THE NEPHROSTOMY TRACT IN PEDIATRIC., BILIARY PUSHER/ GUIDING CATHETER(INDOVASIVE)-BILIARY PUSHER IS USED TO INTRODUCE BILIARY STENT IN BILIARY TRACT, EUS NEEDLE (ENDOSCOPIC ULTRA SOUND NEEDLE) / ENDOSCOPIC NEEDLE(INDOVASIVE)-THE ENDOSCOPIC ULTRA SOUND NEEDLE ASPIRATION SYSTEM IS USED TO SAMPLE TARGETED MUCOSAL AND EXTRAMURAL GASTROINTESTINAL LESIONS THROUGH THE ACCESSORY CHANNEL OF AN ULTRASOUND ENDOSCOPE. THIS DEVICE IS INTENDED TO BE USED WITH AN ULTRASOUND ENDOSCOPE FOR DELIVERY OF INJECTABLE MATERIALS INTO TISSUES DURING ENDOSCOPIC PROCEDURES AND FINE NEEDLE ASPIRATIONS (FNA) OF SUBMUCOSAL LESIONS, MEDIASTINAL MASSES, LYMPH NODES AND INTRAPERITONEAL MASSES WITHIN OR ADJACENT TO THE GASTROINTESTINAL TRACT.,FILIFORM URETHRAL SELF DILATOR/ SUPRAPUBIC, NON-DISPOSABLE CANNULA (INDOVASIVE)-FILIFORM URETHRAL SELF DILATOR IS USED FOR TRAVERSING AND DILATING URETHRAL STRICTURES. THE FILIFORM TIP REPLACES THE NEED FOR SEPARATE FILIFORM AND FLOWERS TO DILATE THE URETHRA,IP (INITIAL PUNCTURE) NEEDLE / GASTRO-

	UROLOGY NEEDLE (INDOVASIVE)-IP NEEDLE IS USED FOR INITIAL PUNCTURE FOR ALL PERCUTANEOUS APPLICATIONS.,ENDOSCOPE / TRANSCERVICAL (AMI NOSCOPE) ENDOSCOPE AND ACCESSORIES (INDOVASIVE, INDOSCOPE, INDOSCOPE-CN)-SCOPES ARE TYPICALLY USED TO: I. HELP THE DOCTOR TO CARRYOUT DIAGNOSIS FOR DETERMINING THE CAUSE OF ANY ABNORMAL SYMPTOMS PATIENT HAVING II. REMOVE A SMALL SAMPLE OF TISSUE, WHICH CAN THEN BE SENT TO A LAB FOR FURTHER TESTING; THIS IS CALLED AN ENDOSCOPIC BIOPSY III. HELP DOCTOR SEE INSIDE THE BODY DURING A SURGICAL PROCEDURE, SUCH AS REPAIRING A STOMACH ULCER, OR REMOVING GALLSTONES OR TUMORS ALSO IF PATIENTS HAVING SYMPTOMS OF ANY OF THE FOLLOWING CONDITIONS: A) INFLAMMATORY BOWEL DISEASES (IBD), SUCH AS ULCERATIVE COLITIS (UC) AND CROHN'S DISEASE B) STOMACH ULCER C) CHRONIC CONSTIPATION D) PANCREATITIS E) GALLSTONES F) UNEXPLAINED BLEEDING IN THE DIGESTIVE TRACT G) TUMORS H) INFECTIONS I) BLOCKAGE OF THE ESOPHAGUS J) GASTROESOPHAGEAL REFLUX DISEASE (GERD) K) HIATAL HERNIA L) UNUSUAL VAGINAL BLEEDING M) BLOOD IN URINE N) OTHER DIGESTIVE TRACT ISSUES,PEG KIT (PERCUTANEOUS ENDOSCOPIC GASTROSTOMY)/ FORCEPS, ENDOSCOPIC(INDOVASIVE)-IT IS A SOFT PLASTIC TUBE THAT IS PUT INTO THE STOMACH THROUGH THE SKIN, USED IT FEED THE PATIENT FOR DECOMPRESSION.,AMPLATZ DILATOR/ STRAIGHT CATHETER (DILATRON, INDOVASIVE)-AMPLATZ DILATOR & SET IS A DEVICE USED TO DILATE THE NEPHROSTOMY TRACT., EVACUATOR/CONTINUOUS IRRIGATION CATHETER(INDOVASIVE)-EVACUATOR IS USED FOR REMOVAL/COLLECTION OF TISSUE SECTIONS DURING TRANSURETHRAL RESECTION OF THE PROSTATE (TURP).,INTRODUCER NEEDLE / GASTRO-UROLOGY NEEDLE (INDOVASIVE)-INTRODUCER NEEDLE IS USED FOR THE PLACEMENT OF A GUIDEWIRE, INTRODUCER NEEDLE IS DESIGNED FOR PERCUTANEOUS ACCESS,VERSATOR/ FORCEPS, ENDOSCOPIC (INDOVASIVE)-USED FOR RECEOPTACLE FOR BENIGN TISSUE MASS DURING GYNAECOLOGICAL PROCEDURE SUCH AS LAPAROSCOPY MYOMECTOMY OR LAPAROSCOPY HYSTERECTOMY,CO-AXIAL DILATOR/CATHETER / SUPRAPUBIC, NON-DISPOSABLE CANNULA (INDOVASIVE)-THESE ARE THE DILATORS ARE USED FOR DILATION OF PERCUTANEOUS TRACK OVER THE GUIDEWIRE.,INFLATION DEVICE / STERILE HYPODERMIC SYRINGES (INDOVASIVE)-INFLATION DEVICE IS A HIGH PRESSURE SYRINGE BARREL, ERGONOMIC PISTON HANDLE, AND A GAUGE USED TO MONITOR THE INFLATION AND DEFLATION OF BALLOON CATHETERS WHEN CONNECTED TO URETERAL BALLOON CATHETERS, THE INFLATION DEVICE MAY BE REFERRED TO AS THE BALLOON INFLATION DEVICE.,GASTRO

	BALLOON DILATOR / BALLOON DILATORS FOR GASTROENTEROLOGY(INDOVASIVE)-THE PRODUCT IS INTENDED FOR THE DILATION OR ADJUVANT DILATION TREATMENT FOR DIGESTIVE TRACT STENOSIS.,URS /ENDOSCOPIC FORCEPS/ FORCEPS ENDOSCOPIC(RETRIVO, INDOVASIVE)-URS FORCEPS IS USED FOR GRASPING, MANIPULATING AND EXTRACTING CALCULI FROM URETERAL AND RENAL PELVIS.,URETERAL BALLOON DILATOR / SUPRAPUBIC, NON-DISPOSABLE CANNULA(INDOVASIVE)-URETERAL BALLOON DILATOR IS USED FOR URETERAL DILATION PRIOR TO URETERAL STONE MANIPULATION OR URETEROSCOPY, AS WELL AS DILATION OF THE INTRAMURAL URETER & URINARY TRACT. ALSO USED FOR WIDENING THE URETERAL STRICTURE.,PENILE CLAMP/SURGICAL SEALENT(INDOVASIVE)-PENILE CLAMP KNOWN ALSO AS A CUNNINGHAM CLAMP IS WORN EXTERNALLY TO CONTROL INCONTINENCE IN MEN. THIS CLAMP HELP PATIENTS MANAGE URINE LEAKAGE.,CYSTO CATHETER / SUPRAPUBIC CATHETER(INDOVASIVE)-CYSTO CATHETER OFFERS A SIMPLIFIED SYSTEM FOR BLADDER DRAINAGE BY SUPRAPUBIC PLACEMENT,RE-ENTRY MALECOT CATHETER / NEPHROSTOMY CATHETER (INDOVASIVE)-RE-ENTRY MALECOT CATHETER IS USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE (INTERNAL & EXTERNAL DRAINAGE), POLYPECTOMY SNARE/ SCLEROTHERAPY CATHETER(INDOVASIVE)-POLYPECTOMY SNARE IS USED FOR ENDOSCOPIC EXCISION OF POLYPS USING MONOPOLAR ELECTROSURGICAL UNIT AND RETRIEVAL OF FOREIGN BODIES FROM G.I. TRACT,AMPLATZ SHEATH / STRAIGHT CATHETER(DILATRON, INDOVASIVE)-AMPLATZ SHEATH IS USED TO ALLOW SMOOTH PASSAGE OF SURGICAL INSTRUMENTS INTO THE NEPHROSTOMY TRACT.,CHIBA NEEDLE / GASTRO-UROLOGY NEEDLE (INDOVASIVE)-CHIBA NEEDLE IS USED FOR PERCUTANEOUS NEPHROSTOMY PROCEDURES, CYTOLOGICAL BIOPSIES, NEEDLE-ASPIRATIONS, THORACENTESIS EXPLORATORY PUNCTURES, TO INJECT CONTRAST DYES.,JEJUNAL FEEDING TUBE / FEEDING TUBE(INDOVASIVE)-JEJUNAL FEEDING TUBE IS USED THROUGH THE CHANNEL OF THE ENDOSCOPE TO PROVIDE SHORT DURATION INTERNAL ACCESS FOR DELIVERY OF NUTRITION OR MEDICATION TO THE SMALL BOWEL.,MEATAL DILATOR / SUPRAPUBIC, NON-DISPOSABLE CANNULA(INDOVASIVE)-MEATAL DILATOR IS USED FOR SELF DILATION OF PENILE URETHRAL MEATUS. STRETCHING OF THE URETHRA OR THE URETHRAL OPENING FOR NARROWING RESULTING IN A POOR URINARY SYSTEM, SCELEROTHERAPY NEEDLE (VARICES/ INJECTOR)(INDOVASIVE)-SCLEROTHERAPY NEEDLE (VARICES) IS USED FOR INJECTION OF SCELEROTHERAPATIC SOLUTION INTO ESOPHAGEAL VARICES.,

	URETERAL DILATOR & SET/ SUPRAPUBIC, NON-DISPOSABLE CANNULA(INDOVASIVE)-URETERAL DILATOR & SET ARE THE SET OF DILATORS USED FOR DILATATION OF THE URETER PRIOR TO URETERORENOSCOPY AND ALSO FOR SEQUENTIAL DILATATION OF THE INTRAMURAL TUNNEL AND URETHRA AND / OR STONE MANIPULATION.,STONE COLLECTOR / BILIARY STONE RETRIEVAL BASKET(INDOVASIVE)-STONE COLLECTOR IS USED TO COLLECT THE STONES PRESENT IN THE URINE,MECHANICAL LITHOTRIPTER / TROCARS(INDOVASIVE)-MECHANICAL LITHOTRIPTER IS INTENDED TO BE USED DURING UROLOGICAL AND/OR GASTROENTEROLOGICAL PROCEDURES TO ENDOSCOPICALLY GRASP, MANIPULATE AND REMOVE CALCULI AND OTHER FOREIGN OBJECTS. THE DEVICE IS INTENDED TO GRASP, CRUSH AND REMOVE URINARY AND/OR BILIARY STONES,PATH FINDER / IRRIGATION PUMP / IRRIGATION AND ASPIRATION CATHETER(INDOVASIVE)-PATH FINDER/ IRRIGATION PUMP IS USED FOR CONTROLLED UROLOGIC IRRIGATION SYSTEM,Y-CONNECTOR(INDOVASIVE)-Y-CONNECTOR IS USED TO SIMPLIFY REDUCE BLOOD LOSS DURING PERCUTANEOUS PROCEDURES BY PROVIDING A SEAL AROUND GUIDE WIRE & OTHER DEVICES. UNIQUE SEAL TECHNOLOGY PROVIDES PROTECTION DURING INTERVENTIONS.,DOUBLE J CATHETERS/DOUBLE J STENT / UPPER URINARY TRACT CATHETER(INDOVASIVE)-DOUBLE J STENT IS USED FOR INTERNAL DRAINAGE FROM KIDNEY TO BLADDER., ENDOMETRIAL TUBE/ MAMMARY BIOPSY NEEDLE(INDOVASIVE)-ENDOMETRIAL TUBE IS USED TO OBTAIN HISTOLOGICAL TISSUES BIOPSY & EXTRACT SAMPLE OF UTERINE MENSTRUAL CONTENT, FASCIAL DILATOR/SUPRAPUBIC, NON-DISPOSABLE CANNULA (INDOVASIVE)-FASCIAL DILATOR IS USED FOR DILATATION OF PERCUTANEOUS TRACK OVER THE GUIDEWIRE FOR FASCIAL DILATION.,PERK (PCNL) BASKET/ BILIARY STONE RETRIEVAL BASKET(RETRIVO, INDOVASIVE)-PERK BASKET EXTRACTOR IS DESIGNED TO PROVIDE RAPID ATRAUMATIC STONE EXTRACTION DURING PERCUTANEOUS NEPHROLITHOTOMY (PCNL). PERK BASKETS ARE USED FOR KIDNEY STONE REMOVAL,URETERAL ACCESS SHEATH / BRAIDED SHAFT CATHETER / VESSEL DIALATOR FOR PERCUTANEOUS CATHETERIZATION (UROX, INDOVASIVE)-URETERAL ACCESS SHEATH / BRAIDED SHAFT CATHETER PROVIDES URETERAL DILATION AND WORKING CHANNEL FOR THE INTRODUCTION OF URETEROSCOPES AND DEVICES DURING URETEROSCOPIC PROCEDURES.,EBUS NEEDLE (ENDO-BRONCHIAL ULTRASOUND NEEDLES) / ENDOSCOPIC NEEDLE (INDOVASIVE)-EBUS ALLOWS PHYSICIANS TO PERFORM A TECHNIQUE KNOWN AS TRANSBRONCHIAL NEEDLE ASPIRATION (TBNA) TO OBTAIN TISSUE OR FLUID SAMPLES FROM THE LUNGS AND SURROUNDING LYMPH

	NODES WITHOUT CONVENTIONAL SURGERY. THE SAMPLES CAN BE USED FOR DIAGNOSING AND STAGING LUNG CANCER, DETECTING INFECTIONS, AND IDENTIFYING INFLAMMATORY DISEASES THAT AFFECT THE LUNGS, SUCH AS SARCOIDOSIS OR OTHER CANCERS LIKE LYMPHOMA.,STONE BASKET / BILIARY STONE RETRIEVAL BASKET (RETRIVO, INDOVASIVE)-STONE BASKET IS USED TO RETRIEVE STONES OR TO RESTRAINT STONE MIGRATION FROM OR WITHIN THE URINARY SYSTEM.,BIOPSY NEEDLE / BIOPSY GUN/ BIOPSY NEEDLE KIT (INDOVASIVE)-THE BIOPSY NEEDLE IS USED FOR TAKING THE TISSUE OF THE PATIENT FOR BIOPSY. INVOLVES REMOVING SOME CELLS EITHER SURGICALLY OR IN A LESS INVASIVE PROCEDURE INVOLVING A HOLLOW NEEDLE FROM A SUSPICIOUS AREA WITHIN THE BODY OR EXAMINING THEM UNDER A MICROSCOPE FOR DIAGNOSIS. ALSO USED FOR RENAL BIOPSIES.,THULIUM FIBER LASER SYSTEM (WITH/WITHOUT ACCESSORIES) / TROCARS (INDOVASIVE, QUANTINO)-THE PRODUCT HAS BEEN DEVELOPED PRIMARILY FOR MEDICAL APPLICATION FOR TISSUE MANIPULATION USING LASER POWER. FEW EXAMPLES OF APPLICATIONS INCLUDE LITHOTRIPSY AND BENIGN PROSTATIC HYPERPLASIA (BPH).,SCREW DILATOR / SUPRAPUBIC, NON-DISPOSABLE CANNULA(INDOVASIVE)-SCREW DILATOR IS USED FOR ONE STEP DILATION. THIS CAN BE USED INSTEAD OF SEQUENTIAL DILATION OR FASCIAL DILATION., URINE BAG WITH CONNECTOR/ URINARY DRAINAGE UNIT (INDOVASIVE)-URINE BAG CONNECTOR IS USED TO CONNECT BETWEEN THE CATHETERS / DILATORS, OR ANY OTHER DRAINAGE DEVICES TO URINE BAG.,MALECOT CATHETER / NEPHROSTOMY CATHETER (INDOVASIVE)-USED FOR EXTERNAL DRAINAGE OF VISCOUS LIQUID FROM RENAL PELVIS OR BLADDER, FOR PCN & SUPRAPUBIC PROCEDURE RESPECTIVELY,GASTRO BASKET (GASTROENTEROLOGY) / BILIARY STONE RETRIEVAL BASKET (INDOVASIVE)-GASTRO BASKET IS USED FOR THE ENDOSCOPIC REMOVAL OF BILIARY STONES AND FOREIGN BODIES.,PCN CATHETER / NEPHROSTOMY CATHETER(INDOVASIVE)-PCN CATHETER / NEPHROSTOMY CATHETER IS USED FOR THE TEMPORARY DRAINAGE BY DIRECT PUNCTURE THOUGH THE SKIN INTO THE KIDNEY FOR THE DISTAL OBSTRUCTION. USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE,TRANSDUCER PROTECTOR / SINGLE NEEDLE HEMODIALYSIS CATHETER/BLOOD LINES(INDOVASIVE)-TRANSDUCER PROTECTOR IS USED FOR HEMODIALYSIS BLOOD LINES TO KEEP THE BLOOD SIDE OF CIRCUIT SEPARATE FROM THE MACHINE SIDE.,SPHINCTEROTOME/PAPILLOTOME / BILIARY STONE RETRIEVAL BASKET(INDOVASIVE)-THE SPHINCTEROTOME/PAPILLOTOME IS INTENDED FOR ACCESSING THE

		COMMON BILE DUCT WHEN STANDARD CANNULATION METHODS HAVE BEEN EXHAUSTED. THIS DEVICE IS SUPPLIED STERILE AND INTENDED FOR SINGLE USE.
3620	MFG/MD/2020/000270	1.License Holder Name: DINESH INDUSTRIES 2.Approving Authority: CHHATTISGARH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL (IP)(PHOENIX)-TO BE STERILIZED BEFORE USE. IT CAN BE USED FOR CUTS, WOUNDS AND INJURIES.

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3621	MFG/MD/2020/000271	1.License Holder Name: JAYON IMPLANTS PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:ARTHROSCOPY(JAYON, OSTRIO)-ARTHROSCOPY IS A MINIMALLY INVASIVE SURGICAL PROCEDURE ON A JOINT IN WHICH AN EXAMINATION AND TREATMENT / PROCEDURE PERFORMED USING AN ARTHROSCOPE, AN ENDOSCOPE THAT IS INSERTED IN TO THE JOINT THROUGH A SMALL INCISION.,SPINAL IMPLANTS(JAYON, OSTRIO)-TO STABILIZE AND STRENGTHEN THE SPINE CONDITIONS INCLUDING SLIPPAGE OF THE SPINE, CHRONIC DEGENERATIVE DISC DISEASE, TRAUMATIC FRACTURE, TUMOR, INFECTIONS AND OTHER FORMS OF SPINAL INSTABILITY INCLUDING SCOLIOSIS.,WIRES, CABLES AND PINS (JAYON, OSTRIO)-SURGICAL WIRES/PINS/CABLES ARE USED TO RE-ATTACH LARGE FRAGMENTS OF BONE. THEY ARE ALSO USED TO PROVIDE ADDITIONAL STABILITY, TRACTION, REDUCTION IN LONG-OBLIQUE OR SPIRAL FRACTURES OF BONES, WHICH HAVE ALREADY BEEN STABILIZED BY OTHER MEANS OR ALONE.,BONE PLATES (JAYON, OSTRIO)-A BONE PLATE USED TO HELP STABILIZE FOR FUSION IN A FRACTURED AREA AND PREVENT DISLODGEMENT OF THE BONE GRAFT IN FRACTURE AREA. A BONE PLATE HAS TWO MECHANICAL FUNCTIONS. IT TRANSMITS FORCES FROM ONE END OF A BONE TO THE OTHER, BYPASSING AND THUS PROTECTING THE AREA OF FRACTURES. IT ALSO HOLDS THE FRACTURE ENDS TOGETHER WHILE MAINTAINING THE PROPER ALIGNMENT OF THE FRAGMENTS THROUGHOUT THE HEALING PROCESS.,SPINAL IMPLANTS(JAYON, OSTRIO)-TO STABILIZE AND STRENGTHEN THE SPINE CONDITIONS INCLUDING SLIPPAGE OF THE SPINE, CHRONIC DEGENERATIVE DISC DISEASE, TRAUMATIC FRACTURE, TUMOR, INFECTIONS AND OTHER FORMS OF SPINAL INSTABILITY INCLUDING SCOLIOSIS.,HEMI ARTHROPLASTY(JAYON, OSTRIO)-THE PROSTHESIS IS COMPOSED OF A METAL STEM THAT FITS INTO THE HOLLOW MARROW SPACE OF THE THIGHBONE (THE FEMUR). IT ALSO HAS A METAL BALL THAT FITS INTO THE SOCKET OF THE HIP JOINT (THE ACETABULUM). HEMI MEANS HALF AND IT IS NOT A TOTAL JOINT REPLACEMENT, A HEMI ARTHROPLASTY IS GENERALLY USED TO TREAT A FRACTURED HIP,MAXILLOFACIAL / CRANIAL IMPLANTS, SURGICAL MESH(JAYON, OSTRIO)-SURGICAL MESH IS INTENDED FOR USE IN FIXATION OF THE CRANIAL AND MAXILLOFACIAL BONE, PROCEDURES SUCH AS RECONSTRUCTION, FRACTURE REPAIR, CRANIOTOMIES AND OSTEOTOMIES. SURGICAL MESH ARE AVAILABLE IN STANDARD AND ANATOMICAL SHAPE FORMS. ,SPINAL IMPLANTS(JAYON, OSTRIO)-TO STABILIZE AND STRENGTHEN THE SPINE CONDITIONS INCLUDING SLIPPAGE OF THE SPINE, CHRONIC

	DEGENERATIVE DISC DISEASE, TRAUMATIC FRACTURE, TUMOR, INFECTIONS AND OTHER FORMS OF SPINAL INSTABILITY INCLUDING SCOLIOSIS.,ARTHROSCOPY , ACL/INTERFERENCE SCREWS(JAYON, OSTRIO)-INTERFERENCE SCREW IS DIRECT TENDON TO TENDON INTERFACE FIXATION DEVICE. IT IS A TYPICAL COMPRESSION FIXATION DEVICE WHICH RELIES ON THE SCREW THREAD TO ENGAGE AND COMPRESS THE GRAFT FOR FIXATION. THIS DEVICE HAS BEEN WIDELY USED WITH ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION (ACL) ,MAXILLOFACIAL / CRANIAL IMPLANTS, SURGICAL MESH(JAYON, OSTRIO)-SURGICAL MESH IS INTENDED FOR USE IN FIXATION OF THE CRANIAL AND MAXILLOFACIAL BONE, PROCEDURES SUCH AS RECONSTRUCTION, FRACTURE REPAIR, CRANIOTOMIES AND OSTEOTOMIES. SURGICAL MESH ARE AVAILABLE IN STANDARD AND ANATOMICAL SHAPE FORMS., INTRAMEDULLARY FIXATION RODS(JAYON, OSTRIO)-INTERLOCKING NAILS ARE METALLIC IMPLANTS USED FOR THE REPAIR OF TRAUMATIC LONG BONE FRACTURES. CLOSED INTERLOCKING INTRAMEDULLARY NAILS IS NOW THE STANDARD IN THE TREATMENT OF LONG BONE FRACTURES. THEY CONSIST OF A LARGE DIAMETER ROD, INSERTED INTO A BONE MEDULLARY CAVITY AND SECURED TO IT WITH LOCKING BOLTS GOING FROM ONE CORTEX TO ANOTHER AND CAPTURING THE NAIL INSIDE THE MEDULLARY CAVITY.,DENTAL IMPLANTS(JAYON, OSTRIO)-DENTAL IMPLANTS FUSE TO THE JAWBONE, THEY PROVIDE STABLE SUPPORT FOR ARTIFICIAL TEETH., SPINAL IMPLANTS(JAYON, OSTRIO)-TO STABILIZE AND STRENGTHEN THE SPINE CONDITIONS INCLUDING SLIPPAGE OF THE SPINE, CHRONIC DEGENERATIVE DISC DISEASE, TRAUMATIC FRACTURE, TUMOR, INFECTIONS AND OTHER FORMS OF SPINAL INSTABILITY INCLUDING SCOLIOSIS.,ARTHROSCOPY , ACL/INTERFERENCE SCREWS(JAYON, OSTRIO)-INTERFERENCE SCREW IS DIRECT TENDON TO TENDON INTERFACE FIXATION DEVICE. IT IS A TYPICAL COMPRESSION FIXATION DEVICE WHICH RELIES ON THE SCREW THREAD TO ENGAGE AND COMPRESS THE GRAFT FOR FIXATION. THIS DEVICE HAS BEEN WIDELY USED WITH ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION (ACL),BONE SCREWS(JAYON, OSTRIO)-A BONE SCREWS ARE USED FOR OSTEOSYNTHESIS IN TRAUMATOLOGY AND ORTHOPEDICS. BONE SCREWS CAN BE USED FOR ATTACHMENTS OF IMPLANTS TO THE BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE. BONE SCREWS ARE AVAILABLE IN DIFFERENT DESIGNS SUCH AS CONVENTIONAL SCREWS (CORTICAL/CANCELLOUS), LOCKING SCREWS, HEADLESS SCREWS, CANNULATED SCREWS, SMALL NAIL/BLADE, SINGLE VS MULTIPLE LEAD THREADS. BONE SCREWS HAVE DIFFERENT CHARACTERISTICS SUCH AS NON SELF TAPPING,

		SELF TAPPING, SELF DRILLING AND SELF DRILLING AND TAPPING. MAXILLOFACIAL / CRANIAL IMPLANTS(JAYON, OSTRIO)-MAXILLOFACIAL/CRANIAL IMPLANTS ARE INDICATED FOR FRACTURE TREATMENT IN MAXILLOFACIAL AND CRANIOPLASTY.
3622	MFG/MD/2020/000272	1.License Holder Name: MEDTECH DEVICES 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER KITS (112 SPECIFICATIONS)(CLEARCATH)-THE CVC IS DESIGNED FOR PLACEMENT IN THE JUGULAR VEIN IN CRITICALLY ILL PATIENTS. IT'S DESIGNED FOR LONG TERM VASCULAR ACCESS. CAREFUL PLACEMENT AND CATHETER MAINTENANCE WILL ENSURE THE USE OF THIS CATHETER OVER AN EXTENDED PERIOD.,GUIDE WIRE (240 SPECIFICATIONS)(CAREWIRE)-GUIDEWIRE IS USED TO GUIDE CATHETER TO LESION ARTERY IN ANGIOGRAPHY PROCEDURE, INTRODUCER SHEATH CATHETER (9 SPECIFICATIONS)(CLEARCATH)-INTRODUCER SHEATH CATHETER IS INTENDED FOR THE PERCUTANEOUS INTRODUCTION AND PLACEMENT OF CATHETERS.

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3623	MFG/MD/2020/000273	1.License Holder Name: HARSORIA HEALTHCARE PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:HEMODIALYSIS CATHETER KIT DOUBLE LUMEN (LONG TERM)(GENERIC NAME, HARSORIA, ELITE HARSORIA, NEOTEC, CADON PLUS, SEMILLAS, MEDSOURCE, REIN.)-A DIALYSIS CATHETER IS A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT. THE DIALYSIS CATHETER CONTAINS TWO LUMENS: VENOUS. ARTERIAL,CENTRAL VENOUS CATHETER KIT TRIPLE LUMEN(GENERIC, HARSORIA,CADON, SEMILLAS)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTION,BLOOD SAMPLING CENTRAL VENOUS PRESSURE MONITORING AND INJECTION CONTRAST MEDIA,CENTRAL VENOUS CATHETER KIT TRIPLE LUMEN(NEOTEC, MEDSOURCE)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTION,BLOOD SAMPLING CENTRAL VENOUS PRESSURE MONITORING AND INJECTION CONTRAST MEDIA.,CENTRAL VENOUS CATHETER KIT SINGLE LUMEN(GENERIC, HARSORIA,CADON, SEMILLAS)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTION,BLOOD SAMPLING CENTRAL VENOUS PRESSURE MONITORING AND INJECTION CONTRAST MEDIA., CENTRAL VENOUS CATHETER KIT SINGLE LUMEN(NEOTEC, MEDSOURCE)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTION,BLOOD SAMPLING CENTRAL VENOUS PRESSURE MONITORING AND INJECTION CONTRAST MEDIA, CENTRAL VENOUS CATHETER KIT DOUBLE LUMEN(GENERIC, HARSORIA,CADON, SEMILLAS)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTION,BLOOD SAMPLING CENTRAL VENOUS PRESSURE MONITORING AND INJECTION CONTRAST MEDIA,CENTRAL VENOUS CATHETER KIT DOUBLE LUMEN (NEOTEC, MEDSOURCE)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTION,BLOOD SAMPLING CENTRAL VENOUS PRESSURE MONITORING AND INJECTION CONTRAST MEDIA,CENTRAL VENOUS CATHETER KIT QUAD LUMEN (GENERIC NAME, HARSORIA, ELITE HARSORIA, NEOTEC, CADON PLUS, SEMILLAS, MEDSOURCE, REIN.)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTION,BLOOD SAMPLING CENTRAL VENOUS PRESSURE MONITORING AND INJECTION CONTRAST MEDIA.

3624	MFG/MD/2020/000274	1.License Holder Name: HARDIK INTERNATIONAL PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE SCREW(HARDIK / ORTHOX)-BONE SCREW IS INTENDED FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE HUMERUS, TIBIA, FIBULA, HAND AND FOOT IN ADULTS AND FOR LONG BONES IN ADOLESCENTS. BONE SCREWS FASTEN PLATES TO BONE, MAINTAIN BONE FRAGMENTS IN THEIR RELATIVE POSITION, OR HOLD TOGETHER FRAGMENTS OF BONE (IN THE CASE OF LAG SCREWS). THEY VARY ACCORDING TO THE MANNER IN WHICH THEY ARE INSERTED INTO BONE, THEIR FUNCTION, SIZE, THE TYPE OF BONE THEY ARE INTENDED FOR, AND THE MANNER IN WHICH THEY COUPLE WITH THE SCREW DRIVER (I.E. SLOT, CRUCIATE, SQUARE HEXAGON).,BONE PIN & WIRE(HARDIK / ORTHOX)-BONE PINS & WIRES ARE INDICATED FOR USE IN FIXATION OF BONE FRACTURES, FOR BONE RECONSTRUCTION, FOR SKELETAL TRACTION IN ALIGNMENT OF LONG BONE FRACTURED SEGMENTS, AND AS GUIDE PINS & WIRES FOR INSERTION OF IMPLANTS AND THE PROTECTION OF FISSURES.,SPINE IMPLANT(HARDIK / ORTHOX)-SPINAL SYSTEM CONSISTS OF A VARIETY OF SHAPES AND SIZES OF RODS, SCREW, TRANSVERSE LINK AS WELL AS CAGES AND CERVICAL IMPLANTS. SCREW IS INTENDED FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF SPINAL BONES, AND FOR SCOLIOSIS. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS. DIFFERENT SIZES ARE AVAILABLE WITH DIFFERENT DESIGN FOR BETTER ALIGNMENT AN AS PER FRACTURE,ENDOPROSTHESIS(HARDIK / ORTHOX)-THE ORTHOPAEDICS ENDOPROSTHESES ARE USED AS A HEMI ARTHROPLASTY FOR THE FOLLOWING INDICATIONS: • FEMORAL NECK FRACTURES, • IDIOPATHIC AVASCULAR NECROSIS, • NONUNIONS, THE PATIENT'S ACETABULAR BONE STOCK MUST BE ADEQUATE TO SUPPORT ARTICULATION WITH THE HEAD OF THE ENDOPROSTHESIS END PROSTHESIS IMPLANT SYSTEM CONSISTS OF A VARIETY OF SHAPES AND SIZES , AUSTIN MOORE HIP PROSTHESIS , THOMPSON HIP PROSTHESISS. THE AUSTIN-MOORE AND THOMPSON ENDOPROSTHESIS SYSTEMS USED FOR THE TREATMENT OF PROXIMAL FEMORAL MANUFACTURED BY SS 316L MATERIAL GRADE A WIDE RANGE OF HEAD SIZES AND STEM DESIGNS ARE AVAILABLE TO ACCOMMODATE THE NEEDS OF INDIVIDUAL PATIENT ANATOMY FOR BETTER ALIGNMENT AN AS PER FRACTURE,BONE NAIL(HARDIK / ORTHOX)-BONE NAILS ARE INTENDED TO BE USED FOR TEMPORARY

		FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMURS, FEMORAL SHAFT, TIBIA AND HUMERUS.,BONE PLATE(HARDIK / ORTHOX)-THE BONE PLATE IS INTENDED FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, DISTAL, TIBIA, FIBULA, HAND AND FOOT IN ADULTS AND FOR LONG BONES IN ADOLESCENTS IN WHOM THE GROWTH PLATES ARE FUSED. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS. THIS SYSTEM CAN BE USED FOR VENTRAL, DORSAL OR ORTHOGONAL APPLICATION.,ARTHROSCOPY IMPLANT(HARDIK / ORTHOX)-THE ARTHROSCOPY IMPLANT SYSTEM IS INTENDED FOR USE IN ARTHROSCOPIC RECONSTRUCTION OF CRUCIATE LIGAMENTS. THIS SYSTEM INCLUDES SUTURE DISKS INTENDED FOR USE IN THE FIXATION OF SOFT TISSUE WITH SUTURES TO BONE FOR RUPTURES OF THE ANTERIOR CRUCIATE LIGAMENT.
3625	MFG/MD/2020/000275	1.License Holder Name: SMB MEDICAL DEVICES PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:TUBAL RINGS(SMB)-CONTRACEPTION IN WOMAN,TCU 380AG IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,COPPER T 380A (TCU 380A/CUT 380A) IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,CU 250 IUD (SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,CU 375 IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,COPPER T 380A (TCU 380A/CUT380A) IUD WITH SAFE LOAD AND PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE

3626	MFG/MD/2020/000276	1.License Holder Name: HEALTHIUM MEDTECH PRIVATE LIMITED 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:STERILE HEMORROIDAL STAPLER-THE HEMORRHOIDAL CIRCULAR STAPLER AND ACCESSORIES HAVE APPLICATION THROUGHOUT THE ANAL CANAL TO PERFORM SURGICAL TREATMENT OF HEMORRHOIDAL DISEASE, STERILE SKIN STAPLER(TRUPLER NEO, TRUPLER ECO, SURGIPLER, SURGI-PLER, HEALIER, HEAL-IER, LINX STAPLER)-:1. STERILE SKIN STAPLER MAY BE USED FOR SKIN CLOSURE IN GENERAL SURGERY IN A VARIETY OF SURGICAL PROCEDURES 2. FOR CLOSURE OF UNINFECTED POST TRAUMATIC WOUNDS. 3. FOR PRIMARY, DELAYED PRIMARY AND SECONDARY CLOSURE OF SURGICAL INCISIONS AND WOUNDS.,STERILIZED UMBILICAL TAPE SCH.F (III)(CINTA UMBILICAL, Q-CLOSETM UMBILICAL COTTON TAPE)-UMBILICAL COTTON TAPE IS USED TO TIE THE UMBILICAL CARD OF THE NEW BORN INFANT WHEN IT IS SEPARATED FROM THE MOTHER DURING DELIVERY.,STERILE SKIN STAPLER(DERMATOR, Q-CLOSE SKIN STAPLER, LINX X-PRESS, TRUPLER)-1. STERILE SKIN STAPLER MAY BE USED FOR SKIN CLOSURE IN GENERAL SURGERY IN A VARIETY OF SURGICAL PROCEDURES 2. FOR CLOSURE OF UNINFECTED POST TRAUMATIC WOUNDS. 3. FOR PRIMARY, DELAYED PRIMARY AND SECONDARY CLOSURE OF SURGICAL INCISIONS AND WOUNDS.,STERILIZED UMBILICAL TAPE SCH.F (III)-UMBILICAL COTTON TAPE IS USED TO TIE THE UMBILICAL CARD OF THE NEW BORN INFANT WHEN IT IS SEPARATED FROM THE MOTHER DURING DELIVERY.,STERILE LINEAR STAPLER-IT IS APPLICABLE TO THE RECONSTRUCTION OF DIGESTIVE TRACT WITH DIFFICULTIES OF EXPOSING THE OPERATIVE EYE, THE RECONSTRUCTION OF ANASTOMOTIC STOMA AFTER THE VISCERAL RESECTIONS AND THE CLOSURE OF AN INCISION OR STUMP.,STERILE LINEAR CUTTER STAPLER-THE LINEAR CUTTER STAPLERS CAN BE APPLIED IN ABDOMINAL, GYNECOLOGICAL, PEDIATRIC AND THORACIC SURGICAL PROCEDURES FOR RESECTION, TRANSECTION AND CREATION OF ANASTOMOSIS.,STERILE ENDO LINEAR CUTTER STAPLER-THE ENDO LINEAR CUTTER STAPLER HAS APPLICATIONS IN ABDOMINAL, GYNECOLOGIC, PEDIATRIC AND THORACIC SURGERY FOR RESECTION, TRANSACTION AND CREATION OF ANASTOMOSIS., STERILE CIRCULAR STAPLER-THE CIRCULAR STAPLERS CAN BE APPLIED THROUGHOUT THE ALIMENTARY TRACT TO CREATE END-TO END, END TO SIDE AND SIDE TO SIDE ANASTOMOSIS.,STERILE SKIN STAPLER-1. STERILE SKIN STAPLER MAY BE USED FOR SKIN CLOSURE IN GENERAL SURGERY IN A VARIETY OF SURGICAL PROCEDURES 2. FOR CLOSURE OF UNINFECTED POST TRAUMATIC WOUNDS. 3. FOR PRIMARY, DELAYED PRIMARY AND SECONDARY CLOSURE OF SURGICAL INCISIONS AND WOUNDS.

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3627	MFG/MD/2020/000277	1.License Holder Name: ADLER MEDIEQUIP PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:BONE PLATES(ENDOFIX)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., SPINE IMPLANTS(ONELOCK)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,SPINE IMPLANTS(CERVITWIN)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY.,SPINE IMPLANTS(CERVITWIN)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY.,SPINE IMPLANTS (CERVITWIN)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY.,SPINE IMPLANTS(CERVITWIN)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY.,JOINT REPLACEMENT PROSTHESIS(ADLER LEGEND)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,SPINE IMPLANTS(ONELOCK)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,SPINE IMPLANTS(CERVITWIN)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY.,HEMI ENDOPROSTHESIS(SUSHRUT (S`RUT))-PARTIAL HIP REPLACEMENT FOR HIP FRACTURES IN ELDERLY PATIENTS.,MODULAR RESECTION PROSTHESIS(RESTOR)-REPLACEMENT OF JOINTS FOLLOWING LIMB SALVAGE SURGERY OR REVISION SURGERY.,SPINE IMPLANTS(CERVIEDGE)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,PINS AND WIRES(SUSHRUT (S`RUT))-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,INTRAMEDULLARY NAILS(ATLAS)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., JOINT REPLACEMENT PROSTHESIS(ADLER)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,HEMI ENDOPROSTHESIS(ADLER)-PARTIAL HIP REPLACEMENT FOR HIP FRACTURES IN ELDERLY PATIENTS.,JOINT REPLACEMENT PROSTHESIS(ADLER ENDOFIT)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,SPINE IMPLANTS (CERVITWIN)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY.,JOINT REPLACEMENT PROSTHESIS(MODULOC)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,SPINE IMPLANTS (ZETA)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,JOINT REPLACEMENT PROSTHESIS(ADLER ENDOFIT)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,SPINE IMPLANTS (ZETA)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY.,SPINE IMPLANTS(ONELOCK)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,INTRAMEDULLARY NAILS(EAZEE)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS(AXILOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,SPINE IMPLANTS (ONELOCK)-TEMPORARY SPINE STABILIZATION AFTER SPINAL

	FUSION SURGERY. ,PINS AND WIRES(UMEX)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS (ADLER)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS(ADLER)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE PLATES(ENDOFIX)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., JOINT REPLACEMENT PROSTHESIS(ADLER)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,BONE PLATES(ENDOFIX)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., INTRAMEDULLARY NAILS(SUSHRUT (S`RUT))-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS (AXILOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,PINS AND WIRES(SUSHRUT (S`RUT))-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., INTRAMEDULLARY NAILS(ATLAS PROXIMA)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,HEMI ENDOPROSTHESIS(SUSHRUT (S`RUT))-PARTIAL HIP REPLACEMENT FOR HIP FRACTURES IN ELDERLY PATIENTS.,INTRAMEDULLARY NAILS(ACCIS)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,JOINT REPLACEMENT PROSTHESIS(ADLER)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,BONE SCREWS (ONELOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,SPINE IMPLANTS(ONELOCK)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,SPINE IMPLANTS (ONELOCK)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,SPINE IMPLANTS(CERVIEDGE)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,SPINE IMPLANTS (CERVIEDGE)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,INTRAMEDULLARY NAILS(EAZEE)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE PLATES (ADLER)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,JOINT REPLACEMENT PROSTHESIS(ADLER)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,SPINE IMPLANTS(ONELOCK)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,BONE PLATES(AXILOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,SPINE IMPLANTS(CERVIEDGE)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,JOINT REPLACEMENT PROSTHESIS(MODULOC)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,JOINT REPLACEMENT PROSTHESIS (MODULOC)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,HEMI ENDOPROSTHESIS(ADLER)-PARTIAL HIP REPLACEMENT FOR HIP FRACTURES IN ELDERLY PATIENTS.,INTRAMEDULLARY NAILS(ACCIS) -TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., BONE PLATES(ENDOFIX)-TEMPORARY STABILIZATION OF

	FRACTURES IN HEALING PHASE.,PINS AND WIRES(ADLER)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., SPINE IMPLANTS(ZETA)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,BONE SCREWS(ONELOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS (ONELOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,SPINE IMPLANTS(ZETA)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,SPINE IMPLANTS(ZETA)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,JOINT REPLACEMENT PROSTHESIS(ADLER)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,SPINE IMPLANTS(CERVIEDGE)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,SPINE IMPLANTS(ZETA)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,BONE SCREWS(ONELOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,SPINE IMPLANTS (ZETA)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,HEMI ENDOPROSTHESIS(ADLER)-PARTIAL HIP REPLACEMENT FOR HIP FRACTURES IN ELDERLY PATIENTS., INTRAMEDULLARY NAILS(ATLAS)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,SPINE IMPLANTS(ZETA)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,INTRAMEDULLARY NAILS(SUSHRUT (S`RUT))-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,MODULAR RESECTION PROSTHESIS(RESTOR)-REPLACEMENT OF JOINTS FOLLOWING LIMB SALVAGE SURGERY OR REVISION SURGERY. ,BONE PLATES(ENDOFIX)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,SPINE IMPLANTS(CERVIEDGE)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,BONE SCREWS (ONELOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,PINS AND WIRES(ADLER)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,SPINE IMPLANTS(ZETA)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,SPINE IMPLANTS(CERVIEDGE)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,BONE SCREWS(ONELOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., INTRAMEDULLARY NAILS(ATLAS)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS(SUSHRUT (S`RUT))-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., HEMI ENDOPROSTHESIS(ADLER)-PARTIAL HIP REPLACEMENT FOR HIP FRACTURES IN ELDERLY PATIENTS.,BONE SCREWS(AXILOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., SPINE IMPLANTS(CERVITWIN)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY.,INTRAMEDULLARY NAILS(EAZEE)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,

	JOINT REPLACEMENT PROSTHESIS(ADLER LEGEND)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,INTRAMEDULLARY NAILS(ACCIS) -TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., BONE PLATES(ADLER)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,JOINT REPLACEMENT PROSTHESIS(MODULOC)- REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,BONE PLATES (SUSHRUT (S`RUT))-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,PINS AND WIRES(ADLER)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,PINS AND WIRES (ADLER)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE PLATES(ADLER)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,INTRAMEDULLARY NAILS(EAZEE)- TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., INTRAMEDULLARY NAILS(ACCIS)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,SPINE IMPLANTS(ONELOCK)- TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,BONE SCREWS(SUSHRUT (S`RUT))-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,MODULAR RESECTION PROSTHESIS (RESTOR)-REPLACEMENT OF JOINTS FOLLOWING LIMB SALVAGE SURGERY OR REVISION SURGERY.,BONE PLATES(AXILOCK)- TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., BONE SCREWS(AXILOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS(ADLER)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE PLATES (AXILOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,INTRAMEDULLARY NAILS(ATLAS)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS (ONELOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS(ONELOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,SPINE IMPLANTS(ONELOCK)- TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,BONE PLATES(ADLER)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE PLATES(ENDOFIX)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE PLATES (AXILOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS(ADLER)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,PINS AND WIRES(UMEX)- TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., SPINE IMPLANTS(CERVIEDGE)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,JOINT REPLACEMENT PROSTHESIS (ADLER)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS., INTRAMEDULLARY NAILS(ATLAS PROXIMA)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE PLATES (SUSHRUT (S`RUT))-TEMPORARY STABILIZATION OF FRACTURES IN

	HEALING PHASE.,BONE SCREWS(ONELOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,JOINT REPLACEMENT PROSTHESIS(ADLER)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,MODULAR RESECTION PROSTHESIS(RESTOR)-REPLACEMENT OF JOINTS FOLLOWING LIMB SALVAGE SURGERY OR REVISION SURGERY. ,BONE SCREWS(EAZEE)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS (ATLAS)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS(ATLAS)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS(ATLAS)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS (EAZEE)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS(EAZEE)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS(ATLAS)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,JOINT REPLACEMENT PROSTHESIS(ADLER)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,BONE SCREWS(EAZEE)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE., INTRAMEDULLARY NAILS(ATLAS PROXIMA)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,SPINE IMPLANTS (ZETA)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,JOINT REPLACEMENT PROSTHESIS(ADLER)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,JOINT REPLACEMENT PROSTHESIS(ADLER)-REPLACEMENT OF JOINTS IN ARTHRITIC PATIENTS.,SPINE IMPLANTS(CERVITWIN)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY.,SPINE IMPLANTS(ONELOCK)-TEMPORARY SPINE STABILIZATION AFTER SPINAL FUSION SURGERY. ,INTRAMEDULLARY NAILS(ATLAS PROXIMA)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.,BONE SCREWS(ONELOCK)-TEMPORARY STABILIZATION OF FRACTURES IN HEALING PHASE.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3628	MFG/MD/2020/000278	1.License Holder Name: SMB CORPORATION OF INDIA 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NON ABSORBABLE BRAIDED POLYESTER SUTURE(SMB)-THIS DEVICE IS INTENDED FOR WOUND CLOSURE,NON ABSORBABLE POLYAMIDE MONOFILAMENT SUTURE(SMB)-THIS DEVICE IS INTENDED FOR WOUND CLOSURE,TCU 380AG IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,CU 375 IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,COPPER T 380A(TCU 380A/CUT 380A)- POST DELIVERY IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,NON ABSORBABLE BRAIDED SILK SUTURE(SMB)-THIS DEVICE IS INTENDED FOR WOUND CLOSURE,NON ABSORBABLE POLYPROPYLENE MONOFILAMENT SUTURE(SMB)-THIS DEVICE IS INTENDED FOR WOUND CLOSURE,NON ABSORBABLE SURGICAL BRAIDED SILK SUTURE WITH NEEDLE(SMB)-THIS DEVICE IS INTENDED FOR WOUND CLOSURE,NON ABSORBABLE SURGICAL POLYPROPYLENE MONO-FILAMENT SUTURE WITH NEEDLE(SMB)-THIS DEVICE IS INTENDED FOR WOUND CLOSURE,TCU 380AG IUD WITH PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,COPPER T 380A(TCU 380A/CUT 380A)IUD WITH PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,TCU 380PLUS IUD(SMB)-INTRAUTERINE CONTRACEPTION IN WOMAN OF CHILD BEARING AGE,CU 375 IUD WITH PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,COPPER T 380A (TCU 380A/CUT 380A)IUD (SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,TUBAL RING(SMB)-CONTRACEPTION IN WOMAN,TCU 375 AU IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,NON ABSORBABLE SURGICAL POLYAMIDE MONOFILAMENT SUTURE WITH NEEDLE(SMB)-THIS DEVICE IS INTENDED FOR WOUND CLOSURE,CU 250 IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,TCU 380 PLUS IUD WITH PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,COPPER T 380A(TCU 380A/CUT 380A)IUD WITH SAFE LOAD AND PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,CU 250 IUD WITH PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,NON ABSORBABLE SURGICAL BRAIDED POLYESTER SUTURE WITH NEEDLE(SMB)-THIS DEVICE IS INTENDED FOR WOUND CLOSURE

3629	MFG/MD/2020/000279	1.License Holder Name: A V PROCESSORS PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:HIP SYSTEM(INOR / INOR XL / SWI / SUNWAYS INOR)-THE DEVICE IS INTENDED TO BE IMPLANTED TO REPLACE WHOLE OR PART OF HIP JOINT,TOTAL KNEE SYSTEM(INOR / INOR XL / SWI / SUNWAYS INOR)-THE DEVICE IS INTENDED TO BE IMPLANTED TO REPLACE WHOLE OR PART OF KNEE JOINT

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3630	MFG/MD/2020/000280	1.License Holder Name: CRYSTAL HYGIENE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:MICROPORUS SURGICAL TAPE/ADHESIVE TAPE NON WOVEN SUPPORT(- -)-MICROPORE TAPE WAS INTENDED FOR USE ON HUMAN SKIN, DEVICES, DRESSINGS, AND TUBING'S..MICROPORE TAPE WAS NOT DESIGNED TO BE USED ON PHOTOS AND OT HER IMPORTANT OBJECTS, AND THE EFFECTS OF THE TAPE OVER TIME ON THESE TYPES OF OBJECTS ARE NOT KNOWN.,EYE PAD(- - -)-FOR EYE DRESSING,X-RAY DETECTABLE ABDOMINAL GAUZE SWAB(GENERIC)-FOR CLEANING AND SWABBING WOUNDS. FOR DRESSING LOW EXUDATES WOUNDS,GAUZE RIBBON B. P.(- - -)-FOR E.N.T. SURGERY, FOR GYNEC SURGERY, FOR BLOOD ABSORPTION, FOR CLEANING AND SWABBING WOUNDS.,ZINC OXIDE ADHESIVE PLASTER(- - -)-ZINC OXIDE PLASTER TAPE IS IDEAL FOR HOLDING IN PLACE OVER A WOUND , CUT, ABRASION OR BLISTER. GAUZE SWAB B.P.(- - -)-FOR CLEANING AND SWABBING WOUNDS. FOR DRESSING LOW EXUDATES WOUNDS.,PLASTER OF PARIS BANDAGE(- - -)-PROVIDE ORTHOPEDIC APPLICATIONS IN WHICH RIGID IMMOBILIZATION IS REQUIRED, INCLUDING FRESH OR UNSTABLE FRACTURE.,COMBINE DRESSING SURGICAL PAD(- - -)-COMBINE DRESSING PAD USED TRAUMA DRESSING AND TO STOP HIGH BLOOD FLOW,COMBINE DRESSING SURGICAL PAD(GENERIC)-COMBINE DRESSING PAD USED TRAUMA DRESSING AND TO STOP HIGH BLOOD FLOW,GAMJEE ROLL(- - -)-USED FOR PRIMARY WOUND DRESSINGS PROMOTES HEALING AND ALSO PROTECTS THE WOUND. FOR SWABBING AND CLEANING WOUNDS FOR DRESSING LOW EXUDATES WOUNDS,GAUZE RIBBON B.P.(GENERIC)-FOR E.N.T. SURGERY, FOR GYNEC SURGERY, FOR BLOOD ABSORPTION, FOR CLEANING AND SWABBING WOUNDS,COTTON CREPE BANDAGE B.P.-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES., GAUZE SWAB B.P.(GENERIC)-FOR CLEANING AND SWABBING WOUNDS. FOR DRESSING LOW EXUDATES WOUNDS,ELASTIC ADHESIVE BANDAGE B.P.-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,EYE PAD(GENERIC)-FOR EYE DRESSING, CANNULA FIXATOR-APPLY WITH STRETCH IN THE REGION OF I. V. CANNULA INSERTION,ABSORBENT GAUZE SWAB WITH X-RAY DETECTABLE THREAD-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,ROLLED GAUZE BANDAGE(- - -)-THIS IS A FAIRLY THIN GAUZE THAT MAKES IT EASY TO WRAP MULTIPLE LAYERS, GAINING MORE CONTROL OF THE THICKNESS IN THE DESIRED AREAS, X-RAY DETECTABLE ABDOMINAL GAUZE SWAB(- - -)-FOR BLOOD

	ABSORPTION DURING ABDOMINAL SURGERY FOR CLEANING AND SWABBING WOUNDS FOR DRESSING LOW EXUDATES WOUNDS , ORTHO ROLL CAST PADDING-A PROSTHETIC AND ORTHOTIC ACCESSORY, INTENDED FOR MEDICAL PURPOSES TO SUPPORT PROTECT, OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE), OR PROSTHESIS.

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3631	MFG/MD/2020/000281	1.License Holder Name: JIMIT MEDICO SURGICALS PRIVATE LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(MITSU)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. , STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(J.M.S.)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., INFUSION SET (FOR EXPORT)(- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE THREE WAY STOP COCK WITH/WITHOUT EXTENSION TUBE FOR SINGLE USE ONLY(EUROMEDD)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,STERILE RECTAL TUBE FOR SINGLE USE ONLY(MEDROP RECTAL TUBE)-A RECTAL TUBE, ALSO CALLED A RECTAL CATHETER, IS A LONG SLENDER TUBE WHICH IS INSERTED INTO THE RECTUM IN ORDER TO RELIEVE FLATULENCE . ,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(J.M.S)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (FOR EXPORT ONLY)(ONE PLUS)-:THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE INTRA VENOUS CANNULAE FOR SINGLE USE ONLY(EUROMEDD INTRAVENOUS CANNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES ., STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY (FOR EXPORT ONLY)(ONE PLUS)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE TRACHEOBRONCHIAL YANKAUR SUCTION CATHETER FOR SINGLE USE ONLY(EUROMEDD YANKAUR SET)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT

	AIR VENT BIS 12655 FOR SINGLE USE ONLY [FOR EXPORT ONLY] (EPIC HEIGHT INTRAVENOUS INFUSION SET)-:THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE SCALP VEIN SET FOR SINGLE USE ONLY(EUROMEDD)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD,INFUSION SET (FOR EXPORT)(- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE URETHRAL/ NELATON CATHETER (PLAIN & THUMB CONTROL) FOR SINGLE USE ONLY(EUROMEDD URETHRAL CATHETER)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE INFANT FEEDING TUBE FOR SINGLE USE ONLY(EUROMEDD)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN.IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING,STERILE DISPOSABLE NASOGASTRIC/RYLE'S TUBE FOR SINGLE USE ONLY (EUROMEDD RYLE'S/NASOGASTRIC TUBE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE.IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,STERILE NELATON CATHETER (PLAIN & THUMB CONTROL) FOR SINGLE USE ONLY(EUROMEDD NELATON CATHETER)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY (EUROMEDD SUCTION CATHETER)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION.,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY(EUROMEDD MUCUS EXTRACTOR)- SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,STERILE UMBLILICAL ARTERY CATHETER FOR SINGLE USE ONLY(EUROMEDD UMBILICAL CATHETER)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS,STERILE DISPOSABLE HIGH PRESSURE MONITORING LINE FOR SINGLE USE ONLY(EUROMEDD)-EXTENSION SETS ARE STERILE DEVICES FOR

		SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(J.M.S.)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,DISPOSABLE STERILE DIAL FLOW REGULATOR WITH OR WITHOUT INFUSION SET FOR SINGLE USE ONLY(EUROMEDD)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.
3632	MFG/MD/2020/000283	1.License Holder Name: M/S AEGIS LIFESCIENCES PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ABSORBABLE GELATIN SPONGE U.S.P.(MERIFEIM)-ABSORBABLE HAEMOSTATIC GELATIN SPONGE CAN BE EFFECTIVELY USED IN VARIOUS SURGERIES FOR HAEMOSTASIS, WHEN CONTROL OF CAPILLARY, VENOUS AND ARTERIOLAR BLEEDING BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS INEFFECTIVE OR IMPRACTICAL.

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3633	MFG/MD/2020/000284	1.License Holder Name: PRYMAX HEALTHCARE LLP 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ARTERIAL CATHETER KIT (PRYMAX CATHE)-INTENDED TO BE USED IN CONJUNCTION WITH STEERABLE GUIDEWIRES IN ORDER TO ACCESS DISCRETE REGIONS OF THE CORONARY AND PERIPHERAL ARTERIAL VASACULTURE, INTRAVENOUS CANNULA(PRYMAX FLON, PRYMAX CAN, PRYMAX ALPHA)-IV CANNULA WITH WINGS & PORT- USED TO PROVIDE EXTRA MEDICATION, THROUGH INJECTION PORT, WITHOUT PAIN. IV CANNULA WITH WINGS & WITHOUT PORT- USED FOR SIMPLE PROCEDURES WHERE INJECTION OF MEDICINE IS NOT REQUIRED DURING INFUSION . IV CANNUAL WITHOUT WINGS & WITHOUT PORT- USED FOR SOFT & SMALL VEIN CANNULATION. ,STRAIGHT CONNECTOR(PRYMAX PERFUSION)-IT CAN BE USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC.,CAUTERY PLATE(PRYMAX SURG)-A CAUTERY PLATE IS PLACED ON THE BODY (USUALLY THE THIGH) BEFORE THE SURGERY TO PROTECT THE PERSON FROM THE HARMFUL EFFECTS OF THE ELECTRICITY.,HEMOSTASIS Y(PRYMAX ANGI)-IT CAN BE USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC.,ANGIO KIT(PRYMAX ANGI)-ANGIO KIT/PTCA KIT IS USED DURING THE ANGIOGRAPHIC /PTCA PROCEDURES TO DIAGNOSE /TREAT CARDIAC BLOCKAGES.,Y CONNECTOR(PRYMAX PERFUSION)-IT CAN BE USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC.,PRESSURE MONITORING LINE(PRYMAX PM)-PRESSURE MONITORING LINE IS USED TO WORK AS A PATHWAY BETWEEN THE INFUSION SITE & SOURCE OF INFUSION.,OXYGENATOR(PRYMAX PERFUSION)-THE OXYGENATOR (WITH AN INTEGRAL HEAT EXCHANGER) IS INTENDED TO BE USED IN AN EXTRACORPOREAL PERFUSION CIRCUIT TO OXYGENATE AND REMOVE CARBON DIOXIDE FROM THE BLOOD AND TO COOL OR WARM THE BLOOD DURING ROUTINE CARDIOPULMONARY BYPASS PROCEDURES.,FLOW REGULATOR LINE (PRYMAX PM)-FLOW REGULATOR LINE WITH /WITHOUT Y INJECTION PORT IS USED TO CONTROL THE AMOUNT OF IV SOLUTION ADMINISTERED TO THE BODY.,AORTIC PUNCH(PRYMAX SURG)-A SURGICAL INSTRUMENT USED TO CREATE A HOLE FOR SUTURING OR ANASTOMOSIS OF A TISSUE, BLOOD VESSEL, ETC.,AV FISTULA NEEDLE(PRYMAX DIALYSIS)-AV FISTULA NEEDLE IS SINGLE-USE STERILE MEDICAL DEVICES INTENDED TO BE USED AS VEIN PUNCTURE FOR HEMODIALYSIS TREATMENT.,LUNG EXERCISER (PRYMAX RESP)-INTENDED TO BE USED IN RESPIRATORY THERAPY TO ENCOURAGE AND MOTIVATE DEEP-BREATHING MANOEUVRES, TYPICALLY FOR THE POSTSURGICAL TREATMENT AND PREVENTION

	OF ATELECTASIS (LUNG COLLAPSE) AND TO HELP FACILITATE AIRWAY OPENING AND CLEARING,HEMODIALYSIS CATHETER KIT (PRYMAX DIALYSIS)-THE HEMODIALYSIS CATHETER KIT IS INDICATED FOR USE IN ATTAINING SHORT TERM VASCULAR ACCESS FOR HEMODIALYSIS, HEMOPERFUSION OR APHERESIS THERAPY VIA THE JUGULAR OR SUBCLAVIAN VEIN,RESPIRATORY CIRCUIT (PRYMAX RESP)-AN ASSEMBLY OF DEVICE DESIGNED TO CONDUCT MEDICAL GASES FROM THE FRESH GAS SUPPLY OUTLET OF AN ANAESTHESIA UNIT/WORKSTATION TO THE PATIENT,FOLEY BALLOON CATHETER(PRYMAX SURG)-FOLEY CATHETER FOR SINGLE USE IS A THIN, STERILE TUBE INSERTED INTO BLADDER TO DRAIN URINE.,EXTENSION TUBE WITH NEEDLE FREE CONNECTOR(PRYMAX PM)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,HME FILTER(PRYMAX RESP)-THIS DEVICE IS USE TO FILTER ANESTHETIC GAS/ AIR TO KEEP THE PATIENT SAFE FROM CONTAMINATION.,3 BALLS RESPIRATORY EXERCISER(APOLLO PHARMACY-RESPIRO LUNG EXERCISER, APOLLO EXPERT-RESPIRO LUNG EXERCISER)-INTENDED TO BE USED IN RESPIRATORY THERAPY TO ENCOURAGE AND MOTIVATE DEEP BREATHING MANOEUVRES, TYPICALLY FOR THE POSTSURGICAL TREATMENT AND PREVENTION OF ATELECTASIS (LUNG COLLAPSE) AND TO HELP FACILITATE AIRWAY OPENING AND CLEARING,HEMODIALYSIS BLOOD TUBING(PRYMAX DIALYSIS)-HEMODIALYSIS BLOOD TUBING DESIGNED SPECIFICALLY TO CONNECT PATIENT WITH AN EXTERNAL SYSTEM THAT EXTRACTS BLOOD OF THE PATIENT TO THE DIALYZER AND REVERTS PATIENT'S BLOOD FROM THE DIALYZER.,CONTROL SYRINGE(PRYMAX ANGI)-CONTROL SYRINGE IS A HAND CONTROLLED DEVICE USED TO INJECT CONTRAST MEDIA DURING ANGIOGRAPHY PROCEDURE,INFUSION SET(PRYMAX PM)-INFUSION SET OR IV SET USED TO ADMINISTERED IV SOLUTION TO THE BODY THROUGH VEINS,GAS LINE FILTER (PRYMAX PERFUSION)-GAS LINE FILTER IS USED FOR REMOVAL OF BACTERIA FROM MEDICAL GASES DURING EXTRA-CORPOREAL CIRCUIT,MANIFOLD(PRYMAX ANGI)-MANIFOLD IS INTENDED FOR CONNECTION BETWEEN THE DEVICES, SUCH LIKE INJECTION SYRINGE, ANGIOGRAPHIC CATHETER, DRIP SET TO THE BOTTLE DELIVERING CONTRAST AGENT OR SALINE FLUSH, OR PRESSURE MONITORING SYSTEM ETC.,PRESSURE MONITORING KIT(PRYMAX PM) -PRESSURE MONITORING KITS ARE USED TO CONTINUOUSLY MONITOR ARTERIAL BLOOD PRESSURE, CENTRAL VENOUS PRESSURE, INTRA-CARDIAC PRESSURE, INTRA-CRANIAL PRESSURE, INTRA-UTERINE PRESSURE, PULMONARY ARTERY PRESSURE OR COMPARTMENT PRESSURE.,INFLATION DEVICE(PRYMAX ANGI)-

	INFLATION DEVICE IS USED TO INFLATION AND DEFLATION OF BALLOON & TO MEASURE THE PRESSURE WITHIN THE BALLOON DURING ANGIOPLASTY / PTCA PROCEDURE. ,THORACIC TROCAR CATHETER(PRYMAX SURG)-THROACIC TROCAR CATHETER SPECIFICALLY INTENDED FOR FAST AND QUICK NON OPERATIVE DRAINAGE FROM THORACIC AND PLEURAL CAVITY. PROXIMAL END PROVIDED WITH TAPERED CONNECTOR FOR EASY CONNECTION TO DRAINAGE CONTAINER.,PURGE LINE(PRYMAX PERFUSION)-PURGE LINE ALLOWS AIR TO BE REMOVED FROM THE ARTERIAL FILTER DURING CARDIOPULMONARY BYPASS SURGERY. THE ONE –WAY VALVE PREVENTS AIR AND RETROGRADE FLOW FROM BEING PUSHED INTO THE ARTERIAL FILTER AS A RESULT OF PRESSURIZED CARDIOTOMY RESERVOIR. WHEN OPEN, A SMALL VOLUME OF ARTERIAL BLOOD IS CONTINUOUSLY SHUNTED OUT OF THE FILTER THROUGH THE PURGE LINE WHICH CARRIES AWAY GASEOUS EMBOLI TO THE CARDIOTOMY RESERVOIR,PRESSURE MONITORING LINE WITH THREE WAY STOP COCK(PRYMAX PM)-PM LINES WITH STOPCOCK IS INDICATED TO BE USED AS AN EXTENSION IN THE CIRCUIT DURING THE NON-INVASIVE BLOOD PRESSURE MEASUREMENT .IT CARRIES THE BLOOD/PRESSURE FROM THE PATIENT TO THE MONITORING SYSTEM/DEVICE.,INTRODUCER NEEDLE(PRYMAX ANGI)-INTRODUCER NEEDLE IS USED FOR SAMPLING AND INJECTION OF BLOOD OR DRUGS TO THE PATIENTS VASCULAR SYSTEM OR GAIN VASCULAR ACCESS FOR THE PLACEMENT OF GUIDE WIRE.,CORONARY ARTERY CANNULA OSTIL(PRYMAX PERFUSION)-: CORONARY ARTERY OSTIAL CANNULA ARE INTENDED FOR USE IN DELIVERY OF CARDIOPLEGIA SOLUTION DIRECTLY TO THE CORONARY ARTERIES DURING CARDIOPULMONARY BYPASS SURGERY OR CANNULATION TECHNIQUE FOR LEFT-SIDED CORONARY ARTERY SURGERY., DISPOSABLE PRESSURE TRANSDUCER(PRYMAX PM)-DEVICE IS USED FOR TRAUMATIC ARTERIO-VENOUS PRESSURE MONITORING., THORACIC DRAINAGE CATHETER(PRYMAX SURG)-THORACIC DRAINAGE CATHETER IS USED FOR POST MEDICAL DRAINAGE AFTER CARDIO THORACIC SURGERY .THORACIC DRAINAGE CATHETER IS A RADIO-OPAQUE POLY VINYL CATHETER WITH MULTIPLE LARGE SIDE PORTS TO FACILITATE DRAINAGE. IT COMES IN VARIOUS SIZES FOR INFANT, PEDIATRIC AND ADULTS. THORACIC DRAINAGE CATHETER IS SUITABLE FOR THORACIC AND ABDOMINAL DRAINAGE,RAPID PRIME LINE(PRYMAX PERFUSION)-RAPID PRIME LINE IS USED TO REDUCE THE PRIMING TIME OF THE CPB CIRCUIT ELEMENTS. THE DEVICE IS SINGLE USE, NON-TOXIC, PYROGEN-FREE & SUPPLIED STERILE. THE DEVICE IS STERILIZED BY ETHYLENE OXIDE.,VESSEL LOOP(PRYMAX SURG)-SILICON VESSEL LOOPS ARE USED TO OCCLUDE, RETRACT AND IDENTIFY VESSELS, VEINS, NERVES AND TENDONS DURING

	SURGICAL PROCEDURES,ARTERIAL CANNULA(PRYMAX PERFUSION)-ARTERIAL CANNULA IS USED DURING THE CARDIOPULMONARY BYPASS SURGERY, SUITABLE FOR THE VAST MAJORITY OF CARDIAC AND VASCULAR SURGERY.FEMORAL ARTERY PERFUSION IS SUITABLE FOR PATIENTS WITH AORTIC CANNULATION DIFFICULTIES, SUCH AS HEART SURGERY AGAIN, AORTIC DISSECTION ANEURYSM SURGERY, AORTIC ANEURYSM,AORTIC CLASSIFICATION, VESSEL WALL IS TOO THIN AND AORTIC IS RELATIVELY SMALL,HIGH PRESSURE TUBING(PRYMAX ANGI)-HIGH PRESSURE TUBING IS THE TUBING TO CARRY THE FLUID / CONTRAST MEDIA TO THE PATIENT DURING ANGIOGRAPHY PROCEDURE. HIGH PRESSURE TUBING IS IDEAL FOR USE IN NUMEROUS MEDICAL DEVICE APPLICATIONS. IT IS COMMONLY USED AS A FLUSH LINE FOR CONTRAST INJECTION IN APPLICATIONS SUCH AS: 1.ANGIOGRAPHIC CATHETERS 2.BALLOON CATHETERS ,PVC TUBING(PRYMAX PERFUSION)-PVC TUBING IS USED AS AN ACCESSORY OF HEART LUNG PACK & CARDIOPLEGIA DELIVERY SYSTEM BY ASSEMBLING OF TWO DIFFERENT OR SAME SIZE OF PVC TUBES WITH TWO DIFFERENT OR SAME SIZE OF CONNECTORS DURING HEART SURGERY. THE DEVICE IS SINGLE USE, NON-TOXIC, PYROGEN-FREE & SUPPLIED STERILE. THE DEVICE IS STERILIZED BY ETHYLENE OXIDE. THE LEVEL OF ETHYLENE OXIDE RESIDUALS IN THE DEVICE IS WITHIN THE LIMITS ESTABLISHED BY NATIONAL REGULATIONS IN THE COUNTRY OF USE.,SUCKER (PRYMAX PERFUSION)-CARDIAC SUCKERS ARE USED TO CLEAR THE SURGICAL SITE OF EXCESS BLOOD OR FLUID. IT CAN BE USED PASSIVELY OR AS A RETRACTOR.,CARDIOPLEGIA DELIVERY SYSTEM (PRYMAX PERFUSION)-CARDIOPLEGIA DELIVERY SYSTEM WHICH CONTROLS, MONITORS, AND DELIVERS OXYGENATED BLOOD AND/OR ASANGUINEOUS SOLUTIONS DURING CARDIOPULMONARY BYPASS PROCEDURES. WARMING AND DELIVERY OF OXYGENATED BLOOD AND/OR ASANGUINEOUS CARDIOPLEGIA SOLUTION.,THREE WAY STOP COCK WITH EXTENSION TUBE(PRYMAX PM)-THREE WAY STOPCOCK WITH EXTENSION TUBE IS USED TO PROVIDE MULTIPLE PORTS & EXTEND THE PATHWAY BETWEEN THE INFUSION SITE & SOURCE OF INFUSION. THE EXTENSION LINES ARE INDICATED TO BE USED AS AN EXTENSION IN THE CIRCUIT DURING THE ANESTHESIA SET-UP IN OR / ICU AND ENSURE FREE FLOW OF THE FLUID., YANKAUER SUCTION SET(PRYMAX SURG)-THIS DEVICE TO BE USE TO SUCK INFECTED BLOOD OR SECRETION FROM THE OPERATIVE SITE., MEASURE VOLUME SET(PRYMAX PM)-THE MEASURE VOLUME SET IS A SINGLE-USE, STERILE, CONSIST OF A FLEXIBLE TUBING WITH A LUER CONNECTOR, DRIP CHAMBER & MEASURING BURETTE SET USED TO ADMINISTERED IV SOLUTION TO THE BODY WITH MEASURING OF SOLUTION. THE MEASURE VOLUME SET IS USED FOR

	THE INFUSION OF INTRAVENOUS FLUIDS. MEASURE VOLUME SET IS USED TO ADMINISTERED IV SOLUTION TO THE BODY THROUGH VEINS WITH MEASURING OF SOLUTION,VENOUS CANNULA(PRYMAX PERFUSION)-VENOUS CANNULA IS INTENDED FOR USE AS A SINGLE CANNULA FOR BOTH VENOUS DRAINAGE AND REINFUSION OF BLOOD VIA AN INTERNAL JUGULAR VEIN DURING EXTRACORPOREAL LIFE SUPPORT PROCEDURES.,PERFUSION TUBING SET(PRYMAX PERFUSION)-PERFUSION TUBING SET ONE WAY/TWO WAY/THREE WAY CARDIOPLEGIA ADAPTERS ARE DESIGNED TO BE USED IN CONJUNCTION WITH AORTIC ROOT AND VESSEL CANNULA.THEY ARE USED FOR DELIVERING THE CARDIOPLEGIA SOLUTION TO HEART DURING CARDIOPULMONARY BYPASS SURGERY.,ARTERIAL FILTER (PRYMAX PERFUSION)-THE DEVICE IS INDICATED TO BE USED IN ALL CARDIOPULMONARY BYPASS PROCEDURES FOR THE REMOVAL OF MICROEMBOLI GREATER THAN 40 MICRON IN SIZE,INCLUIDING GAS EMBOLI,FAT EMBOLI AND AGGREATES COMPOSED OF PLATELETES, DAMAGED RED BLOOD CELLS, BONE CHIPS FROM STERNOTOMY, FLAKES OF PVC TUBING AND OTHER DEBRIS,FROM THE ARTERIAL LINE,MISTER BLOWER(PRYMAX PERFUSION)-MISTER BLOWER DEVICE OFFERS ADVANCED FLUID / GAS MIXING TECHNOLOGY TO CREATE A CONSISTENT, PREDICTABLE BLOOD CLEARING MIST. THE MALLEABLE SHAFT AND ON/OFF CONTROL ON THE HAND PIECE MAKE IT AN EXCELLENT CHOICE FOR FACILITATING A BLOODLESS FIELD.,THREE WAY STOP COCK(PRYMAX PM)-STOPCOCKS ARE TYPICALLY USED TO CONTROL THE DIRECTION OF FLUID FLOW. IT CAN BE USED IN MANY APPLICATIONS INCLUDING ANESTHESIA, IV FLUID DELIVERY, AND PRESSURE MONITORING

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3634	MFG/MD/2020/000285	1.License Holder Name: METAFORM ENTERPRISE 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:SPINAL IMPLANTS (METAFORM)-PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS AS AN ADJUNCT TO FUSION OF THE CERVICAL, THORACIC, LUMBAR, AND/OR SACRAL SPINE .THE COMPANY NAME SPINAL IMPLANTS CONSISTS OF A VARIETY OF SHAPES AND SIZES OF RODS, SCREW, TRANSVERSE LINK AS WELL AS CAGES AND CERVICAL IMPLANTS AND ARE TO BE RIGIDLY LOCKED FOR GETTING BETTER RESULT. SCREW IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF SPINAL BONES, AND FOR SCOLIOSIS. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS,WIRES & PINS(METAFORM)-PINS AND WIRES ARE INTENDED FOR USE IN FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR BONE RECONSTRUCTION, FOR OSTEOTOMNIES IN THE PRESENCE OF ADEQUATE IMMOBILIZATION AND AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS,BONE NAILS(METAFORM)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMURS, FEMORAL SHAFT, TIBIA AND HUMERUS. ALL NAILS ARE USED AS SINGLE IMPLANTS,BONE SCREWS(METAFORM)-THE BONE SCREW IS INTENDED TO USE FOR INTERNAL FIXATION OF BONE FRACTURES AND RECONSTRUCTION OF BONES, THERE ARE SEVERAL TYPES OF SCREW LIKE LOCKING HEAD SCREW, GENERAL CORTICAL SCREW OR COMPRESSION SCREW ARE USED FOR FIXING OF COMPRESSION PLATE, LOCKING PLATES WHICH IS USED FOR OSTEOTOMY PATIENTS EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS,SPINE(METAFORM)-PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS AS AN ADJUNCT TO FUSION OF THE CERVICAL, THORACIC, LUMBAR, AND/OR SACRAL SPINE .THE COMPANY NAME SPINAL IMPLANTS CONSISTS OF A VARIETY OF SHAPES AND SIZES OF RODS, SCREW, TRANSVERSE LINK AS WELL AS CAGES AND CERVICAL IMPLANTS AND ARE TO BE RIGIDLY LOCKED FOR GETTING BETTER RESULT. SCREW IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF SPINAL BONES, AND FOR SCOLIOSIS. EXAMPLES OF THESE INTERNAL FIXATIONS

	AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS,BONE PLATES(METAFORM)-THE BONE PLATE IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, TIBIA, FIBULA, FEMORAL. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS.,BONE PLATES(METAFORM)- THE BONE PLATE IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, TIBIA, FIBULA, FEMORAL. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA- ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS. ,BONE SCREWS(METAFORM)-THE BONE SCREW IS INTENDED TO USE FOR INTERNAL FIXATION OF BONE FRACTURES AND RECONSTRUCTION OF BONES, THERE ARE SEVERAL TYPES OF SCREW LIKE LOCKING HEAD SCREW, GENERAL CORTICAL SCREW OR COMPRESSION SCREW ARE USED FOR FIXING OF COMPRESSION PLATE, LOCKING PLATES WHICH IS USED FOR OSTEOTOMY PATIENTS EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS,BONE NAILS(METAFORM)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMURS, FEMORAL SHAFT, TIBIA AND HUMERUS. ALL NAILS ARE USED AS SINGLE IMPLANTS,WIRES & PINS(METAFORM)-PINS AND WIRES ARE INTENDED FOR USE IN FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR BONE RECONSTRUCTION, FOR OSTEOTOMNIES IN THE PRESENCE OF ADEQUATE IMMOBILIZATION AND AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS

3635	MFG/MD/2020/000286	1.License Holder Name: SCEPTRE MEDICAL (I) PVT. LTD. (UNIT - II) 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:PRE-SATURATED WIPES WITH HYDROGEN PEROXIDE 1.4 % W/V-WET WIPES FOR SURFACE AND MEDICAL DEVICES CLEANING.,NON-WOVEN FABRIC & ISO PROPYL ALCOHOL 70%V/V-FOR DISINFECTANT,PRE-SATURATED WIPES WITH HYDROGEN PEROXIDE 0.5% W/V-WET WIPES FOR SURFACE AND MEDICAL DEVICES CLEANING.,ALCOHOL SWAB-USED AS AN DISINFECTANT,PRE-SATURATED WIPES WITH DIDECYLDIMETHYL AMMONIUM CHLORIDE & BENZYL C12C16 ALKYLDIMETHYLCHLORIDE SOLUTION -WET WIPES FOR SURFACE AND MEDICAL DEVICES CLEANING.,PRE-SATURATED WIPES WITH POLYHEXAMETHYLENE BIGUANIDE-WET WIPES FOR SURFACE & MEDICAL DEVICES CLEANING.,POLYHEXAMETHYLENE BIGUANIDE SOLUTION FOR DECONTAMINATION CAP-ANTIMICROBIAL CLEANSING OF HAIRS AND SCALP IN CASES OF COLONIZATION WITH MULTIDRUG-RESISTANT BACTERIA

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3636	MFG/MD/2020/000288	1.License Holder Name: LOTUS SURGICAL PVT LTD 2.Approving Authority: UTTARAKHAND 3.Device Name(Brand Name)-Intended Use:OPEN SURGERY SHEARS (UBERSONIC MAESTRO)-THE MAESTRO OPEN SHEARS ARE INTENDED FOR USE IN GENERAL AND GYNECOLOGIC SURGERY AND OTHER OPEN SURGICAL PROCEDURES WHERE SOFT TISSUE CUTTING WHEN HEMOSTASIS CONTROL AND MINIMAL THERMAL BURNS ARE REQUIRED. IT CAN BE USED TO ASSIST ELECTRO SURGERY, LASER AND STEEL TOOL OPERATIONS OR REPLACE THESE OPERATIONS., LAPAROSCOPIC SHEARS(UBERSONIC PRO+)-UBERSONIC PRO+ LAPAROSCOPIC SHEARS ARE INDICATED FOR SOFT TISSUE INCISIONS WHEN BLEEDING CONTROL AND MINIMAL THERMAL INJURY ARE DESIRED. THE INSTRUMENTS CAN BE USED AS AN ADJUNCT TO OR SUBSTITUTE FOR ELECTROSURGERY, LASERS AND STEEL SCALPELS IN GENERAL, PLASTIC, PEDIATRIC, GYNECOLOGIC, UROLOGIC, THORACIC, EXPOSURE TO ORTHOPEDIC STRUCTURES AND OTHER OPEN AND ENDOSCOPIC PROCEDURES.,SKIN STAPLER REMOVER(PROSEC)-PROSEC SKIN STAPLER REMOVER IS USED FOR REMOVING STAPLES FROM SKIN.,TROCAR KIT (BLADELESS TROCAR AND VERESS NEEDLE)(PROLAP)-THE TROCAR KIT IS DESIGNED TO BE USE IN GENERAL, THORACIC, UROLOGIC AND GYNECOLOGIC ENDOSCOPIC PROCEDURES TO CREATE AND MAINTAIN PNEUMOPERITONEUM TO ESTABLISH WORKING TUNNELS., LAPAROSCOPIC RETRIEVER(PROLAP)-THE SINGLE USE PROLAP LAPAROSCOPIC RETRIEVER IS DESIGNED TO BE USED FOR RETRIEVING SPECIMEN FROM THE CAVITIES IN LAPAROSCOPIC SURGERIES.,BLADELESS TROCAR(PROLAP)-THE PROLAP BLADELESS TROCAR IS INTENDED TO BE USE IN GENERAL, THORACIC, UROLOGIC AND GYNECOLOGIC ENDOSCOPIC PROCEDURES TO CREATE AND MAINTAIN PNEUMOPERITONEUM TO ESTABLISH WORKING TUNNELS., CURVED CUTTER(PROSEC)-PROSEC CURVED CUTTER IS INTENDED TO USE TO STAPLE AND CUT AT THE SAME TIME IN OPEN THORACIC SURGERY, ELIMINATING THE NEED FOR A SCALPEL.,ENDOSCOPIC RETRIEVER(PROLAP)-THE SINGLE USE PROLAP ENDOSCOPIC RETRIEVER IS INTENDED FOR USE OF RETRIEVING OF SPECIMEN FROM THE CAVITIES IN ENDOSCOPIC SURGERIES.,SINGLE USE SKIN STAPLER(PROSEC, PROSEC PLUS)-THE SKIN STAPLER IS INTENDED TO BE USED FOR SKIN CLOSURE OF WOUNDS, INCISIONS OR LACERATIONS OF THE EPIDERMIS.,OPEN APPLICATOR FOR TITANIUM CLIPS(HEMOSEC)-HEMOSEC OPEN APPLICATOR FOR TITANIUM CLIPS ARE INTENDED FOR USE TO OCCLUDE A VARIETY OF VESSELS OR OTHER TUBULAR STRUCTURES DURING SURGERY.,LAPAROSCOPIC SUCTION AND IRRIGATION CANNULA WITH TUBING SYSTEM(PROLAP) -THE PROLAP LAPAROSCOPIC SUCTION AND IRRIGATION CANNULA

		SYSTEM IS THE SUPPORTING SURGICAL DEVICE OF LAPAROSCOPE, AND IS DESIGNED FOR IRRIGATION AND SUCTION PURPOSE DURING THE LAPAROSCOPIC PROCEDURE.,SINGLE USE TITANIUM TACKER (ENDOTACK)-ENDOTACK™ TITANIUM TACKER IS INDICATED FOR FIXATION OF PROSTHETIC MATERIAL (SURGICAL MESH) TO SOFT TISSUE IN LAPAROSCOPIC AND OPEN SURGERY, SUCH AS HERNIA REPAIR.,VERESS NEEDLE(PROLAP)-THE PROLAP VERESS NEEDLE IS DESIGNED TO BE USED IN GYNECOLOGIC AND ABDOMINAL ENDOSCOPIC PROCEDURES FOR ESTABLISHMENT OF PNEUMOPERITIONEUM.,BIPOLAR AND LAPAROSCOPIC SHEARS (UBERSONIC MARVEL)-THE UBERSONIC MARVEL US & RF LAPAROSCOPIC SURGICAL SHEARS ARE INTENDED FOR USE IN GENERAL AND GYNECOLOGIC SURGERY AND OTHER LAPAROSCOPIC SURGICAL PROCEDURES WHERE SOFT TISSUE CUTTING WHEN HEMOSTASIS CONTROL AND MINIMAL THERMAL BURNS ARE REQUIRED. IT CAN BE USED TO ASSIST ELECTRO SURGERY, LASER AND STEEL TOOL OPERATIONS OR REPLACE THESE OPERATIONS., LINEAR CUTTER(PROSEC)-THE PROSEC LINEAR CUTTER IS INTENDED FOR USE IN THE GASTROINTESTINAL, GYNECOLOGICAL, PEDIATRIC AND THORACIC SURGERIES FOR RESECTION, TRANSECTION AND CREATION OF ANASTOMOSIS.,FR-M NEEDLE(FREEDOM)-THE FR-M NEEDLE IS DESIGNED TO FACILITATE THE PASSAGE OF THE MESH ASSEMBLY THROUGH BODILY TISSUES FOR PLACEMENT THROUGH THE OBTURATOR FORAMEN.,ENDOSCOPIC LINEAR CUTTER AND RELOAD(PROSEC, PROSEC PREMIUM, LOTUS STAR, LOTUS TRISTAR)-THE ENDOSCOPIC LINEAR CUTTER AND RELOAD IS INTENDED FOR RESECTION, TRANSECTION AND CREATION OF SIDE-TO-SIDE ANASTOMOSIS IN ABDOMINAL, GYNECOLOGIC, PEDIATRIC AND THORACIC SURGERY.,LAPAROSCOPIC APPLICATOR FOR TITANIUM CLIPS(HEMOSEC)-HEMOSEC LAPAROSCOPIC APPLICATOR FOR TITANIUM CLIPS ARE INTENDED FOR USE TO OCCLUDE A VARIETY OF VESSELS OR OTHER TUBULAR STRUCTURES DURING SURGERY.
3637	MFG/MD/2020/000289	1.License Holder Name: INDRANEEL MEDITECH 2.Approving Authority: MADHYA PRADESH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON IP-FOR SURGICAL DRESSING & CLEANNING ,ABSORBENT COTTON BP-FOR SURGICAL DRESSINGS & CLEANNING

3638	MFG/MD/2020/000291	1.License Holder Name: APAR INDUSTRIES LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:SIROLIMUS ELUTING BIORESORBABLE VASCULAR SCAFFOLD SYSTEM-STERILE DEVICE IS USED FOR FURTHER MANUFACTURING USE ONLY

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3639	MFG/MD/2020/000292	1.License Holder Name: NEW AGE MEDISYS 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:SPINAL IMPLANTS(NEW AGE, SIGNOVA, XYLEX)-SURGICAL IMPLANTS HAVE GIVEN THE SURGEON A MEANS OF RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,BONE PLATES(NEW AGE, SIGNOVA, XYLEX)-SURGICAL IMPLANTS HAVE GIVEN THE SURGEON A MEANS OF RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,BONE NAILS(NEW AGE, SIGNOVA, XYLEX)-SURGICAL IMPLANTS HAVE GIVEN THE SURGEON A MEANS OF RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,LOCKING SCREWS (NEW AGE, SIGNOVA, XYLEX)-SURGICAL IMPLANTS HAVE GIVEN THE SURGEON A MEANS OF RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,HIP SYSTEM-FEMORAL STEM(NEW AGE, SIGNOVA, XYLEX)-SURGICAL IMPLANTS HAVE GIVEN THE SURGEON A MEANS OF RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,BONE NAILS(NEW AGE, SIGNOVA, XYLEX)-SURGICAL IMPLANTS HAVE GIVEN THE SURGEON A MEANS OF RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,LOCKING PLATES (NEW AGE, SIGNOVA, XYLEX)-SURGICAL IMPLANTS HAVE GIVEN THE SURGEON A MEANS OF RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,BONE SCREWS (NEW AGE, SIGNOVA, XYLEX)-SURGICAL IMPLANTS HAVE GIVEN THE SURGEON A MEANS OF RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,WIRE & PIN(NEW AGE, SIGNOVA, XYLEX)-SURGICAL IMPLANTS HAVE GIVEN THE SURGEON A MEANS OF RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,BONE PLATES(NEW AGE, SIGNOVA, XYLEX)-SURGICAL IMPLANTS HAVE GIVEN THE SURGEON A MEANS OF RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,BONE SCREWS (NEW AGE, SIGNOVA, XYLEX)-SURGICAL IMPLANTS HAVE GIVEN THE SURGEON A MEANS OF RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,LOCKING SCREWS (NEW AGE, SIGNOVA, XYLEX)-SURGICAL IMPLANTS HAVE GIVEN THE SURGEON A MEANS OF RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,WIRE & PIN(NEW AGE, SIGNOVA, XYLEX)-SURGICAL IMPLANTS HAVE GIVEN THE SURGEON A MEANS OF RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.,LOCKING PLATES (NEW AGE, SIGNOVA, XYLEX)-SURGICAL IMPLANTS HAVE GIVEN THE

		SURGEON A MEANS OF RIGID FIXATION FOR FRACTURE MANAGEMENT AND RECONSTRUCTIVE SURGERY.
3640	MFG/MD/2020/000293	1.License Holder Name: RAJA RAMANNA CENTRE FOR ADVANCED TECHNOLOGY, DEPARTMENT OF ATOMIC ENERGY, GOVERNMENT OF INDIA 2.Approving Authority: MADHYA PRADESH 3.Device Name(Brand Name)-Intended Use:BOLSTER SUTURE-NON-LATEX PLASTIC BOLSTERS ARE USED TO HINDER PRESSURE OF ANY TEMPORARY SUTURE AGAINST THE BODY DURING SURGERY., SPECIMEN RECEPTACLES-USED AS A SPECIMEN RECEPTACLE, DISPOSABLE PERFUSION SETS-IT CAN BE USED TO CONNECT TO A PERFUSION SETS OR CATHETER INFUSION FOR INFUSION OF CONTRACT MEDIA ETC.,ALCOHOL SWABS-IT IS A SINGLE USE, STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE.,SURGICAL DRESSING MATERIAL-USED FOR APPLYING MEDICATION TO, OR ABSORBING BODY FLUIDS, CATHETER-A CATHETER (FOR ADULTS) PASSED THROUGH THE NARES AND ADVANCED TO THE DEPTH OF THE NASOPHARYNX TO REMOVE AIR CHOKE OR OBSTRUCTION. A RESUSCITATOR,UMBILICAL OCCLUSION DEVICE-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.
3641	MFG/MD/2020/000294	1.License Holder Name: M/S UPICO MEDICARE PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:DISPOSABLE BLOOD ADMINISTRATION SET(GREEN SAFE)-USE IN DELIVERING REGULATED BLOOD AND BLOOD COMPONENTS TO PATIENT.,DISPOSABLE MEASURED VOLUME INFUSION SET(GREEN SAFE)-USE IN DELIVERING MEASURED AND REGULATED BLOOD AND BLOOD COMPONENTS TO PATIENT.,DISPOSABLE PERFUSION SET/ INFUSION SET(GREEN SAFE)-IV SET IS A COLLECTION OF STERILE DEVICES DESIGNED TO CONDUCT FLUIDS FROM AN INTRAVENOUS (IV) FLUID CONTAINER TO A PATIENT'S VENOUS SYSTEM; USED FOR GRAVITATIONAL INTRAVENOUS ADMINISTRATION

3642	MFG/MD/2020/000295	1.License Holder Name: MESCO SURGICAL 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE DIAL FLOW REGULATOR WITH/ WITHOUT INFUSION SET FOR SINGLE USE ONLY (MESCO)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(MESCO BURETTE SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE TRECHEOBRONCHIAL YANKAUR SUCTION CATHETER FOR SINGLE USE ONLY(MESCO YANKAUR SUCTION SET)-: YANKAUR SUCTION SET ARE USED FOR THE SUCTION FROM THORACIC CAVITY OR/ AND OPERATION SITE DURING SURGICAL PROCEDURE..,STERILE URETHRAL/ NELATON CATHETER FOR SINGLE USE ONLY(MESCO)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE DISPOSABLE INFUSION SET WITH / WITHOUT AIR VENT BIS- 12655 FOR SINGLE USE ONLY(SAFE-T LIFE CARE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE NASOGASTRIC STOMACH / LEVIN'S /RYLE'S TUBE FOR SINGLE USE ONLY.(MESCO)-10. INTENDED USE :IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES. ,STERILE DISPOSABLE HIGH PRESSURE MONITARING LINE FOR SINGLE USE ONLY(MESCO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,STERILE INFANT FEEDING TUBE FOR SINGLE USE ONLY(MESCO)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,STERILE DISPOSABLE INFUSION SET WITH / WITHOUT AIR VENT BIS- 12655 FOR SINGLE USE ONLY(PYROTAK)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY(MESCO INFANT MUCUS EXTRACTOR)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION.,STERILE DISPOSABLE INFUSION SET WITH / WITHOUT

	AIR VENT BIS- 12655 FOR SINGLE USE ONLY(DRIPFLOW)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE RECTAL CATHETER FOR SINGLE USE ONLY(MESCO)-IT IS INSERTED INTO THE RECTUM IN ORDER TO RELIEVE FLATULENCE WHICH HAS BEEN CHRONIC AND WHICH HAS NOT BEEN ALLEVIATED BY OTHER METHODS. ,STERILE DISPOSABLE EXTENSION TUBE WITH/WITHOUT THREEWAY STOP COCK FOR SINGLE USE ONLY(MESCO)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(MESCO BLOOD TRANSFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,4.STERILE DISPOSABLE INFUSION SET WITH / WITHOUT AIR VENT BIS- 12655 FOR SINGLE USE ONLY(INTRAVIN)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE UMBILICAL OCCLUSION DEVICE FOR SINGLE USE ONLY(MESCO CORD CLAMP)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE DISPOSABLE THREE WAY STOP COCK WITH/WITHOUT EXTENSION TUBE FOR SINGLE USE ONLY (MESCO)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING CLASS OF MEDICAL ,STERILE TRACHEOBRONCHIAL SUCTION CATHETER (PLAIN & THUMB CONTROL) FOR SINGLE USE ONLY(MESCO SUCTION CATHETER)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., STERILE DISPOSABLE SCALP VEIN SET FOR SINGLE USE ONLY (MESCO)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD., STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(MESCO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.

3643	MFG/MD/2020/000296	1.License Holder Name: M/S BONE LIFE SURGICALS 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:SPINAL IMPLANTS (SERAPIS)-IT IS INDICATED FOR USE WITH AUTOGENOUS BONE GRAFT IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE ("DDD") AT ONE OR TWO CONTIGUOUS SPINAL LEVELS. , BONE PIN(SERAPIS)-IT MAY BE USED FOR FIXATION OF BONE FRACTURES, FOR BONE RECONSTRUCTIONS, AS A GUIDE PIN FOR INSERTION OF OTHER IMPLANTS, OR IT MAY BE IMPLANTED THROUGH THE SKIN SO THAT A PULLING FORCE (TRACTION) MAY BE APPLIED TO THE SKELETAL SYSTEM.,BONE SCREWS(SERAPIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE. ,BONE PLATES (SERAPIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE. , BONE NAILS(SERAPIS)-INTENDED TO BE IMPLANTED INTO THE MEDULLARY (BONE MARROW) CANAL OF LONG BONES FOR THE FIXATION OF FRACTURES.,BONE WIRE(SERAPIS)-STABILIZATION OF THE FRACTURED BONY PARTS BY DIRECT FIXATION TO ONE ANOTHER WITH SURGICAL WIRES.,BONE WIRE(SERAPIS)-STABILIZATION OF THE FRACTURED BONY PARTS BY DIRECT FIXATION TO ONE ANOTHER WITH SURGICAL WIRES.,BONE PLATES (SERAPIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE. ,BONE SCREWS(SERAPIS)-INTENDED TO REPLACE A MISSING JOINT OR BONE OR TO SUPPORT A DAMAGED BONE. ,BONE PIN(SERAPIS)-IT MAY BE USED FOR FIXATION OF BONE FRACTURES, FOR BONE RECONSTRUCTIONS, AS A GUIDE PIN FOR INSERTION OF OTHER IMPLANTS, OR IT MAY BE IMPLANTED THROUGH THE SKIN SO THAT A PULLING FORCE (TRACTION) MAY BE APPLIED TO THE SKELETAL SYSTEM.,BONE NAILS (SERAPIS)-INTENDED TO BE IMPLANTED INTO THE MEDULLARY (BONE MARROW) CANAL OF LONG BONES FOR THE FIXATION OF FRACTURES. ,SPINAL IMPLANTS(SERAPIS)-IT IS INDICATED FOR USE WITH AUTOGENOUS BONE GRAFT IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE ("DDD") AT ONE OR TWO CONTIGUOUS SPINAL LEVELS.

3644	MFG/MD/2020/000297	1.License Holder Name: A V PROCESSORS PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:HEMI ENDO PROSTHESIS (NA)-INTENDED TO BE IMPLANT TO REPLACE A PORTION OF THE HIP JOINT OR THE HEMI ENDOPROSTHESES ARE INTENDED TO BE USED TO CARRY OUT A PARTIAL OR HEMI REPLACEMENT OF THE FEMORAL HEAD OF THE HIP JOINT

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3645	MFG/MD/2020/000298	1.License Holder Name: M/S SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ABSORBABLE HEMOSTAT FOR SURGICAL USE (OXIDIZED REGENERATED CELLULOSE) (HEMOLUS)-INTERNAL USE, WHOLLY ABSORBABLE, FOR THE CONTROL OF BLEEDING DURING AND AFTER SURGERY, FOR THE GENERAL POPULATION AND FOR THOSE ON ANTICOAGULATION MEDICATION. ABSORBABLE HEMOST(OXIDIZED REGENERATED CELLULOSE) IS USED ADJUNCTIVELY IN SURGICAL PROCEDURES TO ASSIST IN THE CONTROL OF CAPILLARY, VENOUS, AND SMALL ARTERIAL HEMORRHAGE WHEN SURGICAL HEMOSTASIS IS INADEQUATE OR IMPRACTICAL.,BRAIDED COATED SHORT TERM POLY (GLYCOLIDE-L-LACTIDE)/POLYGLACTIN-910 SYNTHETIC ABSORBABLE SUTURE(SOLUS SWIFT 9 10)-SOLUS SWIFT® 910 SUTURE IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO THE ABSORPTION PROPERTIES, THIS TYPE OF SUTURE IS USEFUL FOR SKIN CLOSURE.,STERILE BONE WAX(LOTUS BONE WAX)-LOTUS BONE WAX IS A STERILE MIXTURE OF BEESWAX AND ISOPROPYL PALMITATE, A WAX SOFTENING AGENT, USED TO HELP CONTROL BLEEDING FROM BONE SURFACES.,MONOFILAMENT POLY (P-DIOXANONE) SYNTHETIC ABSORBABLE SUTURE(MASS)-THESE SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION IN MICROSURGERY AND IN OPHTHALMIC SURGERY. THIS TYPE OF SUTURES IS PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT IS REQUIRED.,BRAIDED COATED POLYESTER SYNTHETIC NON-ABSORBABLE SUTURE(ESTERLUS)-BRAIDED COATED POLYESTER SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,BRAIDED COATED SILK SYNTHETIC NON- ABSORBABLE SUTURE(SILKUS)-SILKUS- SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,BRAIDED COATED POLYGLYCOLIC ACID SYNTHETIC ABSORBABLE SUTURE(SOLUS)-SOLUS® - IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION AND/OR LIGATION., MONOFILAMENT POLY(GLYCOLIDE-CO-CAPROLACTONE)(MONOLU$) -MONOLUS SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, WHERE AN ABSORBABLE MATERIAL IS INDICATED.,BRAIDED COATED POLY (GLYCOLIDE-L-LACTIDE)/POLYGLACTIN-910 SYNTHETIC ABSORBABLE SUTURE(SOLUS 910)-SOLUS®910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION

		AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER. THE SAFETY AND EFFECTIVENESS OF THIS SUTURE HAVE NOT BEEN ESTABLISHED.,CHROMIC AND PLAIN CATGUT ABSORBABLE SURGICAL SUTURE (COLLAGEN)(LOGUT/CATGUT)-LOGUT /CATGUT-R ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN PLASTIC SURGERY AND OPHTHALMIC PROCEDURES.,BRAIDED COATED SHORT TERM POLYGLYCOLIC ACID SYNTHETIC ABSORBABLE SUTURE(SOLUS SWIFT)-SOLUS SWIFT- IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO THE ABSORPTION PROPERTIES, THIS SUTURE IS USEFUL FOR SKIN CLOSURE.,MONOFILAMENT POLYPROPYLENE SYNTHETIC NON-ABSORBABLE SUTURE(PROLUS)-PROLUS SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,MONOFILAMENT POLYAMIDE SYNTHETIC NON-ABSORBABLE SUTURE(NYLUS)-NYLUS - SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.
3646	MFG/MD/2020/000299	1.License Holder Name: PLASMA BIOTAL INDIA PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:HIP SYSTEM(INOR / INOR XL / SWI / SUNWAYS INOR)-THE DEVICE IS INTENDED TO BE IMPLANTED TO REPLACE WHOLE OR PART OF HIP JOINT

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3647	MFG/MD/2020/000300	1.License Holder Name: SOLCO BIOMEDICAL COMPANY INDIA PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATES(SOLCO)-ORTHOPEDIC IMPLANTS ARE INTENDED TO BE USED FOR THE INTERNAL FIXATION OF BONE FRACTURES AND BONE RECONSTRUCTION. THE USE OF PLATE IS INDICATED: - WHEN ANATOMICAL ALIGNMENT MUST BE RESTORED ACCURATELY. - WHERE THE USE OF SCREWS ALONE IS INADEQUATE. - WHEN LOAD SHARING MAY BE ACHIEVED WITH CONFIDENCE. IF THIS CANNOT BE GUARANTEED, THEN A BONE GRAFT MAY BE ADDED AT THE SITE OF ANY DEFICIT. THE AREAS OF THE BODY WHERE THE CONDITIONS DESCRIBED ABOVE ARISE COMMONLY ARE: - AROUND JOINTS – FAILURE TO RESTORE A JOINT SURFACE TO ITS NORMAL SHAPE MAY LEAD TO OSTEOARTHRITIS BECAUSE OF UNEVEN WEAR OF THE JOINT SURFACES. - IN THE BONE OF THE FOREARM WHICH ROTATES ABOUT EACH OTHER. - ON THE PELVIS ESPECIALLY AROUND THE ACETABULUM - ON THE FACE AND JAW.,INTRAMEDULLARY NAILS (IM NAILS)(SOLCO.)-THE INTRAMEDULLARY NAIL SYSTEM IS INTENDED FOR SURGICAL MANAGEMENT OF FEMORAL AND TIBIAL FRACTURES INCLUDING OPEN AND CLOSED FRACTURES, PSEUDARTHROSIS AND CORRECTION OSTEOTOMY, PATHOLOGIC FRACTURES, IMPENDING PATHOLOGIC FRACTURES, TUMOR RESECTIONS, NONUNIONS AND MALUNIONS. THE HIP NAILS MAY BE USED FOR BASILAR NECK, SUBTROCHANTERIC AND INTERTROCHANTERIC FRACTURES. THE FEMORAL NAILS MAY BE USED FOR FRACTURES OF THE FEMUR BELOW THE HIP JOINT INCLUDING IPSILATERAL FEMUR FRACTURES, FRACTURES PROXIMAL TO A TOTAL KNEE ARTHROPLASTY AND SUPRACONDYLAR FRACTURES, INCLUDING THOSE WITH INTRAARTICULAR EXTENSION.,INTRAMEDULLARY NAILS (IM NAILS)(SOLCO)-THE INTRAMEDULLARY NAIL SYSTEM IS INTENDED FOR SURGICAL MANAGEMENT OF FEMORAL AND TIBIAL FRACTURES INCLUDING OPEN AND CLOSED FRACTURES, PSEUDARTHROSIS AND CORRECTION OSTEOTOMY, PATHOLOGIC FRACTURES, IMPENDING PATHOLOGIC FRACTURES, TUMOR RESECTIONS, NONUNIONS AND MALUNIONS. THE HIP NAILS MAY BE USED FOR BASILAR NECK, SUBTROCHANTERIC AND INTERTROCHANTERIC FRACTURES. THE FEMORAL NAILS MAY BE USED FOR FRACTURES OF THE FEMUR BELOW THE HIP JOINT INCLUDING IPSILATERAL FEMUR FRACTURES, FRACTURES PROXIMAL TO A TOTAL KNEE ARTHROPLASTY AND SUPRACONDYLAR FRACTURES, INCLUDING THOSE WITH INTRAARTICULAR EXTENSION.,BONE SCREWS(SOLCO)-ORTHOPEDIC IMPLANTS ARE INTENDED TO BE USED FOR THE INTERNAL FIXATION

	OF BONE FRACTURES AND BONE RECONSTRUCTION. BONE SCREWS ARE INTENDED FOR LONG AND SMALL BONE FRACTURE FIXATION. METALLIC BONE SCREWS ARE INTERNAL SUPPORT, WHICH TEMPORARILY ALIGN THE FRACTURE UNTIL BONY FUSION OCCURS., BONE PLATES(SOLCO)-IMPLANTS ARE INTENDED TO BE USED FOR THE INTERNAL FIXATION OF BONE FRACTURES AND BONE RECONSTRUCTION. THE USE OF PLATE IS INDICATED: - WHEN ANATOMICAL ALIGNMENT MUST BE RESTORED ACCURATELY. - WHERE THE USE OF SCREWS ALONE IS INADEQUATE. - WHEN LOAD SHARING MAY BE ACHIEVED WITH CONFIDENCE. IF THIS CANNOT BE GUARANTEED, THEN A BONE GRAFT MAY BE ADDED AT THE SITE OF ANY DEFICIT. THE AREAS OF THE BODY WHERE THE CONDITIONS DESCRIBED ABOVE ARISE COMMONLY ARE: - AROUND JOINTS – FAILURE TO RESTORE A JOINT SURFACE TO ITS NORMAL SHAPE MAY LEAD TO OSTEOARTHRITIS BECAUSE OF UNEVEN WEAR OF THE JOINT SURFACES. - IN THE BONE OF THE FOREARM WHICH ROTATES ABOUT EACH OTHER. - ON THE PELVIS ESPECIALLY AROUND THE ACETABULUM - ON THE FACE AND JAW.,SPINAL IMPLANTS(SOLCO)-SPINAL IMPLANTS ARE BASICALLY INDICATED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THORACIC, LUMBAR, AND SACRAL SPINE: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION.,PINS AND WIRES(SOLCO)-PINS: PINS ARE USED IN FIXATION OF FRACTURES WHERE MINIMAL BONE AND SOFT TISSUE DAMAGE ARE INVOLVED. PINS PROVIDE PROVISIONAL FIXATION LEAVING ROOM FOR ADDITIONAL HARDWARE PLACEMENT. THE PROVISIONAL FIXATION IS PLANNED TO AVOID FAULTY PERMANENT FIXATION. DEPENDING ON THE DIAMETER, PINS MAY ALSO BE USED AS GUIDEWIRES FOR CANNULATED SCREW FIXATION. WIRES: WIRES ARE USED IN THE FIXATION OF FRACTURES IN WHICH LOADING IS MINIMAL. WIRES ARE EASIER TO BEND, SO, ARE SUPPLEMENTED WITH OTHER IMMOBILIZATION DEVICES WHERE NECESSARY. PIN OR WIRE FIXATION IS MOSTLY USED FOR FRACTURES OF THE PHALANGES, METACARPALS, METATARSALS, PROXIMAL HUMERUS AND DISTAL HUMERUS.,PEDICLE SCREW(SOLCO.)-IT IS USED TO INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS,SPINAL IMPLANTS(SOLCO)-SPINAL IMPLANTS

		ARE BASICALLY INDICATED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THORACIC, LUMBAR, AND SACRAL SPINE: DEGENERATIVE DISC DISEASE (DDD) (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; TRAUMA (I.E., FRACTURE OR DISLOCATION); SPINAL STENOSIS; CURVATURES (I.E., SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS); TUMOR; PSEUDOARTHROSIS; AND FAILED PREVIOUS FUSION.,BONE SCREWS (SOLCO)-ORTHOPEDIC IMPLANTS ARE INTENDED TO BE USED FOR THE INTERNAL FIXATION OF BONE FRACTURES AND BONE RECONSTRUCTION. BONE SCREWS ARE INTENDED FOR LONG AND SMALL BONE FRACTURE FIXATION. METALLIC BONE SCREWS ARE INTERNAL SUPPORT, WHICH TEMPORARILY ALIGN THE FRACTURE UNTIL BONY FUSION OCCURS.,PINS AND WIRES(SOLCO)-PINS: PINS ARE USED IN FIXATION OF FRACTURES WHERE MINIMAL BONE AND SOFT TISSUE DAMAGE ARE INVOLVED. PINS PROVIDE PROVISIONAL FIXATION LEAVING ROOM FOR ADDITIONAL HARDWARE PLACEMENT. THE PROVISIONAL FIXATION IS PLANNED TO AVOID FAULTY PERMANENT FIXATION. DEPENDING ON THE DIAMETER, PINS MAY ALSO BE USED AS GUIDEWIRES FOR CANNULATED SCREW FIXATION. WIRES: WIRES ARE USED IN THE FIXATION OF FRACTURES IN WHICH LOADING IS MINIMAL. WIRES ARE EASIER TO BEND, SO, ARE SUPPLEMENTED WITH OTHER IMMOBILIZATION DEVICES WHERE NECESSARY. PIN OR WIRE FIXATION IS MOSTLY USED FOR FRACTURES OF THE PHALANGES, METACARPALS, METATARSALS, PROXIMAL HUMERUS AND DISTAL HUMERUS.
3648	MFG/MD/2020/000301	1.License Holder Name: AUROLAB 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:CORNEAL STORAGE MEDIA(----)-CORNISOL IS A BIOCOMPATIBLE ENHANCED TISSUE CULTURE MEDIA FOR STORAGE OF HUMAN CORNEAS SUITABLE FOR KERATOPLASTY FOR 14 DAYS UNDER REFRIGERATION (2-8 DEGREE CELSIUS)

3649	MFG/MD/2020/000302	1.License Holder Name: REVON RUBBER 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:CONDOM(LOVE RACER)-USED DURING SEXUAL INTERCOURSE TO REDUCE THE PROBABILITY OR PREGNANCY OR A SEXUALLY TRANSMITTED INFECTION (STIS)
3650	MFG/MD/2020/000303	1.License Holder Name: DEVINE MEDITECH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:INTRAOCULAR LENS HYDROPHILIC-AN INTRAOCULAR LENS (IOL) IS A LENS IMPLANTED IN THE EYE USED TO TREAT CATARACTS OR MYOPIA.,INTRAOCULAR LENS HYDROPHOBIC-AN INTRAOCULAR LENS (IOL) IS A LENS IMPLANTED IN THE EYE USED TO TREAT CATARACTS OR MYOPIA., INTRAOCULAR LENS PMMA-AN INTRAOCULAR LENS (IOL) IS A LENS IMPLANTED IN THE EYE USED TO TREAT CATARACTS OR MYOPIA.
3651	MFG/MD/2020/000304	1.License Holder Name: M/S JK BANDAGE INDUSTRIES 2.Approving Authority: JAMMU AND KASHMIR 3.Device Name(Brand Name)-Intended Use:SURGICAL BANDAGE-SURGICAL BANDAGE IS USED FOR DRESSING PURPOSES OF WOUNDS AND INJURIES.

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3652	MFG/MD/2020/000306	1.License Holder Name: MEDORA HEALTHCARE PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:SURGICAL DRESSING(NEO WOUND WEAR)-A SURGICAL DRESSING IS A STERILE PAD OR COMPRESS APPLIED TO A WOUND TO PROMOTE HEALING AND PROTECT THE WOUND FROM FURTHER HARM. A DRESSING IS DESIGNED TO BE IN DIRECT CONTACT WITH THE WOUND, AS DISTINGUISHED FROM A BANDAGE, WHICH IS MOST OFTEN USED TO HOLD A DRESSING IN PLACE.,ABSORBENT GAUZE CLOTH(NEO WOUND WEAR)-FOR CLEAN THE WOUND,ABSORBENT COTTON GAUZE RIBBON(NEO WOUND WEAR)-USED IN DRESSINGS,GAMJEE ROLL(NEO WOUND WEAR)-FOR THE CLEANING AND DRYING PURPOSE,ELASTIC ADHESIVE BANDAGE(NEO WOUND WEAR)-IT IS USUALLY USED TO WRAP SOFT TISSUE INJURIES TO PROVIDE COMPRESSION AND SUPPORT,GAUZE SWAB(NEO WOUND WEAR)-FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, APPLYING ANTISEPTIC,COTTON BANDAGE CLOTH(NEO WOUND WEAR)-TO SUPPORT THE DRAPING.,OPEN WOVE BANDAGE(NEO WOUND WEAR)-IT USED TO COVER THE WOUNDS TO PREVENT IT FROM DUST AND BACTERIA,CREPE BANDAGE(NEO WOUND WEAR)-FOR THE REDUCES SWELLING, SECURES WOUND DRESSING, SUPPORTS STRAINS AND SPRAINS,IV CANNULA FIXATOR(NEO WOUND WEAR)-IV CANNULA FIXATOR IS HELPFUL FOR FIXING IV CANNULA,COTTON GRUDGES AND BANDAGES(NEO WOUND WEAR)-BANDAGES MAY BE USED TO STOP THE FLOW OF BLOOD, ABSORB DRAINAGE, CUSHION THE INJURED AREA, PROVIDE A SAFEGUARD AGAINST CONTAMINATION, HOLD A MEDICATED DRESSING IN PLACE, HOLD A SPLINT IN POSITION.,ABDOMINAL PAD(NEO WOUND WEAR)-TO CLEAN WOUNDS,COMBINED DRESSING PAD(NEO WOUND WEAR)-THESE ARE IDEAL FOR HANDLING HEAVY DRAINAGE, PROMOTING HEALING AND KEEPING THE WOUND DRY FOR OPTIMAL COMFORT AND RELIEF

3653	MFG/MD/2020/000307	1.License Holder Name: HINDUSTAN SYRINGES & MEDICAL DEVICES LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:SAFETY INTRAVENOUS CANNULA (CATHETER) WITH/WITHOUT INJECTION PORT WITH SHARP INJURY PREVENTION FEATURE.(-)-THE IV CANNULA IS INTENDED FOR SHORT TERM ACCESS TO THE PERIPHERAL VEIN FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS.,SINGLE USE HYPODERMIC SYRINGE (AUTO DISABLE SYRINGES WITH RE-USE PREVENTION FEATURE)(-)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY.,SINGLE USE HYPODERMIC SYRINGE (AUTO DISABLE SYRINGES FOR FIXED-DOSE IMMUNIZATION)(KOJAK) -IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY.,SINGLE USE HYPODERMIC SYRINGE WITH NEEDLE (DISPO VAN, UNOLOK, PERFEKTUM AND DISPOJEKT)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY., SINGLE USE HYPODERMIC SYRINGE WITH SAFETY NEEDLE (NEEDLE WITH SHARPS INJURY PREVENTION FEATURE)(-)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY.,SINGLE USE ORAL TIP SYRINGE (AUTO DISABLE SYRINGES WITH RE-USE PREVENTION FEATURE)(KOJAK)-IT IS INTENDED TO BE USED FOR ORAL/ ENTERAL DELIVERY OF FLUID (NOT FOR INJECTION).,SAFETY INTRAVENOUS CANNULA (CATHETER) WITH/WITHOUT INJECTION PORT WITH SHARP INJURY PREVENTION FEATURE.(CATHULA+)-THE IV CANNULA IS INTENDED FOR SHORT TERM ACCESS TO THE PERIPHERAL VEIN FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS., SAFETY INTRAVENOUS CANNULA (CATHETER) WITH/WITHOUT INJECTION PORT WITH SHARP INJURY PREVENTION FEATURE. (CATHY+)-THE IV CANNULA IS INTENDED FOR SHORT TERM ACCESS TO THE PERIPHERAL VEIN FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS,SAFETY INTRAVENOUS CANNULA (CATHETER) WITH/WITHOUT INJECTION PORT WITH SHARP INJURY PREVENTION FEATURE.(CLIP)-THE IV CANNULA IS INTENDED FOR SHORT TERM ACCESS TO THE PERIPHERAL VEIN FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS.,SINGLE USE HYPODERMIC SYRINGE (AUTO DISABLE SYRINGES WITH RE-USE PREVENTION FEATURE) WITH SAFETY NEEDLE (NEEDLE WITH SHARPS INJURY PREVENTION FEATURE)(KOJAK)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY.,SINGLE USE

	HYPODERMIC SYRINGE (AUTO DISABLE SYRINGES FOR FIXED-DOSE IMMUNIZATION) WITH SAFETY NEEDLE (NEEDLE WITH SHARPS INJURY PREVENTION FEATURE)(-)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY.,SINGLE USE HYPODERMIC NEEDLE (-)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY.,SAFETY INTRAVENOUS CANNULA (CATHETER) WITHOUT INJECTION PORT WITH SHARP INJURY PREVENTION FEATURE.(CLIP ® WINGED)-THE IV CANNULA IS INTENDED FOR SHORT TERM ACCESS TO THE PERIPHERAL VEIN FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS,SINGLE USE HYPODERMIC SYRINGE WITH NEEDLE(-)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY,SINGLE USE HYPODERMIC SYRINGE WITHOUT NEEDLE (DISPO VAN, UNOLOK, PERFEKTUM AND DISPOJEKT)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY, SINGLE USE HYPODERMIC SYRINGE WITHOUT NEEDLE(-)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY, SINGLE USE HYPODERMIC SYRINGE WITH NEEDLE(DISPO VAN, UNOLOK, PERFEKTUM AND DISPOJEKT)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY.,SINGLE USE HYPODERMIC SYRINGE (AUTO DISABLE SYRINGES WITH RE-USE PREVENTION FEATURE) WITH SAFETY NEEDLE (NEEDLE WITH SHARPS INJURY PREVENTION FEATURE)(-)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY,SINGLE USE HYPODERMIC SYRINGE WITH NEEDLE(-)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY.,SINGLE USE HYPODERMIC SYRINGE WITHOUT NEEDLE (DISPO VAN, UNOLOK, PERFEKTUM AND DISPOJEKT)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY., SINGLE USE HYPODERMIC SYRINGE (AUTO DISABLE SYRINGES FOR FIXED-DOSE IMMUNIZATION) WITH SAFETY NEEDLE (NEEDLE WITH SHARPS INJURY PREVENTION FEATURE)(KOJAK)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY.,SAFETY INTRAVENOUS CANNULA (CATHETER) WITH INJECTION PORT WITH SHARP INJURY PREVENTION FEATURE.(CLIP ® PORTED)-THE IV CANNULA IS INTENDED FOR SHORT TERM ACCESS TO THE PERIPHERAL VEIN FOR

	THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, SINGLE USE HYPODERMIC SYRINGE (AUTO DISABLE SYRINGES FOR FIXED-DOSE IMMUNIZATION)(KOJAK)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY.,SAFETY INTRAVENOUS CANNULA (CATHETER) WITH/WITHOUT INJECTION PORT WITH SHARP INJURY PREVENTION FEATURE.(CLIP ® VEN)-THE IV CANNULA IS INTENDED FOR SHORT TERM ACCESS TO THE PERIPHERAL VEIN FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, SINGLE USE ORAL TIP SYRINGE(DISPO VAN AND UNOLOK)-IT IS INTENDED TO BE USED FOR ORAL/ ENTERAL DELIVERY OF FLUID (NOT FOR INJECTION).,SINGLE USE HYPODERMIC SYRINGE (AUTO DISABLE SYRINGES WITH RE-USE PREVENTION FEATURE)(KOJAK)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY., SINGLE USE INTRANASAL SYRINGE (AUTO DISABLE SYRINGES WITH RE-USE PREVENTION FEATURE)(KOJAK)-IT IS INTENDED TO BE USED FOR DELIVERY OF DRUG THROUGH NASAL CAVITY (NOT FOR INJECTION).,SAFETY INTRAVENOUS CANNULA (CATHETER) WITHOUT INJECTION PORT WITH SHARP INJURY PREVENTION FEATURE(CLIP ® NEO)-THE IV CANNULA IS INTENDED FOR SHORT TERM ACCESS TO THE PERIPHERAL VEIN FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS.,SINGLE USE INSULIN SYRINGE WITH OR WITHOUT NEEDLE(-)-IT IS INTENDED TO BE USED FOR THE INJECTION OF INSULIN FLUIDS IMMEDIATELY AFTER FILLING FOR TREATMENT OF DIABETES.,SINGLE USE HYPODERMIC SYRINGE WITH SAFETY NEEDLE (NEEDLE WITH SHARPS INJURY PREVENTION FEATURE)(DISPO VAN, UNOLOK, PERFEKTUM AND DISPOJEKT)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY, SINGLE USE HYPODERMIC SYRINGE WITHOUT NEEDLE(-)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY., SINGLE USE HYPODERMIC NEEDLE(DISPO VAN, UNOLOK AND DISPOJEKT)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY.,SINGLE USE INTRANASAL SYRINGE(DISPO VAN AND UNOLOK)-IT IS INTENDED TO BE USED FOR DELIVERY OF DRUG THROUGH NASAL CAVITY (NOT FOR INJECTION).,SINGLE USE HYPODERMIC SYRINGE (AUTO DISABLE SYRINGES FOR FIXED-DOSE IMMUNIZATION)(-)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY.,SINGLE USE HYPODERMIC SAFETY NEEDLE WITH SHARP INJURY PREVENTION FEATURE(DISPOJEKT)-IT IS

	INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY. , SINGLE USE IRRIGATION SYRINGE(DISPO VAN AND UNOLOK)-IT IS INTENDED TO BE USED FOR IRRIGATION OF STOMACH, BLADDER ETC.,SINGLE USE HYPODERMIC SYRINGE (AUTO DISABLE SYRINGES FOR FIXED-DOSE IMMUNIZATION)(-)-IT IS INTENDED TO BE USED FOR INJECTION AND/OR ASPIRATION/OR ADMINISTRATION OF FLUIDS INTO OR WITHDRAW FROM BODY.,SINGLE USE INSULIN SYRINGE WITH OR WITHOUT NEEDLE(DISPO VAN, UNOLOK, PERFEKTUM AND DISPOJEKT)-IT IS INTENDED TO BE USED FOR THE INJECTION OF INSULIN FLUIDS IMMEDIATELY AFTER FILLING FOR TREATMENT OF DIABETES.,BLOOD COLLECTION NEEDLE (VAKU-8)-IT IS INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE & HOLDER FOR COLLECTION OF VENOUS BLOOD. ,INTRAVENOUS CANNULA (CATHETER) WITH AND WITHOUT INJECTION PORT (-)-THE IV CANNULA IS INTENDED FOR SHORT TERM ACCESS TO THE PERIPHERAL VEIN FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS.,INTRAVENOUS CANNULA (CATHETER) WITH AND WITHOUT INJECTION PORT (CATHY, CATHULA, KIT KATH, KIT KATH+ AND DISPOCANN)-THE IV CANNULA IS INTENDED FOR SHORT TERM ACCESS TO THE PERIPHERAL VEIN FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS.

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3654	MFG/MD/2020/000308	1.License Holder Name: CARE MEDICAL DEVICES LTD 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:INTRAVENOUS INFUSION SET(CARE)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER OR CANNULAE., HYPODERMIC SYRINGE(CARE)-SYRINGE: THIS DEVICE IS USED FOR INFUSING INTO HUMAN BODY THROUGH A NEEDLE WHICH IS MOUNTED EXTERNALLY ON THE CONE TIP. THIS DEVICE IS USED TO INFUSE MEDICINE OR TO DRAW BLOOD FROM THE HUMAN BODY FOR TESTING.,BLOOD TRANSFUSION SET(CARE)-BLOOD TRANSFUSION SET IS USED IN DELIVERING MEASURED AND REGULATED BLOOD TO PATIENT. BLOOD TRANSFUSION SET IS MADE OF CYLINDRICAL DRIP CHAMBER WITH / WITHOUT VENT PROVIDED WITH FILTER FOR USE WITH BLOOD BAG OR BLOOD BOTTLE RESPECTIVELY. IT HAS EFFICIENT ROLLER CONTROLLER FOR ACCURATE ADJUSTMENT OF TRANSFUSION RATE AND HAS LATEX FLUSH VALVE BALL FOR EXTRA MEDICATION.,IV CANNULA(CARE)-IV CANNULA IS USED AS A MEDICAL DEVICE ON THE PATIENT WHO IS REQUIRED TO BE ADMINISTERED INTRAVENOUS MEDICINES FREQUENTLY,MEASURED VOLUME INFUSION SETS(CARE)-MEASURED VOLUME INFUSION SETS ARE SINGLE USE, STERILE DEVICES WITH A CYLINDRICAL GRADUATED CONTAINER CALLED BURETTE USED TO ADMINISTER MEASURED VOLUME OF INTRAVENOUS FLUIDS/LIQUIDS AND/OR DRUGS/MEDICINE INTO HUMAN CIRCULATORY SYSTEM. THE BURETTE IS USED TO PREPARE COCKTAILS OF DRUGS AND PHYSIOLOGICAL LIQUIDS FOR INFUSION. IT CAN ALSO BE USED FOR ENTERAL OR PARENTERAL FEEDINGS ESPECIALLY IN PEDIATRIC WARD. IT IS USED IN BETWEEN CONTAINERS OF INFUSION SOLUTION & INTRAVENOUS EQUIPMENT.
3655	MFG/MD/2020/000309	1.License Holder Name: J J IMPLANTS 2.Approving Authority: KERALA 3.Device Name(Brand Name)-Intended Use:NEEDLE FREE INJECTION-DENTAL MEDICATION
3656	MFG/MD/2020/000310	1.License Holder Name: SYNERHEAL PHARMACEUTICALS 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:SILICONE GEL(SCAR FIX)-INDICATED FOR THE MANAGEMENT OF OLD AND NEW HYPERTROPHIC AND KELOID SCARS,SILICONE GEL SHEET(SCAR FIX SHEET)-INDICATED FOR THE MANAGEMENT OF OLD AND NEW HYPERTROPHIC AND KELOID SCARS

3657	MFG/MD/2020/000312	1.License Holder Name: SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE SCREWS(GPC BONE SCREWS / BONE SCREWS)-BONE SCREWS ARE USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,ARTHROPLASTY IMPLANTS(GPC-HIPHEAL ARTHROPLASTY IMPLANTS / ARTHROPLASTY IMPLANTS)-ARTHROPLASTY IMPLANTS ARE USED FOR HIP REPLACEMENT SURGERY,SPINAL IMPLANTS(GPC SPINEHEAL - SPINAL IMPLANTS / SPINAL IMPLANTS)-SPINAL IMPLANTS ARE THE MOST COMMONLY USED FOR THE PURPOSE OF VERTEBRAL FIXATION WITH THE AIM OF REDUCING VERTEBRAL MOBILITY AND THUS AVOIDING POSSIBLE DAMAGE TO THE SPINAL CORD AND/OR SPINAL ROOTS.,STAPLES(GPC STAPLES / STAPLES)-STAPLES ARE INDICATED FOR FIXATION OF ARTHRODESIS, OSTEOTOMIES AND FRACTURES IN HAND OR FOOT SURGERY, LOCKING BONE PLATES(GPC-FIXLOCK BONE PLATES / LOCKING BONE PLATES)-THE BONE PLATES ARE THE DEVICES, USED TO FASTEN THE BONES FOR THE PURPOSE OF FIXATION OF FRACTURED BONES,INTRAMEDULLARY INTERLOCKING NAILS(GPC-INTRAHEAL INTRAMEDULLARY INTERLOCKING NAILS / INTRAMEDULLARY INTERLOCKING NAILS)-INTRAMEDULLARY INTERLOCKING NAILS ARE USED TO TREAT FRACTURES OF LONG BONES OF THE BODY.,BONE PLATES(GPC BONE PLATES / BONE PLATES)-THE BONE PLATES ARE THE DEVICES, USED TO FASTEN THE BONES FOR THE PURPOSE OF FIXATION OF FRACTURED,LOCKING HEAD BONE SCREWS(GPC-FIXLOCK / LOCKING HEAD BONE SCREWS)-BONE SCREWS ARE USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,PINS(GPC PINS / PINS)-PINS ARE USED TO STABILIZE THE FRACTURES OF BONES, ARTHROSCOPY(GPC ARTHROSCOPY / ARTHROSCOPY)-ARTHROSCOPY ARE USED FOR KNEE SURGERY,WIRES(GPC WIRES / WIRES)-WIRES ARE MAINLY INDICATED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENTS

3658	MFG/MD/2020/000313	1.License Holder Name: S K SURGICALS 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:ORTHOPEDIC BONE SS PLATE(S. K. SURGICALS)-IT IS USED TO ASSIST IN HEALING OF BROKEN AND FRACTURED BONE,ORTHOPEDIC BONE TITANIUM PLATE(S. K. SURGICALS)-IT IS USED TO ASSIST IN HEALING OF BROKEN AND FRACTURED BONE,ORTHOPEDIC BONE TITANIUM SCREW(S. K. SURGICALS)-THIS SERVES AS SUPPORT FOR THE INTERNAL FIXATION OF BONES,ORTHOPEDIC BONE SS SCREW(S. K. SURGICALS)-THIS SERVES AS SUPPORT FOR THE INTERNAL FIXATION OF BONES
3659	MFG/MD/2020/000314	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT. LTD. 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:SPINAL IMPLANTS (JAYON, OSTRIO)-TO STABILIZE AND STRENGTHEN THE SPINE CONDITIONS INCLUDING SLIPPAGE OF THE SPINE, CHRONIC DEGENERATIVE DISC DISEASE, TRAUMATIC FRACTURE, TUMOR, INFECTIONS AND OTHER FORMS OF SPINAL INSTABILITY INCLUDING SCOLIOSIS.,ARTHROSCOPY , ACL/INTERFERENCE SCREWS(JAYON, OSTRIO)-INTERFERENCE SCREW IS DIRECT TENDON TO TENDON INTERFACE FIXATION DEVICE. IT IS A TYPICAL COMPRESSION FIXATION DEVICE WHICH RELIES ON THE SCREW THREAD TO ENGAGE AND COMPRESS THE GRAFT FOR FIXATION. THIS DEVICE HAS BEEN WIDELY USED WITH ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION (ACL),MAXILLOFACIAL / CRANIAL IMPLANTS, SURGICAL MESH(JAYON, OSTRIO)-SURGICAL MESH IS INTENDED FOR USE IN FIXATION OF THE CRANIAL AND MAXILLOFACIAL BONE, PROCEDURES SUCH AS RECONSTRUCTION, FRACTURE REPAIR, CRANIOTOMIES AND OSTEOTOMIES. SURGICAL MESH ARE AVAILABLE IN STANDARD AND ANATOMICAL SHAPE FORMS

3660	MFG/MD/2020/000315	1.License Holder Name: SPM MEDICARE 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:MEASURED VOLUME I V SET(N/A)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,IV INFUSION SET(N/A)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,EXTENSION SETS(N/A)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATIONS IN MEDICAL APPLICATIONS.,I V FLOW REGULATOR (N/A)-AN I V SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,BLOOD TRANSFUSION SET(N/A)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE INSERTED INTO A VEIN.,INSULIN SYRINGES(N/A)-INSULIN SYRINGE IS USED TO INJECT INSULIN FOR THE TREATMENT OF DIABETES,3 WAY STOP COCK(N/A)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING., STERILE HYPODERMIC SYRINGES FOR SINGLE USE(N/A)-STERILE HYPODERMIC SYRINGES ARE INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,Y-CONNECTOR(N/A)-IT CAN BE USED TO CONNECT TO A PERFUSION SETS OR CATHETER FOR INFUSION OF CONTRAST MEDIA ETC.
3661	MFG/MD/2020/000316	1.License Holder Name: REENAV LOGISTICS PVT LT 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:BONE SCREWS (SECONDARY PACKING / LABELING / STICKERING / OVERPRINTING / STAMPING)(MIRACLUS)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. SCREWS ARE OF DIFFERENT TYPES E.G. CORTICAL SCREWS, CANCELLOUS SCREWS, CANCELLOUS CANNULATED SCREWS, MALLEOLAR SCREWS, LOCKING BOLT, LAG (DHS/DCS) SCREWS, SHERMAN SCREWS, STEFFEE SCREWS, SHAFT SCREWS, PLUG SCREWS.,SPINAL IMPLANTS (SECONDARY PACKING / LABELING / STICKERING / OVERPRINTING / STAMPING)(MIRACLUS)-SPINAL IMPLANTS ARE USED IN THE SURGICAL PROCEDURES RELATED TO THE SPINALINJURIES AND SPINAL DISEASES.

3662	MFG/MD/2020/000317	1.License Holder Name: INCUMED 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:ARTERIAL INTRODUCER SHEATH-THE ARTERIAL INTRODUCER SHEATH IS USED TO GAIN ARTERIAL ACCESS AND FACILITATE THE INSERTION OF CATHETERS OR OTHER EQUIPMENT FOR DIAGNOSTIC AND VASCULAR INTERVENTIONS. CARDIOLOGY AND RADIOLOGICAL APPLICATIONS, AS THE HEMOSTATIC VALVE MINIMIZES THE BACKFLOW OF BLOOD AND THE ASPIRATION OF AIR CAN BE EXCLUDED TO A LARGE DEGREE.
3663	MFG/MD/2020/000318	1.License Holder Name: SWAN MEDICOT LLP 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL(NUAGE)-COTTON WOOL IS MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES, AND AT HOME FOR FIRST AID, ETC. APART FROM MEDICAL PURPOSES, ABSORBENT COTTON IS ALSO USED FOR MAKING THE CONVENTIONAL TYPES OF SANITARY NAPKINS OR PADS., ABSORBENT COTTON WOOL I.P.(NUAGE)-ABSORBENT COTTON WOOL IS MAINLY USED FOR MEDICAL PURPOSE IN HOSPITALS, NURSING HOMES, DISPENSARIES, AND AT HOME FOR FIRST AID ETC. APART FROM MEDICAL PURPOSES, ABSORBENT COTTON IS ALSO USED FOR MAKING CONVENTIONAL TYPES OF SANITARY NAPKINS OR PADS.
3664	MFG/MD/2020/000319	1.License Holder Name: CARE SURGI COT 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P. (FOR DOMESTIC)(- - -)-DRESSING AEROSOL, NON-ADHERENT DRESSING, WOUND & BURN DRESSING, PERIODONTAL KIT, DRESSING PAD, COTTON DRESSING.,ABSORBENT COTTON WOOL B.P. (FOR EXPORT)(- - -)-DRESSING AEROSOL, NON-ADHERENT DRESSING, WOUND & BURN DRESSING, PERIODONTAL, KIT, DRESSING PAD, COTTON DRESSING.

3665	MFG/MD/2020/000321	1.License Holder Name: MICROTROL STERILIZATION SERVICES PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:INITIAL PUNCTURE NEEDLE(NIL)-INITIAL PUNCTURE OF FASCIA,PERCUTANEOUS NEPHROSTOMY CATHATER(PCN) WITH TROCAR,WITH LOCKING MECHANISM,(PIGTAIL&MALECOT(NIL)-USED FOR TEMPORARY PERCUTANEOUS DRAINAGE OF BLADDER AND ABSCESS,FASCIAL DILATOR(NIL)-DILATION OF FASCIA,PERCUTANEOUS NEPHROSTOMY CATHATER SET,PIGTAIL&MALECOT(NIL)-PERCUTANEOUS DRAINAGE OF URINE FROM KIDNEY, BLADDER, NEPHROSTOMY CATHETERS(NIL) -USED FOR PERCUTANEOUS PLACEMENT OF CATHETER IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE,FASCIAL DILATOR SET (NIL)-USED TO DILATE FASCIA,MULTI PURPOSE DRAINAGE CATHATER PIGTAIL, MALECOT & STRAIGHT, WITH TROCAR, WITH LOCKING MECHANISM(NIL)-FOR PERCUTANEOUS DRAINAGE IN VARIOUS DRAINAGE APPLICATIONS IN NEPHROSTOMY, BILIARY AND ABCESS,MULTI PURPOSE DRAINAGE CATHATER SET PIGTAIL, MALECOT&STRAIGHT(NIL)-FOR PERCUTANEOUS DRAINAGE IN VARIOUS DRAINAGE APPLICATION IN NEPHROSTOMY, BILIARY AND ABCESS

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3666	MFG/MD/2020/000322	1.License Holder Name: RUDRAYA HEALTH CARE 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:PLASTER OF PARIS BANDAGE(RD CAST)-A PROSTHETIC AND ORTHOTIC ACCESSORY , INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT ,OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE),OR PROSTHESIS,PLASTER OF PARIS BANDAGE(NEBPLAST PLASTER OF PARIS BANDAGE)-A PROSTHETIC AND ORTHOTIC ACCESSORY, INTENDED FOR MEDICAL PURPOSE TO SUPPORT, PROTECT, OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE),OR PROSTHESIS.,PLASTER OF PARIS BANDAGE (NIL)-A PROSTHETIC AND ORTHOTIC ACCESSORY , INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT ,OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE),OR PROSTHESIS,PLASTER OF PARIS BANDAGE(PROCARE PLASTER OF PARIS BANDAGE)-A PROSTHETIC AND ORTHOTIC ACCESSORY , INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT ,OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE),OR PROSTHESIS,PLASTER OF PARIS BANDAGE(NEELKANTH (PLASTER OF PARIS BANDAGE))-A PROSTHETIC AND ORTHOTIC ACCESSORY , INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT ,OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE),OR PROSTHESIS,PLASTER OF PARIS BANDAGE(SAMPOP PLASTER OF PARIS BANDAGE)-A PROSTHETIC AND ORTHOTIC ACCESSORY, INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT, OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE), OR PROSTHESIS,PLASTER OF PARIS BANDAGE(LASTO POP PLASTER OF PARIS BANDAGE)-A PROSTHETIC AND ORTHOTIC ACCESSORY , INTENDED FOR MEDICAL PURPOSES TO SUPPORT ,PROTECT ,OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE),OR PROSTHESIS

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3667	MFG/MD/2020/000323	1.License Holder Name: ISCON SURGICALS LIMITED 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:STERILE HYPODERMIC NEEDLES FOR SINGLE USE.(PRICON)-THE DEVICE IS USED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, THE BODY.,STERILE HYPODERMIC SYRINGE WITH NEEDLE ATTACHED(PRICON)-HYPODERMIC SYRINGES ARE USED WITH HYPODERMIC NEEDLES TO INJECT LIQUID INTO BODY TISSUES, OR TO WITHDRAW FLUID OR TISSUE FROM THE BODY.,INFUSION EQUIPMENT FOR MEDICAL USE (PRICON)-INFUSION SETS ARE INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS, MEDICATIONS, NUTRITIONAL FLUIDS. , STERILE HYPODERMIC SYRINGE FOR SINGLE USE (PRICON)-HYPODERMIC SYRINGES FOR INSULIN ARE USED WITH HYPODERMIC NEEDLES TO INJECT LIQUID INTO BODY TISSUES. THE NEEDLE ATTACHED TO THE SYRINGE IS HAVE SMALL DIAMETER AND HENCE ARE USED TO ADMINISTER WATERY LIQUIDS LIKE INSULIN.
3668	MFG/MD/2020/000324	1.License Holder Name: ALLWIN MEDICOT PVT.LTD. 2.Approving Authority: NAGPUR DIVISION 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P (ALLWIN MEDICOT)-FOR EXTERNAL USE ,SURGICAL GAMGEE ROLE COTTON(ALLWIN MEDICOT)-AS A SURGICAL DRESSING ,CHLORHEXIDINE WET WIPES (ALLWIN MEDICOT)-AS A SURGICAL AKIN CLEANING AND PERSONAL HYGIENE

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3669	MFG/MD/2021/000002	1.License Holder Name: NUBENO HEALTHCARE PRIVATE LIMITED 2.Approving Authority: NAGPUR DIVISION 3.Device Name(Brand Name)-Intended Use:SCALP VEIN SET-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,SUCTION CATHETER-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION, PRESSURE MONITORING LINE -PRESSURE MONITORING LINE IS STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS / MEDICATIONS IN MEDICAL APPLICATIONS. EXTENSION SET WITH THREE WAY STOPCOCK: IT IS INTENDED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION AND PRESSURE MONITORING,3-WAY STOP COCK -IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING., MUCUS EXTRACTOR-MUCUS EXTRACTOR IS USED TO EXTRACT MUCUS FROM INFANT,RYLE'S TUBE-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,NASAL OXYGEN CANNULA-THE NASAL OXYGEN CANNULA IS USED FOR EASY APPLICATION AND EFFICIENT ADMINISTRATION OF OXYGEN FOR GREATER COMFORT OF PATIENT,HYPODERMIC NEEDLE -INTENDED FOR THE INJECTION OF MEDICATIONS INTO OR THE WITHDRAWAL OF BODY FLUIDS FROM PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN. ,MALE EXTERNAL CATHETER -THE STERILE MALE EXTERNAL CATHETER IS USED IN MALE PATIENT FOR URINE INCONTINENCE FOR DAY AND NIGHT.,MEASURED VOLUME IV SET-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,TRACHEAL (ENDOTRACHEAL) TUBE-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS,EXTENSION SET-EXTENSION SET: EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS / MEDICATIONS IN MEDICAL APPLICATIONS. EXTENSION SET WITH THREE WAY STOPCOCK: IT IS INTENDED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION AND PRESSURE MONITORING.,I.V. CANNULA(NUFIX)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS,

	AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. I.V. CATHETER IS INSERTED INTO THE PATIENT'S VASCULAR SYSTEM FOR SHORT TERM USE (LESS THAN 30 DAYS) TO WITHDRAW BLOOD SAMPLES, MONITOR BLOOD PRESSURE, OR ADMINISTER FLUIDS INTRAVENOUSLY.,BLOOD ADMINISTRATION SET -BLOOD TRANSFUSION SETS ARE SINGLE USE, STERILE DEVICES USED FOR INFUSION OF BLOOD AND BLOOD COMPONENTS. IT IS USED IN BETWEEN CONTAINERS OF BLOOD AND BLOOD COMPONENTS AND INTRAVENOUS EQUIPMENT/MEDICAL DEVICES. ,STOMACH TUBE-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID, FEEDING TUBE-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING,UMBILICAL OCCLUSION DEVICE-THESE DEVICES MAY BE A CLIP, TIE, TAP OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT,INTRAVENOUS INFUSION SET - INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,HYPODERMIC SYRINGES- INTENDED FOR THE INJECTION OF MEDICATIONS INTO OR THE WITHDRAWAL OF BODY FLUIDS FROM PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.,NELATON CATHETER /FOLEY CATHETER -A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY

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3670	MFG/MD/2021/000003	1.License Holder Name: FREEDOM OPTHALMIC PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:MONOFILAMENT POLYPROPYLENE NONABSORBABLE SURGICAL SUTURE U.S.P. (FREEDOM LENE)-FREEDOM LENE SUTURE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,BRAIDED AND COATED POLYGLYCOLIC ACID, FAST ABSORBABLE, ABSORBABLE SURGICAL SUTURE U.S.P. SYNTHETIC (FREEDOM GLYDE-FAST)-SOFT TISSUE APPROXIMATION AND/OR LIGATION,BRAIDED AND COATED POLYGLACTIN (910 FAST ABSORBABLE) ABSORBABLE SURGICAL SUTURE U.S.P. SYNTHETIC (FREEDOM 910 - FAST)-FREEDOM 910 FAST IS AN ABSORBABLE, STERILE, SURGICAL SUTURE, COMPOSED OF A CO-POLYMER, MADE FROM 90% GLYCOLIDE AND 10% LACTIDE, POLYGLACTIN 910. FREEDOM 910 FAST IS COLORED VIOLET WITH D & C VIOLET NO. 2, CONFORMING TO U.S. CODE OF FEDERAL REGULATIONS. FREEDOM 910 FAST IS AVAILABLE AS UNDYED ALSO. FREEDOM 910 FAST IS COATED WITH UNIQUE COMBINATION OF POLYGLACTIN 370 AND CALCIUM STEARATE FOR ADDED LUBRICATION AND SMOOTHNESS. CHARACTERISTIC RAPID LOSS OF STRENGTH IS ACHIEVED BY USE OF A POLYMER MATERIAL WITH LOWER MOLECULAR WEIGHT THAN REGULAR FREEDOM 910., BLACK BRAIDED SILK NON ABSORBABLE SURGICAL SUTURE U.S.P. (FREEDOM SILK)-FREEDOM SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,MONOFILAMENT POLIGLECAPRONE 25 ABSORBABLE SURGICAL SUTURE, SYNTHETIC (FREEDOM GLYDE MONO)-FREEDOM CRYL MONO SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, WHERE AN ABSORBABLE MATERIAL IS INDICATED.,BRAIDED AND COATED POLYESTER NON ABSORBABLE SURGICAL SUTURE U.S.P. (FREEDOM BOND)-FREEDOM BOND INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES AND ALSO FOR THE FIXATION OF SOFT TISSUE TO BONE TISSUE. ,BRAIDED AND COATED POLYGLYCOLIC ACID ABSORBABLE SURGICAL SUTURE U.S.P. SYNTHETIC (FREEDOM GLYDE)-SOFT TISSUE APPROXIMATION AND/OR LIGATION,MONOFILAMENT POLYAMIDE NON ABSORBABLE SURGICAL SUTURE U.S.P. (FREEDOM LON)-FREEDOM LON SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING CARDIOVASCULAR SURGERY,

		NEUROSURGERY AND OPHTHALMIC PROCEDURE INCLUDING MICROSURGERY., BRAIDED AND COATED POLYGLACTIN 910 ABSORBABLE SURGICAL SUTURE U.S.P. SYNTHETIC (FREEDOM 910)-FREEDOM 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO-SURGERY FOR VESSELS, LESS THAN 2 MM DIAMETER. THE SAFETY AND EFFECTIVENESS OF FREEDOM 910 SUTURES IN CARDIOVASCULAR TISSUE HAVE NOT BEEN FULLY ESTABLISHED., MONOFILAMENT POLYDIOXANONE ABSORBABLE SURGICAL SUTURE, SYNTHETIC(FREEDOM PDS)-FREEDOM PDSSUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PAEDIATRIC CARDIOVASCULAR TISSUE, IN MICROSURGERY, AND IN OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE WITH EXTENDED WOUND SUPPORT (UPTO SIX WEEKS) IS DESIRABLE.
3671	MFG/MD/2021/000004	1.License Holder Name: AGRASEN MEDITECH PRIVATE LIMITED 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:GAUZE (ABSORBENT COTTON GAUZE)(-)-THE ABSORBENT GAUZE ARE USED TO CLEANING, DRYING AND DRESSING WOUNDS A MEDICAL TREATMENT ALSO USED TO SUPPORTIVE MATERIAL FOR DRESSING ETC .GAUZE IS PERFECT FOR DELIVERING ANTISEPTICS TO INJURIES, MOISTURE REMOVAL FROM WOUNDS BEFORE THE EXERTION OF A DRESSING ., COTTON BANDAGE (ROLLED BANDAGE)(-)-:THE COTTON BANDAGES ARE USED TO BIND, WRAP OR AS A SUPPORTIVE MATERIAL FOR WOUNDS ,CUTS, BURNS AND IN DRESSING FOR WOUND HEALING PROCESS .

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3672	MFG/MD/2021/000005	1.License Holder Name: PRYMAX HEALTHCARE LLP, 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:HEART LUNG PACK (PRYMAX PERFUSION)-THIS IS COMBINATION OF PVC TUBING, ARTERIAL FILTER AND CONNECTOR AS EXTRACORPOREAL CIRCUIT TO CARRY BLOOD FROM THE PATIENT TO THE HEART LUNG MACHINE/OXYGENATOR. THIS SET IS INTENDED FOR USE DURING SURGERY REQUIRING CARDIOPULMONARY OR SURGICAL TECHNIQUE.THE DEVICE IS SINGLE USE, NON-TOXIC, PYROGEN-FREE & SUPPLIED STERILE. THE DEVICE IS STERILIZED BY ETHYLENE OXIDE. THE LEVEL OF ETHYLENE OXIDE RESIDUALS IN THE DEVICE IS WITHIN THE LIMITS ESTABLISHED BY NATIONAL REGULATIONS IN THE COUNTRY OF USE.,HEMODIALYSIS CATHETER KIT LONG TERM (PRYMAX DIALYSIS)-A DIALYSIS CATHETER IS A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM A HEMODIALYSIS MACHINE AND A PATIENT. IF A PATIENT REQUIRES LONG-TERM DIALYSIS THERAPY, A CHRONIC DIALYSIS CATHETER WILL BE INSERTED. CHRONIC CATHETERS CONTAIN A DACRON CUFF THAT IS TUNNELED BENEATH THE SKIN APPROXIMATELY 3–8 CM.,CENTRAL VENOUS CATHETER KIT(PRYMAX CATHE)-A CENTRAL VENOUS CATHETER IS A THIN, FLEXIBLE TUBE THAT IS INSERTED INTO A VEIN, USUALLY BELOW THE RIGHT COLLARBONE, AND GUIDED (THREADED) INTO A LARGE VEIN ABOVE THE RIGHT SIDE OF THE HEART CALLED THE SUPERIOR VENA CAVA. IT IS USED TO GIVE INTRAVENOUS FLUIDS, BLOOD TRANSFUSIONS, CHEMOTHERAPY, AND OTHER DRUGS, CAUTERY PENCIL(PRYMAX SURG)-CAUTERY PENCIL IS A MEDICAL DEVICE USED TO FULGURATE, COAGULATE, CUT OR DISSECT BIOLOGICAL TISSUE BY THE APPLYING ELECTRIC CURRENT., GUIDEWIRE(PRYMAX ANGI)-GUIDEWIRE FACILITATES PLACEMENT OF A CATHETER DURING DIAGNOSTIC OR INTERVENTIONAL PERIPHERAL INTRAVASCULAR PROCEDURES INCLUDING BUT NOT LIMITED TO RENAL INTERVENTION. THE WIRE CAN BE TORQUED TO FACILITATE NAVIGATION THROUGH THE VASCULATURE.,INTRODUCER SHEATH KIT(PRYMAX ANGI)-INTRODUCER SHEATH SYSTEM IS INTENDED TO PROVIDE ACCESS AND TO FACILITATE PERCUTANEOUS INTRODUCTION OF GUIDE WIRES, CATHETERS AND OTHER DEVICES INTO THE FEMORAL, POPLITEAL AND INFRAPOPLITEAL ARTERIES WHILE MAINTAINING HEMOSTASIS DURING DIAGNOSTIC AND INTERVENTIONAL PROCEDURES

3673	MFG/MD/2021/000006	1.License Holder Name: ROMSONS SCIENTIFIC & SURGICAL PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:HANDHELD NEBULIZER (PORTNEB)-NEBULIZER SYSTEM IS INTENDED TO ADMINISTER DRUG IN AEROSOL FORM TO THE PATIENT THROUGH INHALATION FOR RESPIRATORY DISORDERS,NEBULIZER COMPRESSOR SYSTEM (MICROGEN)-IT IS A DEVICE USED TO ADMINISTER MEDICINE IN THE FORM OF AEROSOL TO INHALE FOR RESPIRATORY DISORDER., NEBULIZER COMPRESSOR MACHINE WITH ACCESSORIES(NIL)-IT IS A DEVICE USED TO ADMINISTER MEDICINE IN THE FORM OF AEROSOL TO INHALE FOR RESPIRATORY DISORDER.,NEBULIZER COMPRESSOR SYSTEM(ANGEL)-IT IS A DEVICE USED TO ADMINISTER MEDICINE IN THE FORM OF AEROSOL TO INHALE FOR RESPIRATORY DISORDER., PORTABLE NEBULIZER SYSTEM(AEROMAC® PLUS+)-IT IS A DEVICE USED TO ADMINISTER MEDICINE IN THE FORM OF AEROSOL TO INHALE FOR RESPIRATORY DISORDER.,NEBULIZER COMPRESSOR SYSTEM(MAXAIR)-IT IS A DEVICE USED TO ADMINISTER MEDICINE IN THE FORM OF AEROSOL TO INHALE FOR RESPIRATORY DISORDER.
3674	MFG/MD/2021/000007	1.License Holder Name: ROMSONS MEDICONS 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:NEBULIZER(AERO MIST)-IT IS DEVICE USED TO ADMINISTER MEDICATIONS IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDERS.,NEBULIZER(MICRO SOL)-IT IS DEVICE USED TO ADMINISTER MEDICATIONS IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDERS.,NEBULIZER (AERO COMFORT)-IT IS DEVICE USED TO ADMINISTER MEDICATIONS IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDERS. NEBULIZER(ANGEL AEROSOL KIT)-IT IS DEVICE USED TO ADMINISTER MEDICATIONS IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDERS.,NEBULIZER MASK AND CHAMBER WITH OR WITHOUT T PIECE AND MOUTH PIECE(NIL)-IT IS DEVICE USED TO ADMINISTER MEDICATIONS IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDERS.,NEBULIZER(ECO NEBULIZER)-IT IS DEVICE USED TO ADMINISTER MEDICATIONS IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDERS.,NEBULIZER(AERO NEB)-IT IS DEVICE USED TO ADMINISTER MEDICATIONS IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDERS.,NEBULIZER(POWER DROOL)-IT IS DEVICE USED TO ADMINISTER MEDICATIONS IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDERS.,NEBULIZER(AERO COMFORT KIT)-IT IS DEVICE USED TO ADMINISTER MEDICATIONS IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDERS.

3675	MFG/MD/2021/000008	1.License Holder Name: MEDTECH LIFE PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NEBULIZER-DEVICE USED TO DELIVER LIQUID MEDICATION IN AEROSOLIZED FORM TO HUMANS THROUGH THE RESPIRATORY SYSTEM GENERALLY USE FOR RESPIRATORY DISTRESS CONDITIONS.

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3676	MFG/MD/2021/000009	1.License Holder Name: STERIMED MEDICAL DEVICES PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use: URETHRAL CATHETER (NATASO)- A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., TRACHEAL (ENDOTRACHEAL) TUBE (ENDOTRACHEAL TUBES CUFFED)(NATASO)-INSERT THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., LEVINE TUBE (LEVIN/STOMACH TUBES CATHETERS)(NATASO)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS, TRACHEOBRONCHIAL SUCTION CATHETER (SUCTION CATHETER) (NATASO)- CLEARING THE AIRWAYS OF MUCUS, PUS OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION., TRACHEOBRONCHIAL SUCTION CATHETER /SUCTION CATHETER (NORMAL)(NATASO)- CLEARING THE AIRWAYS OF MUCUS, PUS OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,FOLEY CATHETER/FOLEY BALLOON CATHETER (3 WAY, SILICONISED)(NATASO)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., TRACHEAL (ENDOTRACHEAL) TUBE/ENDOTRACHEAL TUBES PLAIN (REINFORCED)(NATASO)-INSERT THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., IRRIGATION AND ASPIRATION CATHETER (SALEM SUMP TUBES CATHETERS)(NATASO)-USED FOR INSTILLING FLUID INTO, WITHDRAWING FLUIDS FROM, SPLINTING OR SUPPRESSING BLEEDING OF THE ALIMENTARY TRACT., KEHR'S "T" TUBES CATHETERS(NATASO)-USED FOR SHORT TERM POST-OPERATIVE DRAINAGE OF COMMON BILE DUCT., CLOSED WOUND DRAINAGE TUBE OR SYSTEM (STERIVAC, CLOSED WOUND SUCTION UNIT CATHETERS)(NATASO)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,FOLEY CATHETER/FOLEY BALLOON CATHETER (3 WAY, 100%-SILICON)(NATASO)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., MALE EXTERNAL CATHETER (NATASO)-AN EXTERNAL CATHETER USED FOR URINE IN-CONTINENCY, TRACHEAL (ENDOTRACHEAL) TUBE/ENDOTRACHEAL TUBES CUFFED (WITH

	SUBGLOTTIC SUCTION)(NATASO)-INSERT THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., RECTAL CATHETERS(NATASO)-RECTUM IN ORDER TO RELIEVE FLATULENCE WHICH HAS BEEN CHRONIC AND WHICH HAS NOT BEEN ALLEVIATED BY OTHER METHODS.,FOLEY CATHETER (FOLEY BALLOON CATHETER 100 % SILICONE)(NATASO)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., TRACHEAL (ENDOTRACHEAL) TUBE/ENDOTRACHEAL TUBES PLAIN (PREFORMED/RAE TUBES, SOUTH ORAL/NASAL)(NATASO)-INSERT THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., NASAL OXYGEN CATHETER (OXYGEN CATHETERS)(NATASO)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY., UPPER URINARY TRACT CATHETER (URETERIC CATHETERS) (NATASO)-THE CATHETER TO THE BLADDER AND SUBSEQUENTLY TO THE UPPER URINARY TRACT.,SUCTION TIP AND CATHETER (YANKAUR SUCTION SET CATHETER)(NATASO)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., TRACHEAL (ENDOTRACHEAL) TUBE (ENDOTRACHEAL TUBES CATHETERS)(NATASO)-INSERT THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,TRACHEOSTOMY TUBE/TRACHEAL TUBE TRACHEOSTOMY TUBE CUFFED (FENESTRATED)(NATASO)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION., NELATON CATHETERS (NATASO)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETER/FOLEY BALLOON CATHETER (2 WAY, 100%-SILICON) (NATASO)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., URETHRAL CATHETER/LOTUS CATHETER(NATASO)- A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETER/FOLEY BALLOON CATHETER (2 WAY, SILICONISED)(NATASO)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY

	VIA THE KIDNEY.,TRACHEOSTOMY TUBE/TRACHEAL TUBE TRACHEOSTOMY TUBE CUFFED (REINFORCED)(NATASO)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION., TRACHEOBRONCHIAL SUCTION CATHETER/SUCTION CATHETER (THUMB CONTROL) (NATASO)- CLEARING THE AIRWAYS OF MUCUS, PUS OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION., TRACHEOSTOMY TUBE/TRACHEAL TUBE TRACHEOSTOMY TUBE CUFFED (WITH INNER CANNULA)(NATASO)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION., CLOSED WOUND DRAINAGE TUBE OR SYSTEM (STERIVAC, CLOSED WOUND SUCTION UNIT CATHETERS) (NATASO)-USED FOR CLOSE WOUND DRAINAGE UNDER NEGATIVE PRESSURE WITH THE OPTION TO USE ONE CATHETER OR TWO CATHETERS SIMULTANEOUSLY.,FOLEY CATHETER/FOLEY BALLOON CATHETER (3 WAY, SILICON ELASTOMER COATED)(NATASO)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETERS (FOLEY BALLOON CATHETER 3 WAY)(NATASO)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., TRACHEAL (ENDOTRACHEAL) TUBE/ENDOTRACHEAL TUBES PLAIN (PREFORMED/RAE TUBES, NORTH ORAL/NASAL) (NATASO)-INSERT THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,CONTINUOUS IRRIGATION CATHETER (THORACIC TROCAR CATHETER)(NATASO)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., FEEDING TUBE (INFANT FEEDING TUBES CATHETERS)(NATASO)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,UMBILICAL ARTERY CATHETER (UMBILICAL CATHETER)(NATASO)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS., NASO GASTRIC TUBE/RYLES TUBE (RYLES TUBES CATHETERS)(NATASO)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES., CONTINUOUS

	IRRIGATION CATHETER (THORACIC DRAINAGE CATHETERS)(NATASO) -INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS.,FOLEY CATHETERS (FOLEY BALLOON CATHETER)(NATASO)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., TRACHEOBRONCHIAL SUCTION CATHETER/SUCTION CATHETER (FINGER TIP)(NATASO)- CLEARING THE AIRWAYS OF MUCUS, PUS OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION., TRACHEAL (ENDOTRACHEAL) TUBE/(ENDOTRACHEAL TUBES PLAIN, SILICONISED)(NATASO)-INSERT THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., TRACHEAL (ENDOTRACHEAL) TUBE/ENDOTRACHEAL TUBE CUFFED (REINFORCED)(NATASO)-INSERT THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,FOLEY CATHETER /FOLEY BALLOON CATHETER (2 WAY, SILICONE ELASTOMER COATED)(NATASO)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., TRACHEAL (ENDOTRACHEAL) TUBE/ENDOTRACHEAL TUBES CUFFED (PREFORMED/RAE TUBES, SOUTH ORAL/NASAL) (NATASO)-INSERT THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., CLOSED WOUND DRAINAGE TUBE OR SYSTEM (REDON DRAINAGE CATHETERS) (NATASO)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS., TRACHEOSTOMY TUBE/TRACHEAL TUBE TRACHEOSTOMY TUBE CUFFED (WITH SUBGLOTTIC SUCTION LINE)(NATASO)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,TRACHEOSTOMY TUBE/TRACHEAL TUBE (TRACHEOSTOMY TUBE CATHETER)(NATASO)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,FOLEY CATHETERS (FOLEY BALLOON CATHETER 2 WAY)(NATASO)-RECTUM IN ORDER TO RELIEVE FLATULENCE WHICH HAS BEEN CHRONIC AND WHICH HAS NOT BEEN ALLEVIATED BY OTHER METHODS., URETHRAL CATHETER/MALECOT CATHETER(NATASO)- A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE

		URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.
3677	MFG/MD/2021/000010	1.License Holder Name: CARE-X SURGICOT INDUSTRY 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P. (CARE-X, NIL)-IT IS INTENDED TO USE FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS
3678	MFG/MD/2021/000011	1.License Holder Name: IMAGE ORTHO SURGICAL PVT. LTD., 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE WIRE AND PINS (IMAGE)-THE WIRES AND PINS ARE USED FOR TEMPORARY DEFINITIVE FIXATION IF THE FRACTURE FRAGMENTS ARE SMALL DURING SOME OPERATIONS. AFTER DEFINITIVE FIXATION THEY ARE THEN REMOVED.,BONE SCREW(IMAGE)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. SCREWS ARE OF DIFFERENT TYPES E.G. CORTI CAL SCREWS, CANCELLOUS SCREWS, CANCELLOUS CANNULATED SCREWS, MALLEOLAR SCREWS, LOCKING BOLT, LAG (DHS/DCS) SCREWS, SHERMAN SCREWS, STEFFEE SCREWS, SHAFT SCREWS, PLUG SCREWS.,BONE NAIL(IMAGE)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. NAILS ARE OF DIFFERENT TYPES WHICH USED IN TIBIA, FEMUR, RADIUS, ULNA, FABULA AND HUMOROUS BONES MAINLY.,BONE PLATE (IMAGE)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. BONE PLATES ARE GENERALLY FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,SPINAL IMPLANT(IMAGE)-SPINAL IMPLANTS ARE USED IN THE SURGICAL PROCEDURES RELATED TO THE SPINAL INJURIES AND SPINAL DISEASES.
3679	MFG/MD/2021/000012	1.License Holder Name: OMEX MEDICAL TECHNOLOGY 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE FOLEY BALLOON CATHETER (INFECTION STOP)-IT IS USED TO ASSIST PEOPLE WHO CANNOT URINATE ON THEIR OWN. A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.

3680	MFG/MD/2021/000013	1.License Holder Name: MEDINOVA ENDOSYS 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ENDOSCOPIC LIGATION DEVICE(ENDOXPERT)-ENDOSCOPIC LIGATION DEVICE IS DESIGNED TO BE USED WITH AN ENDOSCOPE TO DELIVER A LIGATION LOOP DESIGNED TO PREVENT OR CONTROL BLEEDING FOLLOWING POLYPECTOMY OF PEDUNCULATED POLYPS.,POLYPECTOMY SNARE (ENDOXPERT)-THIS DEVICE IS USED WITH AN ELECTROSURGICAL UNIT FOR ENDOSCOPIC POLYPECTOMY. POLYPECTOMY SNARES ARE INDICATED FOR ENDOSCOPIC EXCISION OF POLYPS USING MONOPOLAR ELECTROSURGICAL UNIT AND USED FOR RETRIEVAL OF FOREIGN BODY FROM G.I. TRACT ENDOSCOPICALLY,ERCP CANNULA (ENDOXPERT)-ERCP CANNULA IS USED ENDOSCOPICALLY TO OPACIFY THE BILIARY DUCT WITH RADIOPAQUE CONTRAST MATERIAL FOR FLUOROSCOPIC VIEW.,PEG KIT (ENDOXPERT)-PEG KIT IS USED FOR PERCUTANEOUS ENDOSCOPIC GASTROSTOMY PLACEMENT TO PROVIDE INTERNAL NUTRITION TO PATIENT REQUIRING NUTRITIONAL SUPPORT. ,SINGLE STENT INTRODUCER SYSTEM(ENDOXPERT)-SINGLE ACTION STENT INTRODUCER SYSTEM DESIGNED AND MANUFACTURED BY MEDINOVA ENDOSYS. THIS INTRODUCER ENABLES THE STENT TO BE PRE-LOADED ONTO THE DISTAL TIP OF THE GUIDING CATHETER AND PLACED ENDOSCOPICALLY IN ONE STEP. PRIOR TO PASSAGE OF THE STENT, GUIDING CATHETER AND PUSHER TUBE. WIRE GUIDE MUST BE PLACED. A LUVER LOCK FITTING AT THE PROXIMAL END OF THE INTRODUCER ENABLES USER TO ADJUST GUIDING CATHETER LENGTH,REPLACEMENT PEG TUBE(ENDOXPERT)-USED FOR PERCUTANEOUS ENDOSCOPIC GASTROSTOMY PLACEMENT TO PROVIDE ENTERAL NUTRITION TO PATIENT REQUIRING NUTRITIONAL SUPPORT,JEJUNAL FEEDING TUBE(ENDOXPERT)-JEJUNAL FEEDING TUBES ARE FREQUENTLY USED FOR LONG-TERM ENTERAL NUTRITION. SUPPLIED STERILE AND IT IS FOR SINGLE USE.,NEEDLE KNIFE(ENDOXPERT)-NEEDLE KNIFE IS USED FOR PRE-CUT PAPILLOTOMY.,ACHALASIA BALLOON DILATOR(ENDOXPERT)-ACHALASIA BALLOON DILATOR IS USED FOR DILATION OF THE LOWER ESOPHAGEAL SPHINCTER IN PATIENT WITH ACHALASIA, BALLOON DILATOR-MULTISTAGE(ENDOXPERT)-BALLOON DILATOR-MULTISTAGE IS USED TO DILATE STRICTURES OF THE GASTROINTESTINAL TRACT INCLUDING STRICTURES OF THE ESOPHAGUS / COLONIC BILIARY THROUGH THE SCOPE.,STONE RETRIVAL BASKET(ENDOXPERT)-THIS DEVICE IS USED FOR THE ENDOSCOPIC REMOVAL OF BILIARY STONES AND FOREIGN BODIES, SPHINCTEROTOME(ENDOXPERT)-SPHINCTEROTOME IS USED TO PLACED WIRE GUIDE THROUGH THE SCOPE,BILIARY BALLOON

	DILATOR (ENDOXPERT)-BILIARY BALLOON DILATOR IS USED TO DILATE PAPILLA OR BILIARY STRICTURES THROUGH THE SCOPE, ENDOSCOPIC HEMOCLIP (ENDOCLIP) APPLICATOR(ENDOXPERT)-ENDOSCOPIE HEMOCLIP (ENDOCLIP) APPLICATOR IS USED TO MECHANICALLY BIND BLOOD VESSELS.,STONE EXTRACTION BALLOON(ENDOXPERT)-STONE EXTRACTION BALLOON IS USED FOR ENDOSCOPIC EXTRACTION OF BILIARY STONES,BALLOON INFLATION DEVICE(ENDOXPERT)-BALLOON LNFLATION DEVICE IS USED FOR THE INFLATION OF ESOPHAGEAL AND BILIARY AND ACHALASIA DILATION.,ASPIRATION NEEDLE(ENDOXPERT)-ASPIRATION NEEDLE IS USED FOR ENDOSCOPIC ASPIRATION FROM LUNGS AND BRONCHIOLE.,NASO BILIARY DRAINAGE CATHETER(ENDOXPERT)-NASO BILIARY DRAINAGE CATHETER IS USED TO DRAIN BILE FROM OBSTRUCTED BILIARY DUCT THROUGH NASO.,CYSTOSTOME (ENDOXPERT)-CYSTOTOME IS USED TO ELECTRO SURGICALLY CANNULATE THE TRANS GASTRIC OR TRANS DUODENAL WALL AND INTO A PANCREATIC PSEUDO CYST THAT IS VISIBLY BULGING INTO THE GASTROINTESTINAL TRACT.,FOREIGN BODY HOLDER (ENDOXPERT)-THIS DEVICE IS USED TO RETRIEVE SHARP OBJECTS THROUGH THE SCOPE AND TO PREVENT ESOPHAGUS TARE ALSO FOR RETRIEVAL OF FOREIGN BODIES, TISSUE SPECIMENS, STONES OR CALCULI IN ENDOSCOPIC PROCEDURES OF THE GASTROINTESTINAL TRACT.,WIRE GUIDE(ENDOXPERT)-THIS DEVICE IS USED TO ASSIST IN CANNULATION OF THE BILIARY AND PANCREATIC DUCTS AND TO AID IN BRIDGING DIFFICULT STRICTURES DURING ERCP. USE FOR UPPER GI ESOPHAGUS DILATION PROCESS,LOOP BASKET(ENDOXPERT)-THIS DEVICE IS USED TO RETRIEVE EXCISED POLYPS, TISSUE SAMPLES, FOREIGN BODIES AND CALCULI DURING FLEXIBLE AND RIGID ENDOSCOPY PROCEDURES.,STENT PUSHER(ENDOXPERT)-STENT PUSHER IS USED ENDOSCOPICALLY FOR BILIARY STENT PLACEMENT.,BIOPSY FORCEP (ENDOXPERT)-BIOPSY FORCEPS IS USED ENDOSCOPICALLY TO OBTAIN MUCOSAL TISSUE SAMPLES FROM BRONCHIAL TRACT FOR MICROSCOPIC HISTO-PATHOLOGICAL EXAMINATION.,SCLERO THERAPY NEEDLE(ENDOXPERT)-SCLEROTHERAPHY NEEDLES ARE USED FOR INJECTION OF SCLEROTHERAPATIC SOLUTION IN TO ESOPHAGEAL VARICES. ALSO USED FOR INJECTION OF APPROPRIATE MEDICINE INTO THE GASTROINTESTINAL TRACT. SCLEROTHERAPHY NEEDLES ARE DESIGNED TO PROVIDE ACCESS FOR INJECTION THERAPY APPLICATIONS IN ESCOPHAGEAL VARICES AND MAY ALSO BE USED FOR POLYPECTOMY AND ENDOSCOPIC MUCOSAL RESECTION (EMR).,CYTOLOGY BRUSH(ENDOXPERT)-CYTOLOGY BRUSH USED TO COLLECT CELLS FROM THE UPPER AND LOWER GASTROINTESTINAL TRACTS AS WELL AS FROM THE BILIARY

	SYSTEM.,BILIARY DILATOR(ENDOXPERT)-THIS DEVICE IS USED TO DILATE BILIARY STRICTURES. THIS DEVICE IS INDICATED FOR ADULT USE ONLY.,ESOPHAGEL DILATOR(ENDOXPERT)-THIS DEVICE IS USED TO DILATE ESOPHAGEAL STRICTURES OVER PREVIOUSLY PLACED WIRE GUIDE.,MANUAL LITHOTRIPTOR(ENDOXPERT)-MANUAL LITHOTRIPTOR IS USED FOR C.B.D. STONE LITHOTRIPSY,MULTI BAND LIGATOR(ENDOXPERT)-THIS DEVICE IS USED TO ENDOSCOPICALLY LIGATE ESOPHAGEAL VARICES AT OR ABOVE THE GASTROESOPHAGEAL JUNCTION AND COLONIC VARICES OR TO LIGATE INTERNAL HEMORRHOIDS.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3681	MFG/MD/2021/000014	1.License Holder Name: PASECA HEALTHCARE LLP 2.Approving Authority: NORTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:DRESSING WOUND CARE OCCLUSIVE & HYDROCOLLOID FLEXIBLE FOAM PADDING FOR OPTIMUM HEALING(NA)-:HYDROCOLLOID DRESSINGS ARE USED TO TREAT UNINFECTED WOUNDS. DRESSINGS MAY BE USED, UNDER MEDICAL SUPERVISION, EVEN WHERE AEROBIC INFECTION IS PRESENT; THE INFECTION SHOULD BE TREATED APPROPRIATELY. THE DRESSING IS APPLIED TO A CLEANED WOUND. HYDROCOLLOID PATCHES ARE SOMETIMES USED ON THE FACE FOR ACNE.,DRESSING WOUND(NA)-:APPLYING A DRESSING IS A FIRST AID SKILL, ALTHOUGH MANY PEOPLE UNDERTAKE THE PRACTICE WITH NO TRAINING – ESPECIALLY ON MINOR WOUNDS. MODERN DRESSINGS WILL ALMOST ALL COME IN A PREPACKAGED STERILE WRAPPING, DATE CODED TO ENSURE STERILITY. STERILITY IS NECESSARY TO PREVENT INFECTION FROM PATHOGENS RESIDENT WITHIN THE DRESSING.,ENDOSCOPIC CLIP APPLIER(NA)-SURGICAL STAPLER, SILICONE GEL SHEET(NA)-SILICONE GEL SHEETS ARE SOFT WOUND COVERS COMPOSED OF CROSS-LINKED POLYMERS REINFORCED WITH OR BONDED TO MESH OR FABRIC. THESE DRESSINGS CAN BE USED IN THE TREATMENT OF HYPERTROPHIC AND KELOID SCARS TO IMPROVE APPEARANCE, AS WELL AS HELP PREVENT THE FORMATION OF THESE KIND OF SCARS.,SILK TAPE - SILK +NON WOVEN(NA)-ADHESIVE DRESSINGS HAVE A WIDE RANGE OF APPLICATIONS IN MEDICINE – FROM THE ATTACHMENT OF SMALL MEDICAL EQUIPMENT TO THE TREATMENT OF EXTENSIVE WOUNDS. DEPENDING ON NEEDS, YOU CAN CHOOSE ADHESIVE PRODUCTS IN VARIOUS SHAPES AND FORMS, MADE OF VARIOUS MATERIALS, SUCH AS TEXTILES, NONWOVENS, OR FILM. THE SELECTION OF THE RIGHT ADHESIVE IS VERY IMPORTANT – IT SHOULD BE DETERMINED BY THE INTENDED USE OF THE PRODUCT AND THE DESIRED EFFECT. ACRYLIC AND RUBBER ADHESIVES ARE MOST COMMONLY USED GLUES IN MEDICAL ADHESIVE PRODUCTS.,RELOAD FOR ENDOSCOPIC LINEAR CUTTER(NA)-SURGICAL STAPLING,TRANSPARENT FILM DRESSING (NA)-• ACCELERATE THE AUTO-DEBRIDEMENT HELP THE GENERATION OF GRANULATION AND EPIDERMIS. • REDUCE THE PRESSURE, FRICTION AND SHEARING FORCE TO THE AND IMPROVE THE BLOOD SUPPLY. • SCAB WILL NOT OCCUR, DIVISION OF EPITHELIUM CELLS WILL BE ENHANCED AND EASILY MIGRATED, AND THUS HEALING PROCESS WILL BE SHORTENED.,CHITOSAN SURGICAL DRESSING(NA)-CHITOSAN, AS A CATIONIC NATURAL POLYMER, HAS BEEN WIDELY USED AS A TOPICAL DRESSING IN WOUND MANAGEMENT OWING TO ITS HEMOSTATIC, STIMULATION OF HEALING, ANTIMICROBIAL, NONTOXIC, BIOCOMPATIBLE AND

	BIODEGRADABLE PROPERTIES.,DISPOSABLE ENDOSCOPIC LINEAR CUTTER(NA)-SURGICAL STAPLING,OXIDISED REGENERATED CELLULOSE(NA)-NEGATIVE PRESSURE WOUND THERAPY (NPWT) OR ADVANCED WOUND DRESSINGS, SUCH AS OXIDIZED REGENERATED CELLULOSE (ORC)/COLLAGEN/SILVER-ORC DRESSINGS, CAN BE USED TO PROMOTE GRANULATION TISSUE DEVELOPMENT AND STIMULATE WOUND HEALING IN THESE COMPLEX WOUNDS,VACUUM BLOOD COLLECTION TUBE(NA)-THE SAFELOCK DISPOSABLE BLOOD COLLECTION SETS ARE INTENDED TO BE USED WITH VACUUM BLOOD COLLECTION TUBE FOR VENIPUNCTURE TO COLLECT BLOOD SPECIMENS FROM PATIENTS, AND THE SAFETY SHEATH IS DESIGNED TO PREVENT ACCIDENTAL NEEDLESTICKS. THE PROPOSED DEVICES ARE PROVIDED STERILE, SINGLE USE.,TRANSPARENT FILM DRESSING WITH ABSORBENT PAD(NA)-• PROTECT THE WOUND FROM MICROBIAL INVASION. • KEEP WOUND AREA WARM AND MOIST. • ACCELERATE THE GENERATION OF MULTI-ENZYME, INCREASE THE ACTIVATED ABILITY OF GROWTH FACTOR, AND ACCELERATE THE WOUND HEALING.,LINEAR CUTTER(NA)-SURGICAL STAPLING, MICROPOROUS TAPE -PAPER+NON WOVEN(NA)-MICROPOPOROUS TAPE IS FOR SECURING SMALL TO MEDIUM DRESSINGS (ESPECIALLY ON DAMP SKIN), LIGHTWEIGHT TUBING AND OSTOMY APPLIANCES, AS WELL AS TAPING FRAGILE, AT-RISK SKIN OR WHEN REPEATED TAPING IS NEEDED. ,BANDAGE SELF ADHERENT WRAP-COTTON + ADHESIVE(NA)-SELF-ADHERENT WRAP IS INTENDED FOR USE WRAPPING SPLINTS/ARM BOARDS, AS A COMPRESSION DRESSING, AN OVERWRAP FOR UNNA'S BOOT, FOR HOLDING OTHER DRESSINGS, SECURING IVS AND OTHER DEVICES AND WRAPPING LEGS POST-OPERATIVELY,NON WOVEN GELLING FIBER DRESSING(NA)-GELLING FIBER DRESSING IS INTENDED FOR USE IN THE MANAGEMENT OF MODERATE TO HEAVILY EXUDING ACUTE OR CHRONIC WOUNDS INCLUDING: LOWER LEG ULCERS, PRESSURE ULCERS (STAGE II TO IV) AND DIABETIC ULCERS. SURGICAL WOUNDS (E.G. POST-OPERATIVE, WOUNDS LEFT TO HEAL BY SECONDARY INTENT AND DONOR SITES)., POLYMER CLIP(NA)-SURGCIAL STAPLING,TITANIUM CLIP(NA)-SURGICAL CLIP,DRESSING PRE- OP ADHESIVE DRAPE(NA)-:SURGICAL DRAPES ARE FABRICATED FROM EITHER MULTIPLE- OR SINGLE-USE MATERIALS. THERE IS CONSIDERABLE VARIATION IN DESIGN, DRESSING EXTRA THIN WOUND CARE DRESSING(NA)-EXTRA THIN DRESSING CAN BE USED FOR THE MANAGEMENT OF SUPERFICIAL WOUNDS, DRY TO LIGHTLY EXUDATING DERMAL ULCERS, AND POST-OPERATIVE WOUNDS OR AS A PROTECTIVE DRESSING,CIRCULAR STAPLER(NA)-SURGICAL STAPLERS,FOAM DRESSING FOR NEGATIVE PRESSURE(NA)-FOAM NEGATIVE PRESSURE DRESSING IS DESIGNED TO ABSORB MODERATE TO HEAVY EXUDATE ASSOCIATED WITH

	MODERATE-DEEP WOUNDS AND IS CUSTOMIZABLE TO WOUND SIZE., FOAM TAPE-PE FOAM +ADHESIVE(NA)-AN OUTSTANDING DIMENSIONAL STABILITY AND RECOVERY CHARACTERISTIC THAT PROVIDES OPTIMAL CUSHIONING PROTECTION AGAINST IMPACT., HYDROCOLLOID DRESSING WITH FOAM(NA)- HYDROCOLLOID DRESSING, FOAM BACK IS INDICATED FOR THE MANAGEMENT OF PARTIAL- AND FULL-THICKNESS WOUNDS SUCH AS LEG ULCERS AND PRESSURE ULCERS. HELPS MAINTAIN A MOIST WOUND HEALING ENVIRONMENT TO ASSIST IN AUTOLYTIC DEBRIDEMENT AND PROTECT THE WOUND FROM EXTERNAL CONTAMINATION., HYDROGEL DRESSING(NA)-HYDROGEL WOUND DRESSING IS AN ALGINATE HYDROGEL THAT IS INDICATED FOR THE MANAGEMENT OF DIABETIC ULCERS, FOOT ULCERS, IST AND 2UD DEGREE BURNS, PRESSURE ULCERS STAGES I- IV, CUTS AND ABRASIONS., EMERGENCY BANDAGE(NA)-BANDAGES ARE COMMONLY USED TO TREAT MUSCLE SPRAINS AND STRAINS BY REDUCING THE FLOW OF BLOOD TO A PARTICULAR AREA BY THE APPLICATION OF EVEN STABLE PRESSURE WHICH CAN RESTRICT SWELLING AT THE PLACE OF INJURY. BANDAGES ARE ALSO USED TO TREAT BONE FRACTURES.,LINEAR STAPLER(NA)-SURGICAL STAPLING,HIGHLY ABSORBENT NON WOVEN DRESSING WITH FOAM(NA)-HIGHLY ABSORBENT NON WOVEN DRESSING WITH FOAM USE IN THE MANAGEMENT OF LOW TO HIGHLY EXUDATING LEG ULCERS, SKIN TEARS, AND PRESSURE SORES. THE DRESSING CAN ALSO BE USED FOR 2ND DEGREE BURNS, 2ND DEGREE PARTIAL THICKNESS BURNS, DONOR SITES, POST OPERATIVE WOUNDS AND SKIN ABRASIONS., HEMORRHAGE CONTROL PRESSURE WOUND DRESSING(NA)-MILITARY TRAUMA & HAEMORRHAGE CONTROL WOUND DRESSING BASED ON TRADITIONAL FIELD 4-INCH MILITARY PERSONAL FIELD DRESSING, THE EB IS DESIGNED TO TREAT A VARIETY OF WOUNDS, FROM MINOR TO LIFE THREATENING. AS WITH THE ENTIRE EMERGENCY BANDAGE SERIES, THE FCP01 IS THE FIRST TO INCORPORATE A NUMBER OF INNOVATIVE ELEMENTS FOR IMMEDIATE HEMORRHAGE IN PRE-HOSPITAL EMERGENCY SITUATIONS. THE BUILT-IN, PATENTED PRESSURE APPLICATOR CAN APPLY OVER 30 POUNDS OF PRESSURE DIRECTLY TO A WOUND. THE CLOSURE BAR, WHICH SECURES THE WRAPPING LEADER IN A SIMPLE, FAST AND FAMILIAR MOVEMENT, CAN ALSO BE USED TO EXERT ADDITIONAL PRESSURE ON A WOUND SITE. OTHER UNIQUE FEATURES INCLUDE THE STOP & GO RELEASE, PROVIDING CONTROLLED APPLICATION OF THE BANDAGE WITHOUT THE RISK OF UNRAVELLING, AND THE HANDLE LOOP, A -FOLD OF WRAPPING LEADER ADJACENT TO THE BANDAGE PAD THAT ENABLES THE PROPER OPENING AND POSITIONING OF THE BANDAGE PAD ON THE

	WOUND SITE. FOR SELF-APPLICATION, THE HANDLE LOOP FACILITATES CORRECT BANDAGING – EVEN ONE-HANDED. THE BANDAGE IS DOUBLE VACUUM PACKED TO ENSURE ITS INTEGRITY AND STERILITY WHILE TEAR NOTCHES OPPOSITE EACH OTHER ON THE OUTER PACKAGING ENABLE EASY OPENING.,AUTOMATIC CLIP APPLIER(NA)-SURGICAL STAPLER,OXIDISED CELLULOSE(NA)-NEGATIVE PRESSURE WOUND THERAPY (NPWT) OR ADVANCED WOUND DRESSINGS, SUCH AS OXIDIZED REGENERATED CELLULOSE (ORC)/COLLAGEN/SILVER-ORC DRESSINGS, CAN BE USED TO PROMOTE GRANULATION TISSUE DEVELOPMENT AND STIMULATE WOUND HEALING IN THESE COMPLEX WOUNDS,SKIN STAPLER(NA)-THE STAPLE POINTS PENETRATE THE SKIN AND THEN TURN TO FORM A CLOSED STAPLE, WHICH HOLDS THE TISSUE OF THE WOUND LINE TOGETHER. THE SKIN STAPLER SHOULD BE USED FOR SKIN CLOSURE ONLY OF THE EPIDERMIS AND IS NOT INTENDED FOR USE WITHIN THE BODY OR FOR DEEPER LAYERS OF THE CORIUM (DERMIS) OR OTHER CONNECTIVE TISSUE.,NON WOVEN DRESSING WITH ABSORBENT PAD (NA)-PROTECT THE WOUND FROM MICROBIAL INVASION. • KEEP WOUND AREA WARM AND MOIST. • ACCELERATE THE GENERATION OF MULTI-ENZYME, INCREASE THE ACTIVATED ABILITY OF GROWTH FACTOR, AND ACCELERATE THE WOUND HEALING.,TRANSPARENT FILM DRESSING WITH SILVER PAD(NA)-• PROTECT THE WOUND FROM MICROBIAL INVASION. • KIND OF CELLS (E.G. MACROPHAGE, NEUTROPHILE GRANULOCYTE) ARE ACTIVATED IN THE MOIST ENVIRONMENT, AND OTHER MICROORGANISMS IN THE WOUND COULD BE KILLED. • CARBON DIOXIDE OF THE WOUND IS RAISED, IT CAN ACCELERATE GENERATION OF NEW, VASCULAR AND GRANULATION TISSUE,CARTRIDGE FOR LINEAR CUTTER(NA)-SURGICAL STAPLER,TRANSPARENT MEDICATED DRESSING WITH PAD (NA)-A DRESSING IS A STERILE PAD OR COMPRESS APPLIED TO A WOUND TO PROMOTE HEALING AND PROTECT THE. AS THE DRESSING IS TRANSPARENT, WOUND INSPECTION IS POSSIBLE WITHOUT REMOVING THE DRESSING.,DISPOSABLE HAEMORRHOID CIRCULAR STAPLER(NA)-SURGICAL STAPLER,DRESSING POST -OP MEDICATED(NA)-PROVIDE AN ENVIRONMENT FOR MOIST WOUND HEALING. DESICCATION OF A WOUND IS A MAJOR FACTOR IN RETARDING WOUND HEALING AND INCREASING SCARRING. DRESSINGS THAT PREVENT DESICCATION PROVIDE AN OPTIMAL ENVIRONMENT FOR AUTOLYSIS CELL MIGRATION, GRANULATION, AND RE-EPITHELIALIZATION,CALCIUM ALGINATE DRESSING(NA)-PROTECT THE WOUND FROM MICROBIAL INVASION, KEEP WOUND AREA WARM AND MOIST,RELOAD FOR LINEAR STAPLER(NA)-SURGICAL STAPLER,DRESSING WOUND CARE NON ADHESIVE(NA)-IS A MULTIFUNCTIONAL INTERACTIVE DRESSING DESIGNED TO

	DECREASE PERSISTENT AND PROCEDURAL WOUND PAIN AND ODOR WHILE SUPPORTING BRISK WOUND HEALING,FOAM DRESSING(NA)-USE IN THE MANAGEMENT OF LOW TO HIGHLY EXUDATING LEG ULCERS, SKIN TEARS, AND PRESSURE SORES. THE DRESSING CAN ALSO BE USED FOR 2ND DEGREE BURNS, 2ND DEGREE PARTIAL THICKNESS BURNS, DONOR SITES, POST OPERATIVE WOUNDS AND SKIN ABRASIONS.,POLYPROPYLENE MESH (HERNIA MESH)(NA)- IT CAN BE USED AS CURING HIGHLY EXUDATES INFECTED WOUND TENDING TO BE INFECTED. • IT CAN BE USED FOR DIFFICULT HEALING CHRONIC WOUND (SUCH AS DIABETIC FOOT WOUND, VENOUS LEG ULCER AND SO ON). • IT CAN BE FILLED INTO DEEP WOUND TO KEEP IT FROM BEING INFECTED. • IT CAN BE USED AS ANTI-INFECTION MEANS FOR DONATED AND DONATION WOUNDS,DRESSING WOUND CARE(NA)-STEM BLEEDING – TO HELP TO SEAL THE WOUND TO EXPEDITE THE CLOTTING PROCESS; PROTECTION FROM INFECTION – TO DEFEND THE WOUND AGAINST GERMS AND MECHANICAL DAMAGE; ABSORB EXUDATE – TO SOAK UP BLOOD, PLASMA, AND OTHER FLUIDS EXUDED FROM THE WOUND, CONTAINING IT/THEM IN ONE PLACE AND PREVENTING MACERATION;,HYDROCOLLOID DRESSING(NA)-HYDROCOLLOID DRESSINGS ARE USED TO TREAT UNINFECTED WOUNDS. DRESSINGS MAY BE USED, UNDER MEDICAL SUPERVISION, EVEN WHERE AEROBIC INFECTION IS PRESENT; THE INFECTION SHOULD BE TREATED APPROPRIATELY. THE DRESSING IS APPLIED TO A CLEANED WOUND. HYDROCOLLOID PATCHES ARE SOMETIMES USED ON THE FACE FOR ACNE.,NEEDLE FOR VACCUTAINER 21G & 1.5 INCHES(NA)-VACUTAINER NEEDLES. VACUTAINER SINGLE-SAMPLE VETERINARY NEEDLES CAN BE USED FOR SINGLE TUBE SAMPLES. THEY HAVE AN ADVANCED LOW-ANGLE BEVEL DESIGN AND ARE COATED WITH SILICONE, A LOW FRICTION LUBRICANT, ENSURING VERY GENTLE AND SMOOTH VEIN ENTRY. VACUTAINER MULTI-SAMPLE NEEDLES CAN BE USED FOR MULTIPLE TUBE SAMPLES.,TRANSPARENT MEDICATED WOUND(NA)-TRANSPARENT FILM DRESSINGS PROVIDE A MOIST, HEALING ENVIRONMENT; PROMOTE AUTOLYTIC DEBRIDEMENT; PROTECT THE WOUND FROM MECHANICAL TRAUMA AND BACTERIAL INVASION; AND ACT AS A BLISTER ROOF OR “SECOND SKIN.” BECAUSE THEY'RE FLEXIBLE, THESE DRESSINGS CAN CONFORM TO WOUNDS LOCATED IN AWKWARD LOCATIONS SUCH AS THE ELBOW,DISPOSABLE LINEAR STAPLER(NA)-THE LINEAR CUTTING STAPLER IS USED IN ABDOMINAL SURGERY, THORACIC SURGERY, GYNECOLOGY AND PEDIATRIC SURGERY. GENERALLY, THE STAPLER IS USED FOR RESECTION AND TRANSECTION OF ORGANS OR TISSUES.,DRESSING COLLAGEN WOUND MANAGEMENT(NA)-COLLAGEN WOUND DRESSINGS ARE GELS, PADS, PARTICLES, PASTES, POWDERS, SHEETS

	OR ... TYPE I BOVINE COLLAGEN INTENDED FOR THE MANAGEMENT OF MODERATELY TO HEAVILY . COLLAGENS IN LONG AND SHORT POLYPEPTIDES THAT THE BODY CAN USE IMMEDIATELY.,SILICON FOAM DRERSSING(NA)-SILICONE FOAM DRESSING IS DESIGNED FOR MANAGEMENT OF LOW TO HIGHLYEXUDING PARTIAL AND FULL THICKNESS WOUNDS SUCH AS PRESSURE ULCERS, VENOUS LEG ULCERS, NEUROPATHIC ULCERS, ARTERIAL ULCERS, SKIN TEARS, SURGICAL WOUNDS, SUPERFICIAL PARTIAL THICKNESS BURNS AND DONOR SITES.,SILVER ION DRESSING(NA)-SILVER DRESSINGS ARE THE UP-TO-DATE WOUND CARE PRODUCTS INTENDED TO MANAGE BIOBURDEN IN ACUTE AND CHRONIC WOUNDS.THE SILVER IS THEN RELEASED INTO THE WOUND IN ITS IONIC FORM (AG+) WHICH HAS BEEN DEMONSTRATED TO HAVE A BROAD-SPECTRUM ANTIMICROBIAL EFFECT.,DRESSING STERILE(NA)-A DRESSING IS A STERILE PAD OR COMPRESS APPLIED TO A WOUND TO PROMOTE HEALING AND PROTECT THE WOUND FROM FURTHER HARM.. A DRESSING IS DESIGNED TO BE IN DIRECT CONTACT WITH THE WOUND, AS DISTINGUISHED FROM A BANDAGE, WHICH IS MOST OFTEN USED TO HOLD A DRESSING IN PLACE.,ABSORBABLE GELATIN SPONGE B.P (NA)-ABSORBABLE GELATIN SPONGE, IS INDICATED FOR USE IN SURGICAL PROCEDURES (OTHER THAN NEUROLOGICAL, UROLOGICAL AND OPHTHALMOLOGICAL SURGERY) AS AN ADJUNCT TO HEMOSTASIS WHEN CONTROL OF CAPILLARY, VENOUS AND ARTERIOLAR BLEEDING BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS INEFFECTIVE

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3682	MFG/MD/2021/000015	1.License Holder Name: STERICOTT HEALTH CARE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:GAMJEE ROLL(STERIGAM) -GAMJEE HIGHLY ABSORBENT PADDING IS USED FOR WOUND DRESSING, SUPPORT, PADDING,PROTECTION AND INSULATION., ELASTIC ADHESIVE BANDAGE(STERIPLAST)-THE ELASTICADHESIVE BANDAGE PROVIDES COMPRESSION SUPPORT FOR JOINTS DURING HIGH-STRESS SPORT ACTIVITY. THE ADHESIVE ELASTIC BANDAGES HELP TO MINIMIZE SWELLING AND PROVIDE ADDITIONAL SUPPORT AS AN OVERWRAP. ELASTIC ADHESIVE BANDAGE IS USED FOR SUPPORT STRAPPING FRACTURES, MUSCLES INJURIES, ELBOWS, KNEES, SHOULDERS SPECIALLY REQUIRING ELASTICITY,PARAFFIN GAUZE(STERIFFIN)-PARAFFIN GAUZE IS USED FOR PRIMARY WOUND TREATMENT FOR BURNS, SKIN GRAFTS, ULCERS & OTHER INJURIES., ELASTIC ADHESIVE BANDAGE CANNULA FIXATOR(STERIFIX)-IV CANNULA FIXATOR IS USED FOR PROVIDING BREATHABLE AND QUICK FIXATION DRESSING TOSECURE IV CANNULA AND OTHER INTRAMUSCULAR CATHETERS AND PER CUTANEOUS DEVICES TO THE SKIN.,ADHESIVE TAPE(STERITAPE)-PRESSURE-SENSITIVE ADHESIVE TAPE USED IN SECURE DRESSING MATERIALS TO SKIN. EVEN IT IS MAINLY FOR FIXATION OF DRESSINGS ON NORMAL SKIN SECURING OF: TUBES, CATHETERS, PROBES, CANNULAE.,BANDAGE ROLL(STERIBANDAGE)-BANDAGE ROLL IS EXTENSIVELY USED IN HOSPITALS FOR WIPING, PADDING, DRESSING ETC.DURING THE PROCESS OF SURGERY.,ABSORBENT COTTON(STERICOTTON)-ABSORBENT COTTON ROLLS ARE USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES ETC,COMBINE DRESSING(STERIPAD)-COMBINE DRESSINGS ARE SUITABLE FOR USE, EITHER IN DIRECT CONTACT FOR MEDIUM TO HEAVILY EXUDING WOUNDS, OR AS A SECONDARY DRESSING.,ABSORBENT GAUZE (STERIGAUZE)-ABSORBENT GAUZE CLOTH IS EXTENSIVELY USED IN HOSPITALS FOR WIPING, PADDING,DRESSING ETC. DURING THE PROCESS OF SURGERY.,COTTON CREPE BANDAGE(STERICREPE)-COTTON BANDAGES ARE COMMONLY USED TO TREAT MUSCLE SPRAINS AND STRAINS BY REDUCING THE FLOW OF BLOOD TO A PARTICULAR AREA BY THE APPLICATION OF EVEN STABLE PRESSURE WHICH CAN RESTRICT SWELLING AT THE PLACE OF INJURY. COTTON BANDAGES ARE ALSO USED TO TREAT BONE FRACTURES,MICROPORUS TAPE(STERIPOROUS)-MICROPOROUS SURGICAL PAPER TAPE IS THE NON-STERILE SINGLE USE TAPE HAS HYPOALLERGENIC ADHESIVE USED TO HOLD BANDAGE AND OTHER DRESSINGS ONTO A SKIN,PLASTER OF PARIS(STERIPOP)-PLASTER BANDAGES ARE FAST AND PRACTICAL TO USE, SOAKED IN WATER, THE MOISTENED BANDAGE IS APPLIED TO THE LIMB, HARDENING

		RAPIDLY, TO FORM A RESISTANT CASTING, WHICH DOES NOT LOSE SHAPE. MODELLING PLASTERS ARE USED IN ORTHOPAEDICS AS IMPRESSION AND MODELLING COMPOUNDS
3683	MFG/MD/2021/000017	1.License Holder Name: M/S S.K SURGICALS 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON GAUZE-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS,COTTON ROLLED BANDAGE-COTTON ROLL BANDAGE ARE VERY COMMON AND VERY VERSATILE THIN WOVAN AND BREATHABLE FABRIC BANDAGES THAT CAN BE USED TO SECURE ADDRESSING, IN PLACE OR MAY BE PLACED DIRECTLY OVER A WOUND TO KEEP IT CLEAN WHILE ALLOWING AIR TO PENETRATE TO IMPROVE THE HEALING PROCESS, CREPE BANDAGE-THE MEDIUM WEIGH CREPE BANDAGE IS SUITABLE FOR USE AS DRESSING RETENTION. THE HEAVY WEIGHT CREPE BANDAGE IS SUITABLE FOR USE A SUPPORT FOR SPRAINS AND STRAINS IN JOINT AND MUSCLES. IT ALSO WORKS AS A MODERATE COMPRESSION BANDAGE FOR KNEE SWELLING ANKLE SWELLING AND OTHER RELEVANT INJURIES

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3684	MFG/MD/2021/000018	1.License Holder Name: POLY MEDICURE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION IP & ADDITIVE SAGM SOLUTION-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,TRANSFER BAG-:IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION USP & ADDITIVE SOLUTION ADSOL (FOR EXPORT ONLY)-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS., BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION USP (FOR EXPORT ONLY)-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE (CPDA/CPDA-1) SOLUTION IP-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION USP FOR UMBILICAL CORD BLOOD (FOR EXPORT ONLY)-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION IP & ADDITIVE SAGM II SOLUTION-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE (CPDA/CPDA-1) SOLUTION IP WITH LEUKOCYTE FILTER-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS., BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION IP FOR UMBILICAL CORD BLOOD-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE (CPDA/CPDA-1) SOLUTION IP & ADDITIVE SAGM SOLUTION WITH LEUKOCYTE FILTER-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE (CPDA/CPDA-1) SOLUTION USP & ADDITIVE SAGM SOLUTION WITH LEUKOCYTE FILTER (FOR EXPORT ONLY)-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION IP & ADDITIVE SOLUTION ADSOL-IT IS INDICATED FOR THE

	COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION USP & ADDITIVE SAGM SOLUTION (FOR EXPORT ONLY)-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION USP & ADDITIVE SAGM SOLUTION WITH LEUKOCYTE FILTER (FOR EXPORT ONLY)-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE (CPDA/CPDA-1) SOLUTION USP WITH LEUKOCYTE FILTER (FOR EXPORT ONLY)-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS., BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION IP & ADDITIVE SAGM SOLUTION WITH LEUKOCYTE FILTER-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION IP-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE (CPDA/CPDA-1) SOLUTION USP (FOR EXPORT ONLY)-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE (CPDA/CPDA-1) SOLUTION IP & ADDITIVE SAGM SOLUTION-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS., BLOOD BAG WITH ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP ACD SOLUTION (A) (FOR EXPORT ONLY)-FOR USE WITH AUTOMATED PHERESIS EQUIPMENT IN APHERESIS PROCEDURES, TO PREVENT PLATELET ACTIVATION AND COAGULATION AS BLOOD MOVES THROUGHOUT THE EXTRACORPOREAL UNIT (TUBING SET) IN AN APHERESIS PROCEDURE.,BLOOD BAG WITH ANTICOAGULANT CITRATE DEXTROSE SOLUTION IP, ACD SOLUTION (A)-FOR USE WITH AUTOMATED PHERESIS EQUIPMENT IN APHERESIS PROCEDURES, TO PREVENT PLATELET ACTIVATION AND COAGULATION AS BLOOD MOVES THROUGHOUT THE EXTRACORPOREAL UNIT (TUBING SET) IN AN APHERESIS PROCEDURE.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE (CPDA/CPDA-1) SOLUTION USP & ADDITIVE SAGM SOLUTION (FOR EXPORT ONLY)-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION

	USP ADDITIVE SAGM-II SOLUTION (FOR EXPORT ONLY)-IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF HUMAN BLOOD AND BLOOD COMPONENTS.,BLOOD BAG WITH LEUKOCYTE FILTER (LAB SIDE)-:IT IS INDICATED FOR THE COLLECTION AND PRESERVATION OF LEUKO-DEPLETED HUMAN BLOOD AND BLOOD COMPONENTS.,LEUKOCYTE FILTER (BED SIDE)-IT IS INDICATED FOR THE COLLECTION AND TRANSFUSION OF LEUKO-DEPLETED HUMAN BLOOD AND BLOOD COMPONENTS.

3685	MFG/MD/2021/000019	1.License Holder Name: M/S ROMSONS INTERNATIONAL 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SET(EXXACTA)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION , WITHDRAWAL OF FLUID AND PRESSURE MONITORING .,INFUSION SET NON VENTED(RMS)-INFUSION SET NON VENTED IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,IV FLOW REGULATOR(ROTA FLO)-AN IV SYSTEM AND ADMINSTRATIVE DEVICE OFFERING PRECISION CARE AND CONSISTANT DELIVERY,INTRAVENOUS CANNULA(TRIFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND /OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,NEEDLE FREE CONNECTOR(SAFSITE)-SAF SITE IS STERILE, SINGLE USE DEVICE. IT IS A NEEDLE FREE INTRAVENOUS CONNECTOR GETS ATTACHED TO MALE PORT OF I.V. LINE FOR DIRECT ACCESS / ADMINISTRATION, FEEDING TUBE(INFANT FEEDING TUBE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING.,FEEDING TUBE(FEEDY)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING., EXTENSION SETS(PM-O-LINE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUID/ MEDICATIONS IN MEDICAL APPLICATIONS,INTRAVENOUS CANNULA(MICRON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND /OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,EXTENSION SETS (VEIN-O-LINE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUID/ MEDICATIONS IN MEDICAL APPLICATIONS,MEASURED VOLUME IV SET(VOLUMETRIC SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,I.V. CANNULA WITH OUT INJECTION PORT & WING-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND /OR BLOOD COMPONENTS , OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INTRA VENOUS CANNULA(INTRAVEIN)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND /OR BLOOD COMPONENTS , OR TO FACILITATE THE PLACEMENT OF

	VASCULAR ACCESS DEVICES.,INFUSION SET VENTED(STERI FLO)-INFUSION SET VENTED IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,INFUSION SET VENTED-INFUSION SET VENTED IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., EXTENSION TUBE-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUID/ MEDICATIONS IN MEDICAL APPLICATIONS,EXTENSION SETS-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUID/ MEDICATIONS IN MEDICAL APPLICATIONS,3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SET(BI VALVE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION , WITHDRAWAL OF FLUID AND PRESSURE MONITORING .,MEASURED VOLUME IV SET(BURETTA)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,HEPARIN CAP(HEP - CAP)-HEP CAP IS STERILE, SINGLE USE DEVICE. INTENDED FOR HEPARIN FLUSH BY ATTACHMENT TO THE LUER CONNECTOR OF THE INTRAVENOUS, INFUSION SET VENTED(MICROPERF)-INFUSION SET VENTED IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,I.V. CANNULA WITH WING & THREE WAY STOP COCK-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND /OR BLOOD COMPONENTS , OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INTRAVENOUS CANNULA(VENNULA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND /OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INFUSION SET VENTED(ROMOTROL)-INFUSION SET VENTED IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. , FOLEY CATHETER(SILKO CATH)-A LONG , SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER , EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,INFUSION SET VENTED(RMS)-INFUSION SET VENTED IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INFUSION SET NON VENTED-INFUSION SET NON VENTED IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INTRAVENOUS

	CANNULA(NEOCARE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND /OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,MEASURED VOLUME IV SET(VOLUFIX)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,INFUSION SET VENTED(INFLOW SET)-INFUSION SET VENTED IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INTRAVENOUS CANNULA(INTRAFLON)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND /OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,INFUSION SET VENTED(INFLOW SET)-INFUSION SET VENTED IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,FOLEY CATHETER-A LONG , SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER , EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,INTRAVENOUS CANNULA(VENESAFE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND /OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,THREE WAY STOPCOCK-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINSTRATION OF SOLUTION , WITHDRAWAL OF FLUID AND PRESSURE MONITORING .,INTRAVENOUS CANNULA(NEO-CATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND /OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,EXTENSION SETS (EXTEENA)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUID/ MEDICATIONS IN MEDICAL APPLICATIONS,I. V. CANNULA WITHOUT INJECTION PORT & WITH WING-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND /OR BLOOD COMPONENTS , OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SUCTION TIP AND CATHETER-SUCTION CATHETER FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING, INFUSION SET VENTED(TRANS FLOW)-INFUSION SET VENTED IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,I.V. CANNULA WITH INJECTION PORT & WING-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND /OR BLOOD COMPONENTS , OR TO FACILITATE THE PLACEMENT

	OF VASCULAR ACCESS DEVICES.,INFUSION SET VENTED(STERI SET)-INFUSION SET VENTED IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,EXTENSION SETS(HI-LINE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUID/ MEDICATIONS IN MEDICAL APPLICATIONS,EXTENSION LINE-EXTENSION LINE ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUID/ MEDICATIONS IN MEDICAL APPLICATIONS,FOLEY CATHETER(FOLEY TRAC)-A LONG , SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER , EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,INFUSION SET VENTED(INTRA FLOW -AS)-INFUSION SET VENTED IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. , INTRAVENOUS CANNULA(INTRA CATH-2)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND /OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,SUCTION CATHETER(SUCTION CATHETER)-SUCTION CATHETER FEATURE A WHISTLE TIP AND A THUMB CONTROLPORT FOR PRECISE AND ACCURATE SUCTIONING, FOLEY CATHETER(URO CATH)-A LONG , SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER , EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MINISTRY OF HEALTH, GOVERNMENT OF INDIA सत्यमेव जयते

3686	MFG/MD/2021/000020	1.License Holder Name: SHARMA SURGICAL AND ENGINEERING PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:INTRAMEDULLARY NAIL ((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-INDICATIONS FOR INTERLOCKING INTRAMEDULLARY NAILS INCLUDE SIMPLE LONG BONE FRACTURES (HUMERUS, FEMUR AND TIBIA) SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NON UNIONS AND MALUNIONS; POLYTRAUMA AND MULTIPLE FRACTURES; PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES; RECONSTRUCTION, FOLLOWING TUMOR RESECTION AND GRAFTING; SUPRACONDYLAR FRACTURES; BONE LENGTHENING AND SHORTENING. INTERLOCKING INTRAMEDULLARY NAILS ARE INDICATED FOR FIXATION OF FRACTURES THAT OCCUR IN AND BETWEEN THE PROXIMAL AND DISTAL THIRD OF LONG BONES BEING TREATED.,INTRAMEDULLARY NAIL((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-INDICATIONS FOR INTERLOCKING INTRAMEDULLARY NAILS INCLUDE SIMPLE LONG BONE FRACTURES (HUMERUS, FEMUR AND TIBIA) SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NON UNIONS AND MALUNIONS; POLYTRAUMA AND MULTIPLE FRACTURES; PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES; RECONSTRUCTION, FOLLOWING TUMOR RESECTION AND GRAFTING; SUPRACONDYLAR FRACTURES; BONE LENGTHENING AND SHORTENING. INTERLOCKING INTRAMEDULLARY NAILS ARE INDICATED FOR FIXATION OF FRACTURES THAT OCCUR IN AND BETWEEN THE PROXIMAL AND DISTAL THIRD OF LONG BONES BEING TREATED.,ARTHROSCOPY IMPLANTS((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-ARTHROSCOPY IMPLANTS ARE INTENDED FOR USE IN FIXATION OF SEMITENDINOUS AND/OR GRACILE TENDON GRAFTS. ACL/PCL SCREW IS INTENDED FOR USE IN ANTERIOR/POSTERIOR CRUCIATE LIGAMENT (ACLPCL) RECONSTRUCTION PROCEDURES. ACL/PCL SCREW IS INDICATED FOR FIXATION OF BONE-PATELLAR TENDON- BONE GRAFT TO THE FEMORAL/ TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION, FIXATION OF THE SOFT TISSUE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION AND RECONSTRUCTION OF POSTERIOR CRUCIATE LIGAMENT (PCL)., SPINAL IMPLANTS((1) SSEPL SHARMA SURGICAL (2) PUSHP (3)

	STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-SPINAL IMPLANTS ARE INTENDED TO BE USED AS A TEMPORARY CONSTRUCT THAT ASSISTS NORMAL HEALING AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES. THEY ARE INTENDED TO STABILIZE THE SPINAL OPERATIVE SITE DURING FUSION PROCEDURES AND SHOULD BE REMOVED AFTER FUSION., LOCKING PLATE AND BONE PLATE((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-PLATES ARE INDICATED FOR USE IN FIXATION OF VARIOUS FRACTURED BONES BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING.,BOLTS AND SCREWS((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-FRACTURE FIXATION DEVICES ARE AVAILABLE IN MANY SHAPE AND SIZES. THESE ARE USED ONLY AS AN AID TO HEALING; THEY ARE NOT A SUBSTITUTE FOR NORMAL INTACT TISSUE OR BONE. THE ANATOMY OF HUMAN BONES PRESENTS LIMITATIONS WITH RESPECT TO THE SIZE OR THICKNESS OF IMPLANTS AND THUS ITS STRENGTH IS LIMITED. FULL WEIGHT BEARING PRIOR TO COMPLETE BONE HEALING IS CONTRAINDICATED. WITH REPEATED STRESS IN PATIENTS WITH DELAYED HEALING OR NONUNION, THE APPLIANCE WILL INEVITABLY BEND, BREAK OR PULL OUT OF BONE.,ARTHROSCOPY IMPLANTS((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-ARTHROSCOPY IMPLANTS ARE INTENDED FOR USE IN FIXATION OF SEMITENDINOUS AND/OR GRACILE TENDON GRAFTS. ACL/PCL SCREW IS INTENDED FOR USE IN ANTERIOR/POSTERIOR CRUCIATE LIGAMENT (ACLPCL) RECONSTRUCTION PROCEDURES. ACL/PCL SCREW IS INDICATED FOR FIXATION OF BONE-PATELLAR TENDON- BONE GRAFT TO THE FEMORAL/ TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION, FIXATION OF THE SOFT TISSUE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION AND RECONSTRUCTION OF POSTERIOR CRUCIATE LIGAMENT (PCL)., LOCKING PLATE AND BONE PLATE((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-PLATES ARE INDICATED FOR USE IN FIXATION OF VARIOUS FRACTURED BONES BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING.,PINS AND WIRES((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC

	IMPLANTS)-INDICATIONS FOR PINS AND WIRES INCLUDE FIXATION OF BONE FRACTURES, BONE RECONSTRUCTIONS, AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS AND IMPLANTED THROUGH THE SKIN FOR TRACTION APPLIED TO THE SKELETAL SYSTEM.,PINS AND WIRES((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-INDICATIONS FOR PINS AND WIRES INCLUDE FIXATION OF BONE FRACTURES, BONE RECONSTRUCTIONS, AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS AND IMPLANTED THROUGH THE SKIN FOR TRACTION APPLIED TO THE SKELETAL SYSTEM.,BOLTS AND SCREWS((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-FRACTURE FIXATION DEVICES ARE AVAILABLE IN MANY SHAPE AND SIZES. THESE ARE USED ONLY AS AN AID TO HEALING; THEY ARE NOT A SUBSTITUTE FOR NORMAL INTACT TISSUE OR BONE. THE ANATOMY OF HUMAN BONES PRESENTS LIMITATIONS WITH RESPECT TO THE SIZE OR THICKNESS OF IMPLANTS AND THUS ITS STRENGTH IS LIMITED. FULL WEIGHT BEARING PRIOR TO COMPLETE BONE HEALING IS CONTRAINDICATED. WITH REPEATED STRESS IN PATIENTS WITH DELAYED HEALING OR NONUNION, THE APPLIANCE WILL INEVITABLY BEND, BREAK OR PULL OUT OF BONE.,SPINAL IMPLANTS((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-SPINAL IMPLANTS ARE INTENDED TO BE USED AS A TEMPORARY CONSTRUCT THAT ASSISTS NORMAL HEALING AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES. THEY ARE INTENDED TO STABILIZE THE SPINAL OPERATIVE SITE DURING FUSION PROCEDURES AND SHOULD BE REMOVED AFTER FUSION.,LOCKING PLATE AND BONE PLATE((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-PLATES ARE INDICATED FOR USE IN FIXATION OF VARIOUS FRACTURED BONES BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. THE INTENDED USE OF THESE IMPLANTS IS TO DRAW TWO OR MORE ALIGNED BONE FRAGMENTS TOGETHER TO FACILITATE HEALING.,PINS AND WIRES((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-INDICATIONS FOR PINS AND WIRES INCLUDE FIXATION OF BONE FRACTURES, BONE RECONSTRUCTIONS, AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS AND IMPLANTED THROUGH THE SKIN FOR TRACTION APPLIED TO THE SKELETAL SYSTEM., INTRAMEDULLARY NAIL((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-INDICATIONS FOR INTERLOCKING INTRAMEDULLARY NAILS INCLUDE SIMPLE LONG BONE FRACTURES (HUMERUS, FEMUR AND TIBIA) SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL

	FRACTURES; NON UNIONS AND MALUNIONS; POLYTRAUMA AND MULTIPLE FRACTURES; PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES; RECONSTRUCTION, FOLLOWING TUMOR RESECTION AND GRAFTING; SUPRACONDYLAR FRACTURES; BONE LENGTHENING AND SHORTENING. INTERLOCKING INTRAMEDULLARY NAILS ARE INDICATED FOR FIXATION OF FRACTURES THAT OCCUR IN AND BETWEEN THE PROXIMAL AND DISTAL THIRD OF LONG BONES BEING TREATED.,BOLTS AND SCREWS((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-FRACTURE FIXATION DEVICES ARE AVAILABLE IN MANY SHAPE AND SIZES. THESE ARE USED ONLY AS AN AID TO HEALING. THEY ARE NOT A SUBSTITUTE FOR NORMAL INTACT TISSUE OR BONE. THE ANATOMY OF HUMAN BONES PRESENTS LIMITATIONS WITH RESPECT TO THE SIZE OR THICKNESS OF IMPLANTS AND THUS ITS STRENGTH IS LIMITED. FULL WEIGHT BEARING PRIOR TO COMPLETE BONE HEALING IS CONTRAINDICATED. WITH REPEATED STRESS IN PATIENTS WITH DELAYED HEALING OR NONUNION, THE APPLIANCE WILL INEVITABLY BEND, BREAK OR PULL OUT OF BONE., ARTHROSCOPY IMPLANTS((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-ARTHROSCOPY IMPLANTS ARE INTENDED FOR USE IN FIXATION OF SEMITENDINOUS AND/OR GRACILE TENDON GRAFTS. ACL/PCL SCREW IS INTENDED FOR USE IN ANTERIOR/POSTERIOR CRUCIATE LIGAMENT (ACLPCL) RECONSTRUCTION PROCEDURES. ACL/PCL SCREW IS INDICATED FOR FIXATION OF BONE-PATELLAR TENDON-BONE GRAFT TO THE FEMORAL/ TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION, FIXATION OF THE SOFT TISSUE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION AND RECONSTRUCTION OF POSTERIOR CRUCIATE LIGAMENT (PCL)., SPINAL IMPLANTS((1) SSEPL SHARMA SURGICAL (2) PUSHP (3) STRIGEN (4) SHARMA SURGICALORTHOPEDIC IMPLANTS)-SPINAL IMPLANTS ARE INTENDED TO BE USED AS A TEMPORARY CONSTRUCT THAT ASSISTS NORMAL HEALING AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES. THEY ARE INTENDED TO STABILIZE THE SPINAL OPERATIVE SITE DURING FUSION PROCEDURES AND SHOULD BE REMOVED AFTER FUSION.

3687	MFG/MD/2021/000021	1.License Holder Name: CAREGROUP SIGHT SOLUTION PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:FOLDABLE HYDROPHOBIC INTRAOCULAR LENS (STERILE)(NIL)-INTRAOCULAR LENS IS INTENDED TO USE AS AN IMPLANT FOR REPLACEMENT OF CATARACT LENS FOR VISUAL CORRECTION OF APHAKIA IN CATARACT PATIENT ABOVE 18 YEARS.,:SINGLE PIECE PMMA INTRAOCULAR LENS (STERILE)(NIL)-INTRAOCULAR LENS IS INTENDED TO USE AS AN IMPLANT FOR REPLACEMENT OF CATARACT LENS FOR VISUAL CORRECTION OF APHAKIA IN CATARACT PATIENT ABOVE 18 YEARS.,FOLDABLE HYDROPHILIC ACRYLIC INTRAOCULAR LENS (STERILE)(NIL)-INTRAOCULAR LENS IS INTENDED TO USE AS AN IMPLANT FOR REPLACEMENT OF CATARACT LENS FOR VISUAL CORRECTION OF APHAKIA IN CATARACT PATIENT ABOVE 18 YEARS.

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3688	MFG/MD/2021/000022	1.License Holder Name: UMA SURGICALS 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NAILS, PINS AND WIRES (SAME AS MODEL NAME.)-NAILS ARE USUALLY USED FOR THE FRACTURE OF LONG BONES LIKE THE FEMUR, HUMERUS, TIBIA ETC. THE PURPOSE OF NAILS IS TO IMMOBILIZE THE BONE IN THE CORRECT ALIGNMENT SO THAT THE BONE ENDS DO NOT OVERLAP. THE WIRES ARE FLEXIBLE AND EASY TO BEND AND ARE USUALLY USED IN THE FRACTURES OF THOSE BONES WHERE WEIGHT LOADING IS MINIMAL. PINS ARE USED TO CORRECT SOFT TISSUE DAMAGE AND MINIMAL BONE FRACTURES. THE PURPOSE OF PINS IS THAT IT PROVIDES PROVISIONAL INTERNAL FIXATION.,BONE PLATES(SAME AS MODEL NAME.)-BONE PLATES ARE LIKE INTERNAL SPLINTS HOLDING TOGETHER THE FRACTURED ENDS OF BONE. A BONE PLATE HAS TWO FUNCTIONS. IT TRANSMITS FORCES FROM ONE END OF THE BONE TO THE OTHER, BYPASSING AND THUS PROTECTING THE AREA OF FRACTURES. IT ALSO HOLDS THE FRACTURE ENDS TOGETHER WHILE MAINTAINING PROPER ALIGNMENT OF THE FRAGMENTS THROUGHOUT THE HEALING PROCESS,SPINE IMPLANTS(SAME AS MODEL NAME.)-SPINAL IMPLANTS ARE USED TO STABILIZE THE UNSTABLE SPINE CAUSED BY TRAUMA OR BY SLIPPED VERTEBRAE (SPONDYLOLISTHESIS) ORIGINATING FROM DEGENERATIVE INTERVERTEBRAL DISKS.,BONE SCREW(SAME AS MODEL NAME.)-BONE PLATES & SCREW CONSTRUCT IS LIKE INTERNAL SPLINTS HOLDING TOGETHER THE FRACTURED ENDS OF BONE. SCREWS CAN BE USED WITH INTRAMEDULLARY NAILS AS WELL TO LOCK THEM IN BONE.,ENDO PROSTHESIS REPLACEMENT(SAME AS MODEL NAME.)-IN ORTHOPEDICS AND TRAUMA SURGERY, ENDOPROSTHESIS IS A PROCEDURE FOR REPLACING A JOINT IN THE BODY THAT HAS LOST ITS FUNCTIONALITY EITHER THROUGH INJURY OR DISEASE IN PART OR WHOLE WITH AN IMPLANT. COMMON INDICATORS FOR THE USE OF ENDOPROSTHESIS INCLUDE DEGENERATIVE JOINT CONDITIONS, FRACTURES AND TUMORS.

3689	MFG/MD/2021/000024	1.License Holder Name: ALPHA MEDICARE AND DEVICES PVT LTD UNIT-II 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:NON STERILE MICROPOROUS PAPER TAPE FOR EXPORT ONLY(ALPHA)-DRESSING AEROSOL, NON-ADHERENT, DRESSING, PERIODONTAL, KIT, DRESSING PAD, DRESSING,STERILE GAUSE SWAB B.P.(ALPHA GAUZE SWAB)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,MICROPOROUS PAPER TAPE(ALPHA)-DRESSING AEROSOL, NON-ADHERENT, DRESSING, PERIODONTAL, KIT, DRESSING PAD, DRESSING,ELASTIC ADHESIVE BANDAGE(SUPER PLAST ADHESIVE BANDAGE)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,X RAY DETECTABLE ABDOMINAL PAD - STERILE FOR SINGLE USE ONLY(- - -)-IT IS INTENDED FOR THE USE DURING VARIOUS SURGERIES.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(GRAVITY INFUSION SET)-:TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE GAUSE SWAB B.P. FOR EXPORT ONLY(ALPHA GAUZE SWAB)-GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,STERILE DISPOSABLE UMBILICAL OCCLUSION DEVICE FOR SINGLE USE ONLY(ALPHA UMBILICAL CORD CLAMP)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE DISPOSABLE UMBILICAL OCCLUSION DEVICE FOR SINGLE USE ONLY FOR EXPORT ONLY (ALPHA UMBILICAL CORD CLAMP)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,NON STERILE I.V. CANNULA FIXATOR FOR SINGLE USE ONLY(SUPERFIX CANNULA FIXATOR)-DRESSING AEROSOL, NON-ADHERENT, DRESSING, PERIODONTAL, KIT, DRESSING PAD, DRESSING.,NON STERILE I.V. CANNULA FIXATOR FOR SINGLE USE ONLY FOR EXPORT(CANNUFIX)-DRESSING AEROSOL, NON-ADHERENT, DRESSING, PERIODONTAL, KIT, DRESSING PAD, DRESSING,NON STERILE I.V. CANNULA FIXATOR FOR SINGLE USE ONLY FOR EXPORT ONLY(SUPERFIX CANNULA FIXATOR)-IT IS INTENDED FOR THE USE DURING VARIOUS SURGERIES.,NON STERILE I.V. CANNULA FIXATOR FOR SINGLE USE ONLY(CANNUFIX)-DRESSING AEROSOL, NON-ADHERENT, DRESSING, PERIODONTAL, KIT, DRESSING PAD, DRESSING.

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3690	MFG/MD/2021/000025	1.License Holder Name: ALPHA MEDICARE & DEVICES PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(CALIBER MEASURED VOLUME SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,STERILE INFANT FEEDING TUBE FOR SINGLE USE ONLY(ALPHA INFANT FEEDING TUBE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(SHARP DUAL INFUSION SET)-INTENDED USE:TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(ALPHA BLOOD ADMINISTRATION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE INTRA VENOUS CANNULAE FOR SINGLE USE ONLY(ALPHA-FLOW INTRA VENOUS CANNULAE)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES, STERILE TRACHEOBRONCHIAL SUCTION CATHETER WITH THUMB CONTROL FOR SINGLE USE ONLY(ALPHA SUCTION CATHTER)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING..,STERILE DISPOSABLE SCALP VEIN SET FOR SINGLE USE ONLY (ALPHA SCALP VEIN SET)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD ,STERILE DISPOSABLE INTRA VENOUS CANNULA FOR SINGLE USE ONLY (FOR EXPORT ONLY)(CRYSO-MED)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY (ALPHA SUCTION CATHETER)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (FOR EXPORT ONLY)(CRYSO-MED)-IT IS INTENDED

	FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(SHARP BLOOD TRANSFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE SPINAL NEEDLE FOR SINGLE USE ONLY(ALPHA SPINAL NEEDLE)-INTENDED FOR TRANSIENT DELIVERY OF ANASTHETICS TO PROVIDE REGIONAL ANESTHESIA OR TO FACILITATE PLACEMENT OF AN EPIDURAL CATHETER ,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(SHARP VENTED INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE INFANT MUCUS EXTRACTOR FOR SINGLE USE ONLY (FOR EXPORT ONLY) (CRYSO-MED)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,STERILE DISPOSABLE FLOW REGULATOR WITH EXTENSION LINE FOR SINGLE USE ONLY(DIA FLOW 9 REGULATOR WITH LINE)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY,STERILE DISPOSABLE RYLE'S TUBE FOR SINGLE USE ONLY(ALPHA RYLE'S TUBE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,STERILE DISPOSABLE STOMACH TUBE FOR SINGLE USE ONLY(ALPHA STOMACH TUBE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(CYNO CARE INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(HOPE INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(SHARP DUAL MICRO INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY

	(PLATINUM INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE NELATON CATHETER (PLAIN & THUMB CONTROL) FOR SINGLE USE ONLY(ALPHA NELATON CATHTER)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(GRAVITY INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE CLOSED WOUND SUCTION UNIT FOR SINGLE USE ONLY(ALPHA CLOSED WOUND SUCTION UNIT)-EXTRACT PUS FROM THE WOUND OF A HUMAN BODY, STERILE DISPOSABLE FOLEY BALLOON CATHTER FOR SINGLE USE ONLY(ALPHA FOLEY BALLOON CATHETER)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY. ,STERILE DISPOSABLE FLOW REGULATOR WITH EXTENSION LINE FOR SINGLE USE ONLY(DIA-FLOW)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,STERILE DISPOSABLE ENDOTRACHEAL TUBE FOR SINGLE USE ONLY(ALPHA CHEST DRAINAGE CATHETER)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS. ,STERILE DISPOSABLE THREE WAY STOP COCK WITH/WITHOUT EXTENSION TUBE FOR SINGLE USE ONLY(ALPHA)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(MEDITOP BLOOD ADMINISTRATION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE HIGH PRESSURE MONITORING LINE FOR SINGLE USE ONLY(ALPHA HIGH PRESSURE MONITORING LINE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS THE PART OF THE SYSTEM OF INFUSION OF FLUID/MEDICATION IN THE MEDICAL APPLICATION,STERILE TRACHEOBRONCHIAL YANKAUR SUCTION CATHETER FOR SINGLE USE ONLY(ALPHA YANKAUR SUCTION CATHETER)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,

	STERILE URETHRAL CATHETER FOR SINGLE USE ONLY(ALPHA URETHRAL CATHETER)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE TRACHEOBRONCHIAL EXTRACTOR CATHETER FOR SINGLE USE ONLY (ALPHA INFANT MUCUS EXTRACTOR)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,STERILE DISPOSABLE MEASURED VOLUME BLOOD SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(CALIBER BLOOD MEASURED VOLUME SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,STERILE DISPOSABLE MEASURED VOLUME INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (PAEDIALINE MESURED VOLUME SET)-:IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (CALIFLOW INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE UMBILICAL ARTERY CATHETER FOR SINGLE USE ONLY(ALPHA UMBILICAL ARTERY CATHETER)-ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS,DISPOSABLE THREE WAY STOP COCK FOR SINGLE USE ONLY(ALPHA THREE WAY STOP COCK)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,STERILE DISPOSABLE EXTENSION LINE FOR SINGLE USE ONLY(UNICONNET EXTENSION TUBE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS THE PART OF THE SYSTEM OF INFUSION OF FLUID/MEDICATION IN THE MEDICAL APPLICATION.,STERILE DISPOSABLE ENDOTRACHEAL TUBE FOR SINGLE USE ONLY(ALPHA THORACIC CATHETER)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS. ,STERILE DISPOSABLE NASOGASTRIC TUBE FOR SINGLE USE ONLY(ALPHA NASAL GASTRIC TUBE)-:IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS

		OR FOR GIVING A PERSON EXTRA CALORIES.,STERILE TRACHEOBRONCHIAL SUCTION ABDOMINAL CATHETER FOR SINGLE USE ONLY(ALPHA ABDOMINAL SUCTION CATHETER)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,TERILE DISPOSABLE EXTENSION LINE WITH Y CONNECTOR FOR SINGLE USE ONLY (UNICONNECTOR Y TUBE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS THE PART OF THE SYSTEM OF INFUSION OF FLUID/MEDICATION IN THE MEDICAL APPLICATION.
3691	MFG/MD/2021/000026	1.License Holder Name: VAIBHAVA LAKSHMI PRIYA SURGICALS 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:STERILE INFUSION SET (VENTED & NON VENTED)("NIGHTINGALE" STERILE INFUSION SET (VENTED & NON VENTED) FOR SINGLE USE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT VASCULAR SYSTEM,BLOOD TRANSFUSION SET ("NIGHTINGALE" STERILE BLOOD TRANSFUSION SET FOR SINGLE USE)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENTS VASCULAR SYSTEM,MEASURED VOLUME INFUSION SET ("NIGHTINGALE" STERILE PEDIA FLEX MEASURED VOLUME INFUSION SET (110ML & 150ML) WITH AIR VENT & WITHOUT AIR VENT FOR SINGLE USE ONLY)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENTS VASCULAR SYSTEM,MICRO INFUSION SET (VENTED & NON VENTED) ("NIGHTINGALE" STERILE MICRO INFUSION SET (VENTED & NON VENTED) FOR SINGLE USE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENTS VASCULAR SYSTEM

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3692	MFG/MD/2021/000027	1.License Holder Name: LA-MED HEALTHCARE PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:HEMODIALYSIS KIT (CATHETER)(LA-MED / DYLAX –LM)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENT HEMODIALYSIS KIT IS USED FOR SHORT TERM VASCULAR ACCESS FOR DIALYSIS OR APHERESIS. HEMODIALYSIS KIT IS USUALLY USED TO BUILD A TEMPORARY BLOOD CONNECTION BETWEEN THE PATIENT AND THE DIALYSIS MACHINE FOR ACUTE AND SHORT- TERM DIALYSIS.,YANKAUR SUCTION SET(LA-MED / YANKAUR SUCTION SET PRO)-YANKAUR SUCTION SET ARE USED FOR THE SUCTION FROM THORACIC CAVITY OR/ AND OPERATION SITE DURING SURGICAL PROCEDURE,FOLEY BALLOON CATHETER (LA-MED / U CATH / FOLEY BALLON CATHETER PRO)-FOLEY CATHETERS ARE USED FOR THE EXTRACTION AND COLLECTION OF URINE FROM THE PATIENTS SUFFERING FROM URINARY TRACT PROBLEMS.,IV INFUSION SET(LA-MED / DRIPPY / ONCO GUARD / ONCO GUARD PLUS/ DRIPPY ULTRA / TRANSFIX IV / DRIPPY NV PRO) -THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER OR CANNULAE.,TWIN BORE NASAL OXYGEN SET(TWIN O2 SET / TWIN O2 SET PRO)-THE TWIN BORE NASAL OXYGEN SET IS USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASE AIR FLOW TO A PATIENT OR PERSON WHO HAVE A PRESCRIPTION FOR OXYGEN THERAPY. ,FLOW REGULATOR/IV FLOW REGULATOR(FLOW REG / FLOW REGULATOR PRO)-IT IS AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. INTENDED TO USE TO CONTROL PRECISELY THE FLOW OF INFUSION FLUID UP TO 300ML/HR.,BLOOD TRANSFUSION SET(LA-MED / TRANSFIX BT / BT SET PRO)-BLOOD TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. BLOOD TRANSFUSION SET IS USED IN DELIVERING MEASURED AND REGULATED BLOOD TO PATIENT.,THORACIC DRAINAGE CATHETER(LA-MED)-THE THORACIC DRAINAGE TUBE IS USED TO REMOVE PUS, BLOOD OR OTHER FLUID FROM A WOUND. , SALEM SUMP TUBE(LA-MED)-PASSAGE OF TUBE BY MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUME OF LIQUID. SALEM SUMP TUBE IS USED TO PREVENT THE ACCUMULATION OF GASTRIC SECRETIONS AND AIR.,LEVIN'S TUBE(LA-MED)-LEVIN'S TUBE IS USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENT AND ADMINISTRATION OF TUBE FEEDING AND MEDICATIONS.,HYPODERMIC NEEDLES(LA-MED)-A HYPODERMIC

	SINGLE LUMEN NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN. ,EXTENSION TUBING(LINK / LINK XT / LINK PM / LINK 3XT / LINK CT / UNI CONNECT / BI CONNECT / TRI CONNECT / LINK PM PRO / LINK 3XT PRO / BI-CONNECT PRO / TRI CONNECT PRO)-EXTENSION TUBE ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATION IN MEDICAL APPLICATIONS., MUCUS EXTRACTOR(LA-MED)-INTENDED TO USED FOR CLEARING THE AIRWAYS OF MUCUS TO IMPROVE OXYGENATION AND VENTILATION. MUCUS EXTRACTOR IS USED FOR COLLECTION OF MUCUS FROM PATIENTS.,ENDOTRACHEAL TUBE PLAIN/RE-INFORCED (LA-MED)-AN ENDOTRACHEAL TUBE IS USED IN GENERAL ANESTHESIA, INTENSIVE CARE AND EMERGENCY MEDICINE FOR AIRWAY MANAGEMENT AND MECHANICAL VENTILATION. ,UMBILICAL CORD CLAMP(LA-MED)-UMBILICAL CORD CLAMP IS USED FOR CLAMPING THE UMBILICAL CORD IMMEDIATELY AFTER BIRTH. , MEASURED VOLUME BURETTE SET(LA-MED / DRIPPY PAEDIA / DRIPPY PAEDIA PRO)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUID FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. MEASURE VOLUME SET IS USED IN DELIVERING MEASURED AND REGULATED INTRAVENOUS SOLUTION TO GENERALLY PEDIATRIC PATIENT BUT CAN BE USED SPECIFICALLY IN PATIENTS WHERE DOSAGE IS VERY CRITICAL.,IV CANNULA(LA-MED / PRIMAFLON / IVFLON / NOVOCATH / CANNATECH / PRIMAFLO / PRIMAFLO PRO / IV FLON PRO / PRIMACAN ALPHA / PRIMAPEN / IV NEO ALPHA / PRIMANEOALPHA / IZZY / IVNEO / IVCAN / PRIMACAN / PRIMANEO /PRIMACATH/PRIMASAFE/SYLON/JAPFLON/IV CATH)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. IT IS A DEVICE THROUGH WHICH FLUID IS INTRODUCED OR WITHDRAWN FROM HUMAN CIRCULATION SYSTEM, THROUGH A CATHETER ,MANIFOLD (LA-MED)-INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND PROVIDING ACCESS PORT/PORTS FOR ADMINISTRATION OF A SOLUTION. ,CLOAED WOUND SUCTION SET(VAC SET / SILICO DRAIN / KIDI VAC SET / VAC SET PRO/ KIDI VAC SET PRO)-THE DEVICE IS USED TO REMOVE PUS, BLOOD OR OTHER FLUID FROM A WOUND. , SUCTION CATHETER(LA-MED / OROCATH / SUCTION CATHETER PRO) -THE SUCTION CATHETER HAS BEEN DESIGNED FOR REMOVAL OF SECRETION FROM MOUTH, TRACHEA AND BRONCHIAL TUBE USED IN THE RESPIRATORY TRACT.,STOMACH TUBE(LA-MED)-STOMACH TUBE IS USED FOR THE NUTRITIONAL FEEDING OF NUTRITIONAL

	SUPPLEMENTS. IT IS A MEDICAL DEVICE USED TO PROVIDE NUTRITION TO PATIENTS WHO CANNOT OBTAIN NUTRITION BY MOUTH, ARE UNABLE TO SWALLOW SAFETY, OR NEED NUTRITIONAL SUPPLEMENTATION.,FEMALE/URETHRAL CATHETER(LA-MED)-THE LA-MED FEMALE CATHETER HAS BEEN DESIGNED FOR SHORT TERM BLADDER CATHETERIZATION THROUGH URETHRA IN FEMALES, INFANT FEEDING TUBE(LA-MED / INFANTY /INFANT FEEDING TUBE PRO)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO STOMACH THROUGH MOUTH OR NOSE TO SUPPLY NUTRITION. INFANT FEEDING TUBE IS USED FOR THE NUTRITIONAL FEEDING OF NEONATAL AND PEDIATRIC NUTRITIONAL SUPPLEMENTS.,NELATON CATHETER(LA-MED / NELTO)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER. THE LA-MED NELATON CATHETER HAS BEEN DESIGNED FOR SHORT TERM BLADDER CATHETERIZATION THROUGH URETHRA IN MALES AND FEMALES,THREE WAY STOP COCK(LA-MED / LINK / LINK LR / LINK-3KL / 3 WAY STOP COCK PRO) -IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWN OF FLUIDS AND PRESSURE MONITORING.,REDON DRAIN CATHETER(LA-MED)-THE TUBE IS USED TO REMOVE PUS, BLOOD OR OTHER FLUID FROM A WOUND. THE REDON DRAIN CATHETER HAS BEEN DESIGNED FOR POST-OPERATIVE DRAINAGE.,RYLE'S TUBE(LA-MED / RYLO /RYLE'S TUBE PRO)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.

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3693	MFG/MD/2021/000028	1.License Holder Name: 3M INDIA LIMITED 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:SURGICAL DRESSING(3M TRANSPARENT I.V. DRESSING)-DRESSING-GEL, DRESSING-PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. THE DRESSING COVERS AND PROTECTS THE CATHETER INSERTION SITES AND SECURES DEVICES TO SKIN.,SURGICAL DRESSING(3M TEGADERM I.V. ADVANCED)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. THE DRESSING COVERS AND PROTECTS THE CATHETER INSERTION SITES AND SECURES DEVICES TO SKIN. , SURGICAL DRESSING(3M TEGADERM HP)-DRESSING-GEL, DRESSING-PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. THE DRESSING COVERS AND PROTECTS THE CATHETER INSERTION SITES AND SECURES DEVICES TO SKIN.,SURGICAL DRESSING(3M SOFT CLOTH DRESSING WITH PAD)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. USED FOR POST-OPERATIVE WOUND DRESSING,SURGICAL DRESSING(3M TEGADERM FILM I.V)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. THE DRESSING COVERS AND PROTECTS THE CATHETER INSERTION SITES AND SECURES DEVICES TO SKIN., SURGICAL DRESSING(3M TEGADERM HP + PAD)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. THE DRESSING COVERS AND PROTECTS THE CATHETER INSERTION SITES, WOUND SITES AND SECURES DEVICES TO SKIN,SURGICAL DRESSING(3M SOFT CLOTH IV DRESSING)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE.TO SECURE AND STABILIZE CATHETERS,SURGICAL DRESSING(3M TEGADERM FILM)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. THE DRESSING COVERS AND PROTECTS THE CATHETER INSERTION SITES AND SECURES DEVICES TO SKIN.,SURGICAL DRESSING(3M TEGADERM I.V.)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, WOUND AND BURN DRESSINGS, HYDROGEL

	DRESSING, WOUND AND BURN, OCCLUSIVE. THE DRESSING COVERS AND PROTECTS THE CATHETER INSERTION SITES AND SECURES DEVICES TO SKIN

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3694	MFG/MD/2021/000029	1.License Holder Name: SURGICAL SUTURES PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:MONOFILAMENT POLYPROPYLENE MESH(SEAMLENE MESH, SHALYALE-NE MESH,IM-LENE MESH)-MONOFILAMENT POLYPROPYLENE MESH IS USED FOR ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISIONAL, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS. IT IS USED IN BOTH COLPOSCOPY AND LAPAROTOMY. IT IS USED FOR THE REPAIR OF HERNIA, UTERO-VAGINAL PROLAPSE AND OTHER FACIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT, ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) BRAIDED & COATED POLYGLYCOLIC ACID - UNDYED(SEAMGLYDE FAST, SHALYAGLYDE FAST, IM-GLYDE FAST)-USED FOR SURGERIES LIKES EPISIOTOMY AND CIRCUMCISION & CLOSURE OF SKIN WHERE FAST ABSORBABLE SUTURE REQUIRED., ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) MONOFILAMENT POLYDIOXANONE(SEAMPDS, SHALYAPDS, IM-PDS)-INTENDED FOR THE USE IN ALL TYPE OF SOFT TISSUE APPROXIMATION INCLUDING OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT IS DESIRABLE.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE CATGUT PLAIN(SEAMGUT, SHALYAGUT, IM-GUT)-USED IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, BUT NOT IN CARDIOVASCULAR OR NEUROLOGICAL SURGERY.,NON-ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE BLACK BRAIDED SILK(SEAMSILK, SHALYASILK,IM-SILK)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC SURGERY, CARDIOVASCULAR AND NEUROLOGICAL SURGERY.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) BRAIDED & COATED POLYGLYCOLIC ACID(SEAMGLYDE, SHALYAGLYDE,IM-GLYDE)-USED IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC BUT IT IS NOT FOR USE IN CARDIOVASCULAR & NEUROLOGICAL TISSUES, IT IS USED WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL.,NON-ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE MONOFILAMENT POLYPROPYLENE (SEAMLENE, SHALYALENE,IM-LENE)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC SURGERY, CARDIOVASCULAR AND NEUROLOGICAL

	SURGERY.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) BRAIDED & COATED POLYGLACTIN 910-UNDYED(SEAMCRYL FAST, SHALYACRYL FAST,IM-SYNTH FAST)-INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND/OR LIGATION AND SHOULD NOT BE USED WHERE EXTENDED APPROXIMATION OF TISSUE IS REQUIRED OR IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25(SEAMMONO, SHALYAMONO,IM-PGCL)-USED IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC. BUT IT IS NOT FOR USE IN CARDIOVASCULAR & NEUROLOGICAL TISSUES.,NON-ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE BRAIDED & COATED POLYESTER(SEAMBOND, SHALYABOND,IM-BOND)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC SURGERY, CARDIOVASCULAR AND NEUROLOGICAL SURGERY.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE (SYNTHETIC) BRAIDED & COATED POLYGLACTIN 910(SEAMCRYL, SHALYACRYL,IM-SYNTH)-INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER.,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE CATGUT CHROMIC (SEAMCHROM, SHALYACHROM, IM-GUT)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, BUT NOT IN CARDIOVASCULAR OR NEUROLOGICAL SURGERY.,NON-ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL SUTURE MONOFILAMENT POLYAMIDE(SEAMLON, SHALYALON,IM-LON)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC SURGERY, CARDIOVASCULAR AND NEUROLOGICAL SURGERY.,BONE WAX / STERILIZED BONE WAX(SEAMWAX, SHALYAWAX,IM-WAX)-USED TO CONTROL LOCAL BLEEDING FROM BONE SURFACES. IT ACHIEVES LOCAL HEMOSTASIS OF BONE BY ACTING AS A MECHANICAL (TAMPONADE) BARRIER. IT IS COMMONLY USED IN PATIENTS UNDERGOING ORTHOPEDIC SURGICAL PROCEDURES.

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3695	MFG/MD/2021/000030	1.License Holder Name: PRECURE SURGICAL 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON GAUZE-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS,COTTON BANDAGE ROLL-COTTON ROLL BANDAGE ARE VERY COMMON AND VERY VERSATILE THIN WOVAN AND BREATHABLE FABRIC BANDAGES THAT CAN BE USED TO SECURE ADDRESSING, IN PLACE OR MAY BE PLACED DIRECTLY OVER A WOUND TO KEEP IT CLEAN WHILE ALLOWING AIR TO PENETRATE TO IMPROVE THE HEALING PROCESS, PRESSURE BANDAGE (CREPE BANDAGE)-THE MEDIUM WEIGH CREPE BANDAGE IS SUITABLE FOR USE AS DRESSING RETENTION. THE HEAVY WEIGHT CREPE BANDAGE IS SUITABLE FOR USE A SUPPORT FOR SPRAINS AND STRAINS IN JOINT AND MUSCLES. IT ALSO WORKS AS A MODERATE COMPRESSION BANDAGE FOR KNEE SWELLING ANKLE SWELLING AND OTHER RELEVANT INJURIES
3696	MFG/MD/2021/000031	1.License Holder Name: FOCUZ INTERNATIONAL 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BILIARY STENT-FOCUZ BILIARY STENT WITH FOCUZ PUSHER IS INTENDED FOR DELIVERY OF THE STENT TO BILIARY TRACT FOR DRAINAGE OF THE BILE DUCT, FOR SPLINTING OF BILE DUCT DURING HEALING, OR FOR PROVIDING BILE DUCT PATENCY IN A STRICTURE OR PAST A STONE.,URETERAL CATHETER-THE URETERAL CATHETER (DJ STENT) IS INTENDED TO FACILITATE DRAINAGE FROM THE KIDNEY TO THE BLADDER VIA PLACEMENT ENDOSCOPICALLY OR FLUOROSCOPICALLY. ADDITIONALLY, THE IT IS INTENDED TO INJECT CONTRAST AND SALINE INTO THE RENAL COLLECTING SYSTEM. IT IS INDICATED FOR USE WITH UROLOGICAL PROCEDURES AND/OR CONDITIONS SUCH AS: • PRE-ESWL • POST-ESWL • URETERAL STONE OBSTRUCTION • POST-URETEROSCOPY • UPJ OBSTRUCTION • URETERAL TRAUMA • URETERAL STRICTURE • URETERAL CARCINOMA • RETROPERITONEAL FIBROSIS • ENDOPYELOTOMY • PYELOTOMY • NEPHROLITHOTOMY • URETEROLITHOTOMY

3697	MFG/MD/2021/000032	1.License Holder Name: SAVITA SURGICALS 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:COTTON BANDAGE ROLL-COTTON ROLL BANDAGE ARE VERY COMMON AND VERY VERSATILE THIN WOVAN AND BREATHABLE FABRIC BANDAGES THAT CAN BE USED TO SECURE ADDRESSING, IN PLACE OR MAY BE PLACED DIRECTLY OVER A WOUND TO KEEP IT CLEAN WHILE ALLOWING AIR TO PENETRATE TO IMPROVE THE HEALING PROCESS,ABSORBENT COTTON GAUZE-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS, PRESSURE BANDAGE (CREPE BANDAGE)-THE MEDIUM WEIGH CREPE BANDAGE IS SUITABLE FOR USE AS DRESSING RETENTION. THE HEAVY WEIGHT CREPE BANDAGE IS SUITABLE FOR USE A SUPPORT FOR SPRAINS AND STRAINS IN JOINT AND MUSCLES. IT ALSO WORKS AS A MODERATE COMPRESSION BANDAGE FOR KNEE SWELLING ANKLE SWELLING AND OTHER RELEVANT INJURIES

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3698	MFG/MD/2021/000033	1.License Holder Name: VIGGO MEDICAL DEVICES INDIA PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ENDOTRACHEAL TUBE ETT (TRACHEAL TUBE)(VIGGO ENDOTRACHETUBE)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS,ASPIRATION SYRINGE(VIGGOBULB SYRINGE)-USED FOR EITHER LAPAROSCOPIC ASPIRATION OR INJECTION.,I.V. CANNULA.(VIGGOFLON, VIGGOFLONPRIME, VIGGOVEIN , VIGGOVEIN PRIME VIGGOCANN, &VIGGOFLON-S, VIGGOVEIN-S , VIGGOCANN-S)-THE I.V. CANNULA IS A PASSIVE DEVICES TO PROVIDE TO FOR INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,AUTO DISABLE HYPODERMIC SYRINGE. (VIGGORINGE-ADS)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,A.V. FISTULA NEEDLE(VIGGOLINK)-TO CONNECT BLOOD LINE WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT,DISPOSABLE HYPODERMIC SINGLE USE SYRINGE.(VIGGORINGE)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,SPINAL NEEDLE(VIGGO GLIDE)-IT IS USE FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM.,INJECTION STOPPER NEEDLE FREE ACCESS VALVE WITHOUT & WITH EXTENSION TUBE/LINE/SET (VIGGOPORT VIGGO 1-WAY VIGGO 2WAY VIGGO 3 WAY VIGGO CONNECT & VIGGO CONNECT-S)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUID /MEDICATION IN MEDICAL APPLICATION. " "EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUID /MEDICATION IN MEDICAL APPLICATION. " "EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUID /MEDICATION IN MEDICAL APPLICATION. " EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF SYSTEM FOR THE INFUSION OF FLUID /MEDICATION IN MEDICAL APPLICATION,SUCTION CATHETER(VIGG-O-SUCK)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION,NELATON CATHETER (VIGGOFLUSH)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.OR THE

	NELATON & FEMALE CATHETERS HAVE BEEN DESIGNED FOR SHORT TERM BLADDER CATHETERIZATION THROUGH URETHRA IN MALES. THIS PRODUCT IS MANUFACTURED FROM NON-TOXIC, NON-IRRITANT PVC. UNIVERSAL FUNNEL SHAPE CONNECTOR FOR EASY CONNECTING TO URINE BAG. NELATON CATHETERS ARE GENERALLY USED IN MALE PATIENTS WHILE FEMALE CATHETERS ARE USED IN FEMALE PATIENTS.,THREE WAY STOP COCK WITHOUT & WITH EXTENSION TUBE/LINE/SET.(VIGGOWAY, VIGGOWAY-X VIGGO CONNECT ULTRA)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION , WITHDRAWAL OF FLUID AND PRESSURE MONITORING, BLOOD TRANSFUSION SET(HAEMOFIX & TRANSFIX)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO THE PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED, CLOSED SUCTION SYSTEM(VIGGO CLOSESUCK.)-IT IS INTENDED FOR ENDOTRACHEAL SUCTIONING TO PROVIDE A PATIENT AIRWAY BY REMOVING EXCESS FLUID, SECRETION, EXUDATES AND TRANSUDATE THROUGH THE ARTIFICIAL AIRWAY.,MEASURED VOLUME BURETTE SET(VIGGO INFANT BURETTE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE (NEEDLE OR CATHETER),TWIN BORE NASAL OXYGEN CATHETER(NASO-TWIN SET)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,CHEST DRAINAGE CATHETER WITH AND WITHOUT TROCAR(VIGGO THORADRAIN)-TROCAR IS MADE UP OF AN OBTURATOR (WHICH MAY BE A METAL OR PLASTIC SHARPENED OR NON-BLADED TIP), A CANNULA (BASICALLY A HOLLOW TUBE), AND A SEAL. THE TROCAR FUNCTIONS AS A PORTAL FOR THE SUBSEQUENT PLACEMENT OF OTHER INSTRUMENTS, SUCH AS GRASPERS, SCISSORS, STAPLERS, ETC. IT IS ALSO INTENDED TO REMOVE AIR OR FLUID FOR THE PLEURAL SPACE IN A CLOSED, ONE WAY FASHION.,LARYNGEAL MASK(VIGGO-L-MASK) -INSERTED THROUGH A PATIENT'S MOUTH TO AID VENTILATION OF THE PATIENT DURING EMERGENCY RESUSCITATION BY OCCLUDING (BLOCKING) THE ESOPHAGUS , THEREBY PERMITTING POSITIVE PRESSURE VENTILATION THROUGH TRACHEA.,AUTO DISABLED SYRINGE FOR IMMUNIZATION(VIGGORINGE-IMMI)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,IRRIGATING SYRINGE.(M-PURPOSYRINGE)-CLEANING DEBRIS AWAY FROM THE AREA THE DENTIST IS WORKING ON,FLOW REGULATOR(VIGGOFLO, CONTROFIX,)-AN IV SYSTEM AND ADMINISTRATION DEVICES OFFERING PRECISION CARE AND CONSISTENT. OR FLOW USE IN GRAVITY FLOW SITUATIONS WHICH REQUIRE VARIABLE, ACCURATE

		INFUSION RATES FOR PATIENT SAFETY AND DRUG EFFICACY.,FOLEY BALLOON CATHETER(VIGGOSURE)-FOLEY CATHETERS ARE USED FOR THE EXTRACTION AND COLLECTION OF URINE FROM THE PATIENTS SUFFERING FROM URINARY TRACT PROBLEMS. IT IS MADE FROM NATURAL RUBBER LATEX OR SILICON , PACKED IN DOUBLE WRAP PEEL ABLE POUCH.FOLEY CATHETERS ARE FLEXIBLE TUBES THAT ARE PASSED THROUGH THE URETHRA DURING URINARY CATHETERIZATION AND INTO THE BLADDER TO DRAIN URINE. THEY ARE RETAINED BY MEANS OF A BALLOON AT THE TIP WHICH IS INFLATED WITH STERILE WATER. THE BALLOONS TYPICALLY COME IN TWO DIFFERENT SIZES:,CLOSE WOUND SUCTION /DRAINAGE TUBE OR SYSTEM.(VIGGO DRAIN)-:A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS,BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS,HEMODIALYSIS CATHETER KIT(VIGGOCATH)-A CATHETER USED FOR EXCHANGING THE BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT,EPIDURAL NEEDLE (VIGGO SLIDE)-INTENDED FOR TRANSIENT DELIVERY OF ANESTHETICS TO PROVIDE REGIONAL ANESTHESIA OR FACILITATE PLACEMENT OF AN EPIDURAL CATHETER.,INTRAVENOUS INFUSION SET (I.V. SET)(FLEXICONTROL VIGGOFIX)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE (NEEDLE OR CATHETER),INSULIN SYRINGE.(VIGGO INSULINO) -USED TO INJECT INSULIN FOR THE TREATMENT OF DIABETES
3699	MFG/MD/2021/000034	1.License Holder Name: M/S. PREMIER SURGICALS 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.-USED FOR THE WOUND CARE, SURGICAL DRESSINGS

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MANUFACTURE MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3700	MFG/MD/2021/000036	1.License Holder Name: ENDO-MED TECHNOLOGIES PVT. LTD. 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:GUIDE WIRE-THE GUIDE WIRE IS USED TO GAIN AND MAINTAIN A TRACT INTO A VESSEL AND TO FACILITATE A CATHETER TO SLIDE OVER IT SO THAT FOR THE SMOOTH INSERTION OF THE CATHETER INTO THE DESIRED LOCATION. THE WIRE IS USED FOR GUIDING OF FLEXIBLE DEVICES, WHICH ARE GUIDE WIRE COMPATIBLE, TO THE AREA OF THE HUMAN BODY WHICH WILL BE TREATED.,ENDOSCOPIC SCLEROTHERAPY (EST) NEEDLE CATHETER-THE DEVICE ARE USED FOR ENDOSCOPICALLY OR RADIOLOGICALLY FOR , INJECTION OF MEDICINE OR ASPIRATION OF BODY FLUIDS OR OBTAINING OF CYTOLOGY / TISSUE, SAMPLES FROM GASTROINTESTINAL, RASPIRATORY, UROLOGY, TRACK OR SUB MUCOUS TISSUE . THESE DEVICES ARE SUPPLIED STERILE AND ARE INTENDED FOR SINGLE USE ONLY.,STONE EXTRACTION BASKET-THE DEVICE IS USED FOR THE ENDOSCOPIC REMOVAL OF BILIARY & PANCREATIC STONES, URINARY STONES AND FOREIGN BODIES AND POLYP & TISSUES ETC., HEMOCLIP-THE HEMOCLIP IS INDICATED FOR CLIP PLACEMENT WITHIN THE GASTRO-INTESTINAL(GI) TRACT FOR THE PURPOSE OF: 1. ENDOSCOPIC MARKING, 2. HEMOSTASIS FOR: (1) MUCOSAL/SUB-MUSCOSAL DEFECTS3CM, (2) BLEEDING ULCERS; (3) ARTERIES2MM, (4) POLYPS1.5CM IN DIAMETER, (5) DIVERTICULA IN THE COLON, 3. AS A SUPPLEMENTARY METHOD, CLOSURE OF GI TRACT LUMINAL PERFORATIONS20MM THAT CAN BE TREATED CONSERVATIVELY., DRAINAGE CATHETER(DRAIN-X)-THE DRAINAGE CATHETERS AND RELATED COMPONENTS (INTRODUCER/PUSHER) ARE INTENDED TO AID THE DRAINAGE OF OBSTRUCTED DUCTS WITHIN THE PANCREATIC AND BILIARY TREES. THE DEVICE IS MADE OF A RADIOPAQUE MATERIAL WITH OR WITHOUT FLAPS OR SINGLE OR DOUBLE PIGTAIL WITH MARKING BANDS. THE DRAINAGE CATHETERS ARE DESIGNED TO BE USED DURING ENDOSCOPIC PROCEDURES. MULTI BAND LIGATOR-MULTI BAND LIGATOR SET IS USED TO ENDOSCOPICALY LIGATE ESOPHAGEAL VARICES AT OR ABOVE THE GASTROESPHAGEAL JUNCTION. THIS DEVICE IS INTENDED FOR SINGLE USE AND IS SUPPLIED NON-STERILE. THIS IS ALSO USED TO ENDOSCOPICALLY LIGATE INTERNAL HEMORRHOIDS IN ADULT PATIENTS ONLY.,DILATION BALLOON(EXPANDER)-DILATION BALLOON IS USED FOR DILATATION TREATMENT OF THE STRICTURE OF DIGESTIVE TRACT, URINARY TRACT, RESPIRATORY TRACT INCLUDING ESOPHAGUS, PYLORUS, DUODENUM, COLON, BILE DUCT, CARDIA, URETER, URETHRA, NEPHROS, TRACHEA AND BRONCHUS ETC.,ENDOSCOPIC ULTRASOUND FINE NEEDLE ASPIRATION - (EUS FNA) / ENDO BRONCHIAL ULTRASOUND FINE NEEDLE ASPIRATION –

		(EBUS FNA)-THE DEVICE IS INTENDED TO BE USED FOR ASPIRATION, CYTOLOGY OR BIOPSY SAMPLING THROUGH ENDOSCOPE FOR DIAGNOSIS AND TREATMENT. STERILE EUS/EBUS NEEDLE IS AVAILABLE FOR USE IN CHEST, LUNG, MEDIASTINUM TUMOUR AND PATHOLOGICAL CHANGES OF LYMPHOID TISSUE; DIAGNOSING OF ESOPHAGUS, WALL OF THE STOMACH AND INTESTINE, APPARATUSES WHICH CLOSE TO STOMACH AND INTESTINE, PATHOLOGICAL CHANGES OF LYMPH GLAND; DIAGNOSE THE PANCREATIC TISSUE PUNCTURE, ASPIRATION AND DRAINAGE ETC., STONE EXTRACTION BALLOON-BE USED FOR REMOVAL OF STONES IN BILIARY DUCT.,FORCEPS (FORCEPS BIOPSY/ FOREIGN BODY FORCEPS)-THIS DEVICE IS USED ENDOSCOPICALY TO OBTAIN GASTROINTESTINAL MUCOUS TISSUE BIOPSIES AND FOR REMOVAL OF POLYPS OR FOREIGN OBJECTS FROM G.I TRACT, RESPIRATORY TRACK, UROLOGY TRACK, OR OTHER INTRA LUMINARY CAVITIES, SPHINCTROTOME-SPHINCTROTOME-THE DEVICE IS INTENDED FOR USE IN SELECTIVE CANNULATION OF THE BILIARY DUCTS INCLUDING, BUT NOT LIMITED TO THE COMMON BILE, CYSTIC, RIGHT AND LEFT HEPATIC DUCTS. IT IS DESIGNED TO BE USED DURING ENDOSCOPIC BILIARY PROCEDURES FOR CATHETER INTRODUCTION AND EXCHANGES. THE DEVICE IS SUPPLIED STERILE AND INTENDED FOR SINGLE USE ONLY, CONFIRM THE HEAD DIRECTION HIGH FREQUENCY KNIFE, MANUAL SHAPING WHEN NECESSARY, TO ENSURE THAT THE HEAD END TOWARDS THE FACE IN THE MIDDLE LEFT. WILL GUIDE WIRE PRELOADED HIGH-FREQUENCY KNIFE, ALONG THE ROAD INTO THE ENDOSCOPIC FORCEPS UNTIL ITS END PART APPEARS IN THE ENDOSCOPIC VIEW.,POLYPECTOMY SNARE-POLYPECTOMY SNARE IS USED IN COMBINED USE WITH ENDOSCOPE TO CUTTING POLYPS OR OTHER REDUNDANT TISSUES WITH HIGH-FREQUENCY CURRENT IN DIGESTIVE TRACT.,PERCUTANEOUS ENDOSCOPIC GASTROSTOMY - (PEG) FEEDING TUBE-PERCUTANEOUS ENDOSCOPIC GASTROSTOMY - (PEG) FEEDING TUBE IF USED FOR THE PURPOSE OF FEEDING THE PATIENT WITH LIQUID DIET THROUGH THE PERCUTANIOUS OPENING, WHERE IN THE PATIENT CAN NOT TAKE AN ORAL DIET.
3701	MFG/MD/2021/000037	1.License Holder Name: M/S P.P. CATTLE FEEDS 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS

3702	MFG/MD/2021/000038	1.License Holder Name: ELEVATION MEDISOULTIONS LLP 2.Approving Authority: BIHAR 3.Device Name(Brand Name)-Intended Use:AUTO DISABLE STERILE HYPODERMIC SYRINGES WITH NEEDLE FOR SINGLE USE ONLY (SAFEONE)-AUTO DISABLE SYRINGE IS A PLASTIC DEVICE USED FOR TRANSFER SOLUTION FROM ONE CONTAINER TO ANOTHER AND TO ADMINISTER DRUGS TO PATIENTS,STERILE BLOOD ADMINISTRATION SET(SAFEONE)-BLOOD TRANSFUSION DEVICE IS USED FOR THE PROCESS OF TRANSFERRING BLOOD OR BLOOD PRODUCTS INTO ONE'S CIRCULATION INTRAVENOUSLY,STERILE DISPOSABLE HYPODERMIC NEEDLE FOR SINGLE USE ONLY(SAFEONE)-STERILE SINGLE-USE HYPODERMIC NEEDLES ARE INTENDED FOR THE INJECTION OF INTRAVENOUS & INTRAMUSCULAR FLUIDS IMMEDIATELY AFTER FILLING.,STERILE I.V. INFUSION SET WITHOUT AIR VENT(SAFEONE)-THIS DEVICE IS USED FOR THE INFUSION OF FLUID INTO THE HUMAN BODY THROUGH VEINS. THEY ARE INTENDED TO BE USED FOR INTRAVENOUS INFUSIONS LIKE THE ADMINISTRATION OF DRUGS VITAL FLUIDS LIKE BLOOD AND OTHER FLUIDS LIKE ELECTROLYTE SOLUTION TO THE PATIENTS.,AUTO DISABLE STERILE HYPODERMIC SYRINGES WITHOUT NEEDLE FOR SINGLE USE ONLY(SAFEONE)-A SYRINGE IS A PLASTIC DEVICE USED FOR TRANSFER SOLUTION FROM ONE CONTAINER TO ANOTHER AND TO ADMINISTER DRUGS TO PATIENTS,STERILE HYPODERMIC SYRINGES WITH NEEDLE FOR SINGLE USE ONLY(SAFEONE)-TO TRANSFER SOLUTION FROM ONE CONTAINER TO ANOTHER AND TO ADMINISTER DRUGS TO PATIENTS.,STERILE HYPODERMIC SYRINGES WITHOUT NEEDLE FOR SINGLE USE ONLY(SAFEONE)-A SYRINGE IS A PLASTIC DEVICE USED FOR TRANSFER SOLUTION FROM ONE CONTAINER TO ANOTHER AND TO ADMINISTER DRUGS TO PATIENTS, STERILE I.V. INFUSION SET WITH AIR VENT(SAFEONE)-THIS DEVICE IS USED FOR THE INFUSION OF FLUID INTO THE HUMAN BODY THROUGH VEINS. THEY ARE INTENDED TO BE USED FOR INTRAVENOUS INFUSIONS LIKE THE ADMINISTRATION OF DRUGS VITAL FLUIDS LIKE BLOOD AND OTHER FLUIDS LIKE ELECTROLYTE SOLUTION TO THE PATIENTS.

3703	MFG/MD/2021/000039	1.License Holder Name: CHITRANJAN MEDITECH & FRAGRANCE PVT. LTD. 2.Approving Authority: BIHAR 3.Device Name(Brand Name)-Intended Use:SURGICAL DRESSING PAD-USED FOR COVERING SUTURED WOUNDS/INCISIONS, ON LOW TO MEDIUM EXUDING WOUNDS FOR CUSHIONING IMMOBILIZED JOINTS.,ABSORBENT GAUZE/GAUZE/UNMEDICATED GAUZE/ABSORBENT COTTON GAUZE-ABSORBENT GAUZE ARE MAINLY USED DURING OPERATIONS AND ITS MAIN FUNCTION IS TO ABSORB THE BLOOD FROM WOUND. THE ABSORBENT GAUZE IS MOST VITAL ITEM IN SURGICAL DRESSING. ,BLEACHED BANDAGE FOR PLASTER OF PARIS/ROLLED BANDAGE FOR PLASTER OF PARIS-: EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB,ABSORBENT COTTON WOOL I.P-MEDICAL PURPOSES, SURGICAL OPERATIONS AND SANITARY PURPOSES,BANDAGE CLOTH/ BLEACHED BANDAGE CLOTH/ROLLED BANDAGE/ OPEN WOVE BANDAGE/COTTON BANDAGE CLOTH-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB,COTTON CREPE BANDAGE B.P-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB.
3704	MFG/MD/2021/000040	1.License Holder Name: RJ MEDITECHS PRIVATE LIMITED 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:CLOSED WOUND DRAINAGE SYSTEM(INVO VAC)-A CLOSED WOUND DRAINAGE SYSTEM USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND , THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGIST.

3705	MFG/MD/2021/000041	1.License Holder Name: ROYAL SURGICARE PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use::STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY (UMAFLOW CHEST DRAINAGE CATHETRE WITH/WITHOUT TROCAR)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,MALE EXTERNAL CATHETER(URICATH)- IT IS USE FOR URINE INCONTINENCE FOR DAY AND NIGHT USE IN A MALE PATIENT & IS CONNECTED TO URINE BAG,STERILE TRACHEOBRONCHIAL SUCTION ABDOMINAL CATHETER FOR SINGLE USE ONLY(UMAADK)-:SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,BLOOD ADMINISTRATION SET / BLOOD TRANSFUSION SET (FOR EXPORT ONLY)(UMAFLOW)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,:STERILE DISPOSABLE SCALP VEIN SET FOR SINGLE USE ONLY(UMAFLOW)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD,CLOSED WOUND SUCTION UNIT (FOR EXPORT ONLY) (MINOR VAC SET)-EXTRACT PUS FROM THE WOUND OF A HUMAN BODY,:STERILE DISPOSABLE HIGH PRESSURE MONITORING LINE FOR SINGLE USE ONLY(UMAFLOW)-:EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,URETHRAL / NELATON / RECTAL CATHETER (UMAFLOW)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY (UMAFLOW MUCUS EXTRACTOR)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION.,INFANT FEEDING TUBE (FOR EXPORT ONLY) (UMAFLOW)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH NOSE. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING,STERILE UNDER WATER SEAL CHEST DRAINAGE BOTTLE(UMASEAL)-TO COLLECT THE DRAIN WATER & OTHER MATERIAL FROM THE STOMACH.,INFUSION SET (FOR EXPORT ONLY)(UMAFLOW)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY

	(UMAFLOW)-:TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,HIGH PRESSURE MONITORING LINE (FOR EXPORT ONLY)(UMAFLOW)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATIONS IN MEDICAL APPLICATIONS.,STERILE DISPOSABLE NASOGASTRIC/RYLE'S/DUODENALL TUBE FOR SINGLE USE ONLY (UMAFLOW-)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES., INTRAVENOUS CANNULA - ALL TYPE (FOR EXPORT ONLY) (UMAFLOW)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,STERILE INFANT FEEDING TUBE FOR SINGLE USE ONLY(UMAFLOW)-:A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING,IV FLOW REGULATOR WITH OR WITHOUT INFUSION SET (FOR EXPORT ONLY)(ROYALFLO)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,STERILE URETHRAL/ NELATON/RECTAL CATHETER (PLAIN & THUMB CONTROL) FOR SINGLE USE ONLY (UMAFLOW URETHRAL/ NELATON/RECTAL CATHETER)-:A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,RYLE'S / NASOGASTRIC / GASTRO DUODENAL TUBE (FOR EXPORT ONLY)(UMAFLOW)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,STERILE DISPOSABLE PERITONEAL DIALYSIS KIT CATHETER FOR SINGLE USE ONLY(UMA FLOW PERITONEAL DIALYSIS KIT)-THAT ALLOWS DIALYSIS FLUID TO ENTER THE ABDOMINAL CAVITY, DWELL INSIDE FOR A WHILE, AND THEN DRAIN BACK OUT AGAIN.,RYLE'S / NASOGASTRIC / GASTRO DUODENAL TUBE (FOR EXPORT ONLY)(UMALINE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY(UMAFLOW SUCTION CATHETER)-:CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION.,YANKAUR SUCTION SET (FOR EXPORT ONLY)(VACCUM SUCK)-YANKAUR SUCTION SET ARE USED FOR THE REMOVAL OF

	BLOOD AND FLUIDS DURING SURGERY.,:STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(UMAFLOW)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,NASAL OXYGEN CATHETER (UMAFLOW)-IT IS A DEVICE USE TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP. ,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(UMADRIP)-:IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,ABDOMINAL DRAINAGE KIT (FOR EXPORT ONLY) (UMA-ADK)-ABDOMINAL DRAINAGE KIT ARE USE IN THE POST OPERATIVE DRAINAGE FROM ABDOMINAL AREAS,:DISPOSABLE STERILE DIAL FLOW REGULATOR WITH OR WITHOUT INFUSION SET FOR SINGLE USE ONLY(ROYALFLO)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,MALE EXTERNAL CATHETER(FOR EXPORT ONLY)(URICATH)-IT IS USE FOR URINE INCONTINENCE FOR DAY AND NIGHT USE IN A MALE PATIENT & IS CONNECTED TO URINE BAG, STERILE CLOSED WOUND SUCTION UNIT FOR SINGLE USE ONLY (UMAVAC)-EXTRACT PUS FROM THE WOUND OF A HUMAN BODY, KARMAN CANNULA (FOR EXPORT ONLY)(UMAFLOW)-USED IN IRRIGATION DURING TRANS URETHRAL RESECTION OF PROSTATE GLAND,STERILE DISPOSABLE THREE WAY STOP COCK WITH/WITHOUT EXTENSION TUBE FOR SINGLE USE ONLY(UMAFLOW) -IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,T.U.R. SET (FOR EXPORT ONLY)(UMAFLOW)-USED IN IRRIGATION DURING TRANS URETHRAL RESECTION OF PROSTATE GLAND,STERILE DISPOSABLE SINGLE USE ENDOTRACHEAL & RE-INFORCE ENDOTRACHEAL TUBE WITH & WITHOUT CUFF(UMAFLOW)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION.,UMBILICAL CORD CLAMP (FOR EXPORT ONLY)(UMAFLOW)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE TRACHEOBRONCHIAL YANKAUR SUCTION CATHETER FOR SINGLE USE ONLY(VACCUM SUCK)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,UNDER WATER SEALED DRAINAGE SYSTEM / CHEST DRAINAGE BOTTLE (FOR EXPORT ONLY)(UMASEAL)-TO

	COLLECT THE DRAINAGE IN THE CHEST DRAINAGE BOTTLE WITH THE HELP OF CHEST DRAINAGE CATHETER IN CARDIAC AND THORACIC PROCEDURE.,NON STERILE INTRAVENOUS CANNULA FOR SINGLE USE ONLY(UMAFLOW)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,PERITONEAL DIALYSIS SET / CATHETER/ KIT (FOR EXPORT ONLY)(UMAFLOW)-THAT ALLOWS DIALYSIS FLUID TO ENTER ABDOMINAL CAVITY, DWELL INSIDE FOR A WHILE AND THEN DRAIN BACK OUT AGAIN.,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY -CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION.,CLOSED WOUND SUCTION UNIT (FOR EXPORT ONLY)(UMAVAC)-EXTRACT PUS FROM THE WOUND OF A HUMAN BODY,INFANT MUCUS EXTRACTOR (FOR EXPORT ONLY) (UMAFLOW)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,SCALP VEIN SET (FOR EXPORT ONLY)(UMAFLOW)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD , EXTENSION LINE WITH / WITHOUT THREE WAY STOP COCK (UMAFLOW)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING ,: IV CANNULA FIXATOR (UMAFLOW)-DRESSING AEROSOL, NON-ADHERENT, DRESSING, PERIODONTAL, KIT, DRESSING PAD, DRESSING,INFUSION SET (UMAFLOW)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,AV FISTULA NEEDLE (UMAFLOW)-USE FOR TEMPORARY CANNULATION FOR VASCULAR ACCESS FOR EXTRACORPOREAL BLOOD TREATMENT. THIS DEVICE IS INTENDED TO SINGLE USE ONLY AND IS FOR TEMPORARY CATHETERIZATION LESS THAN 30 DAYS. THE SAFETY FEATURE (FOLDABLE WING AND WING EATER) AIDS IN PREVENTION OF NEEDLE STICK INJURY WHEN REMOVING AND DISCARDING NEEDLE AFTER DIALYSIS SESSION., BLOOD ADMINISTRATION SET / BLOOD TRANSFUSION SET (UMAFLOW)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,DISPOSABLE SYRINGE (ALL TYPE) (UMAFLOW)-IT IS USED BY A DOCTOR TO INJECT THE MEDICINE THROUGH INTRAVENOUS OR INTRAMUSCULAR VEIN FOR TREATMENT OF DISEASE.,UMBILICAL CORD CLAMP(UMAFLOW)-

	THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,: INFANT MUCUS EXTRACTOR(UMAFLOW)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,CLOSED WOUND SUCTION UNIT(UMAVAC / MINOR VAC SET)-EXTRACT PUS FROM THE WOUND OF A HUMAN BODY,: INTRAVENOUS CANNULA – ALL TYPE (UMAFLOW)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES , CHEST DRAINAGE CATHETER / THORACIC DRAINAGE CATHETER (UMAFLOW)-THE THORACIC DRAINAGE CATHETER IS USED TO REMOVE PUS , BLOOD OR OTHER FLUID FROM A WOUND ,YANKAUR SUCTION SET(VACCUM SUCK)-YANKAUR SUCTION SET ARE USED FOR THE REMOVAL OF BLOOD AND FLUIDS DURING SURGERY., ABDOMINAL DRAINAGE KIT(UMA-ADK)-ABDOMINAL DRAINAGE KIT ARE USE IN THE POST OPERATIVE DRAINAGE FROM ABDOMINAL AREAS,ENDOTRACHEAL TUBE(UMAFLOW)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,RYLE'S / NASOGASTRIC / GASTRO DUODENAL / LEVIN'S TUBE(UMAFLOW / UMALINE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES,: IV FLOW REGULATOR WITH OR WITHOUT INFUSION SET (ROYALFLO)- AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY,SUCTION CATHETER(UMAFLOW)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,REDON DRAIN CATHETER(UMAFLOW)-THE CROSS PERFORATED DRAIN ARE SUITABLE FOR USE WITH HIGH VACUUM WOUND DRAINAGE SYSTEM FOR POST-OPERATIVE WOUND DRAINAGE.(IN MEDICAL DRAINAGE REFER TO THE SYSTEMIC WITHDRAWAL OF INCREASE OF DISEASED FLUID, GASES AND DISCHARGES TO RE-ESTABLISH NORMAL CONDITION),EXTENSION LINE WITH / WITHOUT THREE WAY STOP COCK (FOR EXPORT ONLY) (UMAFLOW)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, MEASURED VOLUME SET/BURETTE SET (FOR EXPORT ONLY) (UMADRIP)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,ENDOTRACHEAL TUBE(FOR EXPORT ONLY)(UMAFLOW)-INSERTS THE TUBE WITH THE HELP OF A

	LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,CHEST DRAINAGE CATHETER / THORACIC DRAINAGE CATHETER (FOR EXPORT ONLY)(UMAFLOW)-THE THORACIC DRAINAGE CATHETER IS USED TO REMOVE PUS , BLOOD OR OTHER FLUID FROM A WOUND , UMBILICAL CATHETER/ CANNULA (FOR EXPORT ONLY)(UMAFLOW)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS.,UNDER WATER SEALED CHEST DRAINAGE BOTTLE(UMASEAL)-TO COLLECT THE DRAIN WATER & OTHER MATERIAL FROM THE STOMACH,: INFANT FEEDING TUBE(UMAFLOW)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN.IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING ,UMBILICAL CATHETER / CANNULA (UMAFLOW)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS. ,SUCTION CATHETER (FOR EXPORT ONLY)(UMAFLOW)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,KARMAN CANNULA(UMAFLOW)-USED IN IRRIGATION DURING TRANS URETHRAL RESECTION OF PROSTATE GLAND,SCALP VEIN SET(UMAFLOW)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD,T.U.R. SET(UMAFLOW)-USED IN IRRIGATION DURING TRANS URETHRAL RESECTION OF PROSTATE GLAND,PERITONEAL DIALYSIS SET / CATHETER / KIT(UMAFLOW)-THAT ALLOWS DIALYSIS FLUID TO ENTER ABDOMINAL CAVITY, DWELL INSIDE FOR A WHILE AND THEN DRAIN BACK OUT AGAIN.,: MEASURED VOLUME SET(UMADRIP)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,FOLEY BALLOON CATHETER(UMAFLOW)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY,: HIGH PRESSURE MONITORING LINE (UMAFLOW)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. , STOMACH TUBE (UMAFLOW)-PASSAGE OF A TUBE VIA THE MOUTH

	OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID. , URETHRAL / NELATON / RECTAL CATHETER(UMAFLOW)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,FOLEY BALLOON CATHETER (FOR EXPORT ONLY)(UMAFLOW)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3706	MFG/MD/2021/000042	1.License Holder Name: DELUX SURGICAL 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE MUCUS EXTRACTOR FOR SINGLE USE ONLY(FLORIGHT)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION. ,STERILE DISPOSABLE INFUSION SET WITH AND WITHOUT AIR VENT BIS12655 (FOR EXPORT ONLY)(S K R)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (FLORIGHT)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE RYLE'S / NASOGASTRIC TUBE (FLORIGHT)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,:STERILE DISPOSABLE SCALP VEIN SET FOR SINGLE USE ONLY(FLORIGHT)-:INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD,STERILE DISPOSABLE INFUSION SET WITH AND WITHOUT AIR VENT BIS12655 (- - -)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (FLORIGHT)-:IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,BLOOD ADMINISTRATION SET [FOR EXPORT ONLY](U-MEDIC)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WUTH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(FLORIGHT)-RANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. , STERILE DISPOSABLE INFUSION SET WITH AND WITHOUT AIR VENT BIS12655 (OXFORD)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. , STERILE DISPOSABLE INFANT FEEDING TUBE(FLORIGHT)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH

	YOUR ABDOMEN IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING ,STERILE DISPOSABLE : INTRAVENOUS CANNULA (FLORIGHT)- THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES , STERILE DISPOSABLE UMBILICAL CORD CLAMP(FLORIGHT)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE DISPOSABLE INFUSION SET WITH AND WITHOUT AIR VENT BIS12655 (FOR EXPORT ONLY)(OXFORD)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE INFUSION SET WITH AND WITHOUT AIR VENT BIS 12655 (FOR EXPORT ONLY) (FLORIGHT)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. , STERILE DISPOSABLE TRACHEOBRONCHIAL SUCTION CATHETER (FLORIGHT)-CLEARING THE AIRWAYS OF MUCUS, PUS OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION,STERILE DISPOSABLE INFUSION SET WITH AND WITHOUT AIR VENT BIS 12655 (DUALSAFE)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., STERILE DISPOSABLE INFUSION SET WITH AND WITHOUT AIR VENT BIS 12655 (FOR EXPORT ONLY) (U-MEDIC)-:THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE INFUSION SET WITH AND WITHOUT AIR VENT BIS12655 (FOR EXPORT ONLY)(- - -)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,MEASURE VOLUME IV SET [FOR EXPORT ONLY](U-MEDIC)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.

3707	MFG/MD/2021/000043	1.License Holder Name: TRIDHARA SURGICAL 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(TRIDHARA STERILE DOSPOSABLE INFUSION SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(HEUER B.T.SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(TRIDHARA PERFECT CARE MEASURED VOLUME INFUSION SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. CLASS OF MEDICAL ,STERILE DISPOSABLE UMBILICAL CORD CLAMP FOR SINGLE USE ONLY(MAGAW CORD CLAMP)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE DISPOSABLE MICRO DRIP INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(TRIDHARA MICRO DRIP SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT' S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE., STERILE DISPOSABLE UMBILICAL CORD CLAMP FOR SINGLE USE ONLY(HEUER CORD CLAMP)- THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(TRIDHARA STERILE DISPOSABLE BLOOD ADMINISTRATION SET)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED,STERILE DISPOSABLE ENDOTRACHEAL TUBE FOR SINGLE USE ONLY(MAGAW)-:INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,STERILE INFANT FEEDING TUBE FOR SINGLE USE ONLY (TRIDHARA INFANT FEEDING TUBE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING, STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(MEDIGUARD)-TRANSFUSION SET IS

	USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., STERILA CLOSED WOUND SUCTION SET FOR SINGLE USE ONLY (MAGAW)-EXTRACT PUS FROM THE WOUND OF A HUMAN BODY., STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (MEDIMARK MEASURED VOLUME SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY (HEUER B.T.SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. , STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(ANGEL)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(SAFELIFE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE TRACHEOBRONCHIAL ABDOMINAL DRAINAGE CATHETER FOR SINGLE USE ONLY(MAGAW)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(HEUER MEASURED VOLUME SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE UMBILICAL CORD CLAMP FOR SINGLE USE ONLY(NATASO CORD CLAMP)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY (NATASO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (DAMANI)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(MEDIGUARD B.T. SET)-TRANSFUSION SET IS

	USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., STERILE DISPOSABLE YANKAUR SUCTION SET FOR SINGLE USE ONLY (MAGAW)-YANKAUR SUCTION SET ARE USED FOR THE REMOVAL OF BLOOD AND FLUIDS DURING SURGERY. ,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(NATASO MEASURED VOLUME SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ANGEL)-:TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (HICARE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(MEDIMARK)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY (MAGAW)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENA TION AND VENTILATION.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(HEUER)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(NATASO)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY (MEDIMARK BT SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(PARFECT CARE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (TRIDHARA/MAGAW/ANGLE)-TRANSFUSION SET IS USED TO

	ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE ENDOTRACHEAL TUBE FOR SINGLE USE ONLY(MAGAW)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS. CLASS OF MEDICAL , STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY (TRIDHARA/MAGAW/ANGLE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(HICARE B.T. SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., STERILE DISPOSABLE MEASURED VOLUME INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (TRIDHARA/MAGAW/ANGLE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.

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3708	MFG/MD/2021/000044	1.License Holder Name: TRANSLUMINA THERAPEUTICS LLP 2.Approving Authority: UTTARAKHAND 3.Device Name(Brand Name)-Intended Use:PTCA Y CONNECTOR KIT (TRANS PTCA KIT-PRIME)-THE PTCA Y CONNECTOR KIT IS INTENDED TO MAINTAIN HAEMOSTASIS BEFORE AND DURING THE INTRODUCTION/THE USE AND WITHDRAWAL OF DIAGNOSTIC/INTERVENTIONAL DEVICES DURING INTERVENTIONAL PROCEDURES,INTRODUCER NEEDLE(TRANS-NEEDLE)-INTRODUCER NEEDLE IS USED TO INTRODUCE GUIDEWIRE,ANGIO KIT (TRANS- AT)-ANGIO KIT INTENDED FOR USE AS ACCESSORIES FOR PERCUTANEOUS CORONARY ANGIOGRAPHY (PTCA) PROCEDURE , PTCA Y CONNECTOR KIT(TRANS-PTCA KIT)-THE PTCA Y CONNECTOR KIT IS INTENDED TO MAINTAIN HAEMOSTASIS BEFORE AND DURING THE INTRODUCTION/THE USE AND WITHDRAWAL OF DIAGNOSTIC/INTERVENTIONAL DEVICES DURING INTERVENTIONAL PROCEDURES.,INFLATION DEVICE(TRANS-ID)-AN INFLATION DEVICE IS USED FOR THE INFLATION AND DEFLATION OF A BALLOON DILATATION CATHETER, TO DILATE THE VESSEL OR IMPLANT A STENT. ,MANIFOLD(TRANS-FOLD)-TRANS-FOLD IS INTENDED FOR CONNECTION BETWEEN THE DEVICES, SUCH LIKE INJECTION SYRINGE, ANGIOGRAPHIC CATHETER, DRIP SET TO THE BOTTLE DELIVERING CONTRAST AGENT OR SALINE FLUSH, OR PRESSURE MONITORING SYSTEM, ETC. EACH FLUID CHANNELS CAN BE INDEPENDENTLY CONTROLLED BY SWITCH.,PTCA KIT(TRANS- PT)-PTCA KIT INTENDED FOR USE AS ACCESSORIES FOR PERCUTANEOUS CORONARY ANGIOGRAPHY (PTCA) PROCEDURE
3709	MFG/MD/2021/000045	1.License Holder Name: REENAV LOGISTICS PVT LT 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:SURGICAL DRESSINGS (SECONDARY PACKING / LABELING / STICKERING / OVERPRINTING / STAMPING)(NA)-DRESSING AEROSOL, NON-ADHERENT DRESSING, PERIODONTAL, KIT, DRESSING PAD,DRESSING,COTTON GRUDGES AND BANDAGES (SECONDARY PACKING / LABELING / STICKERING / OVERPRINTING / STAMPING)(NA)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGE, MEDICAL ABSORBENT BANDAGES.

3710	MFG/MD/2021/000047	1.License Holder Name: FUTURA SURGICARE PVT LTD 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:STAPLE REMOVER. (NEXPEL & OTHER OEM BRANDS.)-IT IS INTENDED TO REMOVE THE SURGICAL SKIN STAPLES FROM THE INTACT HEALED SKIN., MICROPOROUS ADHESIVE PAPER TAPE(NETPORE AND OTHER OEM BRANDS.)-IT IS INTENDED TO BE PLACED ON THE INTACT SKIN OF THE PATIENT AS A HOLDING DEVICE TO HOLD/ PASTE OTHER SURGICAL DRESSINGS IN PLACE. IT IS NOT INTENDED TO COME IN CONTACT WITH BLOOD OR BREACHED SKIN.,APPLICATOR FOR LIGATION CLIPS.(NETGRIP & OTHER OEM BRANDS.)-IT IS INTENDED TO PLACE THE LIGATION CLIP THROUGH BODY ORIFICE ON A TUBULAR STRUCTURE.
3711	MFG/MD/2021/000048	1.License Holder Name: VITROMED HEALTHCARE 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:RNA EXTRACTION KITS (NA)-RNA EXTRACTION KIT IS INTENDED FOR MOLECULAR BIOLOGY APPLICATIONS. THIS PRODUCT IS NOT IT INTENDED FOR THE DIAGNOSIS ,PREVENTION OR TREATMENT OF A DISEASE .
3712	MFG/MD/2021/000049	1.License Holder Name: SK HEALTHCARE SURGICALS 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:DISPOSABLE HYPORDERMIC SYRINGE(LYF)-INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY
3713	MFG/MD/2021/000050	1.License Holder Name: SPM MEDICARE 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:ALCOHOL SWAB-IT IS A SINGLE USE , STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE.,SURGICAL GOWN (SPM)-INTENDED TO COVER FULL BODY ACT AS IMPERMEABLE TO BLOOD AND BODY FLUIDS AND ENSURE A HIGH LABEL OF PROTECTION FROM BIOLOGICAL/ INFECTIOUS AGENTS.

3714	MFG/MD/2021/000051	1.License Holder Name: CARENOW MEDICAL PRIVATE LIMITED 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:SURFACE DISINFECTANT WIPES(SCOTCH - BRITE)-SURFACE DISINFECTANT WIPES ARE USED TO DISINFECT SURFACES OF NON - INVASIVE MEDICAL DEVICES AND ON HARD NON - POROUS SURFACES OF: DIAGNOSTIC EQUIPMENT, PATIENT MONITORING EQUIPMENT, DIALYSIS MACHINES, ULTRASOUND PROBES, BED RAILINGS, IV POLES, PULSE OXIMETERS, ECG, STETHOSCOPES, STRETCHERS, CT/MRI/X-RAY MACHINES, TABLES, CABINETS, CARTS, CHAIRS, GRANITE COUNTERS, EXAM TABLE AND OTHERS. NOT TO BE APPLIED ON SKIN.,SURFACE DISINFECTANT WIPES(THERASOL)-SURFACE DISINFECTANT WIPES ARE USED TO DISINFECT SURFACES OF NON - INVASIVE MEDICAL DEVICES AND ON HARD NON - POROUS SURFACES OF: DIAGNOSTIC EQUIPMENT, PATIENT MONITORING EQUIPMENT, DIALYSIS MACHINES, ULTRASOUND PROBES, BED RAILINGS, IV POLES, PULSE OXIMETERS, ECG, STETHOSCOPES, STRETCHERS, CT/MRI/X-RAY MACHINES, TABLES, CABINETS, CARTS, CHAIRS, GRANITE COUNTERS, EXAM TABLE AND OTHERS. NOT TO BE APPLIED ON SKIN.,SURFACE DISINFECTANT WIPES(ECO PROTECT)-SURFACE DISINFECTANT WIPES ARE USED TO DISINFECT SURFACES OF NON - INVASIVE MEDICAL DEVICES AND ON HARD NON - POROUS SURFACES OF: DIAGNOSTIC EQUIPMENT, PATIENT MONITORING EQUIPMENT, DIALYSIS MACHINES, ULTRASOUND PROBES, BED RAILINGS, IV POLES, PULSE OXIMETERS, ECG, STETHOSCOPES, STRETCHERS, CT/MRI/X-RAY MACHINES, TABLES, CABINETS, CARTS, CHAIRS, GRANITE COUNTERS, EXAM TABLE AND OTHERS. NOT TO BE APPLIED ON SKIN.
3715	MFG/MD/2021/000052	1.License Holder Name: M/S STERIMED MEDICAL DEVICES PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:FOLEY CATHETER (FOLEY BALLOON CATHETER 2 WAY)(TRUCATH)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,FOLEY CATHETER (FOLEY BALLOON CATHETER 3 WAY)(TRUCATH)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.

3716	MFG/MD/2021/000053	1.License Holder Name: SAHAJANAND LASER TECHNOLOGY LIMITED (SLTL) 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:COBALT CHROMIUM EVEROLIMUS ELUTING CORONARY STENT WITH DELIVERY SYSTEM (EVEROTRACK)-FOR IMPROVING CORONARY LUMINAL DIAMETER IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO OR RESTENOTIC LESIONS.,PTCA BALLOON CATHETER(FLEXITRACK SC, FLEXITRACK NC)-PTCA BALLOON CATHETER IS INTENDED TO BE USED FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) FOR THE PURPOSE OF IMPROVING MYOCARDIAL BLOOD OW IN THE LOCALIZED STENOTIC LESIONS OF CORONARY ARTERIES.,COBALT CHROMIUM RAPAMYCIN (SIROLIMUS) ELUTING CORONARY STENT WITH DELIVERY SYSTEM(SIROTRACK)-THE SIROTRACK COBALT CHROMIUM SIROLIMUS DRUG ELUTING CORONARY STENT SYSTEM IS INDICATED FOR IMPROVING LUMINAL DIAMETER AND REDUCING RESTENOSIS FOR THE TREATMENT OF DE NOVO LESIONS IN NATIVE CORONARY ARTERIES.
3717	MFG/MD/2021/000054	1.License Holder Name: CEPHAS MEDICAL PRIVATE LIMITED 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:MALE INCONTINENCE CATHETER (SILICONE)(CEPHAS SILICONE MALE EXTERNAL CATHETER (SMEC))-SILICONE MALE EXTERNAL CATHETER(SMEC) USED FOR SINGLE USE, IS INTENDED TO ROLL OVER A MALE PATIENT' S PENIS AND KEPT IN PLACE USING SELF ADHESIVE AVAILABLE IN THE PRODUCT ITSELF TO DIVERT URINE TO A URINE BAG CONNECTED TO THE DEVICE,MALE INCONTINENCE SHEATH/CATHETER, SELF-ADHESIVE(EXTENDED WEAR)-MALE INCONTINENCE SHEATH/CATHETER, SELF-ADHESIVE (EXTENDED WEAR) USED FOR SINGLE USE, IS INTENDED TO ROLL OVER A MALE PATIENT'S PENIS AND KEPT IN PLACE USING SELF ADHESIVE AVAILABLE IN THE PRODUCT ITSELF TO DIVERT URINE TO A URINE BAG CONNECTED TO THE DEVICE.

3718	MFG/MD/2021/000055	1.License Holder Name: MEDIVISION HEALTH CARE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(BIOSAFE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE FOLEY BALLOON CATHETER FOR SINGLE USE ONLY(BIOSAFE/BAXTER LIFE)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY,STERILE INFANT FEEDING TUBE FOR SINGLE USE ONLY (BIOSAFE)-:A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING,STERILE TRACHEOBRONCHIAL MUCUS EXTRACTOR CATHETER FOR SINGLE USE ONLY(BIOSAFE/BAXTER LIFE)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (BAXTERLIFE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE RYLE'S / NASOGASTRIC / GASTRO DUODENAL / LEVIN'S TUBE FOR SINGLE USE ONLY(BIOSAFE/BAXTER LIFE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES,STERILE DISPOSABLE MICRO DRIP INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(BIOSAFE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT' S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE UMBILICAL CORD CLAMP FOR SINGLE USE ONLY(BIOSAFE/BAXTER LIFE)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(BIOSAFE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(ANGEL)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. , STERILE SCALP VEIN SET FOR SINGLE USE ONLY(BIOSAFE/BAXTER

		LIFE)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD, STERILE DISPOSABLE INFUSION SET WITH AND WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (SUPER/SFLOW/ARDIS-A D/NUBENO/ANGEL/ULTRAC)-:THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(DRIP IN/CONET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.
3719	MFG/MD/2021/000056	1.License Holder Name: P H MEDISURGE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(- - -)-:IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. CLASS OF MEDICAL ,STERILE DISPOSABLE SCALP VEIN SET FOR SINGLE USE ONLY(- - -)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD CLASS OF ,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(- - -)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE INFANT FEEDING TUBE FOR SINGLE USE ONLY(- - -)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING CLASS OF MEDICAL , STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(- - -)-:TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.

3720	MFG/MD/2021/000057	1.License Holder Name: BIPSON SURGICAL PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:COMBINE DRESSING SURGICAL PAD STERILISED BY GAMMA RADIATIONS(BIPSON)-A PROSTHETIC AND ORTHOTIC ACCESSORY, INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT, OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE), OR PROSTHESIS.,STERILE GAMJEE ROLL (BIPSON)-ADHESIVE BENDAGES. GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,X RAY DETECTABLE ABDOMINAL PAD - NON STERILE (BIPSON)-IT IS INTENDED FOR THE USE DURING VARIOUS SURGERIES.,GAUZE SWAB B.P.(BIPSON)-DRESSING-GEL, DRESSING-PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE, DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE.

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3721	MFG/MD/2021/000058	1.License Holder Name: M/S VASCULAR CONCEPTS LTD. 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:SIROLIMUS ELUTING STENT SYSTEM- STAINLESS STEEL(PRONOVA SS- SIROLIMUS ELUTING STENT SYSTEM- STAINLESS STEEL)-THE PRONOVA SS CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.5MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT,PTCA CATHETERS(SPEED+ - PTCA CATHETERS)-STENOSIS OF CORONARY ARTERIES,BALLOON EXPANDABLE COVERED STENT SYSTEM- - STAINLESS STEEL STENT WITH PTFE(PROGRAFT - BALLOON EXPANDABLE COVERED STENT SYSTEM - STAINLESS STEEL STENT WITH PTFE)-BALLOON EXPANDABLE COVERED STENT IS INDICATED TO COVER THE DISSECTION (TEAR) CAUSED WHEN A PTCA BALLOON OR STENT IS DEPLOYED IN A LESION. COVERED STENTS ARE USED TO CLOSE RUPTURED ARTERIES, PERFORATED ARTERIES AND TO CLOSE ANEURYSMS.,BALLOON EXPANDABLE PERIPHERAL STENT SYSTEM-RENAL & ILLIAC(PROSTAR PLUS - BALLOON EXPANDABLE PERIPHERAL STENT SYSTEM - RENAL & ILLIAC)-INDICATIONS FOR THE DEPLOYMENT OF THE PROSTAR PLUS PERIPHERAL STENT SYSTEM INCLUDE: 1) ATHEROSCLEROTIC DE NOVO LESIONS. 2) RE-STENOTIC LESIONS OF THE PERIPHERAL ARTERIES, SUCH AS THE RENAL ARTERY OR SUBCLAVIAN ARTERY.,BALLOON EXPANDABLE CORONARY STENT SYSTEM - COBALT CHROMIUM(PROZETA - BALLOON EXPANDABLE CORONARY STENT SYSTEM - COBALT CHROMIUM)-THE PROZETA CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO CORONARY ARTERY LESIONS WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0MM TO 4.0 MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED FOR TREATMENT OF CORONARY ARTERIES.,SIROLIMUS ELUTING STENT SYSTEM - COBALT CHROMIUM(PRONOVA - SIROLIMUS ELUTING STENT SYSTEM - COBALT CHROMIUM)-THE PRONOVA CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT

	PRESENT.,PERIPHERAL STENT SYSTEM-SELF EXPANDABLE NITINOL STENT SYSTEM(RESISTANT - SELF EXPANDABLE NITINOL STENT SYSTEM)-IT IS INDICATED FOR THE FOLLOWING APPLICATIONS- • ATHEROSCLEROTIC DISEASE OF THE PERIPHERAL ARTERIES, EG ILIAC, FEMORALIS AND FEMORALIS SUPERFICIALIS AND IN OTHER VESSELS WHICH CORRESPOND IN THEIR ANATOMIC DIMENSIONS TO THE AVAILABLE SIZES OF THE STENTS. • TREATMENT OF BILE DUCT STRICTURES.,PTCA CATHETERS(SPEED - PTCA CATHETERS)-THE SPEED CATHETERS ARE INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,CORONARY STENT SYSTEM-STAINLESS STEEL BALLOON EXPANDABLE(PROLINK LP- CORONARY STENT SYSTEM-STAINLESS STEEL BALLOON EXPANDABLE)-THE PROLINK LP CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE CORONARY DE NOVO ARTERY LESIONS WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0MM TO 4.5MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT,PTMC BALLOON CATHETER AND ACCESSORIES(ACCURA PTMC BALLOON CATHETER - DOUBLE LUMEN BALLOON DILATATION CATHETER AND ACCESSORIES FOR ACCURA BALLOON CATHETER - STYLET,LA WIRE, METAL STRETCHING TUBE, DILATOR, SYRINGE)-• SYMPTOMATIC ISOLATED MITRAL STENOSIS (MODERATE TO SEVERE), NYHA FUNCTION CLASS II~III. • NO DEFORMITY OF THE MITRAL VALVE, NO SEVERE VALVE CALCIFICATION, NO SUBVALVULAR ABNORMALITY AND NO MARKED VALVE RIGIDITY DETECTED BY ECHOCARDIOGRAPHY. MITRAL VALVE AREA LESS THAN OR EQUAL TO 1.5CM2 AND NO LEFT ATRIAL THROMBUS. • SINUS RHYTHM DEMONSTRATED BY ELECTROCARDIOGRAPHY. • MEAN LEFT ATRIAL PRESSURE GREATER THAN 1.46KPA OR 11MMHG, MEAN MITRAL VALVE PRESSURE GRADIENT DURING DIASTOLE GREATER THAN OR EQUAL TO 1.06 KPA OR 8MMHG. • AS FOR PATIENTS WITH RESTENOSIS AFTER SURGICAL COMMISSUROTOMY, ATRIAL FIBRILLATION, MITRAL VALVE CALCIFICATION, MILD MITRAL OR AORTIC REGURGITATION, PTMC CAN ALSO BE PERFORMED BUT WITH CAUTION. • PATIENTS WITH SEVERE PULMONARY HYPERTENSION, LEFT-OR RIGHT-SIDED HEART FAILURE, OR WITH SIGNIFICANT RENAL OR HEPATIC DISEASE. • PATIENTS UNSUITABLE TO ACCEPT VALVE REPLACEMENT BECAUSE OF OTHER CONDITIONS SUCH AS PREGNANCY OR HAVE CONTRAINDICATIONS FOR LONG-TERM ANTICOAGULATION., SIROLIMUS ELUTING STENT SYSTEM - COBALT CHROMIUM

		DEGRADABLE MATRIX(PRONOVA XR- SIROLIMUS ELUTING STENT SYSTEM - COBALT CHROMIUM DEGRADABLE MATRIX)-THE PRONOVA XR CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.5MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT)AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT.
3722	MFG/MD/2021/000059	1.License Holder Name: GAMMA AGRO-MEDICAL PROCESSINGS PVT. LTD 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:ENDOSSEOUS DENTAL IMPLANT(REFIRM)-REFIRM DENTAL IMPLANTS ARE PLACED ENDOSSEOUSLY IN MANDIBLE OR MAXILLA AS A SUBSTITUTE FOR TOOTH TO ANCHOR A SINGLE OR MULTIPLE TEETH PROSTHESIS, IN CASE OF EDENTULISM OR TOOTH LOSS.

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3723	MFG/MD/2021/000060	1.License Holder Name: SATWIK MEDIEQUIP GLOBAL PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:HYPODERMIC NEEDLES (STERICARE)-IT IS INTENDED FOR USE TO INJECT THE PARENTERALS THROUGH DISPOSABLE SYRINGES OR INFUSION SET OR VASCULAR ACCESS DEVICE,HYPODERMIC NEEDLES(SATWIK ECOFLO SATWIK REGFLO SATWIK PREMFLO)-:IT IS INTENDED FOR USE TO INJECT THE PARENTERALS THROUGH DISPOSABLE SYRINGES OR INFUSION SET OR VASCULAR ACCESS DEVICE,SUCTION TUBING WITH CONNECTORS (SATWIK ECOFLO SATWIK REGFLO SATWIK PREMFLO)-IT PROVIDES SECURE CONNECTIONS TO SUPPORT UNINTERRUPTED PROCEDURES. THE SUCTION TUBING COLLECTION INCLUDES 3 DIAMETER SIZES AND MULTIPLE LENGTHS. FLEXIBLE, LOW COIL MEMORY ALLOWS FOR EASY DRAPING,STOMACH TUBE (STERICARE)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL LAVAGE) TUBE OF SMALL VOLUMES OF LIQUID.,SUCTION TIP AND CATHETER (STERICARE)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE CATHETER AND ACCURATE SUCTIONING.,EXTENSION LINES(STERICARE)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS.,FEEDING TUBE (STERICARE)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING,RYLE'S TUBE(SATWIK ECOFLO SATWIK REGFLO SATWIK PREMFLO)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES,LEVINE TUBE(SATWIK ECOFLO SATWIK REGFLO SATWIK PREMFLO)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS,STOMACH TUBE(SATWIK ECOFLO SATWIK REGFLO SATWIK PREMFLO)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL LAVAGE) TUBE OF SMALL VOLUMES OF LIQUID.,SINGLE USE SYRINGE(SATWIK ECOFLO SATWIK REGFLO SATWIK PREMFLO)-:IT IS INTENDED FOR USE TO INJECT THE PARENTERALS THROUGH DISPOSABLE SYRINGES OR INFUSION SET OR VASCULAR ACCESS DEVICE.,SUCTION TIP AND CATHETER(SATWIK ECOFLO SATWIK REGFLO SATWIK PREMFLO)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE CATHETER AND ACCURATE SUCTIONING,OXYGEN MASK WITH

	TUBING(STERICARE)-OXYGEN MASK WITH TUBING IS DESIGNED FOR CONVENIENT OXYGEN THERAPY,BURETTE SET(SATWIK ECOFLO SATWIK REGFLO SATWIK PREMFLO)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,INFUSION SET(SATWIK ECOFLO SATWIK REGFLO SATWIK PREMFLO)-AN INFUSION SET IS USED WITH DEVICES SUCH AS AN INSULIN PUMP. THE PURPOSE OF AN INFUSION SET IS TO DELIVER INSULIN UNDER THE SKIN, FULLFILLING A SIMILAR FUNCTION LIKE AN INTRAVENOUS LINE,LEVINE TUBE(STERICARE)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,SINGLE USE SYRINGE(STERICARE)-IT IS INTENDED FOR USE TO INJECT THE PARENTERALS THROUGH DISPOSABLE SYRINGES OR INFUSION SET OR VASCULAR ACCESS DEVICE.,SCALP VEIN SET(STERICARE)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,BLOOD TRANSFUSION SET(STERICARE)-TRANSFUSION SET IS USED TO ADMINISTER DISPOSABLE BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER SINGLE USE INSERTED INTO A VEIN.,BURETTE SET(STERICARE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,SUCTION TUBING WITH CONNECTORS(STERICARE)-IT PROVIDES SECURE CONNECTIONS TO SUPPORT UNINTERRUPTED PROCEDURES. THE SUCTION TUBING COLLECTION INCLUDES 3 DIAMETER SIZES AND MULTIPLE LENGTHS. FLEXIBLE, LOW COIL MEMORY ALLOWS FOR EASY DRAPING.,EXTENSION LINES(SATWIK ECOFLO SATWIK REGFLO SATWIK PREMFLO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS,OXYGEN MASK WITH TUBING(SATWIK ECOFLO SATWIK REGFLO SATWIK PREMFLO)-OXYGEN MASK WITH TUBING IS DESIGNED FOR CONVENIENT OXYGEN THERAPY,INFUSION SET(STERICARE)-AN INFUSION SET IS USED WITH DEVICES SUCH AS AN INSULIN PUMP. THE PURPOSE OF AN INFUSION SET IS TO DELIVER INSULIN UNDER THE SKIN, FULLFILLING A SIMILAR FUNCTION LIKE AN INTRAVENOUS LINE.,RYLE'S TUBE (STERICARE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,BLOOD TRANSFUSION SET (SATWIK ECOFLO SATWIK REGFLO SATWIK PREMFLO)-TRANSFUSION SET IS USED TO ADMINISTER DISPOSABLE BLOOD/DRUGS TO A

		PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER SINGLE USE INSERTED INTO A VEIN,SCALP VEIN SET(SATWIK ECOFLO SATWIK REGFLO SATWIK PREMFLO)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD.,FEEDING TUBE(SATWIK ECOFLO SATWIK REGFLO SATWIK PREMFLO)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING
3724	MFG/MD/2021/000061	1.License Holder Name: VISHRAM TEX 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:DRESSING PAD (ABSORBENT COTTON IS 16468 WITH ABSORBENT COTTON GAUZE BP 1988 TYPE 13 LIGHT)(VISHRAM TEX)-DRESSING PAD IS USED IN GENERAL WOUND TREATMENT TO PROMOTE HEALING AND PROTECT THE WOUND FROM FURTHER HARM,ABSORBENT COTTON IS 16468 (VISHRAM TEX)-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS
3725	MFG/MD/2021/000062	1.License Holder Name: ELECTRO MAGNETIC INDUSTRIES 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:GAMMA STERILIZATION OF CLASS D MEDICAL DEVICES-NOT APPLICABLE,GAMMA STERILIZATION OF CLASS C MEDICAL DEVICES-NOT APPLICABLE

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3726	MFG/MD/2021/000063	1.License Holder Name: SREE ARUMUGHAM SURGICALS 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:BANDAGE CLOTH CUT IS 863-IT IS USED TO COVERING WOUNDS, KEEP DRESSINGS IN PLACE, APPLYING PRESSURE CONTROLLING BLEEDING AND SUPPORT A MEDICAL DEVICE SUCH AS A SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO THE BODY.,OPEN WOVE BANDAGE BP 1988 TYPE 2-USED TO SECURE DRESSINGS AND OTHER WOUNDS CARE APPLICATIONS,GAUZE SWABS BP 1988 TYPE 13 LIGHT-USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, APPLYING ANTISEPTIC AND MUCH MORE. IT IS ESPECIALLY USEFUL FOR DRESSING WOUNDS WHERE OTHER FABRICS MIGHT STICK TO THE BURN OR LACERATION.,COMBINE DRESSING PAD B.P 1988 TYPE 12-USED TO ABSORBING FLUIDS FROM LARGE AND HEAVILY BLEEDING WOUNDS TO STOP BLEEDING AND REDUCE INFECTION RISK.,UN BLEACHED CALICO (TRIANGULAR BANDAGE) IS 14306-USED AS AN ARM SLING, COVER FOR HEAD DRESSING, BINDING FOR SPLINT OR AS A TOURNIQUET. ,BANDAGE CLOTH UNCUT IS 863-IT IS USED TO COVERING WOUNDS, KEEP DRESSINGS IN PLACE, APPLYING PRESSURE CONTROLLING BLEEDING AND SUPPORT A MEDICAL DEVICE SUCH AS A SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO THE BODY.,ABSORBENT COTTON GAUZE IS 758-IT IS USED FOR CLEANING, DRYING AND DRESSING WOUNDS DURING MEDICAL TREATMENT. IT IS A SINGLE USE DEVICE.
3727	MFG/MD/2021/000064	1.License Holder Name: G. SURGIWEAR LIMITED UNIT-2 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:STERILIZED ADHESIVE BANDAGES USP(G DRESS)-ADHESIVE SURGICAL DRESSINGS ARE USED FOR COVERING WOUNDS, STITCH LINES ETC. THESE ARE USED TO PROVIDE MECHANICAL COVER AND PROTECTION TO WOUNDS., STERILIZED ADHESIVE FILM BANDAGES/ DRESSINGS-STERILIZED ADHESIVE SURGICAL FILM BANDAGES/DRESSINGS ARE USED FOR COVERING WOUNDS, STITCH LINES ETC. THESE ARE USED TO PROVIDE MECHANICAL COVER AND PROTECTION TO WOUNDS.
3728	MFG/MD/2021/000065	1.License Holder Name: BROWNDOVE HEALTHCARE PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER(CATALYNE)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTION, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MEASURING AND INJECTION OF CONTRAST MEDIA.

3729	MFG/MD/2021/000068	1.License Holder Name: DIVINE INDIA 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:GAUZE SWAB BP 1988 (VIVON)-USED TO ABSORB EXTRUDE OF WOUND, BLOOD AFTER SURGICAL PROCEDURE.,COTTON CREPE BANDAGE BP 1988(VIVON)-IT IS USED IN CASE OF PAINFUL JOINTS, SPRAIN, VARICOSE, VEINS, FRACTURES AND DELOCATIONS. IT CAN ALSO BE USED AS MILD COMPRESSION BANDAGE.,COMBINE DRESSING (X-RAY DETECTABLE ABSORBENT COTTON AND VISCOSE GAUZE BP)(VIVON)-USED TO COVER ALL WOUNDS, PARTICULARLY SUCH AS SURGICAL WOUNDS OR GENERAL CUTS AND LACERATIONS AND ABSORB POSTOPERATIVE BLEEDING WOUND EXUDATE IF ANTICIPATED, EASE PAIN AND PROVIDE PROTECTION FOR NEWLY FORMED TISSUE., GAUZE BALLS SCHEDULE-F II(VIVON)-USED TO ABSORB EXTRUDE OF WOUND, BLOOD AFTER SURGICAL PROCEDURE.,DRESSING KIT (VIVON)-USED TO ABSORB EXTRUDE OF WOUND, BLOOD AFTER SURGICAL PROCEDURE.,ROLLED BANDAGE SCHEDULE F-II(VIVON)-USED FOR BANDAGING OF GAUZES ON CUTS, GRAZES, MINOR ABRASIONS AND BLEEDING WOUNDS.,X-RAY DETECTABLE ABDOMINAL PAD BP 1988(VIVON)-USED TO ABSORB DISCHARGES FROM ABDOMINAL WOUNDS AND GREATLY REDUCE THE RISK OF INFECTION FOR THE USER. ABDOMINAL PADS EFFECTIVELY SEAL OFF THE WOUND AREA AND PREVENT MOISTURE FROM SEEPING OUT.,LAPAROTOMY SPONGE WITH OR WITHOUT X-RAY LINE BIS 10829 : 1993(VIVON)-LAPAROTOMY SPONGES ARE USED TO SOAK UP EXTRA FLUID DURING SURGICAL PROCEDURES.,ABSORBENT GAUZE SCHEDULE-F II(VIVON)-USED TO ABSORB EXTRUDE OF WOUND, BLOOD AFTER SURGICAL PROCEDURE.,X-RAY DETECTABLE GAUZE SWAB BP 1988(VIVON)-USED TO ABSORB DISCHARGES FROM ABDOMINAL WOUNDS AND GREATLY REDUCE THE RISK OF INFECTION FOR THE USER. IT EFFECTIVELY SEAL OFF THE WOUND AREA AND PREVENT MOISTURE FROM SEEPING OUT.
3730	MFG/MD/2021/000069	1.License Holder Name: ADINATH MANUTRADE 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.(-)-THE ABSORBENT COTTON ARE USED TO ABSORB SMALL OF EXUDATES OR BODY FLUIDS AND TO APPLY MEDICATION .

3731	MFG/MD/2021/000070	1.License Holder Name: DEVON INNOVATIONS PRIVATE LIMITED 2.Approving Authority: BILASPUR,SHIMLA,KINNAUR ,SOLAN(OTHER THAN BBN) 3.Device Name(Brand Name)-Intended Use:URETHRAL STENT/ SET (US)-(SHORT/LONG TERM)(DEVON)-USED FOR STENTING THE URETHRA AFTER HYPOSPADIAS OR EPISPADIAS REPAIR AND TO PROVIDE POSTOPERATIVE DRAINAGE OF THE BLADDER,INTERNAL EXTERNAL DRAINAGE CATHETER/ SET(IEDC)(DEVON)-USED FOR TEMPORARY DRAINAGE OF THE BILIARY DUCT,ENDOSCOPIC JEJUNAL FEEDING TUBE(EJFT)(DEVON)-USED THROUGH THE CHANNEL OF THE ENDOSCOPE TO PROVIDE SHORT-DURATION ENTERAL ACCESS FOR DELIVERY OF NUTRITION OR MEDICATION TO THE SMALL BOWEL,NEPHROSTOMY CATHETER(NCD)(DEVON)-USED FOR DRAINAGE OF THE URINE FROM THE BLADDER AT REGULAR INTERVALS,ORVAC(ORV)(ORVAC)-ORVAC IS USED AFTER THE SURGERY (POST OPERATIVE).CLOSED WOUND SUCTION DRAINAGE SYSTEM IS USED FOR REMOVING THE WASTE BLOOD & PUSS FROM THE CLOSED WOUND,SUCTION CATHETER(SC)(DEVON)-SUCTION CATHETERS ARE LONG FLEXIBLE TUBES THAT ARE USED IN INTENSIVE CARE TO REMOVE FLUIDS FROM THE MOUTH AND AIRWAYS OF CRITICALLY ILL PATIENTS,VARIO DRAIN(VD)(VARIO DRAIN)-VARIO DRAIN IS A CLOSED WOUND SUCTION DRAINAGE SYSTEM USED AFTER THE SURGERY (POSTSURGERY) FOR REMOVING THE WASTE BLOOD & PUSS FROM THE CLOSED WOUND., GUIDEWIRES/ZEBRA GUIDEWIRES(GW)(DEVON)-GUIDEWIRES FACILITATE THE DELIVERY OF WIDE VARIETY OF CATHETERS AND STENTS TO A MEDICAL PROCEDURE SITE WITHIN THE BODY AS A TRANSIENT USE,MULTI – BAND LIGATOR BARREL(LMB)(DEVON)-USED TO ENDOSCOPICALLY LIGATE ESOPHAGEAL VARCIES AT OR ABOVE THE GASTROESOPHAGEAL JUNCTION OR TO LIGATE INTERNAL HEMORRHOIDS,URETEROSCOPIC SHEATH(USH)-M/F (DEVON)-URETERAL SHEATHS PROVIDE A CONTINUAL WORKING CHANNEL, SIMPLIFYING URETEROSCOPIC PROCEDURES AND PROTECTING THE URETER DURING MULTIPLE INSTRUMENTS EXCHANGES,AMPLATZ RENAL INTRODUCER/ SET(ARI)(DEVON)-USED FOR NEPHROSTOMY TRACT DILATION AND THE PLACEMENT OF A STRICTURE,PERCUTANEOUS MALECOT NEPHROSTOMY CATHETER/SET(MNDC/PCMS)(DEVON)-USED FOR NEPHROSTOMY DRAINAGE IN THE RENAL PELVIS,FOREIGN BODY RETRIEVER DORMIA BASKET(SB)-FLT/SBHEL/SEG/NIT/GRASPER(DEVON)-USED FOR STONE MANIPULATION AND RETRIEVAL / REMOVAL OF URETERAL STONES FROM THE BLADDER, RENAL PELVIS AND URETER,URETERAL CATHETER(UCB/ UOB (WT/AN/PT/CT/MH)(DEVON)-USED FOR DRAINAGE AND RETROGRADE PYELOGRAM,PERCUTANEOUS PIGTAIL

	SUPRAPUBIC CATHETER / SET(TDCS)(DEVON)-USED TO PROVIDE BLADDER DRAINAGE BY PERCUTANEOUS PLACEMENT OF A PIGTAIL CATHETER.,PERCUTANEOUS PIGTAIL NEPHROSTOMY CATHETER/SET (PTDC/ PCNS)(DEVON)-USED FOR TEMPORARY OR PERMANENT DRAINAGE OF URINE FROM THE KIDNEY,ENDOURETEROTOMY STENT/ SET(INTERNAL)(EPIN)(DEVON)-USED FOR TEMPORARY DRAINAGE FROM THE URETEROPELVIC JUNCTION TO THE BLADDER FOLLOWING INCISION OF A STRICTURE,NASO BILIARY DRAINAGE CATHETER(NBDC)(DEVON)-USED FOR TEMPORARY DRAINAGE OF THE BILIARY DUCT,FINE NEEDLE ASPIRATION CATHETER(FNAC) (DEVON)-USED TO INVESTIGATE SUPERFICIAL LUMPS OR MASSES, ENDOPYELOTOMY STENT/ SET(EPEX)(EXTERNAL)(DEVON)-USED FOR STENTING THE URETEROPELVIC JUNCTION AND THE URETER, KLEARSITE CANNULA(KLST)(KLEARSITE)-KLEARSITE IS USED DURING THE SURGERY (INTER OPERATIVE) FOR REMOVING THE WASTE BLOOD FROM THE WOUND AT THE TIME OF SURGERY & COLLECT THAT INTO THE SUCTION APPARATUS.,DILATOR/SET (UD/FDS/ FUD/FD/UDS/SD/MDF/MDM/MDP)(DEVON)-USED FOR DILATION OF THE URETER PRIOR TO URETEROSCOPY AND/OR STONE MANIPULATION,CUTTING LOOP – (SINGLE / DOUBLE STEM)-CLSS/CLDS(DEVON)-USED TO RESECT TISSUE AND PROVIDE A SMOOTH TISSUE CUT,BILIARY DUCT DRAINAGE CATHETER(BDDC) (DEVON)-USED FOR TRANS-HEPATIC BILIARY DRAINAGE.,LUNG ABCESS DRAINAGE CATHETER(LADC)(DEVON)-USED TO DRAIN FLUIDES,PLEURAL DRAINAGE CATHETER/ SET(PDC)(DEVON)-USED TO DRAIN FLUIDS,HEMODIALYSIS CATHETER SET(HDC)(DEVON)-USED FOR EXCHANGE BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT,PERCUTANEOUS BILIARY DRAINAGE CATHETER/SET(PBDC)(DEVON)-INTENDED FOR PERCUTANEOUS DRAINAGE IN A VARIETY OF DRAINAGE APPLICATIONS,IUI CATHETER/CANNULA(IUI)(DEVON)-USED FOR INTRODUCTION OF WASHED SPERMATOZOA INTO THE UTERINE CAVITY. AVAILABLE IN BOTH STRAIGHT AND CURVED OPTIONS,TIEMAN CATHETER(TIEM) (DEVON)-USED TO AID IN URINATION FOR MEN WHO HAVE ENLARGED PROSTATES OR SUFFER FROM BENIGN PROSTATIC HYPERPLASIA, EXTERNAL BILIARY DRAINAGE CATHETER(EBDC)(DEVON)-USED FOR TEMPORARY DRAINAGE OF THE BILIARY DUCT,URINARY CATHETER (CIC-M/F)(DEVON)-USED FOR DRAINING URINE FROM THE BLADDER IN REGULAR INTERVALS.,SUPRAPUBIC CYSTOSTOMY CATHETER/ SET(SPCS)(DEVON)-USED TO PROVIDE BLADDER DRAINAGE BY PERCUTANEOUS PLACEMENT OF MALECOT CATHETER

3732	MFG/MD/2021/000071	1.License Holder Name: BANGA INDUSTRIES 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (ULTRA, OPTIMA)-TO MEASURE TEMPERATURE OF HUMAN,B.P. MONITOR(ULTRA, OPTIMA)-TO MEASURE BLOOD PRESSURE ,CREPE BANDAGES(OPTIMA, IDEAL CREPE, ULTRA CREPE, SURGI CREPE, PREMIER)-FOR THE REDUCES SWELLING, SECURES WOUND DRESSING, SUPPORTS STRAINS AND SPRAINS,ABSORBENT GAUZE (OPTIMA, ULTRA)-FOR CLEAN THE WOUND,ROLLED BANDAGES (OPTIMA, IDEAL, ULTRA , SURGI , PREMIER)-IT USED TO COVER THE WOUNDS TO PREVENT IT FROM DUST AND BACTERIA

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3733	MFG/MD/2021/000072	1.License Holder Name: PERFECT SURGICARE INDUSTRIES PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:GAMJEE ROLL(PERFECT)-IT IS USED FOR PRIMARY WOUND DRESSINGS OR IT IS APPLIED OVER A DRESSING, THESE ALLOW LOW ADHERENT WOUND INTERFACE, ABDOMINAL PAD(PERFECT)-IT IS USED FOR THE ABSORPTION OF DISCHARGES FROM ABDOMINAL WOUND,NON-WOVEN ADHESIVE DRESSING WITH PAD(PERFECT)-IT IS USE FOR DRESSING TO PROTECT WOUND, POST OPERATIVE USE, DRESSING ON CUTS, LACERATION AND SUTURED WOUNDS,UMBILICAL CORD CLAMP (PERFECT,GENERIC)-THESE DEVICES MAY BE A CLIP,TIE, TAPE OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT. ,ELASTIC ADHESIVE BANDAGE(PERFECT)-THE ELASTIC ADHESIVE BANDAGE IS LIGHT WEIGHT STRAPPING BANDAGE THAT CAN BE USED FOR POST OPERATION DRESSING APPLICATION, ANKLE TAPING, KNEE TAPING, HAND TAPING, AND WRIST TAPING. IT IS FREQUENTLY USE BY SPORTS PHYSIOS IN THE PREVENTION AND TREATMENT OF SPRAINED ANKLE.,ABSORBENT GAUZE CLOTH(PERFECT)-IT IS USED FOR CLEAN THE WOUND, MAJOR AND MINOR INJURY DRESSING AND DURING SURGICAL DRESSING,OPEN WOVE BANDAGE(PERFECT)-IT IS USED TO COVER WOUNDS TO PREVENT IT FROM DUST AND BACTERIA. IT IS USED FOR SECURING DRESSINGS AND OTHER WOUND CARE APPLICATIONS,BLOOD PRESSURE MONITOR/ ANEROID SPHYGMOMANOMETER(PERFECT)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES,DIGITAL THERMOMETER(PERFECT)-IT IS DEVICE USED TO RECORD THE BODY TEMPERATURE,PARAFFIN GAUZE DRESSING(PERFECT)-PARAFFIN GAUZE DRESSING INTENDED TO BE USED IN THE TREATMENT OF ULCERS, BURNS, SKIN GRAFTS (BOTH DONOR AND RECEPTOR SITES) AND VARIOUS TRAUMATIC INJURIES.,FOLEY BALLOON CATHETER (PERFECT)-IT IS USED TO INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY FOR DRAINAGE OF BLADDER ,CORN CAP(PERFECT)-IT IS USED FOR THE EFFECTIVE TREATMENT OF CORNS, WARTS AND VERRUCAS,I.V. CANNULA FIXATOR(PERFECT)-I.V. CANNULA FIXATOR IS HELPFUL FOR FIXING I.V. CANNULA. IT IS DESIGNED TO STRENGTHEN THE CANNULA FIXATOR ON THE BODY AT THE TIME OF DRIPPING AND INJECTING MEDICINES,CREPE BANDAGE(PERFECT)-IT IS USE TO SUPPORT STRAINS AND SPRAINS, SECURING WOUND DRESSING AND PROVIDING COMPRESSION TO ALLEVIATE SWELLING., AUTOMATIC BLOOD PRESSURE MONITOR(PERFECT)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD

		PRESSURES,SURGICAL DRESSING/COMBINED DRESSING PAD (PERFECT,GENERIC)-DRESSING AEROSOL, NON-ADHERENT, DRESSING,PERIODONTAL,KIT,DRESSING PAD,DRESSING,SILICON FOLEY BALLOON CATHETER(PERFECT , URO PATH)-IT IS USED TO INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY FOR DRAINAGE OF BLADDER.,COTTON GRUDGES AND BANDAGES/GAUZE SWAB(SAFE SWAB,GENERIC)-ADHESIVE BANDAGES,GAUGE BANDAGES, PRESSURE BANDAGES,TRACTION BANDAGES,MEDICAL ABSORBENT (FIBER) BANDAGES,THREE WAY STOP COCK(PERFECT)-IT IS USED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,FIBERGLASS CASTING TAPE(PERFECT)-A PROSTHETIC AND ORTHOTIC ACCESSORY, INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT, OR AID IN THE USE OF A CAST, ORTHOSIS (BRACE), OR PROSTHESIS
3734	MFG/MD/2021/000073	1.License Holder Name: M/S NICE REMEDIES 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:BENZALKONIUM CHLORIDE DRESSING STRIP(NICE AID)-SURGICAL DRESSINGS
3735	MFG/MD/2021/000074	1.License Holder Name: ANITA INDUSTRIES 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:MERCURY SPHYGMOMANOMETER(ELKO)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES,ANEROID SPHYGMOMANOMETER(ELKO)-ANEROID SPHYGMOMANOMETER IS INTENDED FOR THE NON-INVASIVE BLOOD PRESSURE MEASUREMENT OF ADULT AND PEDIATRIC, BUT NOT NEONATAL PATIENTS
3736	MFG/MD/2021/000075	1.License Holder Name: AKSHAR GAMMA STERILES LLP 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:GAMMA RADIATION-GAMMA RADIATION TREATMENT OF THE PRODUCT MANUFACTURED BY LOAN LICENSEE FIRM COBALT 60

3737	MFG/MD/2021/000076	1.License Holder Name: R. R. MEDICAL ENTERPRISES PRIVATE LIMITED 2.Approving Authority: BIHAR 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE HYPODERMIC SYRINGE FOR SINGLE USE (WITH AND WITHOUT NEEDLE)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUID FROM THE BODY.,STERILE IV INFUSION SETS WITH AIR VENT AND NON VENT-TRANSFERRING MEDICINE AND FLUID INFUSION.,STERILE HYPODERMIC NEEDLE FOR SINGLE USE-A HYPODERMIC SINGLE NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.
3738	MFG/MD/2021/000077	1.License Holder Name: SAHNISONS MEDICAL DEVICES PRIVATE LIMITED 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:UMBILICAL OCCLUSION DEVICE-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,COTTON GRUDGES AND BANDAGES-A STRIP OF FABRIC USED ESPECIALLY TO COVER, DRESS, AND BIND UP WOUNDS AND A FLEXIBLE STRIP OR BANDAGES USED TO COVER, STRENGTHEN, OR COMPRESS SOMETHING.,STERILE DRAPES-IT IS INTENDED FOR USE DURING VARIOUS SURGICAL PROCEDURES TO ISOLATE THE AREA UNDER PROCEDURE FROM REST OF BODY.
3739	MFG/MD/2021/000078	1.License Holder Name: SAMRAT SURGICALS PVT LTD 2.Approving Authority: JAMMU AND KASHMIR 3.Device Name(Brand Name)-Intended Use:GAUZE CLOTH(DR.)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES, BANDAGE CLOTH(DR.)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES,ABSORBENT COTTON WOOL I.P (DR.)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES,ROLLED CUT BANDAGES(DR.)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES

3740	MFG/MD/2021/000079	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT. LTD. 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:ETHYLENE OXIDE STERILIZATION OF CLASS A AND B PRODUCTS-ETHYLENE OXIDE OF PRODUCTS FALLING UNDER CLASS A & B. INTENDED USE OF THE PRODUCTS WOULD BE AS DECIDED BY THE MEDICAL DEVICE MANUFACTURER.,GAMMA RADIATION OF CLASS A & B PRODUCTS-GAMMA RADIATION OF PRODUCTS FALLING UNDER CLASS A & B. INTENDED USE OF THE MEDICAL DEVICE SHALL BE AS DECIDED BY THE MEDICAL DEVICE MANUFACTURER.
3741	MFG/MD/2021/000080	1.License Holder Name: SMB MEDICAL DEVICES PVT LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:SYRINGE(SMB)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.
3742	MFG/MD/2021/000081	1.License Holder Name: AGROSURG IRRADIATORS(INDIA) PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:CU 250 IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,CU 375 IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,NON ABSORBABLE SURGICAL BRAIDED POLYESTER SUTURE WITH NEEDLE(SMB)-WOUND CLOSER, COPPER T 380A (TCU 380A/CUT 380A) IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,COPPER T 380A (TCU 380A) IUD WITH SAFE LOAD AND PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,TCU 380AG IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,NON ABSORBABLE SURGICAL BRAIDED SILK SUTURE WITH NEEDLE(SMB)-WOUND CLOSER,NON ABSORBABLE SURGICAL POLYAMIDE MONOFILAMENT SUTURE WITH NEEDLE(SMB)-WOUND CLOSER,TUBAL RINGS(SMB)-CONTRACEPTION IN THE WOMEN

3743	MFG/MD/2021/000082	1.License Holder Name: ALFA CORPUSCLES PRIVATE LIMITED 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE SKIN STAPLER(WELFARE MEDICAL)-STERILE DISPOSABLE SKIN STAPLER IS INTENDED TO BE USED FOR THE PRIMARY, DELAYED PRIMARY AND SECONDARY CLOSURE OF THE SKIN WOUNDS IN CASE. • FOR CLOSURE OF UNINFECTED POST TRAUMATIC WOUNDS. • FOR PRIMARY, DELAYED PRIMARY AND SECONDARY CLOSURE OF SURGICAL INCISIONS AND WOUNDS. • FOR SKIN APPROXIMATION IN OTHER CASES. • FOR SKIN GRAFT AND FLAP PLACEMENT.

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3744	MFG/MD/2021/000084	1.License Holder Name: STERIMED SURGICALS (INDIA) PVT. LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:TRACHEOSTOMY TUBE PLAIN(TRACHFLEX)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,ENDOTRACHEAL TUBE CUFFED(CORETUBE)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,ORTHOPAEDIC CASTING BANDAGE (OCBT) / TAPE-A PROSTHETIC AND ORTHOTIC ACCESSORY, INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT, OR AID IN THE USE OF A CAST, ORTHOSIS, OR PROSTHESIS.,CLOSED SUCTION SYSTEM(CORTISLIFE-SC)-IT IS INTENDED FOR ENDOTRACHEAL SUCTIONING TO PROVIDE A PATIENT AIRWAY BY REMOVING EXCESS FLUIDS, SECRETIONS, EXUDATES AND TRANSUDATE THROUGH THE ARTIFICIAL AIRWAY.,ENDOTRACHEAL TUBE PLAIN(CORETUBE-S)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,ENDOTRACHEAL TUBE CUFFED(CORETUBE-SS)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL,CLOSED SUCTION SYSTEM-IT IS INTENDED FOR ENDOTRACHEAL SUCTIONING TO PROVIDE A PATIENT AIRWAY BY REMOVING EXCESS FLUIDS, SECRETIONS, EXUDATES AND TRANSUDATE THROUGH THE ARTIFICIAL AIRWAY.,UMBILICAL TAPE SCHEDULE F-III-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,BANDAGE TRIANGULAR CALICO (IS STANDARD)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES., COTTON CREPE BANDAGE B.P. / IS STANDARD-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,FOLEY BALLOON CATHETER 2 WAY(FOLCATH-S)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,GAUZE AND COTTON TISSUE B.P.-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,ABSORBENT NON-WOVEN GAUZE(GINNI MEDAID)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,TRACHEOSTOMY TUBE PLAIN-A BREATHING TUBE INSERTED INTO A TRACHEOTOMYUSED TO OBTAIN A CLOSED

	CIRCUIT FOR VENTILATION,DISPOSABLE PERFUSION SET / DISPOSABLE INFUSION SET (IV SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN., ENDOTRACHEAL TUBE PLAIN(CORETUBE-RF)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL,TROCAR-A TROCAR IS MADE UP OF AN OBTURATOR (WHICH MAY BE A METAL OR PLASTIC SHARPENED OR NON-BLADED TIP), A CANNULA(BASICALLY A HOLLOW TUBE), AND A SEAL. THE TROCAR FUNCTIONS AS A PORTAL FOR THE SUBSEQUENT PLACEMENT OF OTHER INSTRUMENTS, SUCH AS GRASPERS, SCISSORS, STAPLERS, ETC. IT IS ALSO INTENDED TO REMOVE AIR OR FLUID FOR THE PLEURAL SPACE IN A CLOSED, ONE WAY FASHION., CLOSED SUCTION SYSTEM-IT IS INTENDED FOR ENDOTRACHEAL SUCTIONING TO PROVIDE A PATIENT AIRWAY BY REMOVING EXCESS FLUIDS, SECRETIONS, EXUDATES AND TRANSUDATE THROUGH THE ARTIFICIAL AIRWAY.,SEMIPERMEABLE ADHESIVE DRESSING BP (STERIDERM)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. , MEASURE VOLUME SET-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,ABSORBENT GAUZE (AS PER SCHEDULE F-II)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES., ORTHOPAEDIC CASTING BANDAGE / TAPE(ABLECAST)-A PROSTHETIC AND ORTHOTIC ACCESSORY, INTENDED FOR MEDICAL PURPOSES TO SUPPORT, PROTECT, OR AID IN THE USE OF A CAST, ORTHOSIS, OR PROSTHESIS.,ADHESIVE TAPE NON-WOVEN SUPPORT BP 88-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,GASTROINTESTINAL TUBE/ GASTROSTOMY TUBE (G TUBE)-A GASTROSTOMY TUBE (ALSO CALLED A G-CATHETERS GASTROINTESTINAL TUBE) IS A TUBE INSERTED THROUGH THE TUBE ABDOMEN THAT DELIVERS NUTRITION DIRECTLY TO THE STOMACH, X-RAY DETECTABLE ABSORBENT COTTON GAUZE B.P.-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,FOLEY BALLOON CATHETER 2 WAY(CORECATH-S)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,PERMEABLE WOVEN SURGICAL SYNTHETIC

	ADHESIVE TAPE BP 88-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE.,SUCTION TIP AND CATHETER-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,ADHESIVE TAPE BP 88 / USP (ULTRAPORE PLUS)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,LEVINE TUBE-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDING OR MEDICATIONS.,ENDOTRACHEAL TUBE PLAIN (CORETUBE)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION FO THE TRACHEA, JUST BELOW THE VOCAL CORDS., ENDOTRACHEAL TUBE CUFFED(CORETUBE-RF)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL,ADHESIVE TAPE BP 88 / USP(BONDPORE)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT(FIBER) BANDAGES., ADHESIVE TAPE BP 88 / USP(ULTRAPORE)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,PERMEABLE NONWOVEN SURGICAL ADHESIVE TAPE IS STANDARD(STERIPORE)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,RIBBED COTTON STOCKINETTE BP-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,X-RAY DETECTABLE NON-WOVEN ABDOMINAL PAD(STERIPAD)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. , ADHESIVE TAPE NON-WOVEN SUPPORT BP 88(STERIPORE)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES., GAUZE SWAB B.P. 88-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,ADHESIVE TAPE B.P.-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,A V FISTULA NEEDLE-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT,BLOOD ADMINISTRATION SET / BLOOD TRANSFUSION EQUIPMENTS (BT SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S

	VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,UNBLEACHED CALICO B.P.-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,DENTAL NEEDLE-DENTAL NEEDLES ARE USED TO DELIVER LOCAL ANAESTHETIC TO THE OPERATIVE SITE IN ORDER TO MAKE A PATIENT AS COMFORTABLE AS POSSIBLE.,BANDAGE T SHAPED CALICO (IS STANDARD)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES., CREPE BANDAGE (B.P. 88)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,ADHESIVE TAPE TEXTILE FABRIC B.P.-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,X-RAY DETECTABLE ABSORBENT NONWOVEN GAUZE(X-MEDI GAUZE)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES., NON WOVEN GAUZE AND COTTON TISSUE(COMBIDRESS)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,SUPRAPUBIC CATHETER / SUPRAPUBIC PUNCTION SET-A SUPRAPUBIC CATHETER IS A THIN, STERILE TUBE USED TO DRAIN URINE FROM BLADDER., NASOPHARYNGEAL CATHETER / NASOPHARYNGEAL-A CATHETER (FOR ADULTS) PASSED THROUGH THE NARES AND ADVANCED TO THE DEPTH OF THE NASOPHARYNX TO REMOVE AIR CHOKE OR OBSTRUCTION. A RESUSCITATOR.,ABSORBENT NON-WOVEN GAUZE (MEDI-GAUZE)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,PERMEABLE PLASTIC SURGICAL ADHESIVE TAPE BP 88 (STERIPLAST)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE., FOLEY BALLOON CATHETER 2 WAY(PERICATH / DURACATH)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,ABSORBENT COTTON GAUZE SCHEDULE F-II-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES., TRACHEOSTOMY TUBE / TRACHEAL TUBE-A BREATHING TUBE INSERTED INTO A TRACHEOTOMYUSED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,SEMIPERMEABLE ADHESIVE DRESSING BP-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. ,ELASTIC

	BANDAGE IS STANDARD-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,X-RAY DETECTABLE ABSORBENT NONWOVEN GAUZE(GINNI MEDAID)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,EPIDURAL CATHETER-EPIDURAL CATHETER IS A VERY THIN, FLEXIBLE TUBE THAT IS IMPLANTED INTO SPINE, PERMEABLE PLASTIC SURGICAL ADHESIVE TAPE BP 88-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE.,ADHESIVE TAPE BP 88 / USP-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,ELASTICATED TUBULAR BANDAGE B.P.-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,HEAT AND MOISTURE EXCHANGE FILTER-IT IS INTENDED TO USE FOR AIRWAY MANAGEMENT BY ANAESTHESIA/RESPIRATORY CARE DEPARTMENT.,CLOSED WOUND DRAINAGE TUBE OR SYSTEM-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,EYE NEEDLE-A HYPODERMIC SINGLE LUMEN NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.,ENDOTRACHEAL TUBE WITH CUFF RIGHT BRONCHUS, WITH CUFF LEFT BRONCHUS / ENDOBRONCHEAL TUBE DOUBLE LUMEN(STERITRACH)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,ADHESIVE BANDAGE USP-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,ABSORBENT COTTON GAUZE (BP)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,TRACHEAL TUBE / ENDOTRACHEAL TUBE (STERITRACH)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS., TRACHEOSTOMY TUBE CUFFED-A BREATHING TUBE INSERTED INTO A TRACHEOTOMYUSED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,PERMEABLE NON-WOVEN SURGICAL SYNTHETIC ADHESIVE TAPE B.P. 88-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN,

	OCCLUSIVE.,FOLEY BALLOON CATHETER 3 WAY(PERICATH / DURACATH)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., COTTON AND RUBBER ELASTIC BANDAGE B.P.-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,COTTON CREPE BANDAGE BPC-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,ASPIRATION NEEDLE-USED FOR EITHER LAPAROSCOPIC ASPIRATION OR INJECTION,IV FLOW REGULATOR-AN ACCESSORY OF INFUSION SET-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,FEEDING TUBE-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH ABDOMEN. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING,X-RAY DETECTABLE GAUZE SWAB B.P.-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,ENDOTRACHEAL TUBE PLAIN(STERITRACH)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,ENDOTRACHEAL TUBE CUFFED (STERITRACH)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,RIBBED COTTON AND VISCOSE STOCKINETTE BP-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,BIOPSY NEEDLE-THE GROWTH SAMPLE IS SUCTIONED OUT THROUGH A NEEDLE OR CUT OUT USING A SURGICAL PROCEDURE,ADHESIVE TAPE NON-WOVEN SUPPORT BP 88(STERIPORE)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,X-RAY DETECTABLE ABDOMINAL PAD B.P.-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. , SILICONE FOAM CAVITY WOUND DRESSING BP-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. ,EYE PAD B.P.-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. ,:PERMEABLE PLASTIC SURGICAL SYNTHETIC ADHESIVE TAPE BP 88-DRESSING-GEL,

	DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE.,EPIDURAL NEEDLE-INTENDED FOR TRANSIENT DELIVERY OF ANASTHETICS TO PROVIDE REGIONAL ANESTHESIA OR TO FACILITATE PLACEMENT OF AN EPIDURAL CATHETER,FIRST AID & QUICK AID NON MEDICATED (PERMEABLE PLASTIC WOUND DRESSING, PLASTIC DRESSING-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. ,ALCOHOL SWAB-IT IS A SINGLE USE, STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE.,SPINAL NEEDLE-USED FOR DIAGNOSTIC SAMPLING OF CEREBROSPINAL FLUID, DELIVERING ANESTHETICS AND FOR THE INTRODUCTION OF CONTRAST MEDIUM ,ADHESIVE TAPE B.P. (STERIPORE)-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,FOLEY BALLOON CATHETER 3 WAY(FOLCATH-S)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,SEMIPERMEABLE WATERPROOF PLASTIC SURGICAL ADHESIVE TAPE BP 88-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE.,ENDOTRACHEAL TUBE CUFFED(CORETUBE-S)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL,FOLEY BALLOON CATHETER 3 WAY(CORECATH-S)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY.,PERMEABLE PLASTIC WOUND DRESSING (PERFORATED PLASTIC WOUND DRESSING, POROUS PLASTIC DRESSING-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. , TRACHEOSTOMY TUBE CUFFED(TRACHFLEX)-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION.,ALGINATE DRESSING B.P.-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. ,TRACHEAL TUBE / ENDOTRACHEAL TUBE(STERITRACH)-INSERTS THE TUBE WITH THE

		HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,POLYAMIDE AND CELLULOSE CONTOUR BANDAGE BP-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES., PERMEABLE NON-WOVEN SURGICAL SYNTHETIC ADHESIVE TAPE B.P. 88(STERIFIX)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE., MEGAPORE STERILE (NON WOVEN SURGICAL DRESSING)-DRESSING-GEL, DRESSING- PERMEABLE, MOISTURE DRESSING, TRACHEOSTOMY TUBE DRESSING, WOUND AND BURN DRESSINGS, HYDROGEL DRESSING, WOUND AND BURN, OCCLUSIVE. ,TRACHEOSTOMY TUBE / TRACHEAL TUBE-A BREATHING TUBE INSERTED INTO A TRACHEOTOMYUSED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,NASOGASTRIC TUBE / RYLES TUBE-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES
3745	MFG/MD/2021/000085	1.License Holder Name: M/S ST. STONE MEDICAL DEVICES PRIVATE LIMITED 2.Approving Authority: NORTH EAST SUB ZONE 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER & KIT(CENTVENT)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS, BLOOD SAMPLING, CENTRAL VENOUS PRESSURE MONITORING AND INJECTION OF CONTRAST MEDIA.,GUIDEWIRE(SHINEWIRE)-IT IS INTENDED TO FACILITATE THE PLACEMENT OF BALLOON OF BALLOON DILATION CATHETER DURING PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY(PTA).,PERMANENT HEMODIALYSIS CATHETER KIT (PLATINUM PLUS)-A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HAEMODIALYSIS MACHINE FROM THE PATIENTS

3746	MFG/MD/2021/000086	1.License Holder Name: GLADDEN HEALTHCARE PRIVATE LIMITED 2.Approving Authority: MADHYA PRADESH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL BP-ABSORBENT COTTON IS USED TO PRODUCE DRESSING MATERIAL, PADDING FOR ITEMS OF CLOTHING, QUILTS ETC, ABDOMINAL SPONGES-ABSORBENT COTTON IS USED TO PRODUCE DRESSING MATERIAL, PADDING FOR ITEMS OF CLOTHING, QUILTS ETC.,DENTAL COTTON ROLL IP-ABSORBENT COTTON IS USED TO PRODUCE DRESSING MATERIAL, PADDING FOR ITEMS OF CLOTHING, QUILTS ETC.,ABSORBENT COTTON WOOL IP-ABSORBENT COTTON IS USED TO PRODUCE DRESSING MATERIAL, PADDING FOR ITEMS OF CLOTHING, QUILTS ETC.,GAUZE SWIPE (GAUZE THAN)-ABSORBENT COTTON IS USED TO PRODUCE DRESSING MATERIAL, PADDING FOR ITEMS OF CLOTHING, QUILTS ETC.,GAMZEE ROLL IP-ABSORBENT COTTON IS USED TO PRODUCE DRESSING MATERIAL, PADDING FOR ITEMS OF CLOTHING, QUILTS ETC.,ZIGZAG COTTON ROLL IP -ABSORBENT COTTON IS USED TO PRODUCE DRESSING MATERIAL, PADDING FOR ITEMS OF CLOTHING, QUILTS ETC.,NON ABSORBENT COTTON IP -ABSORBENT COTTON IS USED TO PRODUCE DRESSING MATERIAL, PADDING FOR ITEMS OF CLOTHING, QUILTS ETC.,GAUZE BANDAGE-ABSORBENT COTTON IS USED TO PRODUCE DRESSING MATERIAL, PADDING FOR ITEMS OF CLOTHING, QUILTS ETC.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
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3747	MFG/MD/2021/000087	1.License Holder Name: SUNDARAM MEDICAL DEVICES 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:GAUZE AND COTTON TISSUE BP 1988(SUNDARAM)-GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS,BANDAGE CLOTH- UNCUT IS 863 (SUNDARAM)-THE BANDAGE CLOTH UNCUT IS USED EITHER TO COVERING WOUNDS, TO KEEP DRESSINGS IN PLACE OR TO SUPPORT A MEDICAL DEVICE,X RAY DETECTABLE ABSORBENT COTTON GAUZE IS 16950(SUNDARAM)-THE X-RAY DETECTABLE COTTON GAUZE ARE USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, AND ESPECIALLY USED FOR DRESSING WOUNDS,X-RAY DETECTABLE LAPAROTOMY SPONGES – IS 10829(SUNDARAM)-THE LAPAROTOMY SPONGES IS USED IN SURGICAL PROCEDURES TO ABSORB BLOOD AND OTHER FLUIDS AS WELL AS CLEAN WOUNDS,OPEN WEAVE BANDAGE IS 16469(SUNDARAM)-THE OPEN WEAVE BANDAGE ARE USED FOR FIXING AND HOLDING OF INJURED JOINT OR FRACTURED PART OR ALSO USED FOR FIXING DRESSINGS AND ABSORBING EXUDATES,DRESSING ROLL (ABSORBENT COTTON IS 16468 WITH ABSORBENT GAUZE IS 758)(SUNDARAM)-GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS,ABSORBENT COTTON GAUZE BP 1988 TYPE 17 (FOR EXPORT)(SUNDARAM)-THE ABSORBENT COTTON GAUZE ARE USED FOR CLEANING, DRYING AND DRESSING WOUNDS DURING A MEDICAL TREATMENT,DRESSING PAD (ABSORBENT COTTON IS 16468 WITH ABSORBENT GAUZE IS 758) (SUNDARAM)-GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS,ABSORBENT GAUZE IS 758(SUNDARAM)-THE ABSORBENT GAUZE ARE USED IN GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS,BANDAGE CLOTH- CUT IS 863 (SUNDARAM)-THE BANDAGE CLOTH CUT IS USED EITHER TO COVERING WOUNDS, TO KEEP DRESSINGS IN PLACE OR TO SUPPORT A MEDICAL DEVICE

3748	MFG/MD/2021/000088	1.License Holder Name: PIRAMAL ENTERPRISES LIMITED 2.Approving Authority: MADHYA PRADESH 3.Device Name(Brand Name)-Intended Use:CONTACT LENS CLEANING/NEUTRALIZING SOLUTION(OXYSEPT II UNIT DOSE (9247X))-THE INTENDED USE OF THIS PRODUCT IS TO NEUTRALIZE THE PEROXIDE SOLUTION WHICH IS USED TO REMOVE THE PROTEIN LAYER FROM THE CONTACT LENS WHICH IS DEPOSITED ON THE CONTACT LENS DURING USES OF LENSES.,CONTACT LENS CLEANING/NEUTRALIZING TABLETS(OXYSEPT UPGRADE TABLETS (9081X))-THE INTENDED USE OF THIS PRODUCT IS TO REMOVE THE PROTEIN LAYER FROM THE CONTACT LENS WHICH IS DEPOSITED ON THE CONTACT LENS DURING USES OF LENSES.,CONTACT LENS CLEANING/NEUTRALIZING TABLETS(ULTRAZYME TABLETS (7458X))-THE PRODUCT ULTRAZYME TABLETS (7458X) IS HAVING FUNCTIONALITY TO REMOVE THE PROTEIN LAYER (WHICH IS DEPOSITED WHILE LENSES ARE BEING DISINFECTED) FROM SOFT (HYDROPHILIC) CONTACT LENSES.
3749	MFG/MD/2021/000089	1.License Holder Name: RECUES BIOSCIENCES PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:PLATELET RICH PLASMA KIT(PRECURCELL PRP)-USED FOR SEPARATION OF CONCENTRATED PLATELETS

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3750	MFG/MD/2021/000090	1.License Holder Name: FINE ORTHO 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:SPINAL IMPLANTS (FINEORTHO)-PEDICAL SCREW SYSTEM: THE SPINE PEDICLE SCREW SYSTEM IS A THORACOLUMBOSACRAL (T1-S1) SPINAL FIXATION SYSTEM CONTAINING DEVICES INTENDED FOR USE AS A POSTERIOR PEDICLE SCREW FIXATION SYSTEM. PEDICLE SCREW FIXATION IS LIMITED TO SKELETALLY MATURE PATIENTS. THESE DEVICES ARE INTENDED AS AN ADJUNCT TO FUSION FOR ALL THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E. FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E. SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS), TUMOUR, AND/OR FAILED PREVIOUS FUSION (PSEUDOARTHROSIS). INTERBODY FUSION CAGES: INTERBODY FUSION CAGESHELPS IN MAINTAINING SPACE BETWEEN THE VERTEBRAS, IN PRESERVING SPINAL ALIGNMENT AND PROMOTES SPINAL FUSION. VERTEBRAL BODY REPLACEMENT SYSTEM: IT IS USED TO REPLACE COLLAPSED, DAMAGED OR UNSTABLE VERTEBRAL BODIES DUE TO ANY SORT OF TRAUMA OR TUMOR. THE CERVICAL PLATE SYSTEM: IT IS INTENDED FOR ANTERIOR SCREW FIXATION TO THE CERVICAL SPINE. IT IS TO BE USED IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION OF THE CERVICAL SPINE (C2 TO C7). THE SYSTEM IS INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR SPINE DURING THE DEVELOPMENT OF CERVICAL SPINAL FUSION IN PATIENTS WITH DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E. FRACTURES OR DISLOCATIONS), TUMORS, DEFORMITY (DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS), PSEUDOARTHROSIS, FAILED PREVIOUS FUSION, AND/OR SPINAL STENOSIS,RADIAL HEAD PROSTHESIS(FINEORTHO)-THE RADIAL HEAD PROSTHESIS INTENDED USED FOR PARTIAL REPLACEMENT OF THE ELBOW JOINT BY PRIMARY OR REVISION APPLICATIONS.,MAXILLOFACIAL IMPLANTS(FINEORTHO)-THE MAXILLOFACIAL SYSTEM INTENDED FOR USE AS TRAUMA REPAIR AND RECONSTRUCTION OF THE CRANIO-MAXILLOFACIAL SKELETON, BONE PLATES(FINEORTHO)-THE BONE PLATE IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, TIBIA, FIBULA, FEMORAL. EXAMPLES OF THESE

	INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS,PROSTHESIS(FINEORTHO)-AUSTIN MOORE PROSTHESIS AND THOMSON PROSTHESIS SYSTEMS ARE INTENDED TO FIX THE CONDITIONS LIKE FRACTURE OF FEMORAL NECK AND HEMIARTHROPLASTY CONDITION. ,BONE SCREW (FINEORTHO)-THE BONE SCREW IS INTENDED TO USE FOR INTERNAL FIXATION OF BONE FRACTURES AND RECONSTRUCTION OF BONES, THERE ARE SEVERAL TYPES OF SCREW LIKE LOCKING HEAD SCREW, GENERAL CORTICAL SCREW OR FEMUR HEAD BONE SCREW ARE USED FOR FIXING OF FEMUR HEAD COMPRESSION PLATE, LOCKING PLATES WHICH IS USED FOR OSTEOTOMY PATIENTS EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS ANDMAL-UNIONS.,ARTHROSCOPY IMPLANTS (FINEORTHO)-INTENDED FOR USE FOR REPLACE AND RECONSTRUCTION OF THE ACL & PCL LIGAMENTSAND LIGAMENT REPAIR IN SHOULDER,BONE PLATES(FINEORTHO)-THE BONE PLATE IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, TIBIA, FIBULA, FEMORAL. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS,INTRA-MEDULLARY NAIL(FINEORTHO)-THE INTRA MEDULLARY NAIL IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF THE HUMERUS, TIBIA, FIBULA, FEMORAL BONES. THE I.M.NAIL IS HAVING BETTER STRENGTH WITH GOOD BONE HEALING CAPACITY. DIFFERENT SIZES ARE AVAILABLE WITH DIFFERENT DESIGN FOR BETTER ALIGNMENT OF THE FRACTURE., BONE SCREW(FINEORTHO)-THE BONE SCREW IS INTENDED TO USE FOR INTERNAL FIXATION OF BONE FRACTURES AND RECONSTRUCTION OF BONES, THERE ARE SEVERAL TYPES OF SCREW LIKE LOCKING HEAD SCREW, GENERAL CORTICAL SCREW OR FEMUR HEAD BONE SCREW ARE USED FOR FIXING OF FEMUR HEAD COMPRESSION PLATE, LOCKING PLATES WHICH IS USED FOR OSTEOTOMY PATIENTS EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA- ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS ANDMAL-UNIONS.,PINS, WIRES & STAPLE(FINEORTHO)-THESE IMPLANTS ARE USED IN

	HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PINS, WIRES & STAPLES ARE OF DIFFERENT TYPES WHICH GENERALLY USED WITH EXTERNAL FIXATOR IMPLANTS IN TIBIA, FEMUR & FOREARM BONES.,SPINAL IMPLANTS(FINEORTHO)-PEDICAL SCREW SYSTEM: THE SPINE PEDICLE SCREW SYSTEM IS A THORACOLUMBOSACRAL (T1-S1) SPINAL FIXATION SYSTEM CONTAINING DEVICES INTENDED FOR USE AS A POSTERIOR PEDICLE SCREW FIXATION SYSTEM. PEDICLE SCREW FIXATION IS LIMITED TO SKELETALLY MATURE PATIENTS. THESE DEVICES ARE INTENDED AS AN ADJUNCT TO FUSION FOR ALL THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E. FRACTURE OR DISLOCATION), SPINAL STENOSIS, CURVATURES (I.E. SCOLIOSIS, KYPHOSIS, AND/OR LORDOSIS), TUMOUR, AND/OR FAILED PREVIOUS FUSION (PSEUDOARTHROSIS). INTERBODY FUSION CAGES: INTERBODY FUSION CAGESHELPS IN MAINTAINING SPACE BETWEEN THE VERTEBRAS, IN PRESERVING SPINAL ALIGNMENT AND PROMOTES SPINAL FUSION. VERTEBRAL BODY REPLACEMENT SYSTEM: IT IS USED TO REPLACE COLLAPSED, DAMAGED OR UNSTABLE VERTEBRAL BODIES DUE TO ANY SORT OF TRAUMA OR TUMOR. THE CERVICAL PLATE SYSTEM: IT IS INTENDED FOR ANTERIOR SCREW FIXATION TO THE CERVICAL SPINE. IT IS TO BE USED IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION OF THE CERVICAL SPINE (C2 TO C7). THE SYSTEM IS INDICATED FOR USE IN THE TEMPORARY STABILIZATION OF THE ANTERIOR SPINE DURING THE DEVELOPMENT OF CERVICAL SPINAL FUSION IN PATIENTS WITH DEGENERATIVE DISC DISEASE (AS DEFINED BY NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E. FRACTURES OR DISLOCATIONS), TUMORS, DEFORMITY (DEFINED AS KYPHOSIS, LORDOSIS, OR SCOLIOSIS), PSEUDOARTHROSIS, FAILED PREVIOUS FUSION, AND/OR SPINAL STENOSIS.,RADIAL HEAD PROSTHESIS(FINEORTHO)-THE RADIAL HEAD PROSTHESIS INTENDED USED FOR PARTIAL REPLACEMENT OF THE ELBOW JOINT BY PRIMARY OR REVISION APPLICATIONS.,ARTHROSCOPY IMPLANTS(FINEORTHO)-INTENDED FOR USE FOR REPLACE AND RECONSTRUCTION OF THE ACL & PCL LIGAMENTSAND LIGAMENT REPAIR IN SHOULDER,MAXILLOFACIAL IMPLANTS(FINEORTHO)-THE MAXILLOFACIAL SYSTEM INTENDED FOR USE AS TRAUMA REPAIR AND RECONSTRUCTION OF THE CRANIO-MAXILLOFACIAL SKELETON,INTRA-MEDULLARY NAIL (FINEORTHO)-THE INTRA MEDULLARY NAIL IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF THE

		HUMERUS, TIBIA, FIBULA, FEMORAL BONES. THE I.M.NAIL IS HAVING BETTER STRENGTH WITH GOOD BONE HEALING CAPACITY. DIFFERENT SIZES ARE AVAILABLE WITH DIFFERENT DESIGN FOR BETTER ALIGNMENT OF THE FRACTURE.,PINS, WIRES & STAPLE (FINEORTHO)-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PINS, WIRES & STAPLES ARE OF DIFFERENT TYPES WHICH GENERALLY USED WITH EXTERNAL FIXATOR IMPLANTS IN TIBIA, FEMUR & FOREARMBONES.
3751	MFG/MD/2021/000091	1.License Holder Name: FLORANCE SURGICAL COTTON INDUSTRIES 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL (FLORANCE)-IT IS INTENDED TO USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS
3752	MFG/MD/2021/000092	1.License Holder Name: SMB MEDICAL DEVICES PVT LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:SYRINGE(SMB)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.
3753	MFG/MD/2021/000093	1.License Holder Name: UNIVERSAL ISO-MED (A DIV. OF UNIVERSAL MEDICAP LTD.) 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:CO-60 GAMMA IRRADIATION -NOT APPLICABLE,CO-60 GAMMA IRRADIATION-NOT APPLICABLE
3754	MFG/MD/2021/000094	1.License Holder Name: BRIJ TEXTILES 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:SURGICAL DRESSINGS-A STRIP OF FABRIC USED ESPECIALLY TO COVER, DRESS, AND BIND UP WOUNDS AND A FLEXIBLE STRIP OR BANDAGES USED TO COVER, STRENGTHEN, OR COMPRESS SOMETHING.,UMBILICAL OCCLUSION DEVICE-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.

3755	MFG/MD/2021/000095	1.License Holder Name: UNIVERSAL PROPHYLACTIC PVT.LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:PLAIN NATURAL RUBBER LATEX MALE CONDOMS WITH 4.5% W/W BENZOCAINE AS DESENSITIZER.(NIL)-THE MALE LATEX CONDOM LUBRICATED WITH BENZOCAINE 4.5% W/W IS INTENDED TO BE USED FOR CONTRACEPTIVE AND PROPHYLACTIC PURPOSES. ADDITIONALLY, THE LUBRICANT ON THE CONDOM HELPS IN TEMPORARILY PROLONGING THE TIME UNTIL EJACULATION.,DOTTED NATURAL RUBBER LATEX MALE CONDOMS(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS. ,NATURAL RUBBER LATEX FEMALE CONDOMS(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,DOTTED NATURAL RUBBER LATEX MALE CONDOMS(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS. ,DOTTED NATURAL RUBBER LATEX MALE CONDOMS WITH 4.5% W/W BENZOCAINE AS DESENSITIZER.(NIL)-THE MALE LATEX CONDOM LUBRICATED WITH BENZOCAINE 4.5% W/W IS INTENDED TO BE USED FOR CONTRACEPTIVE AND PROPHYLACTIC PURPOSES. ADDITIONALLY, THE LUBRICANT ON THE CONDOM HELPS IN TEMPORARILY PROLONGING THE TIME UNTIL EJACULATION.,PLAIN NATURAL RUBBER LATEX MALE CONDOMS(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS. ,MULTITEXTURED NATURAL RUBBER LATEX MALE CONDOMS WITH 4.5% W/W BENZOCAINE AS DESENSITIZER.(NIL)-THE MALE LATEX CONDOM LUBRICATED WITH BENZOCAINE 4.5% W/W IS INTENDED TO BE USED FOR CONTRACEPTIVE AND PROPHYLACTIC PURPOSES. ADDITIONALLY, THE LUBRICANT ON THE CONDOM HELPS IN TEMPORARILY PROLONGING THE TIME UNTIL EJACULATION.,MULTITEXTURED NATURAL RUBBER LATEX MALE CONDOMS(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS. ,RIBBED NATURAL RUBBER LATEX MALE CONDOMS(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS.,PLAIN NATURAL RUBBER LATEX MALE CONDOMS.(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS. ,MULTITEXTURED NATURAL RUBBER LATEX MALE CONDOMS(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY TRANSMITTED INFECTIONS. ,NATURAL RUBBER LATEX FEMALE CONDOMS(NIL)-AS A PROTECTION BARRIER FOR UNWANTED PREGNANCY AND SEXUALLY

	TRANSMITTED INFECTIONS.,DOTTED NATURAL RUBBER LATEX MALE CONDOMS WITH 4.5% W/W BENZOCAINE AS DESENSITIZER.(NIL)-THE MALE LATEX CONDOM LUBRICATED WITH BENZOCAINE 4.5% W/W IS INTENDED TO BE USED FOR CONTRACEPTIVE AND PROPHYLACTIC PURPOSES. ADDITIONALLY, THE LUBRICANT ON THE CONDOM HELPS IN TEMPORARILY PROLONGING THE TIME UNTIL EJACULATION., PLAIN NATURAL RUBBER LATEX MALE CONDOMS WITH 4.5% W/W BENZOCAINE AS DESENSITIZER.(NIL)-THE MALE LATEX CONDOM LUBRICATED WITH BENZOCAINE 4.5% W/W IS INTENDED TO BE USED FOR CONTRACEPTIVE AND PROPHYLACTIC PURPOSES. ADDITIONALLY, THE LUBRICANT ON THE CONDOM HELPS IN TEMPORARILY PROLONGING THE TIME UNTIL EJACULATION.

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3756	MFG/MD/2021/000096	1.License Holder Name: BENTLEY HEALTHCARE PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:ABSORBABLE SURGICAL SUTURE USP PLAIN CATGUT(BENGUT, MAXGUT)-INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND/OR LIGATION.,ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) BRAIDED & COATED POLYGLACTIN-910(BENCRYL-910, MYERCRYL, DYNASYNTH, MAXCRYL)--INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) BRAIDED & COATED POLYGLYCOLIC ACID FAST ABSORPTION(BENCRYL RAPID, BENCRYL, DYNAGLYDE FAST)-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS DESIRED.,NONABSORBABLE SURGICAL SUTURE USP MONOFILAMENT POLYPROPYLENE (BENLENE, DYNALENE, MAXLENE, MYERLENE)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION., ABSORBABLE SURGICAL SUTURE USP CHROMIC CATGUT(BENGUT-CR, BENGUT, MAXGUT)-INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND/OR LIGATION.,ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) MONOFILAMENT POLIGLECAPRONE-25 (BENCRYL-MONO, DYNAGLYDE MONO, MYER-MONO)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION., ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) BRAIDED & COATED POLYGLYCOLIC ACID(BENCRYL, DYNAGLYDE)-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION AND/OR LIGATION., NONABSORBABLE SURGICAL SUTURE USP MONOFILAMENT POLYAMIDE(BENLON, DYNALON, MYERLON, MAXLON)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION,ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) MONOFILAMENT POLYDIOXANONE(BENCRYL-PLUS, BENCRYL-PDS, MYER-PDS)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,OB KIT/180(DYNA)-BOTH THE COMPONENTS OF THE KIT ARE SUTURES WHICH ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION. THESE SUTURES ARE COMMONLY USED IN OBSTETRICS SURGERY AND HENCE SUPPLIED AS A KIT.,ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) BRAIDED & COATED POLYGLACTIN-910 FAST ABSORPTION(BENCRYL-910, MYERCRYL, DYNASYNTH FAST, MAXCRYL)-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS DESIRED., ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) BRAIDED & COATED POLYGLACTIN-910 ANTIBACTERIAL SUTURE(BENCRYL-910, DYNASYNTH, MYERCRYL, MAXCRYL)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,

		NONABSORBABLE SURGICAL SUTURE USP BLACK BRAIDED SILK (BENSILK, DYNASILK, MYERSILK, MAXSILK)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION., NONABSORBABLE SURGICAL SUTURE USP BRAIDED & COATED POLYESTER(BENSTER, BEN-BOND, MYER-BOND, BENSTER-C)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.
3757	MFG/MD/2021/000097	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ETHYLENE OXIDE STERILISATION OF CLASS D PRODUCTS-ETHYLENE OXIDE STERILISATION OF MEDICAL DEVICES FALLING UNDER CLASS D. INTENDED USE OF THE PRODUCTS WOULD BE AS DECIDED BY THE MEDICAL DEVICE MANUFACTURER.,ETHYLENE OXIDE STERILISATION OF CLASS C PRODUCTS-ETHYLENE OXIDE STERILISATION OF PRODUCTS FALLING UNDER CLASS C. INTENDED USE OF THE PRODUCTS WOULD BE AS DECIDED BY THE MEDICAL DEVICE MANUFACTURER.
3758	MFG/MD/2021/000098	1.License Holder Name: MERAV HEALTHCARE PRIVATE LIMITED 2.Approving Authority: BIHAR 3.Device Name(Brand Name)-Intended Use:WOUND PATCH (REXWOUND)-THE MEDICAL DEVICE REXWOUND IS SUITABLE FOR HUMANS: TO TREAT WOUNDS, WHICH ARE EXTERNAL, FRESH, SUPERFICIALLY BLEEDING, CONTAMINATED OR EXPOSED TO THE HAZARD OF INFECTION; AS WELL AS WOUNDS, WHICH ARE OLDER AND/OR CHRONIC (NON-SURGICALLY TREATED), EXCLUDING ACTUAL WOUND INFECTIONS (AFTER CONSULTING A MEDICAL DOCTOR). THESE CAN BE WOUNDS AFTER BITES OR AFTER SURGICAL TREATMENTS BY EXTIRPATING AND RINSING THE WOUND AREA.

3759	MFG/MD/2021/000099	1.License Holder Name: CHAK MUSSALAHPUR SWEET HEART LANE 2.Approving Authority: BIHAR 3.Device Name(Brand Name)-Intended Use:SMALL PACKETS OF GAUZE-ABSORBENT GAUZE ARE MAINLY USED DURING OPERATIONS AND ITS MAIN FUNCTION IS TO ABSORB THE BLOOD FROM WOUND. THE ABSORBENT GAUZE IS MOST VITAL ITEM IN SURGICAL DRESSING.,BANDAGE CLOTH-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB.,ABSORBENT GAUZE CLOTH-ABSORBENT GAUZE ARE MAINLY USED DURING OPERATIONS AND ITS MAIN FUNCTION IS TO ABSORB THE BLOOD FROM WOUND. THE ABSORBENT GAUZE IS MOST VITAL ITEM IN SURGICAL DRESSING.,COTTON CREPE BANDAGE B.P.-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB,HANDLOOM SURGICAL BANDAGE ROLLED-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB

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3760	MFG/MD/2021/000100	1.License Holder Name: HEMANT SURGICAL INDUSTRIES LIMITED 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:SKIN STAPLER(NA)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS,CONNECT OR REMOVE PARTS OF BODY DURING SURGERY. ,ENDOTRACHEAL TUBE(NA)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE,AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS ,IV CANNULAE(NA)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES . ,EXTENSION SETS (NA)-"EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS." ,TRANSFUSION AND PERFUSION SET(NA)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,THREE WAY STOP COCK(NA)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING , FOLLEY CATHETERS /URETHRAL CATHETERS(NA)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA ANDBLADDER OR POST ERIORLY VIA THE KIDNEY. ,BLOOD TUBING SET/BLOOD LINES (NA)-THE SINGLE-NEEDLE DIALYSIS, IN WHICH CASE ONLY ONE CANNULA OR A SINGLE- LUMEN CATHETER IS USED TO ACCESS THE BLOOD , MEASURED VOLUME IV SET(NA)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,NASAL OXYGEN CATHETERS (NA)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP. , HAEMODIALYSIS CATHETERS (NA)-A BLOOD ACCESS DEVICE AND ACCESSORIES IS A DEVICE INTENDED TO PROVIDE ACCESS TO A PATIENT'S BLOOD FOR HAEMODIALYSIS OR OTHER CHRONIC USES. , A. V. FISTULA NEEDLE (NA)-TO CONNECT BLOOD LINES WITH THE BLOOD VESSELS THROUGH NEEDLES WHEN DIALYSIS IS CARRIED OUT ,MANIFOLD(NA)-INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT/PORTS FOR ADMINISTRATION OF A SOLUTION. ,SCALP VEIN SET(NA)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD. ,IV FLOW

	REGULATOR(NA)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY. ,EPIDURAL NEEDLES(NA)-INTENDED FOR TRANSIENT DELIVERY OF ANASTHETICS TO PROVIDE REGIONAL ANESTHESIA OR TO FACILITATE PLACEMENT OF AN EPIDURAL CATHETER ,BLOOD COLLECTION NEEDLE(NA)-INTENDED TO BE USED WITH EVACUATED BLOOD COLLECTION TUBE FOR COLLECTION OF VENOUS BLOOD. , SUCTION CATHETERS (NA)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION. ,ANGIOGRAPHIC NEEDLE(NA)-ANGIOGRAPHIC NEEDLE HAS A UNIQUE HUB DESIGN WITH AN ERGONOMIC FEEL AND A BLACK TRIANGLE INDICATOR TO ORIENT THE BEVEL. ,ANAESTHESIA NEEDLE/ SPINAL NEEDLE(NA)-AN ANAESTHESIA CONDUCTION NEEDLE IS A DEVICE USED TO INJECT LOCAL ANAESTHETICS INTO A PATIENT TO PROVIDE REGIONAL ANAESTHESIA

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3761	MFG/MD/2021/000101	1.License Holder Name: NATIONAL HEALTH CARE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ABC'S MV SET/HI-TECH MV SET/CAREDRIP MV SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE URETHRAL/ NELATON/RECTAL CATHETER (PLAIN & THUMB CONTROL) FOR SINGLE USE ONLY(NATIONAL)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE DISPOSABLE INFANT MUCUS EXTRACTOR FOR SINGLE USE ONLY(NATIONAL MUCAS EXTRACTOR)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,STERILE DISPOSABLE EXTENSION TUBE WITH THREE WAY STOP COCK FOR SINGLE USE ONLY(NATIONAL)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING, STERILE NEBULIZER MASK FOR SINGLE USE ONLY(NATIONAL)-IT IS INTENDED TO USE AIRWAY MANAGEMENT BY ANAESTHESIA/ RESPIRATORY CARE DETERMENT,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(ABC'S BT SET/HI-TECH BT SET/HEMOCARE BT SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE TWIN BORE NASAL OXYGEN CATHETER FOR SINGLE USE ONLY(NATIONAL)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP ,STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY (NATIONAL)-`CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(NEON INFUSION SET/PRISTINE INFUSION SET/KABCARE INTRAVENOUS SET)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE EXTENSION TUBE FOR SINGLE USE ONLY(NATIONAL PM LINE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,STERILE

	DISPOSABLE MICRO DRIP INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (CAREDRIP MICRODRIP SET)-:THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE NASOGASTRIC/RYLE' S/DUODENAL TUBE FOR SINGLE USE ONLY(NATIONAL)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(NATIONAL)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. , STERILE TRACHEOBRONCHIAL SUCTION CATHETER FOR SINGLE USE ONLY(NATIONAL MUCUS EXTRACTOR)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,STERILE DISPOSABLE THREE WAY STOP COCK FOR SINGLE USE ONLY(NATIONAL)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(NATIONAL)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ABC'S INFUSION SET/HI-TECH INFUSION SET/CAREDRIP INFUSION SET/IVEE INFUSION SET)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE DISPOSABLE RYLE'S / NASOGASTRIC / GASTRO DUODENAL / LEVIN'S TUBE FOR SINGLE USE ONLY(NATIONAL)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES,STERILE DISPOSABLE UMBILICAL CORD CLAMP (NATIONAL)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE INFANT FEEDING TUBE FOR SINGLE USE ONLY(NATIONAL)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH YOUR ABDOMEN.IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING , STERILE HEAT MOISTURE EXCHANGE FILTER (HME FILTER) FOR

		SINGLE USE ONLY(NATIONAL)-HEAT AND MOISTURE EXCHANGERS (HME) ARE DEVICES USED IN MECHANICALLY VENTILATED PATIENTS INTENDED TO HELP PREVENT COMPLICATIONS DUE TO "DRYING OF THE RESPIRATORY MUCOSA, SUCH AS MUCUS PLUGGING AND ENDOTRACHEAL TUBE (ETT) OCCLUSION." HMES ARE ONE TYPE OF COMMERCIAL HUMIDIFICATION SYSTEM, WHICH ALSO INCLUDE NON-HEATED- ...,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY (NATIONAL)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE OXYGEN MASK FOR SINGLE USE ONLY(NATIONAL)-IT IS INTENDED TO USE AIRWAY MANAGEMENT BY ANAESTHESIA/ RESPIRATORY CARE DETERMENT,STERILE TRACHEOBRONCHIAL YANKAUR SUCTION CATHETER FOR SINGLE USE ONLY(NATIONAL)-YANKAUR SUCTION SET ARE USED FOR THE REMOVAL OF BLOOD AND FLUIDS DURING SURGERY.
3762	MFG/MD/2021/000102	1.License Holder Name: CAREMAX HEALTHCARE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ADHESIVE TAP U.S.P. (CAREPLAST)-A MEDICAL ADHESIVE TAPE IS A DEVICE INTENDED FOR MEDICAL PURPOSES THAT COATED ON ONE SIDE WITH AN ADHESIVE, THE DEVICE IS USED TO COVER AND PROTECT WOUNDS, TO HOLD TOGETHER THE SKIN EDGES OF A WOUND, TO SUPPORT AN INJURED PART OF THE BODY, OR TO SECURE OBJECTS TO THE SKIN.,, ELASTIC ADHESIVE BANDAGE B.P..(ELASTOCARE)-IDEAL BANDAGE FOR SUPPORT STRAPPING FRACTURES, MUSCLES INJURIES, ELBOWS, KNEES, SHOULDERS SPECIALLY REQUIRING ELASTICITY, COTTON CREPE BANDAGE B.P..(FIXOCARE)-COTTON CREPE BANDAGEIS A DEVICE INTENDED FOR STABILIZING JOINTS, TENDONS AND LIGAMENTS DURING VIGOROUS EXERCISE. FIRMLY WRAP AROUND THE ANKLE, WRIST, OR ANY OTHER HIGHLY-USED JOINT TO PREVENT INJURY CAUSED BY MUSCLE STRESS AND FATIGUE.,, ADHESIVE TAPE NON WOVEN SUPPORT B.P.(CARE PORE)-ADHESIVE TAPE NON WOVEN SUPPORT BP IS A DEVICE INTENDED FOR MEDICAL PURPOSES THAT COATED ON ONE SIDE WITH AN ADHESIVE, THE DEVICE IS USED TO COVER AND PROTECT WOUNDS, TO HOLD TOGETHER THE SKIN EDGES OF A WOUND, TO SUPPORT AN INJURED PART OF THE BODY, OR TO SECURE OBJECTS TO THE SKIN.,

3763	MFG/MD/2021/000103	1.License Holder Name: SURYAVANI SPININING MAILLS LTD 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P-ABSORBENT COTTON IS ALSO KNOWN AS SURGICAL COTTON OR COTTON WOOL AND MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC
3764	MFG/MD/2021/000104	1.License Holder Name: PHOENIX INNOVATIVE HEALTHCARE MANUFACTURERS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NEBULIZER-NEBULIZER ARE USED MANY PERSONNEL BUT MASK ARE USED ALONE. THE NEBULIZER IS INTENDED TO BE USED BY MANY PATIENTS AND MASK TO BE USED BY A SINGLE PATIENT AND SHOULD NOT BE SHARED.
3765	MFG/MD/2021/000105	1.License Holder Name: SAMAY SURGICAL 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE NAILS-BONE NAIL IS COMMONLY USED TO FIX THE LONG BONE FRACTURES.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,LOCKING PLATES-LOCKING PLATES ARE USED SURGERY TO HOLD FRACTURES IN PLACE TO ALLOW BONE HEALING., BONE SCREW-BONE SCREWS ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR ALONG WITH BONE PLATES OR INTERLOCKING NAILS,BONE PLATES-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURES IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH SCREW TO PROPERLY ALIGN THE FRACTURED BONE, PINS AND WIRES-PINS AND WIRES ARE USED IN MAXIMUM BONE FRACTURES SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS AND WIRE SUPPORT FIX ABOVE PLATES,LOCKING SCREW-LOCKING SCREW SERVE AS A SUPPORT FOR IMPLANT ON BONE

3766	MFG/MD/2021/000106	1.License Holder Name: EXCELLENT HI-CARE PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:PMMA INTRAOCULAR LENS(RAINBOW LENS ,RAINBOW EDGE, RAINBOW GOLD)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY, HYDROPHILIC ACRYLIC FOLDABLE INTRAOCULAR LENS(RAINBOW FOLD, RAINBOW CLEAR, RAINBOW TRU, RAINBOW-MF ,RAINBOW-TF)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY,: INTRAOCULAR LENS(RAINBOW -PHOB, RAINBOW –PHOB PLUS, RAINBOW –PHOB TF, RAINBOW -TORIC)-FOR REPLACING NATURAL LENS DURING CATARACT SURGERY

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3767	MFG/MD/2021/000107	1.License Holder Name: M/S MICROTROL STERILISATION SERVICES PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:PTCA CATHETERS (SPEED+ - PTCA CATHETERS)-STENOSIS OF CORONARY ARTERIES, SIROLIMUS ELUTING STENT SYSTEM - COBALT CHROMIUM DEGRADABLE MATRIX(PRONOVA XR- SIROLIMUS ELUTING STENT SYSTEM - COBALT CHROMIUM DEGRADABLE MATRIX)-THE PRONOVA XR CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.5MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT)AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT., PERIPHERAL STENT SYSTEM-SELF EXPANDABLE NITINOL STENT SYSTEM(RESISTANT - SELF EXPANDABLE NITINOL STENT SYSTEM)-IT IS INDICATED FOR THE FOLLOWING APPLICATIONS- • ATHEROSCLEROTIC DISEASE OF THE PERIPHERAL ARTERIES, EG ILIAC, FEMORALIS AND FEMORALIS SUPERFICIALIS AND IN OTHER VESSELS WHICH CORRESPOND IN THEIR ANATOMIC DIMENSIONS TO THE AVAILABLE SIZES OF THE STENTS. • TREATMENT OF BILE DUCT STRICTURES.,BALLOON EXPANDABLE PERIPHERAL STENT SYSTEM-RENAL & ILLIAC(PROSTAR PLUS - BALLOON EXPANDABLE PERIPHERAL STENT SYSTEM - RENAL & ILLIAC)-INDICATIONS FOR THE DEPLOYMENT OF THE PROSTAR PLUS PERIPHERAL STENT SYSTEM INCLUDE: 1) ATHEROSCLEROTIC DE NOVO LESIONS. 2) RE-STENOTIC LESIONS OF THE PERIPHERAL ARTERIES, SUCH AS THE RENAL ARTERY OR SUBCLAVIAN ARTERY.,SIROLIMUS ELUTING STENT SYSTEM- STAINLESS STEEL(PRONOVA SS- SIROLIMUS ELUTING STENT SYSTEM- STAINLESS STEEL)-THE PRONOVA SS CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.5MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT,BALLOON EXPANDABLE CORONARY STENT SYSTEM - COBALT CHROMIUM (PROZETA - BALLOON EXPANDABLE CORONARY STENT SYSTEM - COBALT CHROMIUM)-THE PROZETA CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO CORONARY ARTERY LESIONS WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0

	MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED FOR TREATMENT OF CORONARY ARTERIES.,BALLOON EXPANDABLE COVERED STENT SYSTEM- - STAINLESS STEEL STENT WITH PTFE(PROGRAFT - BALLOON EXPANDABLE COVERED STENT SYSTEM - STAINLESS STEEL STENT WITH PTFE)-BALLOON EXPANDABLE COVERED STENT IS INDICATED TO COVER THE DISSECTION (TEAR) CAUSED WHEN A PTCA BALLOON OR STENT IS DEPLOYED IN A LESION. COVERED STENTS ARE USED TO CLOSE RUPTURED ARTERIES, PERFORATED ARTERIES AND TO CLOSE ANEURYSMS.,PTMC BALLOON CATHETER AND ACCESSORIES (ACCURA PTMC BALLOON CATHETER - DOUBLE LUMEN BALLOON DILATATION CATHETER AND ACCESSORIES FOR ACCURA BALLOON CATHETER - STYLET,LA WIRE, METAL STRETCHING TUBE, DILATOR, SYRINGE)-• SYMPTOMATIC ISOLATED MITRAL STENOSIS (MODERATE TO SEVERE), NYHA FUNCTION CLASS II~III. • NO DEFORMITY OF THE MITRAL VALVE, NO SEVERE VALVE CALCIFICATION, NO SUBVALVULAR ABNORMALITY AND NO MARKED VALVE RIGIDITY DETECTED BY ECHOCARDIOGRAPHY. MITRAL VALVE AREA LESS THAN OR EQUAL TO 1.5CM2 AND NO LEFT ATRIAL THROMBUS. • SINUS RHYTHM DEMONSTRATED BY ELECTROCARDIOGRAPHY. • MEAN LEFT ATRIAL PRESSURE GREATER THAN 1.46KPA OR 11MMHG, MEAN MITRAL VALVE PRESSURE GRADIENT DURING DIASTOLE GREATER THAN OR EQUAL TO 1.06 KPA OR 8MMHG. • AS FOR PATIENTS WITH RESTENOSIS AFTER SURGICAL COMMISSUROTOMY, ATRIAL FIBRILLATION, MITRAL VALVE CALCIFICATION, MILD MITRAL OR AORTIC REGURGITATION, PTMC CAN ALSO BE PERFORMED BUT WITH CAUTION. • PATIENTS WITH SEVERE PULMONARY HYPERTENSION, LEFT-OR RIGHT-SIDED HEART FAILURE, OR WITH SIGNIFICANT RENAL OR HEPATIC DISEASE. • PATIENTS UNSUITABLE TO ACCEPT VALVE REPLACEMENT BECAUSE OF OTHER CONDITIONS SUCH AS PREGNANCY OR HAVE CONTRAINDICATIONS FOR LONG-TERM ANTICOAGULATION.,PTCA CATHETERS(SPEED - PTCA CATHETERS)-THE SPEED CATHETERS ARE INDICATED FOR BALLOON DILATATION OF THE STENOTIC PORTION OF A CORONARY ARTERY OR BYPASS GRAFT STENOSIS FOR THE PURPOSE OF IMPROVING MYOCARDIAL PERFUSION.,SIROLIMUS ELUTING STENT SYSTEM - COBALT CHROMIUM(PRONOVA - SIROLIMUS ELUTING STENT SYSTEM - COBALT CHROMIUM)-THE PRONOVA CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE DE NOVO ARTERY LESIONS (LENGTH 40MM) WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0MM TO 4.0MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS

		UNKNOWN AT PRESENT.,CORONARY STENT SYSTEM-STAINLESS STEEL BALLOON EXPANDABLE(PROLINK LP- CORONARY STENT SYSTEM-STAINLESS STEEL BALLOON EXPANDABLE)-THE PROLINK LP CORONARY STENT SYSTEM IS INDICATED FOR USE IN PATIENTS WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE CORONARY DE NOVO ARTERY LESIONS WITH A REFERENCE VESSEL DIAMETER RANGING FROM 2.0MM TO 4.5MM (MAXIMUM STENT DIAMETER 4.5MM, POST-DEPLOYMENT) AND IS INTENDED TO IMPROVE CORONARY LUMINAL DIAMETER. LONG TERM OUTCOME FOR THIS PERMANENT IMPLANT IS UNKNOWN AT PRESENT
3768	MFG/MD/2021/000108	1.License Holder Name: QUALITY NEEDLES PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:LIGATION CLIPS-LIGATION CLIPS HAVE APPLICATION FOR USE ON TUBULAR STRUCTURE OR VESSELS WHERE EVER METAL LIGATION ARE INDICATED,TEMPORARY CARDIAC PACING LEADS-THE TEMPORARY CARDIAC PACING LEADS ARE INTENDED FOR TREATING POST-OPERATIVE CARDIAC ARRHYTHMIAS FOLLOWING HEART SURGERY, E.G. TEMPORARY PACING OR MONITORING,STAINLESS STEEL STERNUM SUTURE-STAINLESS STEEL STERNUM SUTURES ARE INDICATED FOR USE IN ABDOMINAL SURGERY, FOR ORTHOPEDIC PROCEDURES (TENDON OPERATIONS AND CERCLAGES), HERNIA SURGERY AND STERNAL CLOSURE. IT IS DESIGNED TO REMAIN IN THE PATIENT.
3769	MFG/MD/2021/000109	1.License Holder Name: AV PROCESSORS PRIVATE LIMITED 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:INTRAVENOUS INFUSION SET (IV SET)(BIOMEDIX WAI SELEC-3)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE

3770	MFG/MD/2021/000110	1.License Holder Name: SHREE HEALTH CARE INDIA 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:STERILE DRESSING PAD (ABSORBENT COTTON IS 16468 WITH ABSORBENT GAUZE IS 758) (SAFE SWABS)-GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS,STERILE ABSORBENT COTTON GAUZE BP 1988 TYPE 24A(SAFE SWABS)-THE ABSORBENT GAUZE ARE USED IN GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS, ABDOMINAL PAD(SAFE SWABS)-A NON MEDICATED DEVICE IN THE FORM OF PATCH OR SWAB MADE FROM WOVEN MATERIAL AND DESIGNED TO ABSORB FLUIDS FOR MEDICAL PURPOSES IT DOES NOT INCLUDE PETROLATUM. IT IS TYPICALLY USED TO CLEAN , COVER OR PACK WOUNDS AND ABSORB THEIR EXUDATES. THIS IS A SINGLE USE DEVICE,STERILE EYE PAD(SAFE SWABS)-A CUSHION LIKE DEVICE IS MADE VARIOUS MATERIALS INTENDED TO PROTECT THE EYE OR TO ABSORB EYE SECRETIONS. THIS IS A SINGLE USE DEVICE.,X-RAY DETECTABLE GAUZE SWABS IS 10829 (STERILE)(SAFE SWABS)-THE X-RAY DETECTABLE GAUZE SWABS ARE USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, AND ESPECIALLY USED FOR DRESSING WOUNDS,STERILE ABSORBENT COTTON GAUZE BP 1988 TYPE 24B(SAFE SWABS)-THE ABSORBENT COTTON GAUZE ARE USED FOR CLEANING, DRYING AND DRESSING WOUNDS DURING A MEDICAL TREATMENT,DRESSING PAD (ABSORBENT COTTON IS 16468 WITH ABSORBENT GAUZE IS 758)(SAFE SWABS)-GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS, X-RAY DETECTABLE LAPAROTOMY SPONGES IS 10829 (STERILE) (SAFE SWABS)-THE LAPAROTOMY SPONGES IS USED IN SURGICAL PROCEDURES TO ABSORB BLOOD AND OTHER FLUIDS AS WELL AS CLEAN WOUNDS,ABSORBENT COTTON GAUZE BP 1988 TYPE 24B (SAFE SWABS)-THE ABSORBENT COTTON GAUZE ARE USED FOR CLEANING, DRYING AND DRESSING WOUNDS DURING A MEDICAL TREATMENT,X-RAY DETECTABLE GAUZE SWABS IS 10829(SAFE SWABS)-THE X-RAY DETECTABLE GAUZE SWABS ARE USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, AND ESPECIALLY USED FOR DRESSING WOUNDS,X-RAY DETECTABLE LAPAROTOMY SPONGES IS 10829(SAFE SWABS)-THE LAPAROTOMY SPONGES IS USED IN SURGICAL PROCEDURES TO ABSORB BLOOD AND OTHER FLUIDS AS WELL AS CLEAN WOUNDS,ABSORBENT COTTON GAUZE BP 1988 TYPE 24A(SAFE SWABS)-THE ABSORBENT COTTON GAUZE ARE USED FOR CLEANING, DRYING AND DRESSING WOUNDS DURING A MEDICAL TREATMENT,OPEN WEAVE BANDAGE IS

	16469(SAFE SWABS)-THE OPEN WOVEN BANDAGE ARE USED FOR FIXING AND HOLDING OF INJURED JOINT OR FRACTURED PART OR ALSO USED FOR FIXING DRESSINGS AND ABSORBING EXUDATES, OPEN WEAVE BANDAGE IS 16469 (STERILE)(SAFE SWABS)-THE OPEN WEAVE BANDAGE ARE USED FOR FIXING AND HOLDING OF INJURED JOINT OR FRACTURED PART OR ALSO USED FOR FIXING DRESSINGS AND ABSORBING EXUDATES,STERILE ABDOMINAL PAD(SAFE SWABS) -A NON MEDICATED STERILE DEVICE IN THE FORM OF PATCH OR SWAB MADE FROM WOVEN MATERIAL AND DESIGNED TO ABSORB FLUIDS FOR MEDICAL PURPOSES IT DOES NOT INCLUDE PETROLATUM. IT IS TYPICALLY USED TO CLEAN , COVER OR PACK WOUNDS AND ABSORB THEIR EXUDATES. THIS IS A SINGLE USE DEVICE.

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3771	MFG/MD/2021/000111	1.License Holder Name: PRIME HEALTHCARE PRODUCTS PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:BLOOD TRANSFUSION SET(QUEST)-BLOOD COMPONENTS MUST BE FILTERED DURING TRANSFUSION TO REMOVE CLOTS AND SMALL CLUMPS OF PLATELETS AND WHILE BLOOD CELLS THAT FORM DURING COLLECTION AND STORAGE,INFUSION SET(QUEST)-THE DEVICE IS USED IN GRAVITY FEED I.V. THERAPY OR WITH A PRESSURE INFUSER, WHEN AN EXTENDED FLUID PATH IS REQUIRED FOR ADMINISTRATION.,SAFETY INTRAVENOUS CANNULA(PRIME)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE ,MEASURED VOLUME SET OR BURETTE SET(QUEST)- IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,3-WAY STOP COCK WITH EXTENSION TUBE(QUEST)-USED FOR SIMULTANEOUS AND CONTINUOUS INFUSION OF TWO FLUIDS AND CONTROL FLOW DIRECTION, EXTENSION TUBE (QUEST)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATIONS. ,INTRAVENOUS CANNULA WITH SMALL WING & WITHOUT INJECTION PORT(PRIME)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE ,INTRAVENOUS CANNULA WITHOUT WING & INJECTION PORT(PRIME)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE ,INTRAVENOUS CANNULA WITH WING & INJECTION PORT(PRIME)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE ,INTRAVENOUS CANNULA WITH WING & WITHOUT INJECTION PORT(PRIME)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE ,INTRAVENOUS CANNULA WITH SUTURABLE WING & INJECTION PORT(PRIME)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS

		STUDYING BLOOD PRESSURE ,3-WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS(QUEST)-USE FOR SIMULTANEOUS AND CONTINUOUS INFUSION OF TWO FLUIDS AND CONTROL FLOW DIRECTION
3772	MFG/MD/2021/000112	1.License Holder Name: RELISYS MEDICAL DEVICE LIMITED 2.Approving Authority: CDSCO, ZONAL OFFICE, HYDERABAD 3.Device Name(Brand Name)-Intended Use:ARTERIAL INTRODUCER SHEATH-THE ARTERIAL INTRODUCER SHEATH CONSIST OF HOMEOSTATIC VALVE ALLOWS EASY ACCESS FOR ADDITIONAL DEVICES SUCH AS ANGIOGRAPHIC CATHETER OR DIAGNOSTIC CATHETER, GUIDE CATHETER THROUGH THE HOMEOSTATIC VALVE WITH OUT ANY BLOOD LOSS. AND THE SIDE BRANCH TUBE IS WIDELY OPEN FOR THE INJECTION OF RADIOPAQUE FLUID OR MEDICAL FLUIDS
3773	MFG/MD/2021/000113	1.License Holder Name: BHARATH SURGICAL DRESSING COMPANY 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:BANDAGE CLOTH- UN CUT IS 863-THE BANDAGE CLOTH UNCUT ARE USED FOR SIMPLE DRESSING OF SUPERFICIAL WOUNDS TO HOLDING TOGETHER FRACTURED BONES OR BODY PARTS FOR REHABILITATION AND RECOVERY AND IT WAS USED EXTERNAL USE ONLY,BANDAGE CLOTH-CUT IS 863-THE BANDAGE CLOTH UNCUT ARE USED FOR SIMPLE DRESSING OF SUPERFICIAL WOUNDS TO HOLDING TOGETHER FRACTURED BONES OR BODY PARTS FOR REHABILITATION AND RECOVERY. SAME AS FOR UNCUT BANDAGE, EXCEPT FOR SELVEDGES WHICH SHALL NOT BE INCLUDED IN CUT BANDAGES. IN ADDITION, BOTH THE EXTREMES AND EDGES OF CUT BANDAGES SHALL BE STRAIGHT AND EVENLY CUT, WITH REASONABLE FREE FROM LOOSE THREADS AND IT WAS USED EXTERNAL USE ONLY, ABSORBENT GAUZE IS 758-THE NON-STERILE ABSORBENT GAUZE ARE USED TO ABSORB BLOOD AND IT WAS USED EXTERNAL USE ONLY,OPEN WOVE BANDAGE-THE NON-STERILE OPEN WOVEN BANDAGE ARE USED TO SECURE DRESSINGS AND OTHER WOUND CARE APPLICATIONS AND IT WAS USED EXTERNAL USE ONLY

3774	MFG/MD/2021/000114	1.License Holder Name: SRI GOPAL KRISHNA LABS. PVT LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:HAEMOSTATIC GELATIN SPONGE(ABGEL® ABSORBABLE GELATIN SPONGE USP)-ABGEL ® - ABSORBABLE GELATIN SPONGE USP, USED DRY OR SATURATED WITH STERILE SODIUM CHLORIDE SOLUTION, IS INDICATED FOR SURGICAL PROCEDURES FOR HEMOSTASIS, WHEN CONTROL OF CAPILLARY, VENOUS AND ARTERIOLAR BLEEDING BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS INEFFECTIVE OR IMPRACTICAL. ALTHOUGH NOT NECESSARY, ABGEL® - ABSORBABLE GELATIN SPONGE USP CAN BE USED WITH THROMBIN TO ACHIEVE HEMOSTASIS
3775	MFG/MD/2021/000115	1.License Holder Name: EMPORIS IMPLANTS AND SURFACE TRATMENT 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:THERMAL SPRAY COATING (HYDROXYAPATITE POWDER)(NA)-NOT APPLICABLE

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3776	MFG/MD/2021/000116	1.License Holder Name: HOSPITAL EQUIPMENT MANUFACTURING COMPANY 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE WIRE (SS 316 L)(HEMC, INFINITI, AMED, MINARDI, ZORTHOX OST)-BONE WIRE IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE NAILS (TITANIUM)(HEMC, INFINITI, AMED, MINARDI, ZORTHOX OST)-BONE NAILS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PLATE (SS 316 L)(HEMC, INFINITI, AMED, MINARDI, ZORTHOX OST)-BONE PLATE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,SPINAL IMPLANTS (SS 316 L)(HEMC, INFINITI, AMED, MINARDI, ZORTHOX OST)-SPINAL IMPLANT SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PLATE (TITANIUM)(HEMC, INFINITI, AMED, MINARDI, ZORTHOX OST)-BONE PLATE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE SCREWS (SS 316 L)(HEMC, INFINITI, AMED, MINARDI, ZORTHOX OST)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE WIRE (TITANIUM)(HEMC, INFINITI, AMED, MINARDI, ZORTHOX OST)-BONE WIRE IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE SCREWS (TITANIUM)(HEMC, INFINITI, AMED, MINARDI, ZORTHOX OST)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE NAILS (SS 316 L)(HEMC, INFINITI, AMED, MINARDI, ZORTHOX OST)-BONE NAILS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PINS (SS 316 L)(HEMC, INFINITI, AMED, MINARDI, ZORTHOX OST)-BONE PIN IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PIN (TITANIUM)(HEMC, INFINITI, AMED, MINARDI, ZORTHOX OST)-BONE PIN IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,SPINAL IMPLANTS (TITANIUM)(HEMC, INFINITI, AMED, MINARDI, ZORTHOX OST)-SPINAL IMPLANT SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.

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3777	MFG/MD/2021/000117	1.License Holder Name: AGROSURG IRRADIATORS (INDIA) PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:BANDAGE CLOTH, ROLLED BANDAGE SCH F-II-BANDAGE CLOTH ARE TYPICALLY USED IN FIRST RESPONSE TO INJURIES, THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR CLEANING, PACKAGING, SCRUBBING, COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BROOD AND EXUDATES FLUID FROM A WOUND. CLOSELY WOVEN GAUZE IS BEST FOR EXTRA STRENGTH OR GREATER PROTECTION, WHIRE OPEN OR ROOSE WEAVE IS BETTER FOR ABSORBENCY OR DRAINAGE.,KITS-KITS ARE EMERGENCY CARE GIVEN IMMEDIATELY TO AN INJURED PERSON. THE PURPOSE OF KIT FOR E.G. FIRST AID KIT IS TO MINIMIZE INJURY AND FUTURE DISABILITY. LN SERIOUS CASES, FIRST AID MAY BE NECESSARY TO KEEP THE VICTIM ARIVE. THE VARIOUS GAUZES, DRESSINGS AND BANDAGES FOUND IN KITS HAVE DIFFERENT USES. THESE DRESSINGS ARE USED FOR MINOR CUTS AND SKIN INJURIES. SOME KITS SUCH AS PICC HICKMAN ARE USED IN SPECIAL SURGICAL PROCEDURE DURING TREATMENT OF CANCER FIRST AID KIT: 1) ABSORBENT GAUZE SCH F-II 2) ROLLED BANDAGE SCH F-II 3) ABSORBENT COTTON 4) CREPE BANDAGE 5) ADHESIVE TAPE 6) SCISSORS 7) DISPOSABLE GLOVES 8) POVIDONE IODINE OINTMENT 9) ANTISEPTIC LIQUID 10) BANDAID STRIPS HICKMAN PACK: 1)TWO AUTOCLAVABLE POLYPROPYLENE BOWLS 2 .5" DIAMETER & 4 CMS DEPTH SHOULD WITHSTAND TEMP. OF 134~C. (BIODEGRADABLE) 2) SEVEN COTTON BUDS WITH AUTOCLAVABLE POLYPROPYLENE STICK. 3)TWENTY GAUZE PIECES OF 10CM X10CMX8 PLY AS PER SCHEDULE F-II,PEROXIDE BLEACH. 4)TWO GAUZE PIECES AS PER SAMPLE 6CM X 3CM,ONE OF THEM HALF CUT AT THE CENTRE. 5) TWO ABSORBENT TOWELS 16"X 16" 40 GSM FOLDED & PACKED. (HIGH ABSORBENCY, TEAR RESISTANCE, STRONG WET STRENTH). ALL THE ABOVE MATERIAL PACKED IN SINGLE 18"X 18" SMS 40 GSM TOWEL & PUT IN AUTACLAVABLE BAGS PICC PACK: 1)TWO AUTOCLAVABLE POLYPROPYLENE BOWLS 2.5" DIAMETER & 4 CMS. DEPTH SHOULD WITHSTAND TEMP. OF 134C. BIODEGRADEBLE 2)TEN GAUGE PIECES OF 10 CM 10 CM X 8 PLY, PER SCHEDULE F-II, PEROXIDE BLEACH . 4) ONE ABDOMINAL SPONGE OF 30 CM X 30 CM X 8 PLY. 5) ONE 16"X16" ABSORBENT TOWEL 40 GSM. ALL THE ABOVE MATERIAL PACKED IN SINGLE 18"X 18" SMS 40 GSM TOWEL & PUT IN AUTOCLAVABLE BAGS, ROLLED GAUZE SCH F-II-ROLLED GAUZE ARE TYPICALLY USED IN FIRST RESPONSE TO INJURIES, THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR PACKAGING, COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BROOD AND EXUDATES FLUID FROM A WOUND.

	CROSERY WOVEN GAUZE IS BEST FOR EXTRA STRENGTH OR GREATER PROTECTION, WHILE OPEN OR LOOSE WEAVE IS BETTER FOR ABSORBENCY OR DRAINAGE,ABSORBENT GAUZE SWAB SCH F-II-GAUZE SWABS ARE TYPICALLY USED IN FIRST RESPONSE TO INJURIES, THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR CLEANING, PACKAGING, SCRUBBING, COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND. CLOSELY WOVEN GAUZE IS BEST FOR EXTRA STRENGTH OR GREATER PROTECTION, WHILE OPEN OR LOOSE WEAVE IS BETTER FOR ABSORBENCY OR DRAINAGE,COTTON ABSORBENT GAUZE (GAMJEE PAD, GAMJEE ROLL) SCH F-II-GAMJEE PAD/GAMJEE ROLL, ARE TYPICALLY USED IN FIRST RESPONSE TO INJURIES, THEY ARE COMBINED DRESSING PADS MADE FROM ABSORBENT COTTON WHICH IS WRAPPED IN CAUZE CLOTH AND THIS MAKES THEM IDEAL FOR PACKAGING, WRAPPING,COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND,X-RAY DETECTABLE GAUZE SWAB B.P-X RAY DETECTABLE GAUZE SWABS, ARE USED IN LIRST RESPONSE TO INJURIES, THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDES FLUID FROM A WOUND. X RAY DETECTABLE GAUZE SWABS ARE ALSO USED DURING VARIOUS SURGERIES, X RAY THREAD MAKE THEM EASIER TO TRACE INSIDE THE BODY,COTTON ABSORBENT ABDOMINAL PAD SCH F-II-COTTON ABSORBENT ABDOMINAL PADS ARE MAINLY USED DURING SURGERIES. THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND,X-RAY DETECTABLE ABDOMINAL PAD B.P.-X RAY DETECTABLE ABDOMINAL PADS ARE MAINLY USED DURING SURGERIES. THEY ARE MADE FROM SIMPLE COTTON WEAVE AND THIS MAKES THEM IDEAL FOR COVERING AND SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND. X RAY THREAD MAKE THEM EASIER TO TRACE INSIDE THE BODY,ABSORBENT COTTON BALLS I.P.-COTTON BALL ARE TYPICALLY USED IN FIRST RESPONSE TO INJURIES, THEY ARE MADE FROM ABSORBENT COTTON THIS MAKES THEM IDEAL FOR CLEANING, SECURING IN A VARIETY WOUND AND STEMMING AND ABSORBING BLOOD AND EXUDATES FLUID FROM A WOUND

3778	MFG/MD/2021/000118	1.License Holder Name: NIDHI SURGICAL PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:INFRA RED THERMOMETER(PRIMECARE)-IT IS DEVICE USED TO RECORD THE BODY TEMPERATURE.,DIGITAL THERMOMETER(PRIMECARE)-IT IS A DEVICE USED TO RECORD THE BODY TEMPERATURE.
3779	MFG/MD/2021/000119	1.License Holder Name: M/S G.R. BIOURE SURGICAL SYSTEM (P) LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATE(BIOURE)-BONE PLATE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE SCREWS(BIOURE)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.

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3780	MFG/MD/2021/000120	1.License Holder Name: B L LIFESCIENCES PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION (CPDA /CPDA-1 SOLUTION) AS PER USP (FOR EXPORT ONLY)(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,BLOOD BAG WITH ANTICOAGULANT CPD (CITRATE PHOSPHATE DEXTROSE) SOLUTION AS PER IP AND ADDITIVE SOLUTION SAGM(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION (CPD SOLUTION) USP (FOR EXPORT ONLY)(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,BLOOD BAG WITH ANTICOAGULANT CPD (CITRATE PHOSPHATE DEXTROSE) SOLUTION AS PER USP AND ADDITIVE SOLUTION SAGM (FOR EXPORT ONLY)(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION., TRANSFER BAG AS PER IP(NA)-STERILE MEDICAL DEVICE TRANSFER BLOOD BAG IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,UMBILICAL CORD BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION IP(NA)-UMBILICAL CORD BLOOD BAG SYSTEM, CONTAINING ANTICOAGULANT SOLUTION AS PER BAG CAPACITY IS USED FOR COLLECTION, STORAGE, PROCESS, TRANSPORT OF UMBILICAL CORD BLOOD IN CLOSED AND STERILE CONDITIONS.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION (CPD SOLUTION) AS PER IP(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,UMBILICAL CORD BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE (CPD) SOLUTION USP (FOR EXPORT ONLY)(NA)-UMBILICAL CORD BLOOD BAG SYSTEM, CONTAINING ANTICOAGULANT SOLUTION AS PER BAG CAPACITY IS

	USED FOR COLLECTION, STORAGE, PROCESS, TRANSPORT OF UMBILICAL CORD BLOOD IN CLOSED AND STERILE CONDITIONS., TRANSFER BAG AS PER USP (FOR EXPORT ONLY)(NA)-STERILE TRANSFER BLOOD BAG IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION (CPDA/CPDA-1 SOLUTION) AS PER IP(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION AS PER IP AND ADDITIVE SOLUTION SAGM-2(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.,BLOOD BAG WITH ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION AS PER USP AND ADDITIVE SOLUTION SAGM-2 (FOR EXPORT ONLY)(NA)-STERILE MEDICAL DEVICE BLOOD BAG WITH ANTICOAGULANT IS USED TO COLLECT, STORE, PROCESS, TRANSPORT, SEPARATION AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS IN CLOSED AND STERILE CONDITION.

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3781	MFG/MD/2021/000121	1.License Holder Name: QUBIX MEDICARE PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) STERILISED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910(QUBIX-POLYGLACTIN)-QUBIX-POLYGLACTIN IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL POLYPROPYLENE MESH(WELKNIT- MESH)-WELKNIT MESH USED FOR HERNIA REPAIR,ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID FAST(QUBIX- PGA FAST)-QUBIX- PGA FAST IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORTTERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION WOULD BE BENEFICIAL. DUE TO THE ABSORPTION PROFILE QUBIX- PGA FAST IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. QUBIX- PGA FAST IS NOT INTENDED FOR USE IN OPHTHALMIC SURGERY CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE U.S.P (SYNTHETIC) ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE SUTURES(QUBIX-POLYETHYLENE)-HIGH MOLECULAR WEIGHT POLYETHYLENE SUTURE IS INDICATED FOR USE IN APPROXIMATION AND/OR LIGATION OF SOFT TISSUE, INCLUDING THE USE IN CARDIOVASCULAR SURGERIES AND THE USE OF ALLOGRAFT TISSUE FOR ORTHOPEDIC PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE USP (SURGICAL NEEDLED SUTURE COATED POLYESTER (QUBIX-POLYESTER)-QUBIX- POLYESTER IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., NON ABSORBABLE SURGICAL SUTURE USP SURGICAL NEEDLED SUTURE MONOFILAMENT 316 LVM STAINLESS STEEL WIRE(QUBIX-STEEL)-QUBIX_ STEEL STAINLESS STEEL SURGICAL SUTURE IS INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, ORTHOPEDIC PROCEDURES INCLUDING CERCILAGE & TENDON REPAIR AND ALSO IN STERNUM CLOSURE,ABSORBABLE SURGICAL SUTURE USP SURGICAL SUTURE CATGUT WITH NEEDLE - PLAIN(QUBIX- GUT PLAIN)-CATGUT IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES,NON ABSORBABLE SURGICAL SUTURE USP SURGICAL NEEDLED SUTURE (BLACK BRAIDED SILK)(QUBIX-

	SILK)-QUBIX- SILK IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITH NEEDLE - PLAIN(QUBIX- GUT PLAIN)-CATGUT IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,MONOFILAMENT POLYDIOXANONE, KNOTLESS TISSUE-CLOSURE DEVICE, SYNTHETIC ABSORBABLE SURGICAL SUTURES (QUBIX-PDX BARB)-POLYDIOXANONE KNOTLESS TISSUE-CLOSURE DEVICE COMPRISED OF DYED PDO IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE USE OF ABSORBABLE SUTURES IS APPROPRIATE,NON ABSORBABLE SURGICAL SUTURE U.S.P (SYNTHETIC) ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE SUTURES(QUBIX- POLYETHYLENE)-HIGH MOLECULAR WEIGHT POLYETHYLENE SUTURE IS INDICATED FOR USE IN APPROXIMATION AND/OR LIGATION OF SOFT TISSUE, INCLUDING THE USE IN CARDIOVASCULAR SURGERIES AND THE USE OF ALLOGRAFT TISSUE FOR ORTHOPEDIC PROCEDURES.,NON ABSORBABLE SURGICAL SUTURE USP (STERILISED SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE)(QUBIX- POLYPROPYLENE)-QUBIX- POLYPROPYLENE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., NON ABSORBABLE SURGICAL SUTURE USP (SURGICAL NEEDLED SUTURE MONOFILAMENT POLYAMIDE(NYLON)(QUBIX-NYLON)-QUBIX- NYLON IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES, ABSORBABLE SURGICAL SUTURE USP STERILE SURGICAL SUTURE CATGUT WITH NEEDLE- CHROMIC(QUBIX- GUT CHROMIC)-CATGUT IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL POLYPROPYLENE MESH (WELKNIT- MESH)-WELKNIT MESH USED FOR HERNIA REPAIR, ABSORBABLE SURGICAL SUTURE USP, STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID(QUBIX- PGA)-QUBIX- PGA IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.,NON ABSORBABLE SURGICAL SUTURE USP (STERILIZED SURGICAL

	NEEDLED SUTURE MONOFILAMENT POLYAMIDE(NYLON)(QUBIX-NYLON)-QUBIX- NYLON IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES, ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) MONOFILAMENT–POLYDIOXANONE (QUBIX-PDX)-QUBIX- PDX, MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE IN PAEDIATRIC CARDIOVASCULAR TISSUE, MICROSURGERY AND IN OPHTHALMIC SURGERY THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE.,ABSORBABLE SURGICAL SUTURE USP SURGICAL NEEDLED SUTURE (SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID FAST(QUBIX- PGA FAST)-QUBIX- PGA FAST IS INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORTTERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION WOULD BE BENEFICIAL. DUE TO THE ABSORPTION PROFILE QUBIX- PGA FAST IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. QUBIX- PGA FAST IS NOT INTENDED FOR USE IN OPHTHALMIC SURGERY CARDIOVASCULAR AND NEUROLOGICAL PROCEDURES., ABSORBABLE SURGICAL SUTURE (SYNTHETIC) SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910 FAST(QUBIX-POLYGLACTIN FAST)-QUBIX-POLYGLACTIN FAST IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL. DUE TO THE RAPID ABSORPTION PROFILE, QUBIX-POLYGLACTIN FAST IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. QUBIX-POLYGLACTIN FAST IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES,NON ABSORBABLE SURGICAL SUTURE USP STERILIZED SURGICAL NEEDLED SUTURE MONOFILAMENT 316 LVM STAINLESS STEEL WIRE (QUBIX- STEEL)-QUBIX_ STEEL STAINLESS STEEL SURGICAL SUTURE IS INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, ORTHOPEDIC PROCEDURES INCLUDING CERCILAGE & TENDON REPAIR AND ALSO IN STERNUM CLOSURE,ABSORBABLE SURGICAL SUTURE USP SURGICAL NEEDLED SUTURE (SYNTHETIC) MONOFILAMENT–POLYDIOXANONE(QUBIX-PDX)-QUBIX- PDX, MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION, INCLUDING USE

	IN PAEDIATRIC CARDIOVASCULAR TISSUE, MICROSURGERY AND IN OPHTHALMIC SURGERY THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE., NON ABSORBABLE SURGICAL SUTURE USP (STERILIZED SURGICAL NEEDLED SUTURE COATED POLYESTER(QUBIX-POLYESTER)-QUBIX-POLYESTER IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,MONOFILAMENT POLYDIOXANONE, KNOTLESS TISSUE-CLOSURE DEVICE, SYNTHETIC ABSORBABLE SURGICAL SUTURES(QUBIX- PDX BARB)-POLYDIOXANONE KNOTLESS TISSUE-CLOSURE DEVICE COMPRISED OF DYED PDO IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION WHERE USE OF ABSORBABLE SUTURES IS APPROPRIATE.,ABSORBABLE SURGICAL SUTURE SURGICAL NEEDLED SUTURE (SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25(QUBIX- PGCL)-QUBIX- PGCL SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION WHERE AN ABSORBABLE MATERIALS IS INDICATED.,NON ABSORBABLE SURGICAL SUTURE USP STERILISED SURGICAL NEEDLED SUTURE (BLACK BRAIDED SILK)(QUBIX- SILK)-QUBIX- SILK IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE STERILIZED SURGICAL NEEDLED SUTURE (SYNTHETIC) MONOFILAMENT POLIGLECAPRONE 25(QUBIX- PGCL)-QUBIX- PGCL SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION WHERE AN ABSORBABLE MATERIALS IS INDICATED.,ABSORBABLE SURGICAL SUTURE USP, SURGICAL NEEDLED SUTURE (SYNTHETIC) BRAIDED AND COATED POLYGLYCOLIC ACID(QUBIX- PGA)-QUBIX- PGA IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC AND OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES,ABSORBABLE SURGICAL SUTURE USP (SYNTHETIC) SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910(QUBIX-POLYGLACTIN)-QUBIX-POLYGLACTIN IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIO VASCULAR AND NEUROLOGICAL TISSUES,ABSORBABLE SURGICAL SUTURE (SYNTHETIC) STERILIZED SURGICAL NEEDLED SUTURE COATED POLYGLACTIN 910 FAST(QUBIX-POLYGLACTIN FAST)-QUBIX-POLYGLACTIN FAST IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE RAPID ABSORPTION OF

		THE SUTURE WOULD BE BENEFICIAL. DUE TO THE RAPID ABSORPTION PROFILE, QUBIX-POLYGLACTIN FAST IS USEFUL FOR SKIN CLOSURE, PARTICULARLY IN PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION AND CLOSURE OF ORAL MUCOSA. QUBIX-POLYGLACTIN FAST IS ALSO SUCCESSFULLY USED IN OPHTHALMIC SURGERY FOR CONJUNCTIVAL SUTURES,NON ABSORBABLE SURGICAL SUTURE USP (SURGICAL NEEDLED SUTURE MONOFILAMENT POLYPROPYLENE)(QUBIX- POLYPROPYLENE)-QUBIX- POLYPROPYLENE IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL TISSUES., ABSORBABLE SURGICAL SUTURE USP SURGICAL SUTURE CATGUT WITH NEEDLE- CHROMIC(QUBIX- GUT CHROMIC)-CATGUT IS INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC & OPHTHALMIC PROCEDURES BUT NOT FOR USE IN CARDIOVASCULAR AND NEUROLOGICAL TISSUES.
3782	MFG/MD/2021/000122	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:GAMMA/ ETHYLENE OXIDE STERILISATION OF CLASS C PRODUCTS-GAMMA/ ETHYLENE OXIDE STERILISATION OF PRODUCTS FALLING UNDER CLASS C. INTENDED USE OF THE PRODUCTS SHALL BE AS DECIDED BY THE MEDICAL DEVICE MANUFACTURER.,GAMMA/ ETHYLENE OXIDE STERILISATION OF CLASS D PRODUCTS-GAMMA/ ETHYLENE OXIDE STERILISATION OF PRODUCTS FALLING UNDER CLASS D. INTENDED USE OF THE PRODUCTS WOULD BE AS DECIDED BY THE MEDICAL DEVICE MANUFACTURER.
3783	MFG/MD/2021/000123	1.License Holder Name: SWITZ NEUBIO INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:COCHLEAR IMPLANT SYSTEM(NEUBIO-BOLD)-THE BOLD COCHLEAR IMPLANT SYSTEM INTENDED TO RESTORES A SENSATION OF HEARING IN INDIVIDUALS AGED 12 MONTHS AND OLDER WITH SEVERE TO PROFOUND SENSORINEURAL HEARING LOSS DEFINED AS A PURE-TONE AVERAGE (PTA: 500, 1000, 2000, 4000 HT) OF 270 DB HL.

3784	MFG/MD/2021/000124	1.License Holder Name: WIPRO GE HEALTHCARE PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:X-RAY(BRIVO XR115)-BRIVO XR115 MOBILE RADIOGRAPHIC IMAGING SYSTEM IS DESIGNED TO GENERATE DIAGNOSTIC RADIOGRAPHIC X-RAYS THAT MAY BE USED TO DETECT DISEASE OR INJURY EARLY ENOUGH FOR A MEDICAL PROBLEM TO BE MANAGED, TREATED OR CURED. X-RAYS ARE USED IN MANY TYPES OF EXAMINATIONS AND PROCEDURES THAT INCLUDE RADIOGRAPHY TO FIND ORTHOPEDIC DAMAGE, TUMORS, PNEUMONIA AND FOREIGN OBJECTS. THE BRIVO XR115 MOBILE X-RAY SYSTEMS IS INTENDED TO TAKE EXPOSURES UTILIZING FILM-BASED CASSETTES OR COMPUTED RADIOGRAPHY (CR) CASSETTE. THE SYSTEM IS INDICATED FOR USE ON NEONATES, PEDIATRIC, ADULT AND ELDERLY PATIENTS FOR GENERAL PURPOSE DIAGNOSTIC RADIOGRAPHIC EXAMINATIONS AND PROCEDURES. INDICATED USE OF THE SYSTEM IS IRRESPECTIVE OF GENDER, HEIGHT AND WEIGHT. THE MOBILITY OF THE SYSTEM ENABLES GENERAL-PURPOSE RADIOGRAPHIC PROCEDURES THROUGHOUT THE CLINICAL ENVIRONMENT, OR AS NEEDED WITHIN THE EMERGENCY, INTENSIVE CARE (ICU), NEONATAL INTENSIVE CARE UNIT, CARDIAC AND OPERATING DEPARTMENTS, FOR PATIENTS WHO HAVE LIMITED MOBILITY OR IN CASES WHERE IT IS UNSAFE OR IMPRACTICAL TO MOVE THEM TO A TRADITIONAL RAD ROOM. THE BRIVO XR115 IS INDICATED FOR TAKING RADIOGRAPHIC EXPOSURES OF THE SKULL, SPINAL COLUMN, CHEST, ABDOMEN, EXTREMITIES, AND OTHER BODY PARTS WITH THE PATIENT SITTING, STANDING, OR LYING IN PRONE OR SUPINE POSITION.,PET/CT(DISCOVERY IQ)-GE DISCOVERY PET/CT SYSTEMS ARE INTENDED FOR HEAD AND WHOLE-BODY ATTENUATION CORRECTED POSITRON EMISSION TOMOGRAPHY (PET) IMAGING AND LOCALIZATION OF EMISSION ACTIVITY IN PATIENT ANATOMY BY MEANS OF INTEGRATED PET AND CT IMAGES. DISCOVERY PET/CT SYSTEMS ARE TO BE USED BY TRAINED HEALTH CARE PROFESSIONALS FOR IMAGING THE DISTRIBUTION OF RADIO PHARMACEUTICALS IN THE BODY FOR THE ASSESSMENT OF METABOLIC (MOLECULAR) AND PHYSIOLOGIC FUNCTIONS IN PATIENTS OF ALL AGES. THIS CAN ASSIST IN THE EVALUATION, DIAGNOSIS, STAGING, RE-STAGING, AND FOLLOW UP OF LESIONS, DISEASE AND ORGAN FUNCTION SUCH AS (BUT NOT LIMITED TO) CANCER, CARDIOVASCULAR DISEASE, AND BRAIN DYSFUNCTION. THIS DEVICE CAN ALSO ASSIST IN RADIOTHERAPY PLANNING. THE DISCOVERY IQ SYSTEM CAN ALSO BE USED AS A STAND-ALONE HEAD AND WHOLE-BODY MULTI-SLICE COMPUTED TOMOGRAPHY (CT) DIAGNOSTIC IMAGING SYSTEMS,COMPUTED TOMOGRAPHY(REVOLUTION ACTS)-THE SYSTEM IS INTENDED TO BE

		USED FOR HEAD AND WHOLE BODY COMPUTED TOMOGRAPHY. THE GE REVOLUTION ACTS COMPUTED TOMOGRAPHY X-RAY SYSTEM IS INTENDED TO PRODUCE CROSS-SECTIONAL IMAGES OF THE BODY BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA TAKEN AT DIFFERENT ANGLES AND PLANES, PATIENT FOR ALL AGES, INCLUDING AXIAL, CINE, HELICAL. THESE IMAGES MAY BE OBTAINED EITHER WITH OR WITHOUT CONTRAST. THIS DEVICE MAY INCLUDE SIGNAL ANALYSIS AND DISPLAY EQUIPMENT, PATIENT, AND EQUIPMENT SUPPORTS, COMPONENTS AND ACCESSORIES. THIS DEVICE MAY INCLUDE DATA AND IMAGE PROCESSING TO PRODUCE IMAGES IN A VARIETY OF TRANS-AXIAL AND REFORMATTED PLANES. FURTHER THE IMAGES CAN BE POST PROCESSED TO PRODUCE ADDITIONAL IMAGING PLANES OR ANALYSIS RESULTS. THE GE REVOLUTION ACTS CT SCANNER SYSTEM IS INDICATED FOR HEAD, WHOLE BODY, AND VASCULAR X-RAY COMPUTED TOMOGRAPHY APPLICATIONS. THE DEVICE OUTPUT IS A VALUABLE MEDICAL TOOL FOR THE DIAGNOSIS OF DISEASE, TRAUMA, OR ABNORMALITY AND FOR PLANNING, GUIDING, AND MONITORING THERAPY.
3785	MFG/MD/2021/000125	1.License Holder Name: CAREMAX HEALTHCARE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ADHESIVE TAPE USP (CAREPLAST , VAGPLAST , OPTTY PLAST , CAREMAX)-THIS IS USED FOR FIXATION OF PRIMARY DRESSING.,ELASTIC ADHESIVE BANDAGE BP(ELASTOCARE , CAREMAX)-ELASTIC ADHESIVE BANDAGE IS INTENDED USE FOR SUPPORT STRAPPING FRACTURES, ELBOWS, KNEES, SHOULDERS SPECIALLY REQUIRING ELASTICITY. IT IS ALSO USED FOR CORRECTIONAL PURPOSES. EXCELLENT AS PRESSURE DRESSING, PROVIDES ADEQUATE COMPRESSION AND BETTER MOBILITY.,ADHESIVE TAPE NON WOVEN SUPPORT BP (MICROPOROUS SURGICAL TAPE)(CAREPORE , CPORE, NEWPORE , RESURGE , SHIVNOL , CRYSTAL , SARA , SAVIPORE , MEGAPORE, OPTTYPORE , DRESSIPORE , CAREMAX)-THIS IS USEDFOR FIXATION OF PRIMARY DRESSING.,COTTON CREPE BANDAGE BP(CAREMAX, FIXOCARE , ORTHOFLEX, LITZMANN)-COTTON CREPE BANDAGE IS USED FOR MINOR SPRAINS , HEALING OF FRACTURE ETC

3786	MFG/MD/2021/000126	1.License Holder Name: SHREE SUDAMA HATH KARGHA VASTRA UTPADAK SAHKARI SAMITI LTD. 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:ROLLED BANDAGE [AS PER SCHEDULE F(II)](-)-THE ROLL BANDAGES ARE USED TO BIND, WRAP OR AS A SUPPORTIVE MATERIAL FOR WOUNDS, CUTS, BURNS AND IN DRESSING FOR WOUND HEALING PROCESS.,ABSORBENT GAUZE (GAUZE THAN) [AS PER SCHEDULE F(II)](-)-THE GAUZE THAN ARE USED TO CLEANING, DRYING AND DRESSING WOUNDS A MEDICAL TREATMENT .GAUZE IS PERFECT FOR DELIVERING ANTISEPTICS TO INJURIES, MOISTURE REMOVAL FROM WOUNDS BEFORE THE EXERTION OF A DRESSING .
3787	MFG/MD/2021/000127	1.License Holder Name: UNIVERSAL MEDICAP LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:GAUZE SWAB STERILE ABSORBENT-GAUZE SWABS ARE A USEFUL UTILITY PRODUCT IN A KIT CAN BE USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, APPLYING ANTISEPTIC AND MUCH MORE. IT IS ESPECIALLY USEFUL FOR DRESSING WOUNDS WHERE OTHER FABRICS MIGHT STICK TO THE BURN OR LACERATION. STERILE GAUZE SWAB SHOULD BE USED FOR ANY APPLICATION TO AN OPEN WOUND,PARAFFIN GAUZE DRESSING B.P. STERILE-PARAFFIN GAUZE DRESSING B.P. IS A DEVICE INTENDED USED FOR MEDICAL PURPOSE THAT CONSIST OF STERILE PAD APPLIED TO A WOUND TO PROMOTE HEALING AND PROTECT THE WOUND FROM FURTHER HARM. A DRESSING IS DESIGNED TO BE IN DIRECT CONTACT WITH THE WOUND, AS DISTINGUISHED FROM A BANDAGE, WHICH IS MOST OFTEN USED TO HOLD A DRESSING IN PLACE.,EYE PAD - STERILE-EYE PAD IS A DEVICE INTENDED USED TO COVER THE EYES FOR PROTECTION AFTER THE OPERATION.,STERILIZED GAUZE SWAB ABDOMINAL WITH X-RAY DETECTABLE THREAD-STERILIZED GAZE SWAB ABDOMINAL WITH X-RAY DETECTABLE THREAD IS A DEVICE INTENDED USED FOR ABSORBING BLOOD WHILE SURGERY AND AVOID BLOOD SPILL,COMBINE DRESSING - STERILE-COMBINE DRESSING-STERILE IS A DEVICE INTENDED USED FOR HANDLING HEAVY DRAINAGE, PROMOTING HEALING AND KEEPING THE WOUND DRY FOR OPTIMAL COMFORT AND RELIEF. IT IS ESPECIALLY USEFUL FOR DRESSING WOUNDS WHERE OTHER FABRICS MIGHT STICK TO THE BURN OR LACERATION.

3788	MFG/MD/2021/000128	1.License Holder Name: PHOENIX INNOVATIVE HEALTHCARE MANUFACTURERS PRIVATE LIMITED 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER-THERMOMETERS ARE USED MANY PERSONNEL.THE DIGITAL THERMOMETER IS INTENDED TO BE USED BY MANY PATIENTS FOR MEASURING HUMAN OR ANIMAL BODY TEMPERATURE.
3789	MFG/MD/2021/000129	1.License Holder Name: SHRI RAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:FRAMYCETIN GAUZE DRESSING B.P.'93(GENERIC NAME & BRAND LIKE; FRA-TULLE, SOFRA-TULLE)-FOR BURNS, SCALDS, ABRASIONS, LACERATIONS, CRUSH INJURIES, DIABETIC ULCERS, SKIN GRAFTING, PRESSURE SORES, COLOSTOMIES, SURGICAL WOUNDS ETC.,NEOMYCIN, BACITRACIN AND POLYMIXIN B SULPHATE TULLE(GENERIC NAME & BRAND LIKE; SULFHEXSOFRA, N.T. BIOTIC TULLE, FRADIO-TULLE)-FOR BURNS, SCALDS, ABRASIONS, LACERATIONS, CRUSH INJURIES, DIABETIC ULCERS, SKIN GRAFTING, PRESSURE SORES, COLOSTOMIES, SURGICAL WOUNDS ETC.
3790	MFG/MD/2021/000130	1.License Holder Name: AEGIS LIFESCIENCES PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:POLYVINYL ALCOHOL MEDICAL SPONGE DRESSING (ENT SERIES)(SURGI-PVA)-THE PVA ENT SPONGES ARE INTENDED TO BE USED FOR PLACING INSIDE THE NASAL CAVITIES OR EAR CANAL FOR EPISTAXIS AND POST-OPERATIVE SURGERY, WHICH EXPANDS WHEN MOISTENED TO ASSIST IN MANAGEMENT OF FLUIDS I.E. FLUID CONTROL AND DRAINAGE CONTROL AND TAMPONADE OR HAEMOSTASIS., POLYVINYL ALCOHOL MEDICAL SPONGE DRESSING (OPHTHALMIC SERIES)(SURGI-PVA)-THE PVA OPHTHALMIC SPONGES ARE INTENDED TO BE USED IN OPHTHALMIC OR MICROSCOPIC SURGICAL PROCEDURES TO ASSIST IN ABSORBING EXCESS FLUIDS FROM THE OPERATIVE FIELD IN MANAGEMENT OF FLUID I.E. FLUID CONTROL AND DRAINAGE CONTROL.

3791	MFG/MD/2021/000131	1.License Holder Name: EXCEL OPTICS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:SINGLE PIECE PMMA RIGID INTRAOCULAR LENS(EXCELENS, NOVALENS,TRULENS,SOLARIS & FREEDOM)-INTRAOCULAR LENSES (IOL) ARE LENS IMPLANTED IN THE EYE USED TO TREAT CATARACTS OR MYOPIA.,SINGLE PIECE HEMA FOLDABLE INTRAOCULAR LENS(TRUFOLD , NOVAFLEX)-INTRAOCULAR LENSES (IOL) ARE LENS IMPLANTED IN THE EYE USED TO TREAT CATARACTS OR MYOPIA.,HYDROPHOBIC FOLDABLE INTRAOCULAR LENS (TRUEVUE , NOVAFLEX HP)-INTRAOCULAR LENSES (IOL) ARE LENS IMPLANTED IN THE EYE USED TO TREAT CATARACTS OR MYOPIA.

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3792	MFG/MD/2021/000132	1.License Holder Name: SONTEX ROLLED BANDAGE WORKS 2.Approving Authority: MADHYA PRADESH 3.Device Name(Brand Name)-Intended Use:OPEN WOVE BANDAGE BP-OPEN WOVE BANDAGE IS A STRIP OR ROLL OF GAUZE OR OTHER MATERIAL FOR WRAPPING OR BINDING ANY PART OF THE BODY. THIS BANDAGE IS USED TO STOP THE FLOW OF BLOOD, ABSORB DRAINAGE, CUSHION THE INJURED AREA, PROVIDE A SAFEGUARD AGAINST CONTAMINATION, HOLD A MEDICATED DRESSING IN PLACE, HOLD A SPLINT IN POSITION, OR OTHERWISE IMMOBILIZE AN INJURED PART OF THE BODY TO PREVENT FURTHER INJURY AND TO FACILITATE HEALING.,BANDAGE CLOTH -A DRESSING IS A STERILE PAD OR COMPRESS APPLIED TO A WOUND TO PROMOTE HEALING AND PROTECT THE WOUND FROM FURTHER HARM. A DRESSING IS DESIGNED TO BE IN DIRECT CONTACT WITH THE WOUND, AS DISTINGUISHED FROM A BANDAGE, WHICH IS MOST OFTEN USED TO HOLD A DRESSING IN PLACE.,ABSORBENT GAUZE USP -THE LARGE USE OF ABSORBENT COTTON AND ABSORBENT GAUZE FOR SURGICAL DRESSINGS AND IN THE ... ANY ADDITION OF COLORING MATERIAL, PARTICULARLY BLUE, ON PURPOSE OF MODIFYING., ABSORBENT COTTON WOOL IP-ABSORBENT COTTON IS USED FOR SURGICAL DRESSINGS, COSMETIC PURPOSES ETC. IT IS ALSO KNOWN AS SURGICAL COTTON OR COTTON WOOL. IT IS MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, DISPENSARIES AND NURSING HOMES TO ABSORB THE BODY FLUIDS. FOR MAKING CONVENTIONAL TYPE OF SANITARY NAPKINS OR PADS,COTTON CREPE BANDAGE BP-CREPE BANDAGE: MADE OF SOFT MATERIAL & COMFORTABLE ON SKIN. CREPE BANDAGES RELIVE MUSCLE STRAIN, JOINT PAIN, COMPRESSION BANDAGE FOR KNEE, ANKLE SWELLING, ETC.,ABSORBENT GAUZE-ABSORBENT GAUZE SHOULD BE STERILIZED SINCE IT WILL BE USED FOR CLEANING, DRYING AND DRESSING WOUNDS DURING A MEDICAL TREATMENT. GAUZE IS PERFECT FOR DELIVERING ANTISEPTICS TO INJURIES, MOISTURE REMOVAL FROM WOUNDS BEFORE THE EXERTION OF A DRESSING OR AS A DRESSING AS ITS OWN

3793	MFG/MD/2021/000133	1.License Holder Name: CENTENIAL SURGICAL SUTURE LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:NON ABSORBABLE STERILISED UMBILICAL COTTON TAPE(CENIITAPE)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT., STERILISED, SURGICAL SKIN STAPLER(MANIPLIER AZ, MANIPLIER S-2, CLOSE)-SURGICAL STAPLES ARE SPECIALIZED STAPLES USED IN SURGERY IN PLACE OF SUTURES TO CLOSE SKIN WOUNDS, CONNECT OR REMOVE PARTS OF BODY DURING SURGERY.

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3794	MFG/MD/2021/000134	1.License Holder Name: MEDIPLUS (INDIA) LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:I.V CANNULA WITH INJECTION VALVE WITH WINGS-THE I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE,3 WAY STOP COCK WITH EXTENSION TUBE-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING AN ACCESS PORT FOR ADMINISTRATION OF A SOLUTION, WITHDRAWAL OF FLUID, AND PRESSURE MONITORING,I.V CANNULA WITHOUT INJECTION VALVE & WINGS-THE I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE,SAFETY I.V CANNULA WITHOUT INJECTION VALVE WITH WINGS-THE SAFETY I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE,SAFETY I.V CANNULA WITH INJECTION VALVE WITH WINGS-THE SAFETY I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE ,EXTENSION TUBE- EXTENSION TUBE TO BE USED WITH ANY OF THE VARIOUS INFUSION OR TRANSFUSION DEVICE IN ORDER TO ALLOW FOR ATTACHMENT WITH ANY SPECIAL OR GENERAL-PURPOSE MEDICAL DEVICE, IN ORDER TO IMPROVE EASE OF USE, BETTER MANEUVERABILITY FOR THE HEALTHCARE PROFESSIONAL. THIS DEVICE IS TO BE USED IN AMBIENT CONDITIONS AND SHOULD BE USED BY A QUALIFIED DOCTOR OR A PARAMEDIC. THE DURATION OF USE OF THIS PRODUCT IS 72 HOURS (SHORT TERM USE PRODUCT). ,I.V CANNULA WITHOUT INJECTION VALVE WITH WINGS-THE I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE ,SAFETY I.V CANNULA WITHOUT INJECTION VALVE & WINGS-THE SAFETY I.V. CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICE ,3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING AN ACCESS PORT FOR ADMINISTRATION OF A SOLUTION, WITHDRAWAL OF FLUID, AND PRESSURE MONITORING

3795	MFG/MD/2021/000135	1.License Holder Name: AMHAR MEDICARE PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use: 3-WAY STOPCOCK WITH/ WITHOUT EXT. LINE(AMHAR)-USED FOR SIMULTANEOUS AND CONTINUOUS INFUSION OF TWO FLUIDS AND CONTROL FLOW DIRECTION.,PRESSURE MONITORING LINE(AMHAR)-A MODIFIED FIBER OPTIC TRANSDUCER-TIPPED CATHETER SYSTEM FOR MEASURING INTRAMUSCULAR PRESSURE DURING EXERCISE WAS DETERMINED. ,IV SET(AMHAR)-THE TRANSFUSION SET ARE USED TO ADMINISTER INTRA VENOUS FLUID AND MEDICINE INTO HUMAN CIRCULATING SYSTEM BY INTRA VENOUS CATHETER OR CANNULAE., BREATHING (VENTILATOR) CIRCUIT(AMHAR)-A BREATHING CIRCUIT IS A MEDICAL DEVICE USED TO DELIVER OXYGEN AND DELIVER INHALATIONAL ANAESTHETIC AGENTS TO A PATIENT. ORIGINALLY DEVELOPED FOR USE IN ANAESTHESIOLOGY, MANY VARIANTS OF BREATHING SYSTEM ARE IN CLINICAL USE. ,YANKAUR SUCTION SET (AMHAR)-YANKAUR SUCTION SET IS SUITABLE FOR CONVENIENT REMOVAL OF SECRETION, BLOOD AND DEBRIS ETC PER OPERATIVELY YANKAUR SUCTION SET PURPOSIVE FOR THE REMOVAL OF BLOOD AND FLUIDS DURING SURGERY. YANAKUR SUCTION SET IS USED AS GENERAL SUCTION PURPOSE. IT HAS A RIGID TRANSPARENT SUCTION HANDLE AVAILABLE WITH BULB/PLAIN OPEN TIP. IT IS OBTAINABLE WITH AND WITHOUT CONTROL VENTS. ,URINE COLLECTING BAG (AMHAR)-THIS DEVICE IS USED IN UROLOGY PROCEDURE FOR THE COLLECTING OF URINE FROM THE PATIENT FOR DIAGNOSTIC AND / OR TREATMENT PURPOSES. URINE COLLECTING BAG IS USED TO COLLECT URINE FROM URETHRA OF THE PATIENT THROUGH CATHETER. ,OXYGEN MASK WITH/WITHOUT NEBULIZATION KIT(AMHAR)-NEBULIZATION KIT IS A PORTABLE MEDICAL DEVICE USED TO DELIVER MEDICATION TO THE RESPIRATORY TRACT AND LUNGS. IT DOES SO IN THE FORM OF MIST. OXYGEN COMPRESSED AIR CREATE AEROSOL DROPLETS FROM THE MEDICATION, AND THE USER THEN INHALES THIS INTO THE LUNGS. OFTEN THIS INVOLVES WEARING A OXYGEN MASK., BLOOD TRANSFUSION SET(AMHAR)-BLOOD COMPONENTS MUST BE FILTERED DURING TRANSFUSION TO REMOVE CLOTS AND SMALL CLUMPS OF PLATELETS AND WHITE BLOOD CELLS THAT FORM DURING COLLECTION AND STORAGE

3796	MFG/MD/2021/000136	1.License Holder Name: MEDITEC DEVICES 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:NASOPHARYNGEAL AIR WAY TUBE(NA)-WHEN A PATIENT BECOMES UNCONSCIOUS, THE MUSCLES IN THE JAW COMMONLY RELAX AND CAN ALLOW THE TONGUE TO SLIDE BACK AND OBSTRUCT THE AIRWAY. THE PURPOSE OF THE FLARED END IS TO PREVENT THE DEVICE FROM BECOMING LOST INSIDE THE PATIENT'S NOSE. A CATHETER IS PASSED THROUGH NASOPHARYNGEAL THE NARES AND ADVANCED TO THE DEPTH OF THE NASOPHARYNX TO REMOVE AIR CHOKE OR OBSTRUCTION. A RESUSCITATOR.

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3797	MFG/MD/2021/000137	1.License Holder Name: BOND+WELL ORTHO PRODUCTS 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:INTRA MEDULLARY NAIL (BOND+WELL)-THE INTRA MEDULLARY NAIL IS INTENDED TO STABILIZE FRACTURES OF THE PROXIMAL AND DISTAL TIBIA AND THE TIBIAL SHAFT; OPEN AND CLOSED TIBIAL SHAFT FRACTURES; CERTAIN PRE- AND POST-ISTHMIC FRACTURES; AND TIBIAL MALUNIONS AND NON-UNIONS. THE TIBIAL NAILS CAN BE OF INTERLOCKING TIBIAL NAIL, CANNULATED TIBIAL NAIL AND DISTAL TIP DISTAL LOCKING TIBIAL NAIL TYPES.INTRA MEDULLARY NAIL RETROGRADE/ANTEGRADE FEMORAL NAIL SYSTEM IS INTENDED TO STABILIZE FRACTURES OF THE DISTAL FEMUR AND THE FEMORAL SHAFT, INCLUDING SUPRACONDYLAR FRACTURES, INCLUDING THOSE WITH INTRA-ARTICULAR EXTENSION; IPSILATERAL HIP/SHAFT FRACTURES; IPSILATERAL FEMUR/TIBIA FRACTURES; FEMORAL FRACTURES IN MULTIPLE TRAUMA PATIENTS; FRACTURES PROXIMAL TO TOTAL KNEE ARTHROPLASTY; FRACTURES DISTAL TO A HIP IMPLANT; FRACTURES IN THE MORBIDLY OBESE; FRACTURES IN OSTEOPOROTIC BONE, IMPENDING PATHOLOGIC FRACTURES; AND MALUNIONS AND NONUNIONS.,BONE PINS & WIRES(BOND+WELL)- KIRSCHNER WIRES ARE USED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION. INTENDED USE OF THESE WIRES IS IN PATELLA, OLECRANON, AND MALLEOLAR & HAND FRACTURES.STEINMAN PIN ARE GENERALLY USED IN TIBIA & FEMUR BONES ALONG WITH STEINMANN PIN HOLDER. CENTRALLY THREADED STEINMAN PIN (DENHAM PIN) INTENDED USES OF DENHAM PINS ARE TO STABILISE FRACTURES OF TIBIA & FEMUR BONES ALONG WITH STEINMANN PIN HOLDER. ,BONE PLATES(BOND+WELL)- BONE PLATES ARE INTENDED FOR FIXATION OF FRACTURES, OSTEOTOMIES, MALUNION, ARTHRODESIS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL. BONE PLATES ARE PROVIDED IN NON-STERILE PACKAGE., BONE PLATES(BOND+WELL)- BONE PLATES ARE INTENDED FOR FIXATION OF FRACTURES, OSTEOTOMIES, MALUNION, ARTHRODESIS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL. BONE PLATES ARE PROVIDED IN NON-STERILE PACKAGE.,SPINAL IMPLANT (BOND+WELL)-ANTERIOR CERVICAL PLATE AND SCREW: THE ANTERIOR CERVICAL PLATE SYSTEM IS INDICATED FOR

	STABILIZATION OF THE CERVICAL SPINE FROM C2 TO C7 EMPLOYING SCREW FIXATION AT THE ANTERIOR FACE OF THE VERTEBRAL BODIES. SPECIFIC CLINICAL INDICATIONS FOR ANTERIOR PLATING INCLUDE: INSTABILITY CAUSED BY TRAUMA; INSTABILITY ASSOCIATED WITH CORRECTION OF CERVICAL LORDOSIS AND KYPHOSIS DEFORMITY; INSTABILITY ASSOCIATED WITH PSEUDOARTHOSIS AS A RESULT OF PREVIOUSLY FAILED CERVICAL SPINE SURGERY;INSTABILITY ASSOCIATED WITH SINGLE OR MULTIPLE LEVEL CORPECTOMY IN ADVANCED DEGENERATIVE DISC DISEASE, SPINAL CANAL STENOSIS AND CERVICAL MYELOPATHY. . FEMORAL STEM WITH HEAD(BOND+WELL)-BIPOLAR HIP REPLACEMENT SYSTEM AND ARE INTENDED FOR USE IN PARTIAL HIP ARTHROPLASTY & ARE INTENDED FOR CEMENTED OR UNCEMENTED USE. PARTIAL HIP ARTHROPLASTY IS RELIABLE AND EFFECTIVE TREATMENT OPTION FOR HIP FRACTURES AND DISEASED FEMORAL HEADS AND/OR NECKS. THE BIPOLAR SHELL ARTICULATES AGAINST THE HOST ACETABULAR ARTICULAR CARTILAGE, PRESERVING ACETABULAR BONE STOCK FOR FUTURE CONSIDERATIONS. MODULAR HIP REPLACEMENT SYSTEM AND ARE INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY & ARE INTENDED FOR CEMENTED AND/OR UNCEMENTED USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS.,BONE PINS & WIRES(BOND+WELL) -KIRSCHNER WIRES ARE USED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION. INTENDED USE OF THESE WIRES IS IN PATELLA, OLECRANON, AND MALLEOLAR & HAND FRACTURES. STEINMAN PIN ARE GENERALLY USED IN TIBIA & FEMUR BONES ALONG WITH STEINMANN PIN HOLDER. CENTRALLY THREADED STEINMAN PIN, BONE PINS & WIRES(BOND+WELL)- KIRSCHNER WIRES ARE USED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION. INTENDED USE OF THESE WIRES IS IN PATELLA, OLECRANON, AND MALLEOLAR & HAND FRACTURES.STEINMAN PIN ARE GENERALLY USED IN TIBIA & FEMUR BONES ALONG WITH STEINMANN PIN HOLDER. CENTRALLY THREADED STEINMAN PIN (DENHAM PIN)INTENDED USES OF DENHAM PINS ARE TO STABILISE FRACTURES OF TIBIA & FEMUR BONES ALONG WITH STEINMANN PIN HOLDER. ,INTRA MEDULLARY NAIL(BOND+WELL)- TIBIAL NAIL SYSTEM IS INTENDED TO STABILIZE FRACTURES OF THE PROXIMAL AND DISTAL TIBIA AND THE TIBIAL SHAFT; OPEN AND CLOSED TIBIAL SHAFT FRACTURES; CERTAIN PRE- AND POST-ISTHMIC FRACTURES; AND TIBIAL MALUNIONS AND NON-UNIONS. THE TIBIAL NAILS CAN BE OF INTERLOCKING TIBIAL NAIL, CANNULATED TIBIAL NAIL AND DISTAL TIP DISTAL LOCKING TIBIAL

	NAIL TYPES. RETROGRADE/ANTEGRADE FEMORAL NAIL SYSTEM IS INTENDED TO STABILIZE FRACTURES OF THE DISTAL FEMUR AND THE FEMORAL SHAFT, INCLUDING SUPRACONDYLAR FRACTURES, INCLUDING THOSE WITH INTRA-ARTICULAR EXTENSION; IPSILATERAL HIP/SHAFT FRACTURES; IPSILATERAL FEMUR/TIBIA FRACTURES; FEMORAL FRACTURES IN MULTIPLE TRAUMA PATIENTS; FRACTURES PROXIMAL TO TOTAL KNEE ARTHROPLASTY; FRACTURES DISTAL TO A HIP IMPLANT; FRACTURES IN THE MORBIDLY OBESE; FRACTURES IN OSTEOPOROTIC BONE, IMPENDING PATHOLOGIC FRACTURES; AND MALUNIONS AND NONUNIONS. , SPINAL IMPLANT (BOND+WELL)-ANTERIOR CERVICAL PLATE AND SCREW: THE ANTERIOR CERVICAL PLATE SYSTEM IS INDICATED FOR STABILIZATION OF THE CERVICAL SPINE FROM C2 TO C7 EMPLOYING SCREW FIXATION AT THE ANTERIOR FACE OF THE VERTEBRAL BODIES. SPECIFIC CLINICAL INDICATIONS FOR ANTERIOR PLATING INCLUDE: INSTABILITY CAUSED BY TRAUMA; INSTABILITY ASSOCIATED WITH CORRECTION OF CERVICAL LORDOSIS AND KYPHOSIS DEFORMITY; INSTABILITY ASSOCIATED WITH PSEUDOARTHOSIS AS A RESULT OF PREVIOUSLY FAILED CERVICAL SPINE SURGERY;INSTABILITY ASSOCIATED WITH SINGLE OR MULTIPLE LEVEL CORPECTOMY IN ADVANCED DEGENERATIVE DISC DISEASE, SPINAL CANAL STENOSIS AND CERVICAL MYELOPATHY MONOAXIAL SCREWS AND HOOKS WITH SPINAL RODS: ,BONE SCREW (BOND+WELL)-BONE SCREWS WHEN USED IN COMBINATION WITH PLATES ARE INTENDED FOR FIXATION OF VARIOUS FRACTURES, OSTEOTOMIES, MALUNIONS, ARTHRODESIS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL.,BONE SCREW(BOND+WELL)-BONE SCREWS WHEN USED IN COMBINATION WITH PLATES ARE INTENDED FOR FIXATION OF VARIOUS FRACTURES, OSTEOTOMIES, MALUNIONS, ARTHRODESIS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL., BONE PLATES(BOND+WELL)-BONE PLATES ARE INTENDED FOR FIXATION OF FRACTURES, OSTEOTOMIES, MALUNION, ARTHRODESIS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL., INTRA MEDULLARY NAIL(BOND+WELL)- TIBIAL NAIL SYSTEM IS

	INTENDED TO STABILIZE FRACTURES OF THE PROXIMAL AND DISTAL TIBIA AND THE TIBIAL SHAFT; OPEN AND CLOSED TIBIAL SHAFT FRACTURES; CERTAIN PRE- AND POST-ISTHMIC FRACTURES; AND TIBIAL MALUNIONS AND NON-UNIONS. THE TIBIAL NAILS CAN BE OF INTERLOCKING TIBIAL NAIL, CANNULATED TIBIAL NAIL AND DISTAL TIP DISTAL LOCKING TIBIAL NAIL TYPES. RETROGRADE/ANTEGRADE FEMORAL NAIL SYSTEM IS INTENDED TO STABILIZE FRACTURES OF THE DISTAL FEMUR AND THE FEMORAL SHAFT, INCLUDING SUPRACONDYLAR FRACTURES, INCLUDING THOSE WITH INTRA-ARTICULAR EXTENSION; IPSILATERAL HIP/SHAFT FRACTURES; IPSILATERAL FEMUR/TIBIA FRACTURES; FEMORAL FRACTURES IN MULTIPLE TRAUMA PATIENTS; FRACTURES PROXIMAL TO TOTAL KNEE ARTHROPLASTY; FRACTURES DISTAL TO A HIP IMPLANT; FRACTURES IN THE MORBIDLY OBESE; FRACTURES IN OSTEOPOROTIC BONE, IMPENDING PATHOLOGIC FRACTURES; AND MALUNIONS AND NONUNIONS. ,FEMORAL STEM WITH HEAD (BOND+WELL)- BIPOLAR HIP REPLACEMENT SYSTEM AND ARE INTENDED FOR USE IN PARTIAL HIP ARTHROPLASTY & ARE INTENDED FOR CEMENTED OR UNCEMENTED USE. PARTIAL HIP ARTHROPLASTY IS RELIABLE AND EFFECTIVE TREATMENT OPTION FOR HIP FRACTURES AND DISEASED FEMORAL HEADS AND/OR NECKS. THE BIPOLAR SHELL ARTICULATES AGAINST THE HOST ACETABULAR ARTICULAR CARTILAGE, PRESERVING ACETABULAR BONE STOCK FOR FUTURE CONSIDERATIONS. MODULAR HIP REPLACEMENT SYSTEM AND ARE INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY & ARE INTENDED FOR CEMENTED AND/OR UNCEMENTED USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS.,BONE SCREW(BOND+WELL)-BONE SCREWS WHEN USED IN COMBINATION WITH PLATES ARE INTENDED FOR FIXATION OF VARIOUS FRACTURES, OSTEOTOMIES, MALUNIONS, ARTHRODESIS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL.,FEMORAL STEM WITH HEAD(BOND+WELL)-BIPOLAR HIP REPLACEMENT SYSTEM AND ARE INTENDED FOR USE IN PARTIAL HIP ARTHROPLASTY & ARE INTENDED FOR CEMENTED OR UNCEMENTED USE. PARTIAL HIP ARTHROPLASTY IS RELIABLE AND EFFECTIVE TREATMENT OPTION FOR HIP FRACTURES AND DISEASED FEMORAL HEADS AND/OR NECKS. THE BIPOLAR SHELL ARTICULATES AGAINST THE HOST ACETABULAR ARTICULAR CARTILAGE, PRESERVING

		ACETABULAR BONE STOCK FOR FUTURE CONSIDERATIONS. MODULAR HIP REPLACEMENT SYSTEM AND ARE INTENDED FOR USE IN TOTAL HIP ARTHROPLASTY & ARE INTENDED FOR CEMENTED AND/OR UNCEMENTED USE. TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE INCREASED PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT ARTICULATION IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT SOUND BONE TO SEAT AND SUPPORT THE COMPONENTS.,SPINAL IMPLANT (BOND+WELL)-ANTERIOR CERVICAL PLATE AND SCREW: THE ANTERIOR CERVICAL PLATE SYSTEM IS INDICATED FOR STABILIZATION OF THE CERVICAL SPINE FROM C2 TO C7 EMPLOYING SCREW FIXATION AT THE ANTERIOR FACE OF THE VERTEBRAL BODIES. SPECIFIC CLINICAL INDICATIONS FOR ANTERIOR PLATING INCLUDE: INSTABILITY CAUSED BY TRAUMA; INSTABILITY ASSOCIATED WITH CORRECTION OF CERVICAL LORDOSIS AND KYPHOSIS DEFORMITY; INSTABILITY ASSOCIATED WITH PSEUDOARTHOSIS AS A RESULT OF PREVIOUSLY FAILED CERVICAL SPINE SURGERY;INSTABILITY ASSOCIATED WITH SINGLE OR MULTIPLE LEVEL CORPECTOMY IN ADVANCED DEGENERATIVE DISC DISEASE, SPINAL CANAL STENOSIS AND CERVICAL MYELOPATHY.
3798	MFG/MD/2021/000138	1.License Holder Name: DALVI & SONS 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:BONE SCREWS(DALVI)-ARE USED IN DISTAL RADIOUS/ULNA FRACTURES,BONE NAILS & WIRES(DALVI)-FRACTURED, FUSION OF JOINT OR TISSUE FIXATION OR ANCHORAGE. WRIST FIXATION. BONE REDUCTION USED FOR THE INTERNAL FIXATION OF FRACTURES OF LONG BONES,BONE PLATES (DALVI)-BONE PLATE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURE ,FUSION OF JOINTS OR TISSUE USED IN RADIUS AND ULNA BONES WHICH FIXED BY 3.5MM CORTICAL SCREW.,HEML-ENDOPROSTHESIS(DALVI)-ENDO PROTHESIS REPLACEMENT SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURE ,FUSION OF HIP JOINTS AND REPLACEMENT OF THEN.

3799	MFG/MD/2021/000139	1.License Holder Name: POLY MEDICURE LIMITED, A-26, BAIS GODAM, INDUSTRIAL ESTATE, JAIPUR 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:INFUSION SETS (BURETTE TYPE) IS 12655-4/ISO 8536-4&5(MDEVICES BURETTE SET INLINE, MDEVICES BURETTE SET, MDEVICES BURETTE SET (MICRO DROP), MINIFLOWN MEASURED VOLUME SET WITH MICRO FILTER& FLOATING VALVE, INJEX EQUIPO INJEX DE INFUSAO GRAVITATIONAL PARA SILUCAO PARENTERAL, EXEVOL BURETTE SET MEASURED FLUID ADMINISTRATION SET, SENSIMEDICAL BURETA EQUIPO DE VOLUMENES MEDIDOS (BURETTE SET 100 ML), SENSIMEDICAL BURETA EQUIPO DE VOLUMENES MEDIDOS (BURETTE SET 150 ML), MEDECO BURETTE SET, MICRODRIP PRECISION SOLUTION ADMINISTRATION SET, SEBIS EQUIPO DE INFUSION TIPO BURETA CON MICRO GOTERO, CEGA EQUIPO DE INFUSION MICROGOTEO CON BURETA DE,)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,NELATON CATHETER (CATHETER NELATON, SEBIS CATETER NELATON, NELATON CATHETER "ANGEL CARE")-A LONG, SMALL GAUGE CATHETER DESIGNED OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,SUCTION CATHETER (ISO 8836)(SEBIS CATETER DE SUCCION CON CONTROL, SUCTION TUBE, TRO-SUCOCATH (SUCTION CATHETER), TRO-SUCOCATH PLUS (SUCTION CATHETER WITH FINGER TIP CONTROL), TRO-SUCOCATH TC PLUS (SUCTION CATHETER WITH THUMB CONTROL), TRO-ASPICAT -A (SUCTION CATHETER), TRO-ASPICAT -C (SUCTION CATHETER WITH THUMB CONTROL), TRO-ASPICAT -B (SUCTION CATHETER WITH THUMB CONTROL), SEBIS CATETER DE SUCCION CATHETERS, CATETER DE SUCCION CON CONTROL DE SUCCION, SUCTION CATHETER "ANGEL CARE")-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,TUR SET (FIONIAVET UTERUS FLUSHING TUBE, UTERUS FLUSHING TUBE)-INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS.,UMBILICAL CATHETER(UMBILICAL ARTERY CATHETER, CATETER UMBILICAL EM PVC POLYMED, CATETER UMBILICAL EM POLIURETANO POLYMED, SEBIS CATETER UMBILICAL, UMBILICAL CATHETER)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING AND INTRAVASCULAR ACCESS FOR FLUIDS AND

	MEDICATIONS.,NASAL OXYGEN CANNULA/CATHETER-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP., STOMACH TUBE(STOMACH PROBE "ANGEL CARE", STOMACH TUBE)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID.,CLOSED WOUND DRAINAGE SET-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS., GUEDEL AIRWAYS-IT IS MEDICAL DEVICE INSERTED THROUGH THE NOSE OR MOUTH AND USED OCCASIONALLY IN THE MANAGEMENT OF UPPER GASTROINTESTINAL HEMORRHAGE DUE TO OESOPHAGEAL VARIES ,NEBULIZER MASK -NEBULIZER MASK IS USED FOR THE DEEP MEDICATION INTO THE LUNGS WHEN PATIENT IS SUFFERING FROM ASTHMA OR OTHER LUNGS RELATED PROBLEMS. NEBULIZER MASK IS A DRUG DELIVERY DEVICE USED TO ADMINISTER MEDICATION IN THE FORM OF A MIST INHALED INTO THE LUNGS. , FOLEY BALLOON CATHETERS(FOLEY CATHETER "ANGEL CARE", FOLEY BALLOON CATHETERS)-A LONG, SMALL GAUGE CATHETER DESIGNED OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,UMBILICAL CORD CLAMP (EUROMIX CLAMP UMBILICAL, POLYCLAMP, VASO CLAMP(UMBILICAL CORD CLAMP), ALEXPHARM UMBILICAL CORD CLAMP, VASO CLAMP (CLAMP CORDON UMBILICAL), UMBILICAL CORD CLAMP"ANGEL CARE")-THESE DEVICES MAY BE A CLIP, TIE, TAPE,OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT. ,IV FLOW REGULATOR(POLYFLOW IV FLOW REGULATOR, "NEOFLOW (REGULATEUR DE DEBIT POUR SOLUTIONS PARENTERALES), , IV FLOW REGULATOR, FLOW REGULATOR, POLYFLO IV FLOW REGULATOR EXTENSION SET, POLYFLO NOVO IV FLOW REGULATOR EXTENSION SET)-AN IV SYSTEM AND ADMINISTRATION DEVICE OFFERING PRECISION CARE AND CONSISTENT DELIVERY.,THREE WAY STOP COCK -IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,SCALP VEIN SET(BUTTERFLY WINGED INFUSION SET)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD ,THORACIC DRAINAGE CATHETER WITH & WITHOUT TROCAR (STRAIGHT / CURVED))-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY

	ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS,UTERUS FLUSHING TUBE (TUR / IRRIGATION SET)) (EQUINE UTERUS FLUSHING TUBE)-USED FOR INSTILLING FLUIDS INTO WITHDRAWING FLUIDS FROM, SPLINTING BLEEDING OF THE ALIMENTARY TRACT.,OXYGEN CATHETER(OXYGEN TUBE)-DIRECT ADMINISTRATION OF OXYGEN THROUGH THE NASO-PHARYNX., NELATON CATHETER-A LONG, SMALL GAUGE CATHETER DESIGNED OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POST ERIORLY VIA THE KIDNEY., IRRIGATION SET-USED FOR INSTILLING FLUIDS INTO, WITHDRAWING FLUIDS FROM, SPLINTING BLEEDING OF THE ALIMENTARY TRACT. . INFUSION SETS (BURETTE TYPE) IS 12655-4/ISO 8536-4&5(TRO-MICROSET PLUS (MEASURED VOLUME ADMINISTRATION SET), IV MICRO PEDIATRIC DRIP SET, METRISET FOR INFUSION , TRO-SOLUTE PLUS (IV INFUSION SET WITH AIRVENT SPIKE, TRO-MICROSET (MEASURED VOLUME FLUID ADMINISTRATION SET), POLYVOL BURETTE SET , POLYPEDIA MEASURED VOLUME FLUID ADMINISTRATION SET, POLYVOL PRO , BURETTE SET, BURETTE SET IN-LINE, BURETTE SET IN-LINE PORT, BURETTE INFUSION SET, MEASURED VOLUME SET WITH MICRO FILTER & FLOATING VALVE)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,INFUSION SET (IS 12655/ISO 8536-4) (ORMED MICRODRIP IV INFUSION SET WITH AIRVENT WITH LUER LOCK (IV INFUSION SET WITH AIR -VENT SPIKE), CEGA EQUIPO DE INFUSION MICROGOTERO CON BURETA DE, NEOFUSION SET IV INFUSION SET WITH PVC FREE CHAMBER (IV INFUSION SET WITH AIRVENT SPIKE), MICROFUSION IV SET WITHOUT AIR VENT (IV INFUSION SET WITHOUT AIR -VENT SPIKE), MICROFUSION SET WITH AIRVENT FLOW REGULATOR (IV INFUSION SET WITH AIR VENT SPIKE), ONCOFUSION SET (IV INFUSION SET WITH AIR VENT SPIKE), POLYFUSION SET WITH THREE WAY STOP COCK (IV INFUSION SET WITH AIR VENT SPIKE) , BLOOD TAKING SET (IV INFUSION SET WITH AIR VENT SPIKE) , POLYTROL SET(IV INFUSION SET WITH AIR VENT SPIKE), ULTRAFUSION SET I.V.SET WITH AIRVENT & PRIMING FILTER, INFUSION SET , POLYMED SET DE ADMINISTRACION IV MACROGOTERO, POLYMED SET DE ADMINISTRACION IV MICROGOTERO, VENTED I V INFUSION SET, KRUUSE SAFE VET INFUSION SET,)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INFUSION SET (INTRAVENOUS ADMINISTRATION SET WITH & WITHOUT AIRVENT) [IS 12655 -4 & ISO 8536-4] -INFUSION SET IS USED ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED

	INTO A VEIN.,PERITONEAL DIALYSIS SET-THAT ALLOWS DIALYSIS FLUID TO ENTER THE ABDOMINAL CAVITY, DWELL INSIDE FOR A WHILE, AND THEN DRAIN BACK OUT AGAIN.,CVP MANOMETER-IT IS FOR MONITORING CENTRAL VENOUS PRESSURE (CVP),SAMPLING BLOOD AND SIMULTANEOUS ADMINISTRATION OF MULTIPLE IV SOLUTIONS OR DRUGS.,YANKAUR SUCTION SET(POLYSUCTION SET (YANKAUR SUCTION SET), YANKAUR HANDLE, TRO-ASPISET YANKAUER, TRO-ASPISET YANKAUER, POLYSUCTION SET (SET SUCCION YANKAUER CON TUBO Y MANGO, SUCTION TUBE (FOR WASTE FLUID) YANKAUR SUCTION SET, " NEOVALVE (SUCTION CONTROL VALVE), " NEOTUBE (YANKAUR SUCTION TUBE), POLYSUCTION SET (YANKAUR SUCTION SET WITH TUBE & HANDLE))-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,CLOSED WOUND DRAINAGE SET(SEBIVAC UNIDAD CERRADA DE SUCCION DE HERIDAS, SERIVAC CON AGUJA, SERODRAIN, NOVO VAC SET, POLYVAC SET, NEOVAC SET)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND.THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS,RECTAL CATHETER(RECTAL CATHETER, RECTAL CATHETER "ANGEL CARE", CATERER RECTAL)-COLON TUBES ALSO CALLED "TIPS" OR EVEN CATHETERS ARE INSERTED FROM THE RECTAL, THROUGH THE RECTUM TO DELIVER YOUR ENEMA SOLUTION INTO THE COLON (LARGE INTESTINE).,INFUSION SET (IS 12655/ISO 8536-4)(SERIS INFUSION SET WITH AIRVENT, IDA INFUSION SETS, IV ADMINISTRATION SET WITH AIR VENTED 20 DPM, PERFUSION SET, POLYFUSION IV SET WITH AIR VENT (IV INFUSION SET WITH AIR -VENT SPIKE), NOVOFUSION IV SET WITHOUT AIR VENT (IV INFUSION SET WITH AIR VENT SPIKE), POLYFUSION IV SET WITH AIR VENT (IV INFUSION SET WITH AIR -VENT SPIKE), POLYFUSION IV SET WITHOUT AIR VENT (IV INFUSION SET WITHOUT AIR- VENT SPIKE), MICROFUSION IV SET WITH AIR VENT (IV INFUSION SET WITH AIR -VENT SPIKE), ORMED IV INFUSION SET WITH AIRVENT WITH LUER LOCK (IV INFUSION SET WITH AIR -VENT SPIKE), POLYFUSION SET (NON VENTED I.V. INFUSION SET), POLYFUSION VENTED SET(VENTED I.V. INFUSION SET), POLYFUSION SET (VENTED I.V. INFUSION SET), POLYFUSION VENTED SET, MICRO INFUSION SET, IV INFUSION SET WITH AIRVENT & WITHOUT AIRVENT, POLYTROL SET (I.V. INFUION SET WITH FLOW REGULATOR), MICROFUSION SET (MICRO INFUSION SET WITHOUT AIRVENT), MICROFUSION SET (MICRO INFUSION SET WITH AIRVENT), NOVOFUSION SET (I.V. INFUSION SET WITH AIRVENT),)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED

	INTO A VEIN,INFUSION SET (BURETTE TYPE) [IS 12655-4 & ISO 8536-5]-INFUSION SET IS USED ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,FEEDING BAG -THE FEEDING BAG IS USED FOR CONVIENT FEEDING OF NUTRITION THROUGH NASOGASTRIC TUBE TO THE PATIENT (*THROUGH INFANT FEEDING TUBE) ,STOMACH TUBE (KRUUSE STOMACH TUBE)-PASSAGE OF A TUBE VIA THE MOUTH OR NOSE DOWN INTO THE STOMACH FOLLOWED BY SEQUENTIAL ADMINISTRATION AND REMOVAL OF SMALL VOLUMES OF LIQUID.,REDON DRAINAGE TUBE(TRO-DRAINCATH, KD-DRAIN (REDON DRAIN), REDON DRAINAGE TUBE, POLYMED REDON DRAINAGE TUBE, DRENAGGIO TIPO REDON, REDON DRAINAGE TUBE WITH TROCAR)-USED TO PROVIDE CONNECTION TO A DRAINAGE BAG.,INFUSION SET (IS 12655/ISO 8536-4)(SEBIS EQUIPO DE INFUSION MACRO GOTERO (CON TAPA DE VENTILACION Y CONECTOR “Y”), SEBIS EQUIPO DE INFUSION MACRO GOTERO (CON TAPA DE VENTILACION Y BULBO DE LATEX), SEBIS EQUIPO DE INFUSION MICRO GOTERO (CON TAPA DE VENTILACION Y CONECTOR “Y”), SEBIS EQUIPO DE INFUSION QUIRURGICO (CON TAPA DE VENTILACION Y 2 CONECTORES “Y”), SEBIS EQUIPO DE INFUSION MACRO PLUS (CON TAPA DE VENTILACION Y CONECTORE “Y” SIN AGUJA), SEBIS EQUIPO DE INFUSION QUIRURGICO PLUS (CON TAPA DE VENTILACION Y DOBLE SISTEMA “Y” SIN AGUJA), MDEVICES I.V. SET ADOPTER, MDEVICES INFUSION SET, MINIFLOWN INFUSION SET (MICRO INFUSION SET), MINIFLOWN INFUSION SET(MACRO INFUSION SET), REMEDI MICRODRIP SET WITHOUT AIRVENT, REMEDI MICRODRIP SET WITH AIRVENT, REMEDI INFUSION SET WITHOUT AIRVENT , REMEDI INFUSION SET WITH AIRVENT)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,OXYGEN CATHETER-DIRECT ADMINISTRATION OF OXYGEN THROUGH THE NASO-PHARYNX.,ABDOMINAL DRAINAGE SET -A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,FEMALE CATHETER-A LONG, SMALL GAUGE CATHETER DESIGNED OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,SUCTION CATHETER (ISO 8836)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING., TRANSFUSION SET (IS 9824-3/ ISO 1135-4)(MDEVICES TRANSFUSION PUMP SET (BLOOD /SOLUTION ADMINISTRATION), MDEVICES TRANSFER SET, MDEVICES TRANSFUSION SET, MINIFLOWN BLOOD ADMINISTRATION SET WITH AIRVENT, MINIFLOWN BLOOD

	ADMINISTRATION SET WITHOUT AIRVENT, DISPOSABLE PERFUSION SETS , TRANSFUSION PUMP SET, POLYMED TRANSVOL SET (BLOOD TRANSFUSION SET WITHOUT AIRVENT , HAEMOFUSOR SET (BLOOD TRANSFUSION SET), TRANSVOL SET (BLOOD ADMINISTRATION SET WITH & WITHOUT AIRVENT), HAEMOFUSOR SET (BLOOD ADMINISTRATION SET WITH & WITHOUT AIRVENT), KRUUSE BLOOD TRANSFUSION SET, POLYMED TRANSFUSION SET (BLOOD TRANSFUSION SET WITHOUT AIRVENT))-TRANSFUSION SET IS USED ADMINISTER BLOOD TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INFANT FEEDING TUBE -A FEEDING TUBE IS DEVICES THAT'S INSERTED INTO YOUR STOMACH THROUGH ABDOMINAL . IT IS USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING,LEVIN'S TUBE(SEBIS CATETER LEVIN)-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,RYLE'S TUBE(TRO-NUTRICATH)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,BLOOD LINE SET(HAEM-O-LINE)-THE SINGLE-NEEDLE DIALYSIS, IN WHICH CASE ONLY ONE CANNULA OR A SINGLE-LUMEN CATHETER IS USED TO ACCESS THE BLOOD, TRACHEOSTOMY TUBE WITH & WITHOUT CUFFED-A BREATHING TUBE INSERTED INTO A TRACHEOTOMY USED TO OBTAIN A CLOSED CIRCUIT FOR VENTILATION,URETHRAL CATHETER(POLYMED URETHRAL CATHETER)-A LONG, SMALL GAUGE CATHETER DESIGNED OR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,RYLE'S TUBE-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,HIGH PRESSURE VACUUM DRAINAGE BOTTLE WITH EXTENSION TUBE (ULTRAVAK SET)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,ENDOTRACHEAL TUBES (CUFFED & PLAIN) (IS 12504-1/ISO 5361)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,MUCUS EXTRACTOR-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,NASAL OXYGEN CANNULA/CATHETER(NASOCATH, OXYGEN TUBE-NASAL)-IT IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP.,EXTENSION LINE (ISO

	8536-9)(MDEVICES MINIMUM VOLUME EXTENSION SET, MDEVICES MRI MINIMUM VOLUME EXTENSION SET, MDEVICES MICROBORE EXTENSION SET, MDEVICES THREE WAY STOP COCK WITH EXTENSION SET, PVC FREE HIGH PRESSURE EXTENSION LINE (STRAIGHT & COILED), UNI LINE, TRO EXTENSOR (STERILE EXTENSION LINE), KRUUSE T- CONNECTOR ,15 CM MICRO-BORE TUBING, IV EXTENSION SET WITH FLOW REGULATOR, LIGHT SENSITIVE IV EXTENSION SET, BIFUSE EXTENSION SET, IV EXTENSION SET, T CONNECTOR, LINEA DE EXTENSION (MINI VOLUMEN CON CONECTOR T), ALARGADOR ALTA PRESION (800 PSI) LIBRE DE PVC M/H, "ALARGADOR ALTA PRESION EN ESPIRAL(800 PSI) LIBRE PVC", ALARGADOR ALTA PRESION (800 PSI) LIBRE DE PVC M/H, EXTENSION SET (MINI VOLUME WITH T CONNECTOR), EXTENSION SET (MINI VOLUME WITH T-CONNCTOR) (EXTENSION LINE), KRUUSE EXTENSION LINE, EQUIPO DE INFUSION I. V. (CON DOS FILTORS), EXTENSION LINE AS AN ACCESSORY OF INFUSION SET, KRUUSE SAFE VET T-CONNECTOR, HEIDELBERG EXTENSION LINE, TRO EXTENSOR, UNI LINE, THREE WAY EXTENSION LINE, NEOLINE (PROLONGATEUR PE/PE EXTENSION LINE), INFUSION EXTENSION LINE, HEIDEBERG EXTENSION LINE, KRUUSE SAFE VET T-CONNECTOR LIGHT SENSITTIVE IV EXTENSION SET, EXTENSION TUBE OF HIGH PRESSURE "ANGEL CARE", EXTENSION TUBE OF LOW PRESSURE (ANGEL CARE), LINEA DE EXTENSION M/H, LLAVE DE PASO DE TRES VIAS)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION O FLUIDS/MEDICATIONS IN MEDICAL APPLICATION.,UNDER WATER SEAL DRAINAGE BAG/ BOTTLE (POLYDRAIN SET, POLYSEAL KID, POLYSEAL MIDI, POLYSEAL ADULT,)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,INFANT FEEDING TUBE(ALEXPHARM FEEDING CATHETER, FEEDING TUBE, SEBIS CATETER DE ALIMENTACION PEDIATRICO, TRO-NUTRICATH PAED FEEDING TUBE, KRUUSE FEEDING TUBE, POLYFEED TUBE, TRO-NUTRICATH PAED INFANT FEEDING TUBE, NOVOFEED TUBE, FEEDING CATHETER "ANGEL CARE", NOVOFEED, POLYFEED)-A FEEDING TUBE IS DEVICES THAT'S INSERTED INTO YOUR STOMACH THROUGH ABDOMINAL . IT IS USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING,INFUSION SET (WITH AUTO-SHUT VALVE) (IS 12655-4 & ISO 8536-4)(SMART SET UF (SMART SET SYSTEM FOR INTRAVENOUS INFUSION))-INFUSION SET IS USED TO ADMINISTER FLUIDS/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,THORACIC DRAINAGE CATHETER WITH & WITHOUT TROCAR(CATETER DE DRENAJE TORACICO CON TROCAR)-THORACIC DRAINAGE CATHETER IS A

	SURGICAL DRAIN USED FOR POST OPERATIVE DRAINAGE AFTER CARDIO-THORACIC AND THORACIC SURGERY IN ORDER TO REMOVE BLOOD, SECRETIONS AND AIR WHICH ACCUMULATE IN THE THORAX GENERATING ACUTE CARDIO RESPIRATORY INSUFFICIENCY AND SOMETIMES EVEN DEATH.,EXTENSION LINE AS AN ACCESSORY OF INFUSION SET (EXTENSION TUBE) [ISO 8536-9]-TO BE USE AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS IN MEDICAL APPLICATION .CAN BE USED TO CONNECT A PERFUSION SET OR CATHETER FOR INFUSION. ,INFUSION SET (INTRAVENOUS FLUID INFUSION SET WITHOUT AIRVENT) (IS 12655,ISO 8536-4)-INFUSION SET IS USED ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,LEVIN'S TUBE-USED FOR THE ASPIRATION OF GASTRIC AND INTESTINAL CONTENTS AND ADMINISTRATION OF TUBE FEEDINGS OR MEDICATIONS.,INFUSION SET (IS 12655/ISO 8536-4) (BOVIVET INFUSION SET WITH AIRVENT SPIKE FOR BOVINE, SENSIMEDICAL EQUIPO PARA VENOCLISIS NORMOGOTERO (IV SET MACRO WITH AIR VENT ,20DROP) , SENSIMEDICAL EQUIPO PARA VENOCLISIS MICROGOTERO (IV SET MICRO WITH AIR VENT ,60DROP) , NOVOFUSION INFUSION SET (IV INFUSION SET WITH AIR VENT SPIKE), PERFULEX- AIR G (IV INFUSION SET WITH AIR VENT SPIKE), ASEPTA I.V INFUSION SET (IV INFUSION SET WITH AIR VENT SPIKE), MEDECO INFUSION SET(IV INFUSION SET WITH AIR VENT SPIKE), MSM INFUSION SET (IV INFUSION SET WITH AIR VENT SPIKE), UNIPERF PERFUSEUR AVEC SITE D' INJECTION, UNIPERF PERFUSEUR AVEC LUER MOBILE, PHOTOFUSION SET (SET PHOTOFUSION CON VENTILACION PROTEGE CONTRA LA FOTOLISIS), PRIMARY IV SET , EQUIPO DE INFUSION I V (CON DOS FILTROS),PERITONEAL DIALYSIS ADMINISTRATION SET)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,EXTENSION LINE (ISO 8536-9)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR THE INFUSION O FLUIDS/MEDICATIONS IN MEDICAL APPLICATION,INFUSION SET (IS 12655/ISO 8536-4)(PHOTOFUSION SET WITH AIRVENT I.V.INFUSION SET, AUTOFUSION SET, KS (MICROFUSION IV SET WITH AIRVENT), ONCOFUSION SET (AIR-VENT I.V. INFUSION SET), NOVOFUSION SET (AIR-VENT I.V. INFUSION SET), FIONIAVET I V SET ,20DROP/ML, FIONIAVET I V SET ,60DROP/ML, SPIRAL INFUSION SET, MICROTECH IV SET WITH AIRVENT , PHOTOFUSION SET, INTRAVINOUS FLUID INFUSION SET WITH AIRVENT)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,INFUSION SET (I.V. ADMINISTRATION SET WITH & WITHOUT AIRVENT) (IS 12655,ISO

	8536-4)-INFUSION SET IS USED ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,THORACIC DRAINAGE CATHETER WITH & WITHOUT TROCAR(THORAX DRAIN WITH TROCAR, SEBIS CATETER TORACICO SIN TROCAR, SEBIS CATETER TORACICO CON TROCAR, ACTI-FINE THORAX DRAIN TROCAR, FREE LIFE (THORAX DRAINAGE GEBOGEN), FREE LIFE (THORAX DRAINAGE GRADE), CURVED THORACIC DRAINAGE CATHETER WITH & WITHOUT TROCAR, ULTRACATH NOVO-STRAIGHT, SENSI MEDICAL CATHETER PARA DRAINAJE TORACICO CON INDUCTOR, POLYMED CATHETER DRENAJE TRORECICO CON TROCAR UN SOLO USO, SENSIMEDICAL CATETER PARA DRENAJE RECTO , ACTI-FINE THORACIC DRAINAGE CATHETER WITH TROCAR, SEBIS CATHETER TORACICO CON TROCAR, SEBIS CATHETER TORACICO SIN TROCAR, THORAX DRAIN WITH TROCAR, ULTRCATH NOVO-TROCAR, ULTRCATH NOVO-ANGLED, THORACIC CATHETER - STRAIGHT, TROCAR CATHETER, THORACIC CATHETER RIGHT ANGLED)-A SURGICAL DRAIN IS A TUBE USED TO REMOVE PUS, BLOOD OR OTHER FLUIDS FROM A WOUND. THEY ARE COMMONLY PLACED BY SURGEONS OR INTERVENTIONAL RADIOLOGISTS.,MUCUS EXTRACTOR(EUROMIX EXTRACTOR DE MUCUS, NOVASPI ASPIRATEUR DE MUCOSITES 40ML SANS SONDE, NOVASPI ASPIRATEUR DE MUCOSITES 40ML POUR FIBROSCOPE, "NOVASPI ASPIRATEUR DE MUCOSITES PEDIATRIQUE 25ML AVEC SONDES , NOVASPI ASPIRATEUR DE MUCOSITES 40ML AVEC SONDES, NOVASPI ASPIRATEUR DE MUCOSITE 100ML POUR FIBROSCOPE, NOVASPI FLACON 175ML POUR LAVAGE ALVEOLAIRE, NOVASPI ASPIRATEUR DE MUCOSITES PEDIATRIQUE 25ML AVEC SONDES SANS OEIL LATERAL, NOVASPI ASPIRATEUR DE MUCOSITES 25ML SANS SONDE, "NEOASPI ASPIRATEUR DE MUCOSITES 40ML SANS SONDE", " NEOASPI ASPIRATEUR DE MUCOSITES 40ML POUR FIBROSCOPE", " NEOASPI ASPIRATEUR DE MUCOSITES PEDIATRIQUE 25ML AVEC SONDES CH06 & CH10", " NEOASPI ASPIRATEUR DE MUCOSITES 40ML AVEC SONDE CH08 &CH16", " NEOASPI ASPIRATEUR DE MUCOSITE 100ML POUR FIBROSCOPE", " NEOASPI FLACON 175ML POUR LAVAGE ALVEOLAIRE", " NEOASPI ASPIRATEUR DE MUCOSITES PEDIATRIQUE 25ML AVEC SONDES SANS OEIL LATERAL CH06&CH10", " NEOASPI ASPIRATEUR DE MUCOSITES 25ML SANS SONDE ")-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,TUR SET-INTENDED TO BE USED TO INTRODUCE FLUIDS INTO BODY CAVITIES OTHER THAN BLOOD VESSELS, DRAIN FLUIDS FROM BODY CAVITIES, OR EVALUATE CERTAIN PHYSIOLOGIC CONDITIONS.

3800	MFG/MD/2021/000140	1.License Holder Name: NIHAL HEALTHCARE 2.Approving Authority: SOLAN(BBN) 3.Device Name(Brand Name)-Intended Use:STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITHOUT NEEDLE(NIHAL)-DEVICE IS TO BE TO BE USED FOR ACCURATELY INJECTING A PREDETERMINED AMOUNT OF MEDICATIONS OR OTHER LIQUIDS INTO BODY TISSUES OR OTHER MEDIA.,STERILE HYPODERMIC NEEDLES FOR SINGLE USE (NIHAL)-STERILE HYPODERMIC NEEDLES FOR SINGLE USE IS A SLENDER HOLLOW INSTRUMENT INTENDED FOR THE USE IN ASPIRATION AND INJECTION OF FLUIDS FOR MEDICAL PURPOSE., STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITH NEEDLE (NIHAL)-DEVICE IS TO BE TO BE USED FOR ACCURATELY INJECTING A PREDETERMINED AMOUNT OF MEDICATIONS OR OTHER LIQUIDS INTO BODY TISSUES OR OTHER MEDIA.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3801	MFG/MD/2021/000141	1.License Holder Name: ACHIEVER HEALTH CARE PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:CHLORHEXIDINE GUAZE DRESSING-USED AS A PRIMARY WOUND TREATMENT FOR BURNS, SKIN GRAFTS, ULCERS & OTHER INJURIES,ADHESIVE TAPE-ADHESIVE TAPE USED IN MEDICINE AND FIRST AID TO HOLD A BANDAGE OR OTHER DRESSING ONTO A WOUND ,CANNULA FIXATOR-APPLY WITH STRETCH IN THE REGION OF I. V. CANNULA INSERTION,EYE PAD-EYE PAD TO BE STERILE/NON STERILE SINCE IT WILL BE USED FOR DRESSING THAT CAN BE APPLIED OVER AN EYE TO PROTECT IT, COTTON CREPE BANDAGE-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES.,GAUZE RIBBON-APPROPRIATE USE OF GAUZE GAUZE CAN BE USED FOR CLEANSING, PACKING, SCRUBBING, COVERING, AND SECURING IN A VARIETY OF WOUNDS. CLOSELY WOVEN GAUZE IS BEST FOR EXTRA STRENGTH OR GREATER PROTECTION, WHILE OPEN OR LOOSE WEAVE IS BETTER FOR ABSORBENCY OR DRAINAGE,ELASTIC ADHESIVE BANDAGE-ADHESIVE BANDAGES, GAUGE BANDAGES, PRESSURE BANDAGES, TRACTION BANDAGES, MEDICAL ABSORBENT (FIBER) BANDAGES, POVIDONE IODINE NON ADHERENT WOUND DRESSING-USED AS A PRIMARY WOUND TREATMENT FOR BURNS, SKIN GRAFTS, ULCERS & OTHER INJURIES,ABSORBENT GAUZE SWAB WITH X-RAY DETECTABLE THREAD-APPLY WITH STRETCH IN THE REGION OF I. V. CANNULA INSERTION,CHLORHEXIDINE & SILVER SULPHADIZINE TULLE DRESSINGS-IT IS USED TO QUICKLY HEAL FROM BURNS, SCALDS, ABRASIONS, LACERATIONS, DIABETIC ULCERS, PRESSURE SORES, COLOSTOMIES, SURGICAL WOUNDS ETC,PAPER TAPE-PAPER TAPE IS FOR SECURING SMALL TO MEDIUM DRESSINGS,SODIUM FUSIDATE GAUZE DRESSING-SODIUM FUSIDATE GAUZE DRESSING IS INDICATED FOR THE TREATMENT OF SKIN INFECTIONS CAUSED BY STAPHYLOCOCCI, STREPTOCOCCI OR OTHER SENSITIVE ORGANISMS; THE MOST IMPORTANT INDICATIONS BEING: IMPETIGO, SYCOSIS BARBAE, PARONYCHIA, FOLLICULITIS, CARBUNCLES, INFECTED WOUNDS, BOILS, CELLULITIS WITH GRAM-POSITIVE ORGANISMS, ABDOMINAL PAD-ABD PADS, ARE USED FOR LARGE WOUNDS OR FOR WOUNDS REQUIRING HIGH ABSORBENCY,GAUZE BANDAGE-INTENDED USED FOR ALMOST ANY BANDAGE APPLICATION, INCLUDING HOLDING A DRESSING IN PLACE ,PLASTER OF PARIS BANDAGE-BANDAGES OF THIS KIND ARE WRAPPED AROUND BROKEN AND FRACTURED LIMBS TO IMMOBILISE THEM AFTER THEY HAVE BEEN SET. SUCH BANDAGES WILL BE REFERRED TO HEREIN AS "PLASTER OF PARIS" BANDAGES AND THE CEMENTITIOUS POWDERS WITH WHICH THEY ARE IMPREGNATED WILL BE REFERRED TO AS

		"PLASTER OF PARIS",ABSORBENT GAUZE ROLL-A BANDAGE IS A PIECE OF MATERIAL USED TO COVERING WOUNDS,ORTHOPAEDIC BADAGE-ORTHOPEDIC PADDING IS THE WIDE-USED SUPPORTING MATERIAL FOR SURGERY AND SWADDLING OF PLASTER OF PARIS BANDAGES ,ABDOMINAL GAUZE SWAB-ABD SWAB, ARE USED FOR LARGE WOUNDS OR FOR WOUNDS REQUIRING HIGH ABSORBENCY, GAMJEE ROLL-GAMJEE ROLL USED FOR ROUTINE SURGICAL OPERATION AND TRAUMATIC DRESSING,PARAFFIN GAUZE DRESSING-PARAFFIN GAUZE DRESSINGS ARE USED TO DRESS DENUDED AREAS AND HENCE THESE GAUZE ARE SPECIALLY COATED WITH SOFT PARAFFIN JELLY. THE PARAFFIN DRESSING, PARAFFIN GAUZE DRESSING IS NONADHERENT, NON ALLERGENIC GAMMA STERILIZED, WHICH HELPS IN THE SPEEDY RECOVERY OF WOUNDS, BANDAGE CLOTH-A BANDAGE IS A PIECE OF MATERIAL USED TO COVERING WOUNDS ,ABDOMINAL PAD WITH X RAY DETECTABLE THREAD-ABDOMINAL GAUZE SWAB WITH X-RAY DETECTABLE THREAD SHOULD BE STERILIZED SINCE IT WILL BE USED FOR ABDOMINAL SURGERY DURING A MEDICAL TREATMENT,W.O.W BANDAGE-THE WHITE OPEN WOVE COTTON BANDAGE IS IDEAL FOR SECURING WOUND DRESSINGS IN PLACE,COMBINE DRESSING-THE COMBINE DRESSING IS USED TO PACK LARGE BLEEDING WOUNDS AFTER INITIAL BLEEDING CONTROL BY DIRECT PRESSURE
3802	MFG/MD/2021/000142	1.License Holder Name: WELSPUN INDIA LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:GERM REMOVAL WIPES (DOMEX/NATURE PROTECT)-WIPES OFFER A CLEANING PROCEDURE BY THE MECHANICAL ACTION OF WIPING, WHICH CAN REMOVE THE ORGANIC DEBRIS ALONG WITH THE DISINFECTION ACTIVITY.

3803	MFG/MD/2021/000143	1.License Holder Name: UTESHIYA MEDICARE PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:SPINE IMPLANTS (CERVICAL, THORACIC & LUMBER)(UTESHIYA)-THE CERVICAL AND LUMBER SPINE IMPLANTS IS USED FOR THE INTERNAL FIXATION OF POSTERIOR CERVICAL AND THORACOLUMBAR SPINE FRACTURES. CERVICAL AND LUMBER SPINE IMPLANTS IS DESIGNED AND MANUFACTURED IN ACCORDANCE WITH THE ANATOMIC FEATURE OF HUMAN SPINE. IT IS COMPOSED OF CORTEX SCREWS AND PLATES, WHICH ARE APPLICABLE FOR DIFFERENT SEGMENTS OF POSTERIOR SPINE FIXATION.,BONE PLATE(UTESHIYA)-BONE PLATES CAN BE COMBINED WITH BONE SCREWS TO TREAT VARIOUS BONE FRACTURES, INCLUDING LARGE BONE (CLAVICLE, SCAPULA, PELVIS, HUMERUS, ULNA, RADIUS, FEMUR, TIBIA, AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, AND PHALANGES)., ARTHROSCOPY IMPLANTS(UTESHIYA, STATIV , VIPLOK, CEPTRE, MONTURA, HELYSIS, INFILOOP, PROLOOP-ULTRA, PROLOOP-MINI, PROLOOP-XL, SIRONIX, SURESTITCH, SPYKE, IVYSTITCH, CRESCENT)-THE ARTHROSCOPY IMPLANTS ARE SMALLER THAN TRADITIONAL IMPLANTS. SURGEONS VIEW THE JOINT AREA ON A VIDEO MONITOR, AND CAN DIAGNOSE AND REPAIR TORN JOINT TISSUE, SUCH AS LIGAMENTS, MUSCLES, TENDON, ETC. IT IS TECHNICALLY POSSIBLE TO DO AN ARTHROSCOPIC SURGERY OF ALMOST EVERY JOINT, BUT IS MOST COMMONLY USED FOR THE KNEE, SHOULDER, HIP, ELBOW, WRIST, ANKLE, ETC.,NAIL(UTESHIYA)-NAILS ARE INTENDED TO BE IMPLANTED INTO THE MEDULLARY CANAL OF LIMBS FOR ALIGNMENT, STABILIZATION, FIXATION OF FRACTURES CAUSED BY TRAUMA OR DISEASES.,ENDOPROSTHESIS(UTESHIYA)-ENDOPROSTHESIS ARE INTENDED TO RESTORE THE NORMAL FUNCTIONS OF THE MISSING BODY PART,WIRE AND PINS(UTESHIYA)-WIRE AND PINS ARE USED FOR FIXATION OF DIAPHYSEAL AND METAPHYSEAL FRACTURE AND IRREGULAR BONE FRACTURE IN COMBINATION WITH EXTERNAL FIXATORS,DENTAL IMPLANT (UTESHIYA)-DENTAL IMPLANT CAN BE USED TO SUPPORT CROWNS REPLACING SINGLE MISSING TEETH, BRIDGES THAT RESTORE A LARGER SPAN OF MISSING TEETH, OR EVEN DENTURES,BONE SCREW (UTESHIYA)-BONE SCREWS CAN BE USED ALONE OR COMBINED WITH BONE PLATES TO TREAT VARIOUS FRACTURES OF LIMBS AND IRREGULAR BONE.

3804	MFG/MD/2021/000144	1.License Holder Name: ABONE SURGICALS PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:BONE NAILS(ABONE)-BONE NAILS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE SCREWS(ABONE)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PIN (ABONE)-BONE PIN IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,SPINAL IMPLANTS(ABONE)-SPINAL IMPLANT SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PIN (ABONE)-BONE PIN IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE WIRE(ABONE)-BONE WIRE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PLATE(ABONE)-BONE PLATE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE WIRE(ABONE)-BONE WIRE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE NAILS(ABONE)-BONE NAILS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PLATE(ABONE)-BONE PLATE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,SPINAL IMPLANTS (ABONE)-SPINAL IMPLANT SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE SCREWS(ABONE)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.
3805	MFG/MD/2021/000145	1.License Holder Name: ASPINWALL HEALTHCARE PRIVATE LIMITED 2.Approving Authority: KERALA 3.Device Name(Brand Name)-Intended Use:MULTIBAND LIGATOR (ASPINMED)-FOR USE IN ENDOSCOPIC LIGATION OF ESOPHAGEAL VARICES AT OR ABOVE GASTRO ESOPHAGEAL JUNCTION

3806	MFG/MD/2021/000146	1.License Holder Name: BIORAD MEDISYS PVT LTD 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:SELECTIVE CATHETER / UPPER URINARY TRACT CATHETER(UROSAFE)-USED FOR INSERTION DIRECTLY INTO A URETER, EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY THROUGH THE KIDNEY.,SUPRAPUBIC CATHETER(UROSAFE)-A SUPRAPUBIC CATHETER IS USED TO DRAIN URINE FROM THE BLADDER WHEN YOU CANNOT URINATE. THIS TYPE OF CATHETER IS USED IF YOU AREN'T ABLE TO USE A CATHETER THAT IS INSERTED INTO THE URETHRA. THIS IS MAINLY USED IN CASES WHERE THE THICK/VISCOUS LIQUIDS HAS TO BE DRAINED., MEATAL DILATOR / SUPRAPUBIC, NON-DISPOSABLE CANNULA (UROSAFE)-MEATAL DILATOR IS USED FOR SELF DILATION OF PENILE URETHRAL MEATUS. STRETCHING OF THE URETHRA OR THE URETHRAL OPENING FOR NARROWING RESULTING IN A POOR URINARY SYSTEM,CHIBA NEEDLE / GASTRO-UROLOGY NEEDLE (UROSAFE)-USED FOR PERCUTANEOUS NEPHROSTOMY PROCEDURES, CYTOLOGICAL BIOPSIES, NEEDLEASPIRATIONS, THORACENTESIS EXPLORATORY PUNCTURES, TO INJECT CONTRAST DYES.,URS /ENDOSCOPIC FORCEPS/ FORCEPS ENDOSCOPIC (UROSAFE)-URS FORCEPS IS USED FOR GRASPING, MANIPULATING AND EXTRACTING CALCULI FROM URETERAL AND RENAL PELVIS., PERCUTANEOUS TRANSHEPATIC BILIARY DRAINAGE CATHETER (PTBD CATHETER) / RADIOGRAPHIC (NON VASCULAR) CATHETER (MESAFE)-USED FOR PERCUTANEOUS DRAINAGE APPLICATIONS OF BILIARY AND ABSCESS.,RE-ENTRY MALECOT CATHETER / NEPHROSTOMY CATHETER(UROSAFE)-RE-ENTRY MALECOT CATHETER IS USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE (INTERNAL AND EXTERNAL DRAINAGE).,SCELEROTHERAPY NEEDLE (VARICES/ INJECTOR) / SCLEROTHERAPY NEEDLE/ CATHETER(MESAFE)-SCLEROTHERAPHY NEEDLES ARE USED FOR INJECTION OF SCELEROTHERAPATIC SOLUTION IN TO ESOPHAGEAL VARICES. ALSO USED FOR INJECTION OF APPROPRIATE VASOCONSTRICTION/MEDICATION AGENT INTO THE GASTROINTESTINAL TRACT.,BILBAO DOTTER WITH GUIDE WIRE / GASTROINTESTINAL TUBE(MESAFE)-USED TO DELIVER NUTRITION IN TO THE SMALL BOWEL.,PCN CATHETER WITH NEEDLE / NEPHROSTOMY CATHETER(UROSAFE)-THIS DEVICE IS USED FOR THE TEMPORARY DRAINAGE BY DIRECT PUNCTURE THOUGH THE SKIN INTO THE KIDNEY FOR THE DISTAL OBSTRUCTION. USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE.,FOLEY CATHETER(UROSAFE)-USED FOR NEPHROSTOMY DRAINAGE,URETHRAL STENT / URETHRAL CATHETER(UROSAFE)-URETHRAL STENT IS USED FOR STENTING THE

	URETHRA AFTER HYPOSPADIAS OR EPISPADIAS REPAIR,PATH FINDER / IRRIGATION PUMP / IRRIGATION AND ASPIRATION CATHETER(UROSAFE)-PATH FINDER/ IRRIGATION PUMP IS USED FOR CONTROLLED UROLOGIC IRRIGATION SYSTEM,PCN CATHETER WITH LOCKING / NEPHROSTOMY CATHETER(UROSAFE)-THIS DEVICE IS USED FOR THE TEMPORARY DRAINAGE BY DIRECT PUNCTURE THOUGH THE SKIN INTO THE KIDNEY FOR THE DISTAL OBSTRUCTION. USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE.,MALECOT CATHETER / NEPHROSTOMY CATHETER(UROSAFE)-USED FOR EXTERNAL DRAINAGE OF VISCOUS LIQUIDS FROM RENAL PELVIS OR BLADDER, FOR PCN & SUPRAPUBIC PROCEDURES RESPECTIVELY.,HEMODIALYSIS / PERMANENT DIALYSIS CATHETER SET(MESAFE)-USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT., URETERAL ACCESS SHEATH CATHETER / VESSEL DIALATOR FOR PERCUTANEOUS CATHETERIZATION / BRAIDED SHAFT CATHETER (UROSAFE)-URETERAL ACCESS SHEATH USED TO ESTABLISH A CONDUIT DURING ENDOSCOPIC UROLOGICAL PROCEDURES FACILITATING THE PASSAGE OF ENDOSCOPES AND OTHER INSTRUMENTS INTO THE URINARY TRACT. THE WORKING CHANNEL PROTECTS THE URETER DURING REPEATED INSTRUMENT EXCHANGES. THE SHEATH ALSO PROTECTS DELICATE INSTRUMENTS AND SMALLER FLEXIBLE SCOPES FROM DAMAGE., EVACUATOR/CONTINUOUS IRRIGATION CATHETER(UROSAFE)-EVACUATOR IS USED FOR REMOVAL/COLLECTION OF TISSUE SECTIONS DURING TRANSURETHRAL RESECTION OF THE PROSTATE (TURP).,HEMODIALYSIS CATHETER SET-PEDIATRIC / HAEMODIALYSIS CATHETER(MESAFE)-USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT,JEJUNAL FEEDING TUBE, JEJUNAL FEEDING TUBE / CATHETER WITH GUIDE WIRE / FEEDING TUBE(MESAFE)-THE MEDICAL DEVICE, JEJUNAL FEEDING TUBE IS USED WHEN PATIENTS REQUIRE FEEDING PAST THE STOMACH DIRECTLY INTO THE JEJUNUM & IT IS USED TO ENHANCE THE ABSORPTION OF NUTRIENTS AND MINIMIZE THE RISKS OF GASTRIC FEEDING INCLUDING GASTRIC REFLUX AND ASPIRATION., EBUS NEEDLE (ENDO-BRONCHIAL ULTRASOUND NEEDLES) / ENDOSCOPIC NEEDLE(MESAFE)-EBUS ALLOWS PHYSICIANS TO PERFORM A TECHNIQUE KNOWN AS TRANSBRONCHIAL NEEDLE ASPIRATION (TBNA) TO OBTAIN TISSUE OR FLUID SAMPLES FROM THE LUNGS AND SURROUNDING LYMPH NODES WITHOUT CONVENTIONAL SURGERY. THE SAMPLES CAN BE USED FOR DIAGNOSING AND STAGING LUNG CANCER, DETECTING INFECTIONS, AND IDENTIFYING INFLAMMATORY DISEASES THAT AFFECT THE LUNGS, SUCH AS SARCOIDOSIS OR OTHER CANCERS LIKE

	LYMPHOMA.,AMPLATZ DILATOR/ STRAIGHT CATHETER(UROSAFE)-AMPLATZ DILATOR & SET IS A DEVICE USED TO DILATE THE NEPHROSTOMY TRACT.,NASAL BILIARY DRAINAGE CATHETER / OESOPHAGEAL BLAKEMORE TUBE(MESAFE)-IT IS USED FOR BILIARY DUCT DRAINAGE THROUGH NASAL PASSAGE& ALSO FOR TREATMENT OF STRICTURES IN THE DUCTILE SYSTEM. IT INCLUDES A NASAL TRANSFER TUBE AND A CONNECTING TUBE WHICH FACILITATE EASY & SAFE IRRIGATION AND DRAINAGE.,CLEAN INTERMITTENT CATHETER (CIC) / NEPHROSTOMY CATHETER (UROSAFE)-USED FOR NEPHROSTOMY DRAINAGE.,BIOPSY GUN / BIOPSY NEEDLE / ASPIRATION AND INJECTION NEEDLE(UROSAFE)-THE BIOPSY NEEDLE IS USED FOR TAKING THE TISSUE OF THE PATIENT FOR BIOPSY. INVOLVES REMOVING SOME CELLS EITHER SURGICALLY OR IN A LESS INVASIVE PROCEDURE INVOLVING A HOLLOW NEEDLE FROM A SUSPICIOUS AREA WITHIN THE BODY OR EXAMINING THEM UNDER A MICROSCOPE FOR DIAGNOSIS. ALSO USED FOR RENAL BIOPSIES.,URETERAL CATHETER / UPPER URINARY TRACT CATHETER(UROSAFE)-USED FOR EXTERNAL URETHRAL DRAINAGE AND FOR RETROGRADE PYELOGRAM AND NAVIGATION OF THE TORTUOUS URETER THROUGH THE URETHRA.,TURP LOOP / FORCEPS, ENDOSCOPIC(UROSAFE)-:USED TO CUT AND COAGULATE THE PROSTATE GLAND DURING TRANS-URETHRAL RESECTIONS OF THE PROSTATE (TURP).,STONE BASKET / BILIARY STONE RETRIEVAL BASKET(UROSAFE)-STONE BASKET IS USED TO RETRIEVE STONES OR TO RESTRAINT STONE MIGRATION FROM OR WITHIN THE URINARY SYSTEM.,PCN CATHETER / NEPHROSTOMY CATHETER (UROSAFE)-THIS DEVICE IS USED FOR THE TEMPORARY DRAINAGE BY DIRECT PUNCTURE THOUGH THE SKIN INTO THE KIDNEY FOR THE DISTAL OBSTRUCTION. USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE,NOTTINGHAM ONE STEP CATHETER / VESSEL DIALATOR FOR PERCUTANEOUS CATHETERIZATION(UROSAFE)-USED TO DILATE THE INTRAMURAL TUNNEL AND URETERAL IN ONE STEP.,INTRODUCER NEEDLE / GASTRO-UROLOGY NEEDLE(MESAFE)-INTRODUCER NEEDLE IS USED FOR THE PLACEMENT OF A GUIDEWIRE, INTRODUCER NEEDLE IS DESIGNED FOR PERCUTANEOUS ACCESS,GUIDEWIRE/ GUIDING CATHETER (GASTROENTEROLOGY & UROLOGY)(UROSAFE)-GASTRO/URO GUIDE WIRES ARE INTENDED FOR USE IN GASTROENTEROLOGICAL PROCEDURES TO FACILITATE THE PLACEMENT OF VARIOUS GASTROENTEROLOGICAL INSTRUMENTS SUCH AS CATHETER/STENTS/DILATORS ETC AND TO FACILITATE THE PLACEMENT OF ENDOUROLOGICAL INSTRUMENTS DURING DIAGNOSTIC OR TREATMENT PROCEDURES.,HYDROPHILIC GUIDEWIRE (RAPLER) / ARTERIAL CATHETER(UROSAFE, MESAFE)-

	INTENDED TO BE USED IN CONJUNCTION WITH STEERABLE GUIDEWIRES IN ORDER TO ACCESS DISCRETE REGIONS OF THE CORONARY AND PERIPHERAL ARTERIAL VASCULATURE. (HYDROPHILIC COATING, OFFERS EXTRA LUBRICITY, REDUCING FRICTION DRASTICALLY AND ENABLING SMOOTH MANIPULATION)., DUAL LUMEN CATHETER / UPPER URINARY TRACT CATHETER (UROSAFE)-THE DUAL LUMEN CATHETER IS USED FOR DRAINAGE OF URINE, CONTRAST INJECTION, URETERAL DILATION & PLACEMENT OF SAFETY GUIDE WIRE.,INFLATION DEVICE / STERILE HYPODERMIC SYRINGES(UROSAFE)-INFLATION DEVICE IS A HIGH PRESSURE SYRINGE BARREL, ERGONOMIC PISTON HANDLE, AND A GAUGE USED TO MONITOR THE INFLATION AND DEFLATION OF BALLOON CATHETERS WHEN CONNECTED TO URETERAL BALLOON CATHETERS, THE INFLATION DEVICE MAY BE REFERRED TO AS THE BALLOON INFLATION DEVICE.,S-CURVE URETHRAL DILATOR / SUPRAPUBIC, NON-DISPOSABLE CANNULA(UROSAFE)-S - CURVE URETERAL DILATOR IS USED FOR DILATION OF MALE URETHRAL STRICTURES & VESICAL NECK CONTRACTURES. IT SUPPORTS THE NATURAL CURVATURE OF THE MALE URETHRA,STONE COLLECTOR / BILIARY STONE RETRIEVAL BASKET(MESAFE)-STONE COLLECTOR IS USED TO COLLECT THE STONES PRESENT IN THE URINE,URETHRAL DILATOR / SUPRAPUBIC, NON-DISPOSABLE CANNULA(UROSAFE)-URETHRAL DILATORS ARE THE SET OF DILATORS USED FOR DILATATION OF THE URETHRA.,GASTRO BASKET (GASTROENTEROLOGY) / BILIARY STONE RETRIEVAL BASKET (MESAFE)-GASTRO BASKET IS USED FOR THE ENDOSCOPIC REMOVAL OF BILIARY STONES AND FOREIGN BODIES.,EUS NEEDLE (ENDOSCOPIC ULTRA SOUND NEEDLE) / ENDOSCOPIC NEEDLE (MESAFE)-THE ENDOSCOPIC ULTRA SOUND NEEDLE ASPIRATION SYSTEM IS USED TO SAMPLE TARGETED MUCOSAL AND EXTRAMURAL GASTROINTESTINAL LESIONS THROUGH THE ACCESSORY CHANNEL OF AN ULTRASOUND ENDOSCOPE. THIS DEVICE IS INTENDED TO BE USED WITH AN ULTRASOUND ENDOSCOPE FOR DELIVERY OF INJECTABLE MATERIALS INTO TISSUES DURING ENDOSCOPIC PROCEDURES AND FINE NEEDLE ASPIRATIONS (FNA) OF SUBMUCOSAL LESIONS, MEDIASTINAL MASSES, LYMPH NODES AND INTRAPERITONEAL MASSES WITHIN OR ADJACENT TO THE GASTROINTESTINAL TRACT.,SCREW DILATOR / SUPRAPUBIC, NON-DISPOSABLE CANNULA(UROSAFE)-SCREW DILATOR IS USED FOR ONE STEP DILATION. THIS CAN BE USED INSTEAD OF SEQUENTIAL DILATION OR FASCIAL DILATION.,AMPLATZ SHEATH / STRAIGHT CATHETER(UROSAFE)-AMPLATZ SHEATH IS USED TO ALLOW SMOOTH PASSAGE OF SURGICAL INSTRUMENTS INTO THE NEPHROSTOMY TRACT.,IP NEEDLE / INITIAL PUNCTURE

	NEEDLE / GASTRO-UROLOGY NEEDLE(UROSAFE)-IP NEEDLE IS USED FOR INITIAL PUNCTURE FOR ALL PERCUTANEOUS APPLICATIONS.,CYSTO CATHETER / SUPRAPUBIC CATHETER(UROSAFE)-CYSTO CATHETER OFFERS A SIMPLIFIED SYSTEM FOR BLADDER DRAINAGE BY SUPRAPUBIC PLACEMENT.,POLYPECTOMY SNARE/ SCLEROTHERAPY CATHETER(MESAFE)-POLYPECTOMY SNARE IS USED FOR ENDOSCOPIC EXCISION OF POLYPS USING MONOPOLAR ELECTROSURGICAL UNIT AND RETRIEVAL OF FOREIGN BODIES FROM G.I. TRACT,PENILE CLAMP/SURGICAL SEALENT(UROSAFE)-PENILE CLAMP KNOWN ALSO AS A CUNNINGHAM CLAMP IS WORN EXTERNALLY TO CONTROL INCONTINENCE IN MEN. THIS CLAMP HELP PATIENTS MANAGE URINE LEAKAGE.,AMPLATZ DILATOR SET (MINI PERC) / STRAIGHT CATHETER(UROSAFE)-AMPLATZ DILATOR (MINI PERC) IS A DEVICE USED TO DILATE THE NEPHROSTOMY TRACT IN PEDIATRIC.,URETERAL BALLOON DILATOR /CATHETER / VESSEL DIALATOR FOR PERCUTANEOUS CATHETERIZATION(UROSAFE)-IT IS A DILATOR USED FOR URETERAL DILATION PRIOR TO URETERAL STONE MANIPULATION OR URETEROSCOPY, AS WELL AS DILATION OF THE INTRAMURAL URETER & URINARY TRACT. ALSO USED FOR WIDENING THE URETERAL STRICTURE.,LOOP BASKET / BILIARY STONE RETRIEVAL BASKET(MESAFE)-THIS DEVICE IS INTENDED FOR USE IN ENDOSCOPIC RETRIEVAL OF FOREIGN OBJECTS, FOOD BOLUS, TISSUE FRAGMENTS AND EXCISED TISSUE SUCH AS POLYPS.,BILIARY DRAINAGE CATHETER / CHOLANGIOGRAPHY CATHETER(MESAFE)-DRAINAGE CATHETER IS THE TYPE OF STENTS USED TO DRAIN THE BILE DUCTS,URETHRAL TUMOR CATHETER/URETHRAL CATHETER (UROSAFE)-USED FOR TEMPORARY INTERNAL DRAINAGE FROM THE URETERO PELVIC JUNCTION TO THE BLADDER FOLLOWING INCISION OF STRICTURE.,GASTRO BALLOON DILATOR / BALLOON DILATORS FOR GASTROENTEROLOGY(MESAFE)-THE PRODUCT IS INTENDED FOR THE DILATION OR ADJUVANT DILATION TREATMENT FOR DIGESTIVE TRACT STENOSIS.,BILIARY PUSHER/ GUIDING CATHETER (MESAFE)-BILIARY PUSHER IS USED TO INTRODUCE BILIARY STENT IN BILIARY TRACT,DOUBLE J CATHETERS/DOUBLE J STENT / UPPER URINARY TRACT CATHETER (SHORT TERM)(UROSAFE)-DOUBLE J STENT IS USED FOR INTERNAL DRAINAGE FROM KIDNEY TO BLADDER.,ENDOMETRIAL TUBE/ MAMMARY BIOPSY NEEDLE (MESAFE)-:ENDOMETRIAL TUBE IS USED TO OBTAIN HISTOLOGICAL TISSUES BIOPSY & EXTRACT SAMPLE OF UTERINE MENSTRUAL CONTENT,URINE BAG WITH CONNECTOR/ URINARY DRAINAGE UNIT (UROSAFE)-URINE BAG CONNECTOR IS USED TO CONNECT BETWEEN THE CATHETERS / DILATORS, OR ANY OTHER DRAINAGE DEVICES TO URINE BAG.,TRANSDUCER PROTECTOR / SINGLE NEEDLE HEMODIALYSIS CATHETER/BLOOD LINES(MESAFE)-TRANSDUCER

	PROTECTOR IS USED FOR HEMODIALYSIS BLOOD LINES TO KEEP THE BLOOD SIDE OF CIRCUIT SEPARATE FROM THE MACHINE SIDE., NEPHROSTOMY BALLOON DILATOR/ CATHETER / VESSEL DIALATOR FOR PERCUTANEOUS CATHETERIZATION(UROSAFE)-NEPHROSTOMY BALLOON DILATOR USED FOR DILATING THE NEPHROSTOMY TRACK AND FOR THE PLACEMENT OF THE WORKING SHEATH.,PERK (PCNL) BASKET/ BILIARY STONE RETRIEVAL BASKET(UROSAFE)-PERK BASKET EXTRACTOR IS DESIGNED TO PROVIDE RAPID ATRAUMATIC STONE EXTRACTION DURING PERCUTANEOUS NEPHROLITHOTOMY (PCNL). PERK BASKETS ARE USED FOR KIDNEY STONE REMOVAL, ENDOSCOPE / TRANSCERVICAL (AMI NOSCOPE) ENDOSCOPE AND ACCESSORIES(MESAFE)-SCOPES ARE TYPICALLY USED TO: I. HELP THE DOCTOR TO CARRYOUT DIAGNOSIS FOR DETERMINING THE CAUSE OF ANY ABNORMAL SYMPTOMS PATIENT HAVING II. REMOVE A SMALL SAMPLE OF TISSUE, WHICH CAN THEN BE SENT TO A LAB FOR FURTHER TESTING; THIS IS CALLED AN ENDOSCOPIC BIOPSY III. HELP DOCTOR SEE INSIDE THE BODY DURING A SURGICAL PROCEDURE, SUCH AS REPAIRING A STOMACH ULCER, OR REMOVING GALLSTONES OR TUMORS ALSO IF PATIENTS HAVING SYMPTOMS OF ANY OF THE FOLLOWING CONDITIONS: A) INFLAMMATORY BOWEL DISEASES (IBD), SUCH AS ULCERATIVE COLITIS (UC) AND CROHN'S DISEASE B) STOMACH ULCER C) CHRONIC CONSTIPATION D) PANCREATITIS E) GALLSTONES F) UNEXPLAINED BLEEDING IN THE DIGESTIVE TRACT G) TUMORS H) INFECTIONS I) BLOCKAGE OF THE ESOPHAGUS J) GASTROESOPHAGEAL REFLUX DISEASE (GERD) K) HIATAL HERNIA L) UNUSUAL VAGINAL BLEEDING M) BLOOD IN URINE N) OTHER DIGESTIVE TRACT ISSUES,INTRAUTERINE INSEMINATION CATHETER / IN-VITRO FERTILIZATION / EMBRYO TRANSFER CATHETER(MESAFE)-THE IUI CATHETER IS DESIGNED AS POTENTIALLY EFFECTIVE TREATMENT OF ALL CAUSES IN WOMEN FOR ARTIFICIAL INTRA UTERINE INSEMINATION PURPOSE.,FILIFORM URETHRAL SELF DILATOR/ SUPRAPUBIC, NON-DISPOSABLE CANNULA(UROSAFE)-FILIFORM URETHRAL SELF DILATOR IS USED FOR TRAVERSING AND DILATING URETHRAL STRICTURES. THE FILIFORM TIP REPLACES THE NEED FOR SEPARATE FILIFORM AND FLOWERS TO DILATE THE URETHRA,Y-CONNECTOR(UROSAFE)-Y-CONNECTOR IS USED TO SIMPLIFY REDUCE BLOOD LOSS DURING PERCUTANEOUS PROCEDURES BY PROVIDING A SEAL AROUND GUIDE WIRE & OTHER DEVICES. UNIQUE SEAL TECHNOLOGY PROVIDES PROTECTION DURING INTERVENTIONS.,URETERAL DILATOR & SET/ SUPRAPUBIC, NON-DISPOSABLE CANNULA (UROSAFE)-URETERAL DILATOR & SET ARE THE SET OF DILATORS USED FOR DILATATION OF THE URETER PRIOR TO URETERORENOSCOPY AND ALSO FOR SEQUENTIAL DILATATION OF

		THE INTRAMURAL TUNNEL AND URETHRA AND / OR STONE MANIPULATION.,FASCIAL DILATOR/SUPRAPUBIC, NON-DISPOSABLE CANNULA(UROSAFE)-FASCIAL DILATOR IS USED FOR DILATATION OF PERCUTANEOUS TRACK OVER THE GUIDEWIRE FOR FASCIAL DILATION,NEPHROSTOMY CATHETER(UROSAFE)-THIS DEVICE IS USED FOR THE TEMPORARY DRAINAGE BY DIRECT PUNCTURE THOUGH THE SKIN INTO THE KIDNEY FOR THE DISTAL OBSTRUCTION. USED FOR PERCUTANEOUS PLACEMENT IN THE RENAL PELVIS FOR NEPHROSTOMY DRAINAGE.
3807	MFG/MD/2021/000147	1.License Holder Name: RAJESHWARI TEXTILES 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:ABSORBENT GAUZE-ABSORBENT GAUZE IS USED FOR CLEANSING, PACKING, SCRUBBING, COVERING, AND SECURING IN A VARIETY OF WOUNDS.,ADHESIVE TAPE-ADHESIVE TAPE IS USED IN HOSPITALS, CLINICS AND FIRST AID TO HOLD A BANDAGE OR TO SECURE DRESSING MATERIALS TO THE SKIN.,ELASTIC ADHESIVE BANDAGE-THE ELASTIC ADHESIVE BANDAGE IS IDEAL FOR STABILISING JOINTS, TENDONS AND LIGAMENTS DURING VIGOROUS EXERCISE. FIRMLY WRAP AROUND THE ANKLE, WRIST, OR ANY OTHER HIGHLY-USED JOINT TO PREVENT INJURY CAUSED BY MUSCLE STRESS AND FATIGUE. ,COTTON CREPE BANDAGE-A CREPE BANDAGE PROVIDES PRESSURE TO A LIMB OR JOINT. IT IS USED TO REDUCE SWELLING, RELIEVE PAIN, AND PROVIDE SUPPORT FOR WEAK BODY PARTS.,ROLLED BANDAGE-A ROLLED BANDAGE IS A THIN, WOVEN FABRIC THAT IS PLACED OVER A WOUND TO KEEP IT CLEAN SO AIR CAN PENETRATE AND IMPROVE HEALING. IT CAN BE USED DIRECTLY ON A WOUND OR IT CAN SECURE A DRESSING IN PLACE.,PLASTER OF PARIS BANDAGE-PLASTER OF PARIS BANDAGE IS THE TRADITIONAL AND MOST WIDELY USED CAST MATERIAL FOR IMMOBILISATION OF FRACTURES, DISEASED BONES AND JOINTS.,ROLLED BANDAGE FOR PLASTER OF PARIS-ROLLED BANDAGE FOR PLASTER OF PARIS BANDAGE IS USED TO MAKE PLASTER OF PARIS BANDAGES.,ABSORBENT COTTON WOOL-ABSORBENT COTTON IS USED FOR SURGICAL DRESSINGS, IT IS MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, DISPENSARIES AND NURSING HOMES TO ABSORB THE BODY FLUIDS. CLEANING OF SKIN, WOUNDS.

3808	MFG/MD/2021/000148	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ABDOMINAL PAD(NEO WOUND WEAR)-TO CLEAN WOUNDS,ABSORBENT COTTON GAUZE RIBBON(NEO WOUND WEAR)-USED IN DRESSINGS,GAUZE SWAB(NEO WOUND WEAR)-FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, APPLYING ANTISEPTIC,COMBINED DRESSING PAD(NEO WOUND WEAR)-THESE ARE IDEAL FOR HANDLING HEAVY DRAINAGE, PROMOTING HEALING AND KEEPING THE WOUND DRY FOR OPTIMAL COMFORT AND RELIEF,IV CANNULA FIXATOR(NEO WOUND WEAR)-IV CANNULA FIXATOR IS HELPFUL FOR FIXING IV CANNULA,GAMJEE ROLL(NEO WOUND WEAR)-FOR THE CLEANING AND DRYING PURPOSE,ABSORBENT GAUZE CLOTH(NEO WOUND WEAR)-FOR CLEAN THE WOUND
3809	MFG/MD/2021/000149	1.License Holder Name: M/S. VIRCHOW BIOTECH PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:1 ML PREFILLABLE PLASTIC SYRINGE BARREL WITH 27 G X 1/2 NEEDLE (STERILE)-HYPODERMIC SYRINGES (HYPODERMIC MEANS 'BENEATH THE SKIN') CONSIST OF A HOLLOW NEEDLE ATTACHED TO A SYRINGE. THEY PIERCE THE SKIN AND INJECT SUBSTANCES INTO THE BLOODSTREAM. THEY ARE ALSO USED TO EXTRACT LIQUID SUCH AS BLOOD FROM THE BODY.

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION CDSCO MFG CDSCO सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3810	MFG/MD/2021/000150	1.License Holder Name: ZEUS ORTHOCARE PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:JOINT REPLACEMENT PROSTHESIS(ZEUS JOINT REPLACEMENT PROSTHESIS)-BONE SURGERY,BONE PLATE(ZEUS BONE PLATE)-THE BONE PLATE IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, TIBIA, FIBULA, FEMORAL. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA- ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS.,BONE SCREW(ZEUS BONE SCREW)-THE BONE SCREW IS INTENDED TO USE FOR INTERNAL FIXATION OF BONE FRACTURES AND RECONSTRUCTION OF BONES, THERE ARE SEVERAL TYPES OF SCREW LIKE LOCKING HEAD SCREW, GENERAL CORTICAL SCREW OR FEMUR HEAD BONE SCREW ARE USED FOR FIXING OF FEMUR HEAD COMPRESSION PLATE, LOCKING PLATES WHICH IS USED FOR OSTEOTOMY PATIENTS EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS.,WIRES & PINS(ZEUS WIRE & PINS)-WIRES:- THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. WIRES ARE OF DIFFERENT TYPES WHICH USED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENT. WIRES ARE MAINLY INDICATED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION. PINS:-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PINS ARE OF DIFFERENT TYPES WHICH GENERALLY USED WITH EXTERNAL FIXATOR IMPLANTS IN TIBIA, FEMUR & FOREARM BONES.,SPINE IMPLANTS(ZEUS SPINE IMPLANTS)-THE SPINAL IMPLANT SYSTEM IS INTENDED TO PROMOTE FUSION OF THE CERVICAL AND THORACIC SPINE (CI-T3) FOR THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC AS CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; SPINAL STENOSIS; TRAUMA(FRACTURE/DISLOCATION); FAILED PREVIOUS FUSION; AND/OR TUMORS. THE HOOKS AND RODS ARE ALSO INTENDED TO PROVIDE STABILIZATION TO PROMOTE FUSION FOLLOWING REDUCTION OF FRACTURE/DISLOCATION OR TRAUMA IN THE CERVICAL/UPPER THORACIC (CI -T3) SPINE. THE USES OF MULTIAXIL SCREWS (PLOY AXIAL)/ CONNECTORS ARE LIMITED TO

	PLACEMENT IN TI -T3 VERTEBRAE FOR TREATING THORACIC CONDITIONS ONLY. SCREWS ARE NOT INTENDED TO BE PLACED IN THE CERVICAL SPINE. TITANIUM RODS ARE PROVIDED IN VARIOUS LENGTHS AND ARE USED TO CONNECT PEDICLE SCREWS (MONO & PLOY AXIAL) AND CREATE A RIGID STRUCTURE. THE RODS ARE CONNECTED TO THE IMPLANTS BY INTERFERENCE WITH THE ROD SADDLE AND HELD INTO POSITION BY THE LOCKING CAPS. ALL SCREWS, HOOK, RODS AND CAGE ARE USED AS SINGLE IMPLANTS., BONE SCREW(ZEUS BONE SCREW)-THE BONE SCREW IS INTENDED TO USE FOR INTERNAL FIXATION OF BONE FRACTURES AND RECONSTRUCTION OF BONES, THERE ARE SEVERAL TYPES OF SCREW LIKE LOCKING HEAD SCREW, GENERAL CORTICAL SCREW OR FEMUR HEAD BONE SCREW ARE USED FOR FIXING OF FEMUR HEAD COMPRESSION PLATE, LOCKING PLATES WHICH IS USED FOR OSTEOTOMY PATIENTS EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS.,WIRES & PINS(ZEUS WIRE & PINS)-WIRES:-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. WIRES ARE OF DIFFERENT TYPES WHICH USED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENT. WIRES ARE MAINLY INDICATED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION. PINS:-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PINS ARE OF DIFFERENT TYPES WHICH GENERALLY USED WITH EXTERNAL FIXATOR IMPLANTS IN TIBIA, FEMUR & FOREARM BONES.,SPINE IMPLANTS(ZEUS SPINE IMPLANTS)-THE SPINAL IMPLANT SYSTEM IS INTENDED TO PROMOTE FUSION OF THE CERVICAL AND THORACIC SPINE (CI-T3) FOR THE FOLLOWING CONDITIONS: DEGENERATIVE DISC DISEASE (NECK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC AS CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES); SPONDYLOLISTHESIS; SPINAL STENOSIS; TRAUMA(FRACTURE/DISLOCATION); FAILED PREVIOUS FUSION; AND/OR TUMORS. THE HOOKS AND RODS ARE ALSO INTENDED TO PROVIDE STABILIZATION TO PROMOTE FUSION FOLLOWING REDUCTION OF FRACTURE/DISLOCATION OR TRAUMA IN THE CERVICAL/UPPER THORACIC (CI -T3) SPINE. THE USES OF MULTIAXIL SCREWS (PLOY AXIAL)/ CONNECTORS ARE LIMITED TO PLACEMENT IN TI -T3 VERTEBRAE FOR TREATING THORACIC CONDITIONS ONLY. SCREWS ARE NOT INTENDED TO BE PLACED IN THE CERVICAL SPINE. TITANIUM RODS ARE PROVIDED IN VARIOUS LENGTHS AND ARE USED TO CONNECT PEDICLE SCREWS (MONO & PLOY AXIAL) AND CREATE A RIGID STRUCTURE. THE RODS ARE

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	INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA-ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS.,INTERLOCKING NAIL (ZEUS NAILS)-BONE SURGERY,BONE PLATE(ZEUS BONE PLATE)-THE BONE PLATE IS INTENDED TO USE FOR INTERNAL FIXATION OF FRACTURES AND RECONSTRUCTION OF BONES INCLUDING THE SCAPULA, OLECRANON, HUMERUS, RADIUS, ULNA, PELVIS, TIBIA, FIBULA, FEMORAL. EXAMPLES OF THESE INTERNAL FIXATIONS AND RECONSTRUCTIONS INCLUDE COMPRESSION FRACTURES, INTRA-ARTICULAR AND EXTRA- ARTICULAR FRACTURES, DISPLACED FRACTURES, OSTEOTOMIES, NON-UNIONS AND MAL-UNIONS.,WIRES & PINS(ZEUS WIRE & PINS)-WIRES:-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. WIRES ARE OF DIFFERENT TYPES WHICH USED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENT. WIRES ARE MAINLY INDICATED FOR BOTH TEMPORARY AND DEFINITIVE FIXATION. PINS:-THESE IMPLANTS ARE USED IN HUMAN BODY TO UNITE BONES OF DIFFERENT PARTS OF THE BODY. PINS ARE OF DIFFERENT TYPES WHICH GENERALLY USED WITH EXTERNAL FIXATOR IMPLANTS IN TIBIA, FEMUR & FOREARM BONES.,JOINT REPLACEMENT PROSTHESIS(ZEUS JOINT REPLACEMENT PROSTHESIS)-BONE SURGERY,JOINT REPLACEMENT PROSTHESIS (ZEUS JOINT REPLACEMENT PROSTHESIS)-BONE SURGERY, INTERLOCKING NAIL(ZEUS NAILS)-BONE SURGEY

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3811	MFG/MD/2021/000151	1.License Holder Name: ROMSONS GROUP PRIVATE LIMITED 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:INFUSION SETS FOR SINGLE USE(STERI FLO)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN.,INFUSION SET FOR SINGLE USE (INTRAFLOW AS)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN.,ALCOHOL SWABS(NIL)-IT IS SINGLE USE STERILE, DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE.,INFUSION SETS FOR SINGLE USE (MICROGUARD STD)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN.,INFUSION SETS FOR SINGLE USE (NIL)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN.,TRANSFUSION SETS FOR SINGLE USE(NIL)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO A VEIN., MEASURED VOLUME IV SET(PEDIA DRIP PLUS)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,INFUSION SETS FOR SINGLE USE(MICROGUARD)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN, ALCOHOL SWABS(ALCO TIP)-IT IS SINGLE USE STERILE , DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE.,TRANSFUSION SETS FOR SINGLE USE(BURETTA)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO A VEIN.,EXTENSION SETS(NIL)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS APPLICATIONS IN MEDICAL.,MEASURED VOLUME IV SET(VOLUMETRIC SET)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,INFUSION SETS FOR SINGLE USE(INFLOW SET)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN,INFUSION SETS FOR SINGLE USE(ROMOFLOW)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN

	TO VEIN.,EXTENSION SET(ROTA FLO)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/MEDICATIONS APPLICATIONS IN MEDICAL.,HYPODERMIC NEEDLE(NIL)-A HYPODERMIC SINGLE USE NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, PARTS OF BODY BELOW THE SURFACE OF SKIN.,TRANSFUSION SETS FOR SINGLE USE(RM$)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD TO PATIENTS VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO A VEIN.,HYPODERMIC NEEDLE(MEDIGLIDE)-A HYPODERMIC SINGLE USE NEEDLE IS A DEVICE INTENDED TO INJECT FLUIDS INTO, OR WITHDRAW FLUIDS FROM, PARTS OF BODY BELOW THE SURFACE OF SKIN.,INFUSION SETS FOR SINGLE USE(ROMOTROL)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN.,MEASURED VOLUME IV SET(NIL)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,INFUSION SETS FOR SINGLE USE(REGULAR FLUID INFUSION SET)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN.,STERILE HYPODERMIC SYRINGES FOR SINGLE USE(NIL)-INTEND TO INJECT FLUID INTO OR WITHDRAW FLUID FROM THE BODY,INFUSION SETS FOR SINGLE USE(MICROPERF)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN.,INFUSION SETS FOR SINGLE USE(RMS)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN.,MEASURED VOLUME IV SET (BURETTA)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE HYPODERMIC SYRINGES FOR SINGLE USE(INJECTA)-INTEND TO INJECT FLUID INTO OR WITHDRAW FLUID FROM THE BODY,MEASURED VOLUME IV SET (VOLUMETRIC PLUS)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,INFUSION SETS FOR SINGLE USE(TRANS FLOW)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN., ALCOHOL SWABS(ALCO SWAB)-IT IS SINGLE USE STERILE, DEVICE CONTAINING 70% ISOPROPYL ALCOHOL USED FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE.,INFUSION SETS FOR SINGLE USE(INTRA FLOW)-

		INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN.,INFUSION SETS FOR SINGLE USE(SOLU FLO)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN.,MEASURED VOLUME IV SET(VOLUFIX)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,STERILE HYPODERMIC SYRINGES FOR SINGLE USE(ROMO JET)-INTEND TO INJECT FLUID INTO OR WITHDRAW FLUID FROM THE BODY,MEASURED VOLUME IV SET(VOLUFIX PLUS)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENTS VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,MEASURED VOLUME IV SET(PEDIA DRIP)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER IN TO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,INFUSION SETS FOR SINGLE USE(STERI FLO PLUS)-INFUSION SET IS USED TO ADMINISTER DRUGS TO A PATIENT´S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED IN TO VEIN
3812	MFG/MD/2021/000152	1.License Holder Name: UNIT-2 M/S JAJOO SURGICALS PVT. LTD. 2.Approving Authority: MADHYA PRADESH 3.Device Name(Brand Name)-Intended Use:PERMEABLE NON-WOVEN SYNTHETIC ADHESIVE TAPE B.P.-SURGICAL DRESSING,ADHESIVE TAPE USP (PRO JS CARE)-POST OPERATION DRESSING APPLICATION,ELASTIC ADHESIVE BANDAGE- CANNULA FIXATOR B.P. (PRO JS CARE)-DRESSING FIXATOR,ELASTIC ADHESIVE BANDAGE-CANNULA FIXATOR B.P. -DRESSING FIXATOR,COTTON CREPE BANDAGE B.P (PRO JS CARE)-PAIN RELIEF DRESSING BANDAGE, COTTON CREPE BANDAGE B.P ORTHOPEDIC SOFT ROLL(PRO JS CARE)-IT'S A TYPE OF DRESSING BANDAGE TO PROTECT THE SKIN OR WHERE SWELLING IS EXPECTED,ADHESIVE TAPE USP -POST OPERATION DRESSING APPLICATION,PERMEABLE NON-WOVEN SYNTHETIC ADHESIVE TAPE B.P-SURGICAL DRESSING,COTTON CREPE BANDAGE B.P -PAIN RELIEF DRESSING BANDAGE

3813	MFG/MD/2021/000153	1.License Holder Name: PROACTIVE HEALTH INC 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:INFRARED THERMOMETER(POCT)-AN INFRARED THERMOMETER IS A THERMOMETER WHICH INFERS TEMPERATURE FROM A PORTION OF THE THERMAL RADIATION SOMETIMES CALLED BLACK-BODY RADIATION EMITTED BY THE OBJECT BEING MEASURED,DIGITAL THERMOMETERS(POCT)-A THERMOMETER IS A DEVICE THAT MEASURES TEMPERATURE ORA TEMPERATURE GRADIENT .,SPACERS (INSTASPACER, TRANSPACER, QUIKSPACER)-A SPACER IS A DEVICE USED TO INCREASE THE EASE OF ADMINISTERING AEROSOLIZED MEDICATION FROM A METERED-DOSE INHALER. IT ADDS SPACE IN THE FORM OF A TUBE OR “CHAMBER” BETWEEN THE MOUTH AND CANISTER OF MEDICATION.,PLAIN YANKAUER SUCTION(POCT)-YANKAUER IS A SUCTION SET USED FOR THE REMOVAL OF BLOOD AND FLUIDS DURING SURGERY,BLOOD PRESSURE MONITORS(POCT)-A BLOOD PRESSURE MACHINE OR BLOOD PRESSURE MACHINE OR DIGITAL BP MONITOR IS A DIAGNOSTIC TOOL TO CHECK THE BLOOD PRESSURE LEVELS IN THE BODY,SPACERS(INSTASPACER, TRANSPACER, QUIKSPACER)-A SPACER IS A DEVICE USED TO INCREASE THE EASE OF ADMINISTERING AEROSOLIZED MEDICATION FROM A METERED-DOSE INHALER. IT ADDS SPACE IN THE FORM OF A TUBE OR “CHAMBER” BETWEEN THE MOUTH AND CANISTER OF MEDICATION.,YANKAUER SUCTION HANDLE(POCT)-YANKAUER SUCTION HANDLE IS INTENDED FOR SUCTIONING THE BODY FLUID IN COMBINATION WITH ASPIRATOR DURING OPERATION ON THORACIC CAVITY OR ABDOMINAL CAVITY,NASAL IRRIGATION BOTTLE(POCT)-NASAL IRRIGATION BOTTLE IS USED FOR PERSONAL HYGIENE PRACTICE IN WHICH THE NASAL CAVITY IS WASHED TO FLUSH OUT MUCUS AND DEBRIS FROM THE NOSE AND SINUSES, IN ORDER TO ENHANCE NASAL BREATHING.,PULSE OXIMETERS(POCT)-PULSE OXIMETRY IS A NONINVASIVE AND CONTINUOUS METHOD FOR MONITORING THE BLOOD OXYGEN SATURATION LEVEL,ALCOHOL SWABS(POCT)-ALCOHOL SWABS ARE USED TO DISINFECT CUTS, SCRAPES AND INTACT SKIN.,NASAL CANNULA ADULT(POCT)-THE NASAL CANNULA (NC) IS A DEVICE USED TO DELIVER SUPPLEMENTAL OXYGEN OR INCREASED AIRFLOW TO A PATIENT OR PERSON IN NEED OF RESPIRATORY HELP,CATHETER MOUNT(POCT)-CATHETER MOUNT CONNECTS PATIENT ET TO BREATHING CIRCUIT. THIS MINIMIZES THE JERK OF BREATHING TO ET OR TT REDUCING TRAUMA TO TRACHEA,PLAIN YANKAUER SUCTION(POCT)-YANKAUER IS A SUCTION SET USED FOR THE REMOVAL OF BLOOD AND FLUIDS DURING SURGERY

3814	MFG/MD/2021/000154	1.License Holder Name: OM SURGICAL INDUSTRIES 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL(NA)-COTTON WOOL AND MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC. APART FROM MEDICAL PURPOSES ABSORBENT COTTON IS ALSO USED FOR MAKING CONVENTIONAL TYPE OF SANITARY NAPKINS OR PADS

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3815	MFG/MD/2021/000155	1.License Holder Name: MODERN ORTHODONTIC 2.Approving Authority: PUNJAB 3.Device Name(Brand Name)-Intended Use:ORTHODONTIC MOLAR BANDS-ORTHODONTIC MOLAR BANDS ARE RING LIKE STRUCTURES WHICH EMBRACE THE TOOTH. THESE ARE USED FOR THE PURPOSE ON MOLAR TEETH WHERE DIRECT PLACEMENT OF MOLAR TUBES IS NOT POSSIBLE DUE TO HIGHER FORCES OF MASTICATION REQUIRED DURING CHEWING WHICH CAN DISLODGE THE MOLAR TUBES IF PLACED DIRECTLY. SO THE MOLAR BANDS ARE PLACED AROUND THE TEETH AND THE MOLAR TUBES ARE WELDED ON TO THE BANDS FOR PROVIDING GREATER STRENGTH TO THE MOLAR TUBES THEREBY PREVENTING ACCIDENTAL DISLODGING OF THE TUBES., ORTHODONTIC BRACKET - CERAMIC -ORTHODONTIC BRACKETS ARE KNOWN AS DENTAL BRACES IN LAYMAN LANGUAGE. THESE ARE USED FOR THE PURPOSE OF STRAIGHTENING OF CROOKED TEETH. THESE ARE PLACED ON THE TEETH AND THEN THEY ACT AS MEANS OF TRANSFERRING FORCES OF ORTHODONTIC WIRES TO TEETH. ONCE THE TREATMENT WITH BRACES IS OVER, THESE ARE REMOVED FROM THE TEETH AND DISCARDED,ORTHODONTIC BRACKET-STAINLESS STEEL-ORTHODONTIC BRACKETS ARE KNOWN AS DENTAL BRACES IN LAYMAN LANGUAGE. THESE ARE USED FOR THE PURPOSE OF STRAIGHTENING OF CROOKED TEETH. THESE ARE PLACED ON THE TEETH AND THEN THEY ACT AS MEANS OF TRANSFERRING FORCES OF ORTHODONTIC WIRES TO TEETH. ONCE THE TREATMENT WITH BRACES IS OVER, THESE ARE REMOVED FROM THE TEETH AND DISCARDED,ORTHODONTIC ADHESIVES-ORTHODONTIC ADHESIVES HELP IN FIXATION OF ORTHODONTIC BRACKETS, TUBES AND ACCESSORIES ON TEETH. FIRSTLY THE TOOTH SURFACE IS PREPARED BY POLISHING AND APPLYING ETCHANT FOR A CERTAIN PERIOD OF TIME. ETCHANT IS USED TO CREATE ROUGH SURFACE WHICH HELPS IN GAINING SUFFICIENT ADHESION STRENGTH. AFTER THIS, PRIMER IS APPLIED WHICH GOES INTO MICRO-DEFECTS CREATED BY ETCHANT. IT IS THEN FOLLOWED BY APPLICATION OF ADHESIVE WHICH GETS HARDENED EITHER BY CONTACT WITH THE PRIMER OR BY A LIGHT SOURCE.,ORTHODONTIC WIRES - STAINLESS STEEL-ORTHODONTIC WIRES ARE THE MEANS FOR EXERTING PRESSURE ON THE TEETH WHICH RESULTS INTO THE MOVEMENT OF TEETH. DIFFERENT WIRES ARE USED DURING DIFFERENT STAGES OF TREATMENT. THESE WIRES VARY BOTH IN SIZE AND CROSS SECTION AS WELL AS THE ALLOY. DURING THE INITIAL PHASES OF TREATMENT, THINNER WIRES MADE OF TITANIUM ALLOYS ARE USED FOR APPLICATION OF LIGHTER FORCES. SLOWLY, AS THE TREATMENT PROGRESSES, THESE WIRES ARE REPLACED BY MORE THICKER AND STRONGER STAINLESS STEEL WIRES WHICH

	PROVIDE A STRONG TRACK ON WHICH THE TEETH CAN BE MOVED, ORTHODONTIC WIRES- BETA TITANIUM-ORTHODONTIC WIRES ARE THE MEANS FOR EXERTING PRESSURE ON THE TEETH WHICH RESULTS INTO THE MOVEMENT OF TEETH. DIFFERENT WIRES ARE USED DURING DIFFERENT STAGES OF TREATMENT. THESE WIRES VARY BOTH IN SIZE AND CROSS SECTION AS WELL AS THE ALLOY. DURING THE INITIAL PHASES OF TREATMENT, THINNER WIRES MADE OF TITANIUM ALLOYS ARE USED FOR APPLICATION OF LIGHTER FORCES. SLOWLY, AS THE TREATMENT PROGRESSES, THESE WIRES ARE REPLACED BY MORE THICKER AND STRONGER STAINLESS STEEL WIRES WHICH PROVIDE A STRONG TRACK ON WHICH THE TEETH CAN BE MOVED,ORTHODONTIC MOLAR TUBE-ORTHODONTIC MOLAR TUBES ARE TECHNICALLY BRACKETS ONLY. THESE ARE TUBE-LIKE BRACKETS WHICH ARE USED FOR THE PURPOSE OF STRAIGHTENING OF CROOKED MOLAR TEETH. THESE ARE PLACED ON THE MOLAR TEETH AND THEN THEY ACT AS MEANS OF TRANSFERRING FORCES OF ORTHODONTIC WIRES TO MOLAR TEETH. ONCE THE TREATMENT WITH BRACES IS OVER, THESE ARE REMOVED FROM THE MOLAR TEETH AND DISCARDED,ORTHODONTIC ELASTOMERICS-ORTHODONTIC ELASTOMERIC ARE BASICALLY OF THREE TYPES AND ARE USED LIKE DISPOSABLE FORCE EXERTING UNITS AS AND WHEN REQUIRED DURING ORTHODONTIC TREATMENT. ELASTOMERIC CHAINS, ELASTICS, ELASTIC THREAD AND ELASTIC TUBING HELP IN EXERTING “PULLING-FORCES” ON A TOOTH OR A GROUP OF TEETH. TIES ARE USED FOR HOLDING ORTHODONTIC WIRE INTO THE BRACKETS. SEPARATORS HELP IN CREATING DESIRED DISTANCE BETWEEN TWO ADJACENT TEETH IN FACILITATING THE PLACEMENT OF ORTHODONTIC BANDS. ROTATION WEDGES HELP IN DE-ROTATING A ROTATED TOOTH.,ORTHODONTIC WIRES -NI-TI-ORTHODONTIC WIRES ARE THE MEANS FOR EXERTING PRESSURE ON THE TEETH WHICH RESULTS INTO THE MOVEMENT OF TEETH. DIFFERENT WIRES ARE USED DURING DIFFERENT STAGES OF TREATMENT. THESE WIRES VARY BOTH IN SIZE AND CROSS SECTION AS WELL AS THE ALLOY. DURING THE INITIAL PHASES OF TREATMENT, THINNER WIRES MADE OF TITANIUM ALLOYS ARE USED FOR APPLICATION OF LIGHTER FORCES. SLOWLY, AS THE TREATMENT PROGRESSES, THESE WIRES ARE REPLACED BY MORE THICKER AND STRONGER STAINLESS STEEL WIRES WHICH PROVIDE A STRONG TRACK ON WHICH THE TEETH CAN BE MOVED., ORTHODONTIC ACESSORIES-ORTHODONTIC ACCESSORIES ARE THE DEVICES WHICH ARE USED ALONG-WITH MAIN BRACKET-WIRE COMBINATION FOR THE PURPOSES AS GIVEN BELOW; LINGUAL SHEATH HELPS IN HOLDING THE TRANS-PALATAL ARCH BARS WHICH IN TURN HELPS IN MAKING TWO MOLARS ON OPPOSITE SIDE

	AS ONE ANCHORAGE UNIT. LINGUAL BUTTONS, CLEATS, LUGS, DIRECT BOND EYELETS, CRIMPABLE HOOKS, CRIMPABLE BALL HOOKS AND CRIMPABLE STOPS ARE USED AS MEANS OF APPLYING THE ELASTOMERICS AND SPRINGS FOR MOVEMENT OF VARIOUS TEETH. TRANS-PALATAL ARCH BARS HELP IN MAKING TWO MOLARS ON OPPOSITE SIDE AS ONE ANCHORAGE UNIT SO THAT THEY CAN OFFER BETTER RESISTANCE TO MOVEMENT OF FRONT TEETH.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3816	MFG/MD/2021/000156	1.License Holder Name: ORTHOFLEX MEDISYS INDIA PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE NAILS (INTRAMEDULLARY NAILS)(ORTHOFLEX MEDISYS INDIA PVT LTD)-INTERLOCKING NAILS INCLUDE SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL-UNIONS; AND BONE LENGTHENING/SHORTENING. FEMORAL INTERLOCKING NAILS INCLUDE THE INDICATION FOR PROXIMAL, MIDDLE AND DISTAL THIRD FEMORAL SHAFT FRACTURES. TIBIAL INTERLOCKING NAILS ALSO INCLUDE THE SAME INDICATIONS FOR TIBIAL SHAFT FRACTURES. HUMERAL INTERLOCKING NAILS ARE INDICATED FOR HUMERAL SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL-UNIONS, PROXIMAL, MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES; HUMERUS RECONSTRUCTION, FOLLOWING TUMOR RESECTION AND GRAFTING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. R/U INTERLOCKING NAILS ARE INDICATED FOR RADIAL AND ULNAR SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; PROXIMAL MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES. INTERLOCKING RECONSTRUCTION NAILS ARE INDICATED FOR THE FOLLOWING: SUBTROCHANTERIC FRACTURES WITH LESSER TROCHANTERIC INVOLVEMENT; IPSILATERAL FEMORAL SHAFT/NECK FRACTURES; SEVERELY COMMINUTED SHAFT FRACTURES; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; BONE SHORTENING/LENGTHENING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. RETROGRADE NAILS ARE INDICATED FOR SHAFT FRACTURES INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; BONE LENGTHENING/SHORTENING; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; FRACTURES IN OSTEOPOROTIC BONE; SEVERELY COMMINUTED SHAFT FRACTURES; PATHOLOGIC FRACTURES, PSEUDOARTHROSIS, FAILED OSTEOSYNTHESIS; CLOSED SUPRACONDYLAR FRACTURES; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. ADDITIONAL INDICATIONS FOR RETROGRADE NAILS INCLUDE: SEVERELY COMMINUTED SUPRACONDYLAR FRACTURES WITH OR WITHOUT DIFFICULT INTRA-ARTICULAR EXTENSION, FRACTURES THAT REQUIRE OPENING THE KNEE JOINT TO STABILIZE THE FEMORAL CONDYLAR SEGMENT. K-

	NAIL IS INDICATED FOR TIBIA, FEMUR AND HUMREUS SHAFT FRACTURE. GAM NAIL IS INDICATED FOR SUBTROCHANTERIC FRACTURE. ELASTIC NAIL (FLEXIBLE NAIL) IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ENDER'S NAIL IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ANKLE ARTHODESIS NAIL IS INDICATED FOR FOOT AND ANKLE FRACTURE. DIMSC LOCKED NAIL IS INDICATED FOR SUPRACONDYLAR FRACTURE. INTERLOCKING NAIL CAP, NAIL PLUG SAFETY STAR DRIVE (GAM NAIL CAP), INTERLOCKING GUIDE WIRE-SIMPLE AND INTERLOCKING GUIDE WIRE-OLIVE TIP (BALL TIP) ARE INDICATED FOR NAIL AND BONE FIXATION.,BONE NAILS (INTRAMEDULLARY NAILS)(ORTHOFLEX MEDISYS INDIA PVT LTD)-INTERLOCKING NAILS INCLUDE SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL-UNIONS; AND BONE LENGTHENING/SHORTENING. FEMORAL INTERLOCKING NAILS INCLUDE THE INDICATION FOR PROXIMAL, MIDDLE AND DISTAL THIRD FEMORAL SHAFT FRACTURES. TIBIAL INTERLOCKING NAILS ALSO INCLUDE THE SAME INDICATIONS FOR TIBIAL SHAFT FRACTURES. HUMERAL INTERLOCKING NAILS ARE INDICATED FOR HUMERAL SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MAL-UNIONS, PROXIMAL, MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES; HUMERUS RECONSTRUCTION, FOLLOWING TUMOR RESECTION AND GRAFTING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. R/U INTERLOCKING NAILS ARE INDICATED FOR RADIAL AND ULNAR SHAFT FRACTURES, INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; PROXIMAL MIDDLE AND DISTAL THIRD SHAFT FRACTURES; POLYTRAUMA AND/OR MULTIPLE FRACTURES. INTERLOCKING RECONSTRUCTION NAILS ARE INDICATED FOR THE FOLLOWING: SUBTROCHANTERIC FRACTURES WITH LESSER TROCHANTERIC INVOLVEMENT; IPSILATERAL FEMORAL SHAFT/NECK FRACTURES; SEVERELY COMMINUTED SHAFT FRACTURES; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; BONE SHORTENING/LENGTHENING; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. RETROGRADE NAILS ARE INDICATED FOR SHAFT FRACTURES INCLUDING SEVERELY COMMINUTED, SPIRAL, LARGE OBLIQUE AND SEGMENTAL FRACTURES; NONUNION AND MALUNION; BONE LENGTHENING/SHORTENING; FEMUR RECONSTRUCTION FOLLOWING TUMOR RESECTION AND GRAFTING; FRACTURES IN OSTEOPOROTIC BONE; SEVERELY COMMINUTED SHAFT FRACTURES; PATHOLOGIC FRACTURES, PSEUDOARTHROSIS, FAILED OSTEOSYNTHESIS; CLOSED

	SUPRACONDYLAR FRACTURES; AND PROPHYLACTIC NAILING OF IMPENDING PATHOLOGIC FRACTURES. ADDITIONAL INDICATIONS FOR RETROGRADE NAILS INCLUDE: SEVERELY COMMINUTED SUPRACONDYLAR FRACTURES WITH OR WITHOUT DIFFICULT INTRA-ARTICULAR EXTENSION, FRACTURES THAT REQUIRE OPENING THE KNEE JOINT TO STABILIZE THE FEMORAL CONDYLAR SEGMENT. K-NAIL IS INDICATED FOR TIBIA, FEMUR AND HUMREUS SHAFT FRACTURE. GAM NAIL IS INDICATED FOR SUBTROCHANTERIC FRACTURE. ELASTIC NAIL (FLEXIBLE NAIL) IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ENDER'S NAIL IS INDICATED FOR HUMERUS AND TIBIA AND FEMUR FRACTURE. ANKLE ARTHODESIS NAIL IS INDICATED FOR FOOT AND ANKLE FRACTURE. DIMSC LOCKED NAIL IS INDICATED FOR SUPRACONDYLAR FRACTURE. INTERLOCKING NAIL CAP, NAIL PLUG SAFETY STAR DRIVE (GAM NAIL CAP), INTERLOCKING GUIDE WIRE-SIMPLE AND INTERLOCKING GUIDE WIRE-OLIVE TIP (BALL TIP) ARE INDICATED FOR NAIL AND BONE FIXATION.,BONE PLATE(ORTHOFLEX MEDISYS INDIA PVT. LTD.)-BONE PLATES INTENDED TO BE ATTACHED TO FRACTURED LONG BONE FRAGMENT WITH SCREW TO BRIDGE AND STABILIZE THE FRACTURE GAP, AND SHIELD THE SITE FROM STRESS AS THE BONE HEALS. IT MAY ALSO BE USED TO TEMPORARILY AUGMENT BONE FOLLOWING A LENGTHENING PROCEDURE, OR FOR ARTHRODESIS.,ARTHROSCOPY IMPLANTS(ORTHOFLEX MEDISYS INDIA PVT. LTD.)-ARTHROSCOPY IMPLANTS ARE INTENDED FOR USE IN FIXATION OF SEMITENDINOUS AND/OR GRACILE TENDON GRAFTS. ACL/PCL SCREW IS INTENDED FOR USE IN ANTERIOR/POSTERIOR CRUCIATE LIGAMENT (ACL/PCL) RECONSTRUCTION PROCEDURES. ACL/PCL SCREW IS INDICATED FOR FIXATION OF BONE-PATELLAR TENDON- BONE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION, FIXATION OF THE SOFT TISSUE GRAFT TO THE FEMORAL/TIBIAL BONE DRILL HOLE IN THE ANTERIOR CRUCIATE LIGAMENT (ACL) RECONSTRUCTION AND RECONSTRUCTION OF POSTERIOR CRUCIATE LIGAMENT (PCL). THE ARTHROSCOPE IS INTENDED TO BE USED AS AN ENDOSCOPE IN ARTHROSCOPIC PROCEDURES PERFORMED ON THE KNEE, SHOULDER, HIP, WRIST (CARPEL TUNNEL SYNDROME), TEMPORAL MANDIBULAR JOINT, ANKLE, ELBOW, AND FEET (PLANTAR FASCIA RELEASE) TO VIEW THE SURGICAL SITE.,BONE WIRES, PINS & STAPLES(ORTHOFLEX MEDISYS INDIA PVT. LTD.)-INDICATIONS FOR PINS AND WIRES INCLUDE FIXATION OF BONE FRACTURES, BONE RECONSTRUCTIONS, AS GUIDE PINS FOR INSERTION OF OTHER IMPLANTS AND IMPLANTED THROUGH THE SKIN FOR TRACTION APPLIED TO THE SKELETAL SYSTEM. WIRES ARE USED IN THE FIXATION OF FRACTURES IN WHICH LOADING IS

	MINIMAL. WIRES ARE EASIER TO BEND, SO, ARE SUPPLEMENTED WITH OTHER IMMOBILIZATION DEVICES WHERE NECESSARY. PIN OR WIRE FIXATION IS MOSTLY USED FOR FRACTURES OF THE PHALANGES, METACARPALS, METATARSALS, PROXIMAL HUMERUS AND DISTAL HUMERUS. PINS ARE USED IN FIXATION OF FRACTURES WHERE MINIMAL BONE AND SOFT TISSUE DAMAGE ARE INVOLVED. PINS PROVIDE PROVISIONAL FIXATION LEAVING ROOM FOR ADDITIONAL HARDWARE PLACEMENT. THE PROVISIONAL FIXATION IS PLANNED TO AVOID FAULTY PERMANENT FIX TION. DEPENDING ON THE DIAMETER, PINS MAY ALSO BE USED AS GUIDEWIRES FOR CANNULATED SCREW FIXATION. STAPLES ARE USED FOR FRAGMENT FIXATION, WHERE INTER-FRAGMENTAL SCREW FIXATION IS DIFFICULT. THESE ARE AN EFFECTIVE INTERNAL FIXATION METHOD AND ARE WIDELY USED IN FOOT AND ANKLE SURGERY. THE STAPLES ARE ALSO USED IN FIXATION OF SOFT TISSUES TO BONE,BONE PLATES (ORTHOFLEX MEDISYS (I) PVT LTD)-BONE PLATES INTENDED TO BE ATTACHED TO FRACTURED LONG BONE FRAGMENT WITH SCREW TO BRIDGE AND STABILIZE THE FRACTURE GAP, AND SHIELD THE SITE FROM STRESS AS THE BONE HEALS. IT MAY ALSO BE USED TO TEMPORARILY AUGMENT BONE FOLLOWING A LENGTHENING PROCEDURE, OR FOR ARTHRODESIS.,: SPINAL IMPLANTS (ORTHOFLEX MEDISYS INDIA PVT LTD)-SPINAL IMPLANTS ARE INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION IN THE TREATMENT OF THE FOLLOWING ACUTE AND CHRONIC INSTABILITIES OR DEFORMITIES OF THORACIC, LUMBAR, AND SACRAL SPINE: FRACTURE, DISLOCATION, FAILED PREVIOUS FUSION (PSEUDOARTHROSIS), SPINAL STENOSIS, DEGENERATIVE SPONDYLOLISTHESIS WITH OBJECTIVE EVIDENCE OF NEUROLOGICAL IMPAIRMENT, SPINAL DEFORMATIONS SUCH AS SCOLIOSIS OR KYPHOSIS AND LOSS OF STABILITY DUE TO TUMORS. SPINAL IMPLANTS ARE INTENDED TO BE USED AS A TEMPORARY CONSTRUCT THAT ASSISTS NORMAL HEALING AND ARE NOT INTENDED TO REPLACE NORMAL BODY STRUCTURES. THEY ARE INTENDED TO STABILIZE THE SPINAL OPERATIVE SITE DURING FUSION PROCEDURES AND SHOULD BE REMOVED AFTER FUSION. THE IMPLANET SPINE SYSTEM IS INTENDED TO PROVIDE IMMOBILIZATION AND STABILIZATION OF SPINAL SEGMENTS IN SKELETALLY MATURE PATIENTS AS AN ADJUNCT TO FUSION OF THE THORACIC, LUMBAR AND/OR SACRAL SPINE. THE IMPLANET SPINE SYSTEM IS INTENDED FOR POSTERIOR, NON-CERVICAL PEDICLE AND NONPEDICLE FIXATION FOR THE FOLLOWING INDICATIONS: DEGENERATIVE DISC DISEASE (DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN WITH DEGENERATION OF THE DISC CONFIRMED

		BY HISTORY AND RADIOGRAPHIC STUDIES), SPONDYLOLISTHESIS, TRAUMA (I.E., FRACTURE OR DISLOCATION), SPINAL STENOSIS, SPINAL DEFORMITIES (I.E., SCOLIOSIS, KYPHOSIS AND/OR LORDOSIS), TUMOR, PSEUDARTHROSIS, OR REVISION OF A FAILED FUSION ATTEMPT.,BONE SCREW(ORTHOFLEX MEDISYS (I) PVT LTD)-BONE SCREWS INTENDED FOR USE IN INTERNAL FIXATION OF BONES AFFECTED BY TRAUMA OR FOR RECONSTRUCTION OR ARTHRODESIS. SCREWS ALONG WITH PLATES, NAILS, PINS AND WIRES ARE INDICATED FOR PELVIC,SMALL AND LONG BONE FRACTURE FIXATION. SCREWS ARE OF SO MANY DIFFERENT TYPES E.G. (LOCKED SCREWS,LOCKING BOLTS ETC.).,BONE SCREW(ORTHOFLEX MEDISYS INDIA PVT LTD)-ORTHOFLEX MEDISYS (INDIA) PVT. LTD.'S BONE SCREWS WHEN USED IN COMBINATION WITH PLATES ARE INTENDED FOR FIXATION OF VARIOUS FRACTURES, OSTEOTOMIES, MALUNIONS, REPLACEMENT, RECONSTRUCTION, CORRECTION, STABILIZATION OF VARIOUS BONES [CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES] IN GENERAL. THE ORTHOFLEX MEDISYS (INDIA) PVT. LTD.'S BONE WASHER ARE INTENDED TO PREVENT A SCREW HEAD FROM BREAKING THROUGH THE CORTEX OF THE BONE BY DISTRIBUTING THE FORCES/LOAD OVER A LARGE AREA WHEN USED FOR FRACTURE FIXATION OF LARGE BONE AND BONE FRAGMENTS.
3817	MFG/MD/2021/000157	1.License Holder Name: LIFE LINE MEDICAL DEVICES 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (LIFE-LINE, MAX, BEATS,)-IT IS DEVICE USED TO RECORD THE BODY TEMPERATURE.,BLOOD PRESSURE MONITORING DEVICES(LIFE-LINE, MAX, BEATS,)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.
3818	MFG/MD/2021/000158	1.License Holder Name: FIDELIS PRODUCTS PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (FIDELIS HEALTHCARE)-IT IS DEVICE USED TO RECORD THE BODY TEMPERATURE.,BLOOD PRESSURE MONITORING DEVICES(FIDELIS HEALTHCARE)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURE.

3819	MFG/MD/2021/000159	1.License Holder Name: DEVON INNOVATIONS PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:ENDOPRO-AUSTIN MOORE(EAM)(ENDOPRO-AM)-USED IN TOTAL HIP ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED HIP FUNCTION,BILIARY STENT/ SET- WITH/WITHOUT HYDROPHILIC COATED (BS)(BSAF,BSF,DPBS,BSHS,SPBS)(DEVON)-USED TO DRAIN OBSTRUCTED BILIARY DUCTS,URETERAL INDWELLING DOUBLE PIGTAIL STENT/ SET (SHORT/LONG TERM) –WITH/WITHOUT HYDROPHILIC COATED(DJS)(OEO, BEO, OML OEO, OML BEO, BML BEO)(DEVON)-USED FOR TEMPORARY INTERNAL DRAINAGE FROM THE URETEROPELVIC JUNCTION TO THE BLADDER,CEMENT RESTRICTOR(CR)-USED FOR, RESTRICT CEMENT FLOW INTO THE DISTAL FEMORAL SHAFT,DURING TOTAL HIP REPLACEMENT, ENDERNAILS(EN)(ENDERNAIL)-USED FOR TREATEMENT OF PRETROCHANTERIC AND SUBTROCHANTERIC FACTURES IN ELDERLY PATIENTS,MODULAR BIPOLAR ASSEMBLY WITH HEAD(EMFBL/+3.5, EMFBS/-3.5,EMFBM/0)(BIPOLAR-M)-USED IN TOTAL HIP ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED HIP FUNCTION,BILIARY STENT/ SET- WITH/WITHOUT HYDROPHILIC COATED (BS)(BSAF,BSF,DPBS,BSHS,SPBS)(DEVON)-USED TO DRAIN OBSTRUCTED BILIARY DUCTS,STEINMANN PIN-THE PURPOSE OF THE PRODUCTS IS THE RAPID AND COMPLETE RECOVERY OF THE DAMAGED BONE FUNCTION,BILIARY PANCREATIC STENT/SET-WITH/WITHOUT HYDROPHILIC COATED(BPS)(DEVON)-USED TO DRAIN OBSTRUCTED BILIARY DUCTS,URETERAL INDWELLING SINGLE PIGTAIL(MONO-J) STENT/ SET - WITH/WITHOUT HYDROPHILIC COATED(DEVON)-USED FOR TEMPORARY INTERNAL DRAINAGE FROM THE URETEROPELVIC JUNCTION TO THE BLADDER, ILYOSTOMY STENT WITH/WITHOUT HYDROPHILIC COATED(ILS) (DEVON)-USED FOR TEMPORARY DRAINAGE OF URINE FROM THE URETEROPELVIC JUNCTION TO THE EXTERNAL URINE COLLECTION BAG DURING THE CONDITION OF MORE INFECTION IN BLADDER AND URETHRA,KIRSCHNER WIRE(PARTIALLY/FULLY THREADED KIRSCHNER WIRE,L-WIRE,OLIVE WIRE,BAYONET TIP,SINGLE SIDED TROCAR)-(KW)(KIRSCHNER WIRE)-USED FOR INTERNAL FIXATION OF FRACTURES OF SMALL BONE FRAGMENTS TO THEIR PRESENT BONE, ILYOSTOMY STENT WITH/WITHOUT HYDROPHILIC COATED(ILS) (DEVON)-USED FOR TEMPORARY DRAINAGE OF URINE FROM THE URETEROPELVIC JUNCTION TO THE EXTERNAL URINE COLLECTION BAG DURING THE CONDITION OF MORE INFECTION IN BLADDER AND URETHRA,MODULAR HEAD -MULLER TYPE STD(EMHL/M/S/XL/XXL) (ENDOPRO-M)-USED IN TOTAL HIP ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED HIP FUNCTION,BILIARY

	PANCREATIC STENT/SET-WITH/WITHOUT HYDROPHILIC COATED (BPS)(DEVON)-USED TO DRAIN OBSTRUCTED BILIARY DUCTS, INTEGRAL BIPOLAR FOR CHARNLEY(ECIB)(BIPOLAR-C)-USED IN TOTAL HIP ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED HIP FUNCTION,COLLARLESS STEM WITH CENTRALIZER(ECLS)(ENDOPRO-CCS)-USED IN TOTAL HIP ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED HIP FUNCTION,STEINMANN PIN(NIL)-THE PURPOSE OF THE PRODUCTS IS THE RAPID AND COMPLETE RECOVERY OF THE DAMAGED BONE FUNCTION,KIRSCHNER WIRE(PARTIALLY/FULLY THREADED KIRSCHNER WIRE,L-WIRE,OLIVE WIRE,BAYONET TIP, SINGLE SIDED TROCAR)-(KW)(KIRSCHNER WIRE)-USED FOR INTERNAL FIXATION OF FRACTURES OF SMALL BONE FRAGMENTS TO THEIR PRESENT BONE,FIXED BIPOLAR PROSTHESIS TYPE-FENESTRATED/NON FENESTRATED (EBP/EBPF/EBPT/EBPFT/EBPNTR/EBPNFTR)(BIPOLAR)-USED IN TOTAL HIP ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED HIP FUNCTION,URETERAL INDWELLING SINGLE PIGTAIL(MONO-J) STENT/ SET - WITH/WITHOUT HYDROPHILIC COATED(DEVON)-USED FOR TEMPORARY INTERNAL DRAINAGE FROM THE URETEROPELVIC JUNCTION TO THE BLADDER,URETERAL INDWELLING DOUBLE PIGTAIL STENT/ SET (SHORT/LONG TERM) – WITH/WITHOUT HYDROPHILIC COATED(DJS)(OEO, BEO, OML OEO, OML BEO, BML BEO)(DEVON)-USED FOR TEMPORARY INTERNAL DRAINAGE FROM THE URETEROPELVIC JUNCTION TO THE BLADDER, FEMORAL COMPONENT CHARNLEY TYPE -STD(ECS/L/XL)(ENDOPRO-C)-USED IN TOTAL HIP ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED HIP FUNCTION,ACETABULAR CUP CHARNLEY TYPE-LPW/STD(ECCS/ECCL)(ENDOPRO-C)-USED IN TOTAL HIP ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED HIP FUNCTION,MODULAR BIPOLAR FOR MULLER (EMMB)(BIPOLAR-M)-USED IN TOTAL HIP ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED HIP FUNCTION, ACETABULAR CUP MULLER TYPE LPW/15 DEGREE LPW/STD (EMCS/EMCL/EMCLN)(ENDOPRO-M)-USED IN TOTAL HIP ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED HIP FUNCTION,FEMORAL COMPONENT MULLER TYPE -STD (EMS/EMST/L/XL)-WITH/WITHOUT HA COATED(ENDOPRO-M)-USED IN TOTAL HIP ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED HIP FUNCTION,ENDERNAILS(EN)(ENDERNAIL)-USED FOR TREATEMENT OF PRETROCHANTERIC AND SUBTROCHANTERIC FACTURES IN ELDERLY PATIENTS

3820	MFG/MD/2021/000160	1.License Holder Name: INFINITY MEDIQUIP INDIA PRIVATE LIMITED 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER-DIGITAL THERMOMETER IS USE TO TEST THE BODY TEMPERATURE OF THE PATIENT VIA MOUTH, ARMPIT, ANUS .IT CONTAINS AN ELECTRONIC CIRCUIT CONNECTED WITH A SENSOR TO TEST THE BODY TEMPERATURE,DIGITAL THERMOMETER(CODELIFE HEALTHCARE)-DIGITAL THERMOMETER IS USE TO TEST THE BODY TEMPERATURE OF THE PATIENT VIA MOUTH, ARMPIT, ANUS .IT CONTAINS AN ELECTRONIC CIRCUIT CONNECTED WITH A SENSOR TO TEST THE BODY TEMPERATURE,DIGITAL BLOOD PRESSURE MONITOR (INFI)-DIGITAL BP MONITOR IS USED TO MEASURE THE DIASTOLIC, SYSTOLIC BLOOD PRESSURE AND CALCULATING PULSE RATE BY USING AN INFLATABLE CUFF AROUND THE UPPER ARM,DIGITAL THERMOMETER(K&H SUREON)-DIGITAL THERMOMETER IS USE TO TEST THE BODY TEMPERATURE OF THE PATIENT VIA MOUTH, ARMPIT, ANUS .IT CONTAINS AN ELECTRONIC CIRCUIT CONNECTED WITH A SENSOR TO TEST THE BODY TEMPERATURE.,NON CONTACT INFRARED THERMOMETER-IT IS DEVICE USED TO RECORD THE BODY TEMPERATURE,NON CONTACT INFRARED THERMOMETER(INFI)-IT IS DEVICE USED TO RECORD THE BODY TEMPERATURE,DIGITAL BLOOD PRESSURE MONITOR-DIGITAL BP MONITOR IS USED TO MEASURE THE DIASTOLIC, SYSTOLIC BLOOD PRESSURE AND CALCULATING PULSE RATE BY USING AN INFLATABLE CUFF AROUND THE UPPER ARM,DIGITAL THERMOMETER(INFI)-DIGITAL THERMOMETER IS USE TO TEST THE BODY TEMPERATURE OF THE PATIENT VIA MOUTH, ARMPIT, ANUS .IT CONTAINS AN ELECTRONIC CIRCUIT CONNECTED WITH A SENSOR TO TEST THE BODY TEMPERATURE

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3821	MFG/MD/2021/000161	1.License Holder Name: MICROFINE SURGICAL DEVICES 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:COATED AND BRAIDED POLYESTER NON ABSORBABLE SURGICAL SUTURE USP. (MICROBOND)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,COATED AND BRAIDED POLYGLYCOLIC ACID ABSORBABLE SURGICAL SUTURE USP (MICROSYNTH)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,MONOFILAMENT POLYDIOXANONE ABSORBABLE SURGICAL SYNTHETIC SUTURE USP (MICROCRYL-PDS)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,MONOFILAMENT POLIGLECAPRONE-25, ABSORBABLE SURGICAL SYNTHETIC SUTURE USP(MICROCRYL-MONO)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION., MONOFILAMENT POLYPROPYLENE NON ABSORBABLE SURGICAL SUTURE USP(MICROLENE)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,CATGUT CHROMIC/PLAIN, ABSORBABLE SURGICAL SUTURE USP(MICROGUT)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,COATED AND BRAIDED POLYGLACTIN-910 ABSORBABLE SURGICAL SYNTHETIC SUTURE USP.(MICROCRYL)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,BLACK BRAIDED SILK NON ABSORBABLE SURGICAL SUTURE USP(MICROSIL)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.,MONOFILAMENT POLYAMIDE NON ABSORBABLE SURGICAL SUTURE USP(MICROLON)-THE DEVICE IS INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND LIGATION.
3822	MFG/MD/2021/000162	1.License Holder Name: RECOMBIGEN LABORATORIES PVT LTD 2.Approving Authority: NORTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:ALCOHOL SWAB WITH 70% ISOPROPYL ALCOHOL(URISIGN)-THE ALCOHOL SWAB IS A SINGLE USE, STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL. WHEN USED FOR SCRUBBING FOR 5 SECONDS AND ALLOWING DRYING FOR 5 SECONDS, THE ALCOHOL SWAB WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE. IT MAY BE USED IN THE HOME OR HEALTHCARE FACILITY.

3823	MFG/MD/2021/000163	1.License Holder Name: M/S ASTAM DIAGNOSTICS PVT. LTD. 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITORING DEVICES(PRATHAM® BLOOD PRESSURE MONITORING DEVICE)-IT IS DEVICE USED TO MEASURE THE DIASTOLIC AND SYSTOLIC BLOOD PRESSURES.,DIGITAL THERMOMETER(PRATHAM® DIGITAL THERMOMETER)-IT IS DEVICE USED TO RECORD THE BODY TEMPERATURE.
3824	MFG/MD/2021/000164	1.License Holder Name: MOREPEN LABORATORIES LTD. 2.Approving Authority: SOLAN(BBN) 3.Device Name(Brand Name)-Intended Use:BLOOD PRESSURE MONITOR(DR. MOREPEN)-THE DR. MOREPEN BLOOD PRESSURE MONITOR MODEL BP 15 IS A RAPID, SELF PERFORMING, AUTOMATIC SYSTEM FOR THE MEASUREMENT OF SYSTOLIC BLOOD PRESSURE, DIASTOLIC BLOOD PRESSURE AND PULSE RATE ON THE UPPER ARM OF THE USER.,DIGITAL THERMOMETER(DR.MOREPEN DIGICLASSIC)-THE DEVICE IS INTENDED FOR THE MEASUREMENT OF HUMAN BODY TEMPERATURE
3825	MFG/MD/2021/000165	1.License Holder Name: NOBLE PHARMACARE LIMITED 2.Approving Authority: ORISSA 3.Device Name(Brand Name)-Intended Use:AUTO DISABLE (AD) SYRINGE-USED TO INJECT, INFUSE OR WITHDRAW FLUIDS TO ADMINISTER INJECTION OR INFUSE INTRAVENOUS THERAPY INTO THE BLOODSTREAM.,STERILE HYPODERMIC SYRINGES FOR SINGLE USE WITH NEEDLE-USED TO INJECT, INFUSE OR WITHDRAW FLUIDS TO ADMINISTER INJECTION OR INFUSE INTRAVENOUS THERAPY INTO THE BLOODSTREAM.,HYPODERMIC SYRINGES FOR SINGLE USE-USED TO INJECT, INFUSE OR WITHDRAW FLUIDS TO ADMINISTER INJECTION OR INFUSE INTRAVENOUS THERAPY INTO THE BLOODSTREAM., STERILE HYPODERMIC NEEDLE-USED TO ADMINISTER INJECTIONS, INFUSE INTRAVENOUS THERAPY INTO THE BLOOD STREAM OR DRAW FROM THE BODY. ,STERILE HYPODERMIC SYRINGES FOR SINGLE USE-USED TO INJECT, INFUSE OR WITHDRAW FLUIDS TO ADMINISTER INJECTION OR INFUSE INTRAVENOUS THERAPY INTO THE BLOODSTREAM.,AUTO DISABLE (AD) SYRINGE WITH NEEDLE-USED TO INJECT, INFUSE OR WITHDRAW FLUIDS TO ADMINISTER INJECTION OR INFUSE INTRAVENOUS THERAPY INTO THE BLOODSTREAM WIDELY USED FOR IMMUNIZATION PROCESS.

3826	MFG/MD/2021/000166	1.License Holder Name: JAIMANI LIFECARE MEDICAL DEVICES PVT. LTD. 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:I V CANNULA WITH WINGS & WITHOUT PORT(JML CAN)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE,I V CANNULA WITH WINGS & WITH PORT (JML FLON)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE,I V CANNULA WITHOUT WINGS & WITHOUT PORT (JML ON)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE,I V CANNULA WITH SUTURABLE WING AND PORT (JML CATH)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE,I V CANNULA WITH SMALL WING AND WITHOUT PORT(JML NEONATES)-A CATHETER THAT IS INSERTED INTO A VEIN FOR SUPPLYING MEDICATIONS OR NUTRIENTS DIRECTLY INTO THE BLOODSTREAM OR FOR DIAGNOSTIC PURPOSES SUCH AS STUDYING BLOOD PRESSURE

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3827	MFG/MD/2021/000167	1.License Holder Name: SRI SANDANA MAGALINGAM TEXTILES 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:X-RAY DETECTABLE GAUZE SWABS IS 10829(SSMT)-THE NON-STERILE X-RAY DETECTABLE GAUZE SWABS ARE USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL AND TO APPLYING ANTISEPTIC,ABSORBENT COTTON RIBBON GAUZE IS 16670(SSMT)-ABSORBENT COTTON RIBBON GAUZE USED TO CLEAN, COLONIZED, CONTAMINATED OR INFECTED EXUDING WOUNDS, SUCH AS CAVITY WOUNDS AND FISTULAS,ABDOMINAL PAD(SSMT)-THE NON-STERILE ABDOMINAL PAD IS USED TO DRESSING FOR LARGE WOUNDS OR WOUNDS REQUIRE HIGH ABSORBENCY,GAUZE SWAB BP 1988(SSMT)-THE GAUZE SWAB ARE USED FOR CLEANING, DRYING AND DRESSING WOUNDS DURING A MEDICAL TREATMENT,ABSORBENT GAUZE IS 758 (SSMT)-THE ABSORBENT GAUZE ARE USED IN GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS,BANDAGE CLOTH (CUT) IS 863(SSMT)-THE BANDAGE CLOTH CUT IS USED EITHER TO COVERING WOUNDS, TO KEEP DRESSINGS IN PLACE OR TO SUPPORT A MEDICAL DEVICE,X-RAY DETECTABLE ABDOMINAL PAD BP 1988(SSMT)-THE LAPAROTOMY SPONGES IS USED IN SURGICAL PROCEDURES TO ABSORB BLOOD AND OTHER FLUIDS AS WELL AS CLEAN WOUNDS,BANDAGE CLOTH (UNCUT) IS 863(SSMT)-THE BANDAGE CLOTH UNCUT IS USED EITHER TO COVERING WOUNDS, TO KEEP DRESSINGS IN PLACE OR TO SUPPORT A MEDICAL DEVICE,X-RAY DETECTABLE LAPAROTOMY SPONGES IS 10829(SSMT)-THE NON-STERILE X-RAY DETECTABLE LAPAROTOMY SPONGES IS USED TO DRESSING FOR LARGE WOUNDS OR WOUNDS REQUIRE HIGH ABSORBENCY,GAUZE AND COTTON TISSUE BP 1988(SSMT)-GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS

3828	MFG/MD/2021/000168	1.License Holder Name: M V ENTERPRISE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:NON WOVEN DRESSING (NON WOVEN DRESSING)-FOR POST-OPERATIVE, MINOR CUTS, ABRASIONS AND LACERATIONS.,POLYURETHANE FILM DRESSING (POLYURETHANE FILM DRESSING)-FOR POST-OPERATIVE, MINOR CUTS, ABRASIONS AND LACERATIONS.,GAUZE(GAUZE)-FOR POST-OPERATIVE, MINOR CUTS, ABRASIONS AND LACERATIONS.,GAMJEE ROLL(GAMJEE ROLL)-FOR POST-OPERATIVE, MINOR CUTS, ABRASIONS AND LACERATIONS.,COMBINE DRESSING(COMBINE DRESSING)-FOR POST-OPERATIVE, MINOR CUTS, ABRASIONS AND LACERATIONS.
3829	MFG/MD/2021/000169	1.License Holder Name: INDIGENE MEDCORP PRIVATE LIMITED 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:SURGICAL ADHESIVE MICROPOROUS PAPER TAPE(INDIPORE)-DEVICE IS INTENDED TO BE APPLIED ON/COMES IN CONTACT WITH INTACT SKIN AND USED/APPLIED AS A FIXING DEVICE TO OTHER LOW RISK SURGICAL DRESSINGS, TUBINGS IN FIRST AID AND IN POST SURGICAL CARE. IT IS NOT INTENDED TO BE USED ON/APPLIED ON/COME IN CONTACT WITH BREACHED SKIN, BREACHED DERMIS AND BLOOD.
3830	MFG/MD/2021/000170	1.License Holder Name: AGROSURG IRRADIATORS (INDIA) PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:HAEMOSTATIC GELATIN SPONGE(ABGEL ®ABSORBABLE GELATIN SPONGE USP)-INTENDED FOR THE CONTROL OF SURFACE BLEEDING FROM VASCULAR ACCESS SITES AND PERCUTANEOUS CATHETERS OR TUBES / IN VARIOUS SURGERIES FOR HAEMOSTATIS, WHEN CONTROL OF CAPILLARY, VENOUS AND ARTERIOLAR BLEEDING BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURE IS INEFFECTIVE OR IMPRACTICAL.
3831	MFG/MD/2021/000171	1.License Holder Name: NUBENO HEALTHCARE PRIVATE LIMITED 2.Approving Authority: NAGPUR DIVISION 3.Device Name(Brand Name)-Intended Use:HYPODERMIC SYRINGES WITH AND WITHOUT NEEDLE -INTENDED FOR THE INJECTION OF MEDICATIONS INTO OR THE WITHDRAWAL OF BODY FLUIDS FROM PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN.

3832	MFG/MD/2021/000172	1.License Holder Name: VIM MEDITECH PRIVATE LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE PRE FILLABLE GLASS SYRINGE LT 5 ML(- - - -)-INTEND TO INJECT FLUIDS INTO THE BODY,STERILE DISPOSABLE PRE FILLABLE POLYMER SYRINGE LT 2.25 ML(- - -)-INTEND TO INJECT FLUIDS INTO THE BODY, STERILE DISPOSABLE PRE FILLABLE POLYMER SYRINGE LT 5 ML(- - -)-INTEND TO INJECT FLUIDS INTO THE BODY,STERILE DISPOSABLE PRE FILLABLE GLASS SYRINGE SN 1 ML(- - -)-INTEND TO INJECT FLUIDS INTO THE BODY.,STERILE DISPOSABLE PRE FILLABLE GLASS SYRINGE LT 2.25 ML(=- - - -)-INTEND TO INJECT FLUIDS INTO THE BODY,STERILE DISPOSABLE PRE FILLABLE POLYMER SYRINGE LT 1 ML(- - -)-INTEND TO INJECT FLUIDS INTO THE BODY

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3833	MFG/MD/2021/000173	1.License Holder Name: RUDRAKSH PHARMA & SURGICO PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE STOMACH TUBE FOR SINGLE USE ONLY(KLASSIC/ANGEL/JMB/HARIRIAM)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH NOSE. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING,STERILE ABDOMINAL DRAINAGE KIT FOR SINGLE USE ONLY (KLASSIC/ANGEL/JMB/HARIRIAM)-ABDOMINAL DRAINAGE KIT ARE USE IN THE POST OPERATIVE DRAINAGE FROM ABDOMINAL AREAS, STERILE SUCTION CATHETER WITH THUMB CONTROL FOR SINGLE USE ONLY(KLASSIC/ANGEL/JMB/HARIRIAM)-SUCTION CATHETERS FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.,STERILE DISPOSABLE NASOGASTRIC/RYLE'S/DUODENAL TUBE FOR SINGLE USE ONLY (KLASSIC/DISPOWAY/JMB/ANGEL)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES.,STERI;E DISPOSABLE UMBILICAL CATHETER FOR SINGLE USE ONLY(KLASSIC/ANGEL/JMB/HARIRIAM)-UMBILICAL ARTERY CATHETERIZATION PROVIDES DIRECT ACCESS TO THE ARTERIAL BLOOD SUPPLY AND ALLOWS ACCURATE MEASUREMENT OF ARTERIAL BLOOD PRESSURE, A SOURCE OF ARTERIAL BLOOD SAMPLING, AND INTRAVASCULAR ACCESS FOR FLUIDS AND MEDICATIONS.,STERILE CHEST DRAINAGE CATHETER / THORACIC DRAINAGE CATHETER WITH OR WITHOUT TROCAR FOR SINGLE USE ONLY(KLASSIC/ANGEL/JMB/HARIRIAM)-THE THORACIC DRAINAGE CATHETER IS USED TO REMOVE PUS , BLOOD OR OTHER FLUID FROM A WOUND.,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(KLASSIC/DISPOWAY/JMB/ANGEL)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE INTRAVENOUS CANNULA FOR SINGLE USE ONLY (KLASSIC/ANGEL/JMB/HARIRIAM)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES .,STERILE MALE EXTERNAL CATHTHER FOR SINGLE USE ONLY(KLASSIC/ANGEL/JMB/HARIRIAM)-IT IS USE FOR URINE INCONTINENCE FOR DAY AND NIGHT USE IN A MALE PATIENT & IS CONNECTED TO URINE BAG,STERILE CLOSED WOUND SUCTION UNIT FOR SINGLE USE ONLY (KLASSIC/ANGEL/JMB/HARIRIAM)-EXTRACT PUS FROM THE WOUND OF A HUMAN BODY,STERILE DISPOSABLE EXTENSION LINE WITH / WITHOUT THREE WAY STOP COCK FOR SINGLE USE ONLY

	(KLASSIC/ANGEL/JMB/HARIRIAM)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,STERILE KARMAN CANNULA FOR SINGLE USE ONLY(KLASSIC/ANGEL/JMB/HARIRIAM)-USED IN IRRIGATION DURING TRANS URETHRAL RESECTION OF PROSTATE GLAND, STERILE URETHRAL CATHETER FOR SINGLE USE ONLY (KLASSIC/ANGEL/JMB/HARIRIAM)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE DISPODABLE HIGH PRESSURE MONITORING LINE FOR SINGLE USE ONLY(KLASSIC/ANGEL/JMB/HARIRIAM)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR THE INFUSION OF FLUIDS/ MEDICATIONS IN MEDICAL APPLICATIONS., STERILE DISPOSABLE ENDOTRACHEAL TUBE FOR SINGLE USE ONLY (KLASSIC/ANGEL/JMB/HARIRIAM)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CORDS.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (KLASSIC/DISPOWAY/SARACARE/CADI V I. V. SET/HARIRAM/SAFE TRANSFUSION SET/JMB/ ANGEL)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE MICRO DRIP INFUSION SET WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (KLASSIC/ANGEL/JMB/HARIRIAM)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/ DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR A CATHETER INSERTED INTO A VEIN,STERILE DISPOSABLE UMBILICAL CORD CLAMP FOR SINGLE USE ONLY (KLASSIC/ANGEL/JMB/HARIRIAM)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE INFANT MUCUS EXTRACTOR CATHETER FOR SINGLE USE ONLY (KLASSIC/ANGEL/JMB/HARIRIAM)-CLEARING THE AIRWAYS OF MUCUS, PUS, OR ASPIRATED MATERIALS TO IMPROVE OXYGENATION AND VENTILATION.,STERILE DISPOSABLE SCALP VEIN SET FOR SINGLE USE ONLY- - -(KLASSIC/JMB/ANGEL)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD,STERILE FOLEY BALLOON CATHETER 2 WAY AND 3 WAY FOR SINGLE USE ONLY (KLASSIC/ANGEL/JMB/HARIRIAM)-A LONG SMALL GAUGE

		CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE NELATON CATHETER FOR SINGLE USE ONLY(KLASSIC/ANGEL/JMB/HARIRIAM)-A LONG SMALL GAUGE CATHETER DESIGNED FOR INSERTION DIRECTLY INTO A URETER EITHER THROUGH THE URETHRA AND BLADDER OR POSTERIORLY VIA THE KIDNEY.,STERILE YANKAUR SUCTION SET FOR SINGLE USE ONLY(KLASSIC/ANGEL/JMB/HARIRIAM)-YANKAUR SUCTION SET ARE USED FOR THE REMOVAL OF BLOOD AND FLUIDS DURING SURGERY.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY (KLASSIC/DISPOWAY BLOOD AIRVENT/CADI V BLOOD/ PARADIGM/JMB/ANGEL)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFANT FEEDING TUBE FOR SINGLE USE ONLY (KLASSIC/ANGEL/JMB/HARIRIAM)-A FEEDING TUBE IS A DEVICE THAT'S INSERTED INTO YOUR STOMACH THROUGH NOSE. IT'S USED TO SUPPLY NUTRITION WHEN YOU HAVE TROUBLE EATING
3834	MFG/MD/2021/000174	1.License Holder Name: MOHAN PHARMA 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:ROLLED BANDAGE (NON - STERILE)-BANDAGES OR ROLLED BANDAGES ARE USED EXTENSIVELY IN HEALTH CARE INSTITUTIONS AND HOME . THE USES OF BANDAGES RANGE FROM SIMPLE DRESSING OF SUPERFICIAL WOUNDS TO HOLDING TOGETHER FRACTURED BONES OR BODY PARTS FOR REHABILITATION AND RECOVERY.,ABSORBENT GAUZE CLOTH (NON - STERILE)-GAUZE CAN BE USED FOR CLEANSING, PACKING, SCRUBBING, COVERING, AND SECURING IN A VARIETY OF WOUNDS. CLOSELY WOVEN GAUZE IS BEST FOR EXTRA STRENGTH OR GREATER PROTECTION, WHILE OPEN OR LOOSE WEAVE IS BETTER FOR ABSORBENCY OR DRAINAGE.,BANDAGE CLOTH (NON STERILE)-BANDAGES ARE USED EXTENSIVELY IN HEALTH CARE INSTITUTIONS AND HOME THE USES OF BANDAGES RANGE FROM SIMPLE DRESSING OF SUPERFICIAL WOUNDS TO HOLDING TOGETHER FRACTURED BONES OR BODY PARTS FOR REHABILITATION AND RECOVERY

3835	MFG/MD/2021/000175	1.License Holder Name: GREEN APPLE SURGITECH PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:INTRAMEDULLARY LOCKING NAIL(GREEN APPLE / GASPL)-NAILS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE. ,HIP PROSTHESIS (GREEN APPLE / GASPL)- PROSTHESIS IS A DEVICE INTENDED TO BE IMPLANTED TO REPLACE FEMUR PROXIMAL AREA ARE FRACTURED BADLY. PROSTHESIS IS USED IN PROXIMAL FEMUR BONE FRACTURES, WHERE IS FEMUR PROXIMAL AREA ARE FRACTURED BADLY, THE SURGEON REMOVED PROXIMAL AREA AND THEY FIXED PROSTHESIS AND FIX WITH FEMUR DISTAL PART,BONE PLATES (GREEN APPLE / GASPL)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE SCREW(GREEN APPLE / GASPL)-BONE SCREWS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE. ,BONE PLATES(GREEN APPLE / GASPL)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE., SPINE IMPLANTS(GREEN APPLE / GASPL)-SPINAL IMPLANTS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE,BONE SCREW (GREEN APPLE / GASPL)-BONE SCREWS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,PINS & WIRES(GREEN APPLE / GASPL)-PINS AND WIRES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE. ,PINS & WIRES(GREEN APPLE / GASPL)-PINS AND WIRES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,PINS & WIRES(GREEN APPLE / GASPL)-PINS AND WIRES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,

	BONE PLATES(GREEN APPLE / GASPL)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE. ,BONE PLATES(GREEN APPLE / GASPL)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE. ,HIP PROSTHESIS(GREEN APPLE / GASPL)-PROSTHESIS IS A DEVICE INTENDED TO BE IMPLANTED TO REPLACE FEMUR PROXIMAL AREA ARE FRACTURED BADLY. PROSTHESIS IS USED IN PROXIMAL FEMUR BONE FRACTURES, WHERE IS FEMUR PROXIMAL AREA ARE FRACTURED BADLY, THE SURGEON REMOVED PROXIMAL AREA AND THEY FIXED PROSTHESIS AND FIX WITH FEMUR DISTAL PART,INTRAMEDULLARY LOCKING NAIL(GREEN APPLE / GASPL)-NAILS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE., INTRAMEDULLARY LOCKING NAIL(GREEN APPLE / GASPL)-NAILS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE. ,BONE SCREWS(GREEN APPLE / GASPL)-BONE SCREWS ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.,BONE PLATES(GREEN APPLE / GASPL)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE. ,BONE PLATES(GREEN APPLE / GASPL)-BONE PLATES ARE INDICATED FOR USE IN BONE RECONSTRUCTION, OSTEOTOMY, ARTHRODESIS, JOINT FUSION, FRACTURE REPAIR, AND FRACTURE FIXATION, APPROPRIATE FOR THE SIZE OF THE DEVICE.

3836	MFG/MD/2021/000176	1.License Holder Name: CARDIOMAC INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ANGIOGRAPHIC GUIDE WIRE(RADIX)-IT DELIVERS RADIO OPAQUE MEDIA AND THERAPEUTIC AGENTS TO SELECTED SITES IN THE VASCULAR SYSTEM. IT IS ALSO USED TO LEAD A GUIDE WIRE OR A CATHETER INTO THE TARGET SITE.,PTCA CATHETER KIT(PROCONNEKT)-THE CATHETER IS PLACED IN THE OPENING OR OSTIUM OF ONE THE CORONARY ARTERIES., CENTRAL VENOUS CATHETER(AVRO)-IT IS INDICATED FOR USE IN PATIENTS REQUIRING ADMINISTRATION OF SOLUTIONS,BLOOD SAMPLING,CENTRAL VENOUS PRESSURE MONITORING,AND INJECTION OF CONTRAST MEDIA.,INTRODUCER SHEATH(PROCTRA)-INTENDED TO PROVIDE EASIER ACCESS TO THE FEMORAL,POPLITEAL AND INFRAPOPLITEAL ARTERIES.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3837	MFG/MD/2021/000177	1.License Holder Name: M/S MICROTROL STERILISATION SERVICES PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:POLYESTER & POLYURETHANE COMPOSITE DUAL-SIDE 3D MESH FOR INTRA-PERITONEAL PLACEMENT(PROVISC 3D MESH)-PRO- VISC 3D – IS A STERILE POLYESTER AND POLYURETHANE DUAL SIDE MESH IS USED FOR THE INTRA-PERITONEAL PLACEMENT. TREATMENT FOR VENTRAL AND UMBILICAL HERNIAS.,POLY(GLYOCOLIDE-CO-CAPROLACTONE) & POLYPROPYLENE PARTIALLY ABSORBABLE LIGHT WEIGHT MESH FOR HERNIA REPAIR(PRO-AB MESH)-PRO-AB IS A POLYPROPYLENE AND POLY (GLYCOLIDE CO-CAPROLACTONE) COMPOSITE MESH IS USED FOR THE REPAIR OF HERNIA OR OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITIONAL OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT.,MONOFILAMENT POLYESTER NON ABSORBABLE MESH(ESTERLUS MESH)-POLYESTER MESH IS USED FOR ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISION, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS. USED IN BOTH COELIOSCOPY AND LAPAROTOMY.,TITANIUM HAEMOSTATIC CLIP (HEMOSEC)-THE HEMOSEC TITANIUM CLIP IS USED TO OCCLUDE VESSELS. WITH ITS HERRINGBONE SHAPE IT CAN ENCOMPASS THE ENTIRE VESSEL TO BE LIGATED. THE MICRO GEOMETRY OF THE CLIPS INNER SURFACE PROVIDES FOR EXCELLENT GRIP ON THE VESSEL. THIS CLIP MAY BE USED FOR ALL SURGICAL PROCEDURE REQUIRING HAEMOSTATIC OR RADIOGRAPHIC MARKING. CLIP SIZE IS TO BE CHOSEN BY THE USER IN RELATION TO THE INTENDED PROCEDURE TO ENSURE THAT THE WHOLE OF THE TISSUE TO BE LIGATED IS CONTAINED WITHIN THE CLIP.,BRAIDED COATED SILK SYNTHETIC NON- ABSORBABLE SUTURE(SILKUS / SILK-R / PREMISUT SILK / SILKRIL)-SILKUS SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/ OR LIGATION INCLUDING USE IN NEUROLOGICAL PROCEDURE.,BRAIDED COATED POLYESTER SYNTHETIC NON- ABSORBABLE SUTURE(ESTERLUS / POLYESTER / PREMISUT POLYESTER)-ESTERLUS SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/ OR LIGATION INCLUDING USE IN CARDIOVASCULAR SURGERY AND NEUROLOGICAL PROCEDURE.,CHROMIC AND PLAIN CATGUT ABSORBABLE SURGICAL SUTURE (COLLAGEN)(LOGUT / CATGUT-R / PREMISUT CATGUT)-INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND OR LIGATION, INCLUDING USE IN PLASTIC SURGERY AND IN OPHTHALMIC PROCEDURES.,BRAIDED COATED POLY (GLYCOLIDE-L-LACTIDE)/POLYGLACTIN-910 SYNTHETIC ABSORBABLE SUTURE(SOLUS 910 / RENACRYL / PREMISUT PGLA /

	SYLUS 910)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,BRAIDED COATED SHORT TERM POLY (GLYCOLIDE-L-LACTIDE)/POLYGLACTIN-910 SYNTHETIC ABSORBABLE SUTURE(SOLUS SWIFT 910 / PREMISUT PGLAR / SYLUS SWIFT 910)-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL.,MONOFILAMENT POLYPROPYLENE MESH(PROLUS MESH / PREMISUT POLYPROPYLENE MESH / PROLIPRO MESH)-POLYPROPYLENE MESH USED FOR ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISIONAL, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS. USED IN BOTH COELIOSCOPY AND LAPAROTOMY.,MONOFILAMENT KNITTED POLYPROPYLENE MESH(PROLUS ECO MESH)-POLYPROPYLENE MESH USED FOR ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISIONAL, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS. USED IN BOTH COELIOSCOPY AND LAPAROTOMY.,MONOFILAMENT POLYPROPYLENE MESH(FREEDOM VM)-FREEDOM VM (POLYPROPYLENE MESH)- TRANS OBTURATOR SLING SYSTEM IS INTENDED FOR THE PLACEMENT OF A SUB-URETHRAL MESH FOR THE TREATMENT OF FEMALE STRESS INCONTINENCE (SUI) RESULTING FROM URETHRAL HYPER MOBILITY AND / OR INTRINSIC SPHINCTER DEFICIENCY.,POLYESTER & POLYURETHANE COMPOSITE DUAL MESH FOR INTRA-PERITONEAL PLACEMENT(PROVISC MESH)-POLYPROPYLENE MESH USED FOR ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISIONAL, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS. USED IN BOTH COELIOSCOPY AND LAPAROTOMY.,BRAIDED COATED SILK SYNTHETIC NON-ABSORBABLE SUTURE(SILKUS (REEL))-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION., BRAIDED COATED POLYGLYCOLIC ACID SYNTHETIC ABSORBABLE SUTURE(SOLUS / PGA30 / PREMISUT PGA)-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION AND/OR LIGATION.,MONOFILAMENT POLY (P-DIOXANONE) SYNTHETIC ABSORBABLE SUTURE(MASS / PDX60 / PREMISUT PDO)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION IN MICROSURGERY AND IN OPHTHALMIC SURGERY.,MONOFILAMENT POLY (GLYCOLIDE-CO-CAPROLACTONE)/ POLYGLECAPRONE-25 SYNTHETIC ABSORBABLE SUTURE(MONOLUS / PGC 30 / PREMISUT PGCL)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION,,MONOFILAMENT POLYAMIDE SYNTHETIC NON- ABSORBABLE SUTURE(NYLUS / NYLON / PREMISUT NYLON)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/ OR LIGATION INCLUDING USE IN CARDIOVASCULAR SURGERY AND NEUROLOGICAL PROCEDURE.,

	LIGHT WEIGHT MONOFILAMENT POLYPROPYLENE MESH(PROLUS LITE MESH)-POLYPROPYLENE MESH USED FOR ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISIONAL, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS. USED IN BOTH COELIOSCOPY AND LAPAROTOMY.,POLYTETRAFLUOROETHYLENE (PTFE) INTRA-CARDIAC PATCH(PLEDGETS)-PTFE PLEDGETS USED IN VARIOUS APPLICATIONS FOR GENERAL, VASCULAR AND CARDIAC SURGERY. PLEDGETS ARE USED AS BUTTRESSES UNDER SUTURES WHEN THERE IS A POSSIBILITY OF SUTURES TEARING THROUGH TISSUE. PTFE PLEDGETS ARE INDICATED FOR THE PURPOSES OF TISSUE APPROXIMATION, RETRACTION, AND AS A TEMPORARY OR PERMANENT LIGATURE.,BRAIDED COATED SHORT TERM POLYGLYCOLIC ACID SYNTHETIC ABSORBABLE SUTURE(SOLUS SWIFT / PGA15 / PREMISUT PGAR)-INTENDED FOR USE IN SOFT TISSUE APPROXIMATION WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL.,ULTRA LIGHT WEIGHT POLYPROPYLENE MESH(PROLUS ULTRA LITE MESH)-POLYPROPYLENE MESH USED FOR ABDOMINAL WALL REINFORCEMENT, TREATMENT OF INCISIONAL, INGUINAL, FEMORAL, UMBILICAL AND VENTRAL HERNIAS. USED IN BOTH COELIOSCOPY AND LAPAROTOMY.,MONOFILAMENT POLYPROPYLENE SYNTHETIC NON- ABSORBABLE SUTURE(PROLUS / PROLIN-R / POLYPROP / PREMISUT POLYPROPYLENE / PROLIPRO)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/ OR LIGATION INCLUDING USE IN CARDIOVASCULAR SURGERY AND NEUROLOGICAL PROCEDURE.,MONOFILAMENT 316L STAINLESS STEEL SYNTHETIC NON- ABSORBABLE SUTURE(STELUS / PREMISUT STEEL)-INDICATED FOR USE IN ABDOMINAL WOUND CLOSURE, HERNIA REPAIR, STERNA CLOSURE AND ORTHOPEDIC PROCEDURES INCLUDING CERCLAGE AND TENDON REPAIR

3838	MFG/MD/2021/000178	1.License Holder Name: KEYUR PHARMACHEM INDIA PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:STICKERING, STAMPING AND OVERPRINTING ON FINISHED PRODUCT PACKINGS WITHOUT CHANGING ORIGINAL LABEL(NA)-NA,

3839	MFG/MD/2021/000179	1.License Holder Name: M/S ELECTRO MAGNETIC INDUSTRIES 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ABSORBABLE GELATINE SPONGE(SURGISPON®, MEDISPONGE, UNISPONGE, BLOXANG, GEL-SPONGE, HEMOGEL, HEMOSPONGE, PERISPONGE™, SURGIGEL, TOP DENT DENTOSTAN, EVOSPON, CLINIX, HYGITECH, R&S, KENTDENTAL, OCTOCALOGEN, TOPISPON, SURGISENZ, MVG, SCHMIDT, ILION DENTAL, GELASPON, GELASPON KDM, PROCLINIC, BESTDENT, STELLIGEL, BIOSPONGE, FLOSPONG, SMI-SPON, MEDISPON, CLINISPON, I-SPONGE, MERIFEIM, DSI SPONGE, CHIRUSPONGE, MERIFOAM, IDSPONGE, DENTOSPON, KARESPON, HEMOSPON, ALPHA-SPON)-ABSORBABLE HAEMOSTATIC GELATIN SPONGE CAN BE EFFECTIVELY USED IN VARIOUS SURGERIES FOR HAEMOSTASIS, WHEN CONTROL OF CAPILLARY, VENOUS AND ARTERIOLAR BLEEDING BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS INEFFECTIVE OR IMPRACTICAL.,OXIDIZED REGENERATED CELLULOSE HAEMOSTAT(SURGI-ORC)-THE SURGI-ORC HAEMOSTAT IS USED ADJUNCTIVELY IN VARIOUS SURGICAL PROCEDURES TO ASSIST WHEN CONTROL OF BLEEDING FROM CAPILLARY, VENOUS AND SMALL ARTERIOLAR VESSELS, BY PRESSURE, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS EITHER INEFFECTIVE OR IMPRACTICAL. THE SURGI-ORC HAEMOSTAT CAN BE CUT TO SIZE IN ENDOSCOPIC PROCEDURES.,ABSORBABLE GELATIN SPONGE WITH COLLOIDAL SILVER(DENTOSPON)-THE TREATMENT OF ALVEOLI AND WOUND CAVITIES, E.G. AFTER EXTRACTIONS, CYSTECTOMIES, CYSTOSTOMIES, APICAL AMPUTATIONS, MAXILLARY SINUS PERFORATIONS, FOLLOWING SURGICAL REMOVAL OF TUMOURS OR RETAINED TEETH; PREVENTION OF SECONDARY CAVITY FORMATION; PROPHYLAXIS OF WOUND INFECTIONS; SECONDARY HAEMORRHAGE PROPHYLAXIS; AS A DRESSING AFTER GINGIVECTOMY; IN PERIODONTOPATHIES;

3840	MFG/MD/2021/000180	1.License Holder Name: SURGI AID LIFECARE PRIVATE LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ELASTIC ADHESIVE BANDAGE BP- I.V CANNULA FIXATOR(SURGIFIX)-THE IV CANNULA FIXATOR FASTENS THE TUBE FIRMLY TO THE SKIN, WHILST THE PAD COVERS THE POINT OF INJECTION. THE DRESSING ALLOWS AIR AND HUMIDITY TO PASS FREELY. ,ELASTIC ADHESIVE BANDAGE BP (SURGIBAND)-THIS IS USED FOR MAINTAINING DRESSING IN ITS POSITION AFTER OPERATION, FRACTURE OF MANDIBLE RIBS, SPRAINS & MUSCLES INJURIES, ETC. EXCELLENT AS PRESSURE DRESSING, PROVIDES ADEQUATE COMPRESSION AND BETTER MOBILITY,COTTON CREPE BANDAGE(STRAPE CREPE)-THIS IS USED AS A COMPRESSION BANDAGE FOR ALL CHRONIC LEG CONDITION AS PRESSURE DRESSING. • ORTHOPEDIC, REHABILITATION & SPORTS INJURIES. • USED FOR THE TREATMENT OF SPRAINS, ACHES, DISLOCATION, PAINFUL JOINTS, VARICOSE VEINS, CRAMPS, SKIN GRAFTING, POST OPERATIVE CONDITIONS & MUSCLES STRAIN.

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3841	MFG/MD/2021/000181	1.License Holder Name: M/S. S. NATH & CO. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(IDEAL/FINESTER)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE MEASURED VOLUME INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(IDEAL, FINESTER)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE MICRO DRIP INFUSION SET WITH AND WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(IDEAL/FINESTER)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH AND WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (FOR EXPORT ONLY)(TRUCARE)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH AND WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (IDEAL/FINESTER/TRUCARE)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.
3842	MFG/MD/2021/000182	1.License Holder Name: JUPITER REAGENTS 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ALCOHOL SWAB(GAMA DEX)-IT IS A SINGLE USE STERILER DEVICE CONTAINING 70 % ISO PROPYL ALCOHOL USE FOR SCRUBBING AND ALLOWING DRYING AND WILL DISINFECT NEEDLESS ACESS SITES PRIOR TO USE.

3843	MFG/MD/2021/000183	1.License Holder Name: AGROSURG IRRADIATORS(INDIA) PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:TCU 380 PLUS IUD WITH PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,TUBAL RING(SMB)-CONTRACEPTION IN WOMAN, COPPER T 380A(TCU 380A/CUT 380A)- POST DELIVERY IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,NON ABSORBABLE SURGICAL BRAIDED POLYESTER SUTURE WITH NEEDLE(SMB)-THIS DEVICE IS INTENDED FOR WOUND CLOSURE, TCU 380AG IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,CU 250 IUD WITH PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,TCU 380AG IUD WITH PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,CU 250 IUD (SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,NON ABSORBABLE SURGICAL POLYAMIDE MONOFILAMENT SUTURE WITH NEEDLE(SMB)-THIS DEVICE IS INTENDED FOR WOUND CLOSURE,CU 375 IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,TCU 375 AU IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,NON ABSORBABLE SURGICAL BRAIDED SILK SUTURE WITH NEEDLE(SMB)-THIS DEVICE IS INTENDED FOR WOUND CLOSURE, COPPER T 380A (TCU 380A/CUT 380A)IUD(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMEN OF CHILD BEARING AGE,COPPER T 380A(TCU 380A/CUT 380A)IUD WITH PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,COPPER T 380A(TCU 380A/CUT 380A)IUD WITH SAFE LOAD AND PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE,TCU 380PLUS IUD(SMB)-INTRAUTERINE CONTRACEPTION IN WOMAN OF CHILD BEARING AGE,CU 375 IUD WITH PROBE(SMB)-INTRAUTERINE CONTRACEPTION IN THE WOMAN OF CHILD BEARING AGE
3844	MFG/MD/2021/000184	1.License Holder Name: RAXON BIOMEDICAL 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:NEBULISER MACHINE (RAXON RAXNEB)-USED FOR AEROSOL THERAPY FOR BRONCHITIS, ASTHMA, ALLERGIES AND OTHER RESPIRATORY DISORDERS.

3845	MFG/MD/2021/000185	1.License Holder Name: INDOCOAR PHARMA PRIVATE LIMITED 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:COMPRESSION TAPE - ELASTIC ADHESIVE BANDAGE-COMPRESSION TAPE IS BANDAGE IT IS USED EXTERNALLY ,ENDOTRACHEAL TUBE FIXATION TAPE -TO SECURE AND STABILIZE ET TUBES
3846	MFG/MD/2021/000187	1.License Holder Name: SHREE RAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: NORTH DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON GAUZE RIBBON-USED IN DRESSINGS,ABDOMINAL PAD-TO CLEAN WOUNDS,COMBINED DRESSING PAD-THESE ARE IDEAL FOR HANDLING HEAVY DRAINAGE, PROMOTING HEALING AND KEEPING THE WOUND DRY FOR OPTIMAL COMFORT AND RELIEF,IV CANNULA FIXATOR-IV CANNULA FIXATOR IS HELPFUL FOR FIXING IV CANNULA, GAUZE SWAB-FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, APPLYING ANTISEPTIC,GAMJEE ROLL-FOR THE CLEANING AND DRYING PURPOSE,ABSORBENT GAUZE CLOTH-FOR CLEAN THE WOUND
3847	MFG/MD/2021/000188	1.License Holder Name: JIMIT MEDICO SURGICALS PRIVATE LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSAB;E MEASURED VOLUME INFUSION SET BIS 12655(FOR EXPORT ONLY) (NUBENO MEASURED VOLUME SET)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.

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3848	MFG/MD/2021/000189	1.License Holder Name: M/S KESHAVA MEDI DEVICES PVT.LTD 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:INFUSION SET VENTED & NON-VENTED(DORA)-PERFUSION SETS OR I.V. SETS ARE INTENDED FOR INTRAVENOUS FLUID SUPPLY,HYPODERMIC DISPOSABLE SYRINGE WITHOUT NEEDLE(DORA ONE)-TO BE USED ALONG WITH PROPER SIZE OF NEEDLE INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,HYPODERMIC DISPOSABLE SYRINGE WITH NEEDLE(DORA)-IT IS USED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY AND ALSO INSULIN PURPOSE, HYPODERMIC DISPOSABLE SYRINGE WITHOUT NEEDLE(DORA)-TO BE USED ALONG WITH PROPER SIZE OF NEEDLE INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY,HYPODERMIC DISPOSABLE SYRINGE WITH NEEDLE(DORA ONE)-IT IS USED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY, HYPODERMIC DISPOSABLE NEEDLE(DORA ONE)-THE STERILE HYPODERMIC NEEDLES ARE USED WITH A SYRINGE FOR THE INJECTION OF DRUGS AND VACCINES OR FOR THE EXTRACTION OF BLOOD,HYPODERMIC DISPOSABLE SYRINGE WITH NEEDLE(DORA)-IT IS USED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY
3849	MFG/MD/2021/000190	1.License Holder Name: SUGII SURGICAL INDIA PVT. LTD. 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:ABSORBABLE SURGICAL SUTURES USP (SYNTHETIC), STERILISED SURGICAL NEEDLED SUTURE AND STERILISED SURGICAL SUTURE (WITHOUT NEEDLE) , BRAIDED & COATED POLYGLYCOLIC ACID(ZENGLYDE, MENDGLYDE, IM- GLYDE)-USED IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC BUT IT IS NOT FOR USE IN CARDIOVASCULAR & NEUROLOGICAL TISSUES, IT IS USED WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL., ABSORBABLE SURGICAL SUTURES USP, STERILISED SURGICAL NEEDLED SUTURE AND STERILISED SURGICAL SUTURE (WITHOUT NEEDLE), CATGUT CHROMIC(ZENGUT, MENDGUT, IM-GUT)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, BUT NOT IN CARDIOVASCULAR OR NEUROLOGICAL SURGERY.

3850	MFG/MD/2021/000191	1.License Holder Name: BIOSHIELDS-A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: GOA 3.Device Name(Brand Name)-Intended Use:0.55% W/V ORTHO-PHTHALALDEHYDE(OPAHYDE)-OPAHYDE IS INDICATED FOR USE AS A HIGH LEVEL DISINFECTANT (E.G.; GI ENDOSCOPES, ANAESTHESIA EQUIPMENT FOR THE AIRWAY, DIAPHRAGM FITTING RINGS, DENTAL BURRS, HANDPIECES,ETC.) WITH A SOAK TIME OF 12 MINUTES.
3851	MFG/MD/2021/000192	1.License Holder Name: M/S UNIVERSAL MEDICAP LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:POLYVINYL ALCOHOL MEDICAL SPONGE DRESSING (OPHTHALMIC SERIES)(SURGI-PVA)-SURGI-PVA OPHTHALMIC SPONGES ARE INTENDED TO BE USED IN OPHTHALMIC OR MICROSCOPIC SURGICAL PROCEDURES TO ASSIST IN ABSORBING EXCESS FLUIDS FROM THE OPERATIVE FIELD IN MANAGEMENT OF FLUID I.E. FLUID CONTROL AND DRAINAGE CONTROL.,POLYVINYL ALCOHOL MEDICAL SPONGE DRESSING (ENT SERIES)(SURGI-PVA)-SURGI-PVA ENT SPONGES ARE INTENDED TO BE USED FOR PLACING INSIDE THE NASAL CAVITIES OR EAR CANAL FOR EPISTAXIS AND POST-OPERATIVE SURGERY, WHICH EXPANDS WHEN MOISTENED TO ASSIST IN MANAGEMENT OF FLUIDS I.E. FLUID CONTROL AND DRAINAGE CONTROL AND TAMPONADE OR HAEMOSTASIS.
3852	MFG/MD/2021/000193	1.License Holder Name: ASCENT MEDITECH LIMITED 2.Approving Authority: DADRA AND NAGAR HAVELI 3.Device Name(Brand Name)-Intended Use:COTTON CREPE BANDAGE B.P.(FLAMICREPE)-INTENDED USE OF FLAMICREPE IS TO OFFER COMPRESSION AND SUPPORT FOR ORTHOPAEDIC AND GENERAL PURPOSE.,ELASTIC ADHESIVE BANDAGE B.P. I.V.CANNULA FIXATOR (FLAMIGRIP)-FLAMIGRIP IS USED FOR FIXATING I.V. CANNULA SECURELY AND SAFELY.,ADHESIVE TAPE USP(FLAMITAPE)-INTENDED USE OF FLAMITAPE IS TO AFFIX DRESSING IN POSITION ON WOUND.,ELASTIC ADHESIVE BANDAGE B.P.(FLAMIPLAST)-INTENDED USE OF FLAMIPLAST IS, ELASTIC ADHESIVE BANDAGE FOR SUPPORT, COMPRESSION AND FIXATION AFTER SURGERY OR INJURY.

3853	MFG/MD/2021/000194	1.License Holder Name: BL LIFESCIENCES PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER(VENX)-CVC IS USED FOR CATHETERIZATION OF SUPERIOR VENA CAVA USING SELDINGER TECHNIQUE IN INFUSION THERAPY OR PARENTERAL NUTRITION, APPLICATION OF VEIN IRRITATING SOLUTIONS, FOR INTERMITTENT OR CONTINUOUS MONITORING OF CENTRAL VENOUS PRESSURE & FOR BLOOD SAMPLING.,INTRODUCER SET(ANGIX)-INTRODUCER SET INCLUDING ITS ACCESSORIES ARE RECOMMENDED TO USE TO FACILITATE THE CATHETER TO ENTER THROUGH A HEMOSTATIC VALVE WHICH DOES NOT ALLOW THE BLOOD TO FLOW IN TO THE REVERSE DIRECTIONS BUT ALLOWS THE CATHETER TO PASS INTO THE BLOOD VESSEL. TO FACILITATE THE CATHETER TO ENTER THROUGH A HEMOSTATIC VALVE WHICH DOES NOT ALLOW THE BLOOD TO FLOW IN TO THE REVERSE DIRECTIONS BUT ALLOWS THE CATHETER TO PASS INTO THE BLOOD VESSEL.,GUIDEWIRE(ANGIX)-THE GUIDE WIRE IS USED TO ACCESS THE VEIN OR ARTERY WHILE INSERTING THE CANNULA OR SHEATH IN TO THE VESSEL. THIS IS USED FOR PROPER POSITIONING OF THE DEVICE.,HEMODIALYSIS CATHETER(DIAX)-HEMODIALYSIS CATHETER IS A CATHETER USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT.,CENTRAL VENOUS CATHETER KIT(VENX)-CVC KIT IS USED FOR CATHETERIZATION OF SUPERIOR VENA CAVA USING SELDINGER TECHNIQUE IN INFUSION THERAPY OR PARENTERAL NUTRITION, APPLICATION OF VEIN IRRITATING SOLUTIONS, FOR INTERMITTENT OR CONTINUOUS MONITORING OF CENTRAL VENOUS PRESSURE & FOR BLOOD SAMPLING.,INTRODUCER SHEATH(ANGIX)-INTRODUCER SHEATH INCLUDING ITS ACCESSORIES ARE RECOMMENDED TO USE TO FACILITATE THE CATHETER TO ENTER THROUGH A HEMOSTATIC VALVE WHICH DOES NOT ALLOW THE BLOOD TO FLOW IN TO THE REVERSE DIRECTIONS BUT ALLOWS THE CATHETER TO PASS INTO THE BLOOD VESSEL. TO FACILITATE THE CATHETER TO ENTER THROUGH A HEMOSTATIC VALVE WHICH DOES NOT ALLOW THE BLOOD TO FLOW IN TO THE REVERSE DIRECTIONS BUT ALLOWS THE CATHETER TO PASS INTO THE BLOOD VESSEL.,HEMODIALYSIS CATHETER KIT(DIAX)-HEMODIALYSIS CATHETER KIT IS USED FOR EXCHANGING BLOOD TO AND FROM THE HEMODIALYSIS MACHINE FROM THE PATIENT.

3854	MFG/MD/2021/000195	1.License Holder Name: TRANSLUMINA THERAPEUTICS LLP 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:GUIDING CATHETER (AGILE PRO)-THE AGILE PRO-GUIDING CATHETER IS DESIGNED TO PROVIDE A PATHWAY THROUGH WHICH THERAPEUTIC AND DIAGNOSTIC DEVICES ARE INTRODUCED. THE AGILE PRO-GUIDING CATHETER IS INTENDED TO BE USED IN THE CORONARY VASCULAR SYSTEM
3855	MFG/MD/2021/000196	1.License Holder Name: MARUTI MEDITECH PVT LTD 2.Approving Authority: BIHAR 3.Device Name(Brand Name)-Intended Use:STERILE HYPODERMIC SYRINGES WITH NEEDLE FOR SINGLE USE ONLY [STERILISED WITH E. O](LIFE INJECT)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.,STERILE DISPOSABLE HYPODERMIC NEEDLE FOR SINGLE USE ONLY [STERILISED WITH E.O](LIFE INJECT)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY BELOW THE SURFACE.,STERILE I.V. INFUSION SET WITH AIR VENT [STERILIZED WITH E.O](LIFE INJECT)-ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE I.V. INFUSION SET WITHOUT AIR VENT [STERILIZED WITH E.O](LIFE INJECT)-INTEND TO USE TO ADMINISTER DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE HYPODERMIC SYRINGES WITHOUT NEEDLE FOR SINGLE USE ONLY [STERILISED WITH E.O](LIFE INJECT)-INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.

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3856	MFG/MD/2021/000197	1.License Holder Name: JAY HANUMAN BANDAGE MFG CO. 2.Approving Authority: BIHAR 3.Device Name(Brand Name)-Intended Use:COTTON CREPE BANDAGE B.P-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB.,ABSORBENT COTTON WOOL I.P-MEDICAL PURPOSES, SURGICAL OPERATIONS AND SANITARY PURPOSES,ROLLED BANDAGE-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB,ABSORBENT GAUZE-ABSORBENT GAUZE ARE MAINLY USED DURING OPERATIONS AND ITS MAIN FUNCTION IS TO ABSORB THE BLOOD FROM WOUND. THE ABSORBENT GAUZE IS MOST VITAL ITEM IN SURGICAL DRESSING., ABSORBENT COTTON WOOL I.P (ZIG ZAG COTTON)-FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC. ABSORBENT COTTON IS USED TO PRODUCE DRESSING MATERIAL, PADDING FOR ITEMS OF CLOTHING ETC.,BANDAGE CLOTH-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB.

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3857	MFG/MD/2021/000198	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT. LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:TRANSPARENT ADHESIVE DRESSING WITH PAD(-)-1. PRIMARY AND SECONDARY CARE OF LOW TO MODERATE EXUDING WOUND. 2. FIXATION OF I.V CATHETERS 3. POST-OPERATIVE DRESSINGS TO PROTECT CLEAN CLOSED WOUNDS, THEATER INCISE DRAPE PLAIN(-)-TO PREVENT CROSS CONTAMINATION & FOREIGN PARTICLES DURING ALL TYPES OF MEDICAL PROCEDURE (SURGERY).,TRANSPARENT ADHESIVE DRESSING WITHOUT PAD(-)-1. PRIMARY AND SECONDARY CARE OF LOW TO MODERATE EXUDING WOUND. 2. FIXATION OF I.V CATHETERS 3. POST-OPERATIVE DRESSINGS TO PROTECT CLEAN CLOSED WOUNDS,NONWOVEN ADHESIVE DRESSING WITH PAD(-)-1. PRIMARY AND SECONDARY CARE OF LOW TO MODERATE EXUDING WOUND. 2. FIXATION OF I.V CATHETERS 3. POST-OPERATIVE DRESSINGS TO PROTECT CLEAN CLOSED WOUND
3858	MFG/MD/2021/000199	1.License Holder Name: AGROSURG IRRADIATORS (INDIA) PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:HYDROCOLLOID ADHESIVE DRESSING WITHOUT PAD(-)-HYDROCOLLOID DRESSING IS USED TO TREAT UN INFECTED WOUNDS & BURN.,HYDROCOLLOID ADHESIVE DRESSING WITH PAD(-)-HYDROCOLLOID DRESSING IS USED TO TREAT UN INFECTED WOUNDS & BURN.,THEATER INCISE DRAPES ANTIMICROBIAL(-)-TO PREVENT CROSS CONTAMINATION & FOREIGN PARTICLES DURING ALL TYPES OF MEDICAL PROCEDURE (SURGERY).
3859	MFG/MD/2021/000200	1.License Holder Name: BOARD OF RADIATION & ISOTOPE TECHNOLOGY 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:ALCOHOL SWAB-IT IS A SINGLE USE , STERILE DEVICE CONTAINING 70 % ISOPROPYL ALCOHOL USED TO DISINFECT NEEDLE ACCESS SITE PRIOR TO USE

3860	MFG/MD/2021/000201	1.License Holder Name: KOMAL HEALTH CARE PVT. LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:CHLORHEXIDINE GAUZE DRESSING-SURGICAL DRESSING,POVIDONE IODINE-SURGICAL DRESSING,NITROFURAZONE-SURGICAL DRESSING,COMBINE DRESSING-SURGICAL DRESSING,NEOMYCIN SULPHATE TULLE DRESSING-SURGICAL DRESSING,ABDOMINAL PAD SCH F (II)-SURGICAL DRESSING,POVIDONE IODINE AND METRONIDAZOLE-SURGICAL DRESSING,X-RAY DETECTABLE ABDOMINAL PAD-SURGICAL DRESSING,UMBILICAL COTTON TAPE-SURGICAL DRESSING,X-RAY DETACTABLE GAUZE SWAB-SURGICAL DRESSING, KAMPAD-SURGICAL DRESSING,FRAMYCETIN TULLE DRESSING B.P.-SURGICAL DRESSING,CHLORHEXIDINE-SURGICAL DRESSING, ANTIBIOTIC TULLE DRESSING-SURGICAL DRESSING,SODIUM FUSIDATE GAUZE DRESSING B.P.-SURGICAL DRESSING,GAUZE SWAB-SURGICAL DRESSING,GAUZE SWAB SCH F (II)-SURGIAL DRESSING, PARAFFIN-SURGICAL DRESSING,EYE PAD-SURGICAL DRESSING
3861	MFG/MD/2021/000202	1.License Holder Name: KOMAL HEALTH CARE PVT. LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:BANDAGE CLOTH SCH F (II)-SURGICAL DRESSING,ABSORBENT GAUZE(KAMGAUZE)-SURGICAL DRESSING,RIBBON GAUZE-SURGICAL DRESSING,ELASTIC ADHESIVE BANDAGE-SURGICAL DRESSING,PLASTER OF PARIS BANDAGE-SURGICAL DRESSING,ROLLED BANDAGES-SURGICAL DRESSING, ELASTIC ADHESIVE BANDAGE-SURGICAL DRESSING,ABSORBENT GAUZE SCH F (II)-SURGICAL DRESSING,COTTON CREPE BANDAGE-SURGICAL DRESSING,ABSORBENT GAUZE USP-SURGICAL DRESSING
3862	MFG/MD/2021/000203	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT. LTD. 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:NASOPHARYNGEAL AIR WAY TUBE(NA)-WHEN A PATIENT BECOMES UNCONSCIOUS, THE MUSCLES IN THE JAW COMMONLY RELAX AND CAN ALLOW THE TONGUE TO SLIDE BACK AND OBSTRUCT THE AIRWAY. THE PURPOSE OF THE FLARED END IS TO PREVENT THE DEVICE FROM BECOMING LOST INSIDE THE PATIENT'S NOSE. A CATHETER IS PASSED THROUGH NASOPHARYNGEAL THE NARES AND ADVANCED TO THE DEPTH OF THE NASOPHARYNX TO REMOVE AIR CHOKE OR OBSTRUCTION. A RESUSCITATOR.

3863	MFG/MD/2021/000204	1.License Holder Name: A V PROCESSORS PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:EYE PAD-EYE PAD IS USED AS SURGICAL DRESSING MATERIAL FOR EXTERNAL USE FOR EYE CARE IN HOSPITALS.,SURGICAL DRESSING PAD-SURGICAL DRESSING PAD IS USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BLOOD FLUIDS USED AS SURGICAL DRESSING MATERIAL FOR EXTERNAL USE IN HOSPITALS,COTTON GAMJEE PAD-SURGICAL DRESSING PAD IS USED FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BLOOD FLUIDS USED AS SURGICAL DRESSING MATERIAL FOR EXTERNAL USE IN HOSPITALS.,GAUZE SWAB AS PER SCHEDULE F-II OF DRUGS AND COSMETICS ACT- 1940-GAUZE SWAB ARE USED TO PLACE OVER A WOUND BEFORE TAPING, STRAPPING OR BANDAGING UP OR CAN BE SOAKED IN ANTISEPTIC LIQUID AND USED TO WIPE OVER HARD SURFACES. GAUZE SWABS ARE A USEFUL UTILITY PRODUCT IN A KIT AND CAN BE USED FOR PADDING, PROTECTION, BLOOD SPILL WOUND DRESSING, APPLYING ANTISEPTIC AND MUCH MORE IS USED AS SURGICAL DRESSING MATERIAL FOR EXTERNAL USE IN HOSPITALS.
3864	MFG/MD/2021/000205	1.License Holder Name: HICKS THERMOMETERS INDIA LIMITED 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:DIGITAL THERMOMETER (HICKS)-TEST HUMAN BODY TEMPERATURE.,BLOOD PRESSURE MONITOR(HICKS)-TEST HUMAN BODY BLOOD PRESSURE AND HEART BEAT.

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3865	MFG/MD/2021/000206	1.License Holder Name: UNISUR LIFECARE PVT.LTD. 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:MONOFILAMENT POLYPROPYLENE(DYNALENE)-MONOFILAMENT POLYPROPYLENE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.,MONOFILAMENT POLYAMIDE (DYNALON)-MONOFILAMENT POLYAMIDE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION, BLACK BRAIDED SILK (DYNASILK)-BLACK BRAIDED SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION.,FAST ABSORBABLE BRAIDED AND COATED POLYGLACTIN 910(DYNASYNTH FAST)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,MONOFILAMENT POLYGLECAPRONE 25(DYNAGLYDE MONO)-MONOFILAMENT POLYGLECAPRONE 25 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, WHERE AN ABSORBABLE MATERIAL IS INDICATED.,BRAIDED AND COATED POLYGLYCOLIC ACID (DYNAGLYDE)-BRAIDED AND COATED POLYGYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS,BRAIDED AND COATED POLYGLACTIN 910(DYNASYNTH)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS
3866	MFG/MD/2021/000208	1.License Holder Name: SMB CORPORATION OF INDIA 2.Approving Authority: GREATER MUMBAI DIVISION 3.Device Name(Brand Name)-Intended Use:UMBILICAL COTTON TAPE (SMB)-USED TO CLOSED THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT

3867	MFG/MD/2021/000209	1.License Holder Name: BRISK SURGICALS COTTON LTD 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:BANDAGE CLOTH/ OPEN WOVE BANDAGE - SCHEDULE F II(BRISK)-GAUZE & BANDAGES IS USED TO COVER AND PROTECT WOUNDS FROM INFECTION AND FURTHER INJURIES. GAUZE & BANDAGE ARE MADE UP FROM COTTON FIBRES. FOR EXTERNAL USAGE ONLY.,ABSORBENT GAUZE/ GAUZE ROLLED - SCHEDULE F-II(BRISK)-GAUZE & BANDAGE IS USED TO COVER AND PROTECT WOUNDS FROM INFECTION AND FURTHER INJURIES. GAUZE & BANDAGE ARE MADE UP FROM COTTON FIBERS. FOR EXTERNAL USE ONLY.,ABSORBENT COTTON WOOL (I.P/B.P/J.P) (BRISK)-ABSORBENT COTTON WOOL ALSO KNOWN AS SURGICAL COTTON OR COTTON WOOL IS MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES ETC., BECAUSE OF HIGH FLUID ABSORBENCY POWER. FOR EXTERNAL USAGE ONLY

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3868	MFG/MD/2021/000210	1.License Holder Name: S K LOGISTICS 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:STICKERING, STAMPING AND OVERPRINTING ON FINISHED PRODUCT PACKINGS WITHOUT CHANGING ORIGINAL LABEL(NA)-NA,

3869	MFG/MD/2021/000211	1.License Holder Name: ROMSONS INTERNATIONAL UNIT-II 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:NEBULIZER WITH T CONNECTOR AND MOUTH PIECE WITH OR WITHOUT CORRUGATED TUBE(NIL)-SINGLE USE DEVICE INTENDED FOR PROVIDING OR TRANSFERRING PRESCRIBED MEDICATION THROUGH MOUTH PIECE TO THE LUNGS IN AN AEROSOL FORM BY THE PRESSURE OF COMPRESSIVE AIR OR OXYGEN ,NEBULIZER(BENEFIS)-SINGLE USE DEVICE INTENDED FOR PROVIDING OR TRANSFERRING PRESCRIBED MEDICATION IN AEROSOL FORM INTO LUNGS THROUGH COMPRESSIVE AIR OR OXYGEN,NEBULIZER(AERO MIST)-INTENDED FOR PROVIDING OR TRANSFERRING PRESCRIBED MEDICATION IN AEROSOL FORM INTO LUNGS THROUGH COMPRESSIVE AIR OR OXYGEN,NEBULIZER MASK AND CHAMBER WITH OR WITHOUT TEE PIECE AND MOUTH PIECE(NIL)-SINGLE USE DEVICE INTENDED FOR PROVIDING OR TRANSFERRING PRESCRIBED MEDICATION IN AEROSOL FORM INTO LUNGS THROUGH COMPRESSIVE AIR OR OXYGEN.,NEBULIZER (AERO COMFORT)-IT IS A DEVICE USED TO ADMINISTER MEDICINE IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDER. ,NEBULIZER(POWER DROOL)-SINGLE USE DEVICE INTENDED FOR PROVIDING OR TRANSFERRING PRESCRIBED MEDICATION THROUGH MOUTH PIECE TO THE LUNGS IN AN AEROSOL FORM BY THE PRESSURE OF COMPRESSIVE AIR OR OXYGEN , NEBULIZER(LOMAR)-SINGLE USE DEVICE INTENDED FOR PROVIDING OR TRANSFERRING PRESCRIBED MEDICATION IN AEROSOL FORM INTO LUNGS THROUGH COMPRESSIVE AIR OR OXYGEN,JET NEBULIZER(AERO NEB)-IT IS A DEVICE USED TO ADMINISTER MEDICINE IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDER.

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3870	MFG/MD/2021/000212	1.License Holder Name: UNISUR LIFECARE PVT. LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:STERILE BONEWAX (ARNISTERI WAX)-STERILE BONE WAX IS USED TO CONTROL LOCAL BLEEDING FROM BONE SURFACES. IT IS COMMONLY USED IN PATIENTS UNDERGOING ORTHOPAEDIC SURGICAL PROCEDURES, MONOFILAMENT POLYAMIDE(ARNINYLON)-MONOFILAMENT POLYAMIDE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.,BLACK BRAIDED SILK (ARNISILK)-BLACK BRAIDED SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND OR LIGATION., MONOFILAMENT POLYGLECAPRONE 25(ARNIGLYDE MONO)-MONOFILAMENT POLYGLECAPRONE 25 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, WHERE AN ABSORBABLE MATERIAL IS INDICATED., BRAIDED AND COATED POLYGLACTIN 910(ARNISYNTH)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS,MONOFILAMENT POLYPROPYLENE MESH(ARNILENE MESH, ARNISTERI LENE MESH)-MONOFILAMENT POLYPROPYLENE MESH IS USED FOR THE REPAIR OF HERNIA, UTERO-VAGINAL PROLAPSE AND OTHER FASCIAL DEFICIENCIES THAT REQUIRE THE ADDITION OF A REINFORCING OR BRIDGING MATERIAL TO OBTAIN THE DESIRED SURGICAL RESULT. IT CAN BE USED IN ENDOSCOPIC PROCEDURES.,FAST ABSORBABLE BRAIDED AND COATED POLYGLYCOLIC ACID(ARNIGLYDE FAST)-BRAIDED AND COATED POLYGLYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,CATGUT CHROMIC(ARNIGUT)-CATGUT CHROMIC SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES, BRAIDED AND COATED POLYGLYCOLIC ACID (ARNIGLYDE)-BRAIDED AND COATED POLYGLYCOLIC ACID SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,MONOFILAMENT POLYPROPYLENE(ARNILENE, ARNISTERI LENE)-MONOFILAMENT POLYPROPYLENE SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND /OR LIGATION.,FAST ABSORBABLE BRAIDED AND COATED POLYGLACTIN 910(ARNISYNTH FAST)-BRAIDED AND COATED POLYGLACTIN 910 SUTURES ARE INTENDED

		FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICRO SURGERY FOR VESSELS.,CATGUT PLAIN(ARNIGUT)-CATGUT PLAIN SUTURES ARE INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES
3871	MFG/MD/2021/000213	1.License Holder Name: AURUS MEDTECH PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:ENDOTRACHEAL TUBE (N/A)-INSERTS THE TUBE WITH THE HELP OF A LARYNGOSCOPE, AN INSTRUMENT THAT PERMITS TO SEE THE UPPER PORTION OF THE TRACHEA, JUST BELOW THE VOCAL CARDS.,3 WAY STOP COCK AS AN ACCESSORY TO PERFUSION SETS(N/A)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING,TRANSFUSION OR PERFUSION SETS FOR SINGLE USE(N/A)-TRANSFUSION OR PERFUSION SETS FOR SINGLE USE ARE INTENDED FOR ADMINISTER INTRAVENOUS FLUIDS AND/ OR MEDICATION TO A PATIENT INTRAVENOUSLY.,EXTENSION SETS (N/A)-EXTENSION SETS ARE STERILE DEVICES FOR SINGLE USE ONLY. THEY ARE INTENDED TO BE USE AS PART OF A SYSTEM FOR INFUSION OF FLUIDS / MEDICATIONS IN MEDICAL APPLICATIONS., MEASURED VOLUME I V SET(N/A)-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE,FOLEY CATHETER(N/A)-A LONG, SMALL GAUGE CATHETER DESIGNED FOR ISERTATION DIRECTLY INTO A URETER, EITHER THROUGH URETHRA AND BLADER OR POSTERIORLY VIA THE KIDNEY.,INTRAVENOUS CANNULA(N/A)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.,BLOOD TRANSFUSION SET(N/A)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE INSERTED INTO A VEIN.

3872	MFG/MD/2021/000214	1.License Holder Name: SHRI RAM INSTITUTE FOR INDUSTRIAL RESEARCH 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:ALCOHOL SWAB WITH 70% ISOPROPYL ALCOHOL(URISIGN)-THE ALCOHOL SWAB IS A SINGLE USE, STERILE DEVICE CONTAINING 70% ISOPROPYL ALCOHOL. WHEN USED FOR SCRUBBING FOR 5 SECONDS AND ALLOWING DRYING FOR 5 SECONDS, THE ALCOHOL SWAB WILL DISINFECT NEEDLESS ACCESS SITES PRIOR TO USE. IT MAY BE USED IN THE HOME OR HEALTHCARE FACILITY.
3873	MFG/MD/2021/000215	1.License Holder Name: ALLWIN MEDICAL DEVICES 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:PANCREATIC STENT-PANCREATIC STENT IS USED FOR DRAINAGE OF OBSTRUCTED PANCREATIC DUCTS,BILIARY STENT AND INTRODUCER-BILIARY STENT IS USED TO DRAIN OBSTRUCTED BILIARY DUCTS.

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3874	MFG/MD/2021/000216	1.License Holder Name: COLOGENESIS HEALTHCARE PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:COLLAGEN SHEET (COLLOSKIN)-IDEAL FOR INFECTIVE 2ND DEGREE BURNS, SUPERFICIAL BURNS,DEEP DERMAL BURNS FOR 3RD DEGREE BURNS AS A TEMPORARY COVER,TRAUMATIC LOSSS OF SKIN COVER, TEMPORARY WOUND COVER IN AMJOR OPEN WOUNDS,SKIN DONOR SITES.,RECONSTITUTED COLLAGEN SHEET(COLLOGRAFT)-PARTIAL AND FULL THICKNESS WOUNDS,PRESSURE ULCERS,VENOUS ULCERS ,CHRONIC VASCULAR ULCER,DIABETIC ULCER,TRAUMA WOUNDS, SURGICAL WOUNDS,POST LASER SURGERY AND PEDIATRIC WOUNDS, NANO CRYSTALLINE SILVER GEL(NANOCOLL)-IT IS INDICATED FRO TREATMENT OF BURNS AND WOUNDS,GENTAMICIN CREAM (GENCOLL)-BED SORES,PRESSURE ULCERS,DERMAL LESIONS, SECOND DEGREE BURNS,DONOR SITES,DIABETIC WOUNDS,SCAR MANAGEMENT,COLLAGEN SPONGE(COLLOSPON)-PRESSURE ULCERS,VENOUS STASSI ULCERS,DIABETIC ULCERS,ACUTE WOUNDS, PARTIAL THICKNESS BURNS,MODERATE TO HEAVILY DRAINING WOUNDS,COLLAGEN SHEET MESHED(COLLOSKIN M)-IDEAL FRO EXUDATE/INFECTED BURNS AND WOUNDS FOR EASY DRAINAGE OF FLUID,SUPERFICIAL AND DEEP DERMAL BURNS,FOR 3RD DEGREE BURNS AS A TEMPORARY COVER,TRAUMATIC LOSS OF SKIN COVER, TEMPORARY WOUND COVER IN MAJOR OPEN FRACTURE WOUNDS, SKIN DONOR SITES,COLLAGEN PLUG(COLOPLUG)-1.EXTRACTION SITES, 2.4-WALLSOCKETS 3.BIOPSY SITES. 4.ORAL HAEMOSTATIC APPLICATIONS,COLLAGEN PARTICLES WITH MUPIROCIN AND METRONIDAZOLE(COLLOFIBRE MM)-NON HEALING ULCERS, DIABETIC FOOT ULCERS PRESSURE ULCERS VENOUS ULCERS TRAUMATIC WOUNDS SURGICAL WOUNDS INFECTED WOUNDS, COLLAGEN GEL(COLLOGEL)-BED SORES,DERMAL LESIONS,FIRST DEGREE BURNS,DONOR SITES,STRETCH MANGEMENT,SCAR MANAGEMENT,COLLAGEN PARTICLES(COLOCAST)-OSTEOINDUCTIVE ADN OSTEOCONDUCTIVE,STERILE COLLAGEN SPONGE WITH GENTAMICIN(DIACOLL - S)-CARDIOTHORASIC ORTHOPEDIC, GI/ABDOMINAL VASCULAR/PLASTIC DIABETIC FOOT ULCER, COLLAGEN SHEET LYOPHILLISED(COLLOGRAFT L)-IDEAL FOR NON-INFECTIVE WOUNDS,SUPERFICIAL BURNS AND DEEP DERMAL BURNS, COLLAGEN WITH NON ADHERENT BACKING(COLLOGRAFT-B)-ALL TYPES OF SURFACE WOUNDS MODERATE TO HEAVILY DRAINING WOUNDS,STERILE COLLAGEN SHEET(COLOGIDE)-PERIODONTOLGY, ORAL IMPLANTOLOGY.AUGMENTATION,SURGICLA ROOT SECTION, CYSTECTOMY AND OTHER BONE LESION,STERILE DRY COLLAGEN

		SHEET WITH GENTAMICIN(DIACOLL)-DIABETIC FOOT ULCERS, ORTHOPAEDIC SURGERY,TREATMENT OF OSTEOMYELITIS AND SOFT TISSUE INFECTIONS,ABDOMINAL WOUND INFECTIONS,COLLAGEN PARTICLES(COLLOFIBRE)-NON HEALING ULCERS,DIABETIC ULCERS, PRESSURE ULCERS,TRAUMATIC WOUNDS,SURGICAL WOUNDS, INFECTED&NON INFECTED WOUNDS,MINIMALLY HELAVILY DRAINING WOUNDS,UNDERMINED WOUNDS,TUNNELED WOUNDS,3RD DEGREE BURNS
3875	MFG/MD/2021/000217	1.License Holder Name: NEW ROBINSONS SURGICO 2.Approving Authority: WEST BENGAL 3.Device Name(Brand Name)-Intended Use:STANDARD DRESSING NO. 8 HAND AND FOOT DRESSING(MEDIUM)-SURGICAL DRESSING, ABDOMINAL PAD(SPONG) (NON-STERILE)-SURGICAL DRESSING, CLOTH COTTON BANDAGE-SURGICAL DRESSING,ABSORBENT GAUZE-SURGICAL DRESSING,ROLLED BANDAGE(W.O.W)-SURGICAL DRESSING,STANDARD DRESSING NO.7(FINGER DRESSING)-SURGICAL DRESSING,STANDARD DRESSING NO.15(LARGE)-SURGICAL DRESSING,GAUZE SURGICAL LOOSE WOVE UN-MEDICATED-SURGICAL DRESSING,STANDARD DRESSING NO.7(FINGER DRESSING)-SURGICAL DRESSING,ABSORBENT GAUZE-SURGICAL DRESSING, GAUZE SWAB-SURGICAL DRESSING,CELIKO BANDAGE TRIANGULAR-SURGICAL DRESSING,COTTON CREPE BANDAGE(USHA)-SURGICAL DRESSING,GAUZE SURGICAL LOOSE-SURGICAL DRESSING, STANDARD DRESSING NO.14(MEDIUM)-SURGICAL DRESSING,PLAIN LINT B.P.C -SURGICAL DRESSING,STANDARD DRESSING NO.13 -SURGICAL DRESSING,STANDARD DRESSING NO.9 HAND AND FOOT DRESSING(LARGE)-SURGICAL DRESSING

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3876	MFG/MD/2021/000218	1.License Holder Name: FUTURA SURGICARE PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:COATED AND BRAIDED POLYGLACTIN 910, ABSORBABLE SURGICAL SUTURE. ANTIBACTERIAL WITH TRICLOSAN.(CORECRYL PLUS)-POLYGLACTIN 910 ANTIBACTERIAL SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,BONE WAX. (WAXBOND)-BONE WAX IS INDICATED FOR USE IN THE CONTROL OF BLEEDING FROM BONE SURFACES.,MONOFILAMENT POLIGLECAPRONE 25, ABSORBABLE SURGICAL SUTURE. (COREMONO)-POLIGLECAPRONE SUTURES ARE INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, BUT NOT FOR USE IN CARDIOVASCULAR OR NEUROLOGICAL TISSUES, MICROSURGERY OR OPHTHALMIC SURGERY.,COATED AND BRAIDED POLYGLACTIN 910, ABSORBABLE SURGICAL SUTURE. (CORECRYL, CORECRYL FAST)-POLYGLACTIN 910 SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION WHERE ONLY SHORT TIME TISSUE APPROXIMATION IS REQUIRED. DUE TO ITS SHORT TIME ABSORPTION PROFILE IT IS USEFUL IN SKIN CLOSURE, PEDIATRIC SURGERY, EPISIOTOMIES, CIRCUMCISION, CLOSURE OF ORAL MUCOSA, OPHTHALMIC PROCEDURES FOR CONJUNCTIVA SURGERIES.,CATGUT PLAIN, ABSORBABLE SURGICAL SUTURE(COREGUT)-CATGUT SUTURE IS FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION.,CATGUT CHROMIC, ABSORBABLE SURGICAL SUTURE(COREGUT)-CATGUT SUTURE IS FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC PROCEDURES.,MONOFILAMENT POLYTETRAFLUOROETHYLENE SUTURE, NON ABSORBABLE SURGICAL SUTURE. (COREPTFE)-IT IS INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION AND/ OR LIGATION, INCLUDING DENTAL AND GENERAL SURGERIES. THE DEVICE IS NOT INDICATED FOR THE USE IN CARDIOVASCULAR, OPHTHALMIC SURGERY AND PERIPHERAL NEURAL TISSUE.,MONOFILAMENT POLYPROPYLENE, NON ABSORBABLE SURGICAL SUTURE. (CORELENE)-POLYPROPYLENE SUTURE IS SUITABLE FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION. EXCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,SURGICAL STAPLER.(CORESTAP)-STAPLER HAS THE APPLICATION IN SURGERY FOR SKIN CLOSURE. , COATED AND BRAIDED POLYGLYCOLIC ACID, ABSORBABLE SURGICAL SUTURE.(COREGLYDE)-POLYGLYCOLIC ACID SUTURES ARE INDICATED FOR USE IN GENERAL, SOFT TISSUE INCLUDING USE IN OPHTHALMIC. BUT NOT FOR USE IN CARDIO VASCULAR & NEUROLOGICAL TISSUES.,MONOFILAMENT POLYDIOXANONE,

		ABSORBABLE SURGICAL SUTURE.(COREPD)-POLYDIOXANONE MONOFILAMENT SYNTHETIC ABSORBABLE SUTURES ARE INDICATED FOR USE IN ALL TYPES OF SOFT TISSUE APPROXIMATION, INCLUDING USE IN PEDIATRIC CARDIOVASCULAR TISSUE WHERE GROWTH IS EXPECTED TO OCCUR, AND OPHTHALMIC SURGERY. POLYDIOXANONE SUTURE IS NOT INDICATED IN ADULT CARDIOVASCULAR TISSUE, MICROSURGERY AND NEURAL TISSUE. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF AN ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT (UP TO SIX WEEKS) IS DESIRABLE.,MONOFILAMENT POLYDIOXANONE BARBED, ABSORBABLE SURGICAL SUTURE. (CORELOCK)-IT IS INTENDED FOR TISSUE APPROXIMATION WITHOUT THE USAGE OF KNOTS,COATED AND BRAIDED POLYESTER, NON ABSORBABLE SURGICAL SUTURE.(COREBOND)- POLYESTER SUTURES ARE INTENDED FOR USE IN ORTHOPAEDIC, GENERAL AND OPHTHALMIC SURGERY.,BLACK BRAIDED SILK NON ABSORBABLE SURGICAL SUTURE.(CORESILK)-SILK SUTURE IS INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION IN ALL SURGICAL PROCEDURES EXCLUDING USE IN CARDIOVASCULAR, OPHTHALMIC AND NEUROLOGICAL PROCEDURES.,MONOFILAMENT POLYAMIDE, NON ABSORBABLE SURGICAL SUTURE.(CORELON)- POLYAMIDE (NYLON) SUTURE IS SUITABLE FOR CLOSING SKIN SUB CUTICULAR LAYERS. ITS HIGH DEGREE OF ELASTICITY CONTRIBUTES TO ITS GREAT STRENGTH IN THE FINE SIZES, ENABLING THE PLASTIC SURGEONS, THE MICRO SURGEONS & THE OPHTHALMOLOGISTS TO TIE SECURE KNOTS.,MONOFILAMENT STAINLESS STEEL, NON ABSORBABLE SURGICAL SUTURE.(CORESTEEL)-STAINLESS STEEL SURGICAL SUTURE IS INDICATED FOR USE IN STERNAL CLOSURE., MONOFILAMENT POLYPROPYLENE MESH(FLEXMESH)-MESH IS USED IN HERNIA REPAIR AND WEAK TISSUE SUPPORT.
3877	MFG/MD/2021/000219	1.License Holder Name: PHOENIX INNOVATIVE HEALTHCARE MANUFACTURERS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NEBULIZER(CONTROL D NEBULIZER)-IT IS A PIECE OF MEDICAL EQUIPMENT THAT A PERSON WITH ASTHMA OR ANOTHER RESPIRATORY CONDITION CAN USE TO ADMINISTER MEDICATION DIRECTLY AND QUICKLY TO THE LUNGS. THE NEBULIZER IS INTENDED TO BE USED BY MANY PATIENTS AND MASK TO BE USED BY A SINGLE PATIENT AND SHOULD NOT BE SHARED.

3878	MFG/MD/2021/000220	1.License Holder Name: MYSORE WIFILTRONICS PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:TURP LOOPS , ELECTRODES-REDUCED THE SIZE OF PROSTATE GLAND ENTERING THROUGH URINARY TUBE OF MALE PATIENTS BY REMOVING ABNORMAL TISSUES.
3879	MFG/MD/2021/000221	1.License Holder Name: KULKARNI WEAVING MILLS PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:CHITOSAN COATED ABSORBENT GAUZE (DRESSING)(HARMOSTAT)-MILD TO SEVERE BLEEDING WOUND. TEMPORARY TOPICAL DRESSING FOR BLEEDING CONTROL.
3880	MFG/MD/2021/000222	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT. LTD. 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:ETHYLENE OXIDE STERILISATION OF X-RAY DETECTABLE ABDOMINAL PADS (X-RAY DETECTABLE LAPAROTOMY SPONGE)-THE X-RAY DETECTABLE ABDOMINAL PAD IS USED IN SURGICAL PROCEDURES TO ABSORB BLOOD AND OTHER FLUIDS AS WELL AS CLEAN WOUNDS,ETHYLENE OXIDE STERILISATION OF X RAY DETECTABLE GAUZE SWABS-THE X-RAY DETECTABLE GAUZE SWABS ARE USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, AND ESPECIALLY USED FOR DRESSING WOUNDS
3881	MFG/MD/2021/000223	1.License Holder Name: PEARL MEDICAL AIDS & EQUIPMENTS PVT LTD 2.Approving Authority: JAMMU AND KASHMIR 3.Device Name(Brand Name)-Intended Use:BANDAGE CLOTH-USED FOR SUPPORT AND PROCEDURES,ABSORBENT COTTON WOOL I.P.-USED FOR SURGICAL DRESSING AND PROCEDURES,GAUZE CLOTH-USED FOR SURGICAL PROCEDURES,ROLLED CUT BANDAGES-USED FOR SUPPORT AND DRESSING

3882	MFG/MD/2021/000225	1.License Holder Name: SIEMENS HEALTHCARE PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:COMPUTED TOMOGRAPHY(SOMATOM GO.UP)-THIS COMPUTED TOMOGRAPHY SYSTEM INTENDED TO GENERATE AND PROCESS CROSS-SECTIONAL IMAGES OF PATIENTS BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA.THE IMAGES DELIVERED BY THE SYSTEM CAN BE USED BY ANY TRAINED PHYSICIAN AS AN AID IN DIAGNOSIS., MOBILE X-RAY C-ARM SYSTEM(CIOS FIT)-THE CIOS FIT IS A MOBILE X-RAY C-ARM SYSTEM DESIGNED TO PROVIDE X-RAY IMAGING OF THE ANATOMICAL STRUCTURES OF THE PATIENT DURING CLINICAL APPLICATIONS. CLINICAL APPLICATIONS MAY INCLUDE BUT ARE NOT LIMITED TO INTERVENTIONAL FLUOROSCOPIC, UROLOGIC, PAIN MANAGEMENT, ORTHOPEDIC, NEUROLOGIC, VASCULAR, CRITICAL CARE AND EMERGENCY ROOM PROCEDURES. THE PATIENT POPULATION MAY INCLUDE PEDIATRIC PATIENT.,COMPUTED TOMOGRAPHY(SOMATOM GO.NOW)-THIS COMPUTED TOMOGRAPHY SYSTEM INTENDED TO GENERATE AND PROCESS CROSS-SECTIONAL IMAGES OF PATIENTS BY COMPUTER RECONSTRUCTION OF X-RAY TRANSMISSION DATA.THE IMAGES DELIVERED BY THE SYSTEM CAN BE USED BY ANY TRAINED PHYSICIAN AS AN AID IN DIAGNOSIS.

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3883	MFG/MD/2021/000226	1.License Holder Name: M/S REENAV LOGISTICS PVT LT 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:HYALURONIC ACID 15MG + LIDOCAINE HYDROCHLORIDE 3MG(JUVEDERM VOLBELLA WITH LIDOCAINE)-JUVÉDERM VOLBELLA WITH LIDOCAINE CAN BE USED FOR THE TREATMENT OF FINE LINES AND MEDIUM SIZED SKIN DEPRESSIONS SUCH AS PERI-ORAL, PERI ORBITAL, GLABELLAR, NECK AND FOREHEAD LINES BY INJECTION IN THE SUPERFICIAL/MID-DERMIS. JUVÉDERM VOLBELLA WITH LIDOCAINE CAN BE USED TO CORRECT INFRAORBITAL SKIN DEPRESSIONS (TEAR TROUGH) VIA DEEP (SUBMUSCULAR / PRE PERIOSTEAL) INJECTION. JUVÉDERM VOLBELLA WITH LIDOCAINE SHOULD BE INJECTED BY A TRAINED AND REGISTERED MEDICAL PRACTITIONER. THE PRESENCE OF LIDOCAINE IS MEANT TO REDUCE THE PATIENT'S PAIN DURING TREATMENT.,HYALURONIC ACID 24 MG AND LIDOCAINE HYDROCHLORIDE 3 MG(JUVEDERM ULTRA PLUS XC)-JUVEDERM ULTRA PLUS XC IS INTENDED FOR FILLING MID AND/OR DEEP DEPRESSION OF THE SKIN VIA MID AND/OR DEEP DERMIS INJECTION, AND LIP DEFINITION AND ENHANCEMENT. THE PRESENCE OF LIDOCAINE IS MEANT TO REDUCE THE PATIENT'S PAIN DURING TREATMENT.,HYALURONIC ACID 25MG + LIDOCAINE HYDROCHLORIDE 3 MG(JUVEDERM VOLUX)-JUVÉDERM VOLUX IS AN INJECTABLE IMPLANT INTENDED TO RESTORE AND CREATE VOLUME OF THE FACE. THE PRESENCE OF LIDOCAINE IS MEANT TO REDUCE THE PATIENT'S PAIN DURING TREATMENT.,HYALURONIC ACID 12MG + LIDOCAINE HYDROCHLORIDE 3MG(JUVEDERM VOLITE)-JUVÉDERM VOLITE IS AN INJECTABLE IMPLANT USED FOR THE TREATMENT, BY FILLING, OF SUPERFICIAL CUTANEOUS DEPRESSIONS SUCH AS FINE LINES AND FOR ADDITIONAL IMPROVEMENT OF SKIN QUALITY ATTRIBUTES SUCH AS HYDRATION AND ELASTICITY. JUVÉDERM VOLITE SHOULD ONLY BE ADMINISTERED AS SUPERFICIAL INTRA-DERMAL INJECTION BY SPECIALLY TRAINED MEDICAL PRACTITIONER. THE PRESENCE OF LIDOCAINE IS MEANT TO REDUCE THE PATIENT'S PAIN DURING TREATMENT.,HYALURONIC ACID 20MG+ LIDOCAINE HYDROCHLORIDE 3MG(JUVÉDERM VOLUMA WITH LIDOCAINE)-JUVEDERM VOLUMA IS AN INJECTABLE IMPLANT INDICATED TO RESTORE VOLUME OF THE FACE. THE PRESENCE OF LIDOCAINE IS MEANT TO REDUCE THE PAIN DURING THE TREATMENT.,HYALURONIC ACID 17.5 MG AND LIDOCAINE HYDROCHLORIDE 3 MG(JUVEDERM VOLIFT WITH LIDOCAINE)-TREATMENT OF DEEP SKIN DEPRESSIONS, FACE CONTOURING AND VOLUME RESTORATION VIA DEEP DERMIS INJECTION AS WELL AS FOR RESTORATION OF LIP VOLUME BY AN AUTHORIZED MEDICAL

		PRACTITIONER IN ACCORDANCE WITH LOCAL APPLICABLE REGULATION. THE PRESENCE OF LIDOCAINE IS MEANT TO REDUCE THE PATIENTS PAIN DURING TREATMENT.
3884	MFG/MD/2021/000227	1.License Holder Name: ABG SURGICAL 2.Approving Authority: NASHIK DIVISION 3.Device Name(Brand Name)-Intended Use:SURGICAL ABSORBENT COTTON WOOL IP-USED FOR MEDICAL PURPOSES IN HOSPITALS, DISPENSARIES, ETC.
3885	MFG/MD/2021/000228	1.License Holder Name: F4 SURGICALS 2.Approving Authority: JAMMU AND KASHMIR 3.Device Name(Brand Name)-Intended Use:RADIO OPAQUE ABDOMINAL PADS-IT IS USED IN THE SURGERY.,RADIO OPAQUE GAUZE SWAPS-IT IS USE IN SURGERY
3886	MFG/MD/2021/000229	1.License Holder Name: THE STERLING SURGICAL CO 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:NON STERILIZE SURGICAL BANDAGE GAUZE, ABSORBENT GAUZE, BANDAGE CLOTH, GAMJEE ROLL, TRIANGULAR BANDAGE-MEDICAL OPERATION MEDICAL SURGICAL BANDAGE, GAUZE SURGICAL OPERATION SURGICAL DRESSING
3887	MFG/MD/2021/000230	1.License Holder Name: SPM MEDICARE PVT. LTD 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:AUTO DISABLE (AD) SYRINGES FOR IMMUNIZATION-STERILE HYPODERMIC SYRINGES ARE INTENDED TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY.

3888	MFG/MD/2021/000231	1.License Holder Name: JP SURGICAL INDUSTRY 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:GAUZE THAN(NA)-GAUZE IS MADE OF COTTON. IT IS ESPECIALLY USEFUL FOR DRESSING WOUNDS WHERE OTHER FABRICS MIGHTSTICK TO WOUNDS AVAILABLE IN NON STERILE PACK,COTTON GAUZE BANDAGE(NA)-COTTON GAUZE BANDAGES ARE VERY COMMON AND VERY VERSATILE THIN WOVEN AND BREATHABLE FABRIC BANDAGES THAT CAN BE USED TO SECURE A DRESSING IN PLACE, OR MAY BE PLACED DIRECTLY OVER A WOUND TO KEEP IT CLEAN WHILE ALLOWING AIR TO PENETRATE TO IMPROVE HEALING PROCESS.,CREPE BANDAGE (NA)-THE MEDIUM WEIGH CREPE BANDAGE IS SUITABLE FOR USE AS A DRESSING RETENTION. HEAVY WEIGH CREPE BANDAGE IS SUITABLE FOR USE AS A SUPPORT FOR SPRAINS AND STRAINS IN JOINT AND MUSCLES. IT ALSO WORKS AS A MODE RATE COMPRESSION BANDAGE FOR KNEE SWELLING AND OTHER RELEVANT INJURIES.

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3889	MFG/MD/2021/000232	1.License Holder Name: AUXEIN MEDICAL PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:STAPLES-STAPLES ARE INTENDED TO BE USED FOR FRAGMENT FIXATION PARTICULARLY IN SMALL FRAGMENTS ANDWHERE INTERFRAGMENTAL SCREW FIXATION IS NOT POSSIBLE. CONVENTARY STAPLES AREUSED IN TIBIAL OSTEOTOMIES TO CORRECT VARUS OR VALGUS DEFORMITIES. STAPLE USED TO HOLD OSTEOTOMY SITE.,BONE NAIL IMPLANTS-BONE NAIL IMPLANTS ARE COMMONLY USED TO FIX THE LONG BONE FRACTURES.,BONE SCREWS-BONE SCREWS ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR ALONG WITH BONE PLATES OR INTERLOCKING NAILS.,STAPLES-STAPLES ARE INTENDED TO BE USED FOR FRAGMENT FIXATION PARTICULARLY IN SMALL FRAGMENTS ANDWHERE INTERFRAGMENTAL SCREW FIXATION IS NOT POSSIBLE. CONVENTARY STAPLES AREUSED IN TIBIAL OSTEOTOMIES TO CORRECT VARUS OR VALGUS DEFORMITIES. STAPLE USED TO HOLD OSTEOTOMY SITE.,BONE SCREWS-BONE SCREWS ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR ALONG WITH BONE PLATES OR INTERLOCKING NAILS., BONE NAIL IMPLANTS-BONE NAIL IMPLANTS ARE COMMONLY USED TO FIX THE LONG BONE FRACTURES.,ARTHROSCOPY IMPLANTS-THE ARTHROSCOPY SYSTEM IMPLANTS ARE INTENDED TO FIX THE DAMAGED OR DISLOCATEDSOFT TISSUE/LIGAMENTS AND REALIGN TO ITS ORIGINAL POSITION.,ARTHROSCOPY IMPLANTS-THE ARTHROSCOPY SYSTEM IMPLANTS ARE INTENDED TO FIX THE DAMAGED OR DISLOCATED SOFT TISSUE/LIGAMENTS AND REALIGN TO ITS ORIGINAL POSITION.,SPINAL IMPLANT-SPINAL IMPLANTS USED TO FACILITATE FUSION, CORRECT DEFORMITIES, AND STABILIZE AND STRENGTHEN THE SPINE.,PINS , WIRES & WASHERS-THE BONE PINS , WIRES & WASHERS ARE USED WITH IMPLANTS ARE TEMPORARY IMPLANT COMPONENTS THAT ARE INTENDED FOR FRACTURE FIXATION OF BONE AND INSERTION OF IMPLANTS., STAPLES-STAPLES ARE INTENDED TO BE USED FOR FRAGMENT FIXATION PARTICULARLY IN SMALL FRAGMENTS ANDWHERE INTERFRAGMENTAL SCREW FIXATION IS NOT POSSIBLE. CONVENTARY STAPLES AREUSED IN TIBIAL OSTEOTOMIES TO CORRECT VARUS OR VALGUS DEFORMITIES. STAPLE USED TO HOLD OSTEOTOMY SITE.,ARTHROSCOPY IMPLANTS-THE ARTHROSCOPY SYSTEM IMPLANTS ARE INTENDED TO FIX THE DAMAGED OR DISLOCATEDSOFT TISSUE/LIGAMENTS AND REALIGN TO ITS ORIGINAL POSITION.,SPINAL IMPLANT-SPINAL IMPLANTS USED TO

	FACILITATE FUSION, CORRECT DEFORMITIES, AND STABILIZE AND STRENGTHEN THE SPINE.,ARTHROSCOPY IMPLANTS-THE ARTHROSCOPY SYSTEM IMPLANTS ARE INTENDED TO FIX THE DAMAGED OR DISLOCATEDSOFT TISSUE/LIGAMENTS AND REALIGN TO ITS ORIGINAL POSITION.,ENDOPROSTHESIS-ENDOPROSTHESIS ARE SPECIALLY USED IN FEMUR NECK FRACTURE. WHEN FEMUR BONE HEAD IS DAMAGED OR FRACTURED.,PINS , WIRES & WASHERS-THE BONE PINS , WIRES & WASHERS ARE USED WITH IMPLANTS ARE TEMPORARY IMPLANT COMPONENTS THAT ARE INTENDED FOR FRACTURE FIXATION OF BONE AND INSERTION OF IMPLANTS.,BONE PLATES-THE BONE PLATES ARE INTENDED FOR TREATING FRACTURES OF VARIOUS BONES INCLUDING THE CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES).,PINS , WIRES & WASHERS-THE BONE PINS, WIRES AND WASHERS ARE USED WITH IMPLANTS ARE TEMPORARY IMPLANT COMPONENTS THAT ARE INTENDED FOR FRACTURE FIXATION OF BONE AND INSERTION OF IMPLANTS.,BONE PLATES-THE BONE PLATES ARE INTENDED FOR TREATING FRACTURES OF VARIOUS BONES INCLUDING THE CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES).,BONE SCREWS-BONE SCREWS ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR ALONG WITH BONE PLATES OR INTERLOCKING NAILS.,BONE NAIL IMPLANTS-BONE NAIL IMPLANTS ARE COMMONLY USED TO FIX THE LONG BONE FRACTURES.,BONE PLATES-THE BONE PLATES ARE INTENDED FOR TREATING FRACTURES OF VARIOUS BONES INCLUDING THE CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES).,BONE NAIL IMPLANTS-BONE NAIL IMPLANTS ARE COMMONLY USED TO FIX THE LONG BONE FRACTURES.,SPINAL IMPLANT-SPINAL IMPLANTS USED TO FACILITATE FUSION, CORRECT DEFORMITIES, AND STABILIZE AND STRENGTHEN THE SPINE.,BONE PLATES-THE BONE PLATES ARE INTENDED FOR TREATING FRACTURES OF VARIOUS BONES INCLUDING THE CLAVICLE, PELVIS, SCAPULA, LONG BONE (HUMERUS, ULNA, RADIUS, FEMUR, TIBIA AND FIBULA), AND SMALL BONE (METACARPALS, METATARSALS, PHALANGES).,STAPLES-STAPLES ARE INTENDED TO BE USED FOR FRAGMENT FIXATION PARTICULARLY IN SMALL FRAGMENTS ANDWHERE INTERFRAGMENTAL SCREW FIXATION IS NOT POSSIBLE. CONVENTARY STAPLES AREUSED IN TIBIAL OSTEOTOMIES TO

	CORRECT VARUS OR VALGUS DEFORMITIES. STAPLE USED TO HOLD OSTEOTOMY SITE.,PINS , WIRES AND WASHERS-THE BONE PINS, WIRES AND WASHERS ARE USED WITH IMPLANTS ARE TEMPORARY IMPLANT COMPONENTS THAT ARE INTENDED FOR FRACTURE FIXATION OF BONE AND INSERTION OF IMPLANTS.,SPINAL IMPLANT-SPINAL IMPLANTS USED TO FACILITATE FUSION, CORRECT DEFORMITIES, AND STABILIZE AND STRENGTHEN THE SPINE.,BONE SCREWS-BONE SCREWS ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR ALONG WITH BONE PLATES OR INTERLOCKING NAILS.,ENDOPROSTHESIS-ENDOPROSTHESIS ARE SPECIALLY USED IN FEMUR NECK FRACTURE. WHEN FEMUR BONE HEAD IS DAMAGED OR FRACTURED.

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3890	MFG/MD/2021/000233	1.License Holder Name: PREMIER ENTERPRISES 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON GAUZE BP 1988 TYPE 17 (FOR EXPORT)(PREMIER)-THE ABSORBENT COTTON GAUZE ARE USED FOR CLEANING, DRYING AND DRESSING WOUNDS DURING A MEDICAL TREATMENT,OPEN WEAVE BANDAGE IS 16469(PREMIER)-THE OPEN WEAVE BANDAGE ARE USED FOR FIXING AND HOLDING OF INJURED JOINT OR FRACTURED PART OR ALSO USED FOR FIXING DRESSINGS AND ABSORBING EXUDATES, ABSORBENT COTTON GAUZE PH.EUR TYPE 17 (FOR EXPORT) (PREMIER)-THE NON-STERILE ABSORBENT COTTON GAUZE ARE USED TO ABSORB BLOOD AND TO DECREASE THE RISK DURING SURGERY IN OPERATION THEATRE,X-RAY DETECTABLE ABSORBENT COTTON RIBBON GAUZE BP 1988(PREMIER)-ABSORBENT COTTON RIBBON GAUZE USED TO CLEAN, COLONIZED, CONTAMINATED OR INFECTED EXUDING WOUNDS, SUCH AS CAVITY WOUNDS AND FISTULAS,X-RAY DETECTABLE GAUZE SWABS IS 10829(PREMIER)-THE X-RAY DETECTABLE GAUZE SWABS ARE USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, AND ESPECIALLY USED FOR DRESSING WOUNDS,ABSORBENT COTTON RIBBON GAUZE IS 16670(PREMIER)-ABSORBENT COTTON RIBBON GAUZE USED TO CLEAN, COLONIZED, CONTAMINATED OR INFECTED EXUDING WOUNDS, SUCH AS CAVITY WOUNDS AND FISTULAS,X-RAY DETECTABLE LAPAROTOMY SPONGES IS 10829(PREMIER)-THE NON-STERILE X-RAY DETECTABLE LAP SPONGES IS USED TO DRESSING FOR LARGE WOUNDS OR WOUNDS REQUIRE HIGH ABSORBENCY., ABSORBENT GAUZE USP TYPE IV (FOR EXPORT)(PREMIER)-THE ABSORBENT GAUZE ARE USED IN GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS,DRESSING PAD (ABSORBENT COTTON IS 16468 WITH ABSORBENT GAUZE IS 758)(PREMIER)-THE NON-STERILE DRESSING PAD IS APPLIED TO WOUNDS TO PROMOTE HEALING AND PROTECT THE WOUND FORM FURTHER HARM, ABSORBENT GAUZE IS 758(PREMIER)-THE ABSORBENT GAUZE ARE USED IN GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS
3891	MFG/MD/2021/000234	1.License Holder Name: M/S MONI MUKTA TRADING CO. 2.Approving Authority: WEST BENGAL 3.Device Name(Brand Name)-Intended Use:ROLLED BANDAGE (W.O.W)-SURGICAL DRESSINGS,ABSORBENT COTTON WOOL I.P.-SURGICAL DRESSINGS,CREPE BANDAGE B.P.C.-SURGICAL DRESSING

3892	MFG/MD/2021/000235	1.License Holder Name: PRIME ENTERPRISE 2.Approving Authority: WEST BENGAL 3.Device Name(Brand Name)-Intended Use:SURGICAL DRESSING(NIL) -WONDED COVERING SURGICAL DRESSING PURPOSE,SURGICAL DRESSING(NIL)-WONDED COVERING SURGICAL DRESSING PURPOSE, SURGICAL DRESSING(NIL)-WONDED COVERING SURGICAL DRESSING PURPOSE,SURGICAL DRESSING(NIL)-WONDED COVERING SURGICAL DRESSING PURPOSE
3893	MFG/MD/2021/000236	1.License Holder Name: DENTSPLY INDIA PVT. LTD. 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:UNIVERSAL MICROHYBRID COMPOSITE RESTORATIVE(SPECTRUM KIT)-RESTORATIONS OF ALL CAVITY CLASSES IN ANTERIOR AND POSTERIOR TEETH,ROOT CANAL FILLING MATERIAL(GUTTA-PERCHA POINTS)-ENDODONTIC OBTURATOR. INDICATED TO BE THE PREDOMINATE MATERIAL USED TO OBTURATE OR FILL THE CLEANED, SHAPED AND IRRIGATED ROOT CANAL SPACE DURING ROOT CANAL THERAPY.,UNIVERSAL MICROHYBRID COMPOSITE RESTORATIVE(SPECTRUM REFILL)-RESTORATIONS OF ALL CAVITY CLASSES IN ANTERIOR AND POSTERIOR TEETH
3894	MFG/MD/2021/000237	1.License Holder Name: M/S UTESHIYA MEDICARE PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:ARTHROSCOPY IMPLANTS(UTESHIYA, STATIV , VIPLOK, CEPTRE, MONTURA, HELYSIS, INFILOOP, PROLOOP-ULTRA, PROLOOP-MINI, PROLOOP-XL, SIRONIX, SURESTITCH, SPYKE, IVYSTITCH, CRESCENT)-THE ARTHROSCOPY IMPLANTS ARE SMALLER THAN TRADITIONAL IMPLANTS. SURGEONS VIEW THE JOINT AREA ON A VIDEO MONITOR, AND CAN DIAGNOSE AND REPAIR TORN JOINT TISSUE, SUCH AS LIGAMENTS, MUSCLES, TENDON, ETC. IT IS TECHNICALLY POSSIBLE TO DO AN ARTHROSCOPIC SURGERY OF ALMOST EVERY JOINT, BUT IS MOST COMMONLY USED FOR THE KNEE, SHOULDER, HIP, ELBOW, WRIST, ANKLE, ETC.

3895	MFG/MD/2021/000238	1.License Holder Name: SINGH SURGICAL & DRESSING MFG. CO. 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:COTTON BANDAGE (ROLLED BANDAGE) [AS PER SCHEDULE F(II) OF DRUGS RULES](-)-THE COTTON BANDAGES ARE USED TO BIND, WRAP OR AS A SUPPORTIVE MATERIAL FOR WOUNDS ,CUTS, BURNS AND IN DRESSING FOR WOUND HEALING PROCESS.,GAUZE (ABSORBENT COTTON GAUZE) [AS PER SCHEDULE F(II) OF DRUGS RULES](-)-THE ABSORBENT GAUZE IS USED FOR CLEANING, DRYING AND DRESSING WOUNDS IN MEDICAL TREATMENT; ALSO USED AS SUPPORTIVE MATERIAL FOR SURGICAL DRESSING ETC.
3896	MFG/MD/2021/000239	1.License Holder Name: SHRI SURGICAL 2.Approving Authority: RAJASTHAN 3.Device Name(Brand Name)-Intended Use:COTTON BANDAGE (ROLLED BANDAGE) [AS PER SCHEDULE F(II) OF DRUGS RULES](-)-THE COTTON BANDAGES ARE USED TO BIND, WRAP OR AS A SUPPORTIVE MATERIAL FOR WOUNDS ,CUTS, BURNS AND IN DRESSING FOR WOUND HEALING PROCESS,GAUZE (ABSORBENT GAUZE) [AS PER SCHEDULE F(II) OF DRUGS RULES](-)-THE ABSORBENT GAUZE IS USED FOR CLEANING, DRYING AND DRESSING WOUNDS IN MEDICAL TREATMENT, ALSO USED TO SUPPORTIVE MATERIAL FOR DRESSING ETC .
3897	MFG/MD/2021/000240	1.License Holder Name: SPECTRUM MEDTECH PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:SUCTION TIP AND CATHETER(ADLISC)-SUCTION CATHETER FEATURE A WHISTLE TIP AND A THUMB CONTROL PORT FOR PRECISE AND ACCURATE SUCTIONING.
3898	MFG/MD/2021/000241	1.License Holder Name: DAMODAR ENTERPRISE 2.Approving Authority: KARNATAKA 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON IP (DAMODARA ENTERPRISES)-NON-STERILIZED BANDAGE USED UNDER WOUND
3899	MFG/MD/2021/000242	1.License Holder Name: MICROTOL STERILIZATION SERVICES PVT LTD 2.Approving Authority: KOKAN DIVISION 3.Device Name(Brand Name)-Intended Use:SYRINGE(SMB)- INTEND TO INJECT FLUIDS INTO OR WITHDRAW FLUIDS FROM THE BODY

3900	MFG/MD/2021/000243	1.License Holder Name: B L LIFESCIENCES PVT. LTD. 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:BT FILTER(PERFX)-BT FILTER ARE USED DURING BLOOD TRANSFUSION PROCESS TO REMOVE MICROEMBOLI.,PRESSURE MONITORING KIT(IPEX)-PRESSURE MONITORING KIT ARE USED FOR BLOOD PRESSURE SENSING DURING CLINICAL INVASIVE PROCEDURES WITHOUT INTERFERING WITH BLOOD FLOW AND/OR PRESSURE.,NEEDLELESS VALVE(IPEX)-TO BE USED AS AN ACCESSORY OF PRESSURE MONITORING KIT FOR THE ADMINISTRATION OR WITHDRAWAL OF FLUIDS FROM A PATIENT THROUGH A CANNULA/CATHETER PLACE IN THE VEIN OR ARTERY.,PRESSURE MONITORING LINE(IPEX)-THE PRESSURE MONITORING LINES ARE INDICATED TO BE USED FOR THE TRANSMISSION OF WAVES OF INVASIVE BLOOD PRESSURE OF THE PATIENT TO THE VITAL SIGN MONITORING DURING OT/ICU CARE. & FOR FLUID ADMINISTRATION.,FLOW REGULATOR LINE(IPEX)-TO BE USED IN COMBINATION WITH IV DELIVERY LINE TO CONTROL THE FLOW RATE OF IV FLUID.,IV SET(IPEX)-TO ADMINISTER PARENTERAL FLUID/ MEDICATIONS INTO THE PATIENT'S VASCULAR SYSTEM., CONTROL SYRINGE(ANGIX)-CONTROL SYRINGE IS A HAND-CONTROLLED DEVICE USED TO INJECT CONTRAST MEDIA DURING ANGIOGRAPHY PROCEDURE.,MISTER BLOWER(PERFX)-MISTER BLOWER IS INTENDED TO CLEAR AN ANASTOMOTIC SITE FOR IMPROVED VISIBILITY BY PROVIDING CONTROLLED DELIVERY OF CO2 AND SALINE.,YANKAUER SUCTION SET(SURGX)-YANKAUER SUCTION SET IS USED FOR THE REMOVAL OF BLOOD AND FLUIDS DURING THE SURGERY WITHOUT DAMAGING THE BODY TISSUE.,HEAT & MOISTURE EXCHANGER FILTER(IREX)-HME FILTER ARE USED IN MECHANICALLY VENTILATED PATIENTS INTENDED TO HELP PREVENT COMPLICATIONS DUE TO DRYING OF RESPIRATORY MUCOSA SUCH AS MUCUS PLUGGING AND ENDOTRACHEAL TUBE OCCLUSION.,HEMOSTASIS Y(ANGIX)-HEMOSTASIS Y IS USED TO MAINTAIN HEMOSTASIS DURING THE INTRODUCTION, USE AND WITHDRAWAL OF DIAGNOSTIC AND INTERVENTIONAL DEVICES, USED IN ANGIOPLASTY PROCEDURES.,THORACIC DRAINAGE CATHETER (SURGX)-THORACIC DRAINAGE CATHETER IS INTENDED TO DRAIN THE THORACIC CAVITY DURING THE SURGERY.,TUBING(PERFX)-TUBINGS ARE SPARE TUBINGS STERILE MEDICAL GRADES TUBINGS PROVIDED TO BE USED AS AN ACCESSORIES IN EXTRA-CORPOREAL CIRCULATION. THESE ARE THE ACCESSORIES TO HEART LUNG PACK., VENOUS CANNULA(PERFX)-VENOUS CANNULAE/VENOUS CATHETERS IS INTENDED FOR THE PERFUSION OF THE ASCENDING AORTA DURING CARDIOPULMONARY BYPASS.,TORQUE DEVICE (ANGIX)-TORQUE DEVICE IS INTENDED TO MANIPULATE GUIDEWIRE

	MOVEMENT & PLACEMENT; USED FOR EASY MANEUVERABILITY OF GUIDEWIRE DURING INTERVENTIONAL PROCEDURES.,SAMPLING MANIFOLD KIT(PERFX)-SAMPLING MANIFOLDS KITS ARE INTENDED TO SERVE FLOW CONTROL AND DELIVERY DEVICES FOR I.V FLUIDS INJECTION TO THE PATIENT'S VASCULAR SYSTEM.,HLP CONNECTOR (PERFX)-HLP CONNECTORS USED TO CONNECT THE TWO PERFUSION TUBING TO EACH OTHER. THESE ARE THE ACCESSORIES TO HEART LUNG PACK.,INFLATION DEVICE(ANGIX)-INFLATION DEVICE IS USED TO INFLATE & DEFLATE THE BALLOON AND MEASURE THE PRESSURE.,GAS FILTER(PERFX)-GAS FILTER IS INTENDED TO REMOVE BACTERIA TO MINIMIZE CROSS CONTAMINATION BETWEEN PATIENT AND EQUIPMENT. THIS IS AN ACCESSORY OF HEART LUNG PACK.,STOPCOCK(IPEX)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING.,INTRODUCER NEEDLE(ANGIX)-INTRODUCER NEEDLE IS A DEVICE INDICATED TO USE TO CREATE AN INCISION IN THE SKIN OR VESSEL TO FACILITATE OTHER DEVICES TO ENTER INTO THE BODY.,AORTIC CANNULA(PERFX)-AORTIC CANNULA / AORTIC CATHETERS (ARTERIAL CANNULAE/ ARTERIAL CATHETERS) IS INTENDED FOR THE PERFUSION OF THE ASCENDING AORTA DURING CARDIOPULMONARY BYPASS.,HIGH PRESSURE TUBING(ANGIX)-HIGH PRESSURE TUBING IS THE TUBING TO CARRY THE FLUID / CONTRAST MEDIA TO THE PATIENT DURING ANGIOGRAPHY PROCEDURE.,ANGIO KIT(ANGIX)-IT IS USED DURING THE ANGIOGRAPHIC OR PTCA PROCEDURES TO DIAGNOSE/TREAT CARDIAC BLOCKAGES. THESE KITS ARE ESPECIALLY CUSTOMIZED PROCEDURE PACKS DESIGNED AS PER CLINICIAN'S OR HOSPITAL'S PROTOCOL, INDICATED FOR USE DURING CARDIAC & VASCULAR CATHETERIZATION/RADIOLOGY PROCEDURES IN ORDER TO DIAGNOSE THE POSSIBLE BLOCKAGE IN AN ARTERY OR VESSEL.,MANIFOLD(ANGIX)-MANIFOLD IS A HAND-CONTROLLED DEVICE USED DURING THE INJECTION OF CONTRAST MEDIA DURING ANGIOGRAPHY PROCEDURE.,DISPOSABLE PRESSURE TRANSDUCER(IPEX)-DISPOSABLE PRESSURE TRANSDUCER IS USED FOR BLOOD PRESSURE SENSING DURING CLINICAL INVASIVE PROCEDURES WITHOUT INTERFERING PATIENT'S BLOOD FLOW AND/OR PRESSURE.,EXTENSION LINE(IPEX)-EXTENSION LINE/MULTIPLE EXTENSION LINE/INFUSION LINE USED AS AN EXTENSION IN THE CIRCUIT DURING THE ANESTHESIA SET-UP IN OR / ICU AND ENSURE FREE FLOW OF THE FLUID & SAFETY IN BLOOD SAMPLING PROCEDURE.,CHEST DRAINAGE SYSTEM(SURGX)-CHEST DRAINAGE SYSTEM ARE STERILE, SINGLE USE, DISPOSABLE DEVICE FOR COLLECTING BODY FLUIDS FROM THE PATIENTS DURING POST OPERATIVE PROCEDURES.

3901	MFG/MD/2021/000244	1.License Holder Name: BHASKAR SURGICAL PRIVATE LIMITED 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON I.P. WOOL-SURGICAL COTTON OR COTTON WOOL IS MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES, AND AT HOME(FOR FIRST AID). APART FROM MEDICAL PURPOSES, ABSORBENT COTTON IS ALSO USED FOR MAKING A CONVENTIONAL TYPE OF SANITARY NAPKINS OR PADS.
3902	MFG/MD/2021/000245	1.License Holder Name: M/S SRI GOPAL KRISHNA LABS PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:HAEMOSTATIC GELATIN SPONGE (ABGEL™ ABSORBABLE GELATIN SPONGE USP)-ABGEL™- ABSORBABLE GELATIN SPONGE USP, USED DRY OR SATURATED WITH STERILE SODIUM CHLORIDE SOLUTION, IS INDICATED FOR SURGICAL PROCEDURES, LIGATURE AND OTHER CONVENTIONAL PROCEDURES IS INEFFECTIVE OR IMPRACTICAL. ALTHOUGH NOT NECESSARY, ABGEL™- ABSORBABLE GELATIN SPONGE USP CAN BE USED WITH THROMBIN TO ACHIEVE HEMOSTASIS.
3903	MFG/MD/2021/000246	1.License Holder Name: MEHRU MEHTA APANGODDHAR AUDYOGIK SAHAKARI SOCIETY LTD 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:BANDAGE CLOTH-BANDAGE CLOTH USED IN WOUND CARE FOR CLEANING OR COVERING THE WOUND OR BANDAGING THE WOUND AREA OR PLASTIC PACKAGING,BANDAGE GAUZE-BANDAGE GAUZE USED IN WOUND CARE FOR CLEANING OR COVERING THE WOUND OR BANDAGING THE WOUND AREA OR PLASTIC PACKAGING

3904	MFG/MD/2021/000247	1.License Holder Name: M/S RIVARP MEDICAL PVT LTD. 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use: DISTRACTABLE/EXPANDABLE PEEK CAGE- DISTRACTABLE/EXPANDABLE PEEK CAGE IS INDICATED FOR INTERVERTEBRAL BODY FUSION PROCEDURES IN SKELETALLY MATURE PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD) AT ONE OR TWO CONTIGUOUS LEVELS FROM L2-S1. DDD IS DEFINED AS DISCOGENIC BACK PAIN WITH DEGENERATION OF THE DISC CONFIRMED BY PATIENT HISTORY AND RADIOGRAPHIC STUDIES. THESE DDD PATIENTS MAY ALSO HAVE UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVEL (S). THIS DEVICE IS TO BE USED WITH AUTOGENOUS BONE GRAFT AND/OR ALLOGENOUS BONE GRAFT COMPOSED OF CANCELLOUS AND/OR CORTICOCANCELLOUS BONE.THIS CAGE IS TO BE USED WITH SUPPLEMENTAL FIXATION. PATIENTS SHOULD HAVE AT LEAST SIX (6) MONTHS OF NON-OPERATIVE TREATMENT PRIOR TO TREATMENT WITH AN INTERVERTEBRAL CAGE.,ANTERIOR CERVICAL PEEK CAGE SYSTEM-ANTERIOR CERVICAL PEEK CAGE SYSTEM IMPLANTS ARE USED TO FACILITATE INTERVERTEBRAL BODY FUSION IN THE CERVICAL SPINE AND ARE PLACED VIA AN ANTERIOR APPROACH AT THE C2 TO TI DISC LEVELS USING AUTOGRAFT BONE. ANTERIOR CERVICAL CAGE IMPLANTS ARE TO BE USED WITH SUPPLEMENTAL FIXATION. PATIENTS SHOULD HAVE AT LEAST SIX (6) WEEKS OF NON-OPERATIVE TREATMENT PRIOR TO TREATMENT WITH AN INTERVERTEBRAL CAGE. WHERE AS STANDALONE ANTERIOR CERVICAL CAGE IS INTENDED TO BE USED AS SAME AS ANTERIOR CERVICAL CAGE WITH ADDED FEATURE I.E. IT IS A STANDALONE SYSTEM USED WITH THE TWO BONE SCREWS PROVIDED AND REQUIRES NO ADDITIONAL SUPPLEMENTARY FIXATION SYSTEMS.,LUMBAR INTERBODY FUSION PEEK CAGES-THE LUMBAR INTERBODY FUSION PEEK CAGES (PLIF-P , TLIF-P AND OLIF-P) ARE USED FOR, AT EITHER ONE LEVEL OR TWO CONTIGUOUS LEVELS FOR THE TREATMENT OF DEGENERATIVE DISC DISEASE (DDD) WITH UP TO GRADE I SPONDYLOLISTHESIS OR RETROLISTHESIS & ALSO THE DEVICE IS INTENDED FOR USE WITH SUPPLEMENTAL FIXATION AND WITH AUTO GRAFT TO FACILITATE FUSION.

3905	MFG/MD/2021/000248	1.License Holder Name: NUBENO HEALTHCARE PRIVATE LIMITED 2.Approving Authority: NAGPUR DIVISION 3.Device Name(Brand Name)-Intended Use:HYPODERMIC SYRINGES (EUROMEDD)-INTENDED FOR THE INJECTION OF MEDICATIONS INTO OR THE WITHDRAWAL OF BODY FLUIDS FROM PARTS OF THE BODY BELOW THE SURFACE OF THE SKIN ,I.V. CANNULA(EUROMEDD)-THE IV CANNULA IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS, DRUGS, AND/OR BLOOD COMPONENTS, OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES. I.V. CATHETER IS INSERTED INTO THE PATIENT'S VASCULAR SYSTEM FOR SHORT TERM USE (LESS THAN 30 DAYS) TO WITHDRAW BLOOD SAMPLES, MONITOR BLOOD PRESSURE, OR ADMINISTER FLUIDS INTRAVENOUSLY.

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3906	MFG/MD/2021/000249	1.License Holder Name: TRIDENT MEDIQUIP LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:EXTENSION LINE/SET (TRIDENT)-IT IS INTENDED FOR USE IN FOR ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,3-WAY STOPCOCK WITH EXTENSION LINE(TRIDENT)-3-WAY STOP COCK WITH EXTENSION TUBE IS TO BE USED WITH ANY OF THE VARIOUS INFUSION OR TRANSFUSION DEVICES IN ORDER TO ALLOW FOR ATTACHMENT WITH ANY SPECIAL OR GENERAL PURPOSE MEDICAL DEVICE, IN ORDER TO IMPROVE EASE OF USE ALSO TO PROVIDE AN ALTERNATIVE CHANNEL FOR INTRODUCTION OF MEDICINE TO THE PATIENT. ,INTRAVENOUS CANNULA (TRIDENT)-I V CANNULA ALSO KNOWN AS IV CATHETER IS A BEVEL TYPE NEEDLE USED FOR EASIER AND LESS TRAUMATIC INSERT. THIS TUBE OF CATHETER IS FLEXIBLE, KINK RESISTANT AND IS DOUBLE TAPERED WITH ROUNDED TIP FOR SMOOTH INTRODUCTION AND MINIMUM DISCOMFORT TO THE PATIENT.,BLOOD ADMINISTRATION SET(TRIDENT)-IT IS INTENDED FOR USE IN FOR ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,HIGH PRESSURE MONITORING LINE (TRIDENT)-PRESSURE LINE IS INTENDED TO USE AS A JOINT BETWEEN TWO DEVICES, TOPICALLY LIKE MANIFOLDS AND PRESSURE MONITORING SYSTEM, INTERVENTION CATHETER AND THE HIGH-PRESSURE INJECTOR. ALSO, THE PRESSURE LINE IS USED AS AN EXTENSION TO CONNECT MEDICAL INSTRUMENTS.,INFUSION GIVING SET(TRIDENT)-IT IS INTENDED FOR USE IN FOR ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,SCALP VEIN SET (TRIDENT)-THE SCALP VEIN SET IS IDEAL FOR BLOOD SAMPLING AND INJECTION OF SMALL AMOUNTS OF INFUSION SOLUTIONS. IT IS FREQUENTLY USED IN THE TREATMENT OF PATIENTS WITH CONTRACTURES AND IN PEDIATRICS.,I V CANNULA WITH 3-WAY STOPCOCK(TRIDENT)-IT IS INTENDED FOR USE OF I V CANNULA WITH 3-WAY STOPCOCK IS TO PROVIDE 3-WAY FLOW (FROM INLET TO OUTLET, INLET TO SIDE-PORT OR SIDE PORT TO OUTLET) BY USE OF THE HANDLE ON THE TOP OF THE STOPCOCK TO OPEN AND CLOSE LINES. THE DEVICE CAN ALSO BE USED TO REDUCE TO LINES DOWN TO ONE, FOR DRUGS/DRUG INFUSION PURPOSES AND FOR THE ATTACHMENT OF EXTENSION LINES. DISPOSABLE, STERILE AND NON-PYROGENIC., MEASURE VOLUME SET/BURETTE SET(TRIDENT)-IT IS INTENDED FOR USE IN FOR ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,INFUSION GIVING SET WITH FLOW REGULATOR(TRIDENT)-IT

		IS INTENDED FOR USE FLOW REGULATOR INTEGRATED INTO I.V. INFUSION SET FOR PRECISE FLOW CONTROL. . IV FLOW REGULATOR EXTENSION SET ENSURES ACCURATE FLOW CONTROL AND CAN BE USED AS A REPLACEMENT OF IV INFUSION PUMP. FOR THE FOWL RATE CONTROL OF IV FLUIDS DURING INFUSION AND TRANSFUSION, MICRO DRIP SET(TRIDENT)-IT IS INTENDED FOR USE IN FOR ADMINISTRATION OF FLUIDS FROM A CONTAINER INTO THE PATIENT' S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE. ,3-WAY STOPCOCK(TRIDENT)-PROVIDES MULTIPLE ACCESS PORTS DURING INFUSION AND TRANSFUSION FOR STANDARD NON LIPID IV FLUIDS AND OTHER SOLUTIONS. ALSO CAN BE USED DURING IBP MONITORING.
3907	MFG/MD/2021/000250	1.License Holder Name: DEVPARV SURGICO 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(ANGLE,/SOURCE/UNIQUE/NEO-CARE)-TRANSFUSION SET IS USED TO ADMINISTER BLOOD/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN,STERILE RYLE'S / NASOGASTRIC / GASTRO DUODENAL / LEVIN'S TUBE FOR SINGLE USE ONLY(ANGLE, /SOURCE/UNIQUE/NEO-CARE)-IT IS A SPECIAL TUBE THAT CARRIES FOOD AND MEDICINE TO THE STOMACH THROUGH THE NOSE. IT CAN BE USED FOR ALL FEEDINGS OR FOR GIVING A PERSON EXTRA CALORIES,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(ANGLE, /SOURCE/UNIQUE/NEO-CARE)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE UMBILICAL CORD CLAMP FOR SINGLE USE ONLY(ANGLE,/SOURCE/UNIQUE/NEO-CARE)-THESE DEVICES MAY BE A CLIP, TIE, TAPE, OR OTHER ARTICLE USED TO CLOSE THE BLOOD VESSELS IN THE UMBILICAL CORD OF A NEWBORN INFANT.,STERILE SCALP VEIN SET FOR SINGLE USE ONLY(ANGLE, /SOURCE/UNIQUE/NEO-CARE)-INTENDED TO BE USED FOR INSERTION INTO THE PATIENT'S VASCULAR SYSTEM (SINGLE USE ONLY) AS AN IN-DWELLING DEVICE TO ADMINISTER FLUIDS INTRAVENOUSLY OR TO SAMPLE BLOOD

3908	MFG/MD/2021/000251	1.License Holder Name: M/S. LIFELONG MEDITECH PRIVATE LIMITED 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITHOUT NEEDLE(ULTRASAFE)-ADMINISTRATION OF INJECTIONS OR MEDICINAL FLUIDS INTRAMUSCULAR AND INTRAVENOUS. ,STERILE HYPODERMIC SYRINGE FOR SINGLE USE WITH NEEDLE(ULTRASAFE)-ADMINISTRATION OF INJECTIONS OR MEDICINAL FLUIDS INTRAMUSCULAR AND INTRAVENOUS,STERILE HYPODERMIC NEEDLES FOR SINGLE USE(ULTRASAFE)-ADMINISTRATION OF INJECTIONS OR MEDICINAL FLUIDS INTRAMUSCULAR AND INTRAVENOUS.
3909	MFG/MD/2021/000253	1.License Holder Name: PIRAMAL PHARMA LIMITED 2.Approving Authority: MADHYA PRADESH 3.Device Name(Brand Name)-Intended Use:CONTACT LENS CLEANING/NEUTRALIZING SOLUTION(OXYSEPT II UNIT DOSE (9247X))-THE INTENDED USE OF THIS PRODUCT IS TO NEUTRALIZE THE PEROXIDE SOLUTION, WHICH IS USED TO REMOVE THE PROTEIN LAYER FROM THE CONTACT LENS, WHICH IS DEPOSITED ON THE CONTACT LENS DURING THE USE OF LENSES.,CONTACT LENS CLEANING/NEUTRALIZING TABLETS(OXYSEPT UPGRADE TABLETS (9081X))-THE INTENDED USE OF THE PRODUCT OXYSEPT UPGRADE TABLETS (9081X) IS TO REMOVE THE PROTEIN LAYER FROM THE CONTACT LENS, WHICH IS DEPOSITED ON THE CONTACT LENS DURING, USE OF LENSES.
3910	MFG/MD/2021/000254	1.License Holder Name: INFINITY MEDIQUIP INDIA PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:NEBULIZER WITH ACCESSORIES KIT(INFI-NEB)-SINGLE USE DEVICE INTENDED FOR PROVIDING OR TRANSFERRING PRESCRIBED MEDICATION IN AEROSOL FORM INTO LUNGS THROUGH COMPRESSIVE AIR OR OXYGEN. COMPRESSOR NEBULIZER SHALL BE USED UNDER THE SUPERVISION OF A PHYSICIAN OR A RESPIRATORY THERAPIST AND CAN BE USED AT HOMEUNDER MEDICAL EXPERT GUIDANCE ONLY., NEBULIZER WITH ACCESSORIES KIT(MEDIWARE)-IT IS A DEVICE USED TO ADMINISTER MEDICINE IN THE FORM OF AEROSOL TO INHALE FOR TREATMENT OF RESPIRATORY DISORDER

3911	MFG/MD/2021/000255	1.License Holder Name: M. M. SURGICALS 2.Approving Authority: MADHYA PRADESH 3.Device Name(Brand Name)-Intended Use:ABSORBENT GAUZE -FOR SURGICAL DRESSINGS,COTTON CREPE BANDAGE BP-FOR SURGICAL DRESSING,OPEN WOVE BANDAGE-FOR SURGICAL DREESINGS, ABSORBENT COTTON WOOL IP-FOR SURGICAL DRESSING , ABSORBENT COTTON BP-FOR SURGICAL DRESSING,ABSORBENT GAUZE-FOR SURGICAL DRESSING,BANDAGE CLOTH -FOR SURGICAL DRESSING
3912	MFG/MD/2021/000256	1.License Holder Name: ILIFE MEDICAL DEVICES PVT LTD 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:THREE WAY STOP COCK (VANOSAFE)-IT IS INDICATED FOR FLUID FLOW DIRECTIONAL CONTROL AND FOR PROVIDING ACCESS PORT FOR ADMINISTRATION OF SOLUTION, WITHDRAWAL OF FLUID AND PRESSURE MONITORING. ,EXTENSION TUBE(VANOSAFE)-EXTENSION TUBES ARE STERILE DEVICES FOR SINGLE USE ONLY,THEY ARE INTENDED TO BE USED AS PART OF A SYSTEM FOR INFUSION OF FLUIDS/MEDICINES IN MEDICAL APPLICATIONS.,INTRAVENOUS CATHETER(VANOSAFE)-THE IV CANNULA /CATHETER IS A PASSIVE DEVICE TO PROVIDE FOR THE INFUSION OF FLUIDS,DRUGS AND /OR BLOOD COMPONENTS OR TO FACILITATE THE PLACEMENT OF VASCULAR ACCESS DEVICES.
3913	MFG/MD/2021/000258	1.License Holder Name: VIKAS OVERSEAS 2.Approving Authority: PUNJAB 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON WOOL I.P.-FOR APPLYING MEDICATION TO, OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS

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3914	MFG/MD/2021/000259	1.License Holder Name: OYSTER MEDISAFE PRIVATE LIMITED 2.Approving Authority: TELANGANA 3.Device Name(Brand Name)-Intended Use:STERILE HYPODERMIC SYRINGES FOR SINGLE USE-STERILE HYPODERMIC SYRINGES FOR SINGLE USE WITH AND WITHOUT NEEDLE ARE MEDICAL DEVICES THAT ARE DEDICATED FOR THE ASPIRATION AND INJECTION OF FLUIDS, ADMIXTURE OF DRUGS AND EXTRACTION OF BODY FLUIDS., INFUSION SET -INFUSION EQUIPMENT FOR SINGLE USE IS USED FOR GRAVITY INFUSION OF FLUID AND DRUG ADMINISTRATION, INFUSION OF TOTAL PARENTAL NUTRITION, ANTIBIOTICS WITH BOTTLES AND BAGS, AND CYTOSTATICS.,PRESSURE MONITORING LINE-PRESSURE MONITORING LINE IS USED AS A PRESSURE TUBING FOR MEASUREMENT OF PHYSIOLOGICAL PRESSURE CONNECTED TO INFUSION PUMPS.,STERILE SINGLE-USE AUTO DISABLE SYRINGES-STERILE SINGLE-USE AUTO DISABLE SYRINGES, 3-PIECE WITH AND WITHOUT NEEDLE ARE MEDICAL DEVICES THAT ARE DEDICATED FOR THE ASPIRATION AND INJECTION OF FLUIDS, ADMIXTURE OF DRUGS AND EXTRACTION OF BODY FLUIDS.,HYPODERMIC NEEDLES FOR SINGLE USE-HYPODERMIC NEEDLES ARE A SINGLE USE DEVICE USED FOR INJECTIONS, BLOOD SAMPLING OR ASPIRATION OF FLUIDS., BLOOD TRANSFUSION SET-BLOOD TRANSFUSION REFERS TO THE ADMINISTRATION OF BLOOD OR BLOOD COMPONENTS (RED BLOOD CELL CONCENTRATES, PLATELET CONCENTRATES, FRESH FROZEN PLASMA, PLASMA DERIVATES) DIRECTLY INTO A PATIENT'S VENOUS CIRCULATORY SYSTEM.

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3915	MFG/MD/2021/000260	1.License Holder Name: SWEJER HEALTHCARE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:X-RAY DETECTABLE ABDOMINAL PAD (NA)-X-RAY THREAD HELP IN DETECTING THE PRESENCE OF UNWANTED THINGS. DURING SURGERY, IT IS USED TO ABSORB BLOOD &EXUDATES. CLEAN WOUNDS & PREVENT WOUNDS FROM BEING INFECTED.,CREPE BANDAGES(NA)-SUITABLE FOR KEEPING GAUZE IN PLACE, STEMMING BLEEDING, AND PROVIDING LIGHT COMPRESSION. THE HEAVY WEIGHT CREPE BANDAGE IS SUITABLE FOR USE AS SUPPORT FOR SPRAINS AND STRAINS IN JOINTS AND MUSCLES. IT ALSO WORKS AS A MODERATE COMPRESSION BANDAGE FOR KNEE SWELLING, ANKLE SWELLING, AND OTHER RELEVANT INJURIES. USED FOR COVERING SUTURED WOUNDS/INCISIONS, ON LOW TO MEDIUM EXUDING WOUNDS FOR CUSHIONING IMMOBILIZED JOINTS.,ABSORBENT GAUZE ROLL U. S.P. (NA)-ABSORBENT GAUZE ROLL ARE MAINLY USED DURING OPERATIONS AND ITS MAIN FUNCTION IS TO ABSORB THE BLOOD FROM WOUND. THE ABSORBENT GAUZE IS MOST VITAL ITEM IN SURGICAL DRESSING.,BANDAGE CLOTH (NA)-EITHER TO SUPPORT A MEDICAL DEVICE SUCH AS DRESSING OR SPLINT, OR ON ITS OWN TO PROVIDE SUPPORT TO OR TO RESTRICT MOVEMENT OF A PART OF THE BODY. HOLD A DRESSING IN PLACE ON A WOUND MAINTAIN PRESSURE OVER A BULKY PAD TO CONTROL BLEEDING SUPPORT AN INJURED LIMB OR JOINT APPLY PRESSURE TO A LIMB.,GAMJEE ROLLS(NA)-GAMJEE ROLL ARE HIGHLY ABSORBENT COTTON ARE AVAILABLE IN LOW ADHERENT GAUZE COVER AND IS APPLIED OVER DRESSING TO PROVIDE LOW ADHERENT WOUND INTERFACE. GENERALLY USED FOR PRIMARY WOUND DRESSINGS OR IS APPLIED OVER A DRESSING, THESE BANDAGE ROLL ALLOW LOW ADHERENT WOUND INTERFACE.,EYE DRESSING PAD (NA)-SMALL PADS DESIGNED FOR ABSORPTION OF SECRETIONS FROM THE EYES. EYE PADS USUALLY ABSORB TEARS, BLOOD, OR OTHER SECRETIONS DUE TO ACCIDENTAL INJURIES, DISEASES, OR OPHTHALMIC SURGERY.THEY ARE VERY EFFECTIVE IN PROVIDING INSTANT COOLING AND RELAXING EFFECT TO EYES. ,ABSORBENT GAUZE B. P.(NA)-ABSORBENT GAUZE ARE MAINLY USED DURING OPERATIONS AND ITS MAIN FUNCTION IS TO ABSORB THE BLOOD FROM WOUND. THE ABSORBENT GAUZE IS MOST VITAL ITEM IN SURGICAL DRESSING, GAUZE SWABS (NA)-IT USEFUL UTILITY PRODUCT IN A KIT CAN BE USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, APPLYING ANTISEPTIC AND MUCH MORE. IT IS ESPECIALLY USEFUL FOR DRESSING WOUNDS WHERE OTHER FABRICS MIGHT STICK TO THE BURN OR LACERATION.,GAUZE PADS (NA)-GAUZE PADS ARE USED IN A NUMBER OF DIFFERENT APPLICATIONS AND ARE GREAT

		FOR GENERAL CLEANING, DRESSINGS, PREPPING, PACKING AND DEBRIDING WOUNDS. IT CAN ALSO BE USED AS A TEMPORARY ABSORBENT DRESSING OVER WOUNDS.,ROLLED BANDAGES(NA)-A ROLLED BANDAGE IS USED TO SECURE A DRESSING IN PLACE. A ROLLED BANDAGE IS USED AS AN ARM SLING OR AS A PAD TO CONTROL BLEEDING. IT MAY ALSO BE USED TO SUPPORT OR IMMOBILISE AN INJURY TO A BONE OR JOINT OR AS IMPROVISED PADDING OVER A PAINFUL INJURY.
3916	MFG/MD/2021/000261	1.License Holder Name: MICROTROL STERILISATION SERVICES PVT LTD. 2.Approving Authority: HARYANA 3.Device Name(Brand Name)-Intended Use:INTRODUCER NEEDLE (TRANS-NEEDLE)-INTRODUCER NEEDLE IS USED TO INTRODUCE GUIDEWIRE.,PTCA Y CONNECTOR KIT(TRANS-PTCA KIT)-THE PTCA Y CONNECTOR KIT IS INTENDED TO MAINTAIN HAEMOSTASIS BEFORE AND DURING THE INTRODUCTION/THE USE AND WITHDRAWAL OF DIAGNOSTIC/INTERVENTIONAL DEVICES DURING INTERVENTIONAL PROCEDURES.,PTCA KIT(TRANS- PT)-PTCA KIT INTENDED FOR USE AS ACCESSORIES FOR PERCUTANEOUS CORONARY ANGIOGRAPHY (PTCA) PROCEDURE ,INFLATION DEVICE(TRANS-ID)-AN INFLATION DEVICE IS USED FOR THE INFLATION AND DEFLATION OF A BALLOON DILATATION CATHETER, TO DILATE THE VESSEL OR IMPLANT A STENT.,PTCA Y CONNECTOR KIT(TRANS PTCA KIT-PRIME)-THE PTCA Y CONNECTOR KIT IS INTENDED TO MAINTAIN HAEMOSTASIS BEFORE AND DURING THE INTRODUCTION/THE USE AND WITHDRAWAL OF DIAGNOSTIC/INTERVENTIONAL DEVICES DURING INTERVENTIONAL PROCEDURES,ANGIO KIT (TRANS- AT)-ANGIO KIT INTENDED FOR USE AS ACCESSORIES FOR PERCUTANEOUS CORONARY ANGIOGRAPHY (PTCA) PROCEDURE ,MANIFOLD(TRANS-FOLD)-TRANS-FOLD IS INTENDED FOR CONNECTION BETWEEN THE DEVICES, SUCH LIKE INJECTION SYRINGE, ANGIOGRAPHIC CATHETER, DRIP SET TO THE BOTTLE DELIVERING CONTRAST AGENT OR SALINE FLUSH, OR PRESSURE MONITORING SYSTEM, ETC. EACH FLUID CHANNELS CAN BE INDEPENDENTLY

3917	MFG/MD/2021/000262	1.License Holder Name: NOVA MEDICAL DEVICES 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE INFUSION SET WITH AND WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (- - -)-:THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. , STERILE DISPOSABLE MICRO DRIP INTRAVENOUS INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(- - -)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.

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3918	MFG/MD/2021/000263	1.License Holder Name: NARANG MEDICAL LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:SPINAL IMPLANT-TITANIUM(NET)-THESE IMPLANTS ARE INTENDED TO BE USED AS A TEMPORARY OR PERMANENT POSTERIOR,NON CERVICAL IMPLANTS TO CORRECT SPINAL DISORDERS AND PROVIDE STABILIZATION OF THE SPINE TO PERMIT THE BIOLOLOGICAL PROCESS OF SPINAL FUSIONS TO OCCUR.,HIP PROSTHESIS-STAINLESS STEEL(NET)-HIP PROSTHESIS ARE INDICATED FOR DEGENERATED FEMORAL HEAD REPLACEMENT,INTRAMEDULLARY NAILS - TITANIUM(NET)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS.,HIP PROSTHESIS-TITANIUM (NET)-HIP PROSTHESIS ARE INDICATED FOR DEGENERATED FEMORAL HEAD REPLACEMENT.,HIP PROSTHESIS-TITANIUM(NET)-HIP PROSTHESIS ARE INDICATED FOR DEGENERATED FEMORAL HEAD REPLACEMENT,BONE PLATE - TITANIUM(NET)-BONE PLATE IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS., BONE SCREW -TITANIUM(NET)-BONE SCREWS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR BONE RECONSTRUCTION.,BONE PLATE-STAINLESS STEEL(NET)-BONE PLATE IMPLANTS ARE INTENDED FOR TEMPORARY FIXATION, CORRECTION OR STABILIZATION OF BONES IN VARIOUS ANATOMICAL REGIONS.,BONE SCREW-STAINLESS STEEL(NET)-BONE SCREWS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES, FUSION OF JOINTS OR BONE RECONSTRUCTION, INTRAMEDULLARY NAILS-STAINLESS STEEL(NET)-INTRAMEDULLARY NAILING IMPLANTS ARE INTENDED TO BE USED FOR TEMPORARY FIXATION AND STABILIZATION OF LONG BONES IN VARIOUS ANATOMICAL REGIONS SUCH AS PROXIMAL FEMUR, FEMORAL SHAFT, TIBIA AND HUMERUS,ORTHOPAEDIC STAPLES-TITANIUM (NET)-INTENDED FOR FIXATION OF BONE FRACTURES OR BONE RECONSTRUCTION. THE STAPLES ARE ALSO USED IN FIXATION OF SOFT TISSUES TO BONE,ORTHOPAEDIC STAPLES-STAINLESS STEEL (NET)-INTENDED FOR FIXATION OF BONE FRACTURES OR BONE RECONSTRUCTION. THE STAPLES ARE ALSO USED IN FIXATION OF SOFT TISSUES TO BONE,ORTHOPAEDIC PINS AND WIRE (FIXATORS)-STAINLESS STEEL(NET)-THESE IMPLANTS ARE USED IN FIXATION OF BONE FRACTURES, BONE RECONSTRUCTION, SKELETAL TRACTION, ALIGNMENT OF LONG BONE FRACTURED SEGMENTS, TEMPORARY FIXATION, INTRAMEDULLARY FIXATION OF ULNA & CLAVICLE. THESE ARE ALSO USED AS GUIDE PINS & WIRES FOR INSERTION OF

	IMPLANTS

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3919	MFG/MD/2021/000264	1.License Holder Name: PHILIPS INDIA LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:X-RAY MACHINE(BV VECTRA)-THIS PRODUCT IS INTENDED TO BE USED AND OPERATED BY ADEQUATELY TRAINED, QUALIFIED AND AUTHORIZED HEALTHCARE PROFESSIONALS SUCH AS PHYSICIANS, SURGEONS, RADIOLOGISTS AND TECHNOLOGISTS, WHO HAVE FULL UNDERSTANDING OF THE SAFETY INFORMATION AS WELL AS THE CAPABILITIES AND FUNCTIONS OF THE SYSTEM. THE SYSTEM IS USED FOR RADIOLOGICAL GUIDANCE AND VISUALIZATION DURING DIAGNOSTIC AND SURGICAL PROCEDURES ON PATIENTS. THE PATIENTS CAN BE ALL PATIENTS INCLUDING CHILDREN ABOVE THE AGE OF 8 YEARS OLD WHO ARE WITHIN THE LIMITS OF THE SYSTEM OR AS PER THE CLINICAL JUDGMENT OF THE PHYSICIAN. THE SYSTEM IS TO BE USED INSIDE AND OUTSIDE THE OPERATING ROOM, IN A STERILE AS WELL AS NON STERILE ENVIRONMENT WITH A VARIETY OF PROCEDURES. APPLICATION AREAS • ORTHOPEDIC SURGERIES • PAIN MANAGEMENT,X-RAY MACHINE(ZENITION 50)-THE ZENITION 50 DEVICE IS INTENDED TO BE USED AND OPERATED BY ADEQUATELY TRAINED, QUALIFIED AND AUTHORIZED HEALTH CARE PROFESSIONALS WHO HAVE FULL UNDERSTANDING OF THE SAFETY INFORMATION AND EMERGENCY PROCEDURES AS WELL AS THE CAPABILITIES AND FUNCTIONS OF THE DEVICE. THE DEVICE IS USED FOR RADIOLOGICAL GUIDANCE AND VISUALIZATION DURING DIAGNOSTIC, INTERVENTIONAL AND SURGICAL PROCEDURES ON ALL PATIENTS, EXCEPT NEONATES (BIRTH TO ONE MONTH), WITHIN THE LIMITS OF THE DEVICE. THE DEVICE IS TO BE USED IN HEALTH CARE FACILITIES BOTH INSIDE AND OUTSIDE THE OPERATING ROOM, STERILE AS WELL AS NON-STERILE ENVIRONMENT IN A VARIETY OF PROCEDURES. APPLICATIONS: • ORTHOPEDIC • NEURO • ABDOMINAL • VASCULAR • THORACIC • CARDIAC,X-RAY MACHINE(BV ENDURA)-THIS PRODUCT IS INTENDED TO BE INSTALLED, USED AND OPERATED BY ADEQUATELY TRAINED, QUALIFIED AND AUTHORIZED HEALTHCARE PROFESSIONALS SUCH AS PHYSICIANS, SURGEONS, CARDIOLOGISTS, RADIOLOGISTS AND TECHNOLOGISTS, WHO HAVE FULL UNDERSTANDING OF THE SAFETY INFORMATION AND EMERGENCY PROCEDURES AS WELL AS THE CAPABILITIES AND FUNCTIONS OF THE SYSTEM. THE SYSTEM IS USED FOR RADIOLOGIC GUIDANCE AND VISUALIZATION DURING DIAGNOSTIC, INTERVENTIONAL AND SURGICAL PROCEDURES ON PATIENTS. THE PATIENTS ARE ALL PATIENTS EXCEPT BABIES, WITHIN THE LIMITS OF THE SYSTEM. THE SYSTEM IS TO BE USED IN AND OUTSIDE THE OPERATING ROOM, IN A STERILE AS WELL AS NONSTERILE

	ENVIRONMENT WITH A VARIETY OF PROCEDURES. 2D APPLICATION AREAS: • ORTHOPAEDIC • NEURO • ABDOMINAL • VASCULAR • THORACIC • GUIDANCE DURING ENDOSCOPY • FOREIGN BODY REMOVAL • NEEDLE BIOPSY LOCALIZATIONS • COMBINATIONS WITH FLUORO NAVIGATION SYSTEMS • COMBINATIONS WITH LITHOTRIPSY SYSTEMS • PAIN MANAGEMENT,X-RAY MACHINE(BV PULSERA)-THIS PRODUCT IS INTENDED TO BE INSTALLED, USED AND OPERATED BY ADEQUATELY TRAINED, QUALIFIED AND AUTHORIZED HEALTHCARE PROFESSIONALS SUCH AS PHYSICIANS, SURGEONS, CARDIOLOGISTS, RADIOLOGISTS AND TECHNOLOGISTS, WHO HAVE FULL UNDERSTANDING OF THE SAFETY INFORMATION AND EMERGENCY PROCEDURES AS WELL AS THE CAPABILITIES AND FUNCTIONS OF THE SYSTEM. THE SYSTEM IS USED FOR RADIOLOGIC GUIDANCE AND VISUALIZATION DURING DIAGNOSTIC, INTERVENTIONAL AND SURGICAL PROCEDURES ON PATIENTS. THE PATIENTS ARE ALL PATIENTS EXCEPT BABIES, WITHIN THE LIMITS OF THE SYSTEM. THE SYSTEM IS TO BE USED IN AND OUTSIDE THE OPERATING ROOM, IN A STERILE AS WELL AS NONSTERILE ENVIRONMENT WITH A VARIETY OF PROCEDURES. 2D APPLICATION AREAS: • ORTHOPAEDIC • NEURO • ABDOMINAL • VASCULAR • THORACIC • GUIDANCE DURING ENDOSCOPY • FOREIGN BODY REMOVAL • NEEDLE BIOPSY LOCALIZATIONS • COMBINATIONS WITH FLUORO NAVIGATION SYSTEMS • COMBINATIONS WITH LITHOTRIPSY SYSTEMS • PAIN MANAGEMENT • CARDIAC INTERVENTIONS,X-RAY MACHINE (ZENITION 70)-THE ZENITION 70 DEVICE IS INTENDED TO BE USED AND OPERATED BY: ADEQUATELY TRAINED, QUALIFIED AND AUTHORIZED HEALTH CARE PROFESSIONALS WHO HAVE FULL UNDERSTANDING OF THE SAFETY INFORMATION AND EMERGENCY PROCEDURES AS WELL AS THE CAPABILITIES AND FUNCTIONS OF THE DEVICE. THE DEVICE IS USED FOR RADIOLOGICAL GUIDANCE AND VISUALIZATION DURING DIAGNOSTIC, INTERVENTIONAL AND SURGICAL PROCEDURES ON ALL PATIENTS, EXCEPT NEONATES (BIRTH TO ONE MONTH), WITHIN THE LIMITS OF THE DEVICE. THE DEVICE IS TO BE USED IN HEALTH CARE FACILITIES BOTH INSIDE AND OUTSIDE THE OPERATING ROOM, STERILE AS WELL AS NON-STERILE ENVIRONMENT IN A VARIETY OF PROCEDURES. APPLICATIONS: • ORTHOPEDIC • NEURO • ABDOMINAL • VASCULAR • THORACIC • CARDIAC,X-RAY MACHINE(VERADIUS UNITY)-THE VERADIUS UNITY DEVICE IS INTENDED TO BE USED AND OPERATED BY: ADEQUATELY TRAINED, QUALIFIED, AND AUTHORIZED HEALTH CARE PROFESSIONALS SUCH AS PHYSICIANS, SURGEONS, CARDIOLOGISTS, RADIOLOGISTS, AND RADIOGRAPHERS, WHO HAVE FULL UNDERSTANDING OF THE SAFETY INFORMATION AND EMERGENCY PROCEDURES AS WELL AS THE CAPABILITIES AND FUNCTIONS OF

		THE DEVICE. THE DEVICE IS USED FOR RADIOLOGICAL GUIDANCE AND VISUALIZATION DURING DIAGNOSTIC, INTERVENTIONAL, AND SURGICAL PROCEDURES ON ALL PATIENTS EXCEPT NEONATES (BIRTH TO ONE MONTH), WITHIN THE LIMITS OF THE DEVICE. THE DEVICE IS TO BE USED IN HEALTH CARE FACILITIES BOTH INSIDE AND OUTSIDE THE OPERATING ROOM, IN STERILE AS WELL AS NON-STERILE ENVIRONMENTS, IN A VARIETY OF PROCEDURES. APPLICATIONS • ORTHOPEDIC • NEURO • ABDOMINAL • VASCULAR • THORACIC • CARDIAC
3920	MFG/MD/2021/000265	1.License Holder Name: UNIVERSAL ISO-MED (A DIV. OF UNIVERSAL MEDICAP LTD.) 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:CO-60 GAMMA IRRADIATION-NOT APPLICABLE,CO-60 GAMMA IRRADIATION-NOT APPLICABLE
3921	MFG/MD/2021/000266	1.License Holder Name: MEDICURE ENTERPRISES 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:ABSORBENT COTTON GAUZE CLOTH - SCHEDULE FII-GAUZE CAN BE USED FOR CLEANING , PACKING , SCRUBBING , COVERING AND SECURING IN A VARIETY OF WOUNDS. CLOSELY WOVEN GAUZE IS BEST FOR EXTRA STRENGTH OR GREATER PROTECTION WHILE OPEN OR LOOSE WEAVE IS BETTER FOR ABSORBENCY OR DRAINAGE. ,ROLLED BANDAGE - SCHEDULE FII -BANDAGES ARE USED EXTENSIVELY IN HEALTH CARE INSTITUTIONS AND HOME. THE USES OF BANDAGES RANGE FROM SIMPLE DRESSING OF SUPERFICIAL WOUNDS TO HOLDING TOGETHER FRACTURED BONES OR BODY PARTS FOR PARTS FOR REHABILITATION AND RECOVERY.,COTTON BANDAGE - SCHEDULE F II-BANDAGES ARE USED EXTENSIVELY IN HEALTH CARE INSTITUTIONS AND HOME. THE USES OF BANDAGES RANGE FROM SIMPLE DRESSING OF SUPERFICIAL WOUNDS TO HOLDING TOGETHER FRACTURED BONES OR BODY PARTS FOR PARTS FOR REHABILITATION AND RECOVERY.

3922	MFG/MD/2021/000267	1.License Holder Name: SAI GANAPATHI PRODUCTS 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:STERILE INFUSION SET SINGLE USE-TRANSFUSION SET IS USED TO ADMINISTER FLUID/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE BLOOD TRANSFUSION SET-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN .

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3923	MFG/MD/2021/000268	1.License Holder Name: SRI ARUMUGA ENTERPRISES 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:GAUZE SWABS BP 1988 (SAE)-THE NON-STERILE GAUZE SWABS ARE USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL AND TO APPLYING ANTISEPTIC,X-RAY DETECTABLE LAPAROTOMY SPONGES IS 10829 (SAE)-THE LAPAROTOMY SPONGES IS USED IN SURGICAL PROCEDURES TO ABSORB BLOOD AND OTHER FLUIDS AS WELL AS CLEAN WOUNDS,OPEN WEAVE BANDAGE IS 16469(SAE)-THE OPEN WOVEN BANDAGE ARE USED FOR FIXING AND HOLDING OF INJURED JOINT OR FRACTURED PART OR ALSO USED FOR FIXING DRESSINGS AND ABSORBING EXUDATES,DRESSING ROLL (ABSORBENT COTTON IS 16468 WITH ABSORBENT GAUZE IS 758)(SAE)-GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS,ABSORBENT COTTON GAUZE BP 1988 TYPE 17 (FOR EXPORT)(SAE)-THE ABSORBENT COTTON GAUZE ARE USED FOR CLEANING, DRYING AND DRESSING WOUNDS DURING A MEDICAL TREATMENT,GAUZE AND COTTON TISSUE BP 1988(SAE)-GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS,ABSORBENT GAUZE IS 758(SAE)-THE ABSORBENT GAUZE ARE USED IN GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS,BANDAGE CLOTH IS 863(SAE)-THE BANDAGE CLOTH UNCUT IS USED EITHER TO COVERING WOUNDS, TO KEEP DRESSINGS IN PLACE OR TO SUPPORT A MEDICAL DEVICE,ABDOMINAL PAD(SAE)-THE NON-STERILE ABDOMINAL PAD IS USED TO DRESSING FOR LARGE WOUNDS OR WOUNDS REQUIRE HIGH ABSORBENCY,DRESSING PAD (ABSORBENT COTTON IS 16468 WITH ABSORBENT GAUZE IS 758)(SAE)-GENERAL WOUND TREATMENT, ESPECIALLY SUITABLE IN PRIMARY TREATMENT OF DIRTY, INFECTED AND HIGHLY EXUDATIVE WOUNDS, X-RAY DETECTABLE GAUZE SWABS IS 10829(SAE)-THE NON-STERILE X-RAY DETECTABLE GAUZE SWABS ARE USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL AND TO APPLYING ANTISEPTIC

3924	MFG/MD/2021/000269	1.License Holder Name: V R G S ENTERPRISES 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:BANDAGE CLOTH - SCHEDULE FII-BANDAGES ARE USED EXTENSIVELY IN HEALTH CARE INSTITUTIONS AND HOME. THE USES OF BANDAGES RANGE FROM SIMPLE DRESSING OF SUPERFICIAL WOUNDS TO HOLDING TOGETHER FRACTURED BONES OR BODY PARTS FOR PARTS FOR REHABILITATION AND RECOVERY,ROLLED BANDAGE CLOTH - SCHEDULE FII-BANDAGES ARE USED EXTENSIVELY IN HEALTH CARE INSTITUTIONS AND HOME. THE USES OF BANDAGES RANGE FROM SIMPLE DRESSING OF SUPERFICIAL WOUNDS TO HOLDING TOGETHER FRACTURED BONES OR BODY PARTS FOR PARTS FOR REHABILITATION AND RECOVERY.,COTTON CREPE BANDAGE BP - SCHEDULE FII-THE BANDAGES AVAILABLE WITH US INCLUDES ROLLED BANDAGES, COTTON CREPE BANDAGE. THESE ARE USED FOR DRESSING DIFFERENT TYPES OF CUTS, INJURIES AND WOUNDS. THE BANDAGES OFFERED BY US ARE STRONG AND CONVENIENT AND ARE USED WHEN MODERATE COMPRESSION IS REQUIRED, ABSORBENT GAUZE CLOTH - SCHEDULE FII-GAUZE CAN BE USED FOR CLEANING ,PACKING , SCRUBBING , COVERING AND SECURING IN A VARIETY OF WOUNDS. CLOSELY WOVEN GAUZE IS BEST FOR EXTRA STRENGTH OR GREATER PROTECTION WHILE OPEN OR LOOSE WEAVE IS BETTER FOR ABSORBENCY OR DRAINAGE.

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3925	MFG/MD/2021/000270	1.License Holder Name: SOFTOUCH HYGIENE PRODUCTS LIMITED 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:ROLLED GAUZE BANDAGES (INDIVIDUALLY WRAPPED)(SOFTOUCH)-ROLLER GAUZE IS USED FOR DRESSING WOUNDS, PACKING WOUNDS, AND, IN COMBINATION WITH FLEXIBLE MEDICAL TAPE, IMPROVISING BANDAIDS.,T-SHAPED BANDAGES (INDIVIDUALLY WRAPPED) (SOFTOUCH)-USED PRINCIPALLY FOR APPLICATION TO THE GROIN, OR PERINEUM.,COMBINE DRESSING SURGI. PAD(SOFTOUCH)-COMBINE DRESSING SURGI. PAD IS USED FOR THE WOUND DRESSING AS WELL ABSORPTION & RETENTION OF BLOOD SECRETION. IT CAN ALSO BE USED FOR HYGIENIC POST OPERATIVE DRESSING,COTTON WOOL(INDIVIDUAL)(SOFTOUCH)-SURGICAL DRESSING.,ABSORBENT GAUZE SWABS(SOFTOUCH)-GAUZE SWABS ARE A USEFUL UTILITY PRODUCT IN A KIT CAN BE USED FOR WOUND DRESSING, PADDING, PROTECTION, BLOOD SPILL, APPLYING ANTISEPTIC AND MUCH MORE.,PLASTER OF PARIS BANDAGES(PLASTOGEM)-PLASTER OF PARIS BANDAGE IS WIDELY USED IN SEVERAL APPLICATIONS. IT OFFERS COMFORT TO THE PATIENTS. IT IS FREE FROM ALL TYPES OF BACTERIAL INFECTIONS AND IS MADE WITH USE OF EXCELLENT MATERIAL. PATIENTS SUFFERING FROM FRACTURES WOULD GET BENEFIT INSTANTLY BY USAGE OF THIS PRODUCT.,ABSORBENT GAUZE PAD BP(SOFTOUCH HOSPITAL & MATERNITY GAUZE PADS)-THESE ARE USED EXTENSIVELY FOR DRESSING WOUNDS, GENERAL CLEANING AND MINOR PEPPING OF PATIENTS IN HOSPITALS., ABDOMINAL GAUZE SWABS (WITH X-RAY DETECTABLE THREAD) (SOFTOUCH)-USE FOR PACKING OPEN WOUNDS.,STRETCHBAND ROLLED BANDAGES (HOSPITAL QUALITY)(SOFTOUCH) -'STRETCHBAND' ROLLED SUPPORT BANDAGES ARE FOR THE EXTERNAL USE, IN REPLACEMENT TO ALL PRESENTLY AVAILABLE WOVEN AND CUT ROLLED BANDAGES WITH LOOSE THREADS., ABSORBENT GAUZE RIBBON(SOFTOUCH)-FOR GYNEC SURGERY, E.N. T. DRESSING, INTENDED FOR USE IN MANAGEMENT OF CLEAN, USED IN CONTAMINATED EXUDING WOUND LIKE CAVITY WOUND & FISTULAS,CREPE BANDAGES (WITH CLIP)(SOFTOUCH)-CREPE BANDAGESS ARE COMMONLY USED TO TREAT MUSCLE SPRAINS AND STRAINS BY REDUCING THE FLOW OF BLOOD TO A PARTICULAR AREA BY THE APPLICATION OF EVEN STABLE PRESSURE, WHICH CAN RESTRICT SWELLING AT THE PLACE OF INJURY.,GAMJEE ROLL (SOFTOUCH)-GAMJEE ROLL IS APPLIED OVER DRESSING TO PROVIDE LOW ADHERENT WOUND INTERFACE. GENERALLY USED FOR PRIMARY WOUND DRESSINGS OR IS APPLIED OVER A DRESSING, THESE BANDAGE ROLL ALLOW LOW ADHERENT WOUND INTERFACE, EYE PAD(SOFTOUCH)-EYE PADS USUALLY ABSORB TEARS, BLOOD,

	OR OTHER SECRETIONS DUE TO ACCIDENTAL INJURIES, DISEASES, OR OPHTHALMIC SURGERY.,TRIANGULAR BANDAGES (INDIVIDUALLY WRAPPED)(SOFTOUCH)-TRIANGULAR BANDAGES CAN BE USED AS LARGE DRESSINGS, AS SLINGS TO SUPPORT A LIMB, OR TO SECURE A DRESSING IN PLACE.,ORTHO ROLL CAST PADDING(SOFT ROLL)-CAST PADDING ARE USED BEFORE ANY TYPE OF BANDAGE TO PROTECT THE SKIN OR WHERE SWELLING IS EXPECTED. SPECIALLY USED FOR SENSITIVE OR TENDER SKIN, THESE CAST PADDING CAN ALSO BE USED AS LEG ROLL, LONG SPONGES ETC.,MANYTAILED BANDAGES (INDIVIDUALLY WRAPPED)(SOFTOUCH)-A BANDAGE WITH SPLIT ENDS USED FOR THE TRUNK AND LIMBS; A PIECE OF ROLLER TO WHICH SLIPS ARE STITCHED IN AN IMBRICATED FASHION.,PARAFFIN GAUZE DRESSING(SOFTOUCH)-PARAFFIN GAUZE DRESSING HELPS IN SPEEDY RECOVERY OF WOUNDS USED IN THE TREATMENT OF ULCERS, BURNS, SKIN GRAFTS, AND VARIOUS TRAUMATIC INJURIES.

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3926	MFG/MD/2021/000271	1.License Holder Name: HINGARH PHARMACEUTICALS 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:STERILE ROLLER BANDAGE - CONTAINS : - ROLLER BANDAGE SCHEDULE F (II)-ROLLER BANDAGE MAY BE USED TO STOP THE FLOW OF BLOOD, ABSORB DRAINAGE, CUSHION THE INJURED AREA, PROVIDE A SAFEGUARD AGAINST CONTAMINATION, HOLD A MEDICATED DRESSING IN PLACE, HOLD A SPLINT IN POSITION, OR OTHERWISE IMMOBILIZE AN INJURED PART OF THE BODY TO PREVENT FURTHER INJURY AND TO FACILITATE HEALING. ROLLER BANDAGE IS INDIVIDUALLY-WRAPPED, STERILE ROLLER BANDAGE DESIGNED TO PROVIDE SAFEGUARD AGAINST CONTAMINATION TO WOUNDS TO HELP KEEP THEM CLEAN.,DISPOSABLE STERILE INFUSION SET WITH FILTER-TRANSFUSION SET IS USED TO ADMINISTER FLUID/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. ,STERILE COTTON BALLS - CONTAINS : - STERILE ABSORBENT COTTON IP 0.54GMS-ABSORBENT COTTON BALLS ARE USED TO STOP OR PREVENT BLEEDING FROM MINOR PUNCTURES SUCH AS INJECTIONS OR VEIN PUNCTURE. THEY MAY BE SECURED IN PLACE WITH TAPE. MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC. BECAUSE OF ITS PROPERTY OF HIGH FLUID ABSORBENCY.,DISPOSALBLE STERILE MEASURED VOLUME INFUSION SET-IT IS INTENDED FOR USE IN THE ADMINISTRATION OF FLUIDS/DRUGS FROM A CONTAINER INTO THE PATIENT'S VASCULAR SYSTEM THROUGH A VASCULAR ACCESS DEVICE.,DISPOSALBLE STERILE INFUSION SET (MICRO DRIP)-TRANSFUSION SET IS USED TO ADMINISTER FLUID/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN. , DISPOSABLE STERILE BLOOD ADMINISTRATION SET-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN ., STERILE ABSORBENT COTTON I.P - CONTAINS : STERILE ABSORBENT COTTON IP-ABSORBENT COTTON MAINLY USED FOR MEDICAL PURPOSES IN HOSPITALS, NURSING HOMES, DISPENSARIES AND AT HOME (FOR FIRST AID) ETC. BECAUSE OF ITS PROPERTY OF HIGH FLUID ABSORBENCY.,STERILE ABSORBENT GUAZE SWAB - ABSORBENT GAUZE SCHDULE F (II)-A COVERED WOUND HEALS FASTER THAN AN UNCOVERED ONE. GAUZE SWABS ARE DESIGNED TO PROTECT MINOR CUTS, SCRAPES AND BURNS. IT IS MADE OF 100% COTTON TO ENSURE SUPERIOR ABSORBENCY .THESE 12-PLY GAUZE SWABS ARE INDIVIDUALLY-WRAPPED, STERILE GAUZE SWAB DESIGNED TO WICK AWAY FLUID FROM WOUNDS TO HELP KEEP THEM CLEAN. GAUZE SWAB IS USED AS MEDICAL DRESSING .THESE NON-

	ADHESIVE GAUZE SWABS ARE ESSENTIAL FIRST AID SUPPLIES., STERILE EYE PAD - CONTAINS : ABSORBENT GAUZE SCHDULE F (II)- EYE PAD IS A COMBINE DRESSING PAD CUT APPROPRIATELY TO FACILITATE THE SHAPE OF THE EYE. IT IS A STERILE COMBINE DRESSING PAD OR COMPRESS APPLIED TO COVER AND PROTECT SURGICAL SITES IN OPHTHALMIC SURGERIES AND PROMOTES HEALING.,STERILE ABSORBENT GUAZE - CONTAINS :- ABSORBENT GAUZE SCHEDULE F (II)-A COVERED WOUND HEALS FASTER THAN AN UNCOVERED ONE. GAUZE IS DESIGNED TO PROTECT MINOR CUTS, SCRAPES AND BURNS. IT IS MADE OF 100% COTTON TO ENSURE SUPERIOR ABSORBENCY. ABSORBENT GAUZE ARE INDIVIDUALLY-WRAPPED, STERILE GAUZE DESIGNED TO WICK AWAY FLUID FROM WOUNDS TO HELP KEEP THEM CLEAN. GAUZE IS USED AS MEDICAL DRESSING. THIS NON-ADHESIVE GAUZE IS ESSENTIAL FIRST AID SUPPLIES.,STERILE DRESSING PAD - COTAINS : ABSORBANT OVERWRAP AND ABSORBANT COTTON WOOL I.P.-DRESSING PAD IS A STERILE PAD OR COMPRESS APPLIED TO A WOUND TO PROMOTE HEALING AND PROTECT THE WOUND FROM FURTHER HARM. COMBINE DRESSING PAD IS DESIGNED TO BE IN EXTERNAL CONTACT WITH THE WOUND.,DISPOSABLE STERILE INFUSION SET-TRANSFUSION SET IS USED TO ADMINISTER FLUID/DRUGS TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.

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3927	MFG/MD/2021/000272	1.License Holder Name: KAULMED PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:ARTHROSCOPY SYSTEM-ARTHROSCOPY SYSTEM IS USED IN DIFFERENT TYPES OF SHOULDER AND KNEE INJURY MAINLY. IT IS USED TO REPAIR LIGAMENTS, TENDONS,LESIONS ETC.,PINS AND WIRES-PINS AND WIRES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS AND WIRES SUPPORT TO FIX THE BONE PLATES.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,BONE PLATE-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURE IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREW TO PROPERLY ALIGN THE FRACTURED BONE.,PINS AND WIRES-PINS AND WIRES ARE USED IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS AND WIRES SUPPORT TO FIX THE BONE PLATES.,BONE NAIL IMPLANT-BONE NAIL IMPLANTS ARE COMMONLY USED TO FIX THE LONG BONE FRACTURES.,ARTHROSCOPY SYSTEM-ARTHROSCOPY SYSTEM IS MAINLY USED FOR SHOULDER AND KNEE INJURY TO REPAIR LIGAMENTS, TENDONS, LESIONS ETC.,HIP PROSTHESIS-HIP PROSTHESIS ARE SPECIALLY USED IN FEMUR NECK FRACTURE. WHEN FEMUR BONE HEAD IS DAMAGED OR FRACTURED.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,HIP PROSTHESIS-HIP PROSTHESIS ARE SPECIALLY USED IN FEMUR NECK FRACTURE. WHEN FEMUR BONE HEAD IS DAMAGED OR FRACTURED.,BONE PLATE-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURE IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREW TO PROPERLY ALIGN THE FRACTURED BONE.,STAPLES-STAPLES ARE USED IN VARIOUS SURGERY TO SUPPORT BONE FRACTURES, BONE RECONSTRUCTION AND SOFT TISSUES TO BONE, BONE PLATE-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURE IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREW TO PROPERLY ALIGN THE FRACTURED BONE.,BONE PLATE-BONE PLATE IS A IMPLANT USED IN ORTHOPAEDIC SURGERY TO HOLD FRACTURE IN PLACE TO ALLOW BONE HEALING. THE PLATE IS AFFIXED WITH THE SCREW TO PROPERLY ALIGN THE FRACTURED BONE.,STAPLES-STAPLES ARE USED IN VARIOUS SURGERY TO SUPPORT BONE FRACTURES, BONE RECONSTRUCTION AND SOFT TISSUES TO BONE.,SPINAL IMPLANT-SPINAL IMPLANTS ARE USED TO TREAT DEFORMITY AND STABILIZE THE SPINE.,BONE SCREWS-BONE SCREWS ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR

		ALONG WITH BONE PLATES OR INTERLOCKING NAILS.,BONE NAIL IMPLANT-BONE NAIL IMPLANTS ARE COMMONLY USED TO FIX THE LONG BONE FRACTURES.,BONE NAIL IMPLANT-BONE NAIL IMPLANTS ARE COMMONLY USED TO FIX THE LONG BONE FRACTURES.,BONE SCREWS-BONE SCREWS ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR ALONG WITH BONE PLATES OR INTERLOCKING NAILS.,BONE SCREWS-BONE SCREWS ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR ALONG WITH BONE PLATES OR INTERLOCKING NAILS.,BONE NAIL IMPLANT-BONE NAIL IMPLANTS ARE COMMONLY USED TO FIX THE LONG BONE FRACTURES,BONE SCREWS-BONE SCREWS ARE USED DURING THE SURGERY OF FRACTURED BONES. THESE SERVE AS A SUPPORT FOR INTERNAL FIXATION OF BONES. THESE SCREWS ARE USED ALONE OR ALONG WITH BONE PLATES OR INTERLOCKING NAILS.
3928	MFG/MD/2021/000273	1.License Holder Name: VIVAN SURGITEX PVT. LTD. 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:COTTON BANDAGES(NA)-COTTON BANDAGES (CLOTH OR ROLLER) ARE INTENDED TO BE USED ON WOUND OR INJURED SKIN OR TISSUES. ,ABSORBENT COTTON GAUZE(NA)-ABSORBENT COTTON GAUZE WILL BE USED FOR CLEANING, DRYING AND DRESSING WOUNDS DURING A MEDICAL TREATMENT. ABSORBENT COTTON GAUZE IS PERFECT FOR DELIVERING ANTISEPTICS TO INJURIES, MOISTURE REMOVAL FROM WOUNDS BEFORE THE EXERTION OF A DRESSING OR AS A DRESSING AS ITS OWN. THIS DRESSING IS FREE FROM BACTERIA UNTIL WIPED OFF. THE FUNCTION OF ABSORBENT COTTON GAUZE IS TO PROVIDE AN ABSORBENT MATERIAL OF SUFFICIENT TENSILE STRENGTH FOR SURGICAL DRESSING.,ELASTIC ADHESIVE BANDAGES(NA)-ELASTIC ADHESIVE BANDAGE IS USED FOR SUPPORT STRAPPING FRACTURES, MUSCLES INJURIES, ELBOWS, KNEES, SHOULDERS SPECIALLY REQUIRING ELASTICITY. IT IS ALSO USED FOR CORRECTIONAL PURPOSES. IT IS ALSO USED IN RELIEVING MUSCLE STRAIN AND IT PROVIDES COMPRESSION. IT IS USED FOR PROVIDING BREATHABLE AND QUICK FIXATION DRESSING TO SECURE IV CANNULA AND OTHER INTRAMUSCULAR CATHETERS AND PERCUTANEOUS DEVICES TO THE SKIN.,COTTON WOOL(NA)-COTTON WOOL IS INTENDED TO USE FOR APPLYING MEDICATION OR ABSORBING SMALL AMOUNTS OF BODY FLUIDS.

3929	MFG/MD/2021/000274	1.License Holder Name: MICROTROL STERILIZATION SERVICES PVT LTD 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:BONE WAX.-BONE WAX IS INDICATED FOR USE IN THE CONTROL OF BLEEDING FROM BONE SURFACES. BONE WAX ACHIEVES LOCAL HEMOSTASIS OF BONE BY ACTING AS A MECHANICAL (TAMPONADE) BARRIER. IT DOES NOT ACT BIOCHEMICALLY AND IS NONABSORBABLE.,COATED AND BRAIDED POLYGLYCOLIC ACID, ABSORBABLE SURGICAL SUTURE.-POLYGLYCOLIC ACID SUTURE ARE INDICATED FOR USE IN GENERAL, SOFT TISSUE INCLUDING USE IN OPHTHALMIC. BUT NOT FOR USE IN CARDIO VASCULAR & NEUROLOGICAL TISSUES. THIS SUTURE BEING ABSORBABLE SHOULD NOT BE USED WHERE EXTENDED APPROXIMATION OF TISSUE IS REQUIRED.,CATGUT ABSORBABLE SURGICAL SUTURE.-CATGUT SUTURE IS SUITABLE FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN GENERAL CLOSURE, OPHTHALMIC, ORTHOPAEDICS, OBSTETRICS/GYNAECOLOGY , GASTROINTESTINAL TRACT SURGERY.,OXIDIZED REGENERATED CELLULOSE. HEMOSTAT.-THE PRODUCT IS INTENDED TO PROMOTE CLOTTING DURING SURGERY. IT IS USED IN VARIOUS SURGERIES LIKE LAPAROSCOPIC PARTIAL NEPHRECTOMY, GALLBLADDER BED AND IN MINOR SPLENIC INJURY, TO CONTROL HEMORRHAGE FROM AN EDEMATOUS, FRAGILE MUCOSA AND SKIN EDGE AT THE PERIPHERAL SURFACE OF THE STOMA.
3930	MFG/MD/2021/000275	1.License Holder Name: KEYUR PHARMACHEM INDIA PVT. LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:NATURAL INTRAOCULAR LENS(ACRYSOF IQ ASPHERIC NATURAL IOL (SN60WF))-THE ACRYSOF IQ POSTERIOR CHAMBER INTRAOCULAR LENS IS INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY. THIS LENS IS INTENDED FOR PLACEMENT IN THE CAPSULAR BAG.,FOLDABLE INTRAOCULAR LENS(ACRYSOF IOL (SA60AT))-ACRYSOF POSTERIOR CHAMBER INTRAOCULAR LENSES ARE INDICATED FOR THE REPLACEMENT OF THE HUMAN LENS TO ACHIEVE VISUAL CORRECTION OF APHAKIA IN ADULT PATIENTS FOLLOWING CATARACT SURGERY WHEN EXTRACAPSULAR CATARACT EXTRACTION OR PHACOEMULSIFICATION ARE PERFORMED . THESE LENSES ARE INTENDED FOR PLACEMENT IN THE CAPSULAR BAG

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3931	MFG/MD/2021/000276	1.License Holder Name: M/S. ORION SUTURES (INDIA) PRIVATE LIMITED 2.Approving Authority: SUB ZONAL BANGALORE 3.Device Name(Brand Name)-Intended Use:ABSORBABLE SURGICAL SUTURE USP, CHROMIC CATGUT(ORICHROME, LIFE GUT,SUPER GUT)-INDICATED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, BUT NOT IN CARDIOVASCULAR OR NEUROLOGICAL SURGERY., ABSORBABLE SURGICAL SUTURE USP, MONOFILAMENT POLYDIOXANONE(ORYL PD MONO, ORICRYL PDS,LIFE CRYL PDS, SUPER PDS)-INTENDED FOR THE USE IN ALL TYPE OF SOFT TISSUE APPROXIMATION INCLUDING OPHTHALMIC SURGERY. THESE SUTURES ARE PARTICULARLY USEFUL WHERE THE COMBINATION OF ABSORBABLE SUTURE AND EXTENDED WOUND SUPPORT IS DESIRABLE.,NON-ABSORBABLE SURGICAL SUTURE USP, BLACK BRAIDED SILK(DURASIL, ORISILK, LIFE SILK,SUPER SILK)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC SURGERY, CARDIOVASCULAR AND NEUROLOGICAL SURGERY.,NON-ABSORBABLE SURGICAL SUTURE USP, MONOFILAMENT STAINLESS STEEL(ORISTEEL, LIFESTEEL, SUPER STEEL)-INTENDED FOR USE IN CLOSURE OF STERNUM, ORTHOPAEDICS, ABDOMINAL WALL CLOSURE & HERNIA REPAIR.,ABSORBABLE SURGICAL SUTURE USP, MONOFILAMENT POLIGLECAPRONE 25(ORYLMONO,ORICRYL MONO, LIFECRYL MONO,SUPER MONO)-USED IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC. BUT IT IS NOT FOR USE IN CARDIOVASCULAR & NEUROLOGICAL TISSUES.,ABSORBABLE SURGICAL SUTURE USP, BRAIDED & COATED POLYGLYCOLIC ACID(ORYL,ORICRYL,LIFE DEXON,SUPER DEXON)-USED IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC BUT IT IS NOT FOR USE IN CARDIOVASCULAR & NEUROLOGICAL TISSUES, IT IS USED WHERE ONLY SHORT TERM WOUND SUPPORT IS REQUIRED AND WHERE THE RAPID ABSORPTION OF THE SUTURE WOULD BE BENEFICIAL.,ABSORBABLE SURGICAL SUTURE USP, PLAIN CATGUT(ORIGUT, LIFEGUT (P), SUPERGUT (P))-USED IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, BUT NOT IN CARDIOVASCULAR OR NEUROLOGICAL SURGERY.,ABSORBABLE SURGICAL SUTURE USP, BRAIDED & COATED POLYGLACTIN 910(ORYL910, ORICRYL910, LIFE CRYL,SUPER CRYL)-INDICATED FOR USE IN SOFT TISSUE APPROXIMATION AND/OR LIGATION, INCLUDING USE IN OPHTHALMIC SURGERY, PERIPHERAL NERVE ANASTOMOSIS AND MICROSURGERY FOR VESSELS LESS THAN 2 MM DIAMETER.,NON

		ABSORBABLE SURGICAL SUTURE USP, MONOFILAMENT POLYPROPYLENE(SYNTHALIN, ORILENE, LIFE LENE, SUPER LENE)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC SURGERY, CARDIOVASCULAR AND NEUROLOGICAL SURGERY.,NON-ABSORBABLE SURGICAL SUTURE USP, MONOFILAMENT POLYAMIDE (ORLON, LIFE LON, SUPER LON)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC SURGERY, CARDIOVASCULAR AND NEUROLOGICAL SURGERY.,NON ABSORBABLE SURGICAL SUTURE USP, BRAIDED & COATED POLYESTER(NEOBOND, LIFE BOND, SUPER BOND)-INTENDED FOR USE IN GENERAL SOFT TISSUE APPROXIMATION AND/OR LIGATION INCLUDING USE IN OPHTHALMIC SURGERY, CARDIOVASCULAR AND NEUROLOGICAL SURGERY.
3932	MFG/MD/2021/000277	1.License Holder Name: LIFE LINE MEDICAL DEVICES 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:NEBULIZER(LIFE-LINE, MAX, BEATS,)-IT IS A DEVICE USED TO ADMINISTER MEDICATION IN THE FORM OF MIST TO INHALE FOR RESPIRATORY DISORDERS.
3933	MFG/MD/2021/000278	1.License Holder Name: NATIONAL HEALTH CARE 2.Approving Authority: GUJARAT 3.Device Name(Brand Name)-Intended Use:STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY(- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY (FOR EXPORT ONLY)(- - -)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE INFUSION SET WITH/WITHOUT AIR VENT BIS 12655 FOR SINGLE USE ONLY(- - -)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.,STERILE DISPOSABLE BLOOD ADMINISTRATION SET WITH/WITHOUT AIR VENT BIS 9824 FOR SINGLE USE ONLY (FOR EXPORT ONLY)(- - -)-IT IS USED TO ADMINISTER BLOOD FROM A CONTAINER TO A PATIENT'S VASCULAR SYSTEM THROUGH A NEEDLE OR CATHETER INSERTED INTO A VEIN.

3934	MFG/MD/2021/000279	1.License Holder Name: CHANDRA SIDDARDHA SURGICAL DRESSINGS 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:BANDAGE CLOTH SCH FII-USED IN HOSPITALS AND DISPENSARIES,ROLLER BANDAGES SCH FII-USED IN HOSPITALS AND DISPENSARIES,ABSORBENT GAUZE CLOTH-USED IN HOSPITALS AND DISPENSARIES
3935	MFG/MD/2021/000280	1.License Holder Name: VISCOT SURGICALS 2.Approving Authority: ANDHRA PRADESH 3.Device Name(Brand Name)-Intended Use:ROLLER BANDAGES - USED IN HOSPITALS AND DISPENSARIES,ABSORBENT GAUZE CLOTH SCH FII-USED IN HOSPITALS AND DISPENSARIES,BANDAGE CLOTH SCH F II-USED IN HOSPITALS AND DISPENSARIES

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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3936	MFG/MD/2021/000282	1.License Holder Name: D S GLOBAL MEDICARE 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:BONE SCREWS(DS GLOBAL MEDICARE)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE NAILS(DS GLOBAL MEDICARE)-BONE NAILS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PLATE(DS GLOBAL MEDICARE)-BONE PLATE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE SCREWS(DS GLOBAL MEDICARE)-BONE SCREWS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE WIRE(DS GLOBAL MEDICARE)-BONE WIRE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,SPINAL IMPLANTS(DS GLOBAL MEDICARE)-SPINAL IMPLANT SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PLATE(DS GLOBAL MEDICARE)-BONE PLATE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PIN(DS GLOBAL MEDICARE)-BONE PIN IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE PIN(DS GLOBAL MEDICARE)-BONE PIN IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE NAILS(DS GLOBAL MEDICARE)-BONE NAILS SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,BONE WIRE(DS GLOBAL MEDICARE)-BONE WIRE SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.,SPINAL IMPLANTS(DS GLOBAL MEDICARE)-SPINAL IMPLANT SET IS INTENDED TO BE USED FOR THE FIXATION OF BONE FRACTURES FUSION OF JOINTS OR TISSUE FIXATION OR ANCHORAGE.

3937	MFG/MD/2021/000283	1.License Holder Name: IQ MEDITECH PVT. LTD. 2.Approving Authority: UTTAR PRADESH 3.Device Name(Brand Name)-Intended Use:STERILE HYPODERMIC SYRINGES FOR SINGLE USE(GENERIC)-HYPODERMIC SINGLE USE SYRINGES ARE USED INJECT MEDICAMENT IN THE HUMAN AND ANIMAL BODIES AND IT IS ALSO FOR THE VACCINATION OF THE KIDS. IT IS USED FOR THE INTRA MUSCULAR AND INTRA VENOUS IMMEDIATELY AFTER FILING OF THE MEDICAMENTS IN THE SYRINGES. HYPODERMIC SINGLE USE SYRINGES ARE USED TO WITHDRAW FLUIDS FROM BODY.,STERILE TRANSFUSION SET (I.V. SET) FOR SINGLE USE(GENERIC)-IV (INTRAVENOUS) SETS ARE USED FOR PARENTERAL THERAPY THAT DELIVERS LIQUID SUBSTANCES DIRECTLY IN TO VEIN THROUGH A NEEDLE OR CATHETER INSERTED IN TO A VEIN. AN INJECTION CAN BE GIVEN THROUGH THE IV SET FOR WHICH IV SET HAVING AN INJECTION SITE.
3938	MFG/MD/2021/000284	1.License Holder Name: JAYJEET SURGICARE ENTERPRISE 2.Approving Authority: ORISSA 3.Device Name(Brand Name)-Intended Use:SURGICAL BANDAGE , GAUGE AND ROLLER BANDAGE-IT IS INTENDED TO USE IN WOUNDS, INJURED SKIN OR TISSUES AND ALSO PROVIDING EXTERNAL SUPPORT/COMPRESSION
3939	MFG/MD/2021/000286	1.License Holder Name: BOARD OF RADIATION & ISOTOPE TECHNOLOGY 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:AUSTIN MOORE PROSTHESIS-INTENDED FOR ACUTE FEMORAL NECK FRACTURE, NON-UNION OF FEMORAL HEAD AND NECK FRACTURE, AVASCULAR NECROSIS OF FEMORAL HEAD, OSTEO, RHEUMATOID AND POST-ARTHRITICS OF THE HIP WITH MINIMAL ACETABULAR INVOLVEMENT OR DISTORTION.,HAEMOSTATIC GELATIN SPONGE-INTENDED FOR THE CONTROL OF SURFACE BLEEDING FROM VASCULAR ACCESS SITES AND PERCUTANEOUS CATHETERS OR TUBES.

3940	MFG/MD/2021/000287	1.License Holder Name: HYGEIA ORTHO PRIVATE LIMITED 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:BONE PLATES(HYGEIA)-BONE PLATES ARE INTENDED FOR USE IN ALL TYPE OF BONE FRACTURE FIXING WITH THE HELP OF BONE SCREWS AND BONE PLATE FIXES OUTSIDE OF THE BONE AND ITS HOLD THE FACTURE., BONE SCREW(HYGEIA)-BONE SCREW ARE INTENDED FOR USE IN ALL TYPE OF BONE FRACTURE FIXING WITH THE HELP OF BONE SCREWS AND BONE PLATE FIXES OUTSIDE OF THE BONE AND ITS HOLD THE FACTURE.,BONE PLATES(HYGEIA)-BONE PLATES ARE INTENDED FOR USE IN ALL TYPE OF BONE FRACTURE FIXING WITH THE HELP OF BONE SCREWS AND BONE PLATE FIXES OUTSIDE OF THE BONE AND ITS HOLD THE FACTURE.,BONE SCREW(HYGEIA)-BONE SCREW ARE INTENDED FOR USE IN ALL TYPE OF BONE FRACTURE FIXING WITH THE HELP OF BONE SCREWS AND BONE PLATE FIXES OUTSIDE OF THE BONE AND ITS HOLD THE FACTURE.,PINS & WIRES(HYGEIA)-PINS AND WIRES ARE INTENDED FOR USE IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS AND WIRE SUPPORT FIX THE BONE PLATES, BONE SCREWS, IM NAILS, SPINE IMPLANTS ETC. ALL PINS AND WIRE ARE NOT PERMANENTLY USED IN SURGERY.,INTRAMEDULLARY NAILS(HYGEIA)-IM NAILS ARE INTENDED FOR USE IN FEMUR, TIBIA AND HUMERUS BONE FRACTURES, WHERE FOUND THE FACTURES IN PROXIMAL AND DISTAL AREA. ALL TYPES OF IM NAILS ARE USED IN SIDE THE BONE AND ITS PASS THROUGH FACTURES AND HOLD THE FACTURES WITH THE HELP OF BONE SCREWS. AND IT'S A MINIMAL INSERTION SURGERY,INTRAMEDULLARY NAILS(HYGEIA)-IM NAILS ARE INTENDED FOR USE IN FEMUR, TIBIA AND HUMERUS BONE FRACTURES, WHERE FOUND THE FACTURES IN PROXIMAL AND DISTAL AREA. ALL TYPES OF IM NAILS ARE USED IN SIDE THE BONE AND ITS PASS THROUGH FACTURES AND HOLD THE FACTURES WITH THE HELP OF BONE SCREWS. AND IT'S A MINIMAL INSERTION SURGERY,PINS & WIRES(HYGEIA)-PINS AND WIRES ARE INTENDED FOR USE IN MAXIMUM BONE FRACTURE SURGERY TO MAKE INSERTION IN THE BONE AND THROUGH PINS AND WIRE SUPPORT FIX THE BONE PLATES, BONE SCREWS, IM NAILS, SPINE IMPLANTS ETC. ALL PINS AND WIRE ARE NOT PERMANENTLY USED IN SURGERY.

3941	NW(0040)/13/MD	1.License Holder Name: ALFA CORPUSCLES PVT LTD 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:STERILE HERNIA MESH (EASYMESH)-STERILE HERNIA MESH IS A NON ABSORBABLE MESH INTENDED TO BE USED IN THE REPAIR OF ABDOMINAL WALL HERNIA DEFECT AND WEAKNESS THAT REQUIRE REINFORCEMENT WITH A NON ABSORBABLE PROSTHETIC MATERIAL THROUGH OPEN SURGICAL APPROACH OR PREPERITONEAL REPAIR OF ANTERIOR ABDOMINAL WALL HERNIA THROUGH LAPAROSCOPIC APPROACH. STERILE HERNIA MESH IS ALSO SUITABLE IN THE FOLLOWING APPLICATIONS: 1. REPAIR OF CHEST WALL DEFECTS. 2. PELVIC FLOOR REPAIR AS IN RECTAL AND GENITO-URINARY PROLAPSE.
3942	NW(0040)/13/MD	1.License Holder Name: ALFA CORPUSCLES PVT LTD 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:STERILE DIPOSABLE SKIN STAPLER-STERILE DISPOSABLE SKIN STAPLER IS INTENDED TO BE USED FOR THE PRIMARY, DELAYED PRIMARY AND SECONDARY CLOSURE OF THE SKIN WOUNDS IN CASE. • FOR CLOSURE OF UNINFECTED POST TRAUMATIC WOUNDS. • FOR PRIMARY, DELAYED PRIMARY AND SECONDARY CLOSURE OF SURGICAL INCISIONS AND WOUNDS. • FOR SKIN APPROXIMATION IN OTHER CASES. • FOR SKIN GRAFT AND FLAP PLACEMENT.
3943	NW(0098)/17/MB	1.License Holder Name: KUTE WELLNESS INC 2.Approving Authority: NORTH WEST DELHI DIVISION 3.Device Name(Brand Name)-Intended Use:LH(LUTEINIZING HORMONE) CARD/CASSETTE TEST(NA)-INTENDED TEST FOR THE PRELIMINARY SELF TESTING OF LUTEINIZING HORMONE(LH) IN HUMAN URINE.,LH(LUTEINIZING HORMONE) STRIP TEST(NA)-INTENTED TEST FOR THE PRELIMINARY SELF TESTING OF LUTEINIZING HORMONE (LH) IN HUMAN URINE.,LH(LUTEINIZING HORMONE) MIDSTREAM TEST (NA)-INTENDED TEST FOR THE PRELIMINARY SELF TESTING OF LEUTINIZING HORMONE (LH) IN HUMAN URINE.

3944	PD-112	1.License Holder Name: S.H.PITKAR ORTHOTOOLS PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:CEMENT RESTRICTOR (PITKAR)-CEMENT RESTRICTORS ARE INDICATED FOR THE BLOCKAGE OF THE FEMORAL MEDULLARY CANAL PRIOR TO CEMENT INSERTION AND AS AN AID TO CEMENTED HIP ARTHROPLASTY PROCEDURES.,JUPITER HEAD(PITKAR)-JUPITER HEAD ARE INDICATED FOR USE FOR IN PARTIAL HIP ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED HIP FUNCTION IN SKELETALLY MATURE PATIENTS WITH THE FOLLOWING CONDITIONS I.SEVERELY PAINFUL AND/OR DISABLED JOINTS FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR CONGENITAL HIP DYSPLASIA. II.AVASULAR NECROSIS OF THE FEMORAL HEAD OR NECK III.ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK IV.FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. V.CERTAIN CASES OF ANKYLOSIS.,ATLAX PLATE(PITKAR)-THE INTERVERTEBRAL FUSION DEVICE IS INTENDED FOR SPINAL FUSION PROCEDURES AT ONE OR TWO CONTIGUOUS LEVELS IN THE LUMBAR SPINE FROM L2 TO S1 IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD,) WITH UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVEL (S). DDD IS DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN, WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. PATIENTS SHOULD BE SKELETALLY MATURE, AND HAVE HAD AT LEAST 6 MONTHS OF NON-OPERATIVE TREATMENT. THE DEVICE IS INTENDED FOR USE WITH AUTOGENOUS GRAFT, AND WITH SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBOSACRAL SPINE.,ATLAX SPACER(PITKAR)-THE INTERVERTEBRAL FUSION DEVICE IS INTENDED FOR SPINAL FUSION PROCEDURES AT ONE OR TWO CONTIGUOUS LEVELS IN THE LUMBAR SPINE FROM L2 TO S1 IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD,) WITH UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVEL(S). DDD IS DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN, WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. PATIENTS SHOULD BE SKELETALLY MATURE, AND HAVE HAD AT LEAST 6 MONTHS OF NON-OPERATIVE TREATMENT. THE DEVICE IS INTENDED FOR USE WITH AUTOGENOUS GRAFT, AND WITH SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBOSACRAL SPINE.,ATLAX SCREW(PITKAR)-THE INTERVERTEBRAL FUSION DEVICE IS INTENDED FOR SPINAL FUSION

	PROCEDURES AT ONE OR TWO CONTIGUOUS LEVELS IN THE LUMBAR SPINE FROM L2 TO S1 IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD,) WITH UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVEL(S). DDD IS DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN, WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. PATIENTS SHOULD BE SKELETALLY MATURE, AND HAVE HAD AT LEAST 6 MONTHS OF NON-OPERATIVE TREATMENT. THE DEVICE IS INTENDED FOR USE WITH AUTOGENOUS GRAFT, AND WITH SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBOSACRAL SPINE.,ORION STEM MULLER TYPE STRAIGHT (PITKAR)-ORION STEM MULLER TYPE STRAIGHT ARE INDICATED FOR USE FOR IN PARTIAL HIP ARTHROPLASTY FOR REDUCTION OR RELIEF OF PAIN AND/OR IMPROVED HIP FUNCTION IN SKELETALLY MATURE PATIENTS WITH THE FOLLOWING CONDITIONS I.SEVERELY PAINFUL AND/OR DISABLED JOINTS FROM OSTEOARTHRITIS, TRAUMATIC ARTHRITIS OR CONGENITAL HIP DYSPLASIA. II. AVASULAR NECROSIS OF THE FEMORAL HEAD OR NECK III.ACUTE TRAUMATIC FRACTURE OF THE FEMORAL HEAD OR NECK IV.FAILED PREVIOUS HIP SURGERY INCLUDING JOINT RECONSTRUCTION, INTERNAL FIXATION, ARTHRODESIS, HEMIARTHROPLASTY, SURFACE REPLACEMENT ARTHROPLASTY, OR TOTAL HIP REPLACEMENT. V. CERTAIN CASES OF ANKYLOSIS.,SATURN BIPOLAR CUP(PITKAR)-THE BIPOLAR CUP IS FOR UNCEMENTED USE IN CONJUNCTION WITH A STANDARD CEMENTED OR UNCEMENTED FEMORAL REPLACEMENT IMPLANT FOR THE FOLLOWING: A. NON-INFLAMMATORY DEGENERATIVE JOINT DISEASE INCLUDING OSTEOARTHRITIS AND AVASCULAR NECROSIS B. RHEUMATOID ARTHRITIS C. CORRECTION OF FUNCTIONAL DEFORMITY D. TREATMENT OF NON-UNION, FEMORAL NECK FRACTURE AND TROCHANTERIC FRACTURES OF THE PROXIMAL FEMUR WITH HEAD INVOLVEMENT, UNMANAGEABLE USING OTHER TECHNIQUES.,DENTAL ANCHORAGE SCREW (WITH HOLE)(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE.,EXPANDABLE CAGES(PITKAR)- THE INTERVERTEBRAL FUSION DEVICE IS INTENDED FOR SPINAL FUSION PROCEDURES AT ONE OR TWO CONTIGUOUS LEVELS IN THE LUMBAR SPINE FROM L2 TO S1 IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD,) WITH UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVEL(S). DDD IS DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN, WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. PATIENTS SHOULD BE SKELETALLY MATURE, AND HAVE HAD AT LEAST 6 MONTHS OF NON-OPERATIVE TREATMENT. THE DEVICE IS INTENDED FOR USE WITH AUTOGENOUS

	GRAFT, AND WITH SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBOSACRAL SPINE.,TITAX CRANIAL MESH(PITKAR)-THE TITAX CRANIAL MESH IS INTENDED FOR USE IN SELECTIVE TRAUMA OF THE MIDFACE AND CRANIOFACIAL SKELETON, CRANIOFACIAL SURGERY, RECONSTRUCTIVE PROCEDURE, ORTHODONTIC SCREW(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE. ,DENTAL IMPLANT(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE.,DENTAL IMPLANT COVER SCREW(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE.,ABUTMENT SCREW(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE.,SLIM ABUTMENT(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE.,STRAIGHT ABUTMENT(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE.,HYBRID ADJUSTABLE CAGES(PITKAR)-THE INTERVERTEBRAL FUSION DEVICE IS INTENDED FOR SPINAL FUSION PROCEDURES AT ONE OR TWO CONTIGUOUS LEVELS IN THE LUMBAR SPINE FROM L2 TO S1 IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD,) WITH UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVEL(S). DDD IS DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN, WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. PATIENTS SHOULD BE SKELETALLY MATURE, AND HAVE HAD AT LEAST 6 MONTHS OF NON-OPERATIVE TREATMENT. THE DEVICE IS INTENDED FOR USE WITH AUTOGENOUS GRAFT, AND WITH SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBOSACRAL SPINE.,ABUTMENT(PITKAR)-THE IMPLANTS ARE INSTALLED ON THE MAXILLA AND/OR MANDIBLE BY MEANS OF AN ADEQUATE SURGICAL TECHNIQUE.,CAGE WITH PLATE(PITKAR)-THE INTERVERTEBRAL FUSION DEVICE IS INTENDED FOR SPINAL FUSION PROCEDURES AT ONE OR TWO CONTIGUOUS LEVELS IN THE LUMBAR SPINE FROM L2 TO S1 IN PATIENTS WITH DEGENERATIVE DISC DISEASE (DDD,) WITH UP TO GRADE 1 SPONDYLOLISTHESIS OR RETROLISTHESIS AT THE INVOLVED LEVEL(S). DDD IS DEFINED AS BACK PAIN OF DISCOGENIC ORIGIN, WITH DEGENERATION OF THE DISC CONFIRMED BY HISTORY AND RADIOGRAPHIC STUDIES. PATIENTS SHOULD BE SKELETALLY MATURE, AND HAVE HAD AT LEAST 6 MONTHS OF NON-OPERATIVE TREATMENT. THE DEVICE IS INTENDED FOR USE WITH AUTOGENOUS GRAFT, AND WITH

		SUPPLEMENTAL FIXATION SYSTEMS CLEARED FOR USE IN THE LUMBOSACRAL SPINE.
3945	PD/127	1.License Holder Name: POLYBOND INDIA PVT LTD 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, WEST ZONE 3.Device Name(Brand Name)-Intended Use:CENTRAL VENOUS CATHETER-CENTRAL VENOUS CATHETER OR CENTRAL LINE IS A TUBE THAT IS SURGICALLY INSERTED INTO THE SUPERIOR VENA CAVA (A LARGE VEIN) A CV CATHETER IS CONSIDERED WHEN A PATIENT NEEDS A FREQUENT OR CONTINOUS INJECTION MEDICATION OR FLUIDS FOR NUTRITIONAL SUPPORT. CENTRAL VENOUS ACCESS IS THE PLACEMENT OF A VENOUS CATHETER IN A VEIN THAT LEADS DIRECTLY TO THE HEART.

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
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MINISTRY OF HEALTH, GOVERNMENT OF INDIA

3946	PD127&PD/129	1.License Holder Name: POLYBOND INDIA PVT LTD 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:THREE WAY STOP COCK WITH EXTENSION TUBE-THREE WAY STOP COCK IS USED TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM.,FOLEY BALLOON CATHETER-THE PRODUCT IS USED FOR DRAINAGE, CLEANING, HAEMOSTATIC AND MEDICINE INJECTION FOR THE URINARY SYSTEM OF THE PATIENTS,I V SET (DISPOSABLE PERFUSION SET)-THE INFUSION SETS ARE USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER OR CANNULA., MEASURED VOLUME BURETTE SET (MEASURED VOLUME SET)-BURETTE TYPE INFUSION SET IS USED TO ADMINISTER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM BY USING INTRAVENOUS CATHETER OR CANNULA FOR PEDIATRIC USE.,IV CANNULA-IV CANNULA IS USED TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM,INFANT FEEDING TUBE (FEEDING TUBE)-INTENDED USE: INFANT FEEDING TUBE IS USED TO PROVIDE NUTRITIONAL FEEDING THROUGH NASOGASTRIC TRACT TO NEONATES AND INFANTS., BLOOD TRANSFUSION SET (BLOOD ADMINISTRATION KIT)-INFUSION OF BLOOD AND BLOOD COMPONENT,RYLES TUBE-RYLE'S TUBE IS USED TO PROVIDE ACCESS TO NASOGASTRIC TRACT FOR INTRODUCTION OF NUTRITION AND ASPIRATION OF INTESTINAL SECRETION.,THREE WAY STOP COCK-THREE WAY STOP COCK USED TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM.,EXTENSION TUBE (EXTENSION SET)-USED TO DELIVER INTRAVENOUS FLUID AND MEDICINES INTO HUMAN CIRCULATING SYSTEM AND TO EXTEND THE LENGTH OF THE IV LINES. PRODUCT IS USED TO DELIVER INTRAVENOUS FLUID AND MEDICINES AS EXTENDING LINES AT HIGH PRESSURE INTO HUMAN CIRCULATING SYSTEM. ALSO PRESSURE LINE USED AS AN EXTENSION TO CONNECT MEDICAL INSTRUMENT,SUCTION CATHETER-SUCTION CATHETER IS USED TO PROVIDE ACCESS TO RESPIRATORY TRACT TO REMOVE SECRETION WITH MAXIMUM COMFORT TO THE PATIENT,NELATON CATHETER-THE PRODUCT IS USED TO PROVIDE ACCESS TO THE BLADDER CATHETERIZATION THROUGH URETHRA IN CASE OF URINARY RETENTION.,CLOSE WOUND SUCTION UNIT-THE PRODUCT IS USED FOR CLOSED WOUND DRAINAGE OR COLLECTION OF FLUID FROM SURGICAL WOUND UNDER NEGATIVE PRESSURE THROUGH COLLECTION TUBE AND COLLECTION DEVICE WITH AN OPTION TO OPERATE ONE OR TWO CATHETERS SIMULTANEOUSLY THE NEGATIVE PRESSURE IS GENERATED TROUGH BELLOW.,YANKAUER SUCTION SET-YANKAUER SUCTION SET IS USED FOR REMOVAL OF

		BLOOD AND FLUID DURING SURGERY.
3947	PD-143	1.License Holder Name: CEVA POLCHEM PRIVATE LIMITED 2.Approving Authority: PUNE DIVISION 3.Device Name(Brand Name)-Intended Use:ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE 4.74%W/V, ALKYL DIMETHYL ETHYLBENZYL AMMONIUM CHLORIDE 4.74%W/V, ORTHOPHTHALDEHYDE 0.55%W/V(AQUINA STAR)-FOR SURFACE & AERIAL DISINFECTION
3948	POSTAPPR/IVD/2019/000001	1.License Holder Name: MERIL HEALTHCARE PVT. LTD. 2.Approving Authority: CENTRAL DRUG STANDARDS CONTROL ORGANIZATION, AHMEDABAD 3.Device Name(Brand Name)-Intended Use:MEDICAL DEVICE COATING-PVD COATING-AS PER FINISHED PRODUCT MANUFACTURER'S RECOMMENDATION,MEDICAL DEVICE COATING-PLASMA SPRAY COATING-AS PER FINISHED PRODUCT MANUFACTURER'S RECOMMENDATION
3949	S0079/15/MB	1.License Holder Name: VANGUARD DIAGNOSTICS PRIVATE LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:HIV GEN.4 MICROWELL ELISA(VDX)-HIV GEN. 4 MICROWELL ELISA IS A FOURTH GENERATION IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO HIV-1, (GROUP O AND MO, HIV-2 AND P24 ANTIGEN OF HIV-L IN HUMAN SERUM OR PLASMA,HBSAG MICROWELL ELISA (VDX)-HBSAG MICROWELL ELISA IS AN IN VITRO ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN IN HUMAN SERUM OR PLASMA,HCV MICROWELL ELISA(VDX)-HCV IS AN IN VITRO ENZYME IMMUNOASSAY FOR THE QUALITATIVE DETERMINATION OF ANTIBODIES TO HEPATITIS C VIRUS IN HUMAN SERUM OR PLASMA

3950	SC/02/2018	1.License Holder Name: GPC MEDICAL LIMITED 2.Approving Authority: CDSCO -NORTH ZONE, GHAZIABAD 3.Device Name(Brand Name)-Intended Use:CANCELLOUS TRACTION SCREW(GPC CANCELLOUS TRACTION SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,LARGE CANNULATED CANCELLOUS SCREW(GPC LARGE CANNULATED CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE., LIMITED CONTACT DYNAMIC COMPRESSION PLATE (LC-DCP) - NARROW(GPC LIMITED CONTACT DYNAMIC COMPRESSION PLATE (LC-DCP) - NARROW)-USED TO IMMOBILIZE FRACTURED SEGMENTS, ORBITAL PLATE WITH BRIDGE 1.5MM(GPC ORBITAL PLATE WITH BRIDGE 1.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS, SQUARE NAIL FOR ULNA(GPC SQUARE NAIL FOR ULNA)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,T PLATE (SMALL) RIGHT ANGLED WITH 4 HEAD HOLES(GPC T PLATE (SMALL) RIGHT ANGLED WITH 4 HEAD HOLES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CANCELLOUS SCREW(GPC CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,T- PLATE 1.5(GPC T-PLATE 1.5)-USED TO IMMOBILIZE FRACTURED SEGMENTS,LOCKING DISTAL RADIUS BUTTRESS PLATE 2.4MM(GPC LOCKING DISTAL RADIUS BUTTRESS PLATE 2.4MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,T- PLATE 2.0(GPC T- PLATE 2.0)-USED TO IMMOBILIZE FRACTURED SEGMENTS,MANDIBULAR RECONSTRUCTION PLATE 2.7 (GPC MANDIBULAR RECONSTRUCTION PLATE 2.7)-USED TO IMMOBILIZE FRACTURED SEGMENTS,D.C.S. BARREL PLATES(GPC D.C. S. BARREL PLATES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,3 D STRUT PLATE 1.2MM(GPC 3 D STRUT PLATE 1.2MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,RECONSTRUCTION PLATE 2.7 MM SCREWS(GPC RECONSTRUCTION PLATE 2.7MM SCREWS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,L- PLATE 1.5MM(GPC L-PLATE 1.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS, ZYGOMATIC DCP 2.0(GPC ZYGOMATIC DCP 2.0)-USED TO IMMOBILIZE FRACTURED SEGMENTS,DYNAMIC SELF COMPRESSION PLATE BROAD (GPC DYNAMIC SELF COMPRESSION PLATE BROAD)-USED TO IMMOBILIZE FRACTURED SEGMENTS,D.H.S. BARREL PLATES(GPC D.H. S. BARREL PLATES)-USED TO IMMOBILIZE FRACTURED SEGMENTS, DYNAMIC SELF COMPRESSION PLATE NARROW(GPC DYNAMIC SELF COMPRESSION PLATE NARROW)-USED TO IMMOBILIZE FRACTURED SEGMENTS,LIMITED CONTACT DYNAMIC COMPRESSION PLATE (LC-DCP) - BROAD(GPC LIMITED CONTACT DYNAMIC COMPRESSION PLATE (LC-DCP) - BROAD)-USED TO IMMOBILIZE FRACTURED

	SEGMENTS,SHAFT SCREW(GPC SHAFT SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,END CAP FOR PFN NAIL (GPC END CAP FOR PFN NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,LATERAL TIBIAL HEAD BUTTRESS PLATE(GPC LATERAL TIBIAL HEAD BUTTRESS PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,SELF TAPPING LOCKING SCREW(GPC SELF TAPPING LOCKING SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,LOCKING CLAVICLE S SHAPE PLATE(GPC LOCKING CLAVICLE S SHAPE PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,MINI PLATE WITHOUT BRIDGE 2.5MM(GPC MINI PLATE WITHOUT BRIDGE 2.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,RECONSTRUCTION PLATE 4.5MM SCREWS(GPC RECONSTRUCTION PLATE 4.5MM SCREWS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,3 D RECTANGLE PLATE 1.2MM(GPC 3 D RECTANGLE PLATE 1.2MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,UNREAMED FEMORAL NAIL(GPC UNREAMED FEMORAL NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY, CANCELLOUS SCREW(GPC CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,CONDYLAR BUTTRESS PLATE 4.5MM(GPC CONDYLAR BUTTRESS PLATE 4.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,ADAPTATION PLATE 2.0(GPC ADAPTATION PLATE 2.0)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CLOVERLEAF PLATE(GPC CLOVERLEAF PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,ONE THIRD TUBULAR WITH COLLAR(GPC ONE THIRD TUBULAR WITH COLLAR)-USED TO IMMOBILIZE FRACTURED SEGMENTS,D.H.S. BARREL PLATES(GPC D.H. S. BARREL PLATES)-USED TO IMMOBILIZE FRACTURED SEGMENTS, LOCKING PLATE 3.5MM(GPC LOCKING PLATE 3.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,ARCH BAR(GPC ARCH BAR)-USED TO IMMOBILIZE FRACTURED SEGMENTS,T PLATE FOR 4.5MM SCREWS(GPC T PLATE FOR 4.5MM SCREWS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,L- PLATE 2.0(GPC L- PLATE 2.0)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CHIN PLATE (STRAIGHT) 2.0MM (GPC CHIN PLATE (STRAIGHT) 2.0MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,3 D STRUT PLATE 2.MM(GPC 3 D STRUT PLATE 2.MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,3 D STRUT PLATE 1.5MM(GPC 3 D STRUT PLATE 1.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,SUPRA CONDYLAR NAIL / IMSC NAIL(GPC SUPRA CONDYLAR NAIL / IMSC NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,CORTEX SCREW(GPC CORTEX SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE,

	BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,ANGLED BLADE PLATES FOR INTERTROCHANTERIC FEMORAL OSTEOTOMIES IN ADULTS(GPC ANGLED BLADE PLATES FOR INTERTROCHANTERIC FEMORAL OSTEOTOMIES IN ADULTS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,L BUTTRESS PLATES (GPC L BUTTRESS PLATES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,3 D RECTANGLE PLATE 2.0MM(GPC 3 D RECTANGLE PLATE 2.0MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,SINGLE LOCK MONO AXIAL SCREW PEDICLE(GPC SINGLE LOCK MONO AXIAL SCREW PEDICLE)-FOR SPINE SURGERY,SMALL T - PLATE OBLIQUE ANGLED(GPC SMALL T - PLATE OBLIQUE ANGLED)-USED TO IMMOBILIZE FRACTURED SEGMENTS,ANGLE 130º PLATE FOR SMALL, ADULTS & ADOLESCENTS(GPC ANGLE 130º PLATE FOR SMALL, ADULTS & ADOLESCENTS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,ANGLED BLADE PLATES FOR INTERTROCHANTERIC FEMORAL OSTEOTOMIES IN ADULTS(GPC ANGLED BLADE PLATES FOR INTERTROCHANTERIC FEMORAL OSTEOTOMIES IN ADULTS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,LOCKING BOLTS 5.9MM (GPC LOCKING BOLTS 5.9MM)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,DISTAL HUMERUS BONE PLATE(GPC DISTAL HUMERUS BONE PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,DYNAMIC SELF COMPRESSION PLATE FOR 2.0MM SCREWS (GPC DYNAMIC SELF COMPRESSION PLATE FOR 2.0MM SCREWS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,4.5MM LOCKING PROXIMAL TIBIA PLATE(GPC 4.5MM LOCKING PROXIMAL TIBIA PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,DISTAL TIBIA BONE PLATE LEFT/RIGHT(GPC DISTAL TIBIA BONE PLATE LEFT/RIGHT)-USED TO IMMOBILIZE FRACTURED SEGMENTS,END CAP FOR TIBIAL & FEMORAL NAIL(GPC END CAP FOR TIBIAL & FEMORAL NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY, COBRA HEAD PLATE(GPC COBRA HEAD PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,TROCHANTER STABLISING PLATE FOR DHS (GPC TROCHANTER STABLISING PLATE FOR DHS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,OLECRANON PLATE(GPC OLECRANON PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS, CALCANEAL PLATE FOR 3.5MM(GPC CALCANEAL PLATE FOR 3.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,STEFFEE PLATE(GPC STEFFEE PLATE)-FOR SPINE SURGERY,SMALL LOCKING T-PLATE WITH 4 HOLES IN HEAD(GPC SMALL LOCKING T-PLATE WITH 4 HOLES IN HEAD)-USED TO IMMOBILIZE FRACTURED SEGMENTS,END CAP FOR IMSC NAIL(GPC END CAP FOR IMSC NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,Y-PLATE 1.5 & Y-PLATE 2.0(GPC Y-PLATE 1.5 & Y-PLATE 2.0)-USED TO IMMOBILIZE FRACTURED SEGMENTS,TRANSVERSE CONNECTOR (CROSS LINK)

	(GPC TRANSVERSE CONNECTOR (CROSS LINK))-FOR SPINE SURGERY, EMERGENCY SCREW(GPC EMERGENCY SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,HIP PROSTHESIS TYPE THOMPSON LASCANO(GPC HIP PROSTHESIS TYPE THOMPSON LASCANO)-FOR HIP REPLACEMENT SURGERY,BLOUNT STAPLES(GPC BLOUNT STAPLES)-STAPLES ARE USED TO STABILIZE THE FRACTURES OF BONES.,AUSTIN MOORE HIP PROSTHESES(GPC AUSTIN MOORE HIP PROSTHESES)-FOR HIP REPLACEMENT SURGERY, AUSTIN MOORE HIP PROSTHESES(GPC AUSTIN MOORE HIP PROSTHESES)-FOR HIP REPLACEMENT SURGERY,THOMPSON HIP PROSTHESES(GPC THOMPSON HIP PROSTHESES)-FOR HIP REPLACEMENT SURGERY,CERCLAGE WIRE LOOP(GPC CERCLAGE WIRE LOOP)-WIRES ARE MAINLY INDICATED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENTS., THOMPSON HIP PROSTHESES(GPC THOMPSON HIP PROSTHESES)-FOR HIP REPLACEMENT SURGERY,THREADED GUIDE WIRE(GPC THREADED GUIDE WIRE)-WIRES ARE MAINLY INDICATED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENTS.,S.S WIRE ROLL 10M(GPC S.S WIRE ROLL 10M)-WIRES ARE MAINLY INDICATED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENTS.,RECONSTRUCTION NAIL(GPC RECONSTRUCTION NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,PROXIMAL FEMUR LOCKING PLATE(GPC PROXIMAL FEMUR LOCKING PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,AUSTIN MOORE WITH 2 NUTS(GPC AUSTIN MOORE WITH 2 NUTS)-WIRES ARE MAINLY INDICATED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENTS.,L-BUTTRESS LOCKING PLATE(GPC L-BUTTRESS LOCKING PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,HUMERUS NAIL CANNULATED(GPC HUMERUS NAIL CANNULATED)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,KNOWLES PIN DIA 3MM (GPC KNOWLES PIN DIA 3MM)-INS ARE USED TO STABILIZE THE FRACTURES OF BONES.,KNOWLES PIN DIA 4MM(GPC KNOWLES PIN DIA 4MM)-INS ARE USED TO STABILIZE THE FRACTURES OF BONES., THOMPSON HIP PROSTHESES(GPC THOMPSON HIP PROSTHESES)-FOR HIP REPLACEMENT SURGERY,TIBIAL INTERLOCKING NAILS DISTAL(GPC TIBIAL INTERLOCKING NAILS DISTAL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,CORTEX SCREW(GPC CORTEX SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,AUSTIN MOORE HIP PROSTHESES - EXTRA LONG STEM (GPC AUSTIN MOORE HIP PROSTHESES - EXTRA LONG STEM)-FOR HIP REPLACEMENT SURGERY,LOCKING SMALL T-PLATE, OBLIQUE(GPC

	LOCKING SMALL T-PLATE, OBLIQUE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,DHS LOCKING PLATE 135°(GPC DHS LOCKING PLATE 135°)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CORTEX SCREW(GPC CORTEX SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,4.5MM LOCKING T-PLATES(GPC 4.5MM LOCKING T-PLATES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,UNREAMED HUMERAL NAIL(GPC UNREAMED HUMERAL NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,L- AND T- PLATE 2.7MM HAVING 3 HOLES, HEAD IN SHAFT & 2 HOLES IN HEAD(GPC L- AND T-PLATE 2.7MM HAVING 3 HOLES, HEAD IN SHAFT & 2 HOLES IN HEAD)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CORTICAL SCREW, SLOTTED HEAD THREAD(GPC CORTICAL SCREW, SLOTTED HEAD THREAD)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE., HARTSHEEL FRAME(GPC HARTSHEEL FRAME)-FOR SPINE SURGERY, CORTICAL SCREW, SLOTTED HEAD THREAD(GPC CORTICAL SCREW, SLOTTED HEAD THREAD)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,CORTEX SCREW(GPC CORTEX SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,WASHER FOR LARGE SCREW(GPC WASHER FOR LARGE SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,CORTICAL SCREW, SLOTTED HEAD THREAD(GPC CORTICAL SCREW, SLOTTED HEAD THREAD)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,THORACOLUMBAR PLATE(GPC THORACOLUMBAR PLATE)-FOR SPINE SURGERY, CERVICAL SCREW(GPC CERVICAL SCREW)-FOR SPINE SURGERY, DRUMOND WIRE(GPC DRUMOND WIRE)-FOR SPINE SURGERY, NOTCHED SPINAL PLATE 2.7(GPC NOTCHED SPINAL PLATE 2.7)-FOR SPINE SURGERY,BIPOLAR HIP PROSTHESIS(GPC BIPOLAR HIP PROSTHESIS)-FOR HIP REPLACEMENT SURGERY,D.H.S. /LAG SCREW (GPC D.H.S. /LAG SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,HARRINGTON HOOK(GPC HARRINGTON HOOK)-FOR SPINE SURGERY,LUCK ROD(GPC LUCK ROD)-FOR SPINE SURGERY, DORSOLUMBAR PLATE(GPC DORSOLUMBAR PLATE)-FOR SPINE SURGERY,CORTICAL SCREW, SLOTTED HEAD THREAD(GPC CORTICAL SCREW, SLOTTED HEAD THREAD)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,4.5MM BROAD LOCKING PLATES(GPC 4.5 MM BROAD LOCKING PLATES)-USED TO IMMOBILIZE FRACTURED

	SEGMENTS,MINI PLATE WITHOUT BRIDGE 1.5MM(GPC MINI PLATE WITHOUT BRIDGE 1.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,FEMORAL HEAD LOCKING PLATE(GPC FEMORAL HEAD LOCKING PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,3D SQUARE PLATE 2.0MM(GPC 3D SQUARE PLATE 2.0MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,ACETABULAR CUP(GPC ACETABULAR CUP)-FOR HIP REPLACEMENT SURGERY,3D SQUARE PLATE 1.2MM(GPC 3D SQUARE PLATE 1.2MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,MINI PLATE WITHOUT BRIDGE 2.0MM(GPC MINI PLATE WITHOUT BRIDGE 2.0MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,T SHAPE PLATE 2.5MM(GPC T SHAPE PLATE 2.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,I SHAPE PLATE 1.5MM(GPC I SHAPE PLATE 1.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,3D SQUARE PLATE 1.5MM(GPC 3D SQUARE PLATE 1.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,MESH PLATE 1 X 1"(GPC MESH PLATE 1 X 1")-USED TO IMMOBILIZE FRACTURED SEGMENTS, ORBITAL PLATE WITH BRIDGE 2.5MM(GPC ORBITAL PLATE WITH BRIDGE 2.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,RIGHT ANGLE PLATE 1.5MM(GPC RIGHT ANGLE PLATE 1.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,MINI PLATE WITH BRIDGE 2.5MM (GPC MINI PLATE WITH BRIDGE 2.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,I SHAPE PLATE 2.0MM(GPC I SHAPE PLATE 2.0MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,DYNAMIC SELF COMPRESSION PLATE FOR 2.7MM SCREWS(GPC DYNAMIC SELF COMPRESSION PLATE FOR 2.7MM SCREWS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,ORBITAL PLATE 2.0 CURVED(GPC ORBITAL PLATE 2.0 CURVED)-USED TO IMMOBILIZE FRACTURED SEGMENTS, ORBITAL PLATE WITH BRIDGE 2.0MM(GPC ORBITAL PLATE WITH BRIDGE 2.0MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS, CEPHALIC SCREW(GPC CEPHALIC SCREW)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,Z PLATE(GPC Z PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,MINI PLATE WITH BRIDGE 1.5MM(GPC MINI PLATE WITH BRIDGE 1.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,QUARTER TUBULAR PLATE WITH COLLAR(GPC QUARTER TUBULAR PLATE WITH COLLAR)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CORTEX SCREW(GPC CORTEX SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,H-PLATE 1.5MM(GPC H-PLATE 1.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,ADAPTATION PLATE 1.5(GPC ADAPTATION PLATE 1.5)-USED TO IMMOBILIZE FRACTURED SEGMENTS,3.5MM PROXIMAL HUMERUS LOCKING PLATE(GPC 3.5MM PROXIMAL HUMERUS LOCKING PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,3.5MM LOCKING T-PLATE(GPC 3.5MM

	LOCKING T-PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS, LOCKING COMPRESSION SCREW SELF TAPPING(GPC LOCKING COMPRESSION SCREW SELF TAPPING)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,SUTURE DISK(GPC SUTURE DISK)-FOR KNEE SURGERY,ACL SCREW(GPC ACL SCREW)-FOR KNEE SURGERY, ENDO BUTTON(GPC ENDO BUTTON)-FOR KNEE SURGERY,TLIF CAGE (GPC TLIF CAGE)-FOR SPINE SURGERY,EXPANDABLE CAGE(GPC EXPANDABLE CAGE)-FOR SPINE SURGERY,CAGE(GPC CAGE)-FOR SPINE SURGERY,SINGLE LOCK POLY AXIAL SCREW PEDICLE(GPC SINGLE LOCK POLY AXIAL SCREW PEDICLE)-FOR SPINE SURGERY, CAGE(GPC CAGE)-FOR SPINE SURGERY,HARRINGTON ROD(GPC HARRINGTON ROD)-FOR SPINE SURGERY,ROD PUSHER(GPC ROD PUSHER)-FOR SPINE SURGERY,ANTERIOR CERVICAL PLATE (Z-PLATE)(GPC ANTERIOR CERVICAL PLATE (Z-PLATE))-FOR SPINE SURGERY,SQUARE NAIL FOR RADIUS(GPC SQUARE NAIL FOR RADIUS)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY, RUSH NAIL (HOOK INTRAMEDULLARY)(GPC RUSH NAIL (HOOK INTRAMEDULLARY))-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,ROD(GPC ROD)-FOR SPINE SURGERY,ENDER NAIL(GPC ENDER NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,SET SCREW DRIVER(GPC SET SCREW DRIVER)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,SHOULDER PROSTHESIS (GPC SHOULDER PROSTHESIS)-FOR HIP REPLACEMENT SURGERY T SHAPE PLATE 1.5MM(GPC T SHAPE PLATE 1.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,REDUCTION SCREW(GPC REDUCTION SCREW)-FOR SPINE SURGERY,NOSE PLATE H SHAPE(GPC NOSE PLATE H SHAPE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,END CAP FOR HUMERAL NAIL(GPC END CAP FOR HUMERAL NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,CALCANEAL LOCKING PLATE 3.5MM(GPC CALCANEAL LOCKING PLATE 3.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,LOCKING DCS 95°(GPC LOCKING DCS 95°)-USED TO IMMOBILIZE FRACTURED SEGMENTS,ORBITAL PLATE 1.5 (CURVED) (GPC ORBITAL PLATE 1.5 (CURVED))-USED TO IMMOBILIZE FRACTURED SEGMENTS,BROAD PLATE WITH ROUND HOLES(GPC BROAD PLATE WITH ROUND HOLES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,ANGLED BLADE PLATES FOR INTERTROCHANTERIC FEMORAL OSTEOTOMIES IN SMALL, ADULTS & ADOLESCENTS(GPC ANGLED BLADE PLATES FOR INTERTROCHANTERIC FEMORAL OSTEOTOMIES IN SMALL, ADULTS & ADOLESCENTS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,SEMI TUBULAR(GPC SEMI TUBULAR)-USED TO IMMOBILIZE FRACTURED SEGMENTS,NOSE PLATE, X SHAPE(GPC NOSE PLATE, X SHAPE)-USED

	TO IMMOBILIZE FRACTURED SEGMENTS,LOCKING BOLTS 4.5MM(SELF TAPPING)(GPC LOCKING BOLTS 4.5MM(SELF TAPPING))-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,LC D.H.S. BARREL PLATES(GPC LC D.H.S. BARREL PLATES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,JEWETT NAIL PLATE (MODIFIED)(GPC JEWETT NAIL PLATE (MODIFIED))-USED TO IMMOBILIZE FRACTURED SEGMENTS,DOUBLE Y-PLATE 1.5MM & 2.0MM(GPC DOUBLE Y-PLATE 1.5MM & 2.0MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS, DYNAMIC SELF COMPRESSION PLATE(GPC DYNAMIC SELF COMPRESSION PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,ONE THIRD TUBULAR(GPC ONE THIRD TUBULAR)-USED TO IMMOBILIZE FRACTURED SEGMENTS,PAEDIATRIC DHS PLATE(GPC PAEDIATRIC DHS PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,DHS BARREL PLATE DCP HOLES - VARIABLE ANGLE(GPC DHS BARREL PLATE DCP HOLES - VARIABLE ANGLE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,D.H.S. BARREL PLATES(GPC D.H.S. BARREL PLATES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,D.H.S. BARREL PLATES(GPC D.H.S. BARREL PLATES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,DCS BARREL DOUBLE ANGLED PLATE(GPC DCS BARREL DOUBLE ANGLED PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,LOCKING BOLT 2.9 MM(GPC LOCKING BOLT 2.9 MM)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,RECONSTRUCTION LOCKING 3.5MM SCREWS (GPC RECONSTRUCTION LOCKING 3.5MM SCREWS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,END CAP FOR RECONSTRUCTION NAIL(GPC END CAP FOR RECONSTRUCTION NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,TIBIAL NAIL(GPC TIBIAL NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,THREADED KIRSCHNER WIRE(GPC THREADED KIRSCHNER WIRE)-WIRES ARE MAINLY INDICATED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENTS.,LOCKING BOLTS 3.9MM(GPC LOCKING BOLTS 3.9MM)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,NARROW COMPRESSION PLATE ACP HOLES(GPC NARROW COMPRESSION PLATE ACP HOLES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,3 D RECTANGLE PLATE 1.5MM(GPC 3 D RECTANGLE PLATE 1.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,STEFFEE SCREW(GPC STEFFEE SCREW)-FOR SPINE SURGERY,CERVICAL SPINE PLATE 3.5MM SCREW(GPC CERVICAL SPINE PLATE 3.5MM SCREW)-FOR SPINE SURGERY, PAEDIATRIC D.H.S. SCREW(GPC PAEDIATRIC D.H.S. SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE,AUSTIN MOORE HIP PROSTHESES(GPC AUSTIN MOORE HIP PROSTHESES)-FOR HIP REPLACEMENT SURGERY,PIN STEINMANN(GPC PIN STEINMANN)-

	PINS ARE USED TO STABILIZE THE FRACTURES OF BONES.,THORNY STAPLE(GPC THORNY STAPLE)-STAPLES ARE USED TO STABILIZE THE FRACTURES OF BONES.,WASHER FOR SMALL SCREW(WASHER FOR SMALL SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,COVENTRY STAPLE(GPC COVENTRY STAPLE)-STAPLES ARE USED TO STABILIZE THE FRACTURES OF BONES.,PROXIMAL FEMORAL NAIL (LONG PFN)(GPC PROXIMAL FEMORAL NAIL (LONG PFN))-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY, SELF-TAPING CORTEX SCREW(GPC SELF-TAPING CORTEX SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,LOCKING DISTAL RADIUS VARIABLE ANGLE DISTAL RADIUS 2.4MM(GPC LOCKING DISTAL RADIUS VARIABLE ANGLE DISTAL RADIUS 2.4MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,LOCKING PROXIMAL RADIUS PLATE(GPC LOCKING PROXIMAL RADIUS PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,HERBERT CANNULATED BONE SCREW(GPC HERBERT CANNULATED BONE SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,LOCKING PHILOS PLATE(GPC LOCKING PHILOS PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,LOCKING ANTEROLATERAL TIBIA DISTAL PLATE 3.5MM SCREWS(GPC LOCKING ANTEROLATERAL TIBIA DISTAL PLATE 3.5MM SCREWS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CANCELLOUS SCREW(GPC CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,LOCKING MEDIAL DISTAL TIBIA PLATE WITHOUT TAB(GPC LOCKING MEDIAL DISTAL TIBIA PLATE WITHOUT TAB)-USED TO IMMOBILIZE FRACTURED SEGMENTS,LOCKING RIGID PLATE(GPC LOCKING RIGID PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,MALLEOLAR SCREW(GPC MALLEOLAR SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,NARROW LENGTHENING PLATE(GPC NARROW LENGTHENING PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS, BROAD COMPRESSION PLATE ACP HOLES(GPC BROAD COMPRESSION PLATE ACP HOLES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,PROXIMAL FEMUR BONE PLATE(GPC PROXIMAL FEMUR BONE PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,PROXIMAL HUMERUS BONE PLATE(GPC PROXIMAL HUMERUS BONE PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,HERBERT CANNULATED BONE SCREW(GPC HERBERT CANNULATED BONE SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION

	OR ANCHORAGE,MEDIAL PROXIMAL TIBIA BONE PLATE(GPC MEDIAL PROXIMAL TIBIA BONE PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,D.H.S. BARREL PLATES(GPC D.H.S. BARREL PLATES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,FEMORAL NAIL(GPC FEMORAL NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,D.H.S. BARREL PLATES(GPC D.H.S. BARREL PLATES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CANCELLOUS SCREW(GPC CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,BROAD LENGTHENING PLATE ACP HOLES(GPC BROAD LENGTHENING PLATE ACP HOLES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,ANGLE BLADE PLATE 130° FOR ADULTS(GPC ANGLE BLADE PLATE 130° FOR ADULTS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,MEDIAL DISTAL END TIBIAL LOCKING PLATE WITH TAB (GPC MEDIAL DISTAL END TIBIAL LOCKING PLATE WITH TAB)-USED TO IMMOBILIZE FRACTURED SEGMENTS,LECESTRE PLATE(GPC LECESTRE PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS, SHAFT SCREW(GPC SHAFT SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,LOCKING COMPRESSION SCREW SELF TAPPING(GPC LOCKING COMPRESSION SCREW SELF TAPPING)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,MALLEOLAR SCREW (GPC MALLEOLAR SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,CANNULATED CANCELLOUS SCREW(GPC CANNULATED CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,MULTIANGLE LOCKING FEMUR NAIL(GPC MULTIANGLE LOCKING FEMUR NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,CANNULATED CANCELLOUS SCREW(GPC CANNULATED CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,SMALL CANNULATED CANCELLOUS SCREW(GPC SMALL CANNULATED CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,LIMITED CONTACT DYNAMIC COMPRESSION PLATE (LC-DCP) - SMALL(GPC LIMITED CONTACT DYNAMIC COMPRESSION PLATE (LC-DCP) - SMALL)-USED TO IMMOBILIZE FRACTURED SEGMENTS,SMALL CANNULATED CANCELLOUS SCREW(GPC SMALL CANNULATED CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE., LARGE CANNULATED CANCELLOUS SCREW(GPC LARGE

	CANNULATED CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,CANCELLOUS SCREW(GPC CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE., CORTEX SCREW(GPC CORTEX SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,MODULAR BIPOLAR CUP(GPC MODULAR BIPOLAR CUP)-FOR HIP REPLACEMENT SURGERY,PROXIMAL FEMORAL NAIL (PFN)(GPC PROXIMAL FEMORAL NAIL (PFN))-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,DISTAL HUMERUS LOCKING PLATE SIZE 2.7/3.5 DORSOLATERAL(GPC DISTAL HUMERUS LOCKING PLATE SIZE 2.7/3.5 DORSOLATERAL)-USED TO IMMOBILIZE FRACTURED SEGMENTS,L- AND T- PLATE 2.0 FOR FINGER JOINT- HEAT SHAFT WITH 2 HOLES, HEAD WITH 2(GPC L- AND T- PLATE 2.0 FOR FINGER JOINT- HEAT SHAFT WITH 2 HOLES, HEAD WITH 2)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CENTRALLY THREADED STEINMANN PIN(GPC CENTRALLY THREADED STEINMANN PIN)-PINS ARE USED TO STABILIZE THE FRACTURES OF BONES.,KUNTSCHER CLOVERLEAF NAIL(GPC KUNTSCHER CLOVERLEAF NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,BEND KUNTSCHER CLOVERLEAF NAIL TIBIA(GPC BEND KUNTSCHER CLOVERLEAF NAIL TIBIA)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY, LOCKING BOLTS 6.5 MM CANNULATED (SELF TAPPING)(GPC LOCKING BOLTS 6.5 MM CANNULATED (SELF TAPPING))-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,WIRES KIRSCHNER - LANCEOLATE TROCAR/ BAYONET POINT SINGLE/DOUBLE ENDED (GPC WIRES KIRSCHNER - LANCEOLATE TROCAR/ BAYONET POINT SINGLE/DOUBLE ENDED)-WIRES ARE MAINLY INDICATED IN FRACTURES OF BONES SERVING AS LIGAMENT OR MUSCLE ATTACHMENTS.,MONO AXIAL SCREW(GPC MONO AXIAL SCREW)-FOR SPINE SURGERY,RECONSTRUCTION LOCKING PLATE 4.5MM SCREWS (GPC RECONSTRUCTION LOCKING PLATE 4.5MM SCREWS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CANCELLOUS SCREW(GPC CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,4.5MM LOCKING CONDYLAR BUTTRESS PLATE(GPC 4.5 MM LOCKING CONDYLAR BUTTRESS PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,X-PLATE 2.0(GPC X-PLATE 2.0)-USED TO IMMOBILIZE FRACTURED SEGMENTS,SHERMAN BONE PLATES(GPC SHERMAN BONE PLATES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,H-PLATE 2.0(GPC H-PLATE 2.0)-USED TO IMMOBILIZE FRACTURED SEGMENTS,WIRE, SUTURE(GPC WIRE, SUTURE)-WIRES ARE MAINLY INDICATED IN FRACTURES OF BONES SERVING AS

	LIGAMENT OR MUSCLE ATTACHMENTS.,PROXIMAL TIBIA MEDIAL LOCKING PLATE 3.5MM(GPC PROXIMAL TIBIA MEDIAL LOCKING PLATE 3.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS, LOCKING BOLTS 3.4MM(GPC LOCKING BOLTS 3.4MM)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,DISTAL FEMUR BONE PLATE(GPC DISTAL FEMUR BONE PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,LOCKING BOLTS 4.9MM(GPC LOCKING BOLTS 4.9MM)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY, FEMORAL TAPERED STEM(GPC FEMORAL TAPERED STEM)-FOR HIP REPLACEMENT SURGERY,LOCKING BOLTS 7.5MM CANNULATED (SELF TAPPING)(GPC LOCKING BOLTS 7.5MM CANNULATED (SELF TAPPING))-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,LATERAL TIBIAL HEAD BUTTRESS PLATE 4.5MM(GPC LATERAL TIBIAL HEAD BUTTRESS PLATE 4.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,V - NAIL(GPC V - NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,HERBERT CANNULATED BONE SCREW(GPC HERBERT CANNULATED BONE SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,SELF-TAPING CORTEX SCREW(GPC SELF-TAPING CORTEX SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,HOOK PLATE 4.5MM(GPC HOOK PLATE 4.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,T-BUTTRESS LOCKING PLATE(GPC T-BUTTRESS LOCKING PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,MINI PLATE WITH BRIDGE 2.0 MM(GPC MINI PLATE WITH BRIDGE 2.0MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,LOCKING HEAD SCREWS(GPC LOCKING HEAD SCREWS)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,4.5 MM NARROW LOCKING PLATES(GPC 4.5MM NARROW LOCKING PLATES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,T BUTTRESS PLATE FOR 4.5MM SCREWS(GPC T BUTTRESS PLATE FOR 4.5MM SCREWS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,HOOK(GPC HOOK)-FOR SPINE SURGERY,RECONSTRUCTION PLATE 3.5MM SCREWS(GPC RECONSTRUCTION PLATE 3.5MM SCREWS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CHIN PLATE (CURVED)(GPC CHIN PLATE (CURVED))-USED TO IMMOBILIZE FRACTURED SEGMENTS,LOCKING DORSAL RADIUS PLATE(GPC LOCKING DORSAL RADIUS PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS, SPOON PLATES(GPC SPOON PLATES)-USED TO IMMOBILIZE FRACTURED SEGMENTS,T PLATE (SMALL) FOR 3.5MM SCREWS(GPC T PLATE (SMALL) FOR 3.5MM SCREWS)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CONDYLAR 95º PLATE FOR SMALL, ADULTS & ADOLESCENTS(GPC CONDYLAR 95º PLATE FOR SMALL, ADULTS &

	ADOLESCENTS)-USED TO IMMOBILIZE FRACTURED SEGMENTS, DISTAL BOLT(GPC DISTAL BOLT)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,MULTIANGLE TIBIA NAIL(GPC MULTIANGLE TIBIA NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,QUARTER TUBULAR PLATE(GPC QUARTER TUBULAR PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS, INTRA ORAL DISTRACTER2.5MM(GPC INTRA ORAL DISTRACTER2. 5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,Y-RECONSTRUCTION PLATE(GPC Y-RECONSTRUCTION PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,METAPHYSEAL LOCKING PLATE(GPC METAPHYSEAL LOCKING PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CONDYLAR BLADE PLATE 95 DEGREE(GPC CONDYLAR BLADE PLATE 95 DEGREE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CONDYLAR BUTTRESS PLATE(GPC CONDYLAR BUTTRESS PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,CANCELLOUS SCREW(GPC CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,ANGLED RECONSTRUCTION PLATE 2.7(GPC ANGLED RECONSTRUCTION PLATE 2.7)-USED TO IMMOBILIZE FRACTURED SEGMENTS,T SHAPE PLATE 2.0MM(GPC T SHAPE PLATE 2.0MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,UNREAMED TIBIAL NAILS(GPC UNREAMED TIBIAL NAILS)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,I SHAPE PLATE 2.5MM(GPC I SHAPE PLATE 2.5MM)-USED TO IMMOBILIZE FRACTURED SEGMENTS,LOCKING LATERAL PROXIMAL TIBIA PLATE(GPC LOCKING LATERAL PROXIMAL TIBIA PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,FEMORAL NECK BALL(GPC FEMORAL NECK BALL)-FOR HIP REPLACEMENT SURGERY, CLOVERLEAF LOCKING PLATE(GPC CLOVERLEAF LOCKING PLATE)-USED TO IMMOBILIZE FRACTURED SEGMENTS,2.7/3.5MM DISTAL HUMERUS LOCKING PLATE DORSOLATERAL, WITH LATERAL SUPPORT(GPC 2.7/3.5MM DISTAL HUMERUS LOCKING PLATE DORSOLATERAL, WITH LATERAL SUPPORT)-USED TO IMMOBILIZE FRACTURED SEGMENTS,TRANSVERSE CONNECTOR(GPC TRANSVERSE CONNECTOR)-FOR SPINE SURGERY,GAMMA NAIL(GPC GAMMA NAIL)-USED TO TREAT FRACTURES OF LONG BONES OF THE BODY,POLY AXIAL SCREW(GPC POLY AXIAL SCREW)-FOR SPINE SURGERY,D.H.S. COMPRESSION SCREW/BLOCKET SCREW(GPC D.H.S. COMPRESSION SCREW/BLOCKET SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,LOCKING HEAD CANCELLOUS SCREW(GPC LOCKING HEAD CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,LOCKING HEAD

		CANCELLOUS SCREW(GPC LOCKING HEAD CANCELLOUS SCREW)-USED FOR ATTACHMENT OF IMPLANTS TO BONE, BONE TO BONE FIXATION OR FOR SOFT TISSUE FIXATION OR ANCHORAGE.,STRAIGHT PLATES 2.0(GPC STRAIGHT PLATES 2.0)-USED TO IMMOBILIZE FRACTURED SEGMENTS,STRAIGHT PLATES 1.5(GPC STRAIGHT PLATES 1.5)-USED TO IMMOBILIZE FRACTURED SEGMENTS,PLIF CAGE (GPC PLIF CAGE)-FOR SPINE SURGERY
3951	TN00002456	1.License Holder Name: TTK HEALTHCARE LIMITED (ORTHO DIVISION) 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:TOTAL HIP REPLACEMENT SYSTEM(PL REFER ACCESSORIES/COMPONENT SECTION)-TOTAL HIP ARTHROPLASTY IS INTENDED TO PROVIDE PATIENT MOBILITY AND REDUCE PAIN BY REPLACING THE DAMAGED HIP JOINT IN PATIENTS WHERE THERE IS EVIDENCE OF SUFFICIENT BONE STOCK TO SEAT AND SUPPORT THE COMPONENTS.
3952	TN00002473	1.License Holder Name: CARBORUNDUM UNIVERSAL LTD 2.Approving Authority: CENTRAL DRUG STANDARD CONTROL ORGANISATION, SOUTH ZONE 3.Device Name(Brand Name)-Intended Use:ADHESIVE DRESSING BANDAGES FABRIC(CERDAK)-EXUDATE ABSORPTION WOUND DRESSING, BACTEROIO STATIC WOUND DRESSING FOR WOUND CARE
3953	TN00003795	1.License Holder Name: ATHENESE-DX PRIVATE LIMITED 2.Approving Authority: TAMIL NADU 3.Device Name(Brand Name)-Intended Use:FILARIASIS IGG/IGM RAPID TEST (TRUSTLINE)-THE TRUSTLINE FILARIASIS IGG/IGM RAPID TEST IS INTENDED TO BE USED AS A SCREENING TEST AND AS AN AID IN THE DIAGNOSIS OF INFECTION WITH LYMPHATIC FILARIAL PARASITES.